Inhaltsverzeichnis Polatuzumab Vedotin R/R

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Demographics and Baseline Characteristics

	Pola+BR (N=20)	BR (N=17)	All (N=37)
Age (Years)			
n	20	17	37
Mean (SD)	64.4 (13.6)	70.5 (12.7)	67.2 (13.3)
Median	67	74	70
Min - Max	27 - 86	31 - 83	27 - 86
Age Group (Years)			
n	20	17	37
18 - 40	1 (5.0%)	1 (5.9%)	2 (5.4%)
41 - 64	7 (35.0%)	1 (5.9%)	8 (21.6%)
>= 65	12 (60.0%)	15 (88.2%)	27 (73.0%)
Sex			
n	20	17	37
Male	14 (70.0%)	8 (47.1%)	22 (59.5%)
Female	6 (30.0%)	9 (52.9%)	15 (40.5%)
Race			
n	20	17	37
Asian	11 (55.0%)	7 (41.2%)	18 (48.6%)
White	8 (40.0%)	10 (58.8%)	18 (48.6%)
Unknown	1 (5.0%)	0	1 (2.7%)
Ethnicity			
n	20	17	37
Hispanic or Latino	0	1 (5.9%)	1 (2.7%)
Not Hispanic or Latino	19 (95.0%)	16 (94.1%)	35 (94.6%)
Not reported	1 (5.0%)	0	1 (2.7%)
Weight (kg) at Baseline			
n	20	17	37
Mean (SD)	69.04 (18.82)	68.59 (12.52)	68.84 (16.02)

Median	66.5	67.7	67
Min - Max	44.0 - 132.9	48.0 - 90.0	44.0 - 132.9
Height (cm) at Baseline			
n	20	17	37
Mean (SD)	168.2 (12.10)	161.6 (8.90)	165.2 (11.12)
Median	169	162	166.4
Min - Max	146.3 - 195.6	145.0 - 174.0	145.0 - 195.6
ECOG score at Baseline			
n	20	17	37
0	8 (40.0%)	9 (52.9%)	17 (45.9%)
1	8 (40.0%)	6 (35.3%)	14 (37.8%)
2	4 (20.0%)	2 (11.8%)	6 (16.2%)
Bulky disease at Baseline			
n	20	17	37
Yes	8 (40.0%)	1 (5.9%)	9 (24.3%)
No	12 (60.0%)	16 (94.1%)	28 (75.7%)
Primary Reason for Stem Cell Transplant Ineligibility			
n	20	17	37
Age	10 (50.0%)	14 (82.4%)	24 (64.9%)
Co-Morbidities	1 (5.0%)	0	1 (2.7%)
Patient Refused Transplant	5 (25.0%)	1 (5.9%)	6 (16.2%)
Performance Status	0	1 (5.9%)	1 (2.7%)
Other	4 (20.0%)	1 (5.9%)	5 (13.5%)
Duration of response to prior therapy (IxRS)			
n	20	17	37
<=12 Months	12 (60.0%)	14 (82.4%)	26 (70.3%)
>12 Months	8 (40.0%)	3 (17.6%)	11 (29.7%)
Duration of response to prior therapy (CRF)			
n	20	17	37
<=12 Months	13 (65.0%)	15 (88.2%)	28 (75.7%)
>12 Months	7 (35.0%)	2 (11.8%)	9 (24.3%)

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_dm.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_dm_L2_ARMCDPLUS_IT_29365_41543.xls
08DEC2022 17:33

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of Patients who discontinued Study or Treatment

Status / Primary Reason for Discontinuation	Pola+BR (N=20)	BR (N=17)	All (N=37)
Number of Patients Randomized	20 (100.0%)	17 (100.0%)	37 (100.0%)
Number of Patients Treated	19 (95.0%)	17 (100.0%)	36 (97.3%)
Discontinued Study*			
Total	16 (80.0%)	17 (100.0%)	33 (89.2%)
Death	10 (50.0%)	13 (76.5%)	23 (62.2%)
Withdrawal by Subject	2 (10.0%)	3 (17.6%)	5 (13.5%)
Study Terminated By Sponsor	3 (15.0%)	1 (5.9%)	4 (10.8%)
Other	1 (5.0%)	0	1 (2.7%)
Discontinued Polatuzumab Vedotin Treatment or Placebo**			
Total	10 (52.6%)	5 (29.4%)	15 (41.7%)
Adverse Event	5 (26.3%)	1 (5.9%)	6 (16.7%)
Progressive Disease	3 (15.8%)	4 (23.5%)	7 (19.4%)
Withdrawal by Subject	2 (10.5%)	0	2 (5.6%)
Discontinued Bendamustine Treatment**			
Total	11 (57.9%)	13 (76.5%)	24 (66.7%)
Adverse Event	6 (31.6%)	2 (11.8%)	8 (22.2%)
Progressive Disease	3 (15.8%)	8 (47.1%)	11 (30.6%)
Death	0	1 (5.9%)	1 (2.8%)
Lack of Efficacy	0	1 (5.9%)	1 (2.8%)
Withdrawal by Subject	2 (10.5%)	1 (5.9%)	3 (8.3%)
Discontinued Rituximab or Obinutuzumab Treatment**			
Total	10 (52.6%)	13 (76.5%)	23 (63.9%)
Adverse Event	5 (26.3%)	2 (11.8%)	7 (19.4%)
Progressive Disease	3 (15.8%)	8 (47.1%)	11 (30.6%)
Death	0	1 (5.9%)	1 (2.8%)
Lack of Efficacy	0	1 (5.9%)	1 (2.8%)

Withdrawal by Subject	2 (10.5%)	1 (5.9%)	3 (8.3%)

* Percentages are based on the number of patients randomized.
** Percentages are based on the number of patients treated.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ds.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_ds_L2_ARMCDPLUS_IT_29365_41543.xls
08DEC2022 12:36

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Number of Centers/Countries/Geographical Regions with <10, >=10 Patients per Arm

	Center				Country				Geographical region			
	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients
Overall	23	100.0	37	100.0	11	100.0	37	100.0	4	100.0	37	100.0
with <10 patients per arm	23	100.0	37	100.0	11	100.0	37	100.0	4	100.0	37	100.0
with >=10 patients per arm	0	-	0	-	0	-	0	-	0	-	0	-

'<10 patients' category if at least one treatment arm has <10 patients; '>=10 patients' category if all treatment arms have >=10 patients.
Geographical regions: Asia/Pacific, Eastern Europe, North America, Western Europe.
'n': Number of centers/countries/regions; "%": Percent of centers/countries/regions compared to overall number of centers/countries/regions
'n of patients randomized': Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)
'% randomized patients': Percent of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_center.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_center_L2_ARMCDPLUS_IT_29365_41543.xls
07DEC2022 23:37

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Concordance of Stratification Factors by eCRF and IxRS
MODEL: Descriptive
STUDIES: GO29365, YO41543
Stratification Factor: Duration of Response to prior therapy

	Pola+BR (N=20)			BR (N=17)		
	eCRF			eCRF		
	<=12 Months	>12 Months	Total	<=12 Months	>12 Months	Total
IxRS						
<=12 Months	12 (60.0%)	0	12 (60.0%)	14 (82.4%)	0	14 (82.4%)
>12 Months	1 (5.0%)	7 (35.0%)	8 (40.0%)	1 (5.9%)	2 (11.8%)	3 (17.6%)
Total	13	7	20	15	2	17

Percentages are based on N in the column headings.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_strat.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_strat_L2_ARMCDPLUS_IT_29365_41543.xls
08DEC2022 12:37

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: POLATUZUMAB VEDOTIN

	Pola+BR (N=19)
Treatment Duration (Months)	
n	19
Mean (SD)	2.65 (1.56)
Median	3.19
Interquartile Range	1.38 - 3.68
Min - Max	0.0 - 5.9
Number of Cycles	
n	19
Mean (SD)	4.4 (1.8)
Median	5
Interquartile Range	3.0 - 6.0
Min - Max	1 - 6
Total Cumulative Dose (mg)	
n	19
Mean (SD)	548.6 (273.4)
Median	518.4
Interquartile Range	336.6 - 687.6
Min - Max	121 - 1183
Dose intensity (%) adjusted for dose reduction and delay	
n	19
Mean (SD)	93.4 (10.6)
Median	96.5
Interquartile Range	87.3 - 100.5
Min - Max	58 - 102

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: BENDAMUSTINE

	Pola+BR (N=19)	BR (N=17)
Treatment Duration (Months)		
n	19	17
Mean (SD)	2.59 (1.40)	1.91 (1.26)
Median	3.22	1.42
Interquartile Range	1.41 - 3.71	0.72 - 3.03
Min - Max	0.0 - 4.3	0.1 - 3.9
Number of Cycles		
n	19	17
Mean (SD)	4.4 (1.8)	3.6 (1.7)
Median	5	3
Interquartile Range	3.0 - 6.0	2.0 - 5.0
Min - Max	1 - 6	1 - 6
Total Cumulative Dose (mg)		
n	19	17
Mean (SD)	1362.1 (584.5)	1120.3 (544.9)
Median	1533.6	1080
Interquartile Range	957.6 - 1800.0	652.0 - 1396.0
Min - Max	329 - 2161	328 - 2171
Dose intensity (%) adjusted for dose reduction and delay		
n	19	17
Mean (SD)	91.1 (11.4)	97.4 (6.0)
Median	95.5	97.7
Interquartile Range	85.1 - 98.5	95.5 - 101.6
Min - Max	53 - 100	78 - 105

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
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20APR2023 11:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: RITUXIMAB

	Pola+BR (N=19)	BR (N=17)
Treatment Duration (Months)		
n	19	17
Mean (SD)	2.68 (1.56)	1.91 (1.26)
Median	3.22	1.41
Interquartile Range	1.41 - 3.71	0.73 - 3.03
Min - Max	0.0 - 5.9	0.0 - 3.9
Number of Cycles		
n	19	17
Mean (SD)	4.4 (1.8)	3.6 (1.7)
Median	5	3
Interquartile Range	3.0 - 6.0	2.0 - 5.0
Min - Max	1 - 6	1 - 6
Total Cumulative Dose (mg)		
n	19	17
Mean (SD)	2983.9 (1284.9)	2328.8 (1135.9)
Median	3338	2250
Interquartile Range	1995.1 - 3982.5	1354.0 - 2895.0
Min - Max	686 - 5006	683 - 4522
Dose intensity (%) adjusted for dose reduction and delay		
n	19	17
Mean (SD)	93.8 (7.4)	97.3 (5.7)
Median	94.7	98.1
Interquartile Range	89.1 - 100.0	95.6 - 100.0
Min - Max	73 - 100	79 - 105

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
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20APR2023 11:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=19)	BR (N=17)	All (N=36)
n	19	17	36
Median	129	74	99

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 30 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
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08DEC2022 16:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=19)	BR (N=17)	All (N=36)
n	19	17	36
Median	189	133	145.5

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 90 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
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08DEC2022 16:48

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of New Anti-Lymphoma Therapy

	Pola+BR (N=20)	BR (N=17)
Total number of patients with at least one NALT treatment	5 (25.0%)	8 (47.1%)
Total number of NALT treatments	5	9
Total number of patients with at least one NALT treatment before PFS event	2 (10.0%)	3 (17.6%)
Total number of patients with at least one NALT treatment at or after PFS event	2 (10.0%)	3 (17.6%)
Total number of patients with at least one NALT treatment and without PFS event	1 (5.0%)	2 (11.8%)
Radiotherapy		
Total number of patients with at least one treatment	0	0
Total number of treatments	0	0
Systemic therapy		
Total number of patients with at least one treatment	5 (25.0%)	8 (47.1%)
Total number of treatments	5	9
Total number of patients received stem cell transplants	0	0
Autologous transplant	0	0
Allogeneic transplant	0	0
Unknown	0	0
Total number of patients received CAR-T	1 (5.0%)	0
Total number of patients received unknown treatment	0	0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_nalt.sas
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01FEB2023 18:49

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median observation time(of follow up)

Overall Survival

	Pola+BR (N=20)	BR (N=17)	All (N=37)
Patients with event (%)	10 (50.0%)	4 (23.5%)	14 (37.8%)
Latest contributing event			
Alive	10	4	14
Patients without event (%)	10 (50.0%)	13 (76.5%)	23 (62.2%)
Time to event (months)			
Median	58.6	12.1	19.6
95% CI	(13.4, 65.9)	(12.1, NE)	(13.4, 65.9)
25% and 75%-ile	13.4 - 65.9	12.1 - NE	12.6 - 64.5
Range	0 - 67	1 - 25*	0 - 67

Summaries of Duration of Follow-up (median, percentiles) are based on reverse Kaplan-Meier estimates.
* Censored observation.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_obs_time.sas
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08DEC2022 0:31

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Deaths and Primary Reason for Death

	Pola+BR (N=19)		BR (N=17)		All (N=36)	
	n	%	n	%	n	%
All Deaths	10	52.6	13	76.5	23	63.9
Adverse Event	4	21.1	3	17.6	7	19.4
Progressive Disease	6	31.6	10	58.8	16	44.4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_death.sas
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08DEC2022 18:09

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=20)												BR (N=17)												Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		20	100.0	10	50.0	10	50.0	5.4	2.5	16.7	16.7	7.5	NE	17	100.0	13	76.5	4	23.5	4.7	2.0	6.0	6.0	5.1	8.4	0.0687	0.42	0.16	1.10		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the Cox regression models.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
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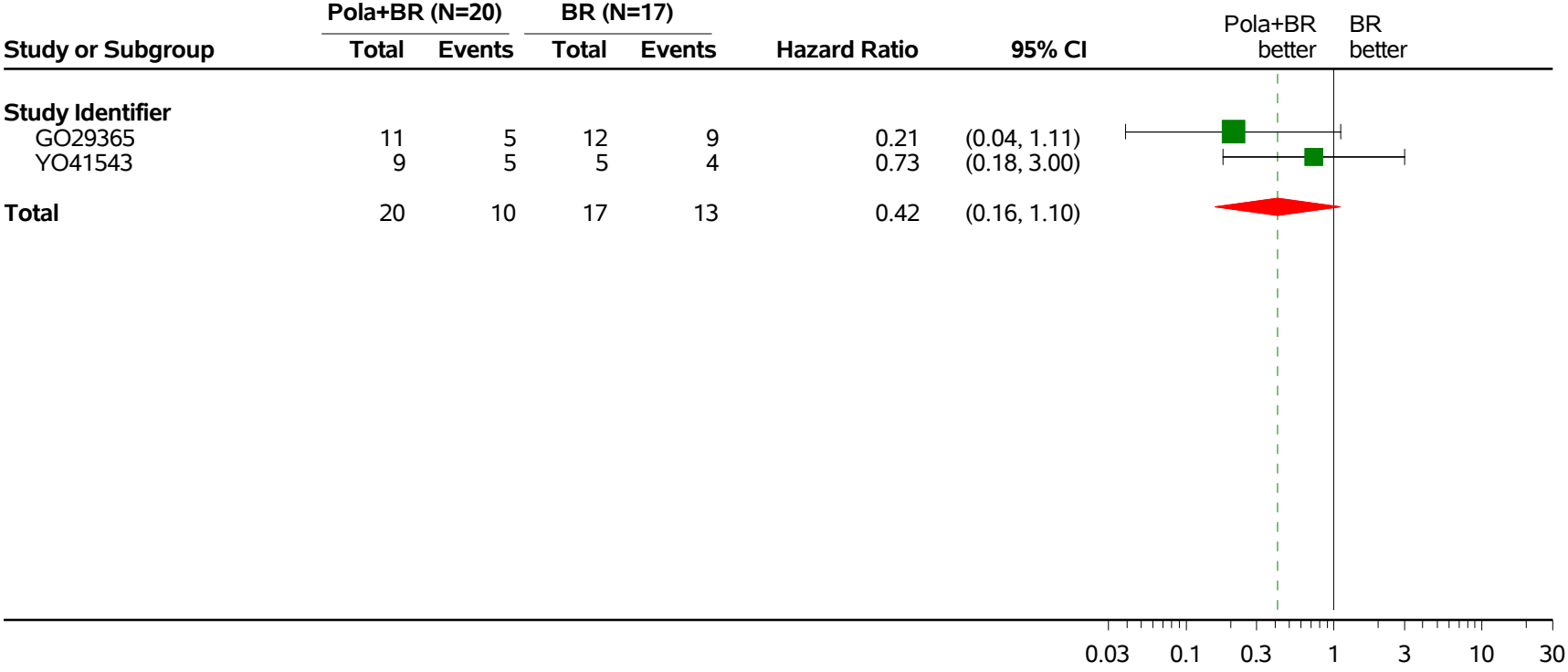
20JAN2023 19:08

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+ Polarose
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=20)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	5	12	9	0.21	(0.04, 1.11)
YO41543	9	5	5	4	0.73	(0.18, 3.00)
Total	20	10	17	13	0.42	(0.16, 1.10)



* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_str_OS_ARMCDPLUS_L2_IT_29365_41543.pdf 14DEC2022 22:44

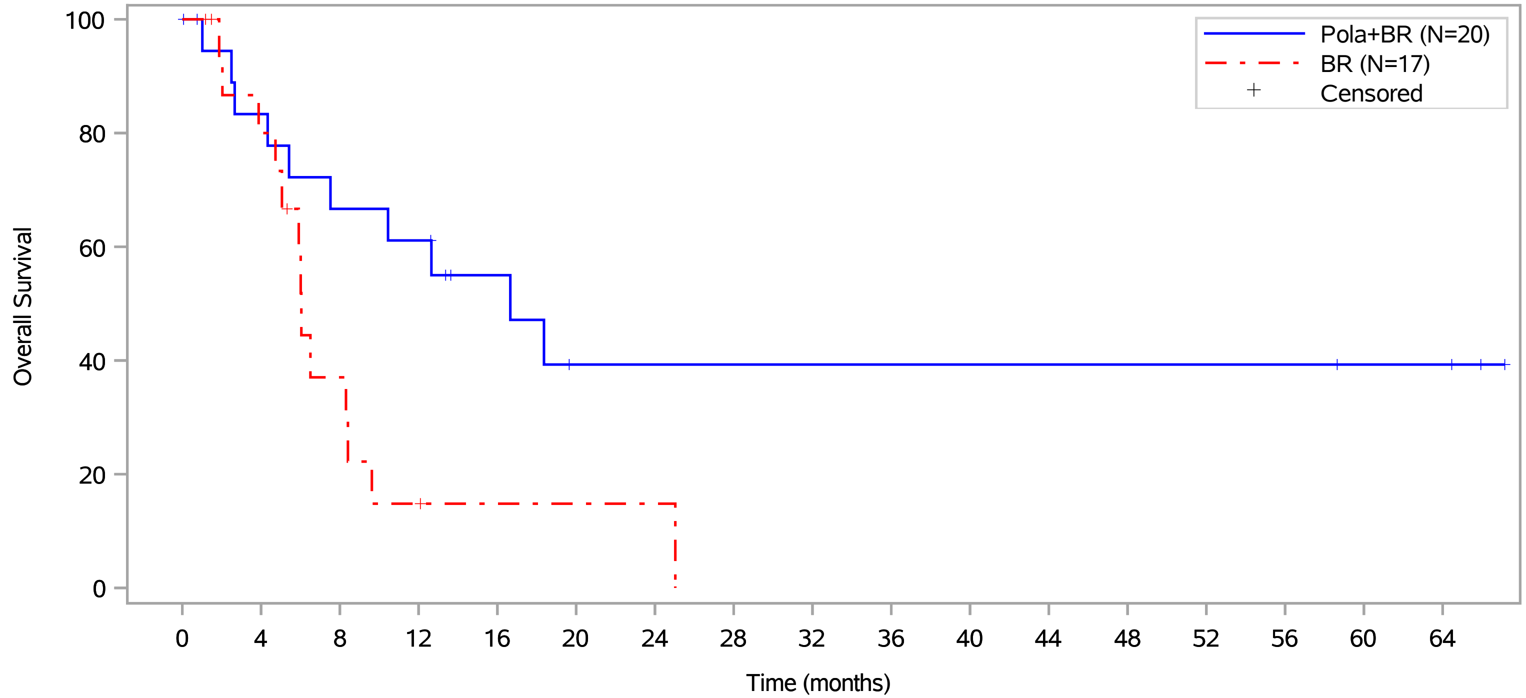
POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=20)												BR (N=17)											Pola + BR vs. BR																	
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	55.0	5	45.5	6	54.5	10.4	1.0	NE	NE	10.4	NE	12	70.6	9	75.0	3	25.0	3.9	1.9	5.9	5.5	3.9	8.4	0.0530	0.21	0.04	1.11		Convergence criterion (GCONV=1E-8) satisfied.	41.7						
	YO41543	9	45.0	5	55.6	4	44.4	4.9	2.7	NE	12.1	4.3	NE	5	29.4	4	80.0	1	20.0	6.0	6.0	9.6	6.5	6.0	NE	0.6614	0.73	0.18	3.00		Convergence criterion (GCONV=1E-8) satisfied.	58.3						
	Total	20	100.0	10	50.0	10	50.0	5.4	2.5	16.7	16.7	7.5	NE	17	100.0	13	76.5	4	23.5	4.7	2.0	6.0	6.0	5.1	8.4	0.0687	0.42	0.16	1.10		Convergence criterion (GCONV=1E-8) satisfied.	100.0	1.26	1	0.2619	20.57	-1.76	0.0780

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_str_OS_ARMCDPLUS_L2_IT_29365_41543.xls
14DEC2022 23:05

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Overall Survival
STUDIES: GO29365, YO41543



Patients at risk																																		
Pola+BR (N=20)	20	17	15	13	12	12	11	7	7	6	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	3	3	1
BR (N=17)	17	14	12	8	5	2	2	1	1	1	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																		
Pola+BR (N=20)	0	2	2	2	2	2	2	5	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	7	7	7	9
BR (N=17)	0	2	2	3	3	3	3	4	4	4	4	4	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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28NOV2022 15:04

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Overall Survival
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=20)												BR (N=17)										log-rank	Pola + BR vs. BR				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		20	100.0	10	50.0	10	50.0	5.4	2.5	16.7	16.7	7.5	NE	17	100.0	13	76.5	4	23.5	4.7	2.0	6.0	6.0	5.1	8.4	0.0144	0.35	0.13	0.84	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	70.0	8	57.1	6	42.9	4.3	2.5	12.6	12.6	4.3	NE	8	47.1	6	75.0	2	25.0	2.0	1.9	8.4	6.0	2.0	NE	0.2454	0.50	0.18	1.57	Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	6	30.0	2	33.3	4	66.7	16.7	10.4	NE	NE	10.4	NE	9	52.9	7	77.8	2	22.2	5.3	3.9	6.5	6.3	4.7	9.6	0.0094	0.05	0.00	0.55	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	40.0	4	50.0	4	50.0	3.3	1.0	NE	NE	2.7	NE	2	11.8	1	50.0	1	50.0	9.6	9.6	NE	NE	9.6	NE	0.7647	1.70	0.17	16.65	Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	12	60.0	6	50.0	6	50.0	10.4	2.5	18.4	16.7	10.4	NE	15	88.2	12	80.0	3	20.0	4.7	2.0	6.0	6.0	4.7	8.3	0.0034	0.22	0.08	0.64	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	9	45.0	6	66.7	3	33.3	2.5	1.0	16.7	12.6	2.5	18.4	14	82.4	11	78.6	3	21.4	4.3	2.0	6.0	6.0	4.7	8.3	0.2685	0.56	0.20	1.58	Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	55.0	4	36.4	7	63.6	5.4	2.7	NE	NE	5.4	NE	3	17.6	2	66.7	1	33.3	5.9	5.9	NE	7.8	5.9	NE	0.2211	0.36	0.06	2.14	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	25.0	2	40.0	3	60.0	14.4	10.4	NE	NE	10.4	NE	3	17.6	3	100.0	0	-	3.9	3.9	NE	4.7	3.9	NE	0.2119	0.32	0.05	2.05	Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	15	75.0	8	53.3	7	46.7	4.3	2.5	16.7	12.6	4.3	NE	14	82.4	10	71.4	4	28.6	5.5	2.0	6.5	6.0	5.9	8.4	0.0728	0.40	0.14	1.13	Convergence criterion (GCONV=1E-8) satisfied.	
Duration of response to prior therapy	<=12 Months	12	60.0	7	58.3	5	41.7	2.7	1.0	7.5	6.5	2.7	NE	14	82.4	10	71.4	4	28.6	4.3	2.0	6.0	6.0	4.7	8.4	0.4689	0.70	0.25	1.90	Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	8	40.0	3	37.5	5	62.5	12.6	10.4	NE	NE	12.6	NE	3	17.6	3	100.0	0	-	5.1	5.1	NE	8.3	5.1	NE	0.0004	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Refractory to last prior anti-lymphoma therapy**	Yes	11	55.0	6	54.5	5	45.5	4.3	1.0	16.7	7.5	4.3	NE	14	82.4	10	71.4	4	28.6	4.3	2.0	6.0	6.0	4.7	8.4	0.4004	0.68	0.22	2.05	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	9	45.0	4	44.4	5	55.6	12.6	2.5	NE	NE	12.6	NE	3	17.6	3	100.0	0	-	5.1	5.1	NE	8.3	5.1	NE	0.0070	0.05	0.00	0.69	Convergence criterion (GCONV=1E-8) satisfied.	
Prior Bone Marrow Transplant	Yes	1	5.0	0	-	1	100.0	NE	NE	NE	NE	NE	NE	0	0.0	0	-	0	-	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-
	No	19	95.0	10	52.6	9	47.4	5.4	2.5	16.7	16.7	5.4	NE	17	100.0	13	76.5	4	23.5	4.7	2.0	6.0	6.0	5.1	8.4	0.0222	0.38	0.16	0.90	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* Indicates convergence problem, Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Study was included as a covariate in the Cox regression models.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
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20JAN2023 19:18

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

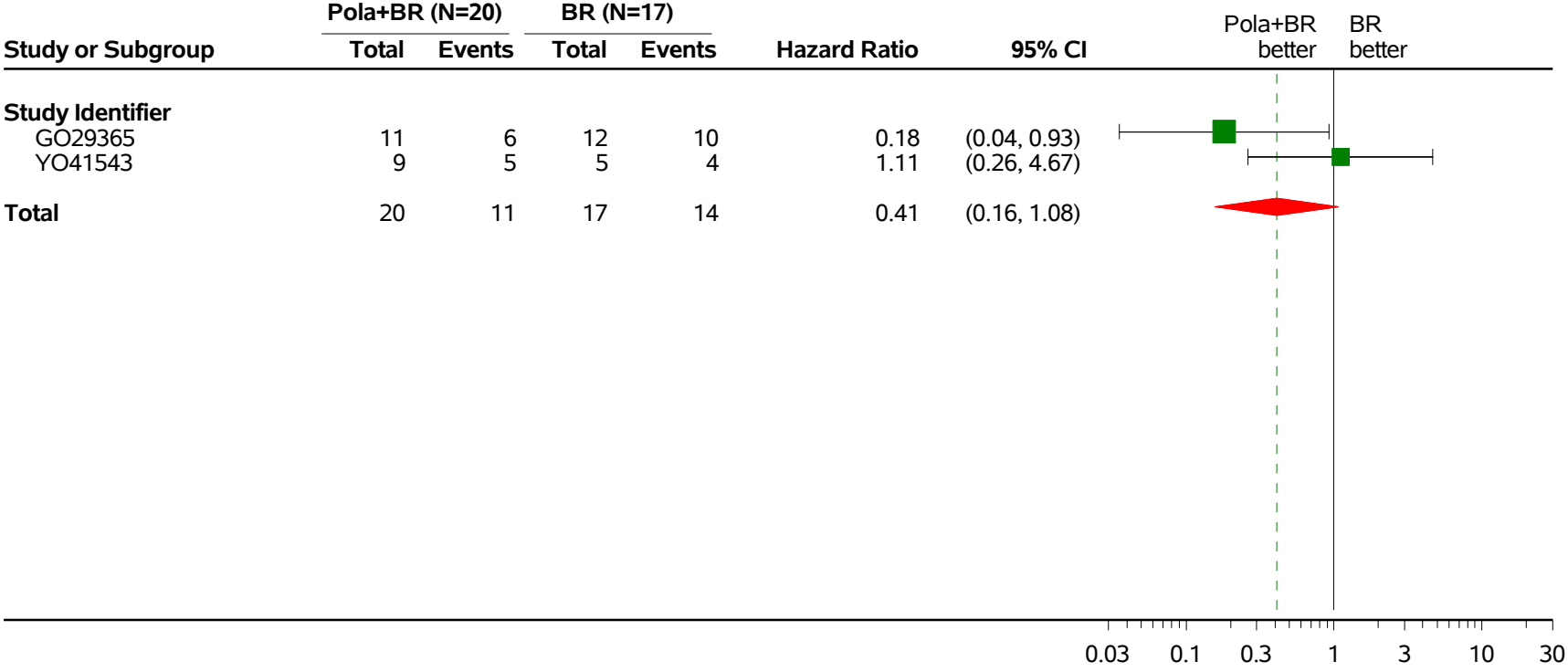
		Pola+BR (N=20)												BR (N=17)												Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		20	100.0	11	55.0	9	45.0	5.4	1.4	11.1	10.8	5.7	NE	17	100.0	14	82.4	3	17.6	2.0	1.4	5.1	5.1	2.1	6.0	0.0668	0.41	0.16	1.08		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the Cox regression models.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_eff_tte_gh_str_PFSIRC_ARMCDPLUS_L2_IT_29365_41543.xls
20JAN2023 18:42

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+ Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=20) Total	Pola+BR (N=20) Events	BR (N=17) Total	BR (N=17) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	11	6	12	10	0.18	(0.04, 0.93)
YO41543	9	5	5	4	1.11	(0.26, 4.67)
Total	20	11	17	14	0.41	(0.16, 1.08)



* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_str_PFSIRC_ARMCDPLUS_L2_IT_29365_41543.pdf 14DEC2022 22:29

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=20)												BR (N=17)											Pola + BR vs. BR																		
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event					log-rank	Hazard Ratio													Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status								Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	55.0	6	54.5	5	45.5	10.4	1.0	14.6	13.6	10.4	NE	12	70.6	10	83.3	2	16.7	1.9	1.0	4.7	4.7	1.9	5.8	0.0278	0.18	0.04	0.93		Convergence criterion (GCONV=1E-8) satisfied.								43.7						
	YO41543	9	45.0	5	55.6	4	44.4	3.6	1.4	NE	5.7	1.9	NE	5	29.4	4	80.0	1	20.0	6.0	1.9	6.0	6.0	1.9	NE	0.8866	1.11	0.26	4.67		Convergence criterion (GCONV=1E-8) satisfied.								56.3						
	Total	20	100.0	11	55.0	9	45.0	5.4	1.4	11.1	10.8	5.7	NE	17	100.0	14	82.4	3	17.6	2.0	1.4	5.1	5.1	2.1	6.0	0.0668	0.41	0.16	1.08		Convergence criterion (GCONV=1E-8) satisfied.								100.0	2.79	1	0.0947	64.18	-1.81	0.0708

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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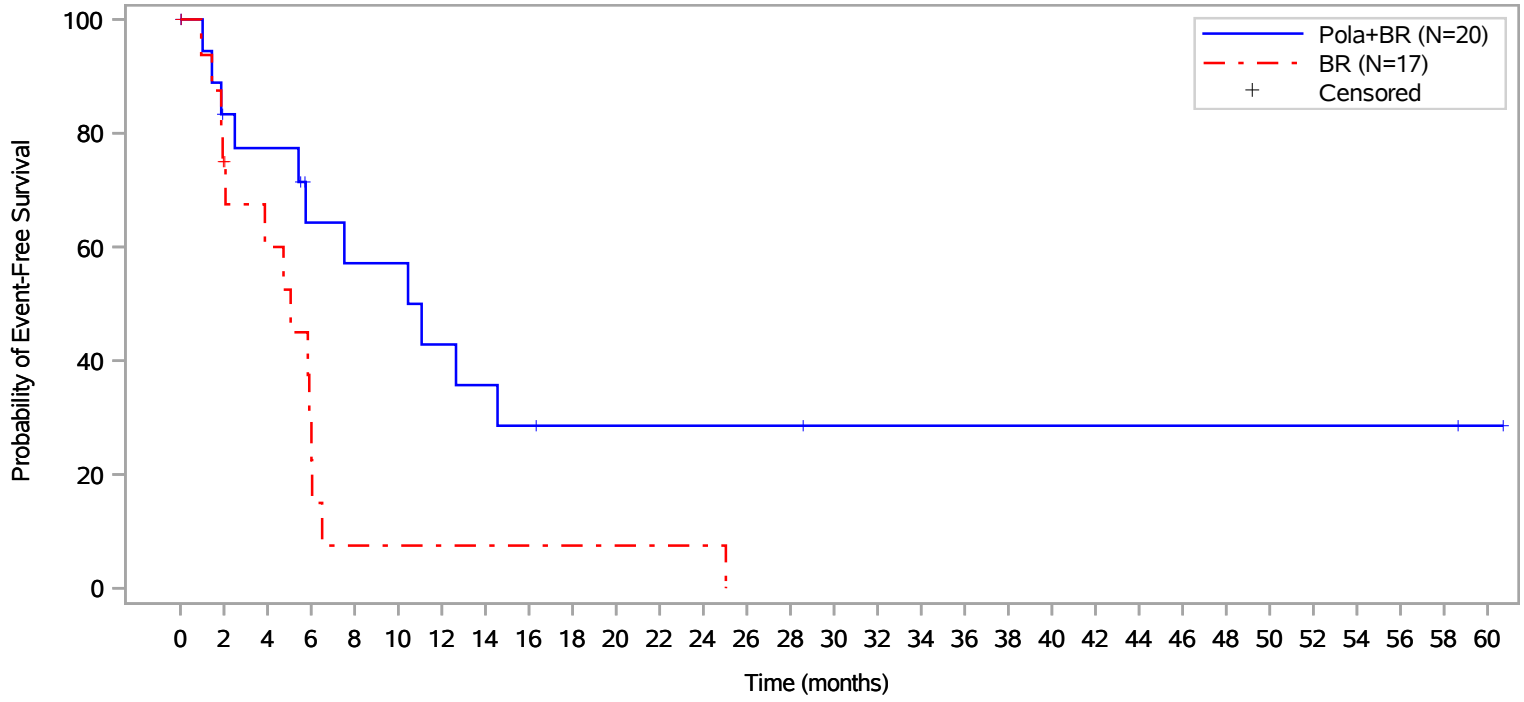
14DEC2022 22:47

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
STUDIES: GO29365, YO41543



Patients at risk																																				
Pola+BR (N=20)	20	14	13	9	8	8	6	5	4	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1			
BR (N=17)	17	11	8	4	1	1	1	1	1	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Patients censored																																		
Pola+BR (N=20)	0	3	3	5	5	5	5	5	5	6	6	6	6	6	6	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	8			
BR (N=17)	0	2	3	3	3	3	3	3	3	3	3	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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28NOV2022 14:29

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=20)												BR (N=17)										Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		20	100.0	11	55.0	9	45.0	5.4	1.4	11.1	10.8	5.7	NE	17	100.0	14	82.4	3	17.6	2.0	1.4	5.1	5.1	2.1	6.0	0.0116	0.37	0.16	0.85	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	70.0	9	64.3	5	35.7	2.5	1.4	11.1	7.5	2.5	14.6	8	47.1	6	75.0	2	25.0	1.9	1.0	5.1	5.1	1.9	6.0	0.3786	0.59	0.20	1.72	Convergence criterion (GCONV=1E-8) satisfied.	0.1452
	Female	6	30.0	2	33.3	4	66.7	10.4	5.7	NE	NE	5.7	NE	9	52.9	8	88.9	1	11.1	3.9	1.4	5.8	5.8	3.9	6.0	0.0087	0.07	0.01	0.76	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	40.0	5	62.5	3	37.5	1.7	1.0	14.6	5.4	1.4	NE	2	11.8	1	50.0	1	50.0	1.9	1.9	NE	NE	1.9	NE	0.9606	1.13	0.11	11.61	Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	12	60.0	6	50.0	6	50.0	7.5	2.9	12.6	11.1	7.5	NE	15	88.2	13	86.7	2	13.3	2.1	1.4	5.1	5.1	2.1	6.0	0.0043	0.24	0.09	0.68	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	9	45.0	6	66.7	3	33.3	2.5	1.0	11.1	7.5	2.5	12.6	14	82.4	12	85.7	2	14.3	2.1	1.4	5.1	5.1	2.1	6.0	0.1566	0.47	0.17	1.31	Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	55.0	5	45.5	6	54.5	5.4	1.4	NE	14.6	5.4	NE	3	17.6	2	66.7	1	33.3	1.9	1.9	NE	5.8	1.9	NE	0.2421	0.20	0.03	1.44	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	25.0	2	40.0	3	60.0	10.8	10.4	NE	NE	10.4	NE	3	17.6	3	100.0	0	-	3.9	3.9	NE	4.7	3.9	NE	0.2119	0.32	0.05	2.05	Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	15	75.0	9	60.0	6	40.0	2.5	1.4	7.5	7.5	2.5	14.6	14	82.4	11	78.6	3	21.4	1.9	1.4	5.8	5.1	1.9	6.0	0.0507	0.38	0.13	1.05	Convergence criterion (GCONV=1E-8) satisfied.	
Duration of response to prior therapy	<=12 Months	12	60.0	7	58.3	5	41.7	1.9	1.0	5.7	5.4	1.9	NE	14	82.4	11	78.6	3	21.4	2.1	1.4	5.9	4.7	2.1	6.0	0.4351	0.68	0.26	1.80	Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	8	40.0	4	50.0	4	50.0	11.1	10.4	14.6	13.6	11.1	NE	3	17.6	3	100.0	0	-	1.9	1.9	NE	5.1	1.9	NE	0.0006	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Refractory to last prior anti-lymphoma therapy**	Yes	11	55.0	6	54.5	5	45.5	1.9	1.0	5.7	5.7	1.9	7.5	14	82.4	11	78.6	3	21.4	2.1	1.4	5.9	4.7	2.1	6.0	0.5374	0.76	0.27	2.18	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	9	45.0	5	55.6	4	44.4	11.1	2.5	14.6	14.6	10.4	NE	3	17.6	3	100.0	0	-	1.9	1.9	NE	5.1	1.9	NE	0.0039	0.06	0.01	0.70	Convergence criterion (GCONV=1E-8) satisfied.	
Prior Bone Marrow Transplant	Yes	1	5.0	0	-	1	100.0	NE	NE	NE	NE	NE	NE	0	0.0	0	-	0	-	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-
	No	19	95.0	11	57.9	8	42.1	5.4	1.4	10.4	10.4	5.4	NE	17	100.0	14	82.4	3	17.6	2.0	1.4	5.1	5.1	2.1	6.0	0.0155	0.38	0.17	0.90	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* Indicates convergence problem, Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Study was included as a covariate in the Cox regression models.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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20JAN2023 18:50

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	19	100.0	0	-	17	100.0	17	100.0	0	-	0.3411	0.65	0.31	1.35		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	14	100.0	0	-	8	47.1	8	100.0	0	-	0.1437	0.38	0.12	1.23		Convergence criterion (GCONV=1E-8) satisfied.	0.1006
	Female	5	26.3	5	100.0	0	-	9	52.9	9	100.0	0	-	0.9024	1.23	0.36	4.22		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	8	100.0	0	-	2	11.8	2	100.0	0	-	0.2189	0.47	0.07	3.22		Convergence criterion (GCONV=1E-8) satisfied.	0.2591
	>= 65	11	57.9	11	100.0	0	-	15	88.2	15	100.0	0	-	0.7992	0.92	0.38	2.19		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	8	100.0	0	-	14	82.4	14	100.0	0	-	0.8431	1.08	0.42	2.77		Convergence criterion (GCONV=1E-8) satisfied.	0.4455
	<3	11	57.9	11	100.0	0	-	3	17.6	3	100.0	0	-	0.5199	0.53	0.12	2.29		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	5	100.0	0	-	3	17.6	3	100.0	0	-	0.4928	0.58	0.12	2.81		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	14	100.0	0	-	14	82.4	14	100.0	0	-	0.6985	0.90	0.36	2.23		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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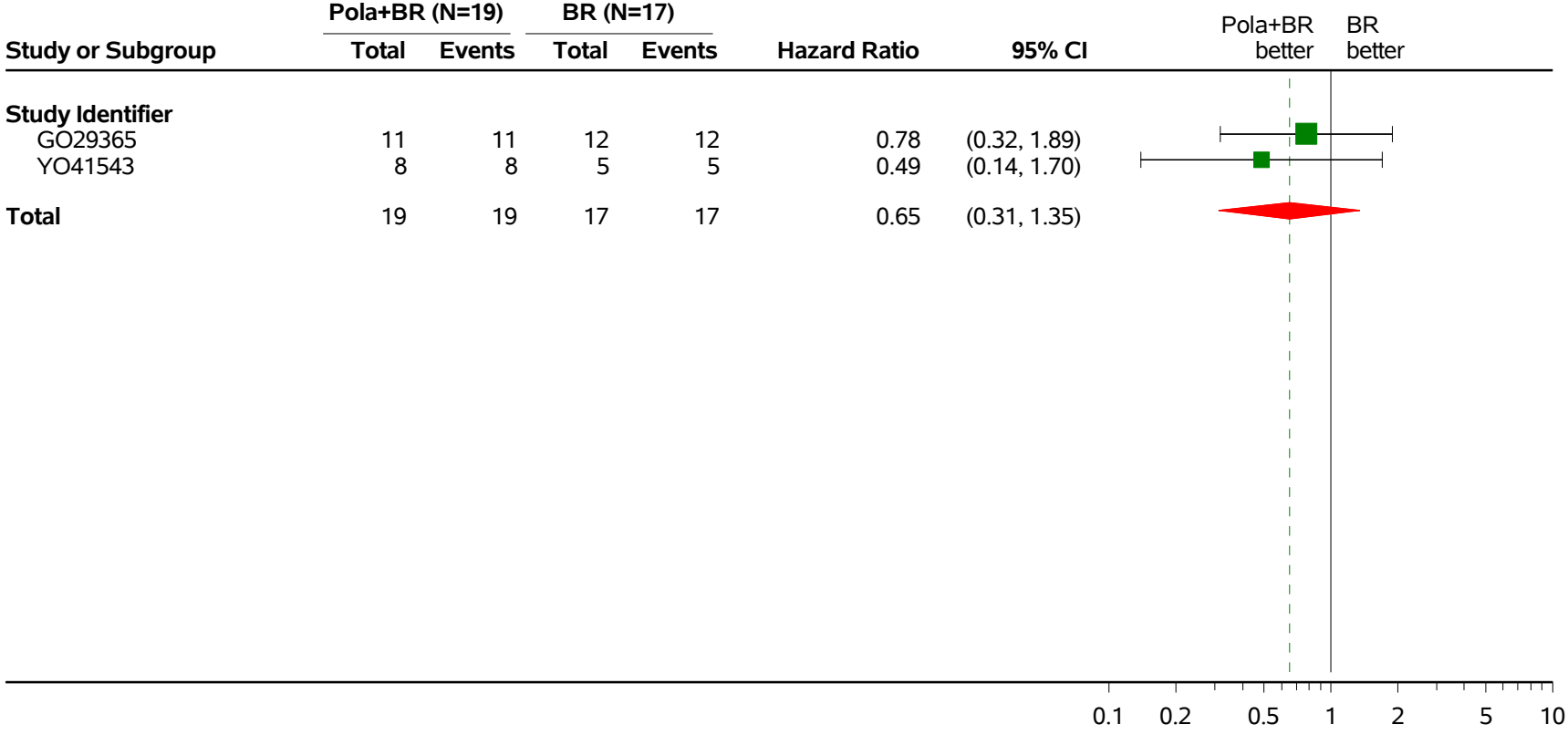
30NOV2022 18:29

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	11	12	12	0.78	(0.32, 1.89)
YO41543	8	8	5	5	0.49	(0.14, 1.70)
Total	19	19	17	17	0.65	(0.31, 1.35)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	11	100.0	0	-	12	70.6	12	100.0	0	-	0.5763	0.78	0.32	1.89		Convergence criterion (GCONV=1E-8) satisfied.		66.4						
	YO41543	8	42.1	8	100.0	0	-	5	29.4	5	100.0	0	-	0.2525	0.49	0.14	1.70		Convergence criterion (GCONV=1E-8) satisfied.		33.6						
	Total	19	100.0	19	100.0	0	-	17	100.0	17	100.0	0	-	0.3411	0.65	0.31	1.35		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.36	1	0.5503	0.00	-1.15	0.2486

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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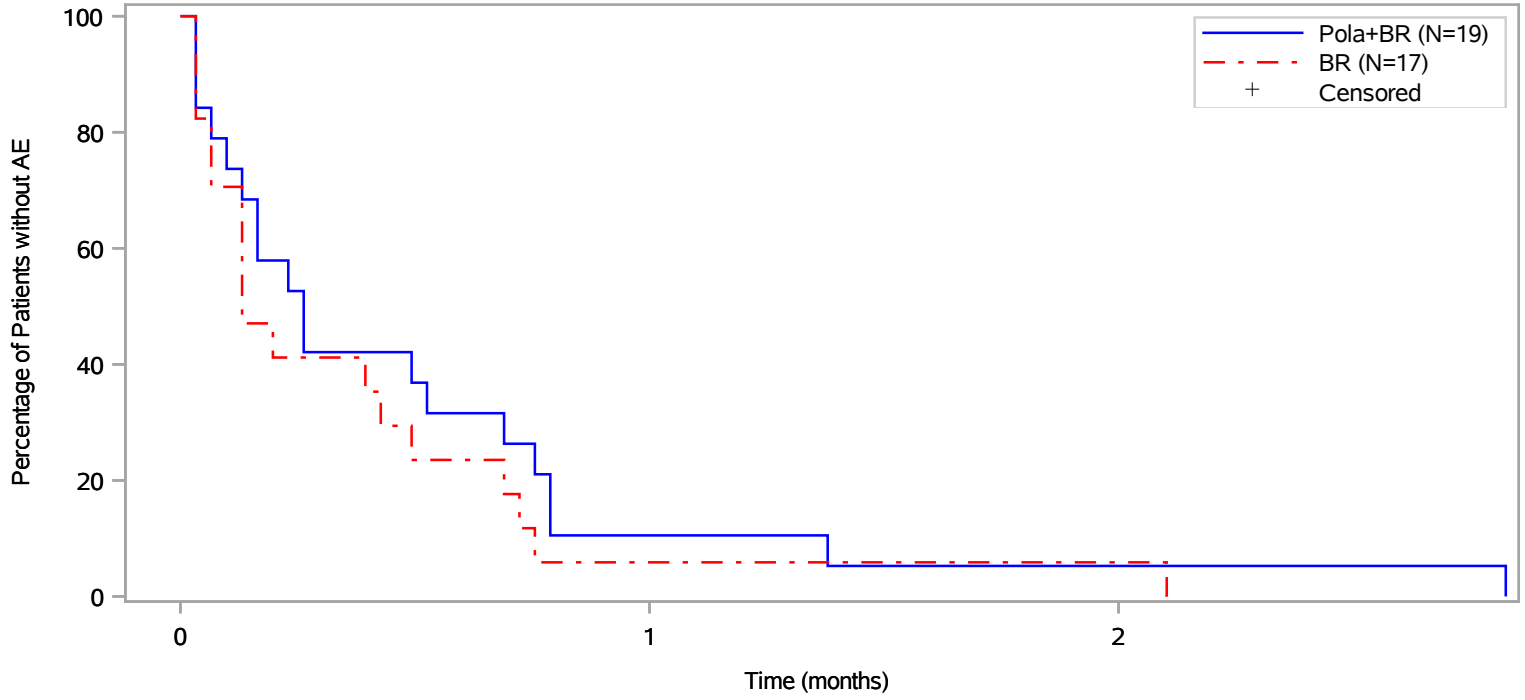
16DEC2022 9:20

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543



Patients at risk			
Pola+BR (N=19)	19	2	1
BR (N=17)	17	1	1
Patients censored			
Pola+BR (N=19)	0	0	0
BR (N=17)	0	0	0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 19:52

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	15	78.9	4	21.1	17	100.0	13	76.5	4	23.5	0.4937	0.81	0.37	1.80		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	10	71.4	4	28.6	8	47.1	6	75.0	2	25.0	0.2823	0.65	0.21	2.00		Convergence criterion (GCONV=1E-8) satisfied.	0.4659
	Female	5	26.3	5	100.0	0	-	9	52.9	7	77.8	2	22.2	0.8192	1.16	0.32	4.15		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	6	75.0	2	25.0	2	11.8	2	100.0	0	-	0.1128	0.25	0.03	2.11		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	9	81.8	2	18.2	15	88.2	11	73.3	4	26.7	0.6729	0.97	0.37	2.52		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	7	87.5	1	12.5	14	82.4	10	71.4	4	28.6	0.9737	1.11	0.40	3.10		Convergence criterion (GCONV=1E-8) satisfied.	0.5289
	<3	11	57.9	8	72.7	3	27.3	3	17.6	3	100.0	0	-	0.3932	0.46	0.10	2.09		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	4	80.0	1	20.0	3	17.6	2	66.7	1	33.3	0.9656	0.96	0.16	5.90		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	11	78.6	3	21.4	14	82.4	11	78.6	3	21.4	0.5450	0.91	0.37	2.23		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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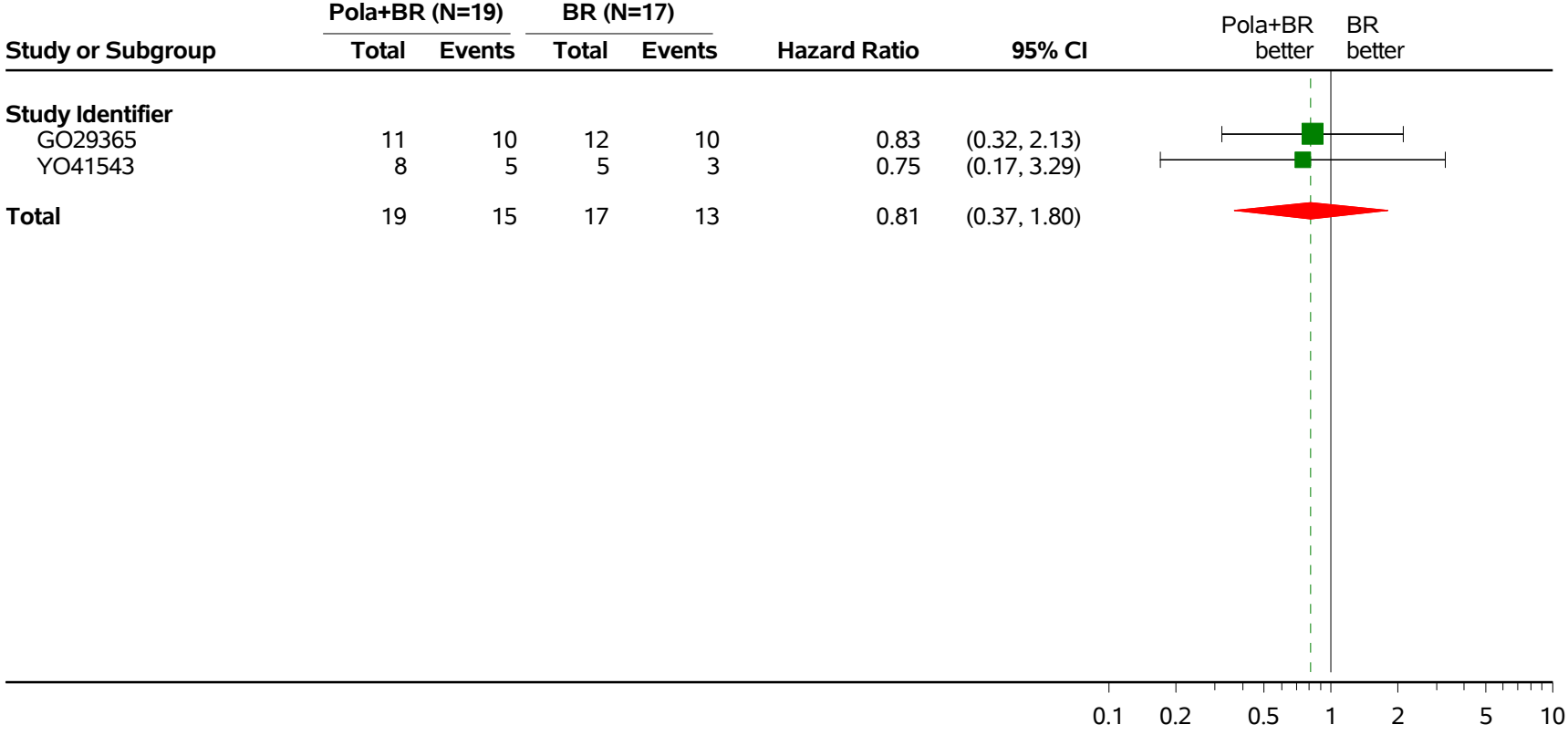
30NOV2022 19:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	10	12	10	0.83	(0.32, 2.13)
YO41543	8	5	5	3	0.75	(0.17, 3.29)
Total	19	15	17	13	0.81	(0.37, 1.80)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	10	90.9	1	9.1	12	70.6	10	83.3	2	16.7	0.6960	0.83	0.32	2.13		Convergence criterion (GCONV=1E-8) satisfied.	71.1						
	YO41543	8	42.1	5	62.5	3	37.5	5	29.4	3	60.0	2	40.0	0.6996	0.75	0.17	3.29		Convergence criterion (GCONV=1E-8) satisfied.	28.9						
	Total	19	100.0	15	78.9	4	21.1	17	100.0	13	76.5	4	23.5	0.4937	0.81	0.37	1.80		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.01	1	0.9056	0.00	-0.51	0.6124

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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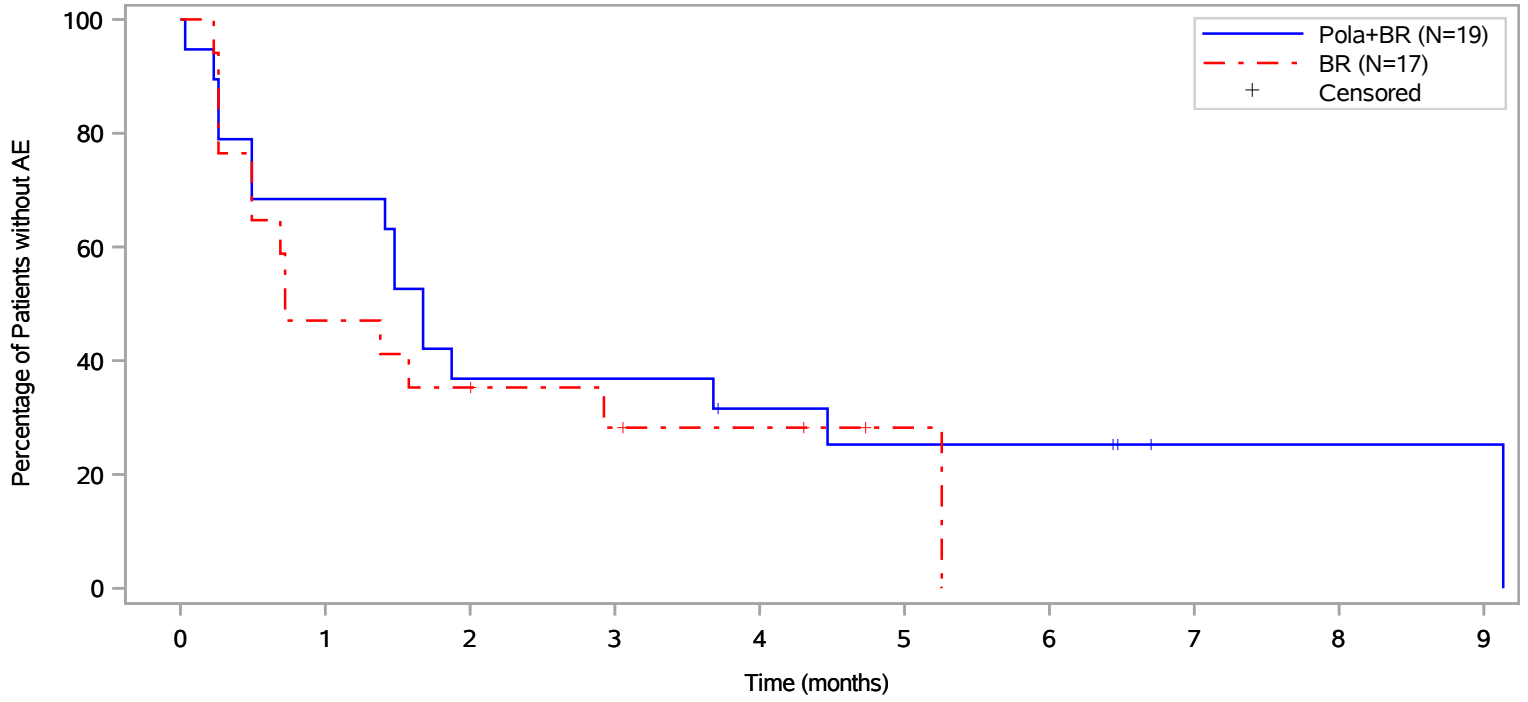
16DEC2022 9:34

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543



Patients at risk										
Pola+BR (N=19)	19	13	7	7	5	4	4	1	1	1
BR (N=17)	17	8	6	4	3	1	NE	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	0	0	0	1	1	1	4	4	4
BR (N=17)	0	0	0	1	2	4	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 19:57

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	12	63.2	7	36.8	17	100.0	12	70.6	5	29.4	0.4126	0.77	0.33	1.78		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	8	57.1	6	42.9	8	47.1	6	75.0	2	25.0	0.1913	0.59	0.18	1.89		Convergence criterion (GCONV=1E-8) satisfied.	0.2588
	Female	5	26.3	4	80.0	1	20.0	9	52.9	6	66.7	3	33.3	0.6586	1.32	0.36	4.84		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	5	62.5	3	37.5	2	11.8	2	100.0	0	-	0.1128	0.21	0.02	1.89		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	7	63.6	4	36.4	15	88.2	10	66.7	5	33.3	0.6997	0.95	0.35	2.59		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	6	75.0	2	25.0	14	82.4	9	64.3	5	35.7	0.9648	1.03	0.34	3.09		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	6	54.5	5	45.5	3	17.6	3	100.0	0	-	0.2385	0.42	0.09	1.97		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	3	60.0	2	40.0	3	17.6	2	66.7	1	33.3	0.9656	0.96	0.16	5.90		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	9	64.3	5	35.7	14	82.4	10	71.4	4	28.6	0.4187	0.81	0.31	2.12		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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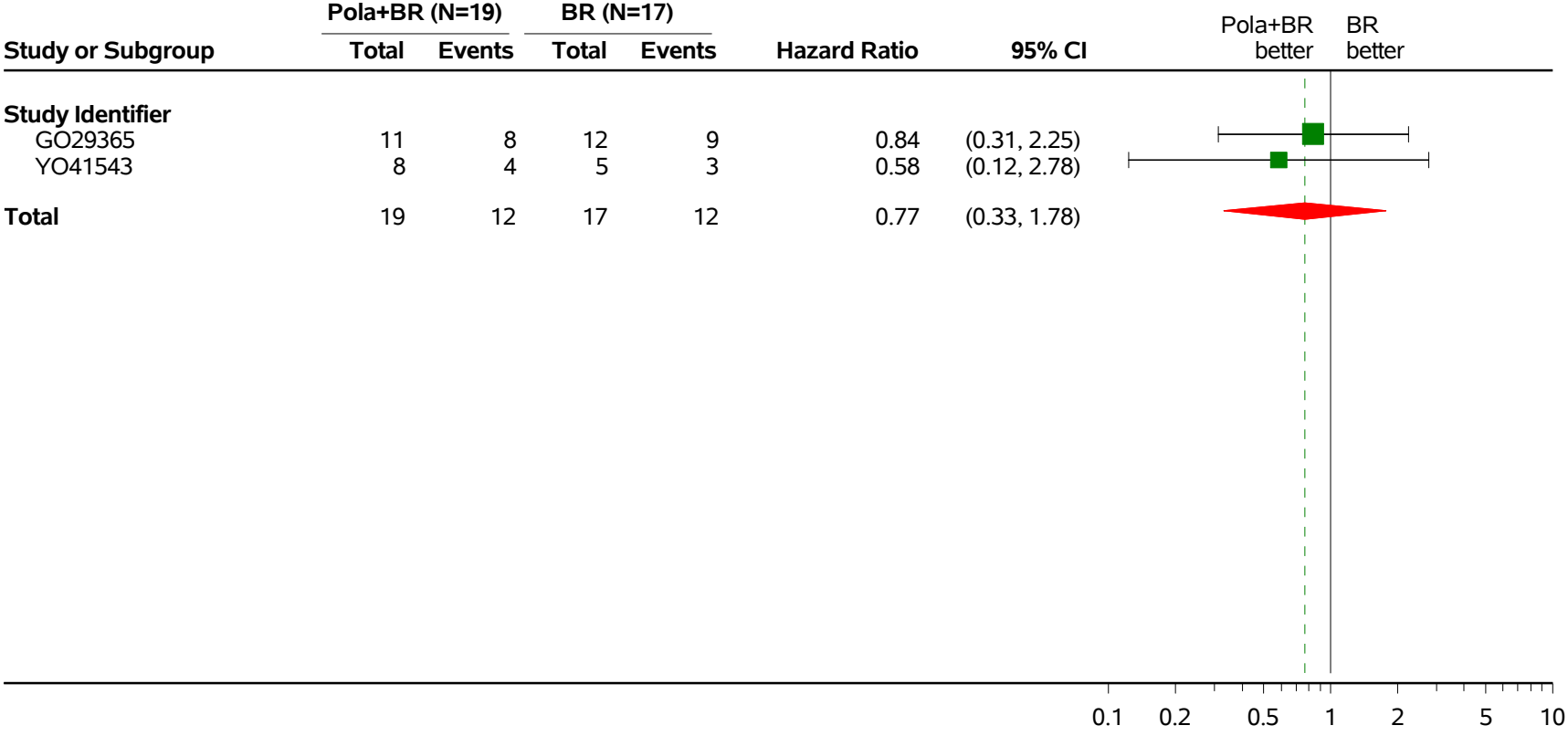
30NOV2022 19:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	8	12	9	0.84	(0.31, 2.25)
YO41543	8	4	5	3	0.58	(0.12, 2.78)
Total	19	12	17	12	0.77	(0.33, 1.78)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	8	72.7	3	27.3	12	70.6	9	75.0	3	25.0	0.7231	0.84	0.31	2.25		Convergence criterion (GCONV=1E-8) satisfied.	71.3						
	YO41543	8	42.1	4	50.0	4	50.0	5	29.4	3	60.0	2	40.0	0.4945	0.58	0.12	2.78		Convergence criterion (GCONV=1E-8) satisfied.	28.7						
	Total	19	100.0	12	63.2	7	36.8	17	100.0	12	70.6	5	29.4	0.4126	0.77	0.33	1.78		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.15	1	0.7017	0.00	-0.62	0.5336

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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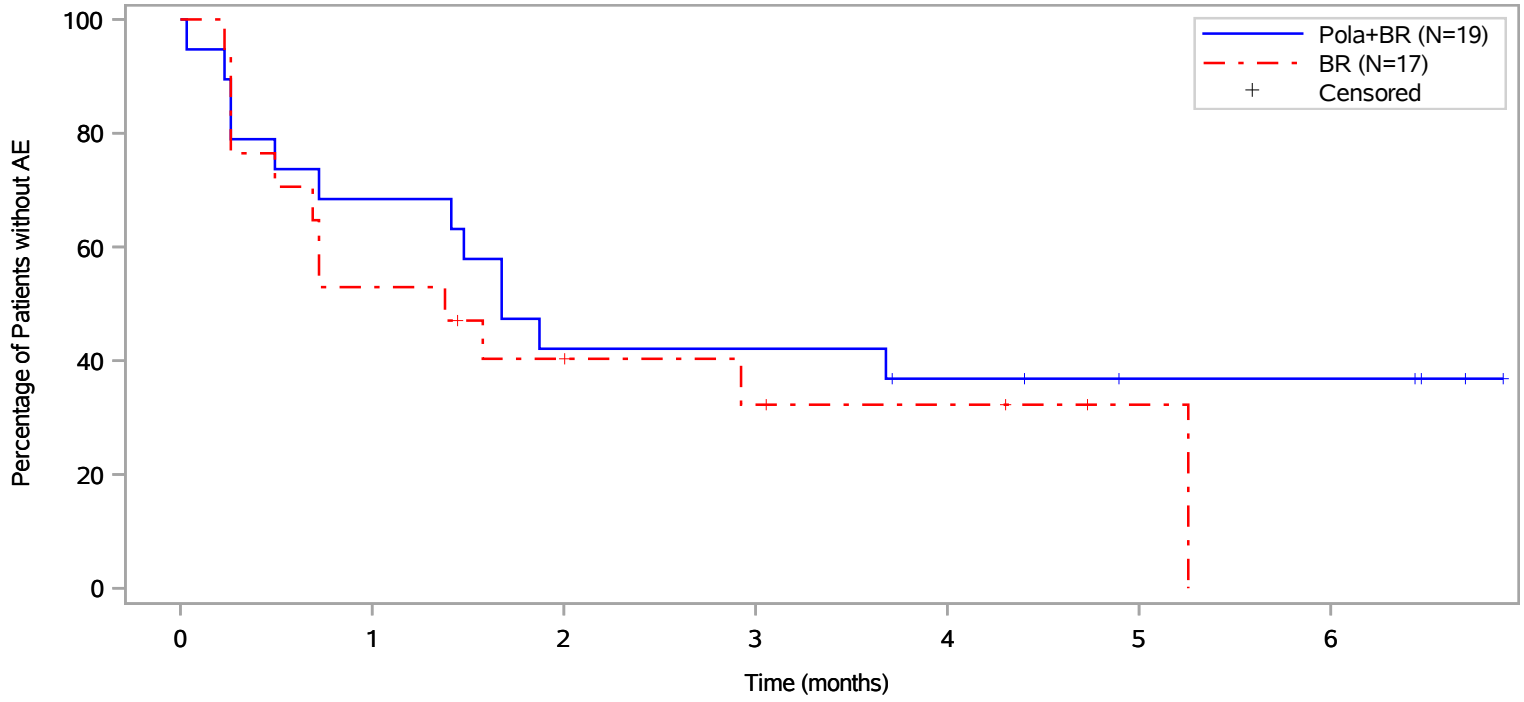
16DEC2022 9:50

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	13	8	8	6	4	4
BR (N=17)	17	9	6	4	3	1	NE
Patients censored							
Pola+BR (N=19)	0	0	0	0	1	3	3
BR (N=17)	0	0	1	2	3	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	9	47.4	10	52.6	17	100.0	7	41.2	10	58.8	0.9601	1.17	0.42	3.27		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	6	42.9	8	57.1	8	47.1	5	62.5	3	37.5	0.3072	0.81	0.22	3.00		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	3	60.0	2	40.0	9	52.9	2	22.2	7	77.8	0.4595	1.46	0.19	11.18		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	4	50.0	4	50.0	2	11.8	0	-	2	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	5	45.5	6	54.5	15	88.2	7	46.7	8	53.3	0.5414	0.91	0.26	3.13		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	4	50.0	4	50.0	14	82.4	7	50.0	7	50.0	0.8681	1.89	0.50	7.19		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	5	45.5	6	54.5	3	17.6	0	-	3	100.0	0.2848	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	2	40.0	3	60.0	3	17.6	2	66.7	1	33.3	0.2220	0.25	0.02	2.79		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	7	50.0	7	50.0	14	82.4	5	35.7	9	64.3	0.5896	2.40	0.71	8.10		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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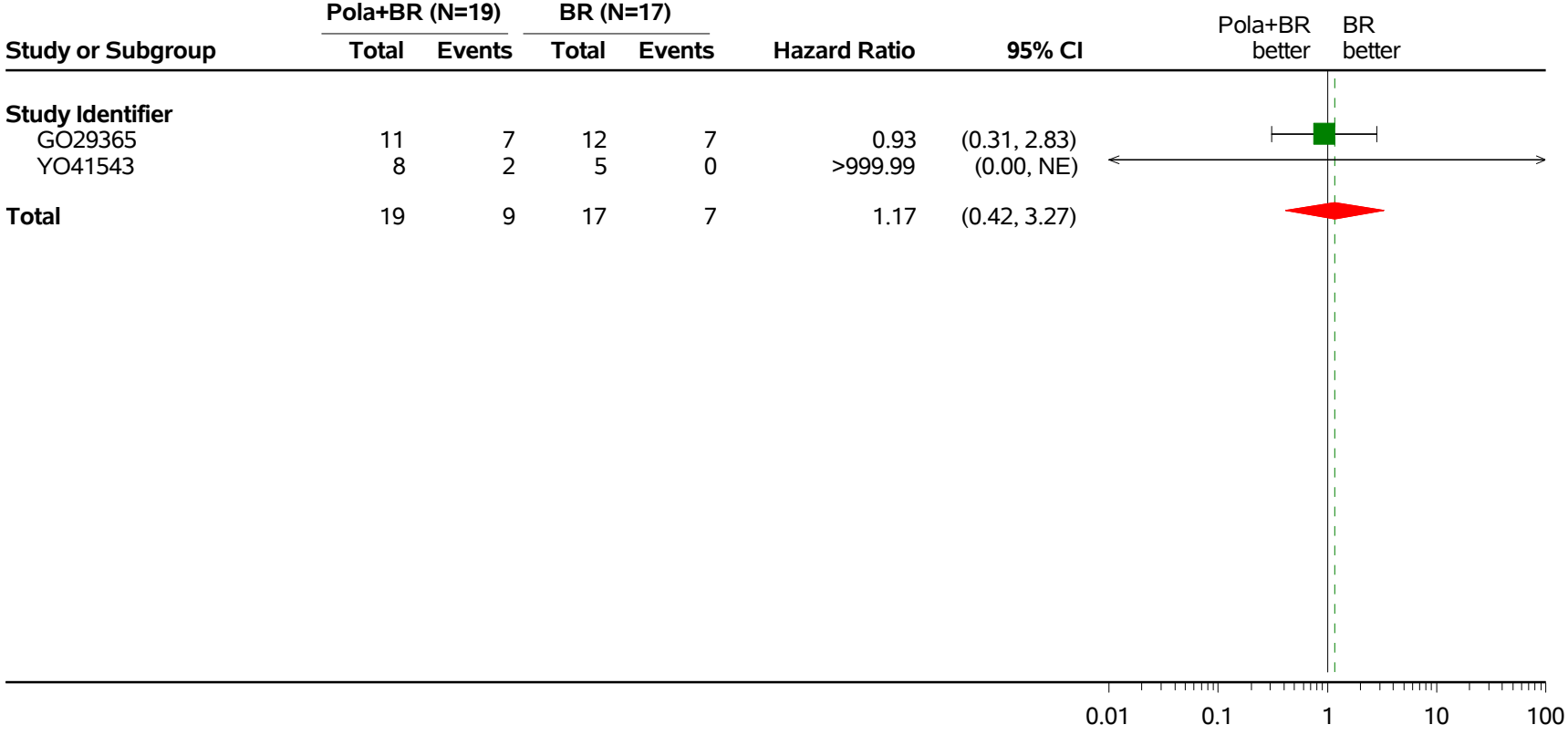
30NOV2022 20:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	7	12	7	0.93	(0.31, 2.83)
YO41543	8	2	5	0	>999.99	(0.00, NE)
Total	19	9	17	7	1.17	(0.42, 3.27)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 15:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	7	63.6	4	36.4	12	70.6	7	58.3	5	41.7	0.9037	0.93	0.31	2.83		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	2	25.0	6	75.0	5	29.4	0	-	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	19	100.0	9	47.4	10	52.6	17	100.0	7	41.2	10	58.8	0.9601	1.17	0.42	3.27		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.15	1	0.6947	0.00	0.29	0.7705

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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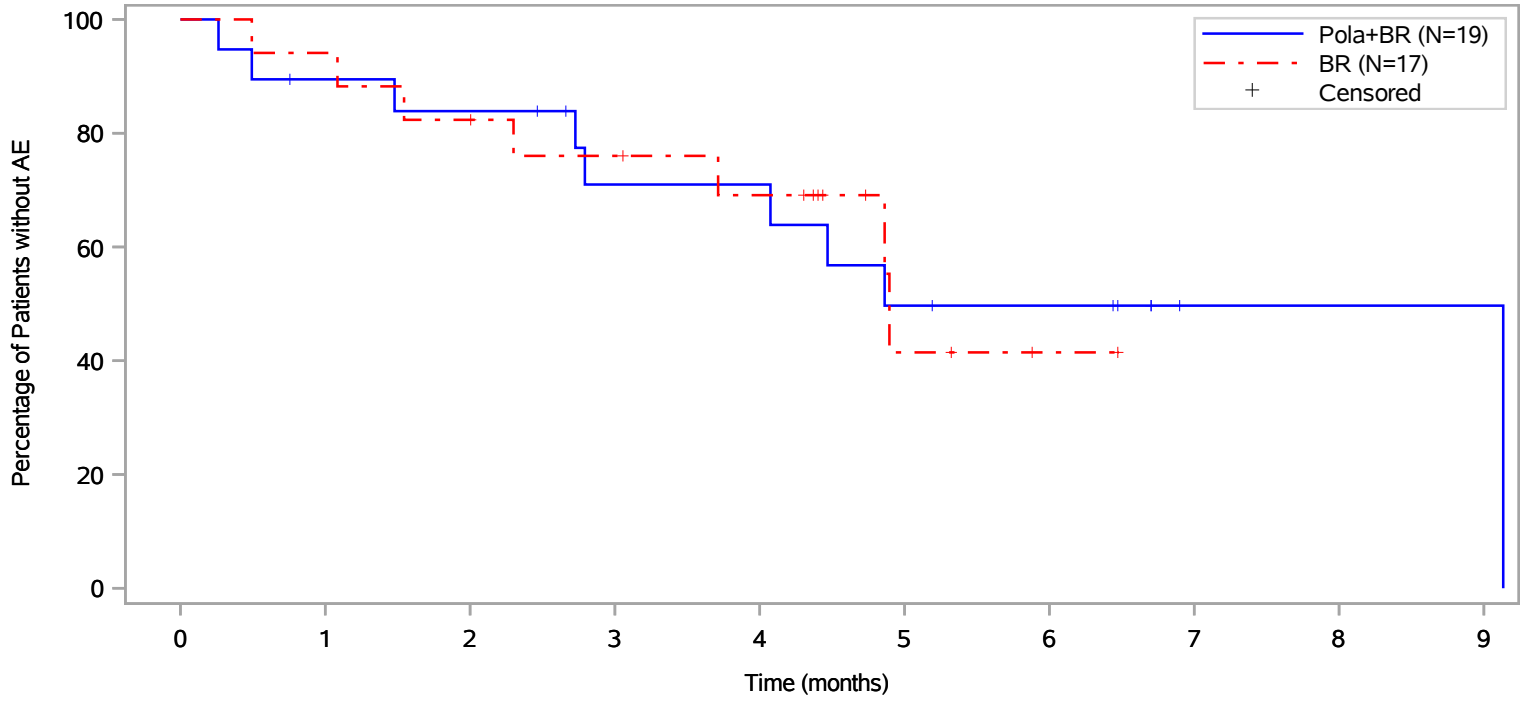
16DEC2022 10:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543



Patients at risk										
Pola+BR (N=19)	19	16	15	11	10	7	6	1	1	1
BR (N=17)	17	16	14	12	10	3	1	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	1	3	4	4	5	10	10	10
BR (N=17)	0	0	0	1	2	7	9	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:08

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	4	21.1	15	78.9	17	100.0	3	17.6	14	82.4	0.3691	0.55	0.09	3.42		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	3	21.4	11	78.6	8	47.1	1	12.5	7	87.5	0.9745	1.98	0.18	22.02		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.0979	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	3	20.0	12	80.0	0.2399	0.33	0.03	3.28		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	3	37.5	5	62.5	14	82.4	2	14.3	12	85.7	0.5512	1.78	0.25	12.67		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	1	9.1	10	90.9	3	17.6	1	33.3	2	66.7	0.0082				*	WARNING: Iteration limit reached without convergence.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	2	14.3	12	85.7	0.6856	1.02	0.14	7.56		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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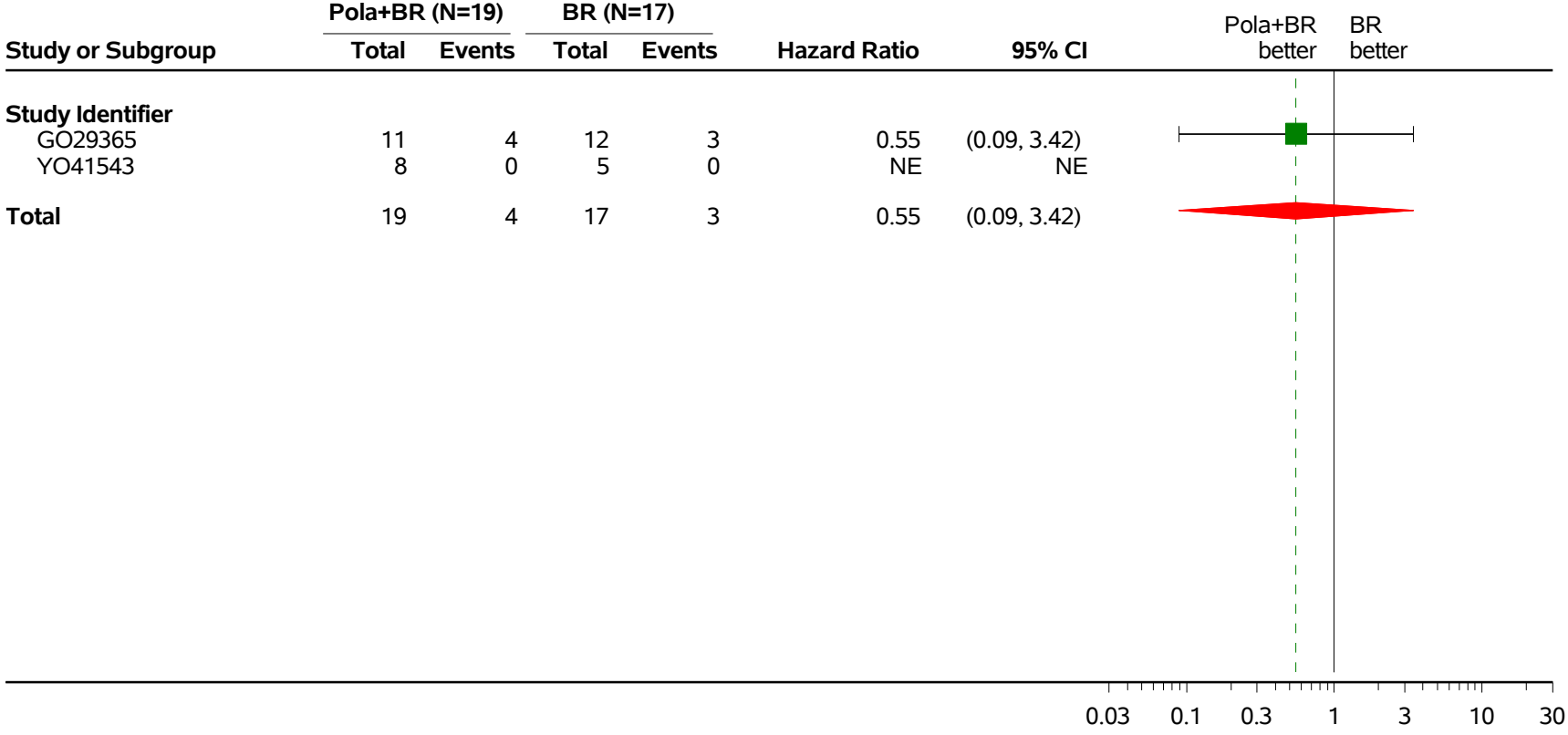
30NOV2022 21:24

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	4	12	3	0.55	(0.09, 3.42)
YO41543	8	0	5	0	NE	NE
Total	19	4	17	3	0.55	(0.09, 3.42)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	4	36.4	7	63.6	12	70.6	3	25.0	9	75.0	0.5171	0.55	0.09	3.42		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	4	21.1	15	78.9	17	100.0	3	17.6	14	82.4	0.3691	0.55	0.09	3.42		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	-0.64	0.5225

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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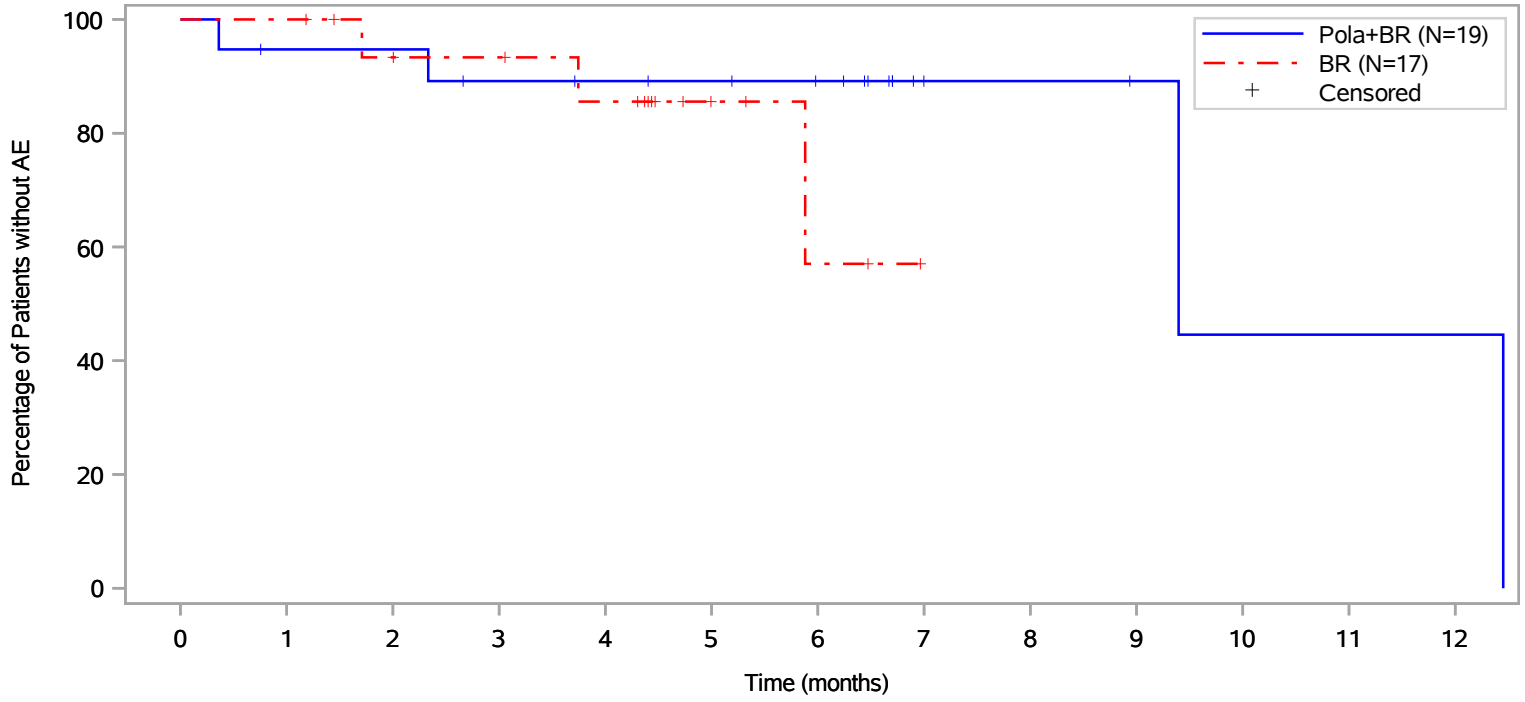
16DEC2022 10:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543



Patients at risk													
Pola+BR (N=19)	19	17	17	15	14	13	11	3	3	2	1	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	1	2	3	4	6	14	14	15	15	15	15
BR (N=17)	0	0	2	3	4	11	12	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	9	47.4	10	52.6	17	100.0	11	64.7	6	35.3	0.0108	0.31	0.11	0.87		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	7	50.0	7	50.0	8	47.1	6	75.0	2	25.0	0.1582	0.58	0.17	1.89		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	9	52.9	5	55.6	4	44.4	0.0083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	4	50.0	4	50.0	2	11.8	0	-	2	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	5	45.5	6	54.5	15	88.2	11	73.3	4	26.7	0.0007	0.11	0.02	0.54		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	5	62.5	3	37.5	14	82.4	9	64.3	5	35.7	0.0824	0.34	0.09	1.32		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	4	36.4	7	63.6	3	17.6	2	66.7	1	33.3	0.2617	0.34	0.05	2.22		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	2	40.0	3	60.0	3	17.6	2	66.7	1	33.3	0.3834	0.36	0.03	4.01		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	7	50.0	7	50.0	14	82.4	9	64.3	5	35.7	0.0437	0.42	0.13	1.31		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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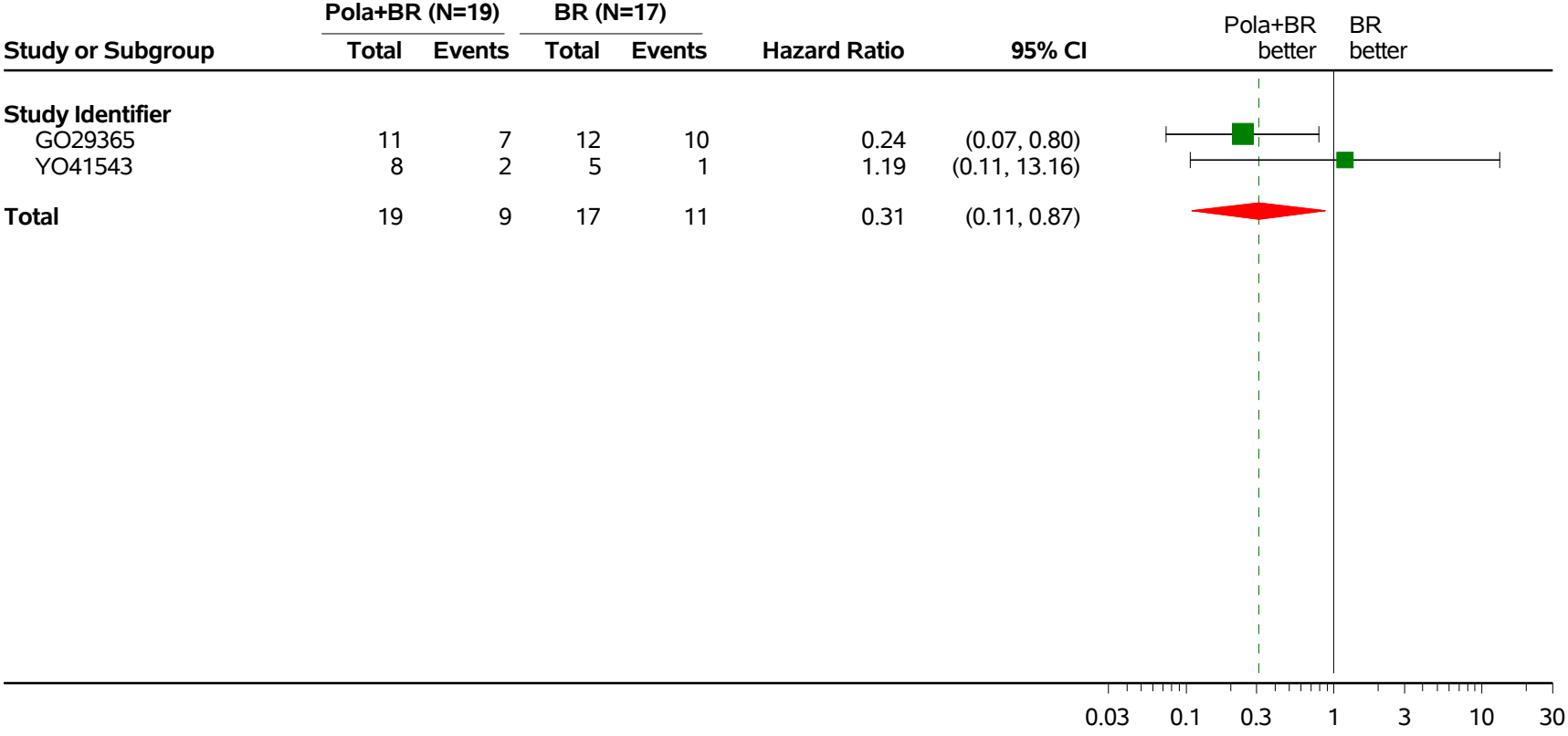
30NOV2022 22:16

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	7	12	10	0.24	(0.07, 0.80)
YO41543	8	2	5	1	1.19	(0.11, 13.16)
Total	19	9	17	11	0.31	(0.11, 0.87)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	7	63.6	4	36.4	12	70.6	10	83.3	2	16.7	0.0123	0.24	0.07	0.80		Convergence criterion (GCONV=1E-8) satisfied.		80.3						
	YO41543	8	42.1	2	25.0	6	75.0	5	29.4	1	20.0	4	80.0	0.8878	1.19	0.11	13.16		Convergence criterion (GCONV=1E-8) satisfied.		19.7						
	Total	19	100.0	9	47.4	10	52.6	17	100.0	11	64.7	6	35.3	0.0108	0.31	0.11	0.87		Convergence criterion (GCONV=1E-8) satisfied.		100.0	1.37	1	0.2421	26.91	-2.22	0.0265

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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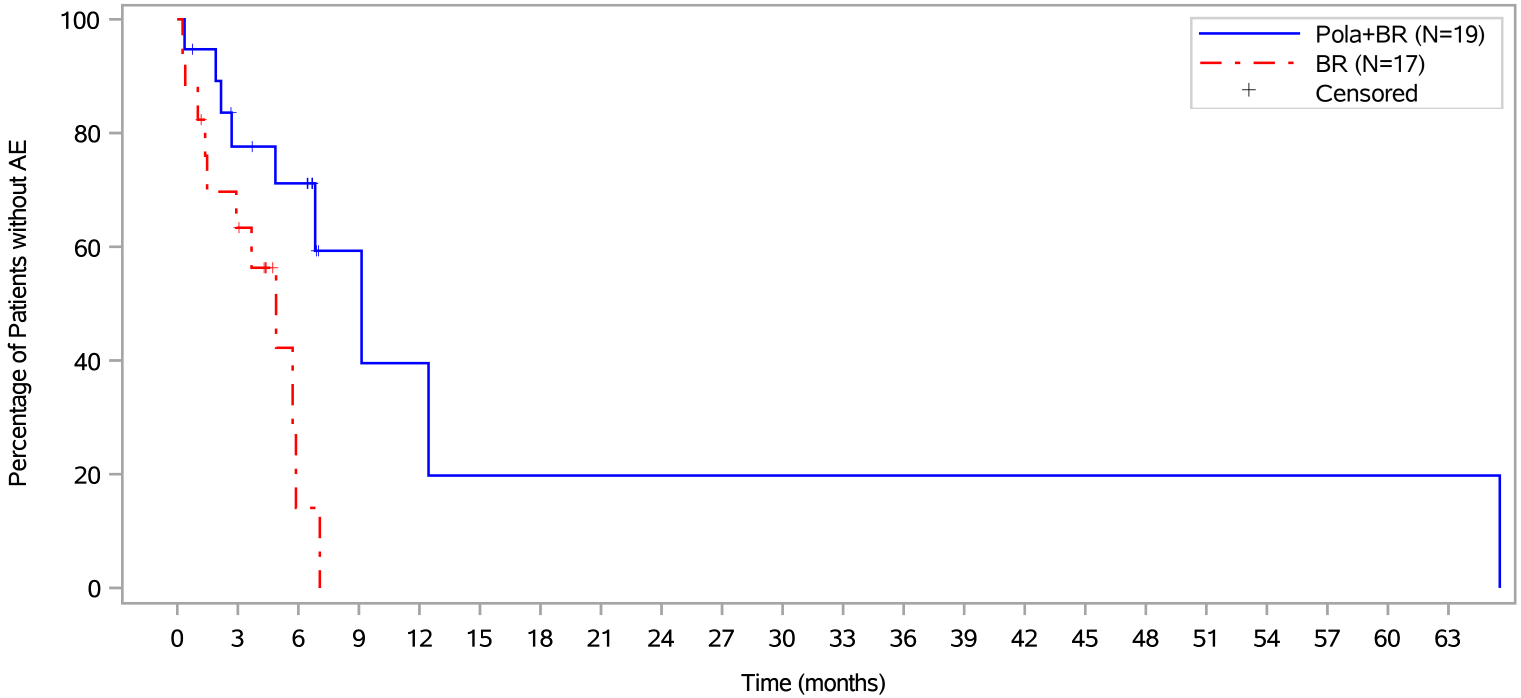
16DEC2022 10:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543



Patients at risk
Pola+BR (N=19) 19 17 16 13 12 11 11 3 3 3 2 2 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
BR (N=17) 17 15 11 10 8 3 1 1 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE
Patients censored
Pola+BR (N=19) 0 1 1 2 3 3 3 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10
BR (N=17) 0 0 1 1 2 6 6 6 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:19

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	6	31.6	13	68.4	17	100.0	3	17.6	14	82.4	0.5705	1.91	0.47	7.83		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	5	35.7	9	64.3	8	47.1	1	12.5	7	87.5	0.3922	6.01	0.69	52.19		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.5530	0.48	0.04	6.11		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4452	1.01	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	3	20.0	12	80.0	0.7253	1.49	0.32	6.92		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	5	62.5	3	37.5	14	82.4	3	21.4	11	78.6	0.1651	3.16	0.74	13.45		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.7276	0.61	0.04	9.93		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	5	35.7	9	64.3	14	82.4	2	14.3	12	85.7	0.4466	2.93	0.55	15.46		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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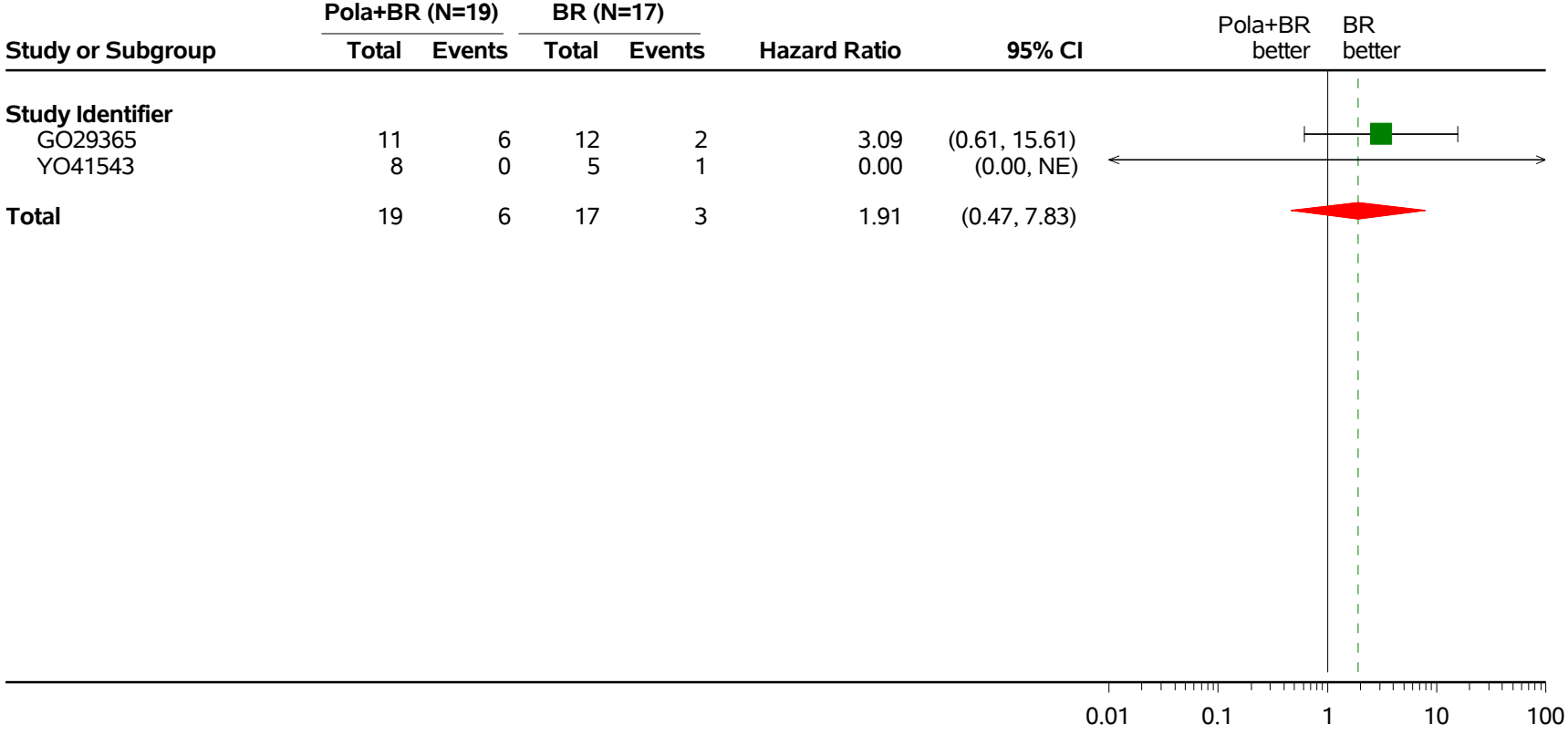
24JAN2023 17:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	6	12	2	3.09	(0.61, 15.61)
YO41543	8	0	5	1	0.00	(0.00, NE)
Total	19	6	17	3	1.91	(0.47, 7.83)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTWDAE_L2_ARMCDPLUSSE_29365_41543.pdf 25OCT2023 8:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	6	54.5	5	45.5	12	70.6	2	16.7	10	83.3	0.1516	3.09	0.61	15.61		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	19	100.0	6	31.6	13	68.4	17	100.0	3	17.6	14	82.4	0.5705	1.91	0.47	7.83		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.34	1	0.5608	0.00	0.90	0.3678

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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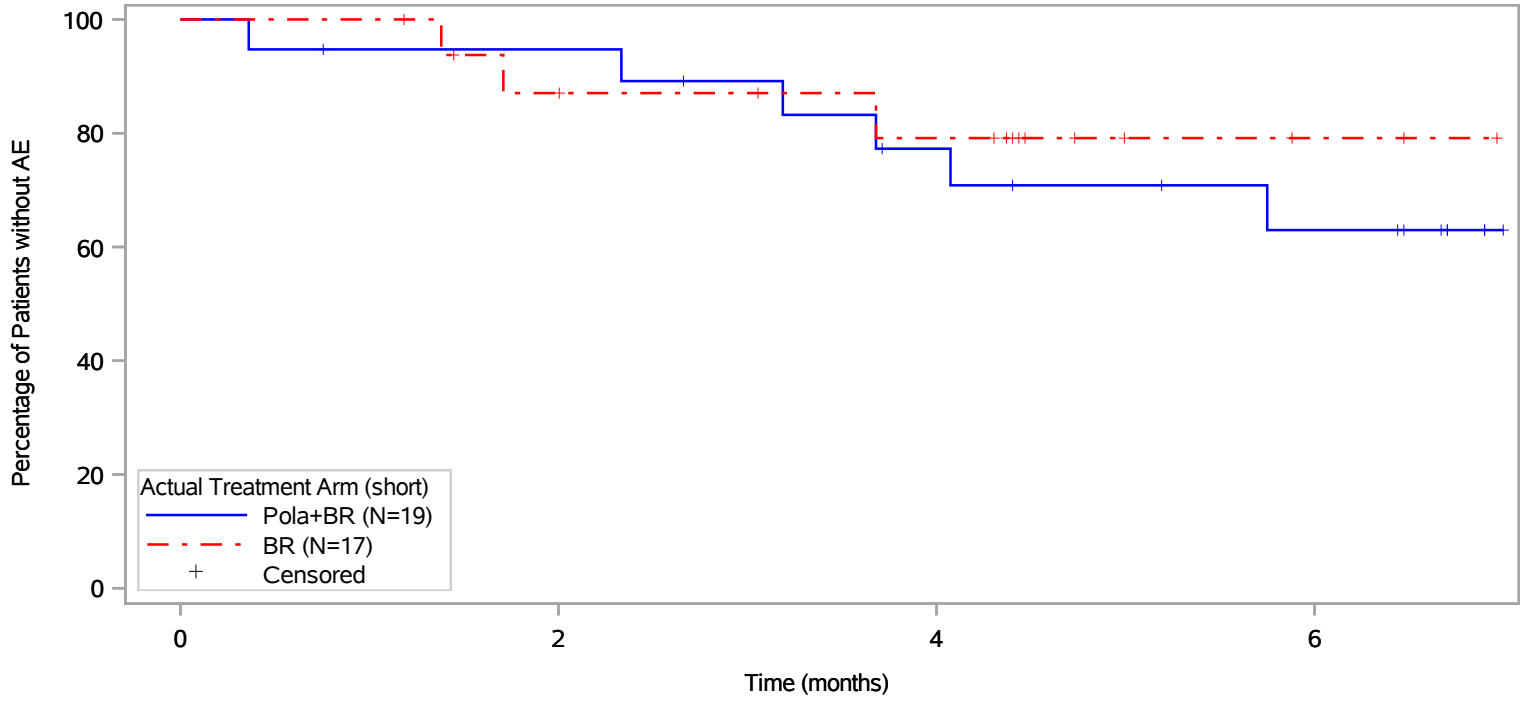
25OCT2023 8:42

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	17	17	15	12	10	8
BR (N=17)	17	17	13	12	10	3	2
Patients censored							
Pola+BR (N=19)	0	1	1	2	3	4	5
BR (N=17)	0	0	2	3	4	11	12

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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24JAN2023 18:56

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	15	78.9	4	21.1	17	100.0	10	58.8	7	41.2	0.3443	1.62	0.72	3.65		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		19	100.0	9	47.4	10	52.6	17	100.0	6	35.3	11	64.7	0.6395	1.32	0.46	3.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1130	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		19	100.0	3	15.8	16	84.2	17	100.0	2	11.8	15	88.2	0.7399	1.36	0.22	8.18		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		19	100.0	8	42.1	11	57.9	17	100.0	6	35.3	11	64.7	0.8114	1.22	0.42	3.54		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		19	100.0	7	36.8	12	63.2	17	100.0	3	17.6	14	82.4	0.2656	2.30	0.59	8.92		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			19	100.0	3	15.8	16	84.2	17	100.0	2	11.8	15	88.2	0.8359	1.07	0.18	6.52		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	BRADYCARDIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SINUS TACHYCARDIA		19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS			19	100.0	3	15.8	16	84.2	17	100.0	0	-	17	100.0	0.0904	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	EAR CONGESTION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.4969	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	EAR PAIN		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	TINNITUS		19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1632	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			19	100.0	13	68.4	6	31.6	17	100.0	10	58.8	7	41.2	0.5220	1.37	0.59	3.20		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.9354	1.10	0.07	17.51		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.9334	1.10	0.07	17.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1228	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ASCITES		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1372	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		19	100.0	1	5.3	18	94.7	17	100.0	3	17.6	14	82.4	0.2745	0.28	0.03	2.76		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		19	100.0	6	31.6	13	68.4	17	100.0	2	11.8	15	88.2	0.1683	3.83	0.76	19.34		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DRY MOUTH		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DYSPEPSIA		19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1751	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DYSPHAGIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	FAECES SOFT		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.4969	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	NAUSEA		19	100.0	8	42.1	11	57.9	17	100.0	8	47.1	9	52.9	0.7788	0.89	0.33	2.39		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	STOMATITIS		19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.6728	2.09	0.19	23.10		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		19	100.0	6	31.6	13	68.4	17	100.0	3	17.6	14	82.4	0.3539	1.67	0.40	6.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			19	100.0	11	57.9	8	42.1	17	100.0	13	76.5	4	23.5	0.1802	0.61	0.26	1.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA		19	100.0	2	10.5	17	89.5	17	100.0	5	29.4	12	70.6	0.1267	0.31	0.06	1.64		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.9504	1.17	0.07	18.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1268	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		19	100.0	5	26.3	14	73.7	17	100.0	6	35.3	11	64.7	0.5262	0.73	0.22	2.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3026	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3476	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA		19	100.0	3	15.8	16	84.2	17	100.0	1	5.9	16	94.1	0.3659	2.90	0.30	28.14		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1398	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN		19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.6265	1.90	0.17	21.46		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		19	100.0	8	42.1	11	57.9	17	100.0	3	17.6	14	82.4	0.2409	2.42	0.62	9.37		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	11	57.9	8	42.1	17	100.0	9	52.9	8	47.1	0.4496	0.70	0.27	1.80		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYSTITIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HEPATITIS B		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION		19	100.0	3	15.8	16	84.2	17	100.0	0	-	17	100.0	0.2957	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.6237	0.47	0.03	8.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LARYNGITIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ORAL HERPES		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1268	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	6	31.6	13	68.4	17	100.0	1	5.9	16	94.1	0.2241	3.60	0.40	32.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INFECTIONS AND INFESTATIONS	RHINITIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SINUSITIS		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2528	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.9062	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			19	100.0	2	10.5	17	89.5	17	100.0	2	11.8	15	88.2	0.9017	1.11	0.16	7.86		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2528	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			19	100.0	9	47.4	10	52.6	17	100.0	9	52.9	8	47.1	0.4600	0.23	0.07	0.76		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED		19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.6422	1.27	0.11	14.04		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED		19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.7651	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INVESTIGATIONS	BLOOD BILIRUBIN INCREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD CREATININE INCREASED		19	100.0	1	5.3	18	94.7	17	100.0	2	11.8	15	88.2	0.3374	0.41	0.04	4.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD GLUCOSE INCREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LIPASE INCREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		19	100.0	0	-	19	100.0	17	100.0	4	23.5	13	76.5	0.0201	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		19	100.0	6	31.6	13	68.4	17	100.0	3	17.6	14	82.4	0.5028	1.13	0.27	4.75		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	OXYGEN SATURATION DECREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		19	100.0	4	21.1	15	78.9	17	100.0	4	23.5	13	76.5	0.4884	0.37	0.08	1.67		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.7745	1.45	0.12	16.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		19	100.0	6	31.6	13	68.4	17	100.0	6	35.3	11	64.7	0.5003	0.21	0.05	0.84		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			19	100.0	8	42.1	11	57.9	17	100.0	8	47.1	9	52.9	0.9616	0.89	0.33	2.44		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		19	100.0	5	26.3	14	73.7	17	100.0	2	11.8	15	88.2	0.3121	2.80	0.54	14.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3026	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.9364	0.60	0.03	10.90		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		19	100.0	2	10.5	17	89.5	17	100.0	2	11.8	15	88.2	0.7013	0.75	0.10	5.64		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.7054	0.75	0.04	12.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		19	100.0	5	26.3	14	73.7	17	100.0	2	11.8	15	88.2	0.3556	1.52	0.28	8.21		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1287	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3026	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			19	100.0	3	15.8	16	84.2	17	100.0	7	41.2	10	58.8	0.0860	0.39	0.10	1.54		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1122	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3026	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.9102	1.04	0.07	16.71		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1307	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3026	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			19	100.0	1	5.3	18	94.7	17	100.0	2	11.8	15	88.2	0.0303	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			19	100.0	8	42.1	11	57.9	17	100.0	5	29.4	12	70.6	0.5431	1.49	0.48	4.61		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DIZZINESS		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.9525	1.14	0.07	18.31		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DYSGEUSIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.4969	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HYPOTONIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEURALGIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2528	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL		19	100.0	5	26.3	14	73.7	17	100.0	0	-	17	100.0	0.0244	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	PARAESTHESIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY		19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1892	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3026	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SYNCOPE		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2528	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS			19	100.0	3	15.8	16	84.2	17	100.0	3	17.6	14	82.4	0.9072	1.17	0.24	5.81		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	ANXIETY		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.9211	1.10	0.07	17.56		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	DEPRESSED MOOD		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	INSOMNIA		19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1632	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	MOOD ALTERED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.9426	0.86	0.05	14.09		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ANURIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3026	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	7	36.8	12	63.2	17	100.0	10	58.8	7	41.2	0.0765	0.49	0.18	1.34		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH		19	100.0	3	15.8	16	84.2	17	100.0	5	29.4	12	70.6	0.1186	0.34	0.08	1.48		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1158	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3476	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS		19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1949	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH		19	100.0	2	10.5	17	89.5	17	100.0	2	11.8	15	88.2	0.8534	1.04	0.15	7.45		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1228	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			19	100.0	4	21.1	15	78.9	17	100.0	7	41.2	10	58.8	0.1544	0.43	0.12	1.53		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		19	100.0	1	5.3	18	94.7	17	100.0	3	17.6	14	82.4	0.1709	0.24	0.02	2.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		19	100.0	2	10.5	17	89.5	17	100.0	3	17.6	14	82.4	0.5425	0.55	0.09	3.38		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3311	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

VASCULAR DISORDERS			19	100.0	5	26.3	14	73.7	17	100.0	6	35.3	11	64.7	0.6672	0.82	0.25	2.72		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2528	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HAEMORRHAGE		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3311	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		19	100.0	3	15.8	16	84.2	17	100.0	1	5.9	16	94.1	0.3302	3.13	0.32	30.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		19	100.0	0	-	19	100.0	17	100.0	3	17.6	14	82.4	0.0606	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTAE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 18:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	8	42.1	5	62.5	3	37.5	2	11.8	0	-	2	100.0	0.1845	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	11	57.9	10	90.9	1	9.1	15	88.2	10	66.7	5	33.3	0.3274	1.76	0.71	4.35		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	8	42.1	5	62.5	3	37.5	2	11.8	0	-	2	100.0	0.2604	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	6	40.0	9	60.0	0.7084	0.85	0.23	3.12		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1780	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4643	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.7217	0.64	0.06	7.09		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.3768	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	11	57.9	6	54.5	5	45.5	15	88.2	6	40.0	9	60.0	0.6770	1.35	0.43	4.23		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4080	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	11	57.9	5	45.5	6	54.5	15	88.2	3	20.0	12	80.0	0.3060	2.19	0.52	9.19		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	8	42.1	3	37.5	5	62.5	2	11.8	1	50.0	1	50.0	0.6825	0.68	0.06	7.69		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	BRADYCARDIA	< 65	8	42.1	0	-	8	100.0	2	11.8	1	50.0	1	50.0	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	BRADYCARDIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4080	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5271	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4452	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR PAIN	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR PAIN	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4452	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	8	42.1	4	50.0	4	50.0	2	11.8	1	50.0	1	50.0	0.9506	1.64	0.14	18.90		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	11	57.9	9	81.8	2	18.2	15	88.2	9	60.0	6	40.0	0.2747	1.90	0.72	5.00		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.8184	1.54	0.10	24.55		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.8391	1.46	0.09	23.41		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2429	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1966	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.2212	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	1	50.0	1	50.0	0.3508	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.2203	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	11	57.9	5	45.5	6	54.5	15	88.2	2	13.3	13	86.7	0.0691	4.66	0.88	24.64		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	DYSPEPSIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	0	-	15	100.0	0.0907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FAECES SOFT	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FAECES SOFT	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	< 65	8	42.1	3	37.5	5	62.5	2	11.8	1	50.0	1	50.0	0.9622	1.11	0.10	12.37		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	>= 65	11	57.9	5	45.5	6	54.5	15	88.2	7	46.7	8	53.3	0.8295	0.91	0.29	2.89		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	1	6.7	14	93.3	0.4328	2.80	0.25	31.00		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	8	42.1	3	37.5	5	62.5	2	11.8	1	50.0	1	50.0	0.7809	0.85	0.07	10.50		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	2	13.3	13	86.7	0.4401	1.79	0.29	10.93		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	8	42.1	4	50.0	4	50.0	2	11.8	0	-	2	100.0	0.2188	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	11	57.9	7	63.6	4	36.4	15	88.2	13	86.7	2	13.3	0.1019	0.48	0.17	1.32		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	5	33.3	10	66.7	0.3184	0.42	0.08	2.24		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.2109	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4452	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	6	40.0	9	60.0	0.3802	0.55	0.13	2.24		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2542	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	1	6.7	14	93.3	0.4237	2.81	0.25	31.13		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.2289	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4452	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	8	42.1	4	50.0	4	50.0	2	11.8	0	-	2	100.0	0.2848	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	3	20.0	12	80.0	0.5745	1.97	0.42	9.30		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	8	42.1	4	50.0	4	50.0	2	11.8	1	50.0	1	50.0	0.8276	1.07	0.10	11.99		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	11	57.9	7	63.6	4	36.4	15	88.2	8	53.3	7	46.7	0.3232	0.55	0.17	1.78		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYSTITIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYSTITIS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2429	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	0	-	15	100.0	0.2155	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.8079	0.66	0.04	12.13		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LARYNGITIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5271	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LARYNGITIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL HERPES	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL HERPES	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.2109	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4643	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	1	6.7	14	93.3	0.4156	2.58	0.23	28.50		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	RHINITIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINITIS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3404	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	1	50.0	1	50.0	0.3793	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173				*	WARNING: Iteration limit reached without convergence.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	11	57.9	2	18.2	9	81.8	15	88.2	2	13.3	13	86.7	0.7698	1.58	0.22	11.20		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2429	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2429	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3404	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	8	42.1	5	62.5	3	37.5	2	11.8	2	100.0	0	-	0.1128	0.32	0.04	2.65		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	11	57.9	4	36.4	7	63.6	15	88.2	7	46.7	8	53.3	0.3291	0.15	0.03	0.84		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.9055	0.82	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.9310	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1955	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	1	50.0	1	50.0	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	3	20.0	12	80.0	0.0990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	8	42.1	4	50.0	4	50.0	2	11.8	1	50.0	1	50.0	0.8092	1.32	0.14	12.02		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	2	13.3	13	86.7	0.7744	0.22	0.02	3.14		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OXYGEN SATURATION DECREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OXYGEN SATURATION DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4315	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	4	26.7	11	73.3	0.2798	0.08	0.01	1.05		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.8126	1.25	0.08	20.39		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	8	42.1	4	50.0	4	50.0	2	11.8	2	100.0	0	-	0.0916	0.36	0.05	2.59		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	4	26.7	11	73.3	0.2333	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	8	42.1	3	37.5	5	62.5	2	11.8	1	50.0	1	50.0	0.7278	0.72	0.06	8.09		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	11	57.9	5	45.5	6	54.5	15	88.2	7	46.7	8	53.3	0.8301	1.09	0.34	3.49		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	2	13.3	13	86.7	0.2383	2.91	0.53	16.03		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5271	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	< 65	8	42.1	0	-	8	100.0	2	11.8	1	50.0	1	50.0	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2429	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	< 65	8	42.1	0	-	8	100.0	2	11.8	1	50.0	1	50.0	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.6663	0.56	0.05	6.30		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	8	42.1	3	37.5	5	62.5	2	11.8	0	-	2	100.0	0.4452	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	2	13.3	13	86.7	0.7634	0.93	0.13	6.88		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.2045	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	1	50.0	1	50.0	0.2163	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	11	57.9	2	18.2	9	81.8	15	88.2	6	40.0	9	60.0	0.2526	0.45	0.09	2.28		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	< 65	8	42.1	0	-	8	100.0	2	11.8	1	50.0	1	50.0	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1682	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	< 65	8	42.1	0	-	8	100.0	2	11.8	1	50.0	1	50.0	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.8563	1.41	0.09	22.64		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2429	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.2017	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173				*	WARNING: Iteration limit reached without convergence.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	8	42.1	3	37.5	5	62.5	2	11.8	0	-	2	100.0	0.2773	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	11	57.9	5	45.5	6	54.5	15	88.2	5	33.3	10	66.7	0.7017	1.37	0.39	4.84		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.7993	1.60	0.10	25.68		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOTONIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOTONIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEURALGIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEURALGIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3404	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4643	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	0	-	15	100.0	0.0412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5271	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3404	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		>= 65	11	57.9	2	18.2	9	81.8	15	88.2	3	20.0	12	80.0	0.8739	0.99	0.16	5.94		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.8567	1.51	0.09	24.30		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	MOOD ALTERED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	MOOD ALTERED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ANURIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ANURIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	8	42.1	3	37.5	5	62.5	2	11.8	0	-	2	100.0	0.3105	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	11	57.9	4	36.4	7	63.6	15	88.2	10	66.7	5	33.3	0.0409	0.34	0.10	1.12		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	5	33.3	10	66.7	0.1370	0.32	0.06	1.69		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1891	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2542	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.6263	0.65	0.06	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1966	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	1	50.0	1	50.0	0.1757	0.28	0.02	4.71		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	11	57.9	3	27.3	8	72.7	15	88.2	6	40.0	9	60.0	0.4086	0.62	0.15	2.52		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	3	20.0	12	80.0	0.3365	0.33	0.03	3.33		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	8	42.1	1	12.5	7	87.5	2	11.8	1	50.0	1	50.0	0.1757	0.28	0.02	4.71		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.7485	0.75	0.07	8.27		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4452	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	11	57.9	3	27.3	8	72.7	15	88.2	6	40.0	9	60.0	0.6822	0.77	0.19	3.16		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3404	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMORRHAGE	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMORRHAGE	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	1	6.7	14	93.3	0.3441	3.46	0.31	38.30		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	11	57.9	0	-	11	100.0	15	88.2	3	20.0	12	80.0	0.1180	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTAE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 18:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	8	42.1	8	100.0	0	-	14	82.4	8	57.1	6	42.9	0.1106	2.29	0.84	6.25		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	11	57.9	7	63.6	4	36.4	3	17.6	2	66.7	1	33.3	0.6258	1.69	0.34	8.35		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	8	42.1	4	50.0	4	50.0	14	82.4	5	35.7	9	64.3	0.5867	1.56	0.41	5.92		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	11	57.9	5	45.5	6	54.5	3	17.6	1	33.3	2	66.7	0.7579	1.36	0.15	12.53		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	2	14.3	12	85.7	0.4659	2.01	0.28	14.34		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	8	42.1	4	50.0	4	50.0	14	82.4	6	42.9	8	57.1	0.5936	1.47	0.41	5.33		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	11	57.9	4	36.4	7	63.6	3	17.6	0	-	3	100.0	0.2245	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	8	42.1	4	50.0	4	50.0	14	82.4	3	21.4	11	78.6	0.1915	2.58	0.58	11.56		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3222	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.2760	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3222	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	BRADYCARDIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	BRADYCARDIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4364	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3306	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR PAIN	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR PAIN	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4492	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	8	42.1	6	75.0	2	25.0	14	82.4	7	50.0	7	50.0	0.1757	2.16	0.68	6.90		Convergence criterion (GCONV=1E-8) satisfied.	0.1749
GASTROINTESTINAL DISORDERS		<3	11	57.9	7	63.6	4	36.4	3	17.6	3	100.0	0	-	0.4133	0.55	0.12	2.59		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.6528	1.83	0.11	29.27		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.3043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.3240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	11	57.9	1	9.1	10	90.9	3	17.6	2	66.7	1	33.3	0.0462	0.11	0.01	1.25		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	8	42.1	3	37.5	5	62.5	14	82.4	0	-	14	100.0	0.0129	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	11	57.9	3	27.3	8	72.7	3	17.6	2	66.7	1	33.3	0.2585	0.58	0.10	3.52		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	DYSPEPSIA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	0	-	14	100.0	0.0530	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FAECES SOFT	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1797	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FAECES SOFT	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	5	35.7	9	64.3	0.5996	0.64	0.12	3.38		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	<3	11	57.9	6	54.5	5	45.5	3	17.6	3	100.0	0	-	0.3493	0.59	0.14	2.54		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	>=3	8	42.1	2	25.0	6	75.0	14	82.4	0	-	14	100.0	0.0503	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	8	42.1	1	12.5	7	87.5	14	82.4	2	14.3	12	85.7	0.9449	0.98	0.09	10.91		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	11	57.9	5	45.5	6	54.5	3	17.6	1	33.3	2	66.7	0.7572	1.29	0.13	12.38		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	8	42.1	5	62.5	3	37.5	14	82.4	11	78.6	3	21.4	0.2884	0.56	0.17	1.77		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	11	57.9	6	54.5	5	45.5	3	17.6	2	66.7	1	33.3	0.7329	0.80	0.15	4.11		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	5	35.7	9	64.3	0.5719	0.62	0.12	3.26		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0082				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.2906	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	8	42.1	2	25.0	6	75.0	14	82.4	5	35.7	9	64.3	0.6759	0.70	0.14	3.67		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	11	57.9	3	27.3	8	72.7	3	17.6	1	33.3	2	66.7	0.8815	1.03	0.10	10.18		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	<3	11	57.9	3	27.3	8	72.7	3	17.6	1	33.3	2	66.7	0.7953	0.83	0.08	8.11		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.3098	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4492	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	2	14.3	12	85.7	0.8873	1.50	0.21	10.79		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	11	57.9	6	54.5	5	45.5	3	17.6	1	33.3	2	66.7	0.6737	1.69	0.19	14.81		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	8	42.1	6	75.0	2	25.0	14	82.4	6	42.9	8	57.1	0.4776	1.45	0.43	4.90		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	11	57.9	5	45.5	6	54.5	3	17.6	3	100.0	0	-	0.0079	0.12	0.02	0.76		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYSTITIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYSTITIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.2367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LARYNGITIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LARYNGITIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL HERPES	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.2906	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL HERPES	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	8	42.1	4	50.0	4	50.0	14	82.4	1	7.1	13	92.9	0.0799	5.87	0.61	56.62		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINITIS	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINITIS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	<3	11	57.9	1	9.1	10	90.9	3	17.6	1	33.3	2	66.7	0.3454	0.18	0.01	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.6528	1.83	0.11	29.27		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	11	57.9	1	9.1	10	90.9	3	17.6	1	33.3	2	66.7	0.3969	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	8	42.1	3	37.5	5	62.5	14	82.4	7	50.0	7	50.0	0.4028	0.19	0.03	1.17		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	11	57.9	6	54.5	5	45.5	3	17.6	2	66.7	1	33.3	0.7890	0.34	0.05	2.15		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4492	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.5290	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.2945	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	3	21.4	11	78.6	0.1645	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	8	42.1	2	25.0	6	75.0	14	82.4	1	7.1	13	92.9	0.4486	1.00	0.05	18.91		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	11	57.9	4	36.4	7	63.6	3	17.6	2	66.7	1	33.3	0.3884	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OXYGEN SATURATION DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OXYGEN SATURATION DECREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	8	42.1	2	25.0	6	75.0	14	82.4	3	21.4	11	78.6	0.8465	0.47	0.06	3.87		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	11	57.9	2	18.2	9	81.8	3	17.6	1	33.3	2	66.7	0.6763	0.52	0.05	5.88		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.6171	2.00	0.13	31.97		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	8	42.1	2	25.0	6	75.0	14	82.4	4	28.6	10	71.4	0.5148	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	11	57.9	4	36.4	7	63.6	3	17.6	2	66.7	1	33.3	0.4450	0.11	0.01	1.22		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	8	42.1	5	62.5	3	37.5	14	82.4	6	42.9	8	57.1	0.2204	3.07	0.80	11.81		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	11	57.9	3	27.3	8	72.7	3	17.6	2	66.7	1	33.3	0.4135	0.49	0.08	2.95		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	8	42.1	4	50.0	4	50.0	14	82.4	1	7.1	13	92.9	0.0206	9.48	1.04	86.83		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	11	57.9	1	9.1	10	90.9	3	17.6	1	33.3	2	66.7	0.3692	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.6812	2.45	0.10	58.92		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	2	14.3	12	85.7	0.9338	0.90	0.08	10.00		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	2	14.3	12	85.7	0.4723	2.63	0.36	19.07		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	6	42.9	8	57.1	0.1740	0.26	0.03	2.18		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	11	57.9	2	18.2	9	81.8	3	17.6	1	33.3	2	66.7	0.5957	0.75	0.07	8.42		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.2774	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.6528	1.83	0.11	29.27		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.2884	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	8	42.1	1	12.5	7	87.5	14	82.4	2	14.3	12	85.7	0.0701	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	8	42.1	3	37.5	5	62.5	14	82.4	3	21.4	11	78.6	0.5033	1.70	0.34	8.45		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	11	57.9	5	45.5	6	54.5	3	17.6	2	66.7	1	33.3	0.6127	0.65	0.12	3.52		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOTONIA	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOTONIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEURALGIA	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEURALGIA	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>=3	8	42.1	2	25.0	6	75.0	14	82.4	0	-	14	100.0	0.0463	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3306	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1410	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		>=3	8	42.1	2	25.0	6	75.0	14	82.4	2	14.3	12	85.7	0.4197	2.47	0.35	17.66		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		<3	11	57.9	1	9.1	10	90.9	3	17.6	1	33.3	2	66.7	0.3454	0.45	0.03	7.18			
PSYCHIATRIC DISORDERS	ANXIETY	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.6452	2.00	0.13	31.98		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	MOOD ALTERED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	MOOD ALTERED	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ANURIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ANURIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	8	42.1	4	50.0	4	50.0	14	82.4	8	57.1	6	42.9	0.4681	0.67	0.20	2.28		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	11	57.9	3	27.3	8	72.7	3	17.6	2	66.7	1	33.3	0.2741	0.44	0.07	2.88		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>=3	8	42.1	1	12.5	7	87.5	14	82.4	4	28.6	10	71.4	0.2994	0.34	0.04	3.05		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	<3	11	57.9	2	18.2	9	81.8	3	17.6	1	33.3	2	66.7	0.2836	0.25	0.02	4.07		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1797	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	<3	11	57.9	2	18.2	9	81.8	3	17.6	1	33.3	2	66.7	0.7021	1.03	0.09	11.48		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.3043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	8	42.1	2	25.0	6	75.0	14	82.4	7	50.0	7	50.0	0.3195	0.46	0.09	2.26		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.5290	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	8	42.1	0	-	8	100.0	14	82.4	3	21.4	11	78.6	0.1692	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	8	42.1	1	12.5	7	87.5	14	82.4	3	21.4	11	78.6	0.6529	0.60	0.06	5.78		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	5	35.7	9	64.3	0.3497	0.32	0.04	2.78		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	11	57.9	4	36.4	7	63.6	3	17.6	1	33.3	2	66.7	0.8590	1.58	0.17	14.48		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMORRHAGE	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMORRHAGE	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.3158	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTAE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 18:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	26.3	4	80.0	1	20.0	3	17.6	2	66.7	1	33.3	0.8070	1.24	0.22	6.90		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	14	73.7	11	78.6	3	21.4	14	82.4	8	57.1	6	42.9	0.4090	1.72	0.68	4.34		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	1	33.3	2	66.7	0.5768	1.98	0.17	22.61		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	14	73.7	7	50.0	7	50.0	14	82.4	5	35.7	9	64.3	0.8304	1.20	0.37	3.89		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	2	14.3	12	85.7	0.6831	1.59	0.26	9.70		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	14	73.7	6	42.9	8	57.1	14	82.4	4	28.6	10	71.4	0.5265	1.72	0.47	6.31		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	1	33.3	2	66.7	0.7222	1.54	0.14	17.22		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	14	73.7	5	35.7	9	64.3	14	82.4	2	14.3	12	85.7	0.3131	2.70	0.52	14.06		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	1	7.1	13	92.9	0.3549	2.29	0.23	22.75		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	BRADYCARDIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	BRADYCARDIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	0	-	14	100.0	0.0792	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR PAIN	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR PAIN	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3657	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1490	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	5	26.3	3	60.0	2	40.0	3	17.6	2	66.7	1	33.3	0.8321	1.22	0.19	7.80		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	14	73.7	10	71.4	4	28.6	14	82.4	8	57.1	6	42.9	0.3365	1.85	0.68	5.02		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.9791	1.41	0.09	22.64		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.9774	1.45	0.09	23.18		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	2	14.3	12	85.7	0.1471	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	3	21.4	11	78.6	0.3156	0.32	0.03	3.14		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	14	73.7	5	35.7	9	64.3	14	82.4	2	14.3	12	85.7	0.2182	5.14	0.96	27.57		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	DYSPEPSIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FAECES SOFT	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FAECES SOFT	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	1	33.3	2	66.7	0.9412	1.09	0.10	12.22		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Non-Europe	14	73.7	6	42.9	8	57.1	14	82.4	7	50.0	7	50.0	0.7649	0.90	0.29	2.77		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.6523	2.72	0.25	30.22		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.7276	0.61	0.04	9.93		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	14	73.7	5	35.7	9	64.3	14	82.4	2	14.3	12	85.7	0.2118	2.19	0.40	11.99		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	26.3	2	40.0	3	60.0	3	17.6	2	66.7	1	33.3	0.1645	0.18	0.01	2.46		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	14	73.7	9	64.3	5	35.7	14	82.4	11	78.6	3	21.4	0.4755	1.03	0.40	2.69		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	2	66.7	1	33.3	0.0559	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	3	21.4	11	78.6	0.5589	0.63	0.10	4.08		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	Europe	5	26.3	0	-	5	100.0	3	17.6	2	66.7	1	33.3	0.0559	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	6	42.9	8	57.1	0.3485	0.66	0.18	2.42		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.5339	2.40	0.21	27.44		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	2	14.3	12	85.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.5831	2.38	0.21	27.62		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	1	33.3	2	66.7	0.9160	1.15	0.09	14.29		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	14	73.7	6	42.9	8	57.1	14	82.4	2	14.3	12	85.7	0.1675	3.83	0.74	19.86		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	26.3	3	60.0	2	40.0	3	17.6	2	66.7	1	33.3	0.4335	0.39	0.04	4.39		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	14	73.7	8	57.1	6	42.9	14	82.4	7	50.0	7	50.0	0.6993	0.83	0.29	2.39		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYSTITIS	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYSTITIS	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Europe	5	26.3	3	60.0	2	40.0	3	17.6	0	-	3	100.0	0.3021	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.6468	0.52	0.03	9.59		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LARYNGITIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LARYNGITIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL HERPES	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL HERPES	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	1	7.1	13	92.9	0.1992	4.20	0.46	38.28		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	RHINITIS	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINITIS	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.9261	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.5266	3.81	0.34	42.50		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	14	73.7	9	64.3	5	35.7	14	82.4	9	64.3	5	35.7	0.4744	0.24	0.07	0.82		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.6031	1.27	0.11	14.04		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.7446	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	2	14.3	12	85.7	0.3748	0.56	0.05	6.18		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3657	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2689	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3657	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	4	28.6	10	71.4	0.0211	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	14	73.7	6	42.9	8	57.1	14	82.4	3	21.4	11	78.6	0.4267	1.17	0.28	4.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OXYGEN SATURATION DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OXYGEN SATURATION DECREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	4	28.6	10	71.4	0.4595	0.39	0.09	1.76		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.7123	1.79	0.15	20.97		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	14	73.7	6	42.9	8	57.1	14	82.4	6	42.9	8	57.1	0.5127	0.21	0.05	0.86		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	14	73.7	8	57.1	6	42.9	14	82.4	8	57.1	6	42.9	0.8042	1.14	0.41	3.23		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	14	73.7	5	35.7	9	64.3	14	82.4	2	14.3	12	85.7	0.2500	4.94	0.91	26.84		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	1.0000	0.60	0.03	10.90		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	2	14.3	12	85.7	0.6912	0.87	0.11	6.71		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.7549	1.02	0.06	16.95		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	14	73.7	5	35.7	9	64.3	14	82.4	2	14.3	12	85.7	0.2772	1.61	0.30	8.78		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	2	14.3	12	85.7	0.1366	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	2	66.7	1	33.3	0.3943	0.37	0.03	4.08		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	5	35.7	9	64.3	0.1573	0.45	0.08	2.42		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2689	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3657	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.6660	0.55	0.03	8.78		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	14	73.7	7	50.0	7	50.0	14	82.4	4	28.6	10	71.4	0.3159	2.33	0.65	8.30		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOTONIA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOTONIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEURALGIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEURALGIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	0	-	14	100.0	0.0367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3657	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.9191	0.87	0.05	13.95		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	2	14.3	12	85.7	0.9704	1.55	0.22	11.03		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.9435	1.37	0.09	21.95		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	MOOD ALTERED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	MOOD ALTERED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.9731	0.98	0.06	16.43		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ANURIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ANURIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3404	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	3	100.0	0	-	0.0101	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	14	73.7	6	42.9	8	57.1	14	82.4	7	50.0	7	50.0	0.4389	1.06	0.34	3.38		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Europe	5	26.3	1	20.0	4	80.0	3	17.6	2	66.7	1	33.3	0.0701	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	3	21.4	11	78.6	0.3427	0.45	0.07	2.80		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	2	14.3	12	85.7	0.1247	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1864	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	2	14.3	12	85.7	0.9116	1.58	0.22	11.59		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Europe	5	26.3	0	-	5	100.0	3	17.6	2	66.7	1	33.3	0.0701	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	7	50.0	7	50.0	0.0777	0.35	0.08	1.43		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	3	21.4	11	78.6	0.1934	0.29	0.03	3.13		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	3	21.4	11	78.6	0.6044	0.65	0.10	4.08		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	5	26.3	2	40.0	3	60.0	3	17.6	2	66.7	1	33.3	0.6189	0.61	0.08	4.46		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	4	28.6	10	71.4	0.7607	0.93	0.20	4.29		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMORRHAGE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMORRHAGE	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.5196	2.47	0.22	28.38		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	2	14.3	12	85.7	0.1395	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTAE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 18:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	10	71.4	4	28.6	8	47.1	6	75.0	2	25.0	0.5509	0.92	0.31	2.74		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	5	100.0	0	-	9	52.9	4	44.4	5	55.6	0.0489	3.65	0.79	16.89		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	14	73.7	7	50.0	7	50.0	8	47.1	3	37.5	5	62.5	0.8680	1.12	0.26	4.75		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	5	26.3	2	40.0	3	60.0	9	52.9	3	33.3	6	66.7	0.8058	1.10	0.18	6.76		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	14	73.7	2	14.3	12	85.7	8	47.1	2	25.0	6	75.0	0.5702	0.71	0.09	5.86		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059				*	WARNING: Iteration limit reached without convergence.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	14	73.7	4	28.6	10	71.4	8	47.1	3	37.5	5	62.5	0.5643	0.81	0.16	4.14		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	5	26.3	4	80.0	1	20.0	9	52.9	3	33.3	6	66.7	0.1939	2.54	0.50	12.84		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	14	73.7	5	35.7	9	64.3	8	47.1	2	25.0	6	75.0	0.7813	1.60	0.29	8.89		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	5	26.3	2	40.0	3	60.0	9	52.9	1	11.1	8	88.9	0.2131	2.81	0.25	31.68		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	14	73.7	3	21.4	11	78.6	8	47.1	1	12.5	7	87.5	0.7655	1.25	0.11	14.38		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	BRADYCARDIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	BRADYCARDIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.2859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.2632	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR PAIN	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR PAIN	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.2632	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	14	73.7	8	57.1	6	42.9	8	47.1	4	50.0	4	50.0	0.6754	1.40	0.38	5.14		Convergence criterion (GCONV=1E-8) satisfied.	0.6021
GASTROINTESTINAL DISORDERS		Female	5	26.3	5	100.0	0	-	9	52.9	6	66.7	3	33.3	0.2751	1.93	0.51	7.30		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.1797	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.1797	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	Male	14	73.7	0	-	14	100.0	8	47.1	2	25.0	6	75.0	0.0417	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	Male	14	73.7	0	-	14	100.0	8	47.1	2	25.0	6	75.0	0.0624	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.7087	0.39	0.02	8.55		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	5	26.3	0	-	5	100.0	9	52.9	2	22.2	7	77.8	0.2774	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	14	73.7	4	28.6	10	71.4	8	47.1	1	12.5	7	87.5	0.4458	4.18	0.44	39.57		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	5	26.3	2	40.0	3	60.0	9	52.9	1	11.1	8	88.9	0.2367	2.57	0.23	28.71		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	DYSPEPSIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.0448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FAECES SOFT	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FAECES SOFT	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	Male	14	73.7	4	28.6	10	71.4	8	47.1	3	37.5	5	62.5	0.6202	0.75	0.15	3.74		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Female	5	26.3	4	80.0	1	20.0	9	52.9	5	55.6	4	44.4	0.4108	1.95	0.44	8.71		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.5922	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	14	73.7	3	21.4	11	78.6	8	47.1	0	-	8	100.0	0.1735	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	5	26.3	3	60.0	2	40.0	9	52.9	3	33.3	6	66.7	0.4935	3.20	0.46	22.20		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	14	73.7	8	57.1	6	42.9	8	47.1	7	87.5	1	12.5	0.0358	0.30	0.08	1.05		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	5	26.3	3	60.0	2	40.0	9	52.9	6	66.7	3	33.3	0.9019	0.95	0.23	3.95		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Male	14	73.7	2	14.3	12	85.7	8	47.1	3	37.5	5	62.5	0.1577	0.36	0.05	2.62		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Female	5	26.3	0	-	5	100.0	9	52.9	2	22.2	7	77.8	0.2473	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	14	73.7	3	21.4	11	78.6	8	47.1	3	37.5	5	62.5	0.4495	0.58	0.10	3.34		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	5	26.3	2	40.0	3	60.0	9	52.9	3	33.3	6	66.7	0.8383	0.69	0.11	4.45		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Female	5	26.3	2	40.0	3	60.0	9	52.9	1	11.1	8	88.9	0.2842	2.16	0.20	23.87		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.3115	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	14	73.7	5	35.7	9	64.3	8	47.1	0	-	8	100.0	0.0949	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	5	26.3	3	60.0	2	40.0	9	52.9	3	33.3	6	66.7	0.3109	1.92	0.35	10.53		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	8	57.1	6	42.9	8	47.1	4	50.0	4	50.0	0.6622	1.00	0.27	3.69		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	3	60.0	2	40.0	9	52.9	5	55.6	4	44.4	0.3188	0.40	0.06	2.48		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYSTITIS	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYSTITIS	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5050	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.1797				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	5	26.3	1	20.0	4	80.0	9	52.9	1	11.1	8	88.9	0.8816	1.00	0.05	22.18		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LARYNGITIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LARYNGITIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL HERPES	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL HERPES	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	4	28.6	10	71.4	8	47.1	0	-	8	100.0	0.2170	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	2	40.0	3	60.0	9	52.9	1	11.1	8	88.9	0.7053	2.12	0.11	39.05		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	RHINITIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINITIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.6528	1.15	0.07	18.59		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	5	26.3	1	20.0	4	80.0	9	52.9	1	11.1	8	88.9	0.6452	1.29	0.08	20.65		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.1797	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.1797	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	14	73.7	8	57.1	6	42.9	8	47.1	4	50.0	4	50.0	0.7854	0.45	0.09	2.16		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	1	20.0	4	80.0	9	52.9	5	55.6	4	44.4	0.0841	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.3115	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.3676	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	2	25.0	6	75.0	0.1544	0.43	0.04	4.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	3	33.3	6	66.7	0.1569	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	14	73.7	5	35.7	9	64.3	8	47.1	0	-	8	100.0	0.0736	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	9	52.9	3	33.3	6	66.7	0.2521	0.22	0.01	4.46		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OXYGEN SATURATION DECREASED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OXYGEN SATURATION DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	14	73.7	3	21.4	11	78.6	8	47.1	1	12.5	7	87.5	0.8363	0.29	0.01	7.55		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	9	52.9	3	33.3	6	66.7	0.2521	0.22	0.01	4.46		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	14	73.7	2	14.3	12	85.7	8	47.1	1	12.5	7	87.5	0.8775	0.89	0.06	12.57		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	14	73.7	5	35.7	9	64.3	8	47.1	1	12.5	7	87.5	0.2888	1.06	0.10	11.24		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	9	52.9	5	55.6	4	44.4	0.0841	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	14	73.7	6	42.9	8	57.1	8	47.1	4	50.0	4	50.0	0.9341	0.80	0.18	3.56		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	5	26.3	2	40.0	3	60.0	9	52.9	4	44.4	5	55.6	0.9199	1.55	0.20	11.89		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	14	73.7	3	21.4	11	78.6	8	47.1	1	12.5	7	87.5	0.6610	3.48	0.36	33.76		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	5	26.3	2	40.0	3	60.0	9	52.9	1	11.1	8	88.9	0.2914	3.35	0.27	42.34		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	14	73.7	2	14.3	12	85.7	8	47.1	1	12.5	7	87.5	0.8592	1.60	0.14	18.24		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.4910	0.77	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	14	73.7	4	28.6	10	71.4	8	47.1	1	12.5	7	87.5	0.4987	0.54	0.04	8.12		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	5	26.3	1	20.0	4	80.0	9	52.9	1	11.1	8	88.9	0.6144	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	14	73.7	2	14.3	12	85.7	8	47.1	4	50.0	4	50.0	0.0351	0.42	0.07	2.31		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	5	26.3	1	20.0	4	80.0	9	52.9	3	33.3	6	66.7	0.6220	0.51	0.05	5.08		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.6278	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.1797	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	14	73.7	6	42.9	8	57.1	8	47.1	3	37.5	5	62.5	0.9803	1.11	0.25	4.92		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	5	26.3	2	40.0	3	60.0	9	52.9	2	22.2	7	77.8	0.6095	1.53	0.21	11.35		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.1797	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOTONIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOTONIA	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEURALGIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEURALGIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Male	14	73.7	4	28.6	10	71.4	8	47.1	0	-	8	100.0	0.1152	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.3112	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Male	14	73.7	3	21.4	11	78.6	8	47.1	2	25.0	6	75.0	0.8325	1.89	0.31	11.38		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.6153	1.08	0.07	17.30		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.2632	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	MOOD ALTERED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	MOOD ALTERED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.6583	0.41	0.02	9.27		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ANURIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ANURIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	6	42.9	8	57.1	8	47.1	6	75.0	2	25.0	0.0172	0.45	0.11	1.80		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	1	20.0	4	80.0	9	52.9	4	44.4	5	55.6	0.3683	0.30	0.03	2.77		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Male	14	73.7	2	14.3	12	85.7	8	47.1	3	37.5	5	62.5	0.0587	0.07	0.00	1.32		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.6139	0.36	0.03	4.01		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Female	5	26.3	0	-	5	100.0	9	52.9	2	22.2	7	77.8	0.2604	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.3312	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Male	14	73.7	1	7.1	13	92.9	8	47.1	2	25.0	6	75.0	0.1526	0.51	0.05	5.66		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	14	73.7	2	14.3	12	85.7	8	47.1	3	37.5	5	62.5	0.2432	0.44	0.06	2.93		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	5	26.3	2	40.0	3	60.0	9	52.9	4	44.4	5	55.6	0.6265	0.67	0.12	3.76		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.7248	0.66	0.06	7.77		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	14	73.7	1	7.1	13	92.9	8	47.1	2	25.0	6	75.0	0.2716	0.24	0.02	3.39		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	5	26.3	1	20.0	4	80.0	9	52.9	1	11.1	8	88.9	0.7053	2.08	0.12	36.58		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	14	73.7	2	14.3	12	85.7	8	47.1	2	25.0	6	75.0	0.5155	0.63	0.08	5.07		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	5	26.3	3	60.0	2	40.0	9	52.9	4	44.4	5	55.6	0.2952	1.48	0.29	7.51		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMORRHAGE	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMORRHAGE	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.1797				*	WARNING: Iteration limit reached without convergence.	
VASCULAR DISORDERS	HYPERTENSION	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.7087	0.39	0.02	8.55		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.0448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	5	26.3	0	-	5	100.0	9	52.9	2	22.2	7	77.8	0.2604	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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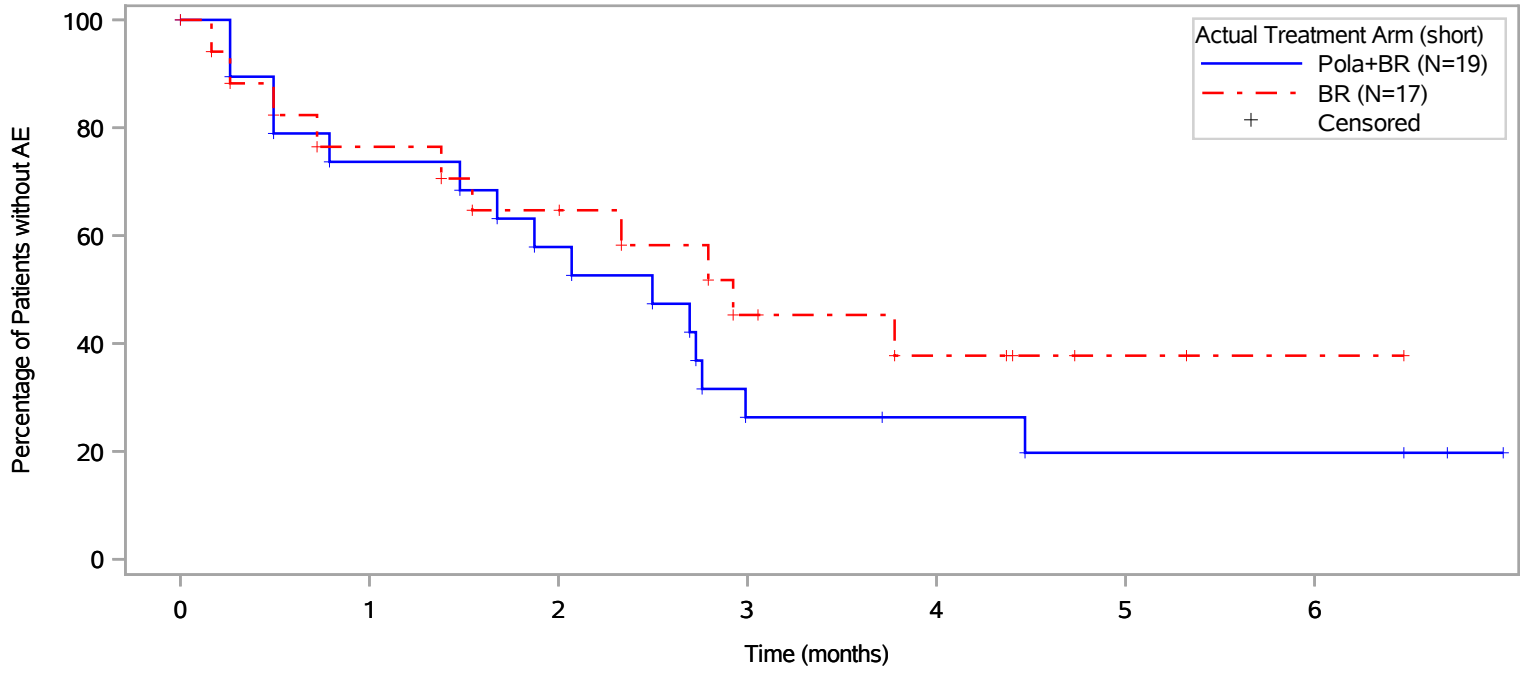
30NOV2022 18:40

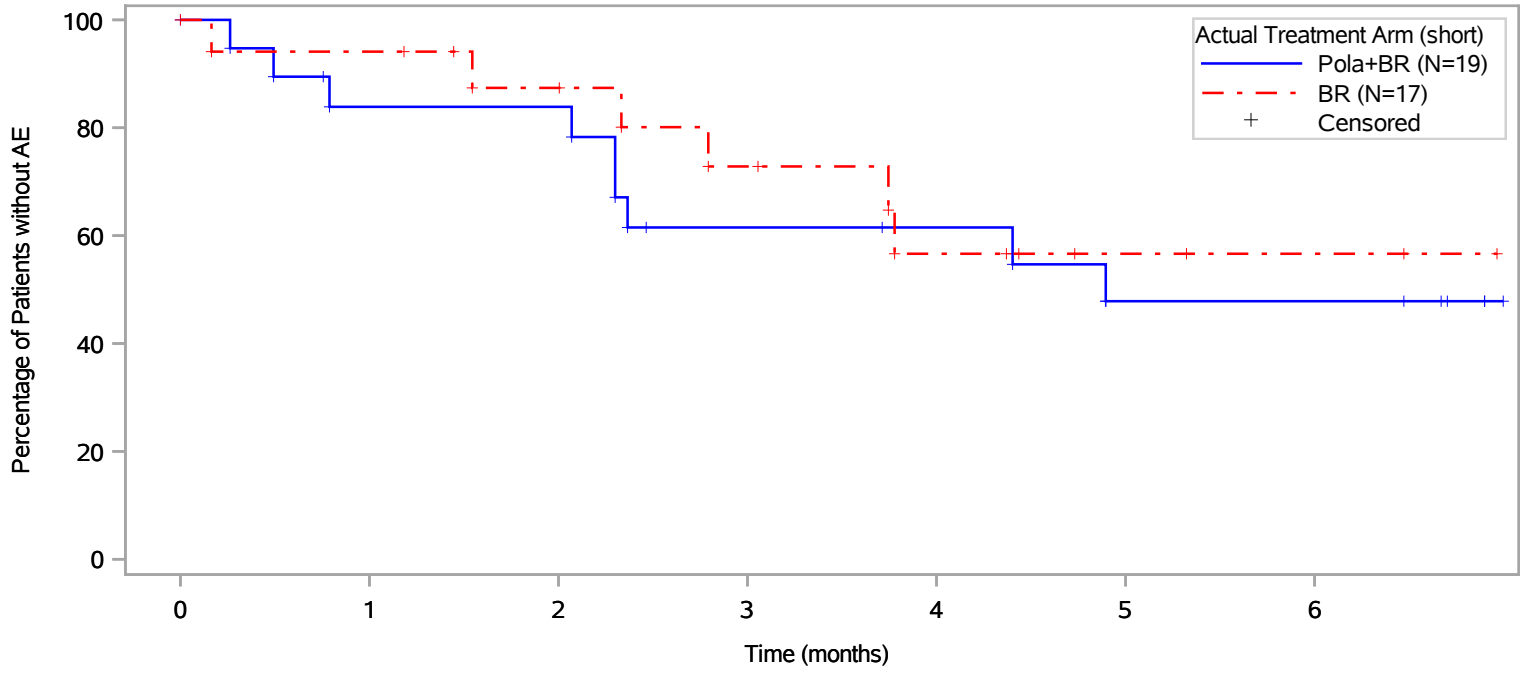
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	14	11	5	4	3	3
BR (N=17)	17	13	11	7	5	2	1
Patients censored							
Pola+BR (N=19)	0	0	0	0	1	1	1
BR (N=17)	0	0	0	1	2	5	6

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA

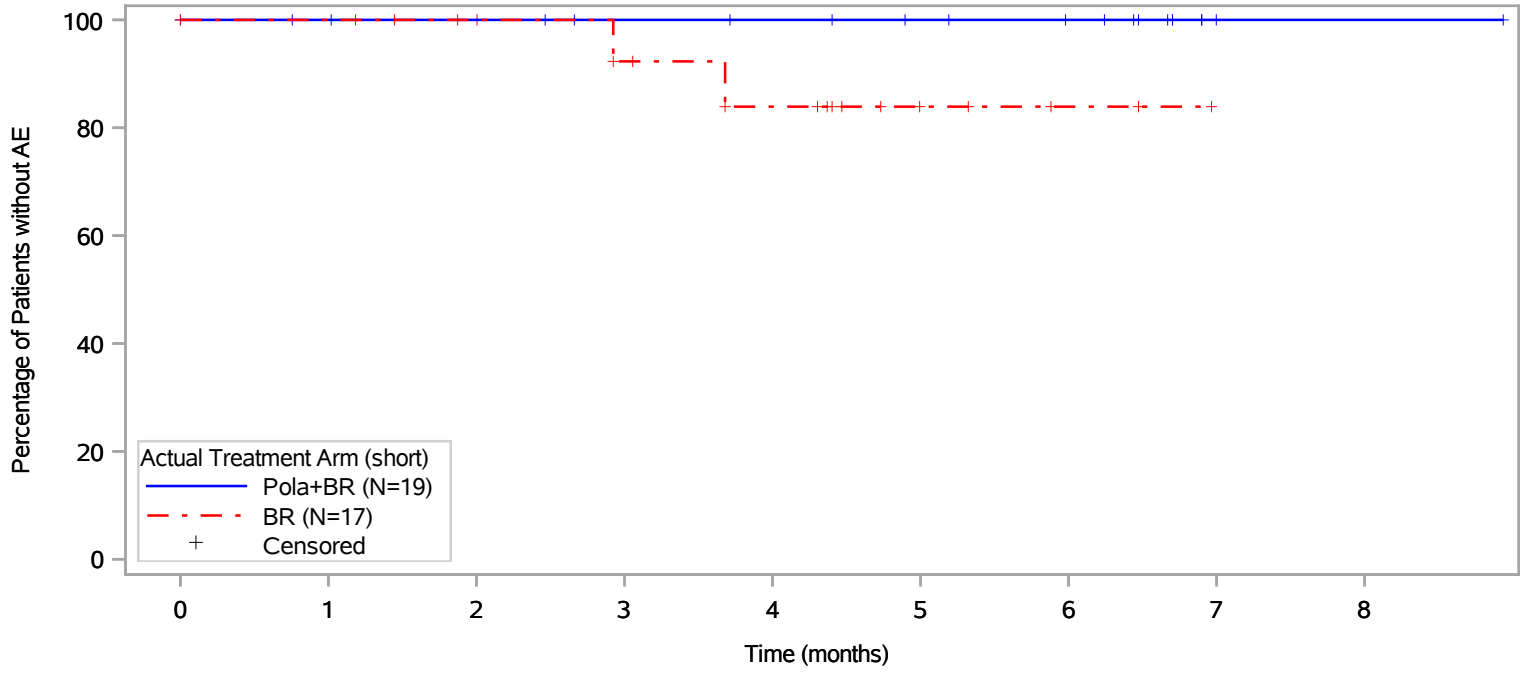


Patients at risk							
Pola+BR (N=19)	19	15	15	10	9	6	6
BR (N=17)	17	16	13	10	7	3	2
Patients censored							
Pola+BR (N=19)	0	1	1	2	3	4	4
BR (N=17)	0	0	2	3	4	8	9

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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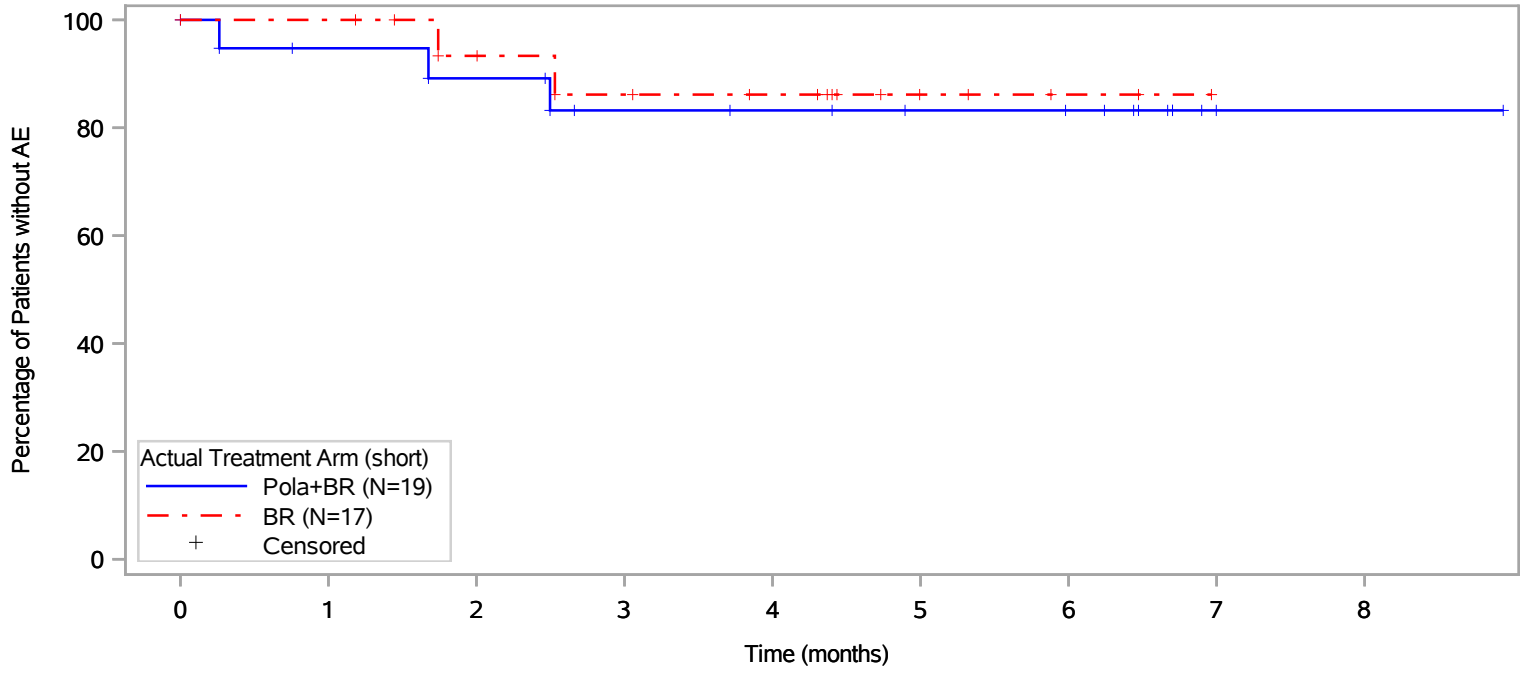
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=19)	19	17	16	13	12	10	9	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	7	15	15
BR (N=17)	0	0	2	3	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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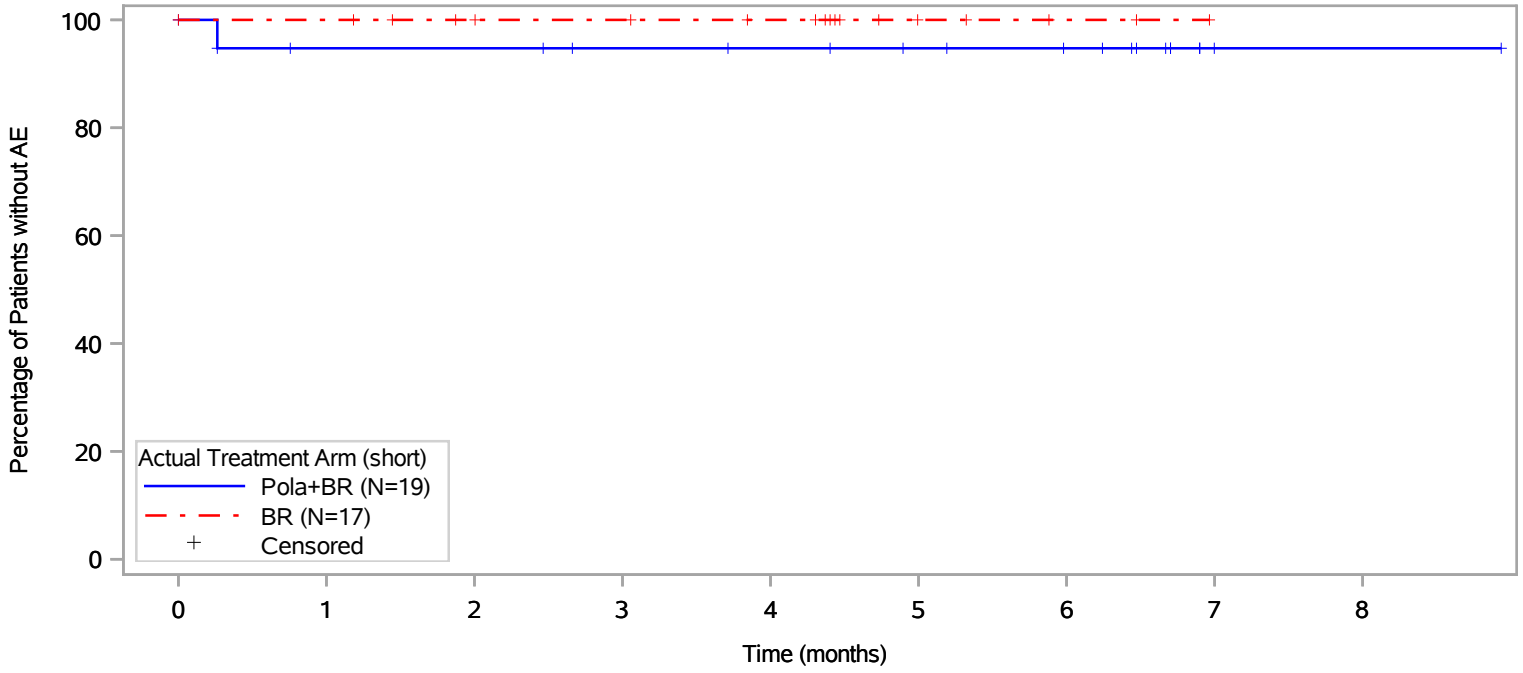
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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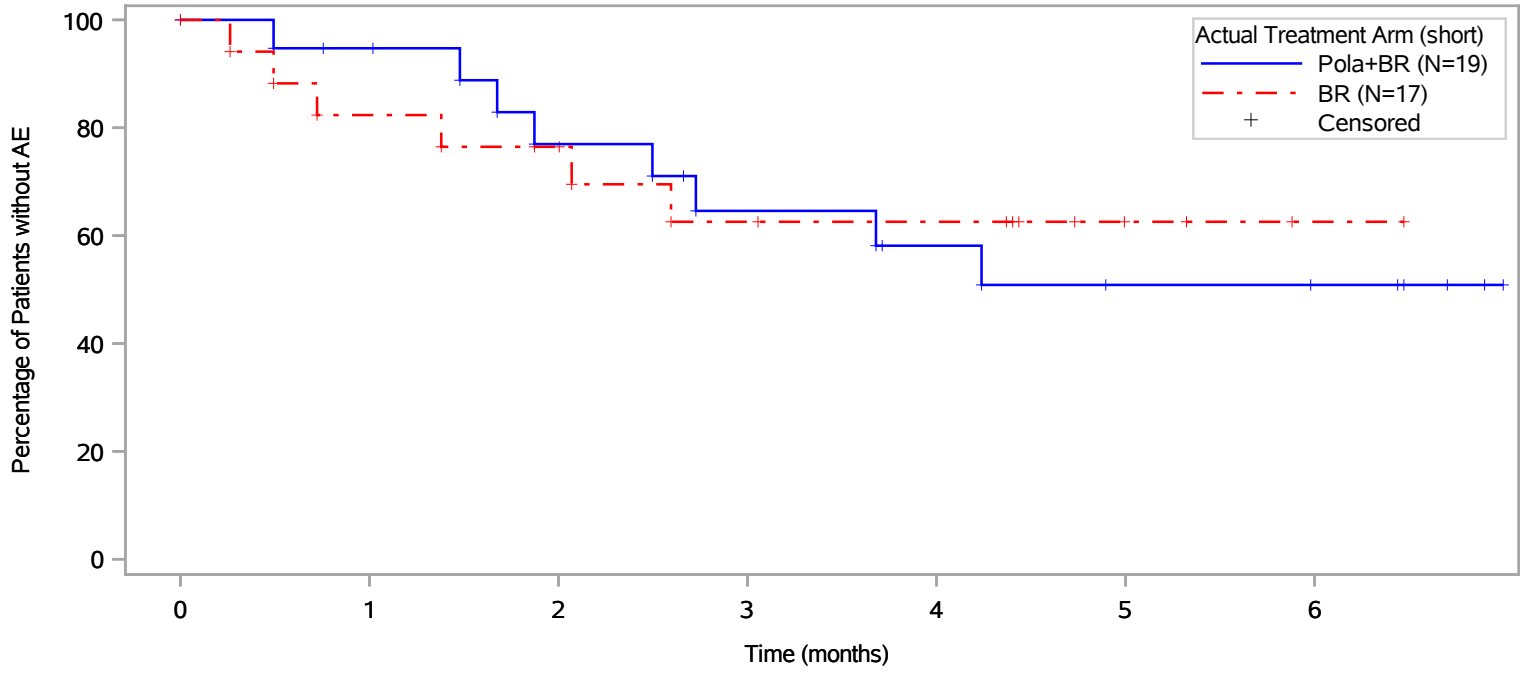
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk							
Pola+BR (N=19)	19	17	13	10	8	6	5
BR (N=17)	17	14	12	9	8	3	1
Patients censored							
Pola+BR (N=19)	0	1	2	3	4	5	6
BR (N=17)	0	0	1	2	3	8	10

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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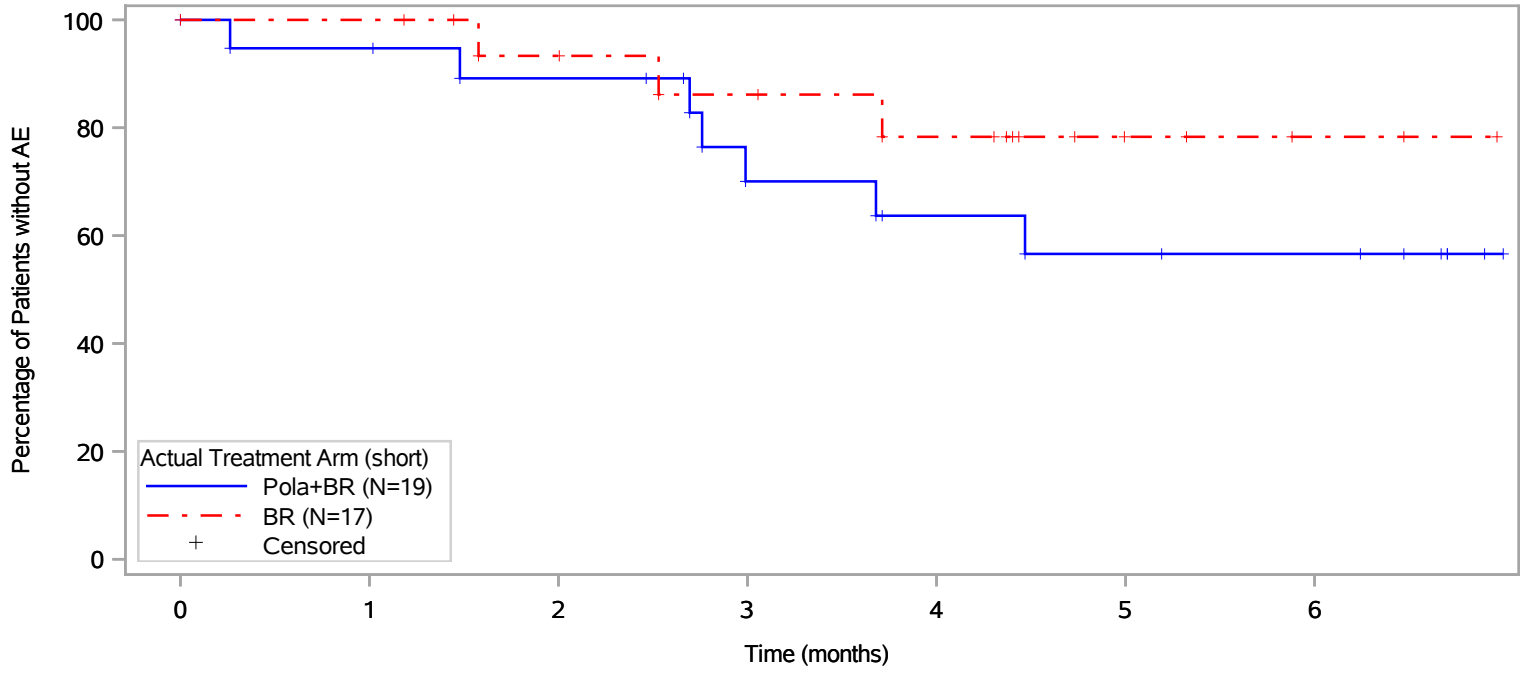
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

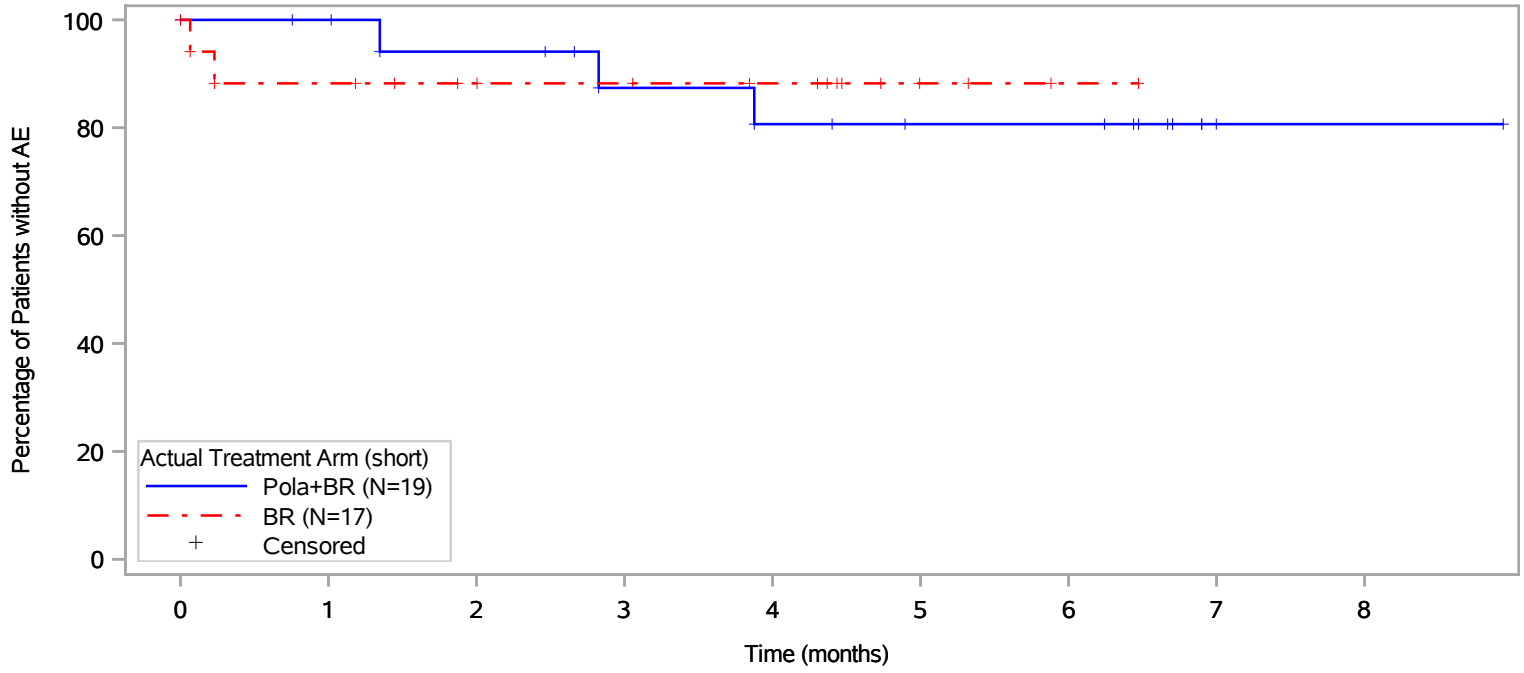
BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk							
Pola+BR (N=19)	19	18	16	11	9	8	7
BR (N=17)	17	17	14	12	10	4	2
Patients censored							
Pola+BR (N=19)	0	0	1	3	4	4	5
BR (N=17)	0	0	2	3	4	10	12

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	16	13	12	10	10	1	1
BR (N=17)	17	15	12	11	9	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	4	6	6	15	15
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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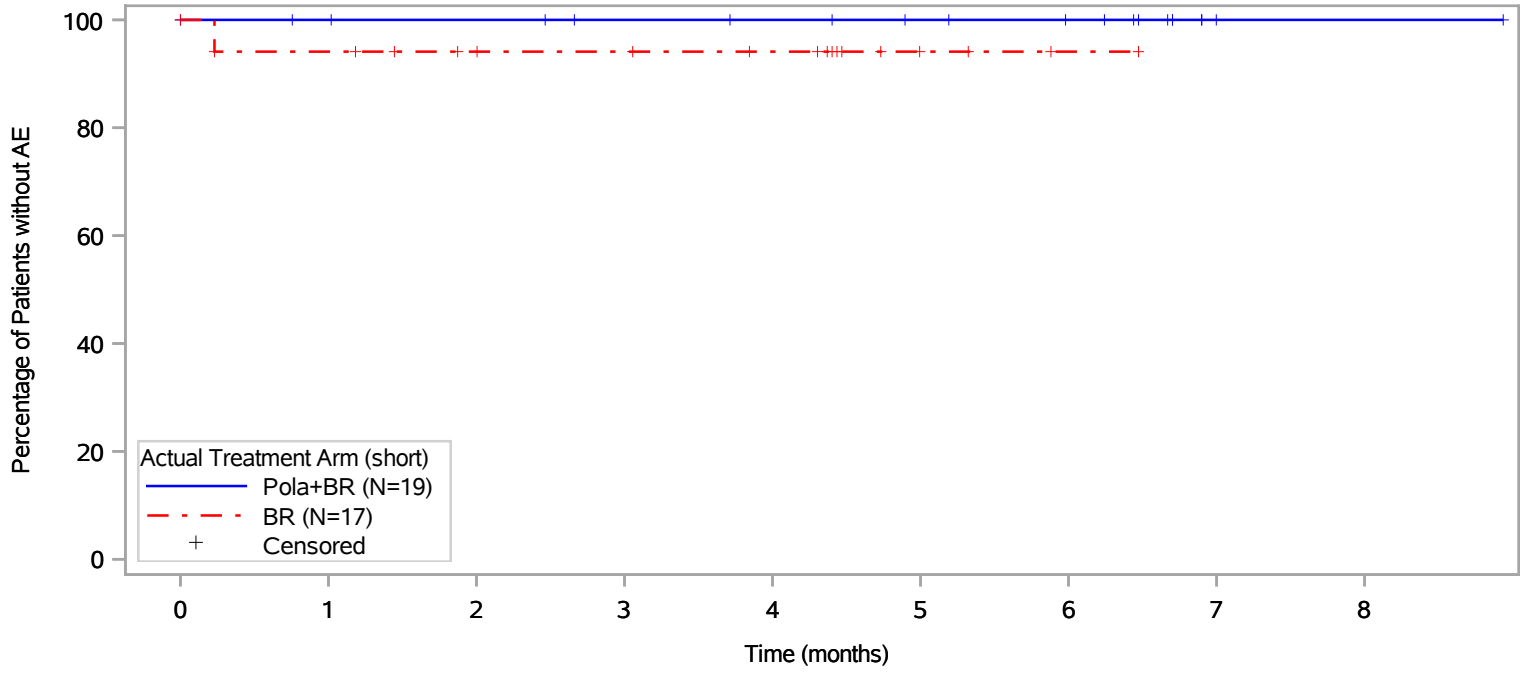
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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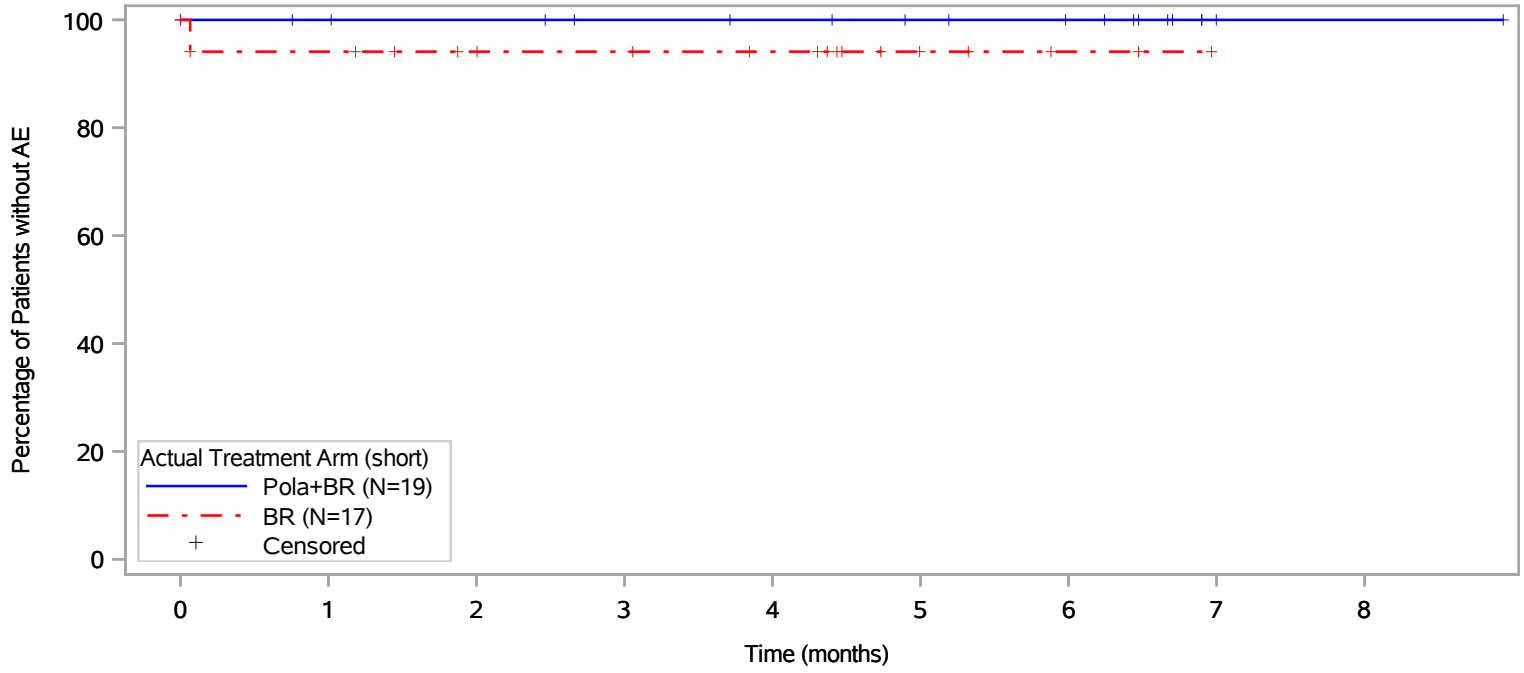
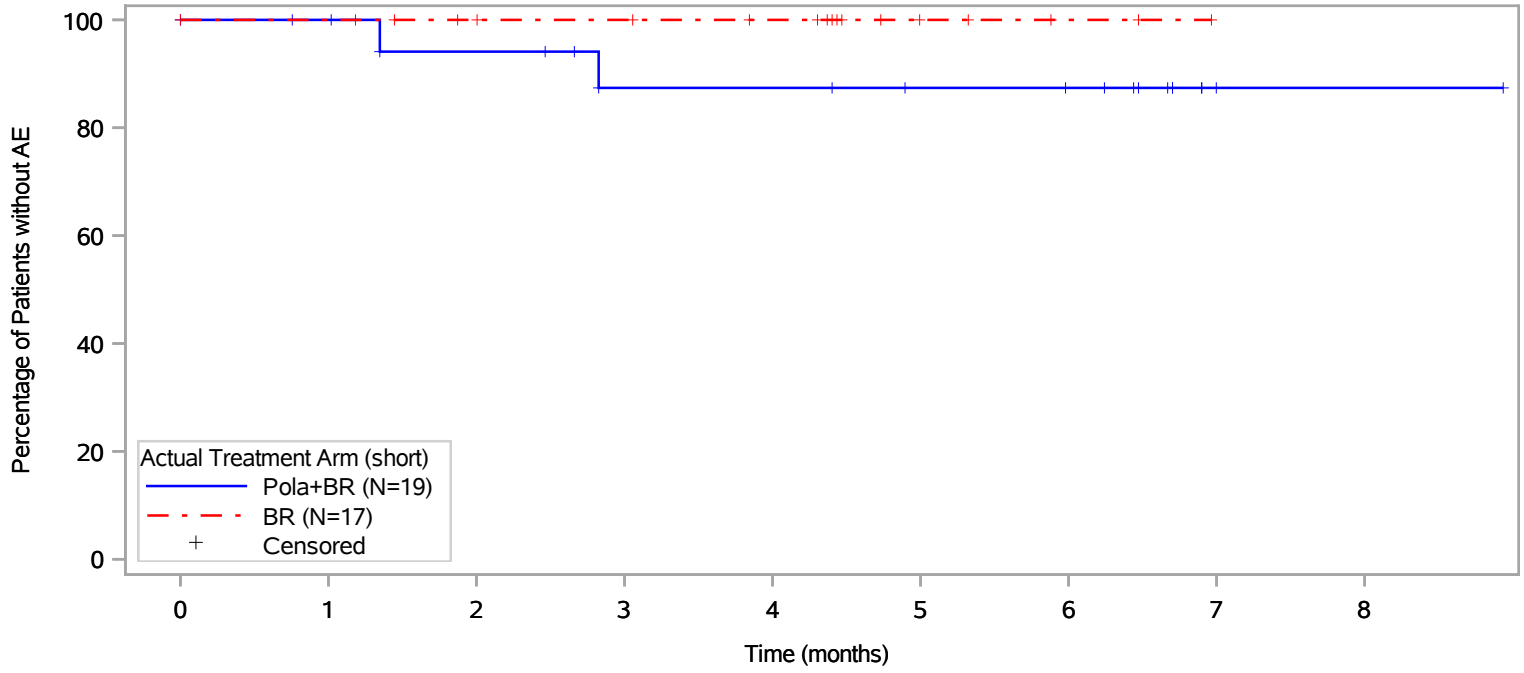
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, BRADYCARDIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SINUS TACHYCARDIA



Patients at risk									
Pola+BR (N=19)	19	18	16	13	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	4	6	7	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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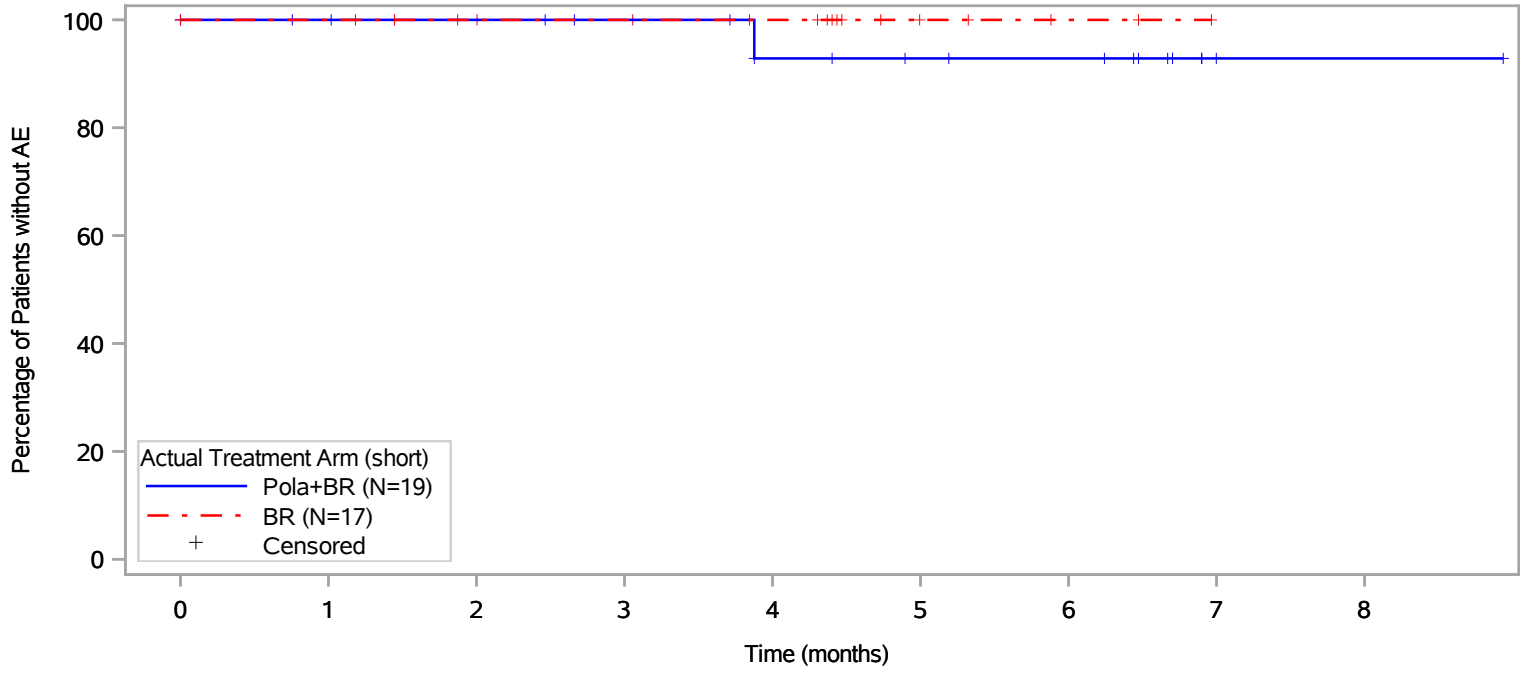
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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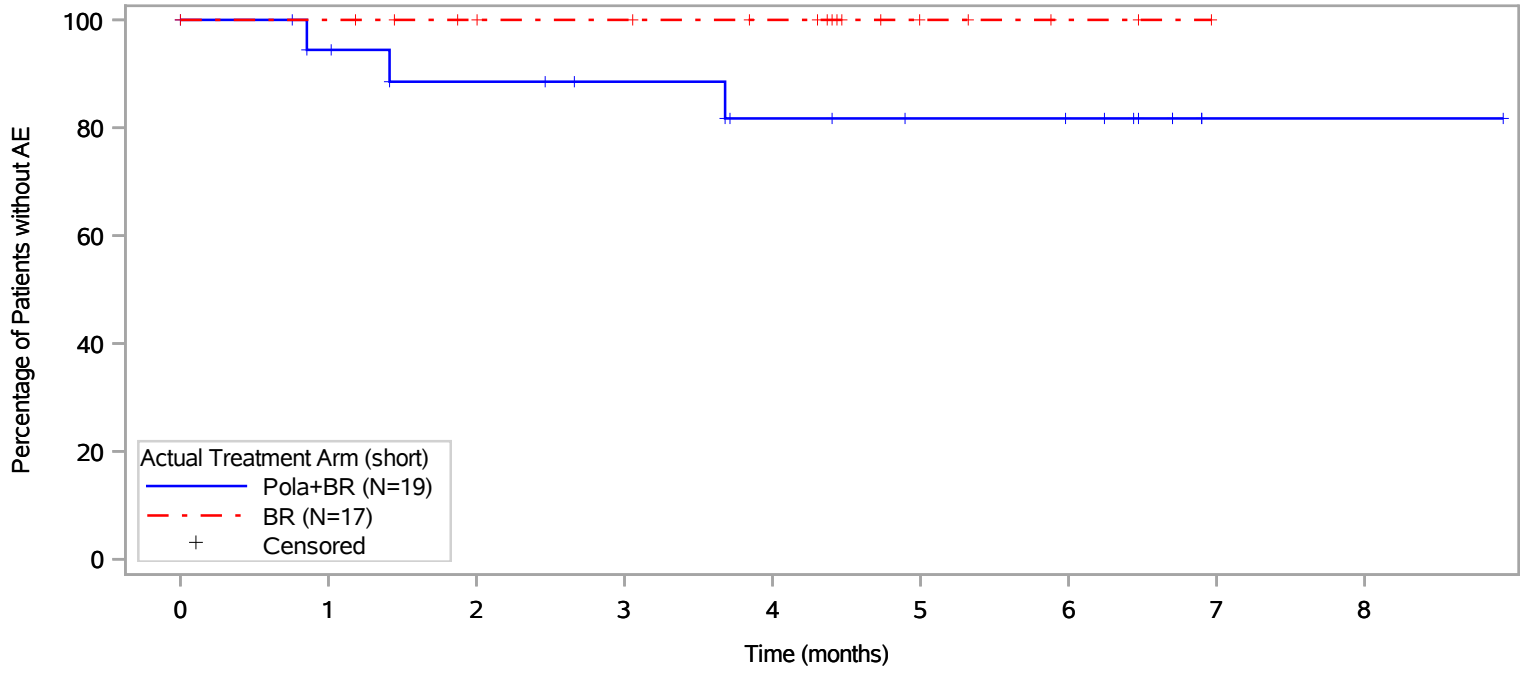
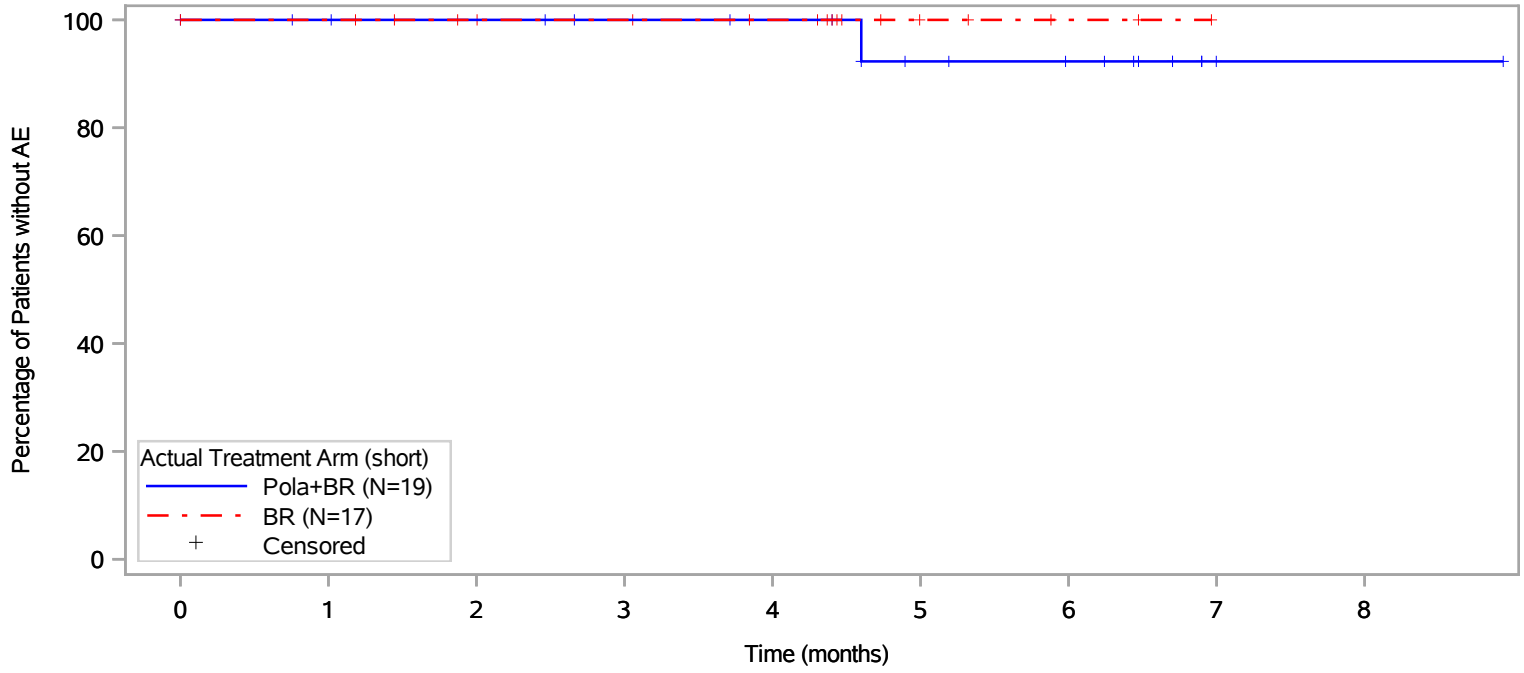
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	17	15	13	11	9	8	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	15	15
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, EAR CONGESTION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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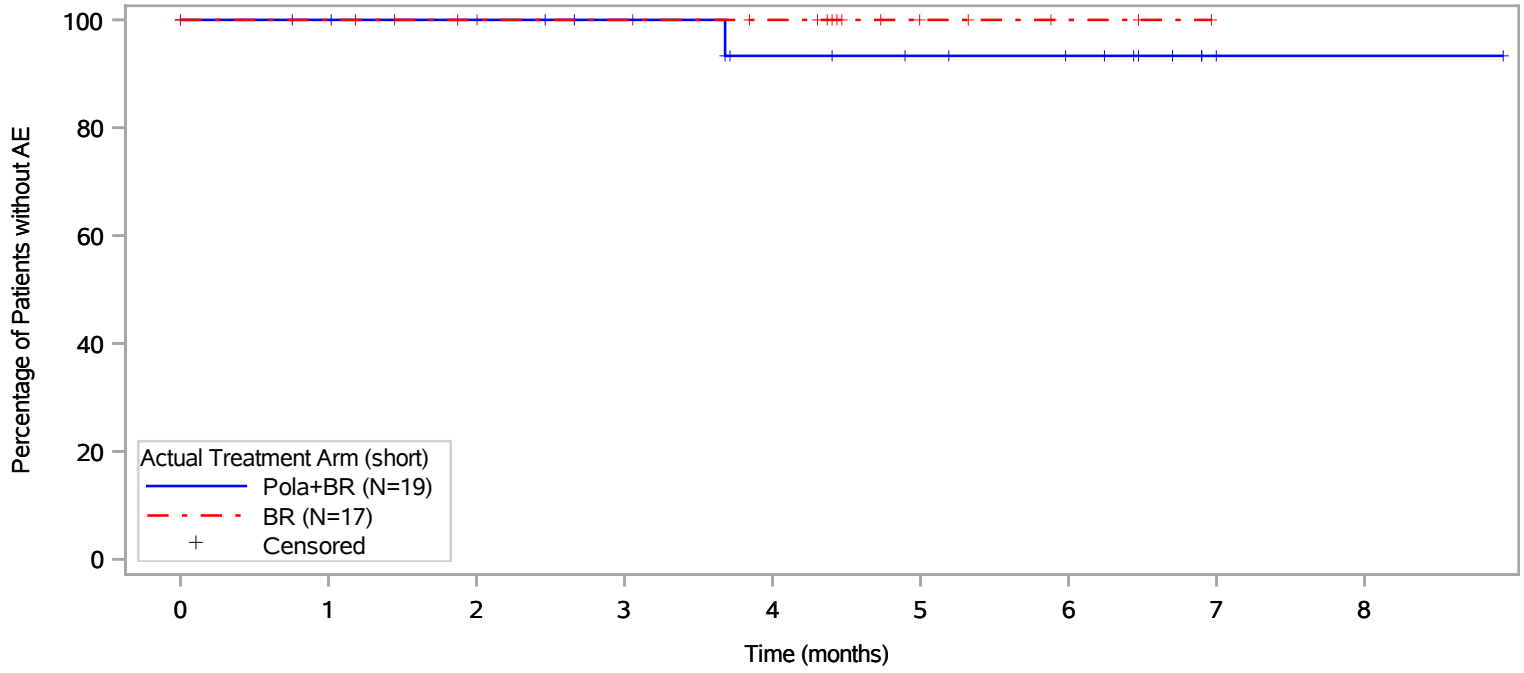
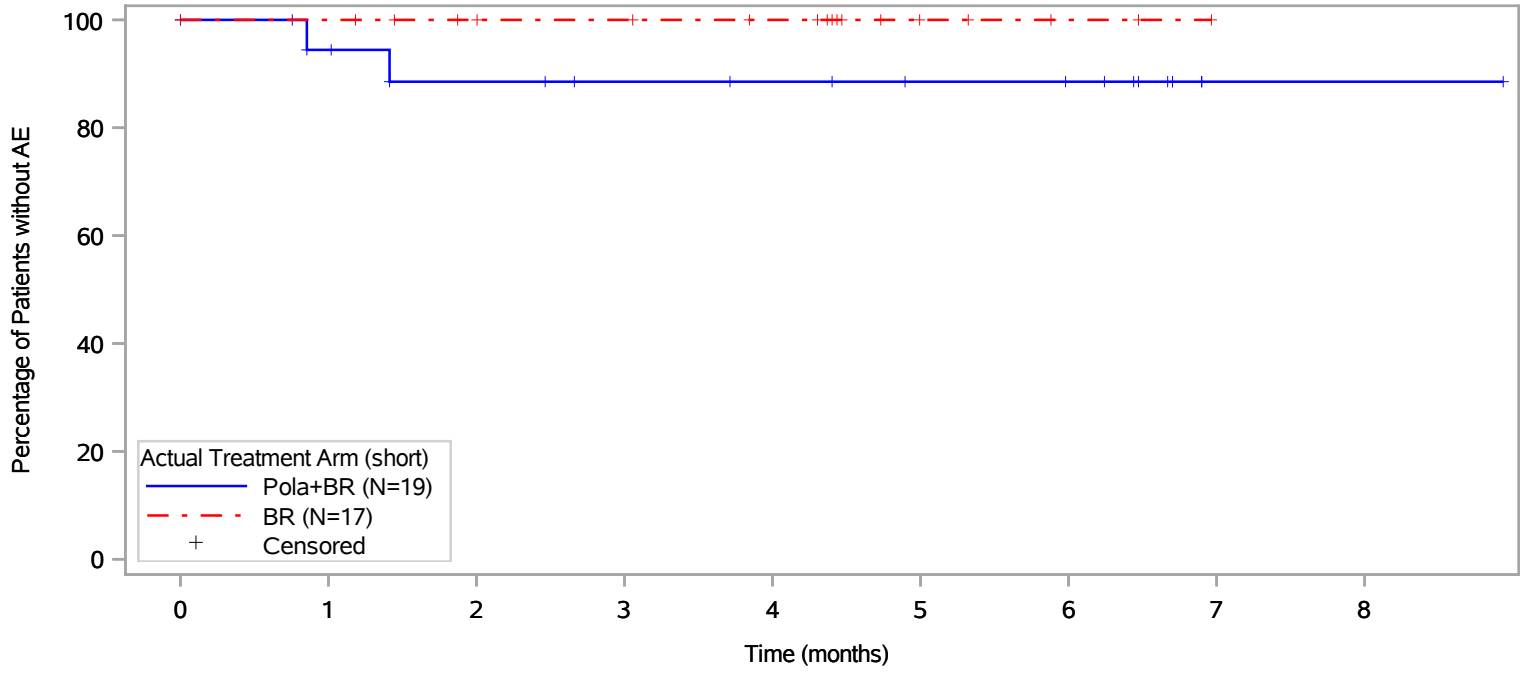
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, EAR PAIN



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, TINNITUS



Patients at risk									
Pola+BR (N=19)	19	17	15	13	12	10	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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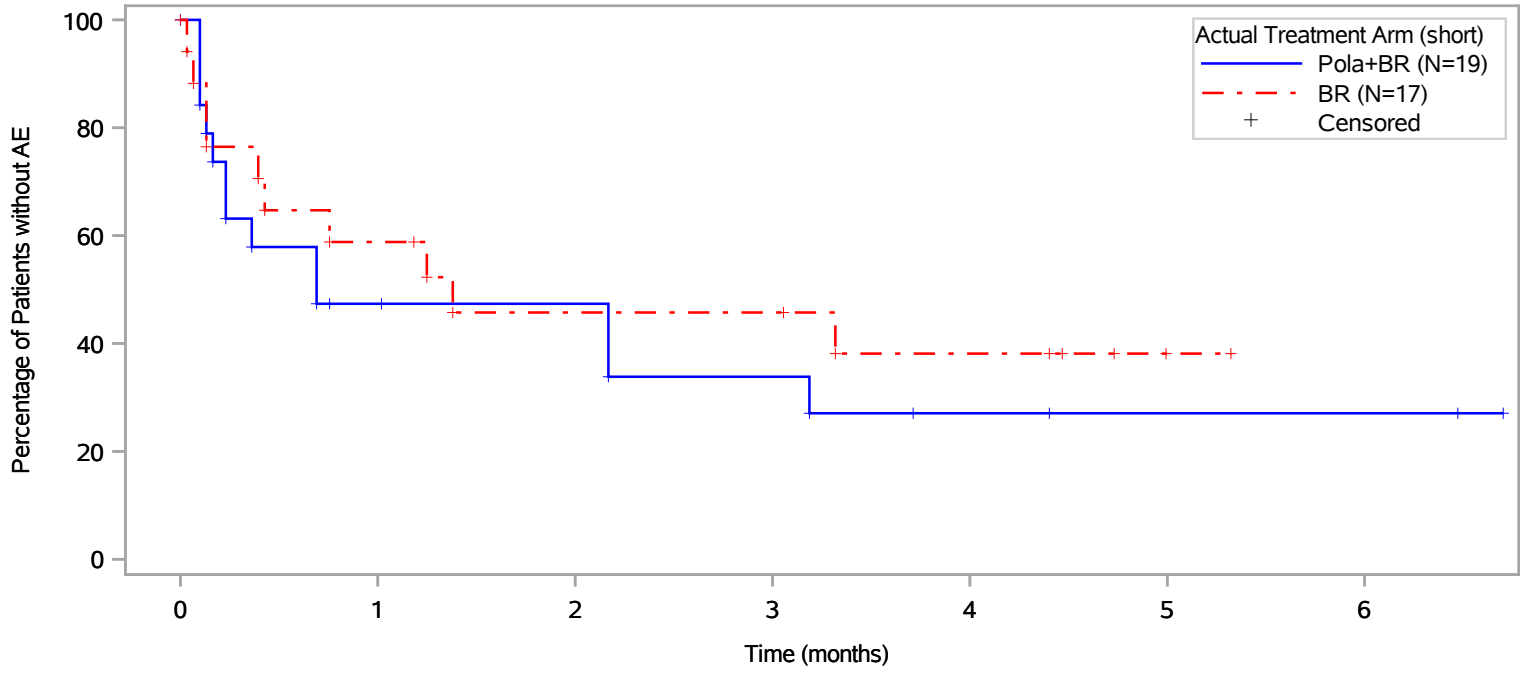
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	8	7	5	3	2	2
BR (N=17)	17	10	7	7	5	1	NE
Patients censored							
Pola+BR (N=19)	0	1	2	2	3	4	4
BR (N=17)	0	0	1	1	2	6	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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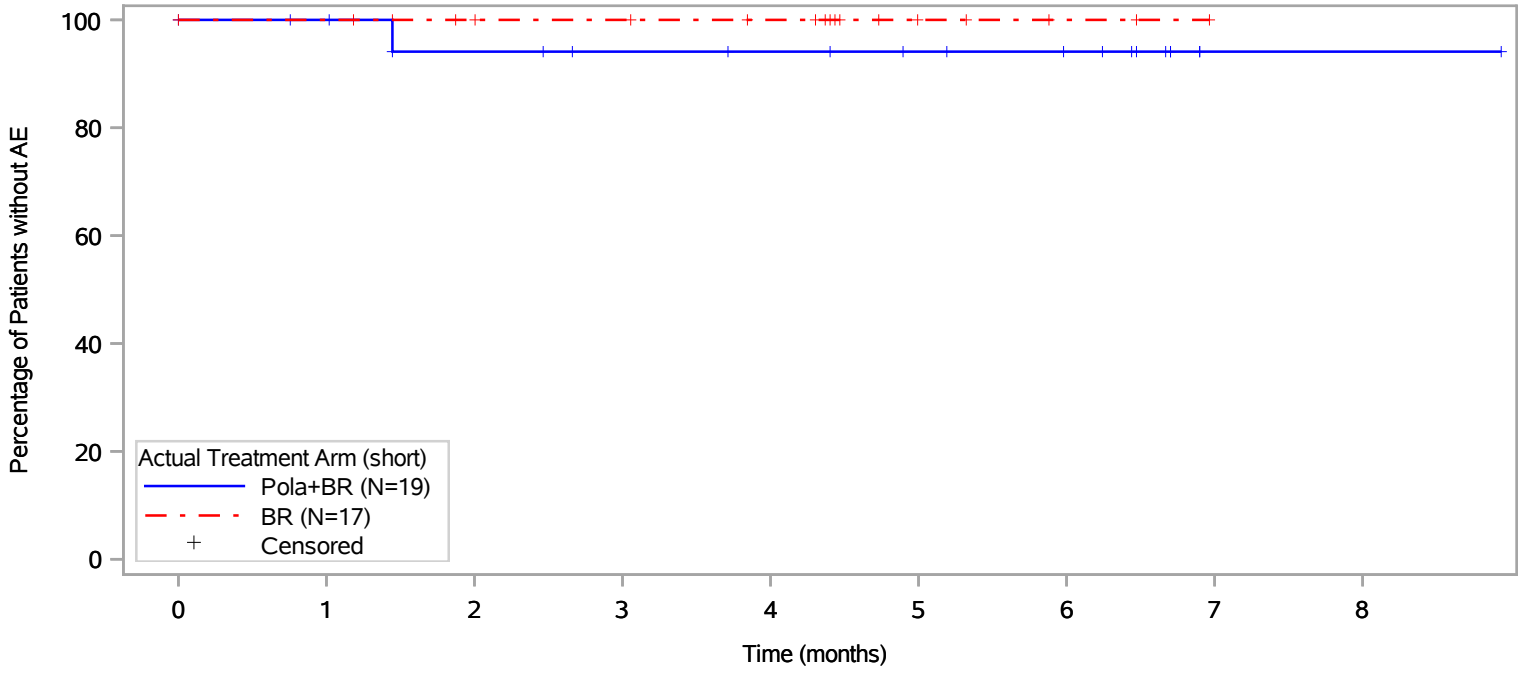
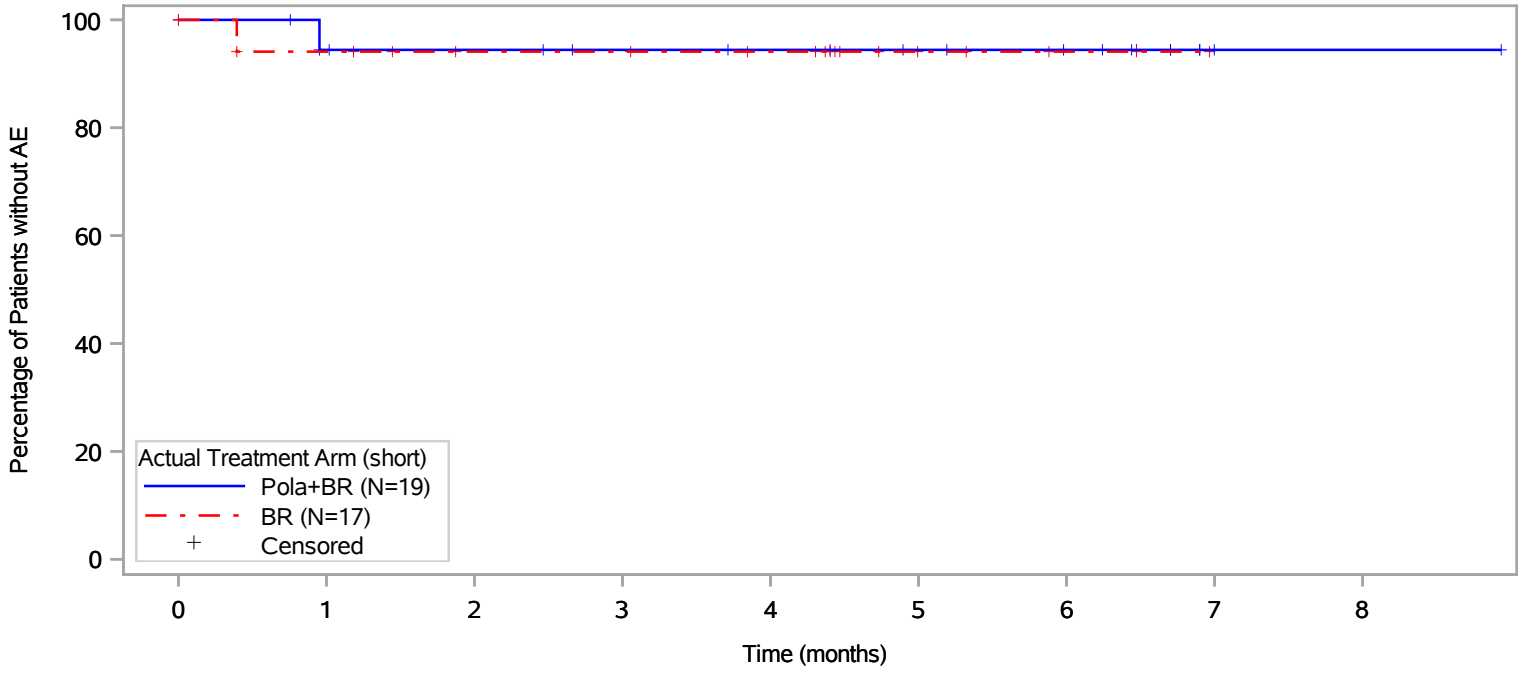
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL DISTENSION



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

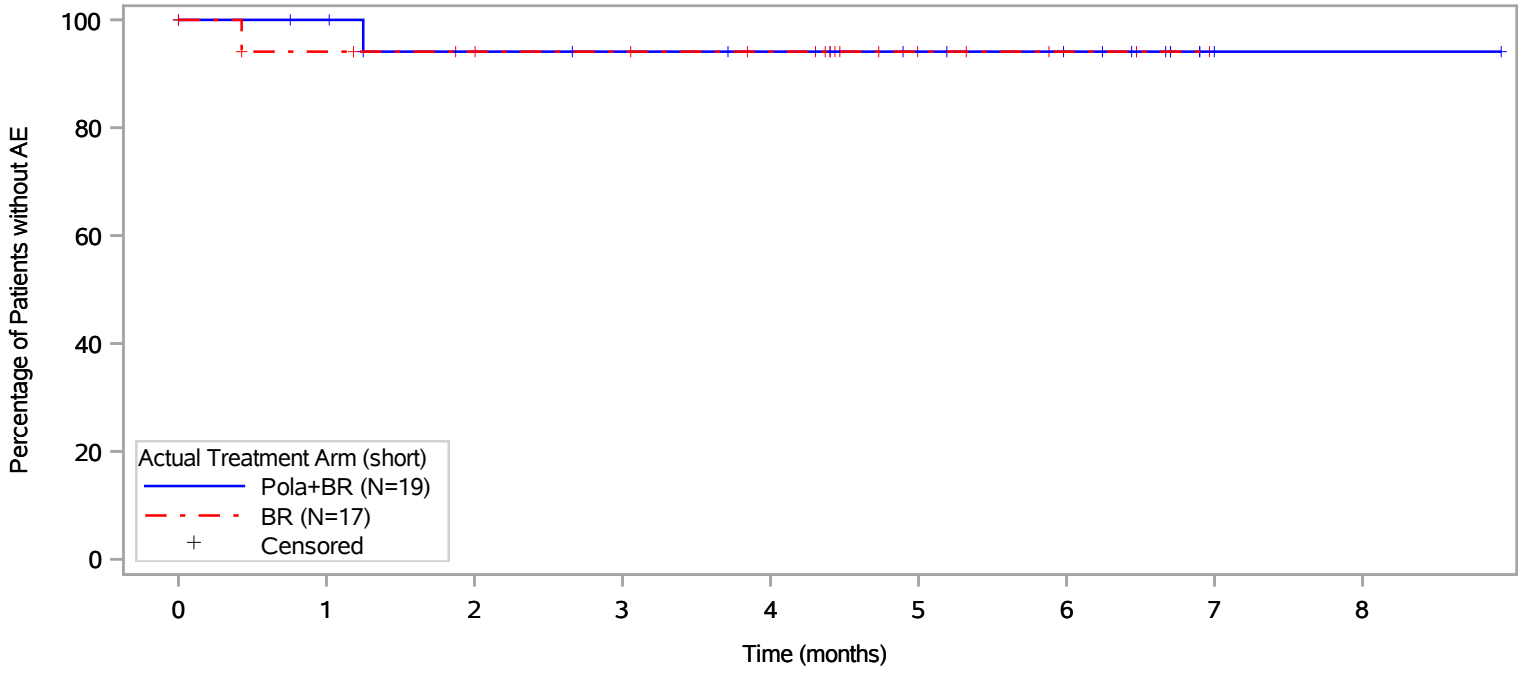
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	16	13	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN UPPER



Patients at risk									
Pola+BR (N=19)	19	18	16	15	14	12	10	1	1
BR (N=17)	17	16	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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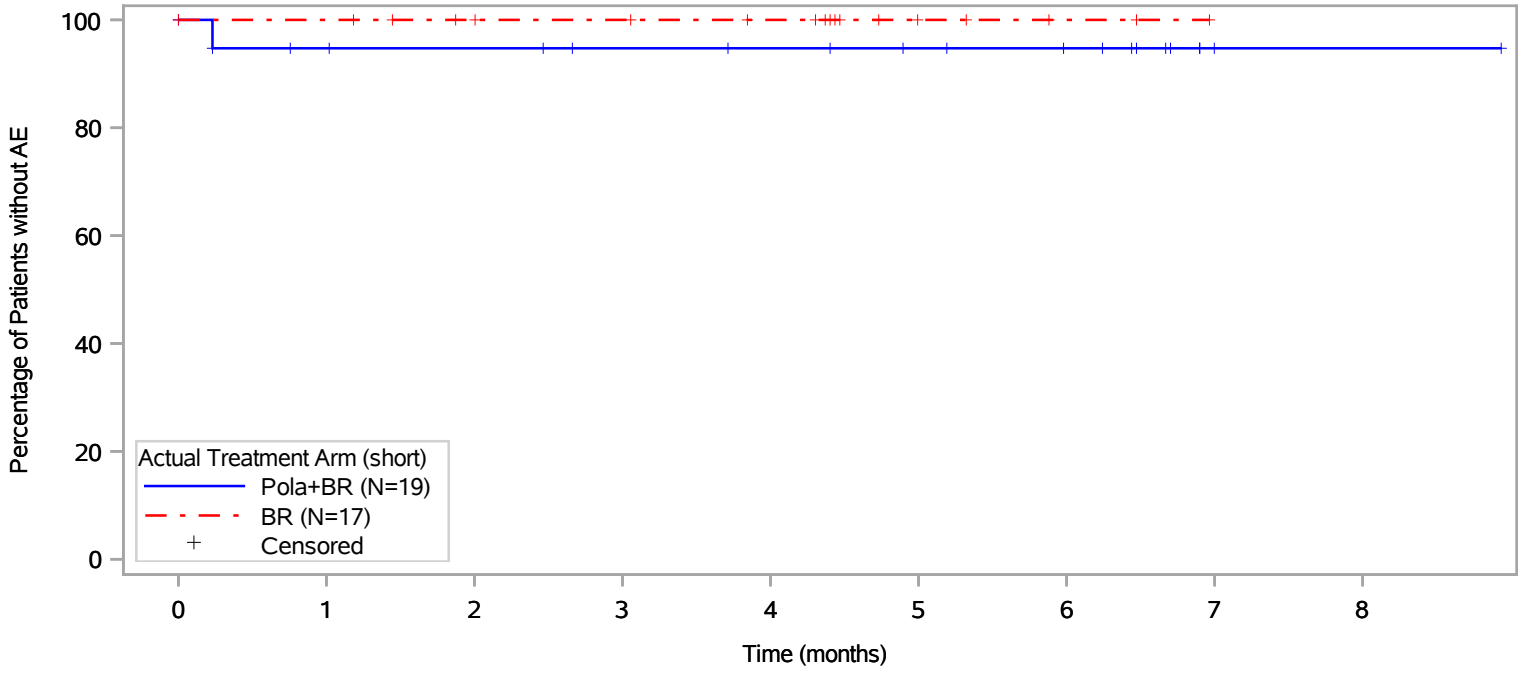
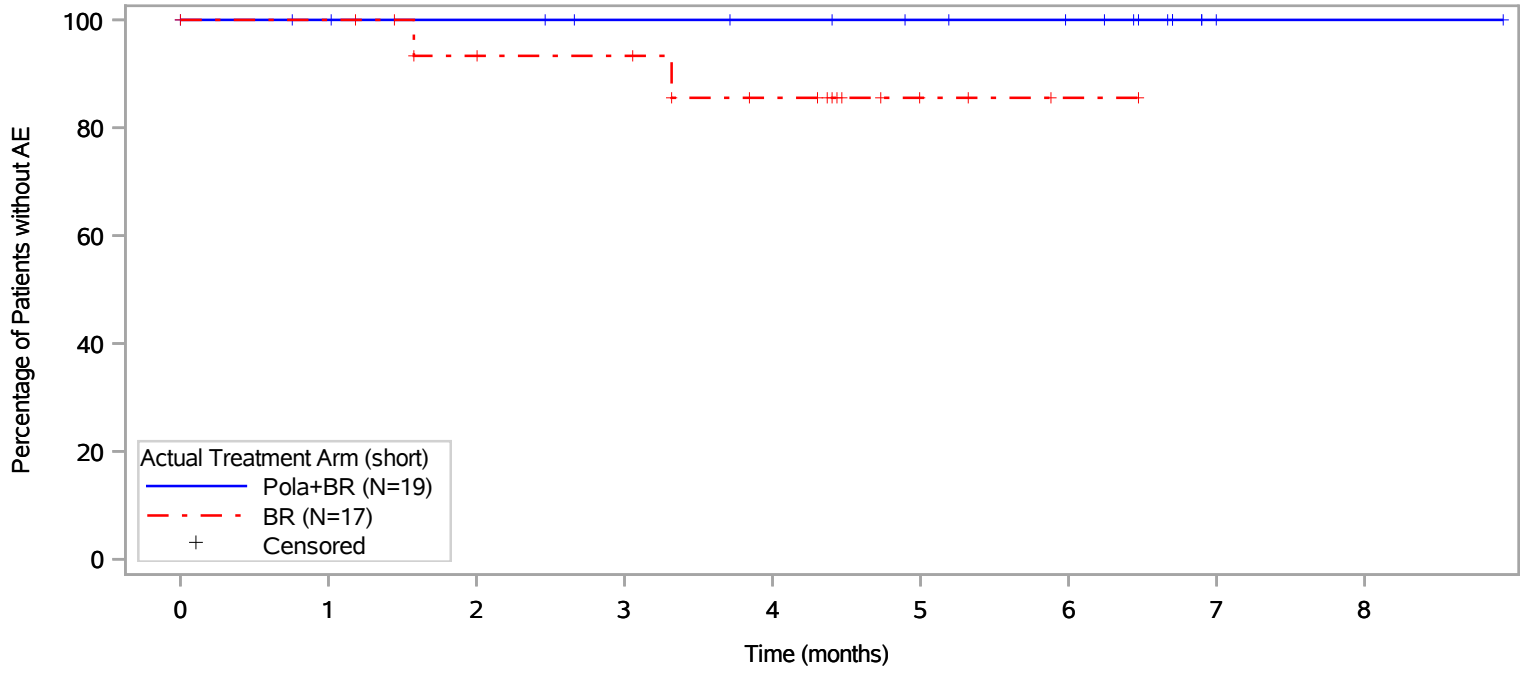
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL RIGIDITY



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, APHTHOUS ULCER



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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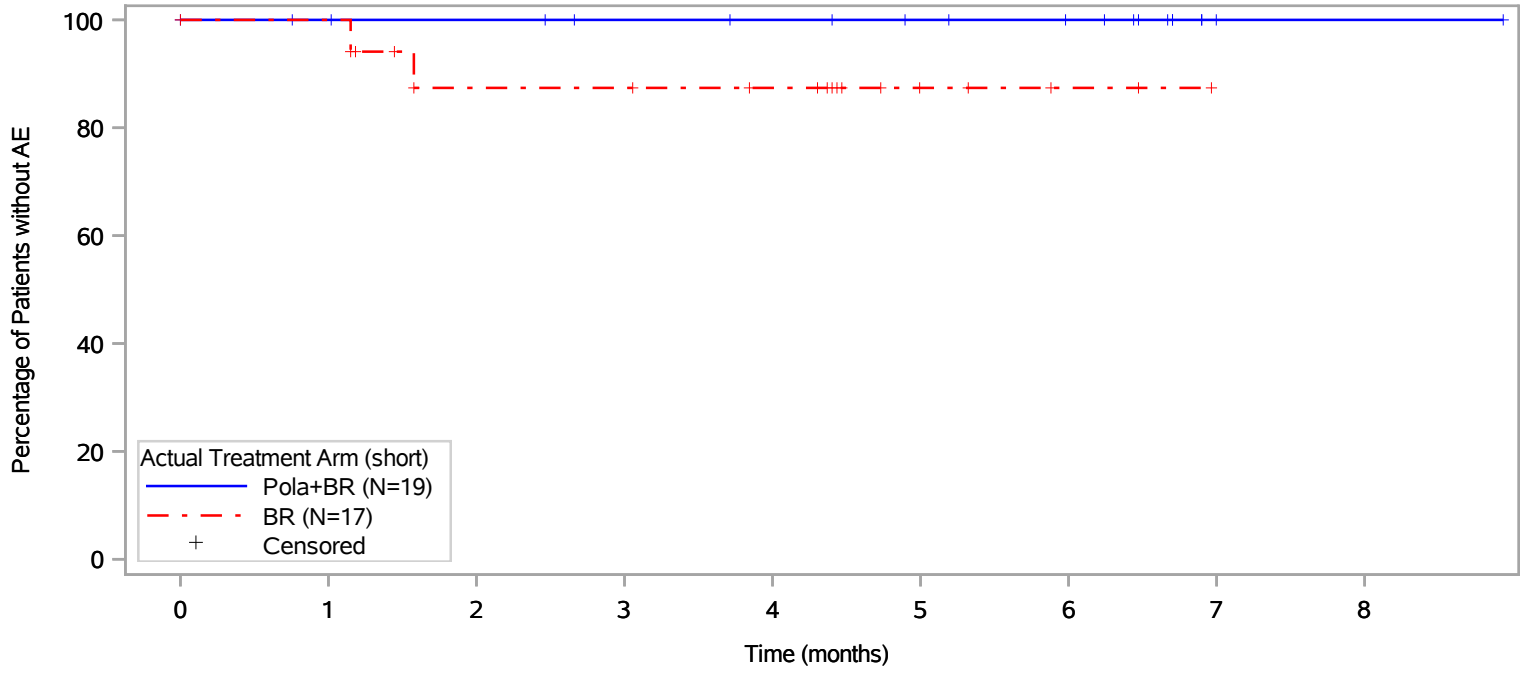
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ASCITES



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	2	4	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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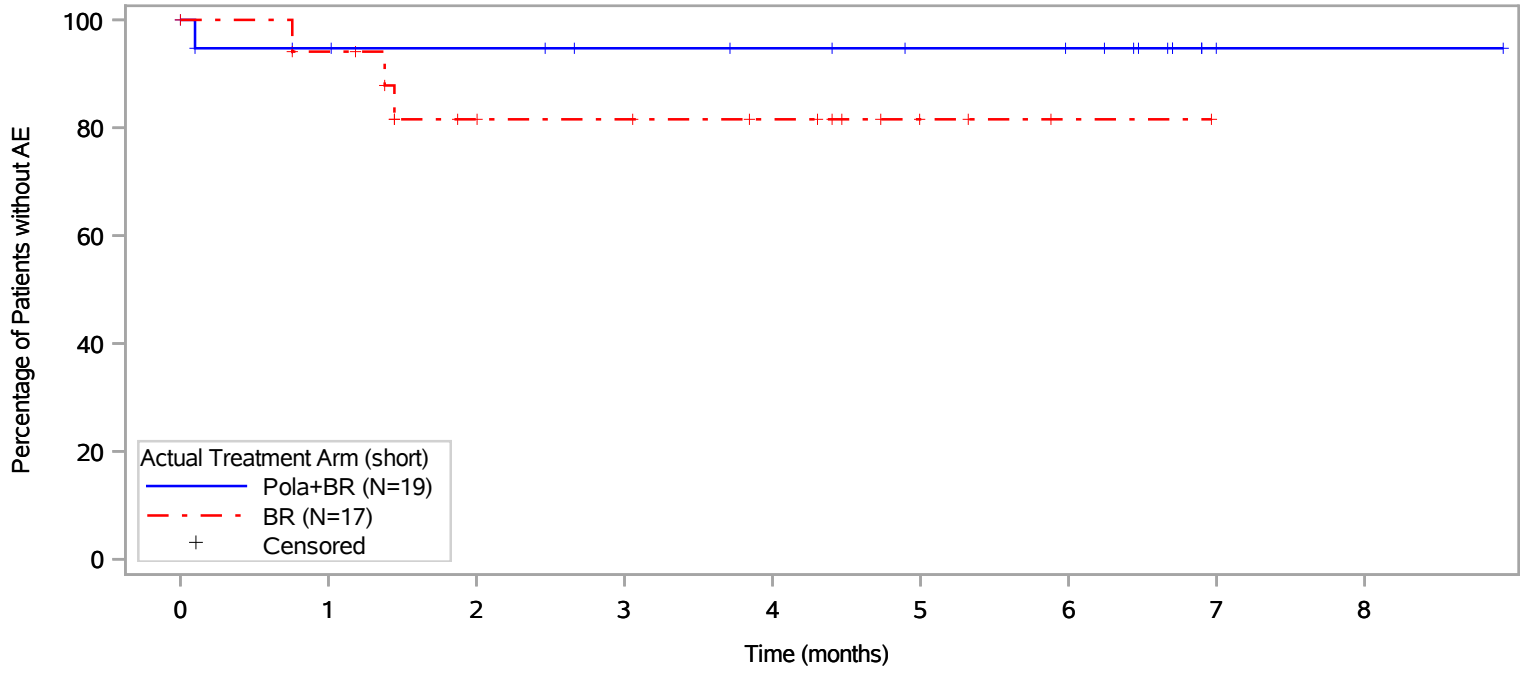
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	10	1	1
BR (N=17)	17	16	11	10	8	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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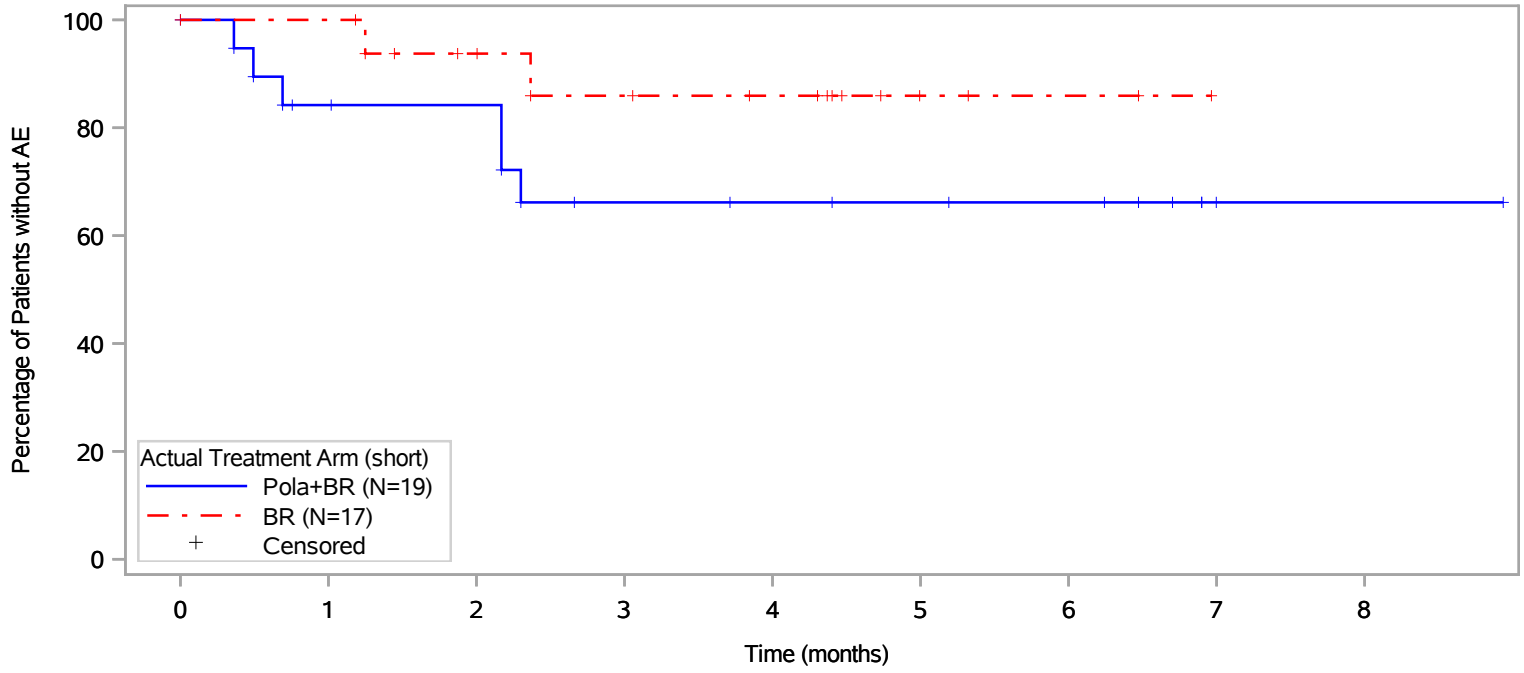
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



Patients at risk									
Pola+BR (N=19)	19	15	14	10	9	8	7	1	1
BR (N=17)	17	17	13	11	9	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	6	12	12
BR (N=17)	0	0	3	4	6	12	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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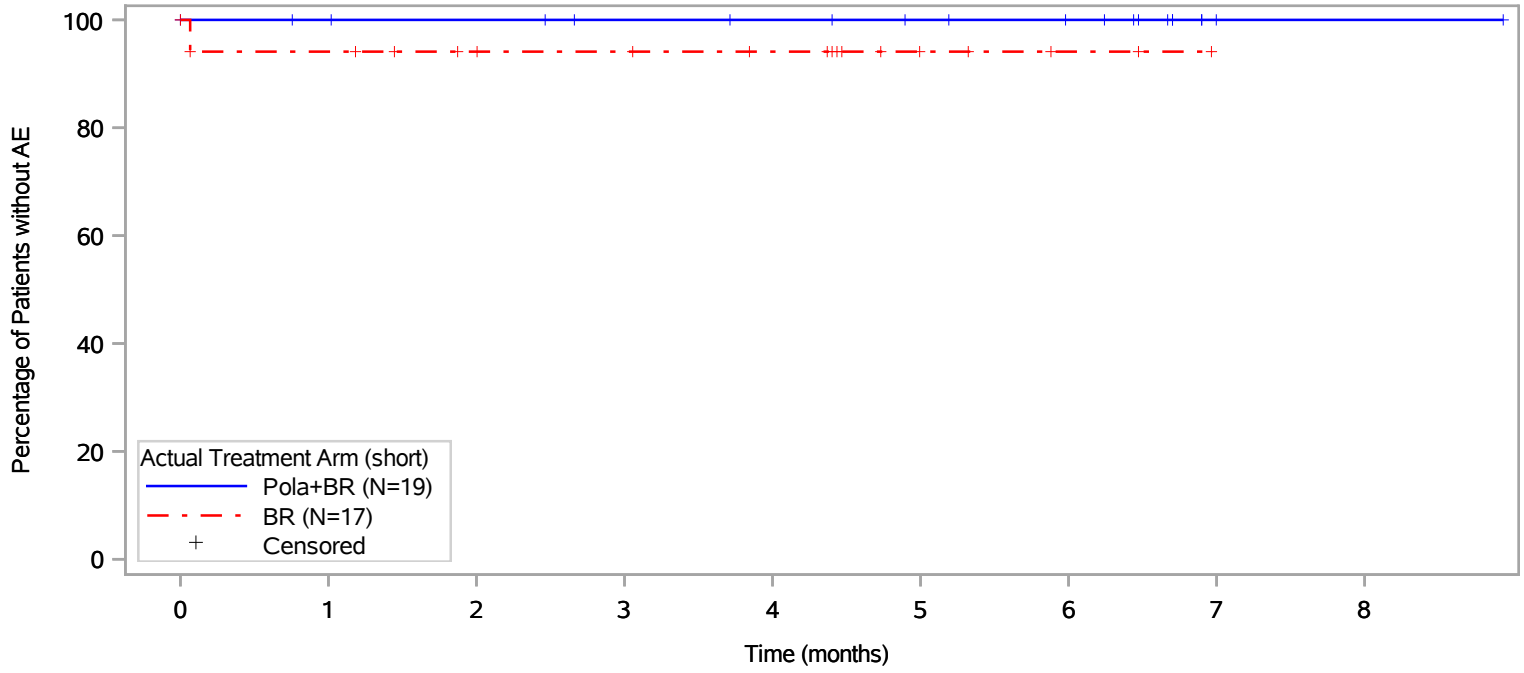
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DRY MOUTH



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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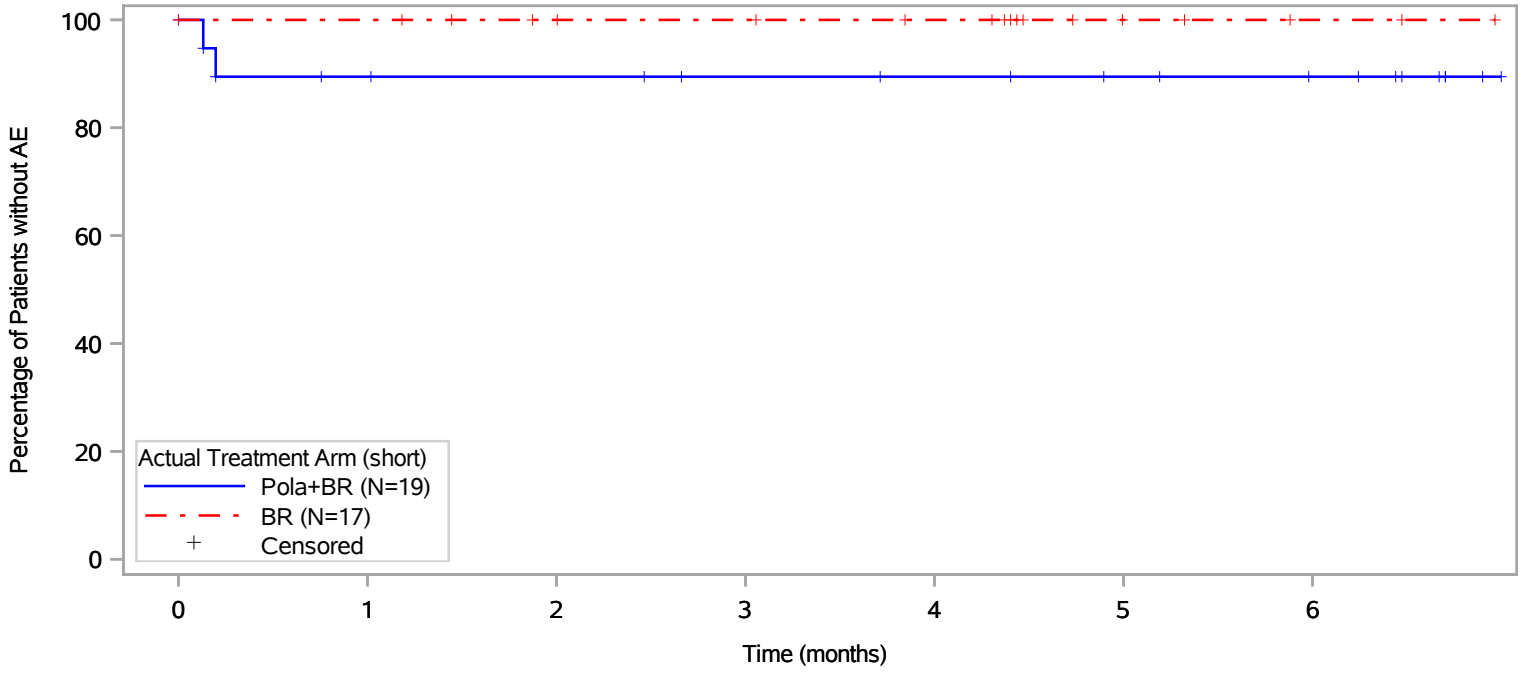
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DYSPEPSIA



Patients at risk							
Pola+BR (N=19)	19	16	15	13	12	10	8
BR (N=17)	17	17	14	13	11	4	2
Patients censored							
Pola+BR (N=19)	0	1	2	4	5	7	9
BR (N=17)	0	0	3	4	6	13	15

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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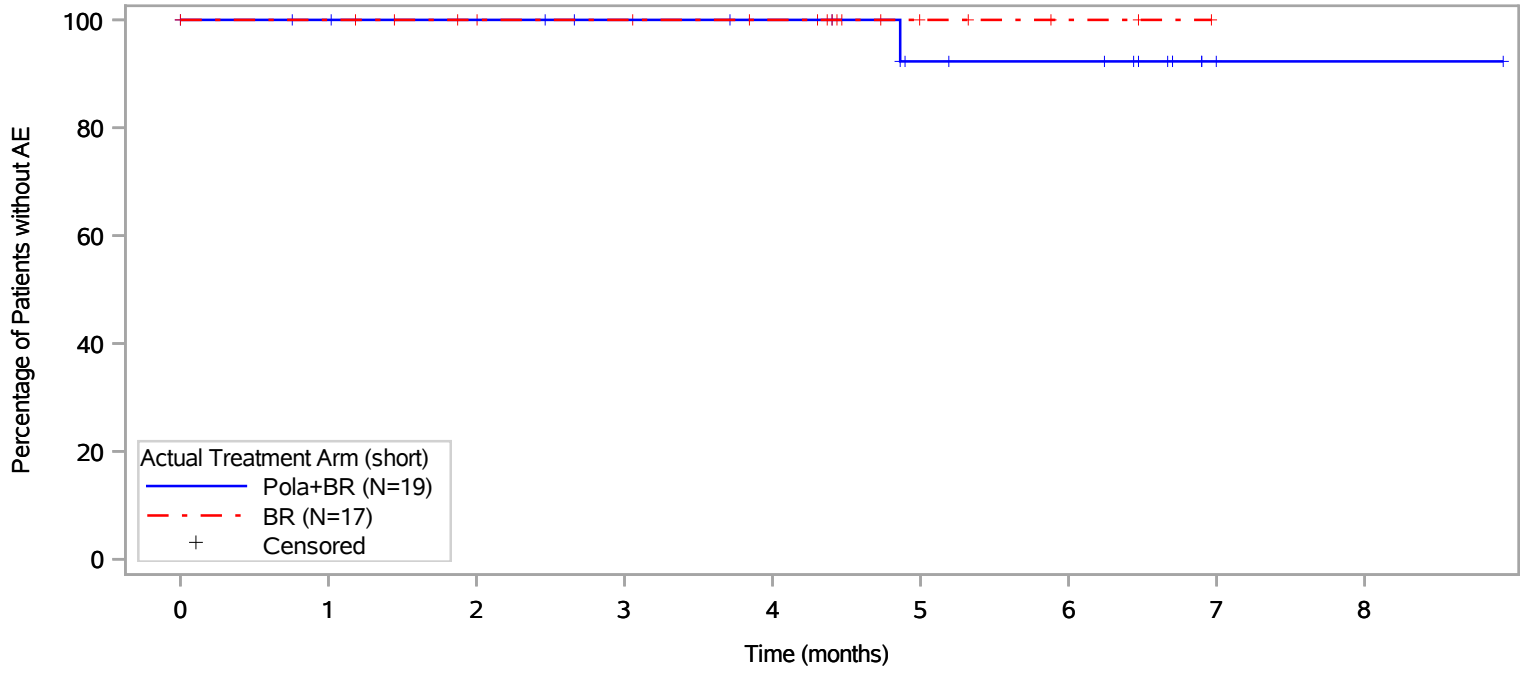
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DYSPHAGIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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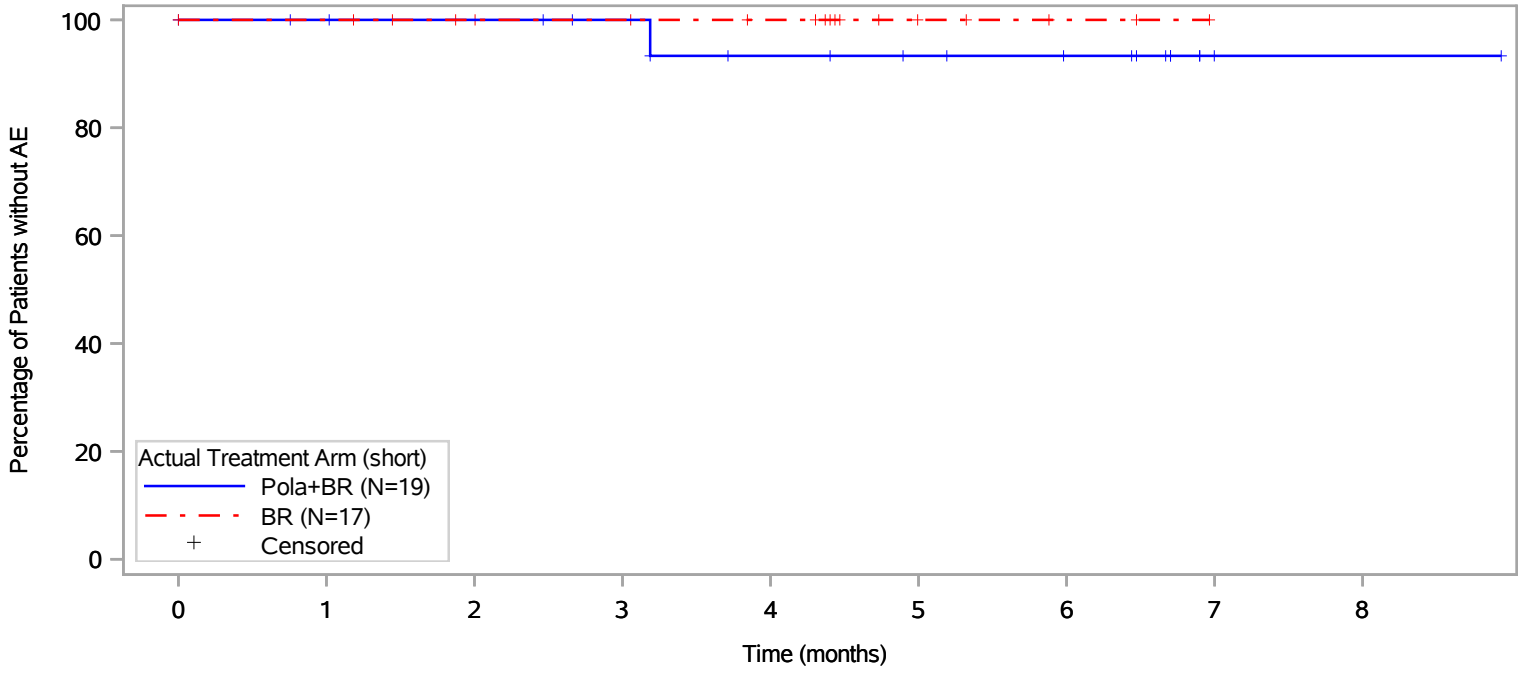
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, FAECES SOFT



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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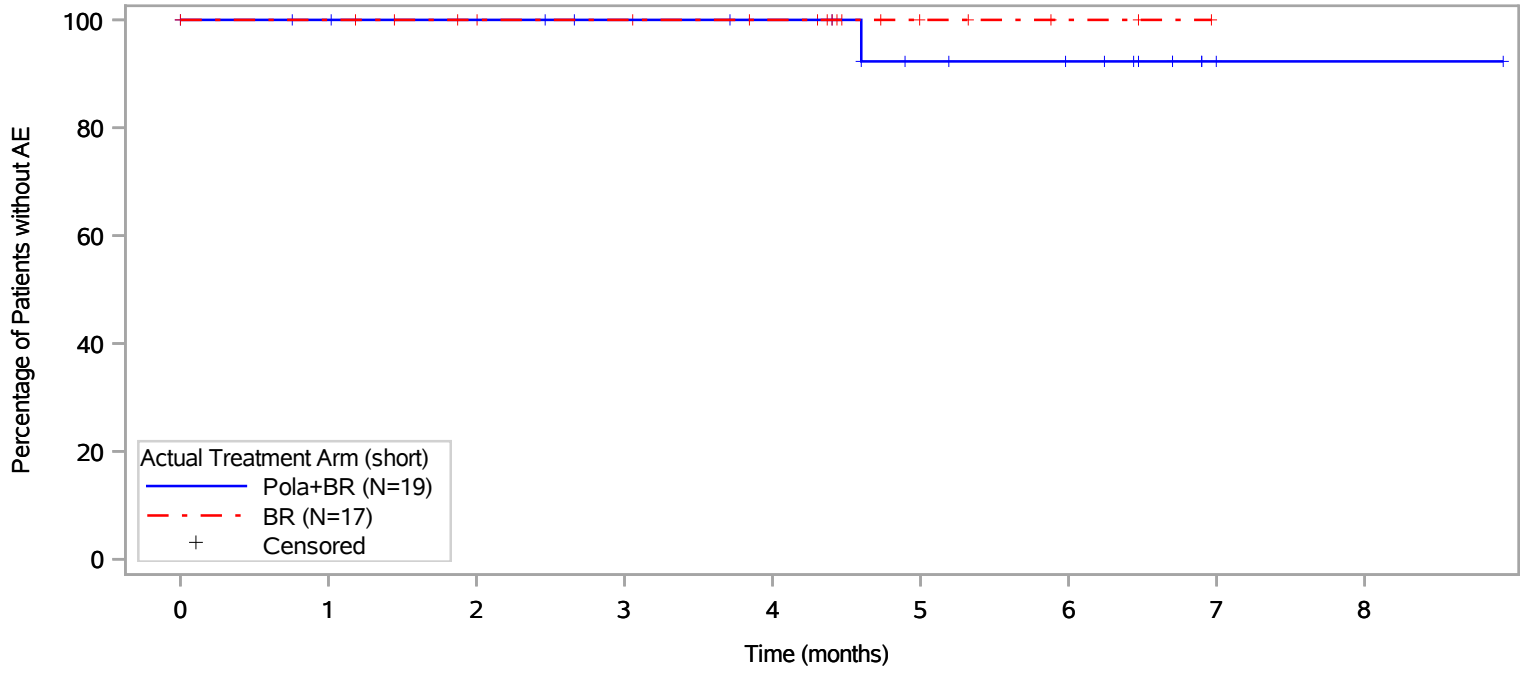
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GINGIVAL PAIN



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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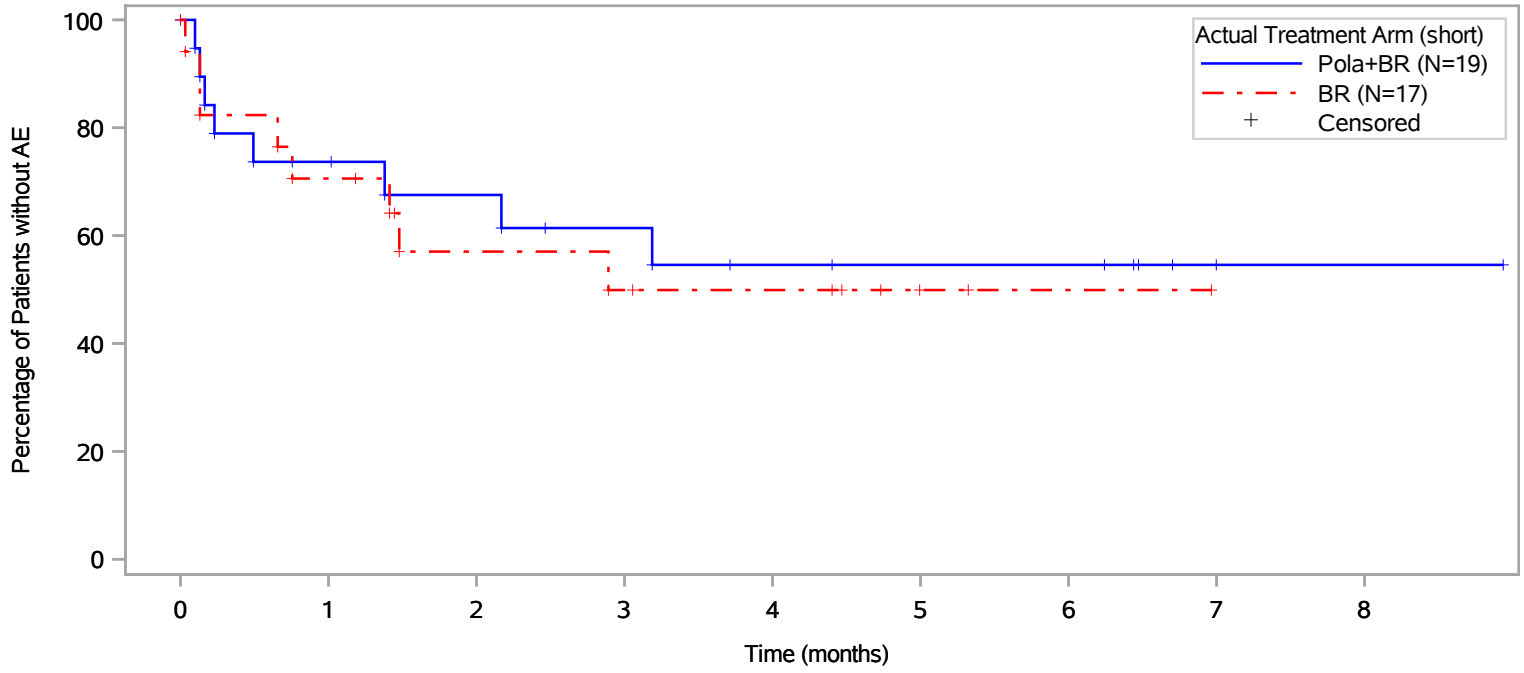
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, NAUSEA



Patients at risk									
Pola+BR (N=19)	19	13	11	9	7	6	6	1	1
BR (N=17)	17	12	8	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	5	10	10
BR (N=17)	0	0	2	2	3	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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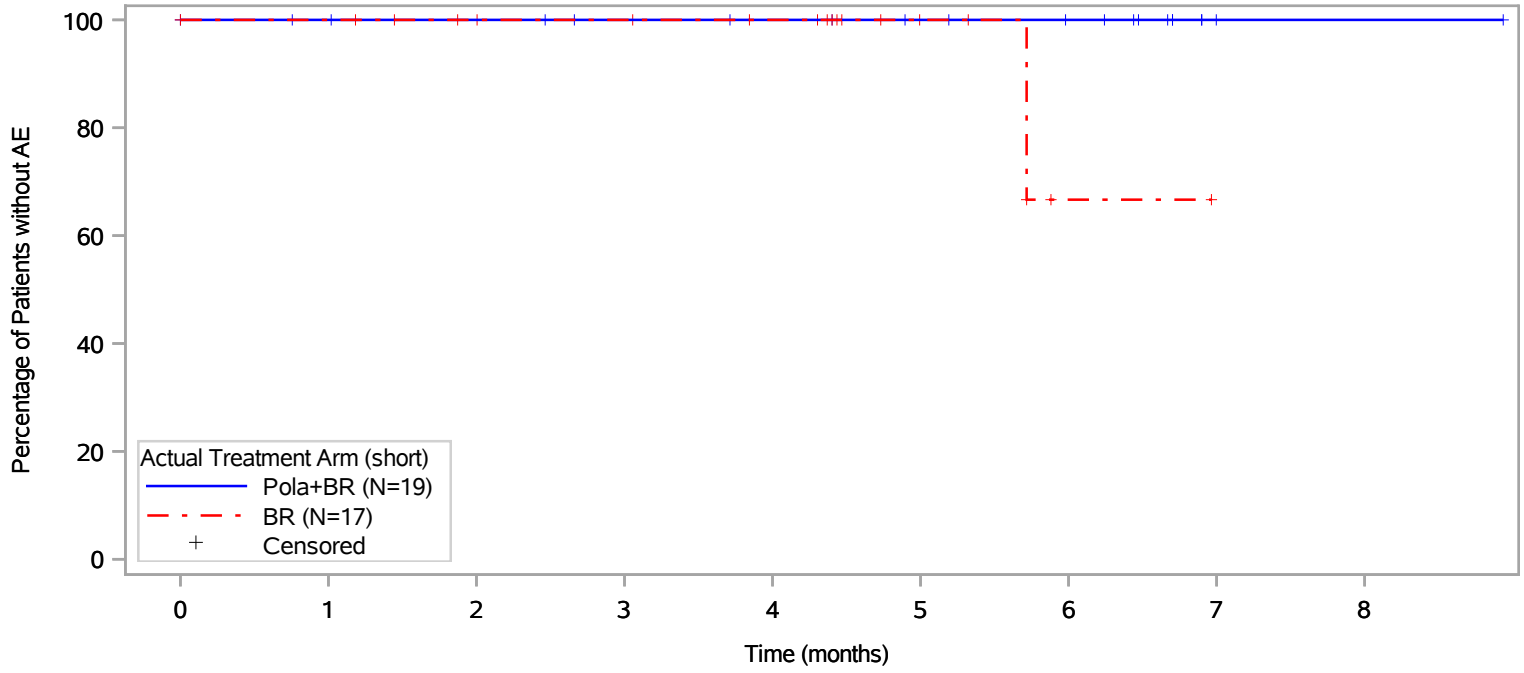
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SMALL INTESTINAL OBSTRUCTION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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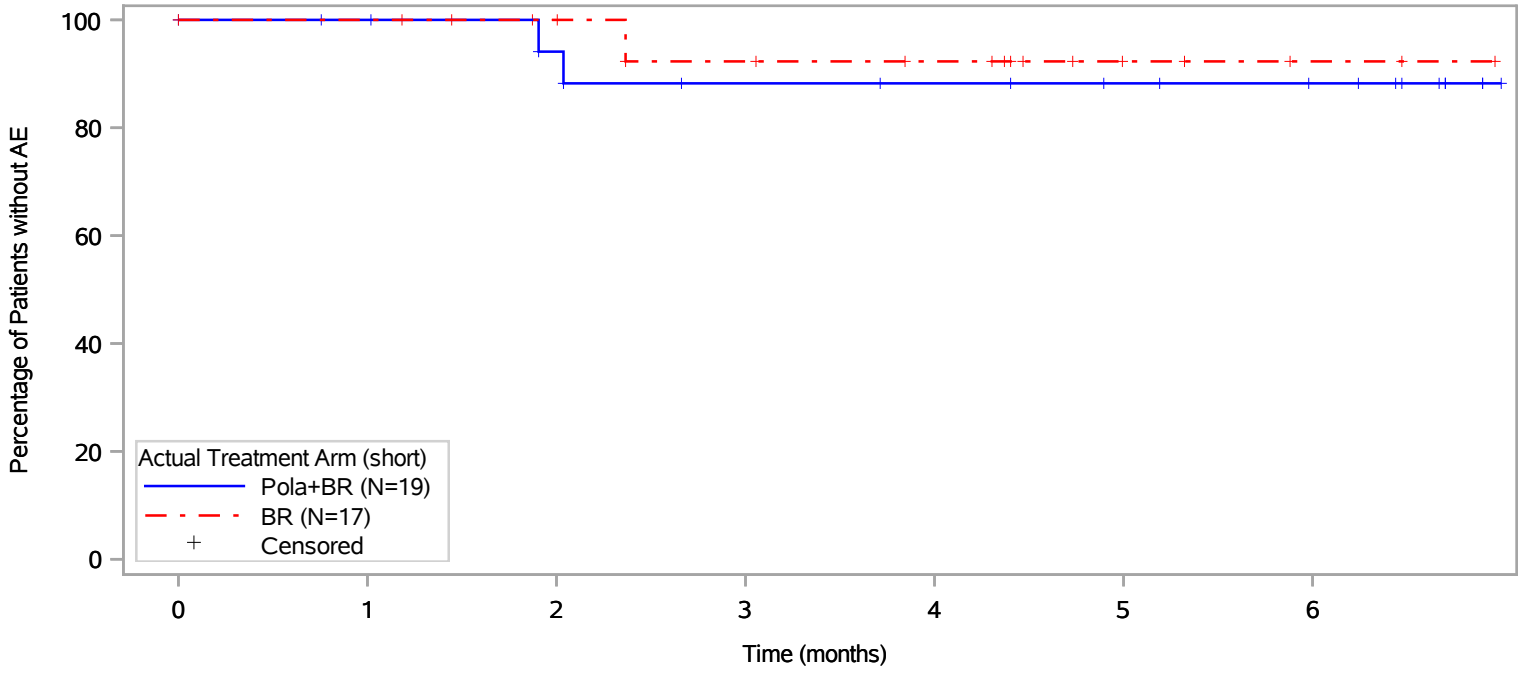
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, STOMATITIS



Patients at risk							
Pola+BR (N=19)	19	18	16	14	13	11	9
BR (N=17)	17	17	14	12	10	4	2
Patients censored							
Pola+BR (N=19)	0	1	2	3	4	6	8
BR (N=17)	0	0	3	4	6	12	14

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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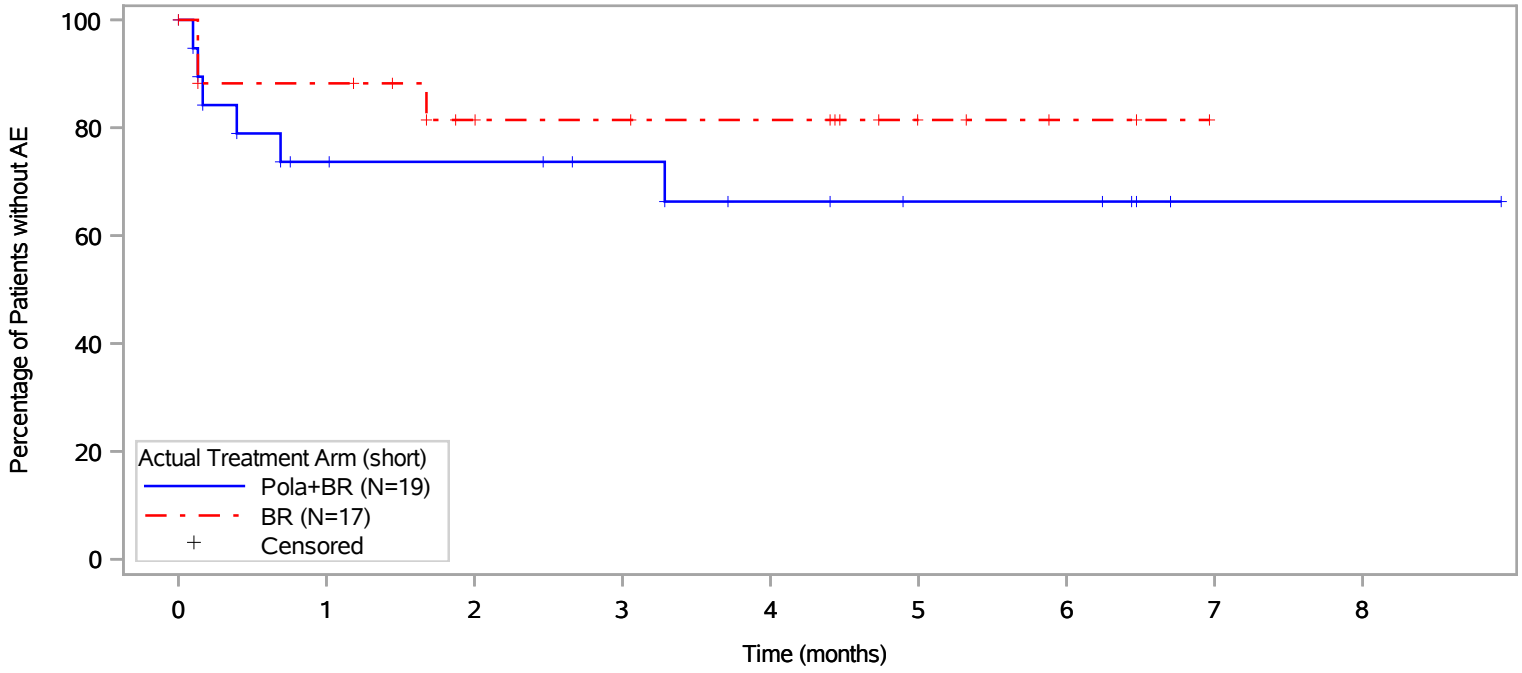
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=19)	19	13	12	10	8	6	6	1	1
BR (N=17)	17	15	11	10	9	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	7	12	12
BR (N=17)	0	0	3	4	5	10	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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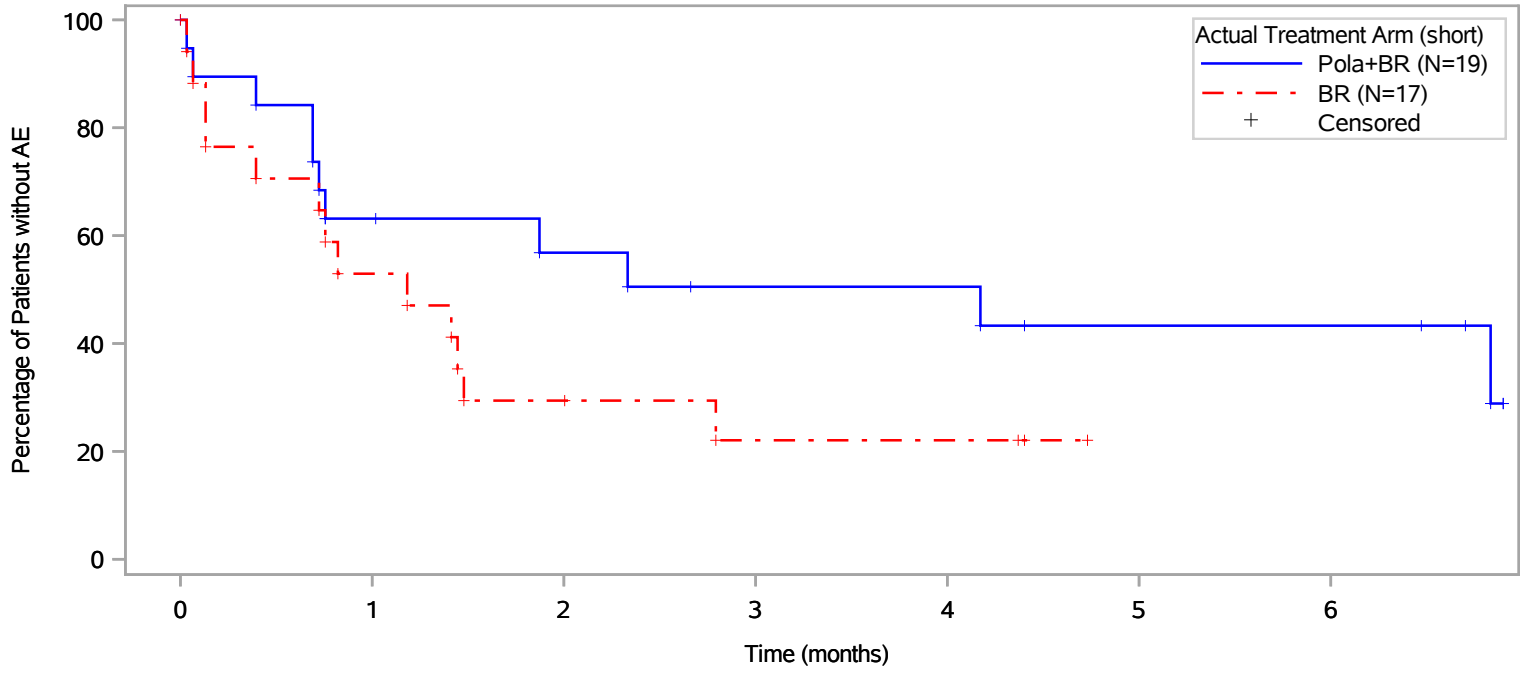
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk							
Pola+BR (N=19)	19	11	9	7	7	5	5
BR (N=17)	17	9	5	3	3	NE	NE
Patients censored							
Pola+BR (N=19)	0	1	2	3	3	4	4
BR (N=17)	0	0	0	1	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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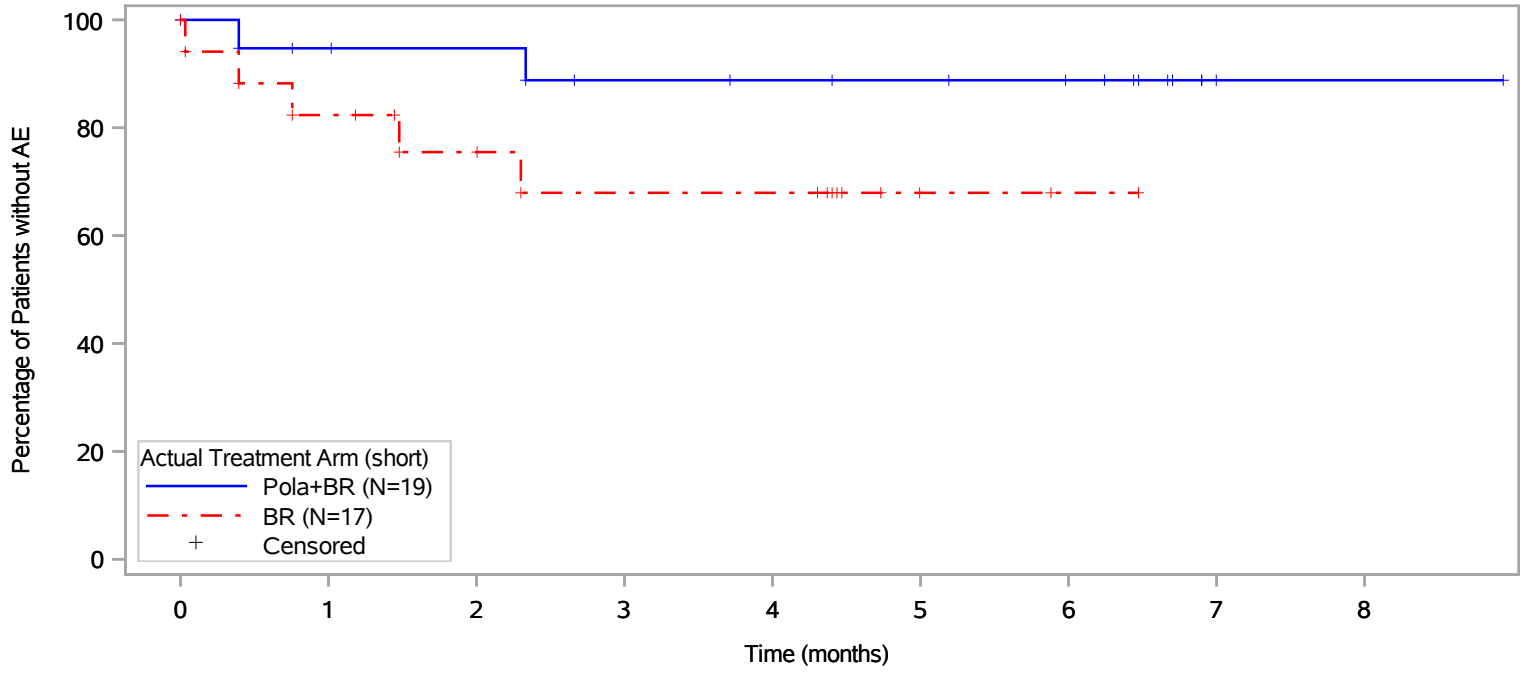
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, ASTHENIA

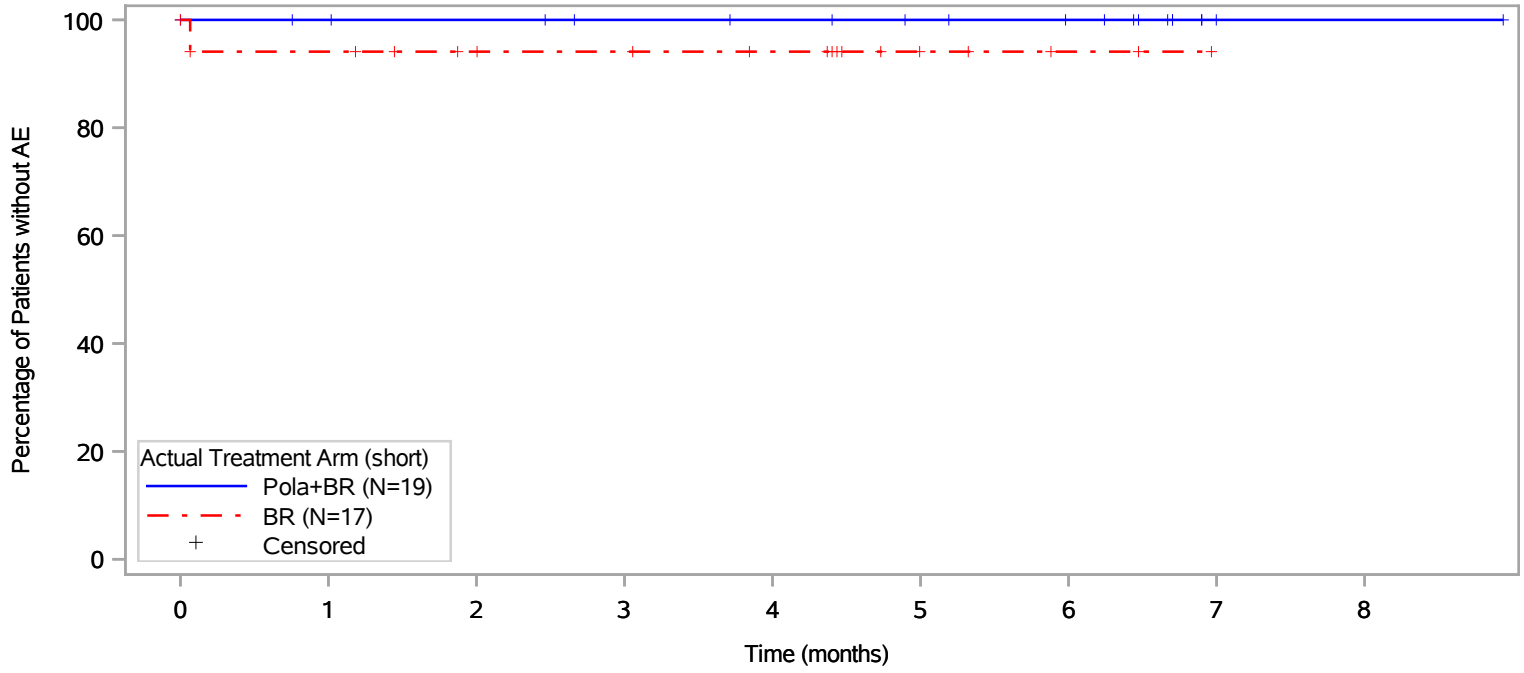


Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	12	10	1	1
BR (N=17)	17	14	11	9	9	2	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	7	16	16
BR (N=17)	0	0	2	3	3	10	11	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHEST DISCOMFORT

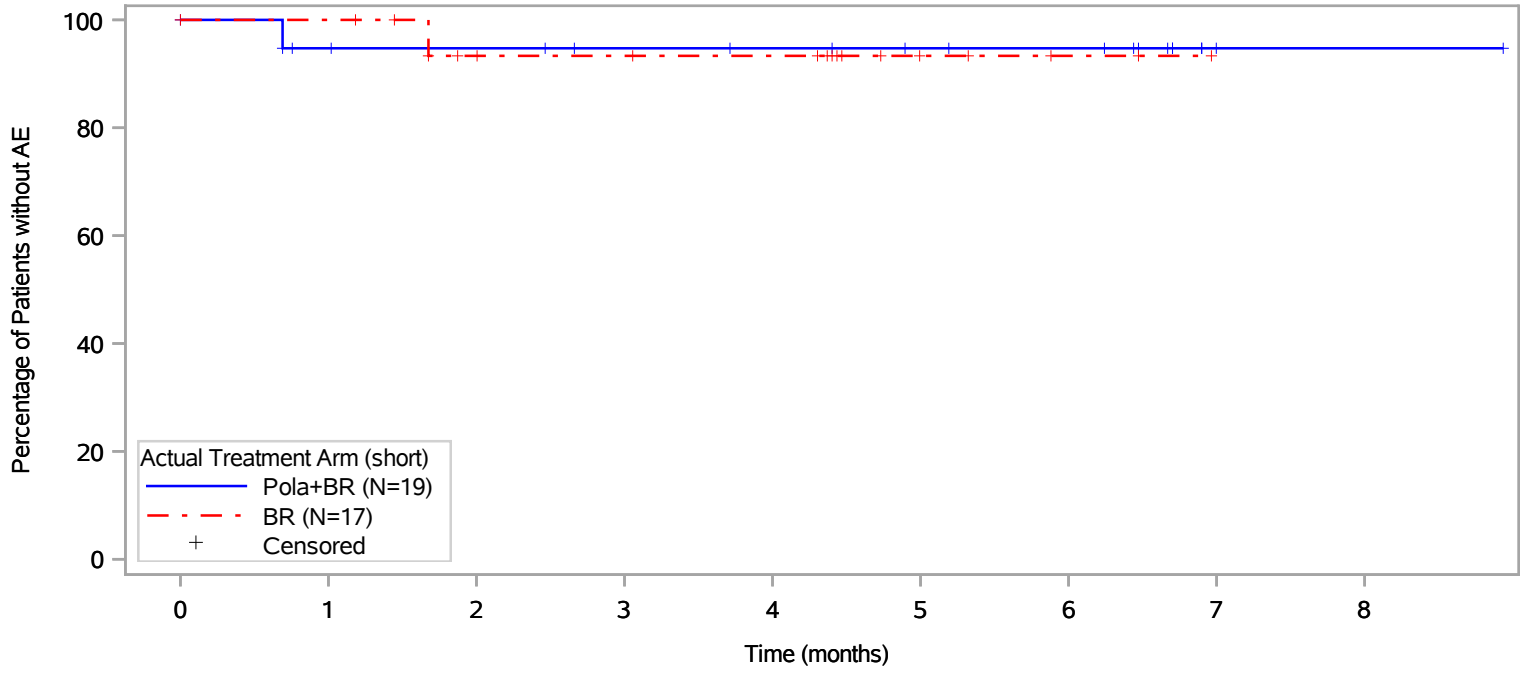


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHILLS



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	10	1	1
BR (N=17)	17	17	13	12	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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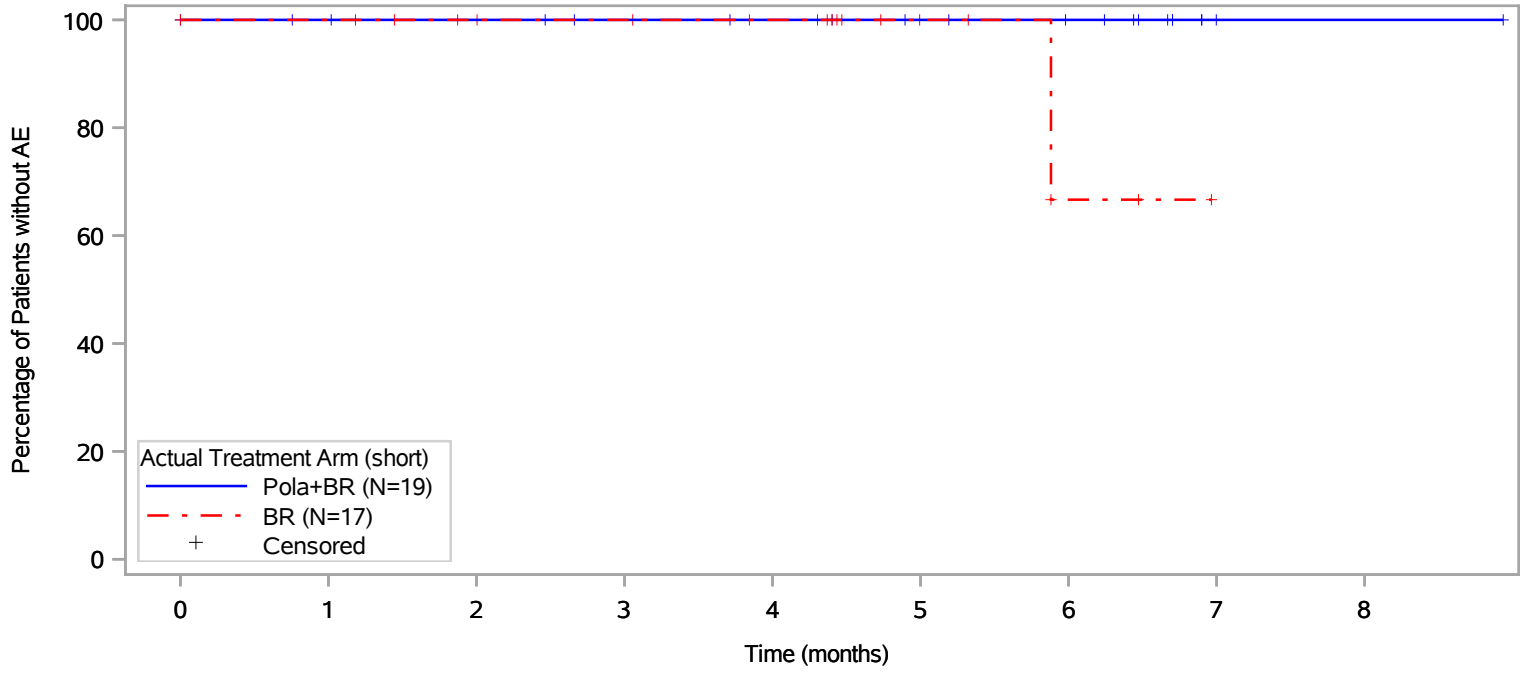
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DEATH

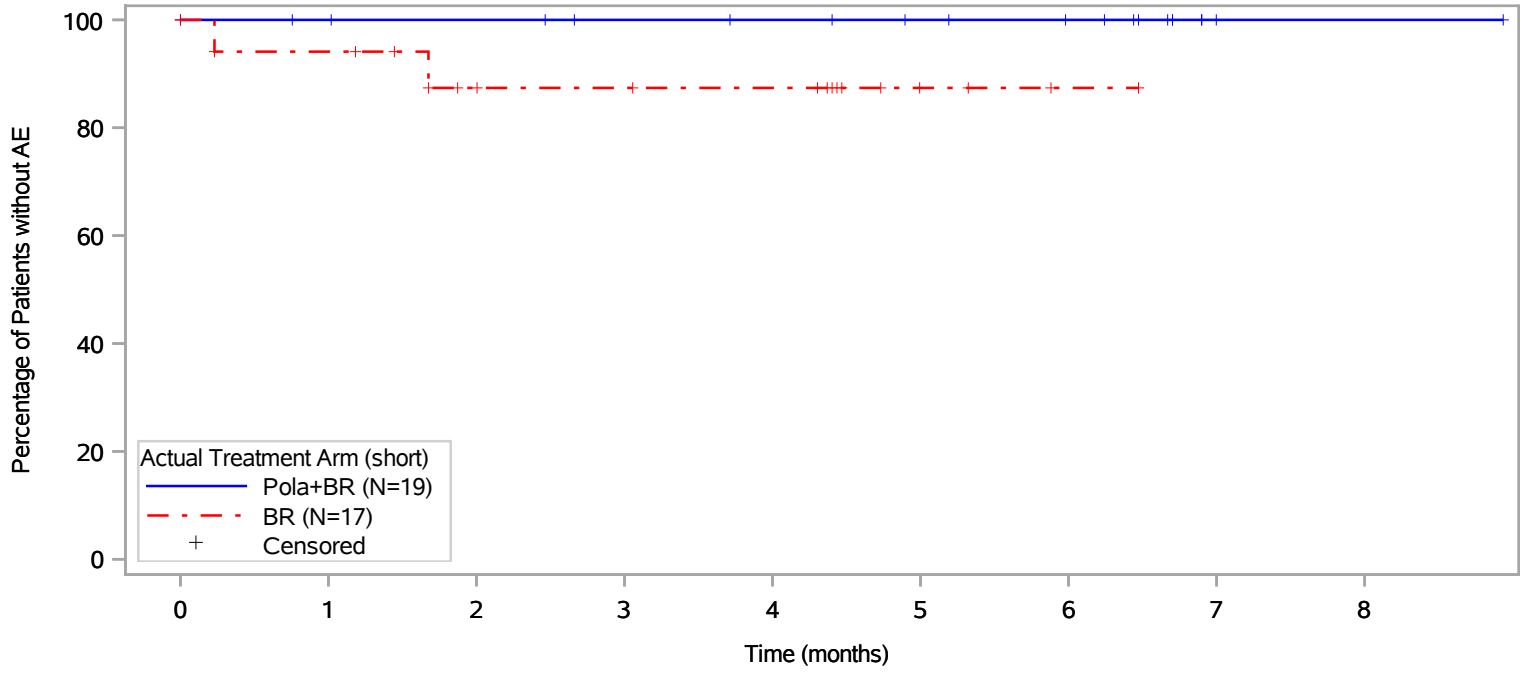


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DISCOMFORT

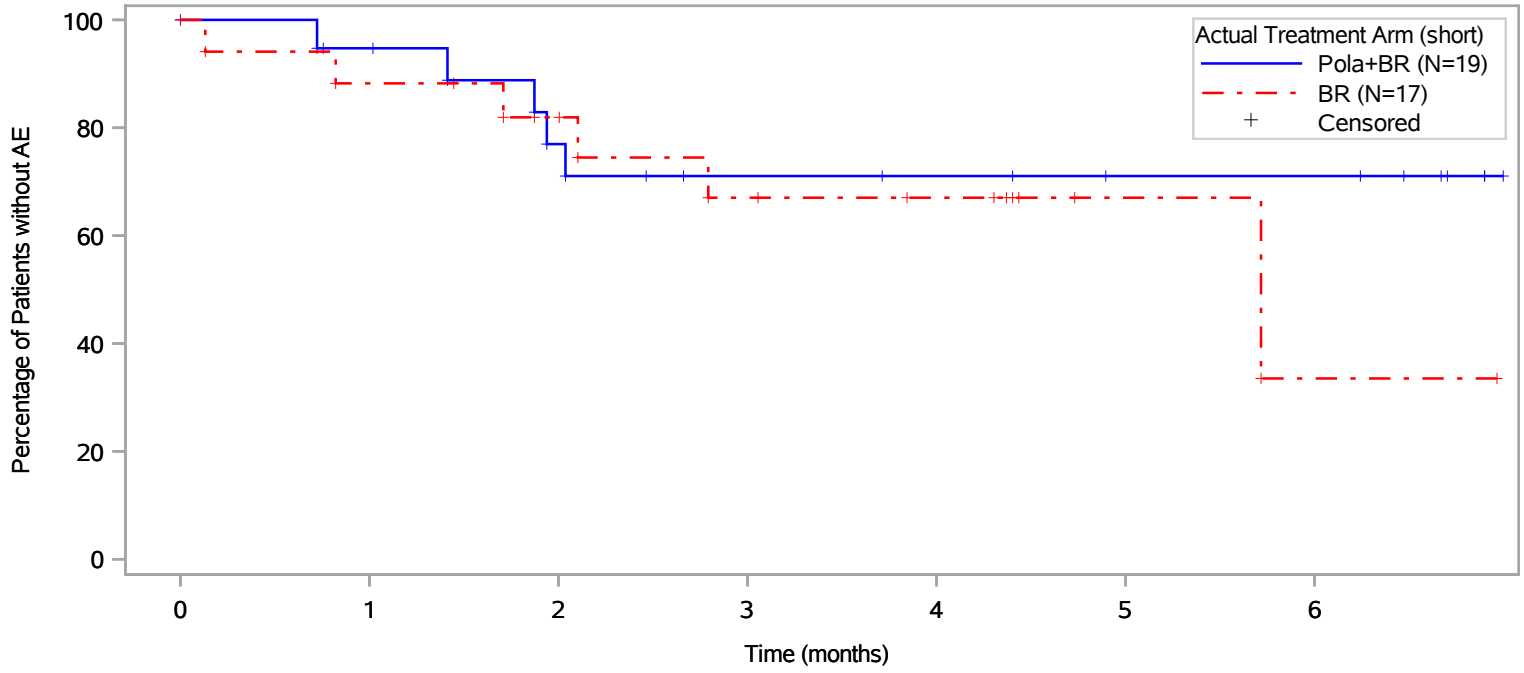


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	12	11	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE



Patients at risk							
Pola+BR (N=19)	19	17	13	10	9	7	7
BR (N=17)	17	15	12	9	7	2	1
Patients censored							
Pola+BR (N=19)	0	1	2	4	5	7	7
BR (N=17)	0	0	2	3	5	10	10

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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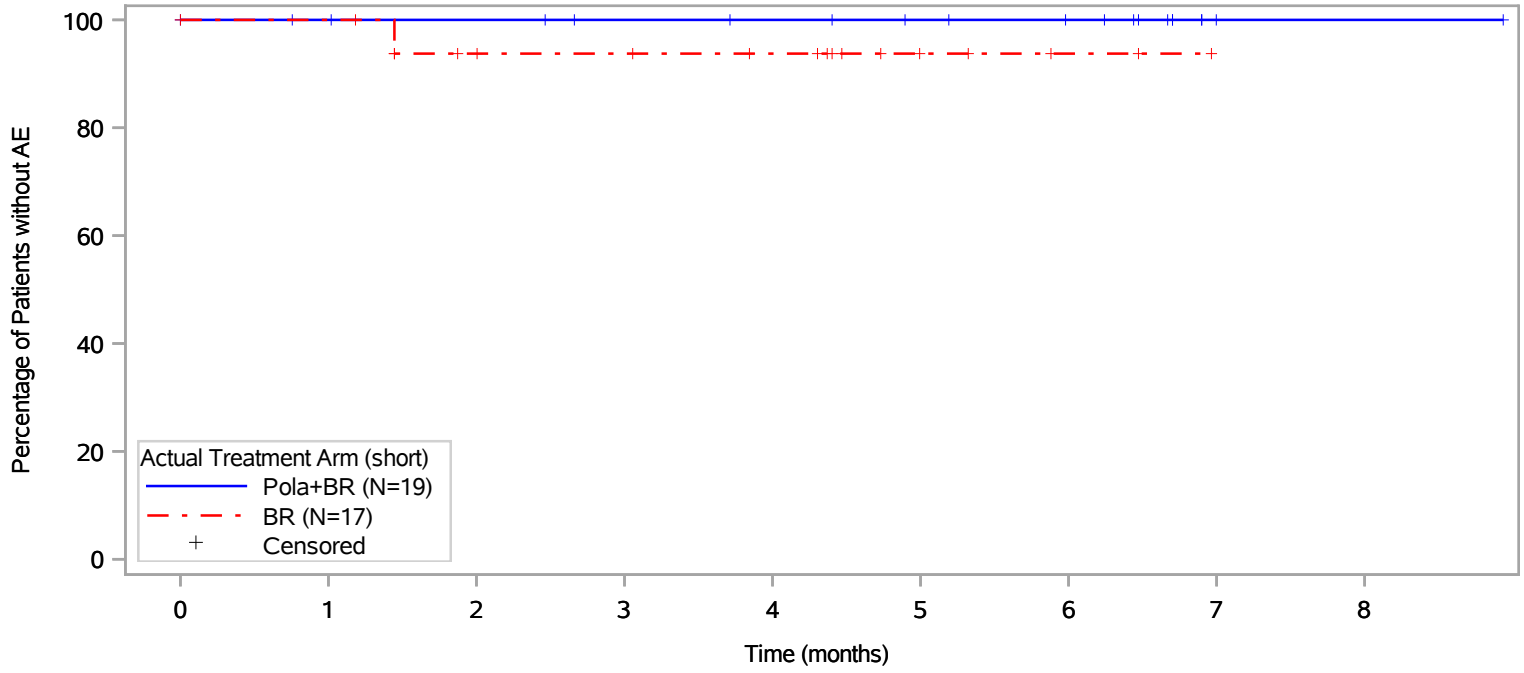
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, INFLUENZA LIKE ILLNESS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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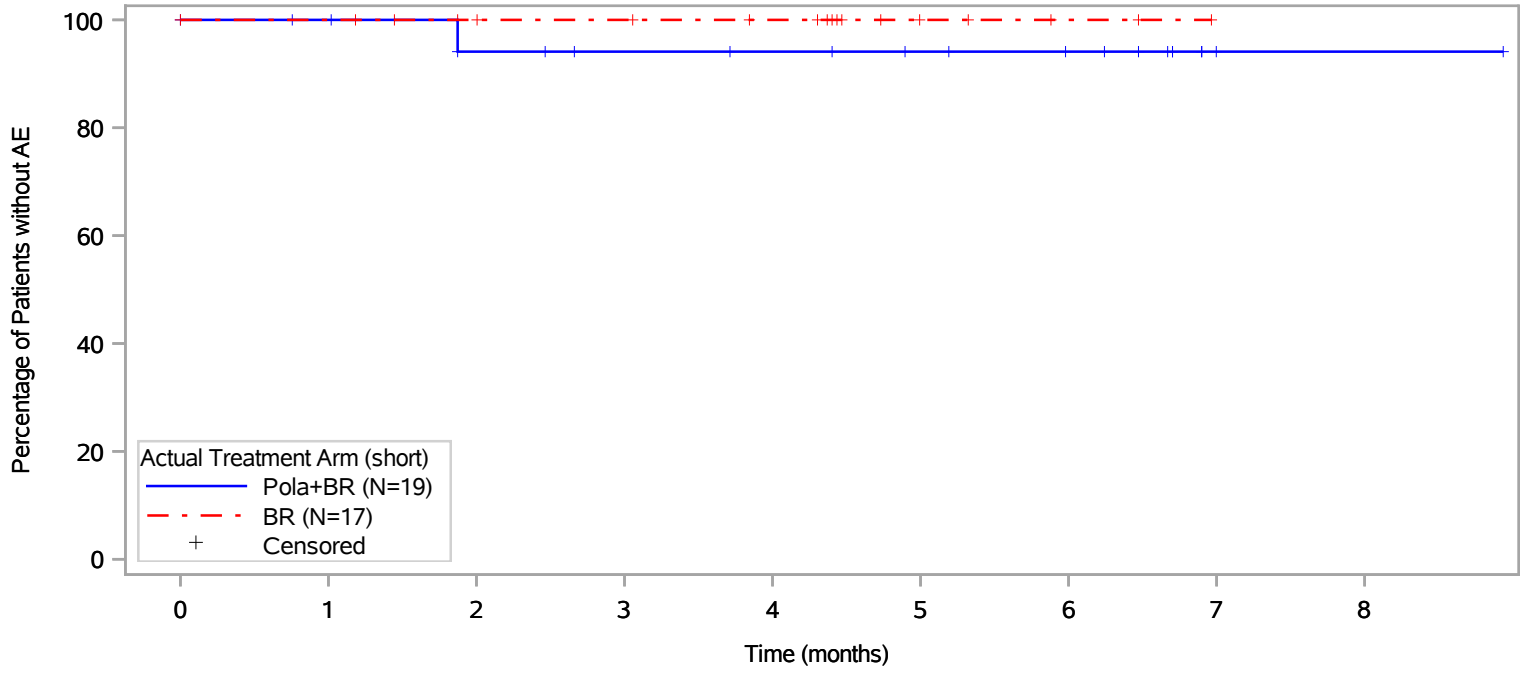
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MALAISE

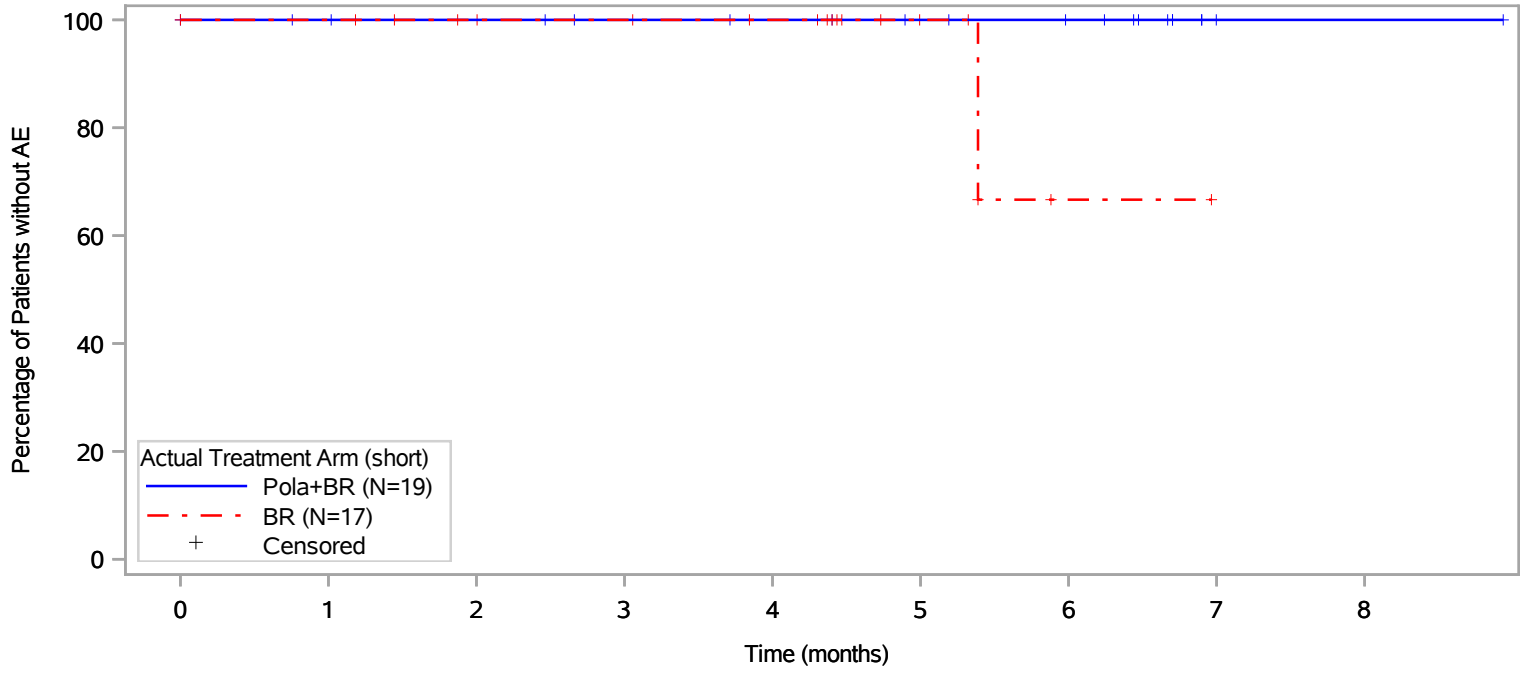


Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MUCOSAL INFLAMMATION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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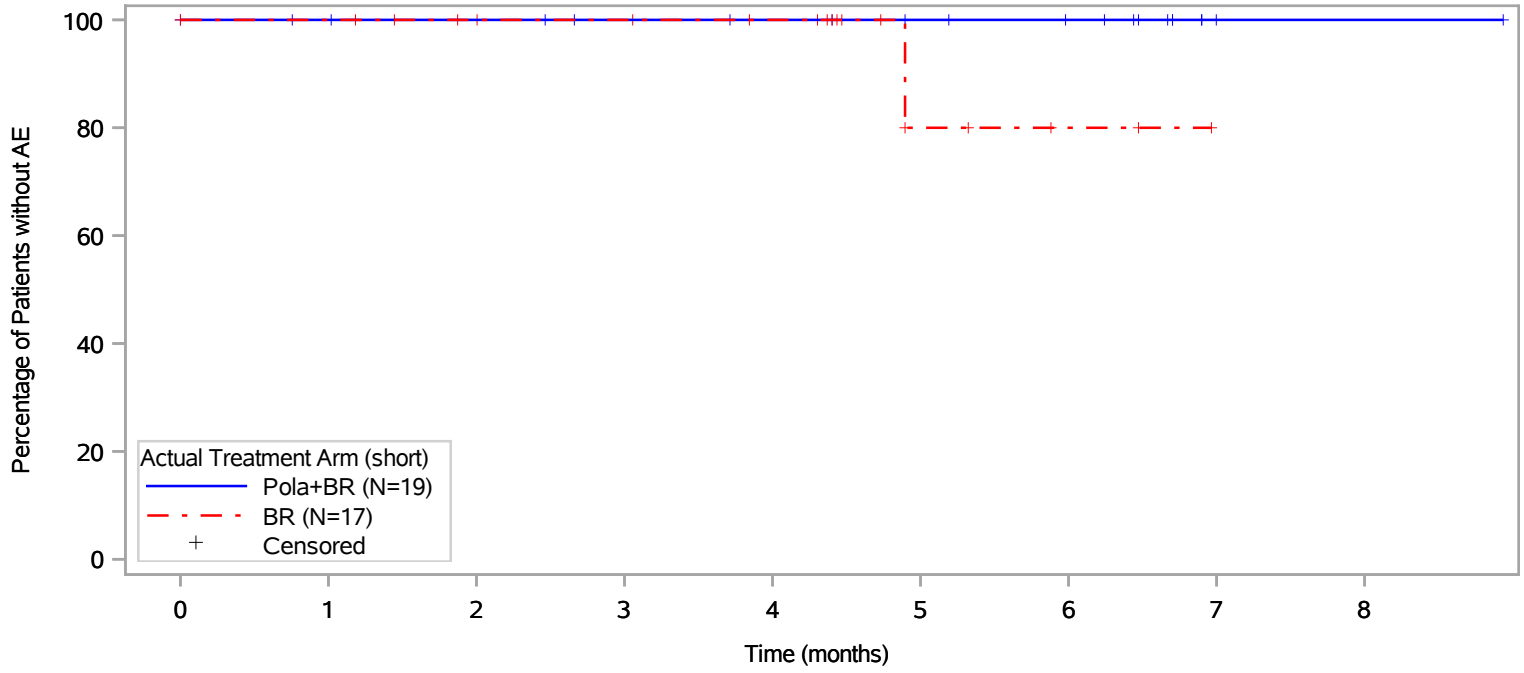
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME

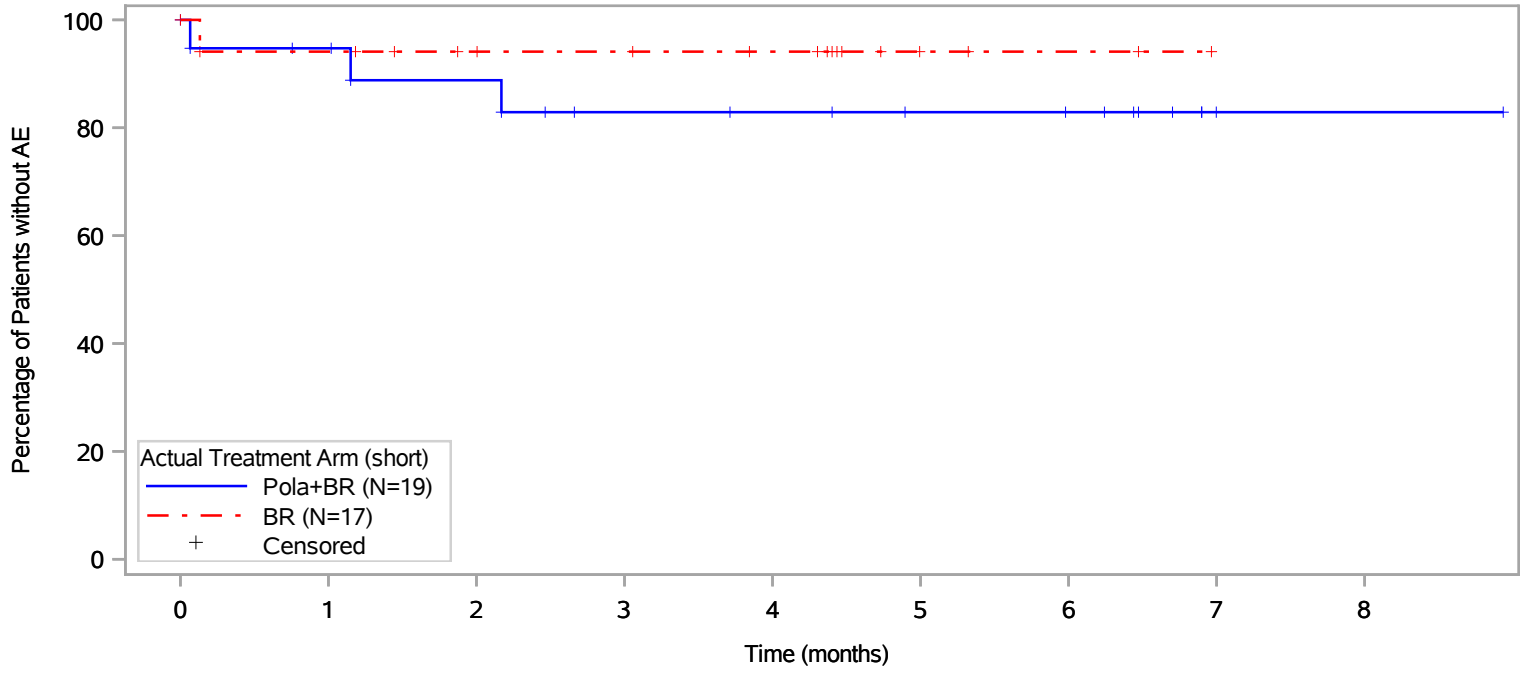


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA

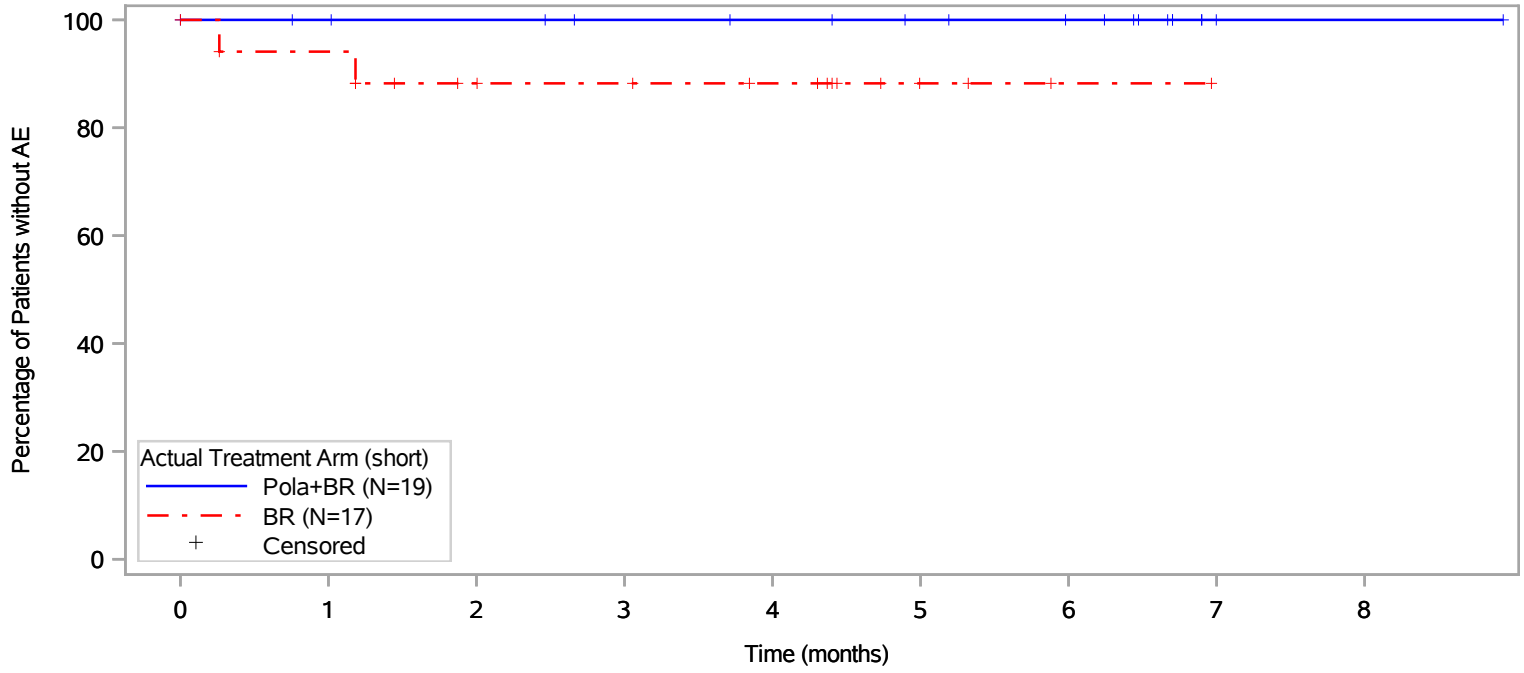


Patients at risk									
Pola+BR (N=19)	19	17	15	12	11	9	8	1	1
BR (N=17)	17	16	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	15	15
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	12	11	9	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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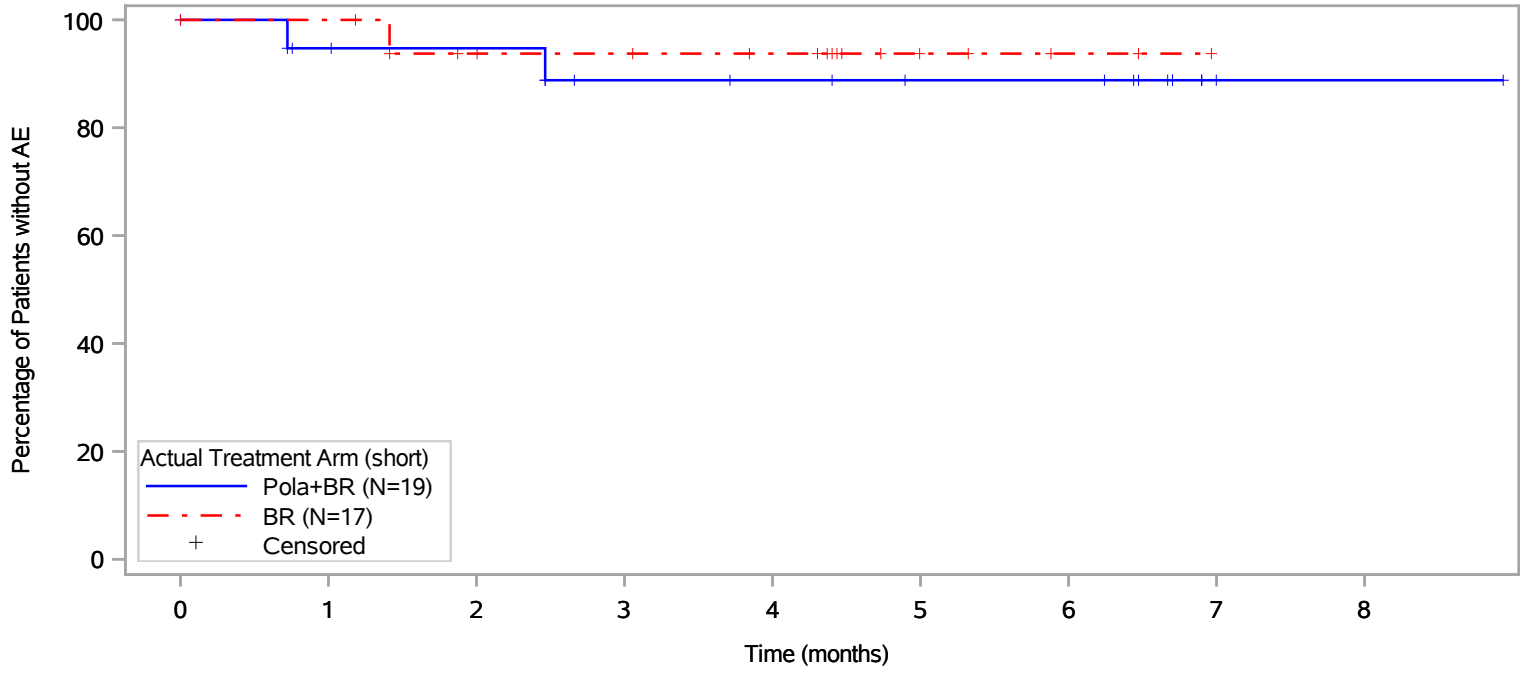
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PAIN

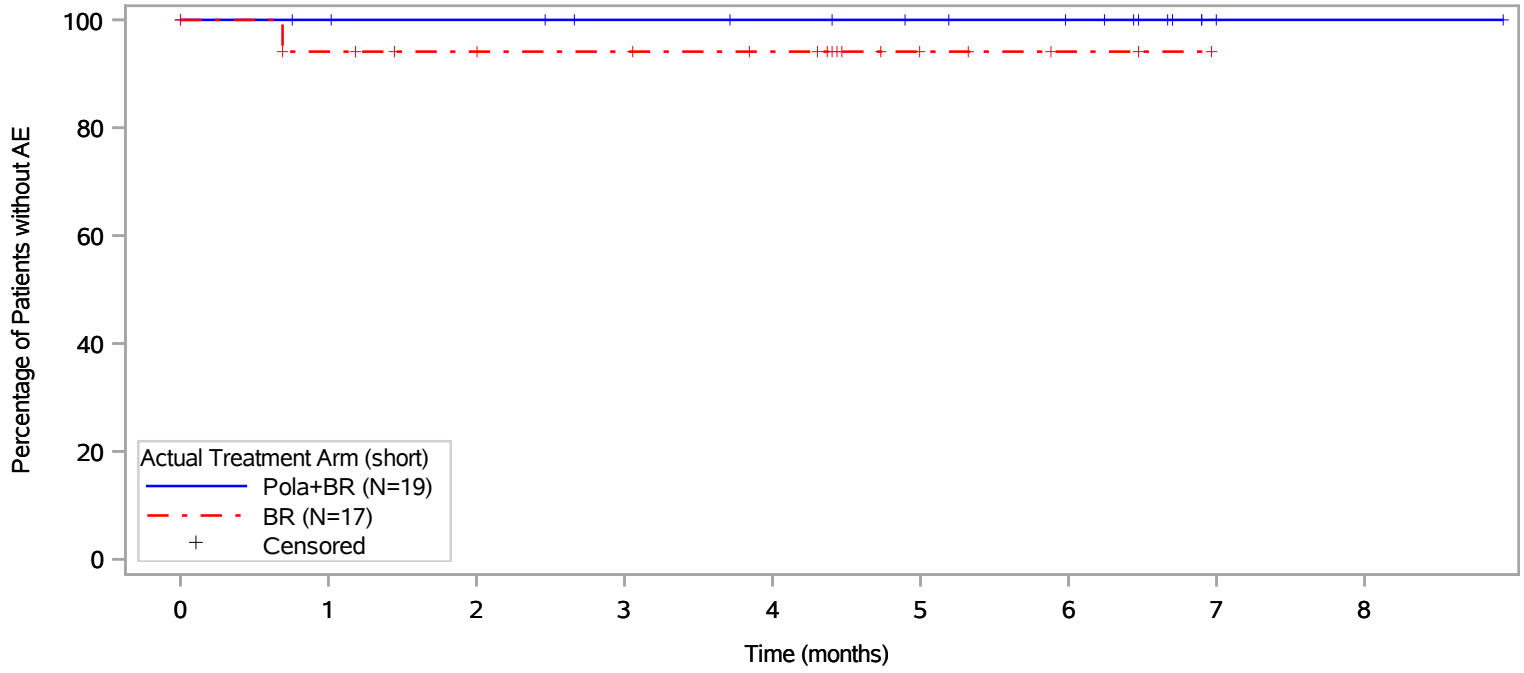


Patients at risk									
Pola+BR (N=19)	19	17	16	13	12	10	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	7	16	16
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PERIPHERAL SWELLING

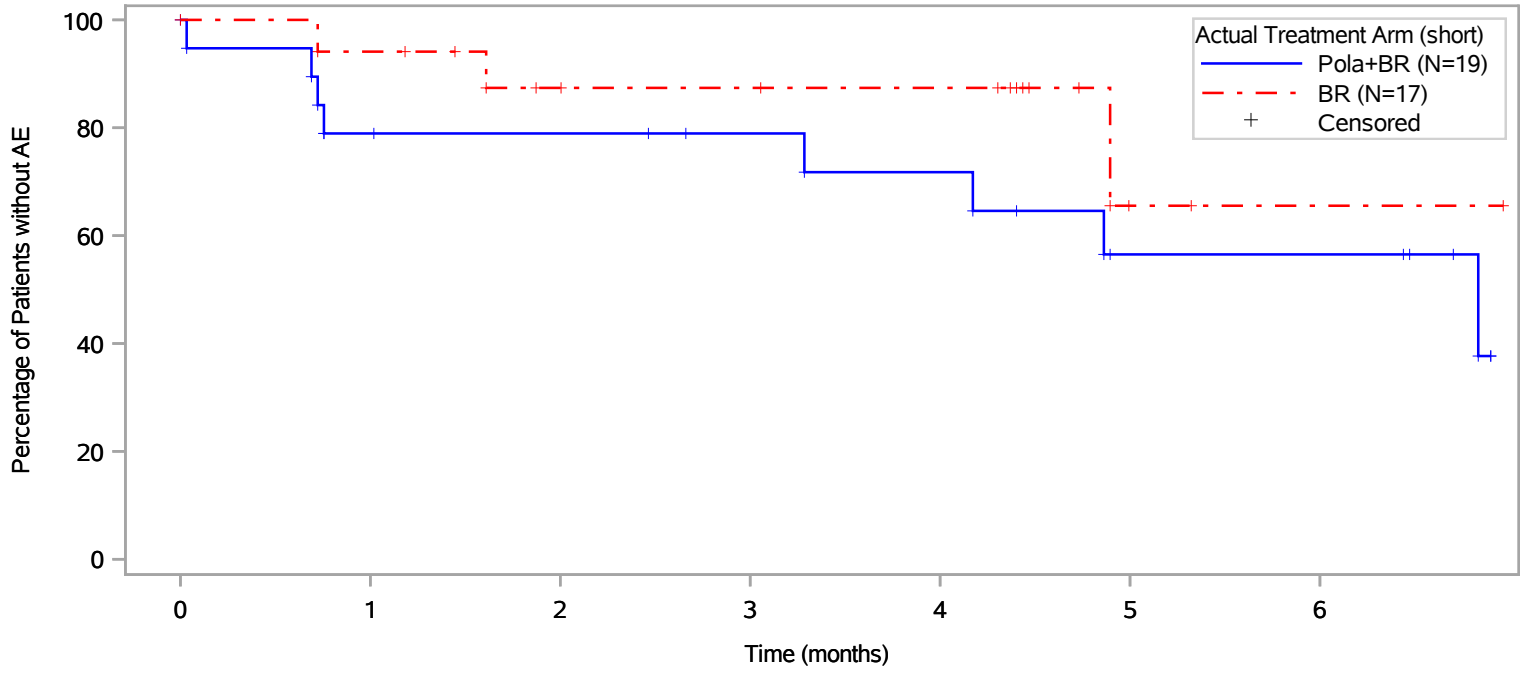


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk							
Pola+BR (N=19)	19	14	13	11	10	6	6
BR (N=17)	17	16	12	11	10	2	1
Patients censored							
Pola+BR (N=19)	0	1	2	4	4	6	6
BR (N=17)	0	0	3	4	5	12	13

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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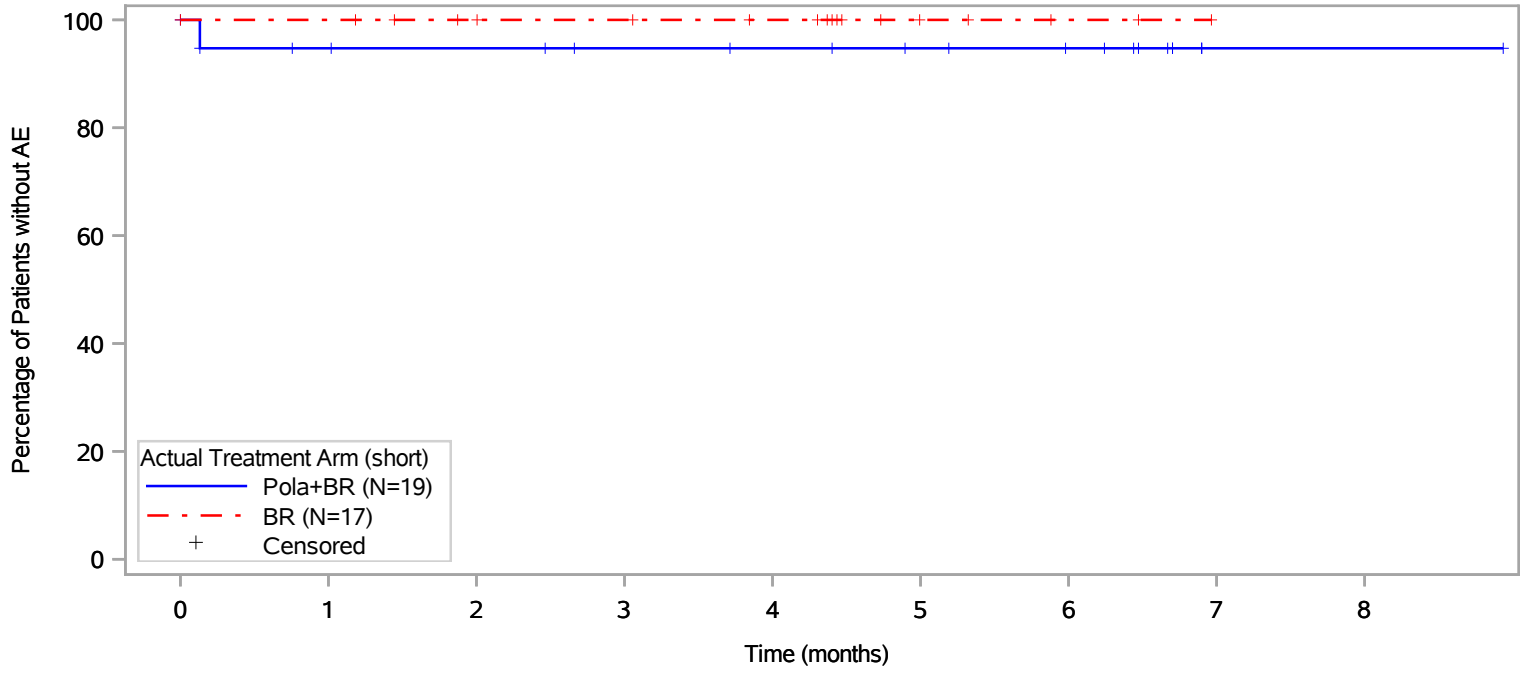
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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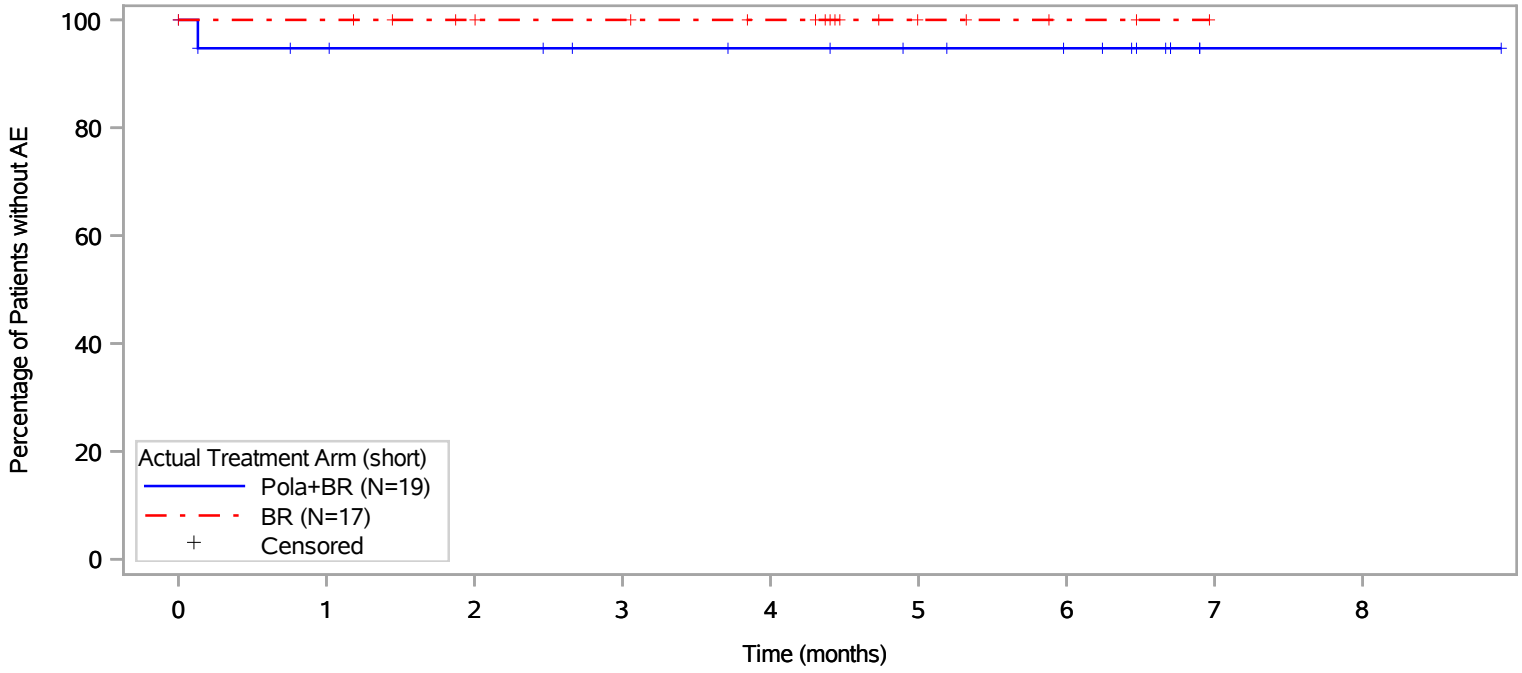
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, ANAPHYLACTIC REACTION



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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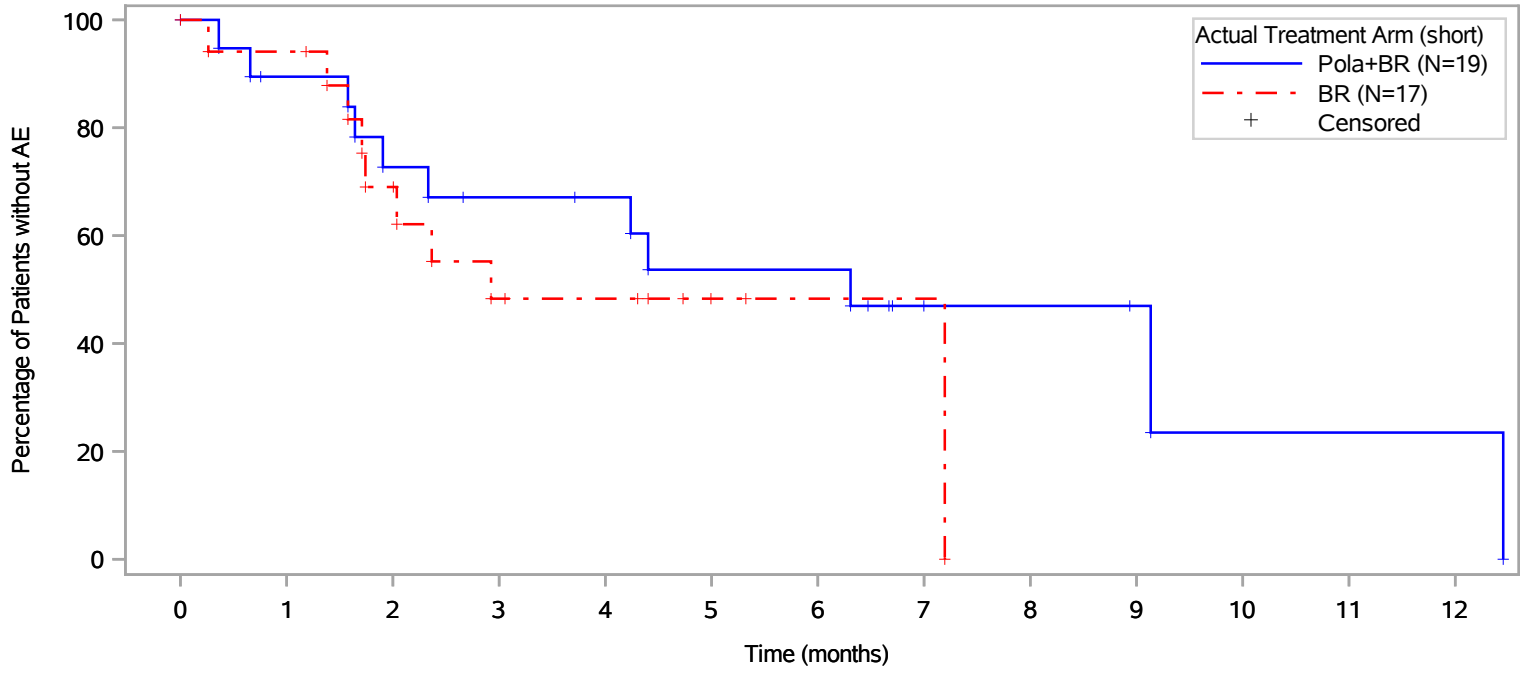
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk													
Pola+BR (N=19)	19	16	13	11	10	8	8	3	3	2	1	1	1
BR (N=17)	17	16	11	7	6	2	1	1	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	1	2	3	3	3	7	7	8	8	8	8
BR (N=17)	0	0	1	2	3	7	8	8	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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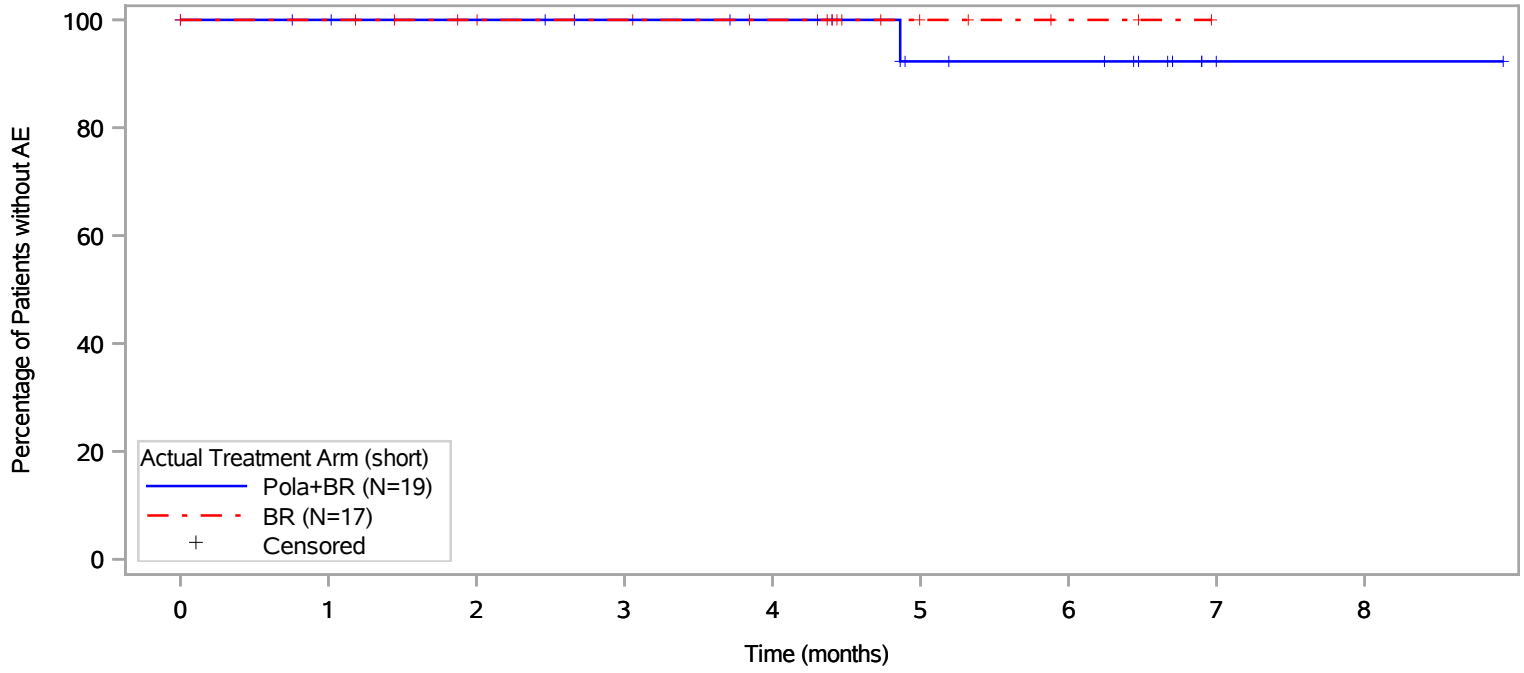
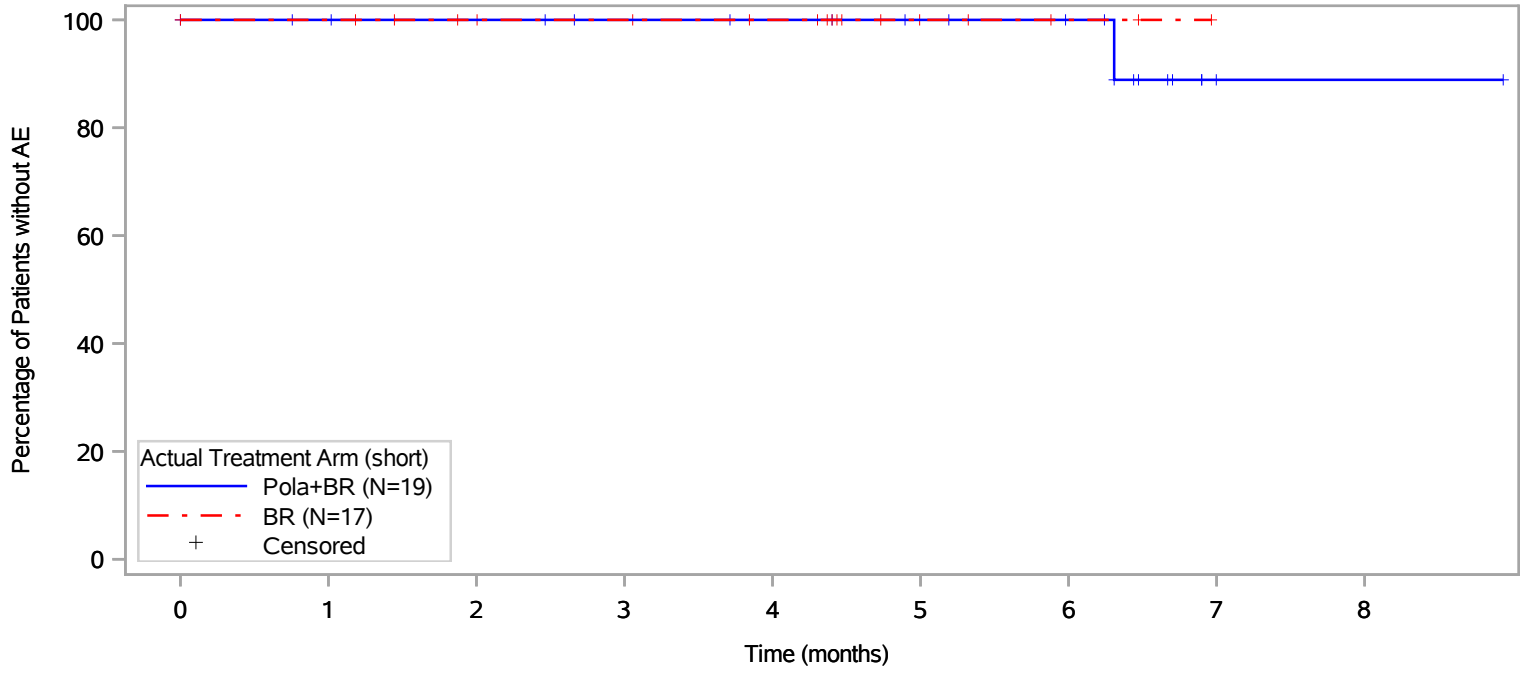
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CEREBRAL TOXOPLASMOSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

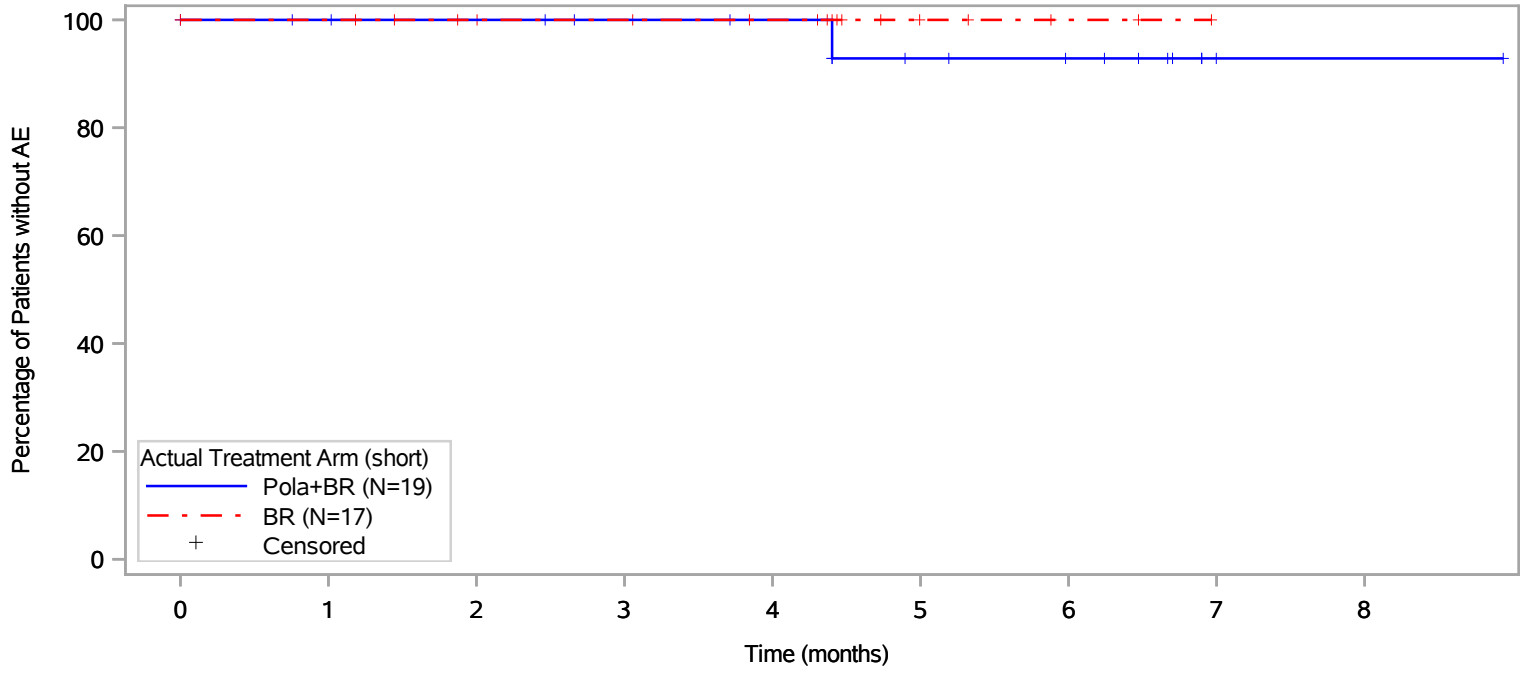
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CYSTITIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HEPATITIS B



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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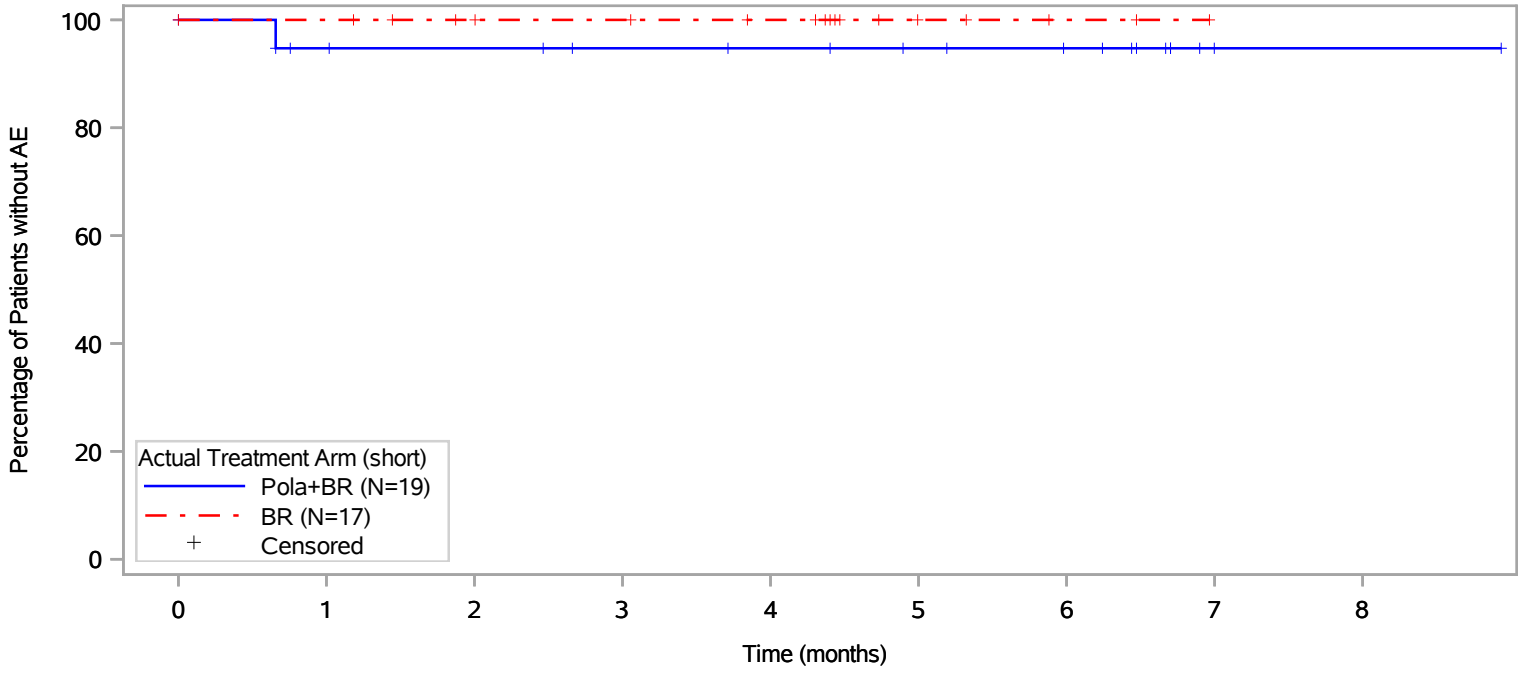
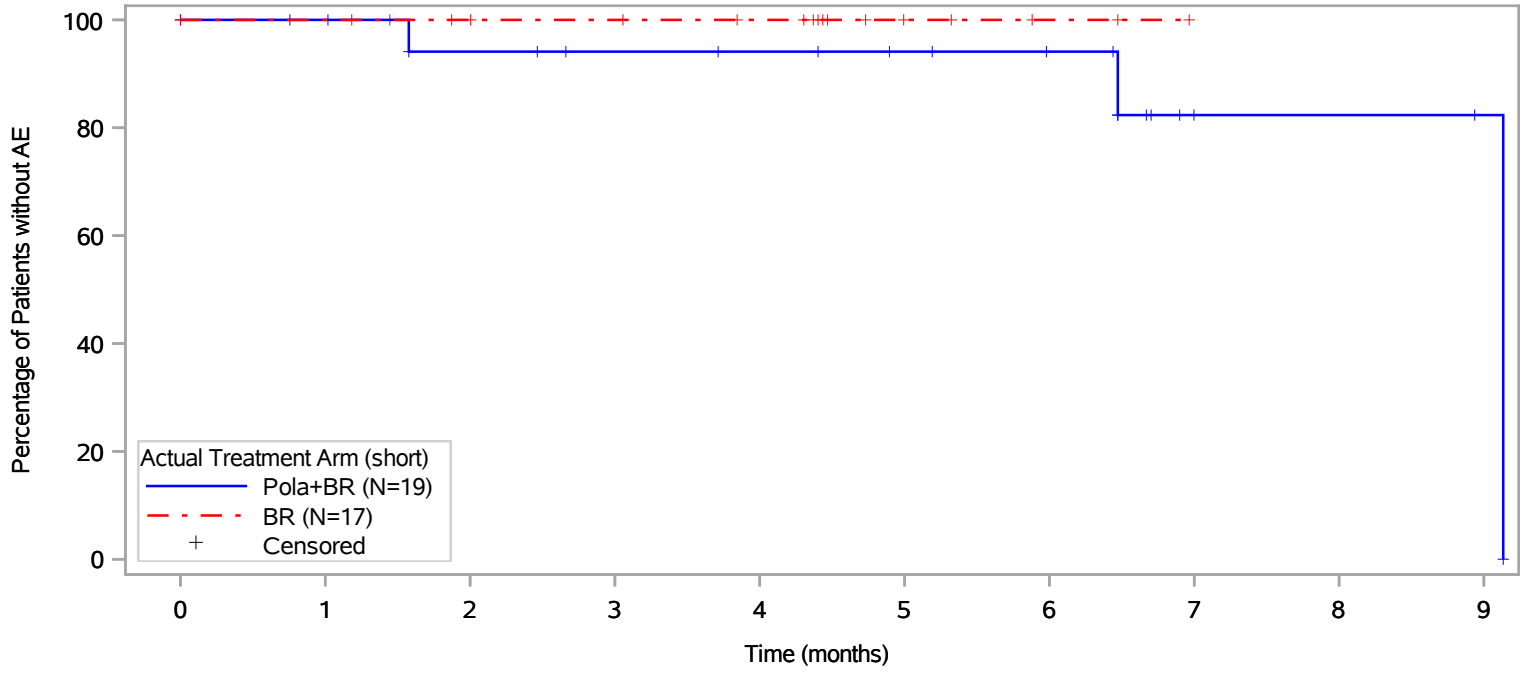
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HEPATITIS B REACTIVATION



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES VIRUS INFECTION

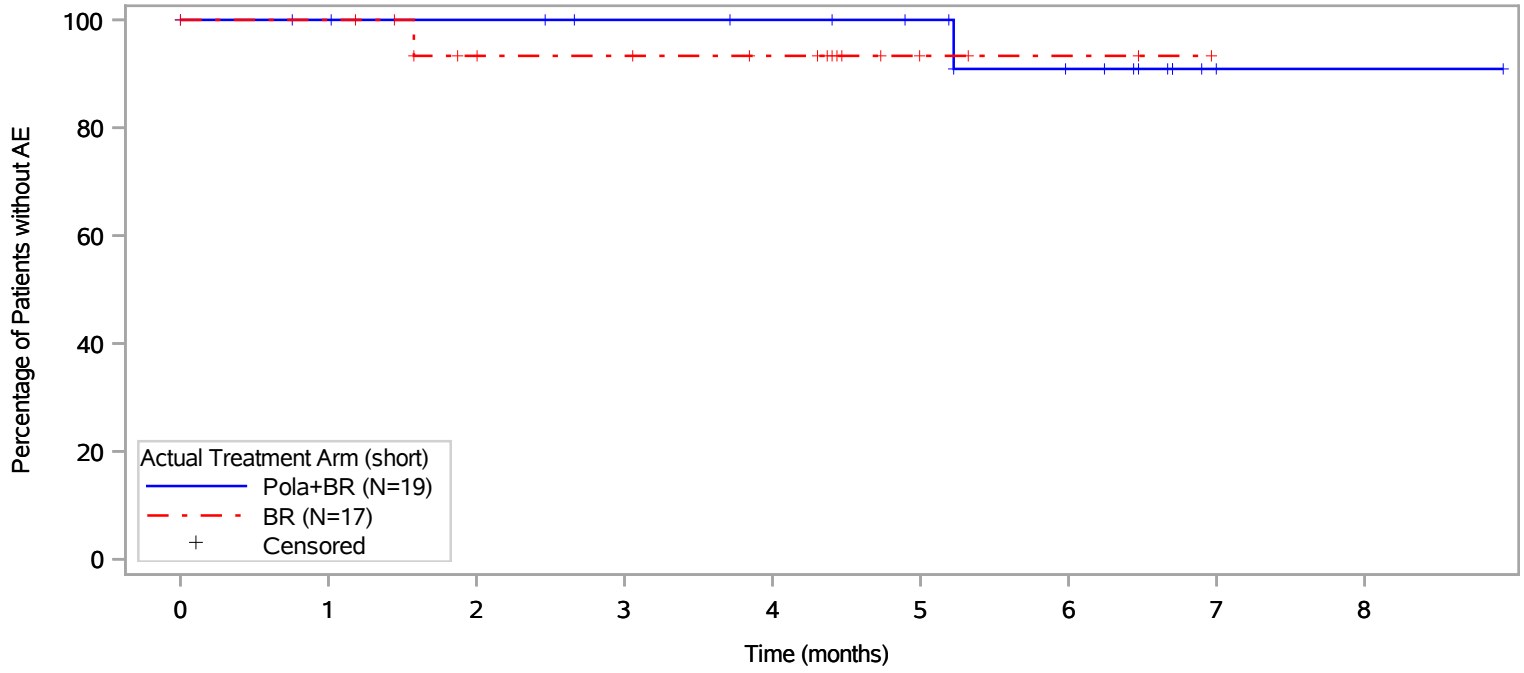


Patients at risk										
Pola+BR (N=19)	19	18	16	14	13	11	9	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	9	15	15	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	9	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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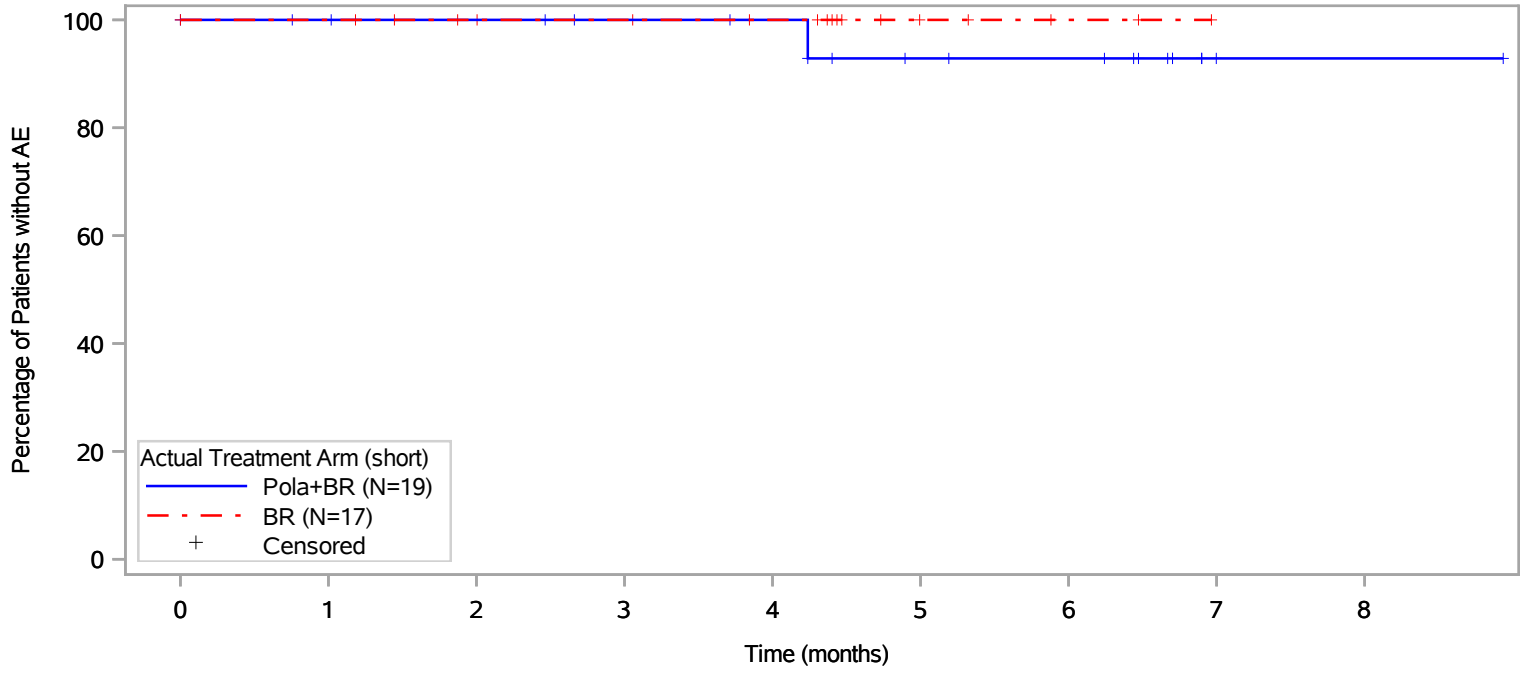
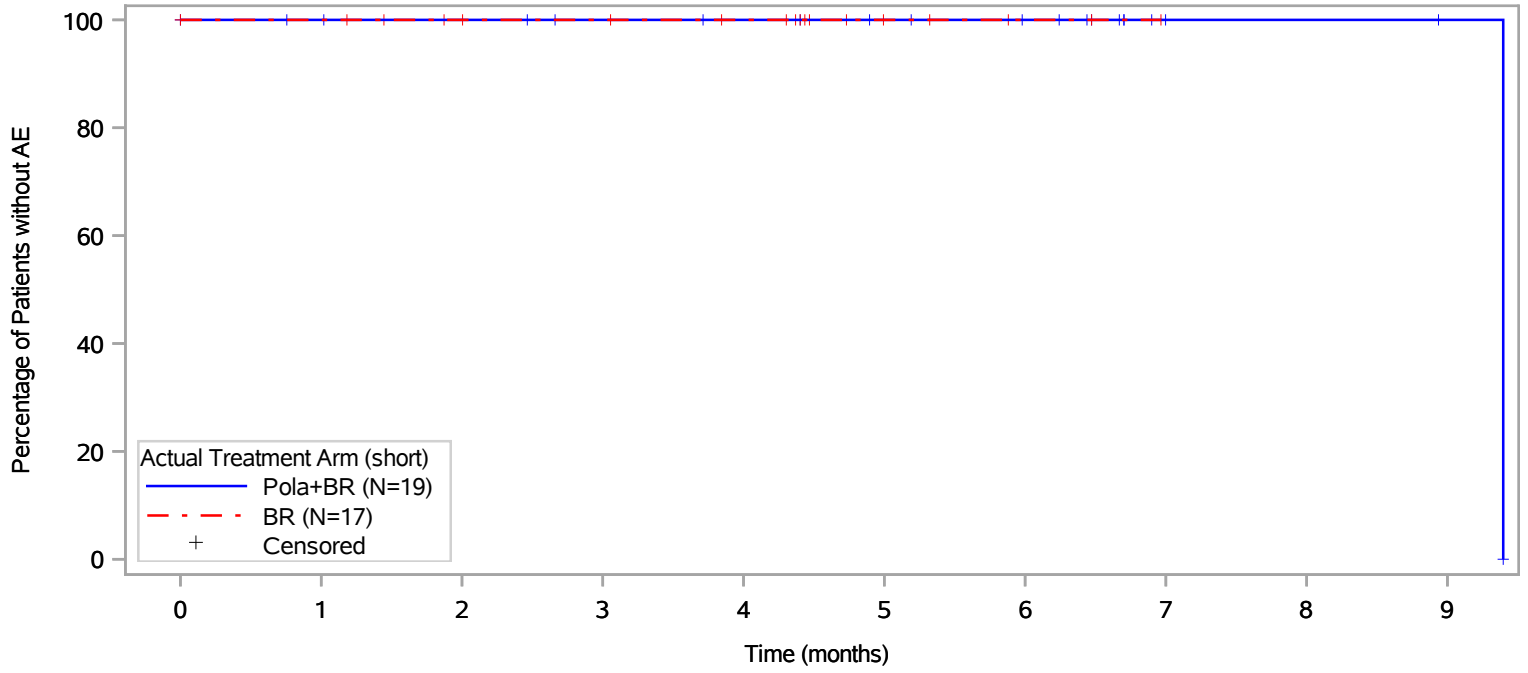
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, LARYNGITIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

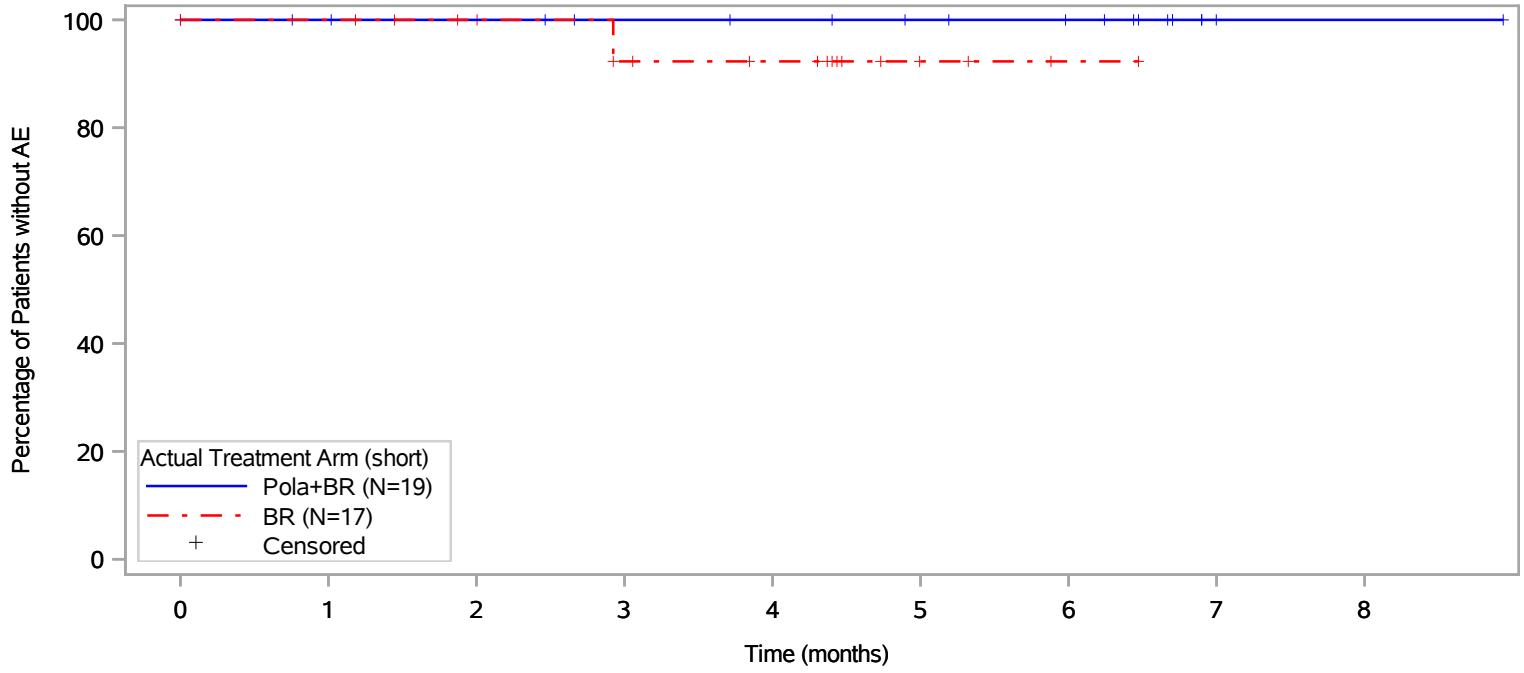
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MENINGOENCEPHALITIS HERPETIC



Patients at risk										
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NASOPHARYNGITIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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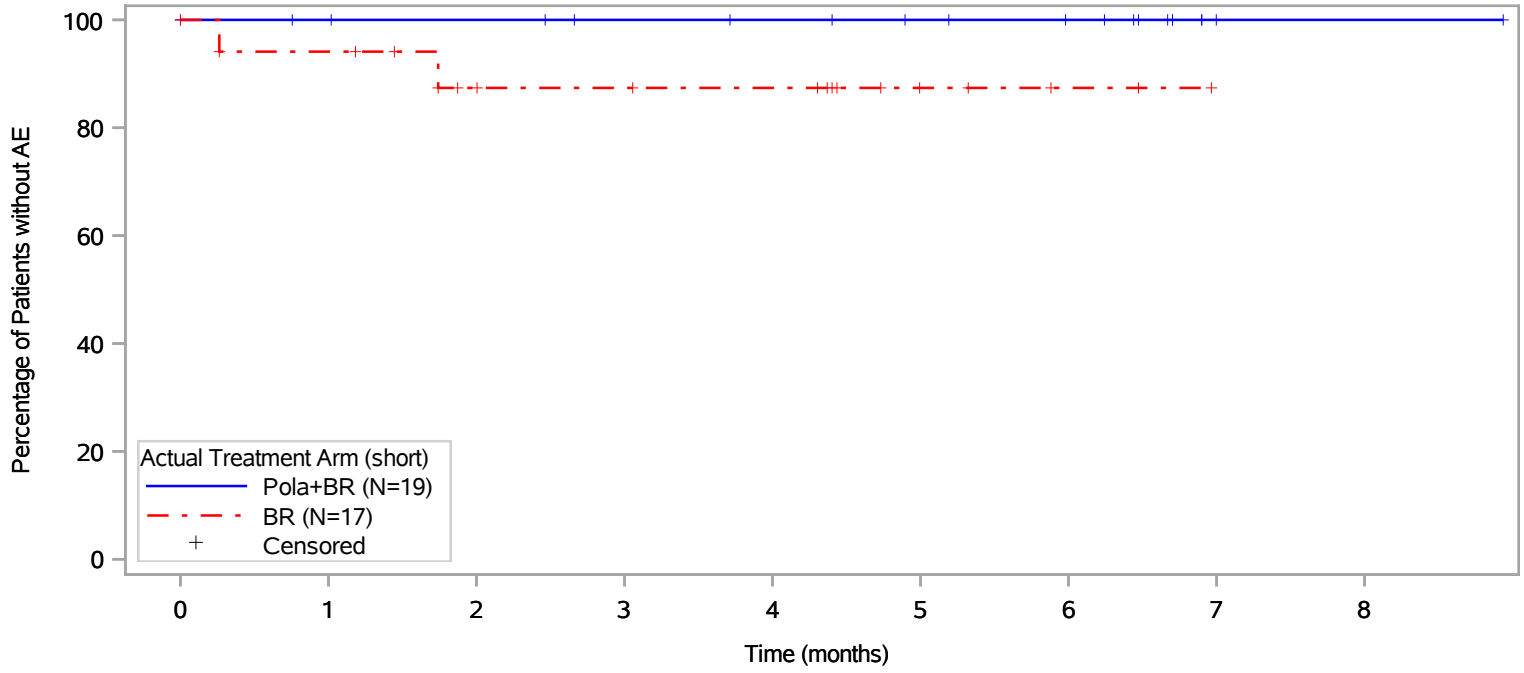
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ORAL HERPES



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	12	11	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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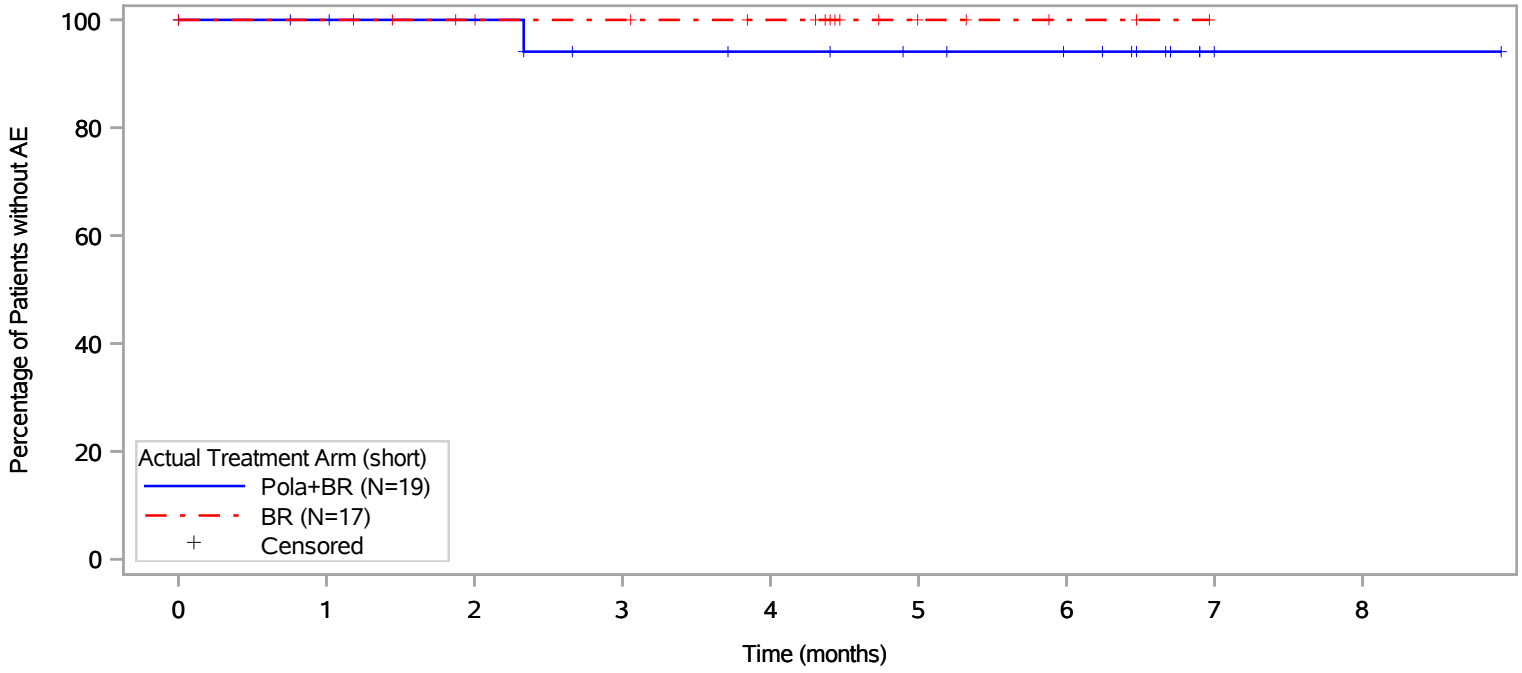
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, OROPHARYNGEAL CANDIDIASIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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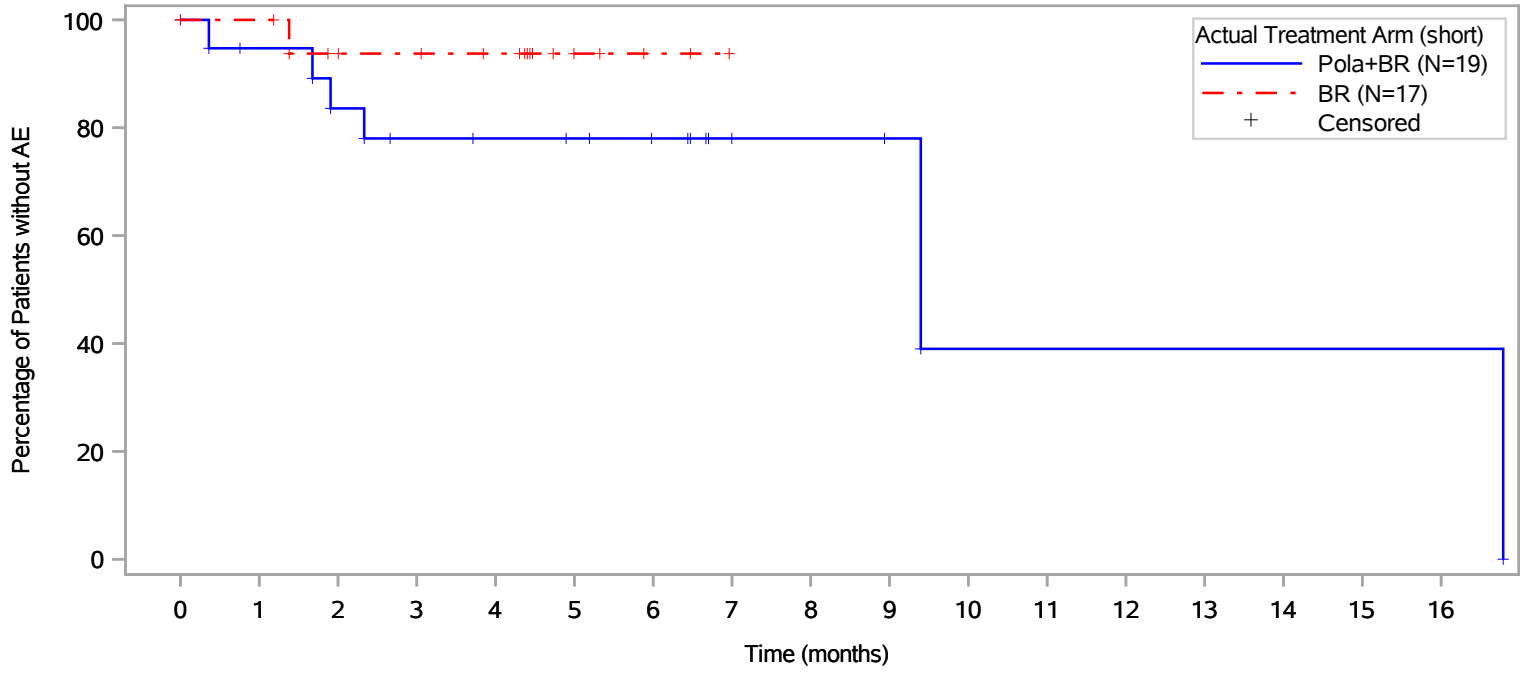
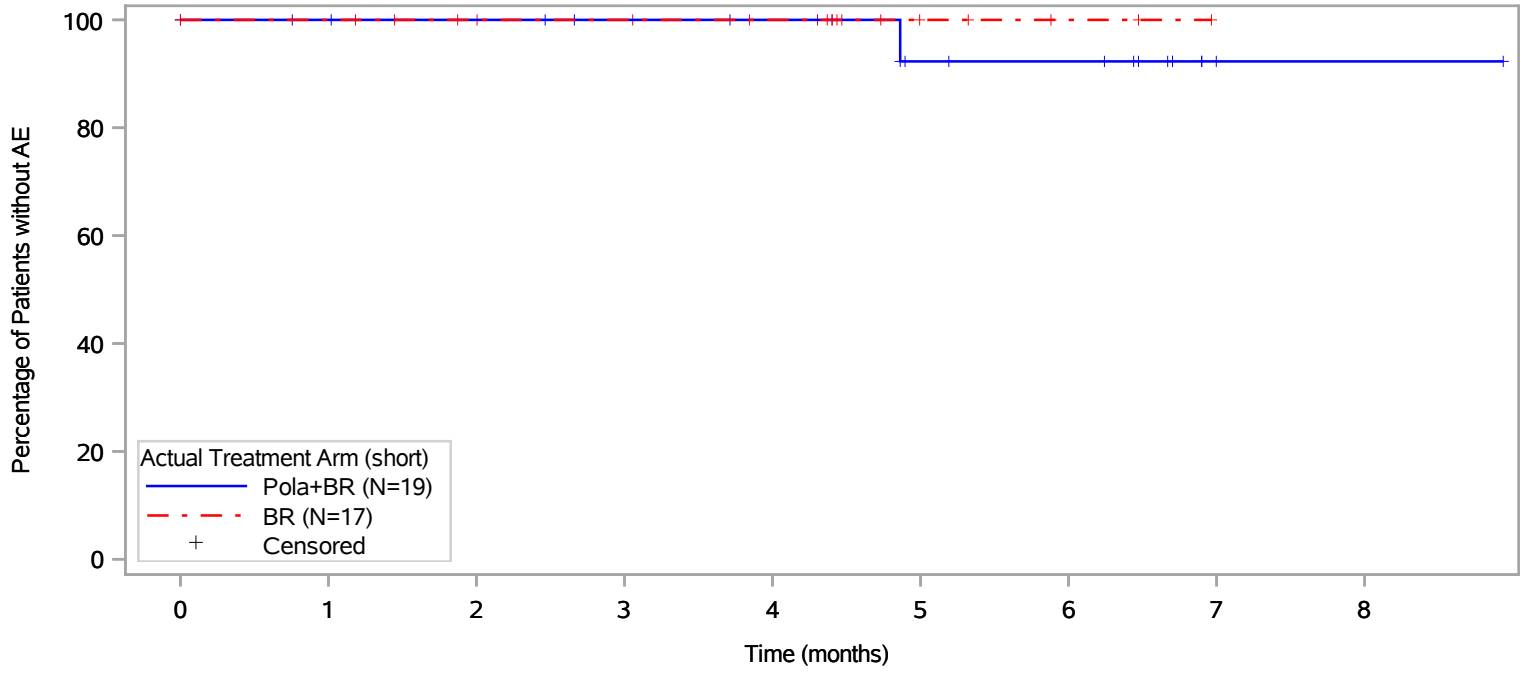
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk																	
Pola+BR (N=19)	19	17	15	13	12	11	9	3	3	2	1	1	1	1	1	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																	
Pola+BR (N=19)	0	1	1	2	3	4	6	12	12	13	13	13	13	13	13	13	13
BR (N=17)	0	0	2	3	5	12	14	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

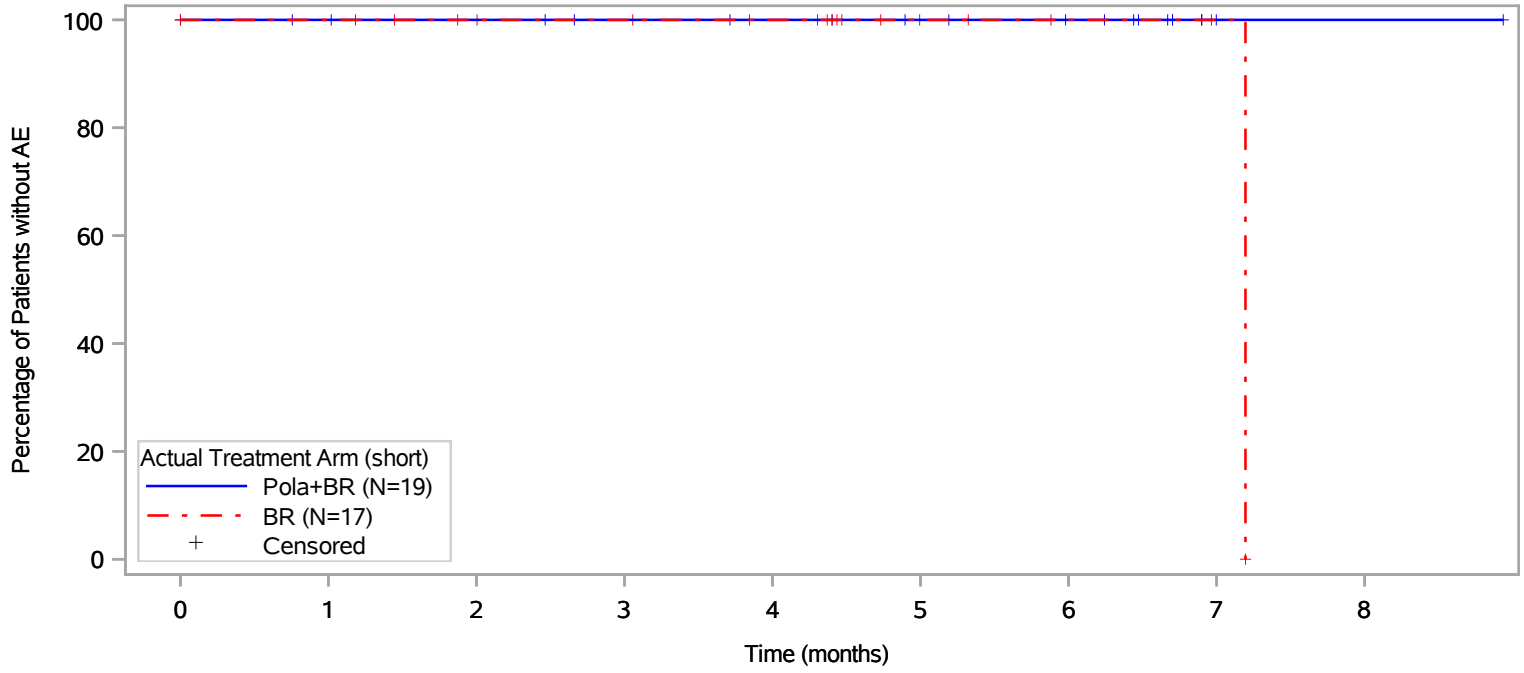
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA CYTOMEGALOVIRAL



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

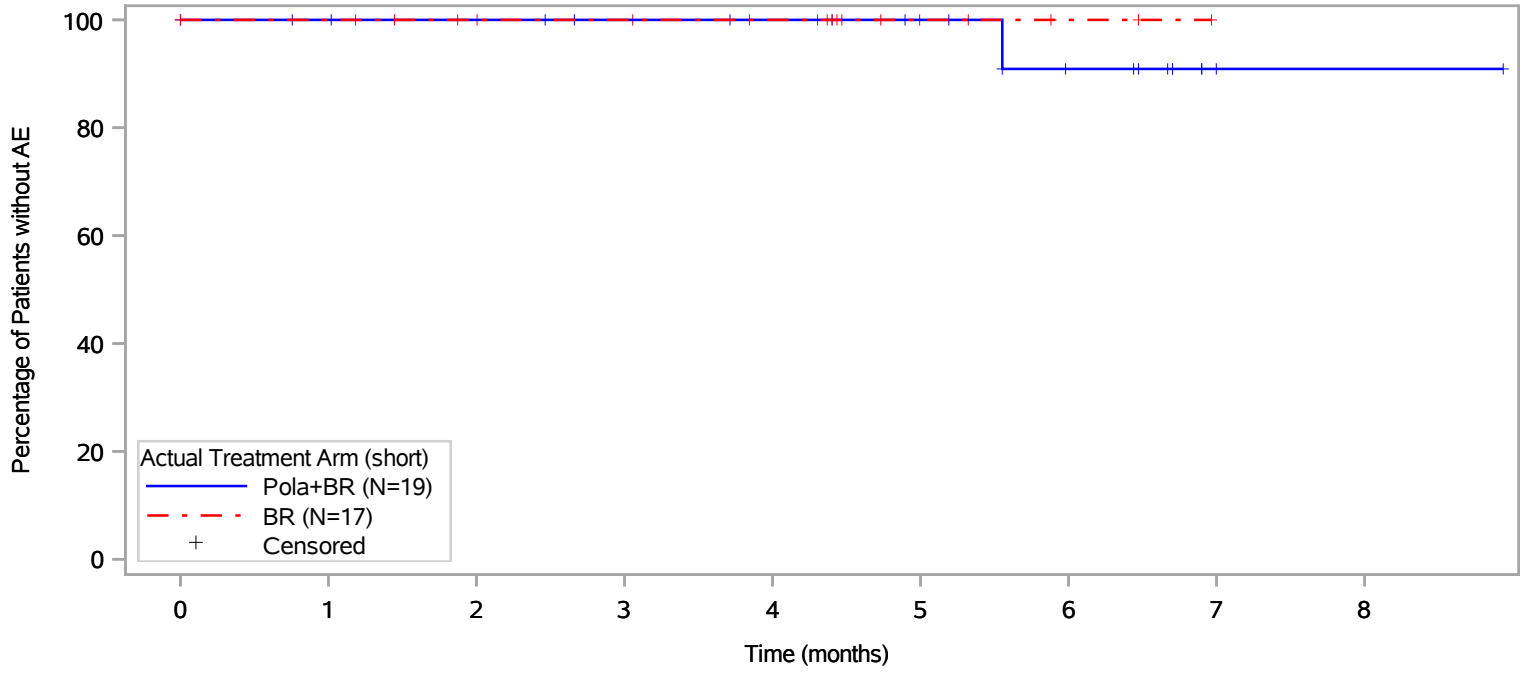
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, POST PROCEDURAL INFECTION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, RHINITIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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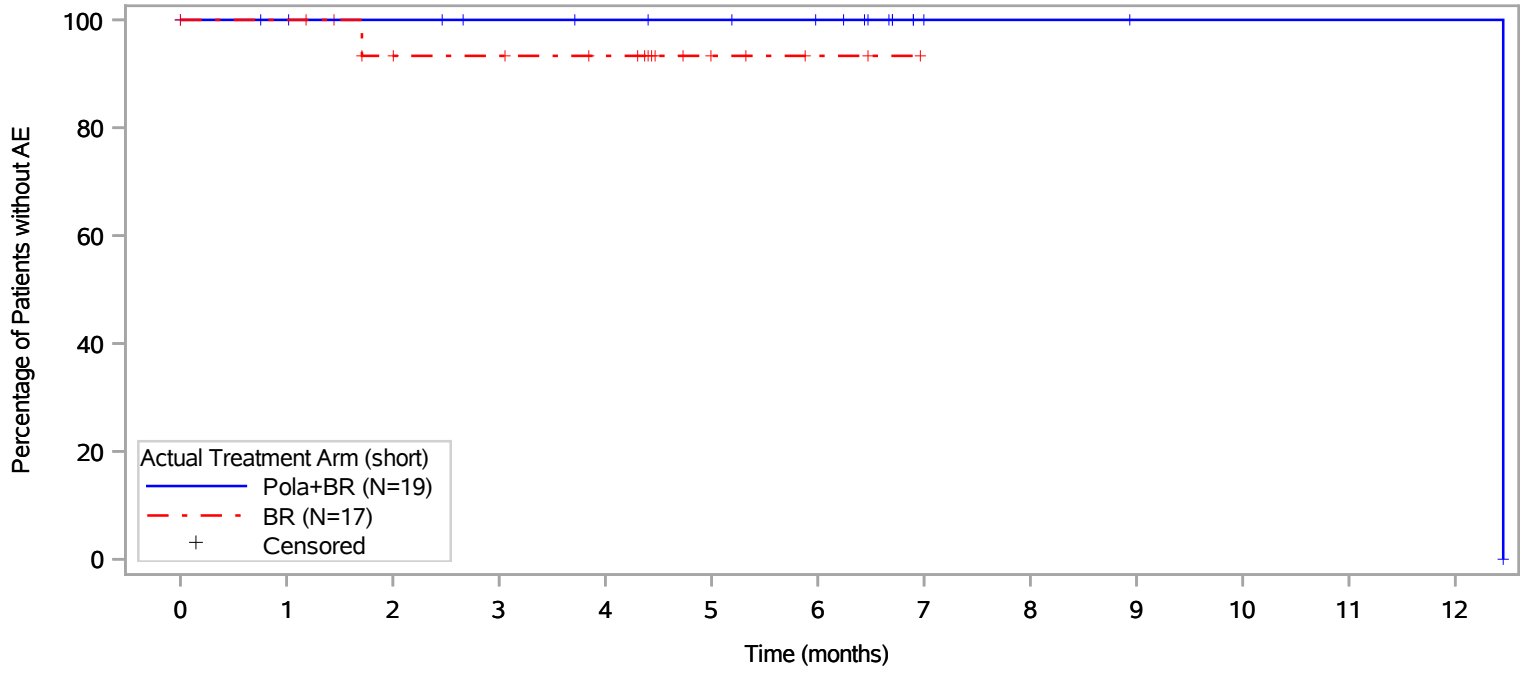
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk													
Pola+BR (N=19)	19	18	17	15	14	13	11	2	2	1	1	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	2	4	5	6	8	17	17	18	18	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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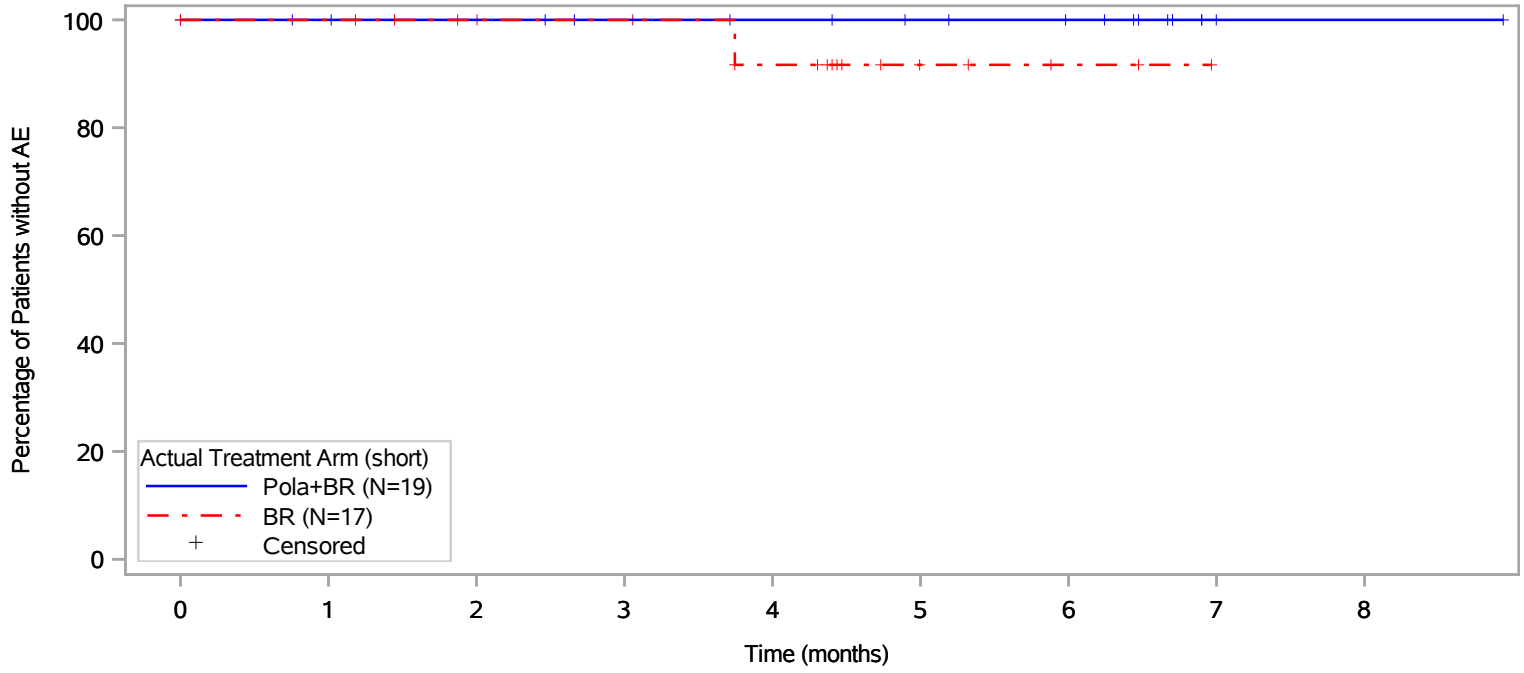
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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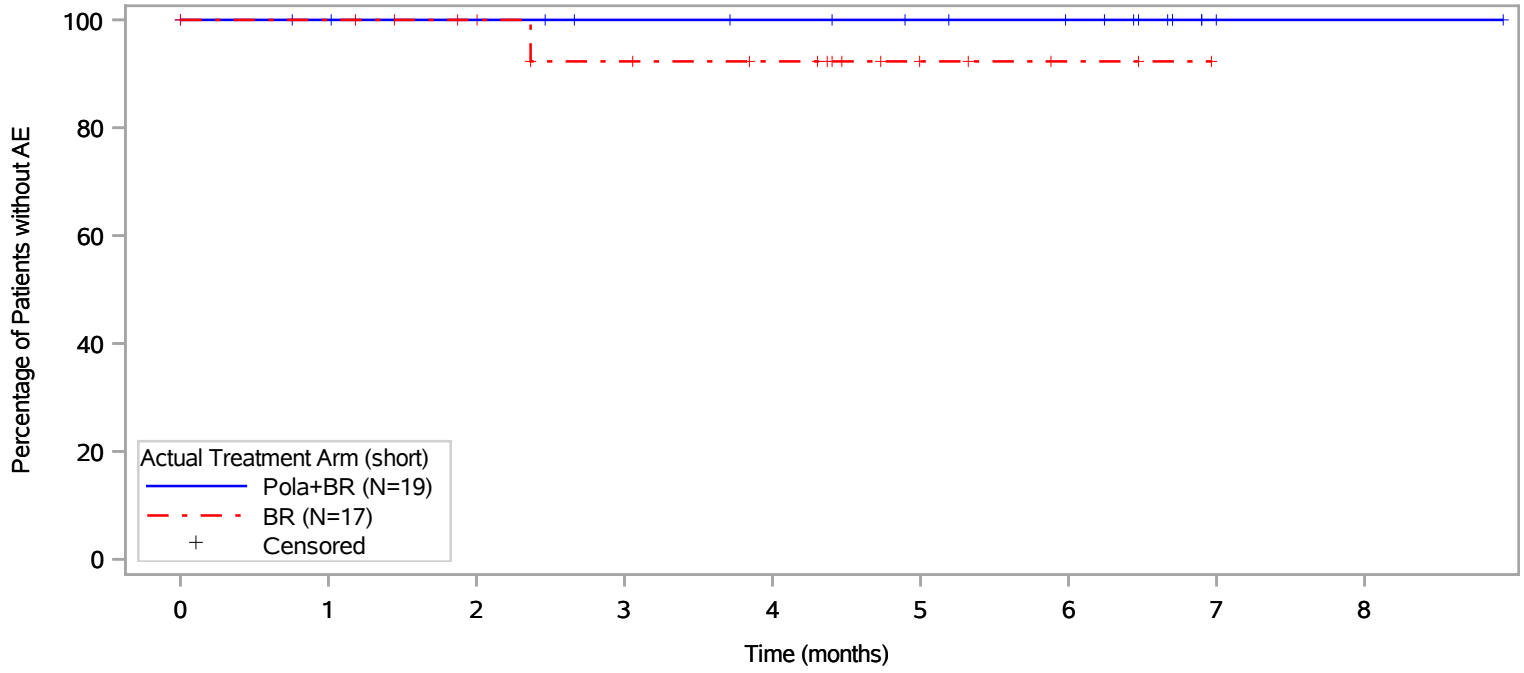
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SINUSITIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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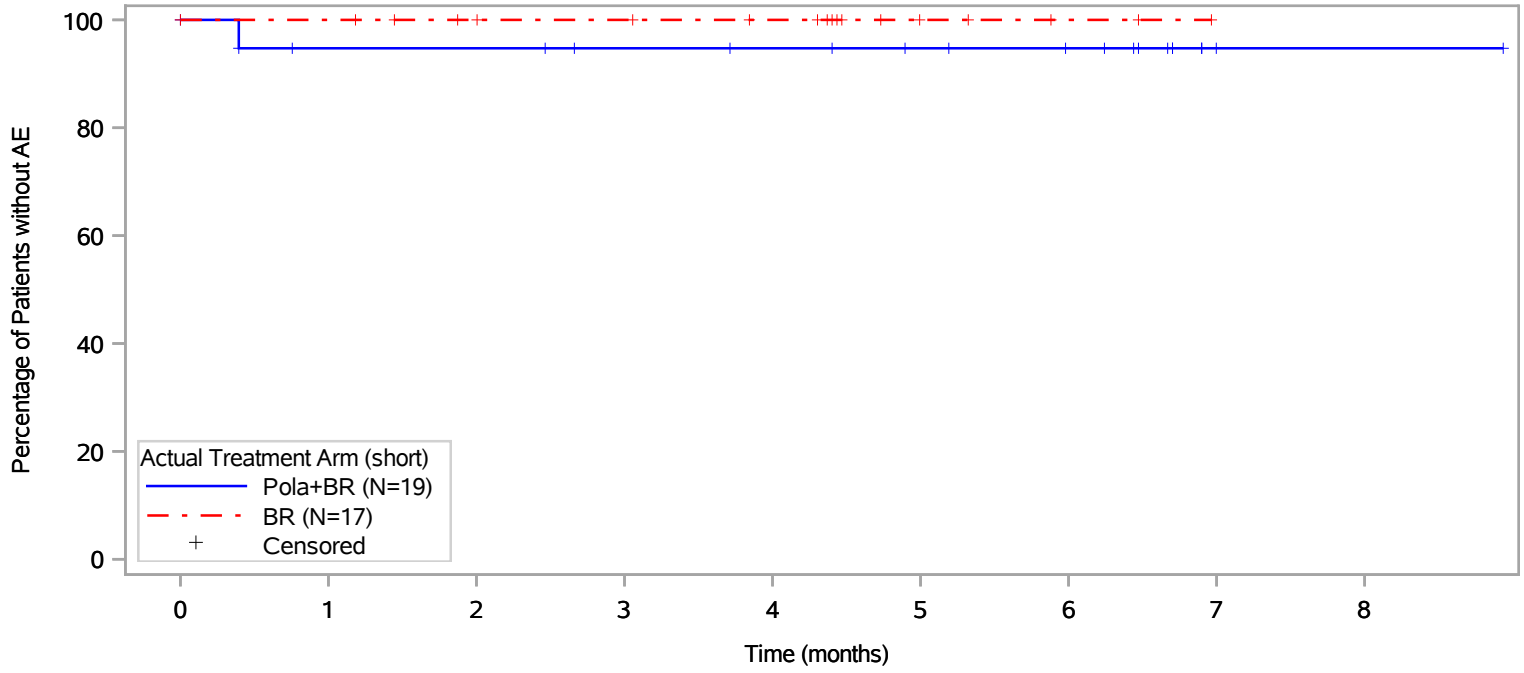
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, STAPHYLOCOCCAL INFECTION



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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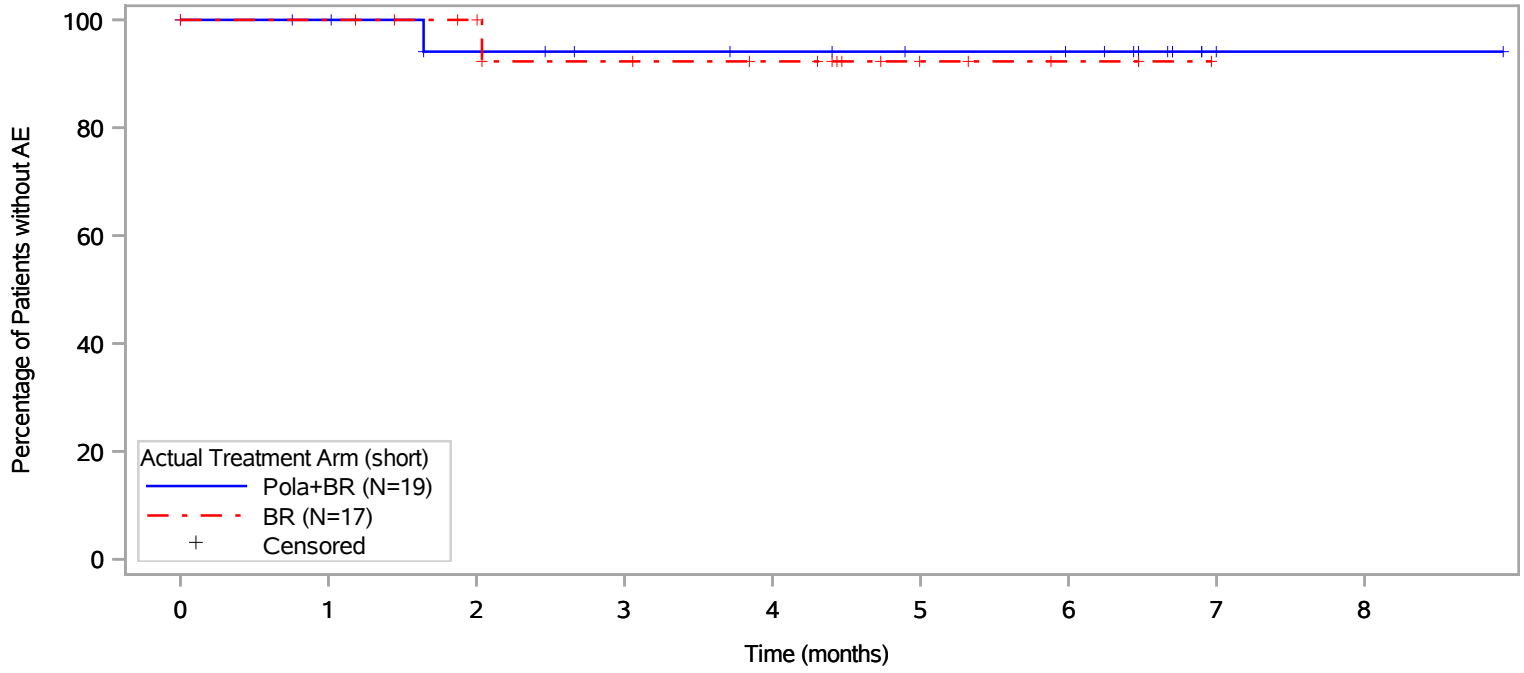
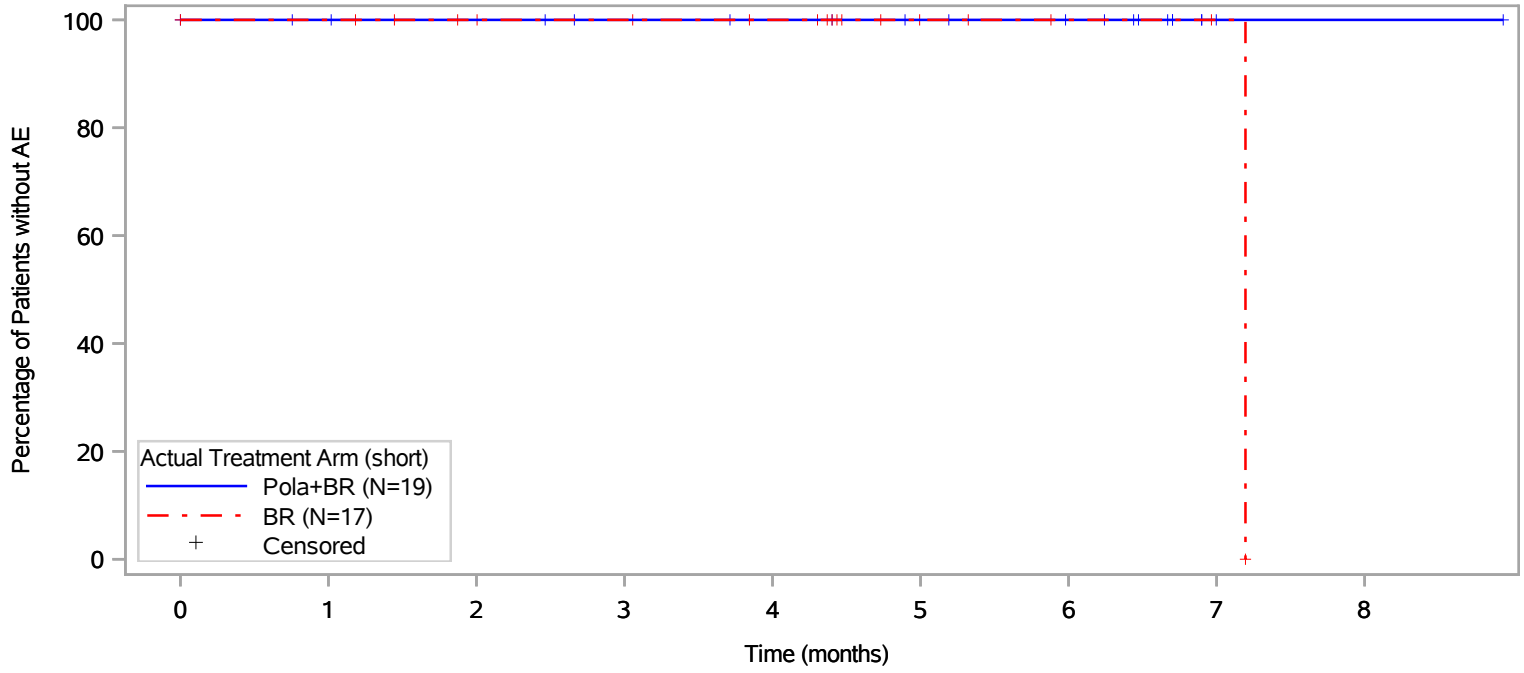
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UPPER RESPIRATORY TRACT INFECTION



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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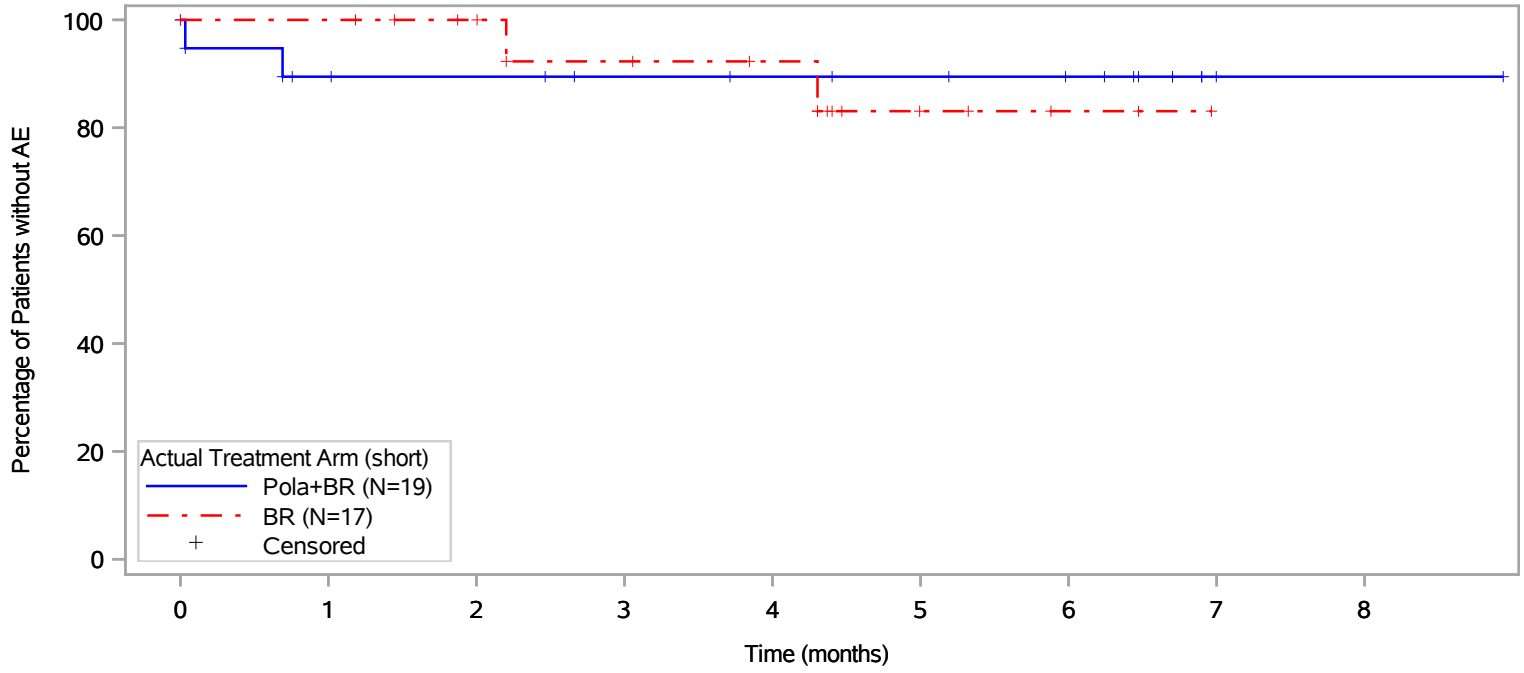
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=19)	19	16	15	13	12	11	9	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	8	16	16
BR (N=17)	0	0	3	4	6	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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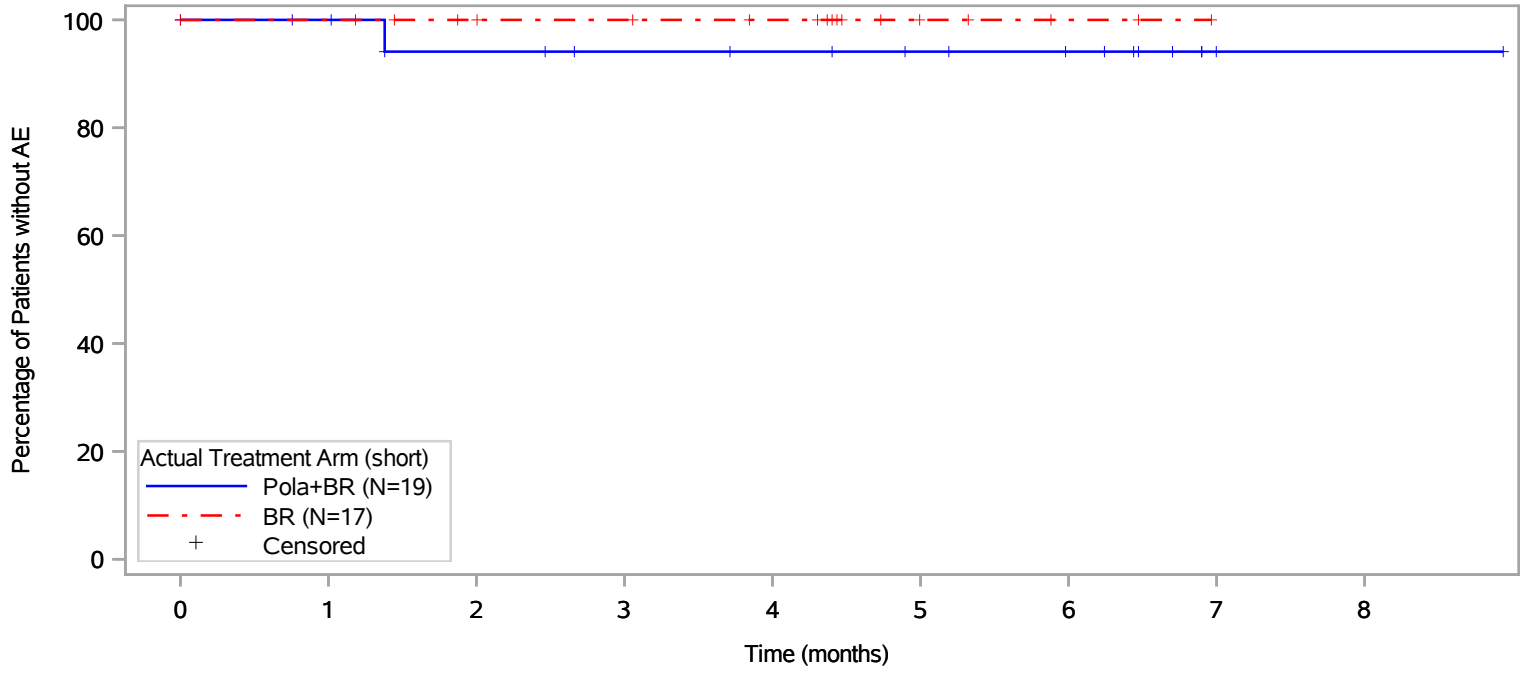
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, CONTUSION



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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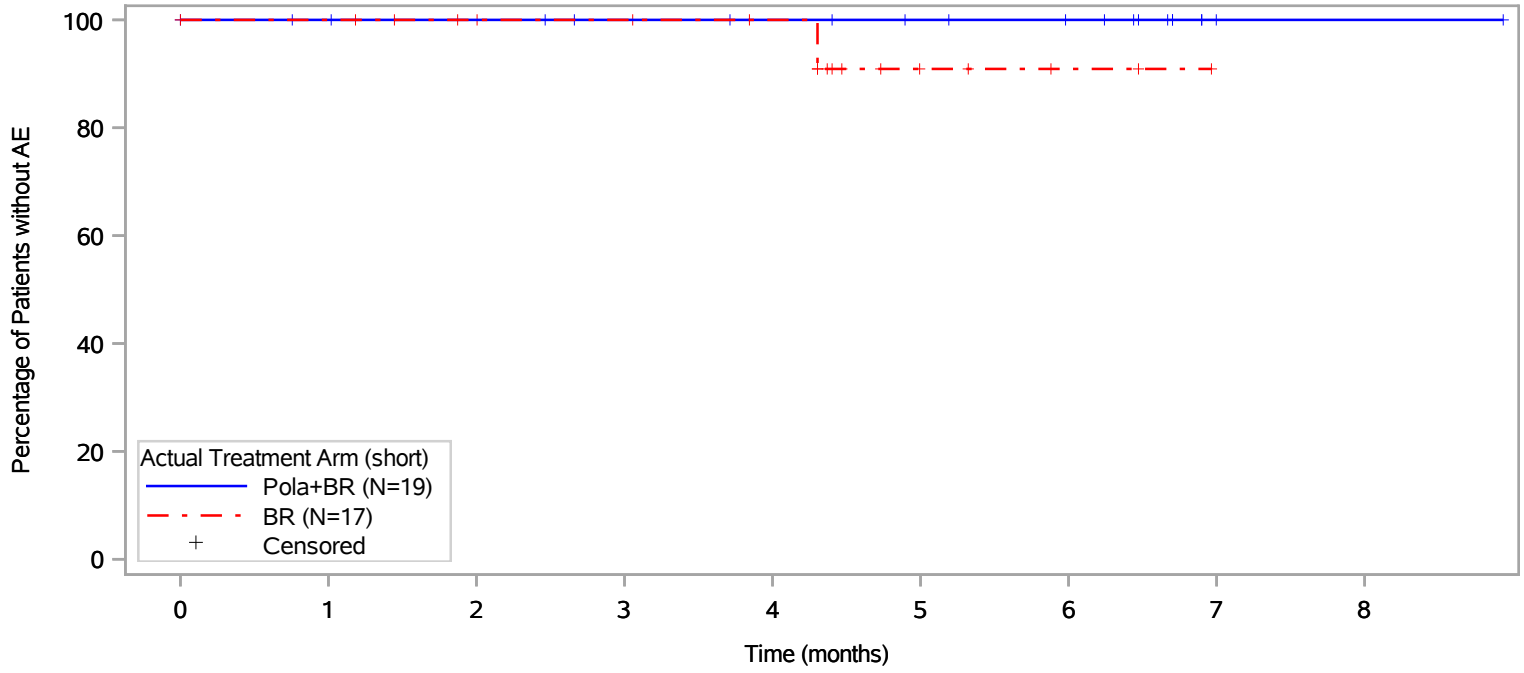
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, EYE CONTUSION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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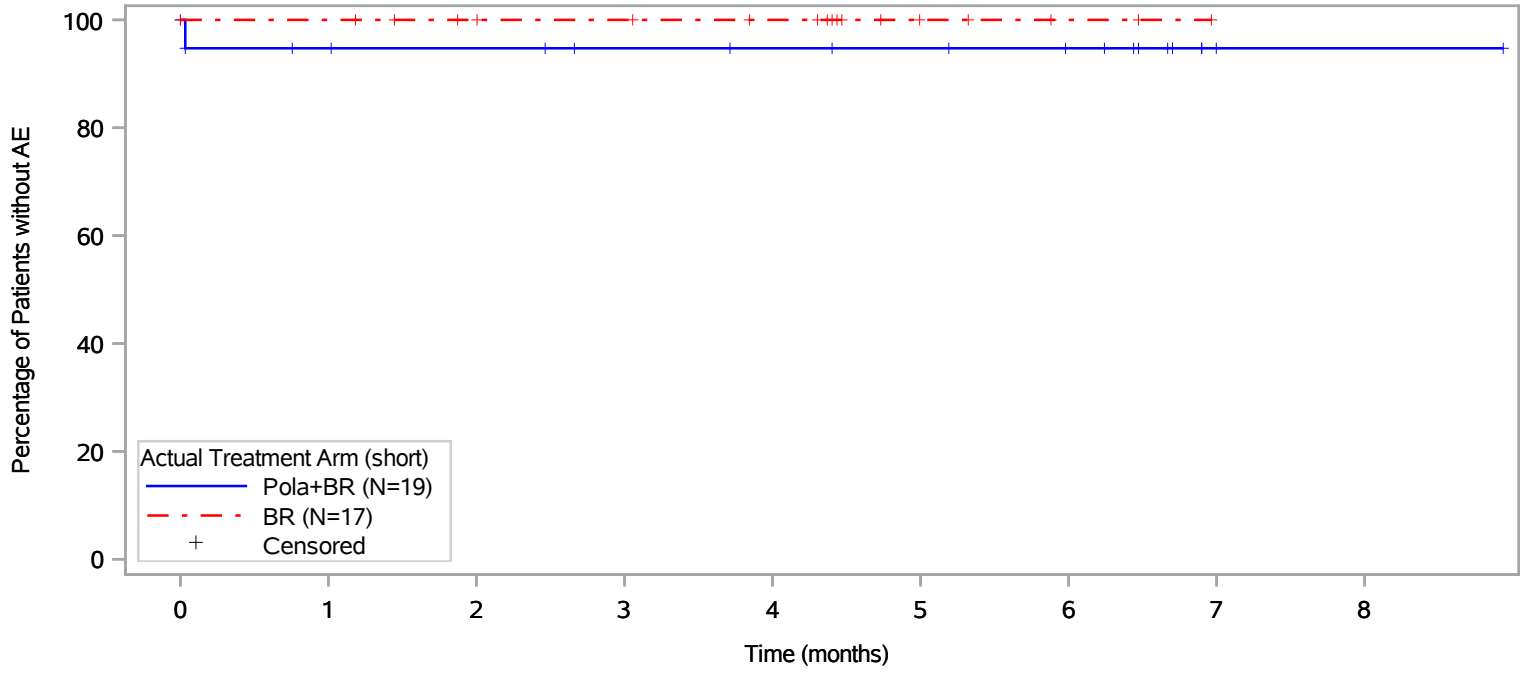
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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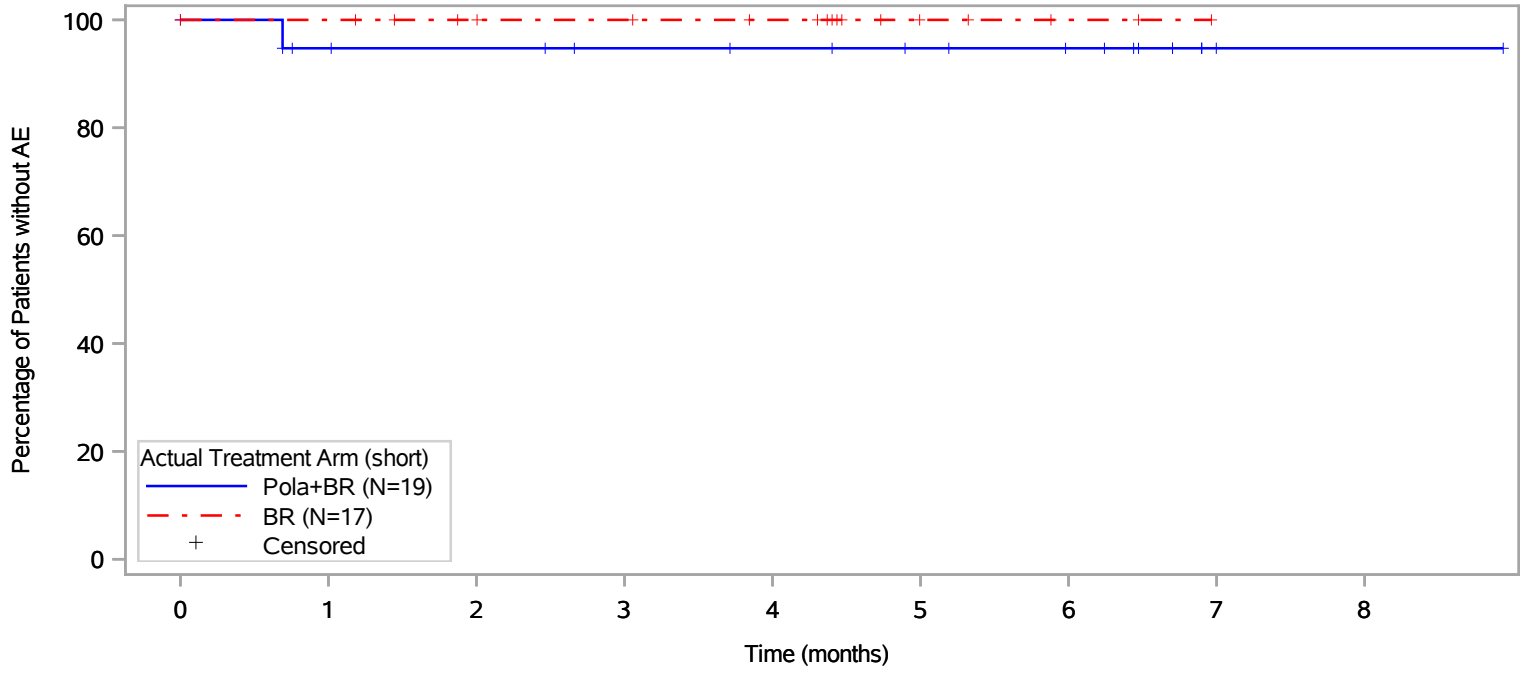
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, INFUSION RELATED REACTION



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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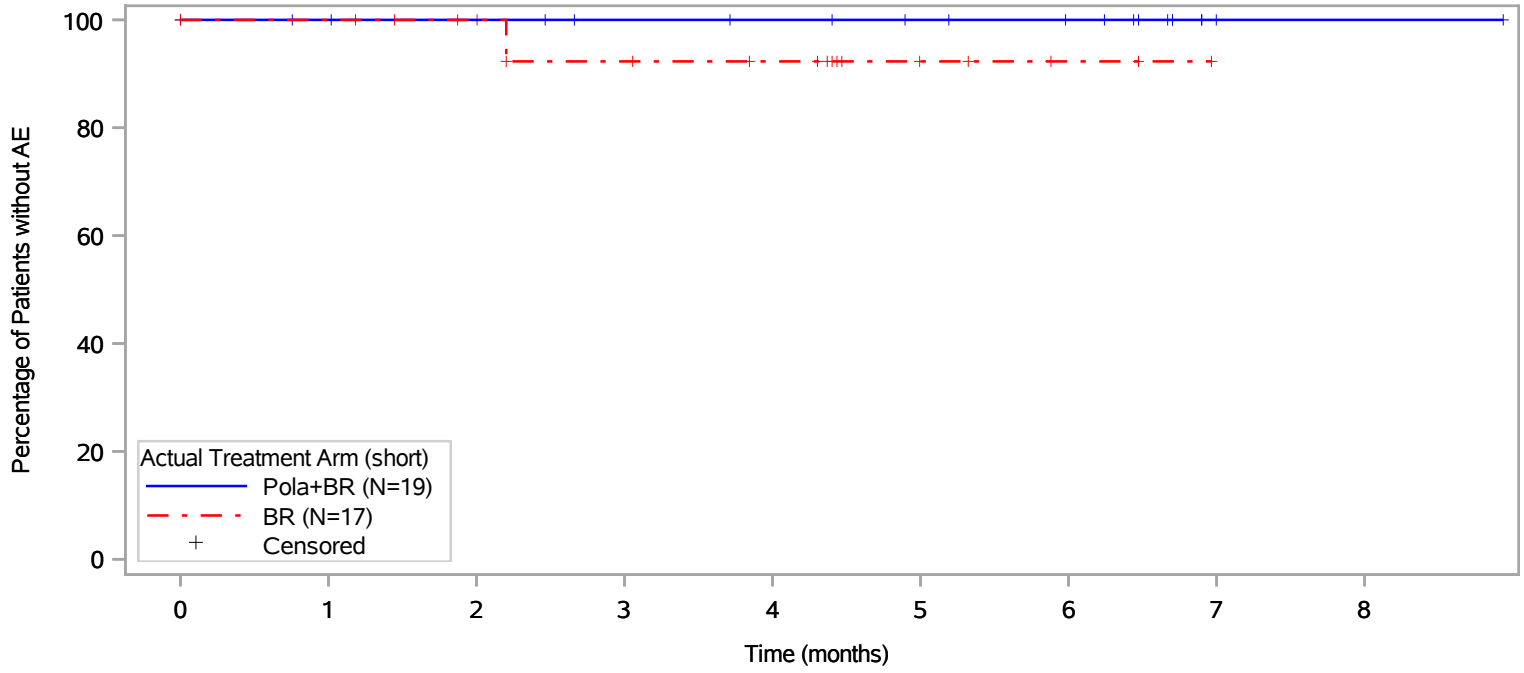
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, SPINAL COMPRESSION FRACTURE



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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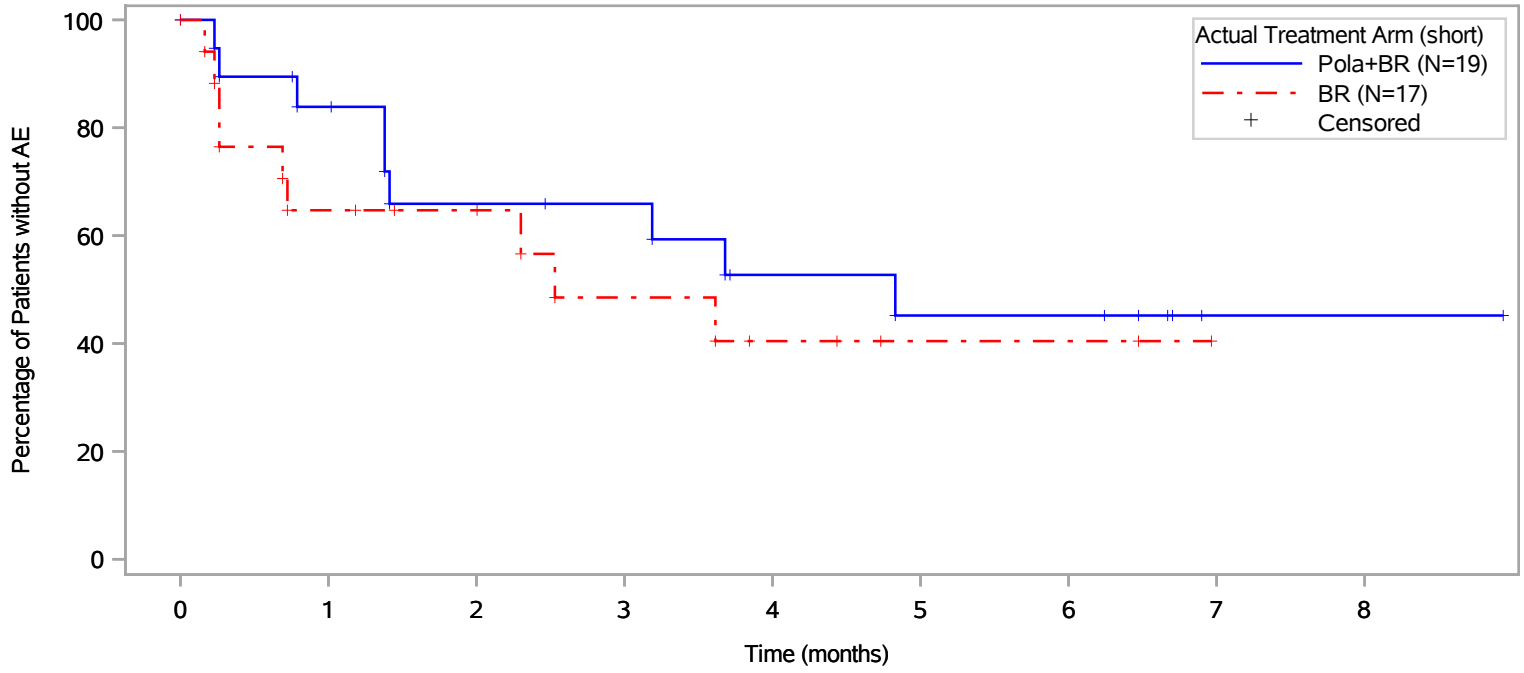
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk									
Pola+BR (N=19)	19	15	11	10	7	6	6	1	1
BR (N=17)	17	11	9	6	4	2	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	4	4	9	9
BR (N=17)	0	0	2	3	4	6	6	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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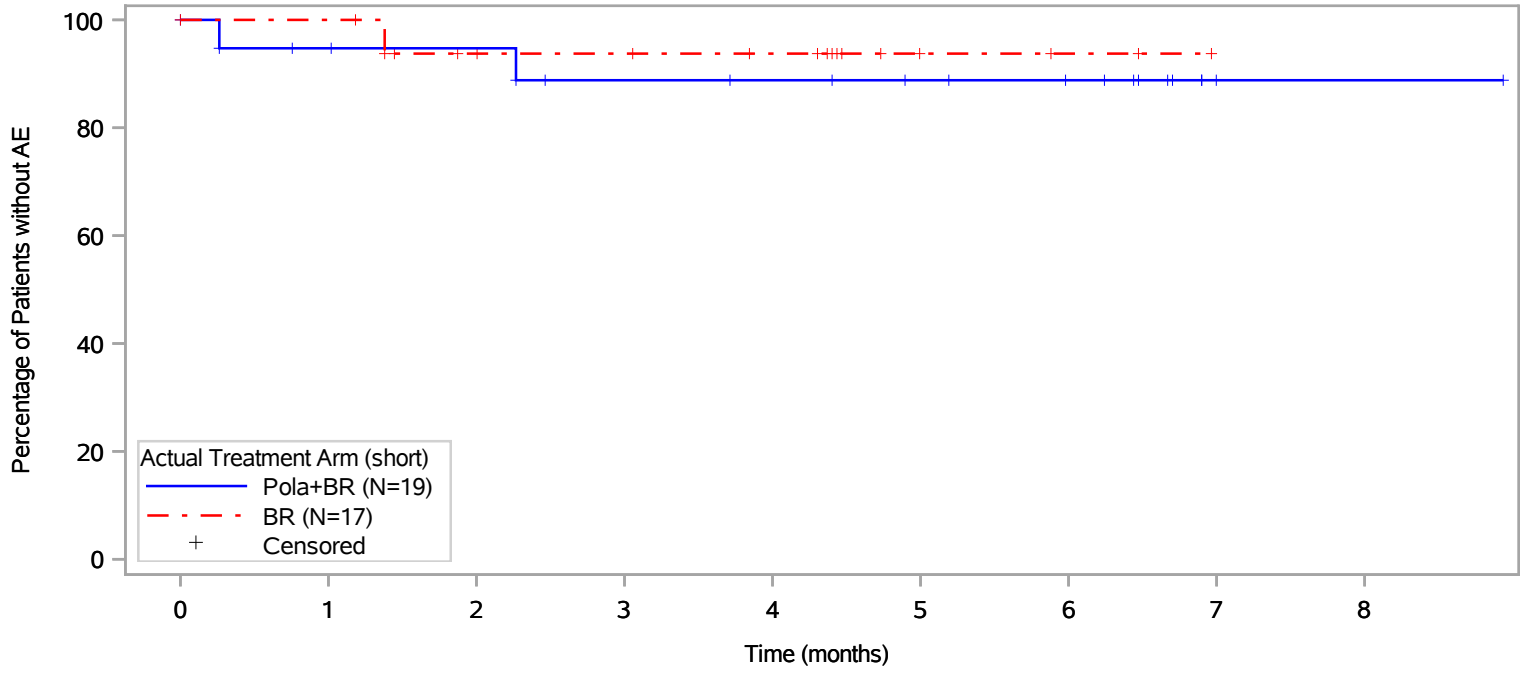
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ALANINE AMINOTRANSFERASE INCREASED



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	16	16
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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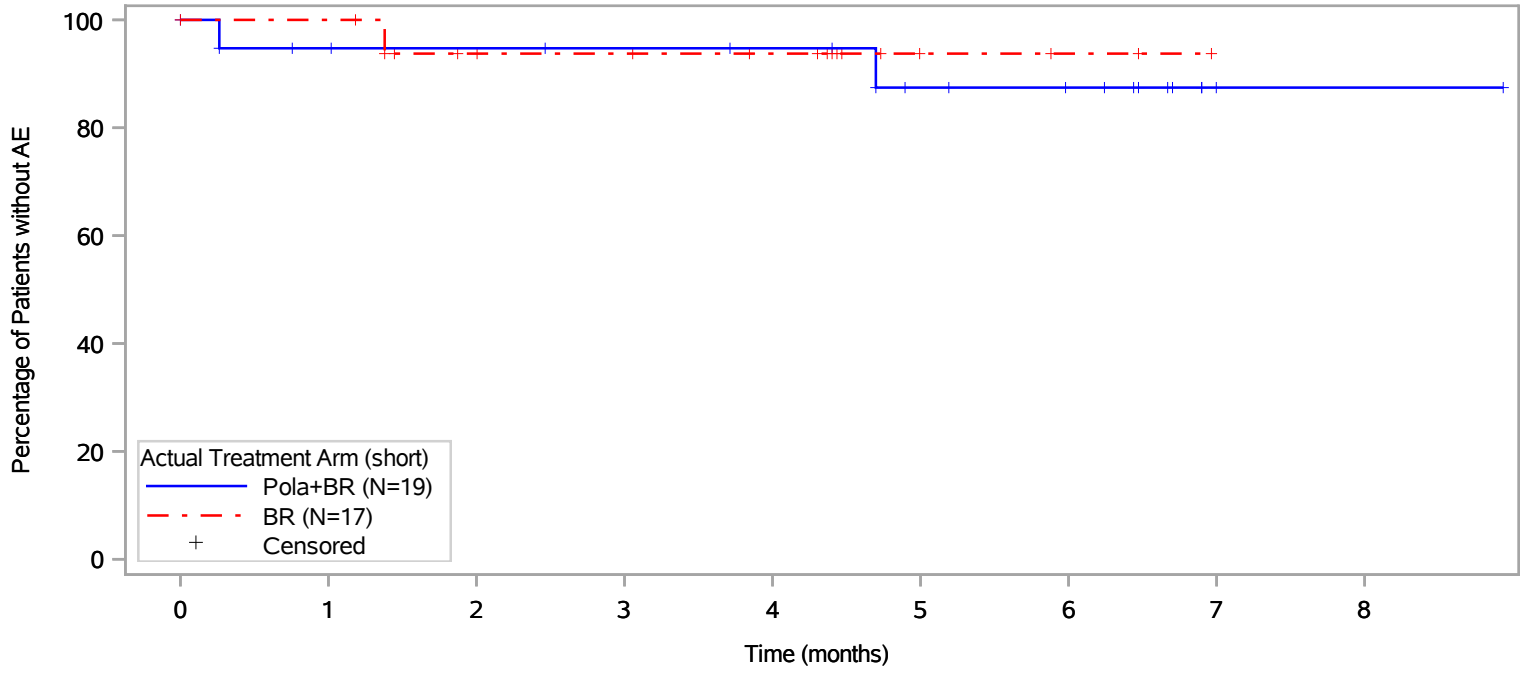
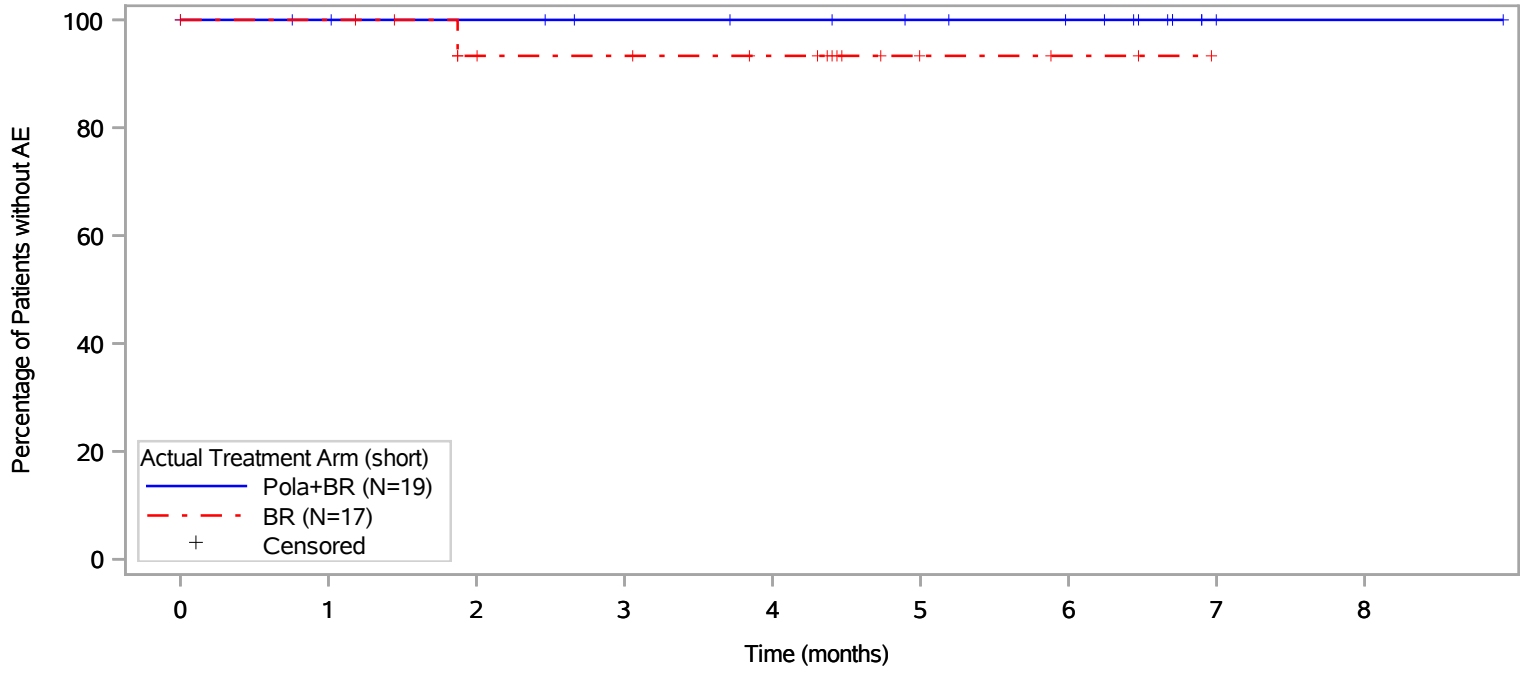
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ASPARTATE AMINOTRANSFERASE INCREASED



Patients at risk									
Pola+BR (N=19)	19	17	16	15	14	11	9	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	16	16
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BILIRUBIN CONJUGATED INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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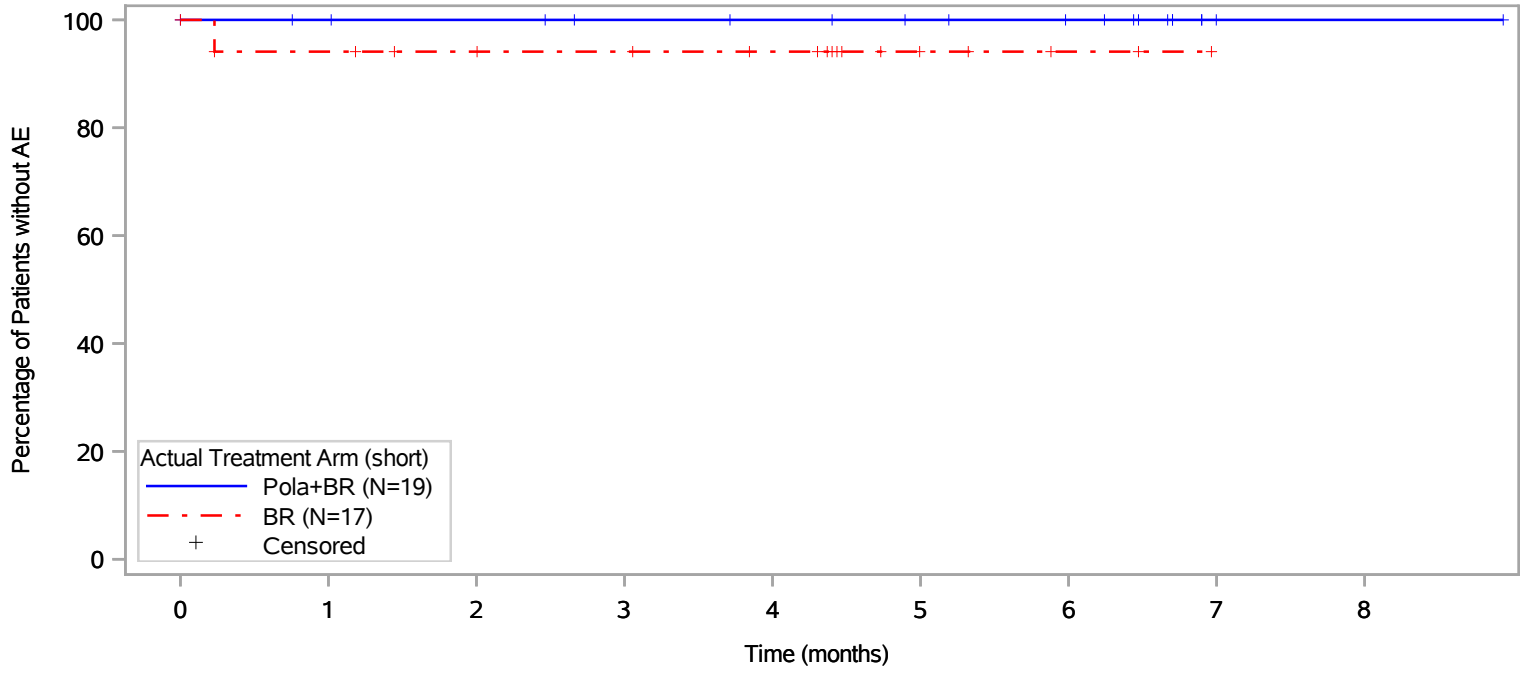
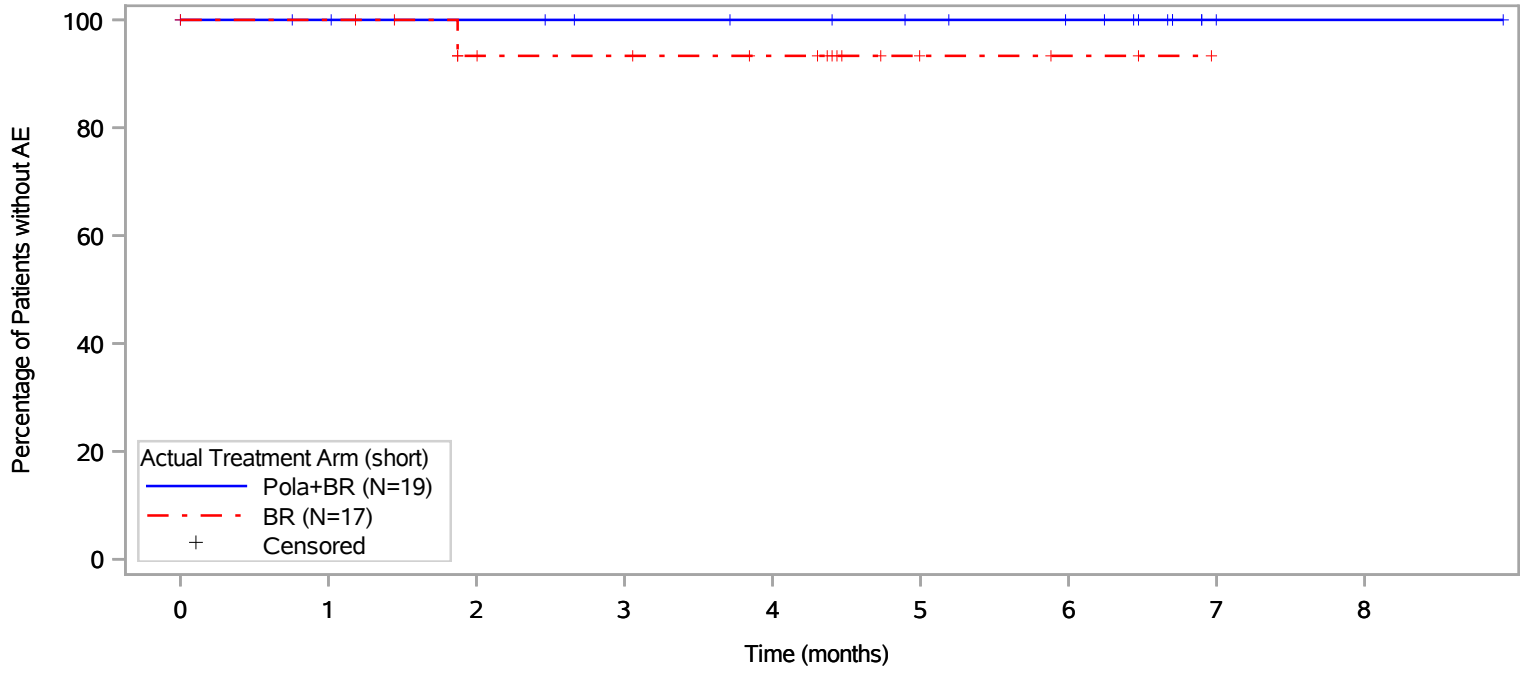
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALKALINE PHOSPHATASE INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD BILIRUBIN INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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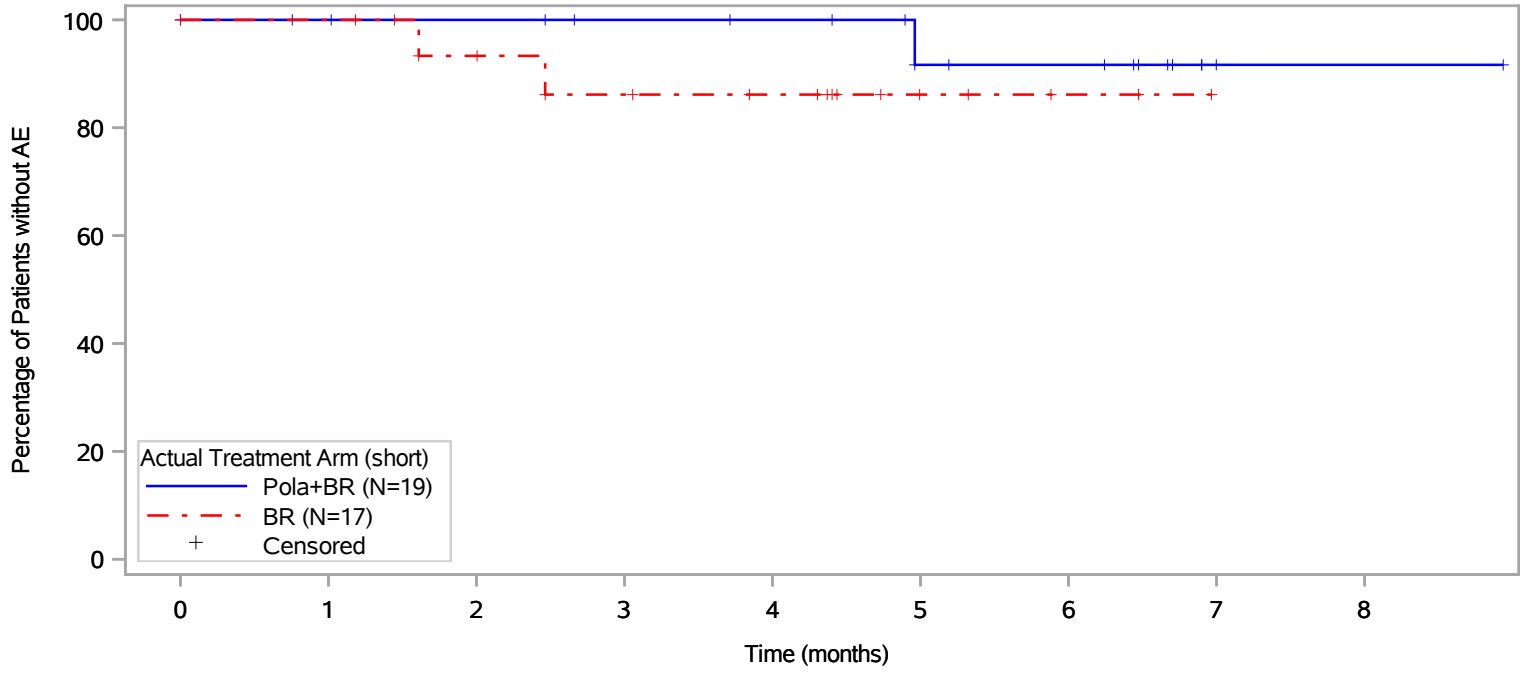
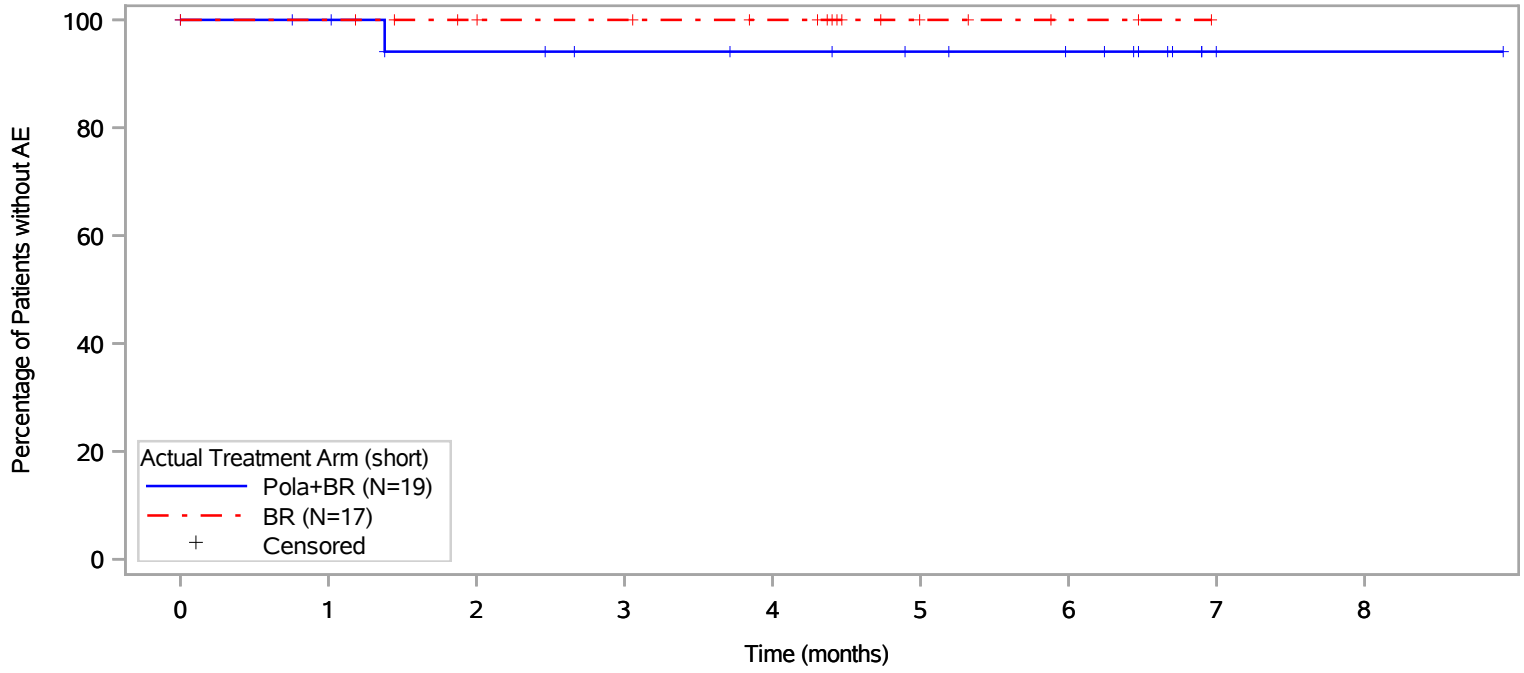
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD CREATININE INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	2	3	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

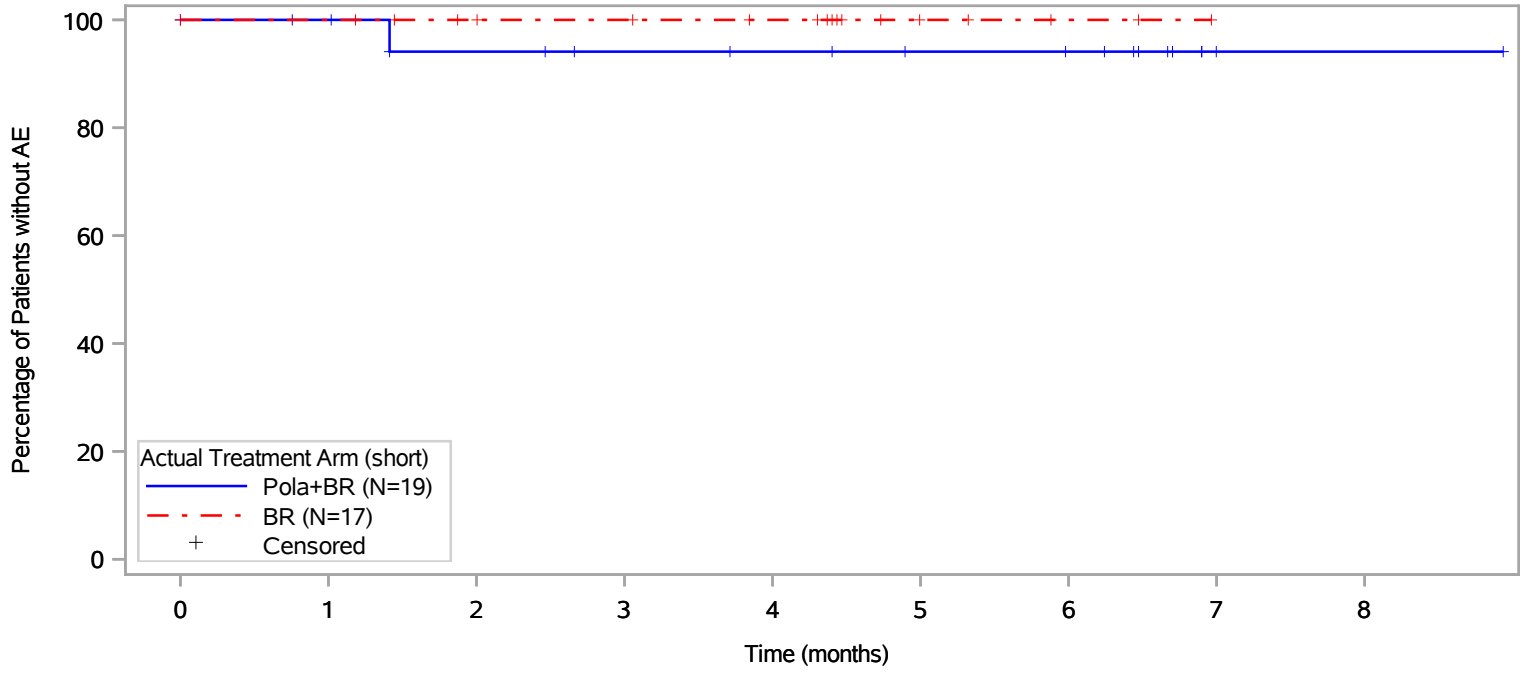
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD GLUCOSE INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

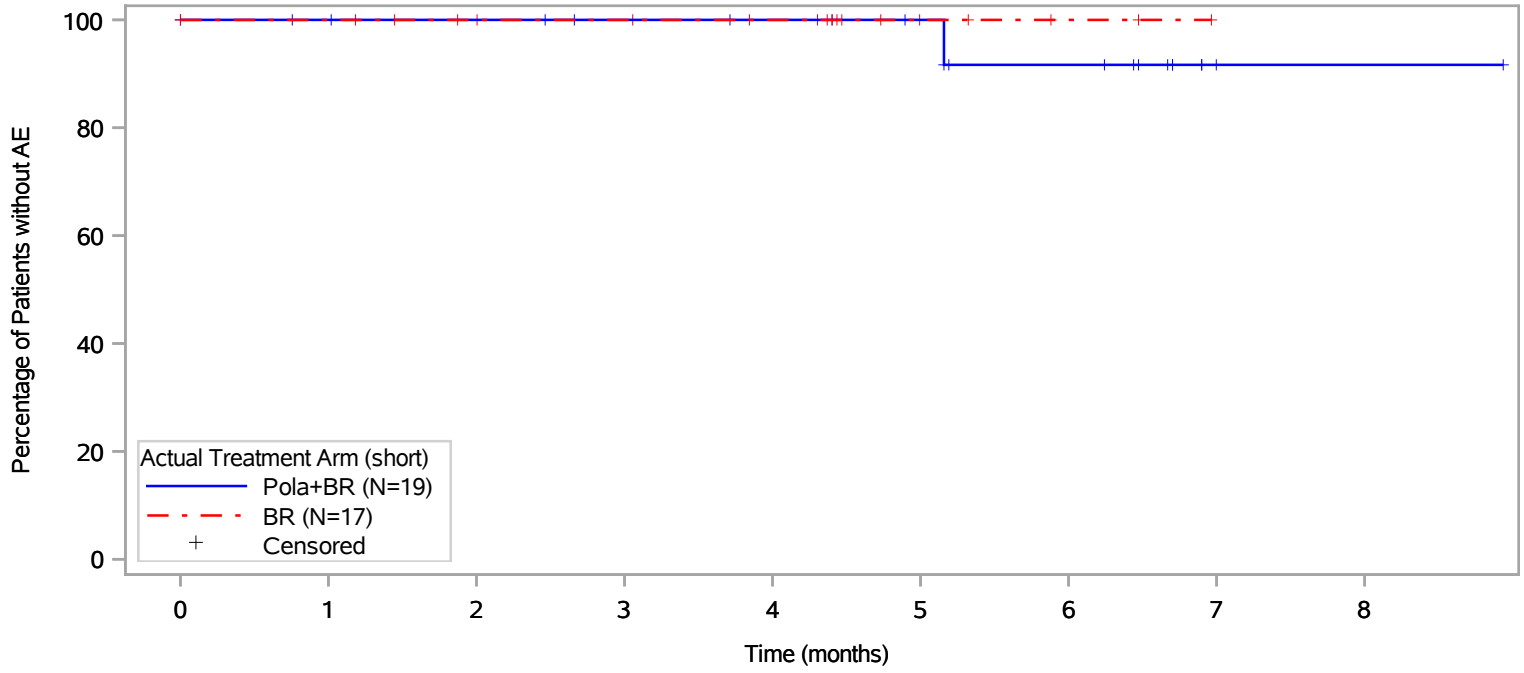
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD LACTATE DEHYDROGENASE INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

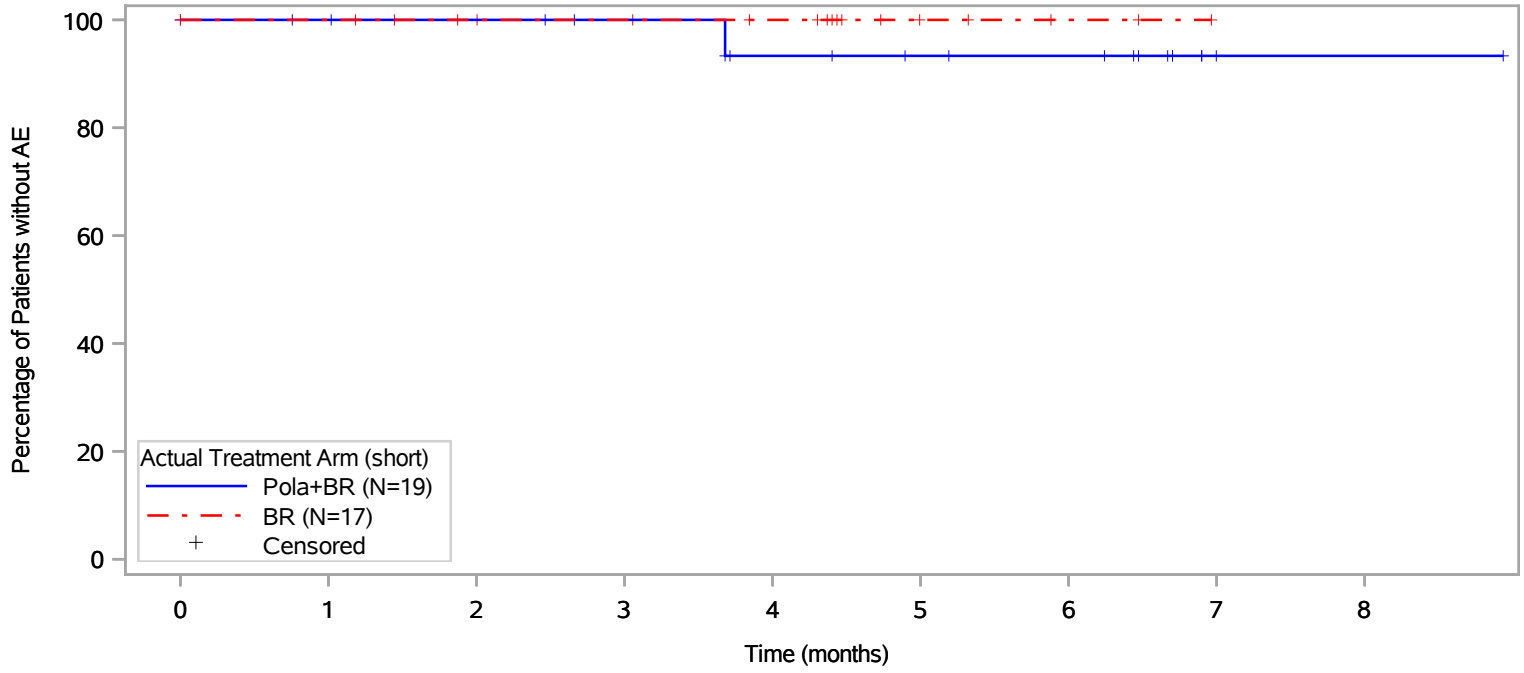
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PHOSPHORUS DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

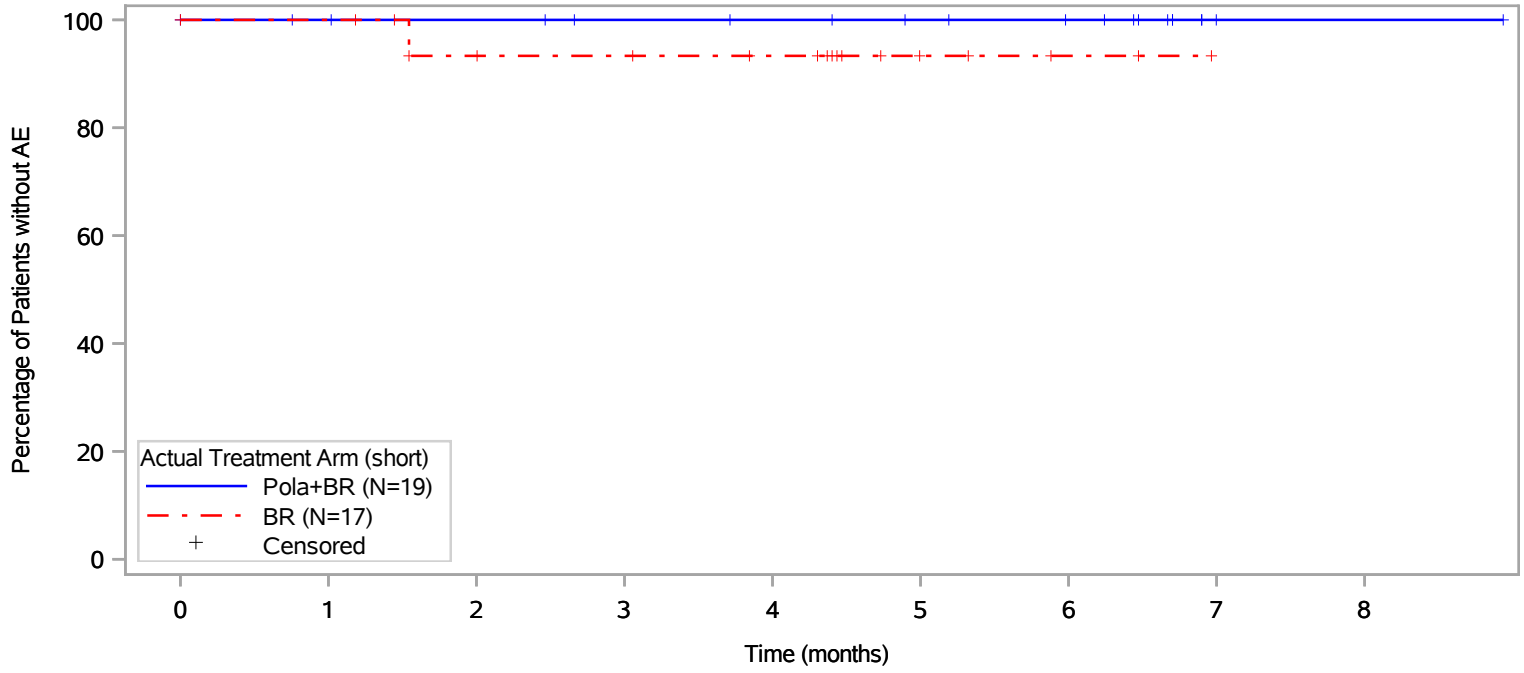
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, C-REACTIVE PROTEIN INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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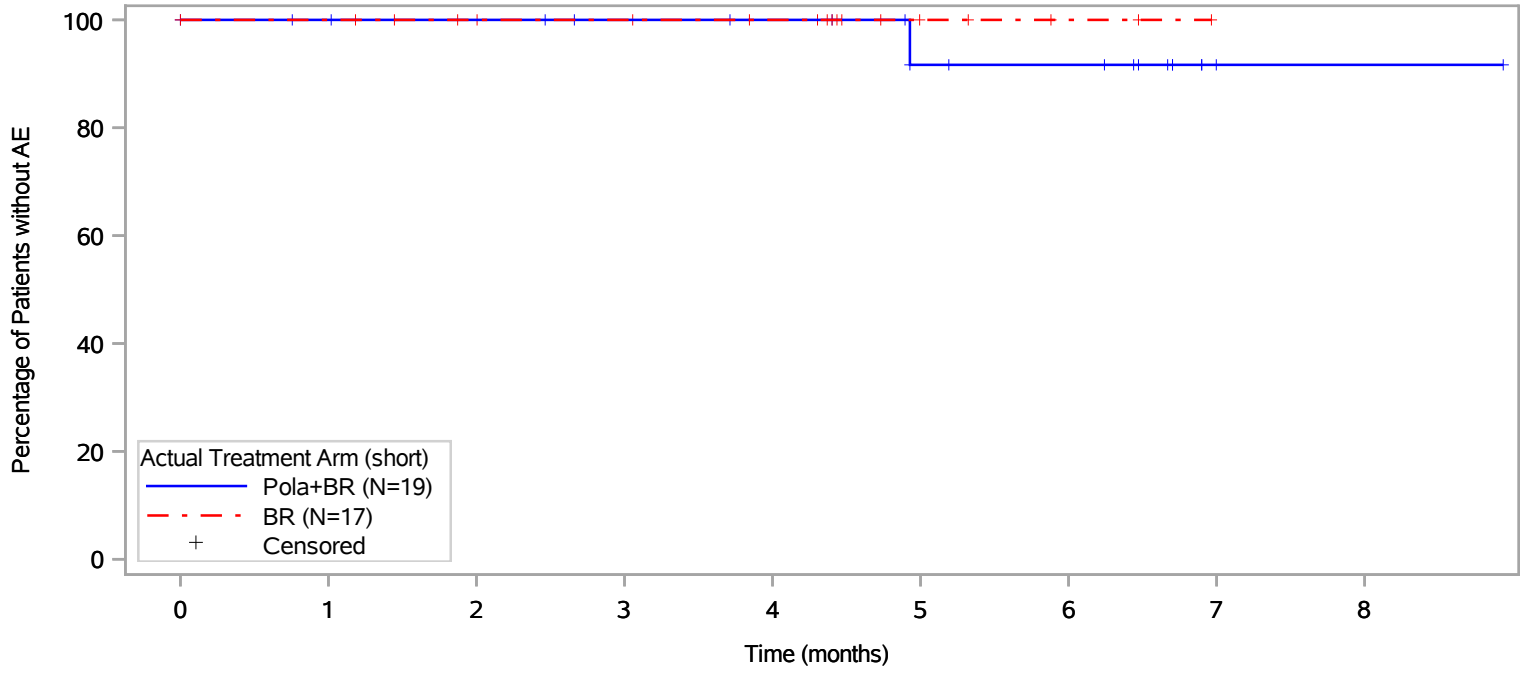
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYTOMEGALOVIRUS TEST POSITIVE



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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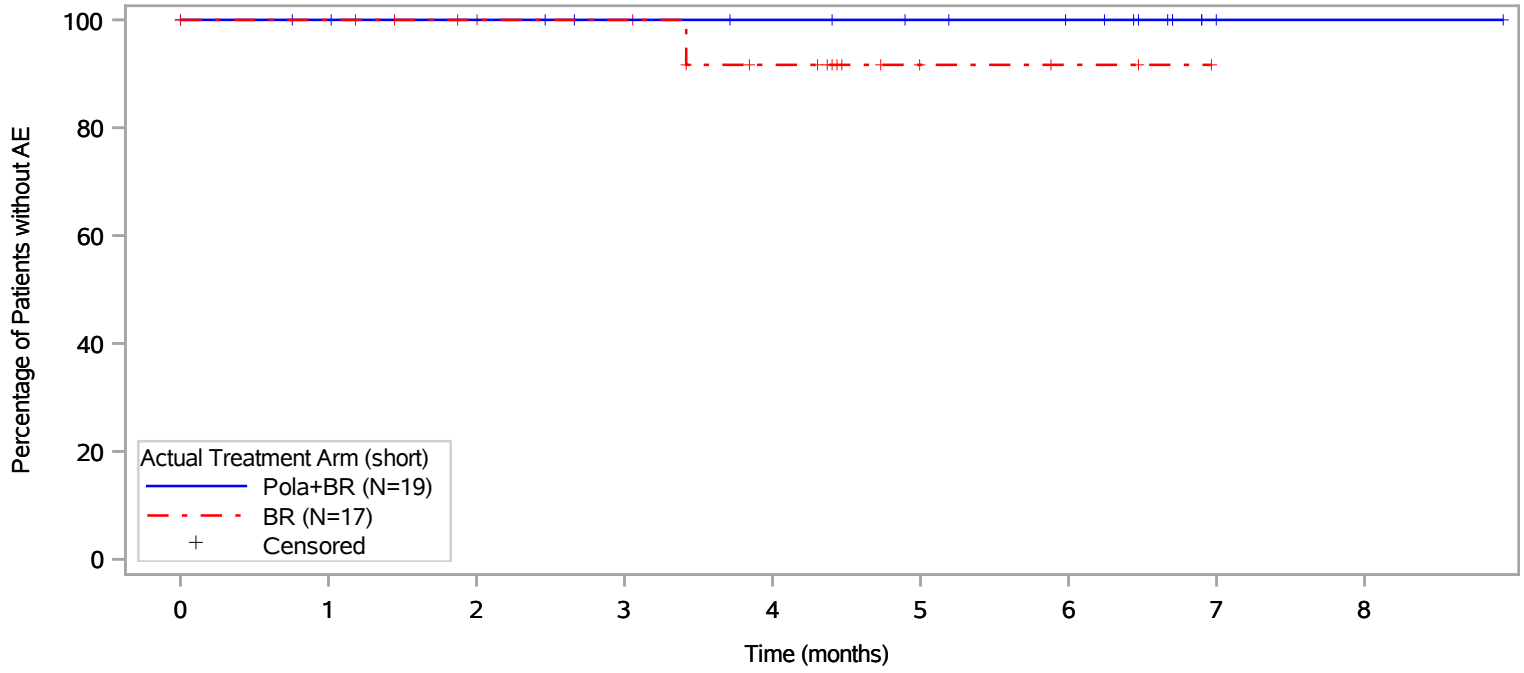
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GAMMA-GLUTAMYLTRANSFERASE INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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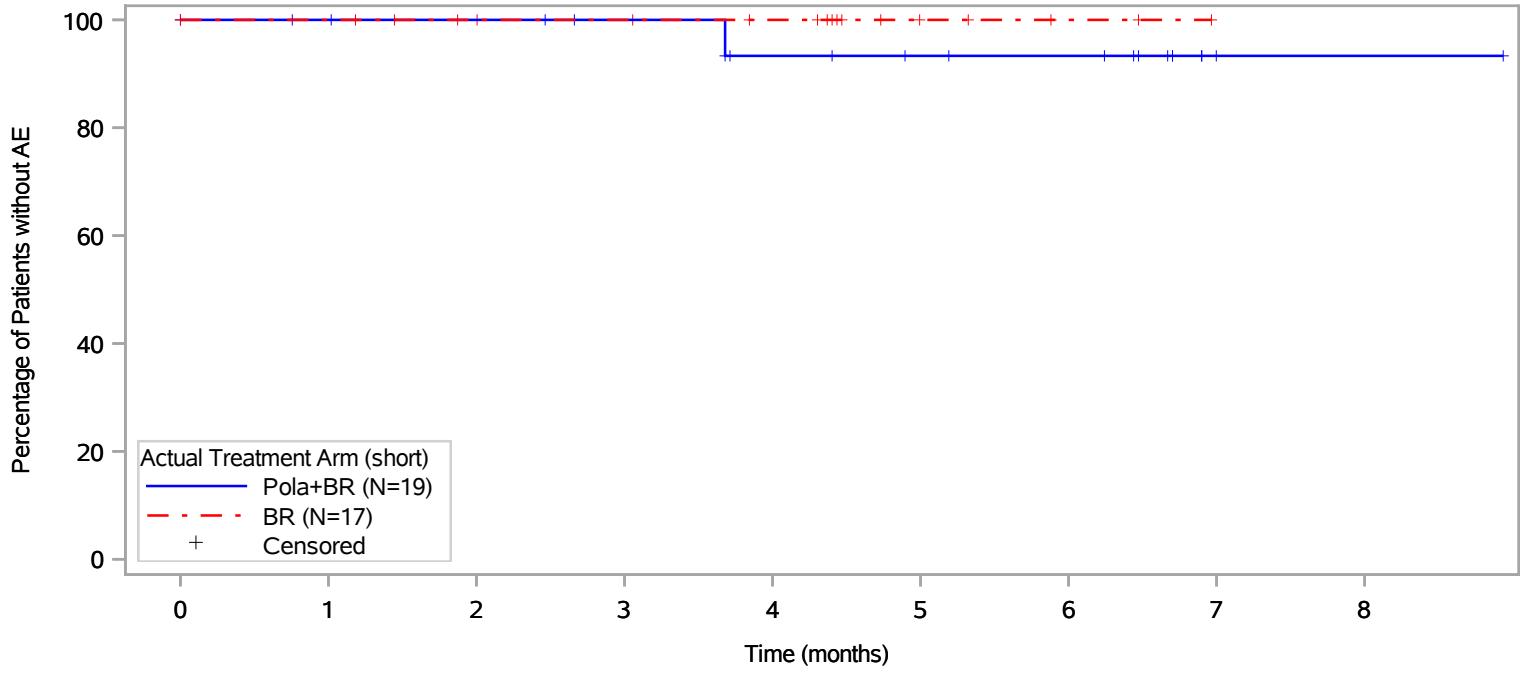
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LIPASE INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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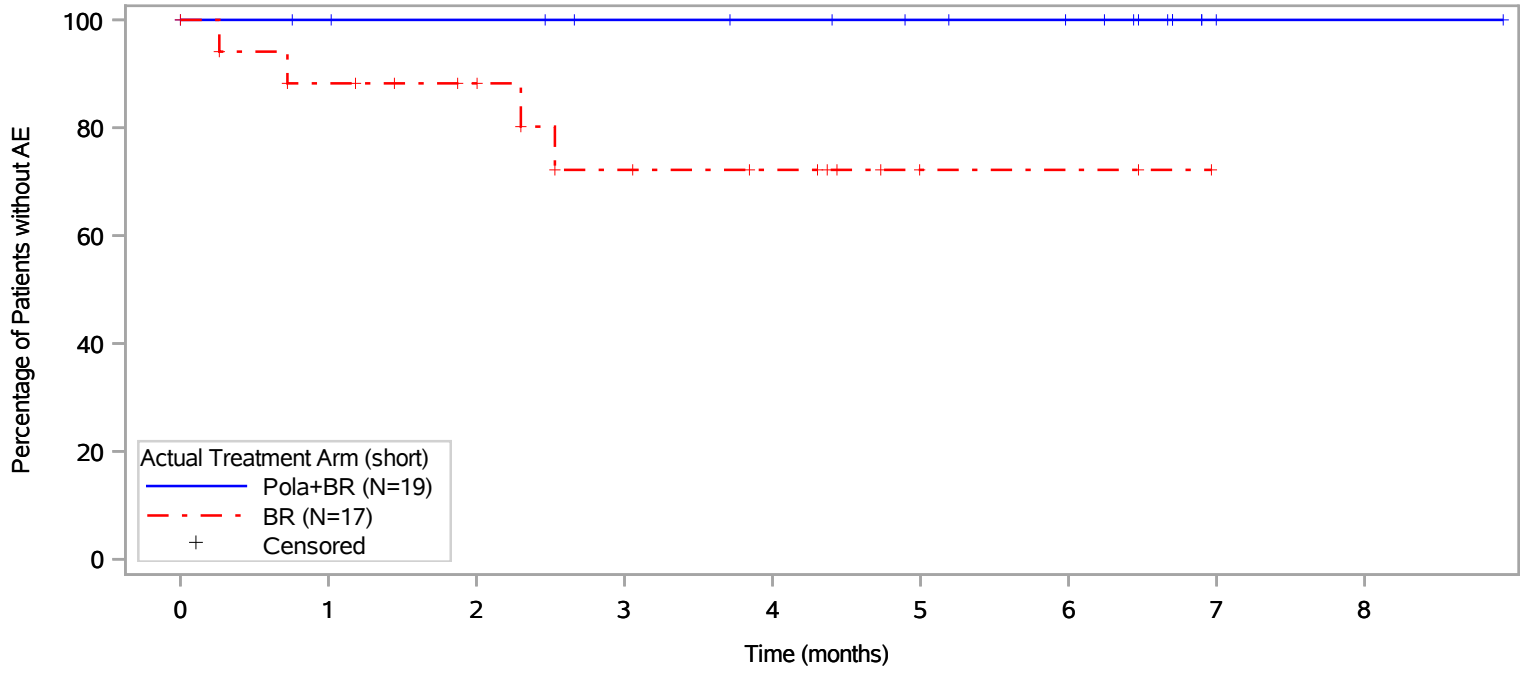
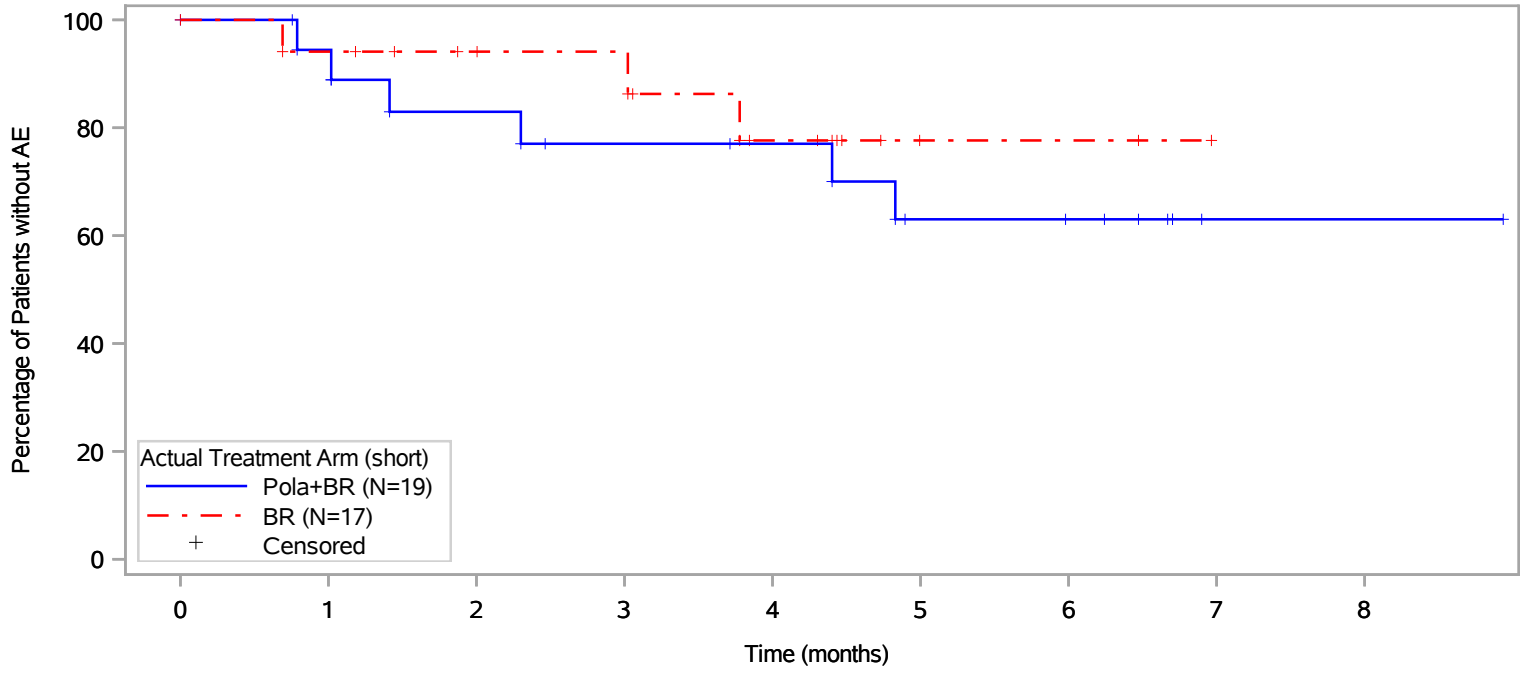
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	15	12	9	7	2	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	11	11	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

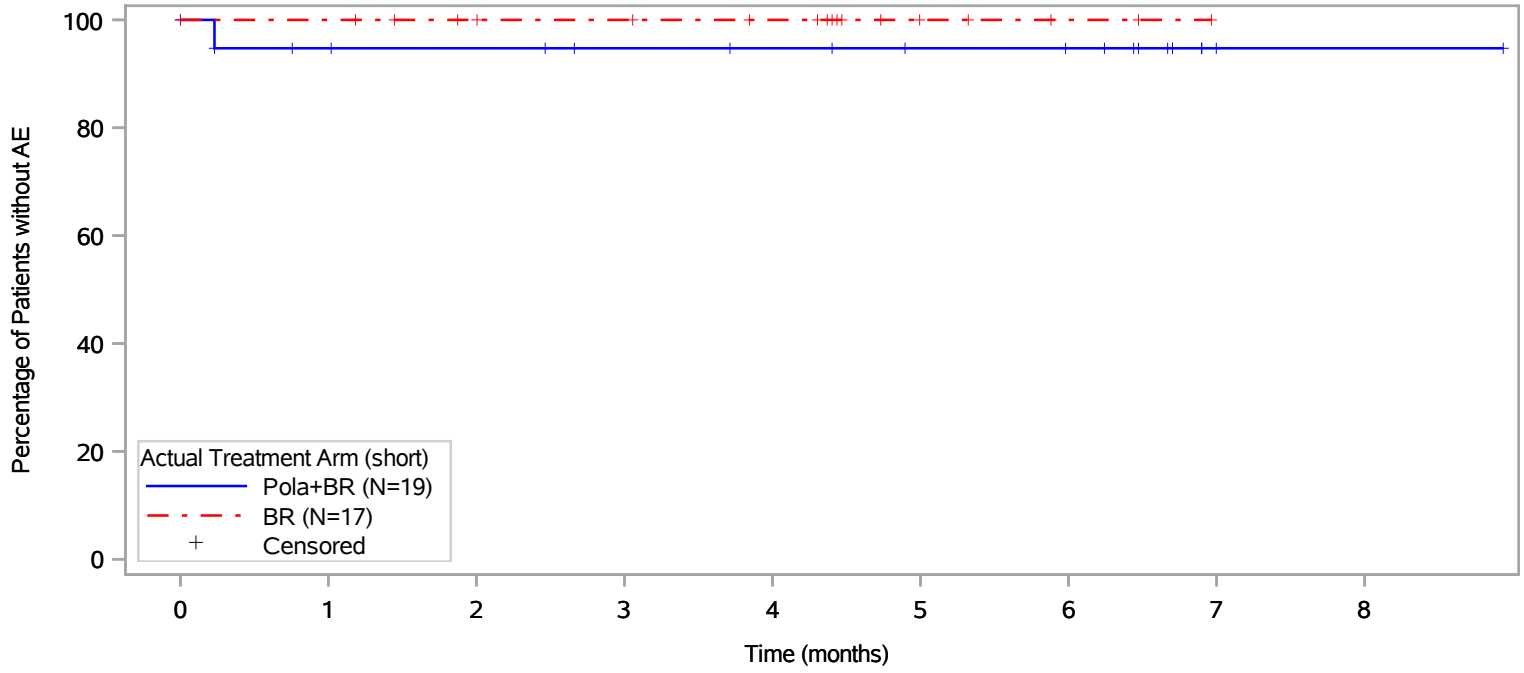
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	17	14	12	11	8	7	1	1
BR (N=17)	17	16	13	12	8	2	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	6	12	12
BR (N=17)	0	0	3	4	6	12	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT INCREASED



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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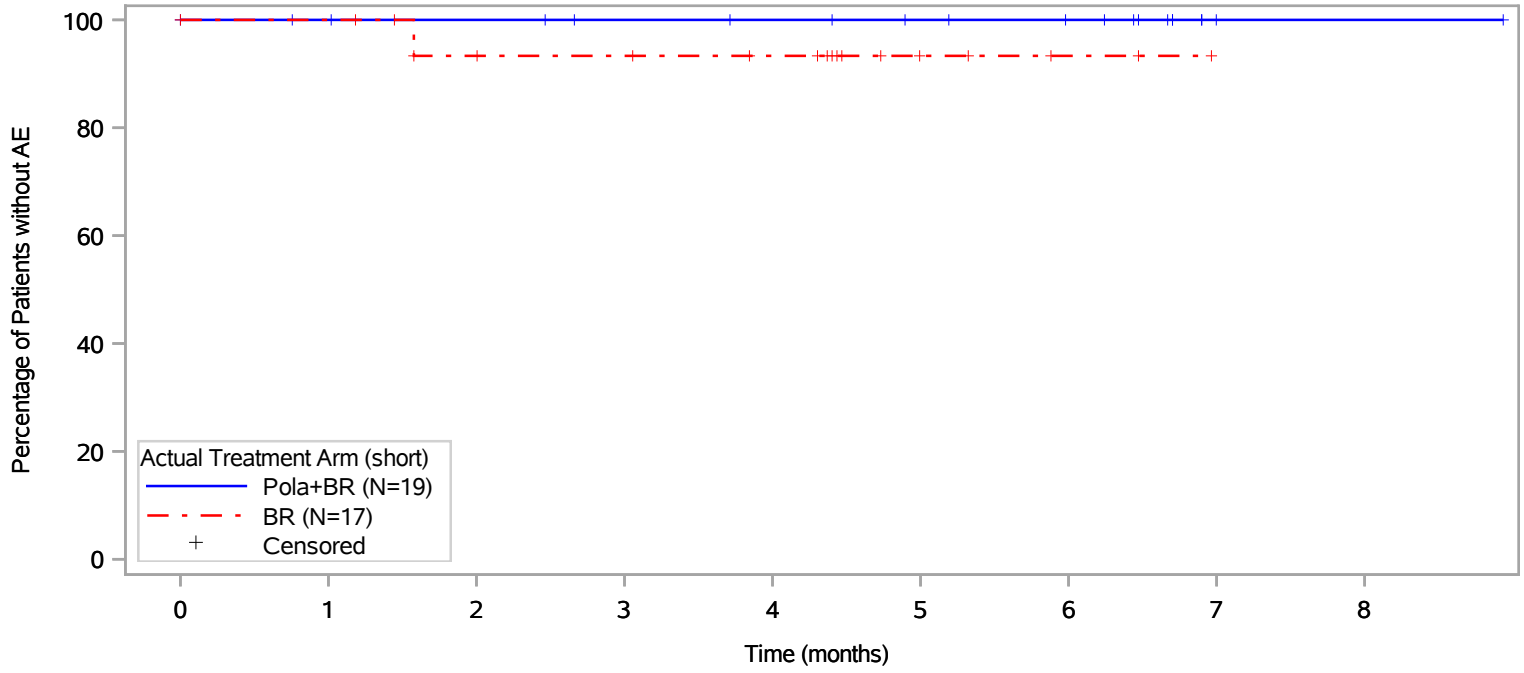
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, OXYGEN SATURATION DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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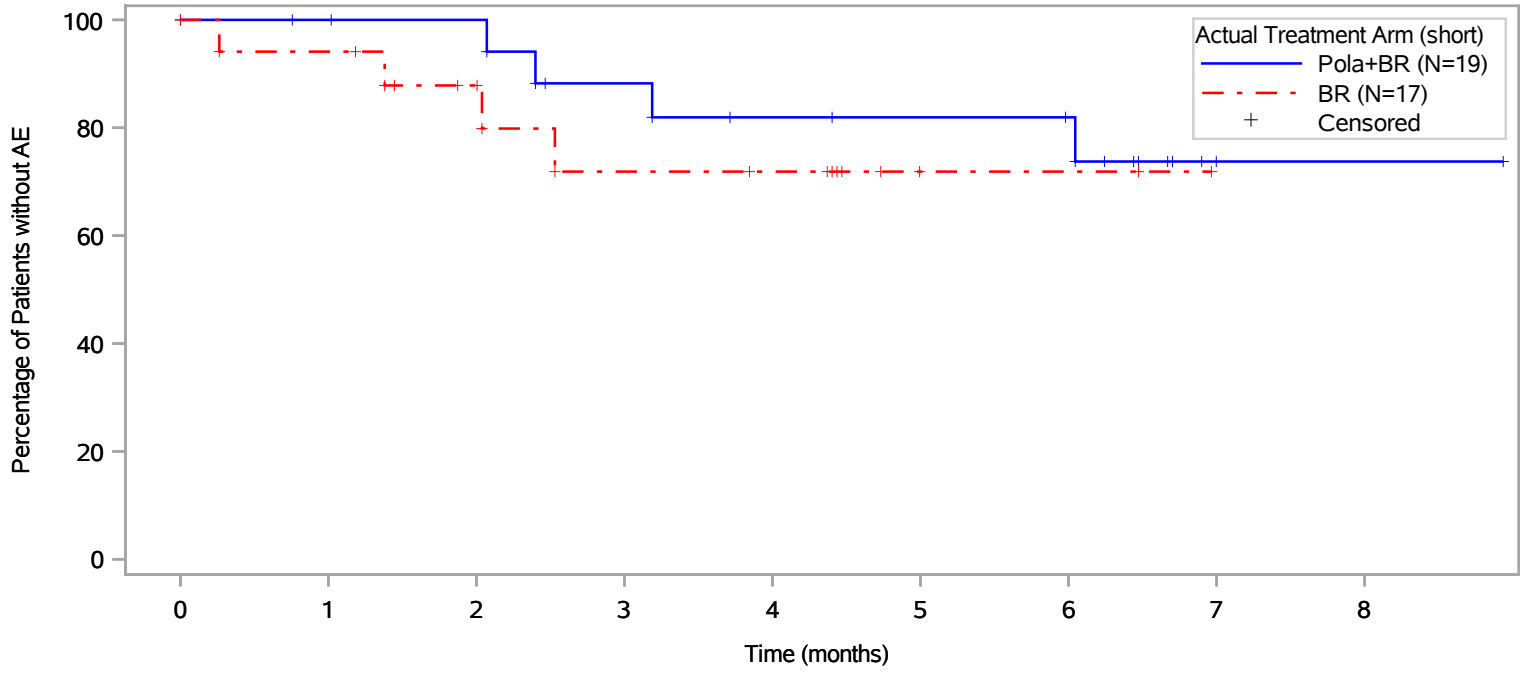
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	14	12	11	10	1	1
BR (N=17)	17	16	12	9	8	2	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	6	14	14
BR (N=17)	0	0	3	4	5	11	11	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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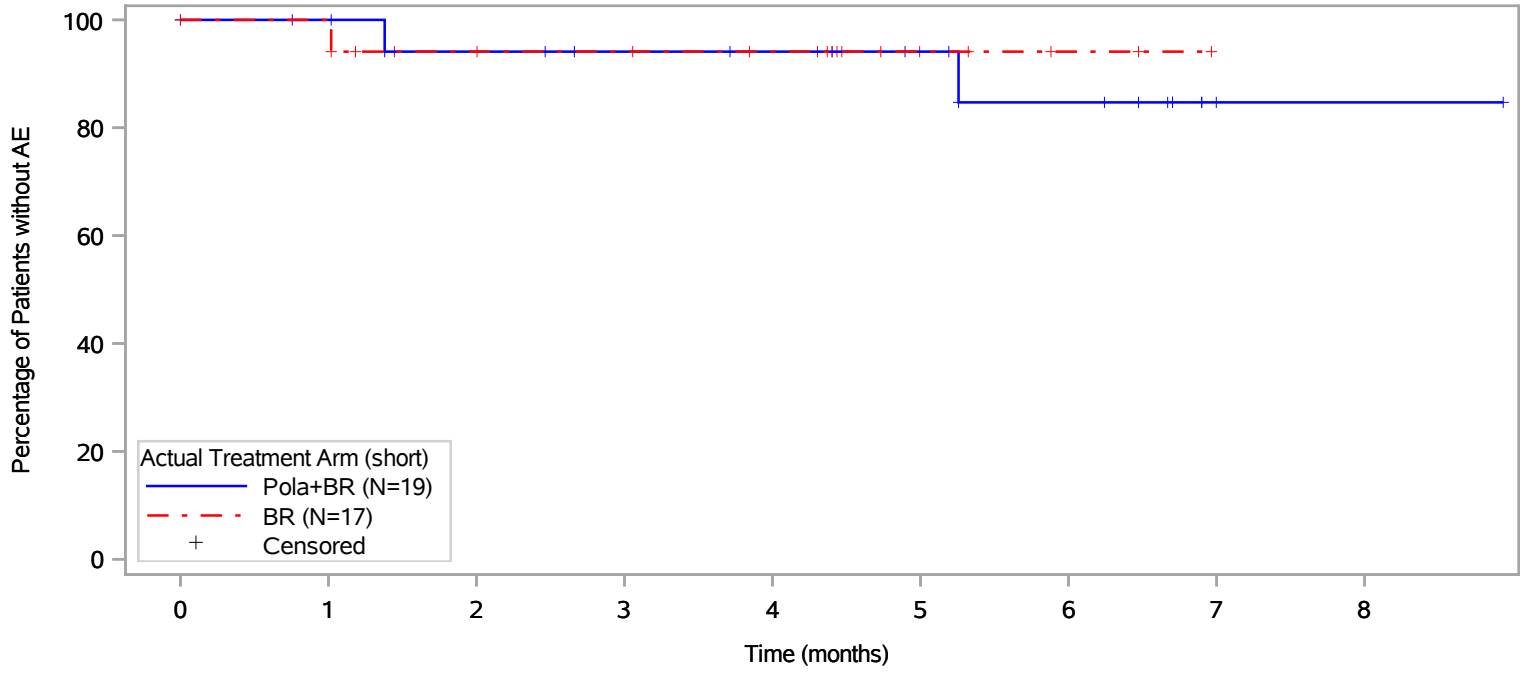
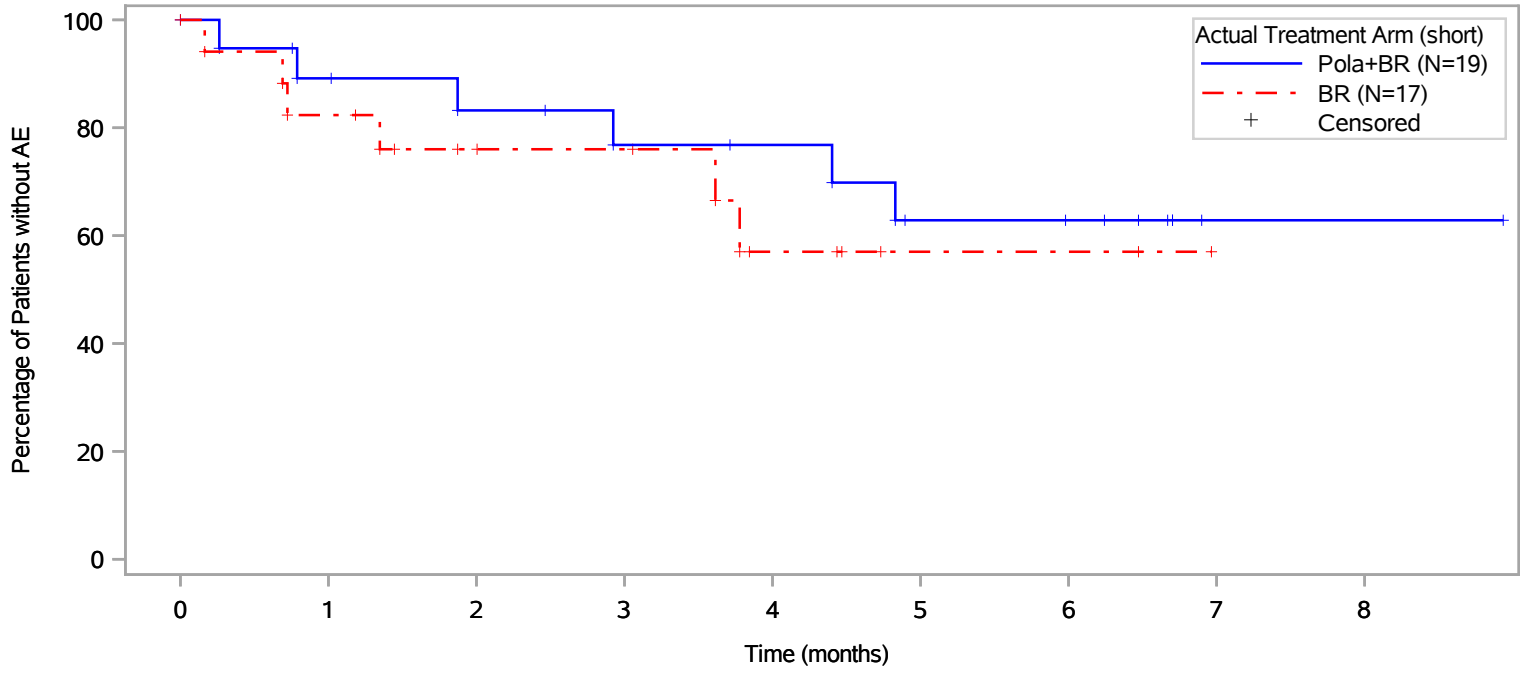
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	16	16
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

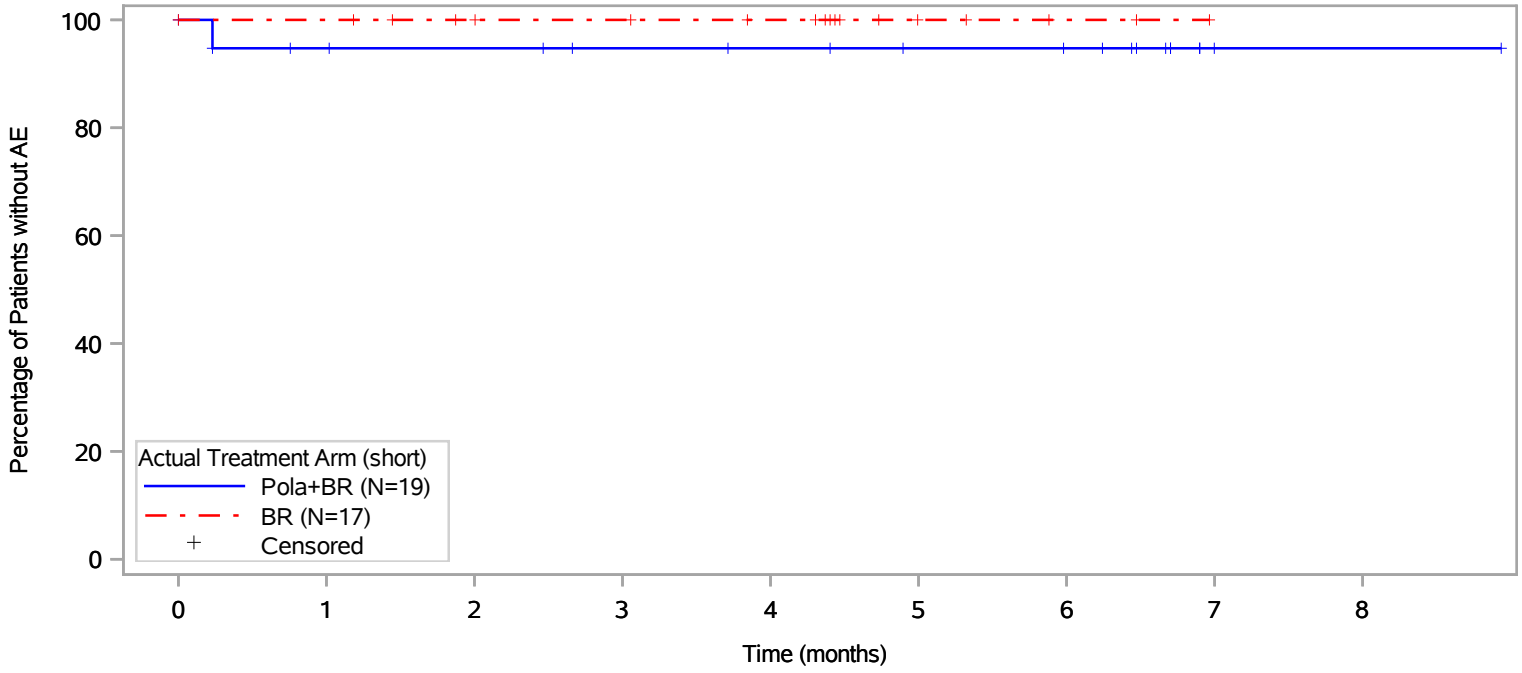
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	16	14	12	11	8	7	1	1
BR (N=17)	17	14	10	9	5	2	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	6	12	12
BR (N=17)	0	0	3	4	6	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

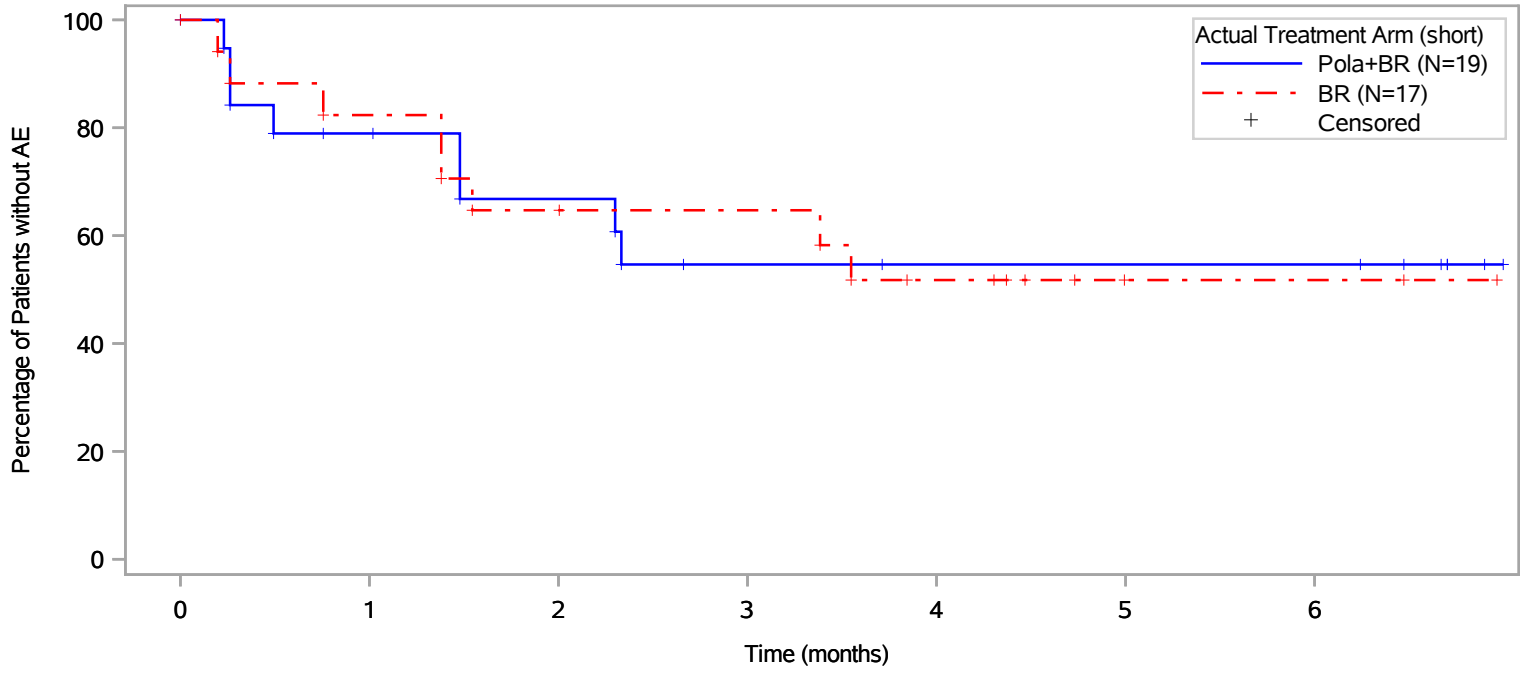
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT INCREASED



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	14	11	8	7	7	7
BR (N=17)	17	14	11	10	7	2	2
Patients censored							
Pola+BR (N=19)	0	1	2	3	4	4	4
BR (N=17)	0	0	0	1	2	7	7

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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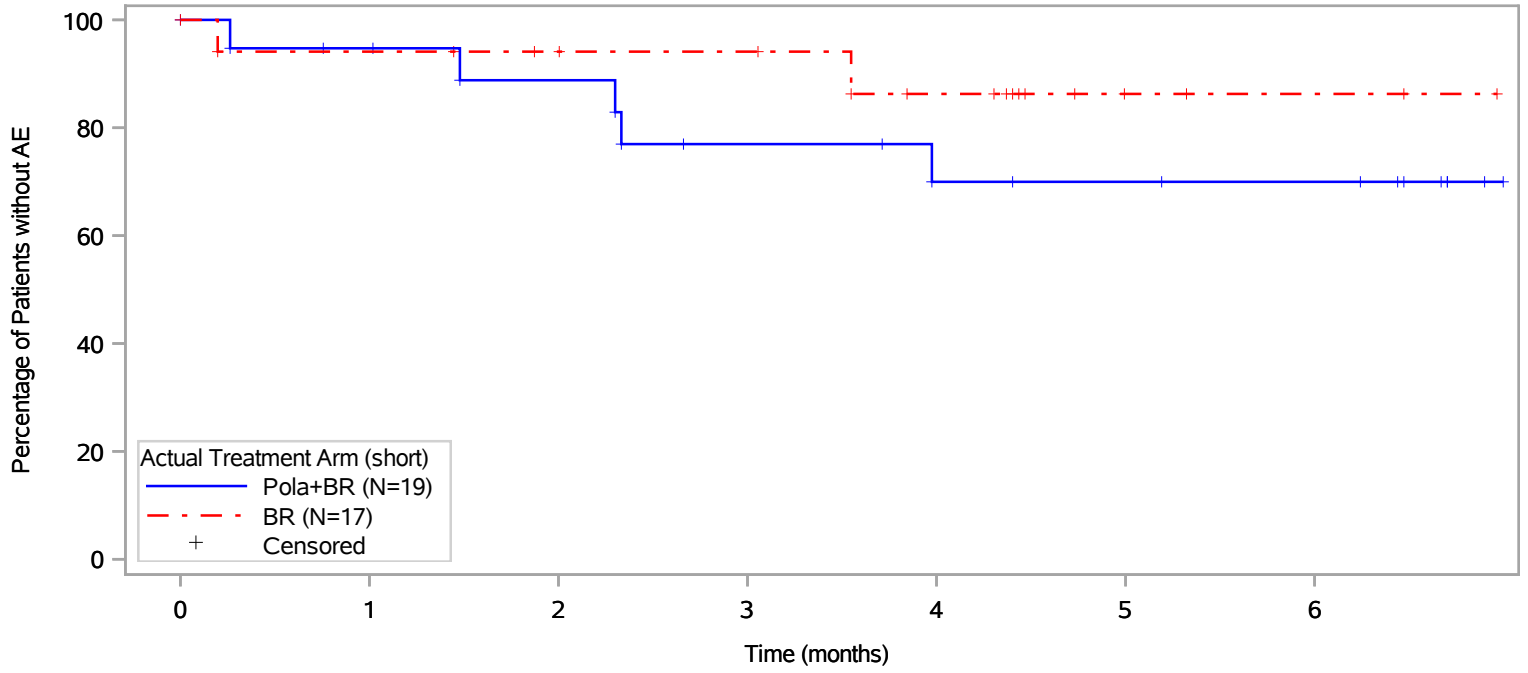
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE



Patients at risk							
Pola+BR (N=19)	19	17	15	12	10	9	8
BR (N=17)	17	16	14	13	10	3	2
Patients censored							
Pola+BR (N=19)	0	1	2	3	4	5	6
BR (N=17)	0	0	2	3	5	12	13

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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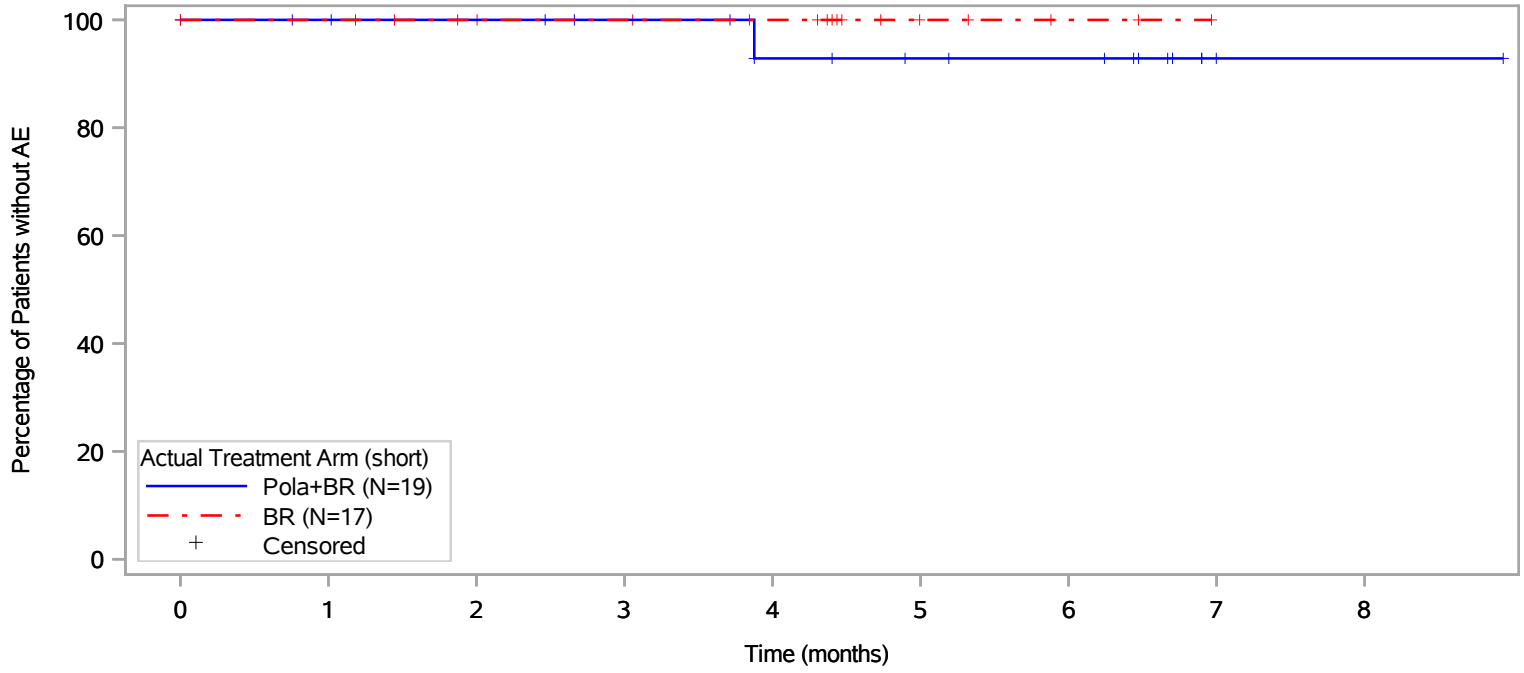
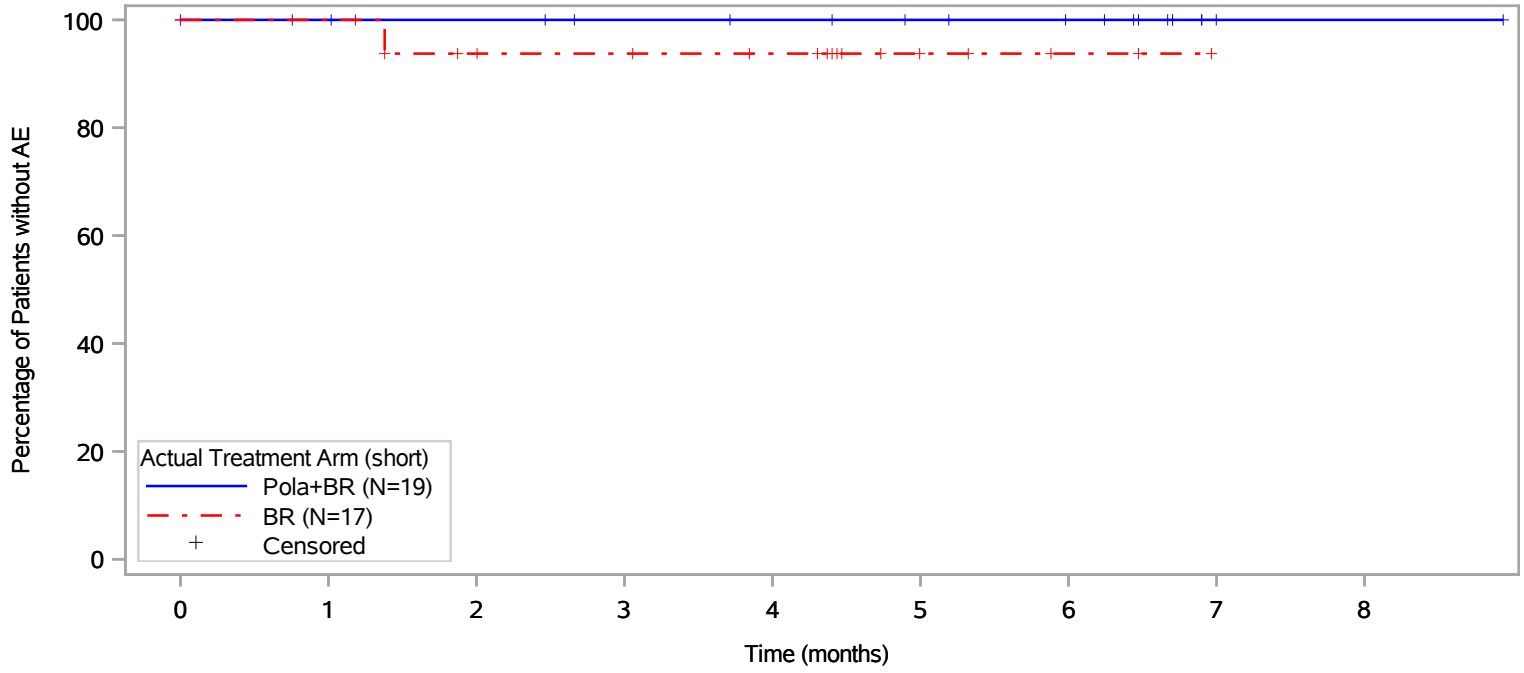
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, DEHYDRATION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, FLUID IMBALANCE



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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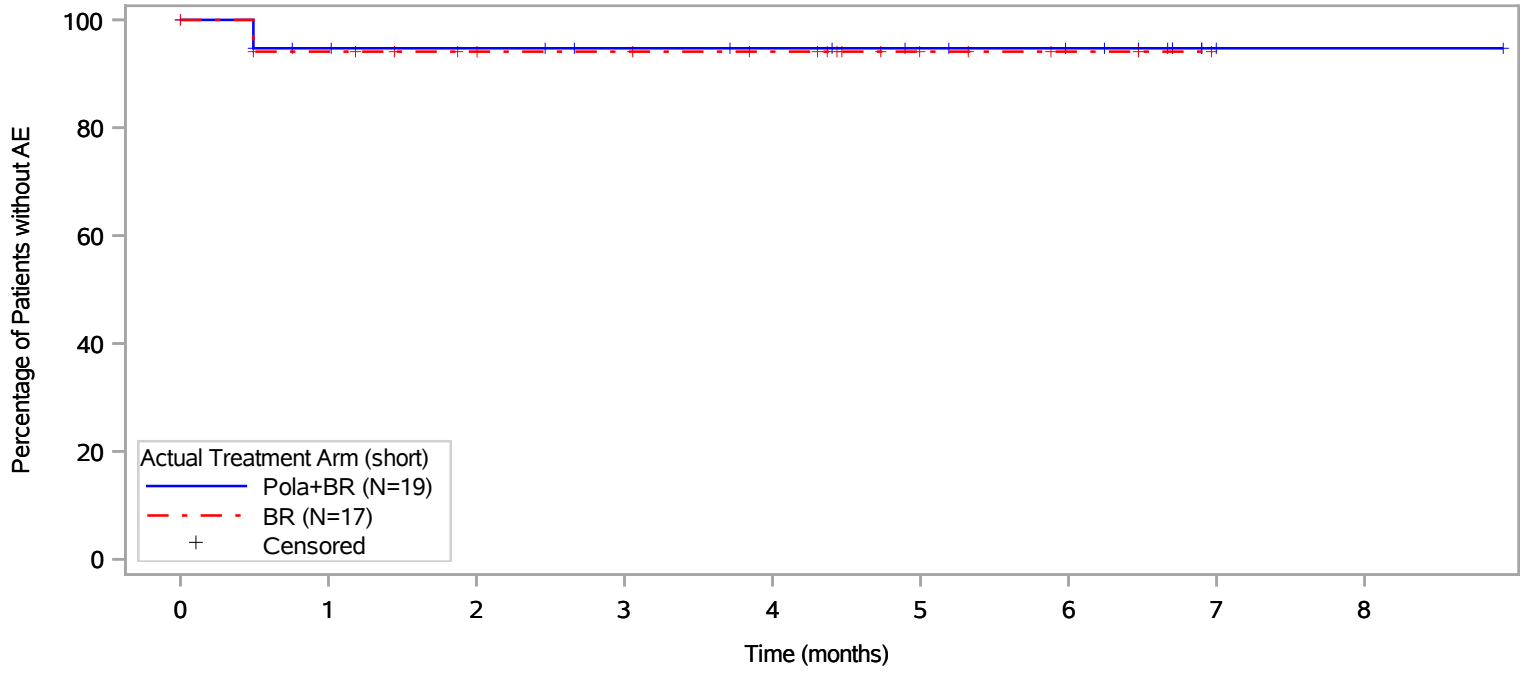
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

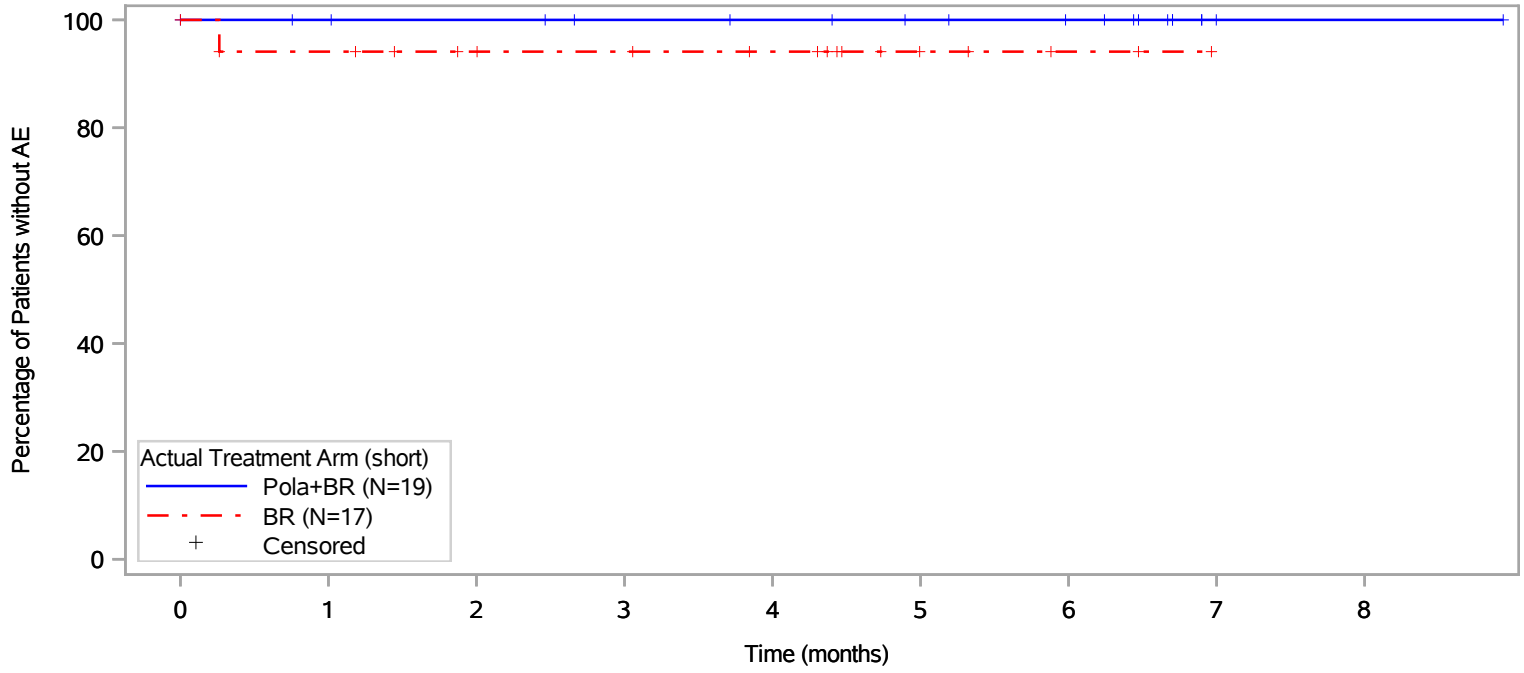
METABOLISM AND NUTRITION DISORDERS, HYPERLIPIDAEMIA



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERURICAEMIA

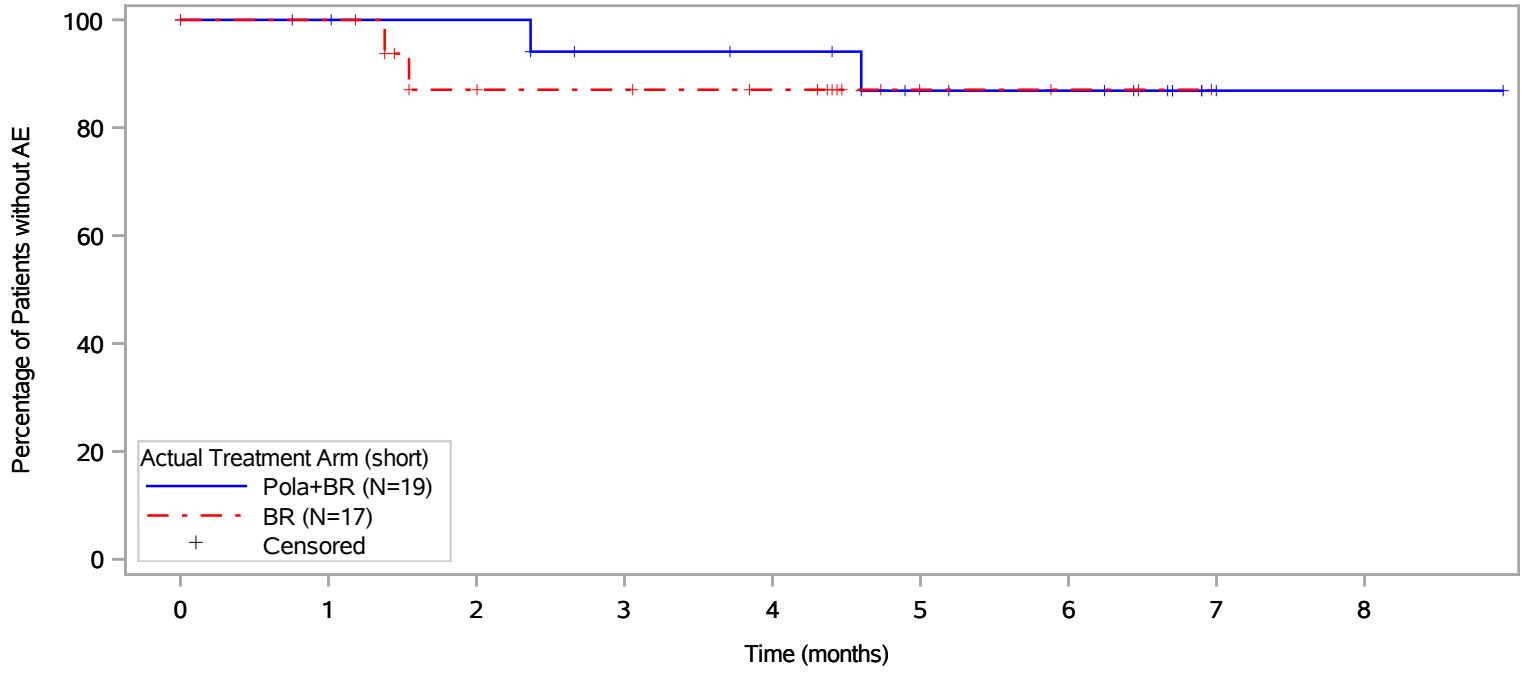


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

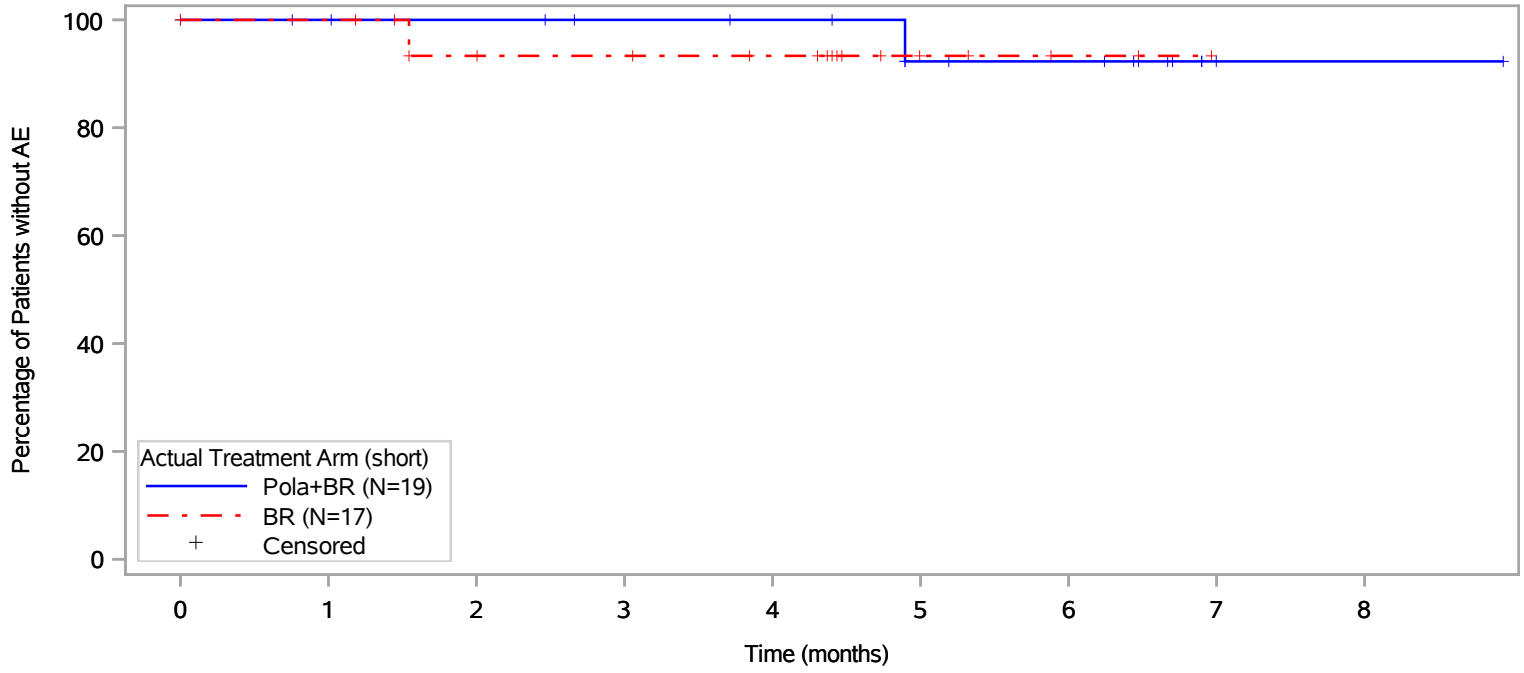
METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	7	16	16
BR (N=17)	0	0	2	3	5	12	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOCALCAEMIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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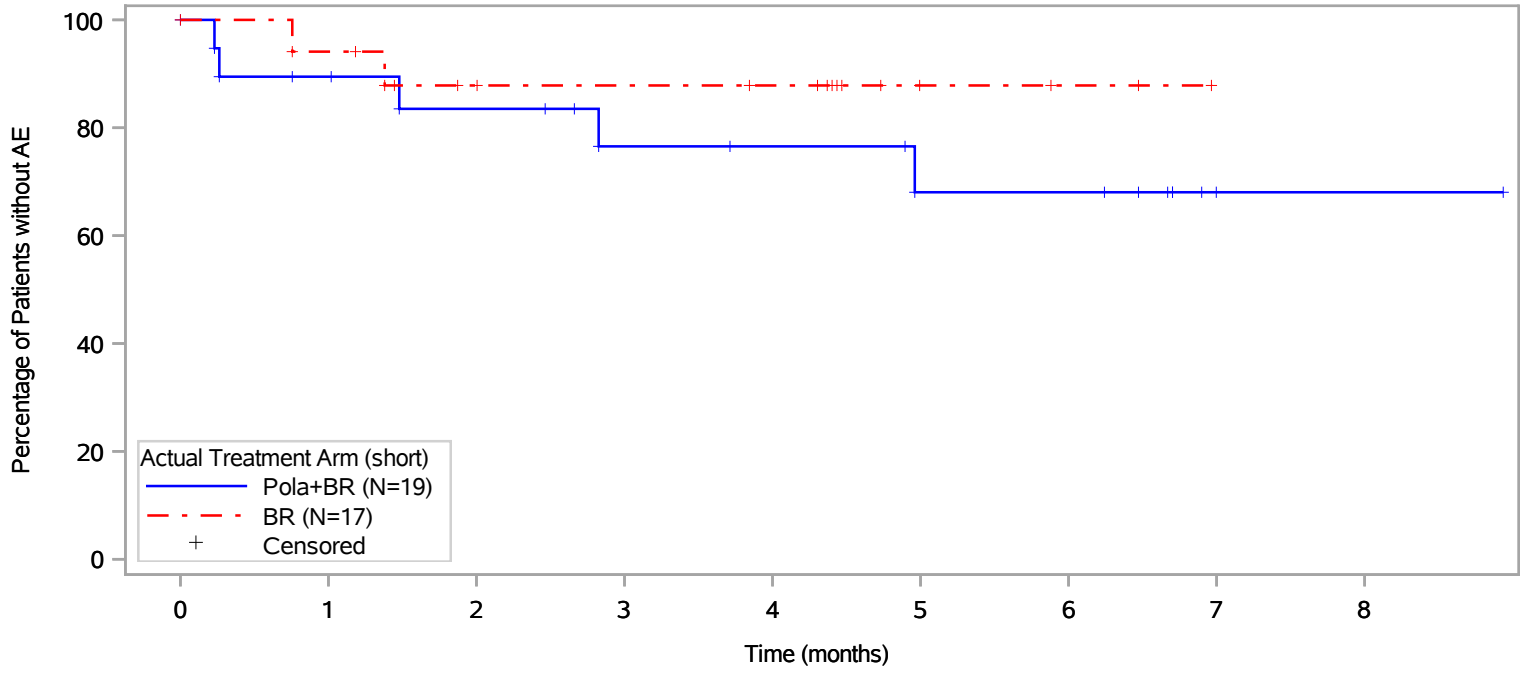
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk									
Pola+BR (N=19)	19	16	14	11	10	8	8	1	1
BR (N=17)	17	16	12	11	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	6	13	13
BR (N=17)	0	0	3	4	5	12	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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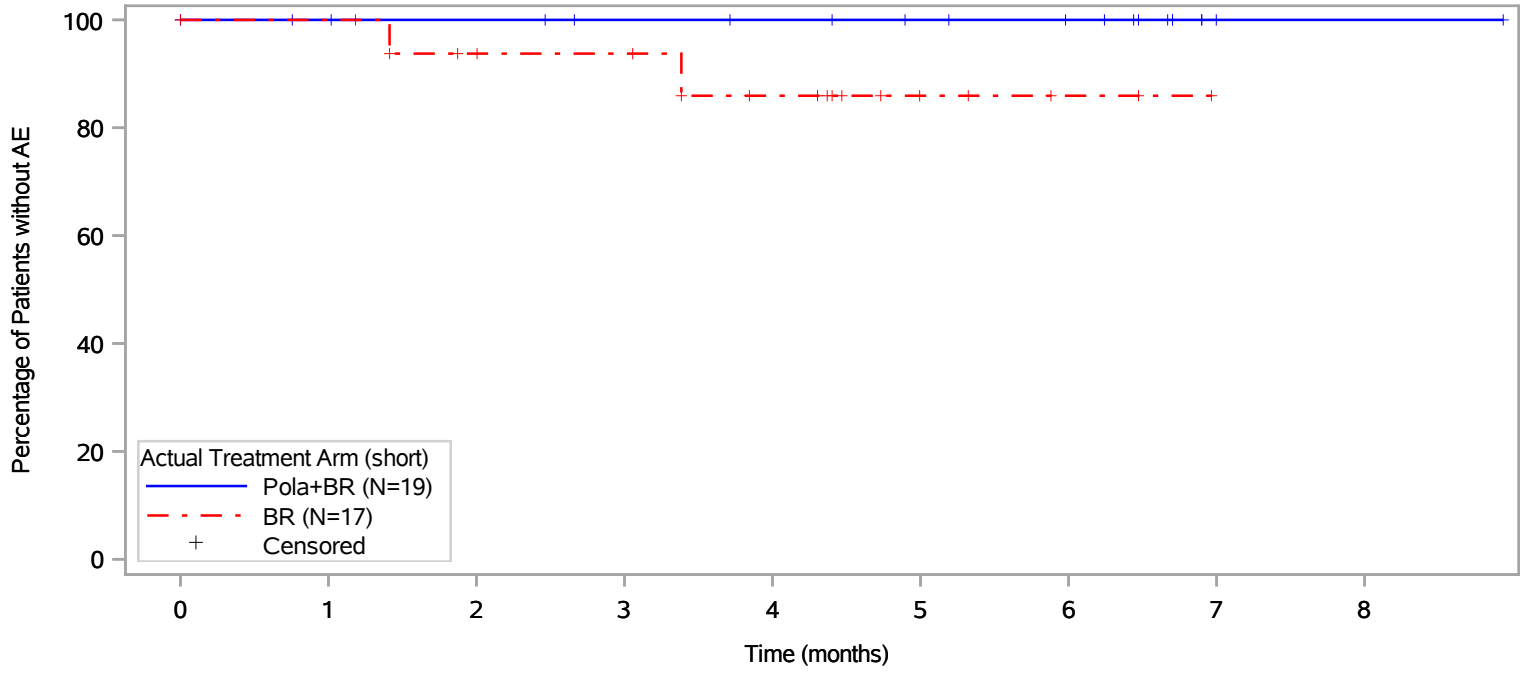
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOMAGNESAEMIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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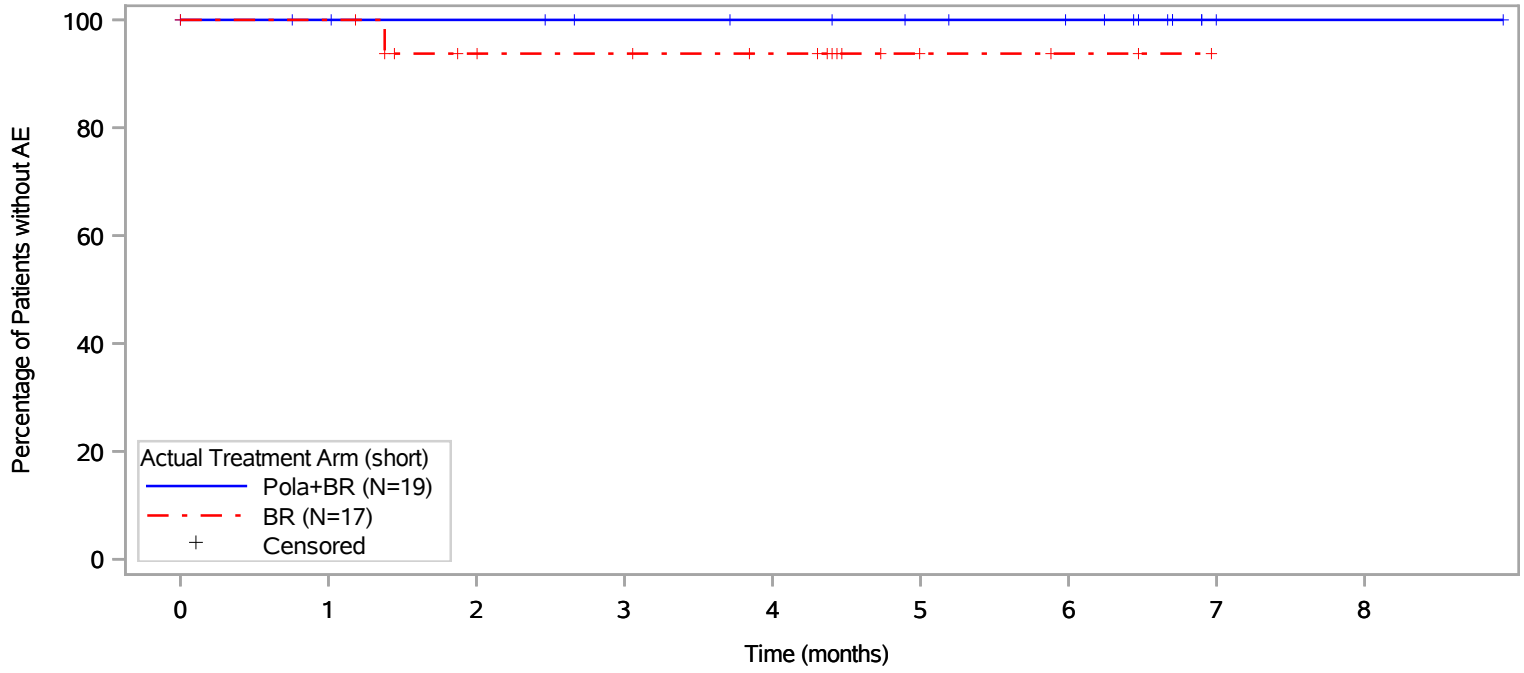
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPONATRAEMIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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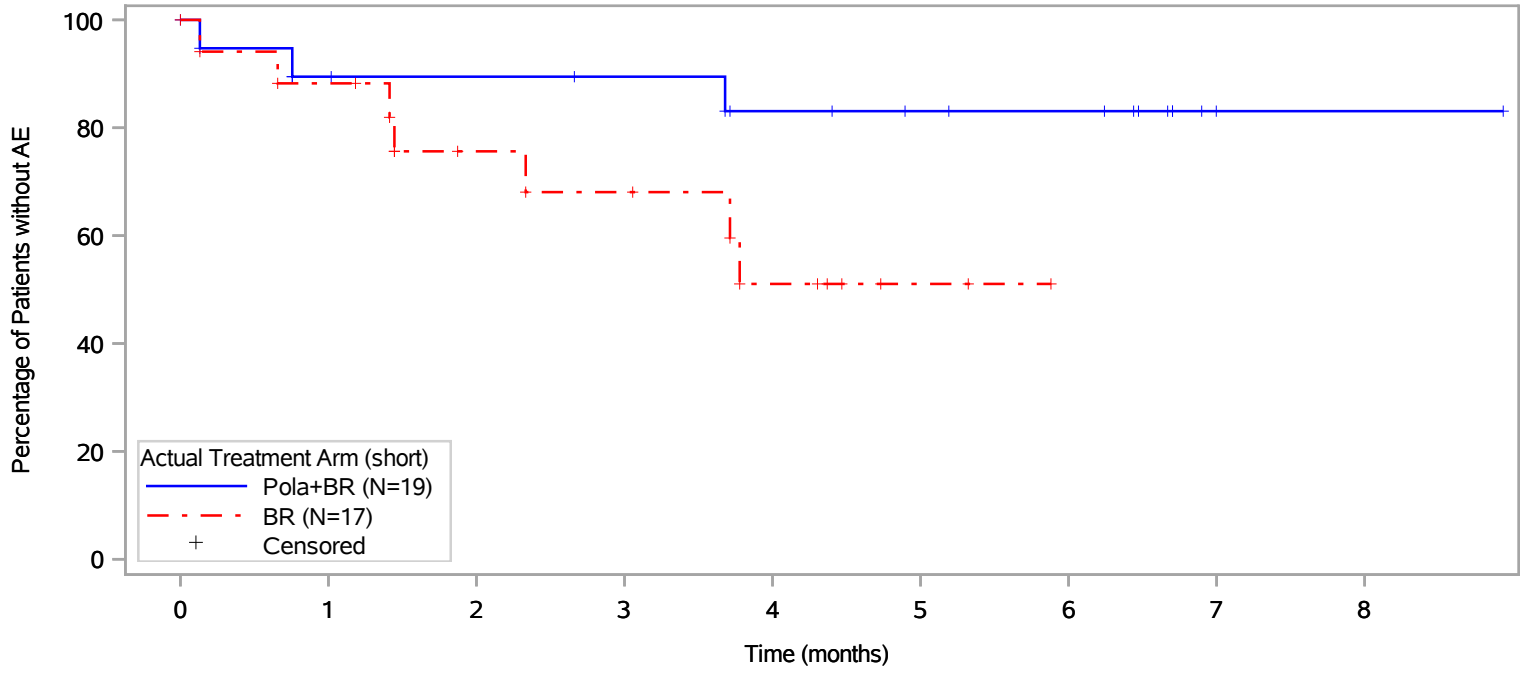
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	16	15	14	12	10	9	1	1
BR (N=17)	17	15	10	9	6	2	NE	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	7	15	15
BR (N=17)	0	0	3	3	4	8	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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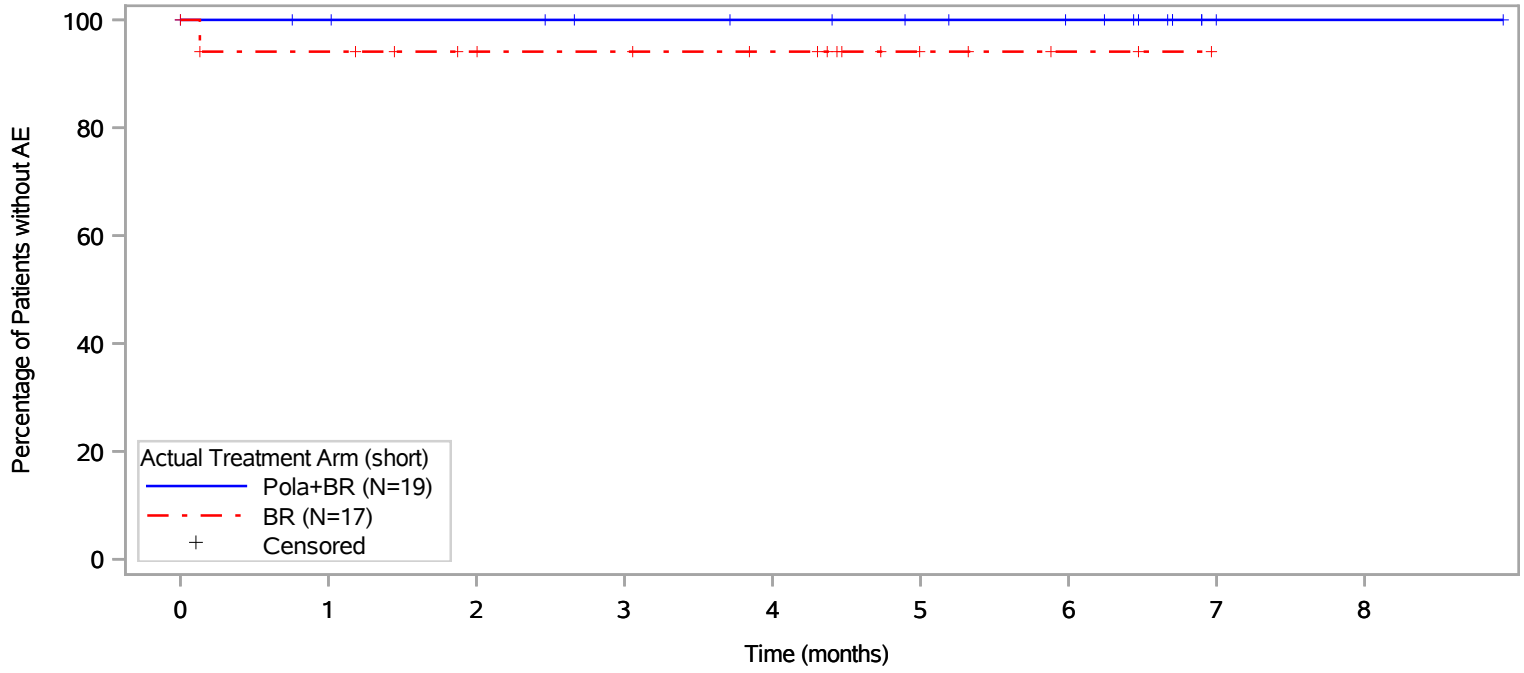
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

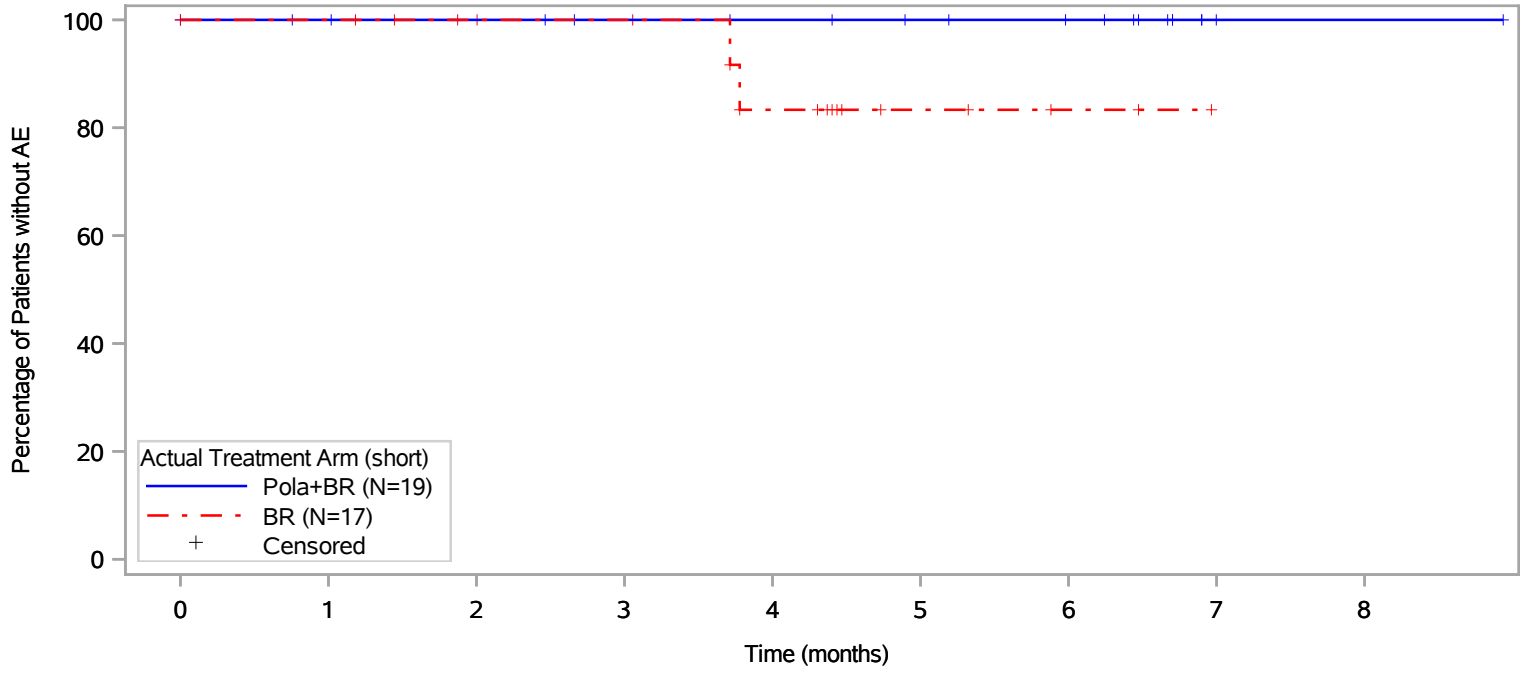
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, ARTHRALGIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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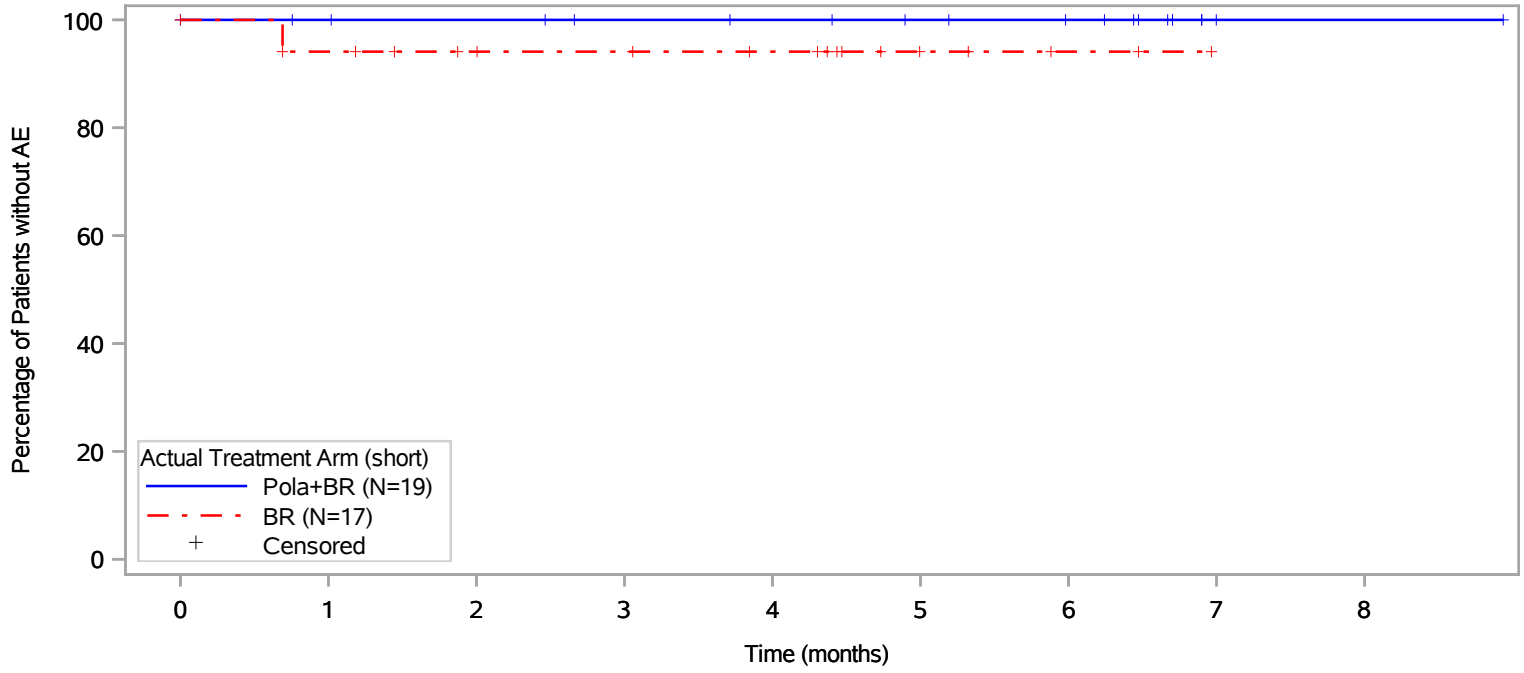
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, LIMB DISCOMFORT

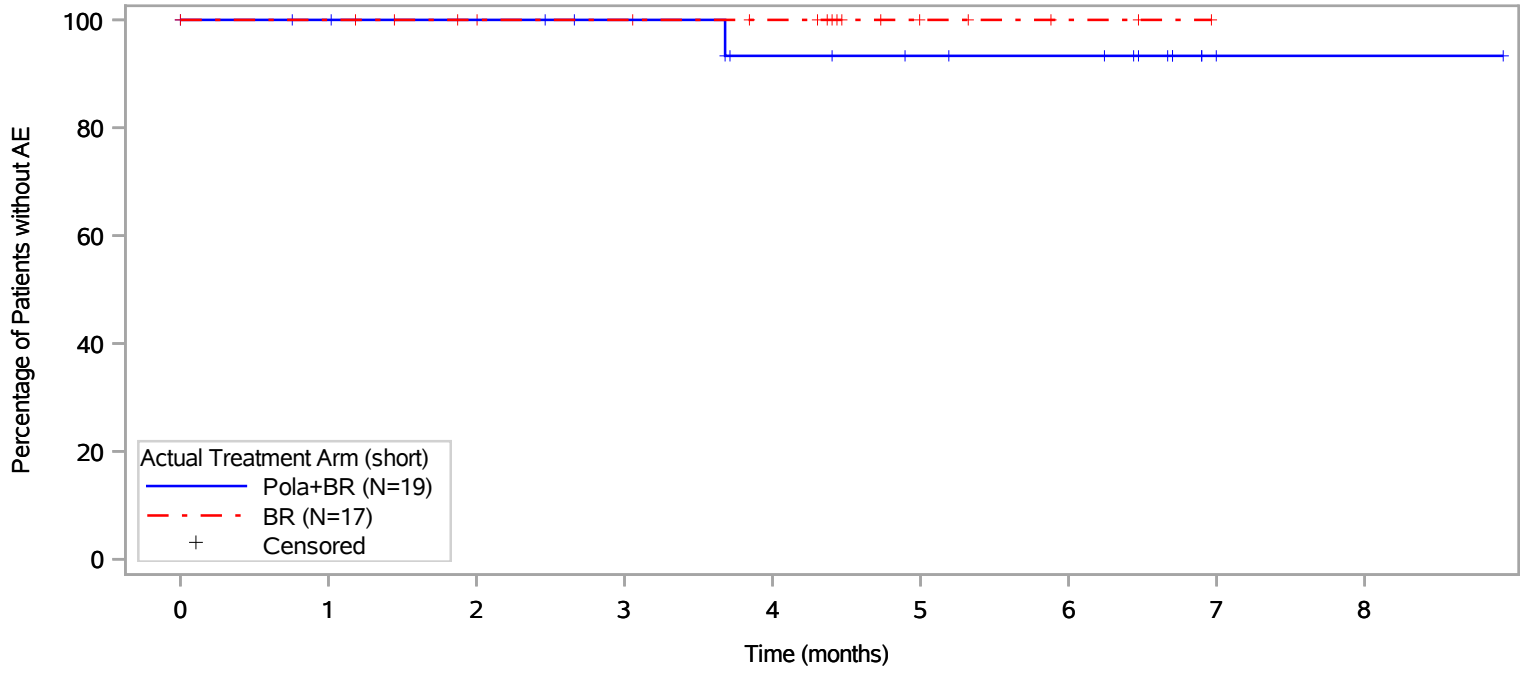


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCLE ATROPHY

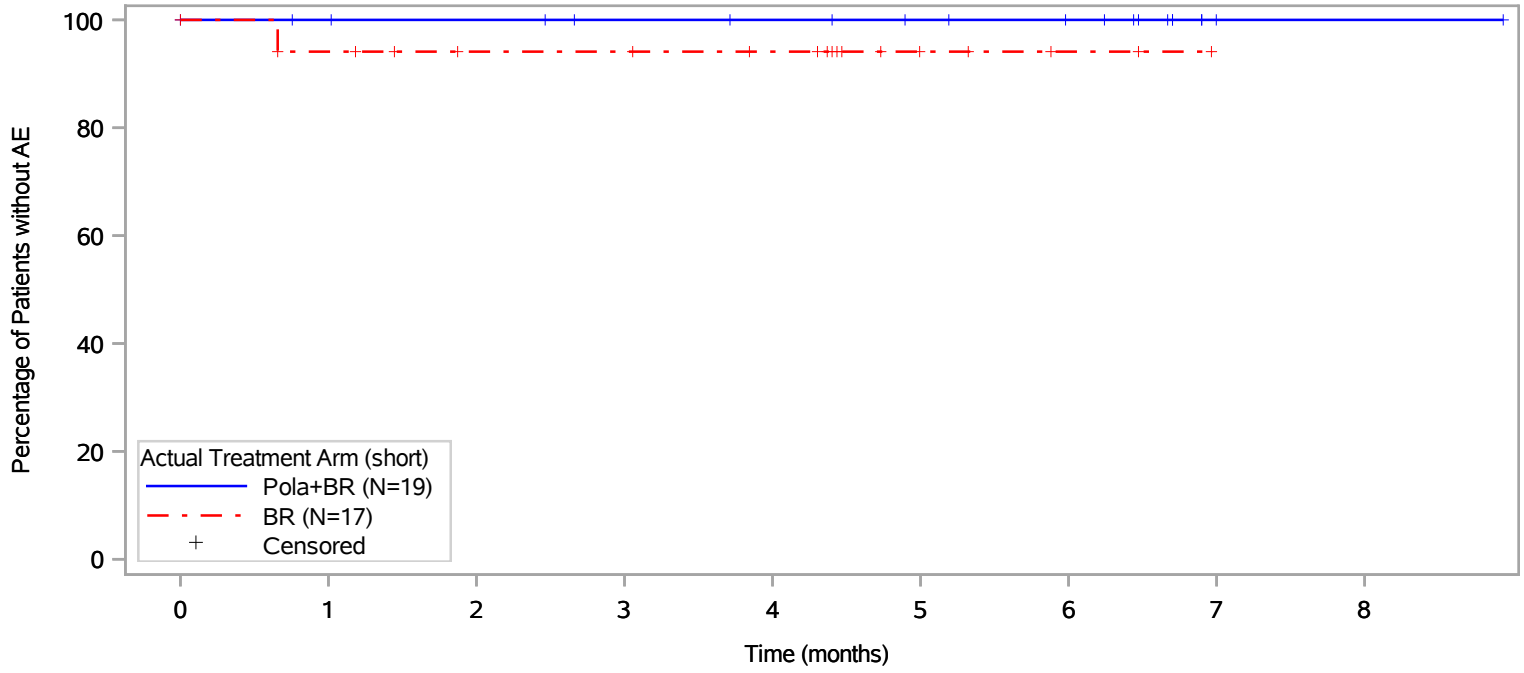


Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULAR WEAKNESS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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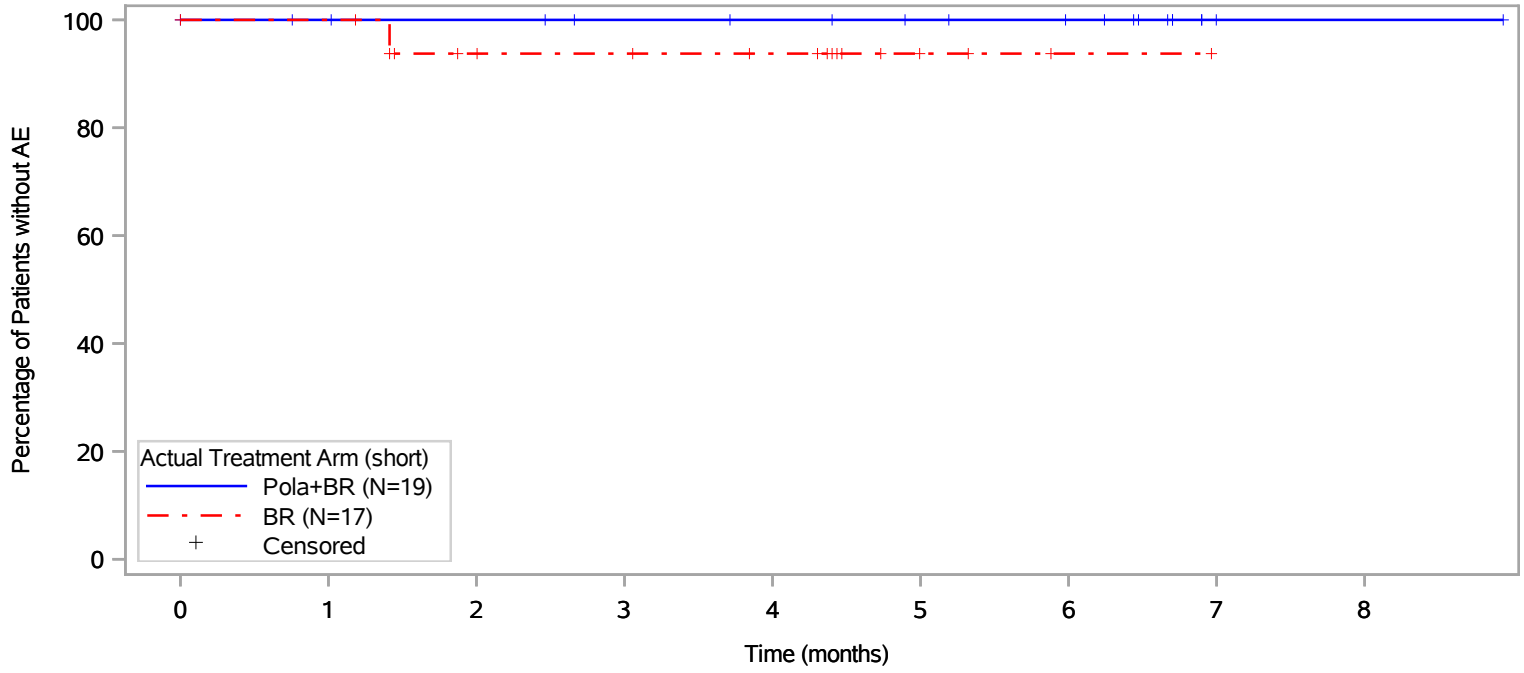
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULOSKELETAL DISCOMFORT



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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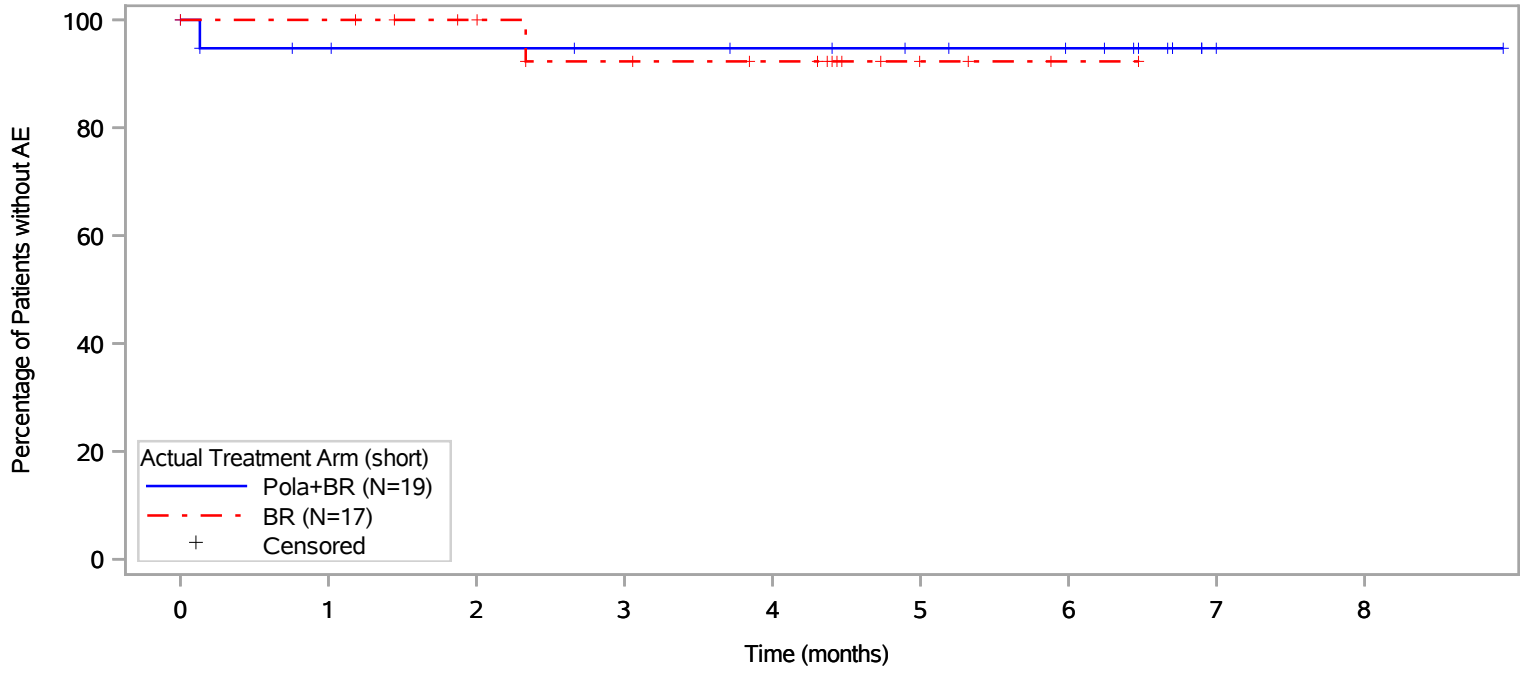
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MYALGIA



Patients at risk									
Pola+BR (N=19)	19	17	16	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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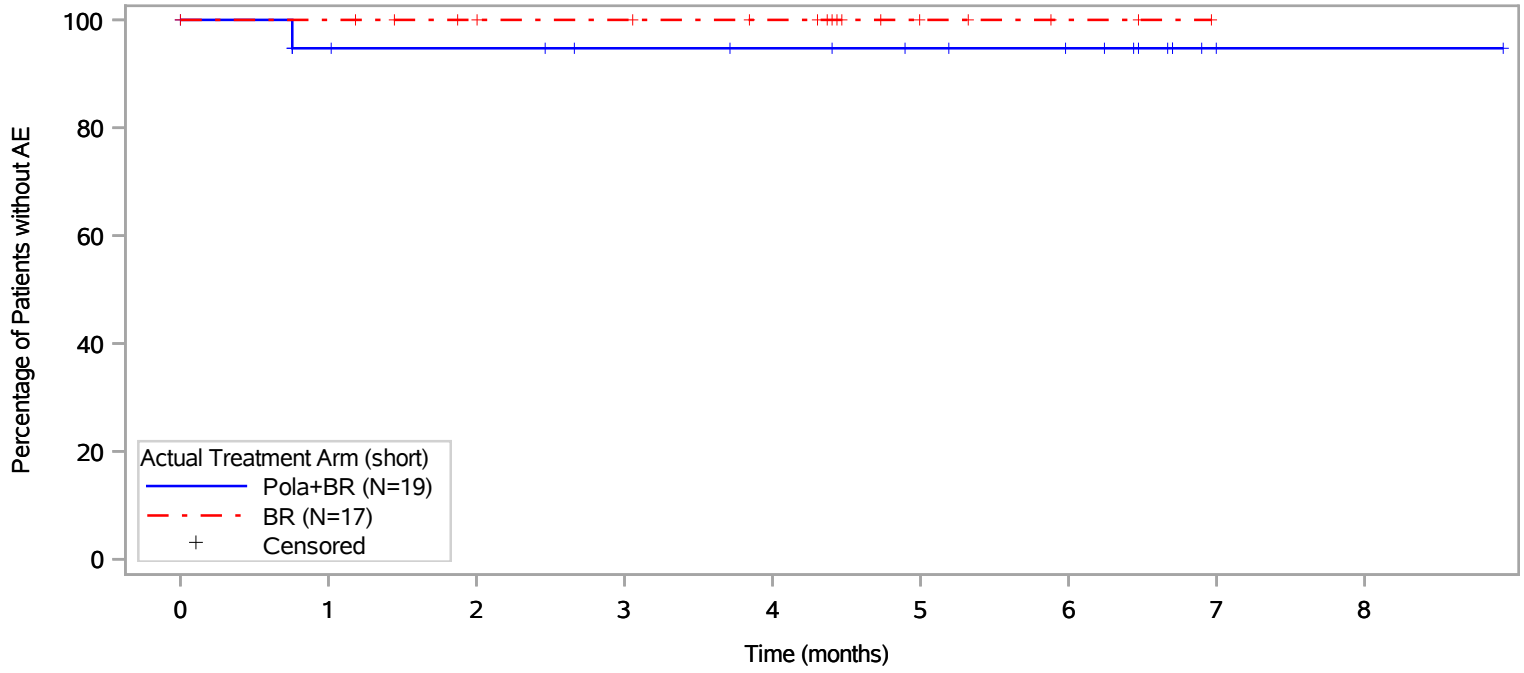
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MYOPATHY



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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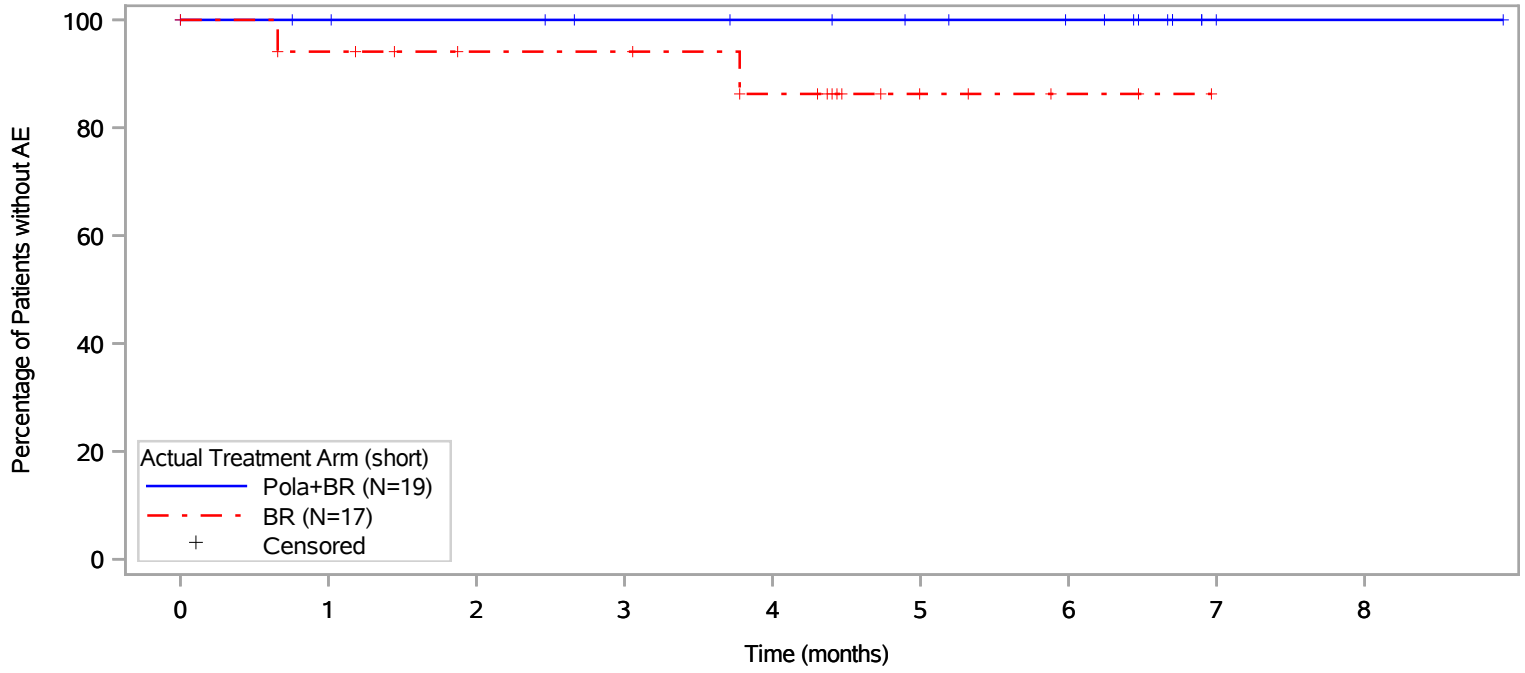
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, PAIN IN EXTREMITY



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	3	4	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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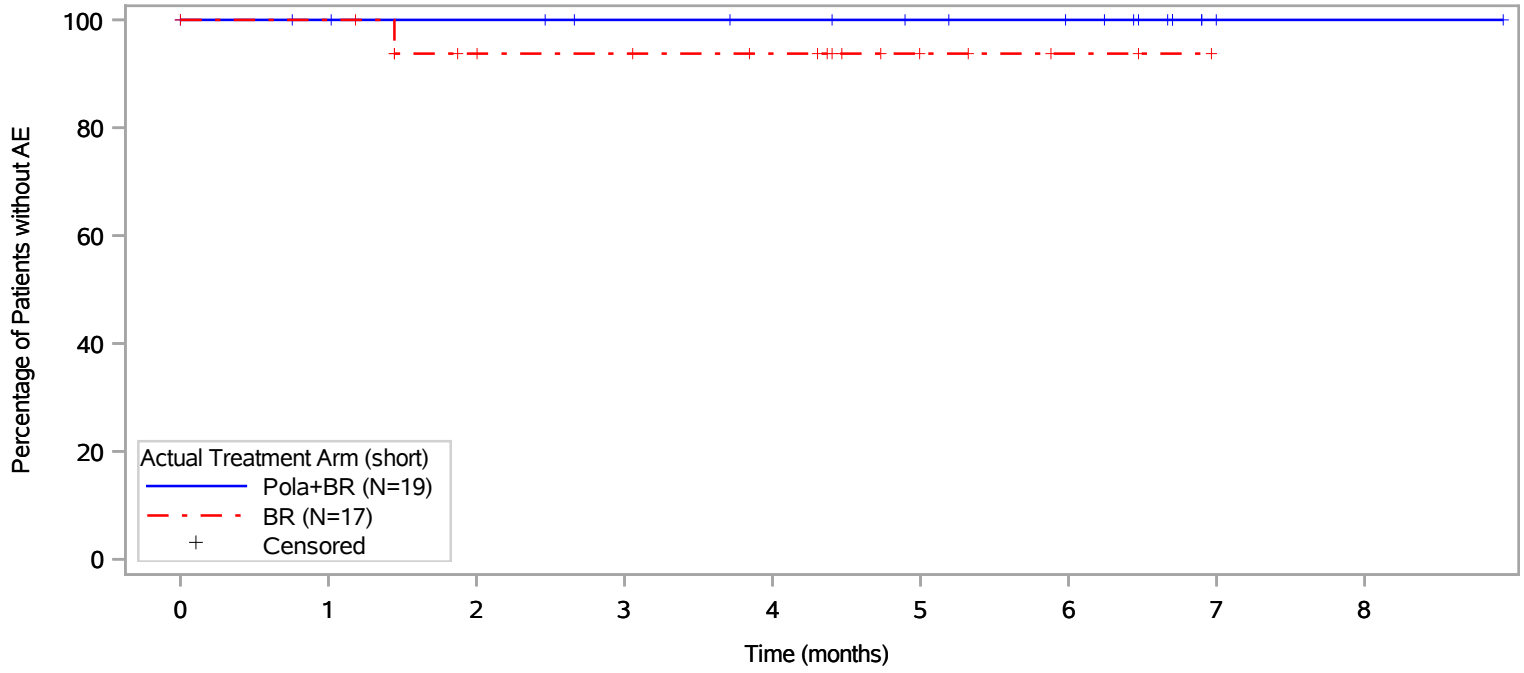
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, PAIN IN JAW



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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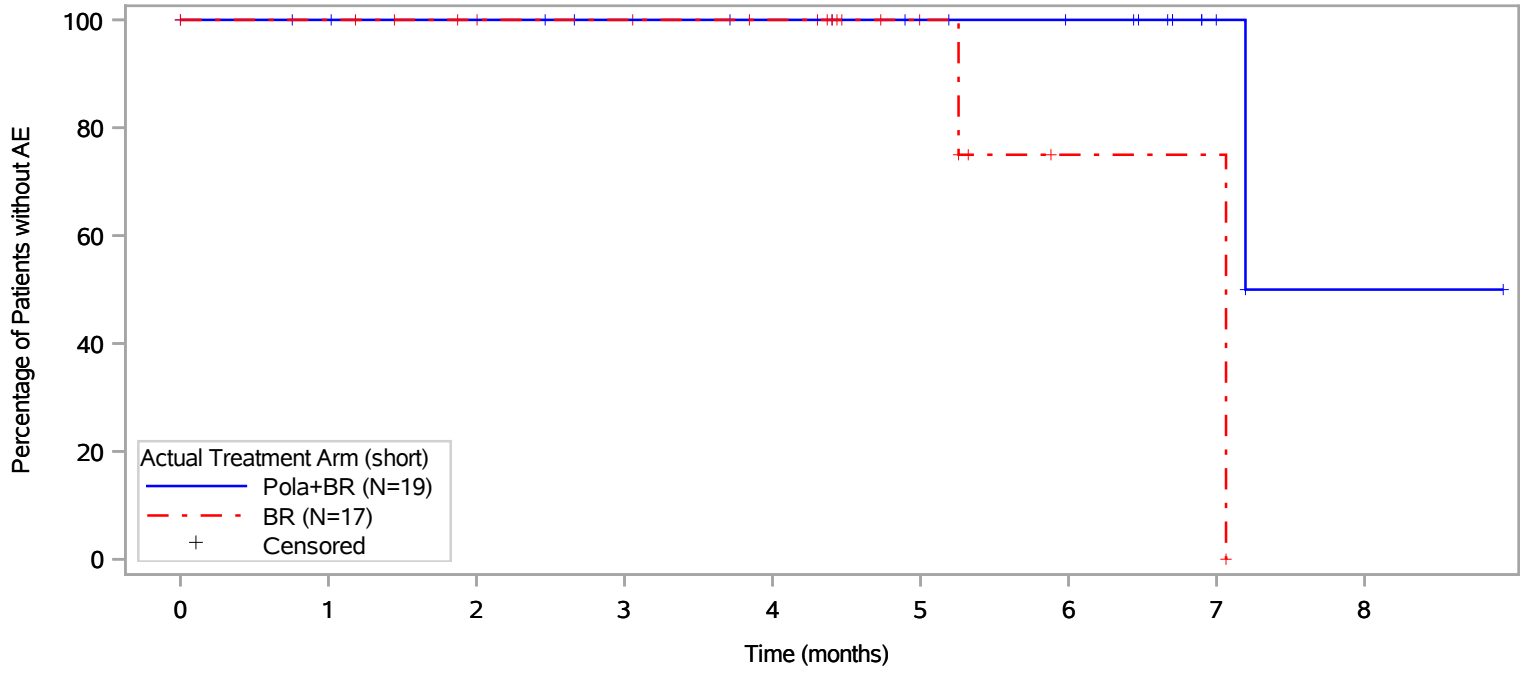
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	1
BR (N=17)	17	17	14	13	11	4	1	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	15	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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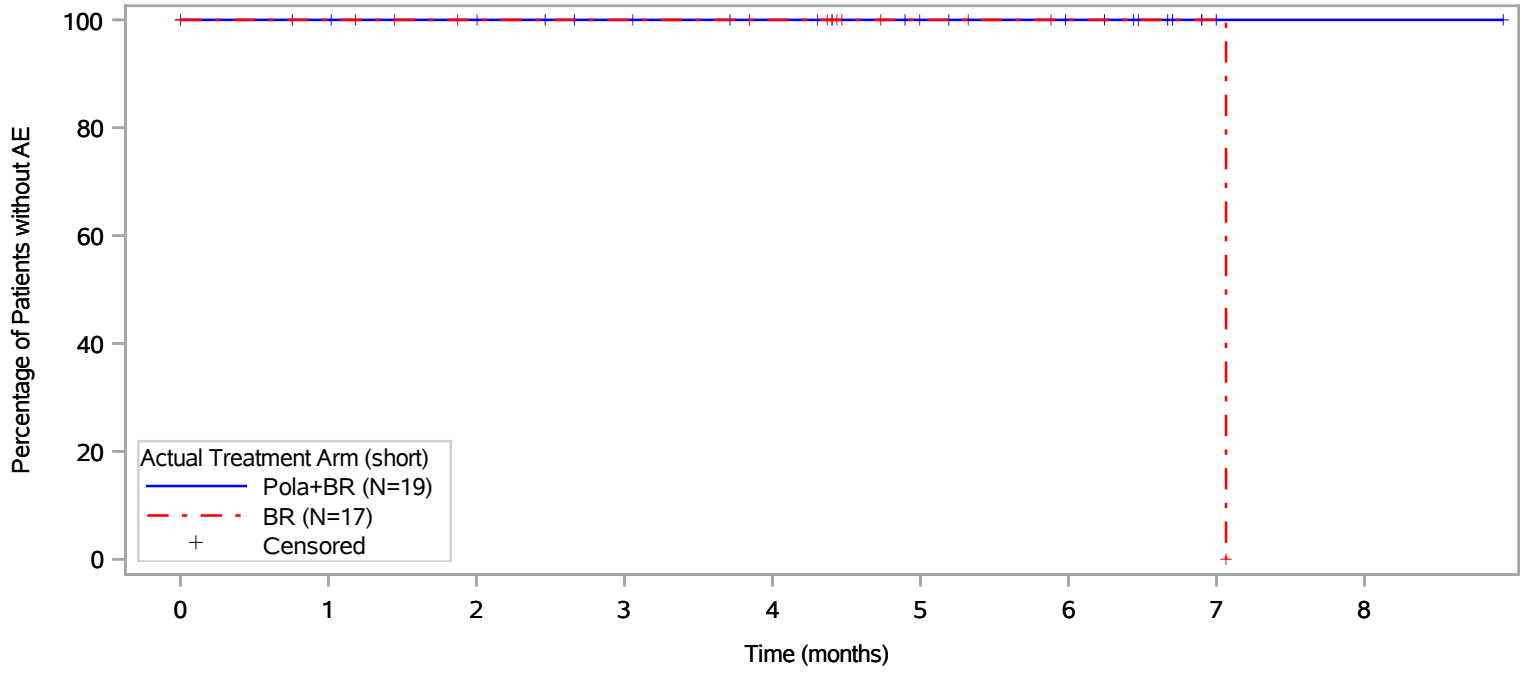
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), EPIGLOTTIC CANCER



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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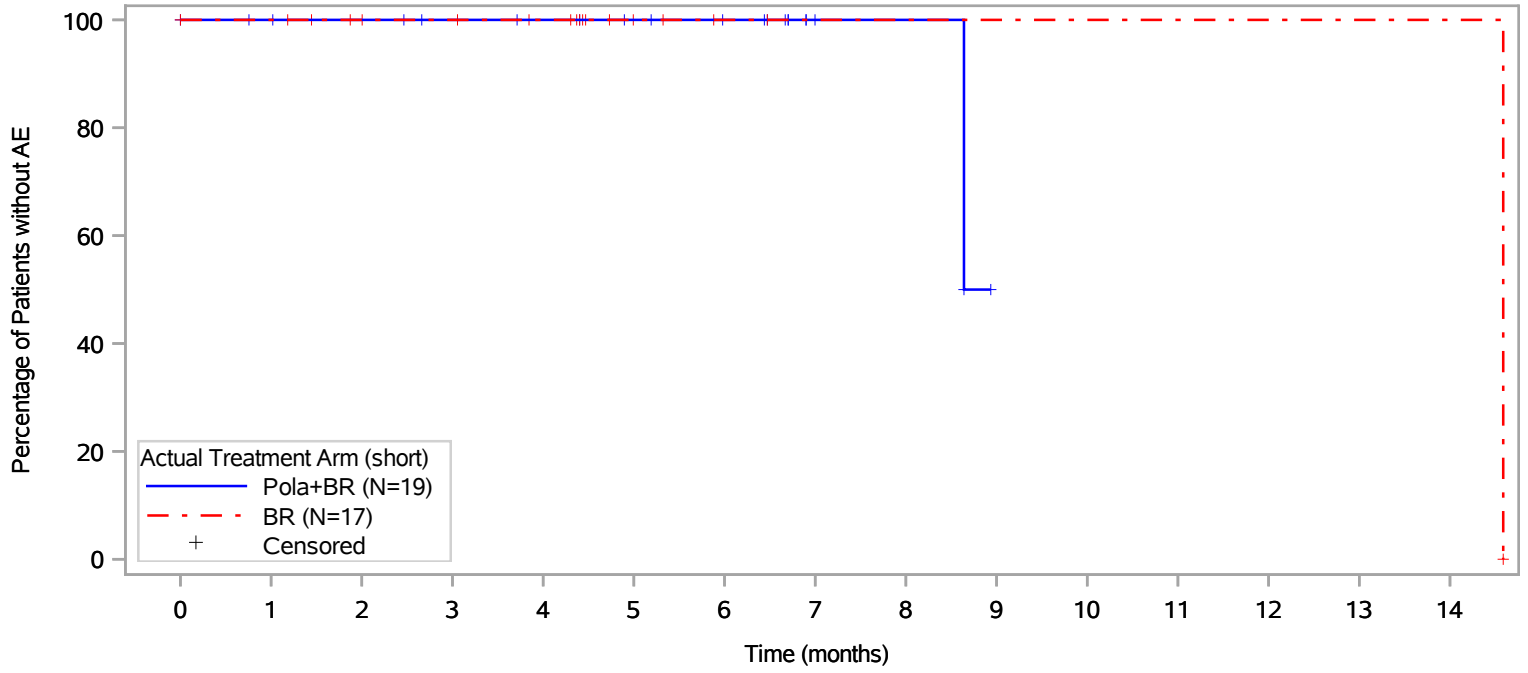
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



Patients at risk															
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	NE	NE	NE	NE	NE	NE
BR (N=17)	17	17	14	13	11	4	2	1	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	NE	NE	NE	NE	NE	NE
BR (N=17)	0	0	3	4	6	13	15	16	16	16	16	16	16	16	16

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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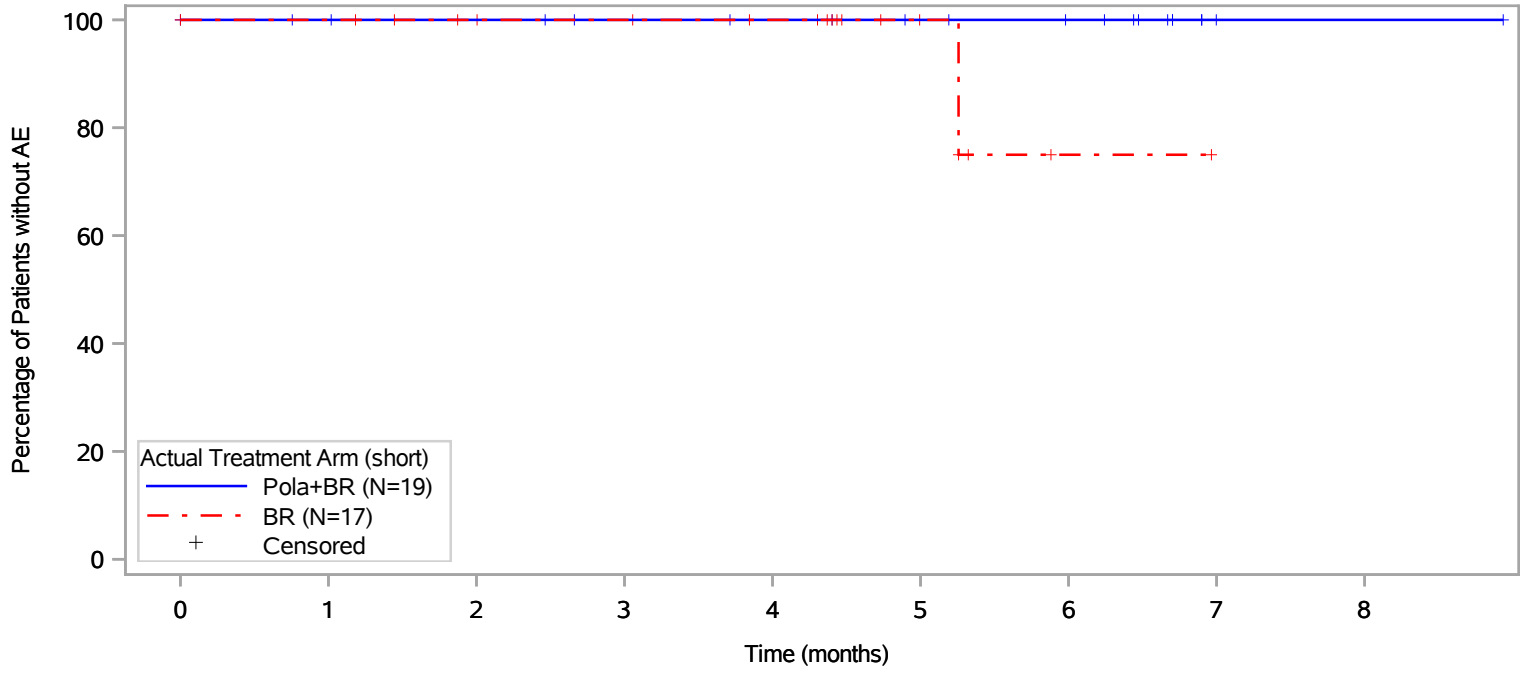
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), PAPILLARY THYROID CANCER



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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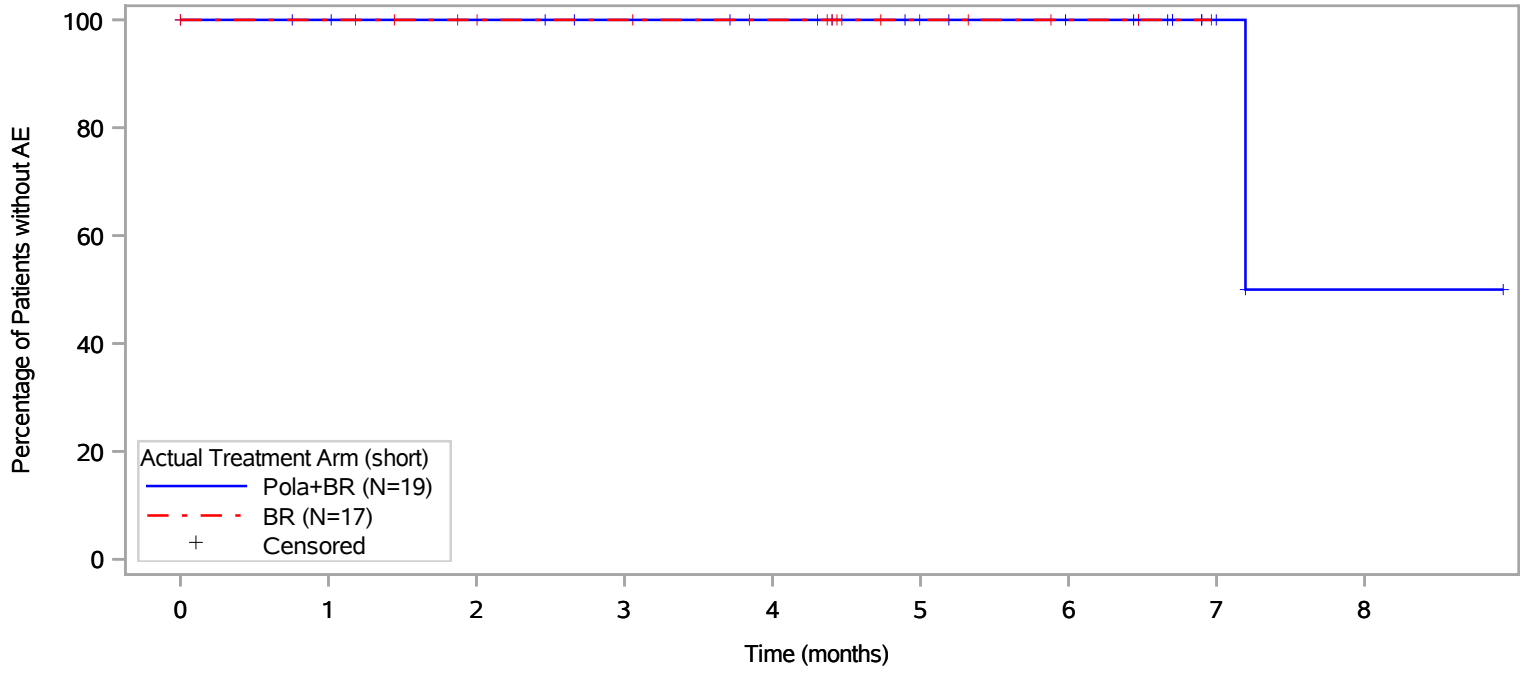
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), SQUAMOUS CELL CARCINOMA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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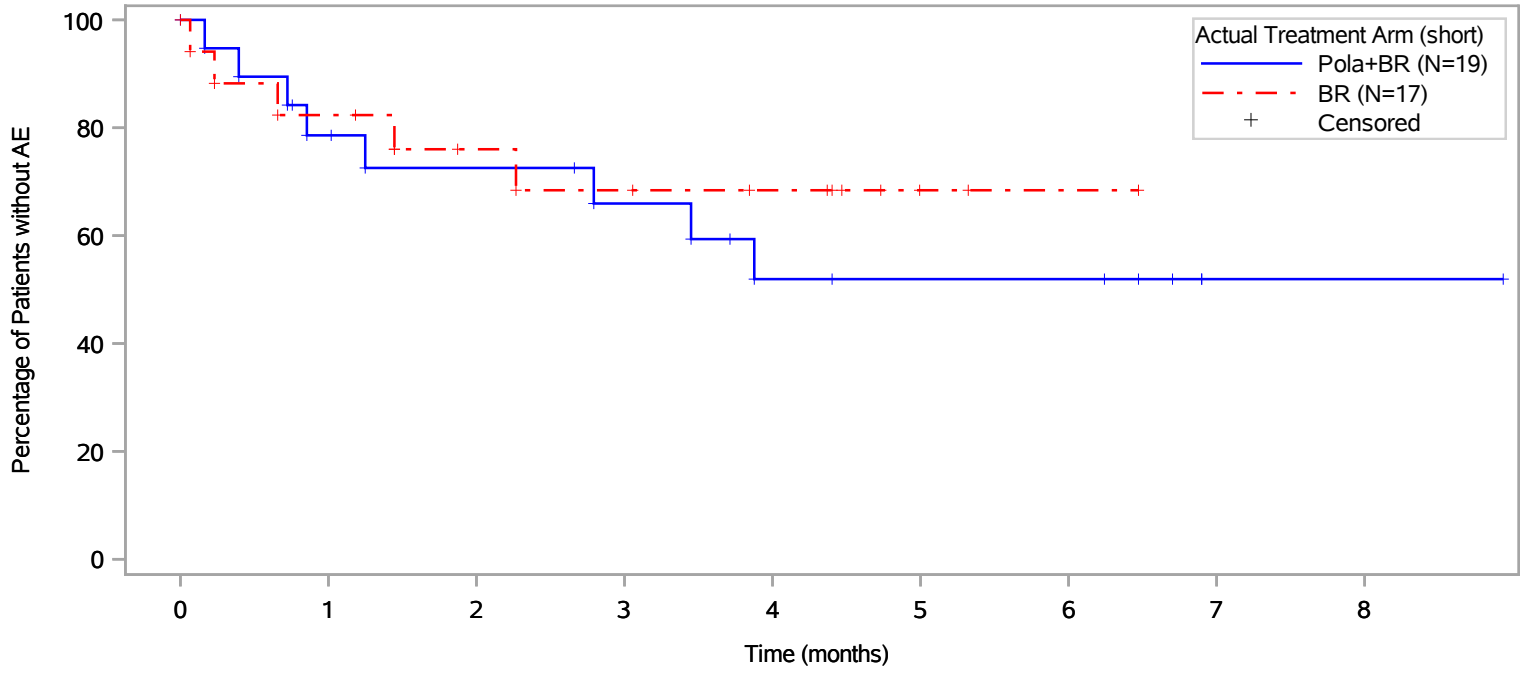
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	14	12	10	7	6	6	1	1
BR (N=17)	17	14	10	9	7	2	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	5	10	10
BR (N=17)	0	0	3	3	5	10	11	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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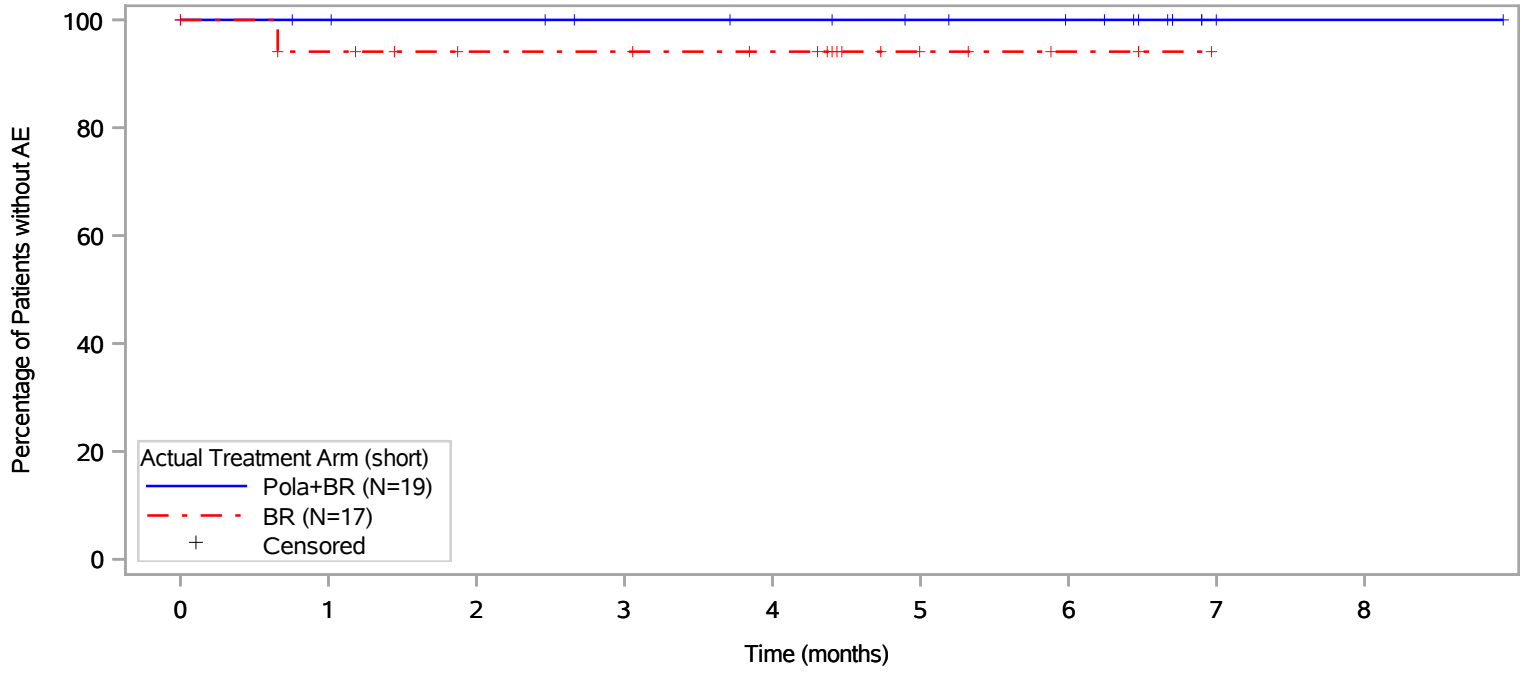
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, DECREASED VIBRATORY SENSE

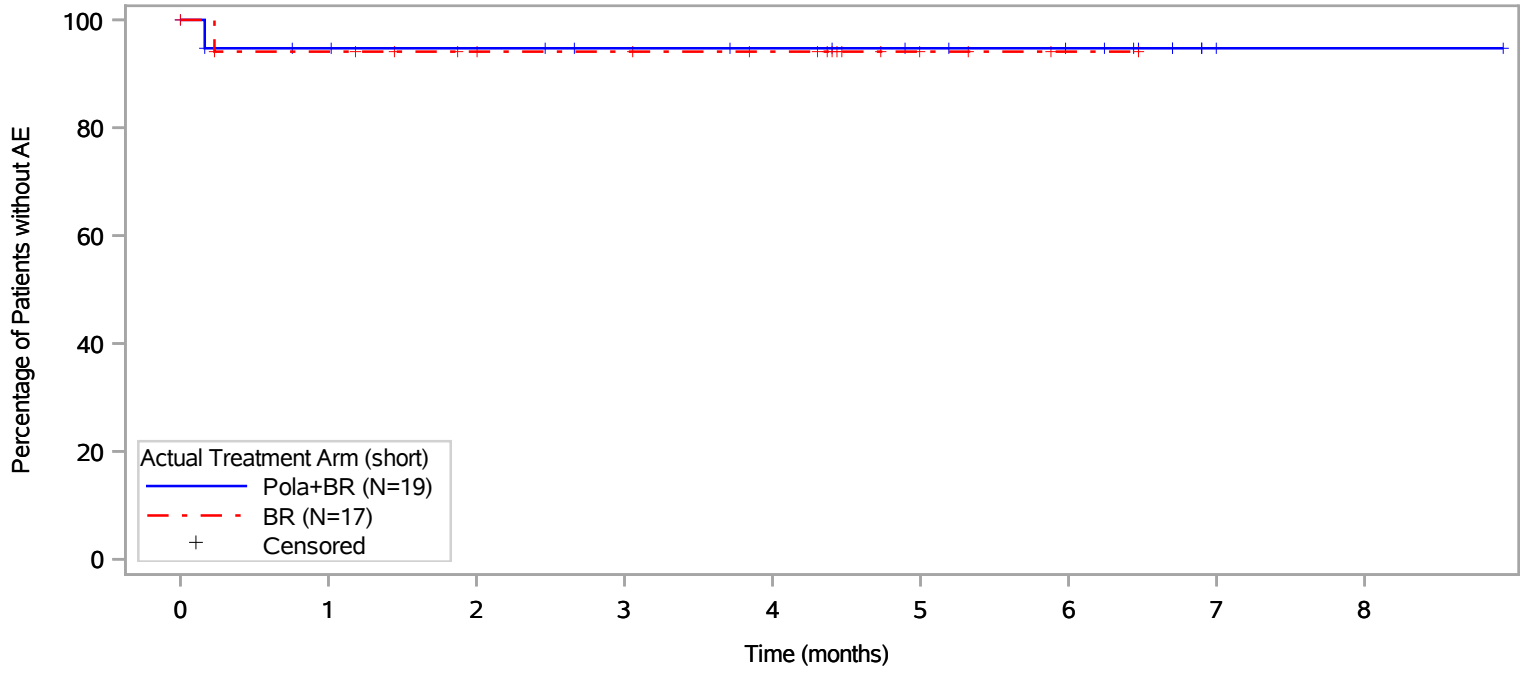


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, DIZZINESS



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	16	13	12	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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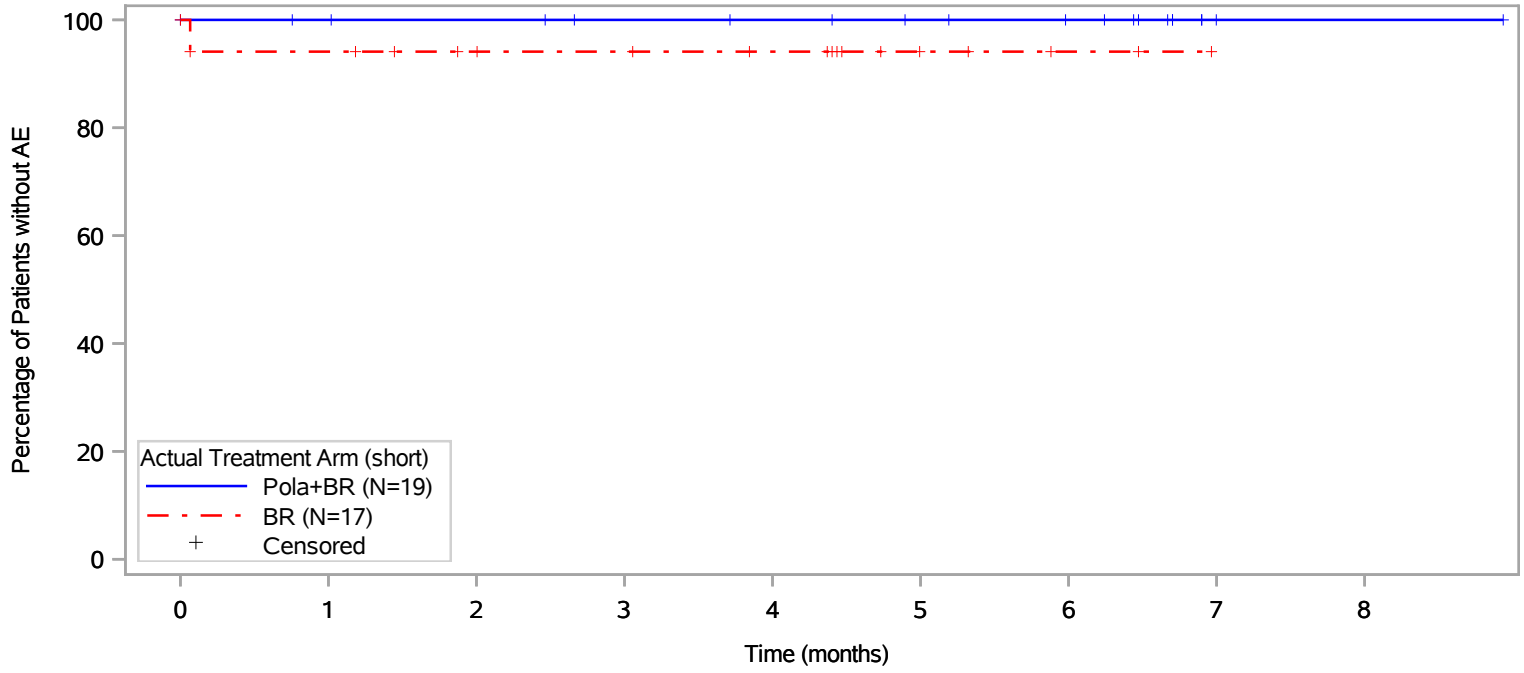
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, DYSGEUSIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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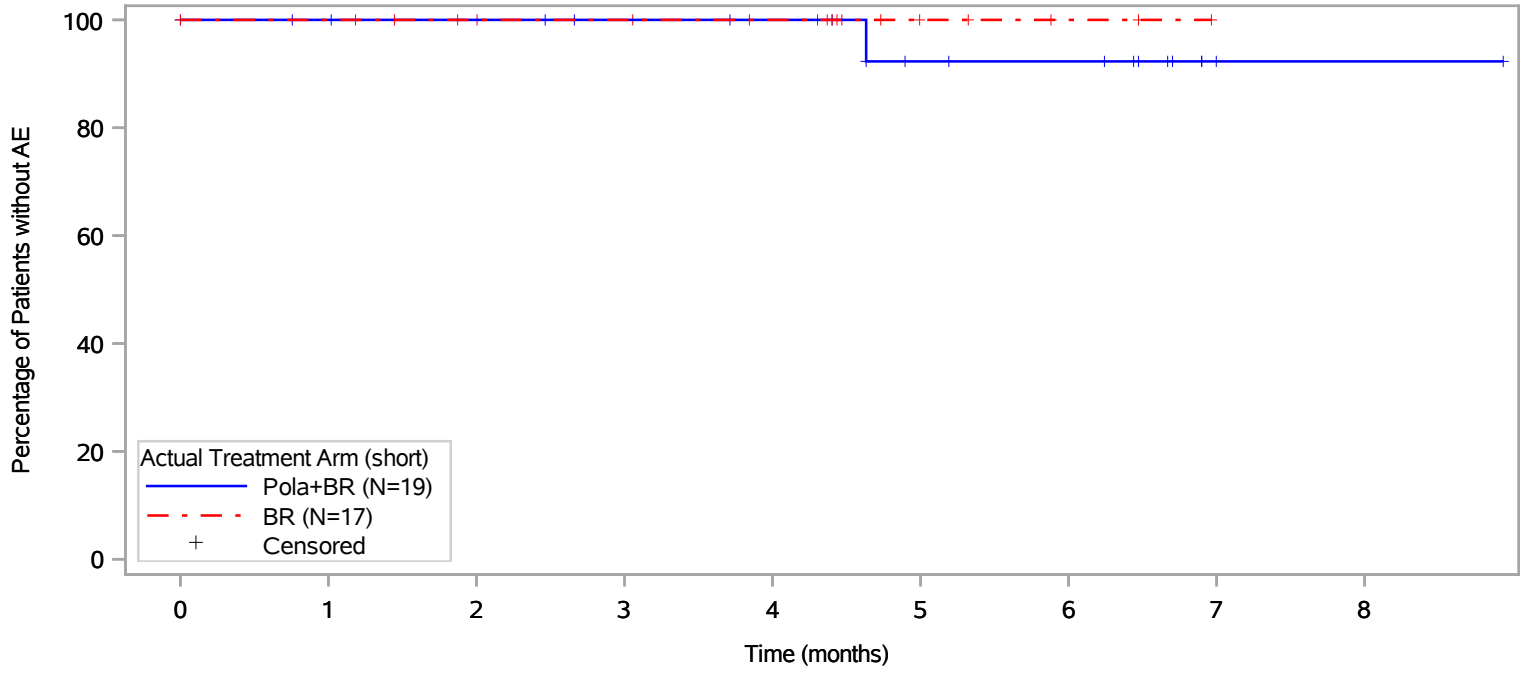
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, FACIAL PARALYSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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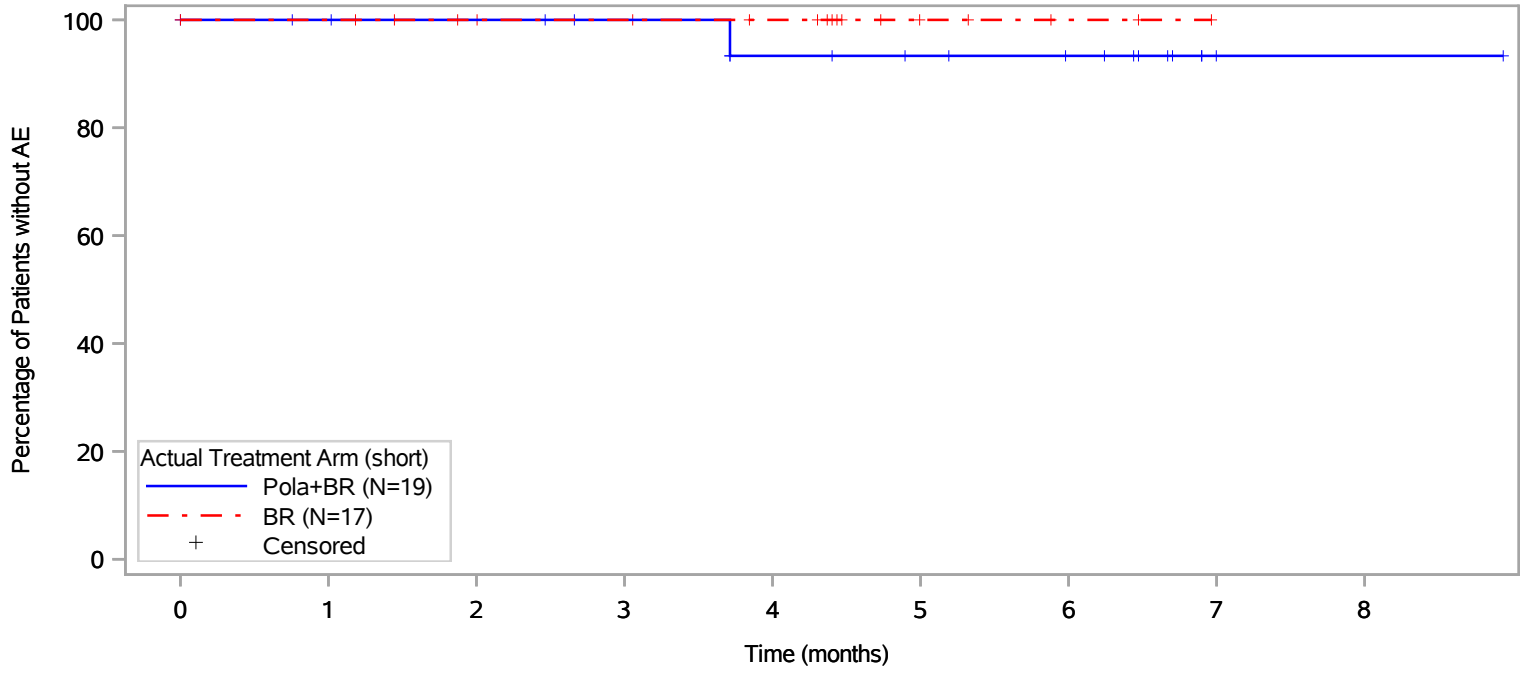
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, HYPOTONIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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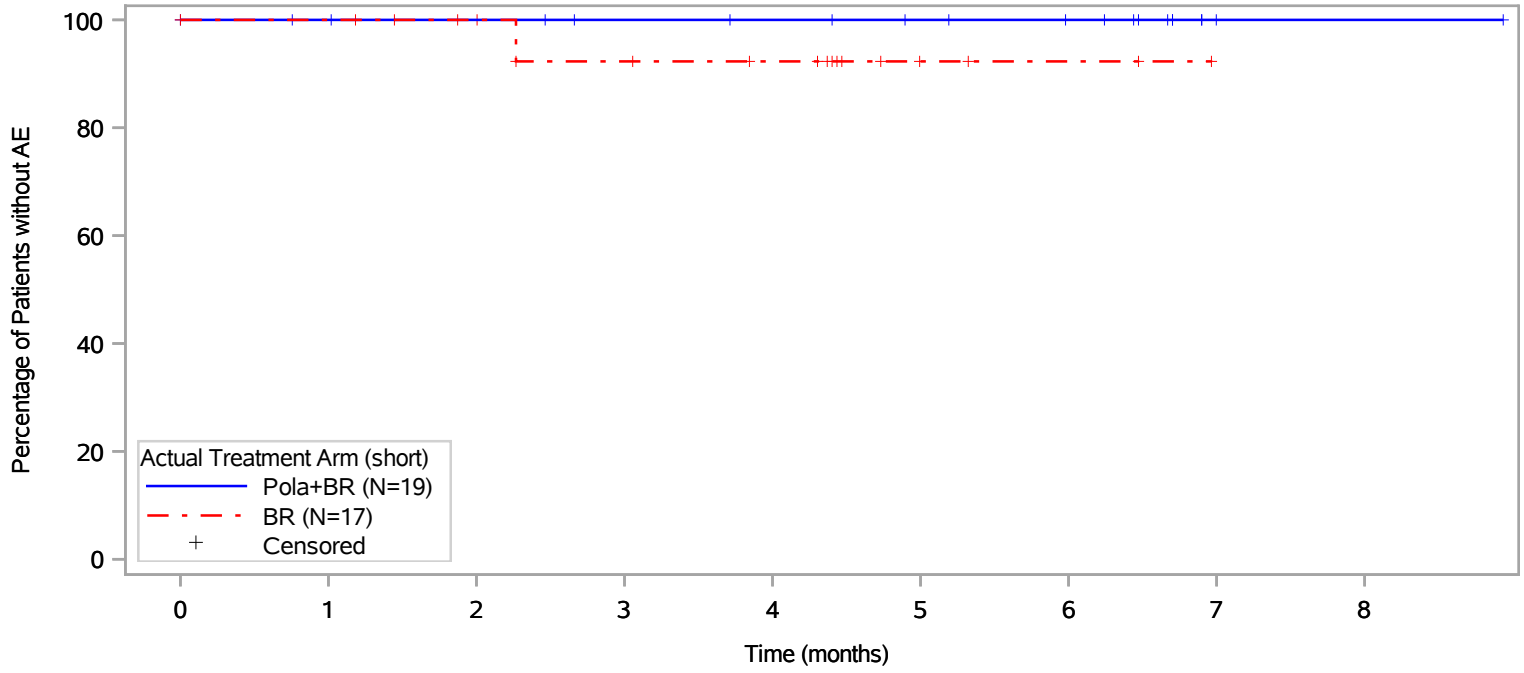
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, NEURALGIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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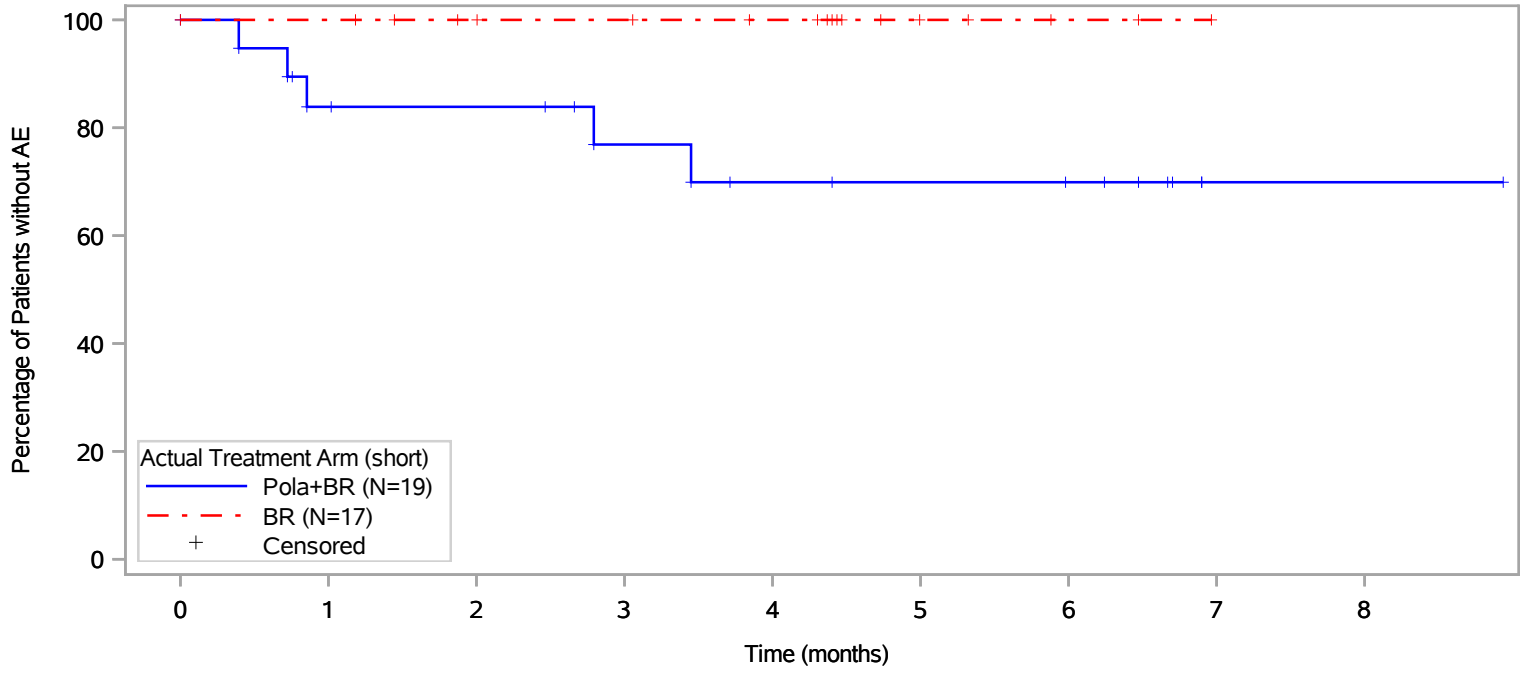
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, NEUROPATHY PERIPHERAL



Patients at risk									
Pola+BR (N=19)	19	15	14	11	9	8	7	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	7	13	13
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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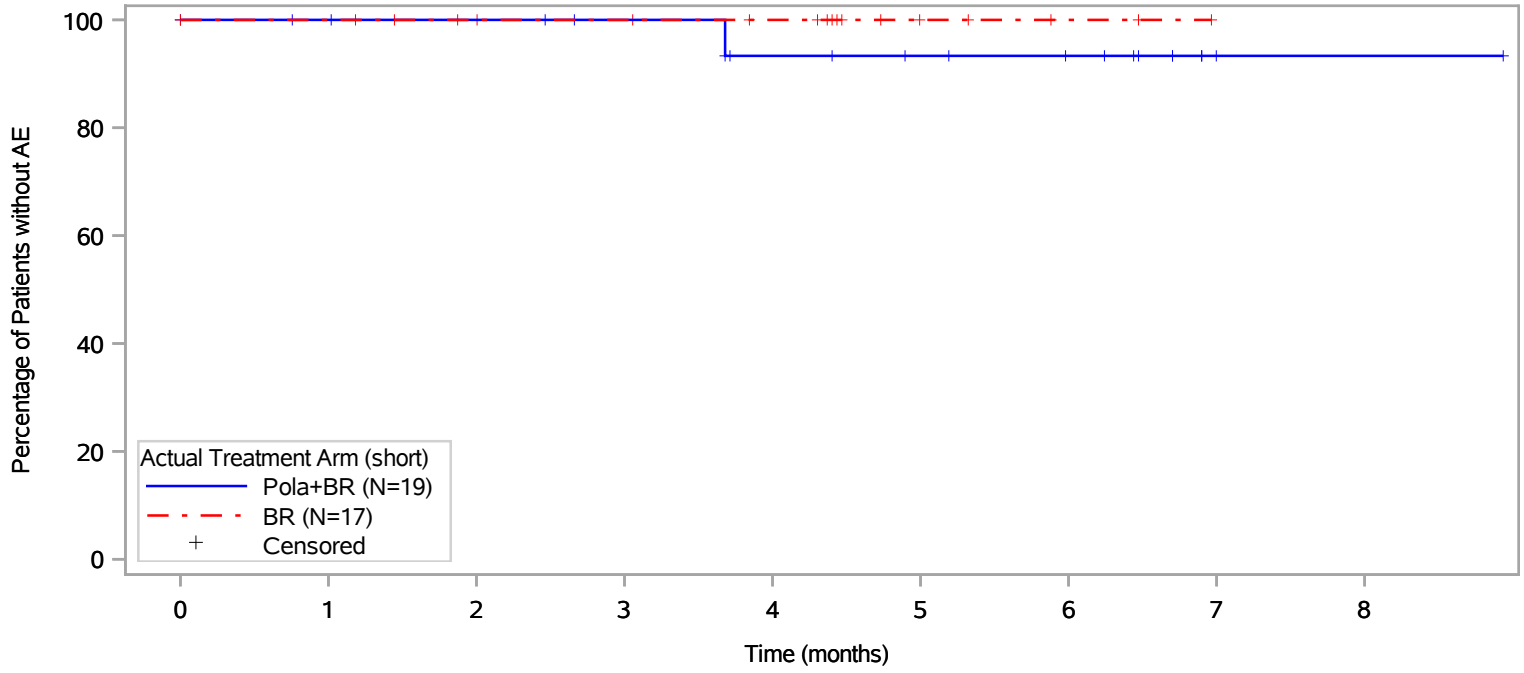
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, PARAESTHESIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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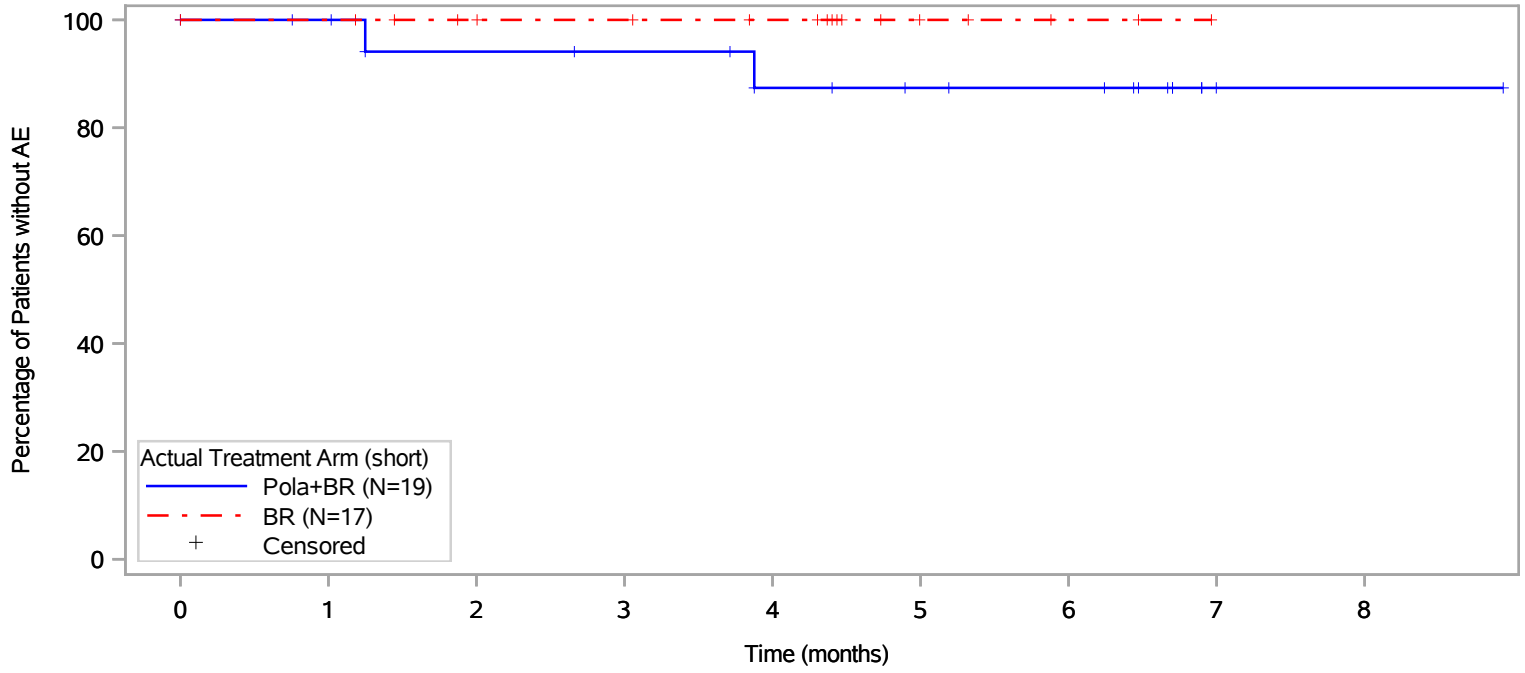
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, PERIPHERAL SENSORY NEUROPATHY



Patients at risk									
Pola+BR (N=19)	19	18	16	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	7	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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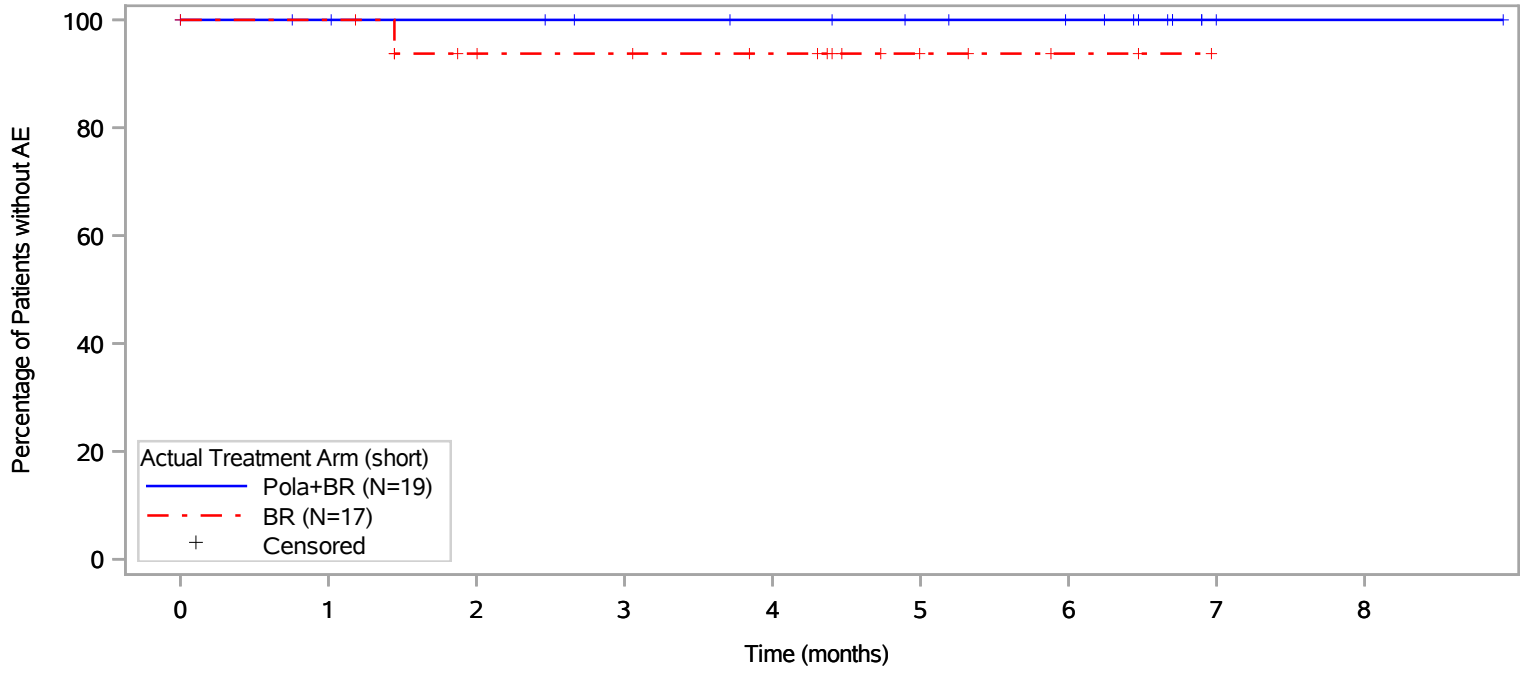
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, RESTLESS LEGS SYNDROME



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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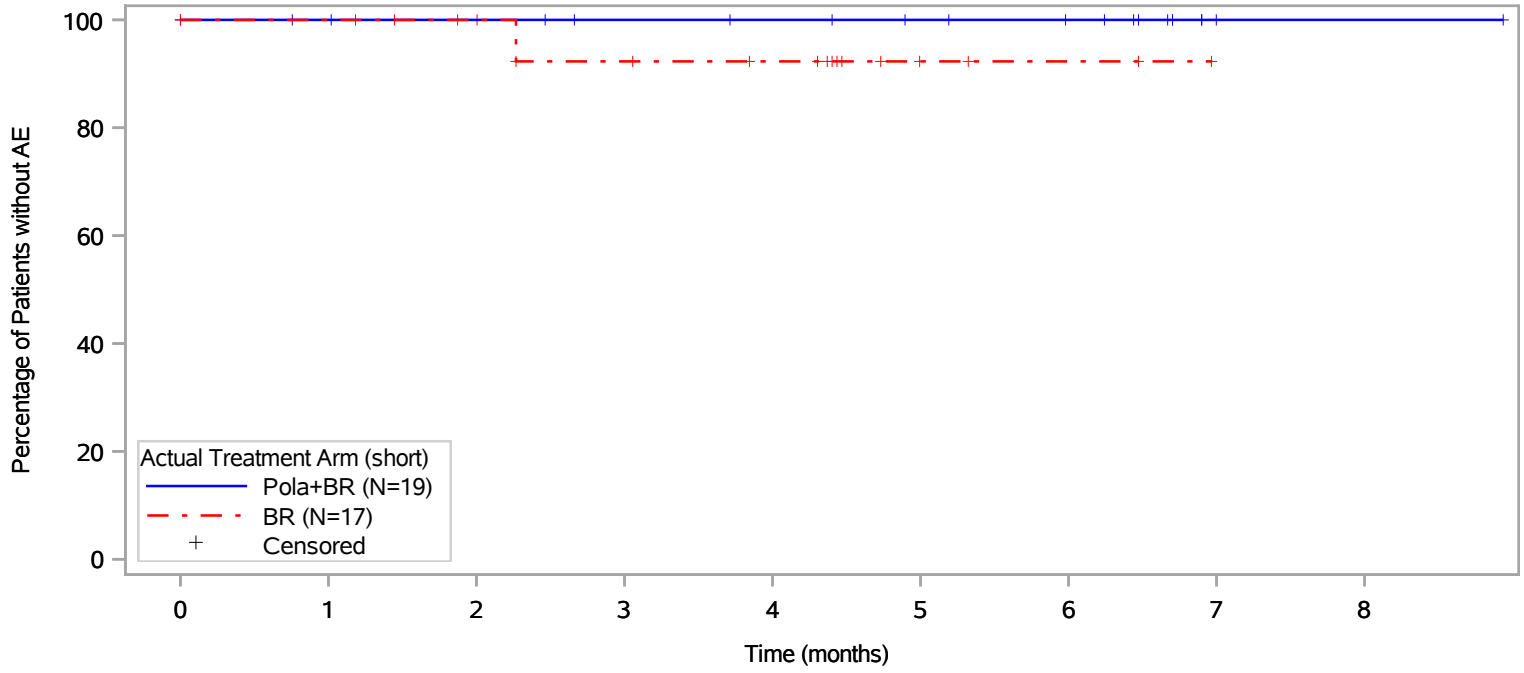
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, SYNCOPE



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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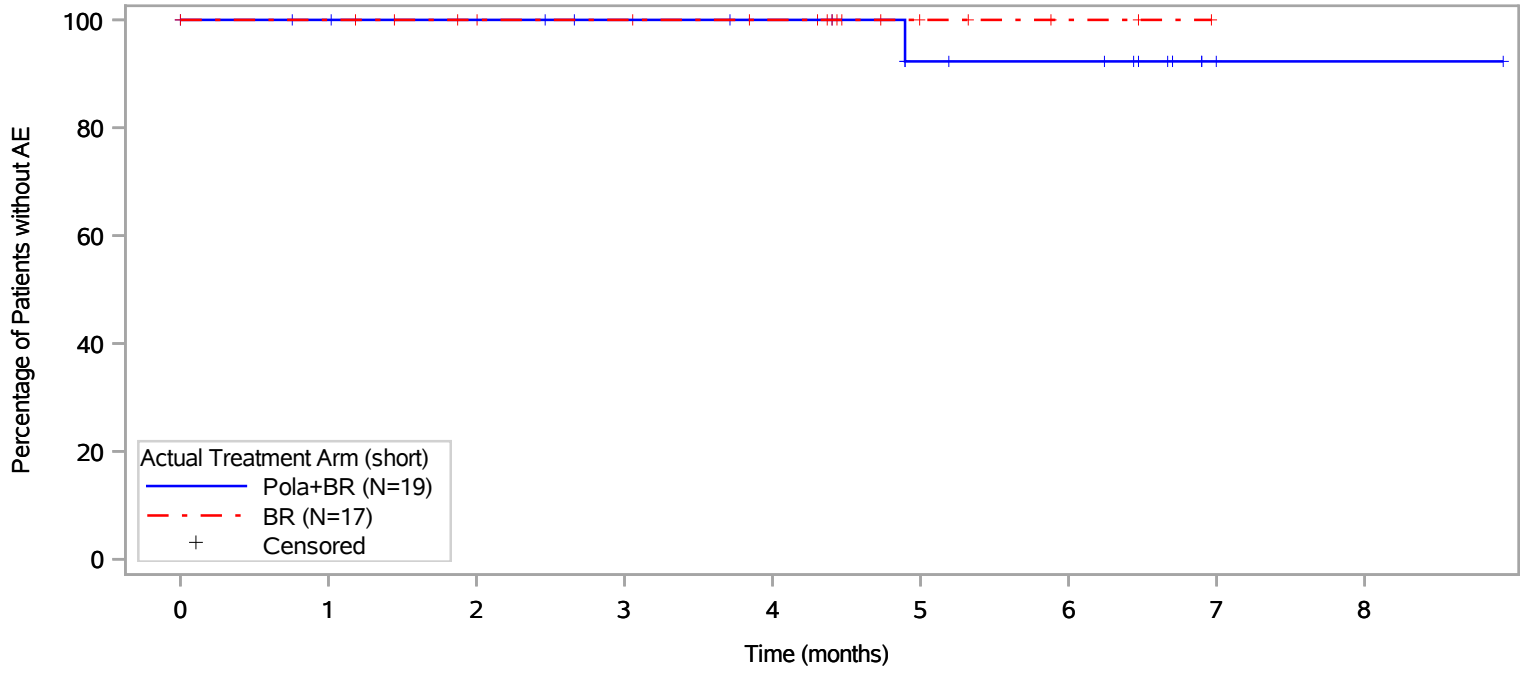
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, VOCAL CORD PARALYSIS

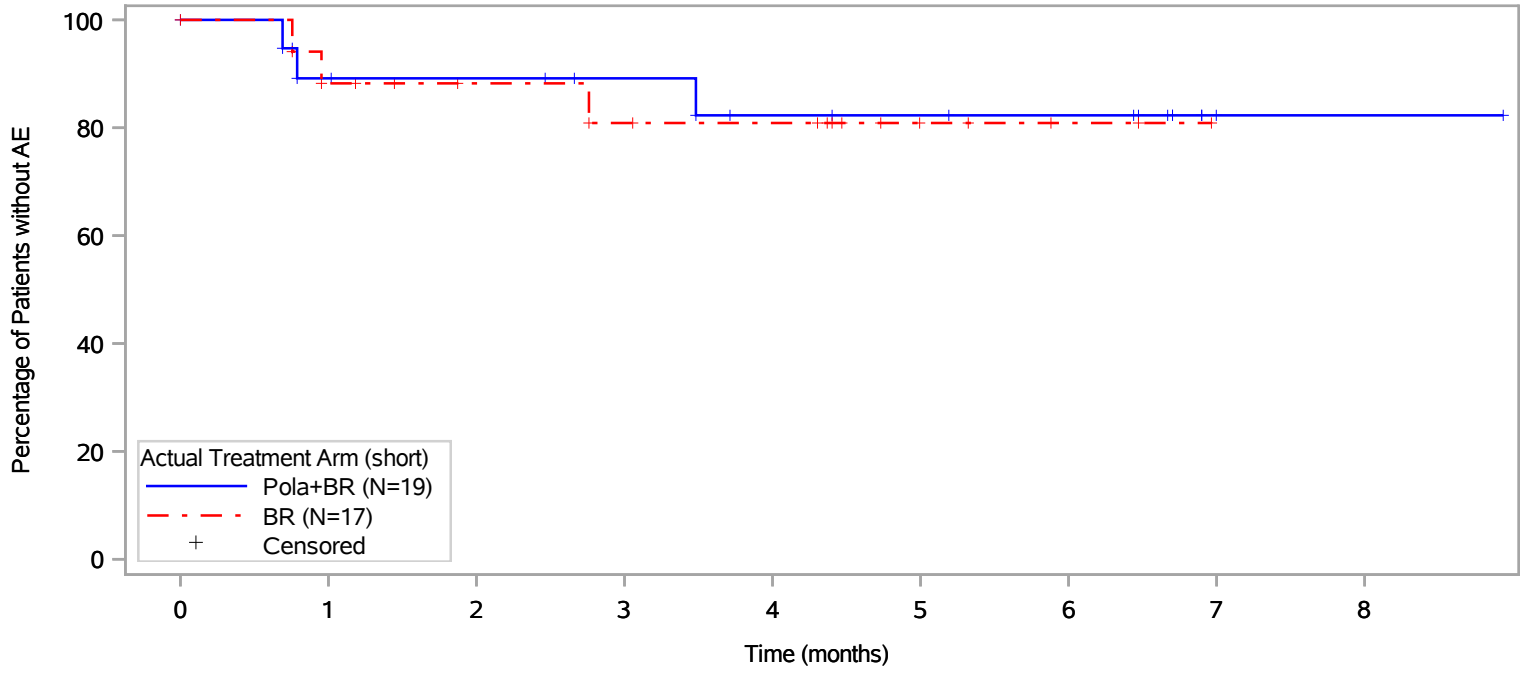


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	16	15	13	11	10	9	1	1
BR (N=17)	17	15	12	11	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	7	15	15
BR (N=17)	0	0	3	3	4	10	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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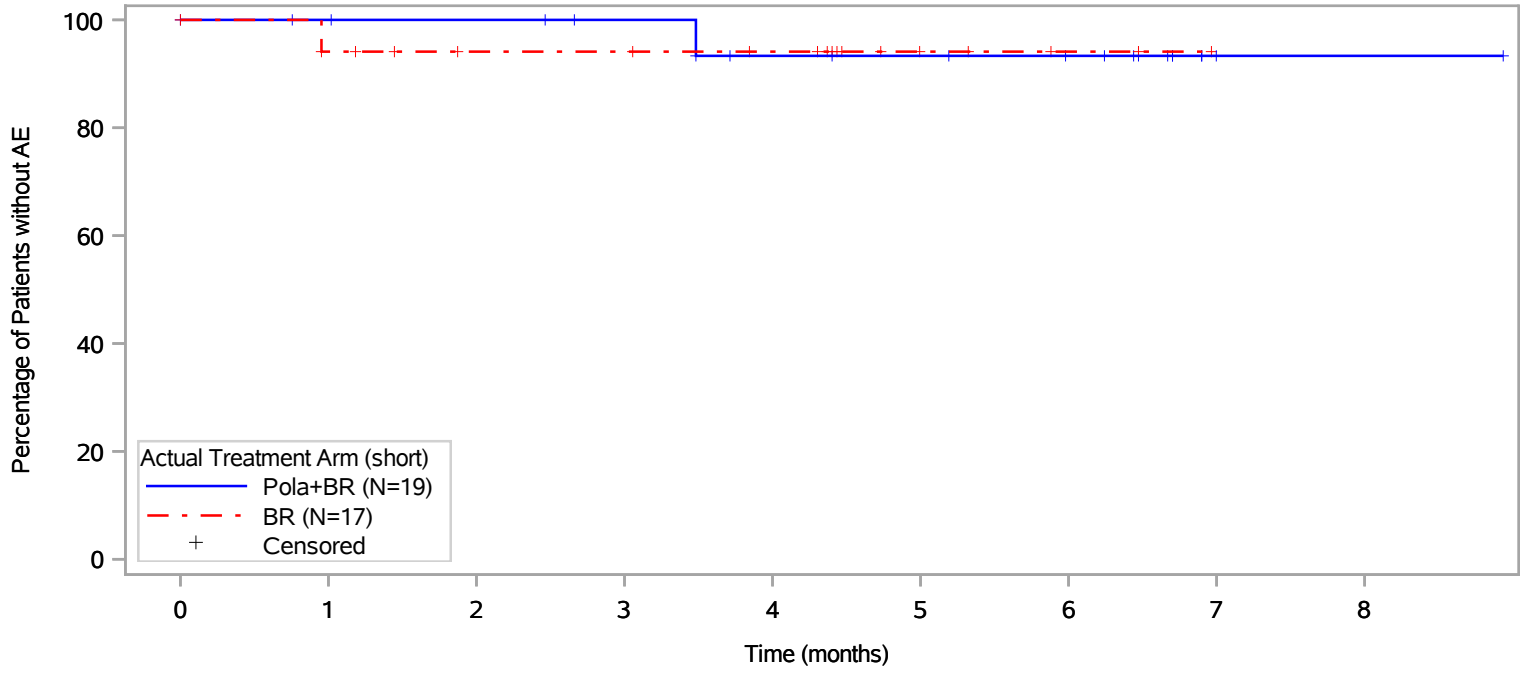
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, ANXIETY



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	12	10	1	1
BR (N=17)	17	16	13	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	8	17	17
BR (N=17)	0	0	3	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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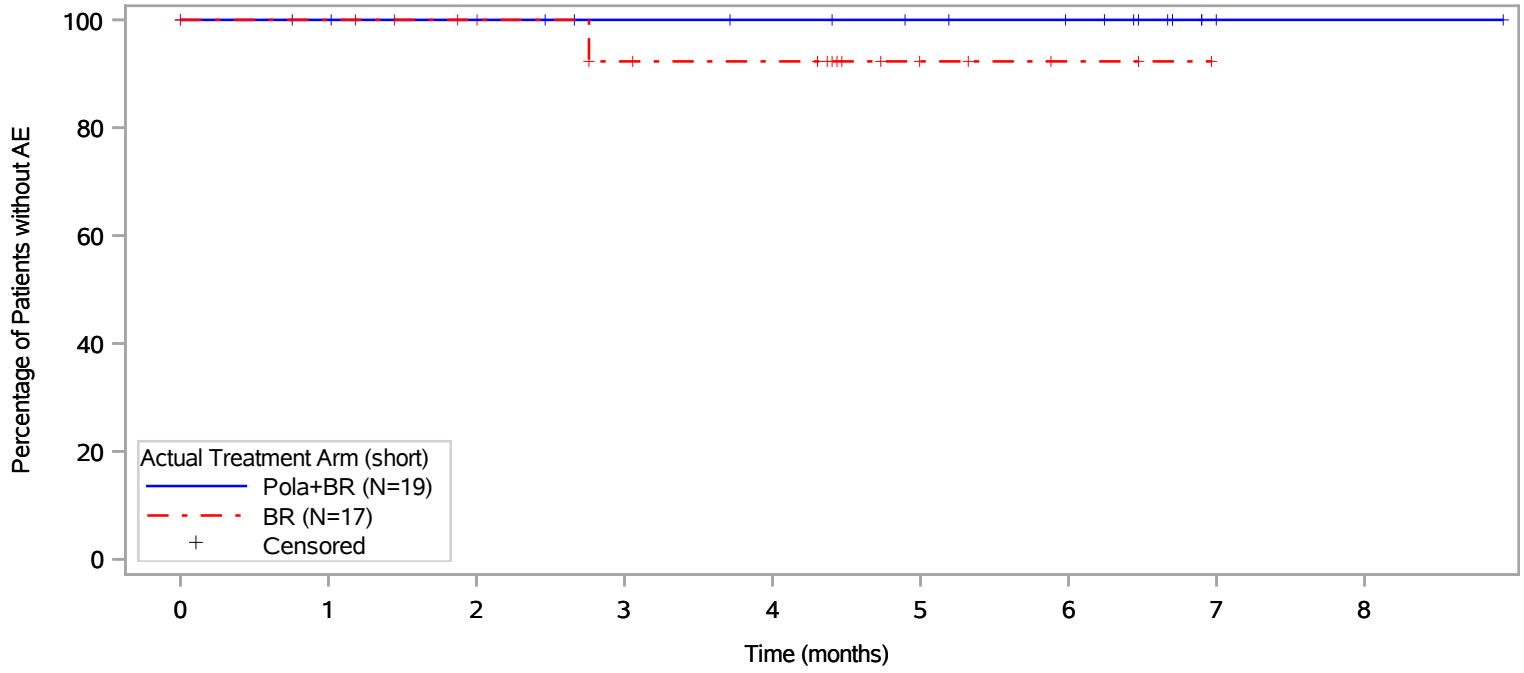
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, DEPRESSED MOOD



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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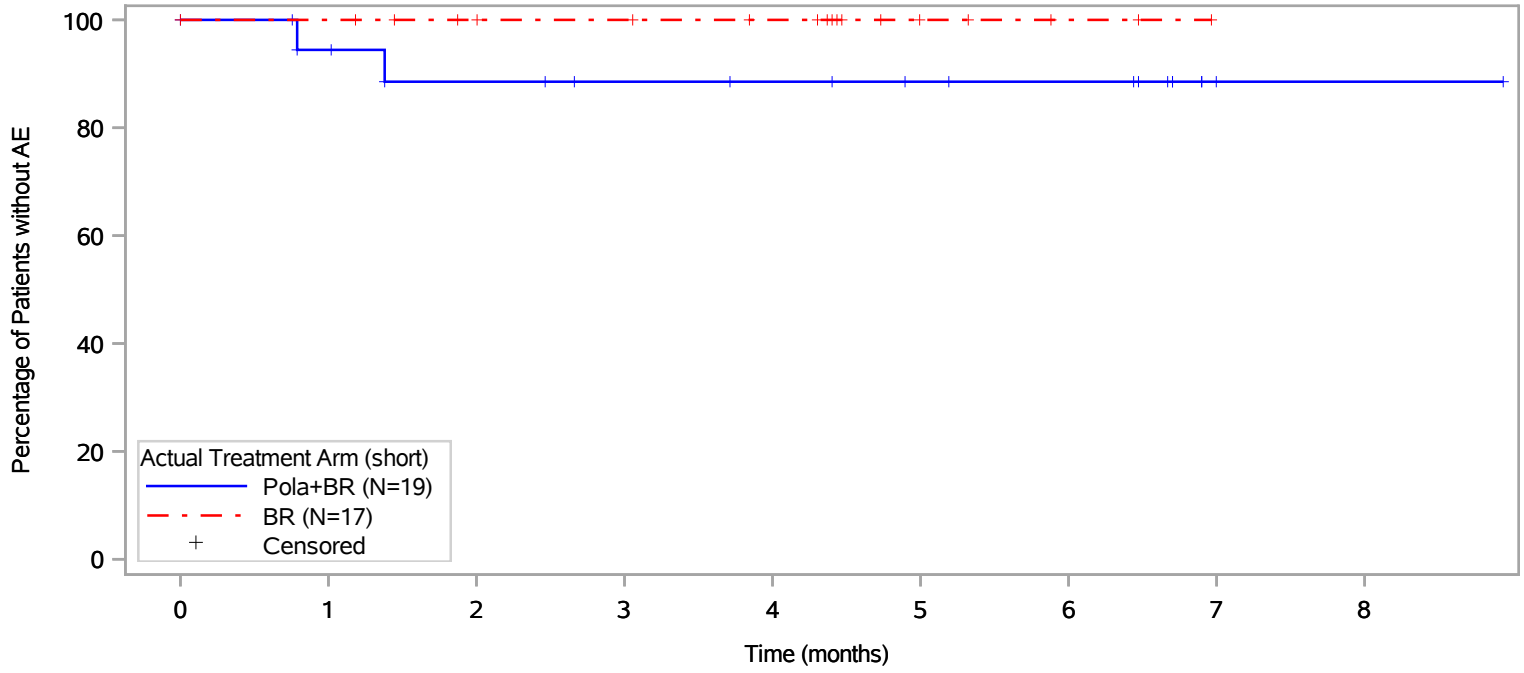
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, INSOMNIA

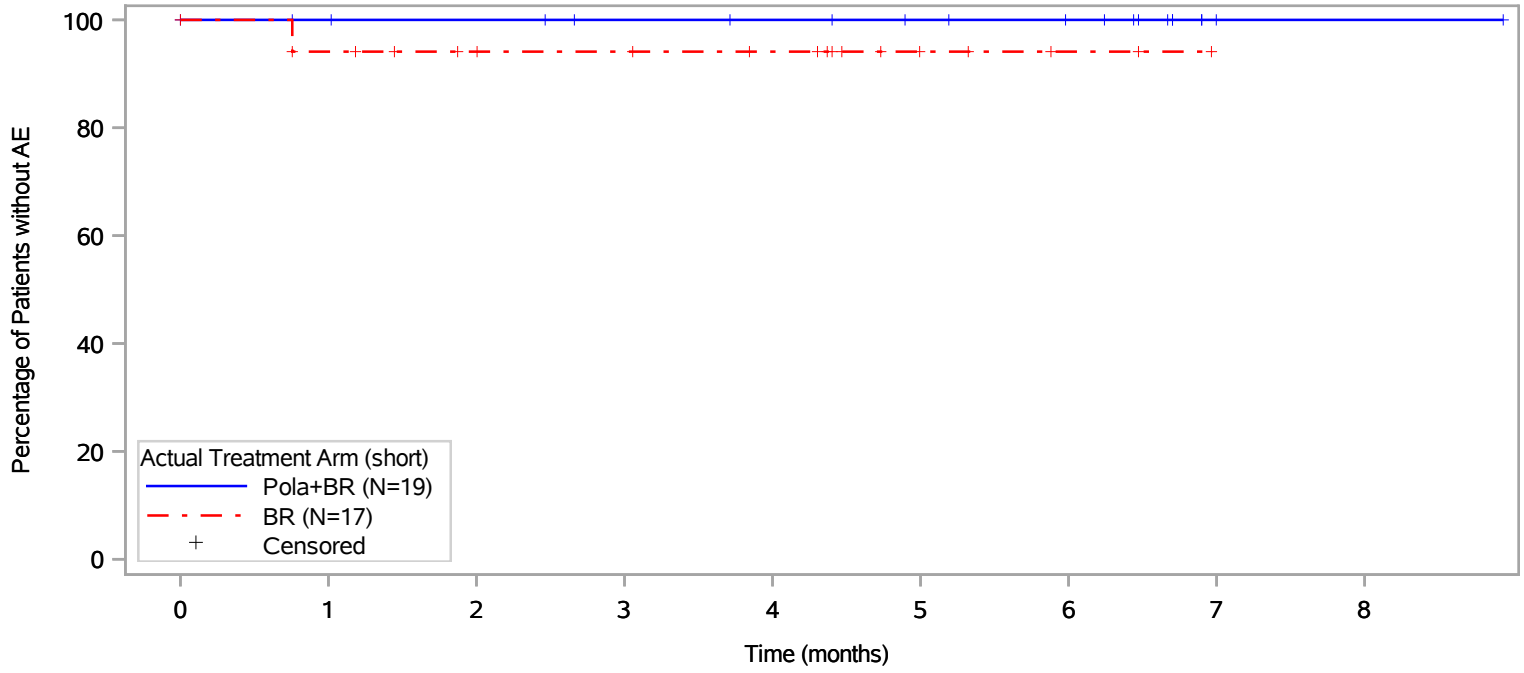


Patients at risk									
Pola+BR (N=19)	19	17	15	13	12	10	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, MOOD ALTERED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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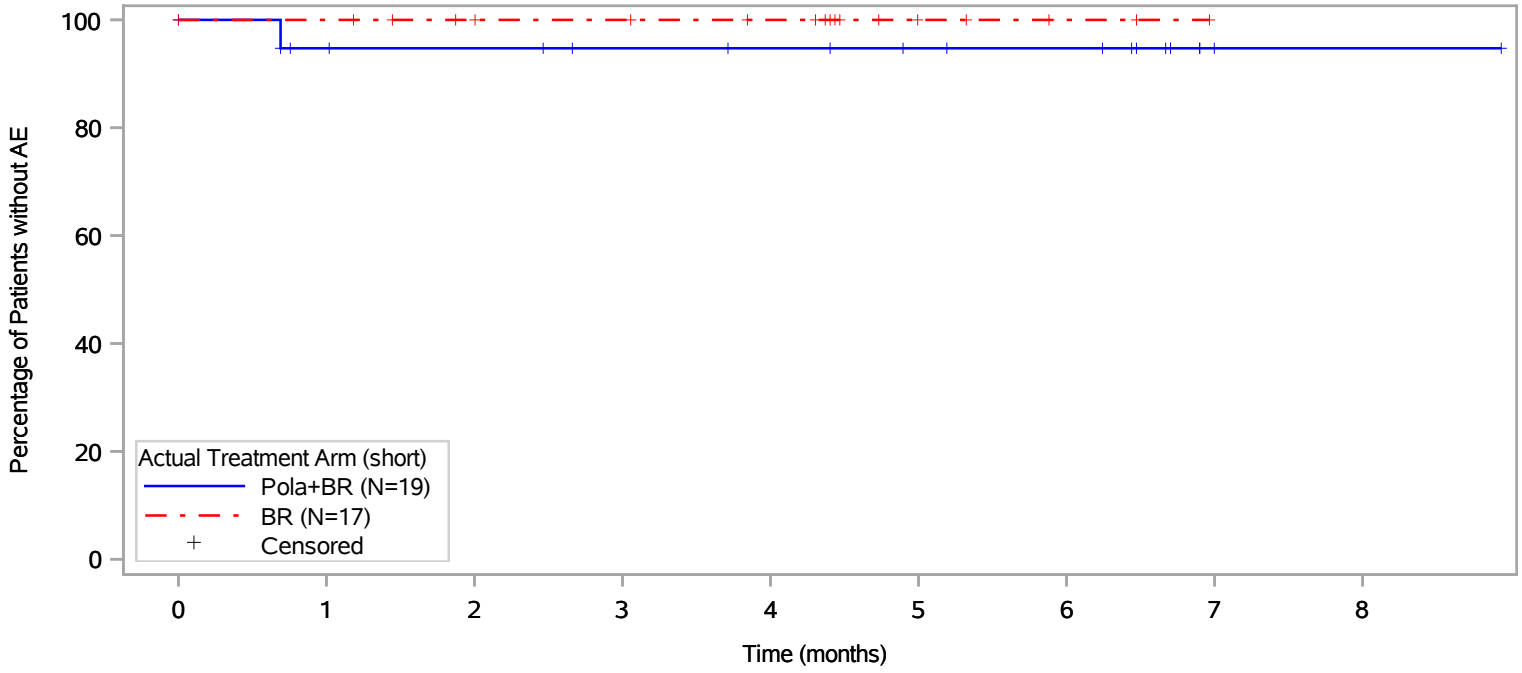
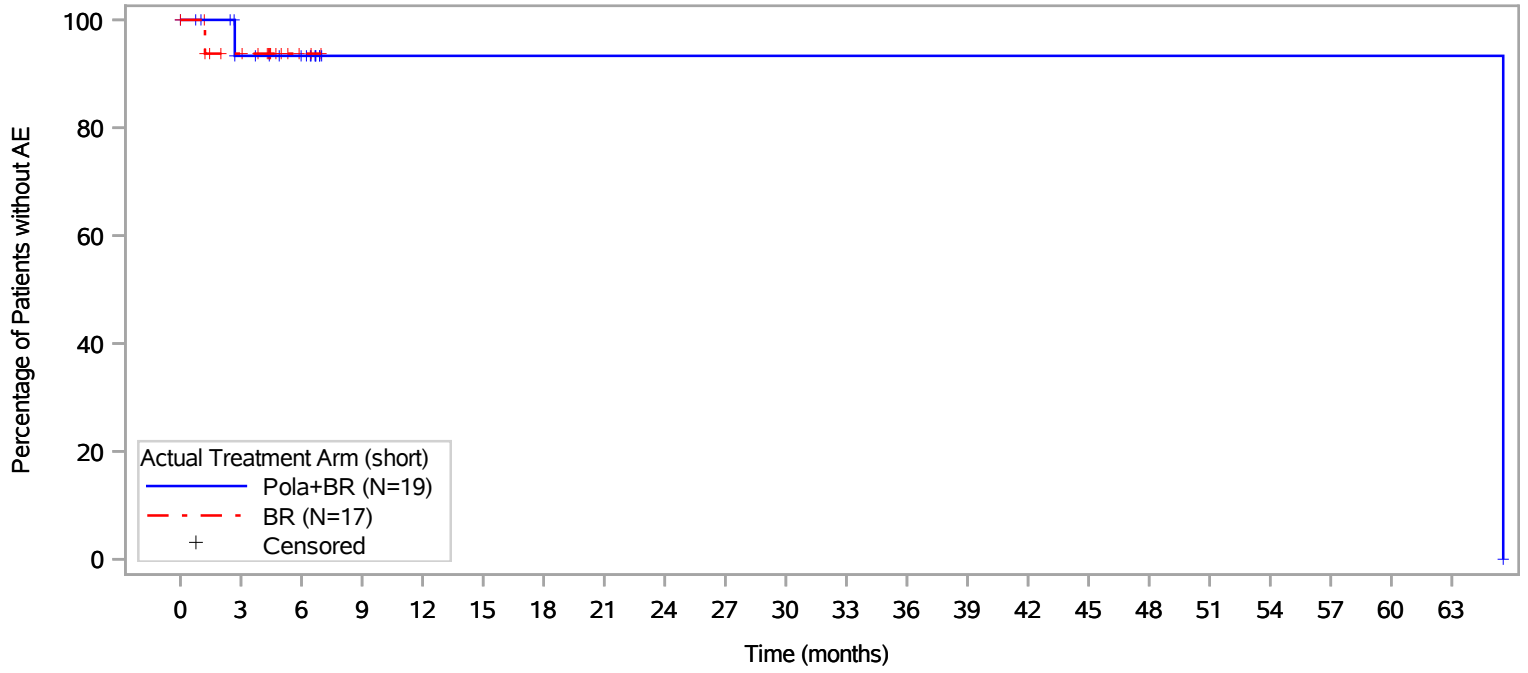
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, POOR QUALITY SLEEP



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk																							
Pola+BR (N=19)	19	14	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=17)	17	13	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=19)	0	4	8	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17
BR (N=17)	0	3	14	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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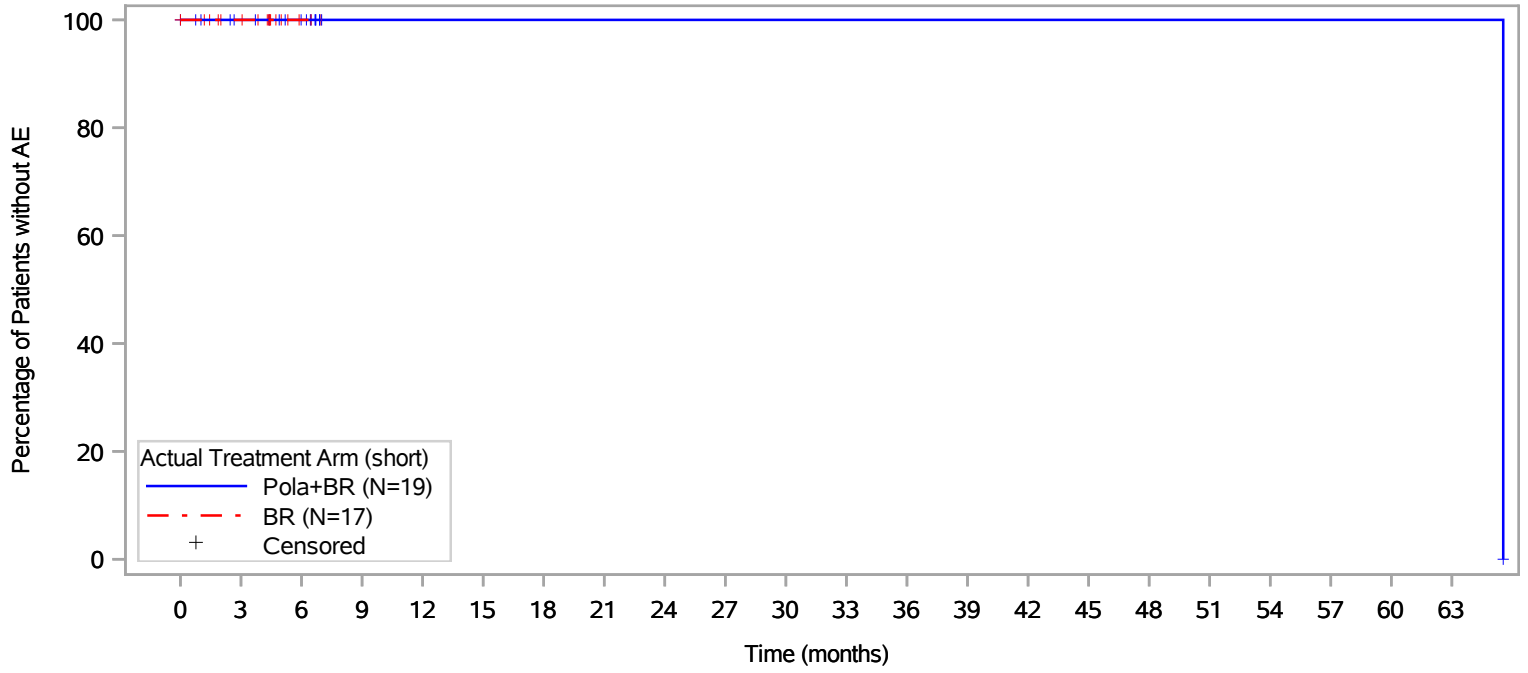
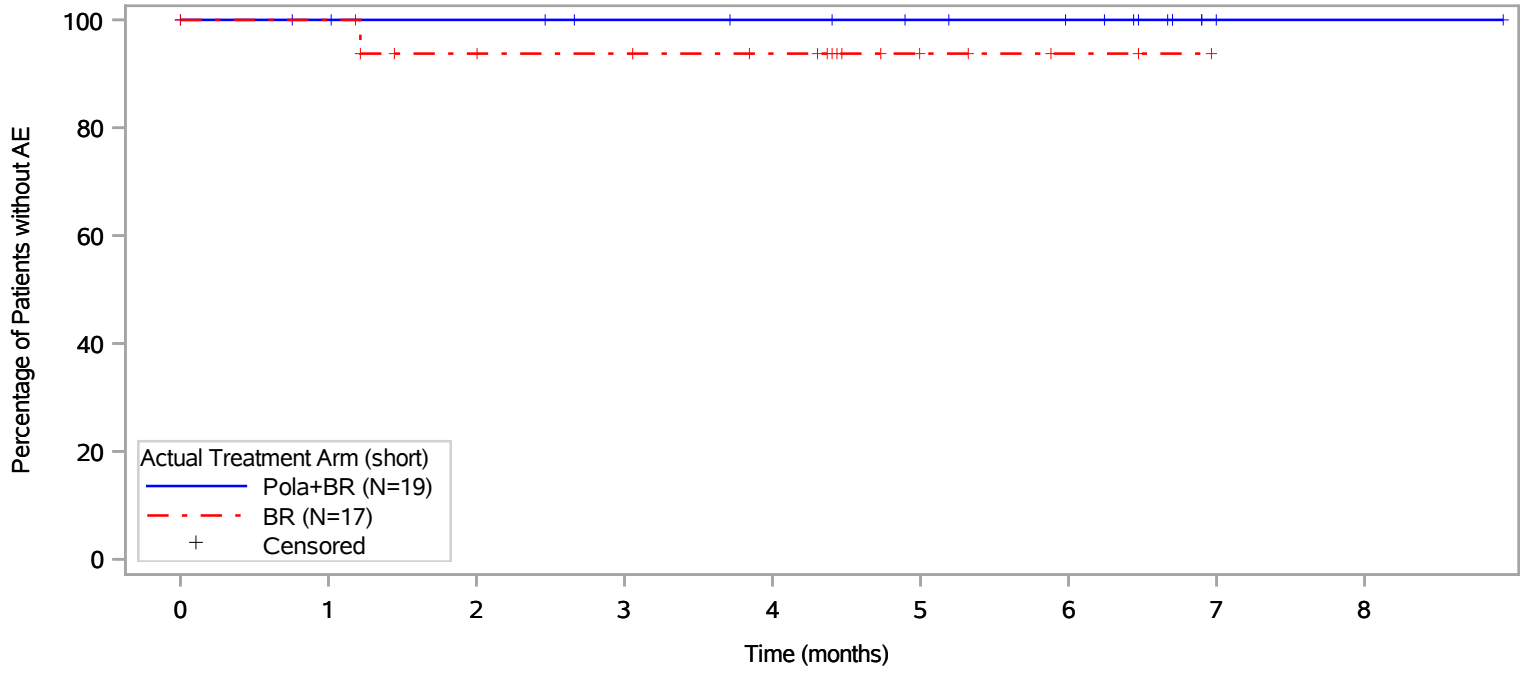
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk																							
Pola+BR (N=19)	19	15	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=17)	17	13	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=19)	0	4	9	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18
BR (N=17)	0	4	15	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ANURIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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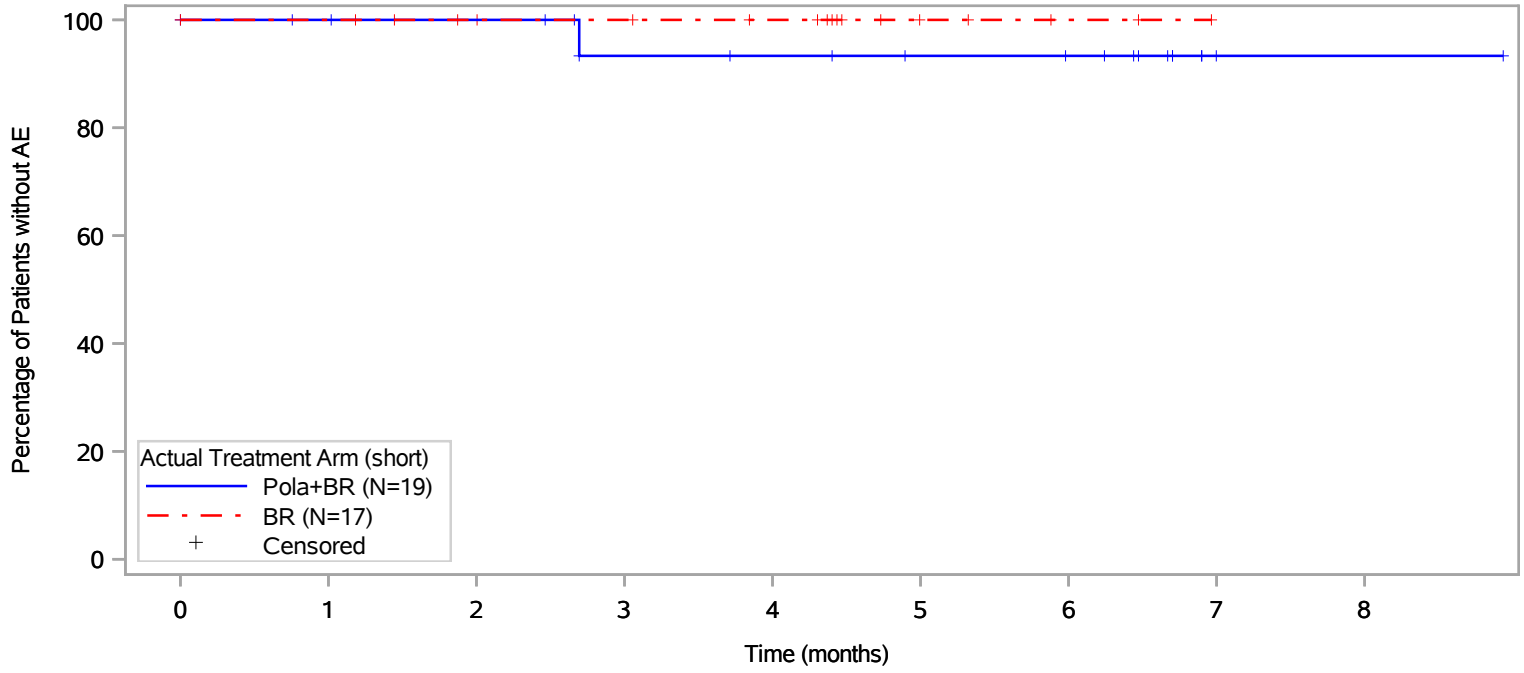
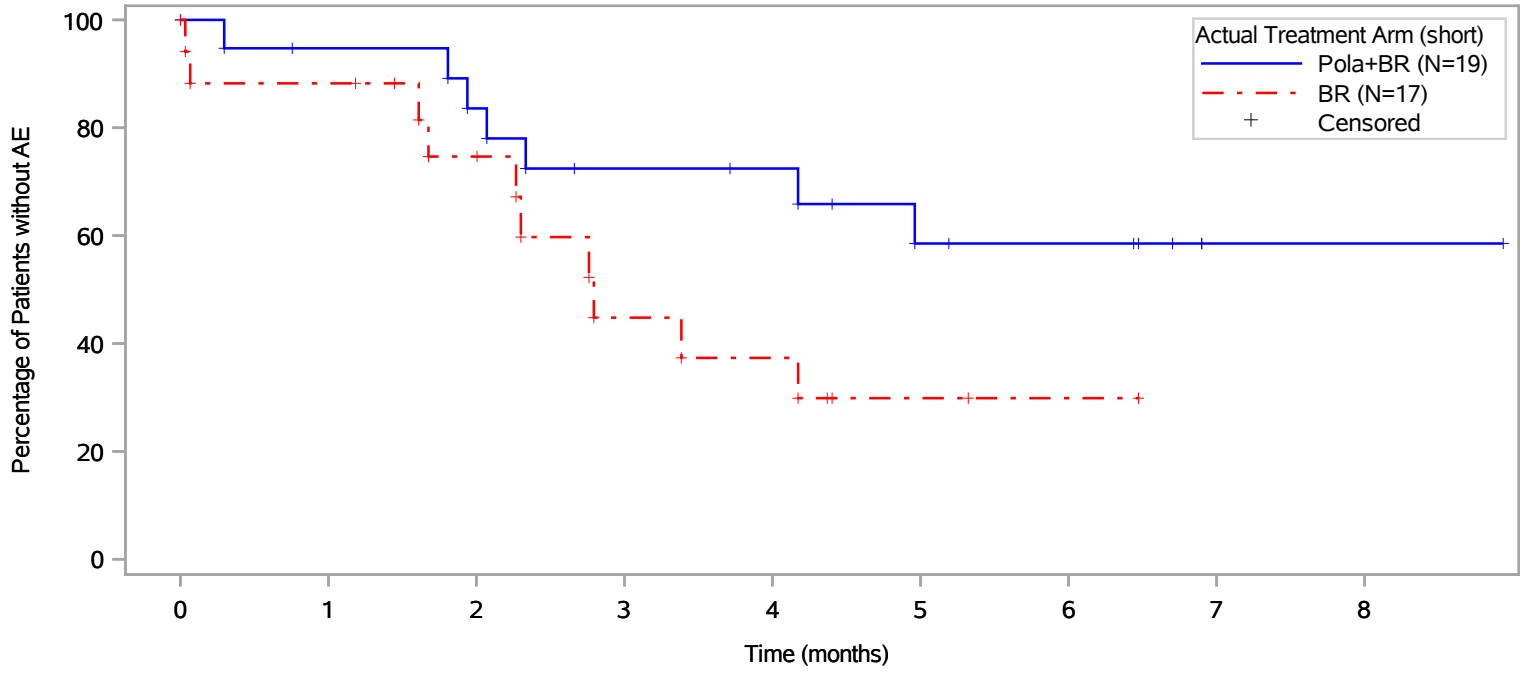
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	14	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	17	15	12	11	8	7	1	1
BR (N=17)	17	15	11	6	5	2	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	2	3	4	5	11	11
BR (N=17)	0	0	2	3	3	5	6	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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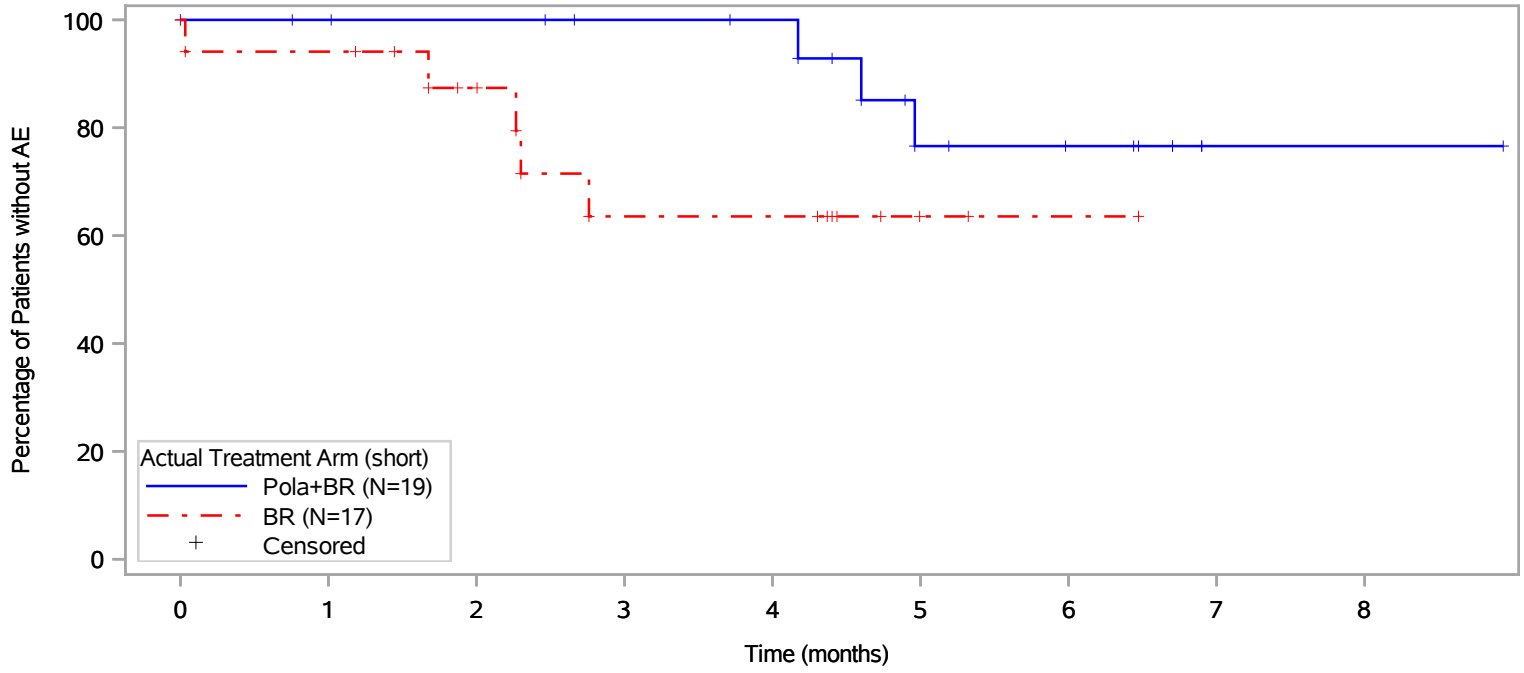
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, COUGH



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	9	7	1	1
BR (N=17)	17	16	12	8	8	2	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	15	15
BR (N=17)	0	0	3	4	4	10	11	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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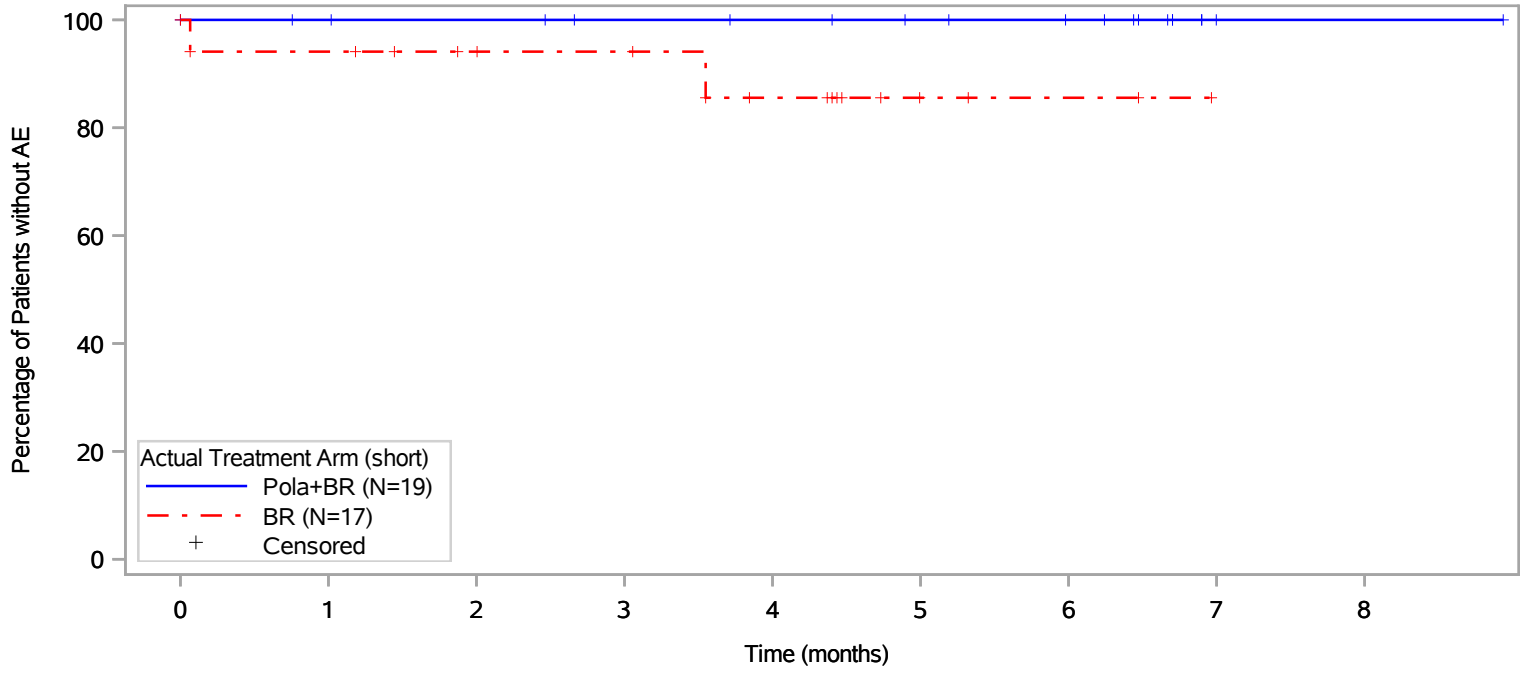
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPNOEA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	9	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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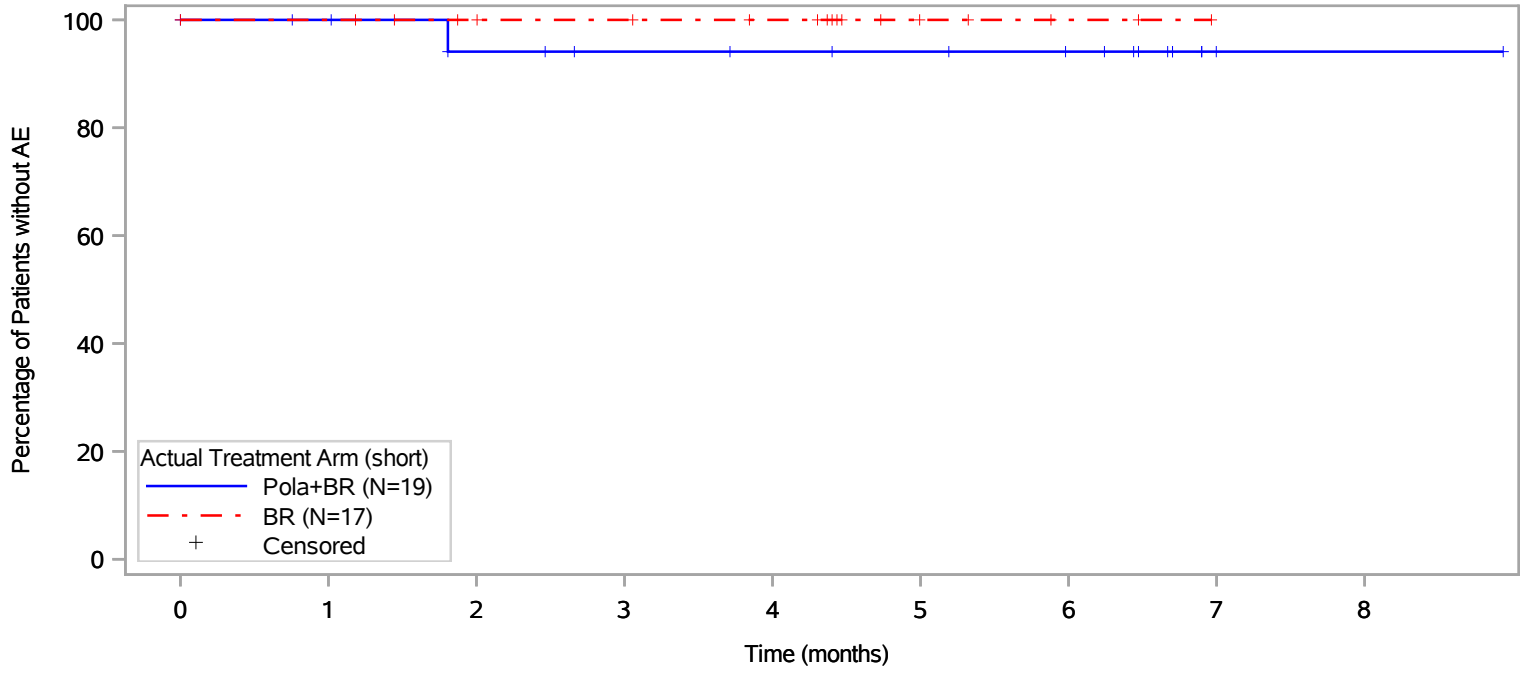
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPNOEA EXERTIONAL



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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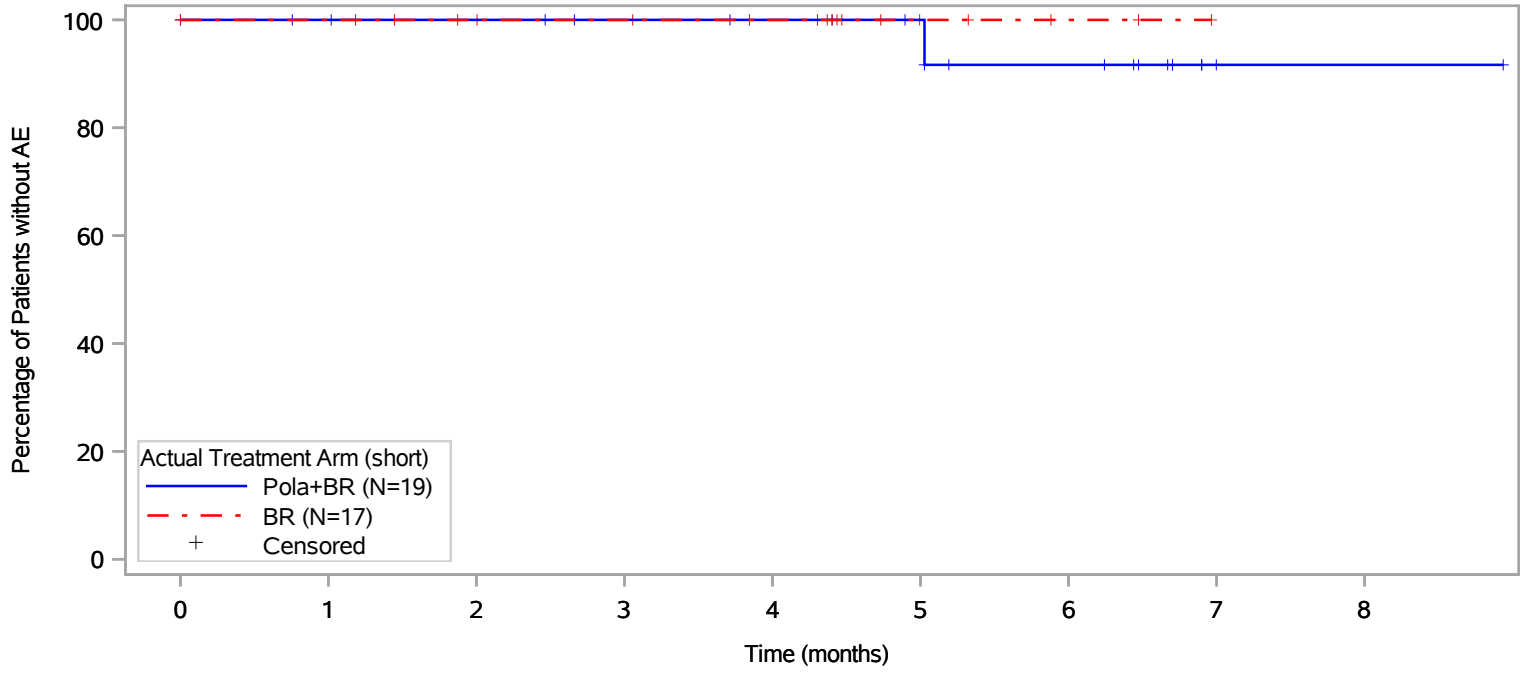
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HICCUPS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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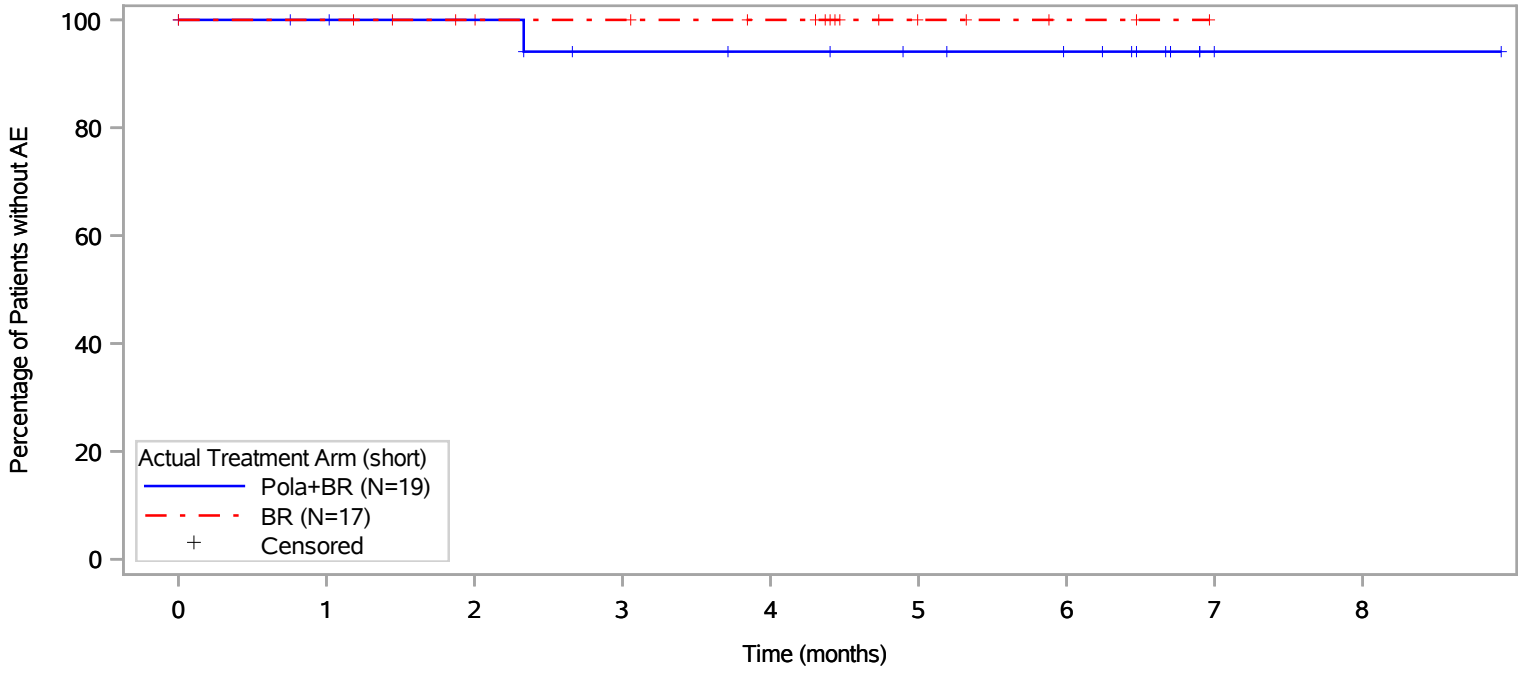
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA

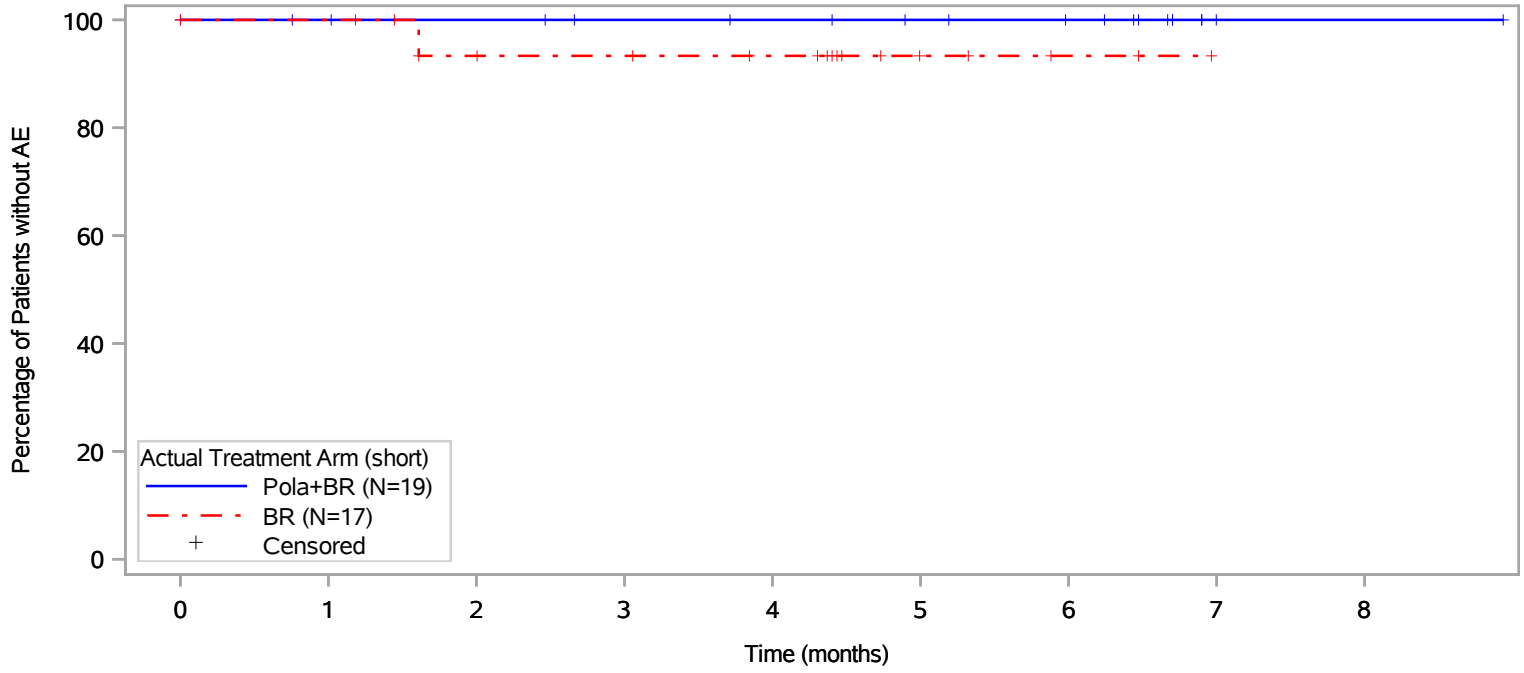


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, LUNG INFILTRATION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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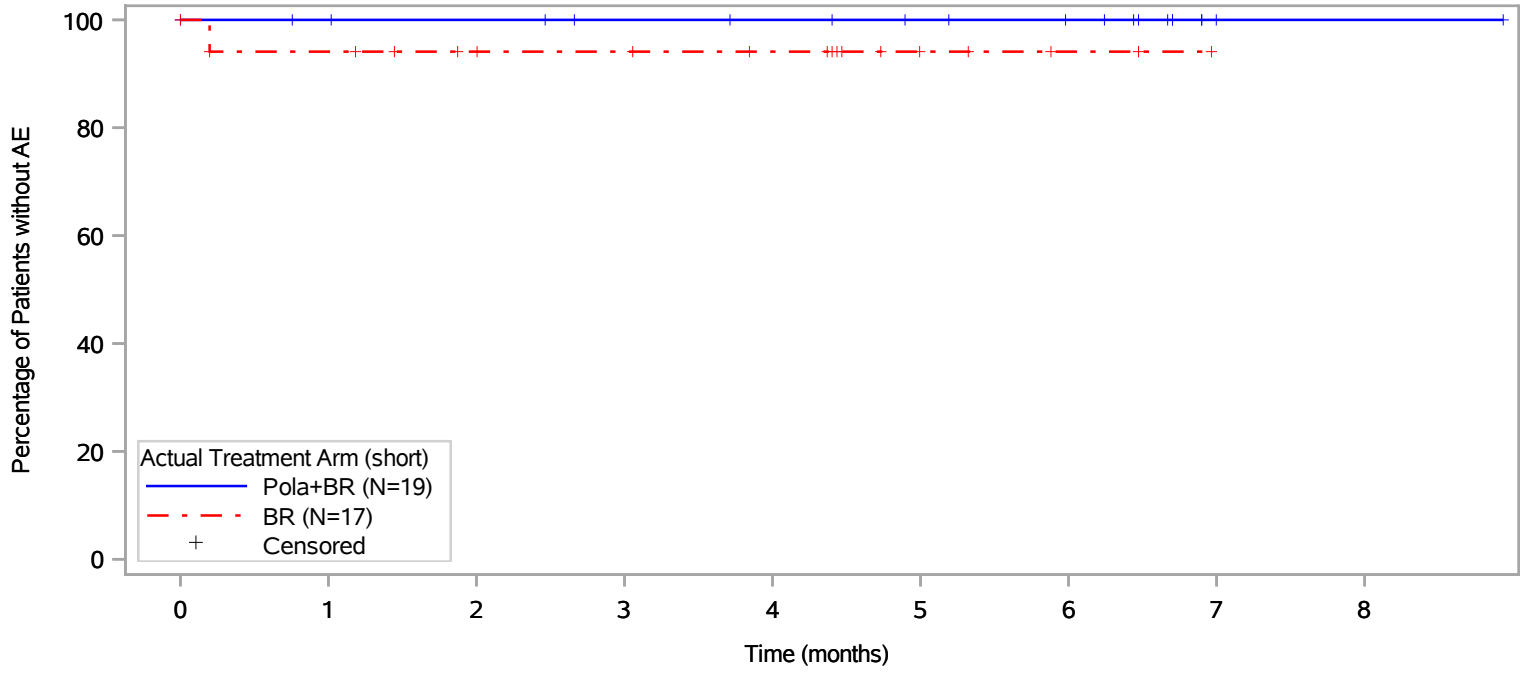
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, OROPHARYNGEAL PAIN

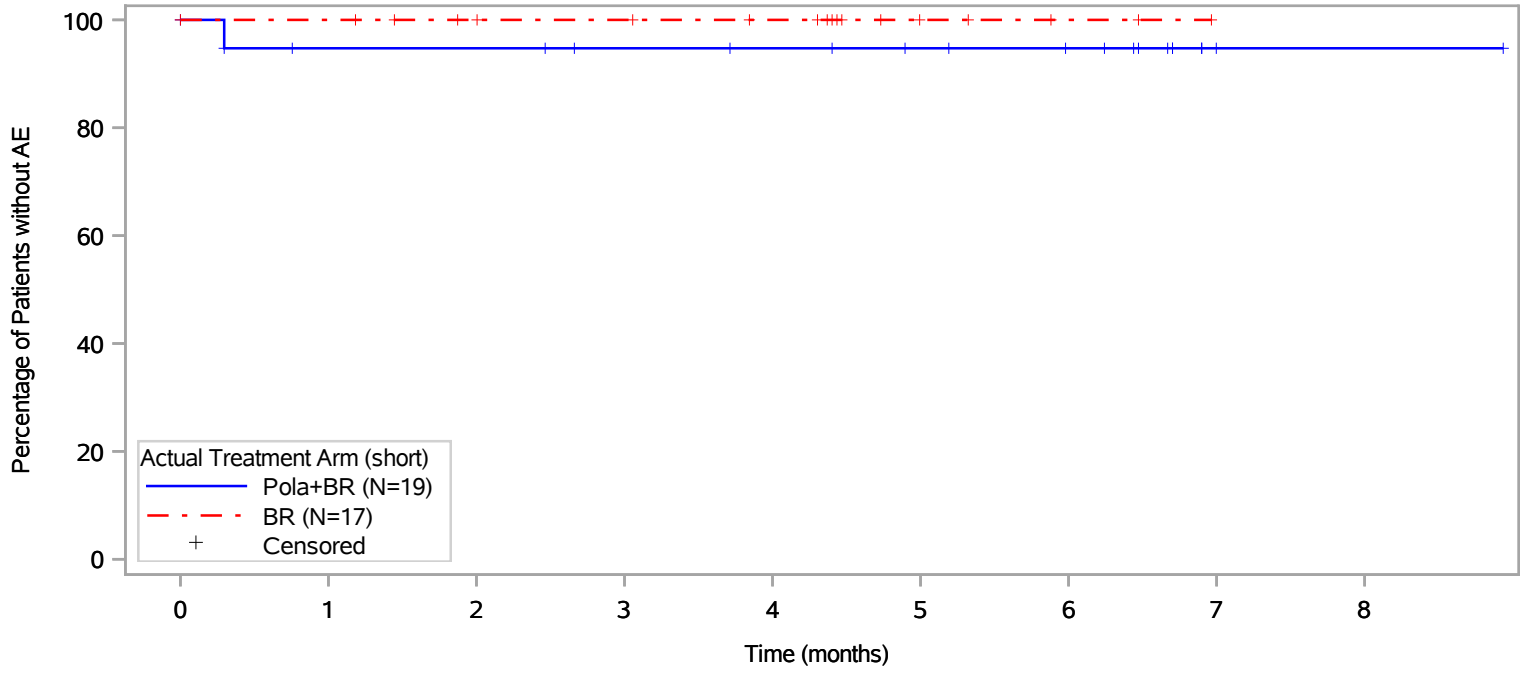


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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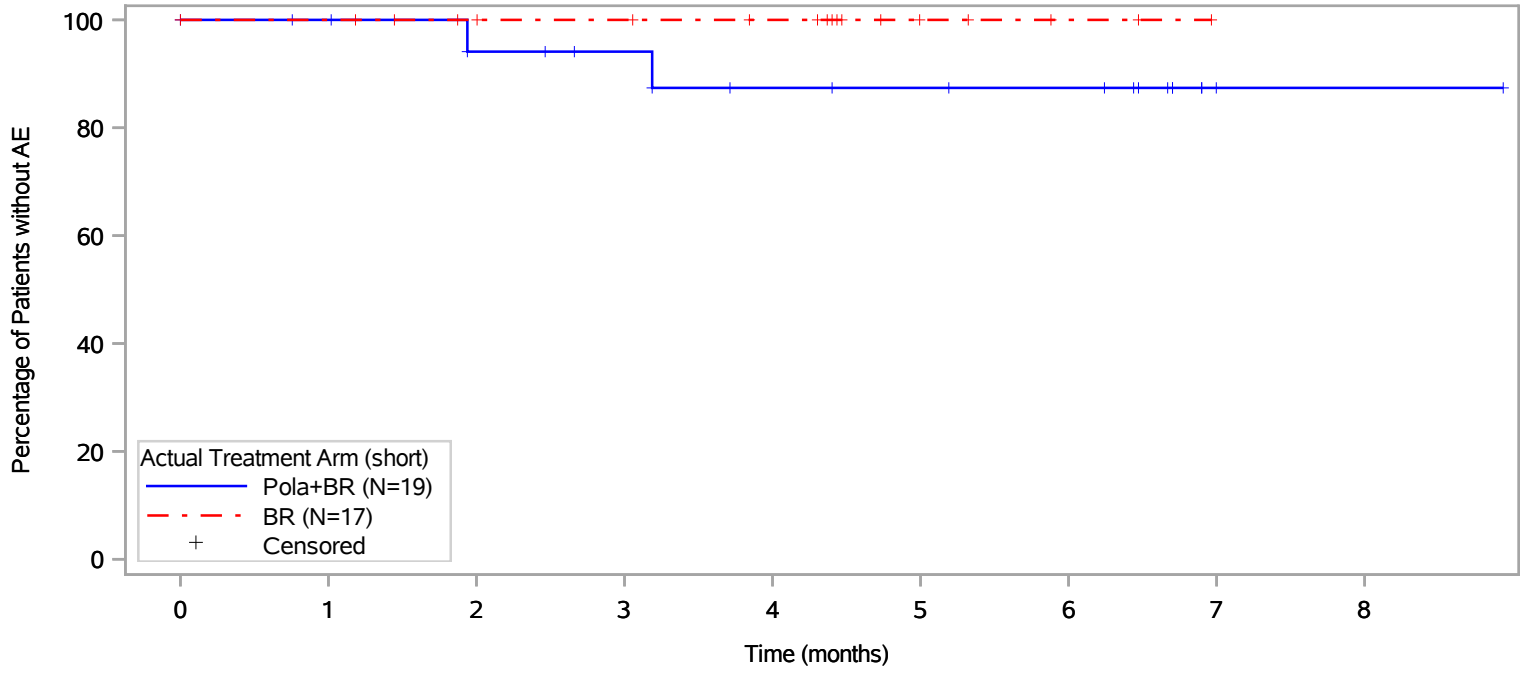
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PNEUMONITIS



Patients at risk									
Pola+BR (N=19)	19	18	16	14	12	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	7	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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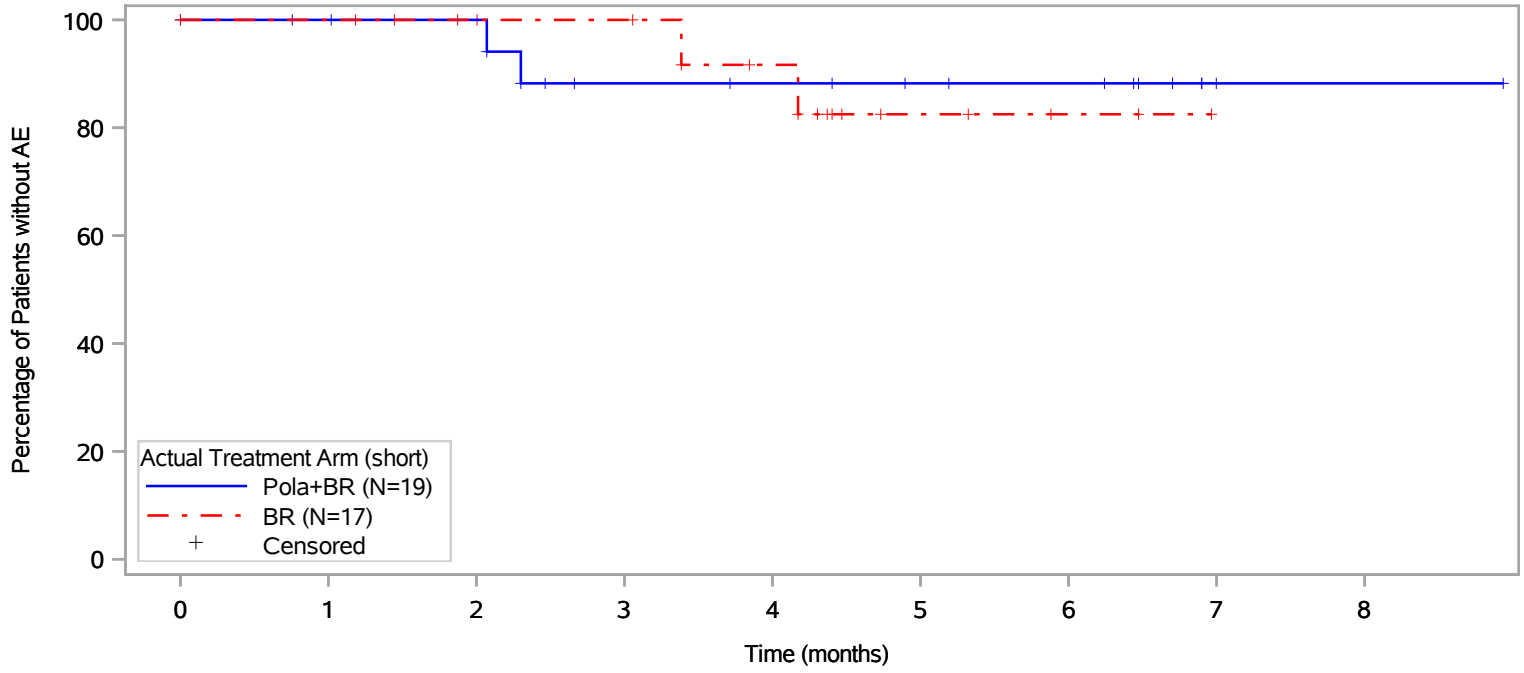
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PRODUCTIVE COUGH



Patients at risk									
Pola+BR (N=19)	19	18	17	13	12	10	9	1	1
BR (N=17)	17	17	14	13	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	16	16
BR (N=17)	0	0	3	4	6	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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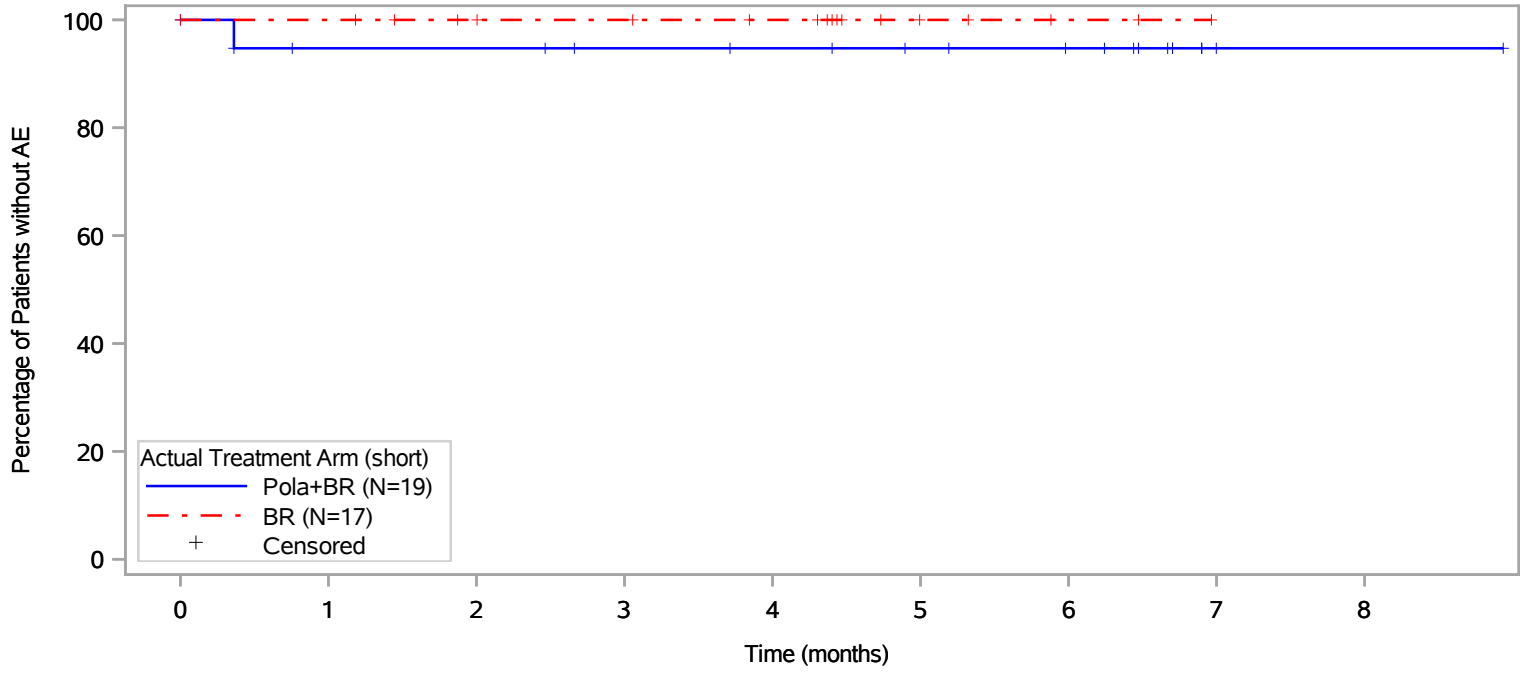
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY OEDEMA



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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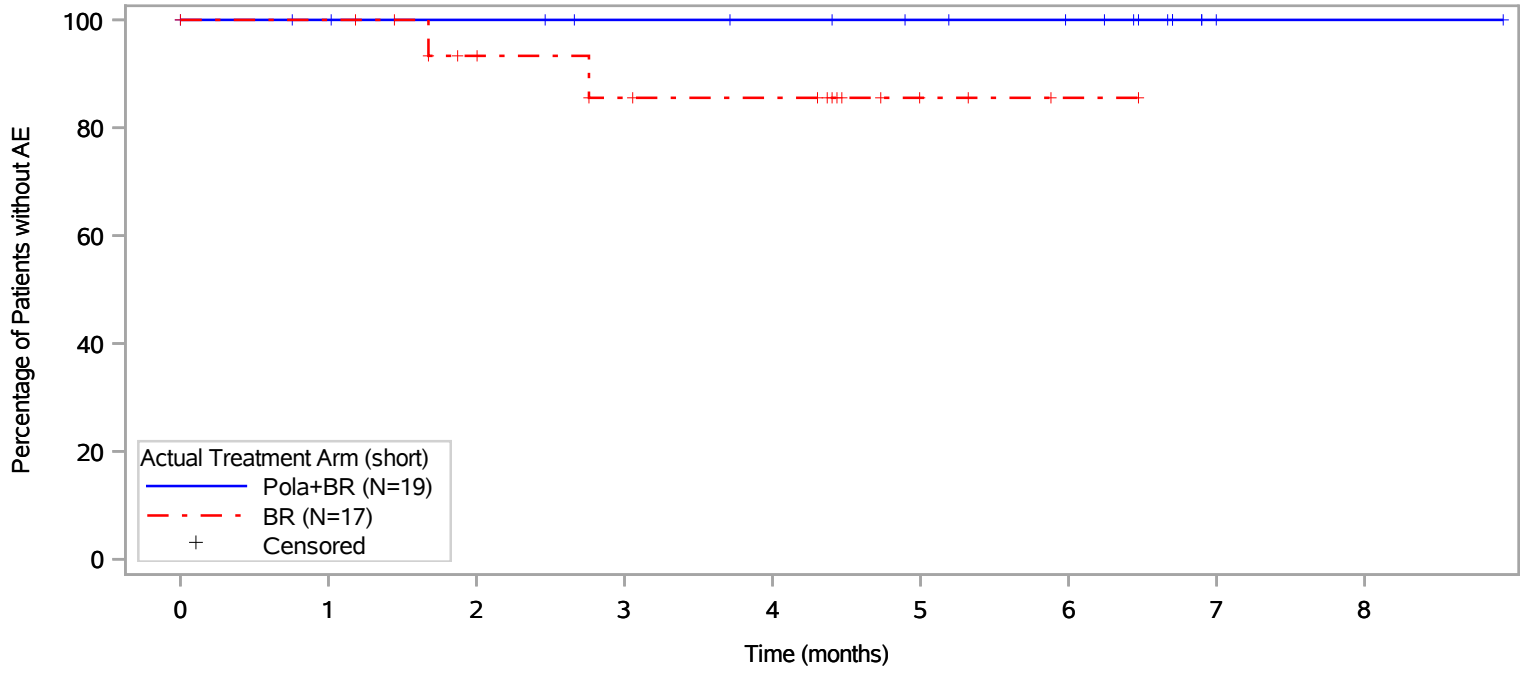
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, RHINORRHOEA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	11	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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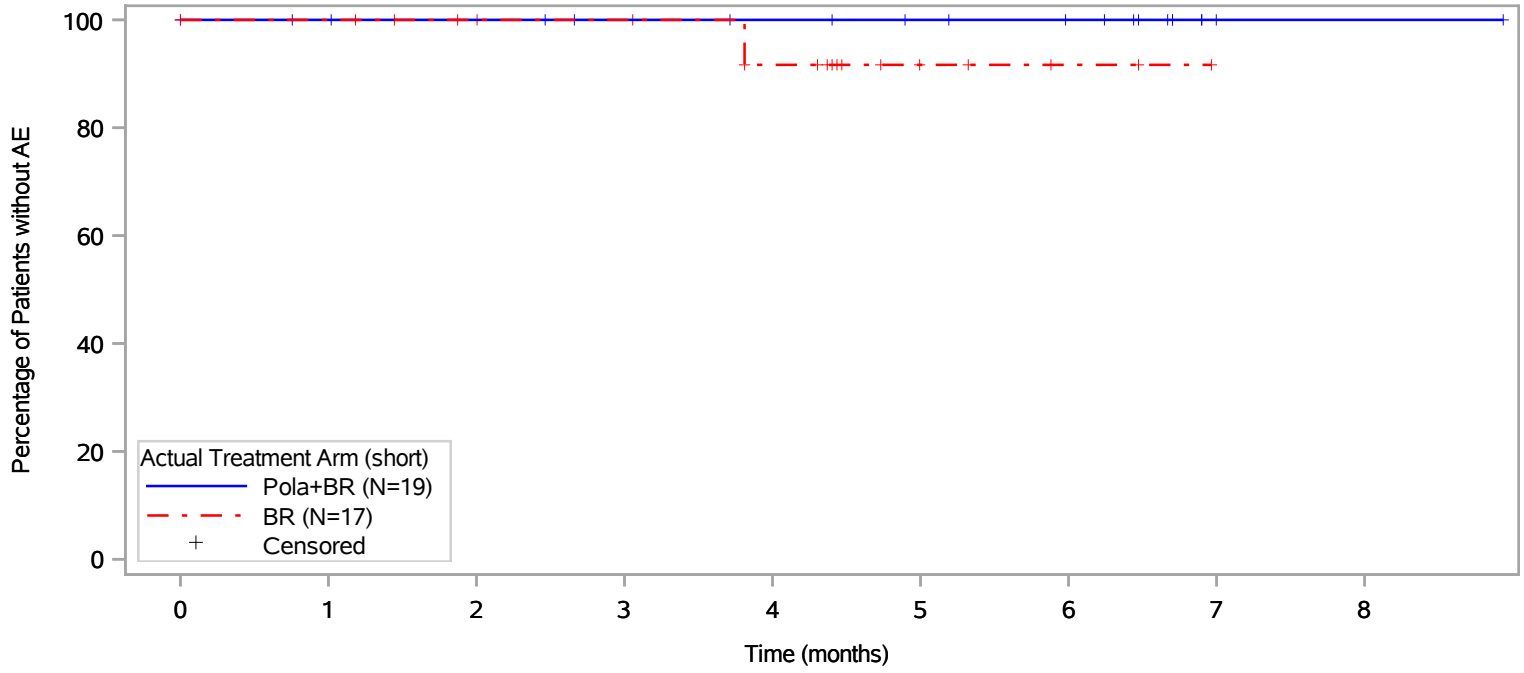
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, TACHYPNOEA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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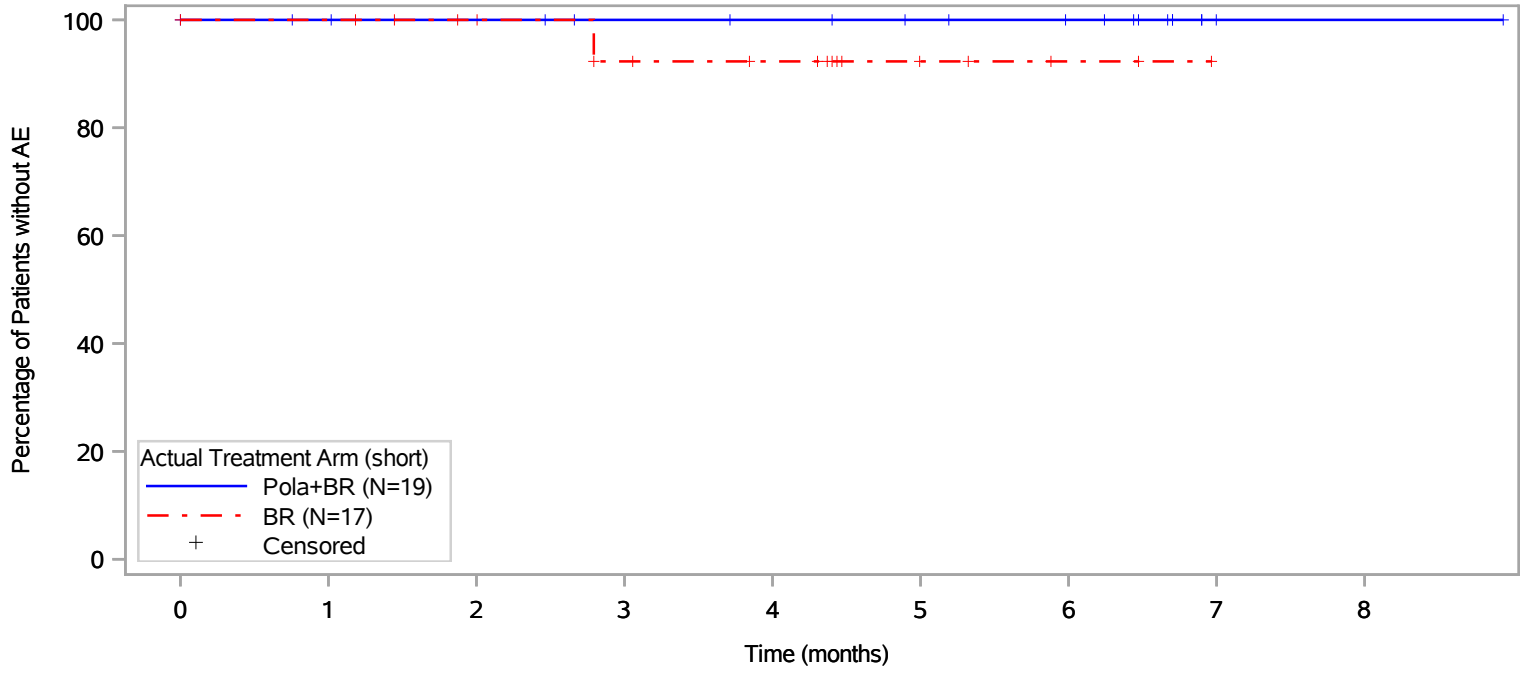
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, UPPER RESPIRATORY TRACT INFLAMMATION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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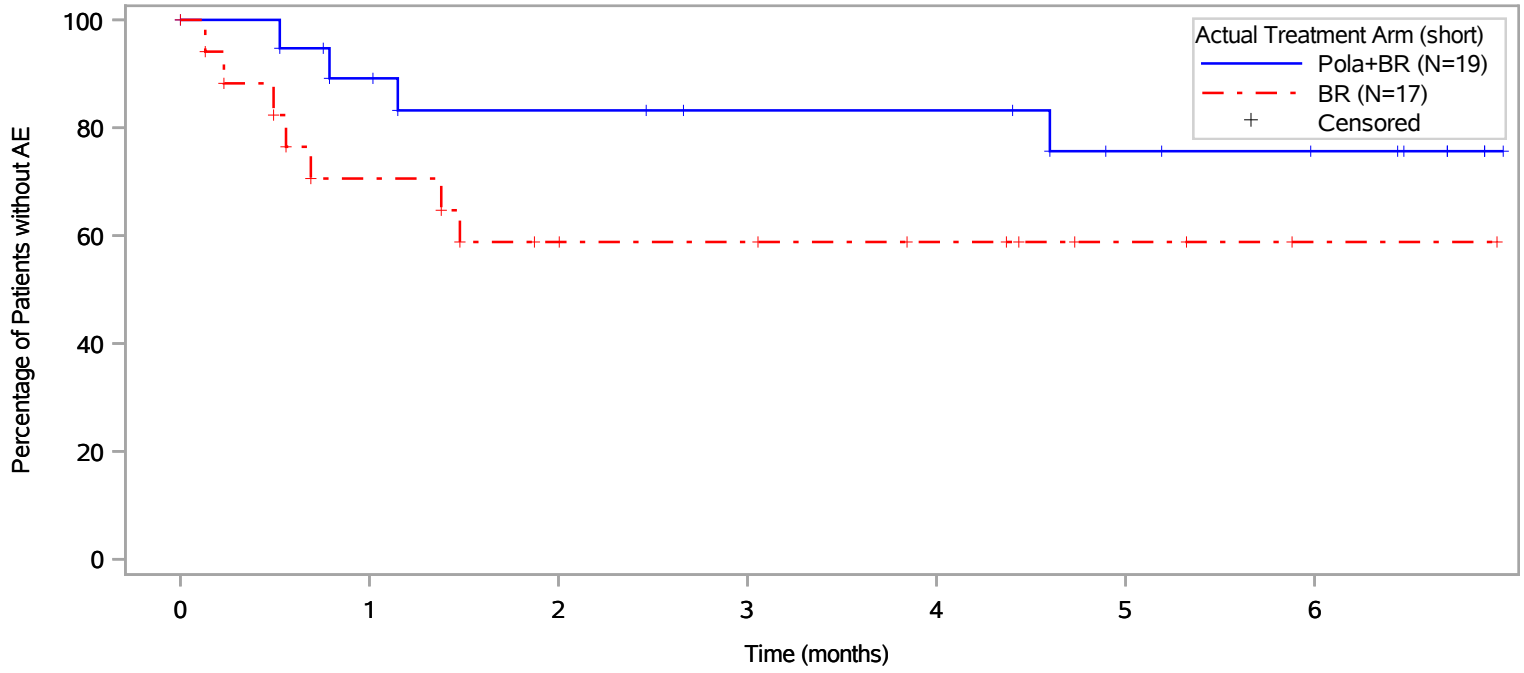
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	16	14	12	12	9	7
BR (N=17)	17	12	9	8	6	3	1
Patients censored							
Pola+BR (N=19)	0	1	2	4	4	6	8
BR (N=17)	0	0	1	2	4	7	9

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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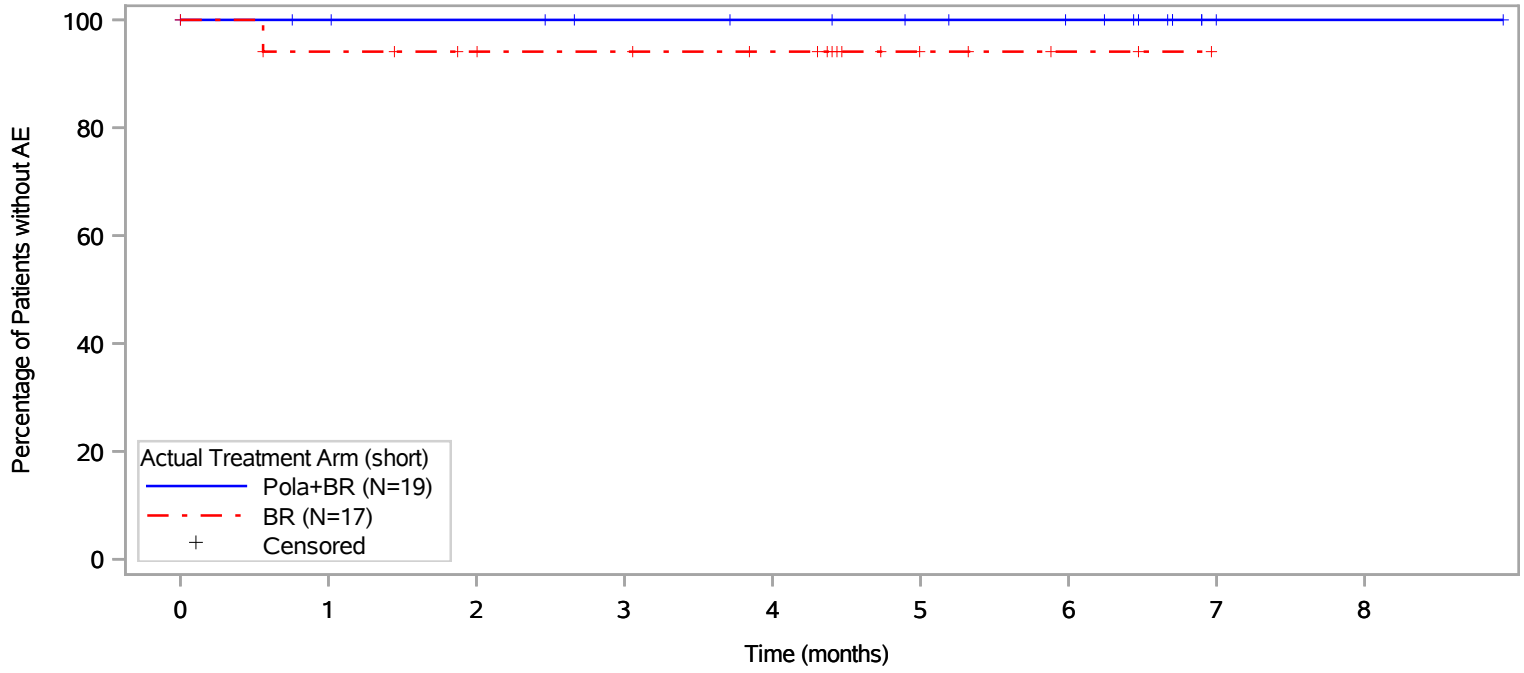
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, ALOPECIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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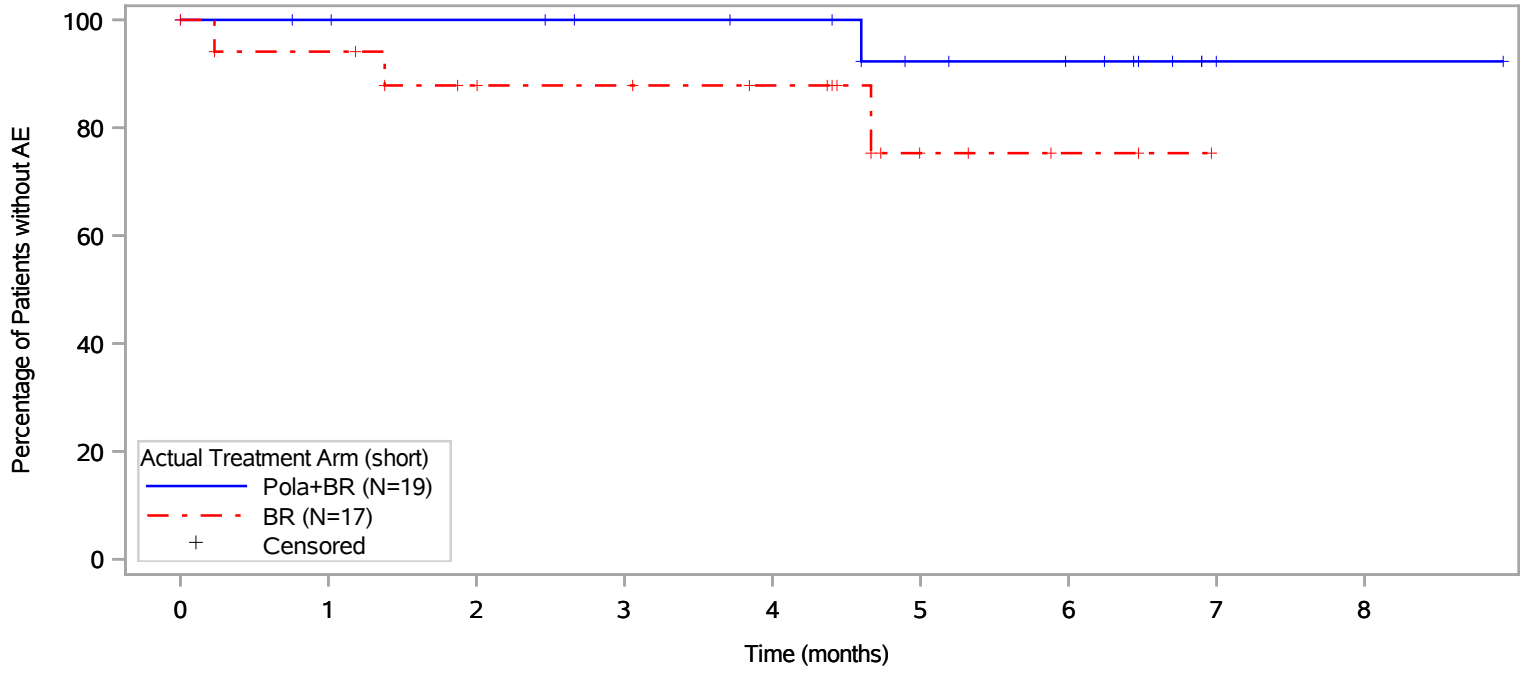
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	9	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	2	3	5	10	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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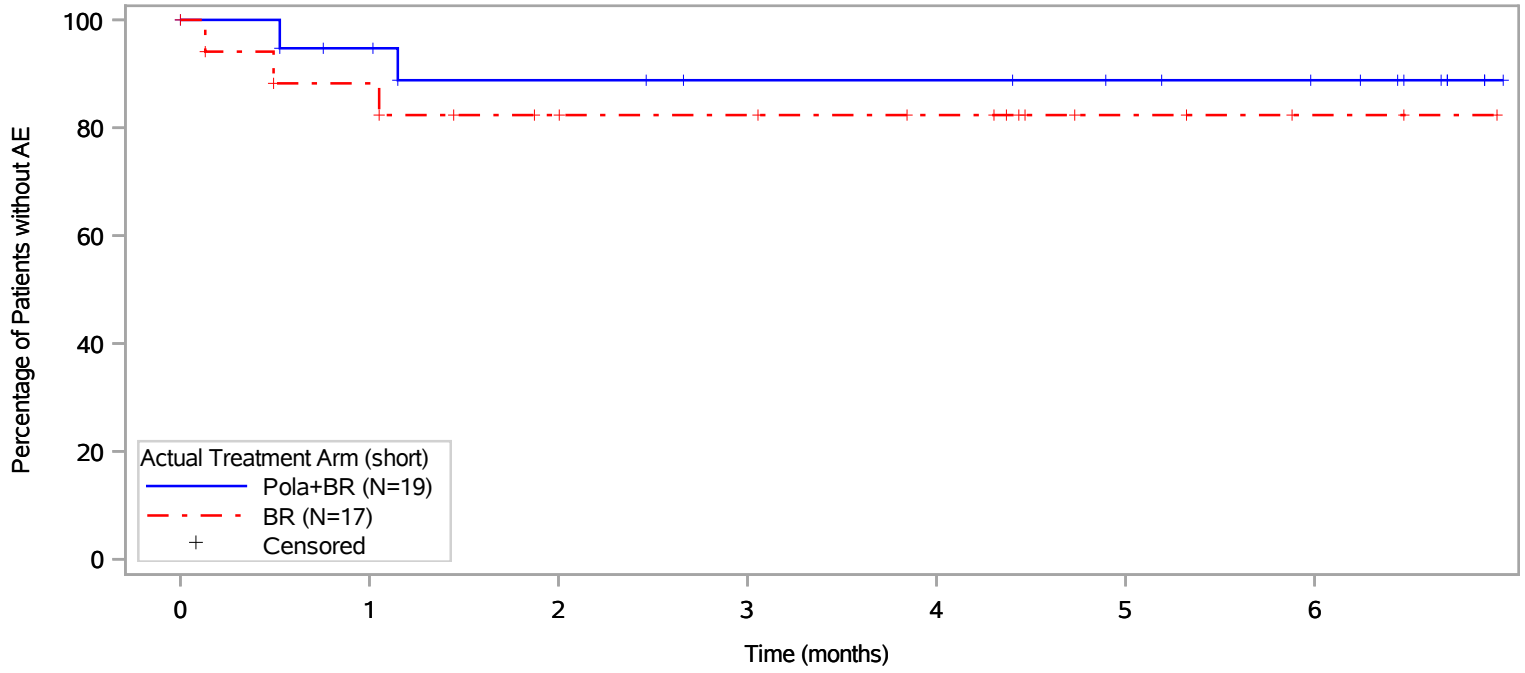
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk							
Pola+BR (N=19)	19	17	15	13	13	11	9
BR (N=17)	17	15	12	11	9	4	2
Patients censored							
Pola+BR (N=19)	0	1	2	4	4	6	8
BR (N=17)	0	0	2	3	5	10	12

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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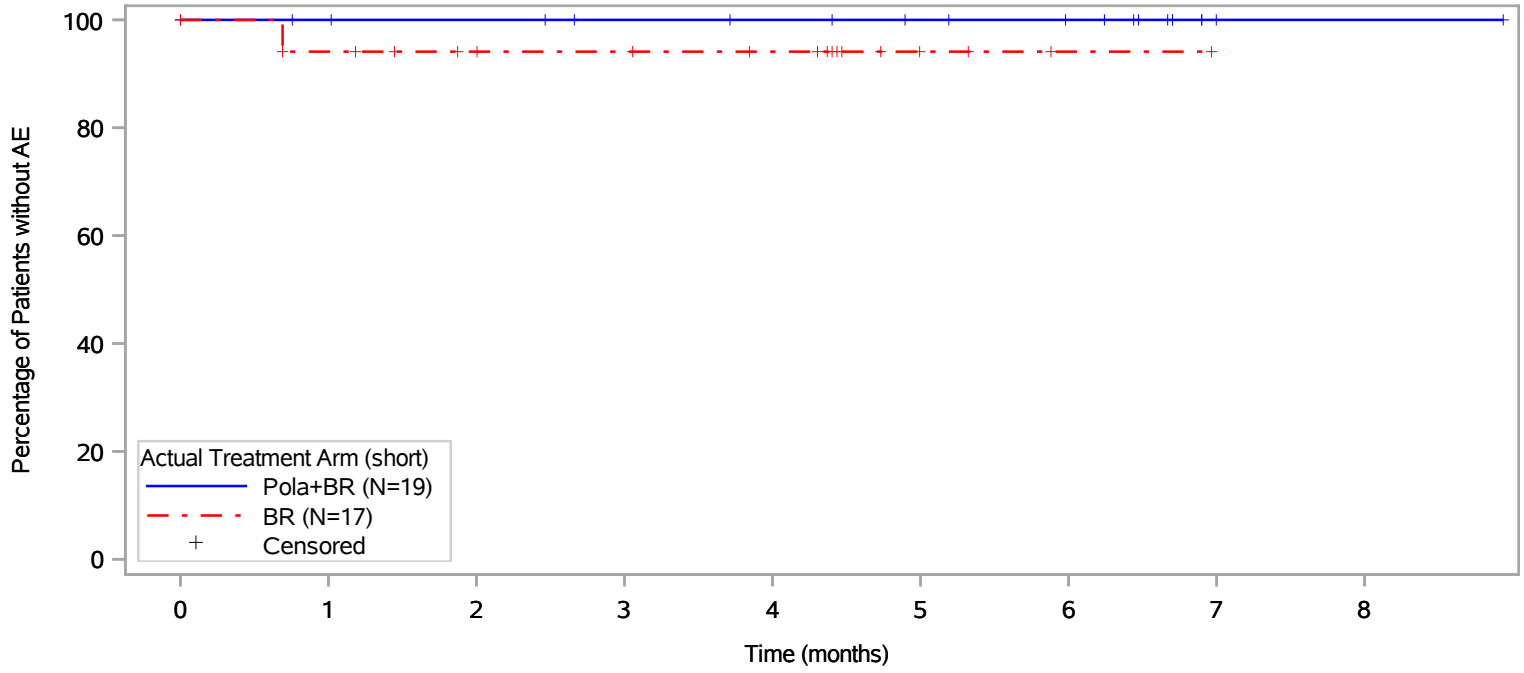
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

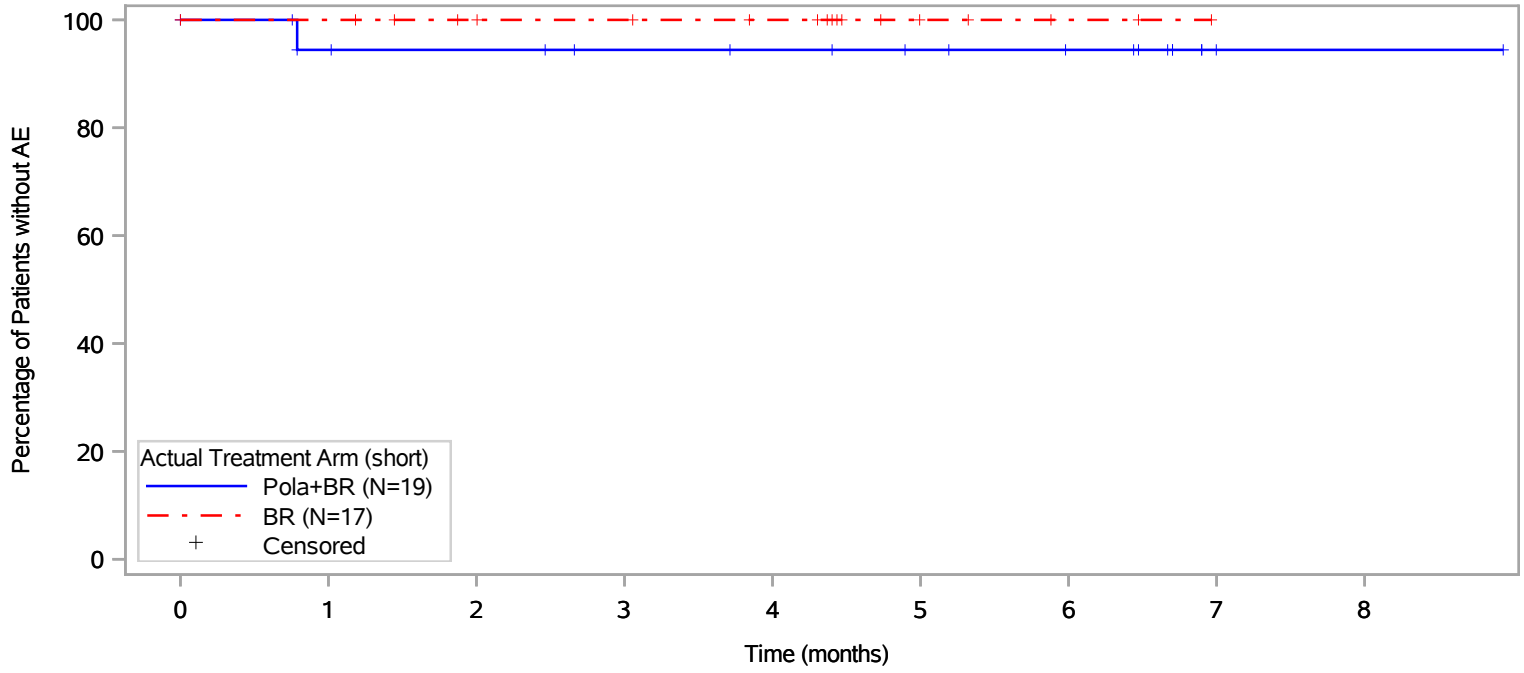
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH MACULO-PAPULAR



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, SOLAR LENTIGO



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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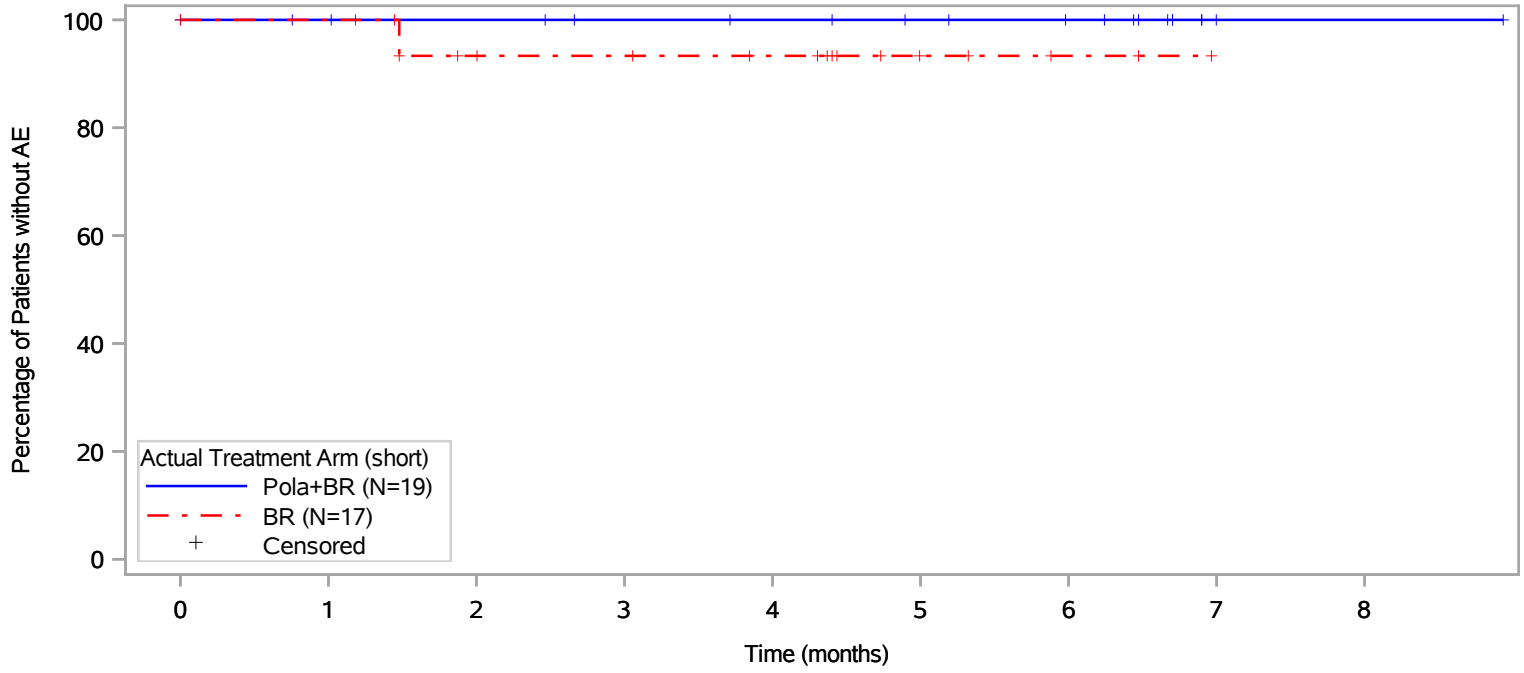
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, URTICARIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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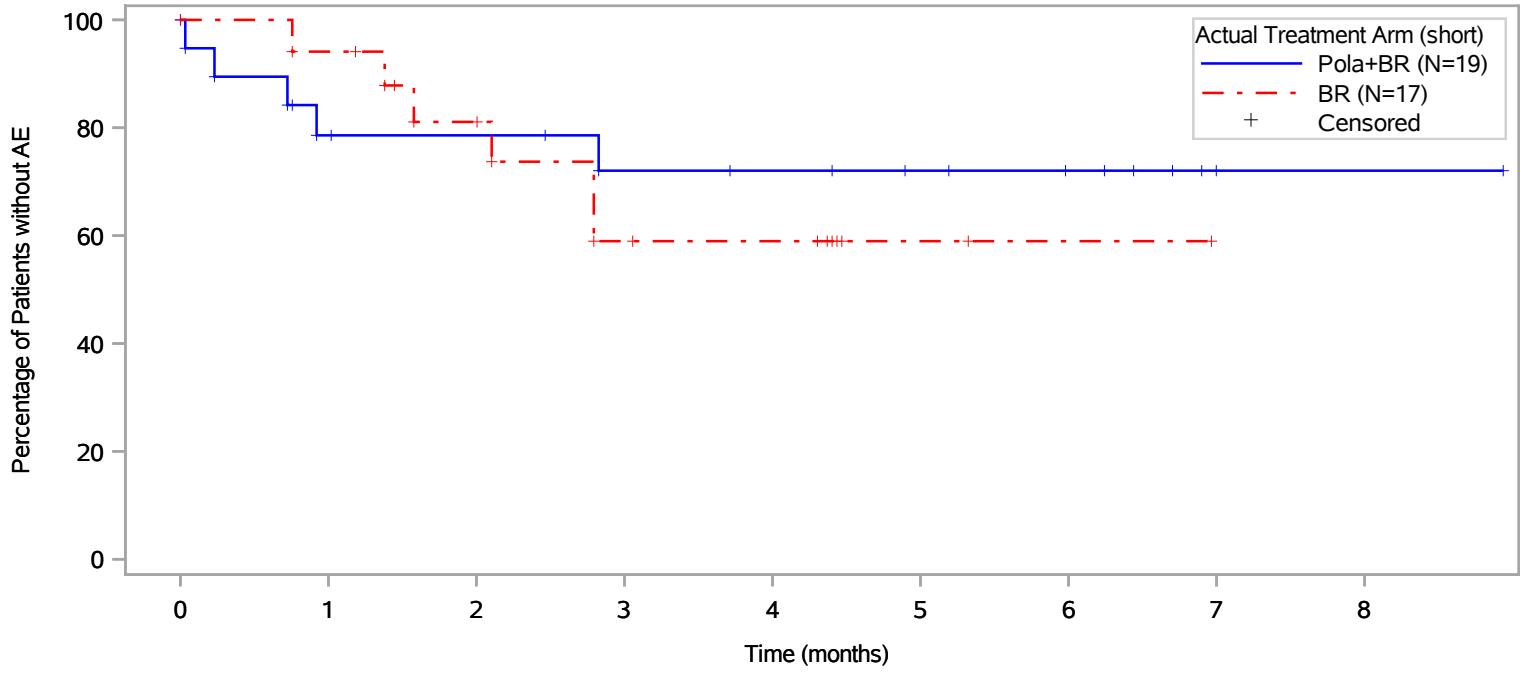
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	14	13	11	10	8	6	1	1
BR (N=17)	17	16	12	8	7	2	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	13	13
BR (N=17)	0	0	2	3	4	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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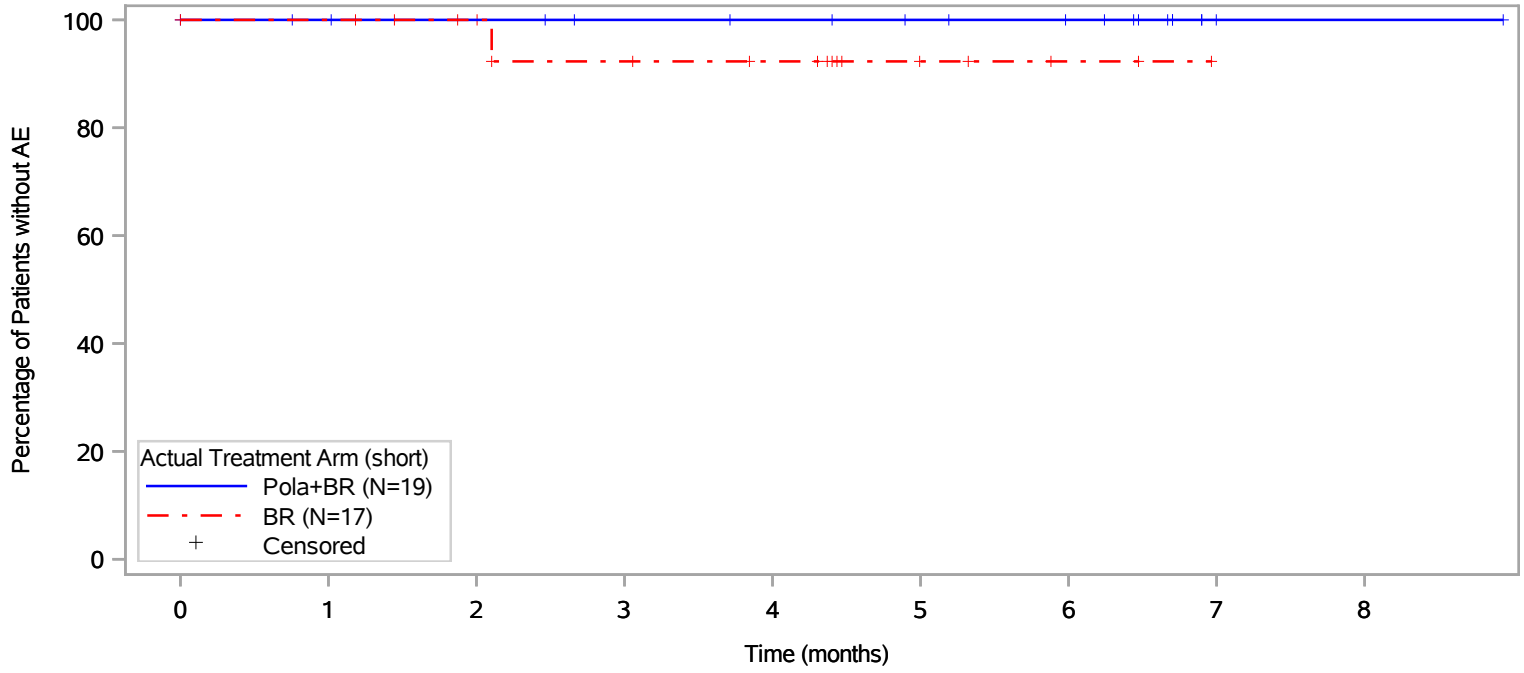
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, AXILLARY VEIN THROMBOSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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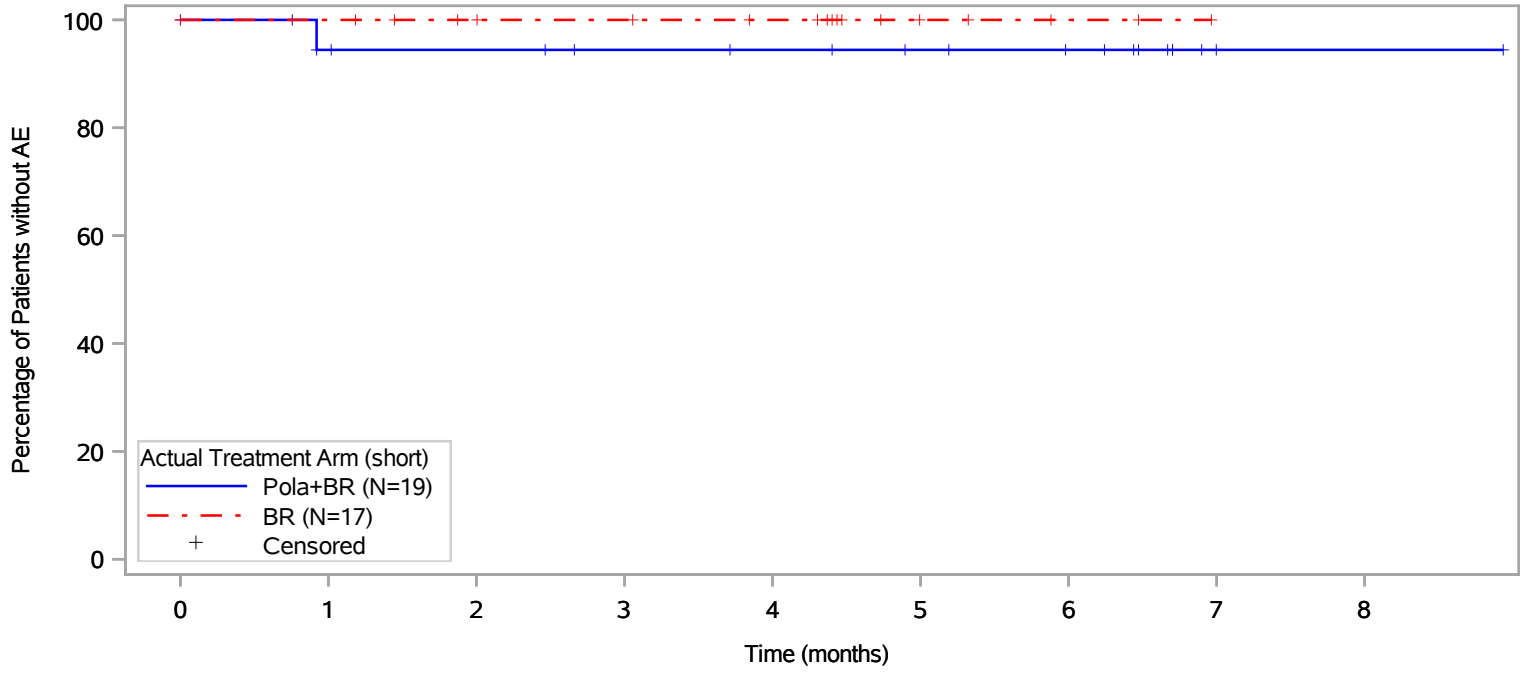
01DEC2022 20:55

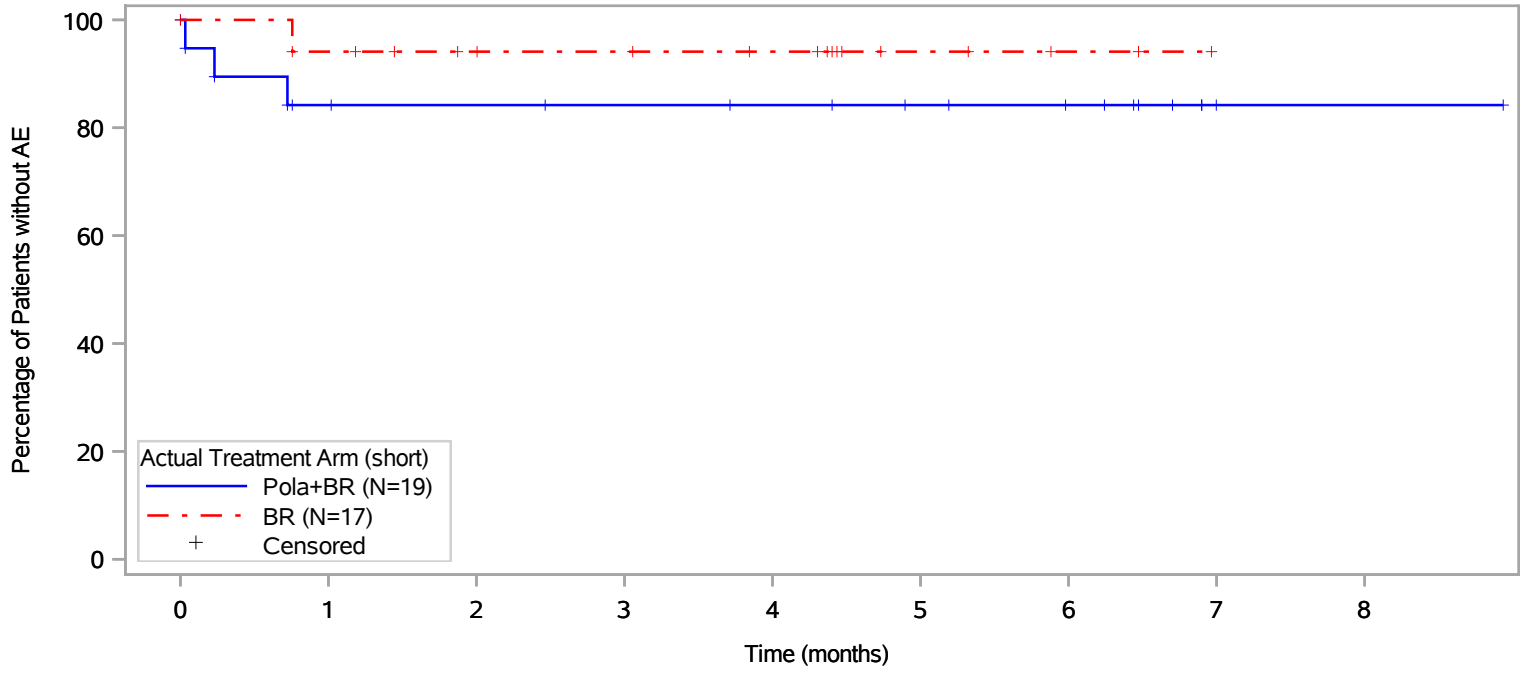
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HAEMORRHAGE



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION



Patients at risk									
Pola+BR (N=19)	19	15	14	13	12	10	8	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	15	15
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
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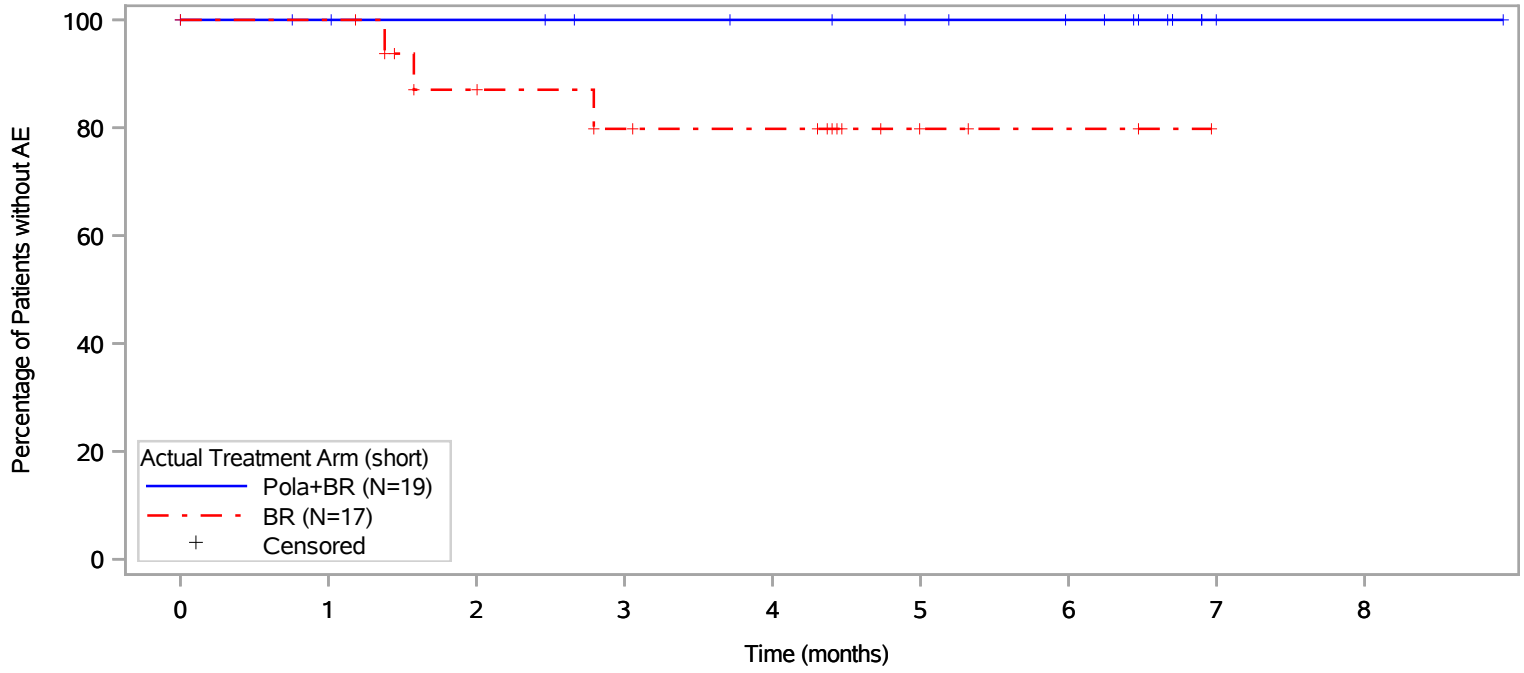
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	11	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	4	11	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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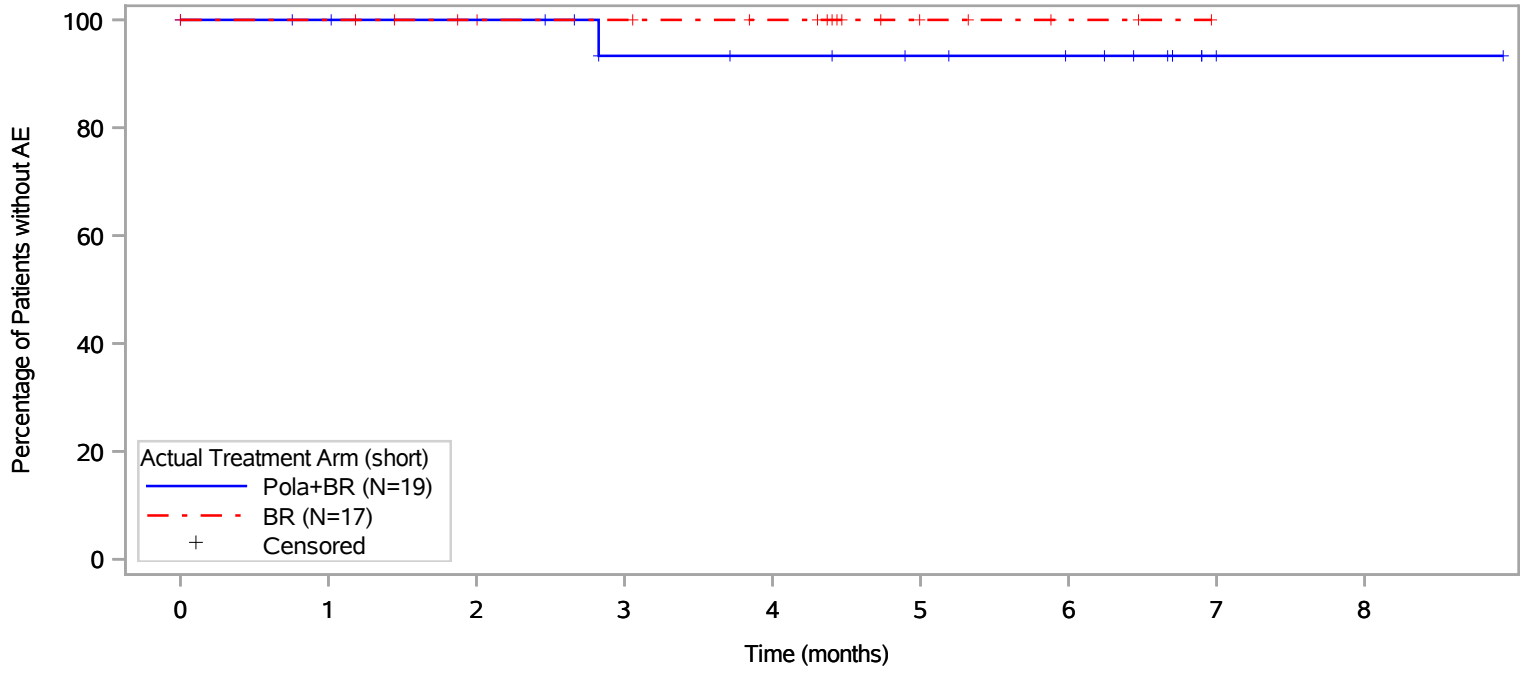
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, PERIPHERAL VENOUS DISEASE



Patients at risk									
Pola+BR (N=19)	19	18	17	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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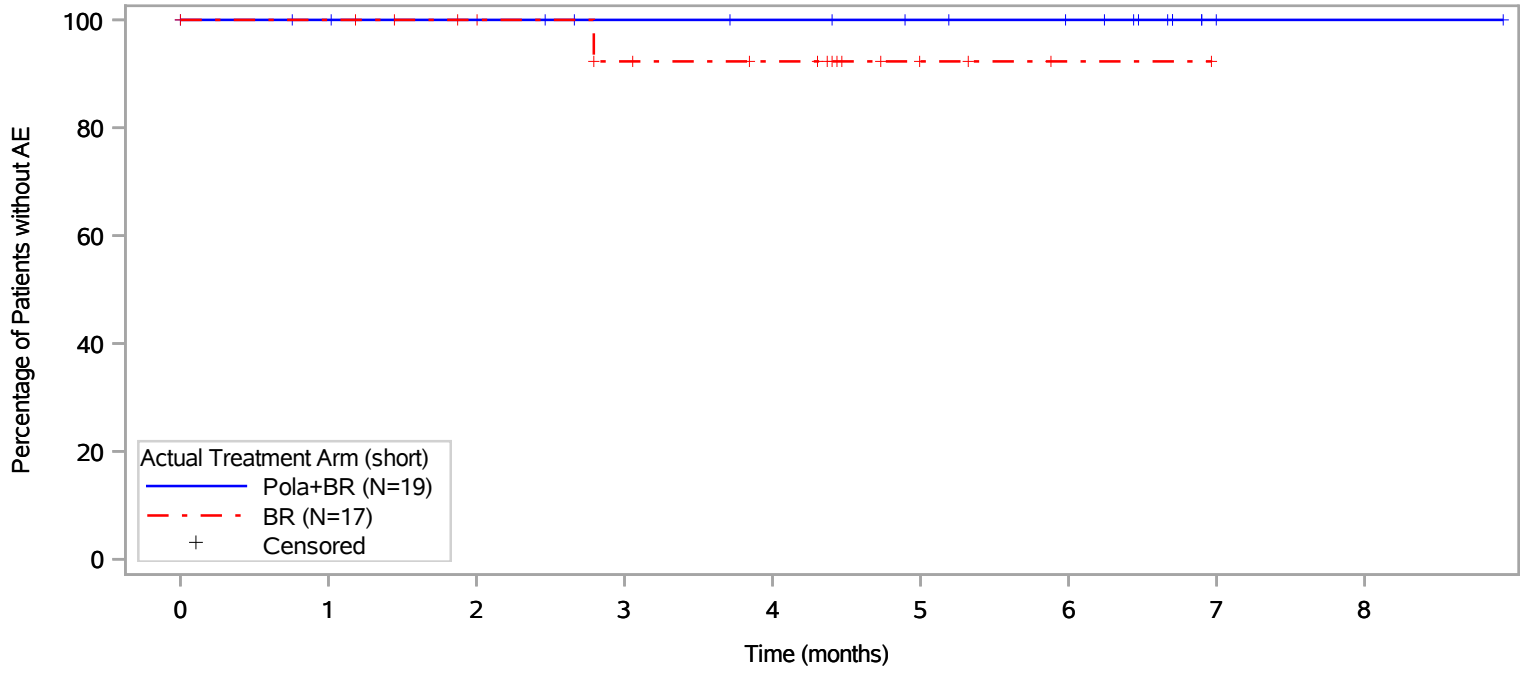
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, PHLEBITIS SUPERFICIAL



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L2_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	10	52.6	9	47.4	17	100.0	7	41.2	10	58.8	0.5633	1.61	0.60	4.32		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		19	100.0	4	21.1	15	78.9	17	100.0	2	11.8	15	88.2	0.5131	2.22	0.41	12.15		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1130	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.9244	0.84	0.05	13.68		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		19	100.0	6	31.6	13	68.4	17	100.0	5	29.4	12	70.6	0.9687	1.19	0.36	3.92		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		19	100.0	4	21.1	15	78.9	17	100.0	3	17.6	14	82.4	0.9265	1.22	0.27	5.49		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			19	100.0	0	-	19	100.0	17	100.0	3	17.6	14	82.4	0.0096	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	5	26.3	14	73.7	17	100.0	4	23.5	13	76.5	0.3345	0.51	0.11	2.35		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	3	15.8	16	84.2	17	100.0	0	-	17	100.0	0.1930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			19	100.0	5	26.3	14	73.7	17	100.0	7	41.2	10	58.8	0.1425	0.31	0.09	1.05		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LIPASE INCREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		19	100.0	0	-	19	100.0	17	100.0	4	23.5	13	76.5	0.0201	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		19	100.0	4	21.1	15	78.9	17	100.0	2	11.8	15	88.2	0.6444	1.24	0.22	6.93		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3026	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.7106	0.72	0.04	12.57		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		19	100.0	4	21.1	15	78.9	17	100.0	3	17.6	14	82.4	0.9545	0.82	0.18	3.77		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.8842	0.79	0.05	12.84		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			19	100.0	1	5.3	18	94.7	17	100.0	2	11.8	15	88.2	0.0303	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.0756	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			19	100.0	3	15.8	16	84.2	17	100.0	0	-	17	100.0	0.0921	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		19	100.0	3	15.8	16	84.2	17	100.0	0	-	17	100.0	0.0921	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 19:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	8	42.1	3	37.5	5	62.5	2	11.8	0	-	2	100.0	0.3514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	11	57.9	7	63.6	4	36.4	15	88.2	7	46.7	8	53.3	0.5135	1.80	0.62	5.25		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	2	13.3	13	86.7	0.4411	2.24	0.37	13.45		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1780	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	11	57.9	5	45.5	6	54.5	15	88.2	5	33.3	10	66.7	0.7025	1.45	0.42	5.06		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	3	20.0	12	80.0	0.9018	1.29	0.26	6.43		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	11	57.9	0	-	11	100.0	15	88.2	3	20.0	12	80.0	0.0287	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	11	57.9	4	36.4	7	63.6	15	88.2	4	26.7	11	73.3	0.3964	0.48	0.08	2.74		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	0	-	15	100.0	0.1123	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	8	42.1	4	50.0	4	50.0	2	11.8	2	100.0	0	-	0.0009	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	5	33.3	10	66.7	0.0566	0.12	0.01	1.24		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	1	50.0	1	50.0	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	3	20.0	12	80.0	0.0990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	8	42.1	3	37.5	5	62.5	2	11.8	1	50.0	1	50.0	0.7819	1.10	0.11	10.67		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.8071	0.62	0.04	10.85		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	8	42.1	3	37.5	5	62.5	2	11.8	1	50.0	1	50.0	0.6159	0.87	0.09	8.51		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.3825	0.34	0.03	4.05		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.9166	1.11	0.07	17.83		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173				*	WARNING: Iteration limit reached without convergence.	

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1414	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.2568	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	11	57.9	2	18.2	9	81.8	15	88.2	0	-	15	100.0	0.0907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	0	-	15	100.0	0.0907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 19:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	8	42.1	6	75.0	2	25.0	14	82.4	6	42.9	8	57.1	0.2000	2.44	0.76	7.87		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	11	57.9	4	36.4	7	63.6	3	17.6	1	33.3	2	66.7	0.7382	1.55	0.17	14.32		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	8	42.1	3	37.5	5	62.5	14	82.4	2	14.3	12	85.7	0.2464	2.64	0.44	15.82		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	8	42.1	3	37.5	5	62.5	14	82.4	5	35.7	9	64.3	0.8196	1.23	0.28	5.30		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3222	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	8	42.1	3	37.5	5	62.5	14	82.4	3	21.4	11	78.6	0.4922	1.95	0.39	9.71		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.1838	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0082				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0082				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	8	42.1	3	37.5	5	62.5	14	82.4	3	21.4	11	78.6	0.9504	1.03	0.16	6.72		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	11	57.9	2	18.2	9	81.8	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	0	-	14	100.0	0.0455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	5	35.7	9	64.3	0.1415	0.17	0.02	1.72		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	11	57.9	4	36.4	7	63.6	3	17.6	2	66.7	1	33.3	0.2232	0.11	0.01	1.29		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	3	21.4	11	78.6	0.1645	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	11	57.9	3	27.3	8	72.7	3	17.6	2	66.7	1	33.3	0.2731	0.10	0.01	1.17		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.9791	1.00	0.06	17.88		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	11	57.9	3	27.3	8	72.7	3	17.6	2	66.7	1	33.3	0.2232	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.6660	1.86	0.12	29.79		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	8	42.1	1	12.5	7	87.5	14	82.4	2	14.3	12	85.7	0.0701	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	8	42.1	2	25.0	6	75.0	14	82.4	0	-	14	100.0	0.0646	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.2132	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 19:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	26.3	3	60.0	2	40.0	3	17.6	2	66.7	1	33.3	0.9656	0.96	0.16	5.90		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	14	73.7	7	50.0	7	50.0	14	82.4	5	35.7	9	64.3	0.5353	1.99	0.62	6.44		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	0	-	3	100.0	0.2087	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	2	14.3	12	85.7	0.8957	1.27	0.18	9.09		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.9506	0.94	0.06	15.70		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	3	21.4	11	78.6	0.7125	1.84	0.40	8.44		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.7766	0.67	0.04	10.77		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	2	14.3	12	85.7	0.8321	1.57	0.26	9.60		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	3	21.4	11	78.6	0.0135	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	3	21.4	11	78.6	0.6443	0.79	0.15	4.05		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1852	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	14	73.7	5	35.7	9	64.3	14	82.4	7	50.0	7	50.0	0.1175	0.32	0.09	1.12		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3657	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3657	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	4	28.6	10	71.4	0.0211	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	2	14.3	12	85.7	0.5999	1.29	0.23	7.24		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.7681	1.00	0.06	16.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	3	21.4	11	78.6	0.9987	0.87	0.19	4.03		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.8993	0.86	0.05	14.17		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.3404	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3404	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1843	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	2	14.3	12	85.7	0.0797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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30NOV2022 19:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	7	50.0	7	50.0	8	47.1	5	62.5	3	37.5	0.5155	1.02	0.30	3.51		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	3	60.0	2	40.0	9	52.9	2	22.2	7	77.8	0.1732	2.45	0.35	17.04		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	14	73.7	2	14.3	12	85.7	8	47.1	2	25.0	6	75.0	0.4349	0.87	0.12	6.29		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.0514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.6583	0.41	0.02	9.27		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	14	73.7	3	21.4	11	78.6	8	47.1	3	37.5	5	62.5	0.4217	0.80	0.15	4.29		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	5	26.3	3	60.0	2	40.0	9	52.9	2	22.2	7	77.8	0.2165	1.95	0.31	12.28		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	14	73.7	3	21.4	11	78.6	8	47.1	2	25.0	6	75.0	0.7398	1.05	0.16	6.99		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	5	26.3	1	20.0	4	80.0	9	52.9	1	11.1	8	88.9	0.6771	1.15	0.07	18.59		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	14	73.7	0	-	14	100.0	8	47.1	2	25.0	6	75.0	0.0217	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	3	21.4	11	78.6	8	47.1	1	12.5	7	87.5	0.8592	1.60	0.14	18.24		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	2	40.0	3	60.0	9	52.9	3	33.3	6	66.7	0.3894	0.32	0.03	3.41		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.2059				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	14	73.7	4	28.6	10	71.4	8	47.1	3	37.5	5	62.5	0.4684	0.50	0.09	2.66		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	1	20.0	4	80.0	9	52.9	4	44.4	5	55.6	0.1546	0.14	0.01	2.74		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	3	33.3	6	66.7	0.1569	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	14	73.7	3	21.4	11	78.6	8	47.1	0	-	8	100.0	0.2071	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.5330	0.67	0.05	9.18		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.4263	0.62	0.03	11.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	14	73.7	3	21.4	11	78.6	8	47.1	1	12.5	7	87.5	0.6953	0.75	0.06	9.38		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.5530	0.69	0.05	9.39		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.3209	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	14	73.7	0	-	14	100.0	8	47.1	2	25.0	6	75.0	0.0217	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.0448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.0448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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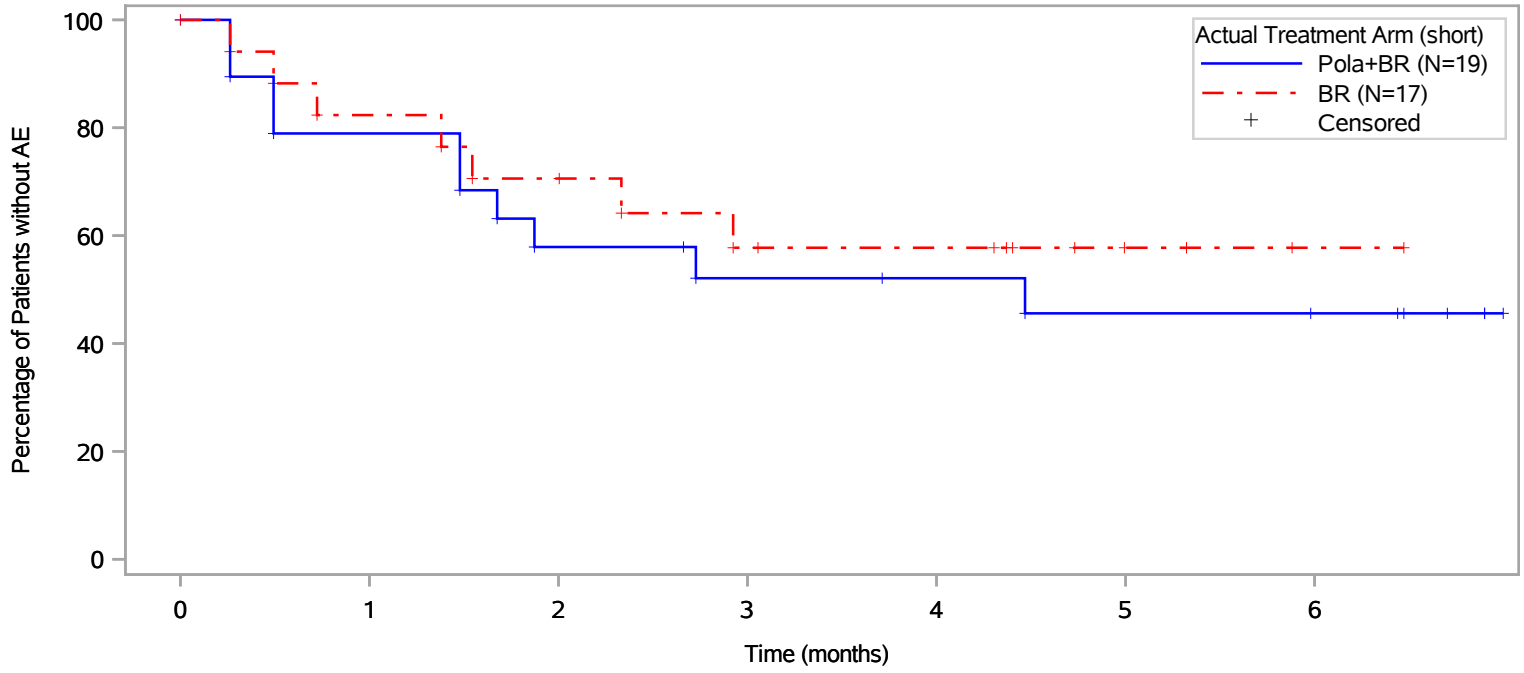
30NOV2022 19:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	15	11	9	8	7	6
BR (N=17)	17	14	12	9	8	3	1
Patients censored							
Pola+BR (N=19)	0	0	0	1	2	2	3
BR (N=17)	0	0	0	1	2	7	9

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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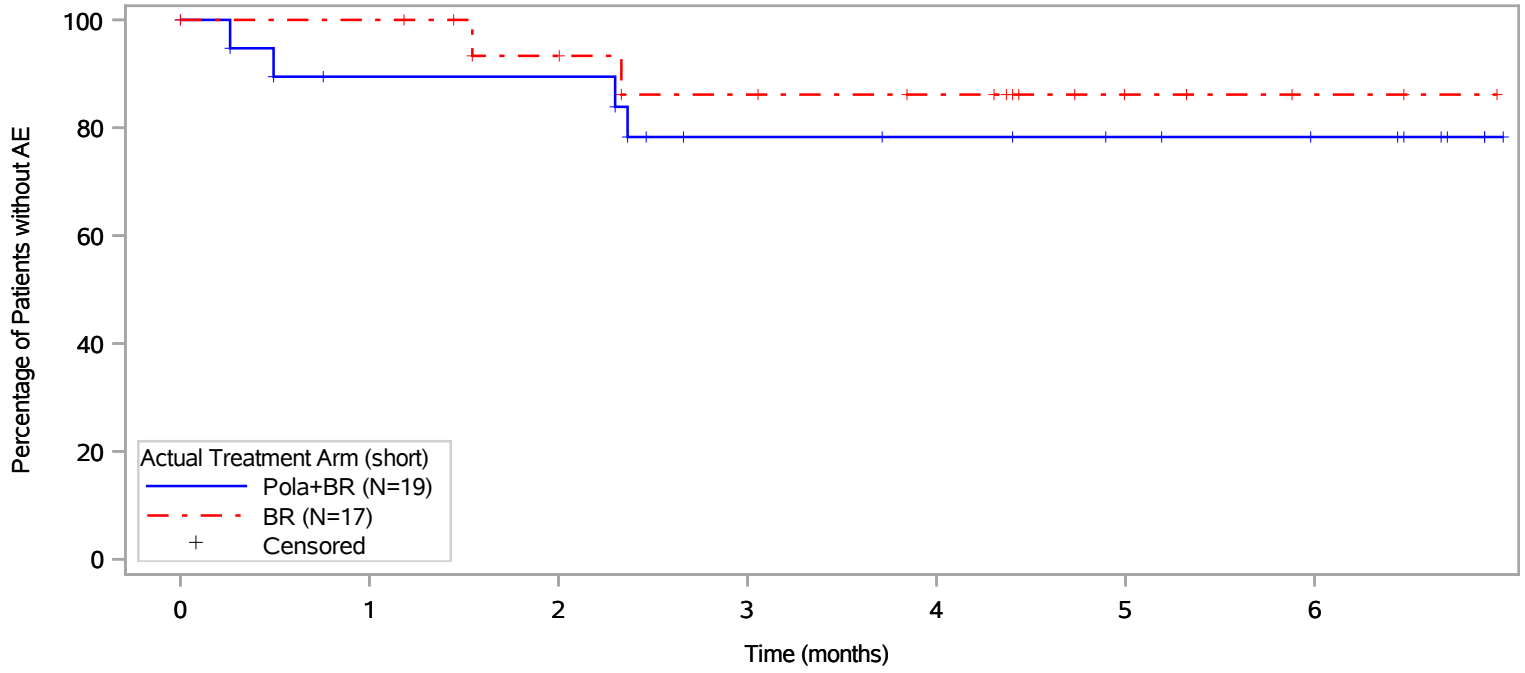
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk							
Pola+BR (N=19)	19	16	16	12	11	9	7
BR (N=17)	17	17	14	12	10	4	2
Patients censored							
Pola+BR (N=19)	0	1	1	3	4	6	8
BR (N=17)	0	0	2	3	5	11	13

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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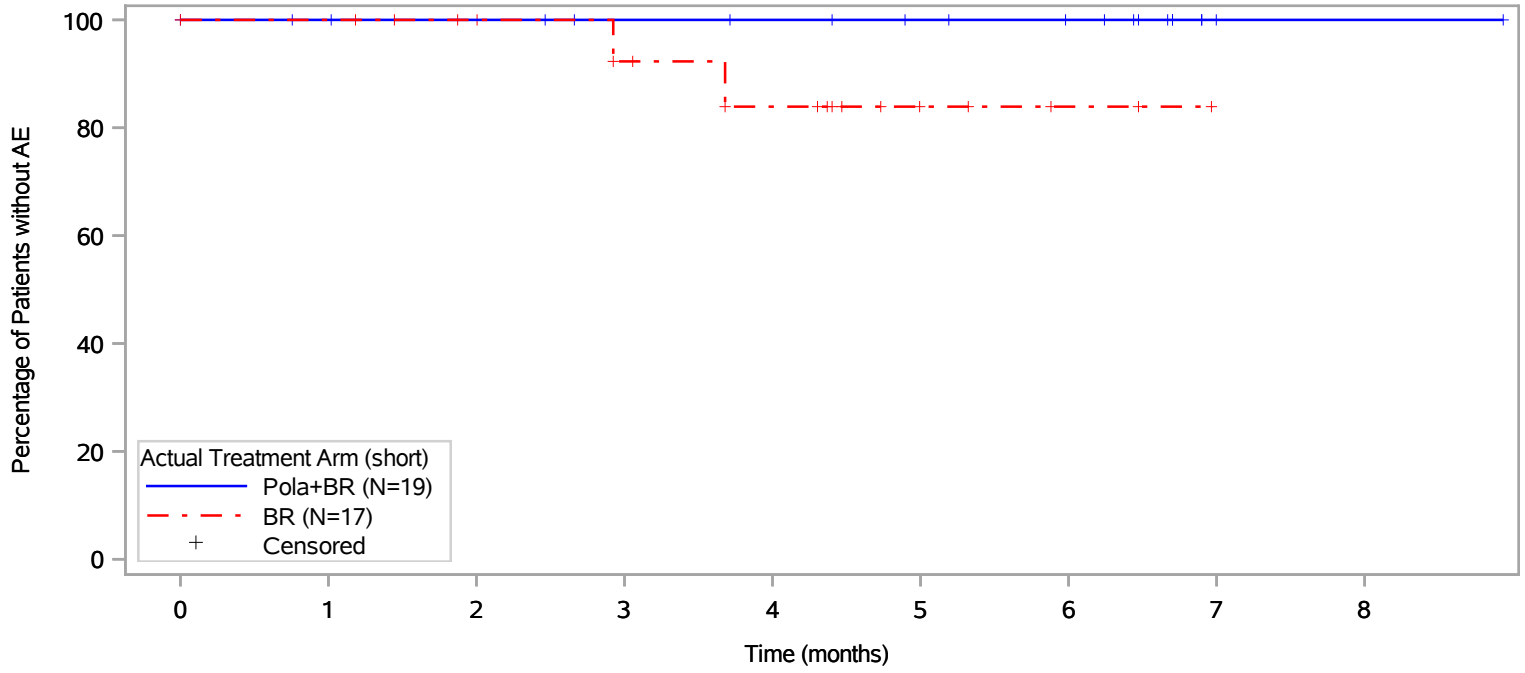
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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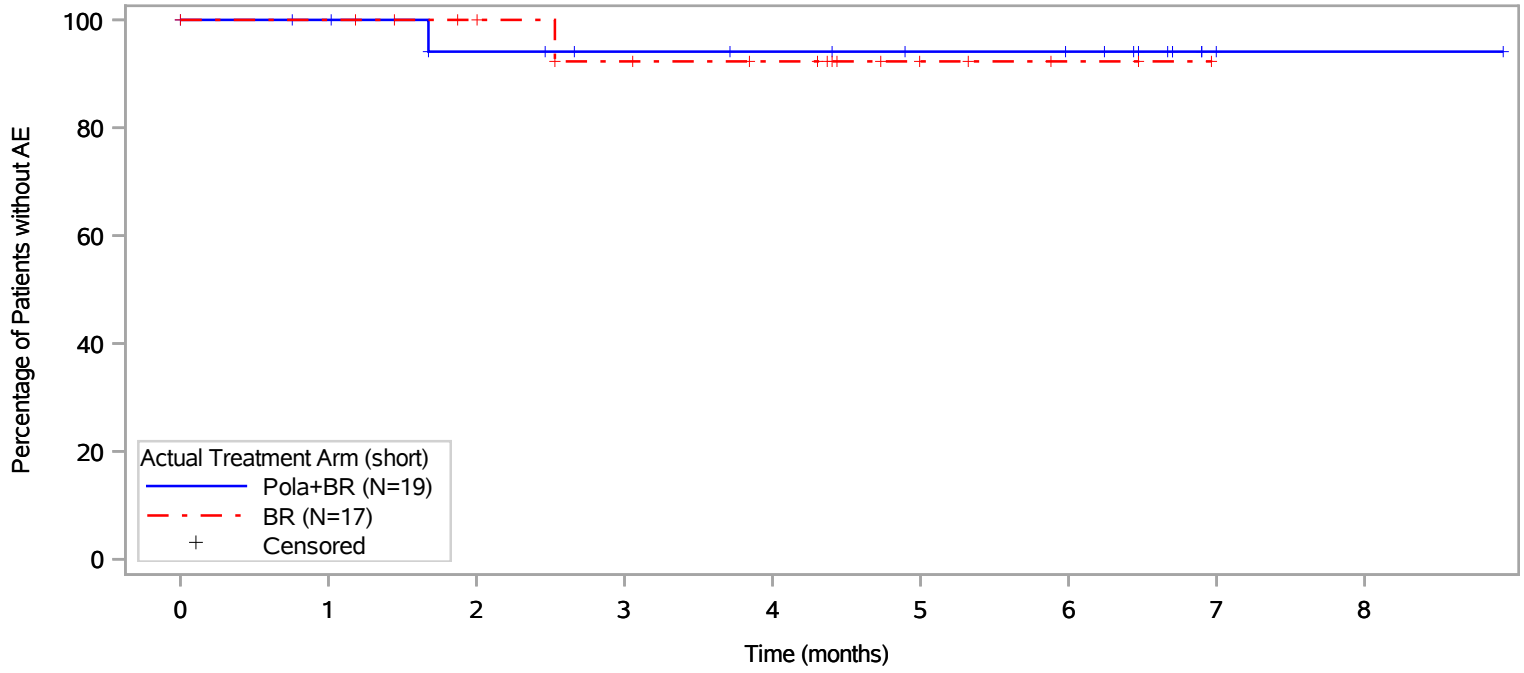
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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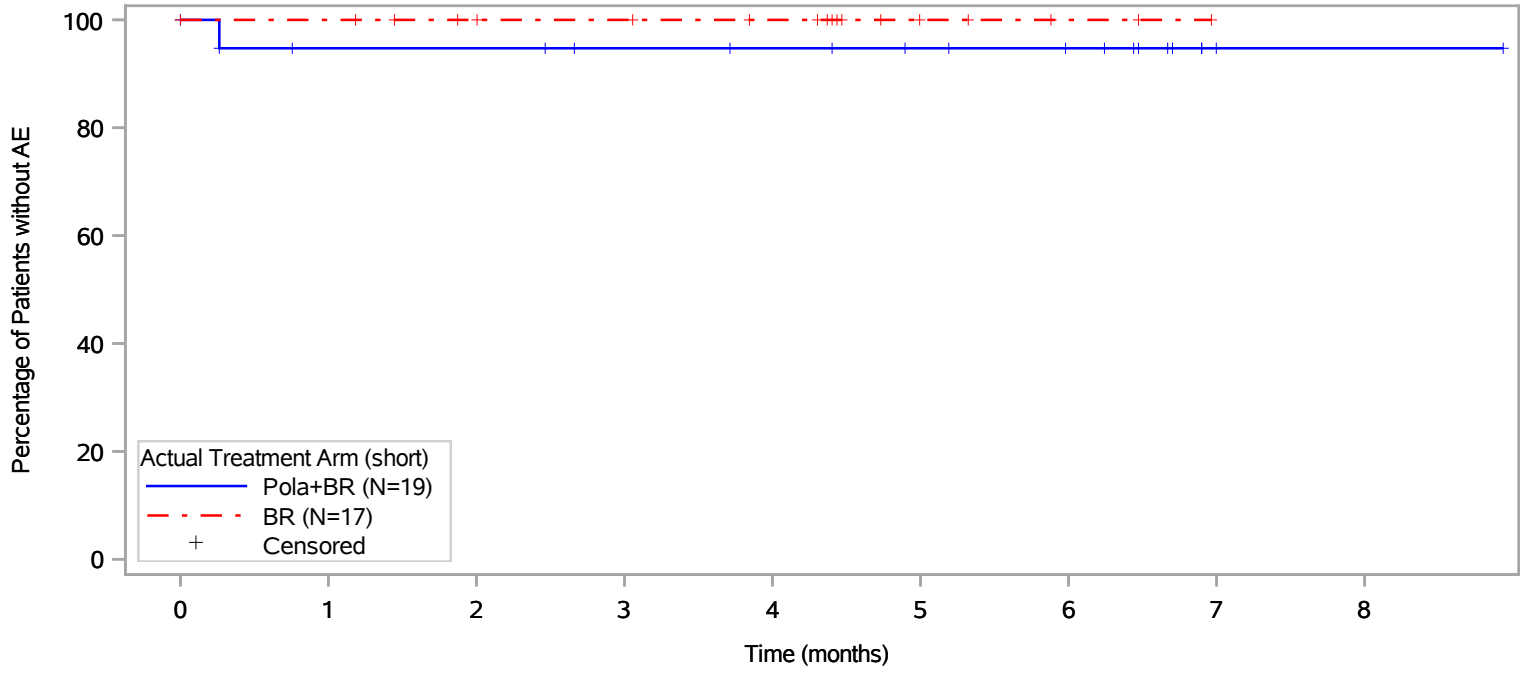
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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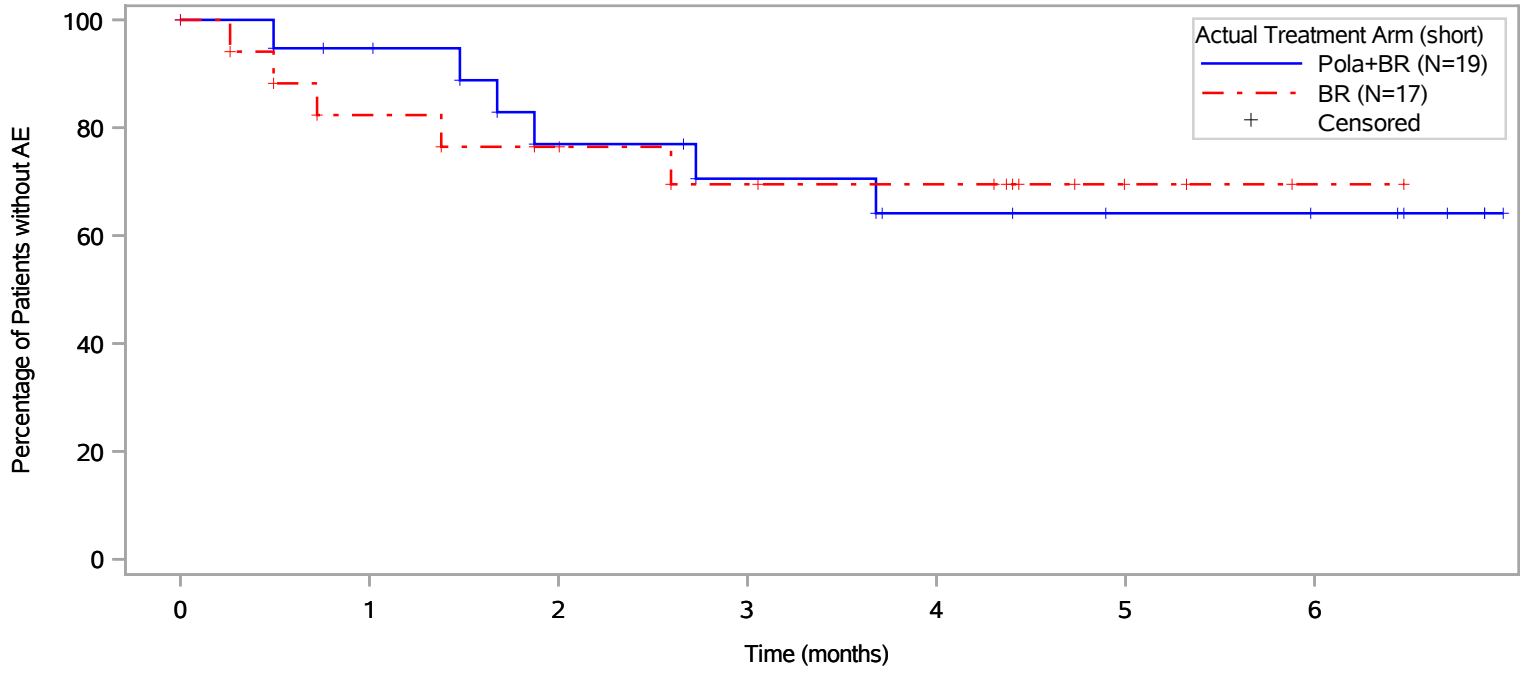
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



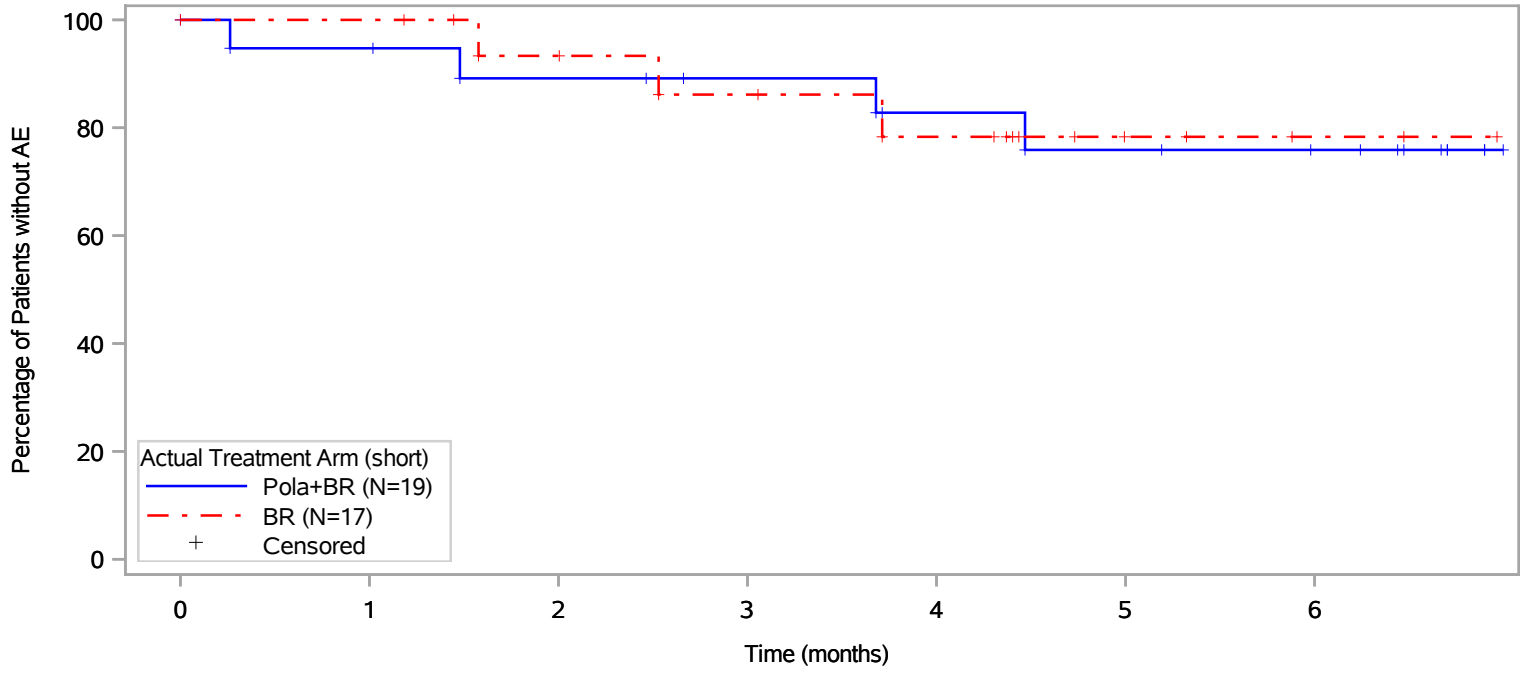
Patients at risk							
Pola+BR (N=19)	19	17	13	11	9	7	6
BR (N=17)	17	14	12	10	9	3	1
Patients censored							
Pola+BR (N=19)	0	1	2	3	4	6	7
BR (N=17)	0	0	1	2	3	9	11

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk							
Pola+BR (N=19)	19	18	16	14	12	11	9
BR (N=17)	17	17	14	12	10	4	2
Patients censored							
Pola+BR (N=19)	0	0	1	3	4	4	6
BR (N=17)	0	0	2	3	4	10	12

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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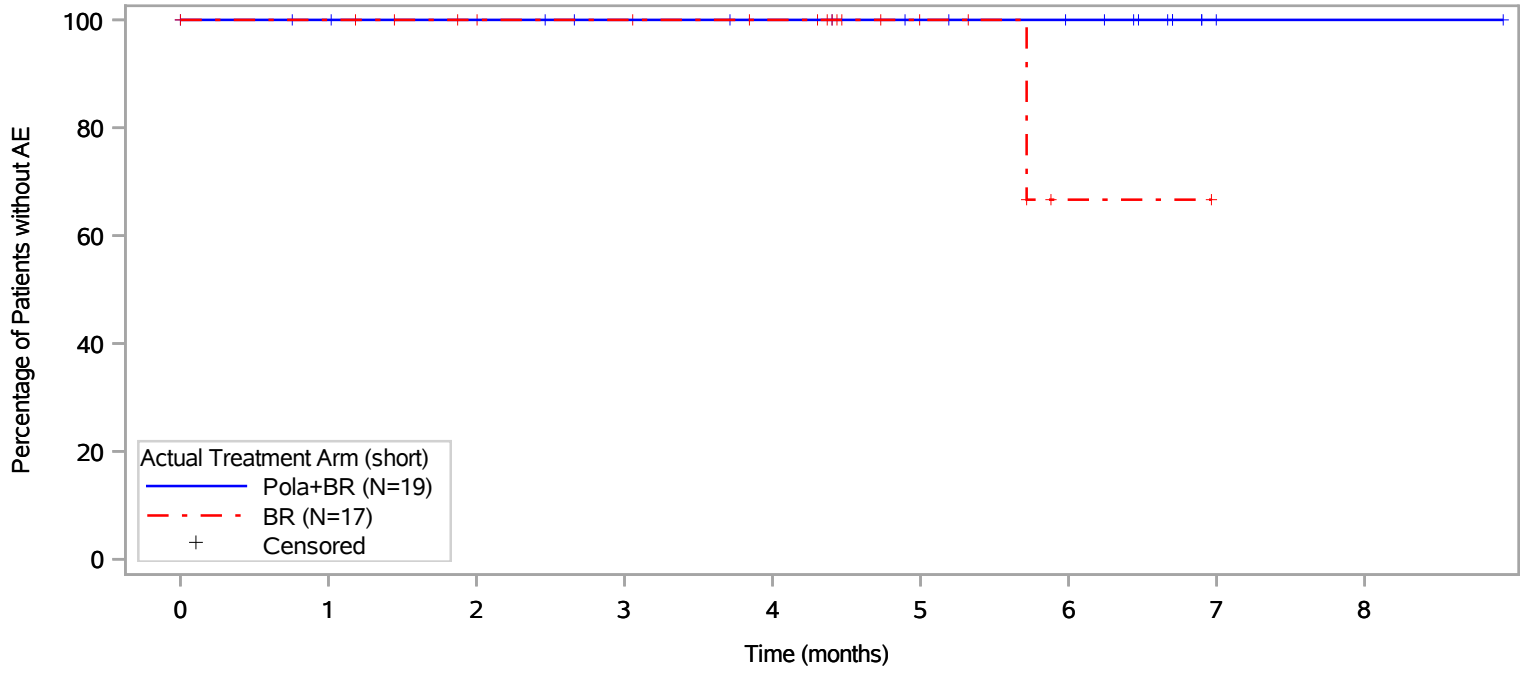
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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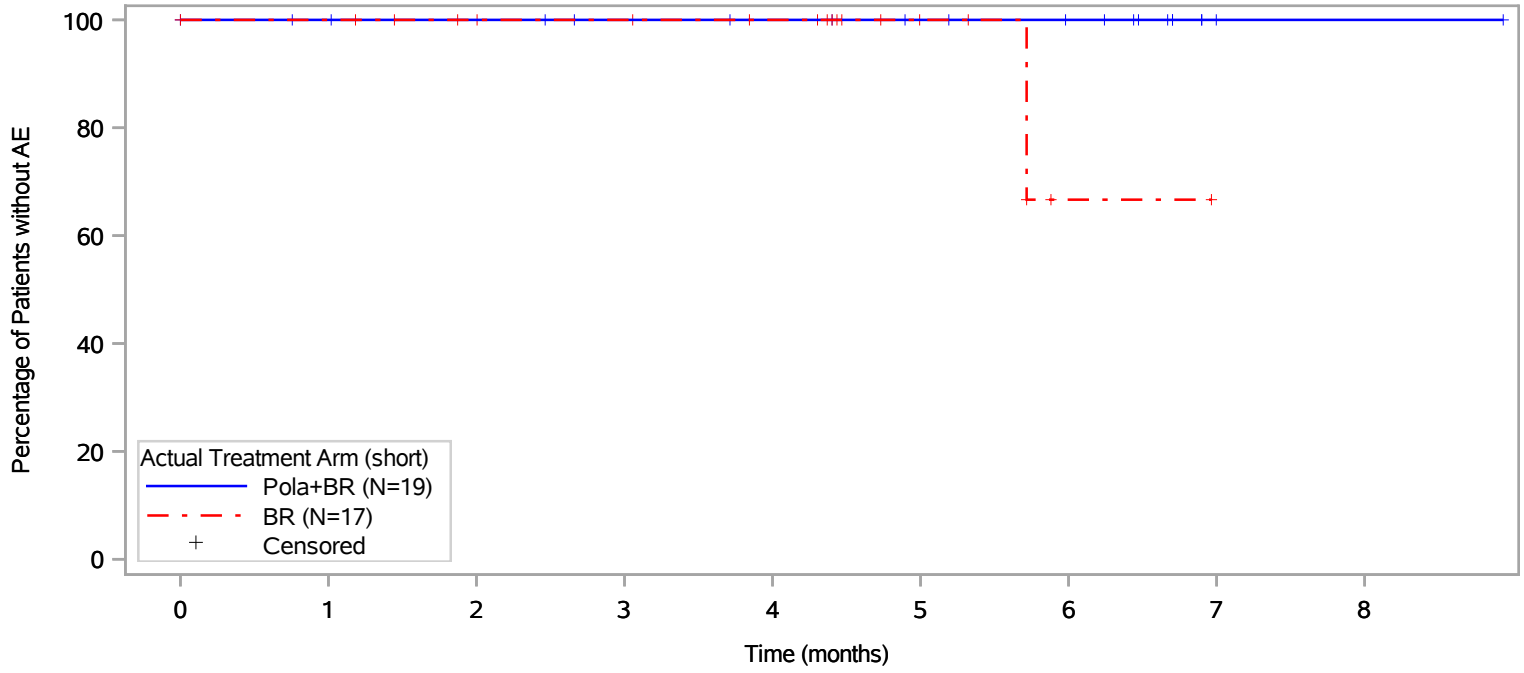
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SMALL INTESTINAL OBSTRUCTION

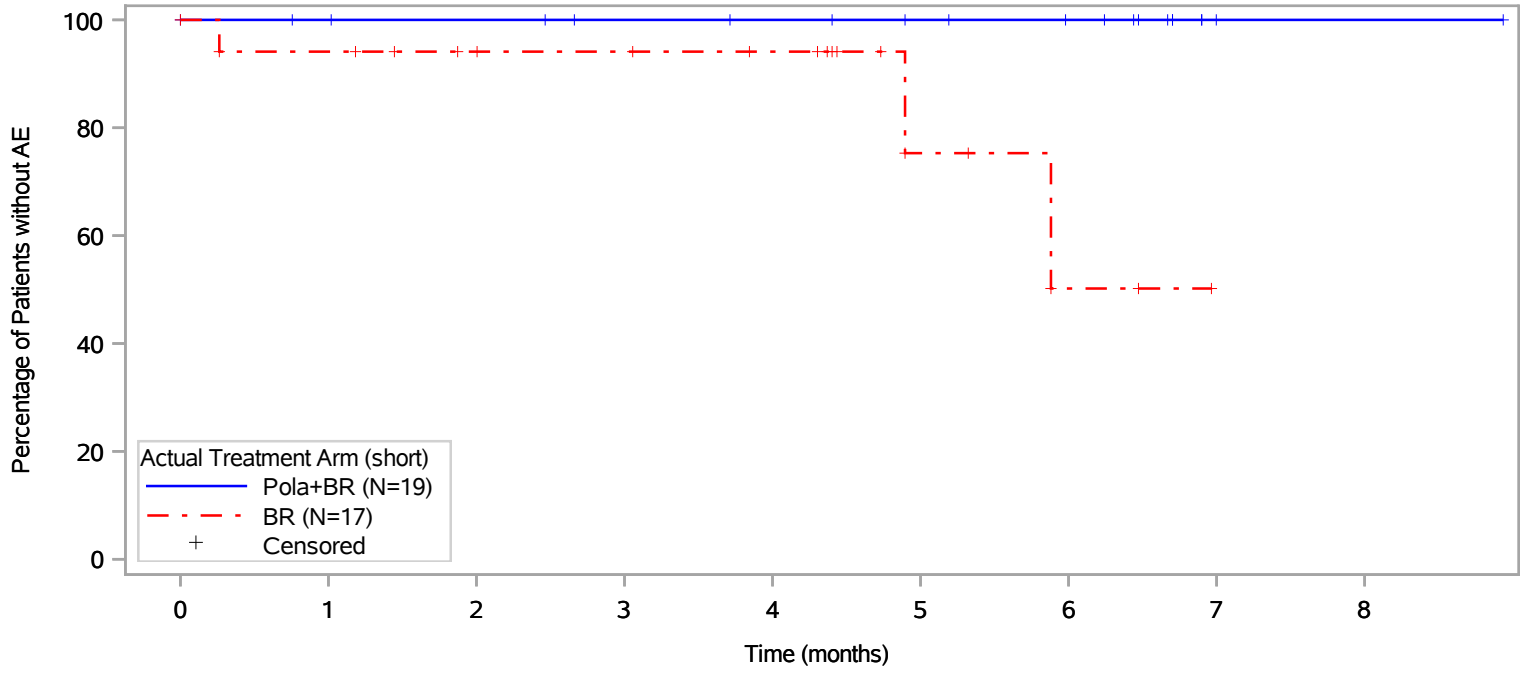


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All

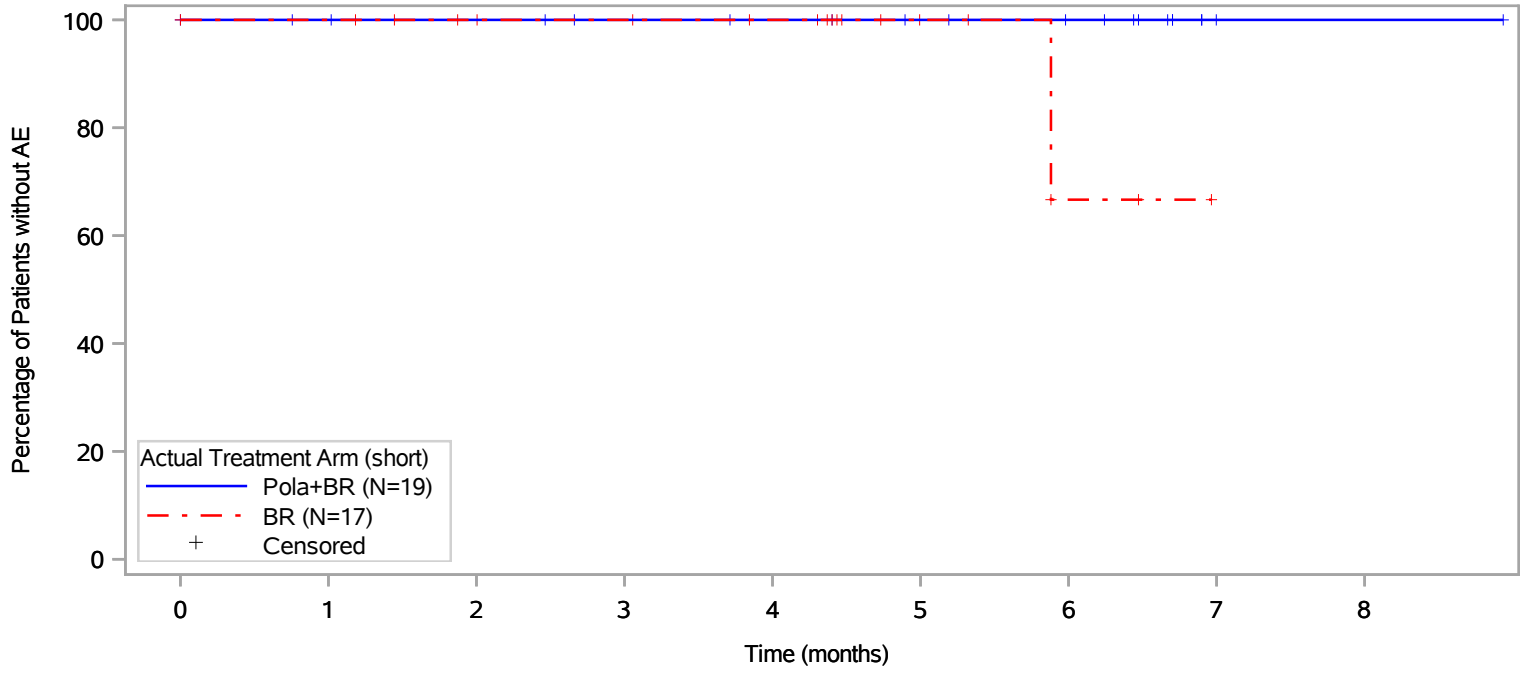


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	11	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DEATH



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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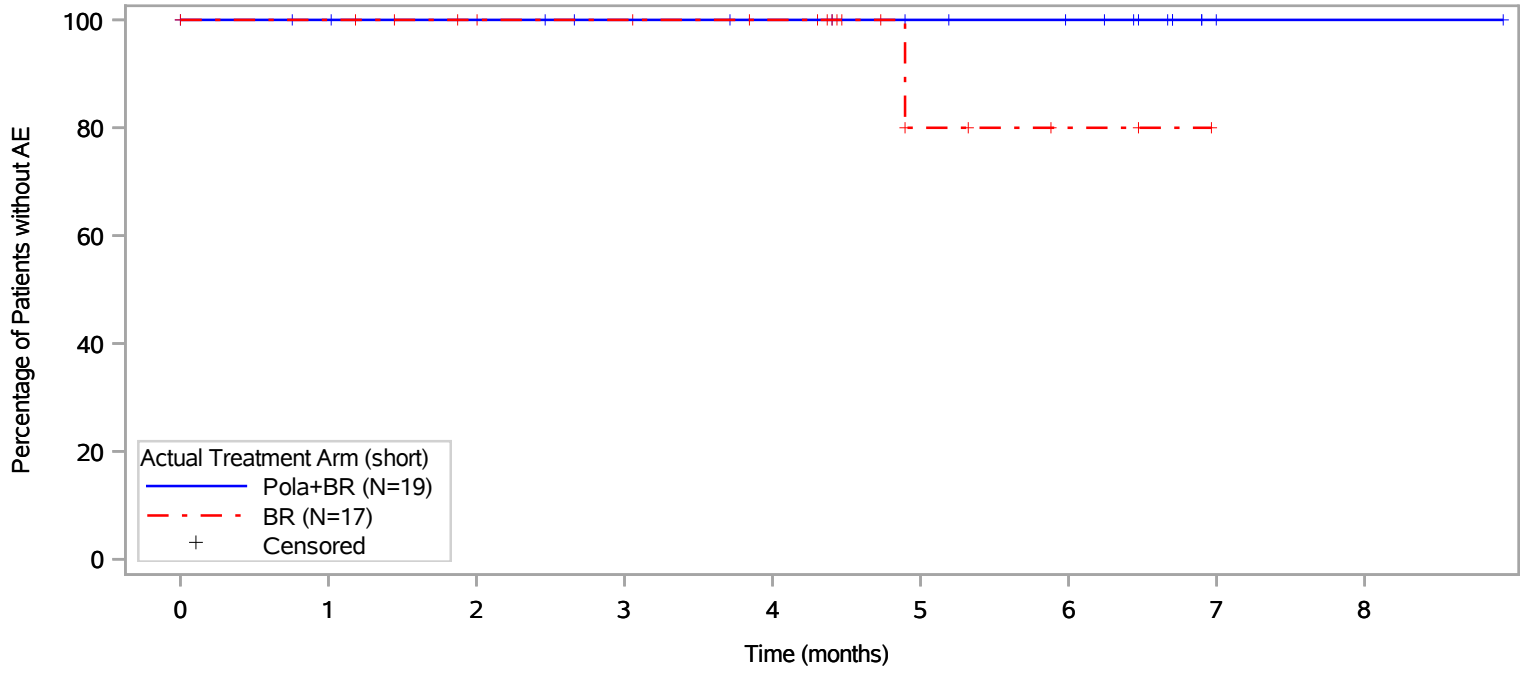
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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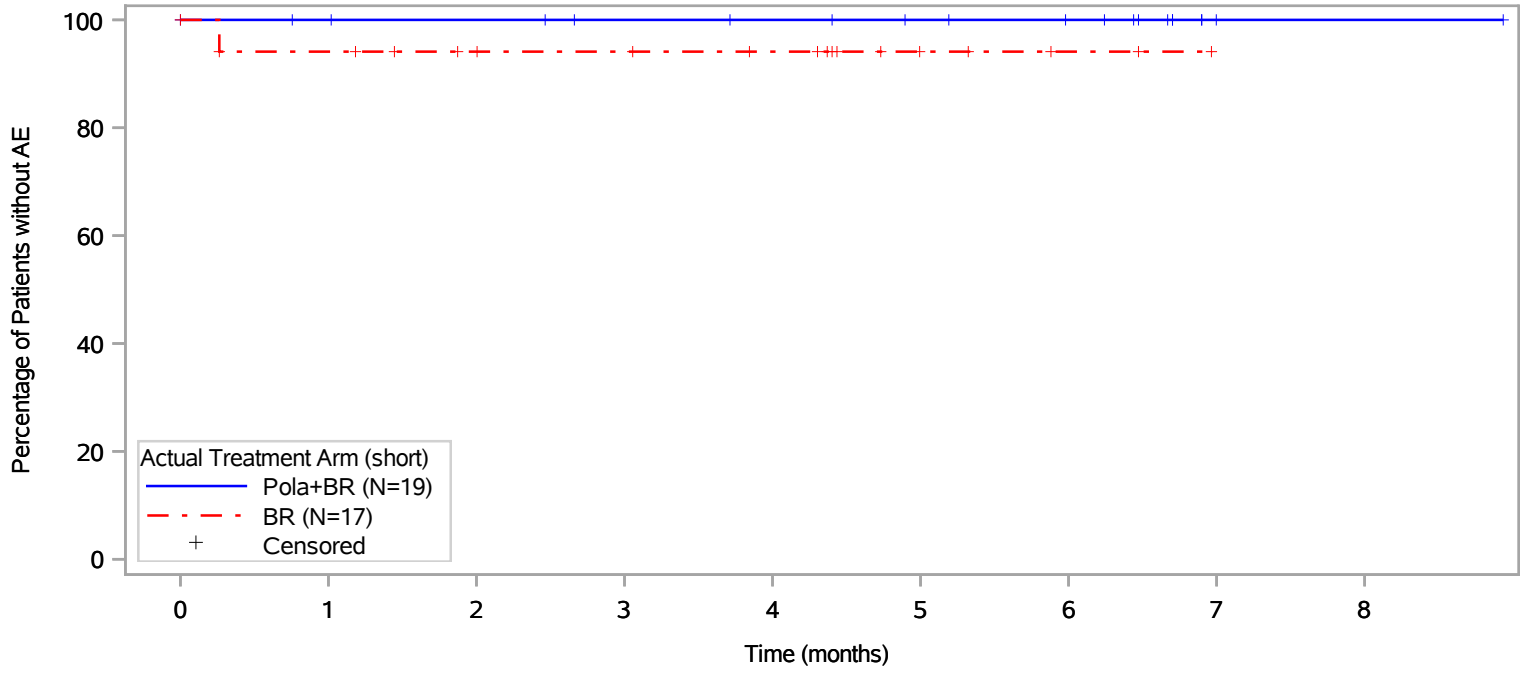
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

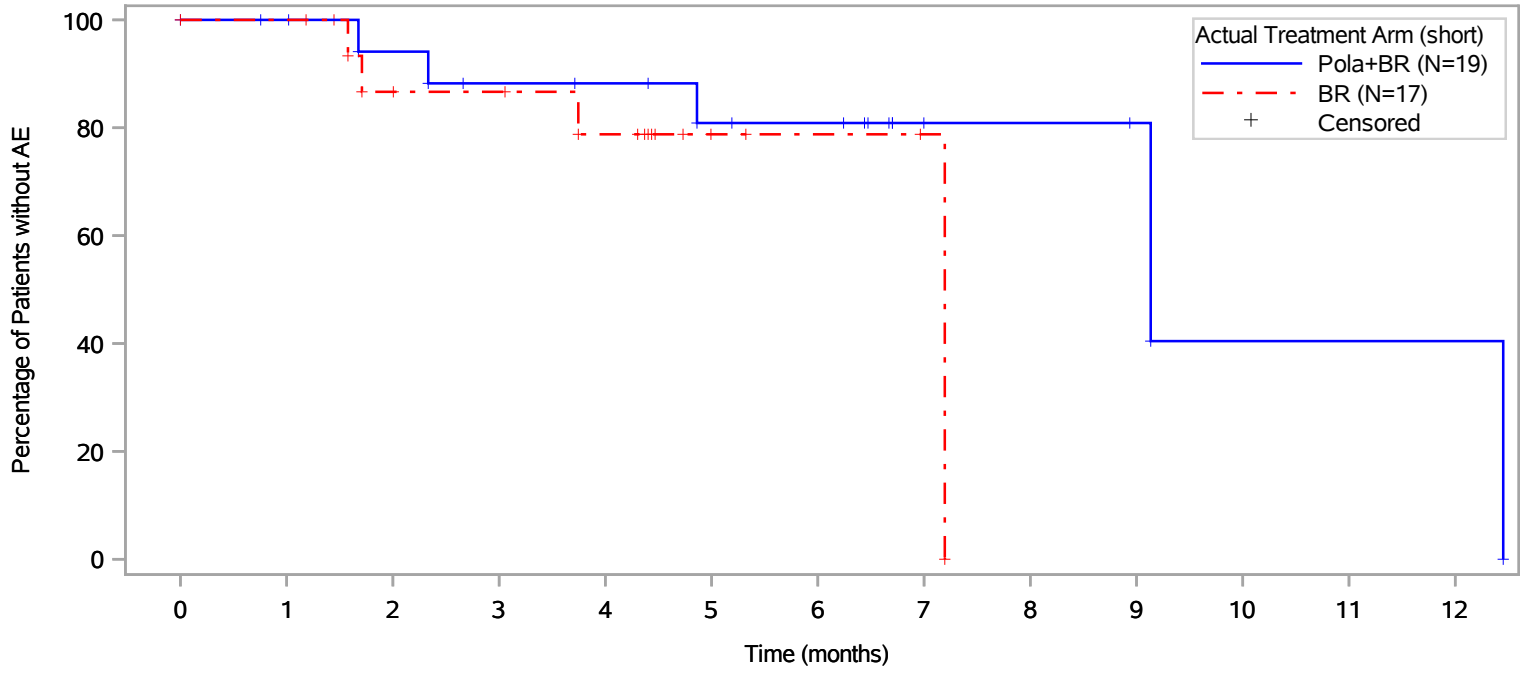
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk													
Pola+BR (N=19)	19	18	16	14	13	11	10	3	3	2	1	1	1
BR (N=17)	17	17	13	12	10	3	2	1	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	2	3	4	5	6	13	13	14	14	14	14
BR (N=17)	0	0	2	3	4	11	12	13	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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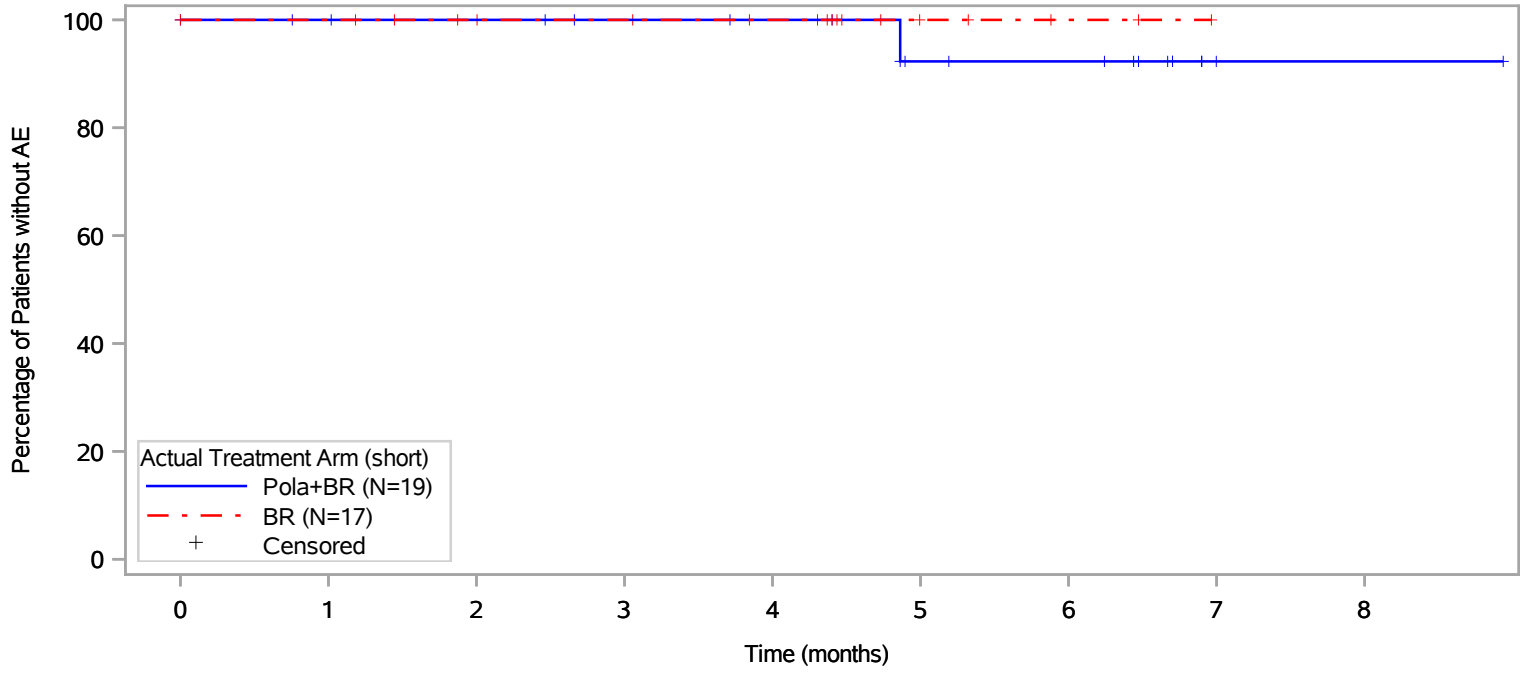
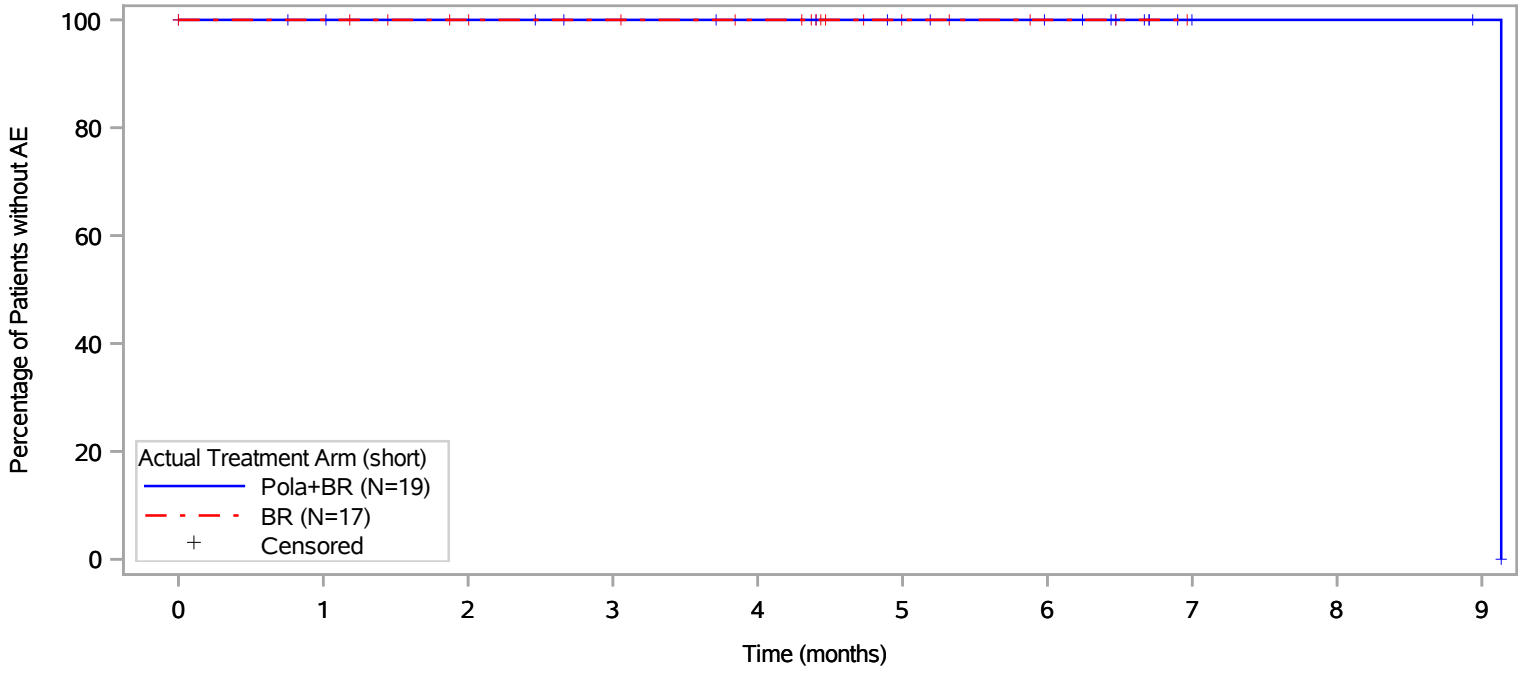
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CEREBRAL TOXOPLASMOSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES VIRUS INFECTION



Patients at risk										
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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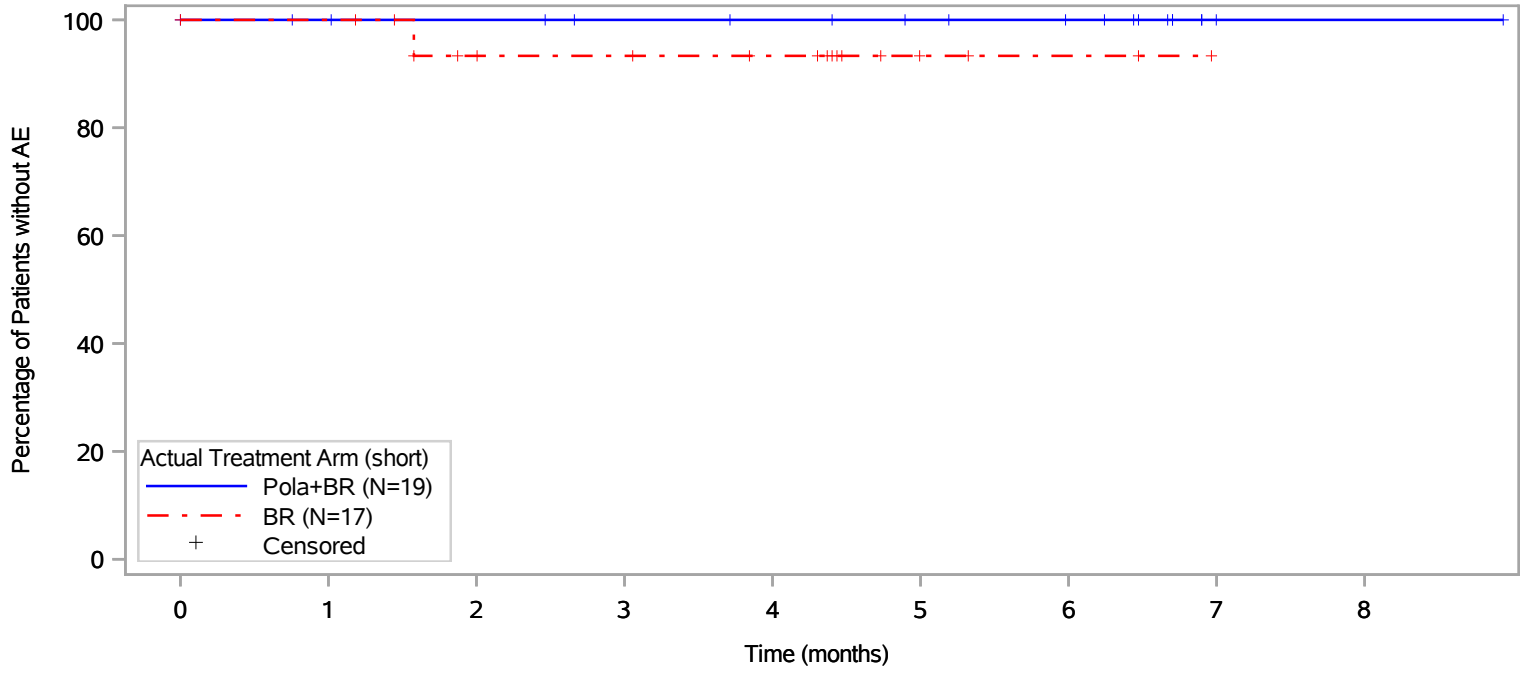
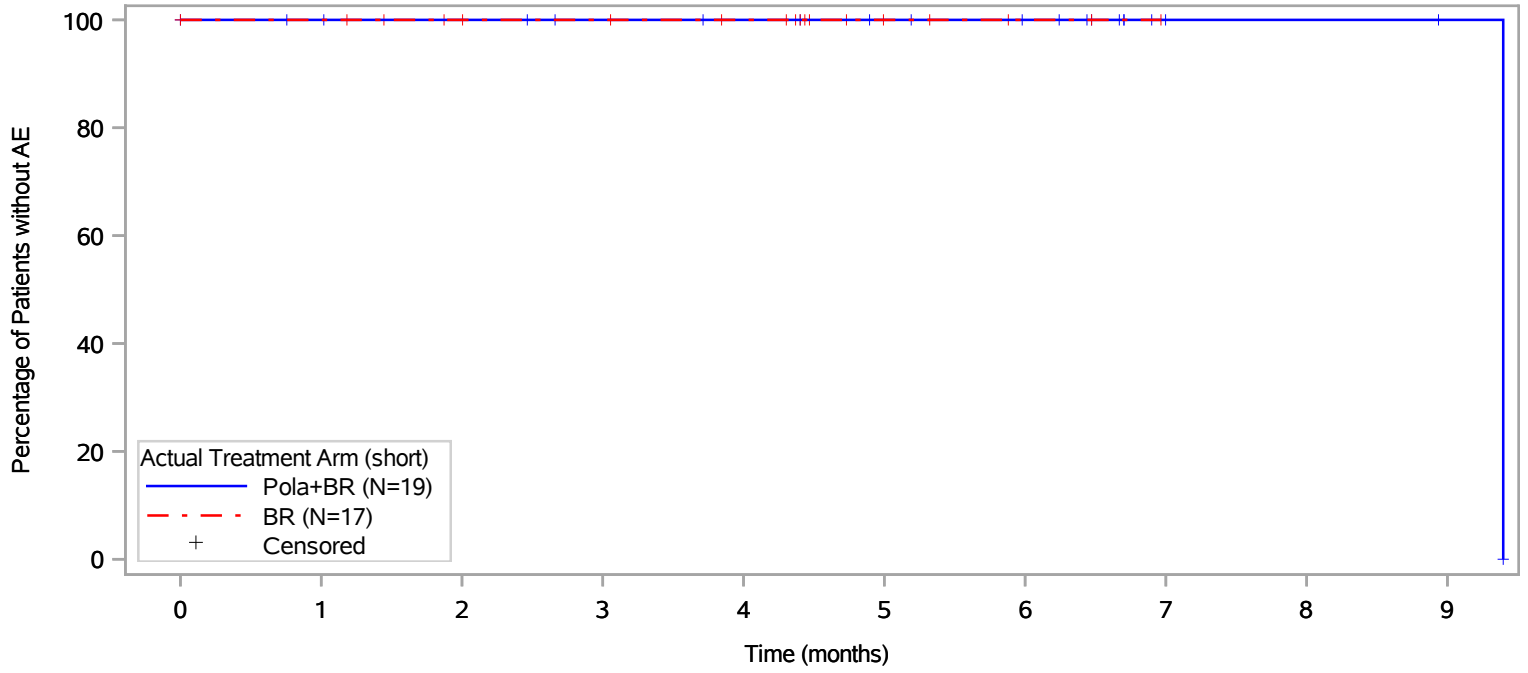
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

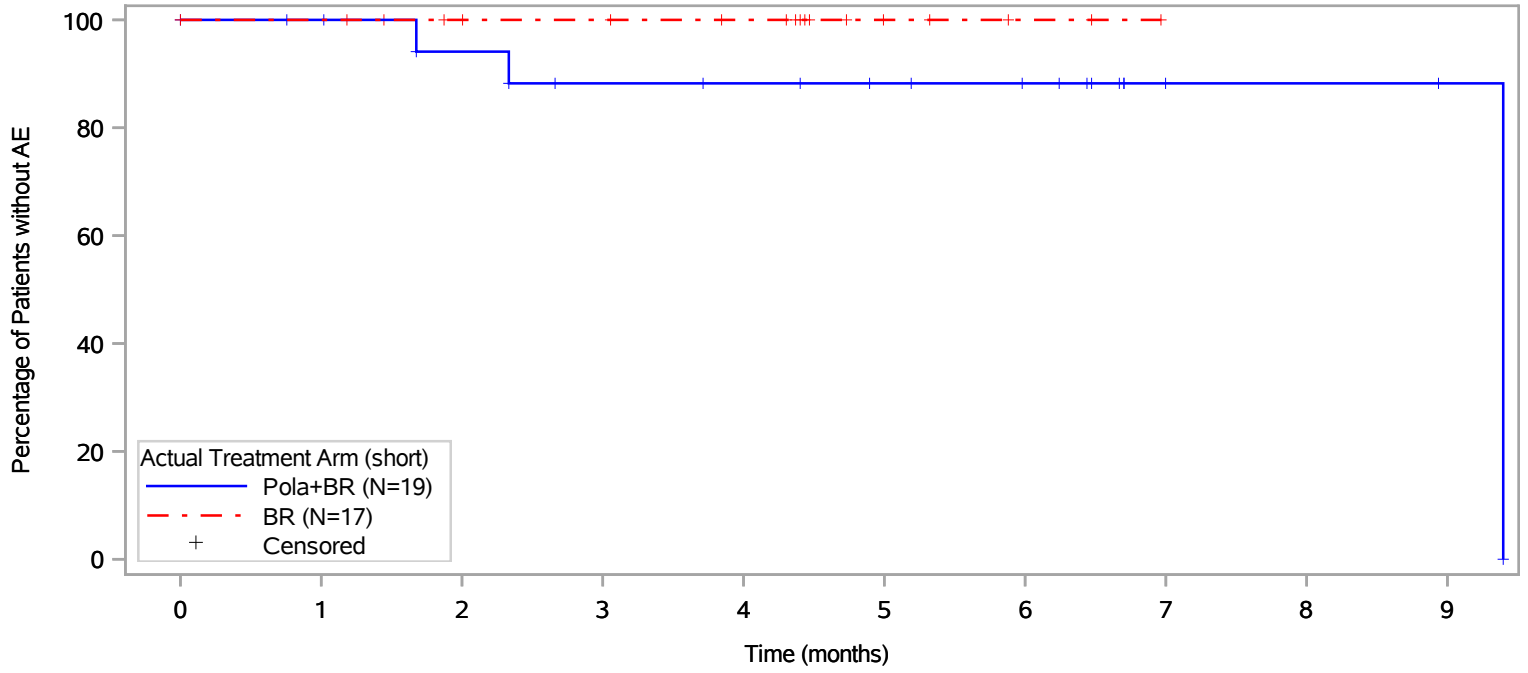
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MENINGOENCEPHALITIS HERPETIC



Patients at risk										
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	9	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	15	15	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
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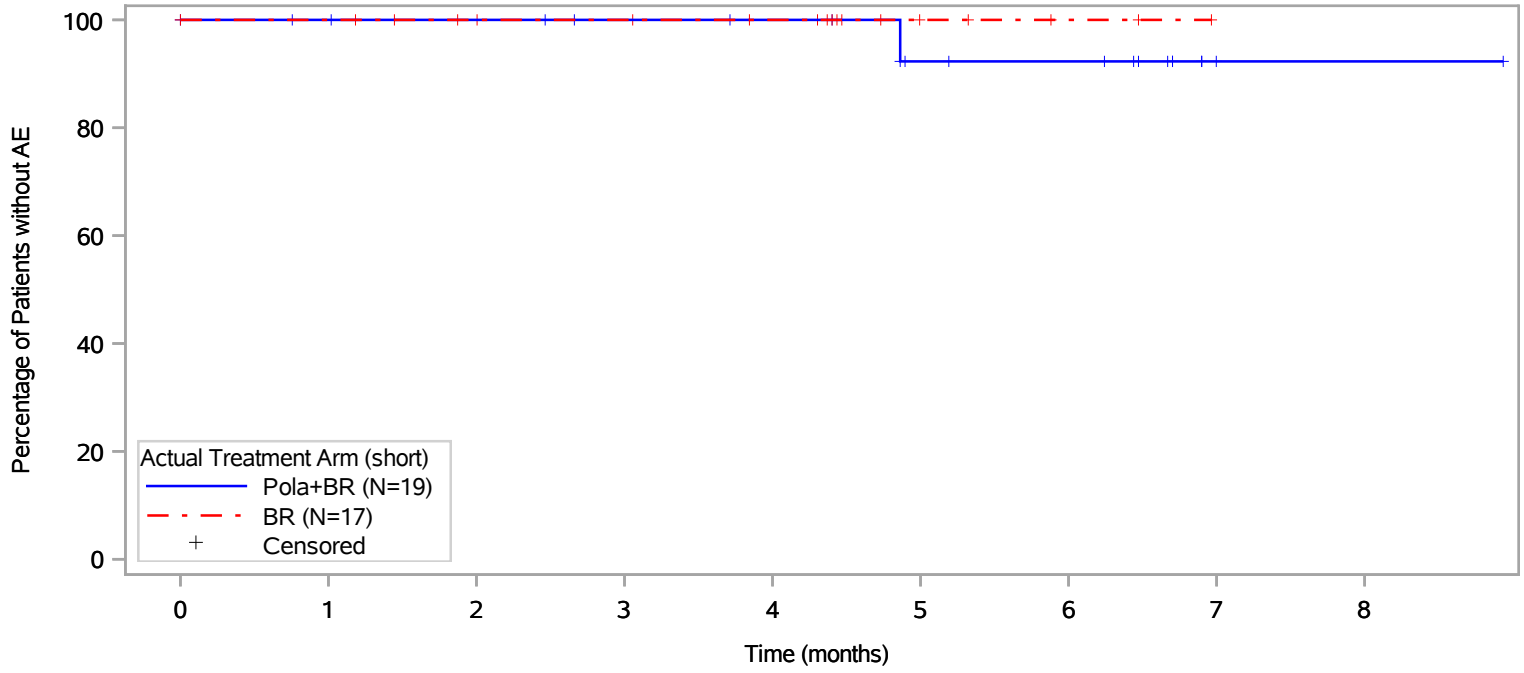
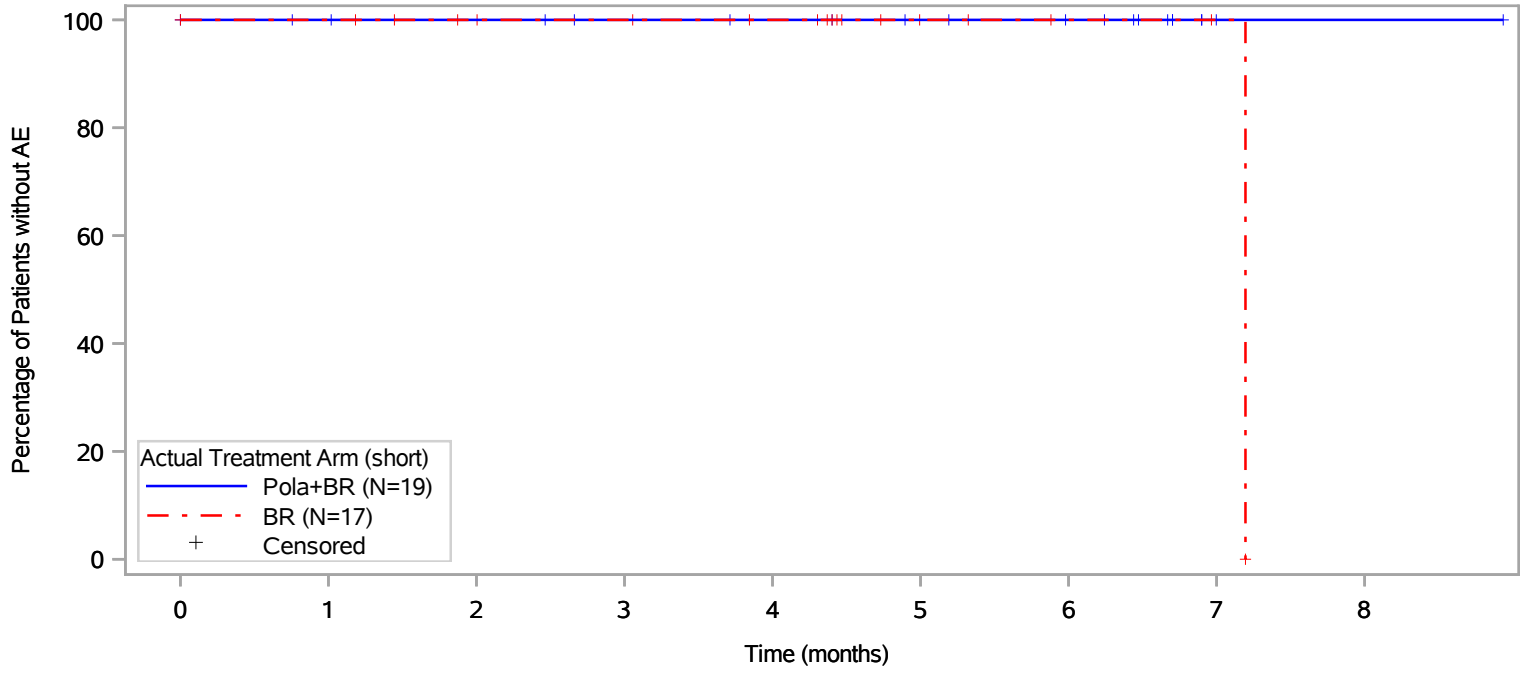
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA CYTOMEGALOVIRAL



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

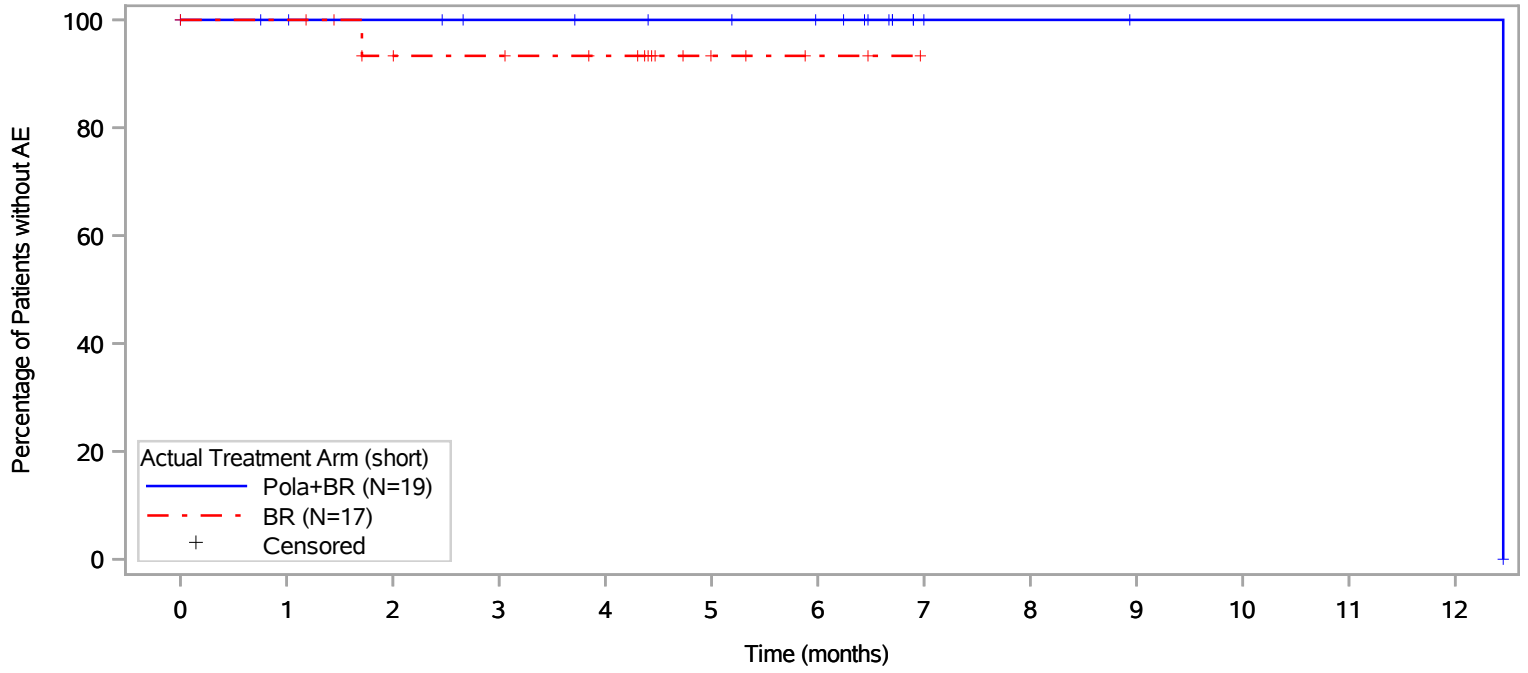
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, POST PROCEDURAL INFECTION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS

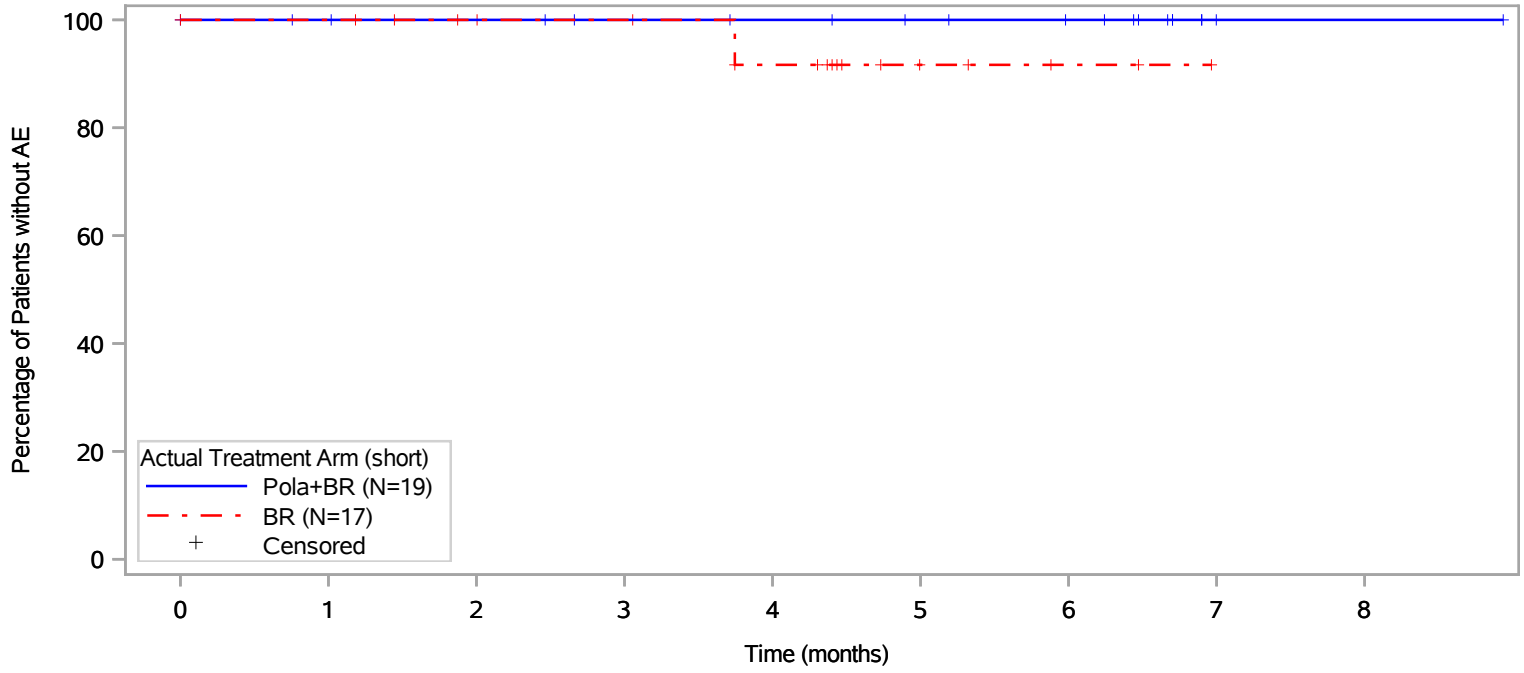


Patients at risk													
Pola+BR (N=19)	19	18	17	15	14	13	11	2	2	1	1	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	2	4	5	6	8	17	17	18	18	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

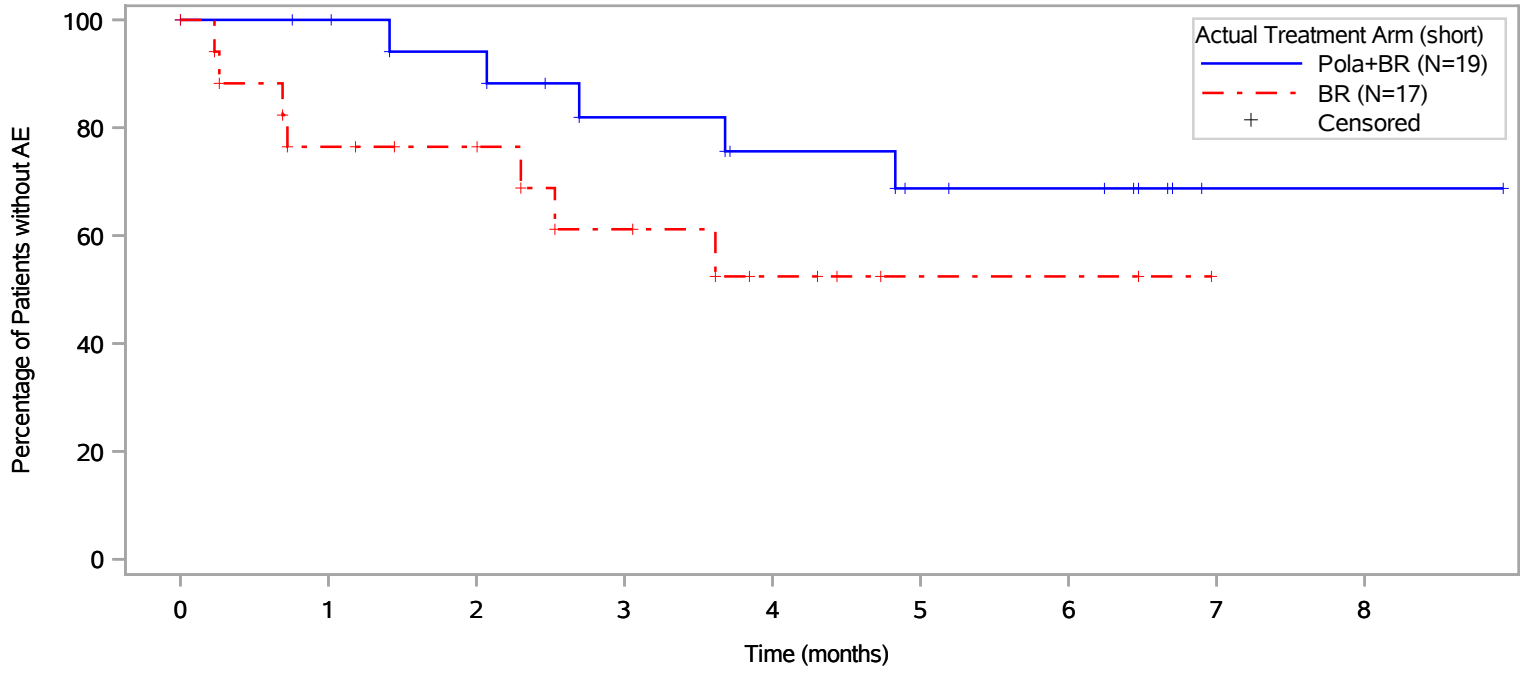
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

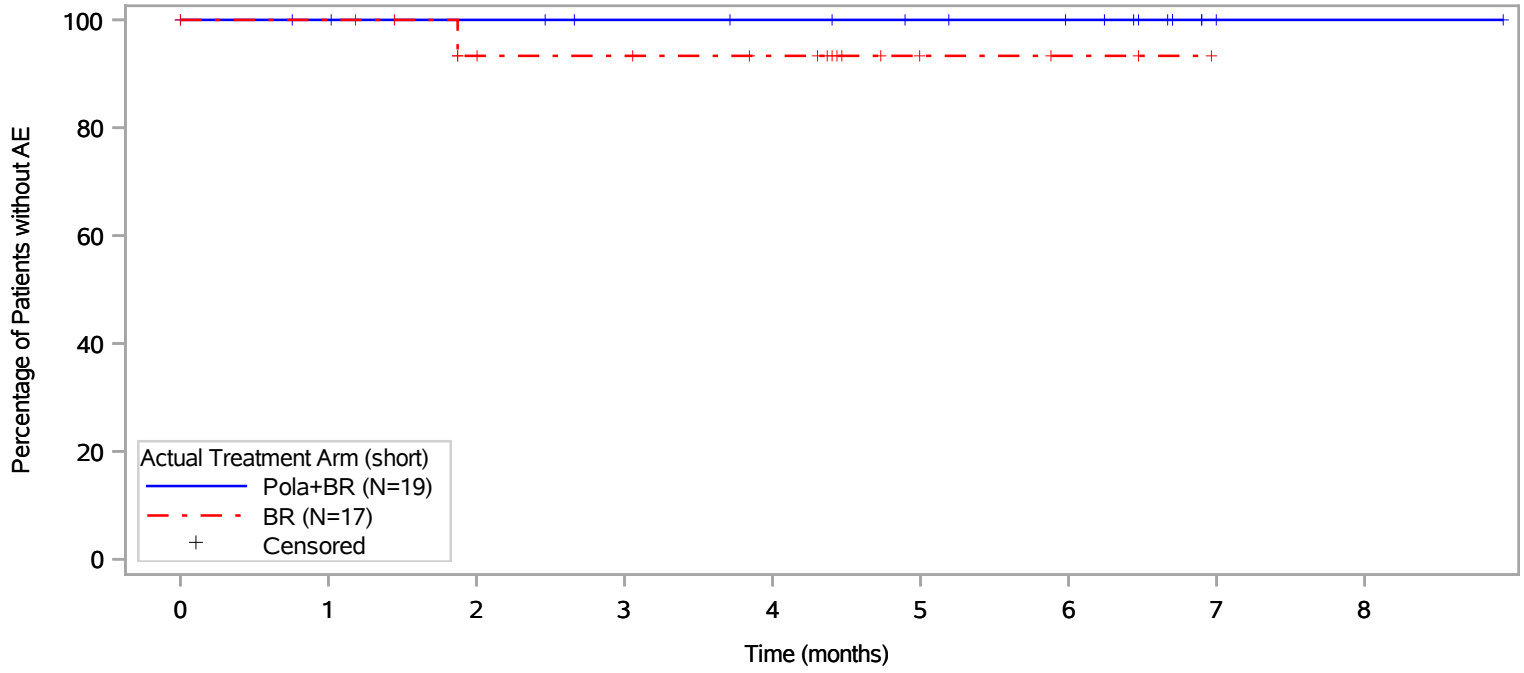


Patients at risk									
Pola+BR (N=19)	19	18	16	13	11	9	8	1	1
BR (N=17)	17	13	11	8	5	2	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	6	13	13
BR (N=17)	0	0	2	3	5	8	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

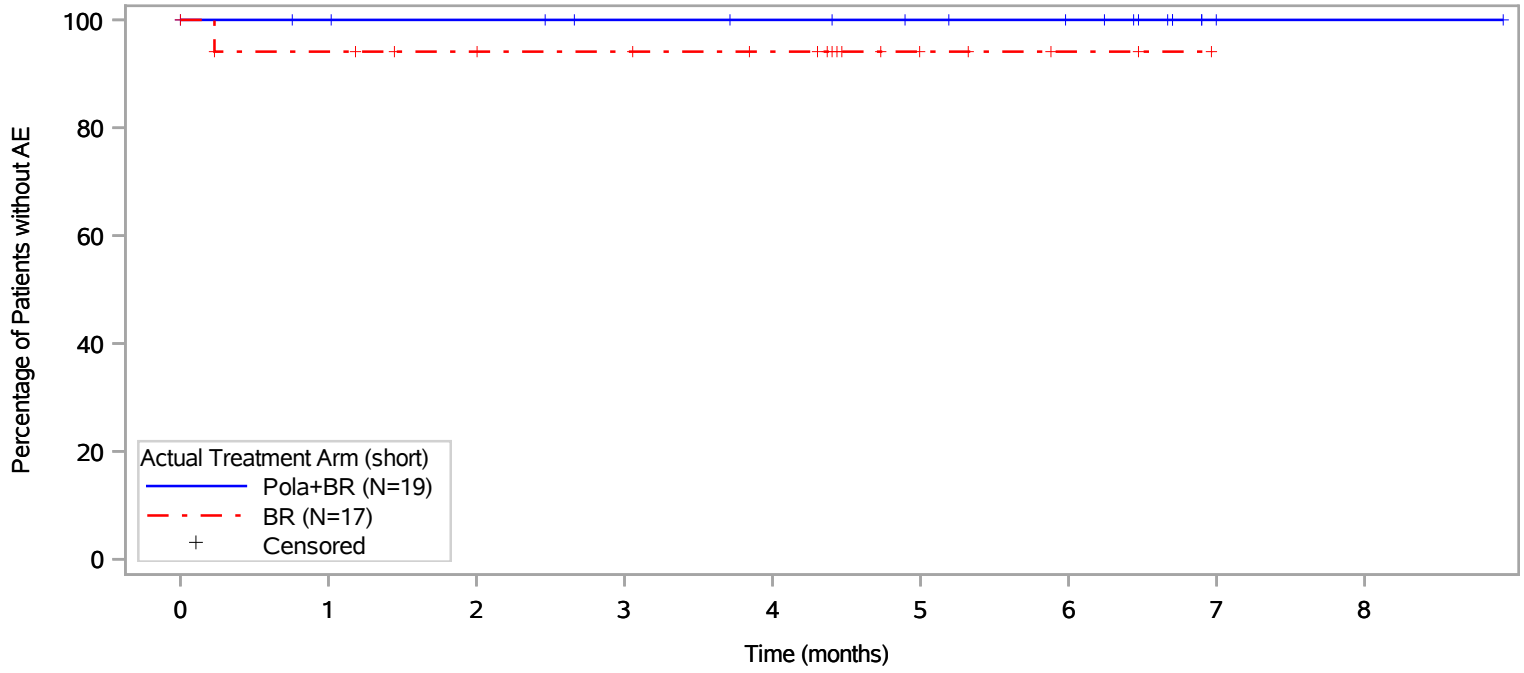
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BILIRUBIN CONJUGATED INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALKALINE PHOSPHATASE INCREASED

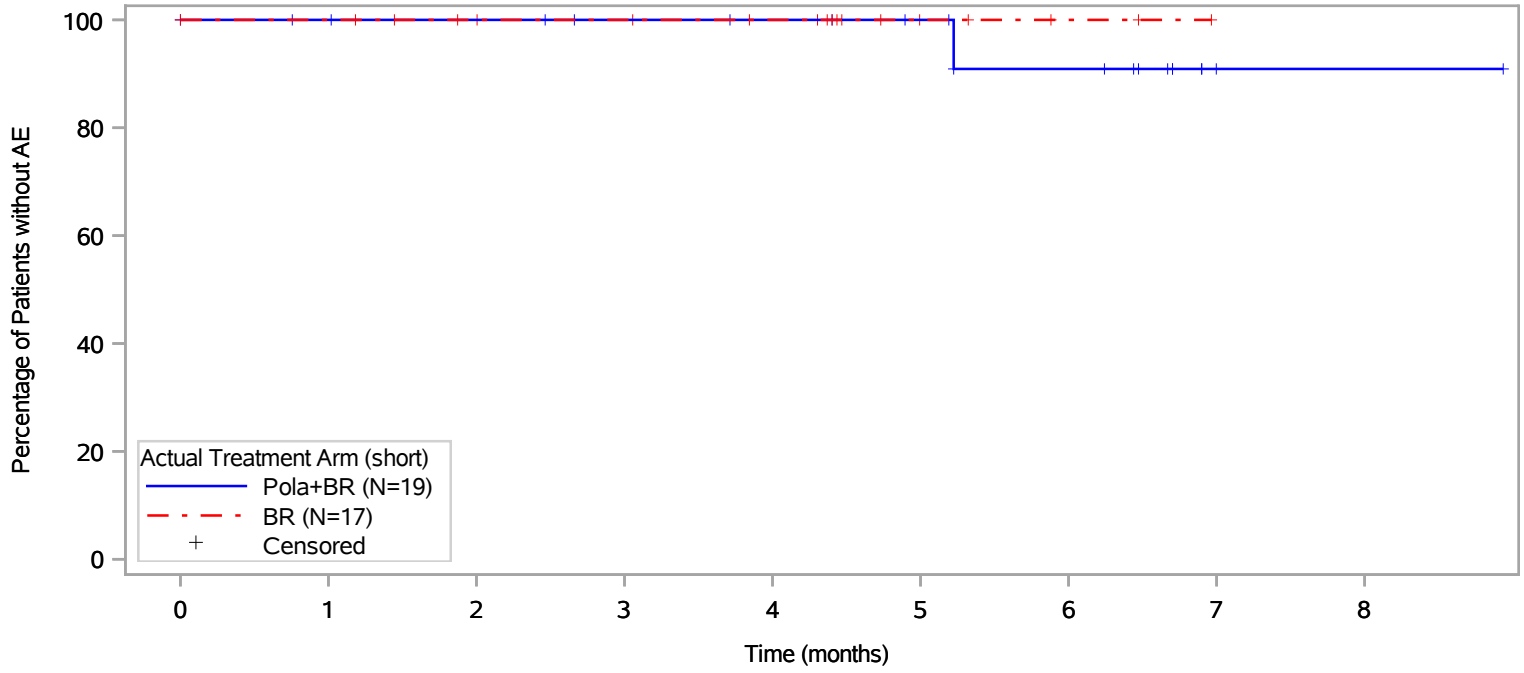


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PHOSPHORUS DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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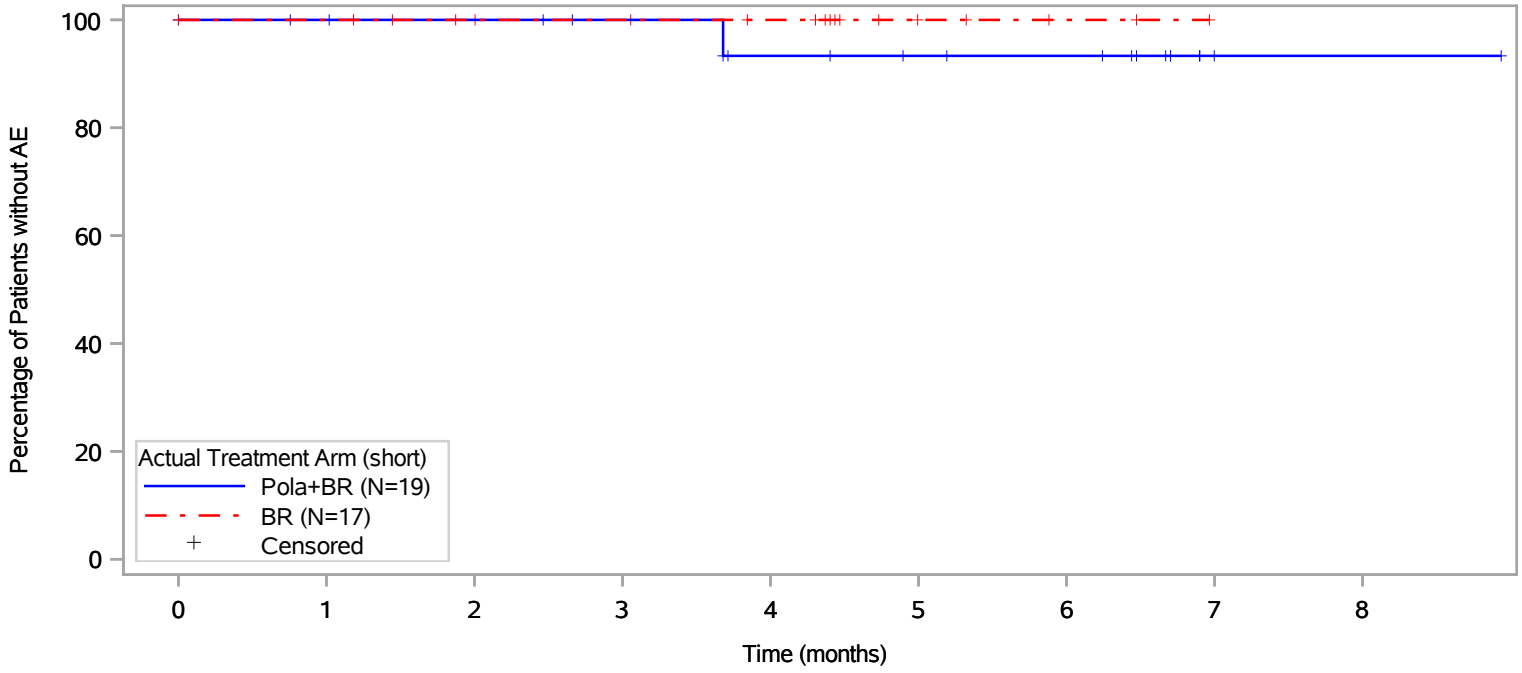
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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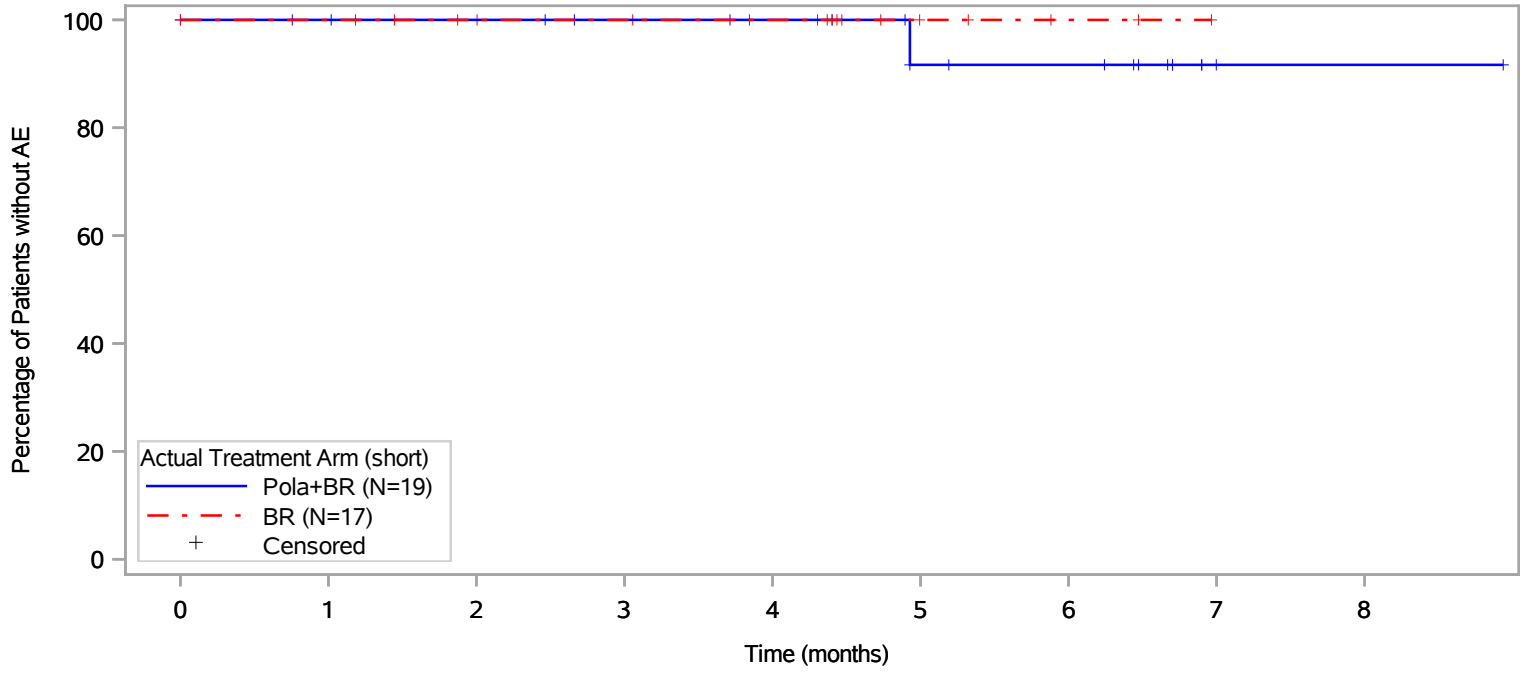
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYTOMEGALOVIRUS TEST POSITIVE



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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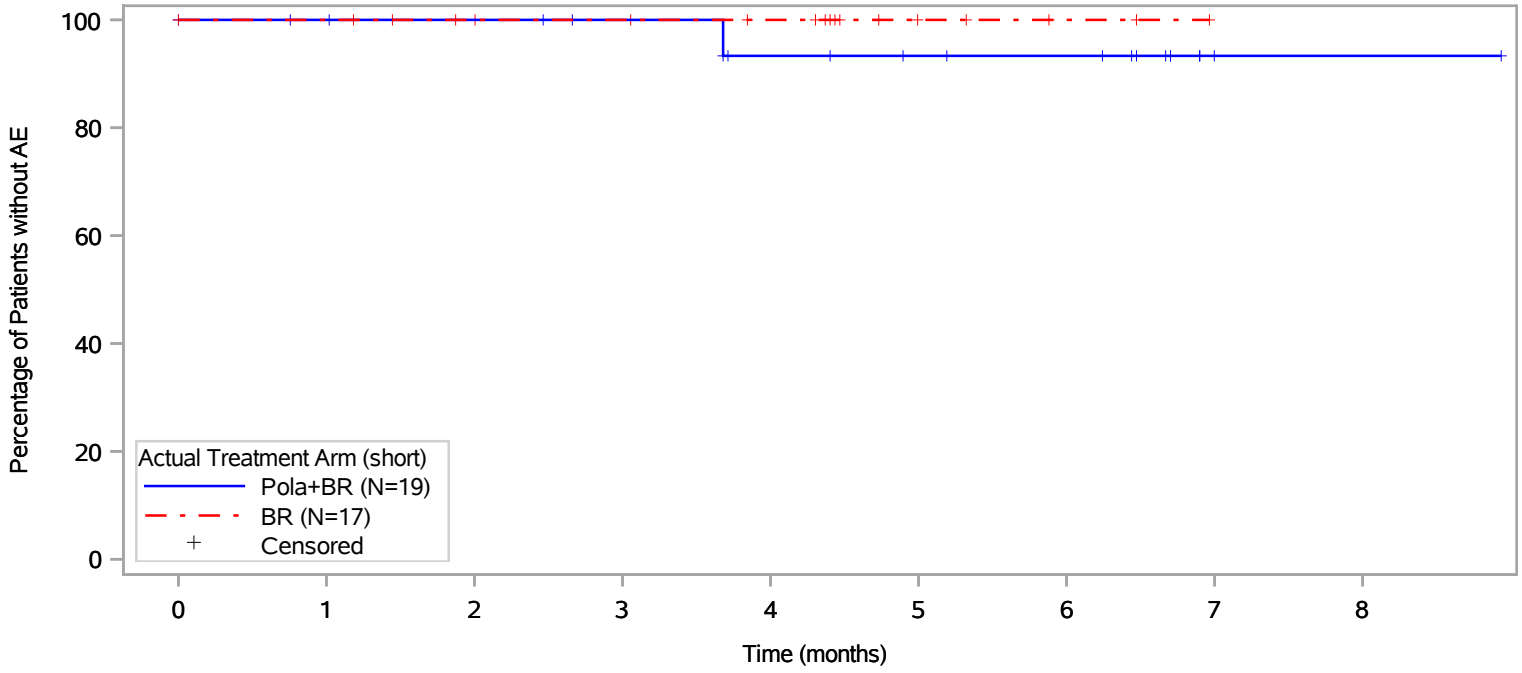
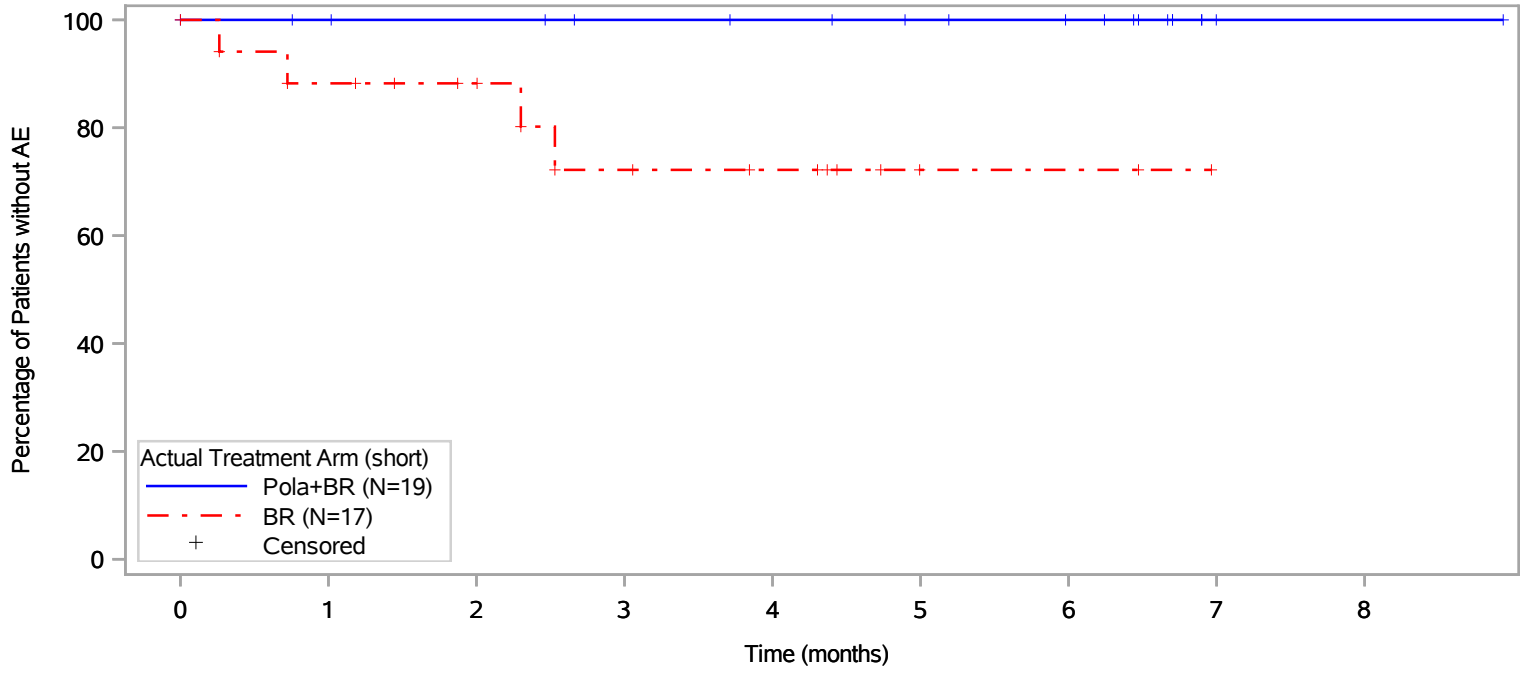
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LIPASE INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	15	12	9	7	2	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	11	11	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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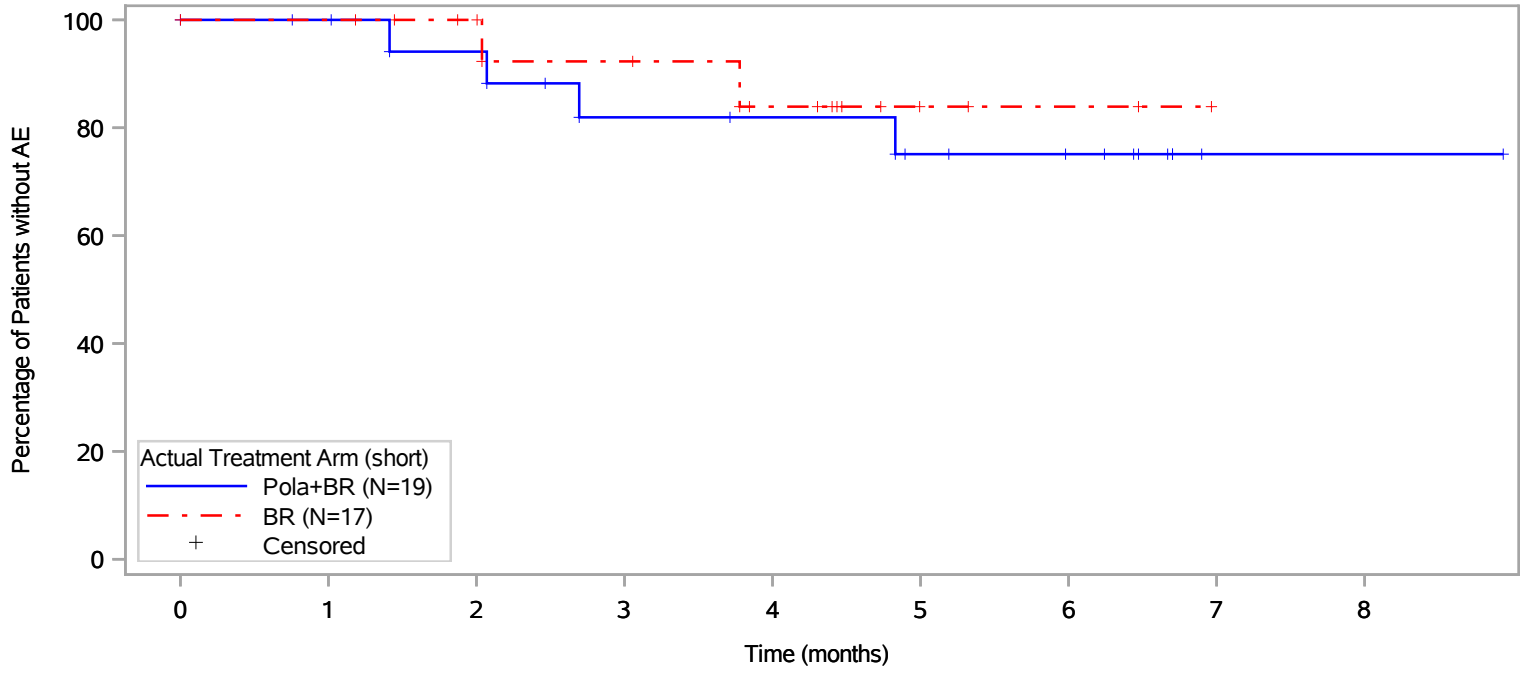
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	16	13	12	10	8	1	1
BR (N=17)	17	17	14	12	9	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	7	14	14
BR (N=17)	0	0	3	4	6	12	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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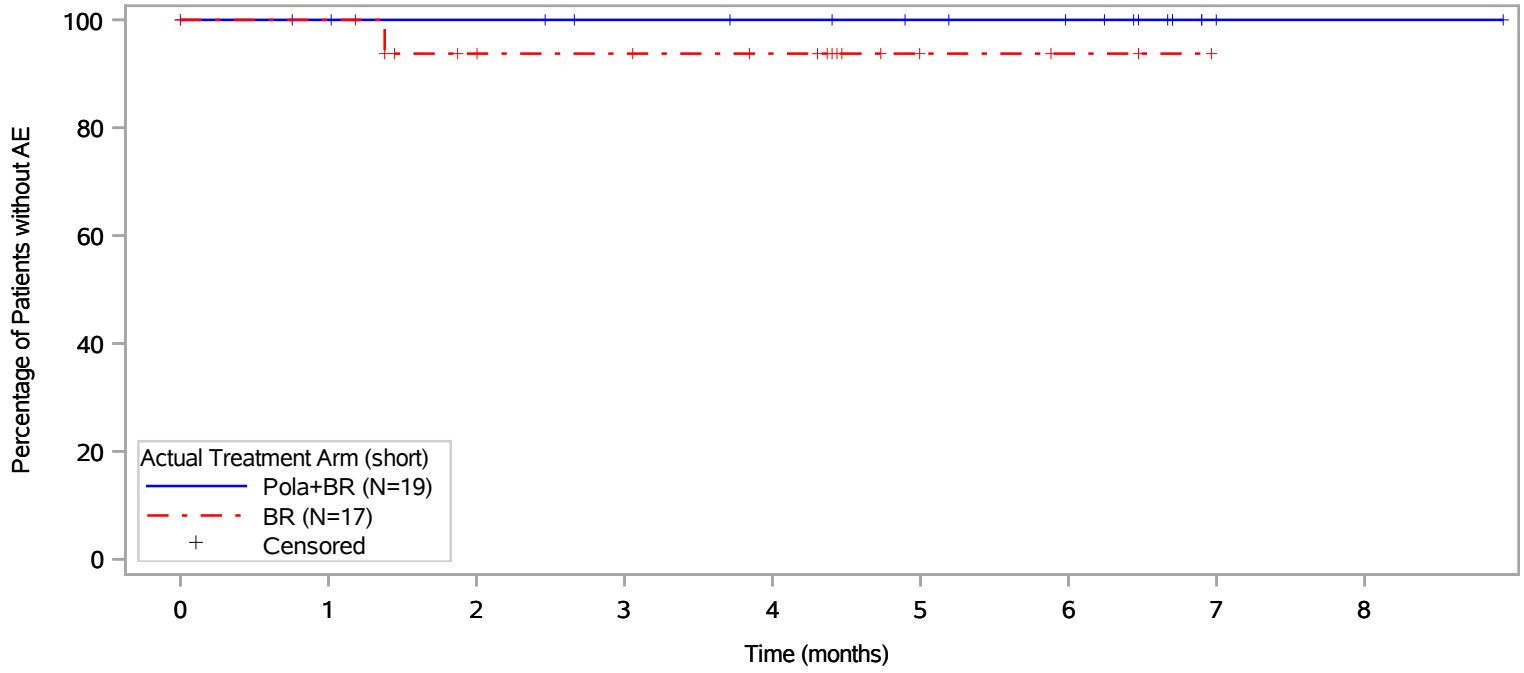
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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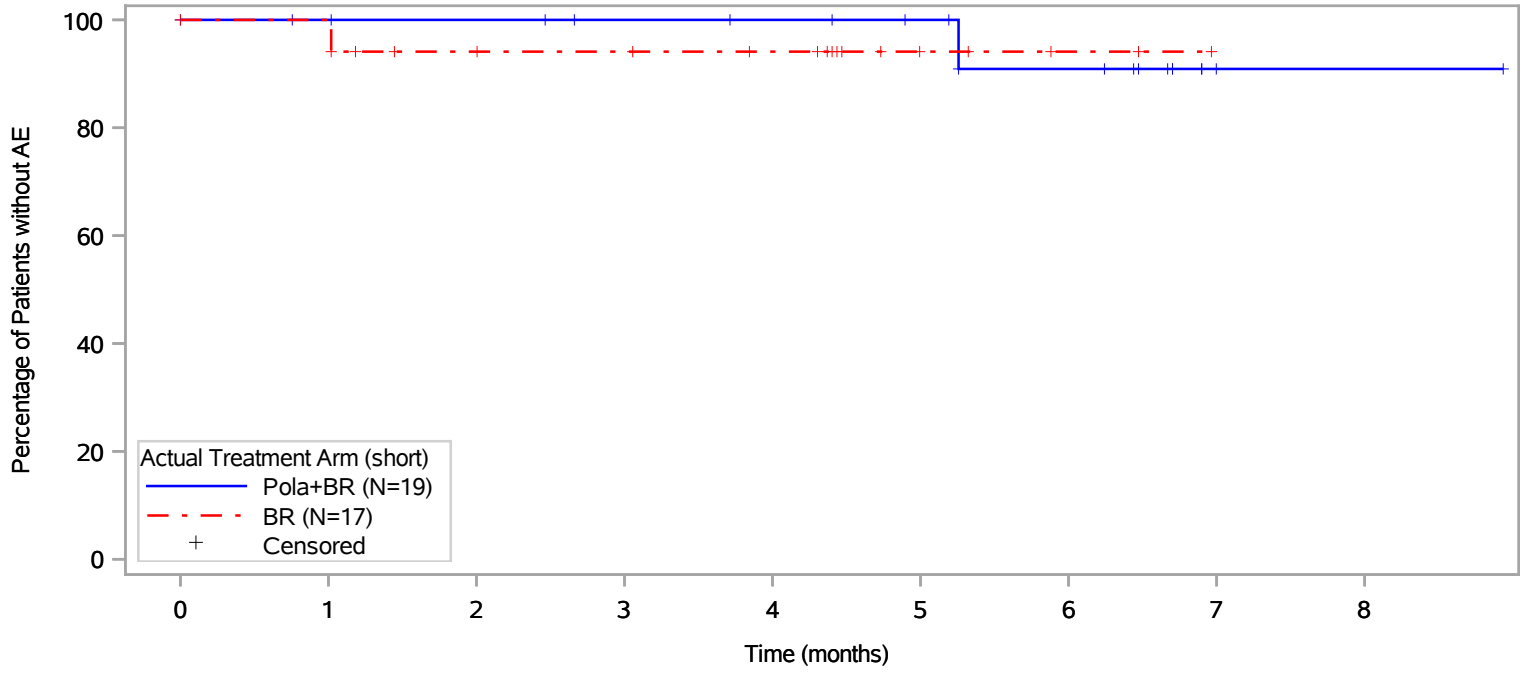
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED

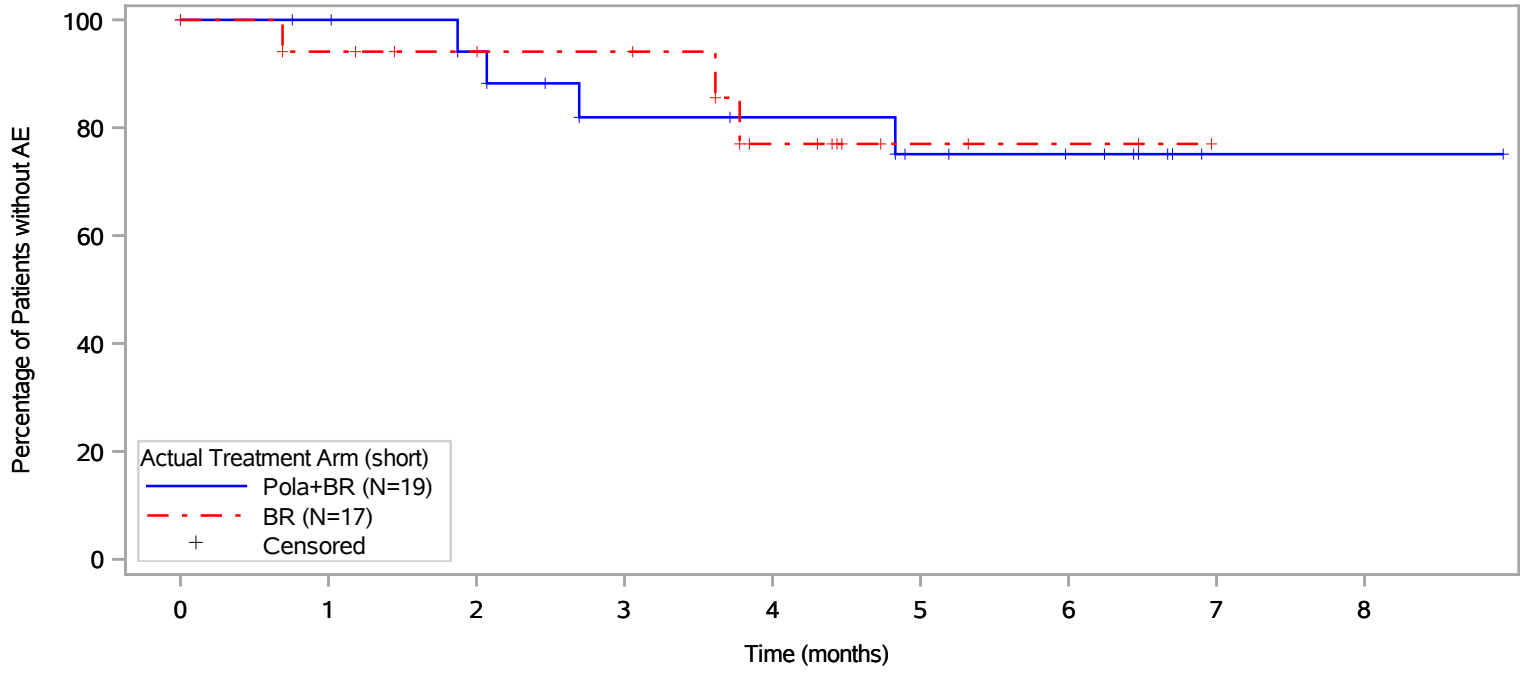


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED

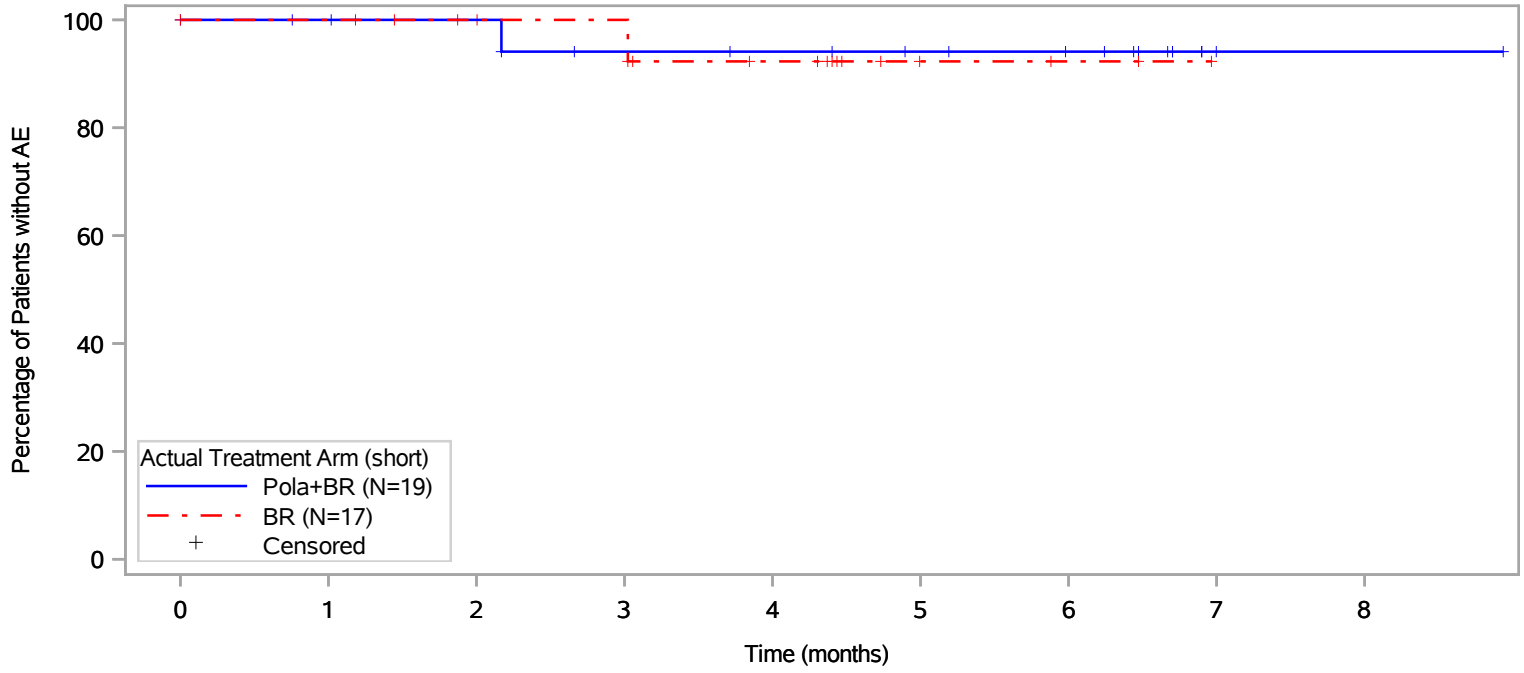


Patients at risk									
Pola+BR (N=19)	19	18	16	13	12	10	8	1	1
BR (N=17)	17	16	13	12	8	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	7	14	14
BR (N=17)	0	0	3	4	6	11	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All

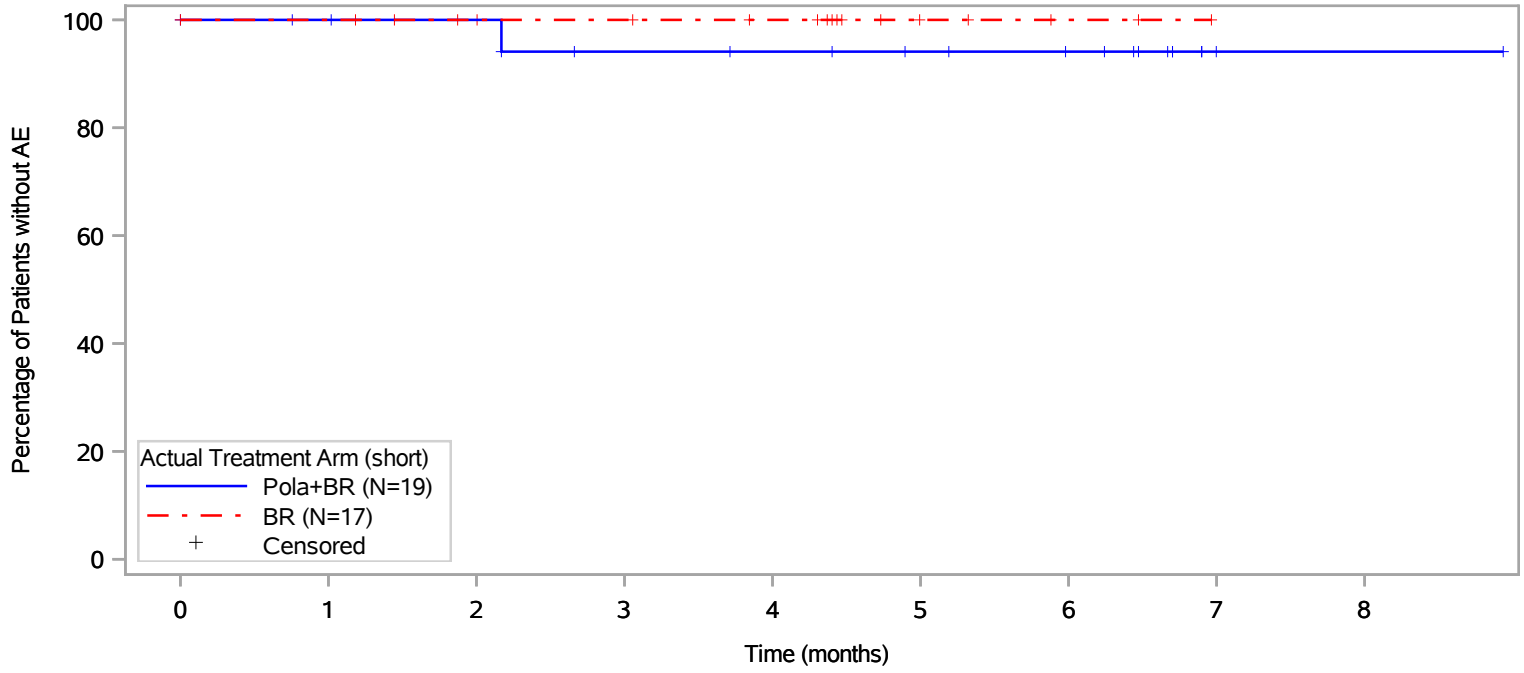


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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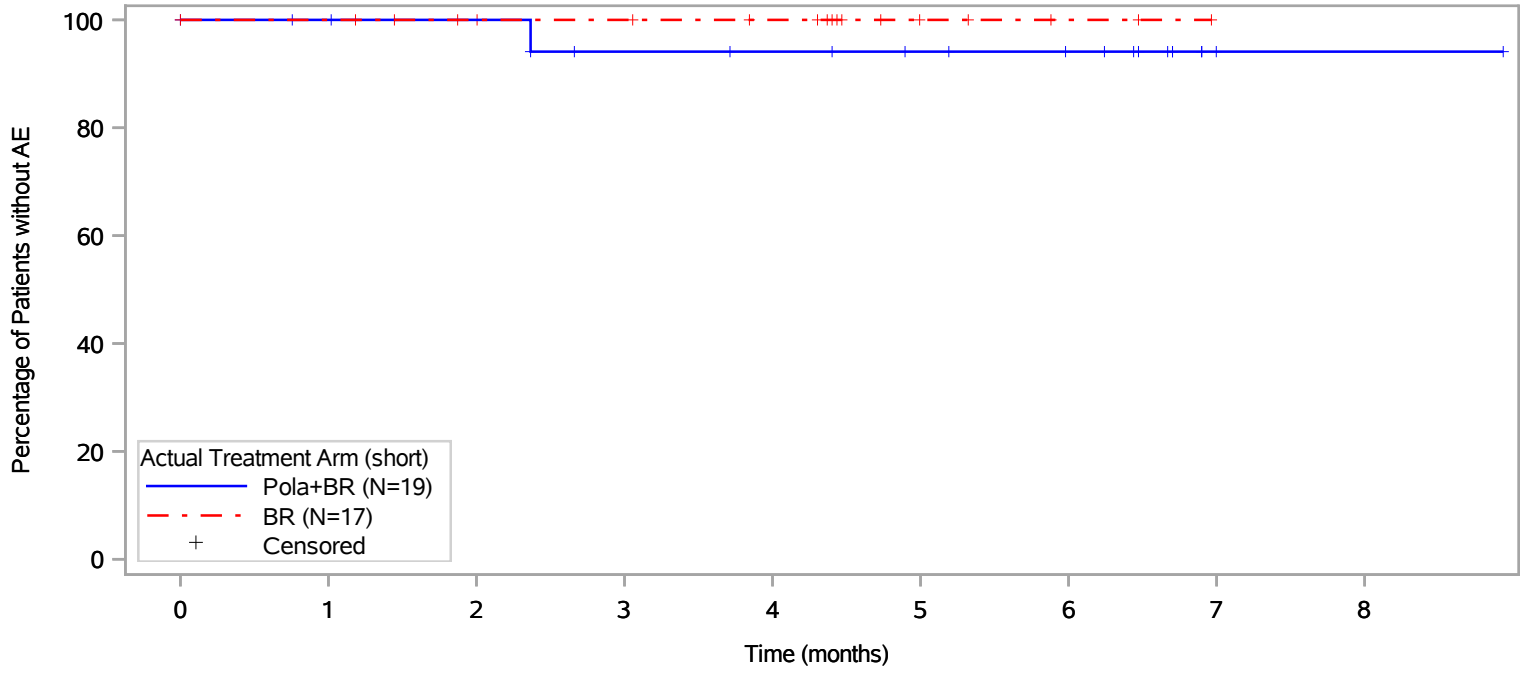
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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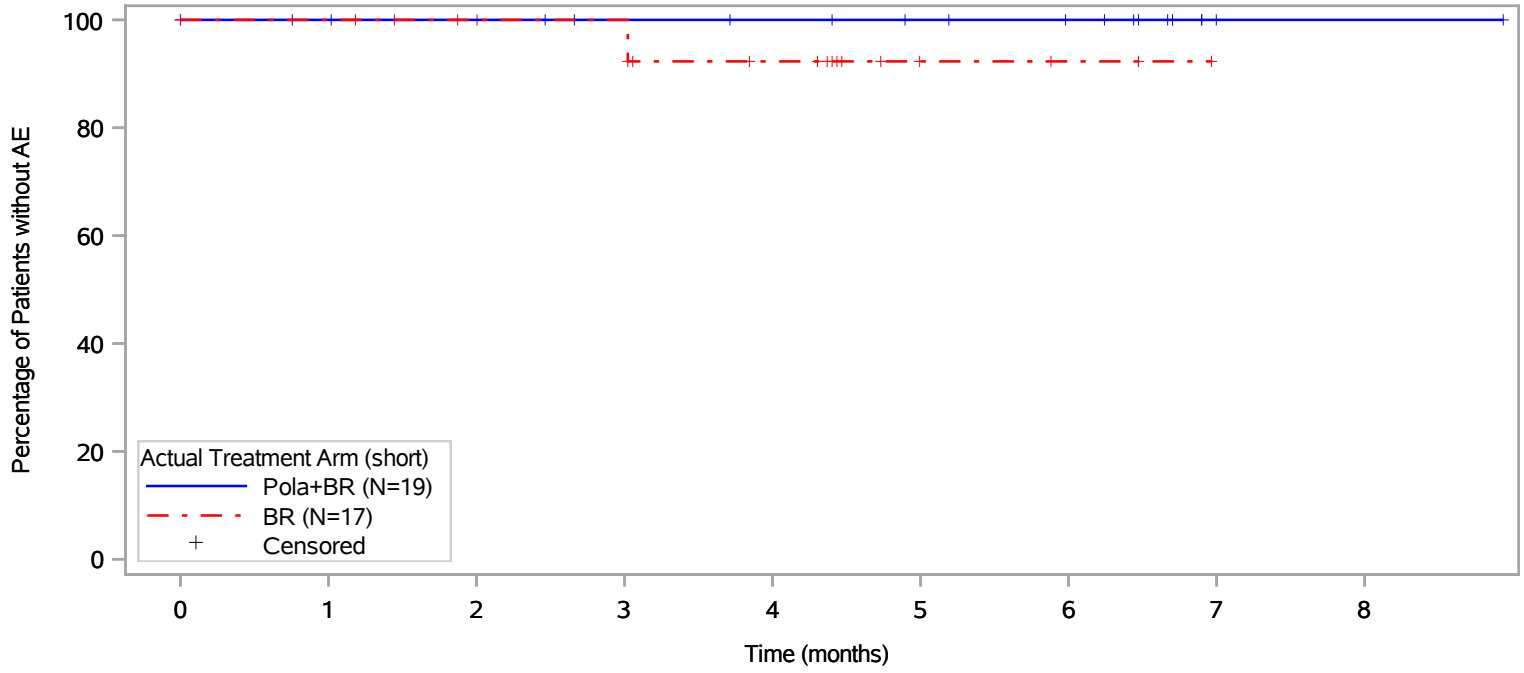
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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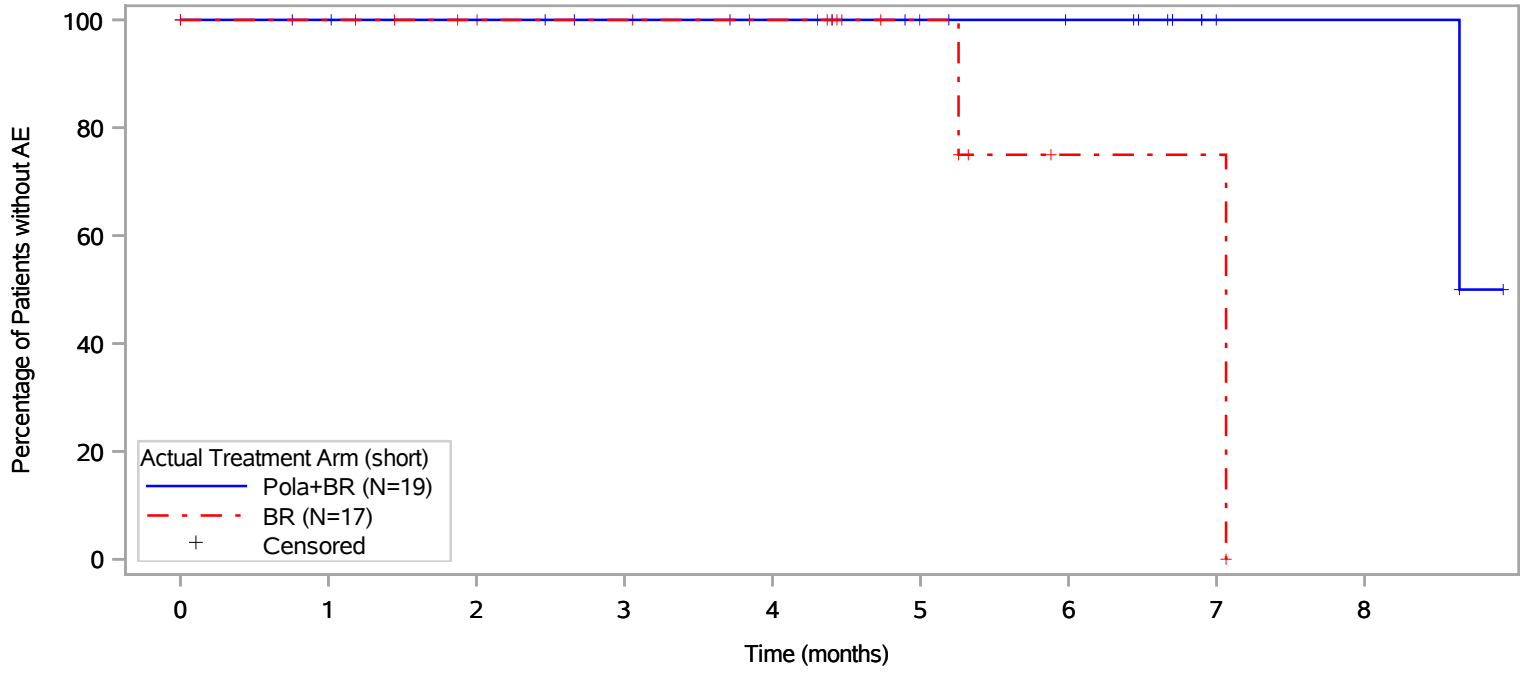
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2
BR (N=17)	17	17	14	13	11	4	1	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	15	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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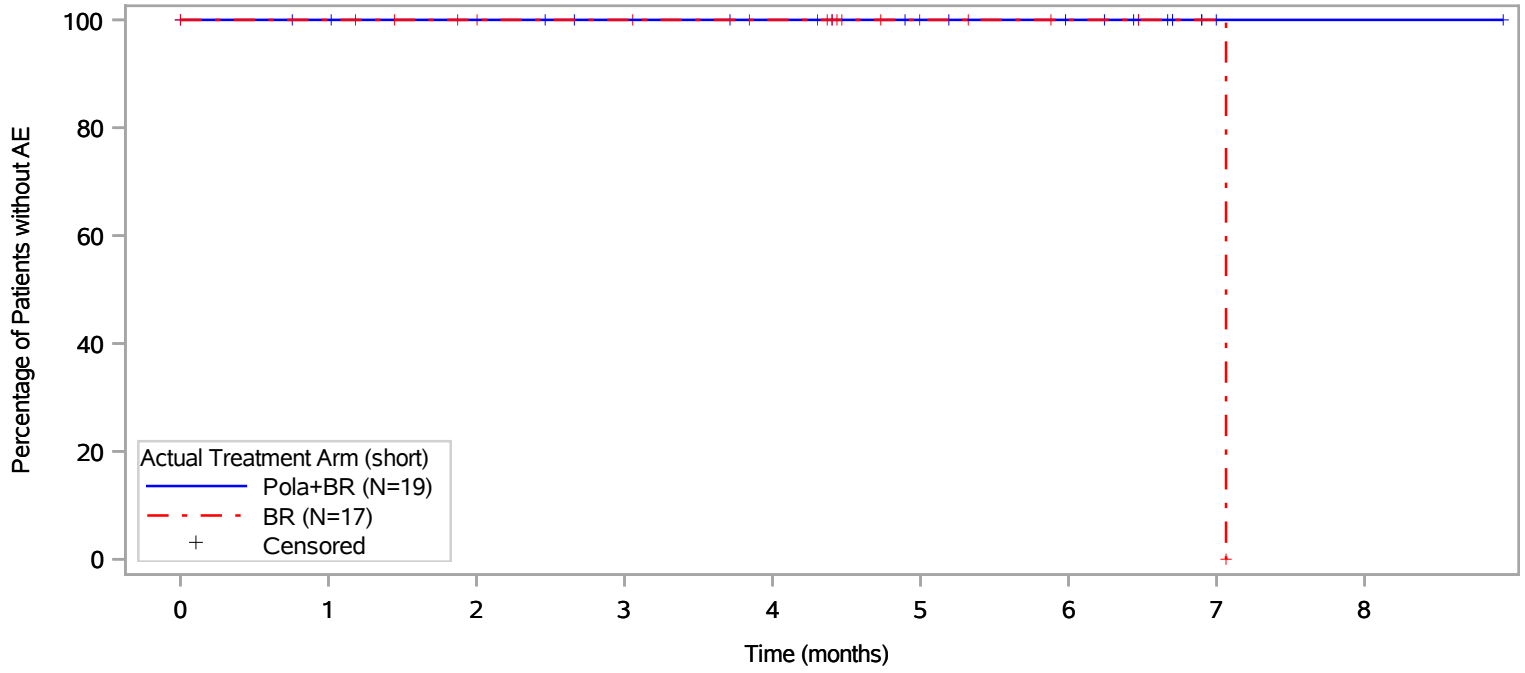
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), EPIGLOTTIC CANCER



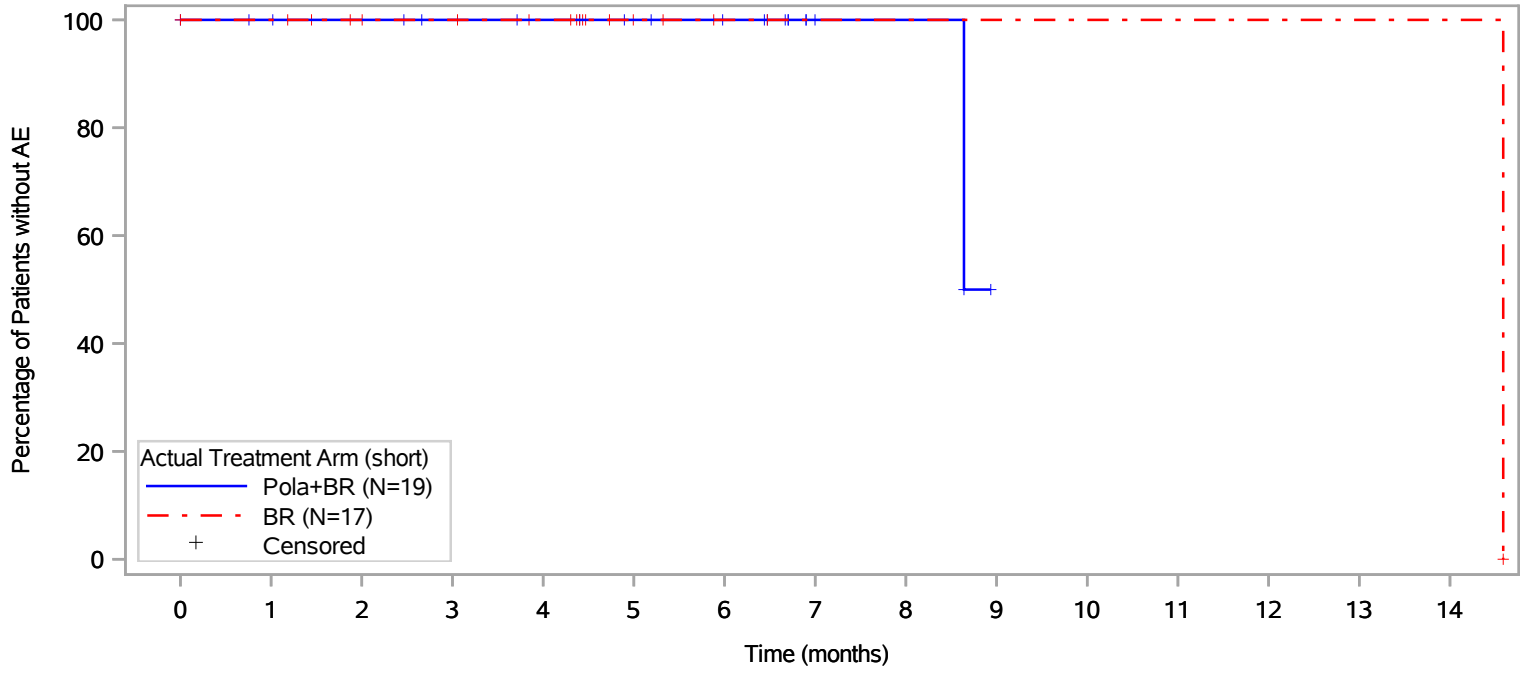
Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



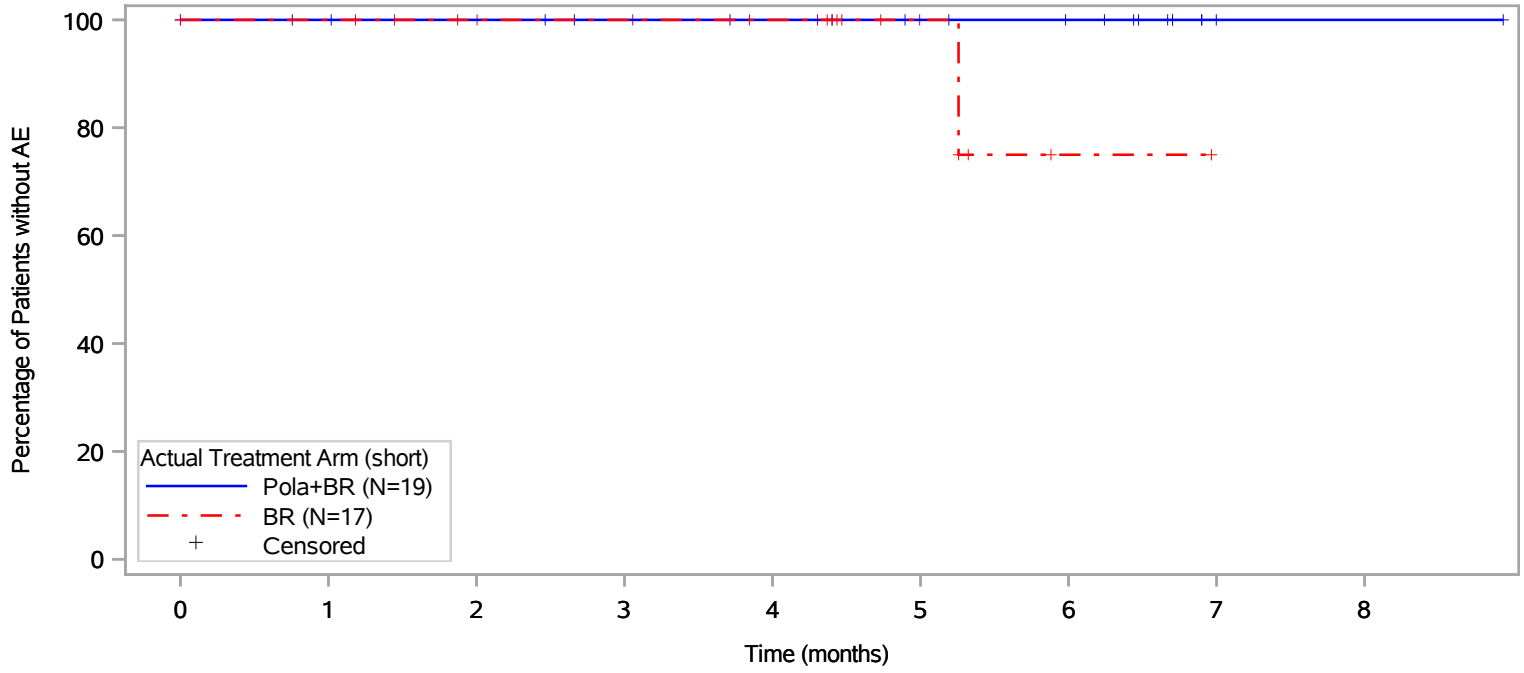
Patients at risk															
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	NE	NE	NE	NE	NE	NE
BR (N=17)	17	17	14	13	11	4	2	1	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	NE	NE	NE	NE	NE	NE
BR (N=17)	0	0	3	4	6	13	15	16	16	16	16	16	16	16	16

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), PAPILLARY THYROID CANCER

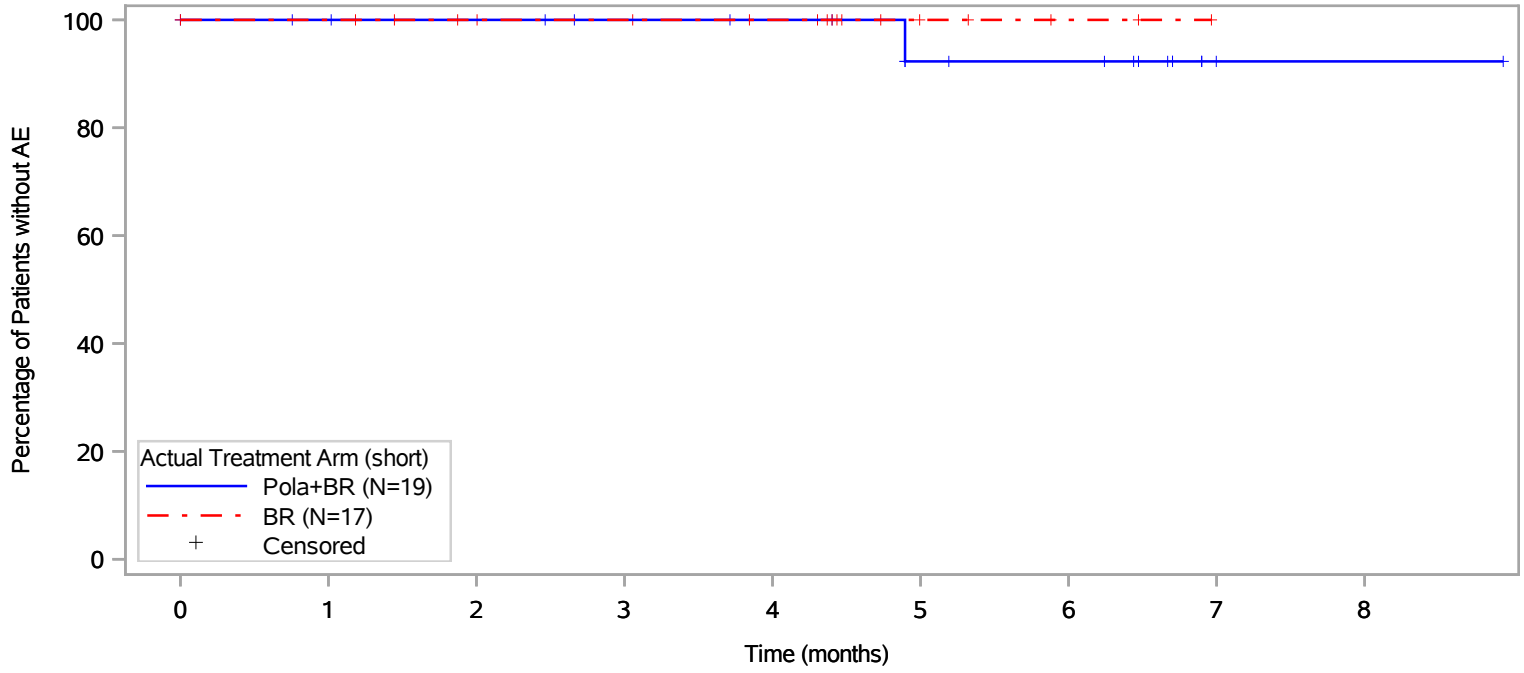


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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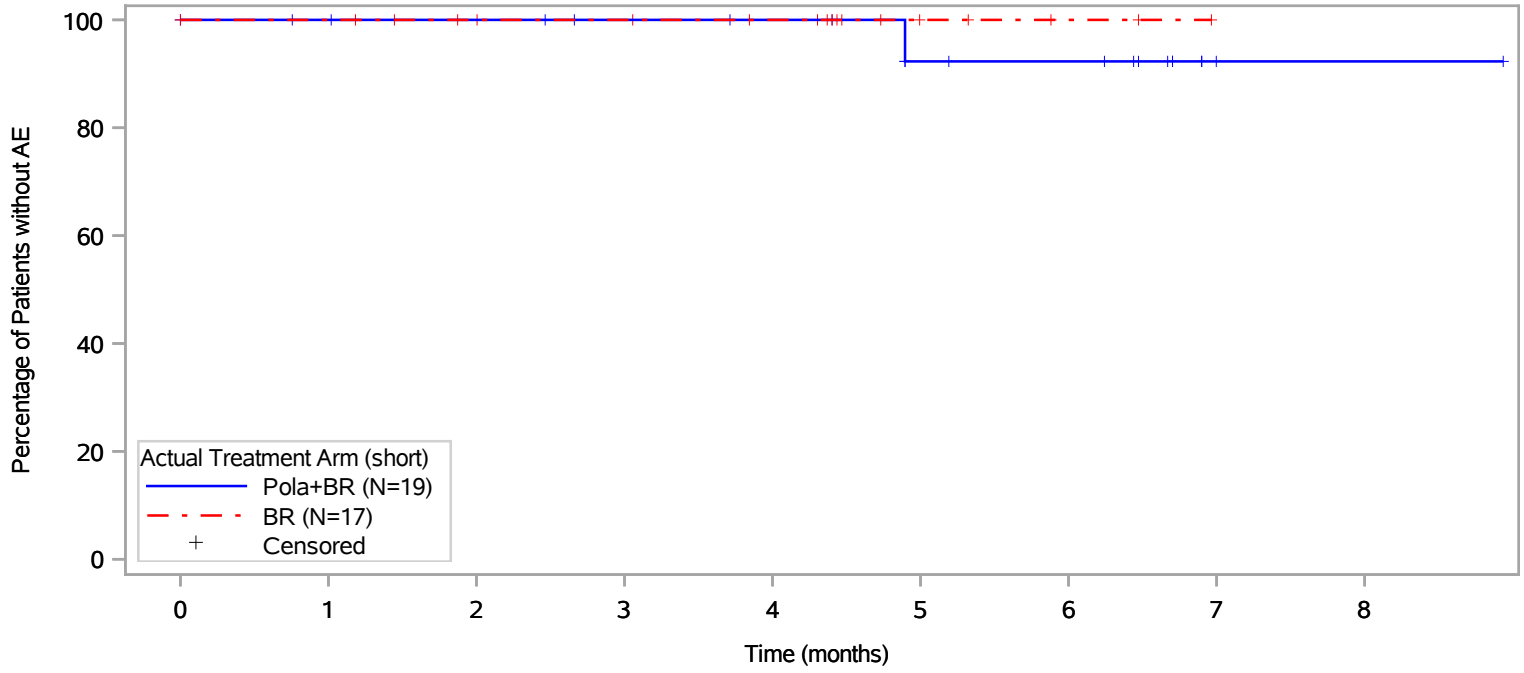
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, VOCAL CORD PARALYSIS

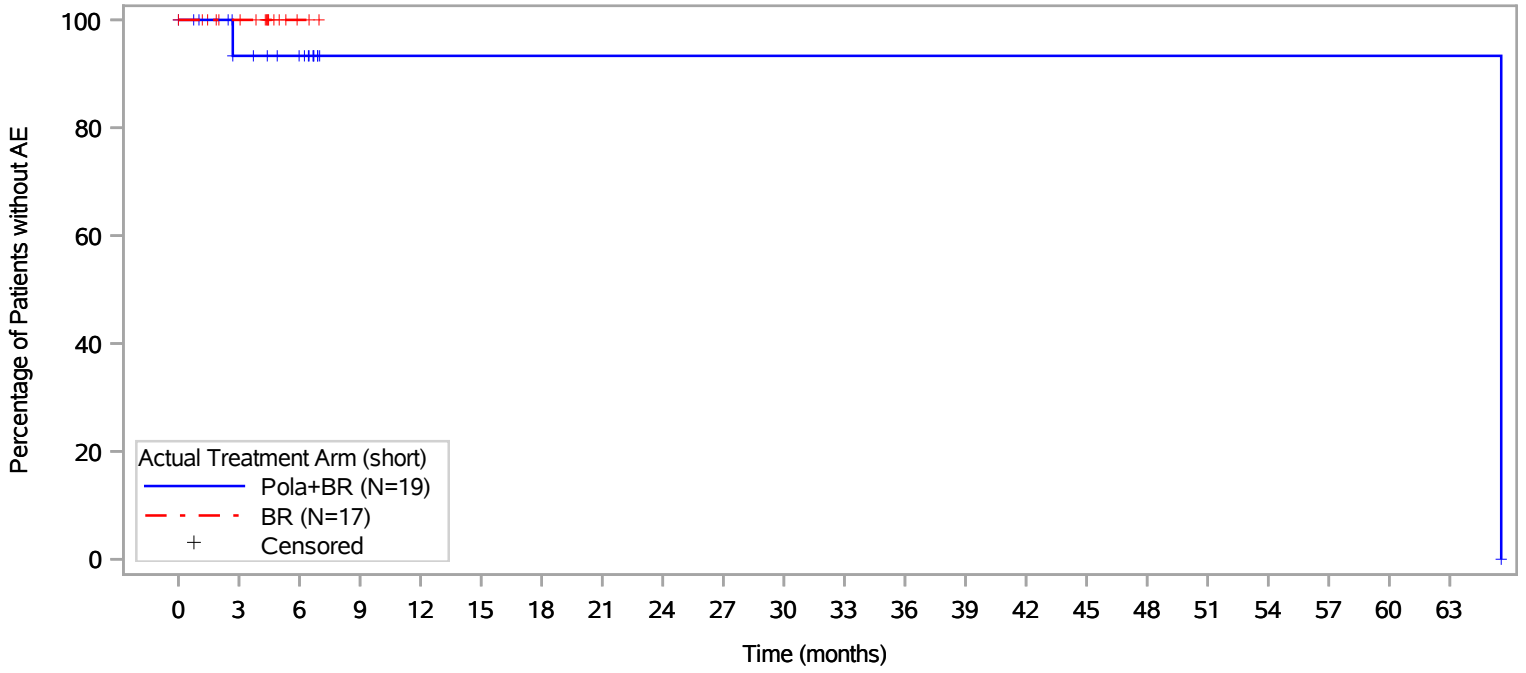


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All

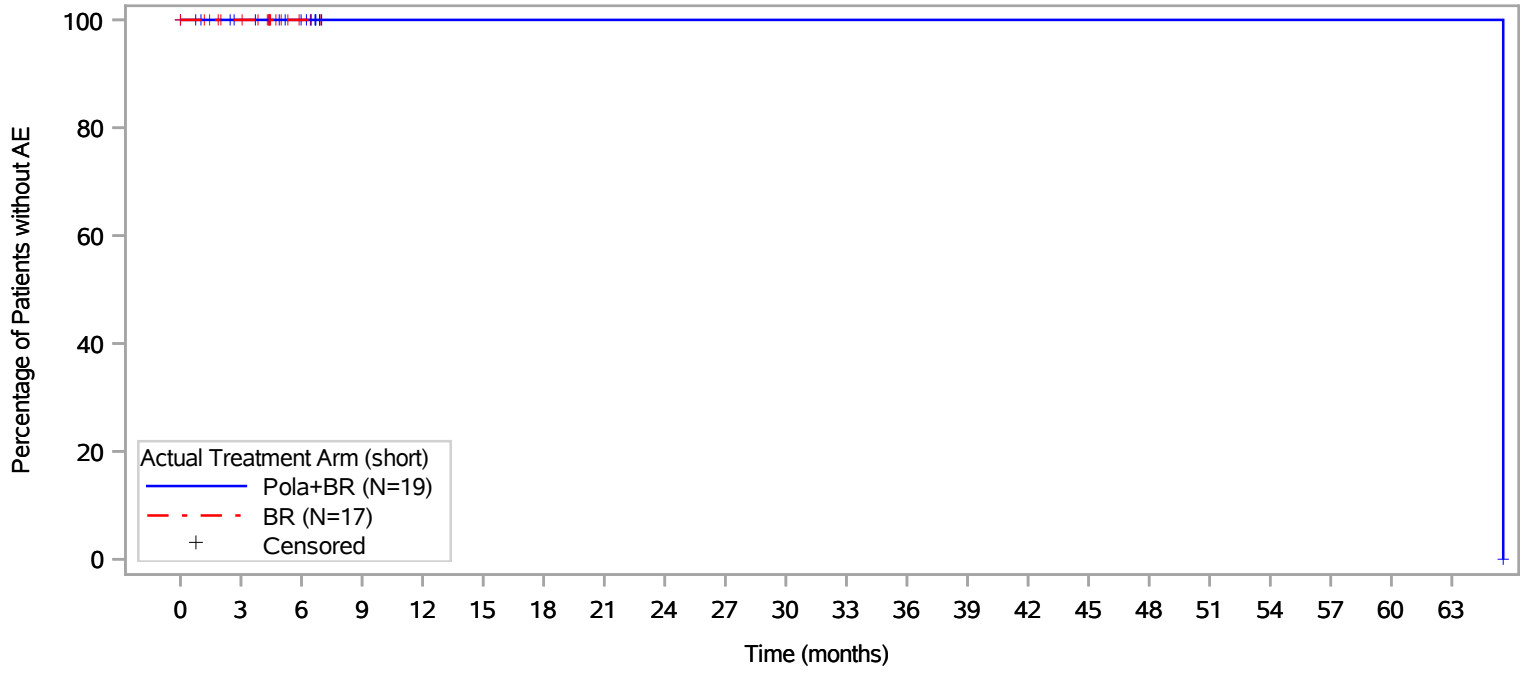


Patients at risk																							
Pola+BR (N=19)	19	14	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=17)	17	13	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=19)	0	4	8	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17
BR (N=17)	0	4	15	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY

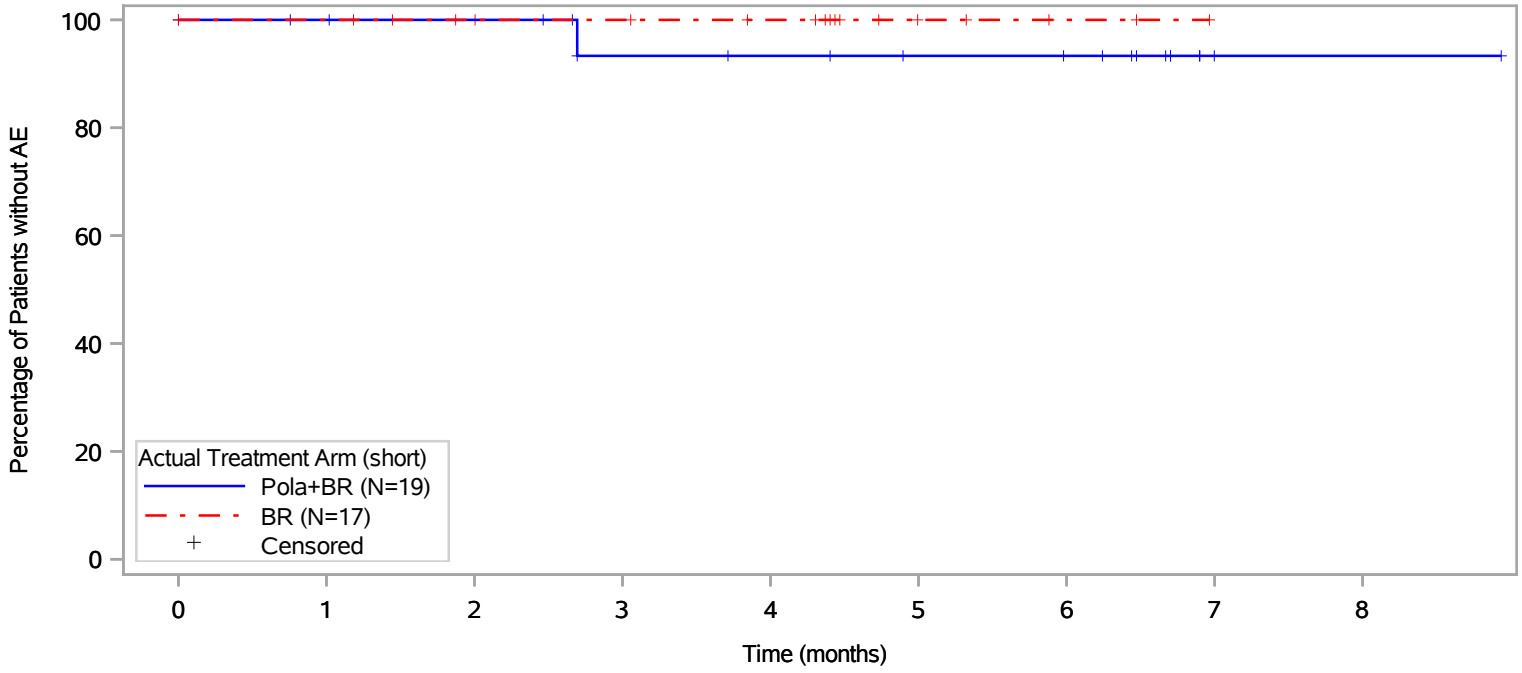


Patients at risk																							
Pola+BR (N=19)	19	15	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=17)	17	13	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=19)	0	4	9	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18
BR (N=17)	0	4	15	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

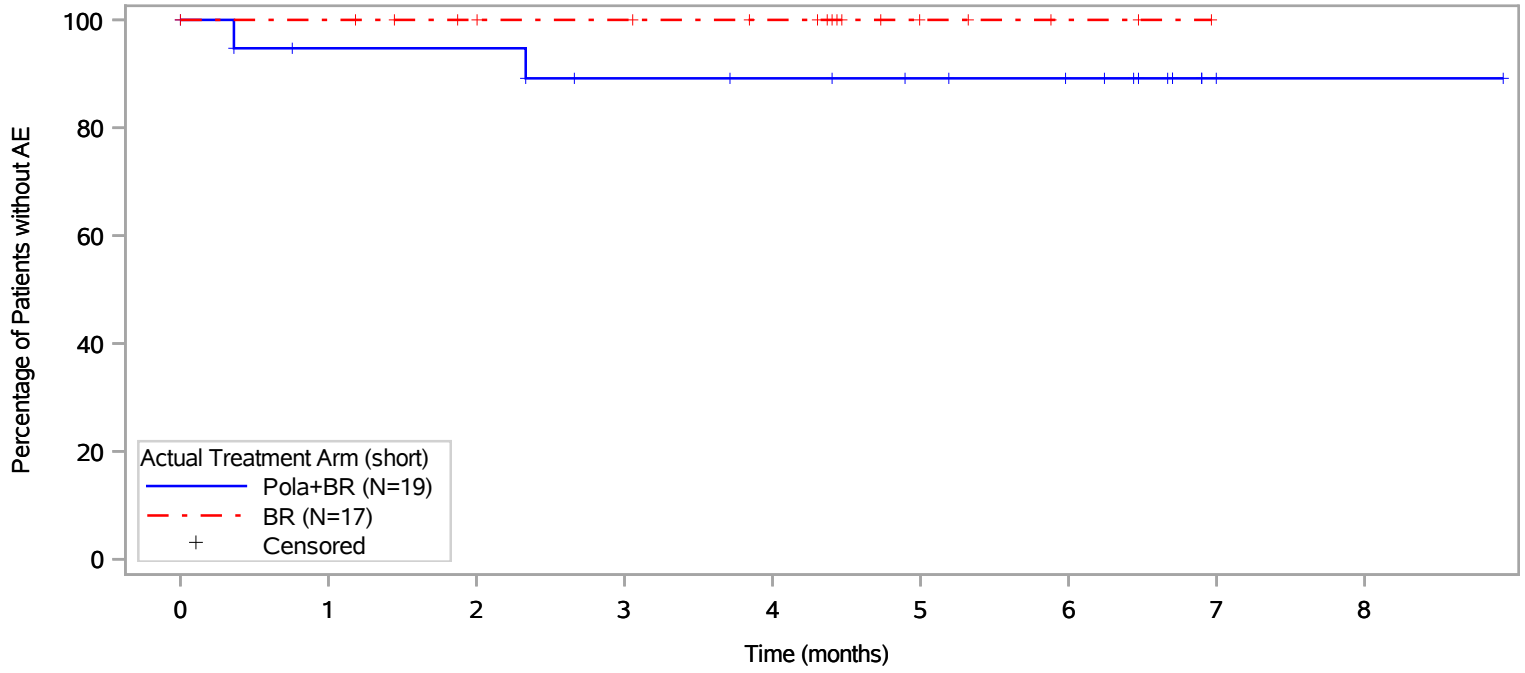
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	14	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All

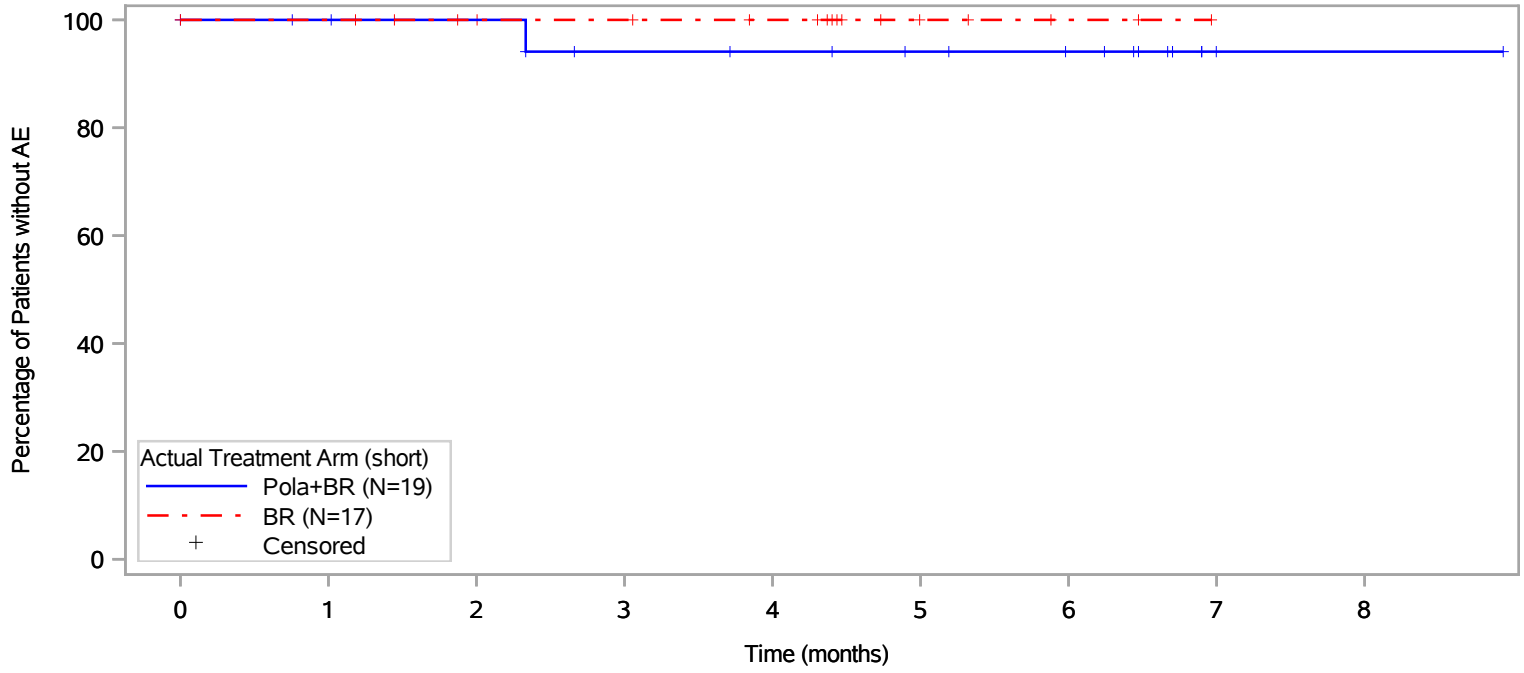


Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	2	3	5	7	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



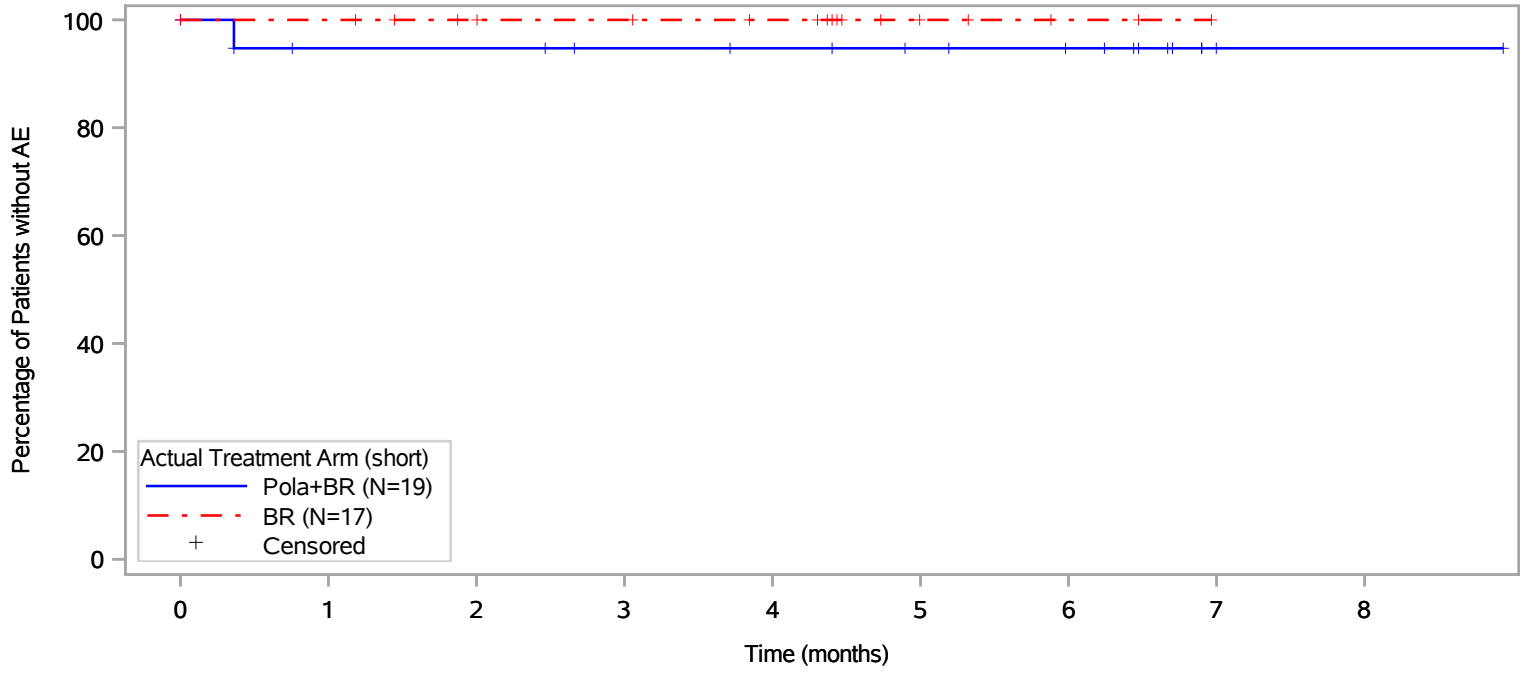
Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY OEDEMA



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
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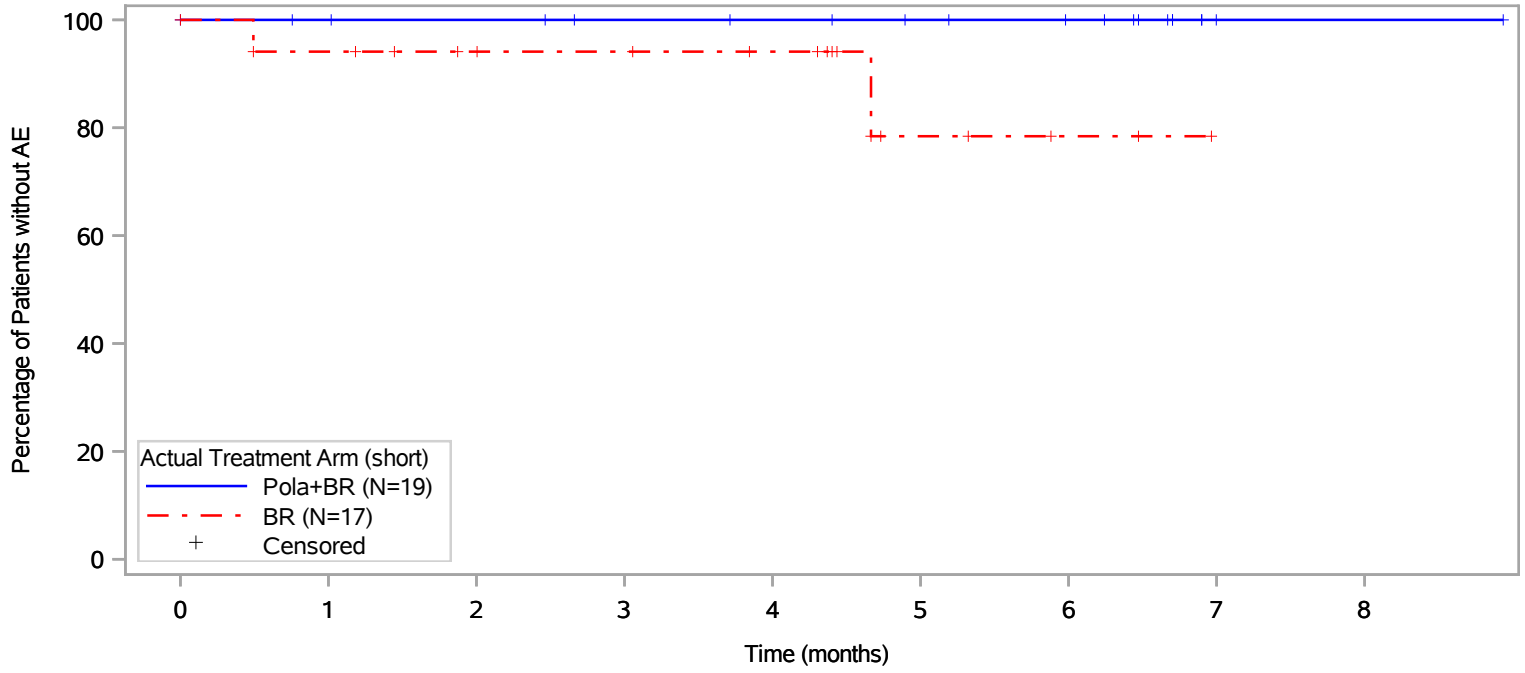
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All

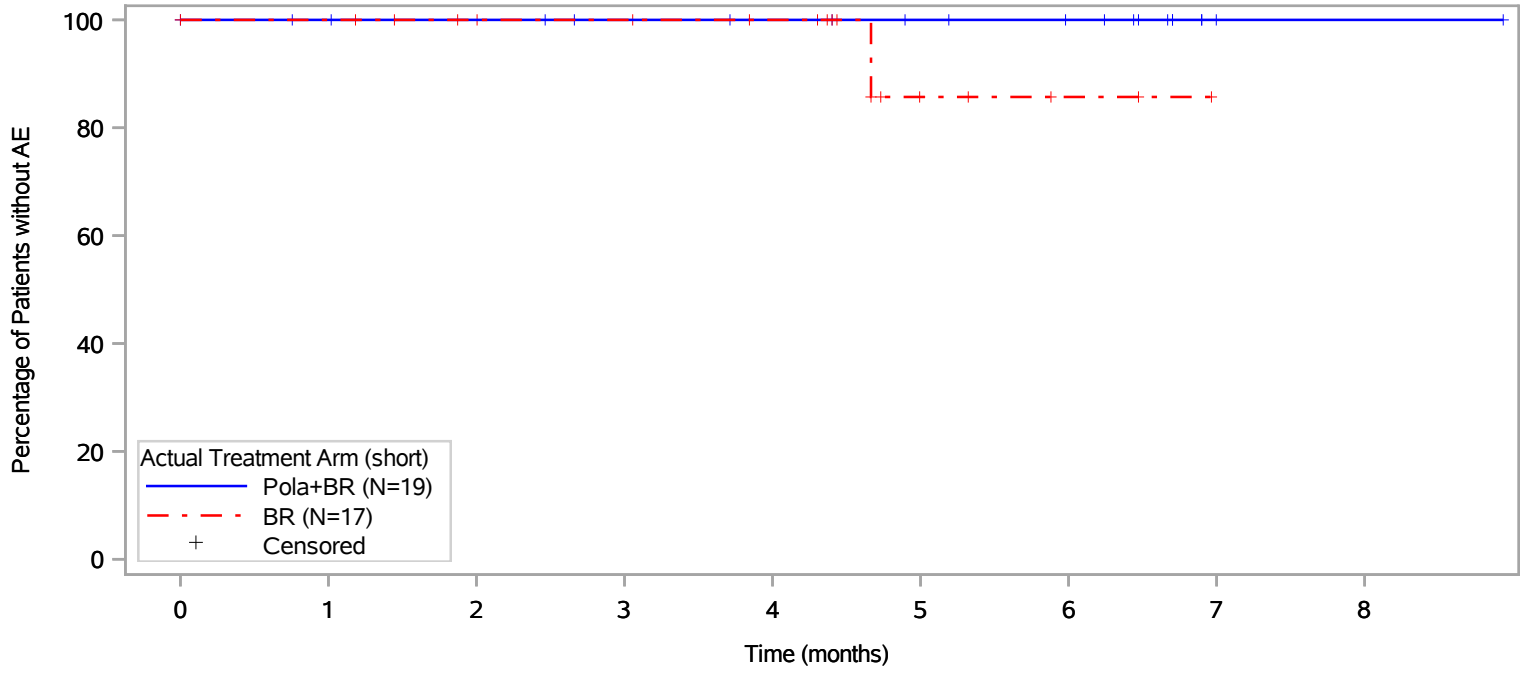


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
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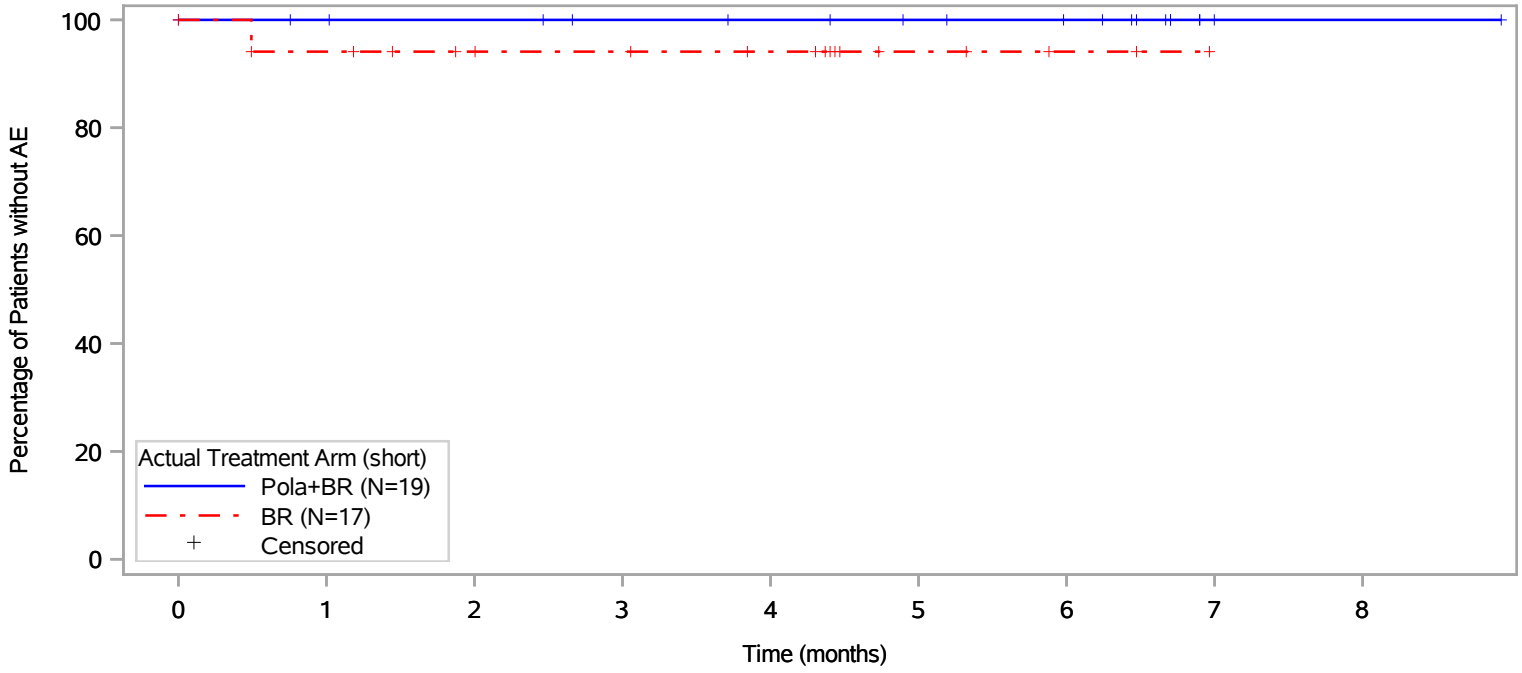
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

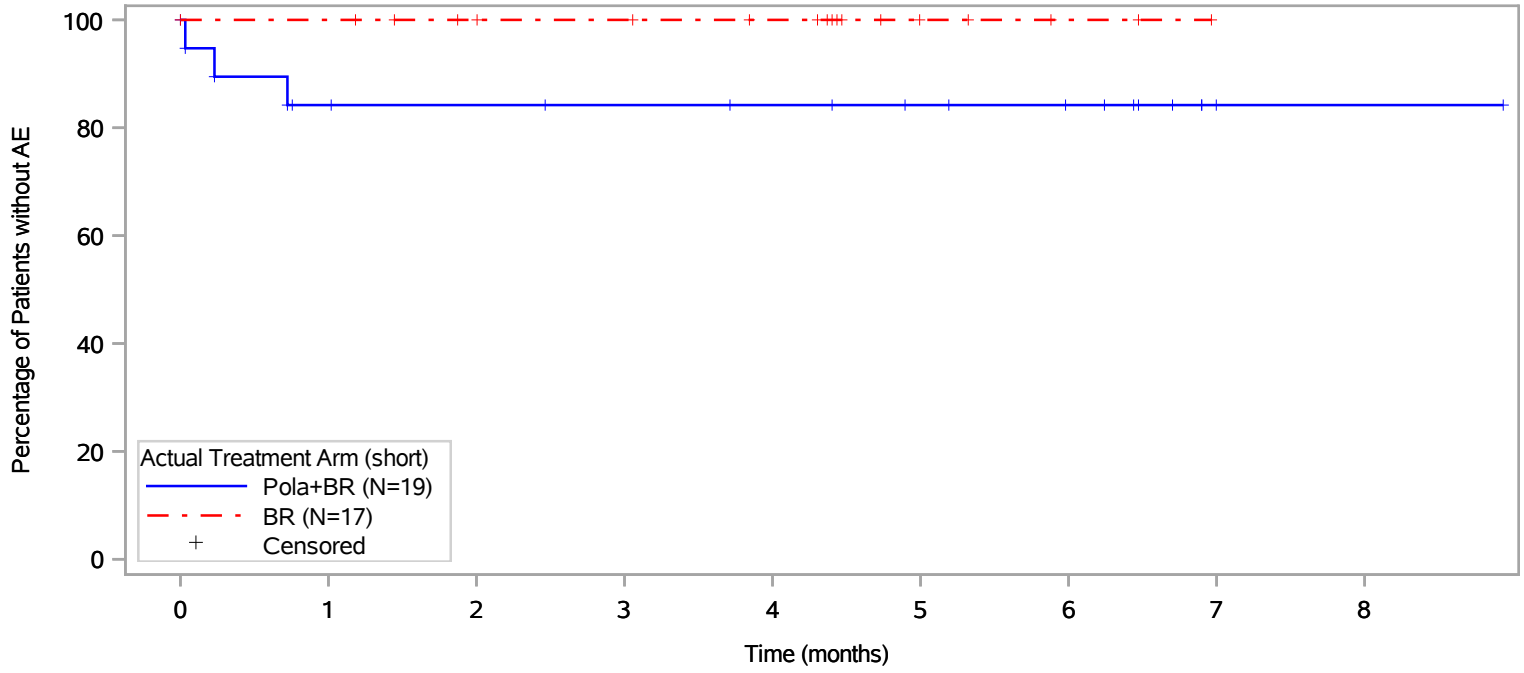
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All

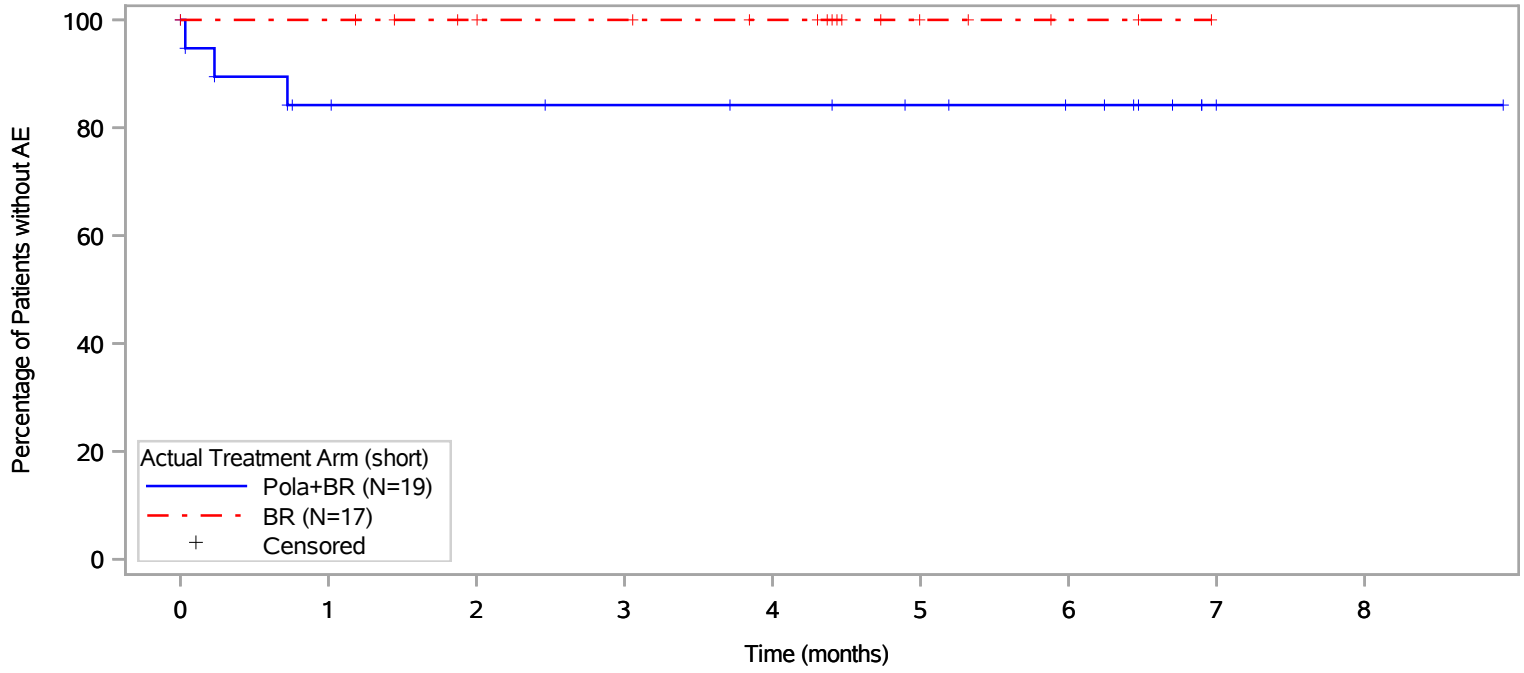


Patients at risk									
Pola+BR (N=19)	19	15	14	13	12	10	8	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	15	15
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION



Patients at risk									
Pola+BR (N=19)	19	15	14	13	12	10	8	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	15	15
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	7	36.8	12	63.2	17	100.0	5	29.4	12	70.6	0.6399	1.65	0.51	5.30		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		19	100.0	4	21.1	15	78.9	17	100.0	1	5.9	16	94.1	0.2380	4.34	0.48	38.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1130	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3476	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		19	100.0	5	26.3	14	73.7	17	100.0	3	17.6	14	82.4	0.6089	1.70	0.40	7.18		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.6897	1.97	0.18	21.79		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	2	10.5	17	89.5	17	100.0	2	11.8	15	88.2	0.7331	0.72	0.10	5.37		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3476	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INVESTIGATIONS			19	100.0	4	21.1	15	78.9	17	100.0	6	35.3	11	64.7	0.1578	0.27	0.07	1.08		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LIPASE INCREASED		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		19	100.0	0	-	19	100.0	17	100.0	3	17.6	14	82.4	0.0530	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		19	100.0	3	15.8	16	84.2	17	100.0	2	11.8	15	88.2	0.9485	0.87	0.14	5.39		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3026	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.7106	0.72	0.04	12.57		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		19	100.0	3	15.8	16	84.2	17	100.0	3	17.6	14	82.4	0.6276	0.57	0.11	2.94		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.8842	0.79	0.05	12.84		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.0646	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

NERVOUS SYSTEM DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			19	100.0	3	15.8	16	84.2	17	100.0	0	-	17	100.0	0.0921	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		19	100.0	3	15.8	16	84.2	17	100.0	0	-	17	100.0	0.0921	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical studies/RO5541077/CDPT7898/GO29365/data analysis/ACE FINAL CSR Pooled/prod/output/t s ttae soc sgl TTGR3AE L2 ARMCDPLUSSE 29365 41543.xls
30NOV2022 20:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4643	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	11	57.9	5	45.5	6	54.5	15	88.2	5	33.3	10	66.7	0.5435	1.76	0.50	6.20		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	1	6.7	14	93.3	0.2031	4.37	0.45	42.05		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1780	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	3	20.0	12	80.0	0.4660	1.99	0.44	9.00		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	1	6.7	14	93.3	0.4666	2.66	0.24	29.39		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.6517	0.55	0.05	6.11		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2542	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173				*	WARNING: Iteration limit reached without convergence.	
INVESTIGATIONS		< 65	8	42.1	3	37.5	5	62.5	2	11.8	2	100.0	0	-	0.0009	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	4	26.7	11	73.3	0.1143	0.14	0.01	1.57		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	1	50.0	1	50.0	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.2017	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	8	42.1	2	25.0	6	75.0	2	11.8	1	50.0	1	50.0	0.5796	0.75	0.07	8.42		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.8071	0.62	0.04	10.85		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	8	42.1	2	25.0	6	75.0	2	11.8	1	50.0	1	50.0	0.3953	0.55	0.05	6.21		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.3825	0.34	0.03	4.05		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.9166	1.11	0.07	17.83		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173				*	WARNING: Iteration limit reached without convergence.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	11	57.9	2	18.2	9	81.8	15	88.2	0	-	15	100.0	0.0907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	0	-	15	100.0	0.0907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical studies/RO5541077/CDPT7898/GO29365/data analysis/ACE FINAL CSR Pooled/prod/output/t s ttae soc sgl TTGR3AE L2 ARMCDPLUSSE 29365 41543.xls
30NOV2022 20:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	8	42.1	5	62.5	3	37.5	14	82.4	4	28.6	10	71.4	0.1260	3.05	0.77	12.00		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	11	57.9	2	18.2	9	81.8	3	17.6	1	33.3	2	66.7	0.7021	0.71	0.06	8.22		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	8	42.1	3	37.5	5	62.5	14	82.4	1	7.1	13	92.9	0.1010	5.11	0.53	49.25		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	8	42.1	3	37.5	5	62.5	14	82.4	3	21.4	11	78.6	0.4016	2.01	0.39	10.30		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4364	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	1	7.1	13	92.9	0.2690	3.55	0.32	39.19		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.8084	1.41	0.08	23.57		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	11	57.9	1	9.1	10	90.9	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	4	28.6	10	71.4	0.2352	0.17	0.01	2.21		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	11	57.9	3	27.3	8	72.7	3	17.6	2	66.7	1	33.3	0.1501	0.11	0.01	1.36		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.2760	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	11	57.9	2	18.2	9	81.8	3	17.6	2	66.7	1	33.3	0.1389	0.09	0.01	1.11		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.9791	1.00	0.06	17.88		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	11	57.9	2	18.2	9	81.8	3	17.6	2	66.7	1	33.3	0.1017	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.6660	1.86	0.12	29.79		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.1278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical studies/RO5541077/CDPT7898/GO29365/data analysis/ACE FINAL CSR Pooled/prod/output/t s ttae soc sgl TTGR3AE L2 ARMCDPLUSSE 29365 41543.xls
30NOV2022 20:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	26.3	3	60.0	2	40.0	3	17.6	2	66.7	1	33.3	0.9656	0.96	0.16	5.90		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	3	21.4	11	78.6	0.6917	1.91	0.42	8.77		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	0	-	3	100.0	0.2087	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.6517	2.48	0.22	27.52		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	26.3	2	40.0	3	60.0	3	17.6	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	1	7.1	13	92.9	0.3156	3.92	0.40	38.71		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.8592	1.12	0.07	17.95		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	2	14.3	12	85.7	0.7664	0.81	0.11	6.04		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INVESTIGATIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	6	42.9	8	57.1	0.1452	0.29	0.07	1.17		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3657	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3657	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	3	21.4	11	78.6	0.0598	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	2	14.3	12	85.7	0.9077	0.91	0.15	5.67		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.7681	1.00	0.06	16.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	3	21.4	11	78.6	0.6531	0.61	0.12	3.16		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.8993	0.86	0.05	14.17		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.3404	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3404	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical studies/RO5541077/CDPT7898/GO29365/data analysis/ACE FINAL CSR Pooled/prod/output/t s ttae soc sgl TTGR3AE L2 ARMCDPLUSSE 29365 41543.xls
30NOV2022 20:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	5	35.7	9	64.3	8	47.1	4	50.0	4	50.0	0.5205	1.10	0.28	4.40		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	2	40.0	3	60.0	9	52.9	1	11.1	8	88.9	0.1716	3.51	0.31	39.60		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	14	73.7	2	14.3	12	85.7	8	47.1	1	12.5	7	87.5	0.9072	1.58	0.14	17.60		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.0514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	14	73.7	3	21.4	11	78.6	8	47.1	2	25.0	6	75.0	0.8208	1.18	0.18	7.71		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	5	26.3	2	40.0	3	60.0	9	52.9	1	11.1	8	88.9	0.2367	2.57	0.23	28.71		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.6278	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.7243	0.69	0.06	8.45		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.2059				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INVESTIGATIONS		Male	14	73.7	3	21.4	11	78.6	8	47.1	2	25.0	6	75.0	0.6755	0.64	0.08	4.87		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	1	20.0	4	80.0	9	52.9	4	44.4	5	55.6	0.1546	0.14	0.01	2.74		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	3	33.3	6	66.7	0.1569	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.3087	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.5330	0.67	0.05	9.18		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.4263	0.62	0.03	11.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	14	73.7	2	14.3	12	85.7	8	47.1	1	12.5	7	87.5	0.9888	0.49	0.03	8.24		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.5530	0.69	0.05	9.39		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.0448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.0448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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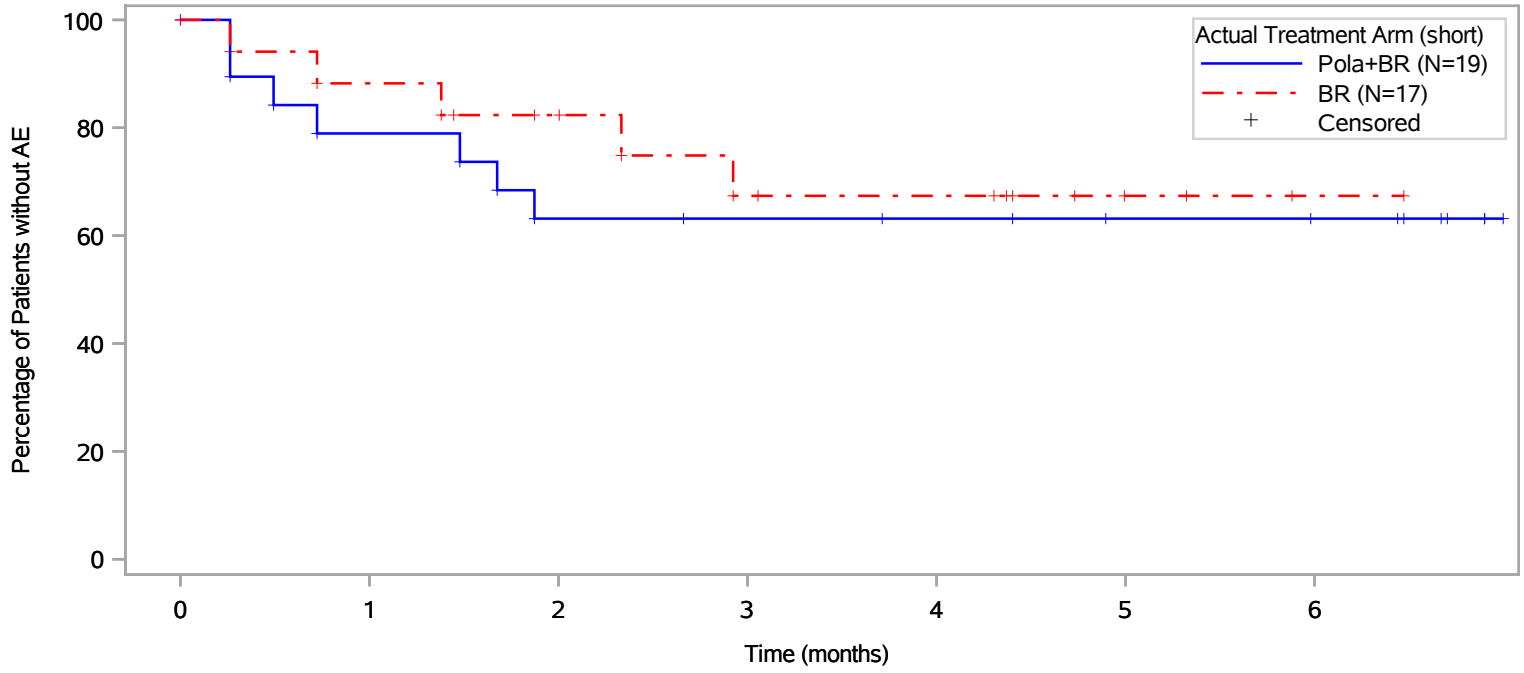
30NOV2022 20:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	15	12	11	10	8	7
BR (N=17)	17	15	12	9	8	3	1
Patients censored							
Pola+BR (N=19)	0	0	0	1	2	4	5
BR (N=17)	0	0	2	3	4	9	11

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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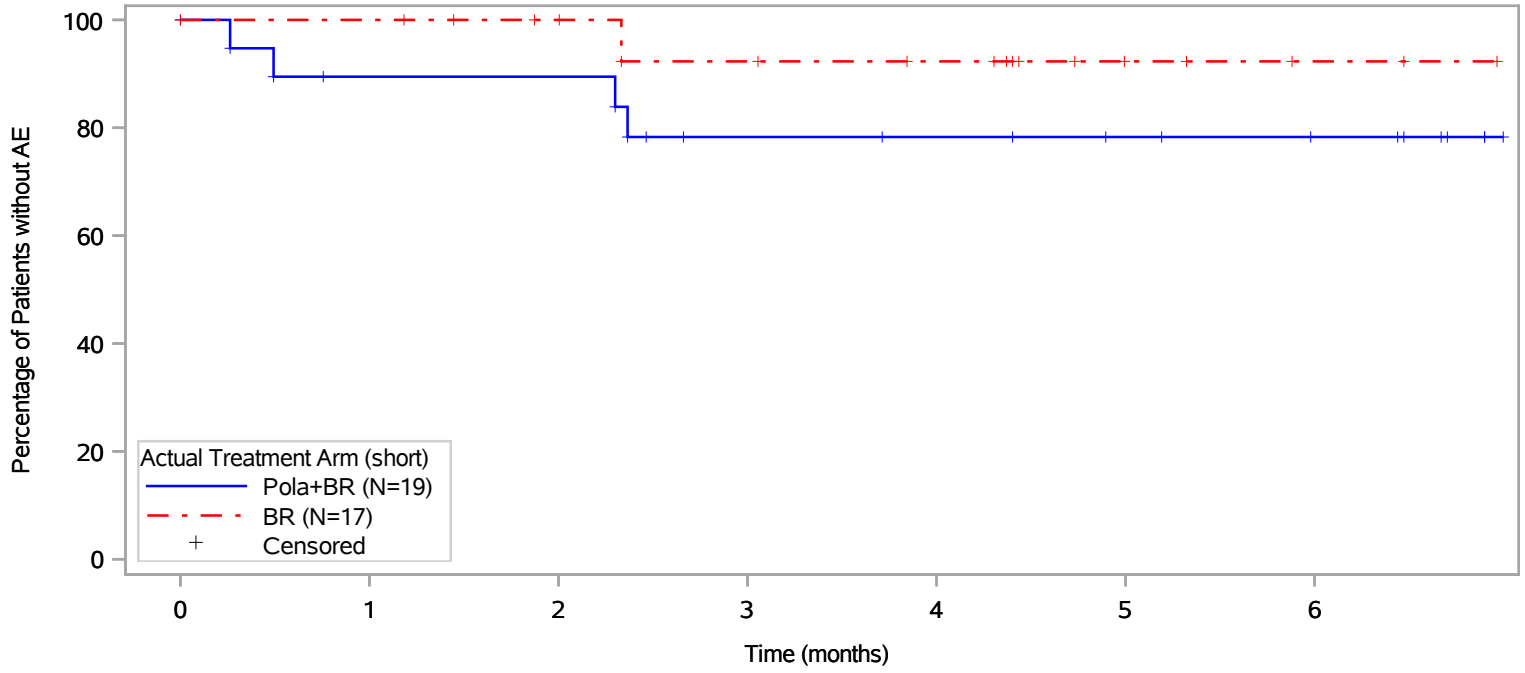
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk							
Pola+BR (N=19)	19	16	16	12	11	9	7
BR (N=17)	17	17	14	12	10	4	2
Patients censored							
Pola+BR (N=19)	0	1	1	3	4	6	8
BR (N=17)	0	0	3	4	6	12	14

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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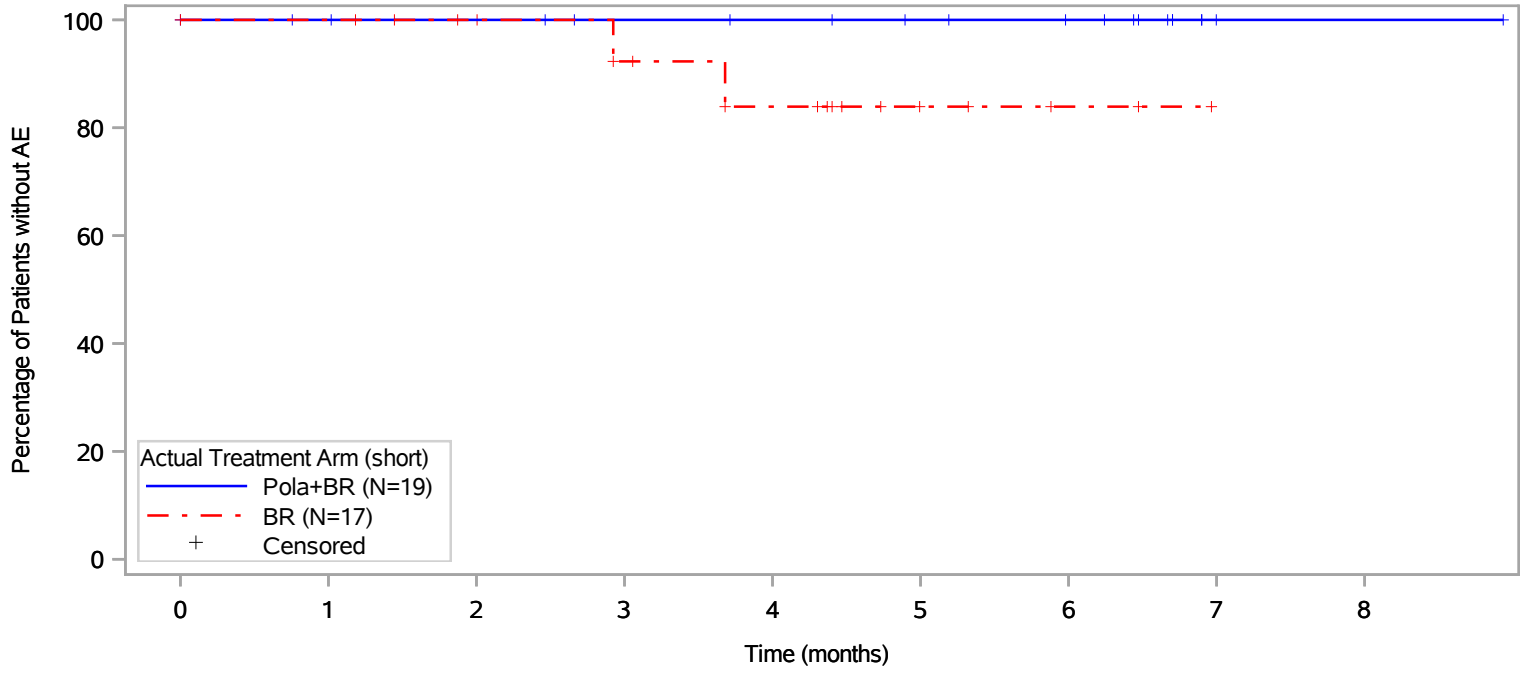
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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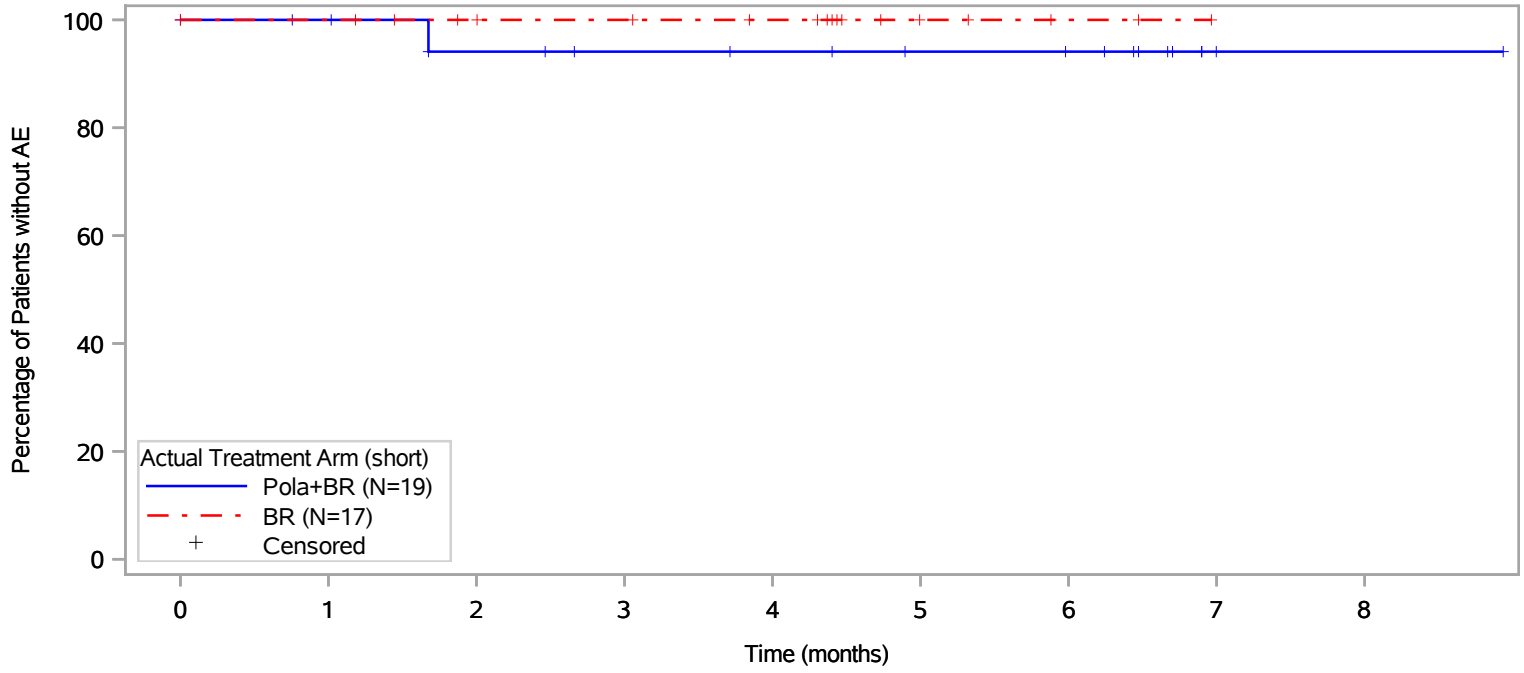
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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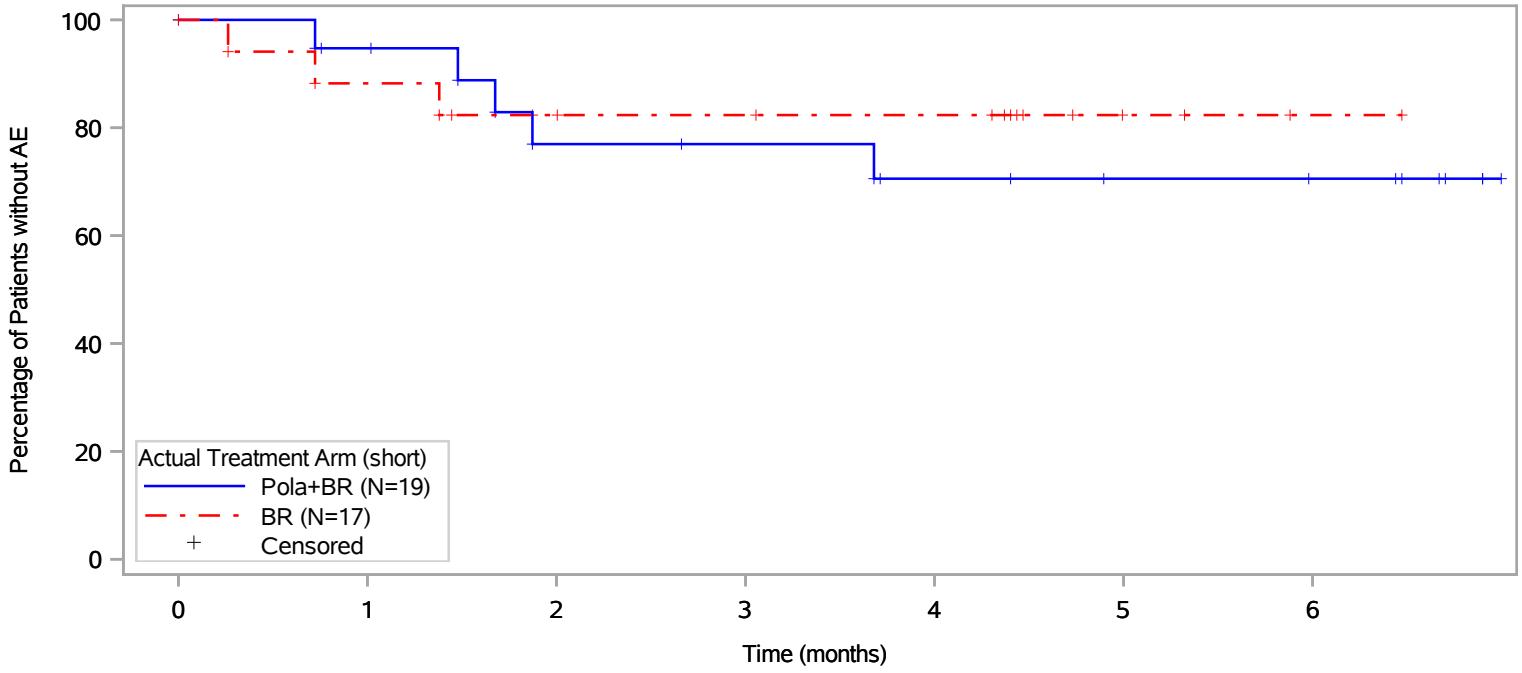
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk							
Pola+BR (N=19)	19	17	13	12	10	8	7
BR (N=17)	17	15	12	11	10	3	1
Patients censored							
Pola+BR (N=19)	0	1	2	3	4	6	7
BR (N=17)	0	0	2	3	4	11	13

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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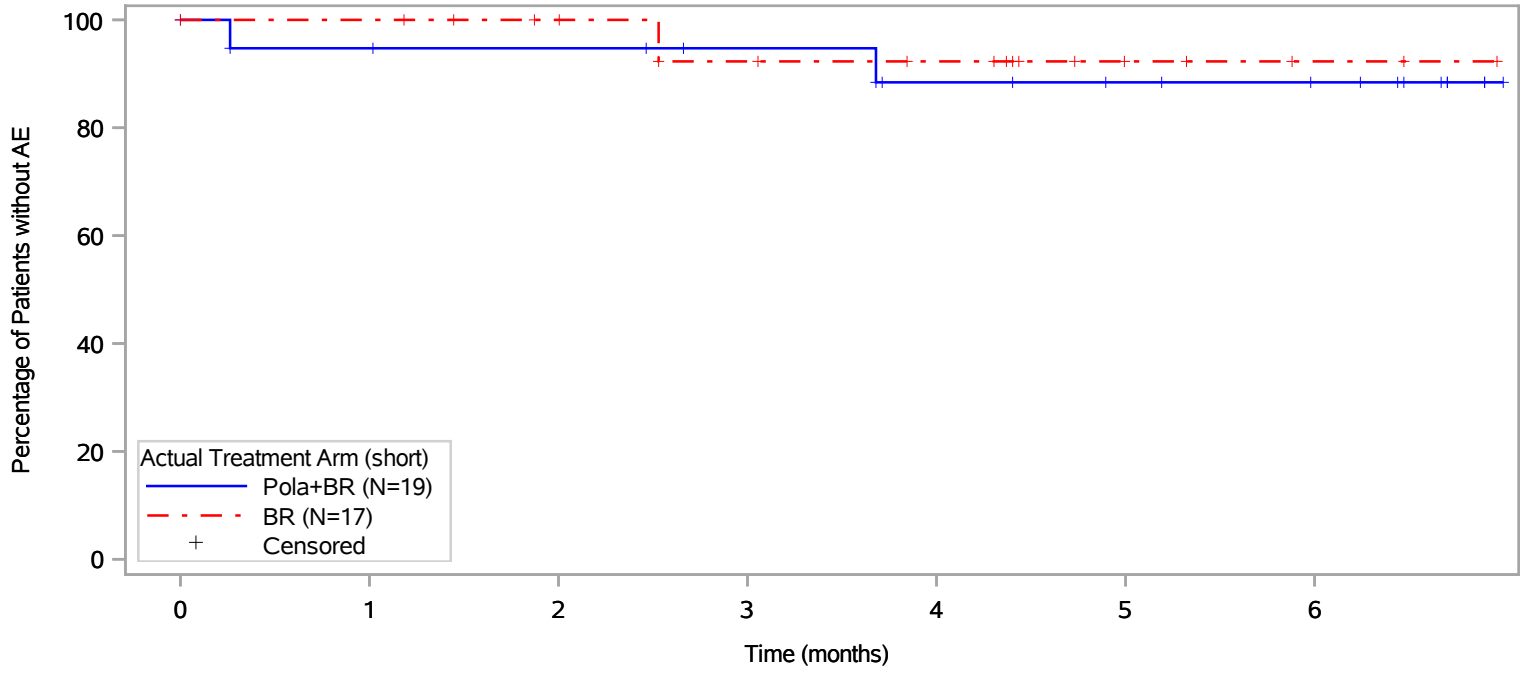
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk							
Pola+BR (N=19)	19	18	17	15	13	11	9
BR (N=17)	17	17	14	12	10	4	2
Patients censored							
Pola+BR (N=19)	0	0	1	3	4	6	8
BR (N=17)	0	0	3	4	6	12	14

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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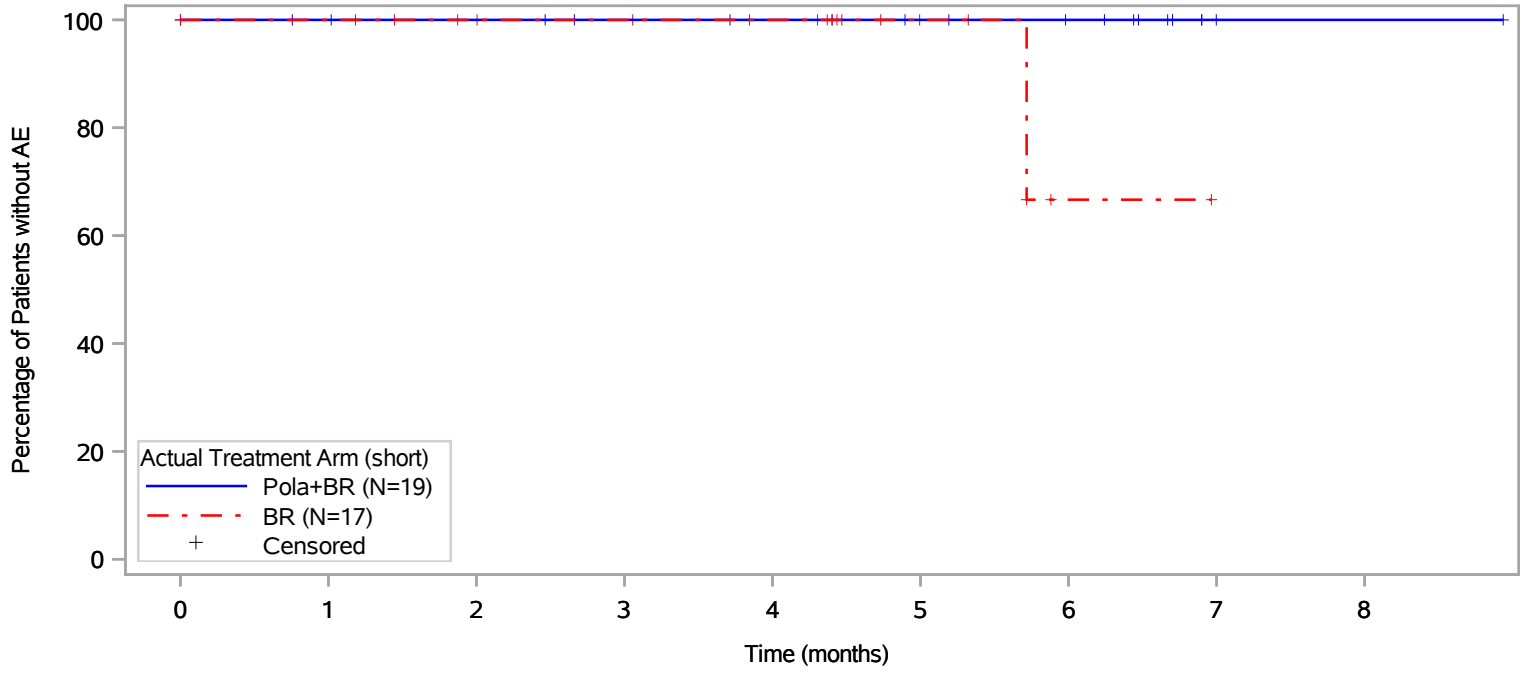
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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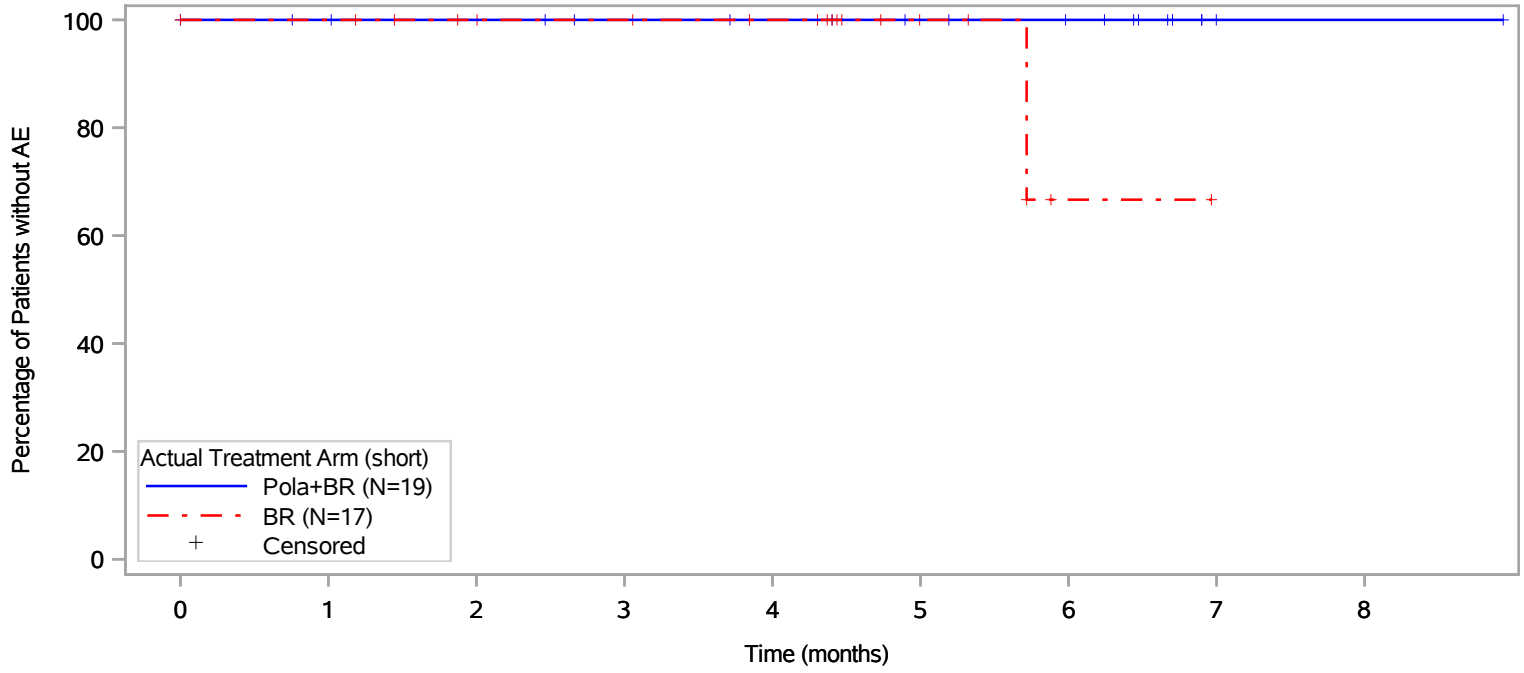
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SMALL INTESTINAL OBSTRUCTION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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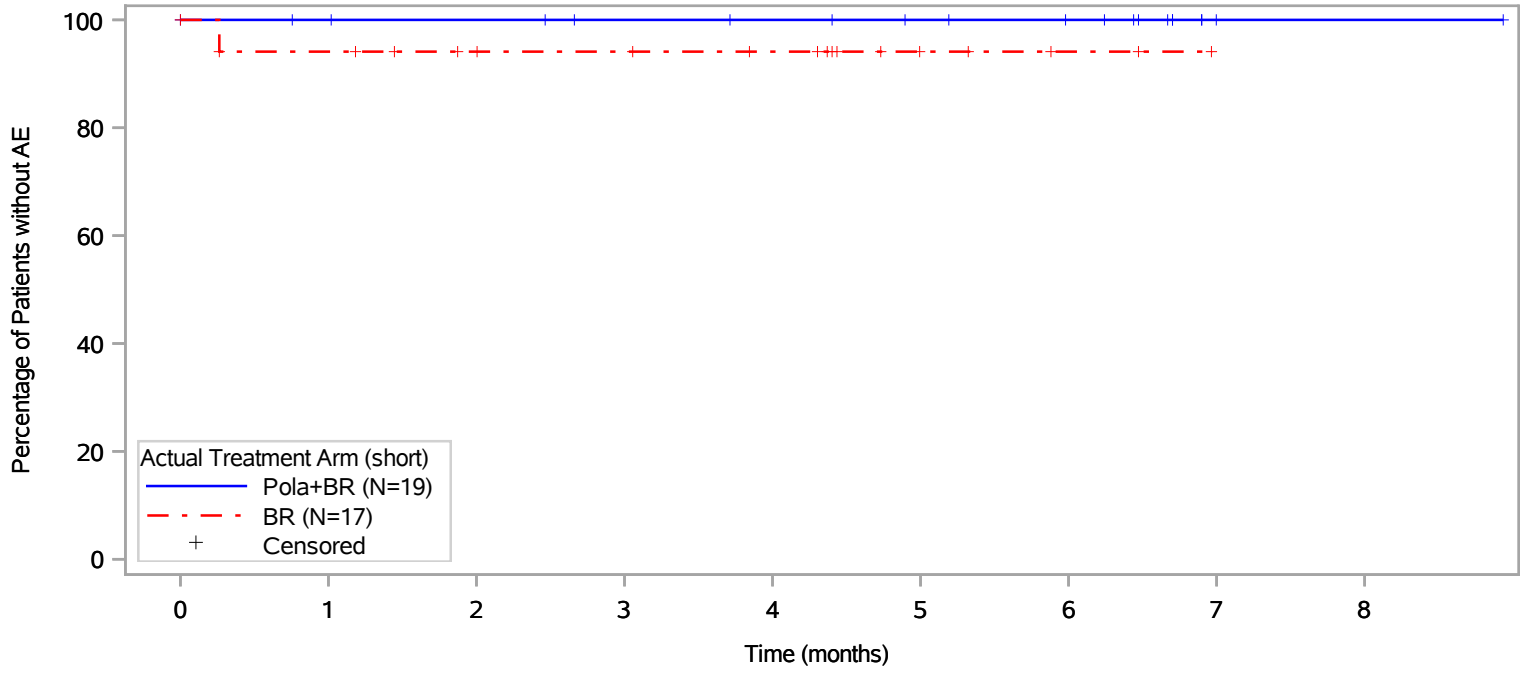
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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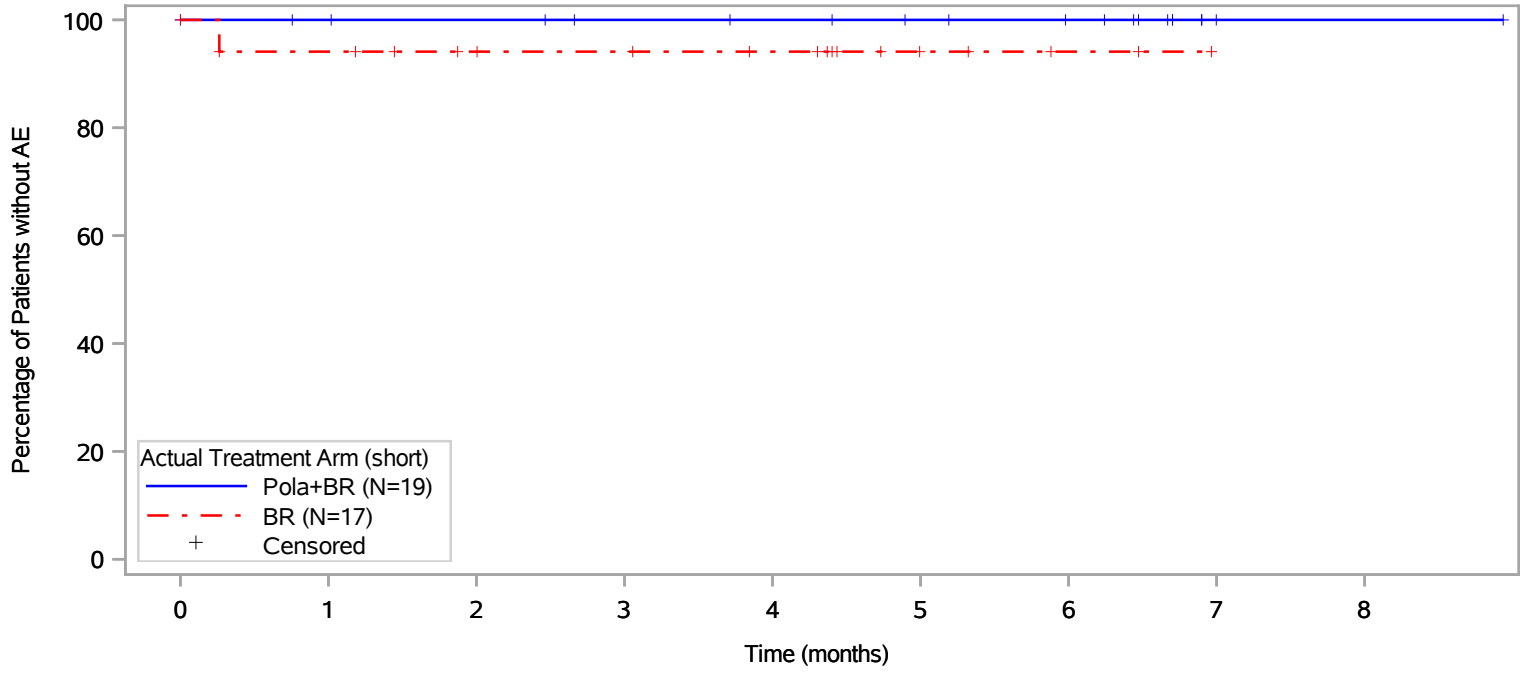
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

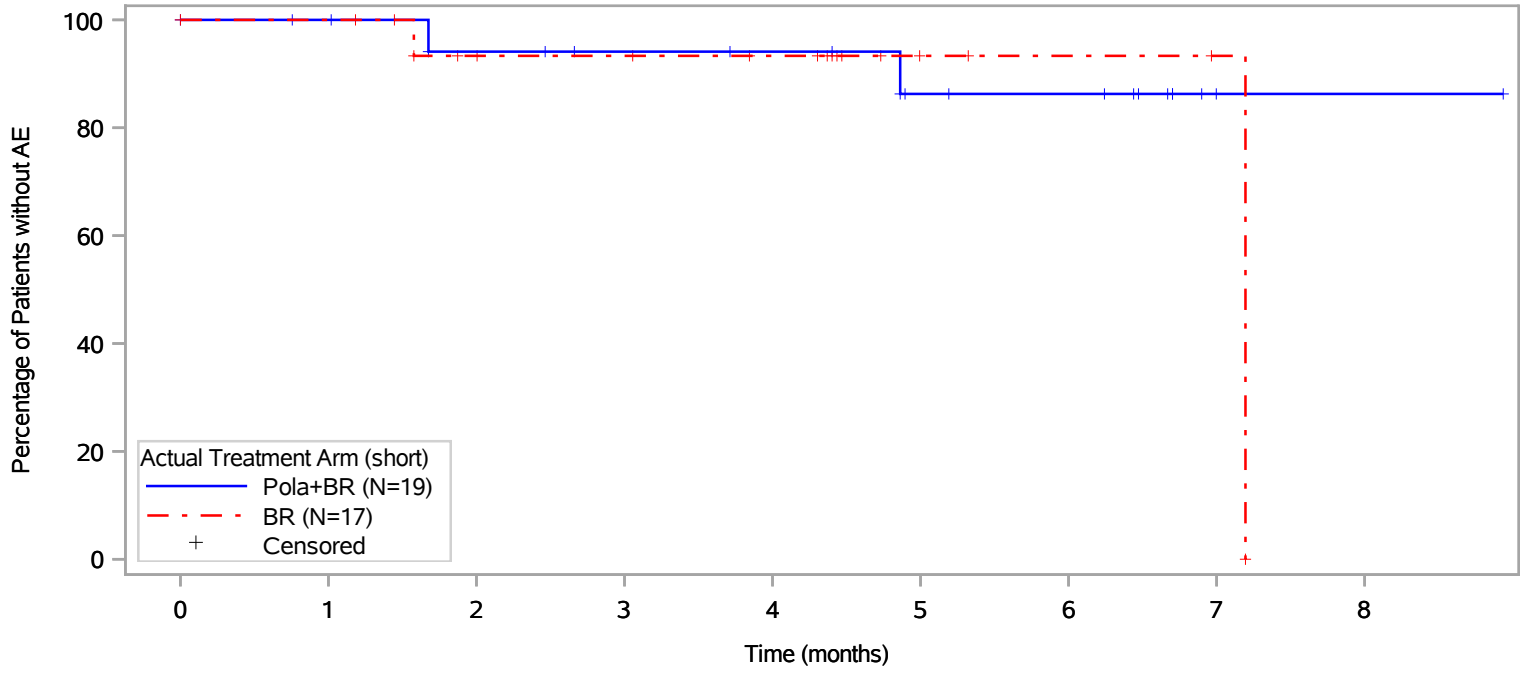
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

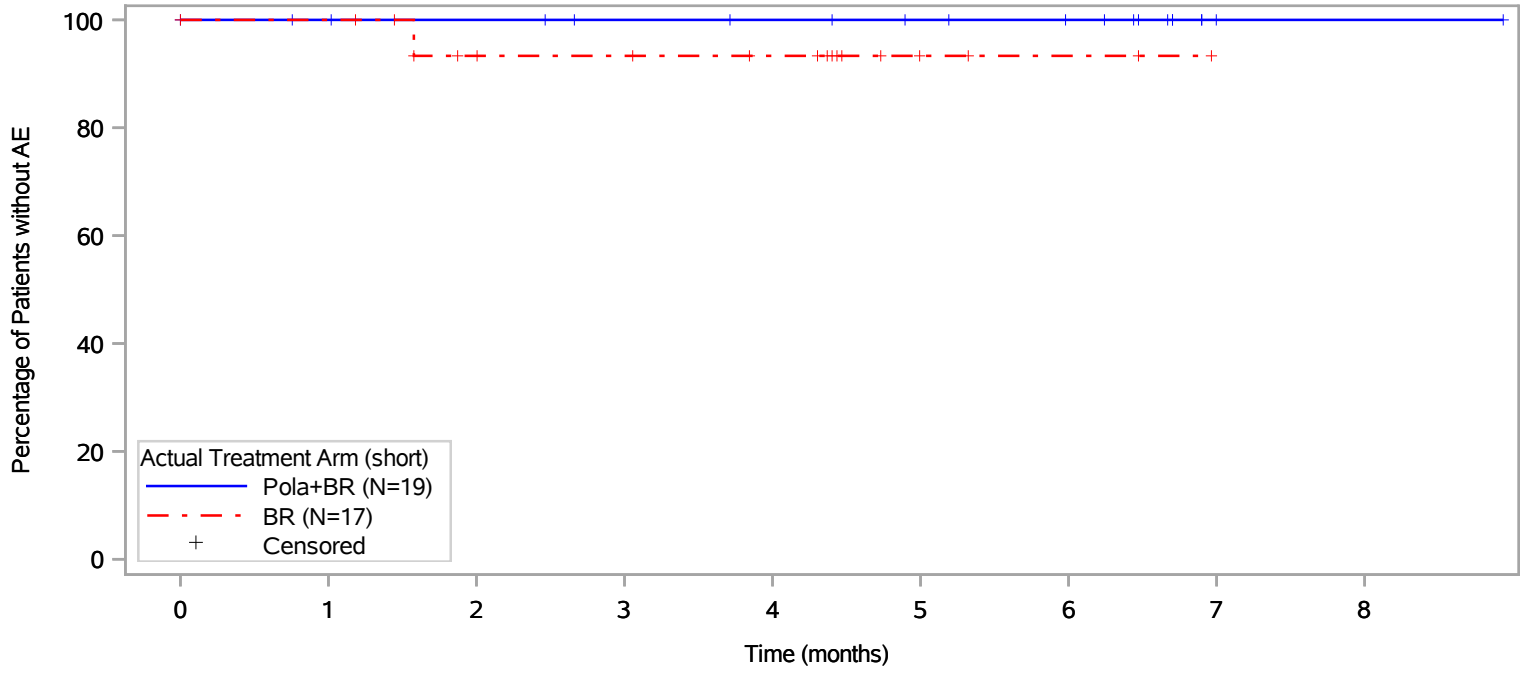
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	10	9	1	1
BR (N=17)	17	17	13	12	10	3	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	16	16
BR (N=17)	0	0	3	4	6	13	14	15	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

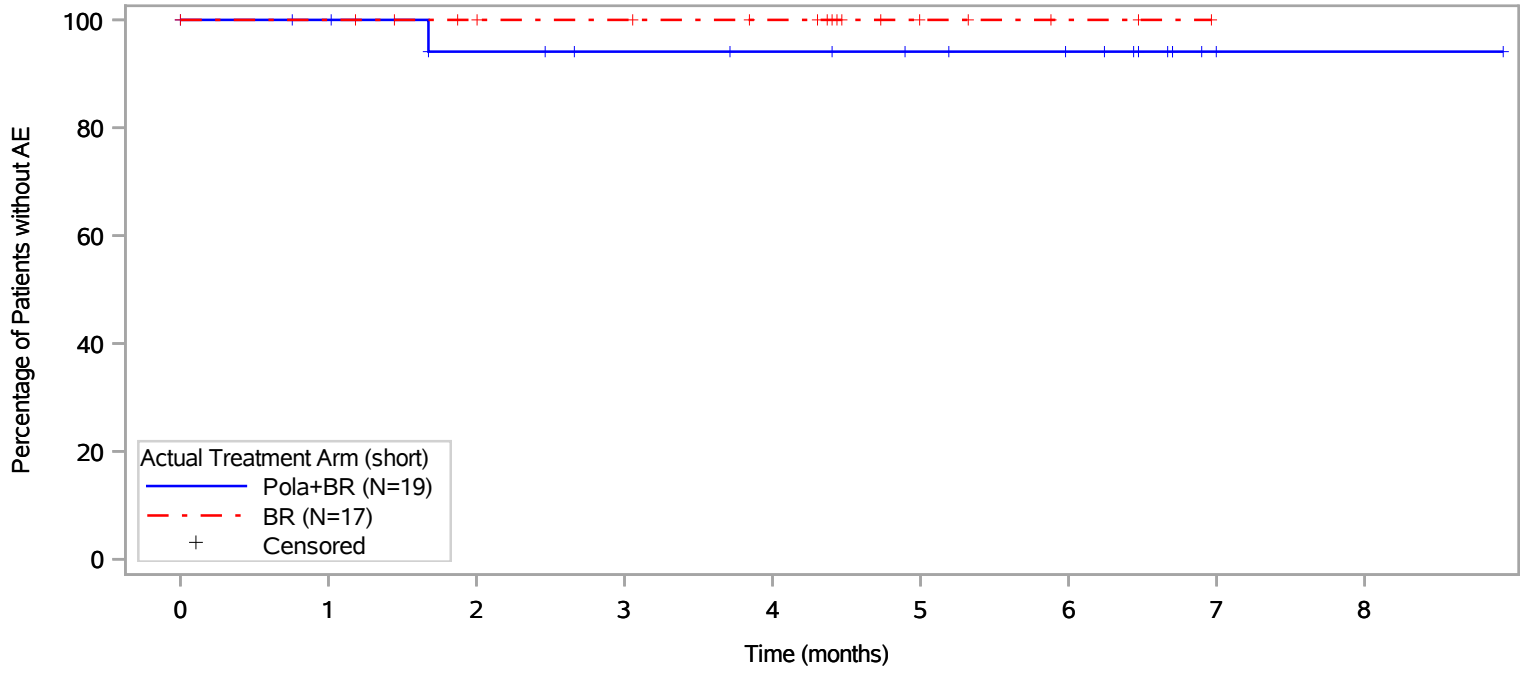
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

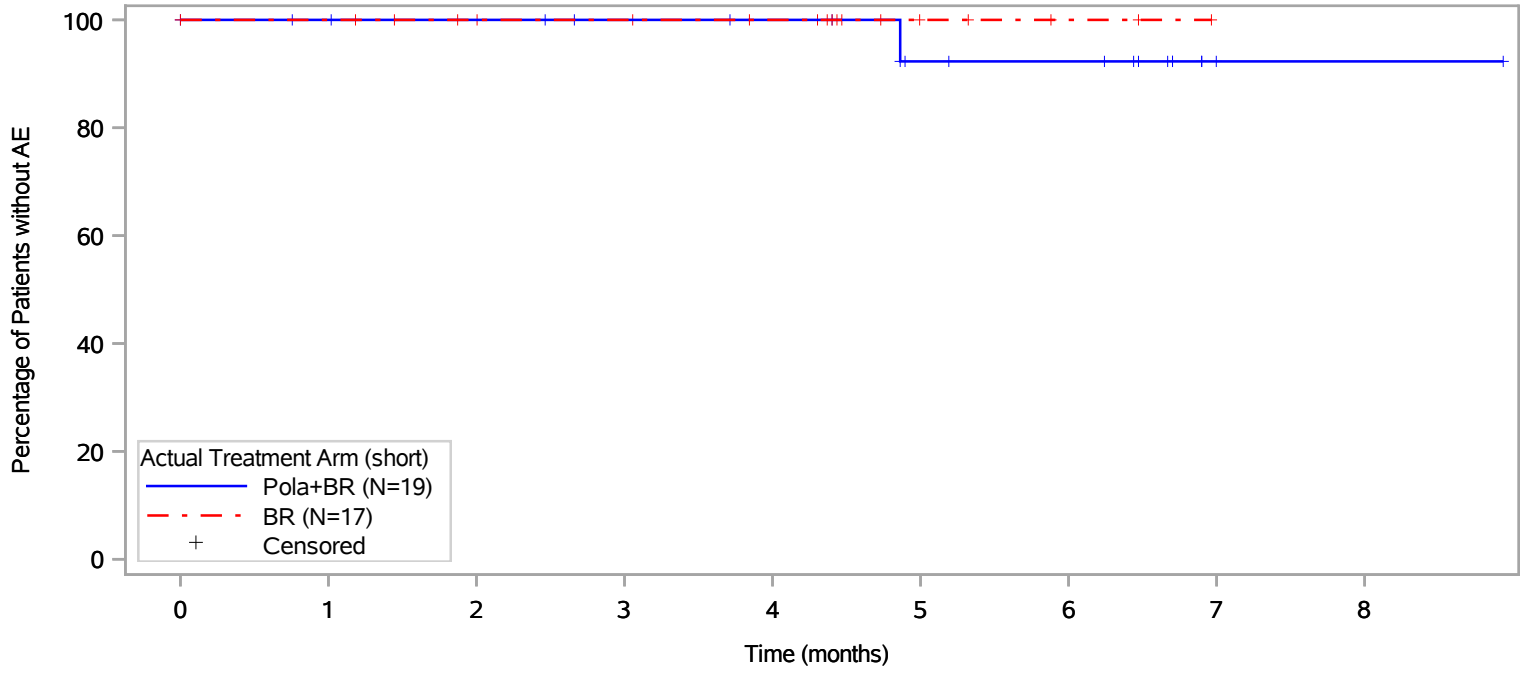
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA CYTOMEGALOVIRAL

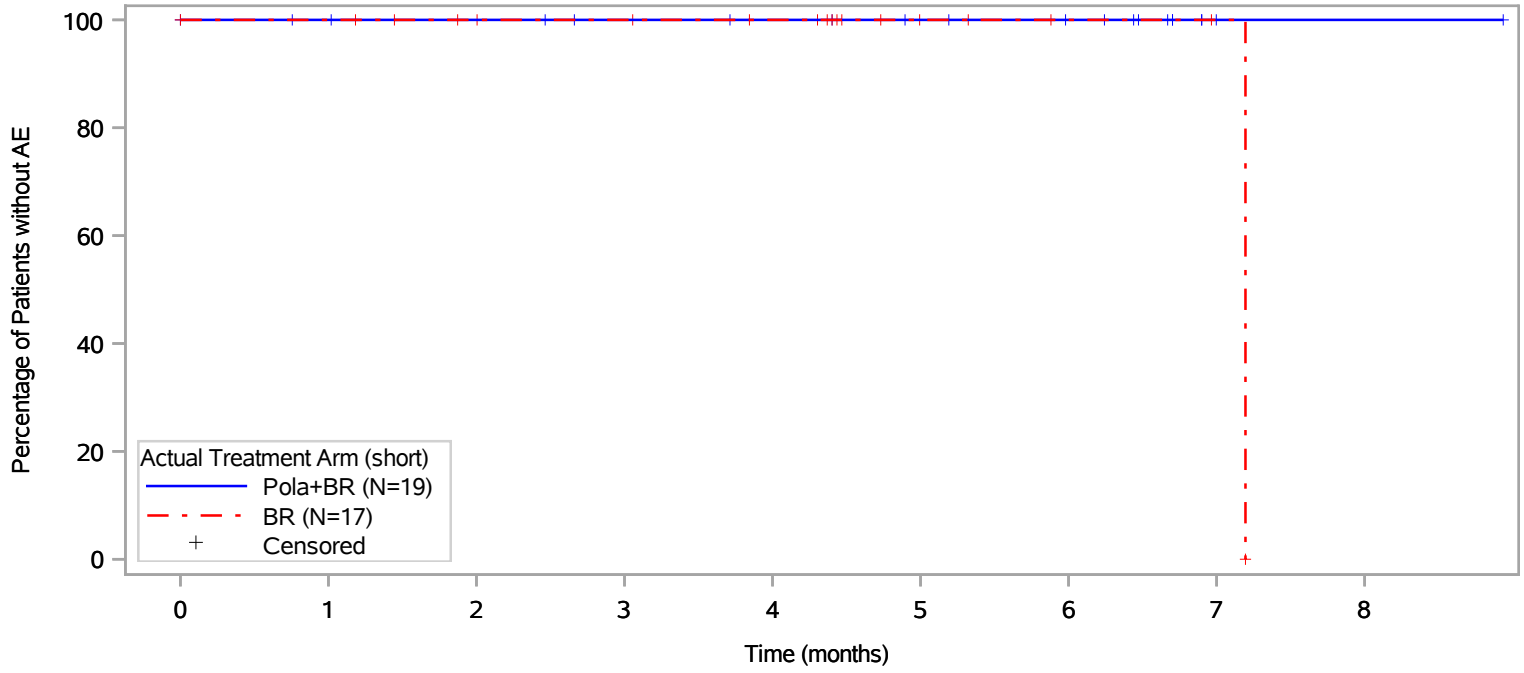


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, POST PROCEDURAL INFECTION

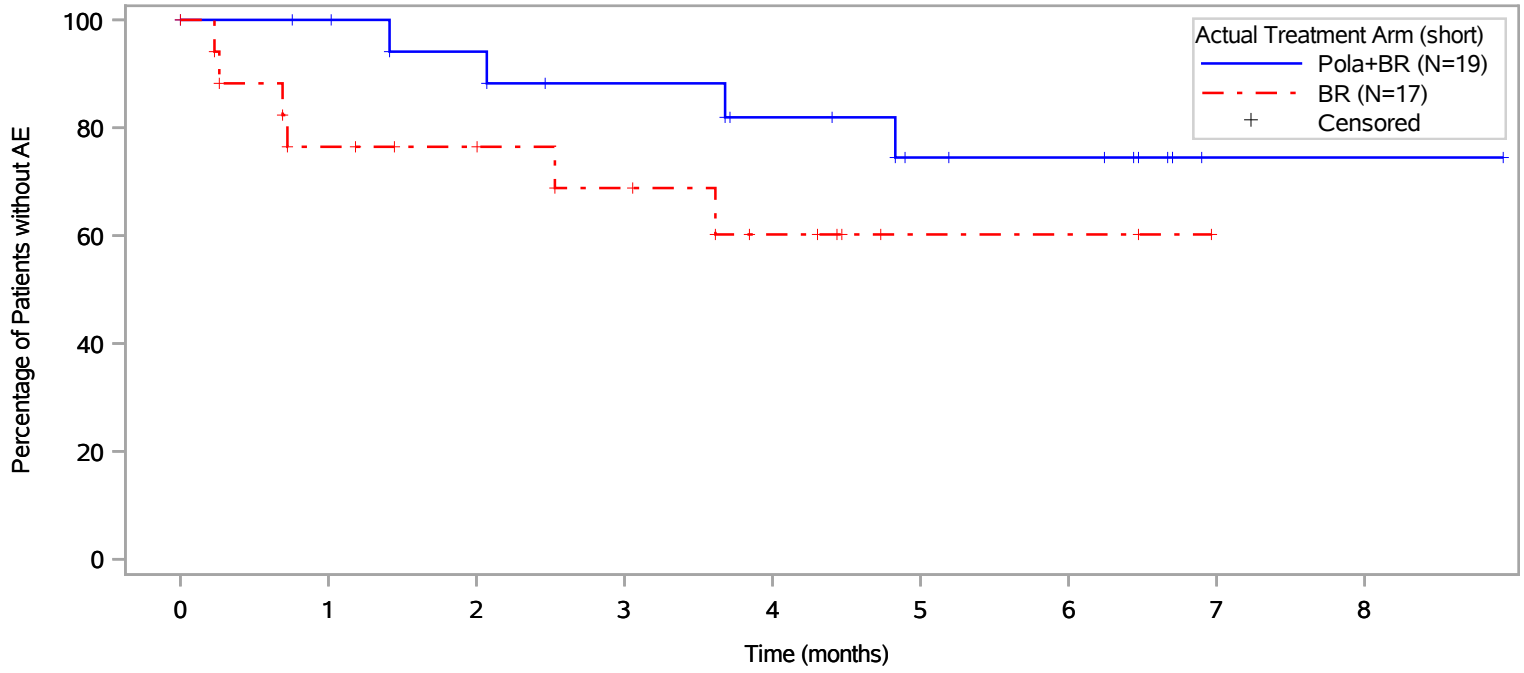


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk									
Pola+BR (N=19)	19	18	16	14	12	9	8	1	1
BR (N=17)	17	13	11	9	6	2	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	7	14	14
BR (N=17)	0	0	2	3	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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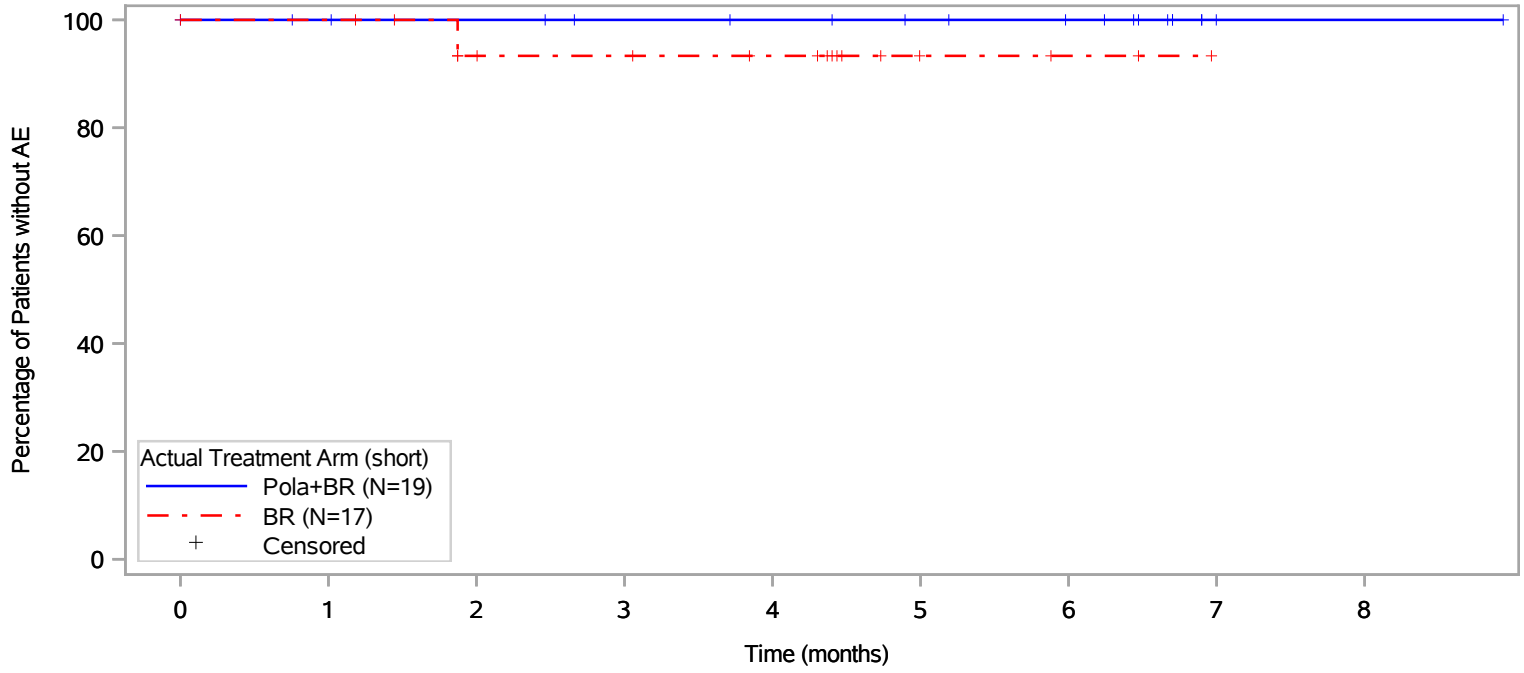
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BILIRUBIN CONJUGATED INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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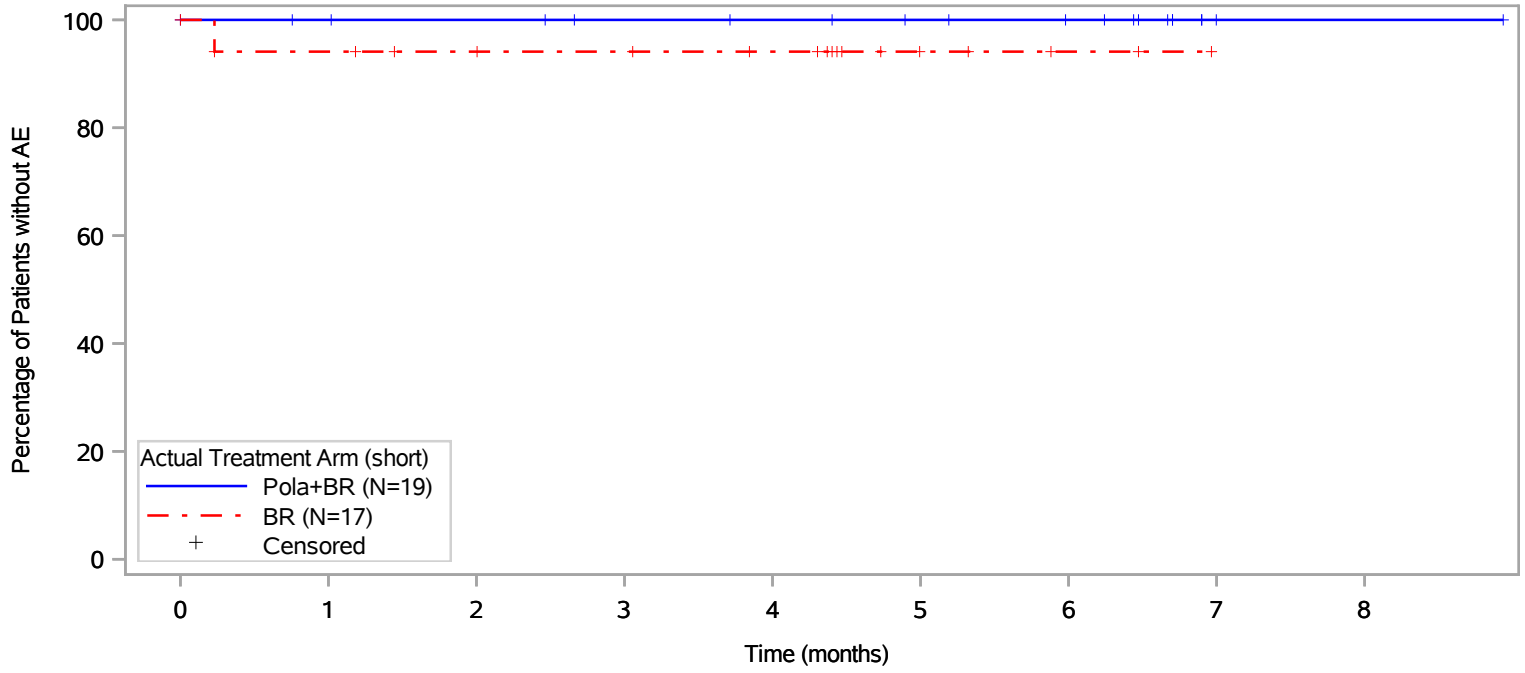
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALKALINE PHOSPHATASE INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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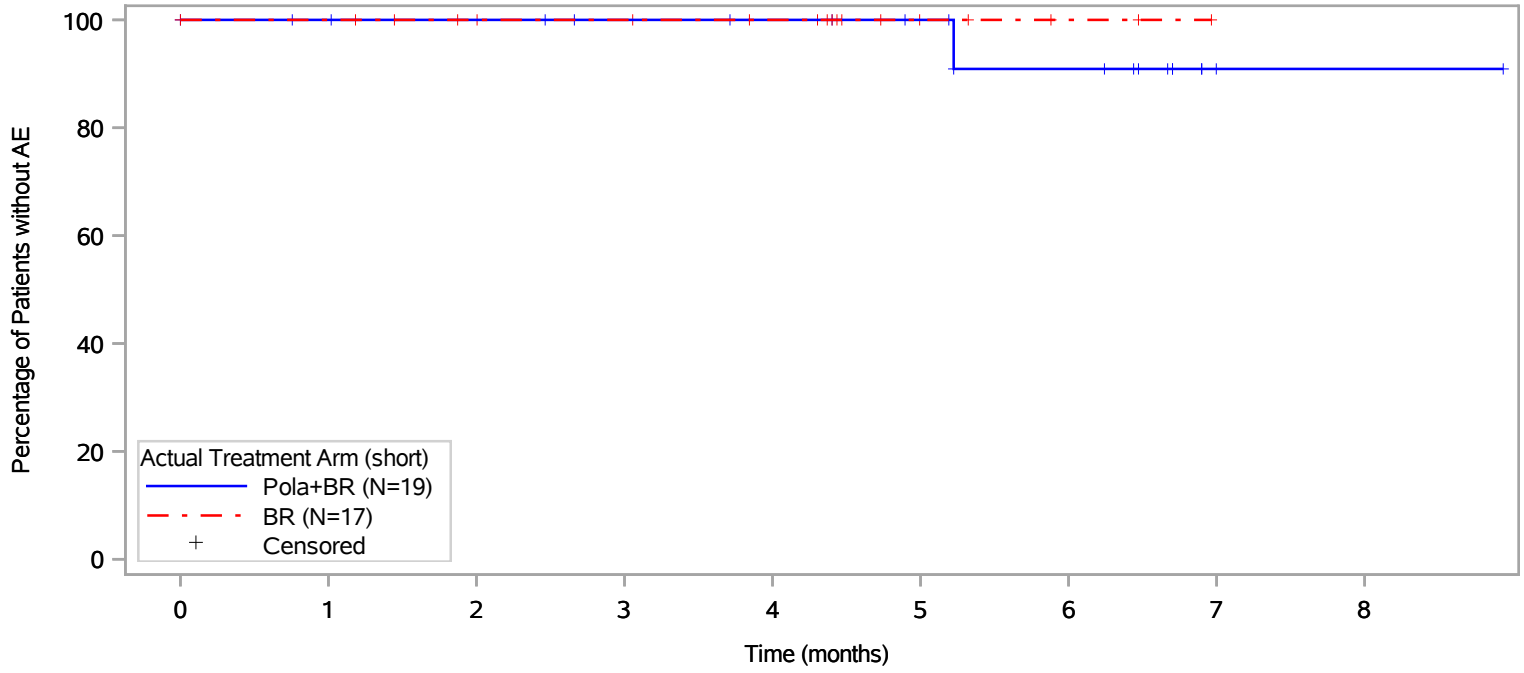
02DEC2022 3:15

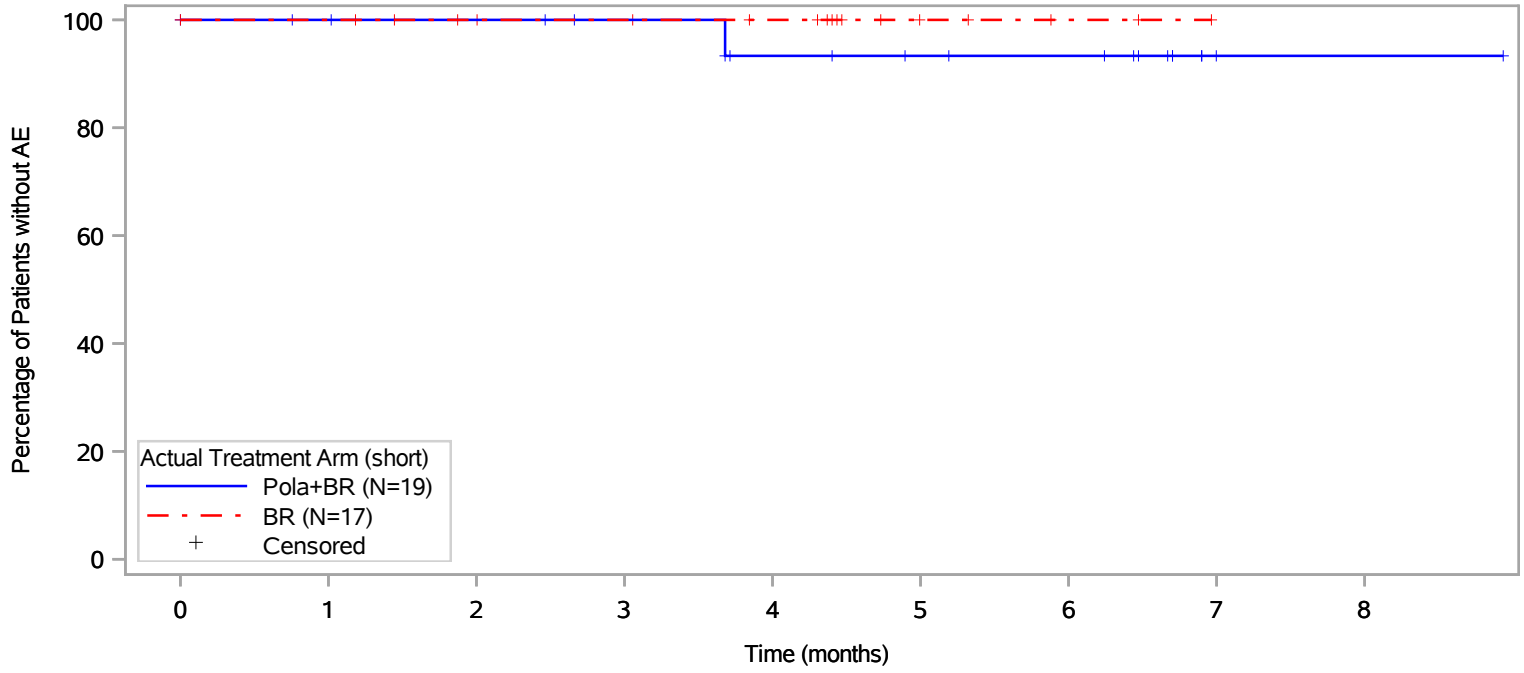
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PHOSPHORUS DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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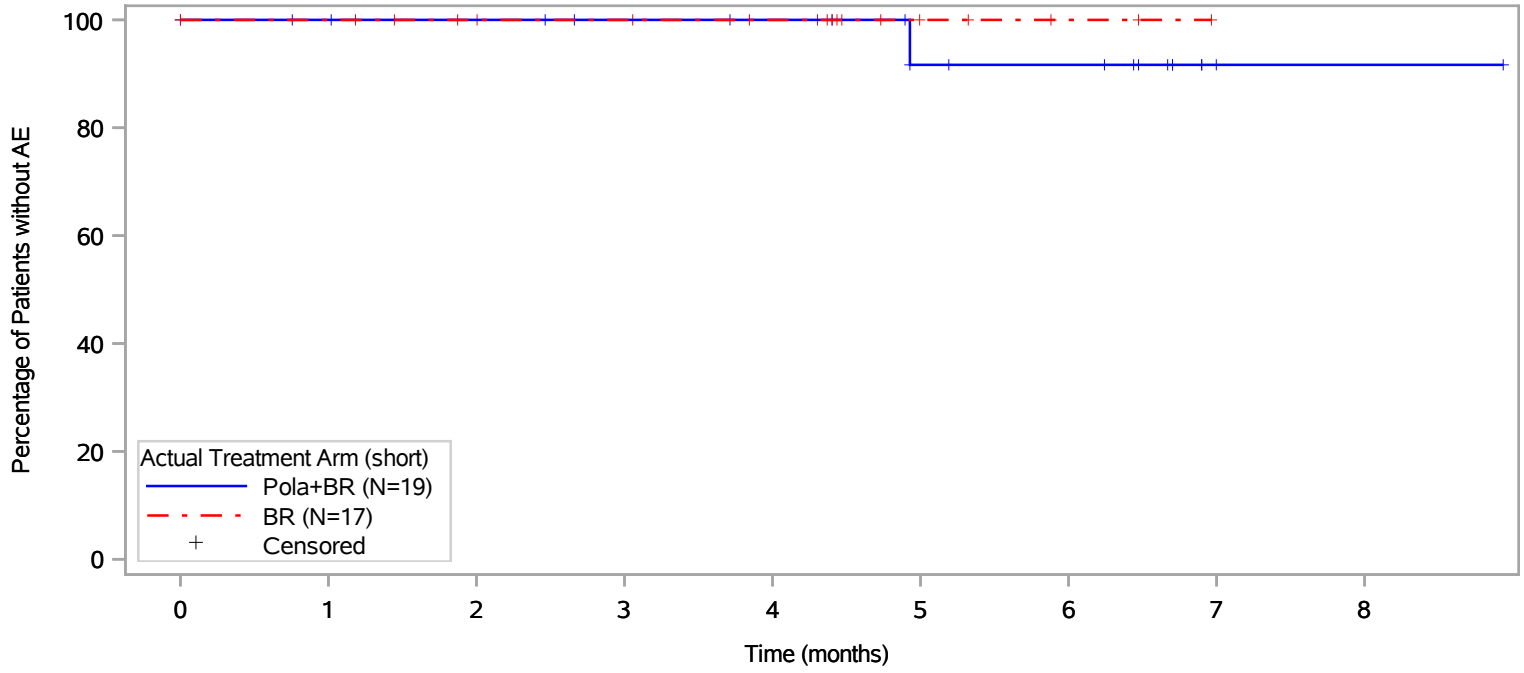
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYTOMEGALOVIRUS TEST POSITIVE



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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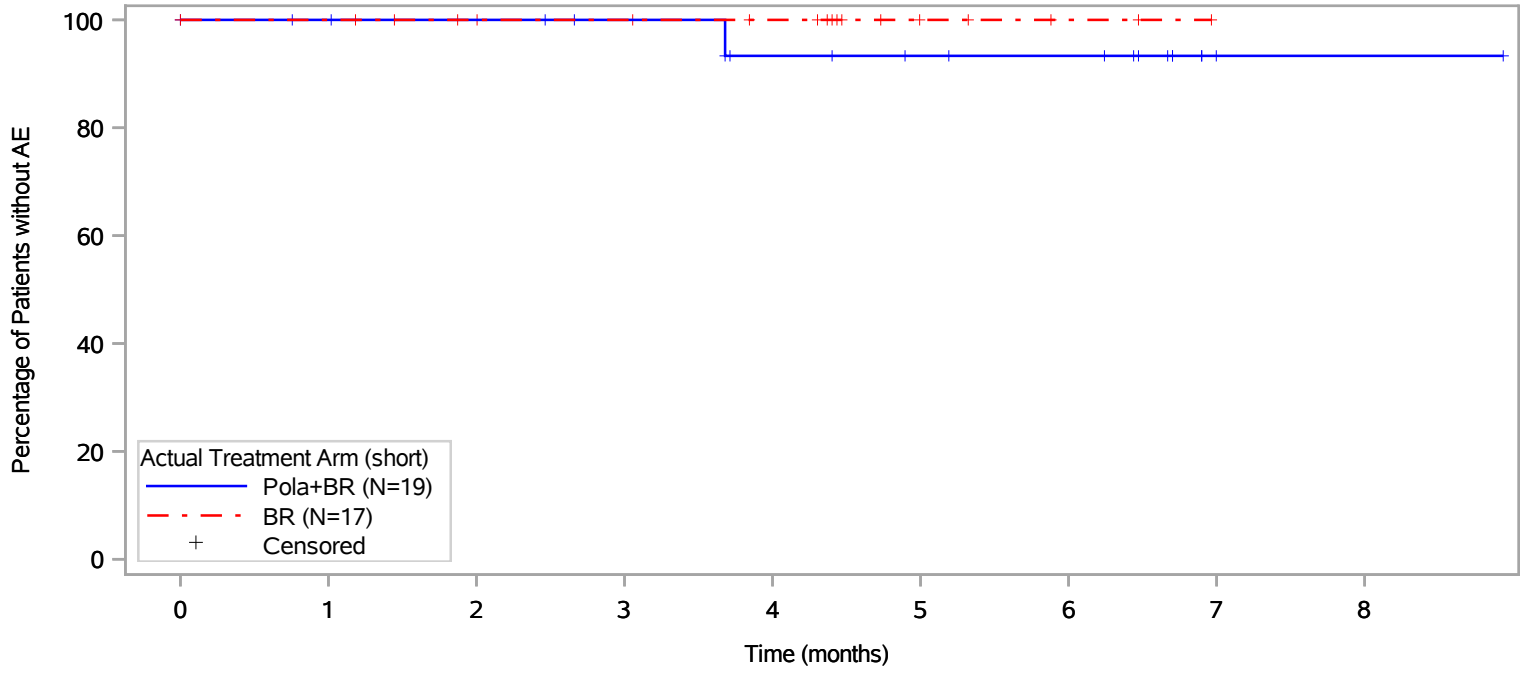
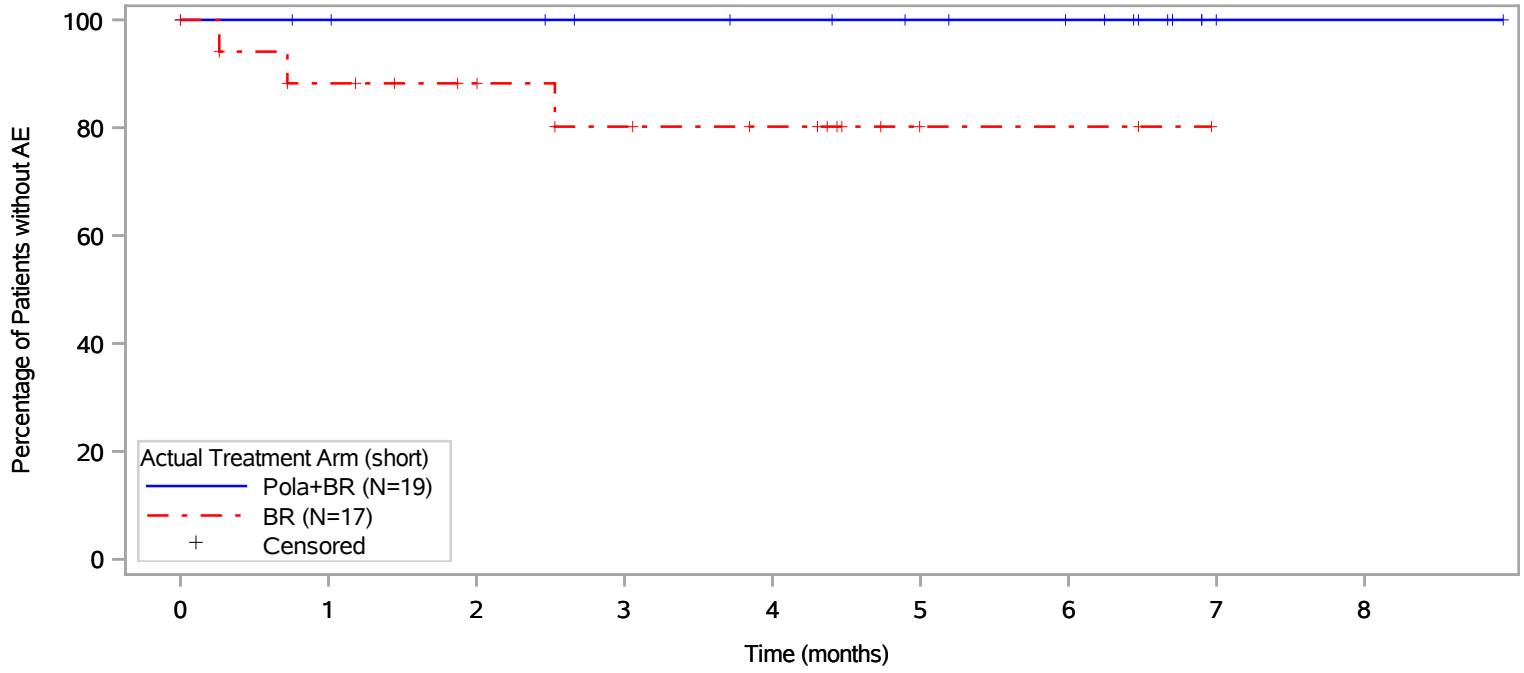
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LIPASE INCREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	15	12	10	8	2	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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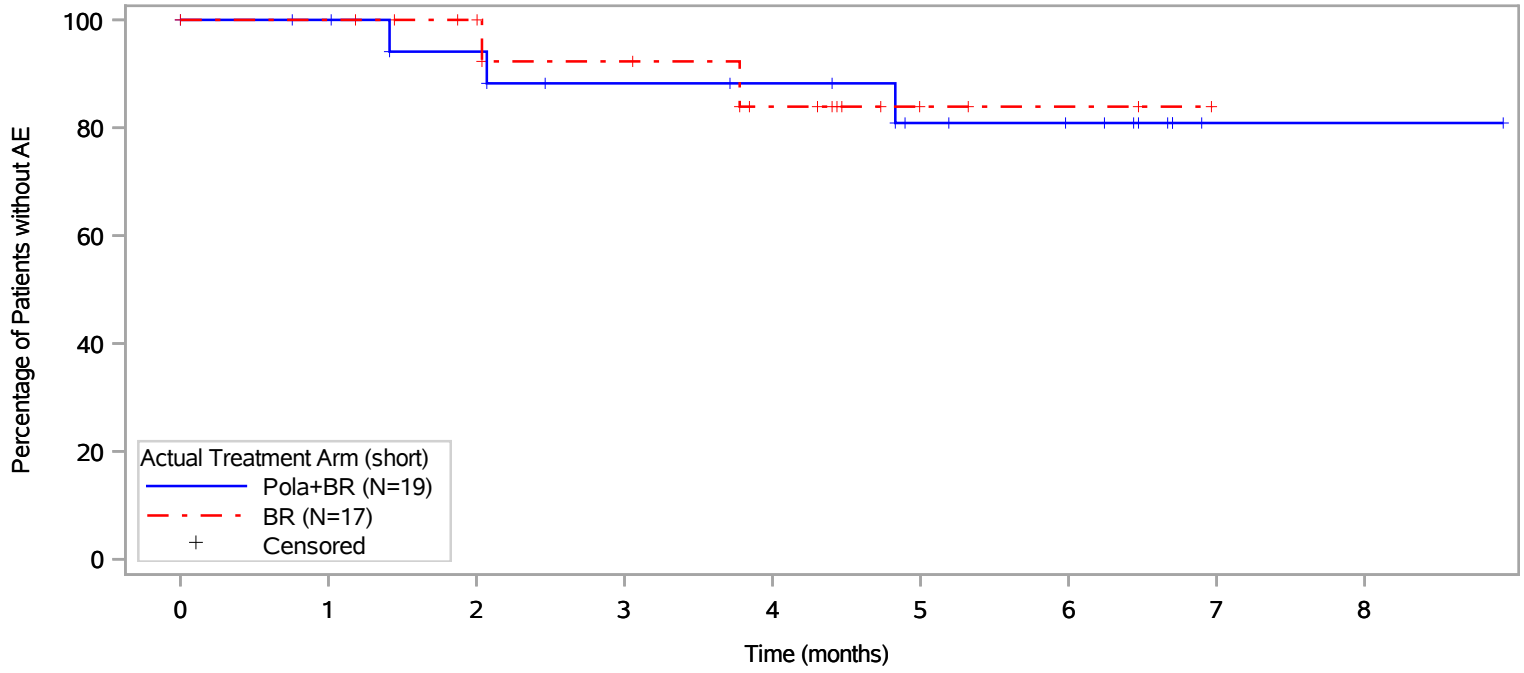
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

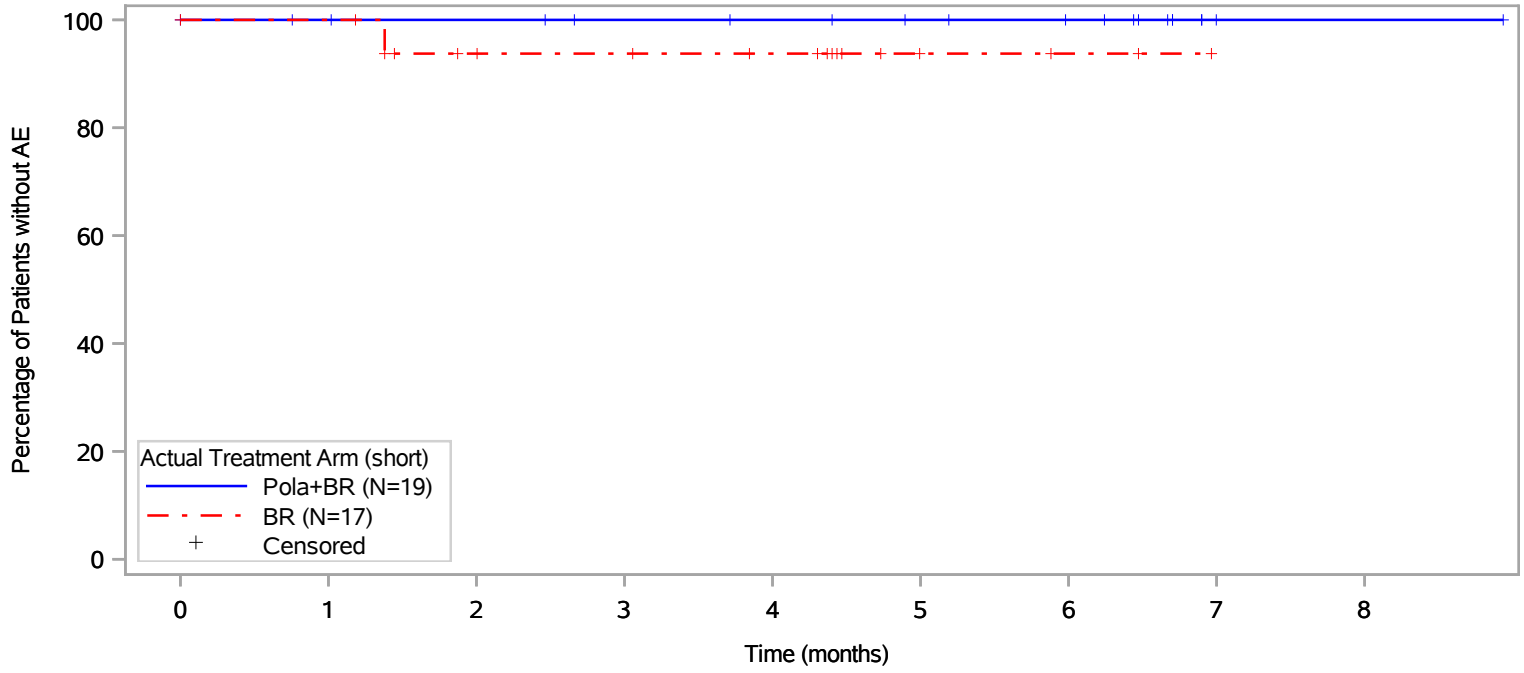


Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	10	8	1	1
BR (N=17)	17	17	14	12	9	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	15	15
BR (N=17)	0	0	3	4	6	12	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

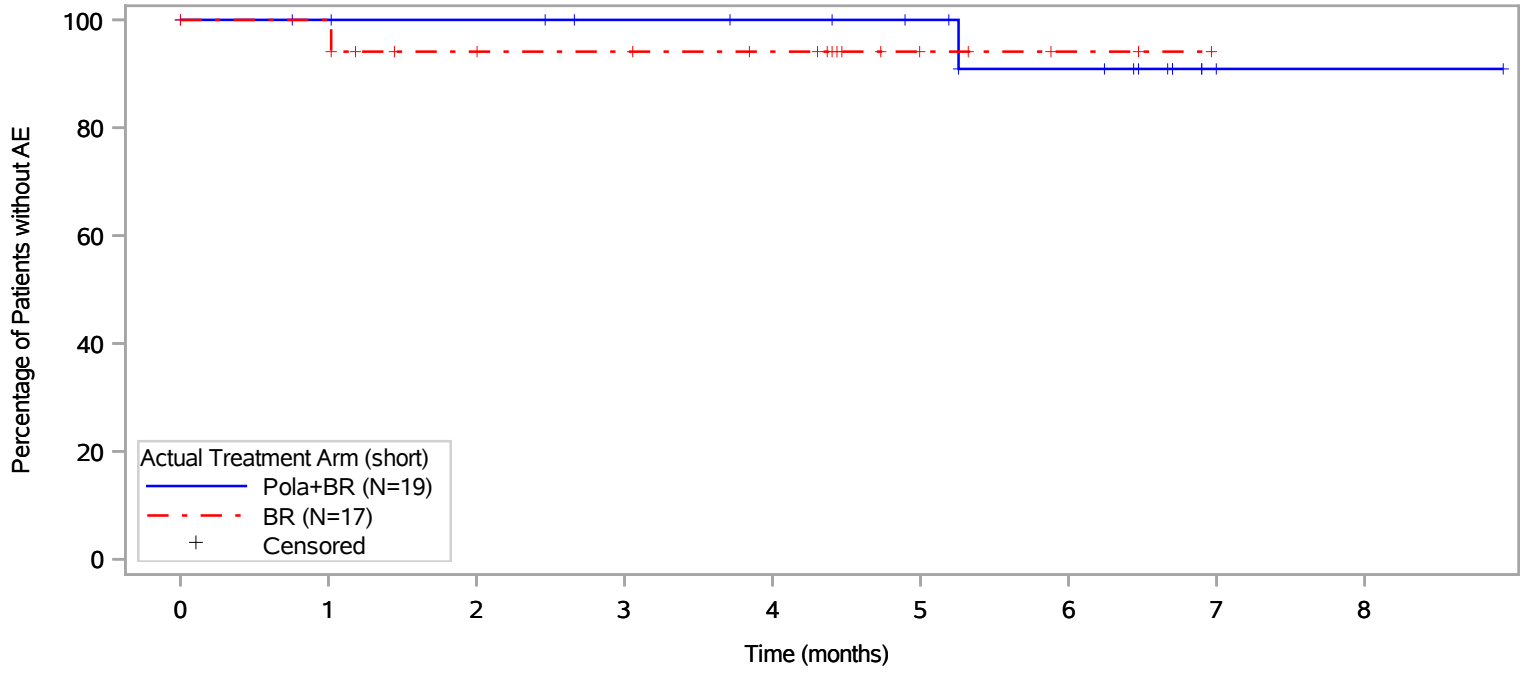


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED

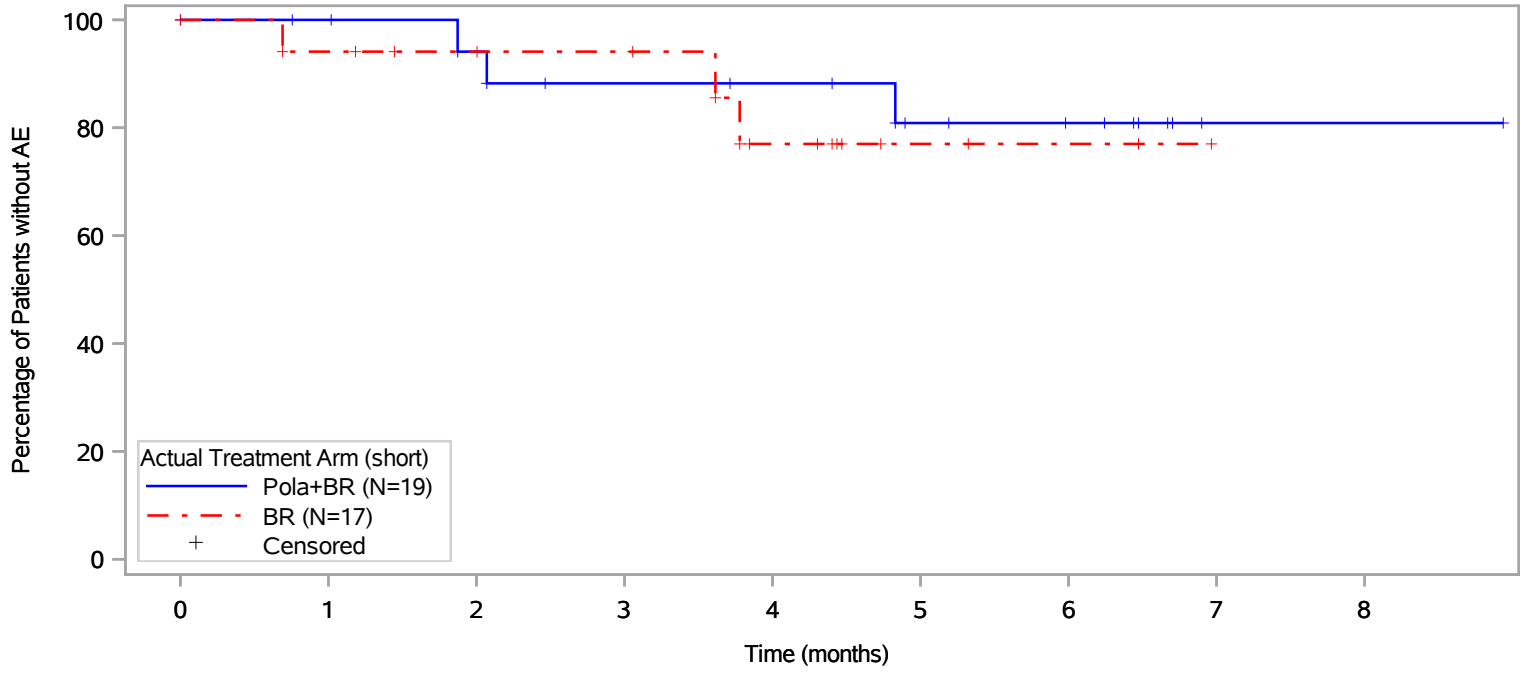


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	10	8	1	1
BR (N=17)	17	16	13	12	8	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	15	15
BR (N=17)	0	0	3	4	6	11	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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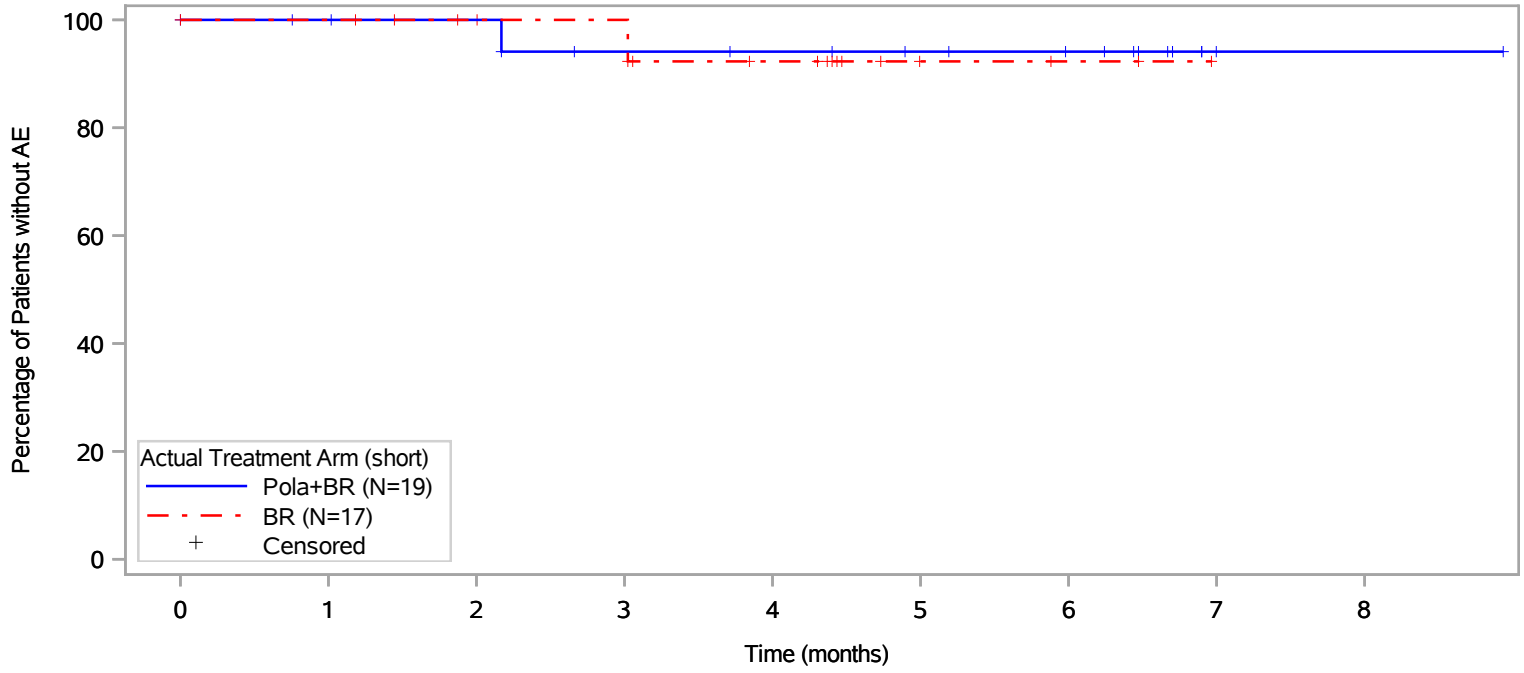
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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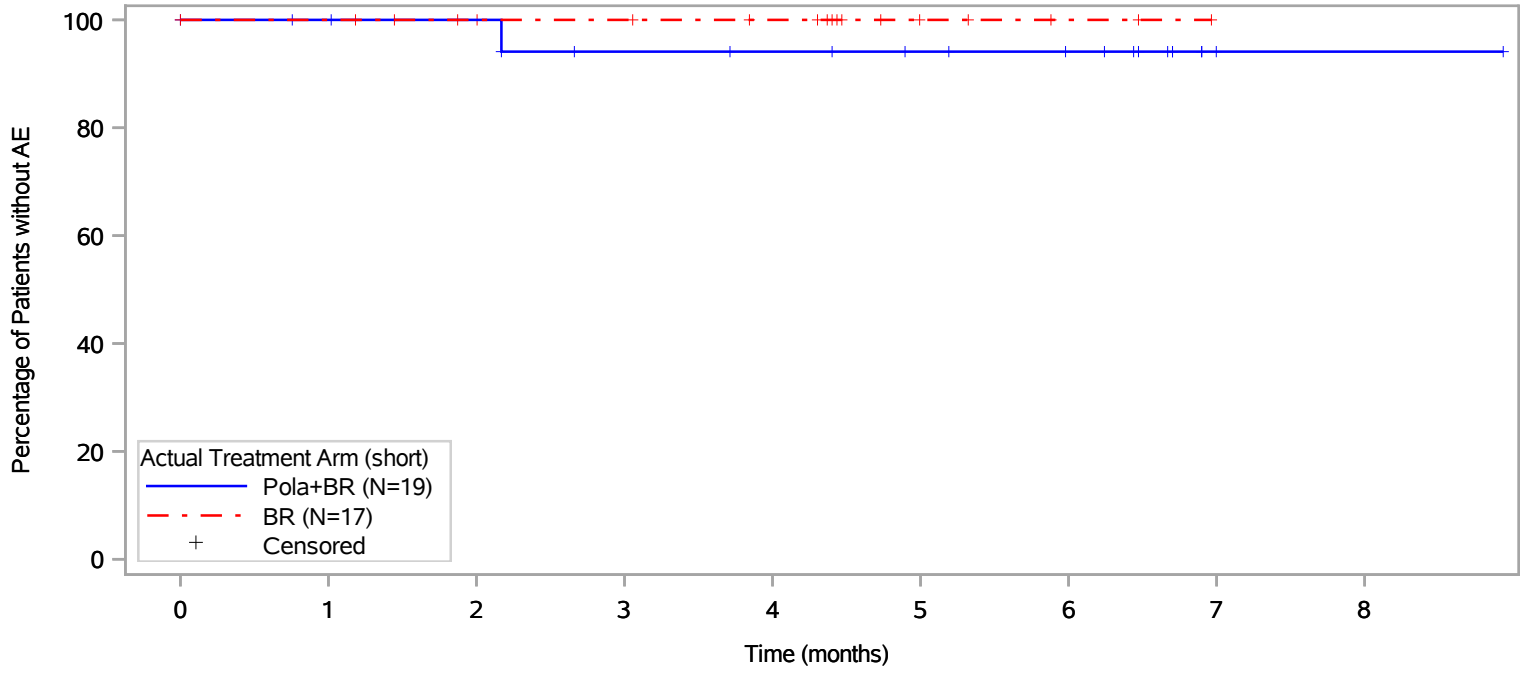
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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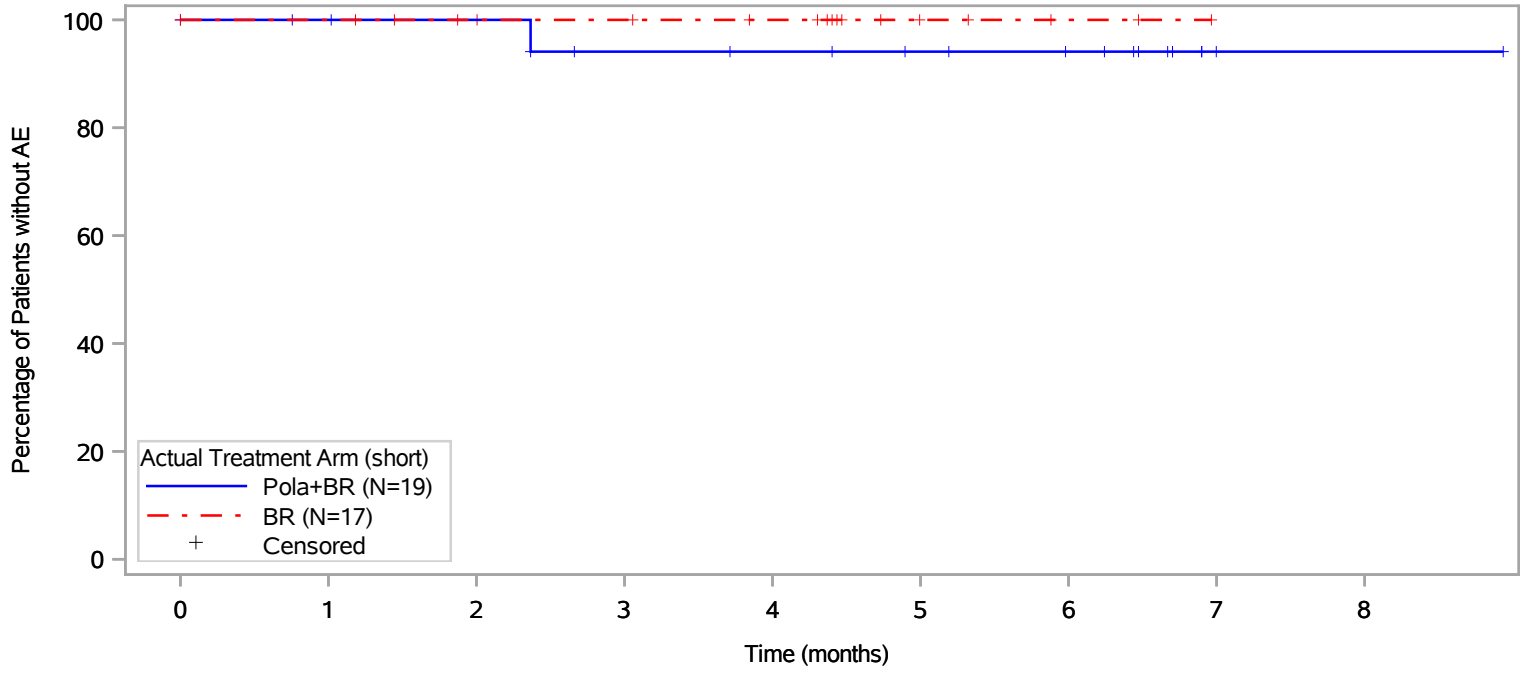
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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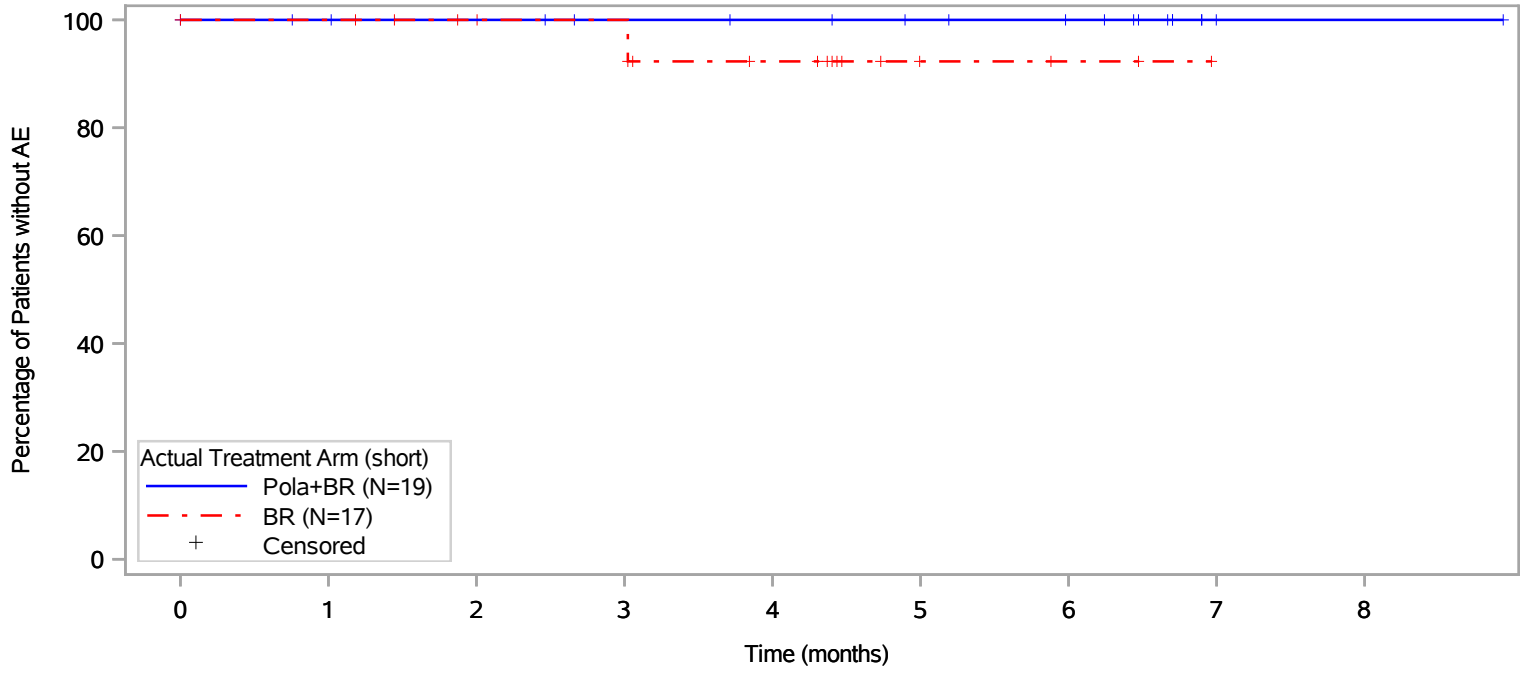
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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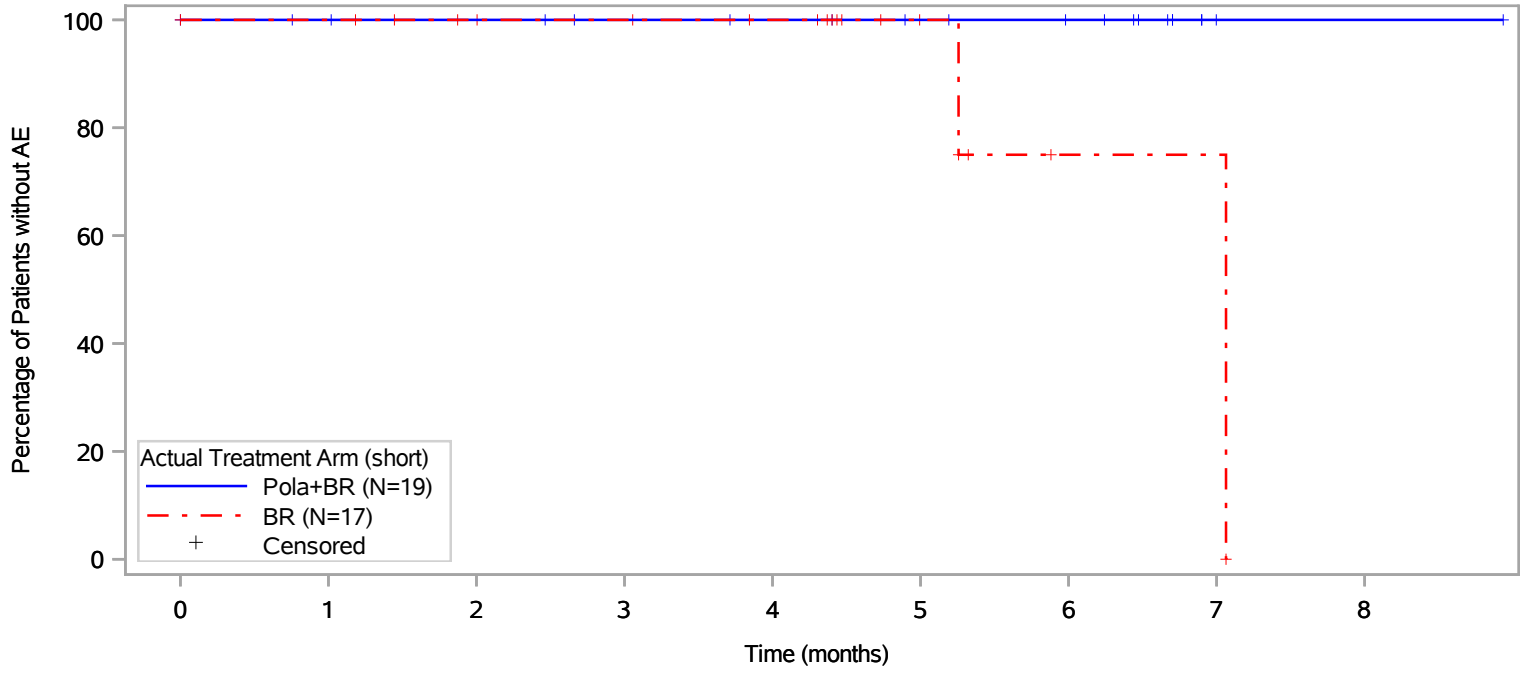
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	15	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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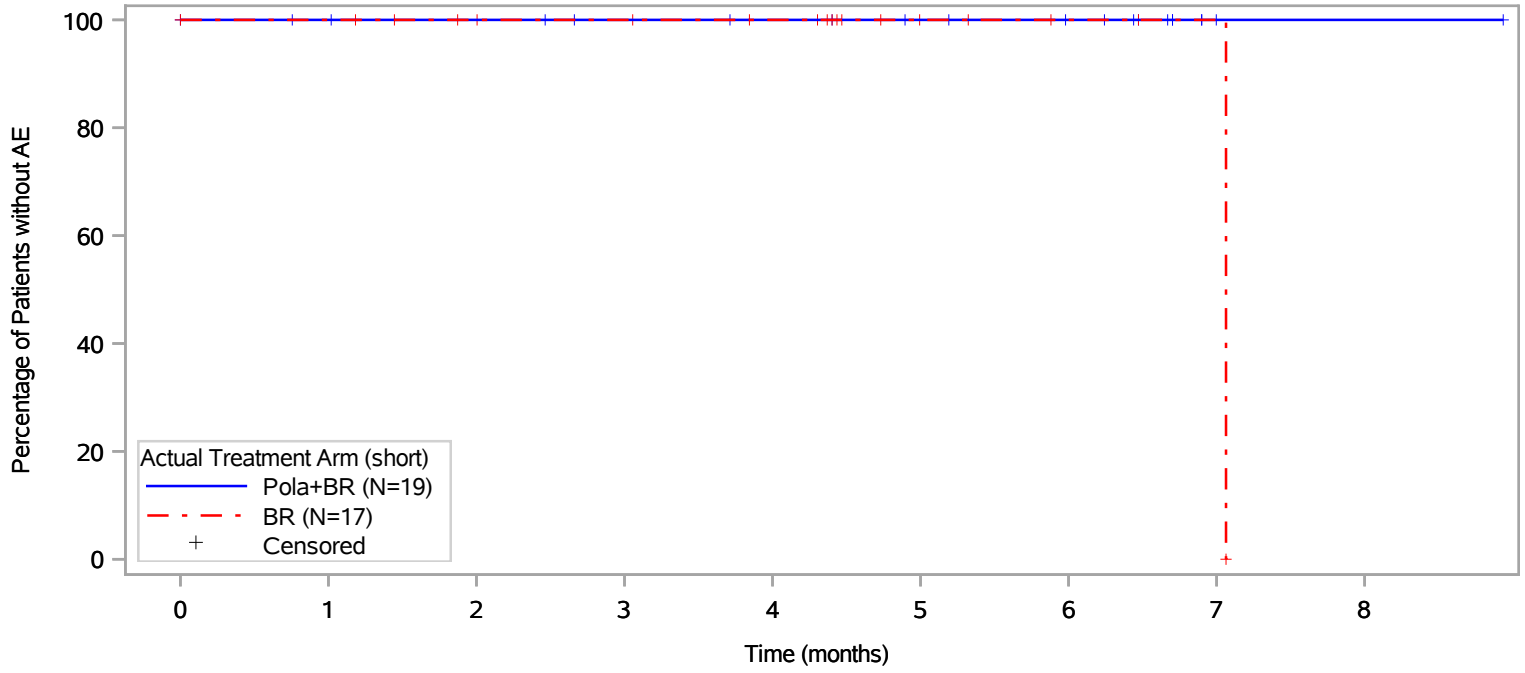
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), EPIGLOTTIC CANCER



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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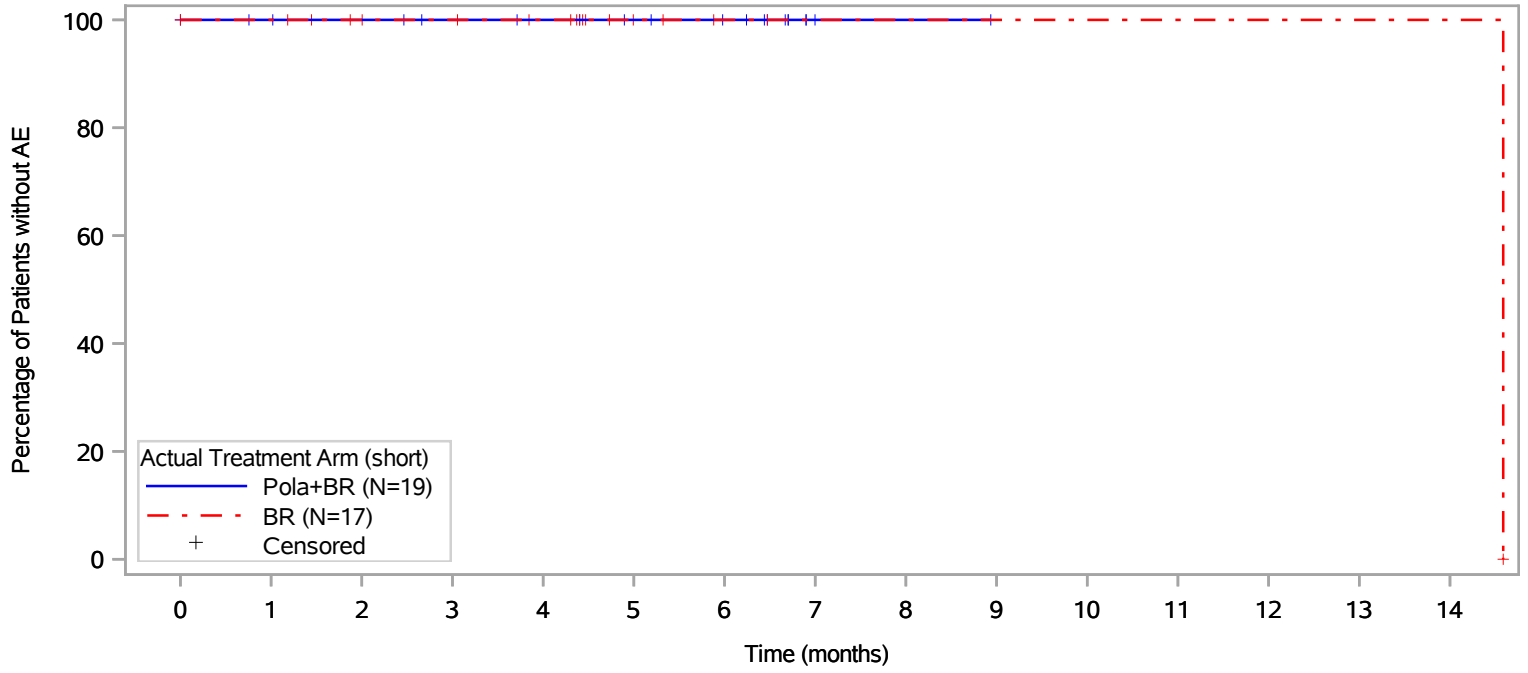
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



Patients at risk															
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1	NE	NE	NE	NE	NE	NE
BR (N=17)	17	17	14	13	11	4	2	1	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18	NE	NE	NE	NE	NE	NE
BR (N=17)	0	0	3	4	6	13	15	16	16	16	16	16	16	16	16

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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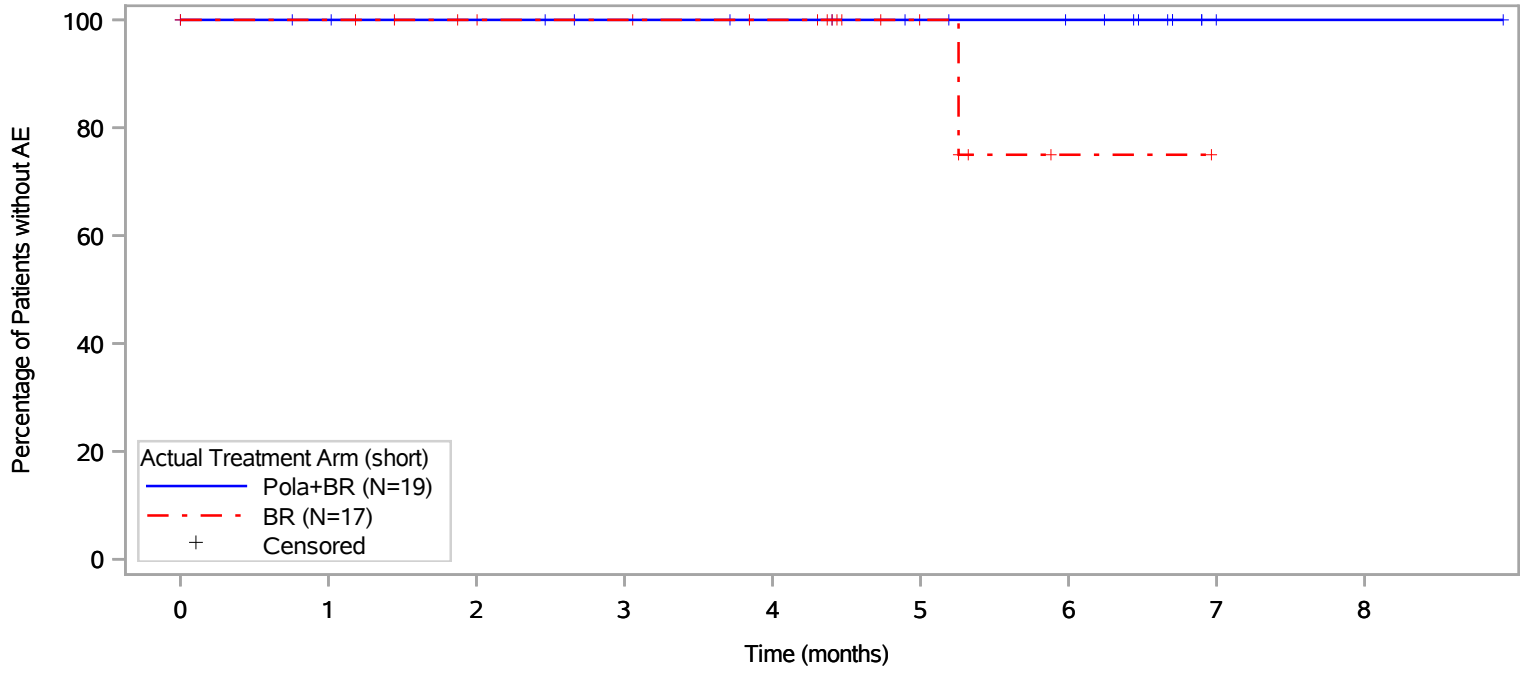
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), PAPILLARY THYROID CANCER

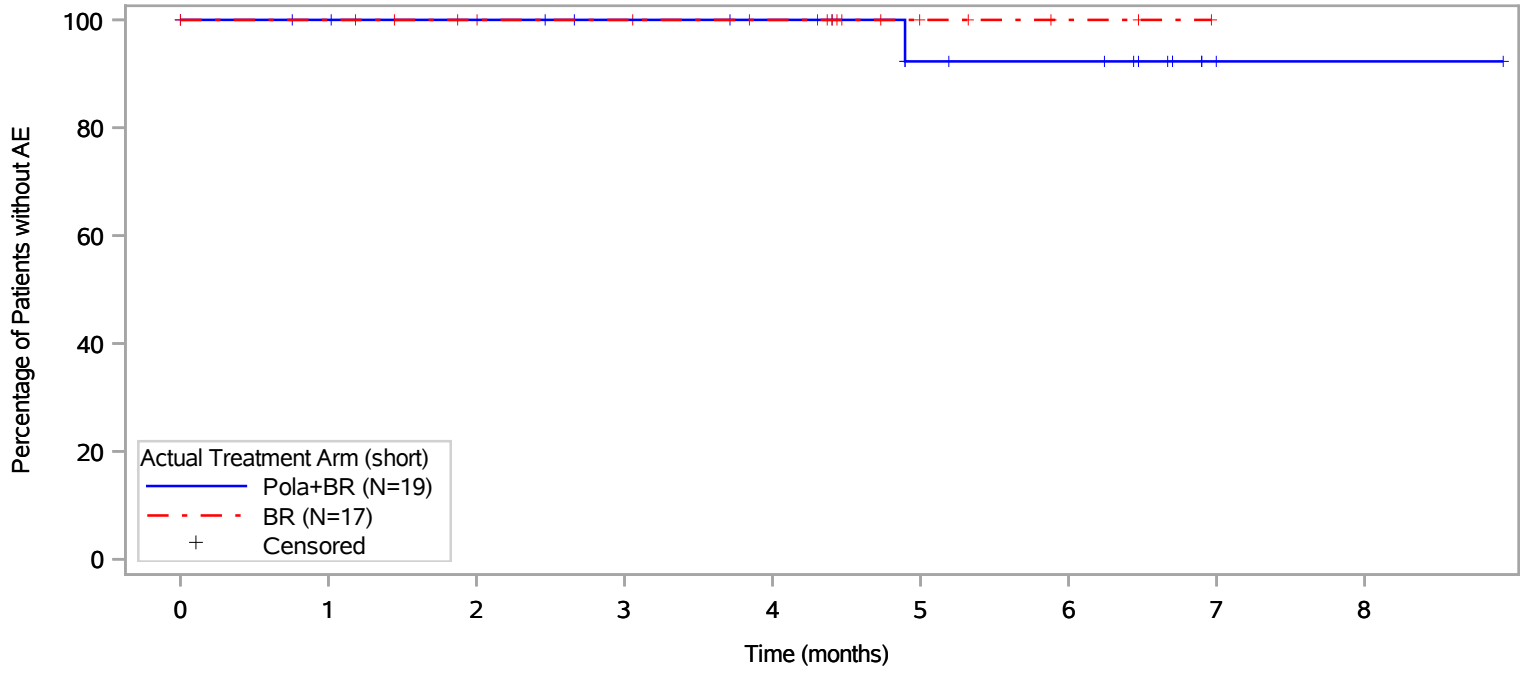


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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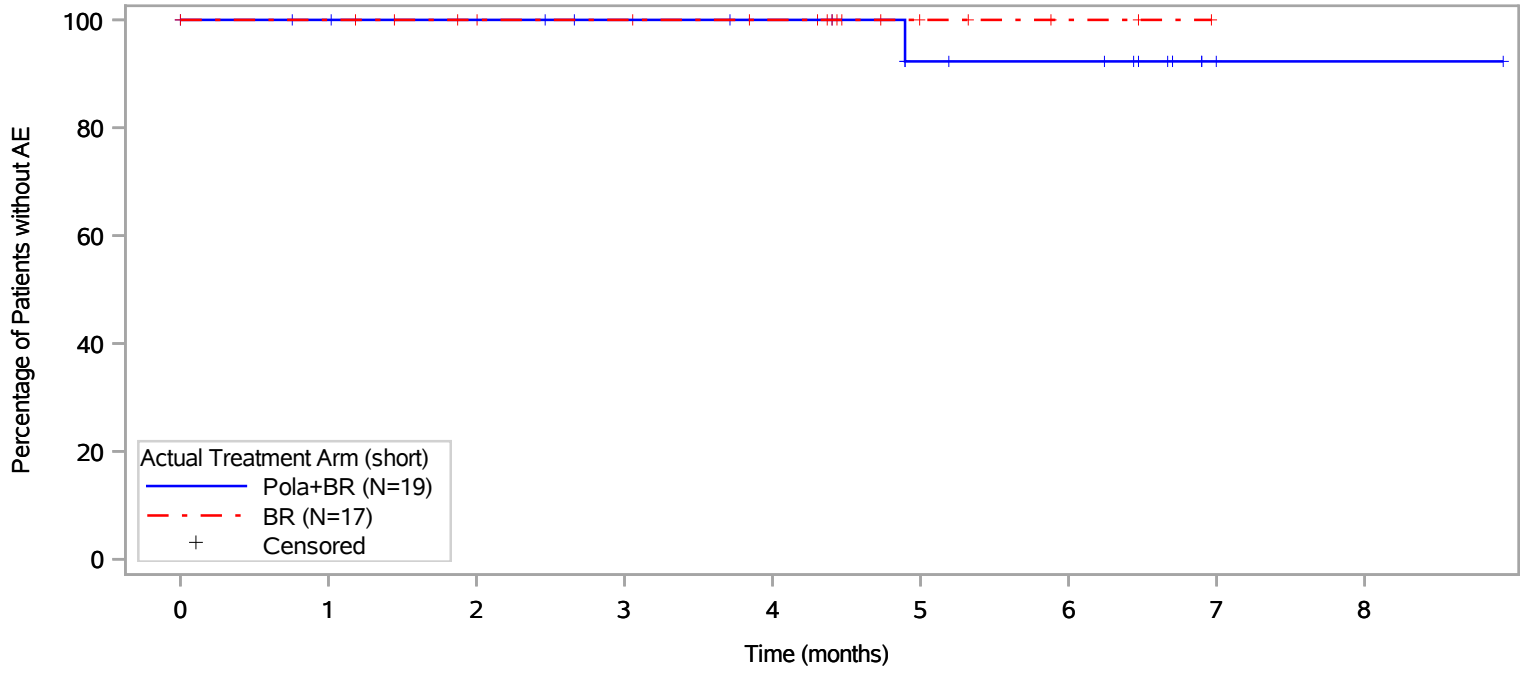
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, VOCAL CORD PARALYSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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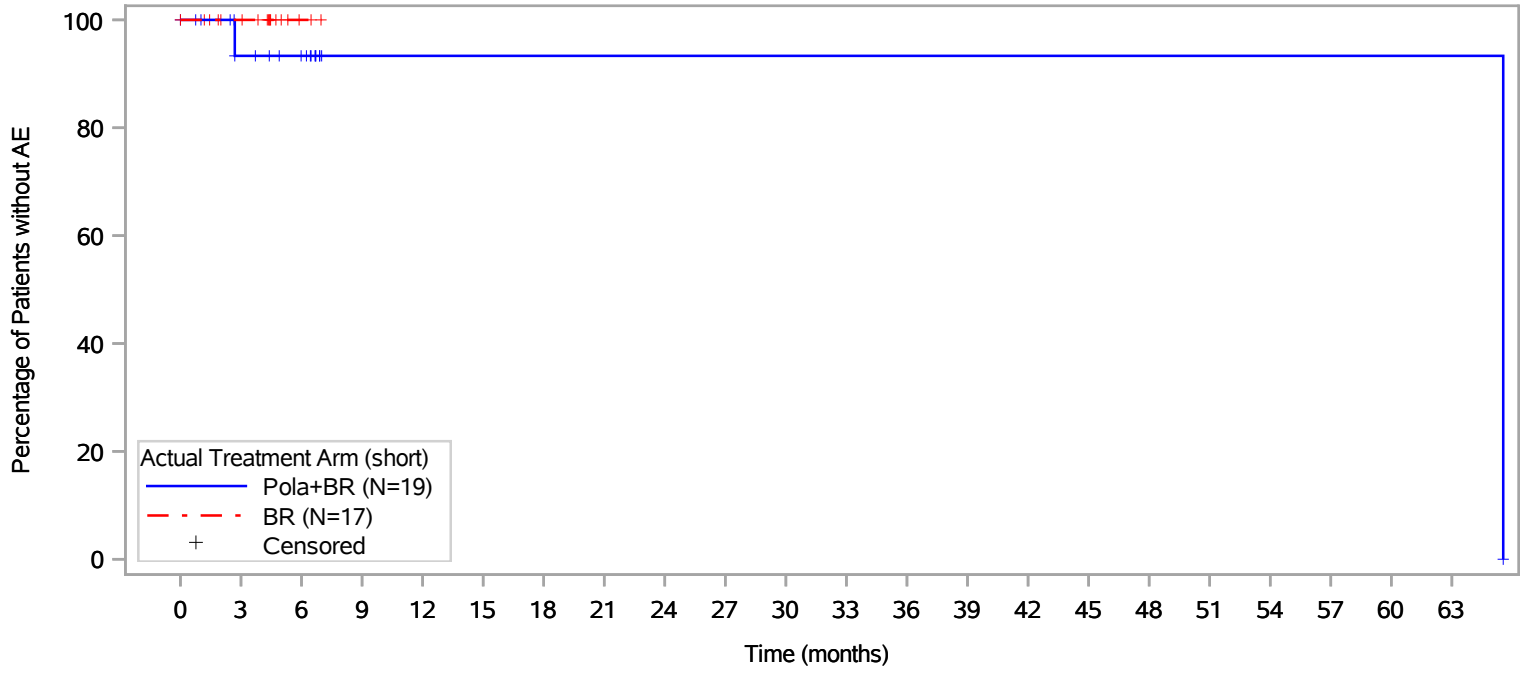
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk																							
Pola+BR (N=19)	19	14	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=17)	17	13	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=19)	0	4	8	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17
BR (N=17)	0	4	15	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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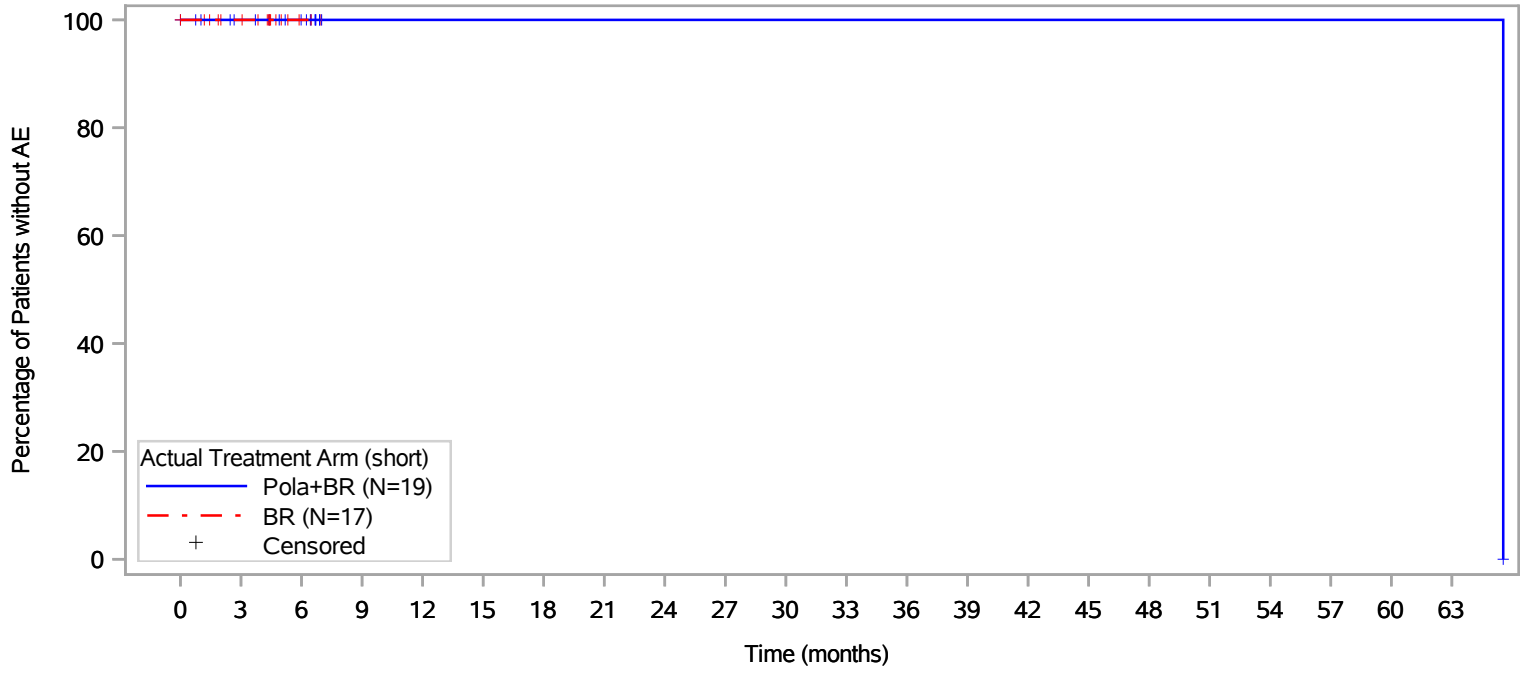
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

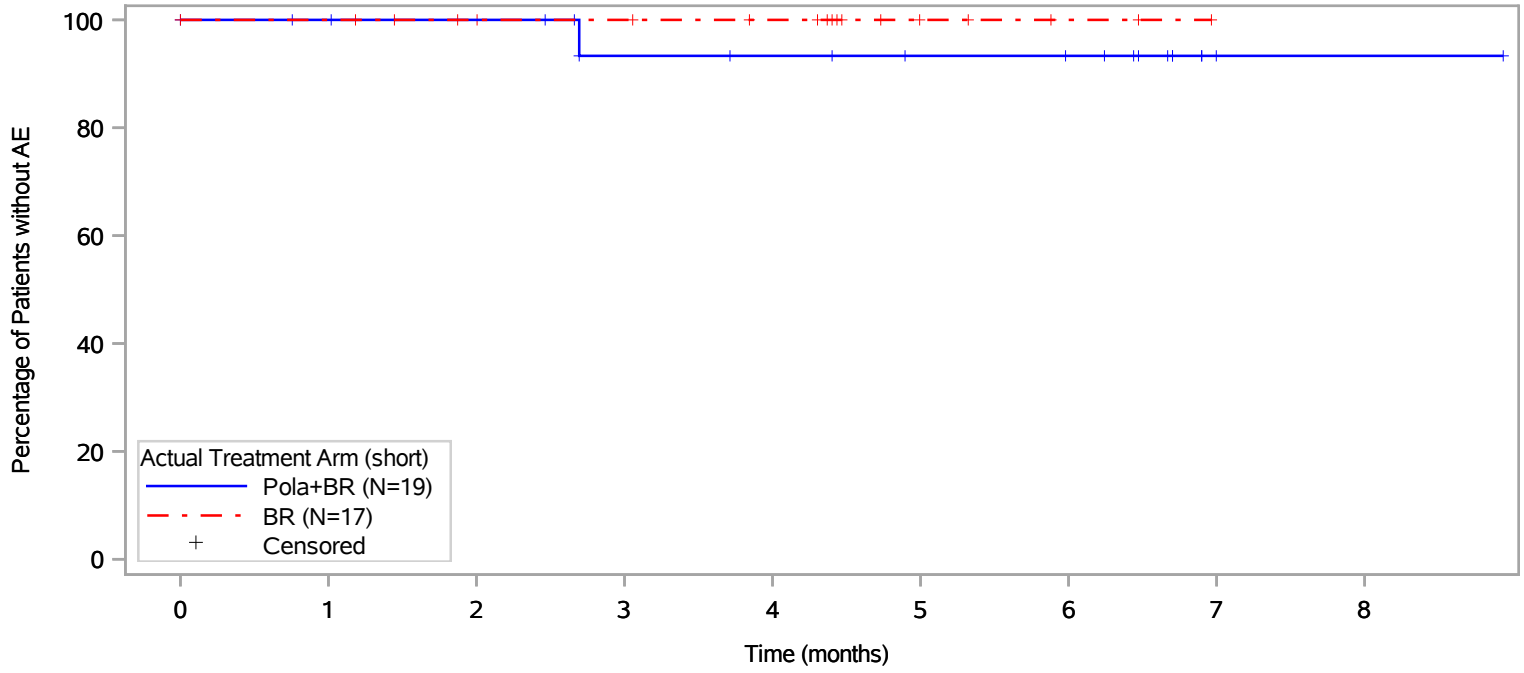
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk																							
Pola+BR (N=19)	19	15	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=17)	17	13	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=19)	0	4	9	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18
BR (N=17)	0	4	15	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

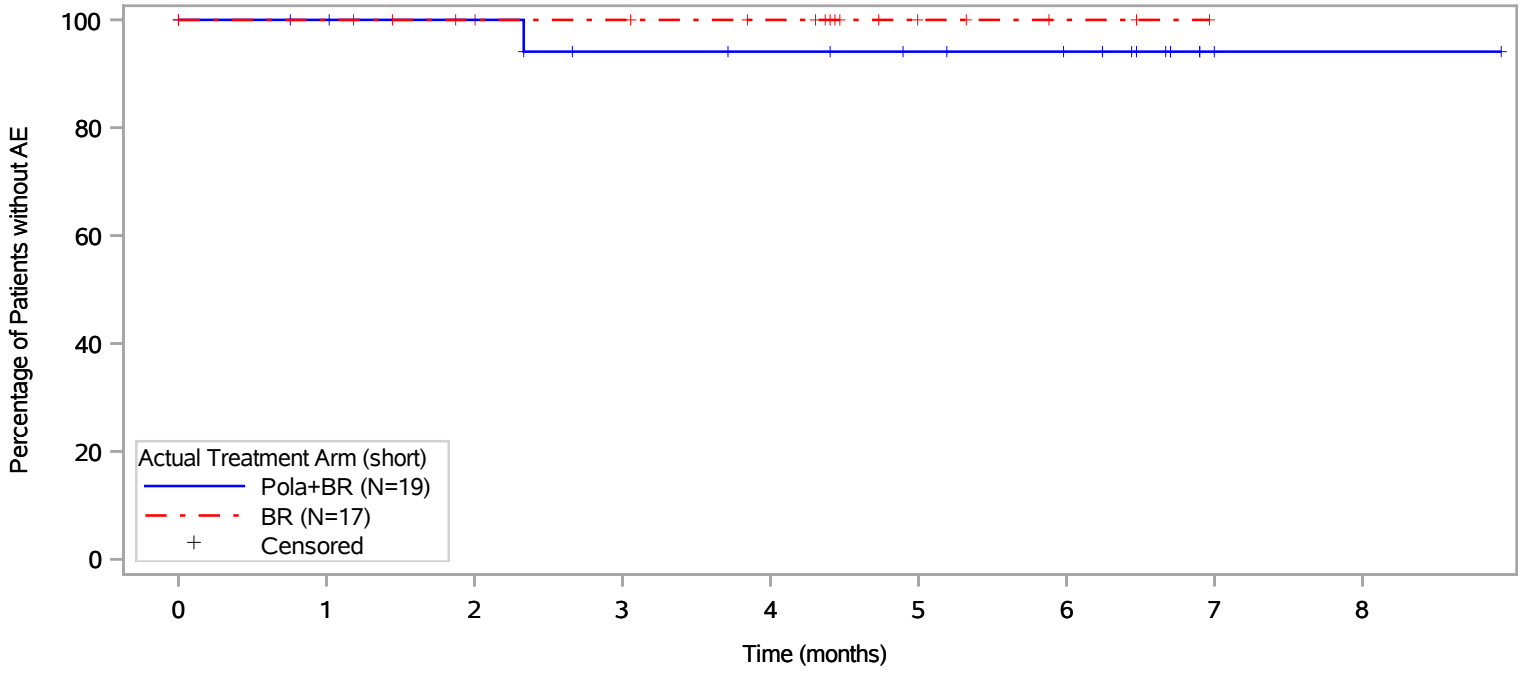
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	14	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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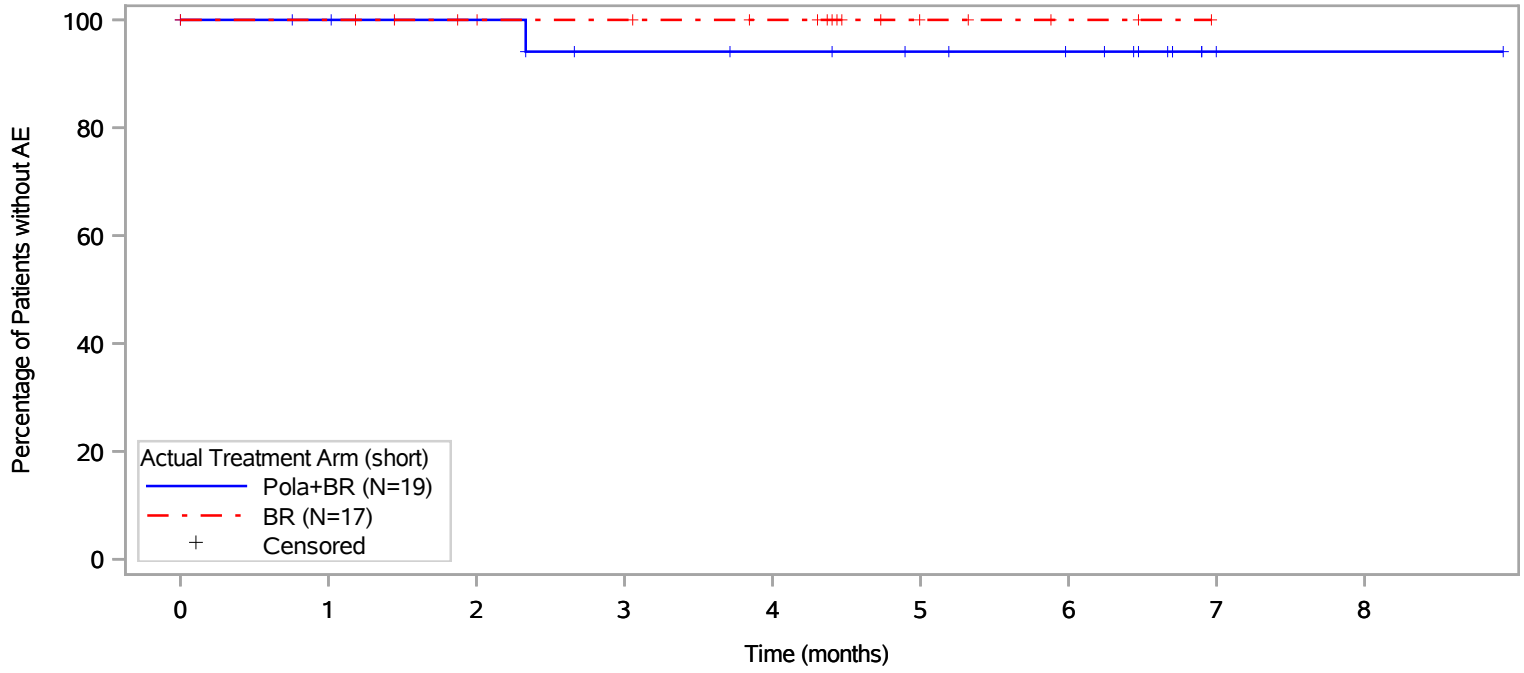
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



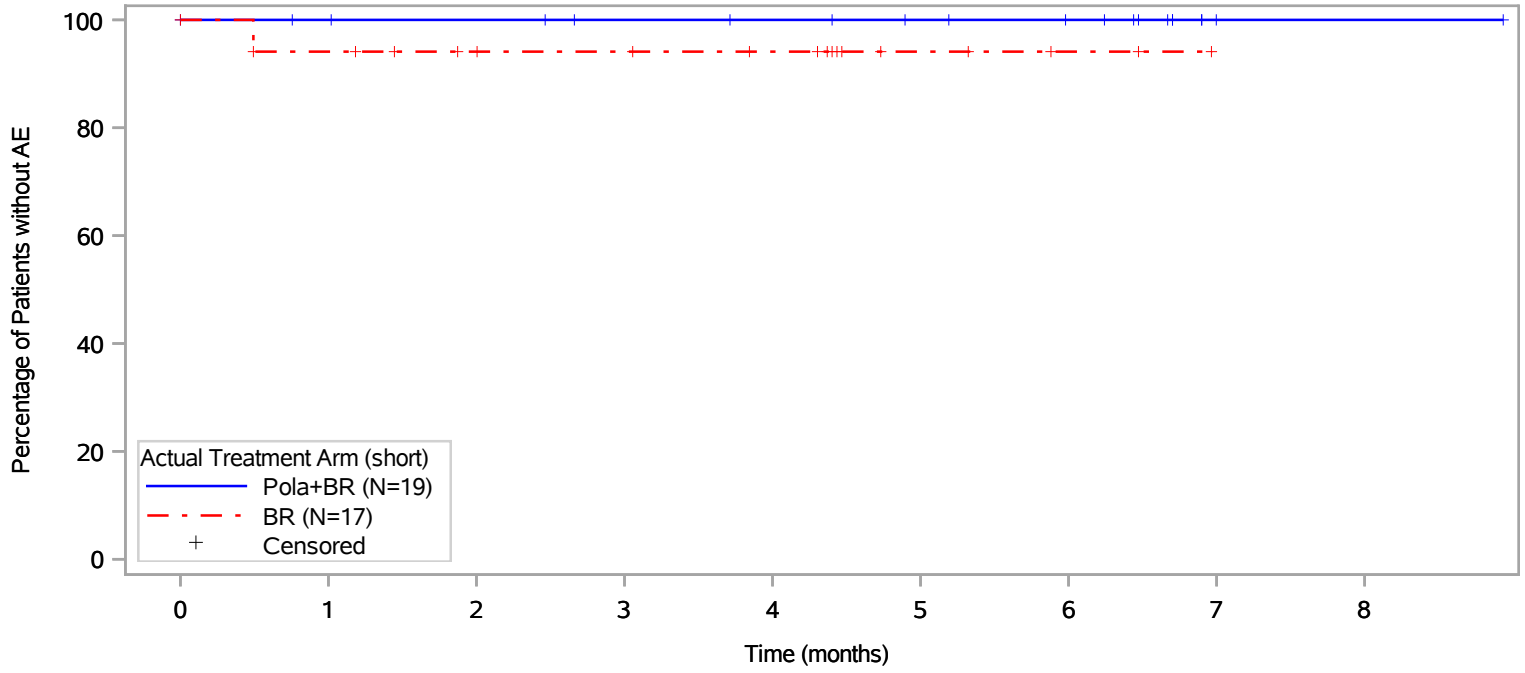
Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All

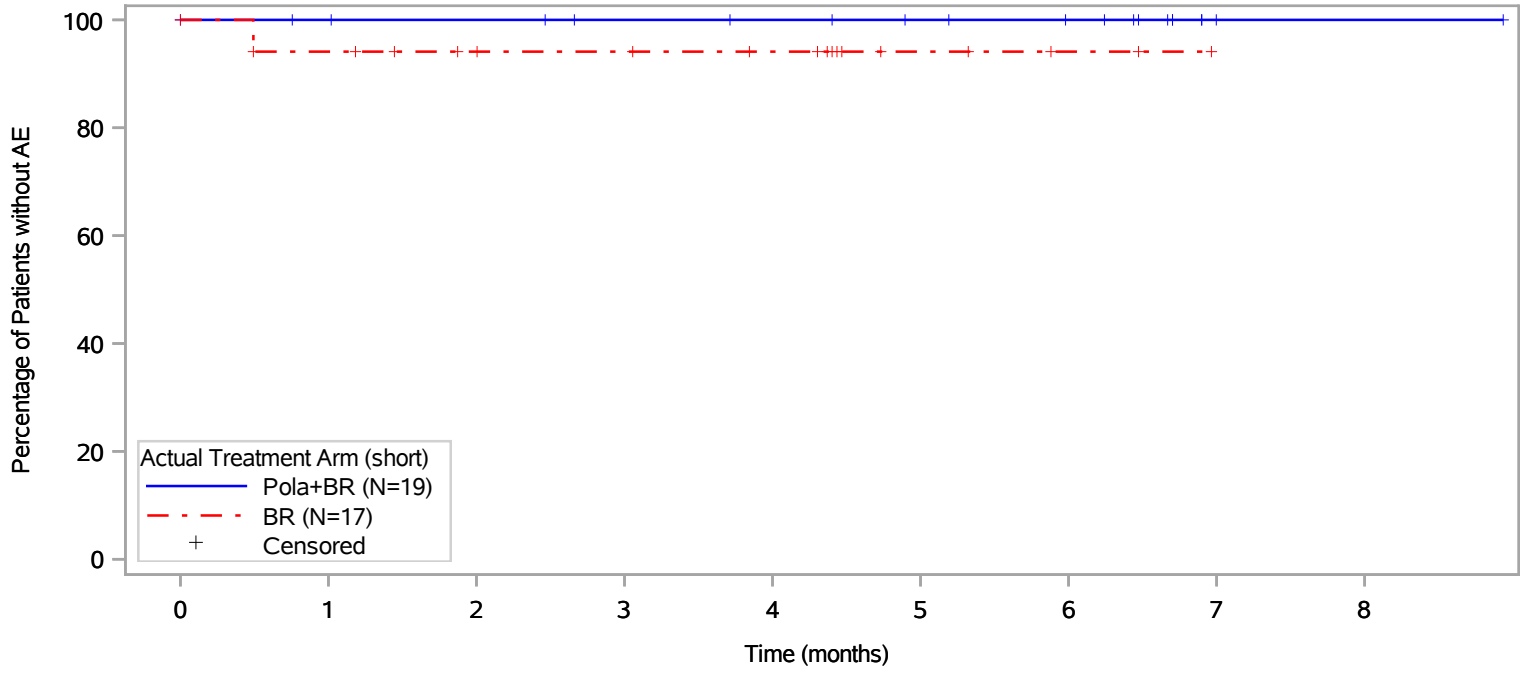


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

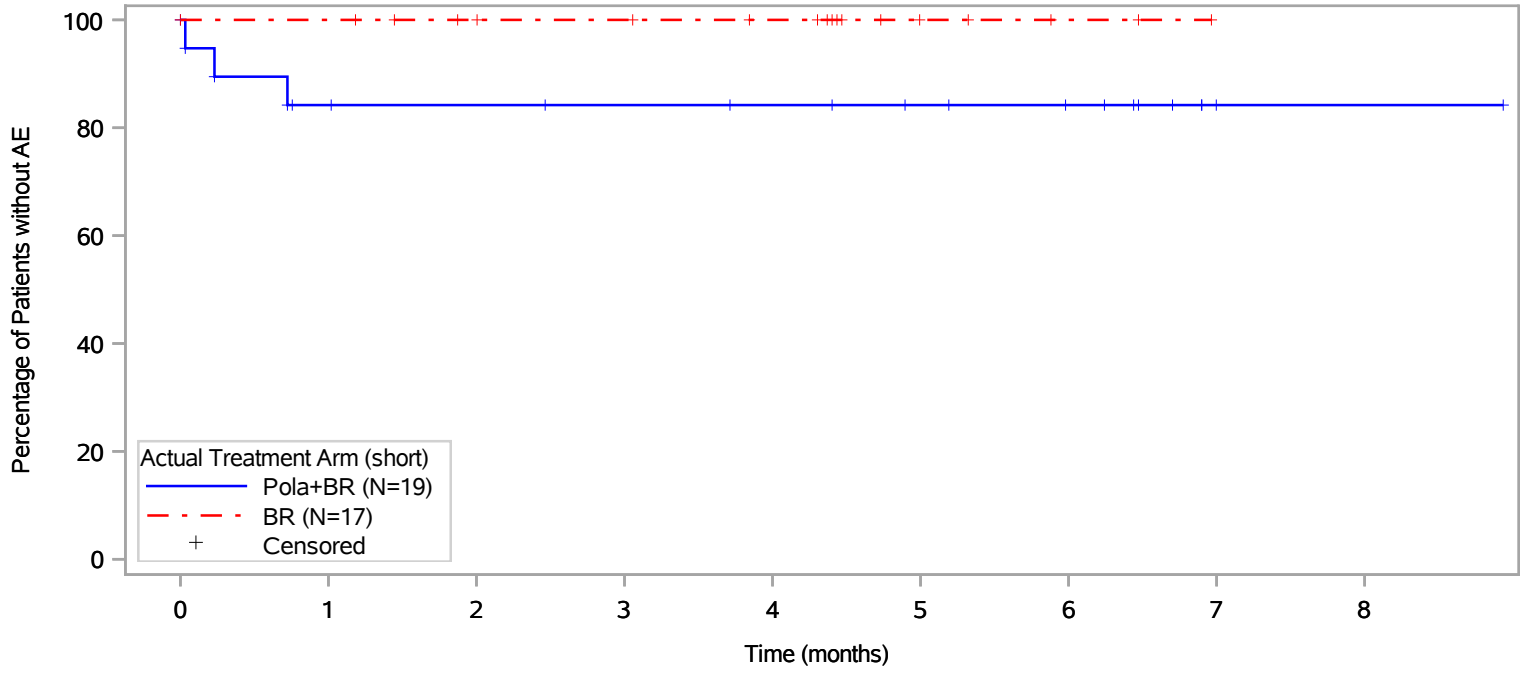
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	15	14	13	12	10	8	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	15	15
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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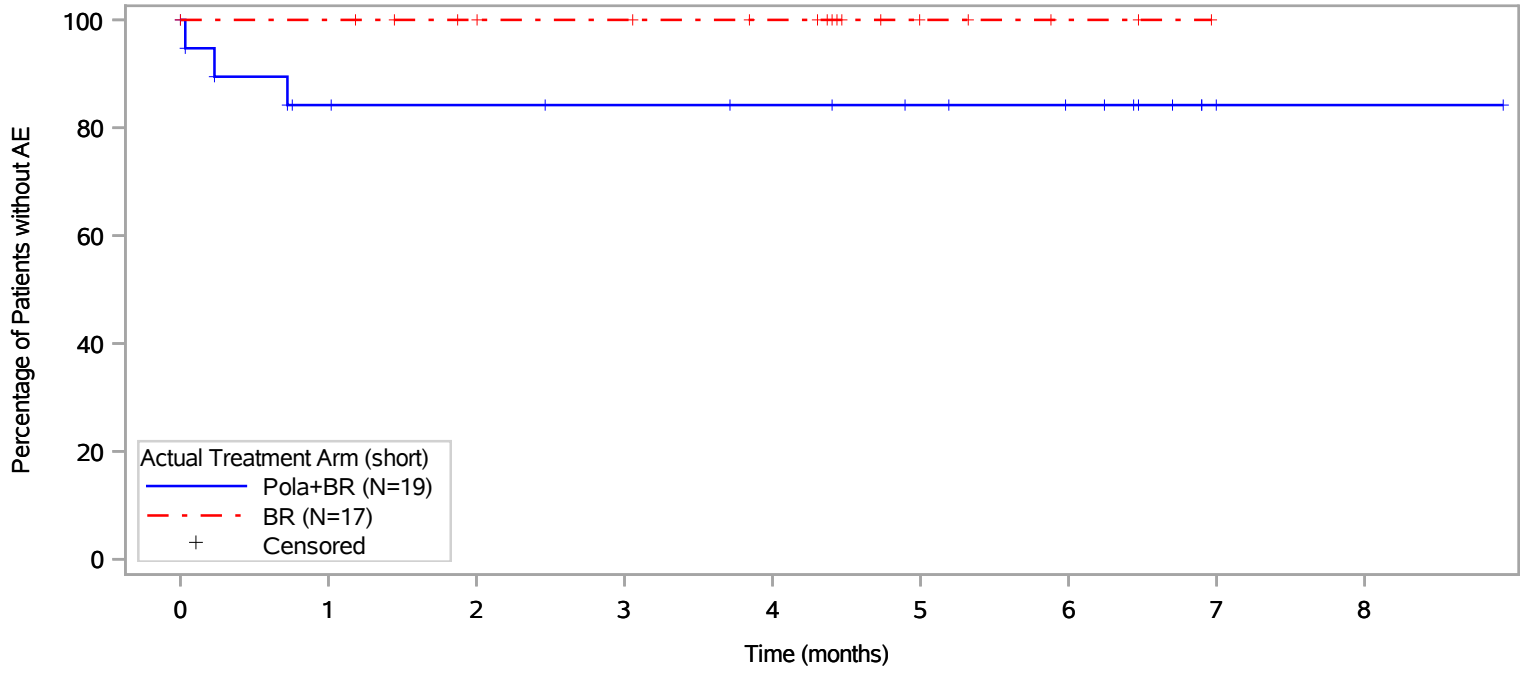
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION



Patients at risk									
Pola+BR (N=19)	19	15	14	13	12	10	8	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	15	15
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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02DEC2022 3:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	6	31.6	13	68.4	17	100.0	6	35.3	11	64.7	0.8047	1.07	0.34	3.37		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2673	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		19	100.0	3	15.8	16	84.2	17	100.0	4	23.5	13	76.5	0.5187	0.79	0.17	3.58		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		19	100.0	2	10.5	17	89.5	17	100.0	3	17.6	14	82.4	0.4609	0.56	0.09	3.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.6934	1.54	0.14	17.07		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2528	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1803	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1892	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4643	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	11	57.9	4	36.4	7	63.6	15	88.2	6	40.0	9	60.0	0.7896	1.09	0.30	3.89		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	4	26.7	11	73.3	0.9296	1.14	0.25	5.16		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	3	20.0	12	80.0	0.3096	0.38	0.04	3.74		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.3919	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3404	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3404	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.3919	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.3919	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.2568	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.2568	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 21:19

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	8	42.1	4	50.0	4	50.0	14	82.4	6	42.9	8	57.1	0.6319	1.98	0.52	7.53		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4364	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	4	28.6	10	71.4	0.9425	1.14	0.20	6.46		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	3	21.4	11	78.6	0.5528	0.57	0.06	5.53		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4262	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4262	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4262	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.xls
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	2	66.7	1	33.3	0.2220	0.25	0.02	2.79		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	14	73.7	5	35.7	9	64.3	14	82.4	4	28.6	10	71.4	0.7660	1.90	0.50	7.29		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2733	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.5151	0.41	0.03	6.62		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	3	21.4	11	78.6	0.6326	1.06	0.17	6.52		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	2	14.3	12	85.7	0.8287	0.97	0.13	7.19		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.6774	1.61	0.15	17.95		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1672	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1786	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.xls
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	4	28.6	10	71.4	8	47.1	4	50.0	4	50.0	0.2859	0.79	0.18	3.43		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	2	40.0	3	60.0	9	52.9	2	22.2	7	77.8	0.4595	1.46	0.19	11.18		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1380	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	3	37.5	5	62.5	0.0444	0.30	0.03	2.92		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	5	26.3	2	40.0	3	60.0	9	52.9	1	11.1	8	88.9	0.2361	2.78	0.23	33.66		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	14	73.7	2	14.3	12	85.7	8	47.1	2	25.0	6	75.0	0.4423	0.54	0.06	5.01		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	14	73.7	2	14.3	12	85.7	8	47.1	1	12.5	7	87.5	0.8868	0.60	0.05	7.73		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.3043	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	14	73.7	2	14.3	12	85.7	8	47.1	0	-	8	100.0	0.3312	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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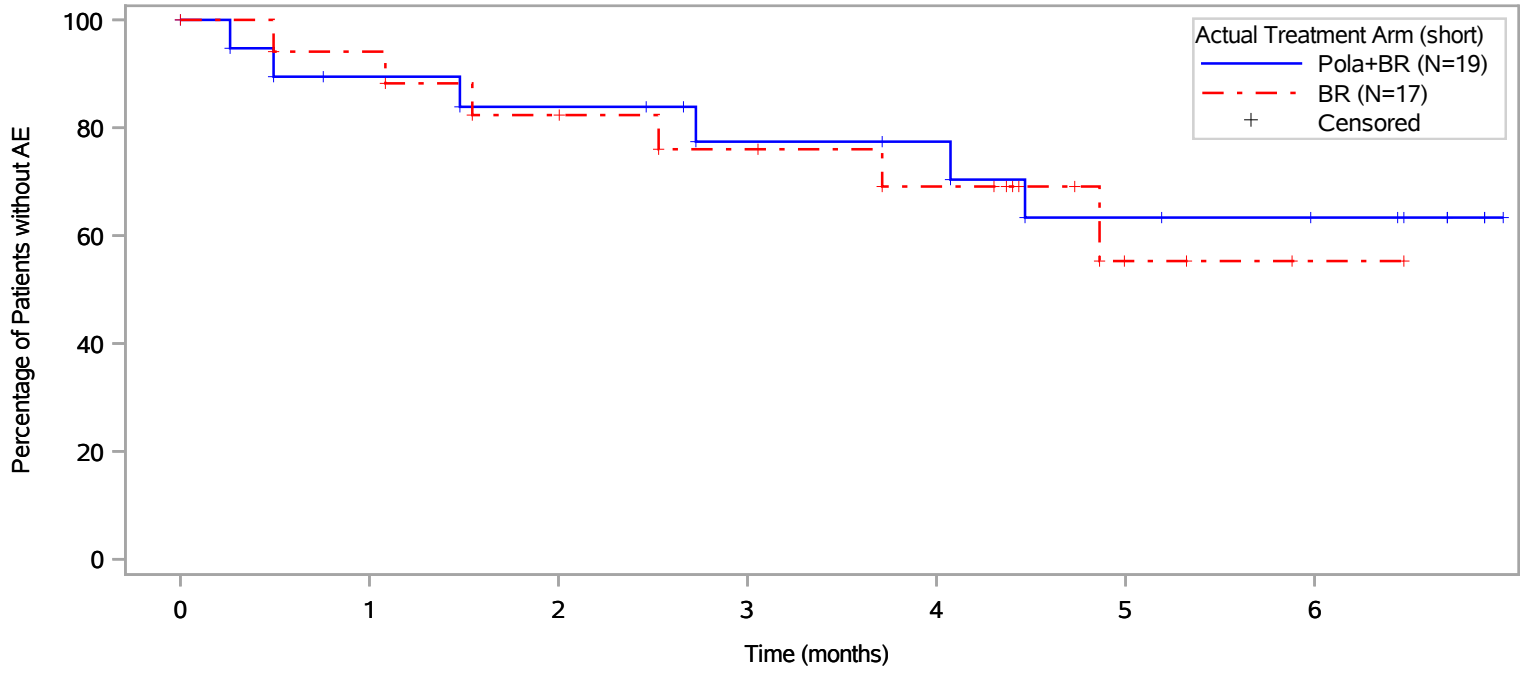
30NOV2022 21:19

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	16	15	12	11	9	7
BR (N=17)	17	16	14	12	10	3	1
Patients censored							
Pola+BR (N=19)	0	1	1	3	4	4	6
BR (N=17)	0	0	0	1	2	8	10

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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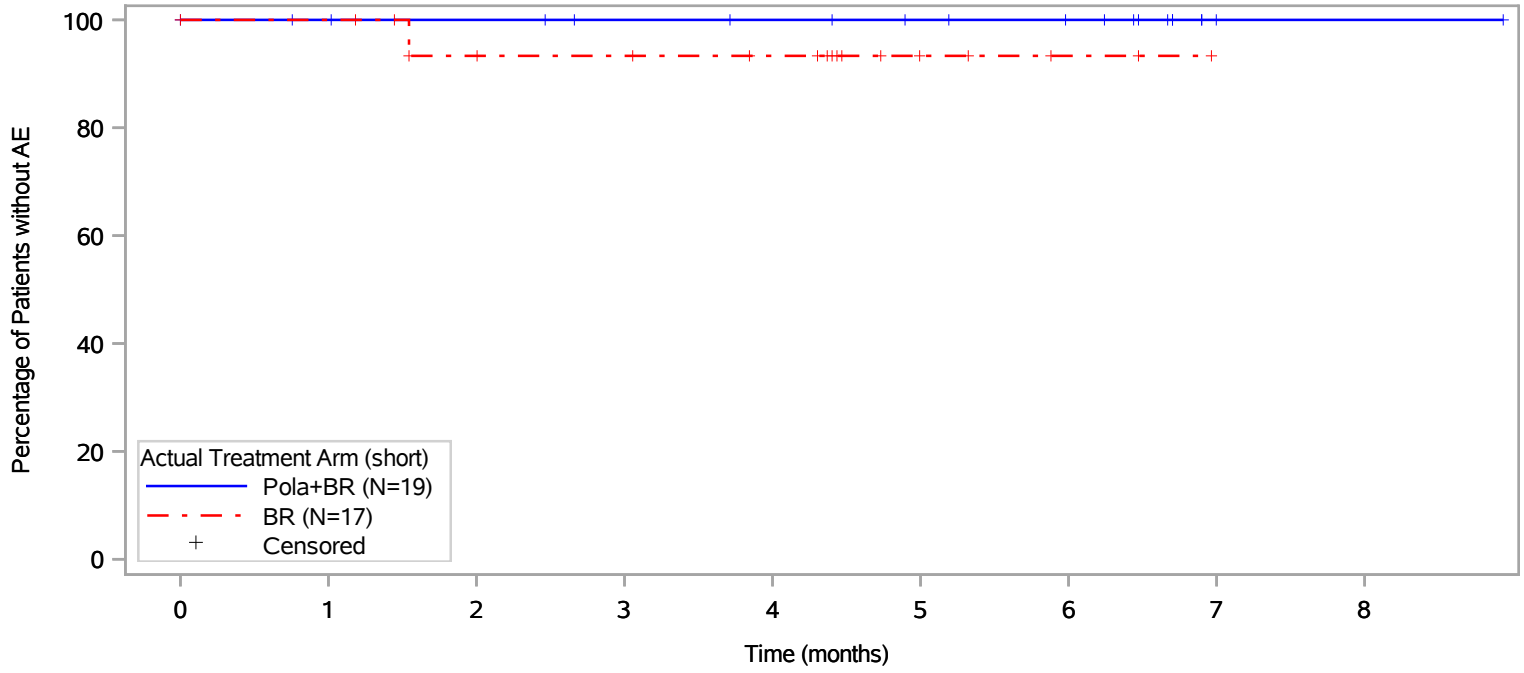
02DEC2022 4:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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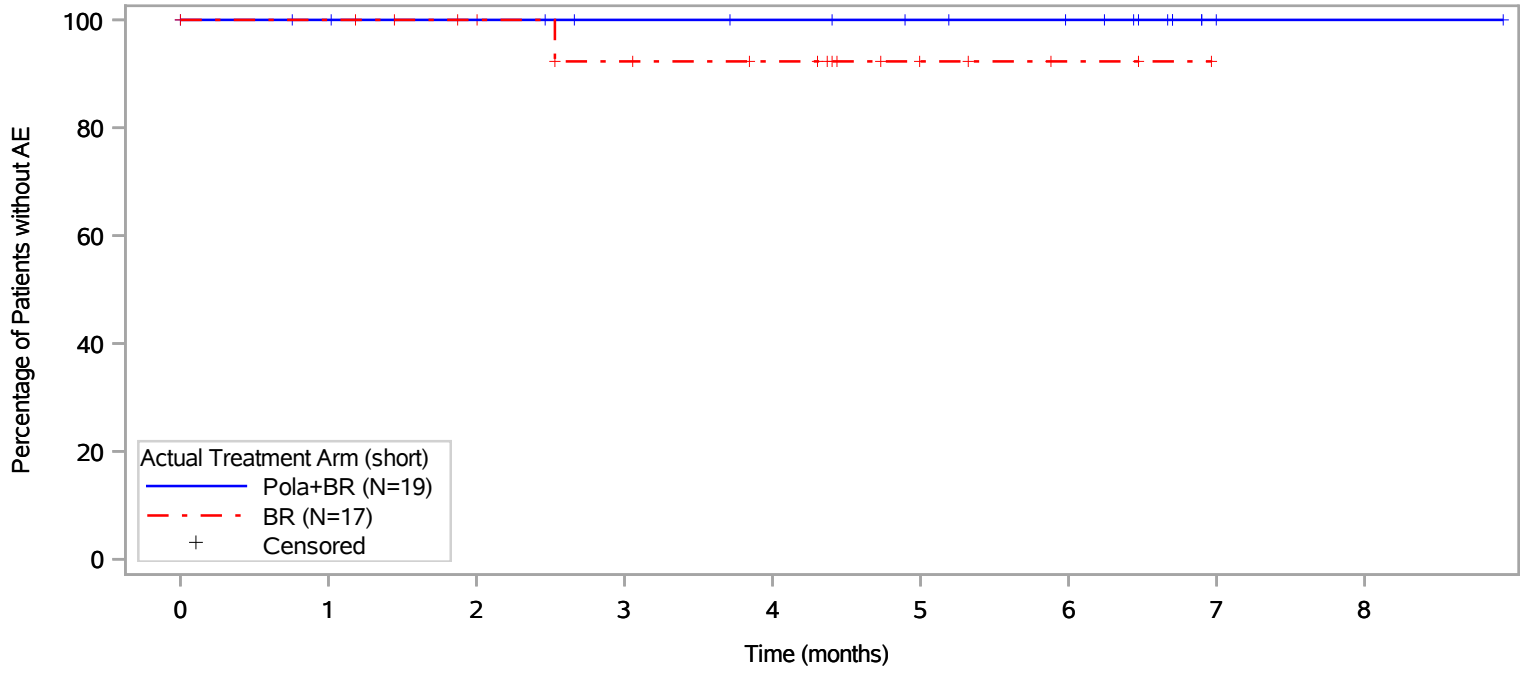
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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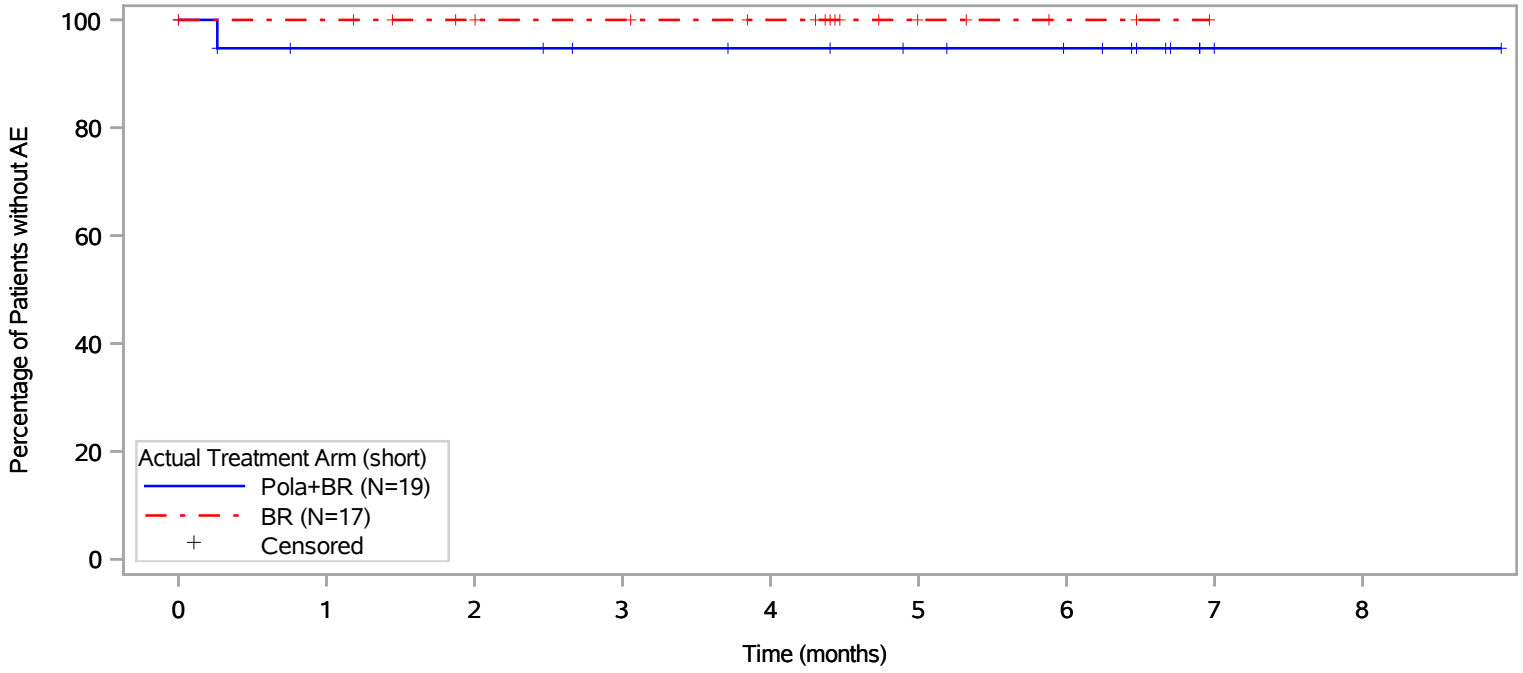
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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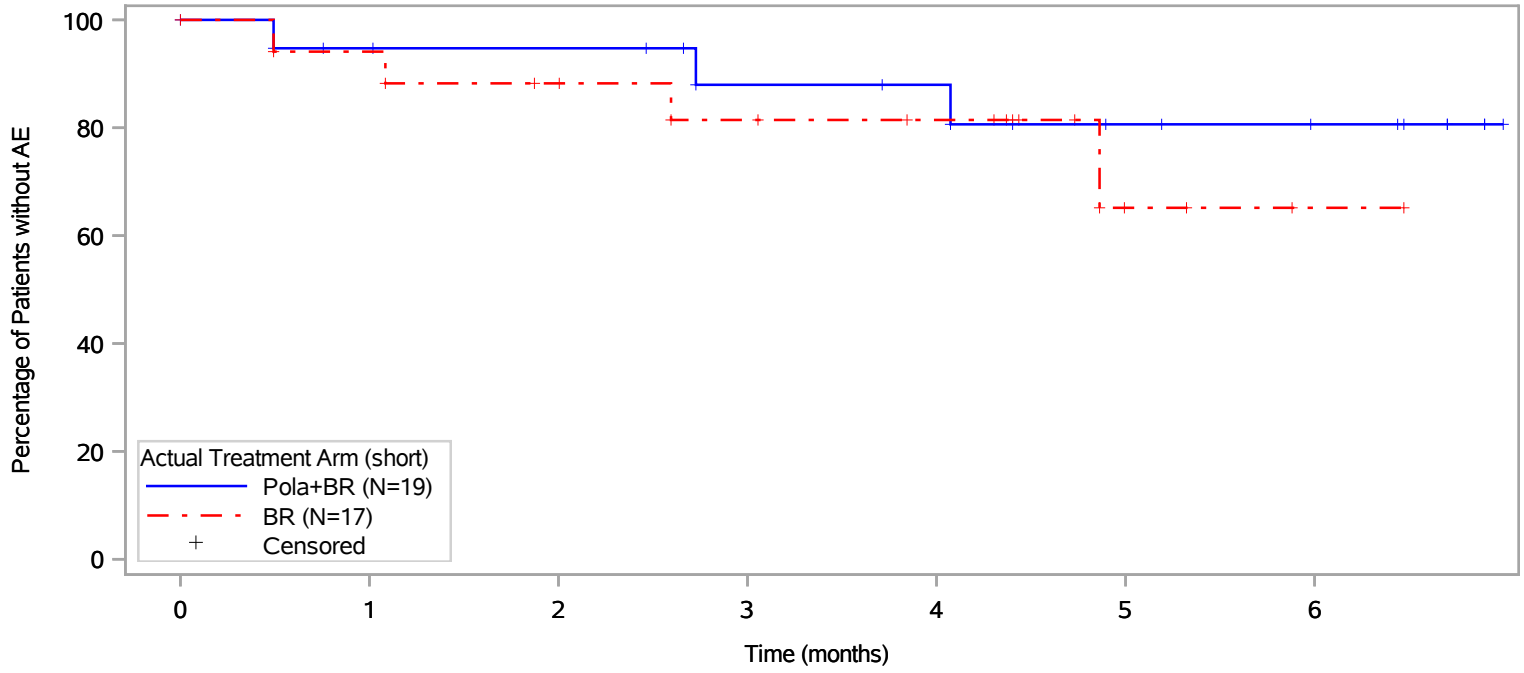
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk							
Pola+BR (N=19)	19	17	16	13	12	9	7
BR (N=17)	17	16	14	12	10	3	1
Patients censored							
Pola+BR (N=19)	0	1	2	4	5	7	9
BR (N=17)	0	0	1	2	4	10	12

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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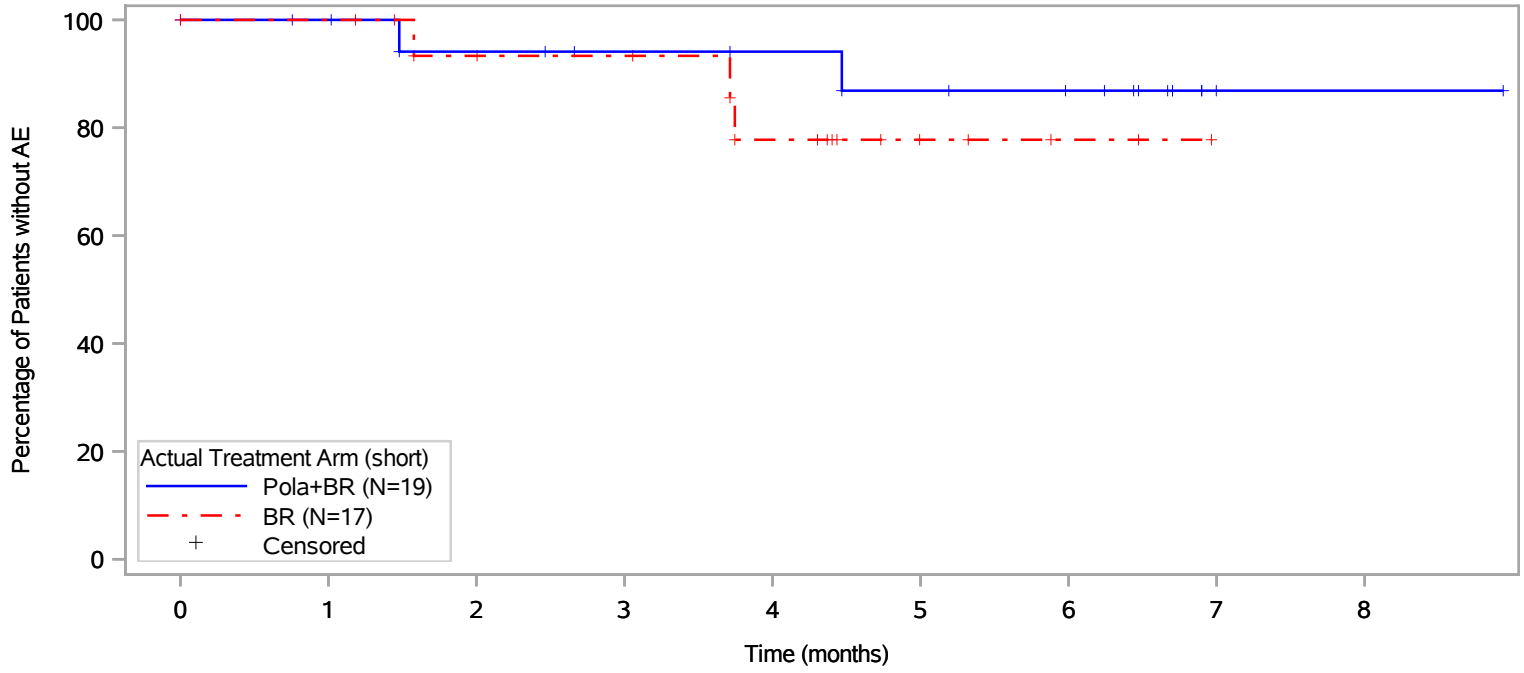
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	12	10	1	1
BR (N=17)	17	17	14	13	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	5	7	16	16
BR (N=17)	0	0	2	3	4	10	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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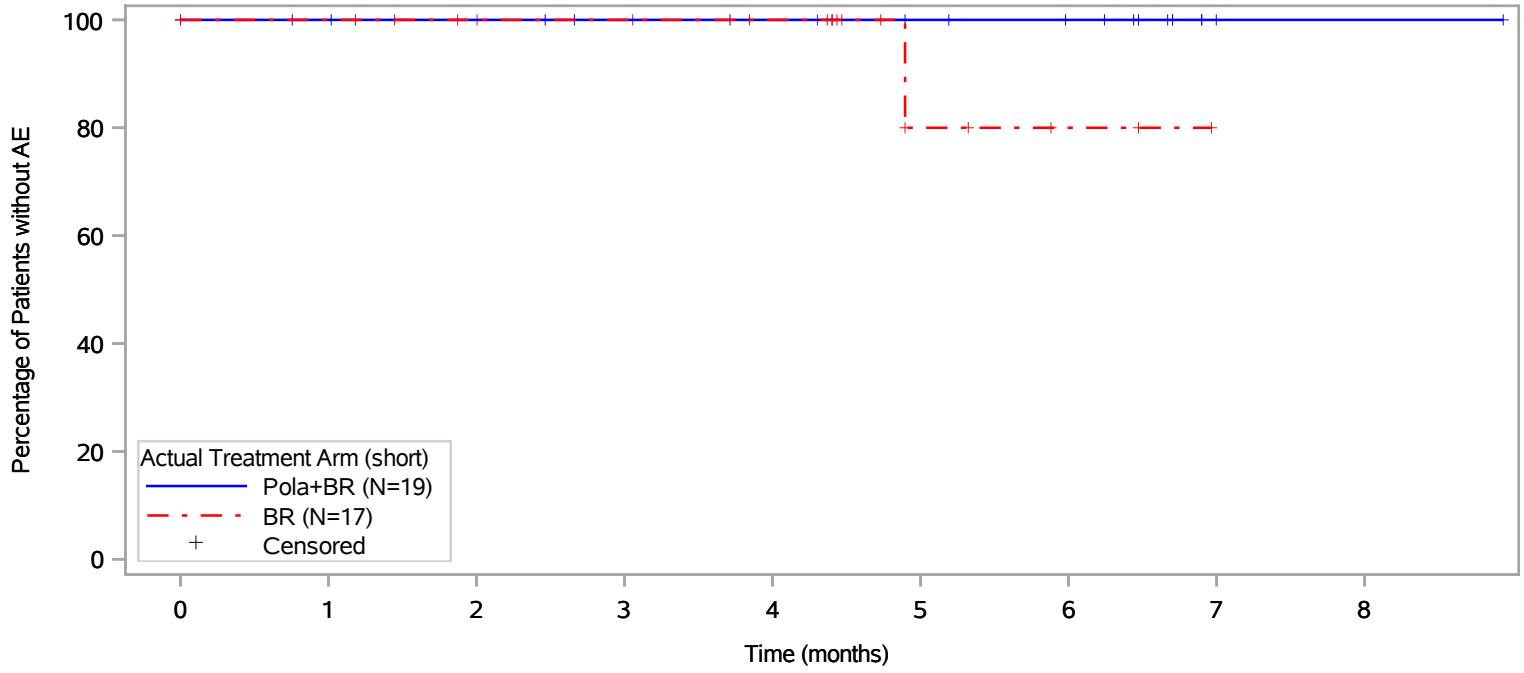
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All

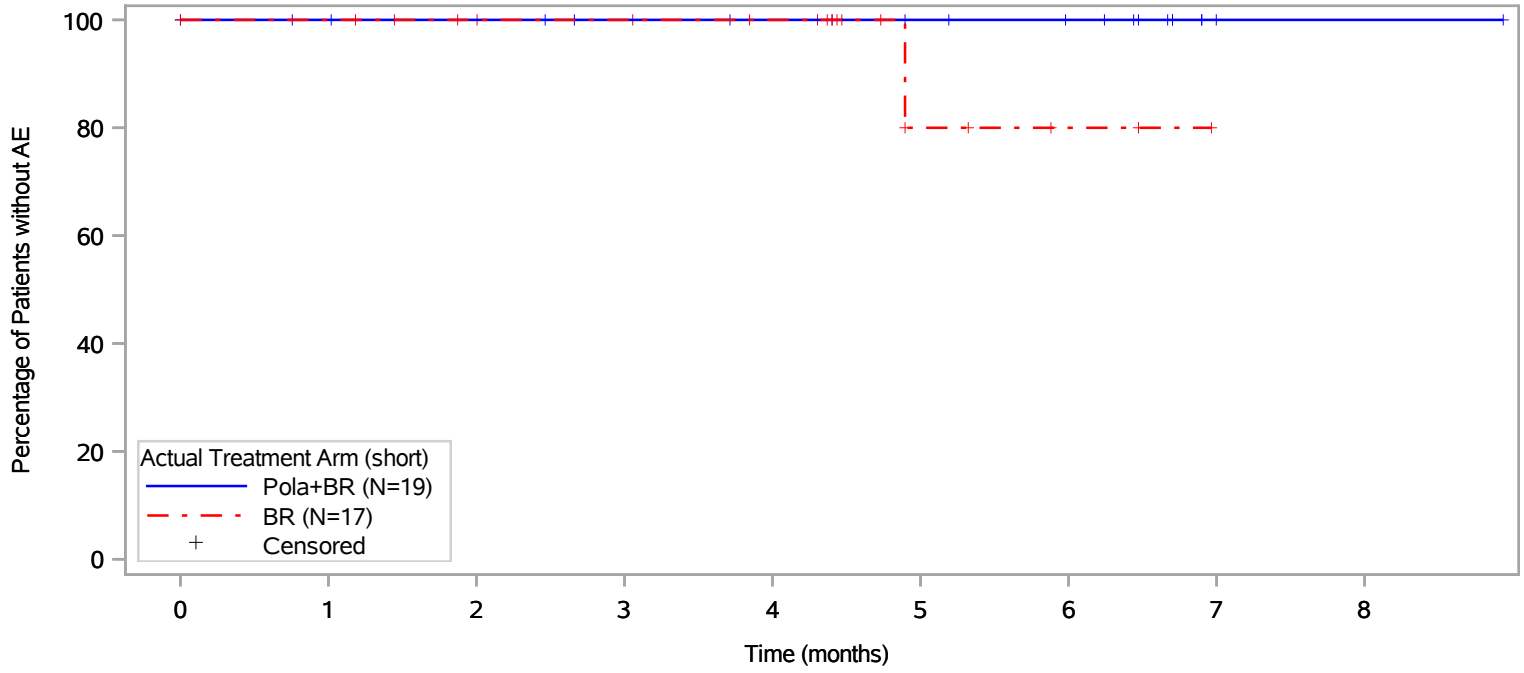


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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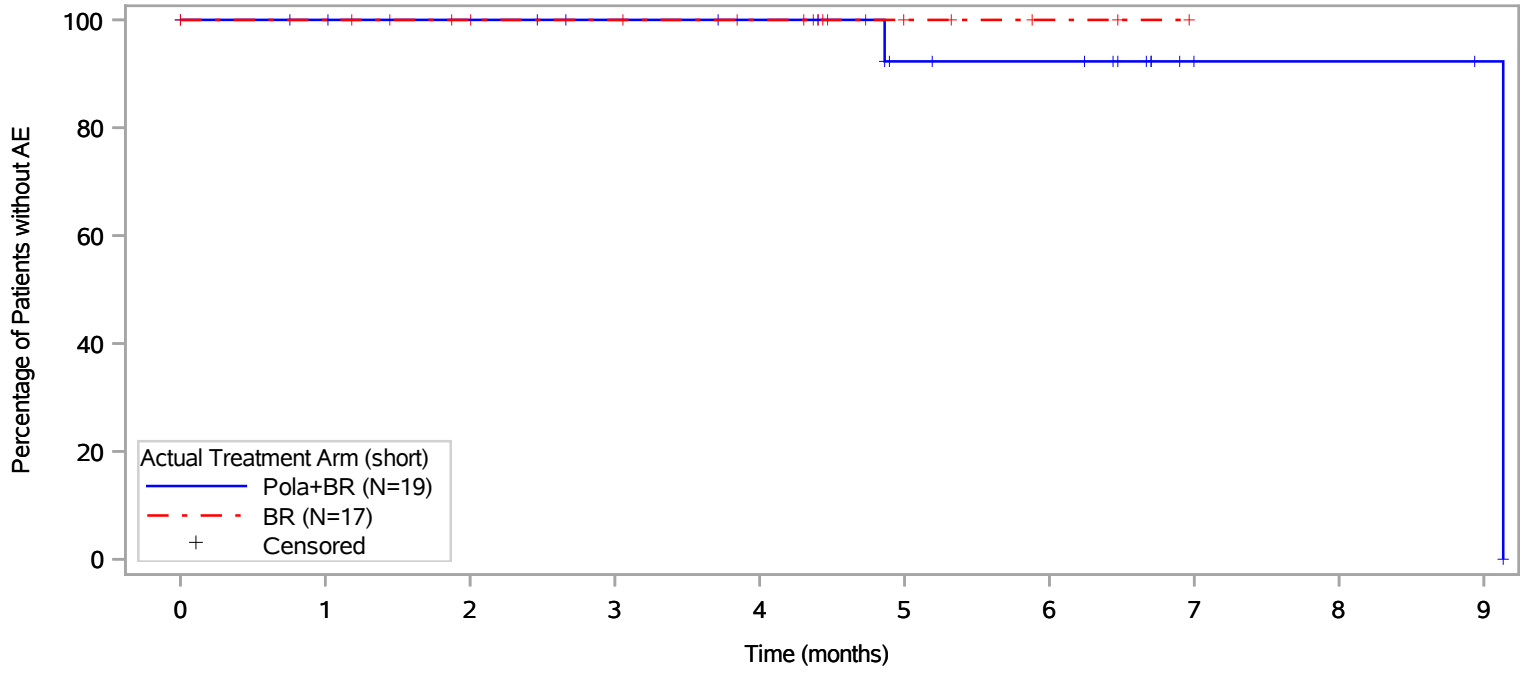
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk										
Pola+BR (N=19)	19	18	17	15	14	11	10	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	8	16	16	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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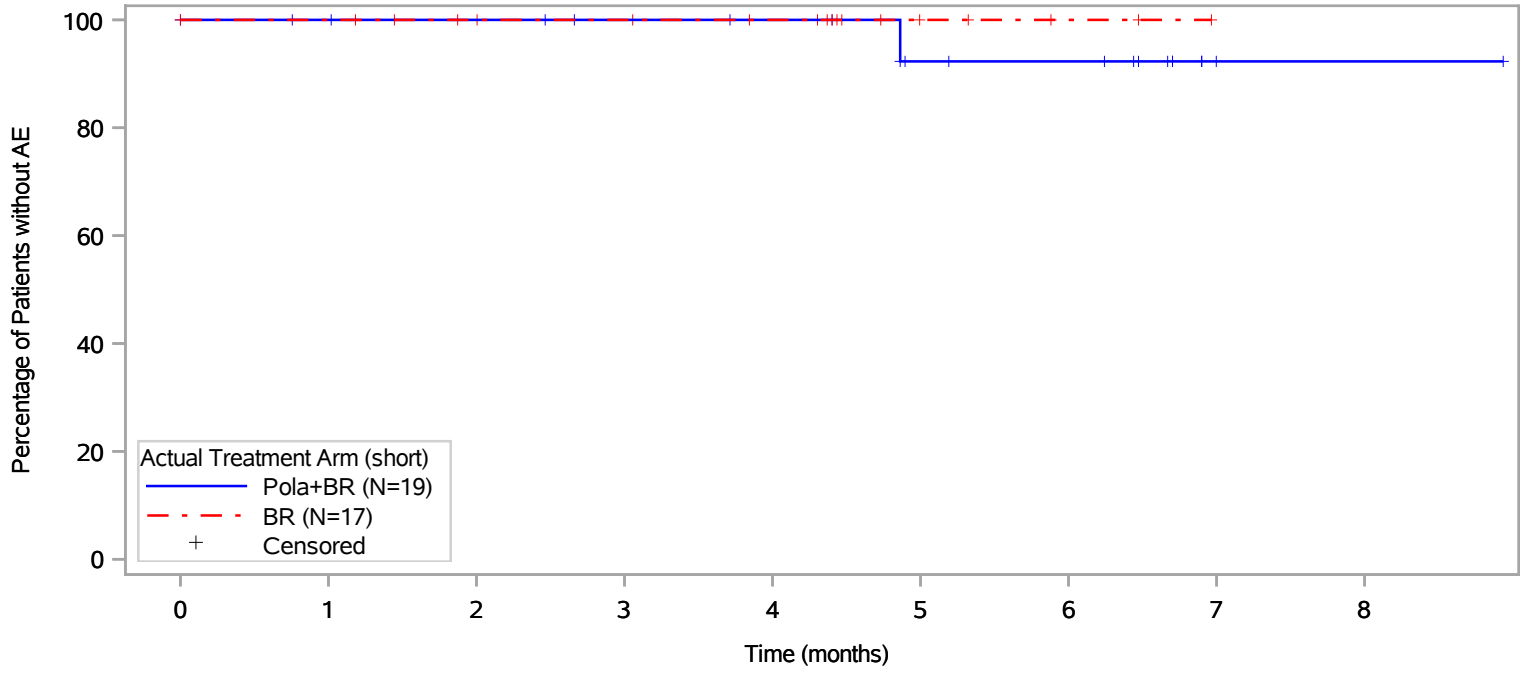
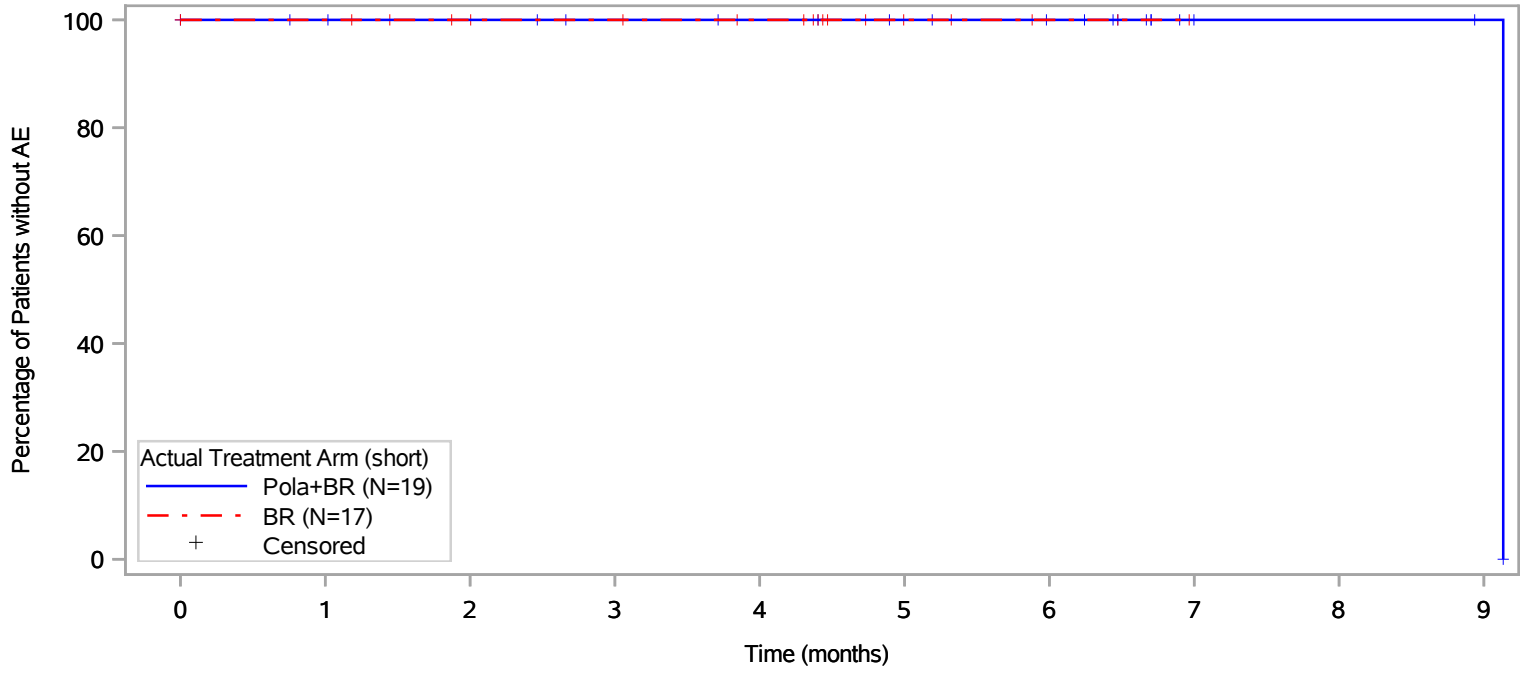
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CEREBRAL TOXOPLASMOSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES VIRUS INFECTION

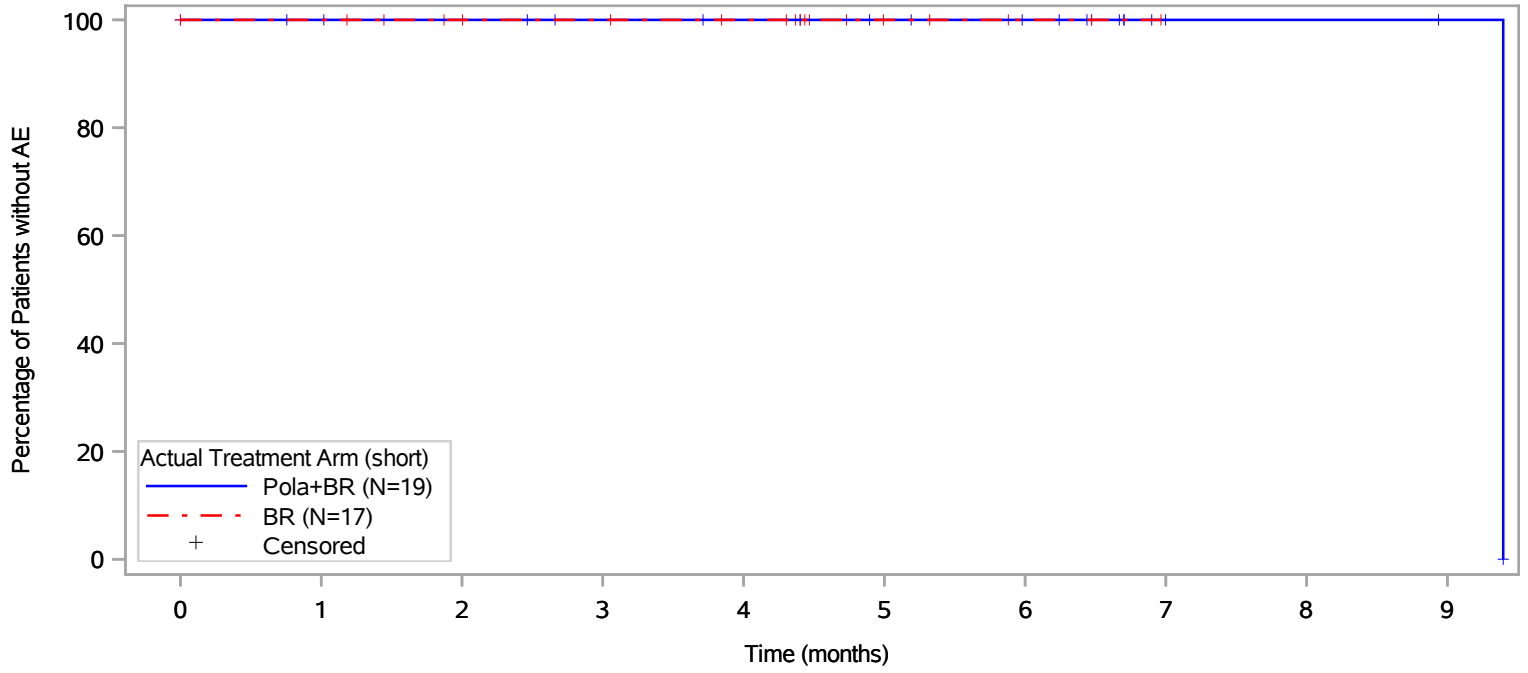


Patients at risk										
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 4:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA

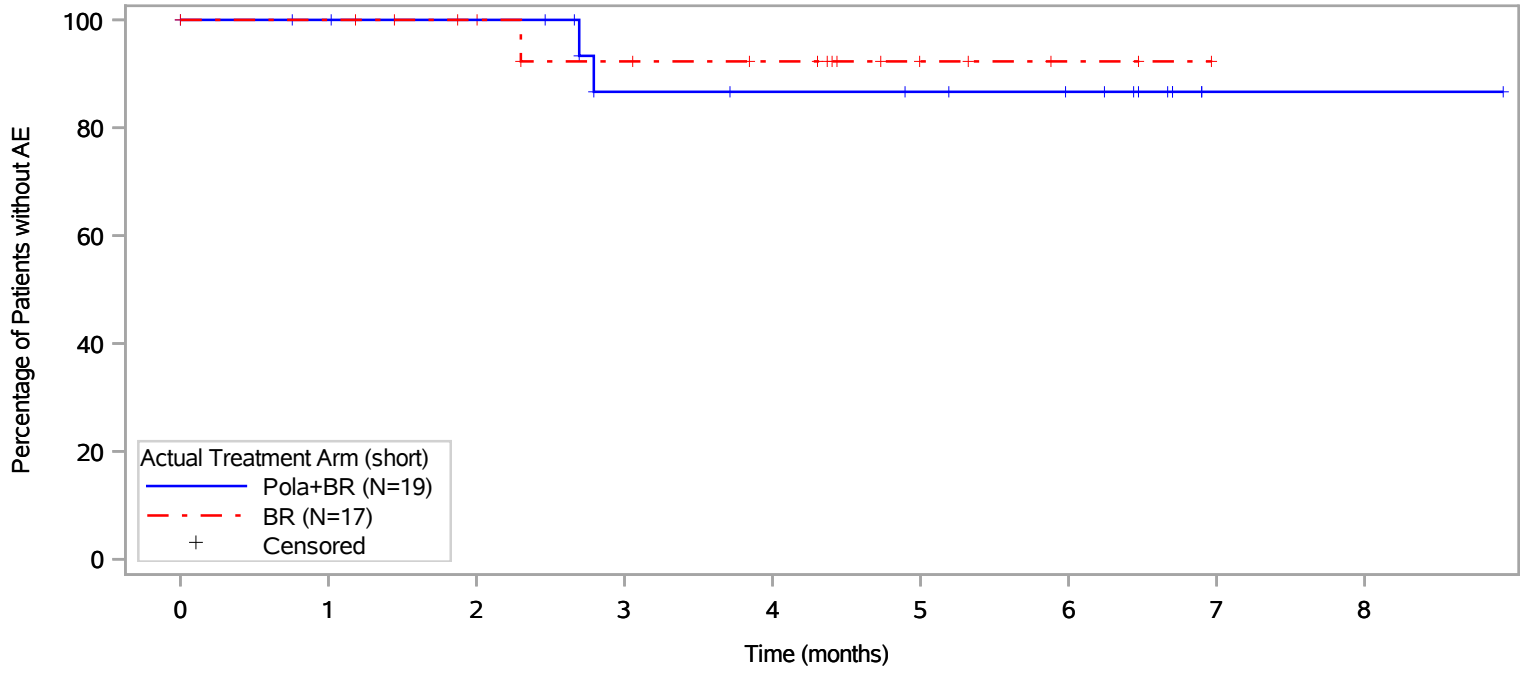


Patients at risk										
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 4:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	13	12	11	9	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	8	16	16
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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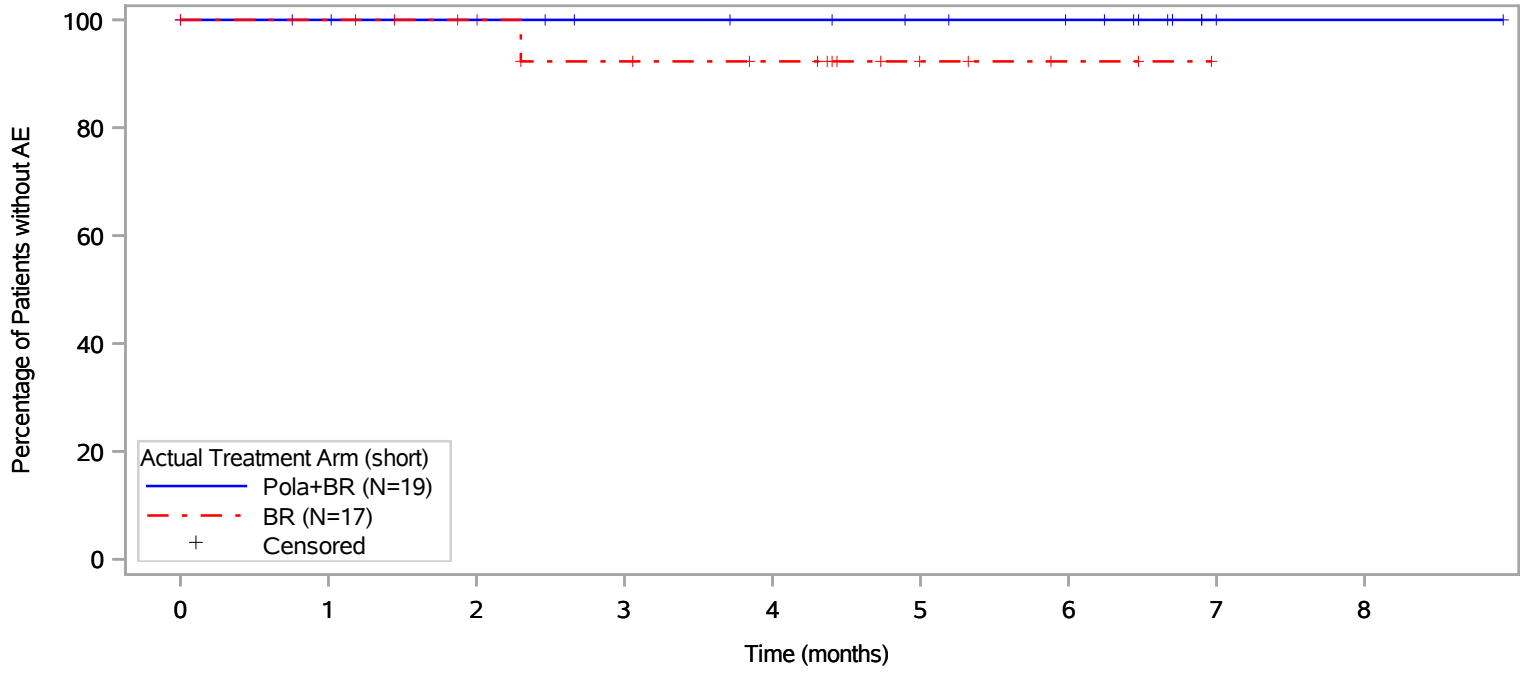
02DEC2022 4:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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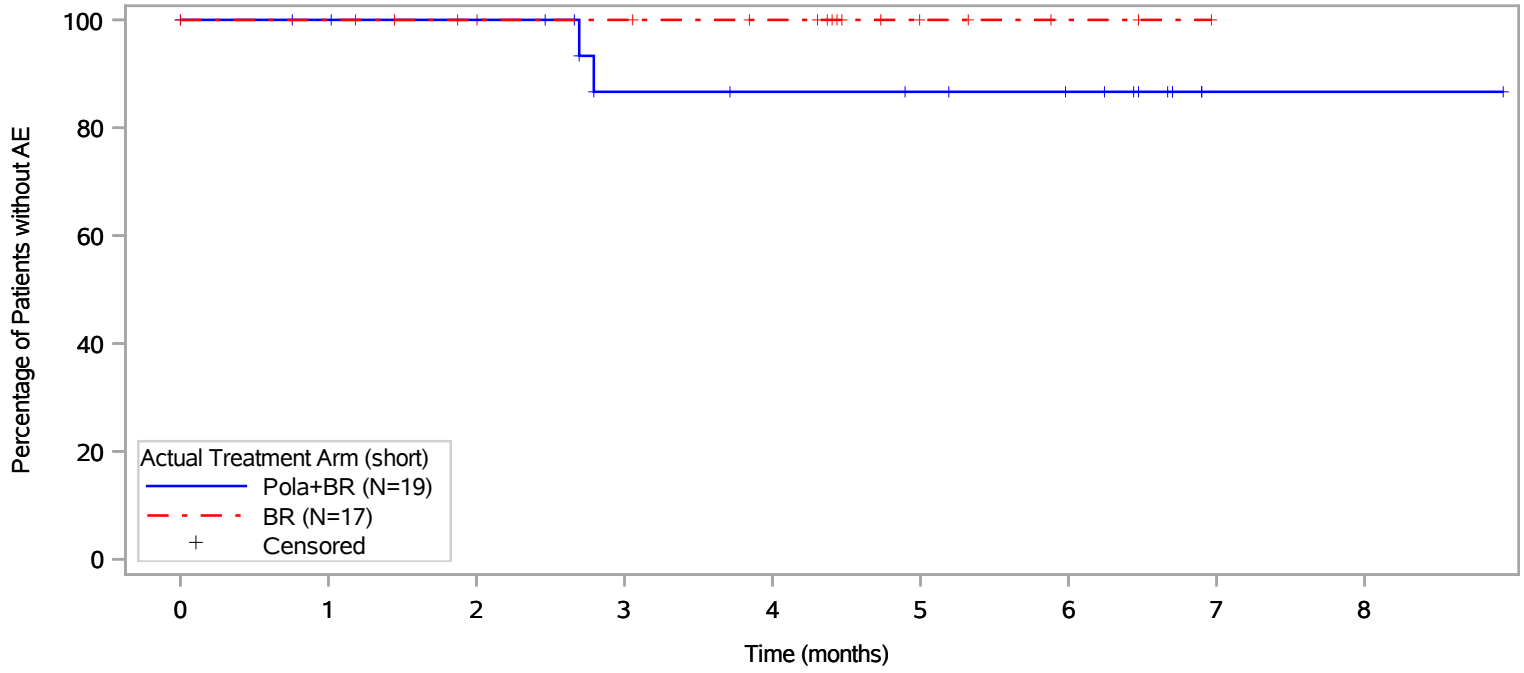
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	13	12	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	8	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.pdf
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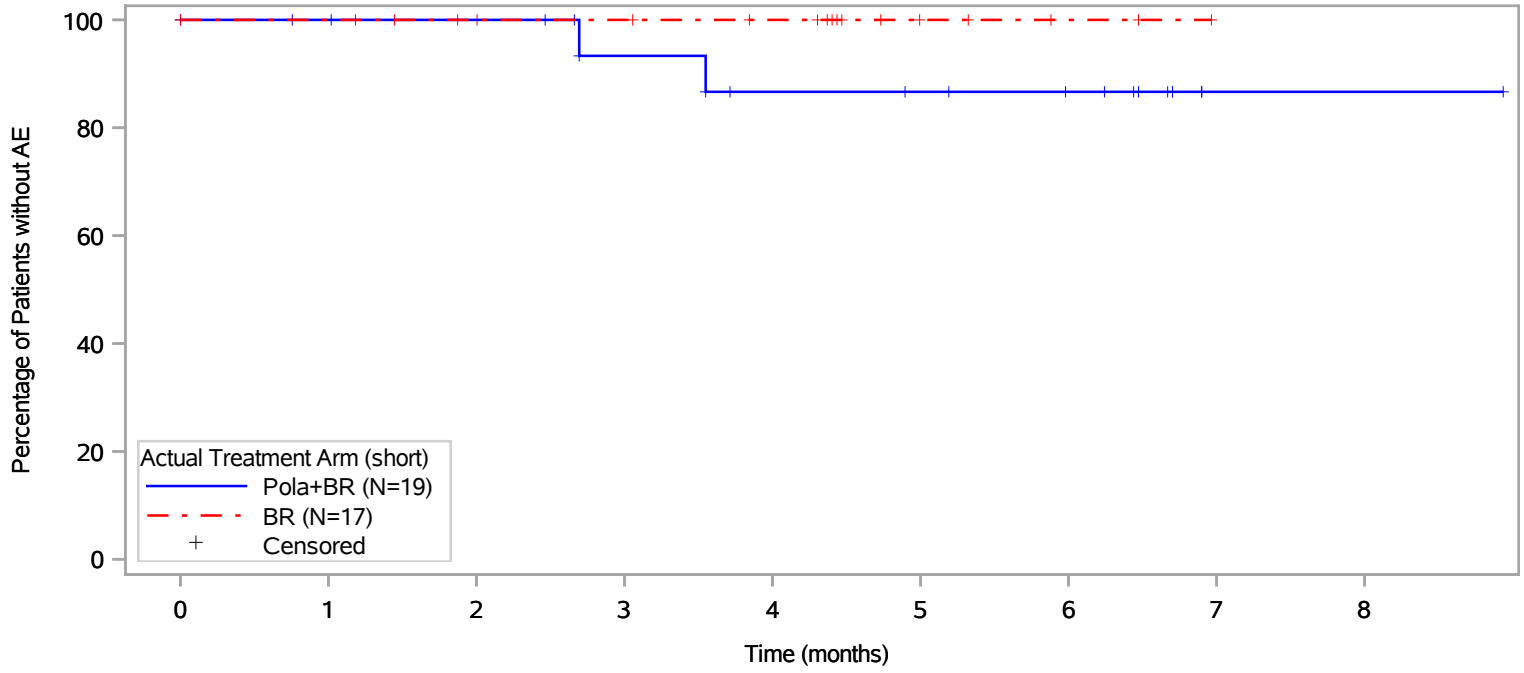
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED

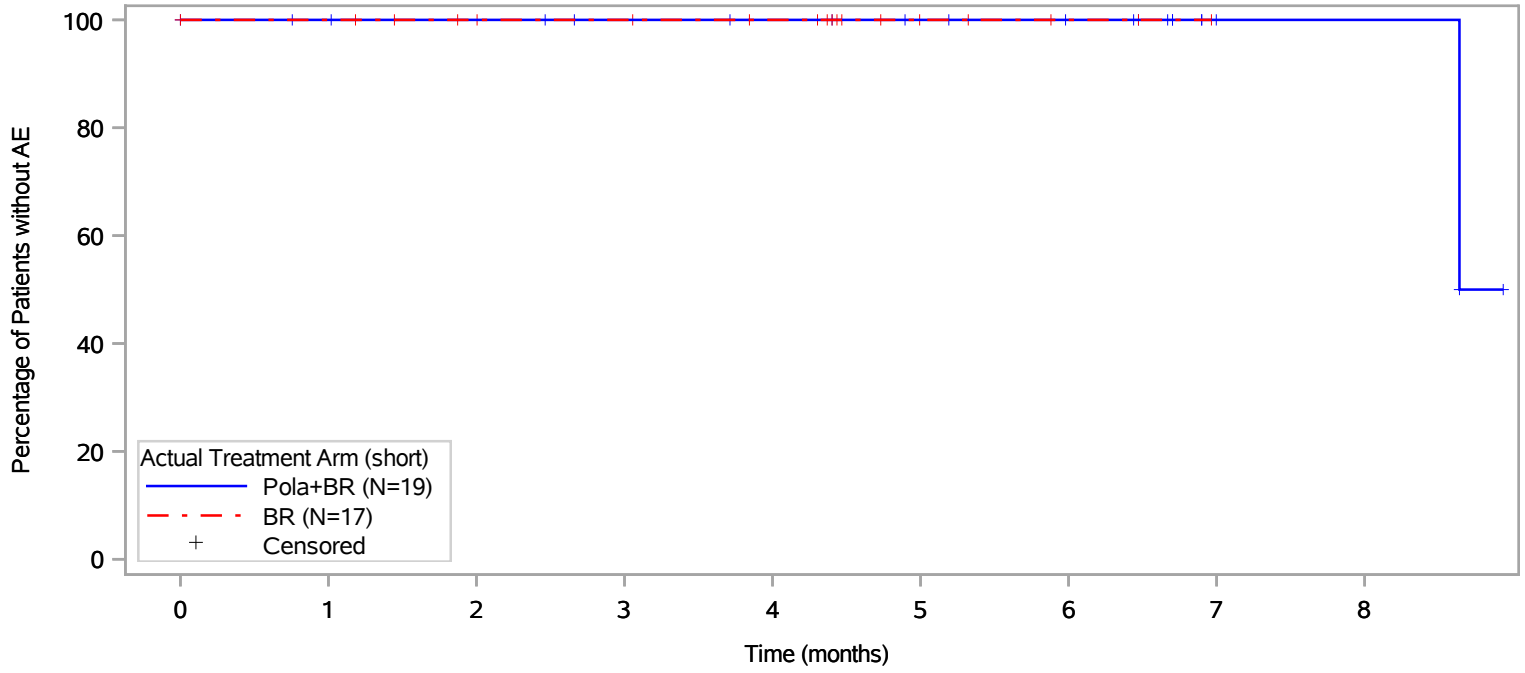


Patients at risk									
Pola+BR (N=19)	19	18	17	14	12	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	8	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.pdf
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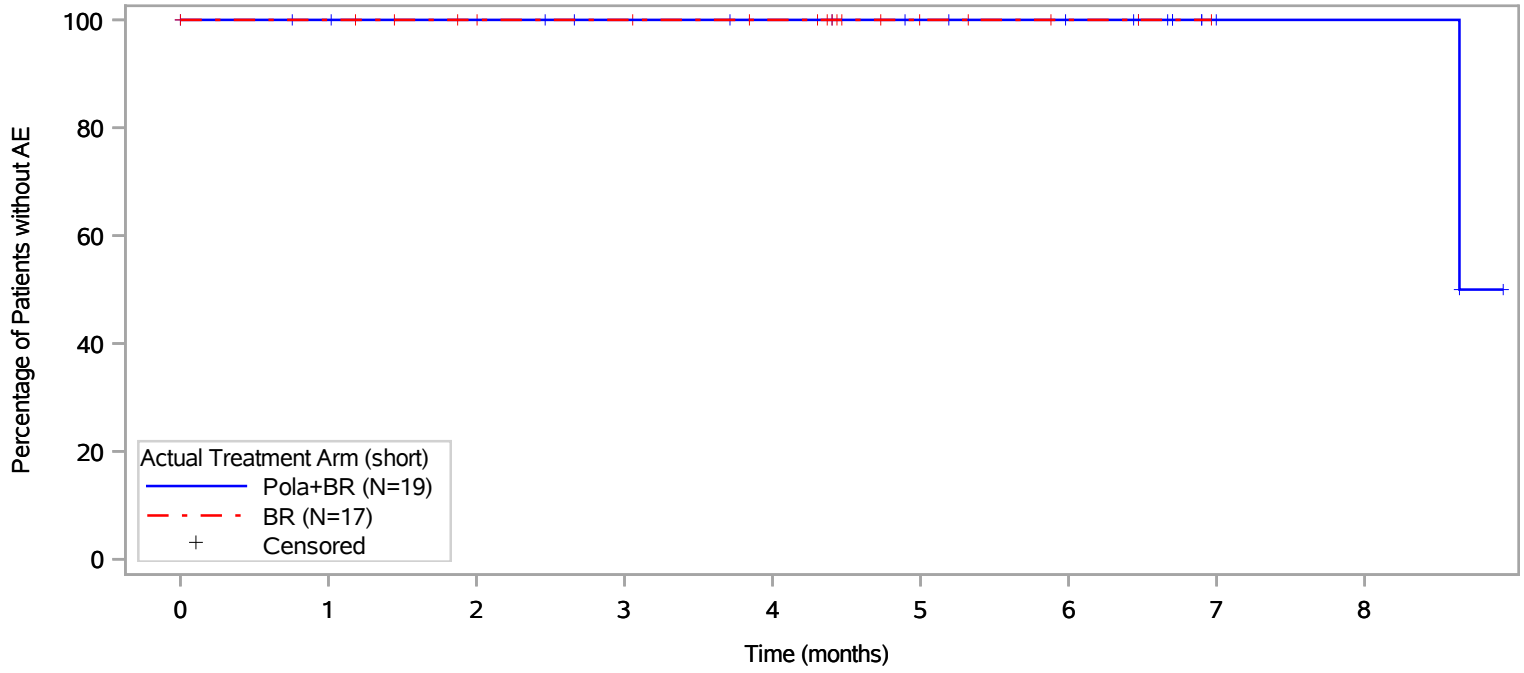
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.pdf
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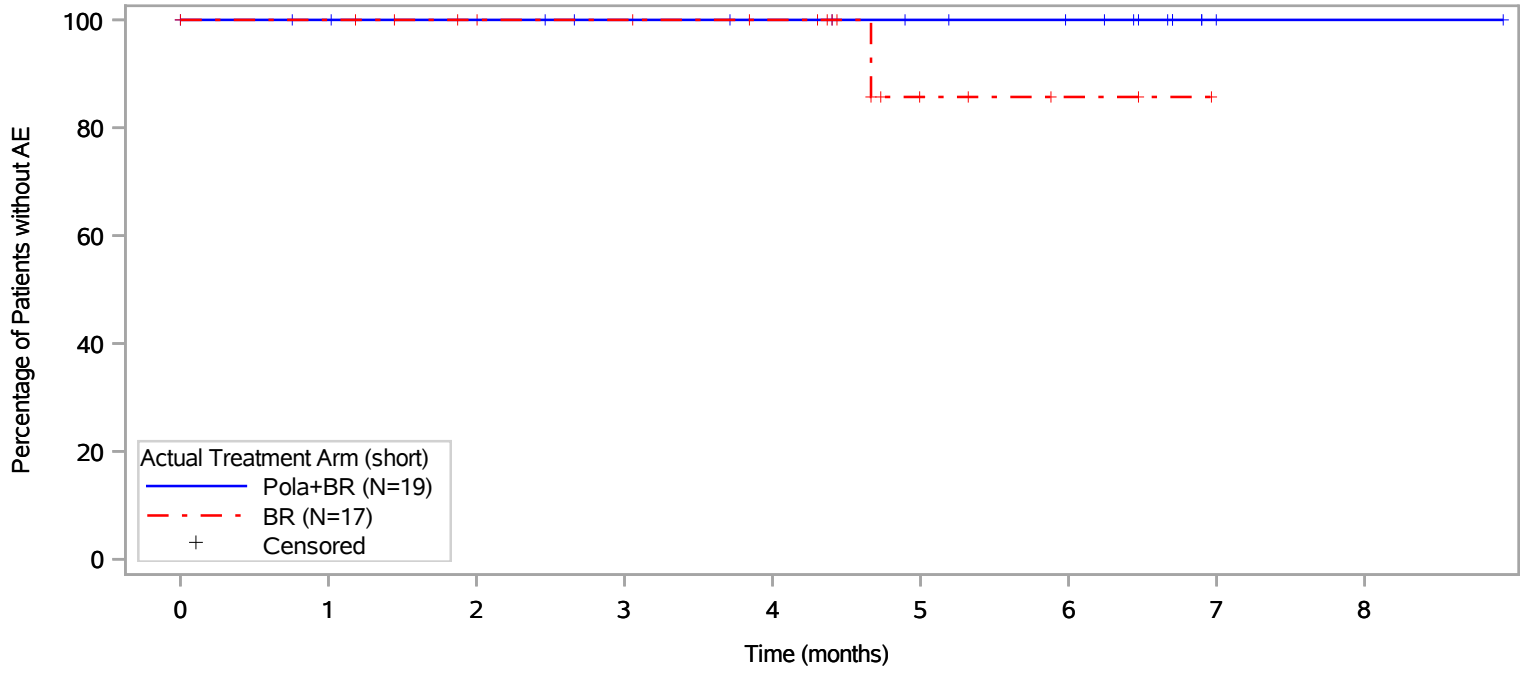
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.pdf
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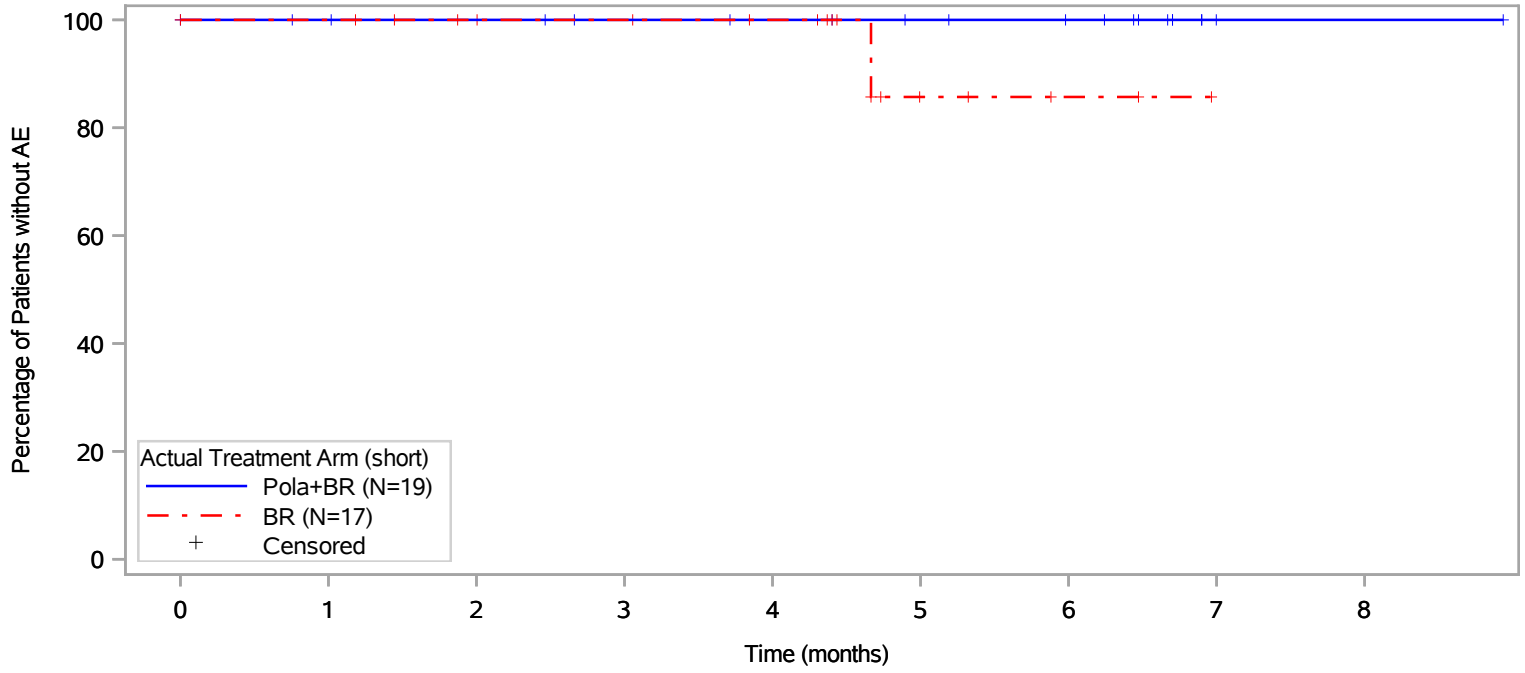
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR4AE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 4:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	3	15.8	16	84.2	17	100.0	2	11.8	15	88.2	0.4604	0.50	0.04	5.50		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR5AE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 22:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	11	57.9	3	27.3	8	72.7	15	88.2	2	13.3	13	86.7	0.6557	0.65	0.06	7.15		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR5AE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 22:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0082				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0082				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS		>=3	8	42.1	2	25.0	6	75.0	14	82.4	2	14.3	12	85.7	0.9370	0.91	0.08	10.04		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.9036	1.18	0.07	19.10		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	2	14.3	12	85.7	8	47.1	1	12.5	7	87.5	0.6111	0.98	0.06	15.89		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	1	20.0	4	80.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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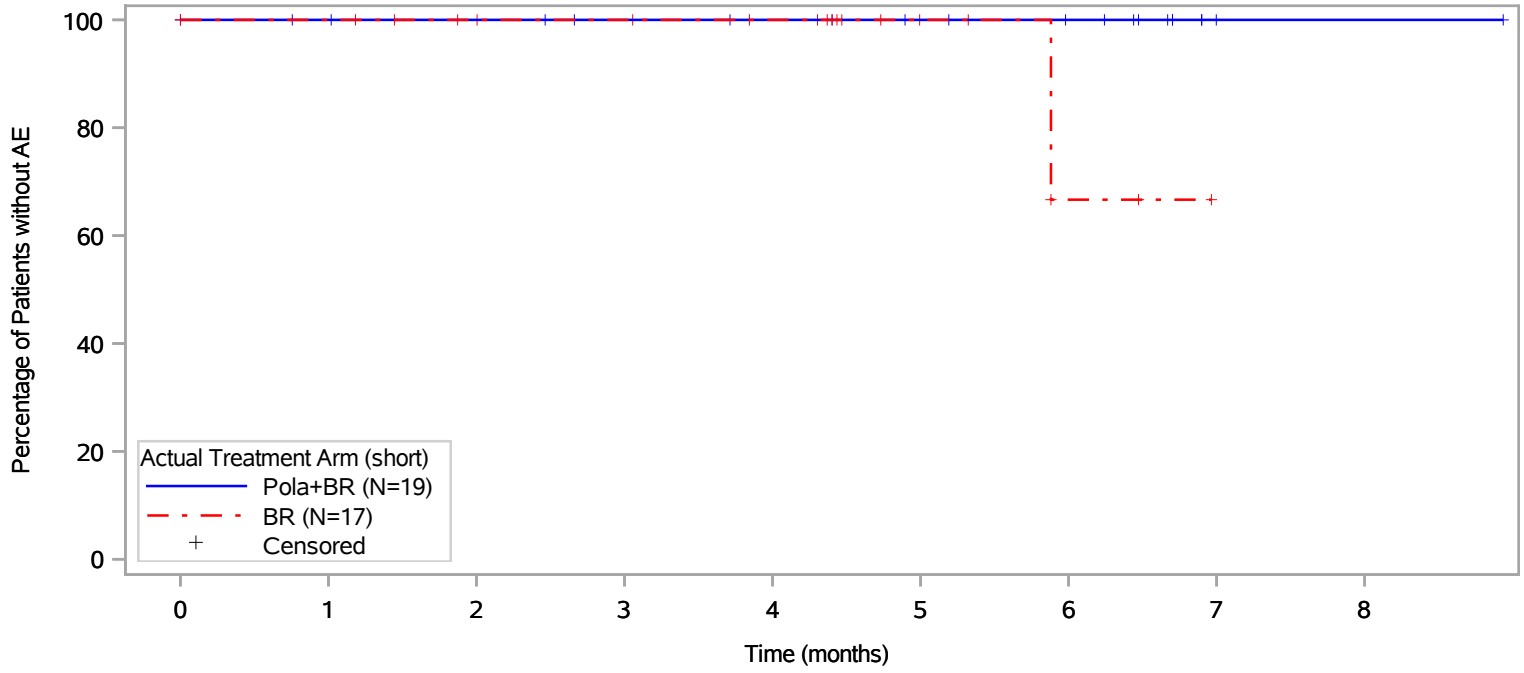
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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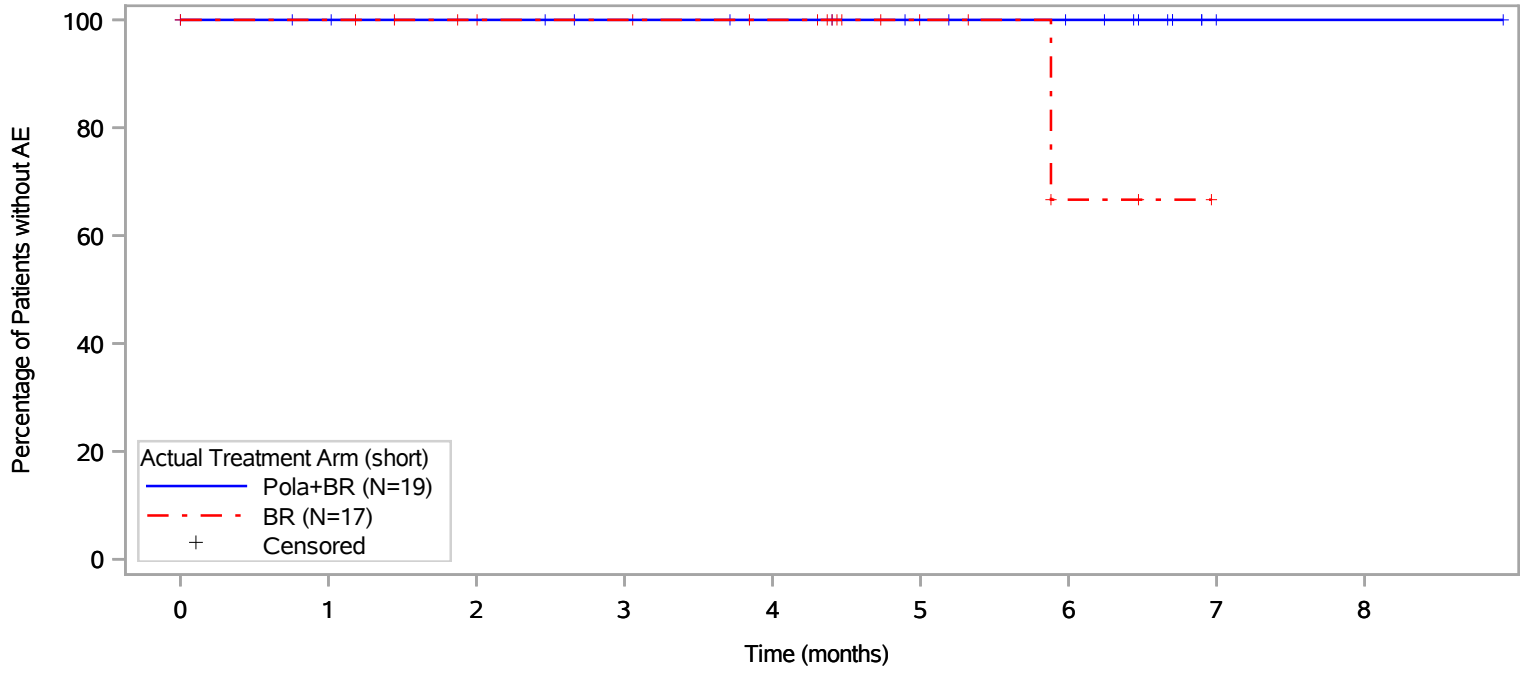
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DEATH



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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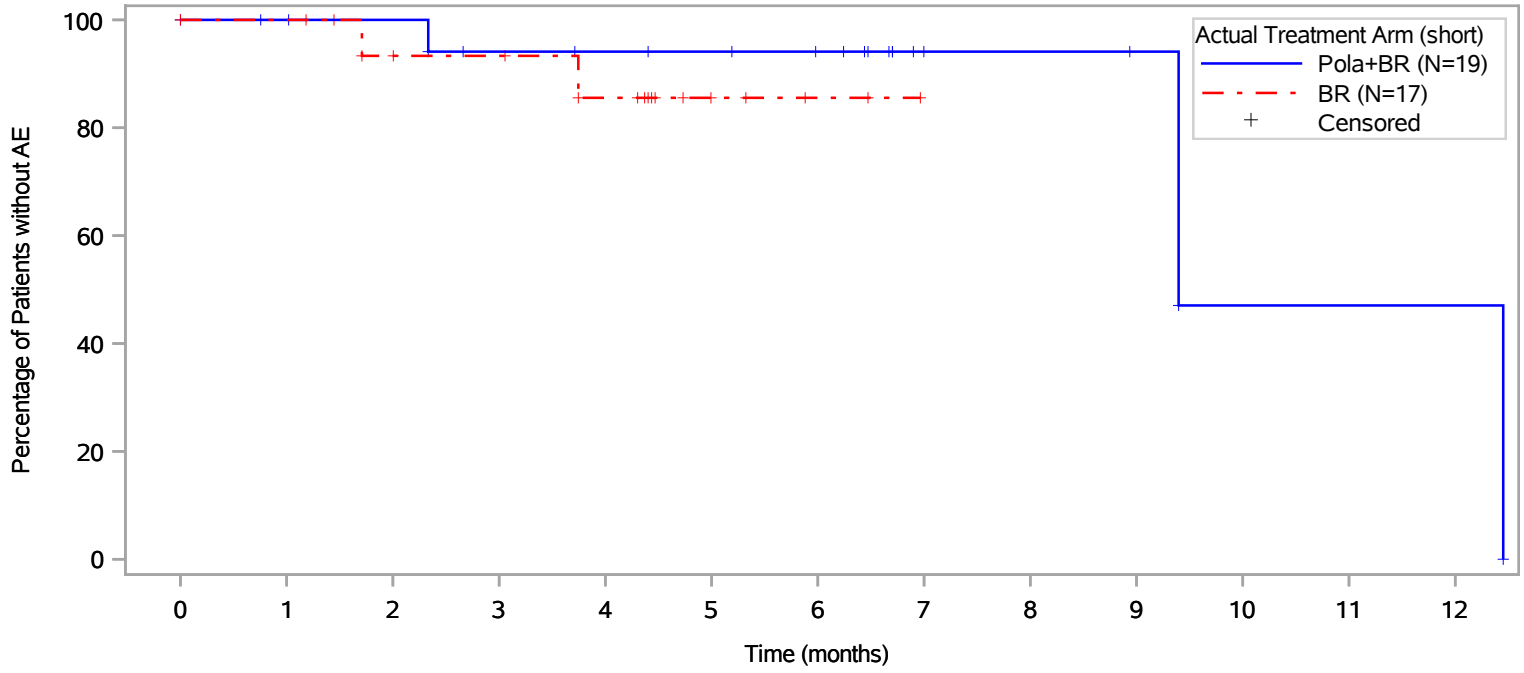
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk													
Pola+BR (N=19)	19	18	17	15	14	13	11	3	3	2	1	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	2	3	4	5	7	15	15	16	16	16	16
BR (N=17)	0	0	2	3	4	11	13	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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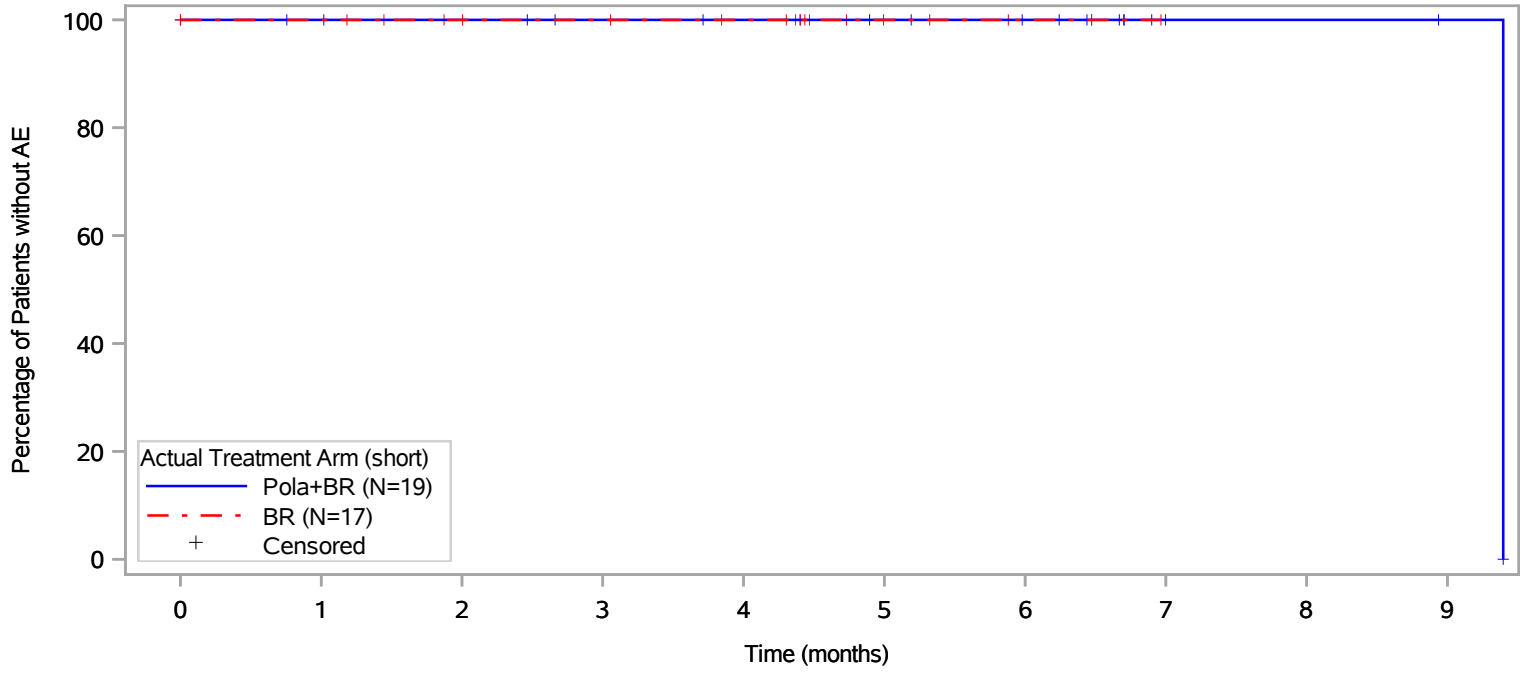
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MENINGOENCEPHALITIS HERPETIC



Patients at risk										
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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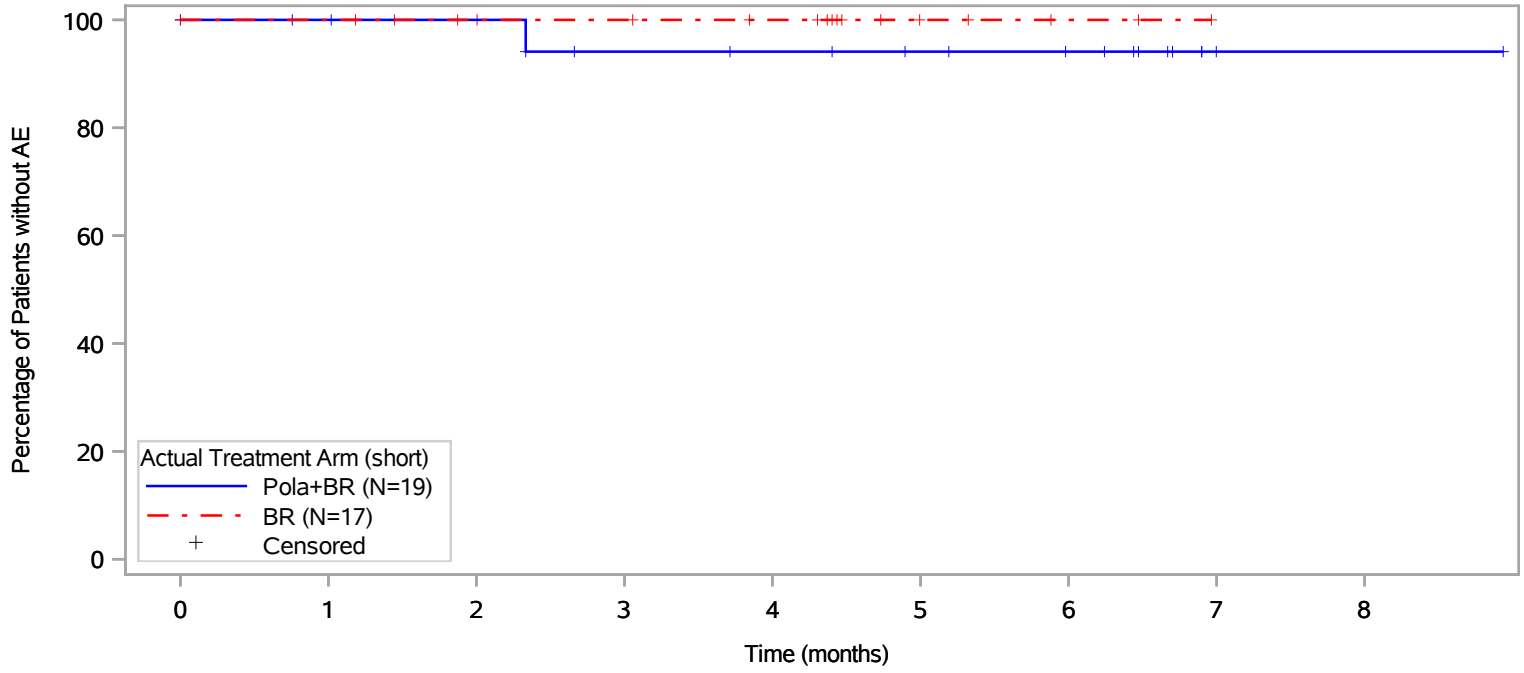
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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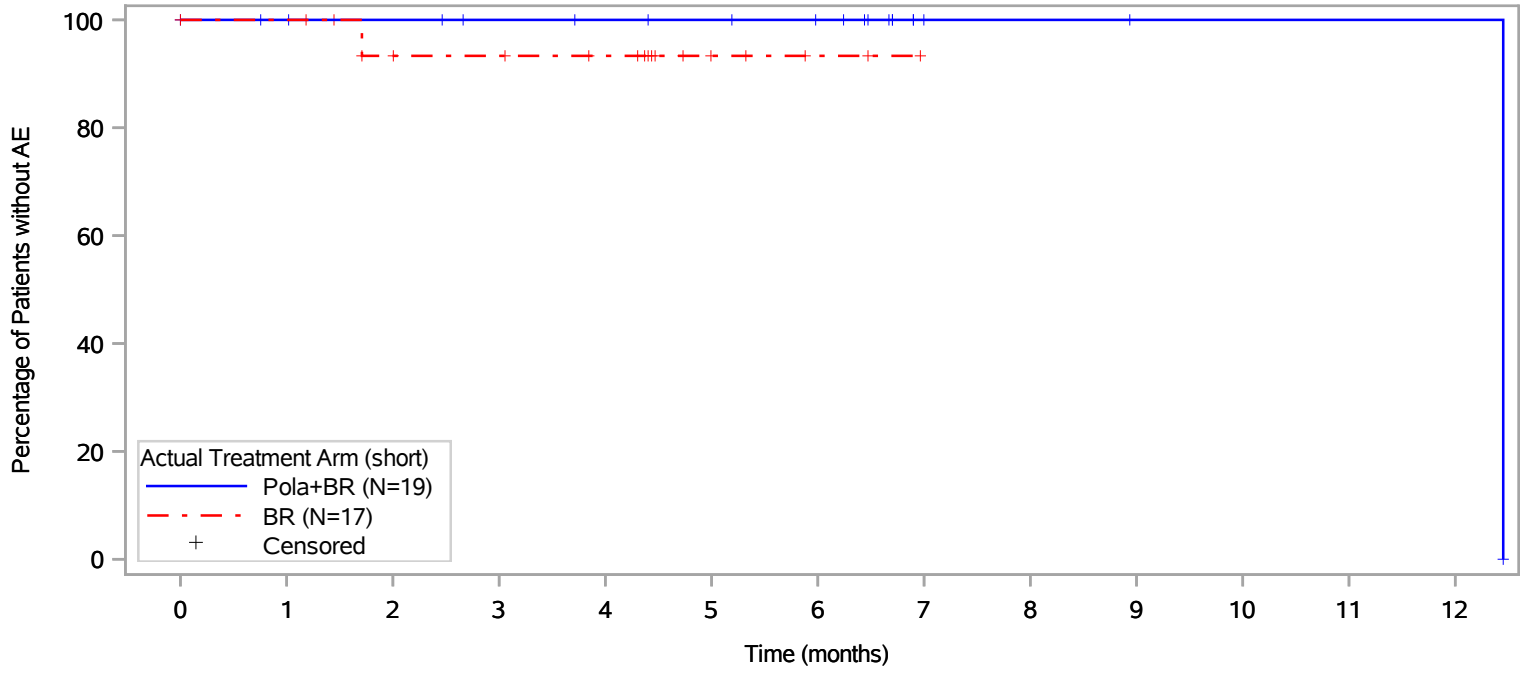
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk													
Pola+BR (N=19)	19	18	17	15	14	13	11	2	2	1	1	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	2	4	5	6	8	17	17	18	18	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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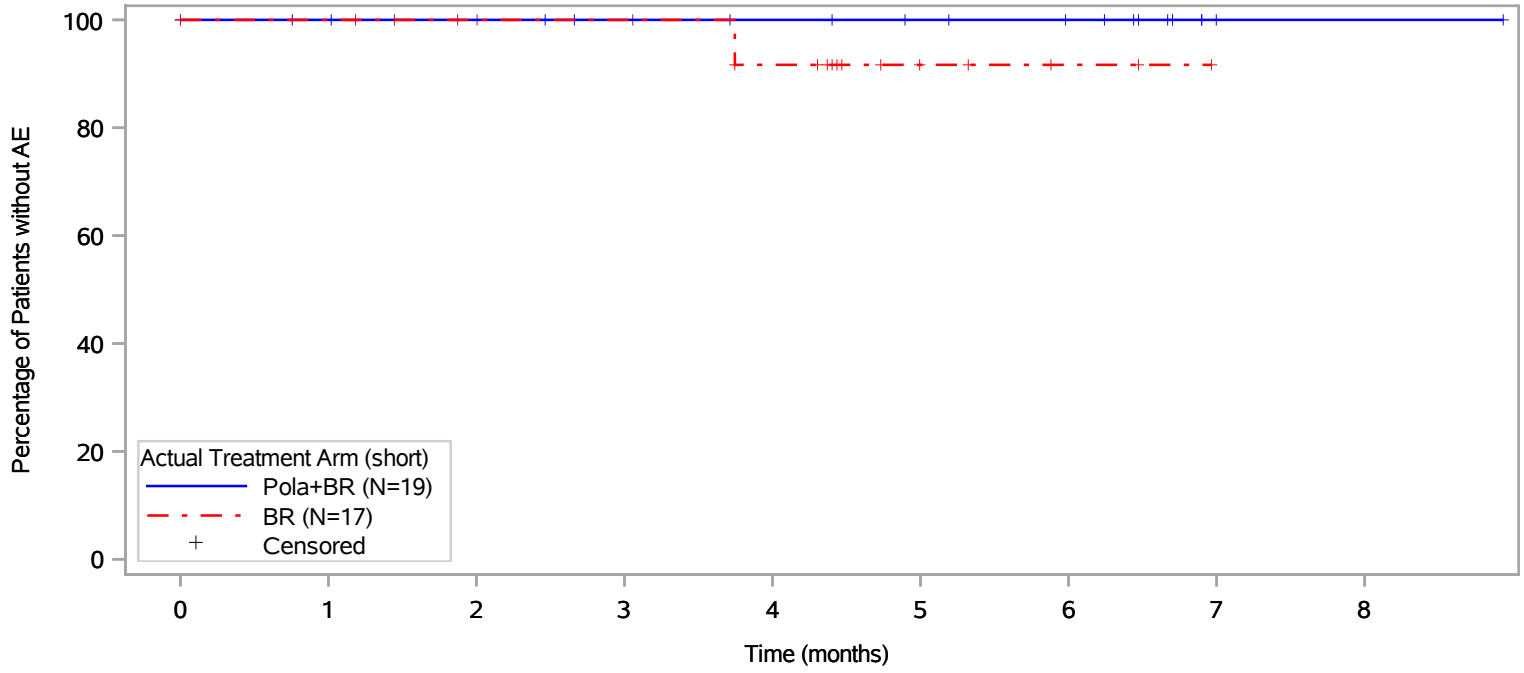
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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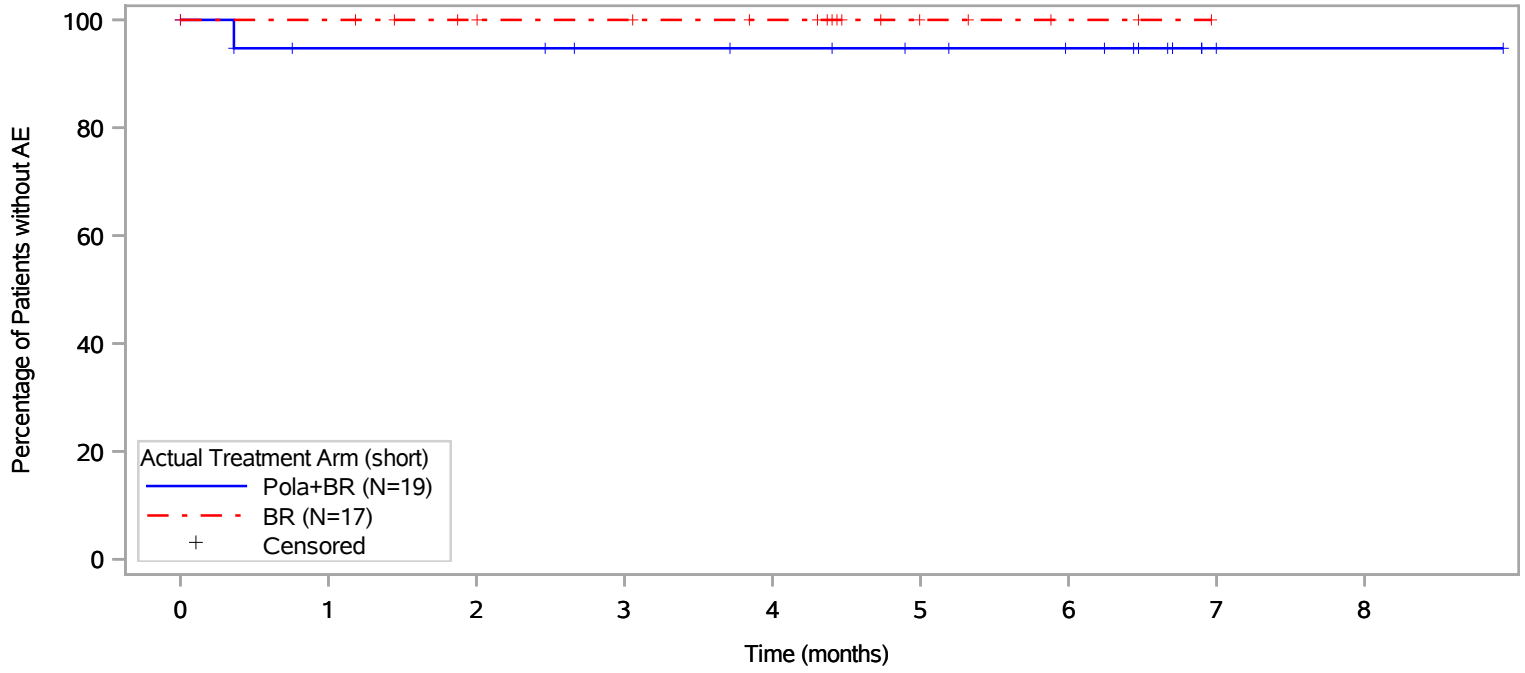
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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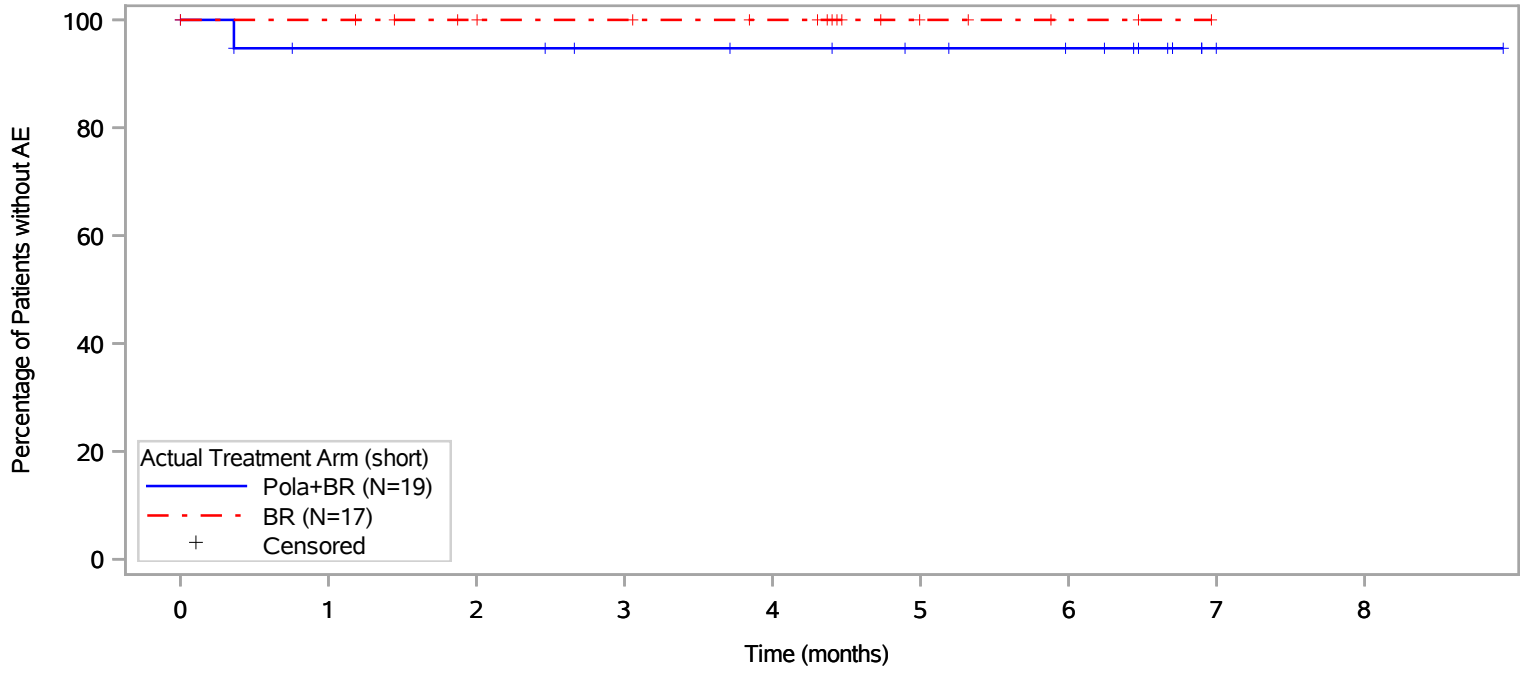
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY OEDEMA



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR5AE_L2_ARMCDPLUSSE_29365_41543.pdf
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1130	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1130	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.0421	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ASCITES		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			19	100.0	1	5.3	18	94.7	17	100.0	4	23.5	13	76.5	0.0131	0.09	0.01	1.00		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	6	31.6	13	68.4	17	100.0	4	23.5	13	76.5	0.3479	0.53	0.11	2.49		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	3	15.8	16	84.2	17	100.0	1	5.9	16	94.1	0.6557	1.79	0.16	19.96		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3035	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3035	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3442	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1780	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1780	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.0837	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	4	26.7	11	73.3	0.0420	0.11	0.01	1.25		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	11	57.9	4	36.4	7	63.6	15	88.2	4	26.7	11	73.3	0.1350	0.21	0.02	2.15		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	1	6.7	14	93.3	0.8787	1.34	0.08	21.61		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3173				*	WARNING: Iteration limit reached without convergence.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTSAE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 23:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.1261	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.5127	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	3	21.4	11	78.6	0.2450	0.25	0.02	2.97		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0082				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0082				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	8	42.1	3	37.5	5	62.5	14	82.4	4	28.6	10	71.4	0.2785	0.29	0.03	2.99		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.5290	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	8	42.1	2	25.0	6	75.0	14	82.4	1	7.1	13	92.9	0.6450	1.84	0.11	29.79		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	0.1859	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTSAE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 23:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	2	14.3	12	85.7	0.0494	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3352	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	4	28.6	10	71.4	0.0056	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	26.3	2	40.0	3	60.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	3	21.4	11	78.6	0.6968	0.88	0.17	4.56		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.6327	2.05	0.18	23.23		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.3404	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3404	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTSAE_L2_ARMCDPLUSSE_29365_41543.xls
30NOV2022 23:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	14	73.7	1	7.1	13	92.9	8	47.1	2	25.0	6	75.0	0.1591	0.39	0.03	4.44		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	5	26.3	0	-	5	100.0	9	52.9	2	22.2	7	77.8	0.0979	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4795				*	WARNING: Iteration limit reached without convergence.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	5	35.7	9	64.3	8	47.1	1	12.5	7	87.5	0.8140	1.85	0.17	19.64		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	1	20.0	4	80.0	9	52.9	3	33.3	6	66.7	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	3	21.4	11	78.6	8	47.1	0	-	8	100.0	0.3286	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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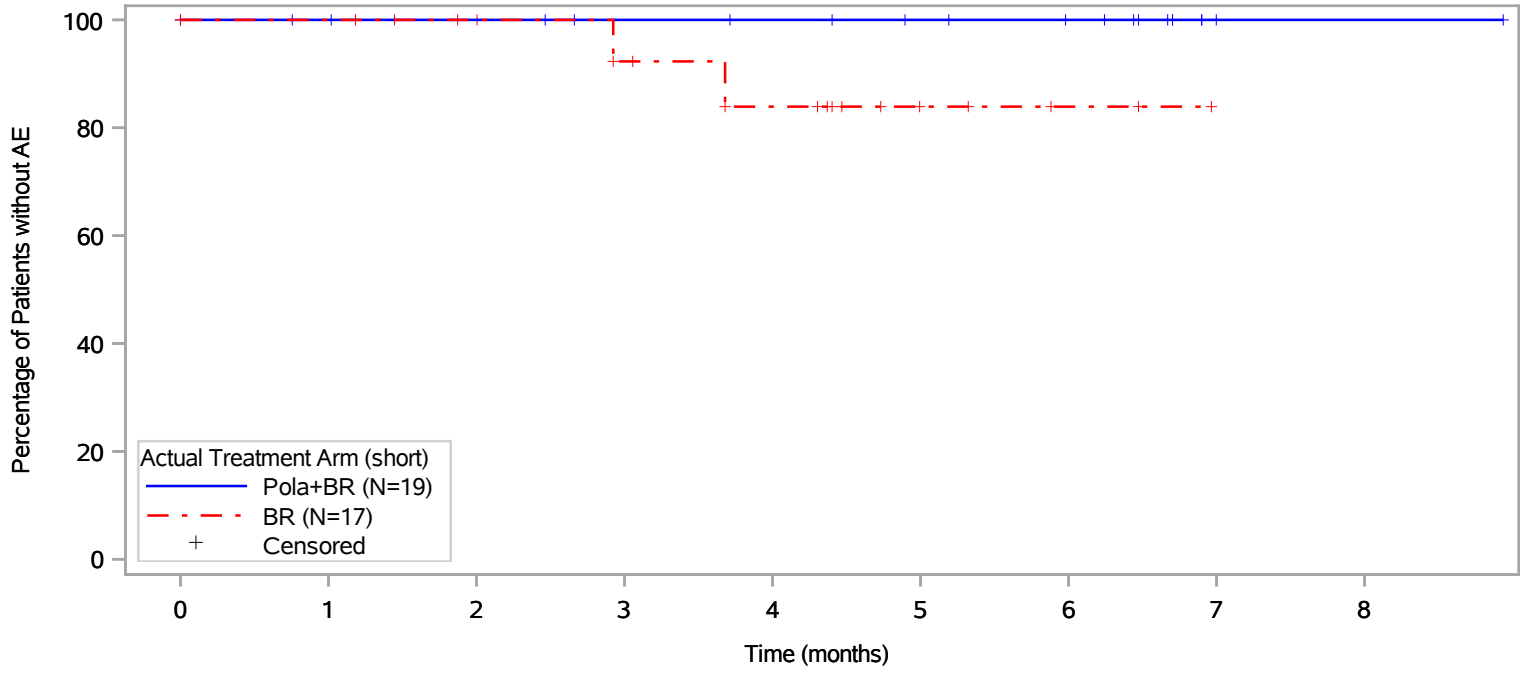
30NOV2022 23:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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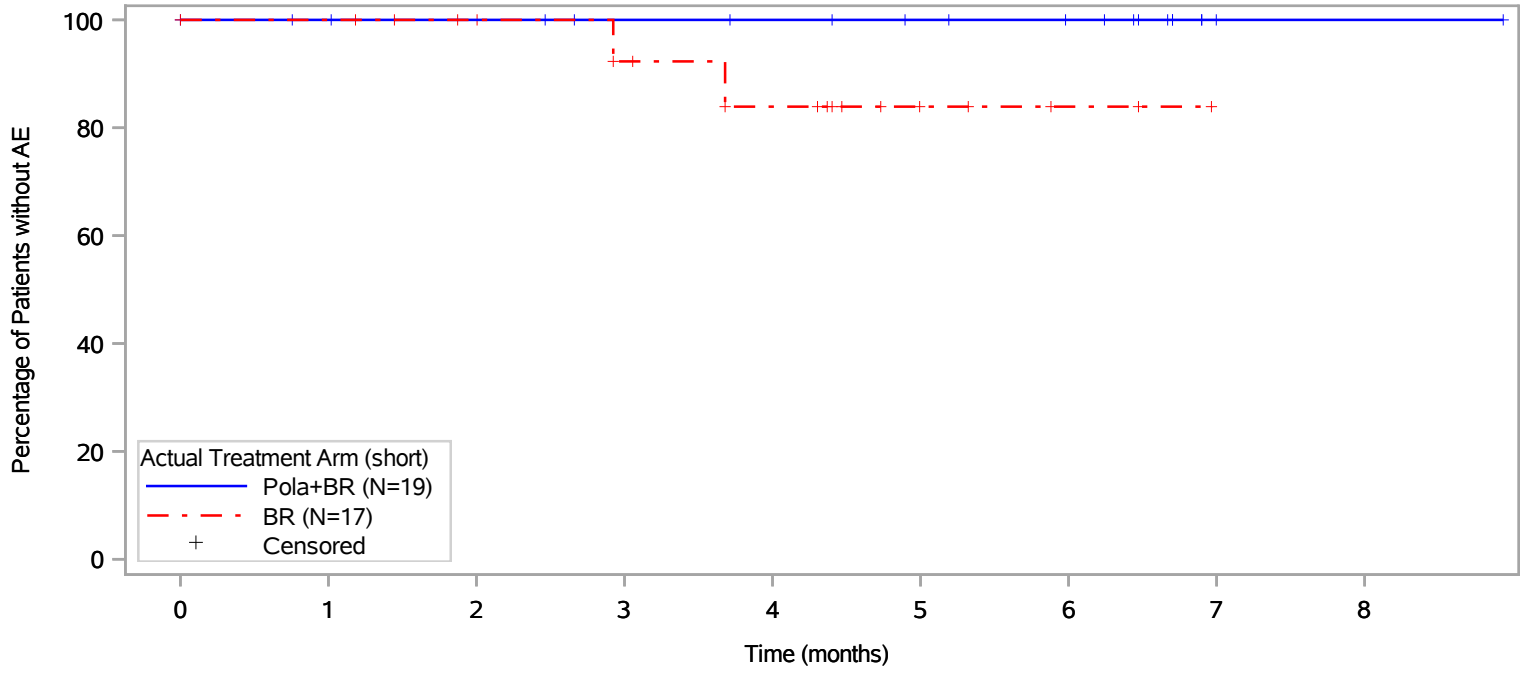
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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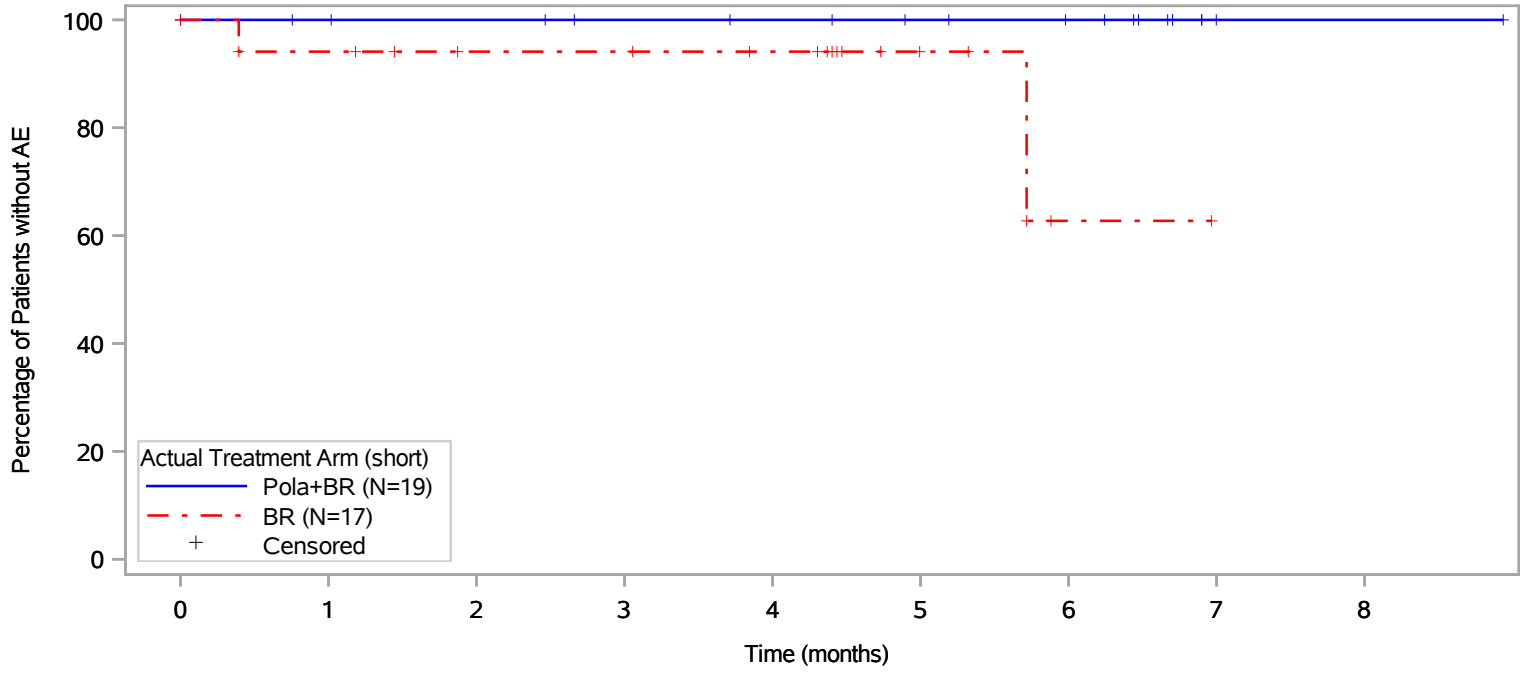
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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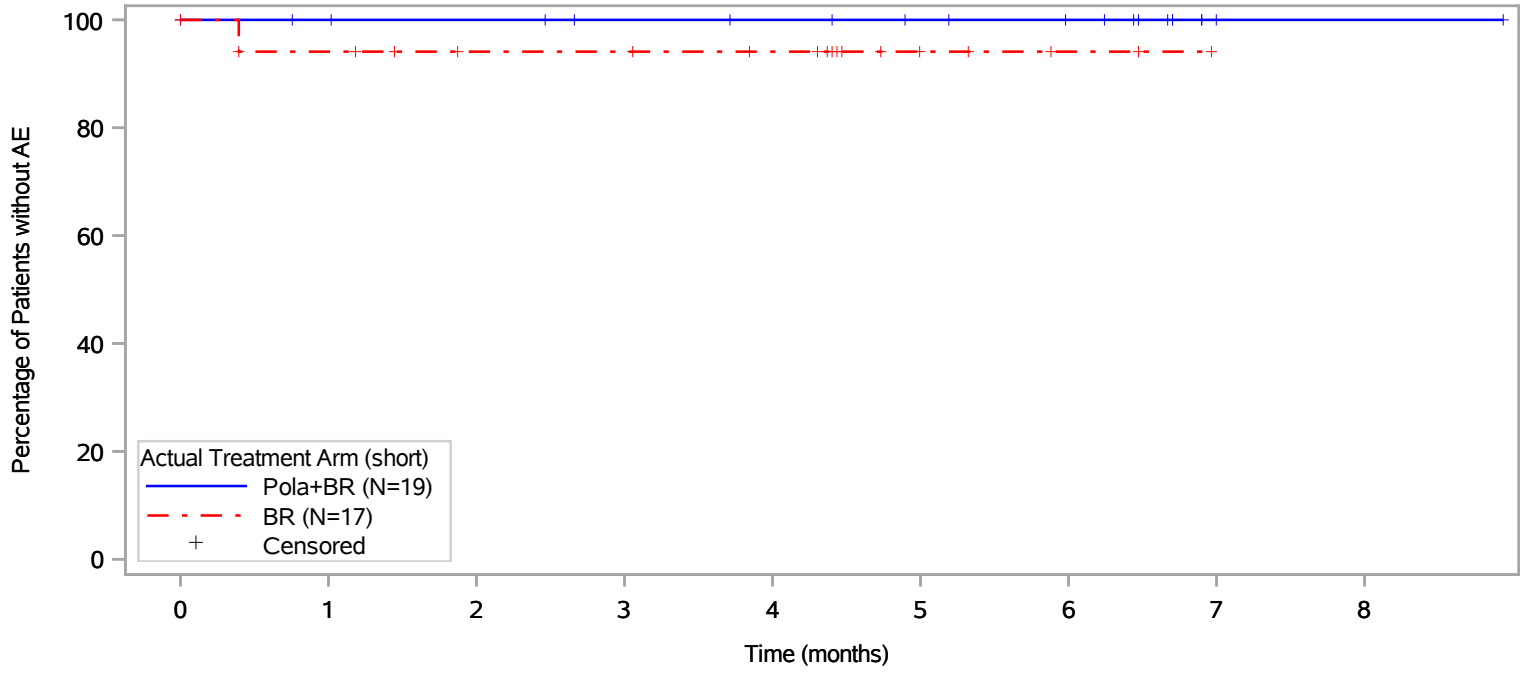
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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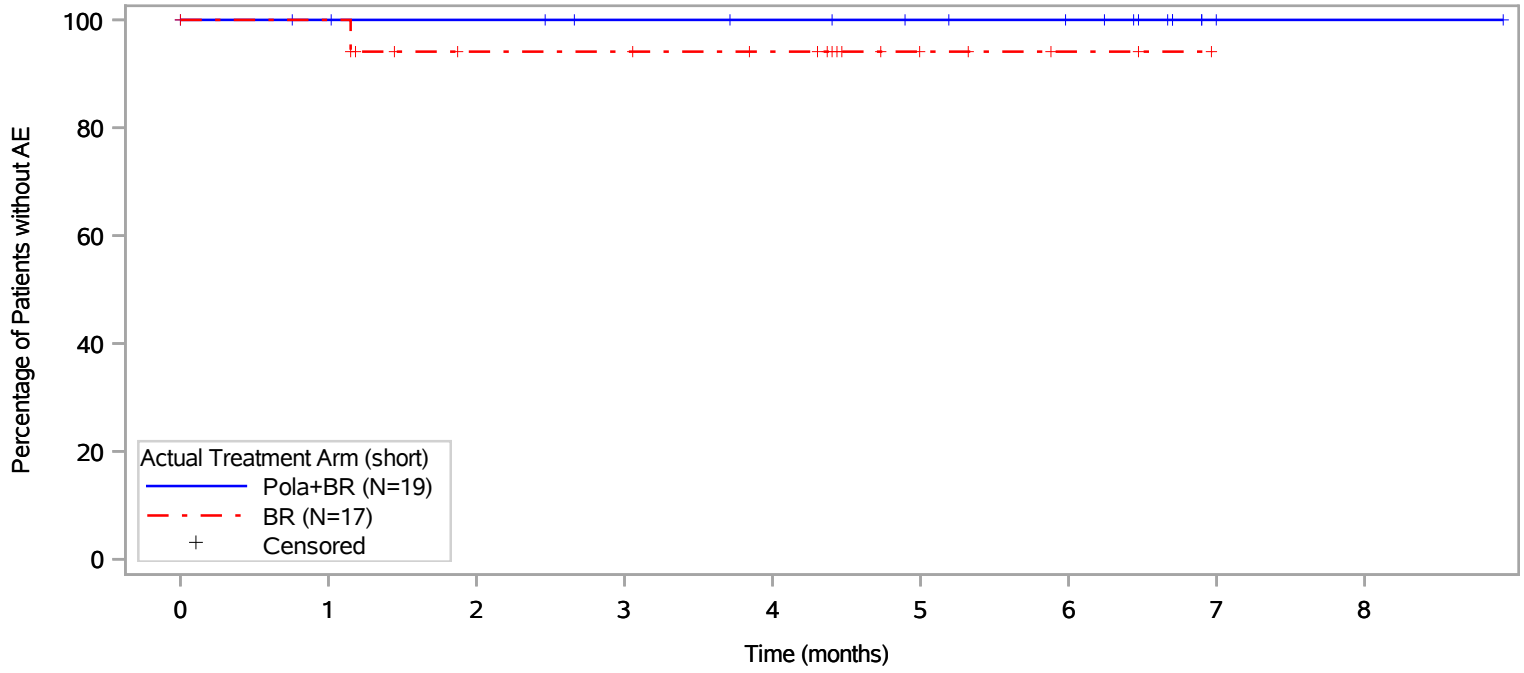
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ASCITES



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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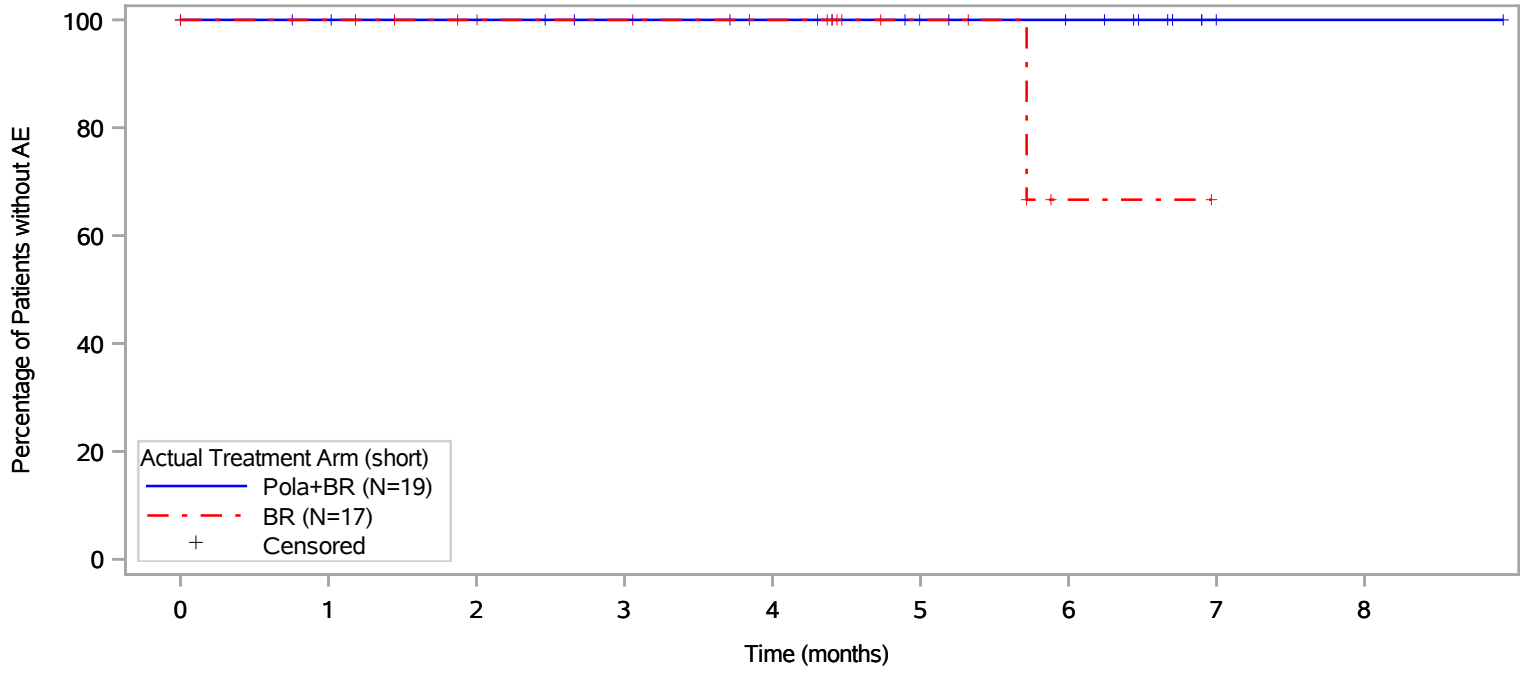
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SMALL INTESTINAL OBSTRUCTION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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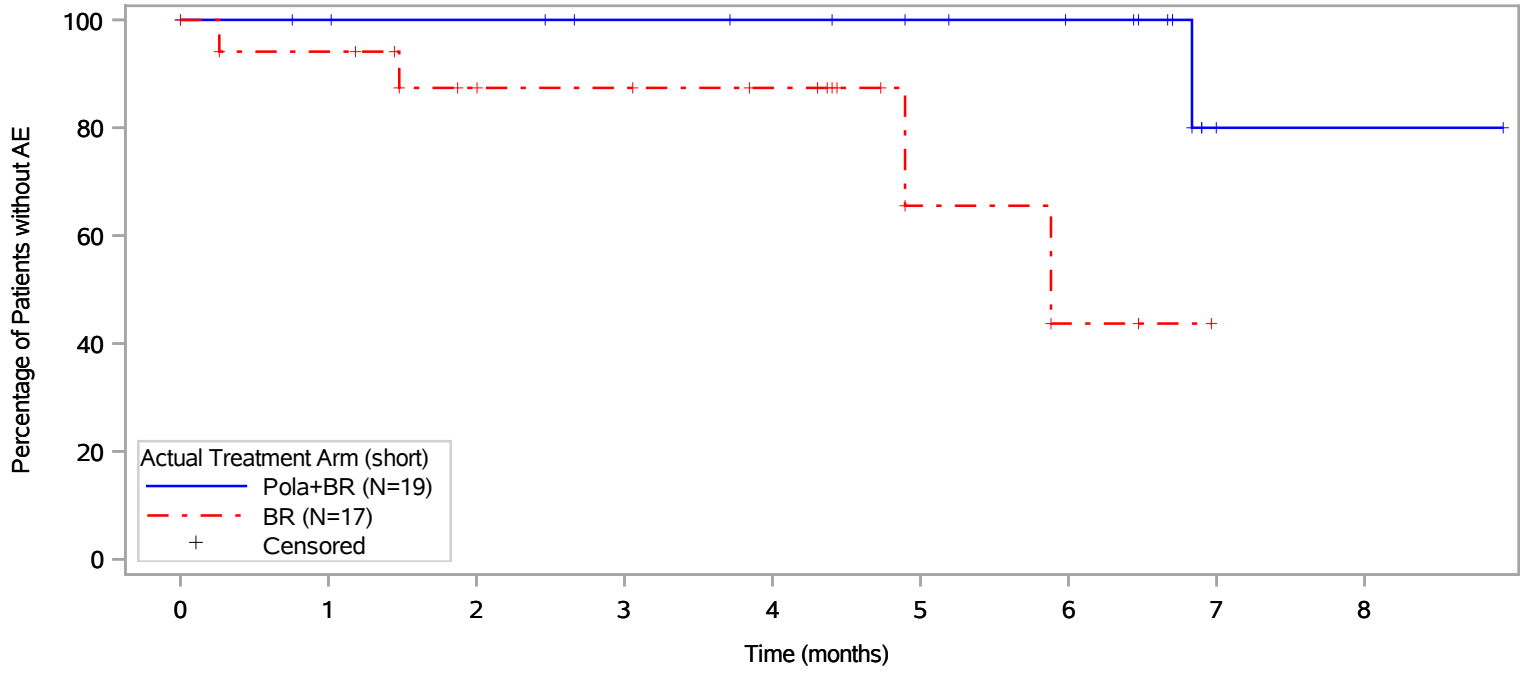
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All

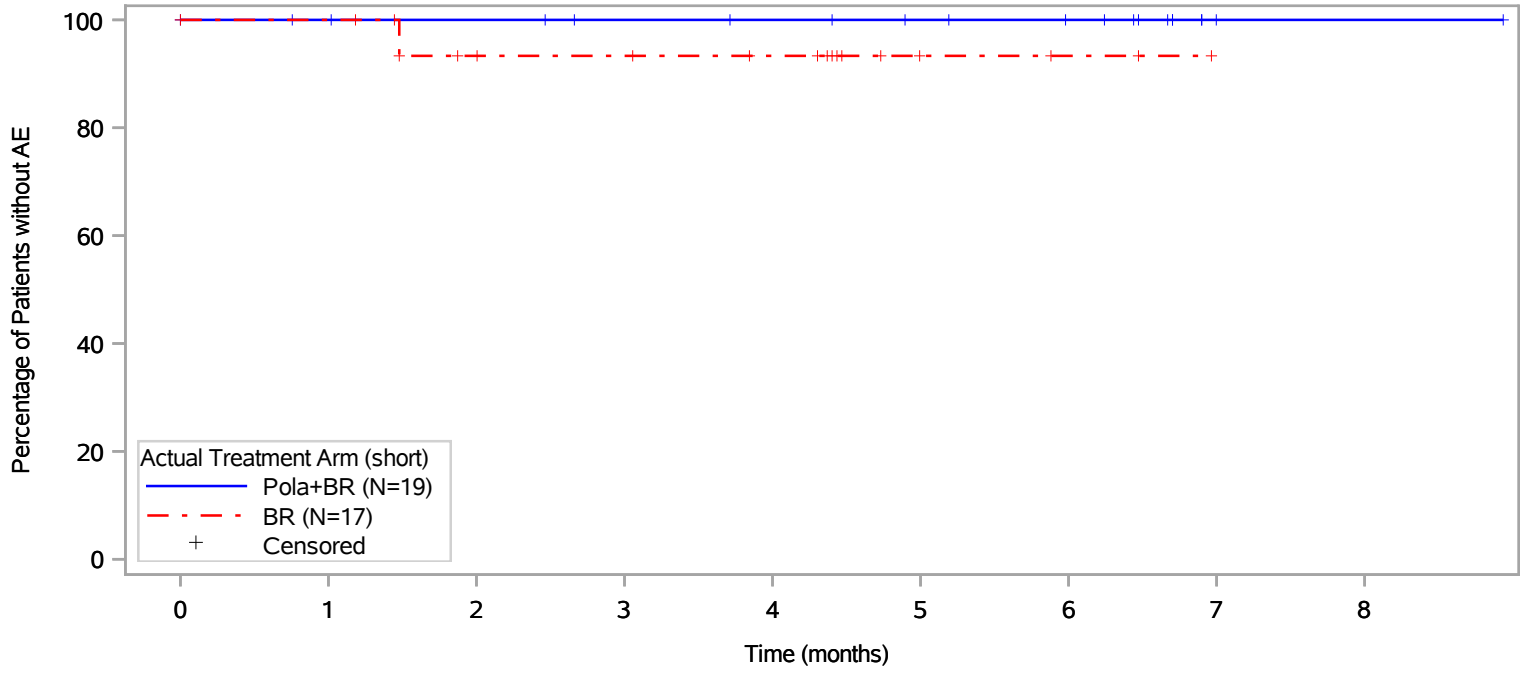


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	12	11	9	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	11	11	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, ASTHENIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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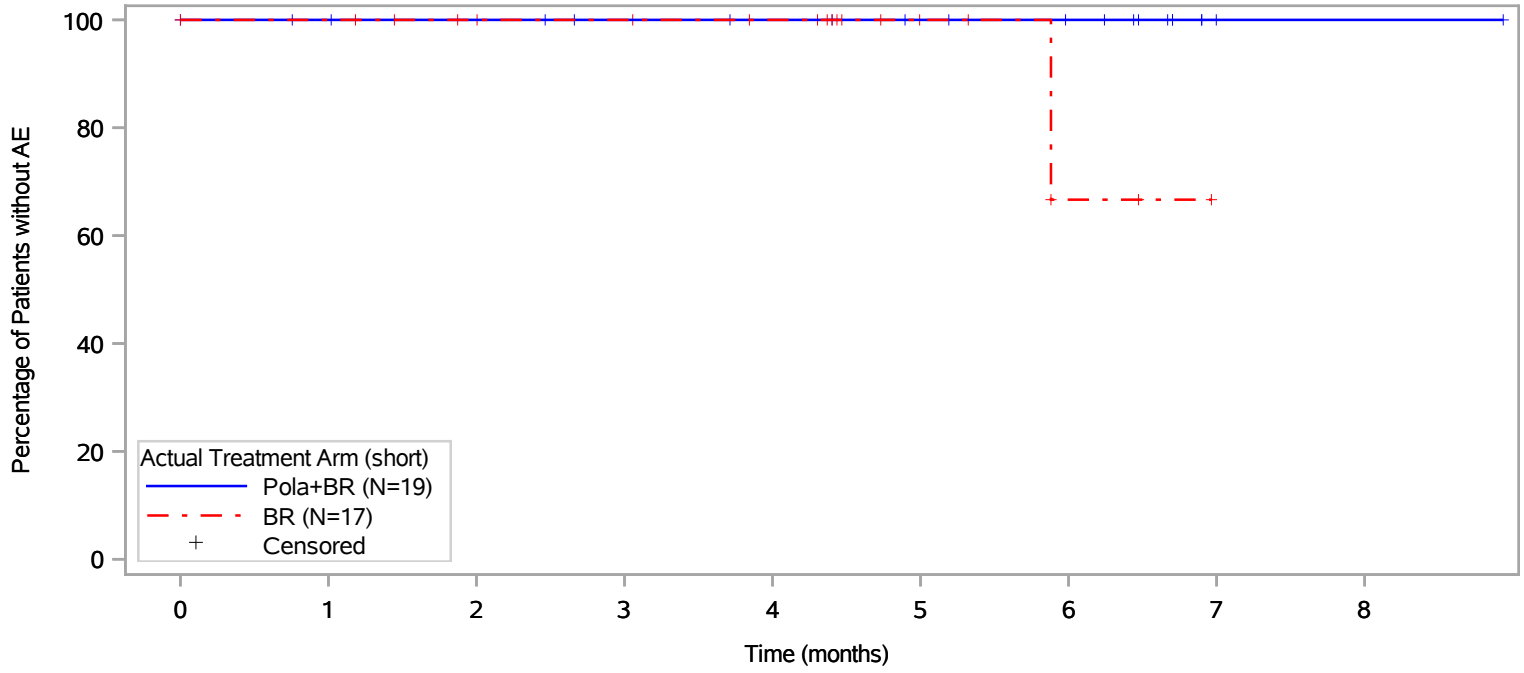
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DEATH



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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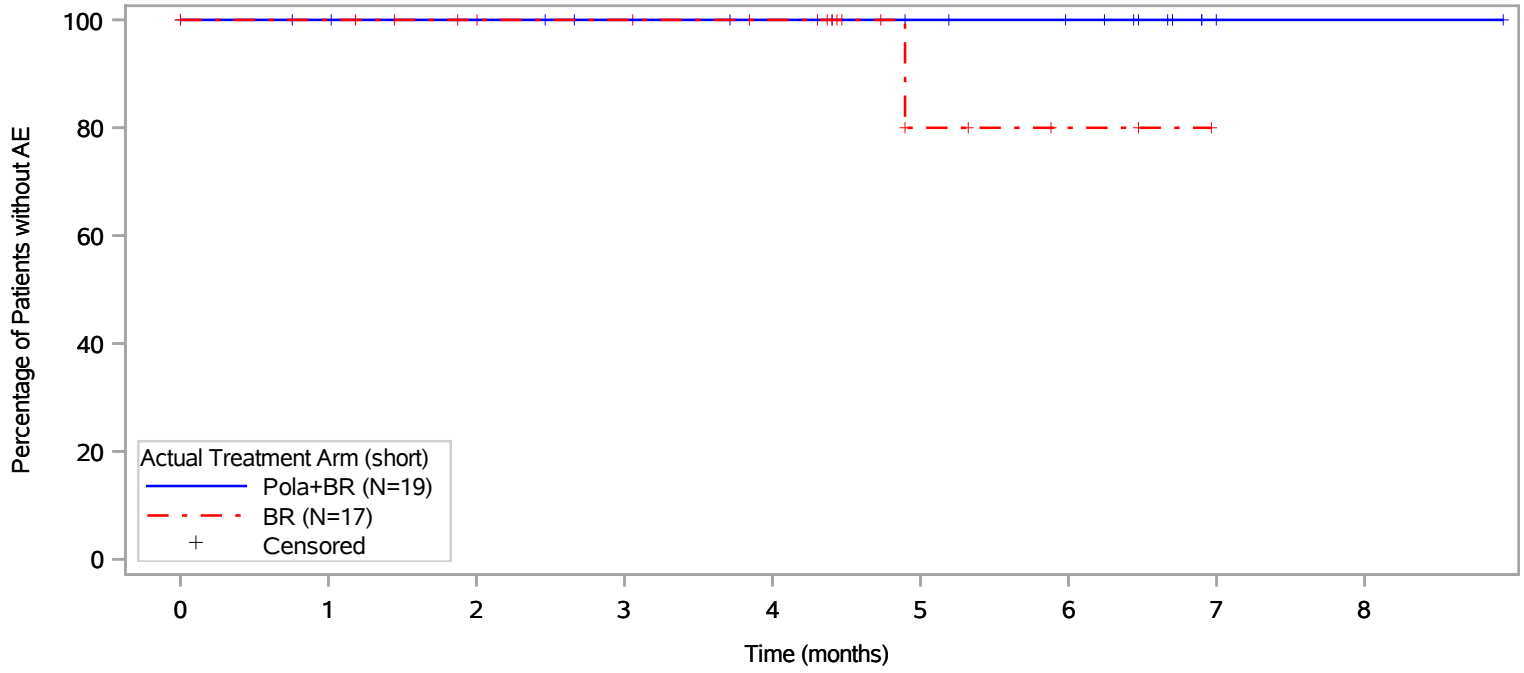
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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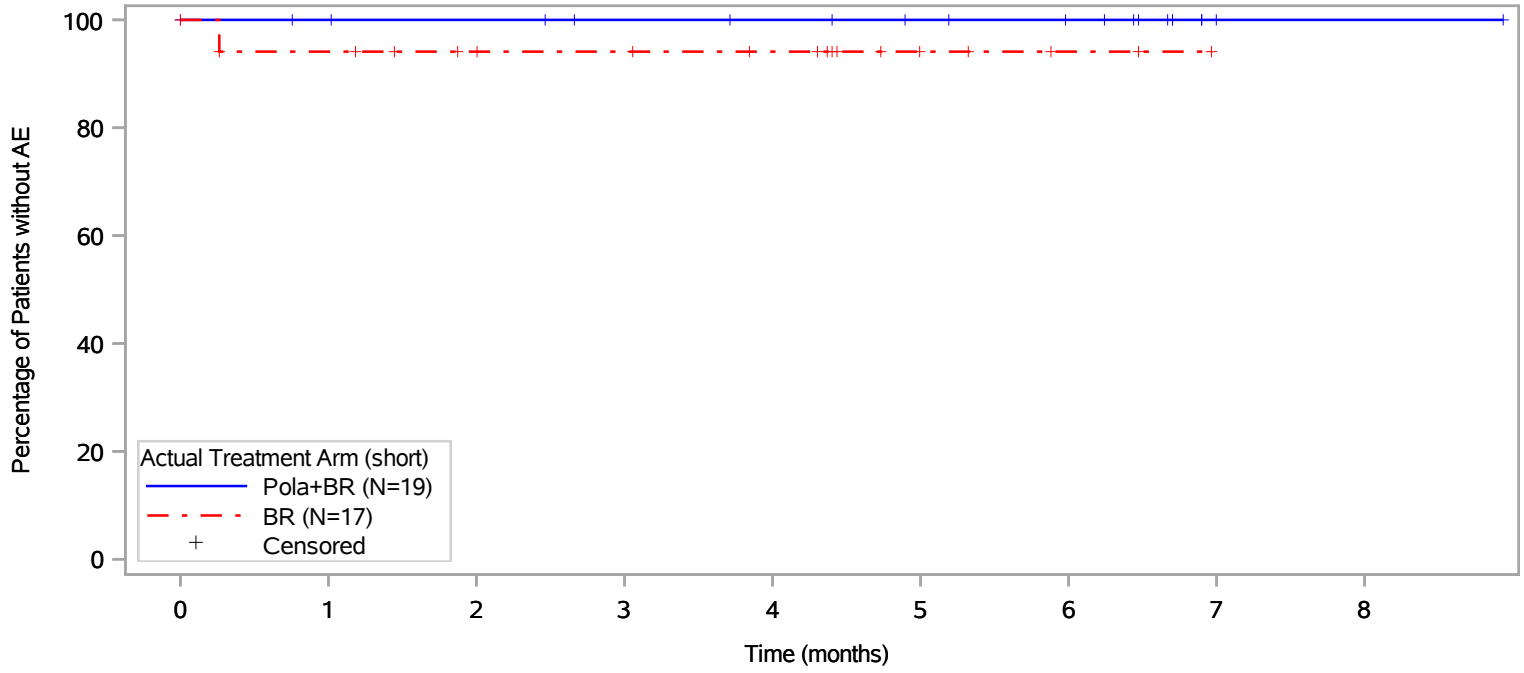
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL

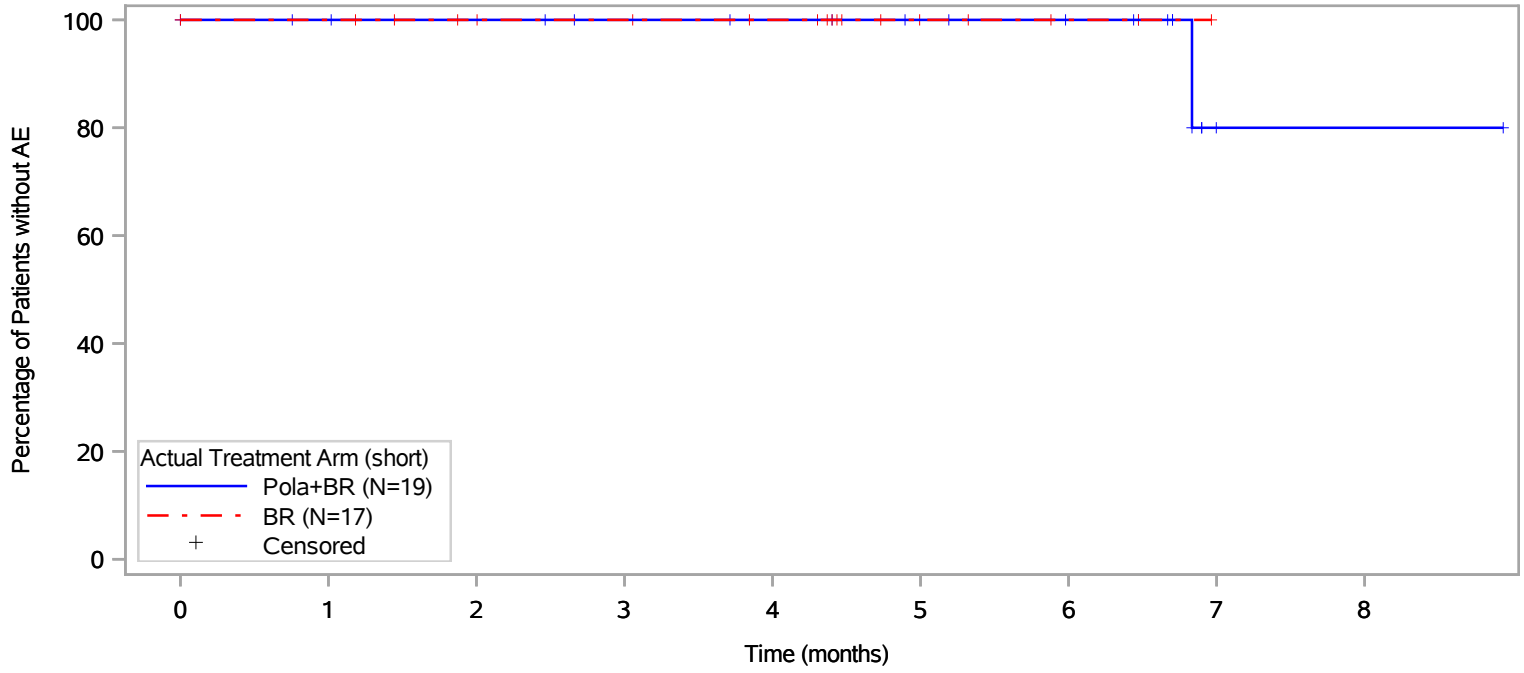


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

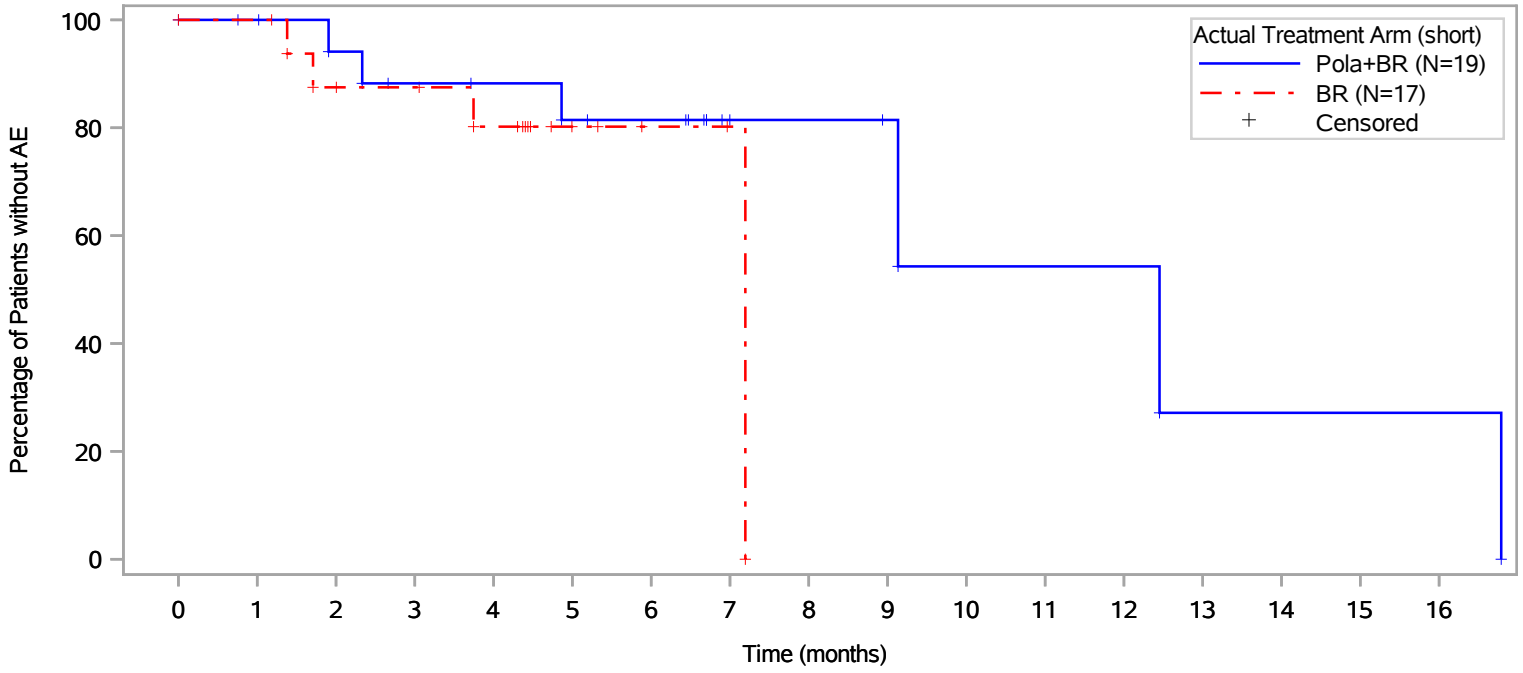
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk																	
Pola+BR (N=19)	19	18	16	14	13	12	11	4	4	3	2	2	2	1	1	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																	
Pola+BR (N=19)	0	1	2	3	4	4	5	12	12	13	13	13	13	13	13	13	13
BR (N=17)	0	0	1	2	3	10	12	13	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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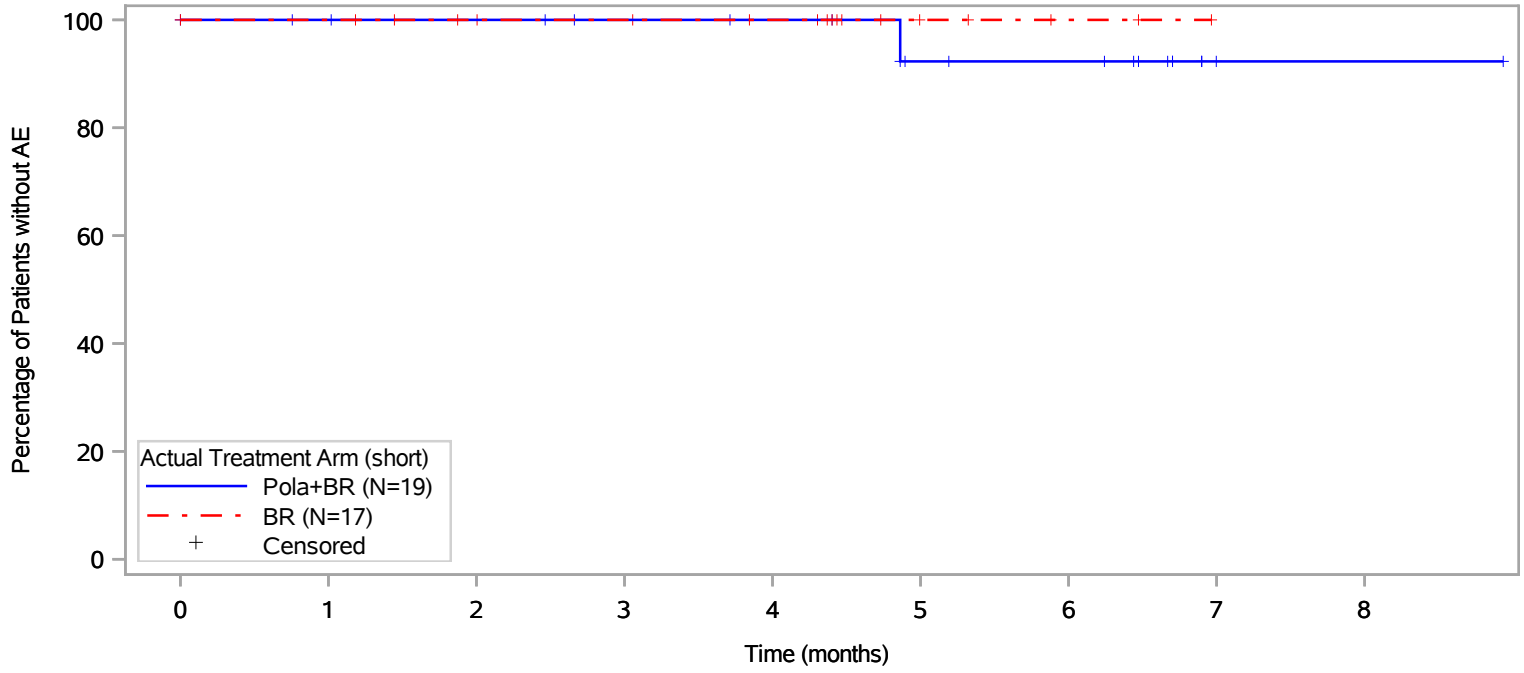
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CEREBRAL TOXOPLASMOSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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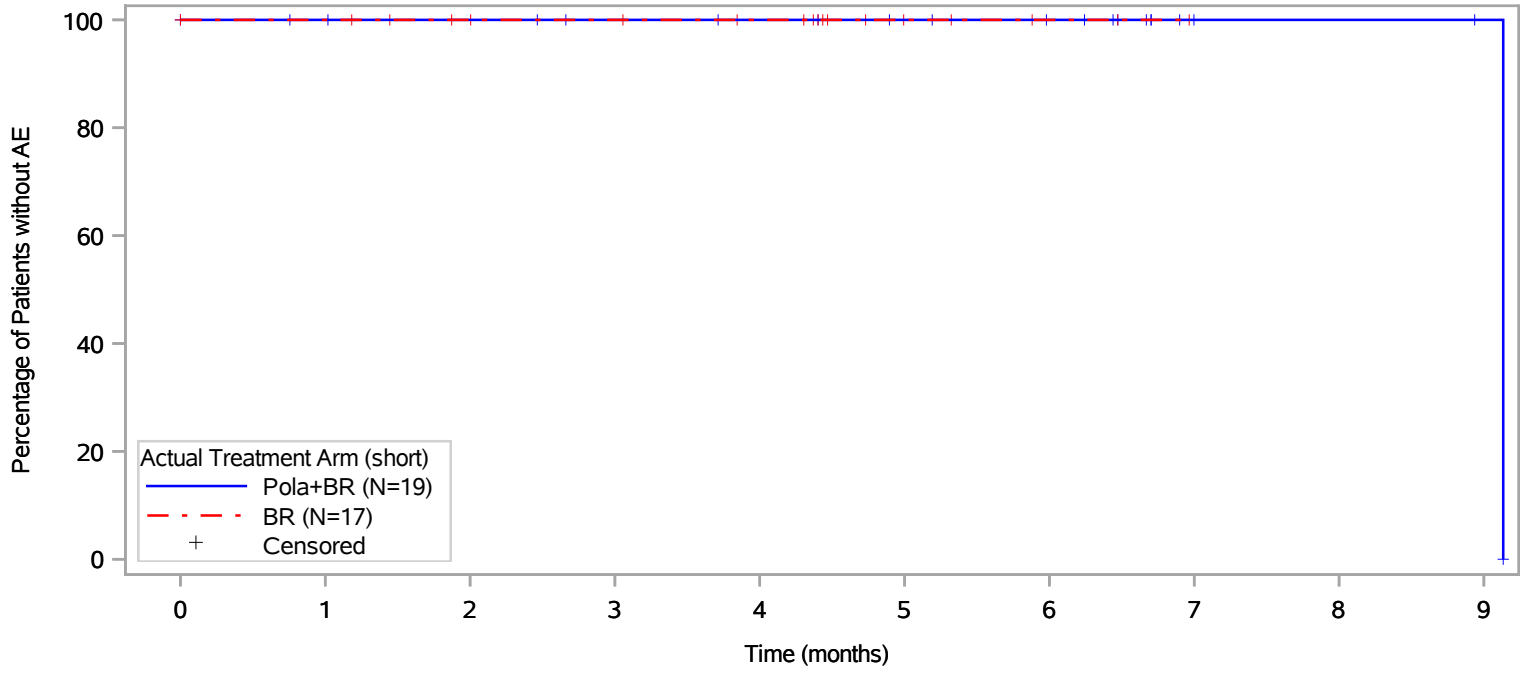
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES VIRUS INFECTION



Patients at risk										
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L2_ARMCDPLUSSE_29365_41543.pdf
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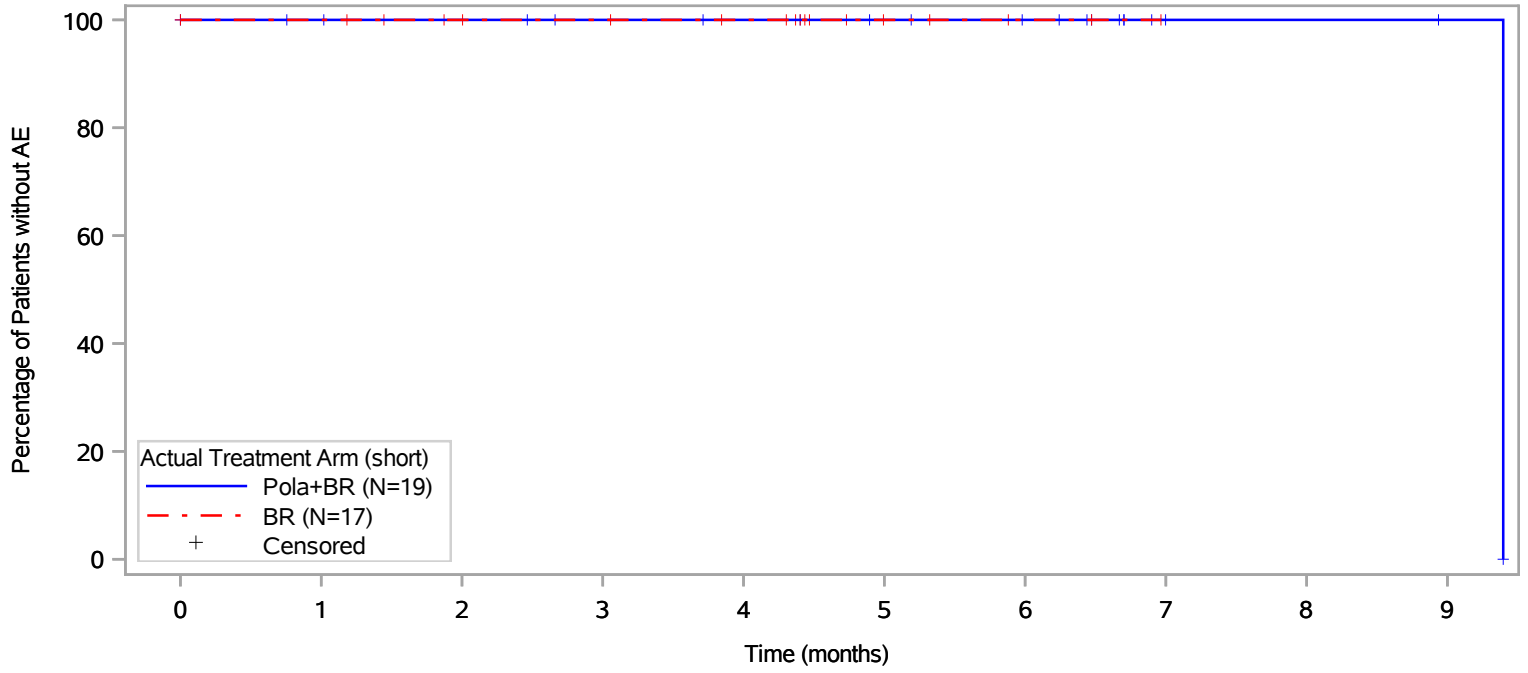
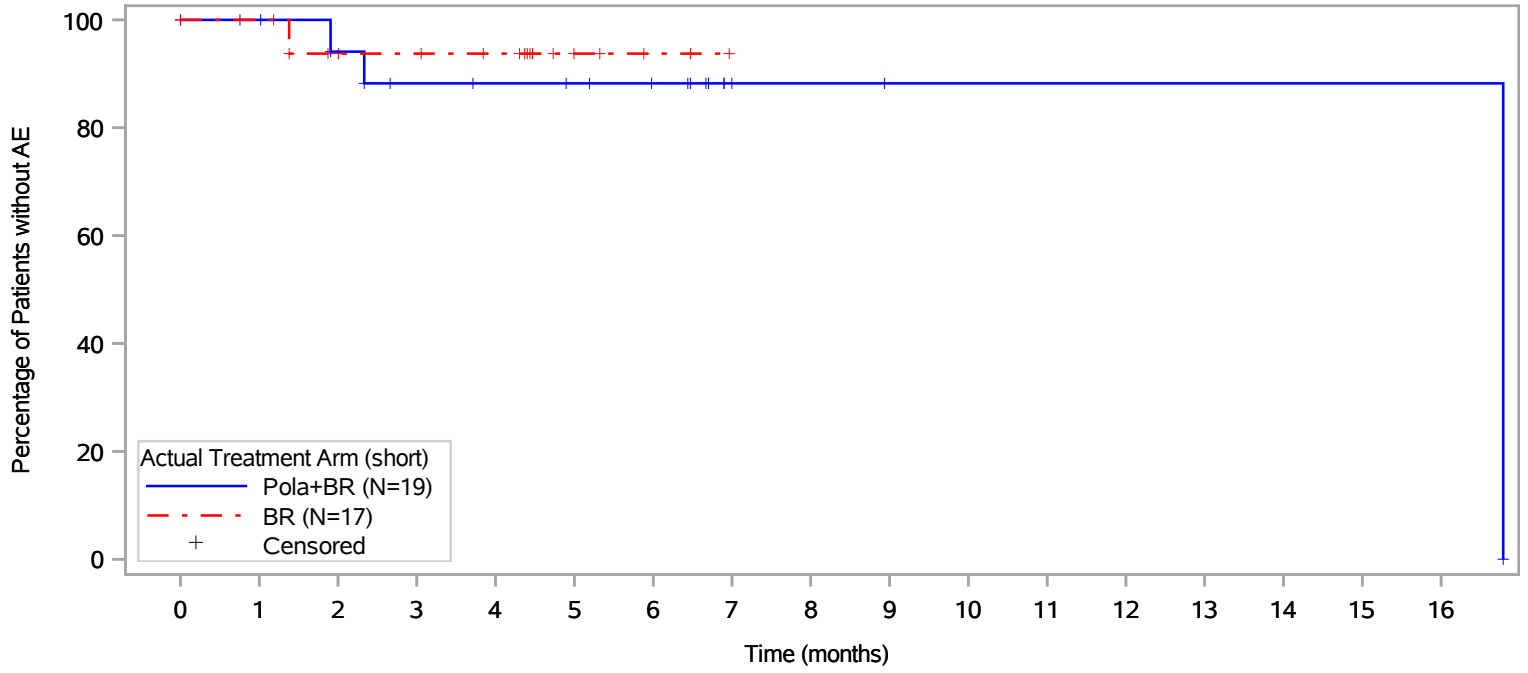
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MENINGOENCEPHALITIS HERPETIC



Patients at risk										
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE
Patients censored										
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk																	
Pola+BR (N=19)	19	18	16	14	13	12	10	2	2	1	1	1	1	1	1	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																	
Pola+BR (N=19)	0	1	2	3	4	5	7	15	15	16	16	16	16	16	16	16	16
BR (N=17)	0	0	2	3	5	12	14	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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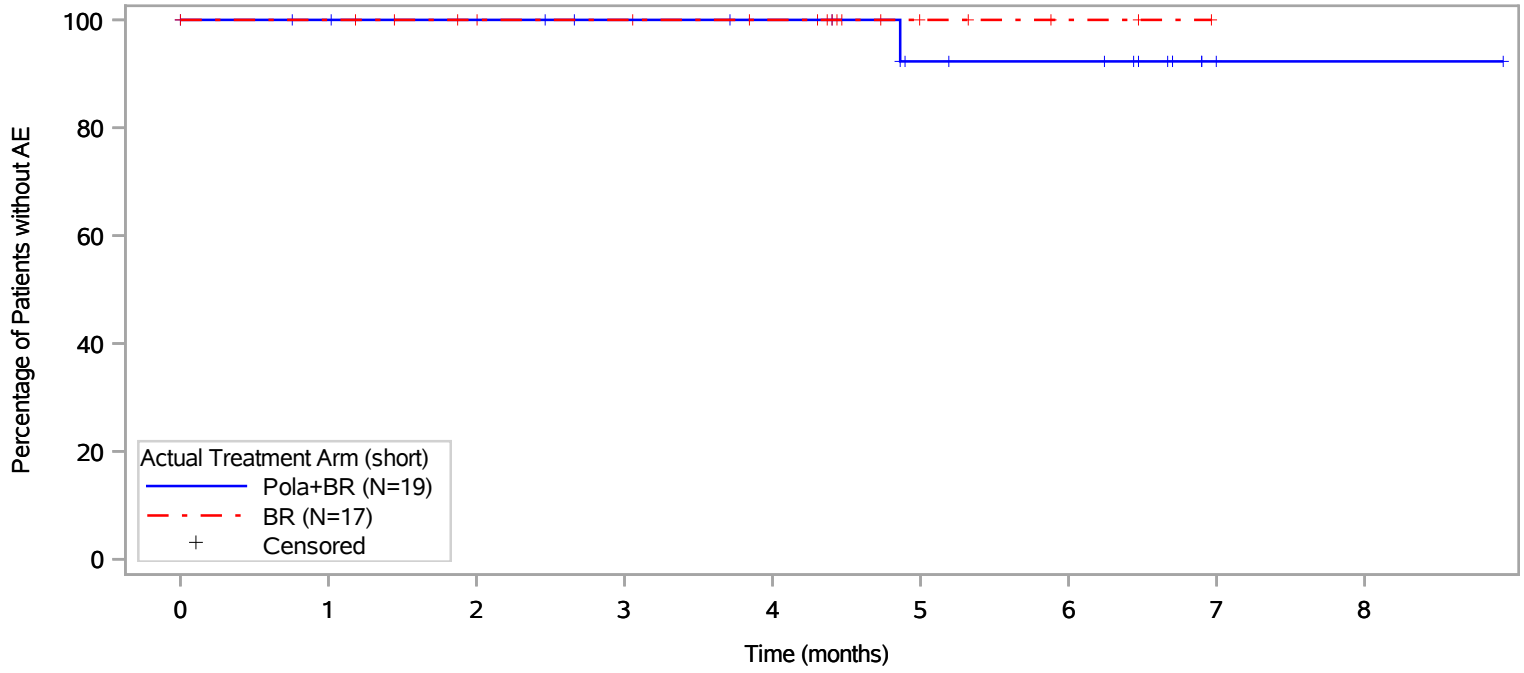
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA CYTOMEGALOVIRAL

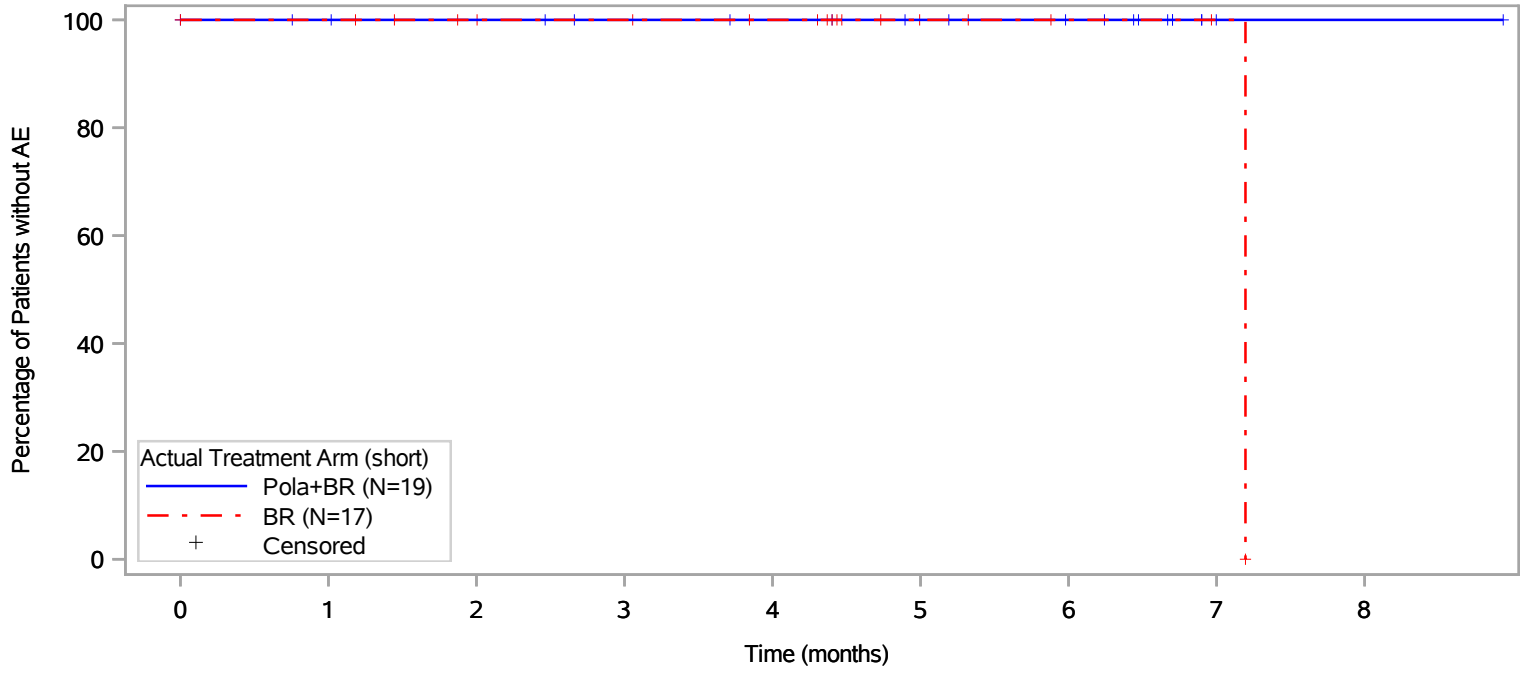


Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, POST PROCEDURAL INFECTION



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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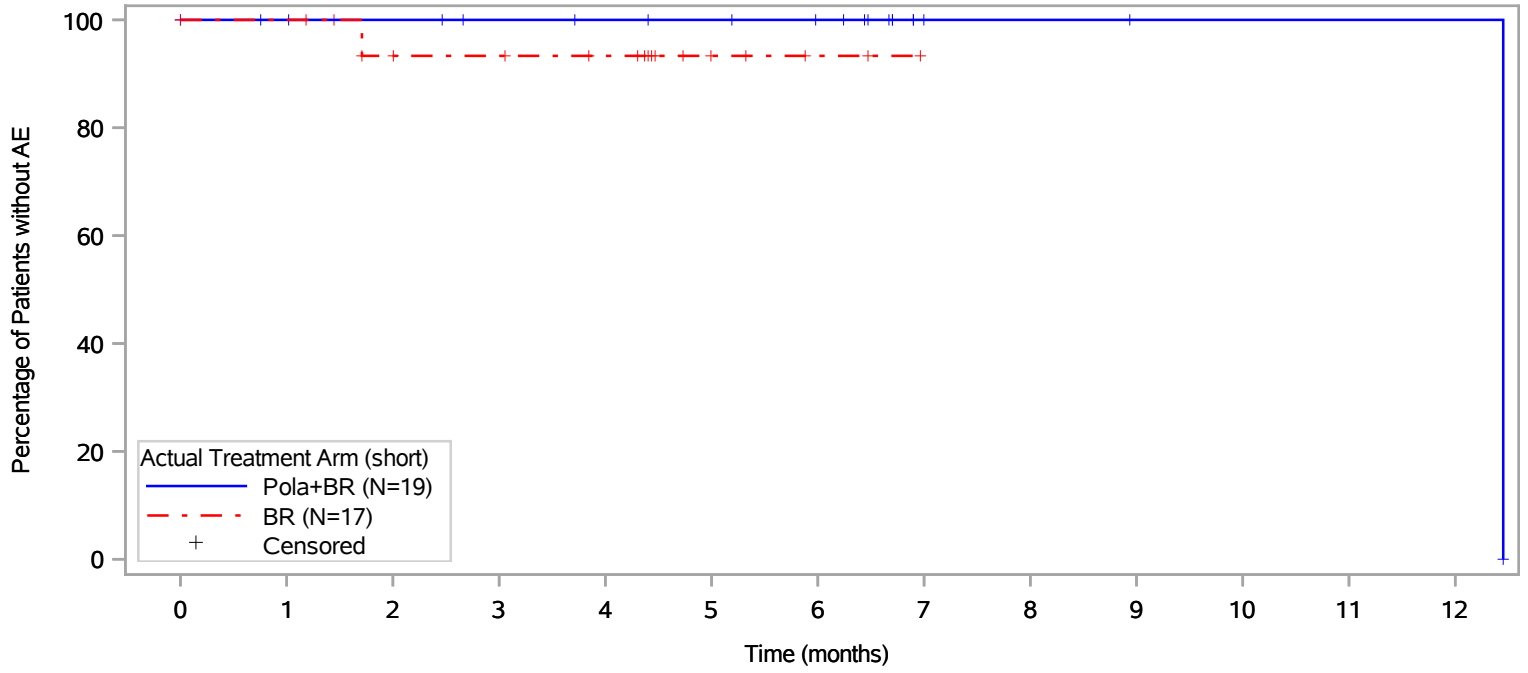
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk													
Pola+BR (N=19)	19	18	17	15	14	13	11	2	2	1	1	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	2	4	5	6	8	17	17	18	18	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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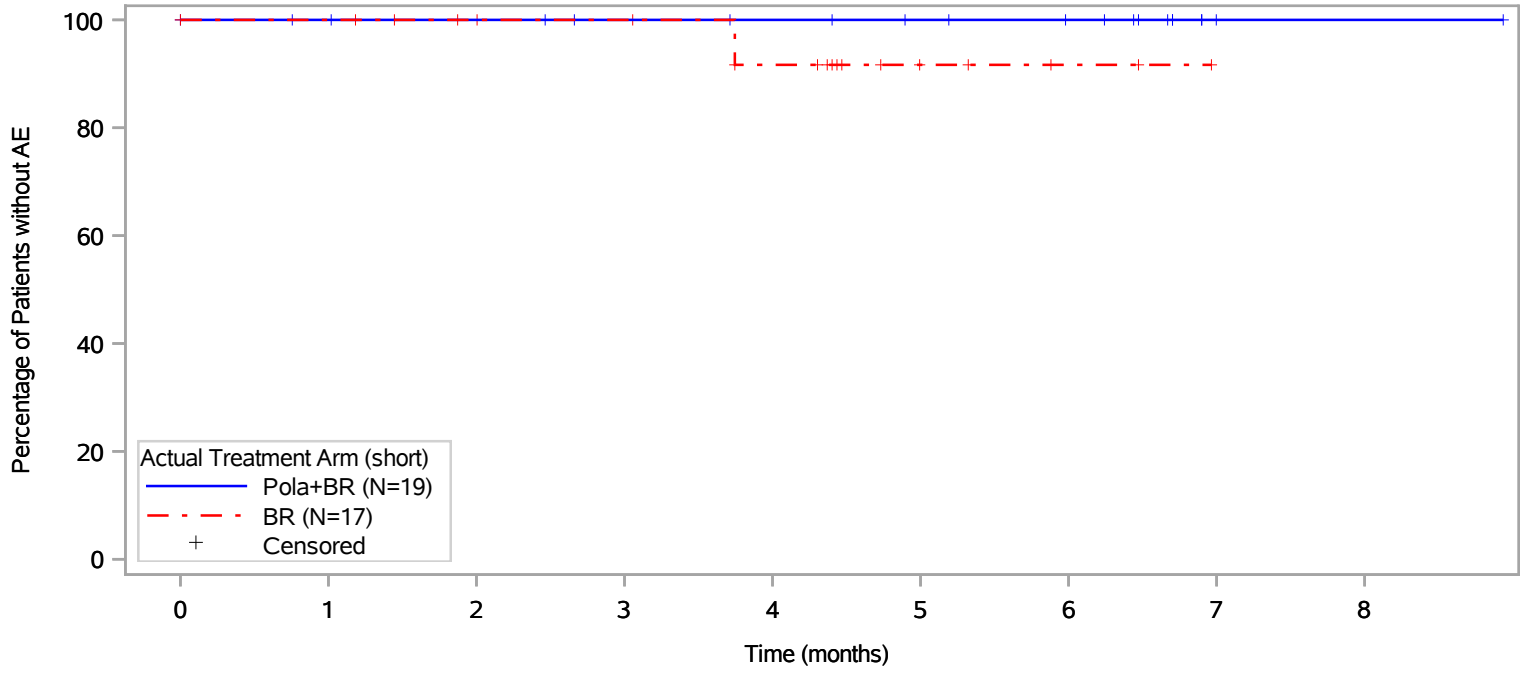
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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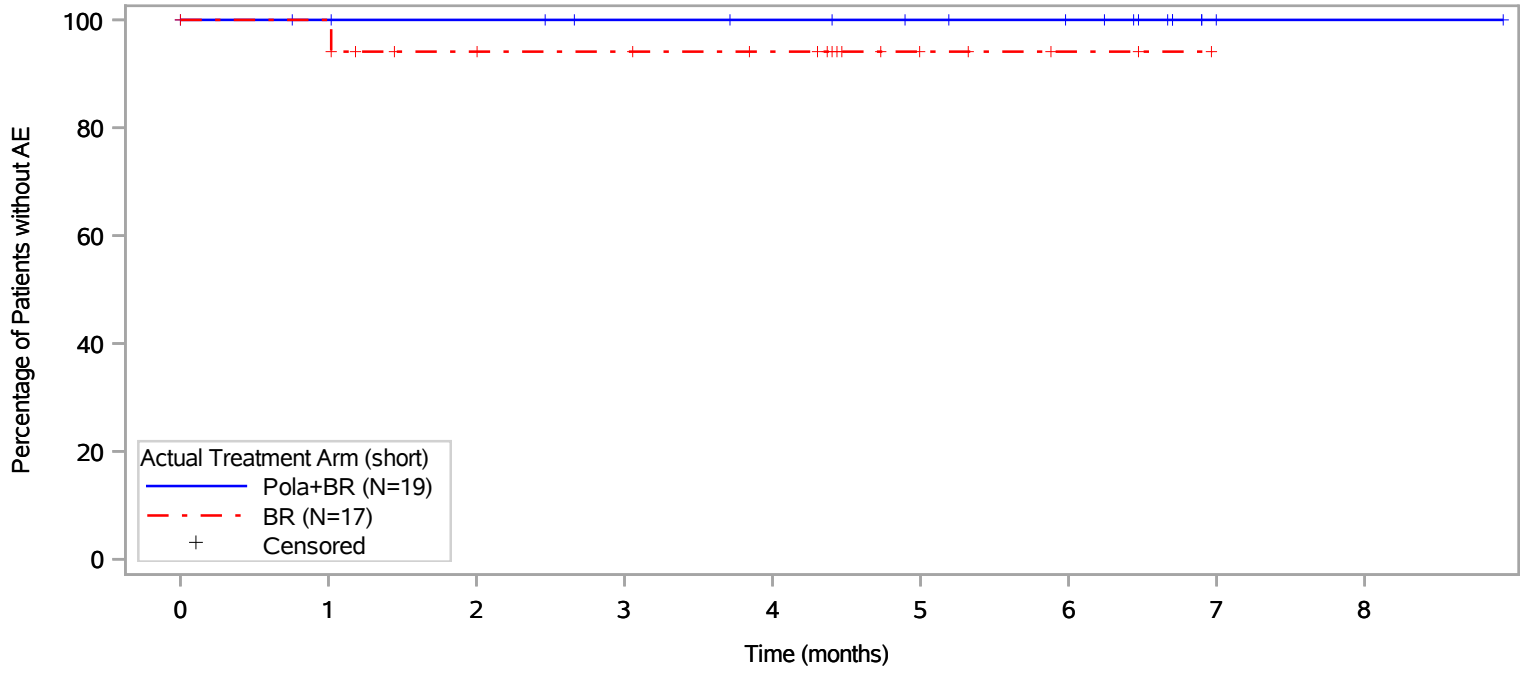
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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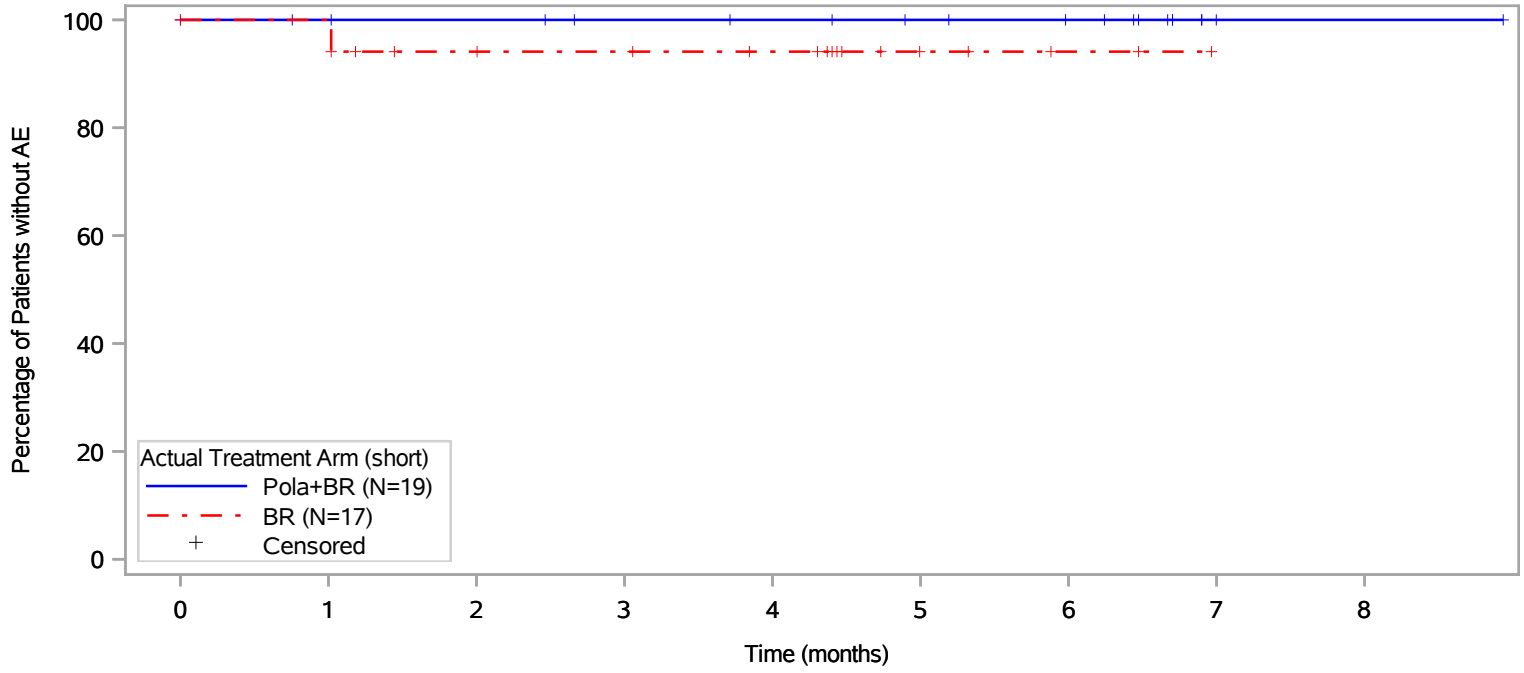
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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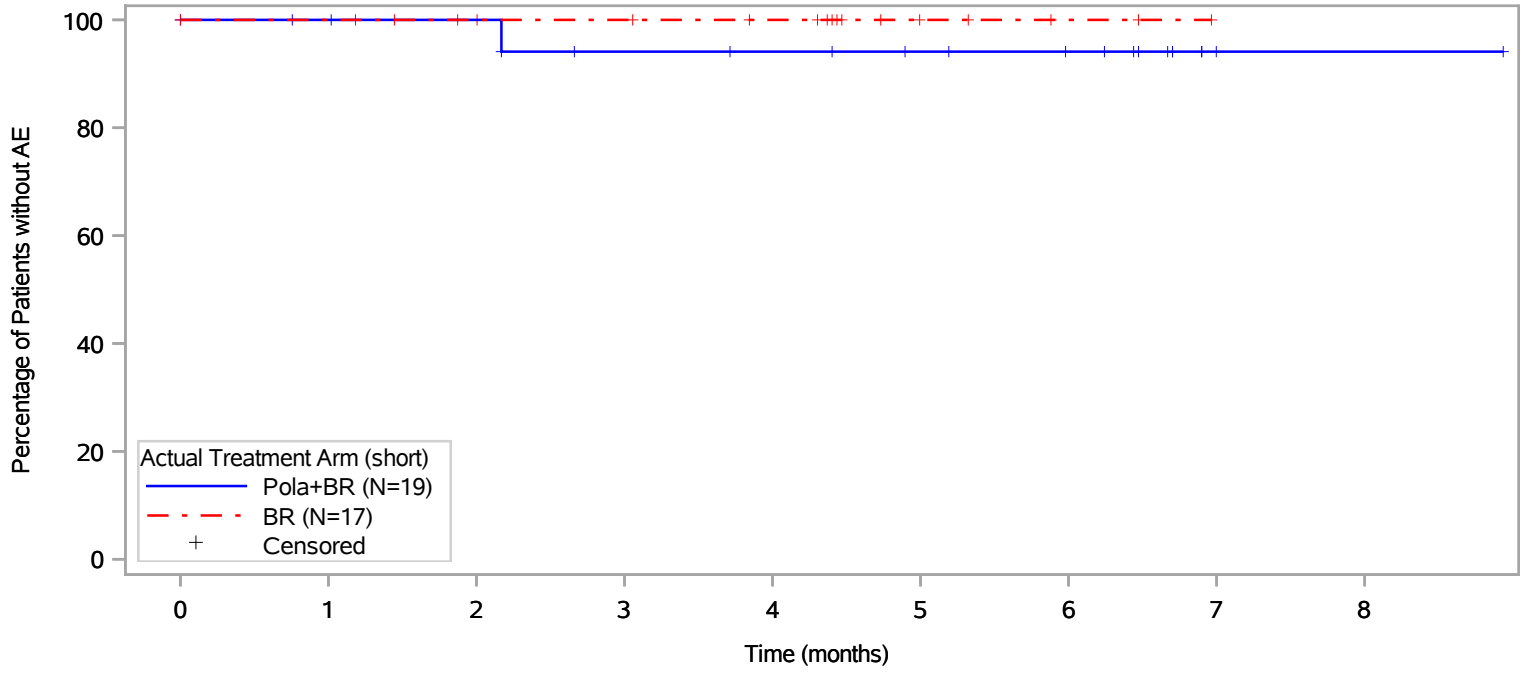
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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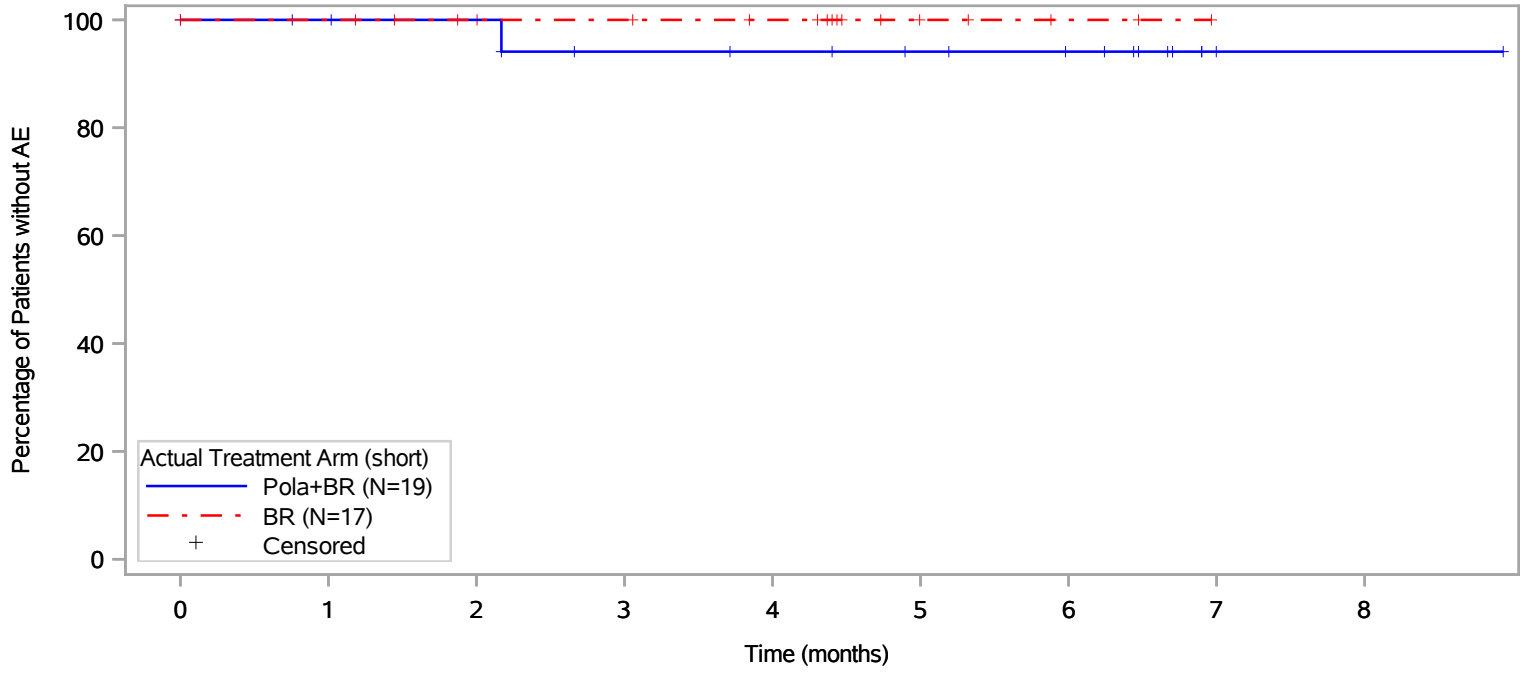
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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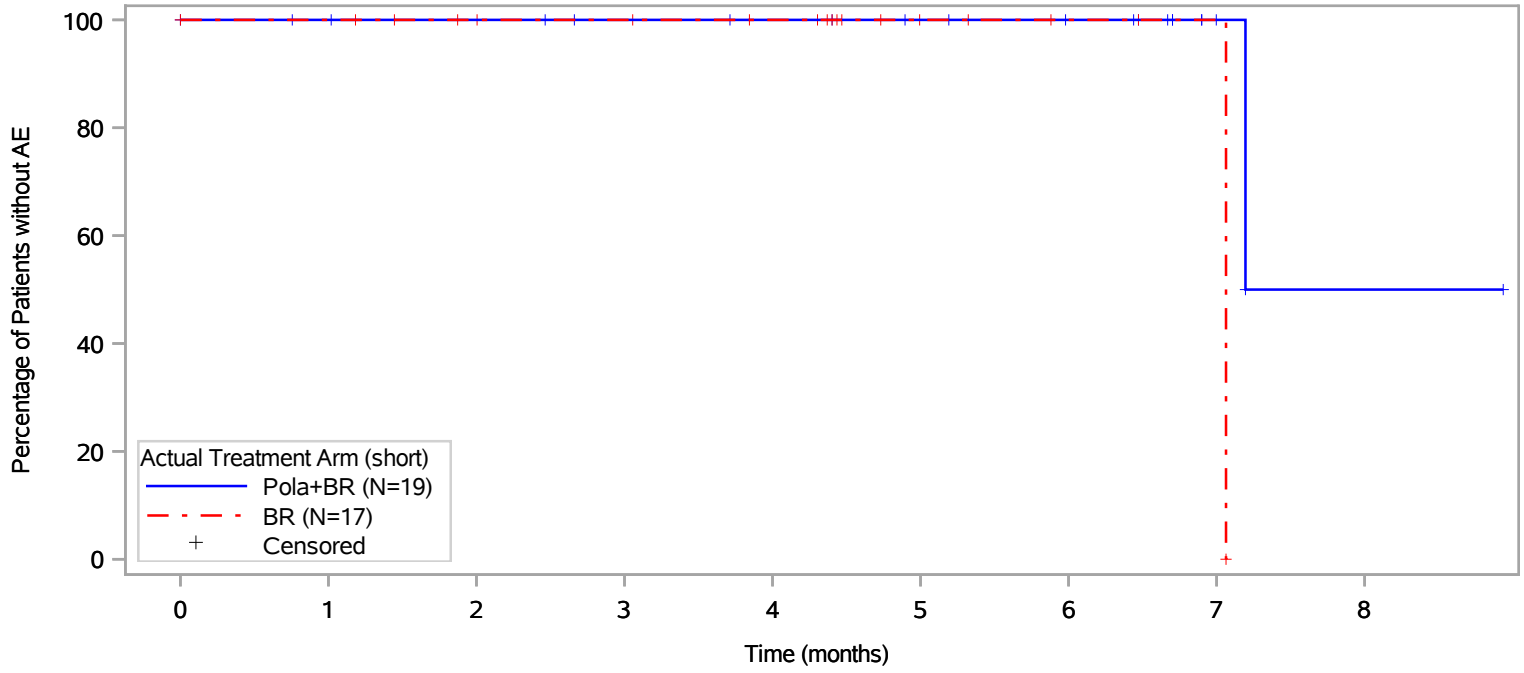
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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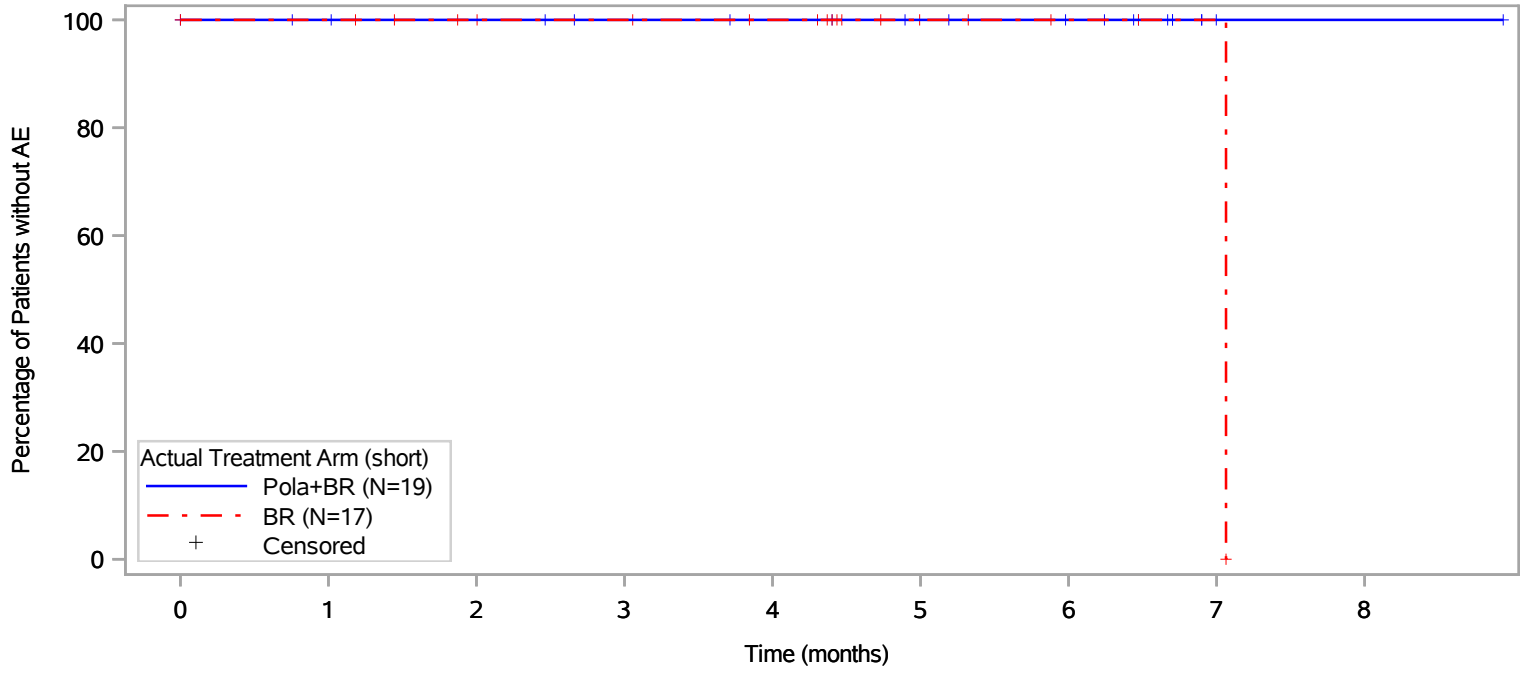
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), EPIGLOTTIC CANCER



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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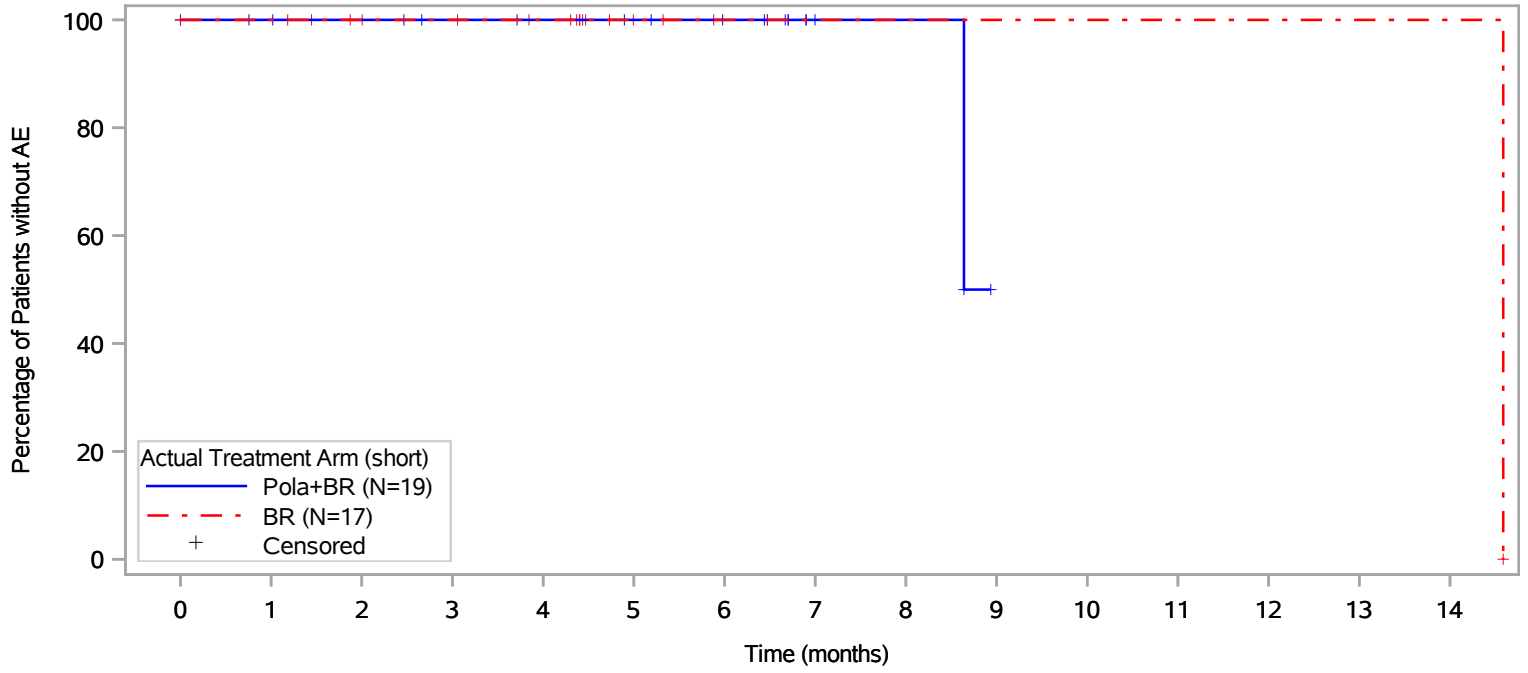
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



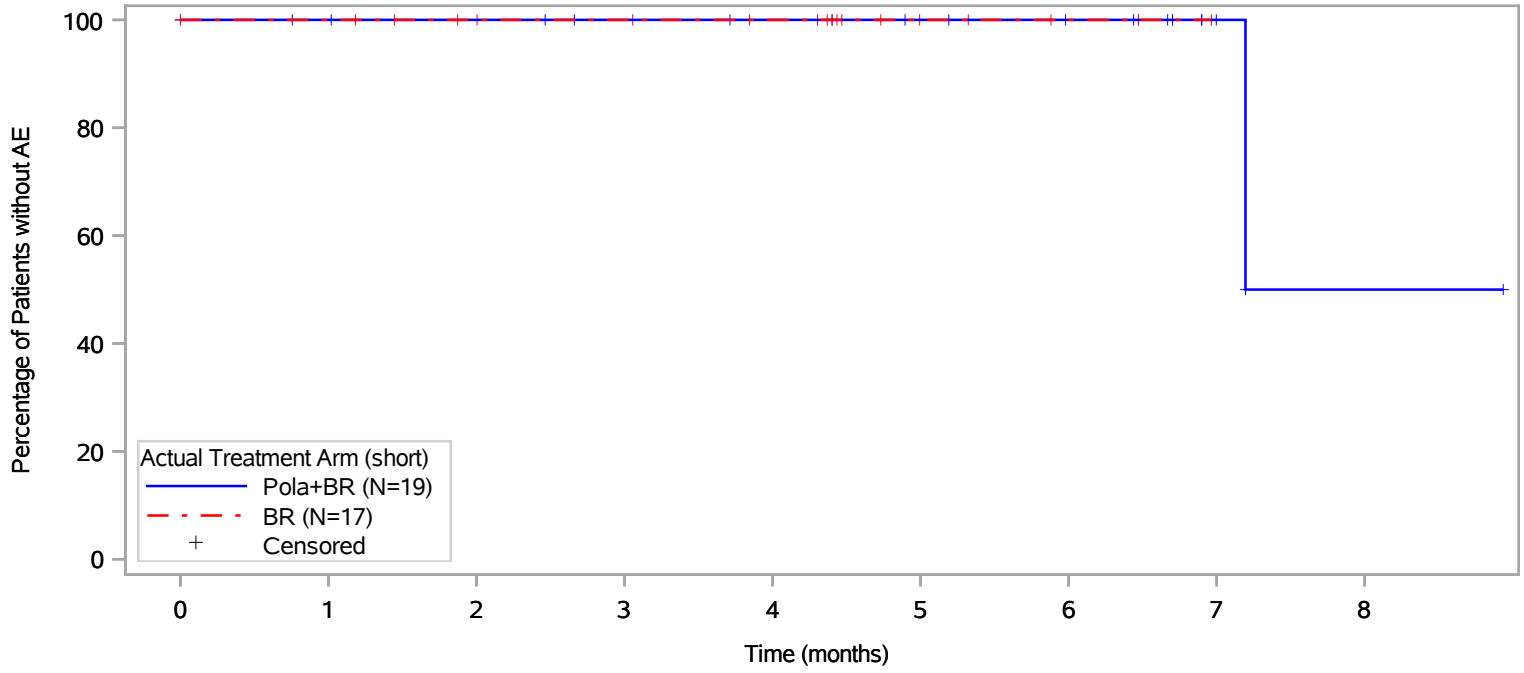
Patients at risk															
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2	NE	NE	NE	NE	NE	NE
BR (N=17)	17	17	14	13	11	4	2	1	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17	NE	NE	NE	NE	NE	NE
BR (N=17)	0	0	3	4	6	13	15	16	16	16	16	16	16	16	16

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), SQUAMOUS CELL CARCINOMA



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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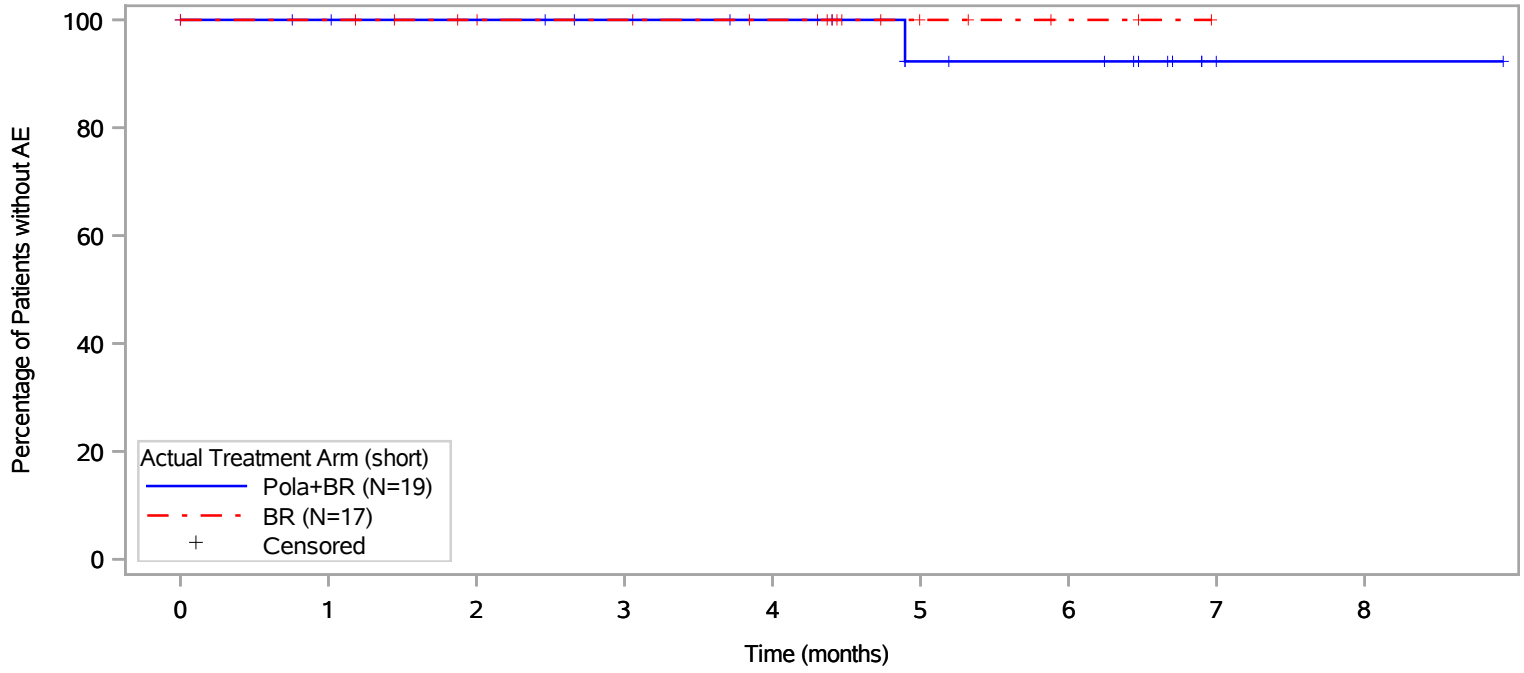
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



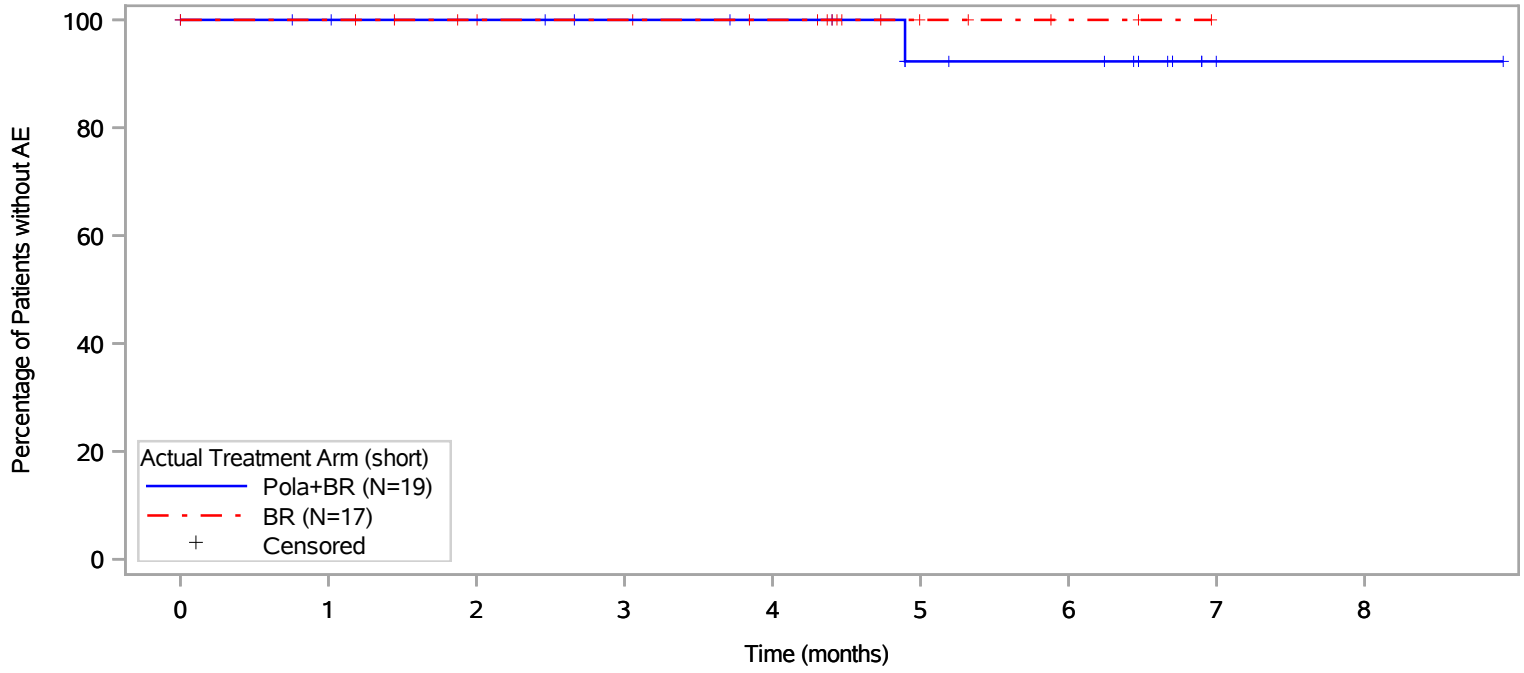
Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, VOCAL CORD PARALYSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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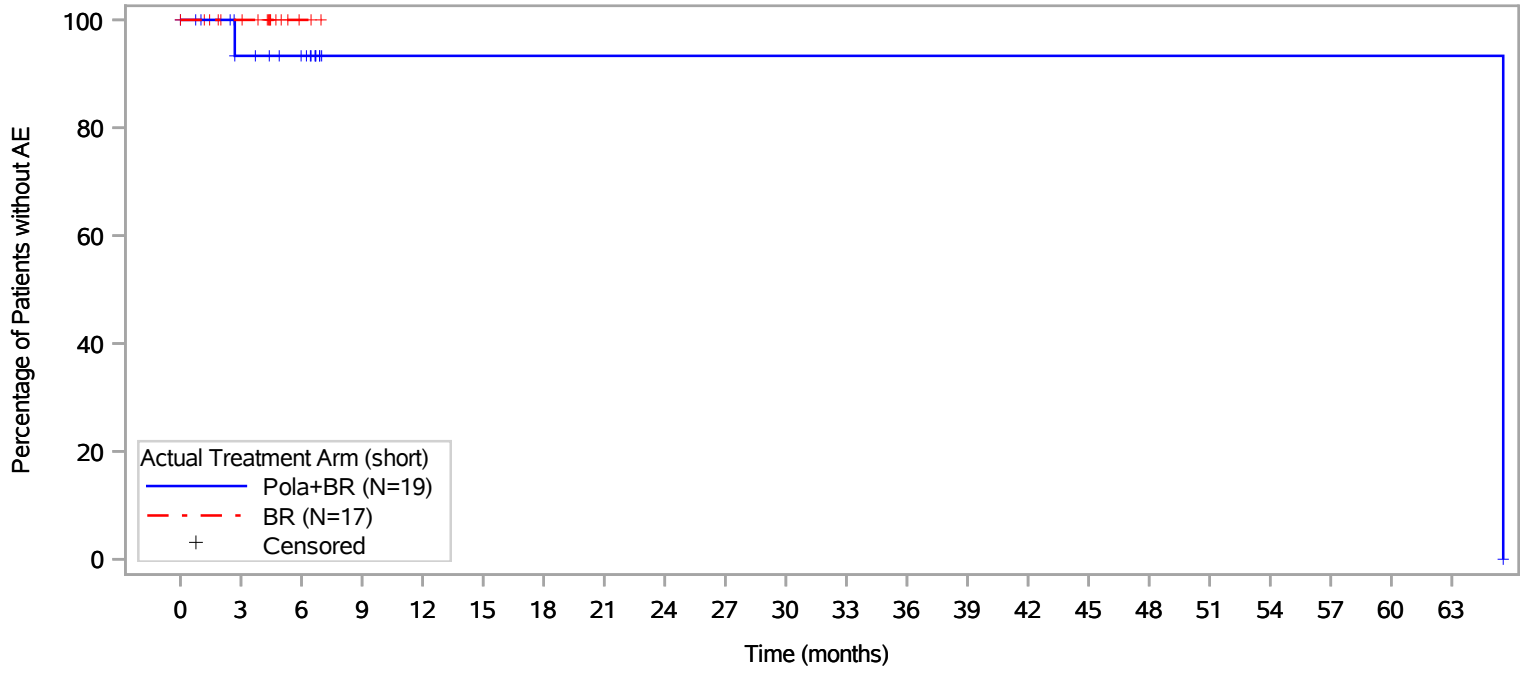
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



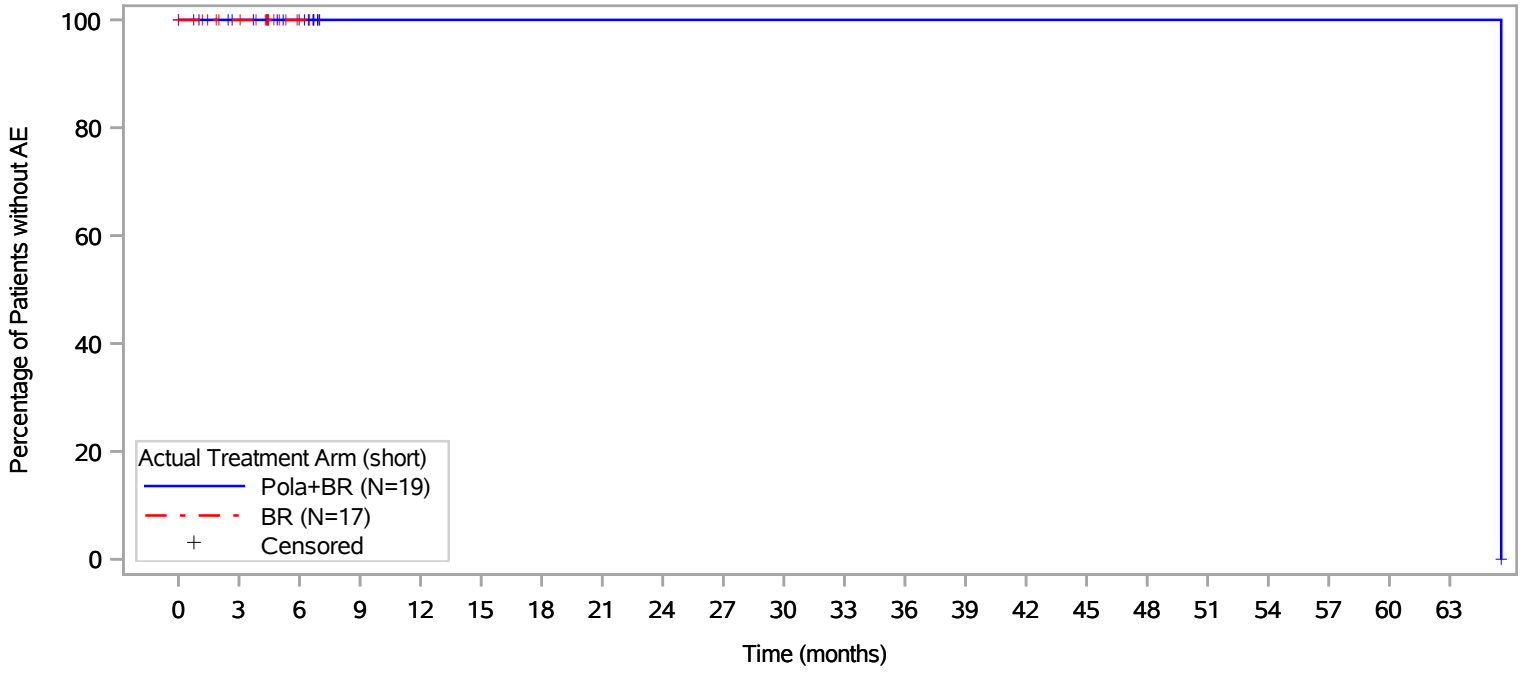
Patients at risk																							
Pola+BR (N=19)	19	14	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=17)	17	13	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=19)	0	4	8	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17
BR (N=17)	0	4	15	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

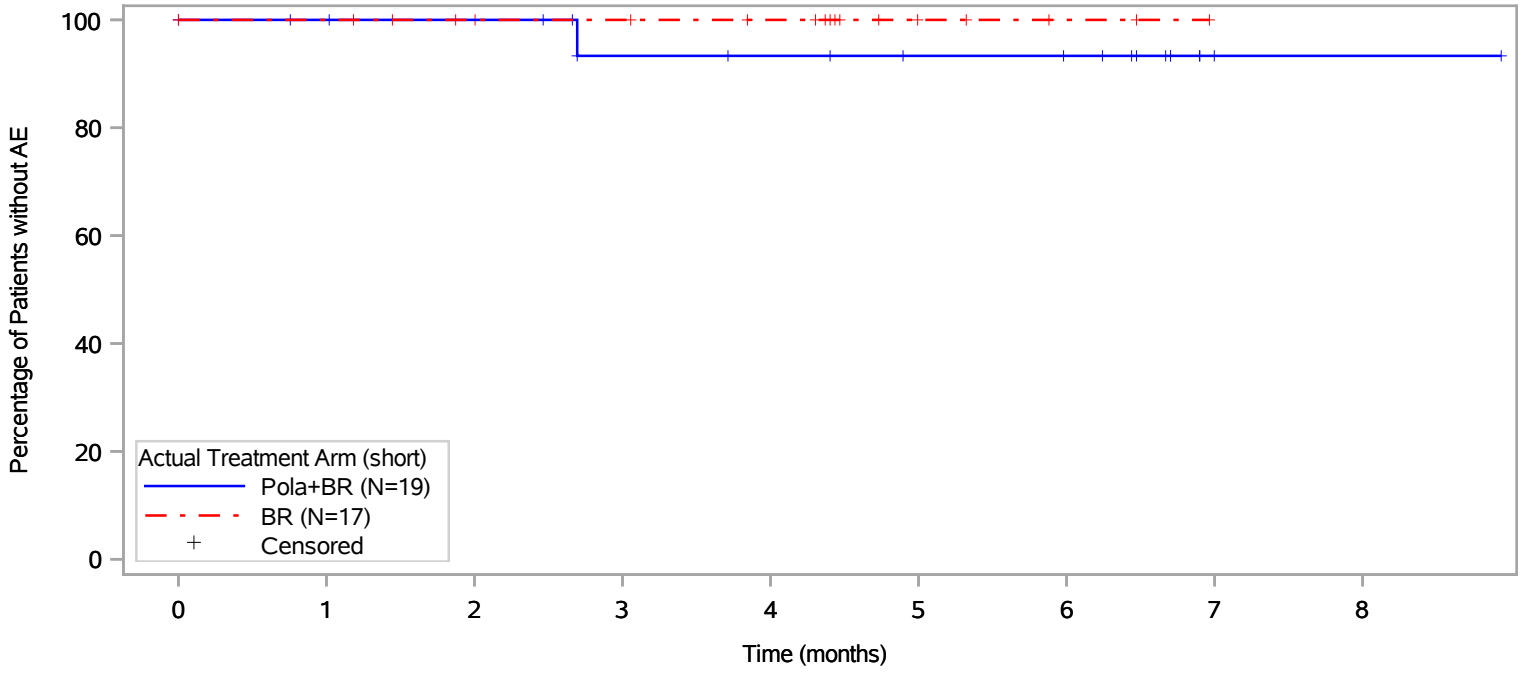
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk																							
Pola+BR (N=19)	19	15	10	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=17)	17	13	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=19)	0	4	9	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18	18
BR (N=17)	0	4	15	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

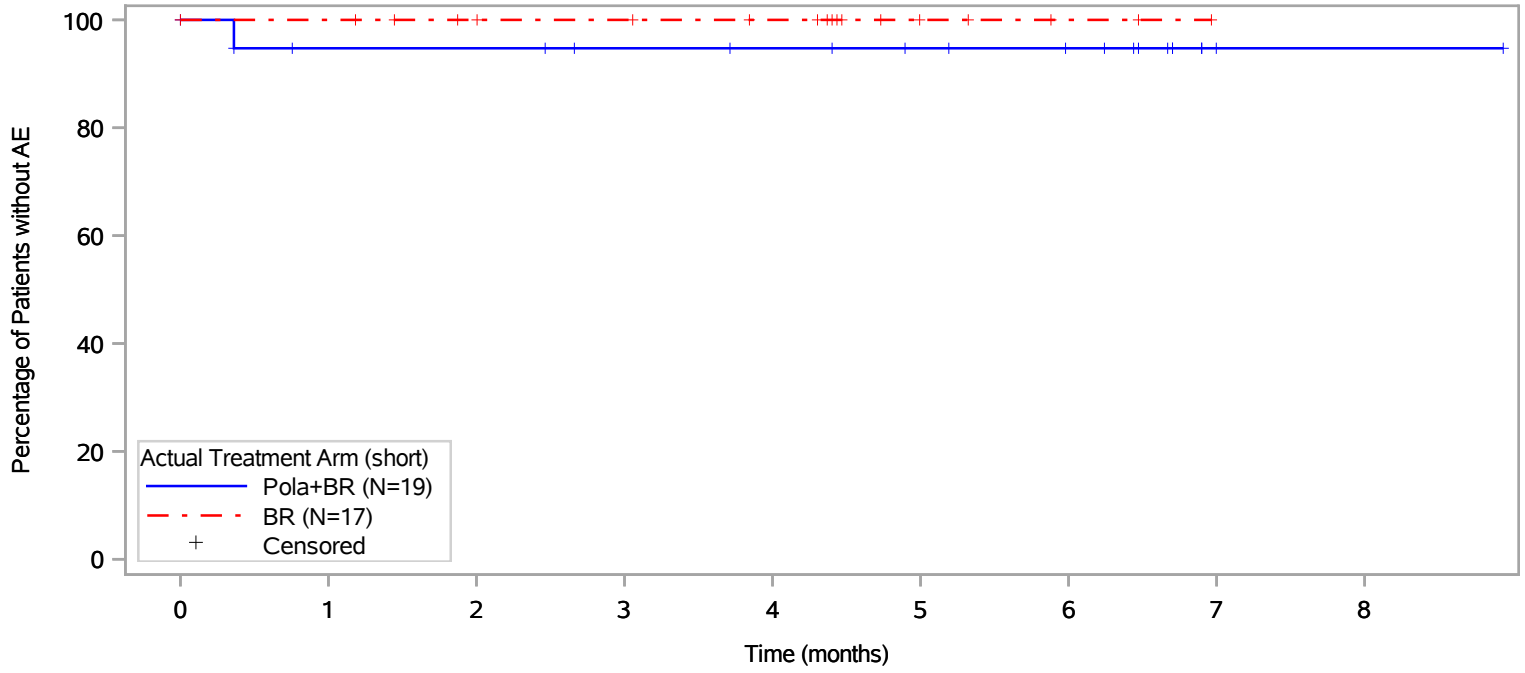
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk									
Pola+BR (N=19)	19	18	17	14	13	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



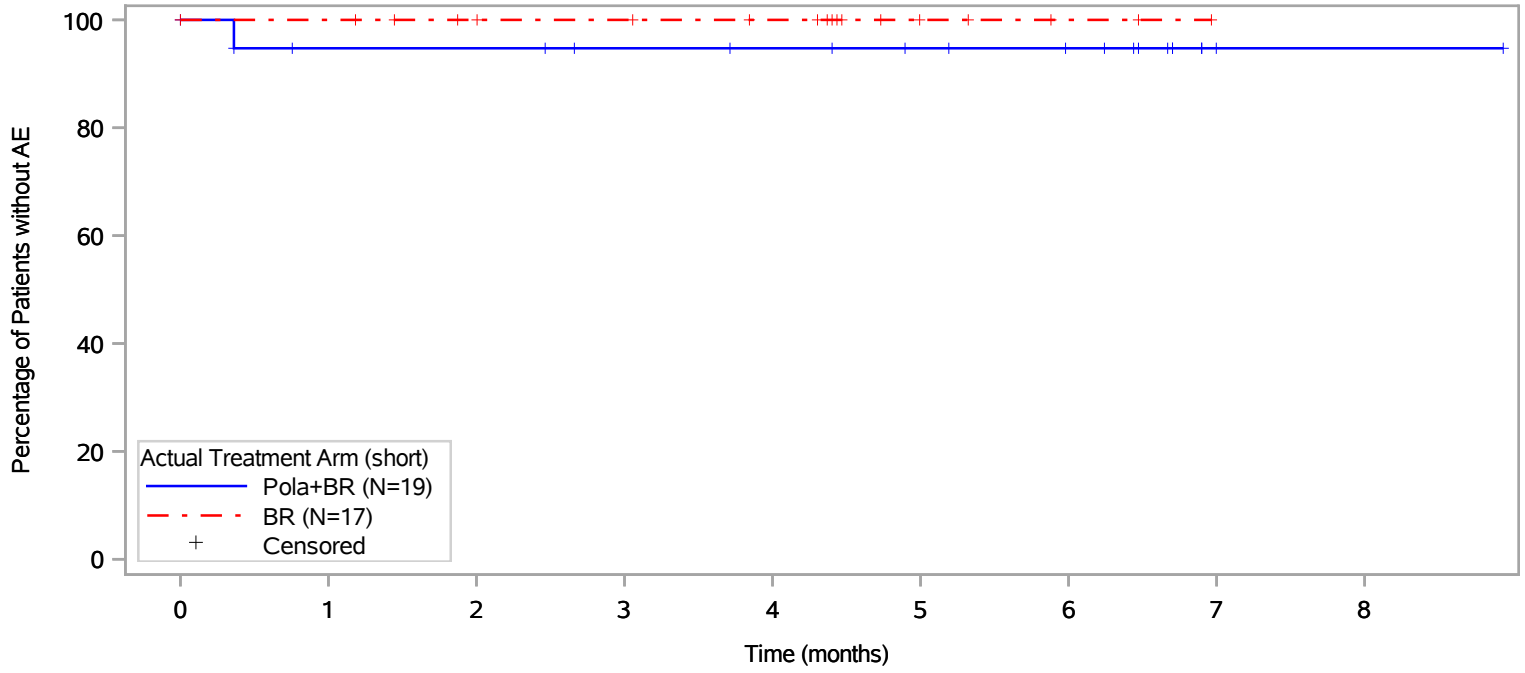
Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY OEDEMA



Patients at risk									
Pola+BR (N=19)	19	17	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	1	3	4	6	8	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L2_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)				BR (N=17)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	2	10.5	17	100.0	1	5.9
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		19	100.0	0	-	17	100.0	1	5.9
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		19	100.0	2	10.5	17	100.0	0	-
INFECTIONS AND INFESTATIONS			19	100.0	1	5.3	17	100.0	1	5.9
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	1	5.3	17	100.0	0	-
INFECTIONS AND INFESTATIONS	SEPSIS		19	100.0	0	-	17	100.0	1	5.9
INVESTIGATIONS			19	100.0	0	-	17	100.0	1	5.9
INVESTIGATIONS	PLATELET COUNT DECREASED		19	100.0	0	-	17	100.0	1	5.9
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			19	100.0	1	5.3	17	100.0	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY		19	100.0	1	5.3	17	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	2	10.5	17	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS		19	100.0	1	5.3	17	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		19	100.0	1	5.3	17	100.0	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)				BR (N=17)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	8	42.1	0	-	2	11.8	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	11	57.9	2	18.2	15	88.2	1	6.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	8	42.1	0	-	2	11.8	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	11	57.9	0	-	15	88.2	1	6.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	8	42.1	0	-	2	11.8	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	11	57.9	2	18.2	15	88.2	0	-
INFECTIONS AND INFESTATIONS		< 65	8	42.1	0	-	2	11.8	0	-
INFECTIONS AND INFESTATIONS		>= 65	11	57.9	1	9.1	15	88.2	1	6.7
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	8	42.1	0	-	2	11.8	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	11	57.9	1	9.1	15	88.2	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	8	42.1	0	-	2	11.8	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	11	57.9	0	-	15	88.2	1	6.7
INVESTIGATIONS		< 65	8	42.1	0	-	2	11.8	0	-
INVESTIGATIONS		>= 65	11	57.9	0	-	15	88.2	1	6.7
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	8	42.1	0	-	2	11.8	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	11	57.9	0	-	15	88.2	1	6.7
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	8	42.1	1	12.5	2	11.8	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	11	57.9	0	-	15	88.2	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	< 65	8	42.1	1	12.5	2	11.8	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	>= 65	11	57.9	0	-	15	88.2	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	8	42.1	1	12.5	2	11.8	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	11	57.9	1	9.1	15	88.2	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	< 65	8	42.1	0	-	2	11.8	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	>= 65	11	57.9	1	9.1	15	88.2	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	8	42.1	1	12.5	2	11.8	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	11	57.9	0	-	15	88.2	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)				BR (N=17)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	8	42.1	2	25.0	14	82.4	1	7.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	11	57.9	0	-	3	17.6	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	8	42.1	0	-	14	82.4	1	7.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	11	57.9	0	-	3	17.6	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	8	42.1	2	25.0	14	82.4	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	11	57.9	0	-	3	17.6	0	-
INFECTIONS AND INFESTATIONS		>=3	8	42.1	1	12.5	14	82.4	1	7.1
INFECTIONS AND INFESTATIONS		<3	11	57.9	0	-	3	17.6	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	8	42.1	1	12.5	14	82.4	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	11	57.9	0	-	3	17.6	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	8	42.1	0	-	14	82.4	1	7.1
INFECTIONS AND INFESTATIONS	SEPSIS	<3	11	57.9	0	-	3	17.6	0	-
INVESTIGATIONS		>=3	8	42.1	0	-	14	82.4	1	7.1
INVESTIGATIONS		<3	11	57.9	0	-	3	17.6	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	8	42.1	0	-	14	82.4	1	7.1
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	11	57.9	0	-	3	17.6	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	8	42.1	0	-	14	82.4	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	11	57.9	1	9.1	3	17.6	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	>=3	8	42.1	0	-	14	82.4	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	<3	11	57.9	1	9.1	3	17.6	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	8	42.1	2	25.0	14	82.4	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	11	57.9	0	-	3	17.6	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	>=3	8	42.1	1	12.5	14	82.4	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	<3	11	57.9	0	-	3	17.6	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	8	42.1	1	12.5	14	82.4	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	11	57.9	0	-	3	17.6	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)				BR (N=17)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	26.3	1	20.0	3	17.6	1	33.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	14	73.7	1	7.1	14	82.4	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	26.3	0	-	3	17.6	1	33.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	14	73.7	0	-	14	82.4	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	26.3	1	20.0	3	17.6	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	14	73.7	1	7.1	14	82.4	0	-
INFECTIONS AND INFESTATIONS		Europe	5	26.3	0	-	3	17.6	0	-
INFECTIONS AND INFESTATIONS		Non-Europe	14	73.7	1	7.1	14	82.4	1	7.1
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	26.3	0	-	3	17.6	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	14	73.7	1	7.1	14	82.4	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	26.3	0	-	3	17.6	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	14	73.7	0	-	14	82.4	1	7.1
INVESTIGATIONS		Europe	5	26.3	0	-	3	17.6	0	-
INVESTIGATIONS		Non-Europe	14	73.7	0	-	14	82.4	1	7.1
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	5	26.3	0	-	3	17.6	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	14	73.7	0	-	14	82.4	1	7.1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	5	26.3	0	-	3	17.6	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	14	73.7	1	7.1	14	82.4	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Europe	5	26.3	0	-	3	17.6	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Non-Europe	14	73.7	1	7.1	14	82.4	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	26.3	0	-	3	17.6	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	14	73.7	2	14.3	14	82.4	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Europe	5	26.3	0	-	3	17.6	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Non-Europe	14	73.7	1	7.1	14	82.4	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	26.3	0	-	3	17.6	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	14	73.7	1	7.1	14	82.4	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)				BR (N=17)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	1	7.1	8	47.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	1	20.0	9	52.9	1	11.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	14	73.7	0	-	8	47.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	5	26.3	0	-	9	52.9	1	11.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	14	73.7	1	7.1	8	47.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	5	26.3	1	20.0	9	52.9	0	-
INFECTIONS AND INFESTATIONS		Male	14	73.7	1	7.1	8	47.1	1	12.5
INFECTIONS AND INFESTATIONS		Female	5	26.3	0	-	9	52.9	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	1	7.1	8	47.1	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	0	-	9	52.9	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	Male	14	73.7	0	-	8	47.1	1	12.5
INFECTIONS AND INFESTATIONS	SEPSIS	Female	5	26.3	0	-	9	52.9	0	-
INVESTIGATIONS		Male	14	73.7	0	-	8	47.1	0	-
INVESTIGATIONS		Female	5	26.3	0	-	9	52.9	1	11.1
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	14	73.7	0	-	8	47.1	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	5	26.3	0	-	9	52.9	1	11.1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	14	73.7	1	7.1	8	47.1	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	5	26.3	0	-	9	52.9	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Male	14	73.7	1	7.1	8	47.1	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Female	5	26.3	0	-	9	52.9	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	2	14.3	8	47.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	0	-	9	52.9	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Male	14	73.7	1	7.1	8	47.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Female	5	26.3	0	-	9	52.9	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	14	73.7	1	7.1	8	47.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	5	26.3	0	-	9	52.9	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTADAP_L2_ARMCDPLUSSE_29365_41543.xls
06APR2023 19:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	0	-	12	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTADAP_L2_ARMCDPLUSSE_29365_41543.xls
25OCT2023 8:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	0	-	12	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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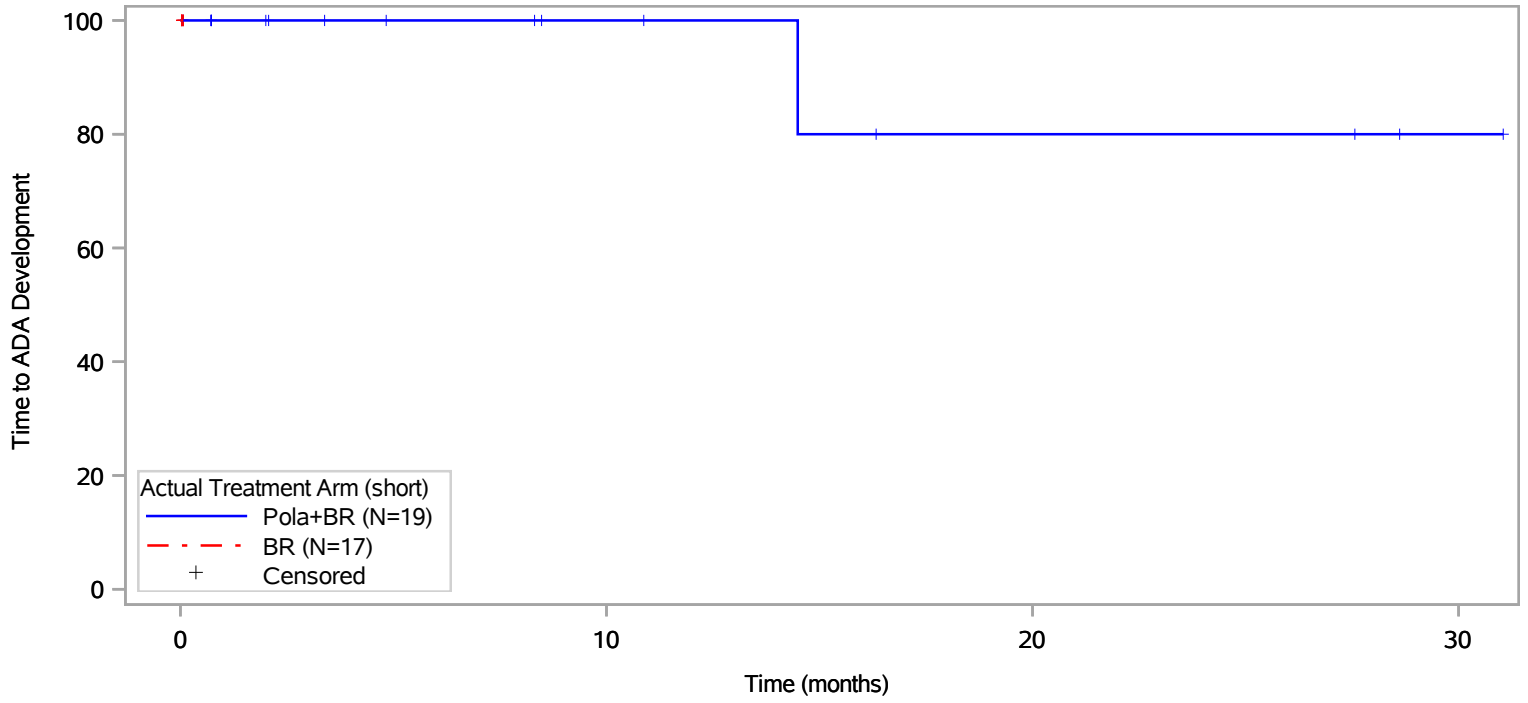
25OCT2023 8:42

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=19)	19	10	8	6	5	4	3	3	3	3	1
BR (N=17)	17	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=19)	0	9	11	13	14	14	15	15	15	15	17
BR (N=17)	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..nalysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTADAP_L2_ARMCDPLUSSE_29365_41543.pdf
06APR2023 19:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

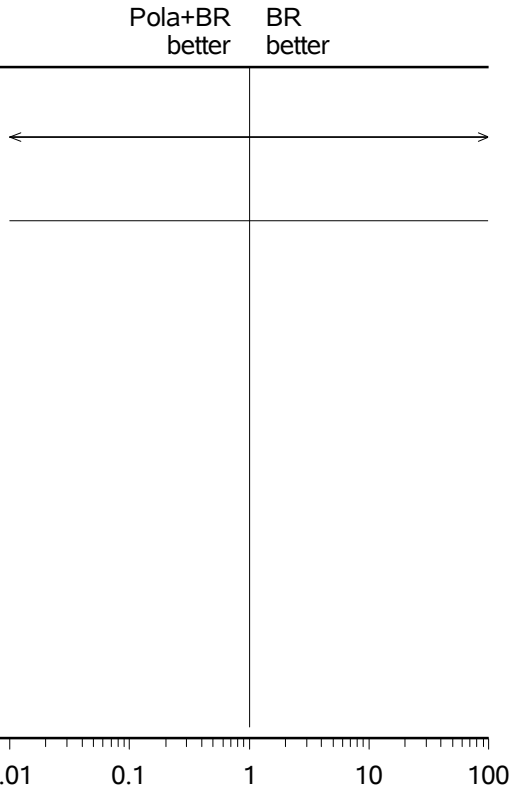
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTALOPE_L2_ARMCDPLUSSE_29365_41543.xls
25JAN2023 9:52

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	1	0.00	(0.00, NE)
YO41543	8	0	5	0	NE	NE
Total	19	0	17	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTALOPE_L2_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 19:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		100.0	NE	NE	NE	NE	0.00	0.9989

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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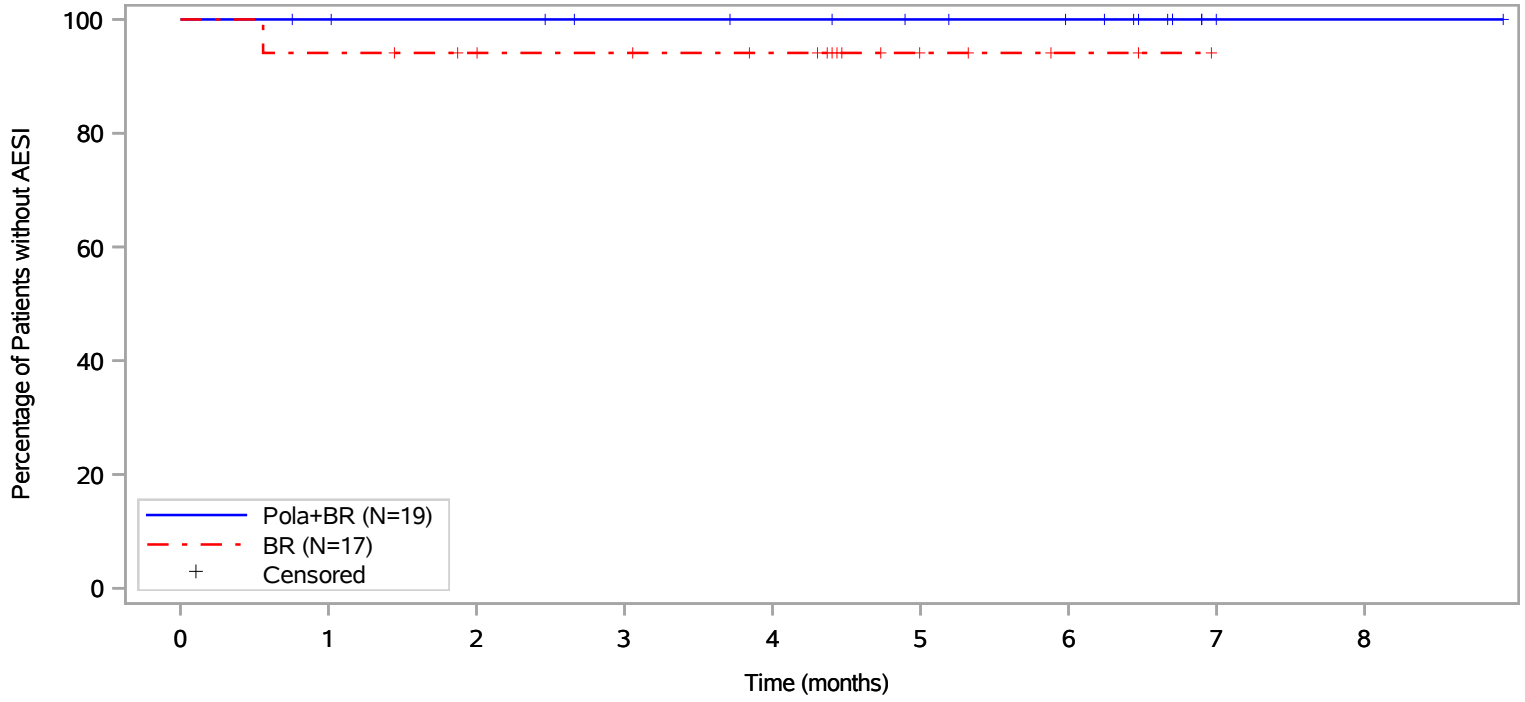
17DEC2022 21:48

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Alopecia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..alysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTALOPE_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTALOPE35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 22:06

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTALOPE35_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 15:41

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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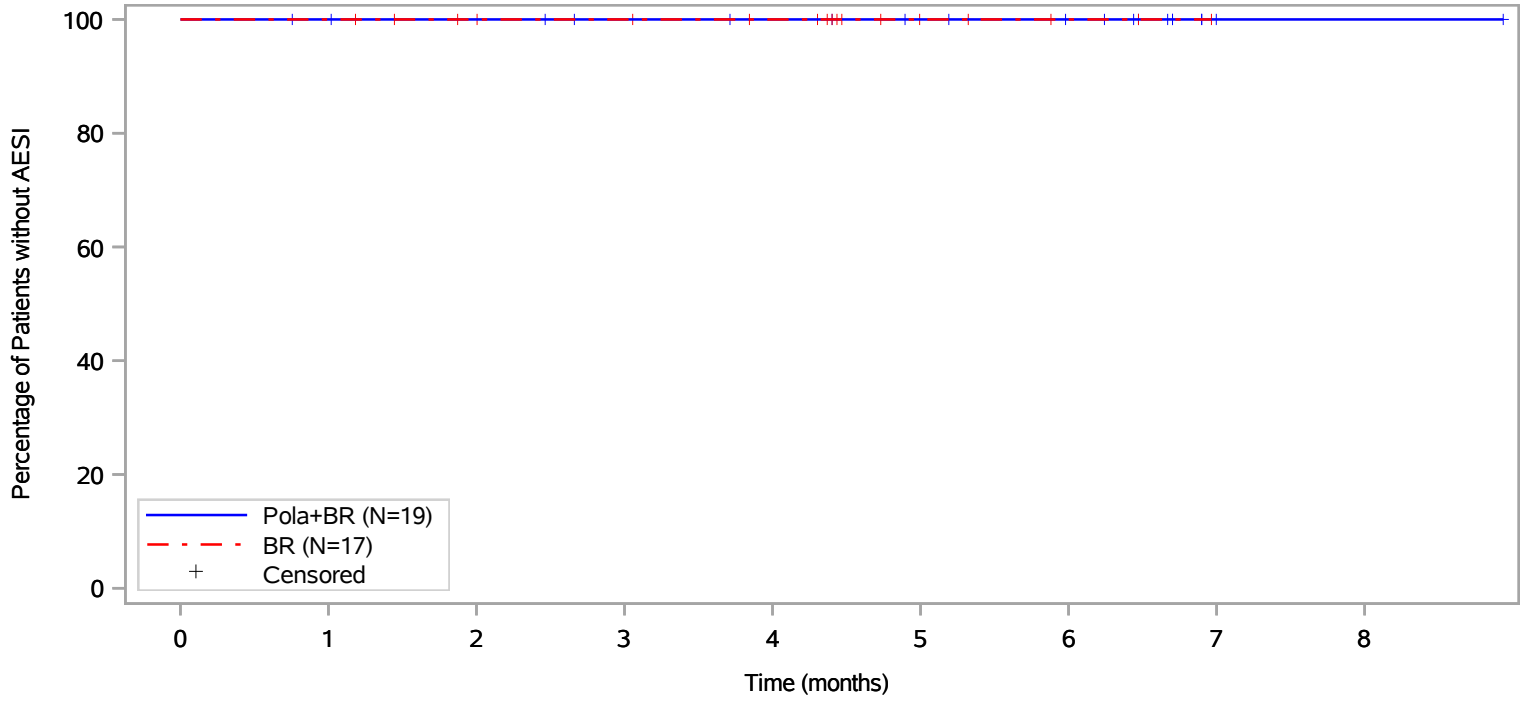
17DEC2022 21:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTALOPE35_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 23:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTALOPES_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTALOPES_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 18:20

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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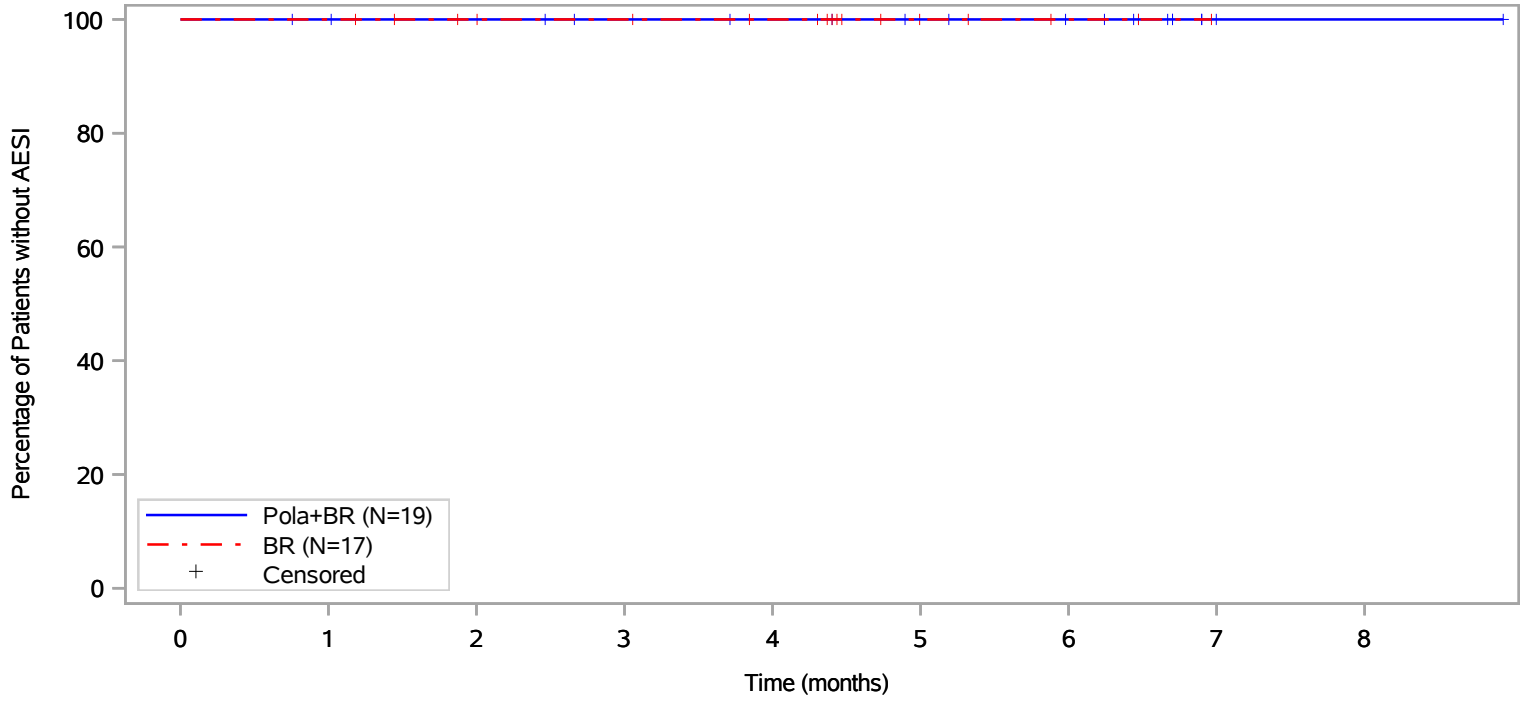
17DEC2022 15:32

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Alopecia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTALOPES_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 2:13

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

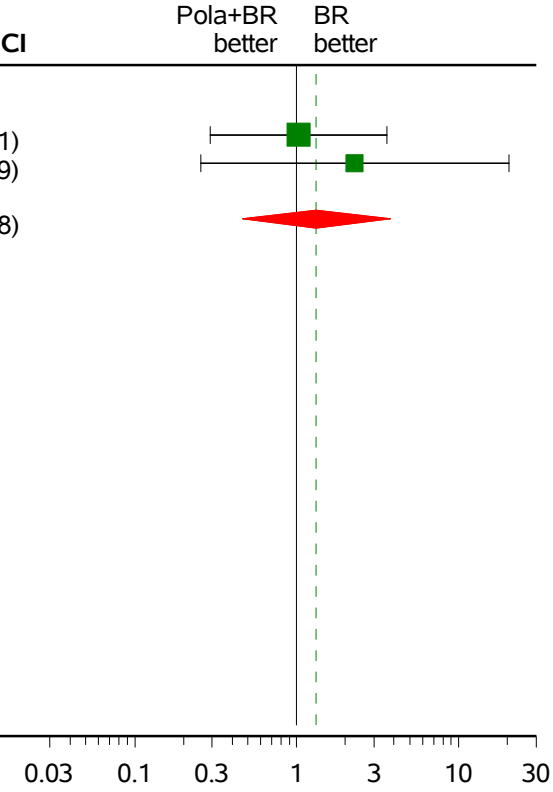
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	9	47.4	10	52.6	17	100.0	6	35.3	11	64.7	0.6395	1.32	0.46	3.78		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	7	50.0	7	50.0	8	47.1	3	37.5	5	62.5	0.8680	1.12	0.26	4.75		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	9	52.9	3	33.3	6	66.7	0.8058	1.10	0.18	6.76		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	5	62.5	3	37.5	2	11.8	0	-	2	100.0	0.2604	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	6	40.0	9	60.0	0.7084	0.85	0.23	3.12		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	4	50.0	4	50.0	14	82.4	5	35.7	9	64.3	0.5867	1.56	0.41	5.92		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	5	45.5	6	54.5	3	17.6	1	33.3	2	66.7	0.7579	1.36	0.15	12.53		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	2	40.0	3	60.0	3	17.6	1	33.3	2	66.7	0.5768	1.98	0.17	22.61		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	7	50.0	7	50.0	14	82.4	5	35.7	9	64.3	0.8304	1.20	0.37	3.89		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTANEIM_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 1:14

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	5	12	5	1.03	(0.29, 3.61)
YO41543	8	4	5	1	2.28	(0.25, 20.49)
Total	19	9	17	6	1.32	(0.46, 3.78)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTANEIM_L2_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 14:39

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	5	45.5	6	54.5	12	70.6	5	41.7	7	58.3	0.9639	1.03	0.29	3.61		Convergence criterion (GCONV=1E-8) satisfied.		75.3						
	YO41543	8	42.1	4	50.0	4	50.0	5	29.4	1	20.0	4	80.0	0.4478	2.28	0.25	20.49		Convergence criterion (GCONV=1E-8) satisfied.		24.7						
	Total	19	100.0	9	47.4	10	52.6	17	100.0	6	35.3	11	64.7	0.6395	1.32	0.46	3.78		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.39	1	0.5315	0.00	0.52	0.6023

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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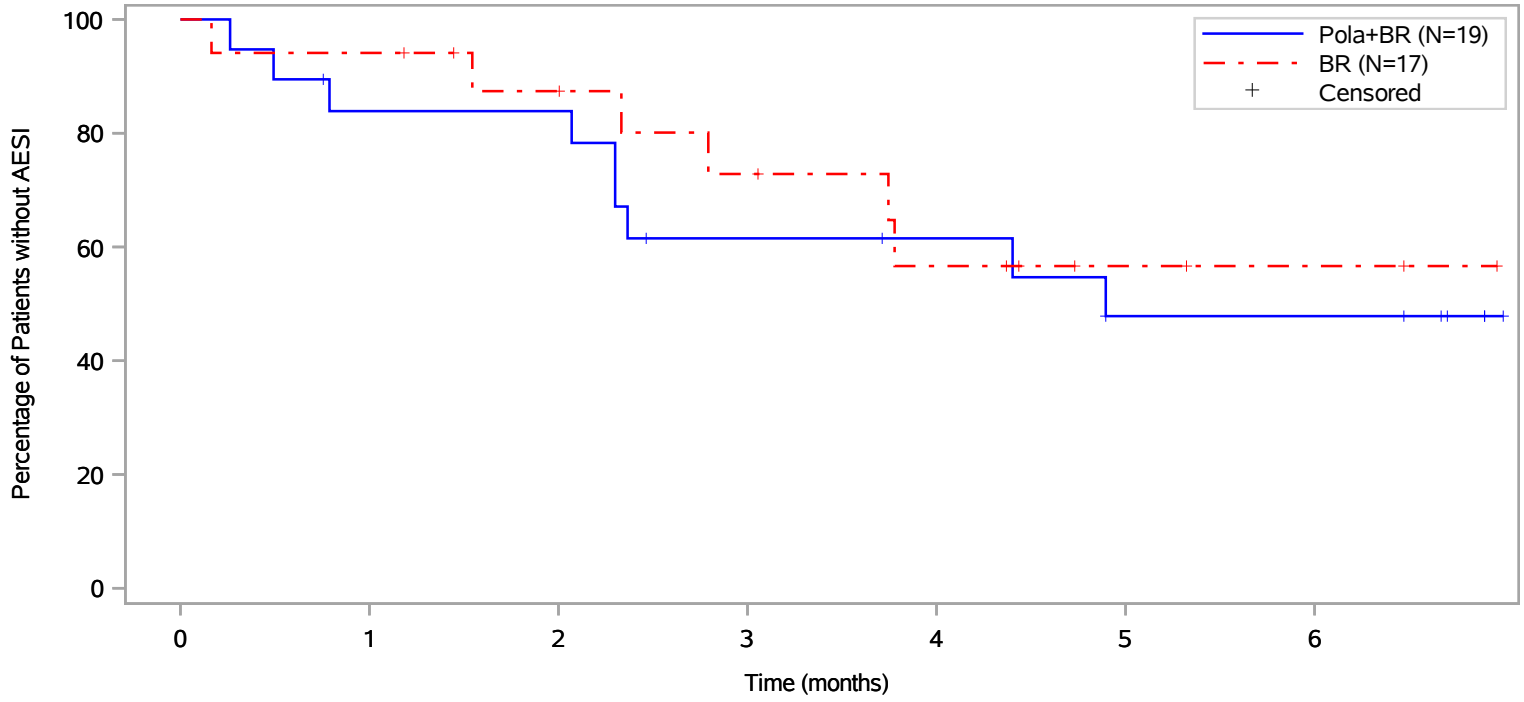
16DEC2022 9:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Anemia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	15	15	10	9	6	6
BR (N=17)	17	16	13	10	7	3	2
Patients censored							
Pola+BR (N=19)	0	1	1	2	3	4	4
BR (N=17)	0	0	2	3	4	8	9

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..alysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTANEIM_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 20:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

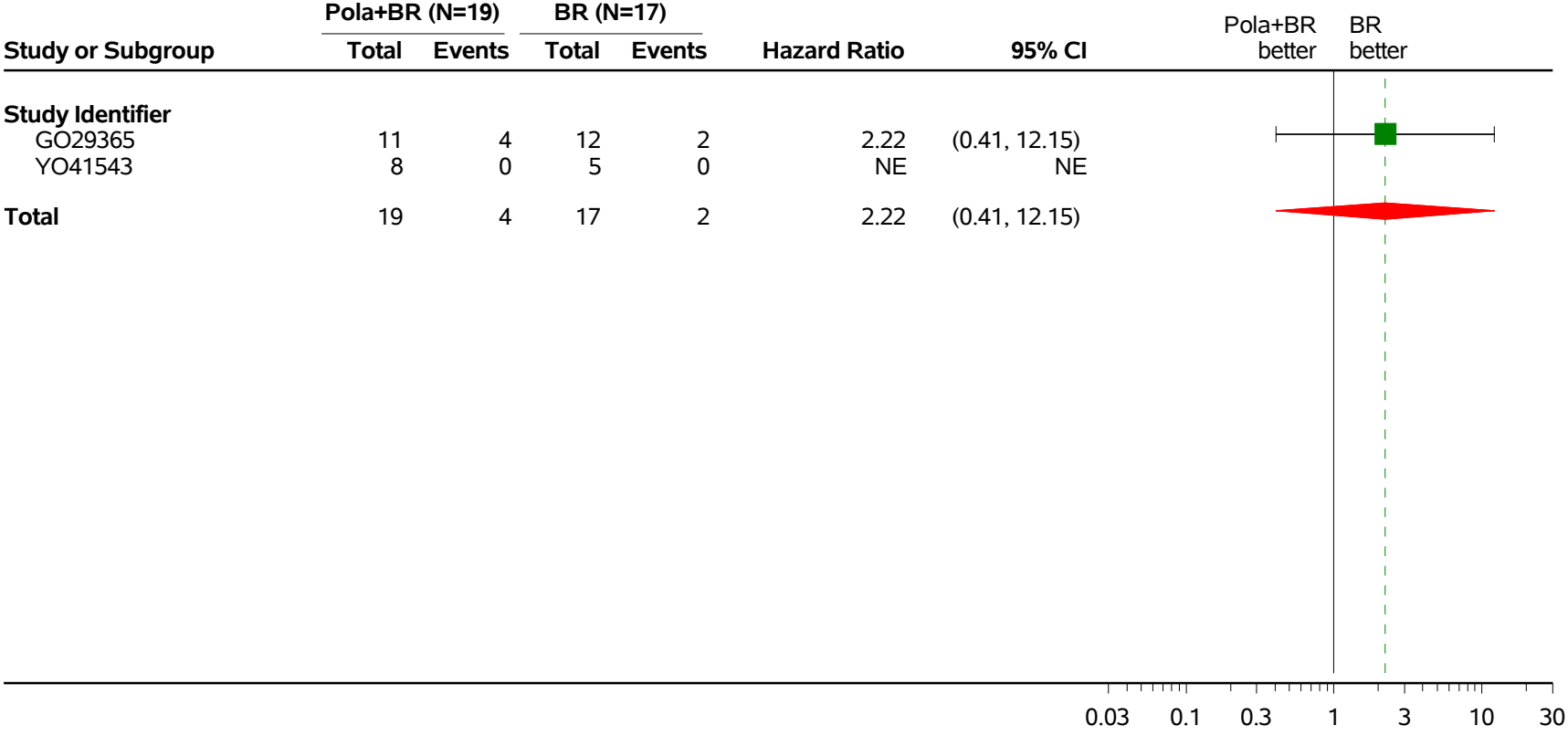
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	4	21.1	15	78.9	17	100.0	2	11.8	15	88.2	0.5131	2.22	0.41	12.15		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	2	14.3	12	85.7	8	47.1	2	25.0	6	75.0	0.4349	0.87	0.12	6.29		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	9	52.9	0	-	9	100.0	0.0514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	2	13.3	13	86.7	0.4411	2.24	0.37	13.45		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	3	37.5	5	62.5	14	82.4	2	14.3	12	85.7	0.2464	2.64	0.44	15.82		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	2	40.0	3	60.0	3	17.6	0	-	3	100.0	0.2087	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	2	14.3	12	85.7	0.8957	1.27	0.18	9.09		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTANEIM35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	4	12	2	2.22	(0.41, 12.15)
YO41543	8	0	5	0	NE	NE
Total	19	4	17	2	2.22	(0.41, 12.15)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi^2	Df	P-value	I^2 (%)	Z	P-value
Study Identifier	GO29365	11	57.9	4	36.4	7	63.6	12	70.6	2	16.7	10	83.3	0.3441	2.22	0.41	12.15		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	4	21.1	15	78.9	17	100.0	2	11.8	15	88.2	0.5131	2.22	0.41	12.15		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.92	0.3568

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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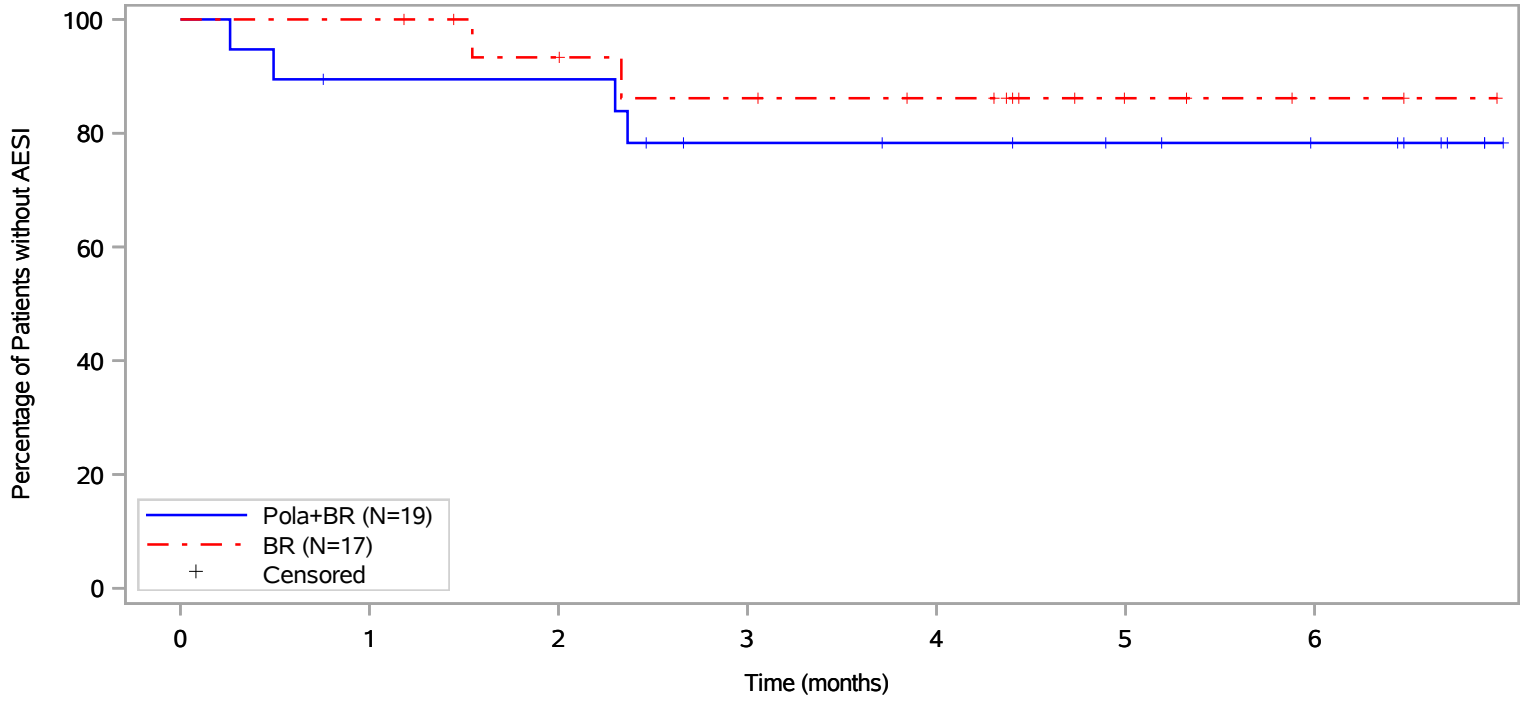
15DEC2022 20:05

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	16	16	12	11	9	7
BR (N=17)	17	17	14	12	10	4	2
Patients censored							
Pola+BR (N=19)	0	1	1	3	4	6	8
BR (N=17)	0	0	2	3	5	11	13

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTANEIM35_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:42

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTANEIMS_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTANEIMS_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 14:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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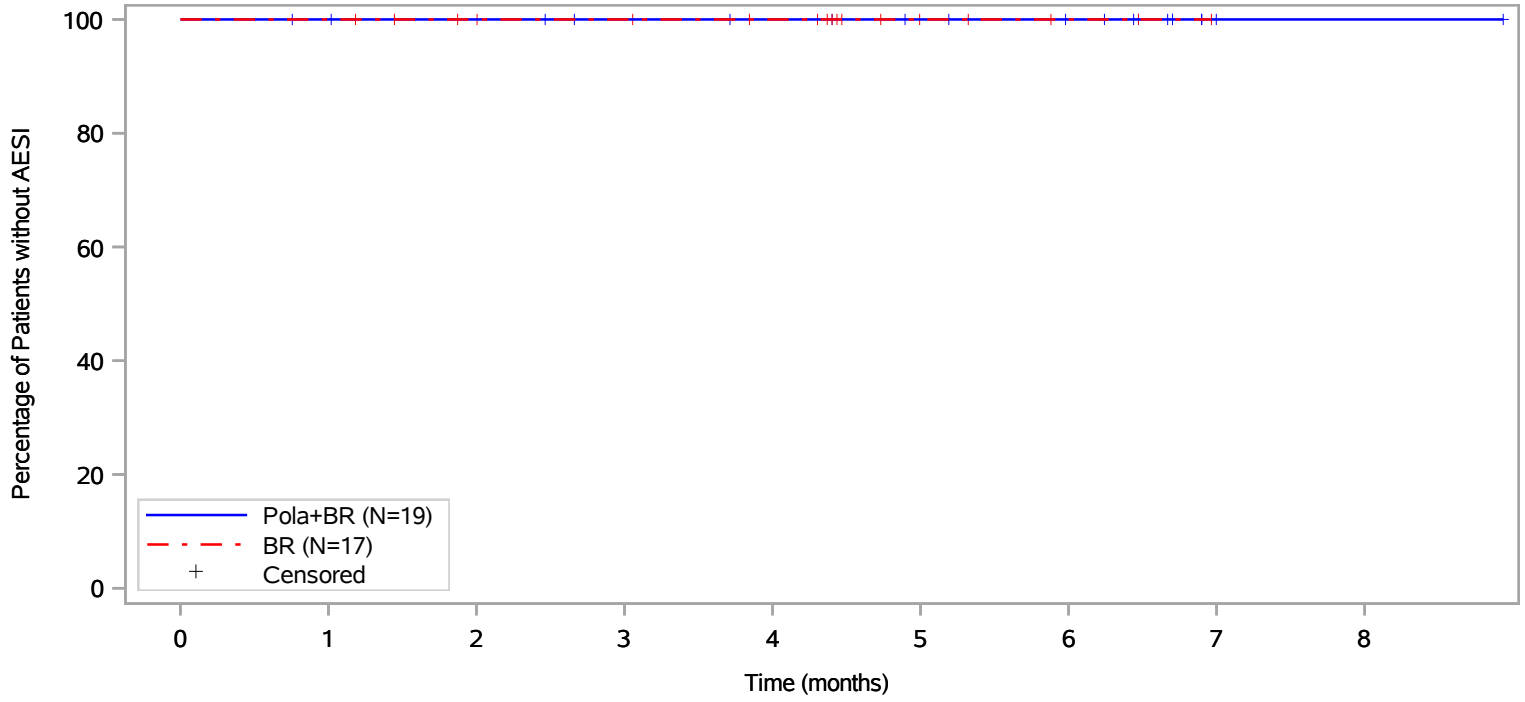
15DEC2022 19:13

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Anemia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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04DEC2022 0:52

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

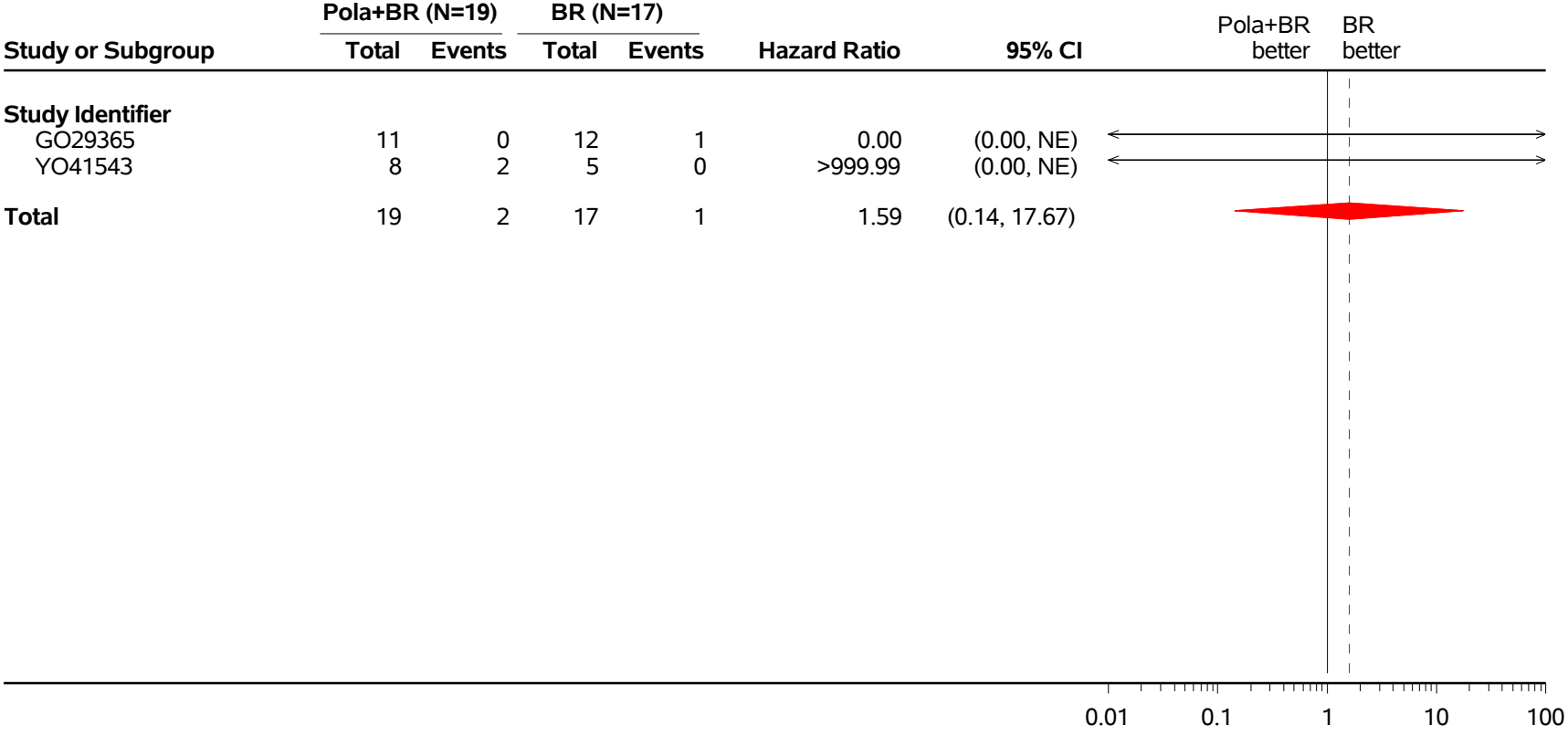
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.6414	1.59	0.14	17.67		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	2	14.3	12	85.7	8	47.1	1	12.5	7	87.5	0.9954	0.63	0.05	8.56		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4080	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4364	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	0	-	14	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTCTAAR_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 20:07

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	1	0.00	(0.00, NE)
YO41543	8	2	5	0	>999.99	(0.00, NE)
Total	19	2	17	1	1.59	(0.14, 17.67)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTCTAAR_L2_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 20:14

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	34.2							
	YO41543	8	42.1	2	25.0	6	75.0	5	29.4	0	-	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	65.8							
	Total	19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.6414	1.59	0.14	17.67		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.00	1	0.9973	0.00		0.37	0.7077

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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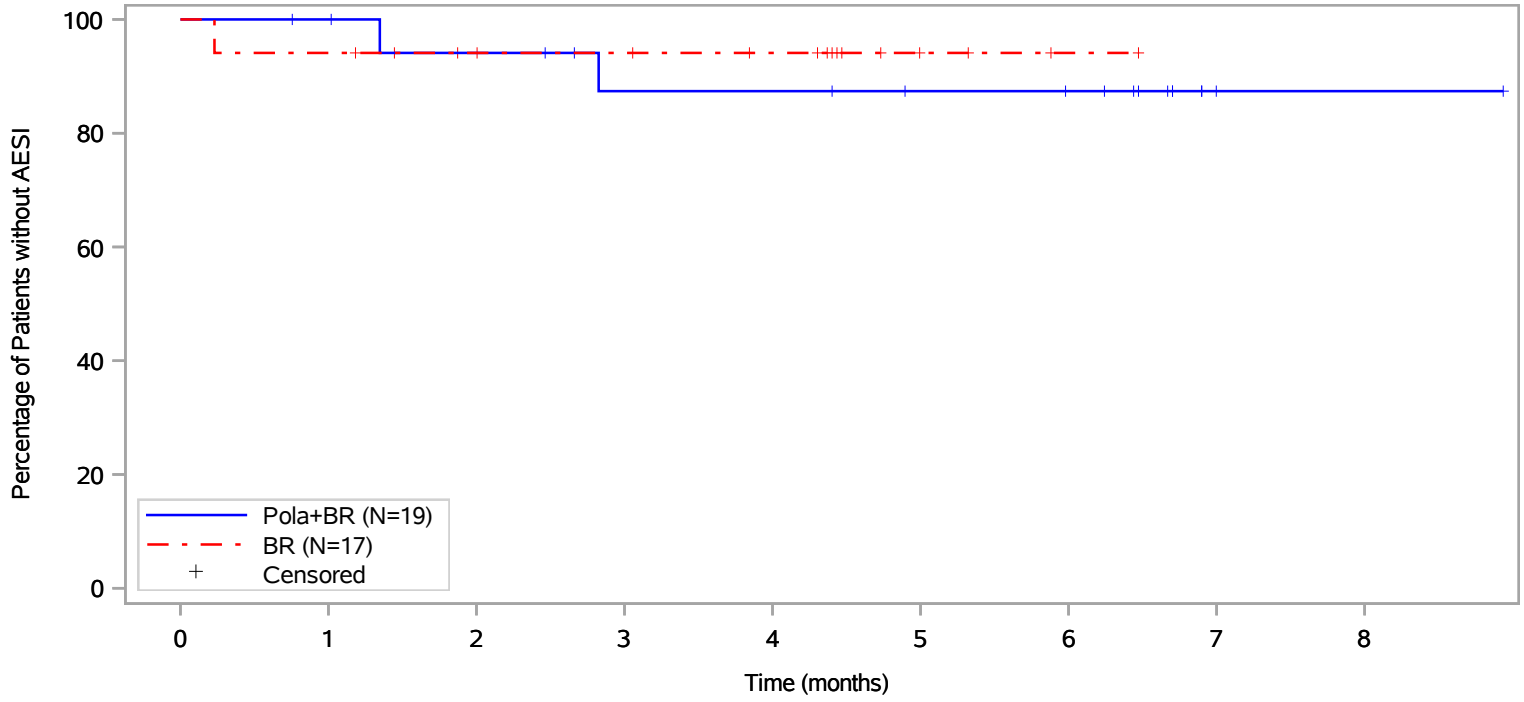
17DEC2022 21:56

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	16	13	13	11	10	1	1
BR (N=17)	17	16	13	12	10	3	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	4	6	7	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..alysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTCTAAR_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:52

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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02DEC2022 22:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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16DEC2022 16:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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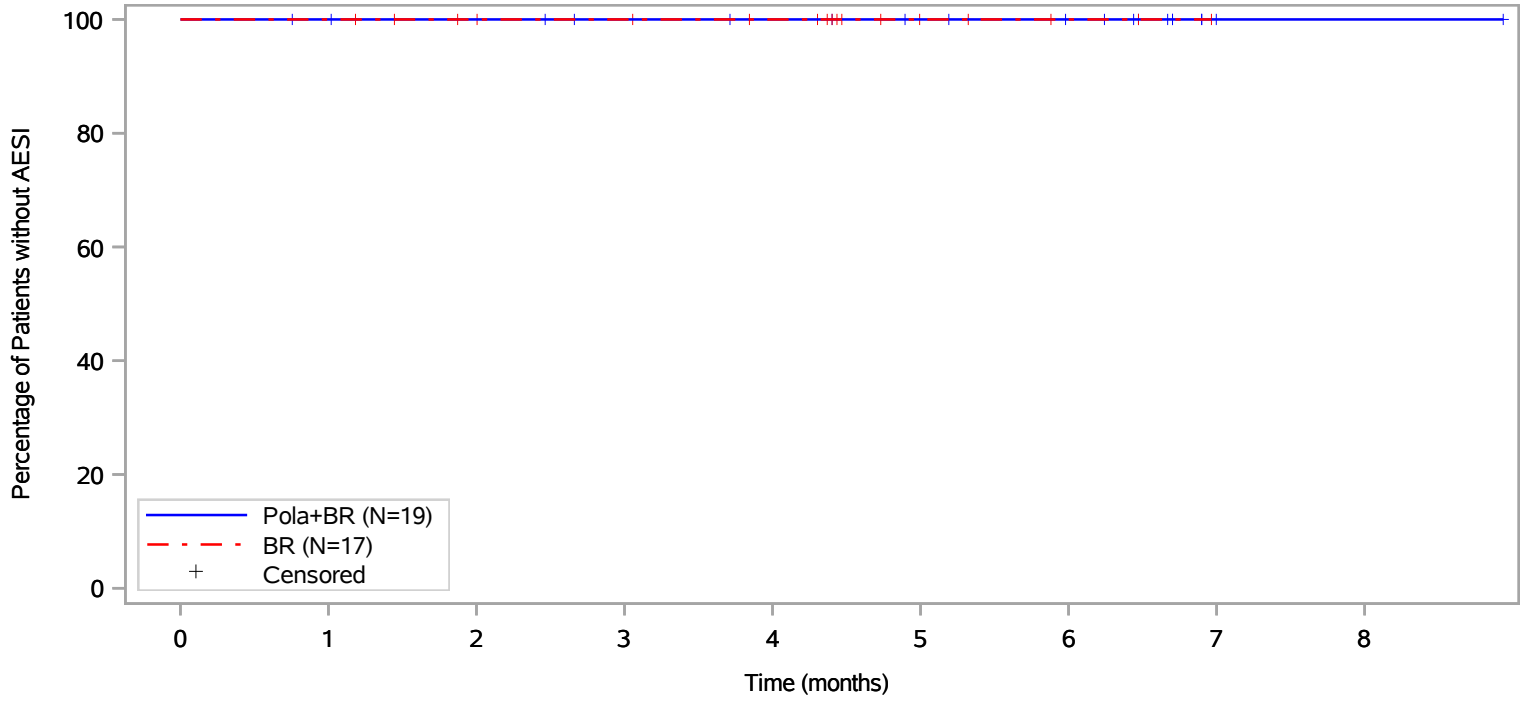
17DEC2022 21:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTCTAAR35_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 0:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTCTAARS_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:57

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTCTAARS_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 19:05

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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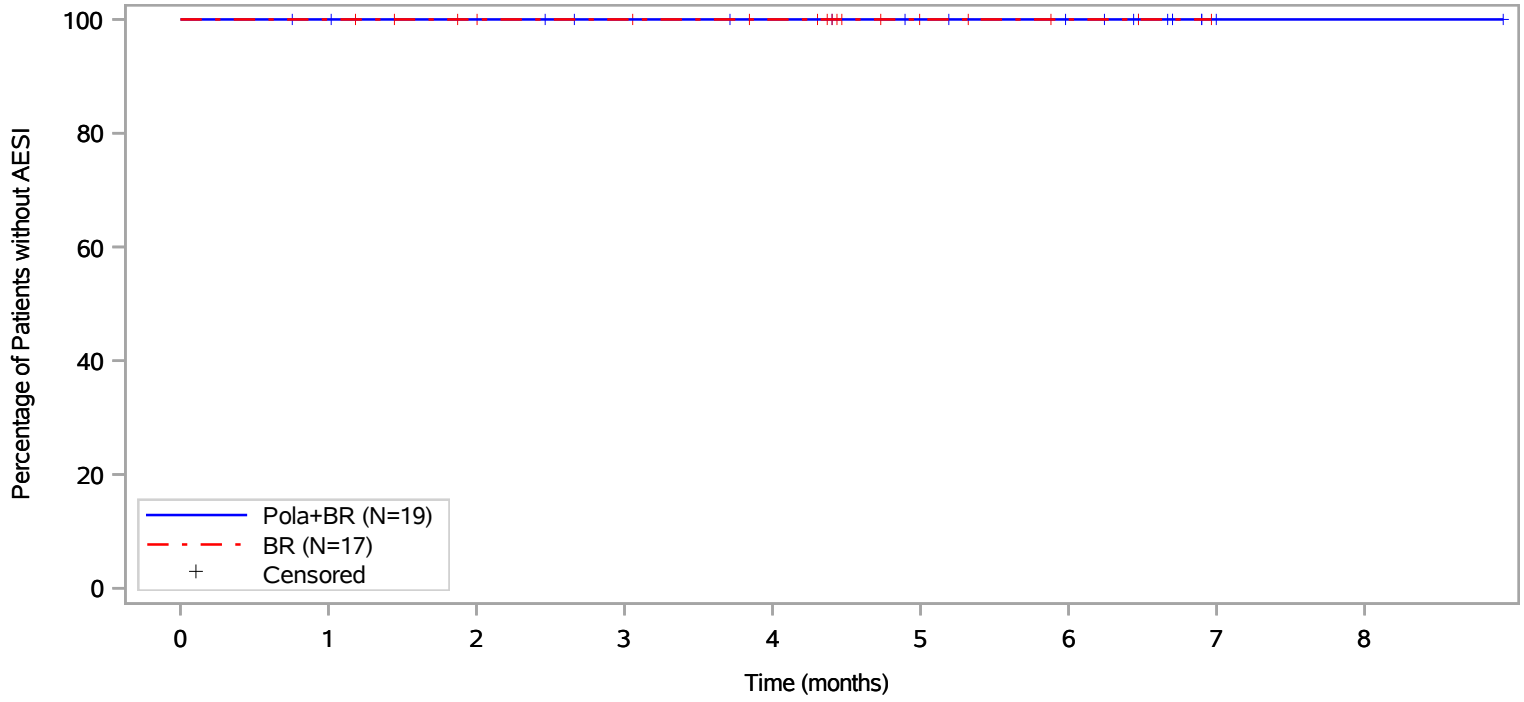
17DEC2022 15:41

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTCTAARS_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 2:20

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTDDIN_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 22:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTDDIN_L2_ARMCDPLUSSE_29365_41543.xls
17DEC2022 17:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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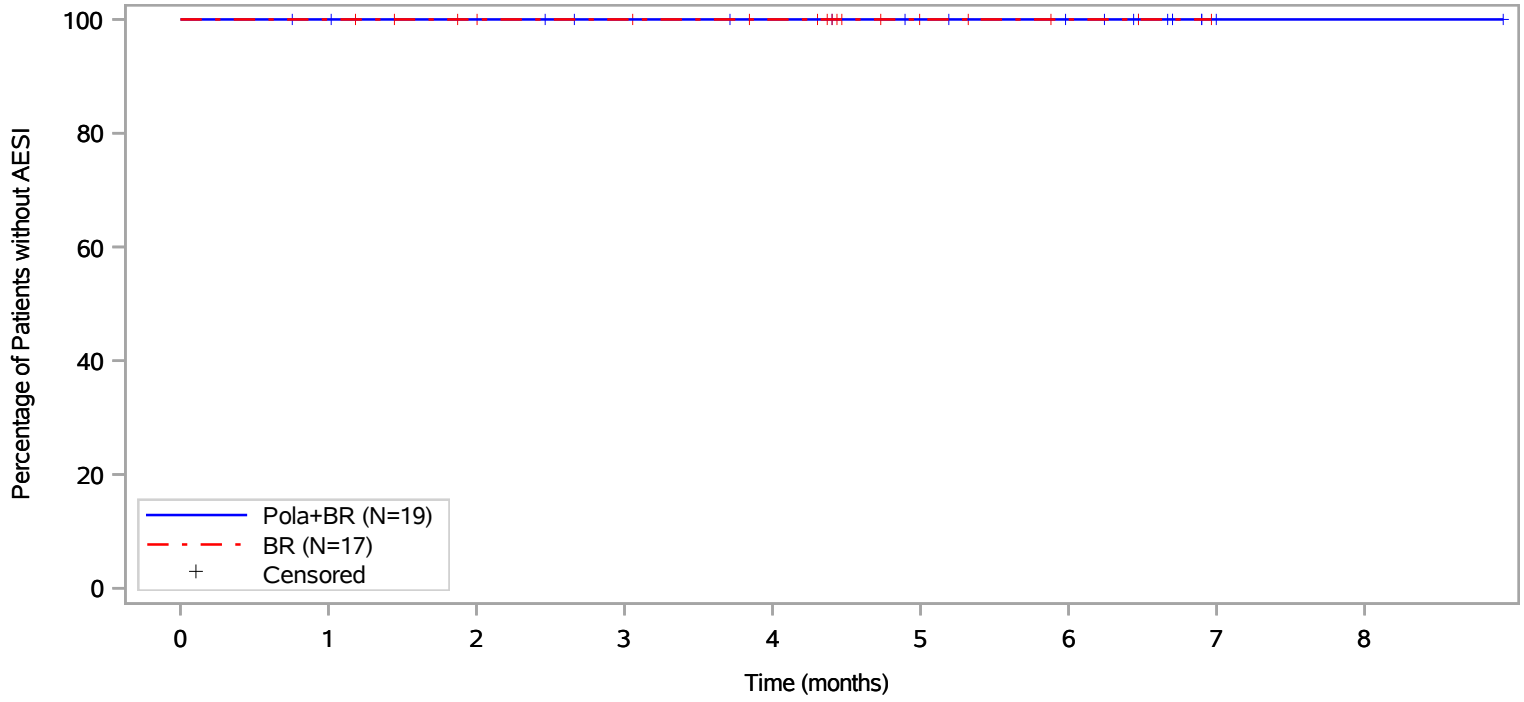
17DEC2022 22:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Drug Drug Interaction
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..nalysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTDDIN_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

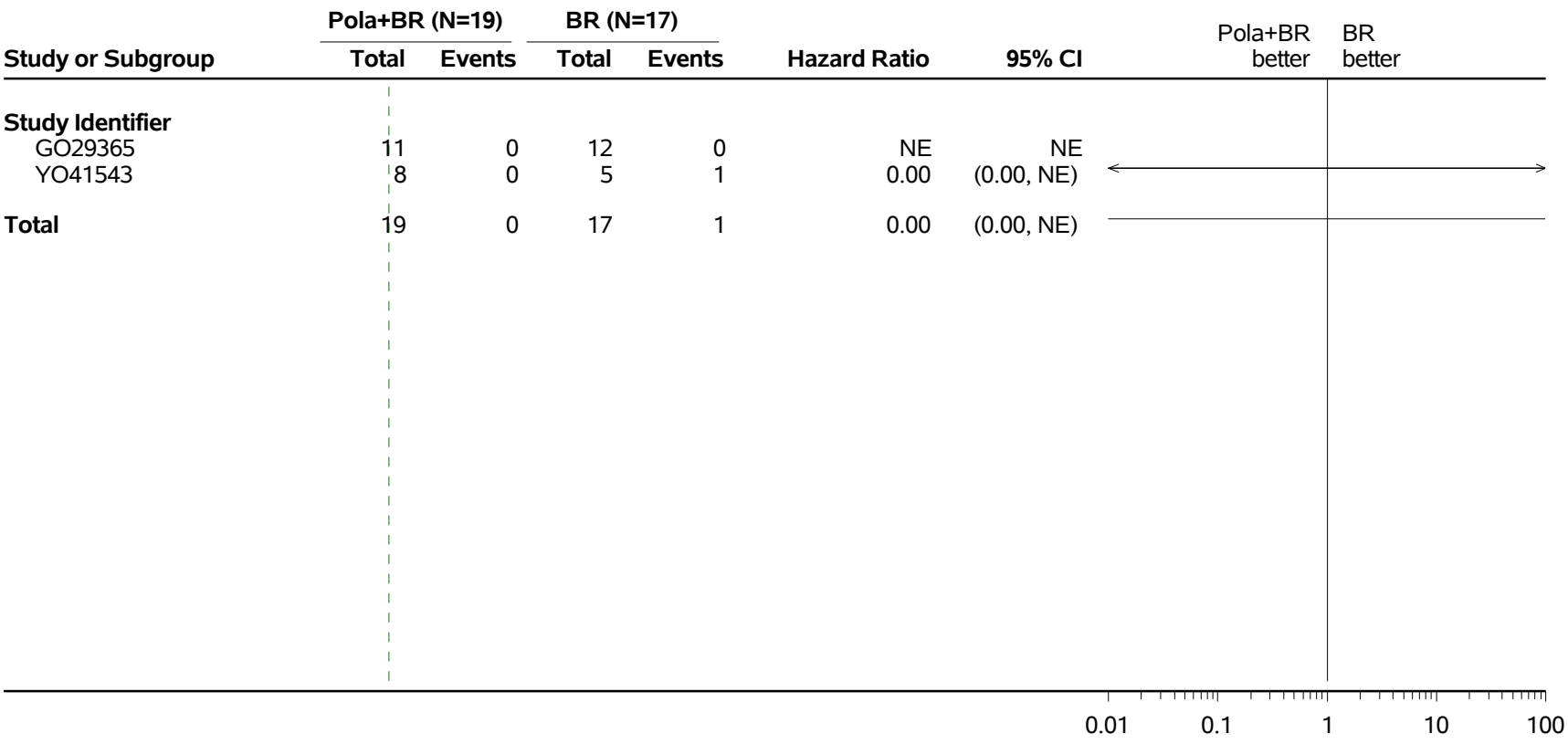
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTDYSGUE_L2_ARMCDPLUSSE_29365_41543.xls
25JAN2023 10:21

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	0	NE	NE
YO41543	8	0	5	1	0.00	(0.00, NE)
Total	19	0	17	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTDYSGUE_L2_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 21:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9990

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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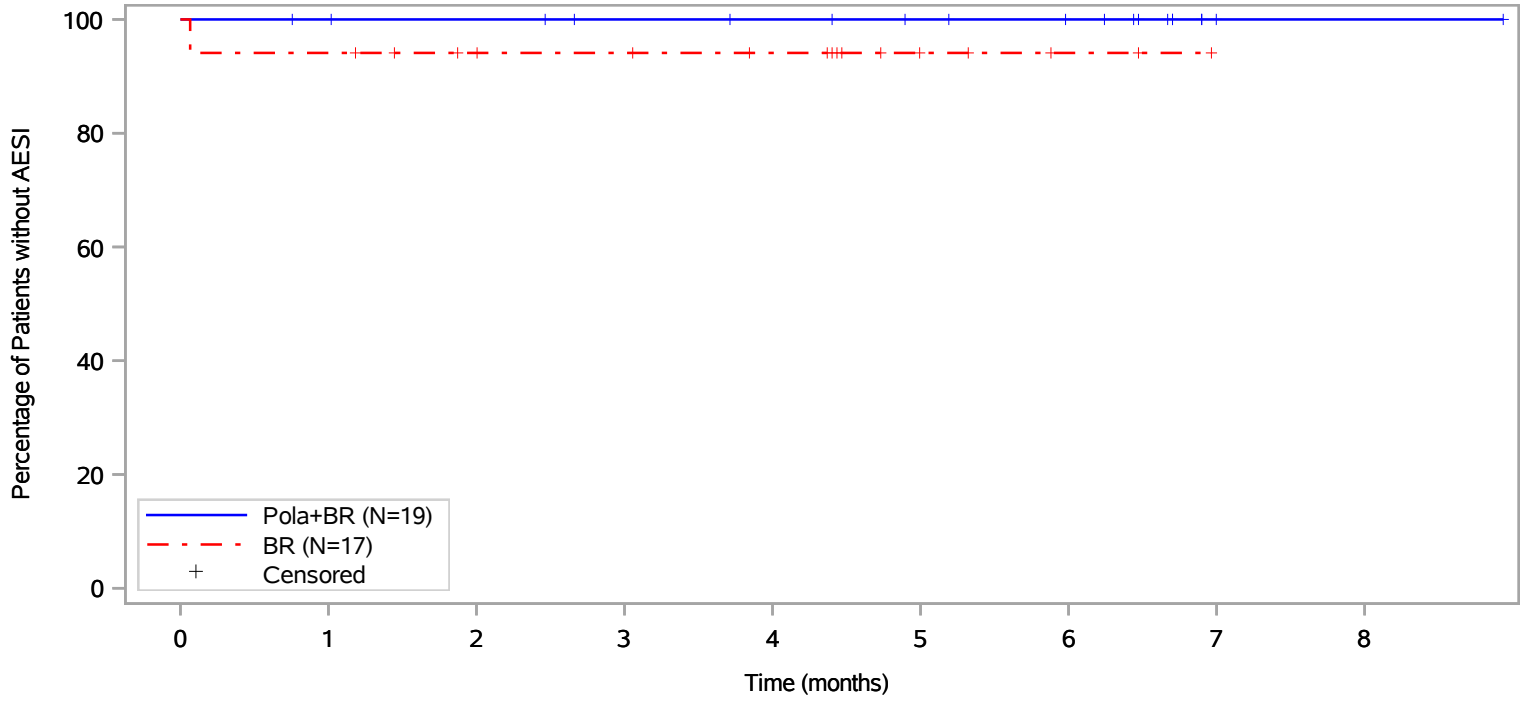
17DEC2022 22:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTDYSGUE_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:04

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTDYSGUE35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 22:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTDYSGUE35_L2_ARMCDPLUSSE_29365_41543.xls
17DEC2022 15:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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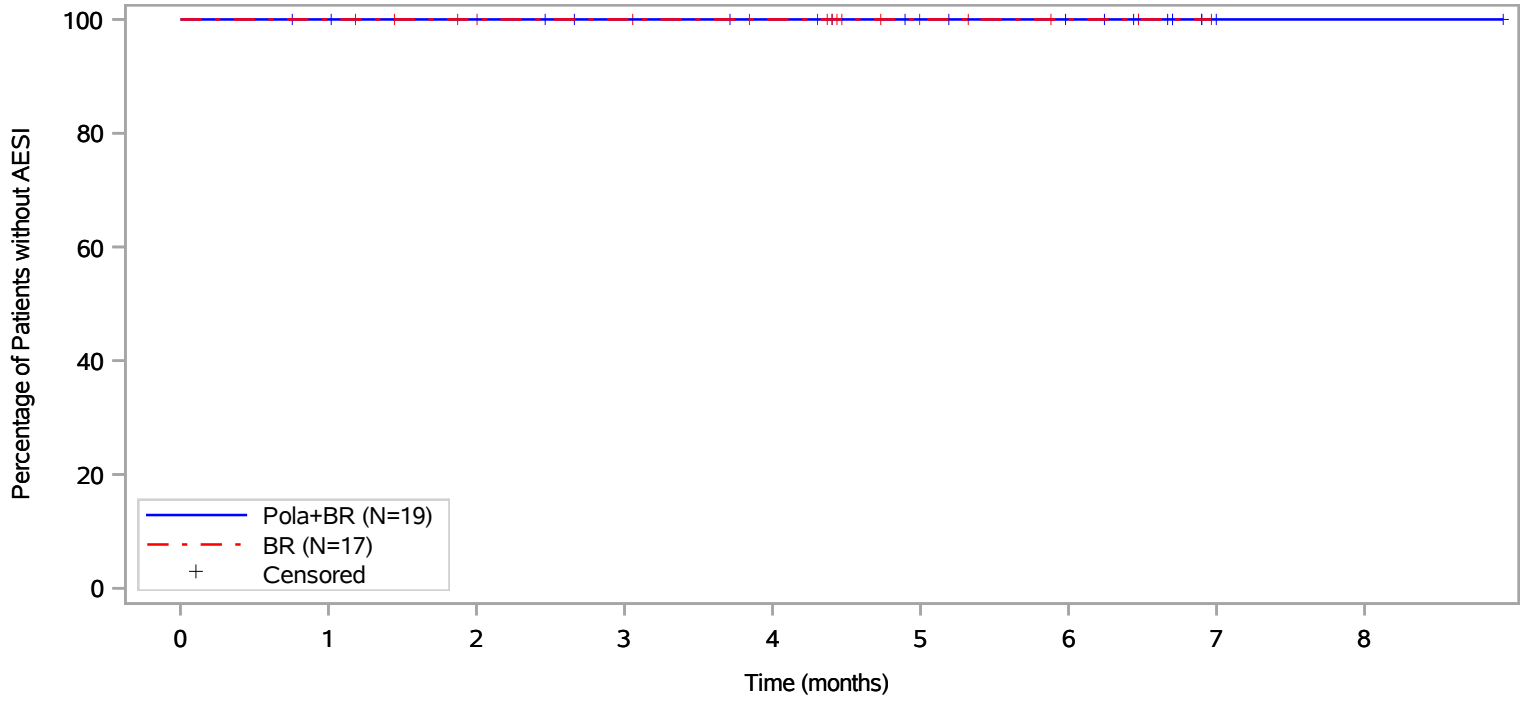
17DEC2022 21:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTDYSGUE35_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 0:16

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTDYSGUES_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 22:14

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTDYSGUES_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 20:32

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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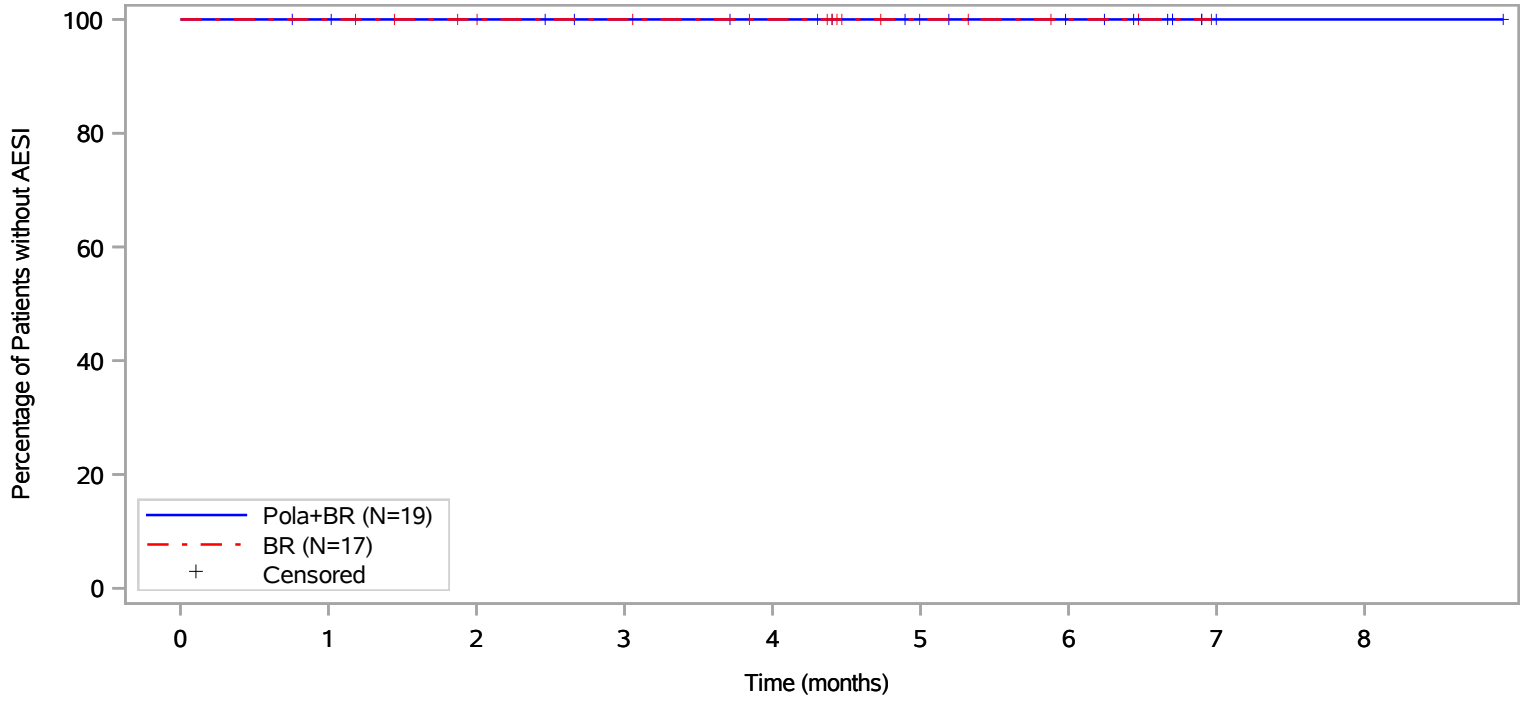
17DEC2022 15:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 2:34

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	7	36.8	12	63.2	17	100.0	10	58.8	7	41.2	0.1371	0.54	0.20	1.44		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	5	35.7	9	64.3	8	47.1	6	75.0	2	25.0	0.0463	0.36	0.09	1.44		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	9	52.9	4	44.4	5	55.6	0.5288	0.50	0.09	2.84		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.4452	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	5	45.5	6	54.5	15	88.2	10	66.7	5	33.3	0.1501	0.47	0.15	1.42		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	4	50.0	4	50.0	14	82.4	9	64.3	5	35.7	0.4989	0.67	0.20	2.22		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	3	27.3	8	72.7	3	17.6	1	33.3	2	66.7	0.8815	1.03	0.10	10.18		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	2	66.7	1	33.3	0.2854	0.29	0.03	3.23		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	6	42.9	8	57.1	14	82.4	8	57.1	6	42.9	0.3415	0.80	0.27	2.44		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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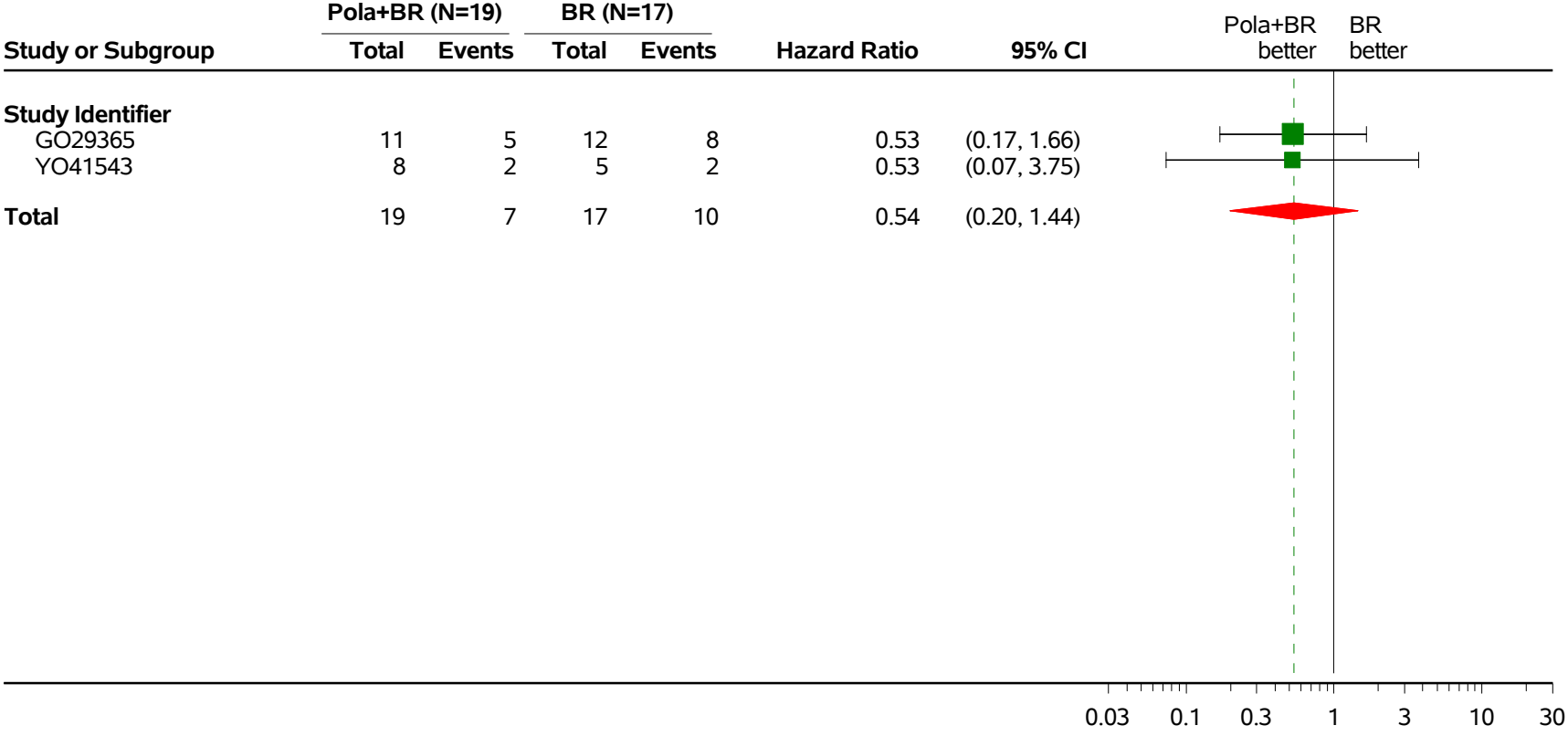
01DEC2022 4:45

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	5	12	8	0.53	(0.17, 1.66)
YO41543	8	2	5	2	0.53	(0.07, 3.75)
Total	19	7	17	10	0.54	(0.20, 1.44)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTFAA_L2_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 9:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	5	45.5	6	54.5	12	70.6	8	66.7	4	33.3	0.2670	0.53	0.17	1.66		Convergence criterion (GCONV=1E-8) satisfied.	74.8							
	YO41543	8	42.1	2	25.0	6	75.0	5	29.4	2	40.0	3	60.0	0.5146	0.53	0.07	3.75		Convergence criterion (GCONV=1E-8) satisfied.	25.2							
	Total	19	100.0	7	36.8	12	63.2	17	100.0	10	58.8	7	41.2	0.1371	0.54	0.20	1.44		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.00	1	0.9780	0.00		-1.23	0.2172

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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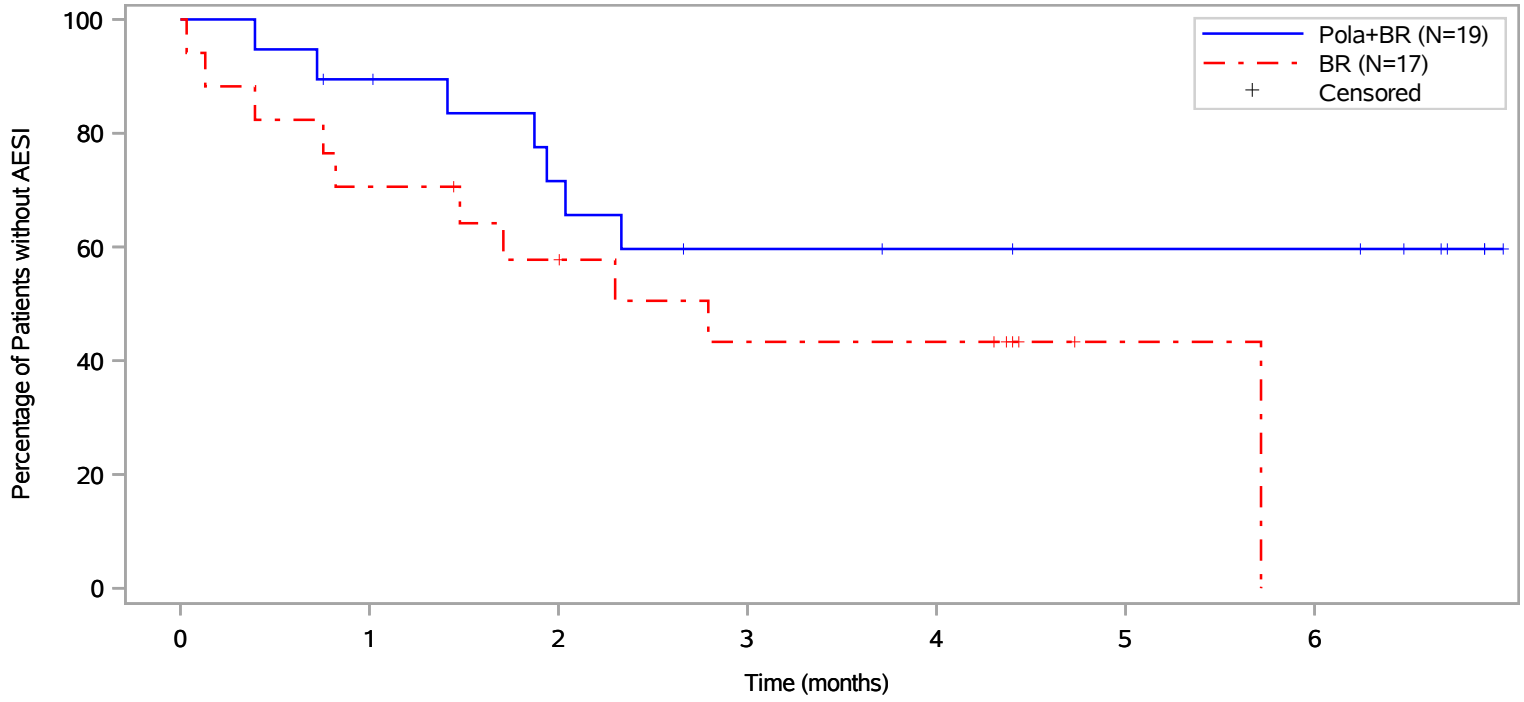
17DEC2022 20:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	16	12	9	8	7	7
BR (N=17)	17	12	9	6	6	1	NE
Patients censored							
Pola+BR (N=19)	0	1	2	3	4	5	5
BR (N=17)	0	0	1	2	2	7	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 21:11

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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02DEC2022 21:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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16DEC2022 9:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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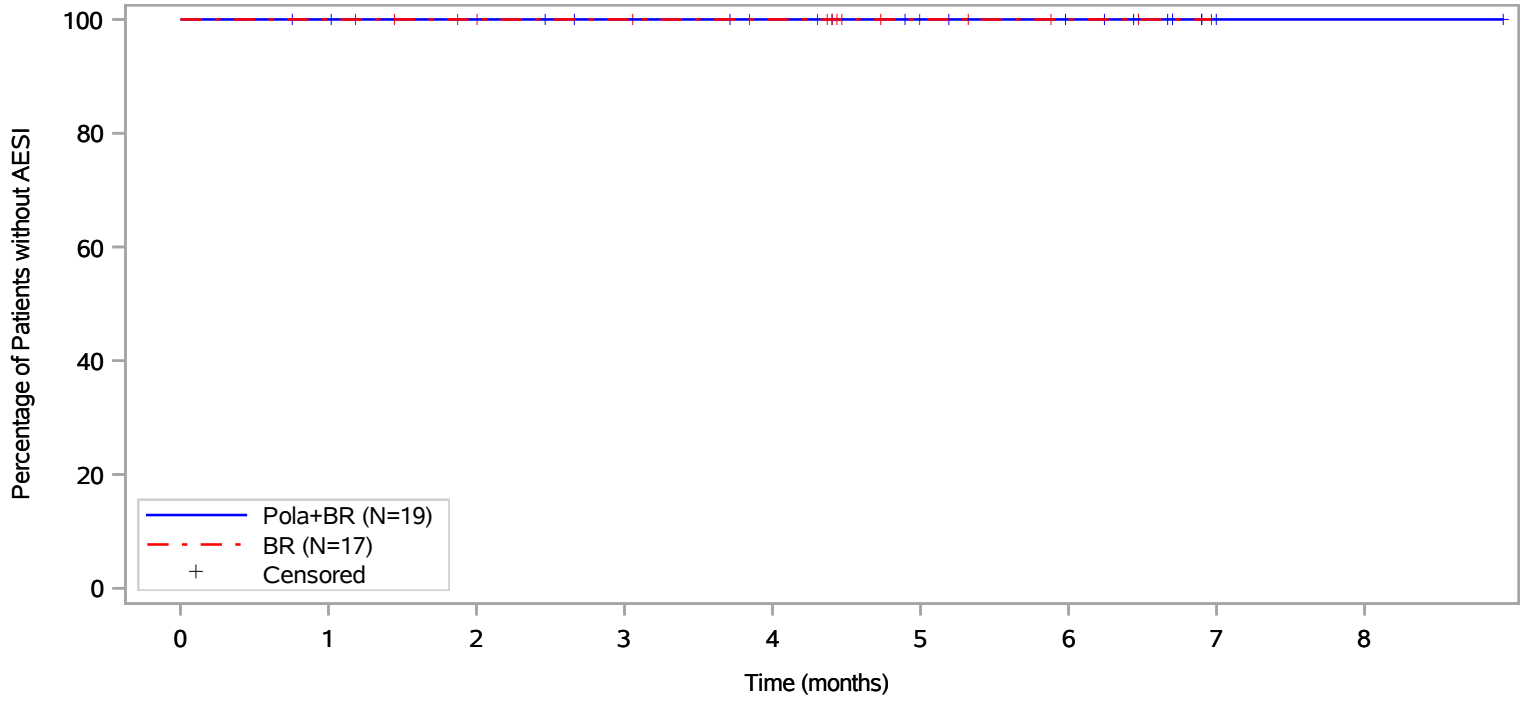
15DEC2022 21:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 23:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.3805	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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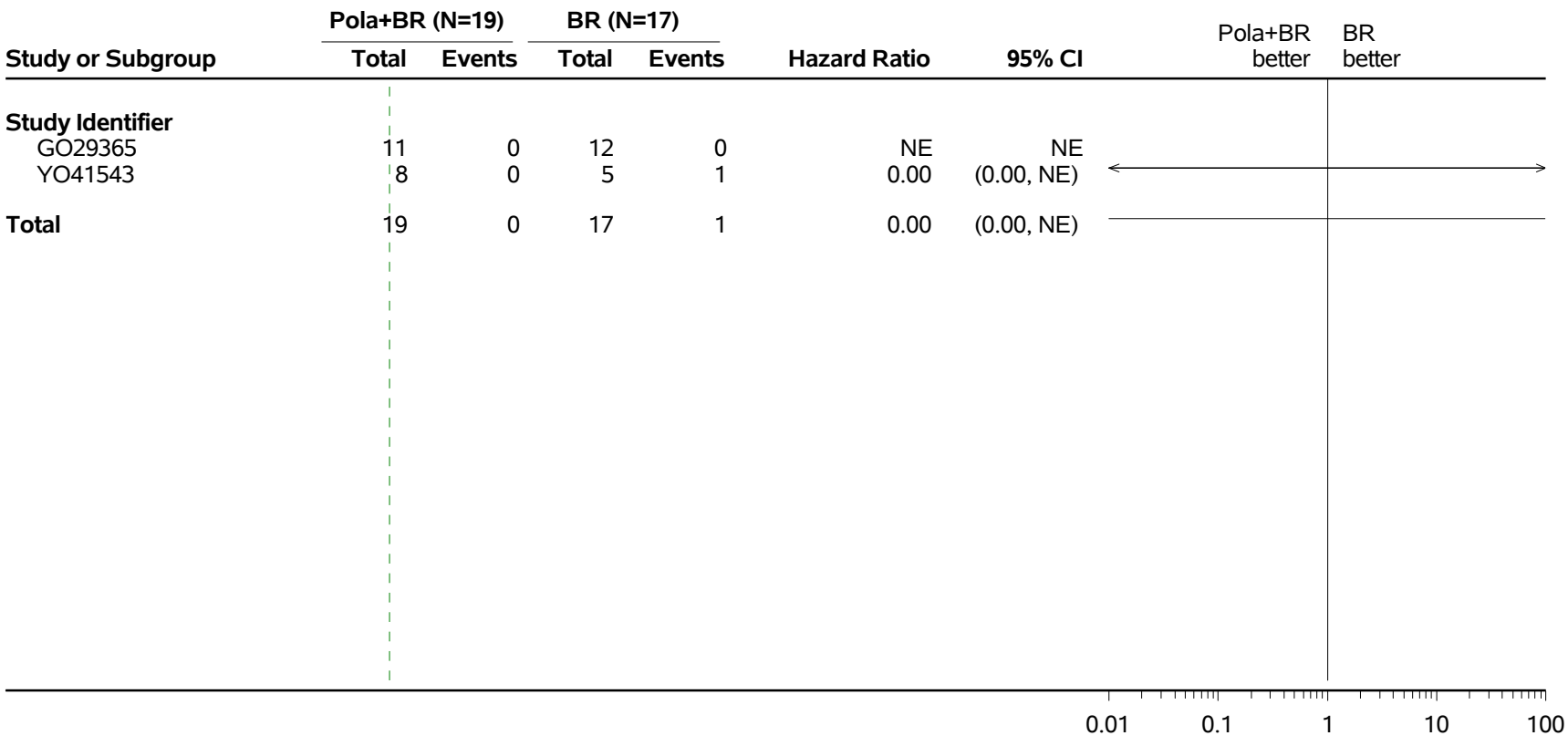
25JAN2023 10:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	0	NE	NE
YO41543	8	0	5	1	0.00	(0.00, NE)
Total	19	0	17	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTFAAS_L2_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 19:08

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2871	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9990

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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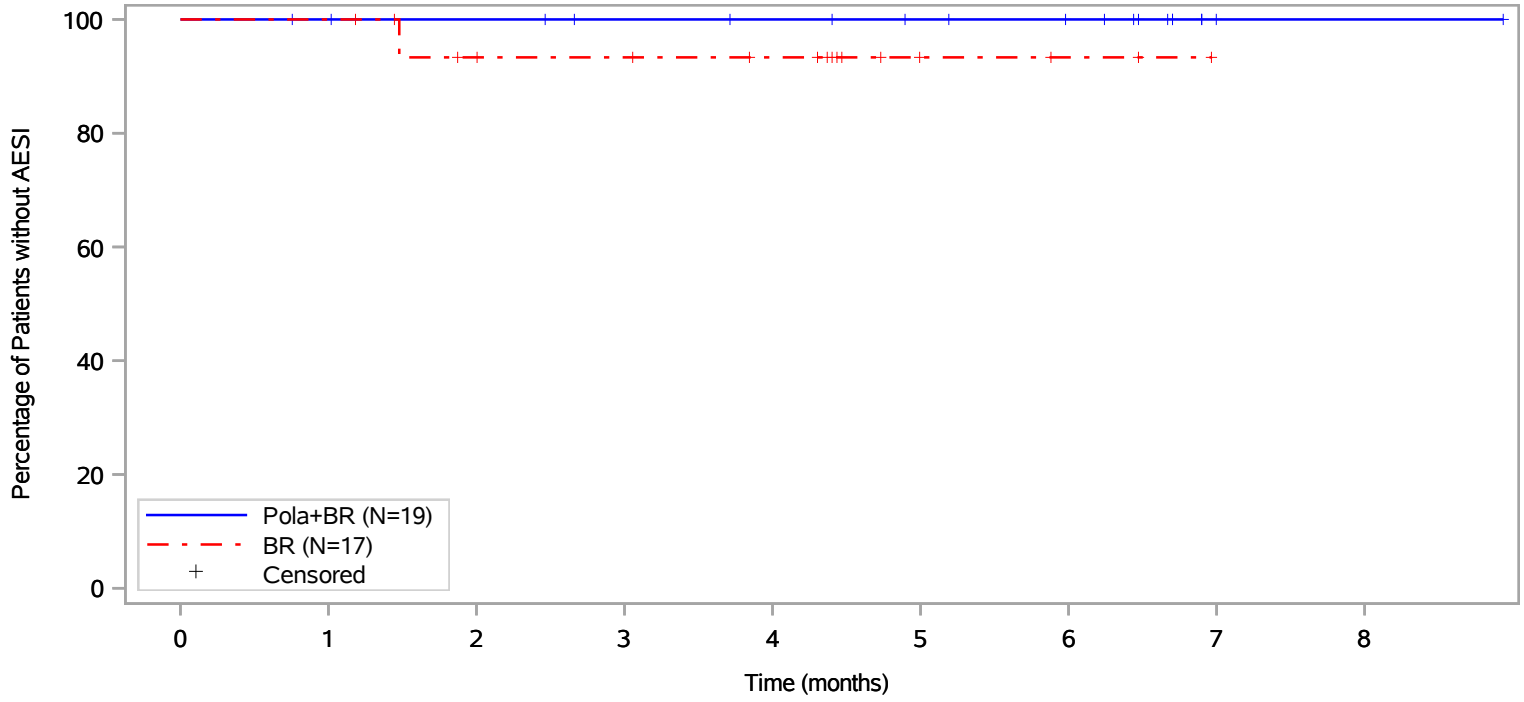
15DEC2022 21:51

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..nalysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTFAAS_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 1:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

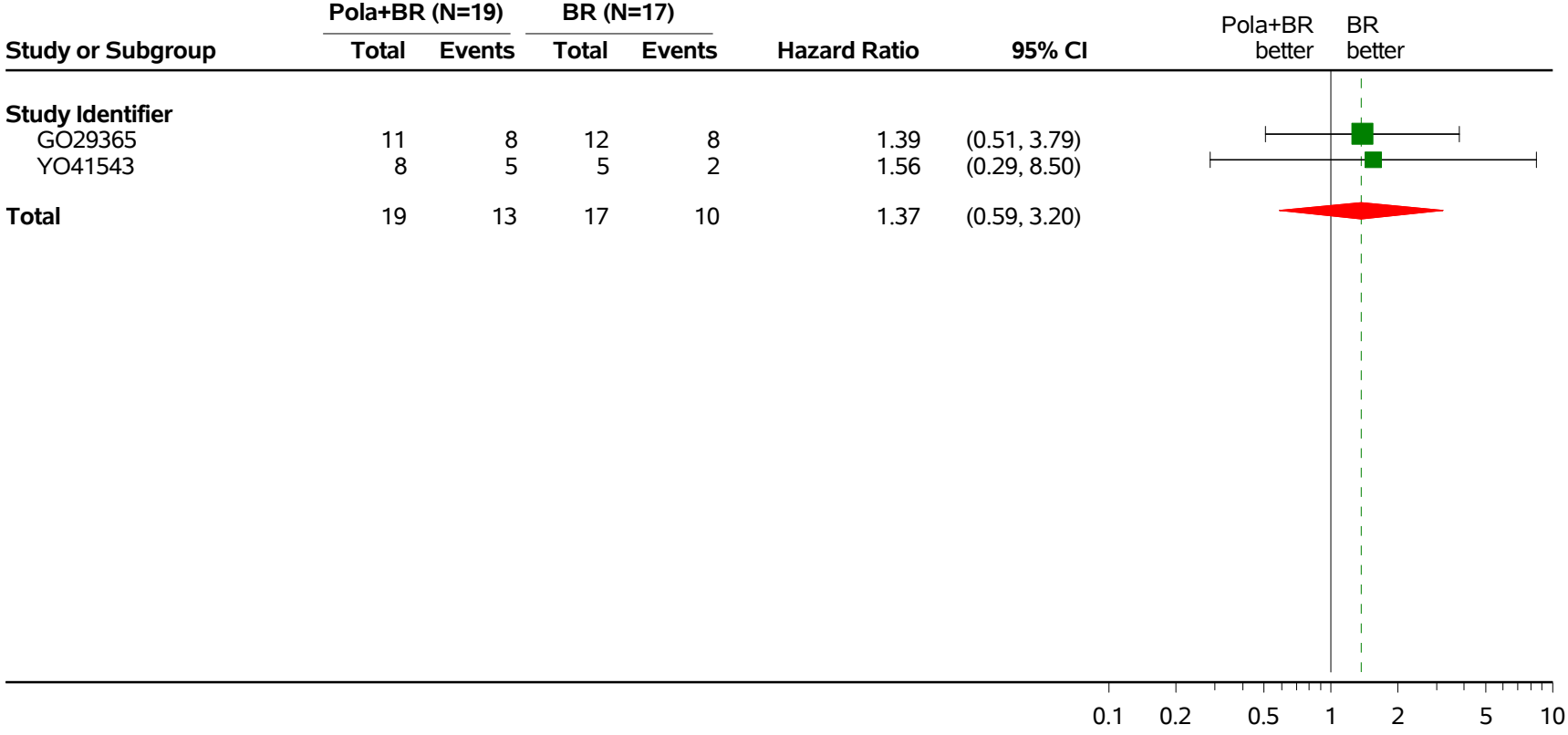
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	13	68.4	6	31.6	17	100.0	10	58.8	7	41.2	0.5220	1.37	0.59	3.20		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	8	57.1	6	42.9	8	47.1	4	50.0	4	50.0	0.6754	1.40	0.38	5.14		Convergence criterion (GCONV=1E-8) satisfied.	0.6021
	Female	5	26.3	5	100.0	0	-	9	52.9	6	66.7	3	33.3	0.2751	1.93	0.51	7.30		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	4	50.0	4	50.0	2	11.8	1	50.0	1	50.0	0.9506	1.64	0.14	18.90		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	9	81.8	2	18.2	15	88.2	9	60.0	6	40.0	0.2747	1.90	0.72	5.00		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	6	75.0	2	25.0	14	82.4	7	50.0	7	50.0	0.1757	2.16	0.68	6.90		Convergence criterion (GCONV=1E-8) satisfied.	0.1749
	<3	11	57.9	7	63.6	4	36.4	3	17.6	3	100.0	0	-	0.4133	0.55	0.12	2.59		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	3	60.0	2	40.0	3	17.6	2	66.7	1	33.3	0.8321	1.22	0.19	7.80		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	10	71.4	4	28.6	14	82.4	8	57.1	6	42.9	0.3365	1.85	0.68	5.02		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGASTOX_L2_ARMCDPLUSSE_29365_41543.xls
30MAR2023 9:37

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	8	12	8	1.39	(0.51, 3.79)
YO41543	8	5	5	2	1.56	(0.29, 8.50)
Total	19	13	17	10	1.37	(0.59, 3.20)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	8	72.7	3	27.3	12	70.6	8	66.7	4	33.3	0.5202	1.39	0.51	3.79		Convergence criterion (GCONV=1E-8) satisfied.	74.0						
	YO41543	8	42.1	5	62.5	3	37.5	5	29.4	2	40.0	3	60.0	0.6065	1.56	0.29	8.50		Convergence criterion (GCONV=1E-8) satisfied.	26.0						
	Total	19	100.0	13	68.4	6	31.6	17	100.0	10	58.8	7	41.2	0.5220	1.37	0.59	3.20		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.02	1	0.8791	0.00	0.72	0.4693

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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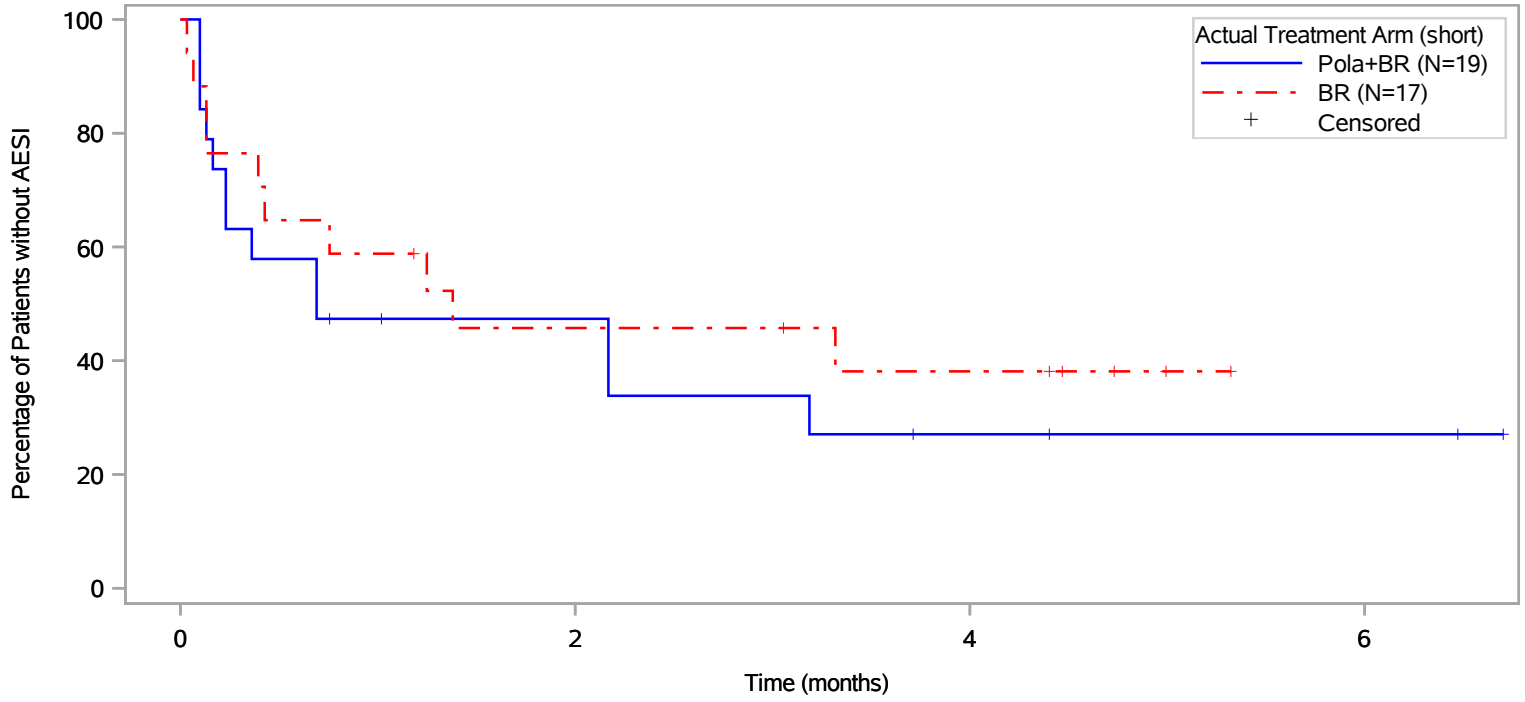
03APR2023 13:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	8	7	5	3	2	2
BR (N=17)	17	10	7	7	5	1	NE
Patients censored							
Pola+BR (N=19)	0	1	2	2	3	4	4
BR (N=17)	0	0	1	1	2	6	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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30MAR2023 11:48

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

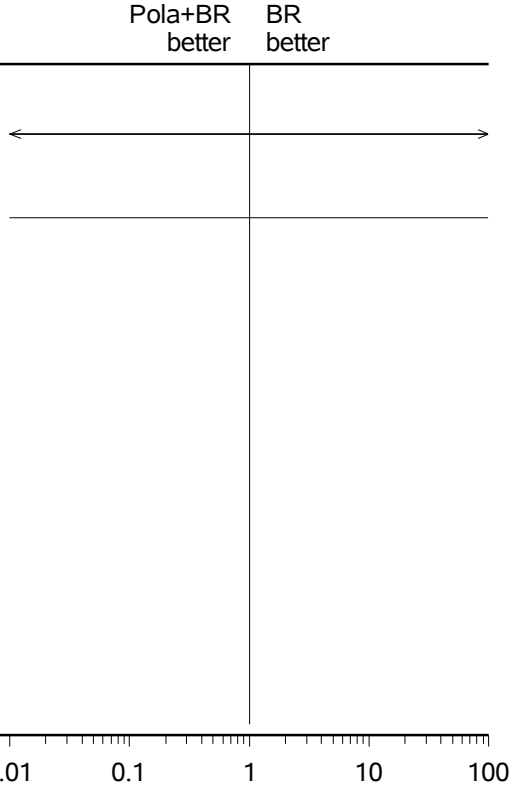
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.0614	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGASTOX35_L2_ARMCDPLUSSE_29365_41543.xls
30MAR2023 11:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	1	0.00	(0.00, NE)
YO41543	8	0	5	0	NE	NE
Total	19	0	17	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9987

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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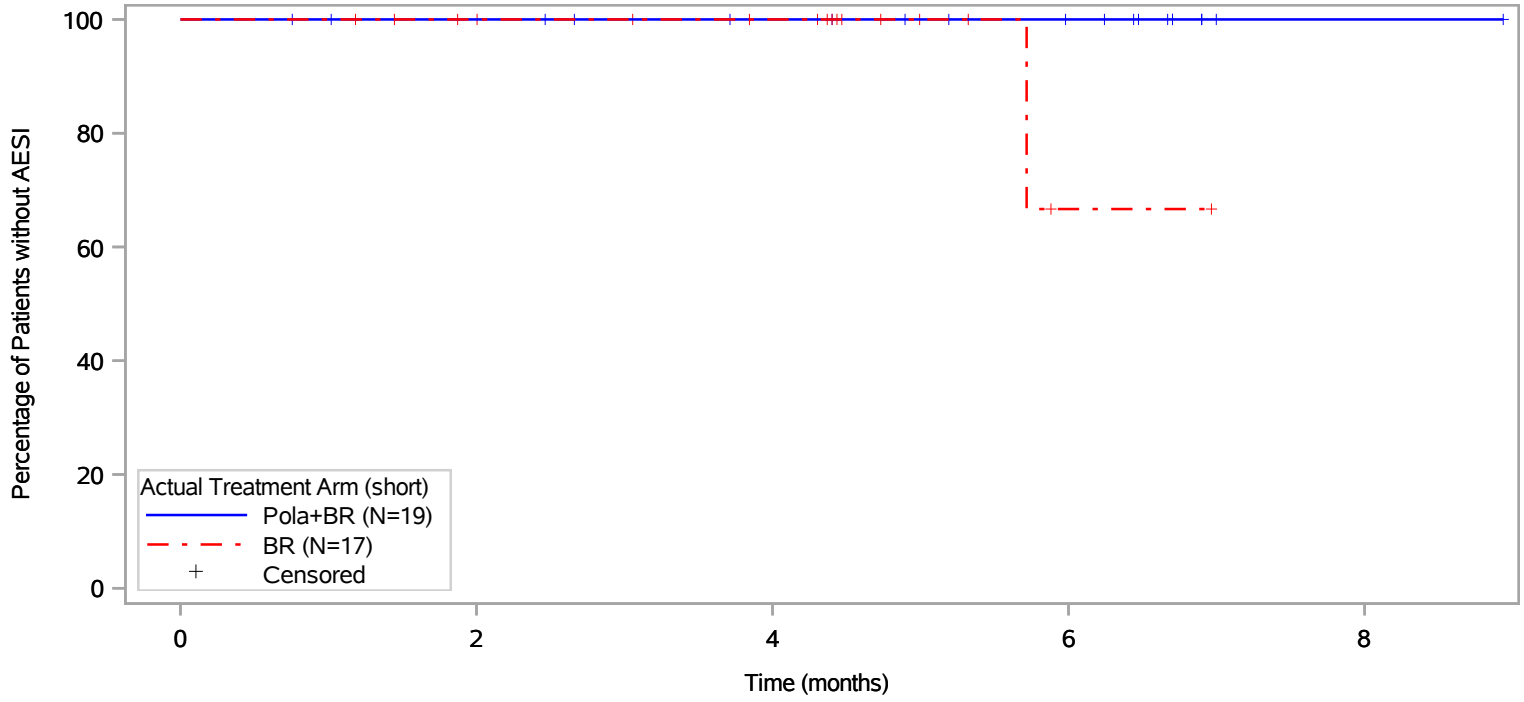
03APR2023 13:39

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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30MAR2023 13:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.0421	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.0837	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	2	14.3	12	85.7	0.1261	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	2	14.3	12	85.7	0.0494	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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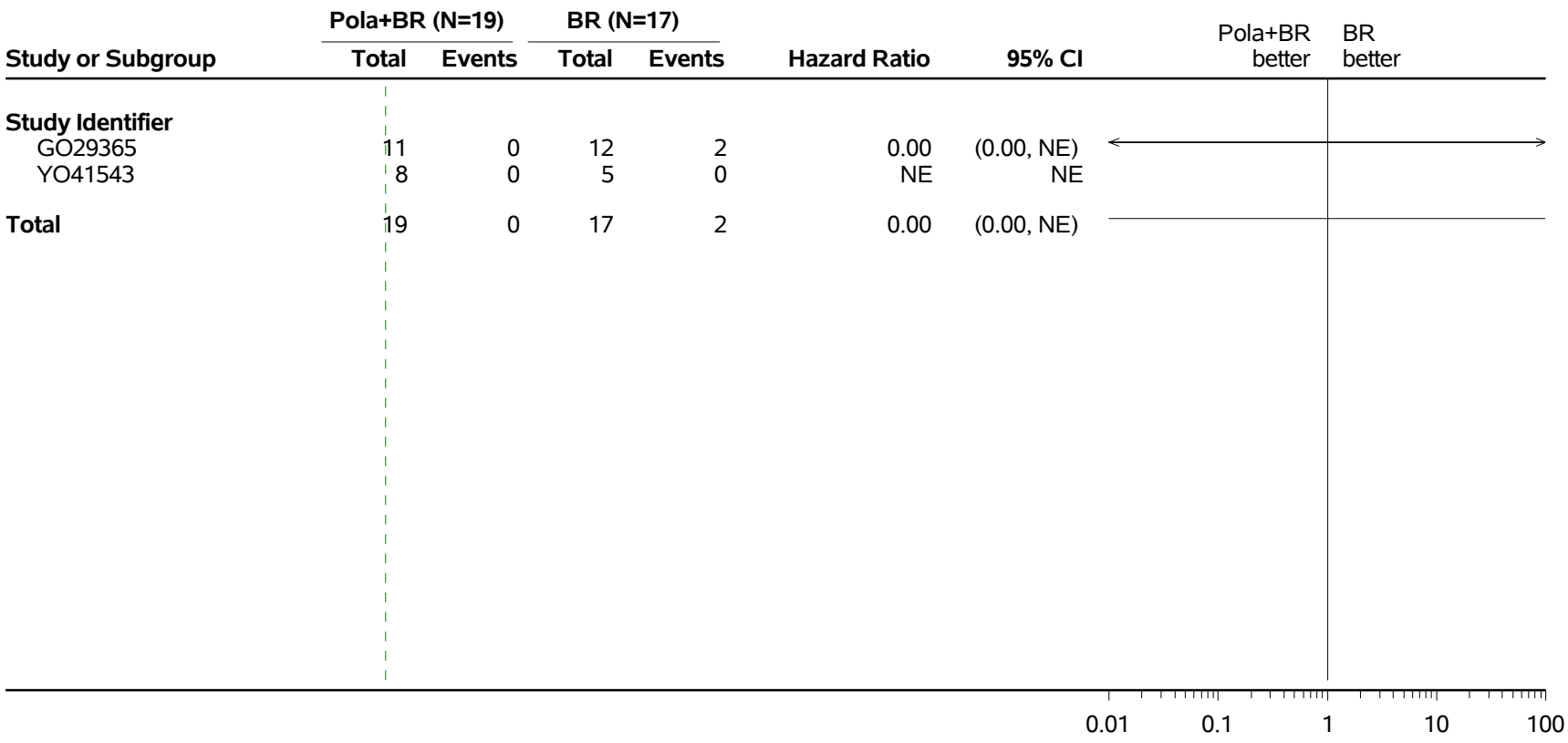
30MAR2023 10:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	2	0.00	(0.00, NE)
YO41543	8	0	5	0	NE	NE
Total	19	0	17	2	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGASTOXS_L2_ARMCDPLUSSE_29365_41543.pdf 30MAR2023 15:36

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	2	16.7	10	83.3	0.0822	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.0421	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9986

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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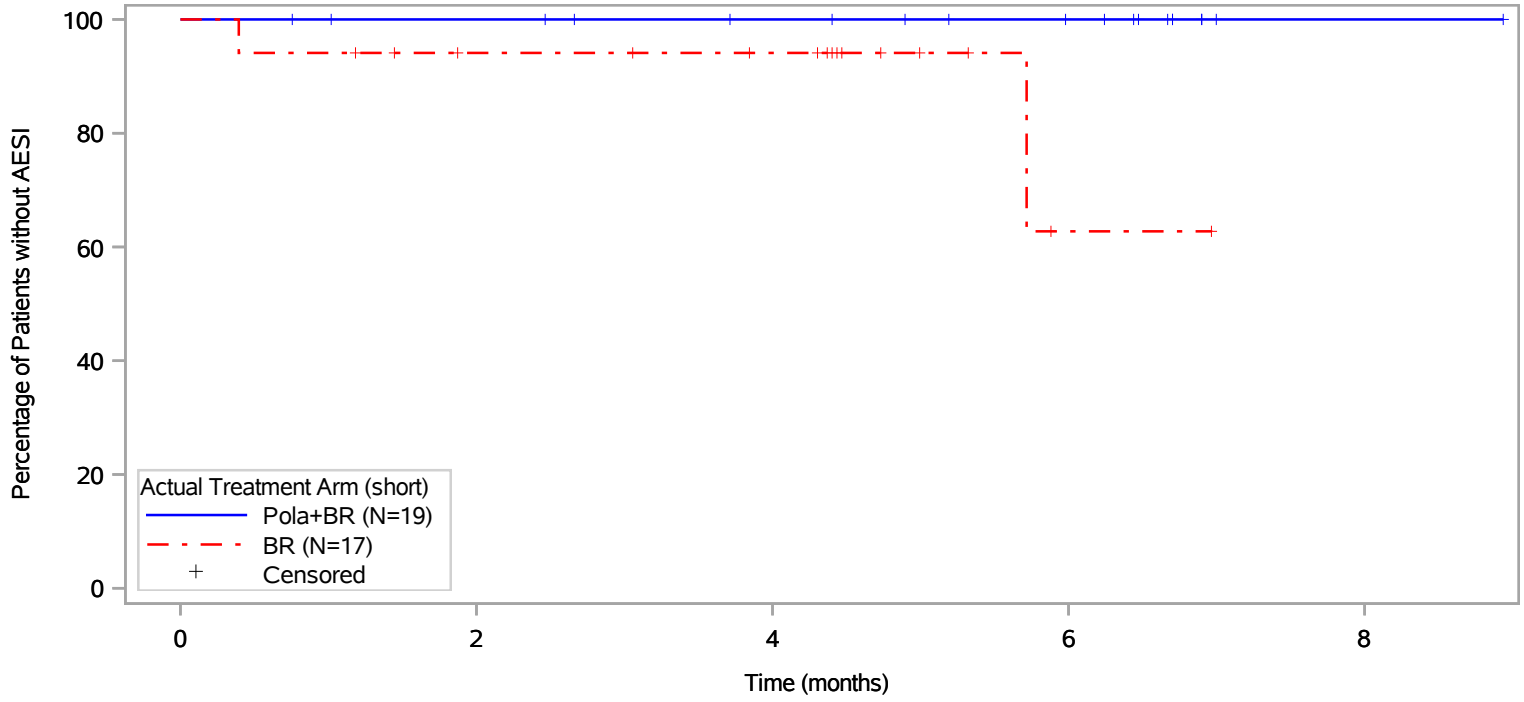
03APR2023 13:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	13	11	4	1	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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30MAR2023 12:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

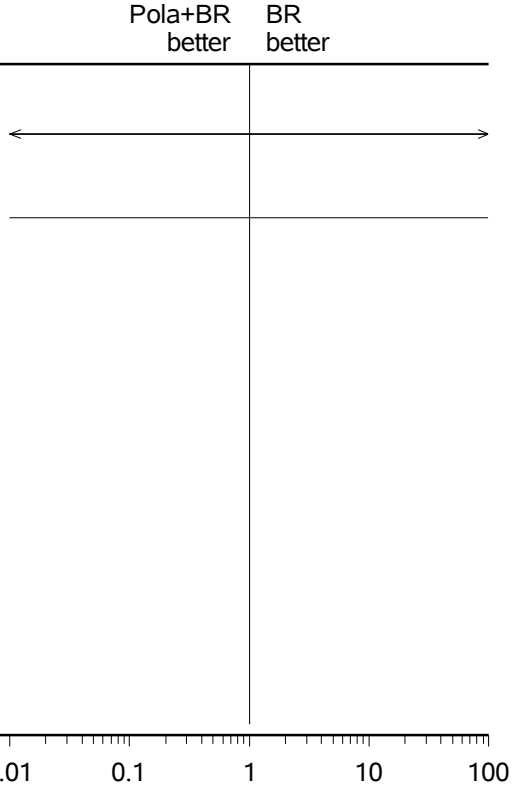
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	17	100.0	2	11.8	15	88.2	0.0303	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	2	14.3	12	85.7	0.0701	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGENCAR_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 21:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	1	12	2	0.00	(0.00, NE)
YO41543	8	0	5	0	NE	NE
Total	19	1	17	2	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	2	16.7	10	83.3	0.0376	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	1	5.3	18	94.7	17	100.0	2	11.8	15	88.2	0.0303	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9987

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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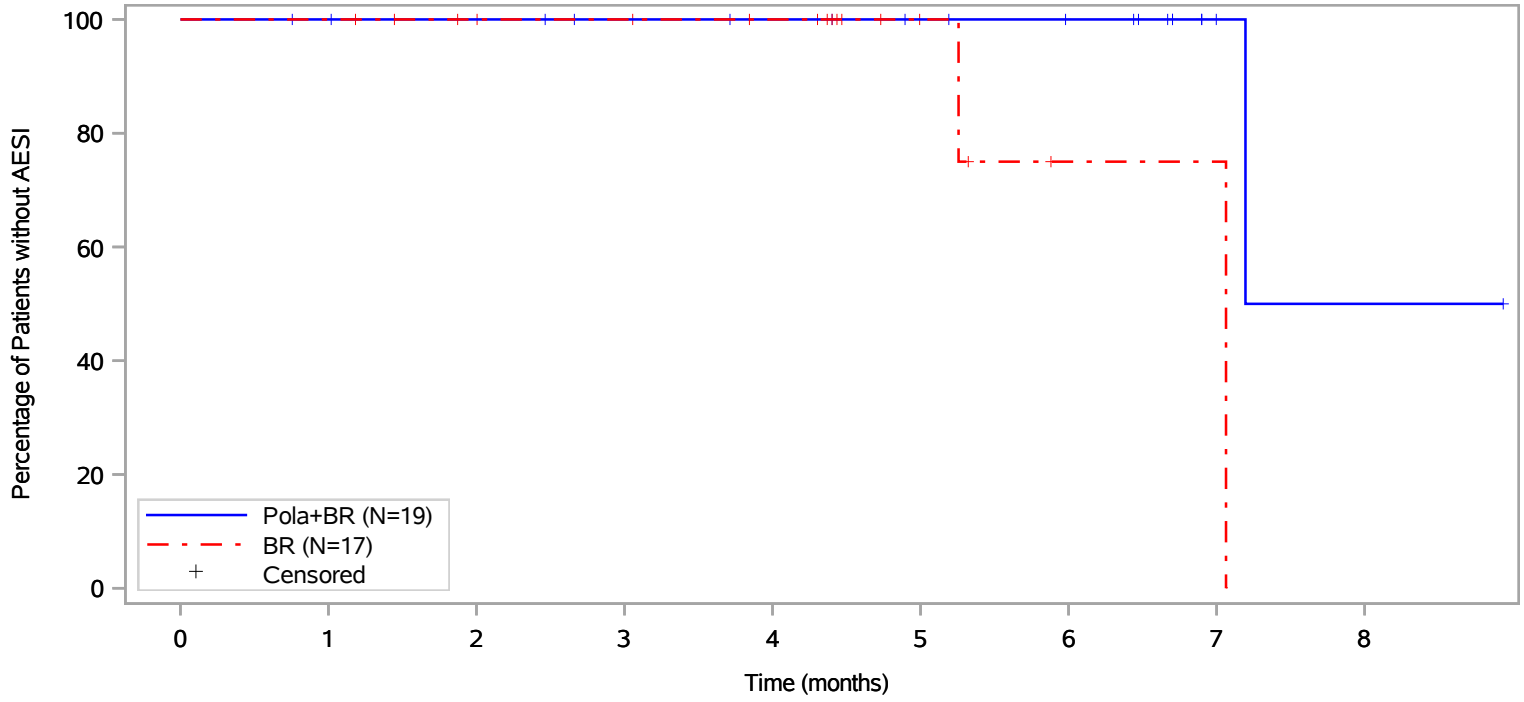
17DEC2022 22:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	1
BR (N=17)	17	17	14	13	11	4	1	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	15	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 22:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

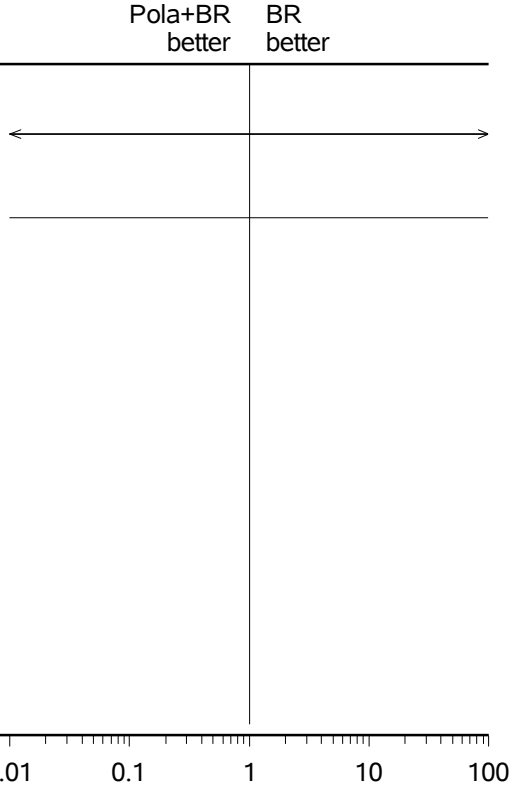
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	17	100.0	2	11.8	15	88.2	0.0303	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	2	14.3	12	85.7	0.0701	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGENCAR35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 22:42

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	1	12	2	0.00	(0.00, NE)
YO41543	8	0	5	0	NE	NE
Total	19	1	17	2	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	2	16.7	10	83.3	0.0376	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	1	5.3	18	94.7	17	100.0	2	11.8	15	88.2	0.0303	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9987

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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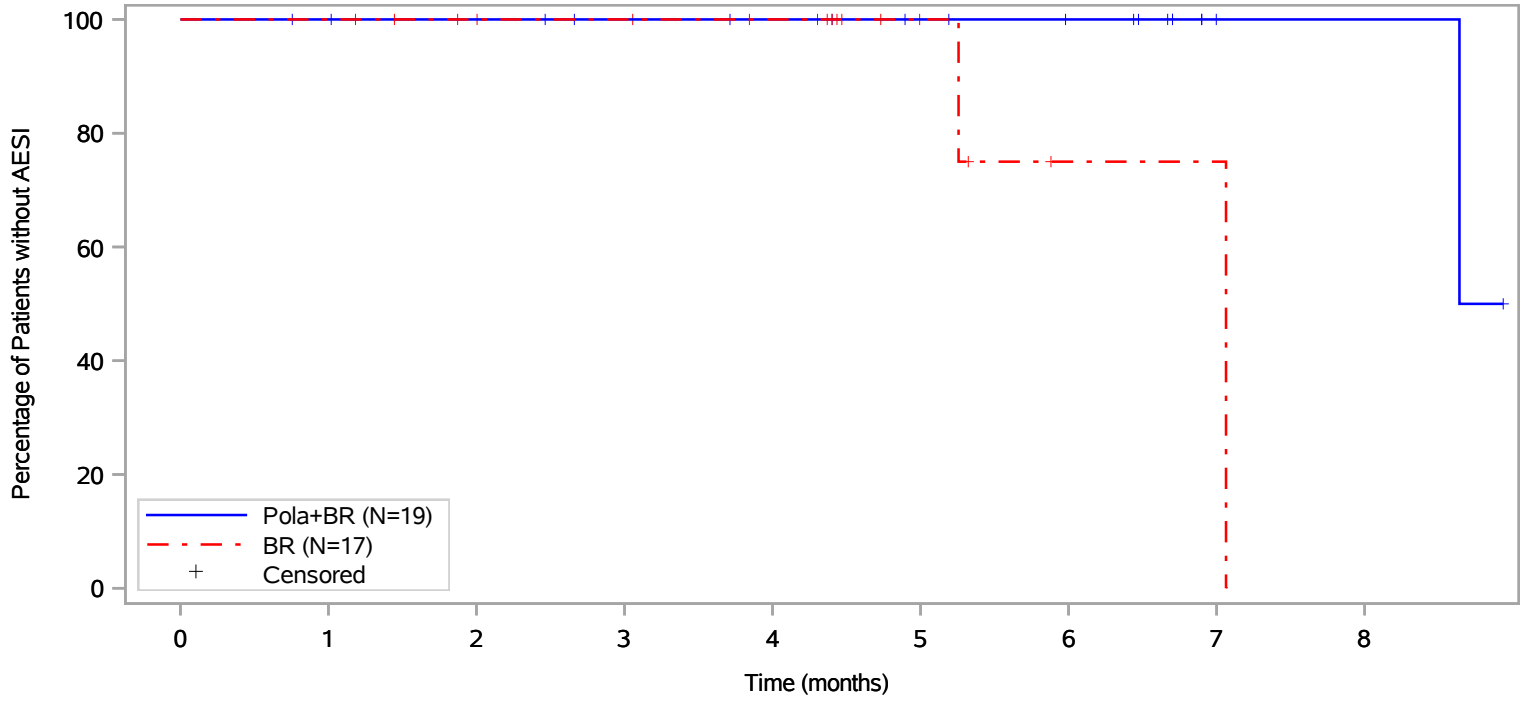
17DEC2022 22:11

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	2
BR (N=17)	17	17	14	13	11	4	1	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	15	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTGENCAR35_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 0:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

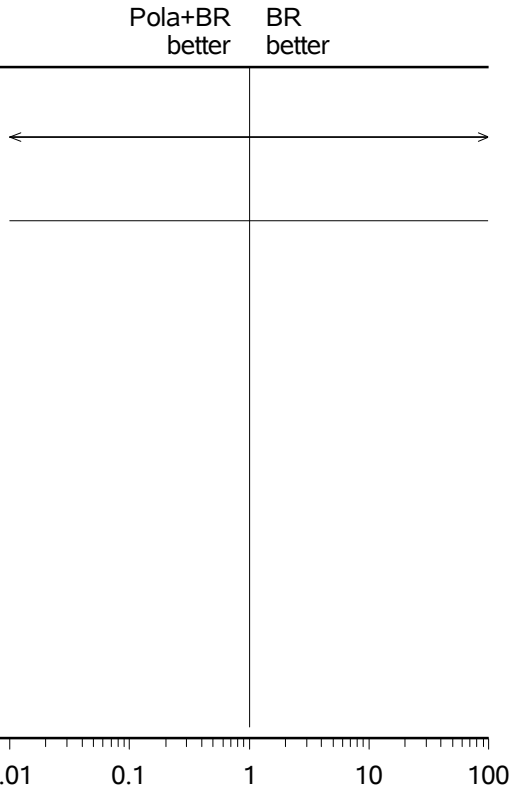
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGENCARS_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 22:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	1	12	1	0.00	(0.00, NE)
YO41543	8	0	5	0	NE	NE
Total	19	1	17	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGENCARS_L2_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 21:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	1	8.3	11	91.7	0.1573	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	1	5.3	18	94.7	17	100.0	1	5.9	16	94.1	0.1573	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9990

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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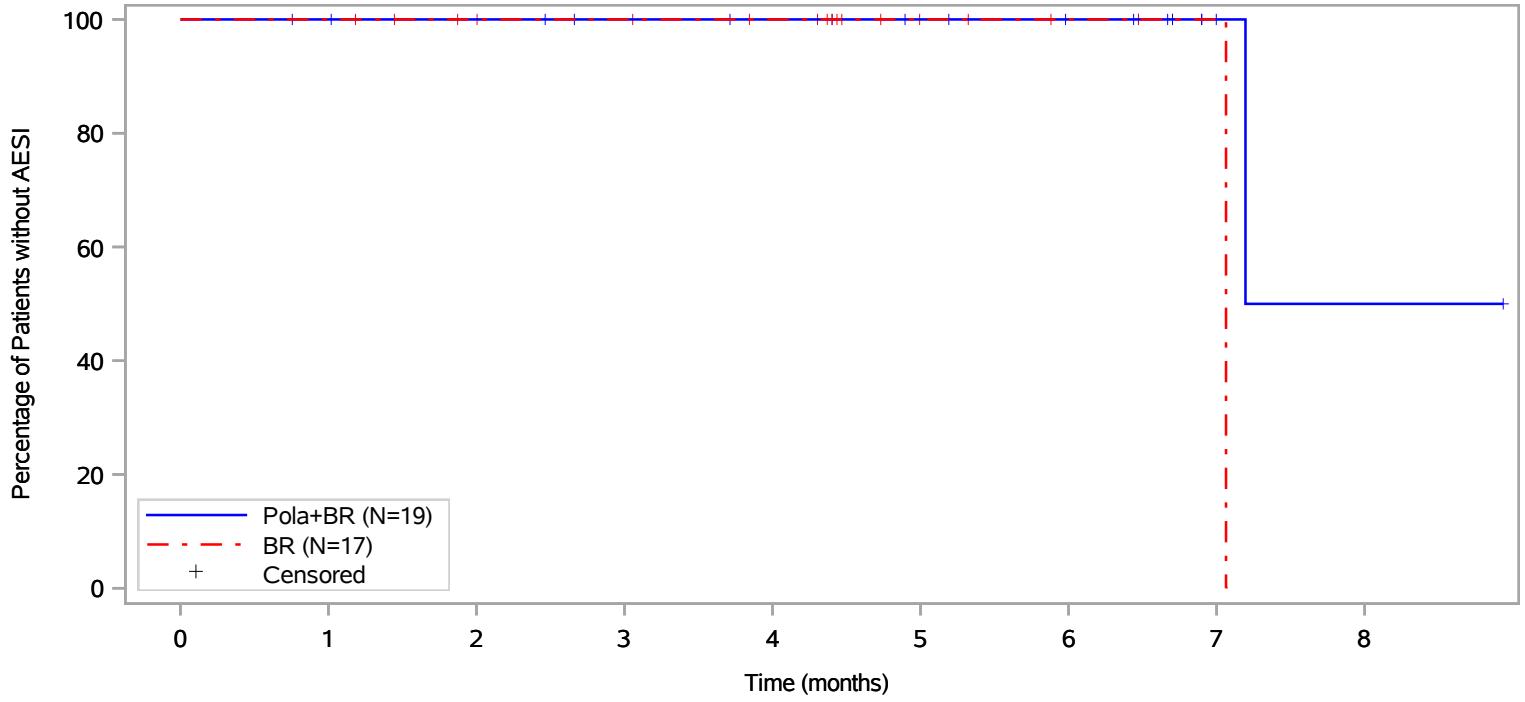
17DEC2022 16:14

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	2	1
BR (N=17)	17	17	14	13	11	4	2	1	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 2:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

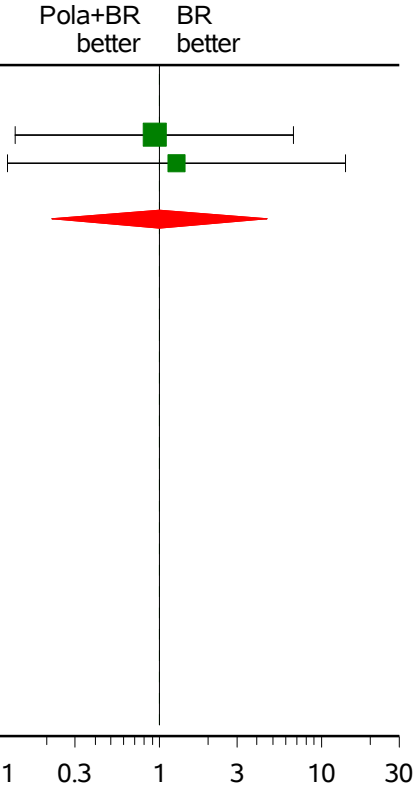
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	4	21.1	15	78.9	17	100.0	3	17.6	14	82.4	0.9613	1.00	0.22	4.58		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	4	28.6	10	71.4	8	47.1	2	25.0	6	75.0	0.9678	1.05	0.17	6.42		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	2	18.2	9	81.8	15	88.2	3	20.0	12	80.0	0.8094	0.76	0.13	4.58		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	3	21.4	11	78.6	0.6514	0.59	0.06	5.74		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.3982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	3	21.4	11	78.6	0.9197	1.13	0.24	5.27		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHEPAT_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 3:50

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	2	12	2	0.93	(0.13, 6.70)
YO41543	8	2	5	1	1.27	(0.11, 14.04)
Total	19	4	17	3	1.00	(0.22, 4.58)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	2	18.2	9	81.8	12	70.6	2	16.7	10	83.3	0.9413	0.93	0.13	6.70		Convergence criterion (GCONV=1E-8) satisfied.	59.7						
	YO41543	8	42.1	2	25.0	6	75.0	5	29.4	1	20.0	4	80.0	0.8450	1.27	0.11	14.04		Convergence criterion (GCONV=1E-8) satisfied.	40.3						
	Total	19	100.0	4	21.1	15	78.9	17	100.0	3	17.6	14	82.4	0.9613	1.00	0.22	4.58		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.04	1	0.8336	0.00	0.00	0.9962

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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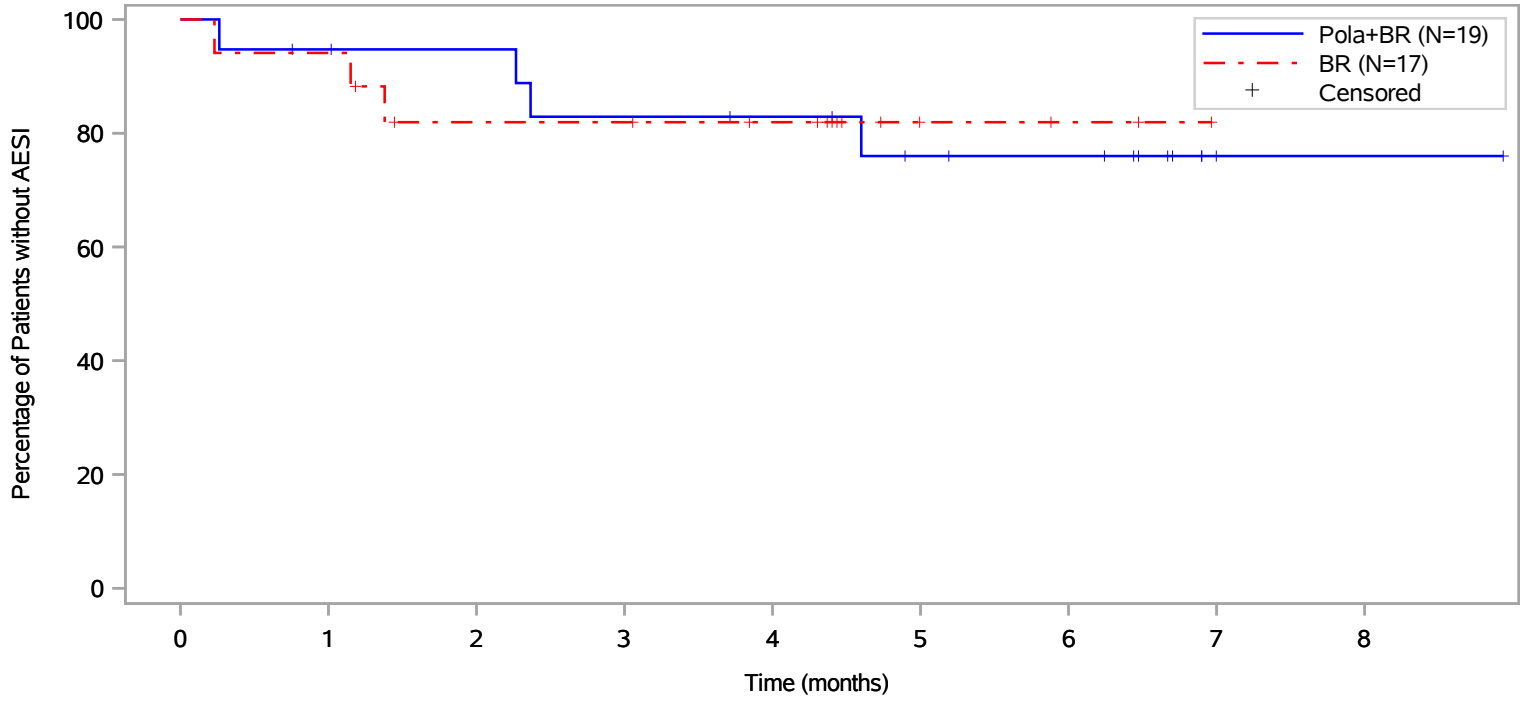
16DEC2022 11:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	17	16	14	13	10	9	1	1
BR (N=17)	17	16	12	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	2	3	5	6	14	14
BR (N=17)	0	0	2	2	4	11	12	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 21:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

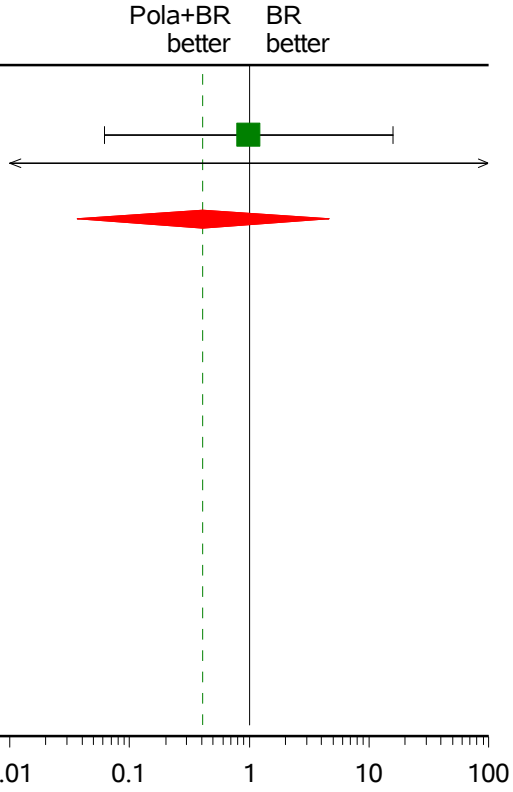
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	17	100.0	2	11.8	15	88.2	0.4411	0.41	0.04	4.61		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	8	47.1	1	12.5	7	87.5	0.6055	0.89	0.06	14.36		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.6611	0.57	0.05	6.33		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	2	14.3	12	85.7	0.8892	0.84	0.08	9.33		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	2	14.3	12	85.7	0.4621	0.47	0.04	5.35		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHEPAT35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	1	12	1	0.98	(0.06, 15.80)
YO41543	8	0	5	1	0.00	(0.00, NE)
Total	19	1	17	2	0.41	(0.04, 4.61)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	1	8.3	11	91.7	0.9913	0.98	0.06	15.80		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	19	100.0	1	5.3	18	94.7	17	100.0	2	11.8	15	88.2	0.4411	0.41	0.04	4.61		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.38	1	0.5358	0.00	-0.72	0.4701

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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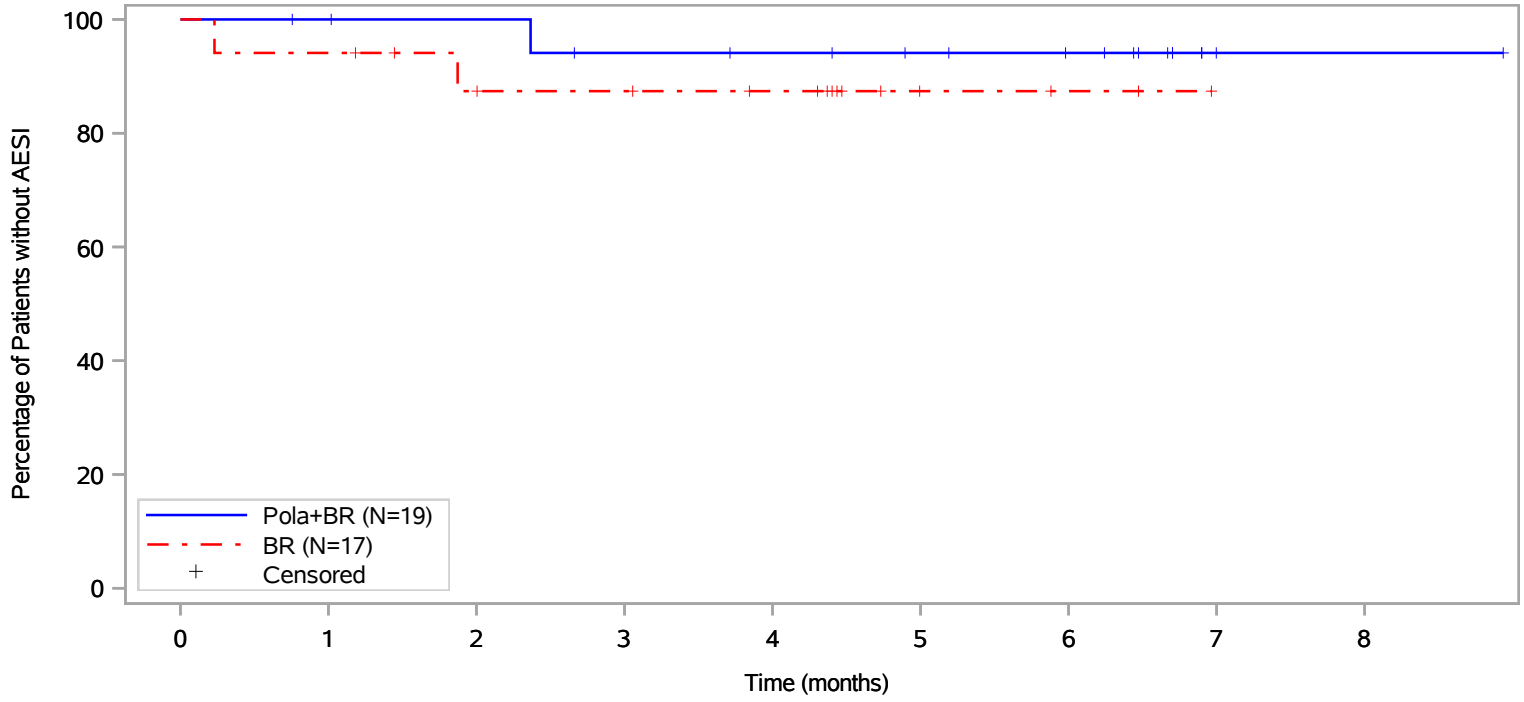
15DEC2022 20:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	17	17
BR (N=17)	0	0	2	3	5	12	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 23:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

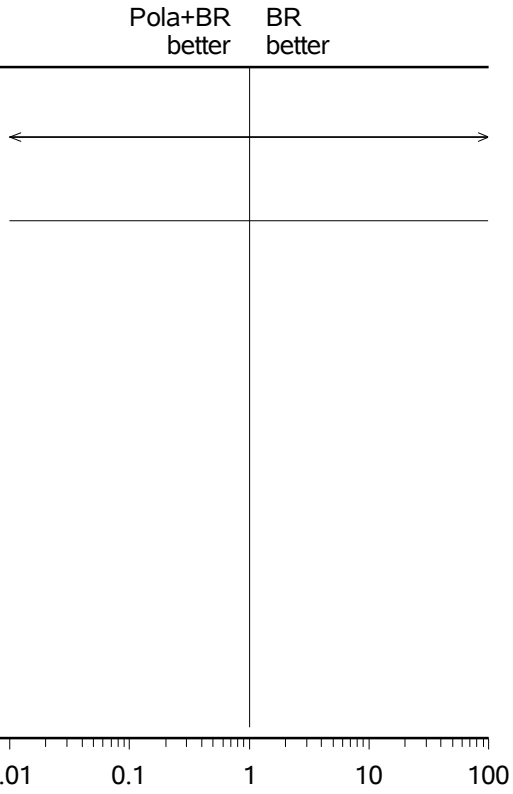
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	1	6.7	14	93.3	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.5127	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3352	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHEPATS_L2_ARMCDPLUSSE_29365_41543.xls
25JAN2023 11:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	1	0.00	(0.00, NE)
YO41543	8	0	5	0	NE	NE
Total	19	0	17	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTHEPATS_L2_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 17:34

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9989

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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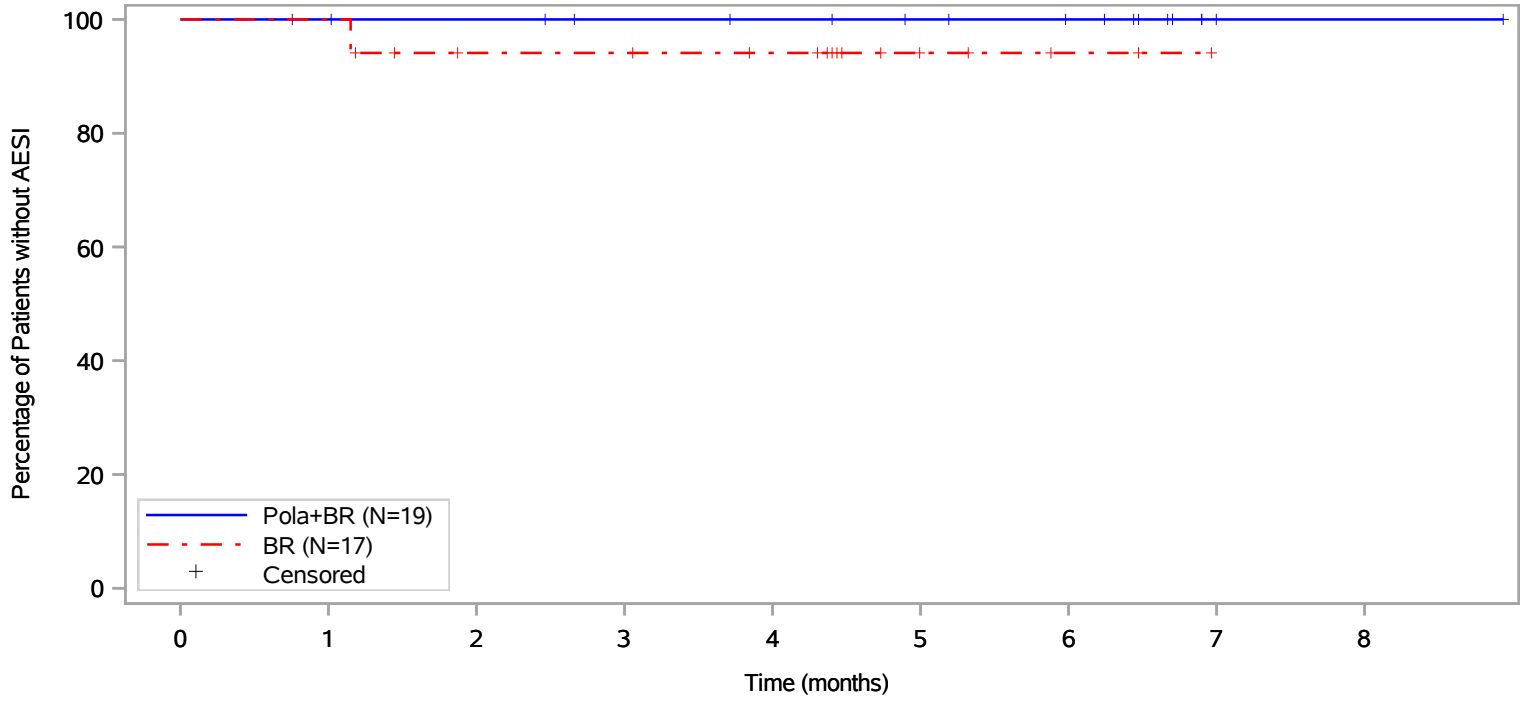
15DEC2022 21:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	13	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTHEPATS_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 1:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

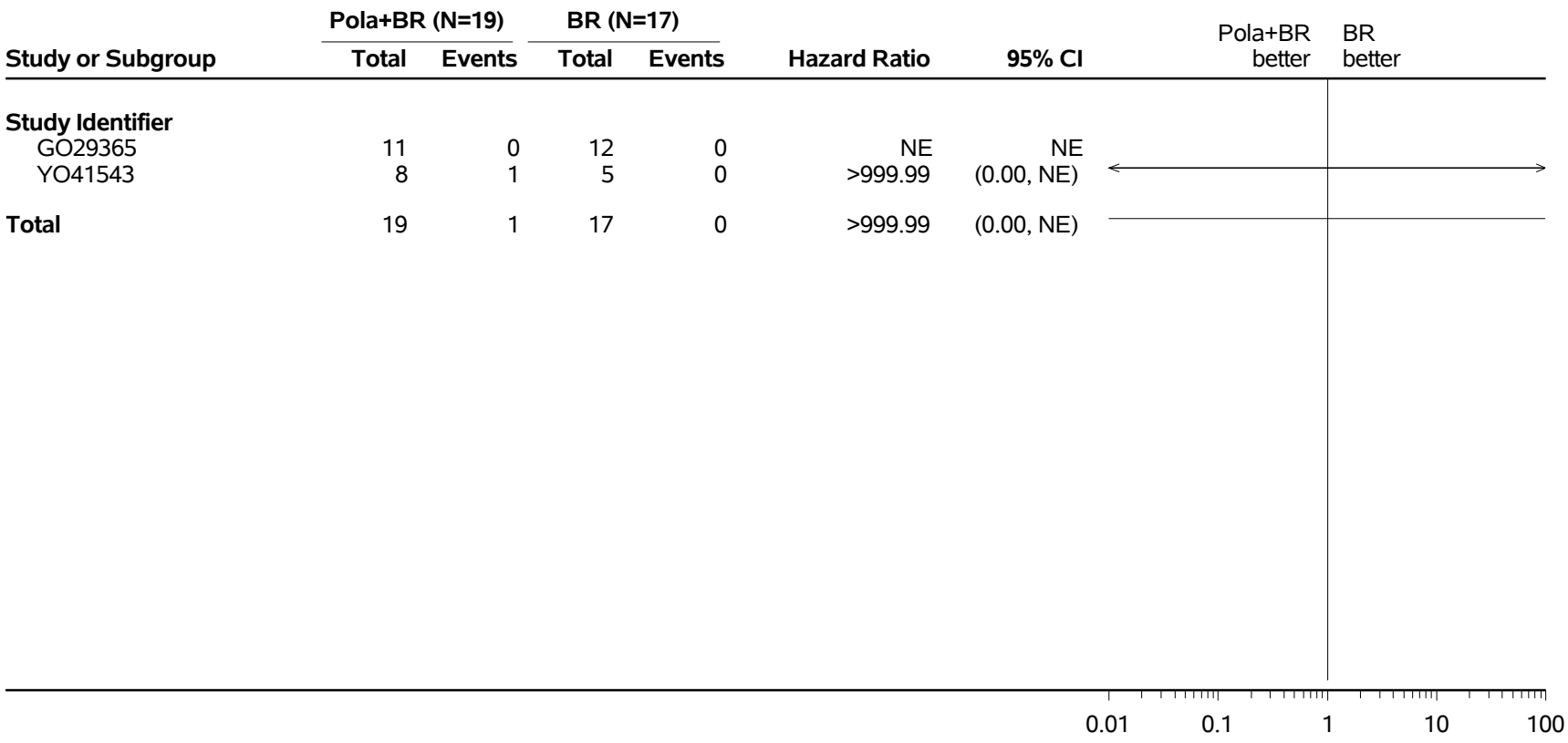
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHYPGL_L2_ARMCDPLUSSE_29365_41543.xls
25JAN2023 11:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	0	NE	NE
YO41543	8	1	5	0	>999.99	(0.00, NE)
Total	19	1	17	0	>999.99	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	1	12.5	7	87.5	5	29.4	0	-	5	100.0	0.4292	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	0.3320	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9990

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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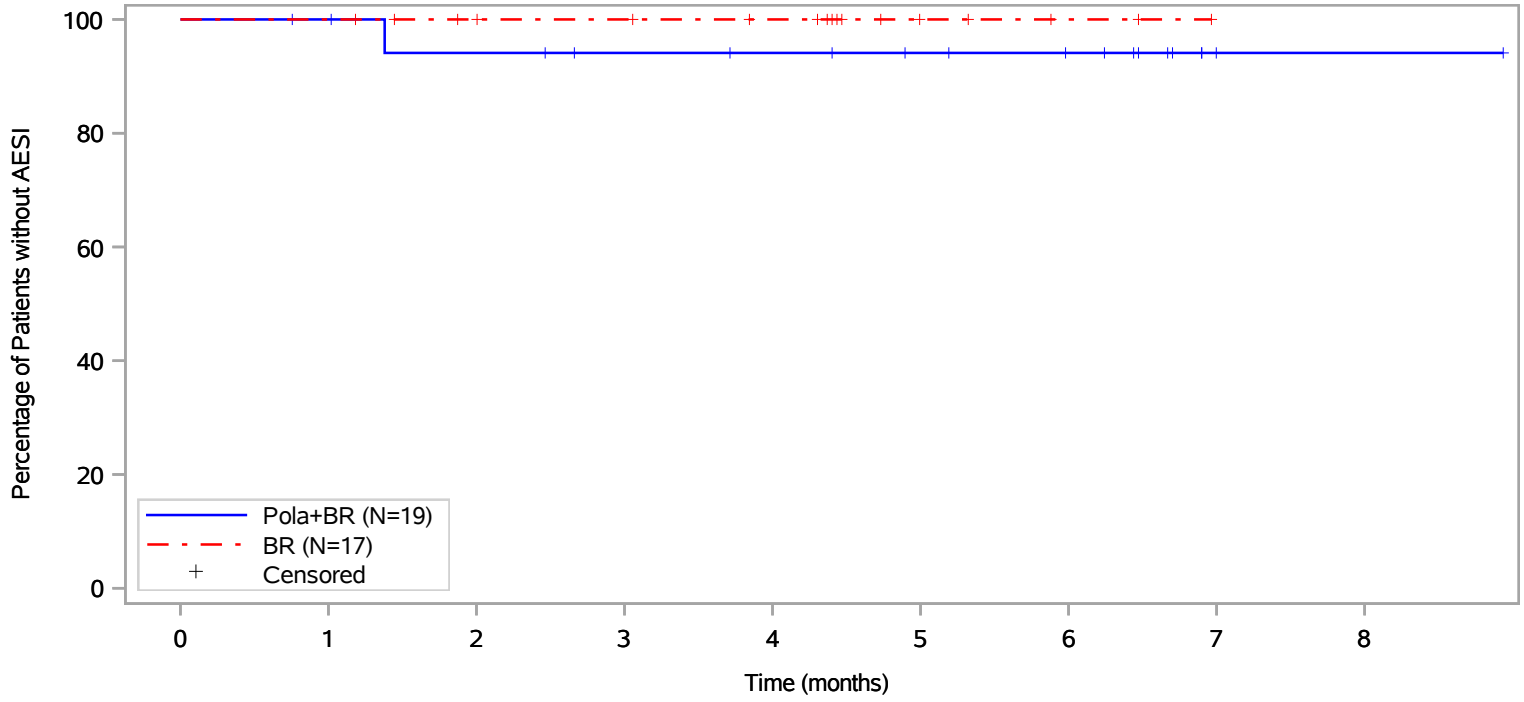
17DEC2022 20:56

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	16	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	17	17
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..alysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTHYPGL_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHYPGL35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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16DEC2022 9:56

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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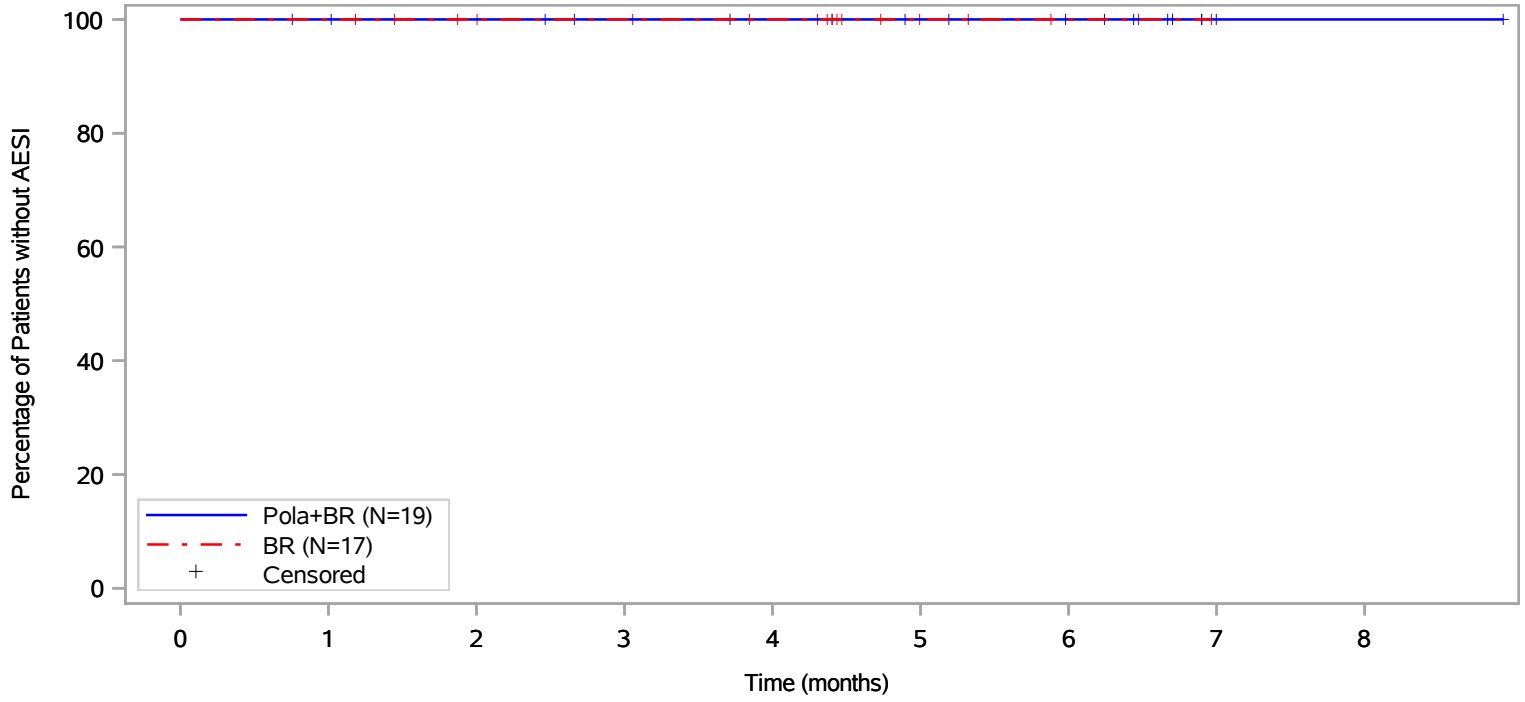
15DEC2022 21:36

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTHYPGL35_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 23:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHYPGLS_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:11

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTHYPGLS_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 10:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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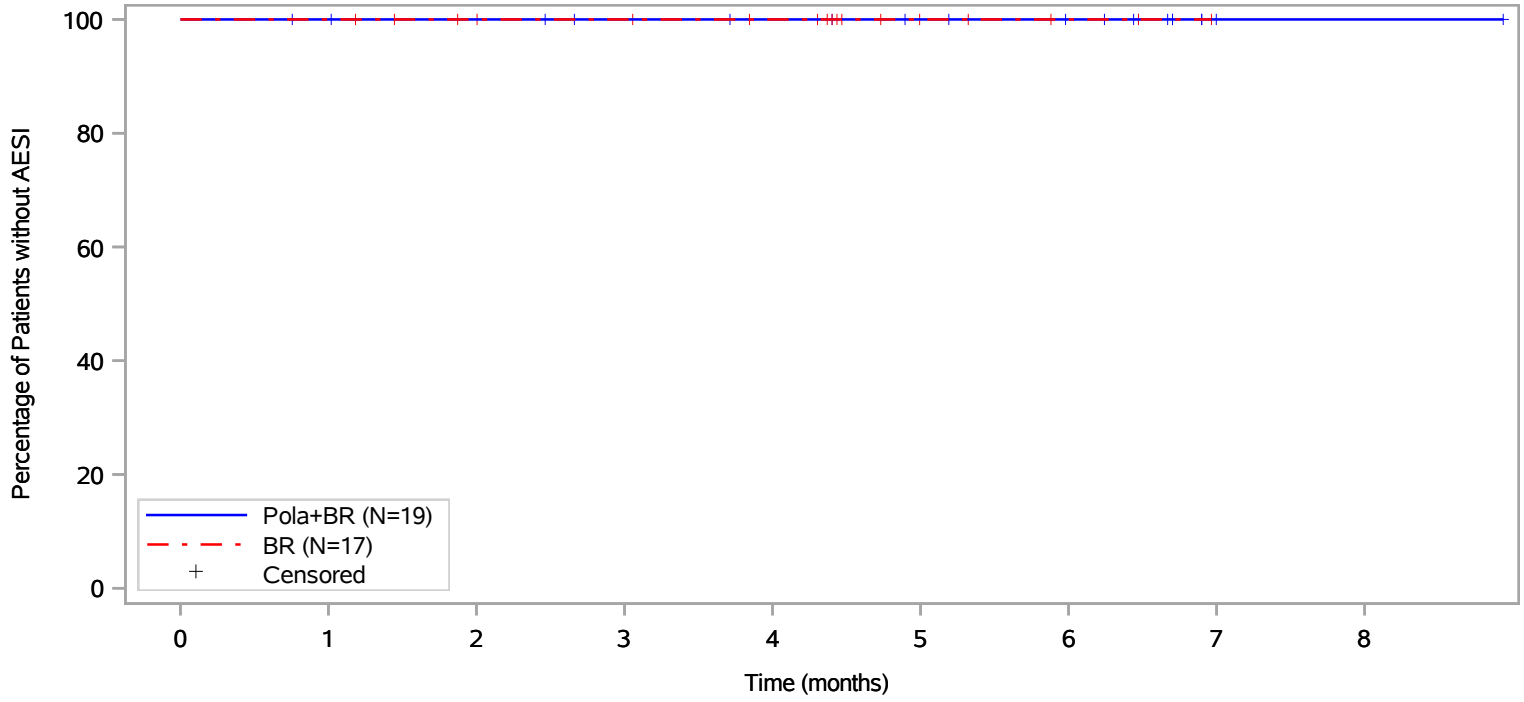
15DEC2022 22:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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04DEC2022 1:36

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

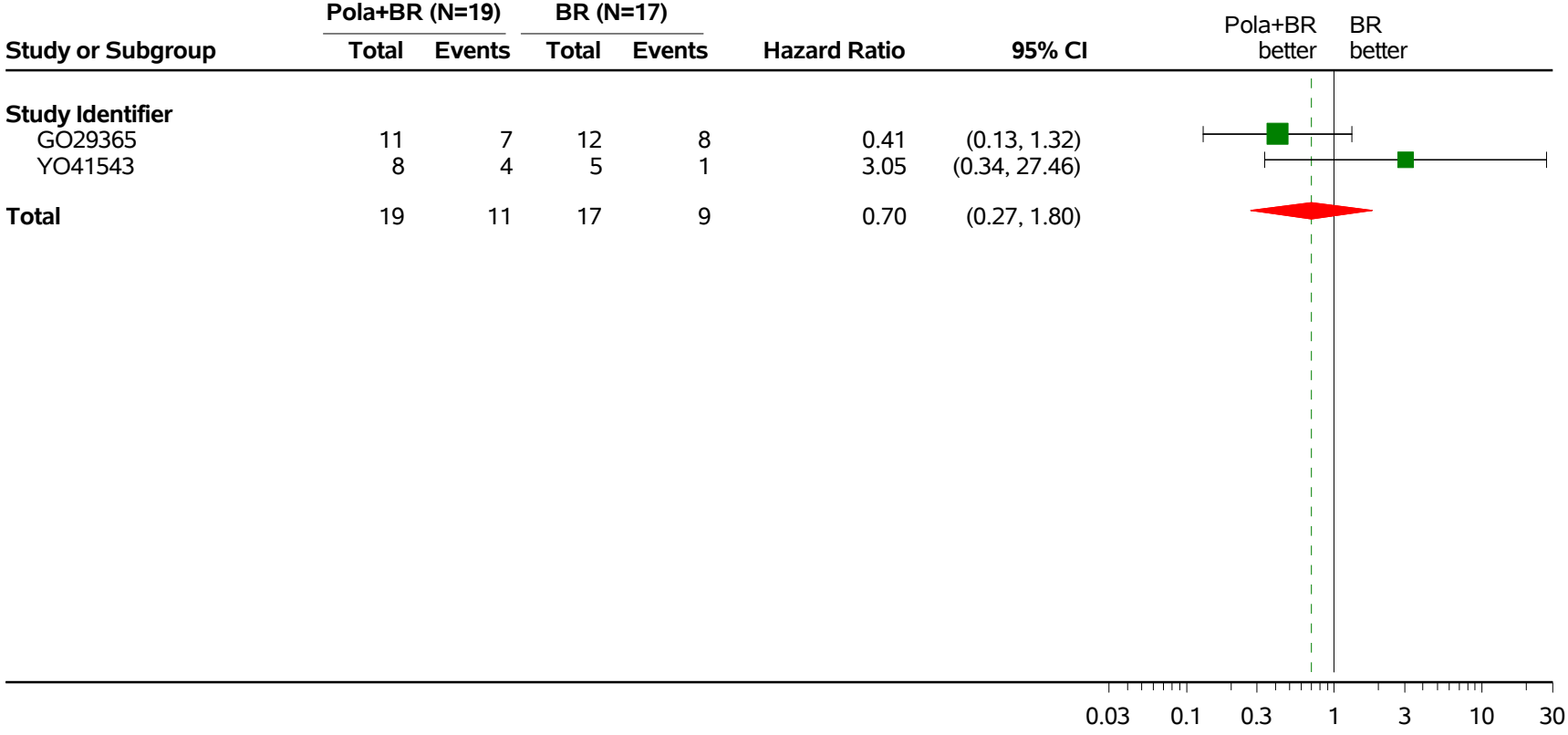
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	11	57.9	8	42.1	17	100.0	9	52.9	8	47.1	0.4496	0.70	0.27	1.80		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	8	57.1	6	42.9	8	47.1	4	50.0	4	50.0	0.6622	1.00	0.27	3.69		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	3	60.0	2	40.0	9	52.9	5	55.6	4	44.4	0.3188	0.40	0.06	2.48		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	4	50.0	4	50.0	2	11.8	1	50.0	1	50.0	0.8276	1.07	0.10	11.99		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	7	63.6	4	36.4	15	88.2	8	53.3	7	46.7	0.3232	0.55	0.17	1.78		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	6	75.0	2	25.0	14	82.4	6	42.9	8	57.1	0.4776	1.45	0.43	4.90		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	5	45.5	6	54.5	3	17.6	3	100.0	0	-	0.0079	0.12	0.02	0.76		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	3	60.0	2	40.0	3	17.6	2	66.7	1	33.3	0.4335	0.39	0.04	4.39		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	8	57.1	6	42.9	14	82.4	7	50.0	7	50.0	0.6993	0.83	0.29	2.39		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTINECT_L2_ARMCDPLUSSE_29365_41543.xls
30MAR2023 9:06

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	7	12	8	0.41	(0.13, 1.32)
YO41543	8	4	5	1	3.05	(0.34, 27.46)
Total	19	11	17	9	0.70	(0.27, 1.80)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTINECT_L2_ARMCDPLUSSE_29365_41543.pdf 30MAR2023 15:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	7	63.6	4	36.4	12	70.6	8	66.7	4	33.3	0.1260	0.41	0.13	1.32		Convergence criterion (GCONV=1E-8) satisfied.	78.2						
	YO41543	8	42.1	4	50.0	4	50.0	5	29.4	1	20.0	4	80.0	0.2949	3.05	0.34	27.46		Convergence criterion (GCONV=1E-8) satisfied.	21.8						
	Total	19	100.0	11	57.9	8	42.1	17	100.0	9	52.9	8	47.1	0.4496	0.70	0.27	1.80		Convergence criterion (GCONV=1E-8) satisfied.	100.0	2.51	1	0.1128	60.24	-0.74	0.4590

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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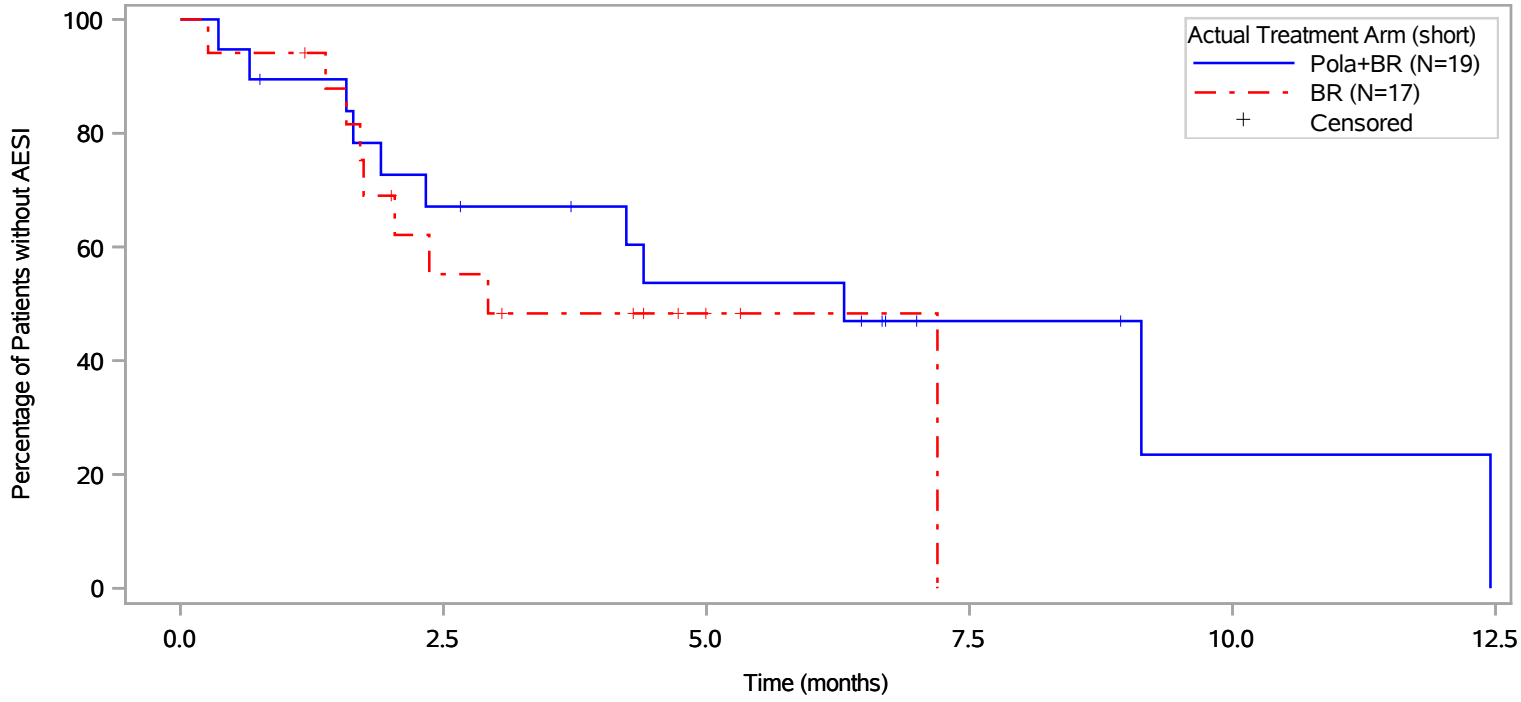
03APR2023 13:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk													
Pola+BR (N=19)	19	16	13	11	10	8	8	3	3	2	1	1	1
BR (N=17)	17	16	11	7	6	2	1	1	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	1	2	3	3	3	7	7	8	8	8	8
BR (N=17)	0	0	1	2	3	7	8	8	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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30MAR2023 11:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	5	26.3	14	73.7	17	100.0	4	23.5	13	76.5	0.3345	0.51	0.11	2.35		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	3	21.4	11	78.6	8	47.1	1	12.5	7	87.5	0.8592	1.60	0.14	18.24		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	9	52.9	3	33.3	6	66.7	0.3894	0.32	0.03	3.41		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	4	26.7	11	73.3	0.3964	0.48	0.08	2.74		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	3	37.5	5	62.5	14	82.4	3	21.4	11	78.6	0.9504	1.03	0.16	6.72		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	2	18.2	9	81.8	3	17.6	1	33.3	2	66.7	0.0555	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	3	21.4	11	78.6	0.6443	0.79	0.15	4.05		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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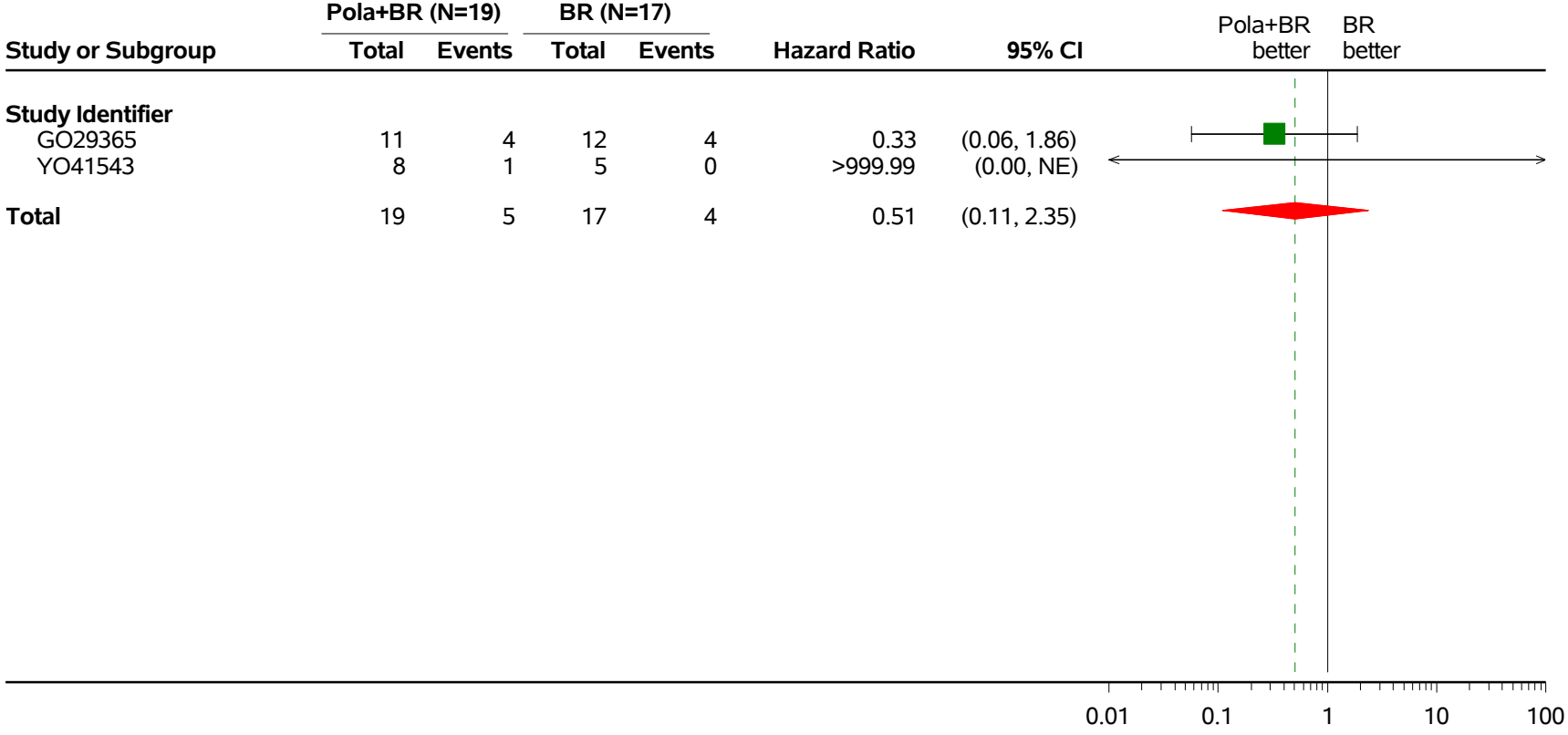
30MAR2023 10:53

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	4	12	4	0.33	(0.06, 1.86)
YO41543	8	1	5	0	>999.99	(0.00, NE)
Total	19	5	17	4	0.51	(0.11, 2.35)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	4	36.4	7	63.6	12	70.6	4	33.3	8	66.7	0.1880	0.33	0.06	1.86		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	1	12.5	7	87.5	5	29.4	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	19	100.0	5	26.3	14	73.7	17	100.0	4	23.5	13	76.5	0.3345	0.51	0.11	2.35		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.25	1	0.6205	0.00	-0.87	0.3854

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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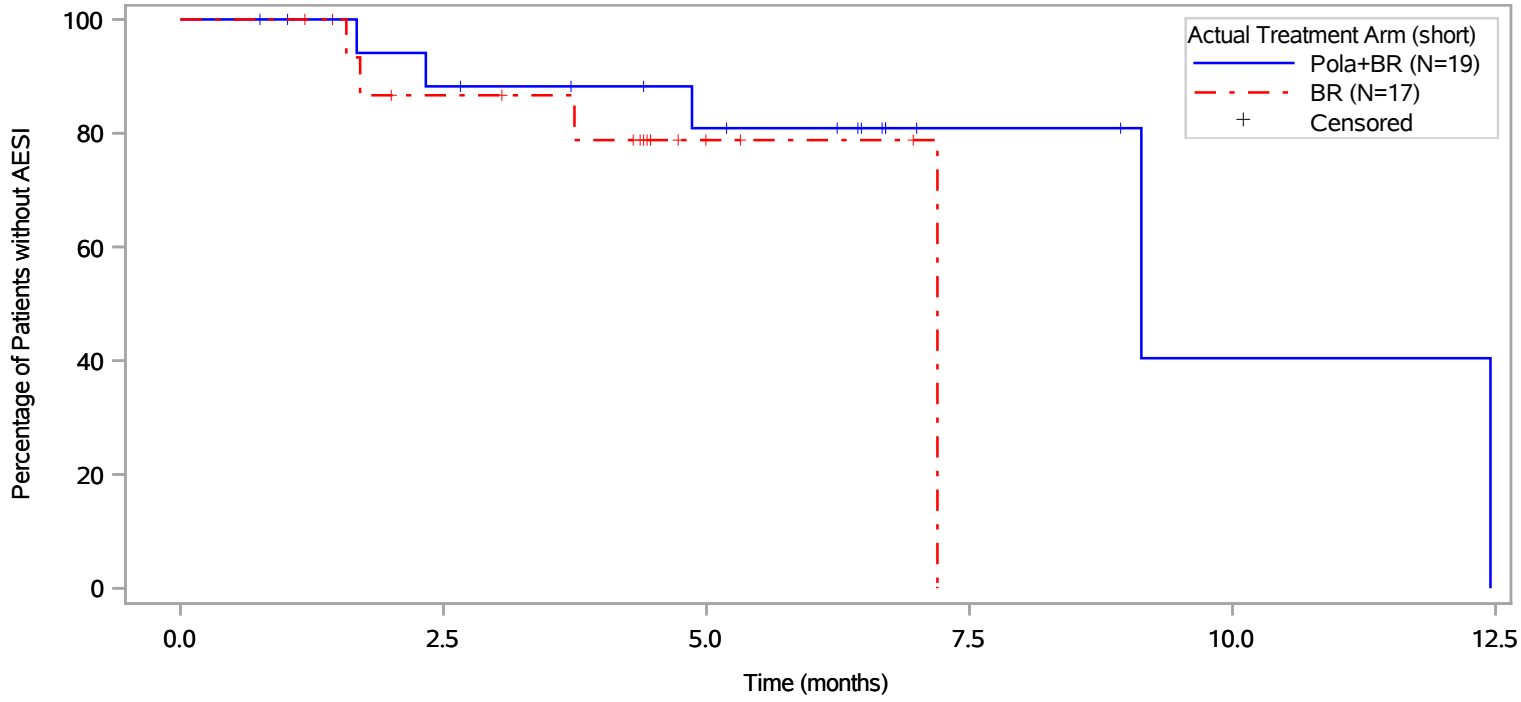
03APR2023 13:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk													
Pola+BR (N=19)	19	18	16	14	13	11	10	3	3	2	1	1	1
BR (N=17)	17	17	13	12	10	3	2	1	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=19)	0	1	2	3	4	5	6	13	13	14	14	14	14
BR (N=17)	0	0	2	3	4	11	12	13	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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30MAR2023 13:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	6	31.6	13	68.4	17	100.0	4	23.5	13	76.5	0.3479	0.53	0.11	2.49		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	5	35.7	9	64.3	8	47.1	1	12.5	7	87.5	0.8140	1.85	0.17	19.64		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	9	52.9	3	33.3	6	66.7	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	2	25.0	6	75.0	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	4	26.7	11	73.3	0.1350	0.21	0.02	2.15		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	3	37.5	5	62.5	14	82.4	4	28.6	10	71.4	0.2785	0.29	0.03	2.99		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	3	27.3	8	72.7	3	17.6	0	-	3	100.0	0.5290	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	2	40.0	3	60.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	3	21.4	11	78.6	0.6968	0.88	0.17	4.56		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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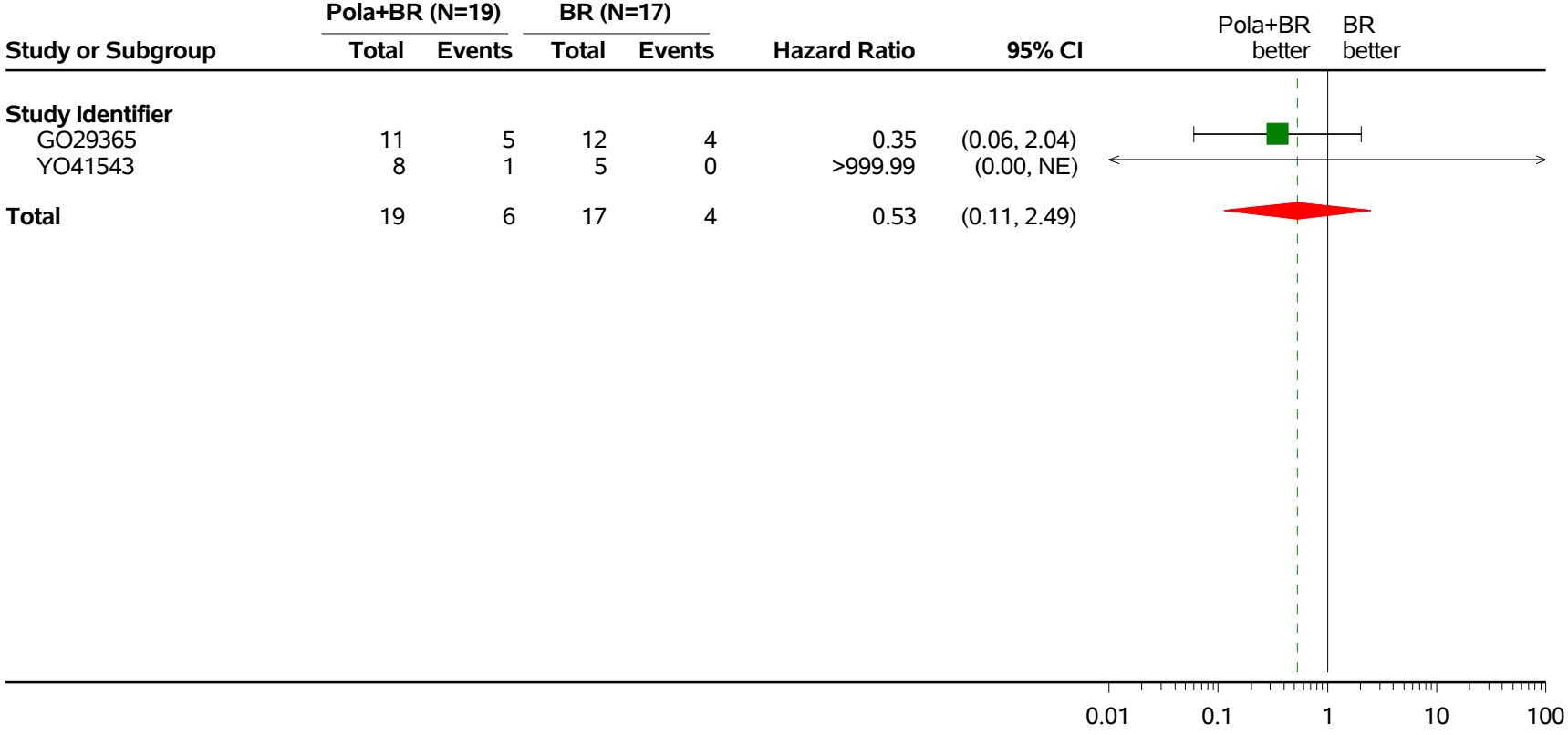
30MAR2023 10:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	5	12	4	0.35	(0.06, 2.04)
YO41543	8	1	5	0	>999.99	(0.00, NE)
Total	19	6	17	4	0.53	(0.11, 2.49)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	5	45.5	6	54.5	12	70.6	4	33.3	8	66.7	0.2265	0.35	0.06	2.04		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	1	12.5	7	87.5	5	29.4	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	19	100.0	6	31.6	13	68.4	17	100.0	4	23.5	13	76.5	0.3479	0.53	0.11	2.49		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.21	1	0.6463	0.00	-0.80	0.4212

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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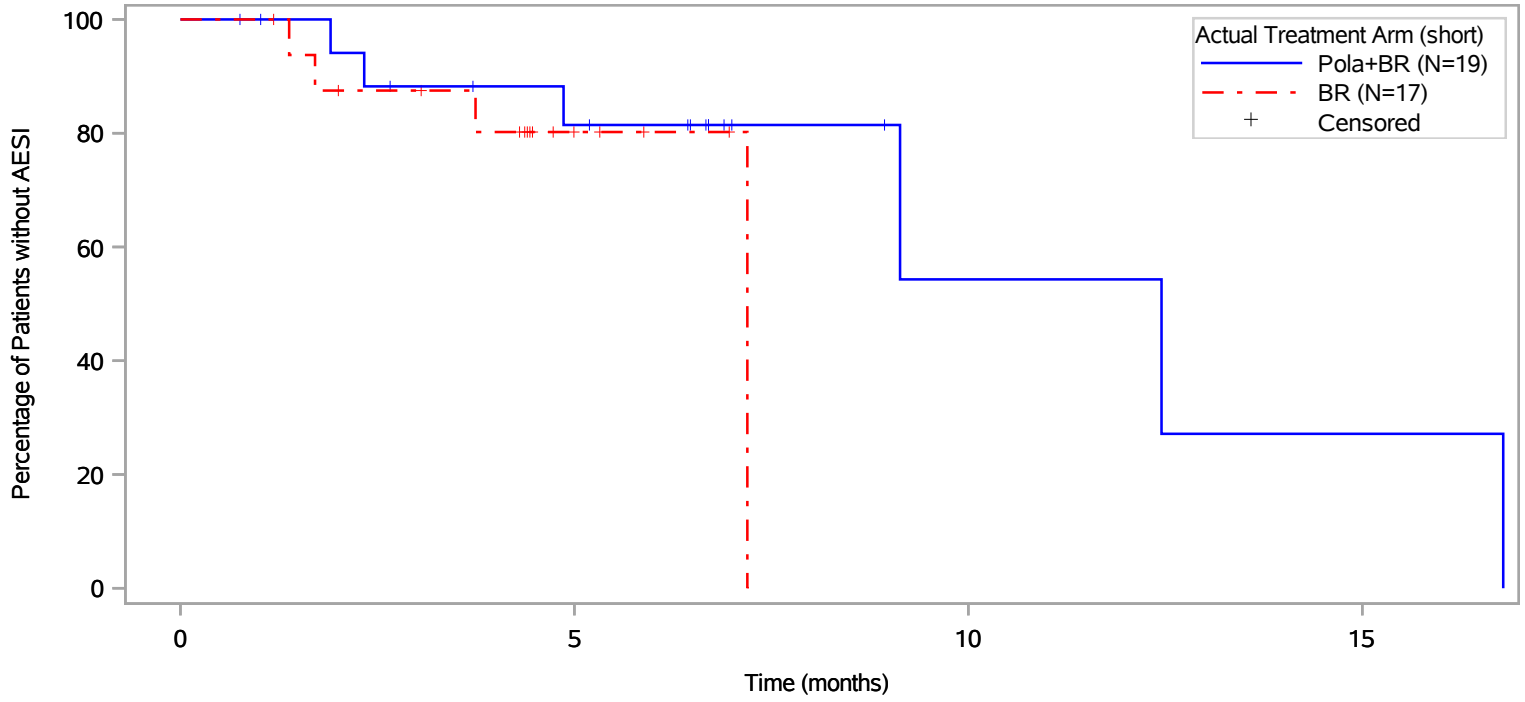
03APR2023 13:24

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk																	
Pola+BR (N=19)	19	18	16	14	13	12	11	4	4	3	2	2	2	1	1	1	1
BR (N=17)	17	17	14	13	11	4	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																	
Pola+BR (N=19)	0	1	2	3	4	4	5	12	12	13	13	13	13	13	13	13	13
BR (N=17)	0	0	1	2	3	10	12	13	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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30MAR2023 12:24

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	6	31.6	13	68.4	17	100.0	6	35.3	11	64.7	0.7509	0.84	0.26	2.70		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	2	14.3	12	85.7	8	47.1	4	50.0	4	50.0	0.0753	0.21	0.03	1.32		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	4	80.0	1	20.0	9	52.9	2	22.2	7	77.8	0.0664	4.35	0.79	23.96		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	2	25.0	6	75.0	2	11.8	1	50.0	1	50.0	0.4959	0.75	0.07	8.42		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	4	36.4	7	63.6	15	88.2	5	33.3	10	66.7	0.9839	1.14	0.30	4.37		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	5	35.7	9	64.3	0.2976	0.33	0.04	2.94		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	5	45.5	6	54.5	3	17.6	1	33.3	2	66.7	0.6425	1.84	0.21	16.01		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	2	40.0	3	60.0	3	17.6	1	33.3	2	66.7	0.9412	1.09	0.10	12.22		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	4	28.6	10	71.4	14	82.4	5	35.7	9	64.3	0.7489	0.80	0.20	3.21		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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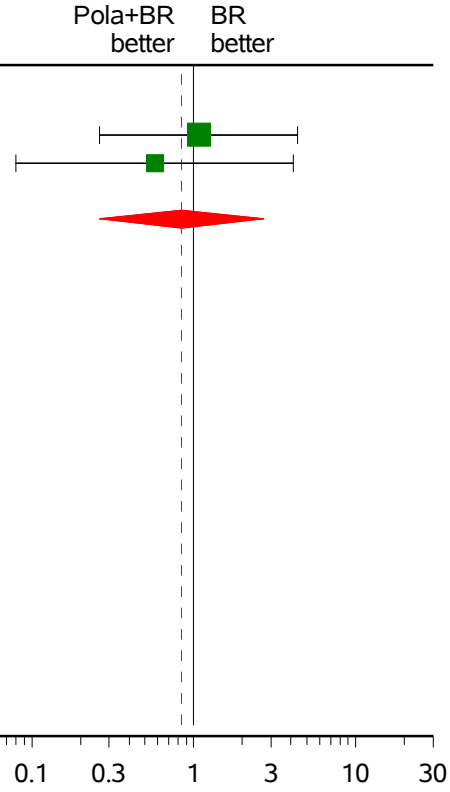
01DEC2022 3:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	4	12	4	1.07	(0.26, 4.37)
YO41543	8	2	5	2	0.58	(0.08, 4.12)
Total	19	6	17	6	0.84	(0.26, 2.70)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	4	36.4	7	63.6	12	70.6	4	33.3	8	66.7	0.9222	1.07	0.26	4.37		Convergence criterion (GCONV=1E-8) satisfied.		66.3						
	YO41543	8	42.1	2	25.0	6	75.0	5	29.4	2	40.0	3	60.0	0.5772	0.58	0.08	4.12		Convergence criterion (GCONV=1E-8) satisfied.		33.7						
	Total	19	100.0	6	31.6	13	68.4	17	100.0	6	35.3	11	64.7	0.7509	0.84	0.26	2.70		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.26	1	0.6115	0.00	-0.29	0.7719

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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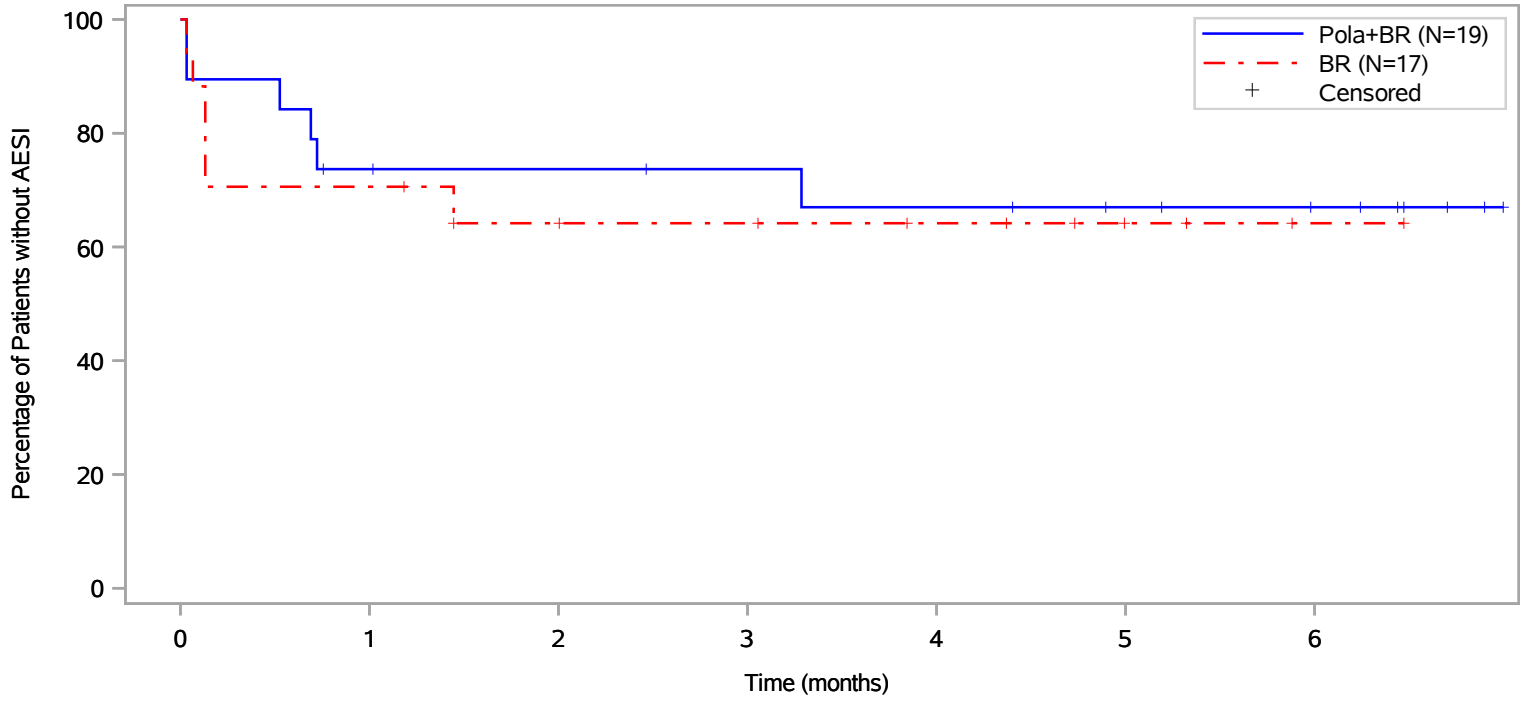
16DEC2022 11:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	13	12	11	10	8	6
BR (N=17)	17	12	9	8	6	3	1
Patients censored							
Pola+BR (N=19)	0	1	2	3	3	5	7
BR (N=17)	0	0	2	3	5	8	10

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1751	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	8	47.1	0	-	8	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	0.1797	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	0.2429	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	2	18.2	9	81.8	3	17.6	0	-	3	100.0	0.4492	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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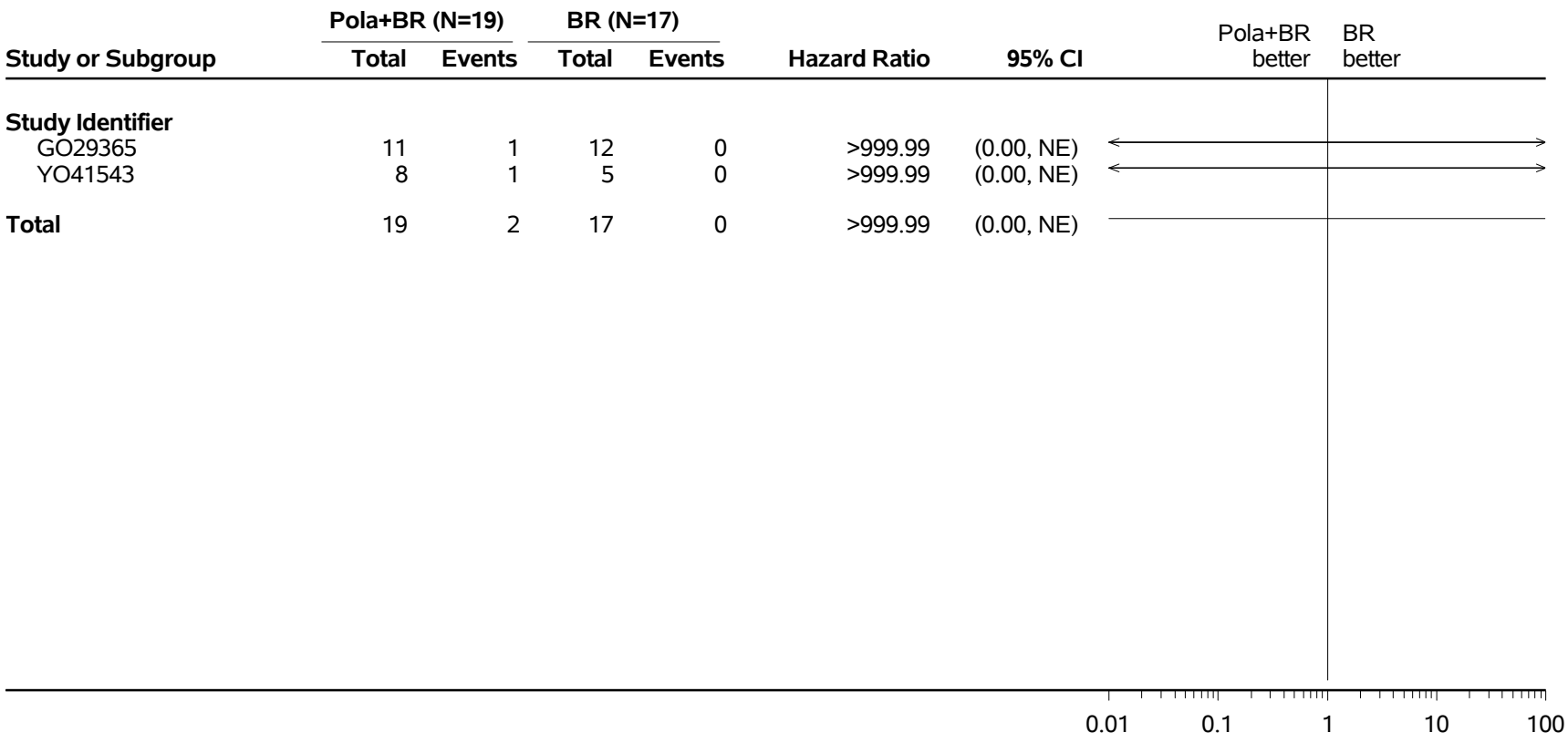
25JAN2023 11:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	1	12	0	>999.99	(0.00, NE)
YO41543	8	1	5	0	>999.99	(0.00, NE)
Total	19	2	17	0	>999.99	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		51.9						
	YO41543	8	42.1	1	12.5	7	87.5	5	29.4	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		48.1						
	Total	19	100.0	2	10.5	17	89.5	17	100.0	0	-	17	100.0	0.1751	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.00	1	1.0000	0.00	0.00	0.9977

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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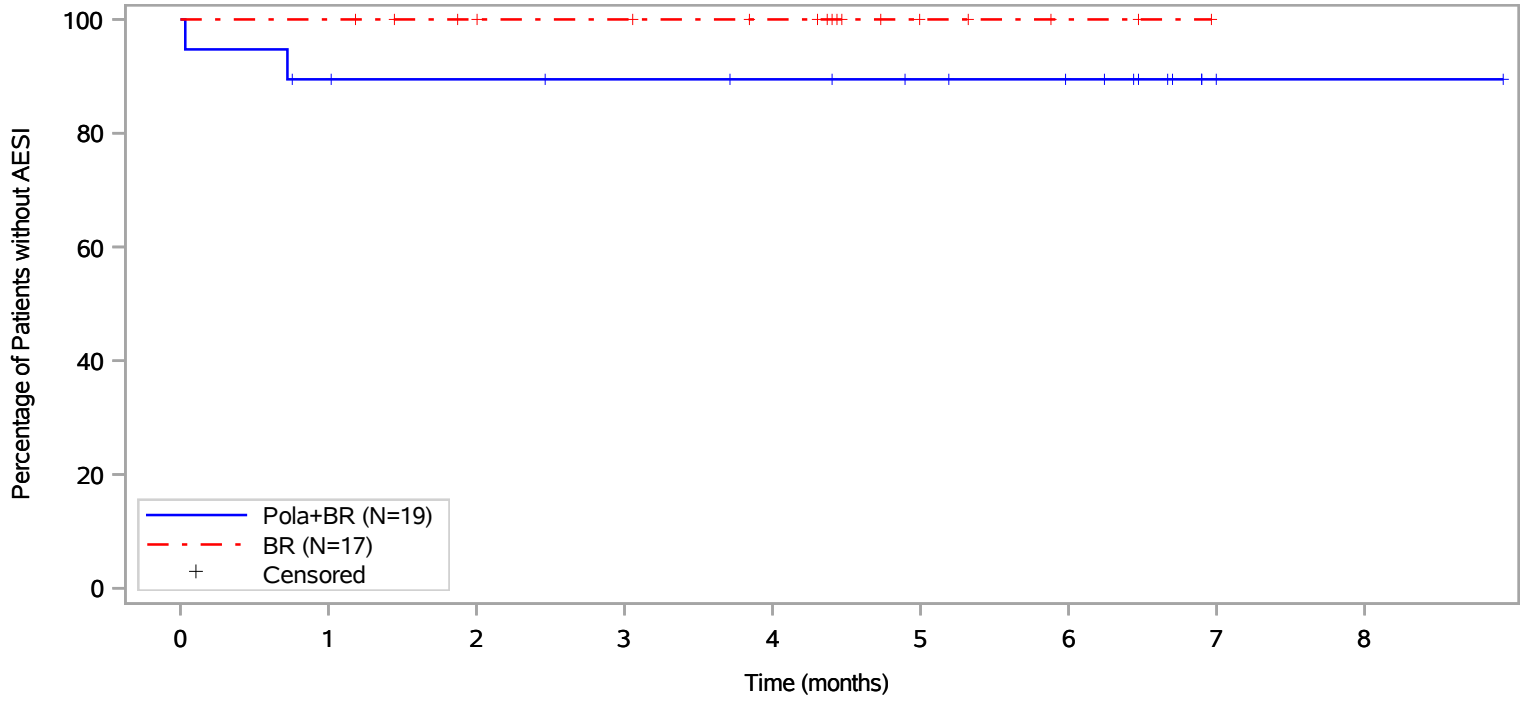
15DEC2022 17:41

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	16	15	14	13	11	9	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	6	8	16	16
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 23:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTIRRS_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTIRRS_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 16:53

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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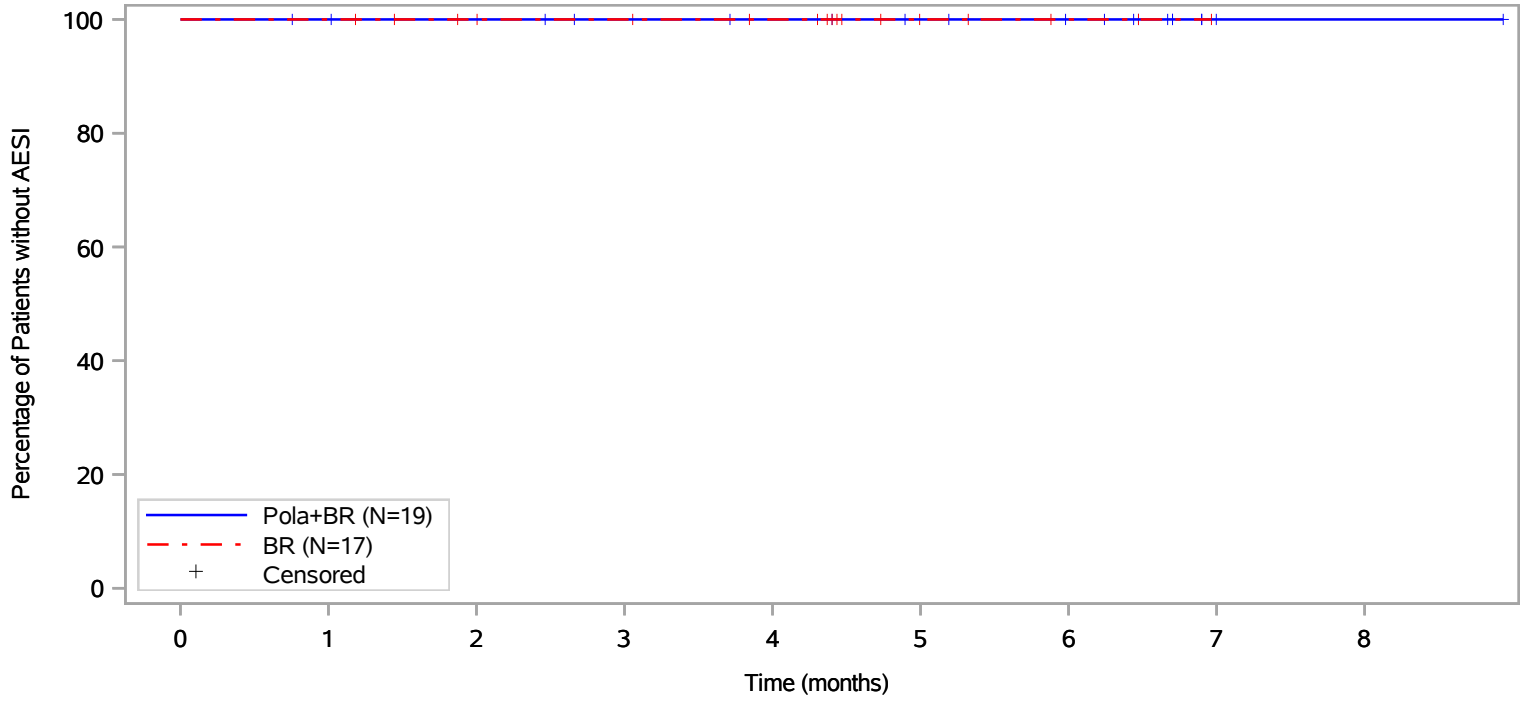
15DEC2022 21:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 1:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

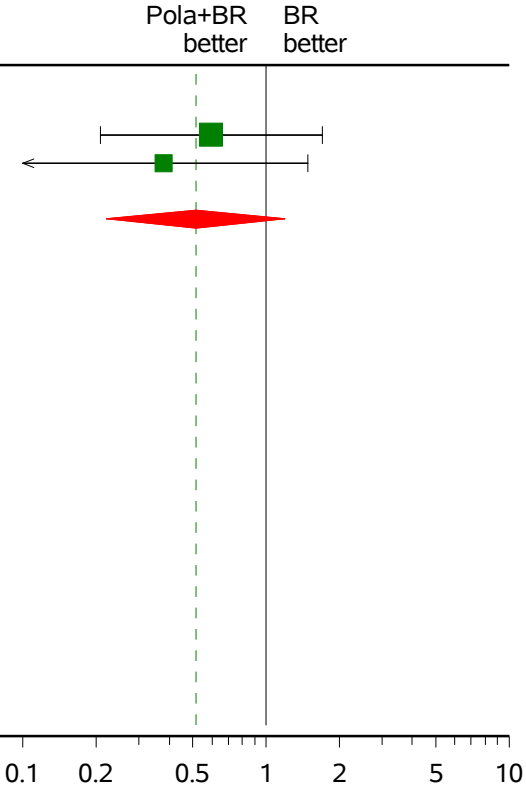
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	12	63.2	7	36.8	17	100.0	13	76.5	4	23.5	0.2241	0.51	0.22	1.20		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	8	57.1	6	42.9	8	47.1	6	75.0	2	25.0	0.4690	0.65	0.20	2.13		Convergence criterion (GCONV=1E-8) satisfied.	0.8714
	Female	5	26.3	4	80.0	1	20.0	9	52.9	7	77.8	2	22.2	0.5011	0.60	0.16	2.24		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	5	62.5	3	37.5	2	11.8	2	100.0	0	-	0.0742	0.17	0.01	2.20		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	7	63.6	4	36.4	15	88.2	11	73.3	4	26.7	0.2861	0.60	0.22	1.62		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	6	75.0	2	25.0	14	82.4	10	71.4	4	28.6	0.8745	0.86	0.29	2.51		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	6	54.5	5	45.5	3	17.6	3	100.0	0	-	0.1660	0.20	0.04	1.10		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	2	40.0	3	60.0	3	17.6	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	10	71.4	4	28.6	14	82.4	11	78.6	3	21.4	0.4373	0.60	0.23	1.55		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTNIFNEU_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 0:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	6	12	9	0.60	(0.21, 1.70)
YO41543	8	6	5	4	0.38	(0.10, 1.49)
Total	19	12	17	13	0.51	(0.22, 1.20)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	6	54.5	5	45.5	12	70.6	9	75.0	3	25.0	0.3283	0.60	0.21	1.70		Convergence criterion (GCONV=1E-8) satisfied.	63.0						
	YO41543	8	42.1	6	75.0	2	25.0	5	29.4	4	80.0	1	20.0	0.1506	0.38	0.10	1.49		Convergence criterion (GCONV=1E-8) satisfied.	37.0						
	Total	19	100.0	12	63.2	7	36.8	17	100.0	13	76.5	4	23.5	0.2241	0.51	0.22	1.20		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.27	1	0.6035	0.00	-1.54	0.1236

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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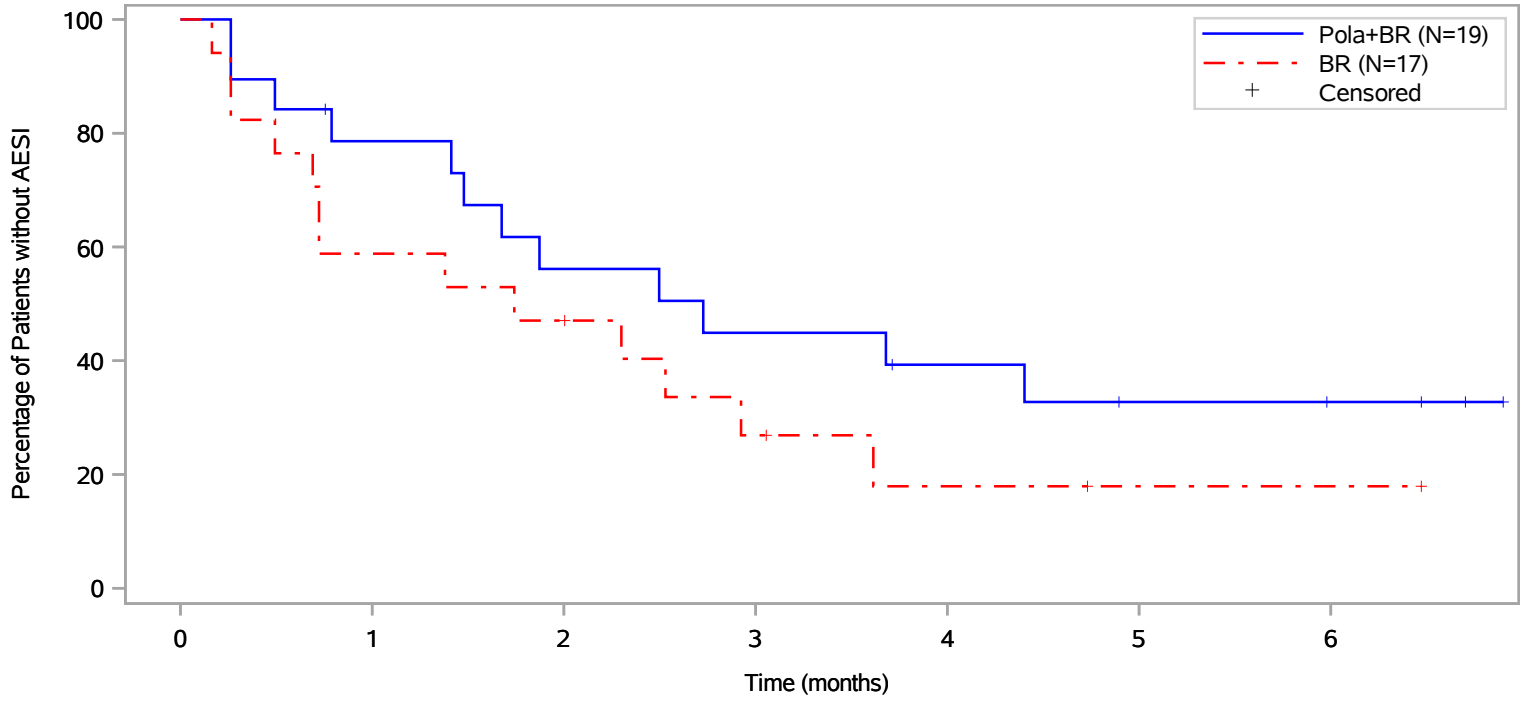
16DEC2022 12:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	14	10	8	6	4	3
BR (N=17)	17	10	8	4	2	1	1
Patients censored							
Pola+BR (N=19)	0	1	1	1	2	3	4
BR (N=17)	0	0	0	1	2	3	3

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	11	57.9	8	42.1	17	100.0	11	64.7	6	35.3	0.3077	0.64	0.27	1.53		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	7	50.0	7	50.0	8	47.1	5	62.5	3	37.5	0.5401	0.78	0.23	2.68		Convergence criterion (GCONV=1E-8) satisfied.	0.8112
	Female	5	26.3	4	80.0	1	20.0	9	52.9	6	66.7	3	33.3	0.7087	0.79	0.21	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	5	62.5	3	37.5	2	11.8	2	100.0	0	-	0.0188	0.10	0.01	1.27		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	6	54.5	5	45.5	15	88.2	9	60.0	6	40.0	0.3809	0.71	0.25	2.08		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	5	62.5	3	37.5	14	82.4	8	57.1	6	42.9	0.9429	1.03	0.32	3.36		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	6	54.5	5	45.5	3	17.6	3	100.0	0	-	0.1005	0.13	0.02	0.88		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	2	40.0	3	60.0	3	17.6	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	9	64.3	5	35.7	14	82.4	9	64.3	5	35.7	0.5711	0.79	0.29	2.13		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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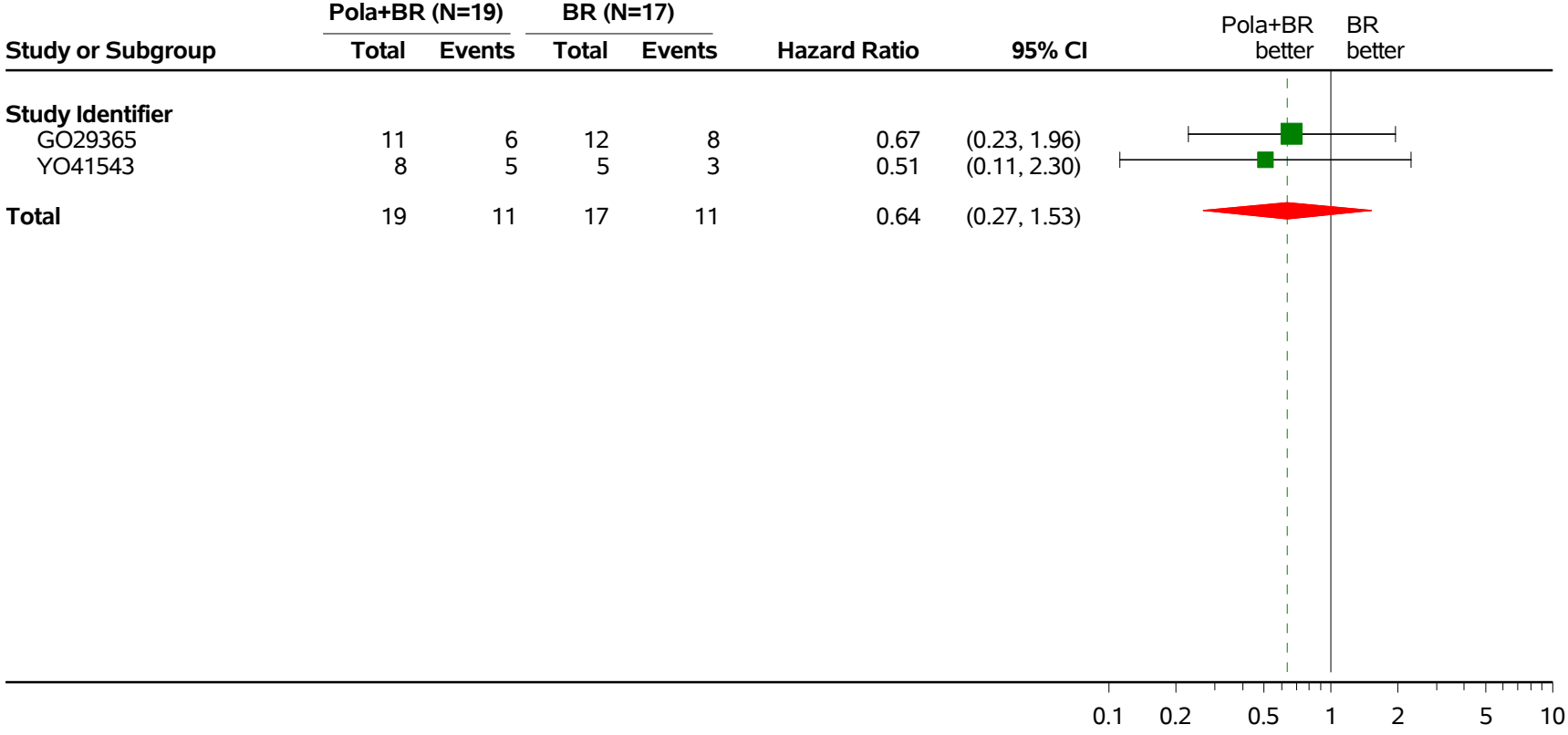
02DEC2022 19:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	6	12	8	0.67	(0.23, 1.96)
YO41543	8	5	5	3	0.51	(0.11, 2.30)
Total	19	11	17	11	0.64	(0.27, 1.53)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTNIFNEU35_L2_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 13:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	6	54.5	5	45.5	12	70.6	8	66.7	4	33.3	0.4588	0.67	0.23	1.96		Convergence criterion (GCONV=1E-8) satisfied.	66.4							
	YO41543	8	42.1	5	62.5	3	37.5	5	29.4	3	60.0	2	40.0	0.3711	0.51	0.11	2.30		Convergence criterion (GCONV=1E-8) satisfied.	33.6							
	Total	19	100.0	11	57.9	8	42.1	17	100.0	11	64.7	6	35.3	0.3077	0.64	0.27	1.53		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.09	1	0.7585	0.00		-1.01	0.3141

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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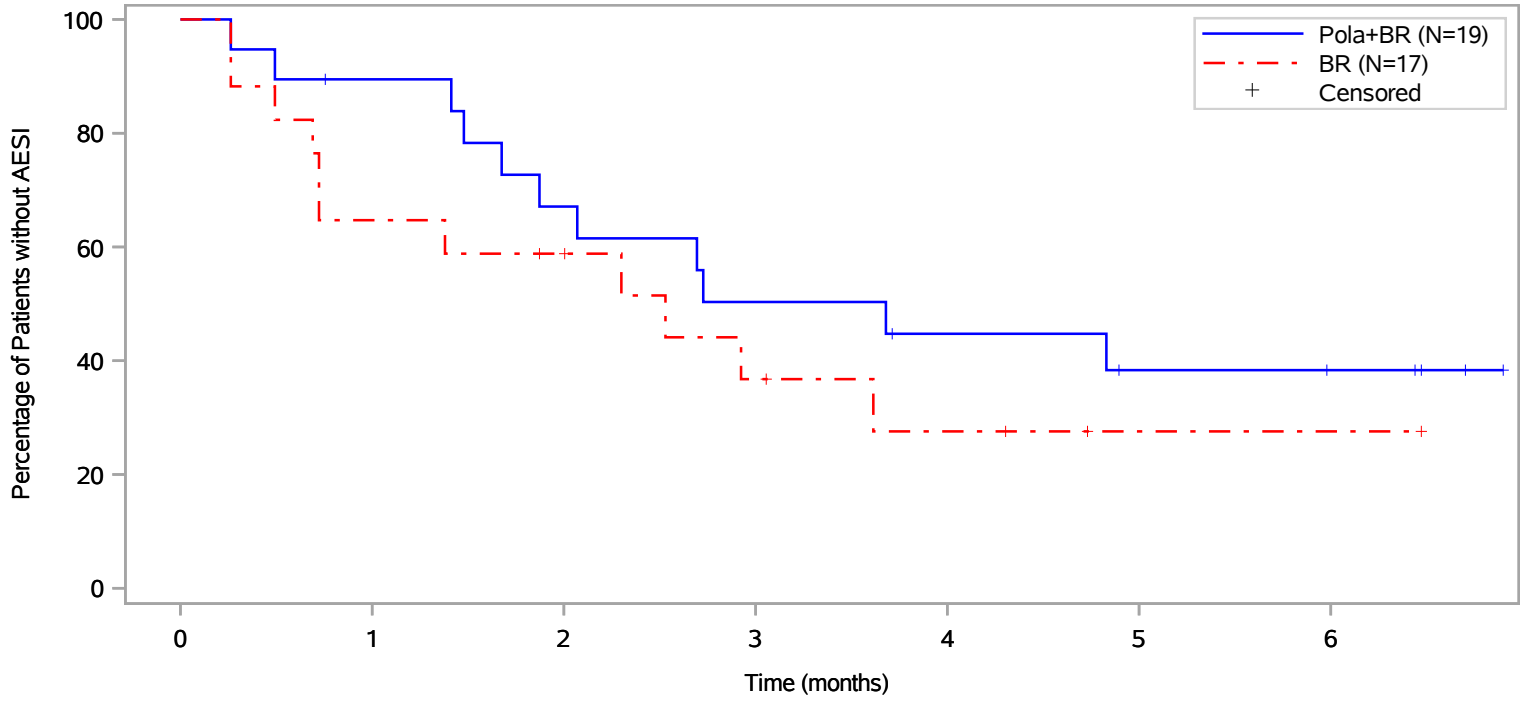
15DEC2022 18:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	16	12	9	7	5	4
BR (N=17)	17	11	9	5	3	1	1
Patients censored							
Pola+BR (N=19)	0	1	1	1	2	3	4
BR (N=17)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 22:29

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

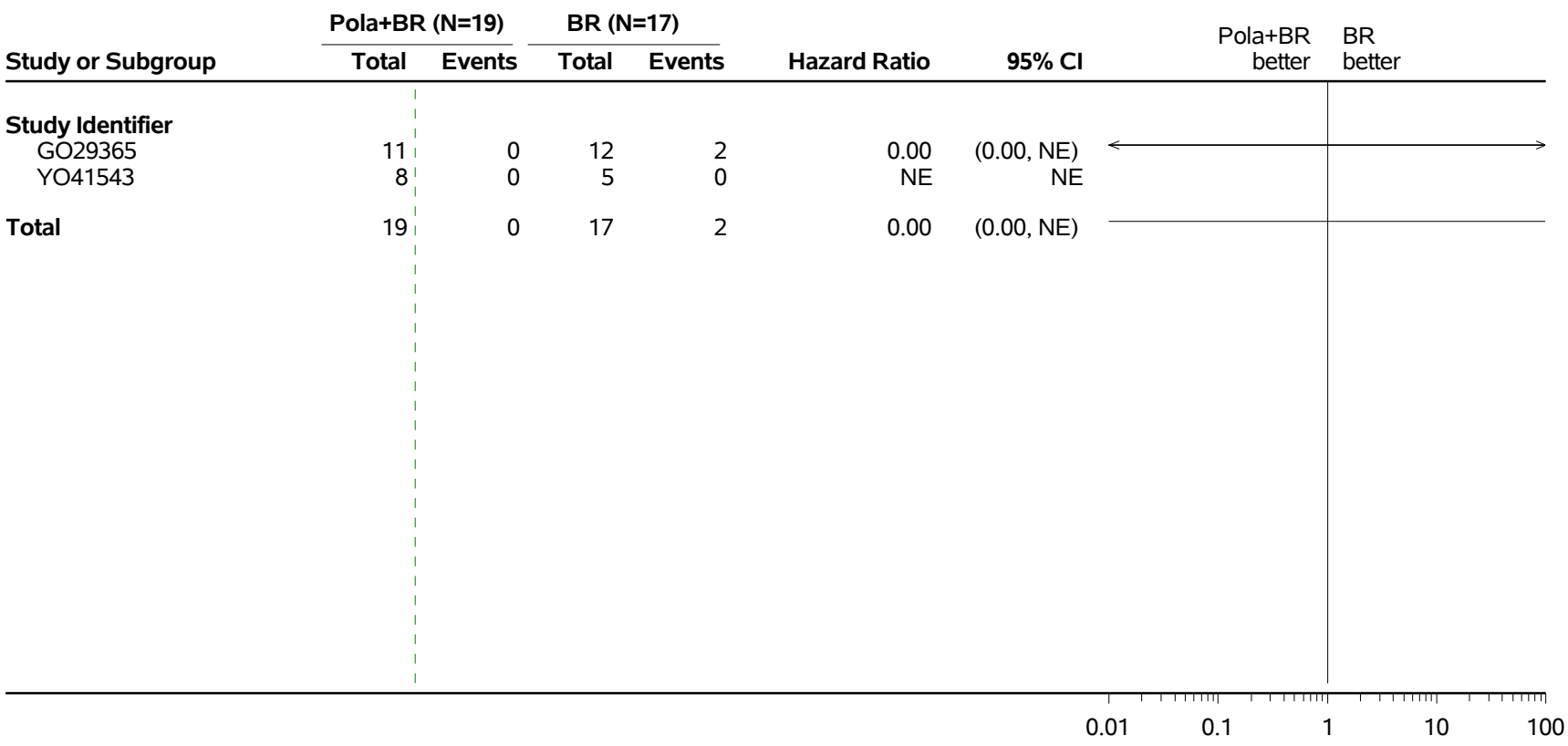
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1130	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	1	12.5	7	87.5	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 65	11	57.9	0	-	11	100.0	15	88.2	2	13.3	13	86.7	0.1780	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	<3	11	57.9	0	-	11	100.0	3	17.6	1	33.3	2	66.7	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.2943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTNIFNEUS_L2_ARMCDPLUSSE_29365_41543.xls
25JAN2023 11:48

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	2	0.00	(0.00, NE)
YO41543	8	0	5	0	NE	NE
Total	19	0	17	2	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTNIFNEUS_L2_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 13:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	2	11.8	15	88.2	0.1130	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9985

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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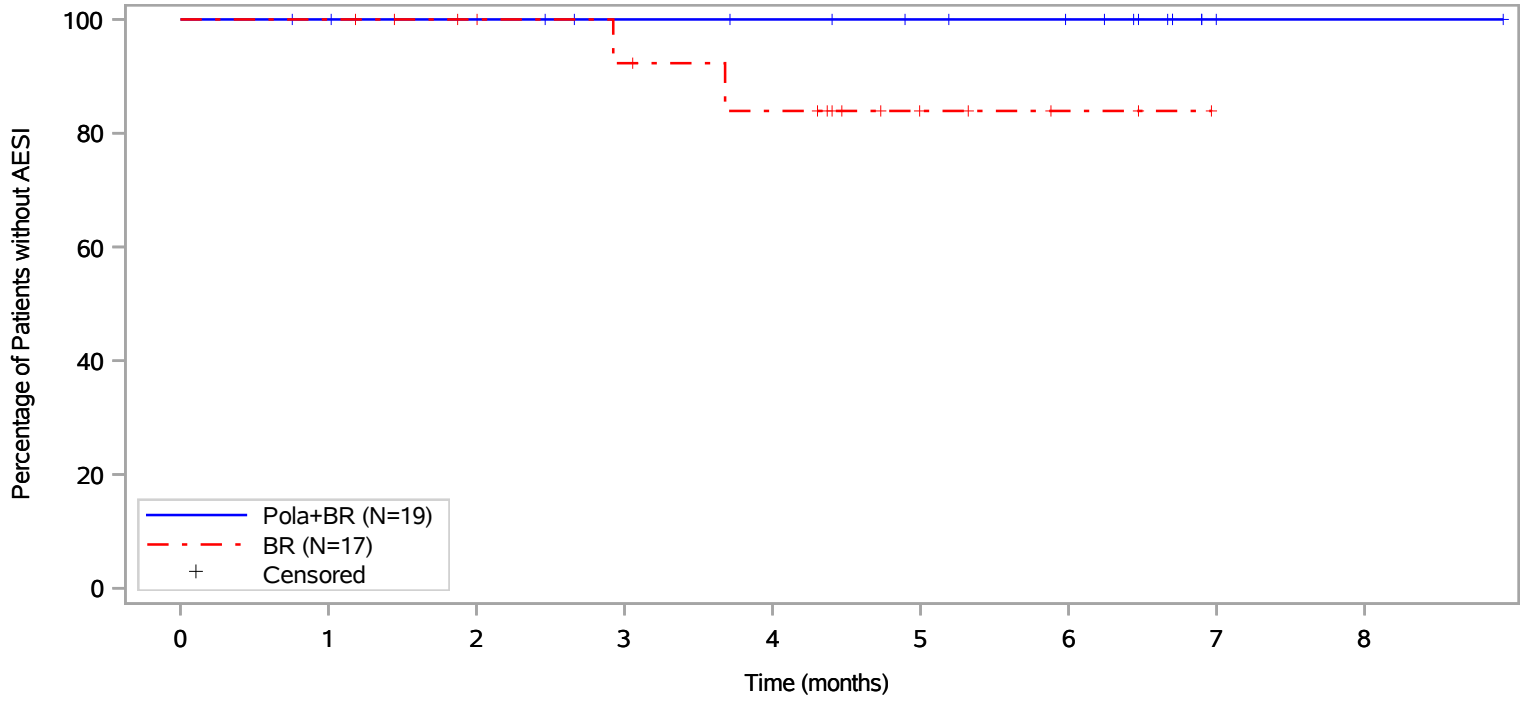
15DEC2022 18:19

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	5	11	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 0:41

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTOCUTOX_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 20:32

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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16DEC2022 20:56

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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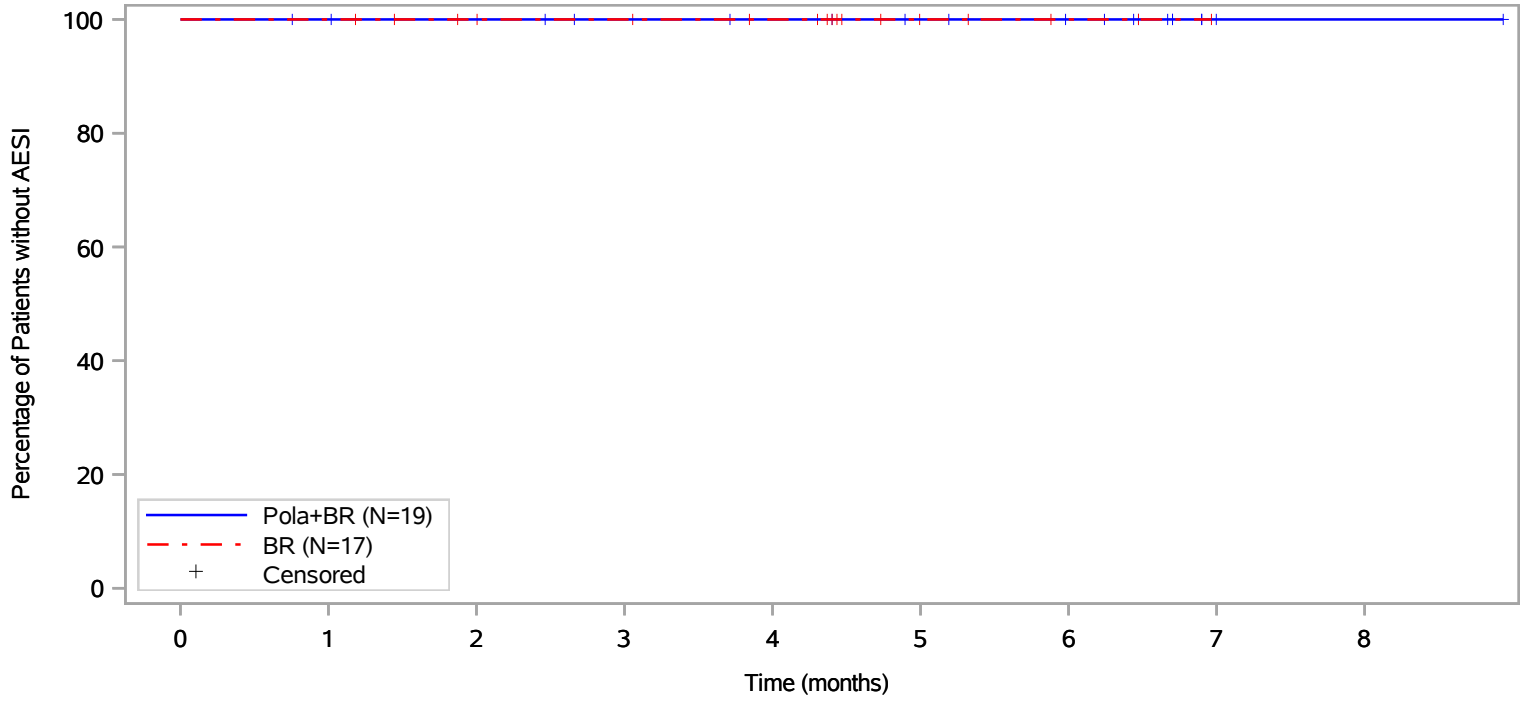
17DEC2022 22:04

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Ocular Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTOCUTOX_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:57

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

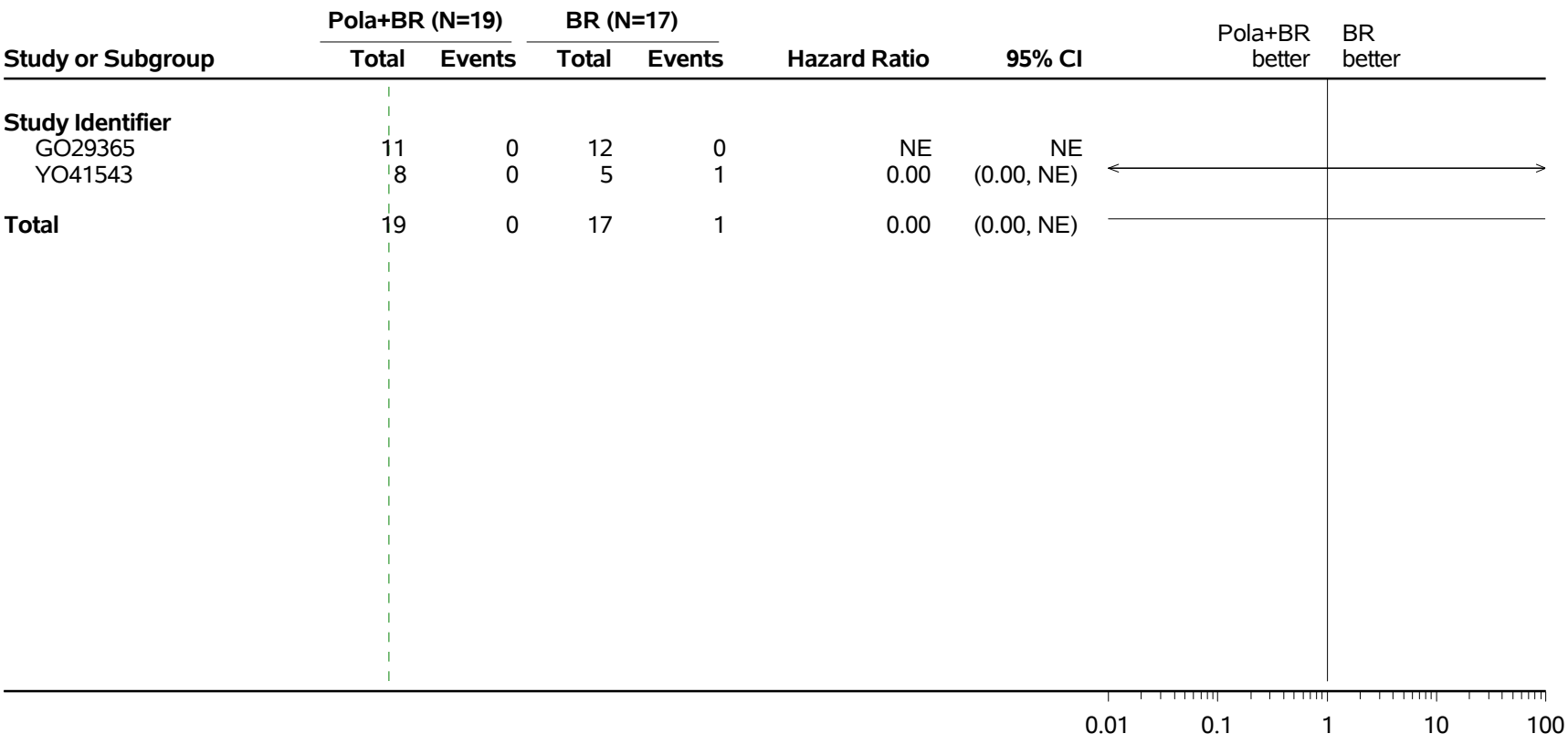
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	1	50.0	1	50.0	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	1	7.1	13	92.9	0.4497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	1	7.1	13	92.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPAIN_L2_ARMCDPLUSSE_29365_41543.xls
25JAN2023 12:04

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	0	12	0	NE	NE
YO41543	8	0	5	1	0.00	(0.00, NE)
Total	19	0	17	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	19	100.0	0	-	19	100.0	17	100.0	1	5.9	16	94.1	0.2904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9990

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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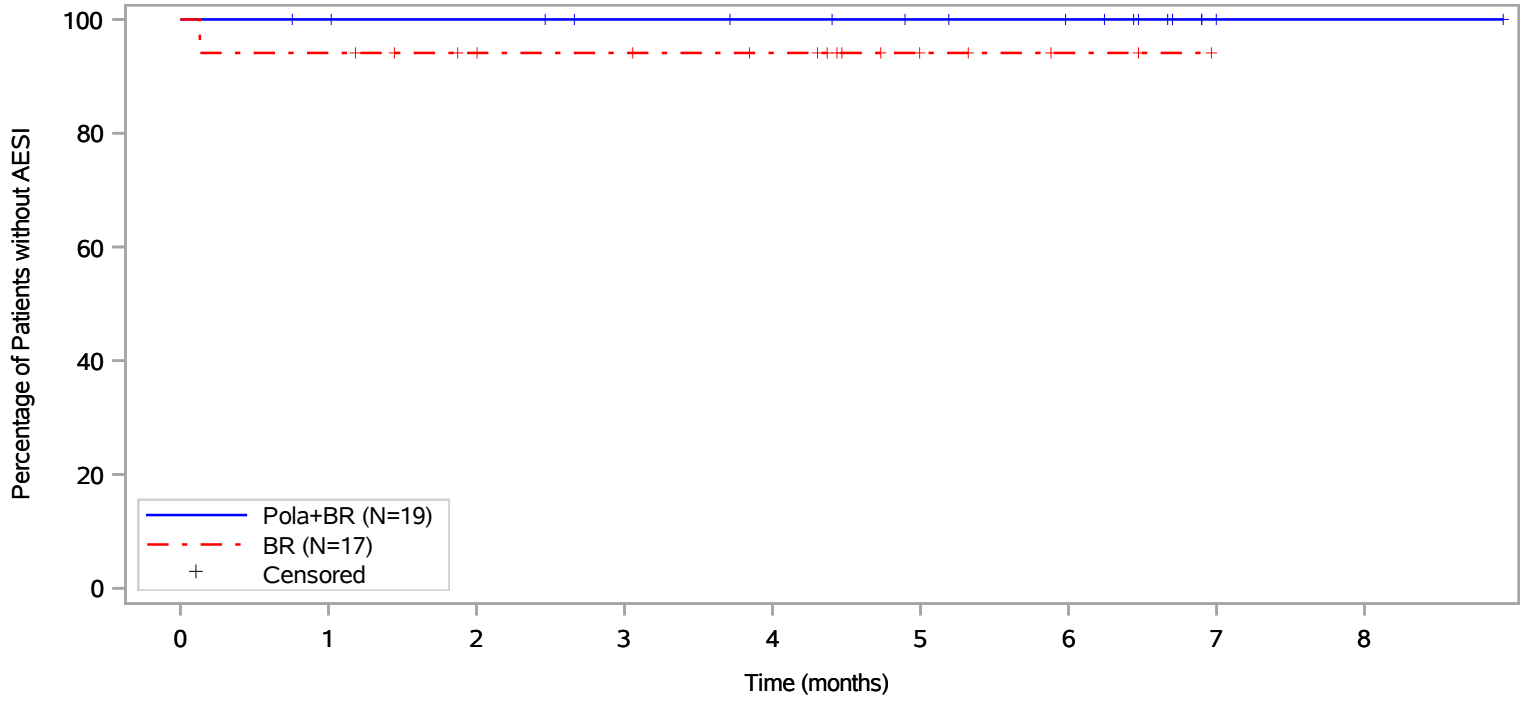
17DEC2022 21:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	16	13	12	10	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..nalysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPAIN_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:39

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPAIN35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPAIN35_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 14:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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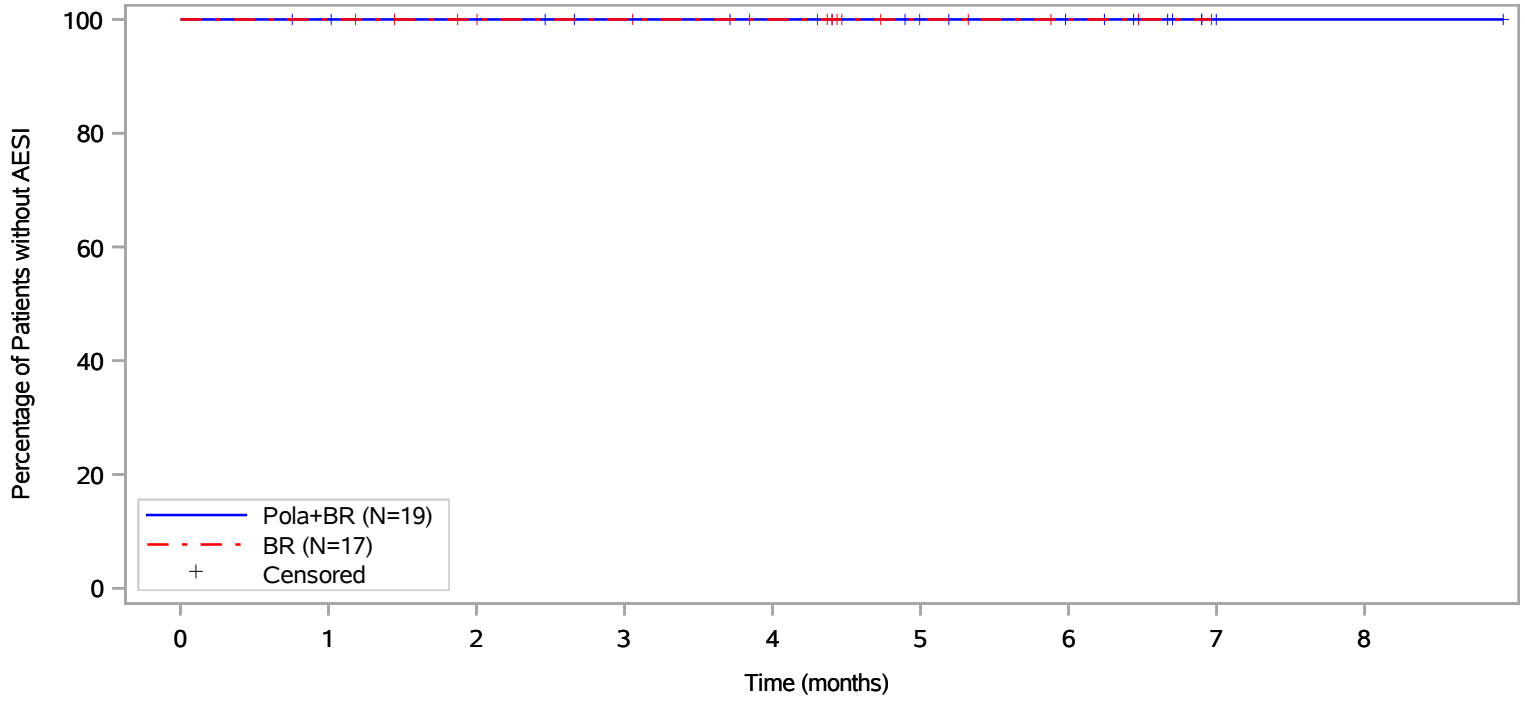
17DEC2022 21:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 23:50

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPAINS_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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16DEC2022 17:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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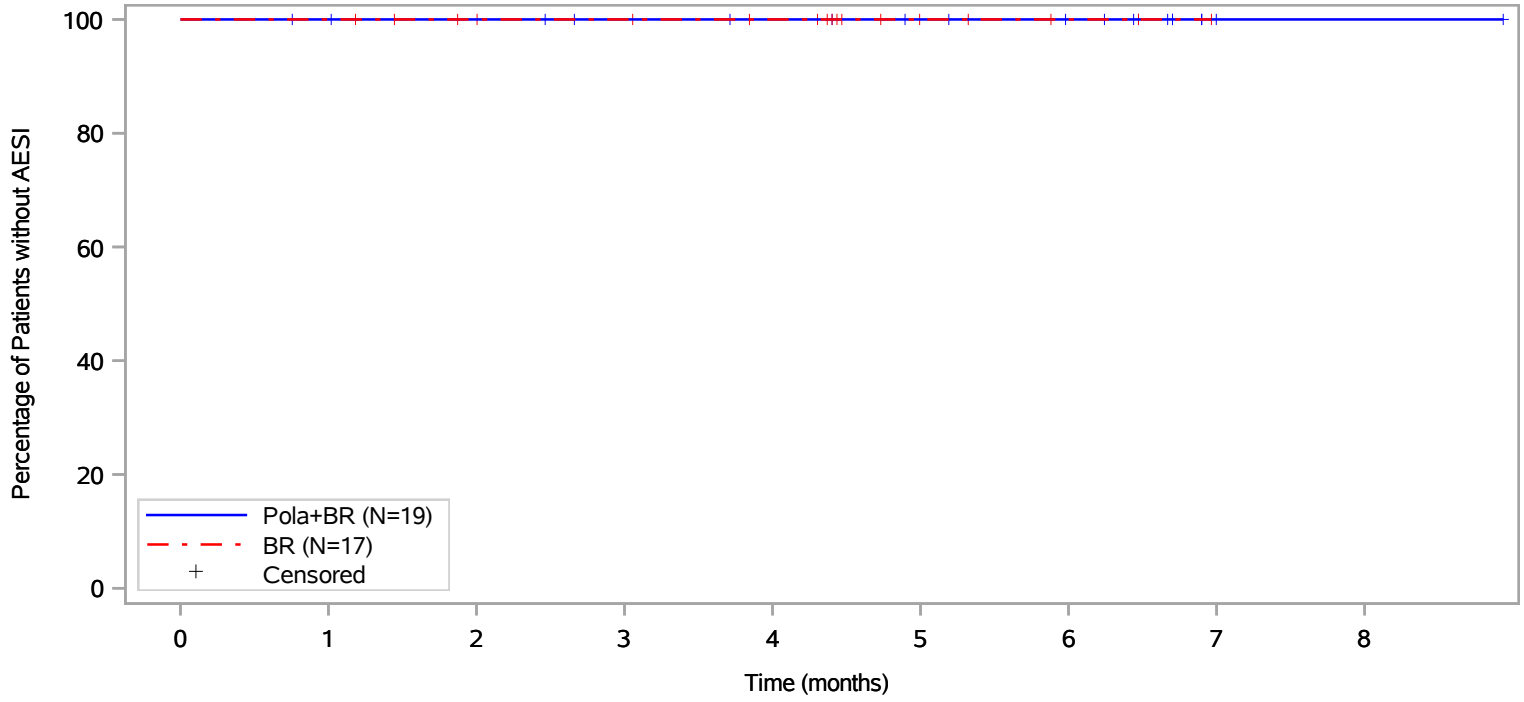
17DEC2022 15:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..alysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPAINS_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 2:05

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

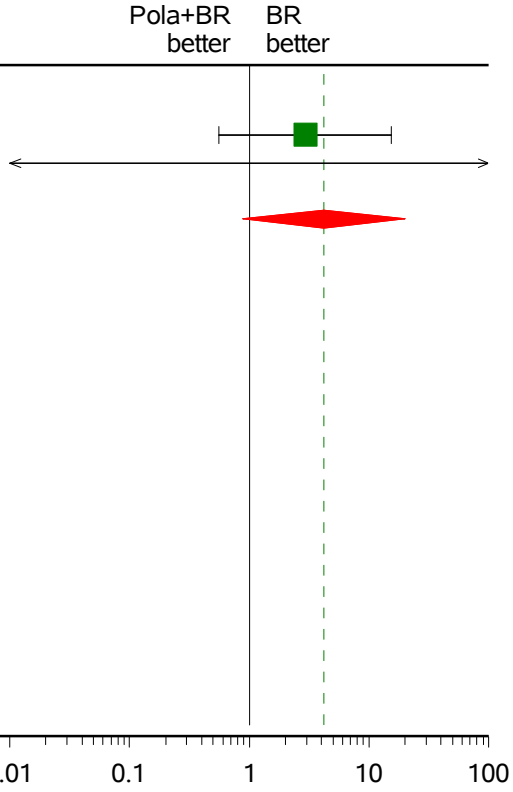
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	8	42.1	11	57.9	17	100.0	2	11.8	15	88.2	0.0569	4.22	0.89	20.07		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	6	42.9	8	57.1	8	47.1	1	12.5	7	87.5	0.1989	3.97	0.44	36.16		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	9	52.9	1	11.1	8	88.9	0.3220	1.82	0.16	20.20		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	3	37.5	5	62.5	2	11.8	0	-	2	100.0	0.3105	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	5	45.5	6	54.5	15	88.2	2	13.3	13	86.7	0.1135	3.78	0.73	19.61		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	3	37.5	5	62.5	14	82.4	1	7.1	13	92.9	0.0688	6.43	0.66	62.26		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	5	45.5	6	54.5	3	17.6	1	33.3	2	66.7	0.7337	1.49	0.17	13.26		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	7	50.0	7	50.0	14	82.4	2	14.3	12	85.7	0.0717	4.56	0.92	22.52		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPHENEU_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 0:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	5	12	2	2.93	(0.56, 15.39)
YO41543	8	3	5	0	>999.99	(0.00, NE)
Total	19	8	17	2	4.22	(0.89, 20.07)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPHENEU_L2_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 13:59

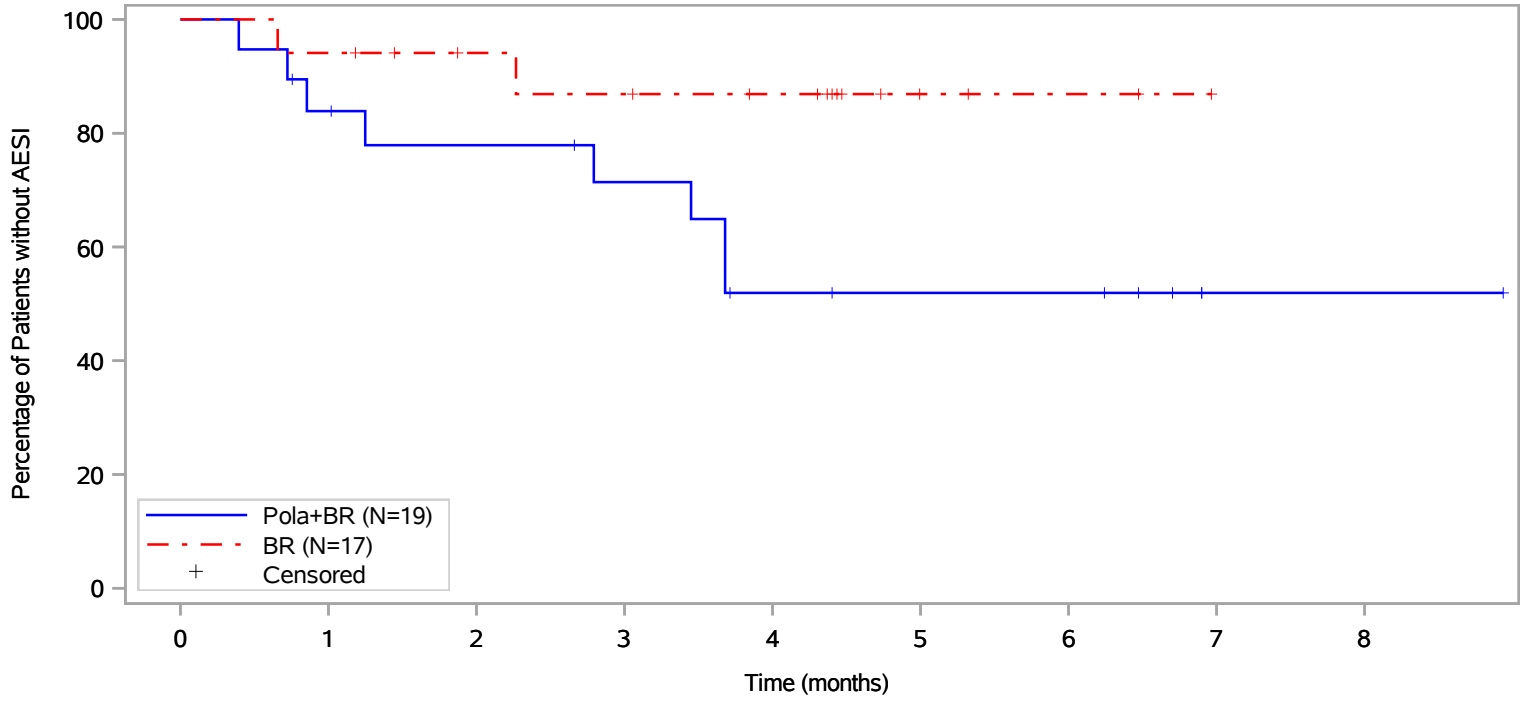
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	5	45.5	6	54.5	12	70.6	2	16.7	10	83.3	0.1837	2.93	0.56	15.39		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	3	37.5	5	62.5	5	29.4	0	-	5	100.0	0.1439	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	19	100.0	8	42.1	11	57.9	17	100.0	2	11.8	15	88.2	0.0569	4.22	0.89	20.07		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.19	1	0.6669	0.00	1.81	0.0704

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTPHENEU_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 12:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	15	13	11	7	6	6	1	1
BR (N=17)	17	16	13	12	10	3	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	3	4	5	5	10	10
BR (N=17)	0	0	3	3	5	12	13	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPHENEU_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 20:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPHENEU35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPHENEU35_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 14:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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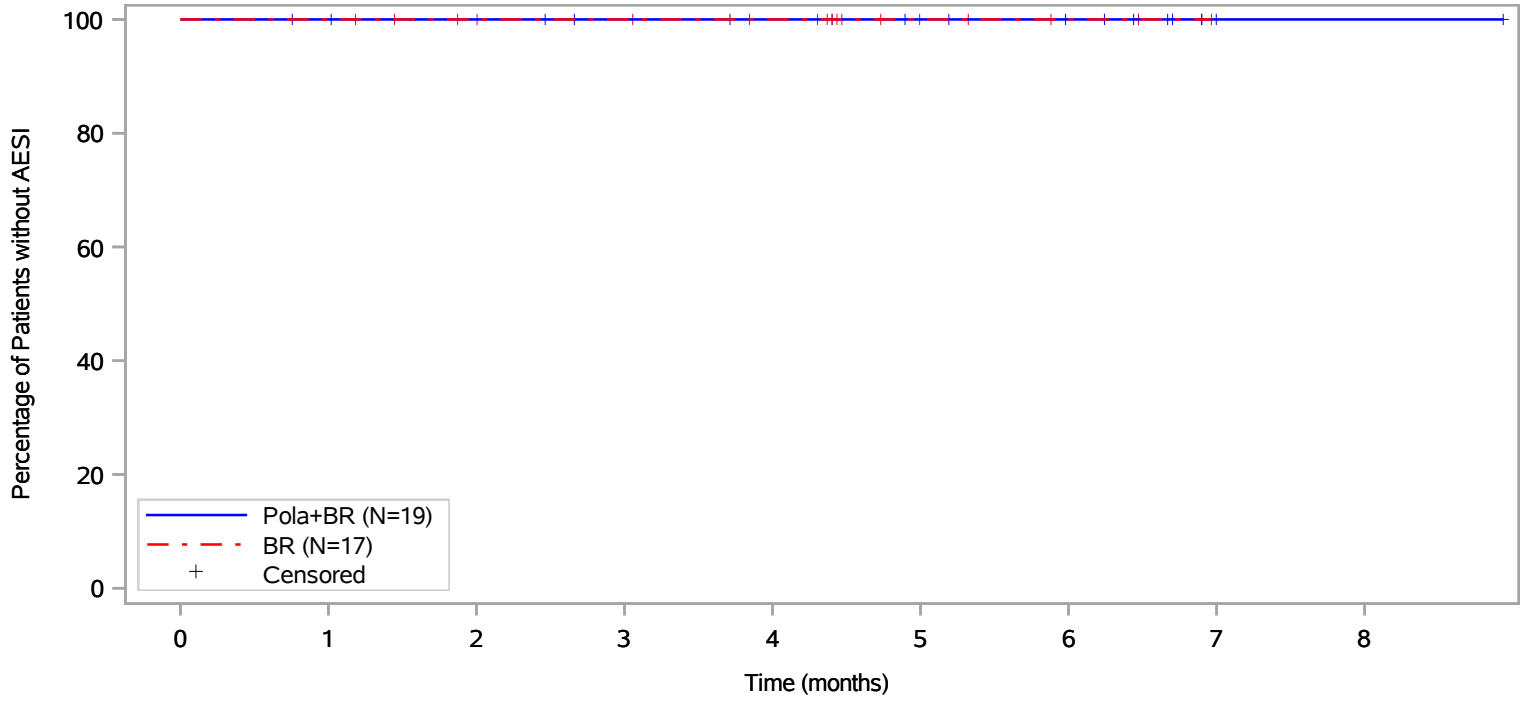
15DEC2022 19:13

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPHENEU35_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPHENEUS_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPHENEUS_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 14:09

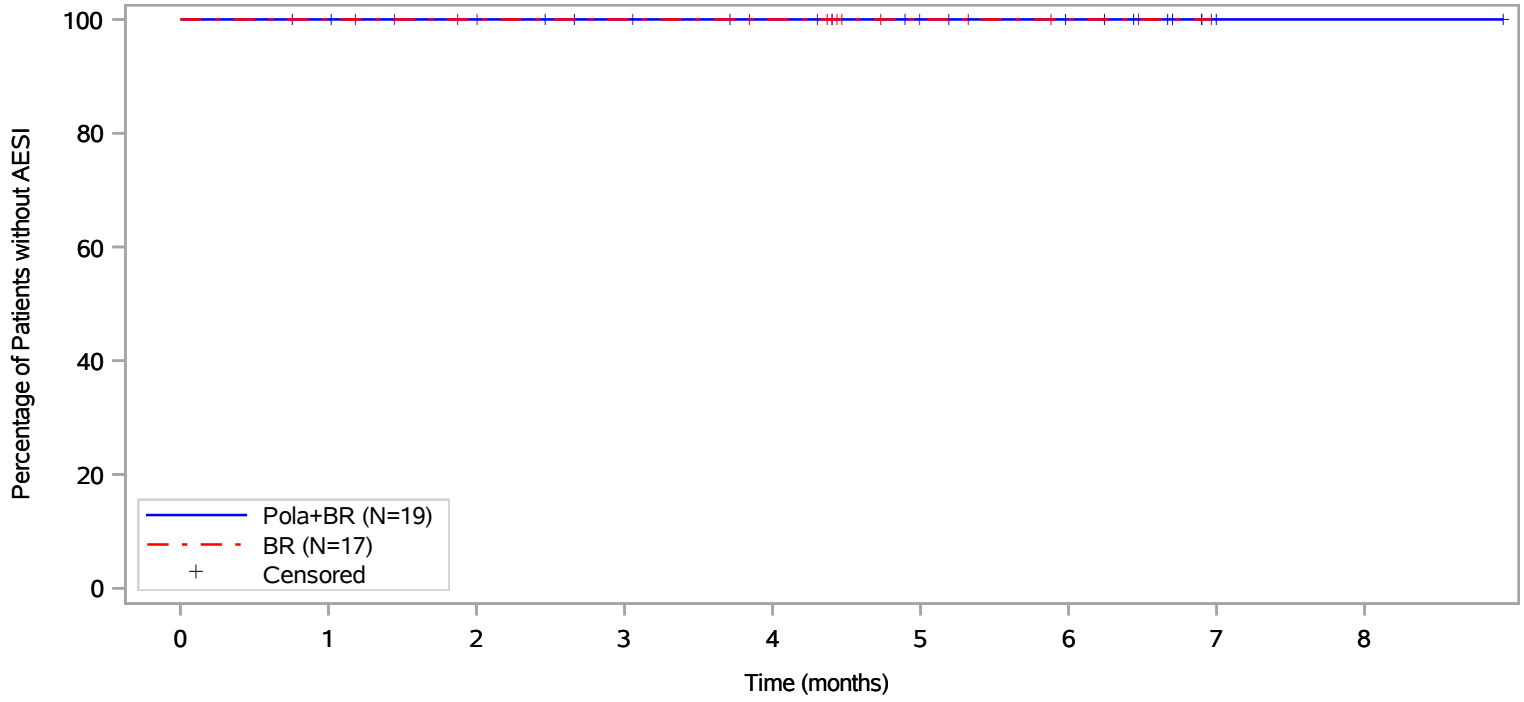
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTPHENEUS_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 18:52

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPHENEUS_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 0:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

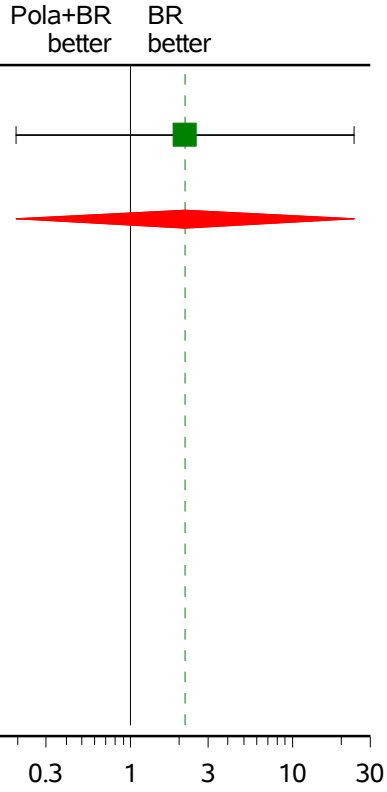
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.6582	2.17	0.20	23.92		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	2	14.3	12	85.7	8	47.1	1	12.5	7	87.5	0.9908	2.34	0.21	25.96		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	1	6.7	14	93.3	0.8965	1.38	0.09	22.07		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	1	7.1	13	92.9	0.6452	2.00	0.13	31.98		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	1	7.1	13	92.9	0.6336	2.83	0.26	31.33		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPULTOX_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 7:16

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	2	12	1	2.17	(0.20, 23.92)
YO41543	8	0	5	0	NE	NE
Total	19	2	17	1	2.17	(0.20, 23.92)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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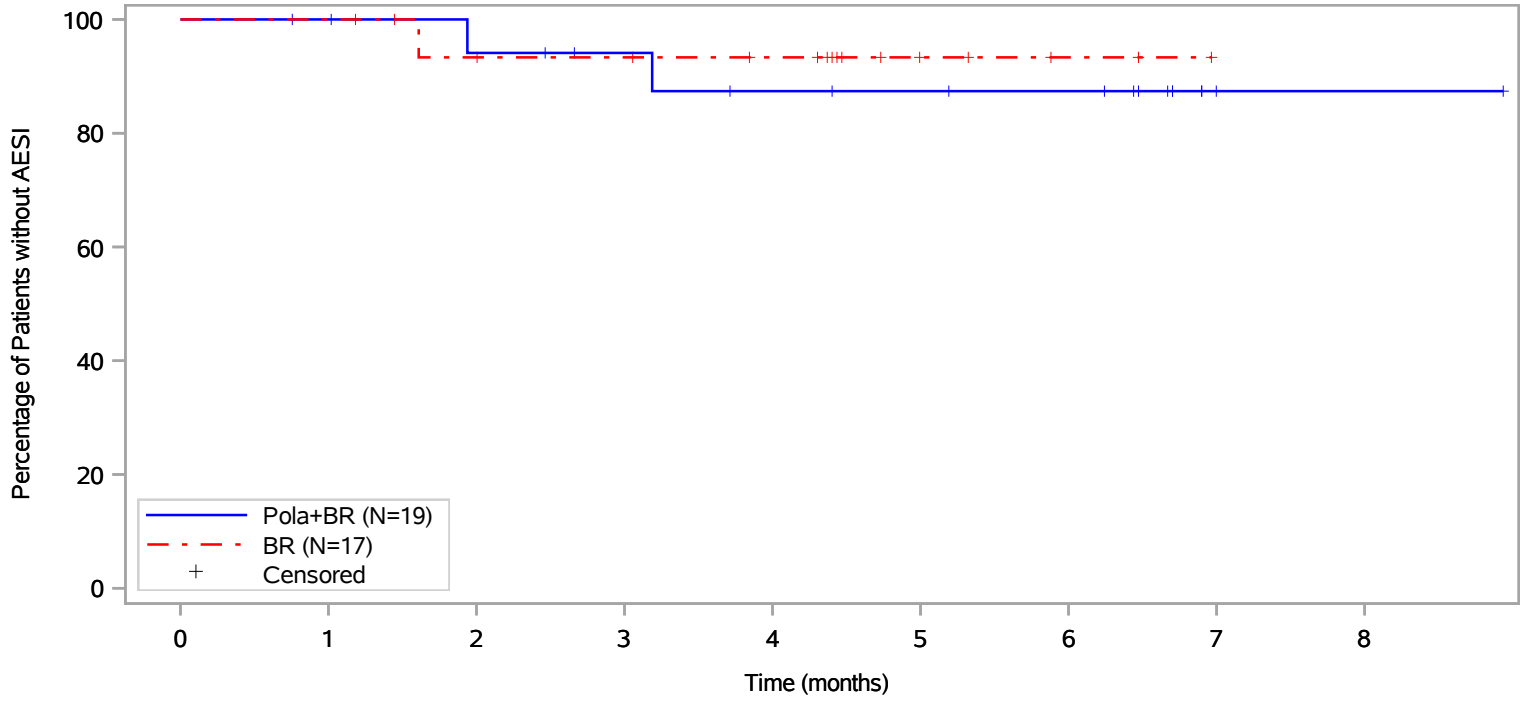
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	2	18.2	9	81.8	12	70.6	1	8.3	11	91.7	0.5176	2.17	0.20	23.92		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	2	10.5	17	89.5	17	100.0	1	5.9	16	94.1	0.6582	2.17	0.20	23.92		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.63	0.5279

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTPULTOX_L2_ARMCDPLUSSE_29365_41543.xls
17DEC2022 21:32

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	16	14	12	11	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	6	7	16	16
BR (N=17)	0	0	2	3	5	12	14	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPULTOX_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPULTOX35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPULTOX35_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 12:39

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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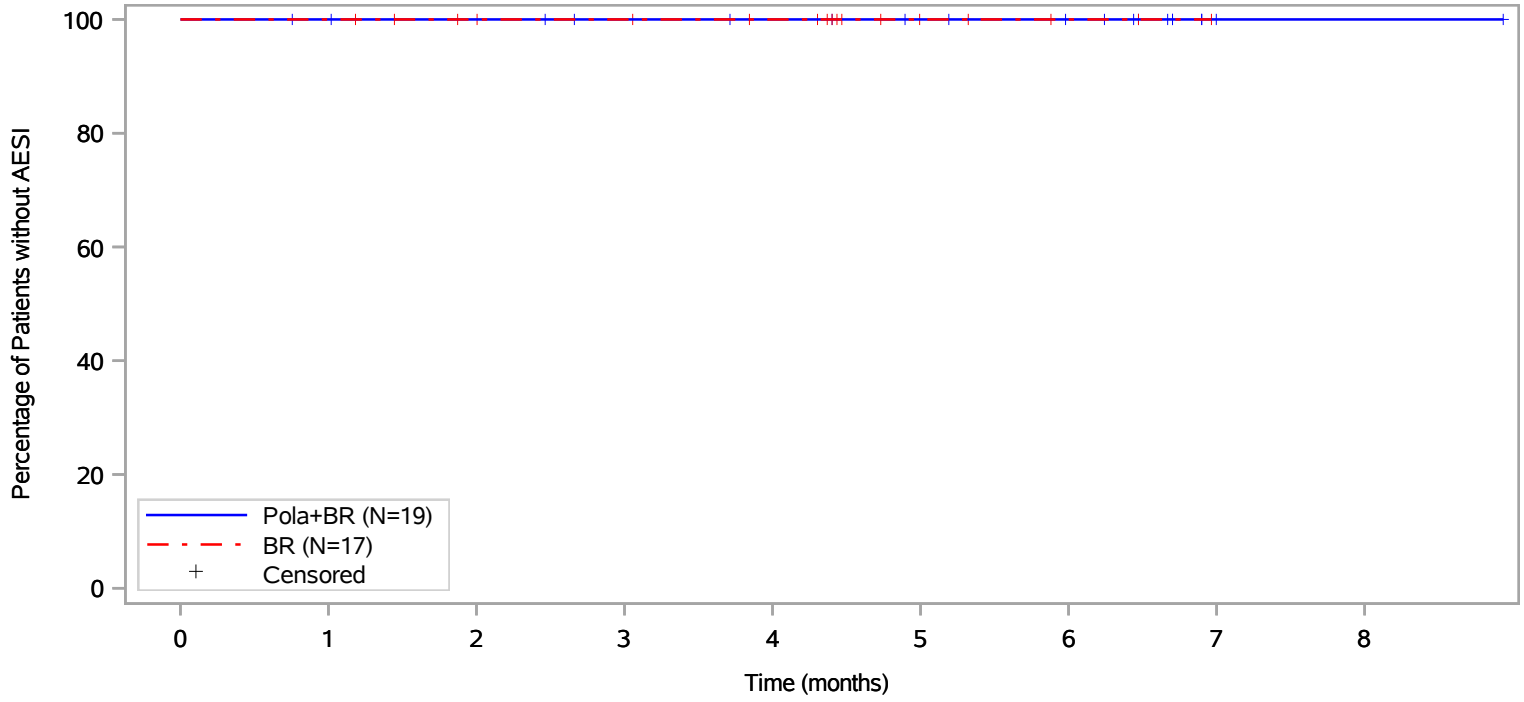
15DEC2022 19:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPULTOX35_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 23:45

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPULTOXS_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:31

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPULTOXS_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 13:02

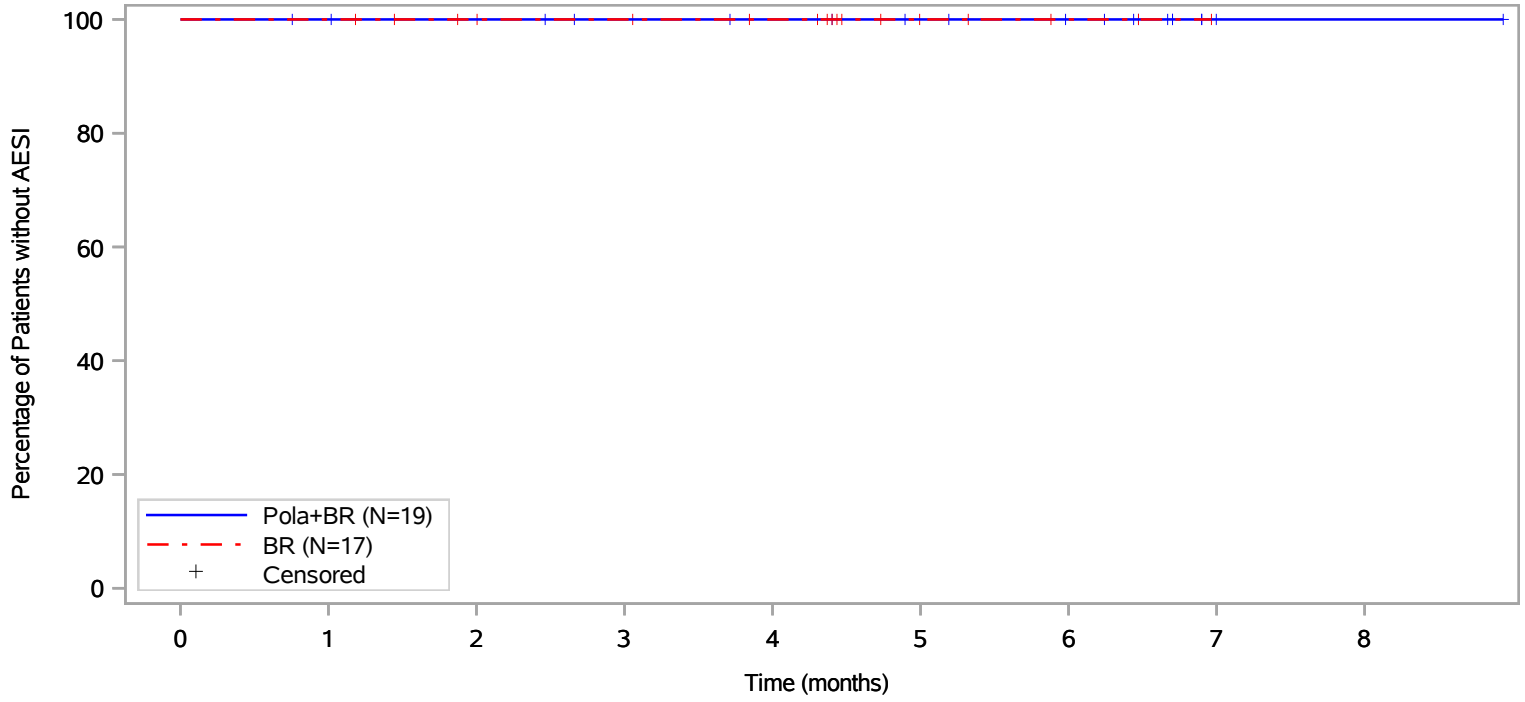
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTPULTOXS_L2_ARMCDPLUSSE_29365_41543.xls
17DEC2022 15:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPULTOXS_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 1:57

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

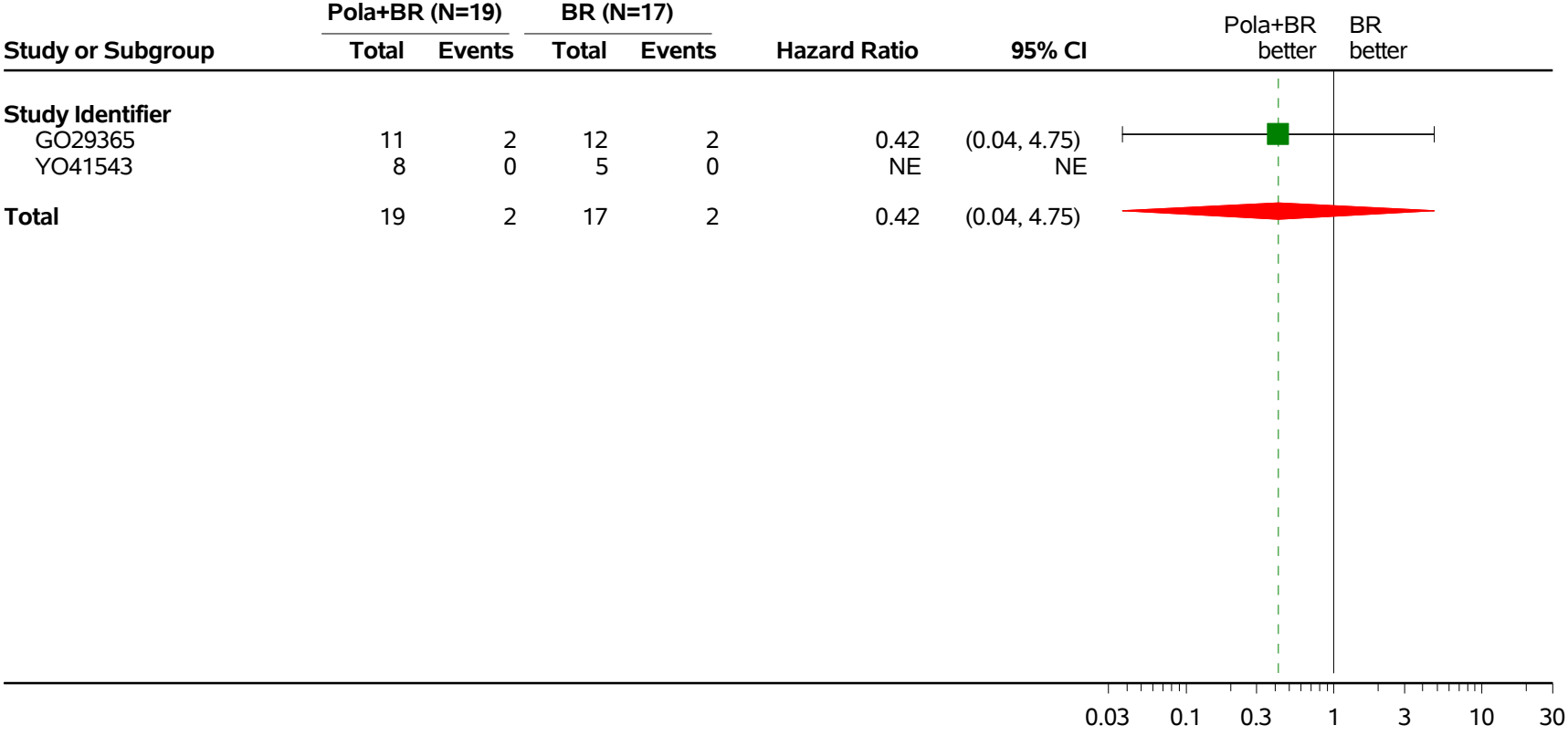
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	2	10.5	17	89.5	17	100.0	2	11.8	15	88.2	0.3475	0.42	0.04	4.75		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	8	47.1	2	25.0	6	75.0	0.1544	0.43	0.04	4.78		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	2	13.3	13	86.7	0.2033	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	2	14.3	12	85.7	0.3034	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.7237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	2	14.3	12	85.7	14	82.4	2	14.3	12	85.7	0.3877	0.58	0.05	6.47		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTRENTOX_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 5:53

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	2	12	2	0.42	(0.04, 4.75)
YO41543	8	0	5	0	NE	NE
Total	19	2	17	2	0.42	(0.04, 4.75)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTRENTOX_L2_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 11:34

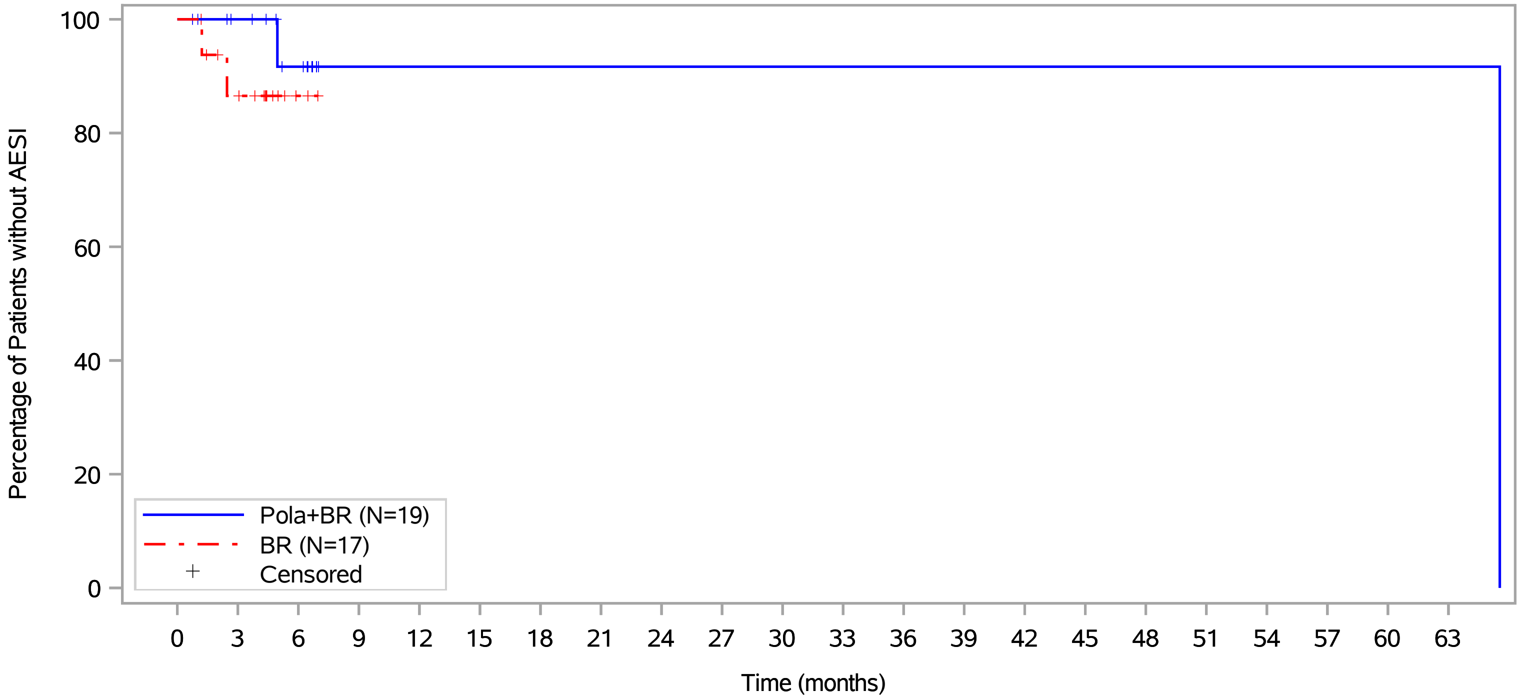
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	2	18.2	9	81.8	12	70.6	2	16.7	10	83.3	0.4705	0.42	0.04	4.75		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	2	10.5	17	89.5	17	100.0	2	11.8	15	88.2	0.3475	0.42	0.04	4.75		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	-0.70	0.4833

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTRENTOX_L2_ARMCDPLUSSE_29365_41543.xls
17DEC2022 21:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk
Pola+BR (N=19) 19 18 17 15 14 11 10 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
BR (N=17) 17 17 14 12 10 4 2 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE
Patients censored
Pola+BR (N=19) 0 1 2 4 5 7 8 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17 17
BR (N=17) 0 0 2 3 5 11 13 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTRENTOX_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTRENTOX35_L2_ARMCDPLUSSE_29365_41543.xls
25JAN2023 12:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTRENTOX35_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 10:41

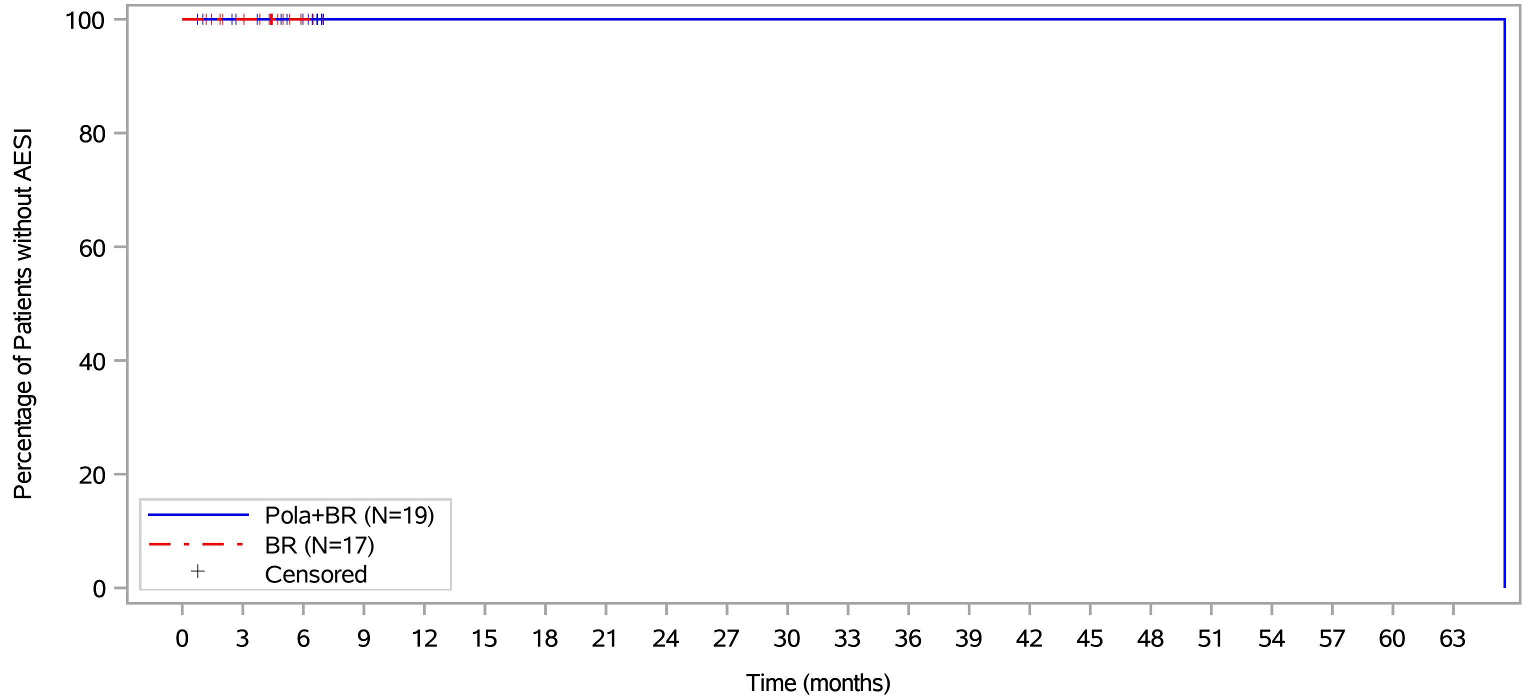
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE							
	Total	19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTRENTOX35_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 21:50

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk
Pola+BR (N=19) 19 18 17 15 14 12 10 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
BR (N=17) 17 17 14 13 11 4 2 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE
Patients censored
Pola+BR (N=19) 0 1 2 4 5 7 9 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18
BR (N=17) 0 0 3 4 6 13 15 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTRENTOX35_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 23:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	1	9.1	10	90.9	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	1	12.5	7	87.5	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	1	7.1	13	92.9	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTRENTOXS_L2_ARMCDPLUSSE_29365_41543.xls
25JAN2023 12:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTRENTOXS_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 11:01

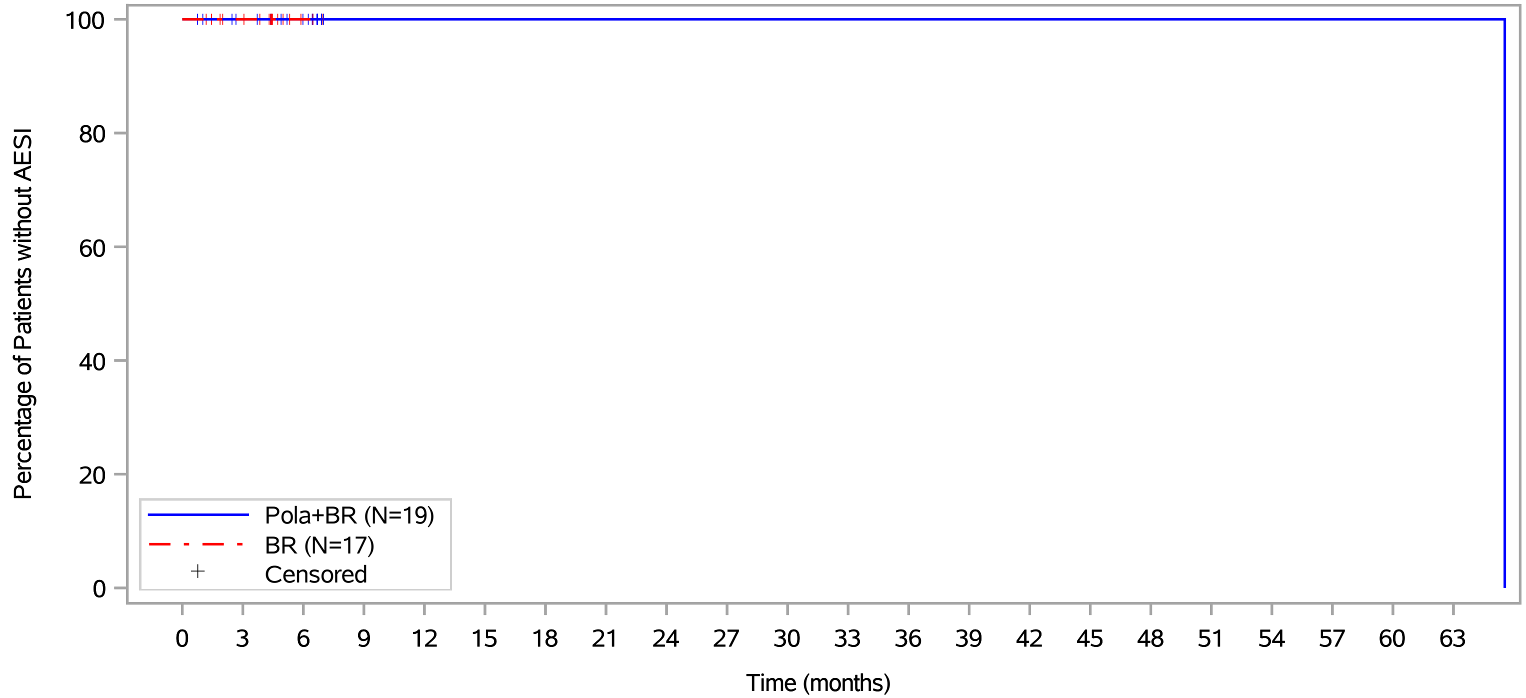
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	1	9.1	10	90.9	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	Total	19	100.0	1	5.3	18	94.7	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTRENTOXS_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 22:13

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk
Pola+BR (N=19) 19 18 17 15 14 12 10 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
BR (N=17) 17 17 14 13 11 4 2 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE
Patients censored
Pola+BR (N=19) 0 1 2 4 5 7 9 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18 18
BR (N=17) 0 0 3 4 6 13 15 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTRENTOXS_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 1:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTREPROD_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 4:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTREPROD_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 9:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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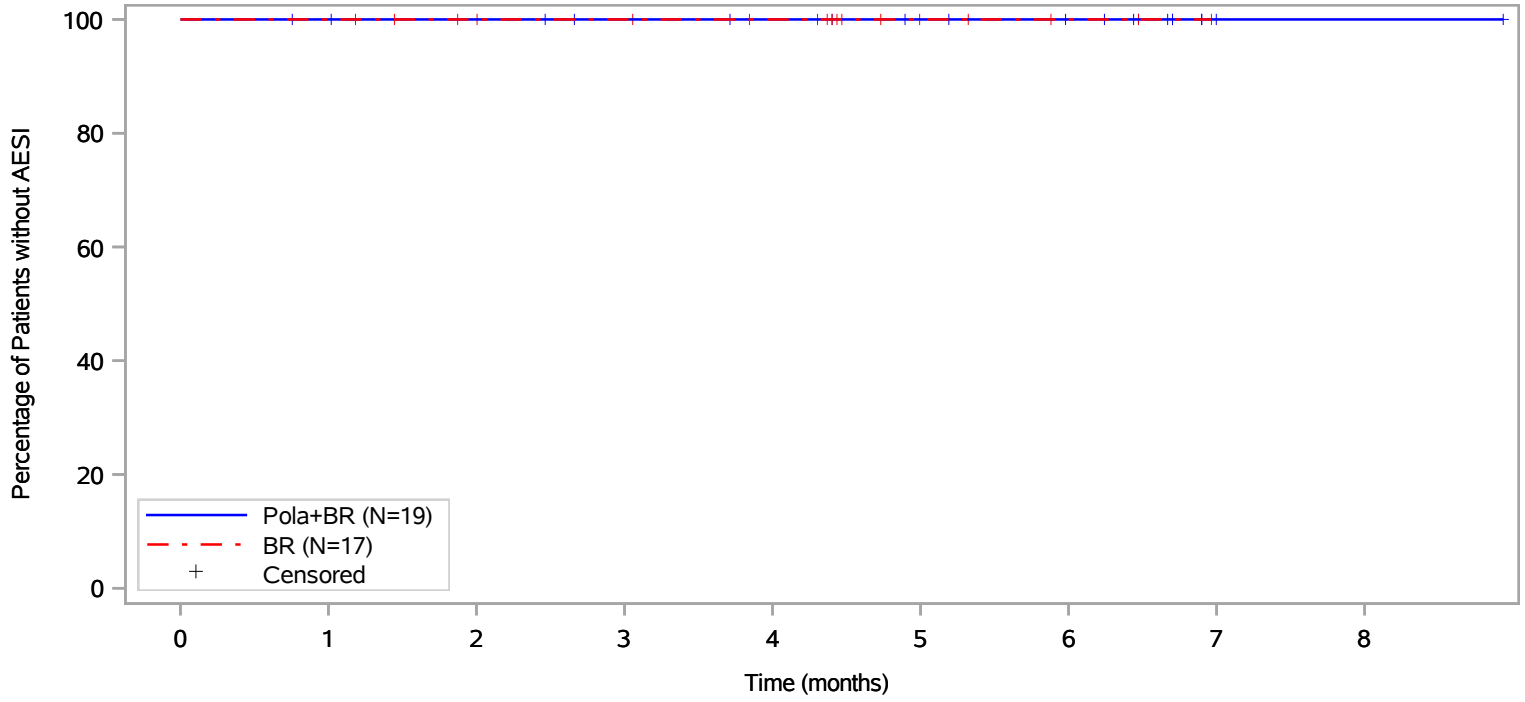
15DEC2022 19:34

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Reproductive Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTREPROD_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:06

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTSTIAMP_L2_ARMCDPLUSSE_29365_41543.xls
04DEC2022 14:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTSTIAMP_L2_ARMCDPLUSSE_29365_41543.xls
17DEC2022 17:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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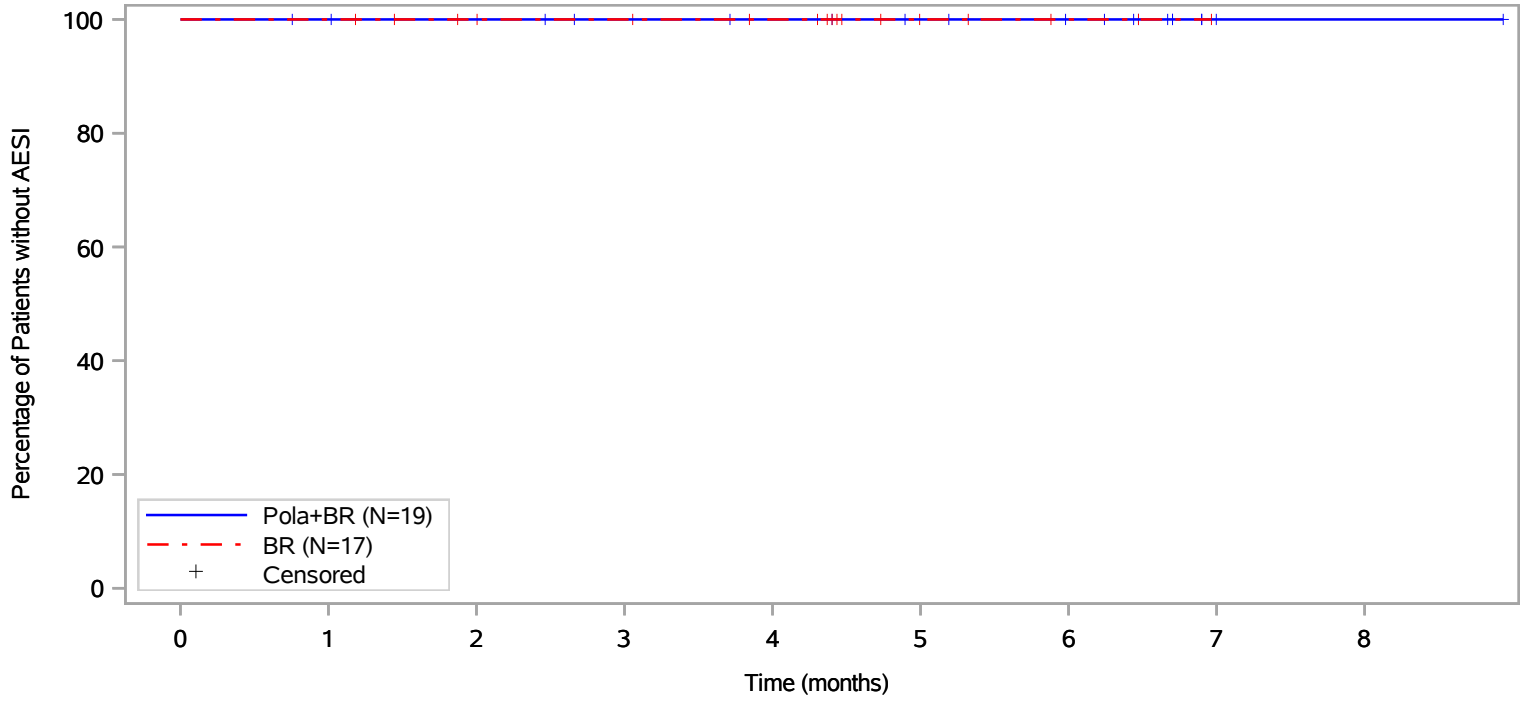
17DEC2022 22:42

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 14:19

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

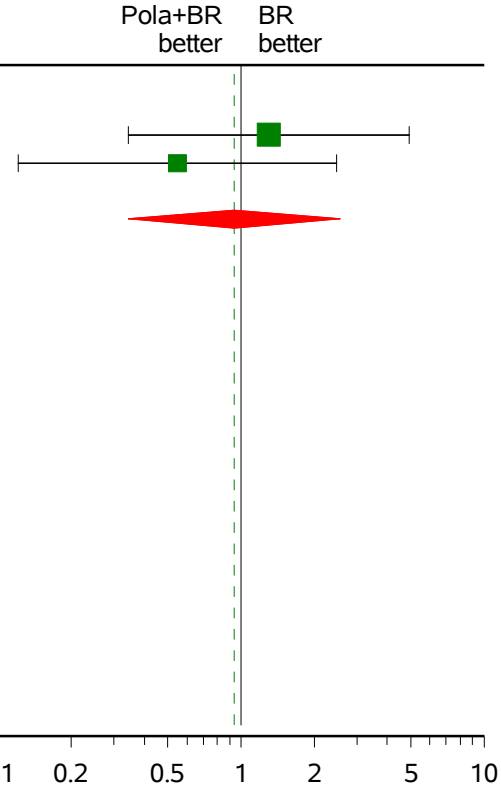
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	10	52.6	9	47.4	17	100.0	7	41.2	10	58.8	0.9226	0.94	0.34	2.55		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	7	50.0	7	50.0	8	47.1	3	37.5	5	62.5	0.8885	0.71	0.13	3.85		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	3	60.0	2	40.0	9	52.9	4	44.4	5	55.6	0.8161	0.88	0.18	4.23		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	4	50.0	4	50.0	2	11.8	0	-	2	100.0	0.2186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	6	54.5	5	45.5	15	88.2	7	46.7	8	53.3	0.6829	0.49	0.13	1.80		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	5	62.5	3	37.5	14	82.4	6	42.9	8	57.1	0.6235	1.14	0.33	3.95		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	5	45.5	6	54.5	3	17.6	1	33.3	2	66.7	0.7054	1.49	0.17	12.78		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	2	40.0	3	60.0	3	17.6	1	33.3	2	66.7	0.7222	1.54	0.14	17.22		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	8	57.1	6	42.9	14	82.4	6	42.9	8	57.1	0.8748	0.82	0.27	2.51		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTTHROM_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 2:05

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	5	12	4	1.31	(0.35, 4.94)
YO41543	8	5	5	3	0.55	(0.12, 2.47)
Total	19	10	17	7	0.94	(0.34, 2.55)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTTHROM_L2_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 15:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	5	45.5	6	54.5	12	70.6	4	33.3	8	66.7	0.6938	1.31	0.35	4.94		Convergence criterion (GCONV=1E-8) satisfied.		56.2						
	YO41543	8	42.1	5	62.5	3	37.5	5	29.4	3	60.0	2	40.0	0.4265	0.55	0.12	2.47		Convergence criterion (GCONV=1E-8) satisfied.		43.8						
	Total	19	100.0	10	52.6	9	47.4	17	100.0	7	41.2	10	58.8	0.9226	0.94	0.34	2.55		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.73	1	0.3935	0.00	-0.13	0.9005

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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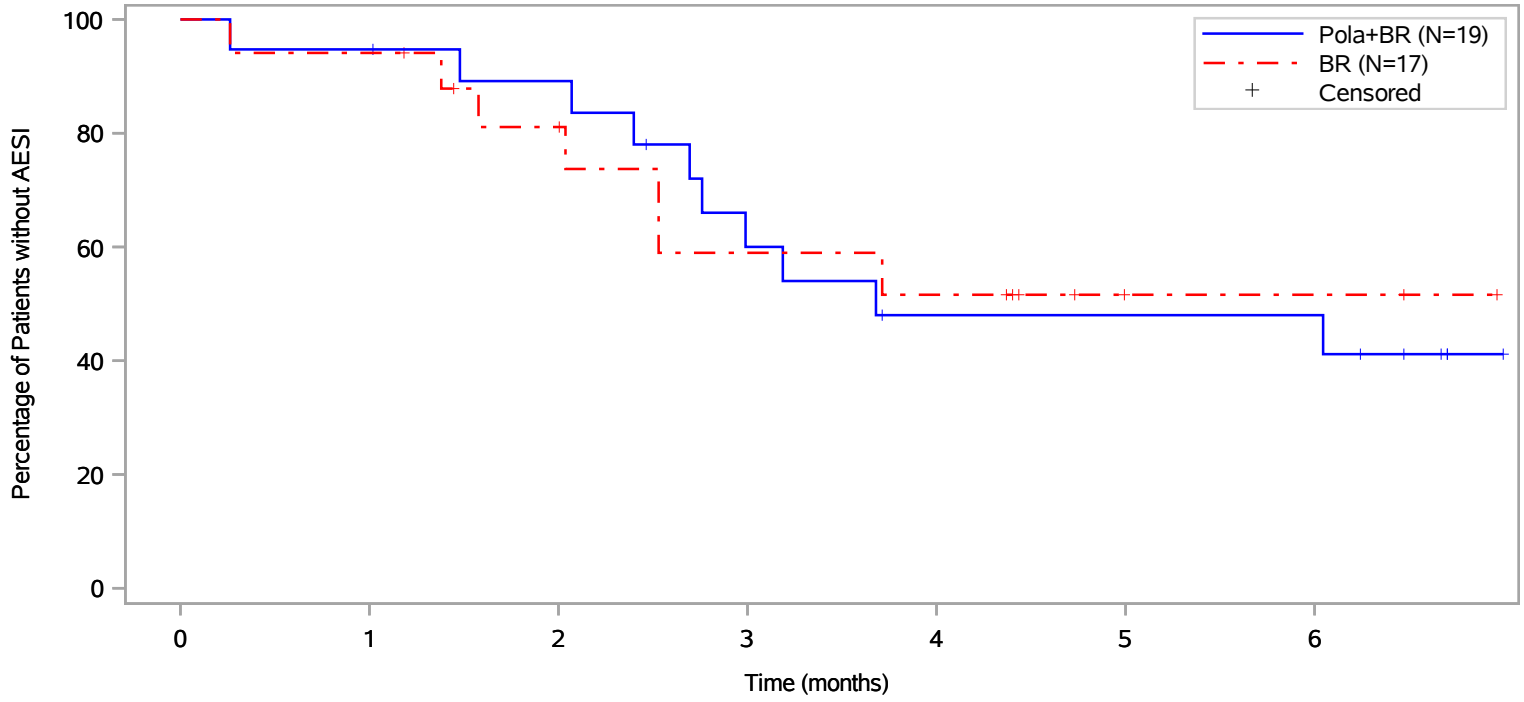
16DEC2022 10:16

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	18	16	10	7	7	7
BR (N=17)	17	16	12	8	7	2	2
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	3	3
BR (N=17)	0	0	2	3	3	8	8

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

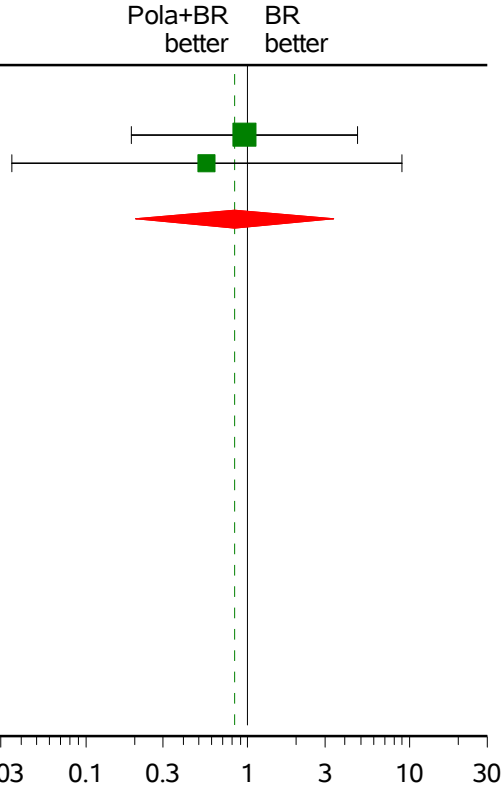
		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	4	21.1	15	78.9	17	100.0	4	23.5	13	76.5	0.7010	0.83	0.20	3.41		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	3	21.4	11	78.6	8	47.1	2	25.0	6	75.0	0.7398	1.05	0.16	6.99		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	9	52.9	2	22.2	7	77.8	0.8699	0.80	0.07	9.29		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	1	12.5	7	87.5	2	11.8	0	-	2	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	3	27.3	8	72.7	15	88.2	4	26.7	11	73.3	0.7530	0.86	0.19	3.97		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	3	37.5	5	62.5	14	82.4	4	28.6	10	71.4	0.7959	1.36	0.30	6.17		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	1	9.1	10	90.9	3	17.6	0	-	3	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	1	20.0	4	80.0	3	17.6	1	33.3	2	66.7	0.7766	0.67	0.04	10.77		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	3	21.4	11	78.6	14	82.4	3	21.4	11	78.6	0.7204	0.89	0.17	4.68		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTTHROM35_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=19)		BR (N=17)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	11	3	12	3	0.96	(0.19, 4.75)
YO41543	8	1	5	1	0.56	(0.03, 8.98)
Total	19	4	17	4	0.83	(0.20, 3.41)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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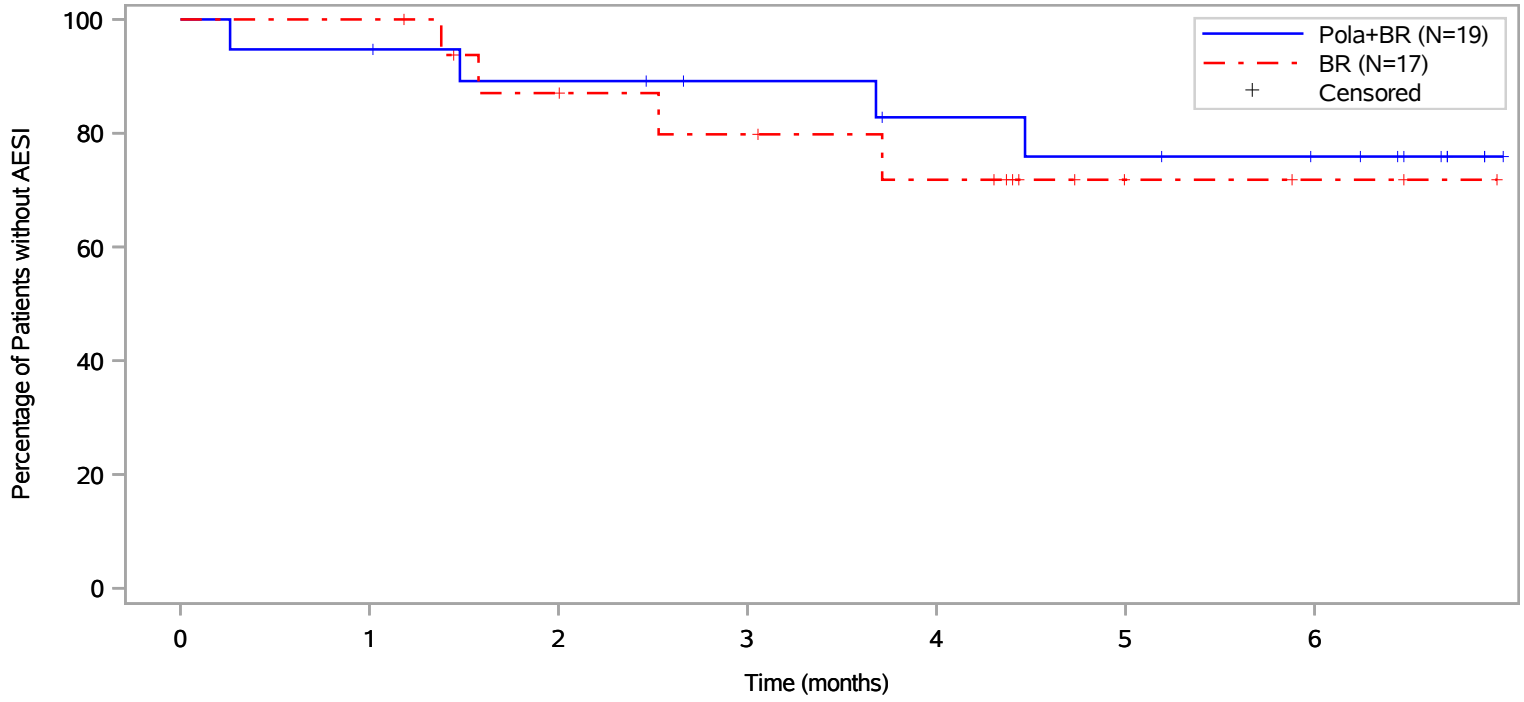
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	3	27.3	8	72.7	12	70.6	3	25.0	9	75.0	0.9552	0.96	0.19	4.75		Convergence criterion (GCONV=1E-8) satisfied.	75.0						
	YO41543	8	42.1	1	12.5	7	87.5	5	29.4	1	20.0	4	80.0	0.6771	0.56	0.03	8.98		Convergence criterion (GCONV=1E-8) satisfied.	25.0						
	Total	19	100.0	4	21.1	15	78.9	17	100.0	4	23.5	13	76.5	0.7010	0.83	0.20	3.41		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.11	1	0.7434	0.00	-0.26	0.7980

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTTHROM35_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 20:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	18	16	14	12	11	9
BR (N=17)	17	17	13	11	9	3	2
Patients censored							
Pola+BR (N=19)	0	0	1	3	4	4	6
BR (N=17)	0	0	2	3	4	10	11

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTTHROM35_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:48

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTTHROMS_L2_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:32

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTTHROMS_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 15:36

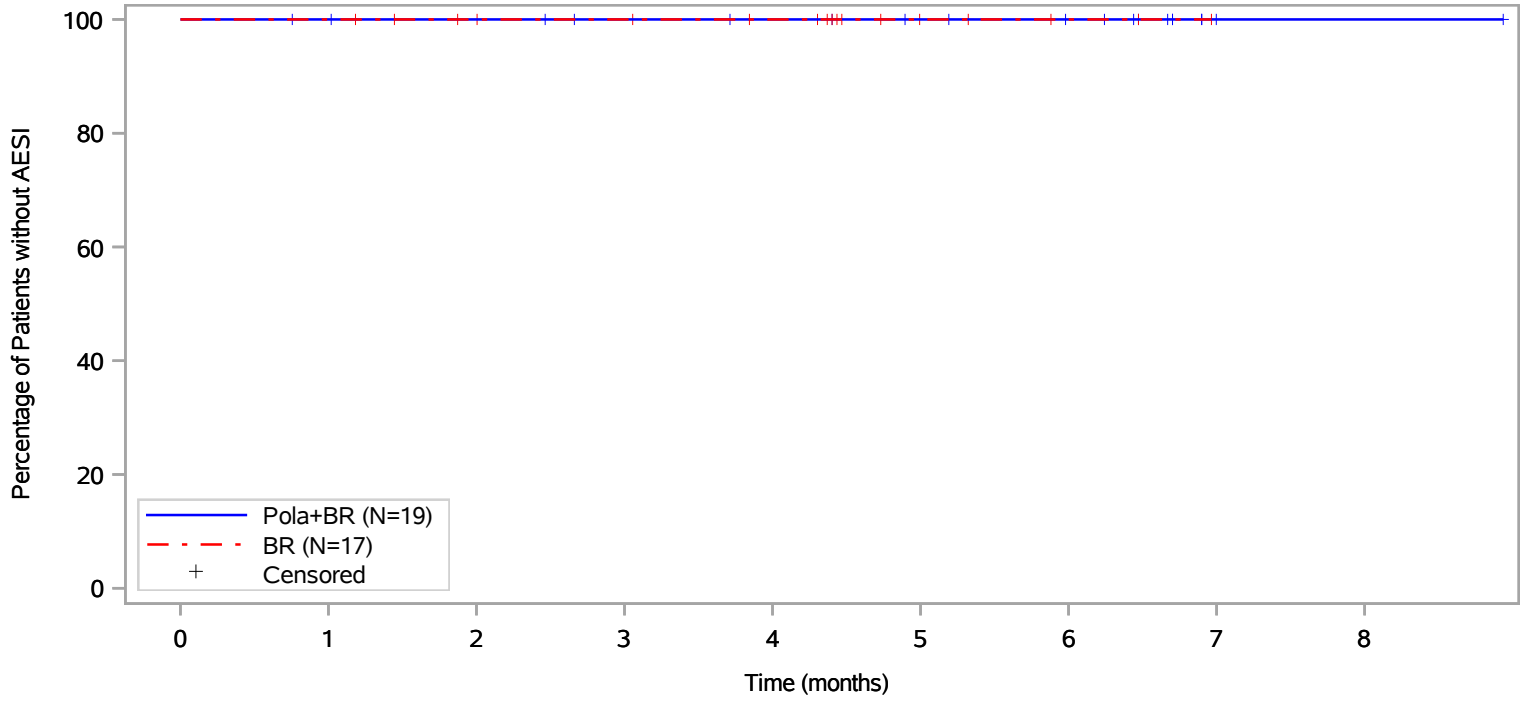
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTTHROMS_L2_ARMCDPLUSSE_29365_41543.xls
15DEC2022 20:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Serious Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTTHROMS_L2_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 0:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	8	47.1	0	-	8	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	9	52.9	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	8	42.1	0	-	8	100.0	2	11.8	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	11	57.9	0	-	11	100.0	15	88.2	0	-	15	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	8	42.1	0	-	8	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	11	57.9	0	-	11	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	26.3	0	-	5	100.0	3	17.6	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	14	73.7	0	-	14	100.0	14	82.4	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTTLS_L2_ARMCDPLUSSE_29365_41543.xls
01DEC2022 21:21

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTTLS_L2_ARMCDPLUSSE_29365_41543.xls
16DEC2022 21:58

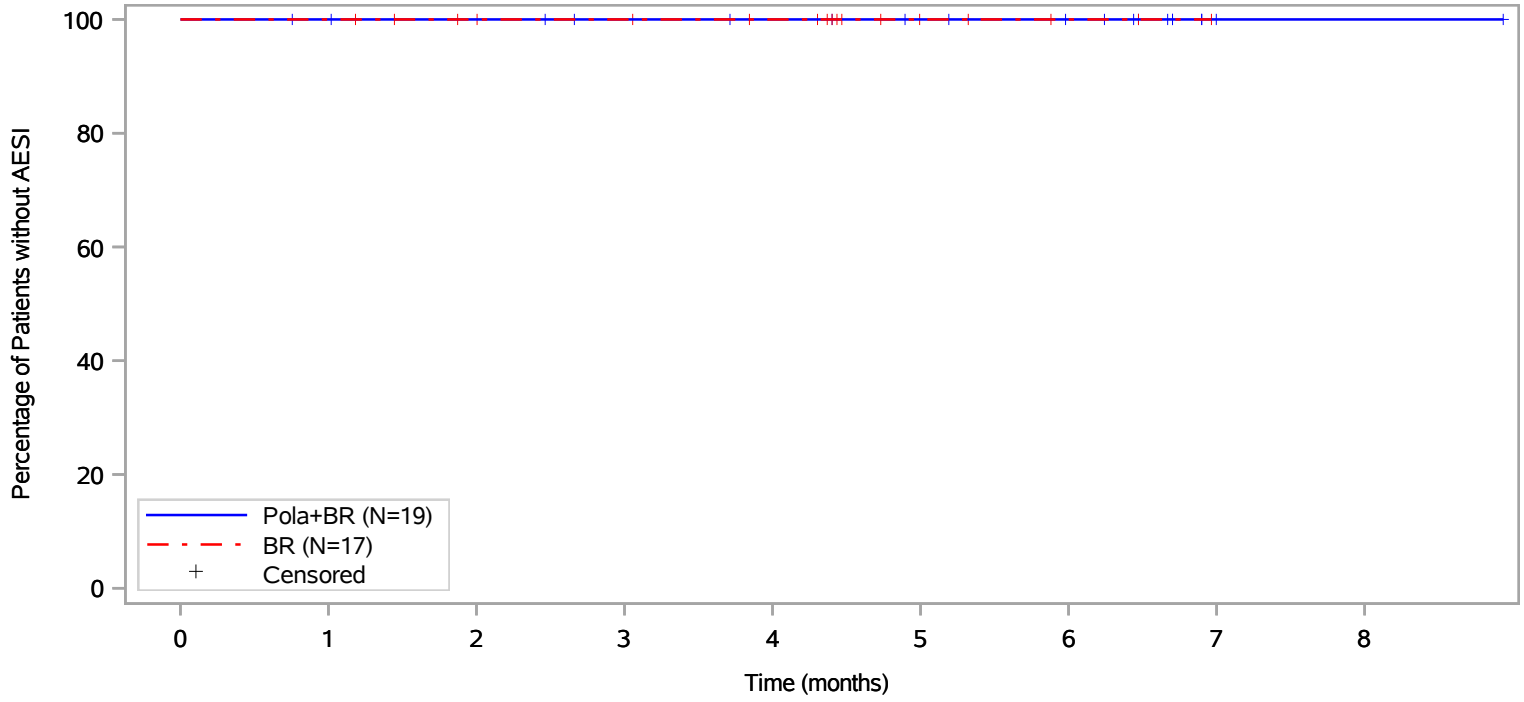
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=19)						BR (N=17)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	11	57.9	0	-	11	100.0	12	70.6	0	-	12	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE							
	YO41543	8	42.1	0	-	8	100.0	5	29.4	0	-	5	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE							
	Total	19	100.0	0	-	19	100.0	17	100.0	0	-	17	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTTLS_L2_ARMCDPLUSSE_29365_41543.xls
17DEC2022 22:20

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=19)	19	18	17	15	14	12	10	1	1
BR (N=17)	17	17	14	13	11	4	2	NE	NE
Patients censored									
Pola+BR (N=19)	0	1	2	4	5	7	9	18	18
BR (N=17)	0	0	3	4	6	13	15	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..analysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTTLS_L2_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=19)															BR (N=17)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																														
All	282	225	79.8	0	0.0	47	16.7	2	0.7	2	0.7	6	2.1	0	0.0	213	129	60.6	0	0.0	72	33.8	3	1.4	4	1.9	5	2.3	0	0.0
Grade 1	141	111	78.7	0	0.0	24	17.0	0	0.0	1	0.7	5	3.5	0	0.0	100	69	69.0	0	0.0	26	26.0	0	0.0	2	2.0	3	3.0	0	0.0
Grade 2	82	65	79.3	0	0.0	15	18.3	0	0.0	1	1.2	1	1.2	0	0.0	69	38	55.1	0	0.0	27	39.1	0	0.0	2	2.9	2	2.9	0	0.0
Grade 3	43	36	83.7	0	0.0	7	16.3	0	0.0	0	0.0	0	0.0	0	0.0	28	15	53.6	0	0.0	13	46.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	14	13	92.9	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0	0	0.0	13	7	53.8	0	0.0	6	46.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0
AEs Grade >=3																														
All	59	49	83.1	0	0.0	8	13.6	2	3.4	0	0.0	0	0.0	0	0.0	44	22	50.0	0	0.0	13	43.2	3	6.8	0	0.0	0	0.0	0	0.0
Grade 3	43	36	83.7	0	0.0	7	16.3	0	0.0	0	0.0	0	0.0	0	0.0	28	15	53.6	0	0.0	13	46.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	14	13	92.9	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0	0	0.0	13	7	53.8	0	0.0	6	46.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0
AEs Grade 3																														
All	43	36	83.7	0	0.0	7	16.3	0	0.0	0	0.0	0	0.0	0	0.0	28	15	53.6	0	0.0	13	46.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	43	36	83.7	0	0.0	7	16.3	0	0.0	0	0.0	0	0.0	0	0.0	28	15	53.6	0	0.0	13	46.4	0	0.0	0	0.0	0	0.0	0	0.0
AEs Grade 4																														
All	14	13	92.9	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0	0	0.0	13	7	53.8	0	0.0	6	46.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	14	13	92.9	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0	0	0.0	13	7	53.8	0	0.0	6	46.2	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																														
All	8	5	62.5	0	0.0	1	12.5	2	25.0	0	0.0	0	0.0	0	0.0	13	3	23.1	0	0.0	7	53.8	3	23.1	0	0.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	1	25.0	0	0.0	3	75.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ae_resolved.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ae_resolved_L2_ARMCDPLUSSE_29365_41543.xls
18APR2023 16:29

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Second-line (2L) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=19)															BR (N=17)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Neutropenia Including Febrile Neutropenia																														
All	59	54	91.5	0	0.0	4	6.8	0	0.0	1	1.7	0	0.0	0	0.0	41	30	73.2	0	0.0	11	26.8	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	7	6	85.7	0	0.0	1	14.3	0	0.0	0	0.0	0	0.0	0	0.0	8	6	75.0	0	0.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	19	18	94.7	0	0.0	0	0.0	0	0.0	1	5.3	0	0.0	0	0.0	10	8	80.0	0	0.0	2	20.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	22	20	90.9	0	0.0	2	9.1	0	0.0	0	0.0	0	0.0	0	0.0	15	10	66.7	0	0.0	5	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	11	10	90.9	0	0.0	1	9.1	0	0.0	0	0.0	0	0.0	0	0.0	8	6	75.0	0	0.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Neutropenia Including Febrile Neutropenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral Neuropathy																														
All	10	7	70.0	0	0.0	2	20.0	0	0.0	0	0.0	1	10.0	0	0.0	3	0	0.0	0	0.0	1	33.3	0	0.0	0	0.0	2	66.7	0	0.0
Grade 1	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0
Grade 2	3	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	1	33.3	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Peripheral Neuropathy																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Anemia																														
All	9	4	44.4	0	0.0	5	55.6	0	0.0	0	0.0	0	0.0	0	0.0	8	3	37.5	0	0.0	5	62.5	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	4	2	50.0	0	0.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Anemia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Thrombocytopenia																														
All	14	11	78.6	0	0.0	3	21.4	0	0.0	0	0.0	0	0.0	0	0.0	8	4	50.0	0	0.0	4	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	5	4	80.0	0	0.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	5	3	60.0	0	0.0	2	40.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Serious Thrombocytopenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infections and Infestations																														
All	17	11	64.7	0	0.0	5	29.4	1	5.9	0	0.0	0	0.0	0	0.0	10	6	60.0	0	0.0	2	20.0	2	20.0	0	0.0	0	0.0	0	0.0
Grade 1	2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	11	8	72.7	0	0.0	3	27.3	0	0.0	0	0.0	0	0.0	0	0.0	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
Serious Infections and Infestations																														
All	4	3	75.0	0	0.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	1	33.3	2	66.7	0	0.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
Infusion Related Reactions																														
All	10	10	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9	7	77.8	0	0.0	2	22.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	7	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	6	75.0	0	0.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Infusion Related Reactions																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hepatic Toxicity																														
All	9	8	88.9	0	0.0	1	11.1	0	0.0	0	0.0	0	0.0	0	0.0	12	4	33.3	0	0.0	8	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	8	7	87.5	0	0.0	1	12.5	0	0.0	0	0.0	0	0.0	0	0.0	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	1	16.7	0	0.0	5	83.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hepatic Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Fatigue and Asthenia																														
All	12	7	58.3	0	0.0	5	41.7	0	0.0	0	0.0	0	0.0	0	0.0	13	6	46.2	0	0.0	6	46.2	0	0.0	1	7.7	0	0.0	0	0.0
Grade 1	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0	7	4	57.1	0	0.0	3	42.9	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0	6	2	33.3	0	0.0	3	50.0	0	0.0	1	16.7	0	0.0	0	0.0
Serious Fatigue and Asthenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hyperglycemias																														
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hyperglycemias																														

All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Renal Toxicity																																
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Renal Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Gastrointestinal Toxicity																																
All	53	47	88.7	0	0.0	4	7.5	0	0.0	1	1.9	1	1.9	0	0.0	31	22	71.0	0	0.0	7	22.6	0	0.0	1	3.2	1	3.2	0	0.0		
Grade 1	37	33	89.2	0	0.0	2	5.4	0	0.0	1	2.7	1	2.7	0	0.0	17	13	76.5	0	0.0	3	17.6	0	0.0	1	5.9	0	0.0	0	0.0		
Grade 2	16	14	87.5	0	0.0	2	12.5	0	0.0	0	0.0	0	0.0	0	0.0	13	8	61.5	0	0.0	4	30.8	0	0.0	0	0.0	1	7.7	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Gastrointestinal Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Pulmonary Toxicity																																
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0		
Grade 1	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0		
Serious Pulmonary Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Joint Pains, Arthralgia, Skeletal Pain																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Joint Pains, Arthralgia, Skeletal Pain																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Alopecia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Alopecia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Cardiac Toxicity and Arrhythmias																																
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0		
Grade 1	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0		
Serious Cardiac Toxicity and Arrhythmias																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Dysgeusia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Dysgeusia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Demographics and Baseline Characteristics

	Pola+BR (N=48)	BR (N=37)	All (N=85)
Age (Years)			
n	48	37	85
Mean (SD)	59.0 (12.3)	61.7 (12.3)	60.2 (12.3)
Median	62	63	62
Min - Max	30 - 81	30 - 84	30 - 84
Age Group (Years)			
n	48	37	85
18 - 40	6 (12.5%)	3 (8.1%)	9 (10.6%)
41 - 64	24 (50.0%)	18 (48.6%)	42 (49.4%)
>= 65	18 (37.5%)	16 (43.2%)	34 (40.0%)
Sex			
n	48	37	85
Male	35 (72.9%)	24 (64.9%)	59 (69.4%)
Female	13 (27.1%)	13 (35.1%)	26 (30.6%)
Race			
n	48	37	85
American Indian or Alaska Native	0	1 (2.7%)	1 (1.2%)
Asian	23 (47.9%)	11 (29.7%)	34 (40.0%)
Black or African American	3 (6.3%)	0	3 (3.5%)
White	18 (37.5%)	21 (56.8%)	39 (45.9%)
Unknown	4 (8.3%)	4 (10.8%)	8 (9.4%)
Ethnicity			
n	48	37	85
Hispanic or Latino	1 (2.1%)	0	1 (1.2%)
Not Hispanic or Latino	44 (91.7%)	34 (91.9%)	78 (91.8%)
Not reported	2 (4.2%)	1 (2.7%)	3 (3.5%)
Unknown	1 (2.1%)	2 (5.4%)	3 (3.5%)
Weight (kg) at Baseline			
n	48	37	85
Mean (SD)	74.19 (16.43)	68.74 (13.26)	71.82 (15.29)

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of Patients who discontinued Study or Treatment

Status / Primary Reason for Discontinuation	Pola+BR (N=48)	BR (N=37)	All (N=85)
Number of Patients Randomized	48 (100.0%)	37 (100.0%)	85 (100.0%)
Number of Patients Treated	47 (97.9%)	36 (97.3%)	83 (97.6%)
Discontinued Study*			
Total	46 (95.8%)	35 (94.6%)	81 (95.3%)
Death	34 (70.8%)	27 (73.0%)	61 (71.8%)
Withdrawal by Subject	5 (10.4%)	3 (8.1%)	8 (9.4%)
Study Terminated By Sponsor	5 (10.4%)	3 (8.1%)	8 (9.4%)
Physician decision	0	2 (5.4%)	2 (2.4%)
Other	2 (4.2%)	0	2 (2.4%)
Discontinued Polatuzumab Vedotin Treatment or Placebo**			
Total	24 (51.1%)	5 (13.9%)	29 (34.9%)
Adverse Event	10 (21.3%)	1 (2.8%)	11 (13.3%)
Progressive Disease	11 (23.4%)	4 (11.1%)	15 (18.1%)
Lack of Efficacy	1 (2.1%)	0	1 (1.2%)
Withdrawal by Subject	1 (2.1%)	0	1 (1.2%)
Other	1 (2.1%)	0	1 (1.2%)
Discontinued Bendamustine Treatment**			
Total	23 (48.9%)	27 (75.0%)	50 (60.2%)
Adverse Event	10 (21.3%)	4 (11.1%)	14 (16.9%)
Progressive Disease	11 (23.4%)	21 (58.3%)	32 (38.6%)
Lack of Efficacy	1 (2.1%)	0	1 (1.2%)
Withdrawal by Subject	1 (2.1%)	0	1 (1.2%)
Physician decision	0	1 (2.8%)	1 (1.2%)
Other	0	1 (2.8%)	1 (1.2%)
Discontinued Rituximab or Obinutuzumab Treatment**			
Total	24 (51.1%)	28 (77.8%)	52 (62.7%)
Adverse Event	10 (21.3%)	4 (11.1%)	14 (16.9%)
Progressive Disease	11 (23.4%)	21 (58.3%)	32 (38.6%)
Lack of Efficacy	1 (2.1%)	0	1 (1.2%)

Withdrawal by Subject	1 (2.1%)	0	1 (1.2%)
Physician decision	0	2 (5.6%)	2 (2.4%)
Other	1 (2.1%)	1 (2.8%)	2 (2.4%)

* Percentages are based on the number of patients randomized.
** Percentages are based on the number of patients treated.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ds.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_ds_L3PLUS_ARMCDPLUS_IT_29365_41543.xls
08DEC2022 12:42

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Number of Centers/Countries/Geographical Regions with <10, >=10 Patients per Arm

	Center				Country				Geographical region			
	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients
Overall	37	100.0	85	100.0	12	100.0	85	100.0	4	100.0	85	100.0
with <10 patients per arm	37	100.0	85	100.0	12	100.0	85	100.0	3	75.0	49	57.6
with >=10 patients per arm	0	-	0	-	0	-	0	-	1	25.0	36	42.4

'<10 patients' category if at least one treatment arm has <10 patients; '>=10 patients' category if all treatment arms have >=10 patients.
Geographical regions: Asia/Pacific, Eastern Europe, North America, Western Europe.
'n': Number of centers/countries/regions; "%": Percent of centers/countries/regions compared to overall number of centers/countries/regions
'n of patients randomized': Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)
'% randomized patients': Percent of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_center.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_center_L3PLUS_ARMCDPLUS_IT_29365_41543.xls
07DEC2022 23:39

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Concordance of Stratification Factors by eCRF and IxRS
MODEL: Descriptive
STUDIES: GO29365, YO41543
Stratification Factor: Duration of Response to prior therapy

	Pola+BR (N=48)			BR (N=37)		
	eCRF			eCRF		
	<=12 Months	>12 Months	Total	<=12 Months	>12 Months	Total
IxRS						
<=12 Months	45 (93.8%)	1 (2.1%)	46 (95.8%)	32 (86.5%)	0	32 (86.5%)
>12 Months	1 (2.1%)	1 (2.1%)	2 (4.2%)	0	5 (13.5%)	5 (13.5%)
Total	46	2	48	32	5	37

Percentages are based on N in the column headings.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_strat.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_strat_L3PLUS_ARMCDPLUS_IT_29365_41543.xls
08DEC2022 12:42

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: POLATUZUMAB VEDOTIN

	Pola+BR (N=47)
Treatment Duration (Months)	
n	47
Mean (SD)	2.69 (1.44)
Median	3.39
Interquartile Range	1.35 - 3.69
Min - Max	0.0 - 5.0
Number of Cycles	
n	47
Mean (SD)	4.5 (1.8)
Median	6
Interquartile Range	3.0 - 6.0
Min - Max	1 - 6
Total Cumulative Dose (mg)	
n	47
Mean (SD)	587.2 (253.1)
Median	668
Interquartile Range	372.6 - 780.0
Min - Max	86 - 972
Dose intensity (%) adjusted for dose reduction and delay	
n	47
Mean (SD)	93.6 (11.1)
Median	98.2
Interquartile Range	88.2 - 101.5
Min - Max	66 - 113

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas

Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_ex_L3PLUS_ARMCDPLUSSE_29365_41543.xls
20APR2023 11:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: BENDAMUSTINE

	Pola+BR (N=47)	BR (N=36)
Treatment Duration (Months)		
n	47	36
Mean (SD)	2.72 (1.44)	1.66 (1.50)
Median	3.42	1.4
Interquartile Range	1.38 - 3.68	0.06 - 3.10
Min - Max	0.0 - 5.1	0.0 - 4.4
Number of Cycles		
n	47	36
Mean (SD)	4.5 (1.8)	3.1 (1.9)
Median	6	3
Interquartile Range	3.0 - 6.0	1.0 - 5.0
Min - Max	1 - 6	1 - 6
Total Cumulative Dose (mg)		
n	47	36
Mean (SD)	1477.5 (604.9)	984.4 (611.1)
Median	1584	880
Interquartile Range	1020.0 - 2023.2	363.6 - 1413.0
Min - Max	252 - 2268	236 - 2095
Dose intensity (%) adjusted for dose reduction and delay		
n	47	36
Mean (SD)	92.5 (11.0)	92.2 (10.2)
Median	95.5	95.5
Interquartile Range	91.3 - 100.0	90.1 - 99.5
Min - Max	61 - 103	64 - 102

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_ex_L3PLUS_ARMCDPLUSSE_29365_41543.xls
20APR2023 11:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: RITUXIMAB

	Pola+BR (N=47)	BR (N=36)
Treatment Duration (Months)		
n	47	36
Mean (SD)	2.72 (1.44)	1.66 (1.50)
Median	3.42	1.4
Interquartile Range	1.39 - 3.72	0.03 - 3.11
Min - Max	0.0 - 5.1	0.0 - 4.4
Number of Cycles		
n	47	36
Mean (SD)	4.5 (1.8)	3.1 (1.9)
Median	6	3
Interquartile Range	3.0 - 6.0	1.0 - 5.0
Min - Max	1 - 6	1 - 6
Total Cumulative Dose (mg)		
n	47	36
Mean (SD)	3123.8 (1280.3)	2103.0 (1326.4)
Median	3307.8	1835
Interquartile Range	2100.0 - 4207.5	757.5 - 3318.0
Min - Max	525 - 4770	491 - 4500
Dose intensity (%) adjusted for dose reduction and delay		
n	47	36
Mean (SD)	93.6 (9.1)	94.4 (8.1)
Median	97.7	97.6
Interquartile Range	91.2 - 100.0	90.7 - 100.0
Min - Max	71 - 105	74 - 102

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_ex_L3PLUS_ARMCDPLUSSE_29365_41543.xls
20APR2023 11:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=47)	BR (N=36)	All (N=83)
n	47	36	83
Median	135	73	95

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 30 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fu_D30_L3PLUS_ARMCDPLUSSE_29365_41543.xls
08DEC2022 16:45

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=47)	BR (N=36)	All (N=83)
n	47	36	83
Median	192	112	139

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 90 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fu_D90_L3PLUS_ARMCDPLUSSE_29365_41543.xls
08DEC2022 16:50

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of New Anti-Lymphoma Therapy

	Pola+BR (N=48)	BR (N=37)
Total number of patients with at least one NALT treatment	27 (56.3%)	19 (51.4%)
Total number of NALT treatments	52	26
Total number of patients with at least one NALT treatment before PFS event	8 (16.7%)	4 (10.8%)
Total number of patients with at least one NALT treatment at or after PFS event	17 (35.4%)	9 (24.3%)
Total number of patients with at least one NALT treatment and without PFS event	2 (4.2%)	6 (16.2%)
Radiotherapy		
Total number of patients with at least one treatment	3 (6.3%)	2 (5.4%)
Total number of treatments	3	2
Systemic therapy		
Total number of patients with at least one treatment	26 (54.2%)	15 (40.5%)
Total number of treatments	49	22
Total number of patients received stem cell transplants	1 (2.1%)	1 (2.7%)
Autologous transplant	0	0
Allogeneic transplant	0	1 (2.7%)
Unknown	1 (2.1%)	0
Total number of patients received CAR-T	5 (10.4%)	0
Total number of patients received unknown treatment	0	2 (5.4%)

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_nalt.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_nalt_L3PLUS_ARMCDPLUS_IT_29365_41543.xls
01FEB2023 18:52

POPULATION: Intent-to-Treat Patients, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median observation time(of follow up)

Overall Survival

	Pola+BR (N=48)	BR (N=37)	All (N=85)
Patients with event (%)	14 (29.2%)	10 (27.0%)	24 (28.2%)
Latest contributing event			
Alive	14	10	24
Patients without event (%)	34 (70.8%)	27 (73.0%)	61 (71.8%)
Time to event (months)			
Median	20.1	26.3	20.1
95% CI	(17.2, 59.9)	(13.5, NE)	(17.4, 59.9)
25% and 75%-ile	17.1 - 59.9	13.5 - 59.4	17.1 - 59.9
Range	0 - 64	0* - 60	0* - 64

Summaries of Duration of Follow-up (median, percentiles) are based on reverse Kaplan-Meier estimates.
* Censored observation.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_obs_time.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_obs_time_OSDFU_L3PLUS_ARMCDPLUS_IT_29365_41543.xls
08DEC2022 0:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Deaths and Primary Reason for Death

	Pola+BR (N=47)		BR (N=36)		All (N=83)	
	n	%	n	%	n	%
All Deaths	34	72.3	27	75.0	61	73.5
Adverse Event	7	14.9	8	22.2	15	18.1
Progressive Disease	26	55.3	19	52.8	45	54.2
Other	1	2.1	0	-	1	1.2

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_death.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_death_L3PLUS_ARMCDPLUSSE_29365_41543.xls
08DEC2022 18:11

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=48)												BR (N=37)												Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		48	100.0	34	70.8	14	29.2	5.5	4.2	8.9	11.2	7.7	13.9	37	100.0	27	73.0	10	27.0	2.4	0.9	3.7	3.9	3.4	8.9	0.0120	0.51	0.30	0.86		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the Cox regression models.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
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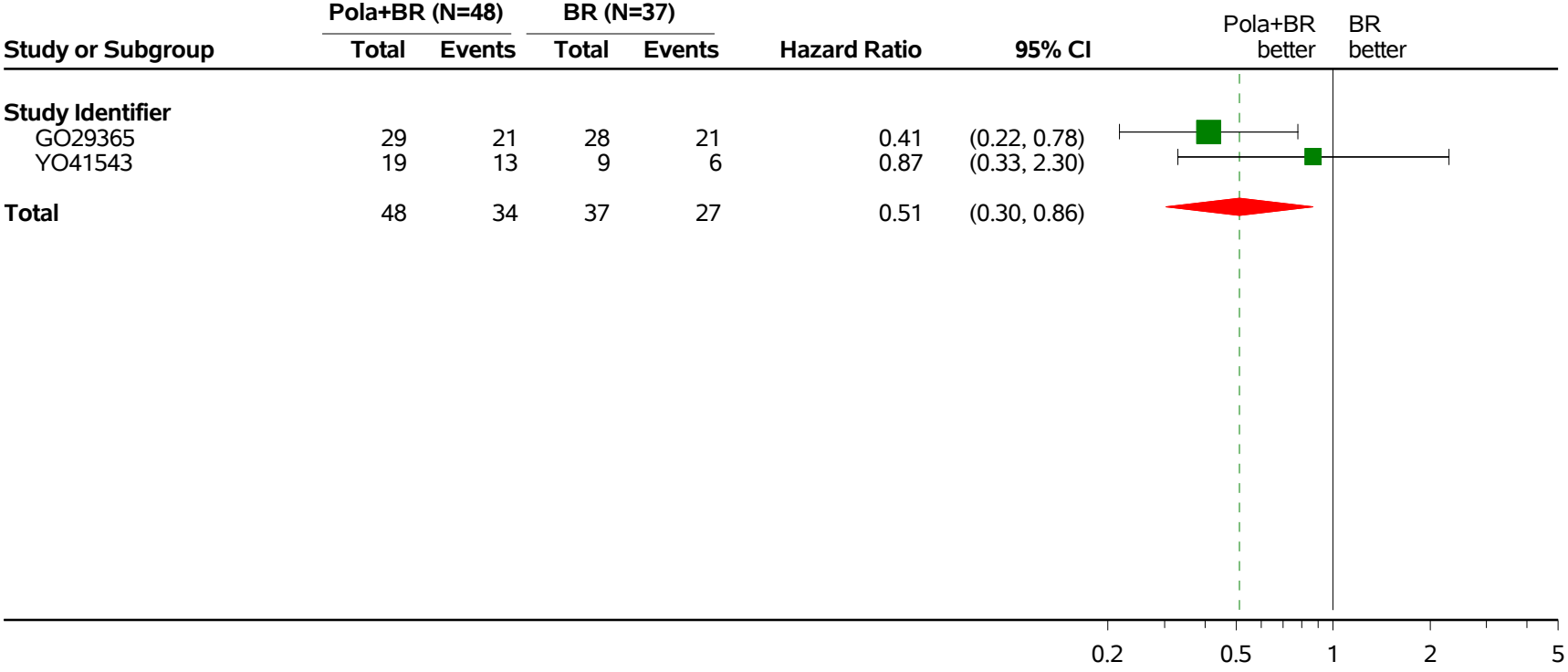
20JAN2023 19:15

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=48)		BR (N=37)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	29	21	28	21	0.41	(0.22, 0.78)
YO41543	19	13	9	6	0.87	(0.33, 2.30)
Total	48	34	37	27	0.51	(0.30, 0.86)



* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_str_OS_ARMCDPLUS_L3PLUS_IT_29365_41543.pdf 14DEC2022 22:49

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=48)												BR (N=37)											Pola + BR vs. BR														
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	29	60.4	21	72.4	8	27.6	6.2	4.1	9.0	11.5	7.7	28.0	28	75.7	21	75.0	7	25.0	2.4	0.8	3.7	3.8	3.2	6.0	0.0051	0.41	0.22	0.78		Convergence criterion (GCONV=1E-8) satisfied.	69.9						
	YO41543	19	39.6	13	68.4	6	31.6	5.5	4.0	10.6	10.9	5.5	14.4	9	24.3	6	66.7	3	33.3	3.6	2.0	11.8	8.8	3.5	NE	0.7765	0.87	0.33	2.30		Convergence criterion (GCONV=1E-8) satisfied.	30.1						
	Total	48	100.0	34	70.8	14	29.2	5.5	4.2	8.9	11.2	7.7	13.9	37	100.0	27	73.0	10	27.0	2.4	0.9	3.7	3.9	3.4	8.9	0.0120	0.51	0.30	0.86		Convergence criterion (GCONV=1E-8) satisfied.	100.0	1.60	1	0.2061	37.44	-2.52	0.0119

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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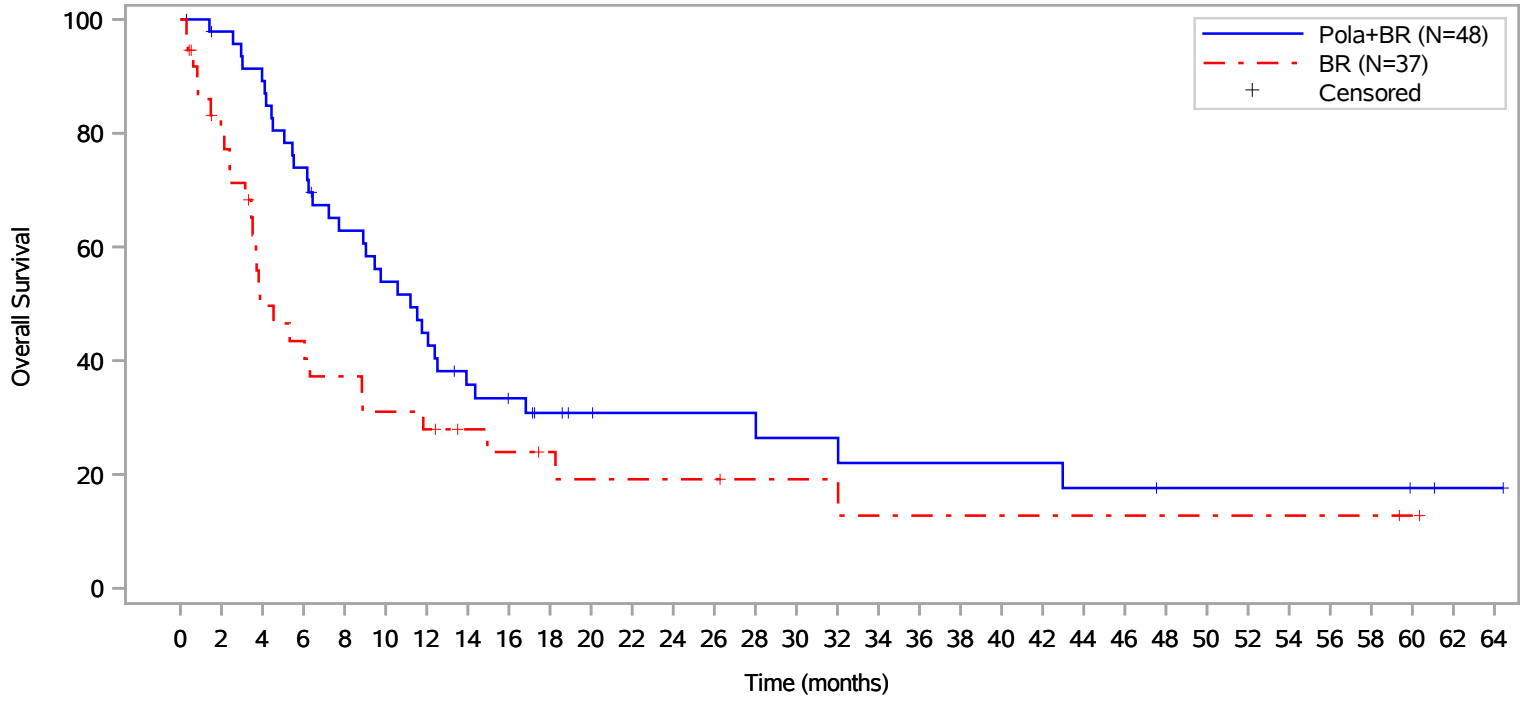
14DEC2022 23:10

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Overall Survival
STUDIES: GO29365, YO41543



Patients at risk																															
Pola+BR (N=48)	48	45	41	34	28	24	20	15	13	10	8	7	7	7	7	6	6	5	5	5	5	5	4	4	3	3	3	3	3	2	1	1
BR (N=37)	37	27	16	14	12	10	9	7	6	5	4	4	4	4	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	1	NE	NE
Patients censored																															
Pola+BR (N=48)	0	2	2	2	3	3	3	4	5	7	9	10	10	10	10	10	10	10	10	10	10	10	10	10	11	11	11	11	11	12	13	13
BR (N=37)	0	3	4	4	4	4	4	6	6	7	7	7	7	7	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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28NOV2022 15:13

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Overall Survival
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=48)												BR (N=37)												Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		48	100.0	34	70.8	14	29.2	5.5	4.2	8.9	11.2	7.7	13.9	37	100.0	27	73.0	10	27.0	2.4	0.9	3.7	3.8	3.4	8.9	0.0411	0.59	0.36	0.98	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	35	72.9	25	71.4	10	28.6	5.5	4.2	8.9	11.5	6.4	14.4	24	64.9	19	79.2	5	20.8	2.3	0.9	3.5	3.7	2.4	8.9	0.0538	0.56	0.30	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.7559
	Female	13	27.1	9	69.2	4	30.8	7.2	4.0	11.2	11.2	7.2	28.0	13	35.1	8	61.5	5	38.5	3.7	0.6	8.8	8.8	3.7	14.9	0.4318	0.68	0.26	1.78	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	30	62.5	22	73.3	8	26.7	5.3	4.0	9.5	10.6	6.2	12.5	21	56.8	15	71.4	6	28.6	2.4	2.0	3.8	3.9	2.4	8.9	0.0783	0.56	0.29	1.10	Convergence criterion (GCONV=1E-8) satisfied.	0.9992
	>= 65	18	37.5	12	66.7	6	33.3	7.7	4.5	13.9	13.9	7.7	43.0	16	43.2	12	75.0	4	25.0	1.5	0.6	4.5	4.5	3.4	14.9	0.2279	0.58	0.26	1.29	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	30	62.5	22	73.3	8	26.7	5.5	4.0	7.2	9.5	6.2	12.1	25	67.6	21	84.0	4	16.0	2.0	0.6	3.5	3.7	2.4	5.3	0.0037	0.42	0.23	0.77	Convergence criterion (GCONV=1E-8) satisfied.	0.0884
	<3	18	37.5	12	66.7	6	33.3	9.0	4.1	12.5	12.5	11.2	32.0	12	32.4	6	50.0	6	50.0	3.8	2.4	14.9	14.9	3.8	NE	0.8279	1.12	0.42	3.00	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	18.8	8	88.9	1	11.1	7.7	4.4	9.5	9.0	7.7	12.4	14	37.8	11	78.6	3	21.4	1.5	0.6	3.8	3.8	1.5	14.9	0.1990	0.55	0.22	1.39	Convergence criterion (GCONV=1E-8) satisfied.	0.7452
	Non-Europe	39	81.3	26	66.7	13	33.3	5.5	4.1	10.6	11.8	6.4	16.8	23	62.2	16	69.6	7	30.4	2.4	2.0	3.9	5.3	3.2	11.8	0.1837	0.65	0.35	1.23	Convergence criterion (GCONV=1E-8) satisfied.	
Duration of response to prior therapy	<=12 Months	46	95.8	33	71.7	13	28.3	5.5	4.2	8.9	10.6	7.2	12.5	32	86.5	24	75.0	8	25.0	2.1	0.9	3.7	3.8	2.4	8.8	0.0115	0.50	0.30	0.86	Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	2	4.2	1	50.0	1	50.0	13.9	13.9	NE	NE	13.8	NE	5	13.5	3	60.0	2	40.0	6.0	3.2	NE	18.3	3.2	NE	0.7709	0.71	0.07	6.97	Convergence criterion (GCONV=1E-8) satisfied.	
Refractory to last prior anti-lymphoma therapy**	Yes	46	95.8	34	73.9	12	26.1	5.5	4.2	8.9	10.8	7.2	12.5	32	86.5	25	78.1	7	21.9	2.1	0.9	3.5	3.7	2.4	6.3	0.0092	0.50	0.30	0.84	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	2	4.2	0	-	2	100.0	NE	NE	NE	NE	NE	NE	5	13.5	2	40.0	3	60.0	12.2	6.0	NE	NE	6.0	NE	0.2807	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Prior Bone Marrow Transplant	Yes	10	20.8	6	60.0	4	40.0	9.5	4.5	16.8	13.9	9.5	NE	7	18.9	3	42.9	4	57.1	3.8	3.2	NE	NE	3.8	NE	0.9856	0.73	0.18	2.95	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	38	79.2	28	73.7	10	26.3	5.5	4.0	7.7	10.6	6.4	12.5	30	81.1	24	80.0	6	20.0	2.1	0.8	3.7	3.7	2.4	8.8	0.0229	0.55	0.31	0.95	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* Indicates convergence problem, Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Study was included as a covariate in the Cox regression models.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
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20JAN2023 19:24

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=48)											BR (N=37)											Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		48	100.0	41	85.4	7	14.6	2.6	1.8	4.7	6.3	4.5	9.8	37	100.0	28	75.7	9	24.3	1.9	0.7	3.2	3.7	2.4	4.6	0.0046	0.48	0.29	0.81		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the Cox regression models.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
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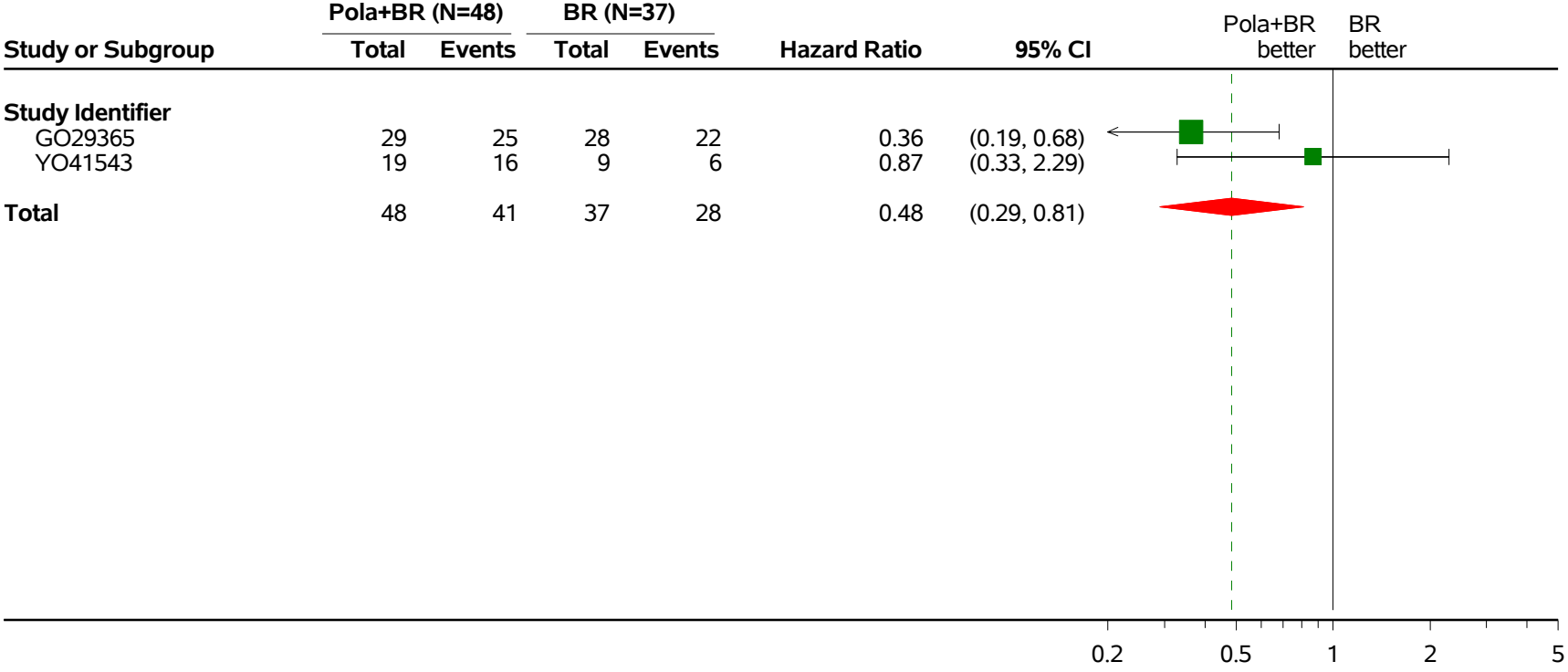
20JAN2023 18:47

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=48)		BR (N=37)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	29	25	28	22	0.36	(0.19, 0.68)
YO41543	19	16	9	6	0.87	(0.33, 2.29)
Total	48	41	37	28	0.48	(0.29, 0.81)



* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=48)												BR (N=37)											Pola + BR vs. BR																		
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event					log-rank	Hazard Ratio												Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status									Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	29	60.4	25	86.2	4	13.8	2.6	1.9	6.2	7.0	4.7	13.4	28	75.7	22	78.6	6	21.4	0.9	0.7	2.8	3.7	1.9	4.1	0.0012	0.36	0.19	0.68		Convergence criterion (GCONV=1E-8) satisfied.									70.2						
	YO41543	19	39.6	16	84.2	3	15.8	2.0	1.5	5.2	5.2	3.8	10.6	9	24.3	6	66.7	3	33.3	2.1	0.7	6.2	4.6	2.1	NE	0.7729	0.87	0.33	2.29		Convergence criterion (GCONV=1E-8) satisfied.									29.8						
	Total	48	100.0	41	85.4	7	14.6	2.6	1.8	4.7	6.3	4.5	9.8	37	100.0	28	75.7	9	24.3	1.8	0.7	3.2	3.7	2.4	4.6	0.0046	0.48	0.29	0.81		Convergence criterion (GCONV=1E-8) satisfied.									100.0	2.19	1	0.1387	54.38	-2.78	0.0055

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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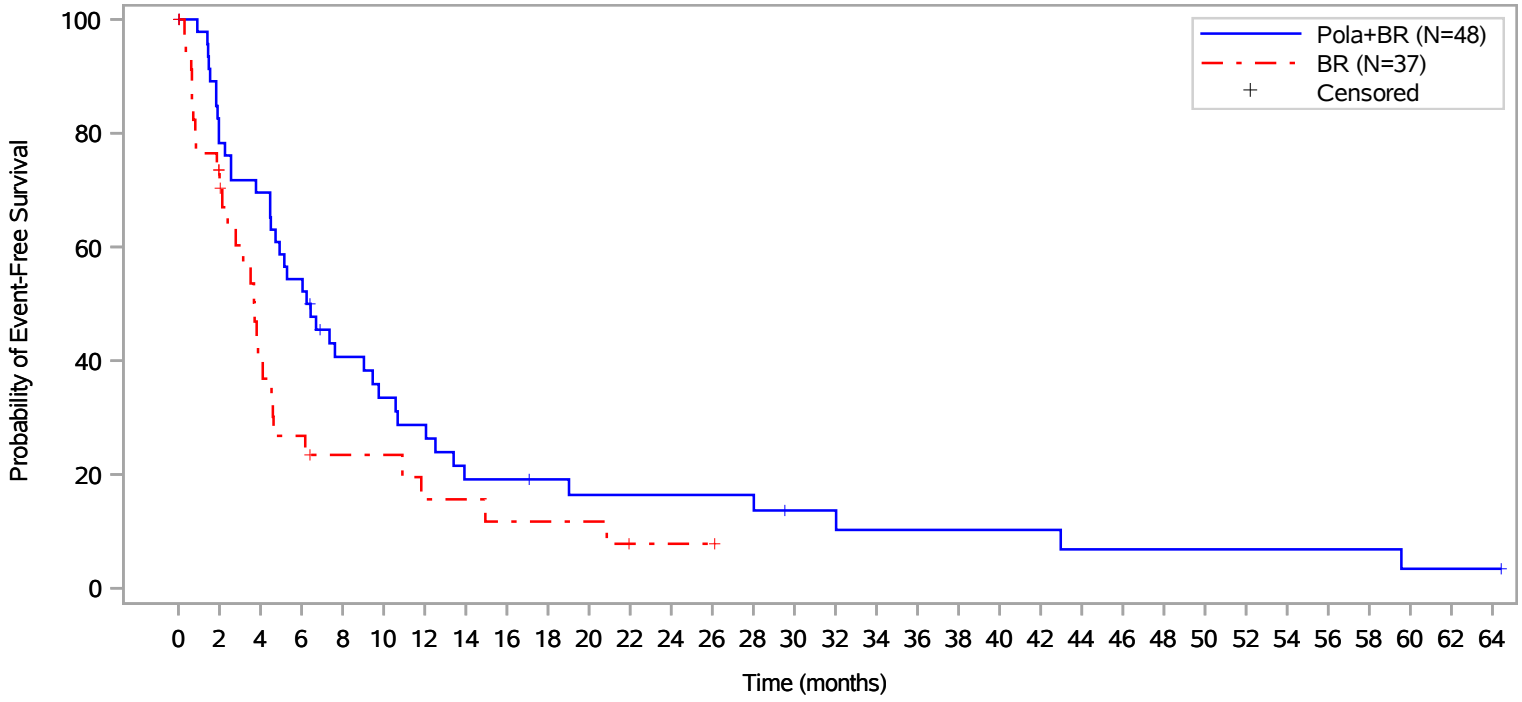
14DEC2022 22:52

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
STUDIES: GO29365, YO41543



Patients at risk																																	
Pola+BR (N=48)	48	36	32	25	17	14	12	8	8	7	6	6	6	6	6	4	4	3	3	3	3	3	2	2	2	2	2	2	2	1	1	1
BR (N=37)	37	23	12	8	6	6	4	4	3	3	3	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																	
Pola+BR (N=48)	0	2	2	2	4	4	4	4	4	5	5	5	5	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
BR (N=37)	0	5	6	6	7	7	7	7	7	7	7	8	8	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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28NOV2022 14:32

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Arms C,D (Study 365)+Polarose
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=48)												BR (N=37)										Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		48	100.0	41	85.4	7	14.6	2.6	1.8	4.7	6.3	4.5	9.8	37	100.0	28	75.7	9	24.3	1.9	0.7	3.2	3.7	2.4	4.6	0.0492	0.60	0.36	0.99	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	35	72.9	29	82.9	6	17.1	3.8	1.9	5.2	6.2	4.7	9.0	24	64.9	20	83.3	4	16.7	1.4	0.7	2.8	3.2	2.0	4.5	0.0245	0.49	0.27	0.90	Convergence criterion (GCONV=1E-8) satisfied.	0.3790
	Female	13	27.1	12	92.3	1	7.7	2.0	1.4	9.5	9.5	2.0	12.5	13	35.1	8	61.5	5	38.5	3.7	0.4	6.2	4.1	3.7	14.9	0.6539	0.80	0.31	2.04	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	30	62.5	25	83.3	5	16.7	2.3	1.8	5.3	6.4	2.6	9.8	21	56.8	15	71.4	6	28.6	2.1	0.7	3.5	3.5	2.4	4.1	0.0923	0.52	0.26	1.03	Convergence criterion (GCONV=1E-8) satisfied.	0.8118
	>= 65	18	37.5	16	88.9	2	11.1	4.5	1.4	6.0	6.0	4.5	13.9	16	43.2	13	81.3	3	18.8	0.9	0.6	3.7	3.7	1.9	10.9	0.2058	0.60	0.27	1.30	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	30	62.5	26	86.7	4	13.3	2.1	1.5	4.5	4.8	3.8	9.5	25	67.6	21	84.0	4	16.0	0.9	0.6	2.8	3.2	1.9	3.9	0.0332	0.52	0.29	0.95	Convergence criterion (GCONV=1E-8) satisfied.	0.4300
	<3	18	37.5	15	83.3	3	16.7	5.2	1.9	7.6	7.6	5.3	28.0	12	32.4	7	58.3	5	41.7	2.0	0.8	4.6	4.6	2.0	NE	0.5779	0.76	0.29	1.95	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	18.8	8	88.9	1	11.1	6.2	2.8	9.0	7.4	6.2	9.5	14	37.8	11	78.6	3	21.4	0.8	0.6	3.8	3.8	0.8	4.6	0.1533	0.50	0.19	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.4975
	Non-Europe	39	81.3	33	84.6	6	15.4	2.0	1.8	4.5	5.3	3.8	10.6	23	62.2	17	73.9	6	26.1	2.9	0.7	3.2	3.2	2.1	4.6	0.1793	0.66	0.36	1.21	Convergence criterion (GCONV=1E-8) satisfied.	
Duration of response to prior therapy	<=12 Months	46	95.8	40	87.0	6	13.0	2.4	1.8	4.7	6.1	4.5	9.0	32	86.5	25	78.1	7	21.9	0.9	0.7	2.8	3.5	2.0	4.1	0.0053	0.48	0.29	0.81	Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	2	4.2	1	50.0	1	50.0	13.9	13.9	NE	NE	13.9	NE	5	13.5	3	60.0	2	40.0	4.6	3.2	NE	10.9	3.2	NE	0.5877	0.54	0.05	5.29	Convergence criterion (GCONV=1E-8) satisfied.	
Refractory to last prior anti-lymphoma therapy**	Yes	46	95.8	39	84.8	7	15.2	2.4	1.8	4.7	6.1	4.5	9.0	32	86.5	26	81.3	6	18.8	0.9	0.7	2.8	3.2	2.0	3.9	0.0038	0.47	0.28	0.79	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	2	4.2	2	100.0	0	-	19.0	19.0	NE	39.3	19.0	NE	5	13.5	2	40.0	3	60.0	7.8	4.6	NE	NE	4.6	NE	0.7822	0.71	0.06	8.02	Convergence criterion (GCONV=1E-8) satisfied.	
Prior Bone Marrow Transplant	Yes	10	20.8	8	80.0	2	20.0	4.5	2.0	13.4	11.4	4.5	NE	7	18.9	3	42.9	4	57.1	3.8	3.2	NE	NE	3.8	NE	0.8269	1.01	0.26	3.94	Convergence criterion (GCONV=1E-8) satisfied.	0.2065
	No	38	79.2	33	86.8	5	13.2	2.3	1.5	4.7	5.7	4.5	9.0	30	81.1	25	83.3	5	16.7	0.8	0.7	2.4	3.5	1.9	4.5	0.0138	0.51	0.29	0.87	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* Indicates convergence problem, Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Study was included as a covariate in the Cox regression models.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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20JAN2023 18:56

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	47	100.0	0	-	36	100.0	35	97.2	1	2.8	0.0245	0.55	0.33	0.91		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	34	100.0	0	-	24	66.7	23	95.8	1	4.2	0.3957	0.77	0.42	1.41		Convergence criterion (GCONV=1E-8) satisfied.	0.0434
	Female	13	27.7	13	100.0	0	-	12	33.3	12	100.0	0	-	0.0009	0.14	0.04	0.49		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	29	100.0	0	-	20	55.6	19	95.0	1	5.0	0.4905	0.72	0.37	1.39		Convergence criterion (GCONV=1E-8) satisfied.	0.0494
	>= 65	18	38.3	18	100.0	0	-	16	44.4	16	100.0	0	-	0.0123	0.32	0.12	0.80		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	29	100.0	0	-	24	66.7	24	100.0	0	-	0.0137	0.41	0.20	0.83		Convergence criterion (GCONV=1E-8) satisfied.	0.2761
	<3	18	38.3	18	100.0	0	-	12	33.3	11	91.7	1	8.3	0.6069	0.81	0.36	1.83		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	9	100.0	0	-	13	36.1	12	92.3	1	7.7	0.1281	0.45	0.15	1.28		Convergence criterion (GCONV=1E-8) satisfied.	0.6550
	Non-Europe	38	80.9	38	100.0	0	-	23	63.9	23	100.0	0	-	0.0796	0.58	0.32	1.06		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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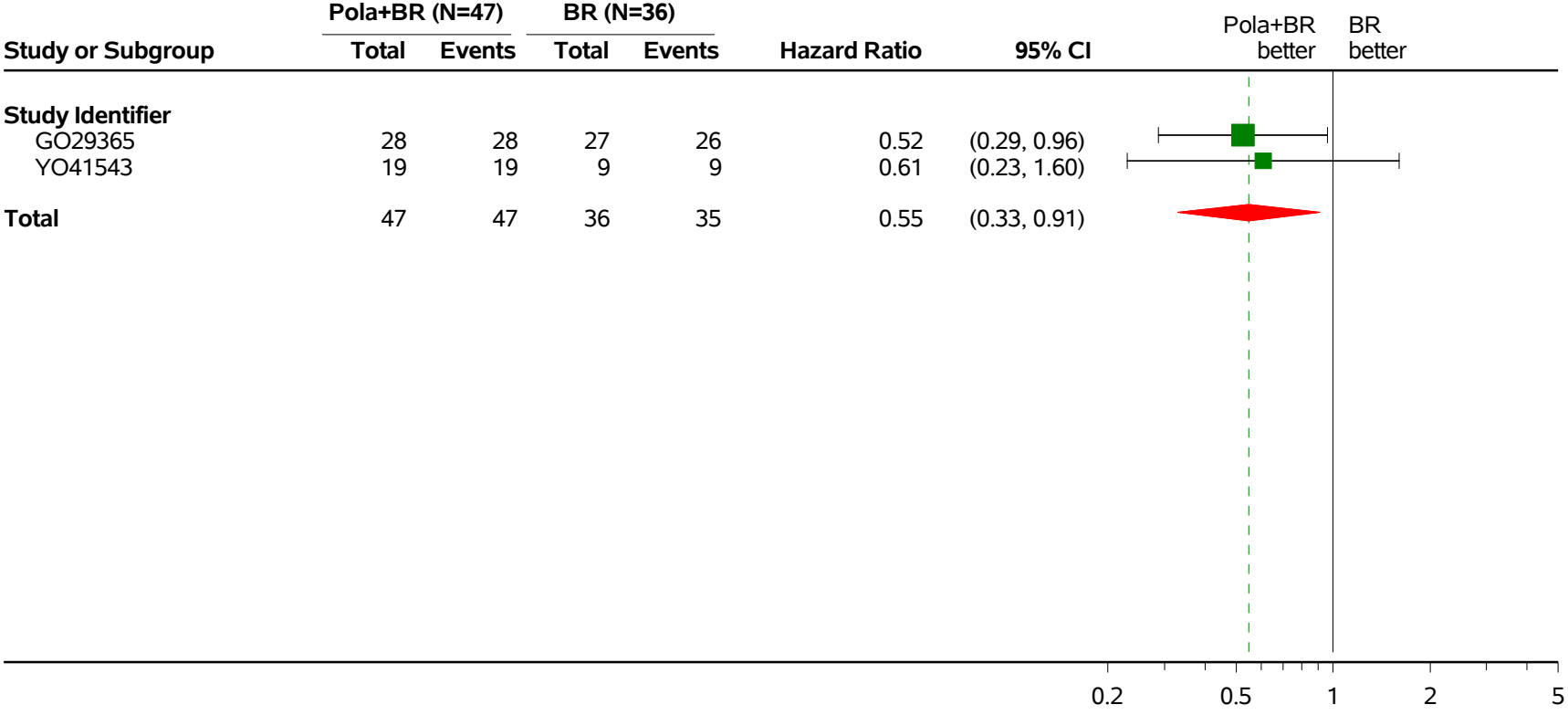
25JAN2023 9:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	28	27	26	0.52	(0.29, 0.96)
YO41543	19	19	9	9	0.61	(0.23, 1.60)
Total	47	47	36	35	0.55	(0.33, 0.91)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	28	100.0	0	-	27	75.0	26	96.3	1	3.7	0.0353	0.52	0.29	0.96			Convergence criterion (GCONV=1E-8) satisfied.	71.9							
	YO41543	19	40.4	19	100.0	0	-	9	25.0	9	100.0	0	-	0.3104	0.61	0.23	1.60			Convergence criterion (GCONV=1E-8) satisfied.	28.1							
	Total	47	100.0	47	100.0	0	-	36	100.0	35	97.2	1	2.8	0.0245	0.55	0.33	0.91			Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.06	1	0.8039	0.00		-2.32	0.0204

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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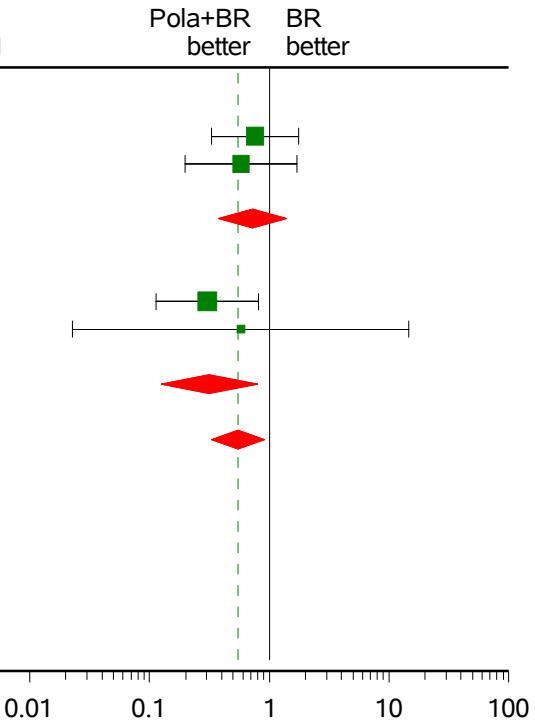
16DEC2022 9:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics by Age

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
< 65						
GO29365	13	13	13	12	0.76	(0.33, 1.76)
YO41543	16	16	7	7	0.58	(0.20, 1.70)
Subtotal	29	29	20	19	0.72	(0.37, 1.39)
>= 65						
GO29365	15	15	14	14	0.30	(0.11, 0.81)
YO41543	3	3	2	2	0.58	(0.02, 14.74)
Subtotal	18	18	16	16	0.32	(0.12, 0.80)
Total	47	47	36	35	0.55	(0.33, 0.91)



* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Subtotal and Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics by Age

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR															
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect		Test for subgroup differences			
Age (years)	Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value	Chi²	Df	P-value	I² (%)
< 65	Study Identifier	GO29365	13	27.7	13	100.0	0	-	13	36.1	12	92.3	1	7.7	0.5231	0.76	0.33	1.76		Convergence criterion (GCONV=1E-8) satisfied.	41.6										
		YO41543	16	34.0	16	100.0	0	-	7	19.4	7	100.0	0	-	0.3183	0.58	0.20	1.70		Convergence criterion (GCONV=1E-8) satisfied.	25.5										
		Subtotal	29	61.7	29	100.0	0	-	20	55.6	19	95.0	1	5.0	0.4905	0.72	0.37	1.39		Convergence criterion (GCONV=1E-8) satisfied.	67.1	0.17	1	0.6809	0.00	-0.98	0.3286				
>= 65	Study Identifier	GO29365	15	31.9	15	100.0	0	-	14	38.9	14	100.0	0	-	0.0143	0.30	0.11	0.81		Convergence criterion (GCONV=1E-8) satisfied.	30.1										
		YO41543	3	6.4	3	100.0	0	-	2	5.6	2	100.0	0	-	0.7389	0.58	0.02	14.74		Convergence criterion (GCONV=1E-8) satisfied.	2.8										
		Subtotal	18	38.3	18	100.0	0	-	16	44.4	16	100.0	0	-	0.0123	0.32	0.12	0.80		Convergence criterion (GCONV=1E-8) satisfied.	32.9	0.14	1	0.7064	0.00	-2.44	0.0147				
Total			47	100.0	47	100.0	0	-	36	100.0	35	97.2	1	2.8	0.0245	0.55	0.33	0.91		Convergence criterion (GCONV=1E-8) satisfied.	100.0	2.01	3	0.5699	0.00	-2.32	0.0204	2.02	1	0.1548	50.60

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Subtotal and Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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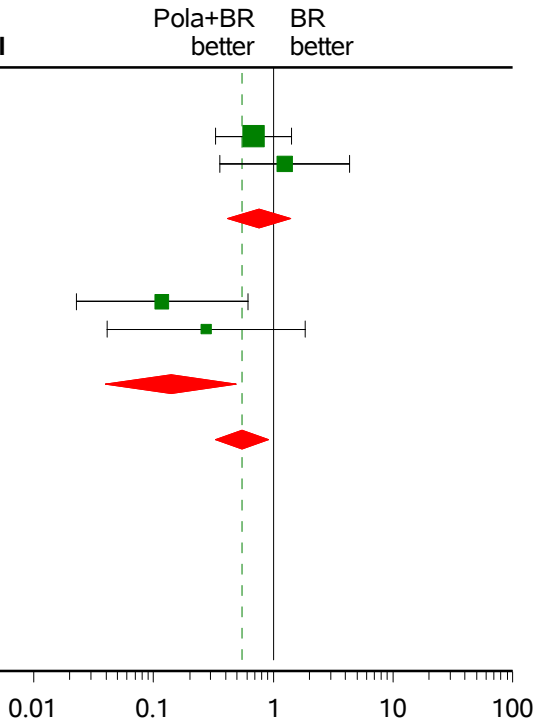
16DEC2022 17:32

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics by Sex

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Male						
GO29365	20	20	18	17	0.68	(0.33, 1.41)
YO41543	14	14	6	6	1.24	(0.36, 4.31)
Subtotal	34	34	24	23	0.77	(0.42, 1.41)
Female						
GO29365	8	8	9	9	0.12	(0.02, 0.61)
YO41543	5	5	3	3	0.27	(0.04, 1.84)
Subtotal	13	13	12	12	0.14	(0.04, 0.49)
Total	47	47	36	35	0.55	(0.33, 0.91)



* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Subtotal and Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics by Sex

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR																	
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect		Test for subgroup differences				
Sex	Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value	Chi²	Df	P-value	I² (%)	
Male	Study Identifier	GO29365	20	42.6	20	100.0	0	-	18	50.0	17	94.4	1	5.6	0.3020	0.68	0.33	1.41		Convergence criterion (GCONV=1E-8) satisfied.	59.7											
		YO41543	14	29.8	14	100.0	0	-	6	16.7	6	100.0	0	-	0.7362	1.24	0.36	4.31		Convergence criterion (GCONV=1E-8) satisfied.	20.1											
		Subtotal	34	72.3	34	100.0	0	-	24	66.7	23	95.8	1	4.2	0.3957	0.77	0.42	1.41		Convergence criterion (GCONV=1E-8) satisfied.	79.9	0.66	1	0.4149	0.00	-0.86	0.3893					
Female	Study Identifier	GO29365	8	17.0	8	100.0	0	-	9	25.0	9	100.0	0	-	0.0042	0.12	0.02	0.61		Convergence criterion (GCONV=1E-8) satisfied.	11.5											
		YO41543	5	10.6	5	100.0	0	-	3	8.3	3	100.0	0	-	0.1609	0.27	0.04	1.84		Convergence criterion (GCONV=1E-8) satisfied.	8.6											
		Subtotal	13	27.7	13	100.0	0	-	12	33.3	12	100.0	0	-	0.0009	0.14	0.04	0.49		Convergence criterion (GCONV=1E-8) satisfied.	20.1	0.53	1	0.4687	0.00	-3.07	0.0022					
Total			47	100.0	47	100.0	0	-	36	100.0	35	97.2	1	2.8	0.0245	0.55	0.33	0.91		Convergence criterion (GCONV=1E-8) satisfied.	100.0	5.86	3	0.1185	48.82	-2.32	0.0204	5.70	1	0.0169	82.47	

* indicates convergence problem. Result is uninterpretable.
Study was included as a covariate in the analyses of the Subtotal and Total row.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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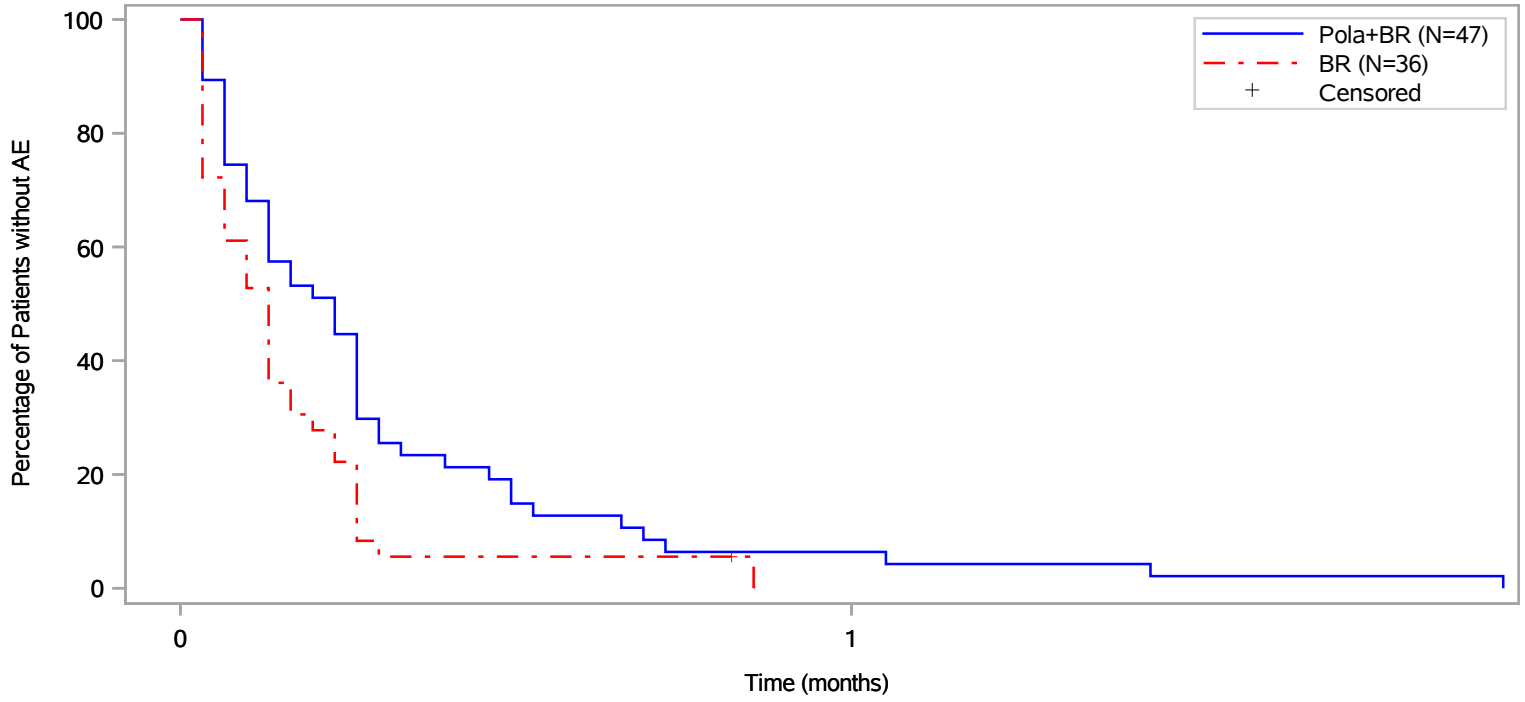
16DEC2022 15:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543



Patients at risk		
Pola+BR (N=47)	47	3
BR (N=36)	36	NE
Patients censored		
Pola+BR (N=47)	0	0
BR (N=36)	0	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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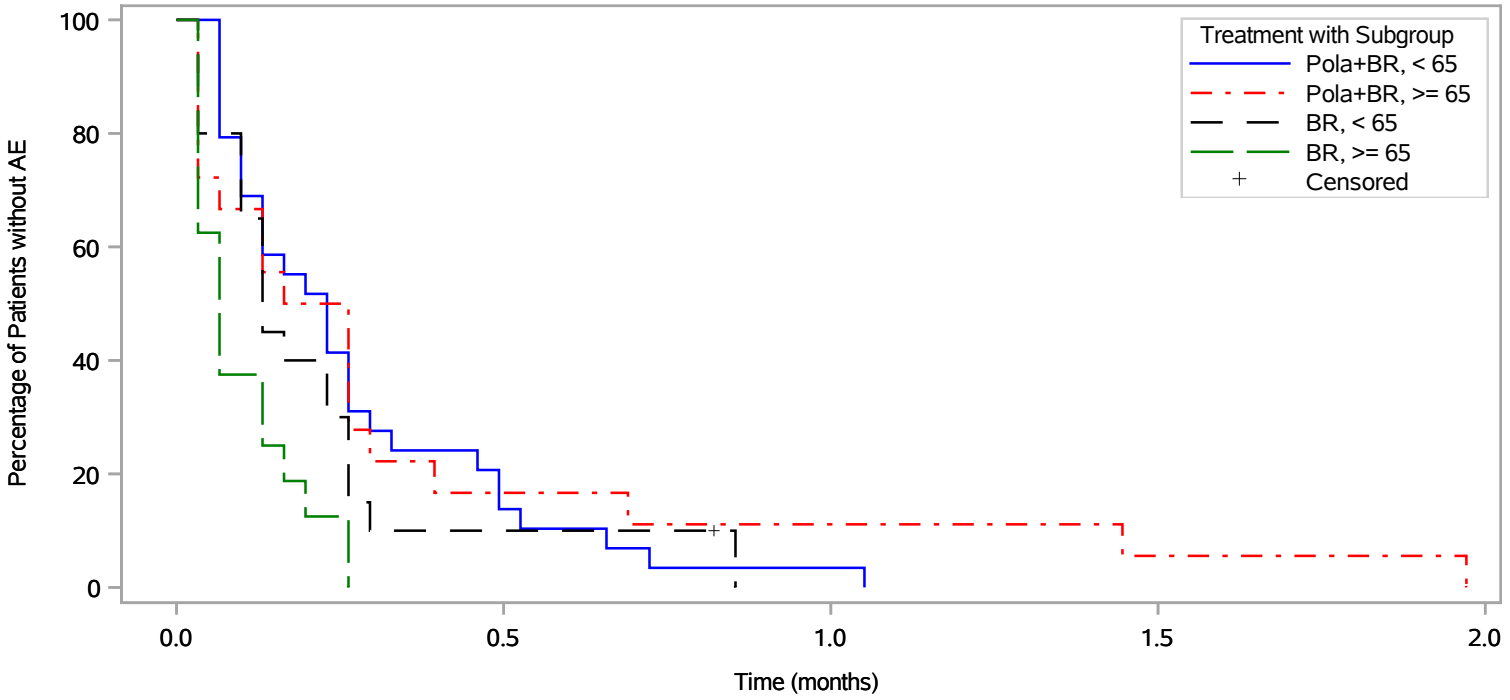
03DEC2022 19:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

Age (years)



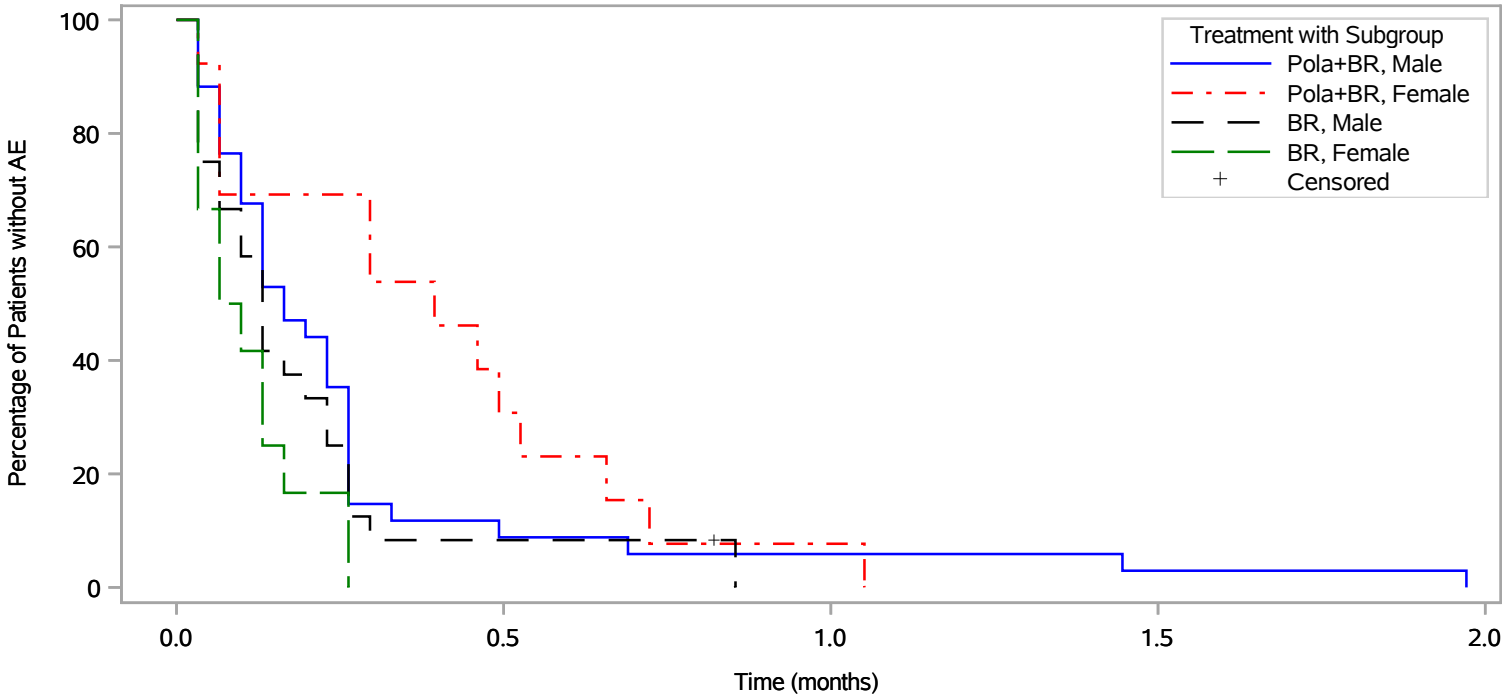
Patients at risk		
Pola+BR, < 65	29	1
Pola+BR, >= 65	18	2
BR, < 65	20	NE
BR, >= 65	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_sg1_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
17JAN2023 14:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

Sex



Patients at risk		
Pola+BR, Male	34	2
Pola+BR, Female	13	1
BR, Male	24	NE
BR, Female	12	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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17JAN2023 14:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

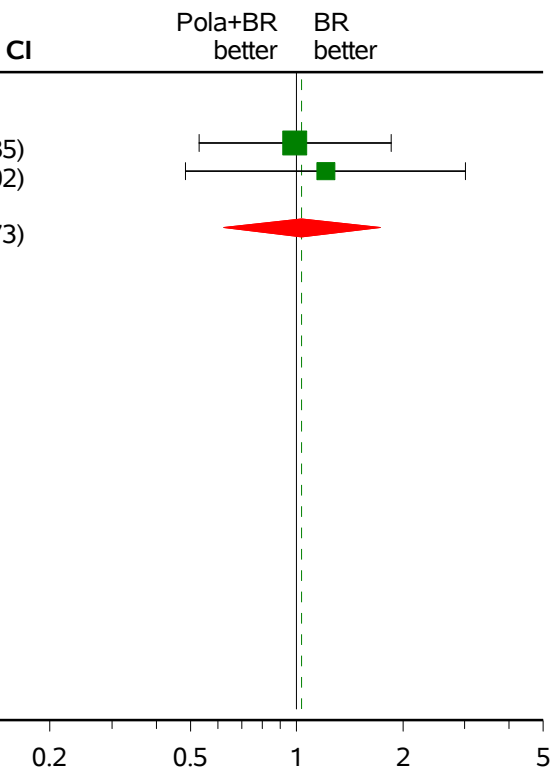
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	40	85.1	7	14.9	36	100.0	27	75.0	9	25.0	0.7902	1.04	0.62	1.73		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	29	85.3	5	14.7	24	66.7	19	79.2	5	20.8	0.8858	1.04	0.56	1.90		Convergence criterion (GCONV=1E-8) satisfied.	0.9074
	Female	13	27.7	11	84.6	2	15.4	12	33.3	8	66.7	4	33.3	0.8244	1.08	0.40	2.86		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	24	82.8	5	17.2	20	55.6	14	70.0	6	30.0	0.2380	1.40	0.69	2.84		Convergence criterion (GCONV=1E-8) satisfied.	0.2954
	>= 65	18	38.3	16	88.9	2	11.1	16	44.4	13	81.3	3	18.8	0.2242	0.67	0.29	1.54		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	26	89.7	3	10.3	24	66.7	19	79.2	5	20.8	0.9639	0.88	0.46	1.69		Convergence criterion (GCONV=1E-8) satisfied.	0.6049
	<3	18	38.3	14	77.8	4	22.2	12	33.3	8	66.7	4	33.3	0.6407	1.24	0.51	3.01		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	7	77.8	2	22.2	13	36.1	9	69.2	4	30.8	0.5250	0.71	0.24	2.06		Convergence criterion (GCONV=1E-8) satisfied.	0.4798
	Non-Europe	38	80.9	33	86.8	5	13.2	23	63.9	18	78.3	5	21.7	0.6123	1.15	0.63	2.11		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 19:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	24	27	19	0.99	(0.53, 1.85)
YO41543	19	16	9	8	1.21	(0.49, 3.02)
Total	47	40	36	27	1.04	(0.62, 1.73)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 14:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	24	85.7	4	14.3	27	75.0	19	70.4	8	29.6	0.9713	0.99	0.53	1.85		Convergence criterion (GCONV=1E-8) satisfied.		68.0						
	YO41543	19	40.4	16	84.2	3	15.8	9	25.0	8	88.9	1	11.1	0.6823	1.21	0.49	3.02		Convergence criterion (GCONV=1E-8) satisfied.		32.0						
	Total	47	100.0	40	85.1	7	14.9	36	100.0	27	75.0	9	25.0	0.7902	1.04	0.62	1.73		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.13	1	0.7159	0.00	0.13	0.8933

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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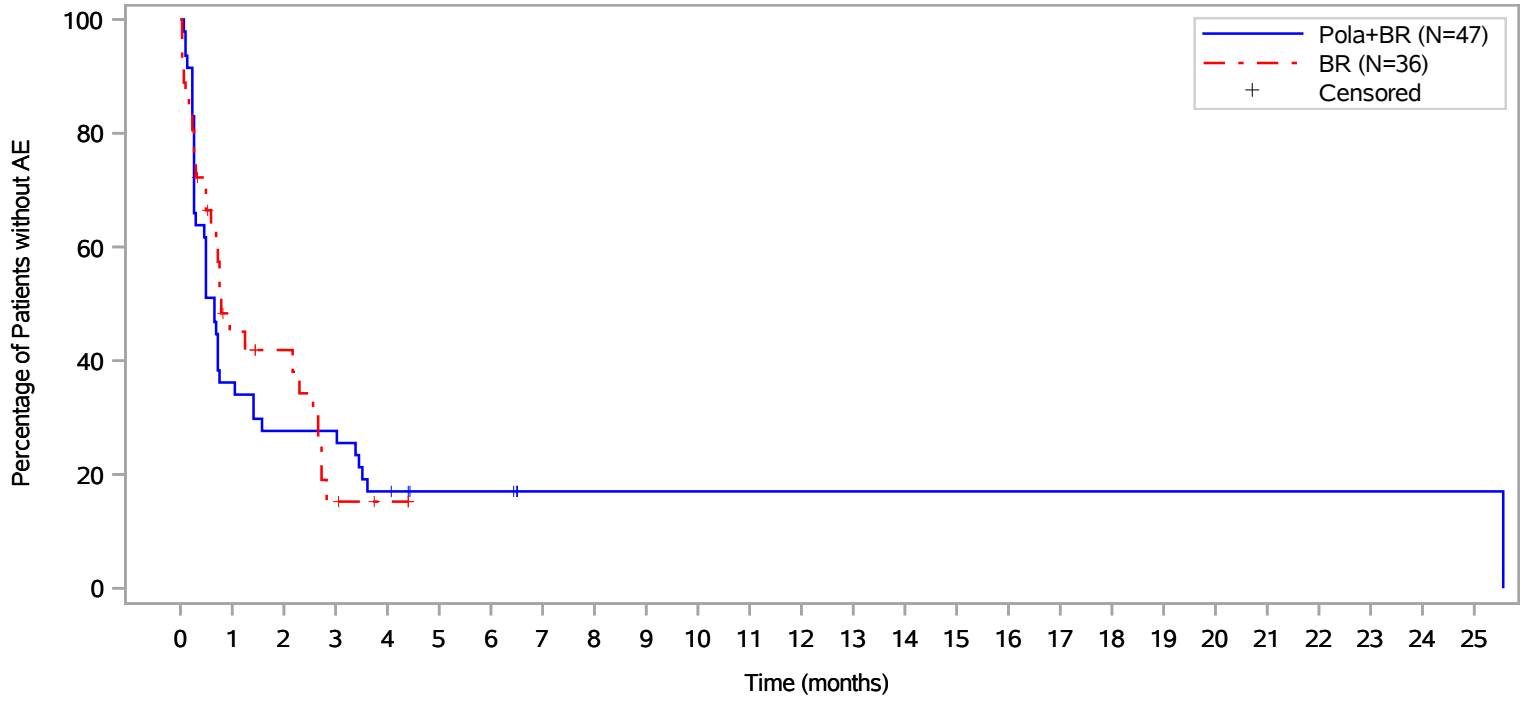
16DEC2022 9:45

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543



Patients at risk																											
Pola+BR (N=47)	47	17	13	13	8	5	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	14	11	4	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																											
Pola+BR (N=47)	0	0	0	0	0	3	3	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7	7
BR (N=36)	0	3	5	5	7	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 19:59

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

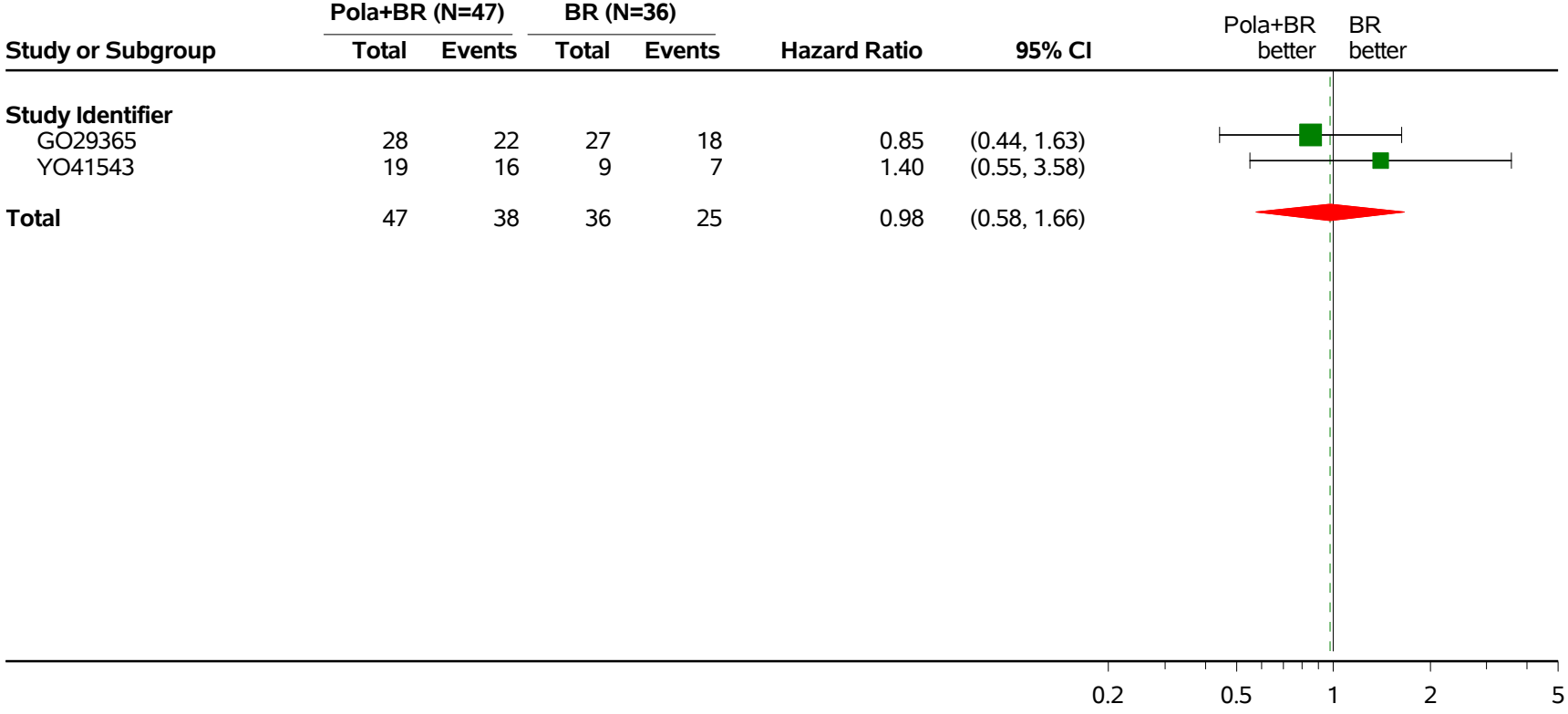
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	38	80.9	9	19.1	36	100.0	25	69.4	11	30.6	0.9984	0.98	0.58	1.66		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	28	82.4	6	17.6	24	66.7	17	70.8	7	29.2	0.9109	1.03	0.55	1.94		Convergence criterion (GCONV=1E-8) satisfied.	0.5984
	Female	13	27.7	10	76.9	3	23.1	12	33.3	8	66.7	4	33.3	0.8231	0.85	0.32	2.25		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	23	79.3	6	20.7	20	55.6	12	60.0	8	40.0	0.1359	1.63	0.78	3.40		Convergence criterion (GCONV=1E-8) satisfied.	0.0640
	>= 65	18	38.3	15	83.3	3	16.7	16	44.4	13	81.3	3	18.8	0.0436	0.43	0.18	1.00		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	24	82.8	5	17.2	24	66.7	17	70.8	7	29.2	0.7500	0.81	0.41	1.61		Convergence criterion (GCONV=1E-8) satisfied.	0.5211
	<3	18	38.3	14	77.8	4	22.2	12	33.3	8	66.7	4	33.3	0.6407	1.24	0.51	3.01		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	7	77.8	2	22.2	13	36.1	8	61.5	5	38.5	0.6660	0.79	0.26	2.35		Convergence criterion (GCONV=1E-8) satisfied.	0.7207
	Non-Europe	38	80.9	31	81.6	7	18.4	23	63.9	17	73.9	6	26.1	0.8968	1.04	0.56	1.93		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 20:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	22	27	18	0.85	(0.44, 1.63)
YO41543	19	16	9	7	1.40	(0.55, 3.58)
Total	47	38	36	25	0.98	(0.58, 1.66)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 15:32

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	22	78.6	6	21.4	27	75.0	18	66.7	9	33.3	0.6264	0.85	0.44	1.63		Convergence criterion (GCONV=1E-8) satisfied.	67.3							
	YO41543	19	40.4	16	84.2	3	15.8	9	25.0	7	77.8	2	22.2	0.4774	1.40	0.55	3.58		Convergence criterion (GCONV=1E-8) satisfied.	32.7							
	Total	47	100.0	38	80.9	9	19.1	36	100.0	25	69.4	11	30.6	0.9984	0.98	0.58	1.66		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.75	1	0.3879	0.00		-0.09	0.9320

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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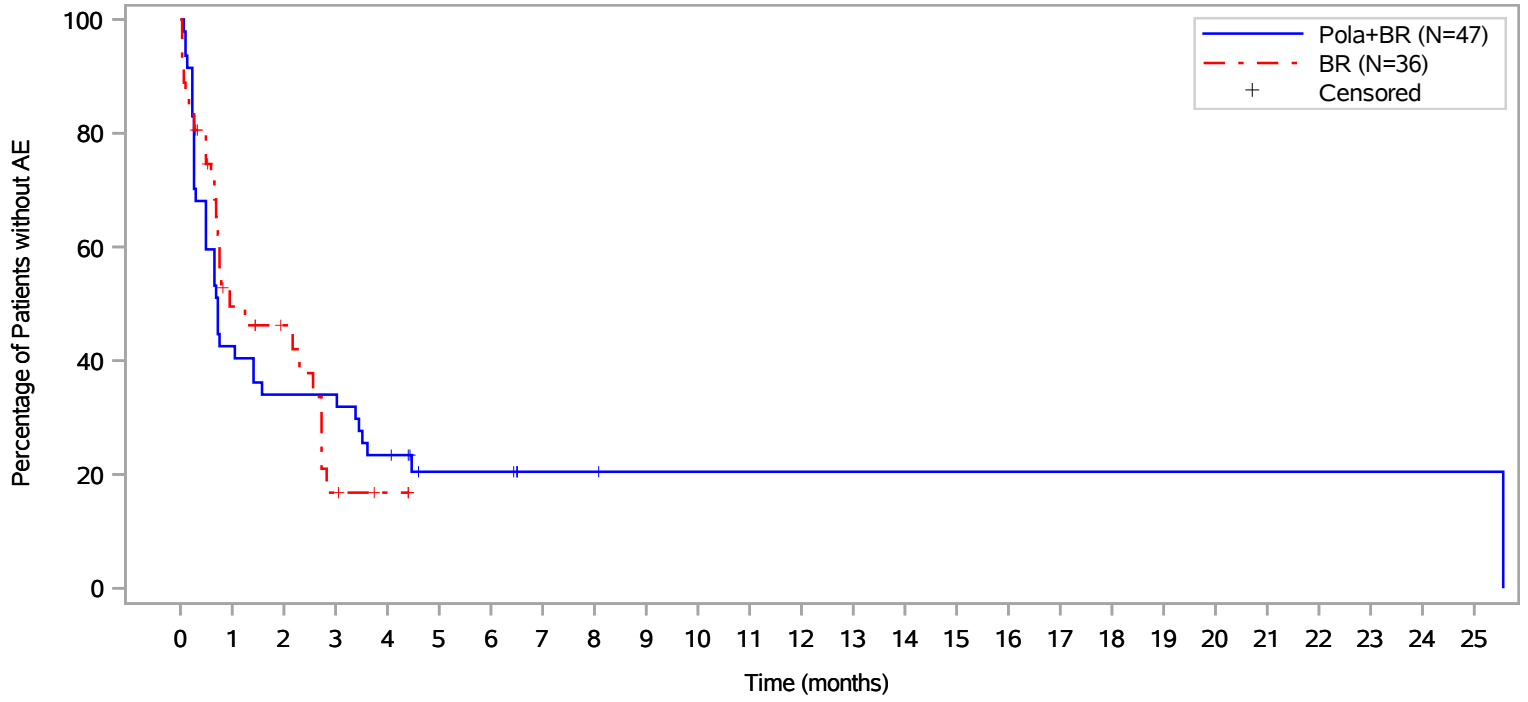
16DEC2022 10:05

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543



Patients at risk																											
Pola+BR (N=47)	47	20	16	16	11	6	6	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	15	11	4	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																											
Pola+BR (N=47)	0	0	0	0	0	4	4	8	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9
BR (N=36)	0	4	7	7	9	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:04

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	23	48.9	24	51.1	36	100.0	13	36.1	23	63.9	0.7440	1.13	0.56	2.25		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	17	50.0	17	50.0	24	66.7	10	41.7	14	58.3	0.9924	0.99	0.45	2.20		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	6	46.2	7	53.8	12	33.3	3	25.0	9	75.0	0.7037	1.40	0.33	5.92		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	13	44.8	16	55.2	20	55.6	8	40.0	12	60.0	0.7139	0.89	0.35	2.25		Convergence criterion (GCONV=1E-8) satisfied.	0.5137
	>= 65	18	38.3	10	55.6	8	44.4	16	44.4	5	31.3	11	68.8	0.5259	1.55	0.50	4.85		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	15	51.7	14	48.3	24	66.7	11	45.8	13	54.2	0.5956	0.80	0.35	1.80		Convergence criterion (GCONV=1E-8) satisfied.	0.1503
	<3	18	38.3	8	44.4	10	55.6	12	33.3	2	16.7	10	83.3	0.2419	2.47	0.51	11.93		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	2	22.2	7	77.8	13	36.1	4	30.8	9	69.2	0.8079	0.80	0.13	4.81		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	21	55.3	17	44.7	23	63.9	9	39.1	14	60.9	0.7342	1.17	0.53	2.61		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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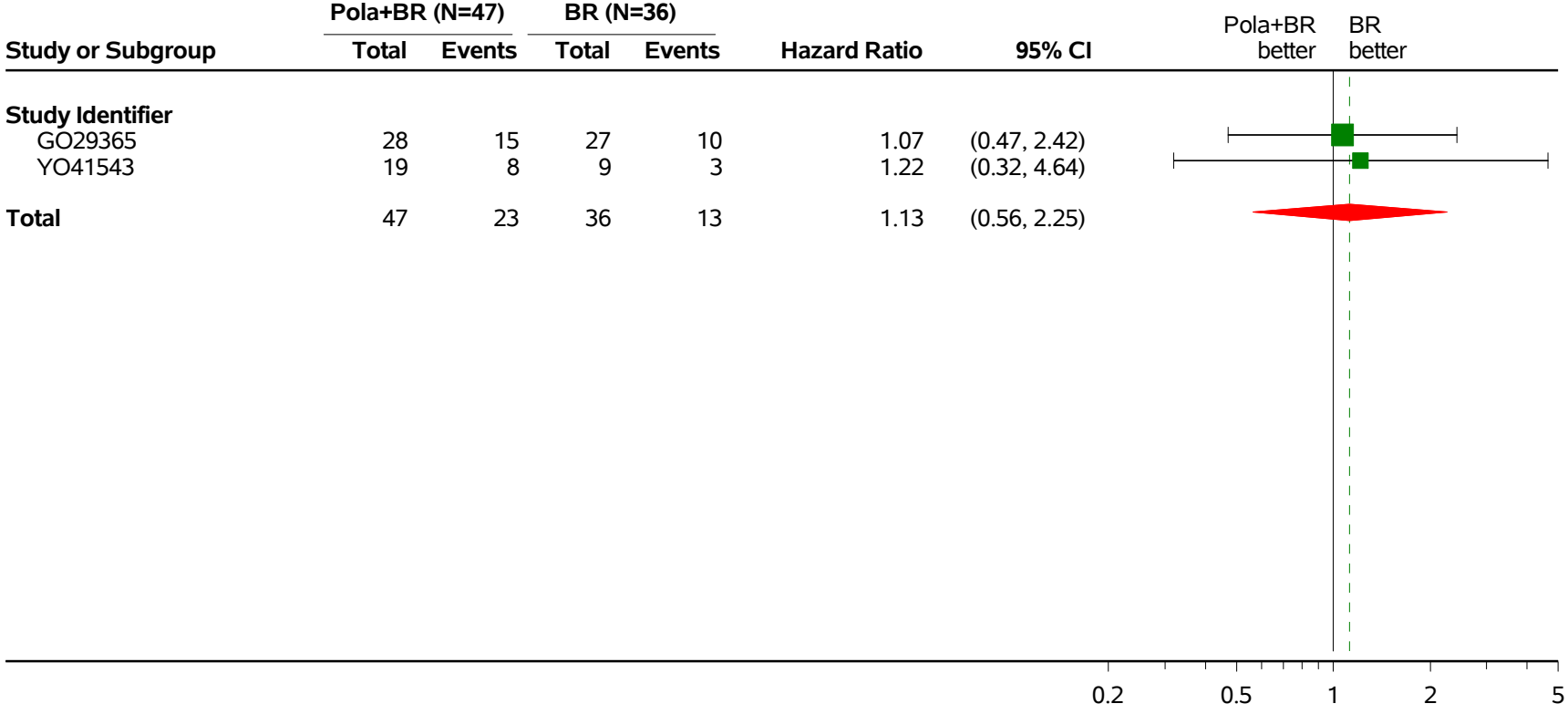
30NOV2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	15	27	10	1.07	(0.47, 2.42)
YO41543	19	8	9	3	1.22	(0.32, 4.64)
Total	47	23	36	13	1.13	(0.56, 2.25)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGR4AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 16:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	15	53.6	13	46.4	27	75.0	10	37.0	17	63.0	0.8730	1.07	0.47	2.42		Convergence criterion (GCONV=1E-8) satisfied.	72.9						
	YO41543	19	40.4	8	42.1	11	57.9	9	25.0	3	33.3	6	66.7	0.7749	1.22	0.32	4.64		Convergence criterion (GCONV=1E-8) satisfied.	27.1						
	Total	47	100.0	23	48.9	24	51.1	36	100.0	13	36.1	23	63.9	0.7440	1.13	0.56	2.25		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.03	1	0.8664	0.00	0.34	0.7375

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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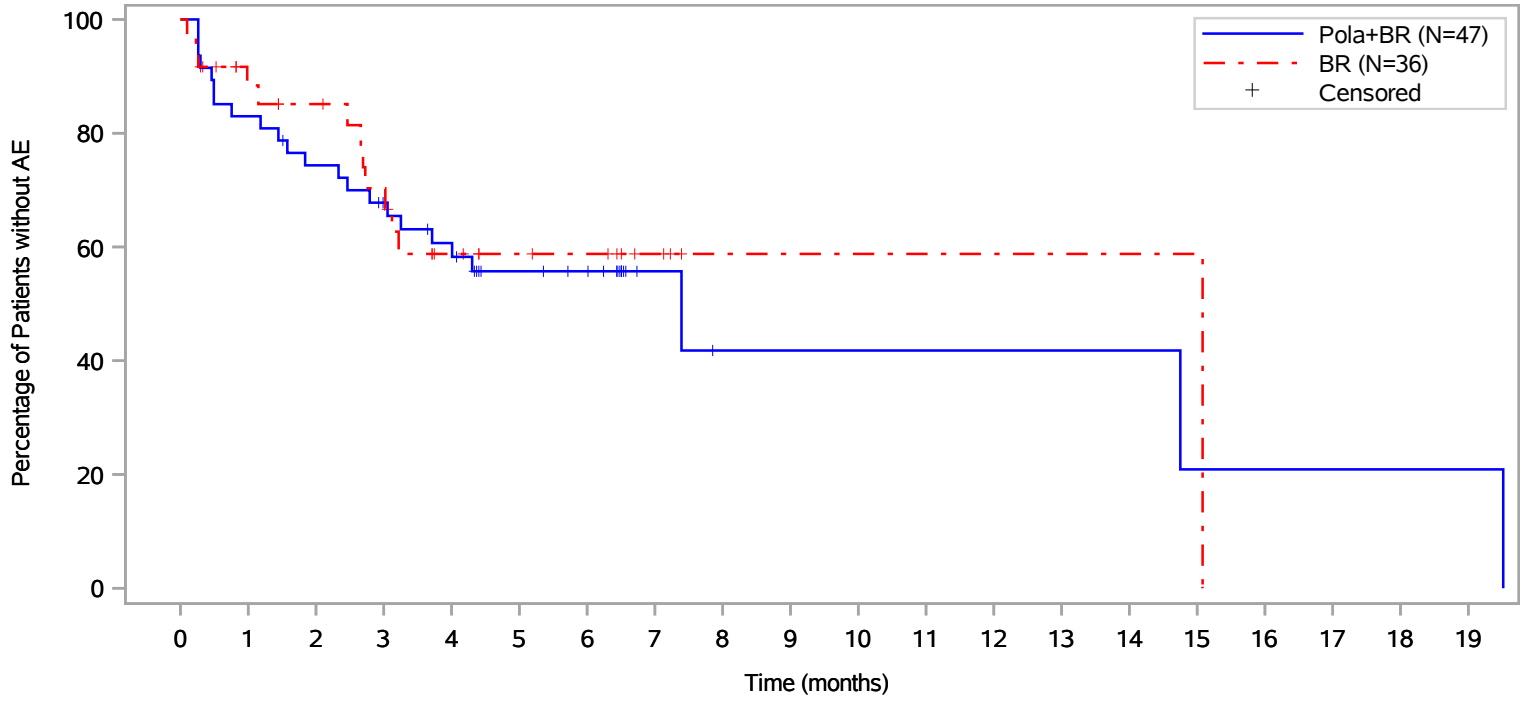
16DEC2022 10:21

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=47)	47	39	34	29	25	18	16	4	2	2	2	2	2	2	2	1	1	1	1	1
BR (N=36)	36	27	24	19	12	9	8	4	1	1	1	1	1	1	1	1	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	1	3	4	9	11	23	24	24	24	24	24	24	24	24	24	24	24	24
BR (N=36)	0	5	7	8	12	15	16	20	23	23	23	23	23	23	23	23	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

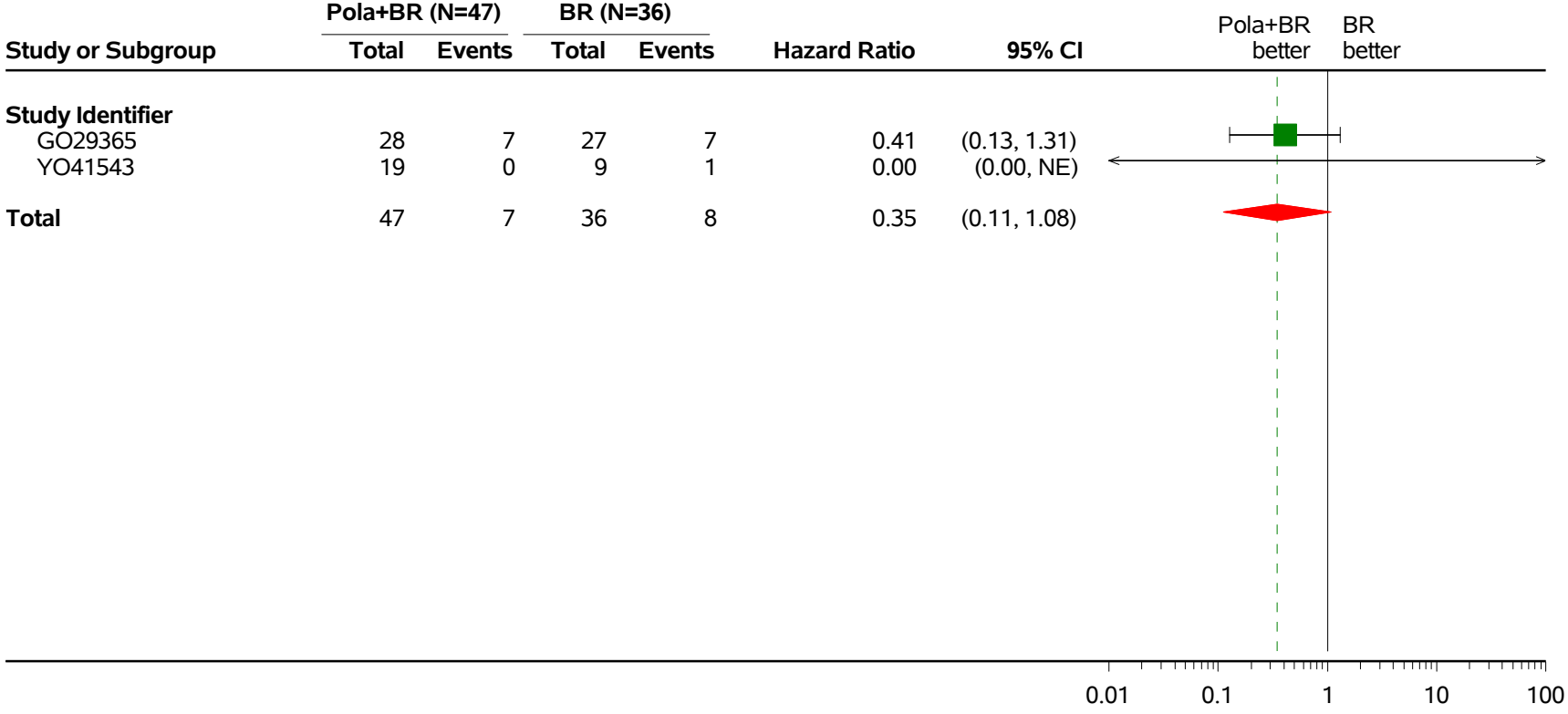
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	7	14.9	40	85.1	36	100.0	8	22.2	28	77.8	0.0438	0.35	0.11	1.08		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	6	17.6	28	82.4	24	66.7	5	20.8	19	79.2	0.0839	0.35	0.09	1.32		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	3	25.0	9	75.0	0.3415	0.37	0.03	4.07		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	3	10.3	26	89.7	20	55.6	4	20.0	16	80.0	0.0454	0.24	0.04	1.38		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	4	22.2	14	77.8	16	44.4	4	25.0	12	75.0	0.1569	0.29	0.05	1.63		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	4	13.8	25	86.2	24	66.7	6	25.0	18	75.0	0.0437	0.29	0.07	1.18		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	3	16.7	15	83.3	12	33.3	2	16.7	10	83.3	0.6144	0.58	0.08	4.24		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	2	22.2	7	77.8	13	36.1	5	38.5	8	61.5	0.0813	0.18	0.02	1.56		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	3	13.0	20	87.0	0.1322	0.27	0.04	1.69		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGR5AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 21:42

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=47) Total	Pola+BR (N=47) Events	BR (N=36) Total	BR (N=36) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	28	7	27	7	0.41	(0.13, 1.31)
YO41543	19	0	9	1	0.00	(0.00, NE)
Total	47	7	36	8	0.35	(0.11, 1.08)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	7	25.0	21	75.0	27	75.0	7	25.9	20	74.1	0.1209	0.41	0.13	1.31		Convergence criterion (GCONV=1E-8) satisfied.	100.0							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0							
	Total	47	100.0	7	14.9	40	85.1	36	100.0	8	22.2	28	77.8	0.0438	0.35	0.11	1.08		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.08	1	0.7813	0.00		-1.83	0.0666

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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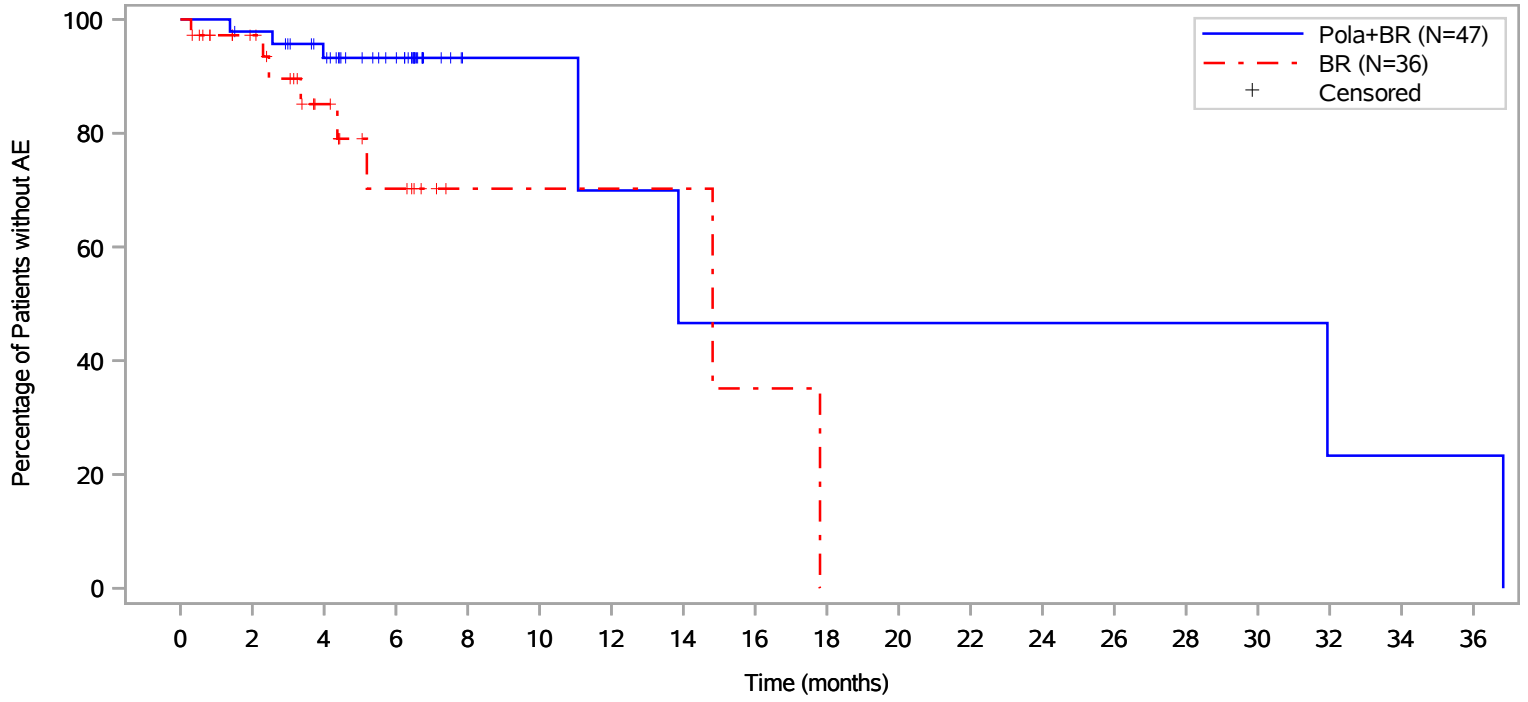
16DEC2022 10:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543



Patients at risk																																									
Pola+BR (N=47)	47	47	45	42	38	31	27	8	4	4	4	4	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1					
BR (N=36)	36	30	27	23	15	10	8	4	2	2	2	2	2	2	2	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			
Patients censored																																								
Pola+BR (N=47)	0	0	1	3	6	13	17	36	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40					
BR (N=36)	0	5	8	10	17	21	22	26	28	28	28	28	28	28	28	28	28	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE			

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						log-rank	Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored			Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	30	63.8	17	36.2	36	100.0	16	44.4	20	55.6	0.8404	1.08	0.58	2.01		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	23	67.6	11	32.4	24	66.7	11	45.8	13	54.2	0.7724	1.12	0.53	2.36		Convergence criterion (GCONV=1E-8) satisfied.	0.6761
	Female	13	27.7	7	53.8	6	46.2	12	33.3	5	41.7	7	58.3	0.8089	0.82	0.25	2.75		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	16	55.2	13	44.8	20	55.6	8	40.0	12	60.0	0.7900	1.19	0.50	2.85		Convergence criterion (GCONV=1E-8) satisfied.	0.7101
	>= 65	18	38.3	14	77.8	4	22.2	16	44.4	8	50.0	8	50.0	0.9974	0.98	0.39	2.44		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	19	65.5	10	34.5	24	66.7	11	45.8	13	54.2	0.9859	1.01	0.46	2.21		Convergence criterion (GCONV=1E-8) satisfied.	0.7131
	<3	18	38.3	11	61.1	7	38.9	12	33.3	5	41.7	7	58.3	0.8733	1.04	0.35	3.14		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	6	66.7	3	33.3	13	36.1	8	61.5	5	38.5	0.5127	0.69	0.22	2.13		Convergence criterion (GCONV=1E-8) satisfied.	0.1793
	Non-Europe	38	80.9	24	63.2	14	36.8	23	63.9	8	34.8	15	65.2	0.3909	1.42	0.63	3.23		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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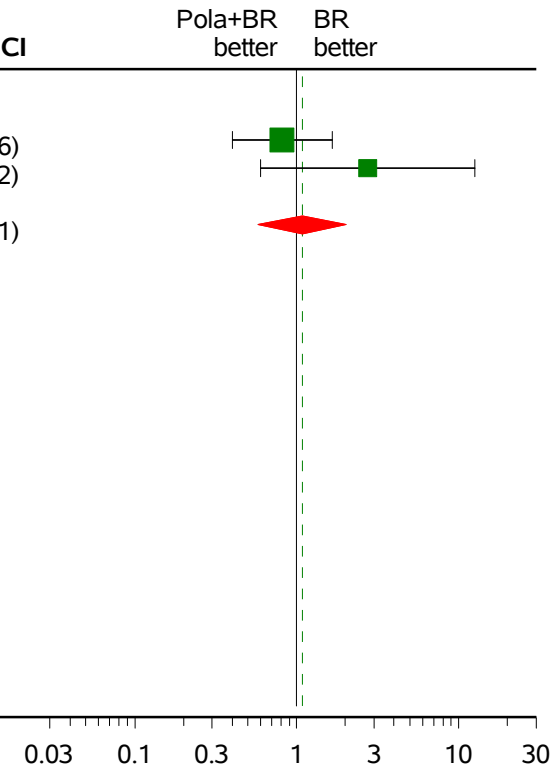
30NOV2022 22:31

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	20	27	14	0.81	(0.40, 1.66)
YO41543	19	10	9	2	2.75	(0.60, 12.62)
Total	47	30	36	16	1.08	(0.58, 2.01)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	20	71.4	8	28.6	27	75.0	14	51.9	13	48.1	0.5672	0.81	0.40	1.66		Convergence criterion (GCONV=1E-8) satisfied.	82.1						
	YO41543	19	40.4	10	52.6	9	47.4	9	25.0	2	22.2	7	77.8	0.1744	2.75	0.60	12.62		Convergence criterion (GCONV=1E-8) satisfied.	17.9						
	Total	47	100.0	30	63.8	17	36.2	36	100.0	16	44.4	20	55.6	0.8404	1.08	0.58	2.01		Convergence criterion (GCONV=1E-8) satisfied.	100.0	2.06	1	0.1509	51.54	0.24	0.8075

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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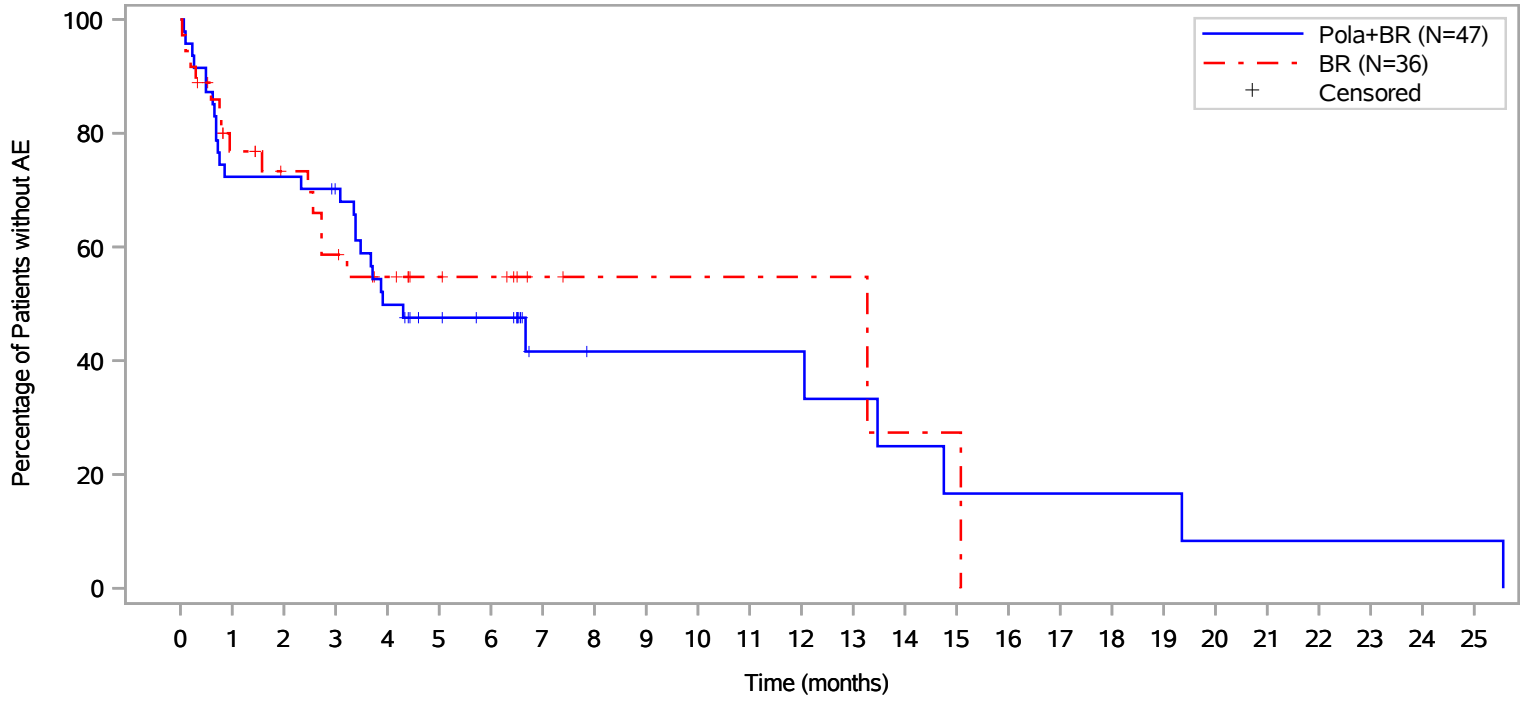
17DEC2022 7:13

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543



Patients at risk																										
Pola+BR (N=47)	47	34	34	31	22	17	15	6	5	5	5	5	5	4	3	2	2	2	2	2	1	1	1	1	1	1
BR (N=36)	36	24	20	16	12	8	7	3	2	2	2	2	2	2	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	0	2	2	6	8	16	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17	17
BR (N=36)	0	4	7	7	10	14	15	19	20	20	20	20	20	20	20	20	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:21

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	10	21.3	37	78.7	36	100.0	4	11.1	32	88.9	0.4740	1.60	0.50	5.15		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	6	17.6	28	82.4	24	66.7	4	16.7	20	83.3	0.7568	0.92	0.25	3.33		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	4	30.8	9	69.2	12	33.3	0	-	12	100.0	0.0849	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	6	20.7	23	79.3	20	55.6	3	15.0	17	85.0	0.9057	1.13	0.28	4.66		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	4	22.2	14	77.8	16	44.4	1	6.3	15	93.8	0.3257	2.92	0.31	27.23		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	8	27.6	21	72.4	24	66.7	3	12.5	21	87.5	0.4533	1.75	0.45	6.75		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	2	11.1	16	88.9	12	33.3	1	8.3	11	91.7	0.9209	1.10	0.10	12.15		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	1	11.1	8	88.9	13	36.1	2	15.4	11	84.6	0.6040	0.53	0.05	5.98		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	9	23.7	29	76.3	23	63.9	2	8.7	21	91.3	0.2902	2.33	0.50	10.82		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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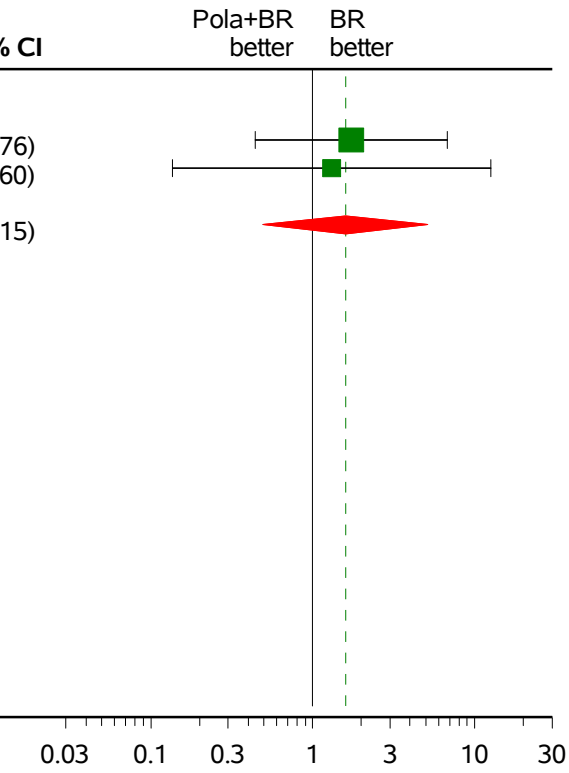
24JAN2023 17:19

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	7	27	3	1.73	(0.44, 6.76)
YO41543	19	3	9	1	1.31	(0.14, 12.60)
Total	47	10	36	4	1.60	(0.50, 5.15)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTWDAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 25OCT2023 8:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	7	25.0	21	75.0	27	75.0	3	11.1	24	88.9	0.4231	1.73	0.44	6.76		Convergence criterion (GCONV=1E-8) satisfied.	73.5						
	YO41543	19	40.4	3	15.8	16	84.2	9	25.0	1	11.1	8	88.9	0.8163	1.31	0.14	12.60		Convergence criterion (GCONV=1E-8) satisfied.	26.5						
	Total	47	100.0	10	21.3	37	78.7	36	100.0	4	11.1	32	88.9	0.4740	1.60	0.50	5.15		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.04	1	0.8341	0.00	0.78	0.4333

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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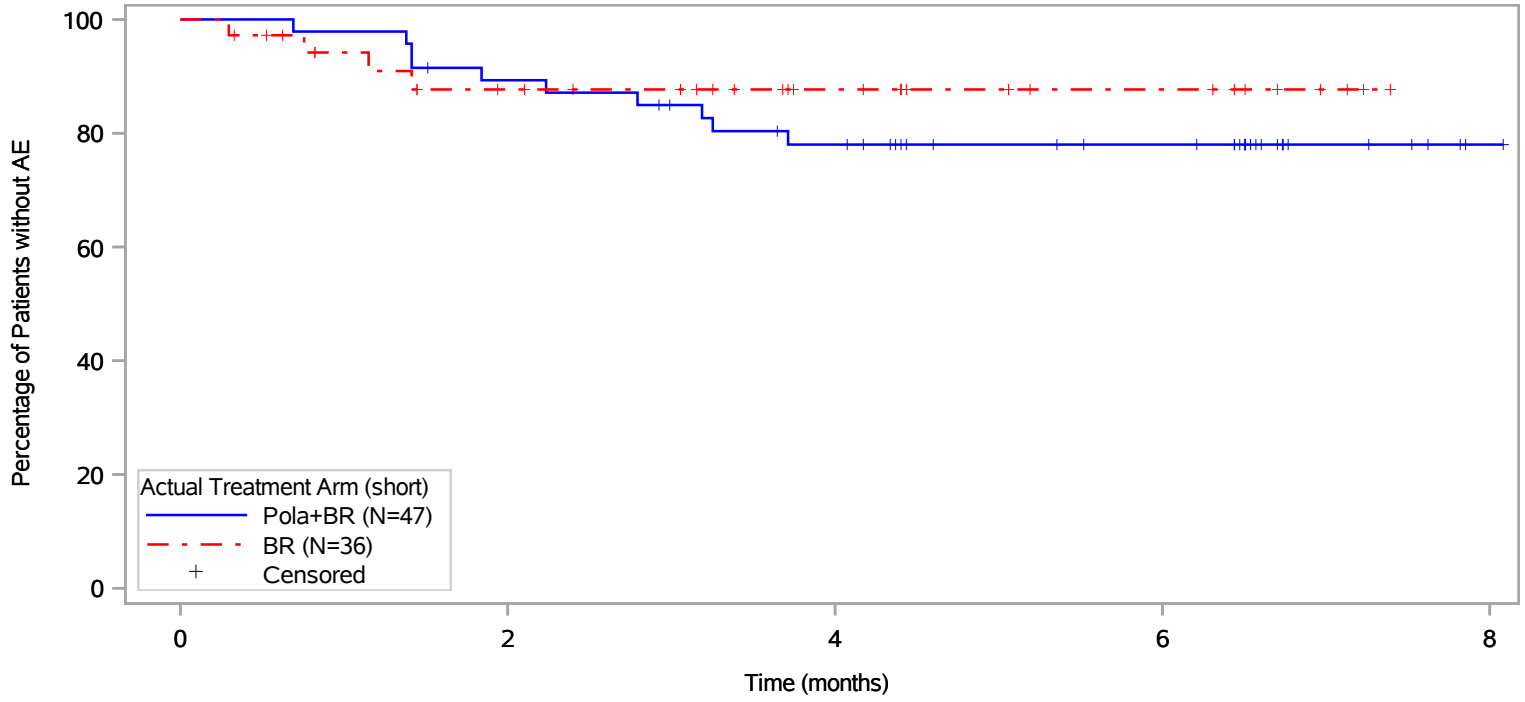
25OCT2023 8:42

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	46	41	37	33	26	24	6	1
BR (N=36)	36	29	24	22	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	4	11	13	31	36
BR (N=36)	0	5	8	10	17	22	24	29	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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24JAN2023 19:08

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			47	100.0	35	74.5	12	25.5	36	100.0	21	58.3	15	41.7	0.4958	1.23	0.71	2.14		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		47	100.0	28	59.6	19	40.4	36	100.0	9	25.0	27	75.0	0.0303	2.17	1.02	4.63		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		47	100.0	4	8.5	43	91.5	36	100.0	3	8.3	33	91.7	0.9464	1.22	0.22	6.74		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.5676	0.42	0.03	6.68		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		47	100.0	5	10.6	42	89.4	36	100.0	3	8.3	33	91.7	0.9174	1.22	0.29	5.13		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		47	100.0	4	8.5	43	91.5	36	100.0	0	-	36	100.0	0.0839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.6852	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		47	100.0	17	36.2	30	63.8	36	100.0	12	33.3	24	66.7	0.6691	1.07	0.50	2.27		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.4302	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		47	100.0	16	34.0	31	66.0	36	100.0	11	30.6	25	69.4	0.7430	1.02	0.47	2.22		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			47	100.0	5	10.6	42	89.4	36	100.0	9	25.0	27	75.0	0.0775	0.37	0.12	1.14		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		47	100.0	0	-	47	100.0	36	100.0	3	8.3	33	91.7	0.0339	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FLUTTER		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0852	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	CARDIAC FAILURE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	PALPITATIONS		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7301	0.44	0.03	7.07		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	PNEUMOPERICARDIUM		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SINUS TACHYCARDIA		47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3280	0.26	0.02	2.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYARRHYTHMIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		47	100.0	3	6.4	44	93.6	36	100.0	2	5.6	34	94.4	0.9058	1.22	0.20	7.45		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS			47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.1037	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	DEAFNESS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	TINNITUS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EYE DISORDERS			47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EYE DISORDERS	ASTHENOPIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			47	100.0	36	76.6	11	23.4	36	100.0	22	61.1	14	38.9	0.7272	1.14	0.66	1.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		47	100.0	5	10.6	42	89.4	36	100.0	3	8.3	33	91.7	0.8958	1.17	0.28	4.94		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER		47	100.0	6	12.8	41	87.2	36	100.0	1	2.8	35	97.2	0.1453	4.46	0.53	37.33		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		47	100.0	9	19.1	38	80.9	36	100.0	7	19.4	29	80.6	0.7652	0.95	0.35	2.59		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		47	100.0	17	36.2	30	63.8	36	100.0	9	25.0	27	75.0	0.7087	1.21	0.54	2.75		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DRY MOUTH		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.6618	0.59	0.03	10.28		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.4960	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DYSPEPSIA		47	100.0	2	4.3	45	95.7	36	100.0	2	5.6	34	94.4	0.6336	0.73	0.10	5.30		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DYSPHAGIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	FLATULENCE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTRITIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	HAEMATEMESIS		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2560	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ILEUS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

GASTROINTESTINAL DISORDERS	LIP DRY		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5298	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	NAUSEA		47	100.0	15	31.9	32	68.1	36	100.0	12	33.3	24	66.7	0.6893	0.85	0.39	1.83		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	STOMATITIS		47	100.0	2	4.3	45	95.7	36	100.0	3	8.3	33	91.7	0.2670	0.39	0.06	2.41		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SUBILEUS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4021	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	TOOTHACHE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7239	0.43	0.03	6.88		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		47	100.0	11	23.4	36	76.6	36	100.0	6	16.7	30	83.3	0.4720	1.29	0.47	3.53		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			47	100.0	34	72.3	13	27.7	36	100.0	20	55.6	16	44.4	0.4537	1.25	0.71	2.19		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA		47	100.0	2	4.3	45	95.7	36	100.0	3	8.3	33	91.7	0.3399	0.51	0.09	3.10		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.0783	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT		47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3887	0.35	0.03	4.05		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS		47	100.0	4	8.5	43	91.5	36	100.0	2	5.6	34	94.4	0.8369	1.31	0.23	7.32		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1999	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		47	100.0	18	38.3	29	61.7	36	100.0	13	36.1	23	63.9	0.7133	0.87	0.42	1.80		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4302	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5695	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0712	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		47	100.0	4	8.5	43	91.5	36	100.0	1	2.8	35	97.2	0.3431	2.69	0.29	24.66		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		47	100.0	16	34.0	31	66.0	36	100.0	7	19.4	29	80.6	0.2947	1.62	0.66	3.96		Convergence criterion (GCONV=1E-8) satisfied.	NE
HEPATOBILIARY DISORDERS			47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS			47	100.0	3	6.4	44	93.6	36	100.0	0	-	36	100.0	0.2274	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5218	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			47	100.0	21	44.7	26	55.3	36	100.0	14	38.9	22	61.1	0.4501	0.79	0.39	1.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	BRONCHITIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CELLULITIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4849	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7120	0.71	0.04	11.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0789	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ERYSIPELAS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.5827	0.44	0.03	7.57		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		47	100.0	3	6.4	44	93.6	36	100.0	0	-	36	100.0	0.3969	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFLUENZA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2327	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4849	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2953	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		47	100.0	7	14.9	40	85.1	36	100.0	4	11.1	32	88.9	0.8499	1.11	0.32	3.82		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PYURIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.5628	0.48	0.03	7.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1623	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SINUSITIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.6056	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION		47	100.0	2	4.3	45	95.7	36	100.0	2	5.6	34	94.4	0.6319	0.65	0.09	4.75		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.6230	0.47	0.03	8.04		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UROSEPSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			47	100.0	4	8.5	43	91.5	36	100.0	6	16.7	30	83.3	0.0976	0.37	0.10	1.33		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1418	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0748	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4353	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1418	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1418	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5820	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			47	100.0	30	63.8	17	36.2	36	100.0	17	47.2	19	52.8	0.7887	0.92	0.49	1.75		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED		47	100.0	7	14.9	40	85.1	36	100.0	0	-	36	100.0	0.0341	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	AMYLASE INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4193	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ANION GAP DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4550	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED		47	100.0	7	14.9	40	85.1	36	100.0	0	-	36	100.0	0.0248	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.8401	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALBUMIN DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.8232	0.66	0.04	10.87		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.3336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2988	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD CALCIUM DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD CREATININE INCREASED		47	100.0	6	12.8	41	87.2	36	100.0	3	8.3	33	91.7	0.6768	1.20	0.30	4.84		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD GLUCOSE DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED		47	100.0	4	8.5	43	91.5	36	100.0	0	-	36	100.0	0.0988	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INVESTIGATIONS	BLOOD POTASSIUM DECREASED		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.7121	1.26	0.11	14.33		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PRESSURE INCREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD SODIUM DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD UREA INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD URIC ACID INCREASED		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2233	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD URINE PRESENT		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED		47	100.0	3	6.4	44	93.6	36	100.0	1	2.8	35	97.2	0.7626	1.32	0.14	12.87		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4302	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYSTATIN C INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7395	0.43	0.03	6.88		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	FIBRIN D DIMER INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED		47	100.0	3	6.4	44	93.6	36	100.0	0	-	36	100.0	0.1404	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	HAEMOGLOBIN DECREASED		47	100.0	2	4.3	45	95.7	36	100.0	2	5.6	34	94.4	0.7098	0.64	0.09	4.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	HEART RATE INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4353	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LIPASE INCREASED		47	100.0	3	6.4	44	93.6	36	100.0	0	-	36	100.0	0.1970	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		47	100.0	9	19.1	38	80.9	36	100.0	9	25.0	27	75.0	0.4663	0.34	0.12	1.00		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.8560	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MONOCYTE COUNT DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2049	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.8241	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MORAXELLA TEST POSITIVE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		47	100.0	14	29.8	33	70.2	36	100.0	6	16.7	30	83.3	0.3947	1.39	0.53	3.66		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.8560	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NITRITE URINE PRESENT		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	OCCULT BLOOD POSITIVE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2465	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		47	100.0	16	34.0	31	66.0	36	100.0	5	13.9	31	86.1	0.2303	1.64	0.60	4.53		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PROCALCITONIN INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PROTEIN TOTAL DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4550	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PROTEIN URINE PRESENT		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.3791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	TRANSAMINASES INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	URINE OUTPUT DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2327	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	VITAMIN D DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4472	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		47	100.0	8	17.0	39	83.0	36	100.0	3	8.3	33	91.7	0.5819	1.41	0.37	5.35		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		47	100.0	15	31.9	32	68.1	36	100.0	7	19.4	29	80.6	0.5317	1.11	0.45	2.77		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			47	100.0	26	55.3	21	44.7	36	100.0	17	47.2	19	52.8	0.8540	1.03	0.55	1.93		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		47	100.0	11	23.4	36	76.6	36	100.0	8	22.2	28	77.8	0.8524	0.90	0.36	2.26		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4849	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4353	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0885	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2134	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA		47	100.0	4	8.5	43	91.5	36	100.0	0	-	36	100.0	0.1023	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA		47	100.0	4	8.5	43	91.5	36	100.0	1	2.8	35	97.2	0.3125	2.23	0.24	20.67		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		47	100.0	6	12.8	41	87.2	36	100.0	2	5.6	34	94.4	0.4828	1.68	0.33	8.44		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA		47	100.0	4	8.5	43	91.5	36	100.0	1	2.8	35	97.2	0.3510	2.36	0.26	21.54		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		47	100.0	11	23.4	36	76.6	36	100.0	5	13.9	31	86.1	0.4377	1.33	0.46	3.87		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3457	0.39	0.04	4.37		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA		47	100.0	4	8.5	43	91.5	36	100.0	1	2.8	35	97.2	0.4545	1.85	0.21	16.56		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA		47	100.0	3	6.4	44	93.6	36	100.0	1	2.8	35	97.2	0.5230	2.21	0.23	21.66		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4742	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			47	100.0	14	29.8	33	70.2	36	100.0	7	19.4	29	80.6	0.7505	1.40	0.55	3.56		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA		47	100.0	5	10.6	42	89.4	36	100.0	2	5.6	34	94.4	0.5298	1.97	0.38	10.29		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		47	100.0	3	6.4	44	93.6	36	100.0	2	5.6	34	94.4	0.9099	0.96	0.16	5.91		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.0783	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.8468	1.49	0.13	16.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2563	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2523	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2598	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			47	100.0	19	40.4	28	59.6	36	100.0	9	25.0	27	75.0	0.2146	1.91	0.83	4.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DIZZINESS		47	100.0	4	8.5	43	91.5	36	100.0	3	8.3	33	91.7	0.8143	0.94	0.21	4.24		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DYSGEUSIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HEADACHE		47	100.0	4	8.5	43	91.5	36	100.0	2	5.6	34	94.4	0.6828	1.61	0.29	8.90		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2837	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HYPOSMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL		47	100.0	9	19.1	38	80.9	36	100.0	2	5.6	34	94.4	0.1582	3.10	0.66	14.49		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	PARAESTHESIA		47	100.0	3	6.4	44	93.6	36	100.0	0	-	36	100.0	0.1558	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY		47	100.0	4	8.5	43	91.5	36	100.0	0	-	36	100.0	0.0985	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SOMNOLENCE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2327	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SYNCOPE		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.8604	1.49	0.14	16.44		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	TREMOR		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS			47	100.0	5	10.6	42	89.4	36	100.0	4	11.1	32	88.9	0.7705	0.96	0.25	3.60		Convergence criterion (GCONV=1E-8) satisfied.	NE

PSYCHIATRIC DISORDERS	ANXIETY		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.8135	1.61	0.15	17.87		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	APATHY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2049	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	DEPRESSION		47	100.0	1	2.1	46	97.9	36	100.0	3	8.3	33	91.7	0.1178	0.23	0.02	2.26		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	INSOMNIA		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7904	0.63	0.04	10.35		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			47	100.0	4	8.5	43	91.5	36	100.0	2	5.6	34	94.4	0.8574	0.90	0.15	5.50		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7757	0.80	0.05	12.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HAEMATURIA		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.6154	0.48	0.03	7.86		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	MICTURITION URGENCY		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4639	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	POLLAKIURIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4639	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL INJURY		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2407	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			47	100.0	14	29.8	33	70.2	36	100.0	8	22.2	28	77.8	0.9461	1.00	0.41	2.41		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH		47	100.0	6	12.8	41	87.2	36	100.0	4	11.1	32	88.9	0.8336	0.91	0.25	3.31		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2049	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA		47	100.0	3	6.4	44	93.6	36	100.0	1	2.8	35	97.2	0.6045	2.17	0.22	21.30		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0610	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.3135	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1722	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.8340	0.82	0.07	9.44		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		47	100.0	2	4.3	45	95.7	36	100.0	4	11.1	32	88.9	0.0899	0.27	0.05	1.48		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4472	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.6056	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			47	100.0	12	25.5	35	74.5	36	100.0	8	22.2	28	77.8	0.7717	0.90	0.36	2.22		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		47	100.0	7	14.9	40	85.1	36	100.0	2	5.6	34	94.4	0.3816	2.04	0.42	9.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		47	100.0	2	4.3	45	95.7	36	100.0	4	11.1	32	88.9	0.1798	0.33	0.06	1.82		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1999	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.8085	0.63	0.04	10.52		Convergence criterion (GCONV=1E-8) satisfied.	NE

SURGICAL AND MEDICAL PROCEDURES			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4193	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4193	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			47	100.0	11	23.4	36	76.6	36	100.0	6	16.7	30	83.3	0.6838	1.21	0.45	3.29		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS		47	100.0	2	4.3	45	95.7	36	100.0	2	5.6	34	94.4	0.6159	0.71	0.10	5.11		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	FLUSHING		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1999	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HAEMATOMA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		47	100.0	5	10.6	42	89.4	36	100.0	2	5.6	34	94.4	0.6010	1.51	0.29	7.90		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	VENOUS THROMBOSIS		47	100.0	3	6.4	44	93.6	36	100.0	0	-	36	100.0	0.1580	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 18:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	29	61.7	24	82.8	5	17.2	20	55.6	11	55.0	9	45.0	0.1792	1.78	0.85	3.70		Convergence criterion (GCONV=1E-8) satisfied.	0.1369
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	18	38.3	11	61.1	7	38.9	16	44.4	10	62.5	6	37.5	0.5149	0.75	0.31	1.80		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	29	61.7	21	72.4	8	27.6	20	55.6	5	25.0	15	75.0	0.0164	3.09	1.15	8.34		Convergence criterion (GCONV=1E-8) satisfied.	0.3088
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	18	38.3	7	38.9	11	61.1	16	44.4	4	25.0	12	75.0	0.8622	1.32	0.36	4.83		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	2	10.0	18	90.0	0.4122	0.53	0.07	3.86		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.3171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.4499	0.30	0.02	4.99		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	29	61.7	4	13.8	25	86.2	20	55.6	3	15.0	17	85.0	0.7922	1.07	0.24	4.85		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	29	61.7	3	10.3	26	89.7	20	55.6	0	-	20	100.0	0.1500	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6063	0.37	0.02	5.93		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	29	61.7	9	31.0	20	69.0	20	55.6	7	35.0	13	65.0	0.6645	1.21	0.44	3.32		Convergence criterion (GCONV=1E-8) satisfied.	0.9889
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	18	38.3	8	44.4	10	55.6	16	44.4	5	31.3	11	68.8	0.9776	1.04	0.34	3.22		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	29	61.7	10	34.5	19	65.5	20	55.6	6	30.0	14	70.0	0.9510	1.37	0.49	3.83		Convergence criterion (GCONV=1E-8) satisfied.	0.5024
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	18	38.3	6	33.3	12	66.7	16	44.4	5	31.3	11	68.8	0.5824	0.73	0.22	2.41		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	29	61.7	2	6.9	27	93.1	20	55.6	4	20.0	16	80.0	0.0835	0.20	0.03	1.19		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	18	38.3	3	16.7	15	83.3	16	44.4	5	31.3	11	68.8	0.4423	0.56	0.12	2.52		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	2	12.5	14	87.5	0.1005	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PALPITATIONS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6801	0.38	0.02	6.14		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PALPITATIONS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PNEUMOPERICARDIUM	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PNEUMOPERICARDIUM	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	< 65	29	61.7	0	-	29	100.0	20	55.6	2	10.0	18	90.0	0.0766	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

CARDIAC DISORDERS	TACHYARRHYTHMIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYARRHYTHMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7871	0.66	0.04	11.07		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.6609	1.79	0.16	20.31		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	DEAFNESS	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	DEAFNESS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2733	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS	ASTHENOPIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS	ASTHENOPIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2733	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	29	61.7	23	79.3	6	20.7	20	55.6	11	55.0	9	45.0	0.3477	1.49	0.71	3.15		Convergence criterion (GCONV=1E-8) satisfied.	0.1863
GASTROINTESTINAL DISORDERS		>= 65	18	38.3	13	72.2	5	27.8	16	44.4	11	68.8	5	31.3	0.5795	0.73	0.32	1.70		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2546	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	3	18.8	13	81.3	0.7298	0.76	0.15	3.76		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	< 65	29	61.7	4	13.8	25	86.2	20	55.6	1	5.0	19	95.0	0.3601	2.90	0.32	26.66		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2262	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4956	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	29	61.7	4	13.8	25	86.2	20	55.6	4	20.0	16	80.0	0.4526	0.69	0.17	2.86		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	18	38.3	5	27.8	13	72.2	16	44.4	3	18.8	13	81.3	0.6934	1.33	0.32	5.62		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	29	61.7	12	41.4	17	58.6	20	55.6	3	15.0	17	85.0	0.1697	2.55	0.71	9.16		Convergence criterion (GCONV=1E-8) satisfied.	0.0497
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	18	38.3	5	27.8	13	72.2	16	44.4	6	37.5	10	62.5	0.2772	0.49	0.15	1.61		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.7528	1.42	0.13	15.86		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FLATULENCE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FLATULENCE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4956	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRITIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRITIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	LIP DRY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	LIP DRY	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	< 65	29	61.7	10	34.5	19	65.5	20	55.6	6	30.0	14	70.0	0.8824	1.02	0.36	2.85		Convergence criterion (GCONV=1E-8) satisfied.	0.4881
GASTROINTESTINAL DISORDERS	NAUSEA	>= 65	18	38.3	5	27.8	13	72.2	16	44.4	6	37.5	10	62.5	0.4637	0.64	0.19	2.16		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	< 65	29	61.7	2	6.9	27	93.1	20	55.6	3	15.0	17	85.0	0.2257	0.42	0.07	2.56		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SUBILEUS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SUBILEUS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TOOTHACHE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GASTROINTESTINAL DISORDERS	TOOTHACHE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6706	0.37	0.02	5.97		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	29	61.7	9	31.0	20	69.0	20	55.6	5	25.0	15	75.0	0.5968	1.23	0.40	3.74		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.7272	1.57	0.14	17.37		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	29	61.7	21	72.4	8	27.6	20	55.6	13	65.0	7	35.0	0.8862	1.06	0.52	2.15		Convergence criterion (GCONV=1E-8) satisfied.	0.5680
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	18	38.3	13	72.2	5	27.8	16	44.4	7	43.8	9	56.3	0.3409	1.50	0.59	3.81		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	3	15.0	17	85.0	0.1203	0.27	0.03	2.60		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0578	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.3426	0.36	0.03	4.16		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7626	0.63	0.04	10.66		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	1	6.3	15	93.8	0.5113	1.94	0.20	18.92		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1915	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	29	61.7	10	34.5	19	65.5	20	55.6	7	35.0	13	65.0	0.6165	0.73	0.27	1.98		Convergence criterion (GCONV=1E-8) satisfied.	0.7532
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	18	38.3	8	44.4	10	55.6	16	44.4	6	37.5	10	62.5	0.9667	1.02	0.35	2.97		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4956	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1644	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	29	61.7	2	6.9	27	93.1	20	55.6	1	5.0	19	95.0	0.7694	1.23	0.11	14.06		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.1761	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	29	61.7	13	44.8	16	55.2	20	55.6	6	30.0	14	70.0	0.4314	1.56	0.58	4.19		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	1	6.3	15	93.8	0.4777	2.22	0.23	21.47		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1782	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1782	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3270	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4945	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4945	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	29	61.7	11	37.9	18	62.1	20	55.6	6	30.0	14	70.0	0.7362	0.84	0.30	2.38		Convergence criterion (GCONV=1E-8) satisfied.	0.5635
INFECTIONS AND INFESTATIONS		>= 65	18	38.3	10	55.6	8	44.4	16	44.4	8	50.0	8	50.0	0.5165	0.67	0.25	1.77		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	BRONCHITIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	BRONCHITIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CELLULITIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CELLULITIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	2	10.0	18	90.0	0.0724	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ERYSIPELAS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ERYSIPELAS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	29	61.7	2	6.9	27	93.1	20	55.6	1	5.0	19	95.0	0.4977	0.38	0.02	6.98		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFLUENZA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFLUENZA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2568	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	29	61.7	4	13.8	25	86.2	20	55.6	2	10.0	18	90.0	0.8616	1.16	0.21	6.50		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	2	12.5	14	87.5	0.8490	1.26	0.21	7.62		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PYURIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PYURIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.6457	0.44	0.03	7.45		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.6744	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6465	0.51	0.03	8.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.7887	0.69	0.04	11.04		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	3	15.0	17	85.0	0.0275	0.12	0.01	1.29		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	18	38.3	3	16.7	15	83.3	16	44.4	3	18.8	13	81.3	0.6902	0.79	0.16	3.95		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0956	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1422	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4212	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0956	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0956	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.6080	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	29	61.7	20	69.0	9	31.0	20	55.6	9	45.0	11	55.0	0.3572	1.14	0.48	2.70		Convergence criterion (GCONV=1E-8) satisfied.	0.4507
INVESTIGATIONS		>= 65	18	38.3	10	55.6	8	44.4	16	44.4	8	50.0	8	50.0	0.3797	0.59	0.22	1.59		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	< 65	29	61.7	6	20.7	23	79.3	20	55.6	0	-	20	100.0	0.0622	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	AMYLASE INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	AMYLASE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ANION GAP DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4878	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ANION GAP DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	29	61.7	7	24.1	22	75.9	20	55.6	0	-	20	100.0	0.0280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2733	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3734	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3252	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CALCIUM DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CALCIUM DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	< 65	29	61.7	4	13.8	25	86.2	20	55.6	0	-	20	100.0	0.0877	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	3	18.8	13	81.3	0.3421	0.50	0.08	3.06		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	< 65	29	61.7	4	13.8	25	86.2	20	55.6	0	-	20	100.0	0.1172	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2250	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2361	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1644	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD SODIUM DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD SODIUM DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD UREA INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD UREA INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URIC ACID INCREASED	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2421	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URIC ACID INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URINE PRESENT	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URINE PRESENT	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	< 65	29	61.7	3	10.3	26	89.7	20	55.6	1	5.0	19	95.0	0.8929	1.09	0.11	10.79		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4439	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYSTATIN C INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYSTATIN C INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	29	61.7	3	10.3	26	89.7	20	55.6	0	-	20	100.0	0.1535	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	< 65	29	61.7	2	6.9	27	93.1	20	55.6	1	5.0	19	95.0	0.8349	1.15	0.10	13.00		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HEART RATE INCREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HEART RATE INCREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4212	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	< 65	29	61.7	3	10.3	26	89.7	20	55.6	0	-	20	100.0	0.2170	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	29	61.7	7	24.1	22	75.9	20	55.6	6	30.0	14	70.0	0.6335	0.36	0.10	1.28		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	3	18.8	13	81.3	0.5114	0.41	0.05	3.18		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.8013	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONOCYTE COUNT DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONOCYTE COUNT DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7729	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	29	61.7	13	44.8	16	55.2	20	55.6	3	15.0	17	85.0	0.0732	2.66	0.75	9.48		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	3	18.8	13	81.3	0.1341	0.12	0.01	1.64		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.6650	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.8013	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OCCULT BLOOD POSITIVE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OCCULT BLOOD POSITIVE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	29	61.7	13	44.8	16	55.2	20	55.6	2	10.0	18	90.0	0.0589	3.26	0.72	14.65		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	3	18.8	13	81.3	0.5193	0.72	0.14	3.76		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROCALCITONIN INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROCALCITONIN INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN TOTAL DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4878	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN TOTAL DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	PROTEIN URINE PRESENT	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3981	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN URINE PRESENT	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	VITAMIN D DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	VITAMIN D DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	29	61.7	3	10.3	26	89.7	20	55.6	2	10.0	18	90.0	0.8044	0.63	0.10	3.83		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	18	38.3	5	27.8	13	72.2	16	44.4	1	6.3	15	93.8	0.2658	3.31	0.38	28.98		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	29	61.7	14	48.3	15	51.7	20	55.6	3	15.0	17	85.0	0.0647	2.54	0.72	8.98		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	4	25.0	12	75.0	0.0592	0.12	0.01	1.19		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	29	61.7	19	65.5	10	34.5	20	55.6	11	55.0	9	45.0	0.7379	1.07	0.49	2.33		Convergence criterion (GCONV=1E-8) satisfied.	0.6905
METABOLISM AND NUTRITION DISORDERS		>= 65	18	38.3	7	38.9	11	61.1	16	44.4	6	37.5	10	62.5	0.7873	0.85	0.28	2.56		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	29	61.7	6	20.7	23	79.3	20	55.6	6	30.0	14	70.0	0.3123	0.53	0.17	1.70		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	18	38.3	5	27.8	13	72.2	16	44.4	2	12.5	14	87.5	0.4078	1.98	0.38	10.32		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4439	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1915	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	< 65	29	61.7	4	13.8	25	86.2	20	55.6	0	-	20	100.0	0.1136	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.6080	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	< 65	29	61.7	4	13.8	25	86.2	20	55.6	1	5.0	19	95.0	0.3465	2.15	0.23	20.18		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	29	61.7	4	13.8	25	86.2	20	55.6	2	10.0	18	90.0	0.9838	0.92	0.16	5.19		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2321	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	1	5.0	19	95.0	0.8482	1.08	0.09	12.55		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2321	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2733	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	29	61.7	9	31.0	20	69.0	20	55.6	5	25.0	15	75.0	0.8331	1.00	0.33	3.04		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2233	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7275	0.84	0.05	13.43		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	< 65	29	61.7	4	13.8	25	86.2	20	55.6	1	5.0	19	95.0	0.4995	1.57	0.17	14.10		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7871	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2399	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	29	61.7	6	20.7	23	79.3	20	55.6	4	20.0	16	80.0	0.7222	1.00	0.27	3.68		Convergence criterion (GCONV=1E-8) satisfied.	0.4873
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	18	38.3	8	44.4	10	55.6	16	44.4	3	18.8	13	81.3	0.3446	1.99	0.51	7.76		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	< 65	29	61.7	3	10.3	26	89.7	20	55.6	0	-	20	100.0	0.1576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	2	12.5	14	87.5	0.7609	0.70	0.10	5.02		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	29	61.7	2	6.9	27	93.1	20	55.6	1	5.0	19	95.0	0.9429	1.22	0.10	14.42		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.8215	0.71	0.04	11.39		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0578	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.8255	1.30	0.12	14.40		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2109	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	29	61.7	11	37.9	18	62.1	20	55.6	5	25.0	15	75.0	0.6152	1.65	0.56	4.90		Convergence criterion (GCONV=1E-8) satisfied.	0.6885
NERVOUS SYSTEM DISORDERS		>= 65	18	38.3	8	44.4	10	55.6	16	44.4	4	25.0	12	75.0	0.2088	2.26	0.60	8.53		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.2298	0.28	0.02	3.20		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	1	6.3	15	93.8	0.4777	2.18	0.23	21.10		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	< 65	29	61.7	4	13.8	25	86.2	20	55.6	2	10.0	18	90.0	0.7620	1.69	0.30	9.43		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HEADACHE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOSMIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOSMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	< 65	29	61.7	5	17.2	24	82.8	20	55.6	1	5.0	19	95.0	0.2904	3.11	0.35	27.42		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>= 65	18	38.3	4	22.2	14	77.8	16	44.4	1	6.3	15	93.8	0.3130	2.77	0.31	25.05		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2341	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2893	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.1987	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2568	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	< 65	29	61.7	2	6.9	27	93.1	20	55.6	1	5.0	19	95.0	0.8974	1.71	0.15	18.84		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	TREMOR	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	TREMOR	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.2991	0.33	0.03	3.75		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		>= 65	18	38.3	4	22.2	14	77.8	16	44.4	2	12.5	14	87.5	0.5823	1.62	0.29	8.86		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.7395	1.49	0.13	16.60		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	APATHY	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1915	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	APATHY	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1644	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	2	12.5	14	87.5	0.3872	0.35	0.03	3.87		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	29	61.7	3	10.3	26	89.7	20	55.6	1	5.0	19	95.0	0.9559	1.21	0.10	14.00		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.7773	0.65	0.04	10.41		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.5729	0.46	0.03	7.69		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RENAL AND URINARY DISORDERS	POLLAKIURIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	POLLAKIURIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL INJURY	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	29	61.7	8	27.6	21	72.4	20	55.6	5	25.0	15	75.0	0.5875	0.78	0.25	2.47		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	18	38.3	6	33.3	12	66.7	16	44.4	3	18.8	13	81.3	0.5657	1.48	0.36	5.98		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	< 65	29	61.7	3	10.3	26	89.7	20	55.6	2	10.0	18	90.0	0.7774	0.93	0.15	5.78		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	2	12.5	14	87.5	0.9306	1.11	0.18	6.73		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6018	0.63	0.04	10.88		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	< 65	29	61.7	0	-	29	100.0	20	55.6	2	10.0	18	90.0	0.0456	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1317	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3743	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.1380	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	3	15.0	17	85.0	0.0602	0.16	0.02	1.63		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.7349	0.57	0.04	9.11		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4720	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.6744	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	29	61.7	7	24.1	22	75.9	20	55.6	6	30.0	14	70.0	0.2886	0.56	0.18	1.71		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	18	38.3	5	27.8	13	72.2	16	44.4	2	12.5	14	87.5	0.4302	1.93	0.37	10.15		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	29	61.7	5	17.2	24	82.8	20	55.6	1	5.0	19	95.0	0.4004	2.50	0.28	21.98		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.7480	1.47	0.13	16.43		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	29	61.7	2	6.9	27	93.1	20	55.6	2	10.0	18	90.0	0.6254	0.60	0.08	4.40		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	18	38.3	0	-	18	100.0	16	44.4	2	12.5	14	87.5	0.1063	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1915	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	29	61.7	7	24.1	22	75.9	20	55.6	3	15.0	17	85.0	0.5731	1.46	0.37	5.74		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	18	38.3	4	22.2	14	77.8	16	44.4	3	18.8	13	81.3	0.9234	0.99	0.22	4.49		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.8207	1.25	0.11	13.83		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	FLUSHING	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1915	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	FLUSHING	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMATOMA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMATOMA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	29	61.7	3	10.3	26	89.7	20	55.6	1	5.0	19	95.0	0.6382	1.73	0.17	17.14		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.8274	1.46	0.13	16.49		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	VENOUS THROMBOSIS	< 65	29	61.7	3	10.3	26	89.7	20	55.6	0	-	20	100.0	0.1805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	VENOUS THROMBOSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 18:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	29	61.7	23	79.3	6	20.7	24	66.7	14	58.3	10	41.7	0.5184	1.29	0.65	2.55		Convergence criterion (GCONV=1E-8) satisfied.	0.7493
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	18	38.3	12	66.7	6	33.3	12	33.3	7	58.3	5	41.7	0.7732	1.14	0.44	2.97		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	29	61.7	17	58.6	12	41.4	24	66.7	6	25.0	18	75.0	0.1513	1.71	0.66	4.43		Convergence criterion (GCONV=1E-8) satisfied.	0.5458
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	18	38.3	11	61.1	7	38.9	12	33.3	3	25.0	9	75.0	0.1100	2.75	0.76	9.97		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	2	8.3	22	91.7	0.9000	1.42	0.13	16.03		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	1	8.3	11	91.7	0.9182	1.10	0.10	12.20		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.5460	0.38	0.02	6.08		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	29	61.7	3	10.3	26	89.7	24	66.7	2	8.3	22	91.7	0.9803	1.16	0.19	7.07		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	1	8.3	11	91.7	0.8559	1.27	0.11	13.99		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	29	61.7	3	10.3	26	89.7	24	66.7	0	-	24	100.0	0.1306	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1742	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	29	61.7	9	31.0	20	69.0	24	66.7	8	33.3	16	66.7	0.2590	0.71	0.26	1.95		Convergence criterion (GCONV=1E-8) satisfied.	0.3281
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	18	38.3	8	44.4	10	55.6	12	33.3	4	33.3	8	66.7	0.6058	1.59	0.47	5.39		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4275	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	29	61.7	10	34.5	19	65.5	24	66.7	5	20.8	19	79.2	0.5684	1.73	0.58	5.18		Convergence criterion (GCONV=1E-8) satisfied.	0.1096
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	18	38.3	6	33.3	12	66.7	12	33.3	6	50.0	6	50.0	0.2189	0.51	0.16	1.62		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	29	61.7	4	13.8	25	86.2	24	66.7	5	20.8	19	79.2	0.3203	0.49	0.13	1.89		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	4	33.3	8	66.7	0.1118	0.19	0.02	1.85		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	29	61.7	0	-	29	100.0	24	66.7	2	8.3	22	91.7	0.0797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2509	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	>=3	29	61.7	0	-	29	100.0	24	66.7	2	8.3	22	91.7	0.0904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PALPITATIONS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PALPITATIONS	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PNEUMOPERICARDIUM	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PNEUMOPERICARDIUM	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	2	8.3	22	91.7	0.3236	0.24	0.02	2.81		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

CARDIAC DISORDERS	TACHYARRHYTHMIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYARRHYTHMIA	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	2	8.3	22	91.7	0.8352	0.92	0.12	6.90		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	DEAFNESS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	DEAFNESS	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2509	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS	ASTHENOPIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2509	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS	ASTHENOPIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	29	61.7	20	69.0	9	31.0	24	66.7	15	62.5	9	37.5	0.7292	0.96	0.47	1.93		Convergence criterion (GCONV=1E-8) satisfied.	0.3505
GASTROINTESTINAL DISORDERS		<3	18	38.3	16	88.9	2	11.1	12	33.3	7	58.3	5	41.7	0.2935	1.58	0.63	3.95		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	29	61.7	5	17.2	24	82.8	24	66.7	3	12.5	21	87.5	0.8669	1.29	0.30	5.56		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.8007	0.96	0.06	15.41		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	<3	18	38.3	5	27.8	13	72.2	12	33.3	0	-	12	100.0	0.0583	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4631	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	29	61.7	5	17.2	24	82.8	24	66.7	4	16.7	20	83.3	0.8657	1.04	0.27	3.99		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	18	38.3	4	22.2	14	77.8	12	33.3	3	25.0	9	75.0	0.7336	0.80	0.18	3.64		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	29	61.7	7	24.1	22	75.9	24	66.7	4	16.7	20	83.3	0.7750	1.16	0.33	4.06		Convergence criterion (GCONV=1E-8) satisfied.	0.8087
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	18	38.3	10	55.6	8	44.4	12	33.3	5	41.7	7	58.3	0.9492	0.91	0.31	2.72		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	2	8.3	22	91.7	0.3969	0.50	0.05	5.62		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FLATULENCE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FLATULENCE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4631	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRITIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRITIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2249	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2509	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	LIP DRY	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	LIP DRY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4945	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	>=3	29	61.7	12	41.4	17	58.6	24	66.7	8	33.3	16	66.7	0.8007	1.12	0.45	2.83		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	<3	18	38.3	3	16.7	15	83.3	12	33.3	4	33.3	8	66.7	0.2764	0.44	0.10	2.00		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	>=3	29	61.7	2	6.9	27	93.1	24	66.7	2	8.3	22	91.7	0.5781	0.63	0.09	4.67		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SUBILEUS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3948	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SUBILEUS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TOOTHACHE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GASTROINTESTINAL DISORDERS	TOOTHACHE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	29	61.7	7	24.1	22	75.9	24	66.7	4	16.7	20	83.3	0.5701	1.12	0.32	3.95		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	18	38.3	4	22.2	14	77.8	12	33.3	2	16.7	10	83.3	0.6547	1.49	0.27	8.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	29	61.7	20	69.0	9	31.0	24	66.7	12	50.0	12	50.0	0.5743	1.28	0.61	2.67		Convergence criterion (GCONV=1E-8) satisfied.	0.8665
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	18	38.3	14	77.8	4	22.2	12	33.3	8	66.7	4	33.3	0.7798	1.13	0.47	2.75		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	3	12.5	21	87.5	0.3426	0.59	0.10	3.56		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>=3	29	61.7	1	3.4	28	96.6	24	66.7	2	8.3	22	91.7	0.4139	0.38	0.03	4.51		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>=3	29	61.7	2	6.9	27	93.1	24	66.7	2	8.3	22	91.7	0.6835	0.75	0.10	5.54		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.3251	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1994	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	29	61.7	10	34.5	19	65.5	24	66.7	7	29.2	17	70.8	0.9245	0.89	0.33	2.41		Convergence criterion (GCONV=1E-8) satisfied.	0.7504
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	18	38.3	8	44.4	10	55.6	12	33.3	6	50.0	6	50.0	0.6048	0.77	0.26	2.23		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	29	61.7	4	13.8	25	86.2	24	66.7	1	4.2	23	95.8	0.3233	2.87	0.30	27.09		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	29	61.7	7	24.1	22	75.9	24	66.7	3	12.5	21	87.5	0.4854	1.65	0.42	6.54		Convergence criterion (GCONV=1E-8) satisfied.	0.9179
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	18	38.3	9	50.0	9	50.0	12	33.3	4	33.3	8	66.7	0.5098	1.53	0.46	5.06		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1939	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1939	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.3990	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	29	61.7	16	55.2	13	44.8	24	66.7	10	41.7	14	58.3	0.7595	0.92	0.40	2.09		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	18	38.3	5	27.8	13	72.2	12	33.3	4	33.3	8	66.7	0.3484	0.52	0.13	2.10		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	BRONCHITIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	BRONCHITIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CELLULITIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CELLULITIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7195	0.85	0.05	13.55		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ERYSIPELAS	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ERYSIPELAS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.5858	0.43	0.02	7.63		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFLUENZA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFLUENZA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4984	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2968	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	29	61.7	5	17.2	24	82.8	24	66.7	2	8.3	22	91.7	0.4951	1.55	0.29	8.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	2	16.7	10	83.3	0.5715	0.61	0.08	4.43		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PYURIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PYURIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.5456	0.55	0.03	8.94		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7322	0.54	0.03	9.57		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.7407	0.64	0.04	10.25		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.6524	0.48	0.03	8.48		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	29	61.7	3	10.3	26	89.7	24	66.7	5	20.8	19	79.2	0.1252	0.37	0.08	1.58		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.5102	0.29	0.01	6.09		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	>=3	29	61.7	0	-	29	100.0	24	66.7	2	8.3	22	91.7	0.0766	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4359	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	29	61.7	19	65.5	10	34.5	24	66.7	12	50.0	12	50.0	0.8340	0.88	0.41	1.89		Convergence criterion (GCONV=1E-8) satisfied.	0.7029
INVESTIGATIONS		<3	18	38.3	11	61.1	7	38.9	12	33.3	5	41.7	7	58.3	0.7785	1.02	0.31	3.37		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>=3	29	61.7	4	13.8	25	86.2	24	66.7	0	-	24	100.0	0.0869	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	<3	18	38.3	3	16.7	15	83.3	12	33.3	0	-	12	100.0	0.2048	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	AMYLASE INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4101	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	AMYLASE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ANION GAP DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4543	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ANION GAP DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>=3	29	61.7	5	17.2	24	82.8	24	66.7	0	-	24	100.0	0.0546	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.7887	0.67	0.04	10.77		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.3409	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CALCIUM DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CALCIUM DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	>=3	29	61.7	3	10.3	26	89.7	24	66.7	3	12.5	21	87.5	0.5800	0.54	0.11	2.74		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	<3	18	38.3	3	16.7	15	83.3	12	33.3	0	-	12	100.0	0.1533	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	>=3	29	61.7	4	13.8	25	86.2	24	66.7	0	-	24	100.0	0.0919	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2378	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.1943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD SODIUM DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD SODIUM DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD UREA INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD UREA INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URIC ACID INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3948	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URIC ACID INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URINE PRESENT	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URINE PRESENT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>=3	29	61.7	3	10.3	26	89.7	24	66.7	1	4.2	23	95.8	0.7808	1.19	0.12	11.74		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4275	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYSTATIN C INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYSTATIN C INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7324	0.36	0.02	5.86		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2241	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	2	16.7	10	83.3	0.0767	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HEART RATE INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4359	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HEART RATE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.3288	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	29	61.7	7	24.1	22	75.9	24	66.7	5	20.8	19	79.2	0.8666	0.45	0.12	1.69		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	18	38.3	2	11.1	16	88.9	12	33.3	4	33.3	8	66.7	0.1504	0.26	0.04	1.60		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.9033	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONOCYTE COUNT DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONOCYTE COUNT DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.8545	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	29	61.7	9	31.0	20	69.0	24	66.7	2	8.3	22	91.7	0.1526	2.16	0.46	10.15		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	18	38.3	5	27.8	13	72.2	12	33.3	4	33.3	8	66.7	0.7398	2.08	0.44	9.81		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.6056	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.9033	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OCCULT BLOOD POSITIVE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2615	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OCCULT BLOOD POSITIVE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	29	61.7	10	34.5	19	65.5	24	66.7	2	8.3	22	91.7	0.1273	2.80	0.61	12.81		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	18	38.3	6	33.3	12	66.7	12	33.3	3	25.0	9	75.0	0.9712	0.92	0.22	3.84		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROCALCITONIN INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROCALCITONIN INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN TOTAL DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN TOTAL DECREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	PROTEIN URINE PRESENT	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.3933	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN URINE PRESENT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2399	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	VITAMIN D DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	VITAMIN D DECREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	29	61.7	4	13.8	25	86.2	24	66.7	3	12.5	21	87.5	0.5875	0.64	0.14	3.00		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	18	38.3	4	22.2	14	77.8	12	33.3	0	-	12	100.0	0.1119	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	29	61.7	10	34.5	19	65.5	24	66.7	4	16.7	20	83.3	0.4167	1.03	0.31	3.42		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	18	38.3	5	27.8	13	72.2	12	33.3	3	25.0	9	75.0	0.9817	1.98	0.42	9.44		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	29	61.7	16	55.2	13	44.8	24	66.7	13	54.2	11	45.8	0.7963	0.79	0.36	1.73		Convergence criterion (GCONV=1E-8) satisfied.	0.2793
METABOLISM AND NUTRITION DISORDERS		<3	18	38.3	10	55.6	8	44.4	12	33.3	4	33.3	8	66.7	0.3650	1.68	0.52	5.43		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	29	61.7	7	24.1	22	75.9	24	66.7	7	29.2	17	70.8	0.4604	0.63	0.21	1.87		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	18	38.3	4	22.2	14	77.8	12	33.3	1	8.3	11	91.7	0.3548	2.69	0.30	24.04		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	>=3	29	61.7	0	-	29	100.0	24	66.7	2	8.3	22	91.7	0.0955	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.1943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	>=3	29	61.7	4	13.8	25	86.2	24	66.7	0	-	24	100.0	0.0953	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5741	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>=3	29	61.7	4	13.8	25	86.2	24	66.7	1	4.2	23	95.8	0.2809	2.19	0.23	20.84		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	29	61.7	5	17.2	24	82.8	24	66.7	2	8.3	22	91.7	0.6249	1.52	0.28	8.12		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>=3	29	61.7	3	10.3	26	89.7	24	66.7	1	4.2	23	95.8	0.4871	2.06	0.20	20.77		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	29	61.7	6	20.7	23	79.3	24	66.7	4	16.7	20	83.3	0.9475	0.82	0.23	2.96		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	18	38.3	5	27.8	13	72.2	12	33.3	1	8.3	11	91.7	0.2252	3.54	0.41	30.29		Convergence criterion (GCONV=1E-8) satisfied.	

METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.7407	0.64	0.04	10.25		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	>=3	29	61.7	3	10.3	26	89.7	24	66.7	1	4.2	23	95.8	0.6539	1.17	0.12	11.28		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>=3	29	61.7	3	10.3	26	89.7	24	66.7	1	4.2	23	95.8	0.4976	2.52	0.25	25.13		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	29	61.7	7	24.1	22	75.9	24	66.7	6	25.0	18	75.0	0.3763	0.79	0.24	2.54		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	18	38.3	7	38.9	11	61.1	12	33.3	1	8.3	11	91.7	0.1200	4.63	0.57	37.76		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>=3	29	61.7	3	10.3	26	89.7	24	66.7	2	8.3	22	91.7	0.9558	1.17	0.19	7.31		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.7940	1.89	0.17	21.40		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.6134	0.52	0.03	8.50		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.6991	0.58	0.04	9.22		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4101	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2558	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	29	61.7	11	37.9	18	62.1	24	66.7	8	33.3	16	66.7	0.9040	1.28	0.49	3.36		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	18	38.3	8	44.4	10	55.6	12	33.3	1	8.3	11	91.7	0.0606	6.08	0.76	48.80		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.0578	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1052	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	>=3	29	61.7	3	10.3	26	89.7	24	66.7	2	8.3	22	91.7	0.9935	1.37	0.23	8.26		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.6862	0.54	0.03	8.75		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	>=3	29	61.7	2	6.9	27	93.1	24	66.7	2	8.3	22	91.7	0.7163	0.78	0.11	5.77		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HEADACHE	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOSMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOSMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>=3	29	61.7	5	17.2	24	82.8	24	66.7	2	8.3	22	91.7	0.5879	1.79	0.34	9.53		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	<3	18	38.3	4	22.2	14	77.8	12	33.3	0	-	12	100.0	0.1040	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>=3	29	61.7	3	10.3	26	89.7	24	66.7	0	-	24	100.0	0.1474	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2534	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2517	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2399	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2620	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	TREMOR	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	TREMOR	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		>=3	29	61.7	4	13.8	25	86.2	24	66.7	2	8.3	22	91.7	0.6924	1.80	0.32	10.10		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	2	16.7	10	83.3	0.2934	0.29	0.03	3.32		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2305	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	APATHY	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	APATHY	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7551	0.86	0.05	14.28		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSION	<3	18	38.3	0	-	18	100.0	12	33.3	2	16.7	10	83.3	0.0639	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.8013	0.64	0.04	10.89		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	29	61.7	3	10.3	26	89.7	24	66.7	1	4.2	23	95.8	0.6508	1.92	0.19	19.03		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.5979	0.45	0.03	7.70		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RENAL AND URINARY DISORDERS	POLLAKIURIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	POLLAKIURIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL INJURY	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2361	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	29	61.7	10	34.5	19	65.5	24	66.7	4	16.7	20	83.3	0.5200	1.53	0.47	5.02		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	18	38.3	4	22.2	14	77.8	12	33.3	4	33.3	8	66.7	0.3389	0.46	0.11	1.91		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>=3	29	61.7	3	10.3	26	89.7	24	66.7	2	8.3	22	91.7	0.9347	0.93	0.15	5.73		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	<3	18	38.3	3	16.7	15	83.3	12	33.3	2	16.7	10	83.3	0.8387	0.79	0.12	5.04		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.7797	2.03	0.18	22.62		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.3190	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.0393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.3403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	29	61.7	2	6.9	27	93.1	24	66.7	2	8.3	22	91.7	0.4308	0.50	0.07	3.75		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	18	38.3	0	-	18	100.0	12	33.3	2	16.7	10	83.3	0.0678	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	29	61.7	9	31.0	20	69.0	24	66.7	5	20.8	19	79.2	0.8257	1.13	0.37	3.47		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	18	38.3	3	16.7	15	83.3	12	33.3	3	25.0	9	75.0	0.4319	0.51	0.10	2.56		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4414	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	29	61.7	5	17.2	24	82.8	24	66.7	0	-	24	100.0	0.0823	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	18	38.3	2	11.1	16	88.9	12	33.3	2	16.7	10	83.3	0.4702	0.46	0.06	3.35		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	29	61.7	2	6.9	27	93.1	24	66.7	3	12.5	21	87.5	0.3858	0.45	0.07	2.80		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1994	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES		>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES		<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	29	61.7	7	24.1	22	75.9	24	66.7	6	25.0	18	75.0	0.6628	0.78	0.26	2.37		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	18	38.3	4	22.2	14	77.8	12	33.3	0	-	12	100.0	0.0987	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	2	8.3	22	91.7	0.3494	0.46	0.04	5.13		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	FLUSHING	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1994	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	FLUSHING	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMATOMA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMATOMA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	29	61.7	3	10.3	26	89.7	24	66.7	2	8.3	22	91.7	0.9452	0.83	0.14	5.14		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2735	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	VENOUS THROMBOSIS	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	VENOUS THROMBOSIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 18:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	19.1	5	55.6	4	44.4	13	36.1	6	46.2	7	53.8	0.6920	0.78	0.23	2.64		Convergence criterion (GCONV=1E-8) satisfied.	0.5348
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	38	80.9	30	78.9	8	21.1	23	63.9	15	65.2	8	34.8	0.5289	1.26	0.67	2.37		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	9	19.1	4	44.4	5	55.6	13	36.1	0	-	13	100.0	0.0487	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	38	80.9	24	63.2	14	36.8	23	63.9	9	39.1	14	60.9	0.2283	1.60	0.74	3.46		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	2	8.7	21	91.3	0.8165	0.85	0.15	4.72		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.4708	0.42	0.03	6.68		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	2	8.7	21	91.3	0.7125	1.51	0.29	7.79		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	0	-	23	100.0	0.1205	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5915	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	19.1	3	33.3	6	66.7	13	36.1	5	38.5	8	61.5	0.5366	0.64	0.15	2.71		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	38	80.9	14	36.8	24	63.2	23	63.9	7	30.4	16	69.6	0.9415	1.21	0.48	3.09		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	19.1	2	22.2	7	77.8	13	36.1	3	23.1	10	76.9	0.8681	0.86	0.14	5.16		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	38	80.9	14	36.8	24	63.2	23	63.9	8	34.8	15	65.2	0.7177	0.97	0.40	2.34		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	9	19.1	2	22.2	7	77.8	13	36.1	3	23.1	10	76.9	0.7289	1.42	0.19	10.34		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	6	26.1	17	73.9	0.0209	0.22	0.05	0.89		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	2	8.7	21	91.3	0.0507	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	2	8.7	21	91.3	0.0554	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PALPITATIONS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PALPITATIONS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6278	0.44	0.03	7.07		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PNEUMOPERICARDIUM	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PNEUMOPERICARDIUM	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	2	8.7	21	91.3	0.2392	0.24	0.02	2.72		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

CARDIAC DISORDERS	TACHYARRHYTHMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYARRHYTHMIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1687	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	9	19.1	2	22.2	7	77.8	13	36.1	1	7.7	12	92.3	0.3646	2.94	0.26	33.68		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7149	0.59	0.04	9.52		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	DEAFNESS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	DEAFNESS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS	ASTHENOPIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS	ASTHENOPIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	9	19.1	7	77.8	2	22.2	13	36.1	6	46.2	7	53.8	0.4130	1.58	0.53	4.72		Convergence criterion (GCONV=1E-8) satisfied.	0.4672
GASTROINTESTINAL DISORDERS		Non-Europe	38	80.9	29	76.3	9	23.7	23	63.9	16	69.6	7	30.4	0.8811	0.97	0.52	1.81		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5571	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	2	8.7	21	91.3	0.7255	1.42	0.27	7.38		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Europe	9	19.1	2	22.2	7	77.8	13	36.1	0	-	13	100.0	0.1198	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	1	4.3	22	95.7	0.4592	2.28	0.25	20.42		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4990	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.8160	1.39	0.09	22.20		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	38	80.9	8	21.1	30	78.9	23	63.9	6	26.1	17	73.9	0.5105	0.75	0.26	2.20		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	9	19.1	3	33.3	6	66.7	13	36.1	4	30.8	9	69.2	0.8077	0.83	0.18	3.73		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	38	80.9	14	36.8	24	63.2	23	63.9	5	21.7	18	78.3	0.4473	1.49	0.53	4.16		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5742	0.46	0.03	7.93		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.8961	0.83	0.05	13.31		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7077	0.71	0.04	11.36		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FLATULENCE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FLATULENCE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4990	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRITIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRITIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2843	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3017	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	LIP DRY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	LIP DRY	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	2	15.4	11	84.6	0.6077	0.53	0.05	6.09		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Non-Europe	38	80.9	14	36.8	24	63.2	23	63.9	10	43.5	13	56.5	0.5775	0.80	0.35	1.82		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	3	13.0	20	87.0	0.0600	0.15	0.02	1.50		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SUBILEUS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SUBILEUS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TOOTHACHE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GASTROINTESTINAL DISORDERS	TOOTHACHE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6203	0.43	0.03	6.88		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	9	19.1	2	22.2	7	77.8	13	36.1	0	-	13	100.0	0.0800	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	38	80.9	9	23.7	29	76.3	23	63.9	6	26.1	17	73.9	0.8763	0.89	0.32	2.52		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	19.1	5	55.6	4	44.4	13	36.1	6	46.2	7	53.8	0.7528	0.82	0.24	2.80		Convergence criterion (GCONV=1E-8) satisfied.	0.4487
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	38	80.9	29	76.3	9	23.7	23	63.9	14	60.9	9	39.1	0.4139	1.34	0.70	2.56		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Europe	9	19.1	2	22.2	7	77.8	13	36.1	1	7.7	12	92.3	0.5142	2.19	0.20	24.42		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	2	8.7	21	91.3	0.0629	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.0588	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	2	8.7	21	91.3	0.2774	0.30	0.03	3.36		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.7752	0.67	0.04	10.97		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	1	4.3	22	95.7	0.6603	1.76	0.18	17.14		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1738	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	3	23.1	10	76.9	0.3135	0.32	0.03	3.23		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	38	80.9	17	44.7	21	55.3	23	63.9	10	43.5	13	56.5	0.7693	0.92	0.42	2.02		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4990	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	2	8.7	21	91.3	0.0478	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	0	-	23	100.0	0.1554	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4675	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	9	19.1	2	22.2	7	77.8	13	36.1	2	15.4	11	84.6	0.7217	1.43	0.20	10.12		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	38	80.9	14	36.8	24	63.2	23	63.9	5	21.7	18	78.3	0.3375	1.65	0.59	4.60		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1687	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1687	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3454	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	19.1	5	55.6	4	44.4	13	36.1	7	53.8	6	46.2	0.4665	0.65	0.20	2.09		Convergence criterion (GCONV=1E-8) satisfied.	0.7039
INFECTIONS AND INFESTATIONS		Non-Europe	38	80.9	16	42.1	22	57.9	23	63.9	7	30.4	16	69.6	0.8785	0.94	0.37	2.35		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	BRONCHITIS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	BRONCHITIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CELLULITIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CELLULITIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4622	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	2	8.7	21	91.3	0.0511	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ERYSIPELAS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ERYSIPELAS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	1	4.3	22	95.7	0.4803	0.37	0.02	6.38		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFLUENZA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFLUENZA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.9301	1.13	0.07	18.50		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	38	80.9	6	15.8	32	84.2	23	63.9	3	13.0	20	87.0	0.9575	0.96	0.24	3.90		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PYURIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PYURIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5571	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Europe	9	19.1	2	22.2	7	77.8	13	36.1	1	7.7	12	92.3	0.5251	2.14	0.19	23.76		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	3	23.1	10	76.9	0.0917	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	3	13.0	20	87.0	0.4857	0.58	0.13	2.70		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.0881	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4675	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1391	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4622	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.0881	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.0881	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6106	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	19.1	2	22.2	7	77.8	13	36.1	3	23.1	10	76.9	0.5880	0.61	0.10	3.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	38	80.9	28	73.7	10	26.3	23	63.9	14	60.9	9	39.1	0.7388	0.88	0.44	1.77		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	0	-	23	100.0	0.0499	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	AMYLASE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	AMYLASE INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4622	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ANION GAP DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ANION GAP DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4927	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	0	-	23	100.0	0.0404	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7149	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7023	0.58	0.04	9.31		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3463	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CALCIUM DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CALCIUM DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Non-Europe	38	80.9	6	15.8	32	84.2	23	63.9	2	8.7	21	91.3	0.5309	1.61	0.32	8.04		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	0	-	23	100.0	0.1345	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2925	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	1	4.3	22	95.7	0.8584	1.14	0.10	12.74		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD SODIUM DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD SODIUM DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD UREA INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD UREA INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URIC ACID INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URIC ACID INCREASED	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2789	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URINE PRESENT	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URINE PRESENT	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	1	4.3	22	95.7	0.8930	1.22	0.13	11.81		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYSTATIN C INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYSTATIN C INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6437	0.43	0.03	6.88		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4675	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4675	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	0	-	23	100.0	0.1850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	1	4.3	22	95.7	0.9087	1.09	0.10	12.05		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HEART RATE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HEART RATE INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4622	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3628	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	38	80.9	9	23.7	29	76.3	23	63.9	9	39.1	14	60.9	0.1763	0.33	0.11	0.96		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7271	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONOCYTE COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONOCYTE COUNT DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7028	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	38	80.9	14	36.8	24	63.2	23	63.9	6	26.1	17	73.9	0.6568	1.35	0.51	3.56		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7271	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OCCULT BLOOD POSITIVE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OCCULT BLOOD POSITIVE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	38	80.9	16	42.1	22	57.9	23	63.9	5	21.7	18	78.3	0.4481	1.55	0.56	4.28		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROCALCITONIN INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROCALCITONIN INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5571	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN TOTAL DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN TOTAL DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4927	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	PROTEIN URINE PRESENT	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN URINE PRESENT	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3988	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5571	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	VITAMIN D DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	VITAMIN D DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	3	13.0	20	87.0	0.9070	1.08	0.28	4.20		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	38	80.9	15	39.5	23	60.5	23	63.9	6	26.1	17	73.9	0.6166	1.26	0.48	3.29		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	9	19.1	3	33.3	6	66.7	13	36.1	5	38.5	8	61.5	0.4765	0.59	0.14	2.54		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	38	80.9	23	60.5	15	39.5	23	63.9	12	52.2	11	47.8	0.6790	1.16	0.57	2.37		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	9	19.1	2	22.2	7	77.8	13	36.1	2	15.4	11	84.6	0.9201	1.11	0.15	7.96		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	38	80.9	9	23.7	29	76.3	23	63.9	6	26.1	17	73.9	0.7163	0.82	0.29	2.33		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2680	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5571	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	0	-	23	100.0	0.1285	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6038	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	1	4.3	22	95.7	0.4311	2.09	0.23	19.22		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	38	80.9	6	15.8	32	84.2	23	63.9	2	8.7	21	91.3	0.6372	1.47	0.29	7.32		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	1	4.3	22	95.7	0.4653	2.11	0.23	19.06		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	38	80.9	10	26.3	28	73.7	23	63.9	5	21.7	18	78.3	0.8619	1.07	0.36	3.14		Convergence criterion (GCONV=1E-8) satisfied.	

METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6735	0.63	0.04	10.06		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	1	4.3	22	95.7	0.5453	1.85	0.21	16.56		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	1	4.3	22	95.7	0.6608	1.77	0.18	17.27		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5239	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	9	19.1	3	33.3	6	66.7	13	36.1	0	-	13	100.0	0.0417	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	38	80.9	11	28.9	27	71.1	23	63.9	7	30.4	16	69.6	0.3720	0.73	0.27	1.95		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Europe	9	19.1	2	22.2	7	77.8	13	36.1	0	-	13	100.0	0.1198	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	2	8.7	21	91.3	0.7692	0.86	0.14	5.23		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	2	8.7	21	91.3	0.7637	0.80	0.13	4.86		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.0588	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6377	0.57	0.04	9.07		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2917	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3105	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	19.1	2	22.2	7	77.8	13	36.1	3	23.1	10	76.9	0.9477	1.07	0.15	7.85		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	38	80.9	17	44.7	21	55.3	23	63.9	6	26.1	17	73.9	0.2883	1.93	0.75	4.93		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	3	13.0	20	87.0	0.6270	0.77	0.17	3.45		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HEADACHE	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	2	8.7	21	91.3	0.8731	1.29	0.23	7.12		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3361	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOSMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOSMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Non-Europe	38	80.9	8	21.1	30	78.9	23	63.9	2	8.7	21	91.3	0.3525	2.24	0.47	10.60		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	0	-	23	100.0	0.1970	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	0	-	23	100.0	0.1882	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6148	0.57	0.04	9.12		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	TREMOR	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	TREMOR	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	3	13.0	20	87.0	0.8642	1.02	0.24	4.29		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	1	4.3	22	95.7	0.9350	1.29	0.12	14.22		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	APATHY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	APATHY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	2	8.7	21	91.3	0.1845	0.25	0.02	2.74		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6776	0.55	0.03	8.94		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	1	4.3	22	95.7	0.7536	1.50	0.15	14.50		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5436	0.43	0.03	7.01		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RENAL AND URINARY DISORDERS	POLLAKIURIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	POLLAKIURIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL INJURY	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5571	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2899	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	19.1	2	22.2	7	77.8	13	36.1	3	23.1	10	76.9	0.8203	0.81	0.13	4.97		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	38	80.9	12	31.6	26	68.4	23	63.9	5	21.7	18	78.3	0.8317	1.08	0.38	3.11		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Europe	9	19.1	1	11.1	8	88.9	13	36.1	2	15.4	11	84.6	0.6478	0.57	0.05	6.41		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	2	8.7	21	91.3	0.8310	1.19	0.23	6.24		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	1	4.3	22	95.7	0.9269	0.95	0.08	10.88		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	2	8.7	21	91.3	0.0428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3487	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.7752	0.67	0.04	10.97		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	4	17.4	19	82.6	0.0465	0.20	0.04	1.13		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6481	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	9	19.1	2	22.2	7	77.8	13	36.1	1	7.7	12	92.3	0.4973	2.26	0.20	25.15		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	38	80.9	10	26.3	28	73.7	23	63.9	7	30.4	16	69.6	0.3754	0.64	0.24	1.70		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	2	8.7	21	91.3	0.5287	1.68	0.34	8.21		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	3	13.0	20	87.0	0.2411	0.36	0.06	2.18		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1738	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4622	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4622	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	3	23.1	10	76.9	0.1191	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	38	80.9	11	28.9	27	71.1	23	63.9	3	13.0	20	87.0	0.2555	2.07	0.58	7.46		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	1	4.3	22	95.7	0.9445	0.95	0.08	10.66		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	FLUSHING	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	FLUSHING	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1738	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMATOMA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMATOMA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2789	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	2	8.7	21	91.3	0.7591	1.30	0.25	6.76		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	VENOUS THROMBOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	VENOUS THROMBOSIS	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	0	-	23	100.0	0.2055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 18:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	34	72.3	25	73.5	9	26.5	24	66.7	13	54.2	11	45.8	0.5831	1.22	0.62	2.42	Convergence criterion (GCONV=1E-8) satisfied.	0.8640
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	13	27.7	10	76.9	3	23.1	12	33.3	8	66.7	4	33.3	0.4804	1.40	0.53	3.68	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	34	72.3	20	58.8	14	41.2	24	66.7	6	25.0	18	75.0	0.0847	2.17	0.87	5.43	Convergence criterion (GCONV=1E-8) satisfied.	0.9859
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	13	27.7	8	61.5	5	38.5	12	33.3	3	25.0	9	75.0	0.1888	2.03	0.53	7.83	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	3	12.5	21	87.5	0.4434	0.56	0.08	4.05	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2212	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6547	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2482	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	34	72.3	4	11.8	30	88.2	24	66.7	2	8.3	22	91.7	0.8243	1.36	0.25	7.52	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8403	0.87	0.05	13.95	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.1452	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3576	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.6261	0.35	0.02	5.57	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	34	72.3	10	29.4	24	70.6	24	66.7	7	29.2	17	70.8	0.4638	0.89	0.32	2.42	Convergence criterion (GCONV=1E-8) satisfied.	0.5038
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	13	27.7	7	53.8	6	46.2	12	33.3	5	41.7	7	58.3	0.7516	1.41	0.44	4.55	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.4363	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	34	72.3	8	23.5	26	76.5	24	66.7	7	29.2	17	70.8	0.4040	0.77	0.28	2.16	Convergence criterion (GCONV=1E-8) satisfied.	0.3118
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	13	27.7	8	61.5	5	38.5	12	33.3	4	33.3	8	66.7	0.4951	1.67	0.48	5.77	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	34	72.3	4	11.8	30	88.2	24	66.7	6	25.0	18	75.0	0.0898	0.33	0.09	1.21	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	3	25.0	9	75.0	0.4672	0.42	0.04	4.67	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	34	72.3	0	-	34	100.0	24	66.7	2	8.3	22	91.7	0.0661	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PALPITATIONS	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1573	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PALPITATIONS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PNEUMOPERICARDIUM	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PNEUMOPERICARDIUM	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.7221	0.36	0.02	5.86	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

CARDIAC DISORDERS	TACHYARRHYTHMIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1875	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYARRHYTHMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.7920	1.76	0.16	19.39		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.9304	0.80	0.05	13.13		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	DEAFNESS	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	DEAFNESS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS		Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS	ASTHENOPIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS	ASTHENOPIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	34	72.3	26	76.5	8	23.5	24	66.7	14	58.3	10	41.7	0.5935	1.25	0.64	2.44		Convergence criterion (GCONV=1E-8) satisfied.	0.6171
GASTROINTESTINAL DISORDERS		Female	13	27.7	10	76.9	3	23.1	12	33.3	8	66.7	4	33.3	0.8024	0.90	0.35	2.30		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	34	72.3	4	11.8	30	88.2	24	66.7	2	8.3	22	91.7	0.7516	1.34	0.24	7.48		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8635	0.85	0.05	13.65		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.5657	2.36	0.24	22.69		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Female	13	27.7	3	23.1	10	76.9	12	33.3	0	-	12	100.0	0.1087	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	34	72.3	6	17.6	28	82.4	24	66.7	6	25.0	18	75.0	0.4109	0.71	0.22	2.24		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	13	27.7	3	23.1	10	76.9	12	33.3	1	8.3	11	91.7	0.4775	2.29	0.24	22.20		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	34	72.3	13	38.2	21	61.8	24	66.7	6	25.0	18	75.0	0.5976	1.32	0.50	3.50		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	13	27.7	4	30.8	9	69.2	12	33.3	3	25.0	9	75.0	0.9039	0.89	0.18	4.52		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8349	0.75	0.04	12.70		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.5448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.9285	1.39	0.12	15.83		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FLATULENCE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FLATULENCE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRITIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRITIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.2412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	LIP DRY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	LIP DRY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	Male	34	72.3	12	35.3	22	64.7	24	66.7	8	33.3	16	66.7	0.9534	0.95	0.38	2.36		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Female	13	27.7	3	23.1	10	76.9	12	33.3	4	33.3	8	66.7	0.4622	0.57	0.12	2.65		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1510	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	Male	34	72.3	0	-	34	100.0	24	66.7	3	12.5	21	87.5	0.0071	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2100	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SUBILEUS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SUBILEUS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TOOTHACHE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GASTROINTESTINAL DISORDERS	TOOTHACHE	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	34	72.3	9	26.5	25	73.5	24	66.7	3	12.5	21	87.5	0.1832	2.17	0.58	8.08		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	13	27.7	2	15.4	11	84.6	12	33.3	3	25.0	9	75.0	0.4196	0.44	0.07	2.79		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	34	72.3	25	73.5	9	26.5	24	66.7	14	58.3	10	41.7	0.5188	1.19	0.61	2.33		Convergence criterion (GCONV=1E-8) satisfied.	0.9229
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	13	27.7	9	69.2	4	30.8	12	33.3	6	50.0	6	50.0	0.8312	0.99	0.34	2.92		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.9111	1.43	0.13	15.85		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Female	13	27.7	0	-	13	100.0	12	33.3	2	16.7	10	83.3	0.1231	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.0359	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.3574	0.33	0.03	3.81		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.7054	1.66	0.16	17.03		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8638	0.90	0.06	14.59		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	34	72.3	13	38.2	21	61.8	24	66.7	9	37.5	15	62.5	0.7866	0.76	0.32	1.83		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	13	27.7	5	38.5	8	61.5	12	33.3	4	33.3	8	66.7	0.8053	0.86	0.22	3.30		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4363	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Male	34	72.3	0	-	34	100.0	24	66.7	2	8.3	22	91.7	0.0654	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.1900	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.9774	0.87	0.05	14.21		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4480	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	34	72.3	10	29.4	24	70.6	24	66.7	4	16.7	20	83.3	0.4440	1.60	0.49	5.19		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	13	27.7	6	46.2	7	53.8	12	33.3	3	25.0	9	75.0	0.4308	1.74	0.43	6.97		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS		Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1875	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1875	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.3349	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	34	72.3	15	44.1	19	55.9	24	66.7	9	37.5	15	62.5	0.4241	0.75	0.32	1.79		Convergence criterion (GCONV=1E-8) satisfied.	0.9583
INFECTIONS AND INFESTATIONS		Female	13	27.7	6	46.2	7	53.8	12	33.3	5	41.7	7	58.3	0.8413	0.88	0.27	2.91		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	BRONCHITIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	BRONCHITIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CELLULITIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CELLULITIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.6739	0.69	0.04	11.03		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	2	8.3	22	91.7	0.0749	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ERYSIPELAS	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ERYSIPELAS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	13	27.7	2	15.4	11	84.6	12	33.3	1	8.3	11	91.7	0.7305	0.60	0.04	9.96		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.4591	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFLUENZA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFLUENZA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2303	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	34	72.3	4	11.8	30	88.2	24	66.7	4	16.7	20	83.3	0.3407	0.53	0.13	2.18		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	13	27.7	3	23.1	10	76.9	12	33.3	0	-	12	100.0	0.1148	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PYURIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PYURIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1287	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.7390	0.77	0.05	12.30		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8510	0.70	0.04	11.55		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	34	72.3	3	8.8	31	91.2	24	66.7	3	12.5	21	87.5	0.4704	0.56	0.11	2.83		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	13	27.7	1	7.7	12	92.3	12	33.3	3	25.0	9	75.0	0.1140	0.15	0.01	1.70		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.0986	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4480	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	Male	34	72.3	0	-	34	100.0	24	66.7	2	8.3	22	91.7	0.0617	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.0986	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.0986	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	34	72.3	21	61.8	13	38.2	24	66.7	10	41.7	14	58.3	0.5006	1.13	0.50	2.55		Convergence criterion (GCONV=1E-8) satisfied.	0.3372
INVESTIGATIONS		Female	13	27.7	9	69.2	4	30.8	12	33.3	7	58.3	5	41.7	0.5253	0.46	0.15	1.42		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.1780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Female	13	27.7	4	30.8	9	69.2	12	33.3	0	-	12	100.0	0.0779	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	AMYLASE INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	AMYLASE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ANION GAP DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ANION GAP DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Male	34	72.3	4	11.8	30	88.2	24	66.7	0	-	24	100.0	0.1077	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Female	13	27.7	3	23.1	10	76.9	12	33.3	0	-	12	100.0	0.1161	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.8010	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.3704	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.3366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CALCIUM DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CALCIUM DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	Male	34	72.3	5	14.7	29	85.3	24	66.7	1	4.2	23	95.8	0.2155	2.79	0.32	24.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	2	16.7	10	83.3	0.3066	0.31	0.03	3.44		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.1559	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.2519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.8128	0.63	0.04	10.56		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD SODIUM DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD SODIUM DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD UREA INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD UREA INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URIC ACID INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URIC ACID INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URINE PRESENT	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URINE PRESENT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.7998	0.67	0.06	7.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4363	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYSTATIN C INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYSTATIN C INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.7221	0.36	0.02	5.86		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4480	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4480	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.1481	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8226	1.10	0.10	12.40		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HEART RATE INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HEART RATE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.2195	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	34	72.3	9	26.5	25	73.5	24	66.7	6	25.0	18	75.0	0.9784	0.58	0.18	1.89		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	3	25.0	9	75.0	0.0546	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONOCYTE COUNT DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONOCYTE COUNT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	34	72.3	11	32.4	23	67.6	24	66.7	4	16.7	20	83.3	0.3922	1.50	0.46	4.82		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	13	27.7	3	23.1	10	76.9	12	33.3	2	16.7	10	83.3	0.8500	1.18	0.20	7.15		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OCCULT BLOOD POSITIVE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OCCULT BLOOD POSITIVE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	34	72.3	12	35.3	22	64.7	24	66.7	3	12.5	21	87.5	0.2291	1.46	0.40	5.28		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	13	27.7	4	30.8	9	69.2	12	33.3	2	16.7	10	83.3	0.6843	1.59	0.26	9.48		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROCALCITONIN INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROCALCITONIN INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN TOTAL DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4725	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN TOTAL DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	PROTEIN URINE PRESENT	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.4318	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN URINE PRESENT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	VITAMIN D DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	VITAMIN D DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	34	72.3	8	23.5	26	76.5	24	66.7	1	4.2	23	95.8	0.1346	4.19	0.52	33.68		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	2	16.7	10	83.3	0.0862	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	34	72.3	11	32.4	23	67.6	24	66.7	4	16.7	20	83.3	0.4770	1.36	0.43	4.36		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	13	27.7	4	30.8	9	69.2	12	33.3	3	25.0	9	75.0	0.9643	0.88	0.19	4.02		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	34	72.3	21	61.8	13	38.2	24	66.7	13	54.2	11	45.8	0.8659	1.02	0.50	2.08		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	13	27.7	5	38.5	8	61.5	12	33.3	4	33.3	8	66.7	0.9663	1.02	0.27	3.92		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	34	72.3	10	29.4	24	70.6	24	66.7	6	25.0	18	75.0	0.8634	1.07	0.39	2.99		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	13	27.7	1	7.7	12	92.3	12	33.3	2	16.7	10	83.3	0.4173	0.37	0.03	4.27		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.2313	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.1634	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.5042	1.60	0.16	16.44		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	34	72.3	5	14.7	29	85.3	24	66.7	2	8.3	22	91.7	0.7720	1.14	0.22	6.06		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.5452	1.45	0.15	14.41		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	34	72.3	7	20.6	27	79.4	24	66.7	3	12.5	21	87.5	0.5945	1.20	0.31	4.70		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	13	27.7	4	30.8	9	69.2	12	33.3	2	16.7	10	83.3	0.5790	1.52	0.27	8.55		Convergence criterion (GCONV=1E-8) satisfied.	

METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.3168	0.38	0.03	4.17		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.7913	1.00	0.10	9.67		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8119	1.37	0.12	15.50		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	34	72.3	11	32.4	23	67.6	24	66.7	6	25.0	18	75.0	0.9957	1.23	0.44	3.47		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	13	27.7	3	23.1	10	76.9	12	33.3	1	8.3	11	91.7	0.4869	2.34	0.24	22.89		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Male	34	72.3	5	14.7	29	85.3	24	66.7	1	4.2	23	95.8	0.2654	4.10	0.48	35.29		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	34	72.3	3	8.8	31	91.2	24	66.7	2	8.3	22	91.7	0.8671	0.94	0.15	5.83		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.0359	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8773	1.46	0.13	16.08		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.2650	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.1995	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	34	72.3	13	38.2	21	61.8	24	66.7	8	33.3	16	66.7	0.6297	1.45	0.57	3.73		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	13	27.7	6	46.2	7	53.8	12	33.3	1	8.3	11	91.7	0.1009	5.09	0.61	42.42		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	Male	34	72.3	3	8.8	31	91.2	24	66.7	2	8.3	22	91.7	0.9297	1.02	0.17	6.21		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8027	0.76	0.05	12.42		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.5075	2.75	0.28	26.78		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HEADACHE	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8272	0.71	0.04	11.52		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOSMIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOSMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Male	34	72.3	5	14.7	29	85.3	24	66.7	2	8.3	22	91.7	0.7711	1.37	0.26	7.26		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Female	13	27.7	4	30.8	9	69.2	12	33.3	0	-	12	100.0	0.0658	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.1606	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Male	34	72.3	4	11.8	30	88.2	24	66.7	0	-	24	100.0	0.1037	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8874	1.50	0.14	16.51		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	TREMOR	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	TREMOR	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Male	34	72.3	4	11.8	30	88.2	24	66.7	3	12.5	21	87.5	0.7387	0.90	0.20	4.11		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.9774	1.20	0.08	19.26		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.6971	0.70	0.04	11.18		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	APATHY	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	APATHY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSION	Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.2137	0.30	0.03	3.34		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.7892	0.61	0.04	10.21		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	34	72.3	4	11.8	30	88.2	24	66.7	1	4.2	23	95.8	0.6957	1.70	0.17	16.77		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.5547	0.41	0.02	6.94		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4945	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RENAL AND URINARY DISORDERS	POLLAKIURIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4945	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	POLLAKIURIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL INJURY	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.2412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	34	72.3	8	23.5	26	76.5	24	66.7	5	20.8	19	79.2	0.8717	0.94	0.30	2.93		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	13	27.7	6	46.2	7	53.8	12	33.3	3	25.0	9	75.0	0.7976	1.06	0.25	4.43		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Male	34	72.3	3	8.8	31	91.2	24	66.7	3	12.5	21	87.5	0.5667	0.63	0.13	3.18		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Female	13	27.7	3	23.1	10	76.9	12	33.3	1	8.3	11	91.7	0.5424	2.12	0.22	20.57		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.2698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8349	0.75	0.04	12.70		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Male	34	72.3	0	-	34	100.0	24	66.7	2	8.3	22	91.7	0.0526	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.4187	0.33	0.02	6.42		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	34	72.3	1	2.9	33	97.1	24	66.7	3	12.5	21	87.5	0.0595	0.16	0.02	1.53		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8091	0.69	0.04	12.04		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	34	72.3	9	26.5	25	73.5	24	66.7	7	29.2	17	70.8	0.4975	0.73	0.27	2.01		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	13	27.7	3	23.1	10	76.9	12	33.3	1	8.3	11	91.7	0.5006	2.15	0.22	20.95		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4480	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4480	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	34	72.3	4	11.8	30	88.2	24	66.7	2	8.3	22	91.7	0.9022	1.14	0.20	6.47		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	13	27.7	3	23.1	10	76.9	12	33.3	0	-	12	100.0	0.1485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	34	72.3	1	2.9	33	97.1	24	66.7	4	16.7	20	83.3	0.0496	0.16	0.02	1.44		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.7804	0.59	0.03	9.91		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES		Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES		Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	34	72.3	9	26.5	25	73.5	24	66.7	4	16.7	20	83.3	0.5482	1.37	0.42	4.50		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	13	27.7	2	15.4	11	84.6	12	33.3	2	16.7	10	83.3	0.8152	0.80	0.11	5.75		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.2457	0.32	0.03	3.58		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	FLUSHING	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	FLUSHING	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMATOMA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMATOMA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.2362	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	34	72.3	4	11.8	30	88.2	24	66.7	2	8.3	22	91.7	0.9345	1.09	0.20	6.10		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	VENOUS THROMBOSIS	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.2362	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	VENOUS THROMBOSIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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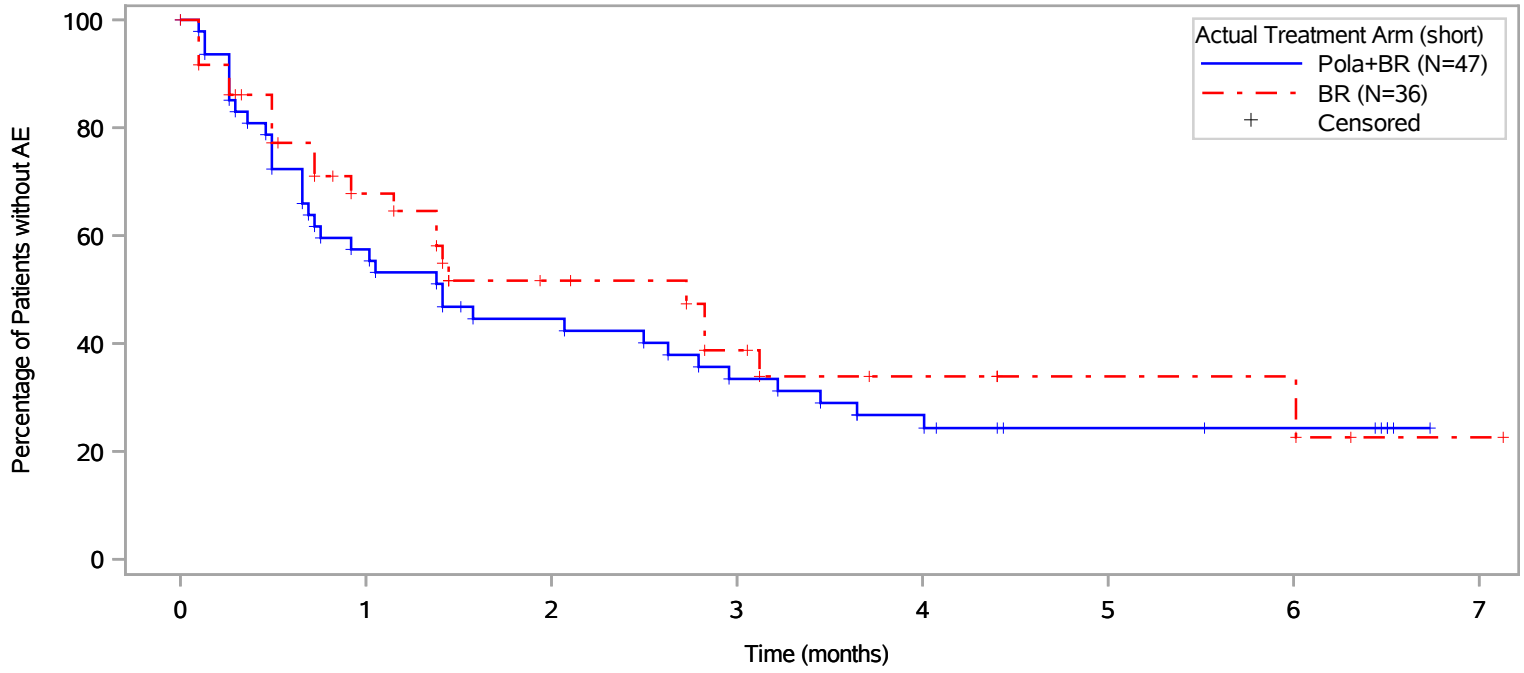
30NOV2022 18:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk								
Pola+BR (N=47)	47	27	20	15	11	7	6	NE
BR (N=36)	36	21	13	9	6	3	3	1
Patients censored								
Pola+BR (N=47)	0	0	1	1	2	5	6	NE
BR (N=36)	0	4	7	8	10	13	13	14

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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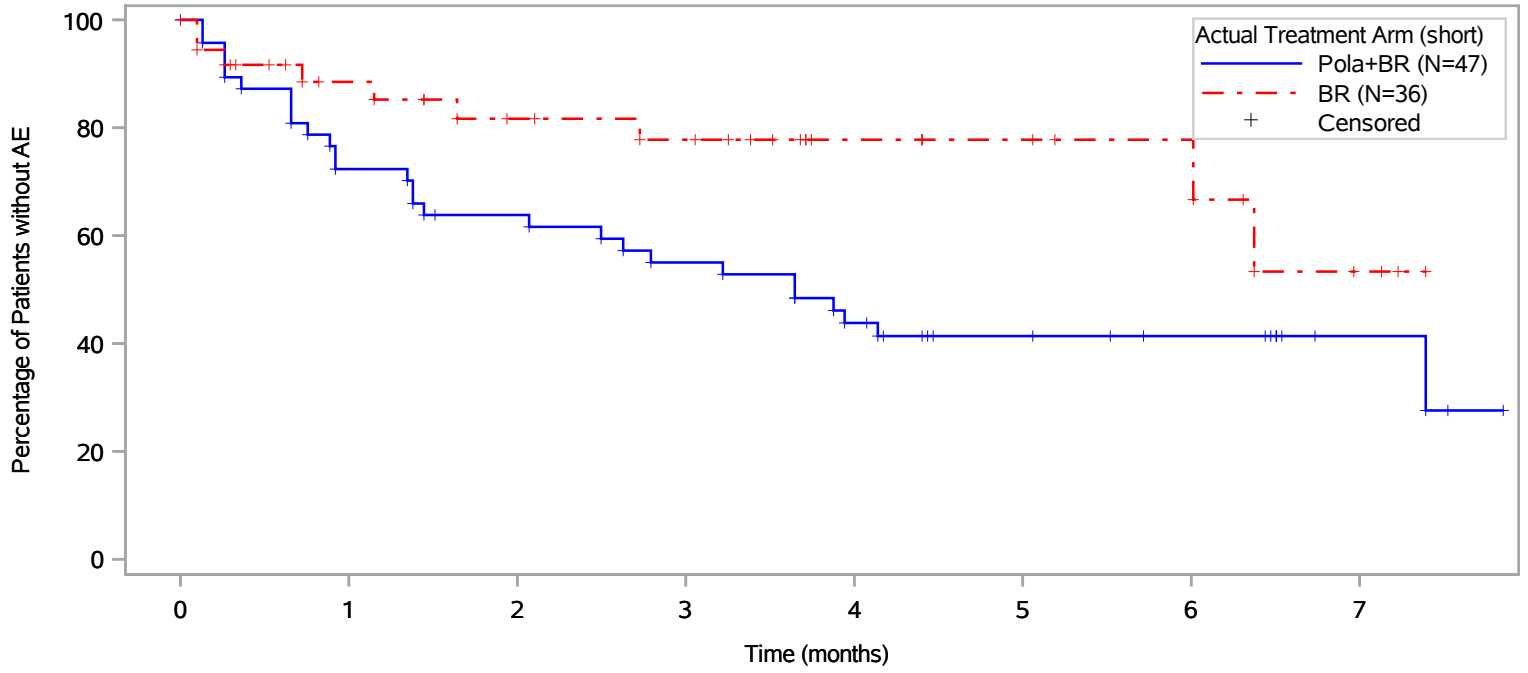
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk								
Pola+BR (N=47)	47	34	29	25	19	13	10	3
BR (N=36)	36	27	22	20	12	9	7	3
Patients censored								
Pola+BR (N=47)	0	0	1	1	2	7	10	17
BR (N=36)	0	5	8	9	17	20	22	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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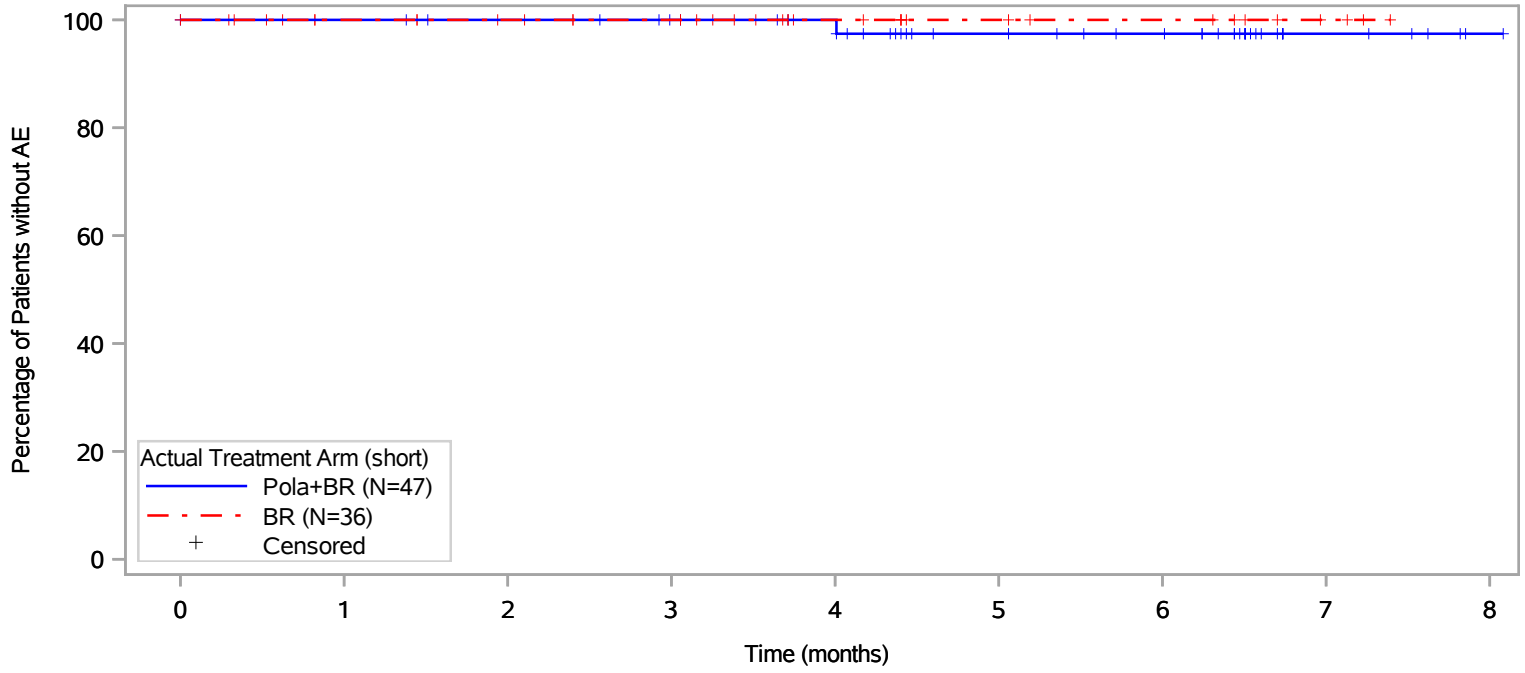
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, COAGULOPATHY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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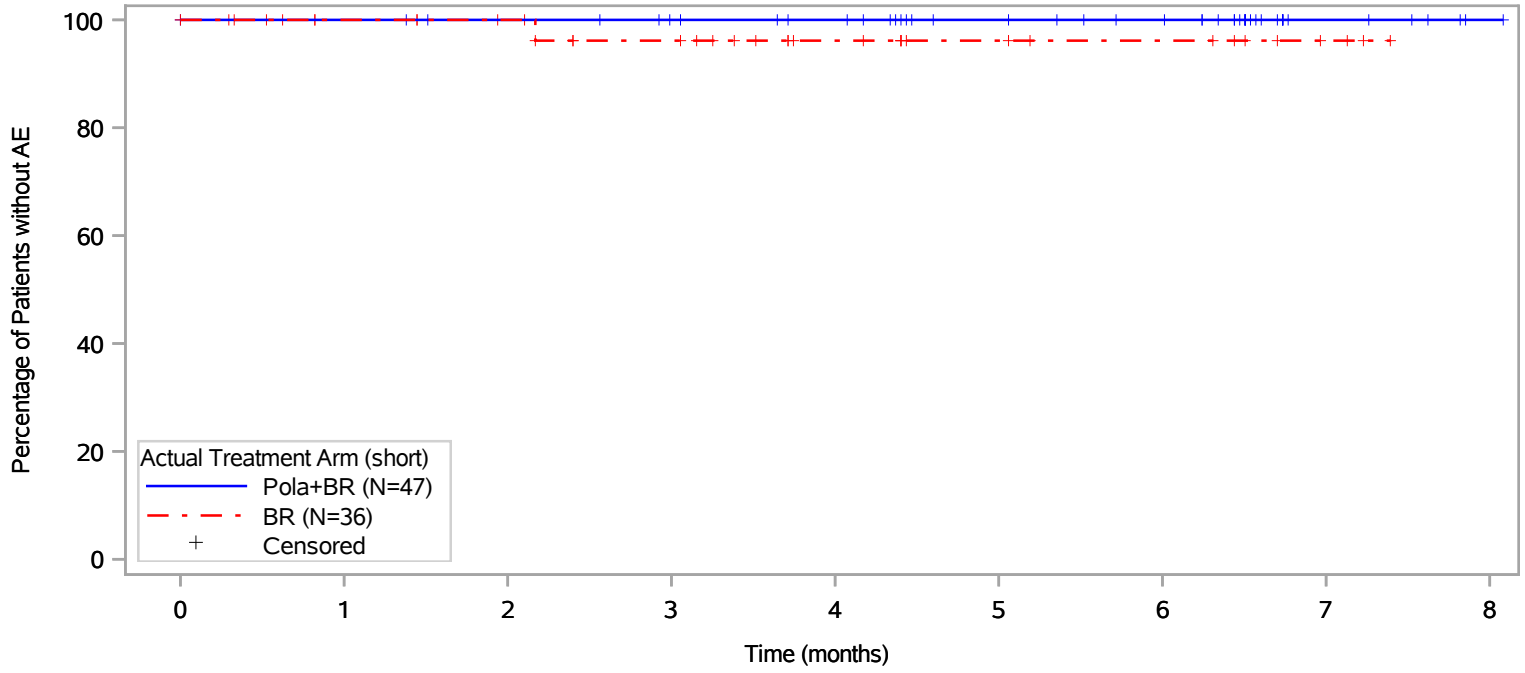
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE BONE MARROW APLASIA

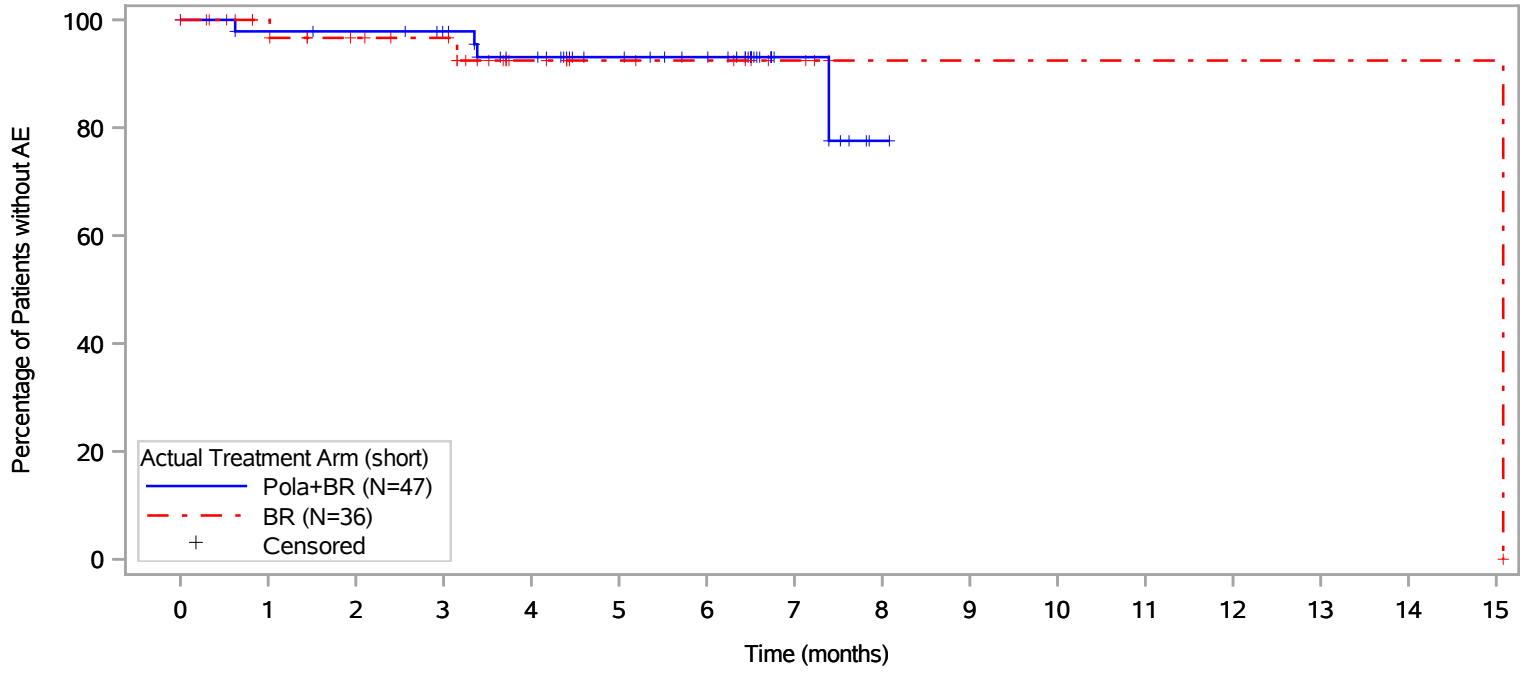


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk																
Pola+BR (N=47)	47	46	45	42	37	29	25	6	1	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	26	24	14	9	8	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=47)	0	0	1	4	7	15	19	38	42	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	11	20	25	26	30	33	33	33	33	33	33	33	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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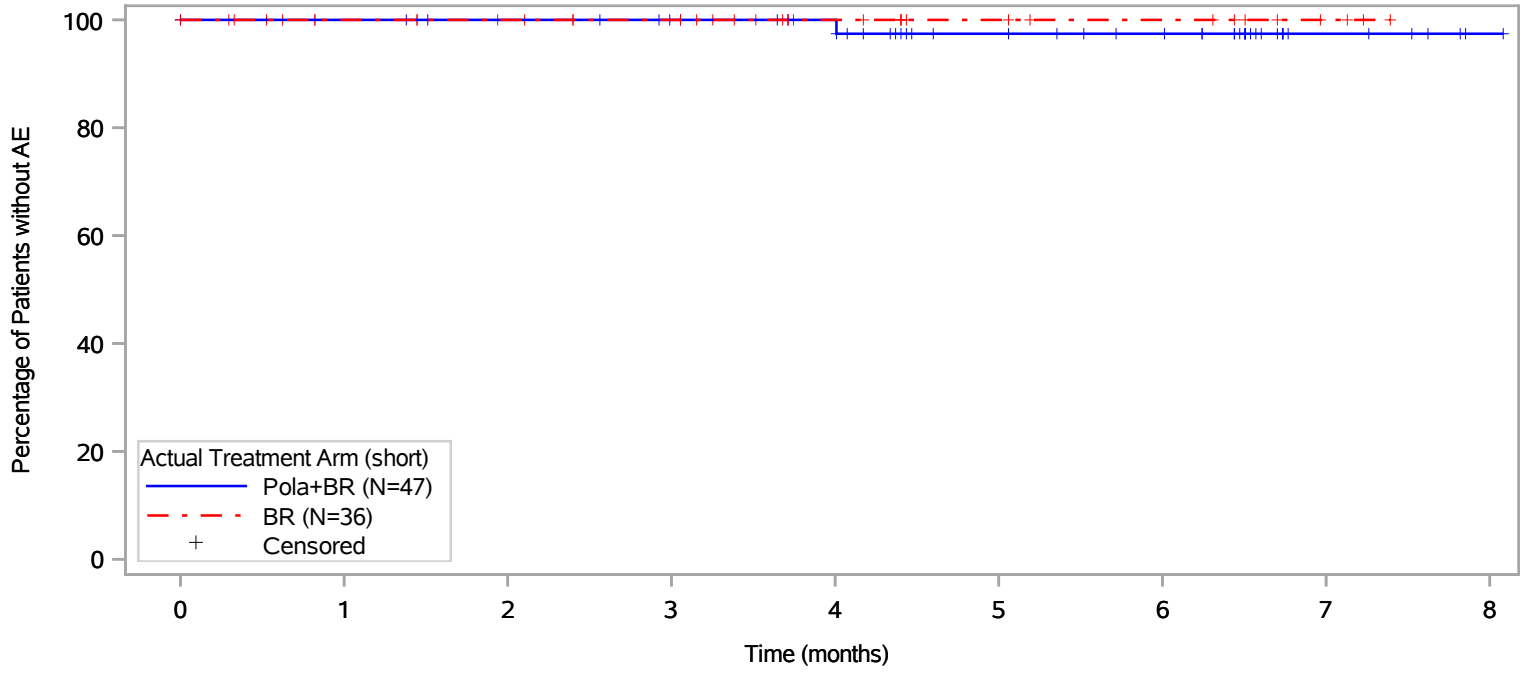
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, HYPOGLOBULINAEMIA

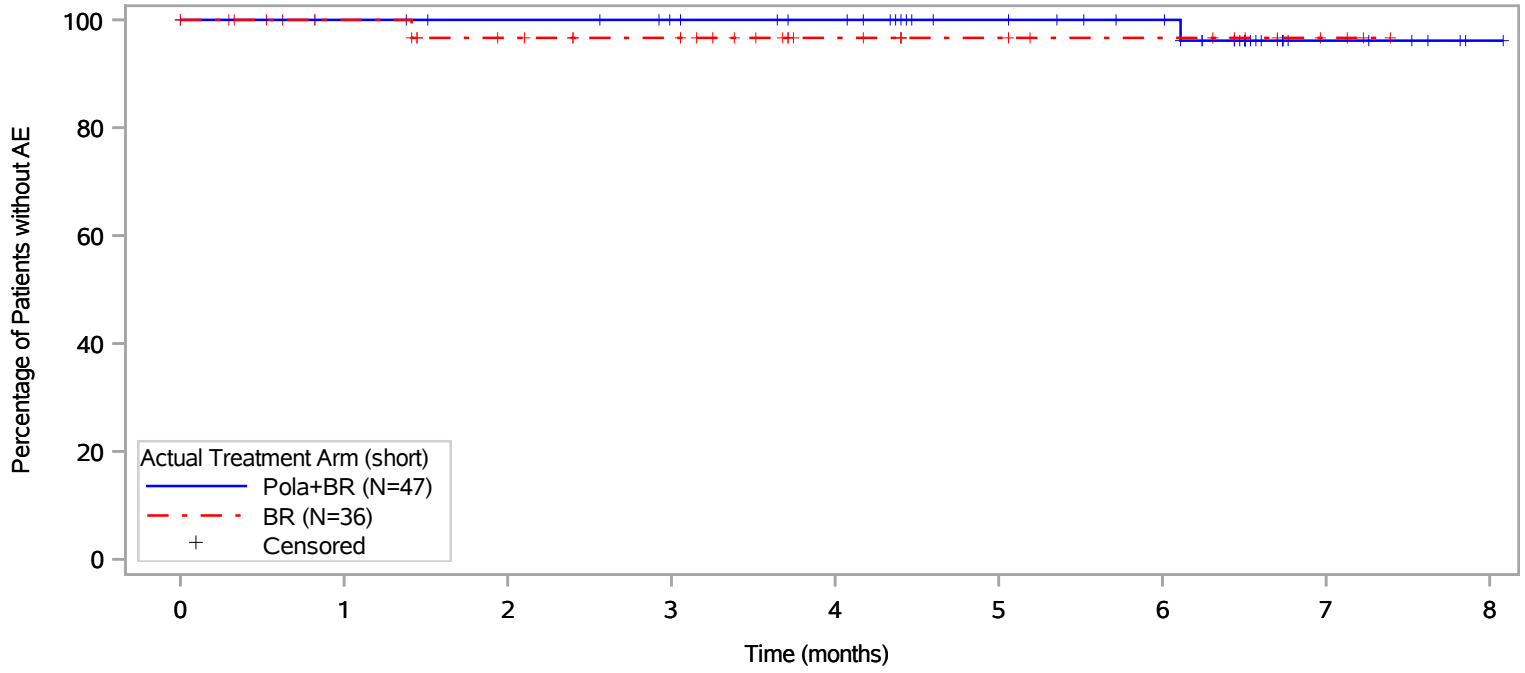


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOCYTOSIS



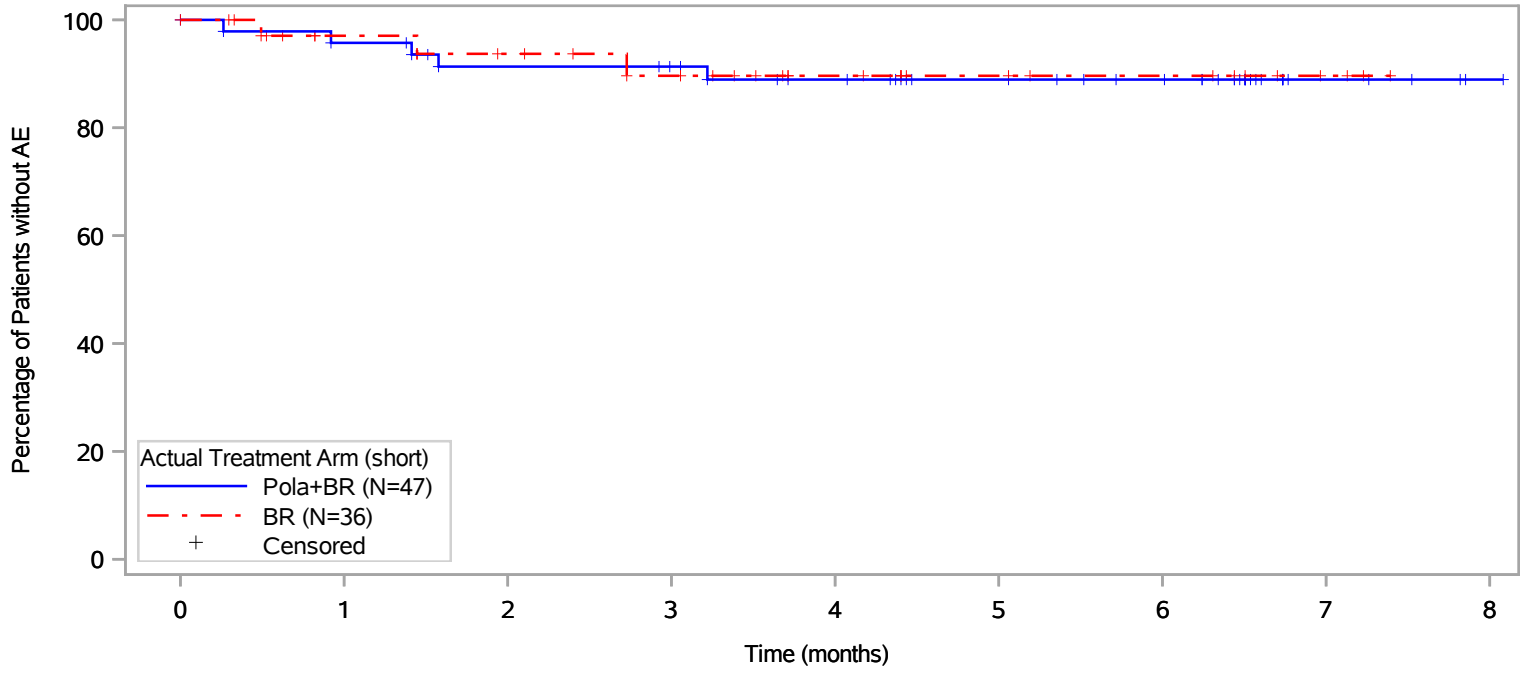
Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA

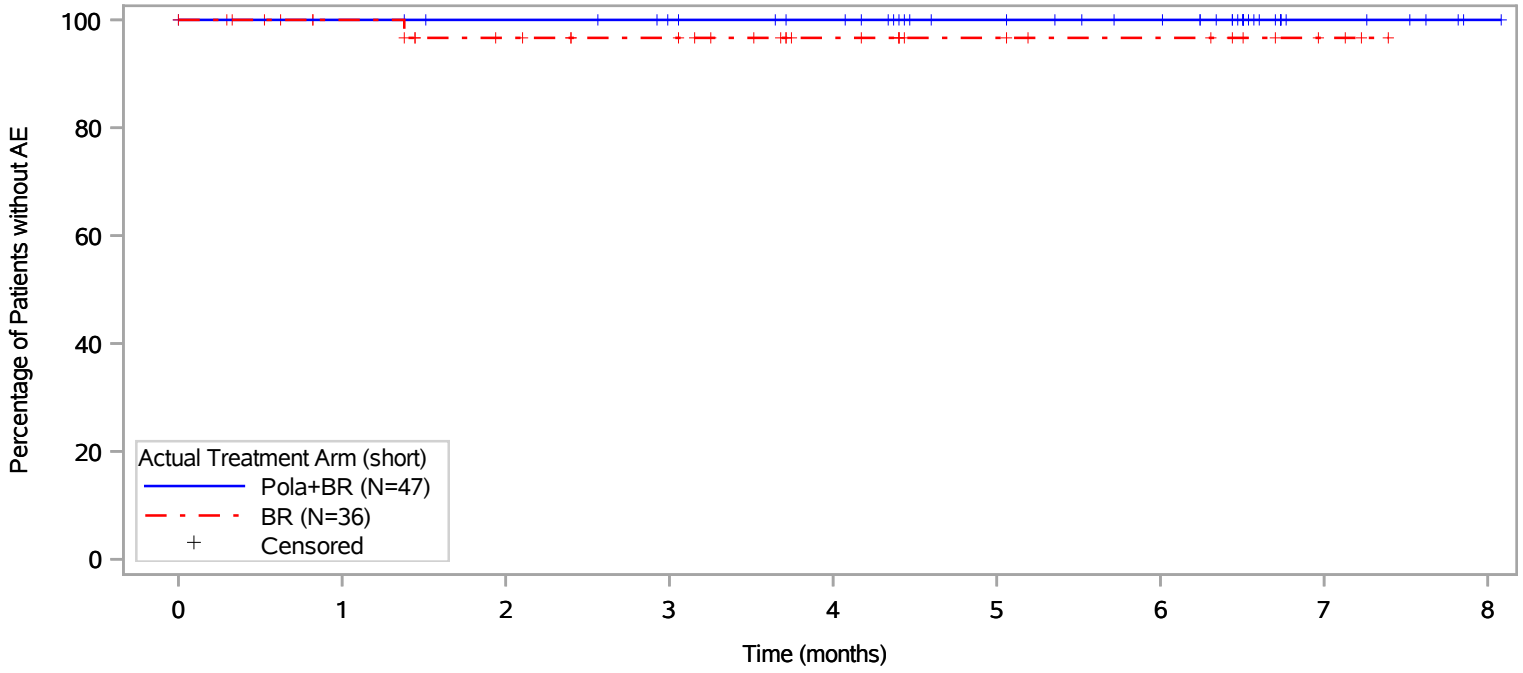


Patients at risk									
Pola+BR (N=47)	47	45	41	39	35	29	25	5	1
BR (N=36)	36	29	25	22	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	13	17	37	41
BR (N=36)	0	6	9	11	18	23	25	30	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPH NODE PAIN



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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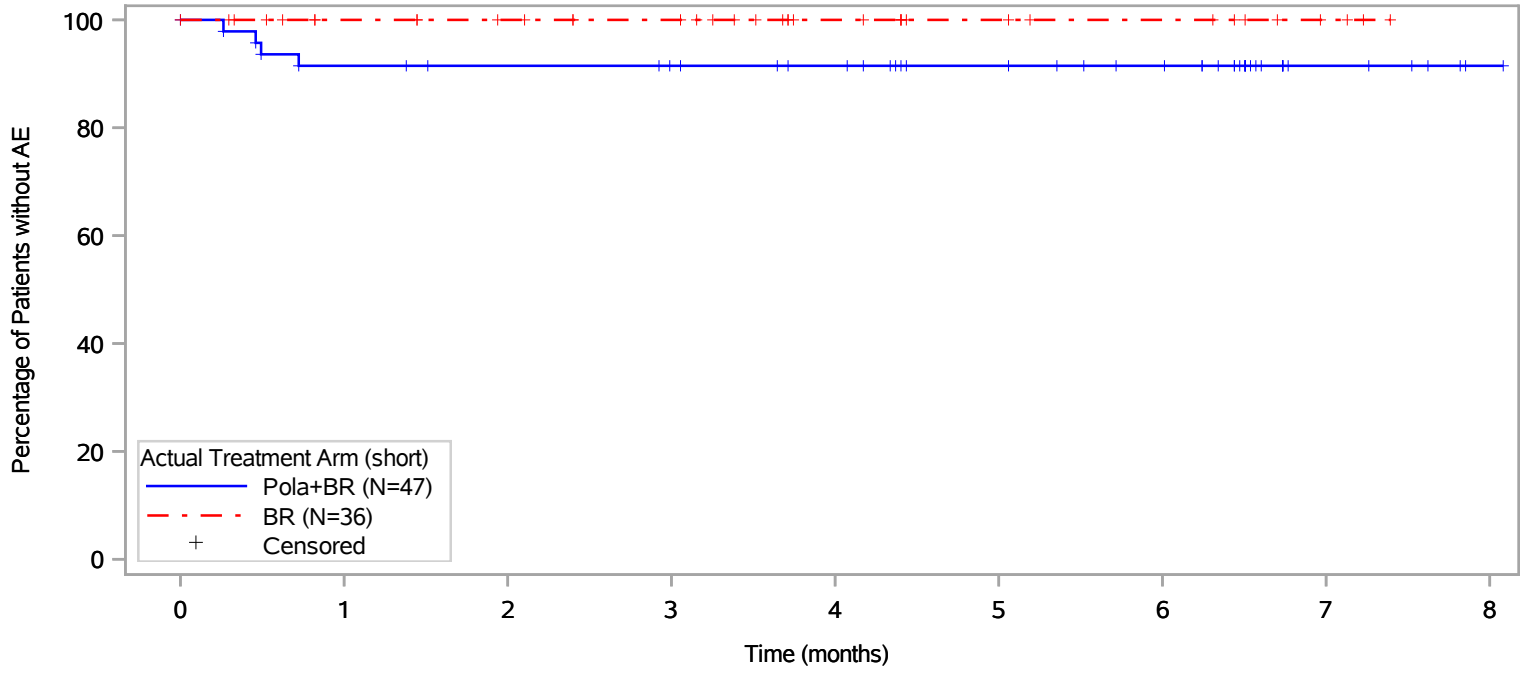
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

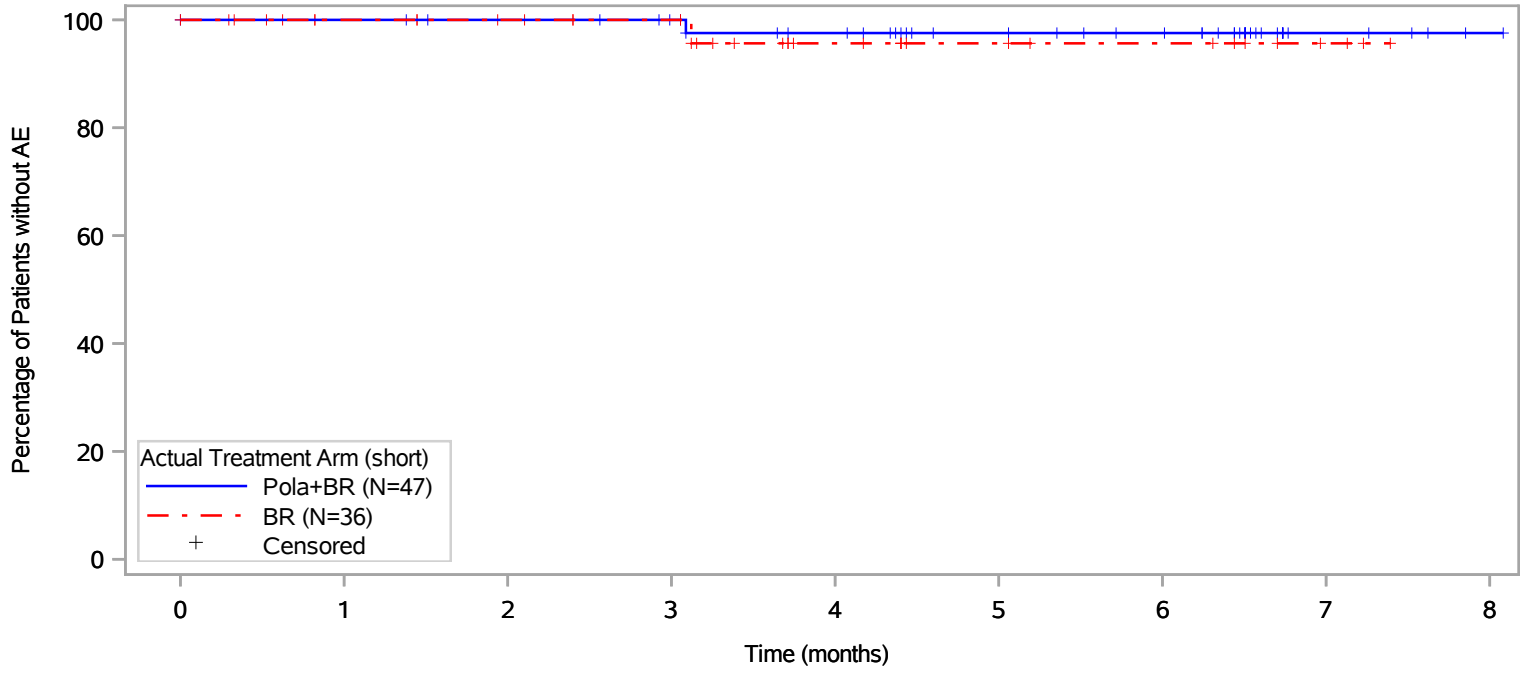
BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA



Patients at risk									
Pola+BR (N=47)	47	43	41	39	36	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	13	17	37	42
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, MYELOSUPPRESSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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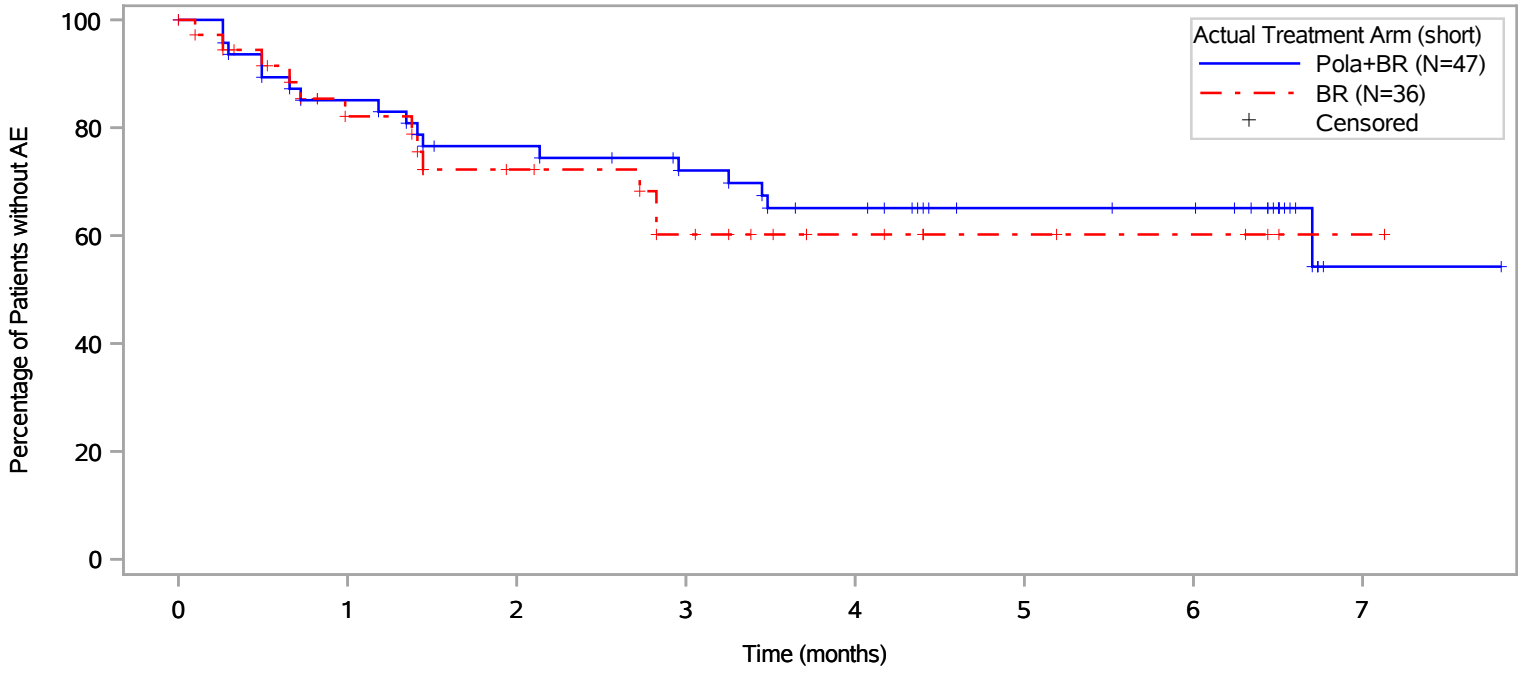
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk								
Pola+BR (N=47)	47	40	35	31	27	20	19	1
BR (N=36)	36	25	19	15	9	5	4	1
Patients censored								
Pola+BR (N=47)	0	0	1	3	4	11	12	29
BR (N=36)	0	5	8	9	15	19	20	23

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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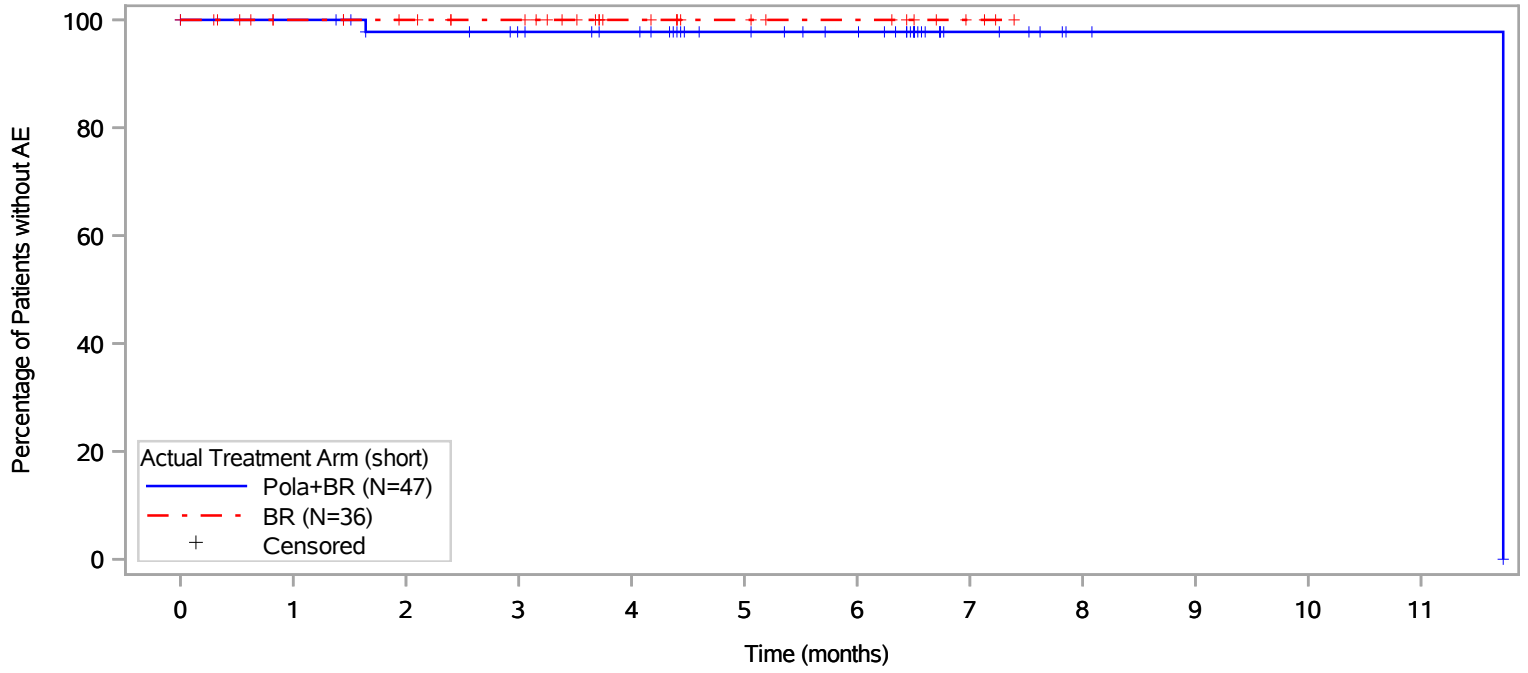
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA

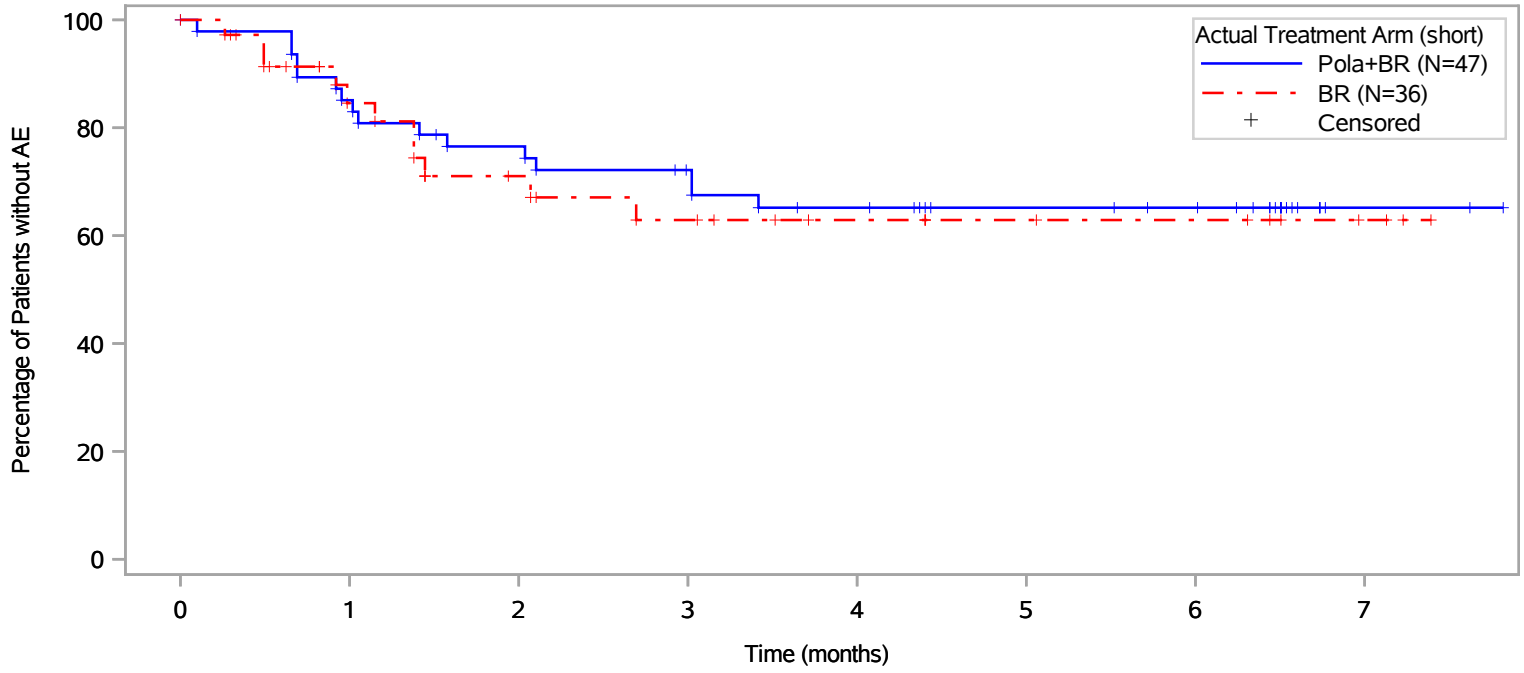


Patients at risk												
Pola+BR (N=47)	47	47	44	41	38	30	26	7	2	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44	45	45	45
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk								
Pola+BR (N=47)	47	40	35	31	27	22	20	2
BR (N=36)	36	25	18	15	11	8	7	3
Patients censored								
Pola+BR (N=47)	0	0	1	3	4	9	11	29
BR (N=36)	0	6	9	10	14	17	18	22

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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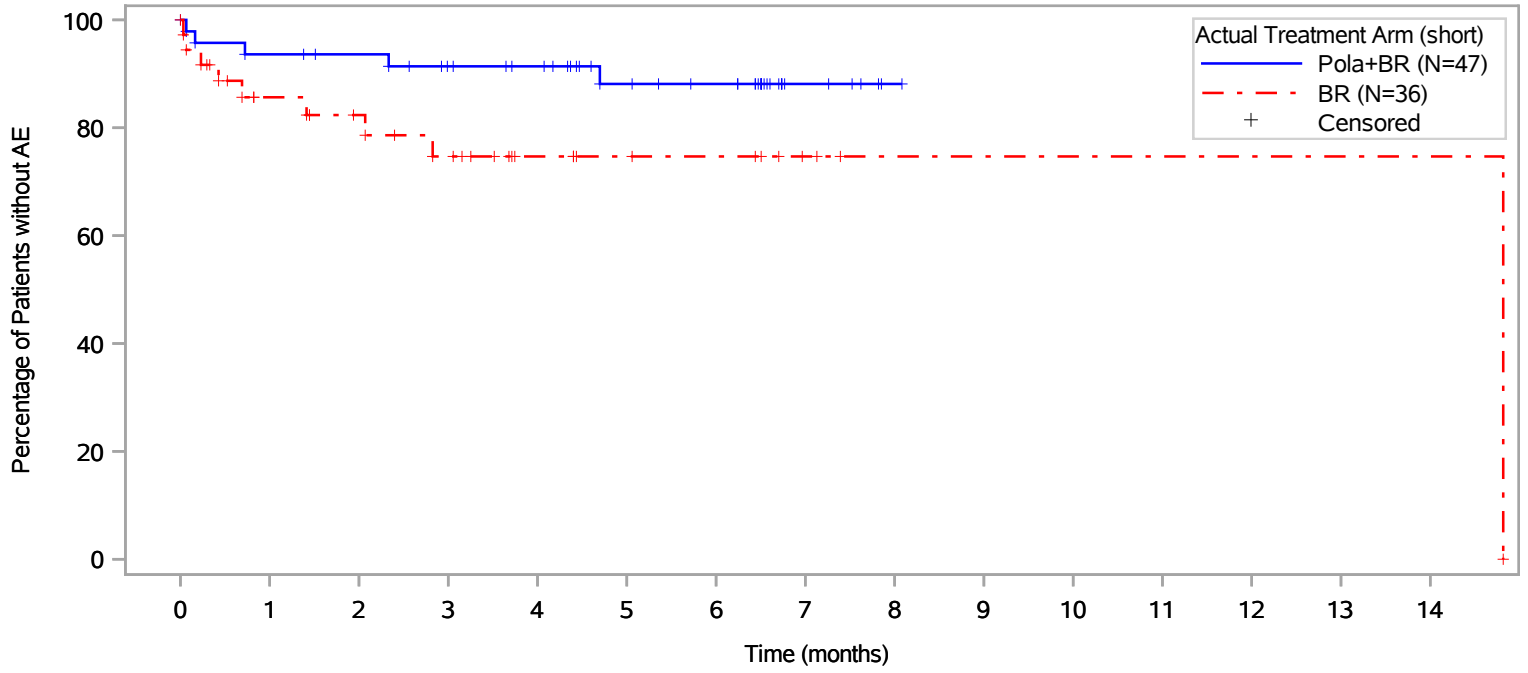
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk															
Pola+BR (N=47)	47	44	42	38	35	27	24	6	1	NE	NE	NE	NE	NE	NE
BR (N=36)	36	26	22	19	12	8	7	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	15	18	36	41	NE	NE	NE	NE	NE	NE
BR (N=36)	0	5	8	9	16	20	21	25	27	27	27	27	27	27	27

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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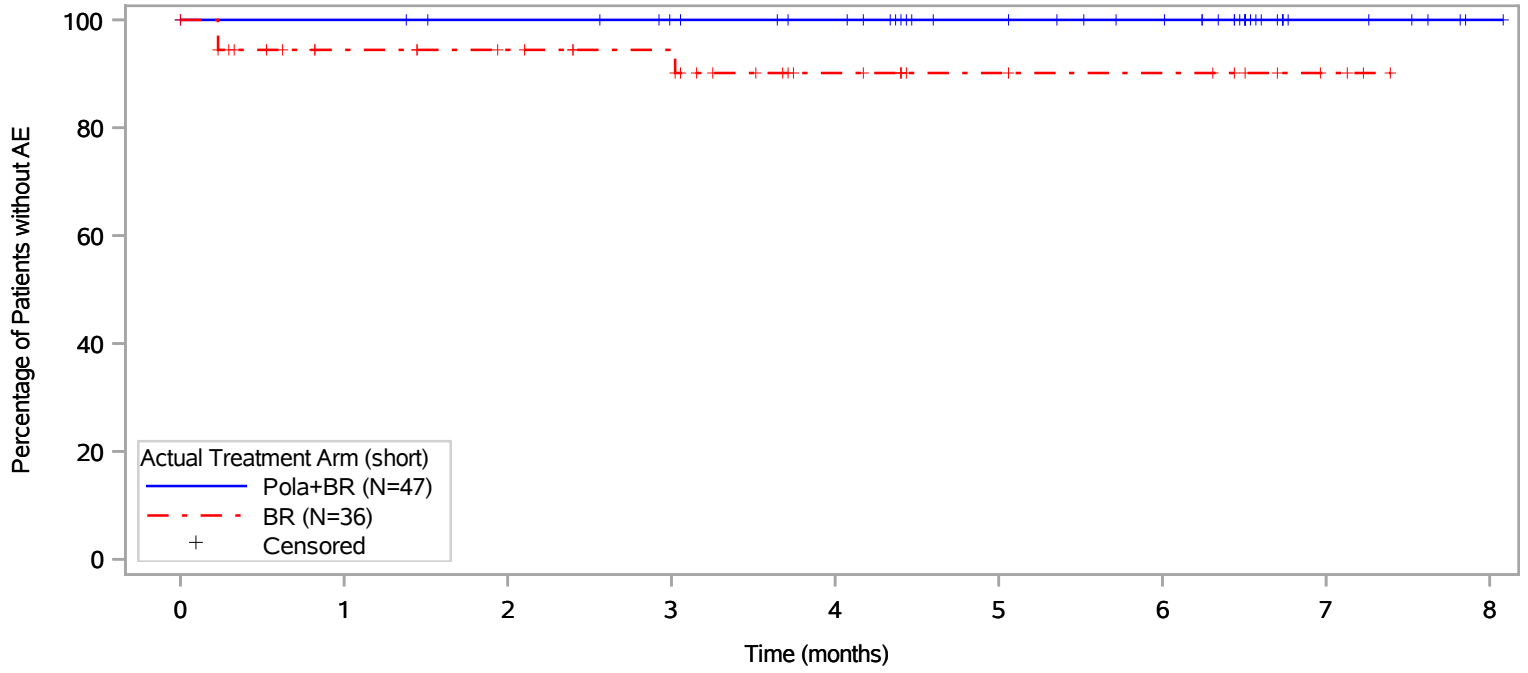
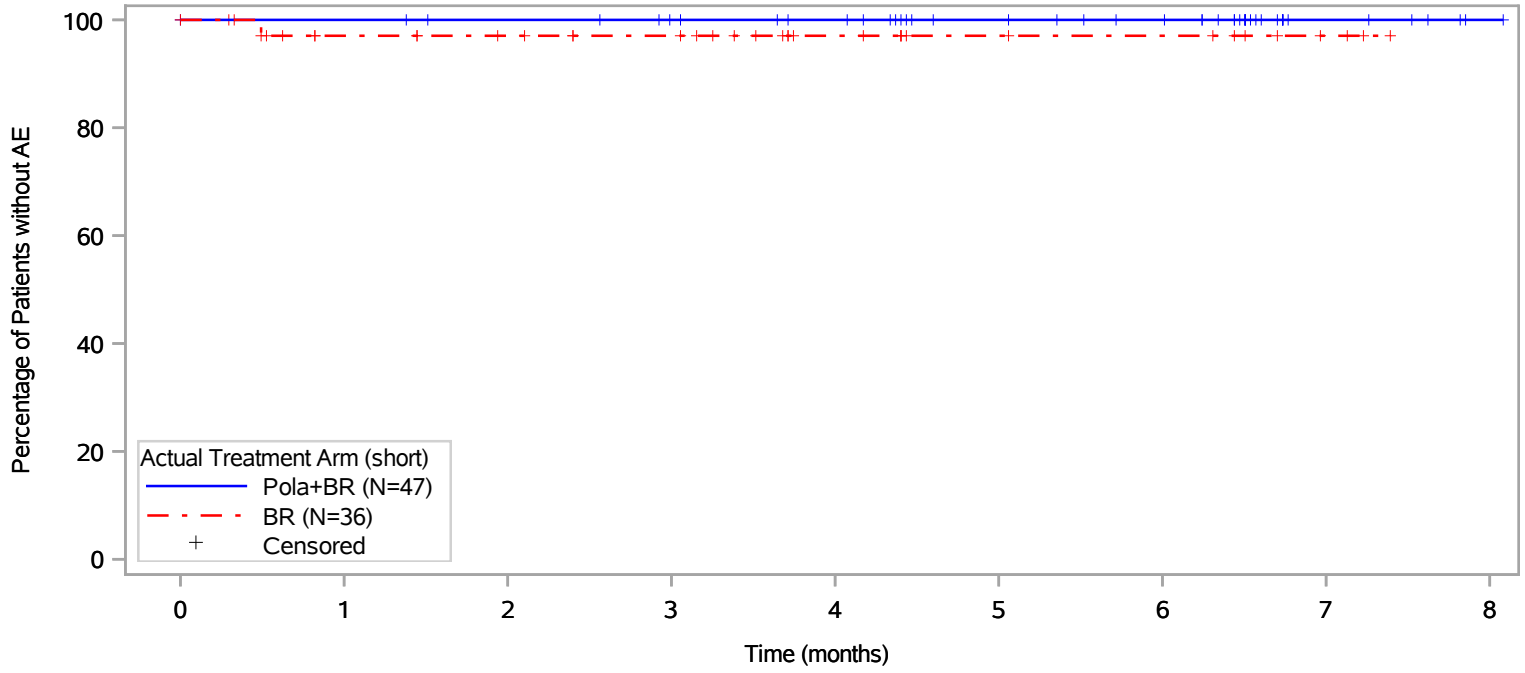
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	28	25	22	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	19	24	25	30	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FLUTTER



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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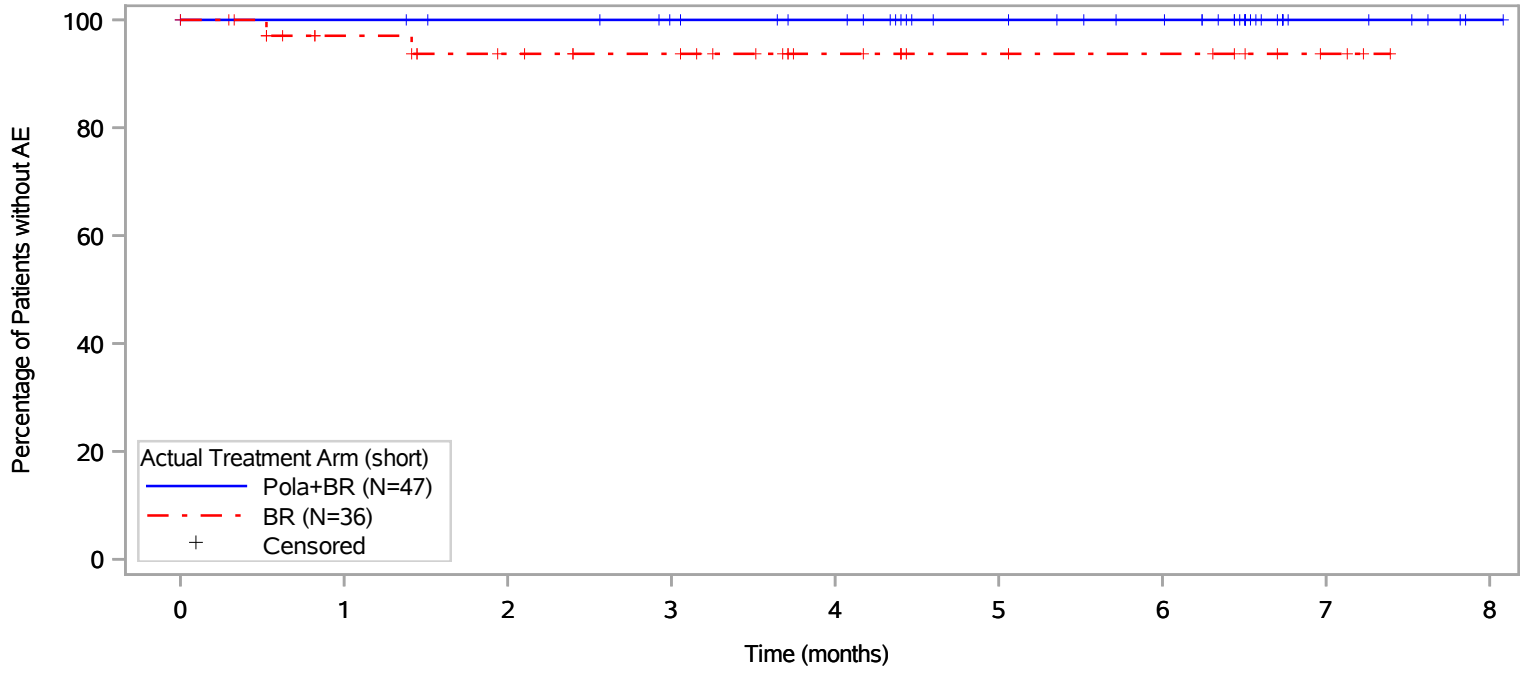
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

CARDIAC DISORDERS, ATRIOVENTRICULAR BLOCK FIRST DEGREE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	25	22	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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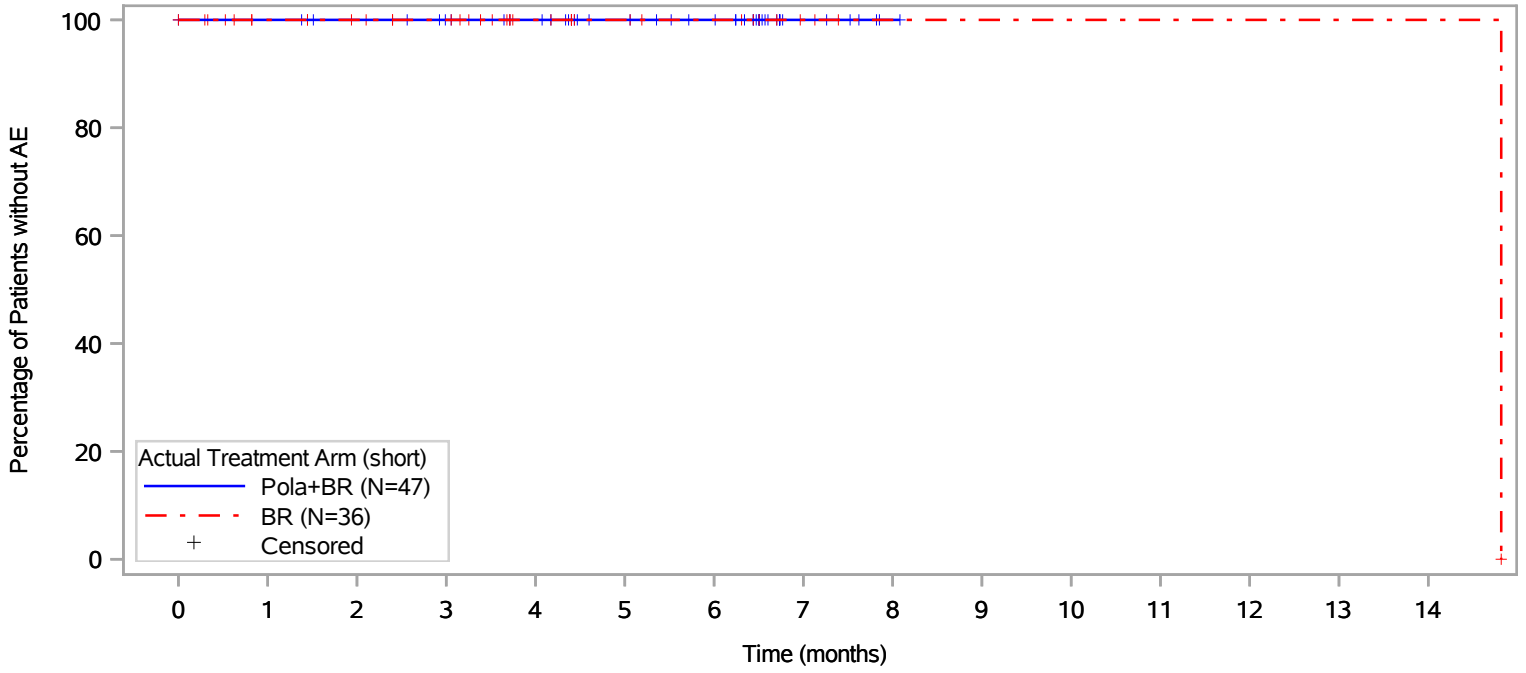
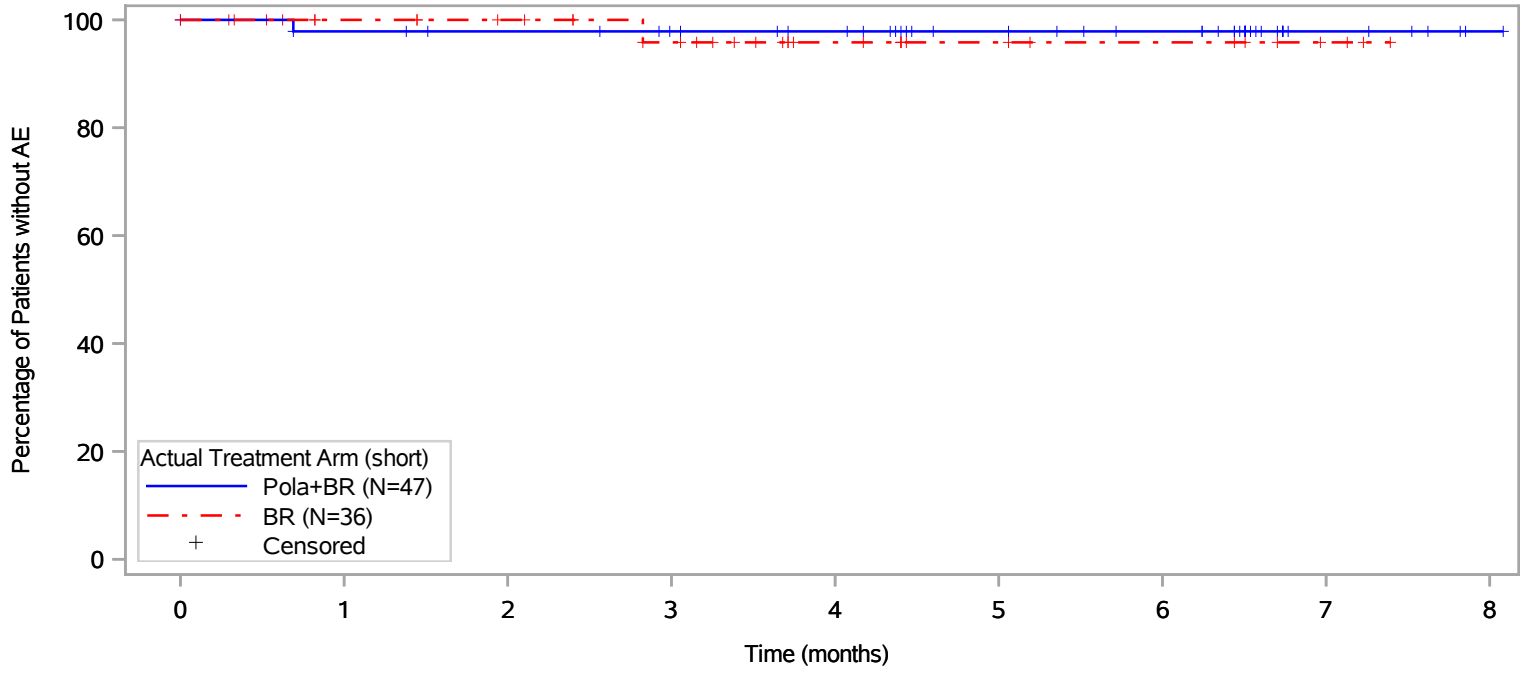
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, CARDIAC FAILURE



Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	33	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

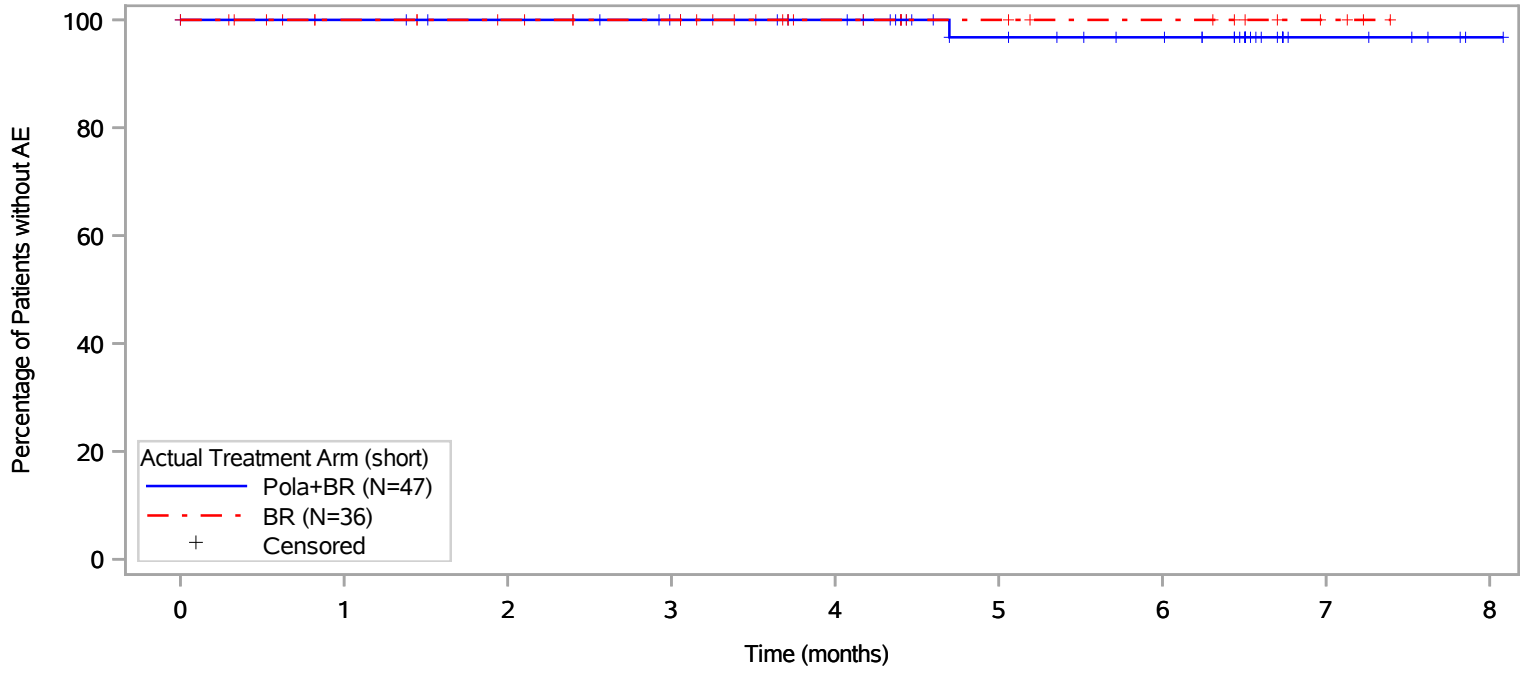
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, PALPITATIONS



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	23	14	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, PNEUMOPERICARDIUM



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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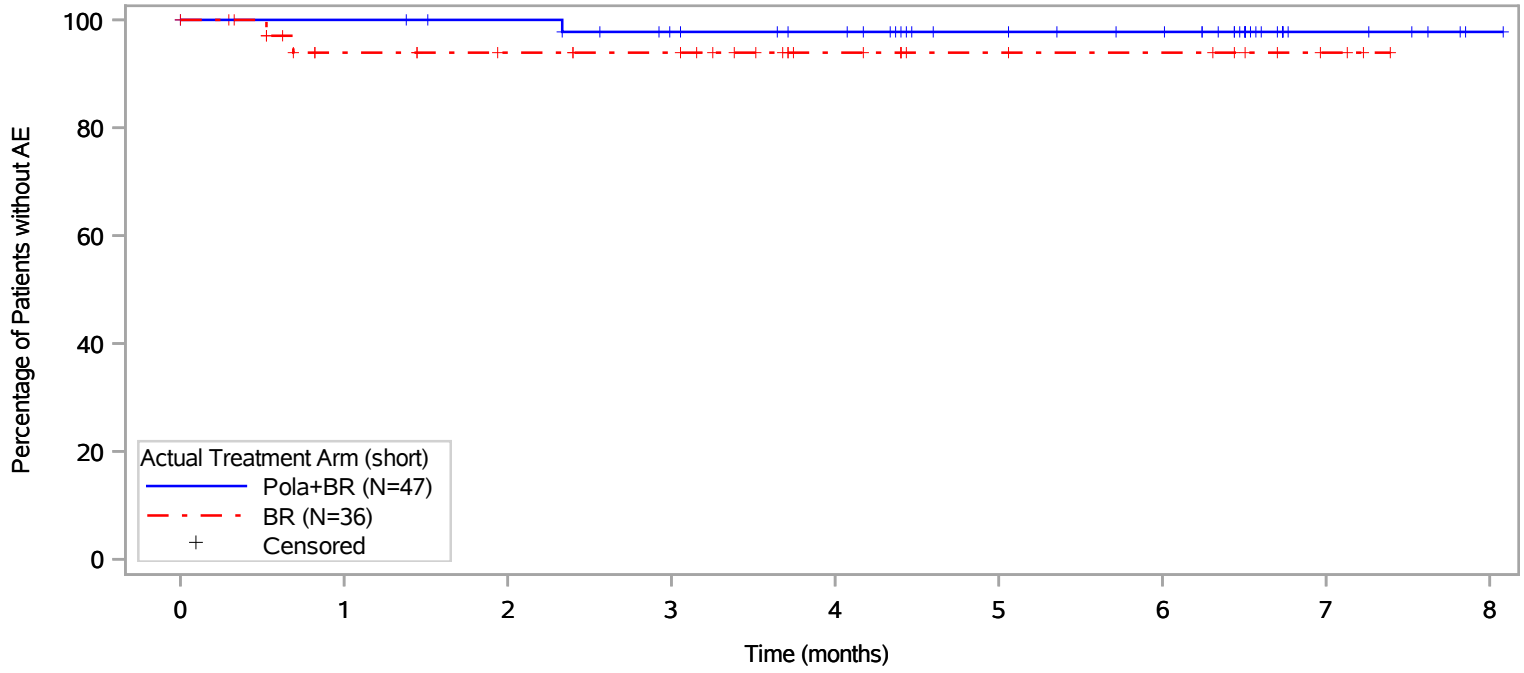
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SINUS TACHYCARDIA



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	27	6	1
BR (N=36)	36	28	25	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	11	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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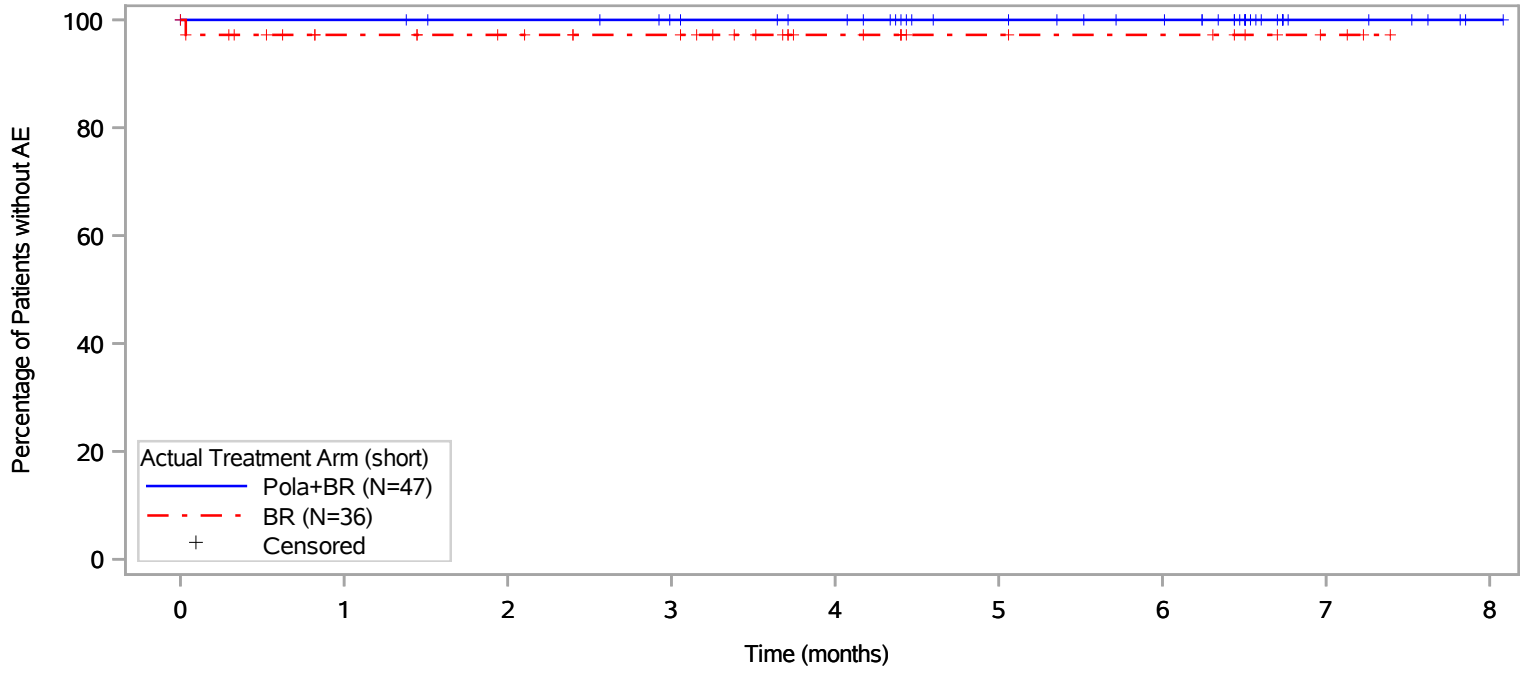
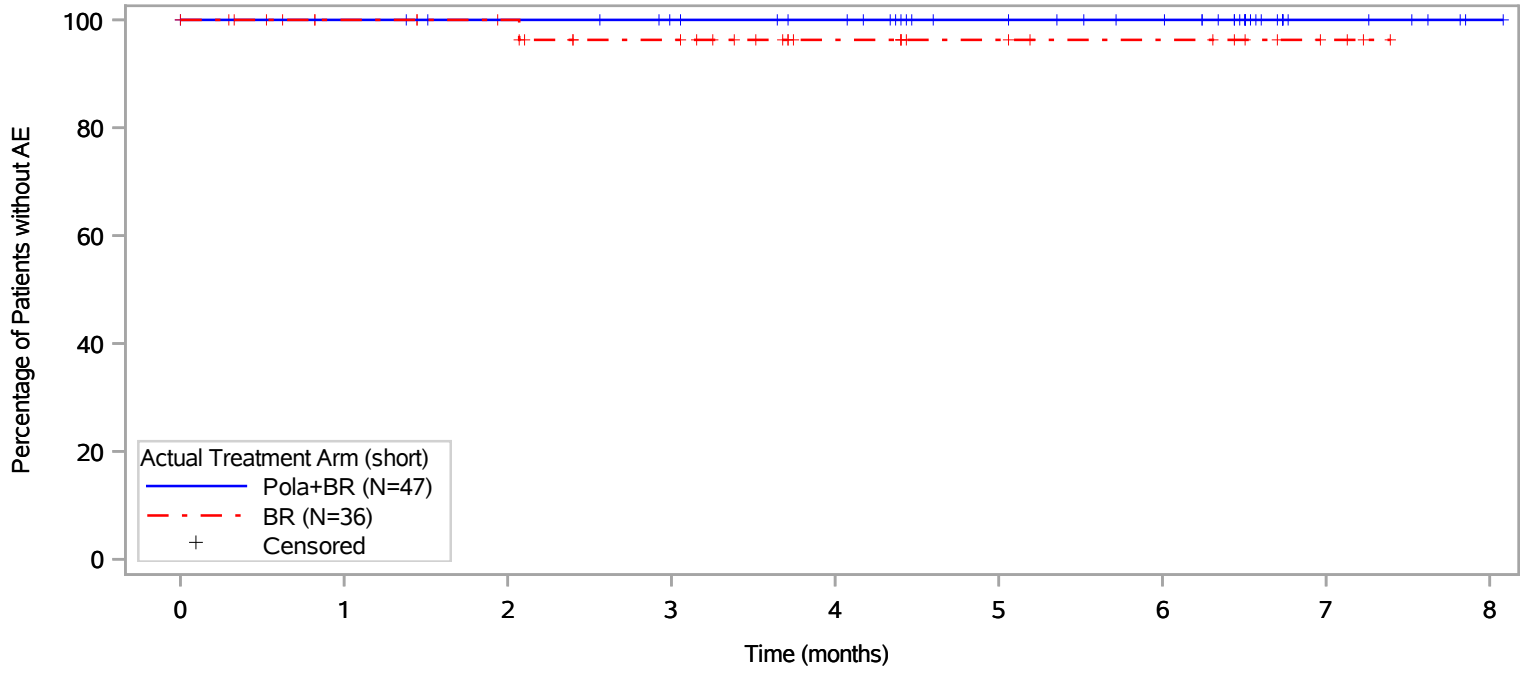
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SUPRAVENTRICULAR TACHYCARDIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

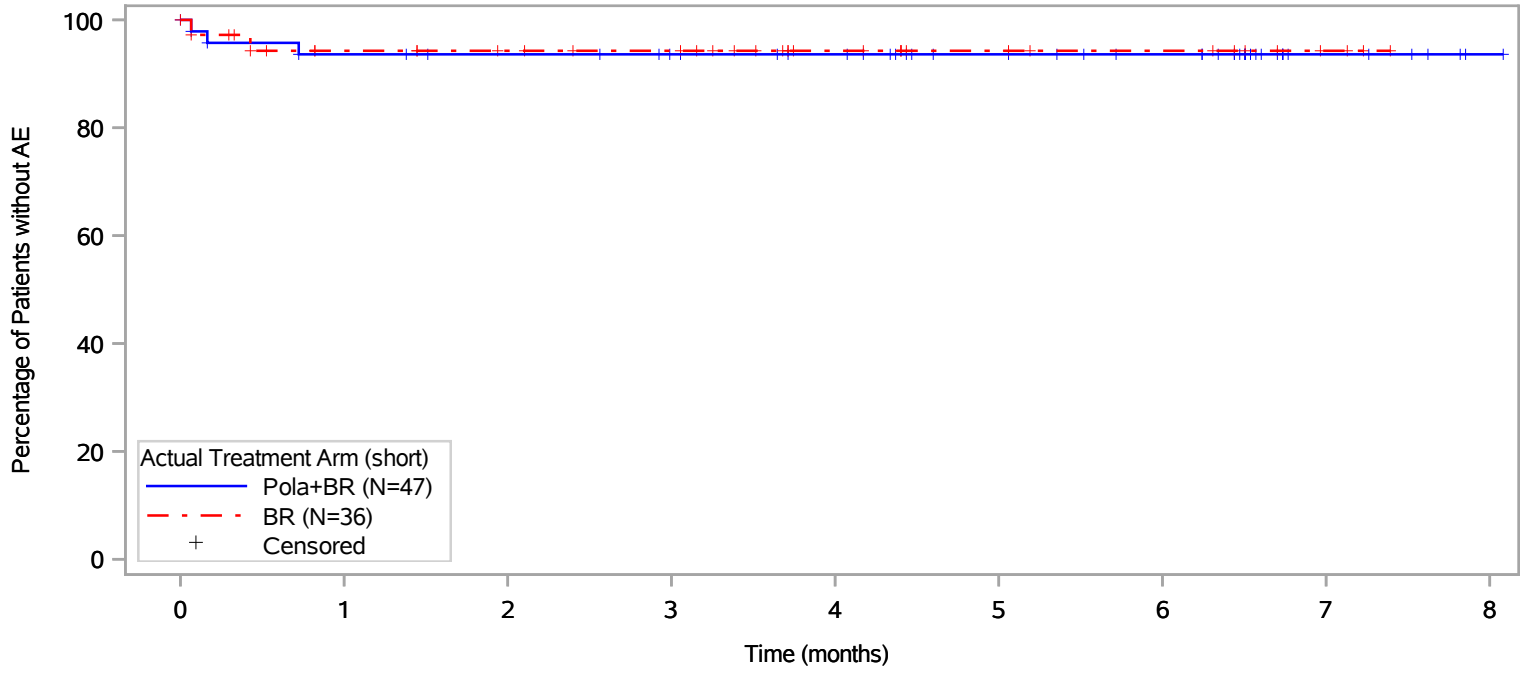
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYARRHYTHMIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=47)	47	44	42	39	36	29	25	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	38	43
BR (N=36)	0	5	8	10	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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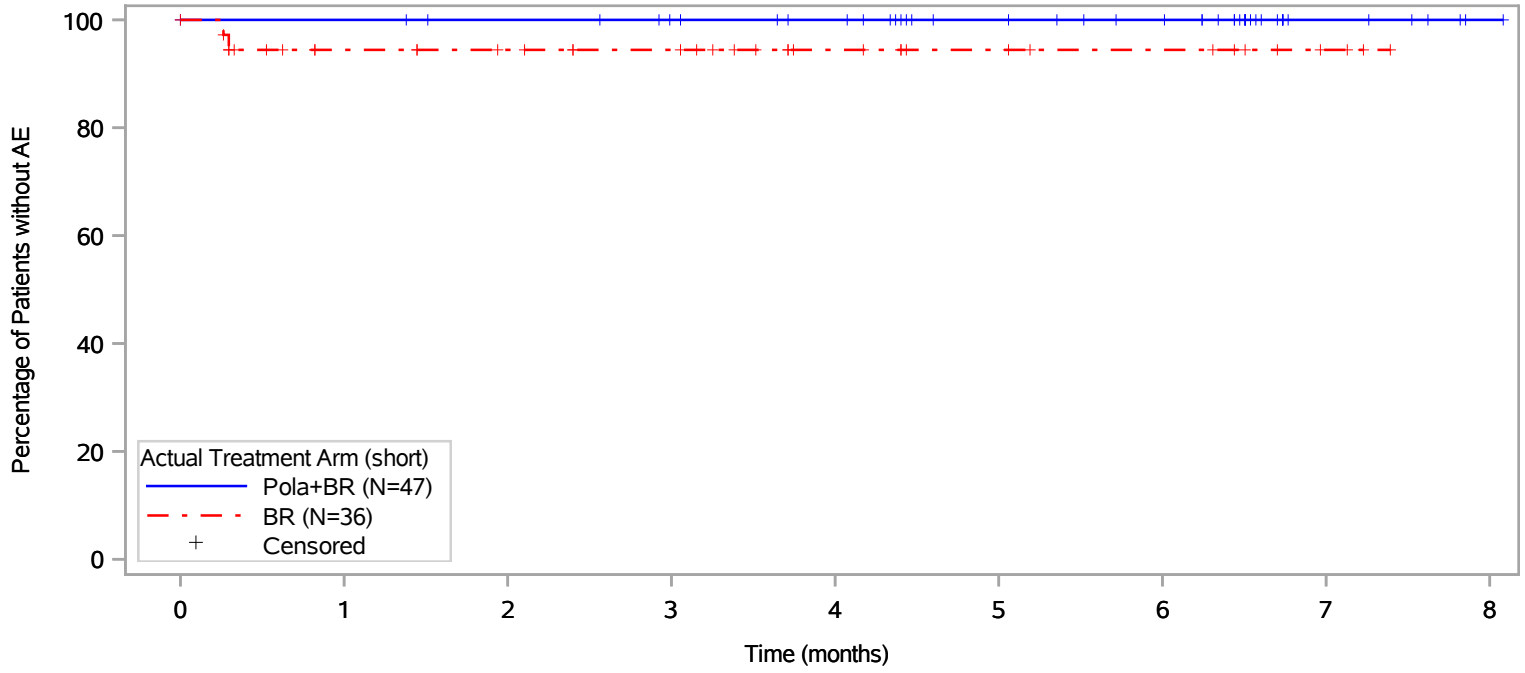
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, All

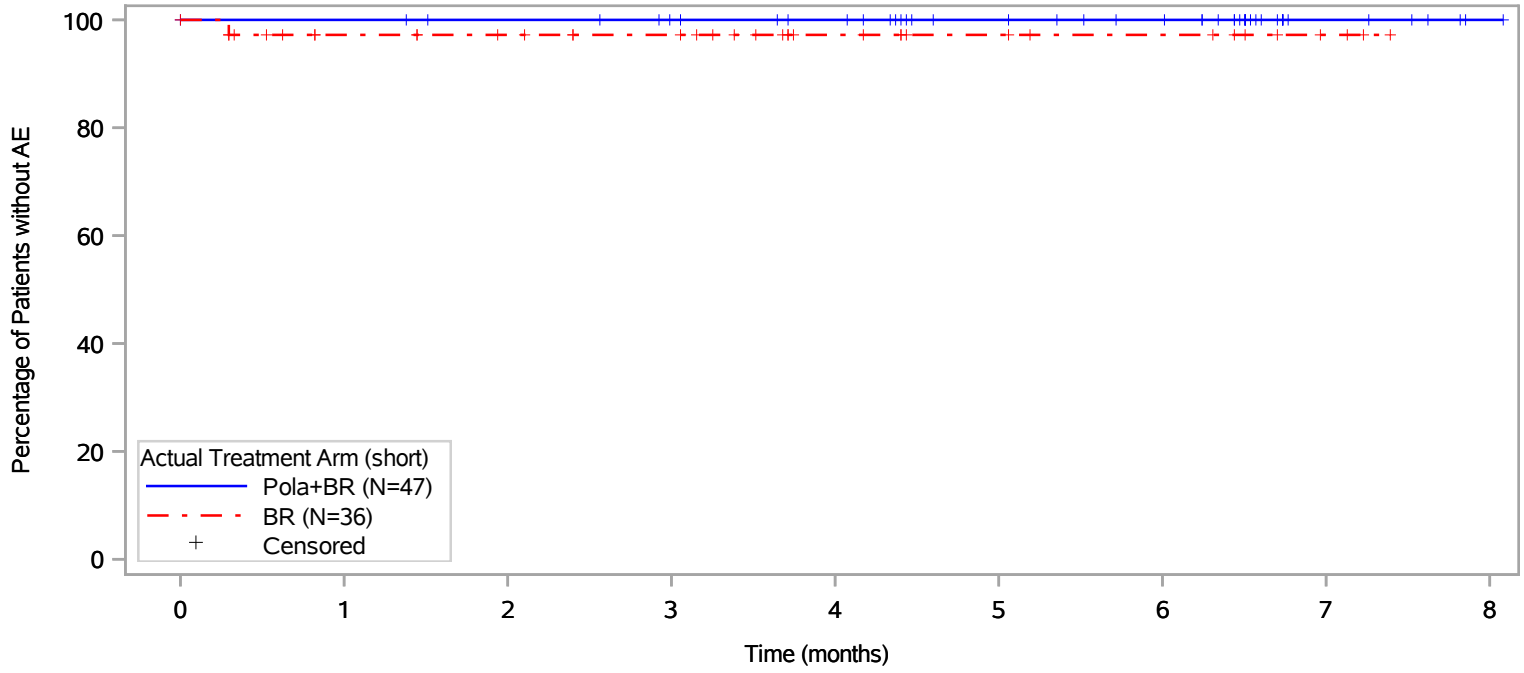


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	28	25	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

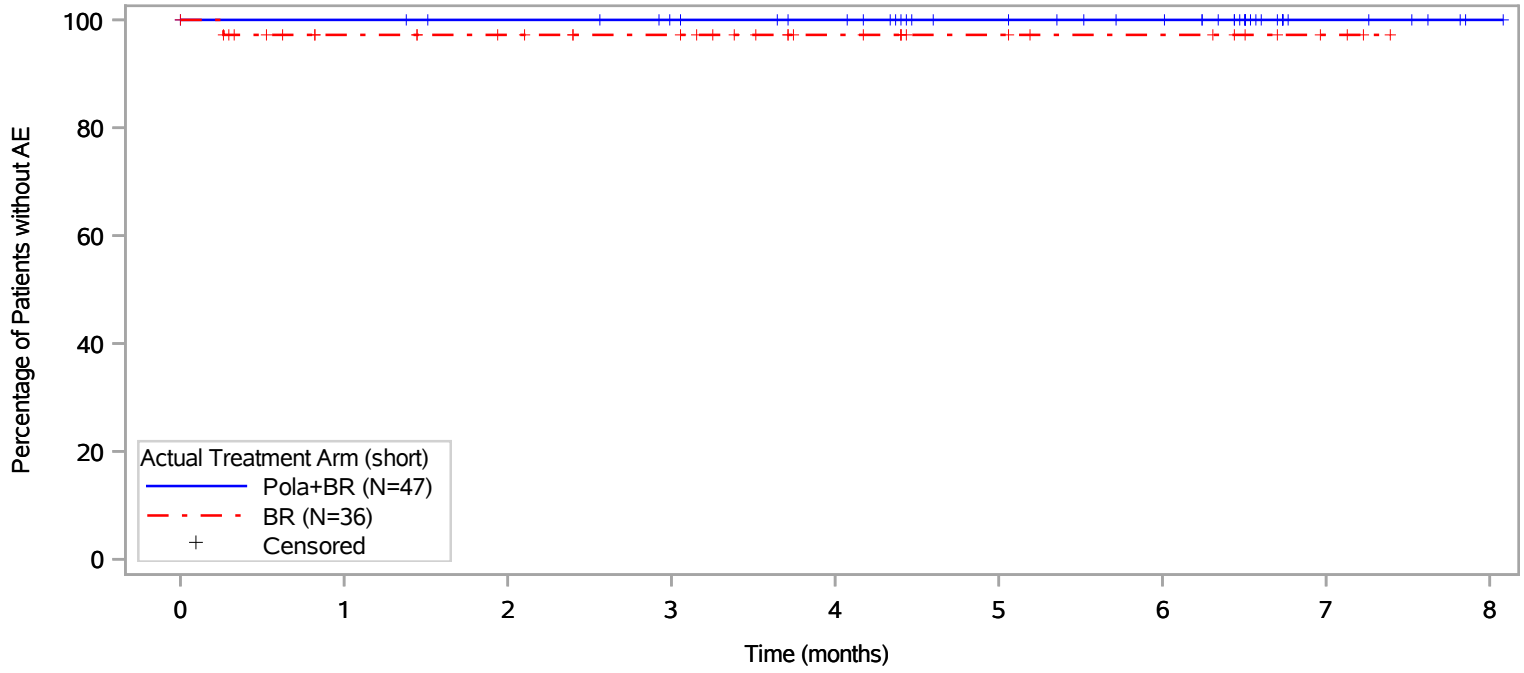
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, DEAFNESS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, TINNITUS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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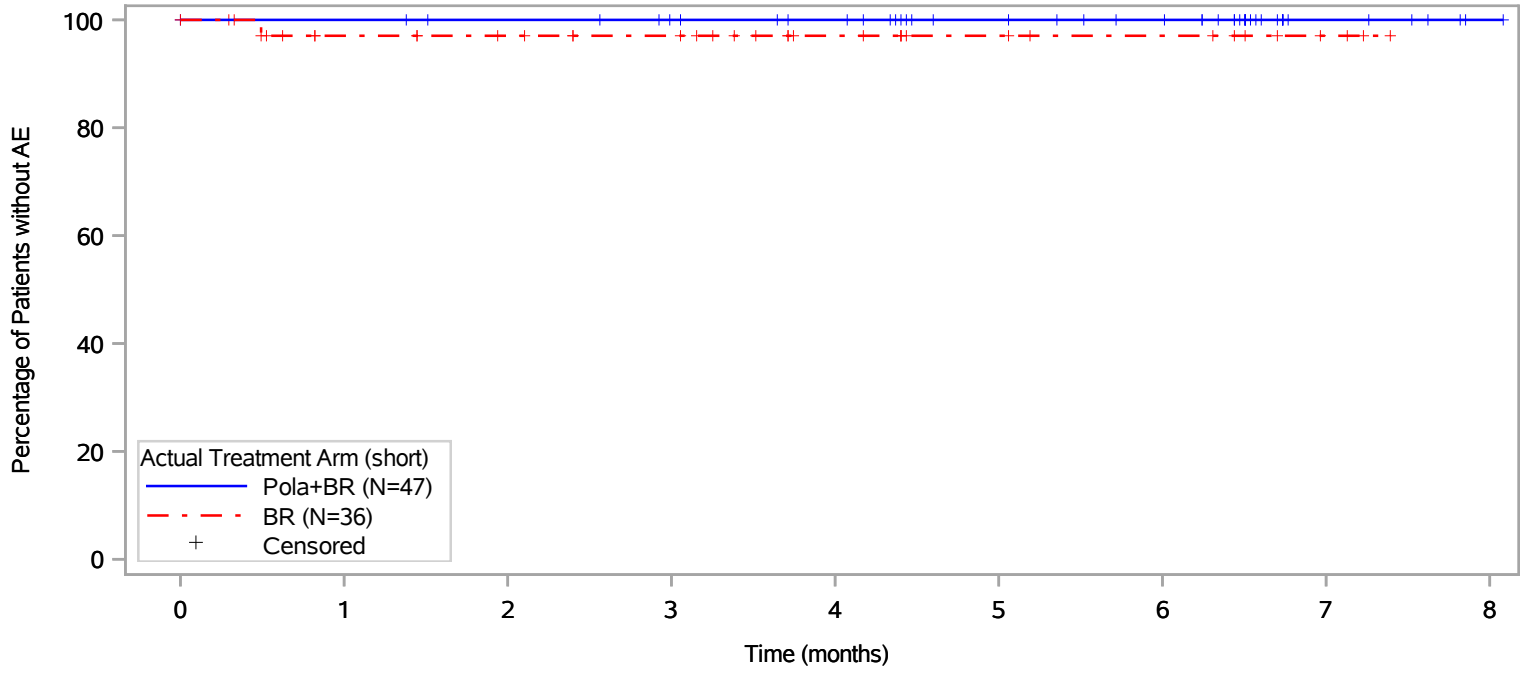
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EYE DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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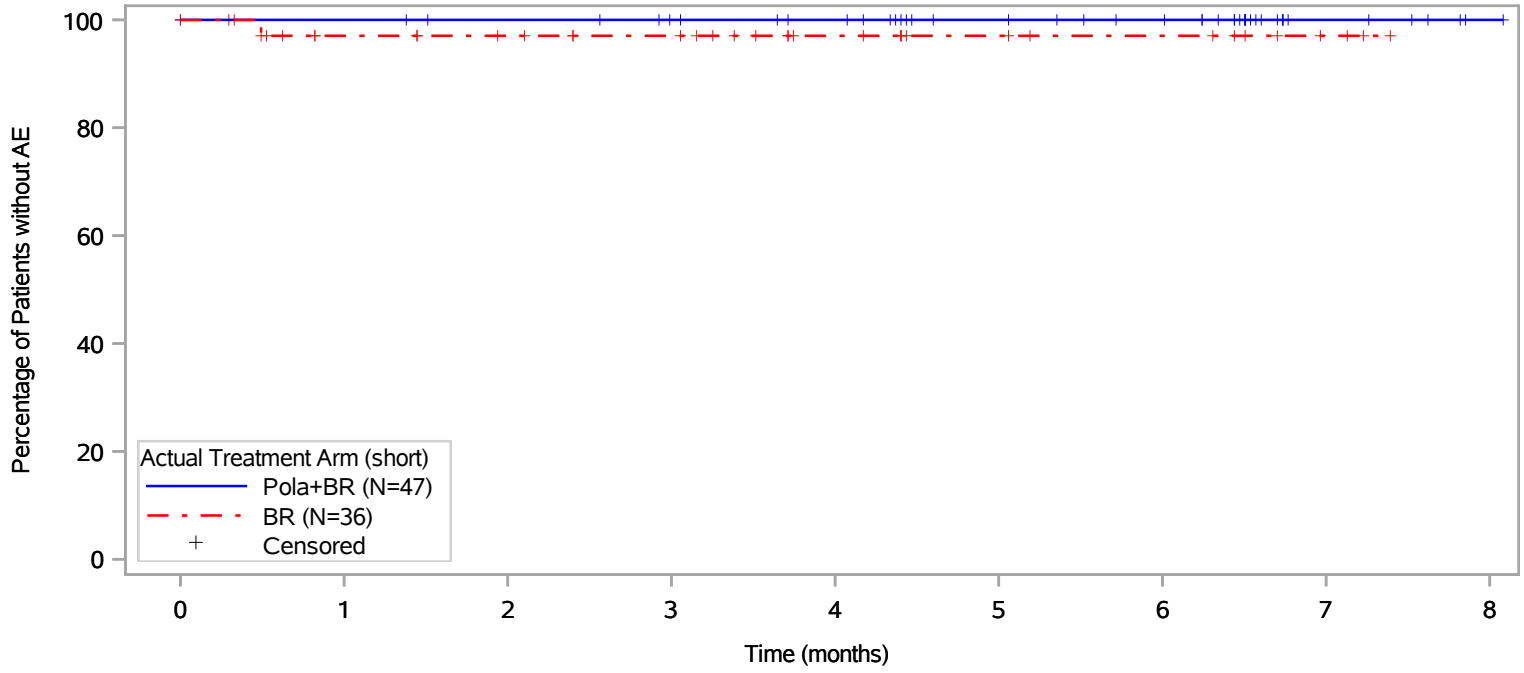
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EYE DISORDERS, ASTHENOPIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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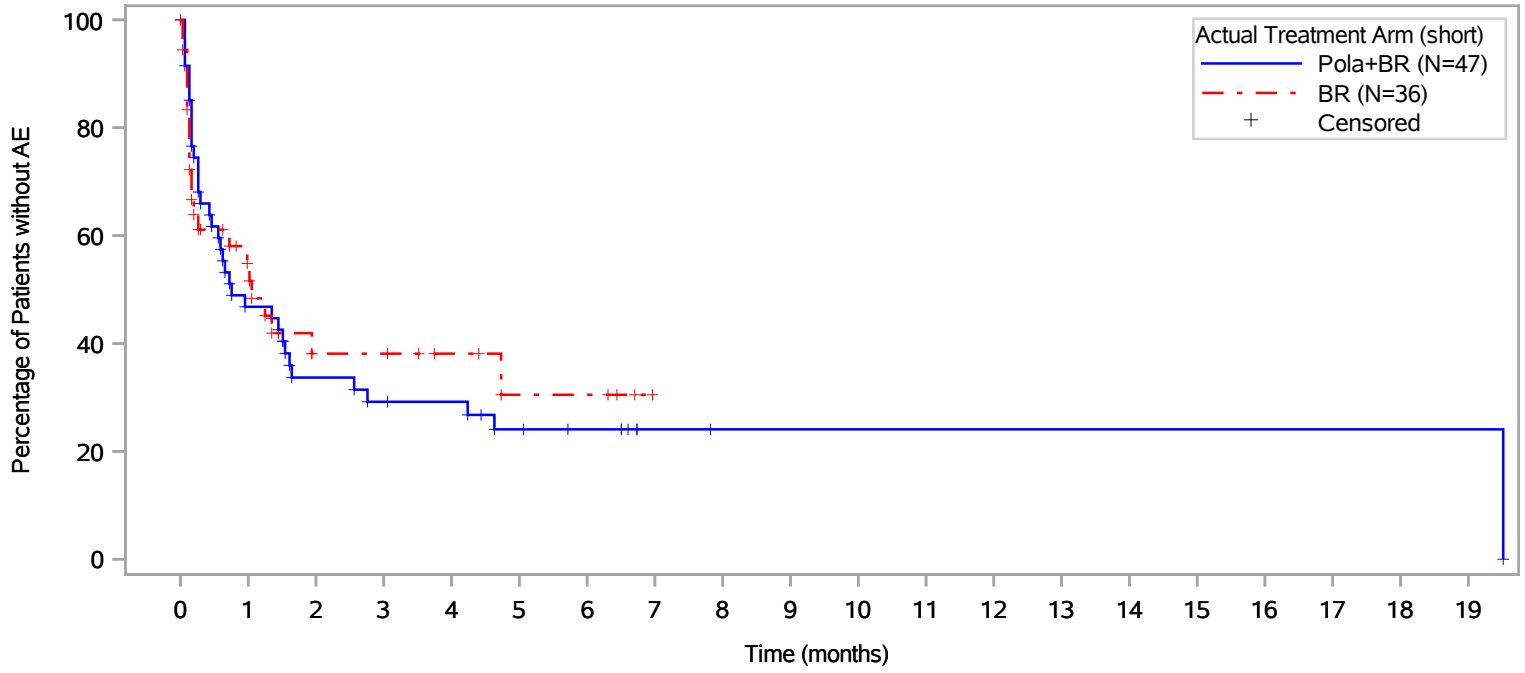
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk																				
Pola+BR (N=47)	47	22	15	13	12	9	7	2	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	17	9	9	6	4	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	1	1	2	3	5	10	11	11	11	11	11	11	11	11	11	11	11	11
BR (N=36)	0	3	6	6	9	10	10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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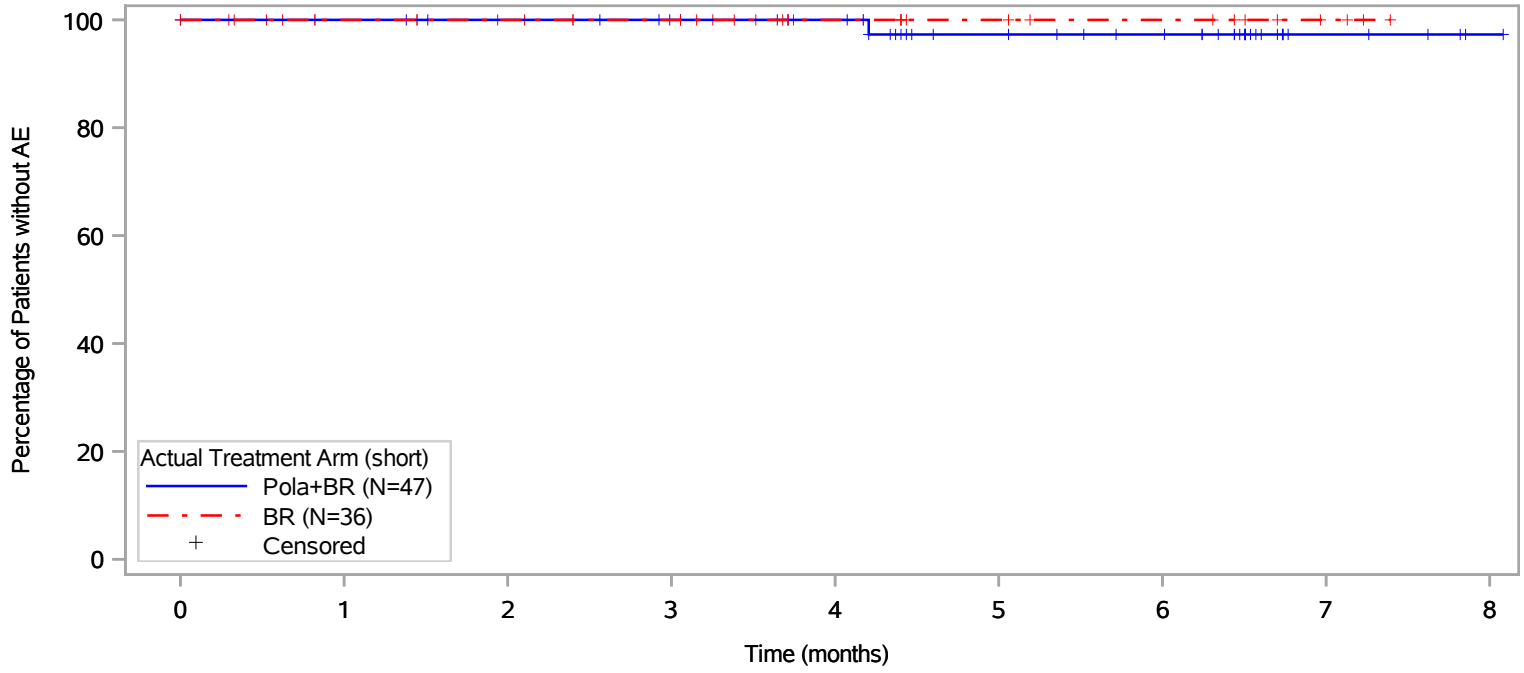
01DEC2022 22:30

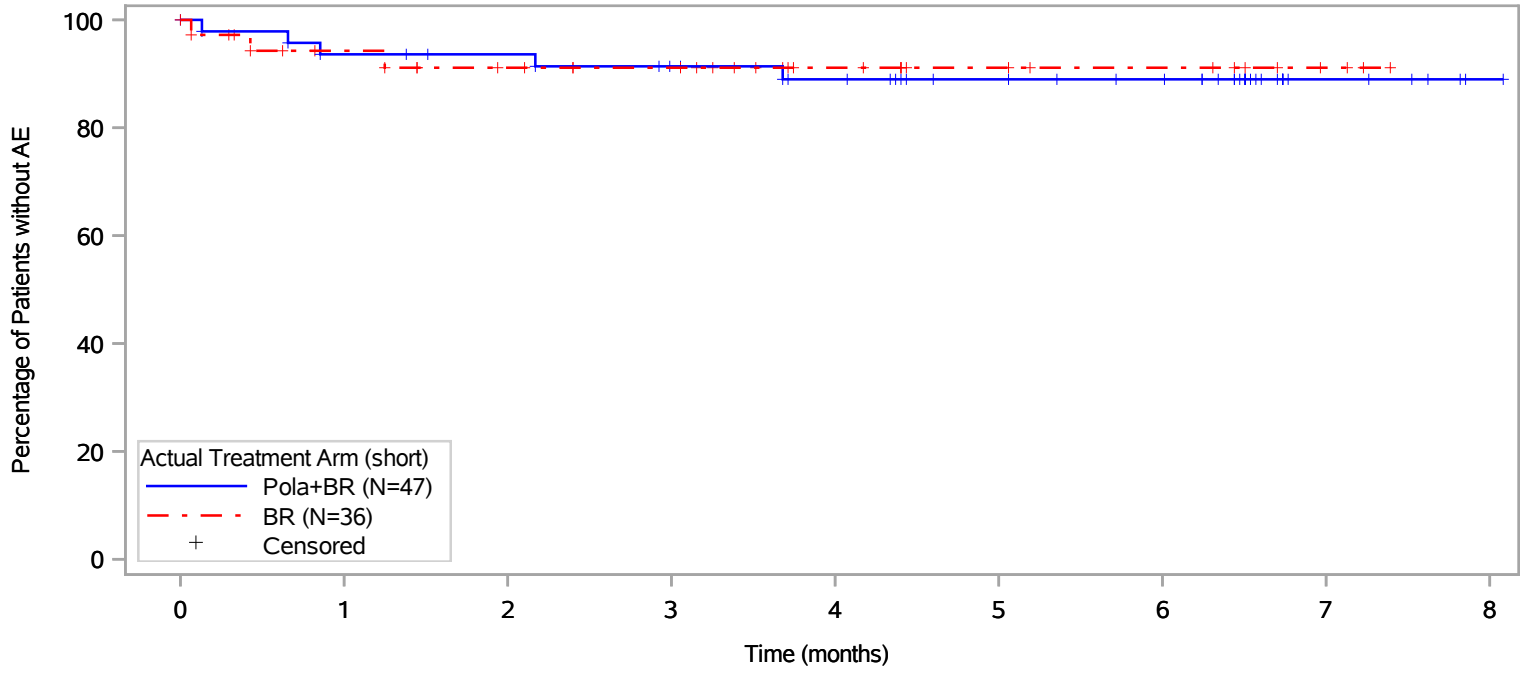
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL DISTENSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=47)	47	44	42	39	36	30	27	6	1
BR (N=36)	36	30	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	6	12	15	36	41
BR (N=36)	0	4	7	10	18	23	25	30	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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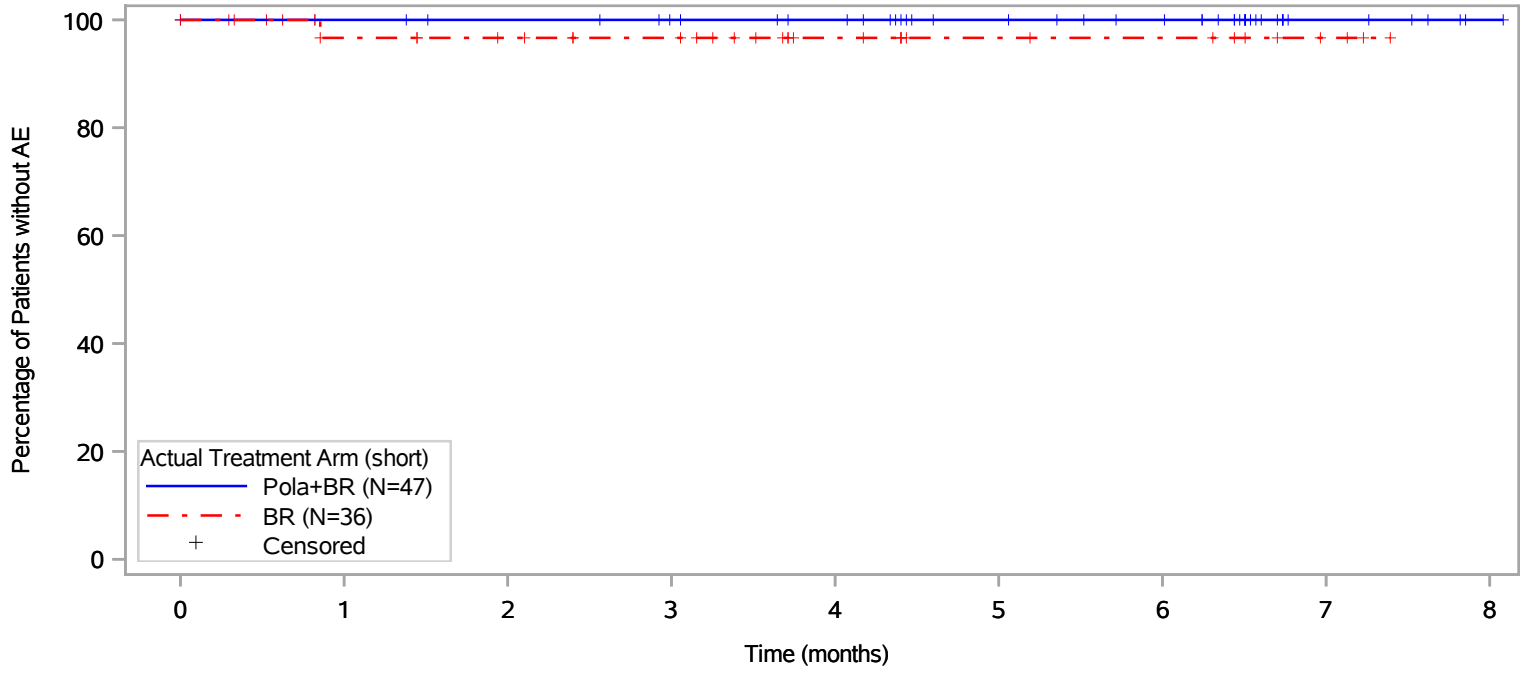
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN LOWER



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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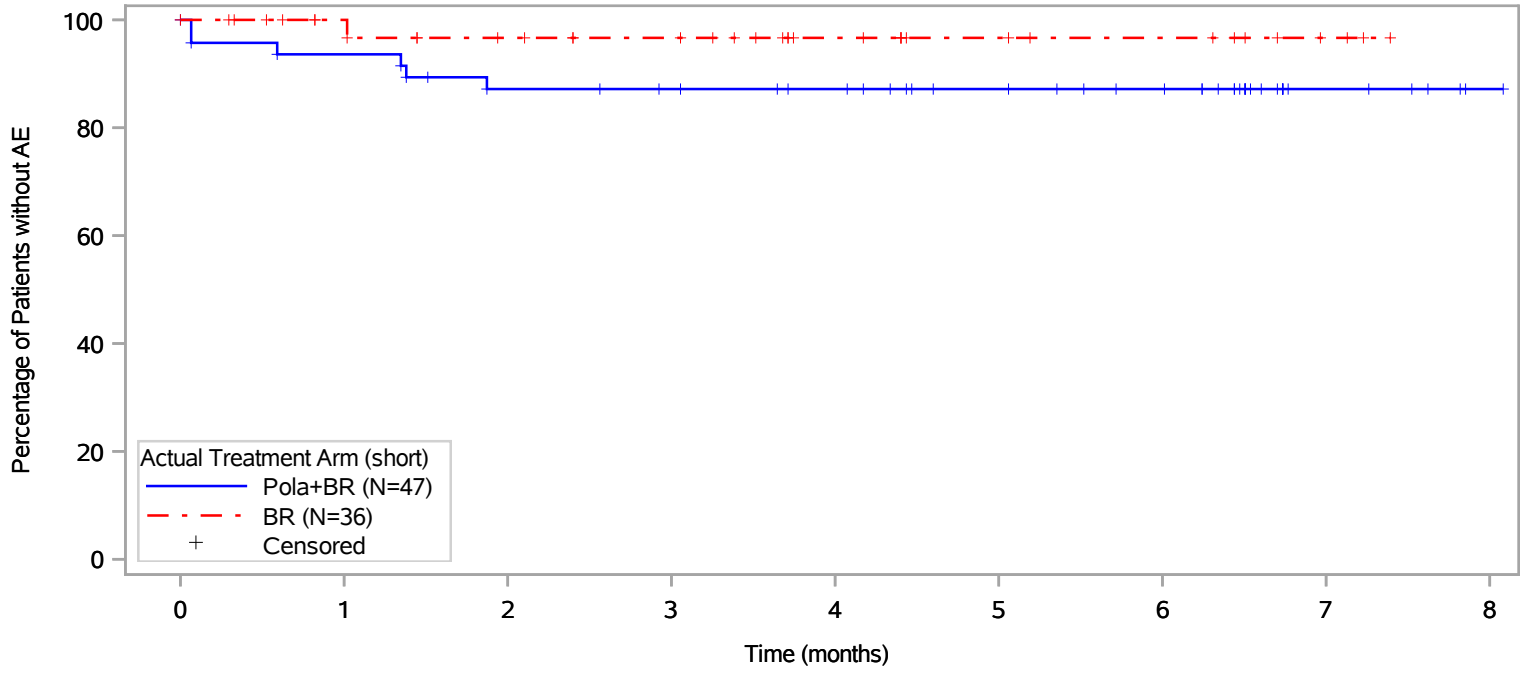
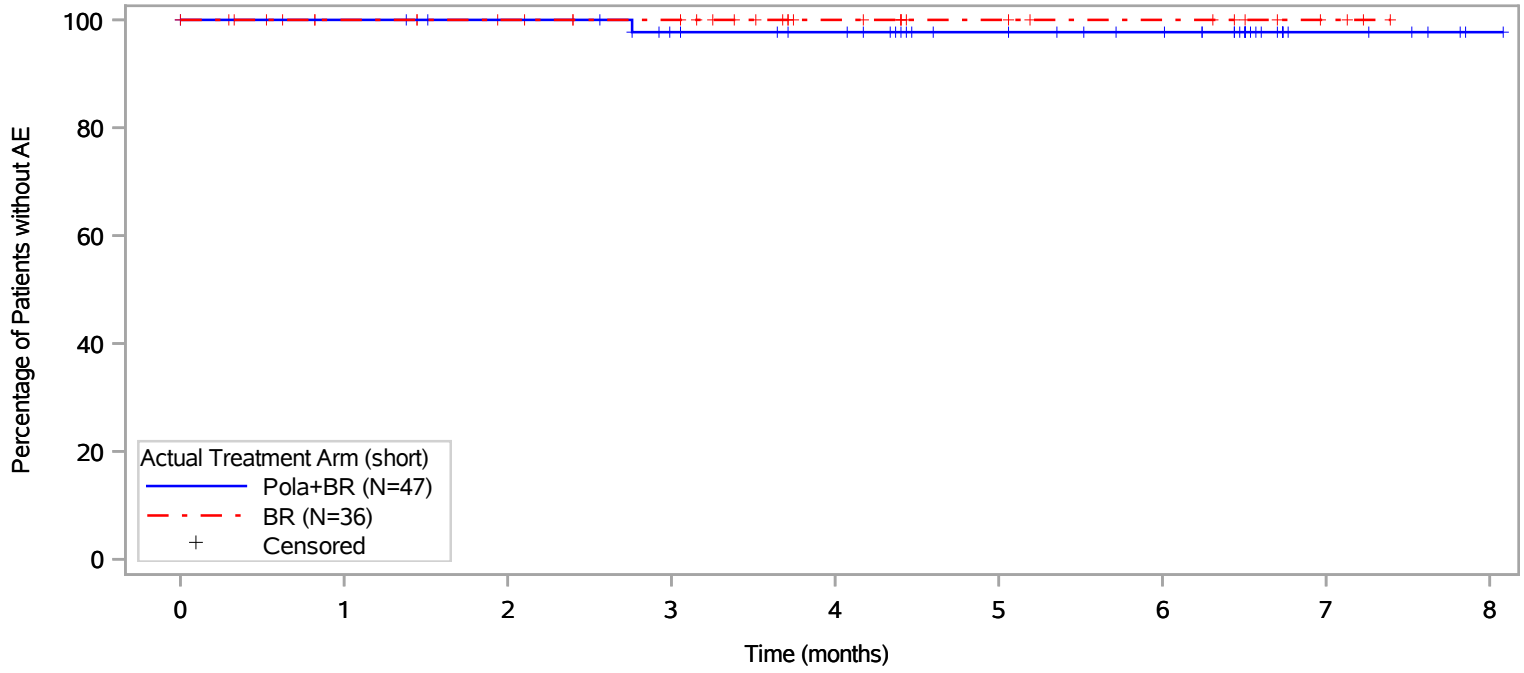
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN UPPER



Patients at risk									
Pola+BR (N=47)	47	44	40	38	35	29	25	6	1
BR (N=36)	36	30	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	6	12	16	35	40
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CHRONIC GASTRITIS



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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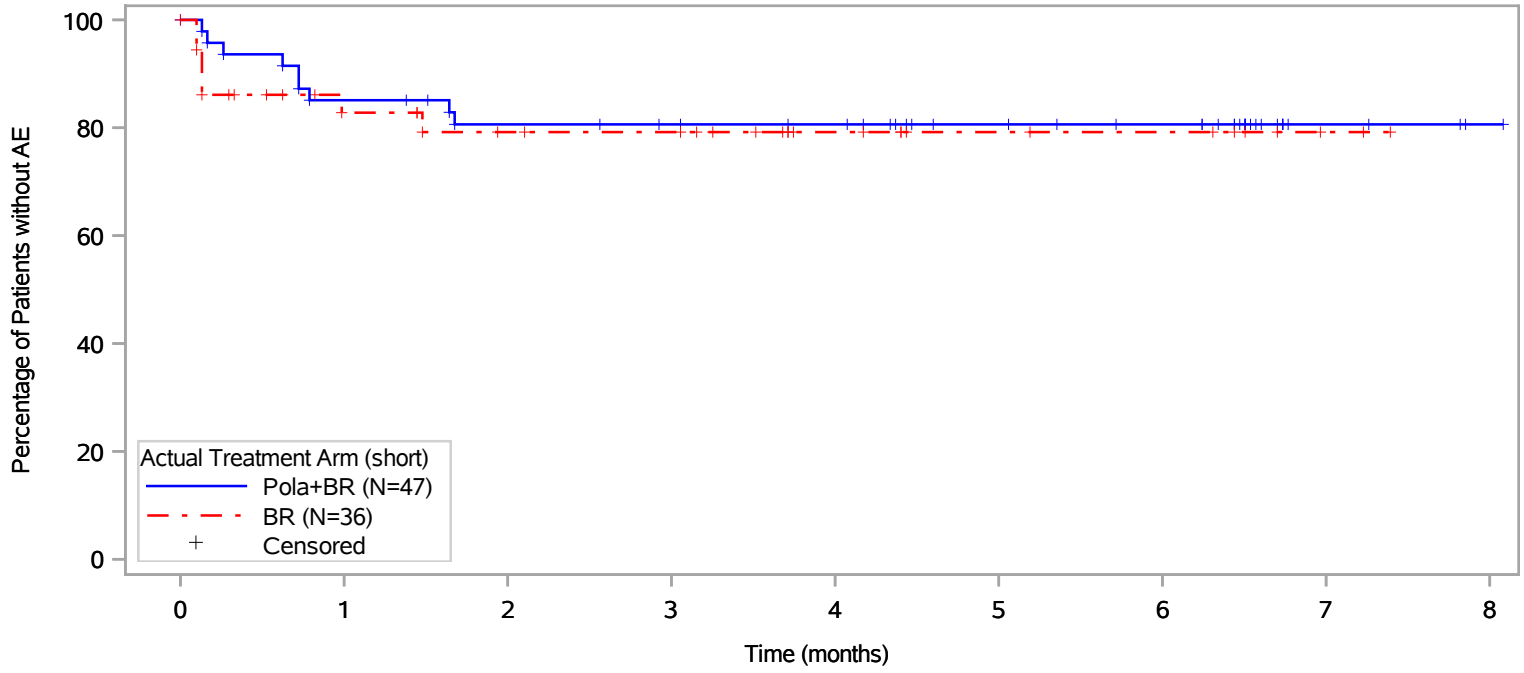
01DEC2022 22:30

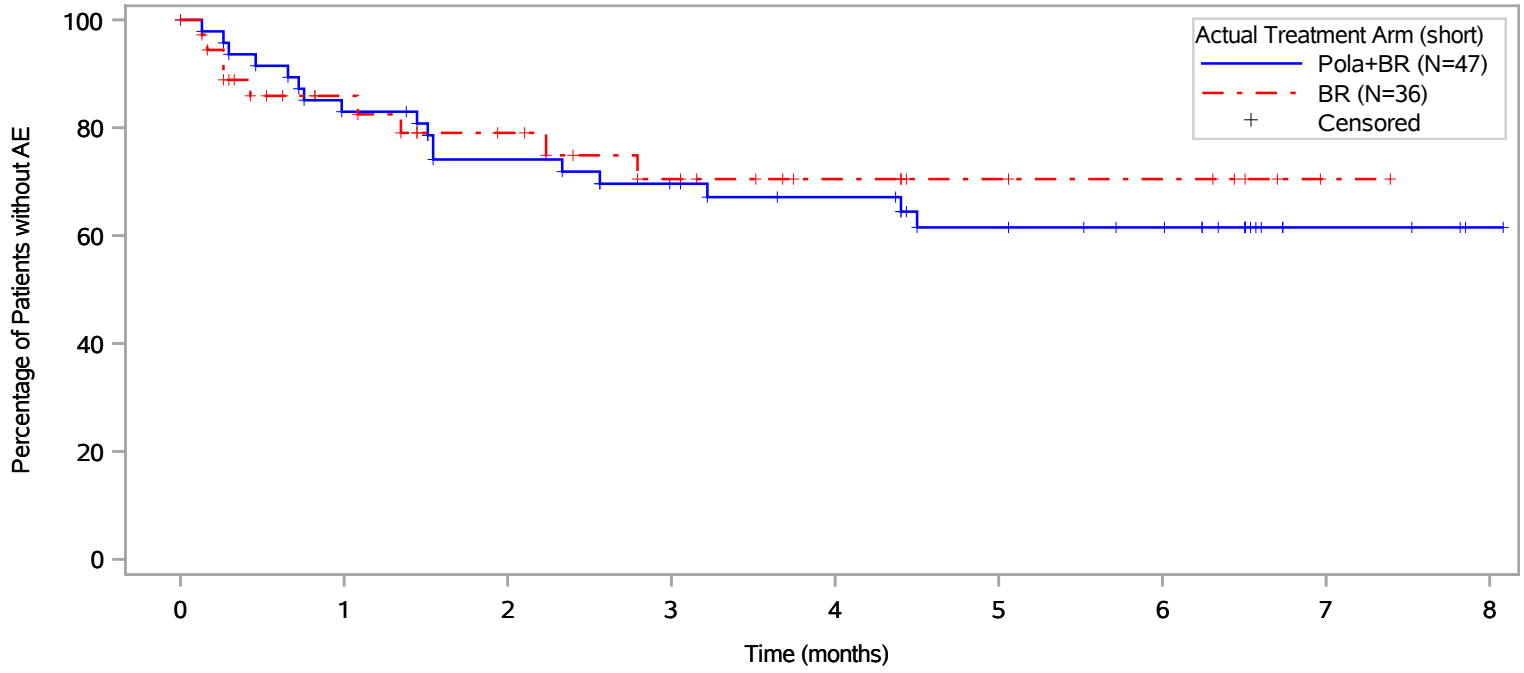
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk									
Pola+BR (N=47)	47	40	36	34	32	25	22	4	1
BR (N=36)	36	25	21	20	12	8	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	6	13	16	34	37
BR (N=36)	0	5	8	9	17	21	22	27	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



Patients at risk									
Pola+BR (N=47)	47	39	33	29	26	21	18	4	1
BR (N=36)	36	25	20	16	11	7	6	1	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	6	9	12	26	29
BR (N=36)	0	6	9	11	16	20	21	26	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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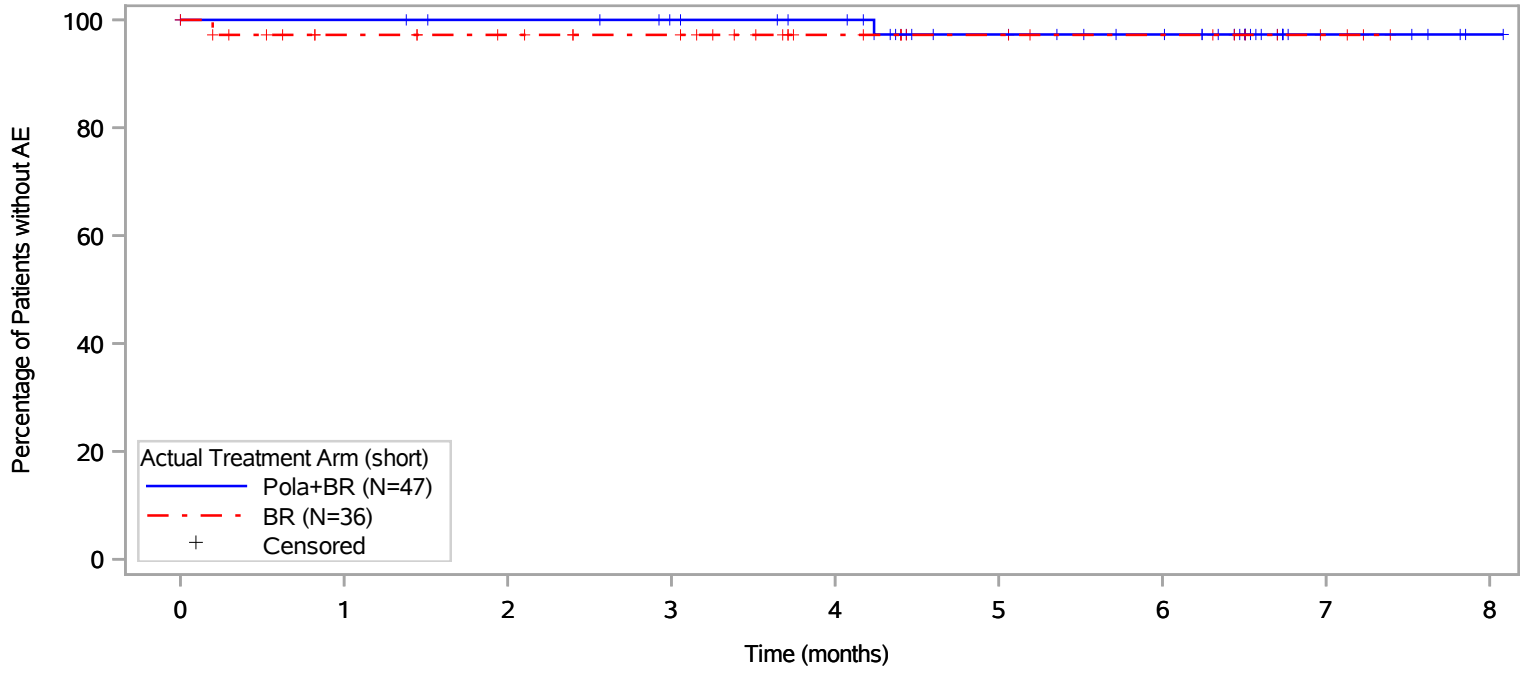
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DRY MOUTH

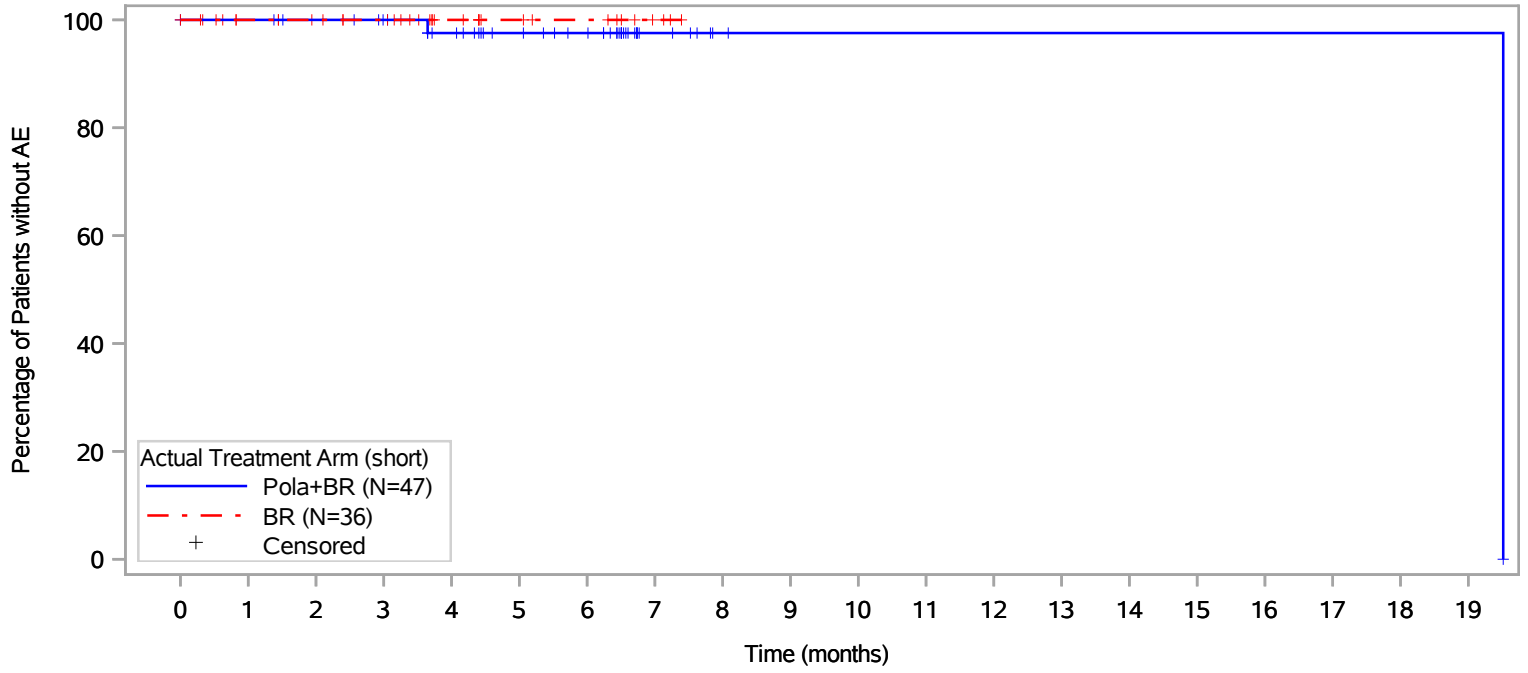


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	5	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

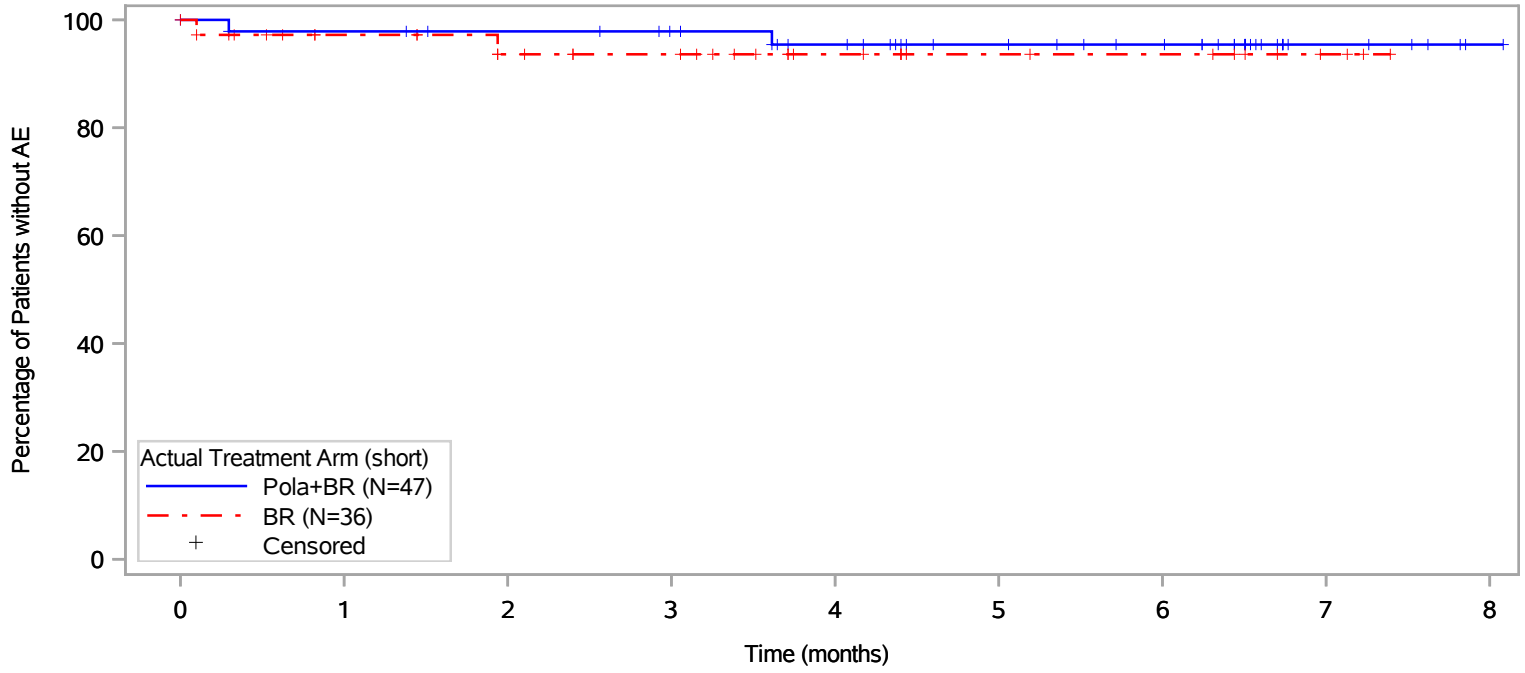
GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk																				
Pola+BR (N=47)	47	47	45	42	38	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	8	15	19	39	44	45	45	45	45	45	45	45	45	45	45	45
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

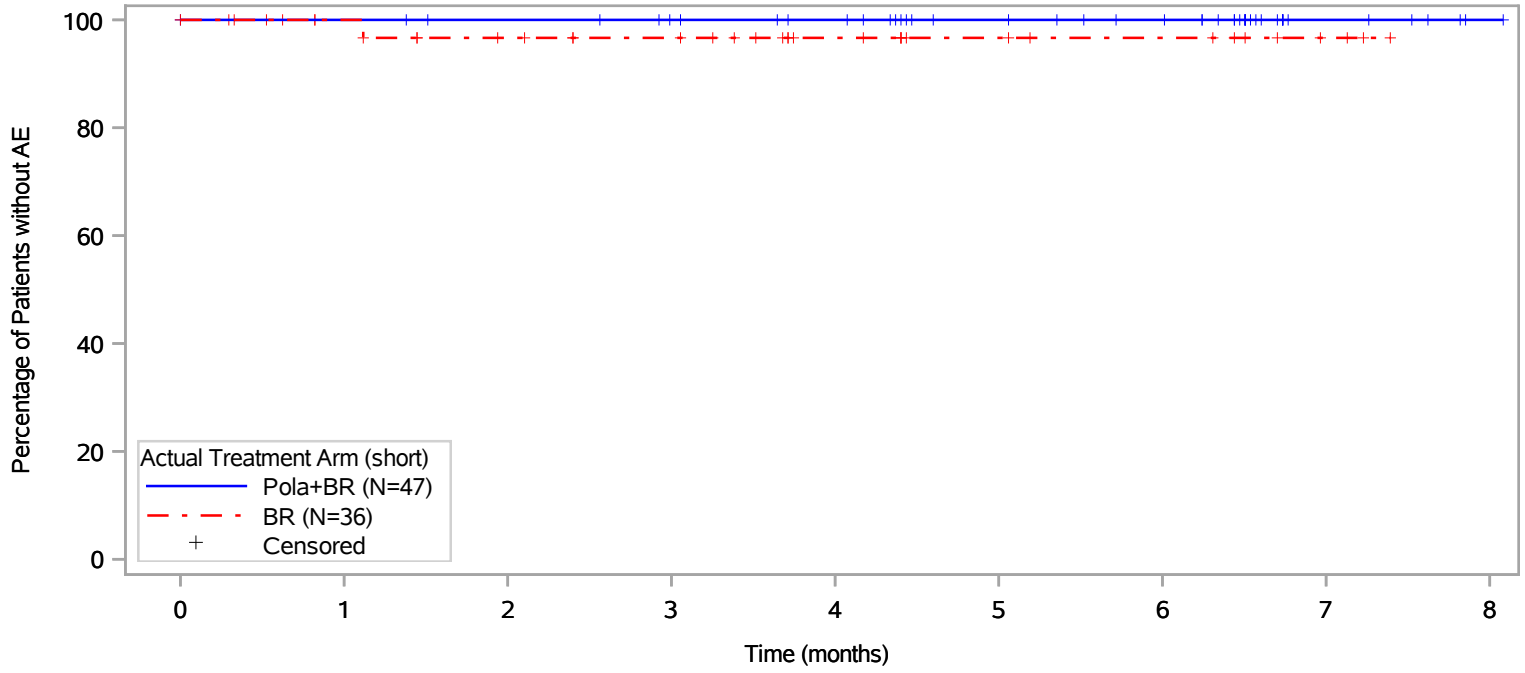
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DYSPEPSIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	37	30	26	6	1
BR (N=36)	36	29	25	22	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	39	44
BR (N=36)	0	6	9	12	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DYSPHAGIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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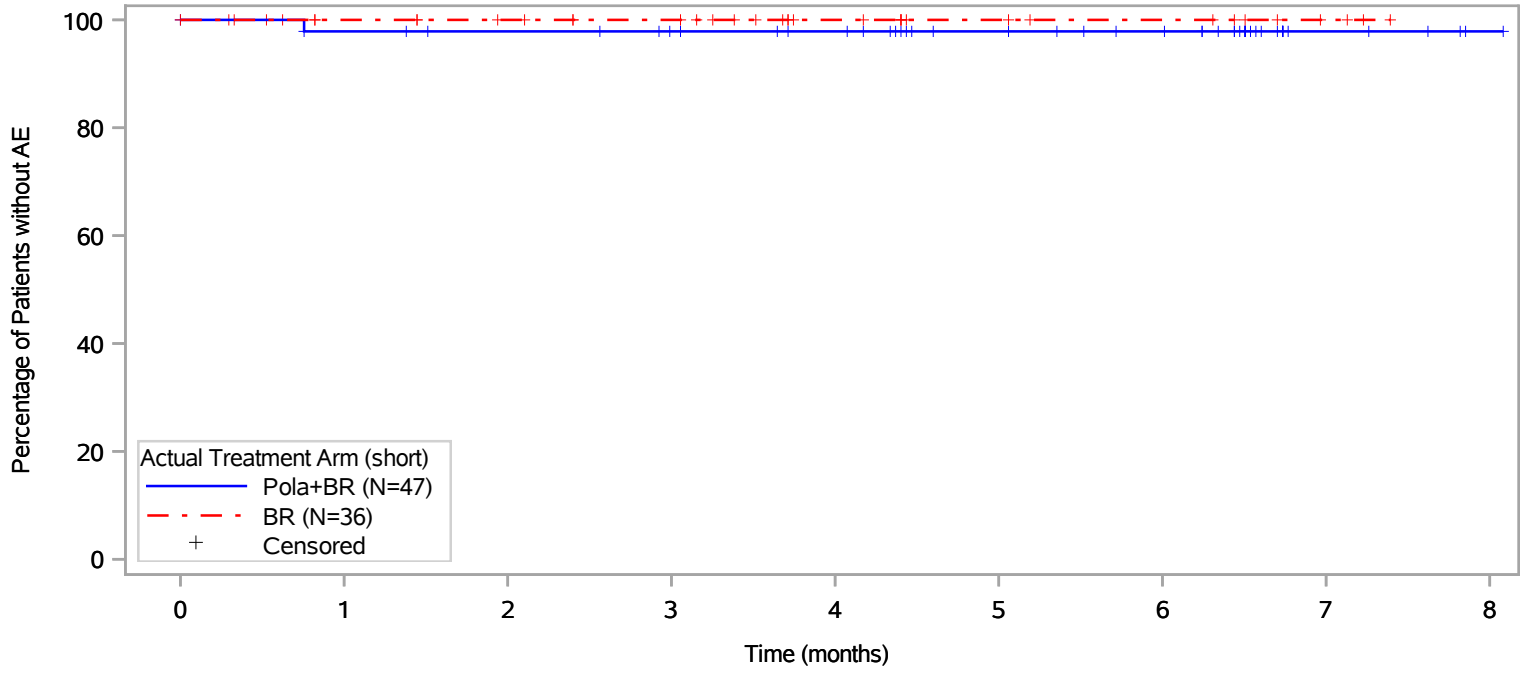
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, FLATULENCE



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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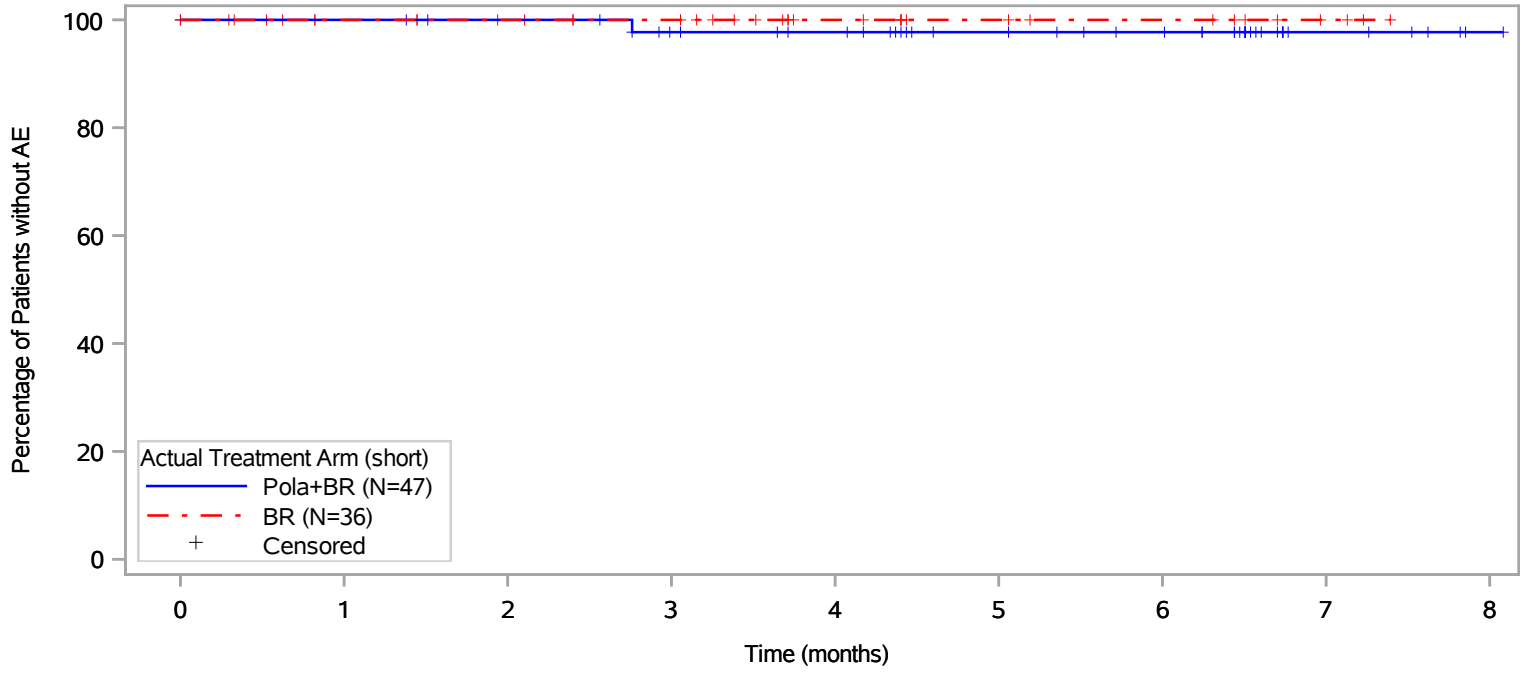
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTRIC POLYPS



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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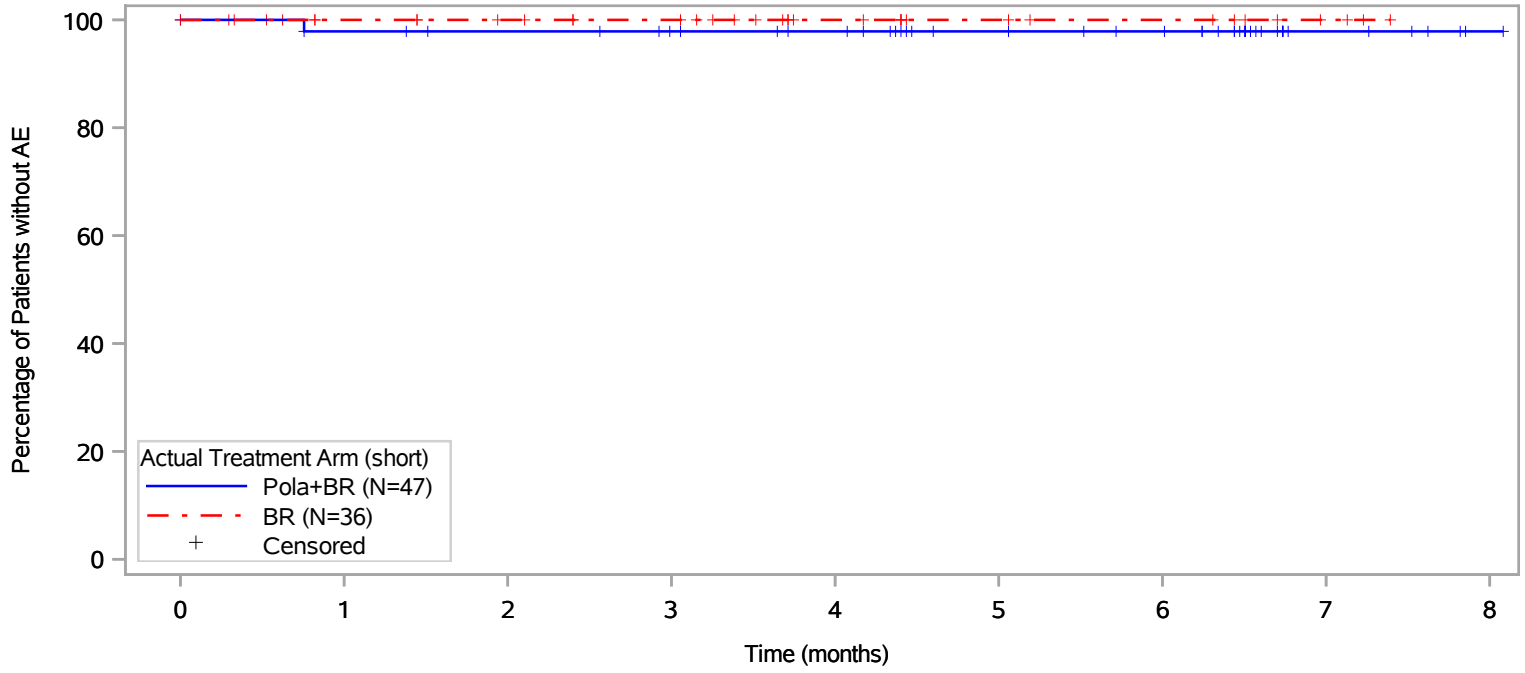
01DEC2022 22:30

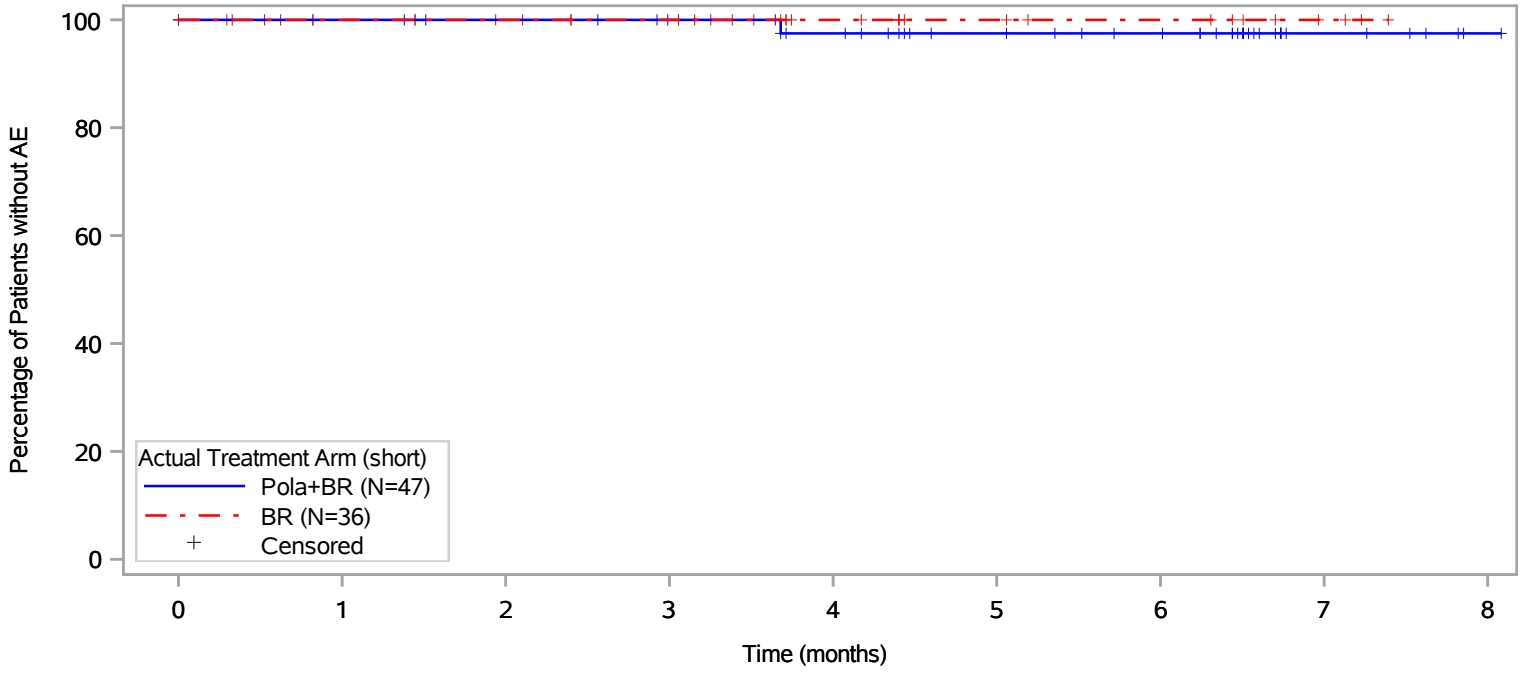
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTRITIS



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTROINTESTINAL HAEMORRHAGE

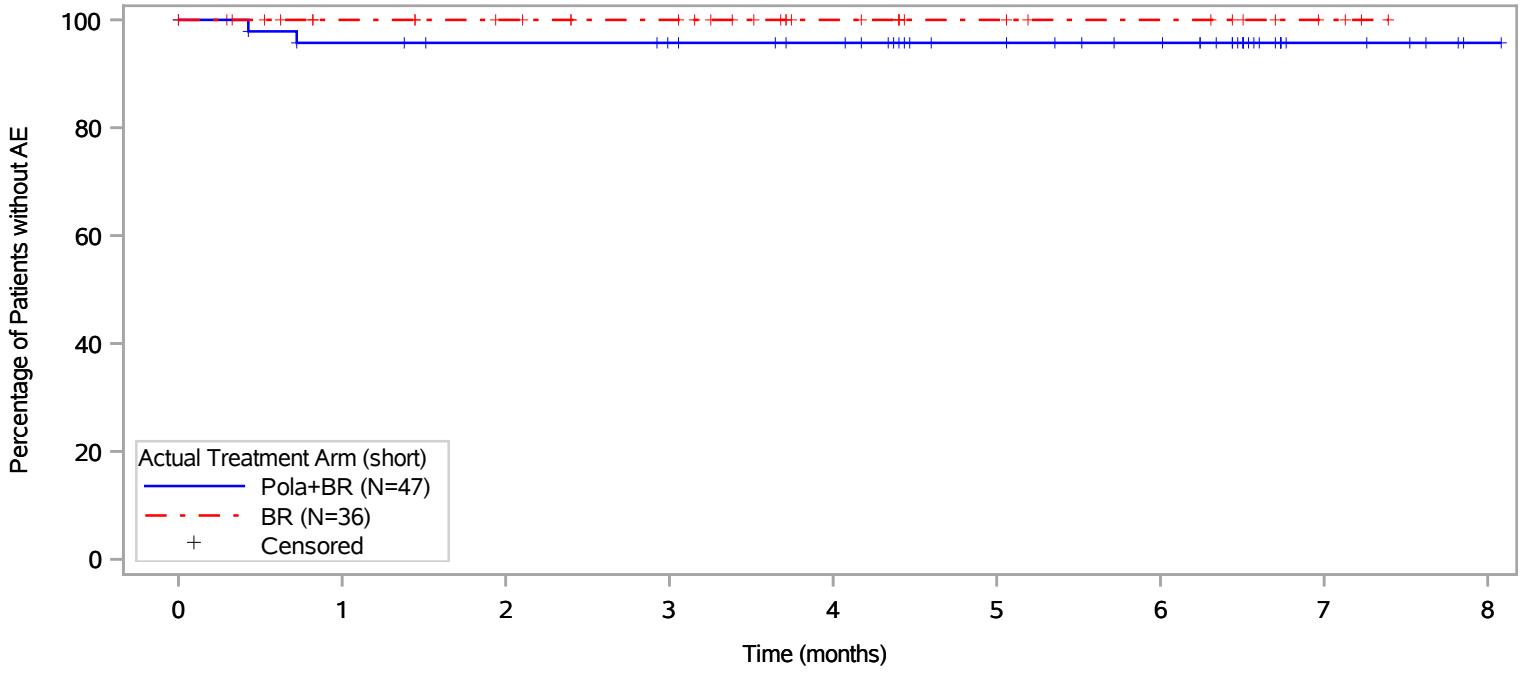


Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

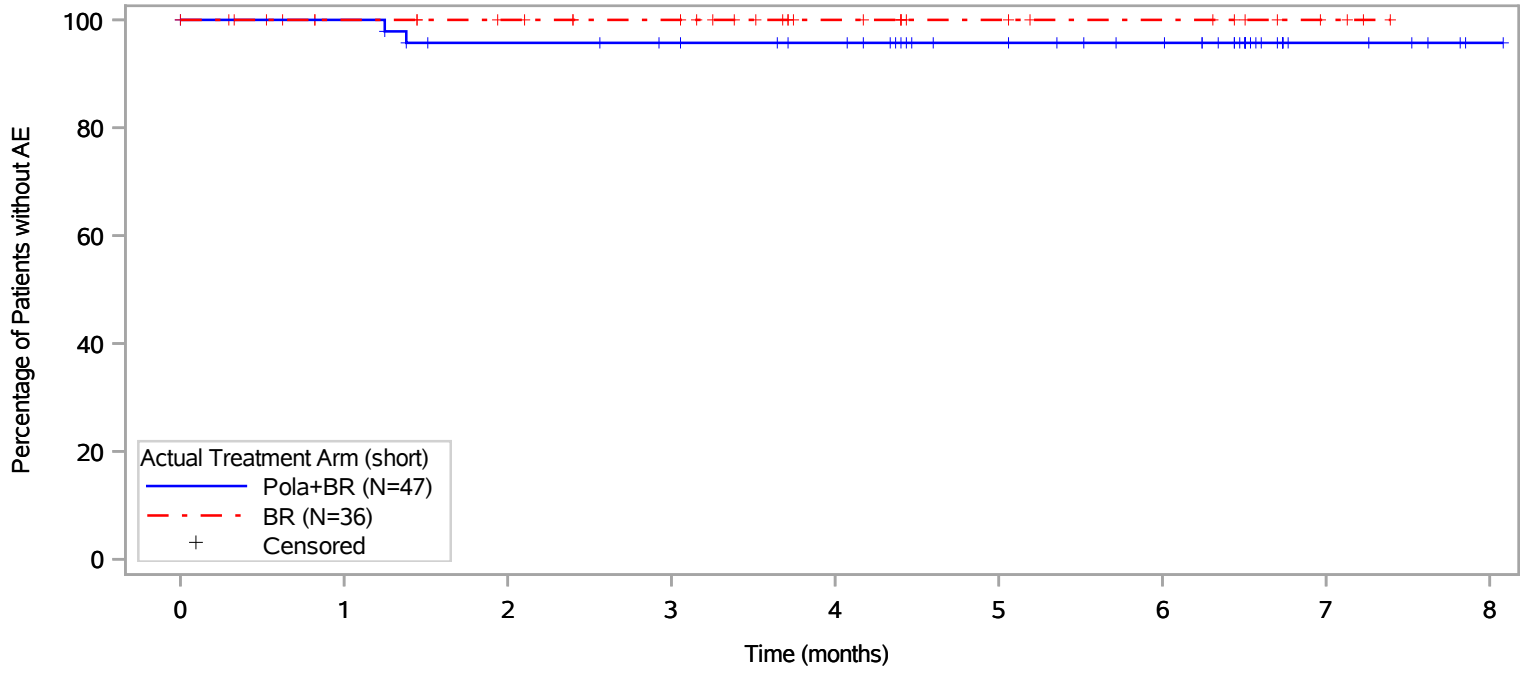
GASTROINTESTINAL DISORDERS, GASTROOESOPHAGEAL REFLUX DISEASE



Patients at risk									
Pola+BR (N=47)	47	45	43	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

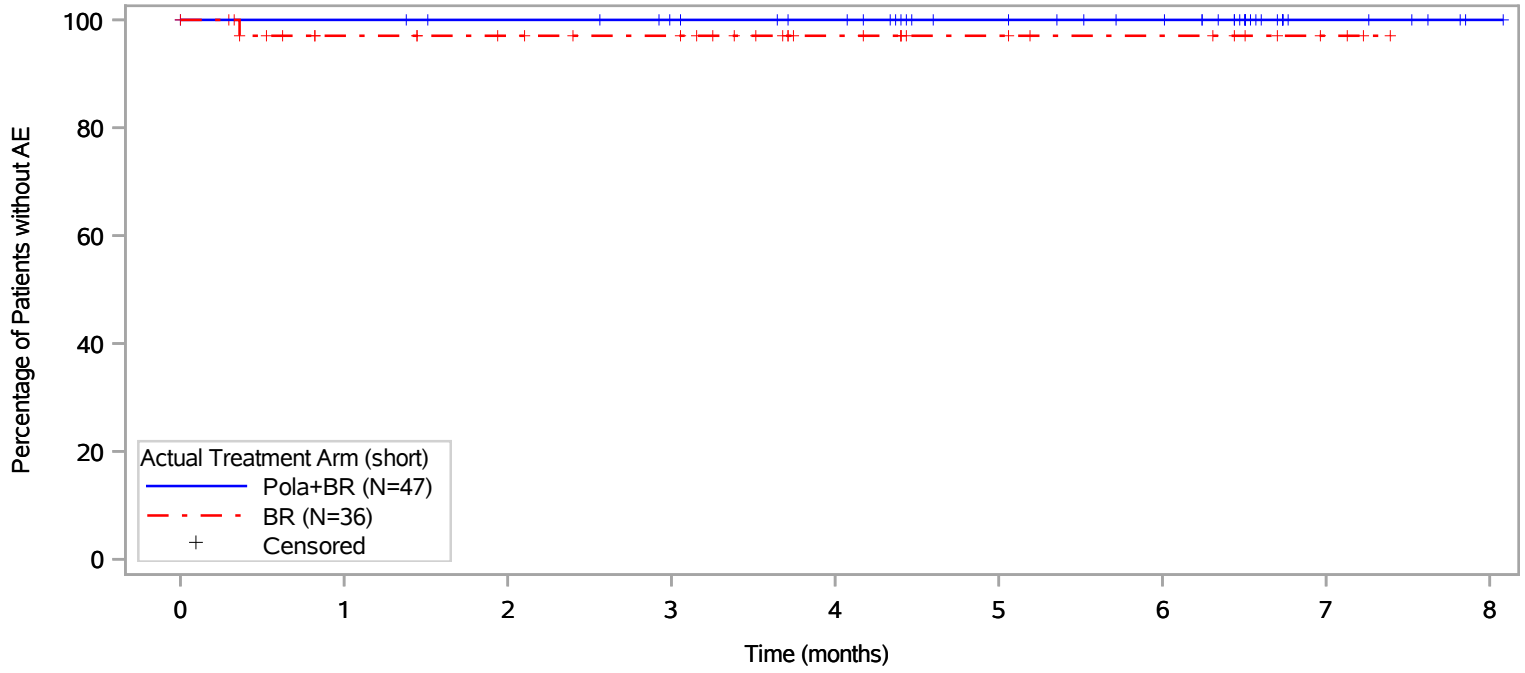
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, HAEMATEMESIS



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	6	14	18	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, HAEMATOCHEZIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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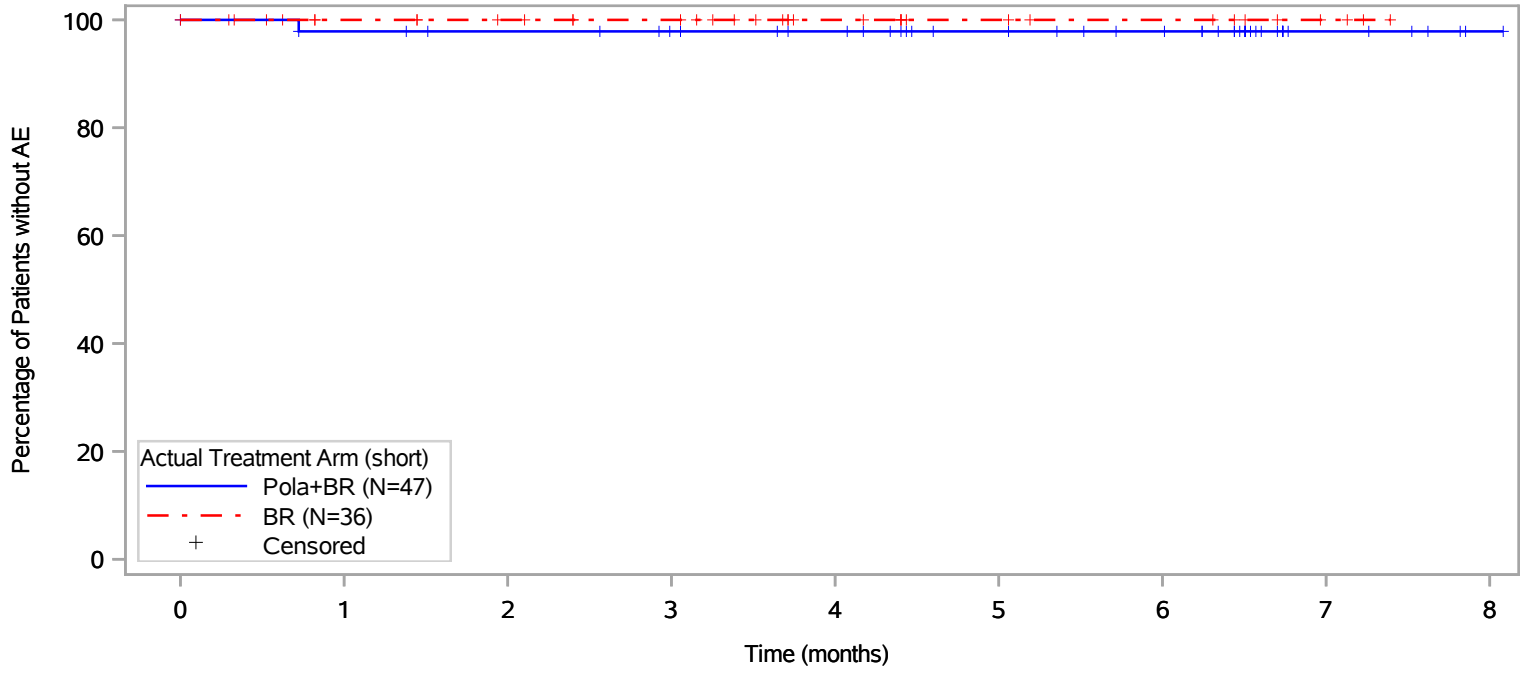
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, HYPERCHLORHYDRIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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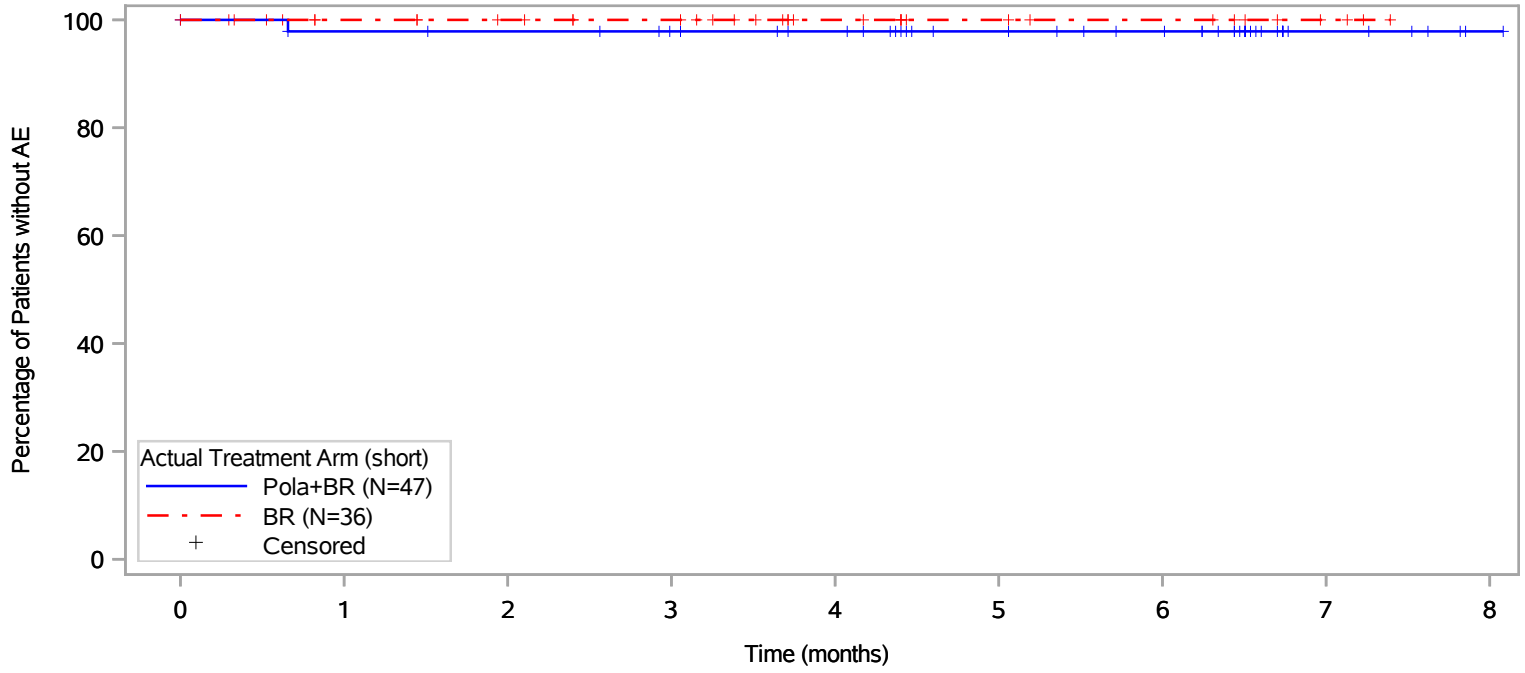
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ILEUS



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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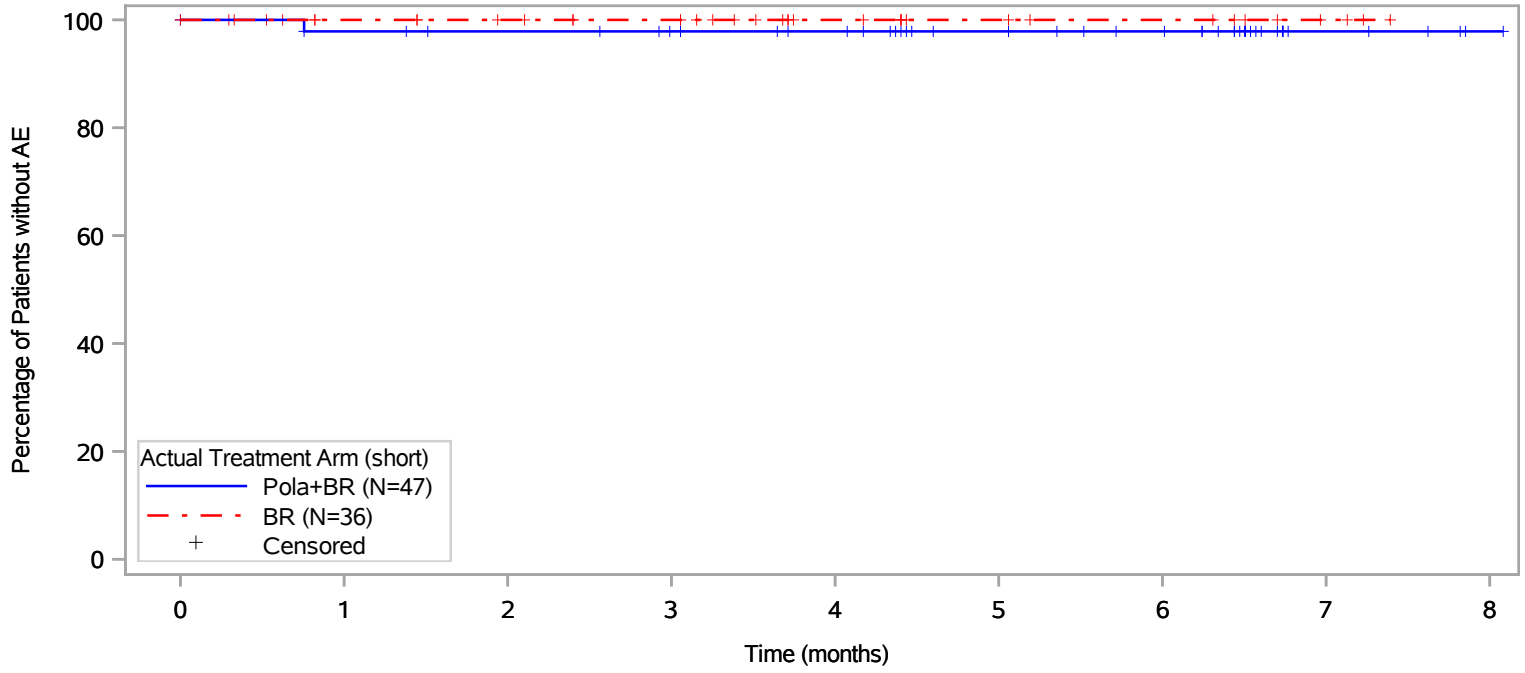
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, LIP DRY



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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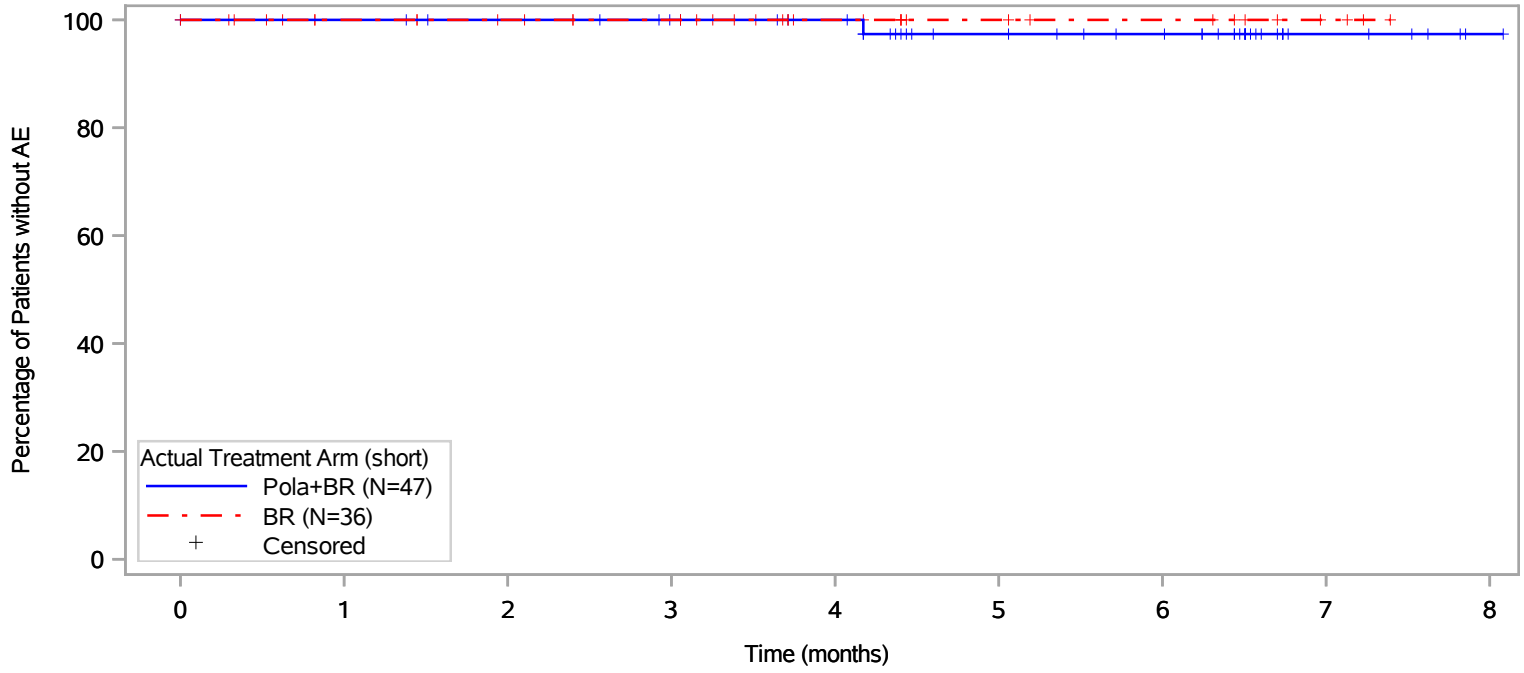
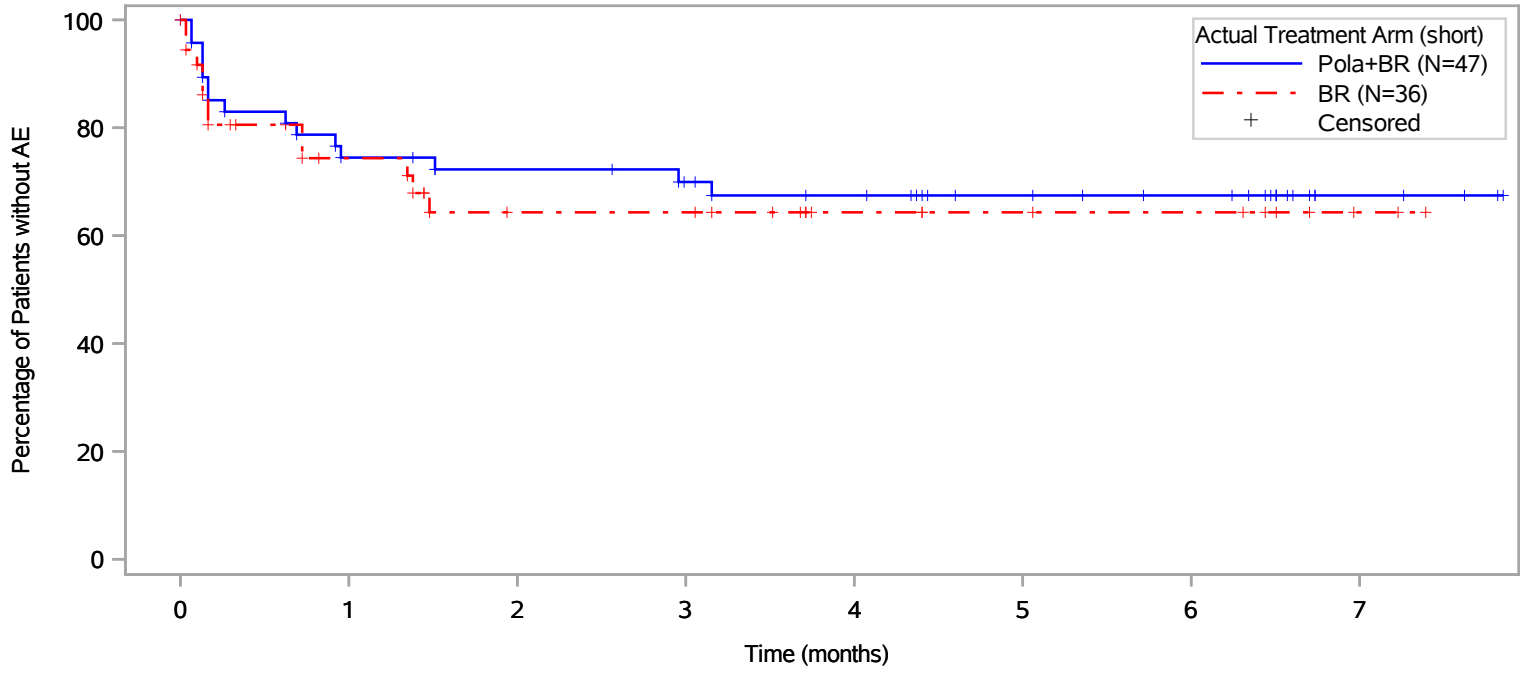
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, MOUTH ULCERATION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, NAUSEA



Patients at risk								
Pola+BR (N=47)	47	35	32	29	26	20	17	4
BR (N=36)	36	23	17	17	10	8	7	2
Patients censored								
Pola+BR (N=47)	0	0	2	4	6	12	15	28
BR (N=36)	0	4	7	7	14	16	17	22

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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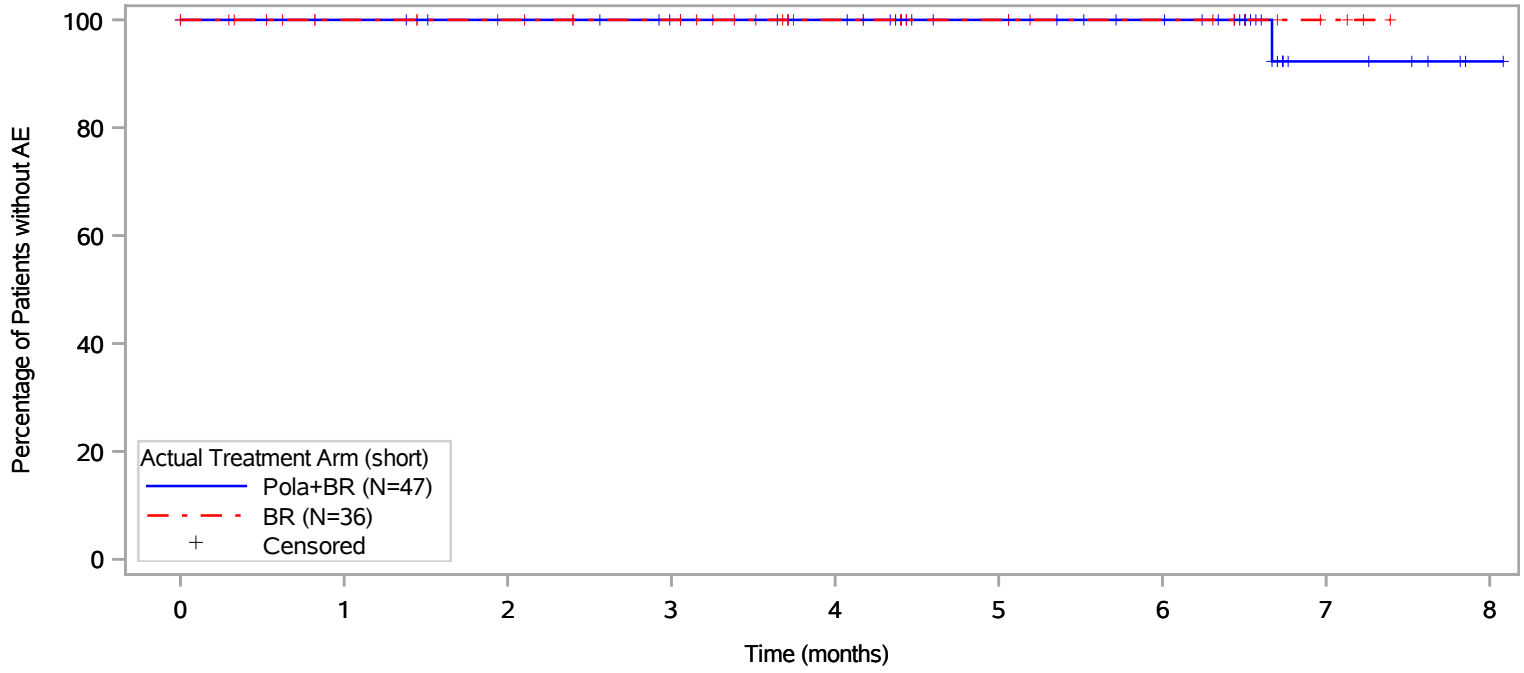
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, OBSTRUCTION GASTRIC



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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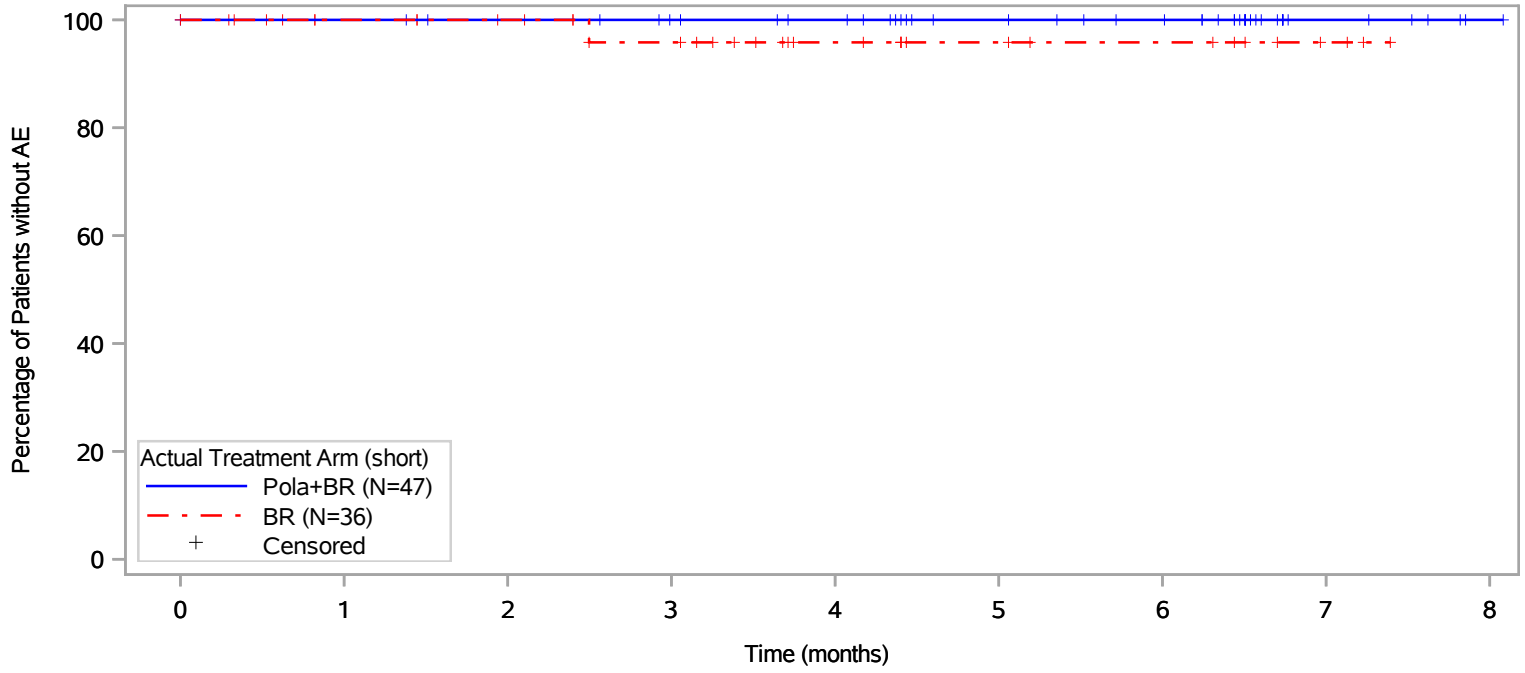
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS

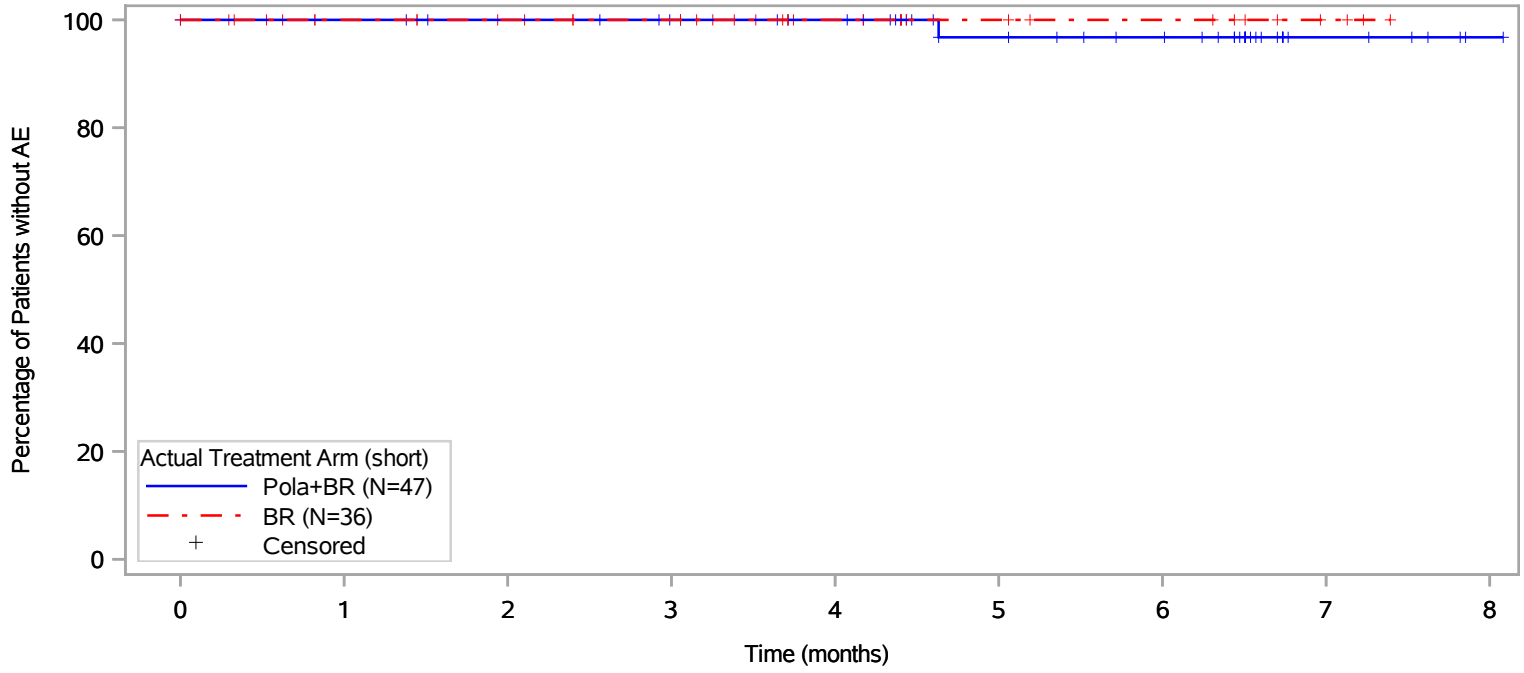


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS ACUTE

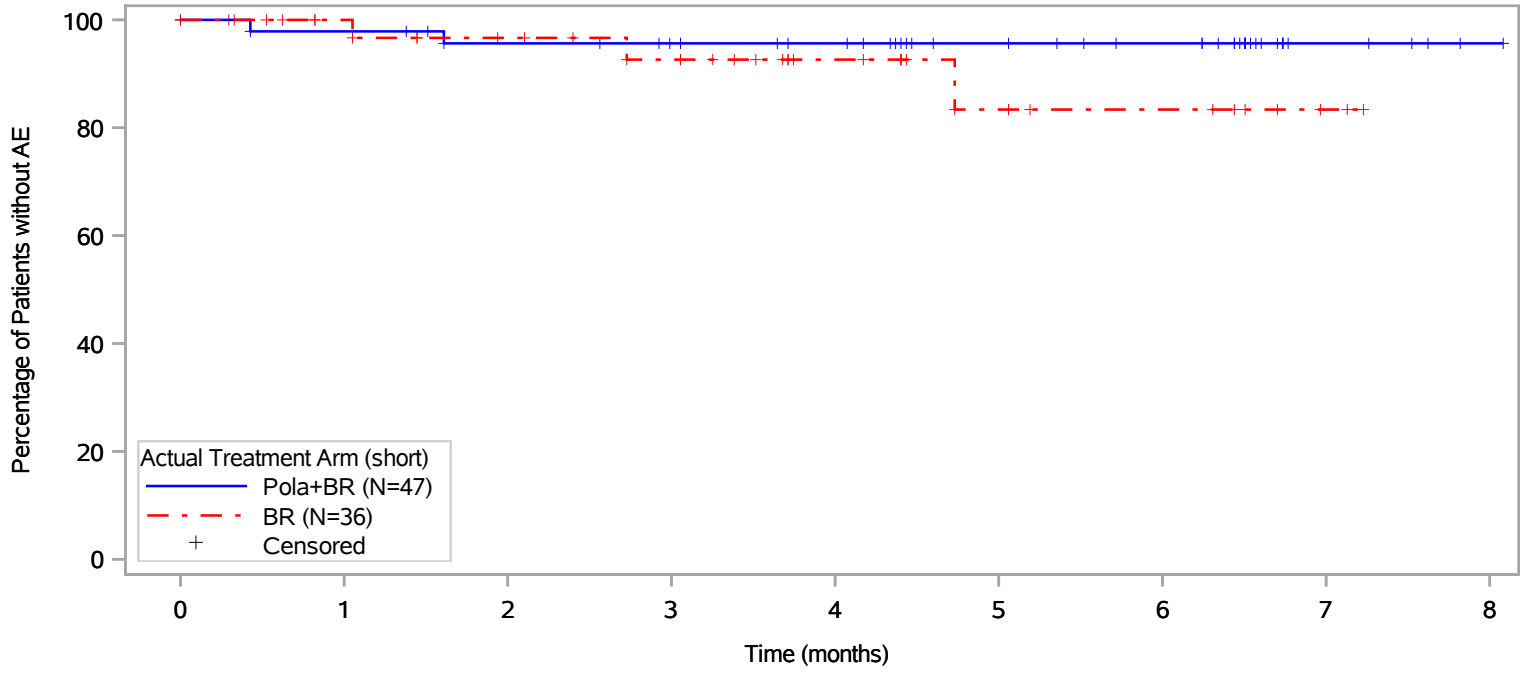


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, STOMATITIS



Patients at risk									
Pola+BR (N=47)	47	46	43	40	37	29	25	5	1
BR (N=36)	36	30	26	23	15	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	44
BR (N=36)	0	6	9	11	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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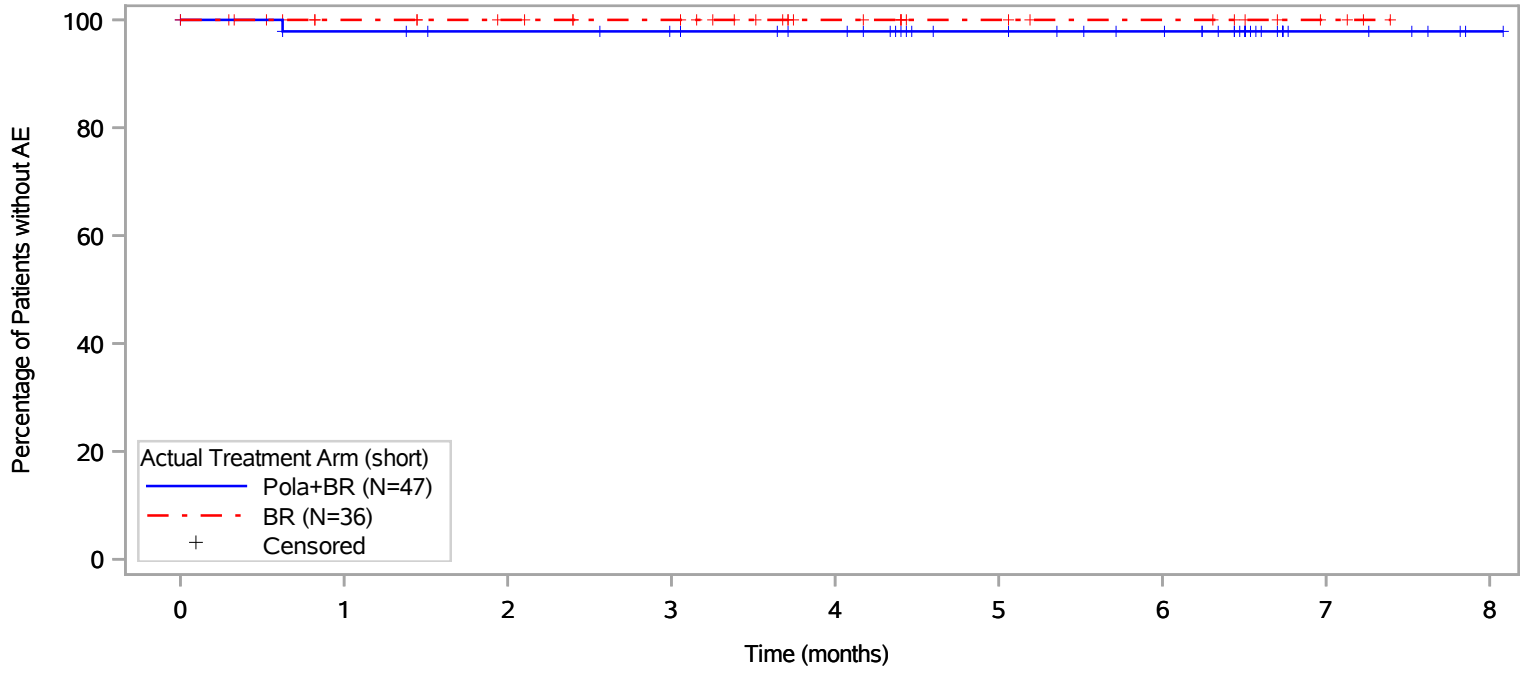
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SUBILEUS



Patients at risk									
Pola+BR (N=47)	47	46	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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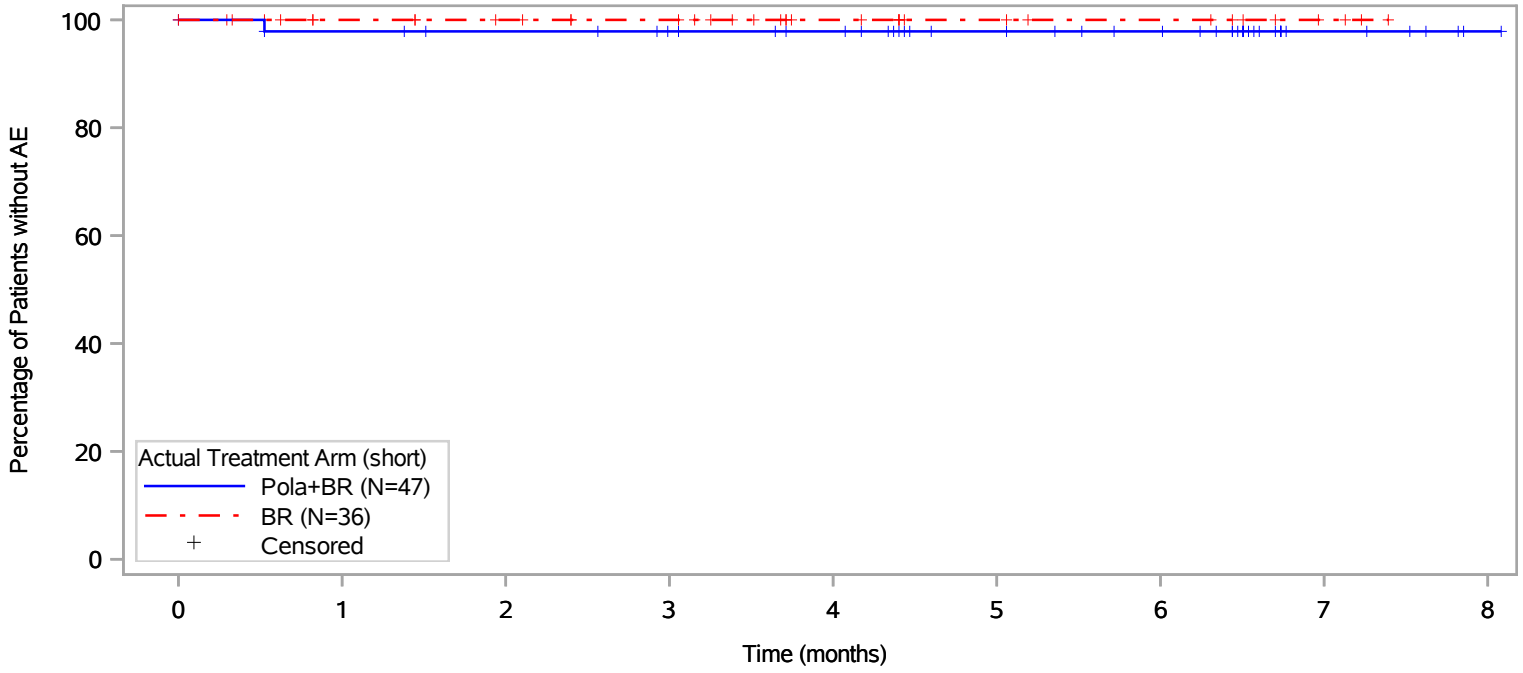
01DEC2022 22:30

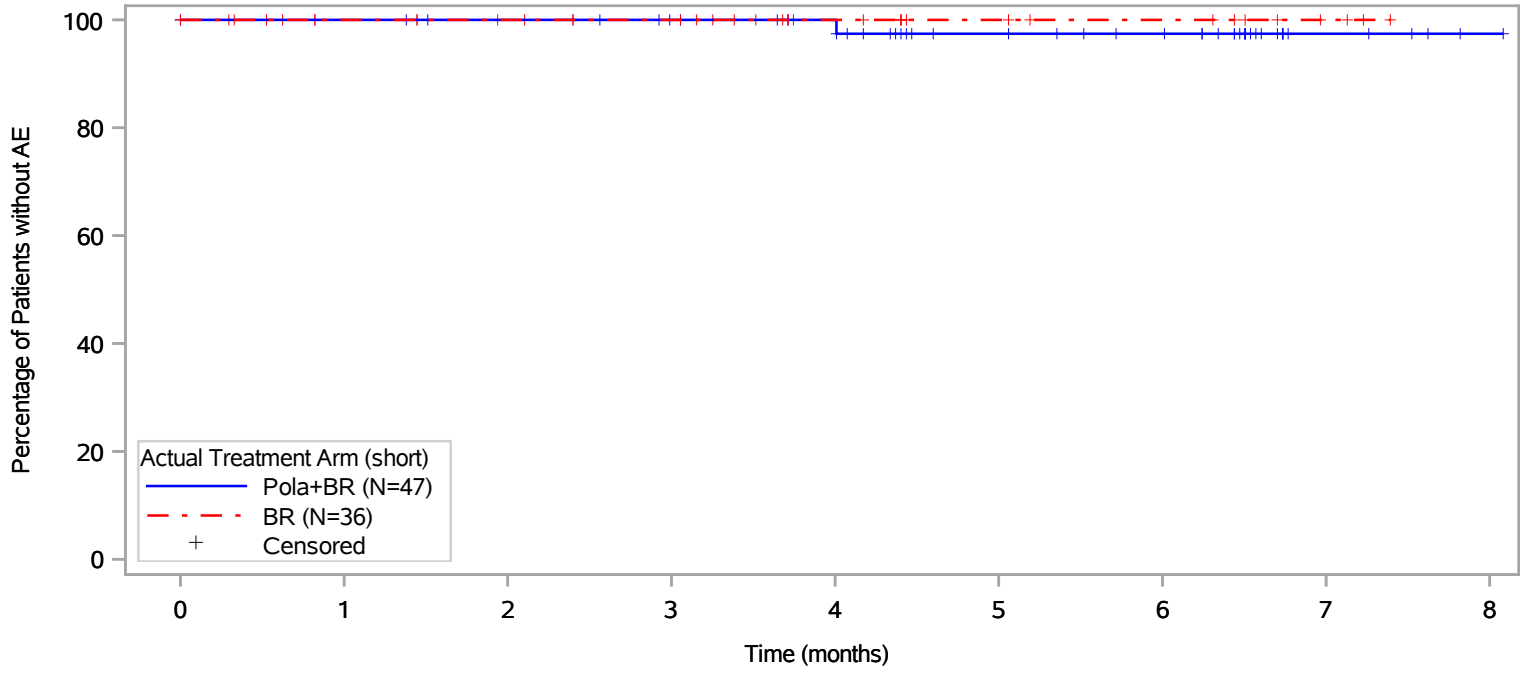
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, TONGUE EXFOLIATION



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, TOOTHACHE

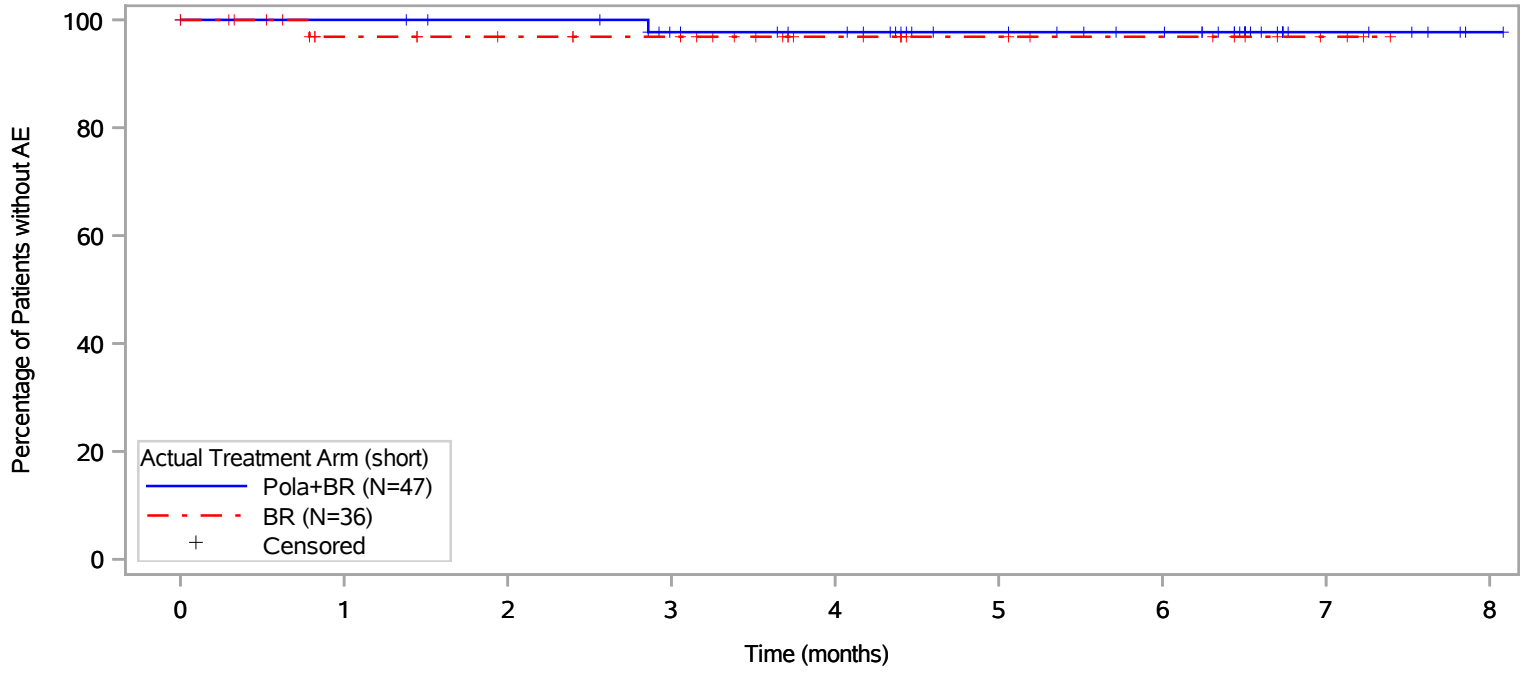


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, UPPER GASTROINTESTINAL HAEMORRHAGE

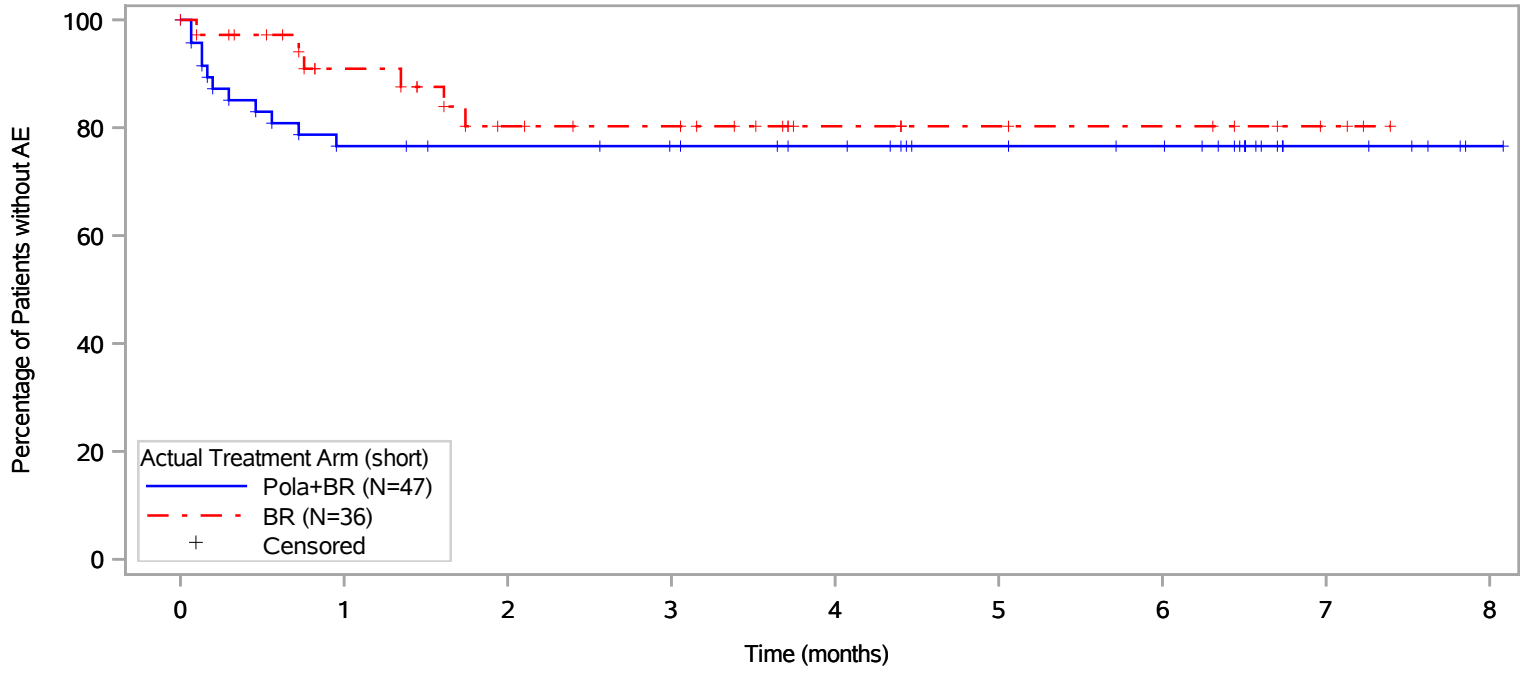


Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=47)	47	36	34	32	29	24	22	6	1
BR (N=36)	36	27	21	19	11	8	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	12	14	30	35
BR (N=36)	0	6	9	11	19	22	23	27	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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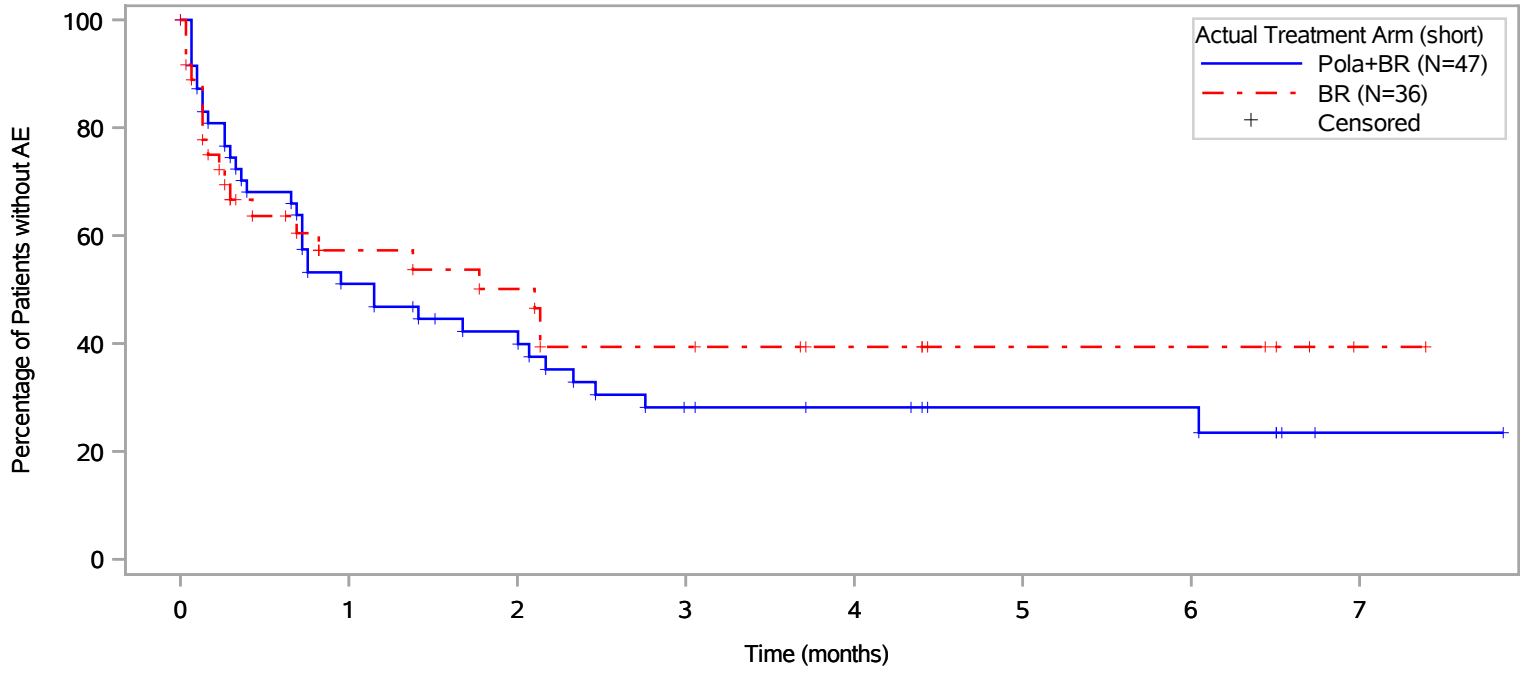
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk								
Pola+BR (N=47)	47	24	18	11	9	6	6	1
BR (N=36)	36	16	14	11	8	5	5	1
Patients censored								
Pola+BR (N=47)	0	0	2	3	5	8	8	12
BR (N=36)	0	5	5	5	8	11	11	15

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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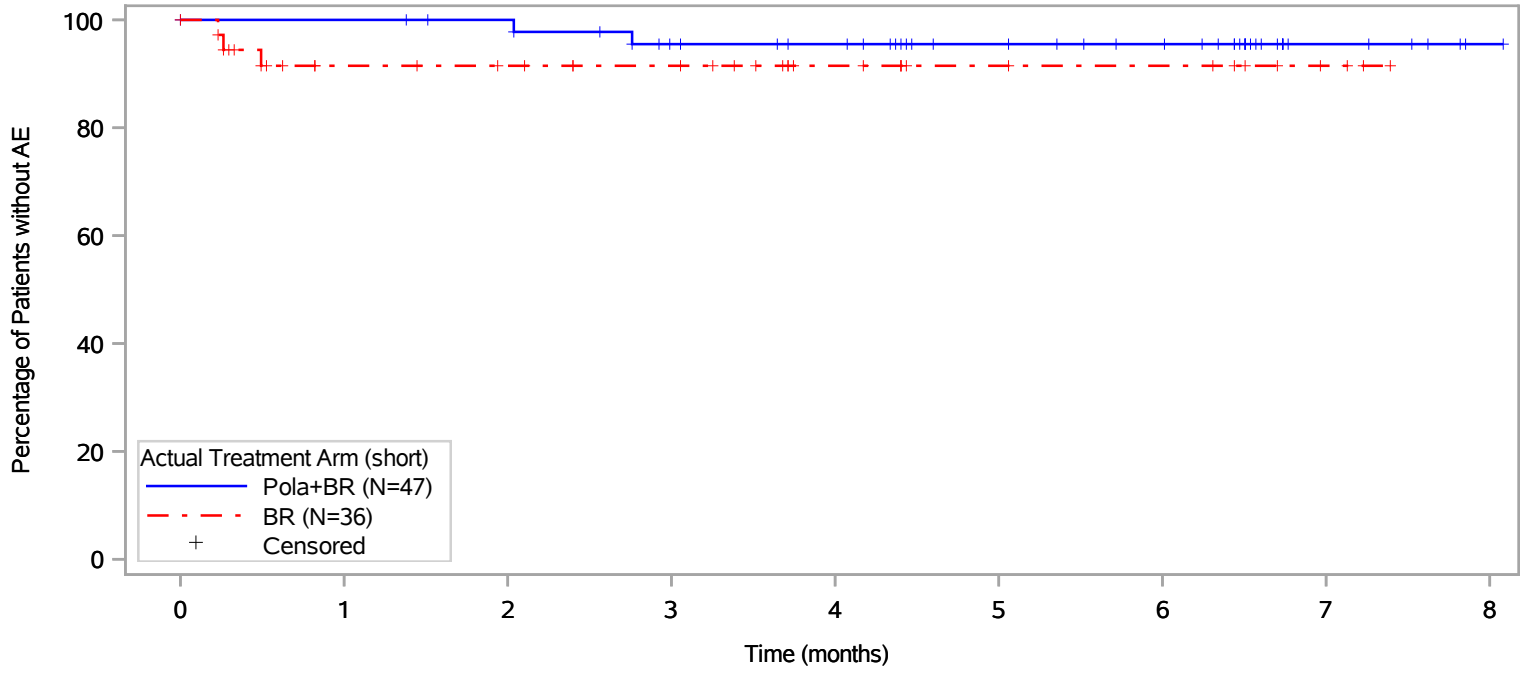
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, ASTHENIA



Patients at risk									
Pola+BR (N=47)	47	47	45	40	37	29	25	6	1
BR (N=36)	36	27	25	22	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	6	8	11	19	24	25	30	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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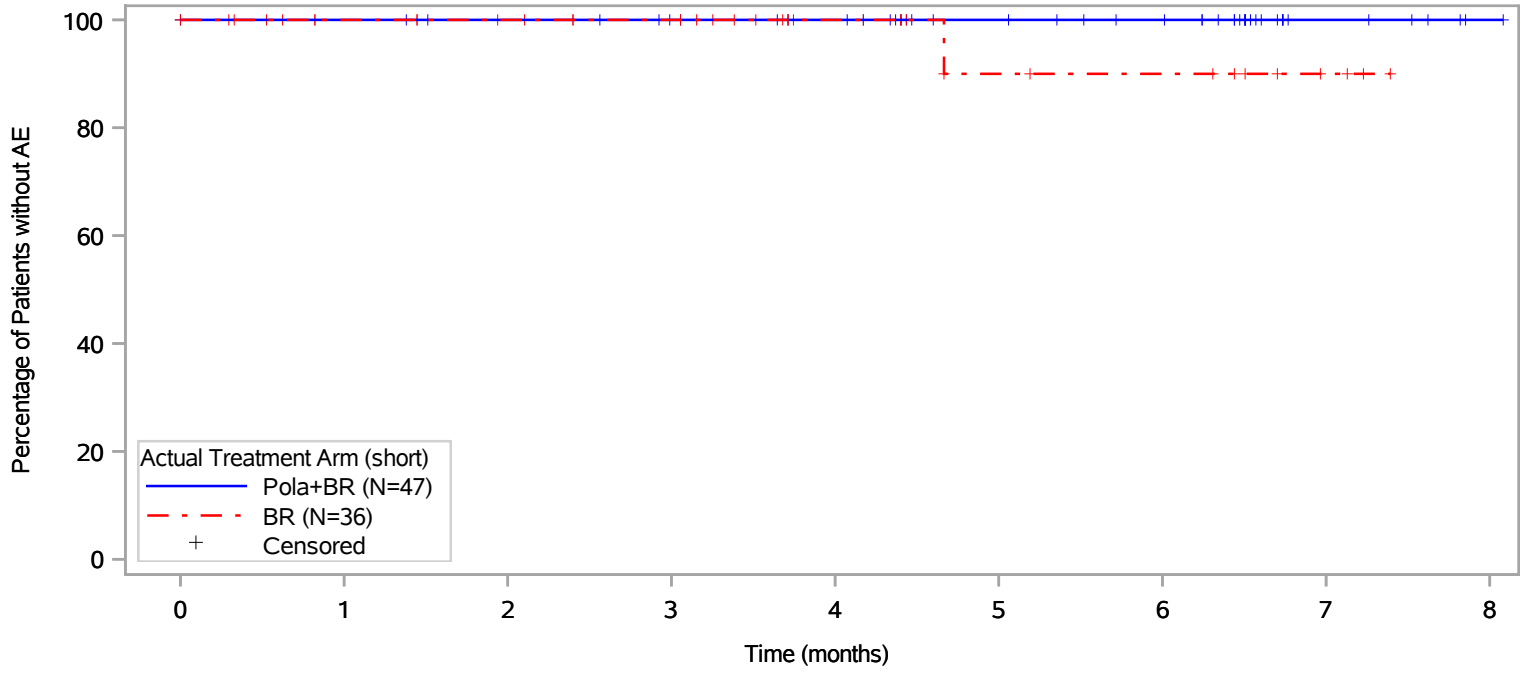
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, AXILLARY PAIN

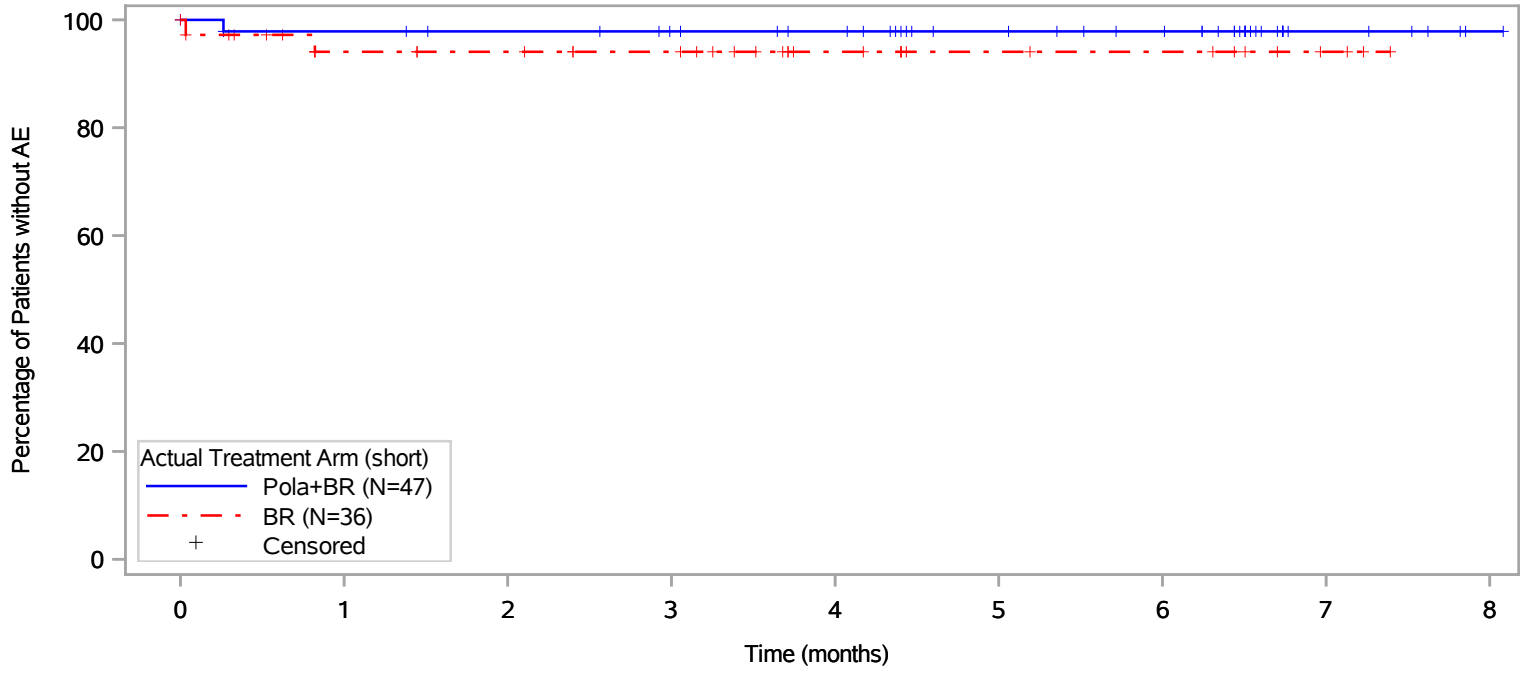


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHEST DISCOMFORT



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	28	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	8	11	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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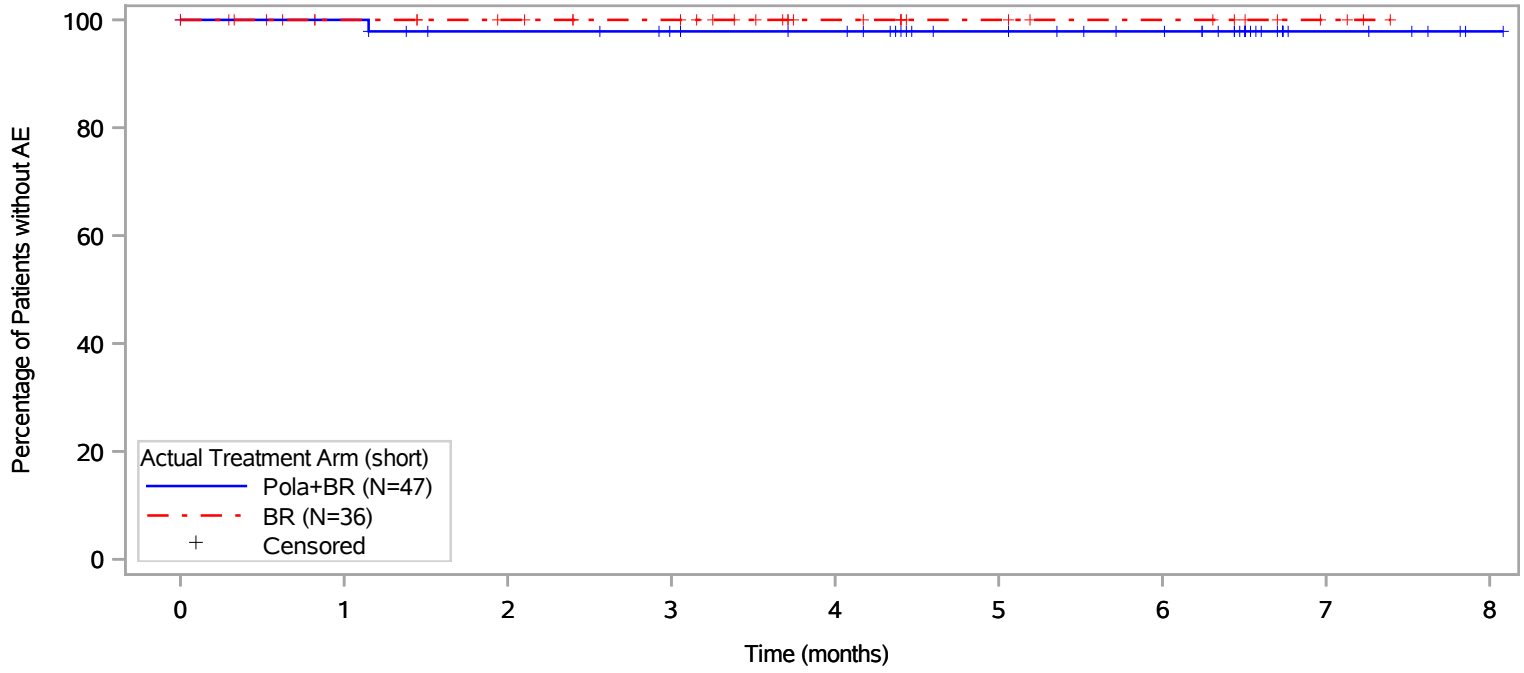
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHEST PAIN

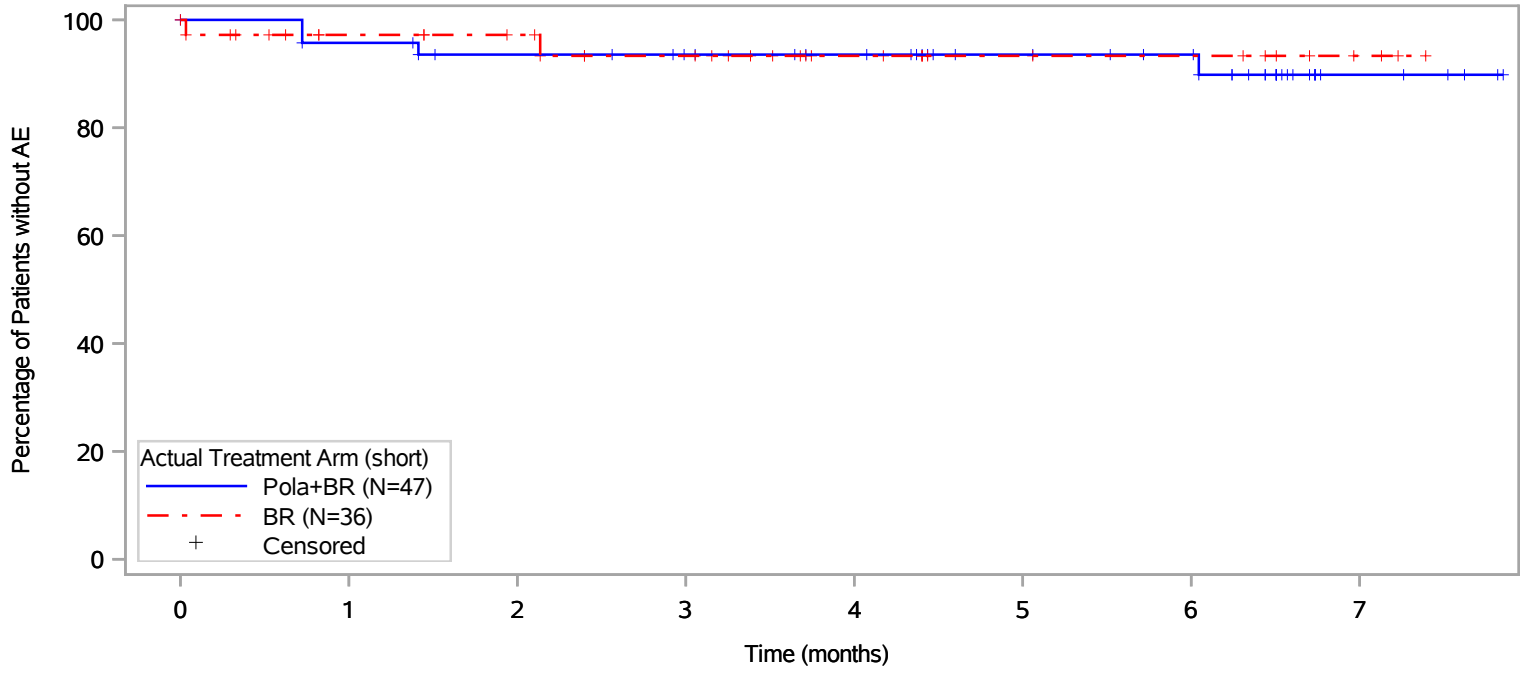


Patients at risk									
Pola+BR (N=47)	47	47	44	41	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHILLS



Patients at risk								
Pola+BR (N=47)	47	45	42	39	36	29	26	5
BR (N=36)	36	29	26	22	14	9	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	15	18	38
BR (N=36)	0	6	9	12	20	25	26	31

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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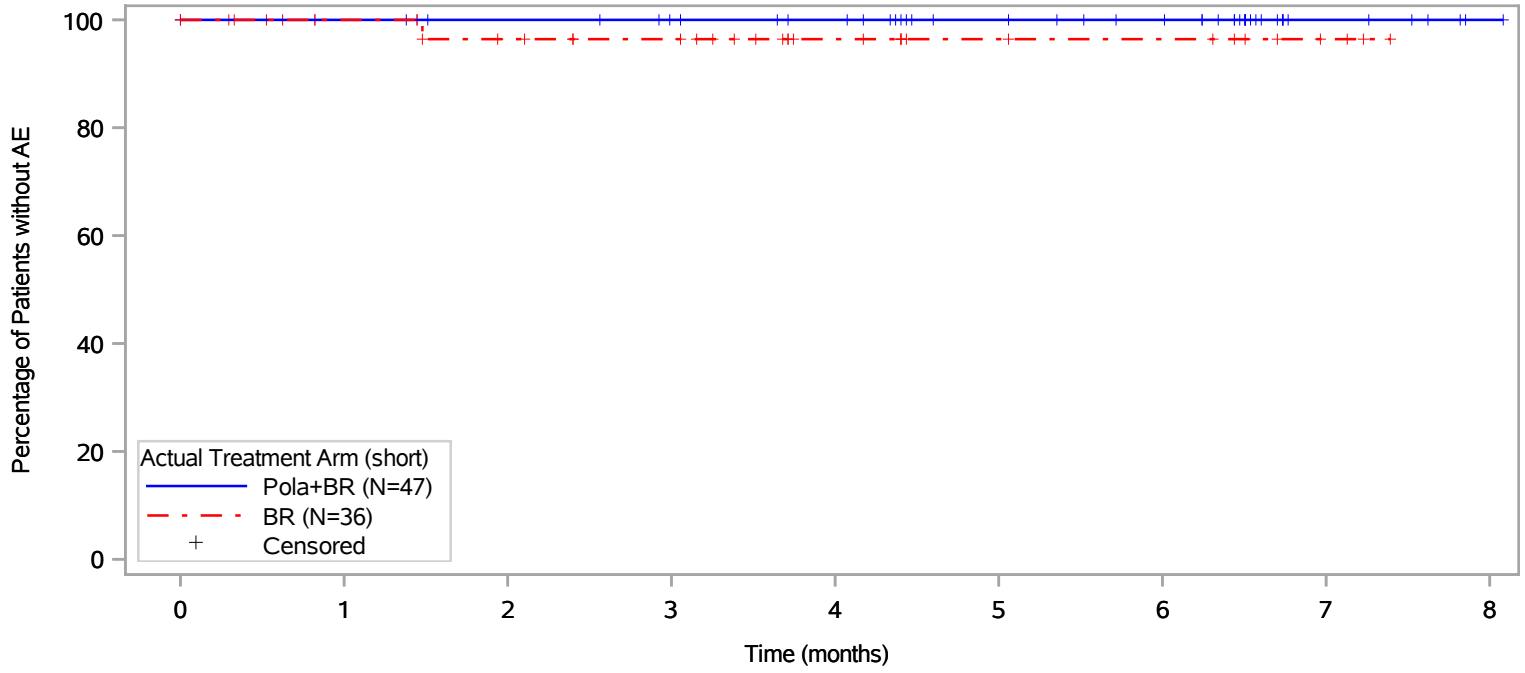
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

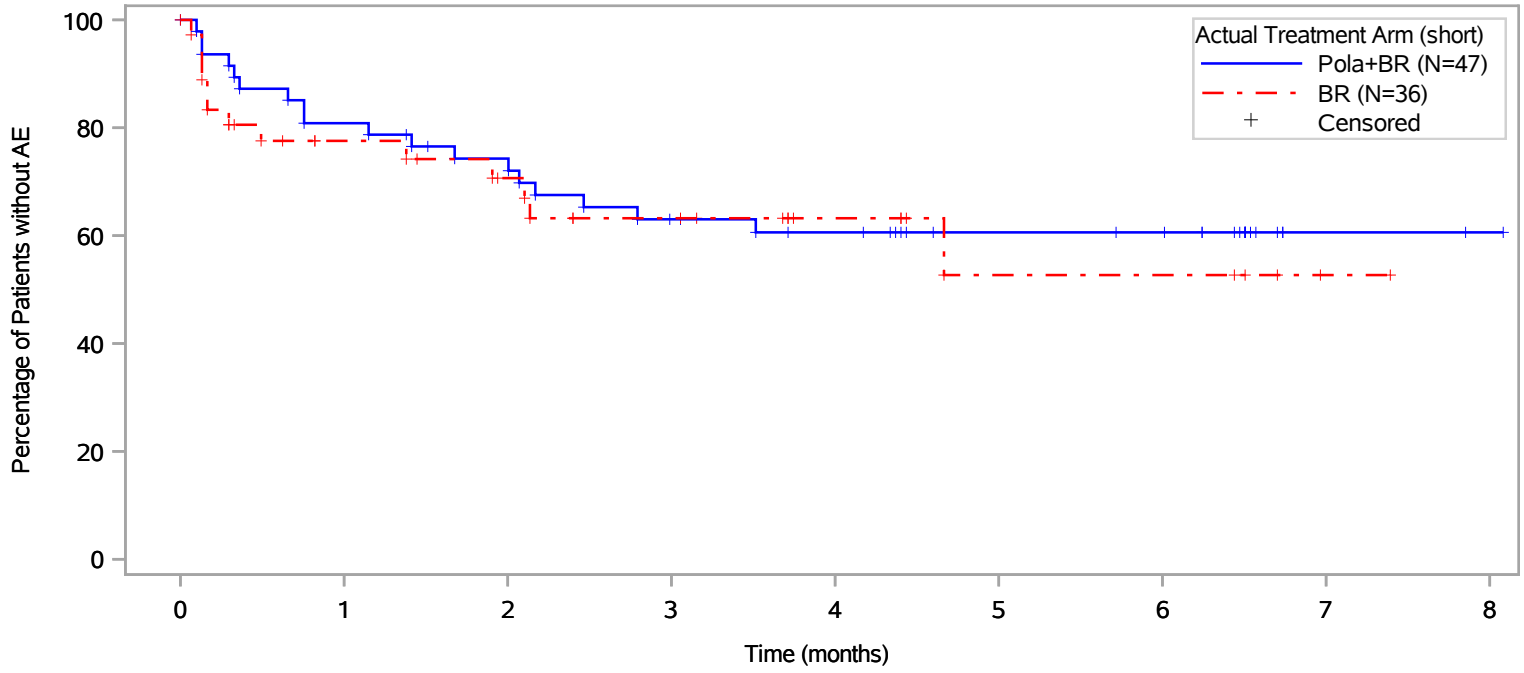
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FACE OEDEMA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE



Patients at risk									
Pola+BR (N=47)	47	38	33	27	24	18	17	2	1
BR (N=36)	36	23	19	15	9	5	5	1	NE
Patients censored									
Pola+BR (N=47)	0	0	2	3	5	11	12	27	28
BR (N=36)	0	5	7	9	15	18	18	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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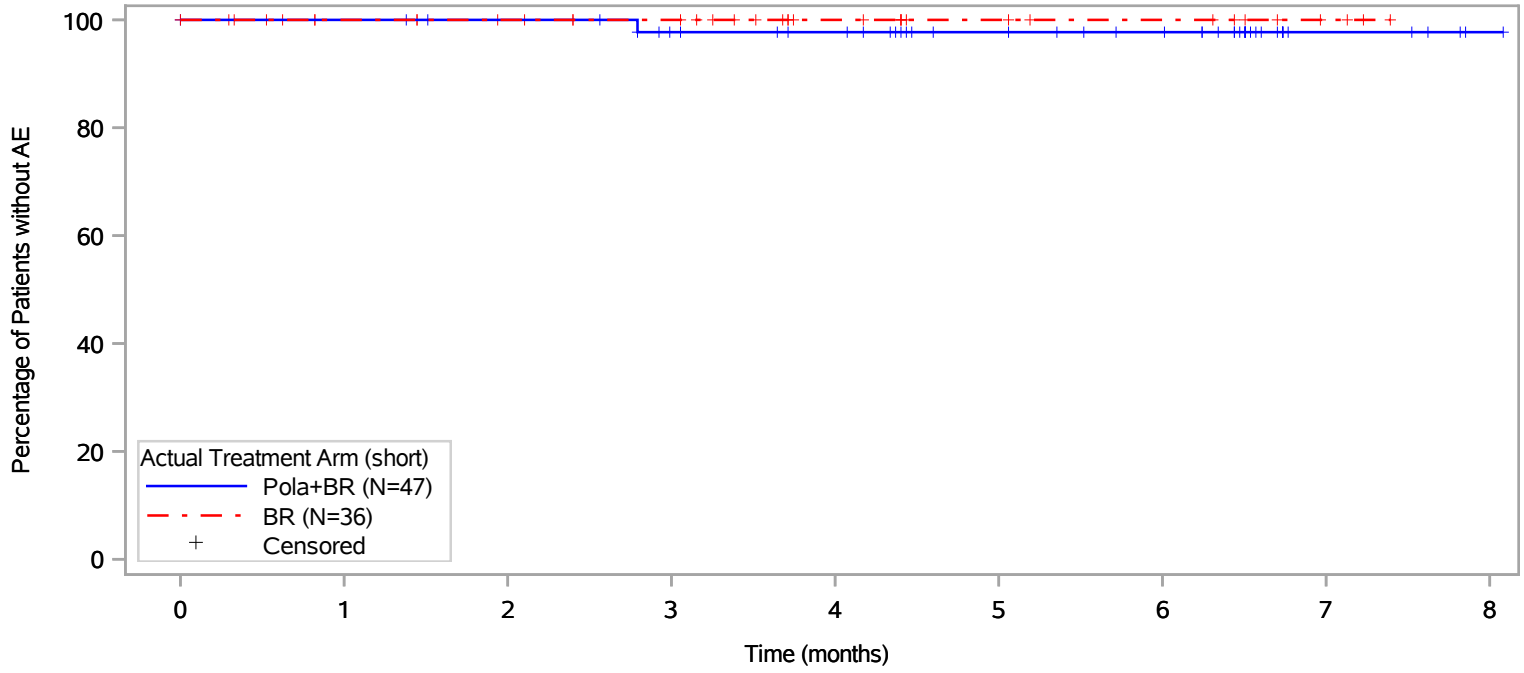
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FEELING COLD



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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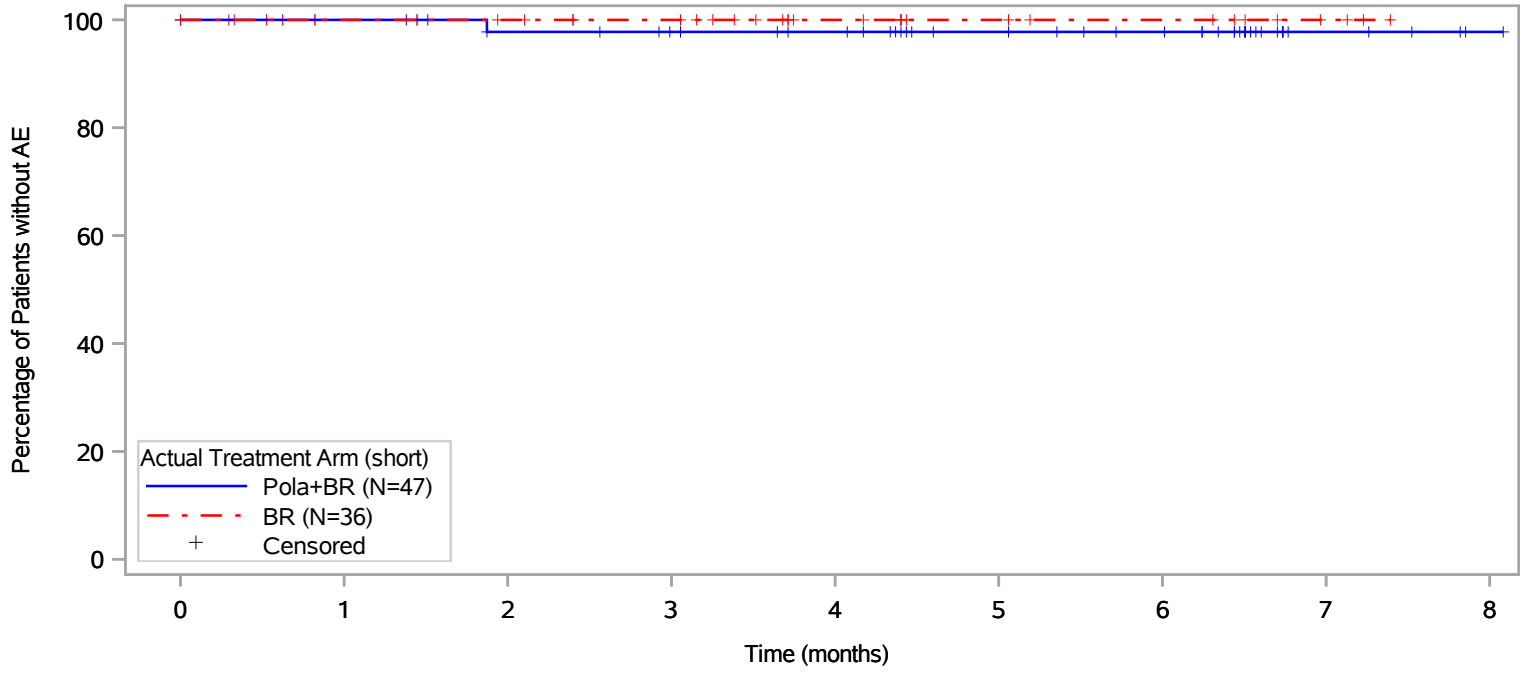
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, GAIT DISTURBANCE



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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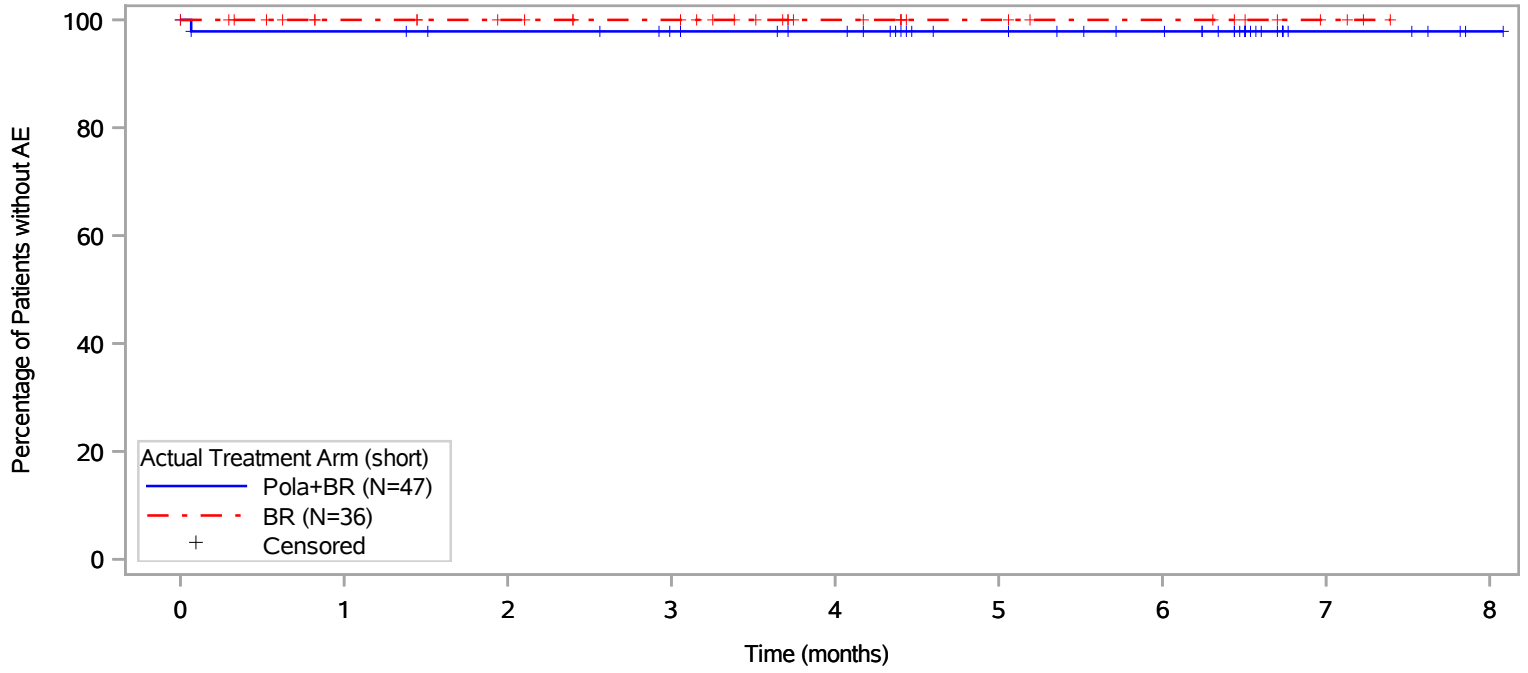
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, INJECTION SITE PAIN

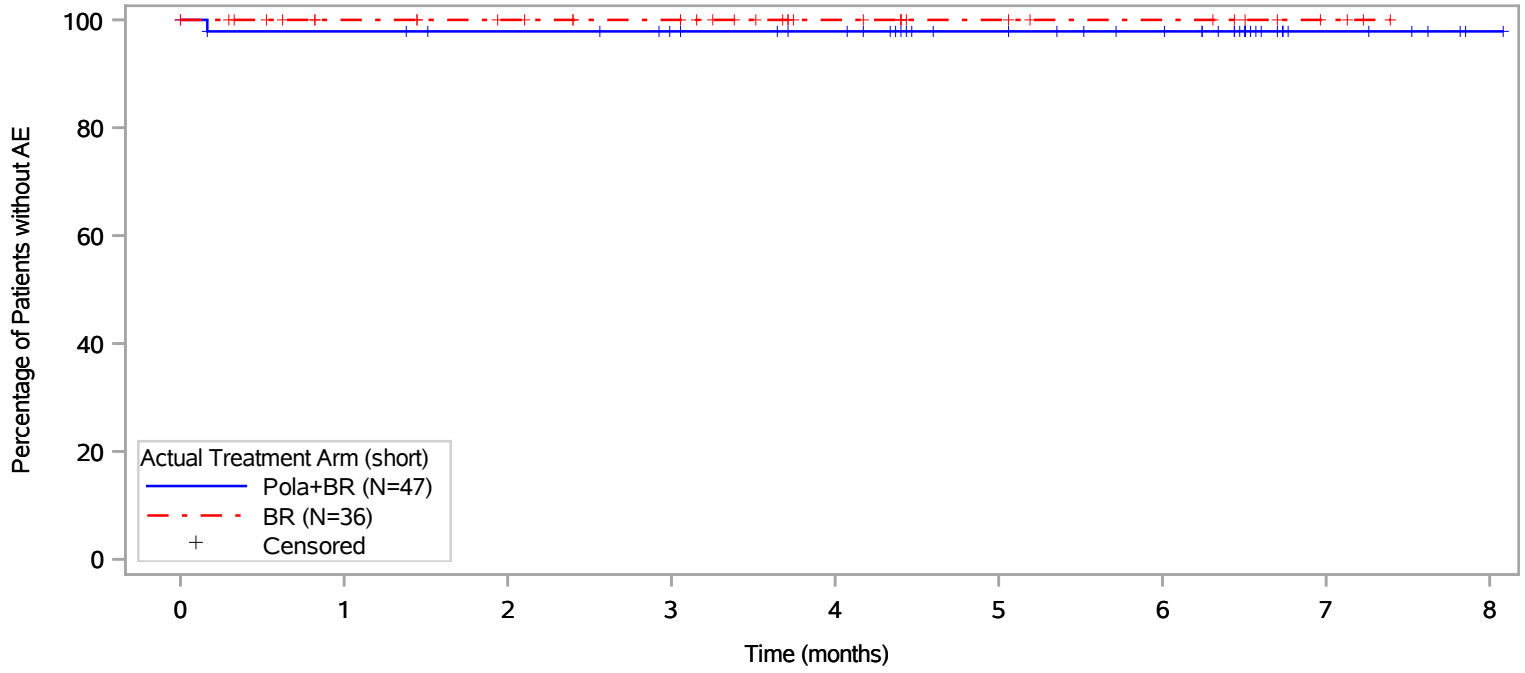


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MALAISE

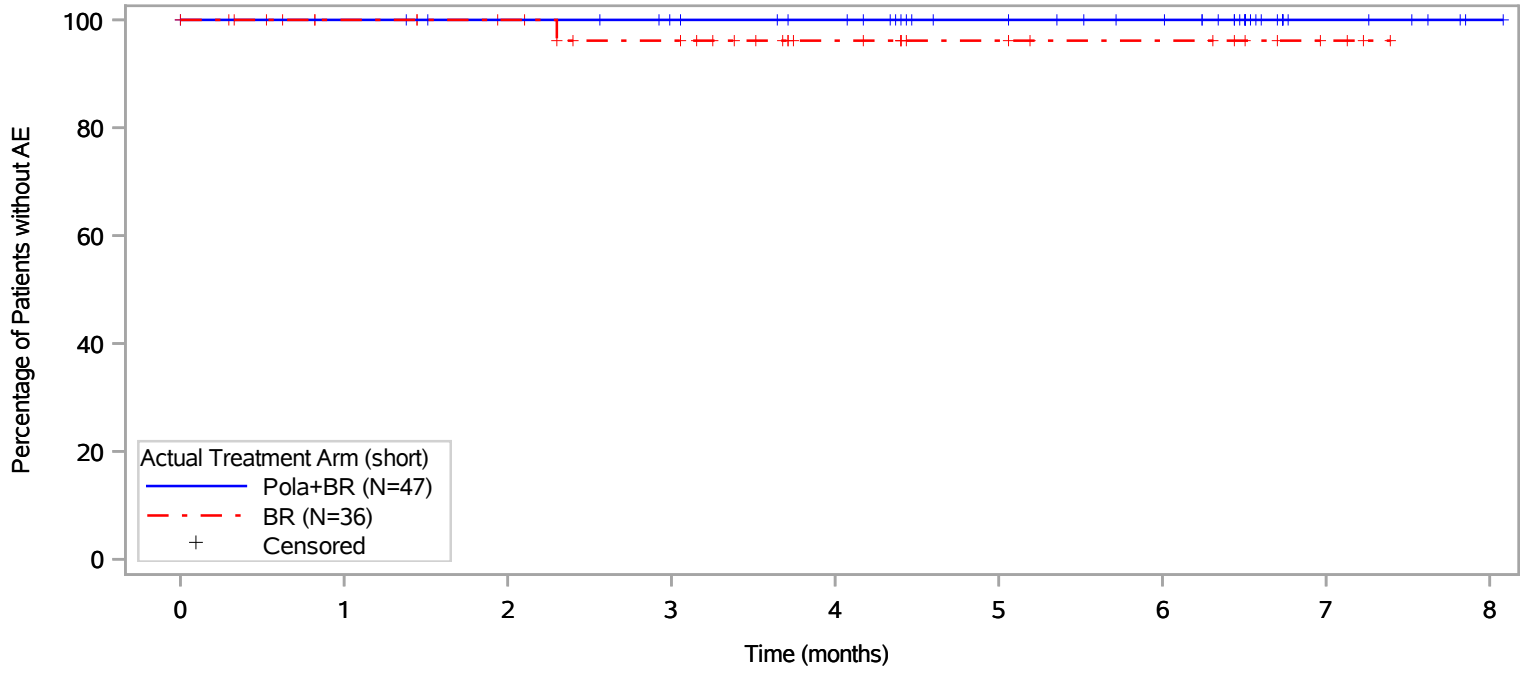


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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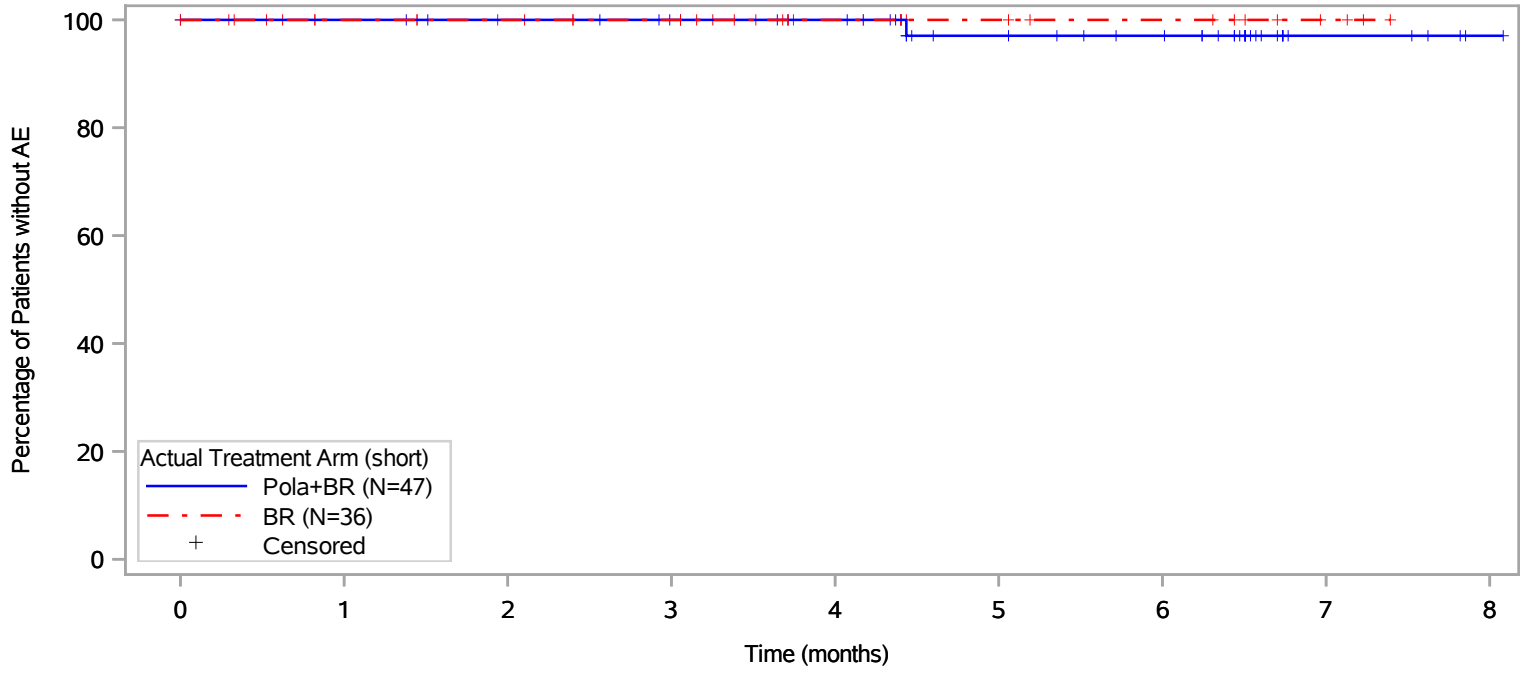
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, NON-CARDIAC CHEST PAIN



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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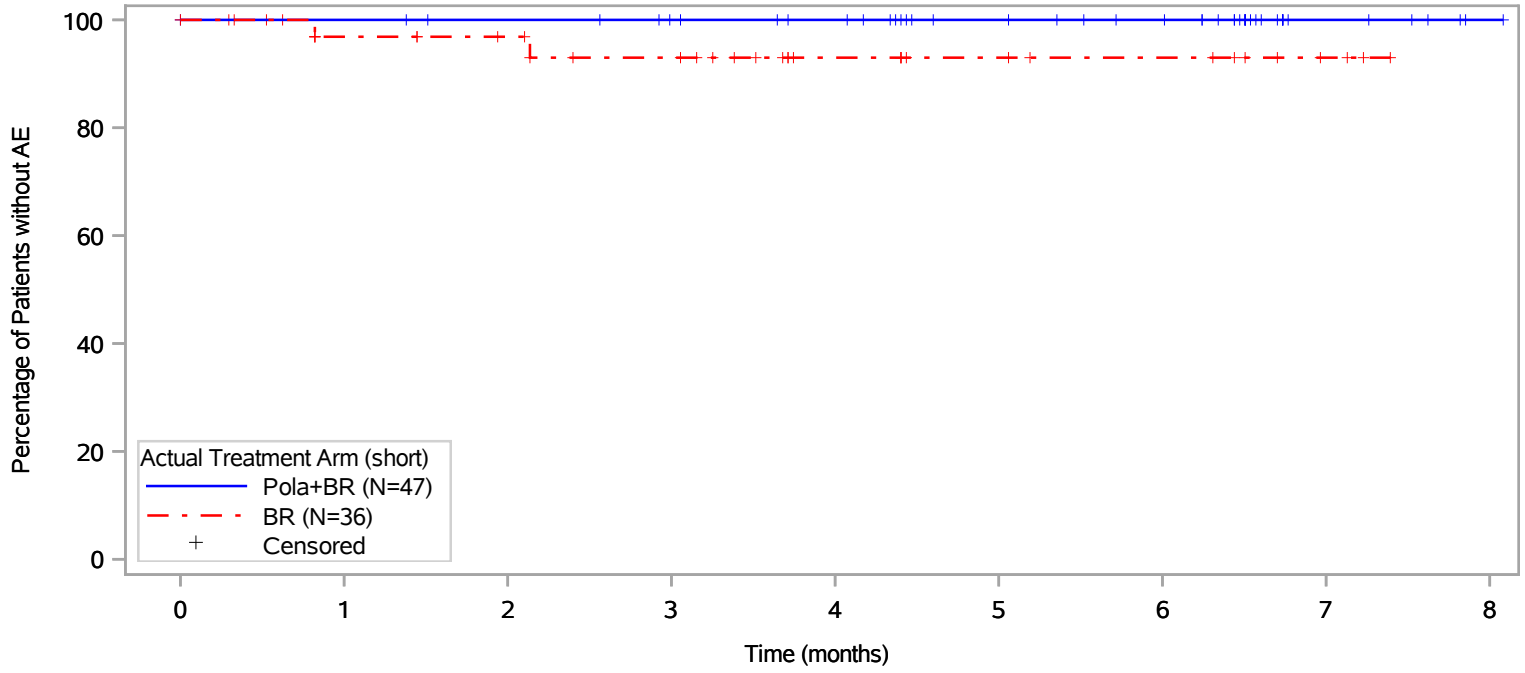
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA

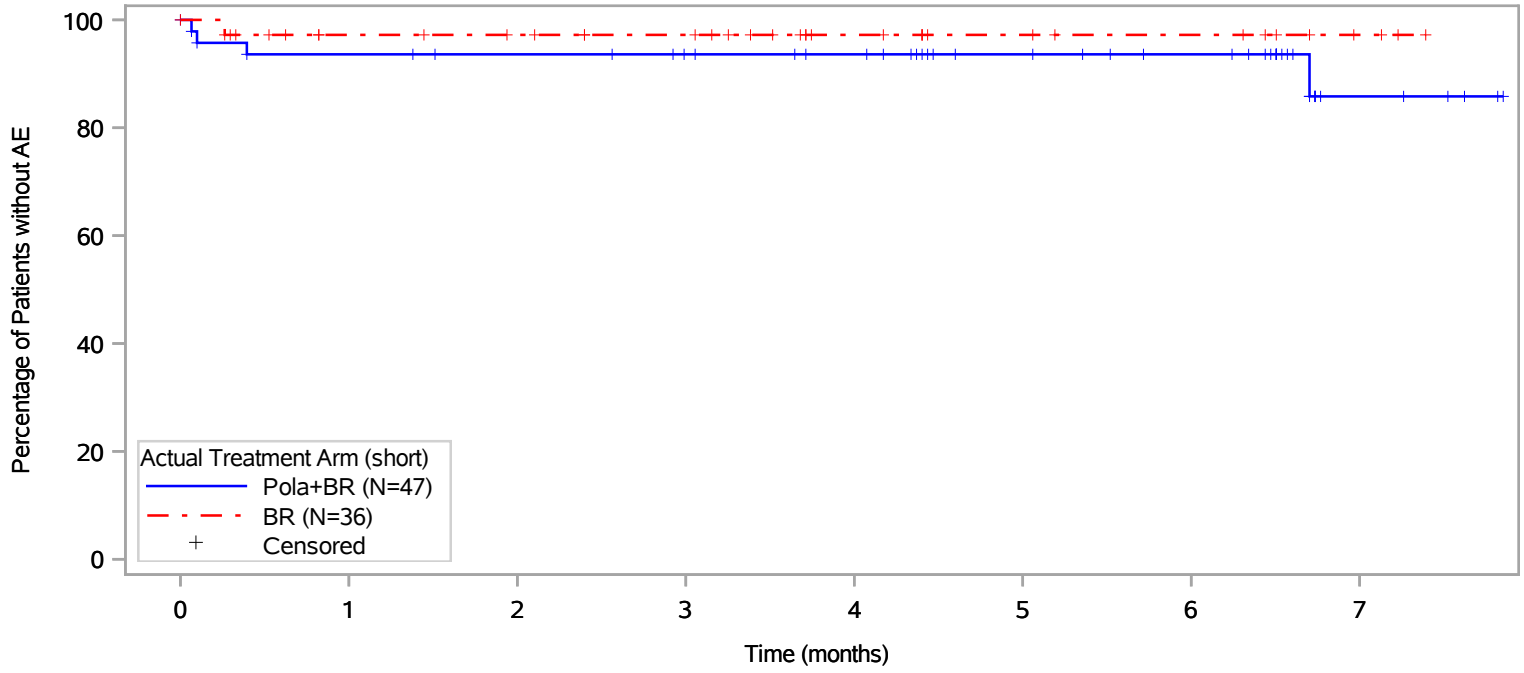


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL



Patients at risk								
Pola+BR (N=47)	47	44	42	39	36	28	24	5
BR (N=36)	36	29	27	24	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	16	20	38
BR (N=36)	0	6	8	11	20	25	27	32

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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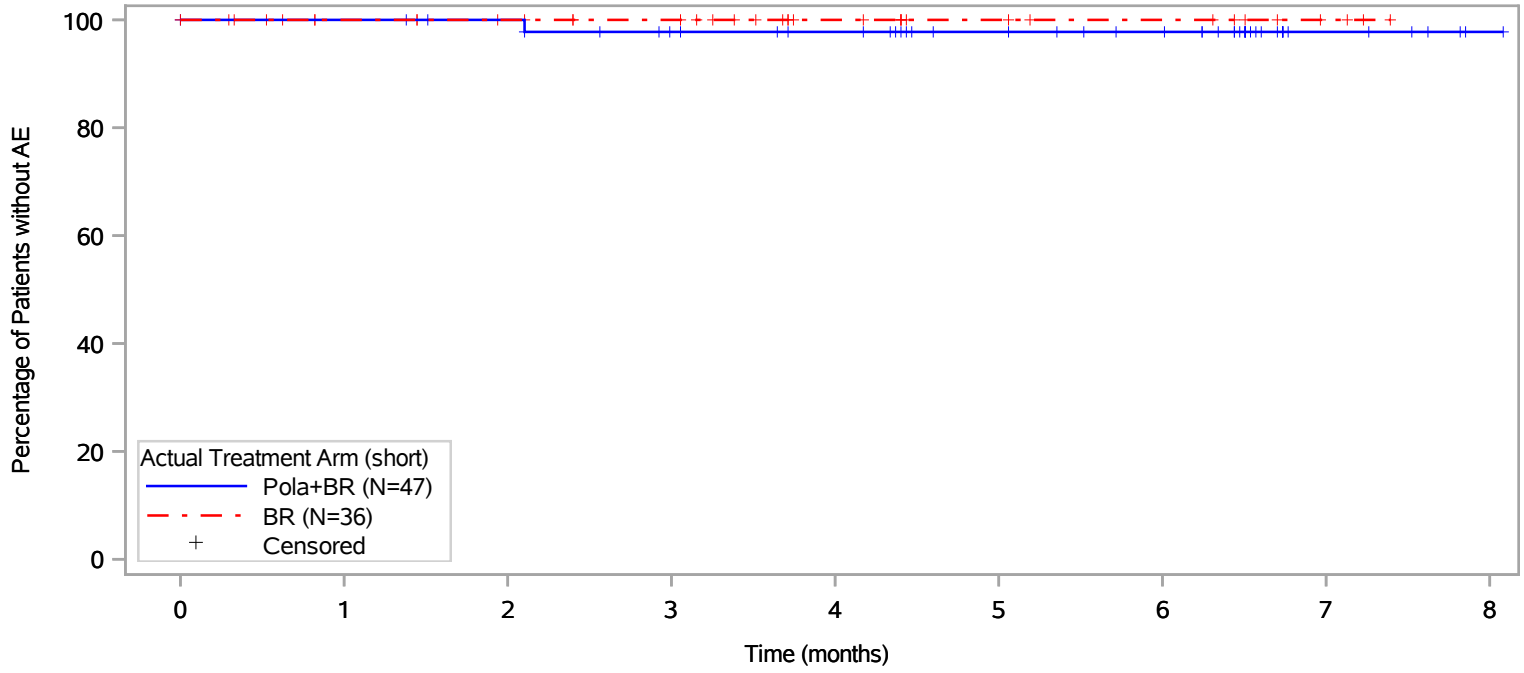
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PAIN



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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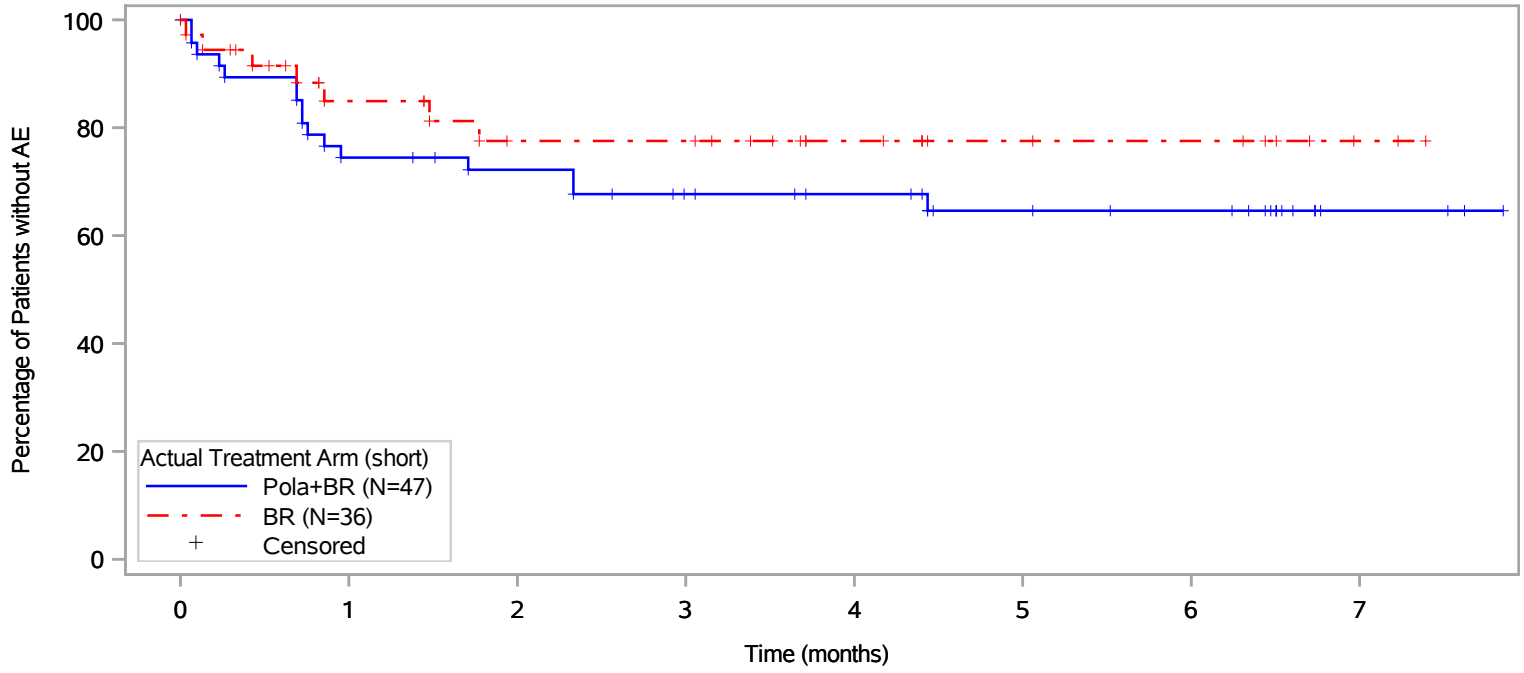
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk								
Pola+BR (N=47)	47	35	32	27	24	19	17	3
BR (N=36)	36	25	20	20	13	8	7	2
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	12	14	28
BR (N=36)	0	6	9	9	16	21	22	27

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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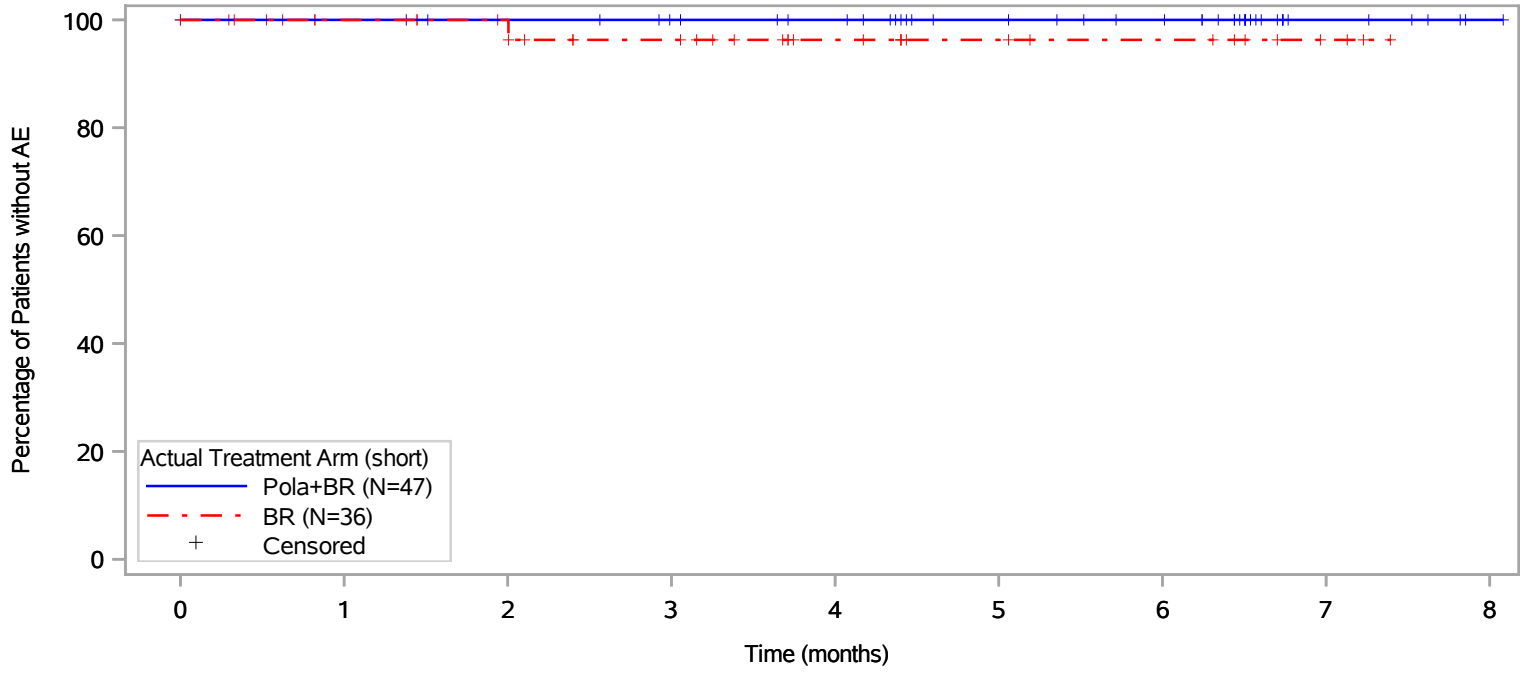
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
HEPATOBILIARY DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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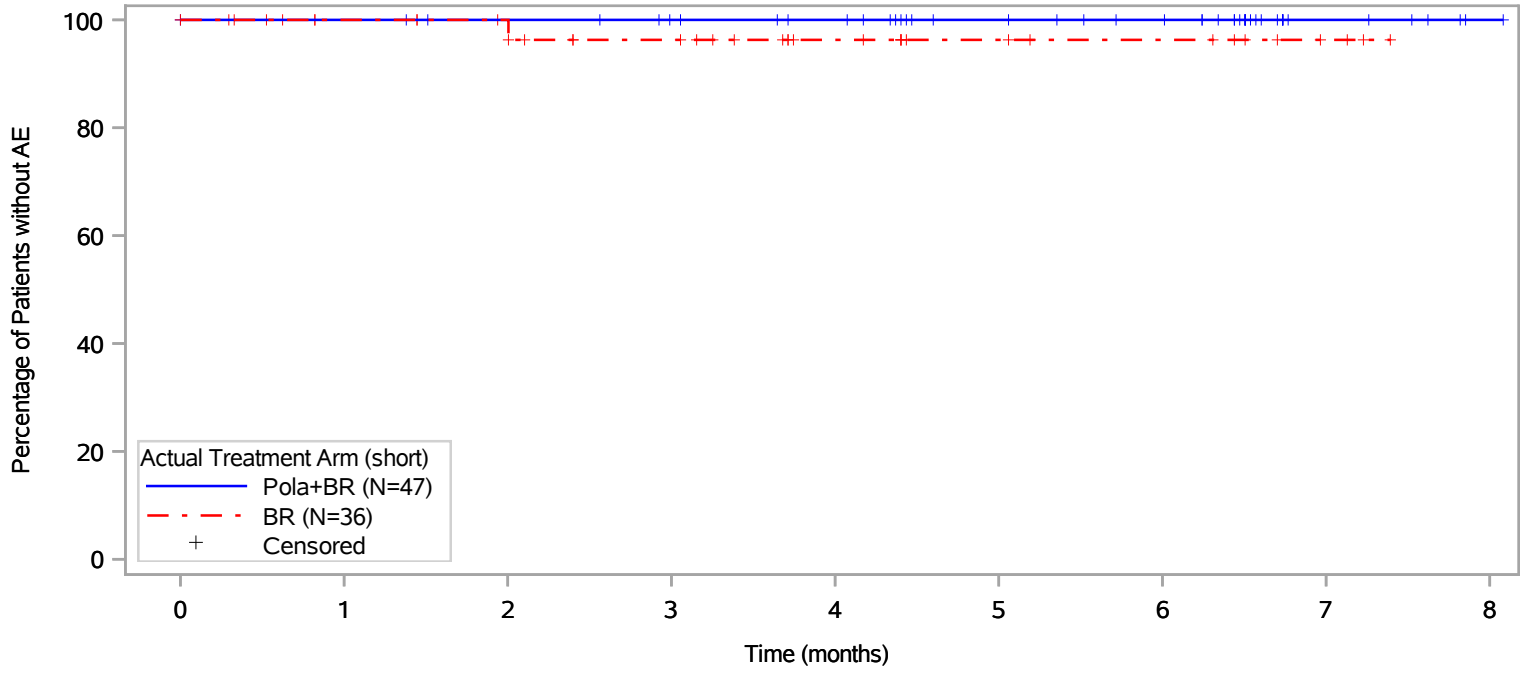
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
HEPATOBILIARY DISORDERS, HEPATIC FUNCTION ABNORMAL



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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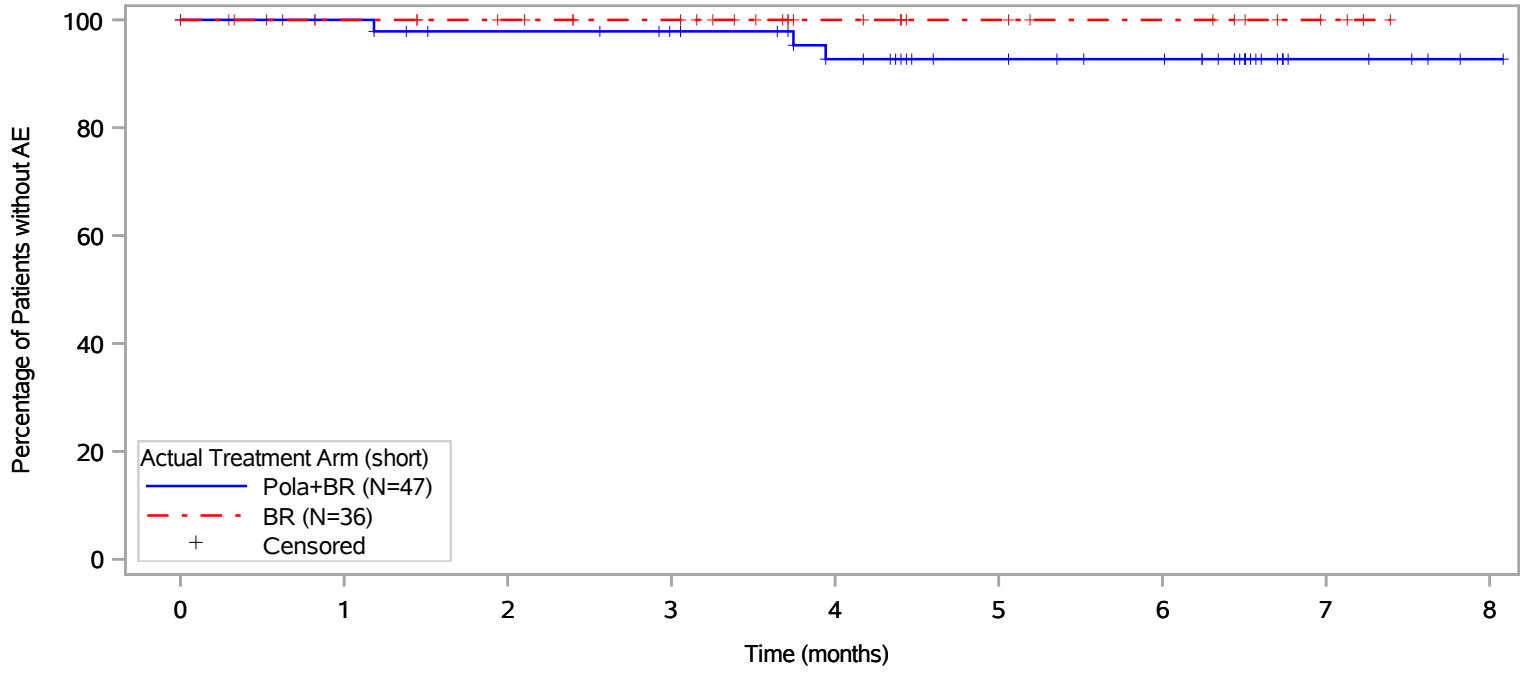
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	44	41	36	29	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	18	39	43
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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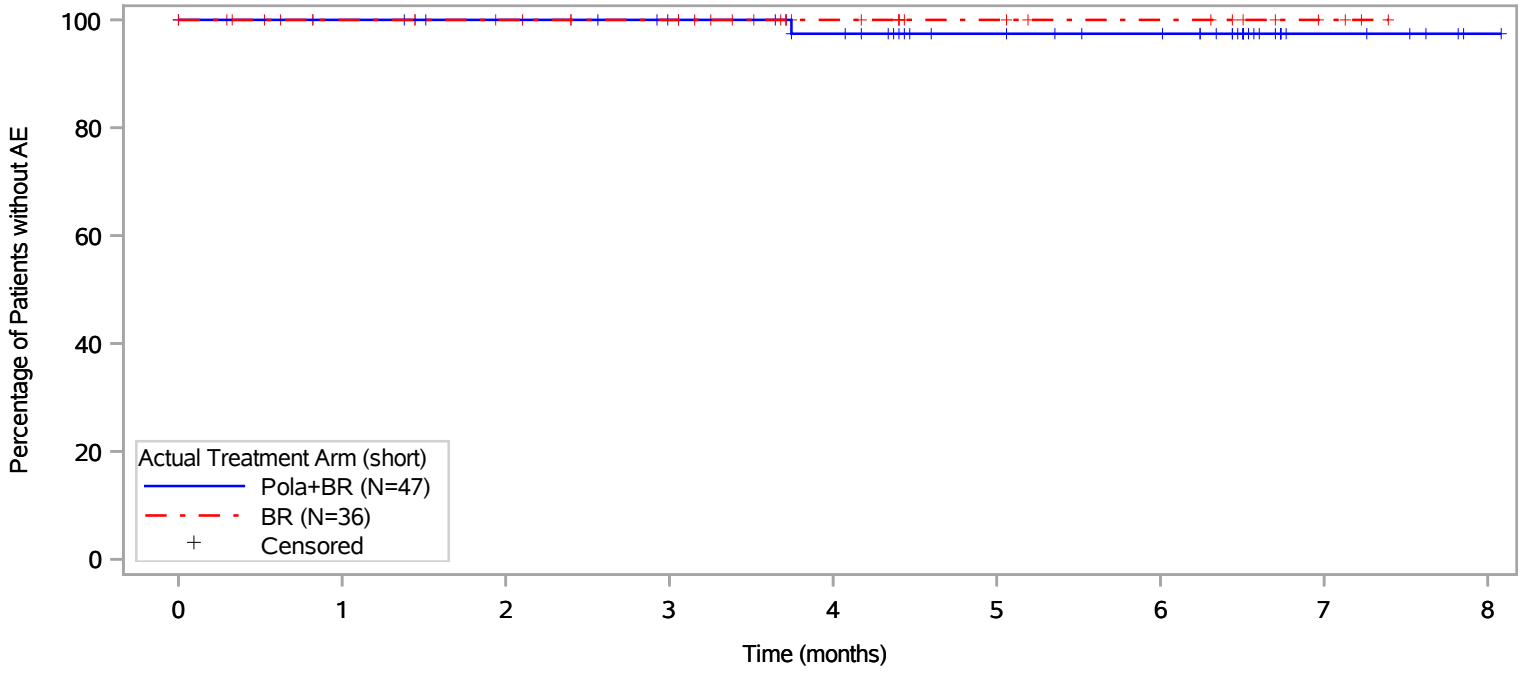
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, AMYLOIDOSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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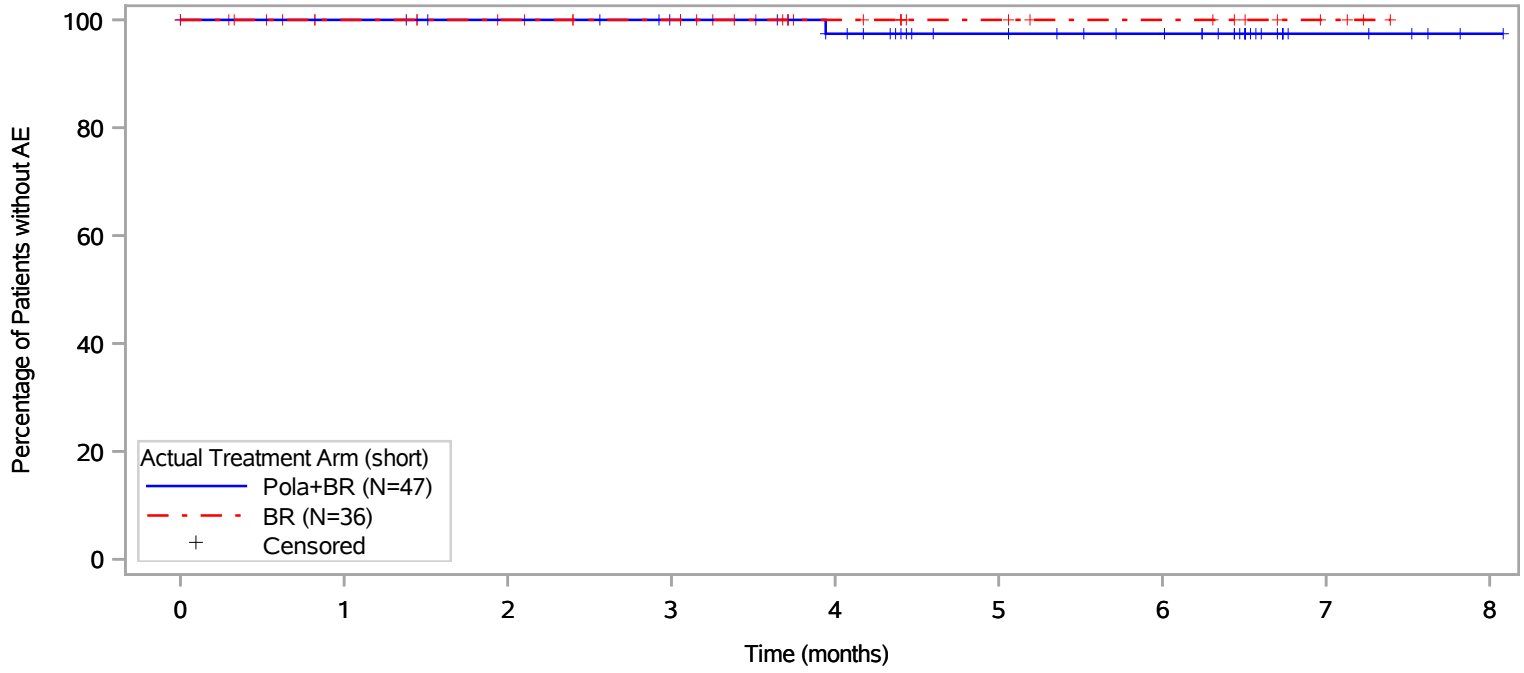
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, HYPOGAMMAGLOBULINAEMIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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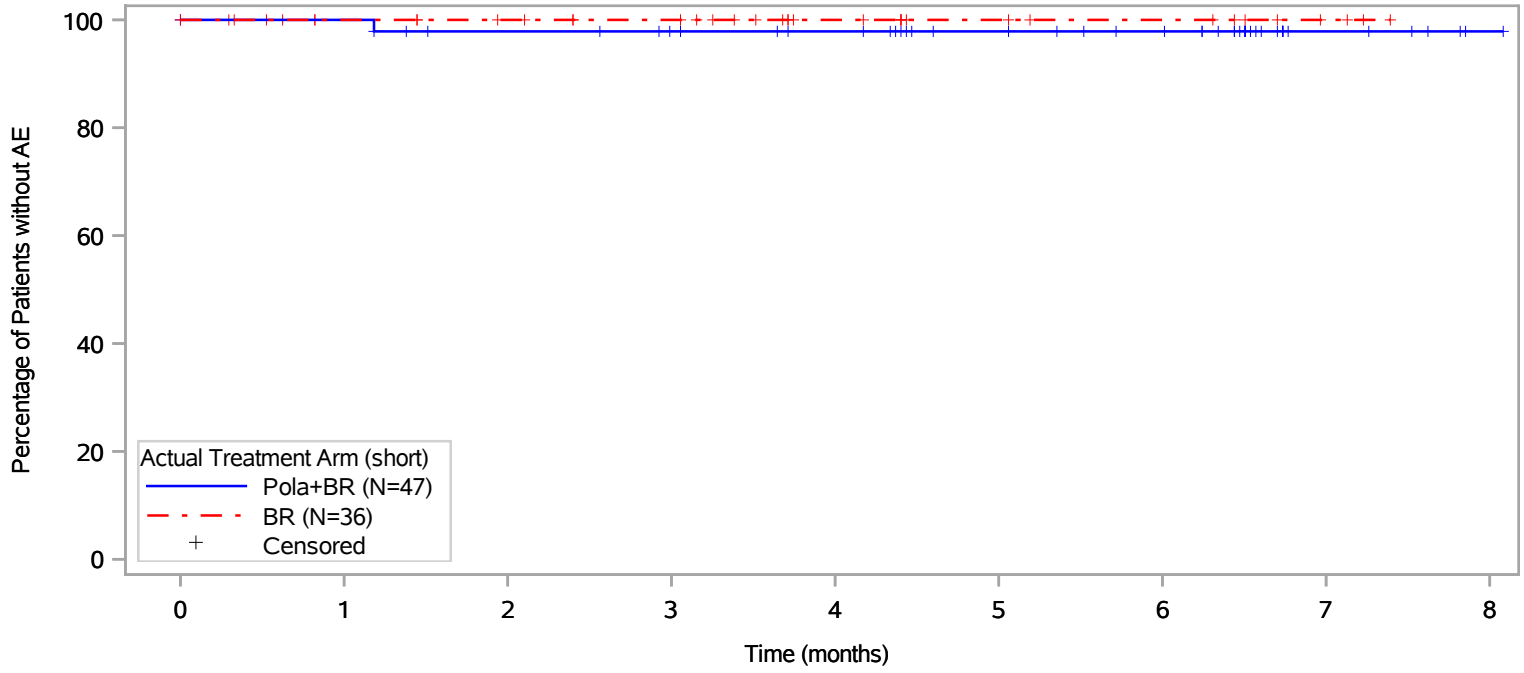
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, SEASONAL ALLERGY



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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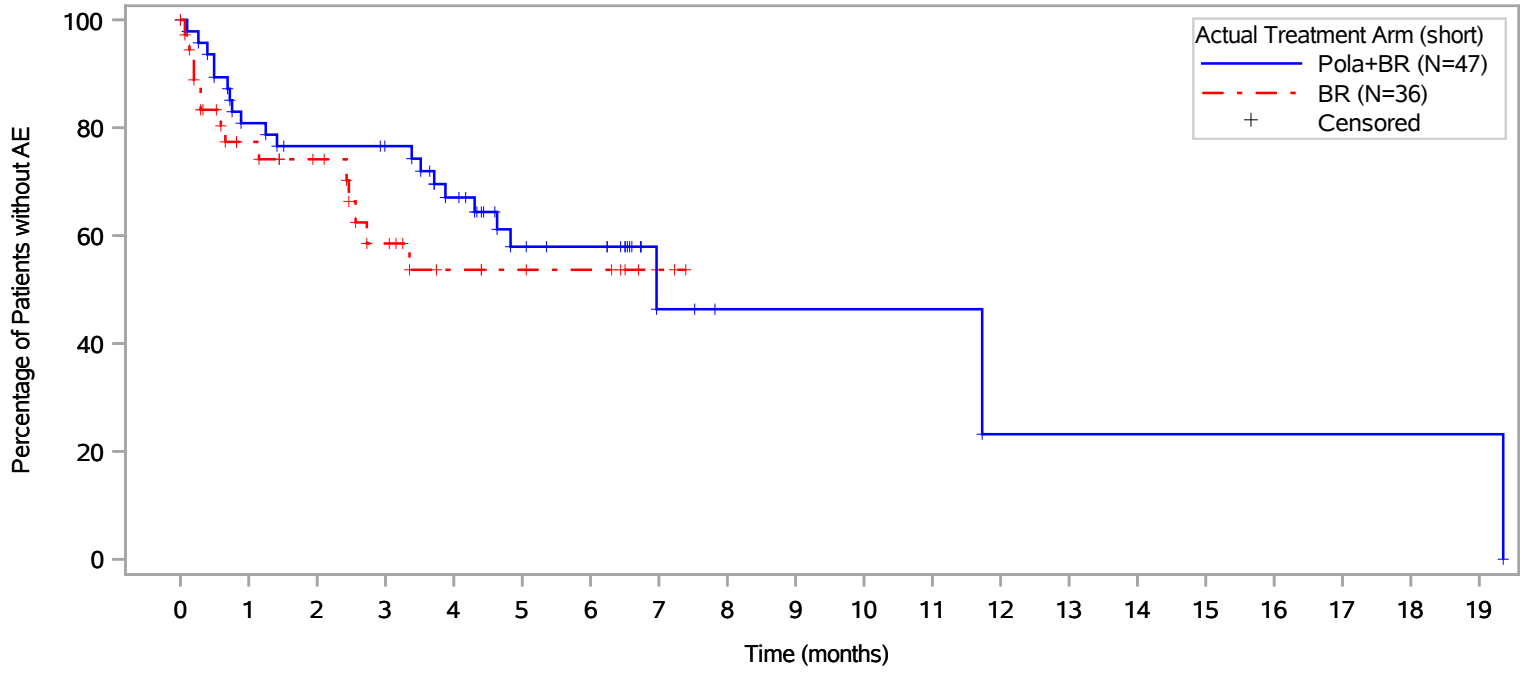
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk																				
Pola+BR (N=47)	47	38	35	33	27	18	16	4	2	2	2	2	1	1	1	1	1	1	1	1
BR (N=36)	36	24	20	15	10	8	7	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	1	3	5	11	13	24	26	26	26	26	26	26	26	26	26	26	26	26
BR (N=36)	0	4	7	8	12	14	15	20	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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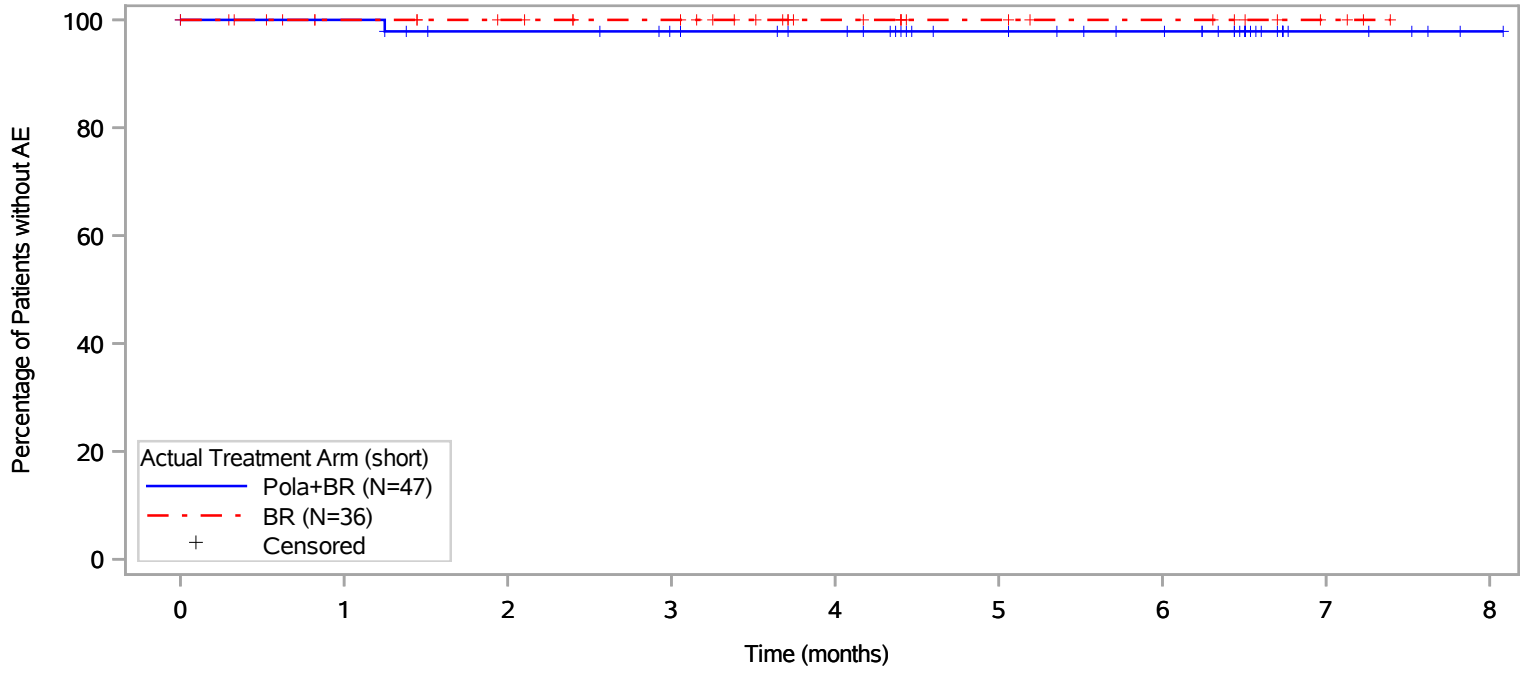
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, BRONCHITIS



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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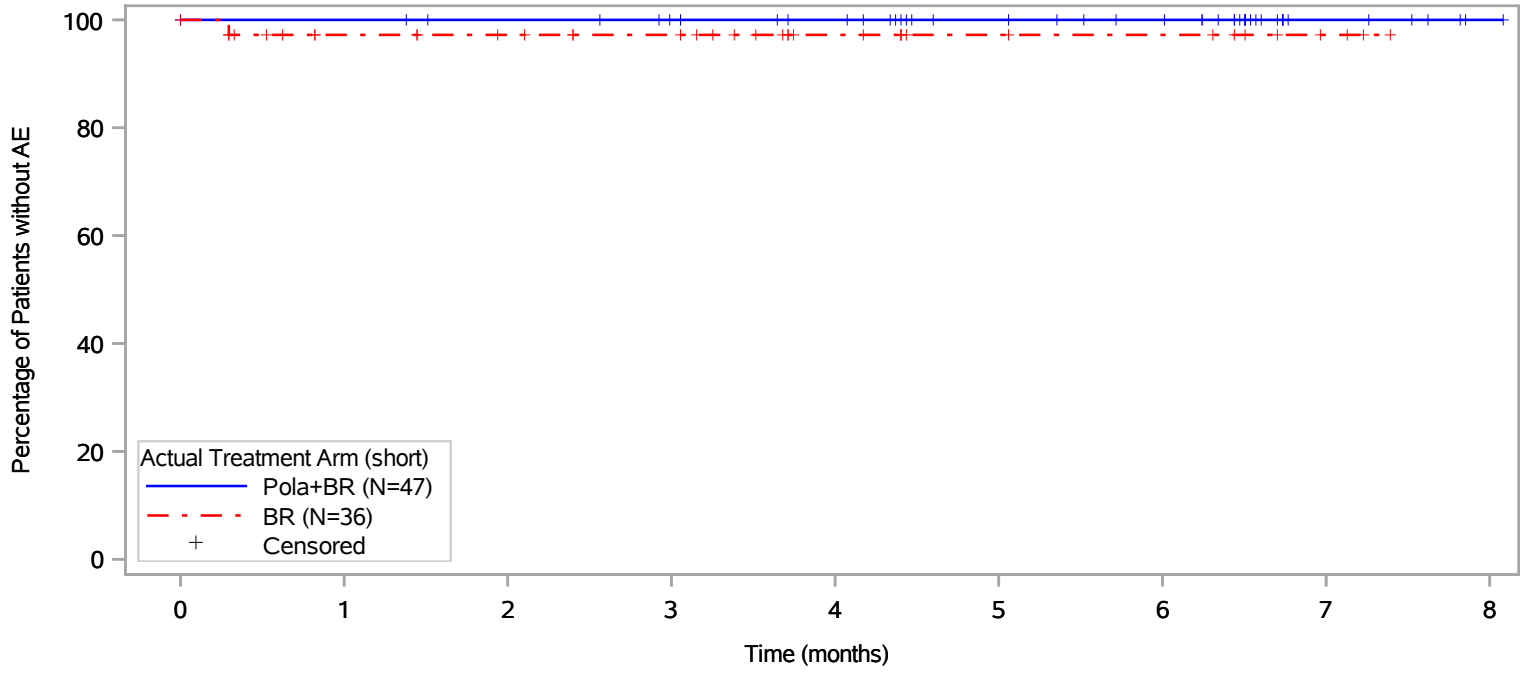
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CANDIDA INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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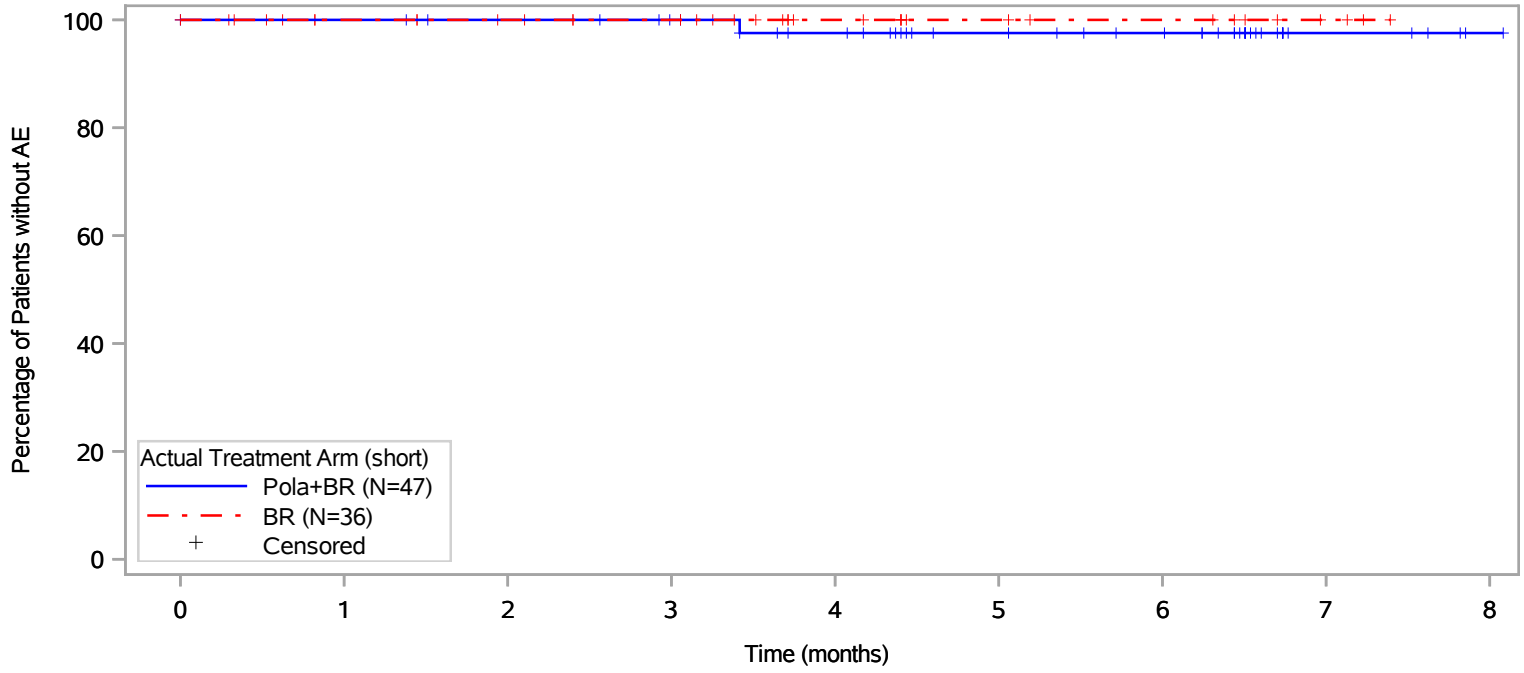
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CELLULITIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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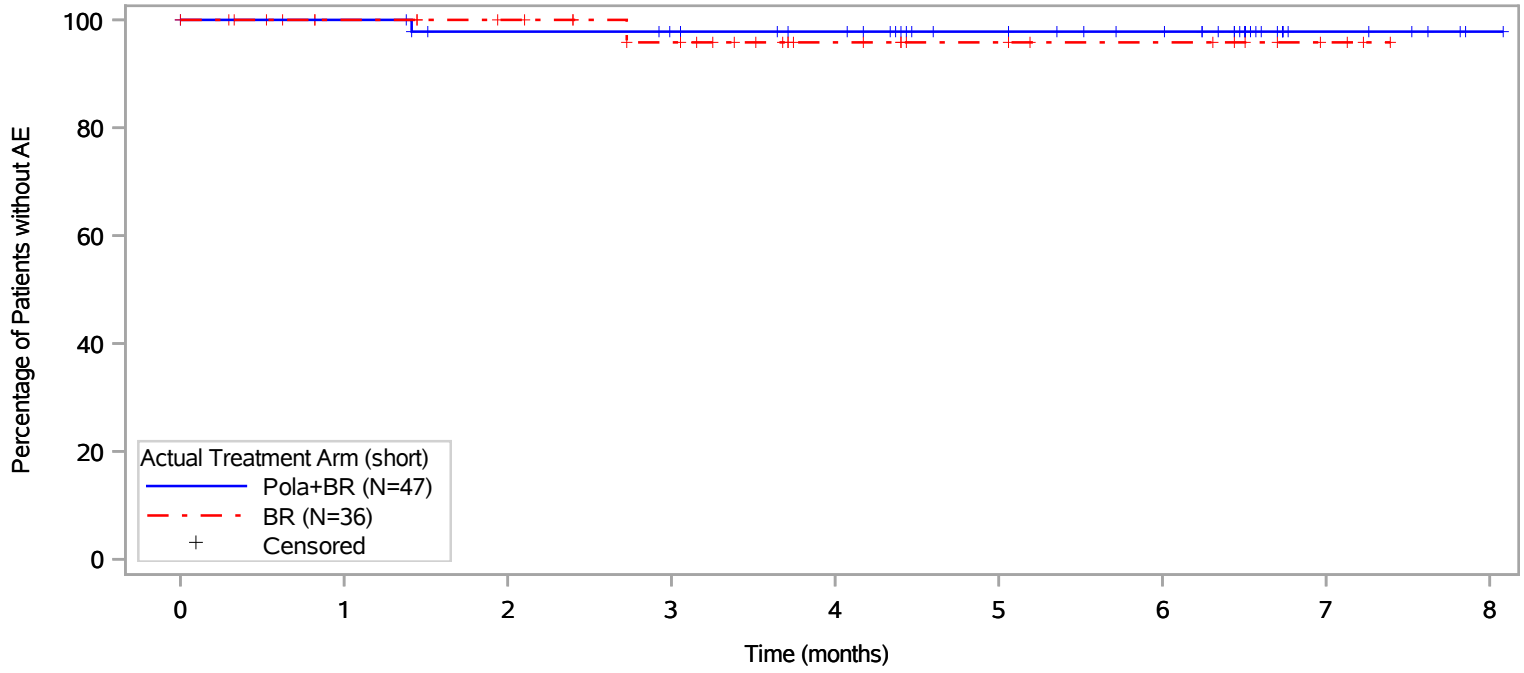
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

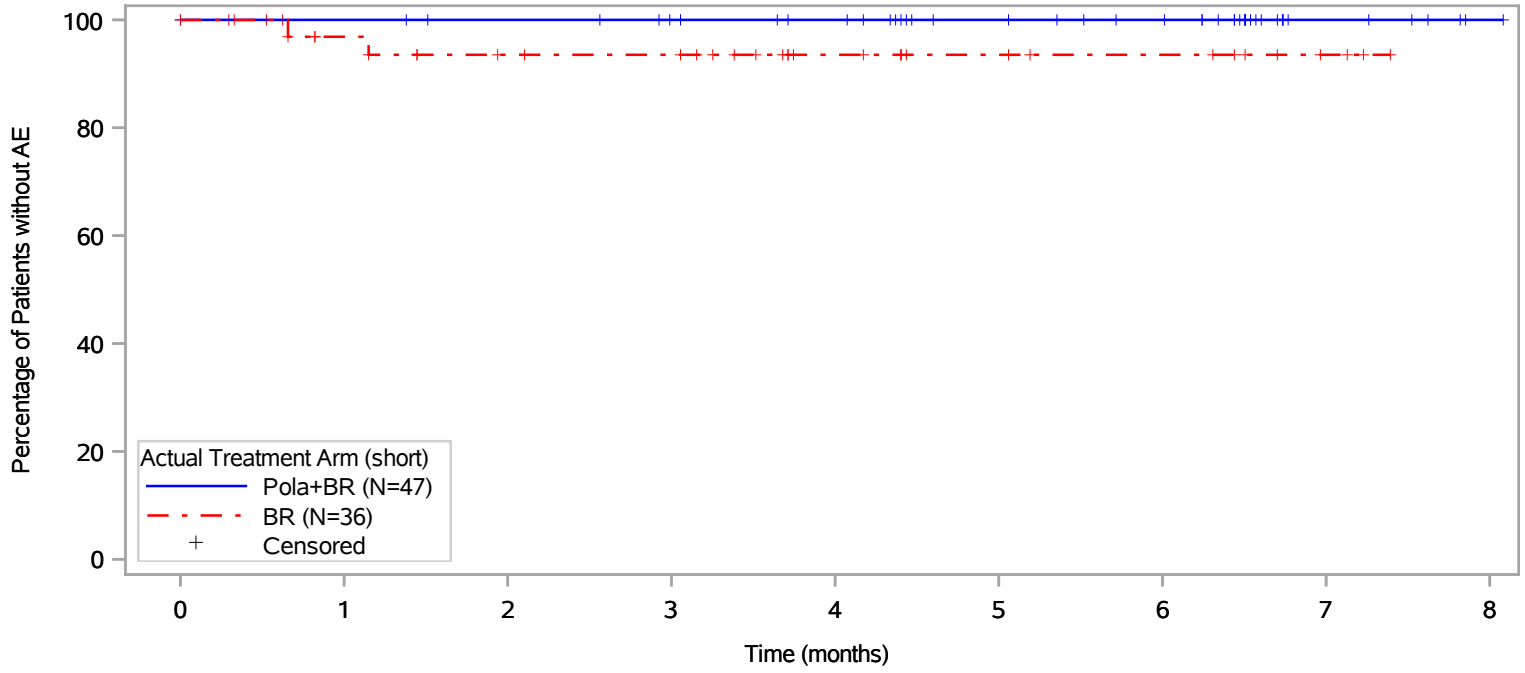
INFECTIONS AND INFESTATIONS, CYTOMEGALOVIRUS INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, DEVICE RELATED INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	25	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	10	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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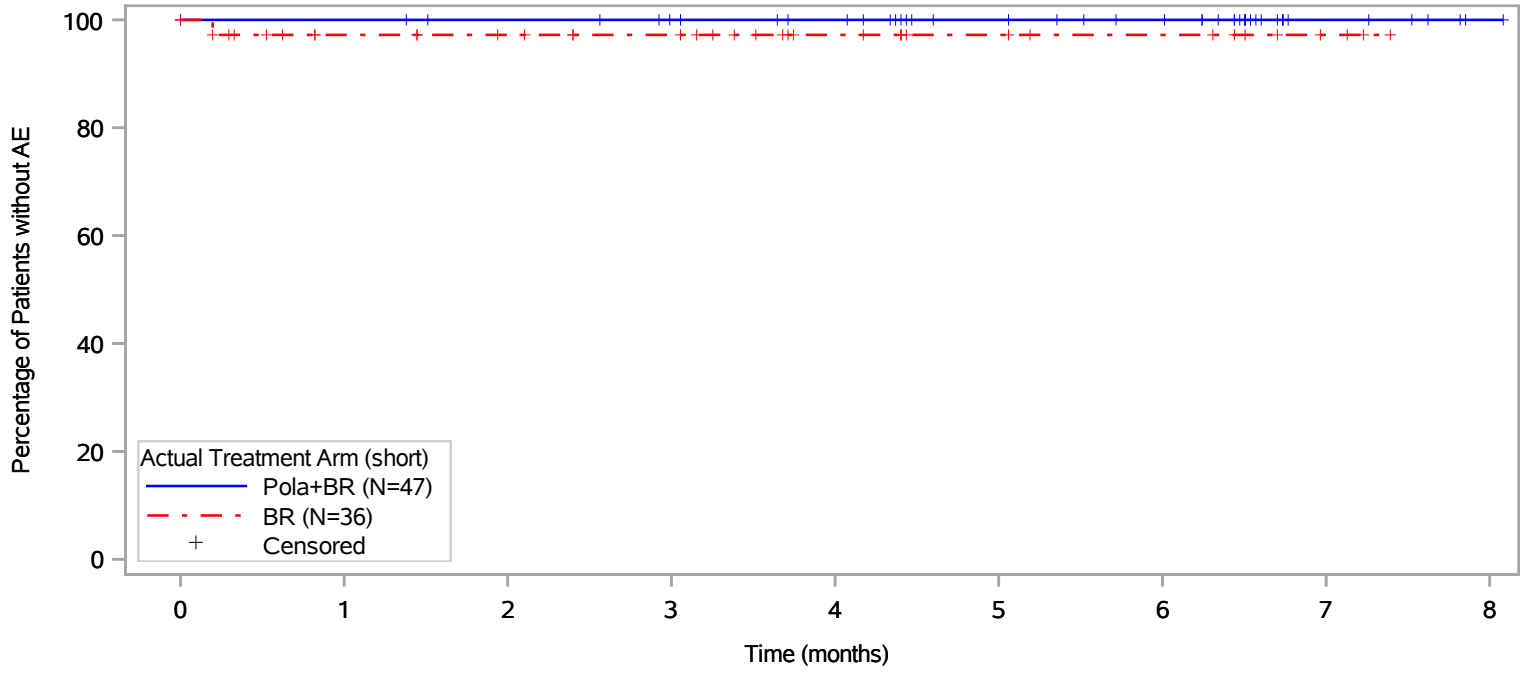
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ENTEROCOLITIS VIRAL



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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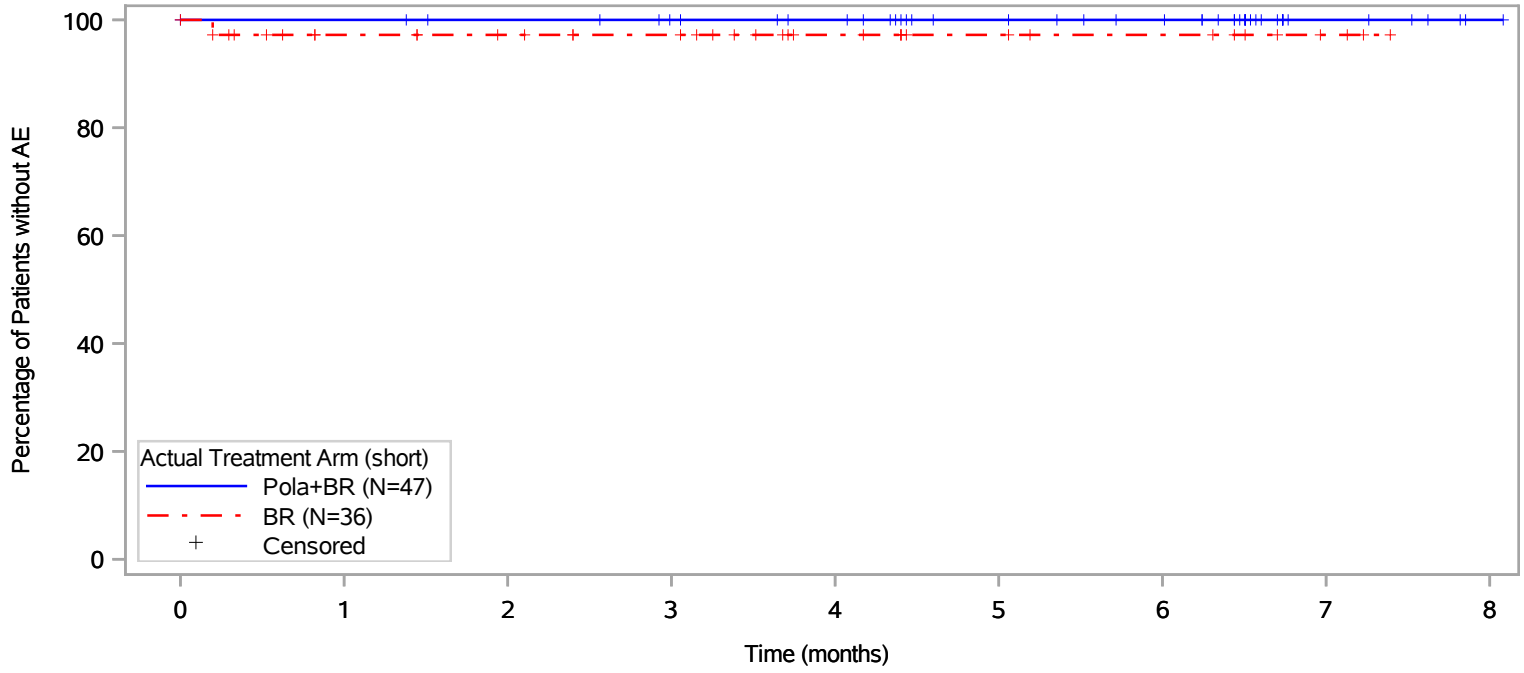
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ERYSIPELAS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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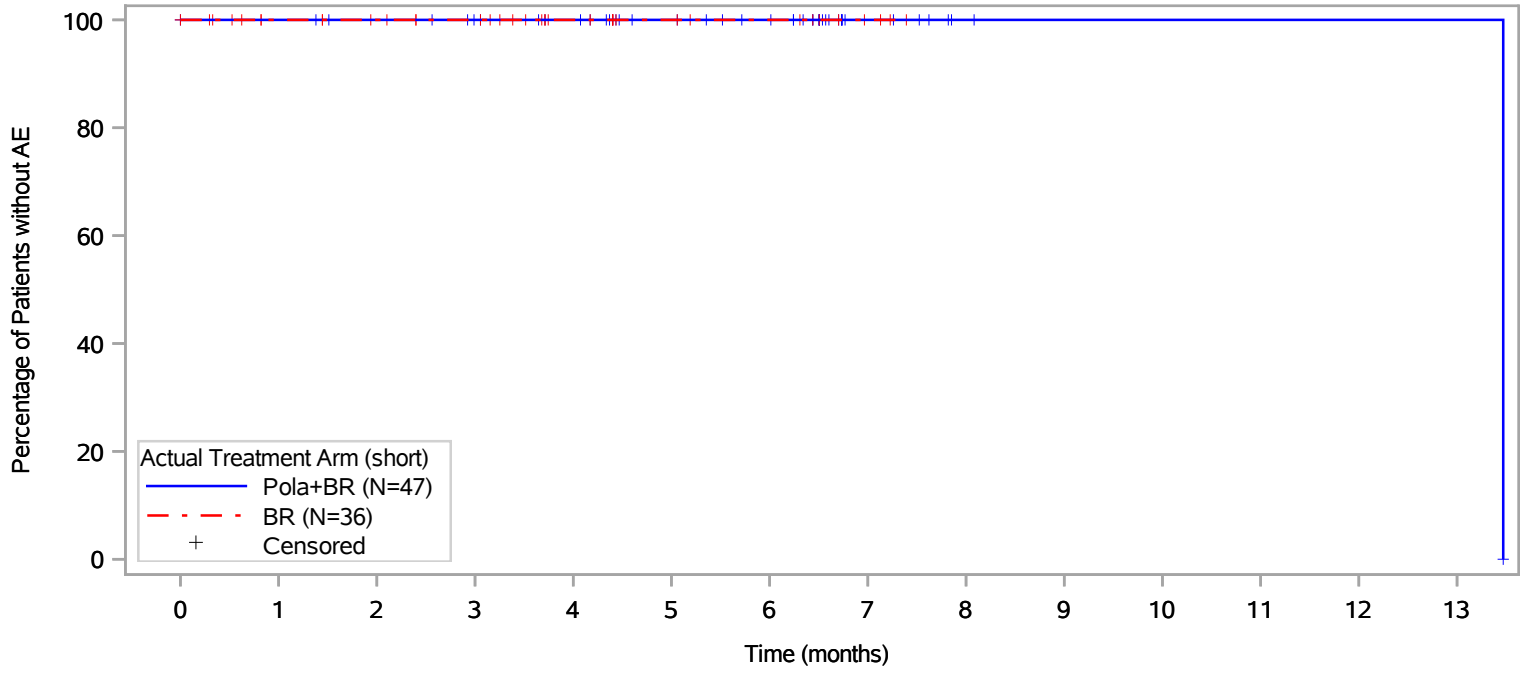
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, GASTROINTESTINAL BACTERIAL INFECTION



Patients at risk														
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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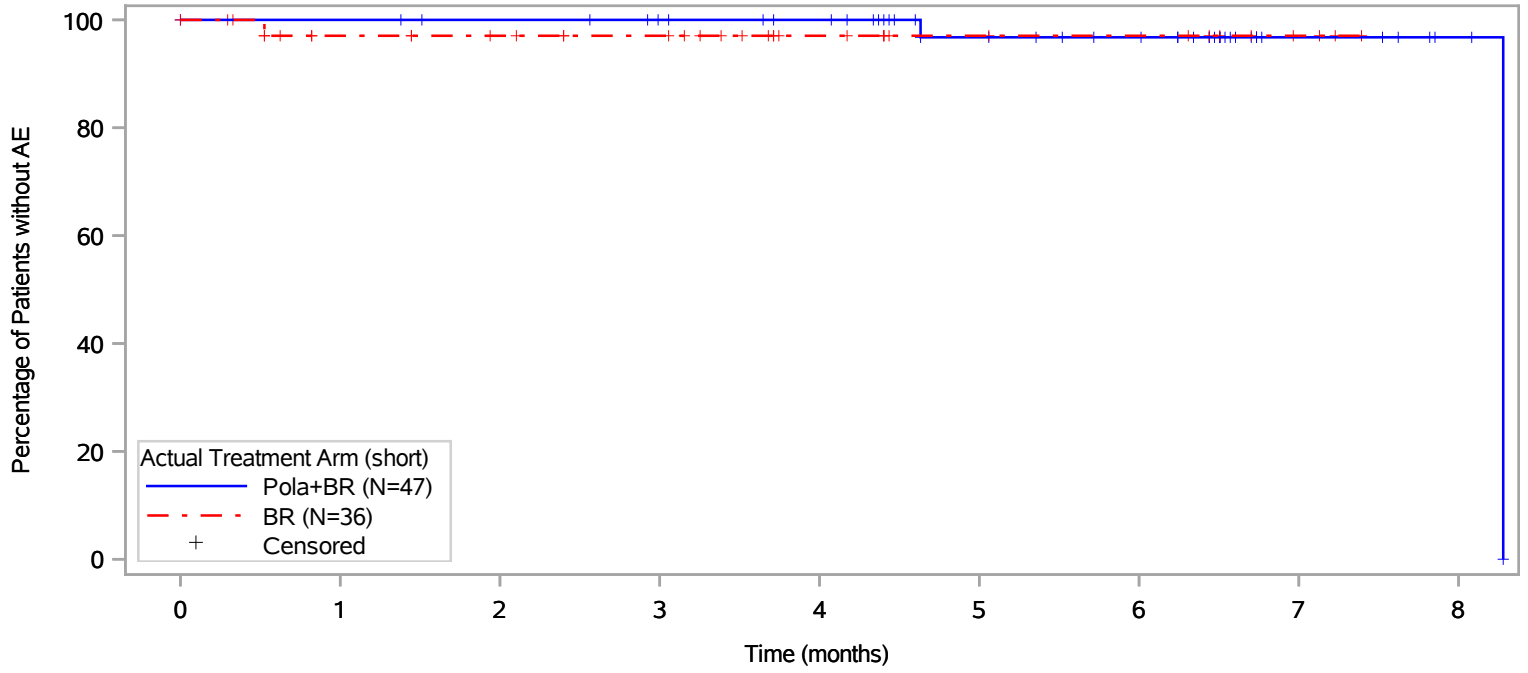
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	2
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	44
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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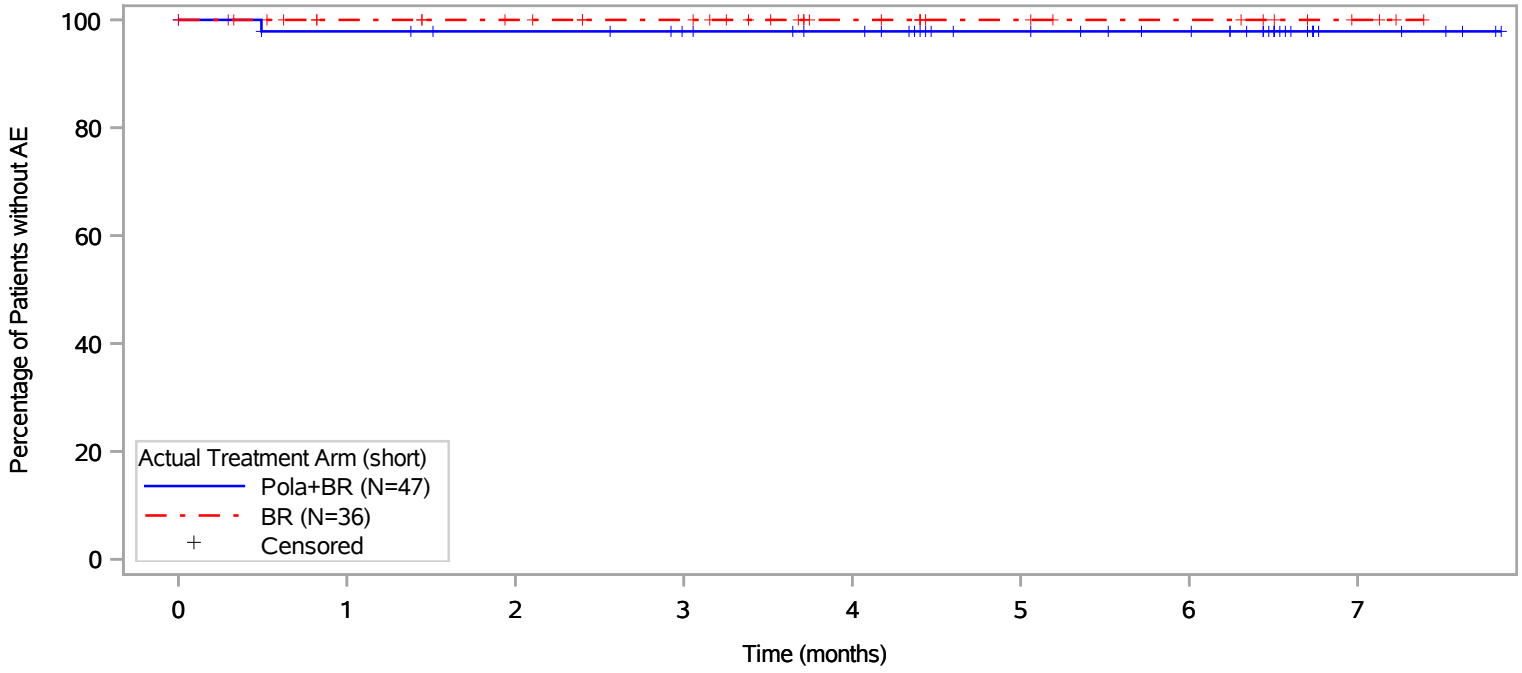
01DEC2022 22:30

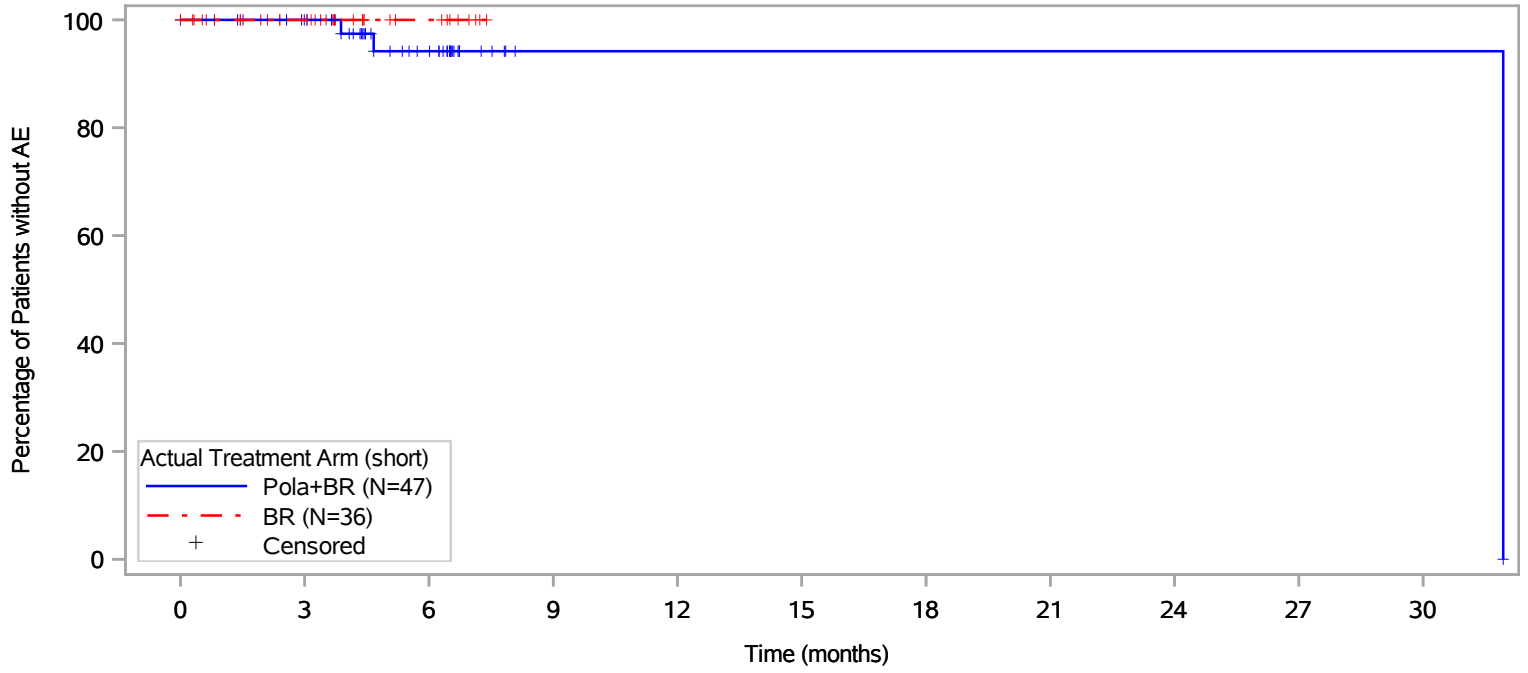
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HUMAN ANAPLASMOSIS



Patients at risk								
Pola+BR (N=47)	47	46	44	41	38	30	26	5
BR (N=36)	36	30	27	24	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	16	20	41
BR (N=36)	0	6	9	12	21	26	28	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION

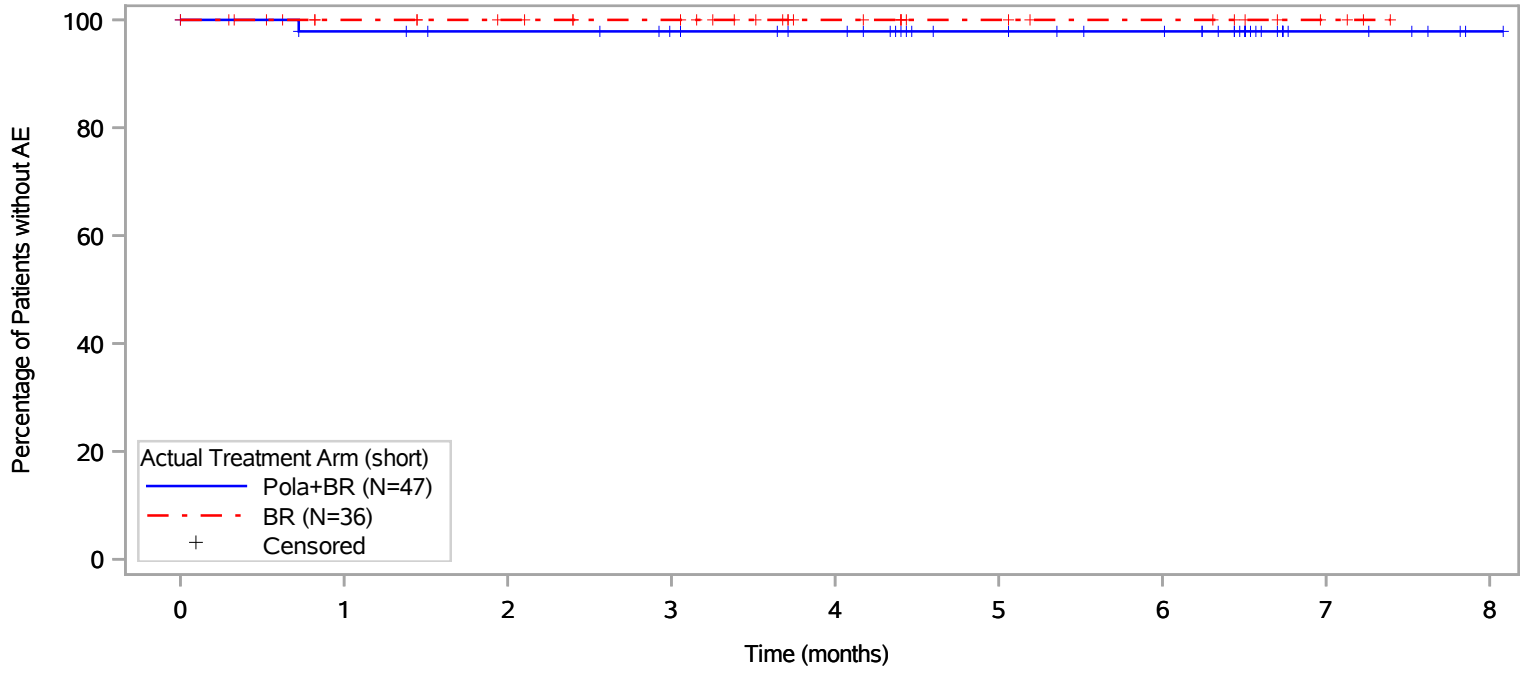


Patients at risk											
Pola+BR (N=47)	47	42	25	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	5	20	44	44	44	44	44	44	44	44
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

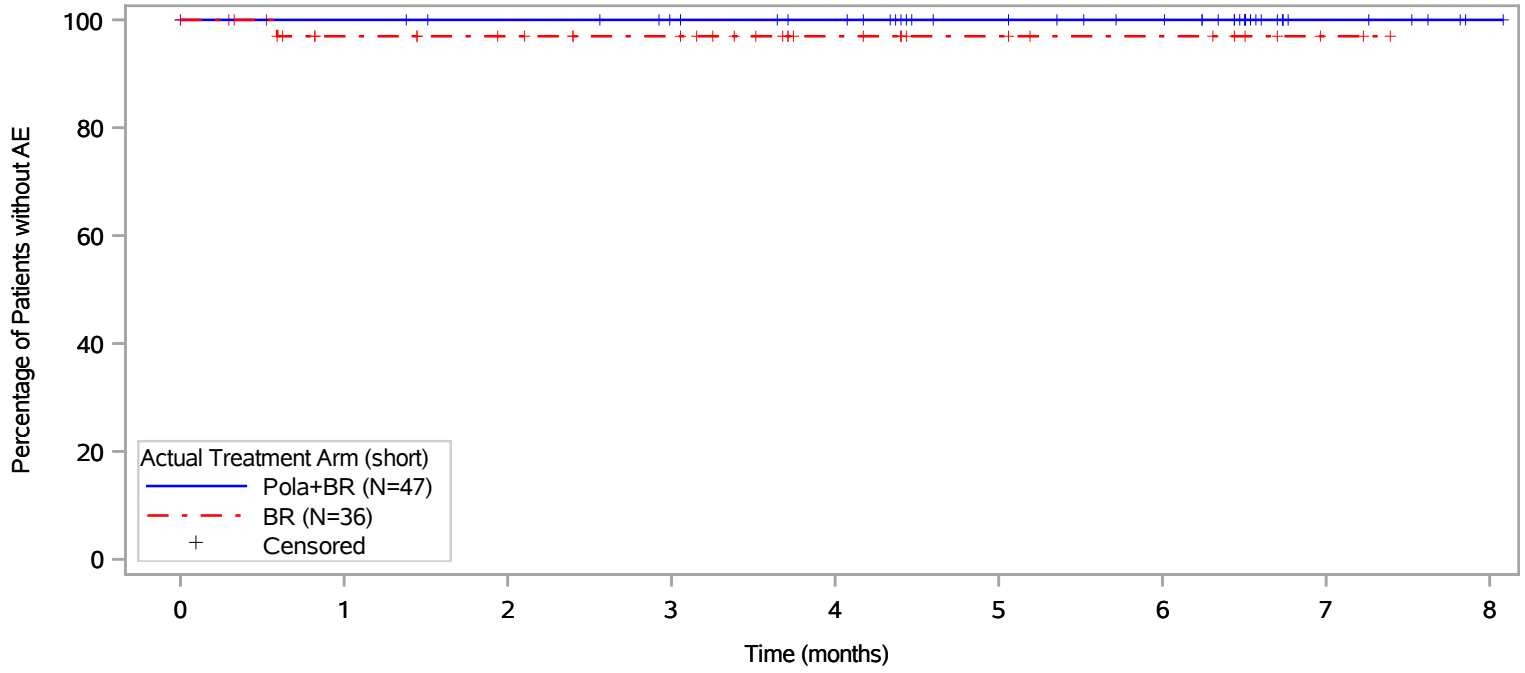
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFLUENZA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, LOWER RESPIRATORY TRACT INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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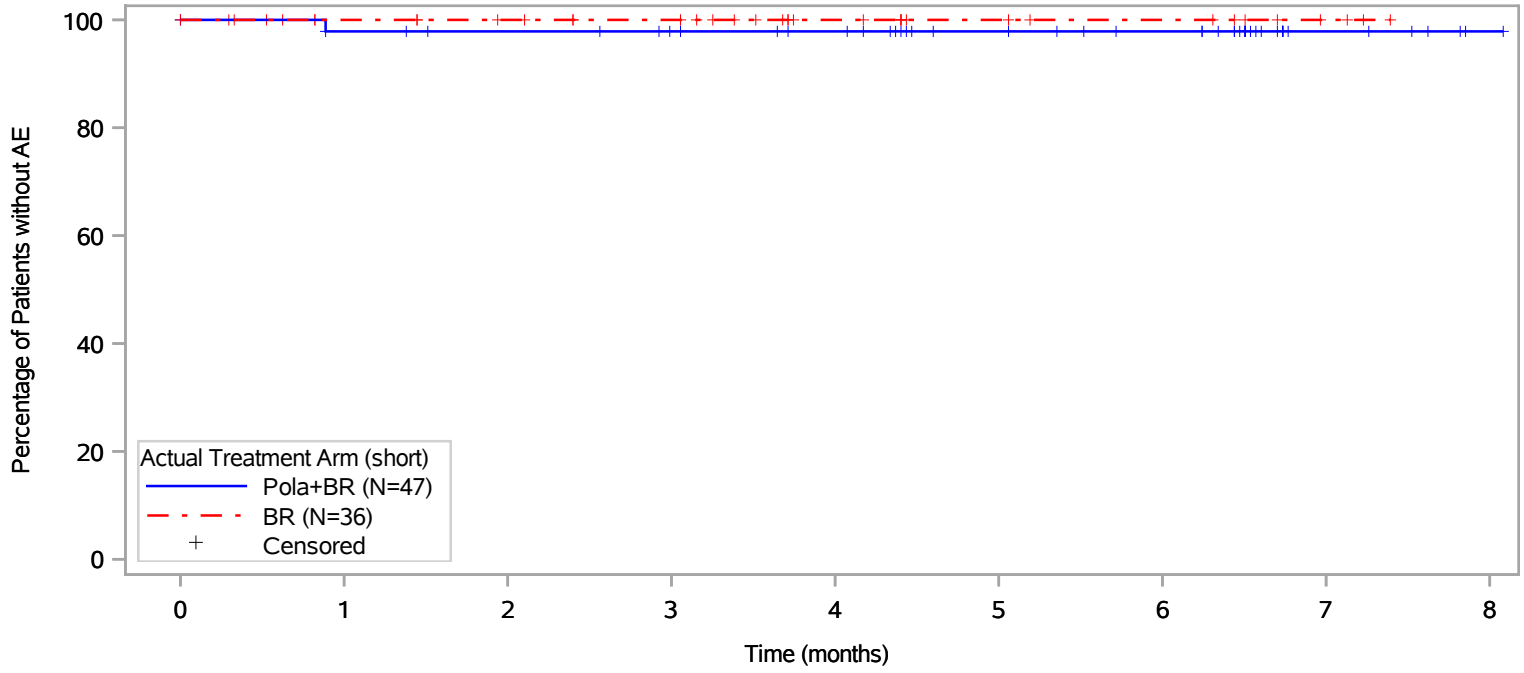
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MYCOPLASMA INFECTION



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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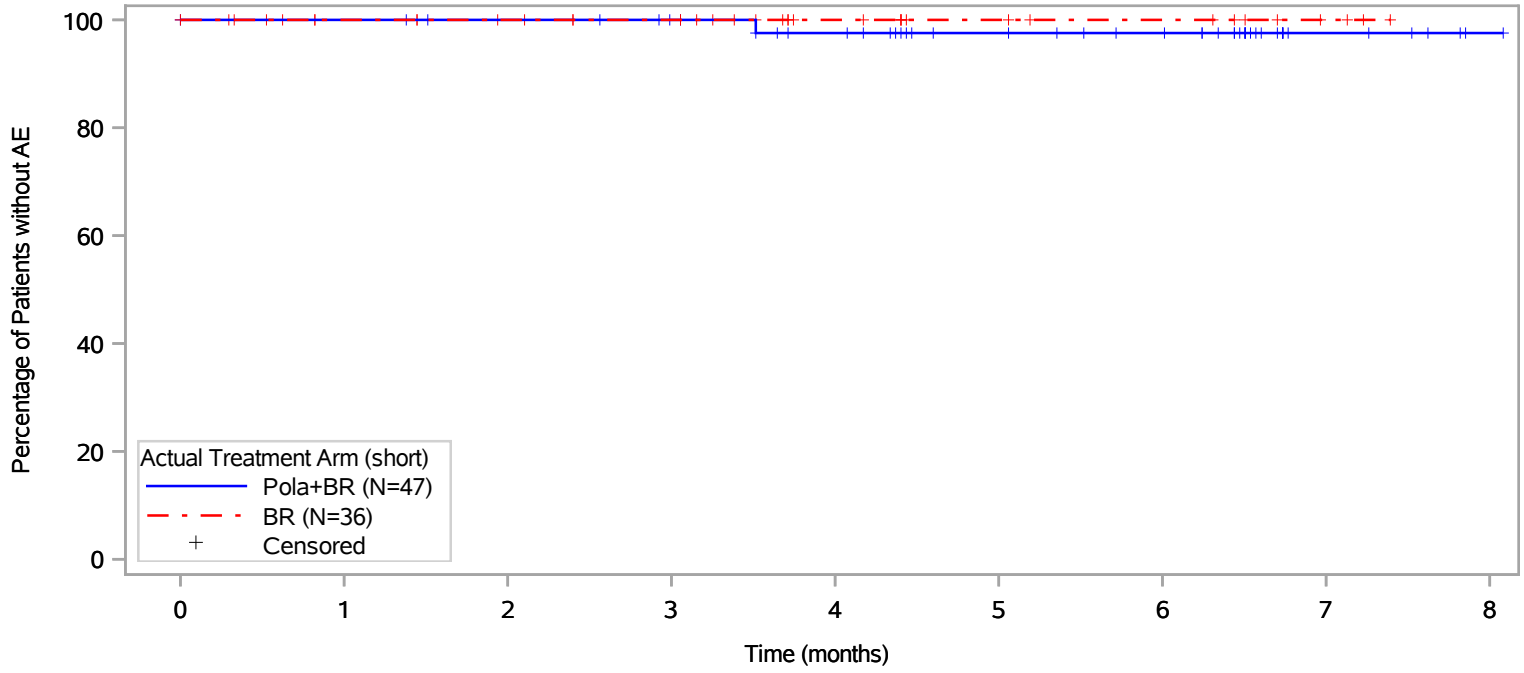
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NASOPHARYNGITIS

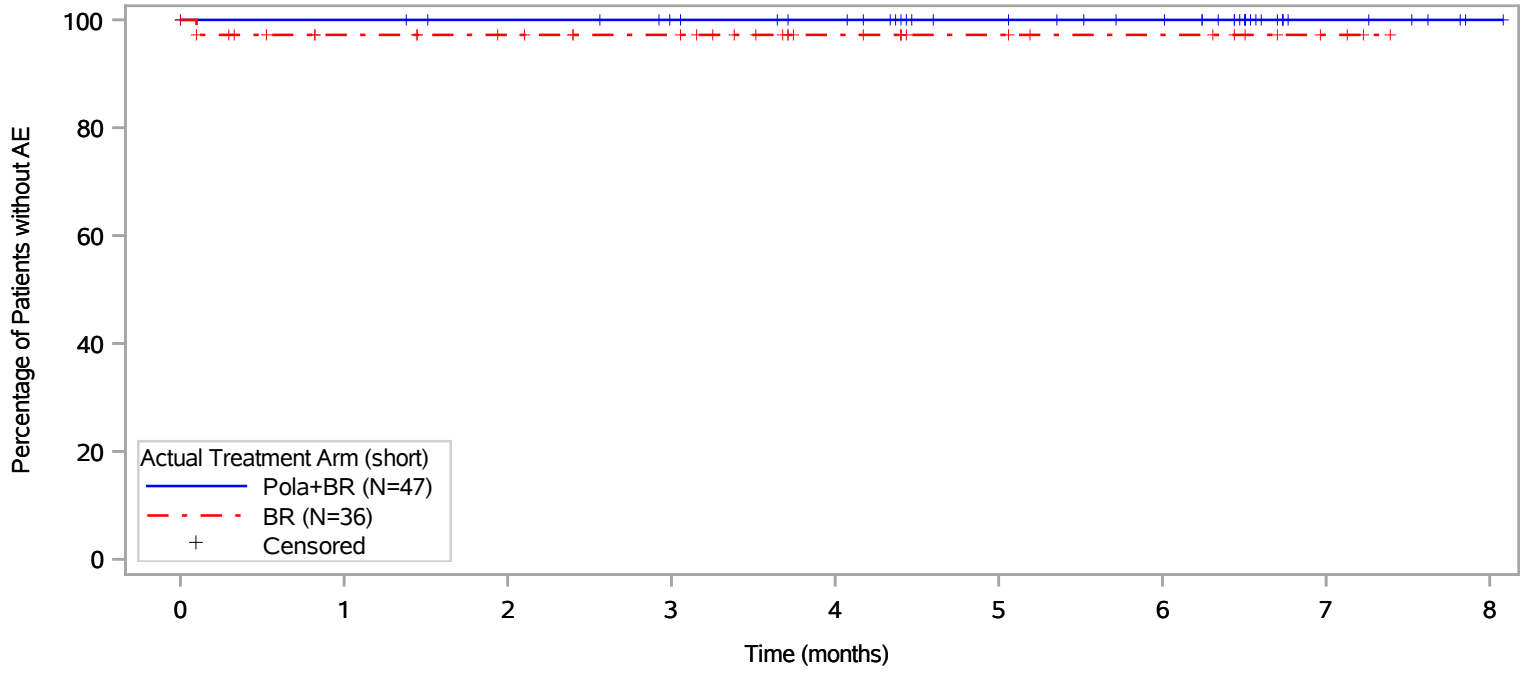


Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NEUTROPENIC SEPSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	5	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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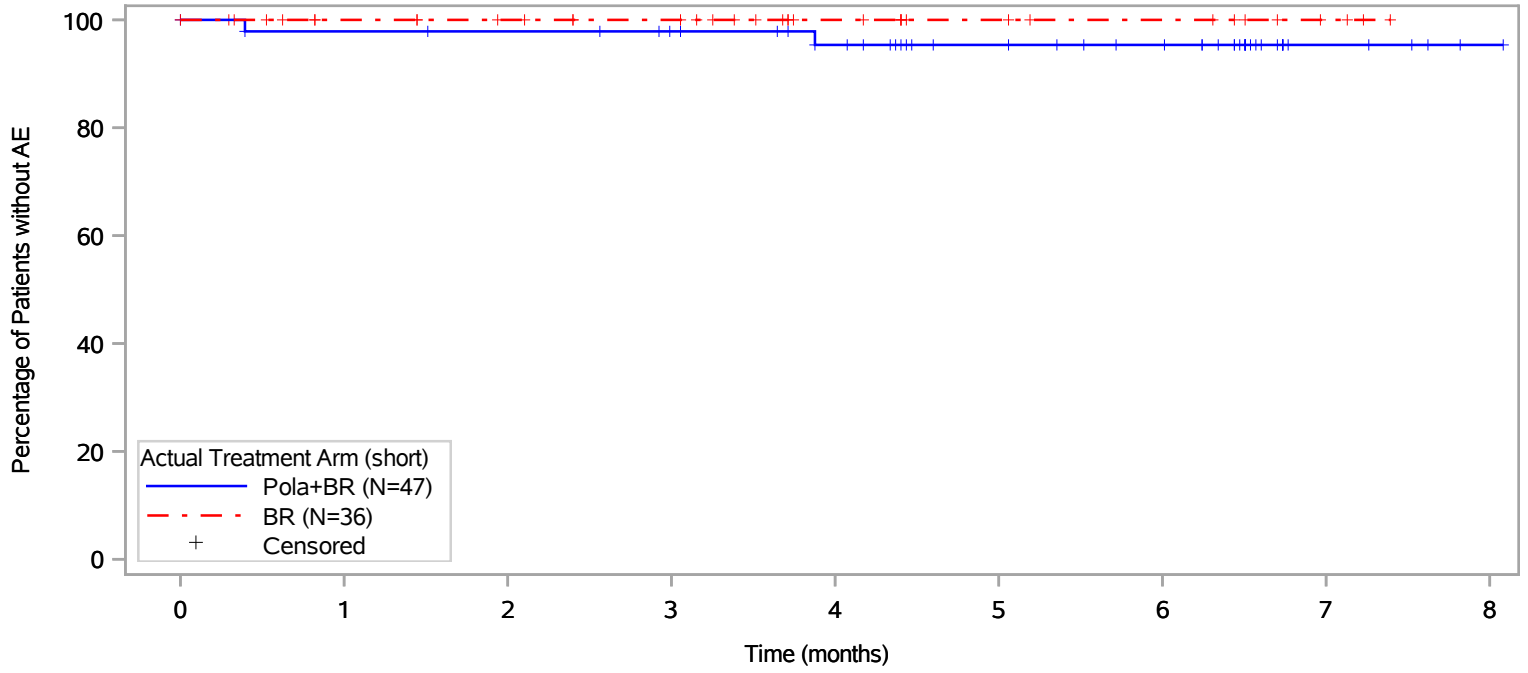
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ORAL CANDIDIASIS



Patients at risk									
Pola+BR (N=47)	47	46	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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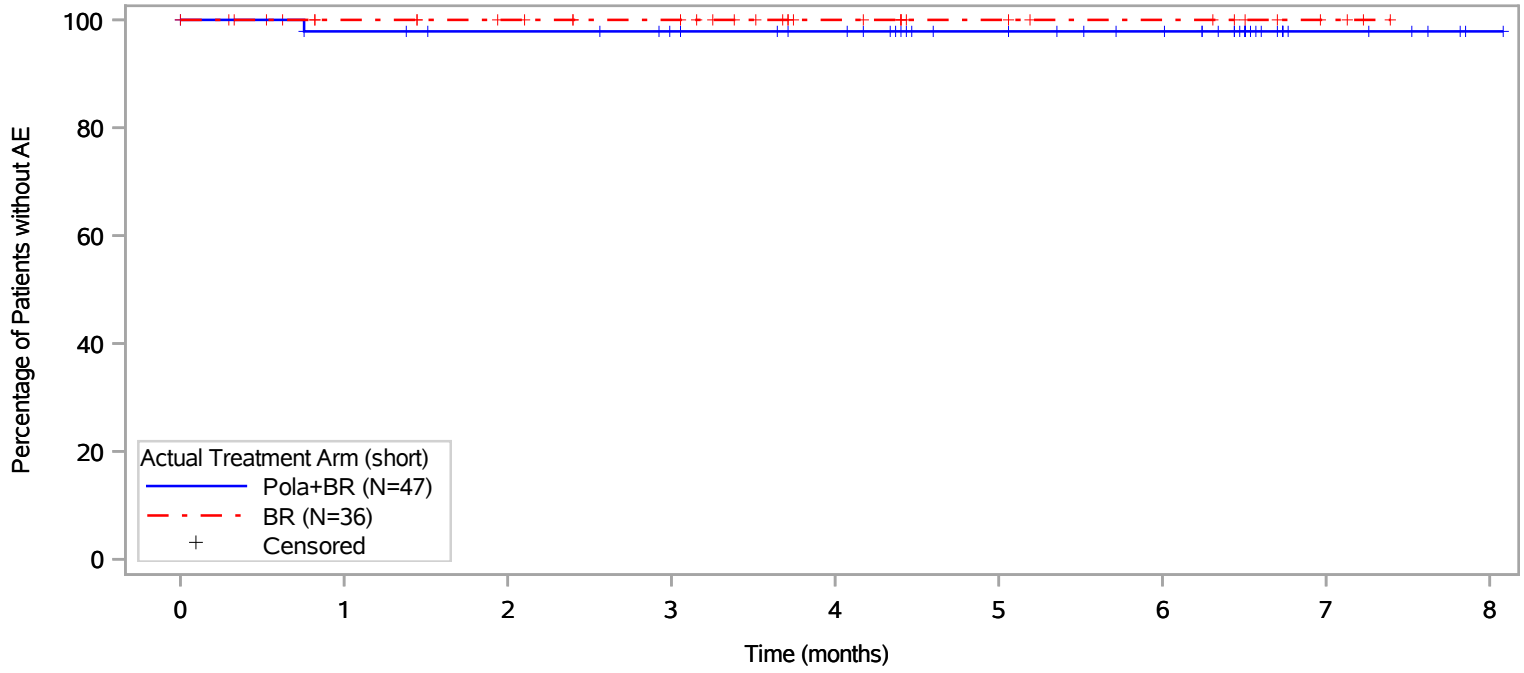
01DEC2022 22:30

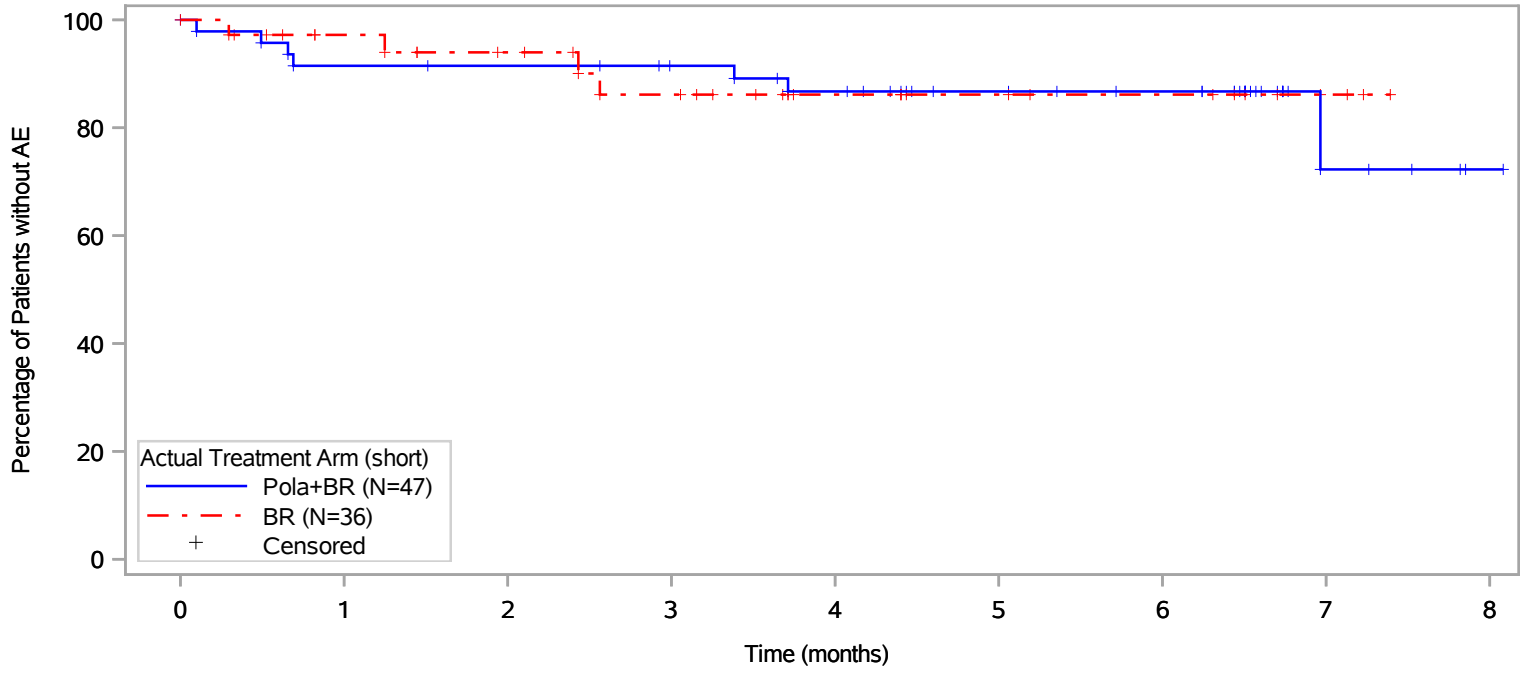
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMOCYSTIS JIROVECII PNEUMONIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA

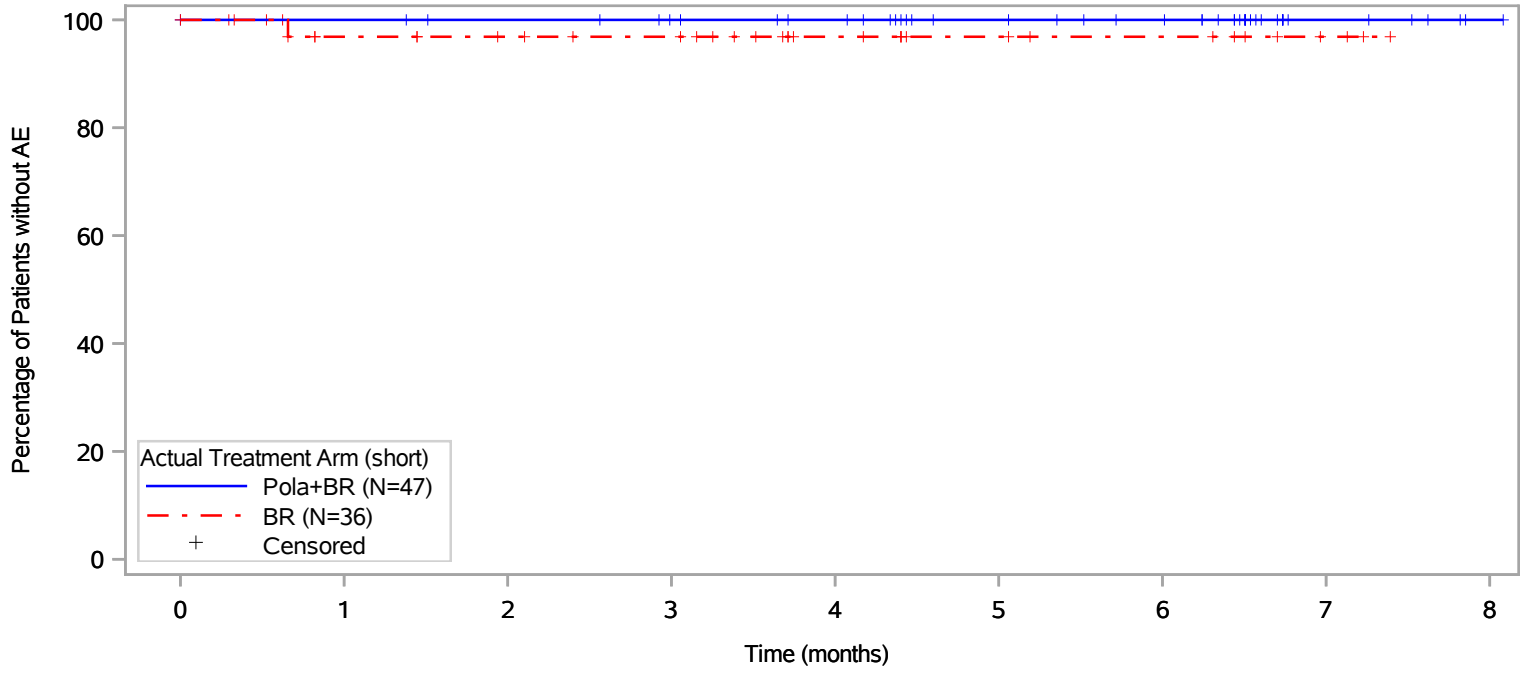


Patients at risk									
Pola+BR (N=47)	47	43	42	39	35	28	25	5	1
BR (N=36)	36	30	26	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	6	13	16	35	39
BR (N=36)	0	5	8	10	18	22	24	29	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA FUNGAL



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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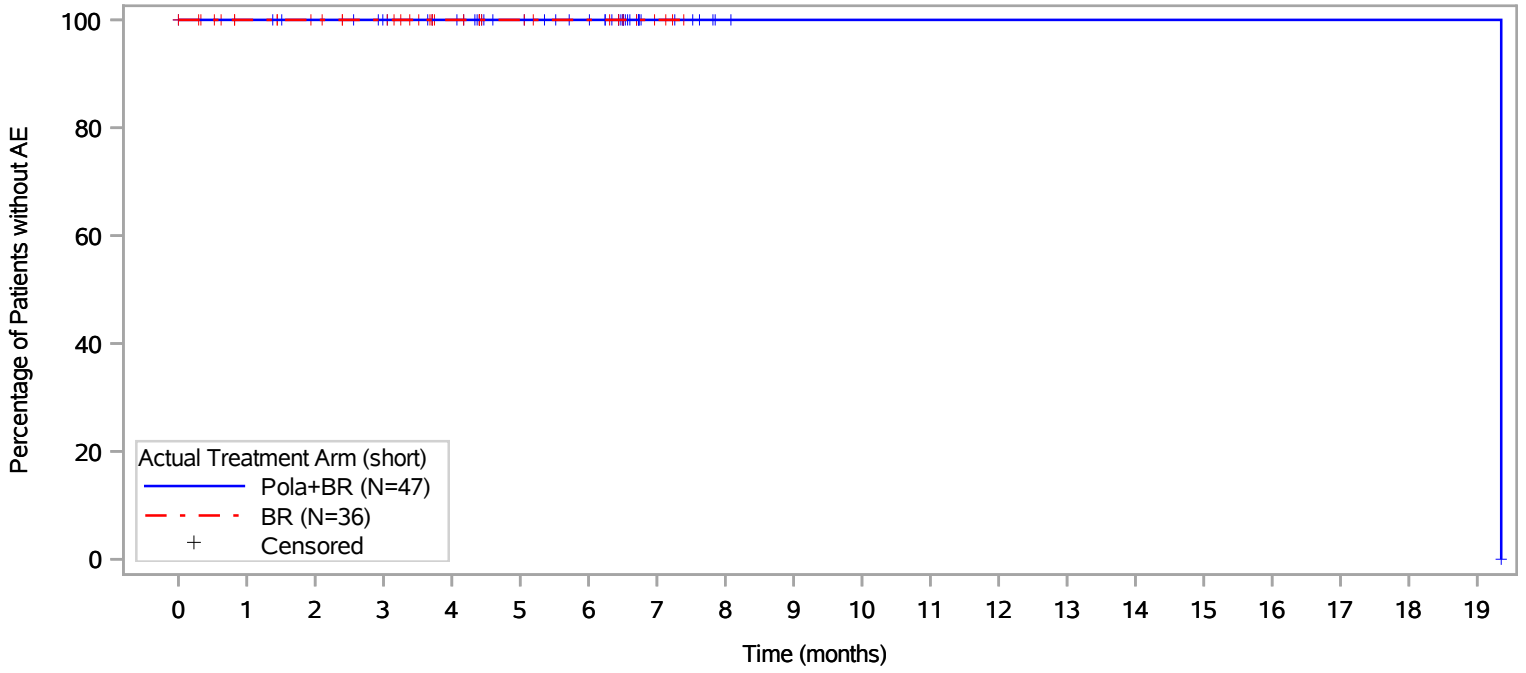
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA PNEUMOCOCCAL

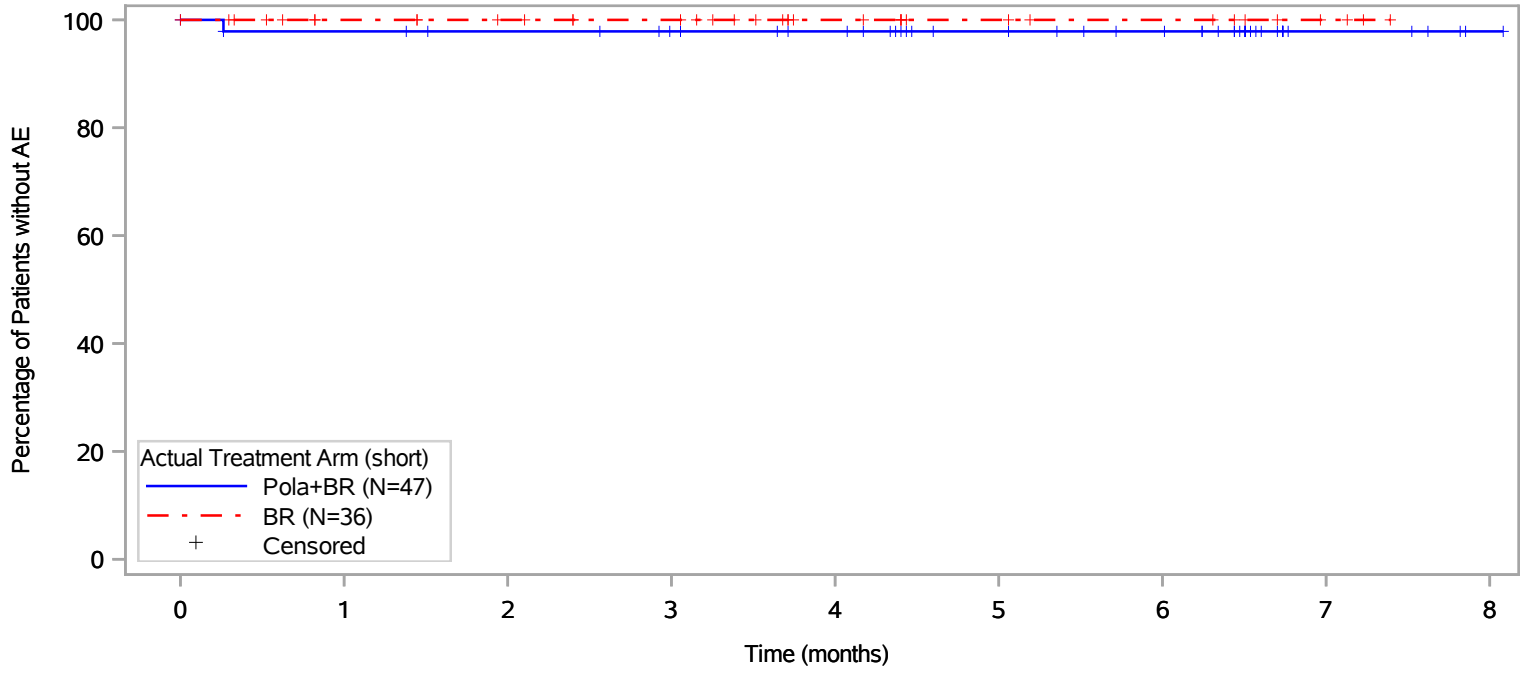


Patients at risk																				
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PYURIA

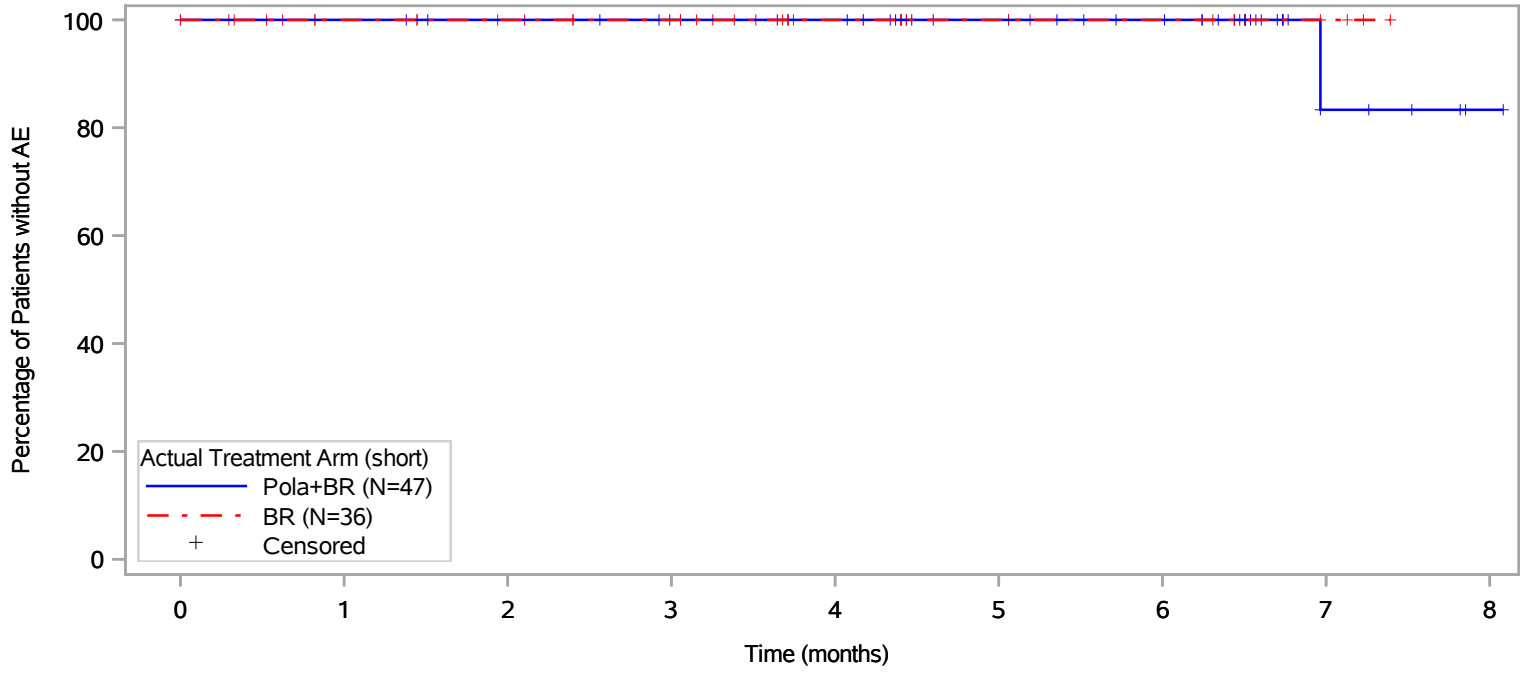


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, RHINOVIRUS INFECTION

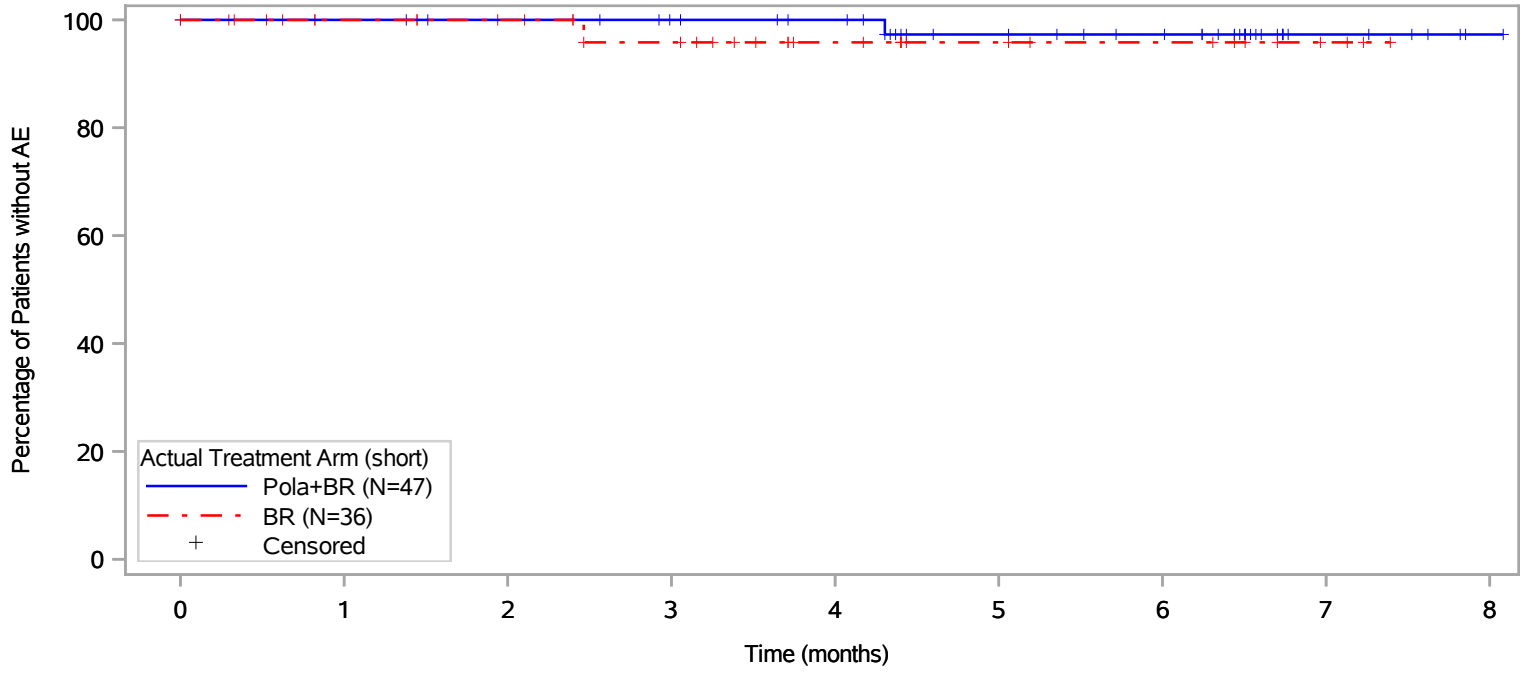


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS

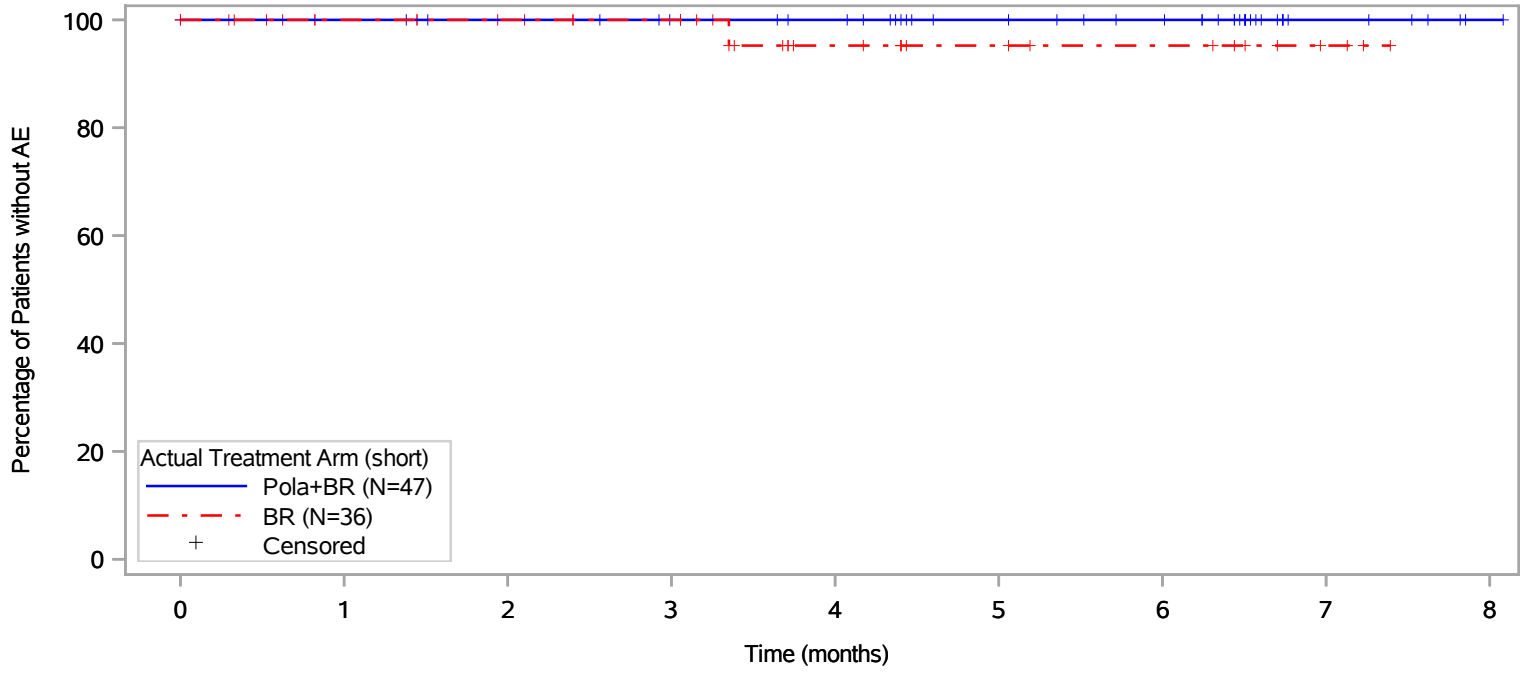


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

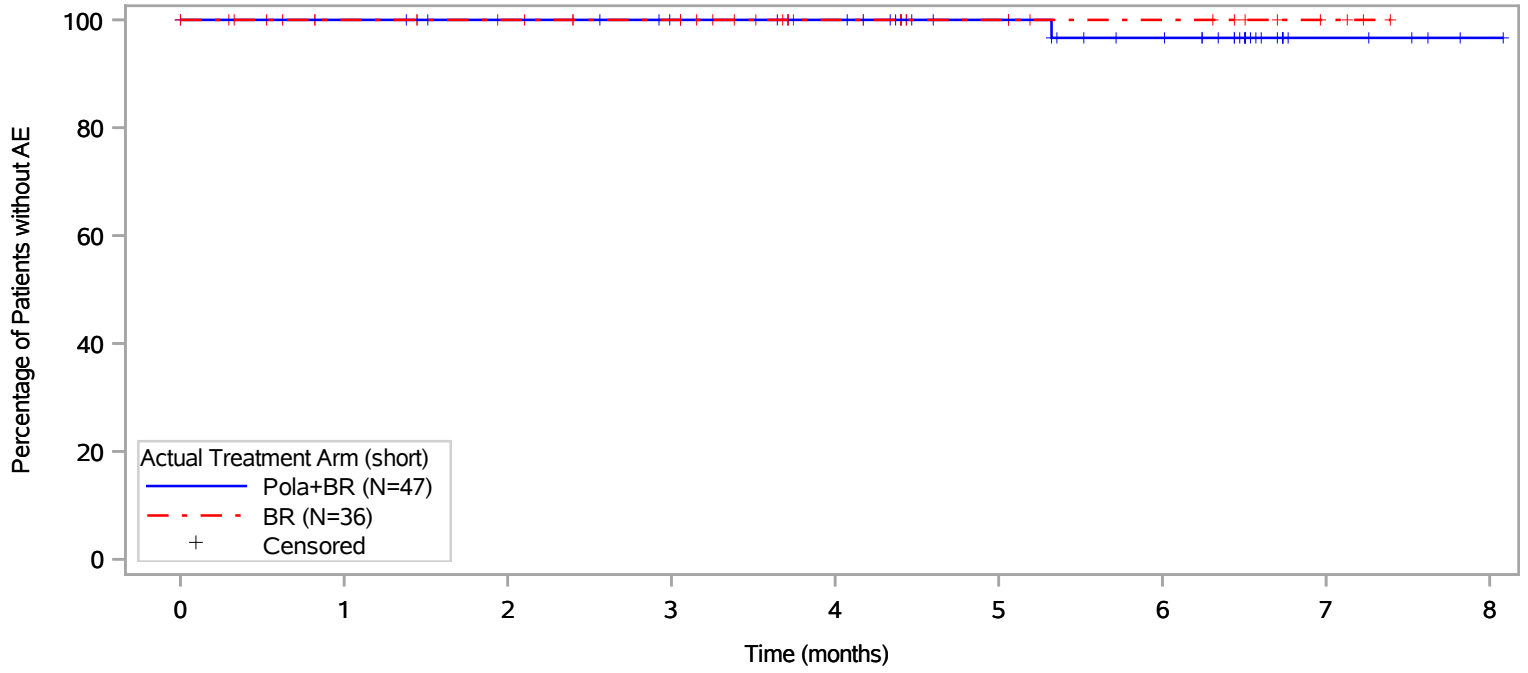
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

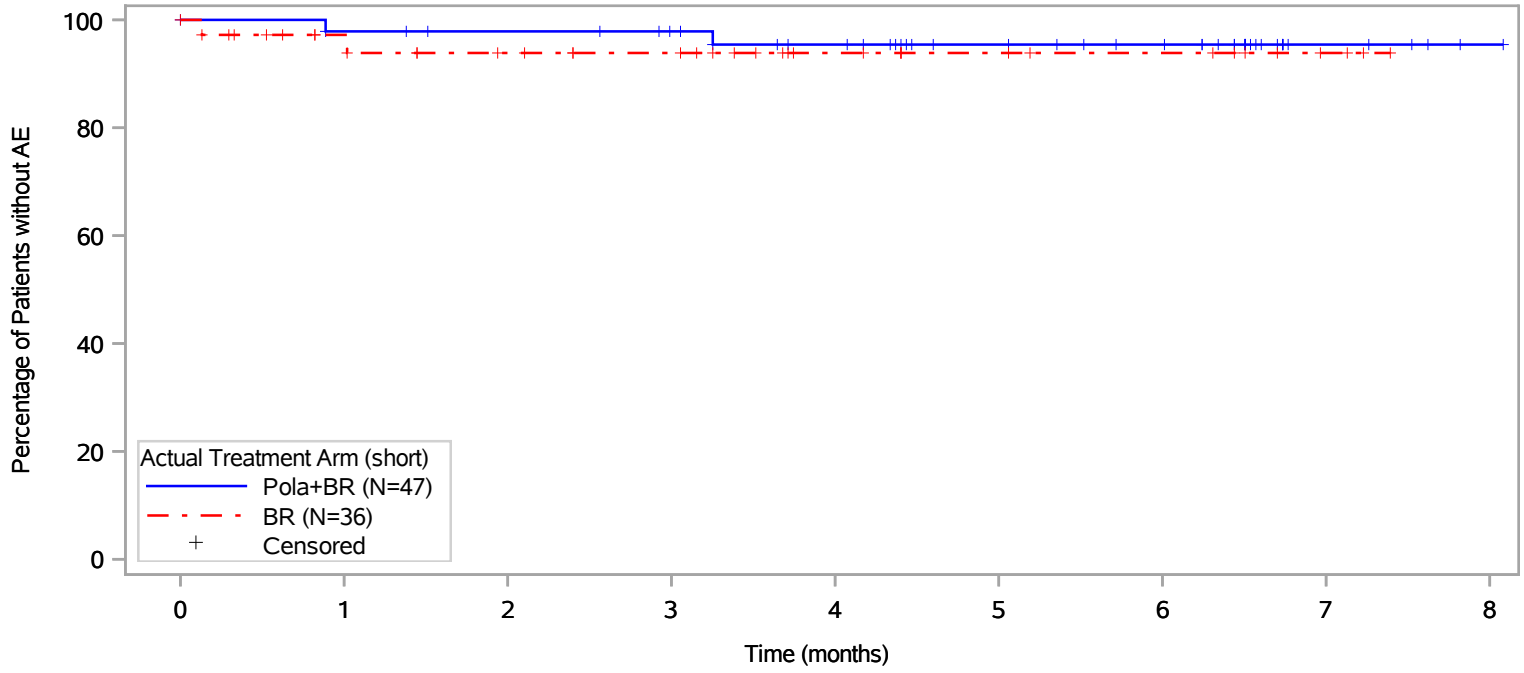
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SINUSITIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UPPER RESPIRATORY TRACT INFECTION

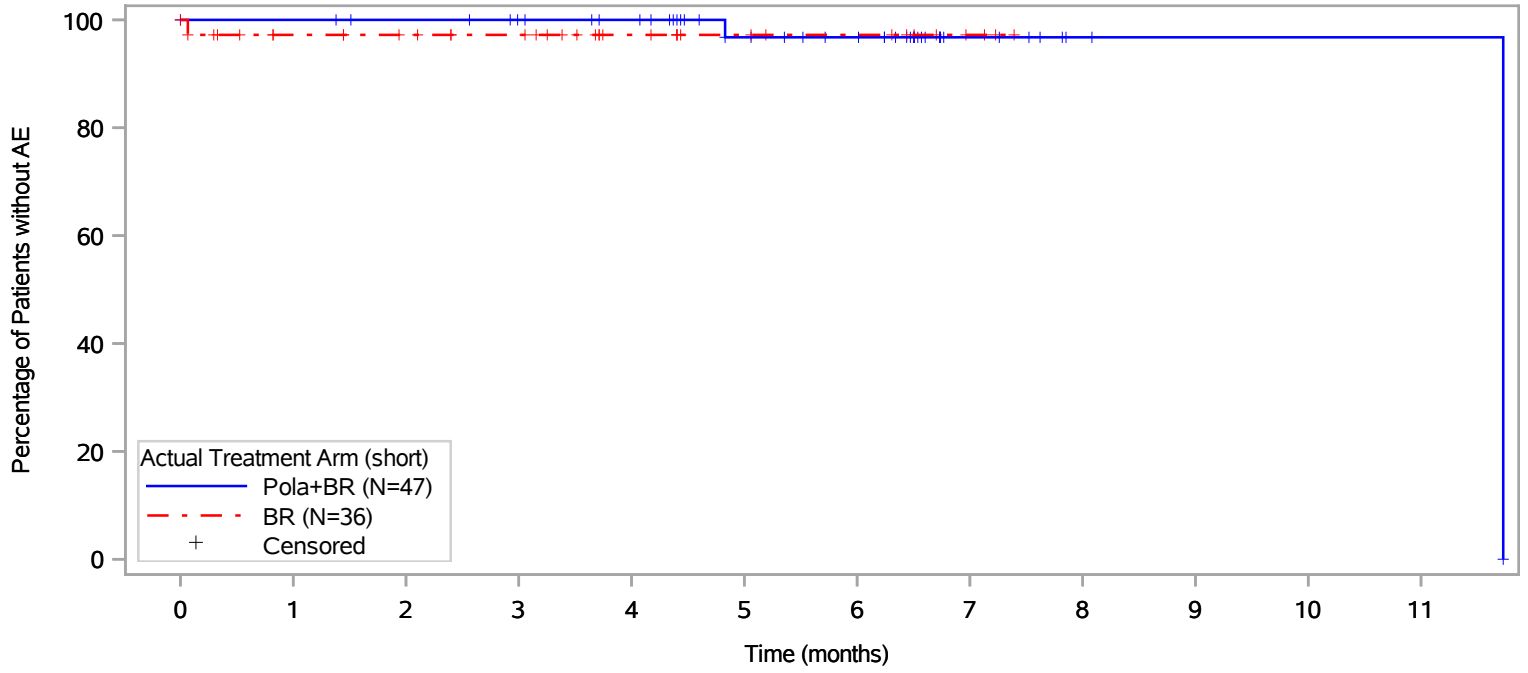


Patients at risk									
Pola+BR (N=47)	47	46	44	41	37	29	25	5	1
BR (N=36)	36	29	25	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	44
BR (N=36)	0	6	9	12	20	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk												
Pola+BR (N=47)	47	47	45	42	39	30	26	7	2	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44	45	45	45
BR (N=36)	0	5	8	11	20	25	27	32	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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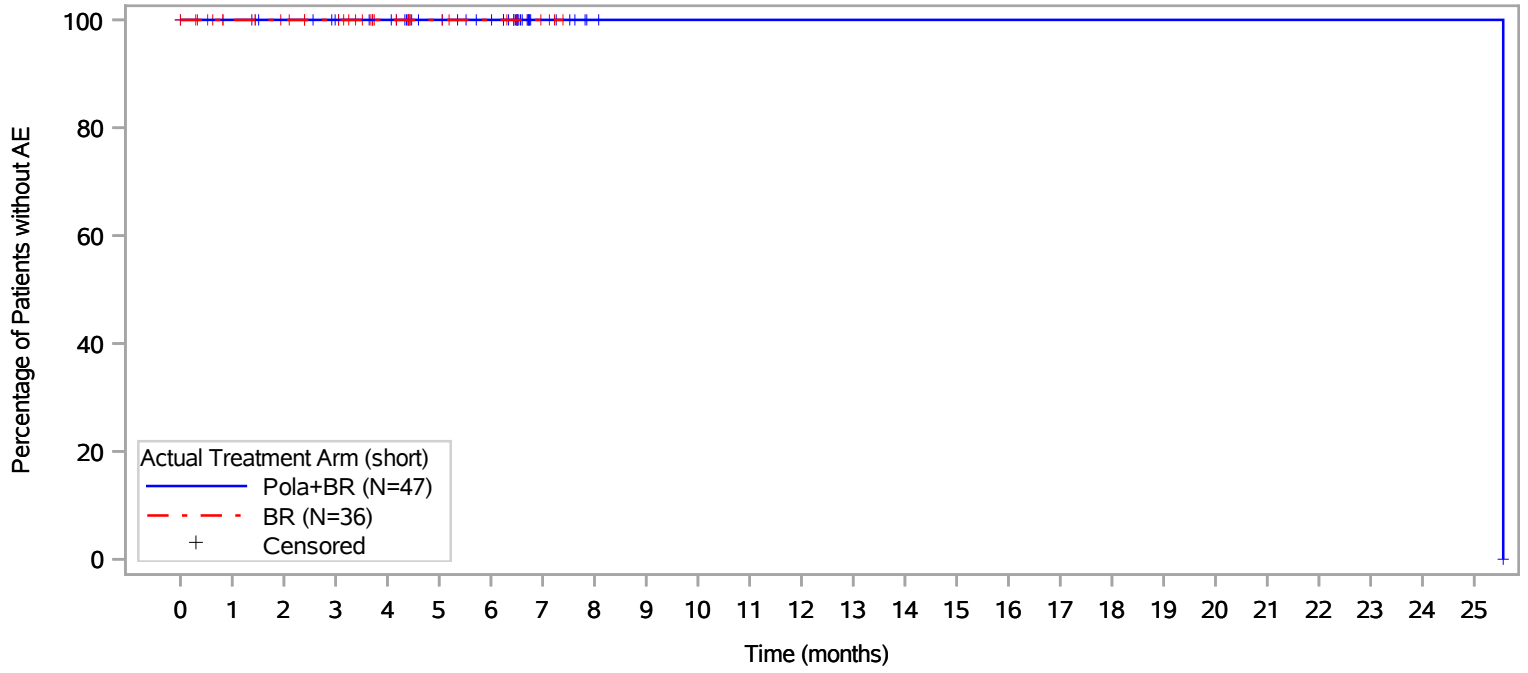
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UROSEPSIS

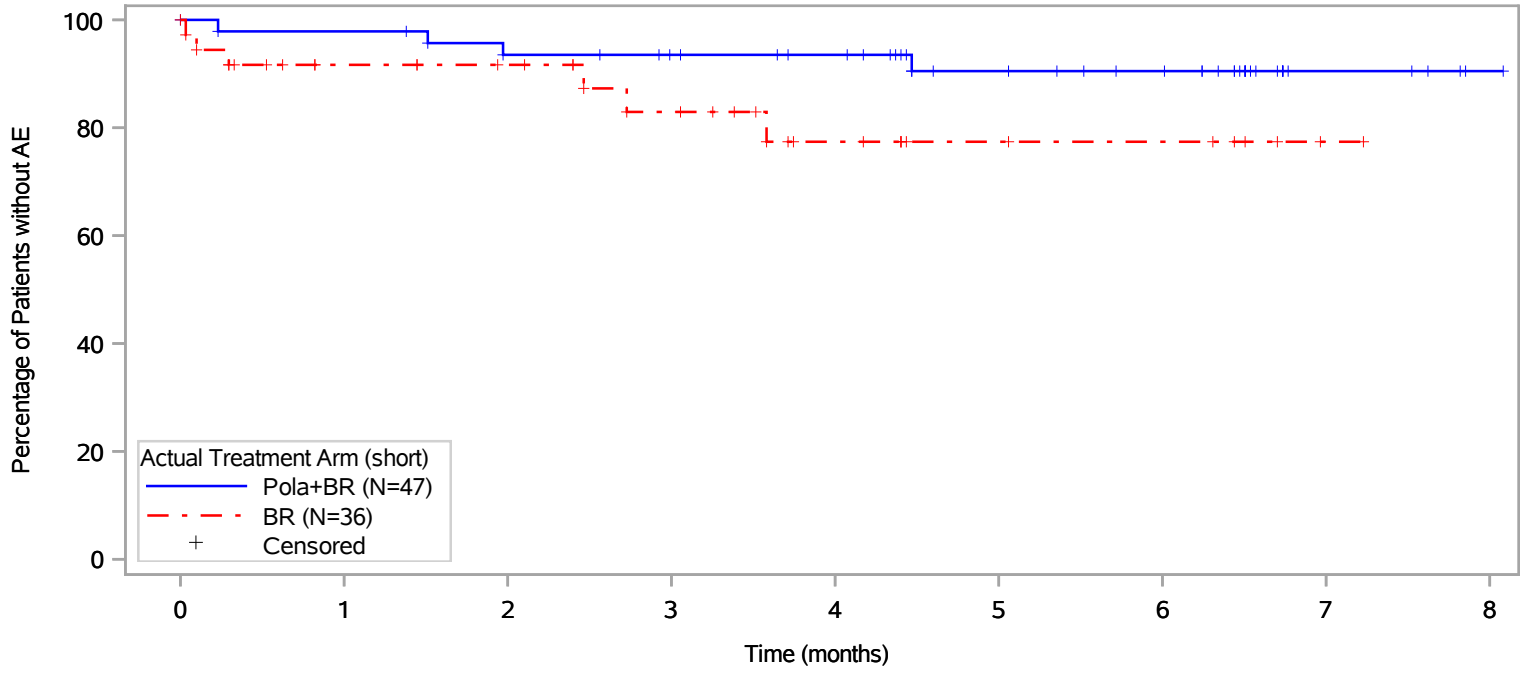


Patients at risk																										
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=47)	47	46	43	40	37	28	24	5	1
BR (N=36)	36	27	24	19	12	7	6	1	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	38	42
BR (N=36)	0	6	9	12	18	23	24	29	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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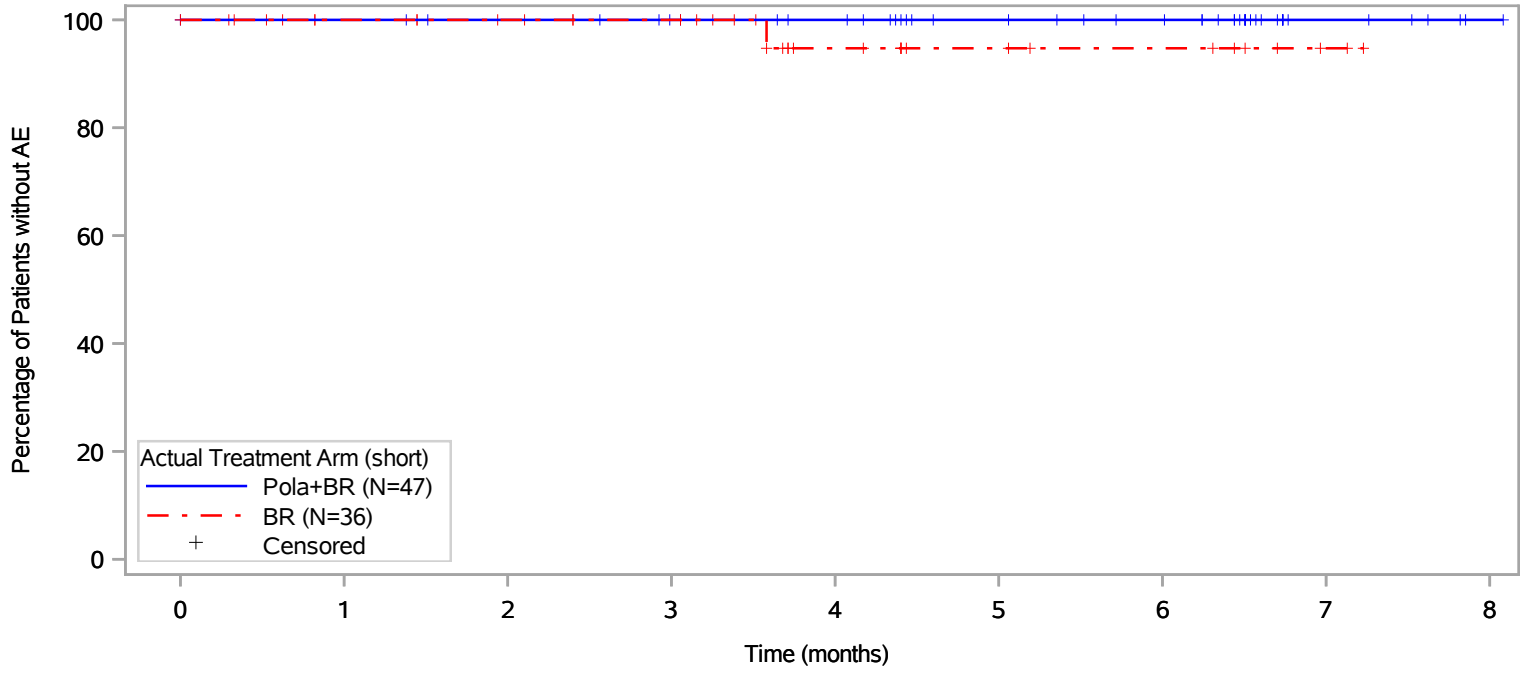
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FACIAL BONES FRACTURE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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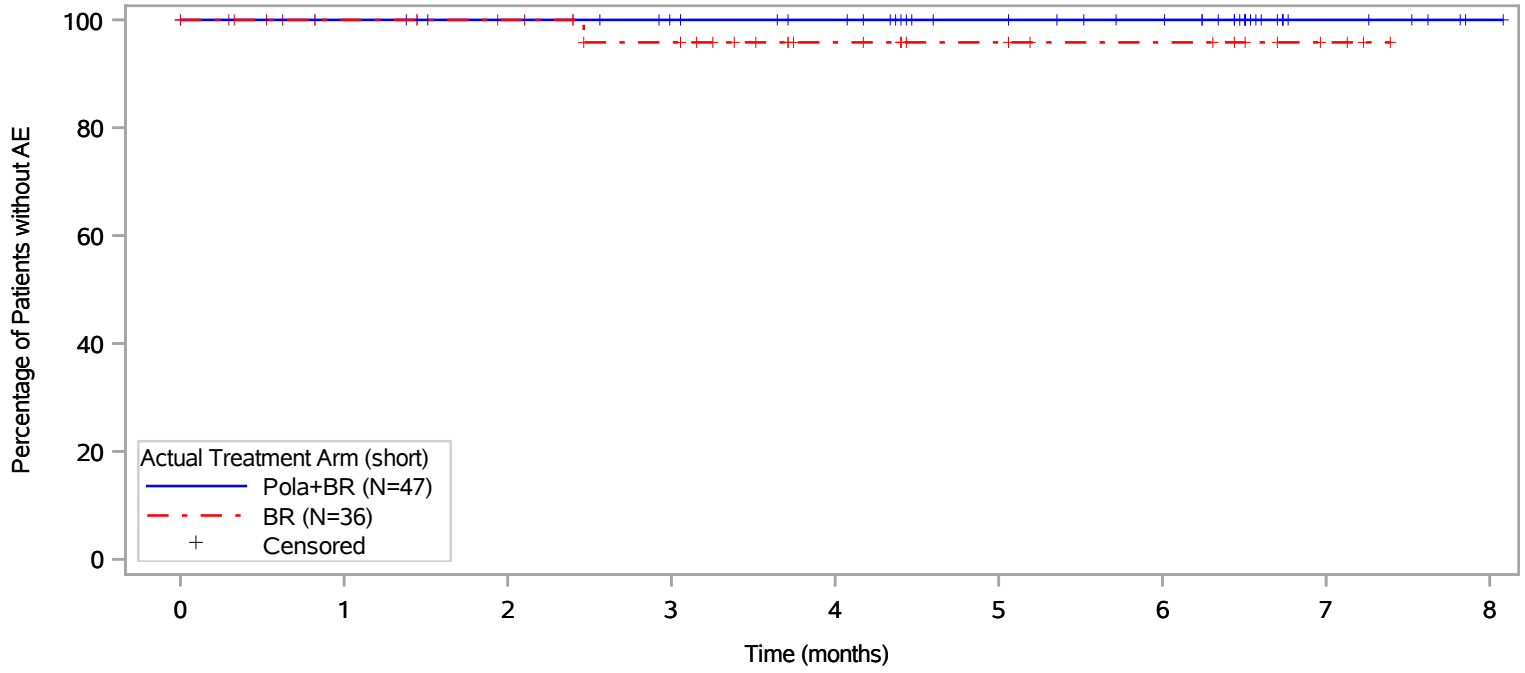
01DEC2022 22:30

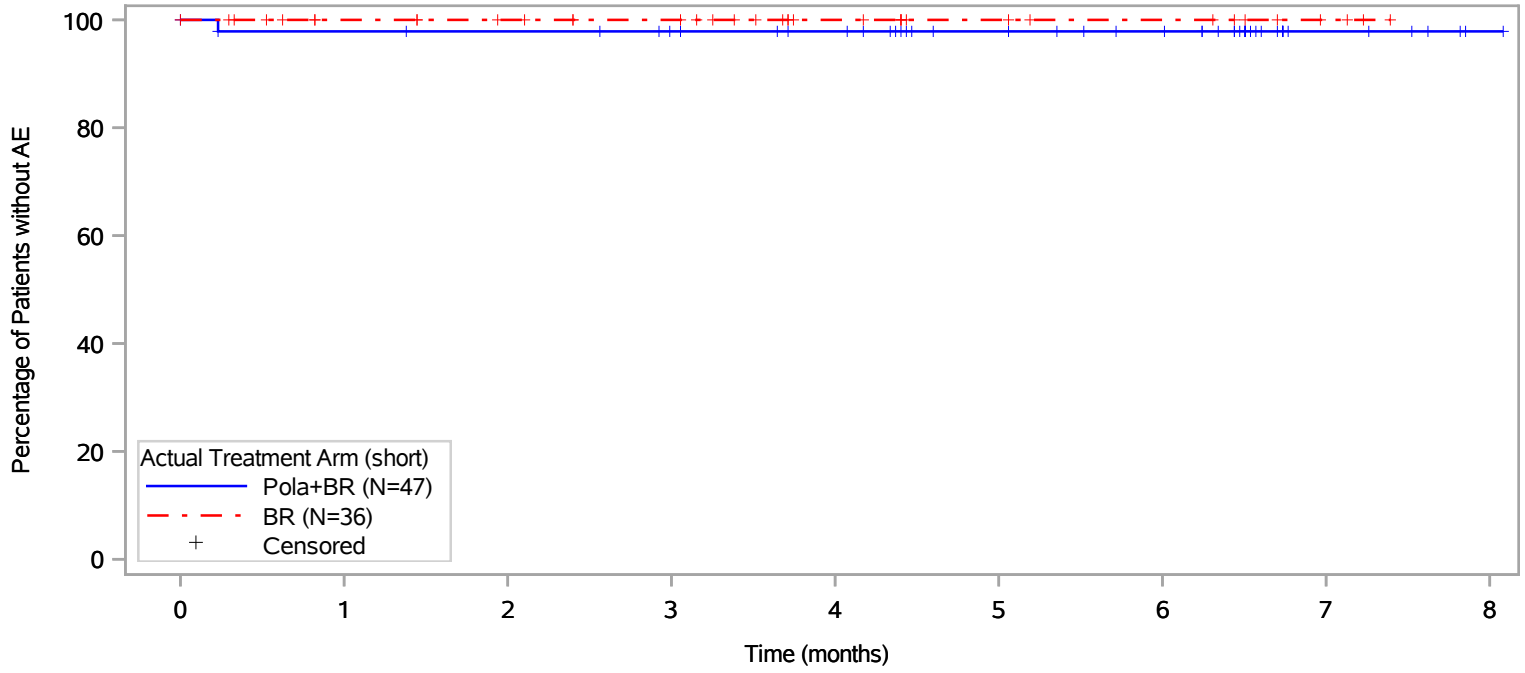
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

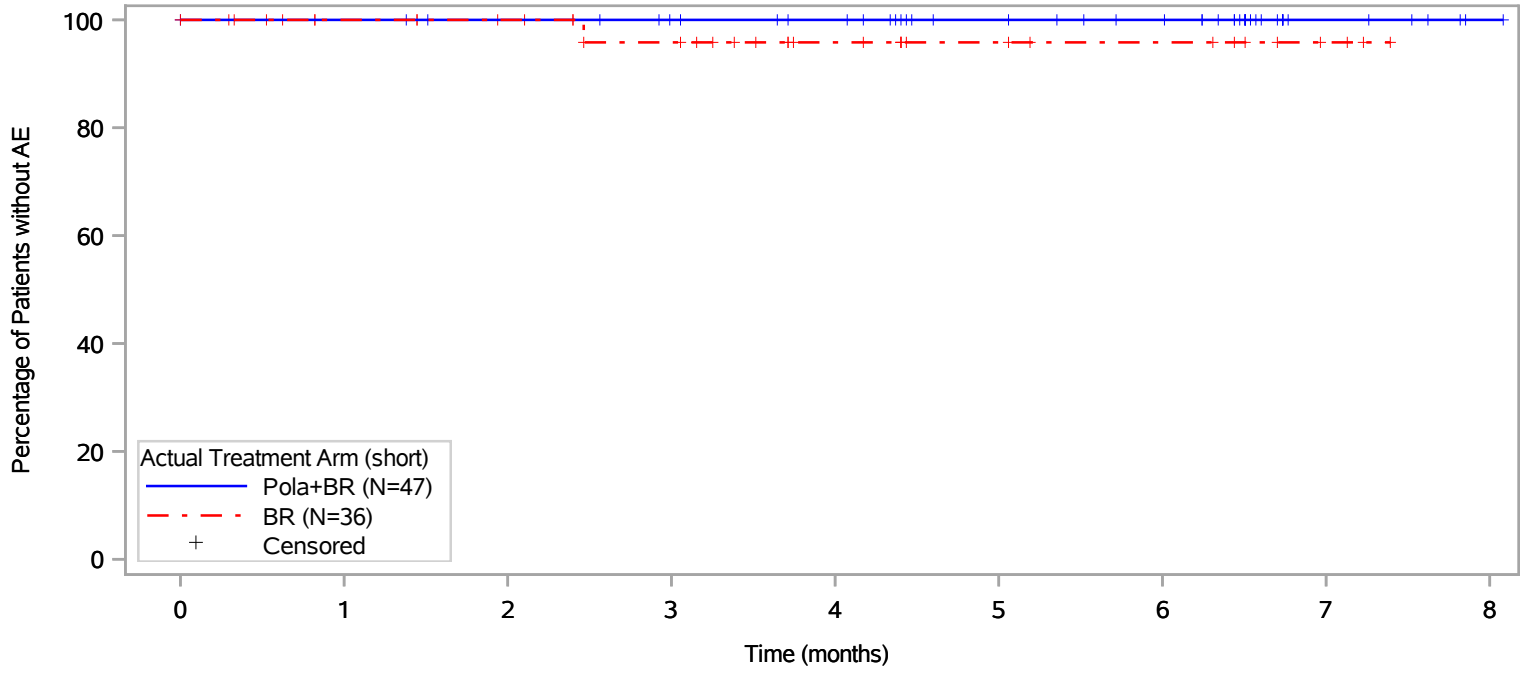
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FEMUR FRACTURE



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, HEAD INJURY

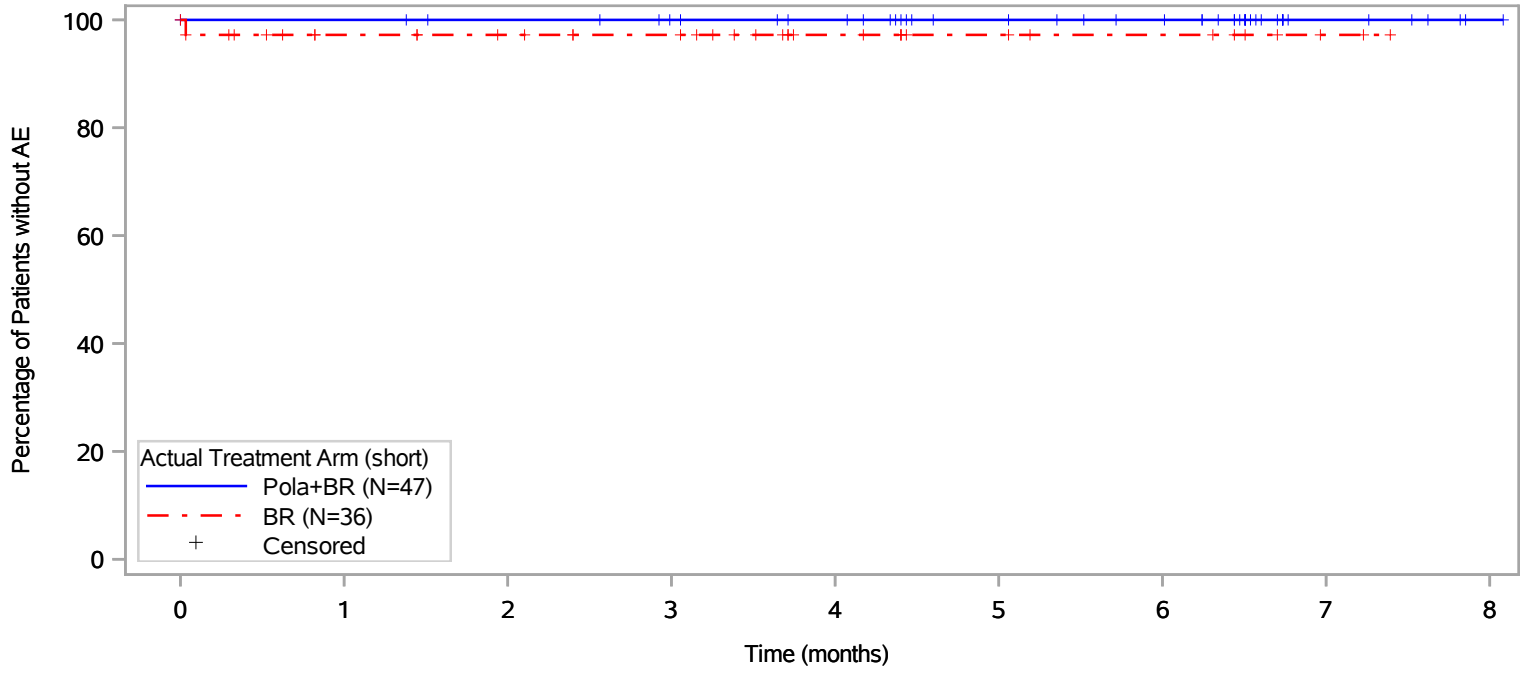


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

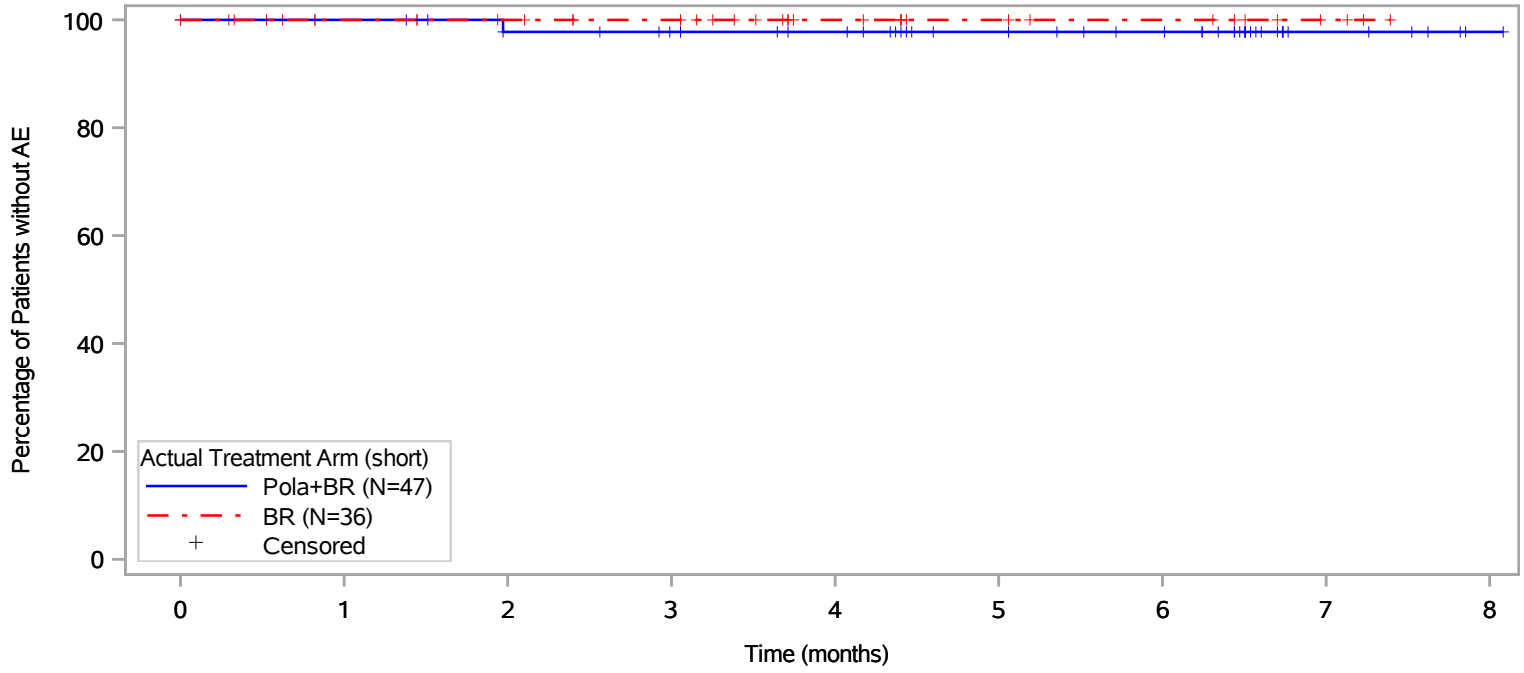
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, INFUSION RELATED REACTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, INJURY



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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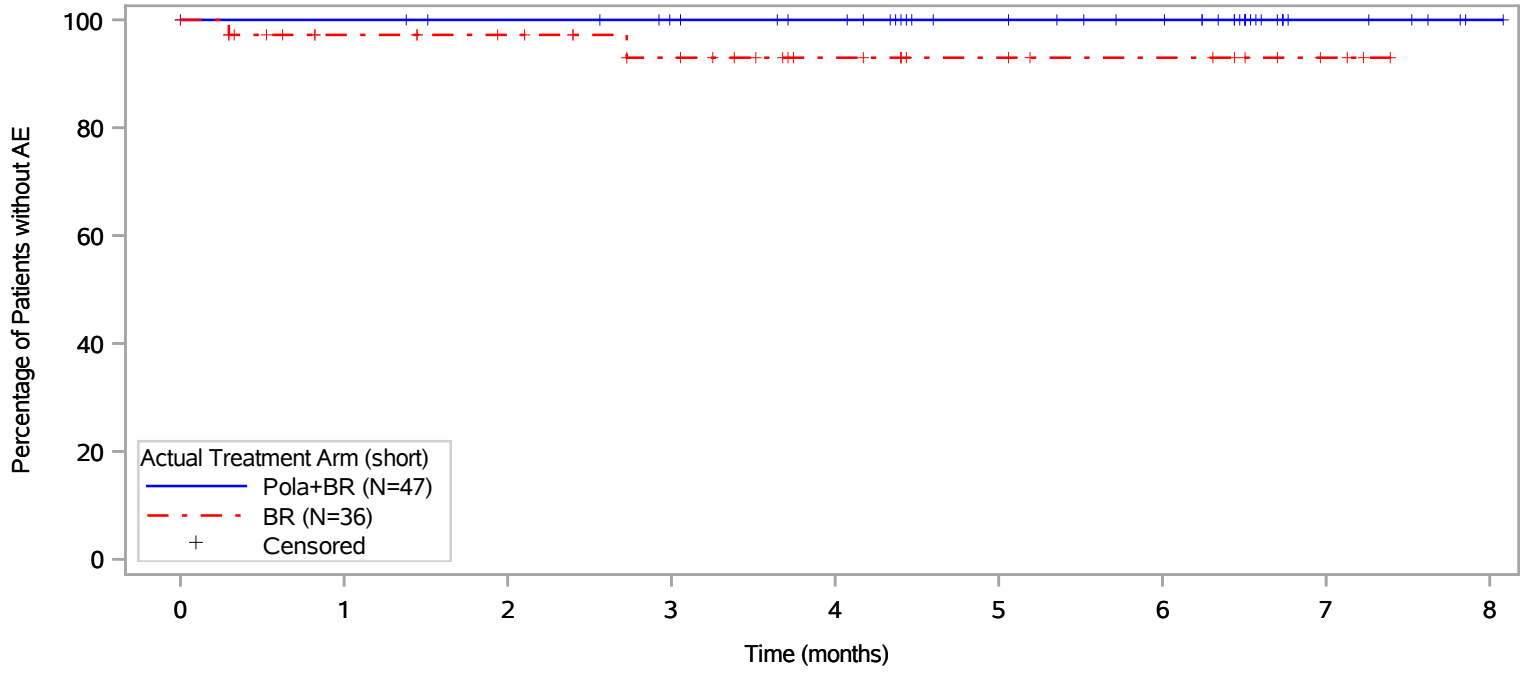
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, LIMB INJURY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	22	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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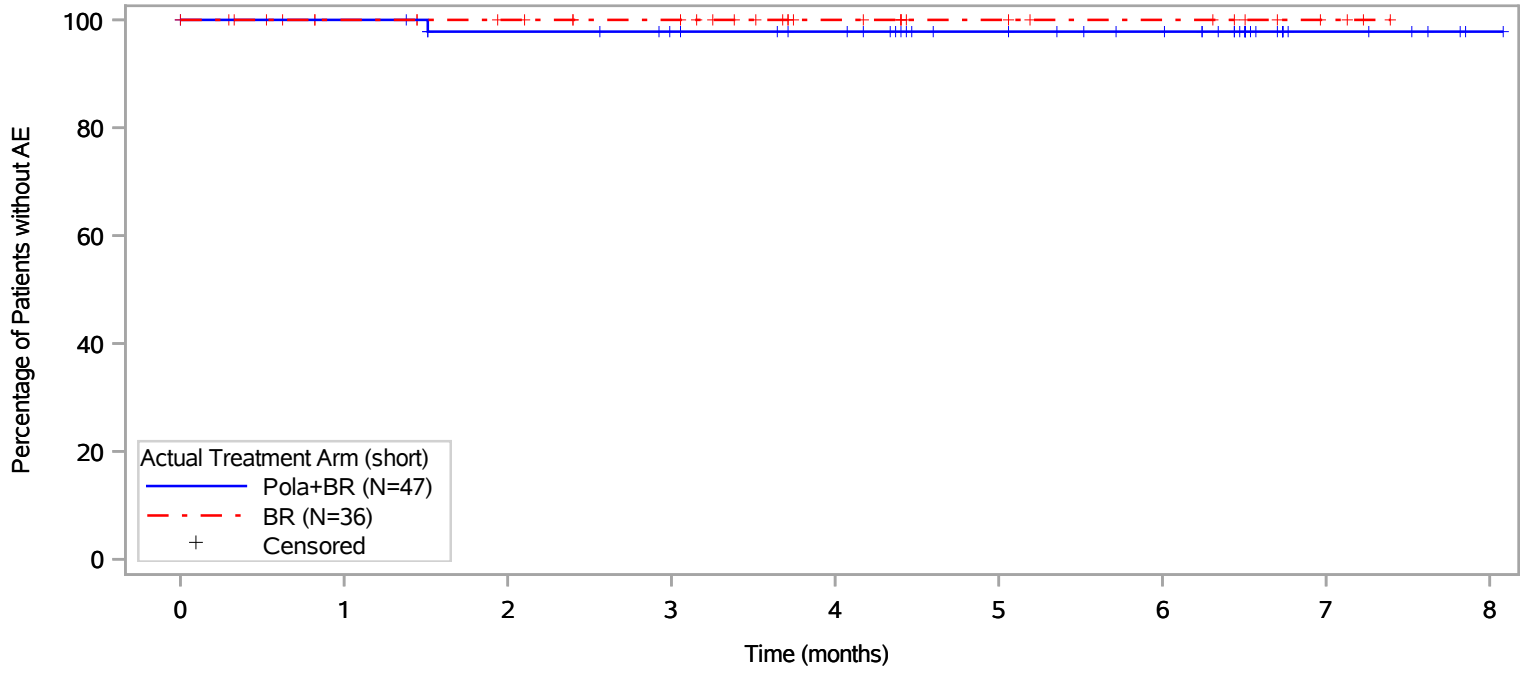
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, SKIN INJURY



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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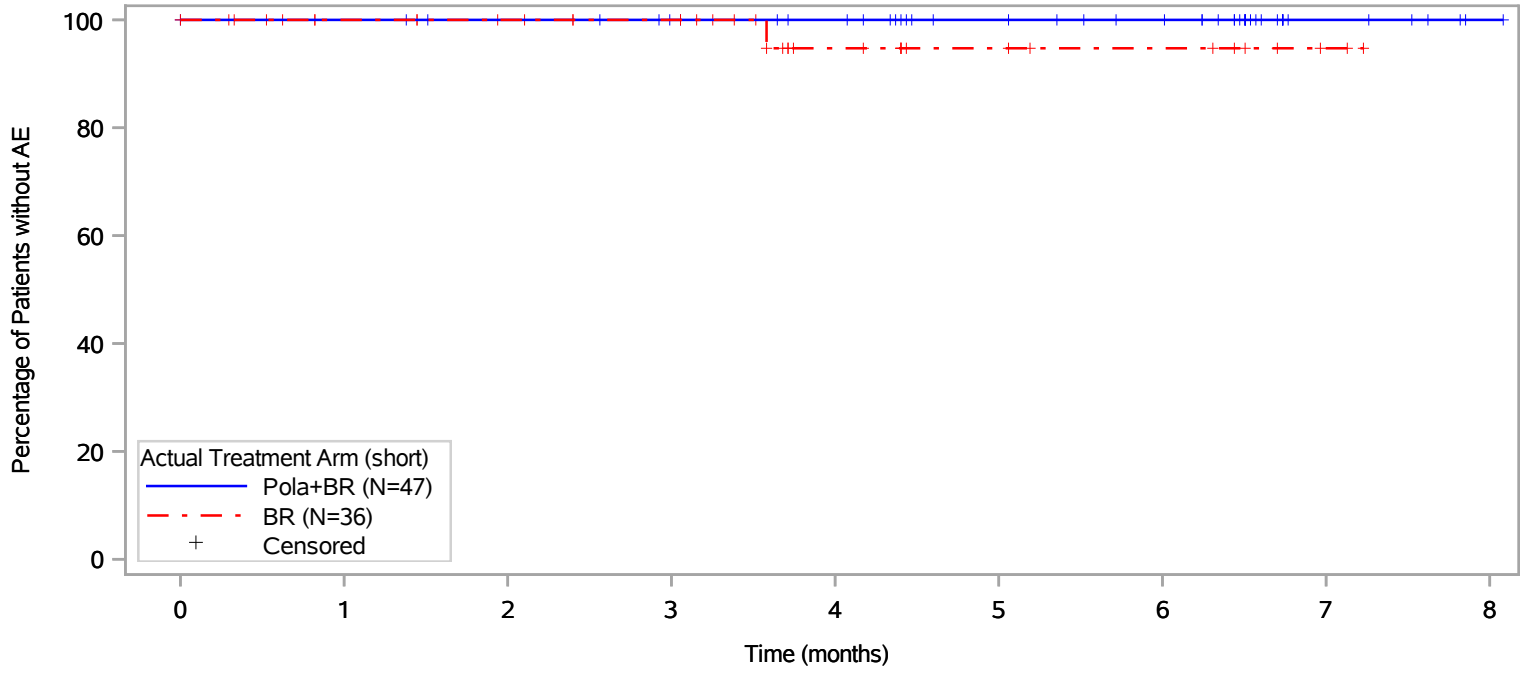
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, SKIN LACERATION

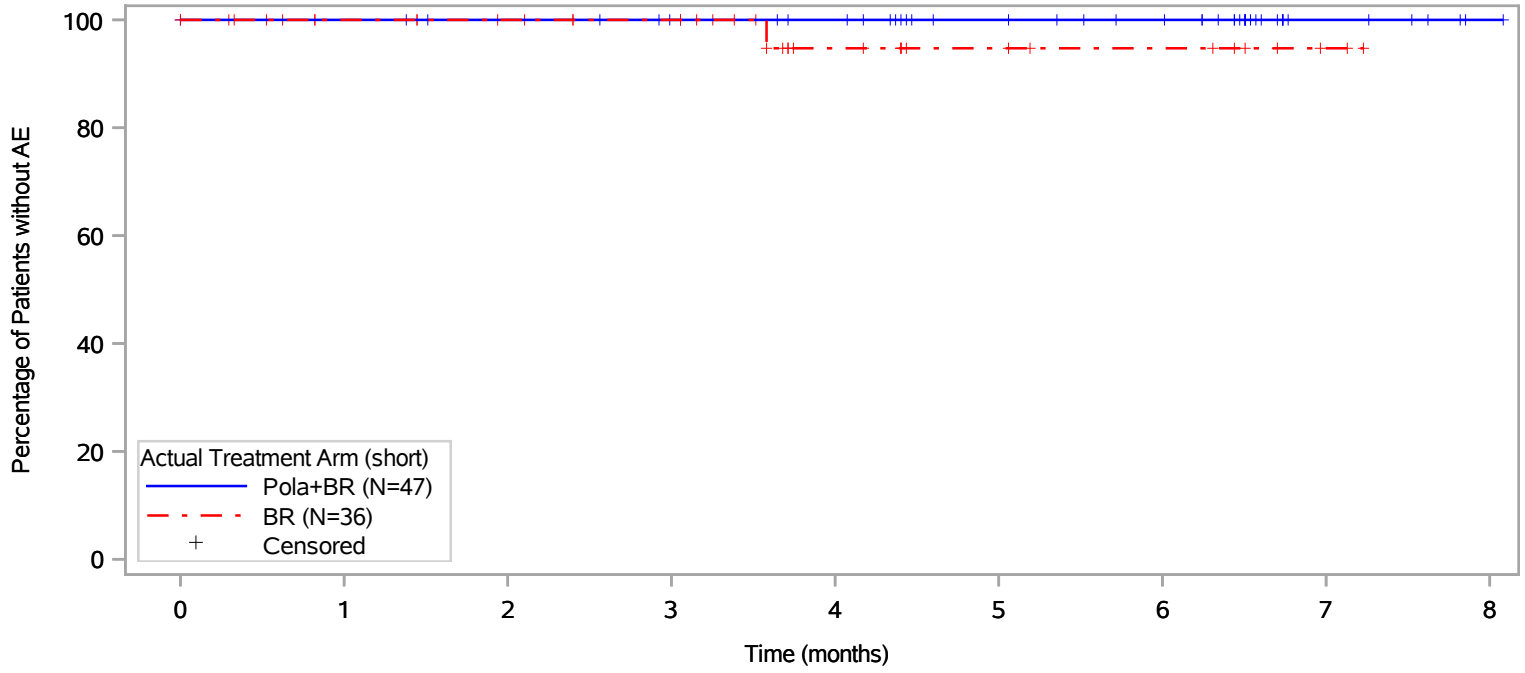


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, TOOTH FRACTURE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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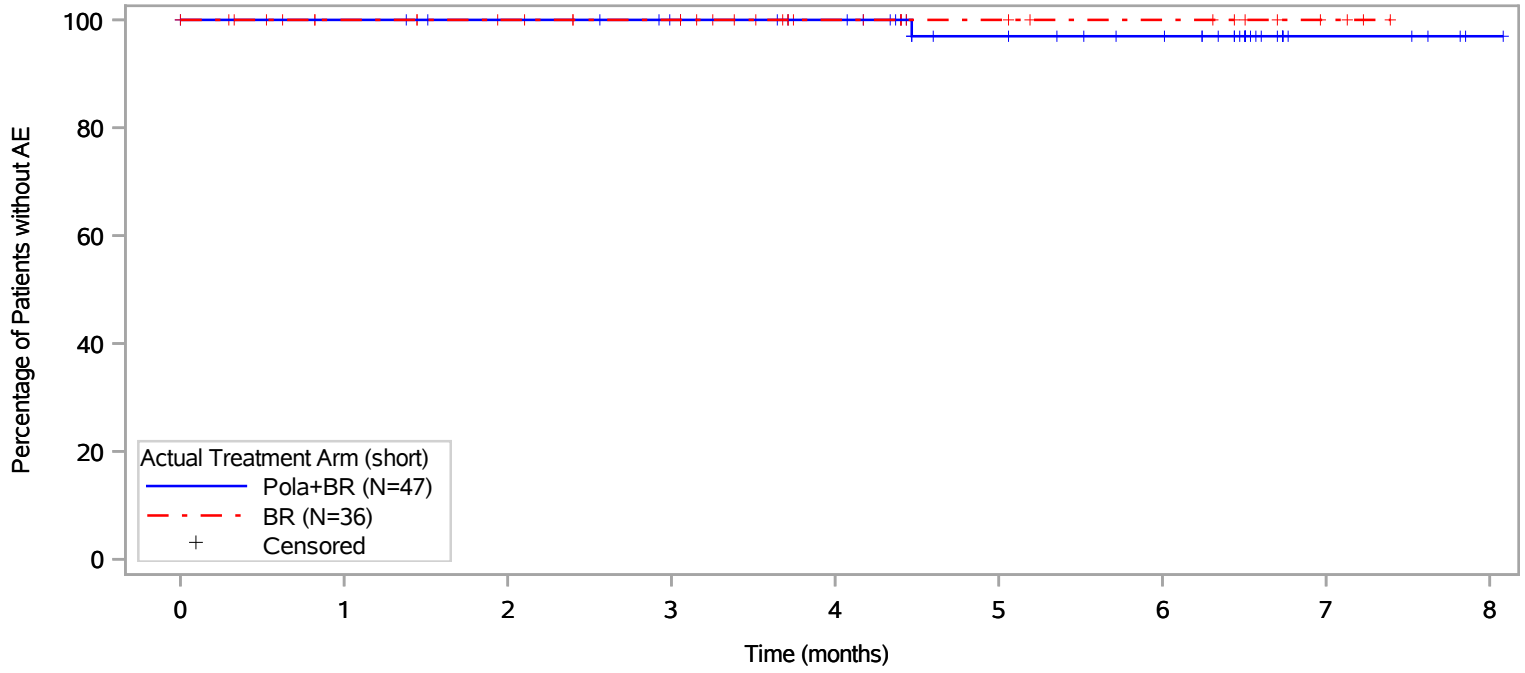
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, TRANSFUSION REACTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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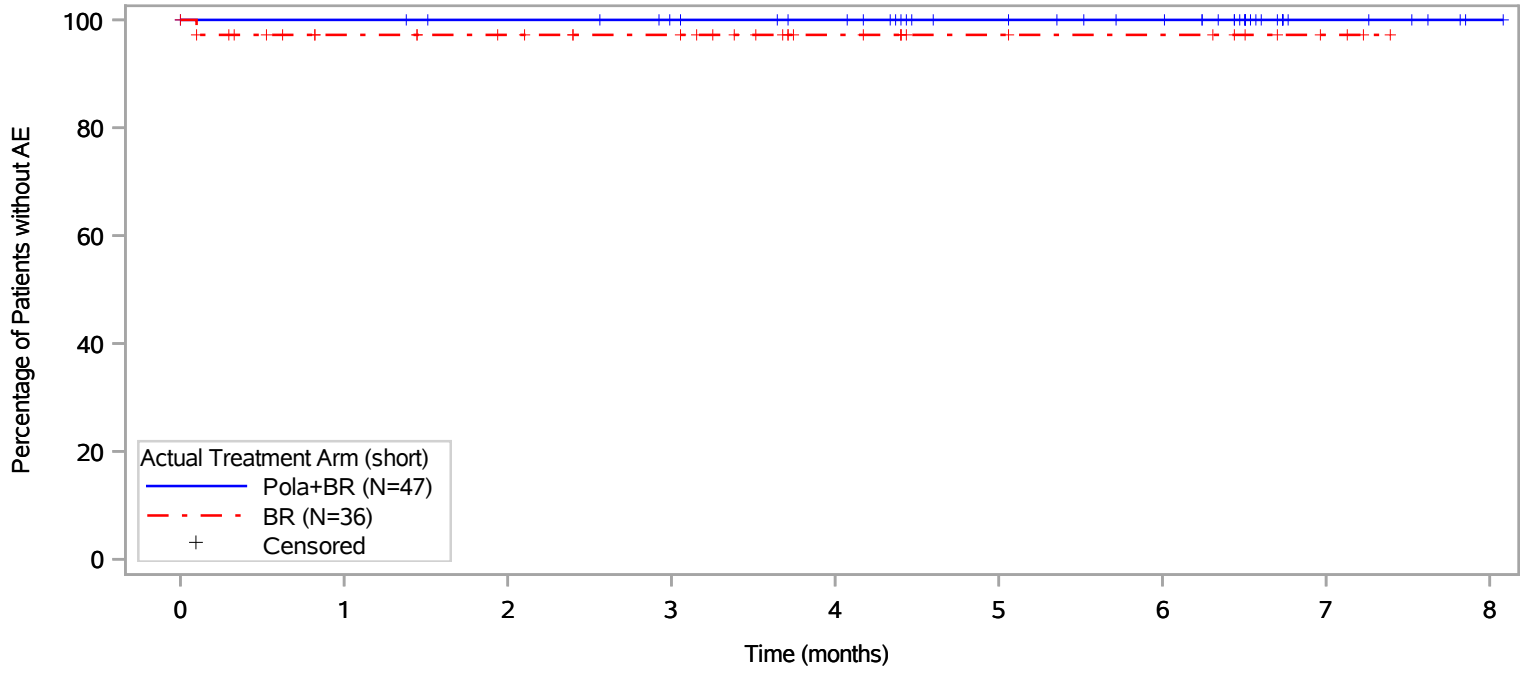
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, VASCULAR ACCESS SITE PAIN



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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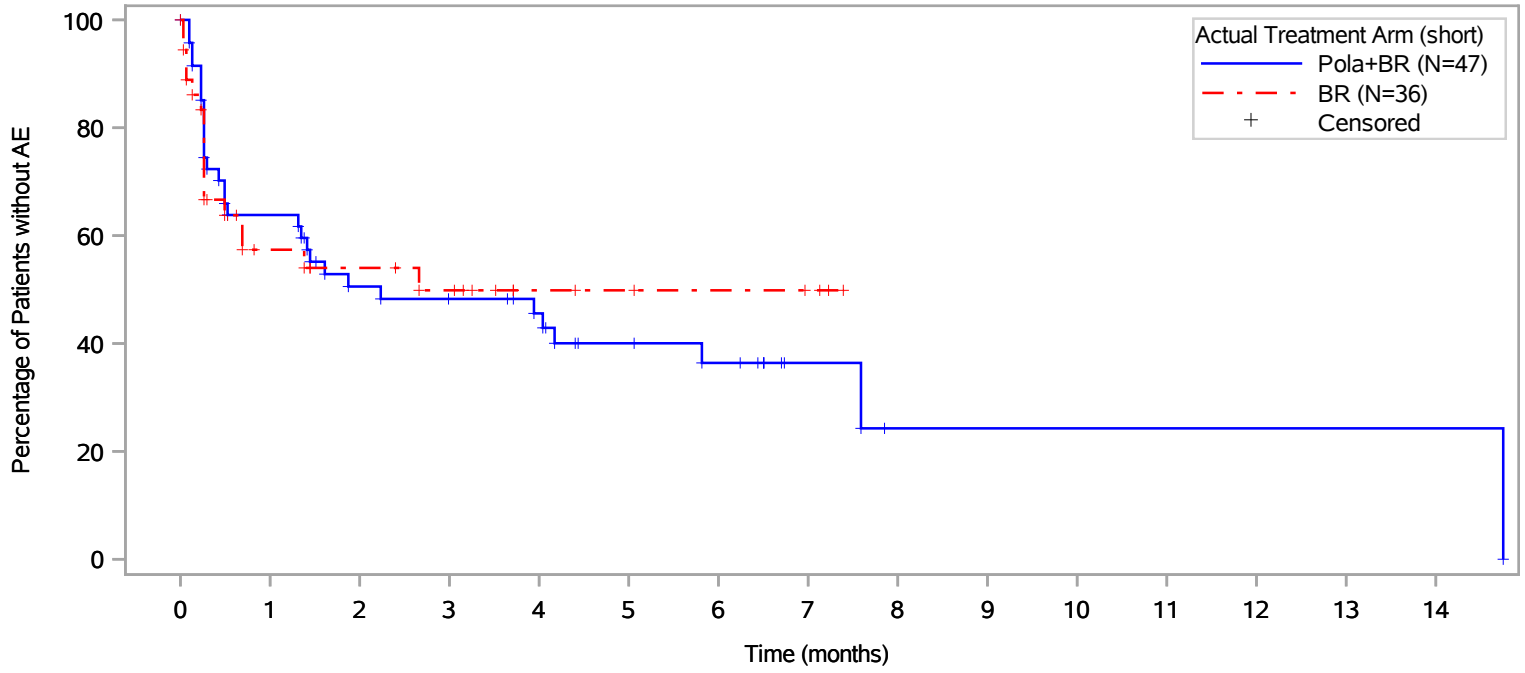
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk															
Pola+BR (N=47)	47	30	22	20	17	12	10	3	1	1	1	1	1	1	1
BR (N=36)	36	17	14	12	6	5	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	3	5	8	9	16	17	17	17	17	17	17	17
BR (N=36)	0	4	6	7	13	14	15	16	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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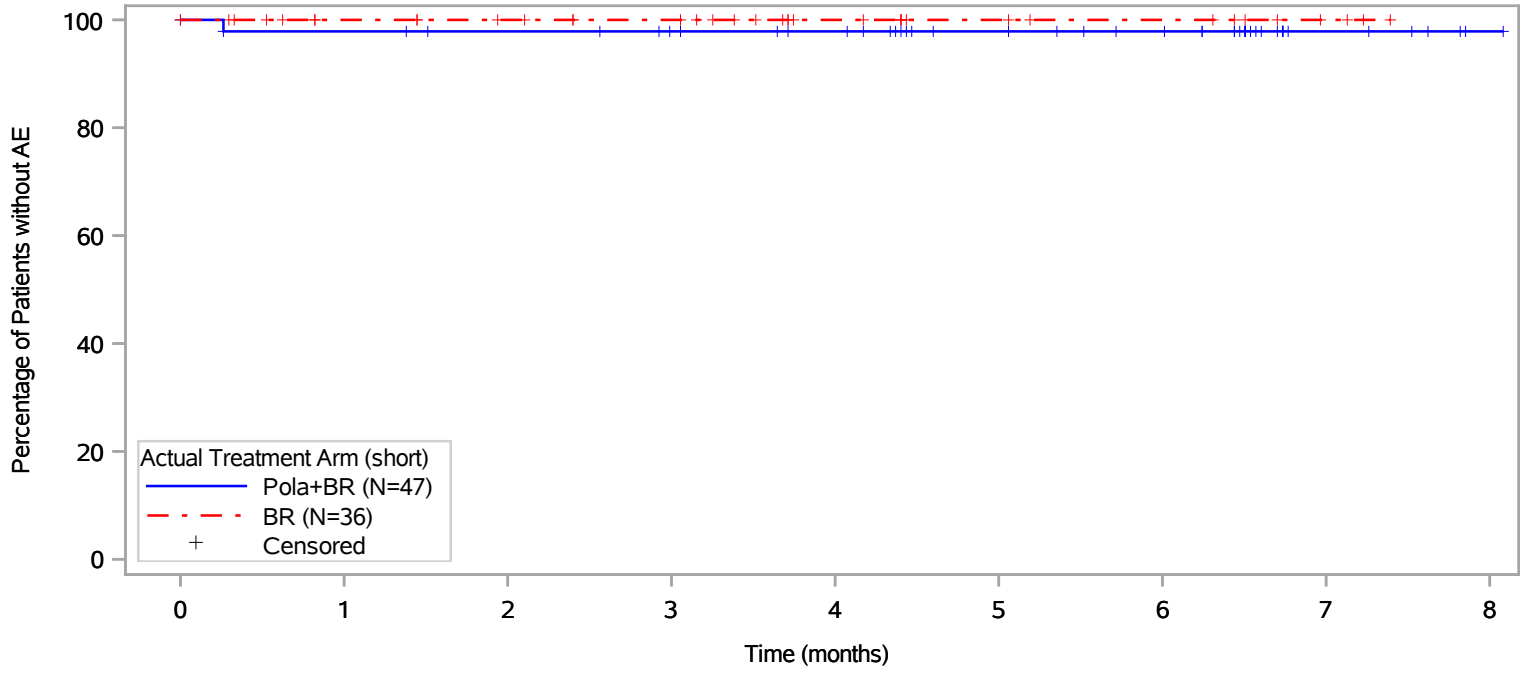
01DEC2022 22:30

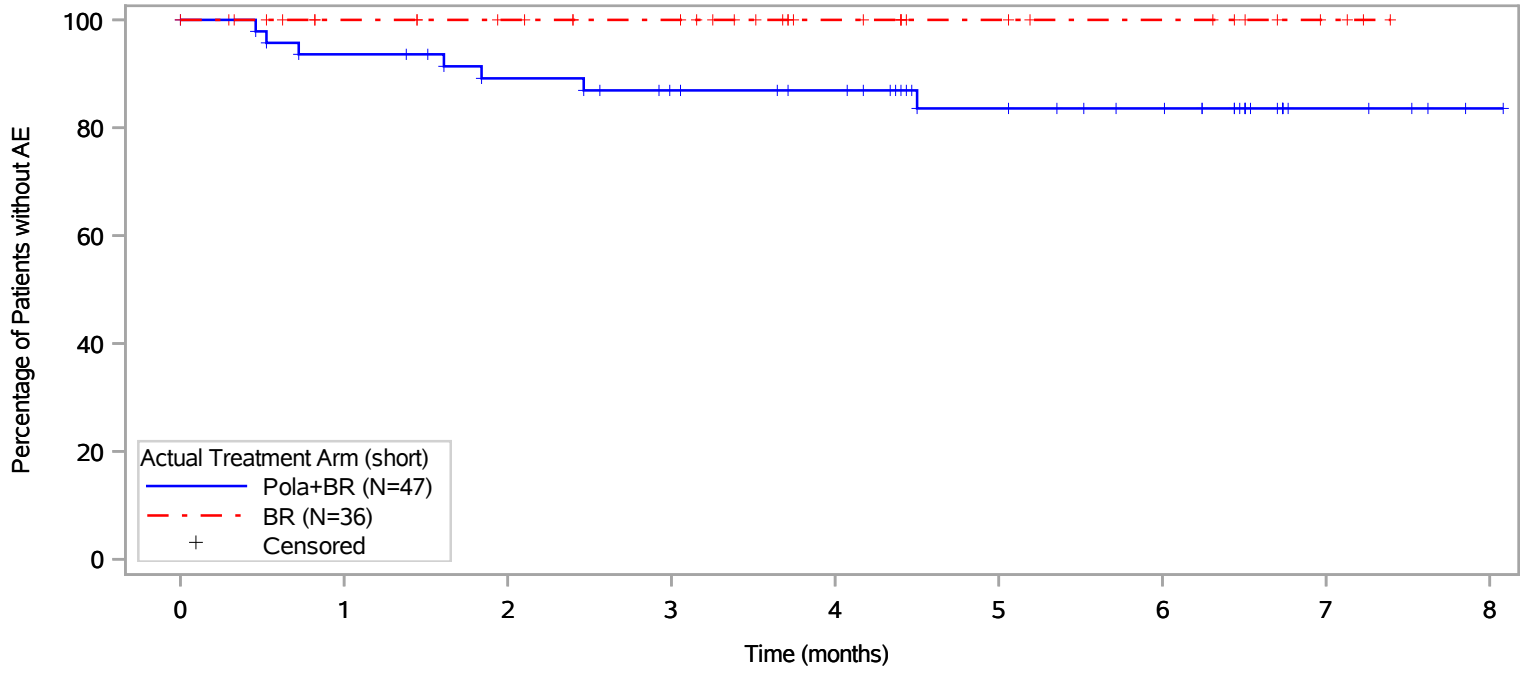
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ADENOSINE DEAMINASE INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

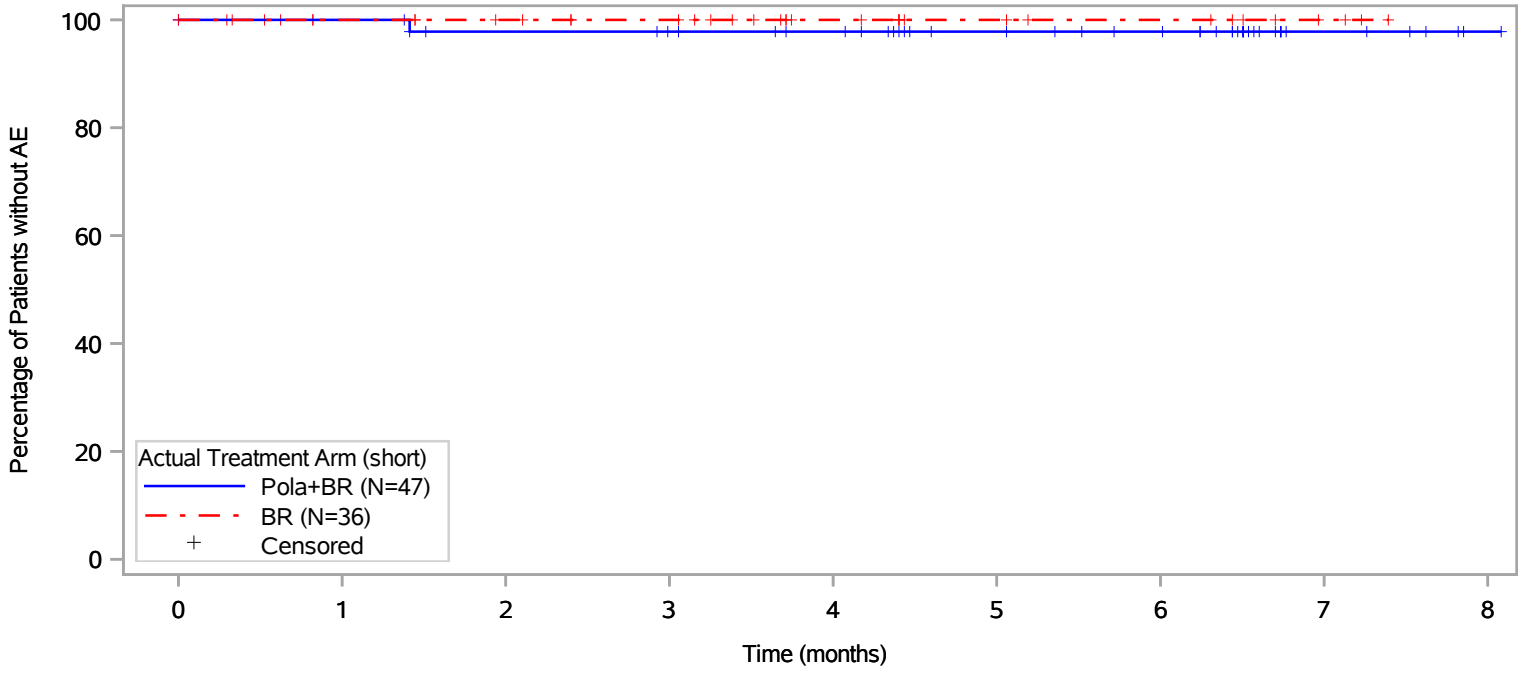
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ALANINE AMINOTRANSFERASE INCREASED



Patients at risk									
Pola+BR (N=47)	47	44	40	36	33	25	21	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	35	39
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

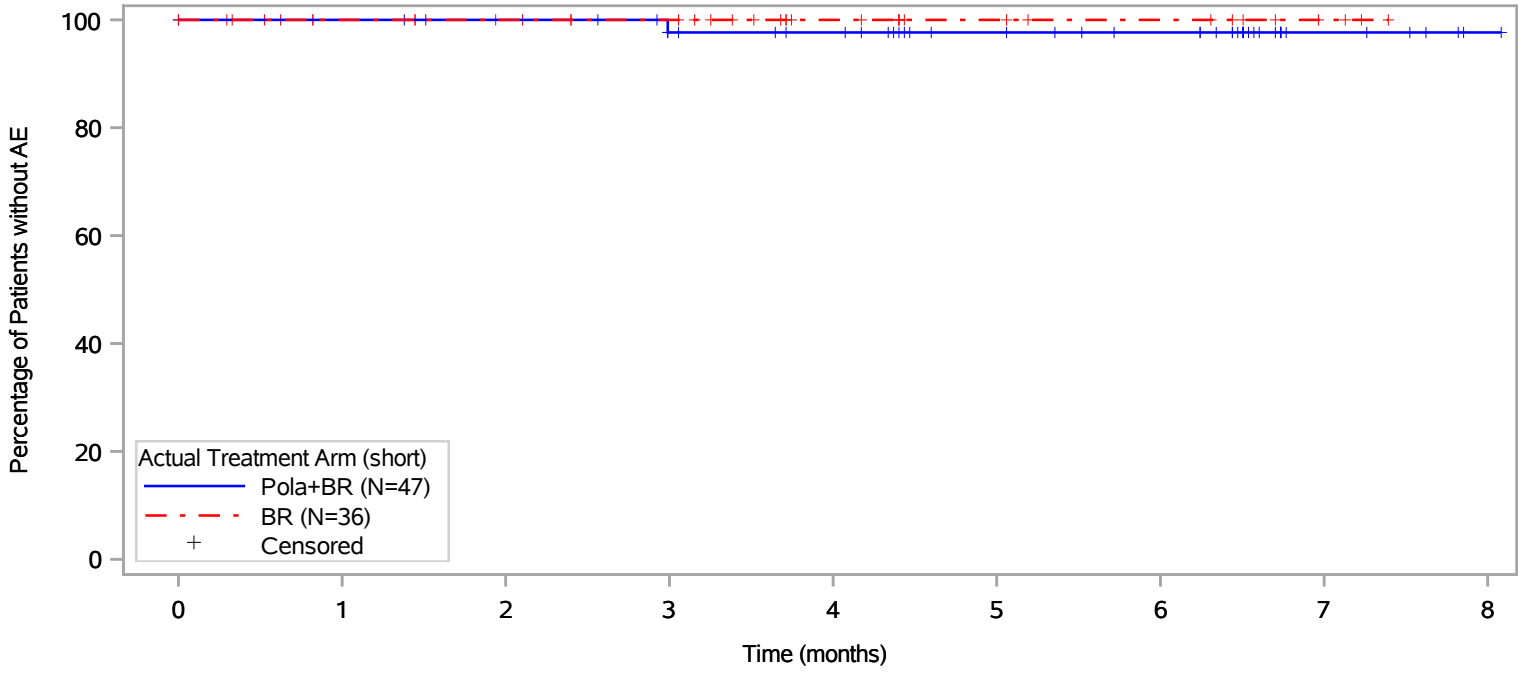
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, AMYLASE INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ANION GAP DECREASED

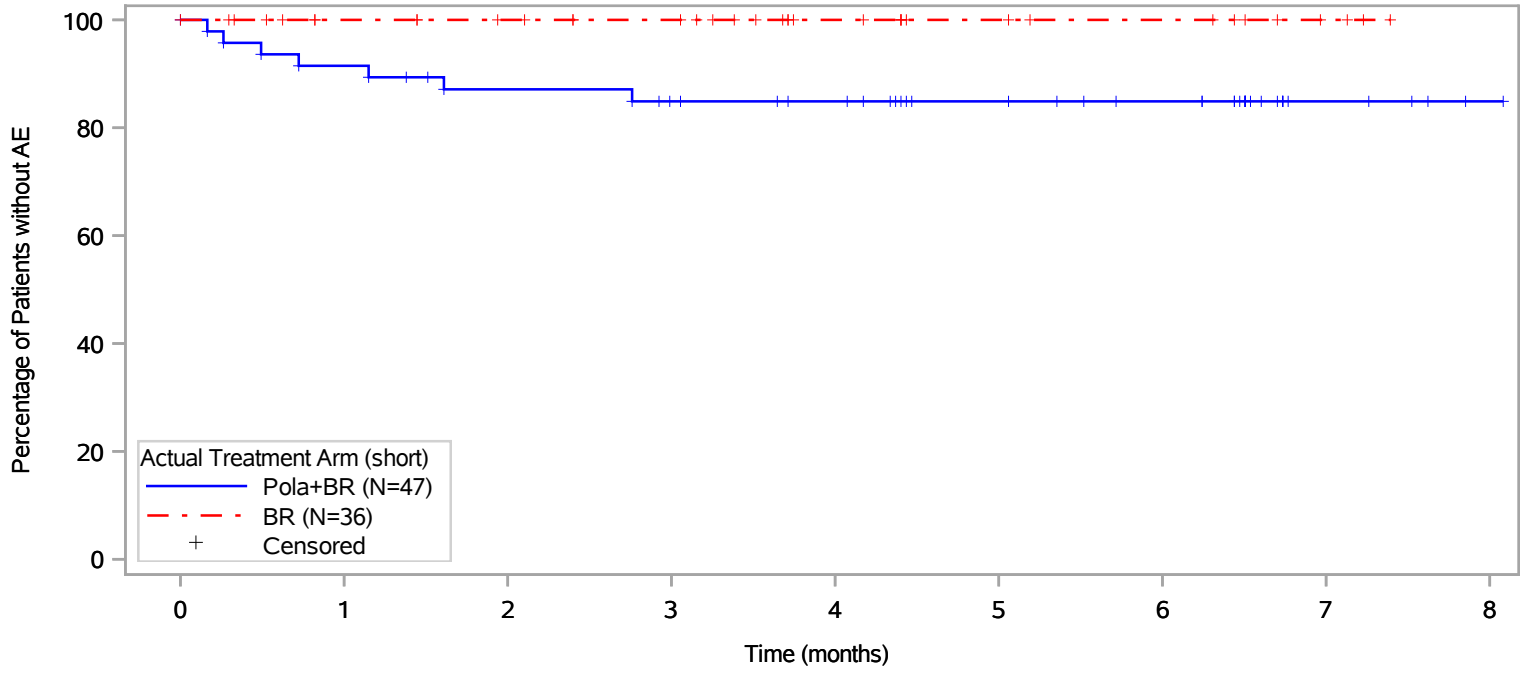


Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ASPARTATE AMINOTRANSFERASE INCREASED

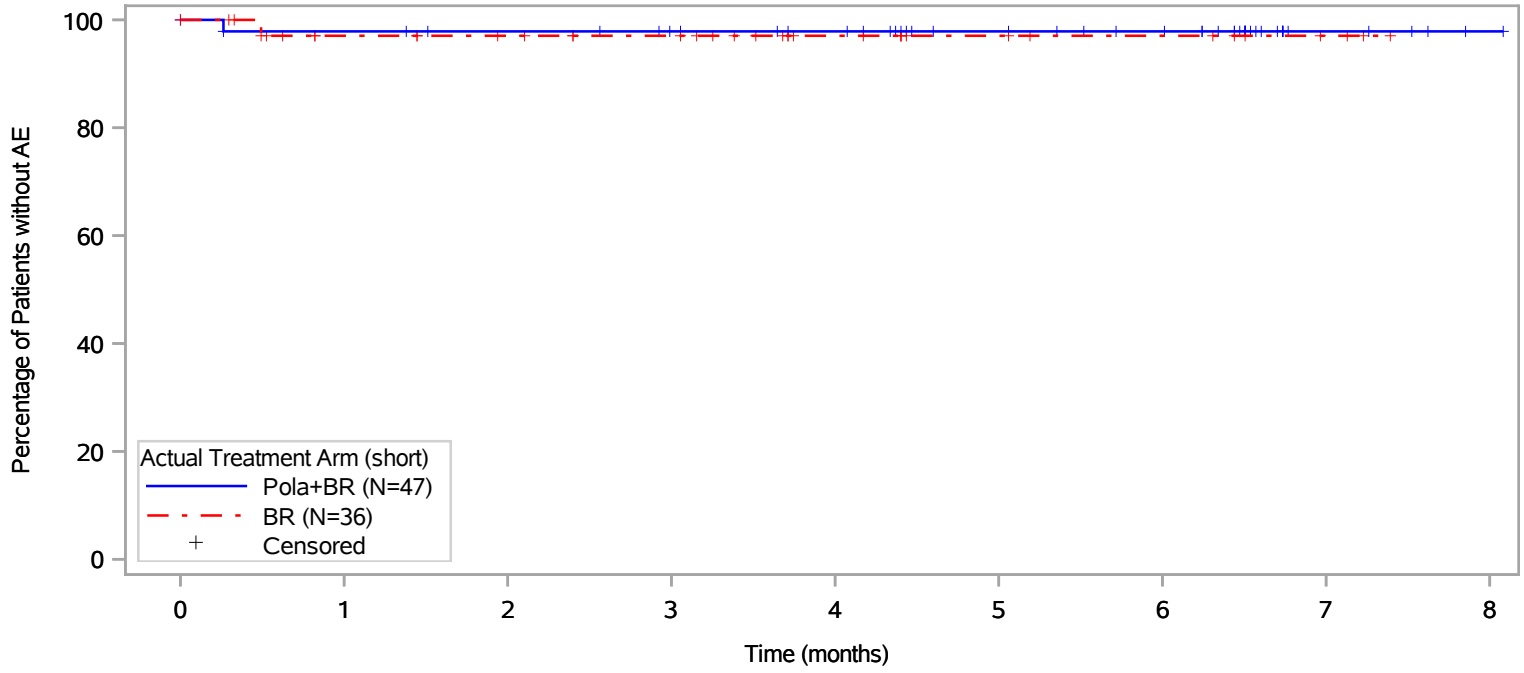


Patients at risk									
Pola+BR (N=47)	47	43	39	36	33	26	22	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	18	35	39
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

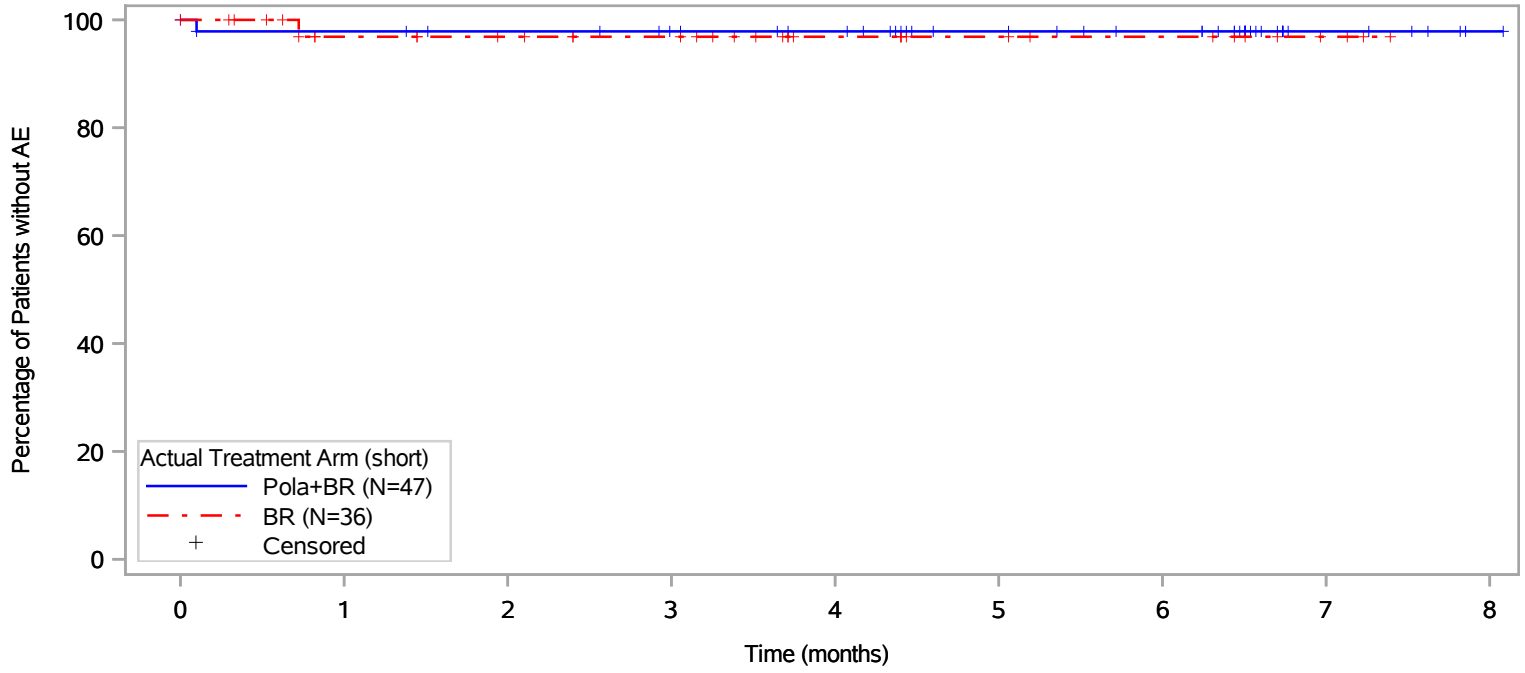
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BILIRUBIN CONJUGATED INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	5	1
BR (N=36)	36	29	26	23	14	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

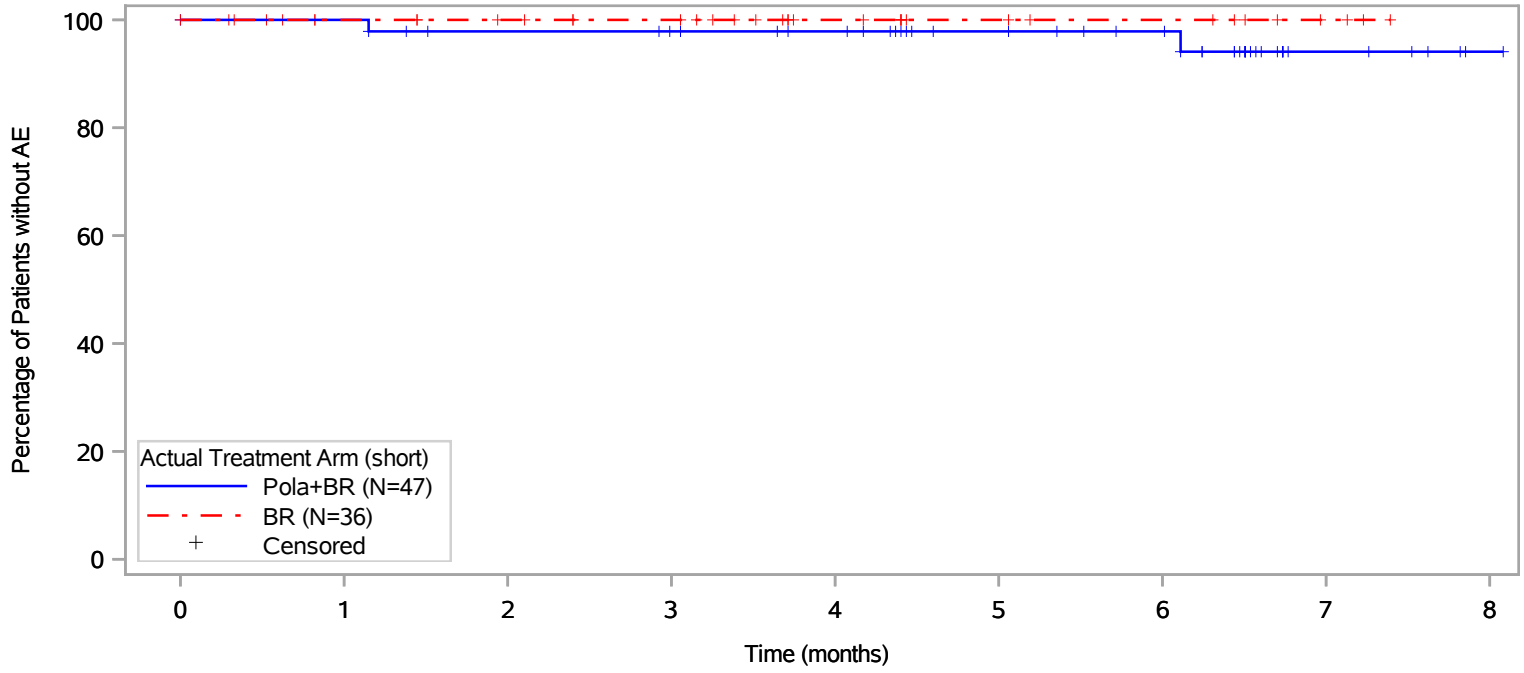
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALBUMIN DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

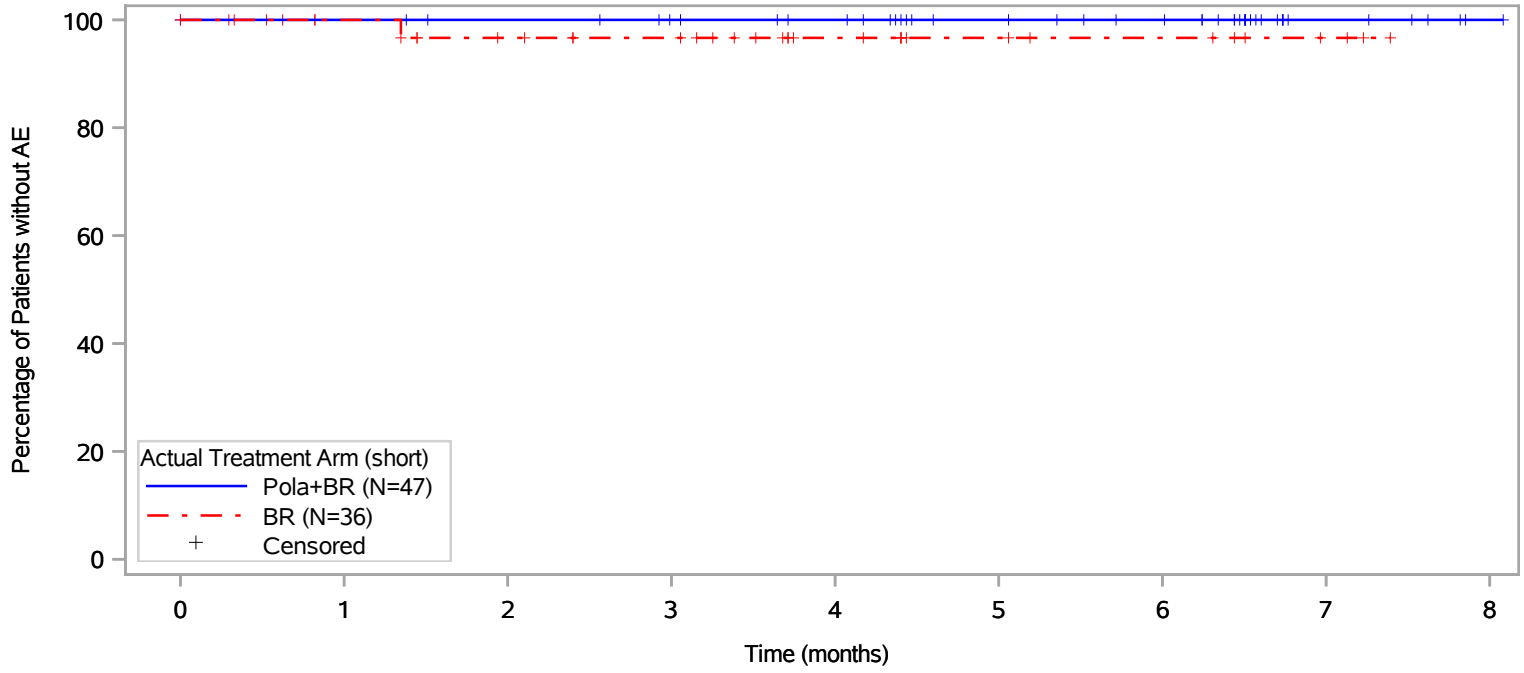
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALKALINE PHOSPHATASE INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

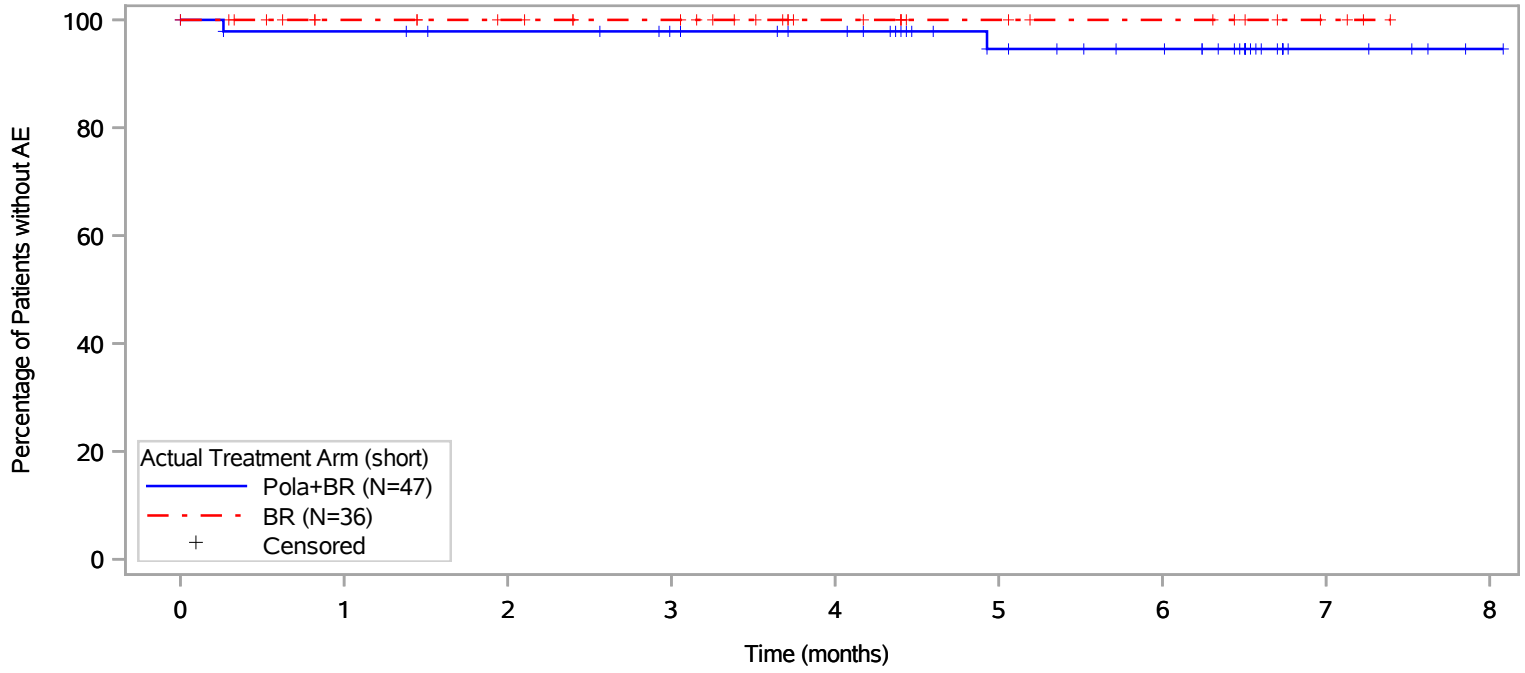
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD BILIRUBIN DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	23	14	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD BILIRUBIN INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	29	25	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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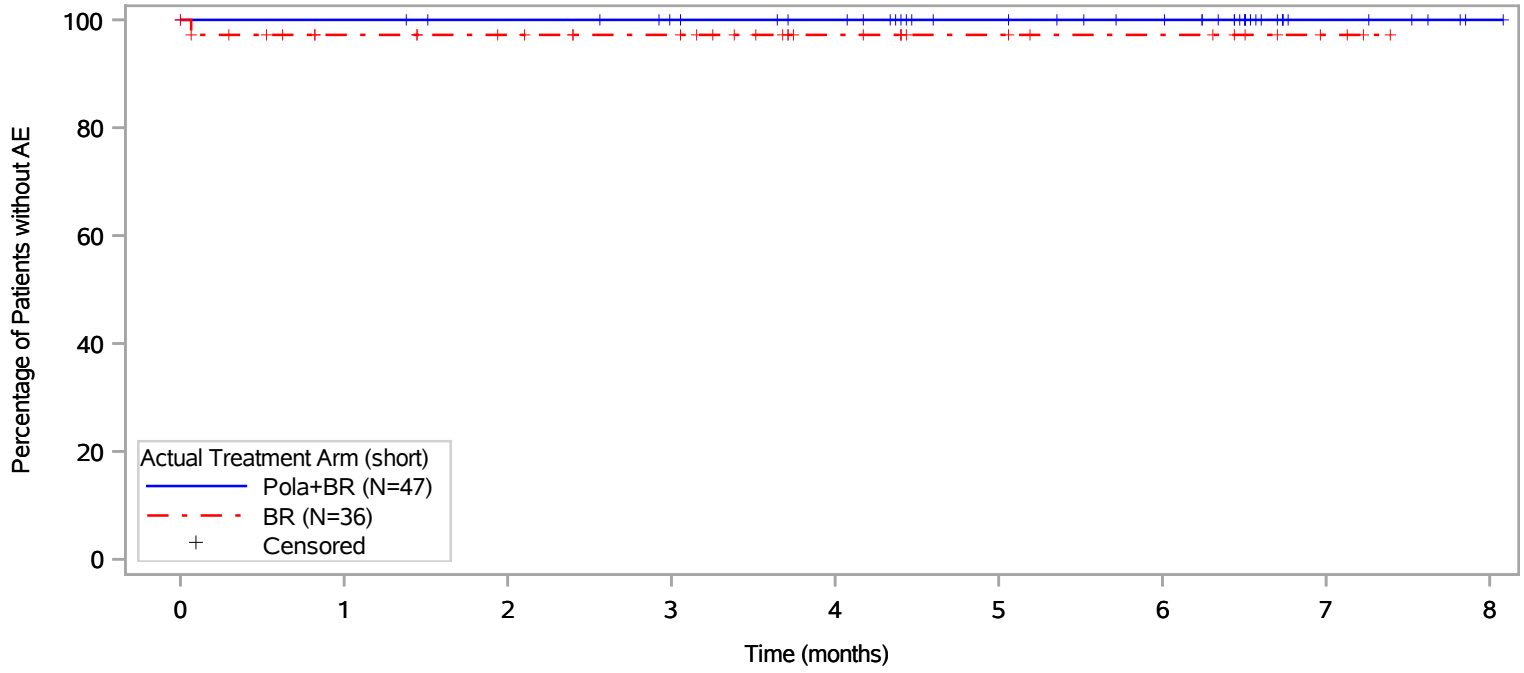
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD CALCIUM DECREASED

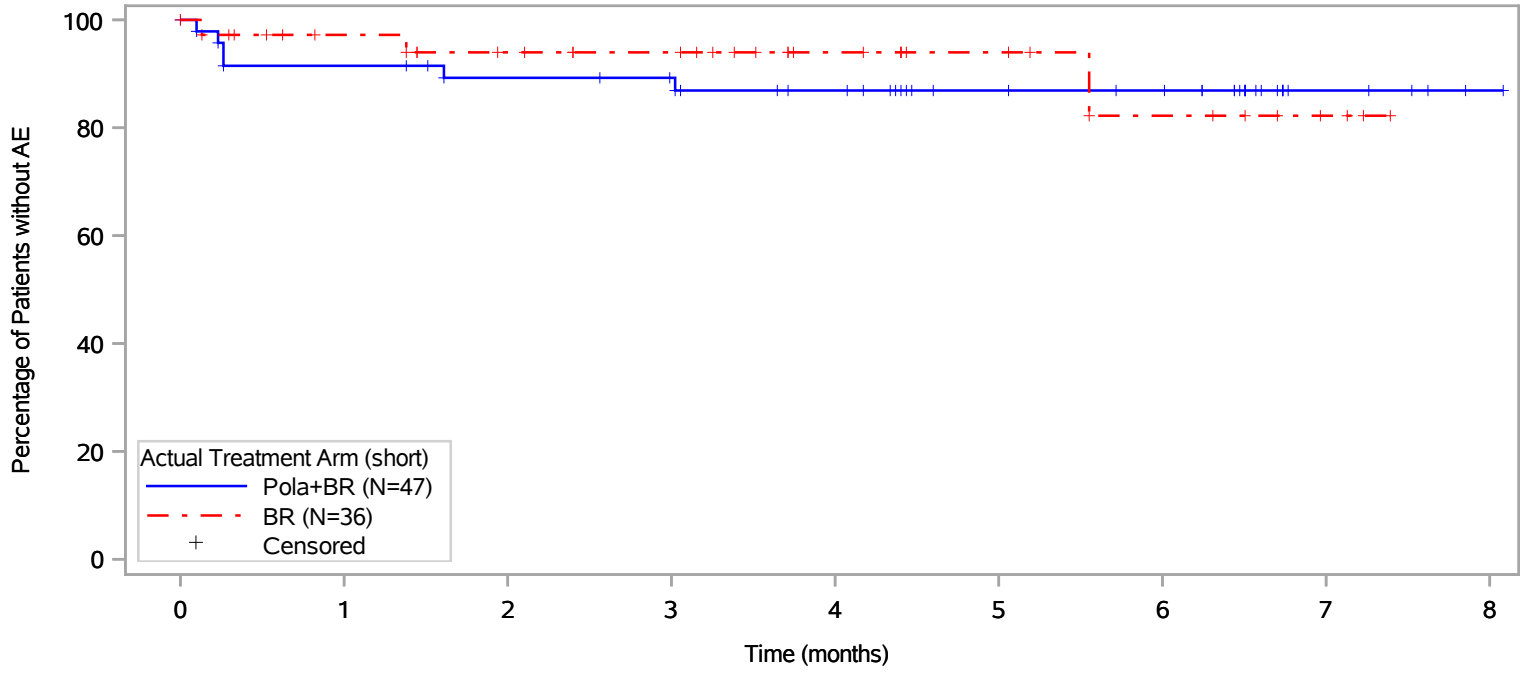


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	5	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD CREATININE INCREASED

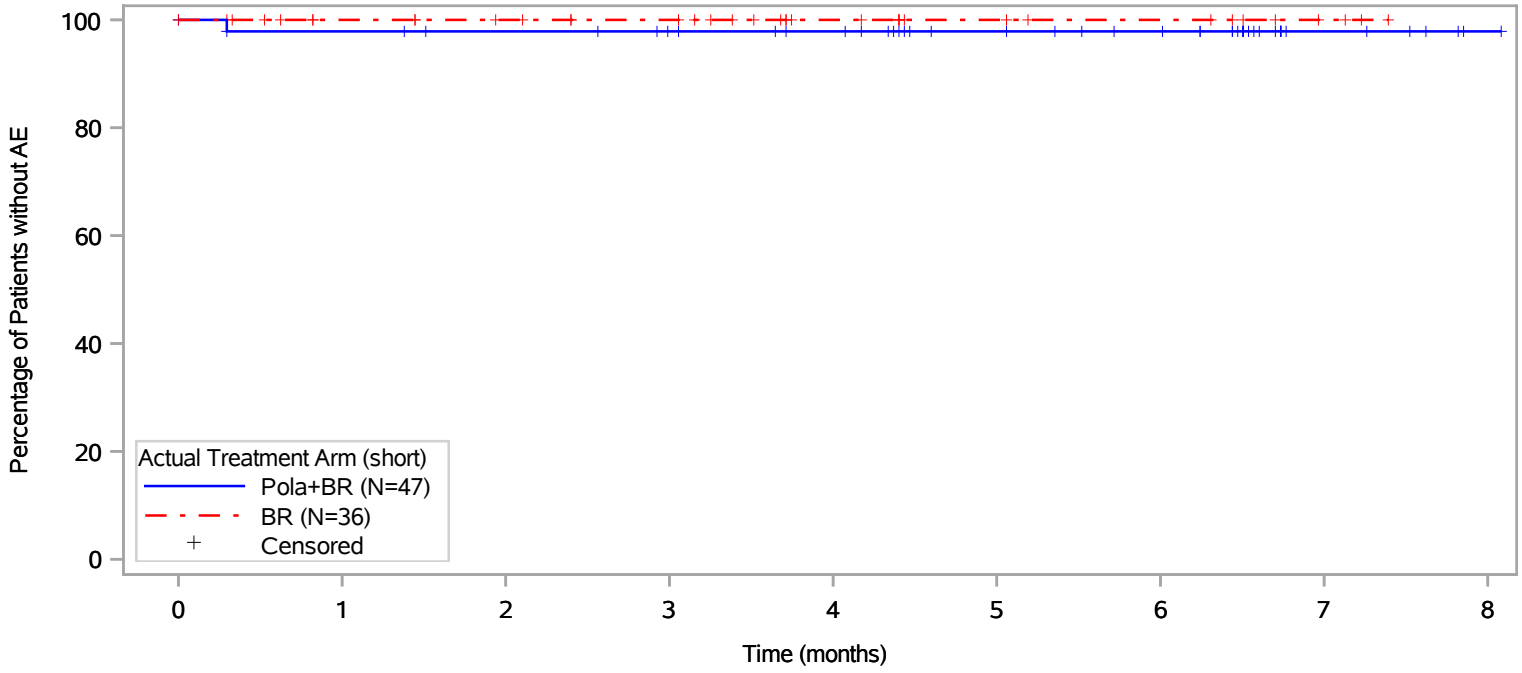


Patients at risk									
Pola+BR (N=47)	47	43	40	38	34	26	24	5	1
BR (N=36)	36	30	26	23	15	10	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	17	36	40
BR (N=36)	0	5	8	11	19	24	26	30	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD FIBRINOGEN DECREASED

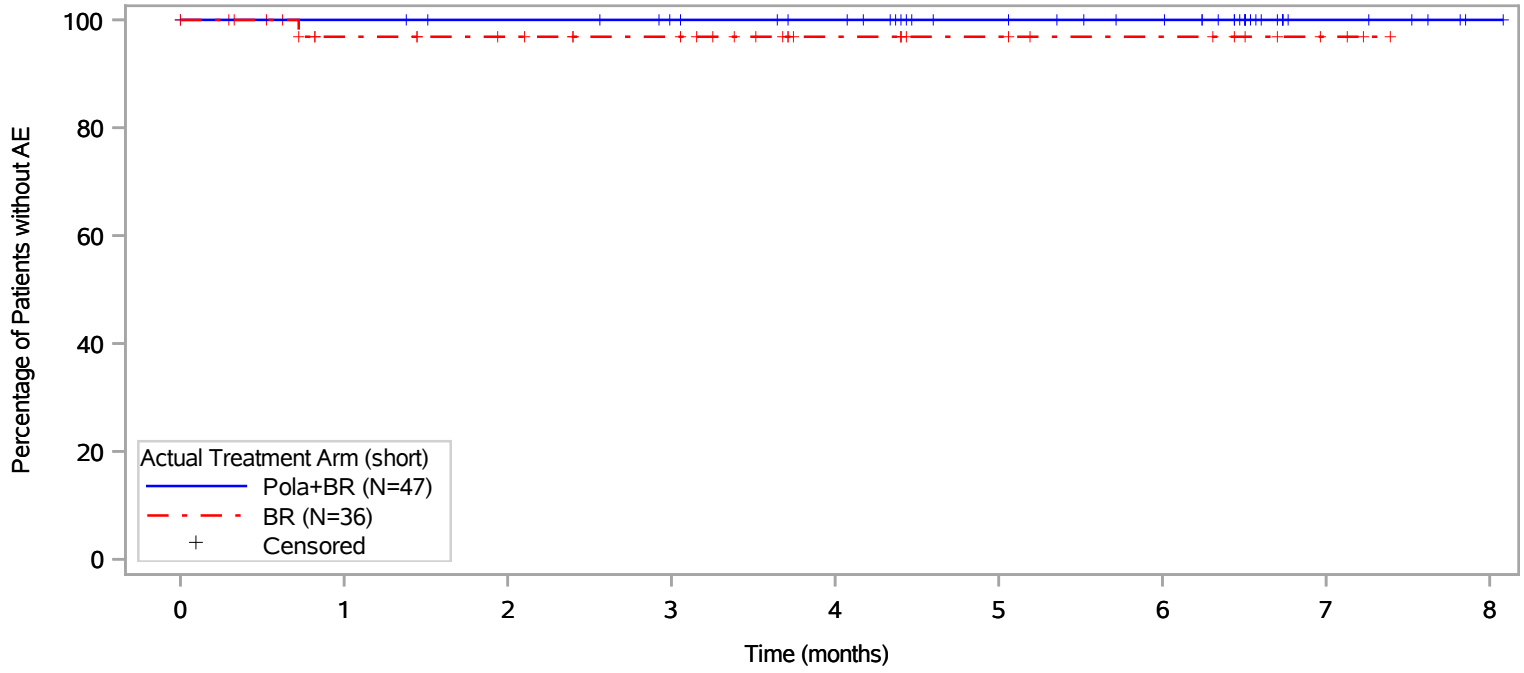


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD GLUCOSE DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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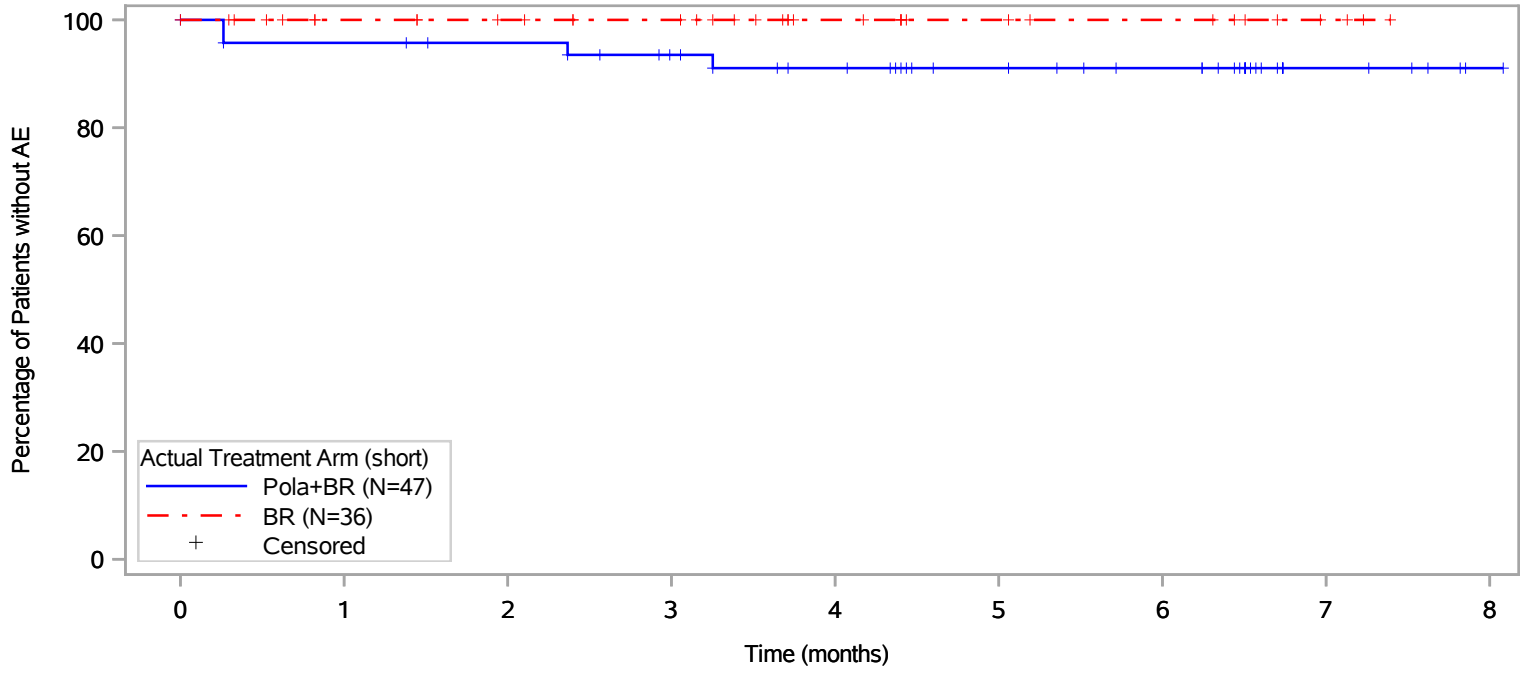
01DEC2022 22:30

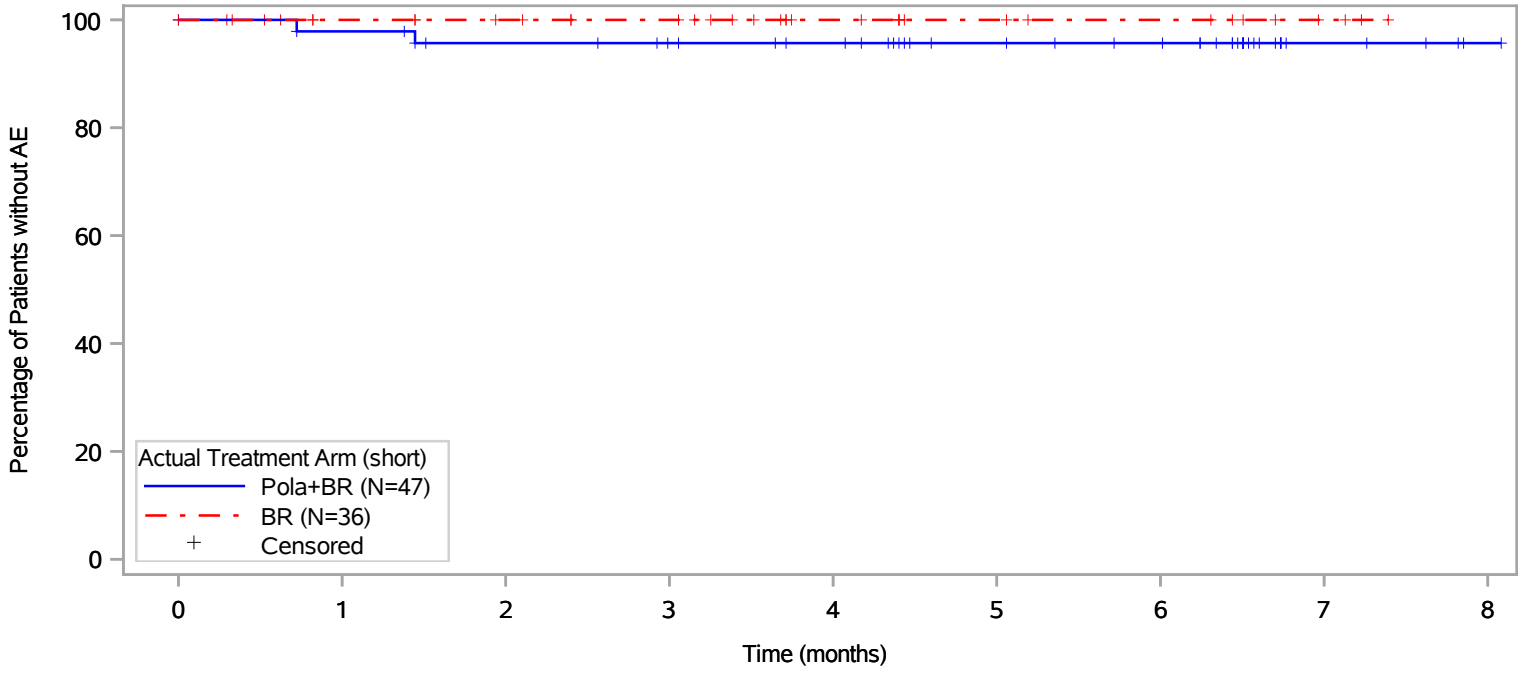
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD LACTATE DEHYDROGENASE INCREASED



Patients at risk									
Pola+BR (N=47)	47	45	43	39	35	28	24	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	37	42
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

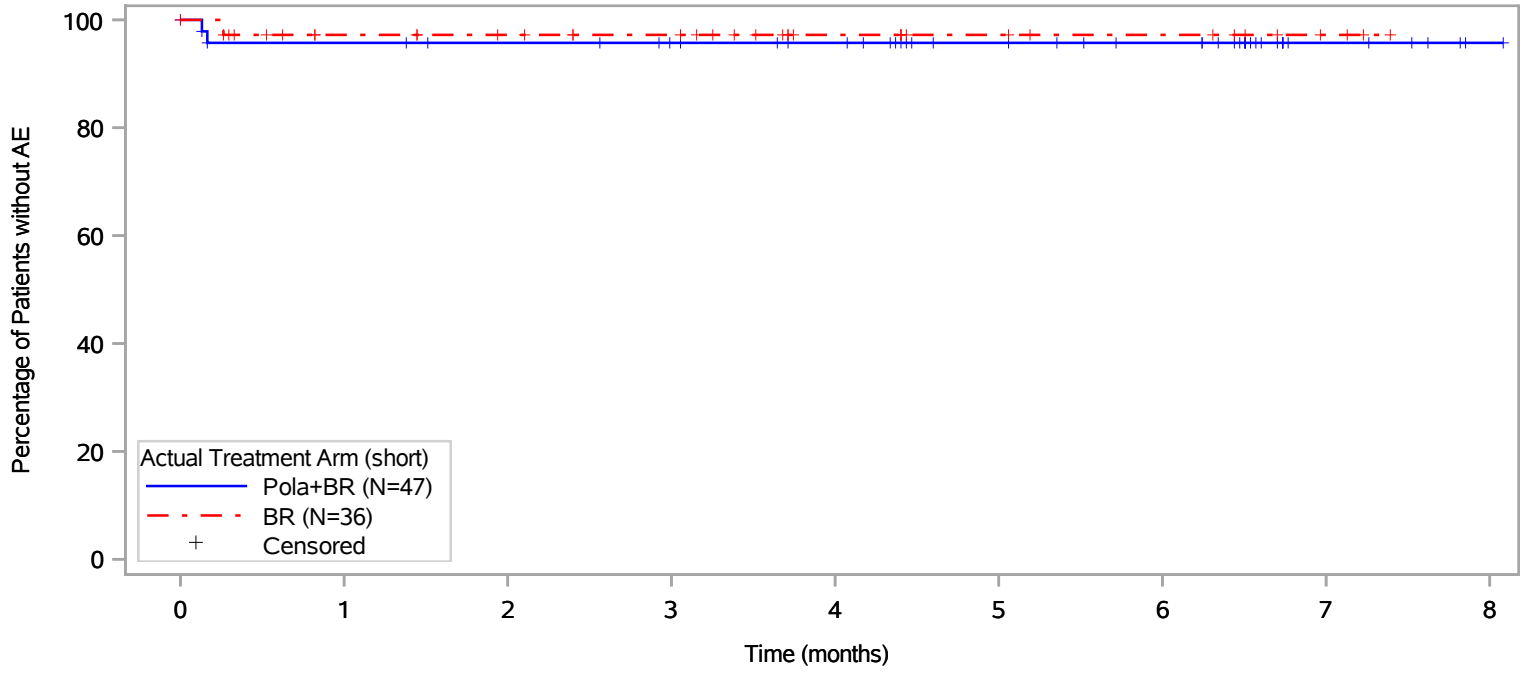
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD MAGNESIUM DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	43	40	37	29	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

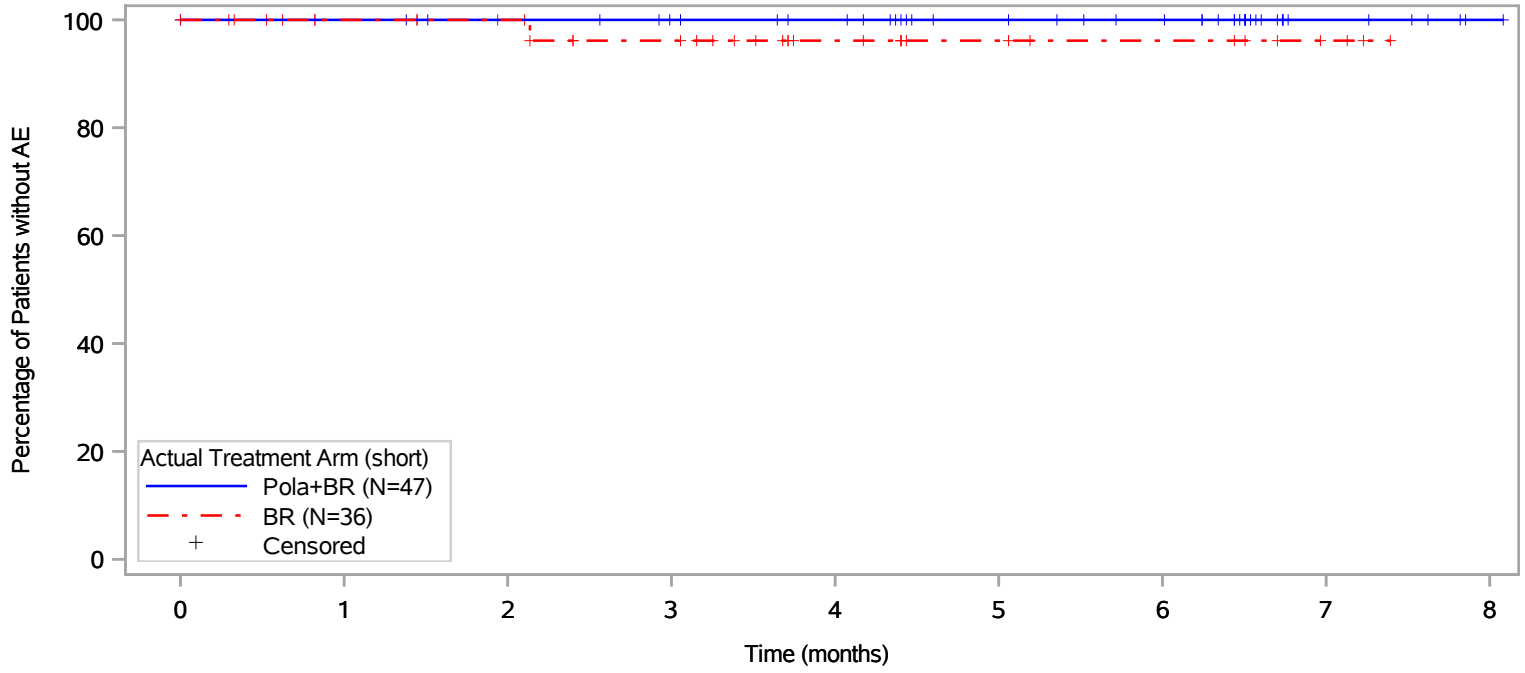
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED



Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	29	25	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

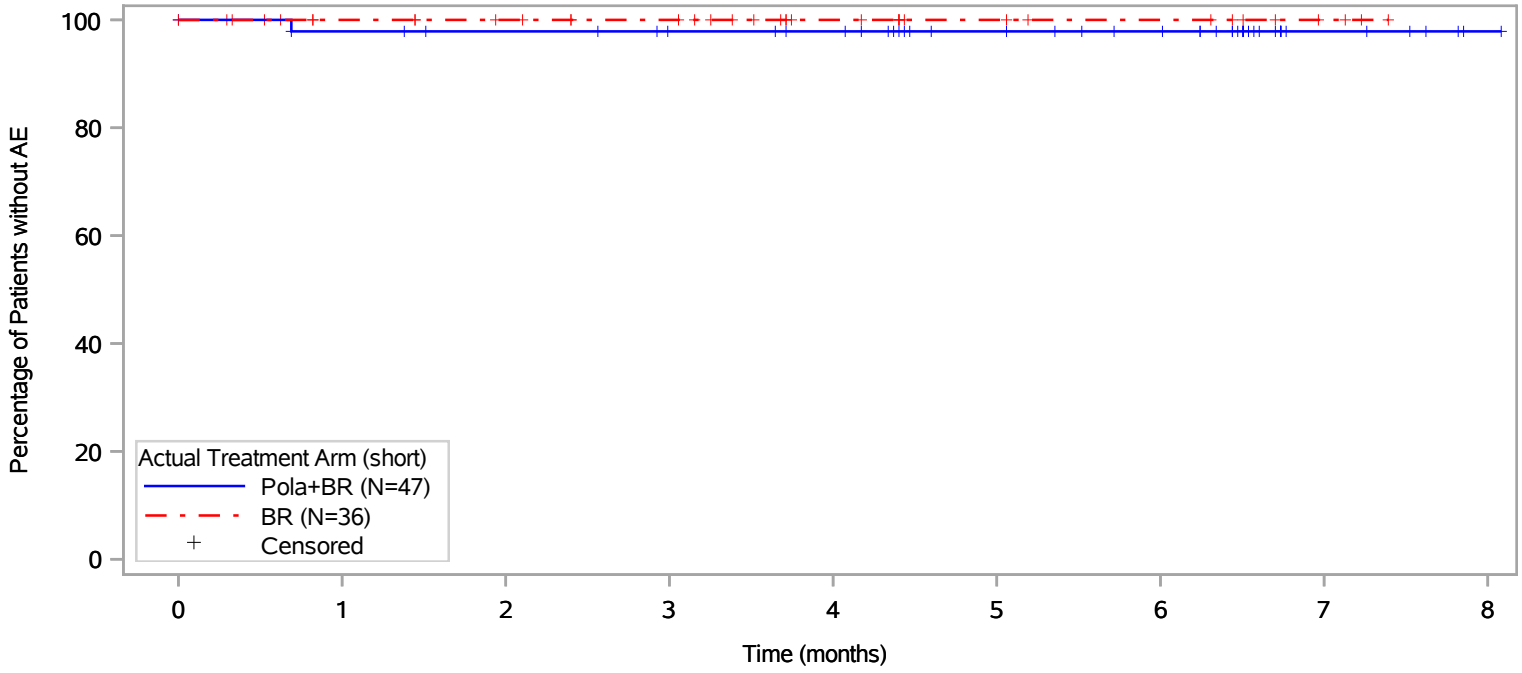
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PRESSURE INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

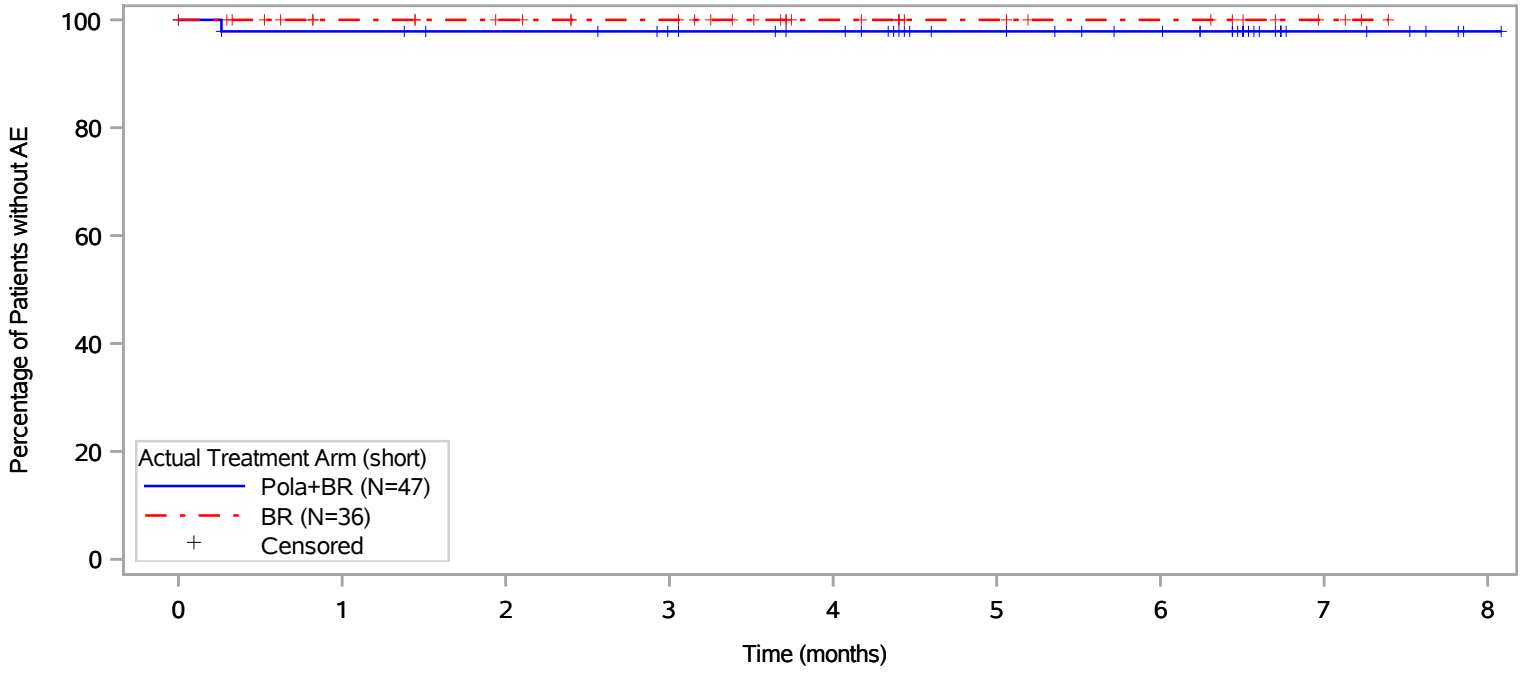
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD SODIUM DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD UREA INCREASED

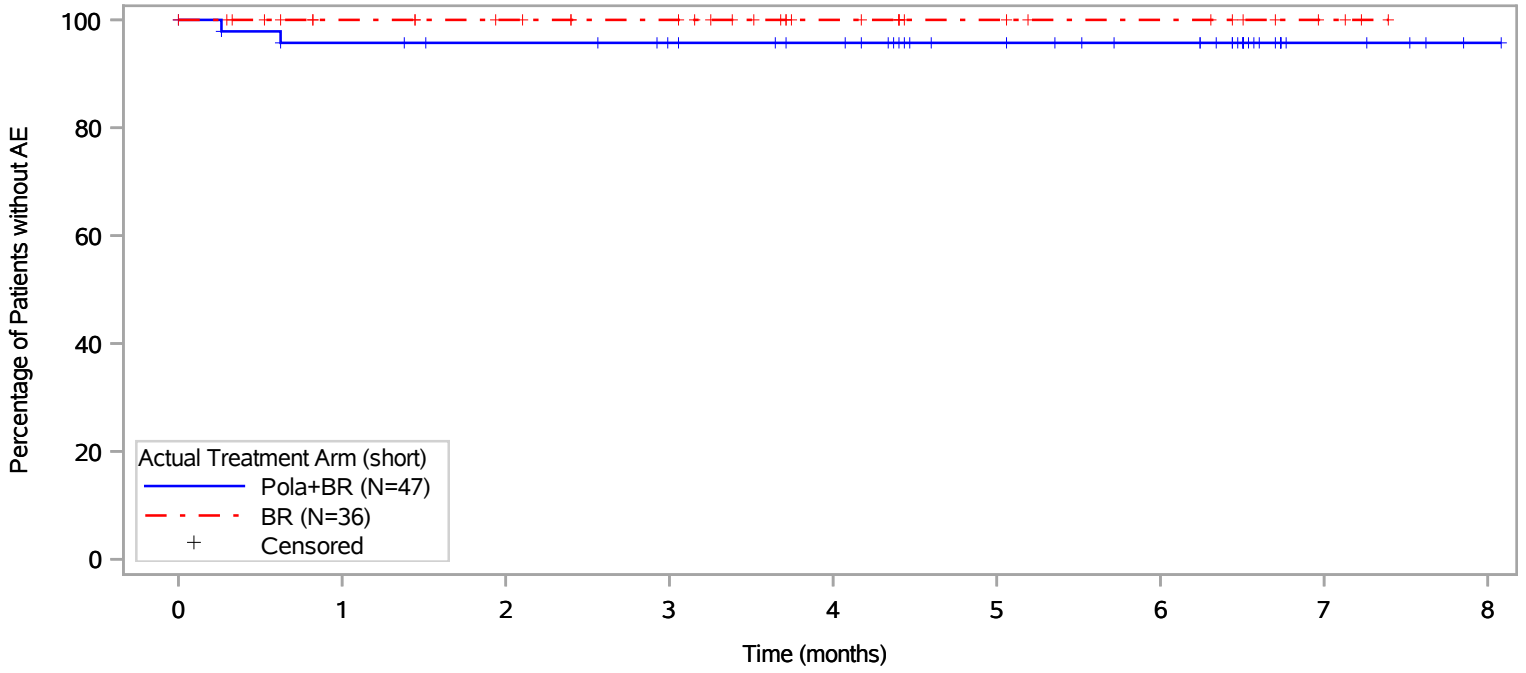


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD URIC ACID INCREASED

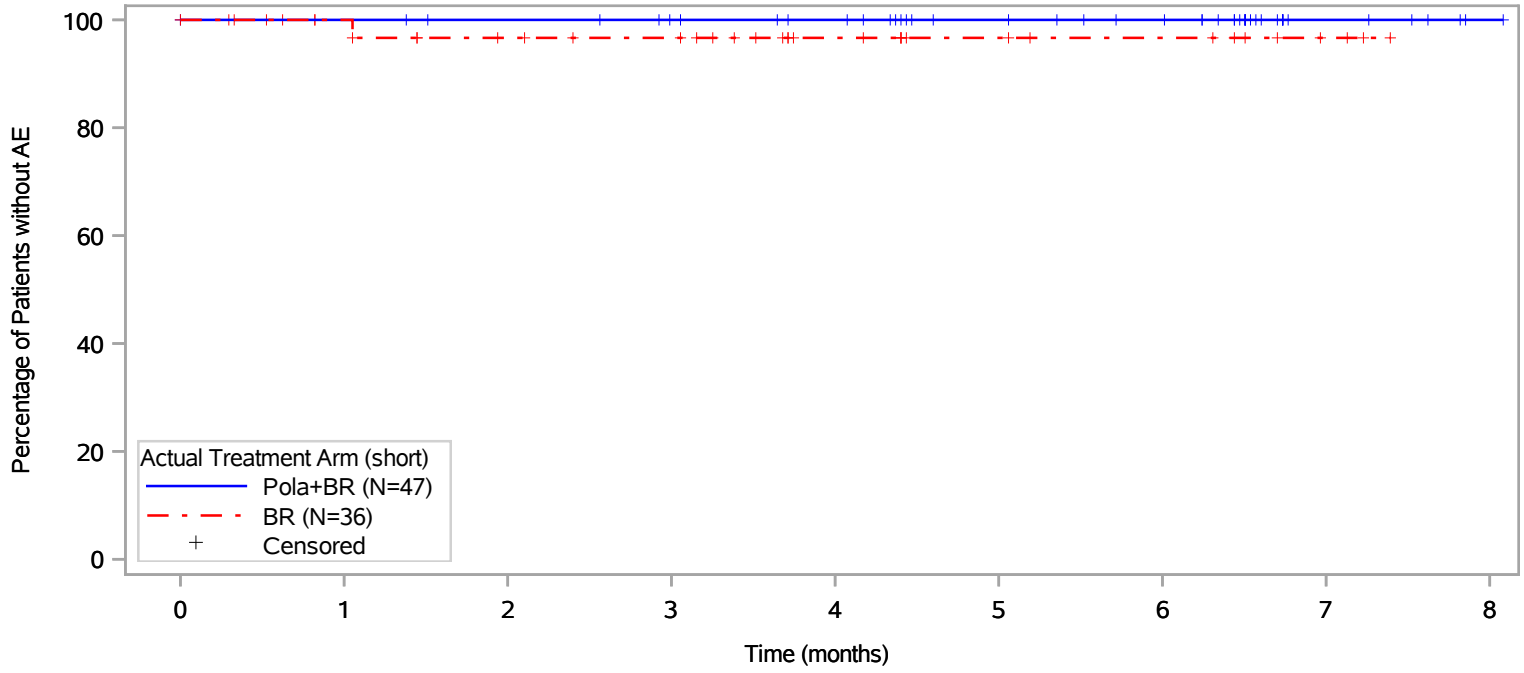


Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	29	25	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD URINE PRESENT



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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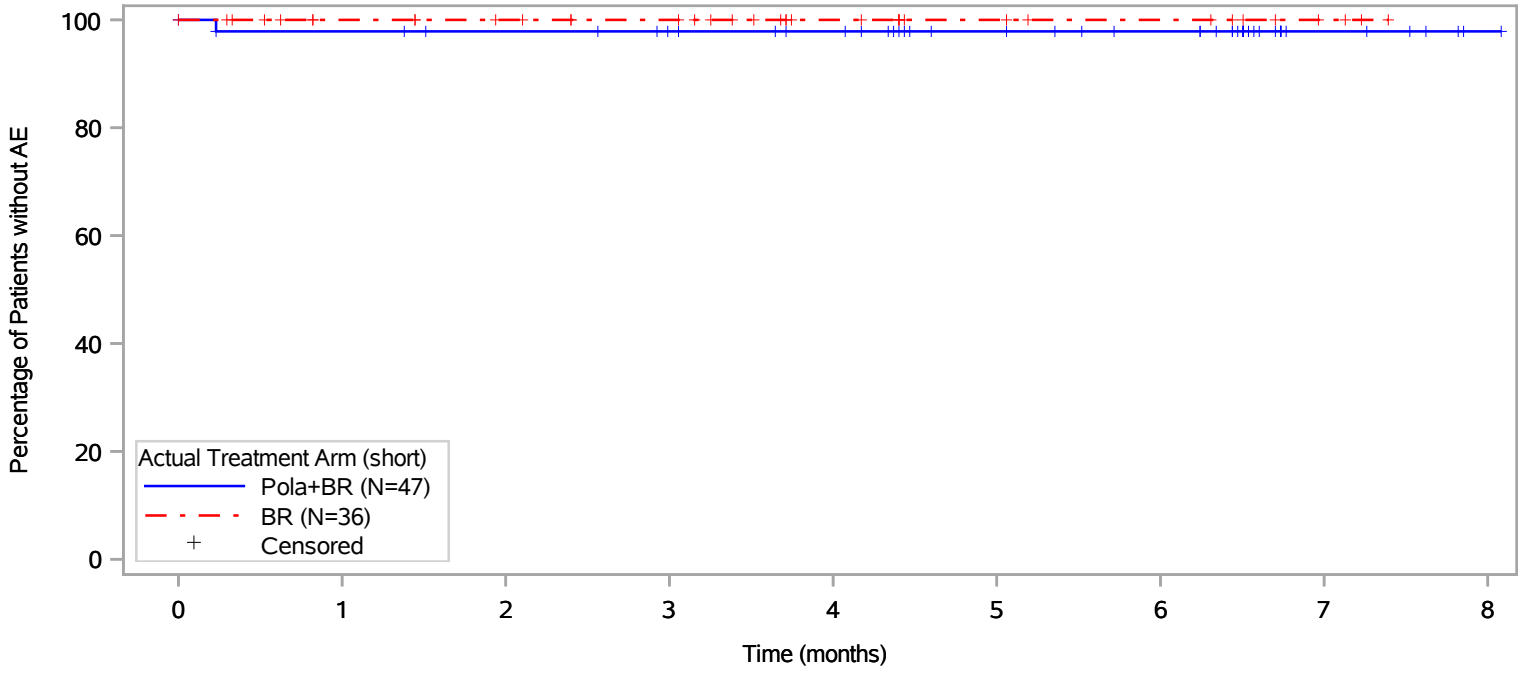
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BRAIN NATRIURETIC PEPTIDE INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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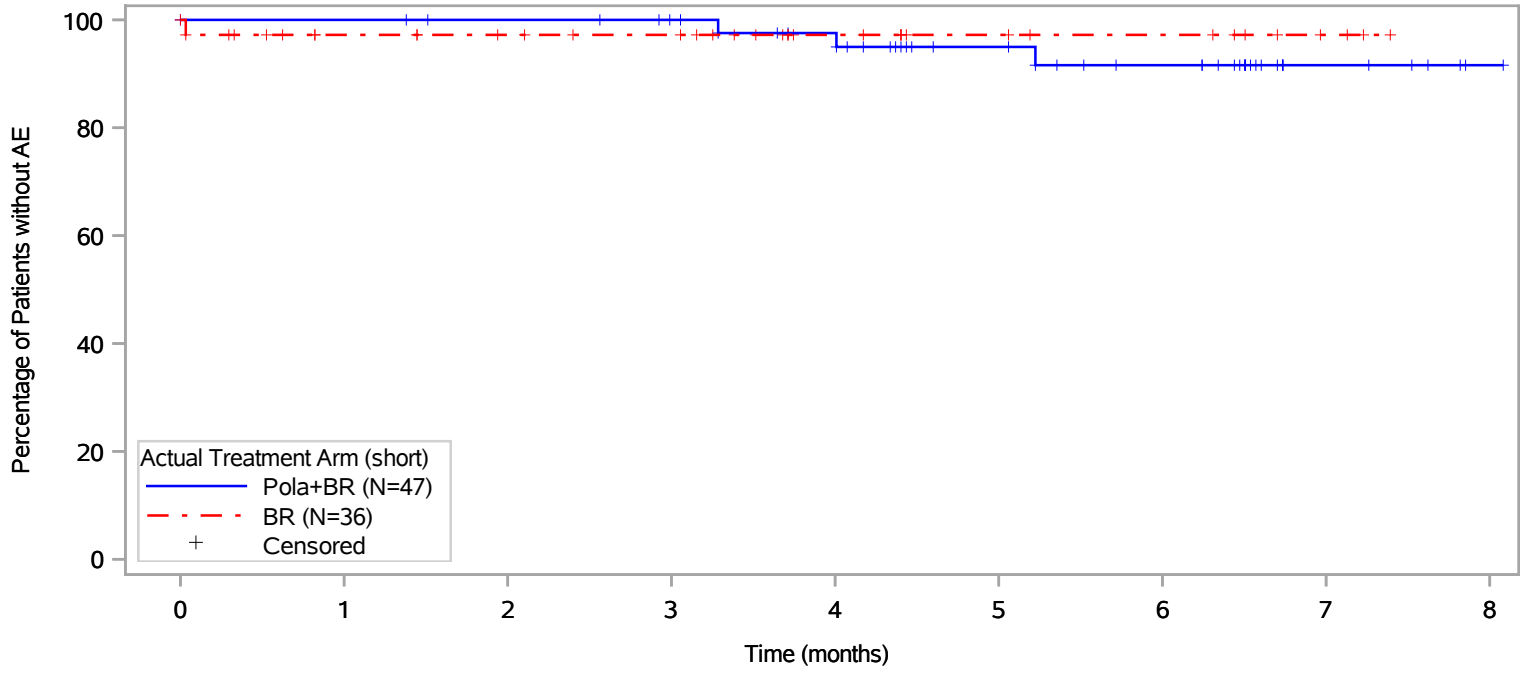
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, C-REACTIVE PROTEIN INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	29	24	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	38	43
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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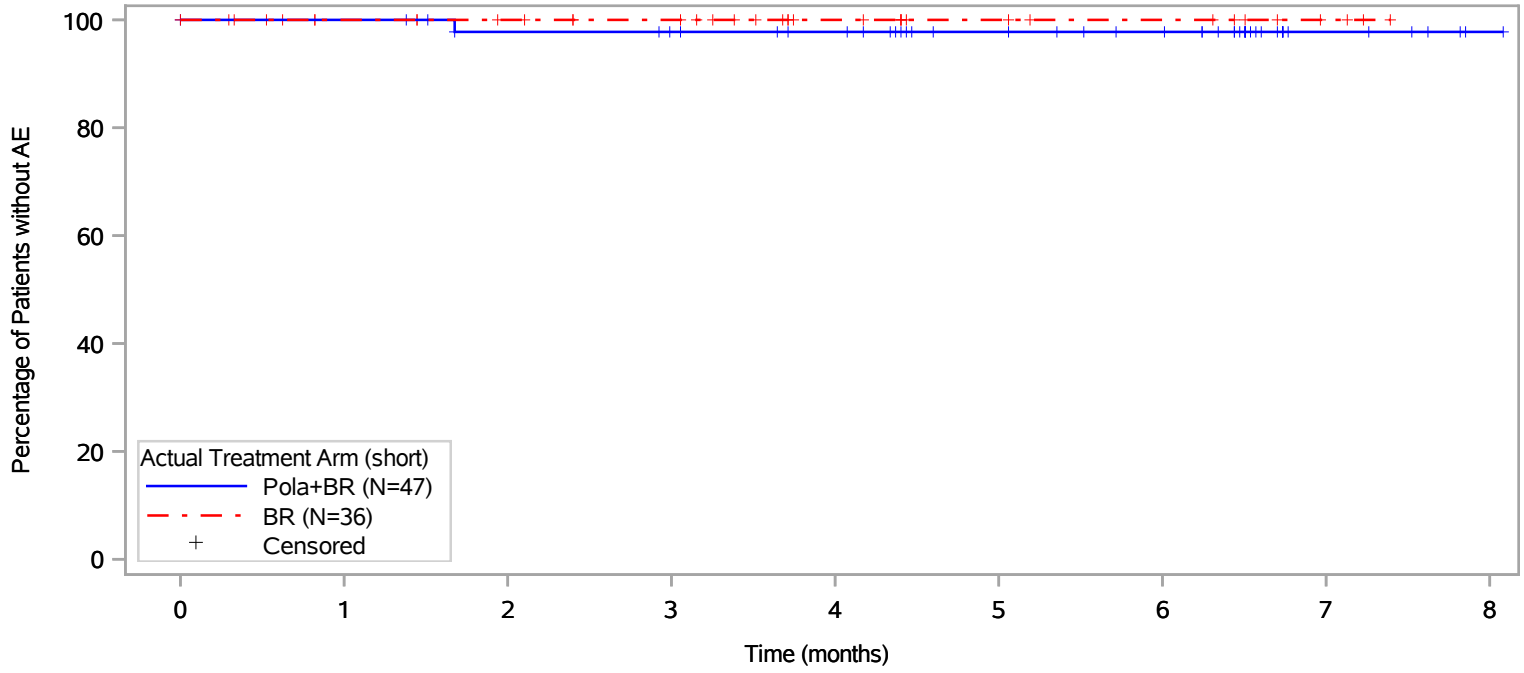
01DEC2022 22:30

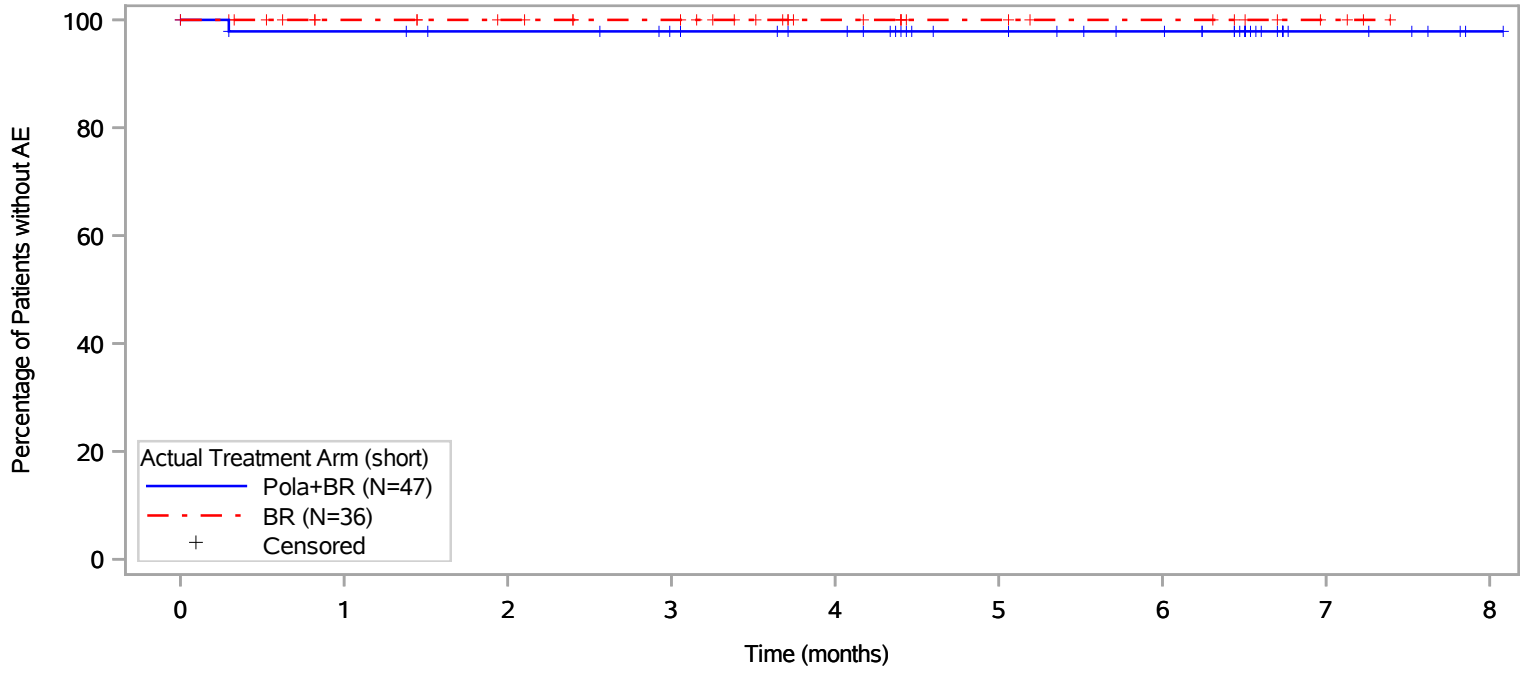
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CLOSTRIDIUM TEST POSITIVE



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYSTATIN C INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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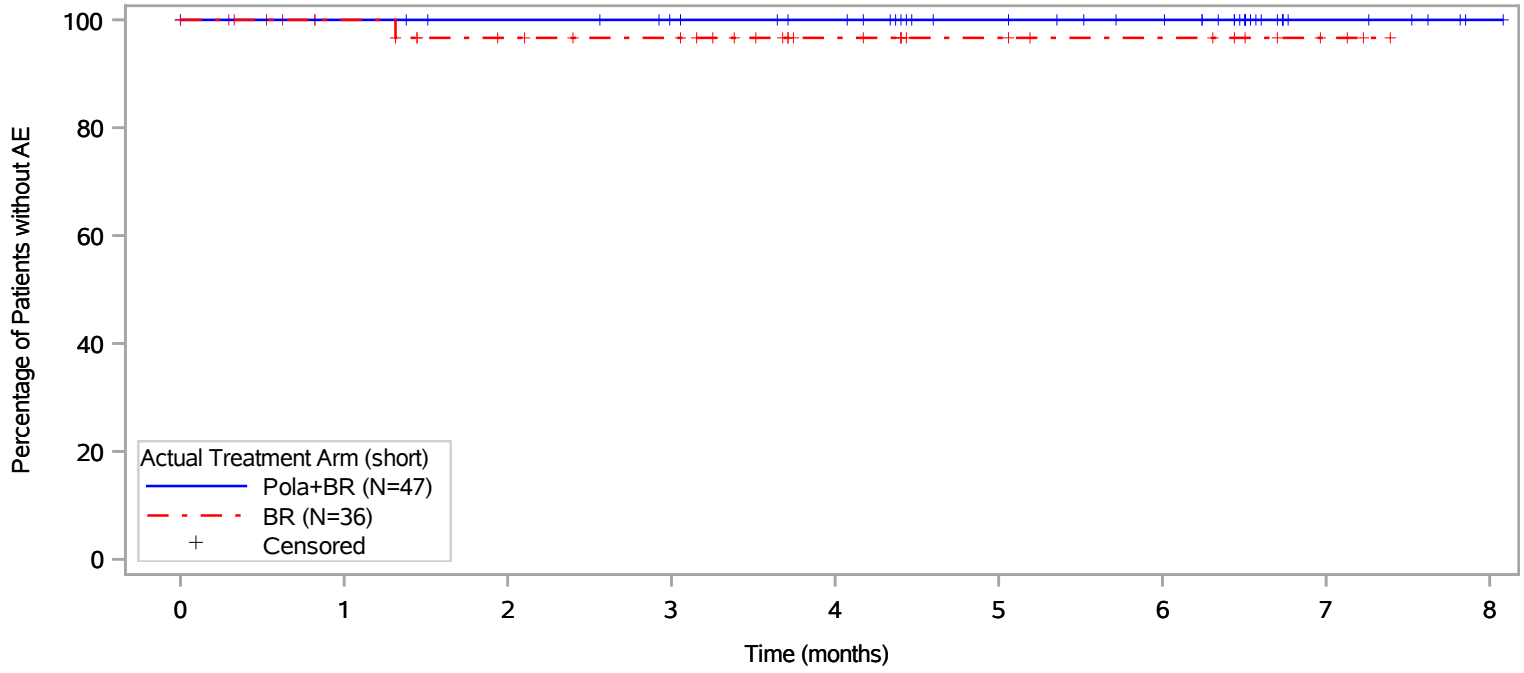
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYTOMEGALOVIRUS TEST POSITIVE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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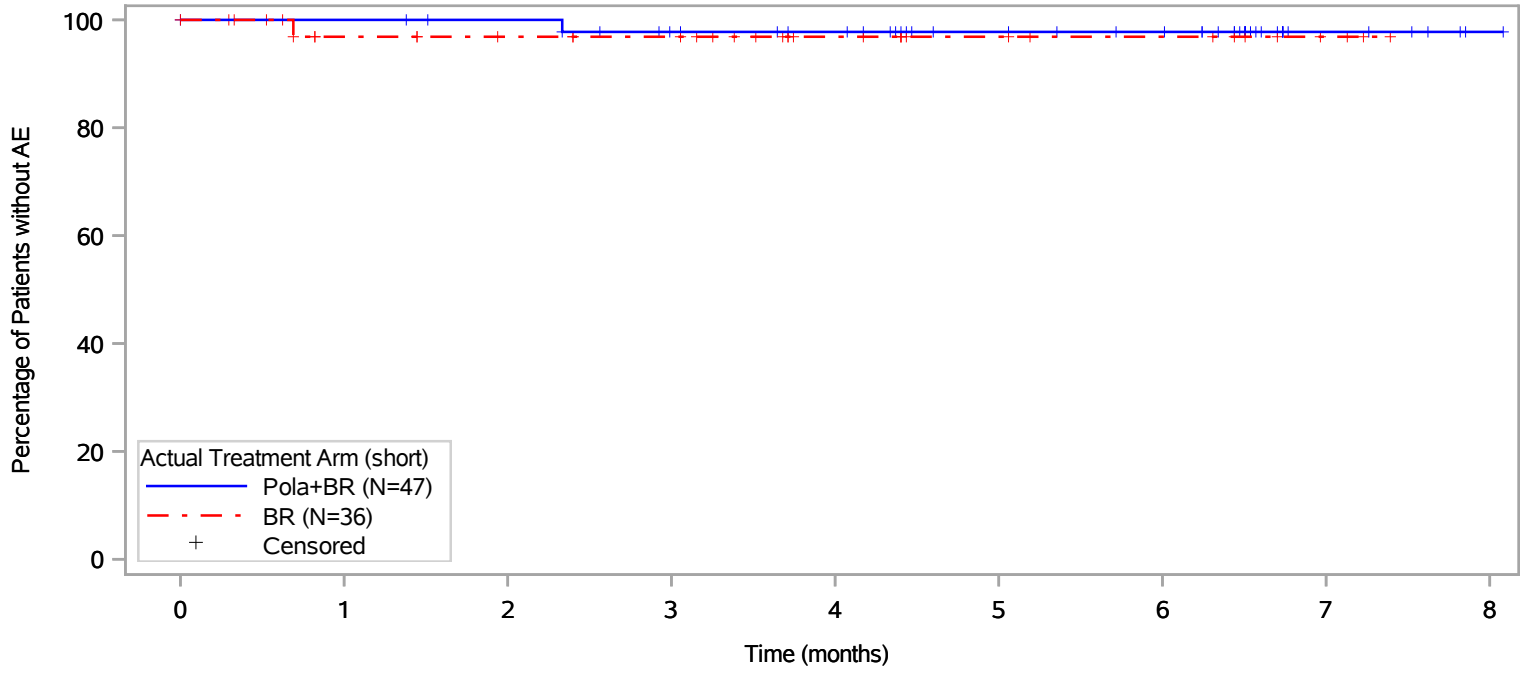
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ELECTROCARDIOGRAM HIGH VOLTAGE



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	27	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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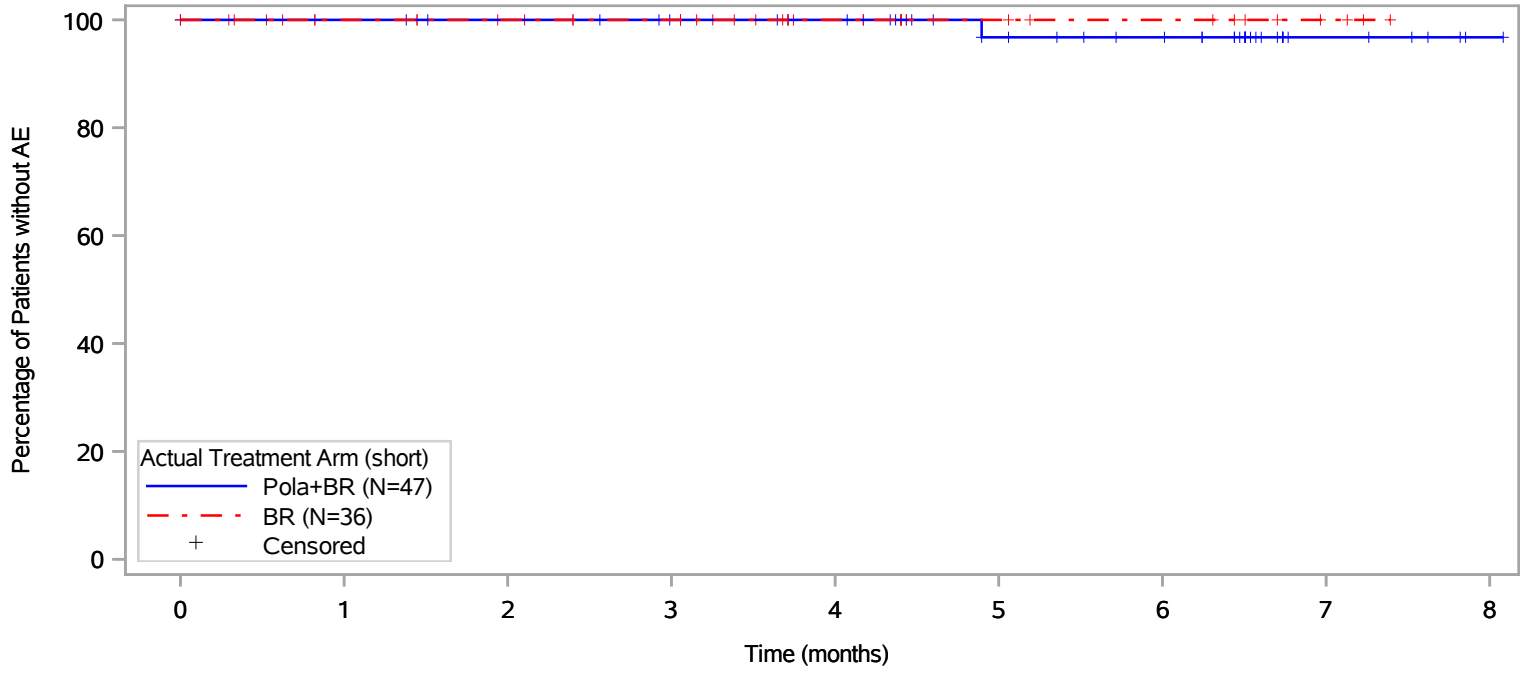
01DEC2022 22:30

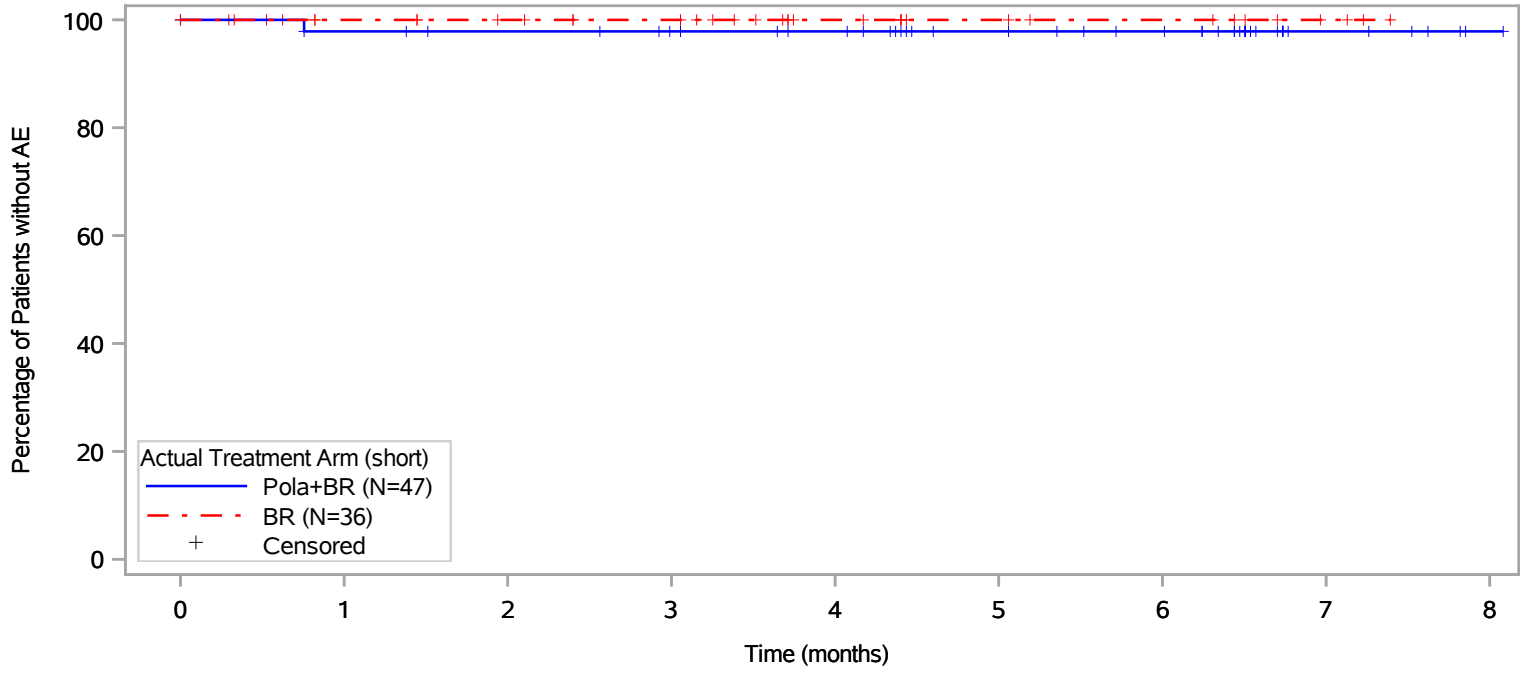
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ELECTROCARDIOGRAM QT PROLONGED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ELECTROCARDIOGRAM ST SEGMENT ELEVATION



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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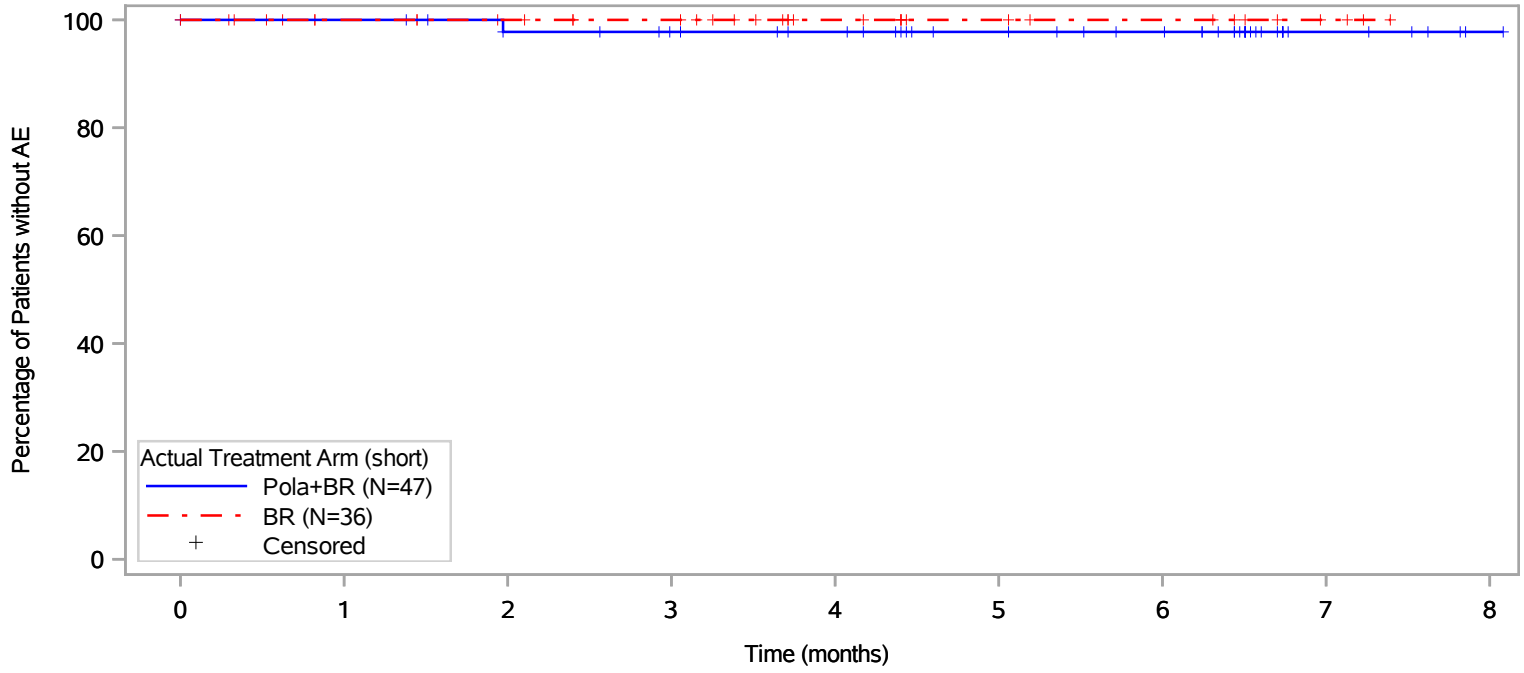
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, EOSINOPHIL COUNT INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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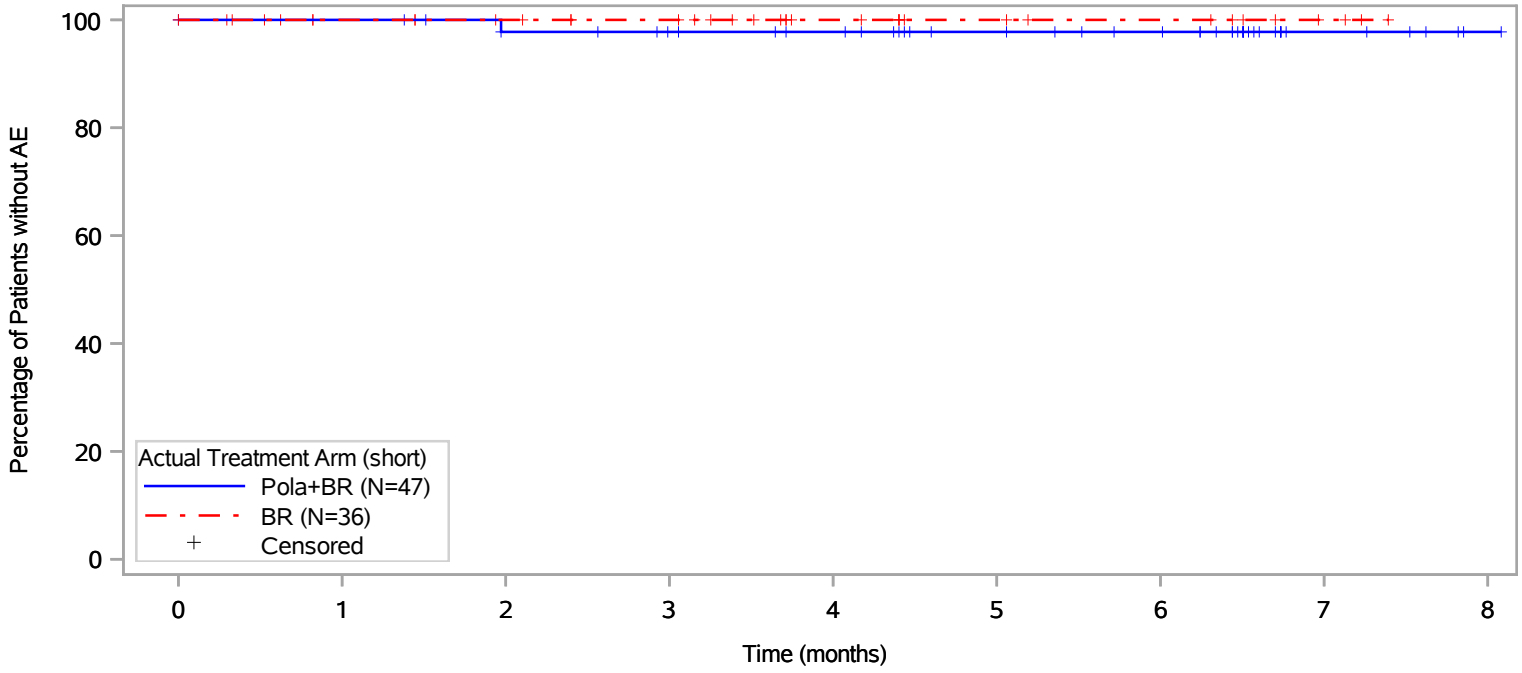
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, EOSINOPHIL PERCENTAGE INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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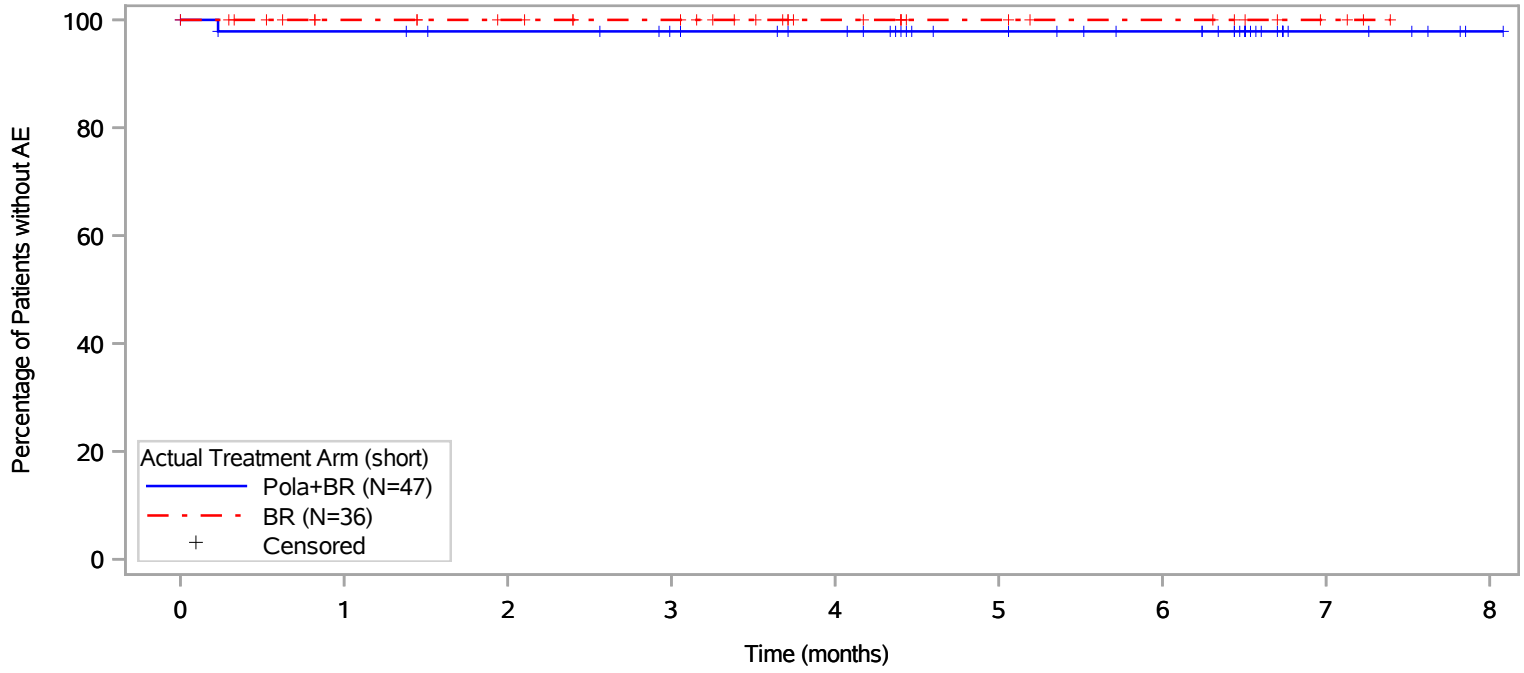
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, EPSTEIN-BARR VIRUS ANTIBODY POSITIVE



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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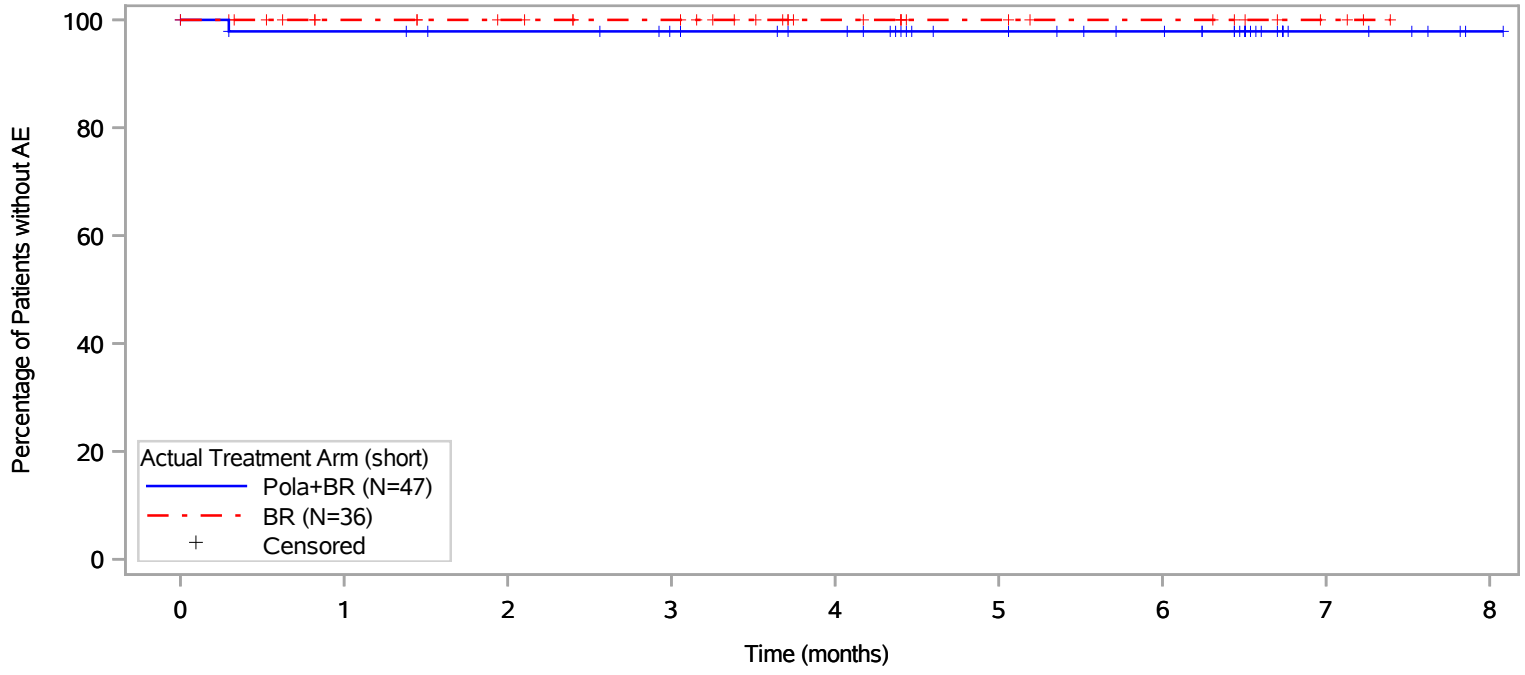
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, FIBRIN D DIMER INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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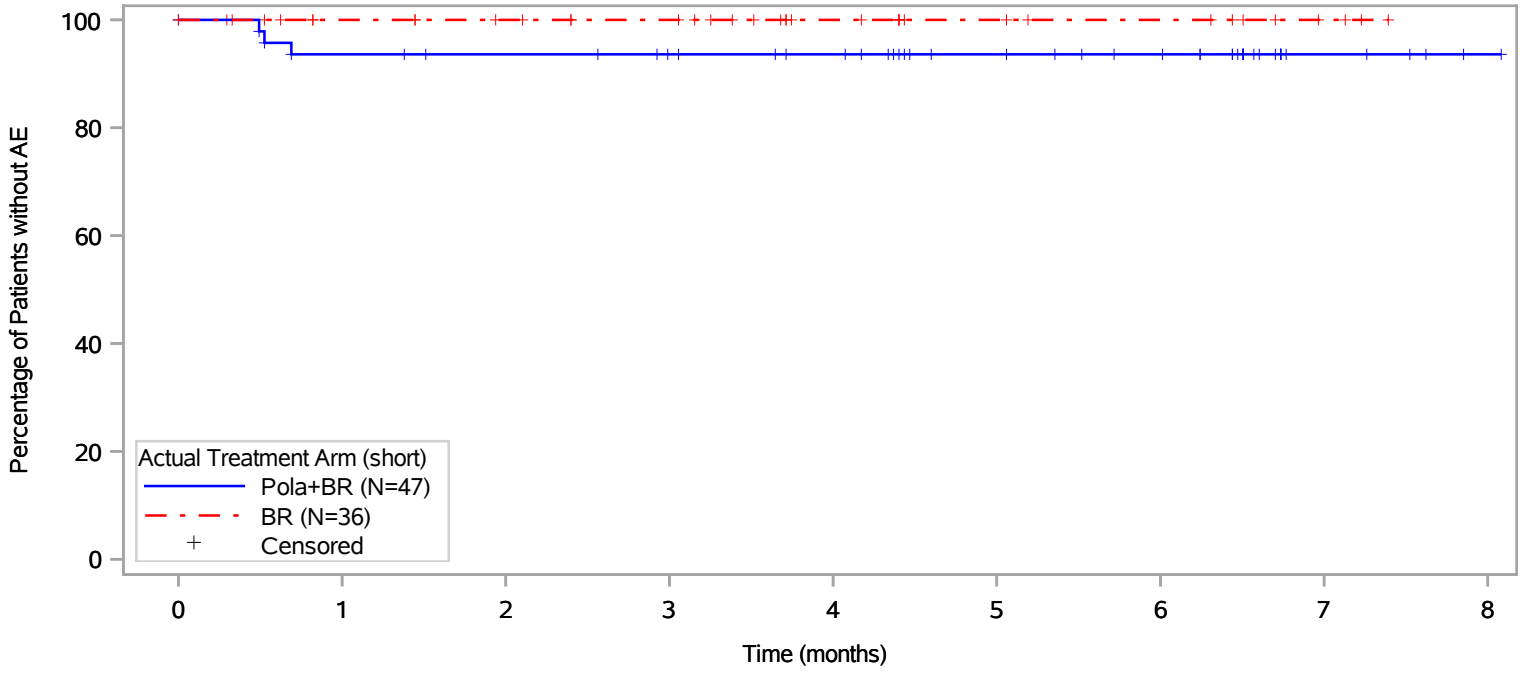
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GAMMA-GLUTAMYLTRANSFERASE INCREASED



Patients at risk									
Pola+BR (N=47)	47	44	42	39	36	28	24	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	43
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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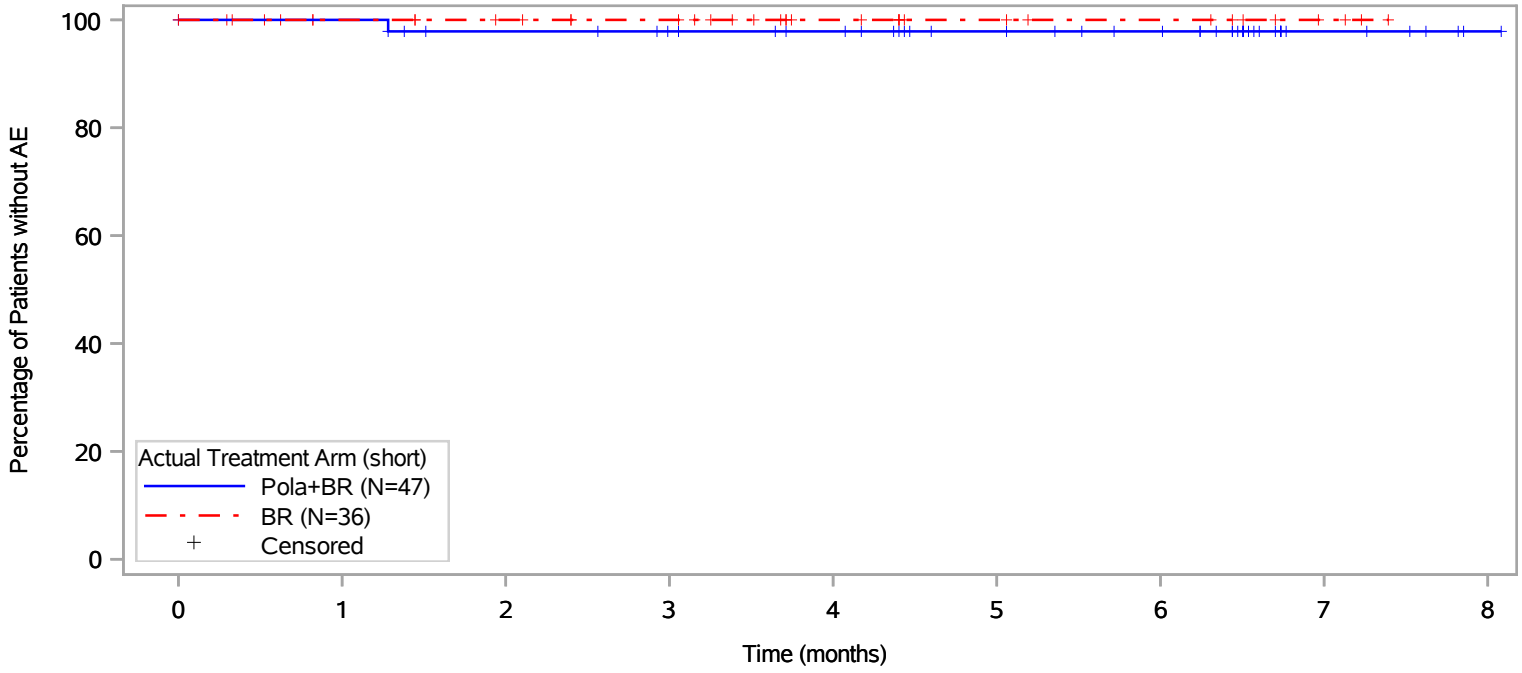
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GLOMERULAR FILTRATION RATE DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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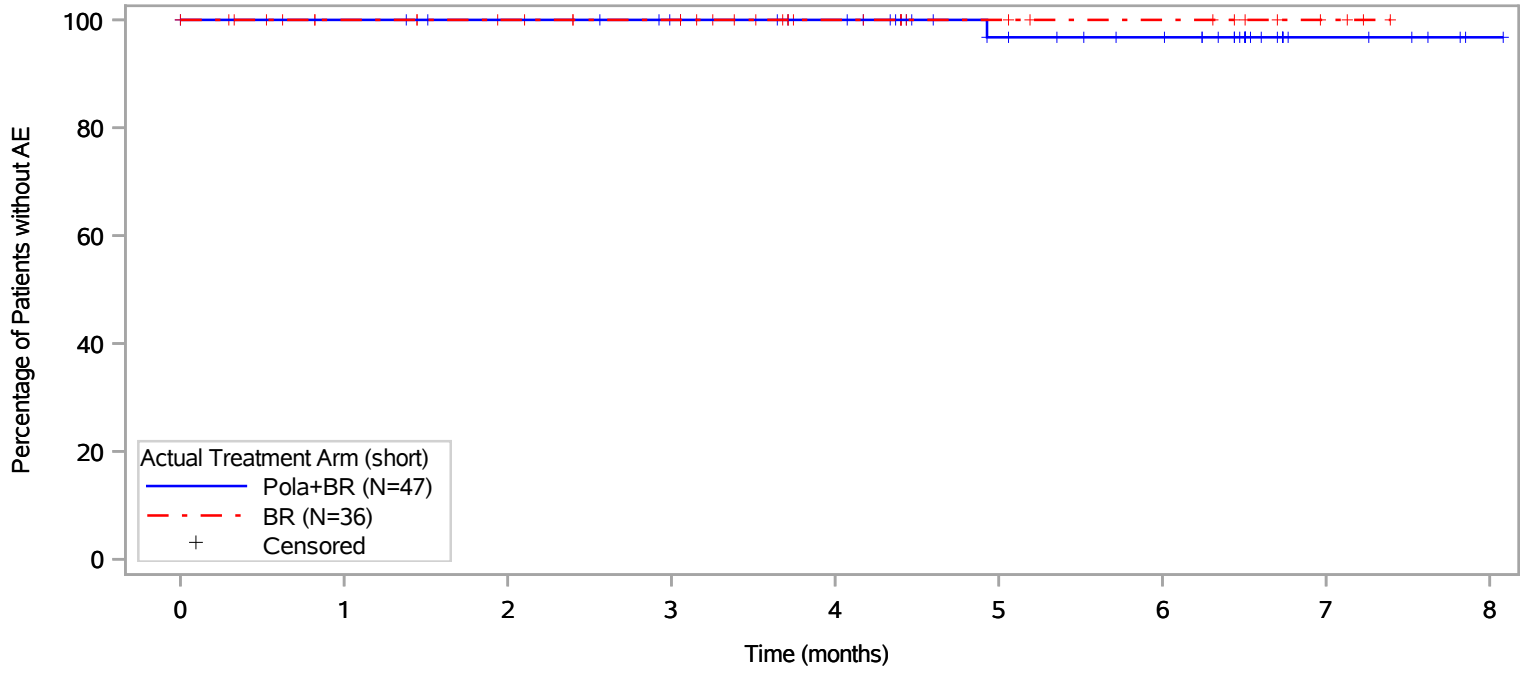
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GRANULOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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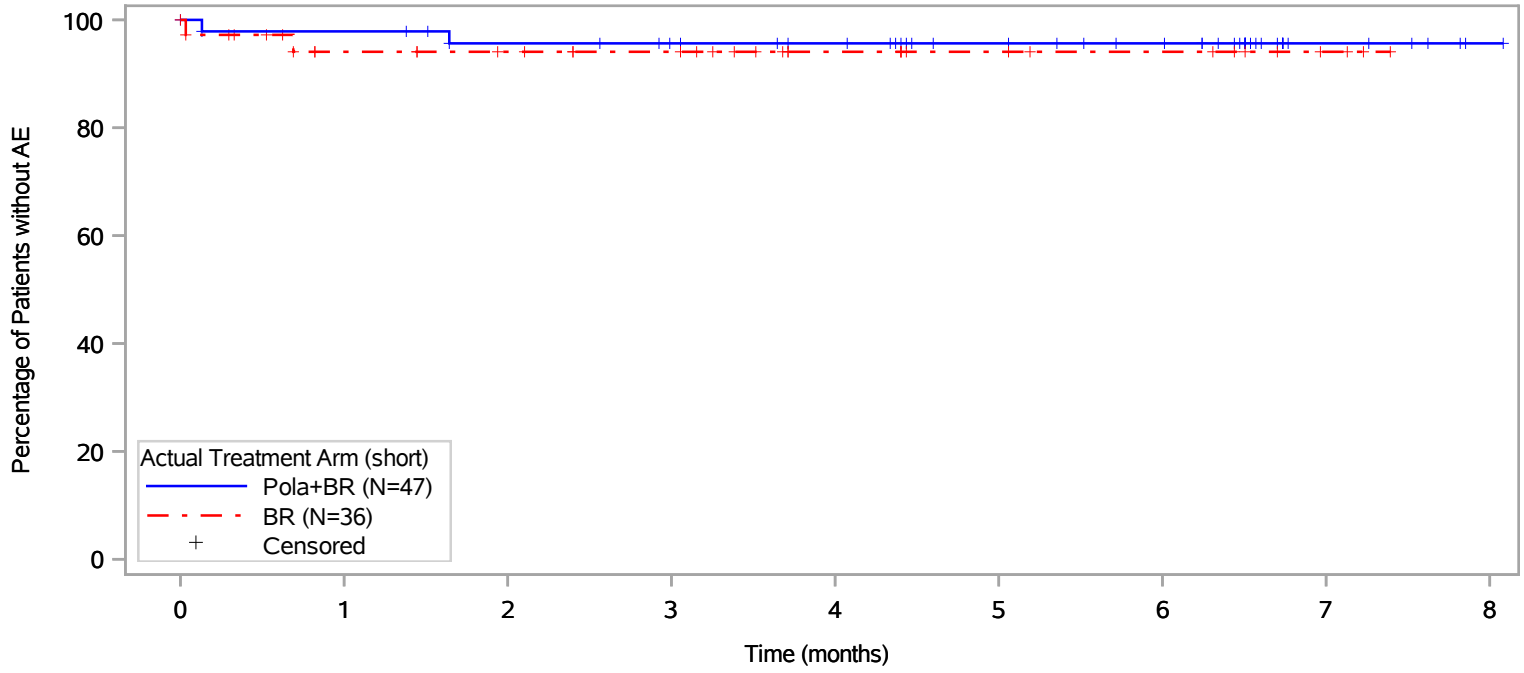
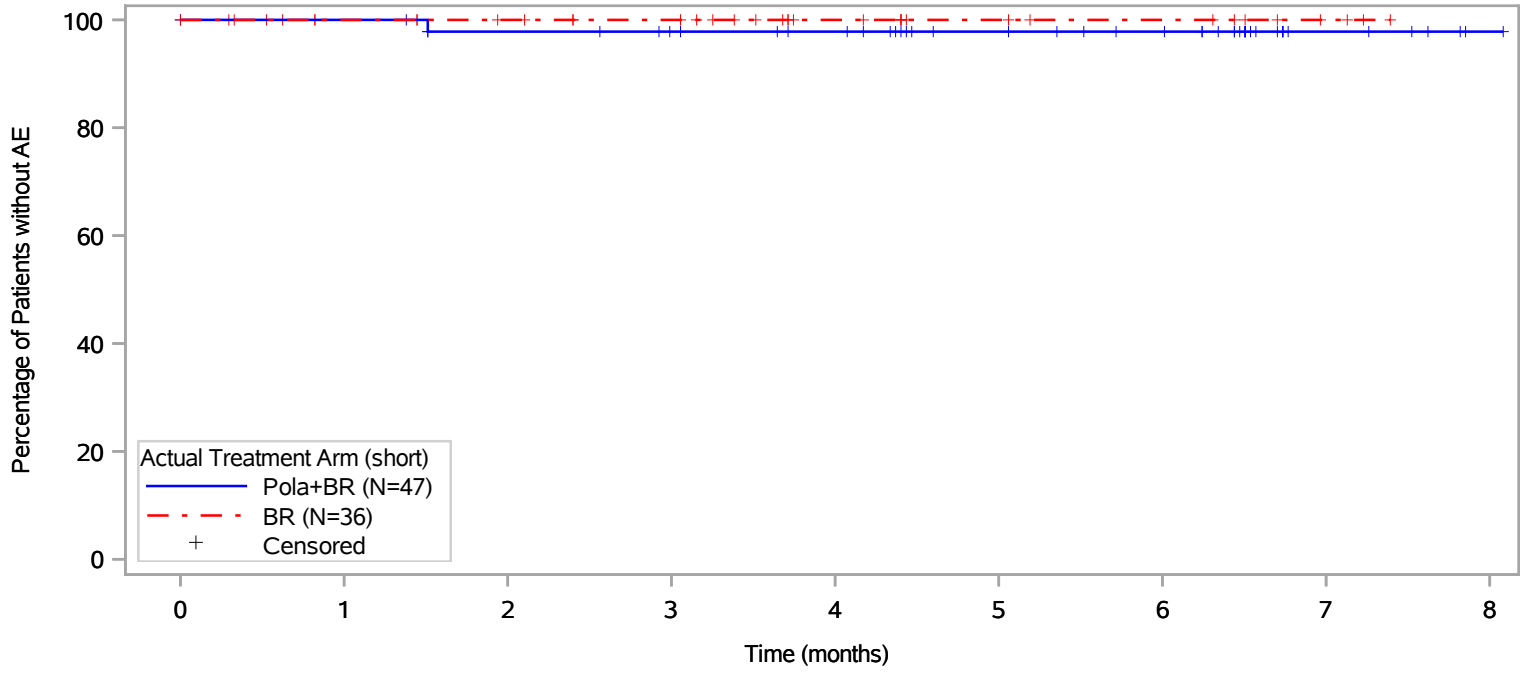
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, HAEMOGLOBIN DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	43	40	37	30	26	6	1
BR (N=36)	36	28	25	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	39	44
BR (N=36)	0	6	9	12	20	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, HEART RATE INCREASED

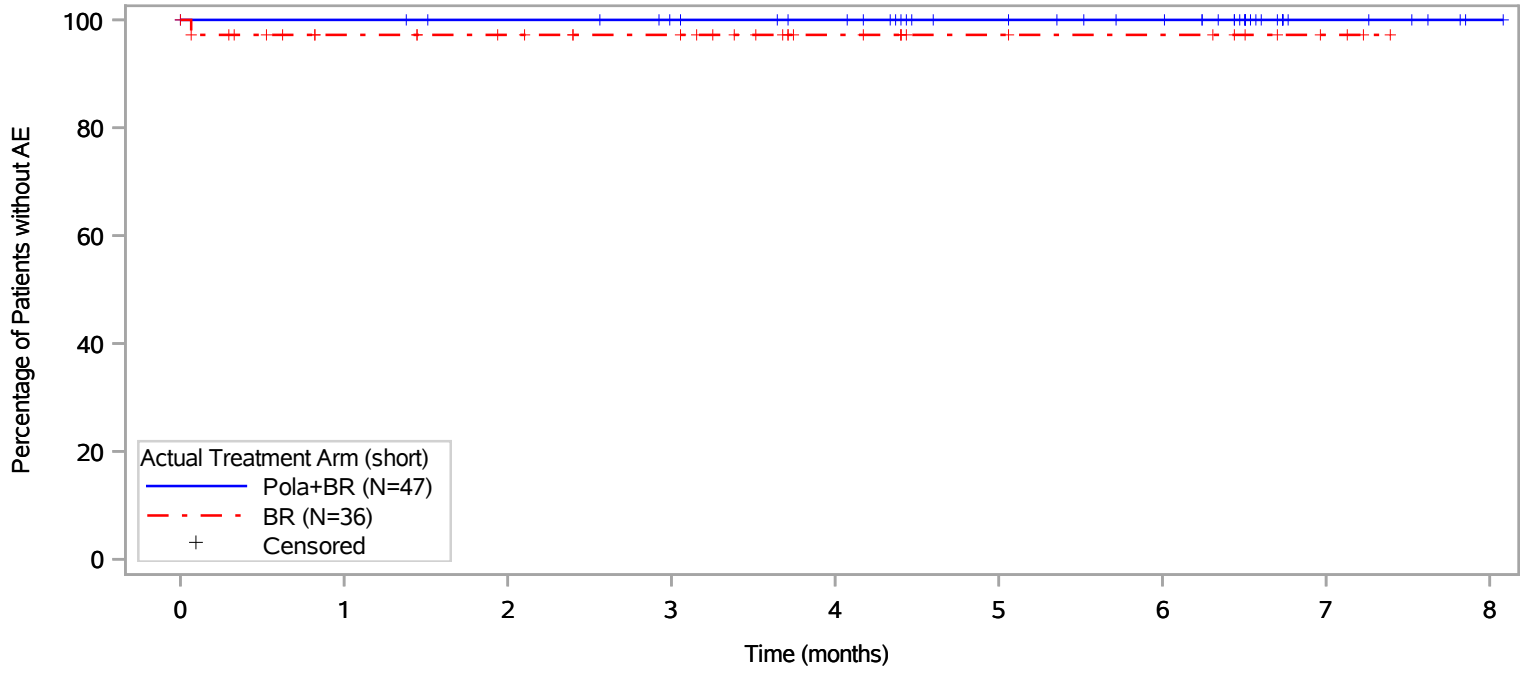


Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, INTERNATIONAL NORMALISED RATIO INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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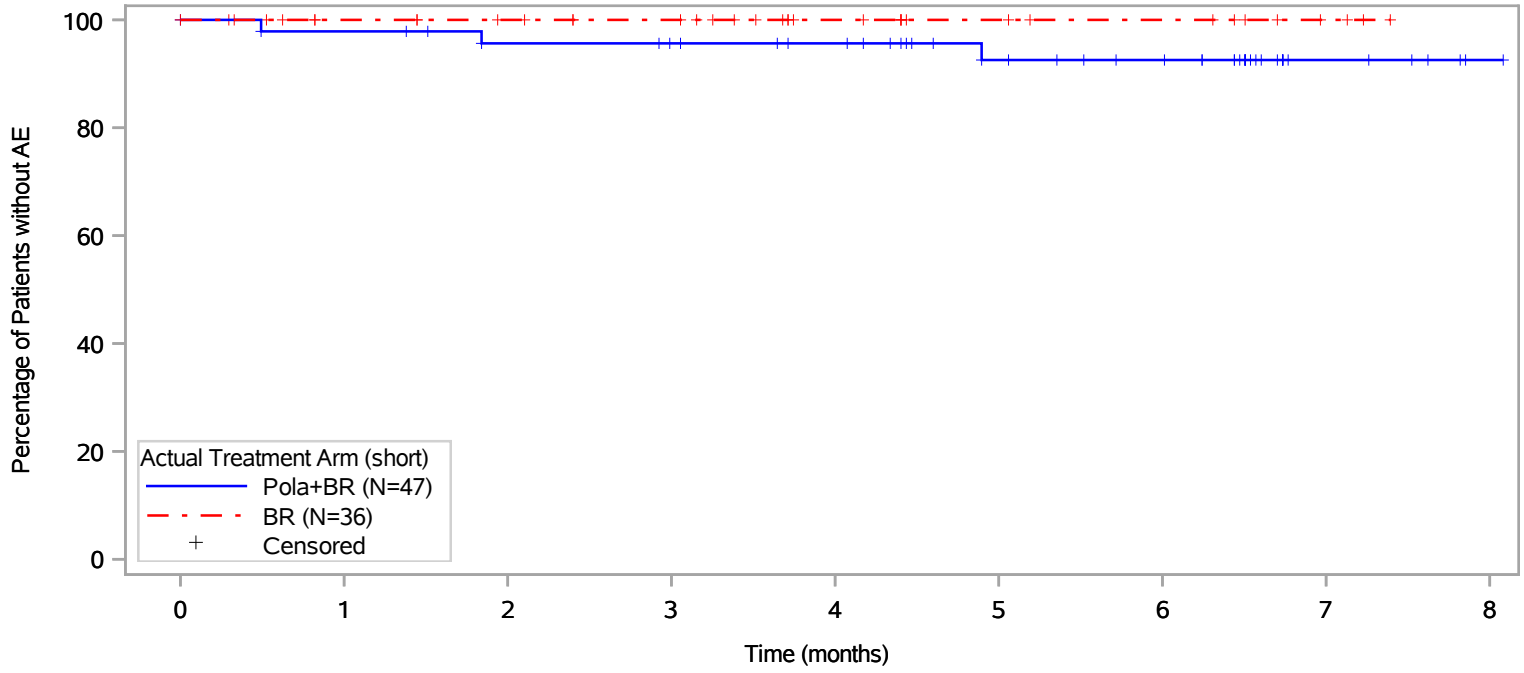
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LIPASE INCREASED

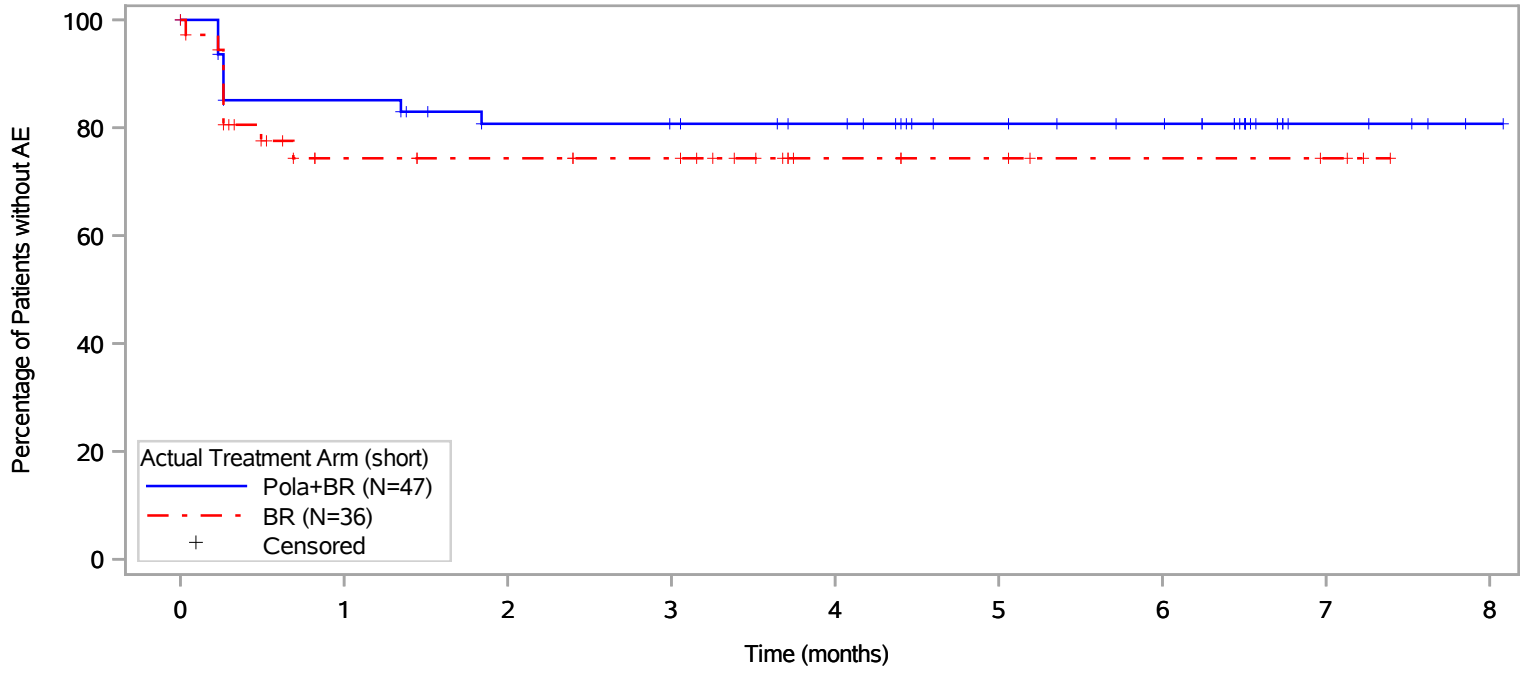


Patients at risk									
Pola+BR (N=47)	47	46	43	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	18	38	43
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

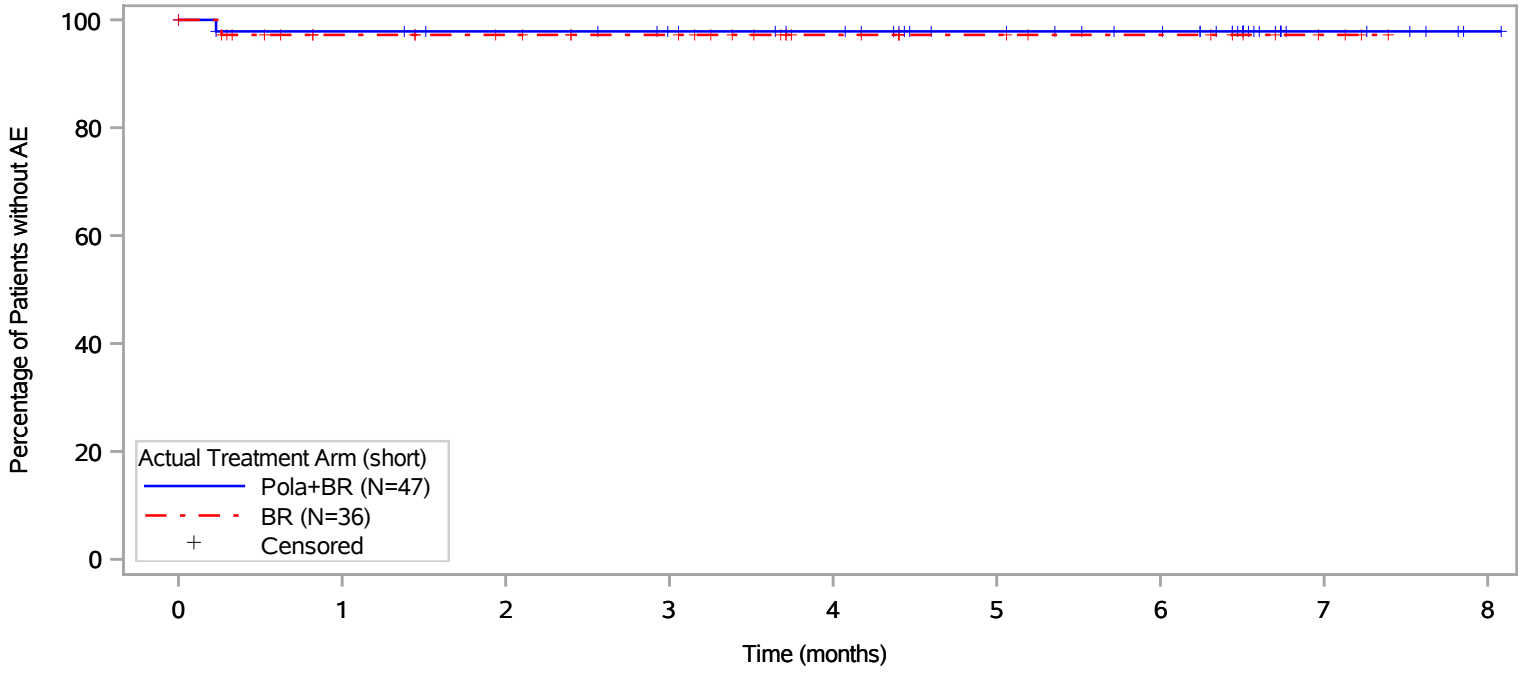
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	40	36	35	32	25	22	5	1
BR (N=36)	36	21	19	17	8	6	4	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	3	6	13	16	33	37
BR (N=36)	0	6	8	10	19	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

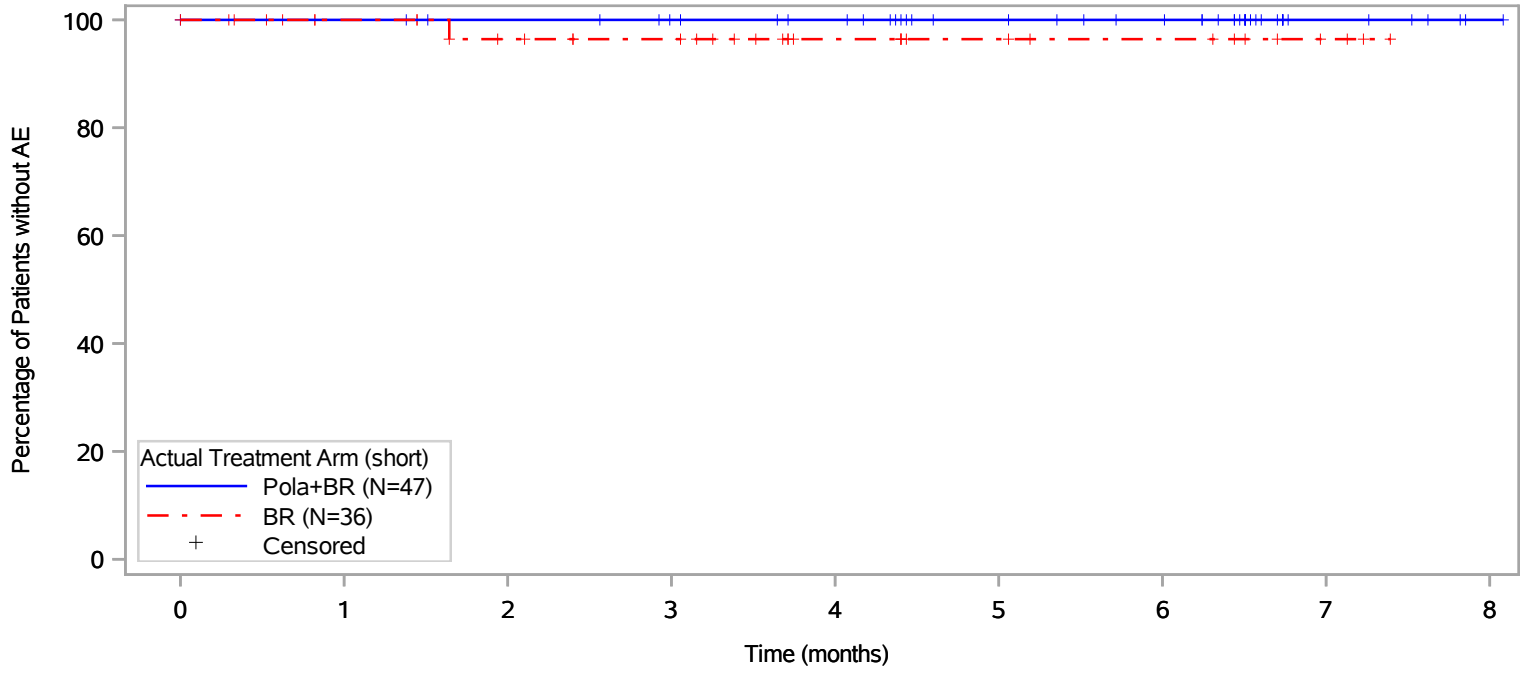
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE PERCENTAGE DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MONOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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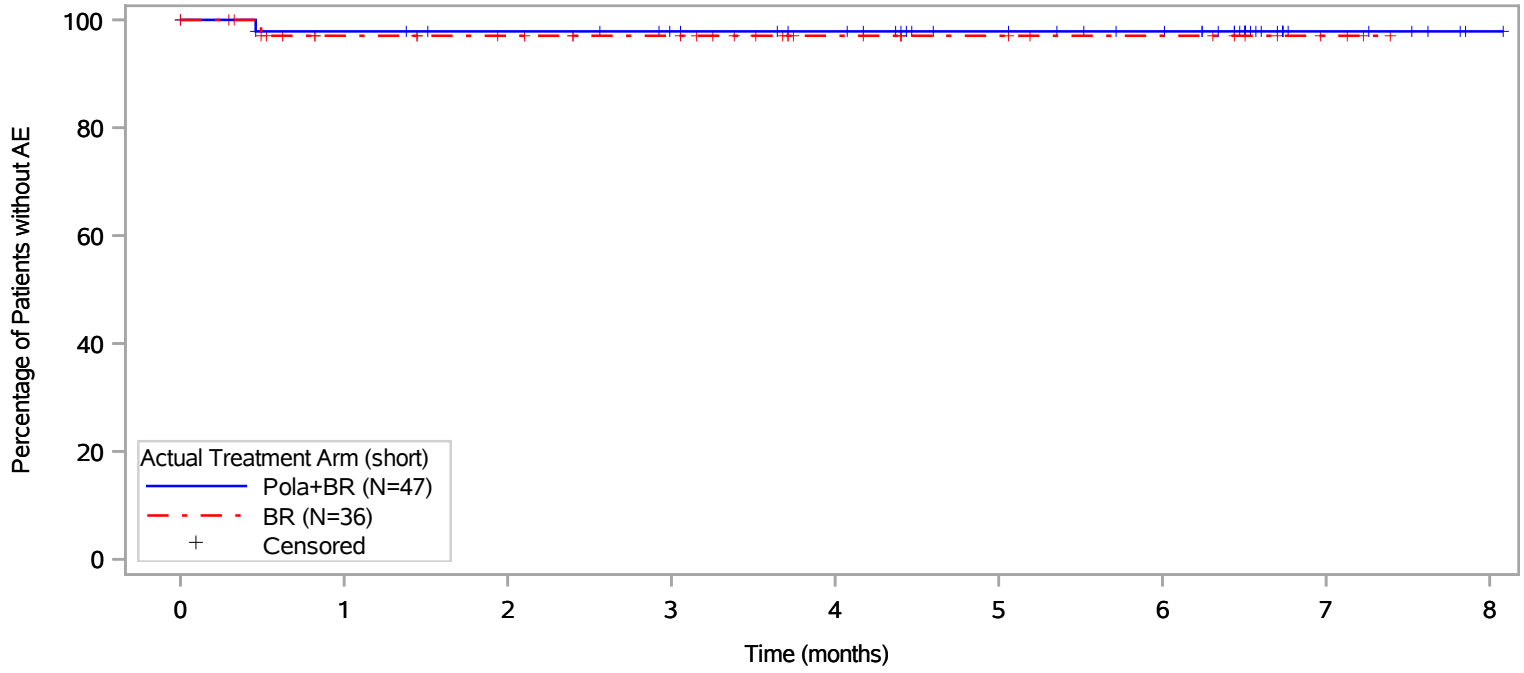
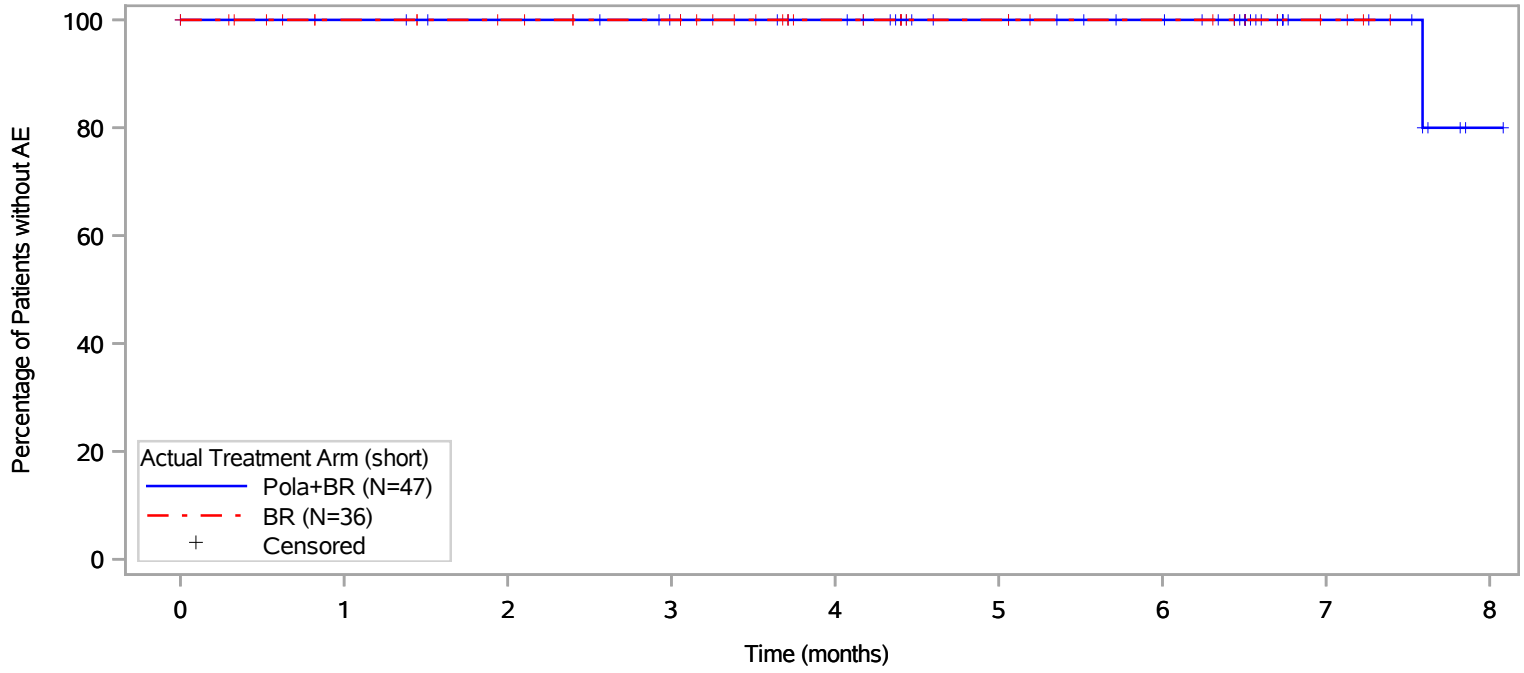
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MONONUCLEAR CELL COUNT INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

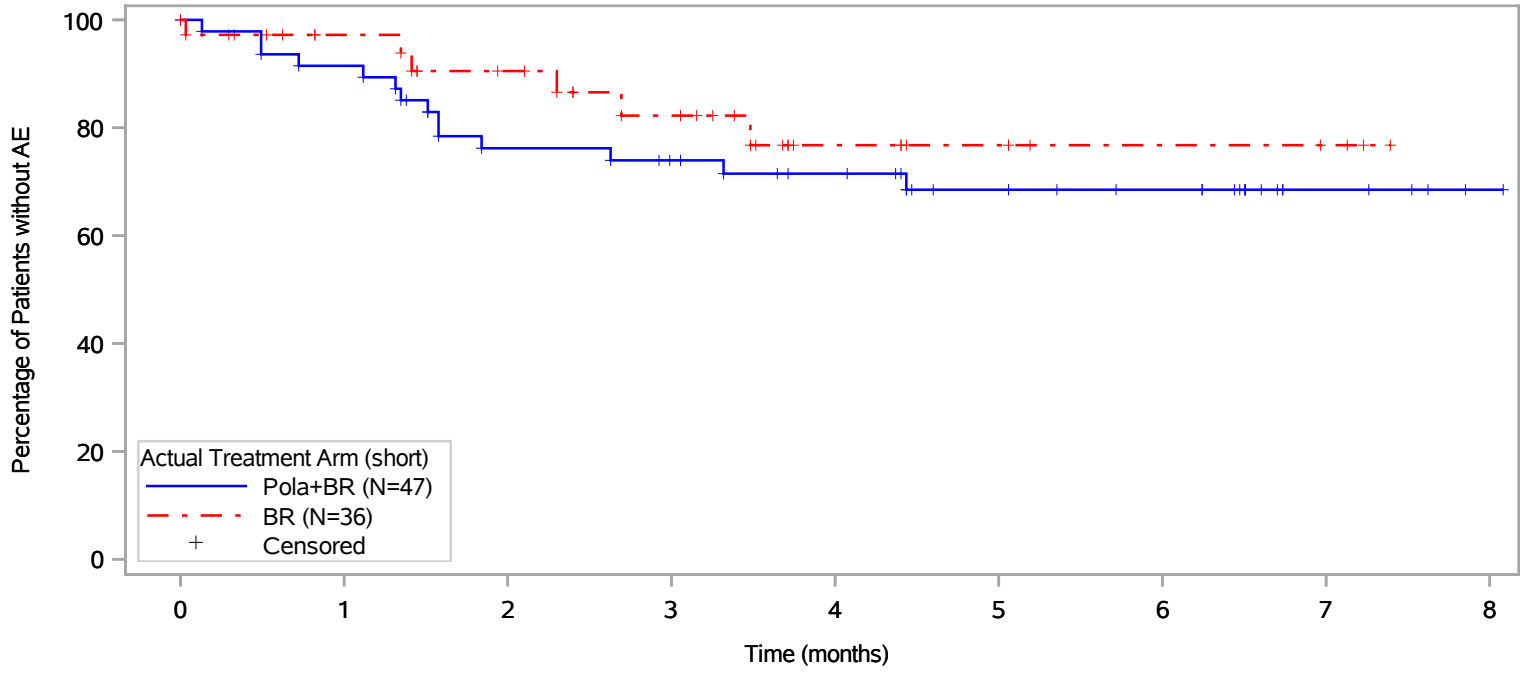
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MORAXELLA TEST POSITIVE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	7	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	43	34	31	27	20	17	5	1
BR (N=36)	36	29	24	19	9	6	4	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	13	16	28	32
BR (N=36)	0	6	9	12	21	24	26	27	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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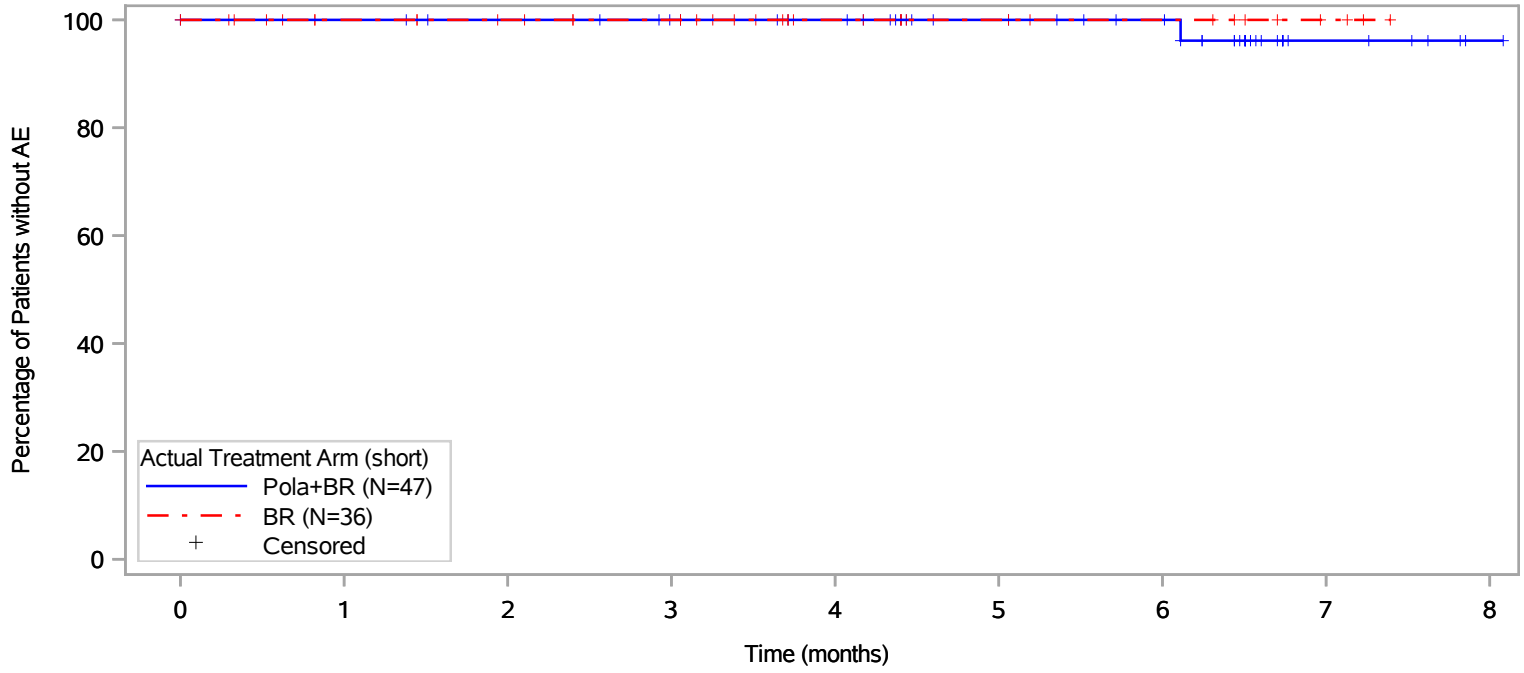
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT INCREASED

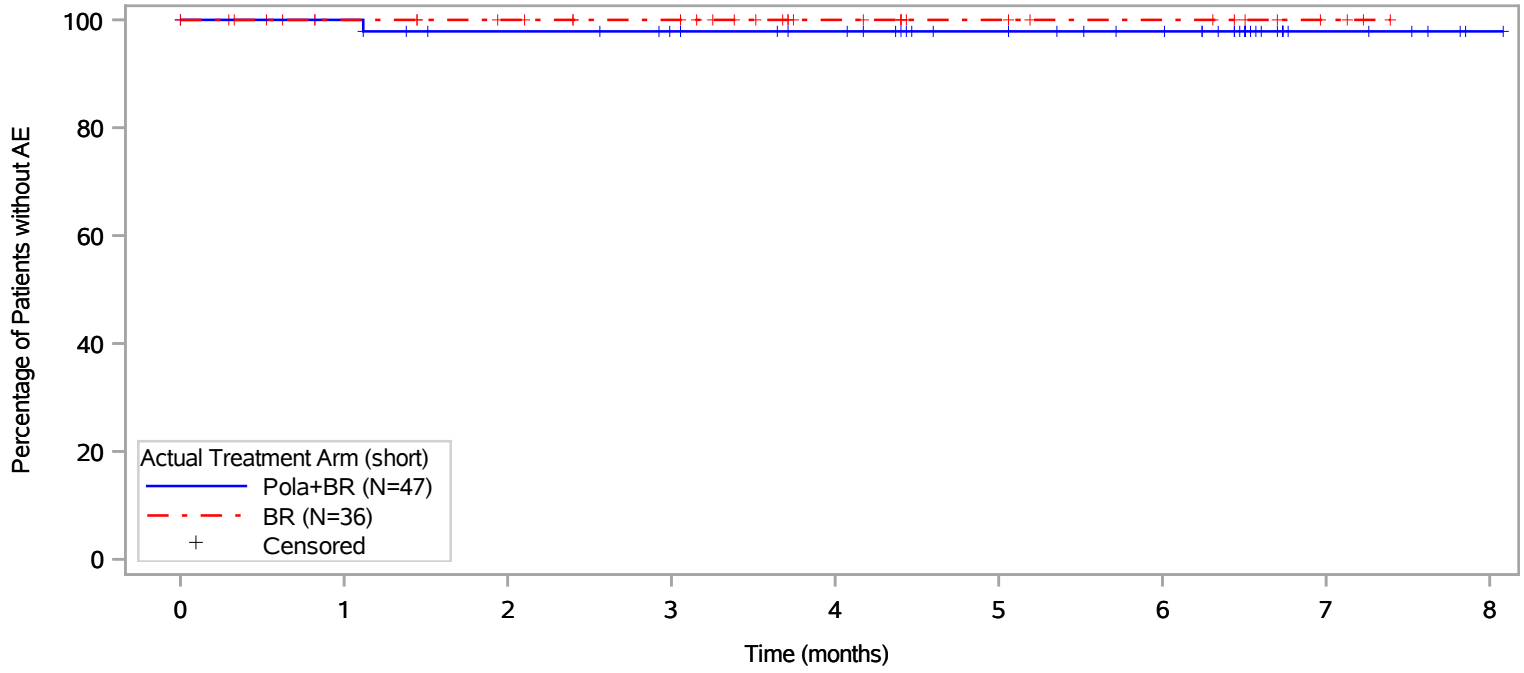


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

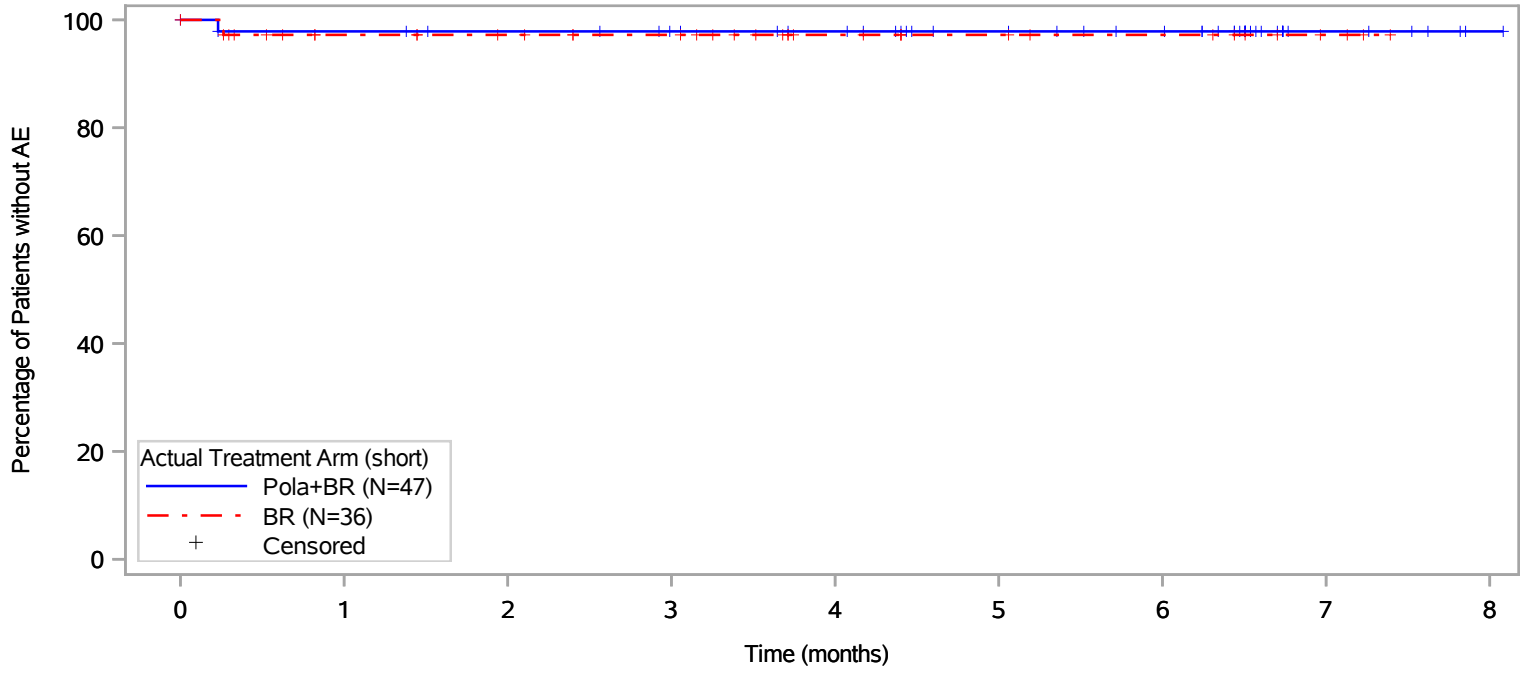
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL PERCENTAGE DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

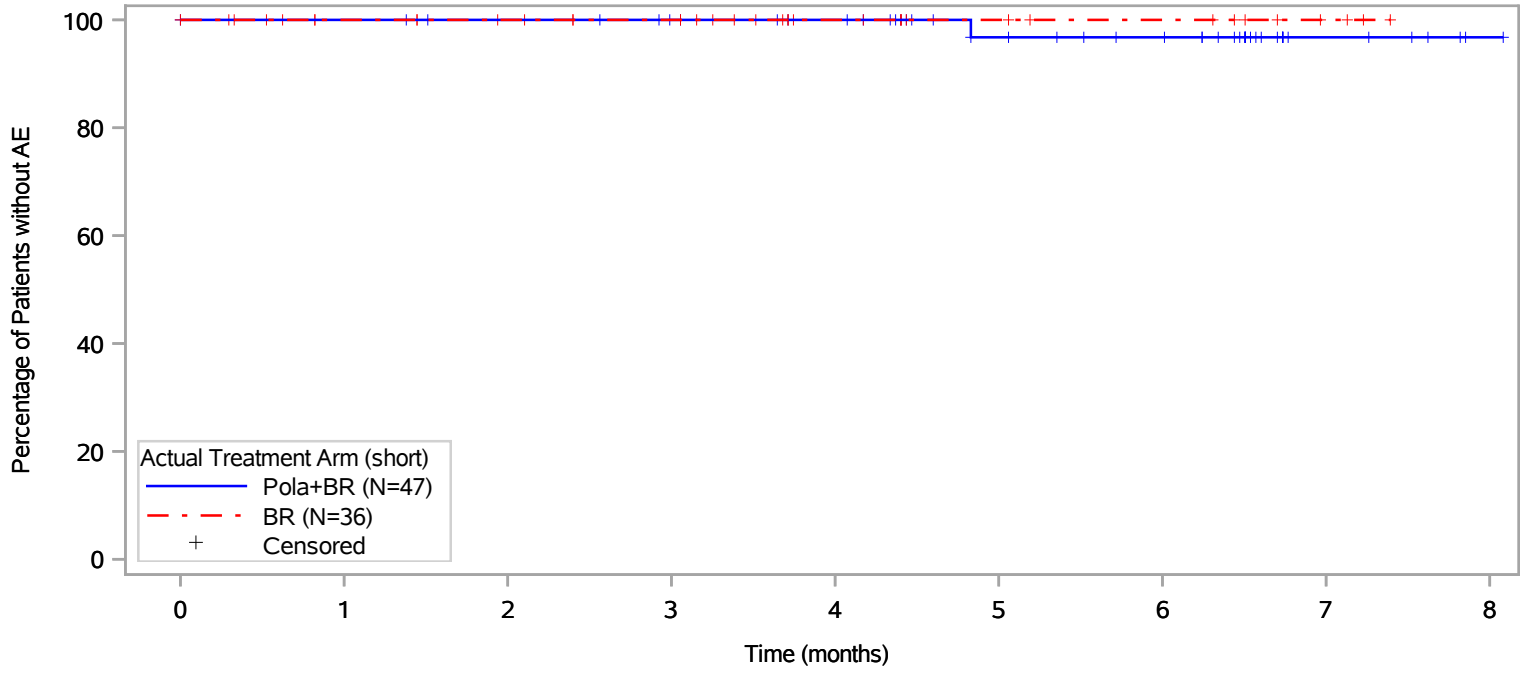
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL PERCENTAGE INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NITRITE URINE PRESENT



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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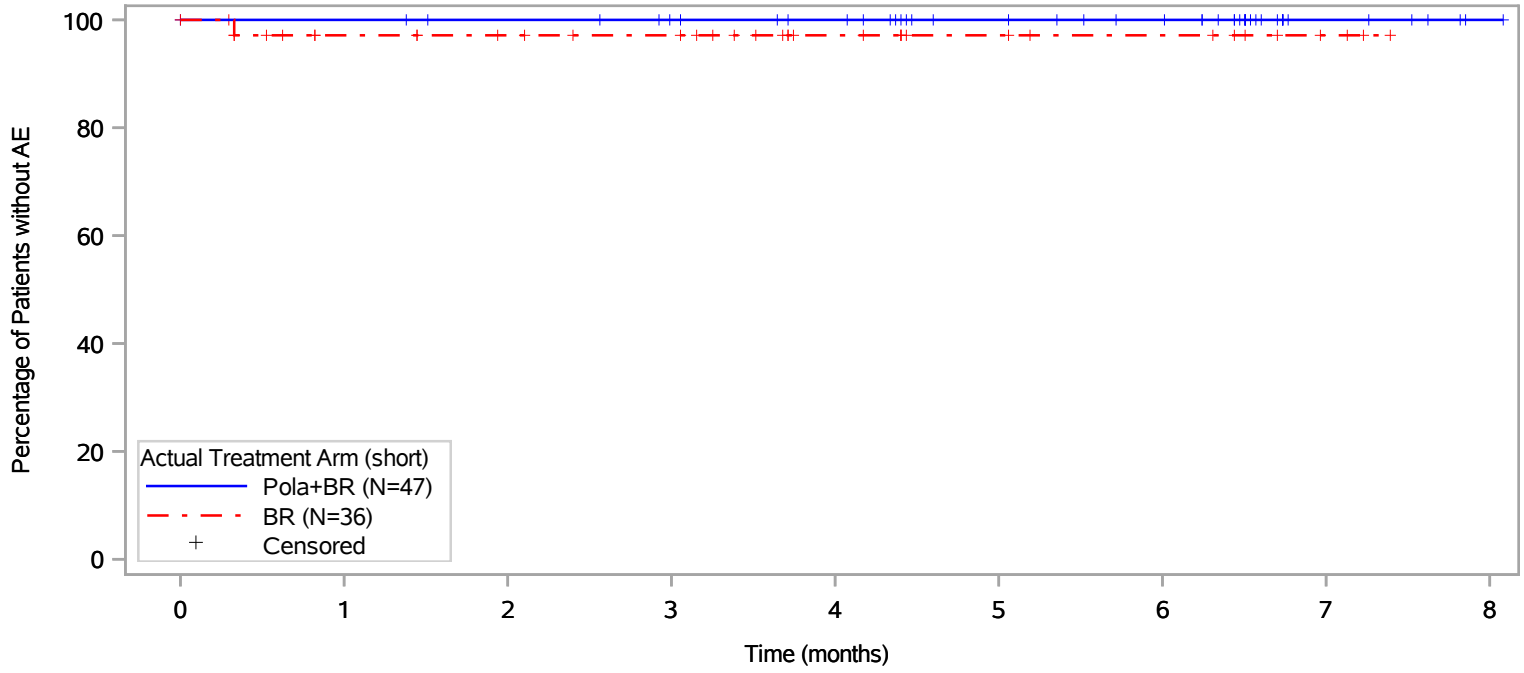
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, OCCULT BLOOD POSITIVE

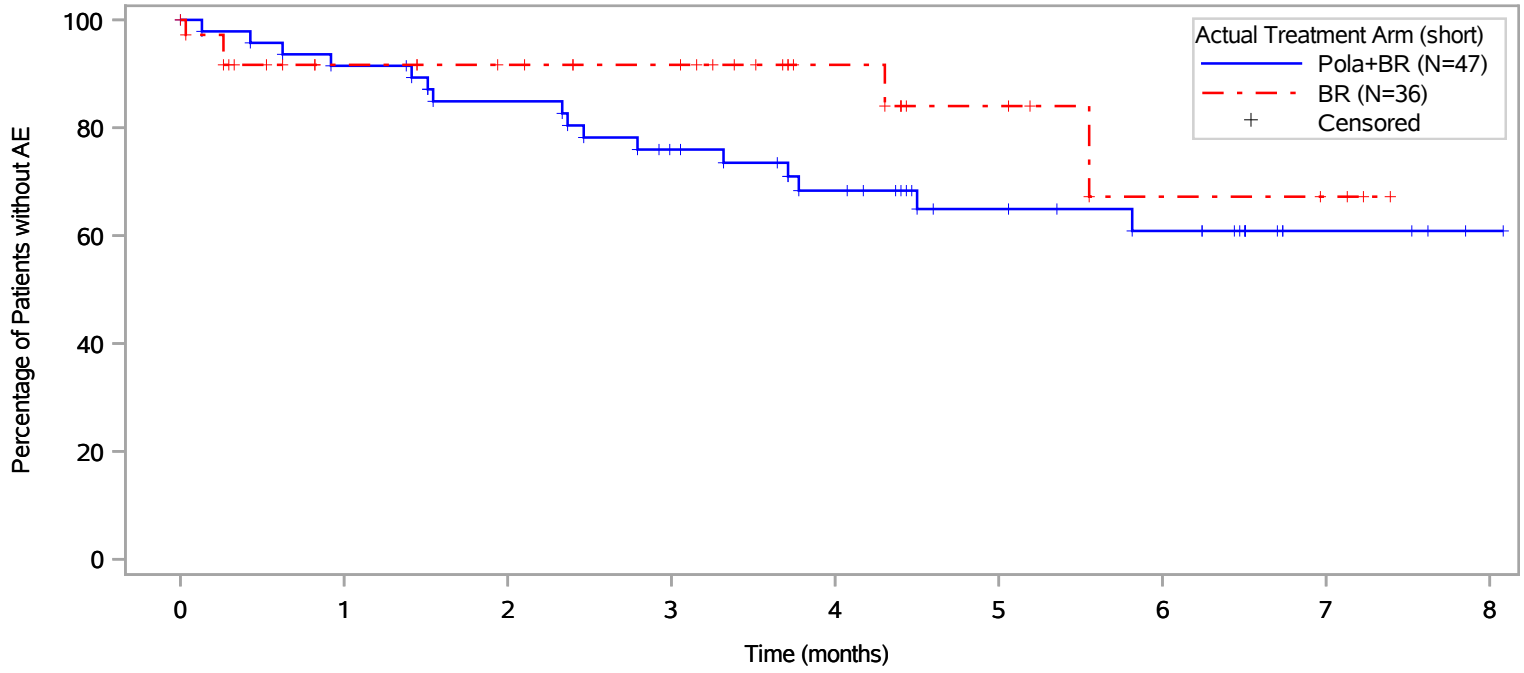


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

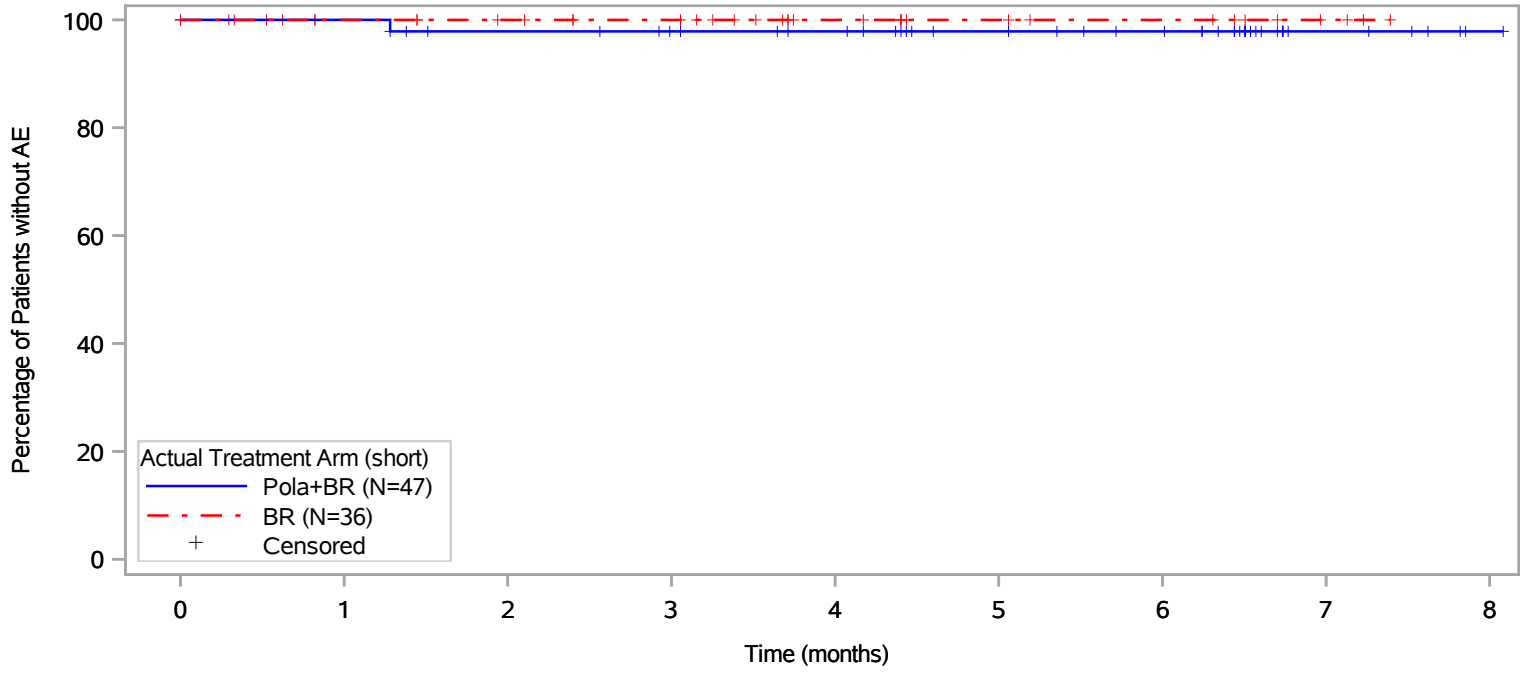
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	43	38	32	26	18	15	4	1
BR (N=36)	36	27	24	21	12	7	4	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	16	27	30
BR (N=36)	0	6	9	12	21	25	27	28	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

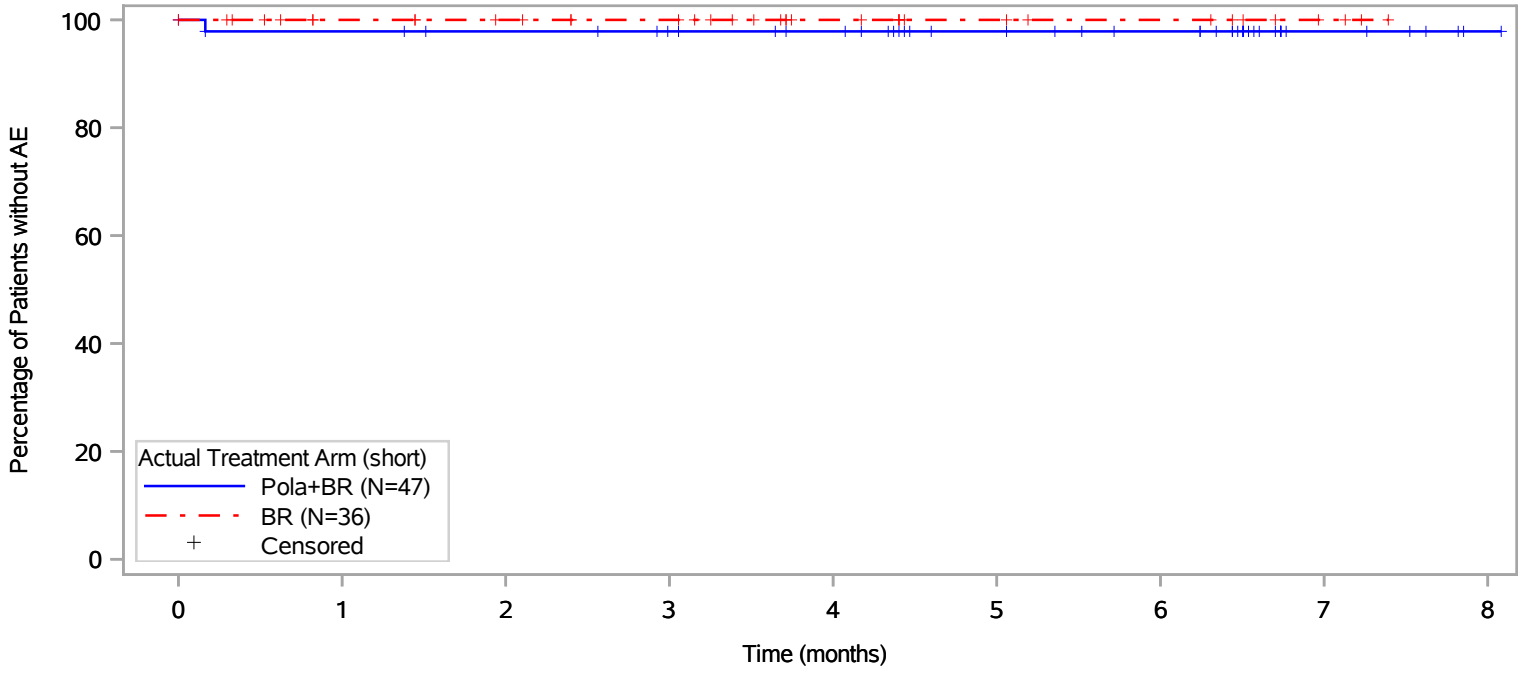
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PROCALCITONIN INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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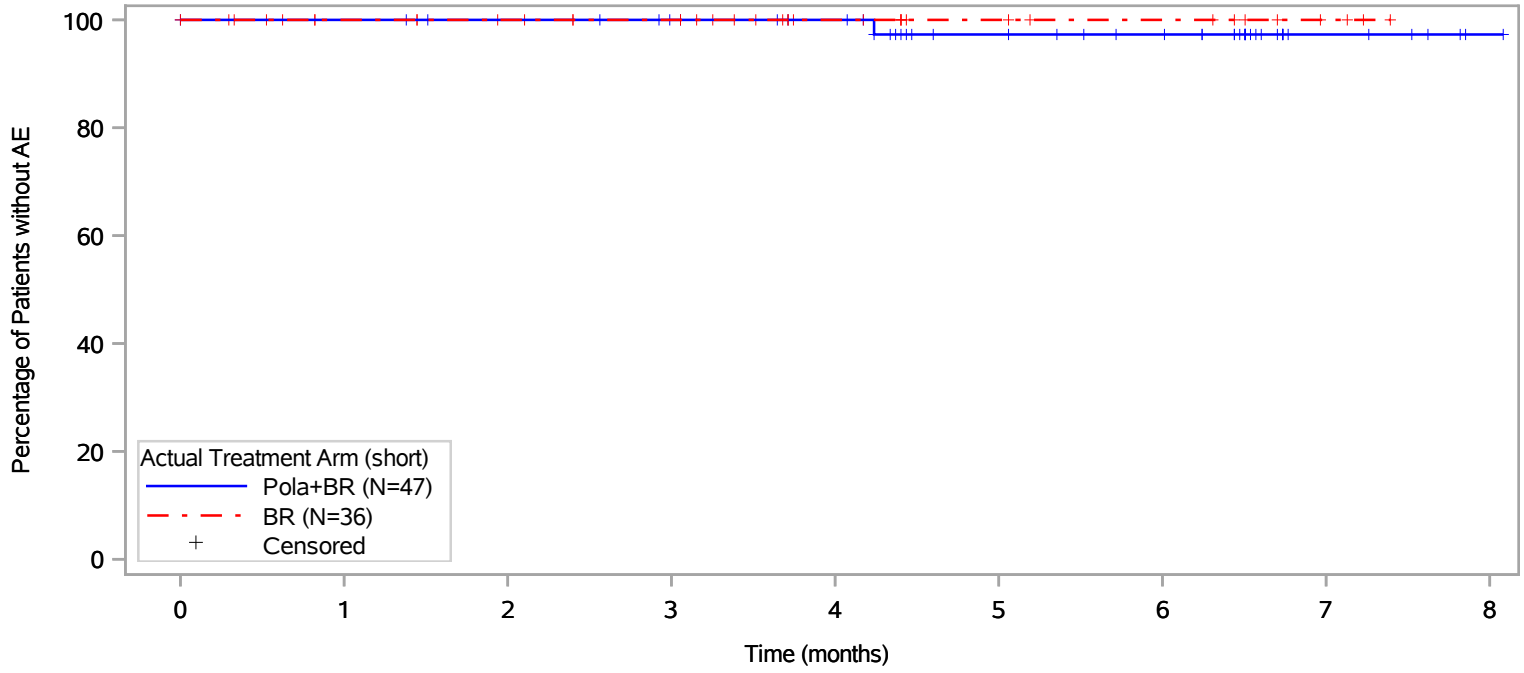
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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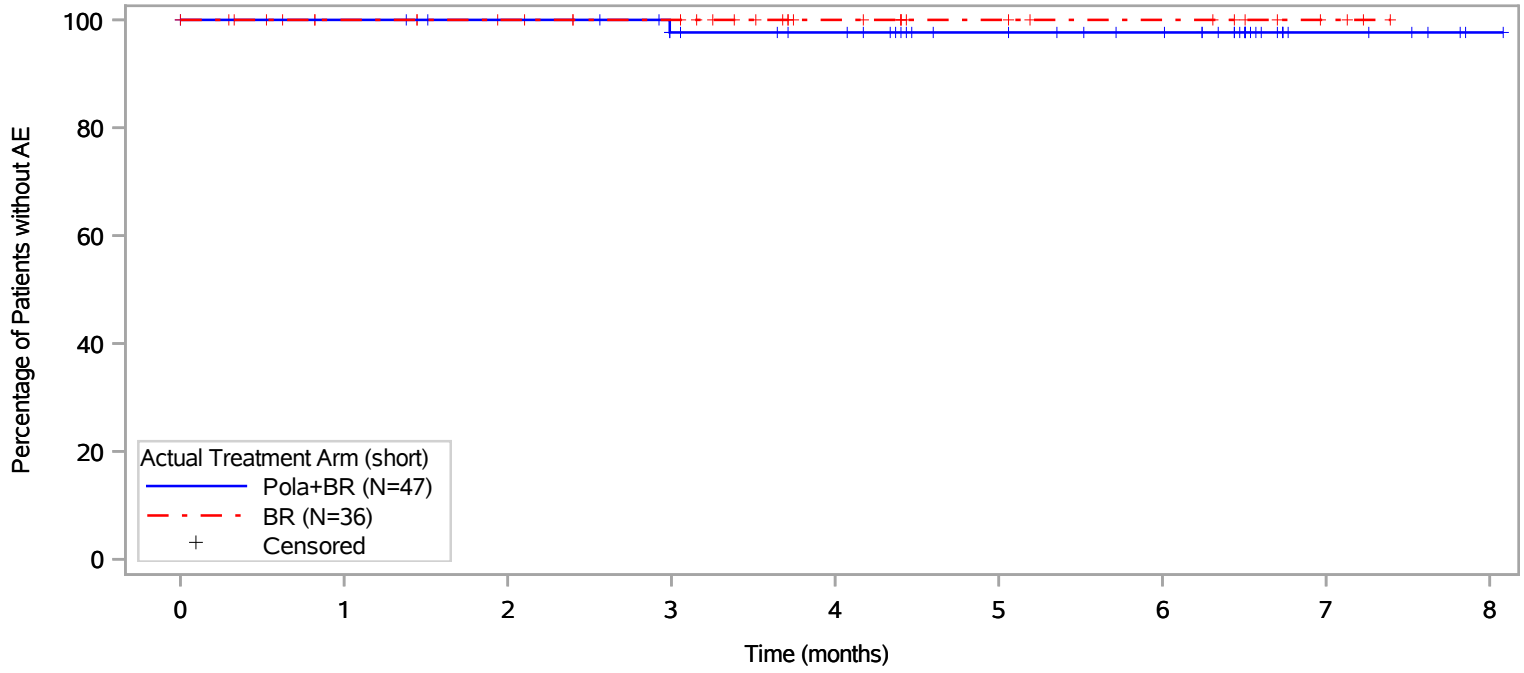
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PROTEIN TOTAL DECREASED

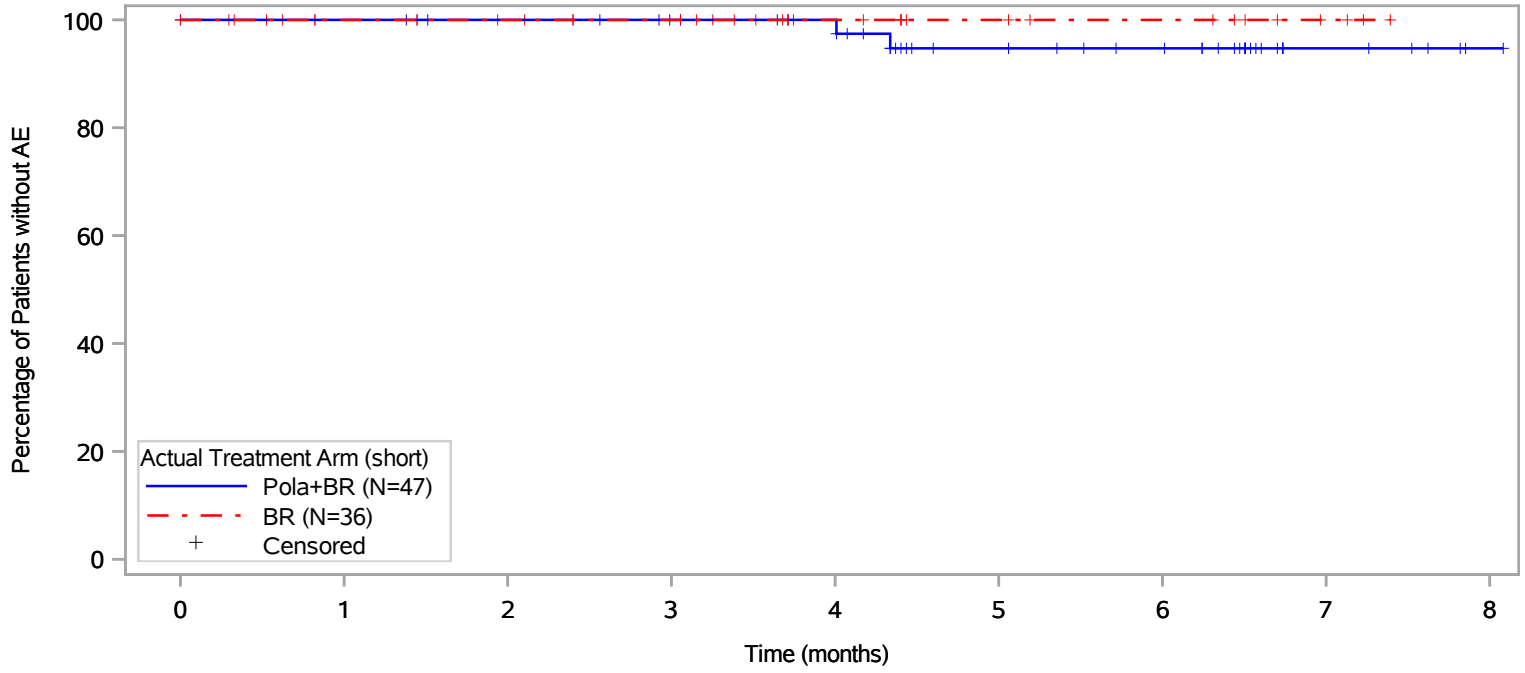


Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PROTEIN URINE PRESENT

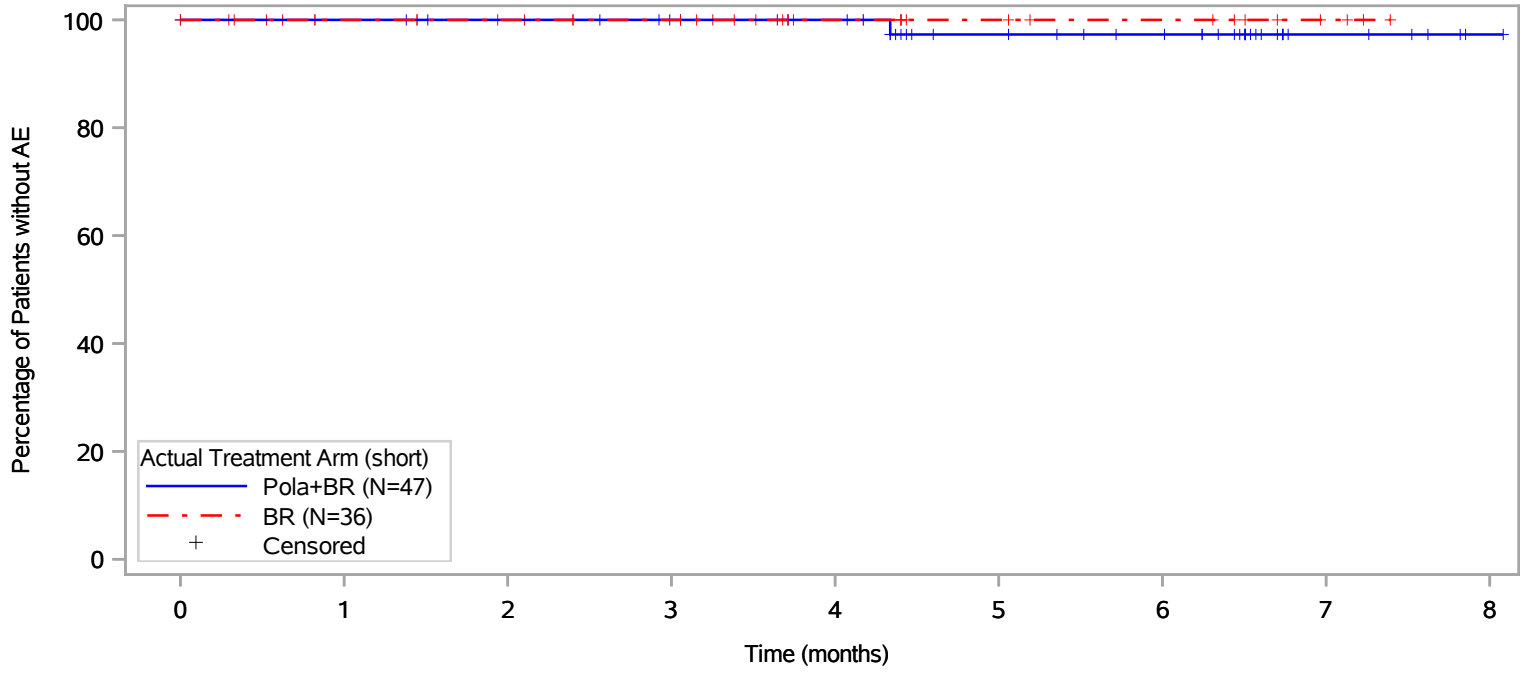


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	29	25	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, RED BLOOD CELLS URINE POSITIVE

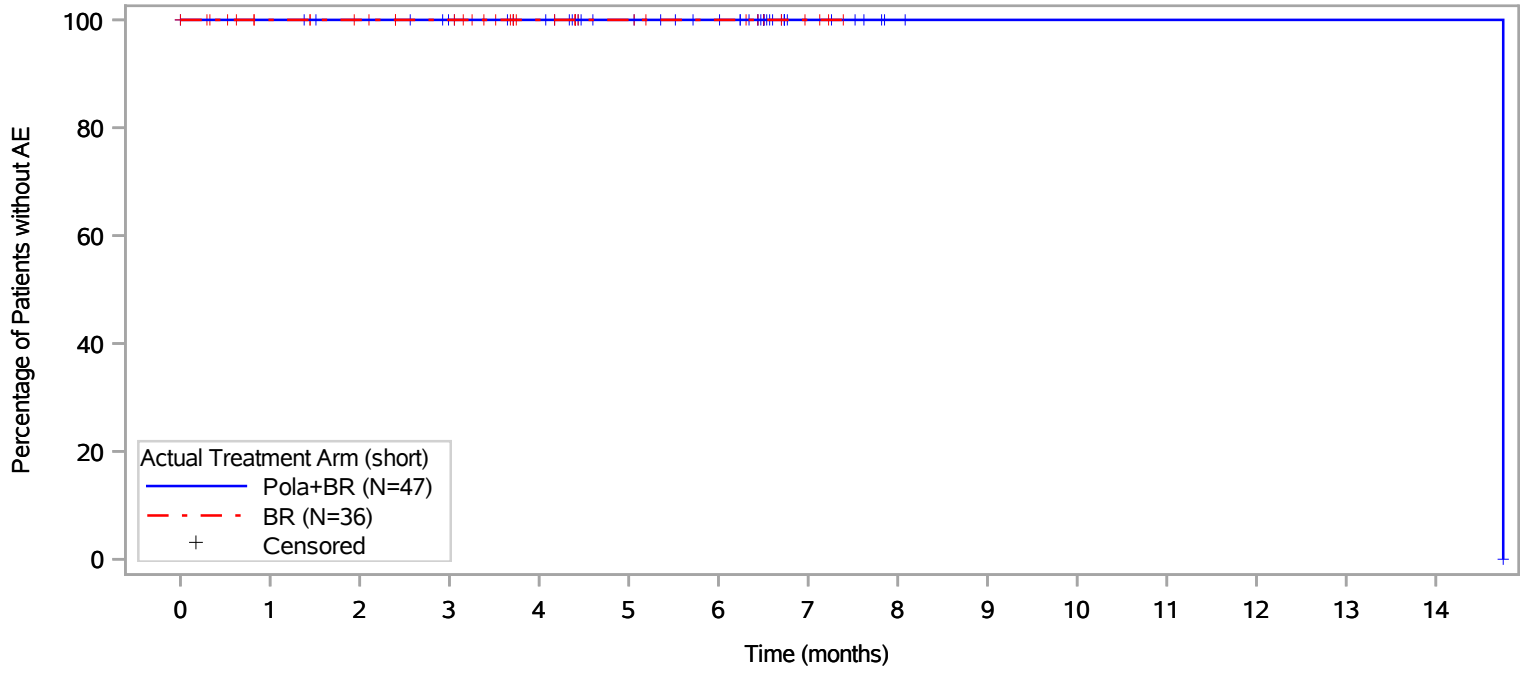


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, TRANSAMINASES INCREASED



Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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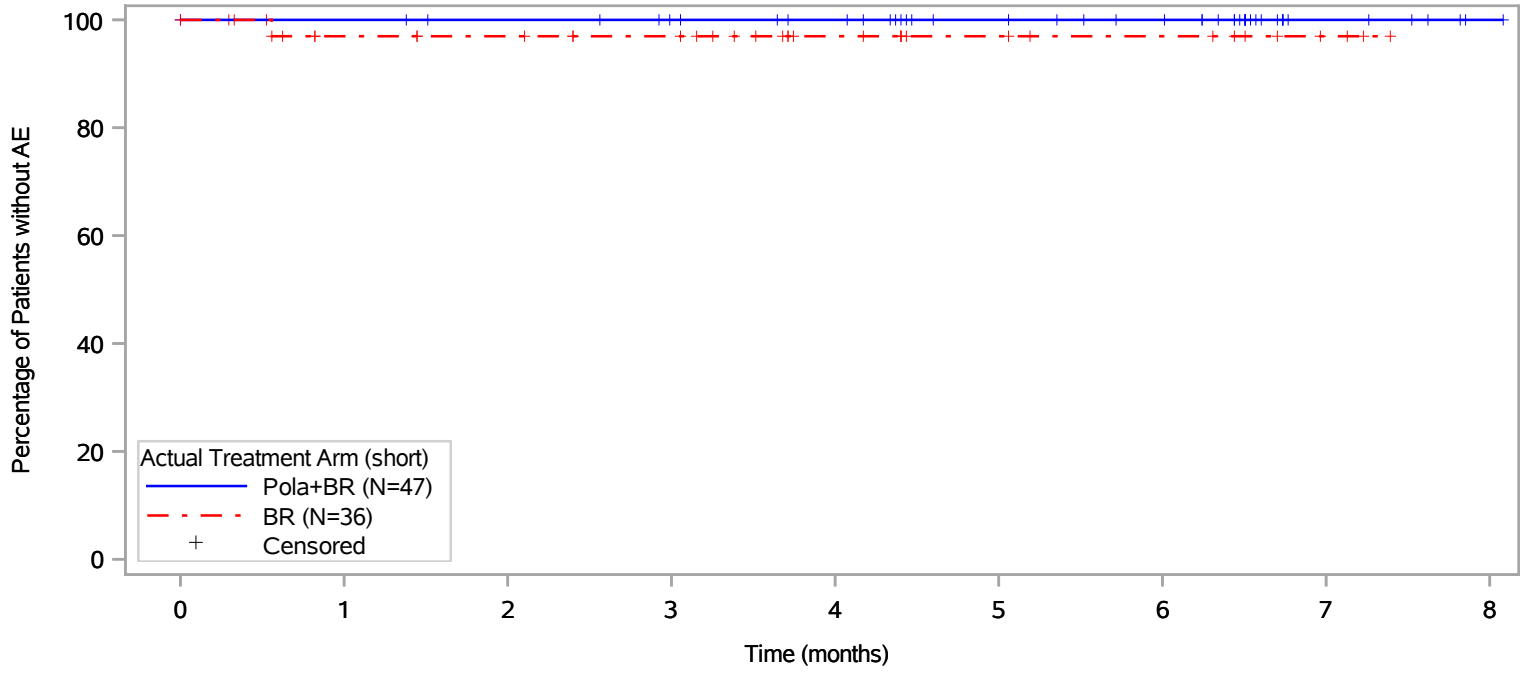
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, URINE OUTPUT DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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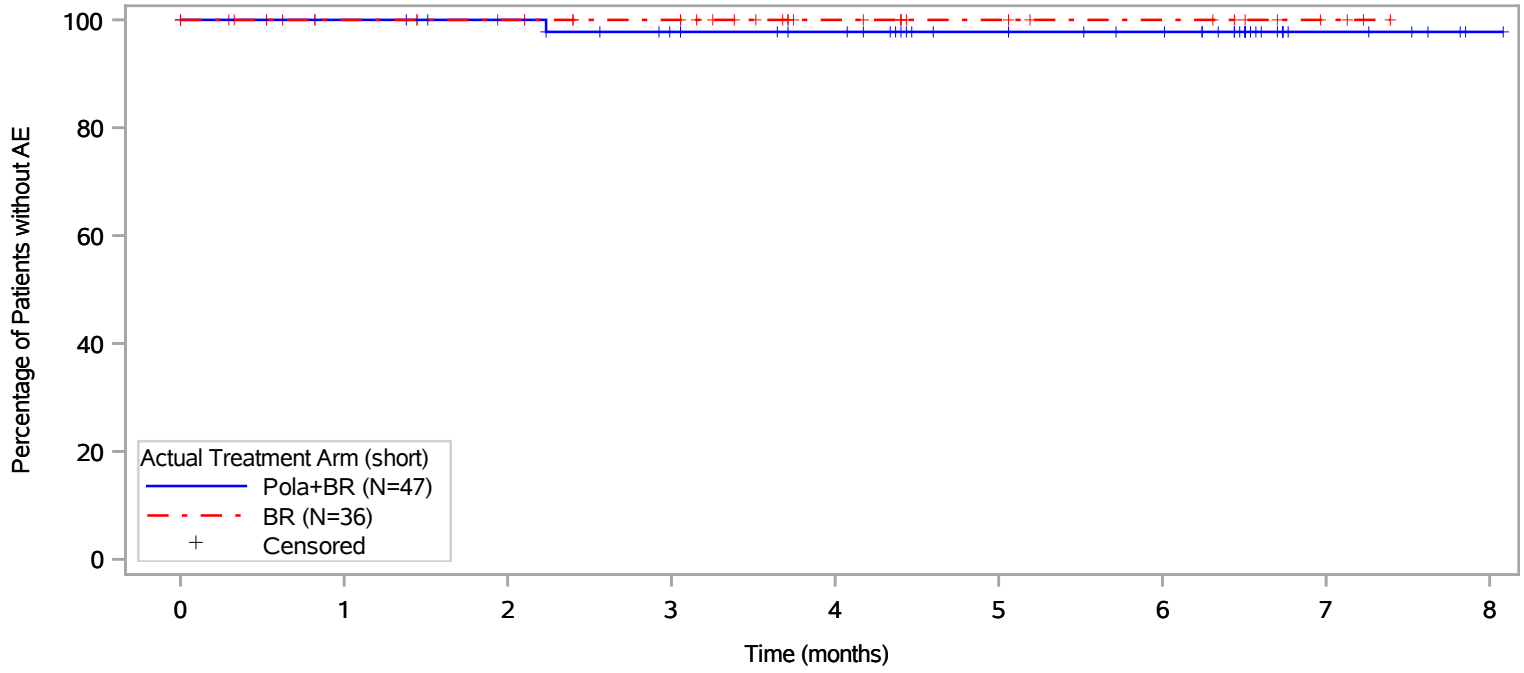
01DEC2022 22:30

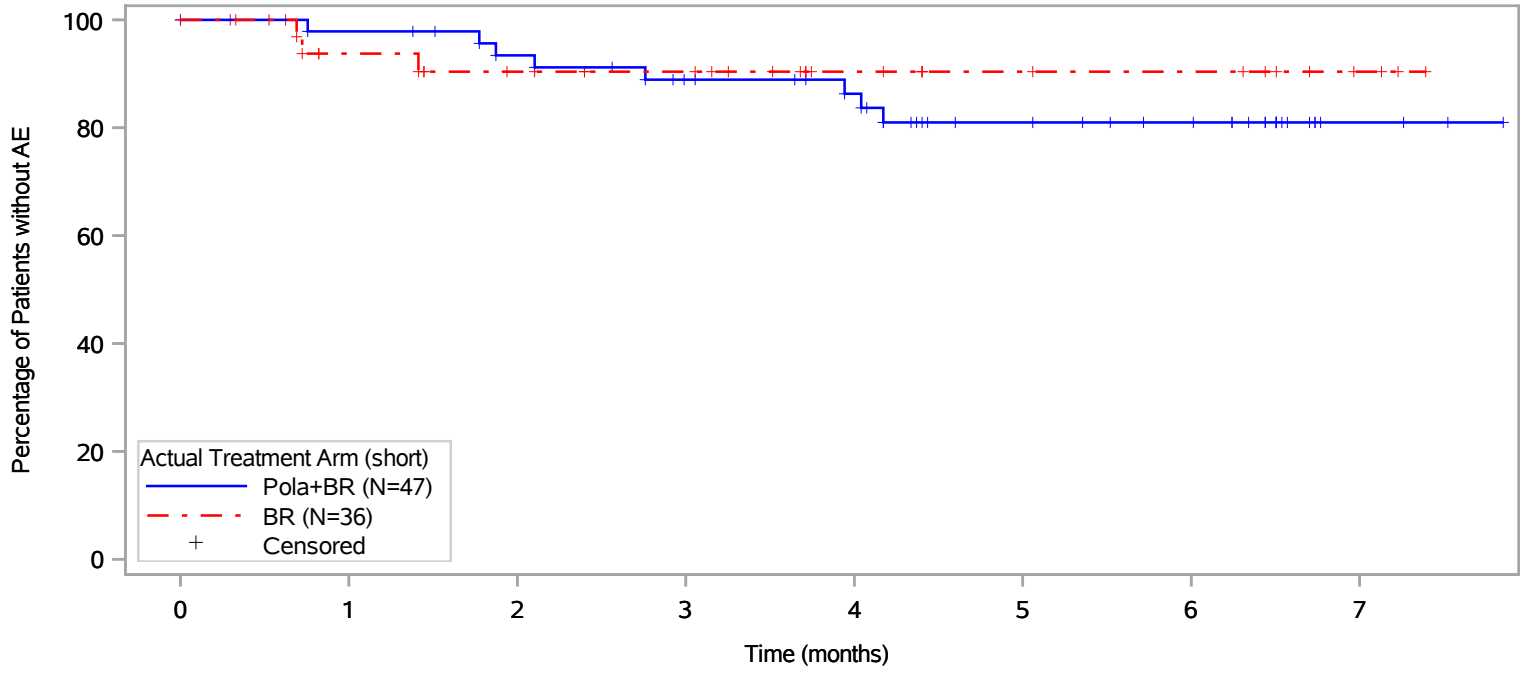
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, VITAMIN D DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

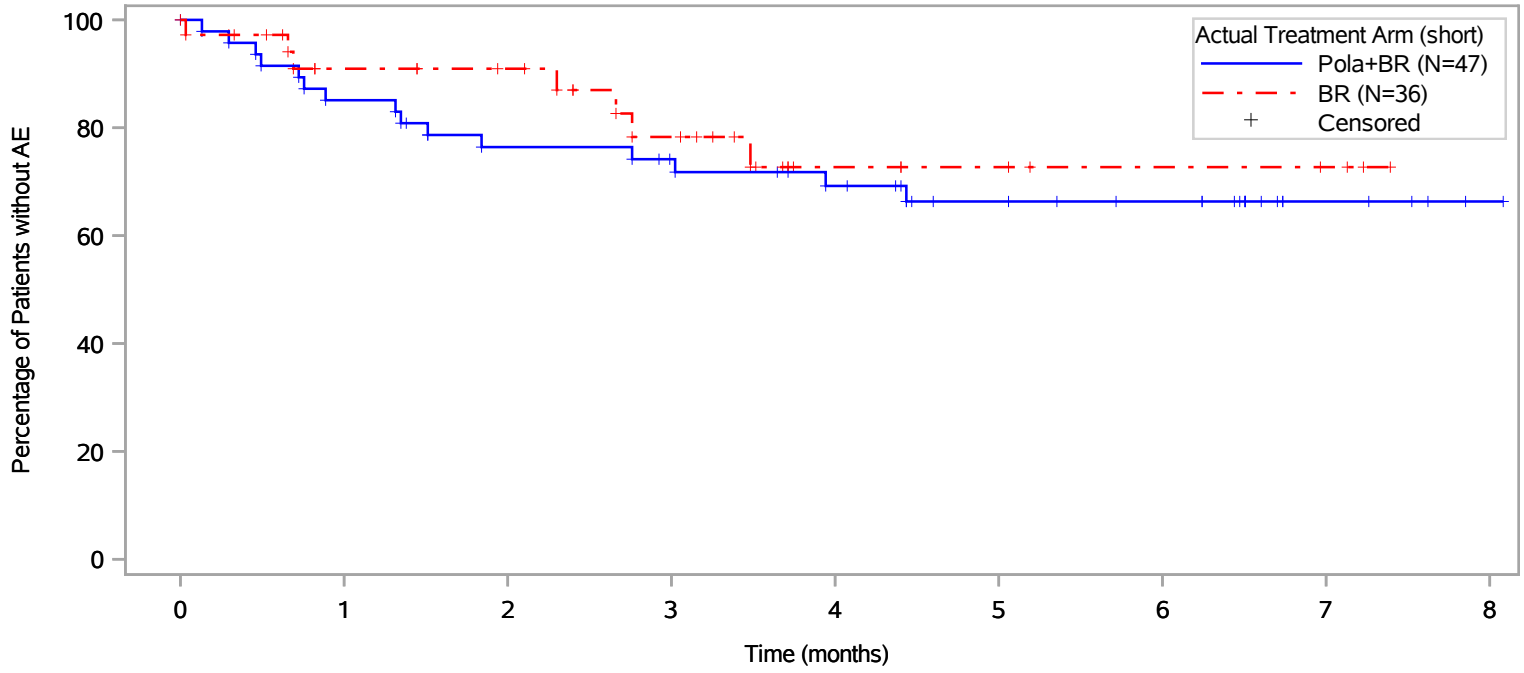
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED



Patients at risk								
Pola+BR (N=47)	47	46	42	37	33	24	20	3
BR (N=36)	36	28	24	21	13	9	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	15	19	36
BR (N=36)	0	6	9	12	20	24	25	30

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	40	34	31	27	20	17	5	1
BR (N=36)	36	27	24	18	8	6	4	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	6	12	15	27	31
BR (N=36)	0	6	9	12	21	23	25	26	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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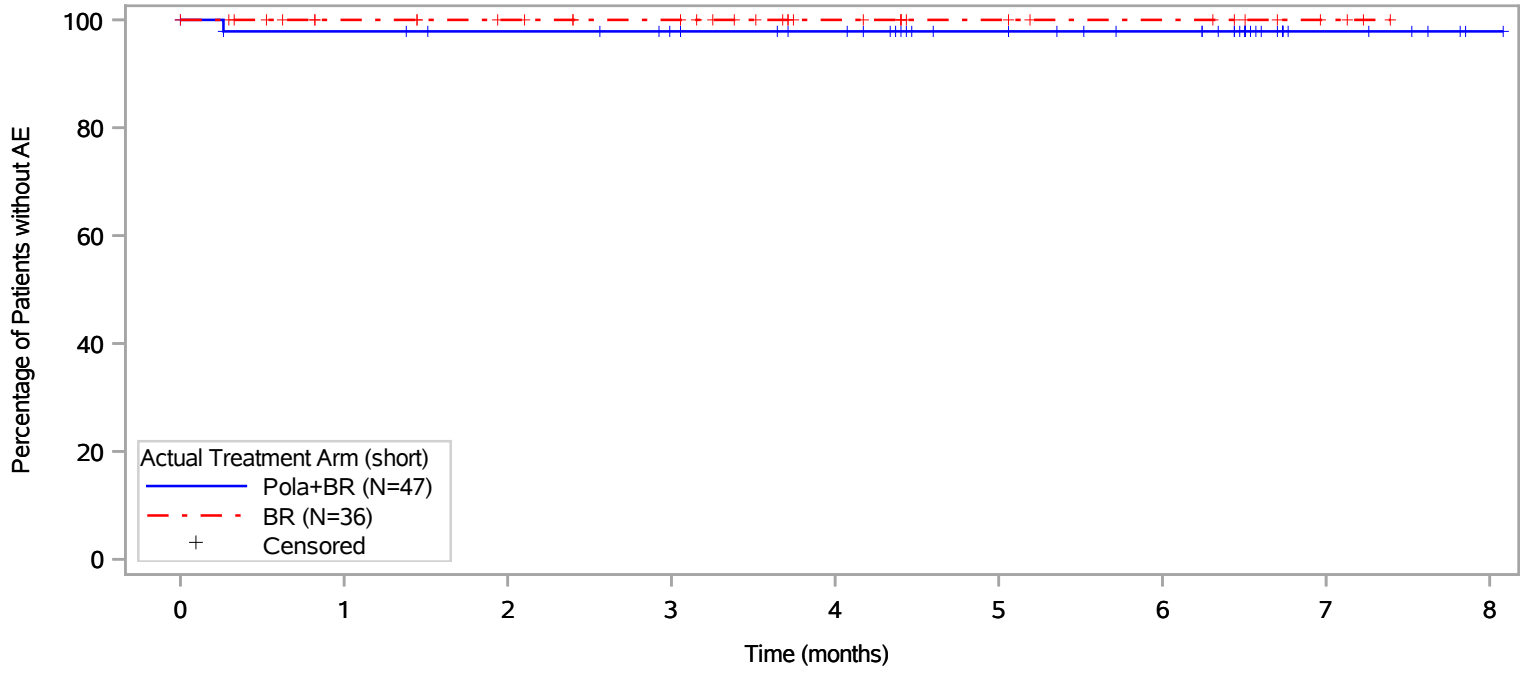
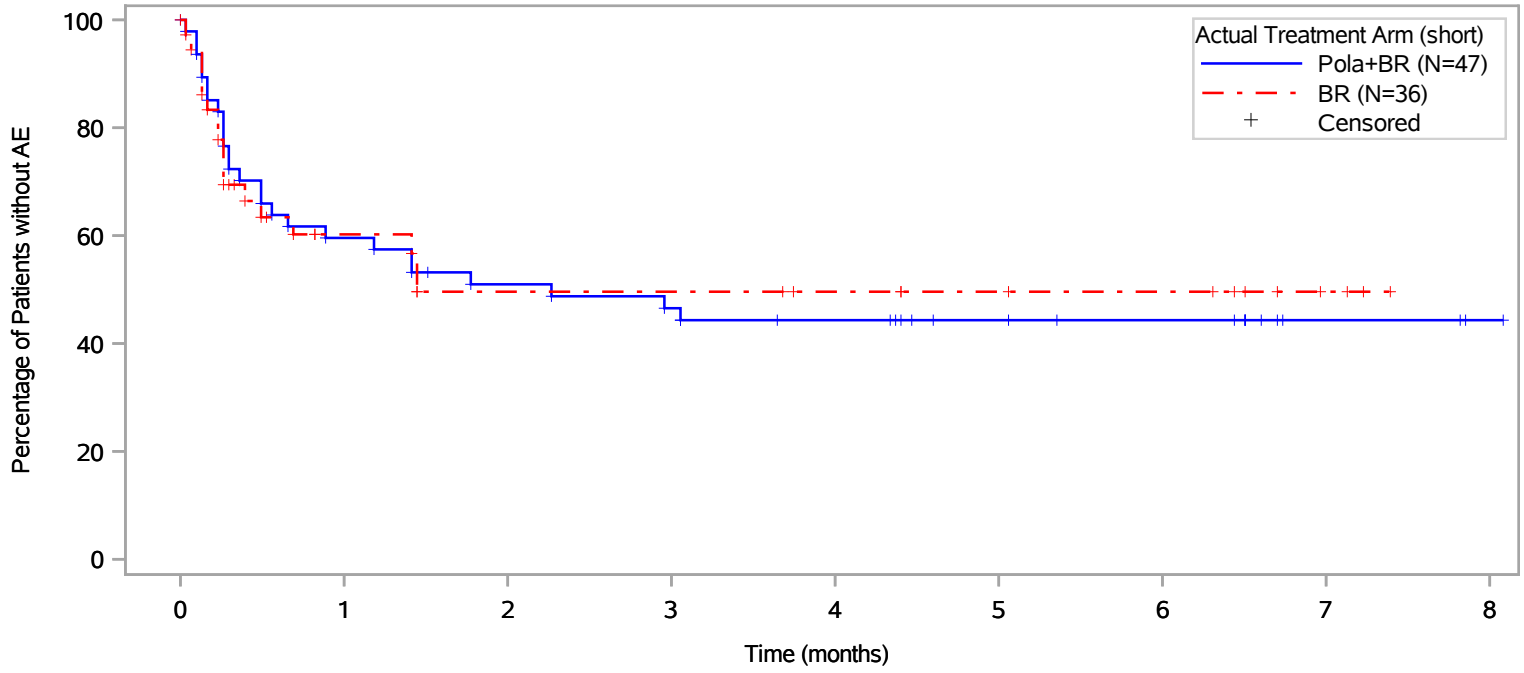
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	28	23	21	18	13	11	3	1
BR (N=36)	36	17	13	13	11	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	1	3	8	10	18	20
BR (N=36)	0	5	6	6	8	10	11	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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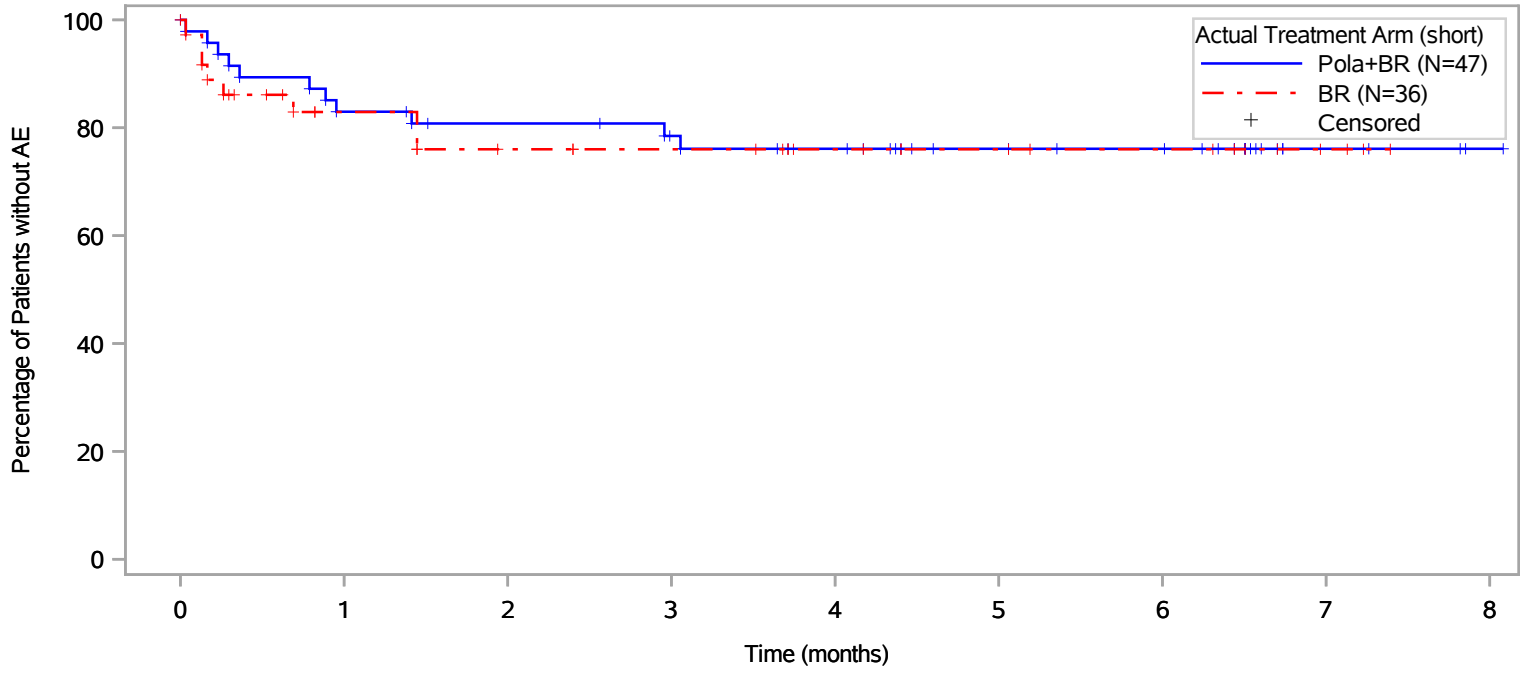
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

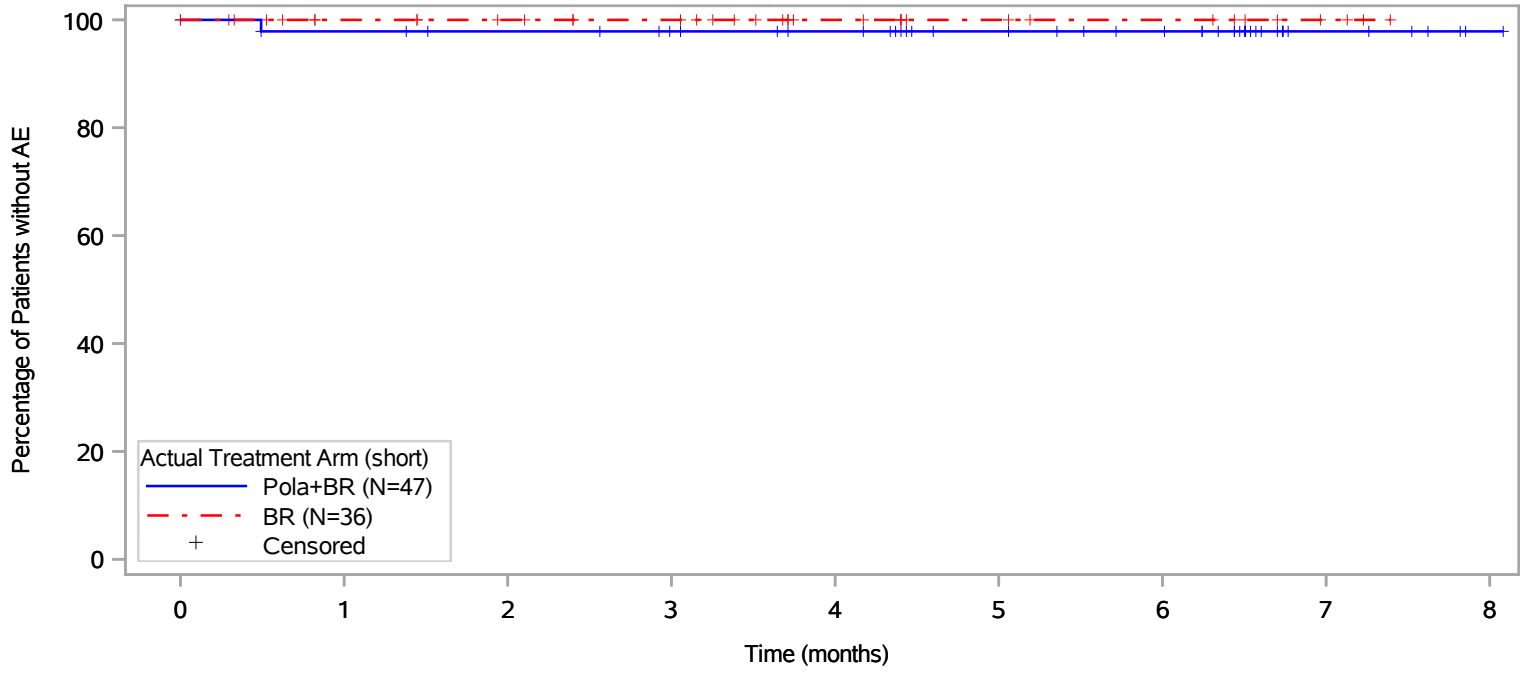
METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE



Patients at risk									
Pola+BR (N=47)	47	39	36	33	29	22	20	4	1
BR (N=36)	36	24	20	18	13	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	16	32	35
BR (N=36)	0	6	8	10	15	18	20	25	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, DEHYDRATION

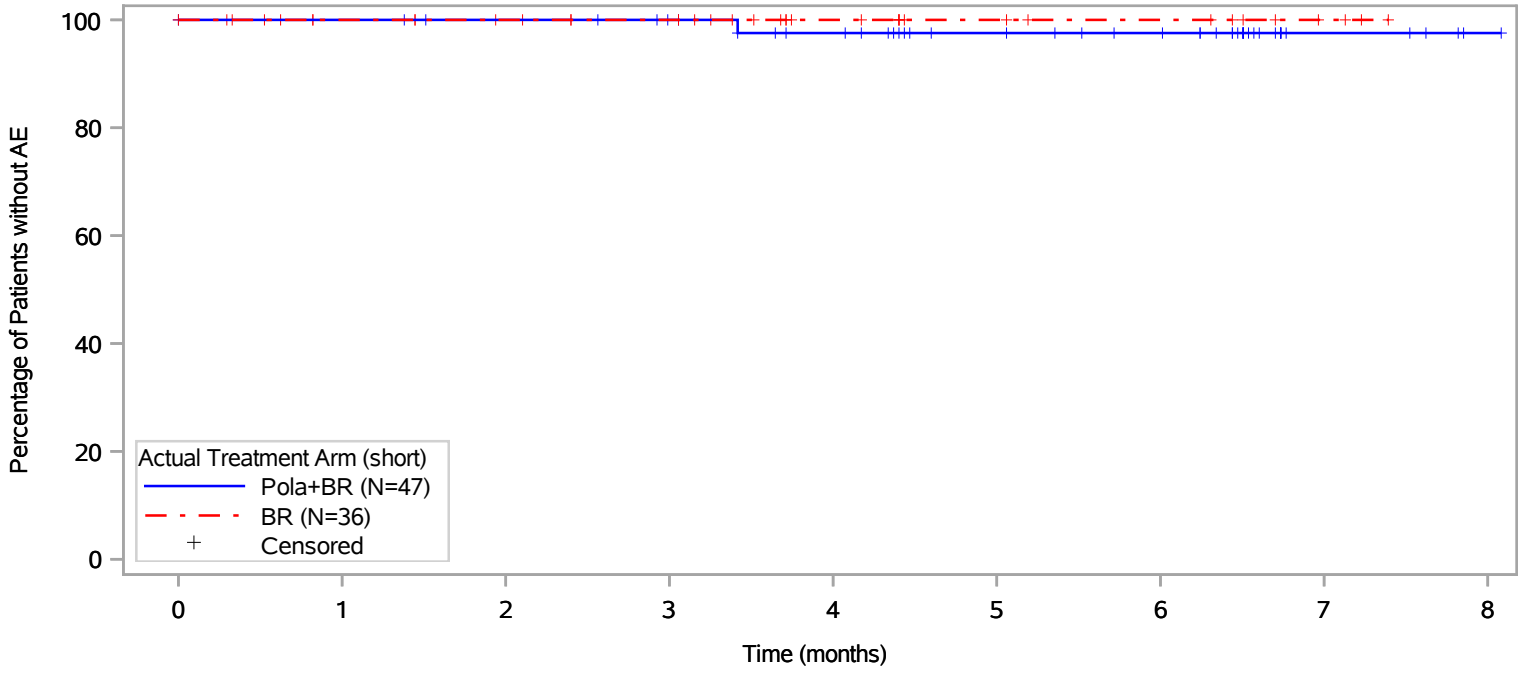


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, ELECTROLYTE IMBALANCE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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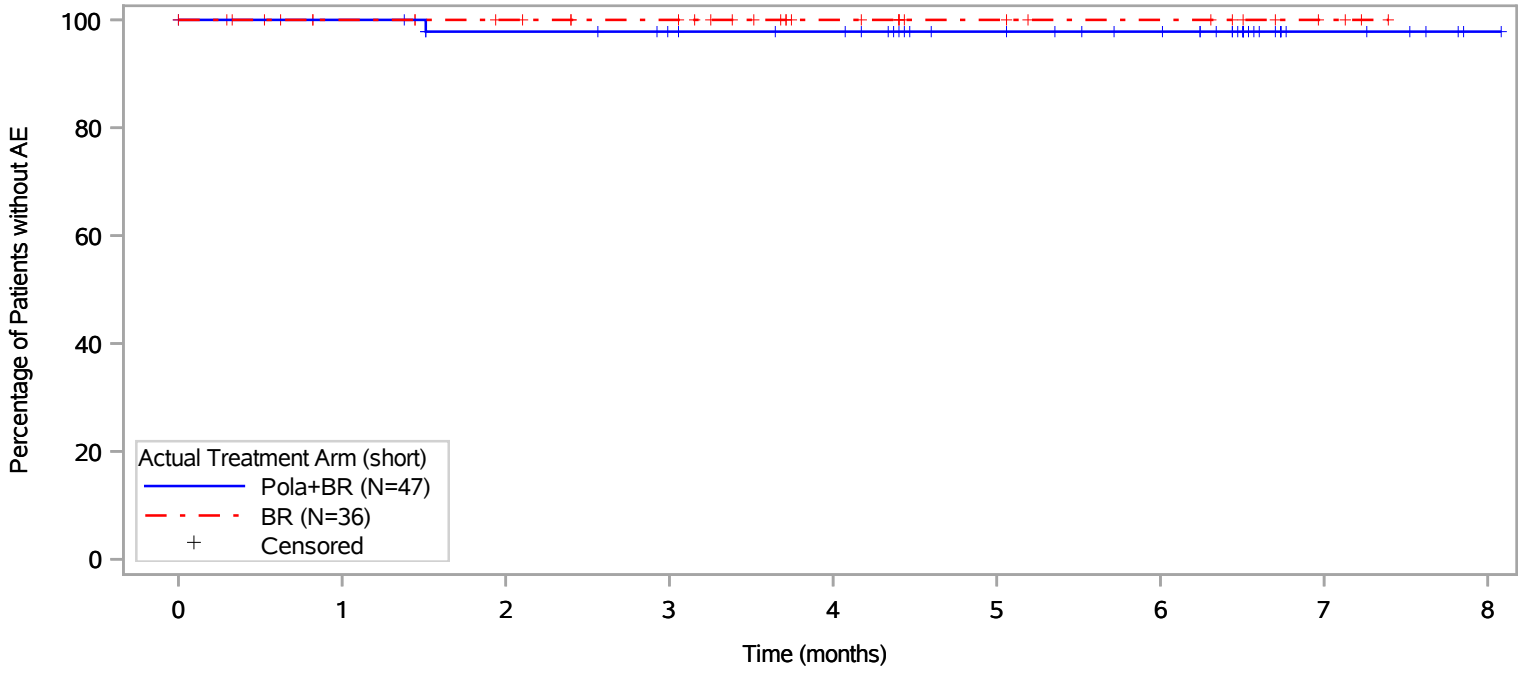
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, FOLATE DEFICIENCY

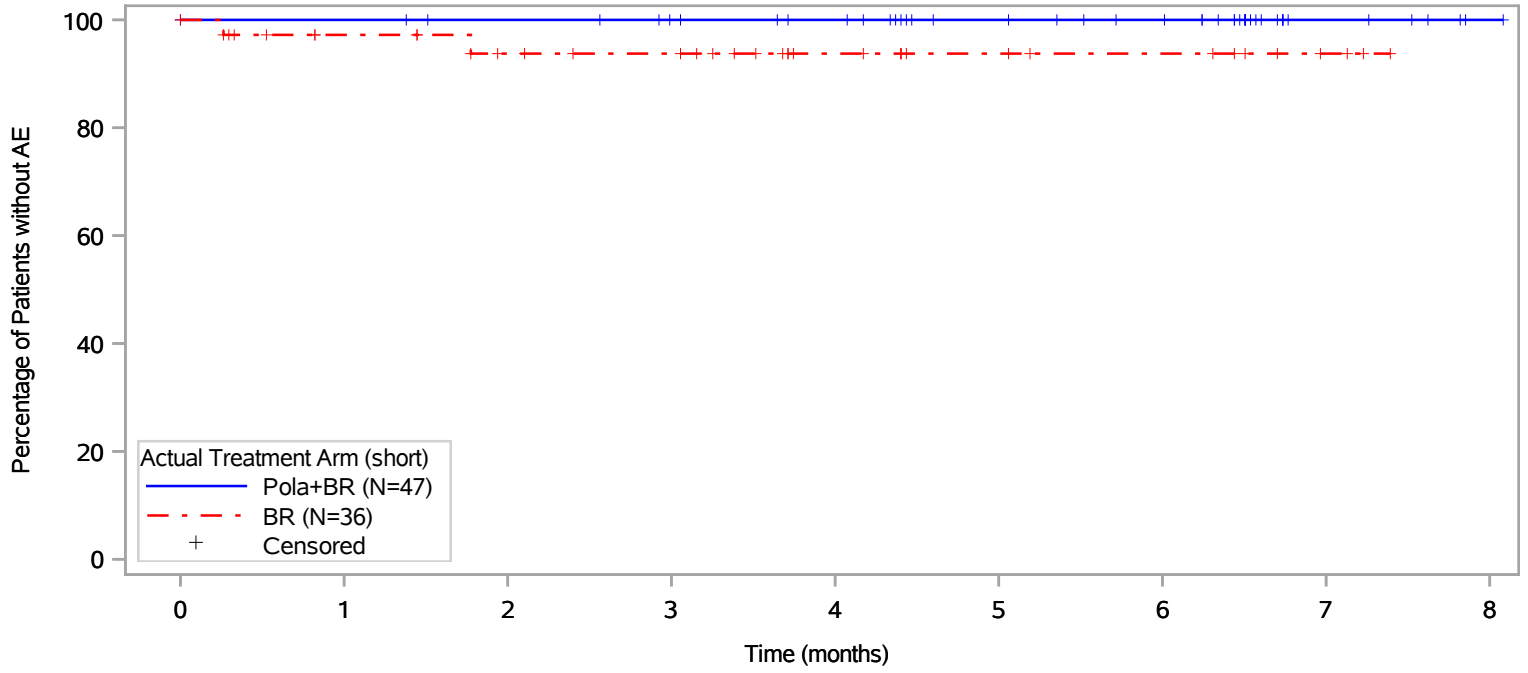


Patients at risk									
Pola+BR (N=47)	47	47	44	41	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPERCALCAEMIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	5	8	10	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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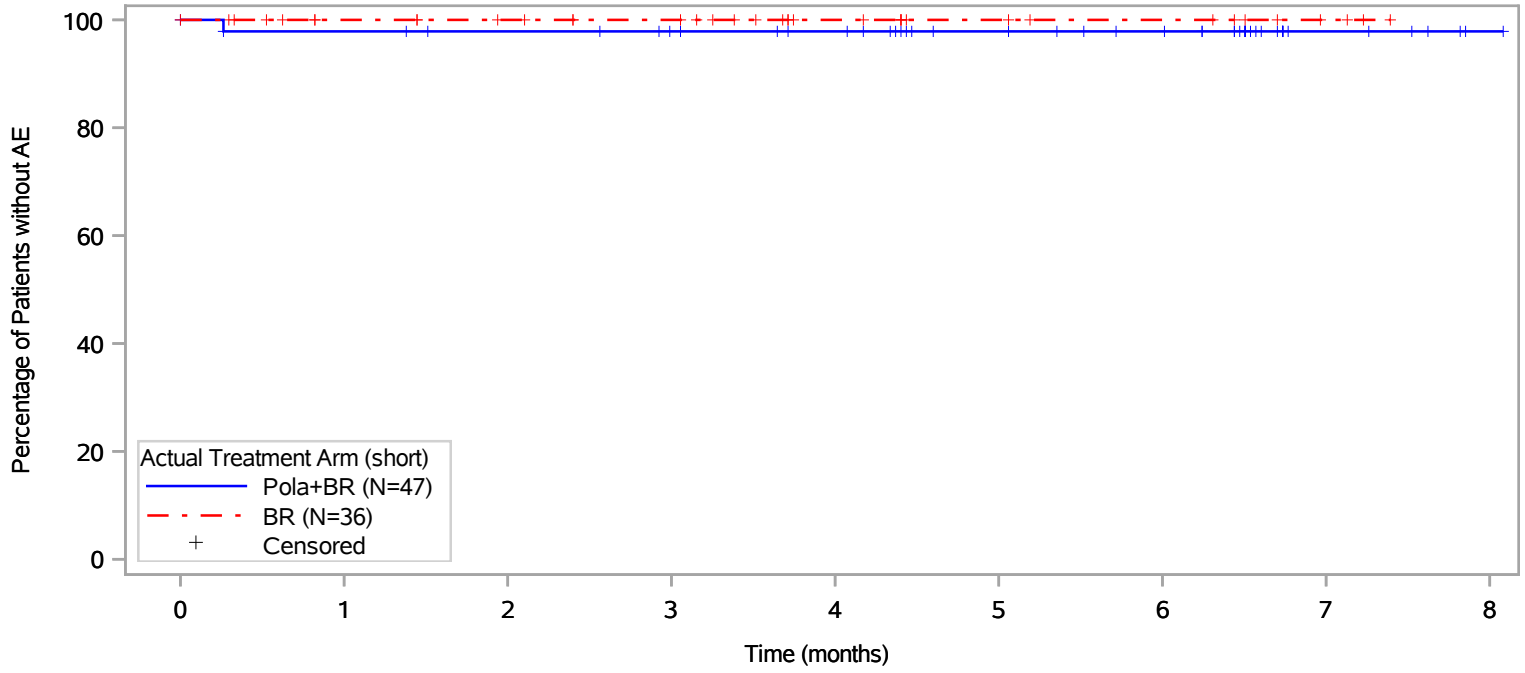
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERCHOLESTEROLAEMIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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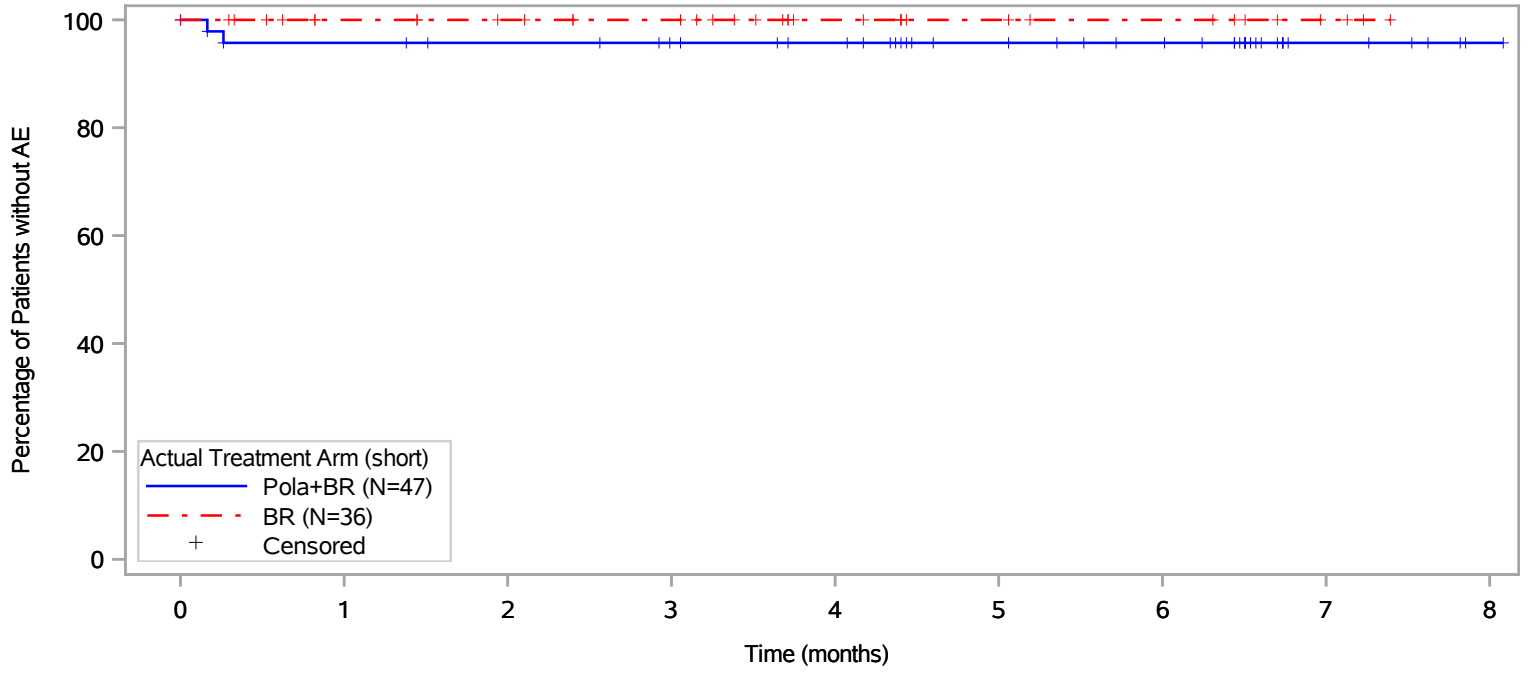
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERGLYCAEMIA



Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	29	25	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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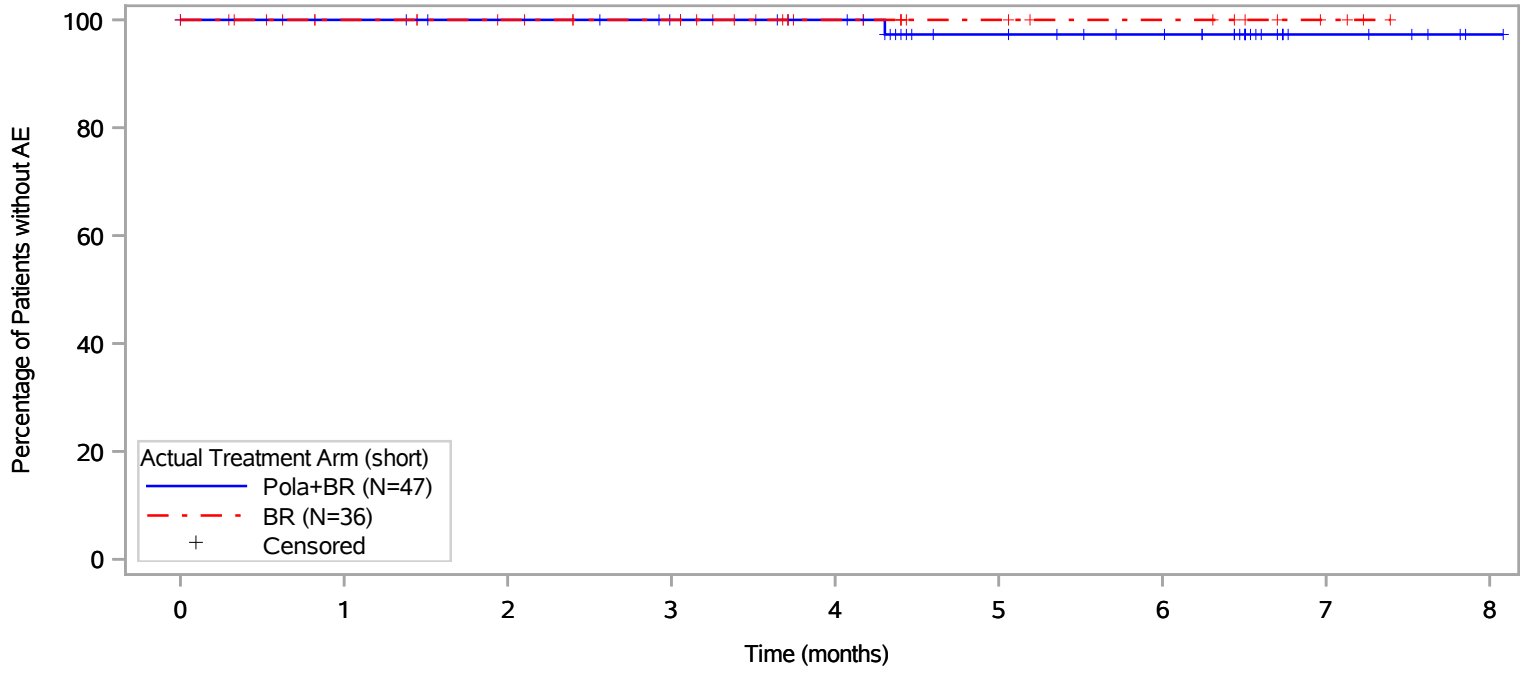
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPERKALAEMIA

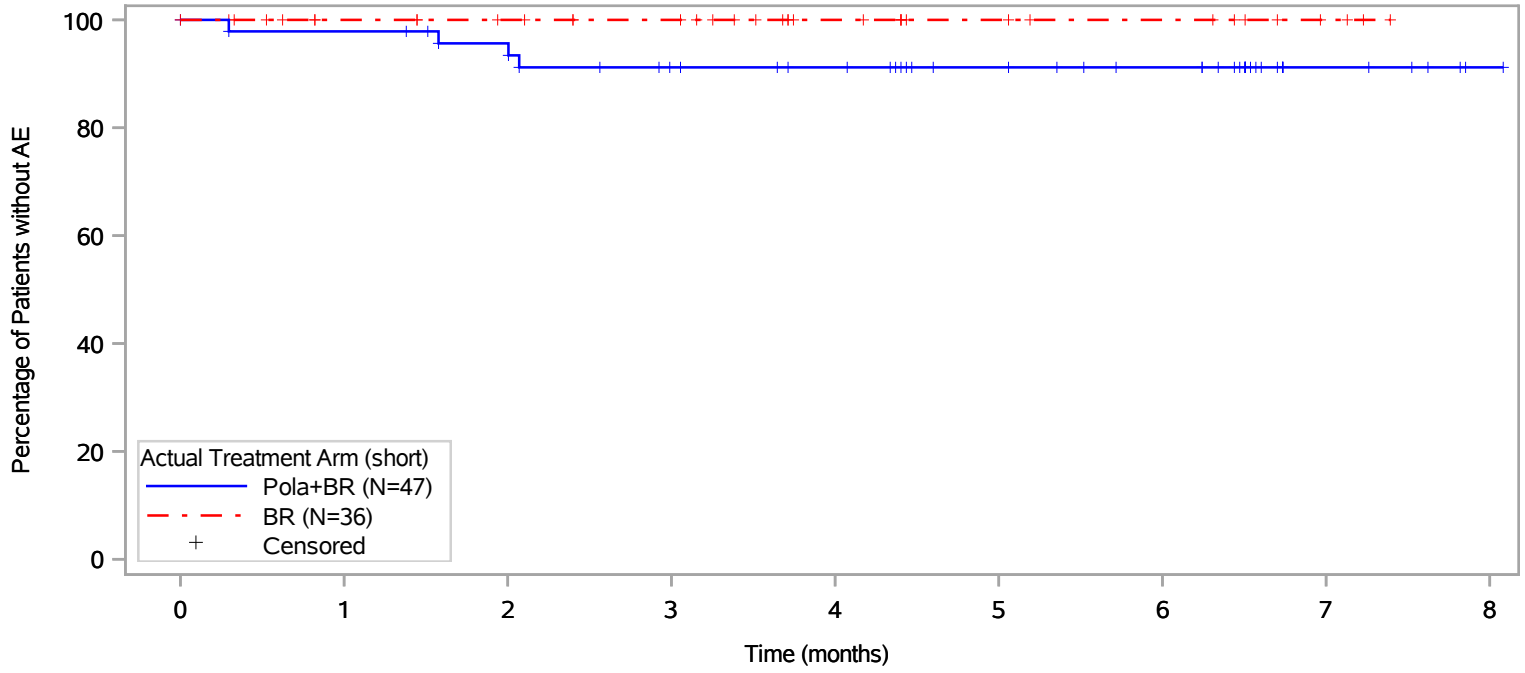


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPERLIPIDAEMIA

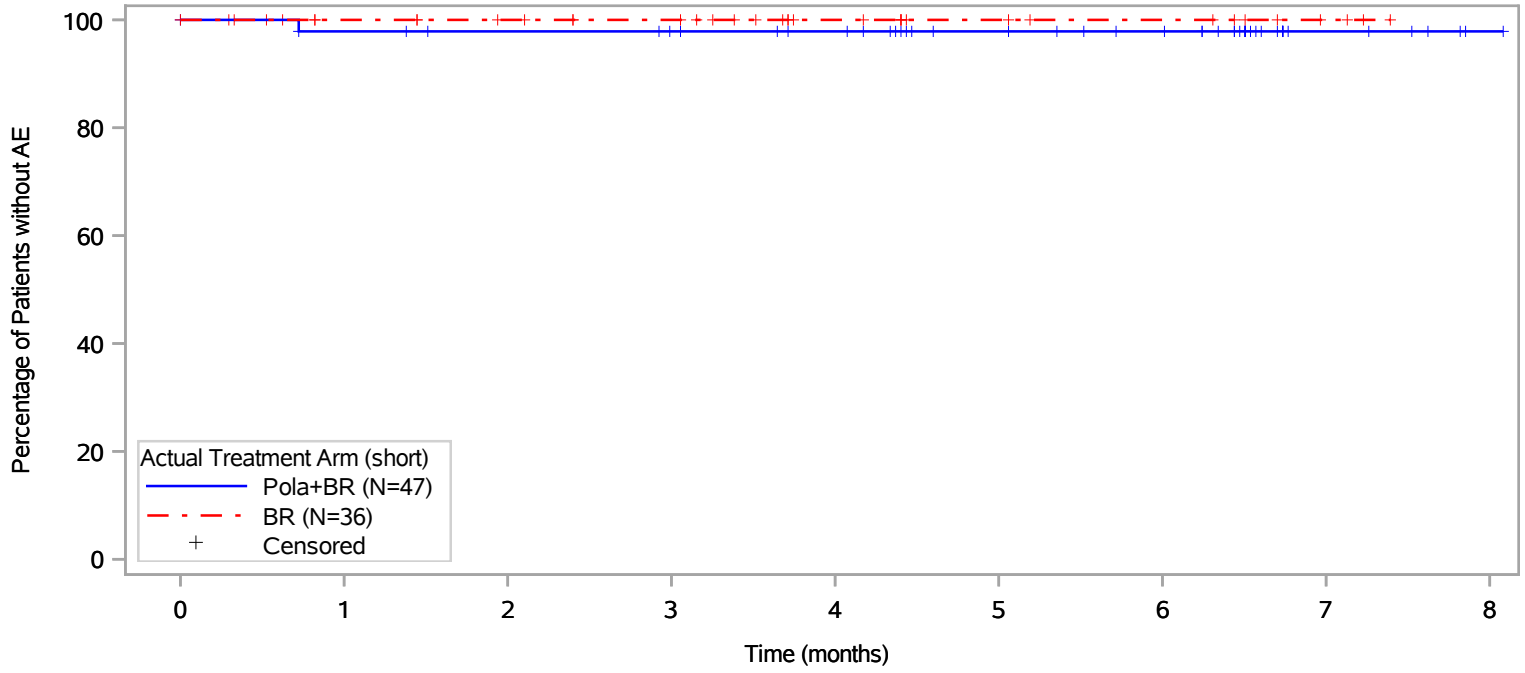


Patients at risk									
Pola+BR (N=47)	47	46	43	38	35	28	24	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	37	42
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPERMAGNESAEMIA

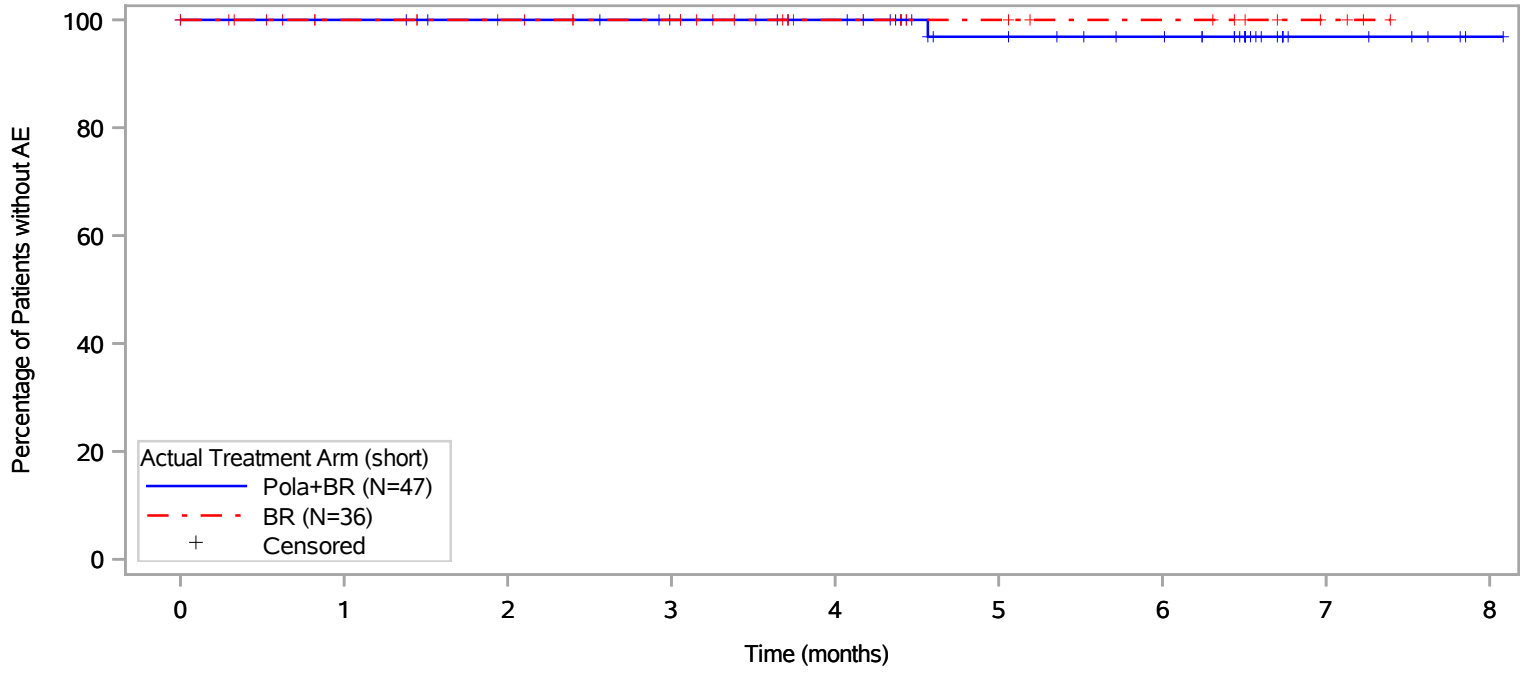


Patients at risk									
Pola+BR (N=47)	47	46	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPERNATRAEMIA

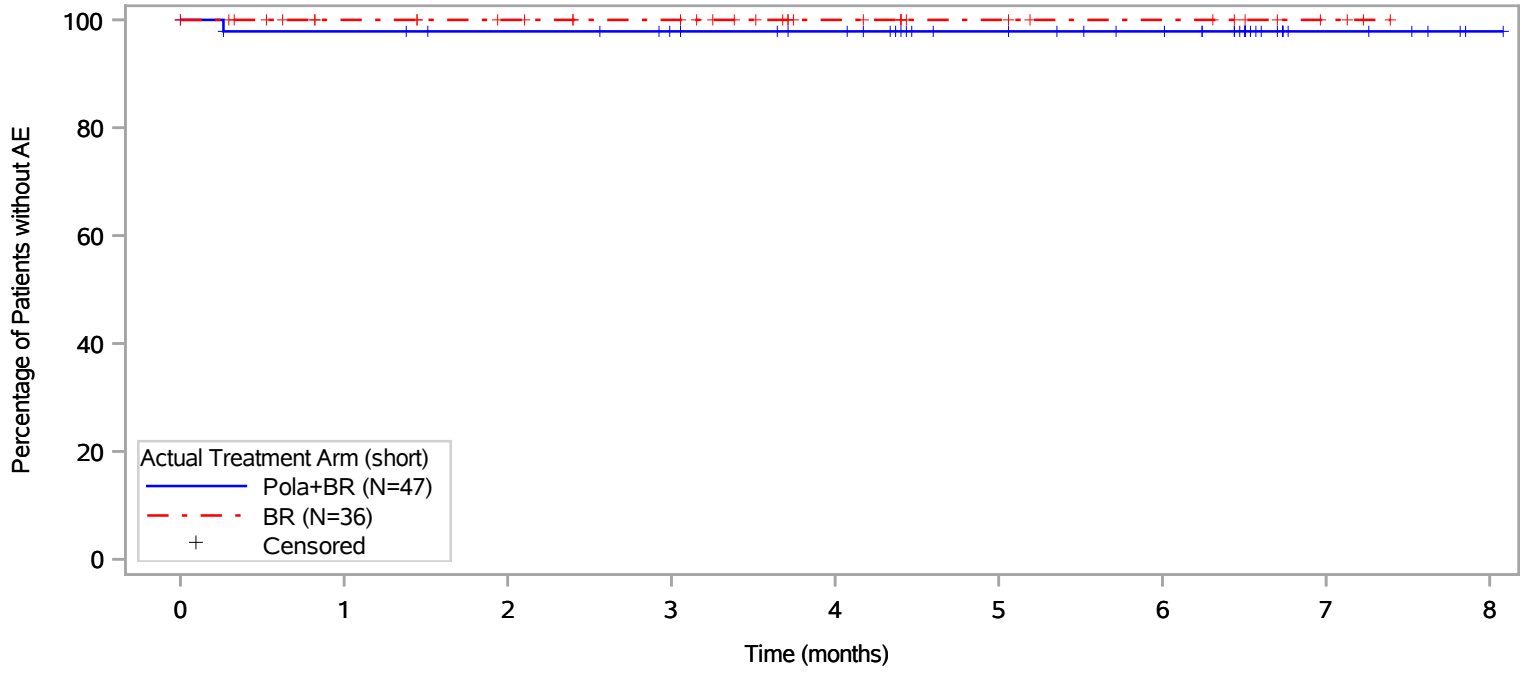


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPERTRIGLYCERIDAEMIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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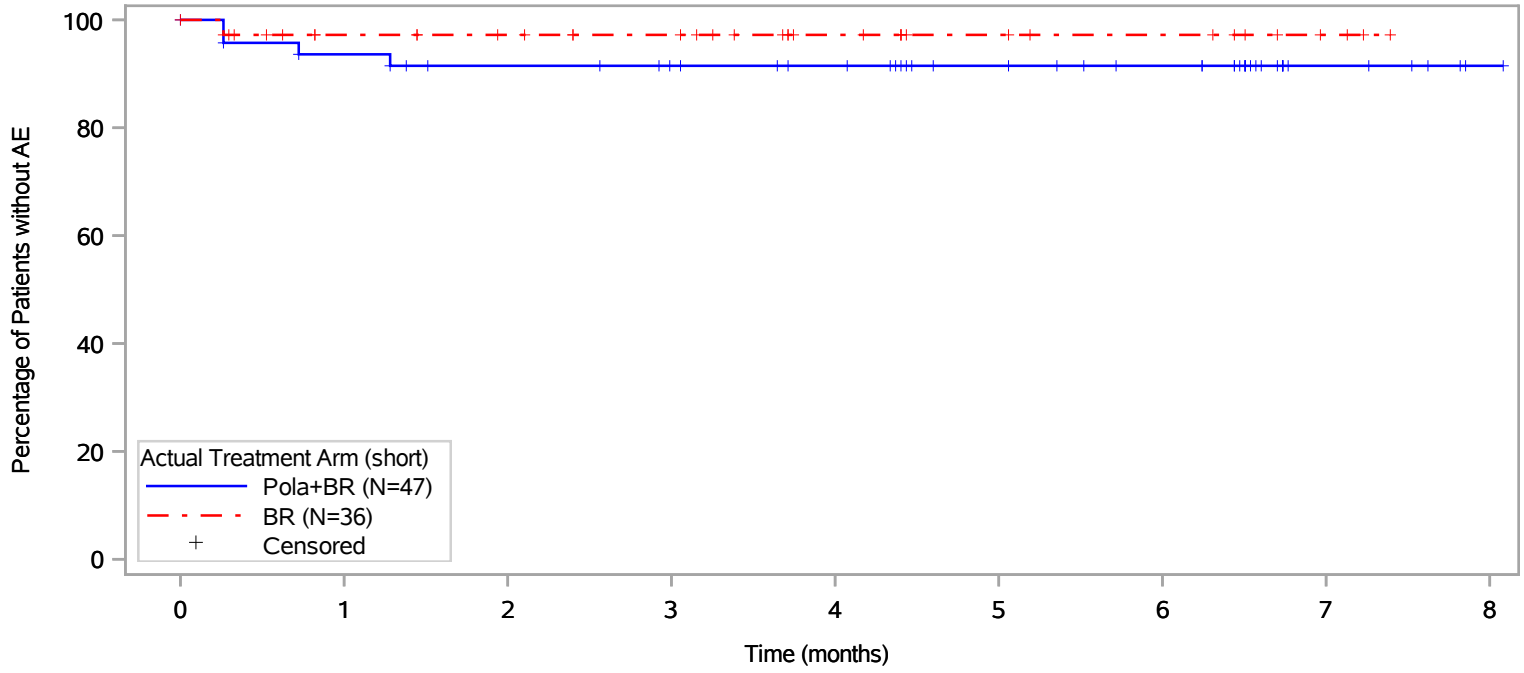
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERURICAEMIA

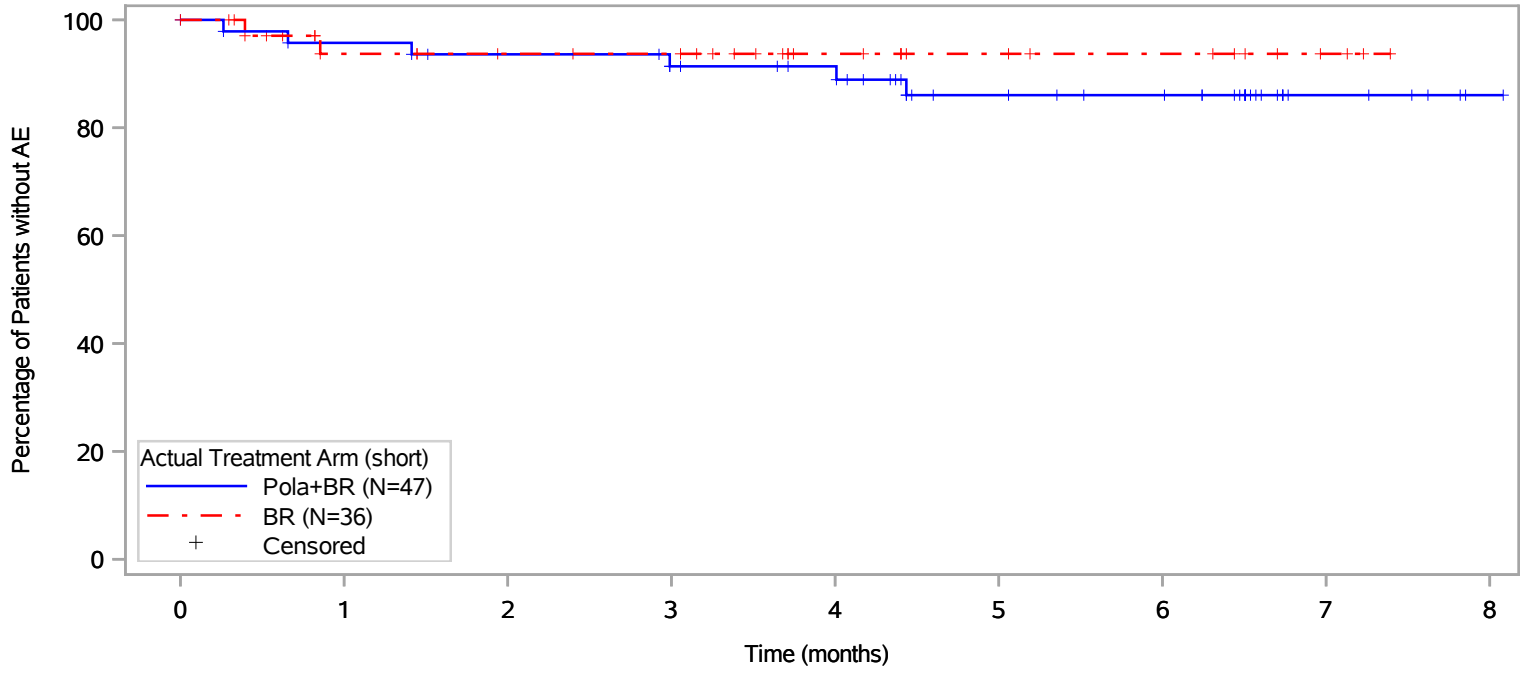


Patients at risk									
Pola+BR (N=47)	47	44	41	38	35	28	24	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	37	42
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA



Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	27	24	6	1
BR (N=36)	36	28	25	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	6	14	17	35	40
BR (N=36)	0	6	9	10	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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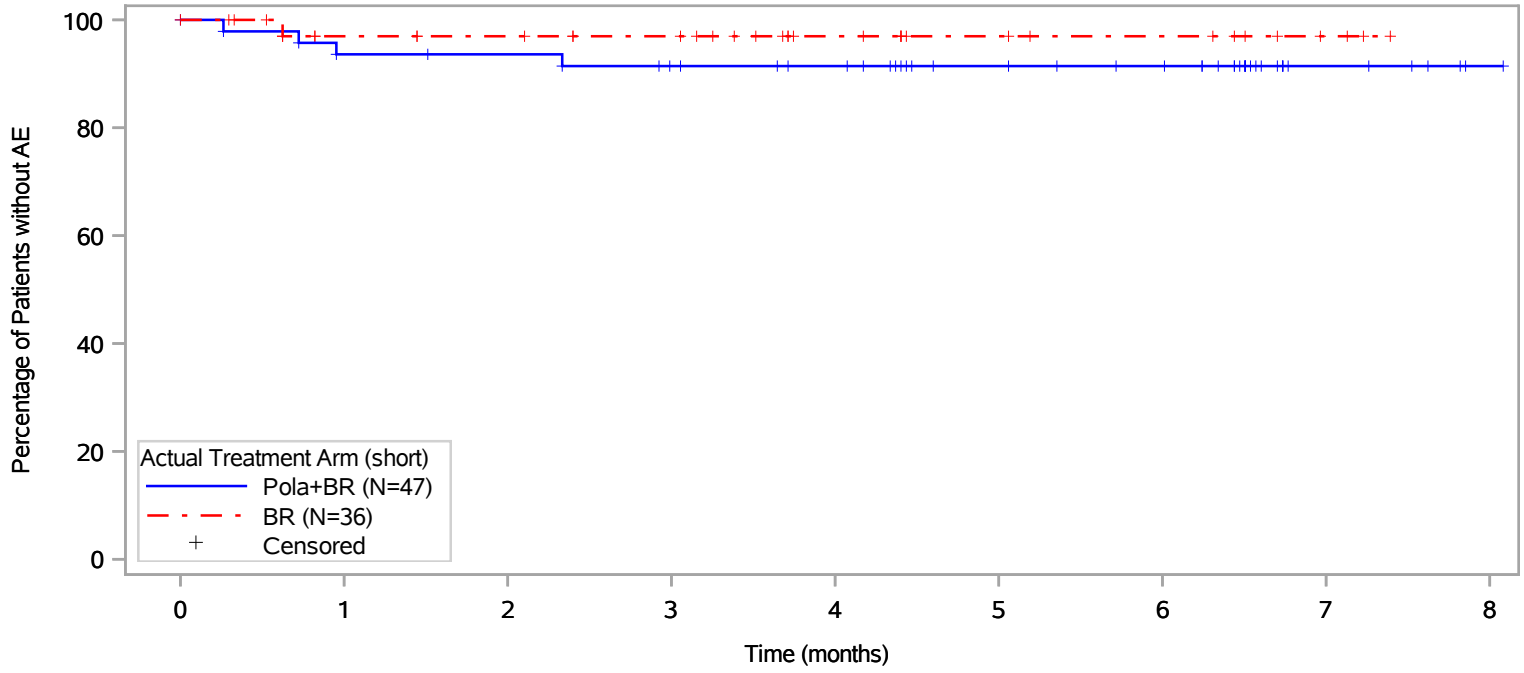
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOCALCAEMIA



Patients at risk									
Pola+BR (N=47)	47	44	43	40	37	29	26	6	1
BR (N=36)	36	29	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	6	14	17	37	42
BR (N=36)	0	6	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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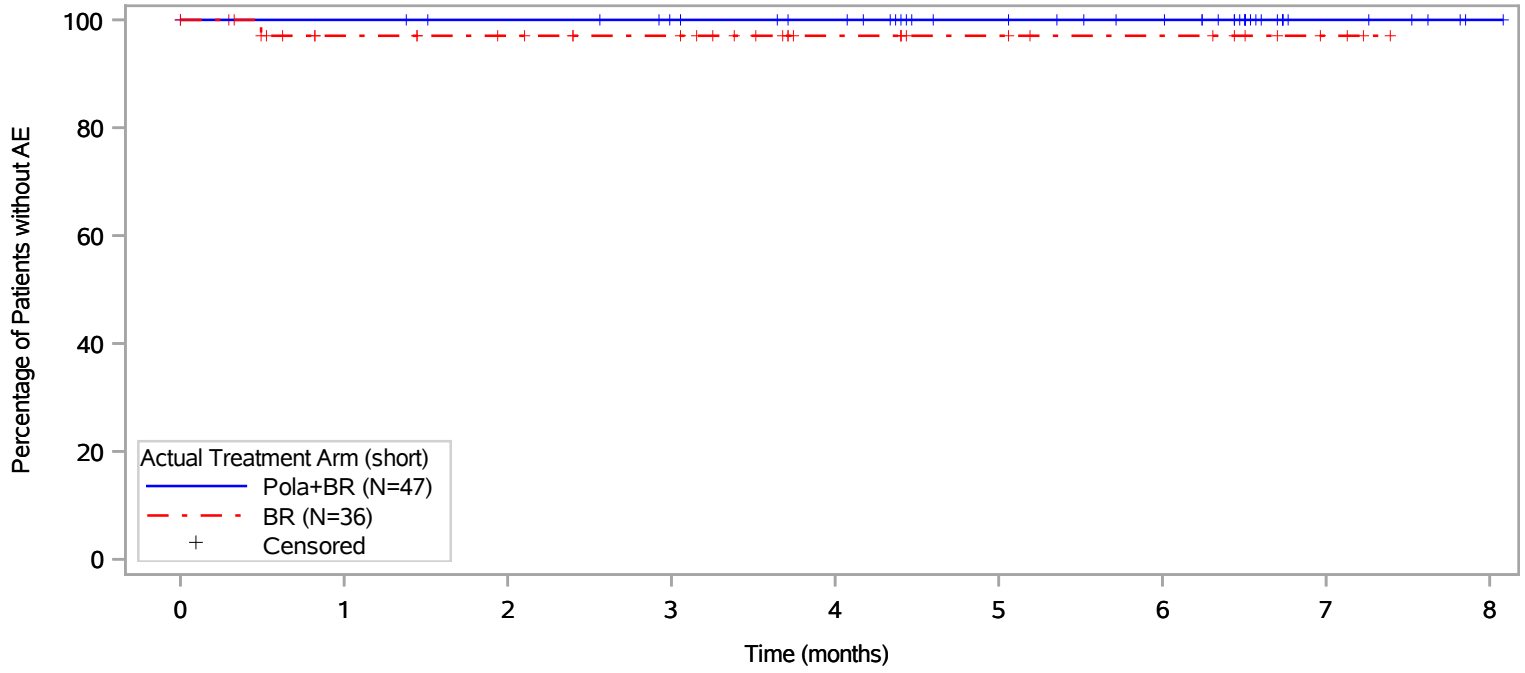
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOGLYCAEMIA

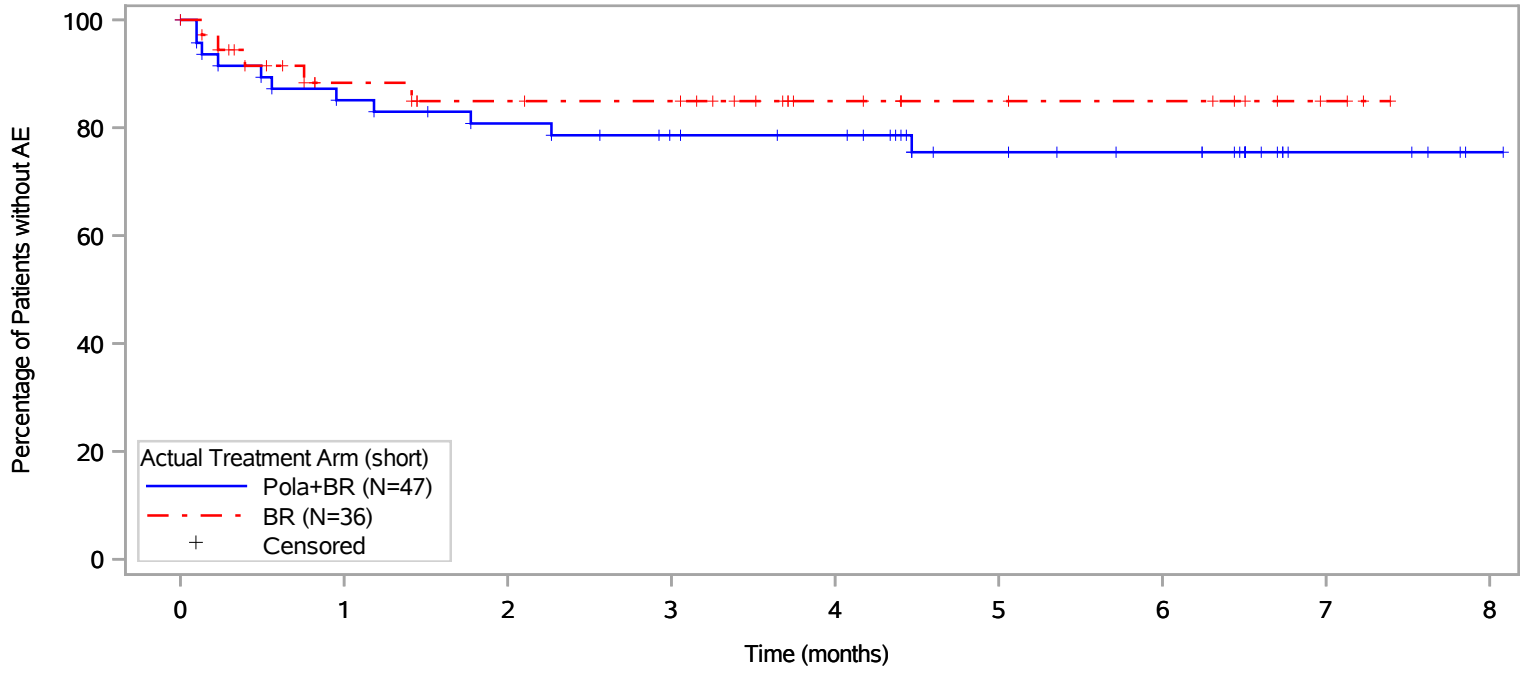


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA

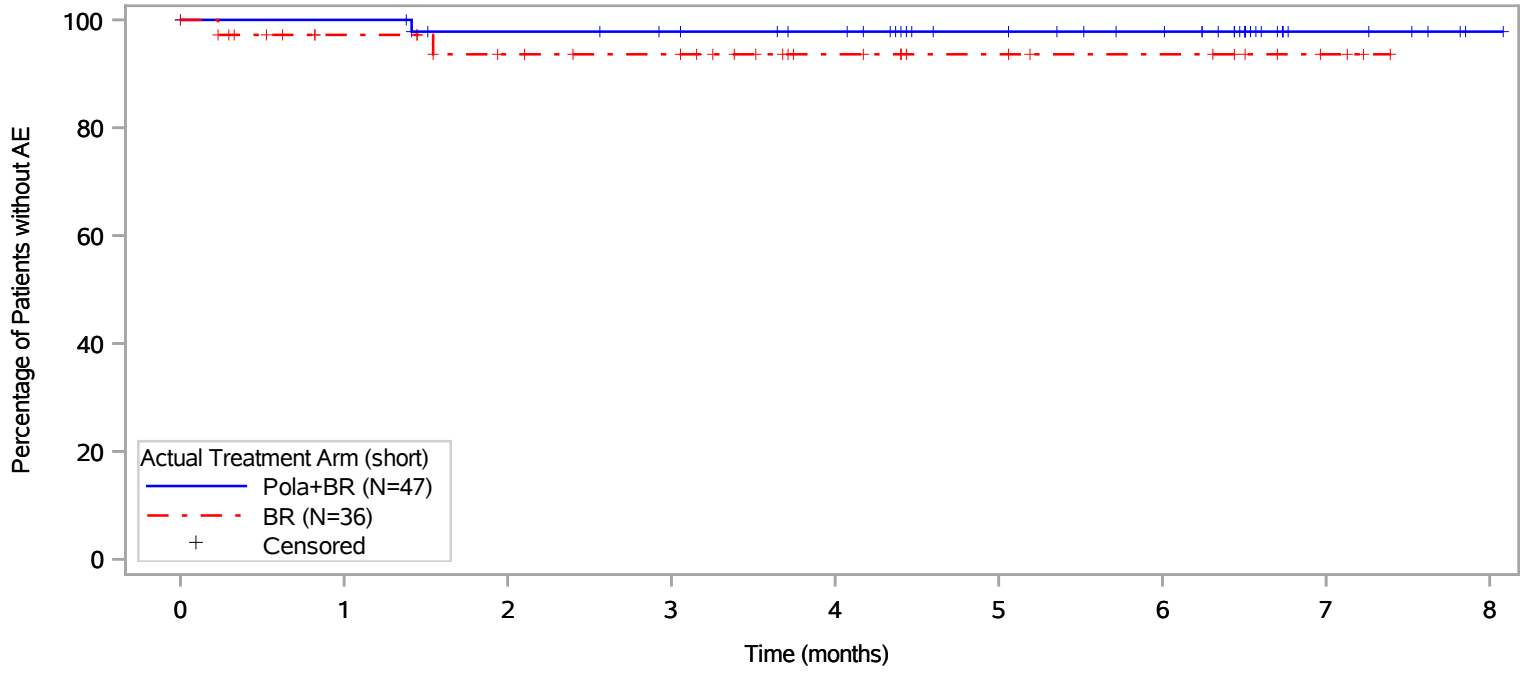


Patients at risk									
Pola+BR (N=47)	47	40	37	33	31	22	19	5	1
BR (N=36)	36	26	23	22	13	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	6	14	17	31	35
BR (N=36)	0	6	8	9	18	22	23	28	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOMAGNESAEMIA



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	29	25	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	11	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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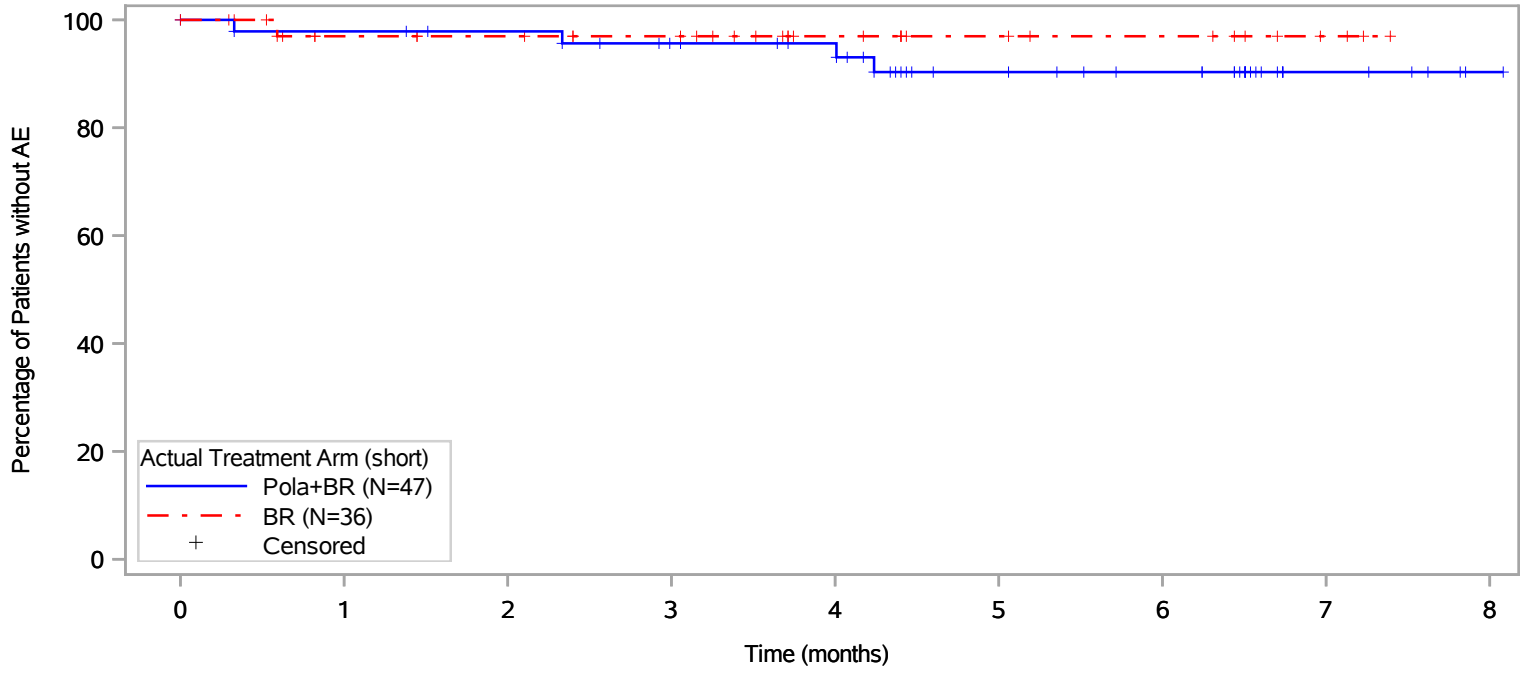
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPONATRAEMIA

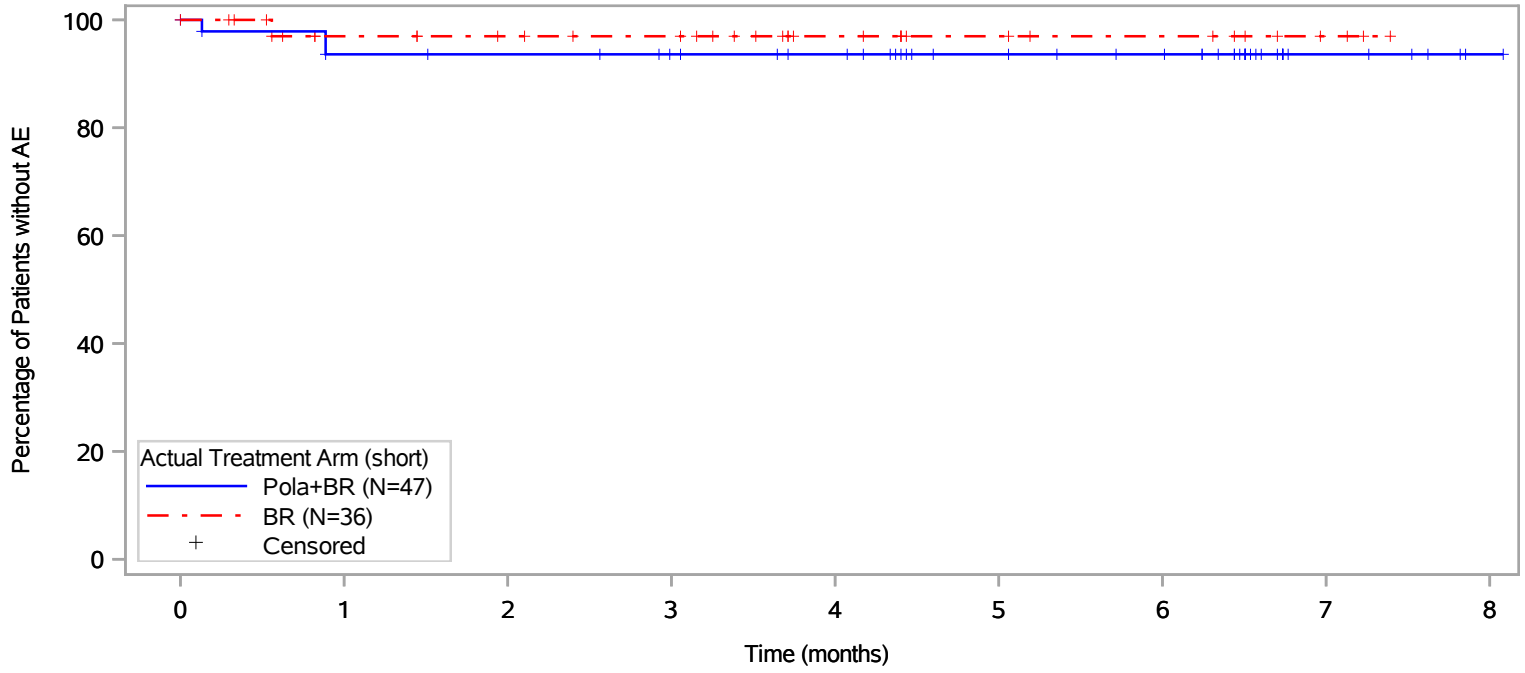


Patients at risk									
Pola+BR (N=47)	47	46	44	40	37	27	23	6	1
BR (N=36)	36	29	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	37	42
BR (N=36)	0	6	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOPHOSPHATAEMIA



Patients at risk									
Pola+BR (N=47)	47	44	43	40	37	29	26	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	18	38	43
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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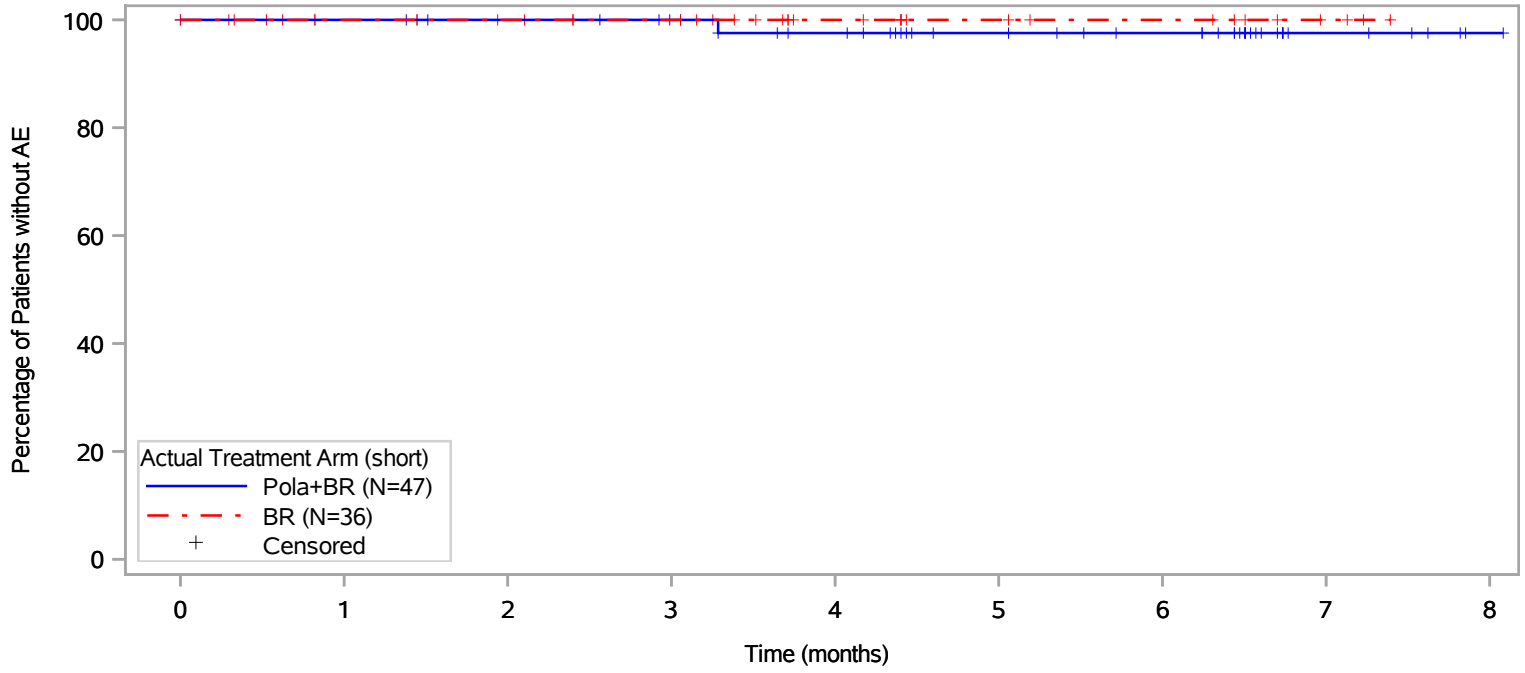
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

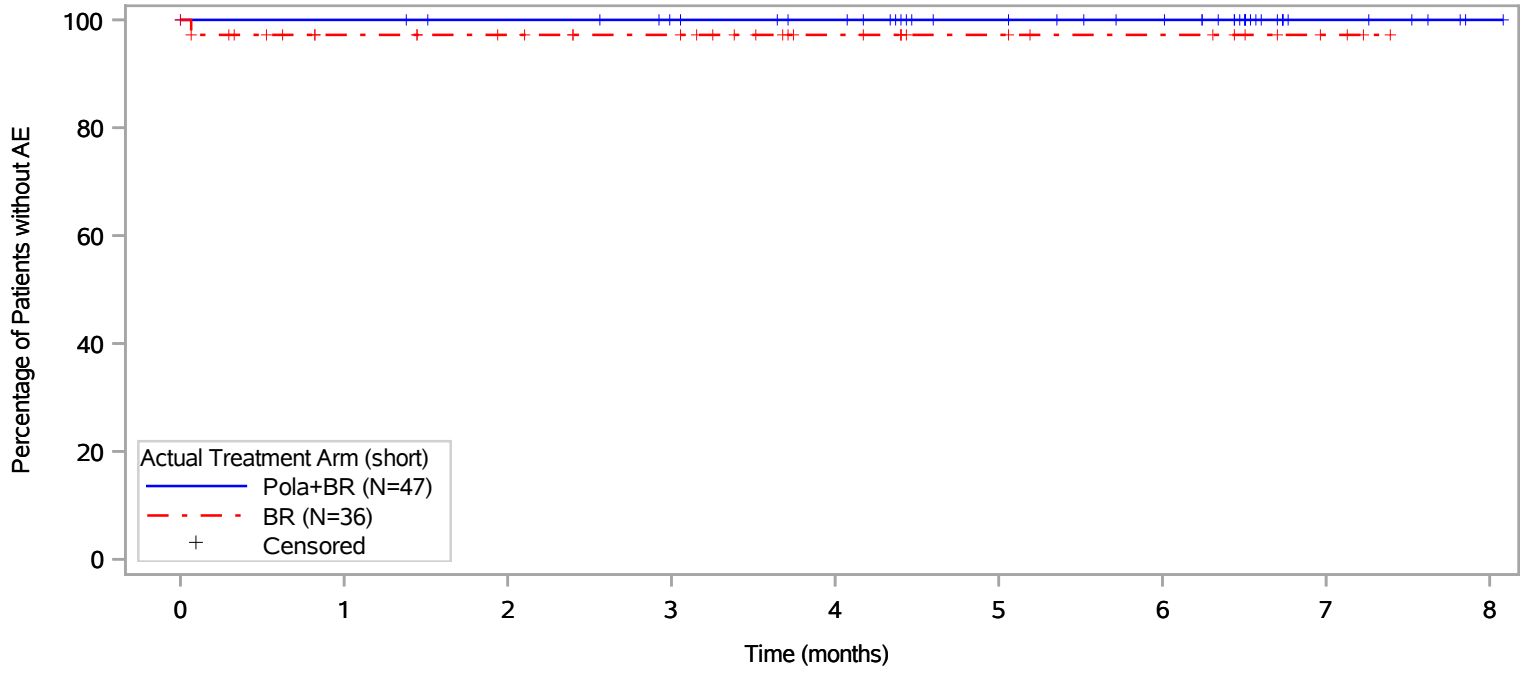
METABOLISM AND NUTRITION DISORDERS, HYPOPROTEINAEMIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

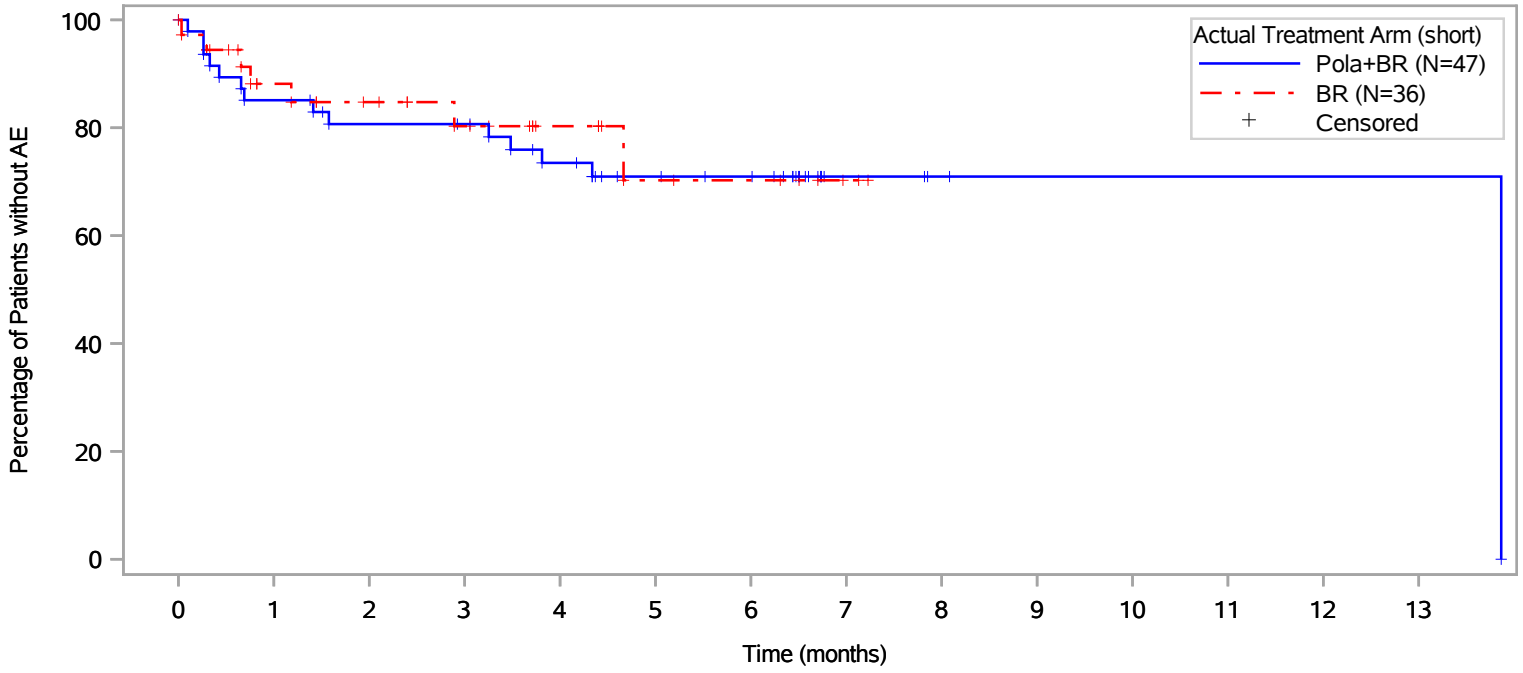
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, TYPE 2 DIABETES MELLITUS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk														
Pola+BR (N=47)	47	40	36	35	30	24	22	4	2	1	1	1	1	1
BR (N=36)	36	26	22	18	12	7	6	2	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	3	5	10	12	30	32	33	33	33	33	33
BR (N=36)	0	6	9	12	18	22	23	27	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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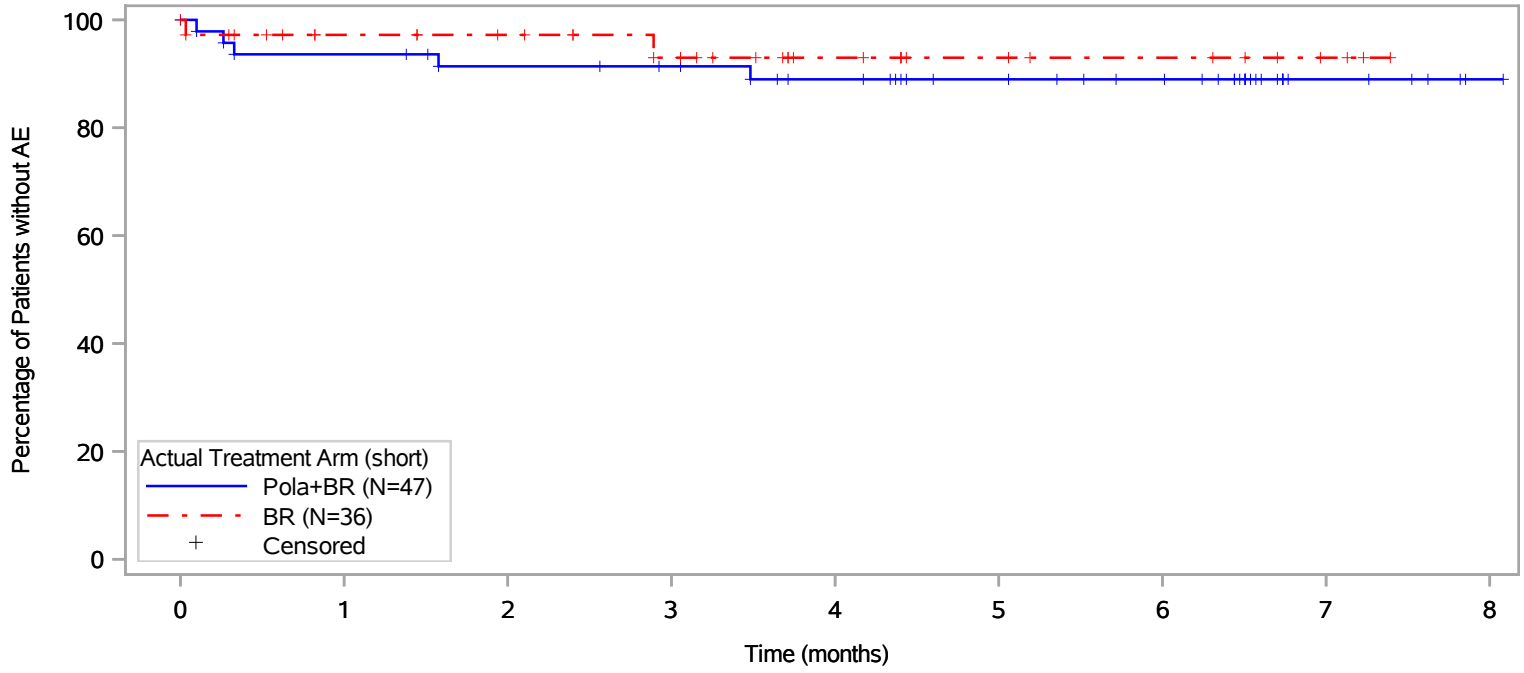
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, ARTHRALGIA



Patients at risk									
Pola+BR (N=47)	47	44	41	39	35	29	25	6	1
BR (N=36)	36	29	26	22	14	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	13	17	36	41
BR (N=36)	0	6	9	12	20	25	27	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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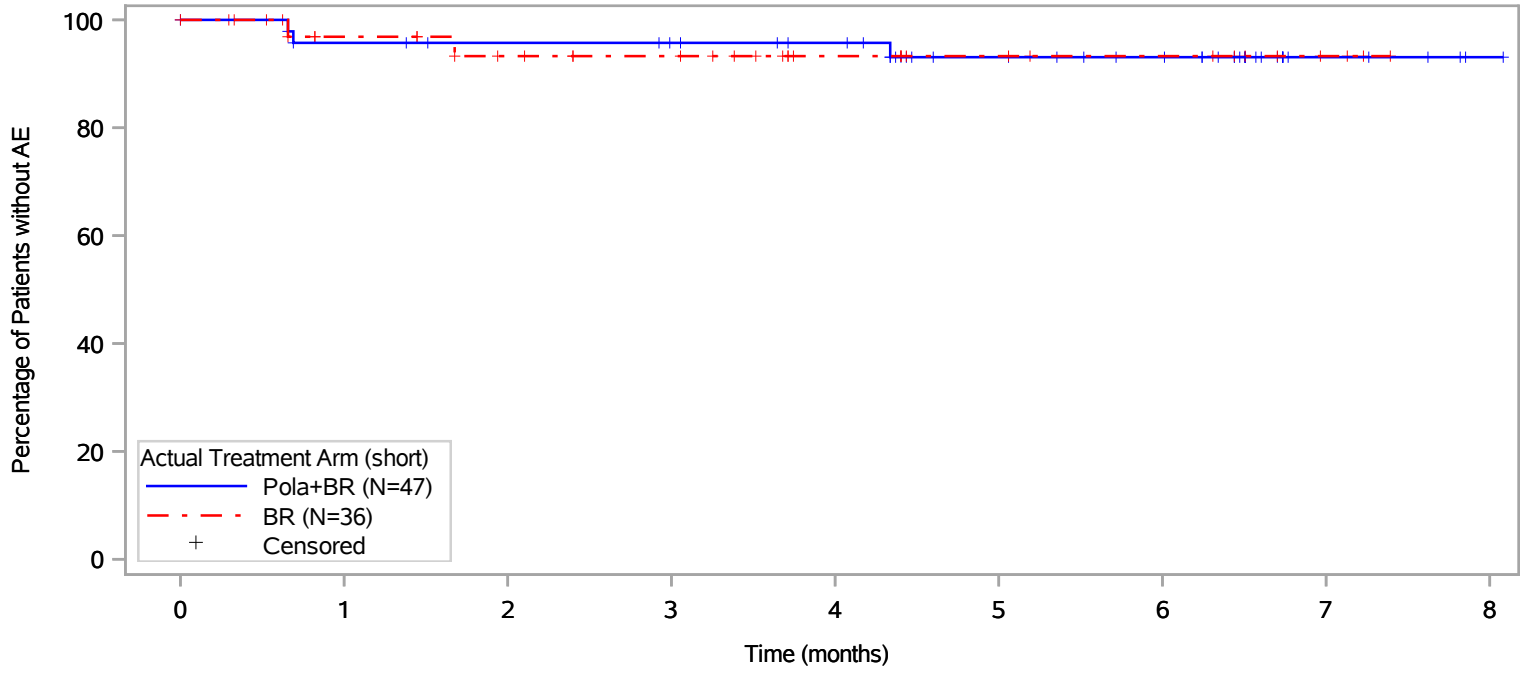
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN



Patients at risk									
Pola+BR (N=47)	47	45	43	41	38	29	25	5	1
BR (N=36)	36	29	25	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	39	43
BR (N=36)	0	6	9	12	20	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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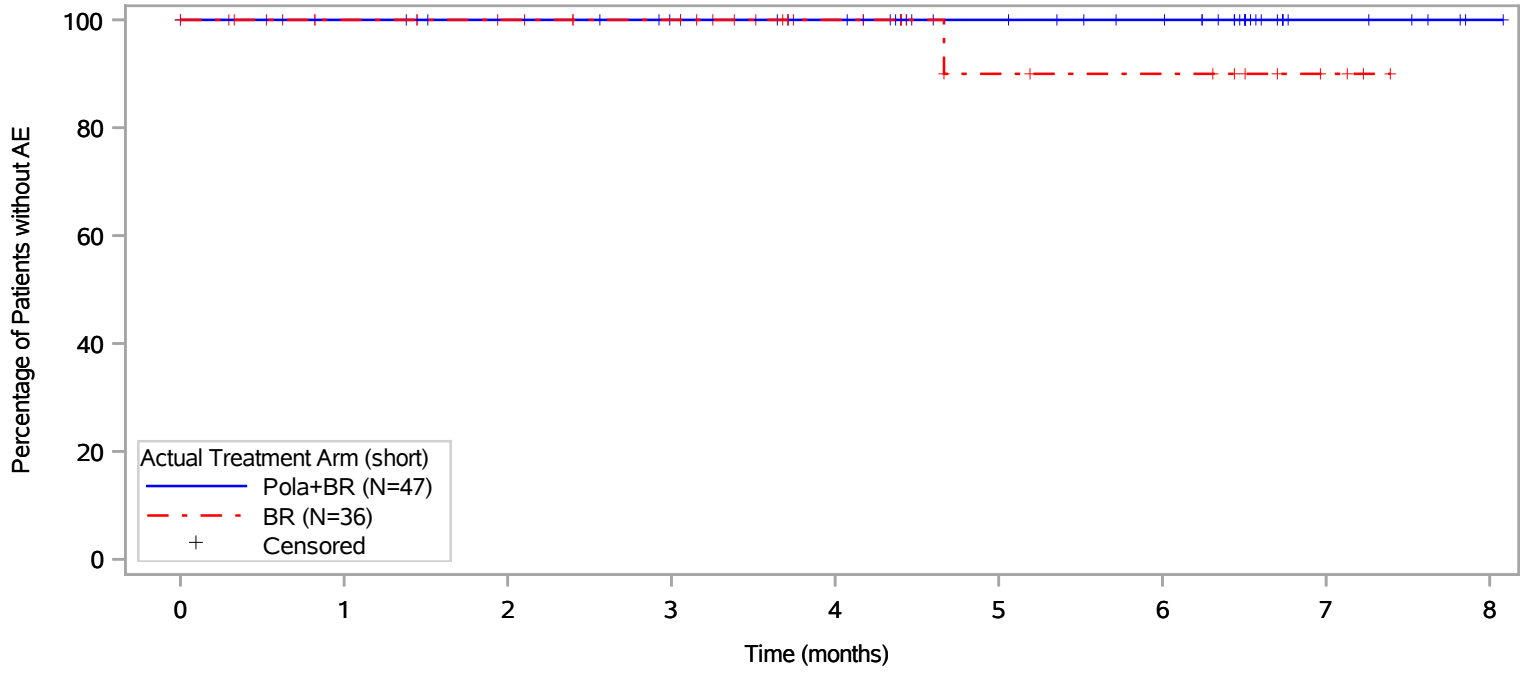
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, GROIN PAIN

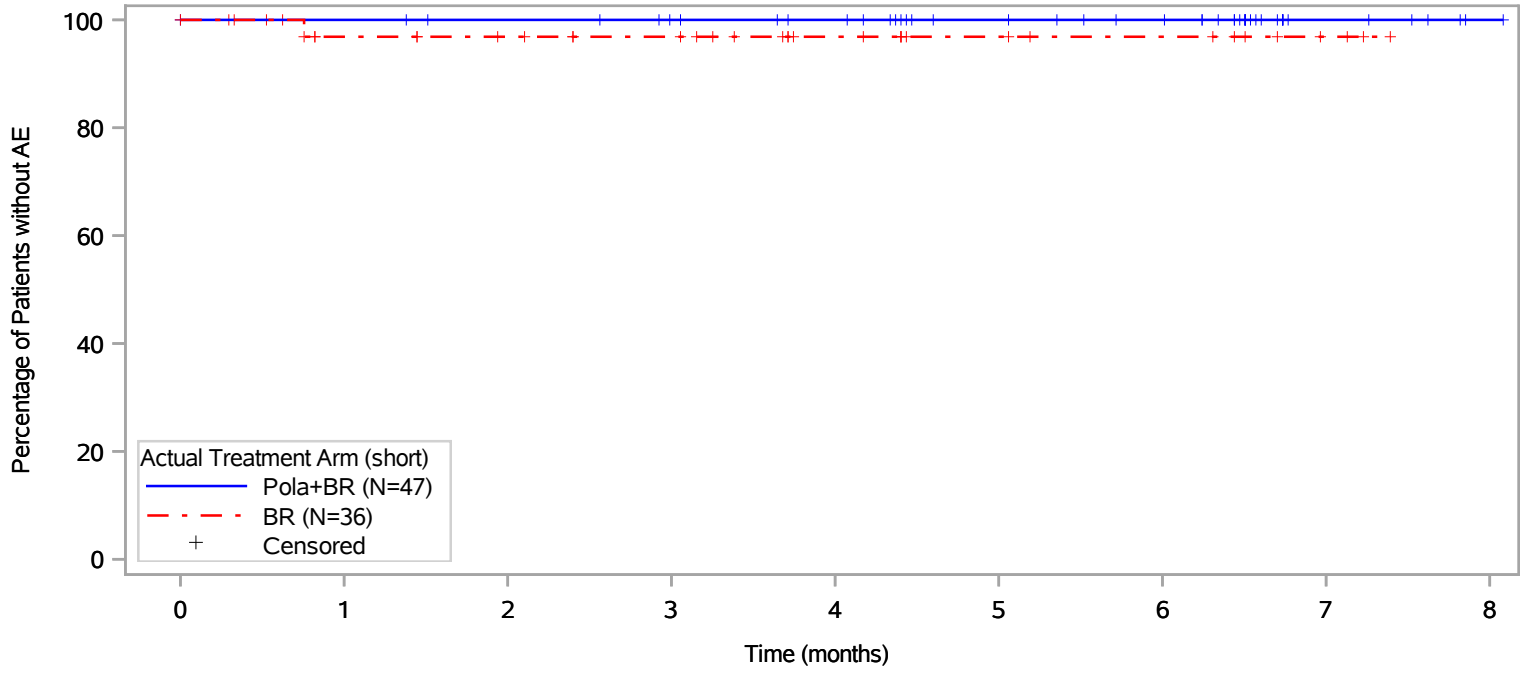


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, INTERVERTEBRAL DISC PROTRUSION

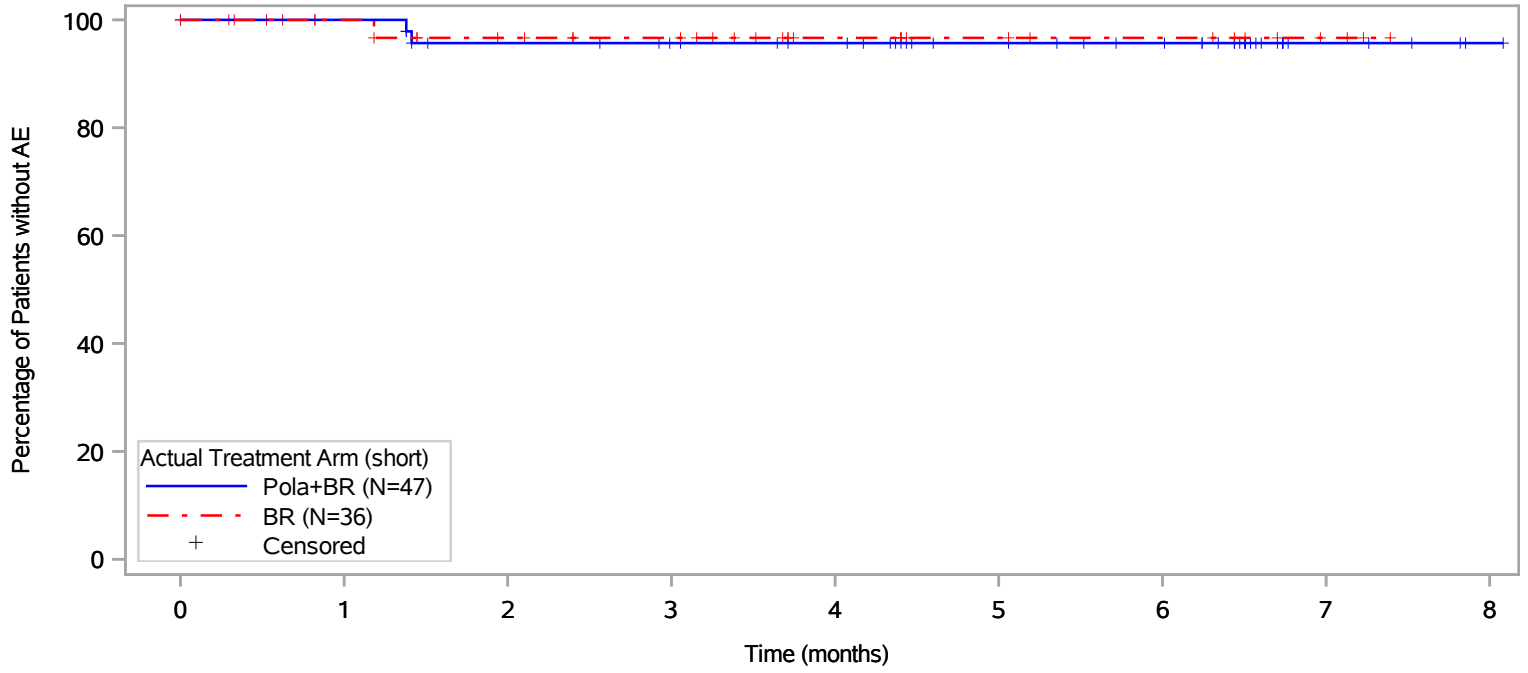


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCLE SPASMS

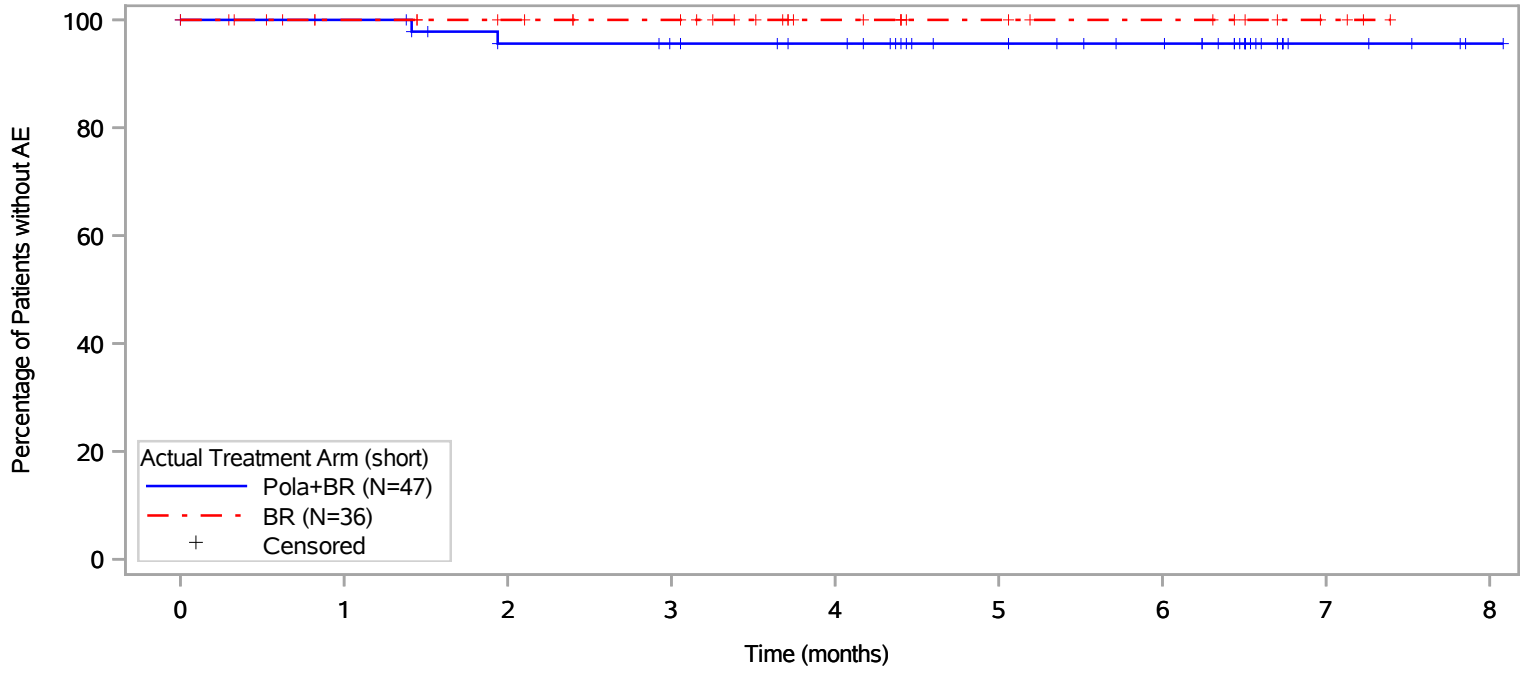


Patients at risk									
Pola+BR (N=47)	47	47	43	40	37	29	25	5	1
BR (N=36)	36	30	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	44
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULAR WEAKNESS



Patients at risk									
Pola+BR (N=47)	47	47	43	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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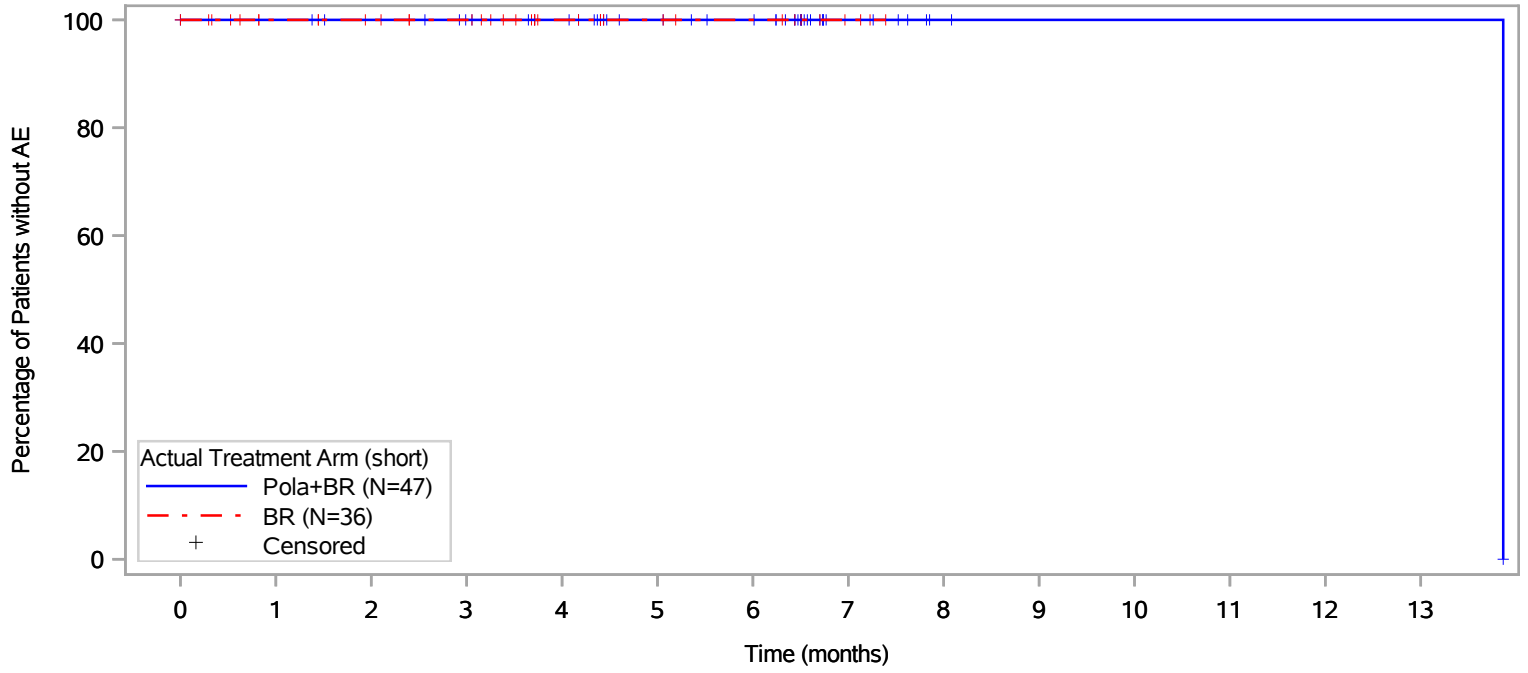
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULOSKELETAL CHEST PAIN



Patients at risk														
Pola+BR (N=47)	47	47	45	42	39	31	28	7	2	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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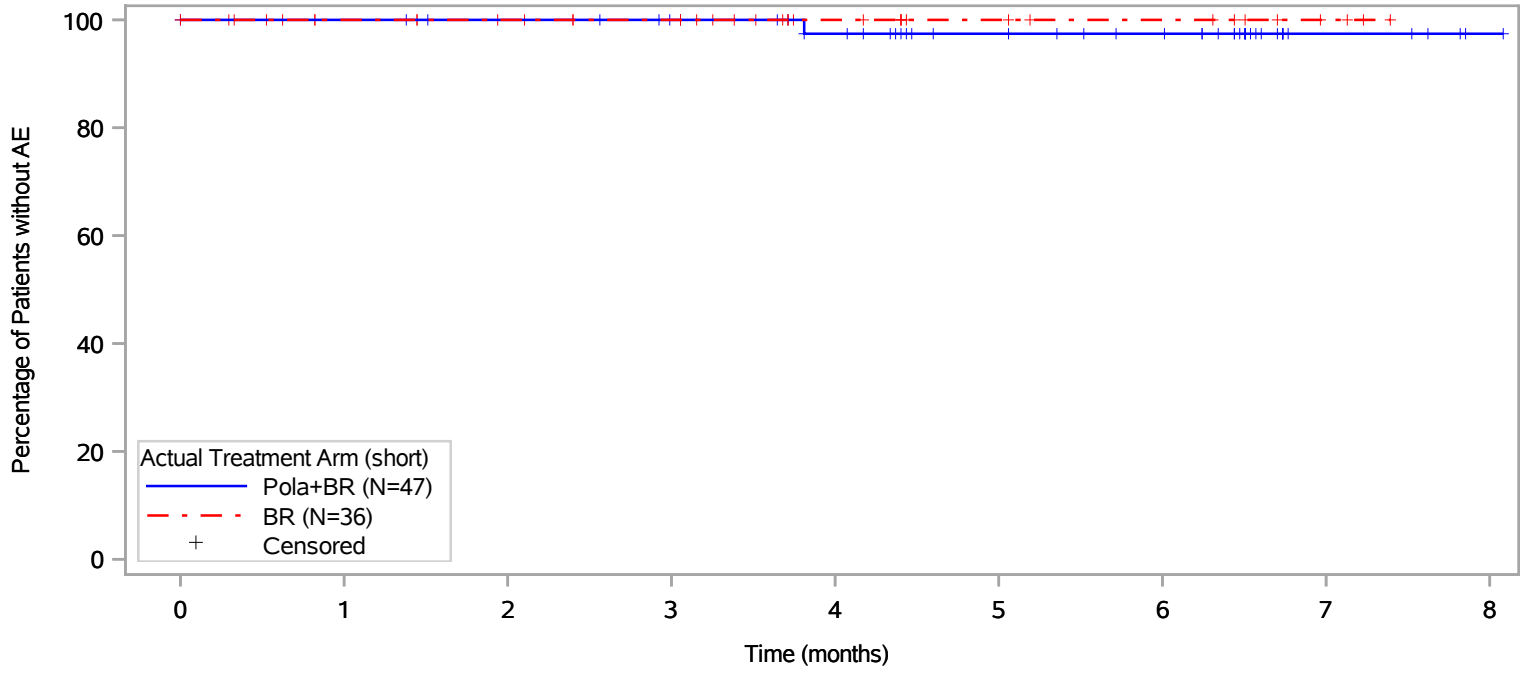
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULOSKELETAL PAIN



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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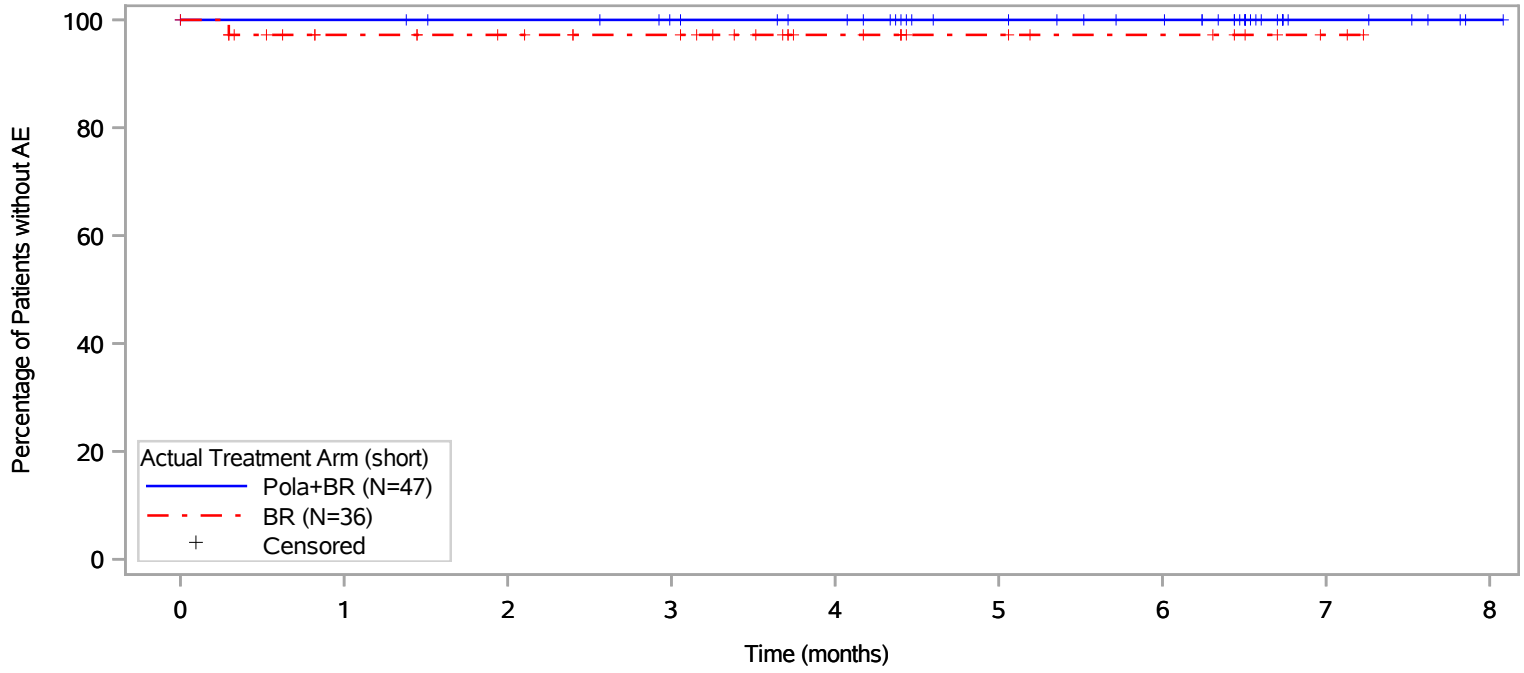
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MYALGIA



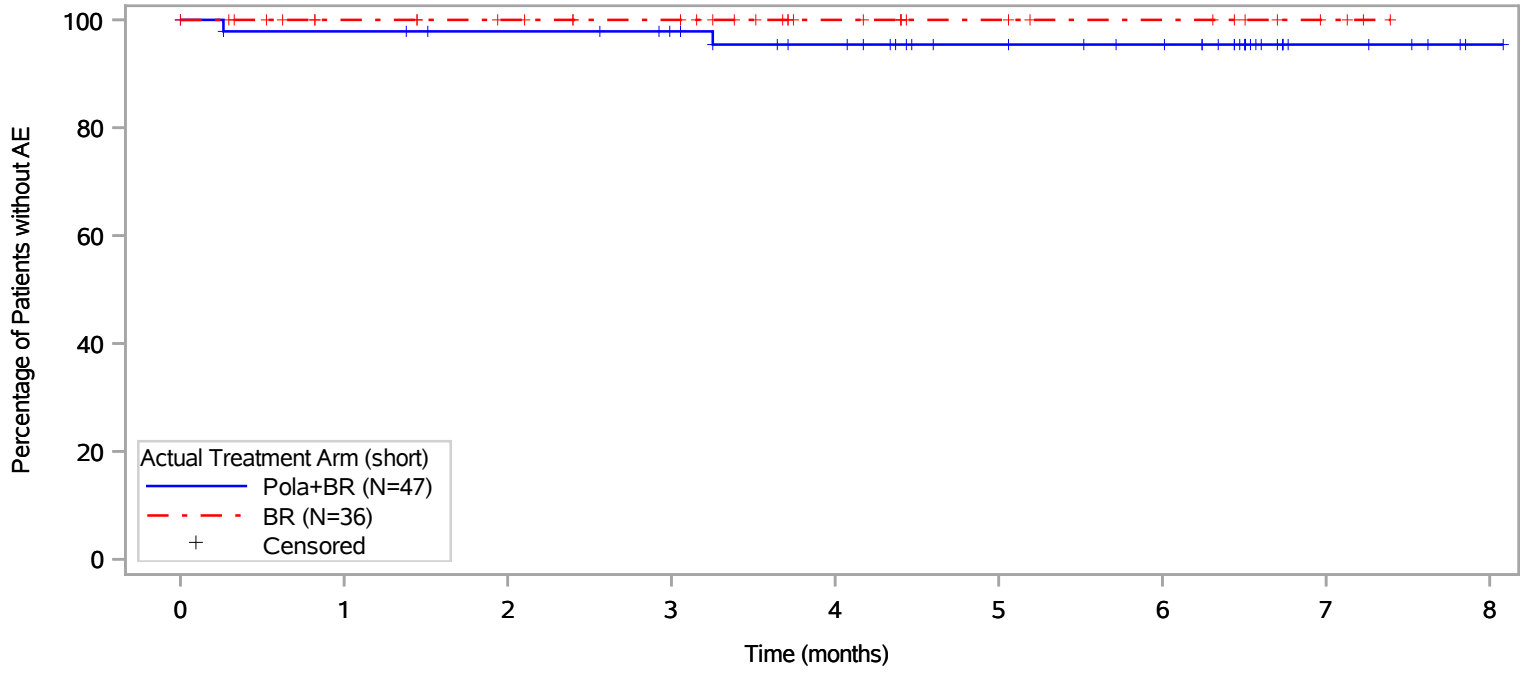
Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, NECK PAIN



Patients at risk									
Pola+BR (N=47)	47	46	44	41	37	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	18	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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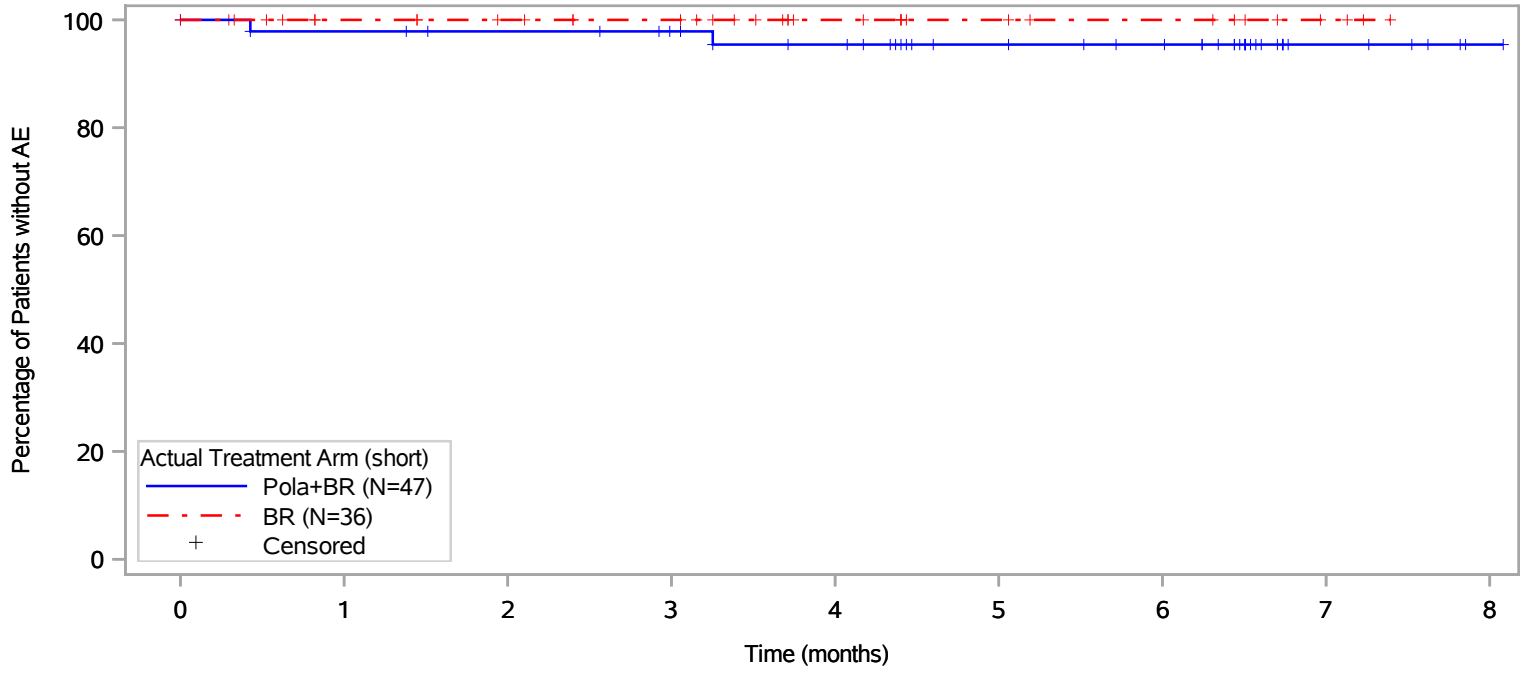
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, PAIN IN EXTREMITY



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	18	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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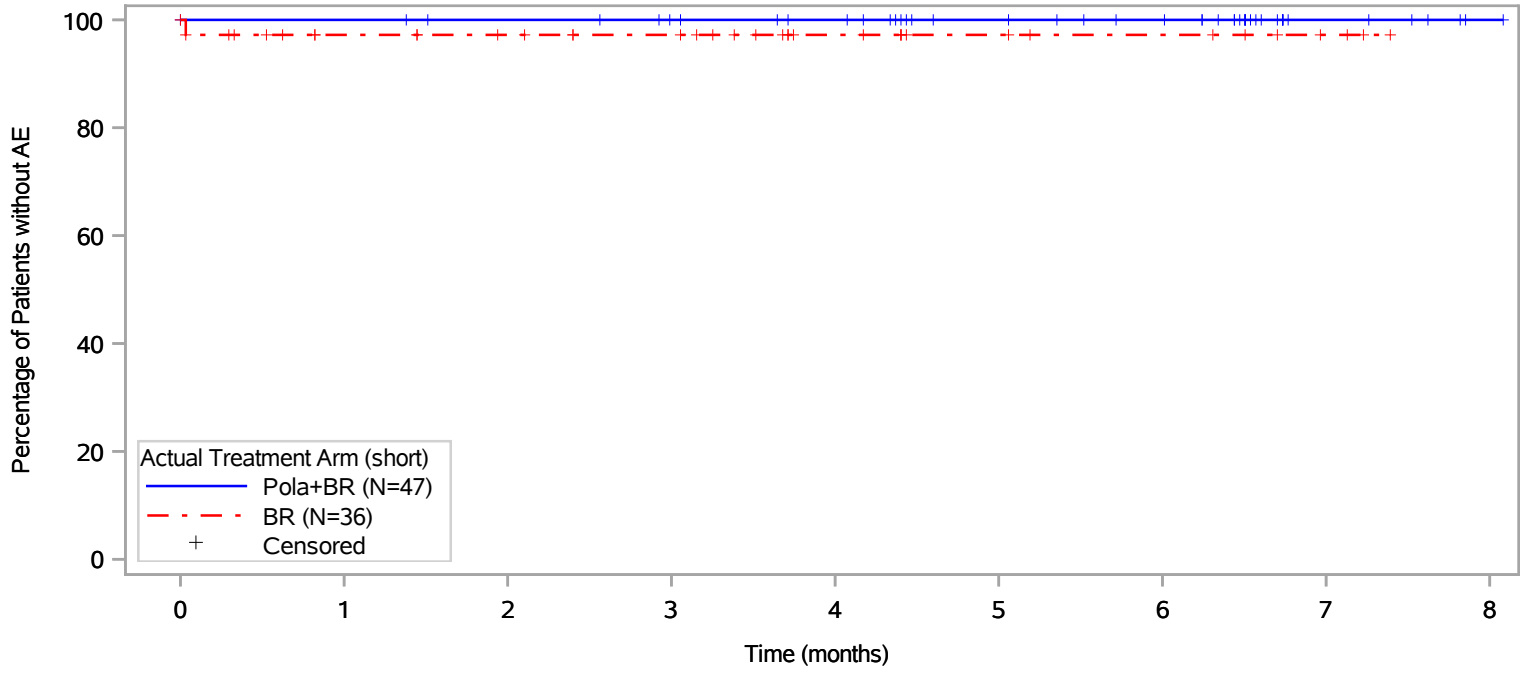
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, SPINAL PAIN



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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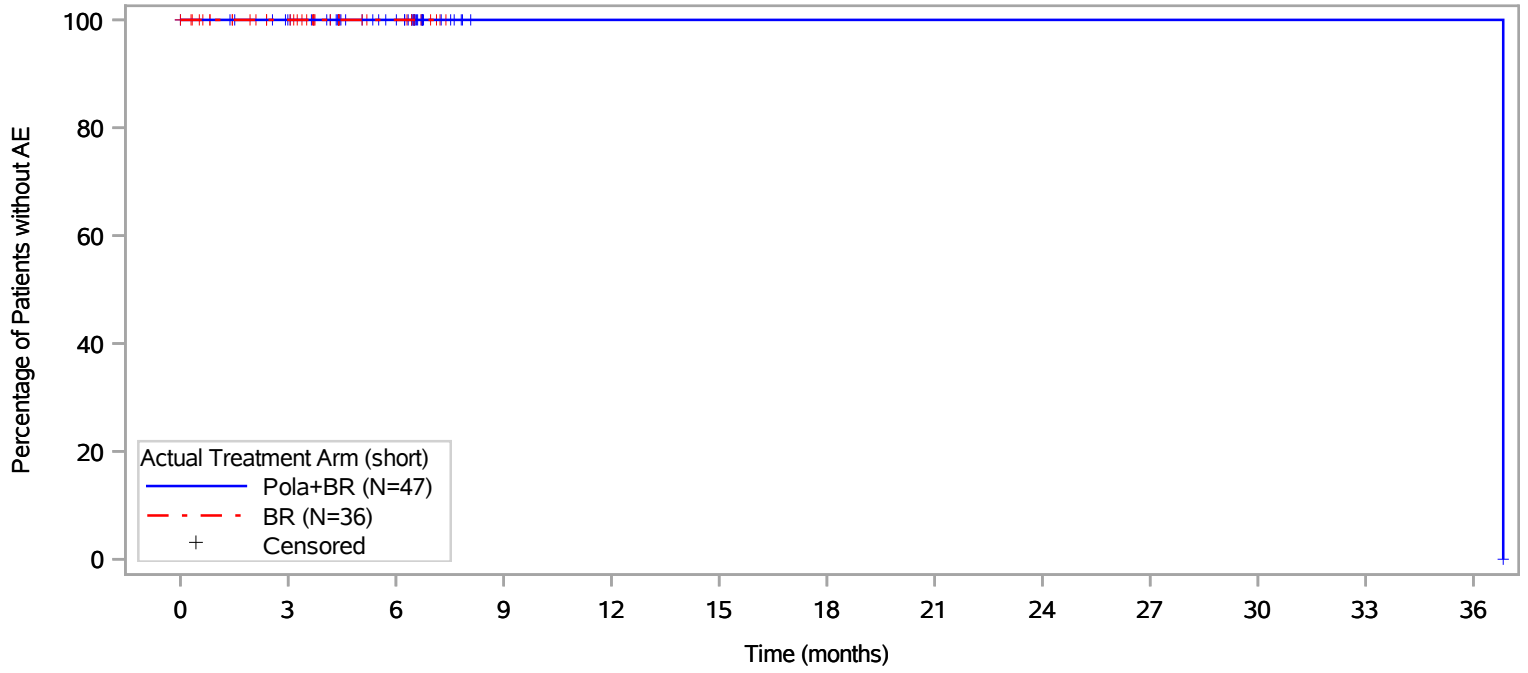
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk													
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=47)	0	5	20	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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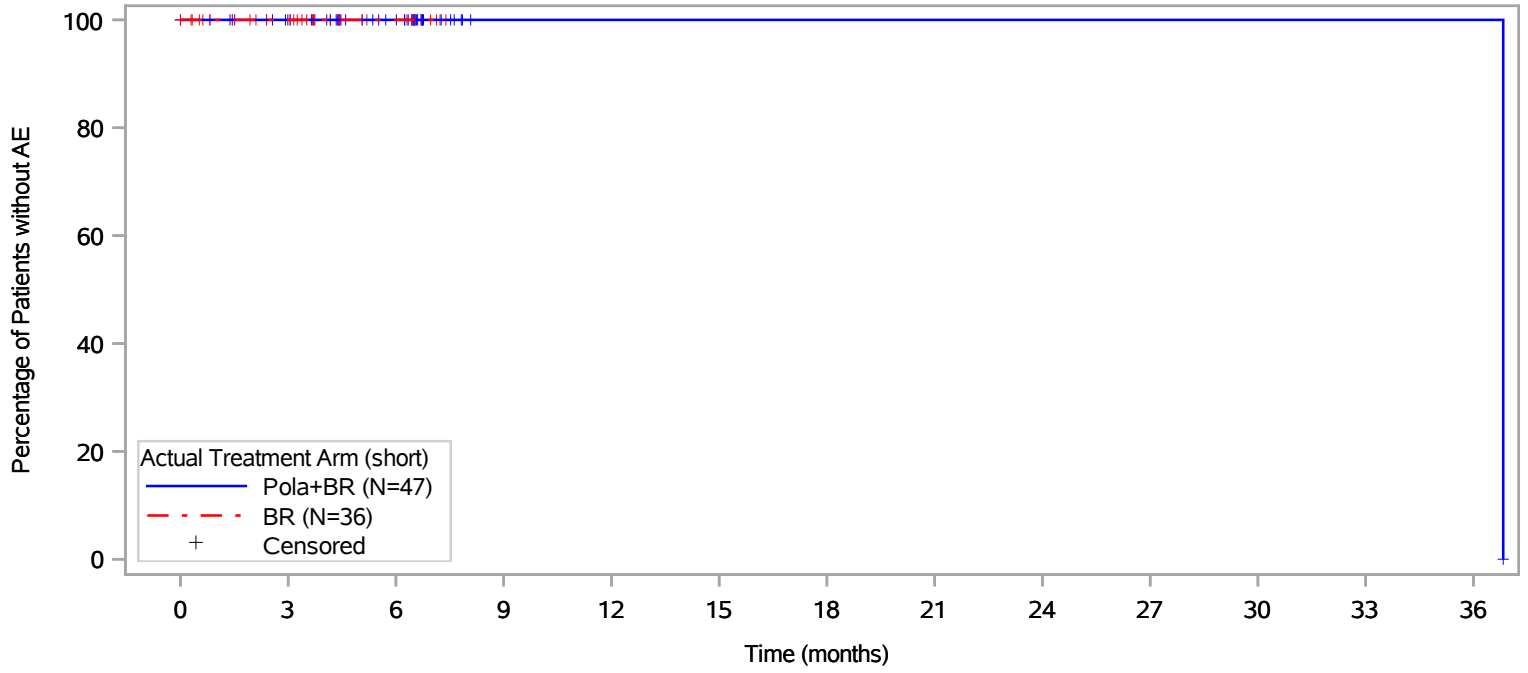
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MALIGNANT MELANOMA

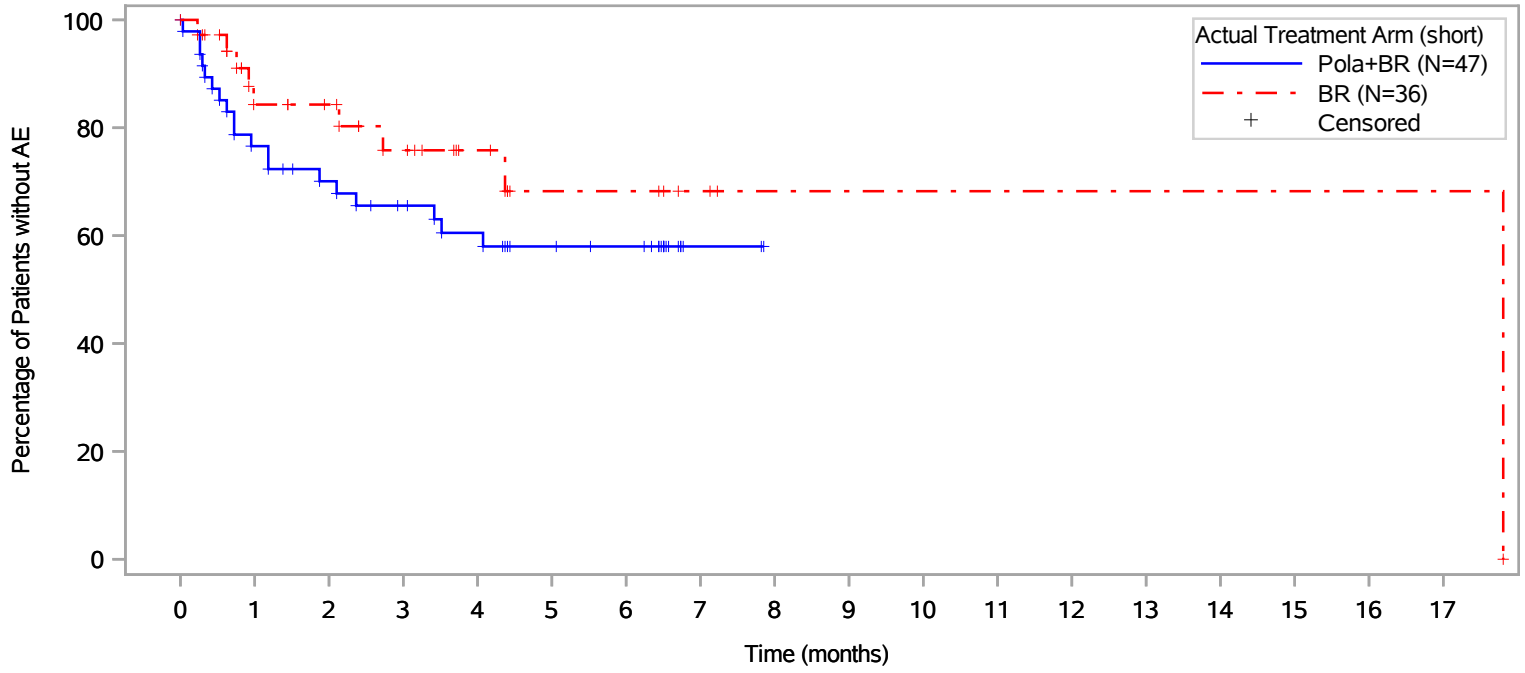


Patients at risk													
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=47)	0	5	20	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk																		
Pola+BR (N=47)	47	36	31	27	24	19	17	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	25	22	17	11	6	6	3	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=47)	0	0	2	4	5	9	11	26	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	18	22	22	25	27	27	27	27	27	27	27	27	27	27

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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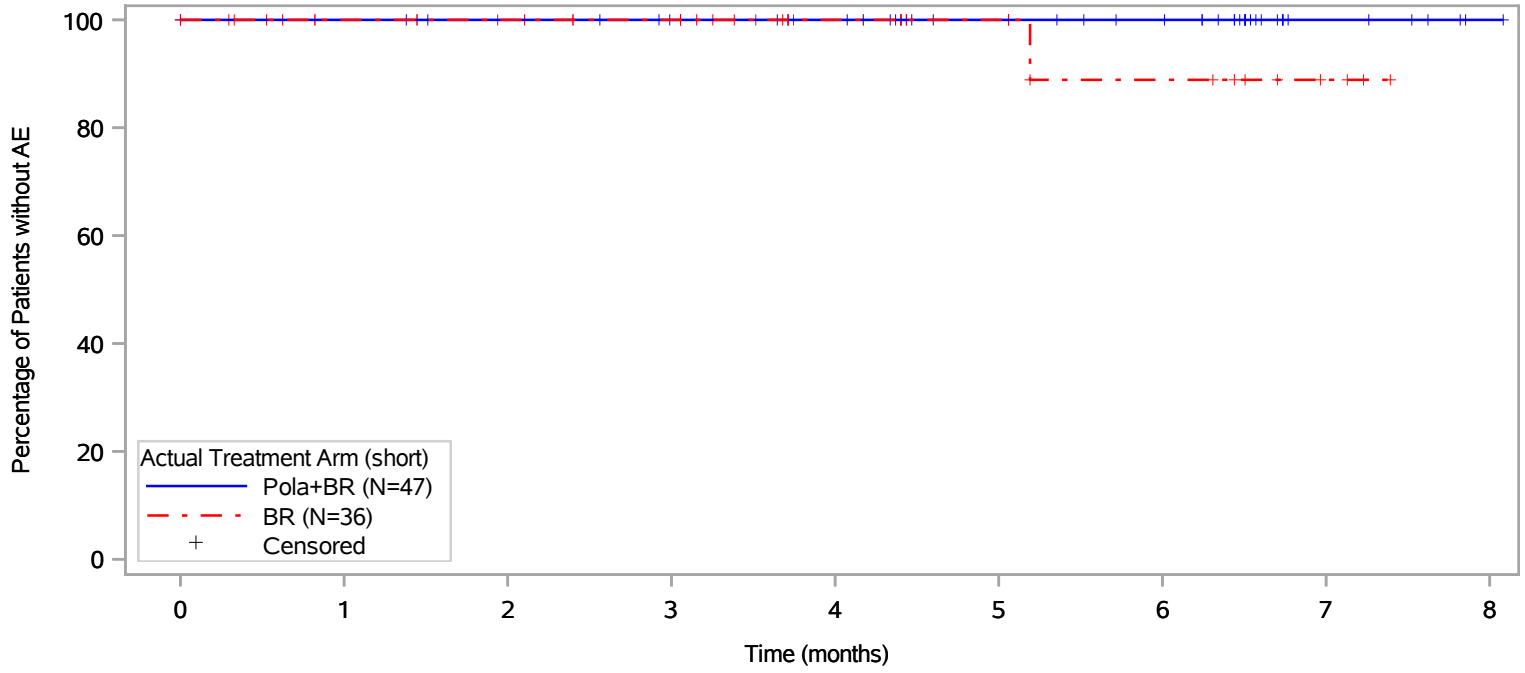
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, CEREBRAL HAEMORRHAGE

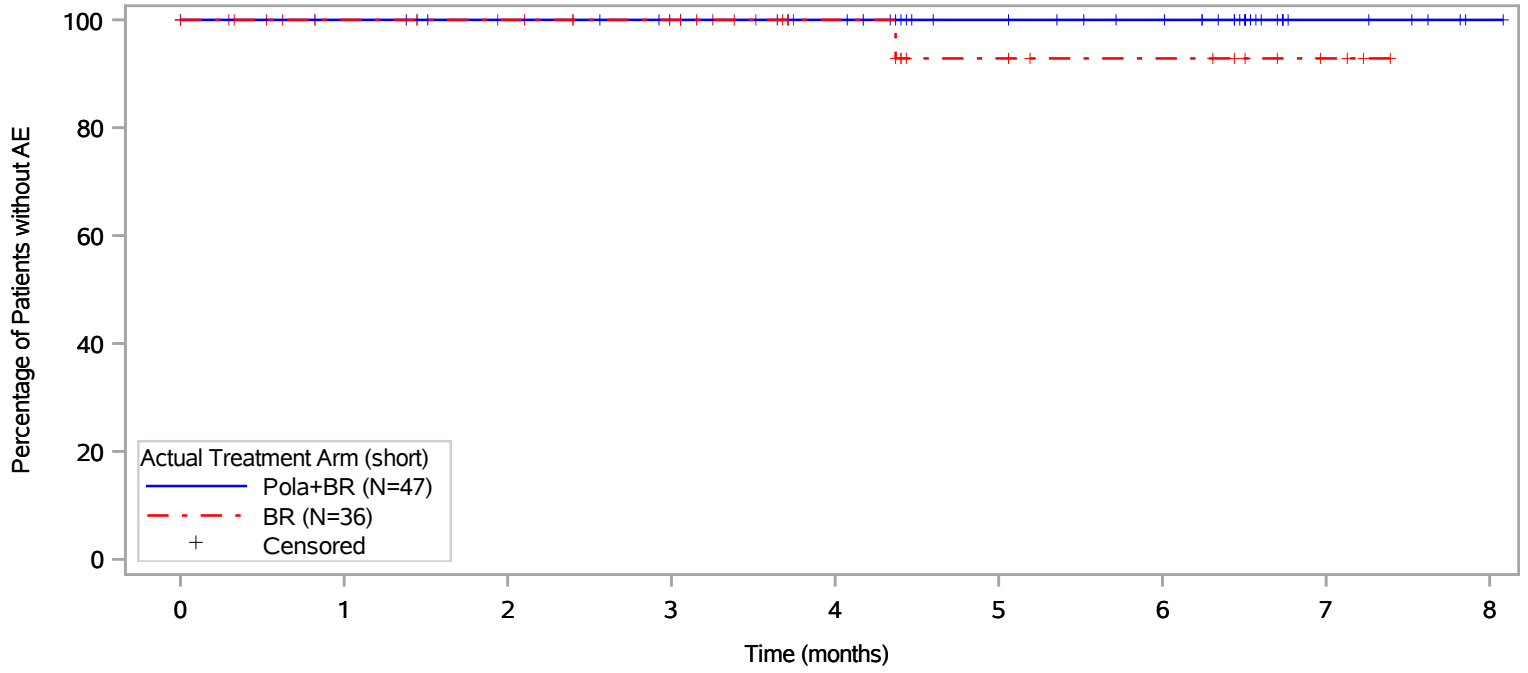


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, CEREBROVASCULAR ACCIDENT



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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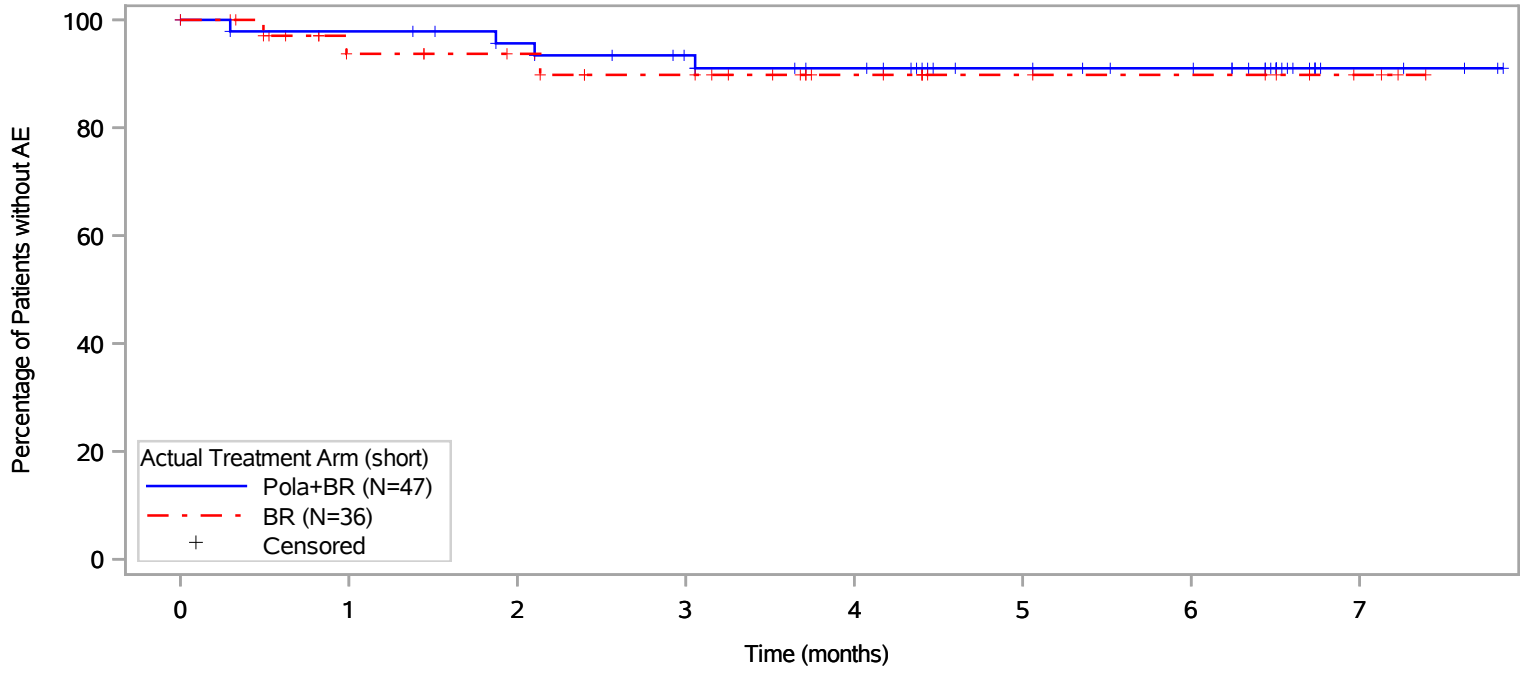
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, DIZZINESS



Patients at risk								
Pola+BR (N=47)	47	46	43	39	35	27	24	4
BR (N=36)	36	28	25	21	13	8	7	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	16	19	39
BR (N=36)	0	6	9	12	20	25	26	30

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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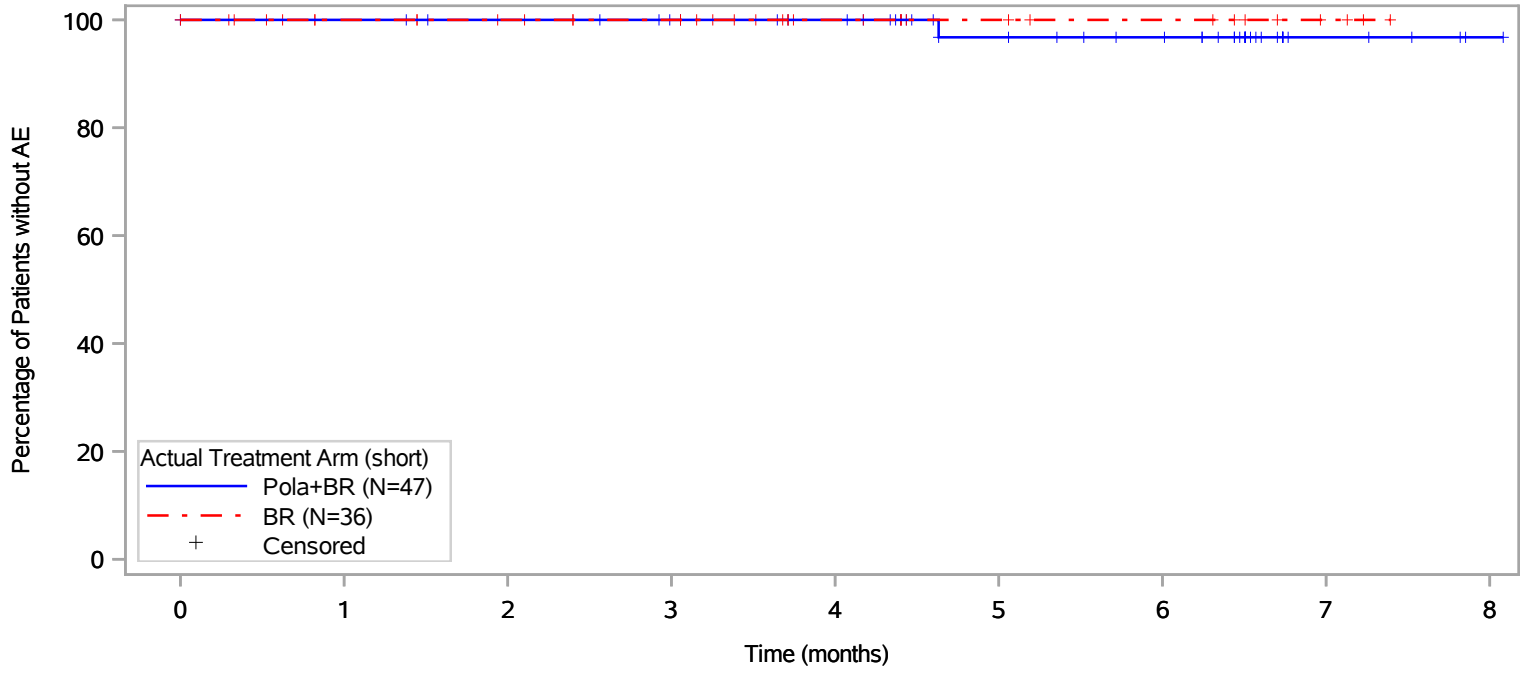
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, DYSGEUSIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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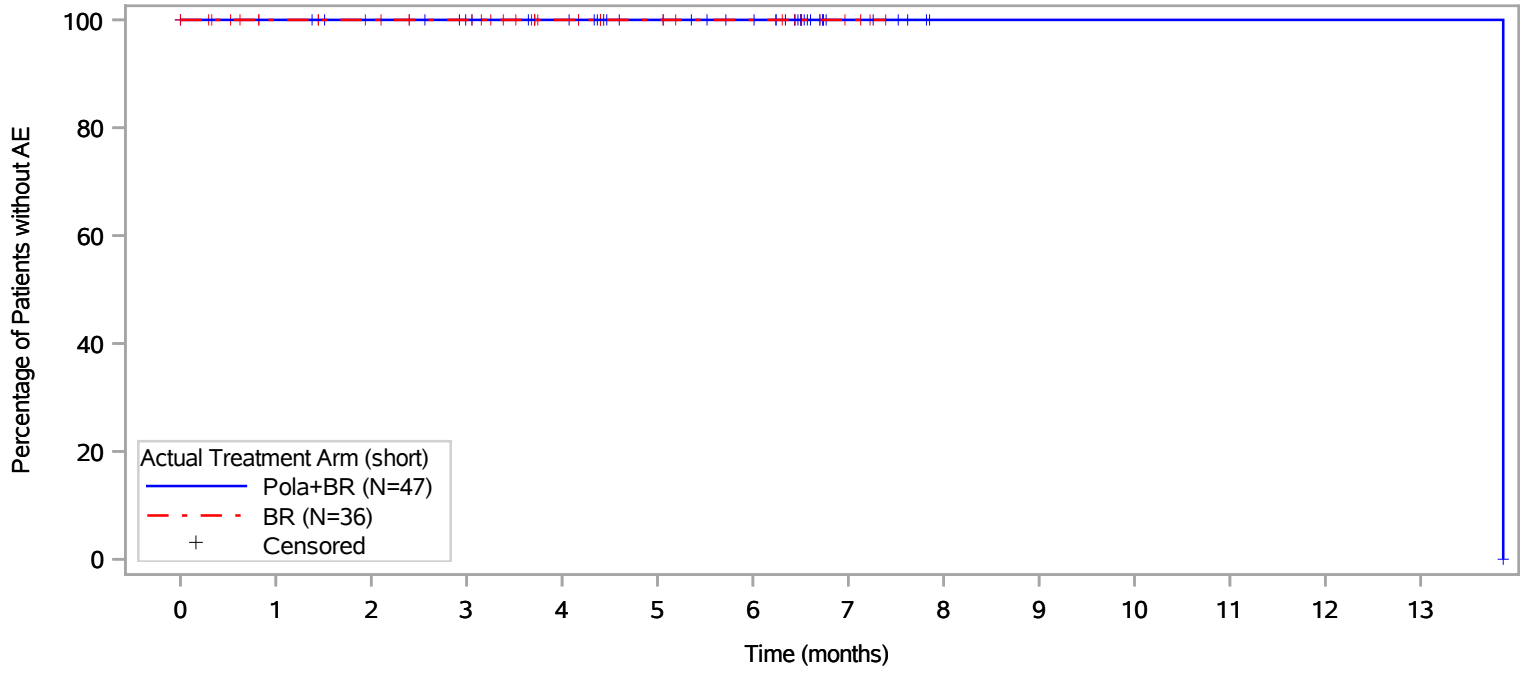
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HAEMORRHAGE INTRACRANIAL



Patients at risk														
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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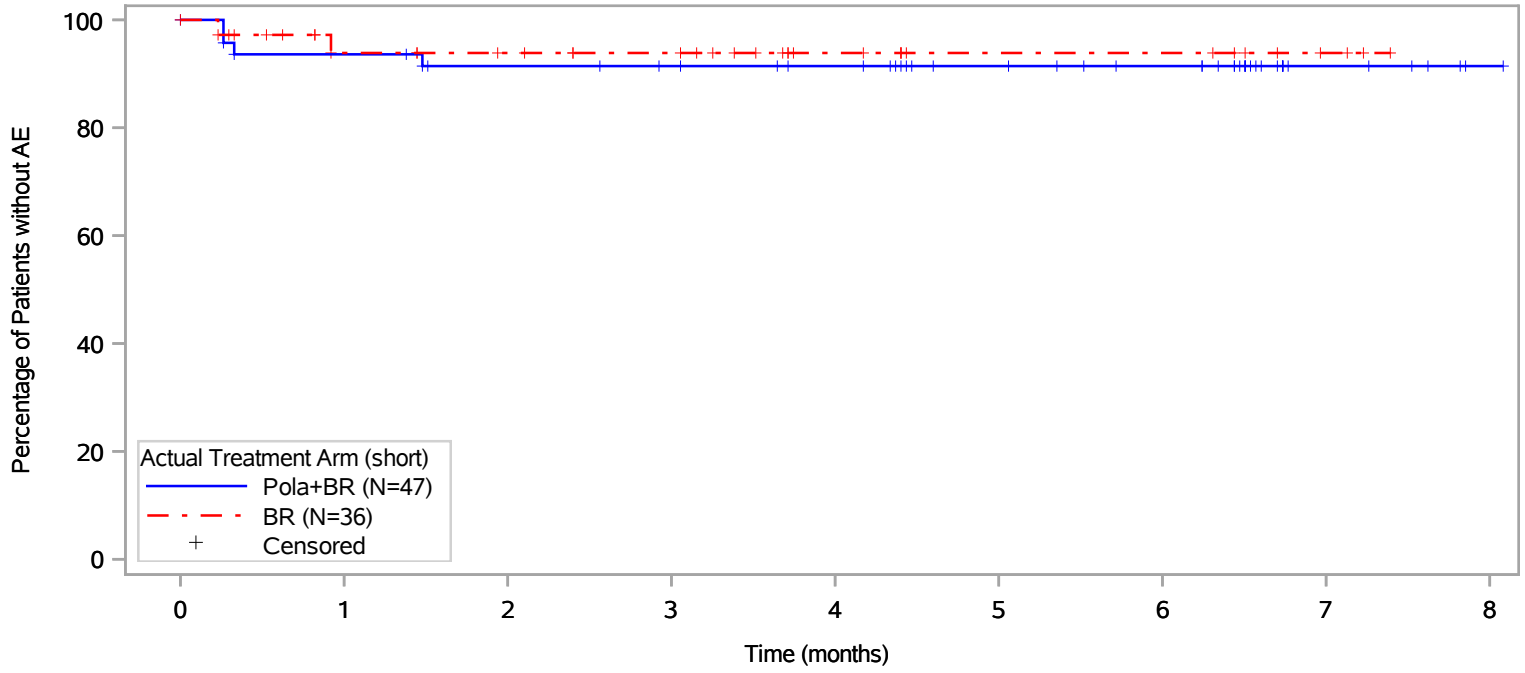
01DEC2022 22:30

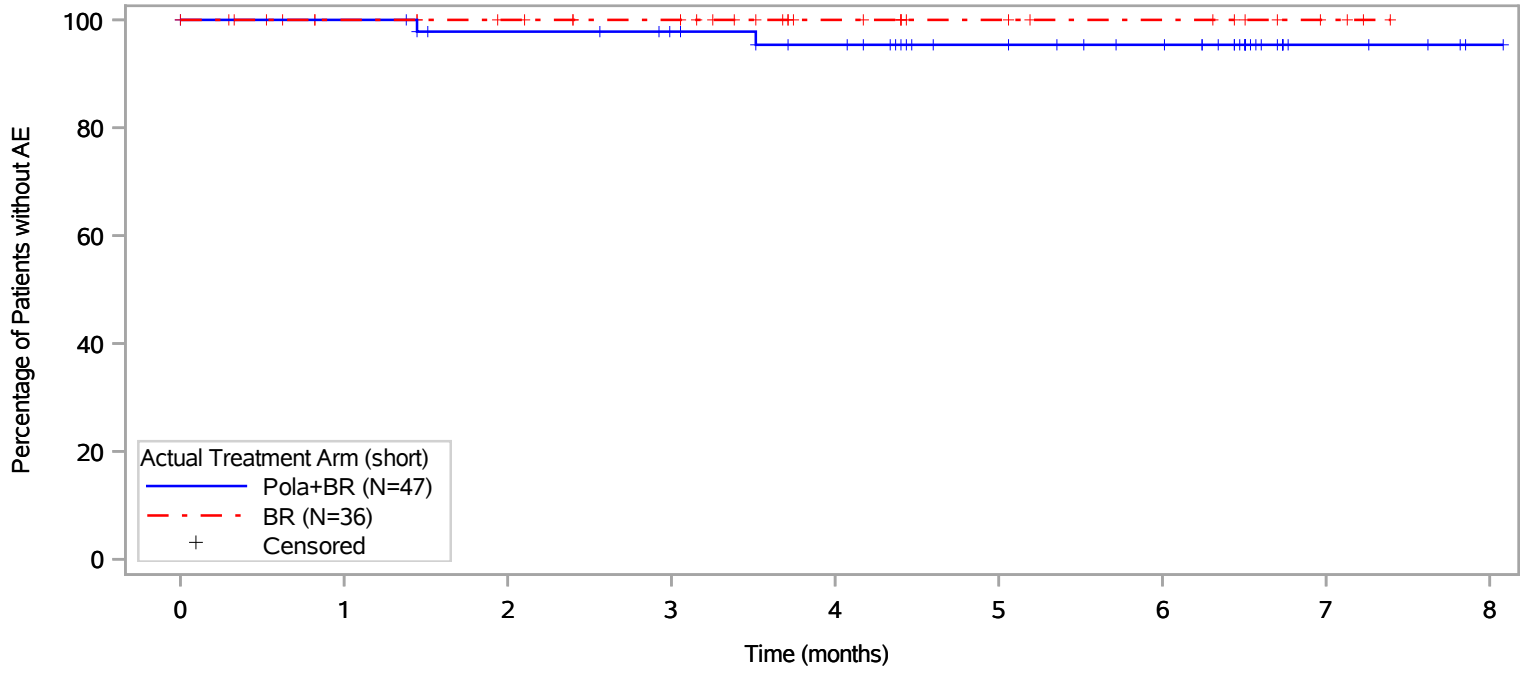
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, HEADACHE



Patients at risk									
Pola+BR (N=47)	47	44	41	39	36	29	25	6	1
BR (N=36)	36	28	25	22	13	8	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	18	37	42
BR (N=36)	0	6	9	12	21	26	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, HYPOAESTHESIA



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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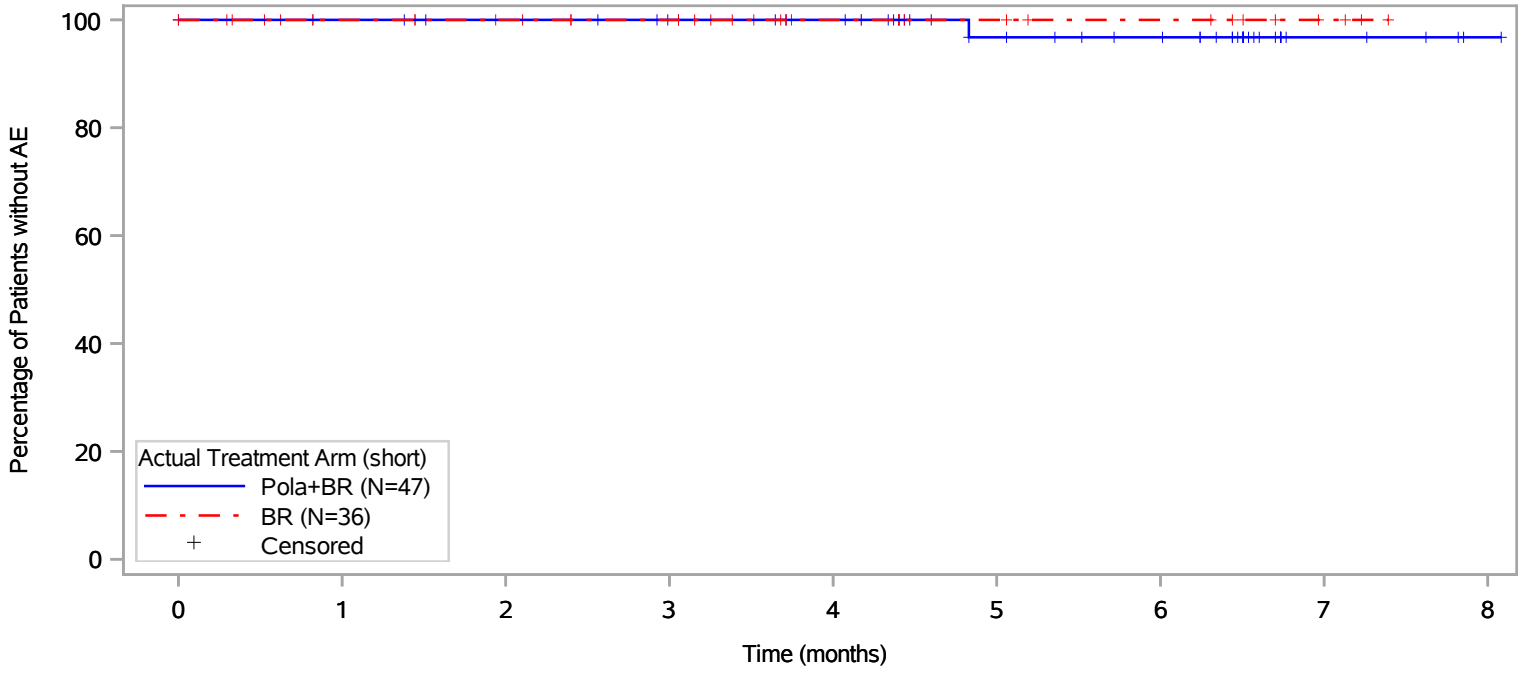
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, HYPOGEUSIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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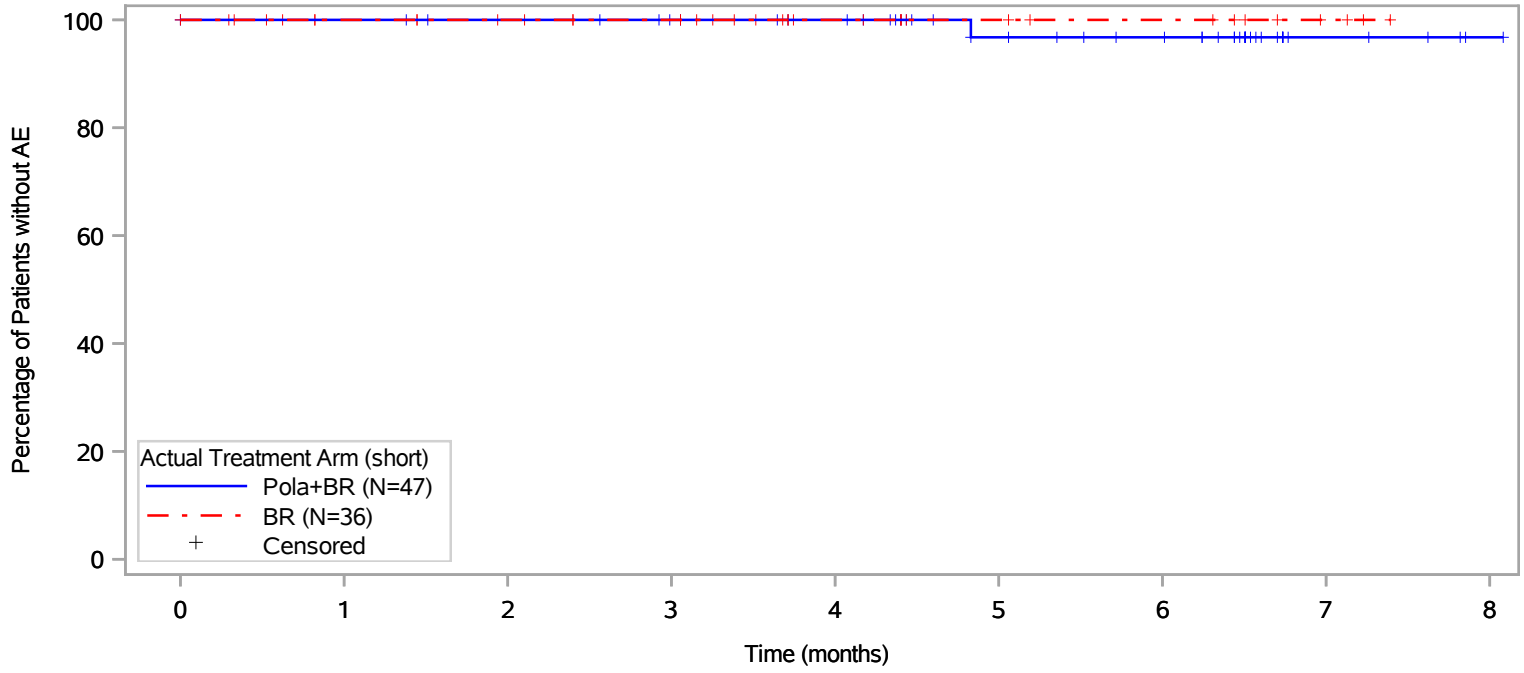
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, HYPOSMIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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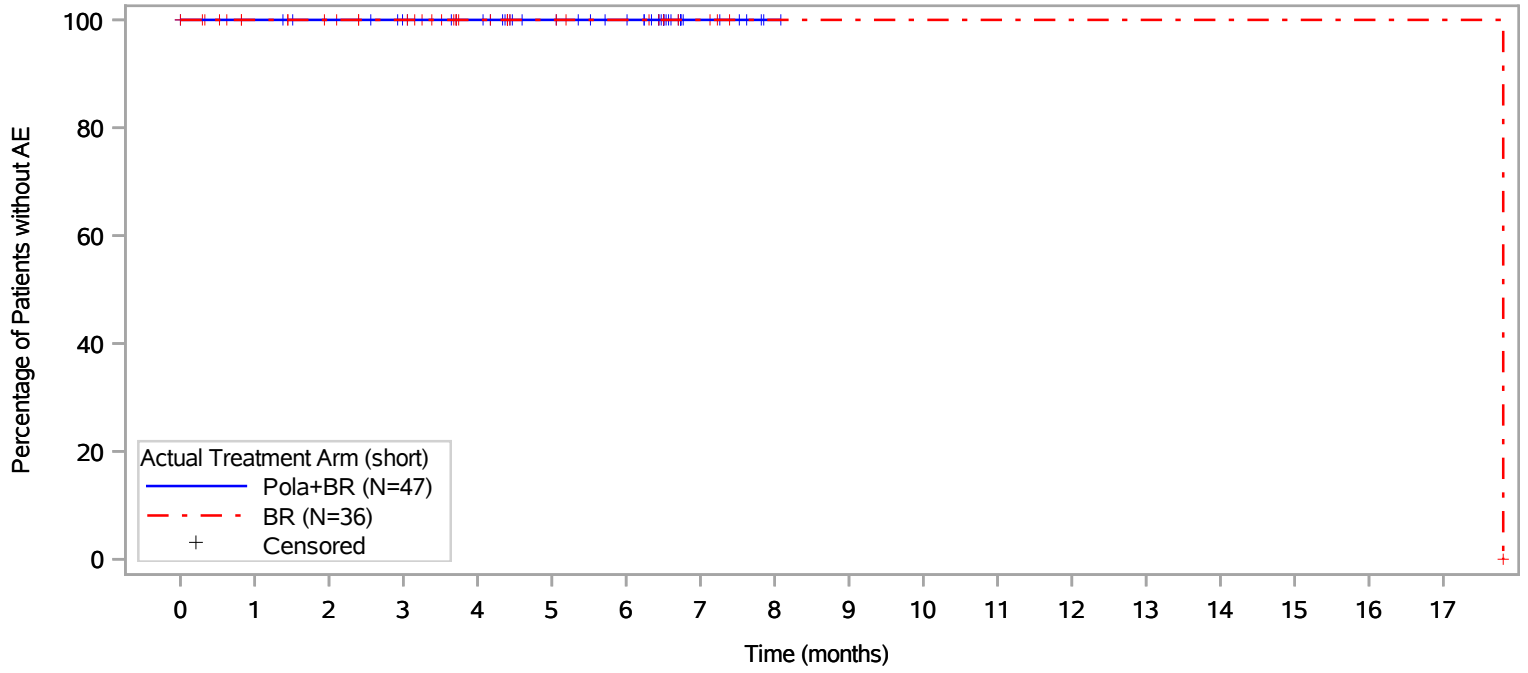
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, LEUKOENCEPHALOPATHY



Patients at risk																		
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	32	35	35	35	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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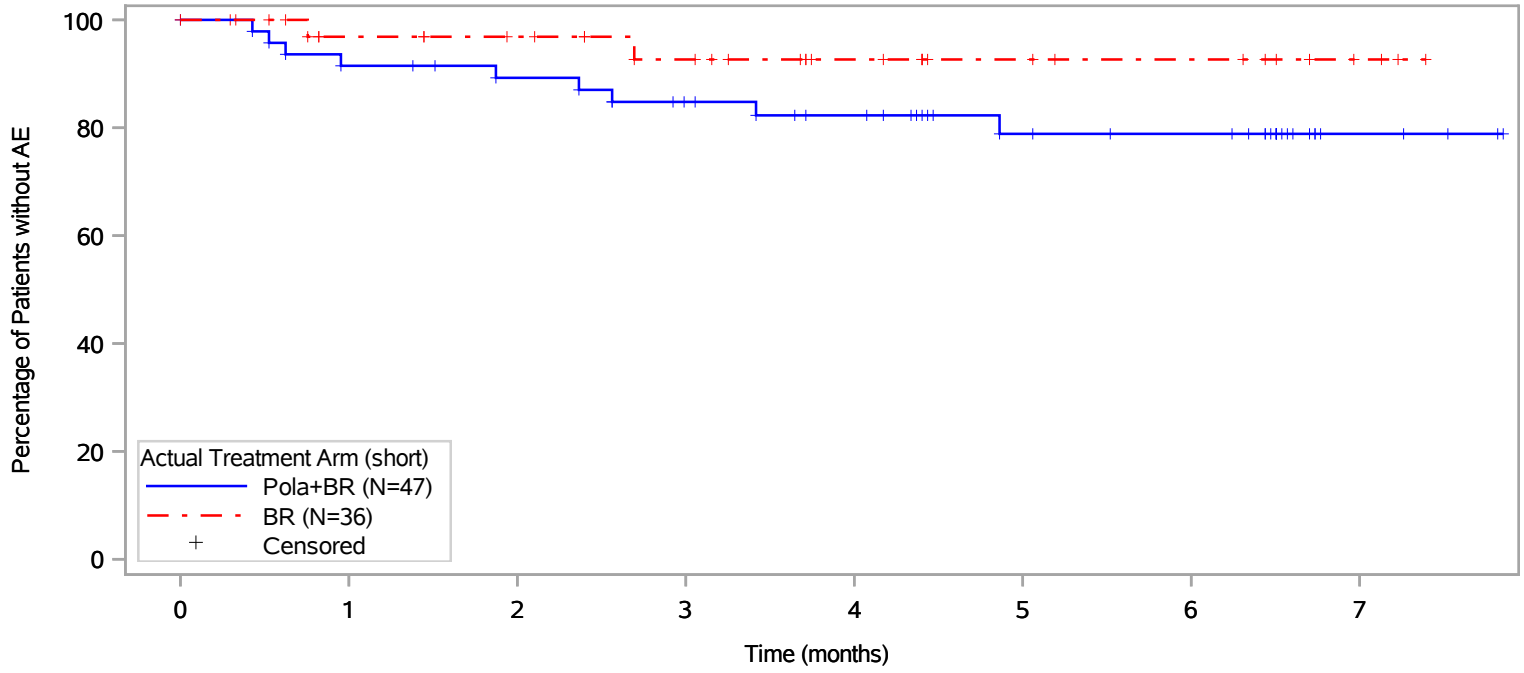
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, NEUROPATHY PERIPHERAL



Patients at risk								
Pola+BR (N=47)	47	43	40	35	31	23	21	4
BR (N=36)	36	29	26	22	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	15	17	34
BR (N=36)	0	6	9	12	19	24	26	31

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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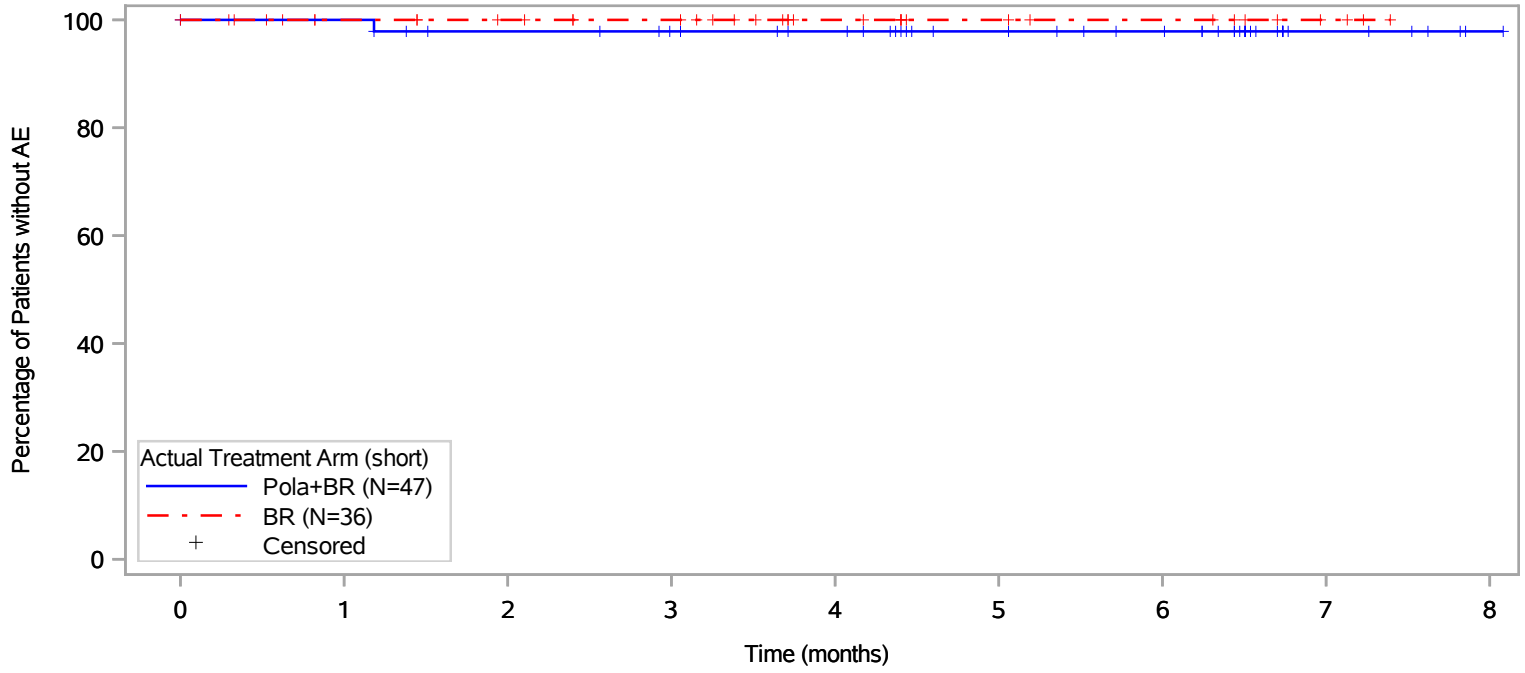
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, NEUROTOXICITY



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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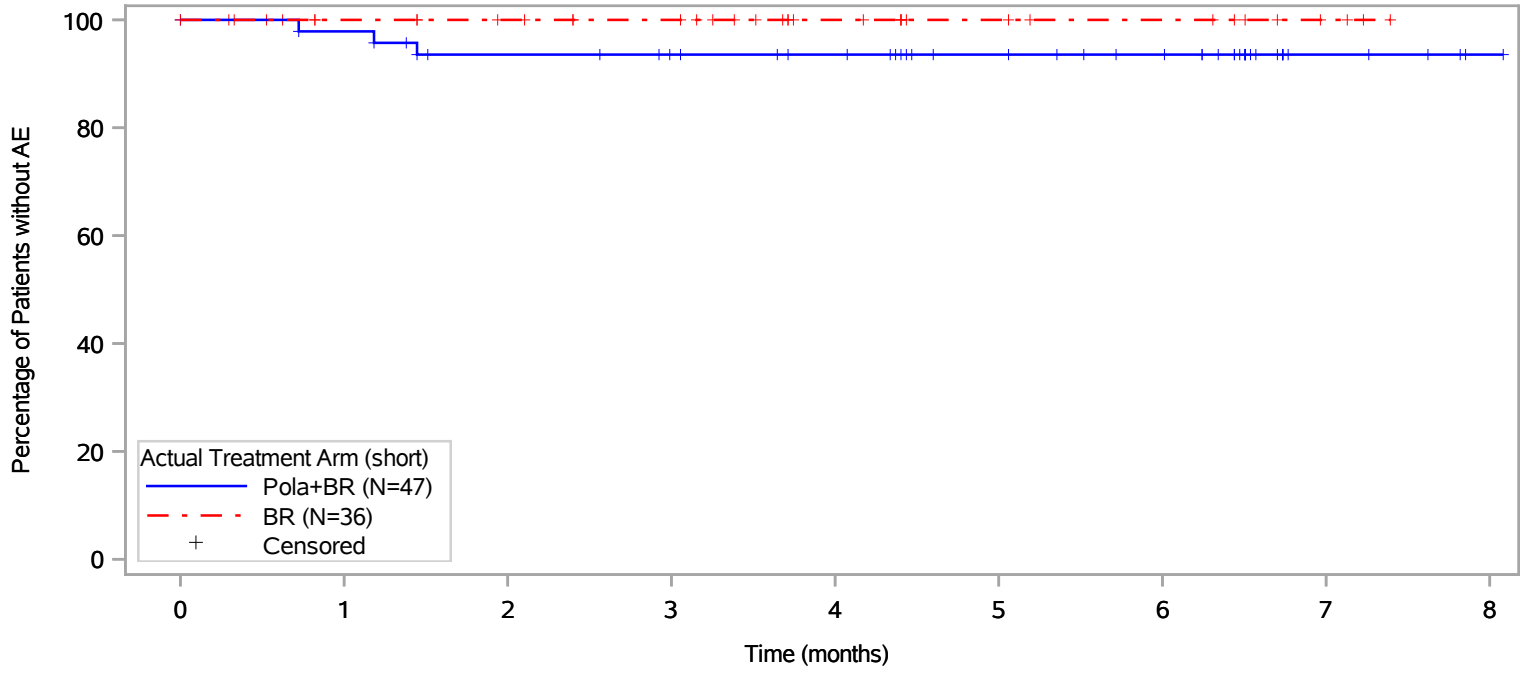
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, PARAESTHESIA

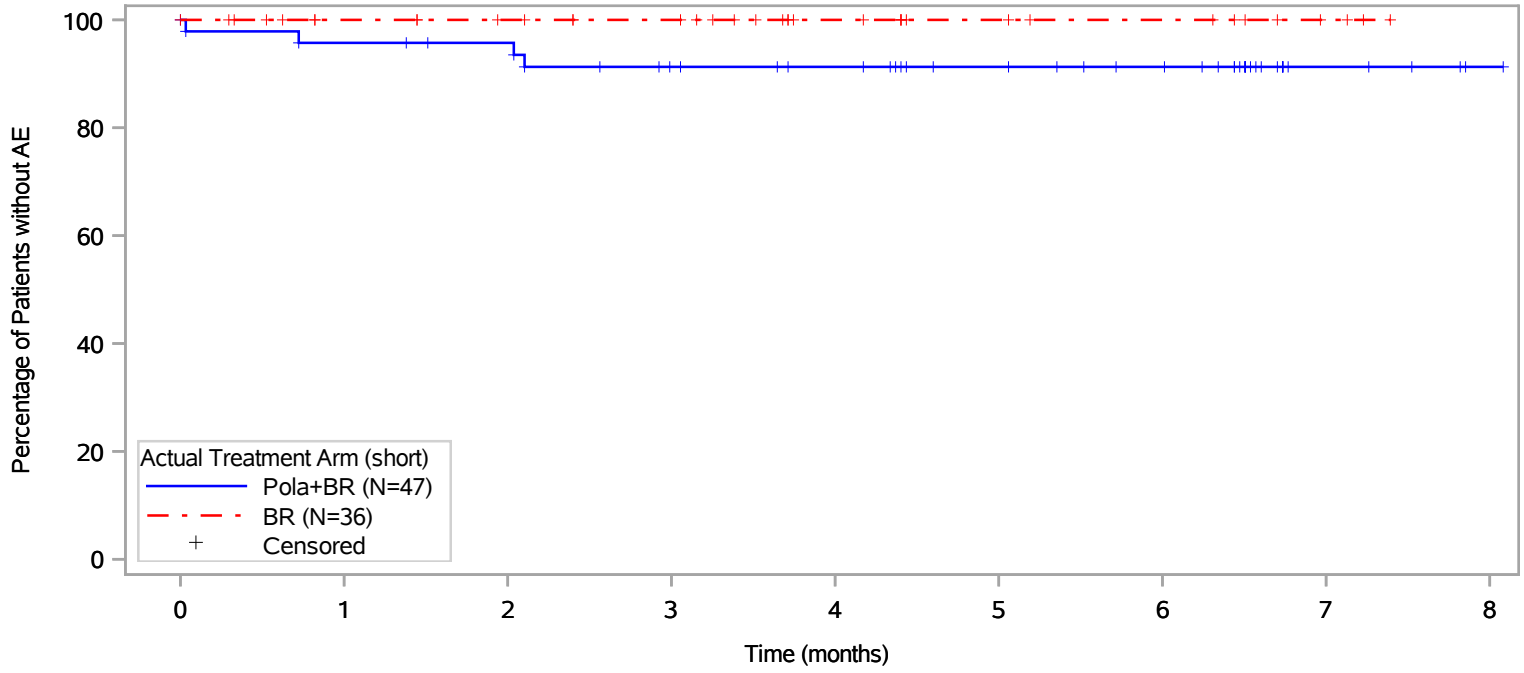


Patients at risk									
Pola+BR (N=47)	47	46	42	39	36	29	25	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	39	43
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

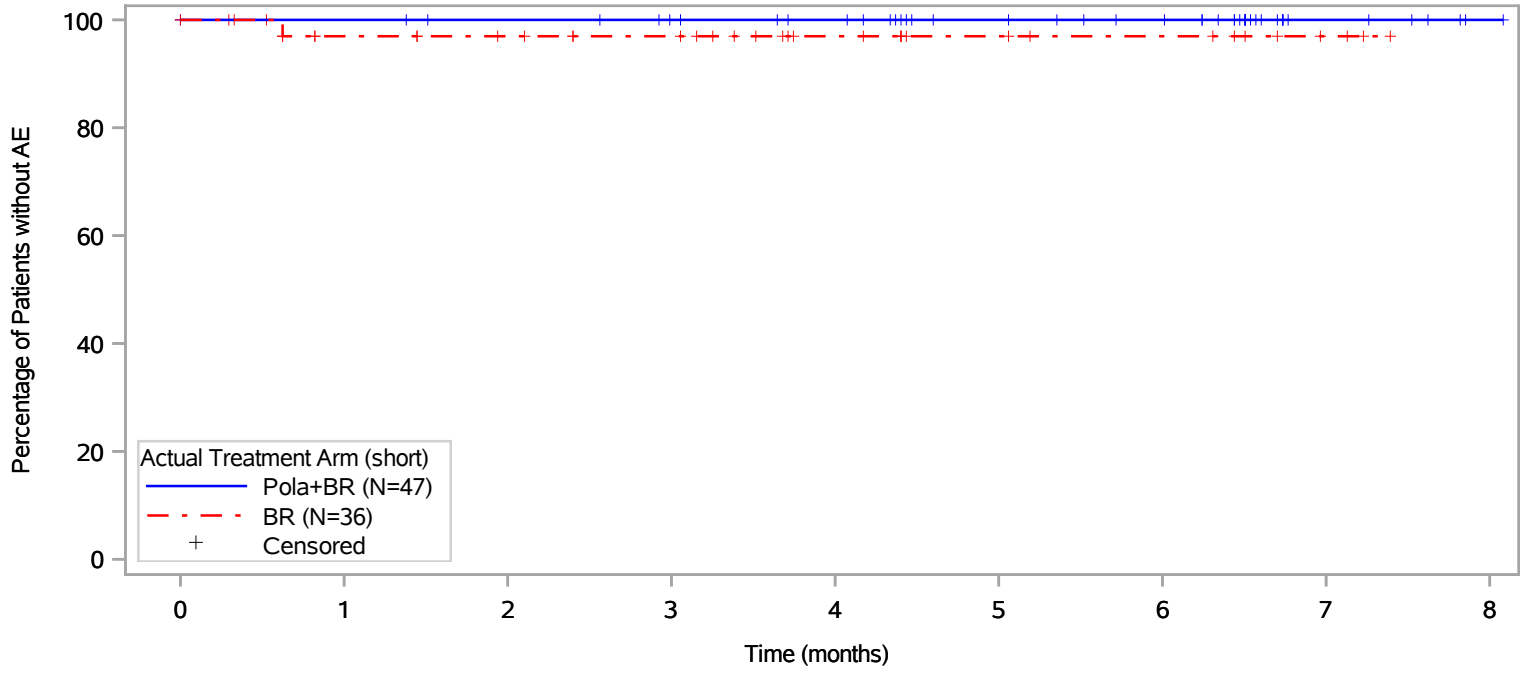
NERVOUS SYSTEM DISORDERS, PERIPHERAL SENSORY NEUROPATHY



Patients at risk									
Pola+BR (N=47)	47	45	43	38	35	29	25	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	14	18	38	42
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

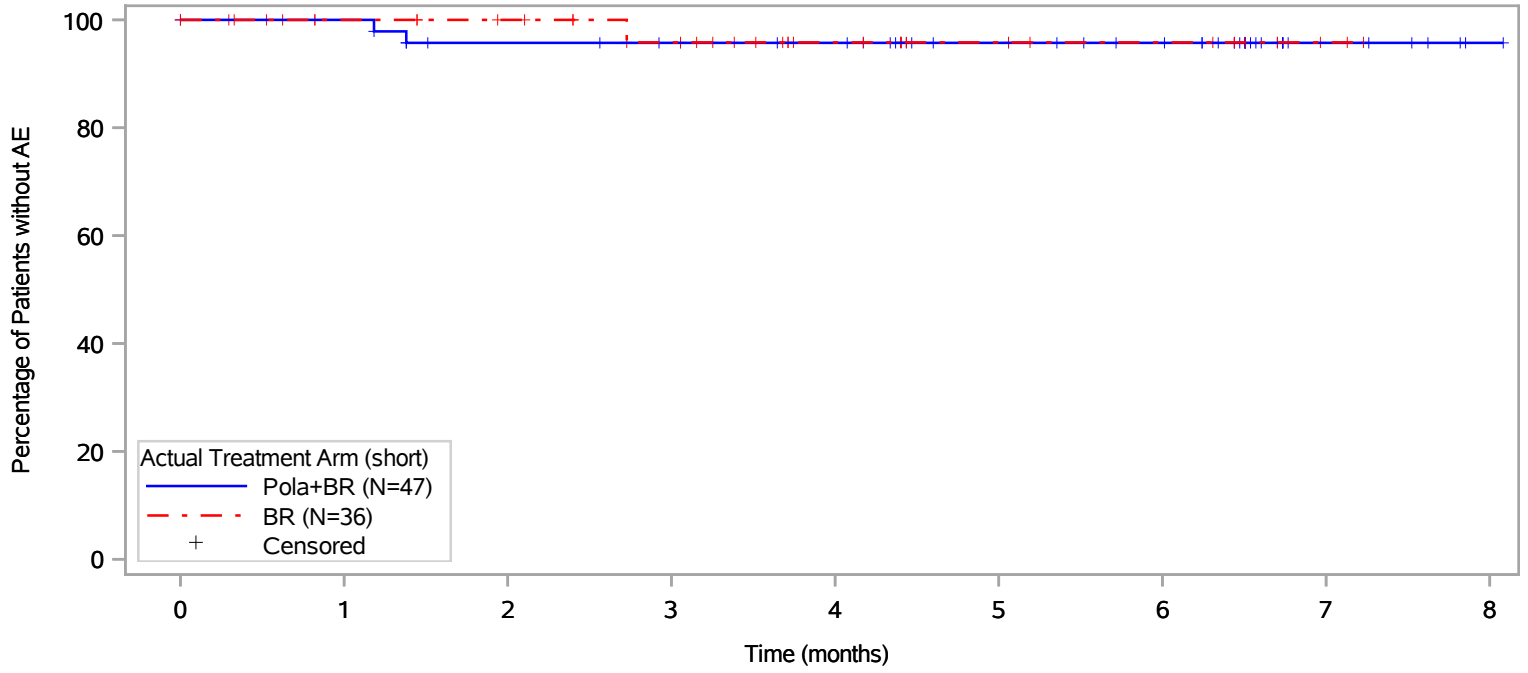
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, SOMNOLENCE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, SYNCOPE



Patients at risk									
Pola+BR (N=47)	47	47	43	41	39	31	27	6	1
BR (N=36)	36	30	27	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	6	14	18	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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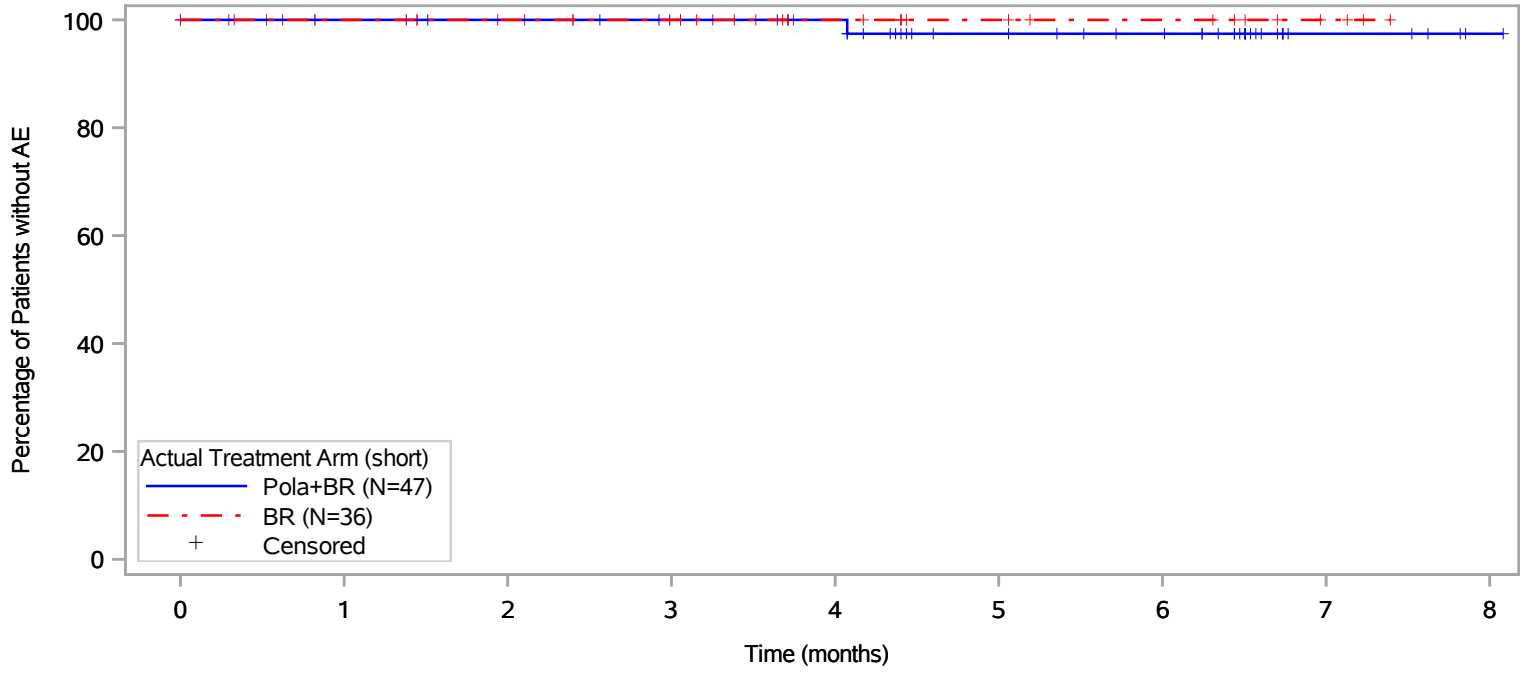
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, TREMOR



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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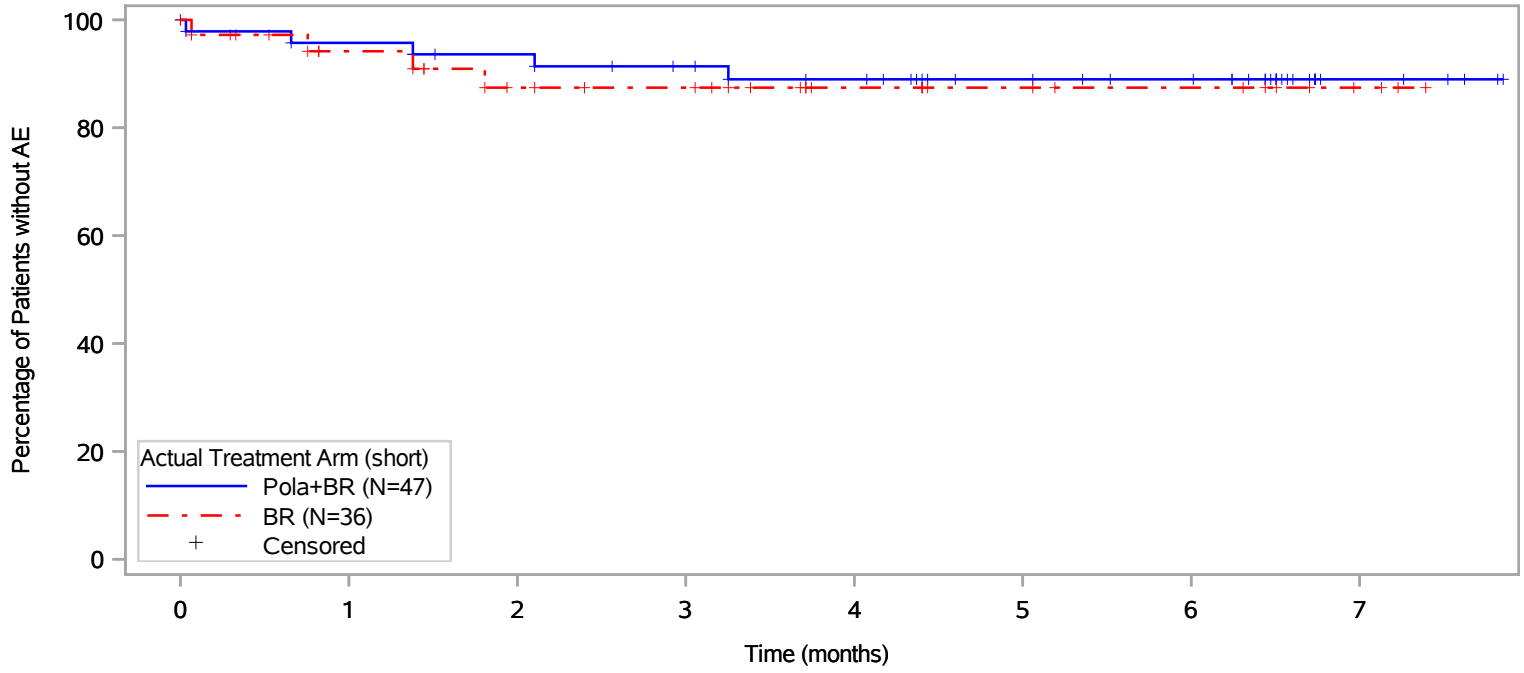
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, All



Patients at risk								
Pola+BR (N=47)	47	45	42	39	36	29	26	5
BR (N=36)	36	29	24	22	14	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	4	6	13	16	37
BR (N=36)	0	5	8	10	18	22	24	29

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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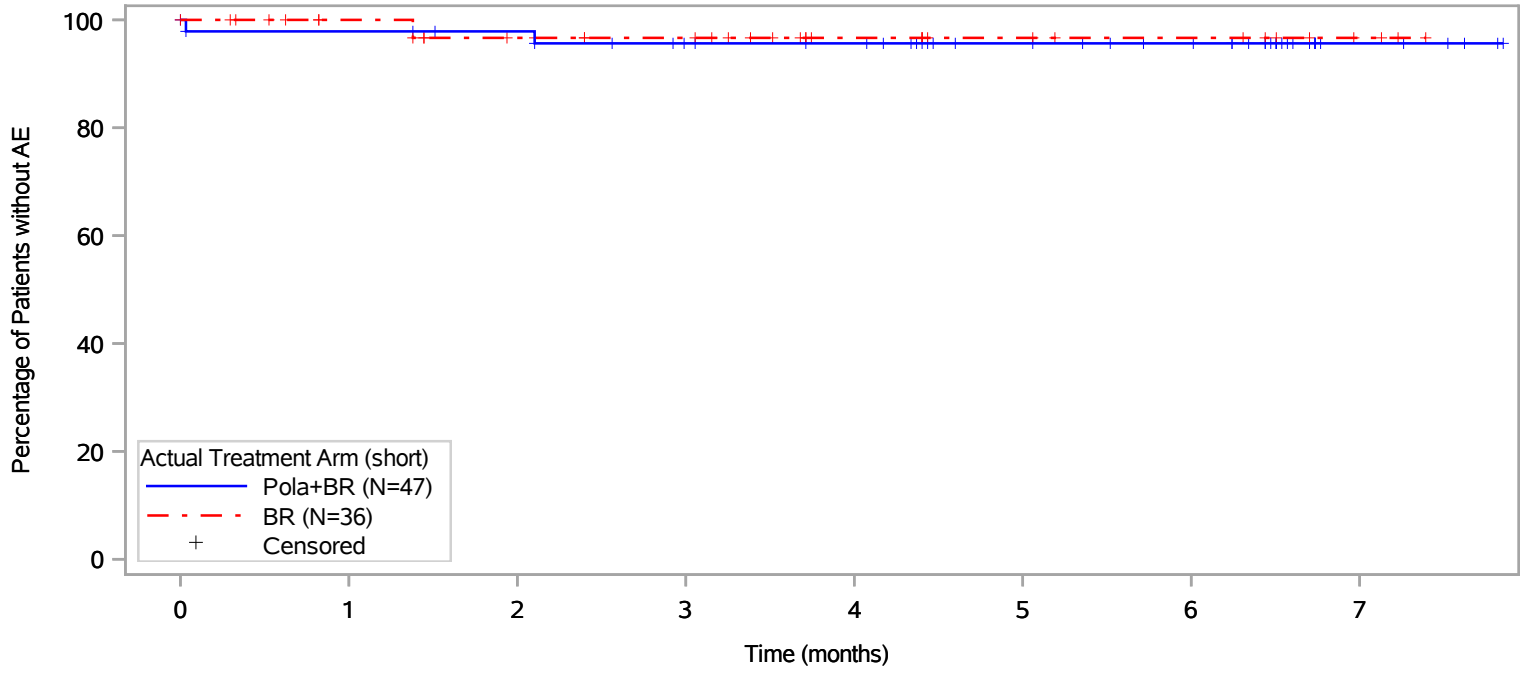
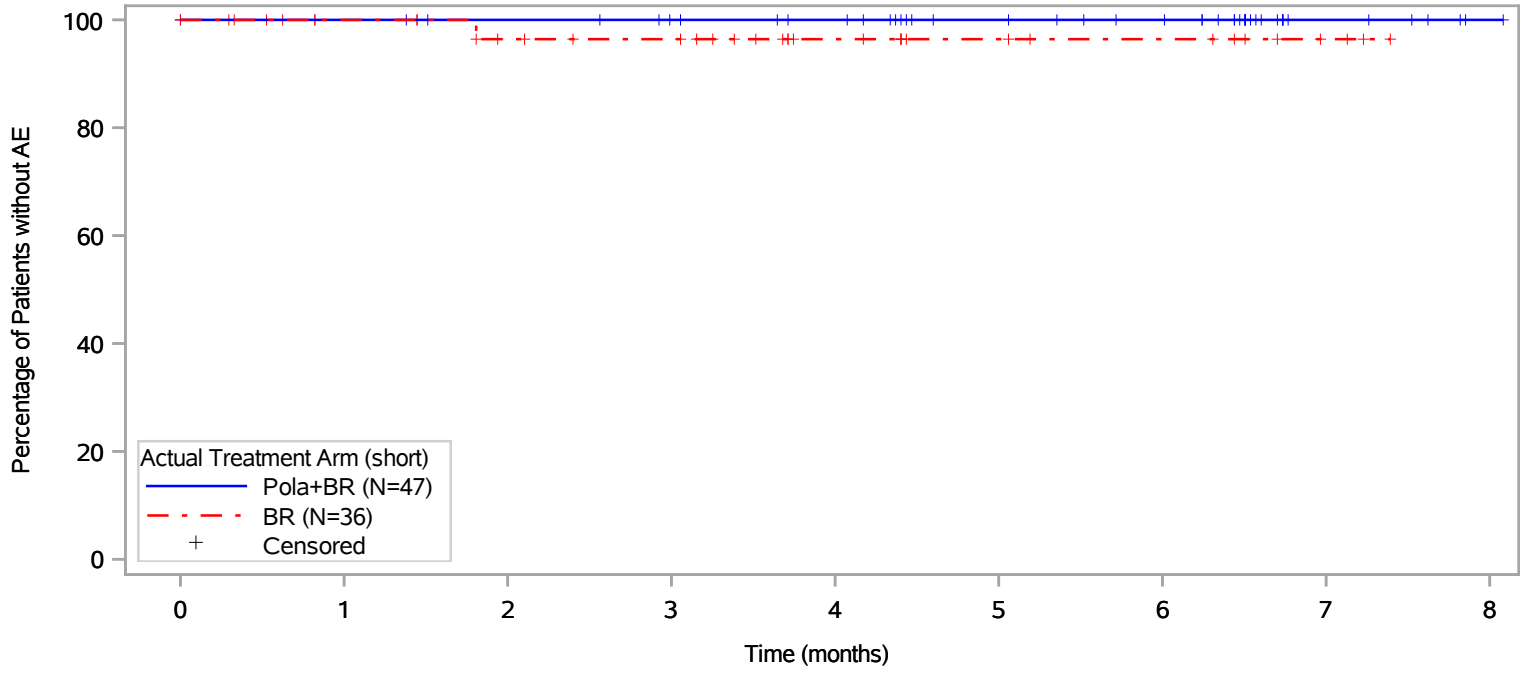
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, ANXIETY



Patients at risk								
Pola+BR (N=47)	47	46	44	40	38	30	26	5
BR (N=36)	36	30	26	23	14	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	7	15	19	40
BR (N=36)	0	6	9	12	21	25	27	32

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, APATHY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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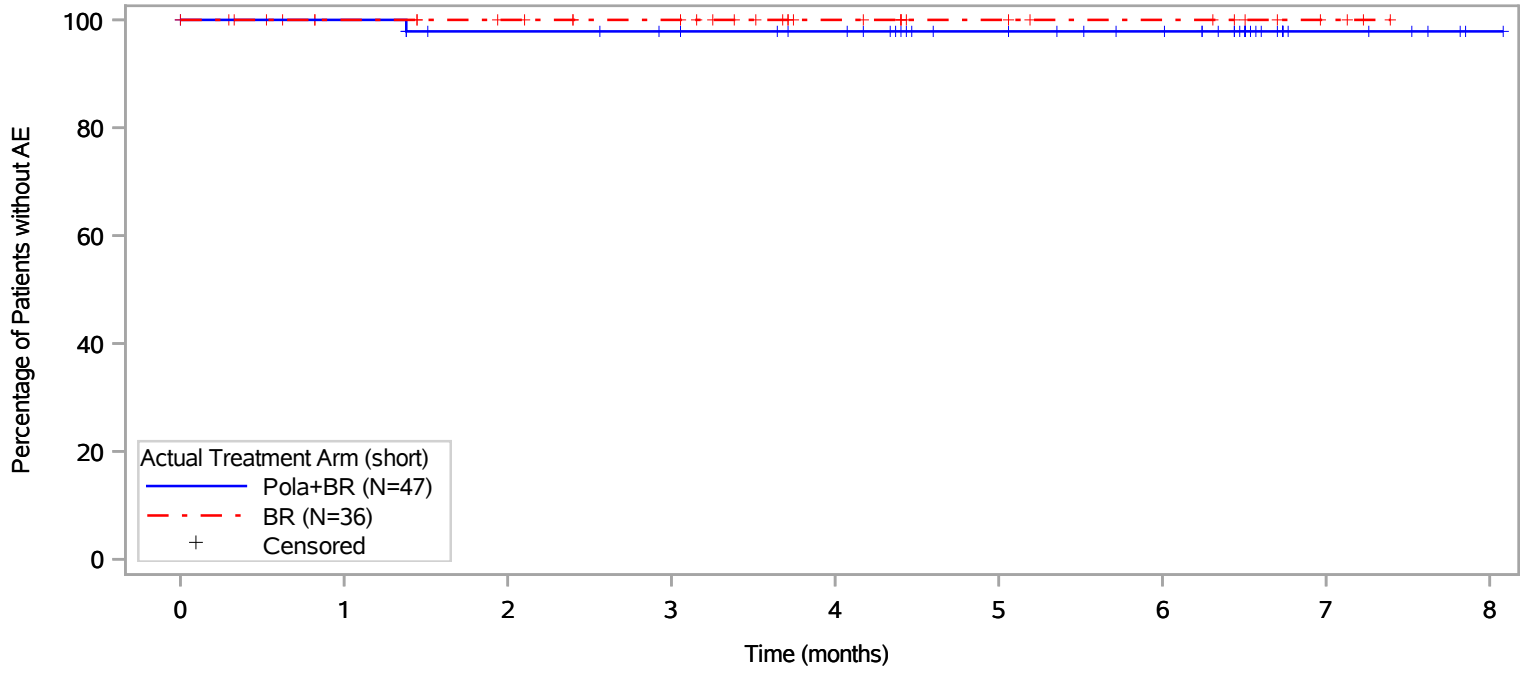
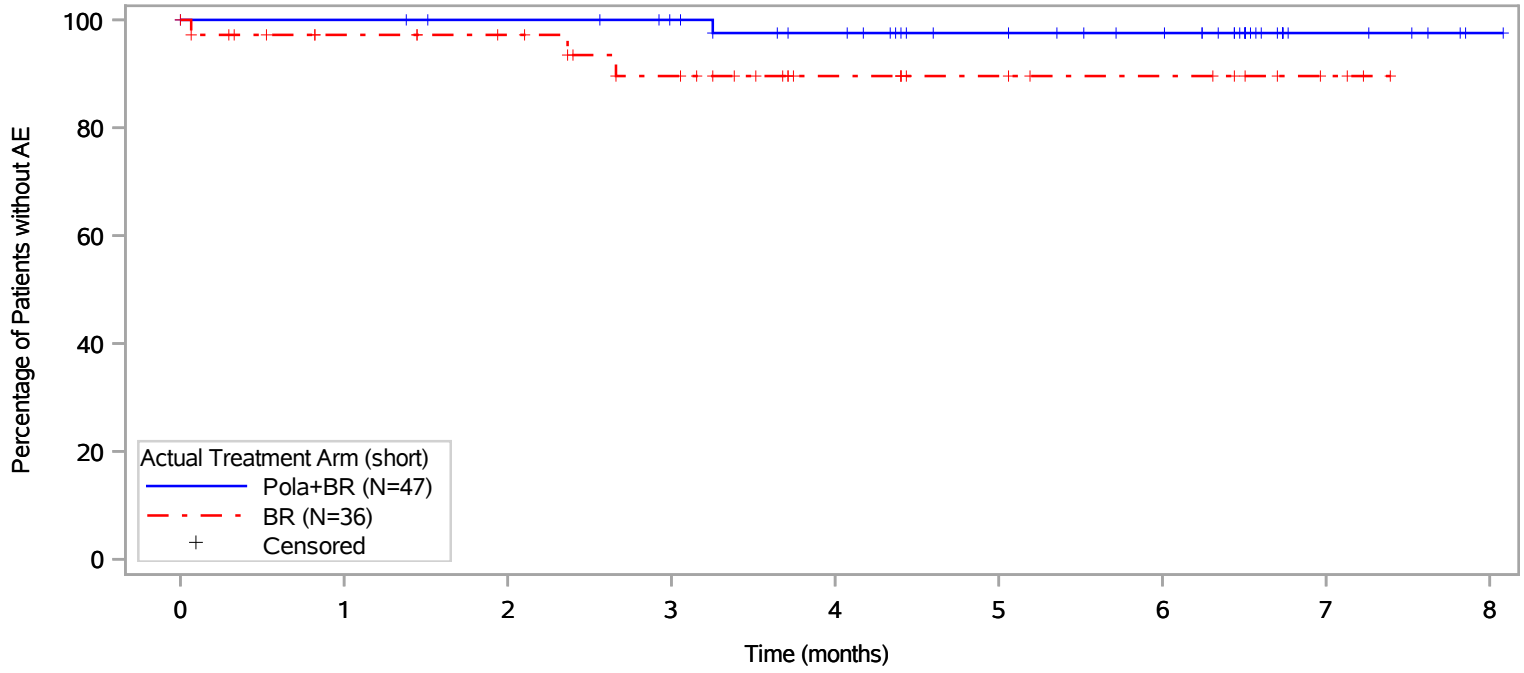
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, CONFUSIONAL STATE



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

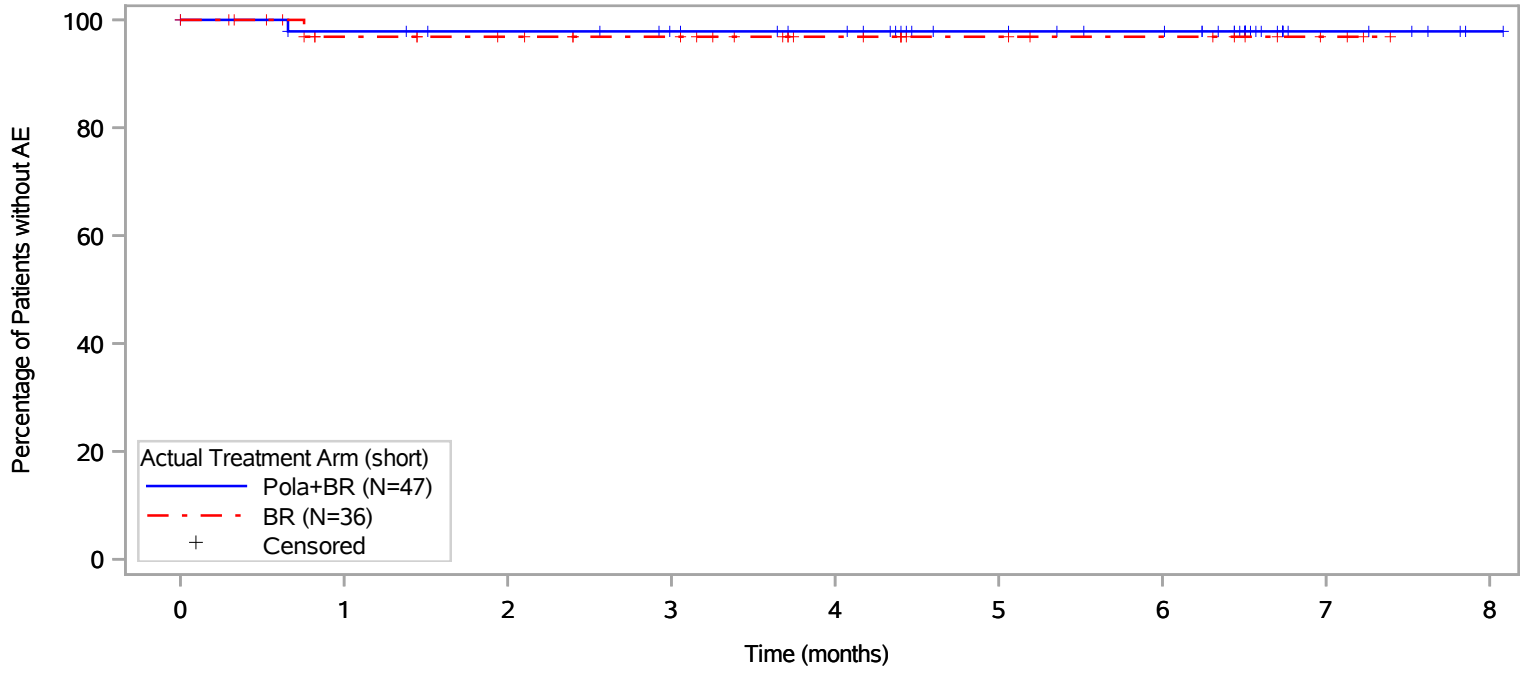
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, DEPRESSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	6	1
BR (N=36)	36	30	27	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	5	8	10	19	23	25	30	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, INSOMNIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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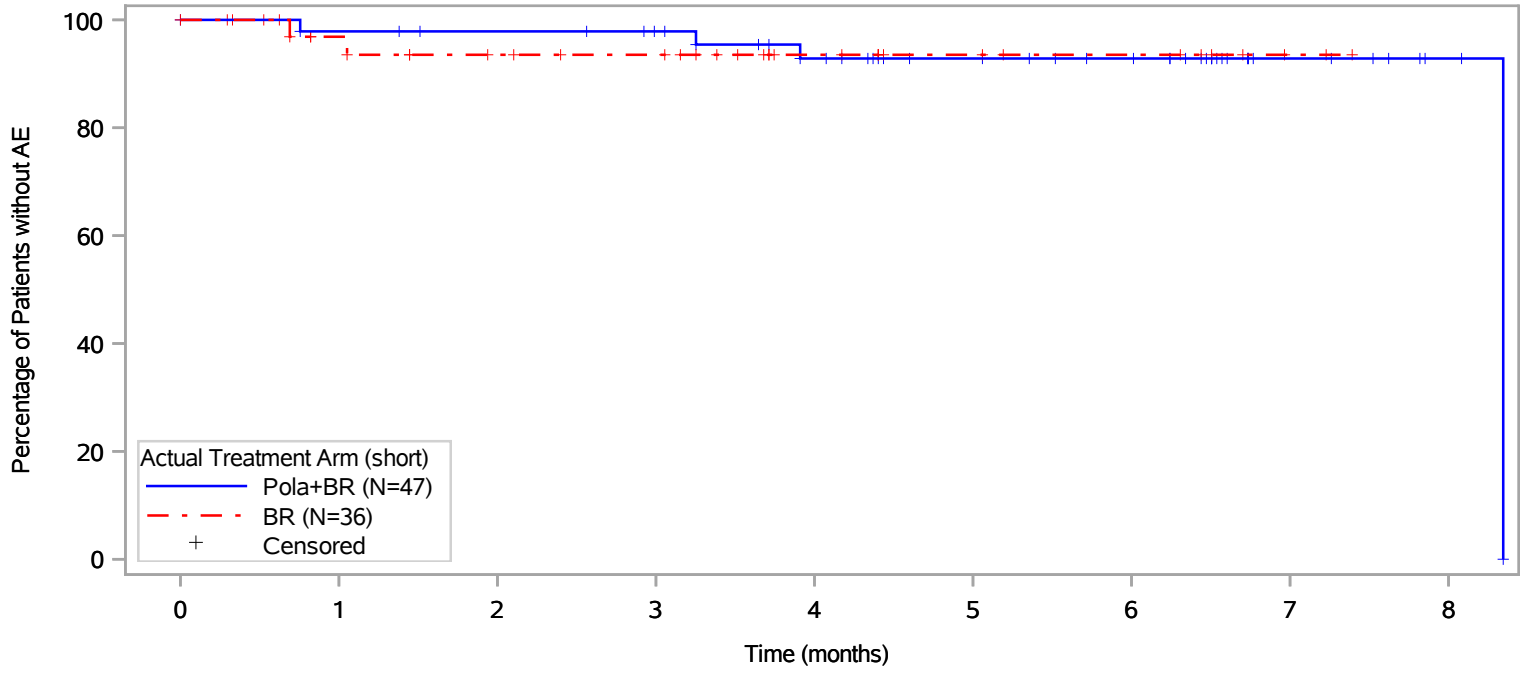
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	46	44	41	36	29	25	7	2
BR (N=36)	36	29	25	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	37	42
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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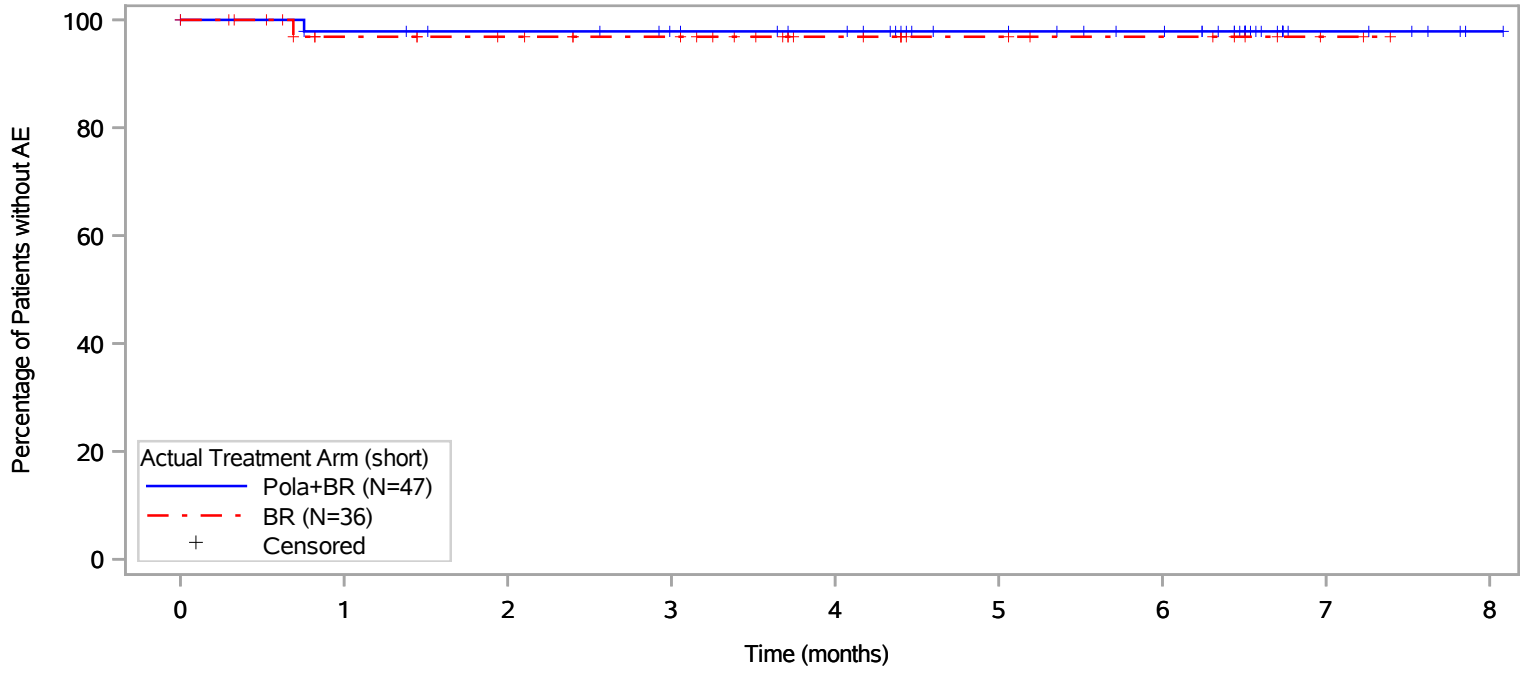
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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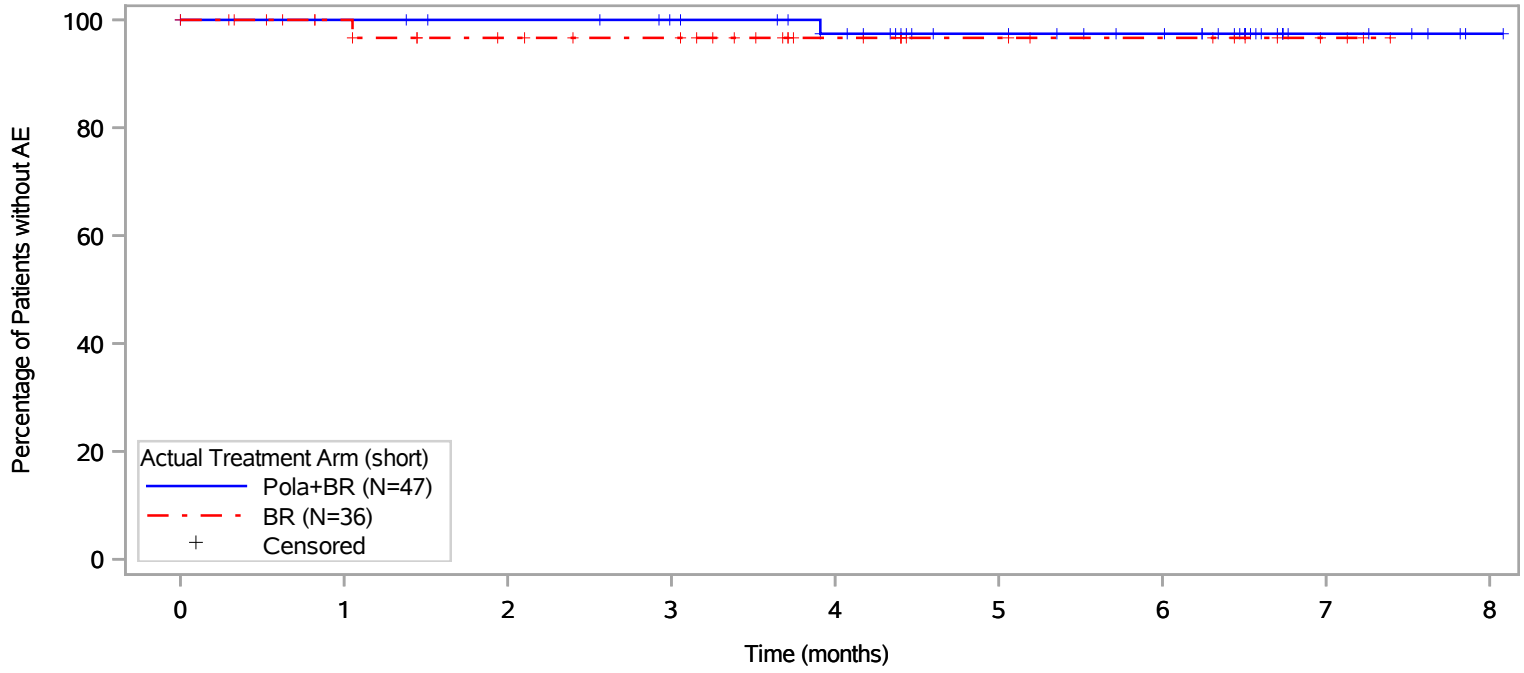
01DEC2022 22:30

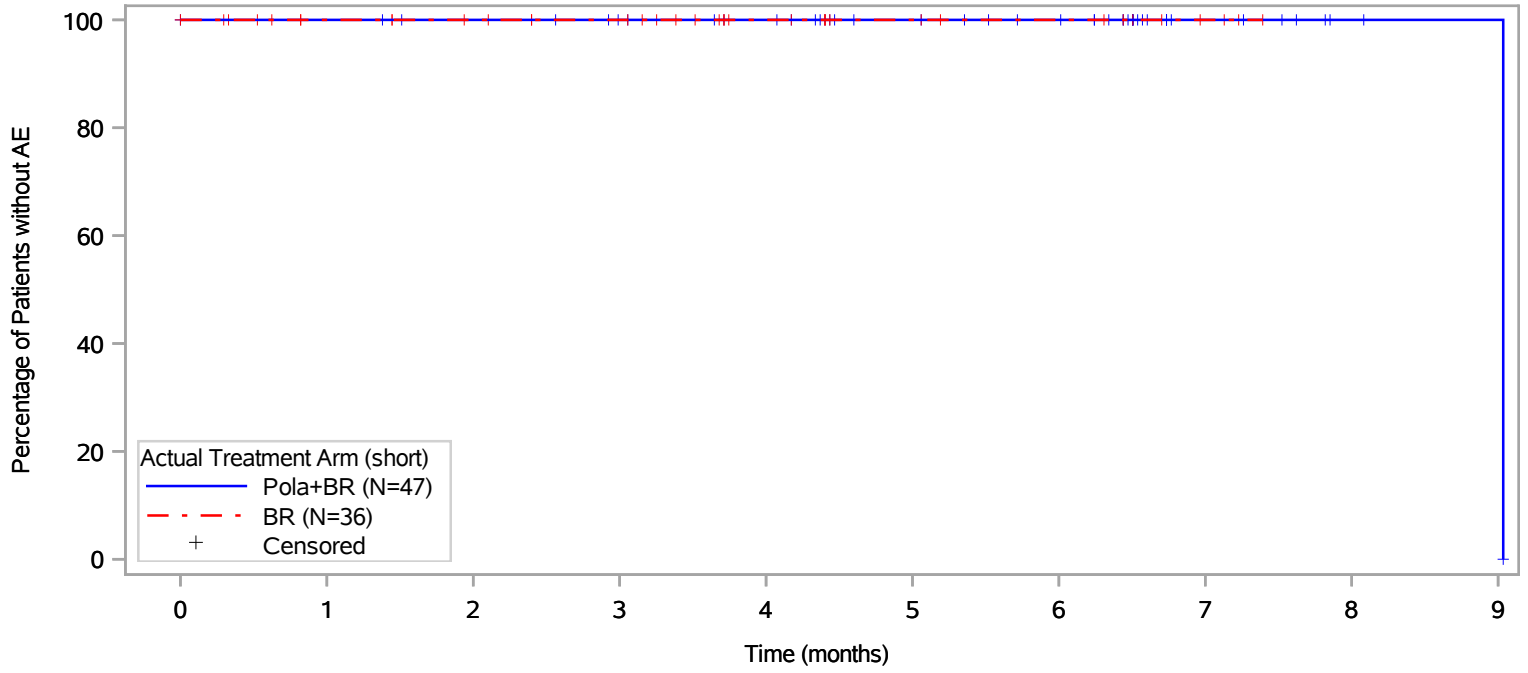
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HAEMATURIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk										
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE
Patients censored										
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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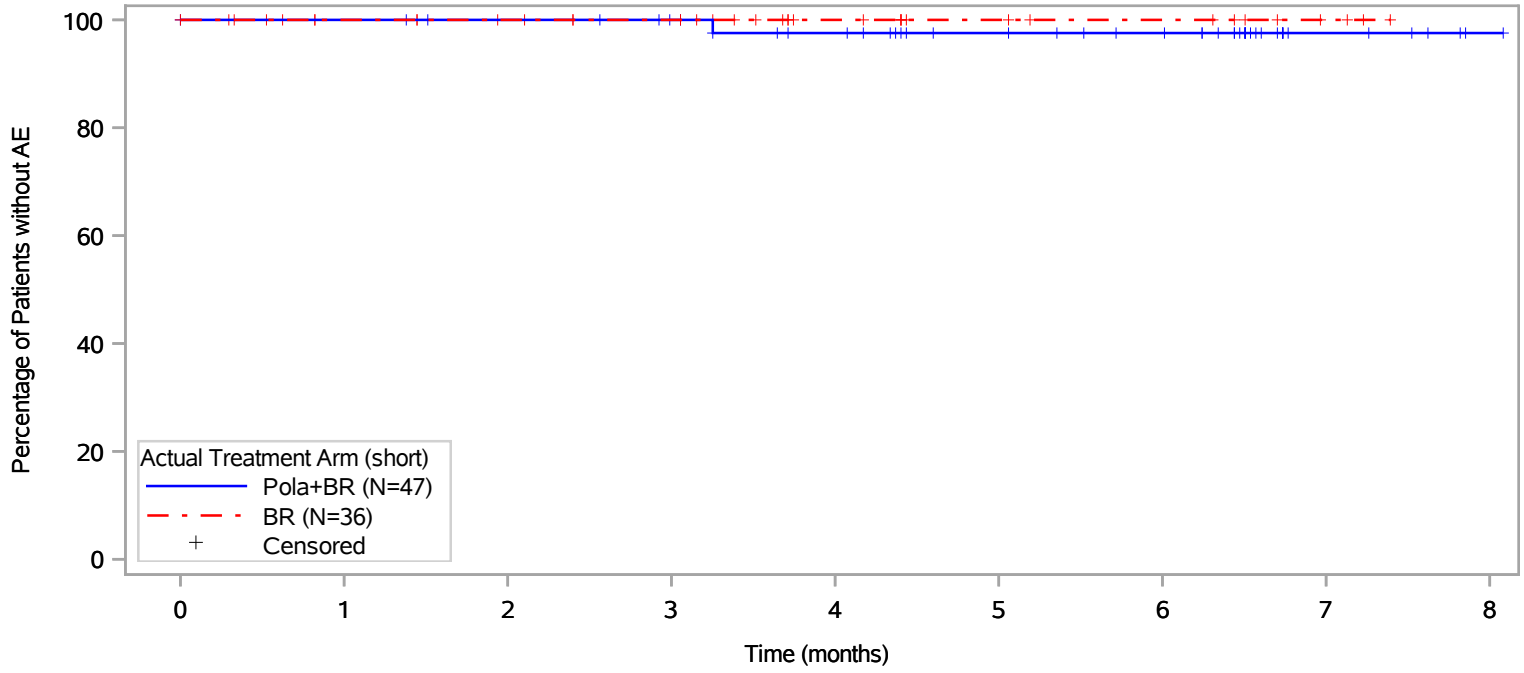
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RENAL AND URINARY DISORDERS, MICTURITION URGENCY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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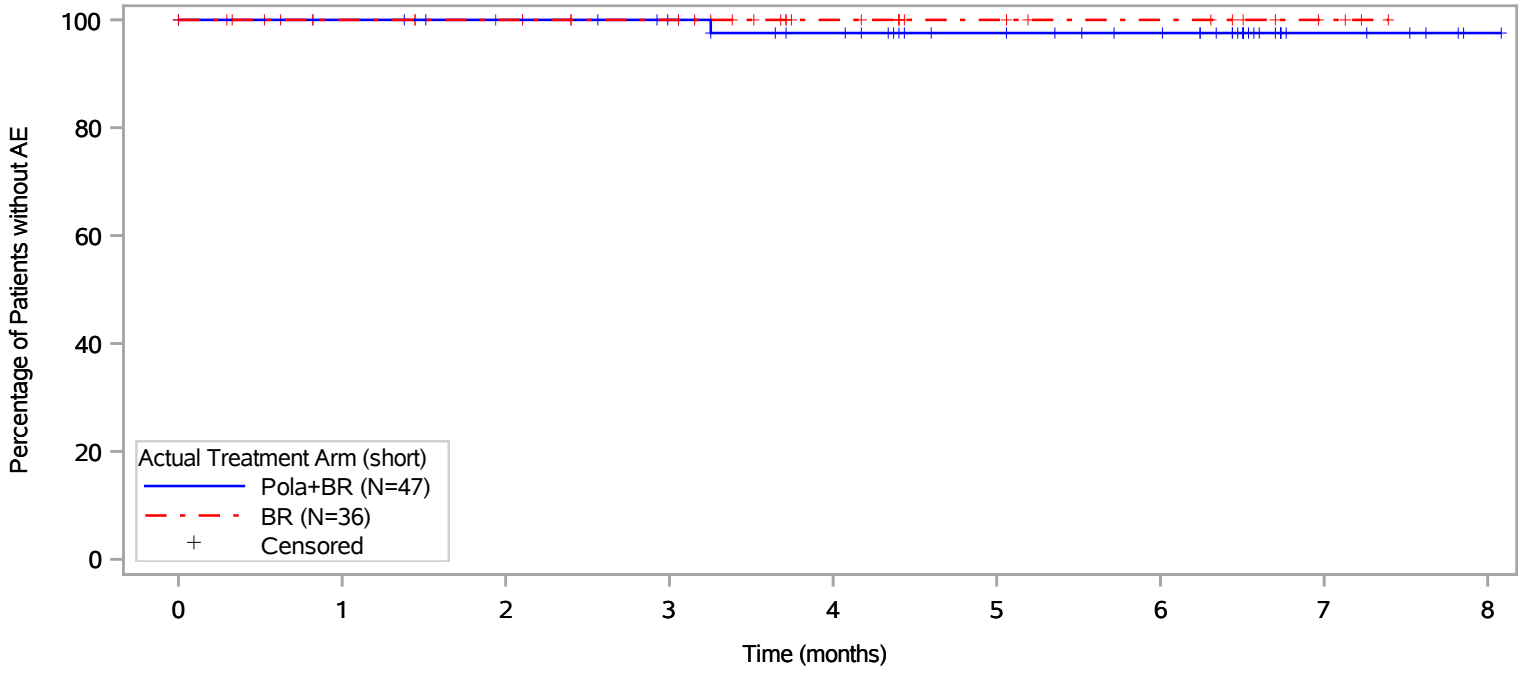
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, POLLAKIURIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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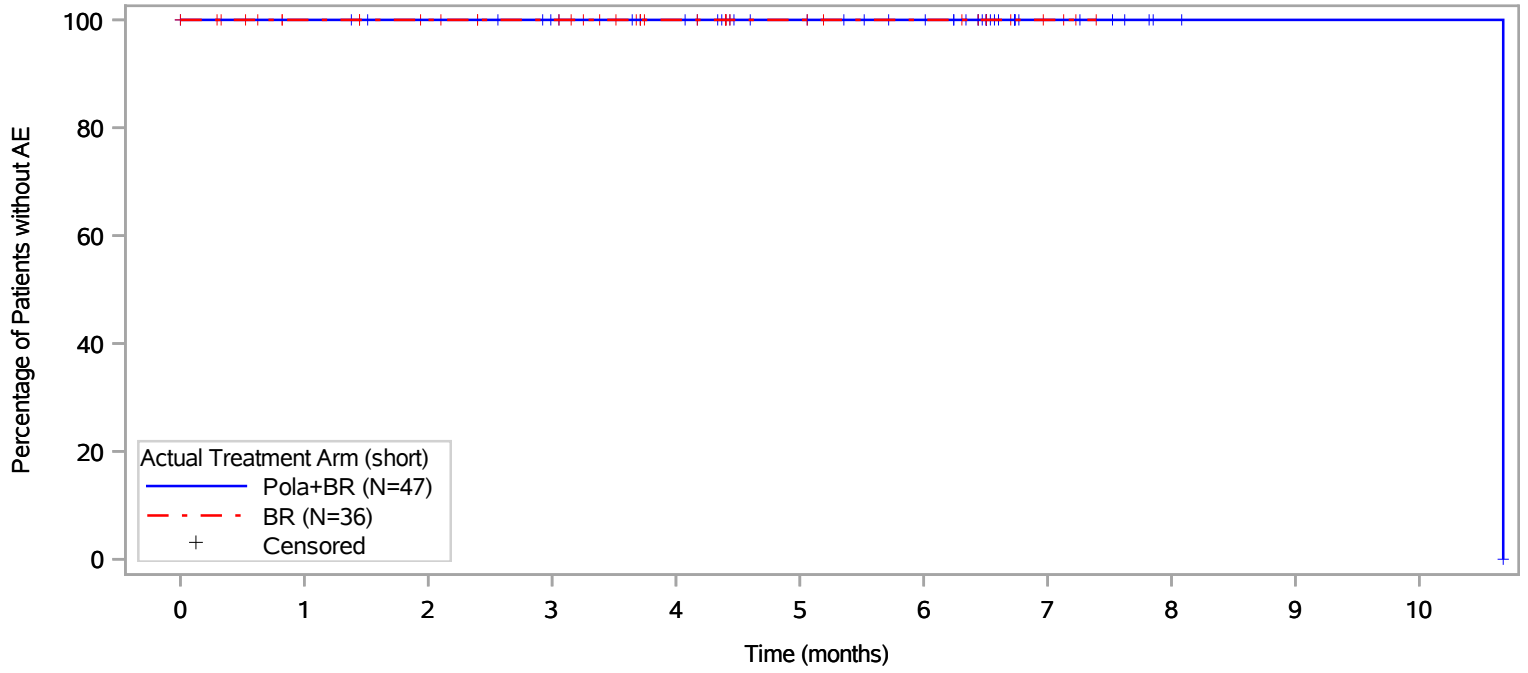
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE

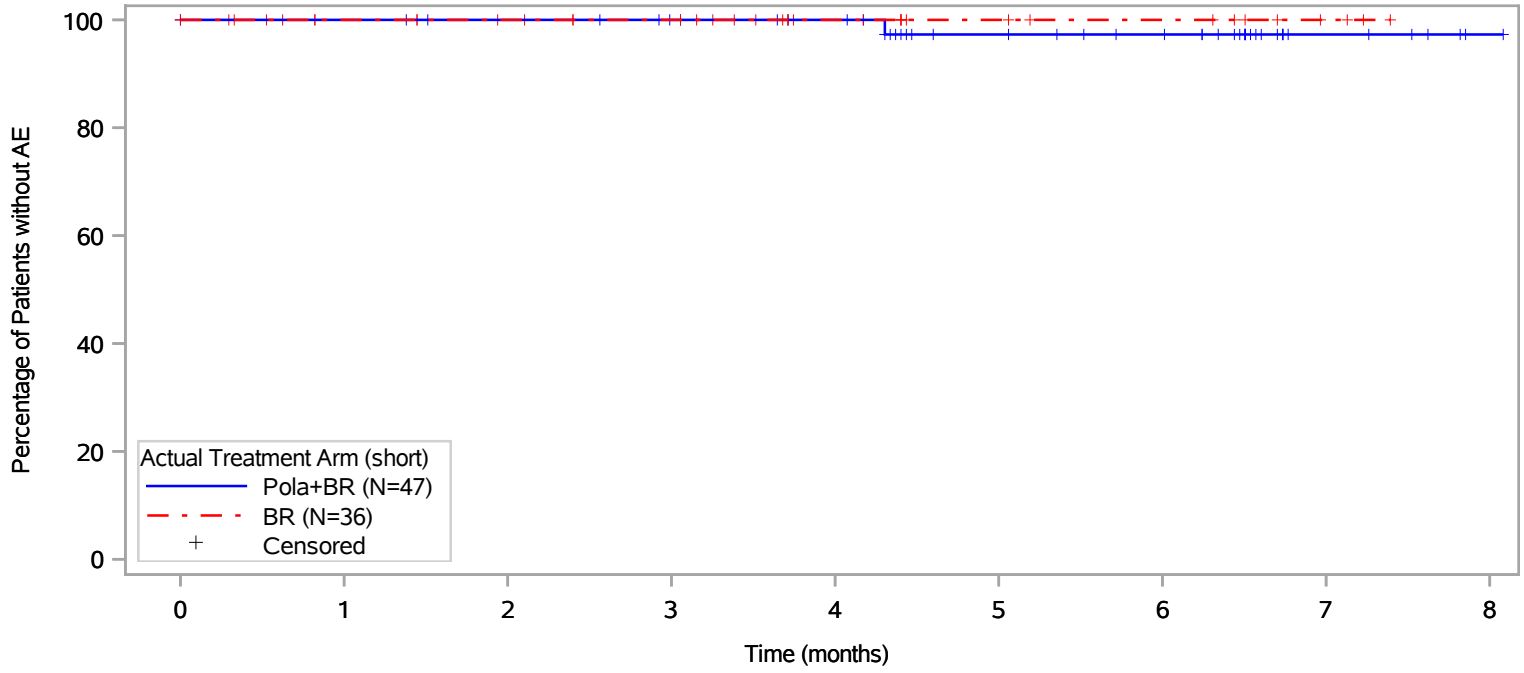


Patients at risk											
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL INJURY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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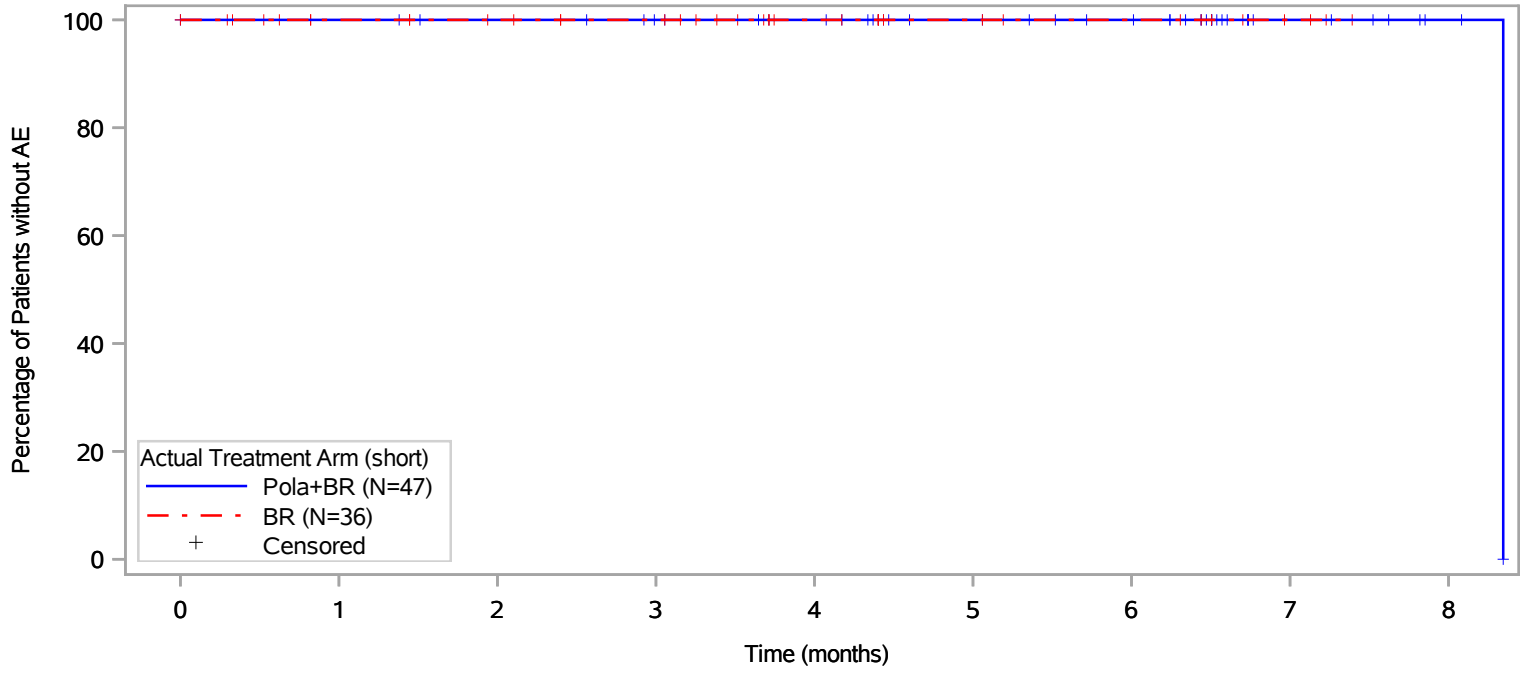
01DEC2022 22:30

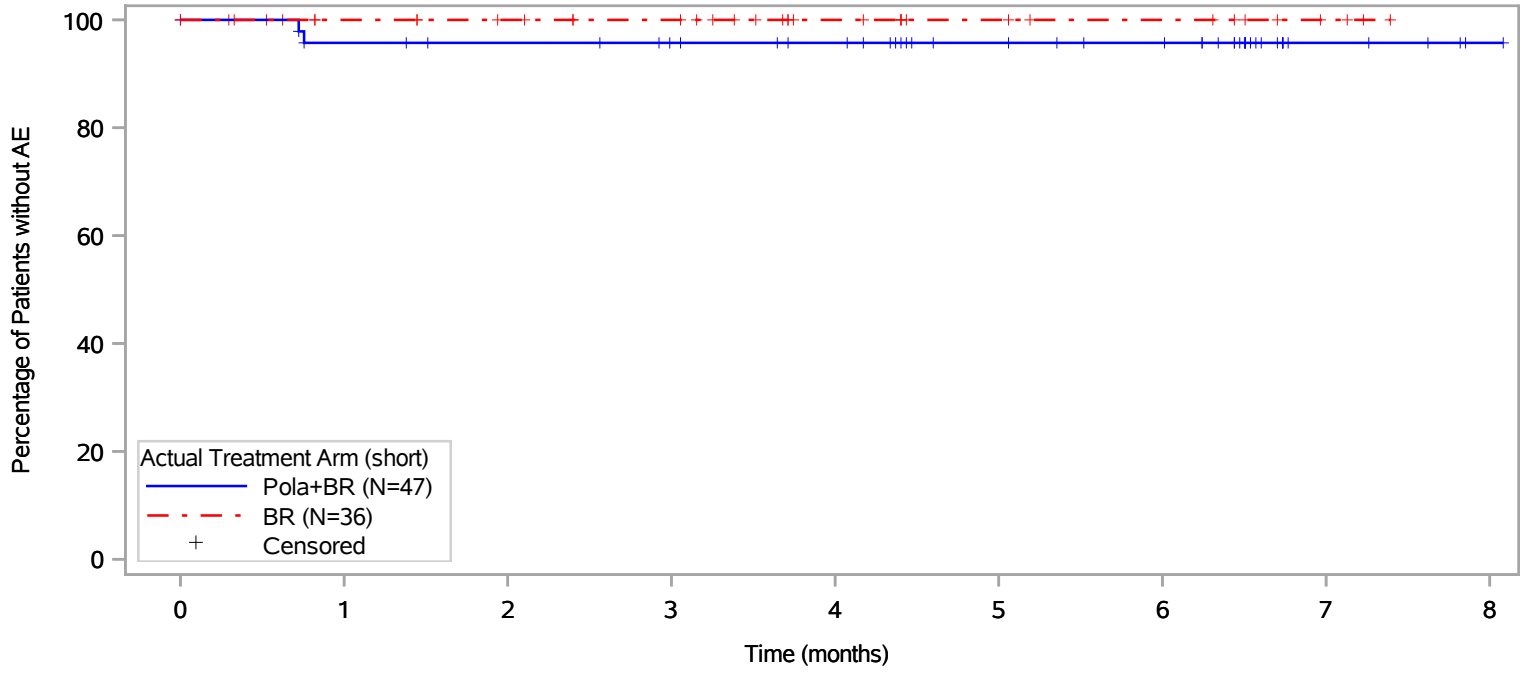
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL TUBULAR DISORDER



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
REPRODUCTIVE SYSTEM AND BREAST DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	29	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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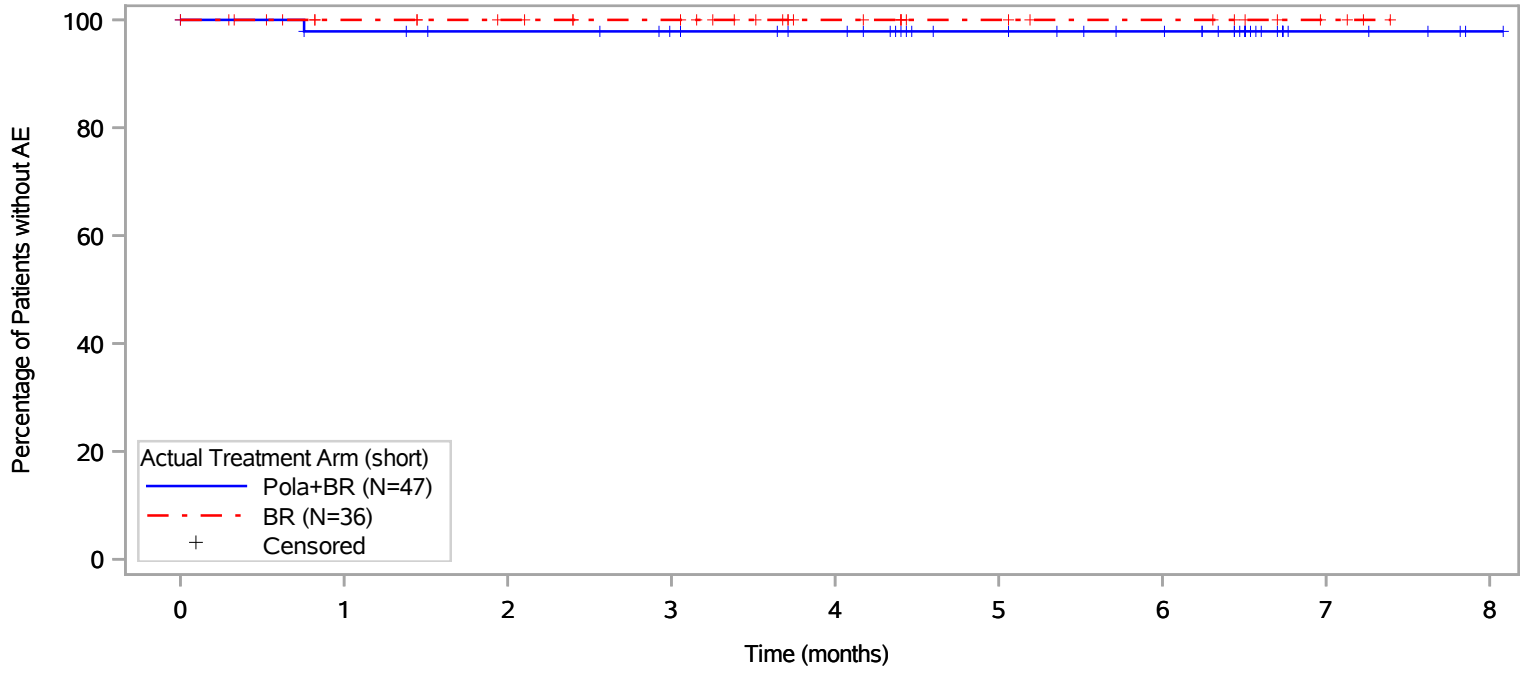
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

REPRODUCTIVE SYSTEM AND BREAST DISORDERS, ERECTILE DYSFUNCTION

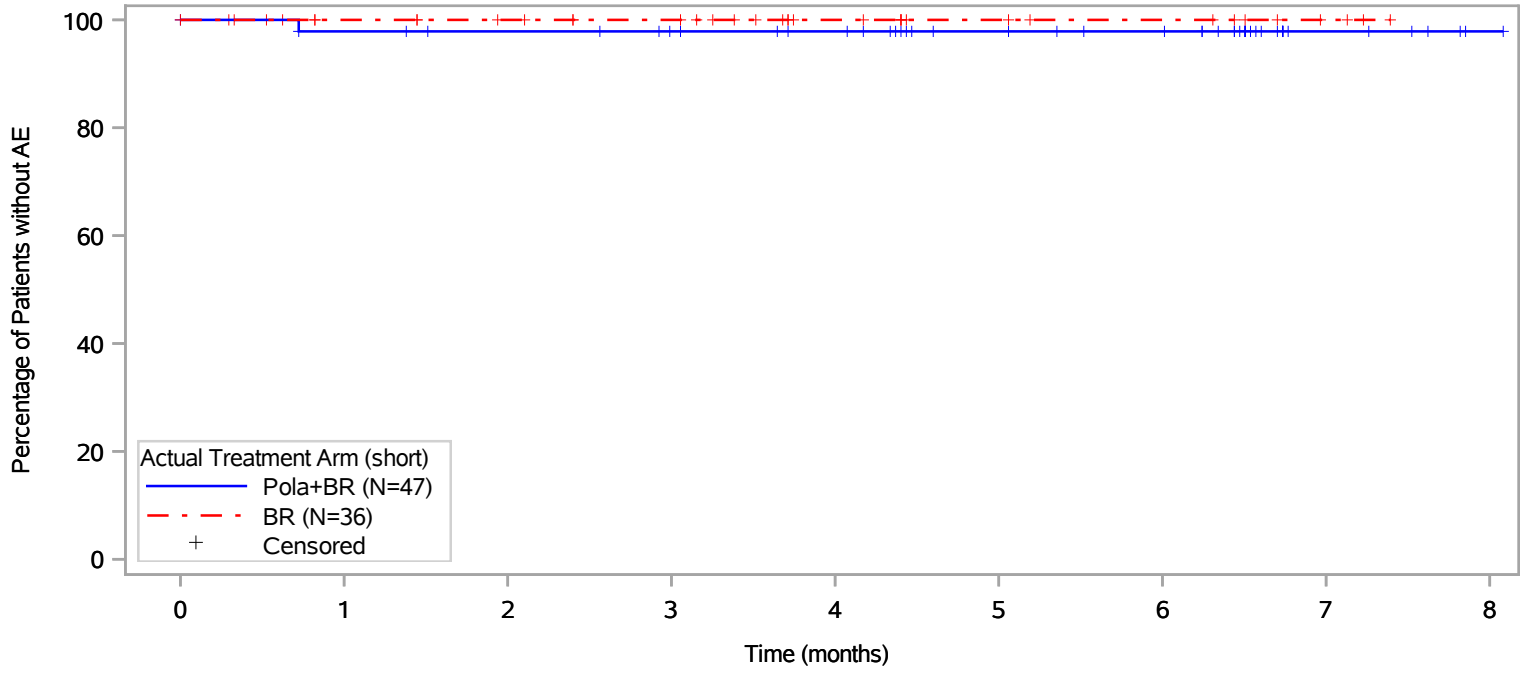


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

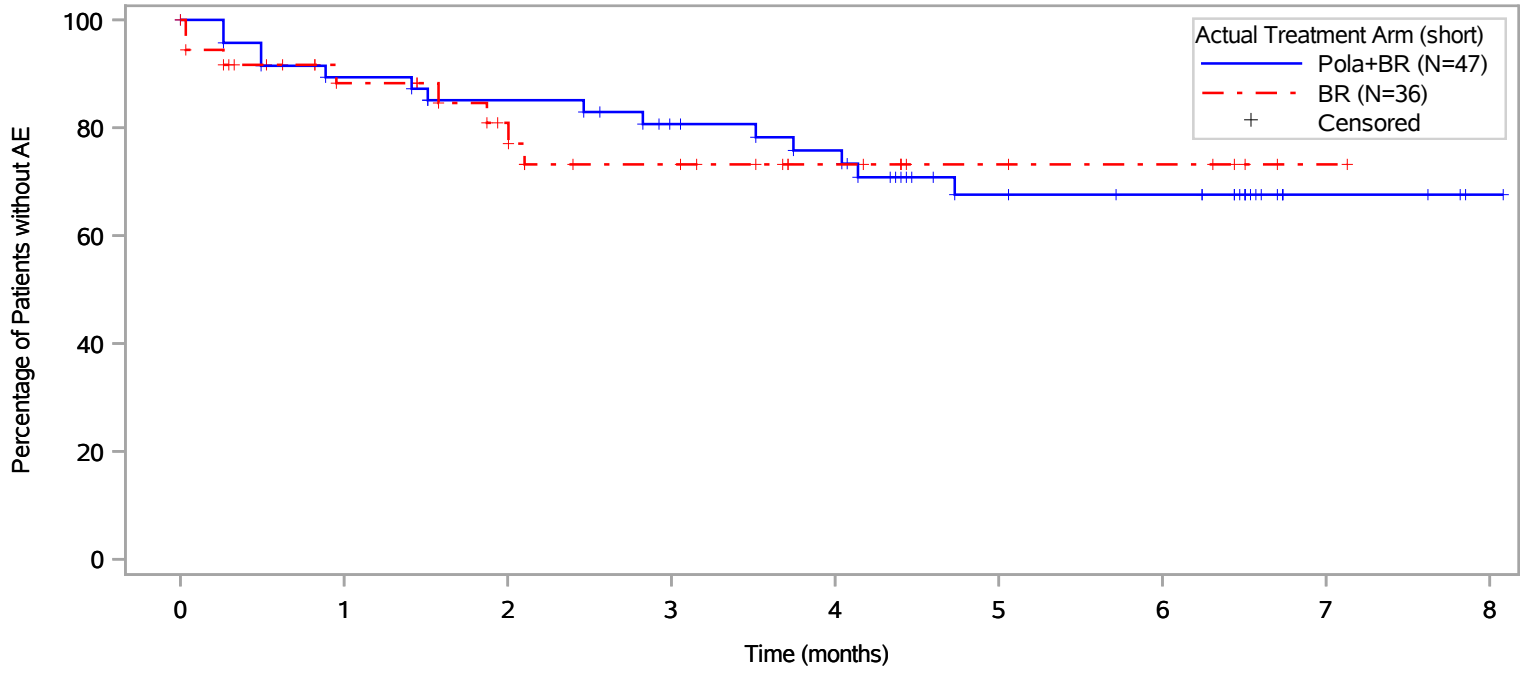
REPRODUCTIVE SYSTEM AND BREAST DISORDERS, GYNAECOMASTIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	42	39	34	31	21	19	4	1
BR (N=36)	36	26	21	17	11	6	5	1	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	5	12	14	29	32
BR (N=36)	0	6	9	11	17	22	23	27	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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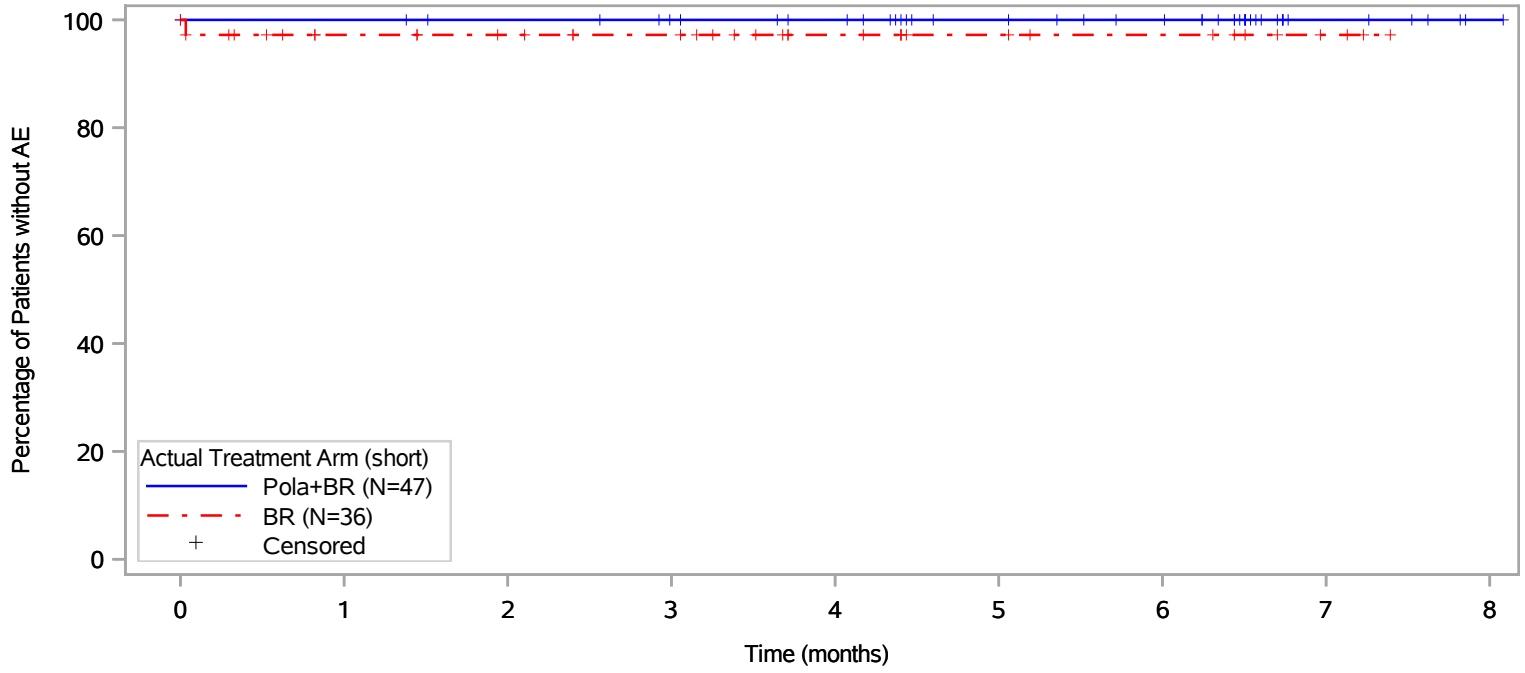
01DEC2022 22:30

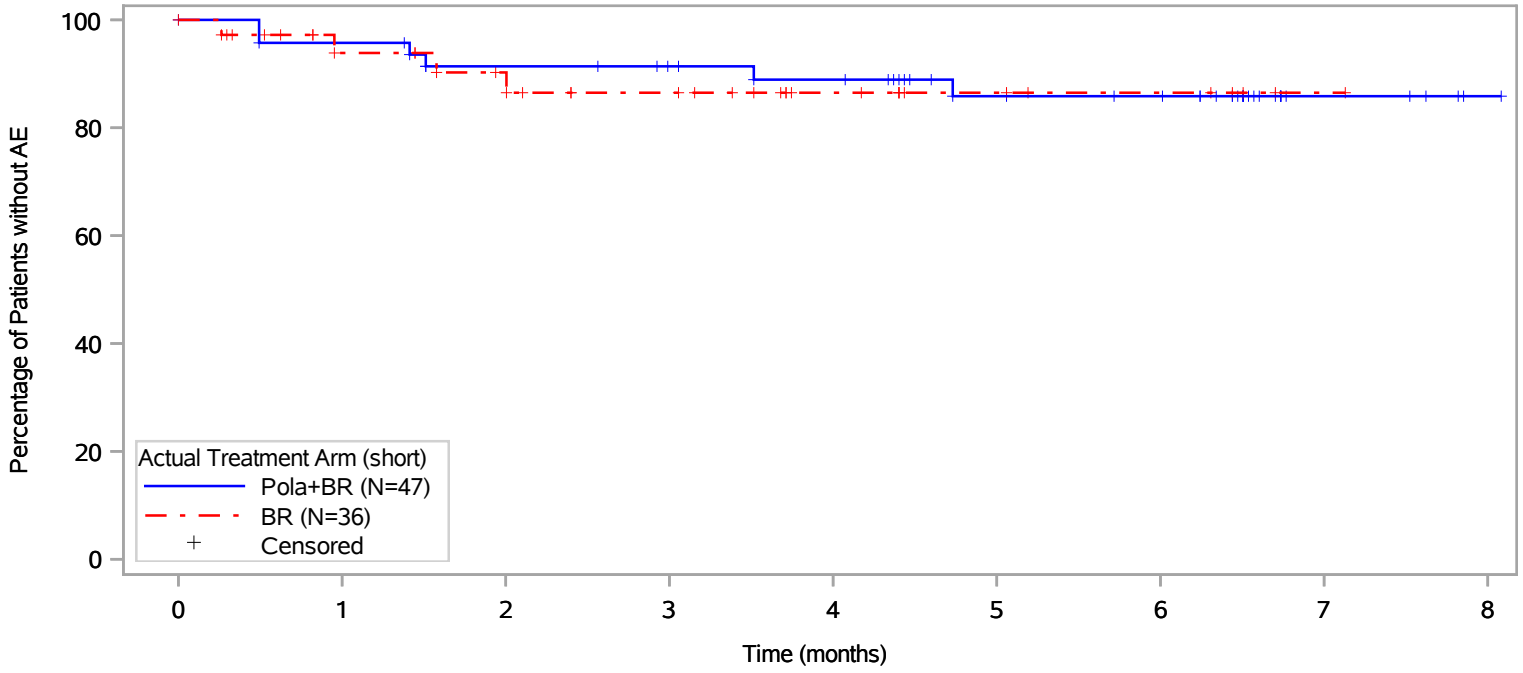
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, ASPHYXIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, COUGH



Patients at risk									
Pola+BR (N=47)	47	45	41	38	36	28	26	5	1
BR (N=36)	36	28	24	20	12	7	5	1	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	6	13	15	36	40
BR (N=36)	0	6	9	12	20	25	27	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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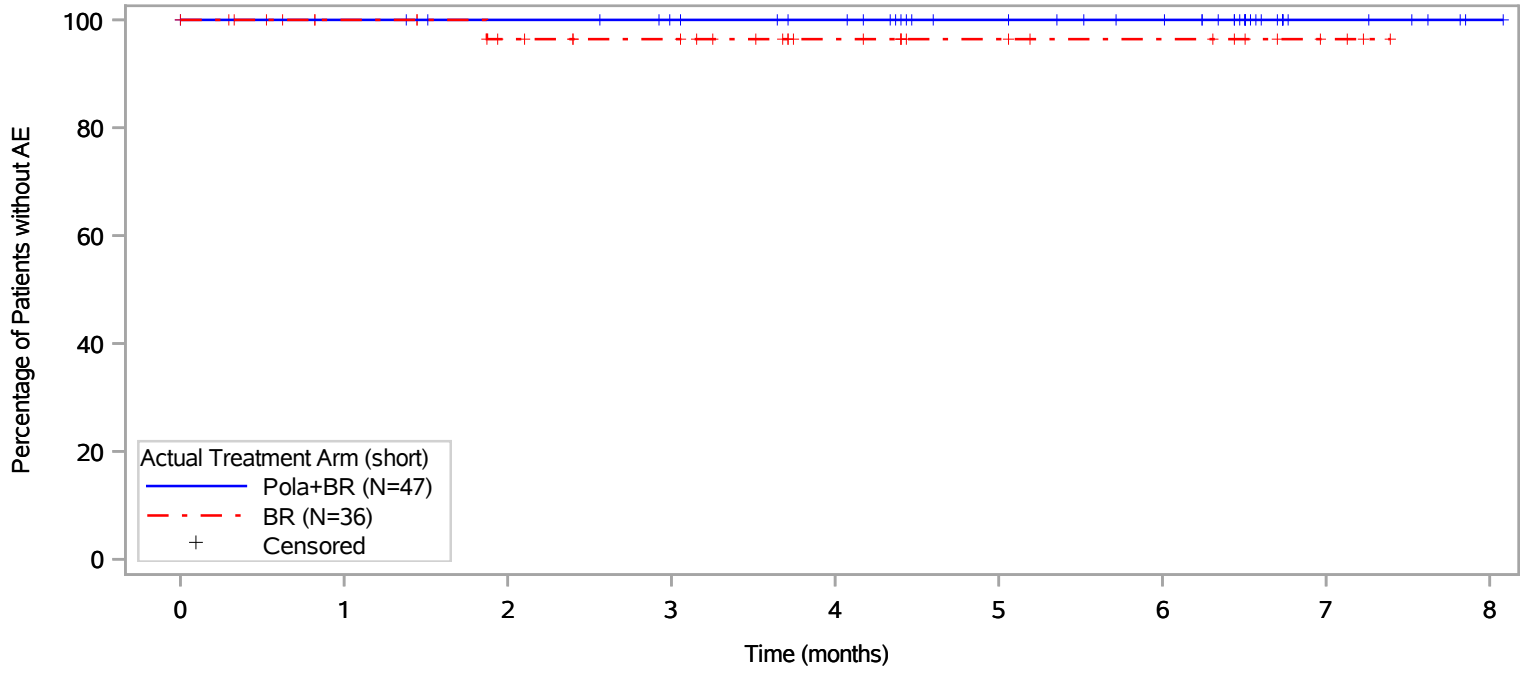
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPHONIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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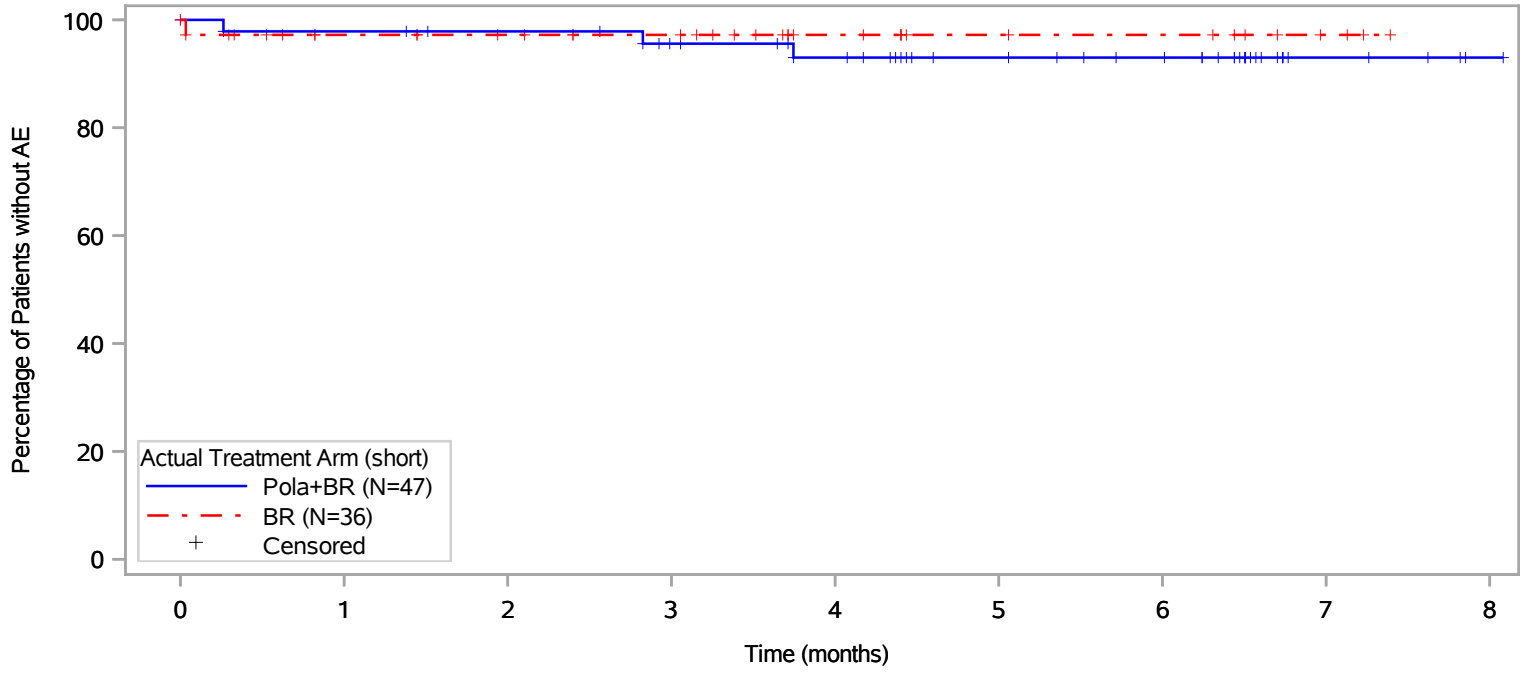
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPNOEA



Patients at risk									
Pola+BR (N=47)	47	46	44	40	36	28	24	5	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	43
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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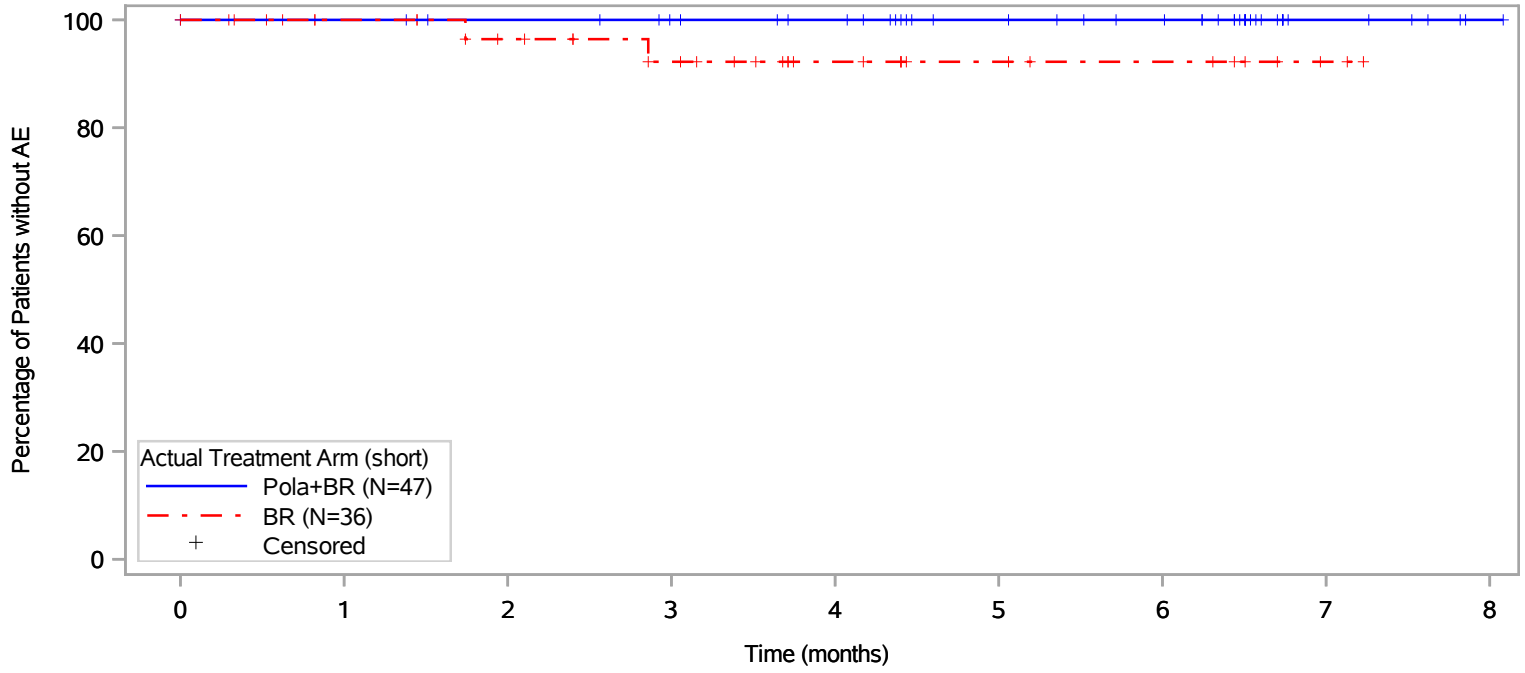
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPNOEA EXERTIONAL



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	22	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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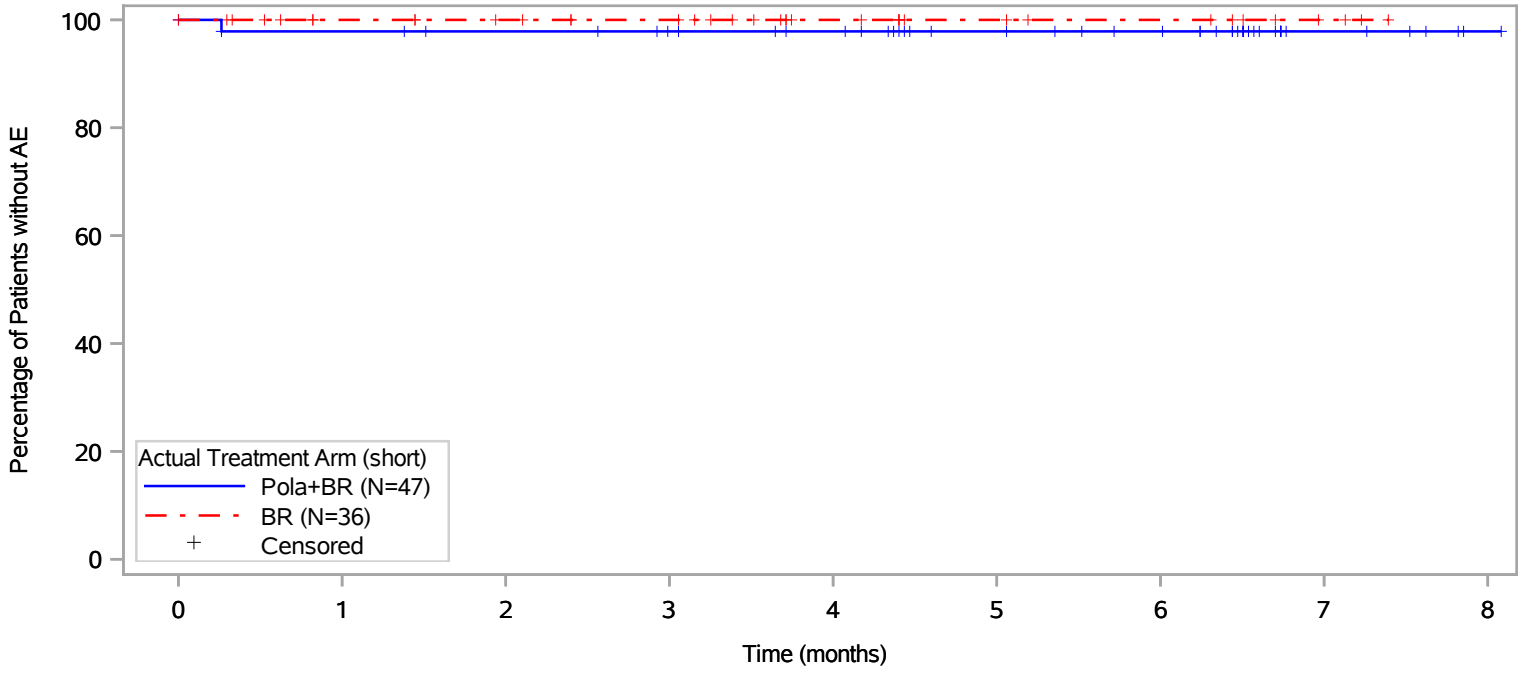
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, EPISTAXIS



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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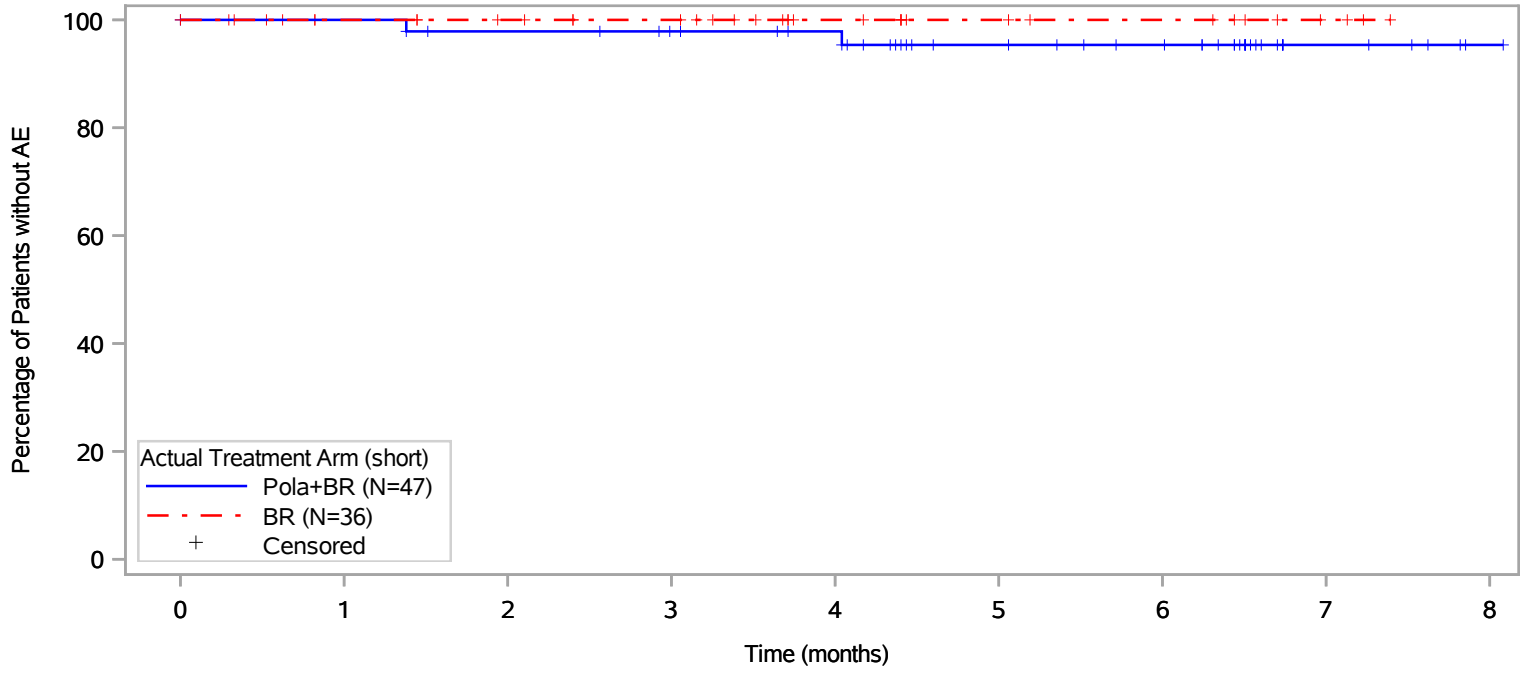
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HAEMOPTYSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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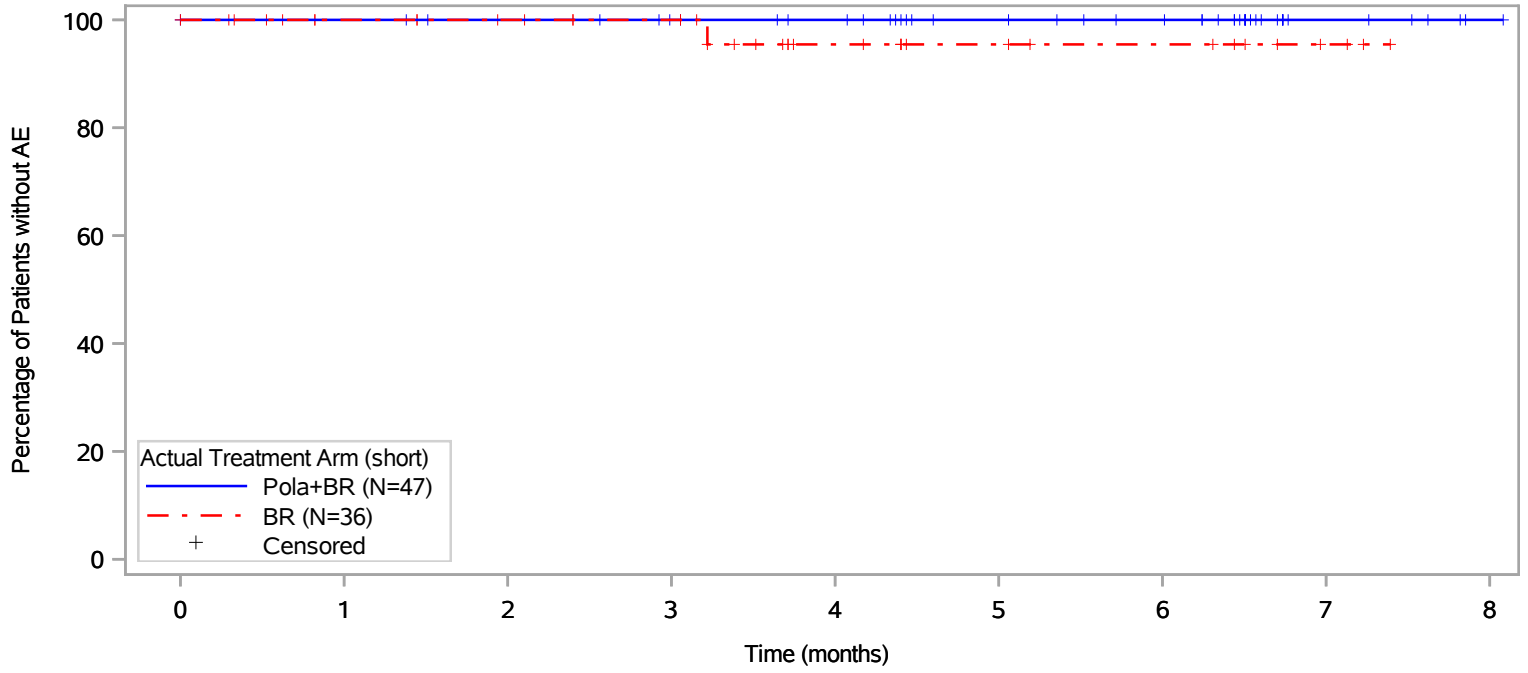
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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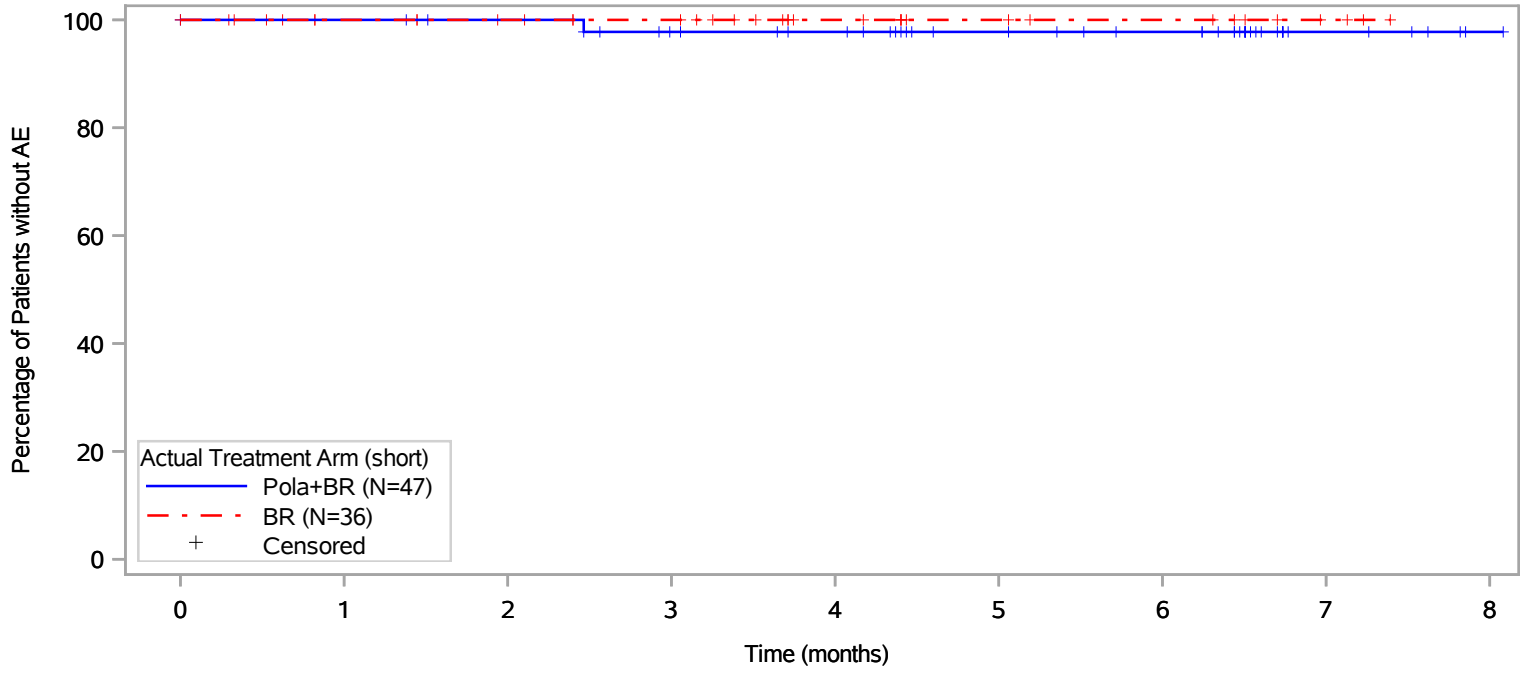
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, INTERSTITIAL LUNG DISEASE



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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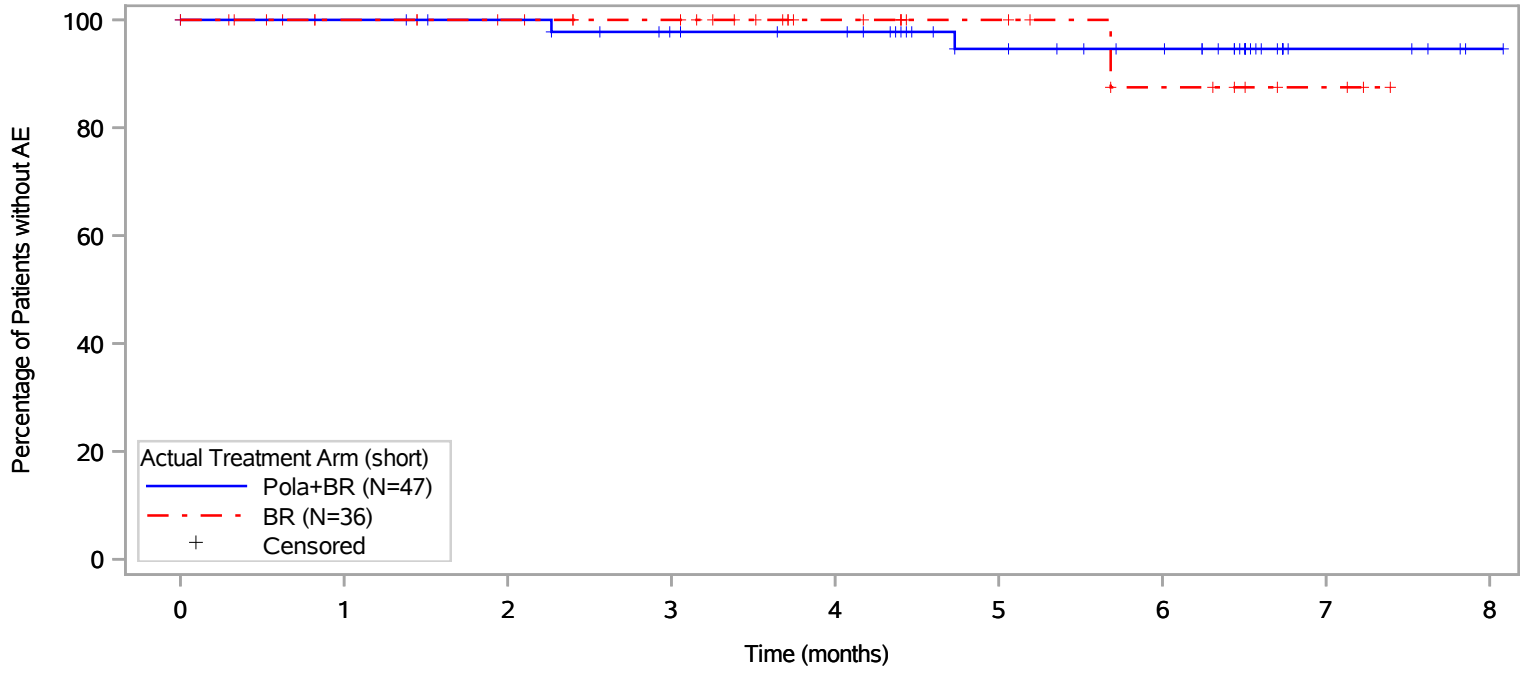
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, OROPHARYNGEAL PAIN



Patients at risk									
Pola+BR (N=47)	47	47	45	41	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	44
BR (N=36)	0	6	9	12	21	26	28	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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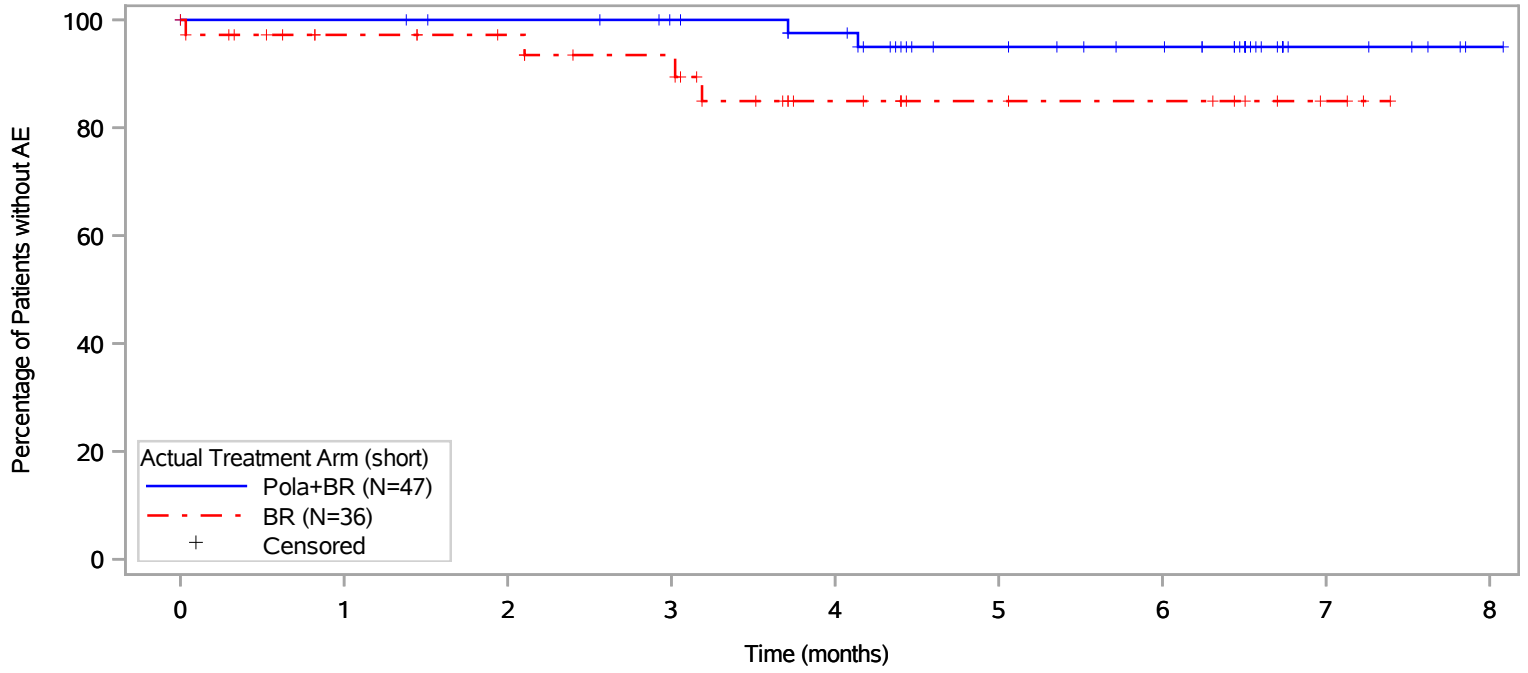
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	39	44
BR (N=36)	0	6	9	11	18	23	24	29	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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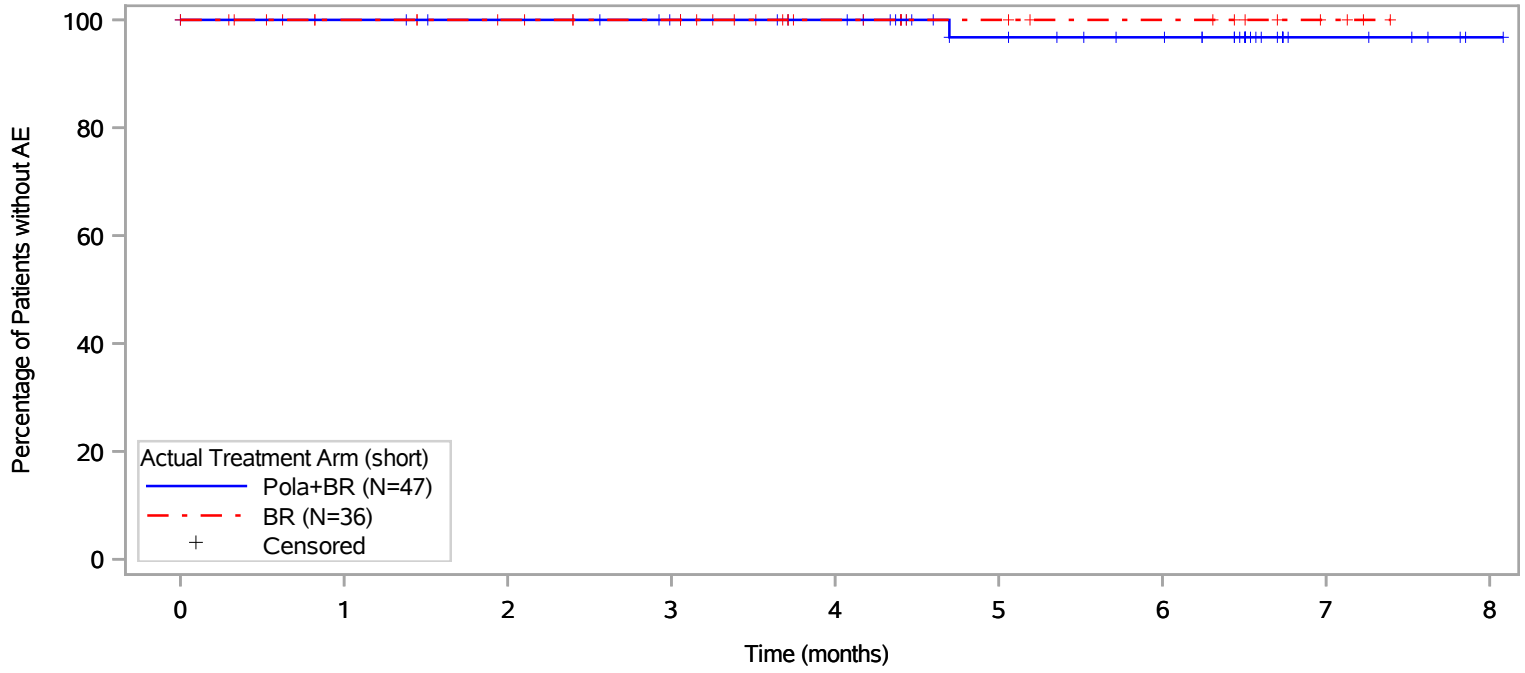
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PNEUMOMEDIASTINUM



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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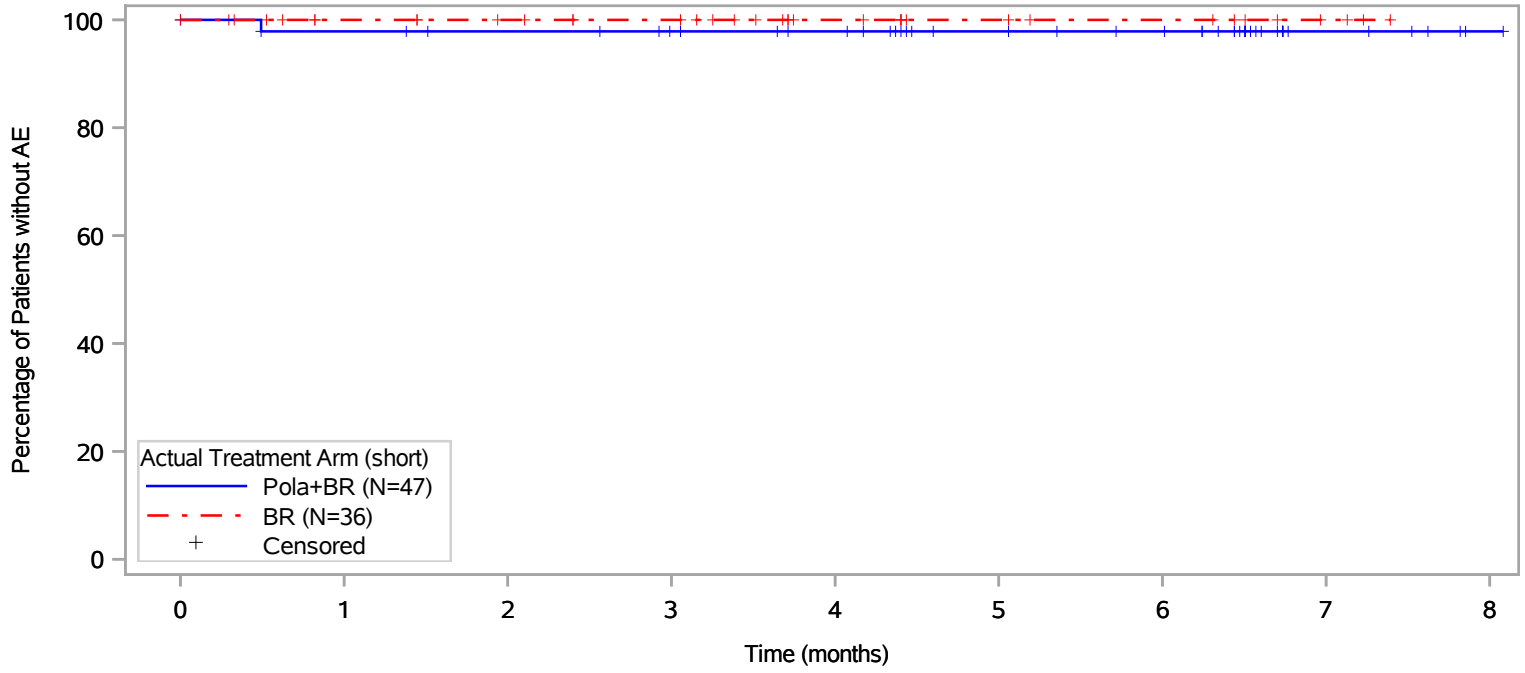
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PRODUCTIVE COUGH



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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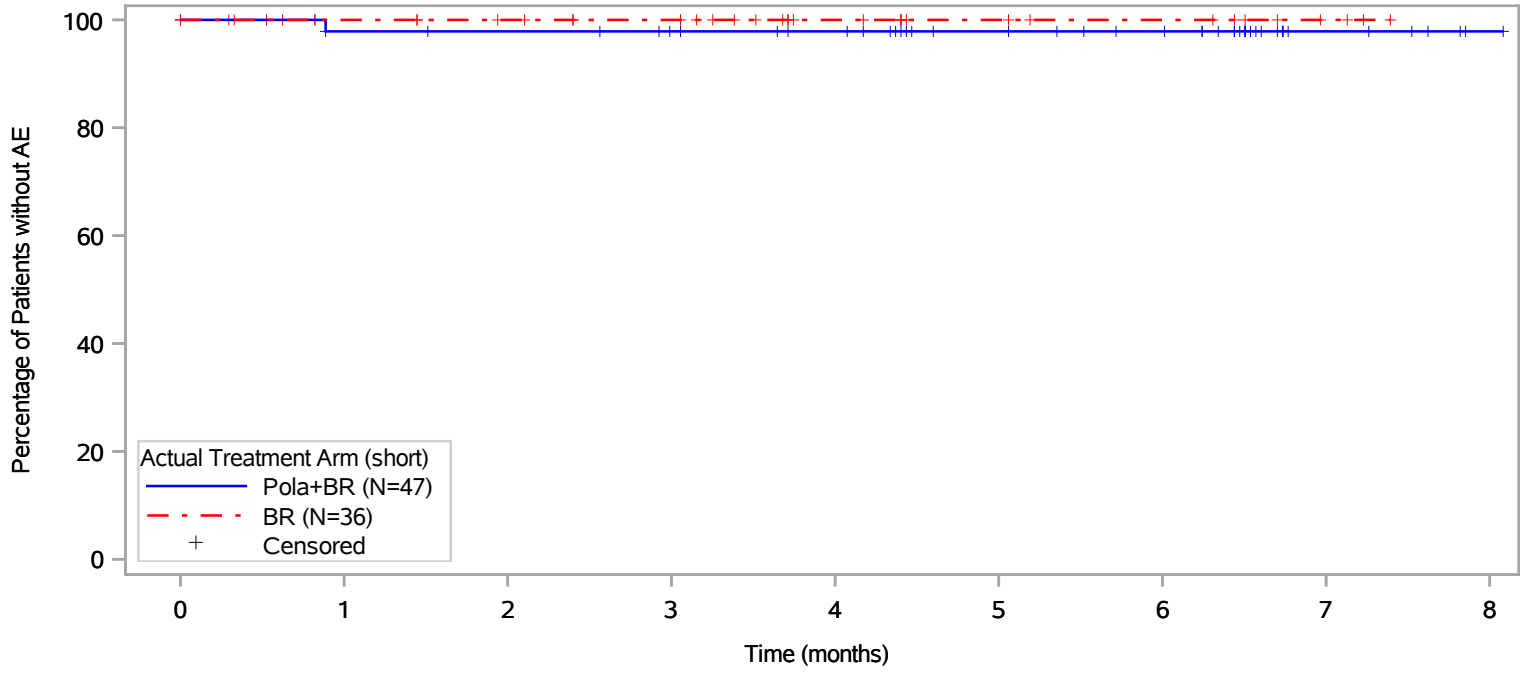
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY EMBOLISM



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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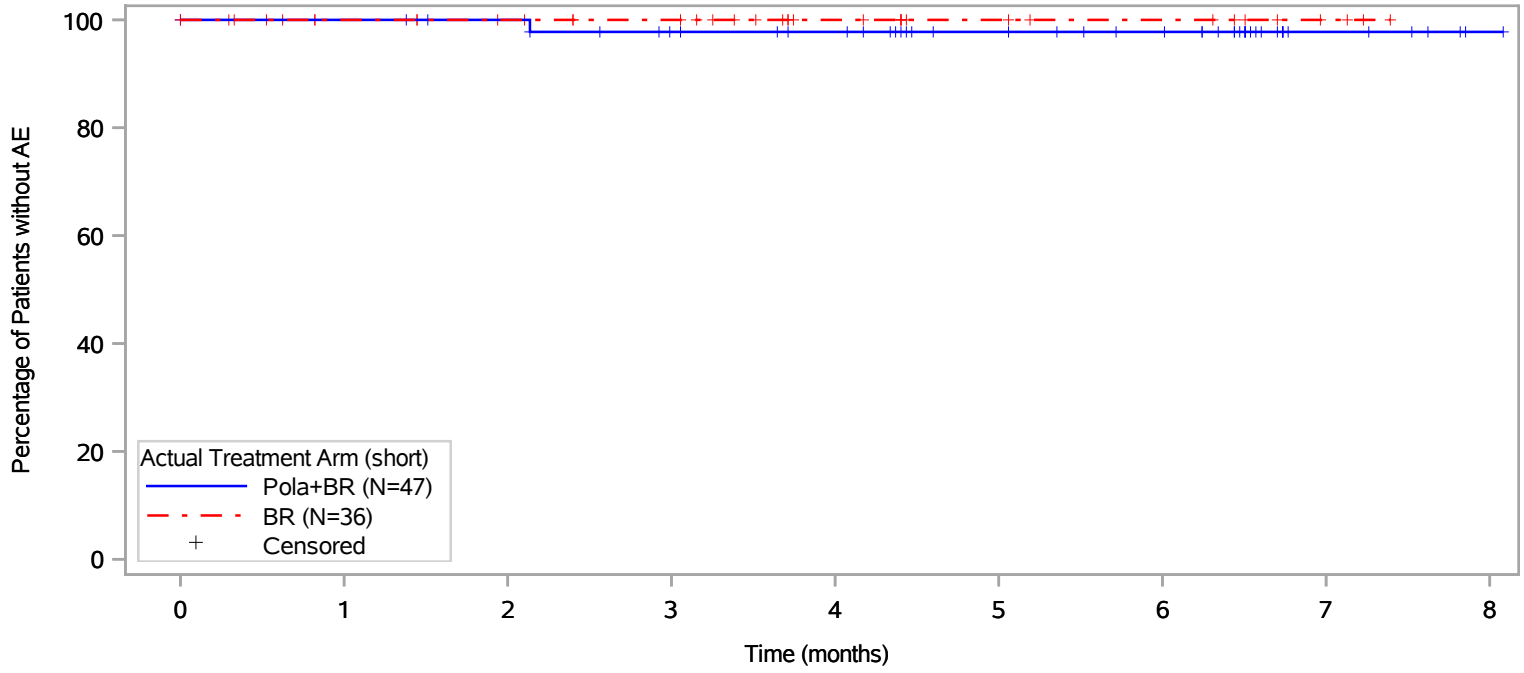
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, RHINORRHOEA



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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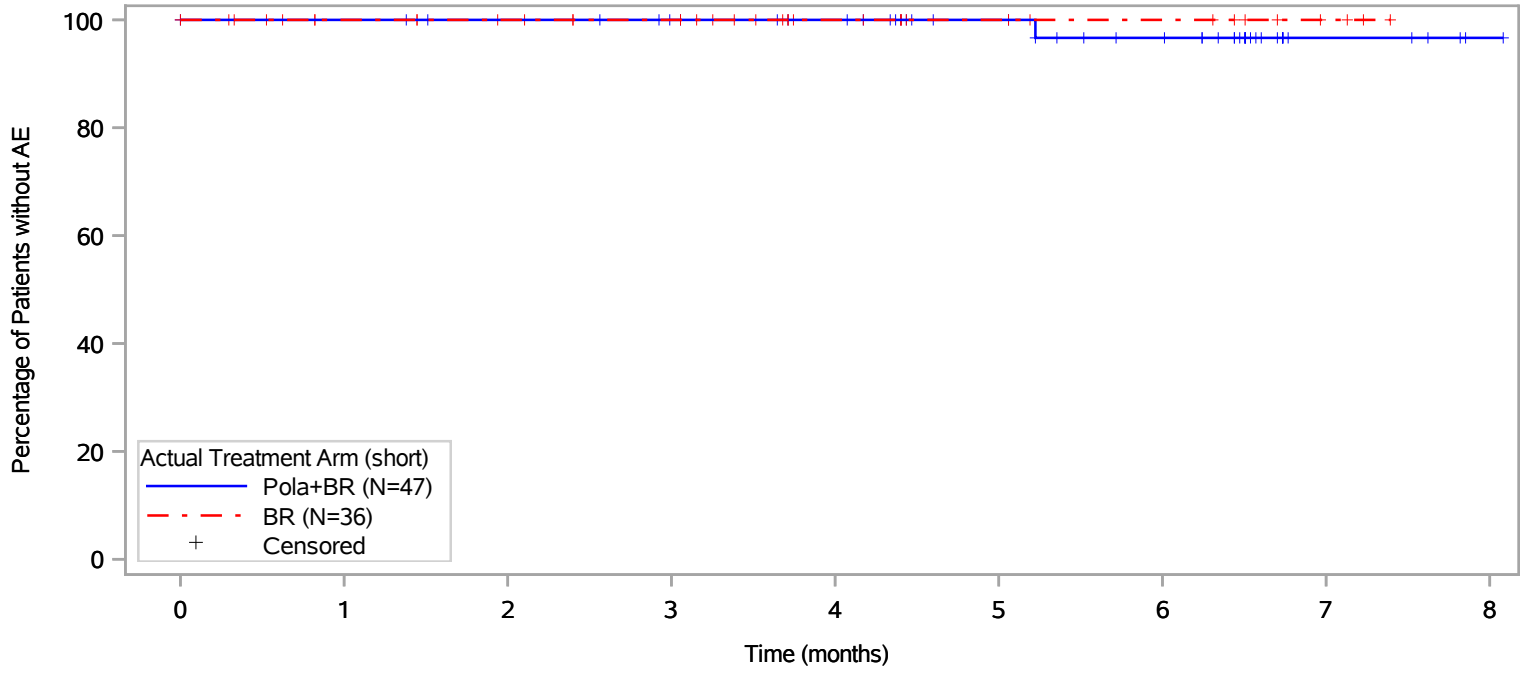
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, UPPER-AIRWAY COUGH SYNDROME



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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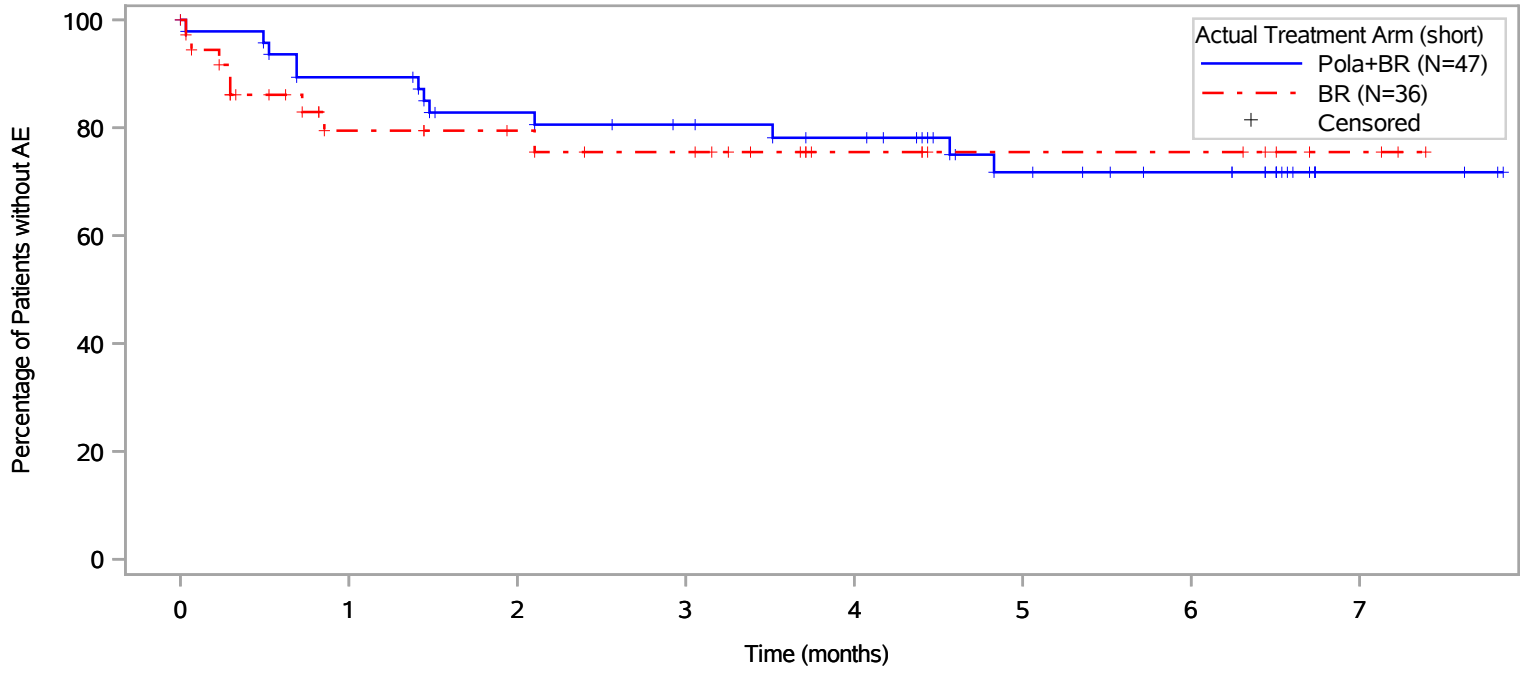
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk								
Pola+BR (N=47)	47	42	37	34	31	22	18	3
BR (N=36)	36	23	20	18	10	7	7	3
Patients censored								
Pola+BR (N=47)	0	0	2	4	6	13	17	32
BR (N=36)	0	6	9	10	18	21	21	25

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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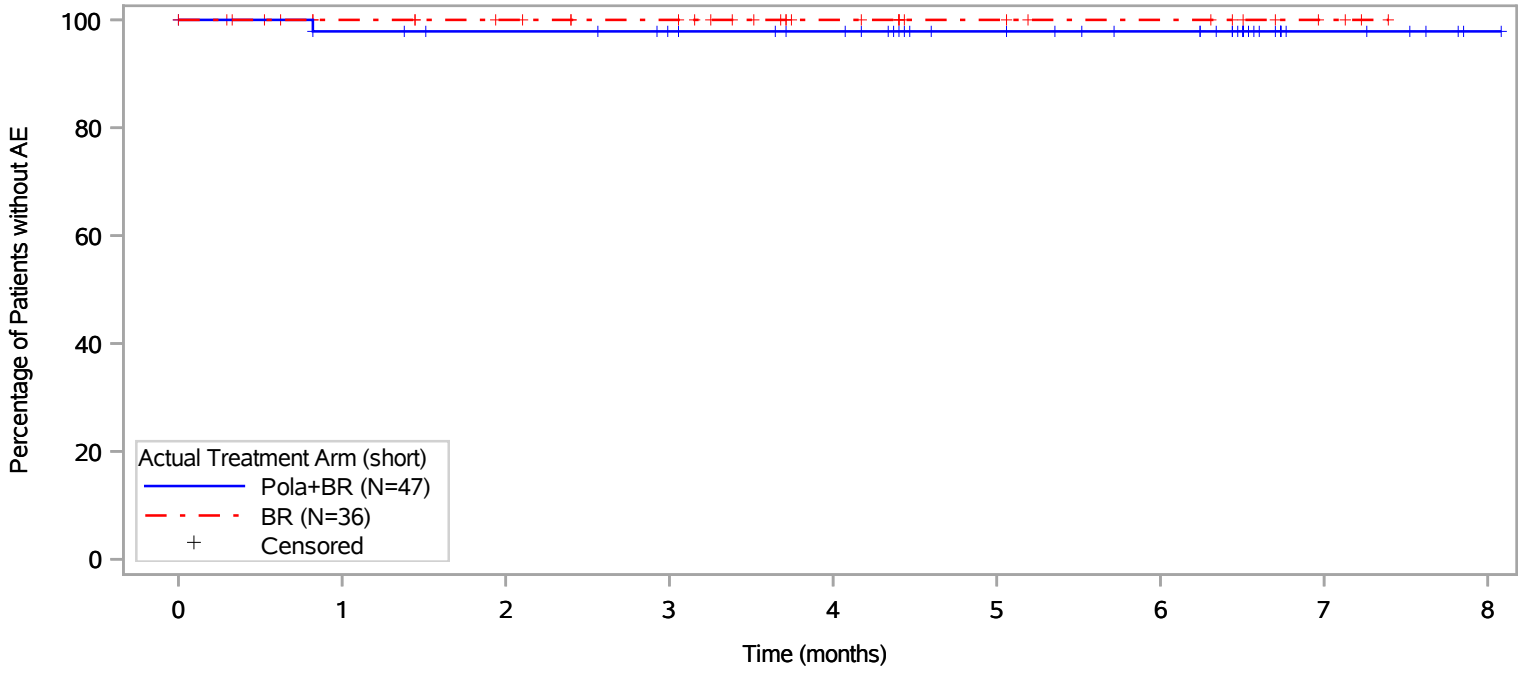
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, ALOPECIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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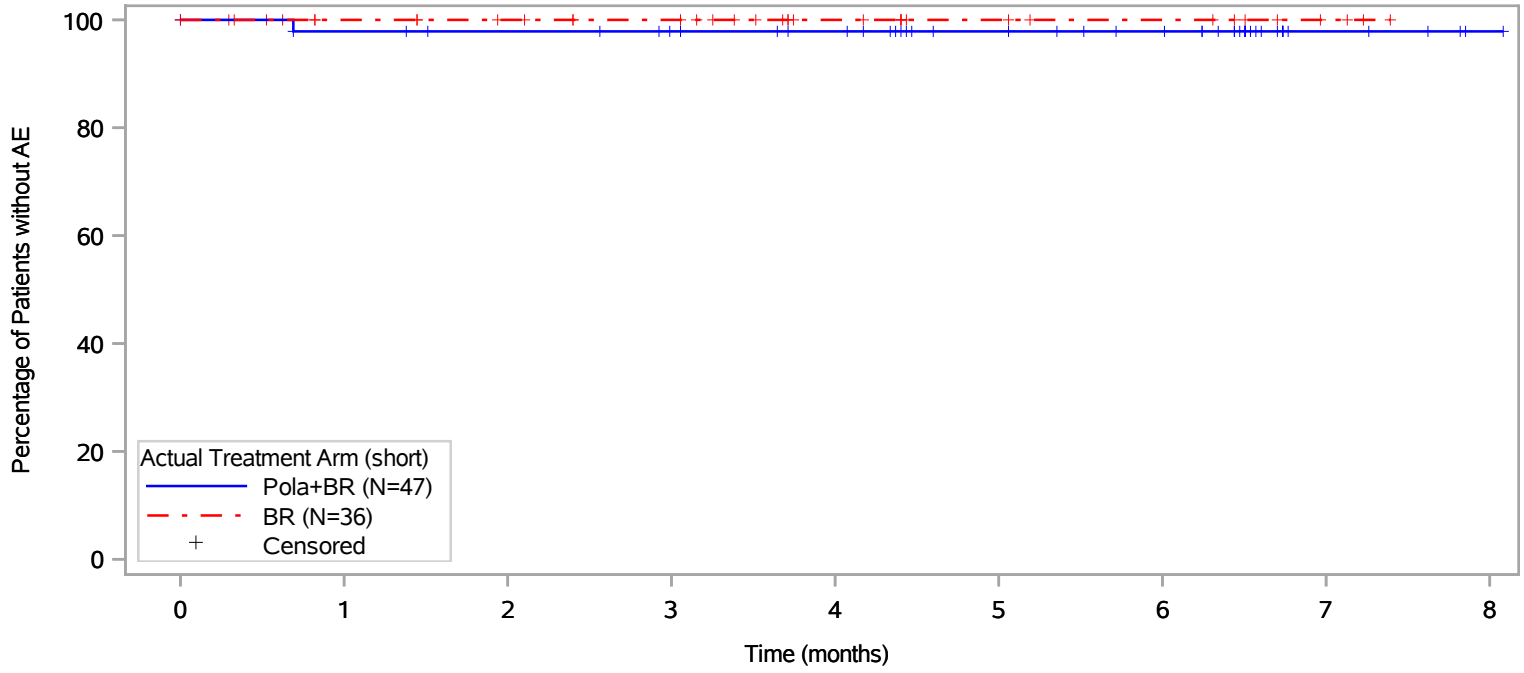
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, BUTTERFLY RASH



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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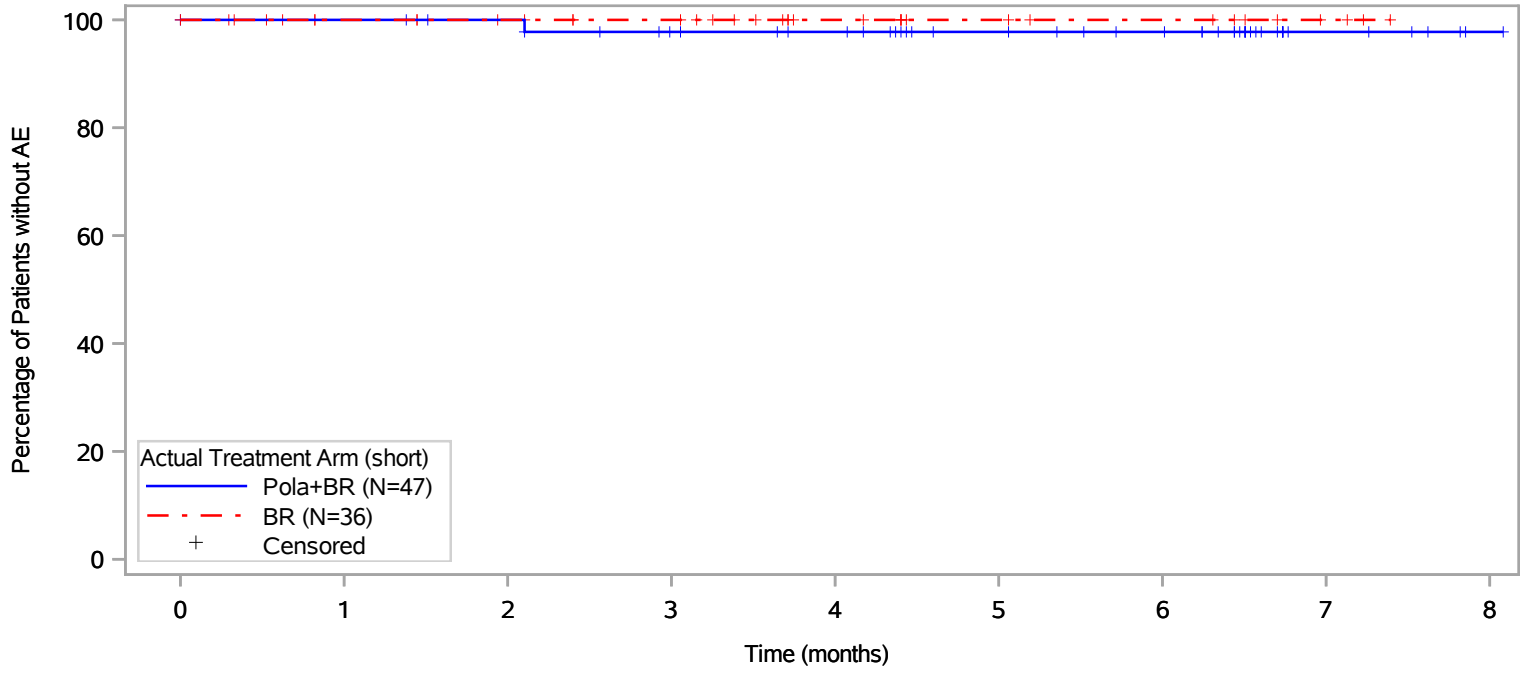
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DERMATITIS EXFOLIATIVE GENERALISED



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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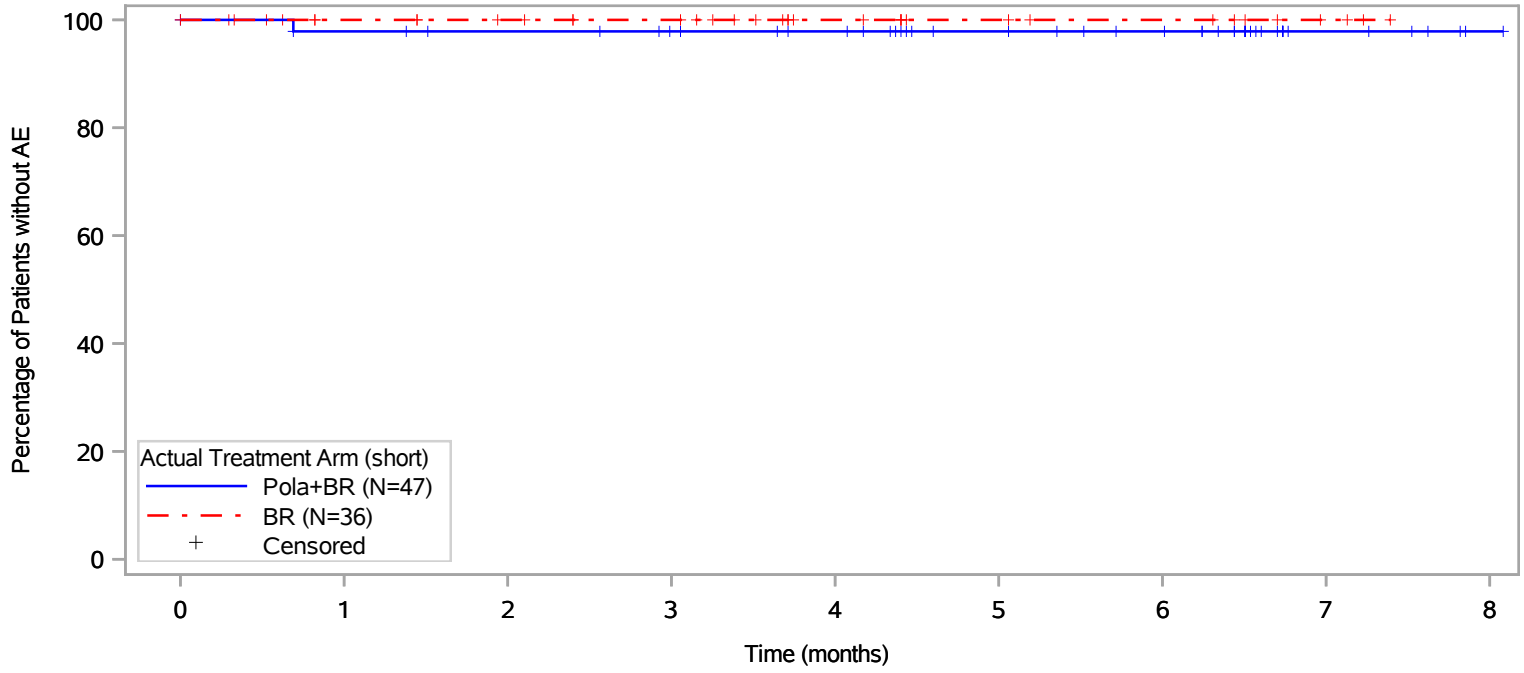
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DRUG ERUPTION



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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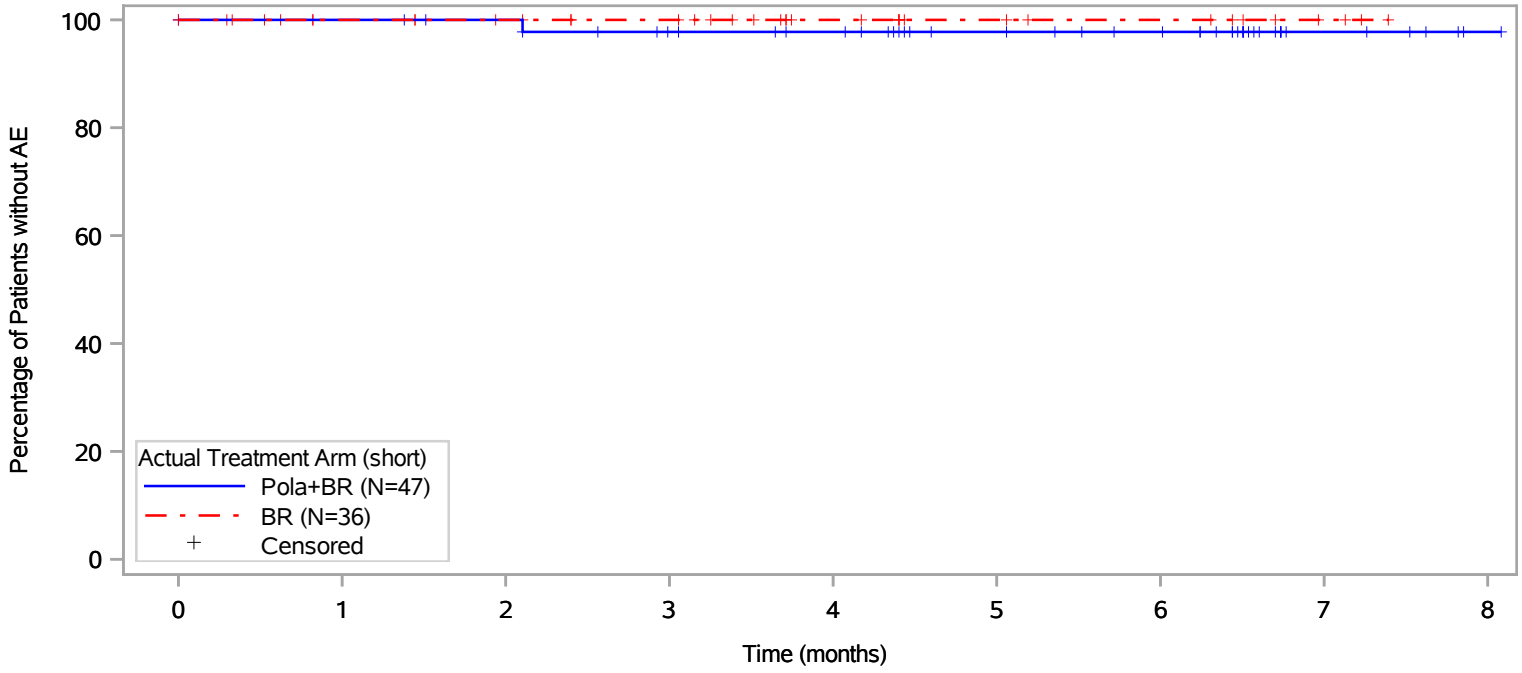
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DRY SKIN



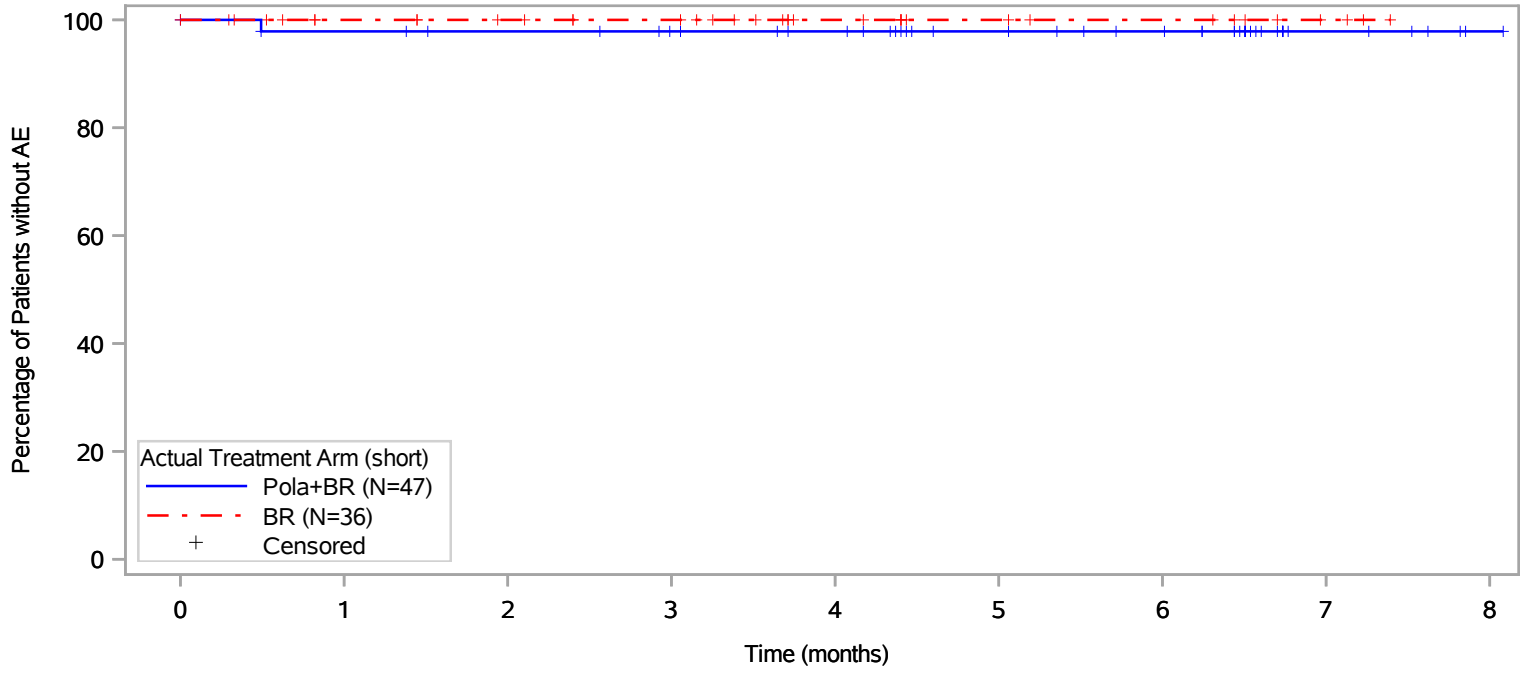
Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, ECZEMA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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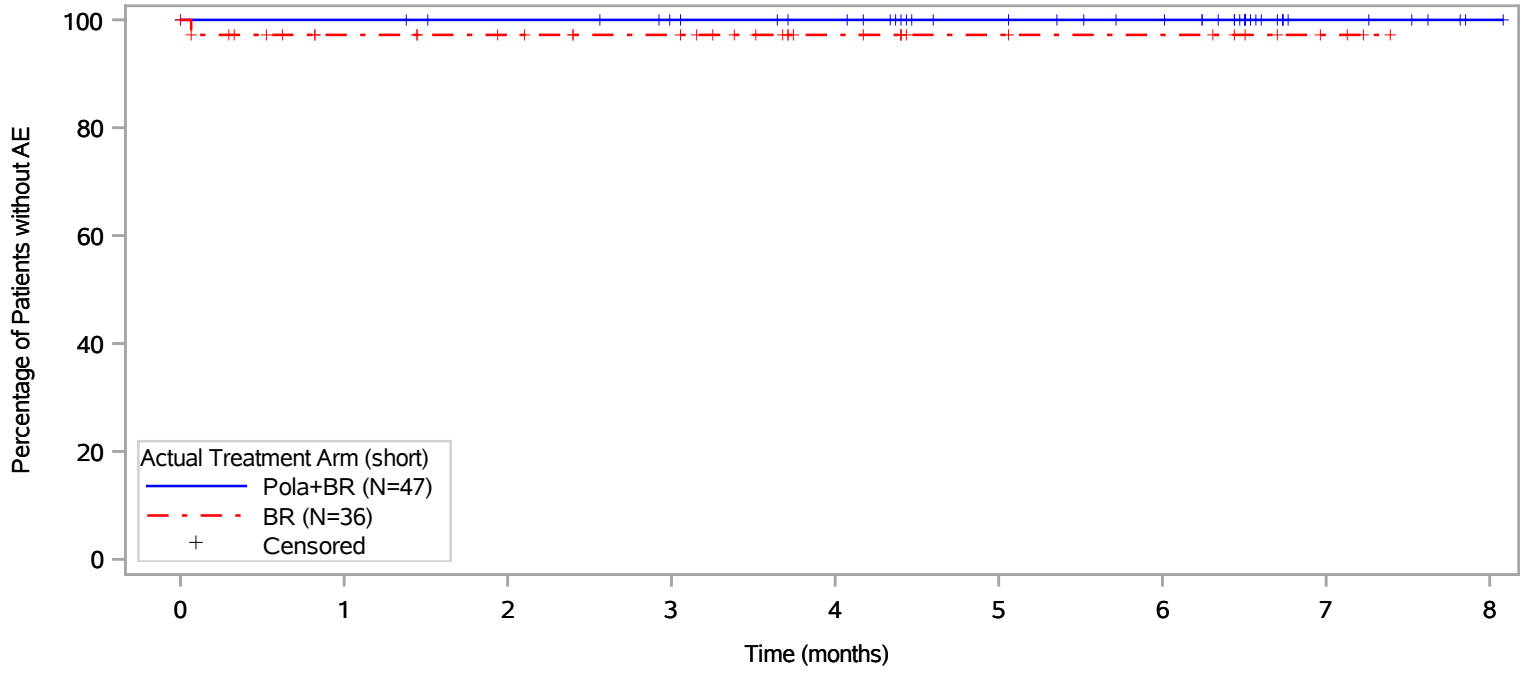
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, NIGHT SWEATS



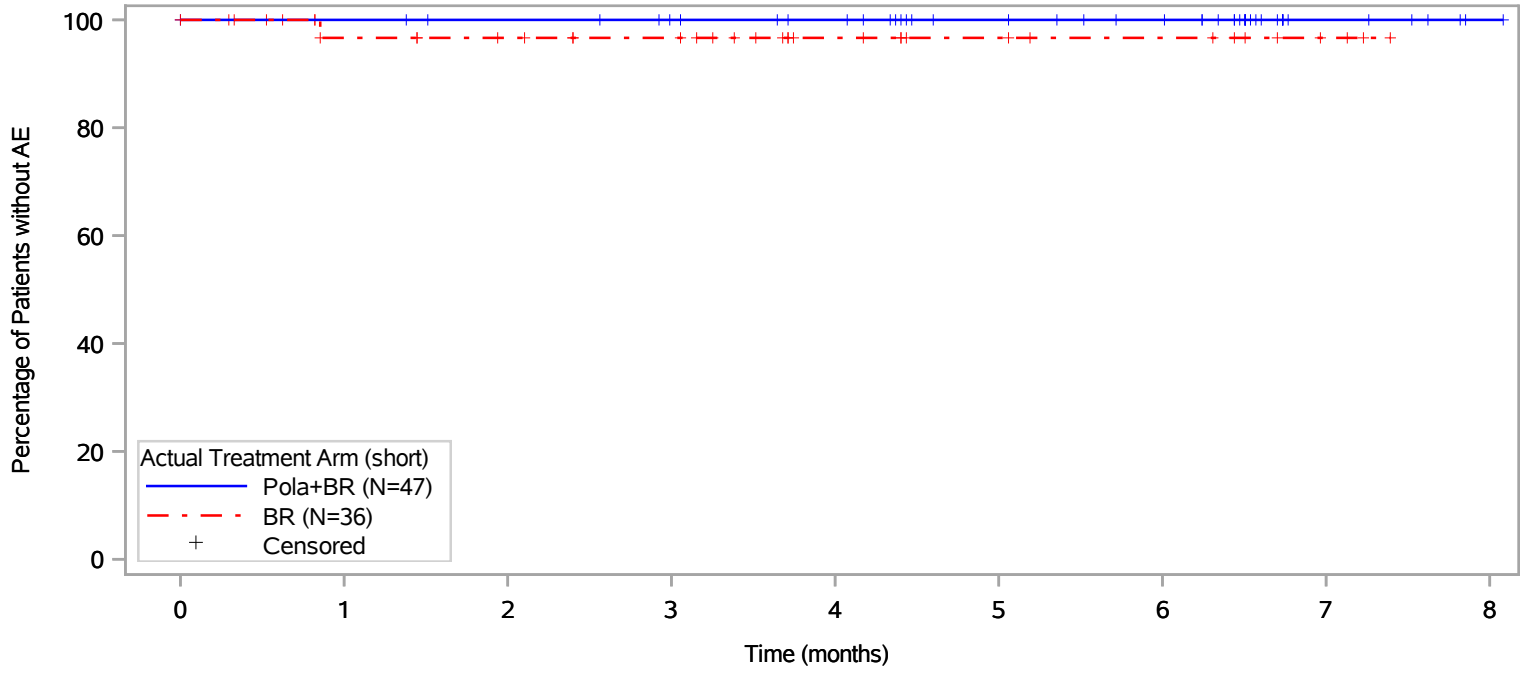
Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PAPULE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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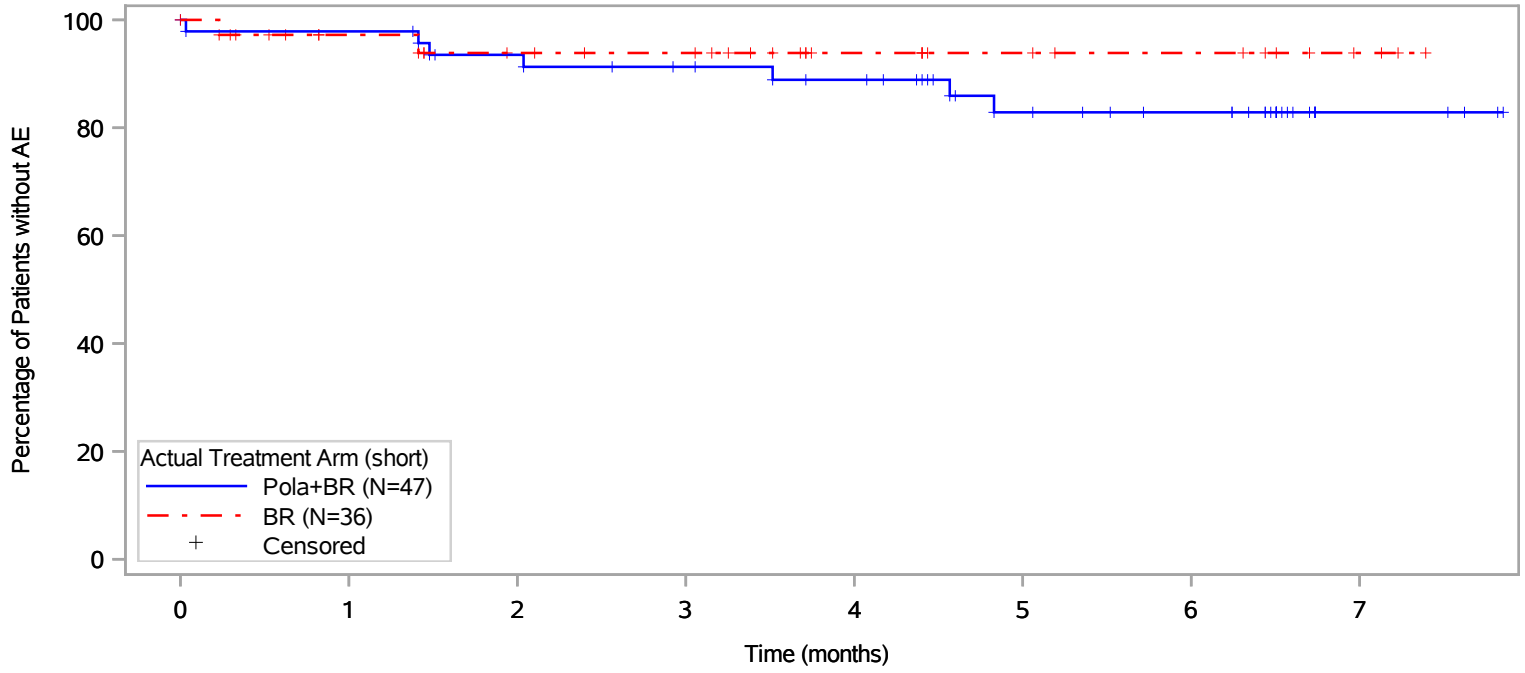
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS



Patients at risk								
Pola+BR (N=47)	47	46	42	39	36	27	23	4
BR (N=36)	36	29	25	23	14	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	4	6	13	17	36
BR (N=36)	0	6	9	11	20	24	26	31

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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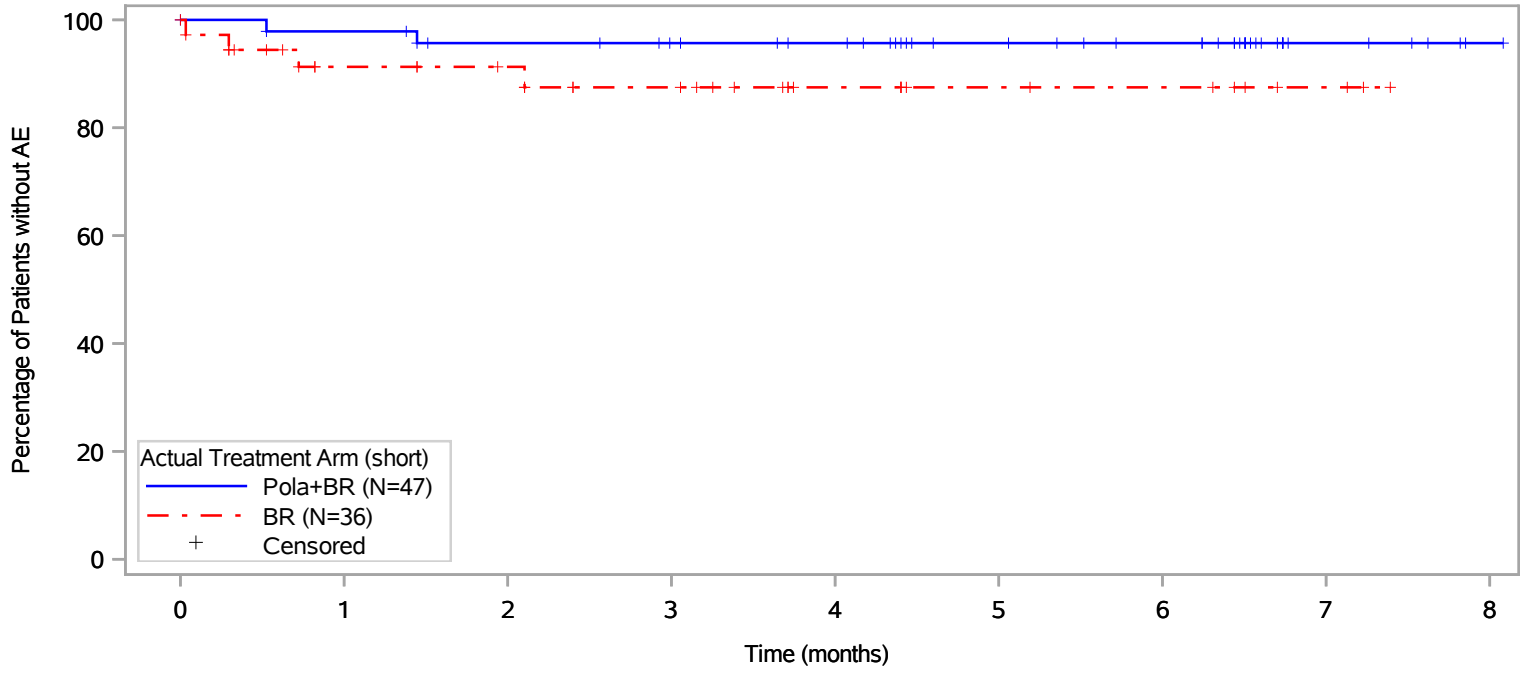
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=47)	47	46	43	40	37	29	25	6	1
BR (N=36)	36	27	24	20	12	8	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	6	9	12	20	24	25	29	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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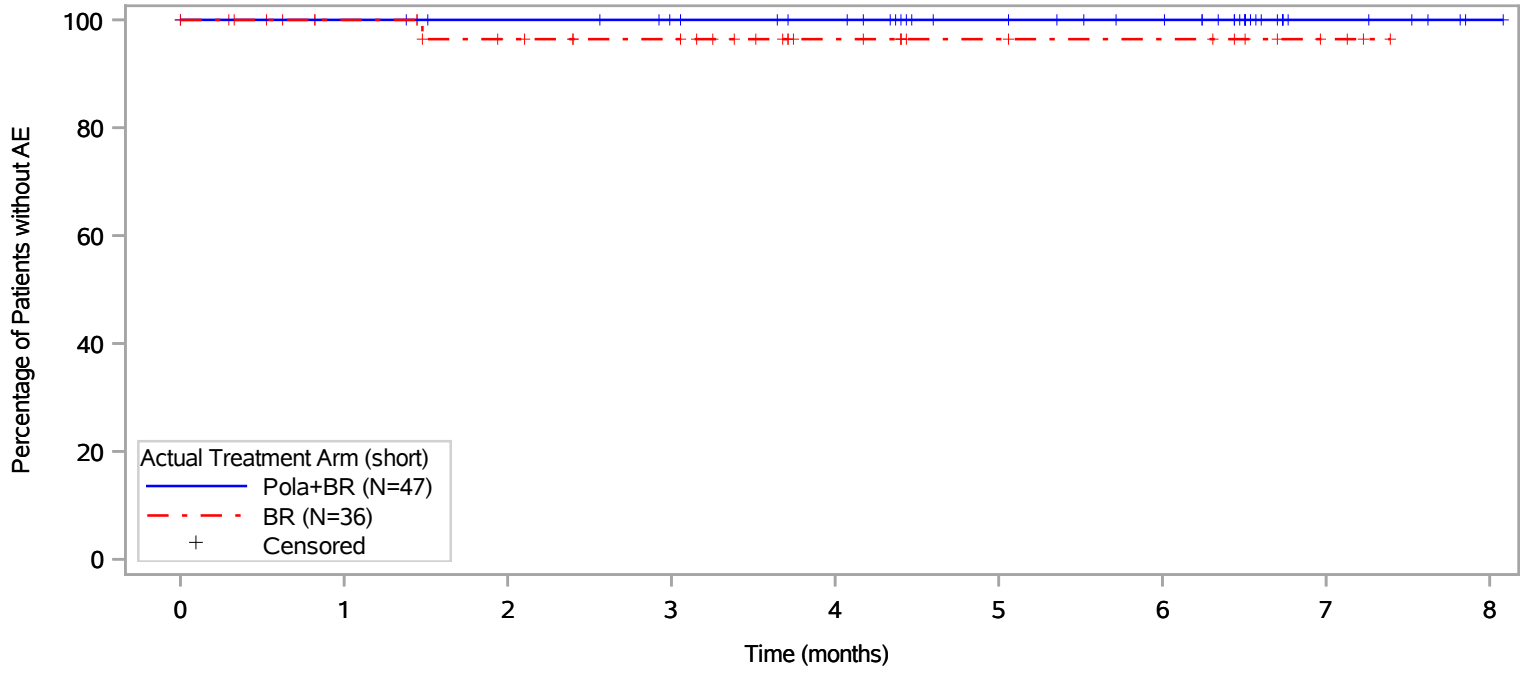
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH ERYTHEMATOUS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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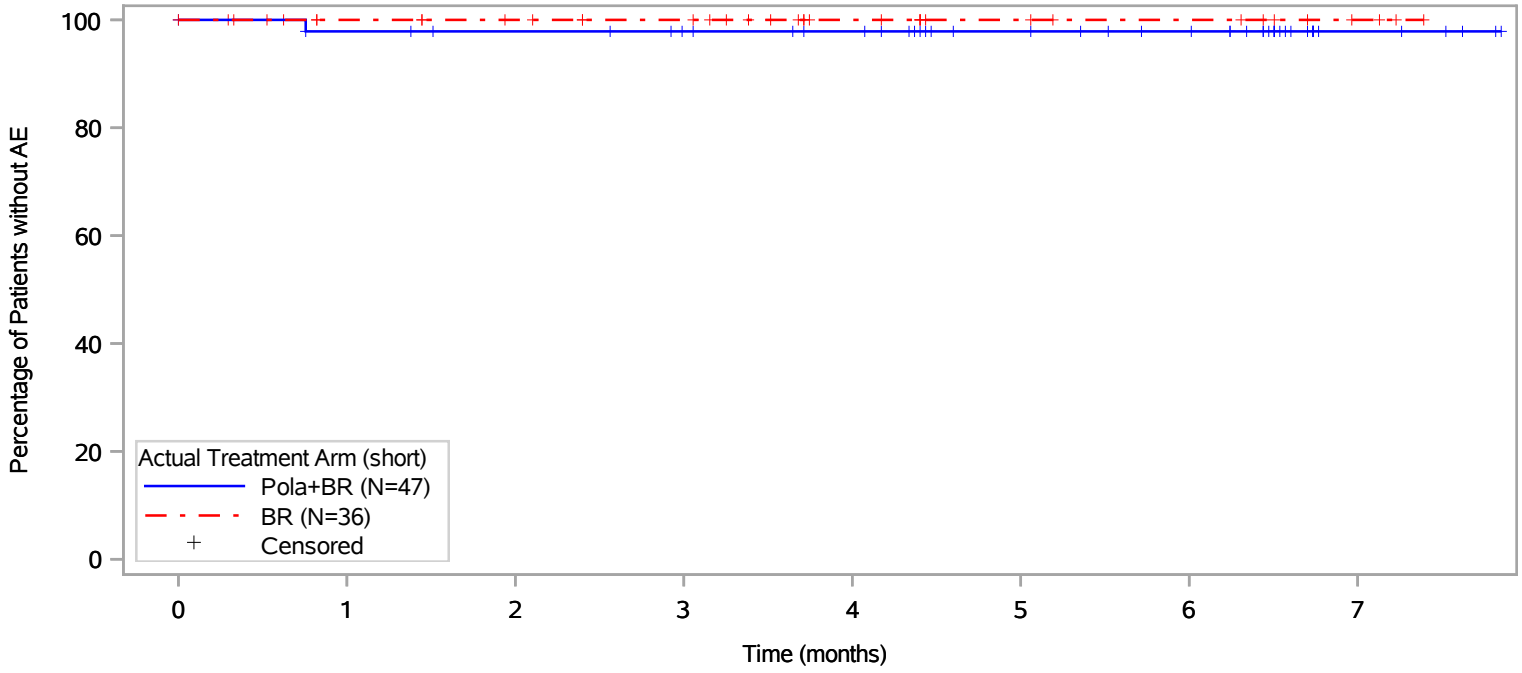
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH MACULO-PAPULAR



Patients at risk								
Pola+BR (N=47)	47	46	44	41	38	30	26	5
BR (N=36)	36	30	27	24	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	16	20	41
BR (N=36)	0	6	9	12	21	26	28	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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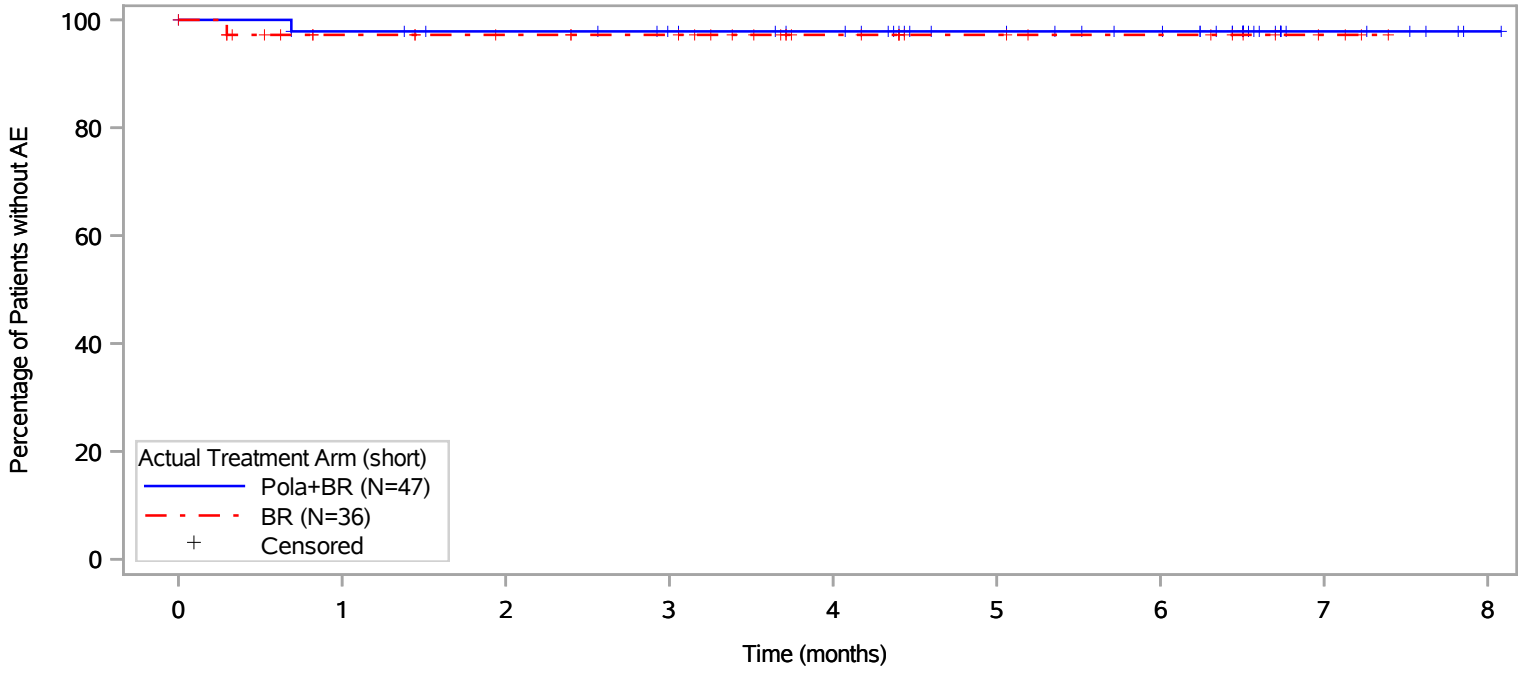
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, URTICARIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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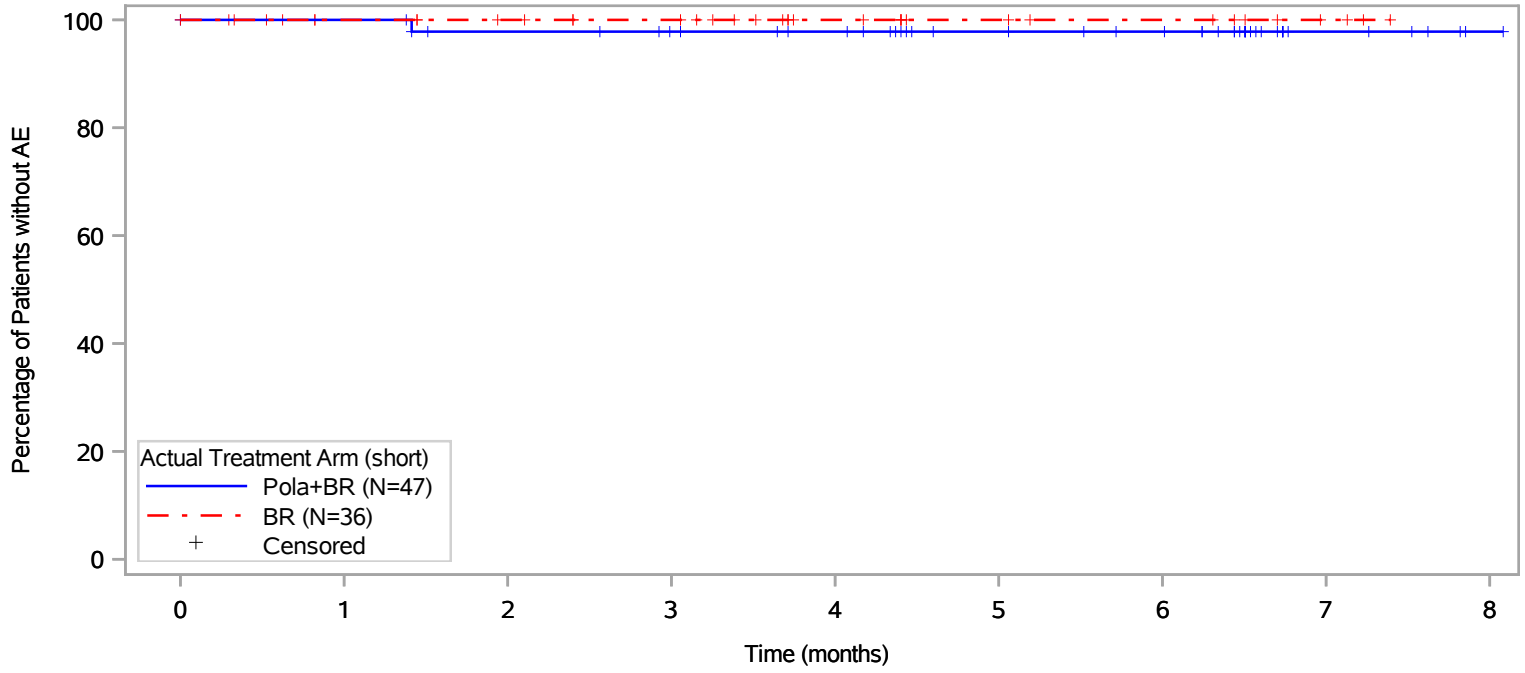
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SURGICAL AND MEDICAL PROCEDURES, All



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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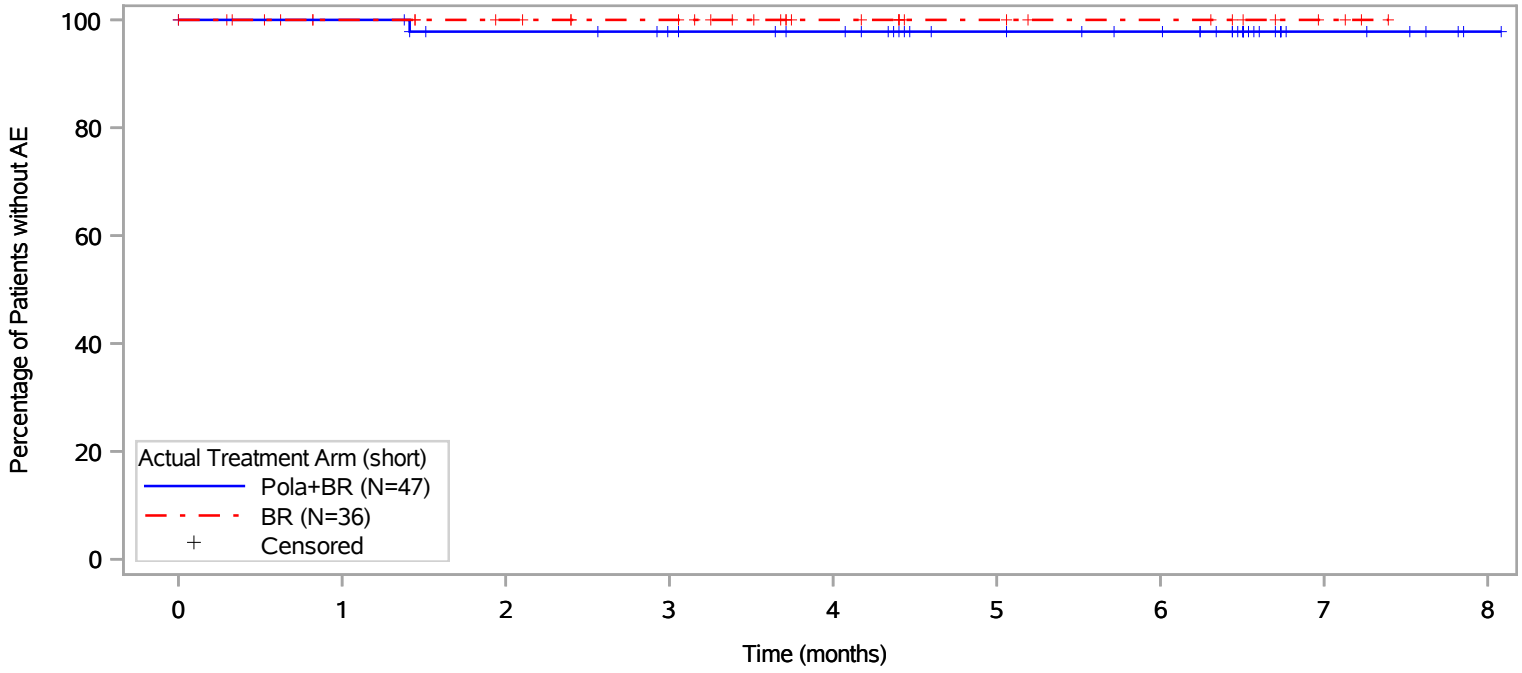
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SURGICAL AND MEDICAL PROCEDURES, SINUS OPERATION

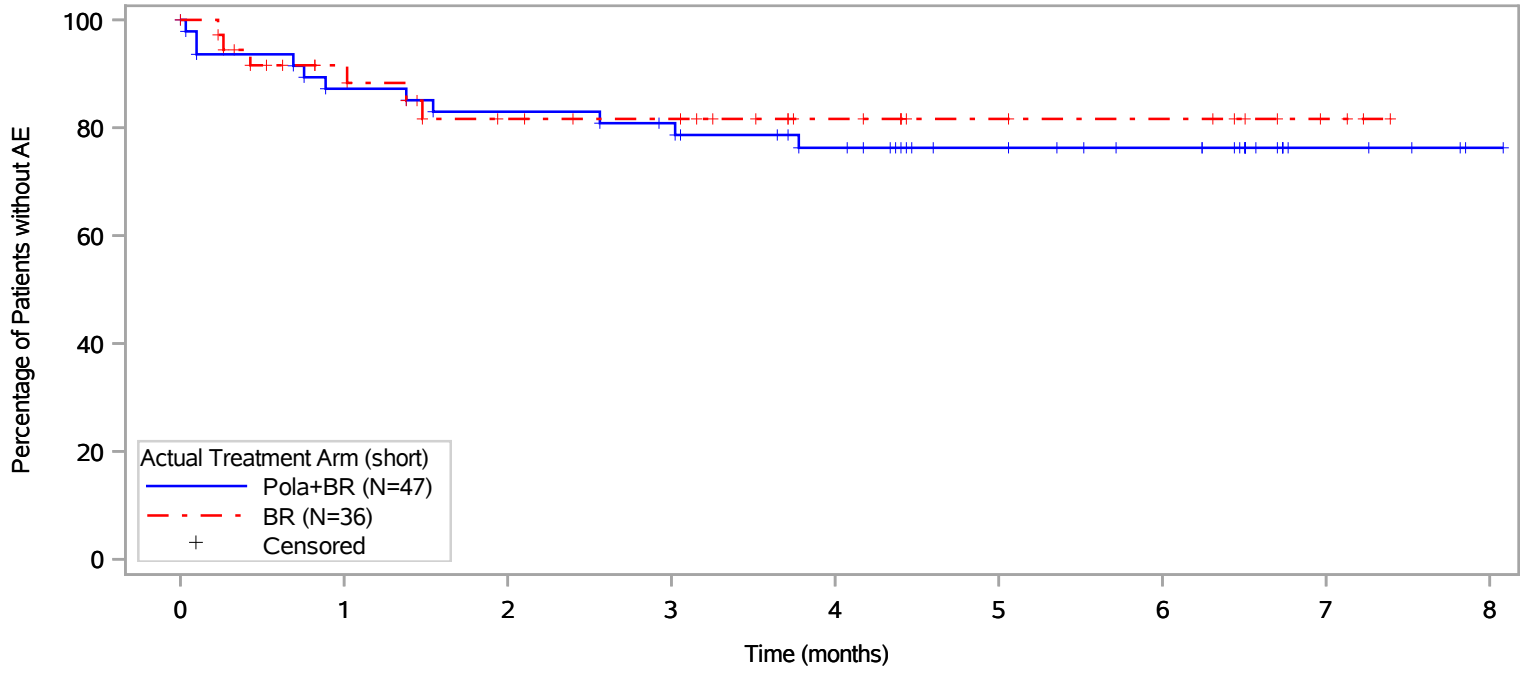


Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All

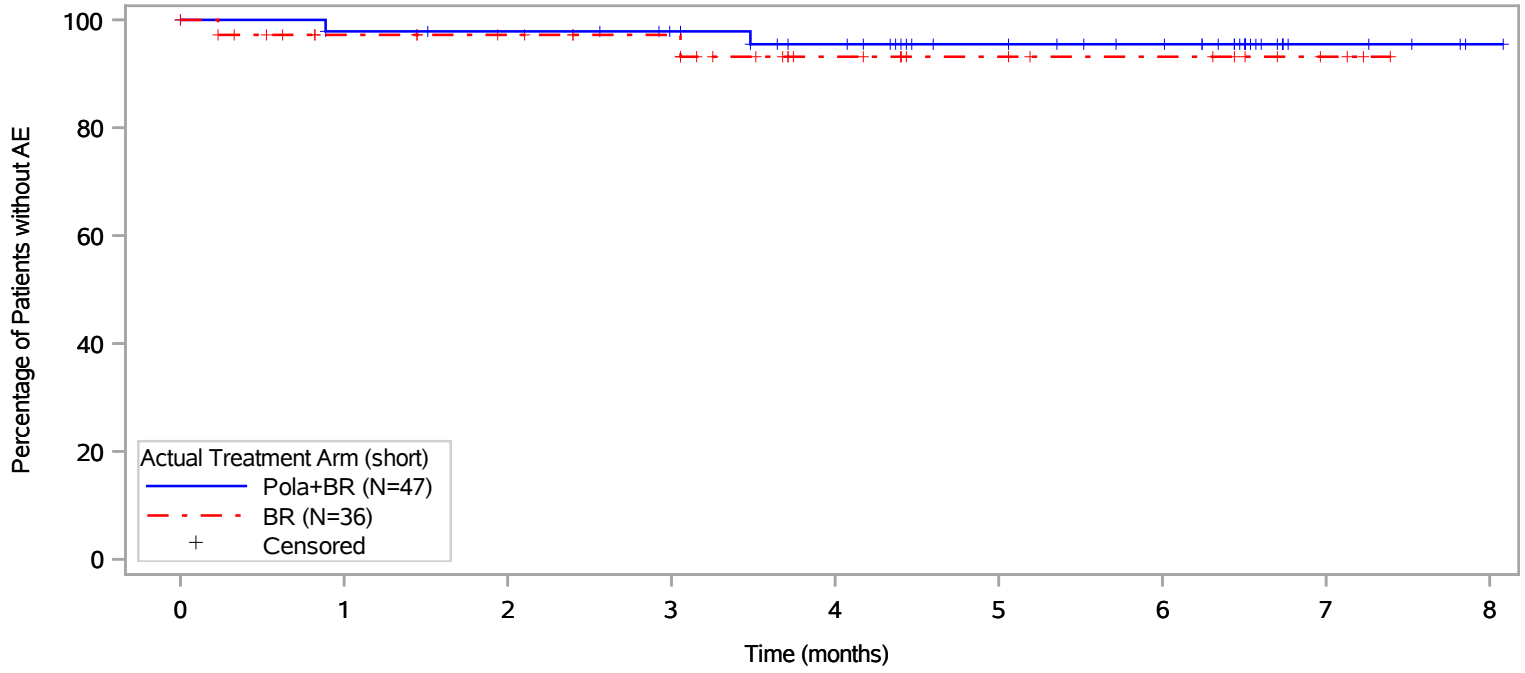


Patients at risk									
Pola+BR (N=47)	47	41	39	37	32	24	20	5	1
BR (N=36)	36	28	23	21	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	0	1	4	12	16	31	35
BR (N=36)	0	5	7	9	16	21	22	27	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DEEP VEIN THROMBOSIS

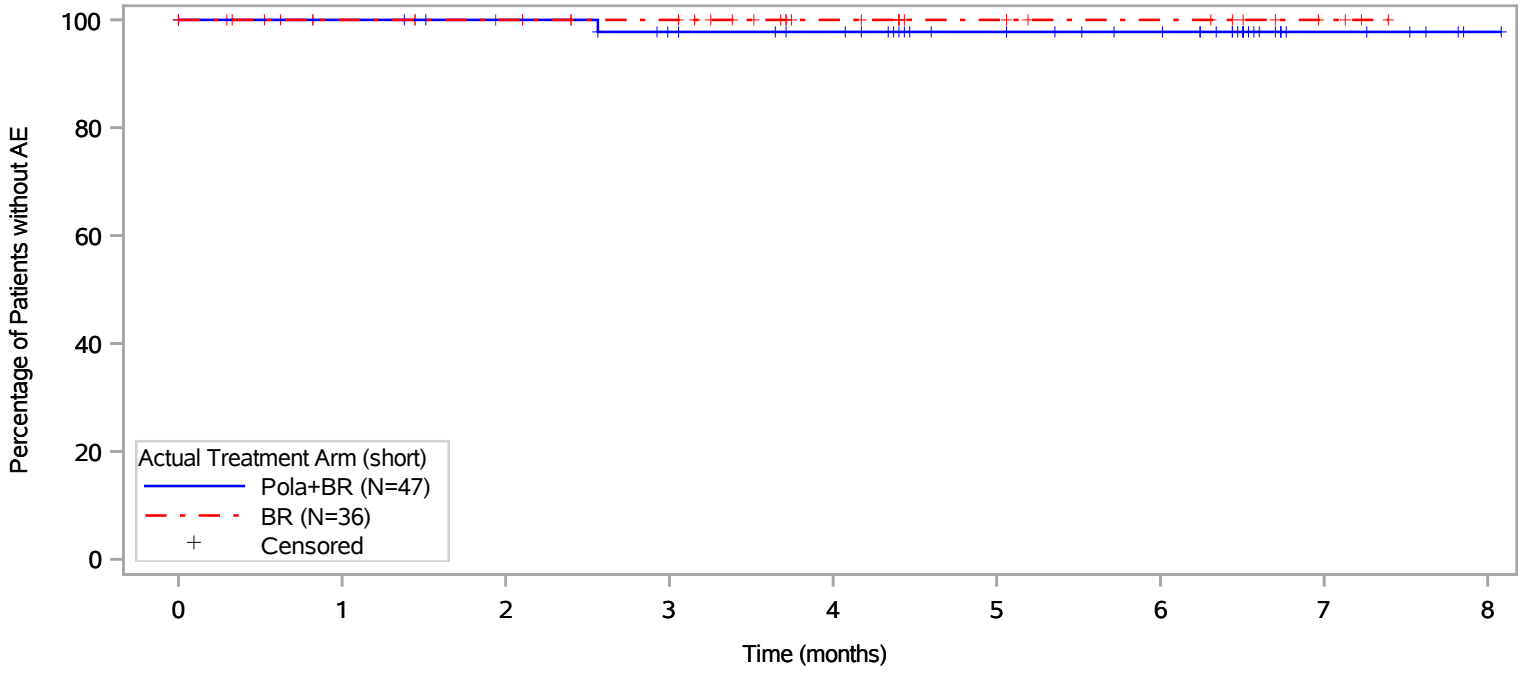


Patients at risk									
Pola+BR (N=47)	47	46	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	44
BR (N=36)	0	5	8	11	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DISTRIBUTIVE SHOCK

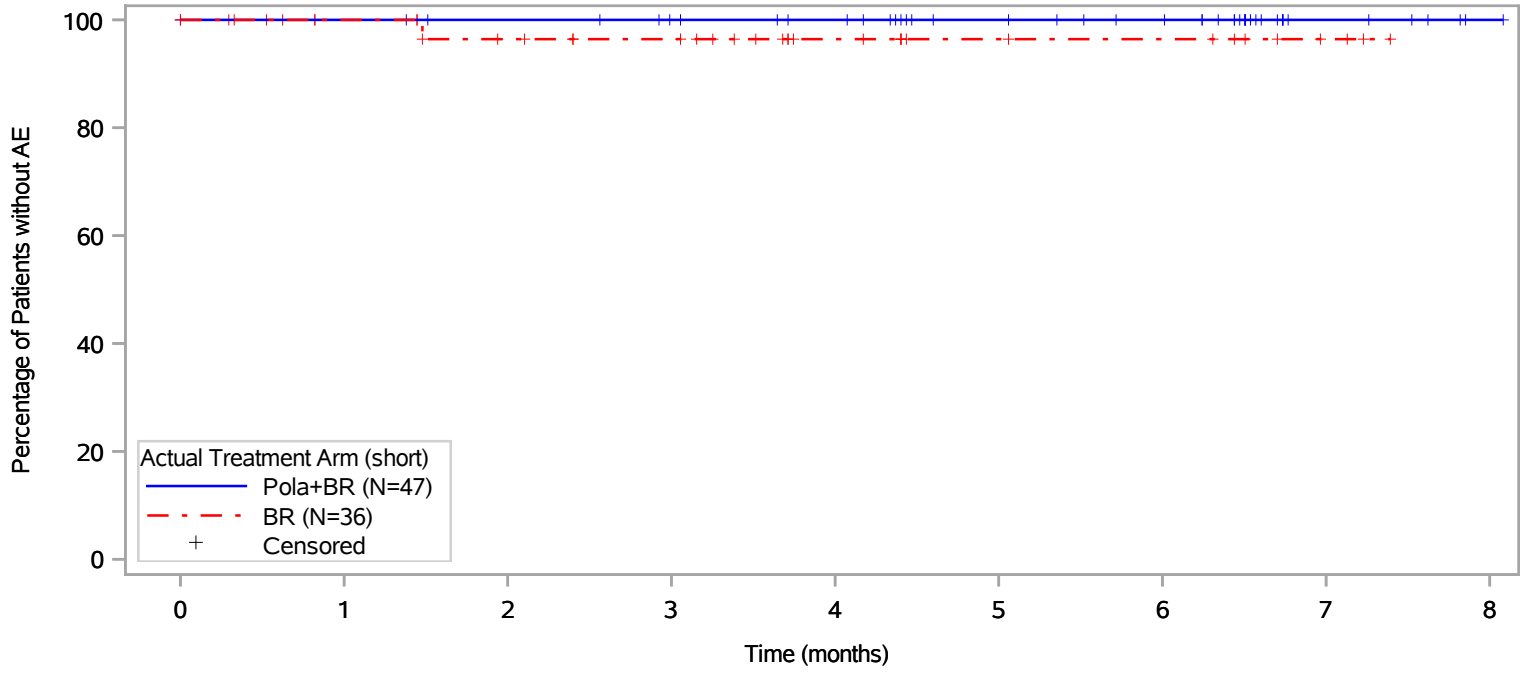


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, FLUSHING



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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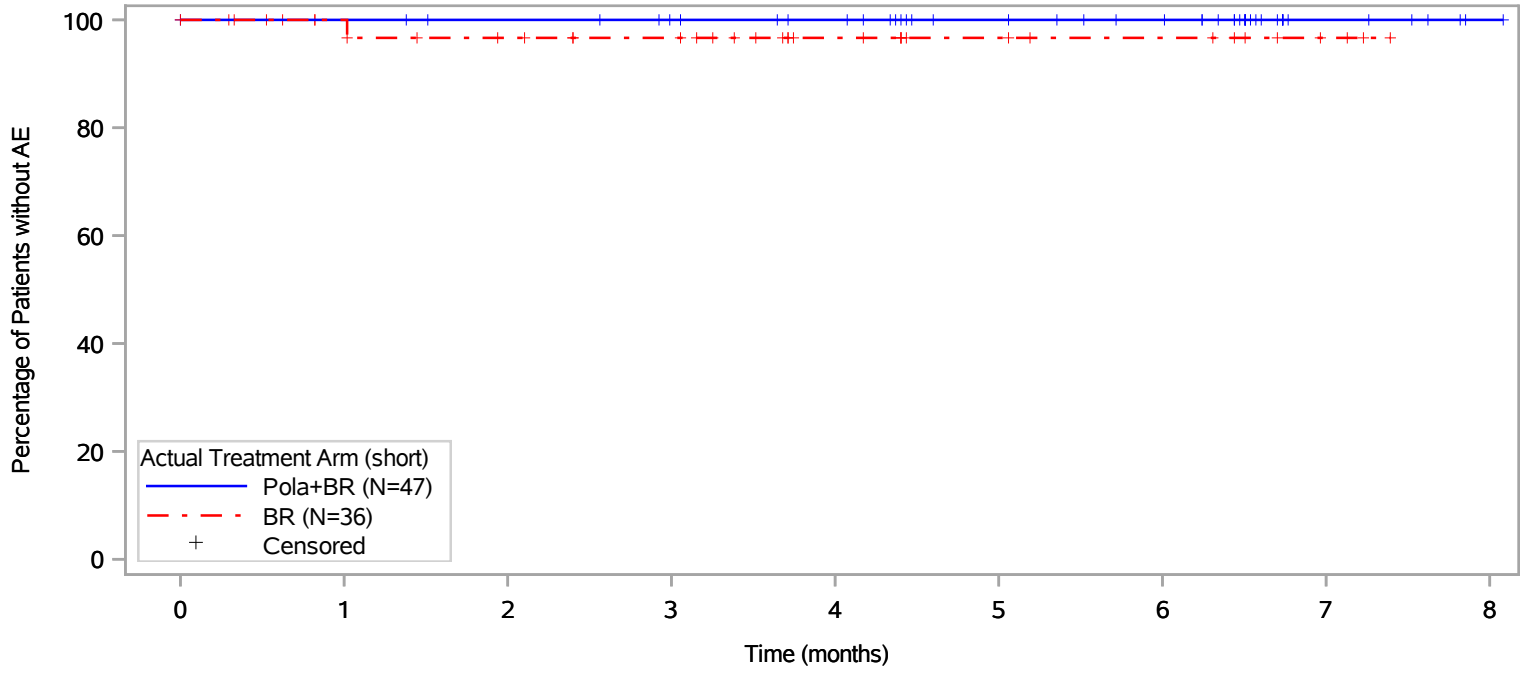
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HAEMATOMA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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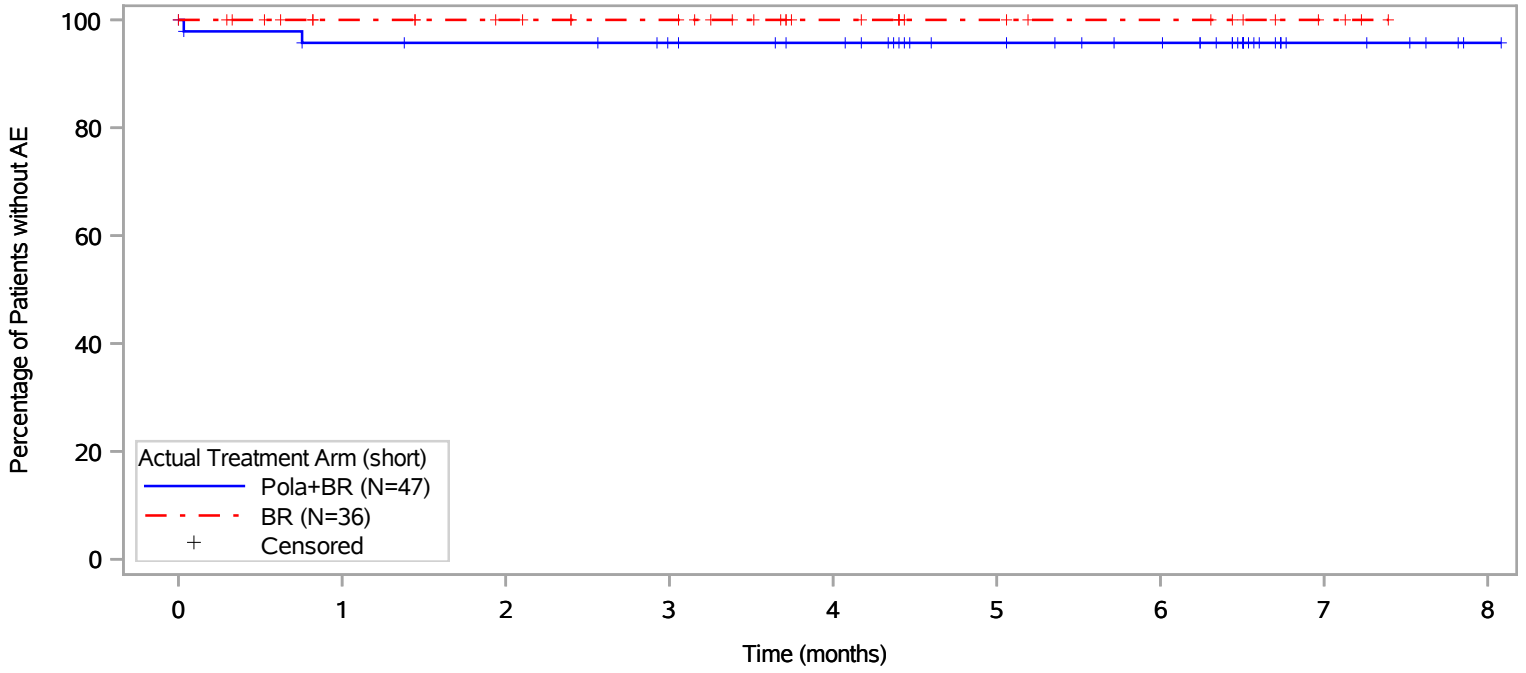
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION

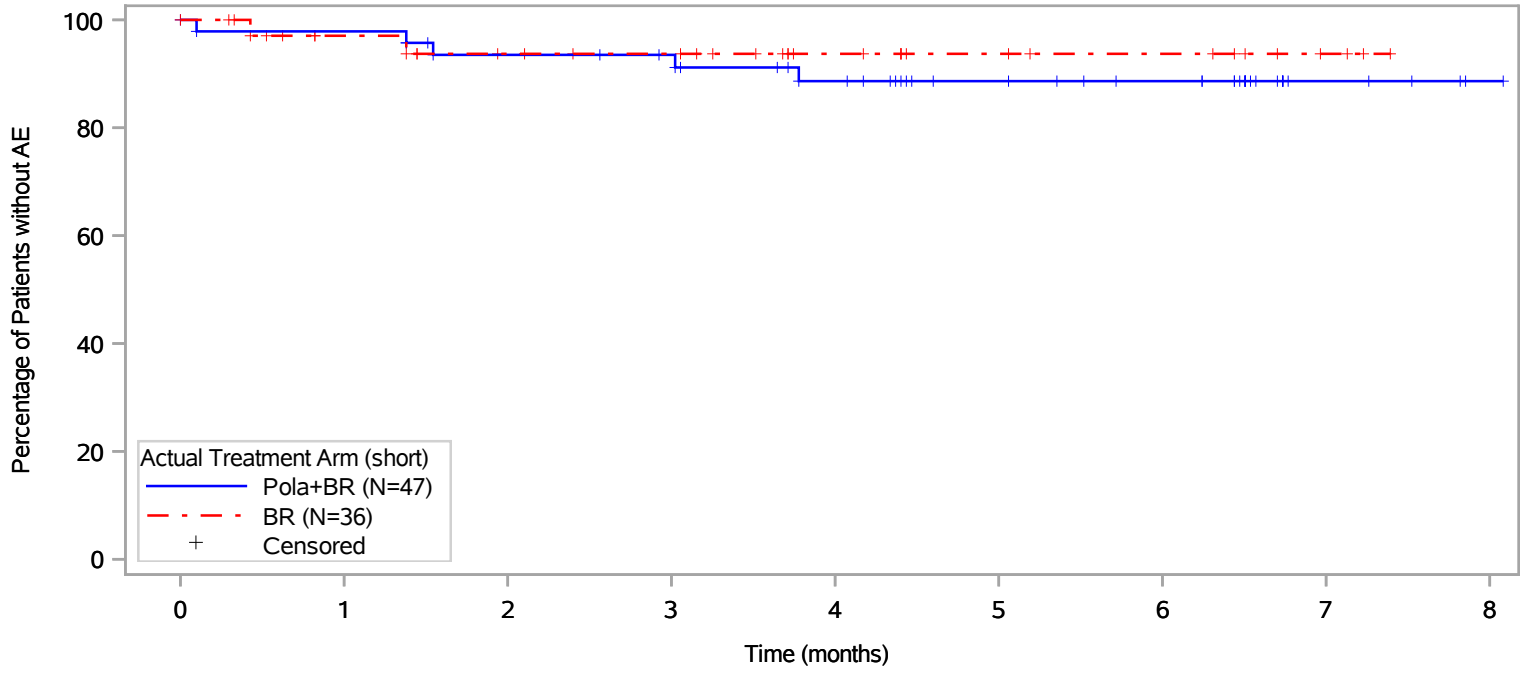


Patients at risk									
Pola+BR (N=47)	47	45	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION



Patients at risk									
Pola+BR (N=47)	47	46	42	40	35	27	23	5	1
BR (N=36)	36	29	25	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	37	41
BR (N=36)	0	6	9	11	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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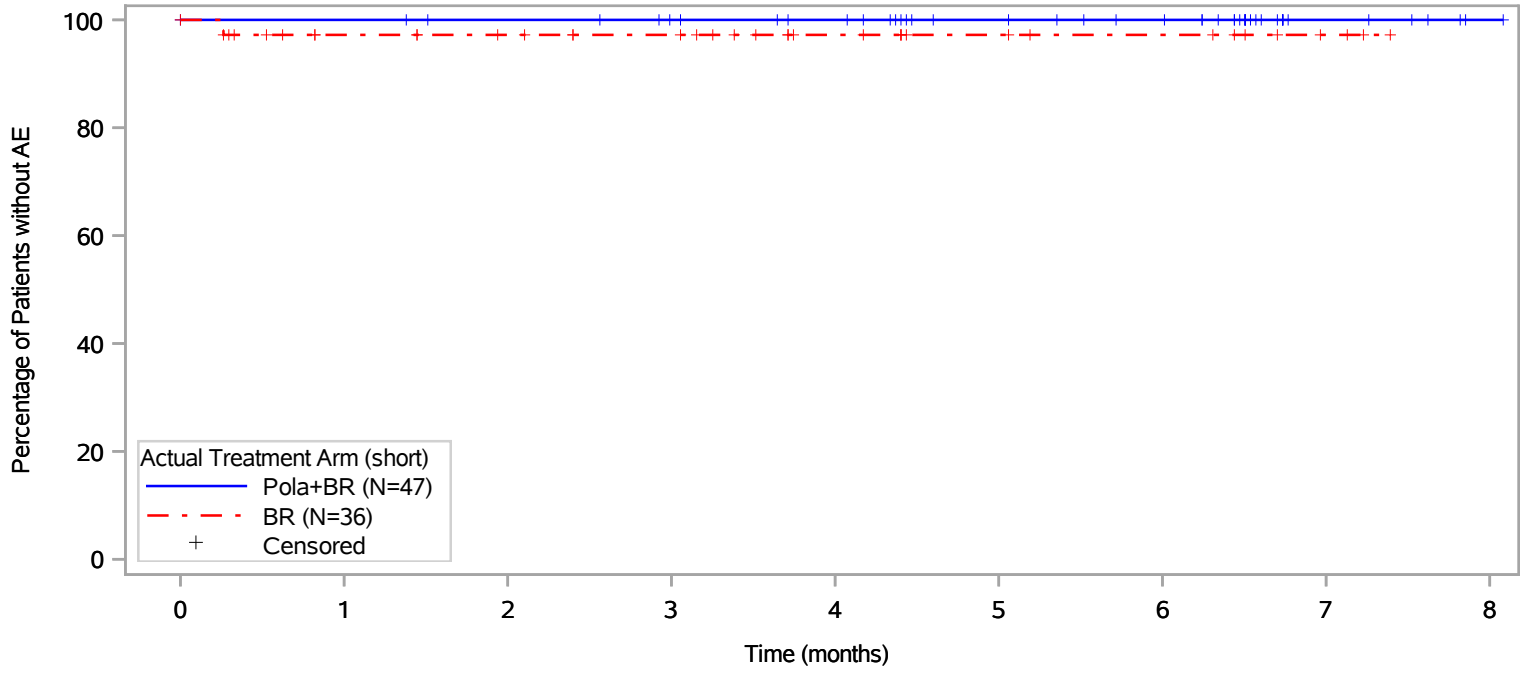
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, ORTHOSTATIC HYPOTENSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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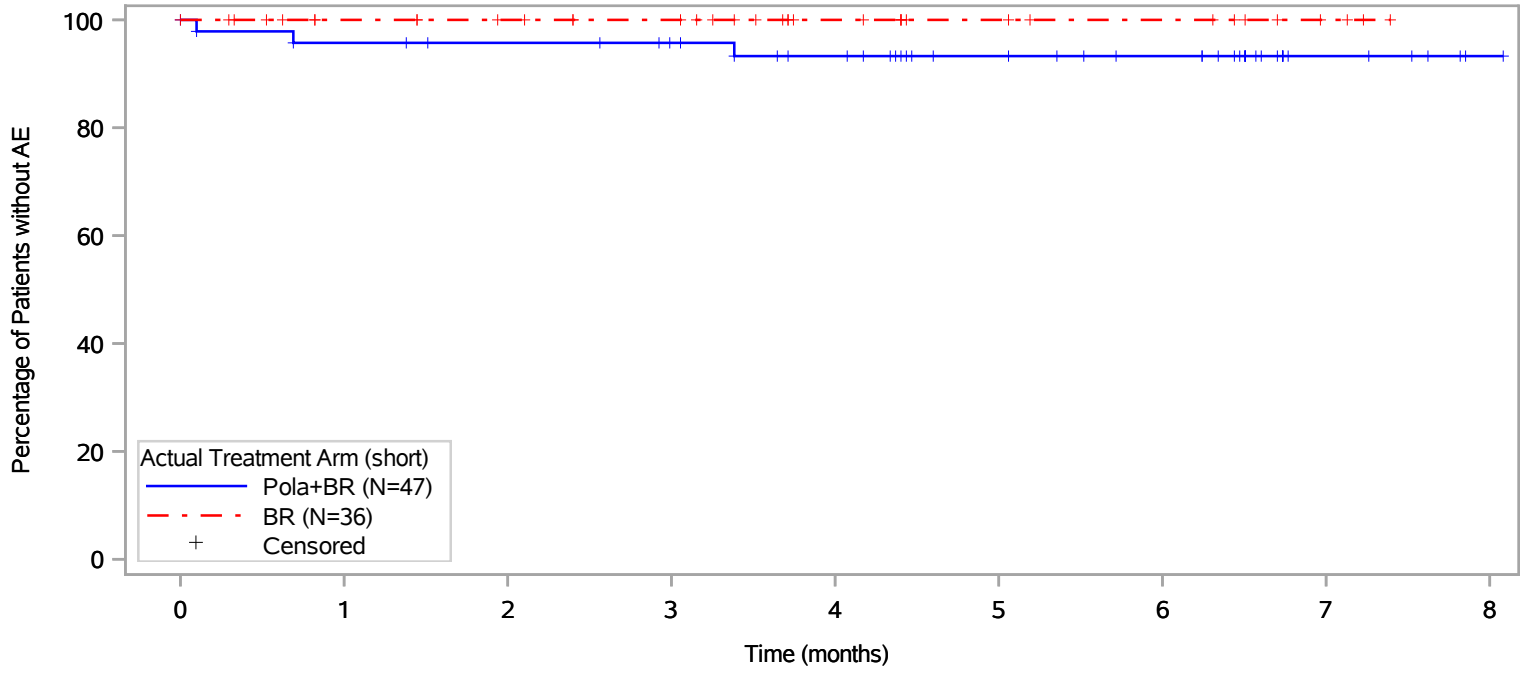
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, VENOUS THROMBOSIS



Patients at risk									
Pola+BR (N=47)	47	45	43	40	36	28	24	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	38	43
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
01DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			47	100.0	27	57.4	20	42.6	36	100.0	17	47.2	19	52.8	0.8619	1.18	0.63	2.19		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		47	100.0	13	27.7	34	72.3	36	100.0	5	13.9	31	86.1	0.3468	1.65	0.58	4.69		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		47	100.0	4	8.5	43	91.5	36	100.0	3	8.3	33	91.7	0.9464	1.22	0.22	6.74		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		47	100.0	3	6.4	44	93.6	36	100.0	2	5.6	34	94.4	0.9734	1.18	0.20	7.08		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		47	100.0	4	8.5	43	91.5	36	100.0	0	-	36	100.0	0.0863	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.6852	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		47	100.0	14	29.8	33	70.2	36	100.0	9	25.0	27	75.0	0.9304	1.27	0.54	2.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.4302	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		47	100.0	13	27.7	34	72.3	36	100.0	6	16.7	30	83.3	0.7050	1.37	0.51	3.65		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	2	5.6	34	94.4	0.7329	1.54	0.14	17.41		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FLUTTER		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	CARDIAC FAILURE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2134	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			47	100.0	10	21.3	37	78.7	36	100.0	5	13.9	31	86.1	0.9260	1.17	0.39	3.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		47	100.0	3	6.4	44	93.6	36	100.0	1	2.8	35	97.2	0.6110	1.88	0.19	18.26		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2049	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3310	0.39	0.04	4.34		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.4960	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ILEUS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4472	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			47	100.0	2	4.3	45	95.7	36	100.0	2	5.6	34	94.4	0.6387	0.75	0.10	5.39		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7135	0.68	0.04	11.35		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			47	100.0	14	29.8	33	70.2	36	100.0	9	25.0	27	75.0	0.3981	0.68	0.28	1.66		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2327	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INFECTIONS AND INFESTATIONS	PNEUMONIA		47	100.0	6	12.8	41	87.2	36	100.0	2	5.6	34	94.4	0.4062	1.78	0.35	8.95		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.5628	0.48	0.03	7.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1623	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.6230	0.47	0.03	8.04		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UROSEPSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7506	0.58	0.03	9.63		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			47	100.0	19	40.4	28	59.6	36	100.0	8	22.2	28	77.8	0.3735	1.09	0.45	2.63		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PRESSURE INCREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	FIBRIN D DIMER INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	HAEMOGLOBIN DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		47	100.0	8	17.0	39	83.0	36	100.0	7	19.4	29	80.6	0.7062	0.54	0.18	1.58		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.8560	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MORAXELLA TEST POSITIVE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		47	100.0	12	25.5	35	74.5	36	100.0	2	5.6	34	94.4	0.0911	3.08	0.69	13.81		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NITRITE URINE PRESENT		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		47	100.0	7	14.9	40	85.1	36	100.0	1	2.8	35	97.2	0.1774	3.60	0.44	29.38		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	TRANSAMINASES INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	URINE OUTPUT DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2327	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		47	100.0	10	21.3	37	78.7	36	100.0	2	5.6	34	94.4	0.1843	2.62	0.57	11.98		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			47	100.0	8	17.0	39	83.0	36	100.0	2	5.6	34	94.4	0.1719	2.65	0.56	12.58		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		47	100.0	8	17.0	39	83.0	36	100.0	1	2.8	35	97.2	0.0657	5.20	0.65	41.83		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7659	0.78	0.05	12.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3427	0.33	0.03	3.71		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7658	0.77	0.05	12.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	4	11.1	32	88.9	0.2191	0.34	0.05	2.16		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SYNCOPE		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7123	0.71	0.04	11.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.6161	0.48	0.03	7.93		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HAEMATURIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	2	5.6	34	94.4	0.6028	0.62	0.09	4.48		Convergence criterion (GCONV=1E-8) satisfied.	NE

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1722	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0732	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3684	0.43	0.04	4.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0933	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			47	100.0	5	10.6	42	89.4	36	100.0	0	-	36	100.0	0.0947	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		47	100.0	3	6.4	44	93.6	36	100.0	0	-	36	100.0	0.2062	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 19:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	29	61.7	18	62.1	11	37.9	20	55.6	9	45.0	11	55.0	0.5486	1.63	0.71	3.71		Convergence criterion (GCONV=1E-8) satisfied.	0.1871
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	18	38.3	9	50.0	9	50.0	16	44.4	8	50.0	8	50.0	0.6385	0.76	0.29	2.02		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	29	61.7	10	34.5	19	65.5	20	55.6	3	15.0	17	85.0	0.2391	2.22	0.60	8.20		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	2	12.5	14	87.5	0.7432	0.73	0.10	5.22		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	2	10.0	18	90.0	0.4122	0.53	0.07	3.86		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.3171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	2	10.0	18	90.0	0.6165	0.88	0.12	6.29		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	29	61.7	3	10.3	26	89.7	20	55.6	0	-	20	100.0	0.1537	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6063	0.37	0.02	5.93		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	29	61.7	8	27.6	21	72.4	20	55.6	6	30.0	14	70.0	0.7495	1.22	0.41	3.60		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	18	38.3	6	33.3	12	66.7	16	44.4	3	18.8	13	81.3	0.5609	1.48	0.37	5.99		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	29	61.7	7	24.1	22	75.9	20	55.6	4	20.0	16	80.0	0.8210	1.04	0.29	3.72		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	18	38.3	6	33.3	12	66.7	16	44.4	2	12.5	14	87.5	0.3525	2.01	0.40	9.98		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7774	0.65	0.04	10.94		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	29	61.7	6	20.7	23	79.3	20	55.6	2	10.0	18	90.0	0.4581	2.33	0.46	11.85		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	18	38.3	4	22.2	14	77.8	16	44.4	3	18.8	13	81.3	0.5894	0.59	0.12	2.97		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.7264	0.58	0.04	9.30		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1915	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	18	38.3	0	-	18	100.0	16	44.4	2	12.5	14	87.5	0.1005	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GASTROINTESTINAL DISORDERS	PANCREATITIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4720	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.3035	0.44	0.04	4.89		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1644	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	29	61.7	6	20.7	23	79.3	20	55.6	3	15.0	17	85.0	0.9983	0.91	0.22	3.74		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	18	38.3	8	44.4	10	55.6	16	44.4	6	37.5	10	62.5	0.2803	0.50	0.15	1.68		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2568	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	29	61.7	4	13.8	25	86.2	20	55.6	1	5.0	19	95.0	0.4502	2.17	0.24	19.90		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.6611	1.88	0.17	21.09		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.6457	0.44	0.03	7.45		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	UROSEPSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.8617	0.80	0.05	12.75		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	29	61.7	15	51.7	14	48.3	20	55.6	4	20.0	16	80.0	0.1429	1.56	0.49	5.00		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	18	38.3	4	22.2	14	77.8	16	44.4	4	25.0	12	75.0	0.4593	0.67	0.14	3.19		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1644	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2733	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	29	61.7	6	20.7	23	79.3	20	55.6	4	20.0	16	80.0	0.9615	0.66	0.17	2.55		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	3	18.8	13	81.3	0.4895	0.69	0.10	4.89		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.8013	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	29	61.7	11	37.9	18	62.1	20	55.6	1	5.0	19	95.0	0.0546	5.04	0.65	39.28		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.7636	0.71	0.04	11.79		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	29	61.7	6	20.7	23	79.3	20	55.6	0	-	20	100.0	0.0928	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.7646	0.65	0.04	10.47		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	29	61.7	9	31.0	20	69.0	20	55.6	0	-	20	100.0	0.0320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	2	12.5	14	87.5	0.3137	0.34	0.03	3.81		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	29	61.7	7	24.1	22	75.9	20	55.6	2	10.0	18	90.0	0.2808	2.25	0.46	11.02		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	29	61.7	7	24.1	22	75.9	20	55.6	1	5.0	19	95.0	0.1148	4.34	0.53	35.82		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7729	0.65	0.04	10.94		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.1348	0.22	0.02	2.81		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	2	12.5	14	87.5	0.7505	0.55	0.03	10.01		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6653	0.78	0.05	12.57		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.2147	0.26	0.02	2.96		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1317	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	29	61.7	0	-	29	100.0	20	55.6	2	10.0	18	90.0	0.0504	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	2	12.5	14	87.5	0.4028	0.38	0.03	4.22		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	18	38.3	0	-	18	100.0	16	44.4	2	12.5	14	87.5	0.1063	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	29	61.7	3	10.3	26	89.7	20	55.6	0	-	20	100.0	0.2351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2446	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3309	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 19:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	29	61.7	16	55.2	13	44.8	24	66.7	12	50.0	12	50.0	0.5874	0.98	0.45	2.12		Convergence criterion (GCONV=1E-8) satisfied.	0.5058
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	18	38.3	11	61.1	7	38.9	12	33.3	5	41.7	7	58.3	0.3830	1.57	0.54	4.59		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	29	61.7	8	27.6	21	72.4	24	66.7	3	12.5	21	87.5	0.4958	1.50	0.39	5.80		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	18	38.3	5	27.8	13	72.2	12	33.3	2	16.7	10	83.3	0.5311	1.67	0.32	8.66		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	2	8.3	22	91.7	0.9000	1.42	0.13	16.03		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	1	8.3	11	91.7	0.9182	1.10	0.10	12.20		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	2	8.3	22	91.7	0.3265	0.44	0.04	4.91		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2558	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	29	61.7	3	10.3	26	89.7	24	66.7	0	-	24	100.0	0.1339	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1742	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	29	61.7	6	20.7	23	79.3	24	66.7	7	29.2	17	70.8	0.2269	0.62	0.20	1.91		Convergence criterion (GCONV=1E-8) satisfied.	0.0687
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	18	38.3	8	44.4	10	55.6	12	33.3	2	16.7	10	83.3	0.1329	3.54	0.75	16.76		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4275	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	29	61.7	8	27.6	21	72.4	24	66.7	3	12.5	21	87.5	0.4336	2.14	0.56	8.16		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	18	38.3	5	27.8	13	72.2	12	33.3	3	25.0	9	75.0	0.6546	0.67	0.15	3.02		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.6878	1.76	0.15	20.44		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2509	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.1943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	29	61.7	7	24.1	22	75.9	24	66.7	4	16.7	20	83.3	0.7669	0.96	0.26	3.54		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	18	38.3	3	16.7	15	83.3	12	33.3	1	8.3	11	91.7	0.6166	1.75	0.18	16.90		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	29	61.7	3	10.3	26	89.7	24	66.7	1	4.2	23	95.8	0.6208	1.98	0.20	19.52		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.7489	0.65	0.04	10.45		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GASTROINTESTINAL DISORDERS	PANCREATITIS	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.8135	1.81	0.16	20.74		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7077	0.74	0.04	12.88		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	29	61.7	11	37.9	18	62.1	24	66.7	6	25.0	18	75.0	0.8852	0.89	0.31	2.55		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	18	38.3	3	16.7	15	83.3	12	33.3	3	25.0	9	75.0	0.1761	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	29	61.7	4	13.8	25	86.2	24	66.7	2	8.3	22	91.7	0.7077	1.12	0.20	6.32		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2745	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.5456	0.55	0.03	8.94		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.6524	0.48	0.03	8.48		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	UROSEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7648	0.58	0.03	10.17		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	29	61.7	13	44.8	16	55.2	24	66.7	5	20.8	19	79.2	0.2147	1.12	0.37	3.42		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	18	38.3	6	33.3	12	66.7	12	33.3	3	25.0	9	75.0	0.9408	1.04	0.24	4.58		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	29	61.7	6	20.7	23	79.3	24	66.7	4	16.7	20	83.3	0.7575	0.61	0.15	2.47		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	18	38.3	2	11.1	16	88.9	12	33.3	3	25.0	9	75.0	0.3165	0.45	0.08	2.73		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.9033	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	29	61.7	8	27.6	21	72.4	24	66.7	0	-	24	100.0	0.0324	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	18	38.3	4	22.2	14	77.8	12	33.3	2	16.7	10	83.3	0.9691	1.03	0.17	6.25		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	29	61.7	4	13.8	25	86.2	24	66.7	0	-	24	100.0	0.1255	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	18	38.3	3	16.7	15	83.3	12	33.3	1	8.3	11	91.7	0.6815	1.70	0.18	16.48		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2399	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	29	61.7	7	24.1	22	75.9	24	66.7	1	4.2	23	95.8	0.1866	3.24	0.39	26.57		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	18	38.3	3	16.7	15	83.3	12	33.3	1	8.3	11	91.7	0.6602	1.99	0.20	19.30		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	29	61.7	4	13.8	25	86.2	24	66.7	1	4.2	23	95.8	0.3401	2.44	0.27	22.47		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	18	38.3	4	22.2	14	77.8	12	33.3	1	8.3	11	91.7	0.3457	2.75	0.31	24.60		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	29	61.7	4	13.8	25	86.2	24	66.7	0	-	24	100.0	0.0971	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	18	38.3	4	22.2	14	77.8	12	33.3	1	8.3	11	91.7	0.3457	2.75	0.31	24.60		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7761	0.89	0.06	14.36		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.8013	0.64	0.04	10.89		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	4	16.7	20	83.3	0.0568	0.14	0.01	1.50		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.0578	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1052	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.8480	1.35	0.12	15.66		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.7887	0.72	0.05	11.53		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	29	61.7	3	10.3	26	89.7	24	66.7	0	-	24	100.0	0.2189	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2735	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2735	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 19:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	19.1	4	44.4	5	55.6	13	36.1	5	38.5	8	61.5	0.6731	0.75	0.20	2.84		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	38	80.9	23	60.5	15	39.5	23	63.9	12	52.2	11	47.8	0.7859	1.24	0.61	2.53		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	38	80.9	12	31.6	26	68.4	23	63.9	5	21.7	18	78.3	0.6301	1.32	0.46	3.77		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	2	8.7	21	91.3	0.8165	0.85	0.15	4.72		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	2	8.7	21	91.3	0.7967	0.91	0.15	5.50		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	0	-	23	100.0	0.1227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5915	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	19.1	2	22.2	7	77.8	13	36.1	3	23.1	10	76.9	0.6746	0.68	0.11	4.18		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	38	80.9	12	31.6	26	68.4	23	63.9	6	26.1	17	73.9	0.8277	1.36	0.50	3.69		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	19.1	2	22.2	7	77.8	13	36.1	1	7.7	12	92.3	0.4861	2.29	0.21	25.40		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	38	80.9	11	28.9	27	71.1	23	63.9	5	21.7	18	78.3	0.9656	0.99	0.34	2.92		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7077	0.58	0.04	9.41		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	9	19.1	3	33.3	6	66.7	13	36.1	2	15.4	11	84.6	0.6289	1.55	0.26	9.40		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	3	13.0	20	87.0	0.9271	1.00	0.24	4.12		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	0	-	23	100.0	0.2249	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.8671	1.27	0.08	20.38		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1391	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GASTROINTESTINAL DISORDERS	PANCREATITIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	2	8.7	21	91.3	0.1920	0.23	0.02	2.65		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5734	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	19.1	4	44.4	5	55.6	13	36.1	6	46.2	7	53.8	0.1287	0.30	0.06	1.54		Convergence criterion (GCONV=1E-8) satisfied.	0.0562
INFECTIONS AND INFESTATIONS		Non-Europe	38	80.9	10	26.3	28	73.7	23	63.9	3	13.0	20	87.0	0.6219	1.38	0.37	5.17		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.9301	1.13	0.07	18.50		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	1	4.3	22	95.7	0.4296	2.18	0.25	19.11		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5571	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	UROSEPSIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	38	80.9	19	50.0	19	50.0	23	63.9	7	30.4	16	69.6	0.5542	1.18	0.47	2.97		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	38	80.9	8	21.1	30	78.9	23	63.9	7	30.4	16	69.6	0.3793	0.51	0.17	1.50		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7271	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	38	80.9	12	31.6	26	68.4	23	63.9	2	8.7	21	91.3	0.1530	3.03	0.68	13.56		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	1	4.3	22	95.7	0.2453	3.25	0.40	26.48		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	38	80.9	10	26.3	28	73.7	23	63.9	1	4.3	22	95.7	0.1047	5.06	0.65	39.56		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	2	8.7	21	91.3	0.3909	1.94	0.40	9.39		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	1	4.3	22	95.7	0.1661	3.85	0.47	31.34		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6437	0.58	0.04	9.24		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	2	8.7	21	91.3	0.2622	0.29	0.03	3.21		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6795	0.64	0.04	10.22		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	2	15.4	11	84.6	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	2	8.7	21	91.3	0.1288	0.14	0.01	1.94		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6148	0.57	0.04	9.12		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	2	8.7	21	91.3	0.4537	0.49	0.07	3.53		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	2	8.7	21	91.3	0.0444	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.8671	1.27	0.08	20.38		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	0	-	23	100.0	0.1236	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	0	-	23	100.0	0.2410	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 19:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	34	72.3	17	50.0	17	50.0	24	66.7	12	50.0	12	50.0	0.3622	0.79	0.37	1.68		Convergence criterion (GCONV=1E-8) satisfied.	0.0467
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	13	27.7	10	76.9	3	23.1	12	33.3	5	41.7	7	58.3	0.0866	2.58	0.87	7.69		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	34	72.3	7	20.6	27	79.4	24	66.7	5	20.8	19	79.2	0.5189	0.72	0.22	2.33		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	13	27.7	6	46.2	7	53.8	12	33.3	0	-	12	100.0	0.0165	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	3	12.5	21	87.5	0.4434	0.56	0.08	4.05		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2212	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	2	8.3	22	91.7	0.9025	1.12	0.19	6.76		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.1513	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.6261	0.35	0.02	5.57		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	34	72.3	8	23.5	26	76.5	24	66.7	6	25.0	18	75.0	0.6180	0.96	0.33	2.83		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	13	27.7	6	46.2	7	53.8	12	33.3	3	25.0	9	75.0	0.4189	1.93	0.47	7.86		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.4363	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	34	72.3	7	20.6	27	79.4	24	66.7	5	20.8	19	79.2	0.4345	0.73	0.22	2.41		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	13	27.7	6	46.2	7	53.8	12	33.3	1	8.3	11	91.7	0.1167	4.86	0.58	40.43		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	2	16.7	10	83.3	0.9304	0.80	0.05	13.13		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	34	72.3	8	23.5	26	76.5	24	66.7	5	20.8	19	79.2	0.6288	0.85	0.26	2.72		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2335	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8450	1.30	0.12	14.57		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.3002	0.38	0.03	4.21		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.5448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1510	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GASTROINTESTINAL DISORDERS	PANCREATITIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.7422	0.81	0.05	13.06		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8510	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8510	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	34	72.3	12	35.3	22	64.7	24	66.7	6	25.0	18	75.0	0.5073	0.71	0.25	2.03		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	13	27.7	2	15.4	11	84.6	12	33.3	3	25.0	9	75.0	0.4580	0.51	0.09	3.07		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	34	72.3	4	11.8	30	88.2	24	66.7	2	8.3	22	91.7	0.9595	1.04	0.18	5.82		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.1963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1287	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	UROSEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	34	72.3	15	44.1	19	55.9	24	66.7	5	20.8	19	79.2	0.2060	1.75	0.61	5.02		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	13	27.7	4	30.8	9	69.2	12	33.3	3	25.0	9	75.0	0.6712	0.24	0.03	1.80		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	34	72.3	8	23.5	26	76.5	24	66.7	4	16.7	20	83.3	0.5979	1.05	0.30	3.71		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	3	25.0	9	75.0	0.0546	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	34	72.3	11	32.4	23	67.6	24	66.7	2	8.3	22	91.7	0.2040	1.85	0.40	8.65		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	34	72.3	6	17.6	28	82.4	24	66.7	1	4.2	23	95.8	0.2526	2.75	0.33	23.01		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	34	72.3	9	26.5	25	73.5	24	66.7	2	8.3	22	91.7	0.3757	1.96	0.42	9.10		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	34	72.3	4	11.8	30	88.2	24	66.7	2	8.3	22	91.7	0.6959	1.30	0.23	7.16		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	13	27.7	4	30.8	9	69.2	12	33.3	0	-	12	100.0	0.0669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	34	72.3	4	11.8	30	88.2	24	66.7	1	4.2	23	95.8	0.3318	2.49	0.27	22.53		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	13	27.7	4	30.8	9	69.2	12	33.3	0	-	12	100.0	0.0669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.3367	0.32	0.03	3.66		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.7591	0.79	0.05	12.67		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	34	72.3	2	5.9	32	94.1	24	66.7	3	12.5	21	87.5	0.5460	0.60	0.08	4.54		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.6823	0.71	0.04	11.32		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	13	27.7	2	15.4	11	84.6	12	33.3	1	8.3	11	91.7	0.7866	1.41	0.13	15.75		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.3502	0.42	0.04	4.67		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	34	72.3	0	-	34	100.0	24	66.7	2	8.3	22	91.7	0.0853	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	34	72.3	4	11.8	30	88.2	24	66.7	0	-	24	100.0	0.1612	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.2264	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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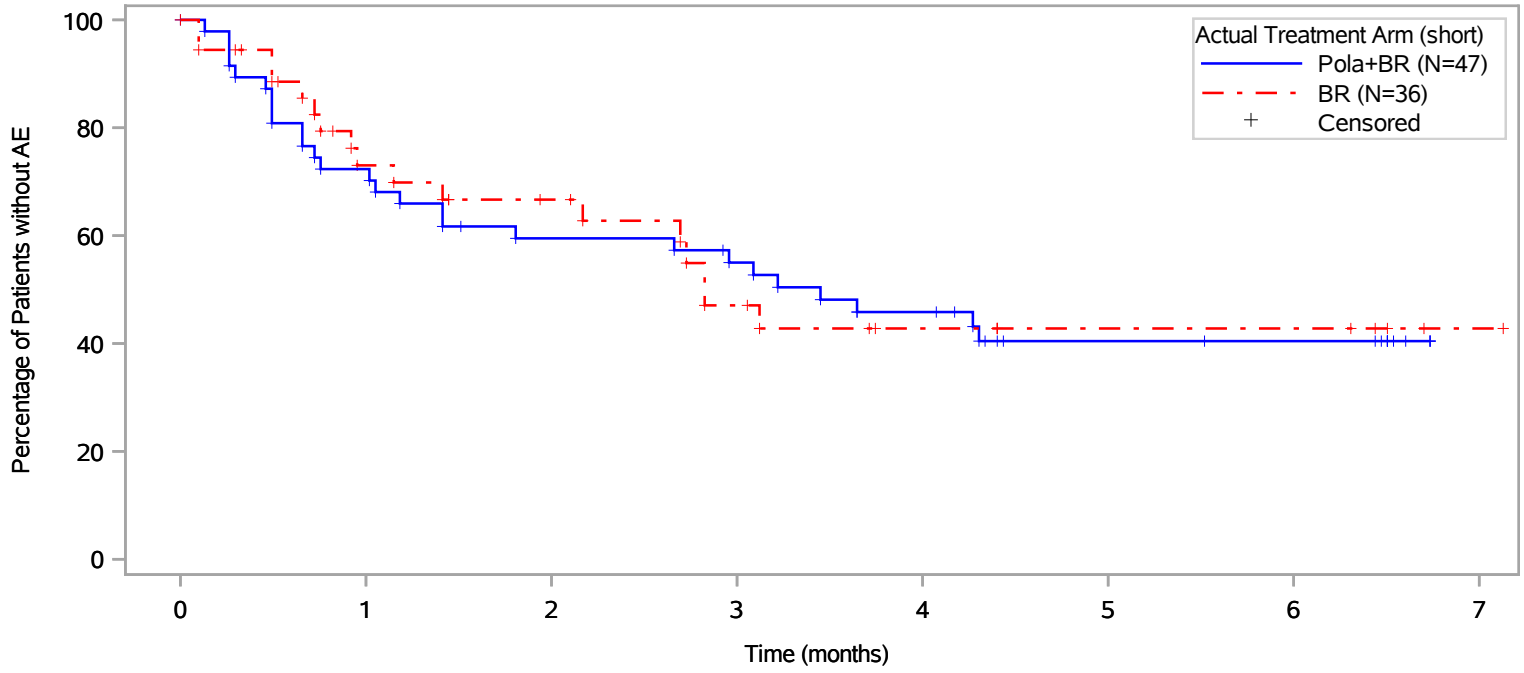
30NOV2022 19:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk								
Pola+BR (N=47)	47	34	27	24	19	12	11	NE
BR (N=36)	36	23	18	12	8	5	5	1
Patients censored								
Pola+BR (N=47)	0	0	1	2	3	8	9	NE
BR (N=36)	0	4	7	8	11	14	14	18

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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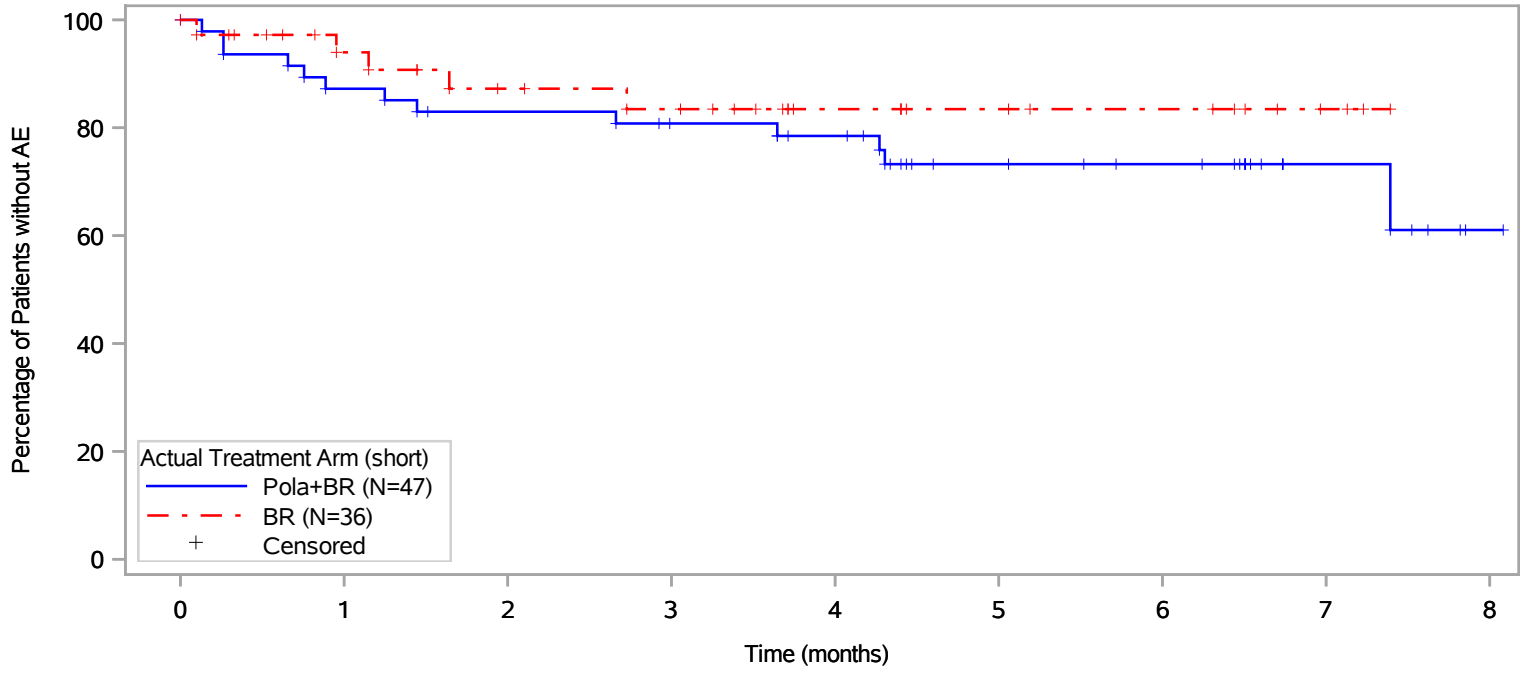
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA

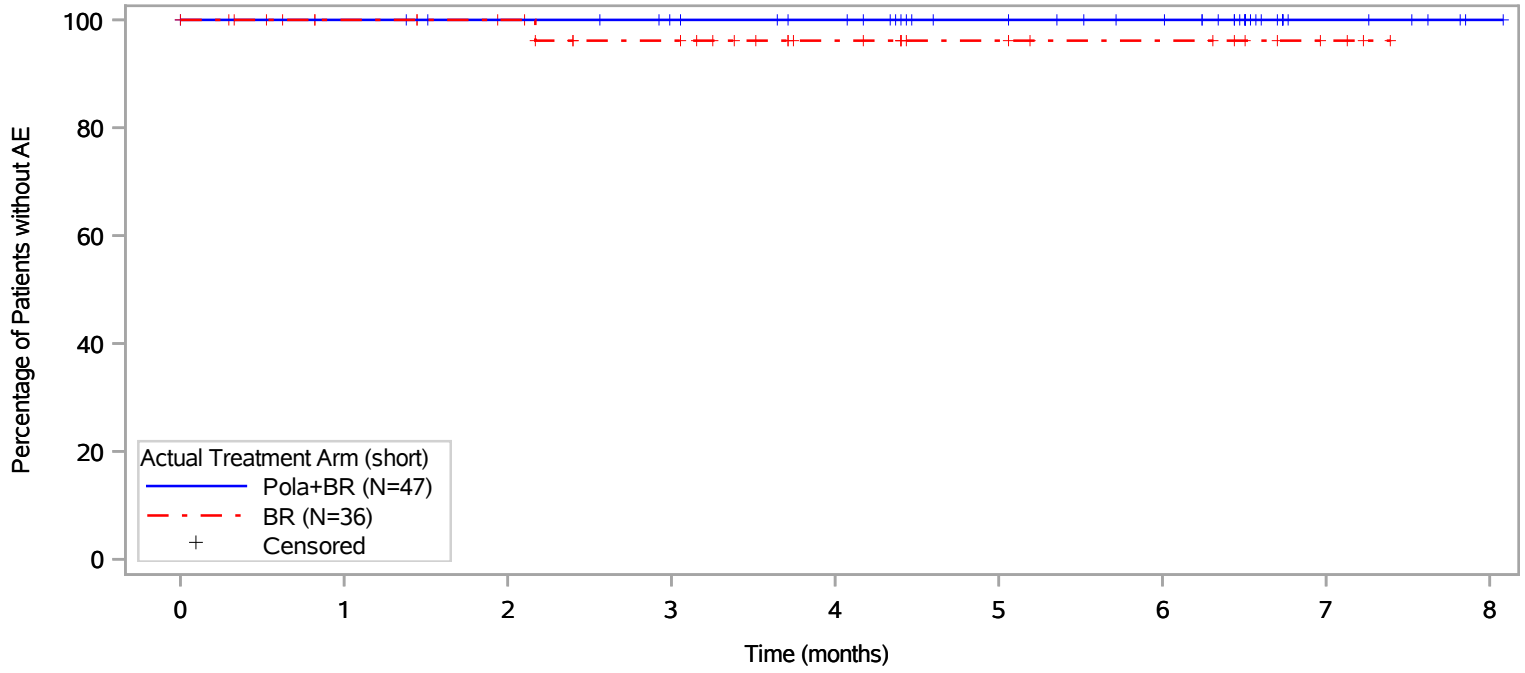


Patients at risk									
Pola+BR (N=47)	47	41	38	35	32	23	20	6	1
BR (N=36)	36	29	24	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	5	12	15	29	33
BR (N=36)	0	5	8	9	17	21	23	28	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE BONE MARROW APLASIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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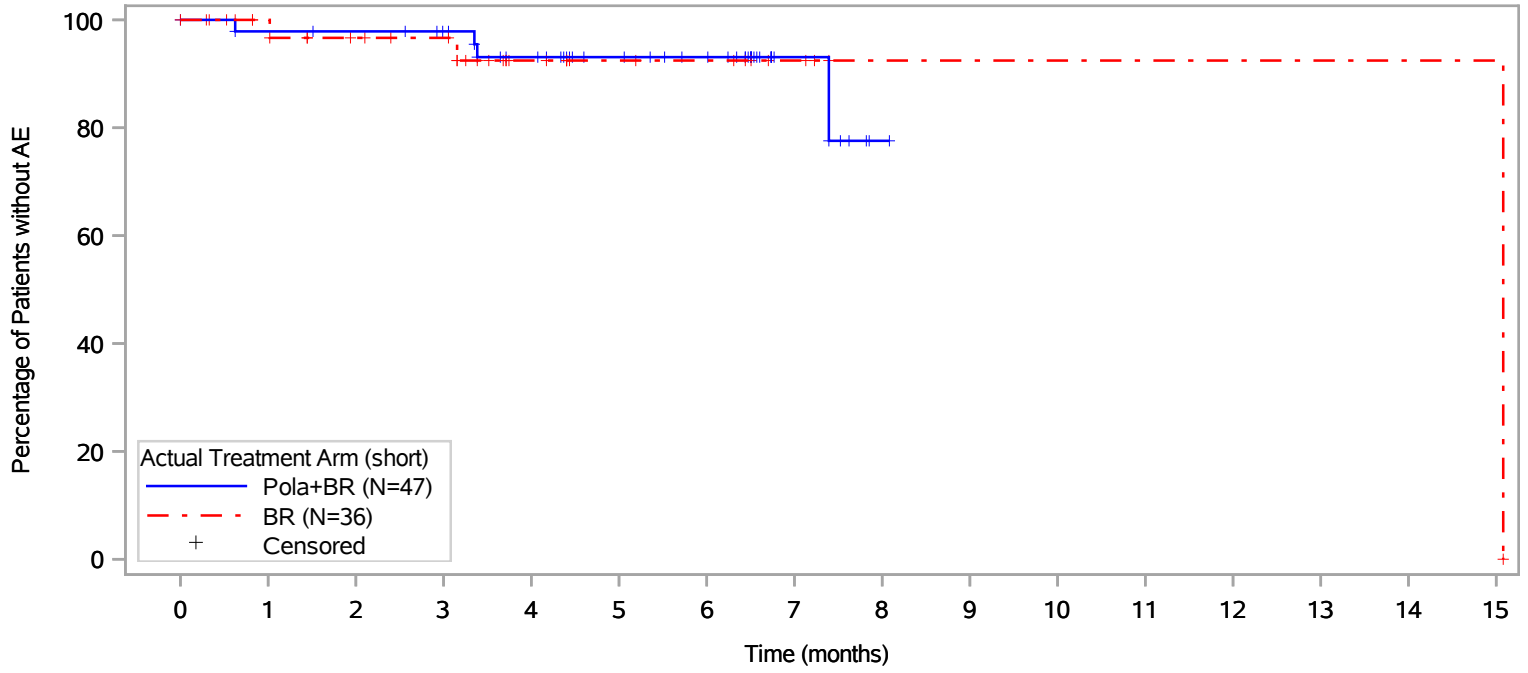
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA

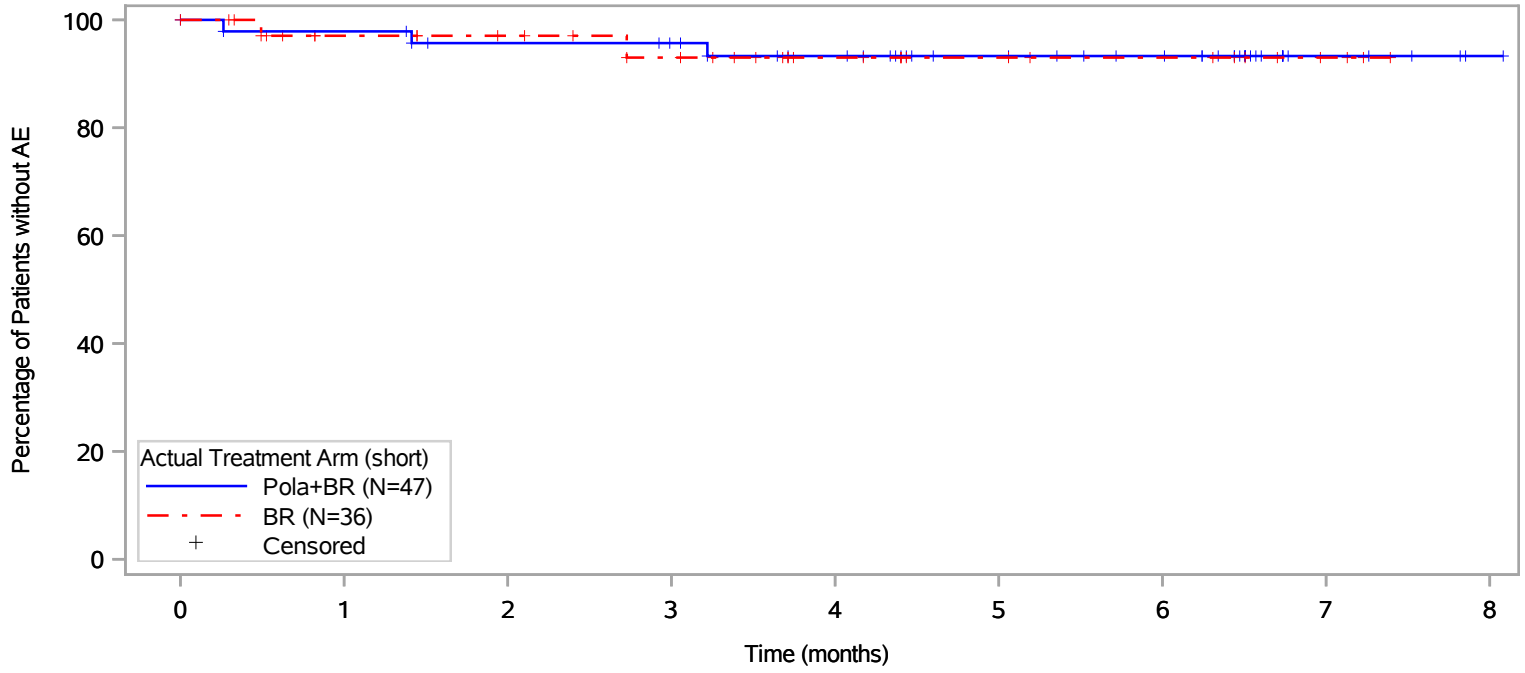


Patients at risk																
Pola+BR (N=47)	47	46	45	42	37	29	25	6	1	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	26	24	14	9	8	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=47)	0	0	1	4	7	15	19	38	42	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	11	20	25	26	30	33	33	33	33	33	33	33	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=47)	47	46	43	41	37	29	25	5	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	39	43
BR (N=36)	0	6	9	11	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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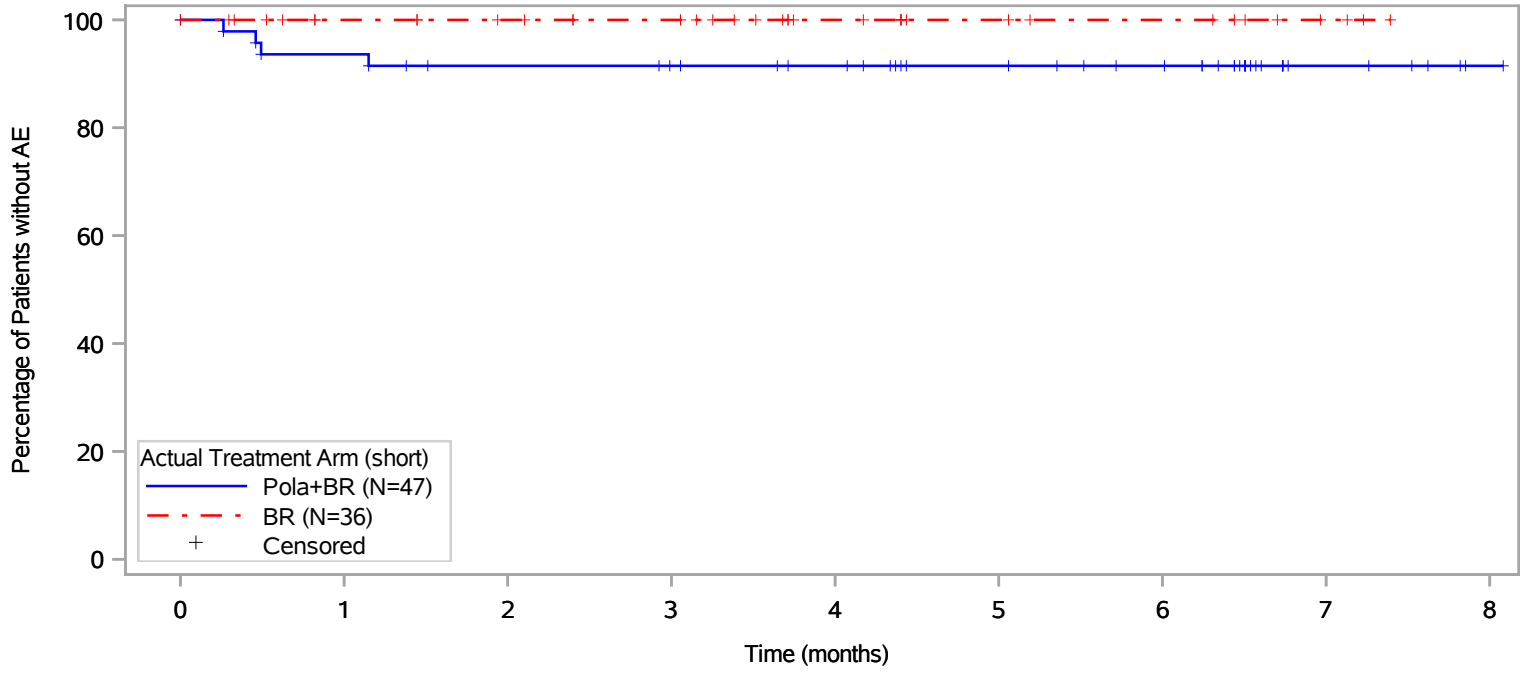
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA

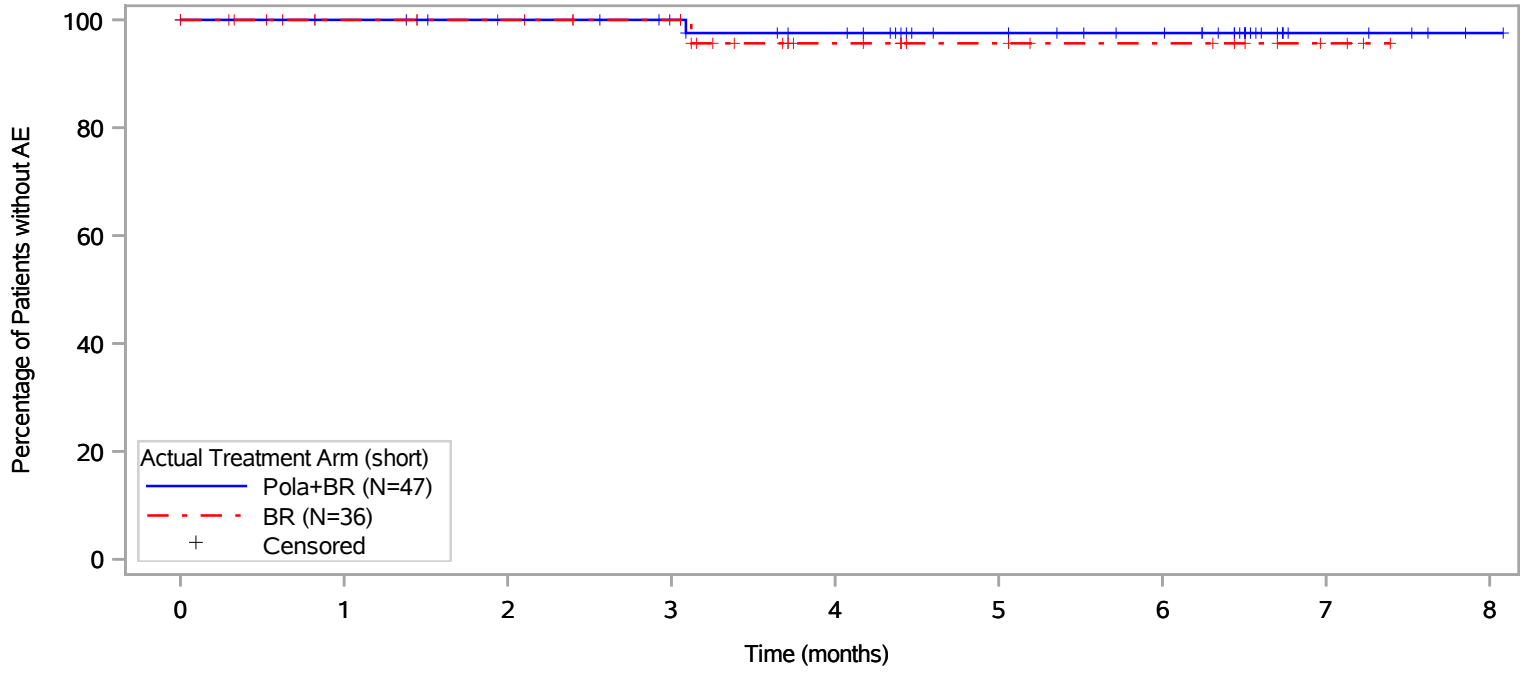


Patients at risk									
Pola+BR (N=47)	47	44	41	39	36	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	13	17	37	42
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, MYELOSUPPRESSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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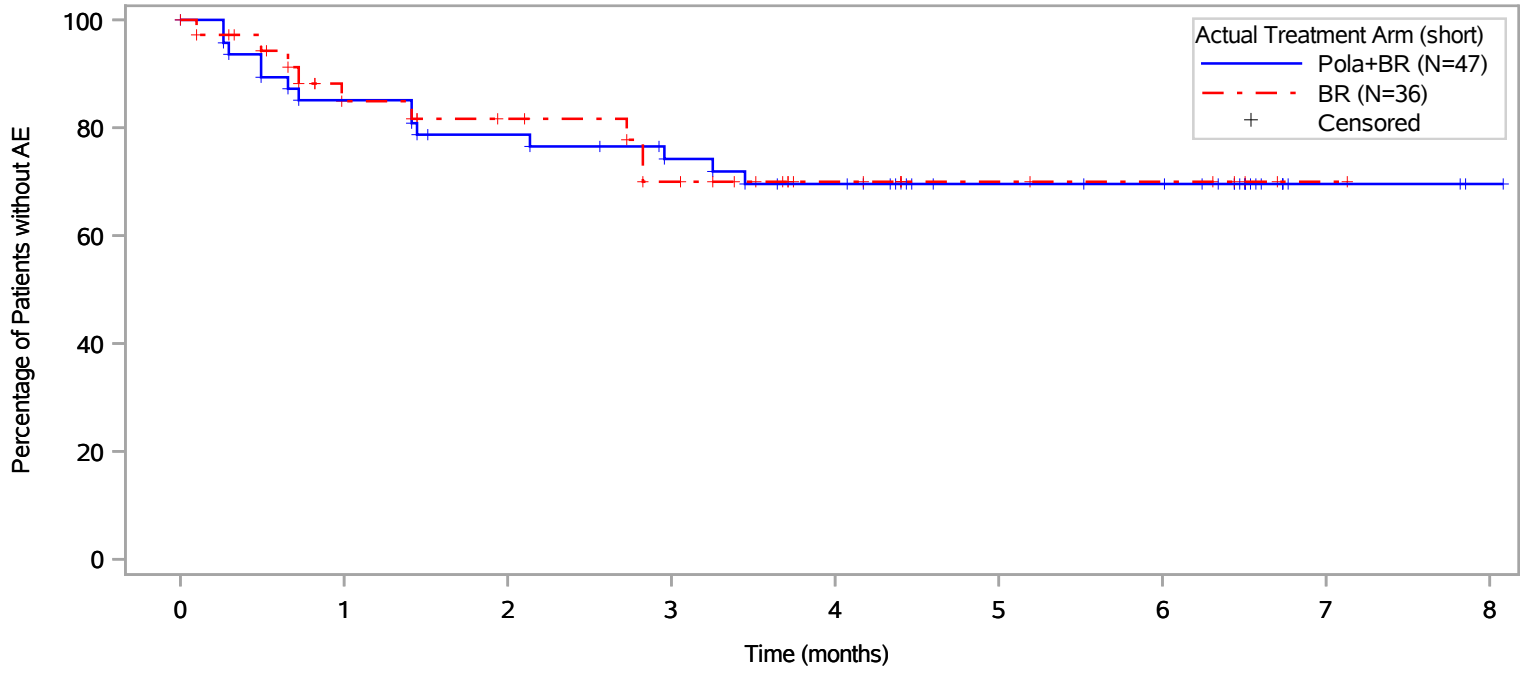
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk									
Pola+BR (N=47)	47	40	36	32	29	21	20	3	1
BR (N=36)	36	26	22	18	10	6	5	1	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	4	12	13	30	32
BR (N=36)	0	5	8	9	17	21	22	26	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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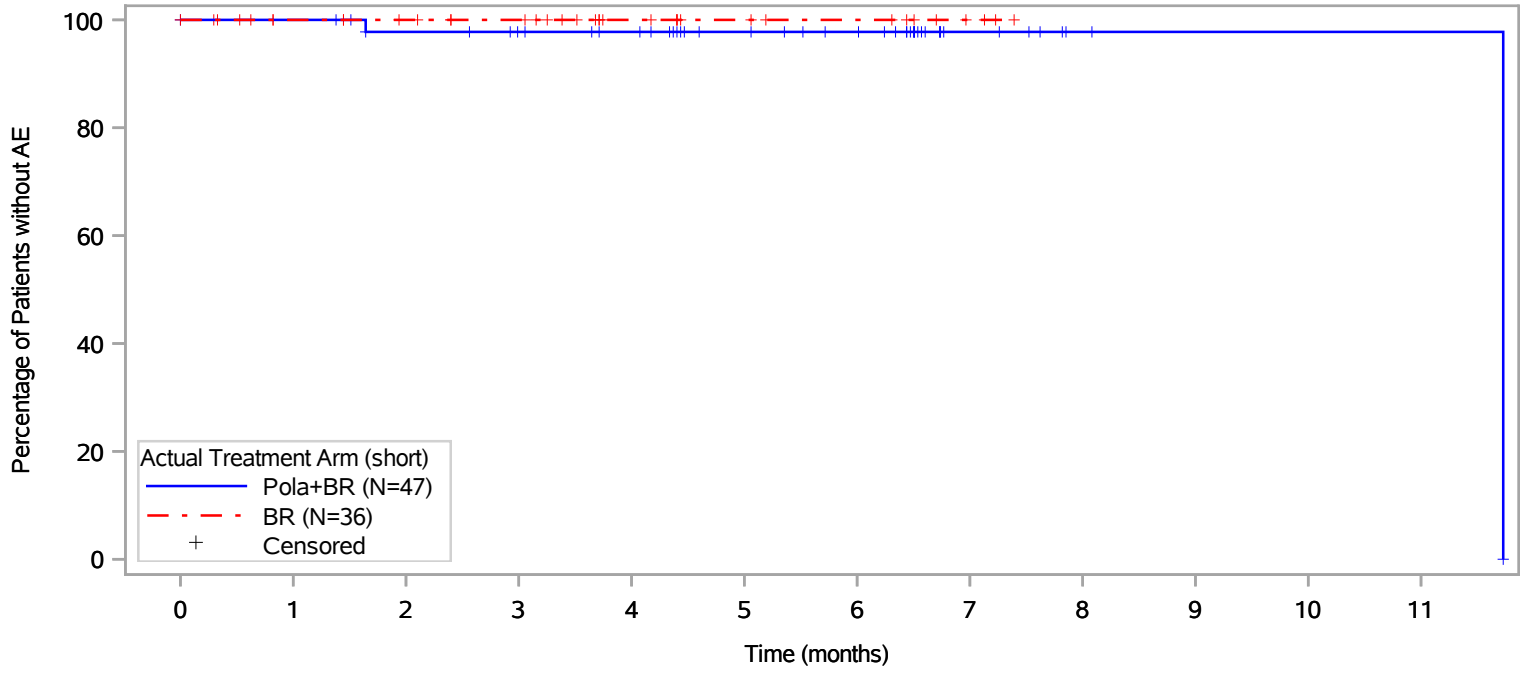
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA

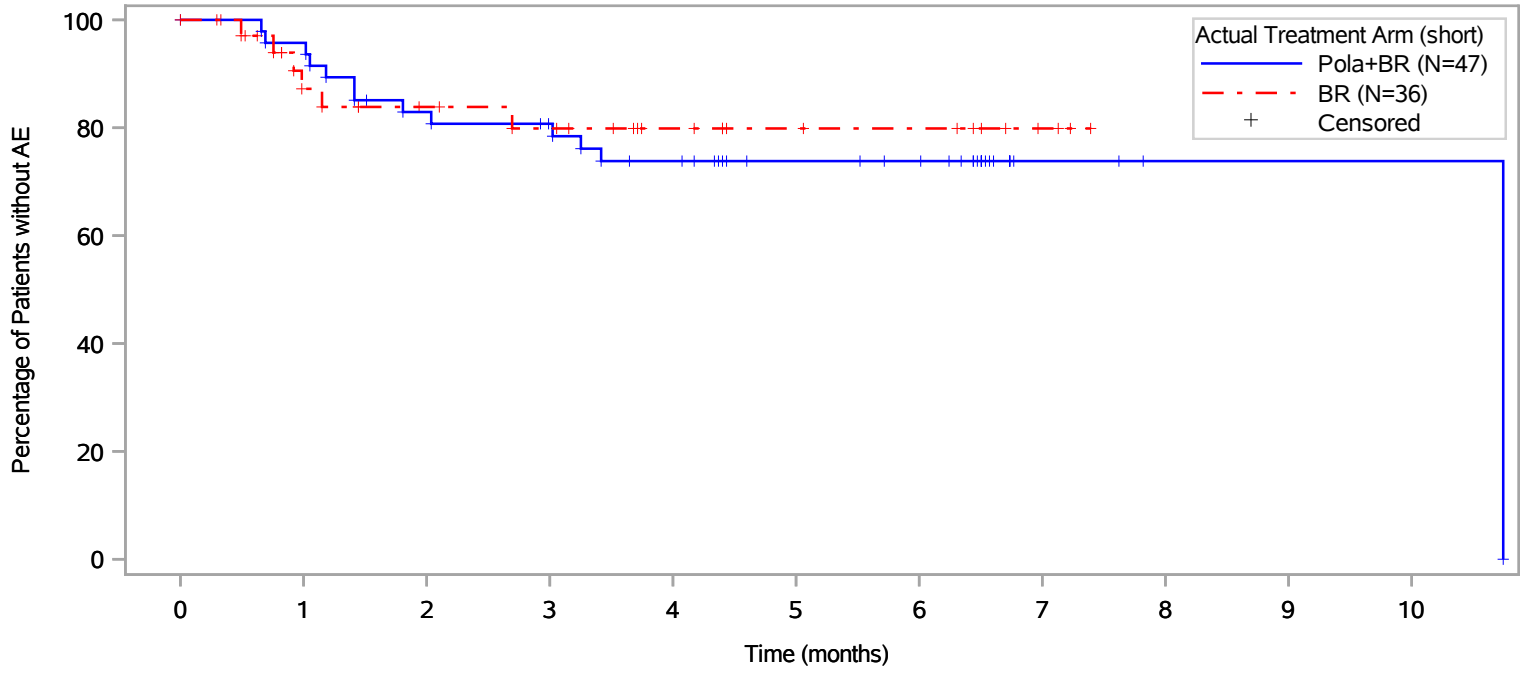


Patients at risk												
Pola+BR (N=47)	47	47	44	41	38	30	26	7	2	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44	45	45	45
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk											
Pola+BR (N=47)	47	45	38	35	31	24	22	3	1	1	1
BR (N=36)	36	26	22	20	14	9	8	3	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	0	1	3	4	11	13	32	34	34	34
BR (N=36)	0	6	9	10	16	21	22	27	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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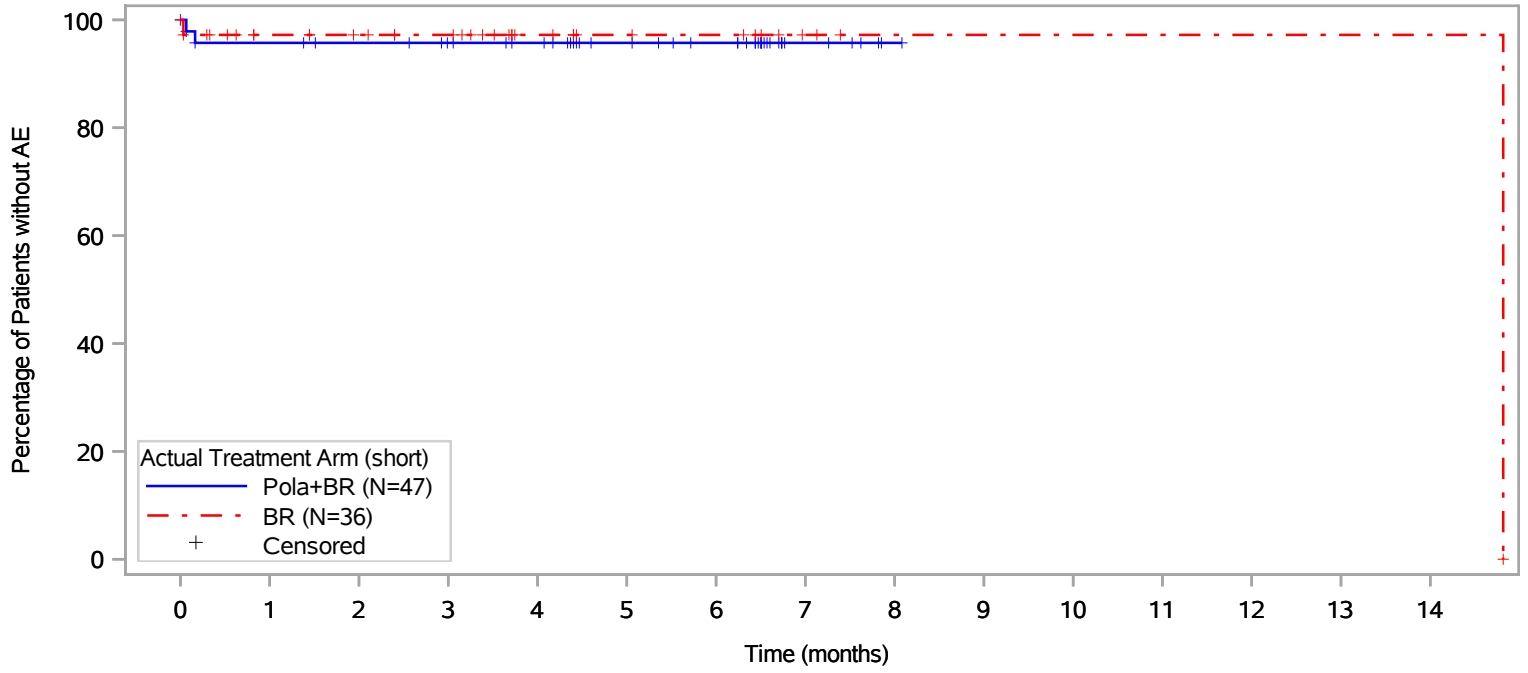
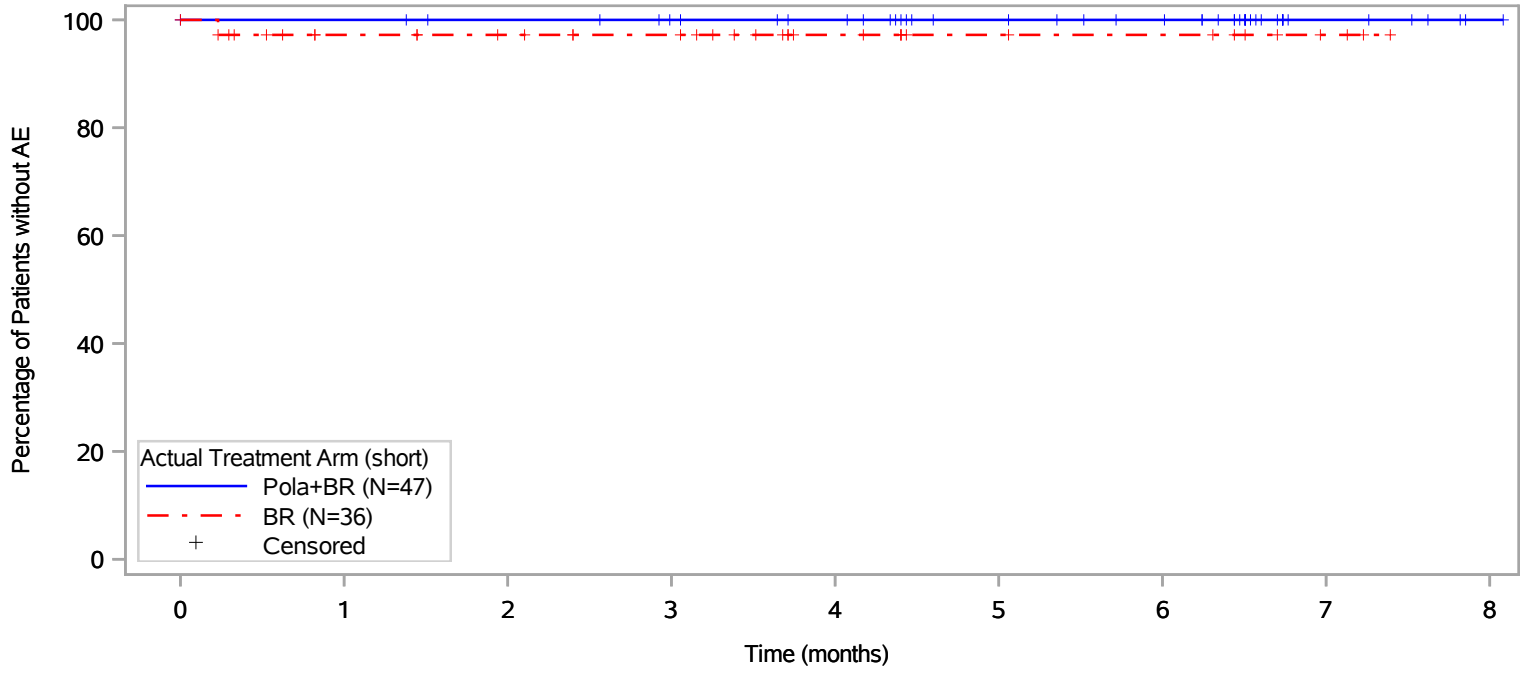
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk															
Pola+BR (N=47)	47	45	43	40	37	29	25	6	1	NE	NE	NE	NE	NE	NE
BR (N=36)	36	29	26	23	14	9	8	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	27	32	34	34	34	34	34	34	34

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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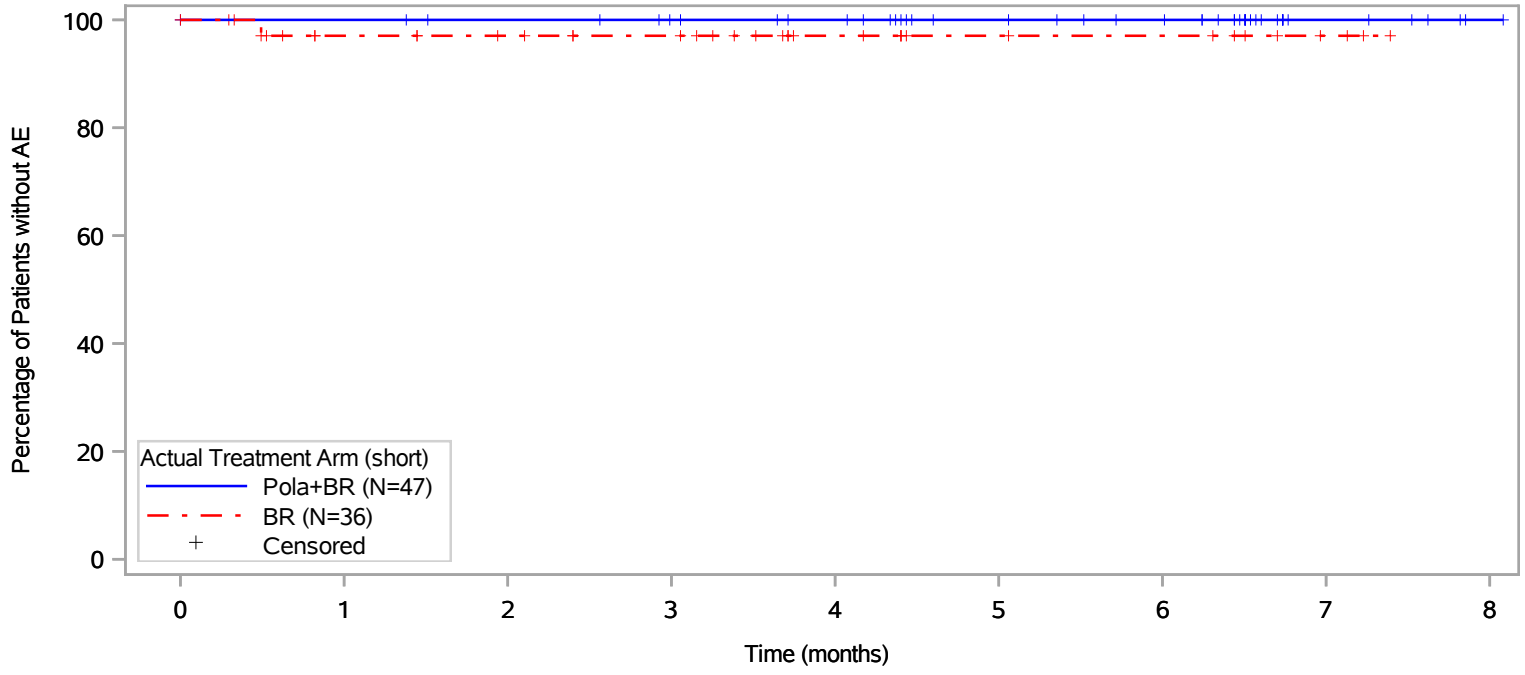
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FLUTTER



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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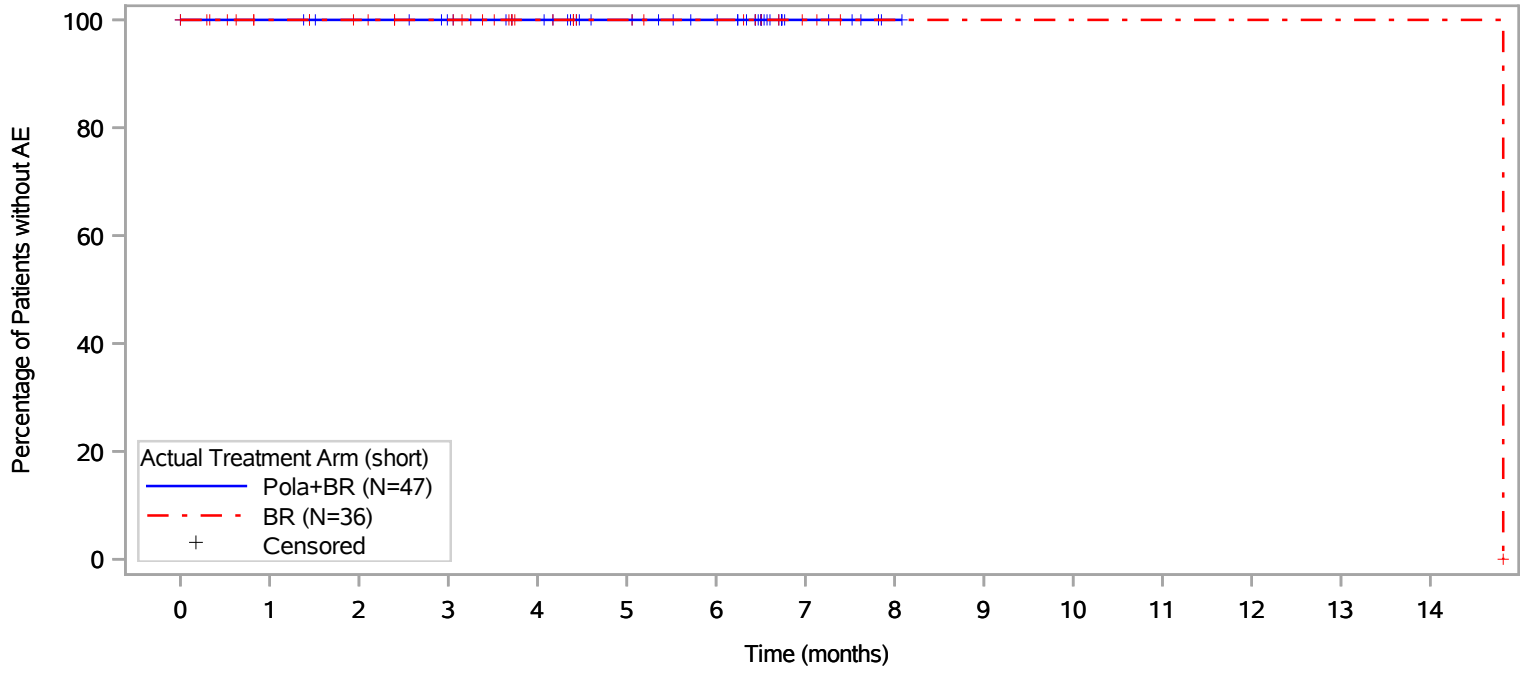
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, CARDIAC FAILURE

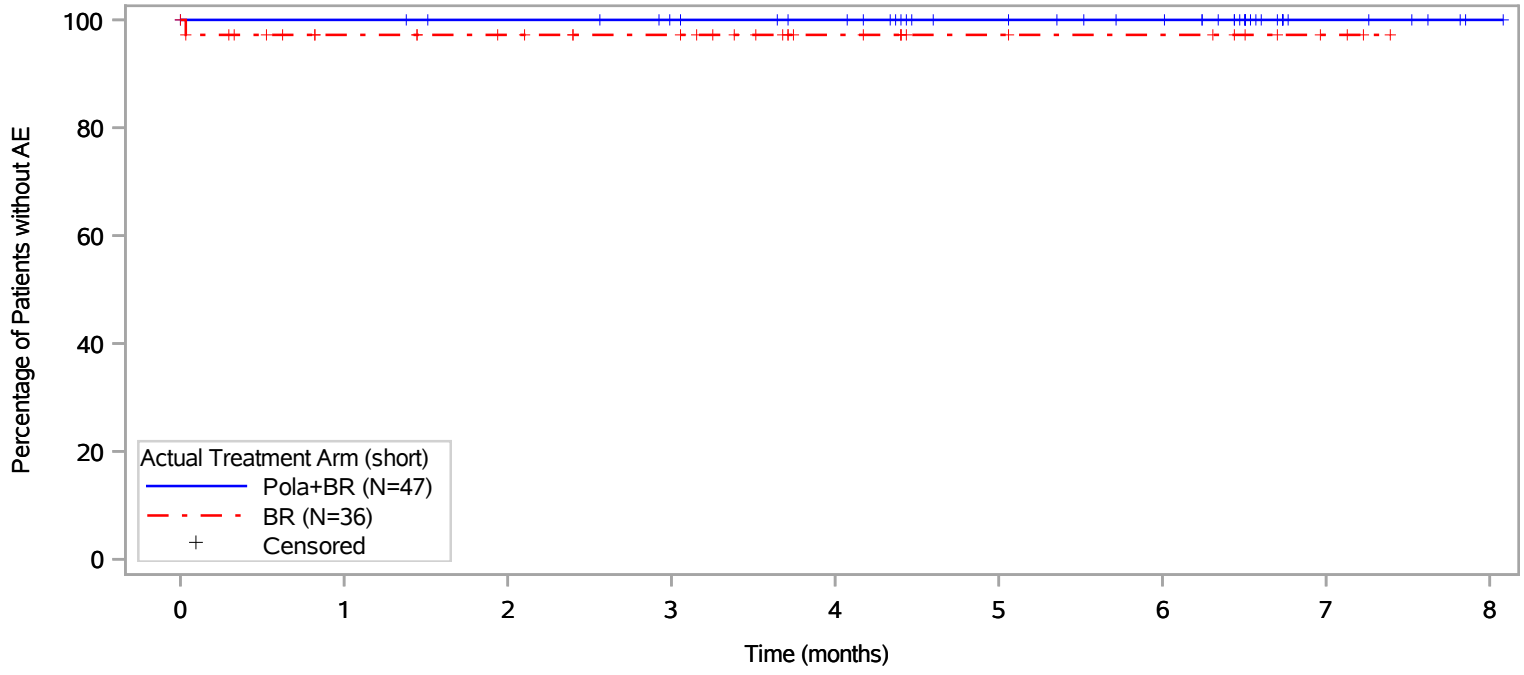


Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	33	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

CARDIAC DISORDERS, SUPRAVENTRICULAR TACHYCARDIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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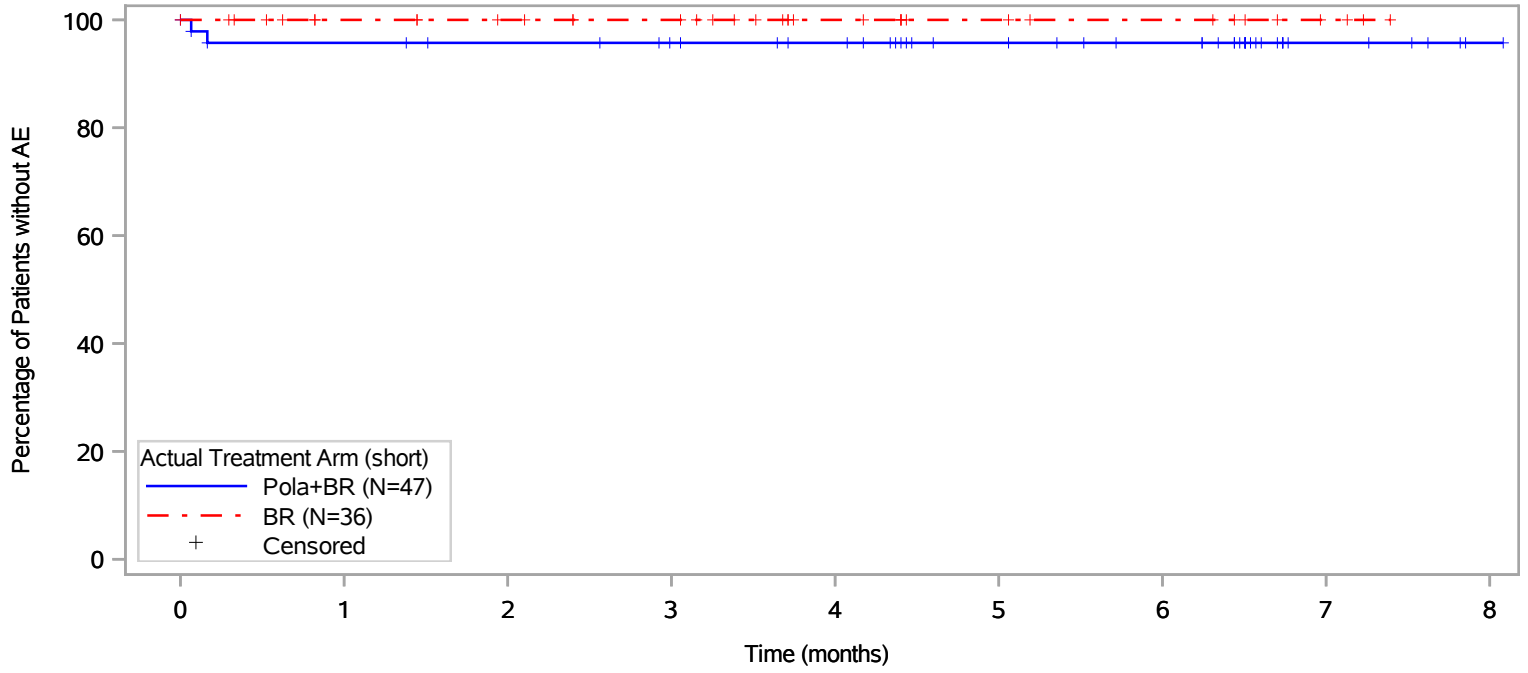
02DEC2022 2:28

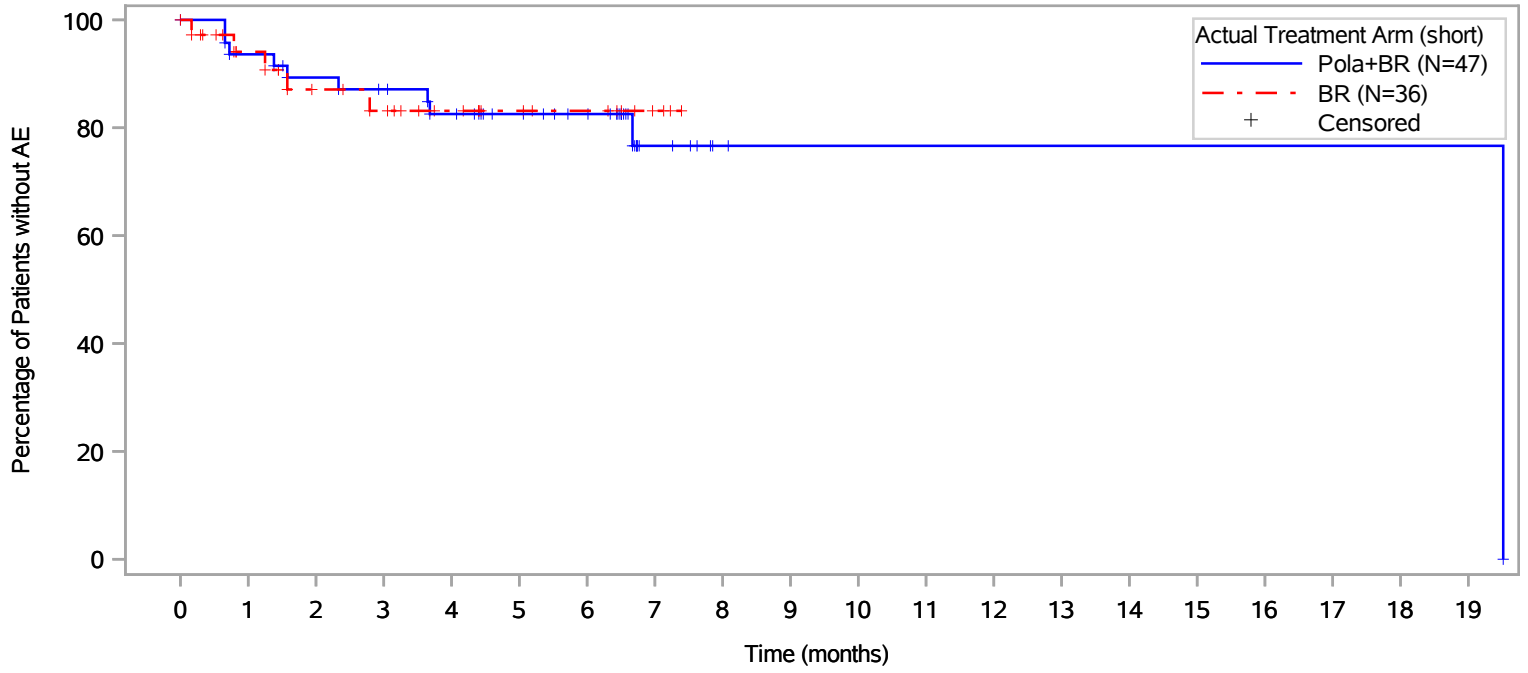
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	29	25	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk																				
Pola+BR (N=47)	47	44	41	39	36	30	26	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	28	23	21	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	1	2	3	9	13	31	36	37	37	37	37	37	37	37	37	37	37	37
BR (N=36)	0	6	9	10	16	21	23	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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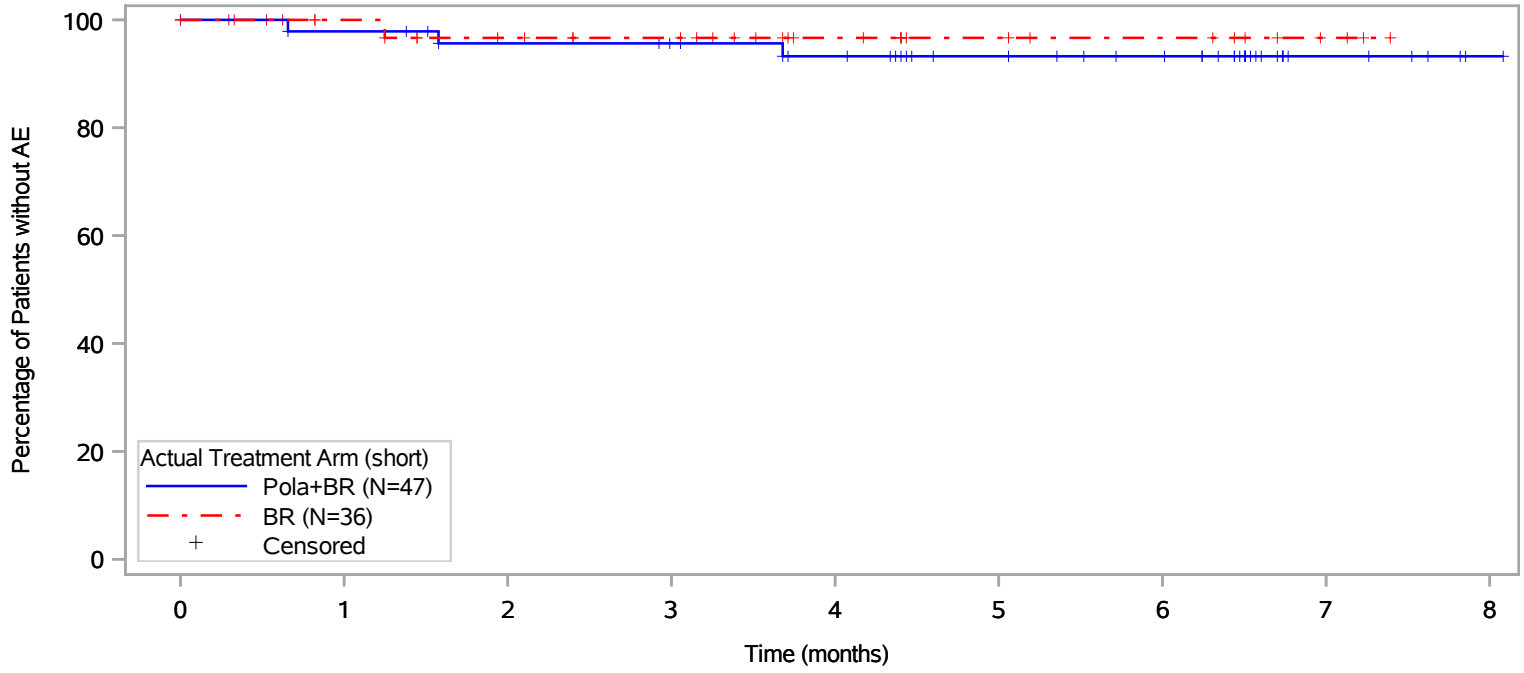
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN

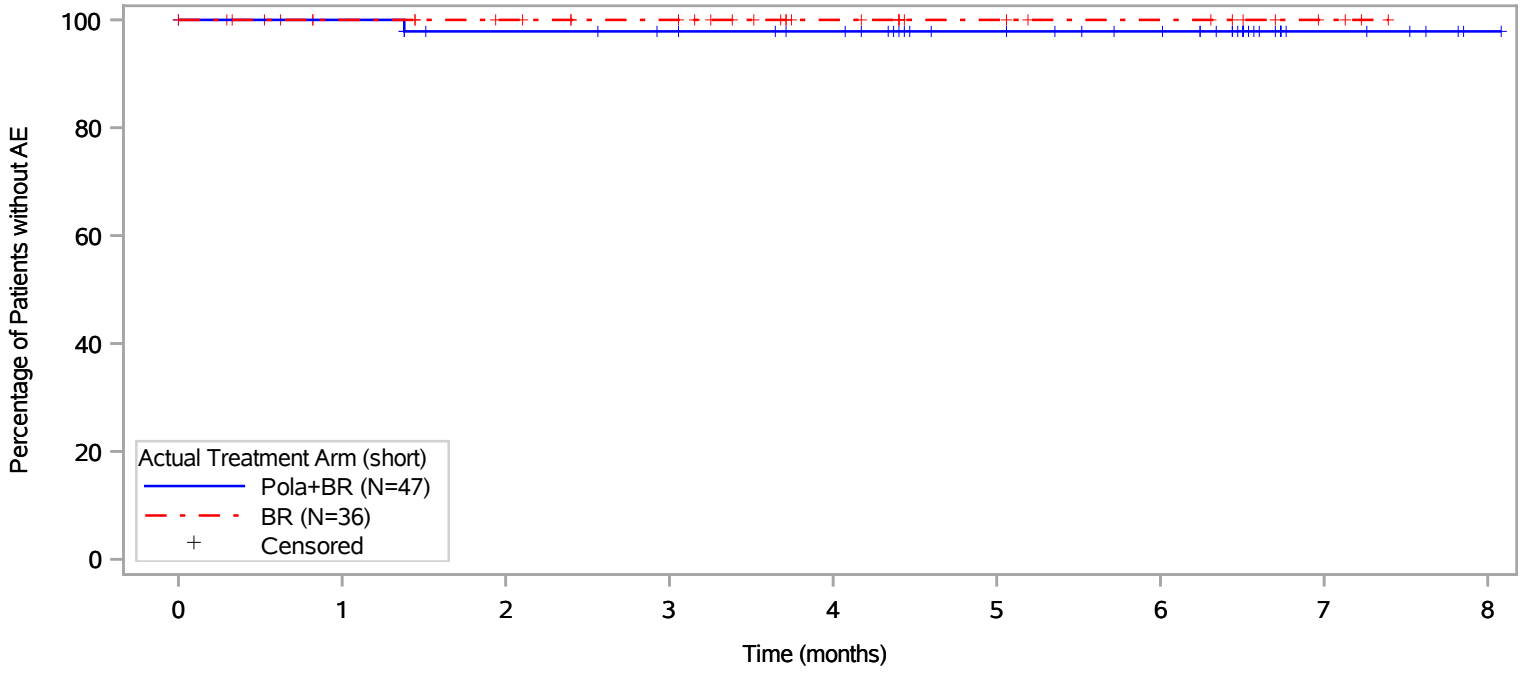


Patients at risk									
Pola+BR (N=47)	47	46	43	41	38	31	27	6	1
BR (N=36)	36	30	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	6	13	17	38	43
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN UPPER



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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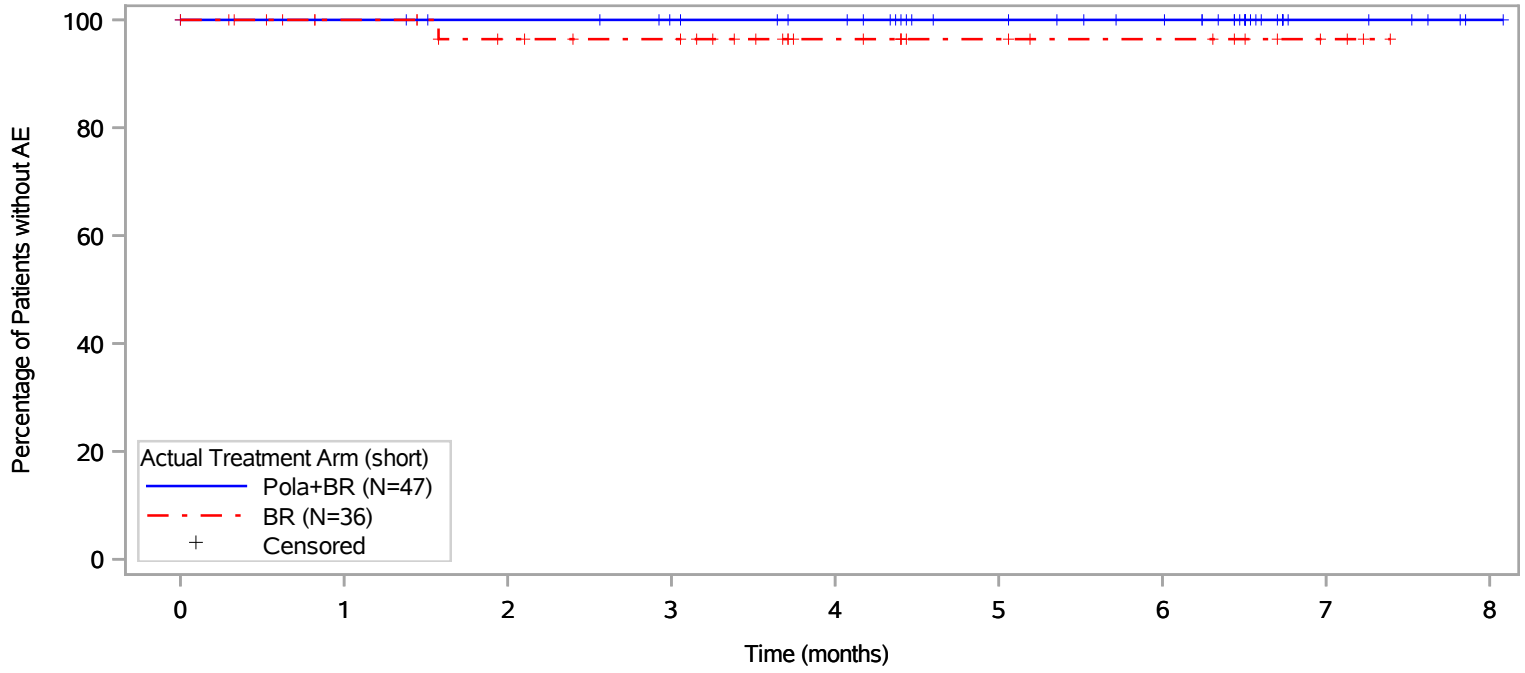
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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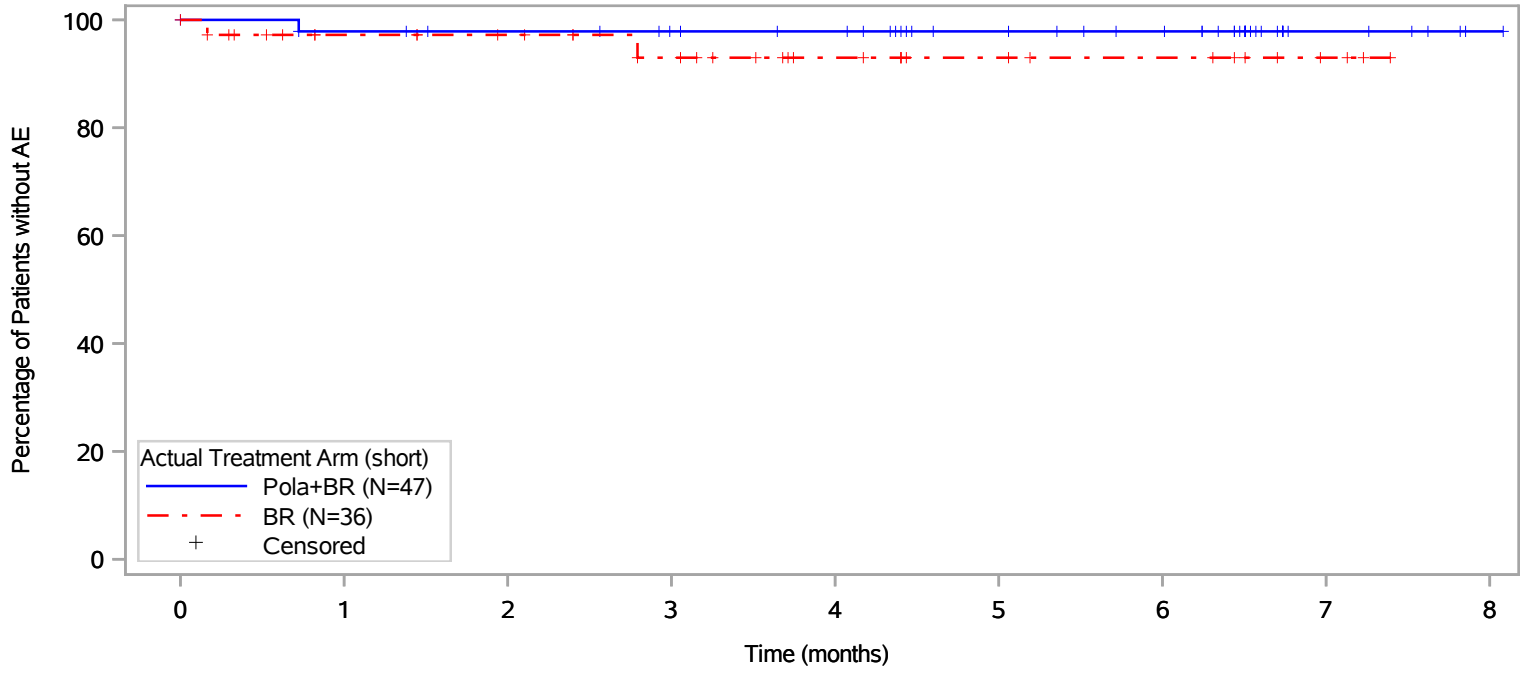
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA

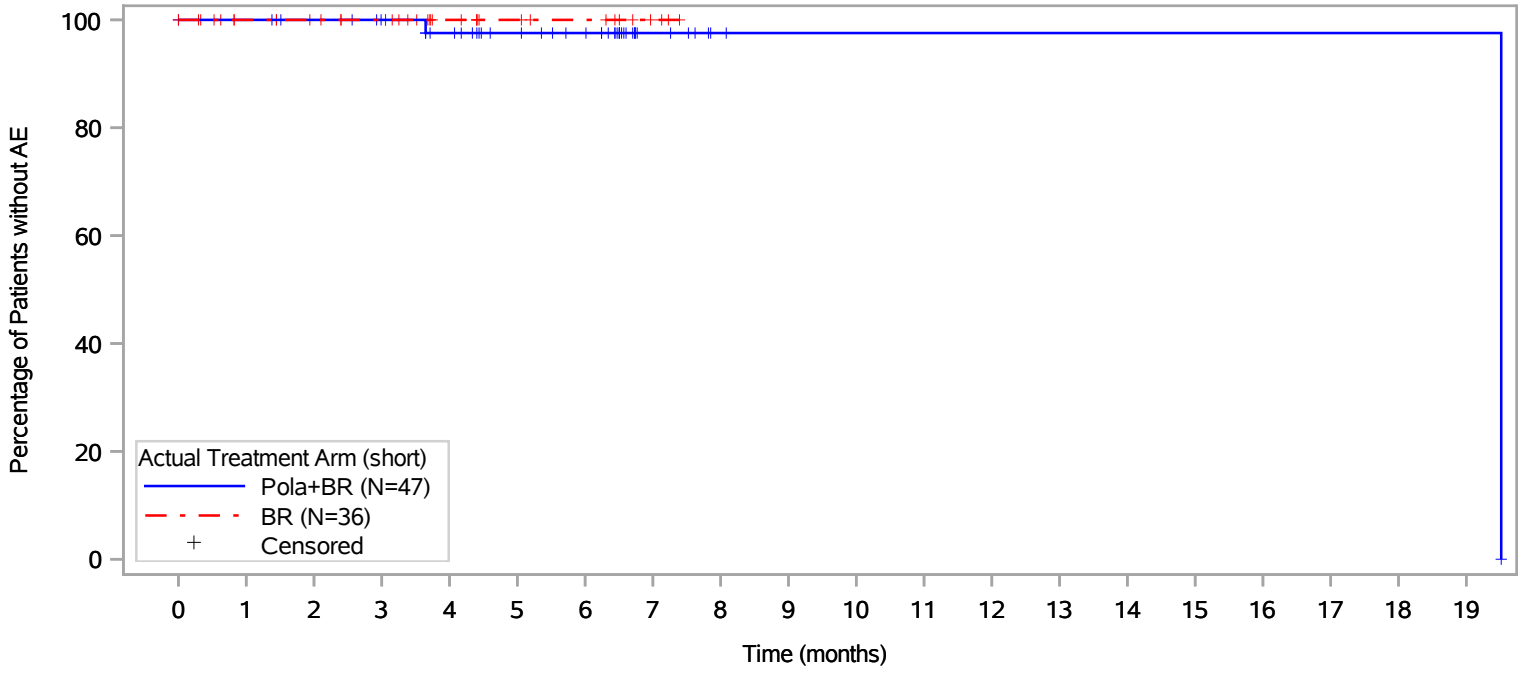


Patients at risk									
Pola+BR (N=47)	47	46	44	41	39	31	27	6	1
BR (N=36)	36	29	26	22	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

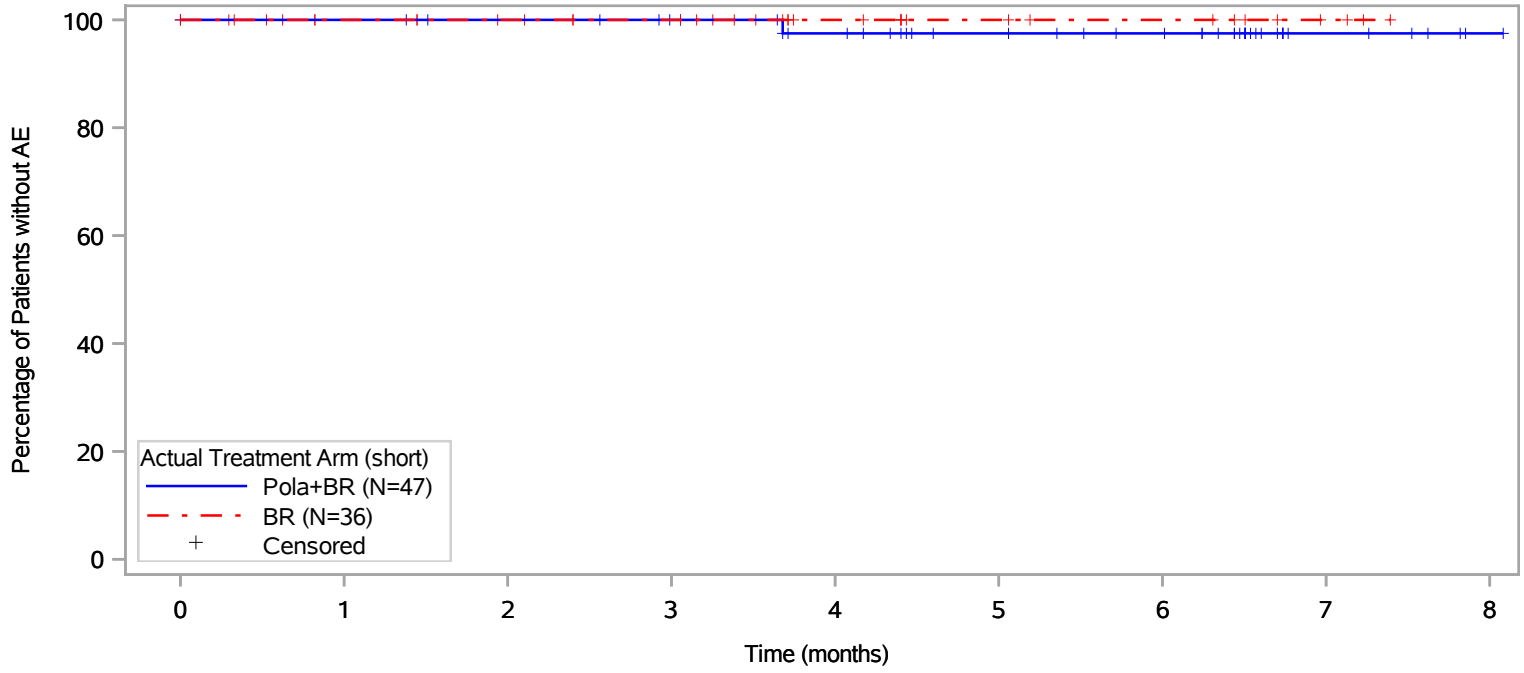
GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk																				
Pola+BR (N=47)	47	47	45	42	38	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	8	15	19	39	44	45	45	45	45	45	45	45	45	45	45	45
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTROINTESTINAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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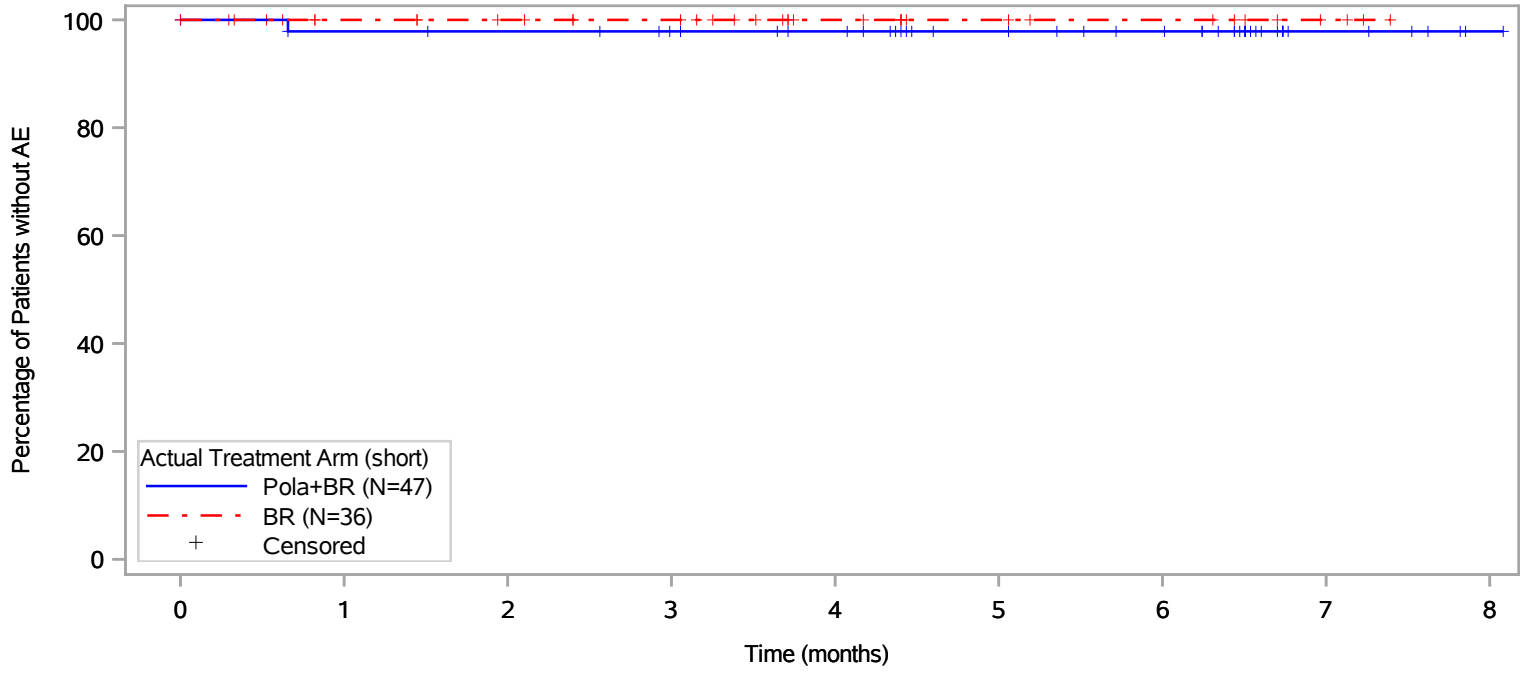
02DEC2022 2:28

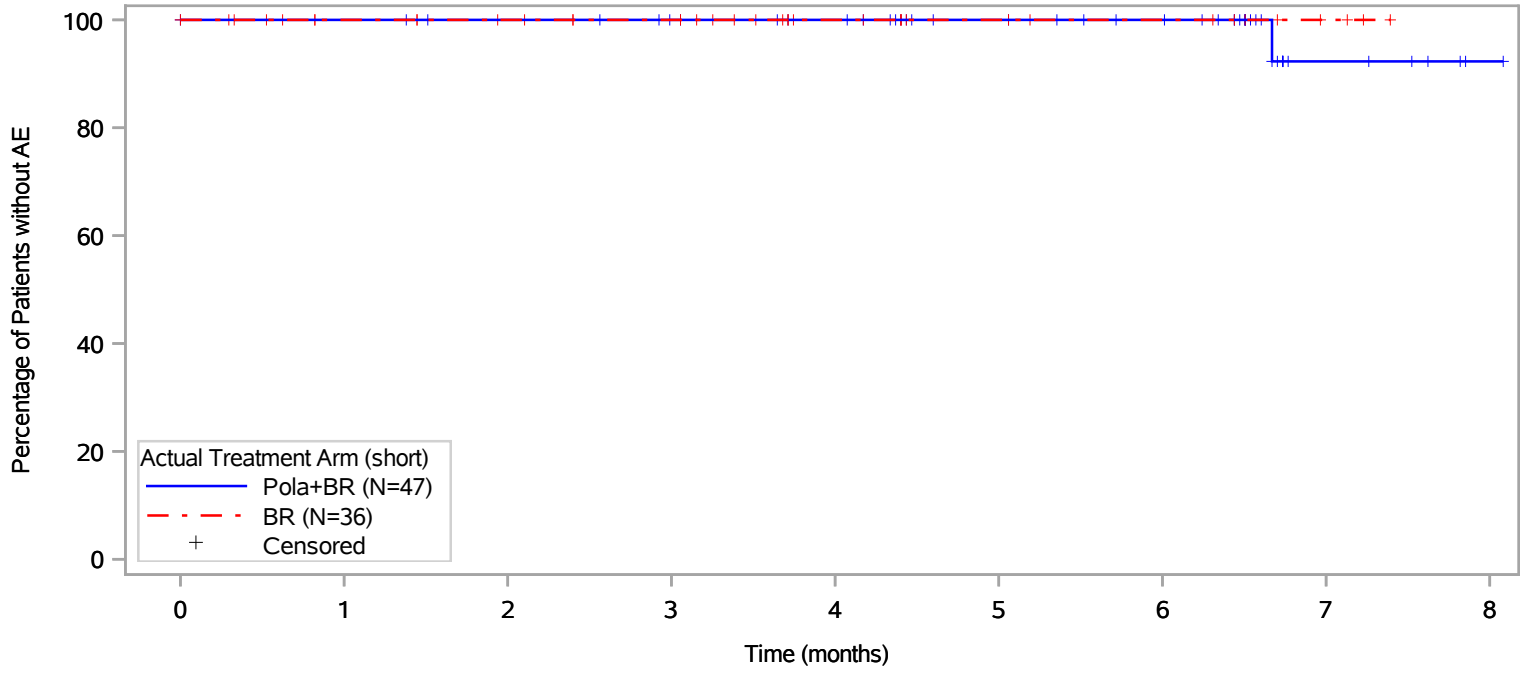
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ILEUS



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, OBSTRUCTION GASTRIC



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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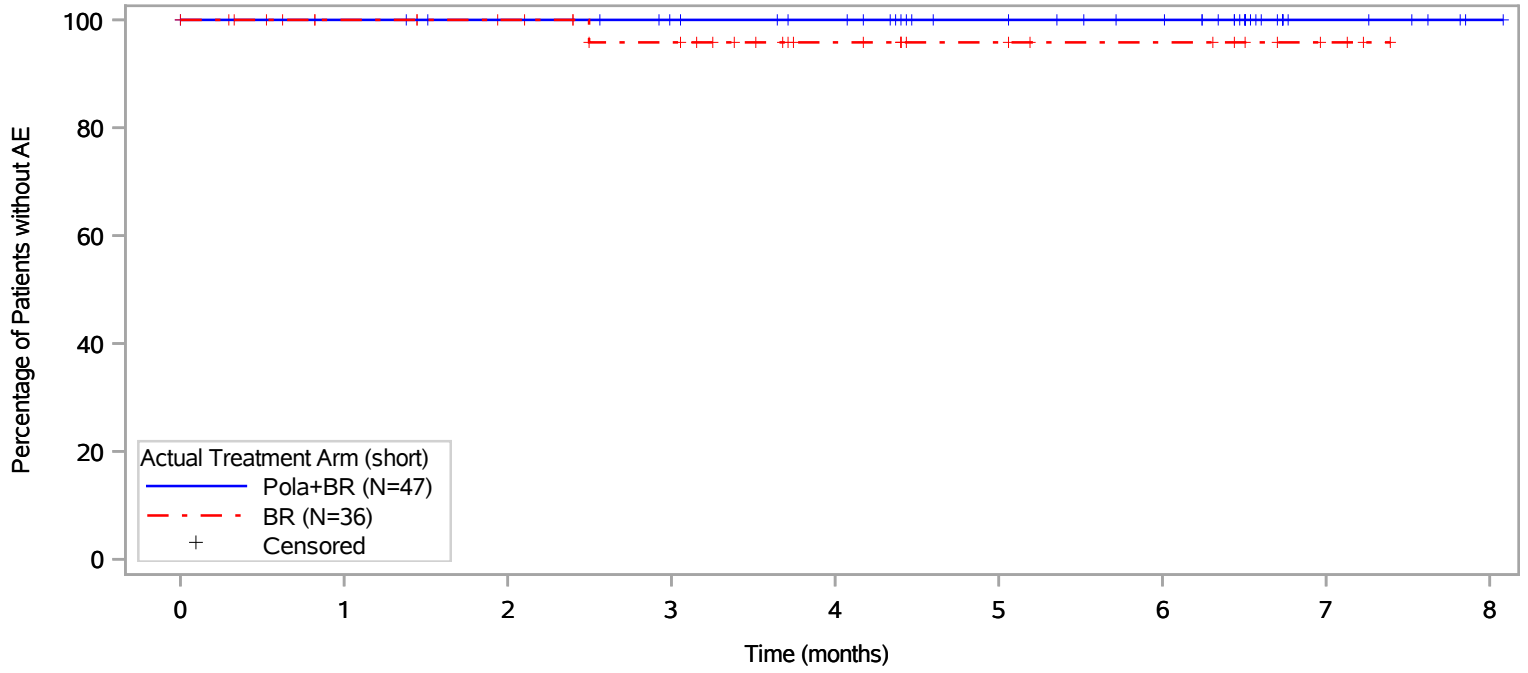
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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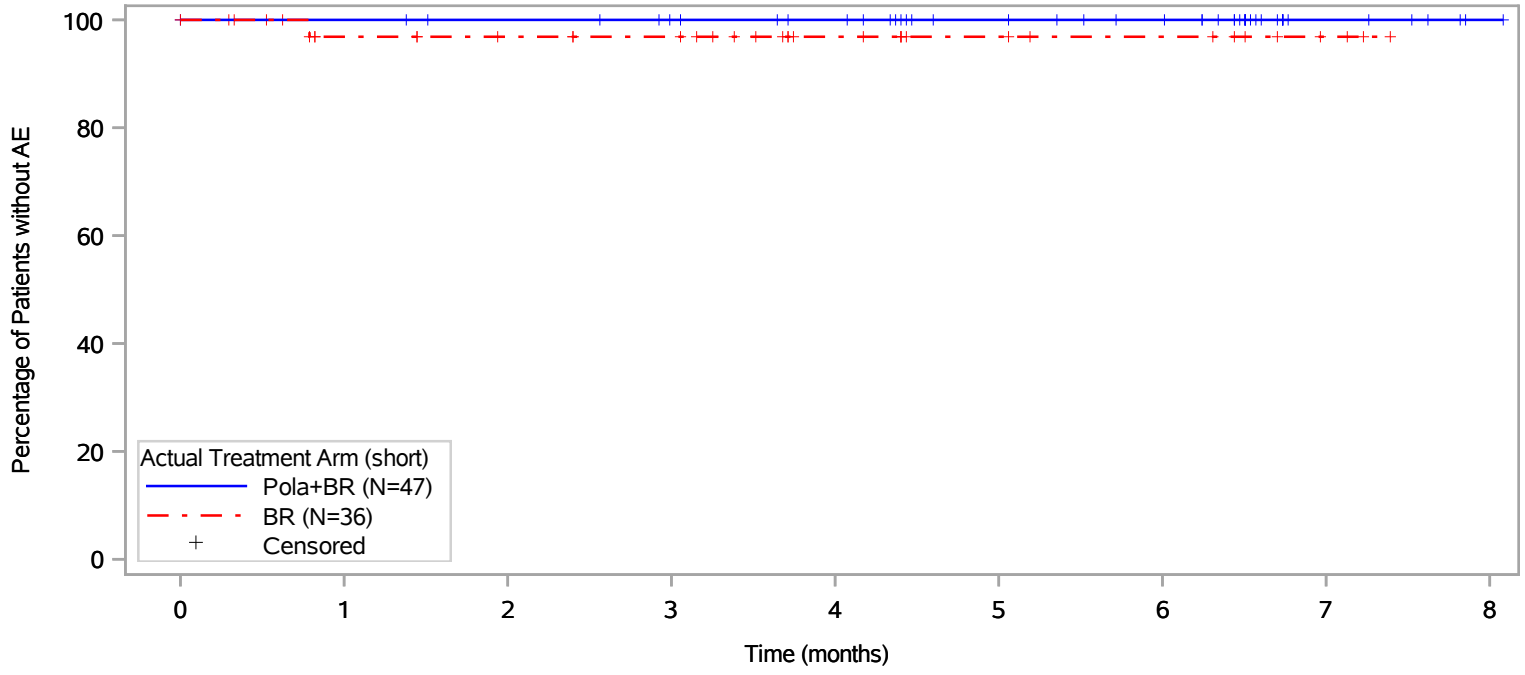
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, UPPER GASTROINTESTINAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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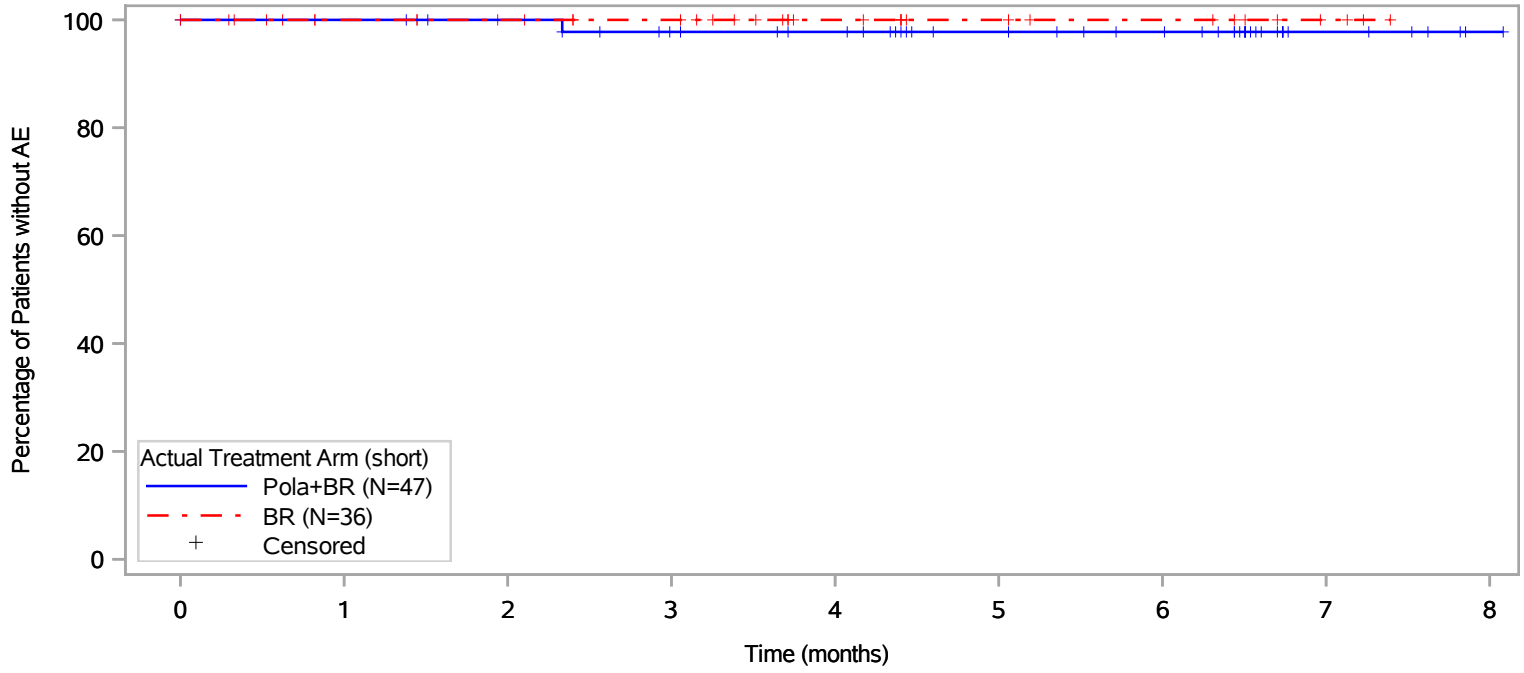
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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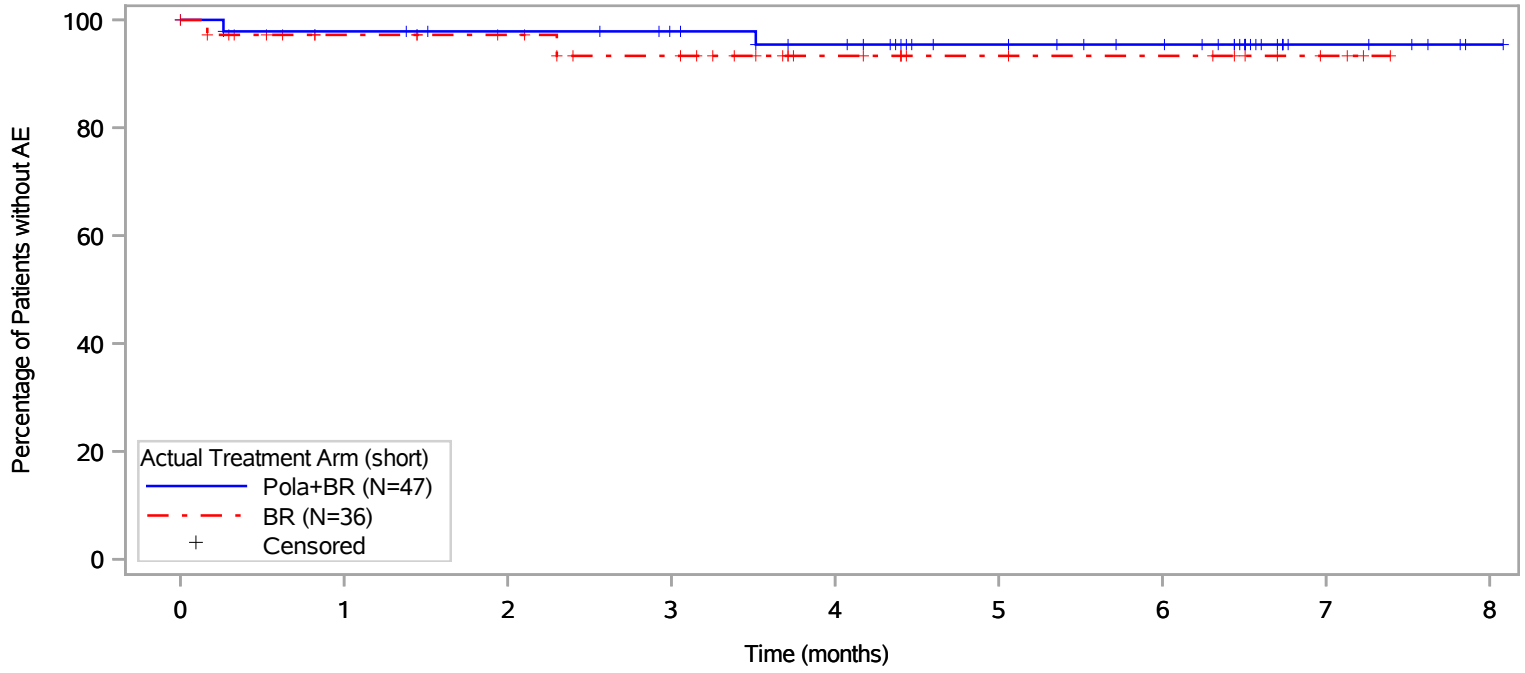
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	39	44
BR (N=36)	0	6	9	11	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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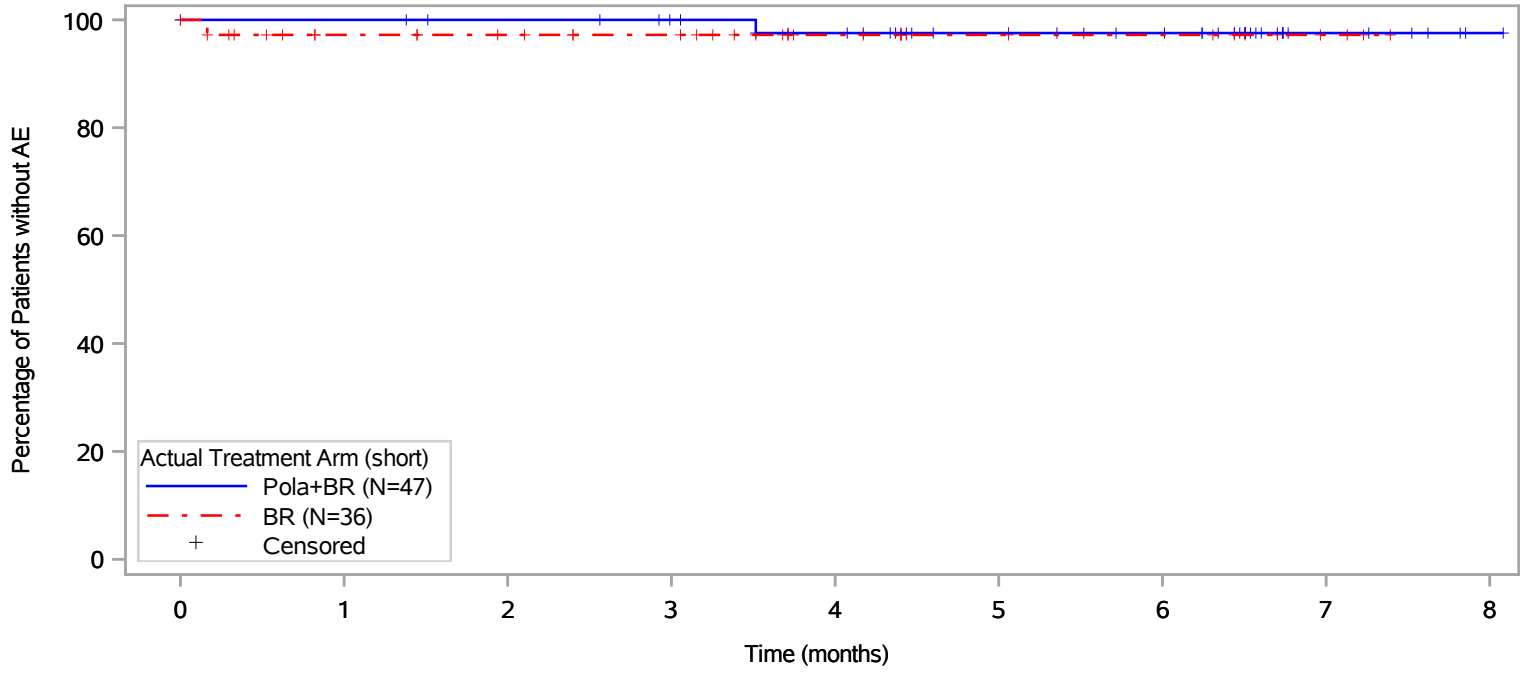
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE

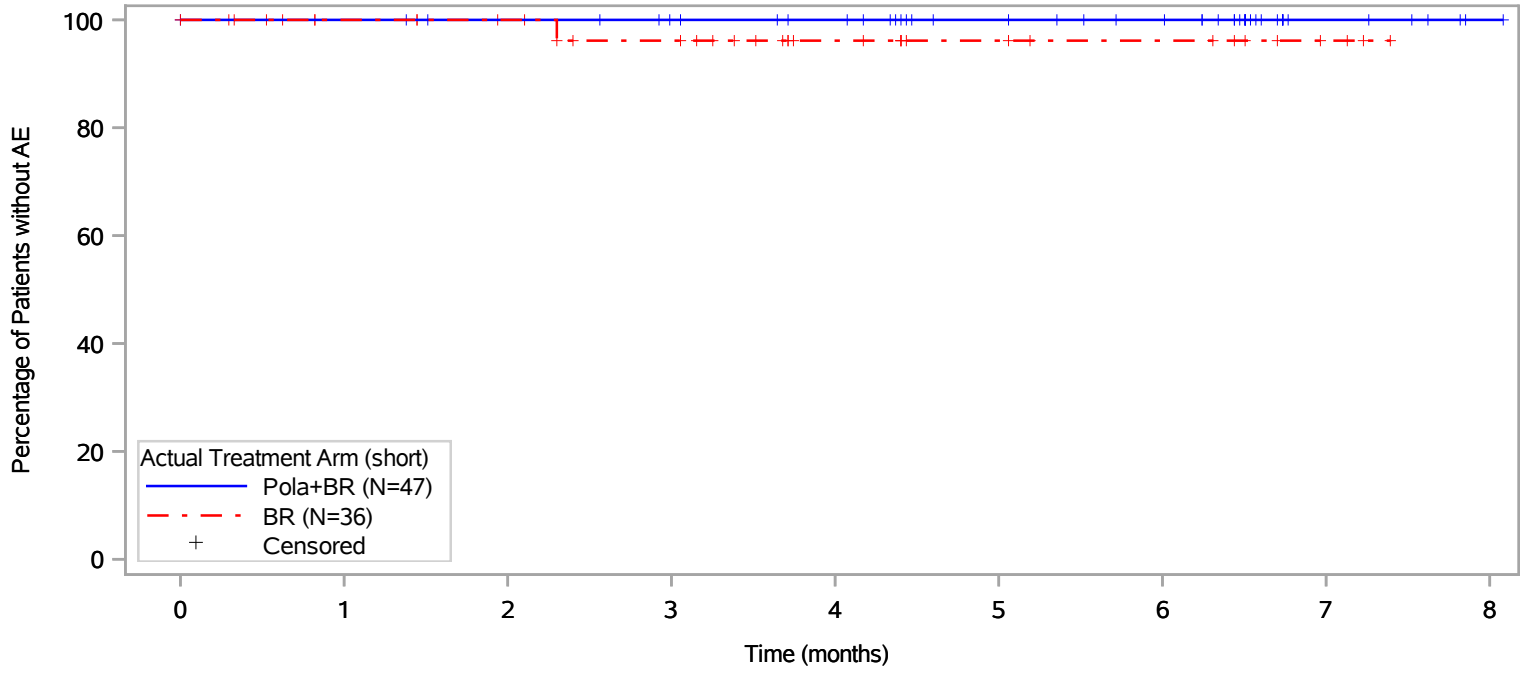


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME

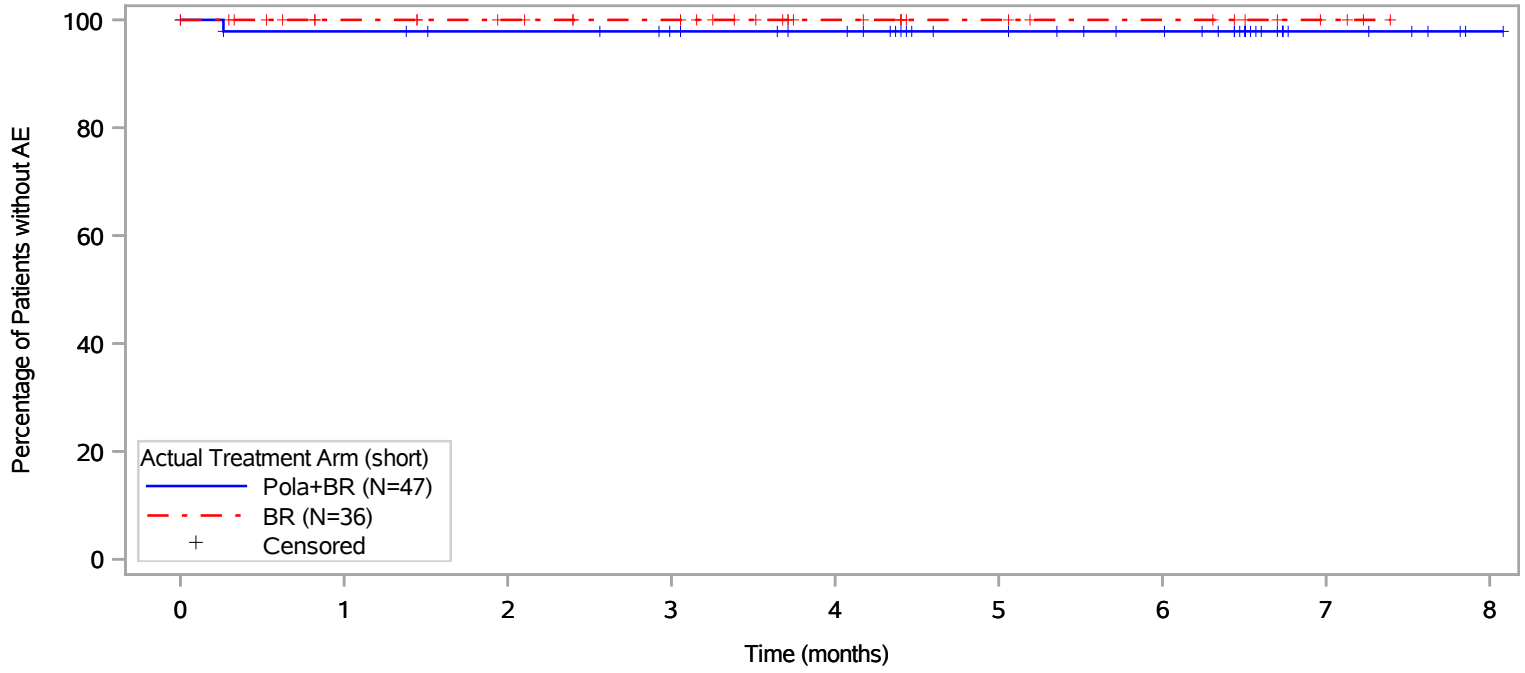


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

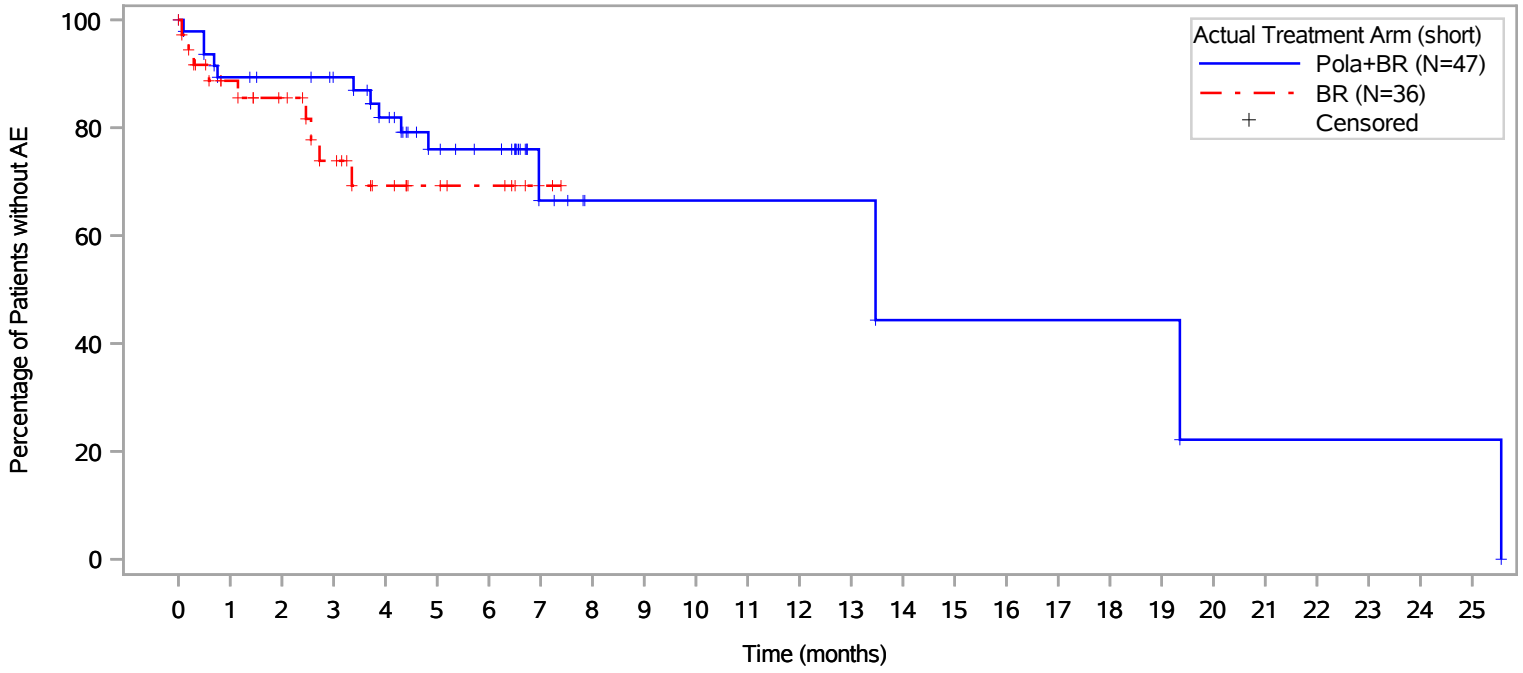
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk																										
Pola+BR (N=47)	47	42	40	37	32	24	21	7	3	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=36)	36	28	24	19	13	9	7	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	2	5	7	13	16	29	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33
BR (N=36)	0	4	7	9	14	18	20	25	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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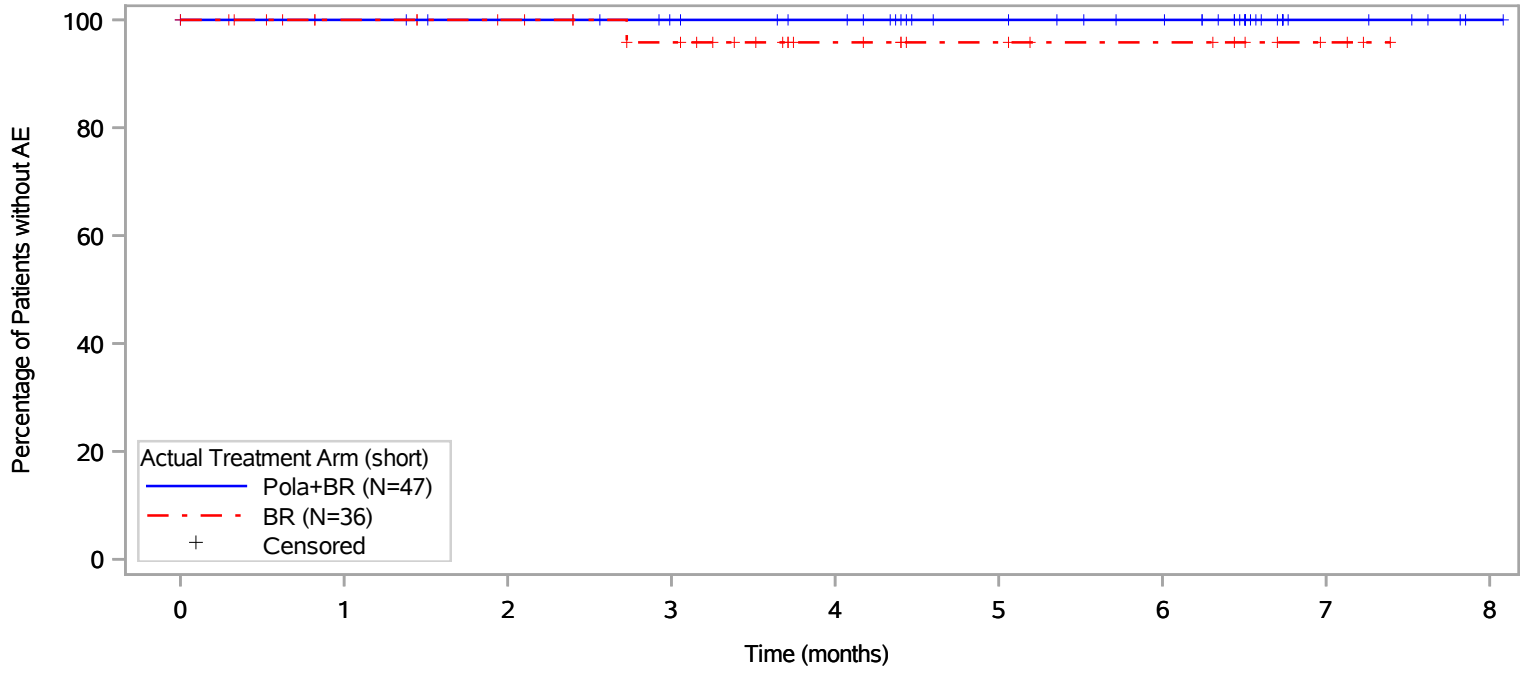
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, CYTOMEGALOVIRUS INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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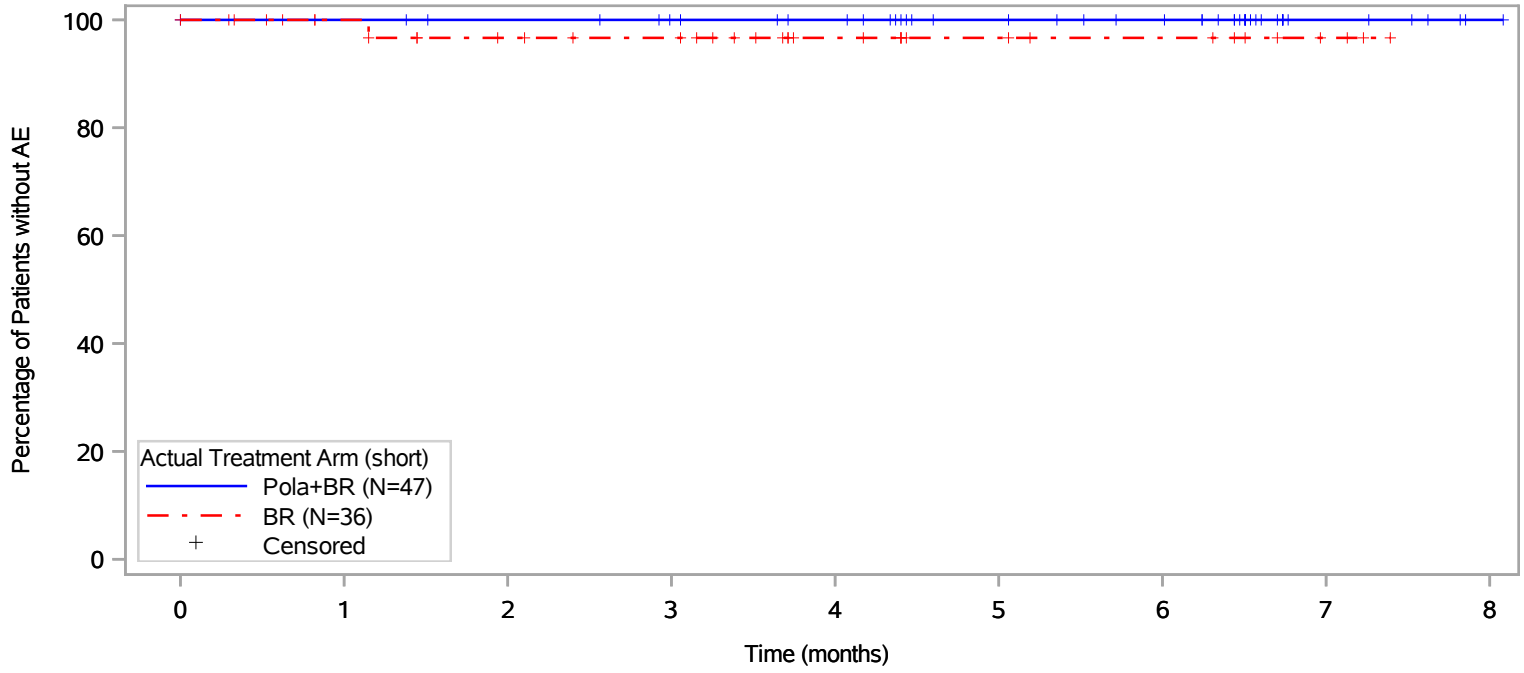
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, DEVICE RELATED INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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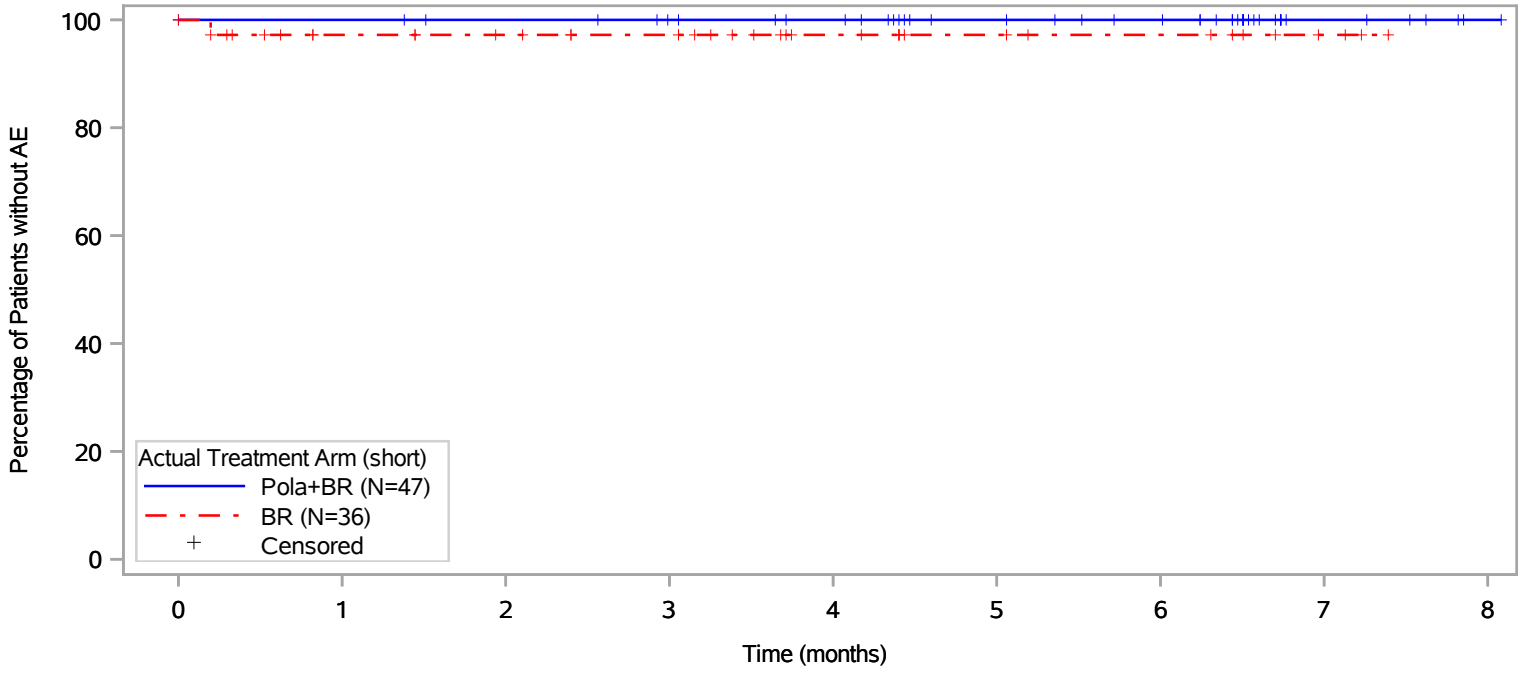
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, ENTEROCOLITIS VIRAL



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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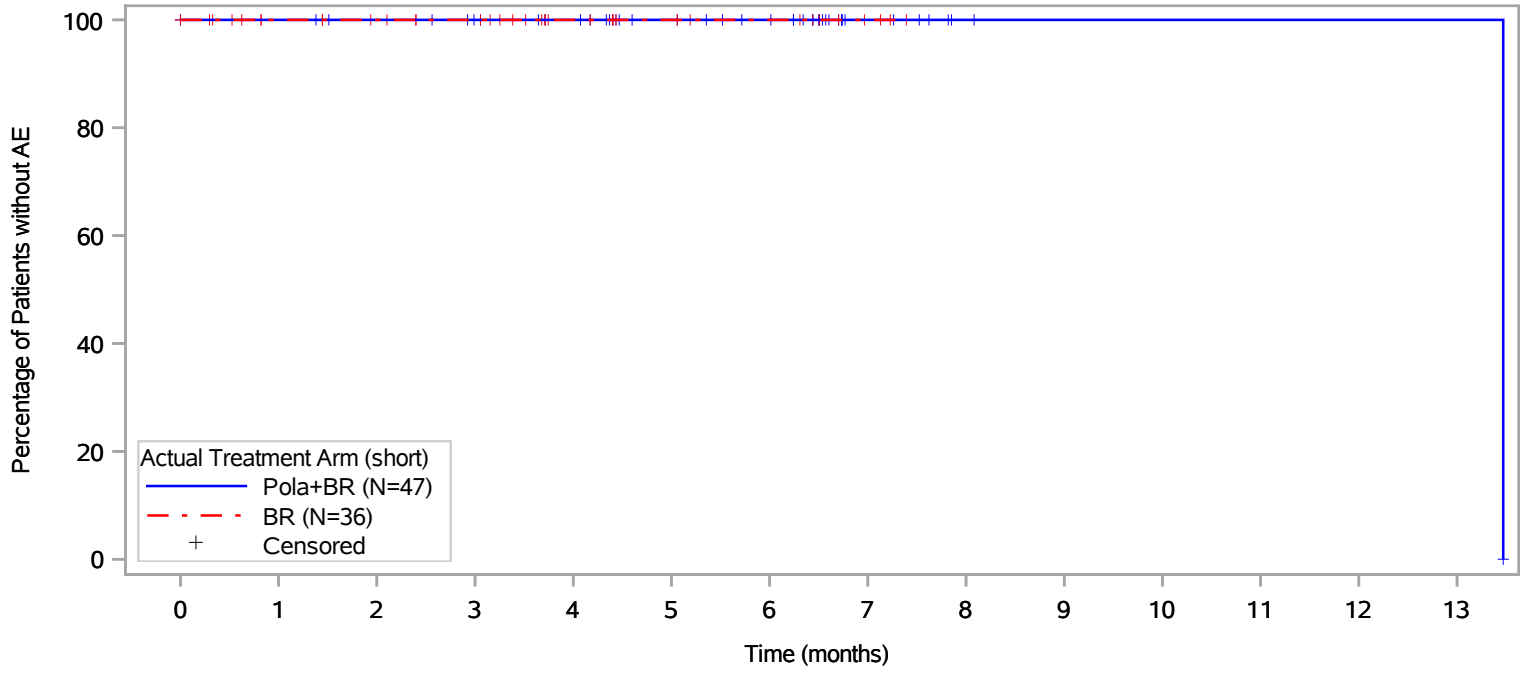
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

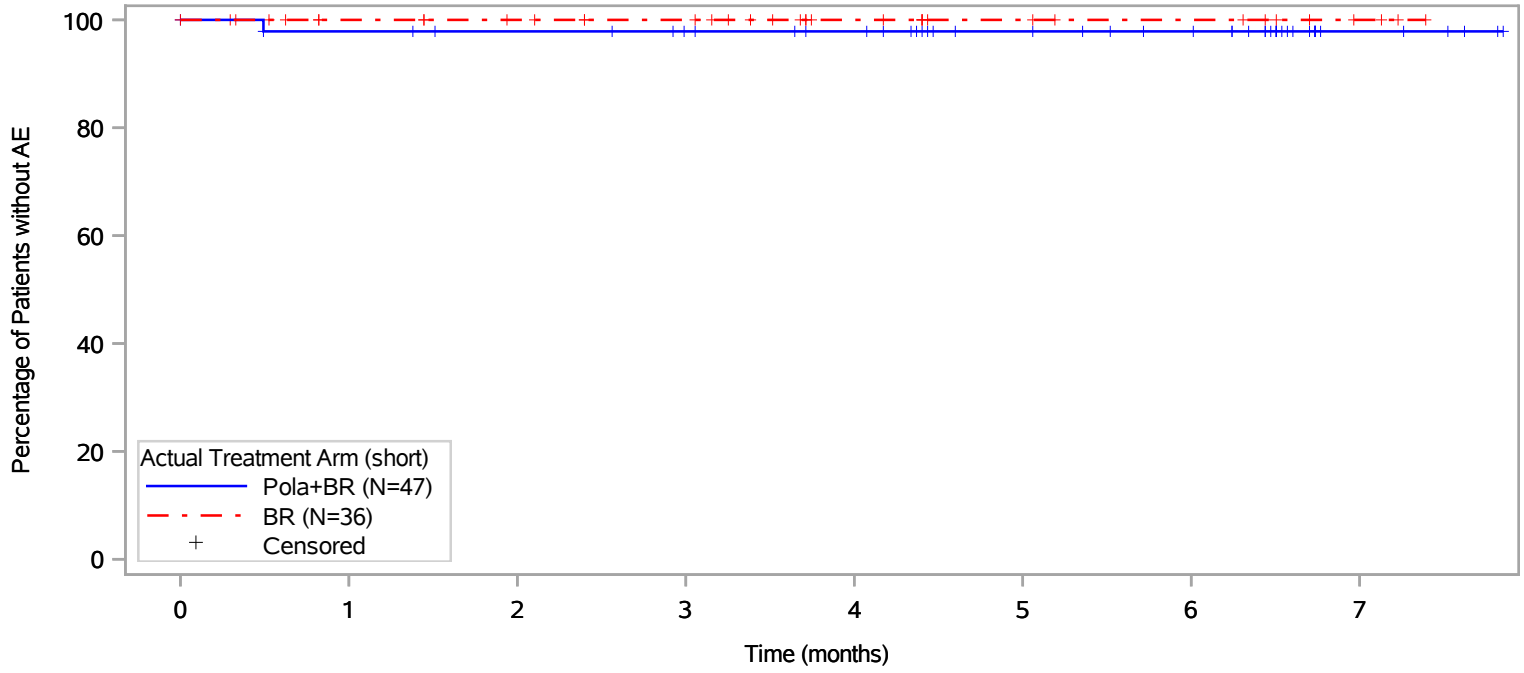
INFECTIONS AND INFESTATIONS, GASTROINTESTINAL BACTERIAL INFECTION



Patients at risk														
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

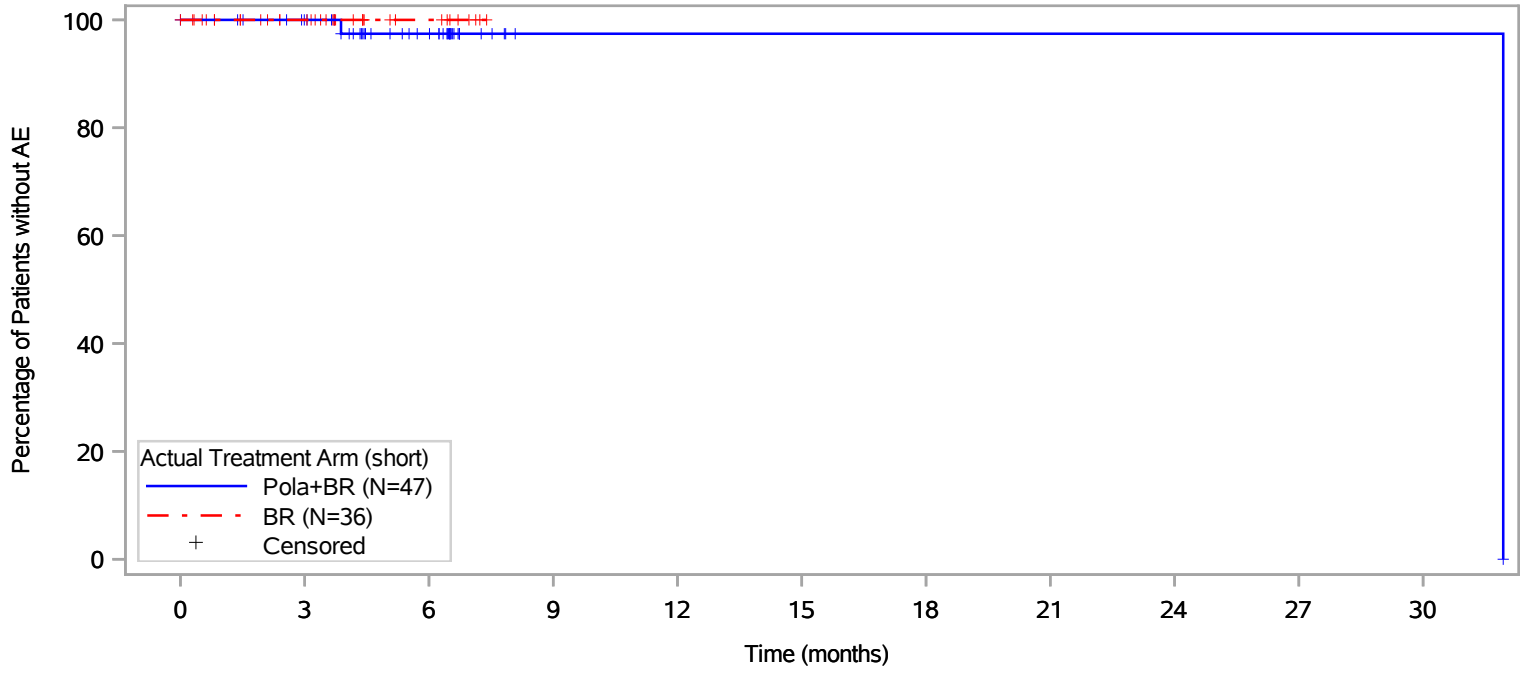
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HUMAN ANAPLASMOSIS



Patients at risk								
Pola+BR (N=47)	47	46	44	41	38	30	26	5
BR (N=36)	36	30	27	24	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	16	20	41
BR (N=36)	0	6	9	12	21	26	28	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk											
Pola+BR (N=47)	47	42	26	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	5	20	45	45	45	45	45	45	45	45
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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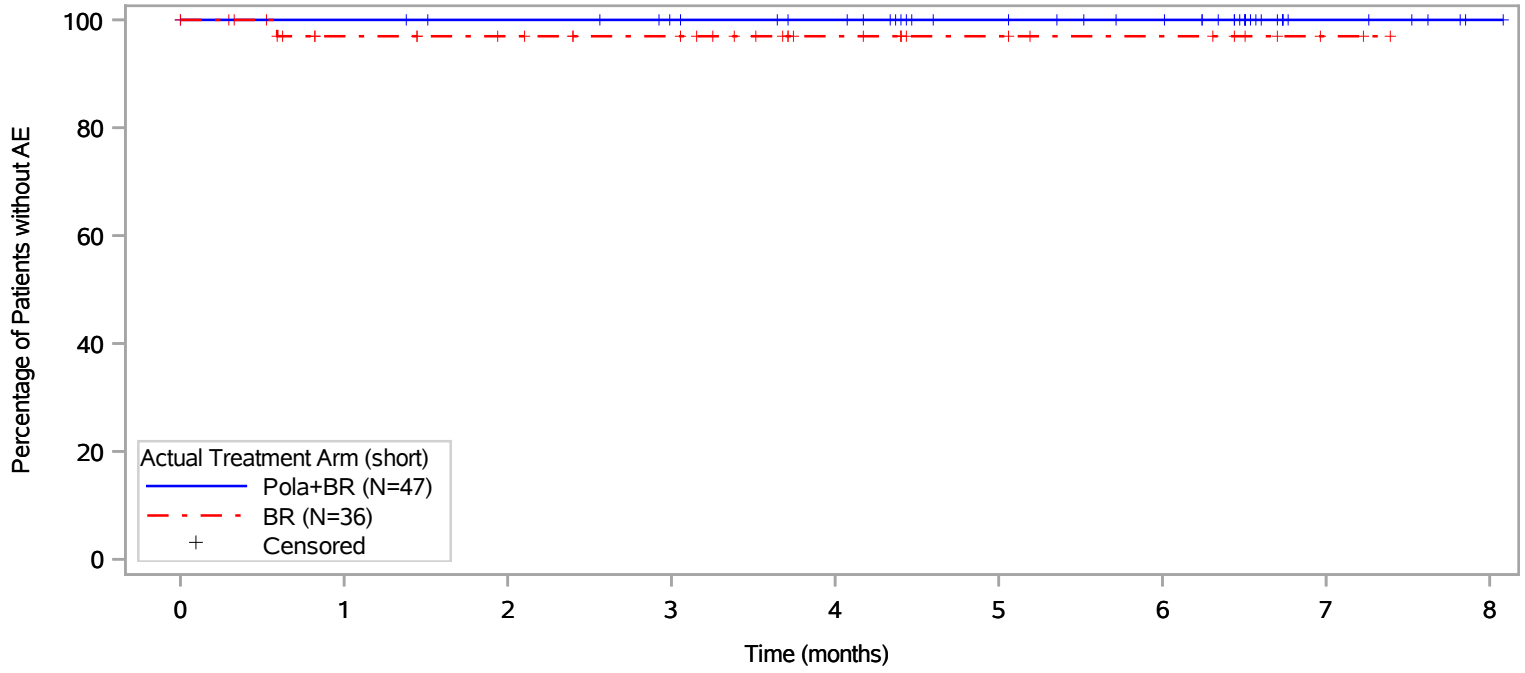
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, LOWER RESPIRATORY TRACT INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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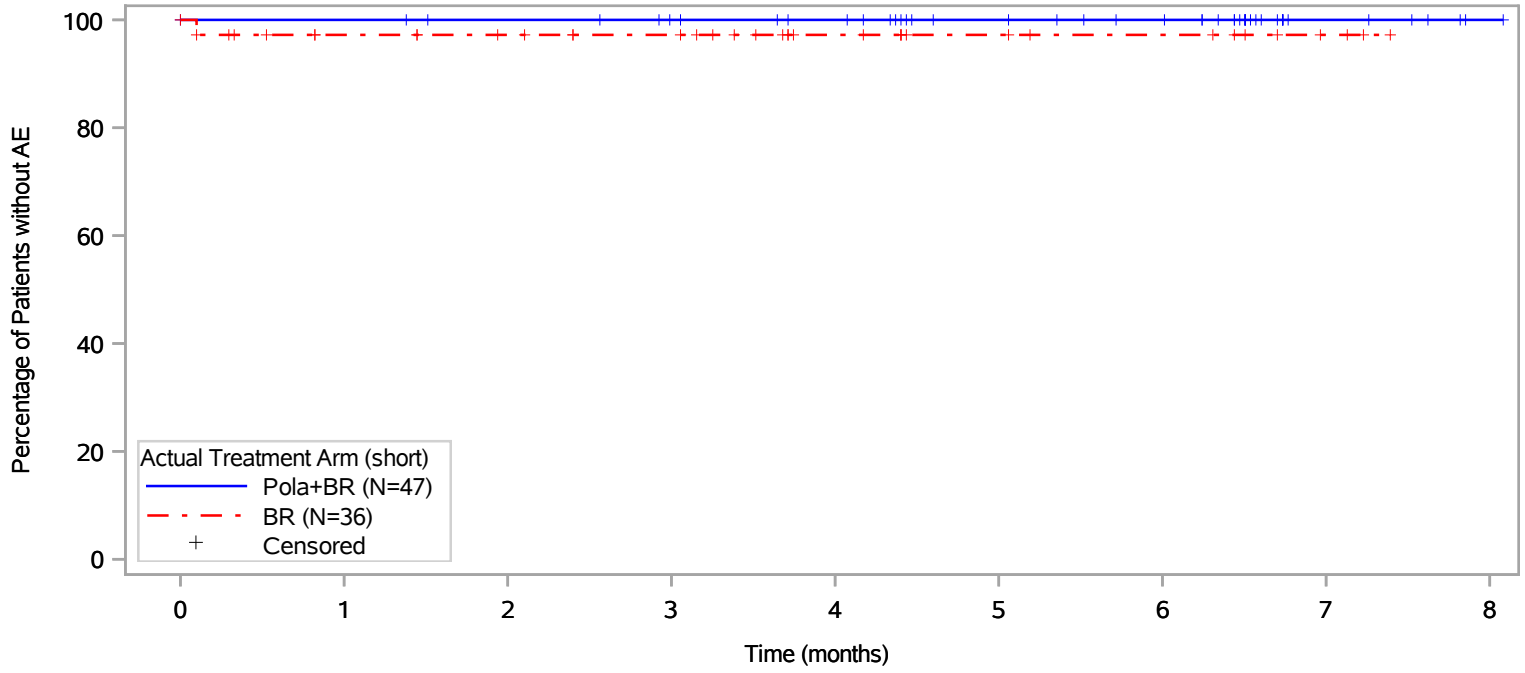
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NEUTROPENIC SEPSIS

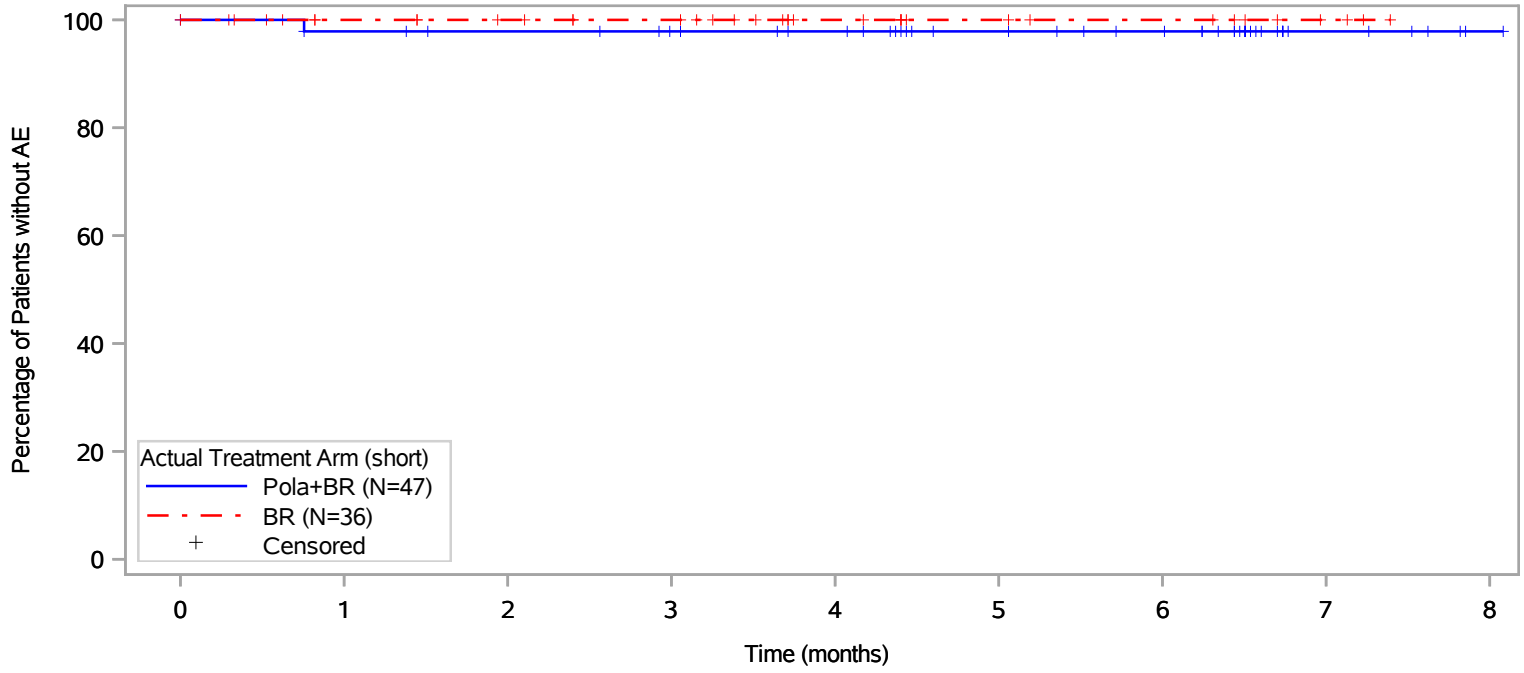


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	5	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, PNEUMOCYSTIS JIROVECII PNEUMONIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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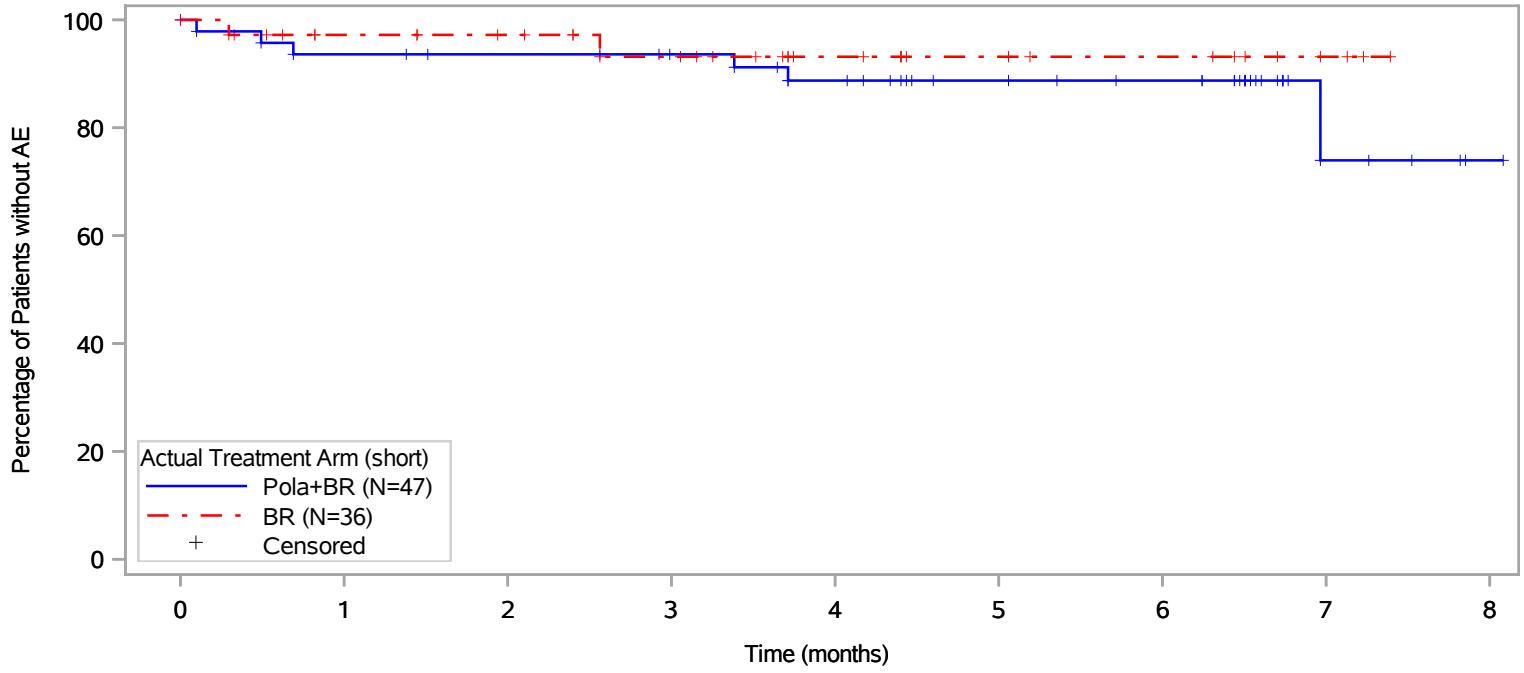
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=47)	47	44	42	39	35	28	25	5	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	14	17	36	40
BR (N=36)	0	5	8	11	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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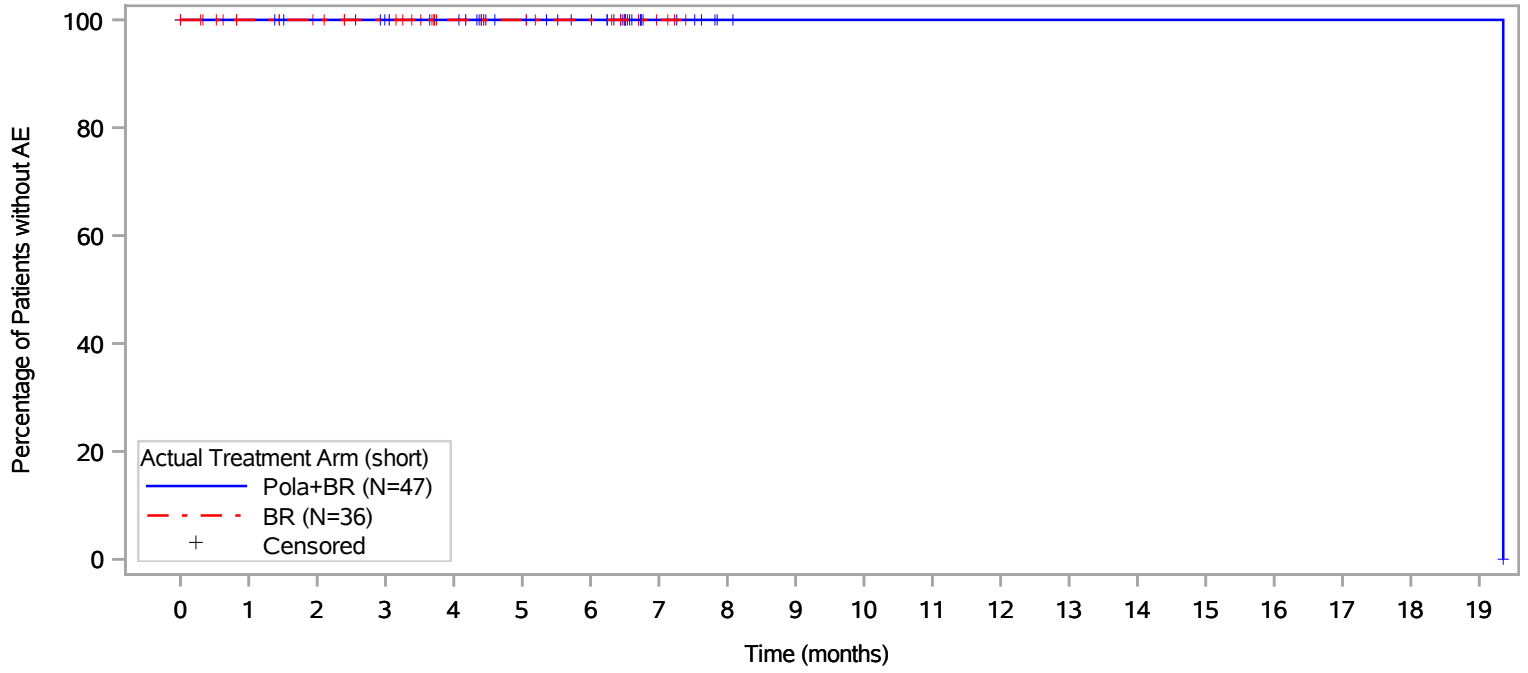
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

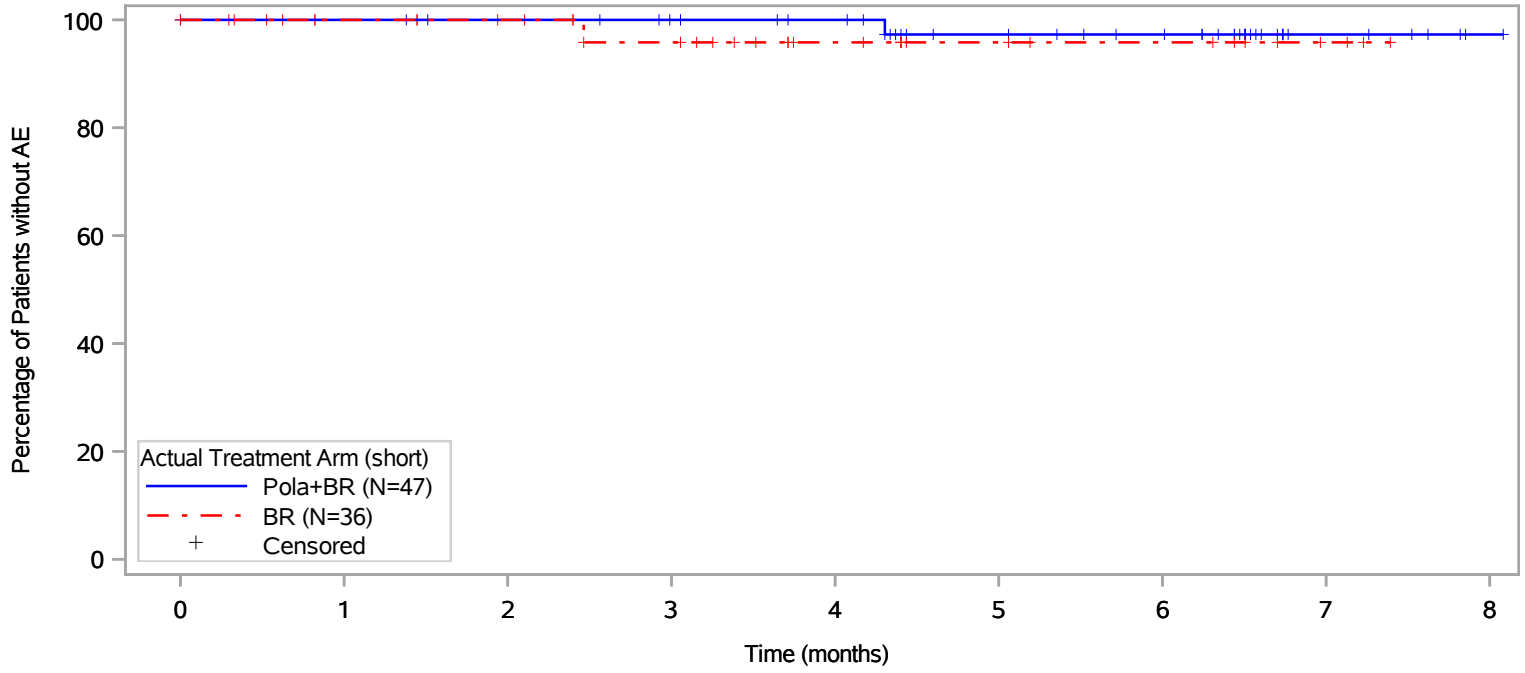
INFECTIONS AND INFESTATIONS, PNEUMONIA PNEUMOCOCCAL



Patients at risk																				
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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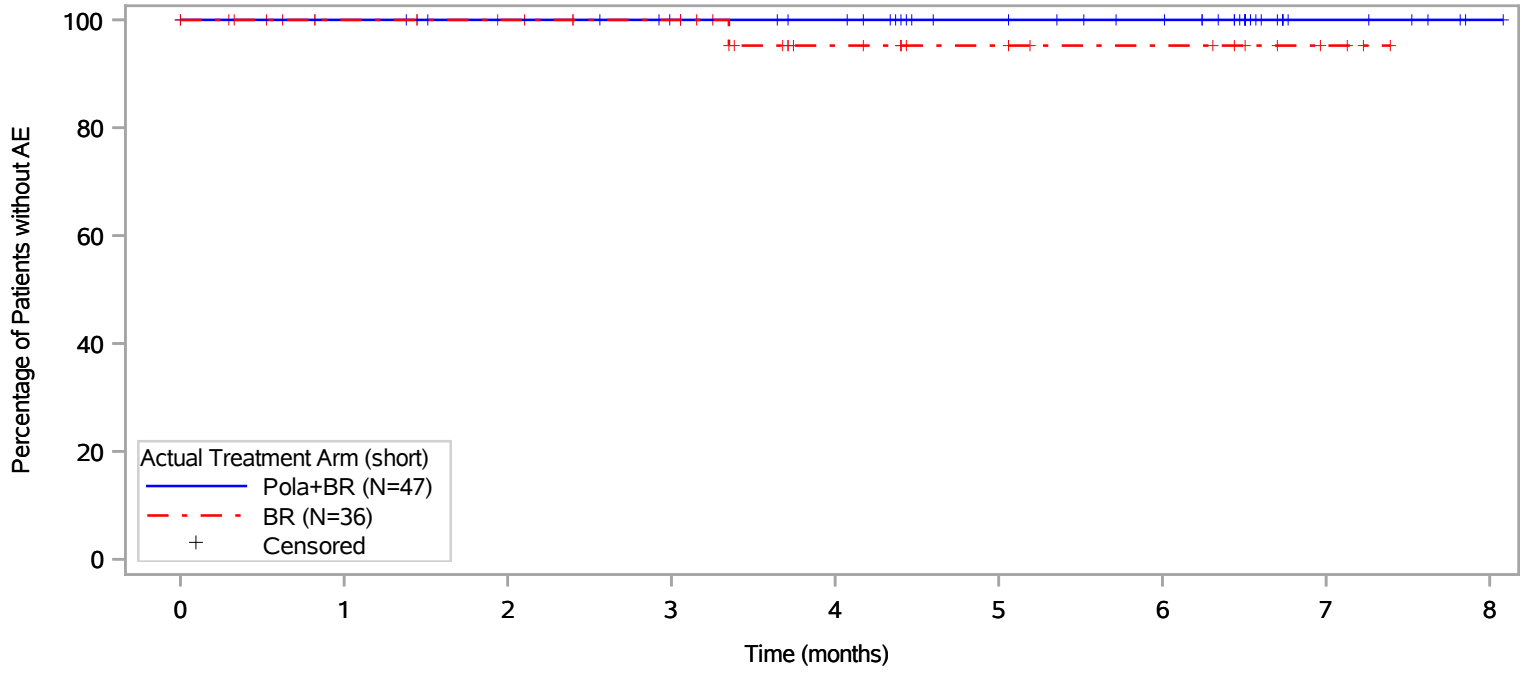
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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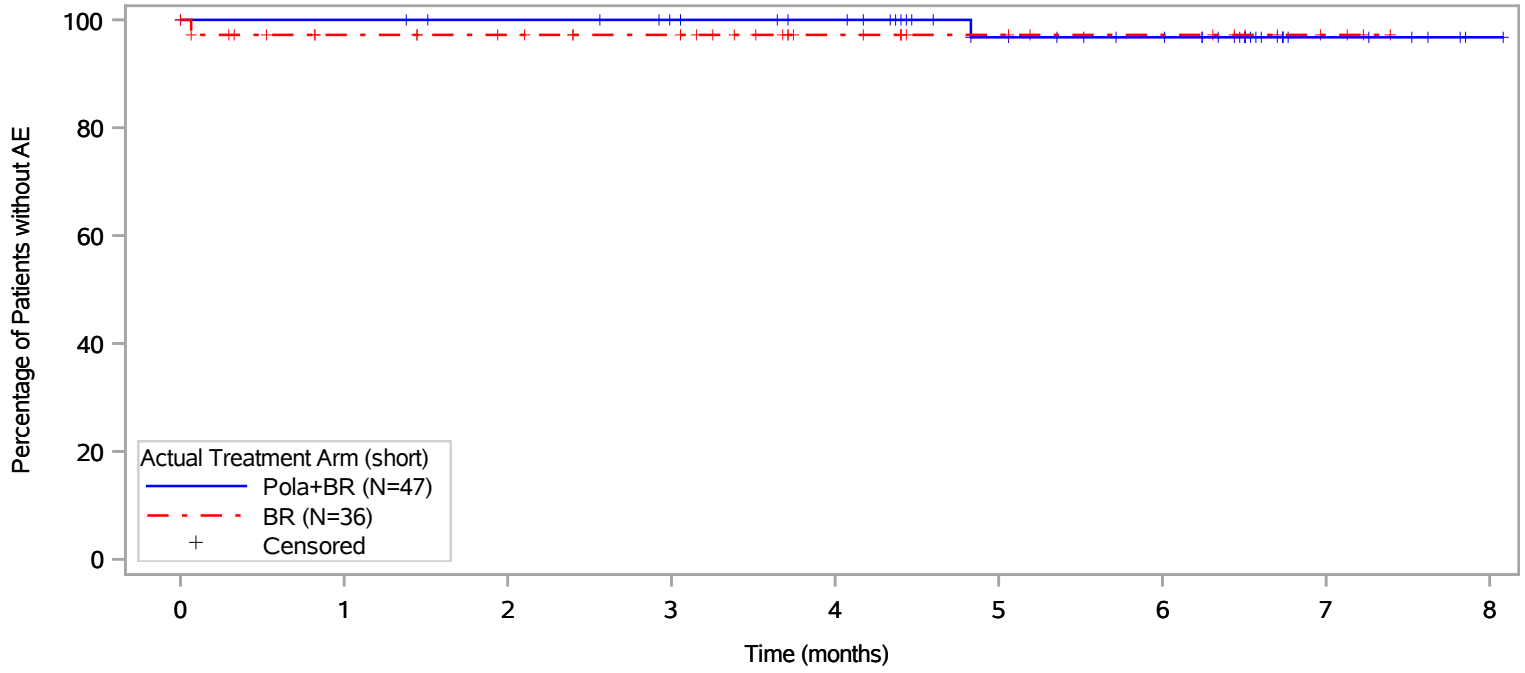
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	5	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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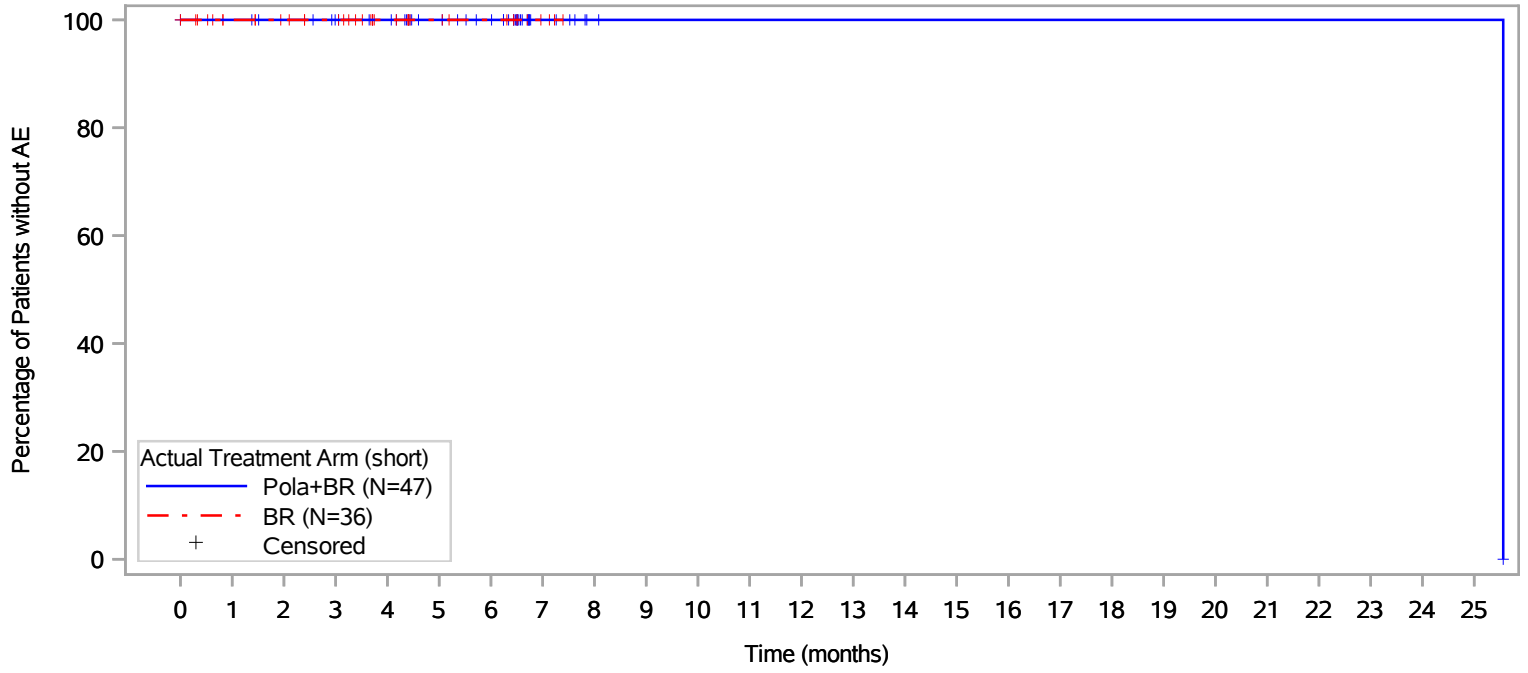
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UROSEPSIS



Patients at risk																										
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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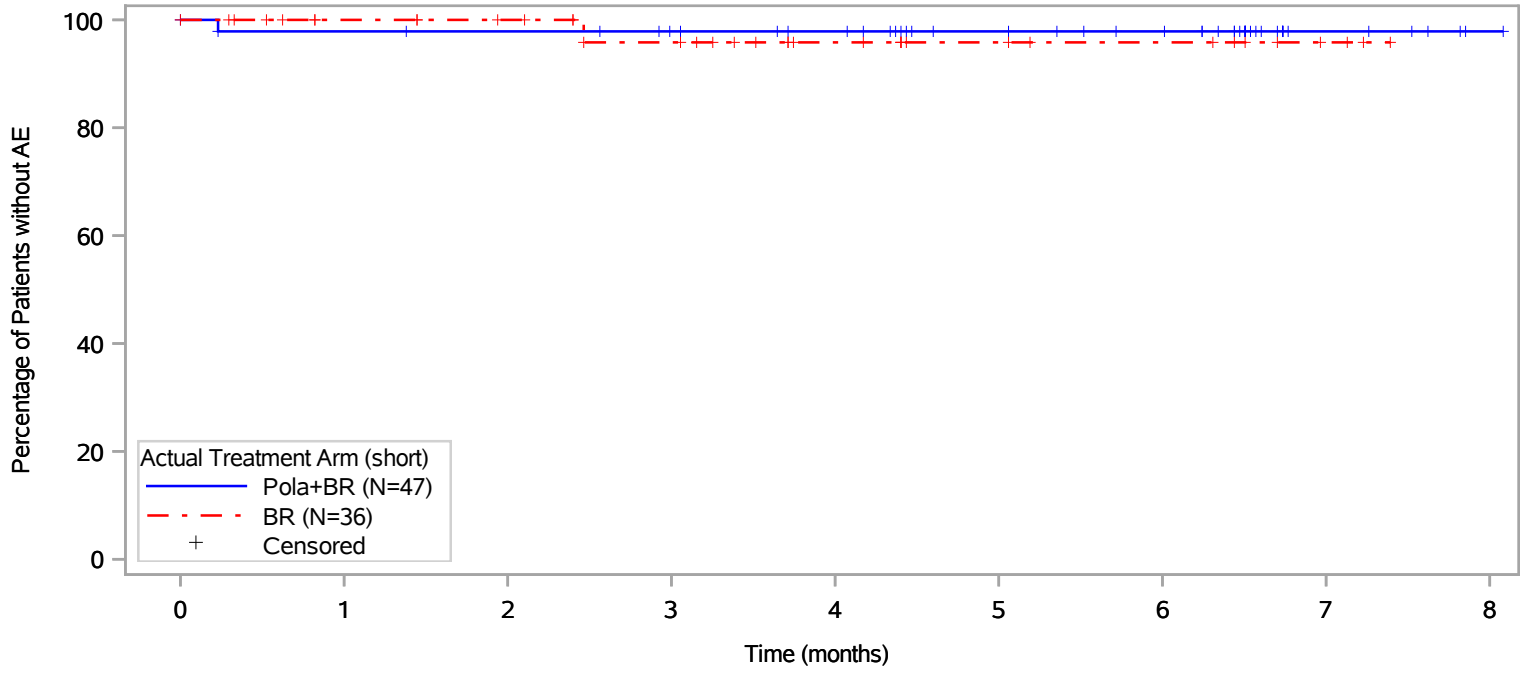
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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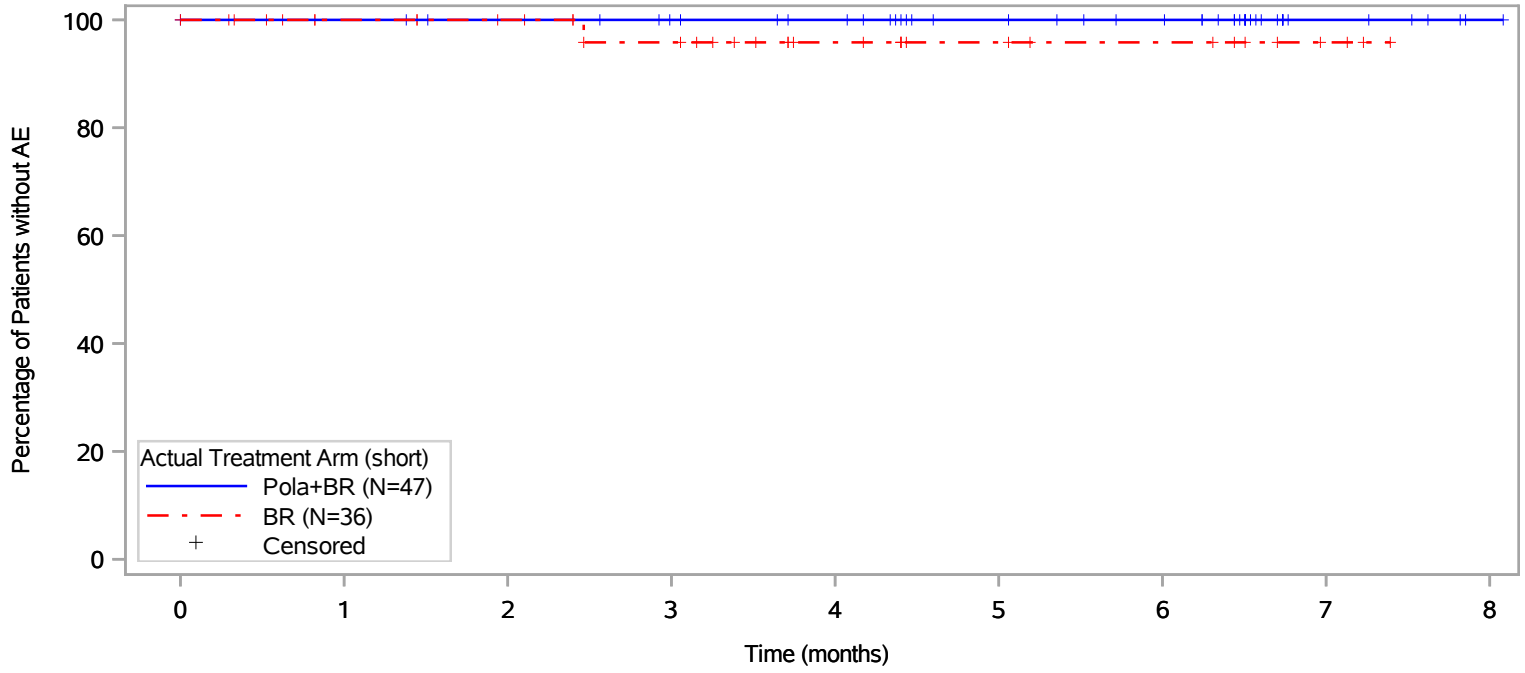
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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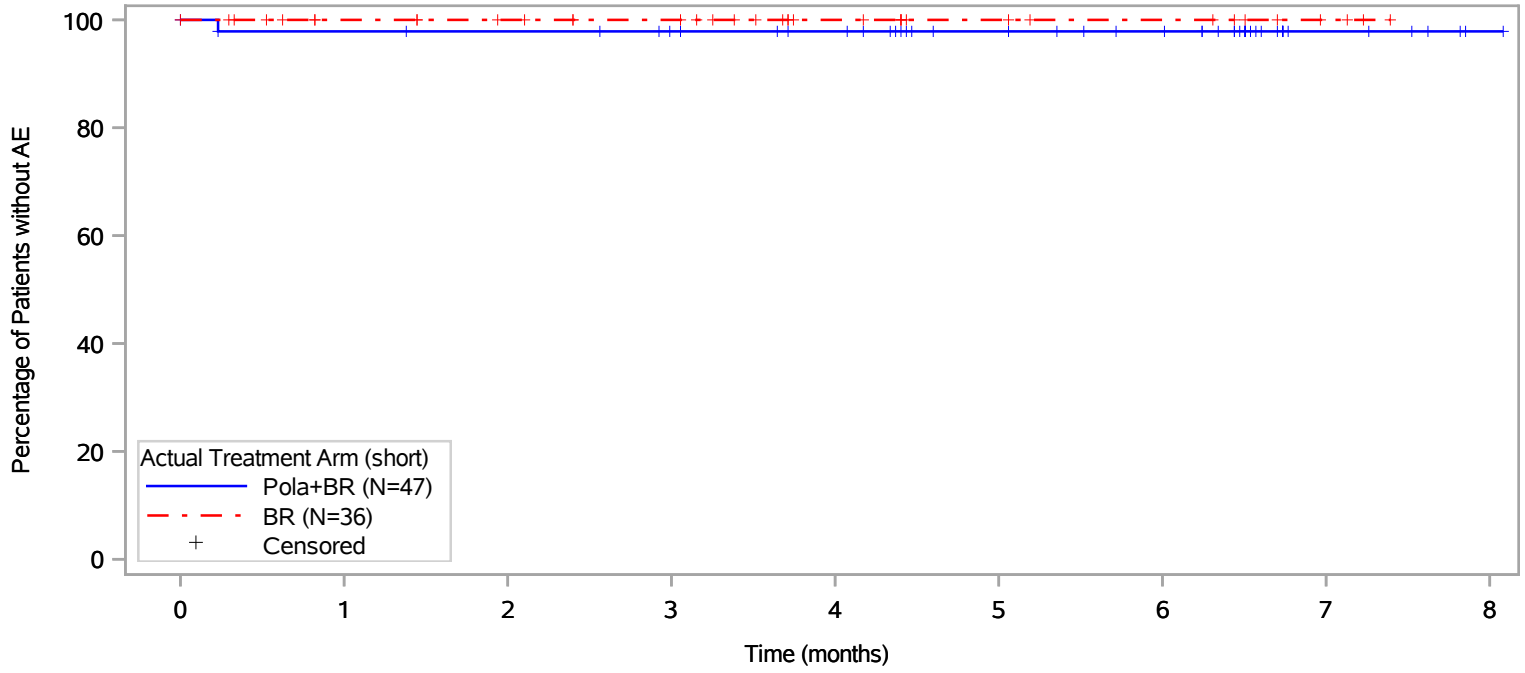
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FEMUR FRACTURE



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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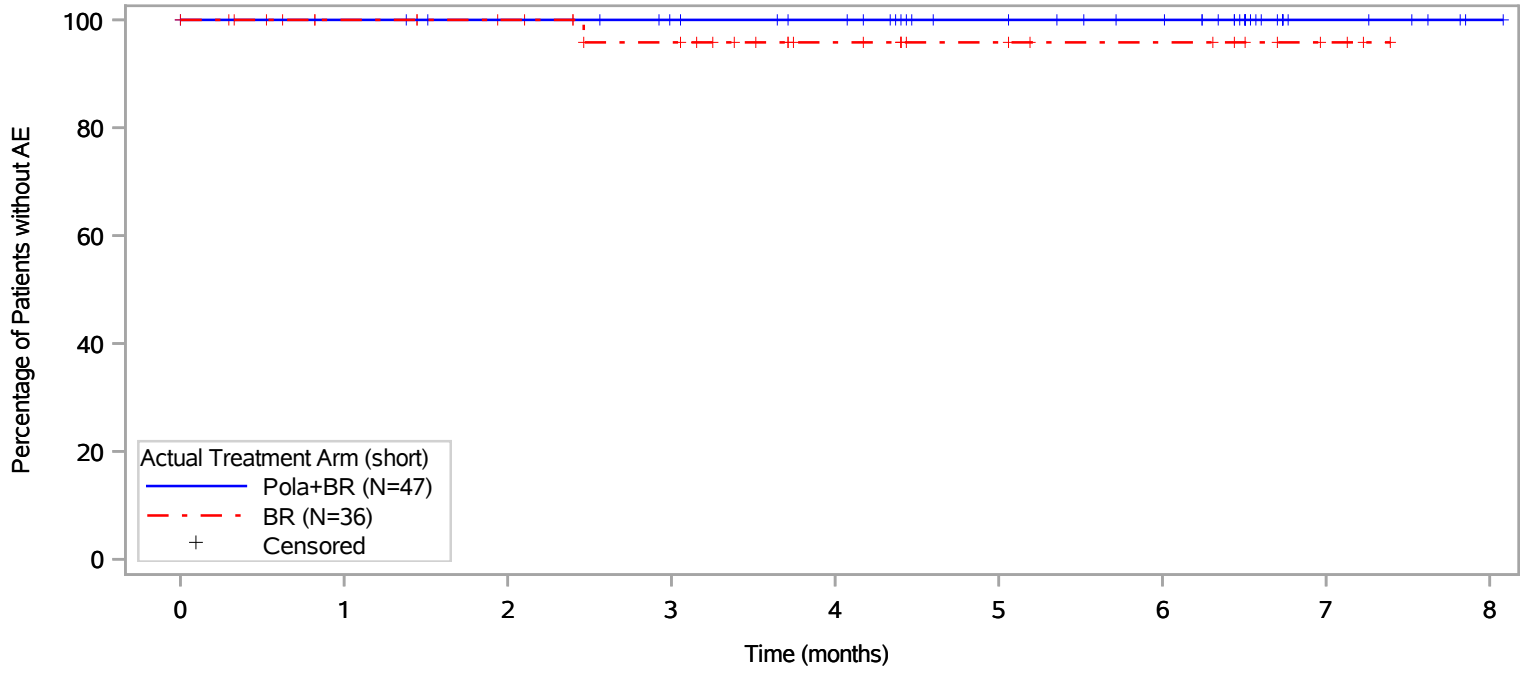
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

INJURY, POISONING AND PROCEDURAL COMPLICATIONS, HEAD INJURY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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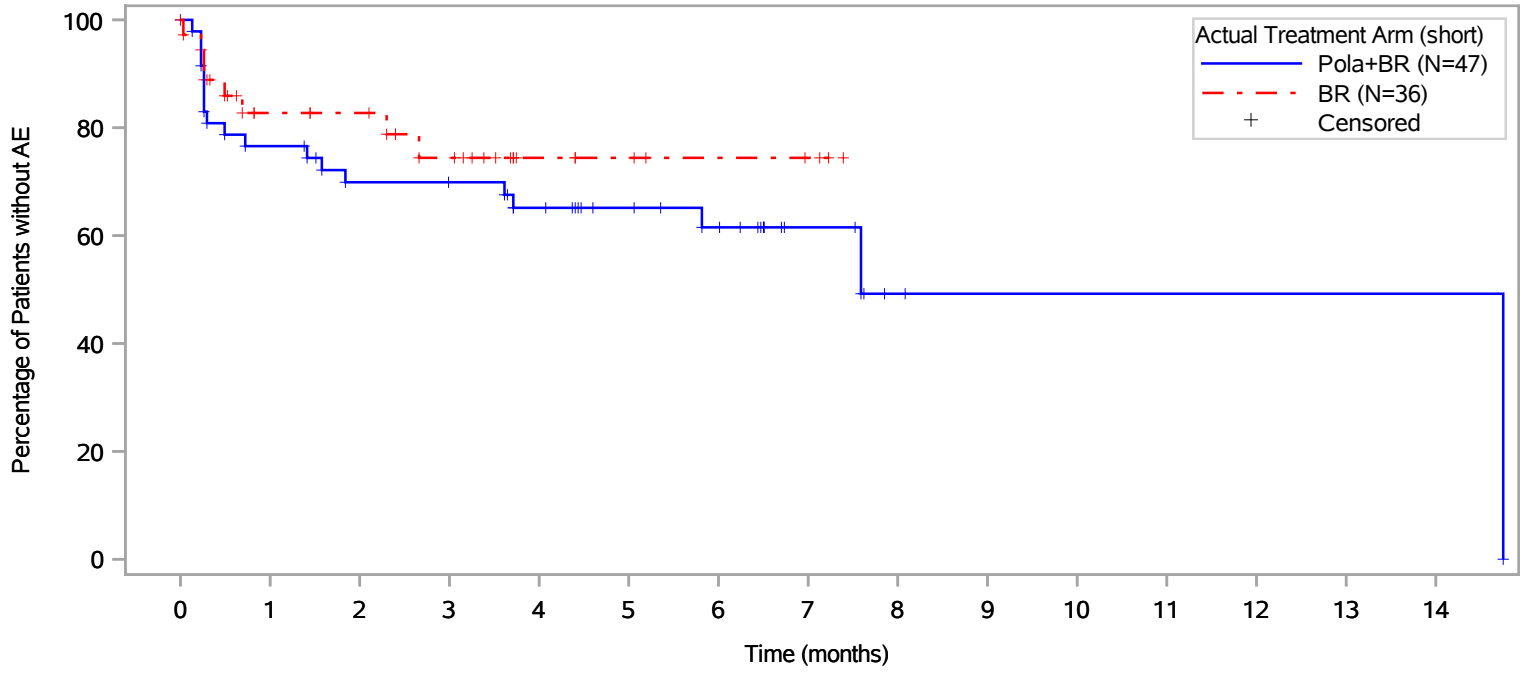
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk															
Pola+BR (N=47)	47	36	31	30	26	20	17	6	2	1	1	1	1	1	1
BR (N=36)	36	24	22	17	8	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	3	5	11	13	24	27	28	28	28	28	28	28
BR (N=36)	0	6	8	11	20	22	24	25	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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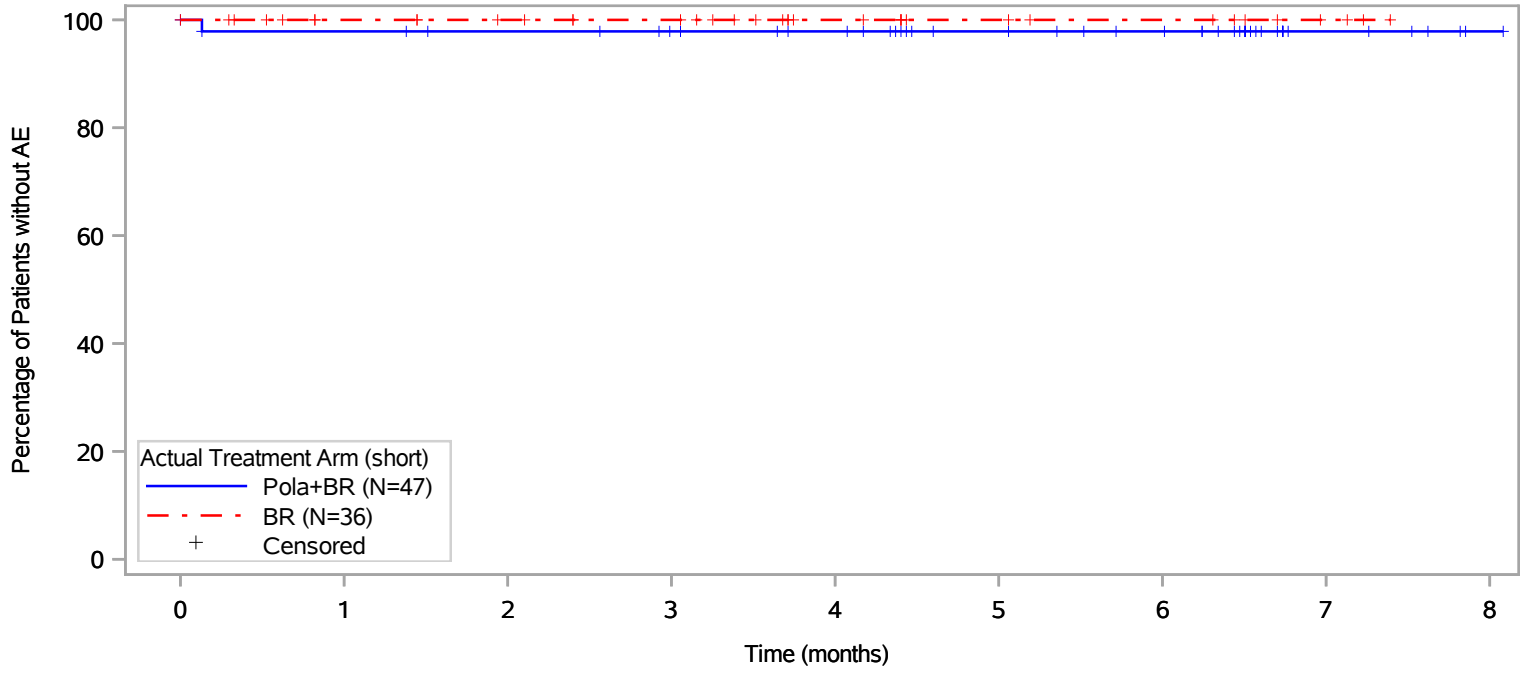
02DEC2022 2:28

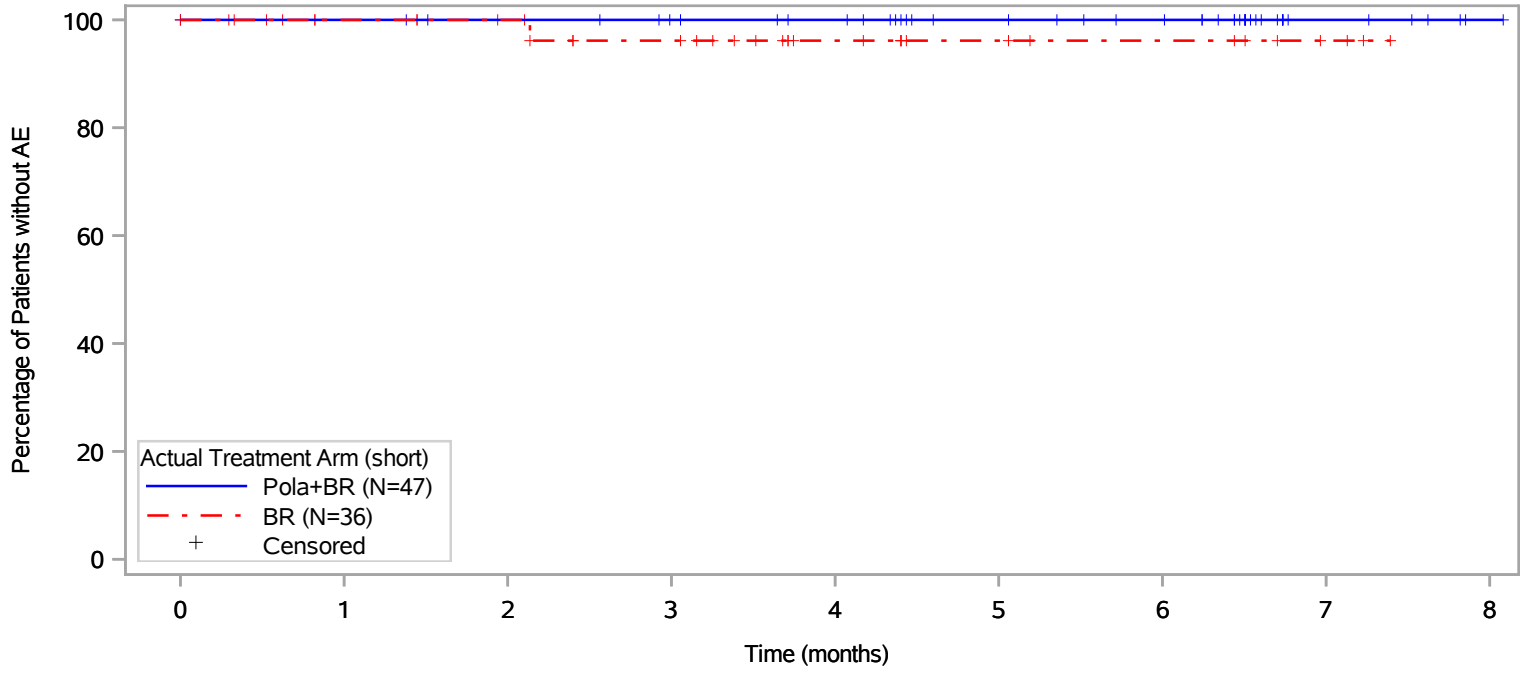
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PRESSURE INCREASED

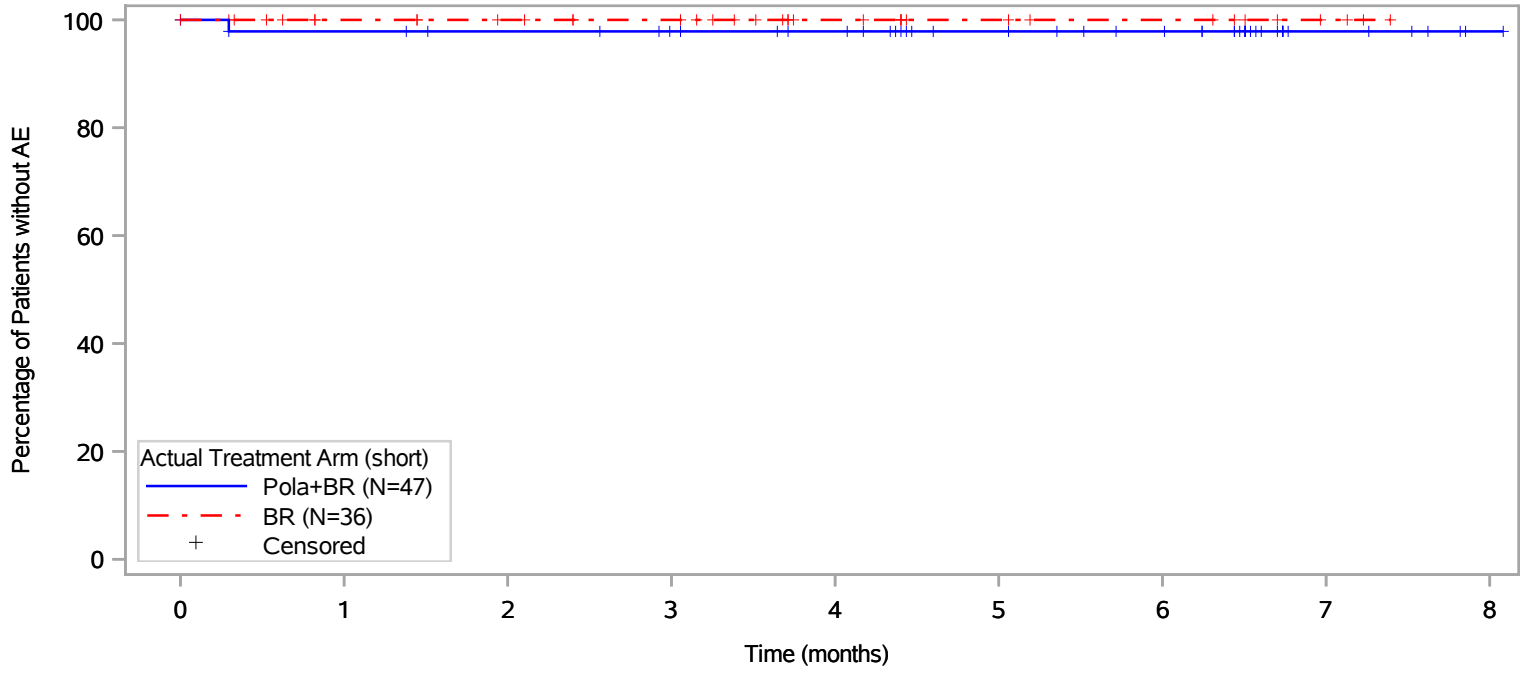


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, FIBRIN D DIMER INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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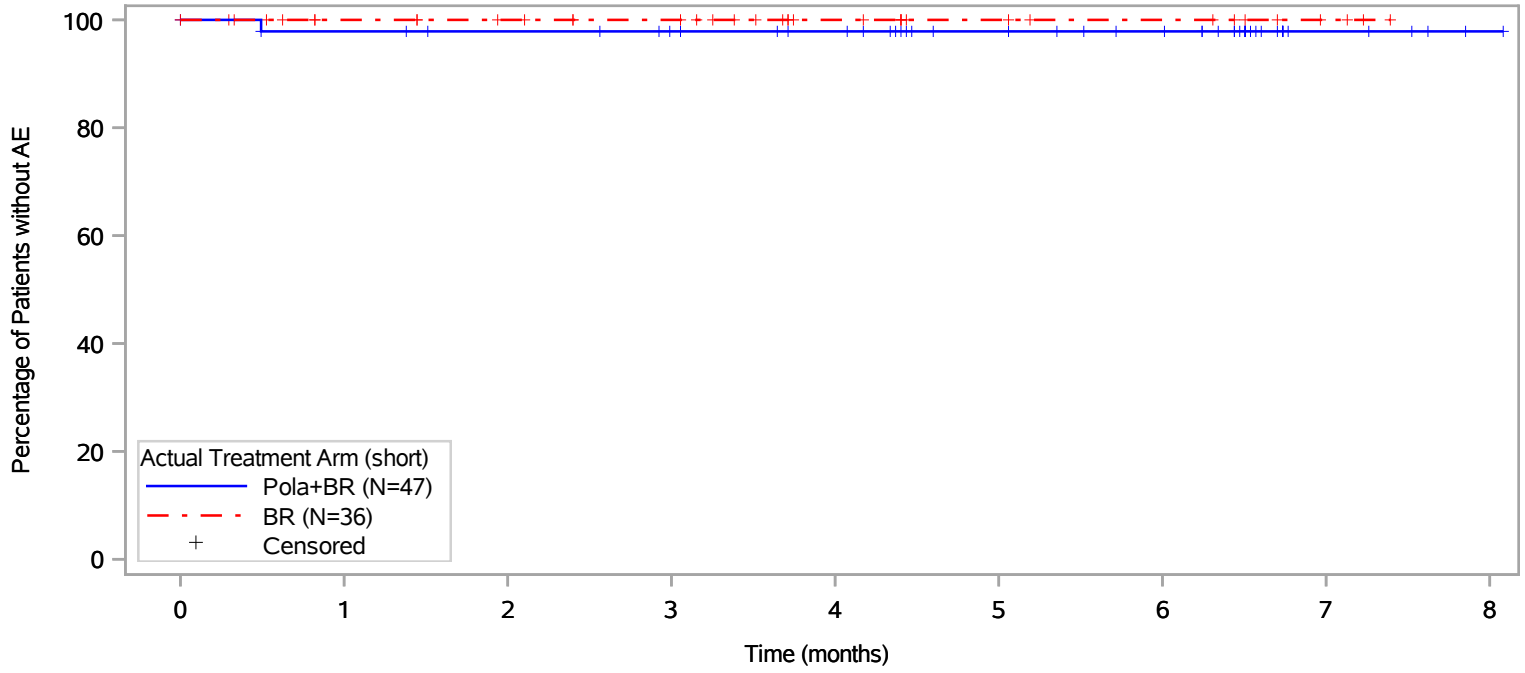
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GAMMA-GLUTAMYLTRANSFERASE INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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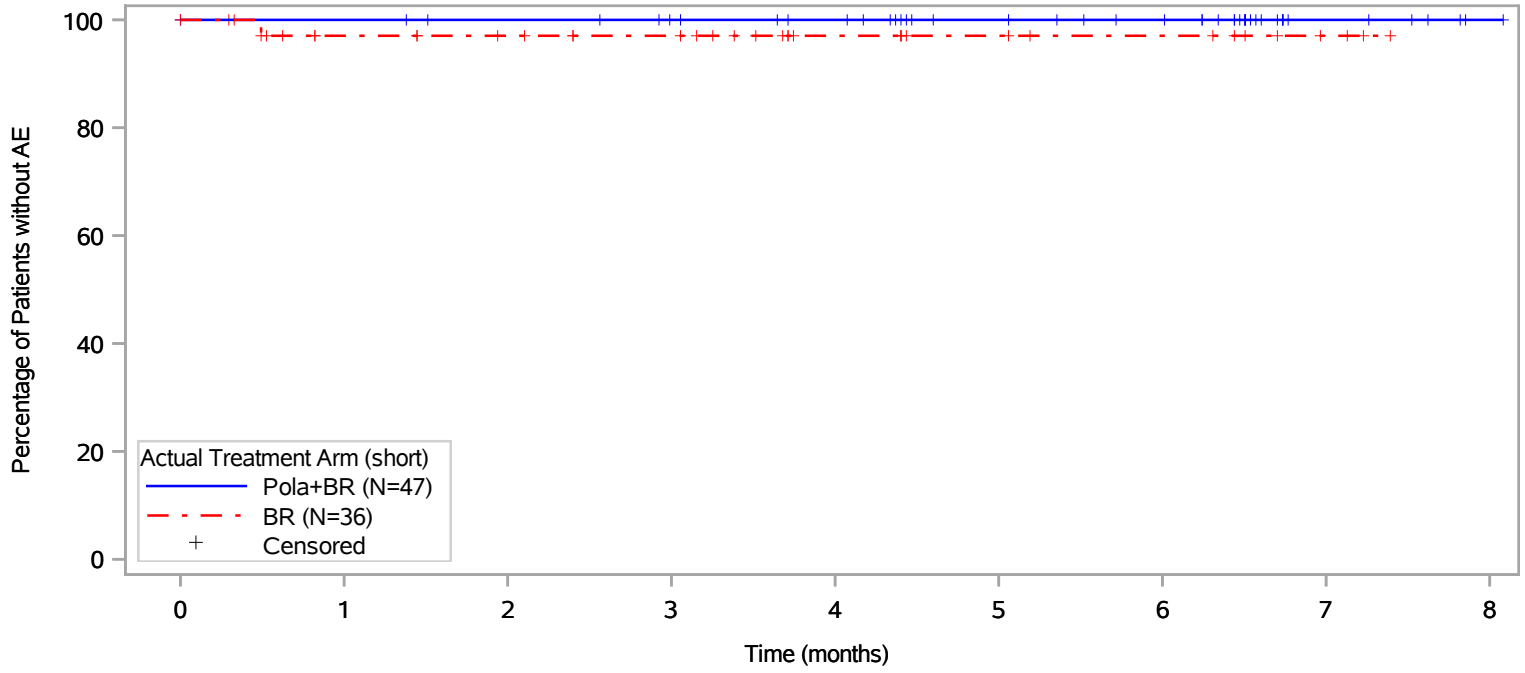
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, HAEMOGLOBIN DECREASED

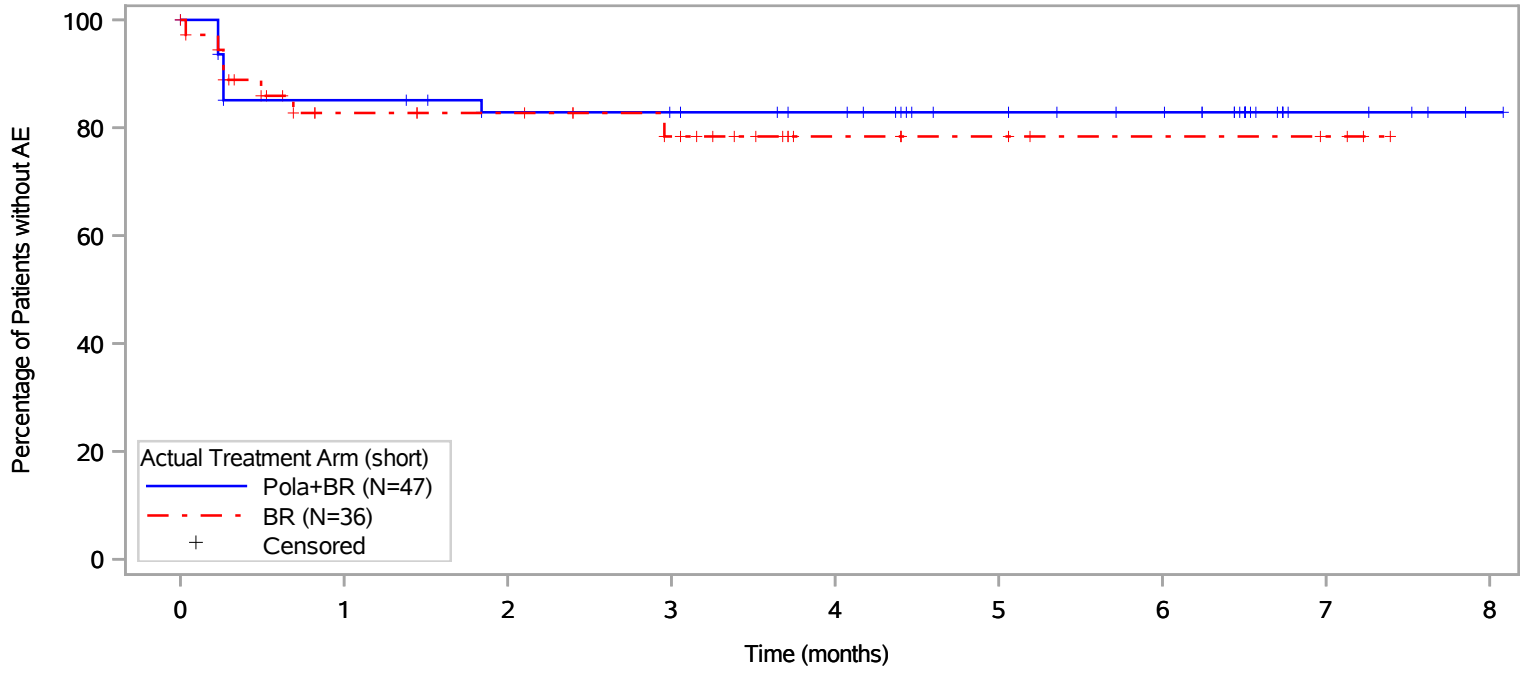


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:28

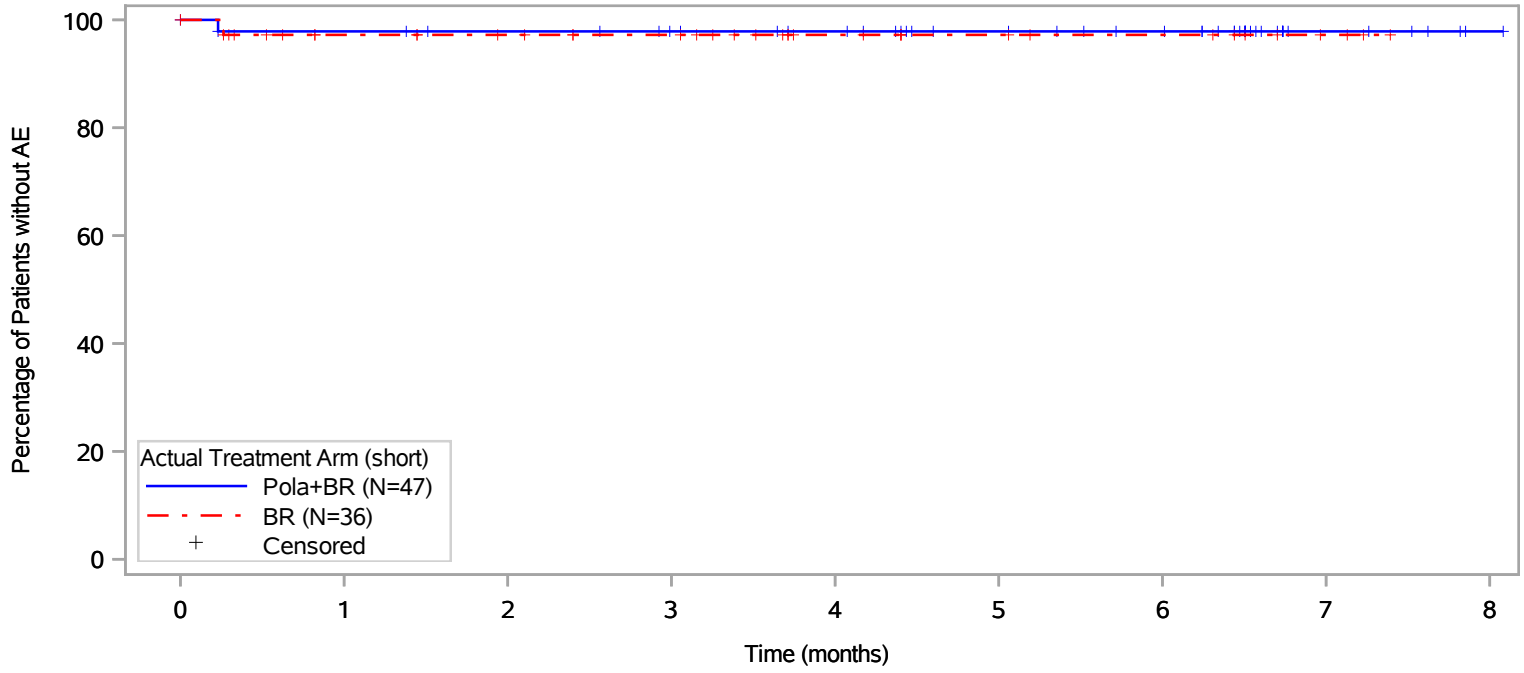
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	40	37	36	33	26	23	5	1
BR (N=36)	36	24	22	18	9	6	4	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	3	6	13	16	34	38
BR (N=36)	0	6	8	11	20	23	25	26	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE PERCENTAGE DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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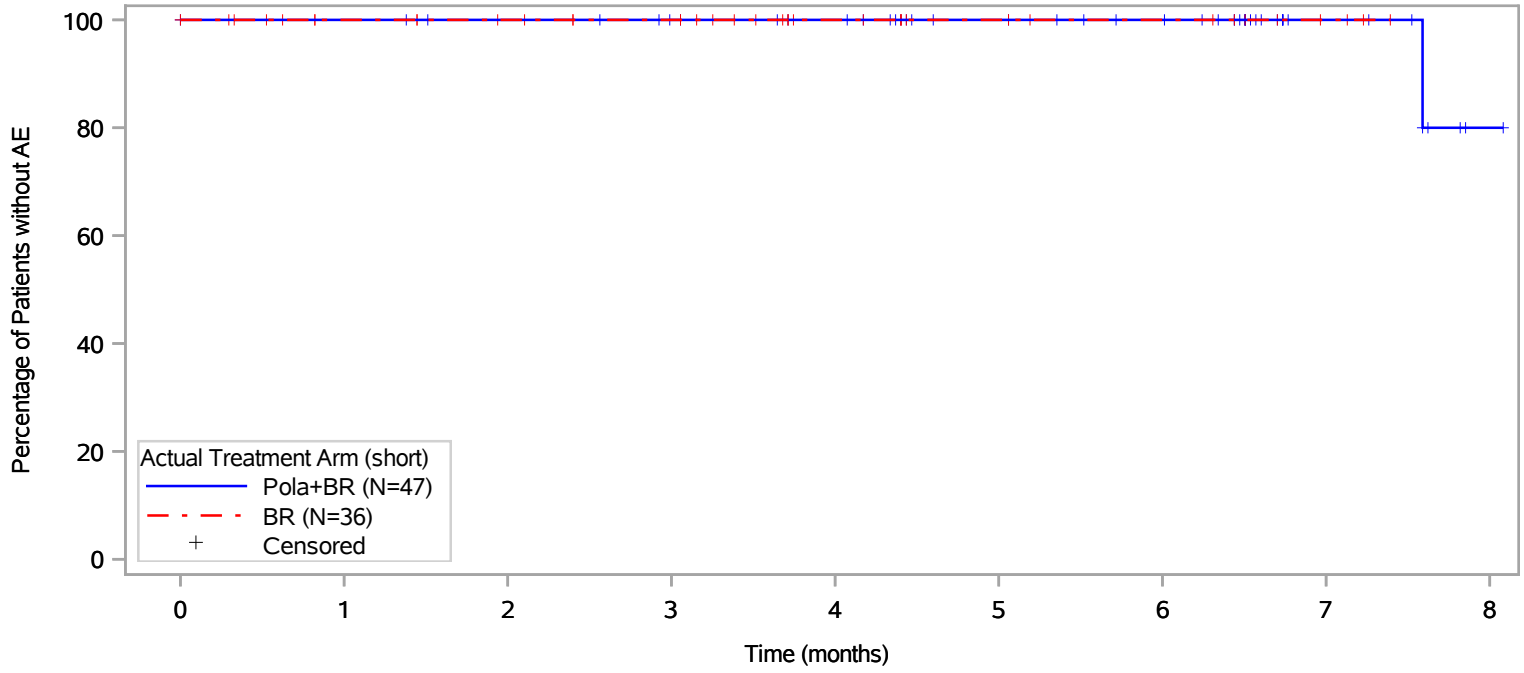
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MORAXELLA TEST POSITIVE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	7	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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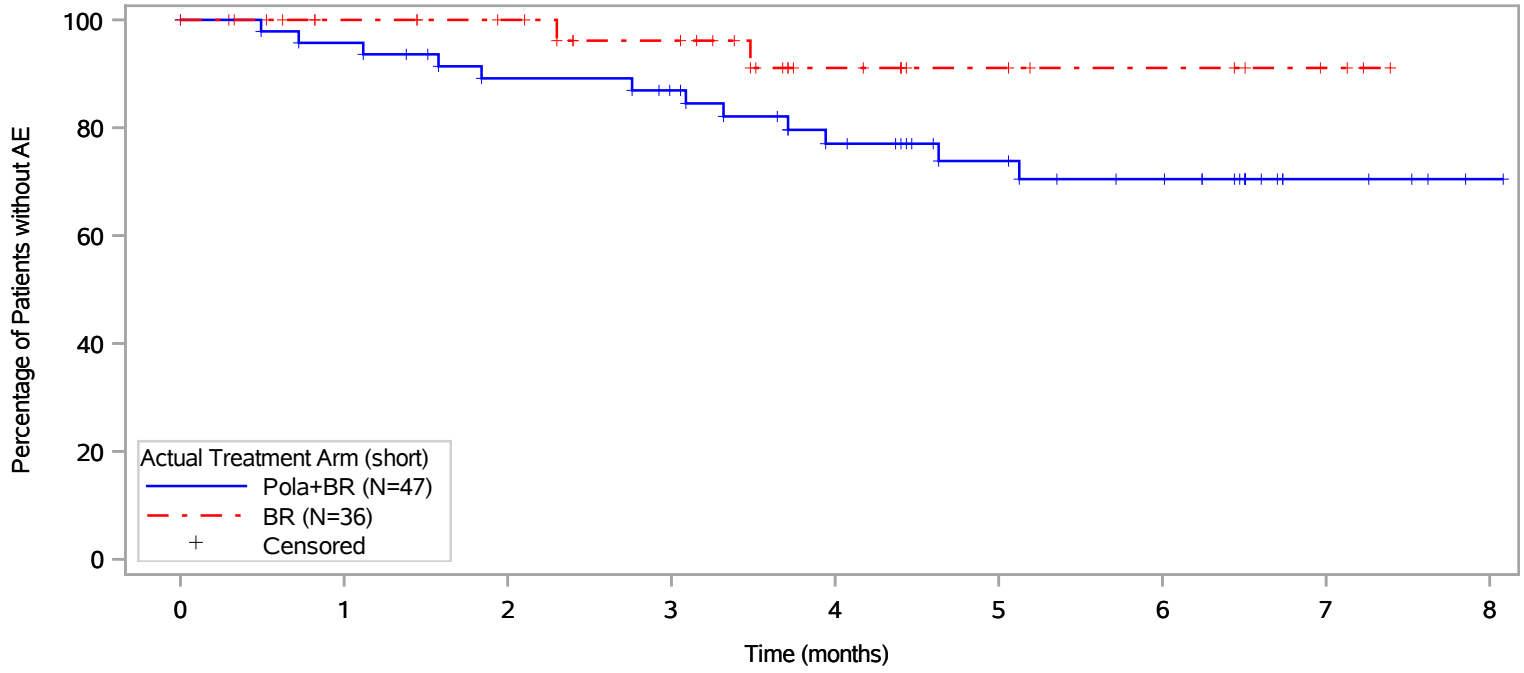
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	45	40	37	30	23	19	5	1
BR (N=36)	36	30	27	23	13	8	6	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	13	16	30	34
BR (N=36)	0	6	9	12	21	26	28	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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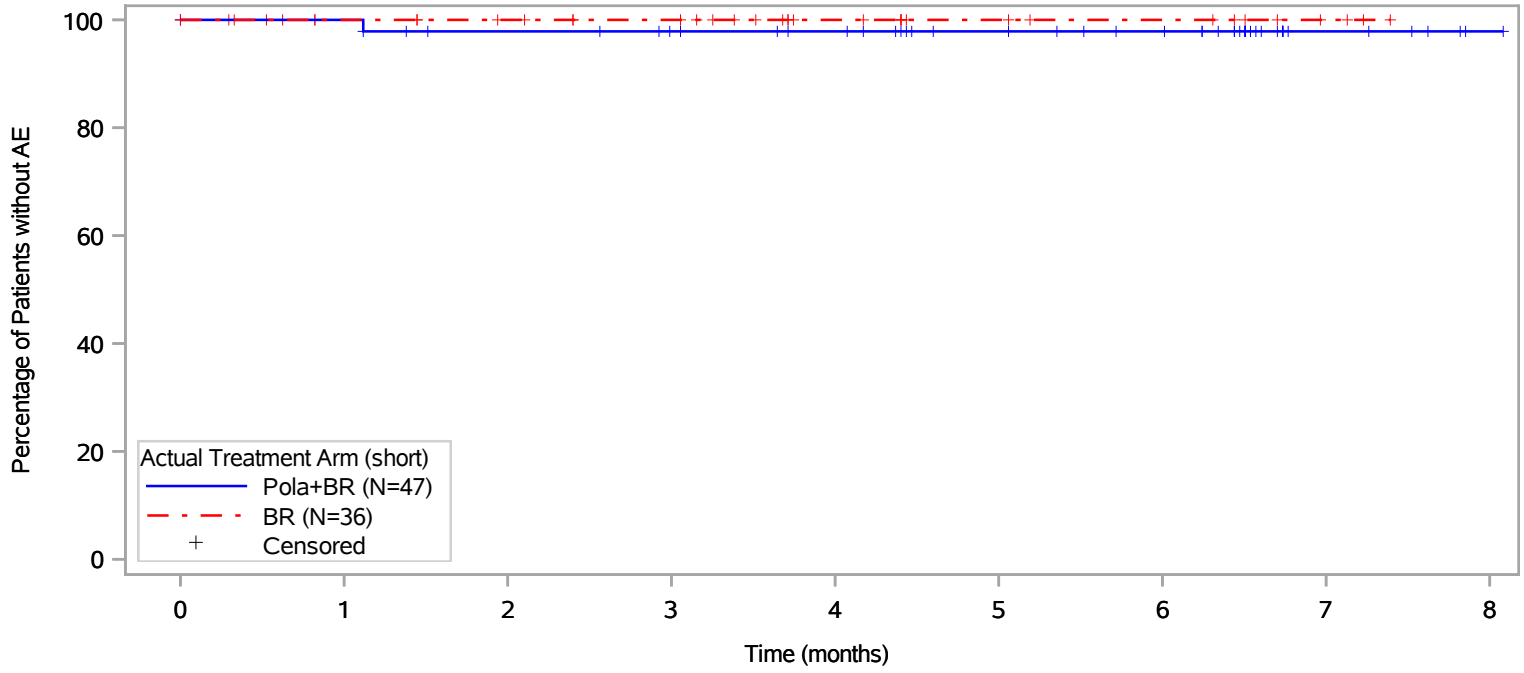
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL PERCENTAGE DECREASED

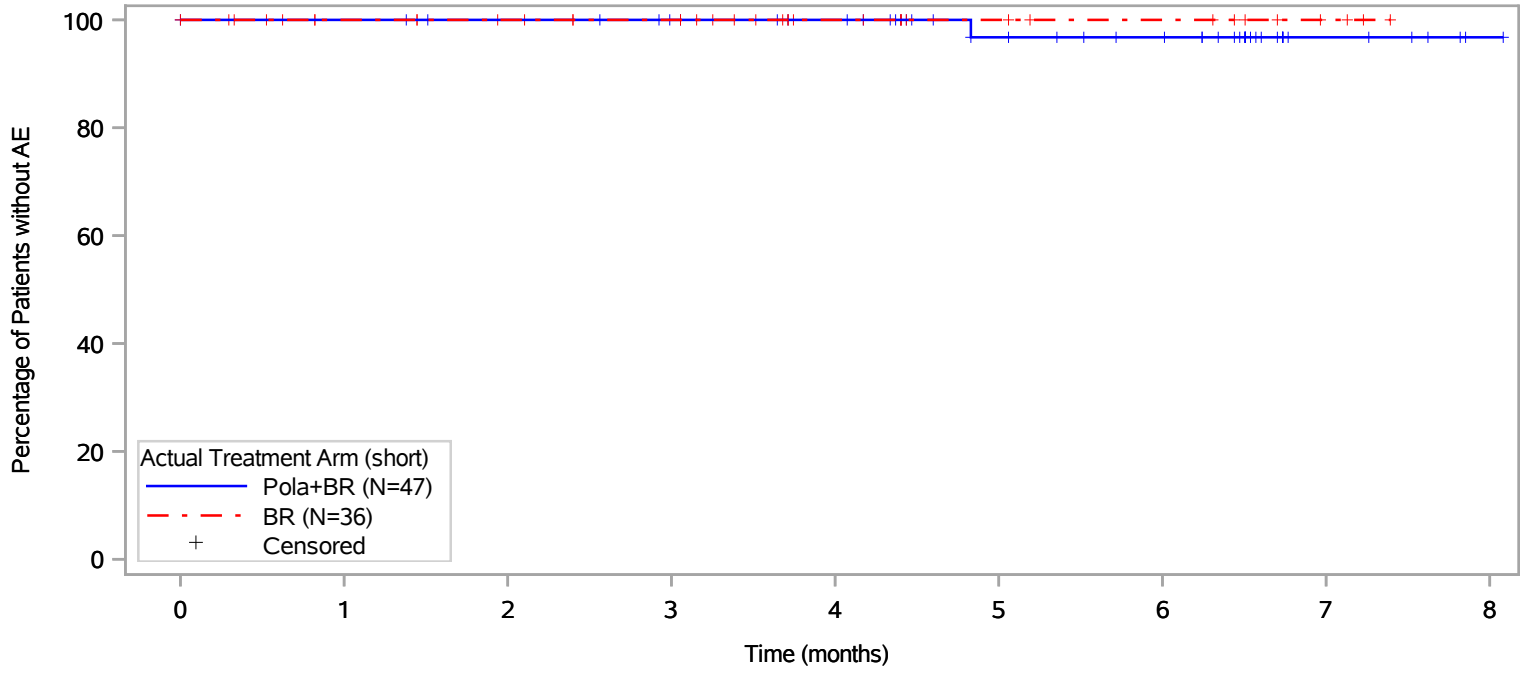


Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NITRITE URINE PRESENT

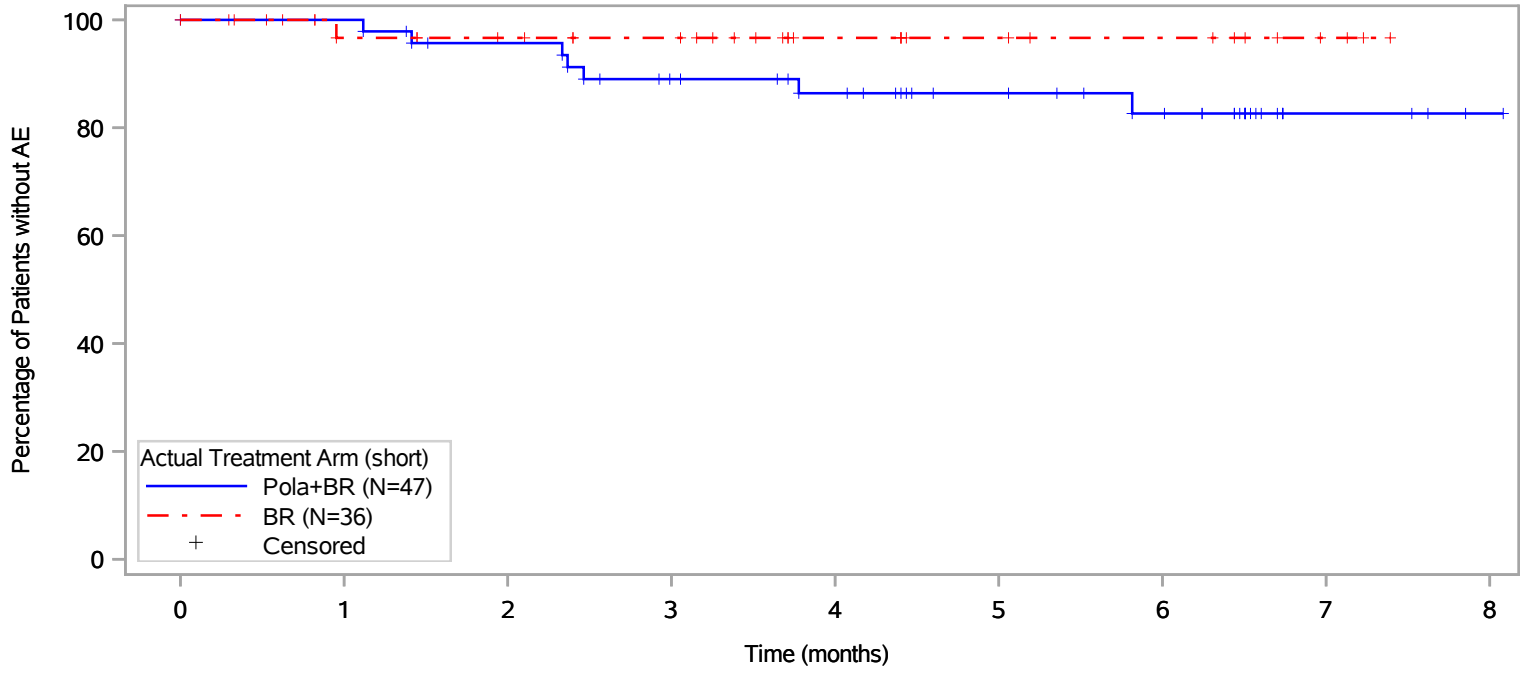


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

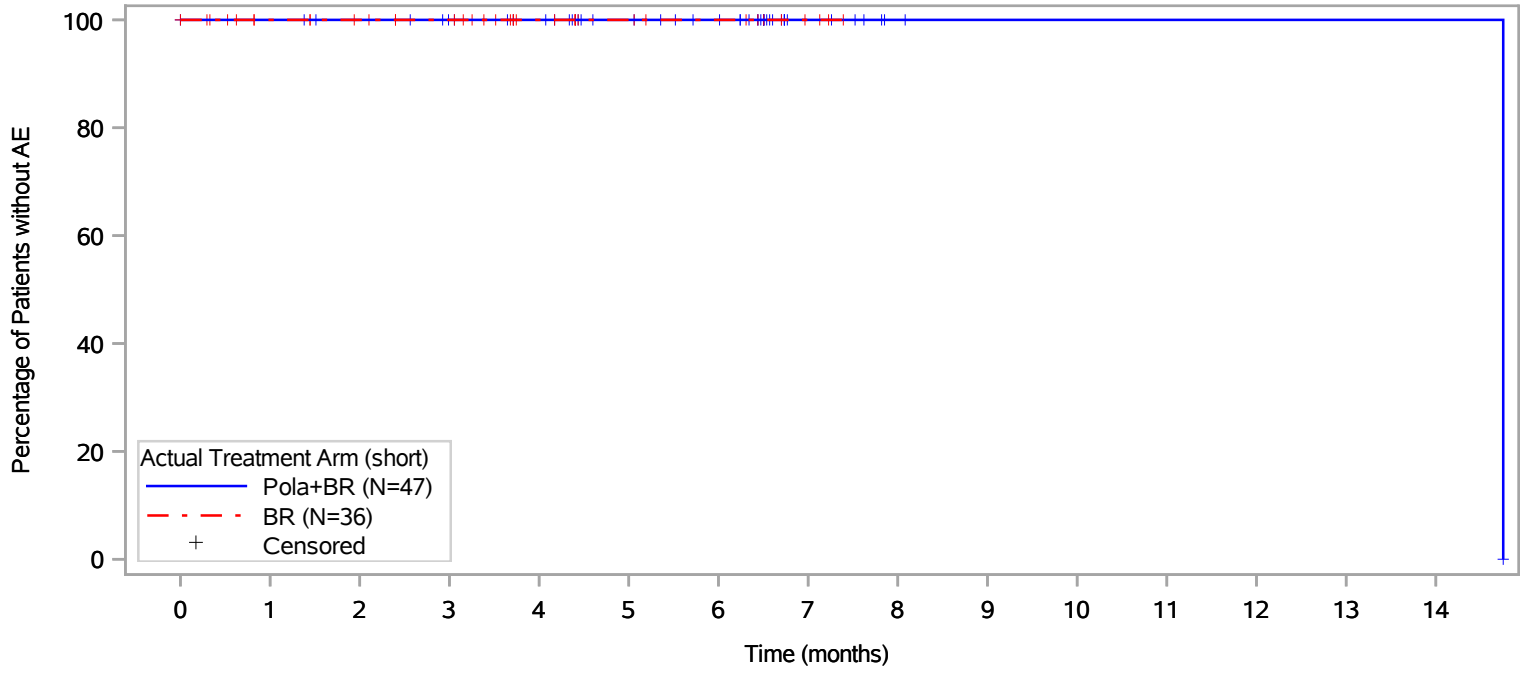


Patients at risk									
Pola+BR (N=47)	47	47	43	37	33	26	22	4	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	18	36	39
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, TRANSAMINASES INCREASED



Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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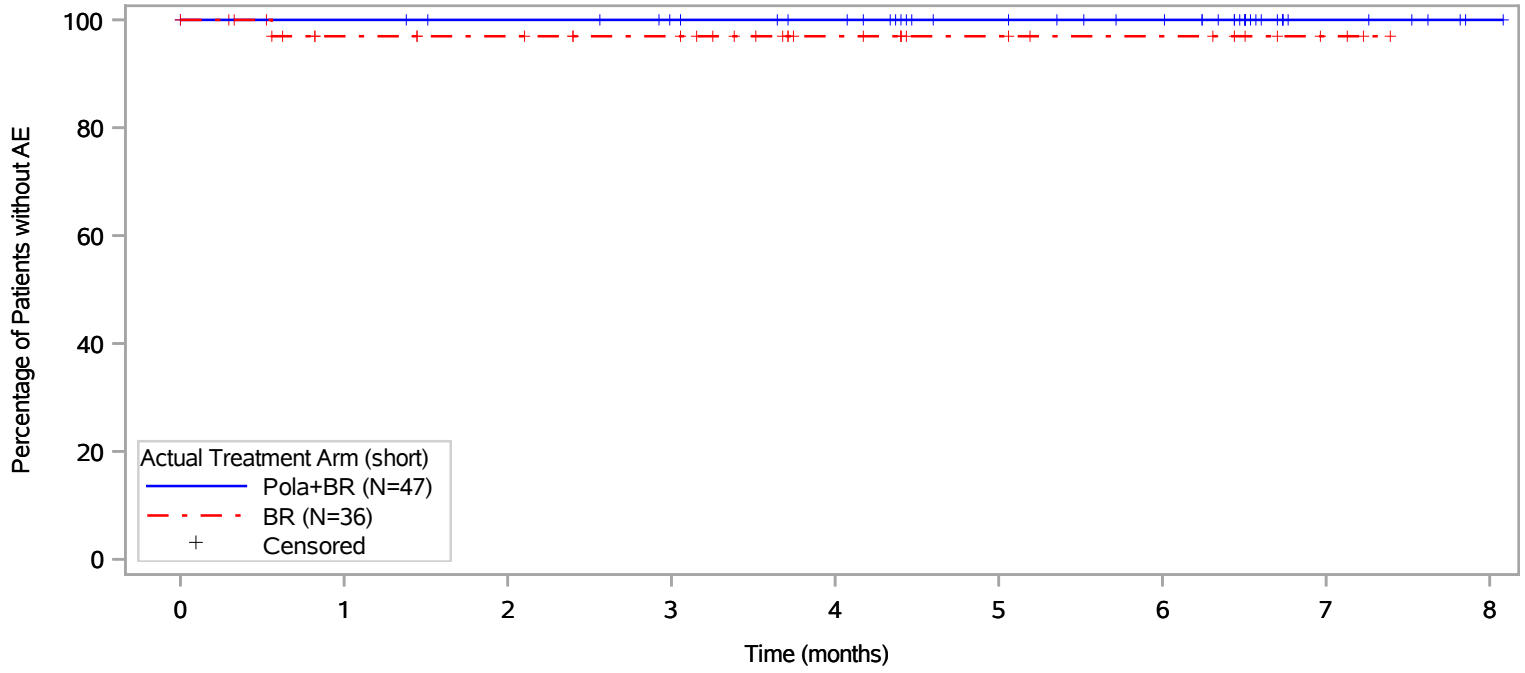
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, URINE OUTPUT DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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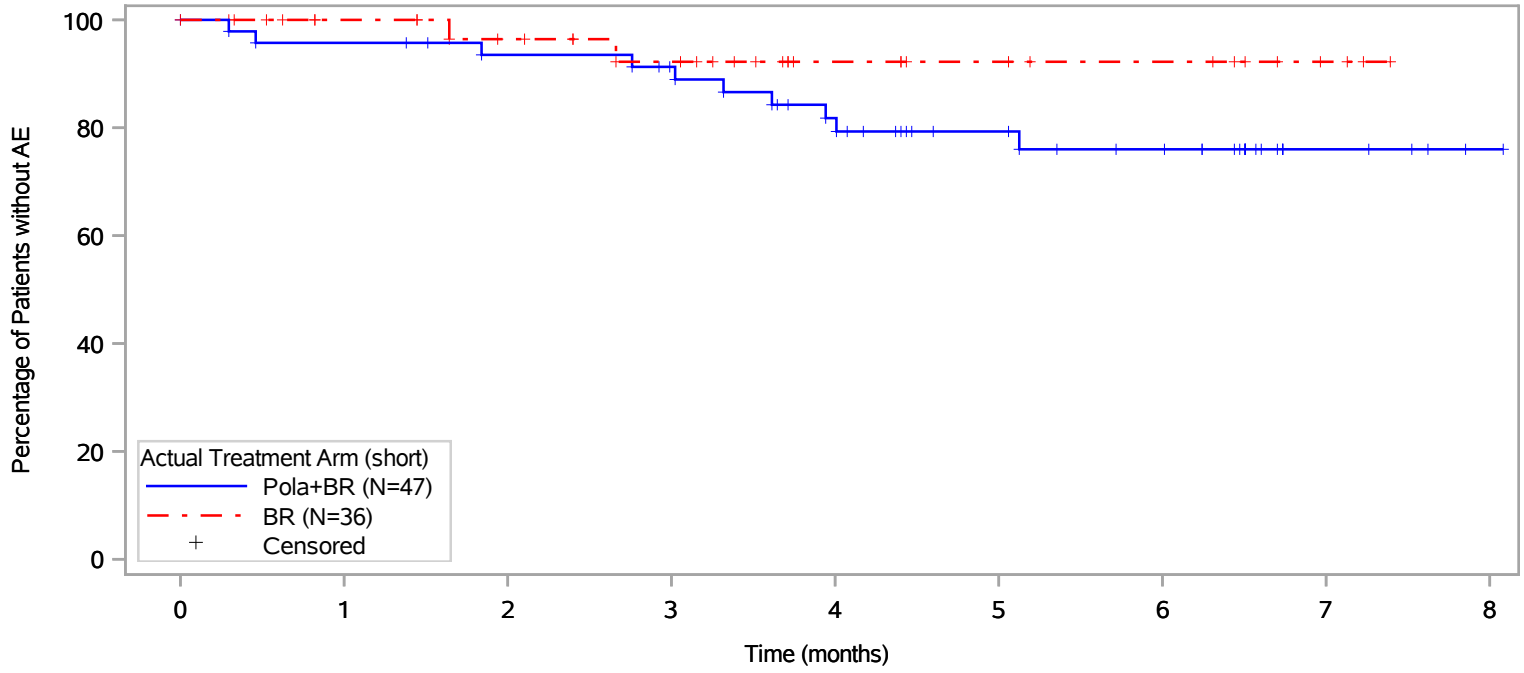
02DEC2022 2:28

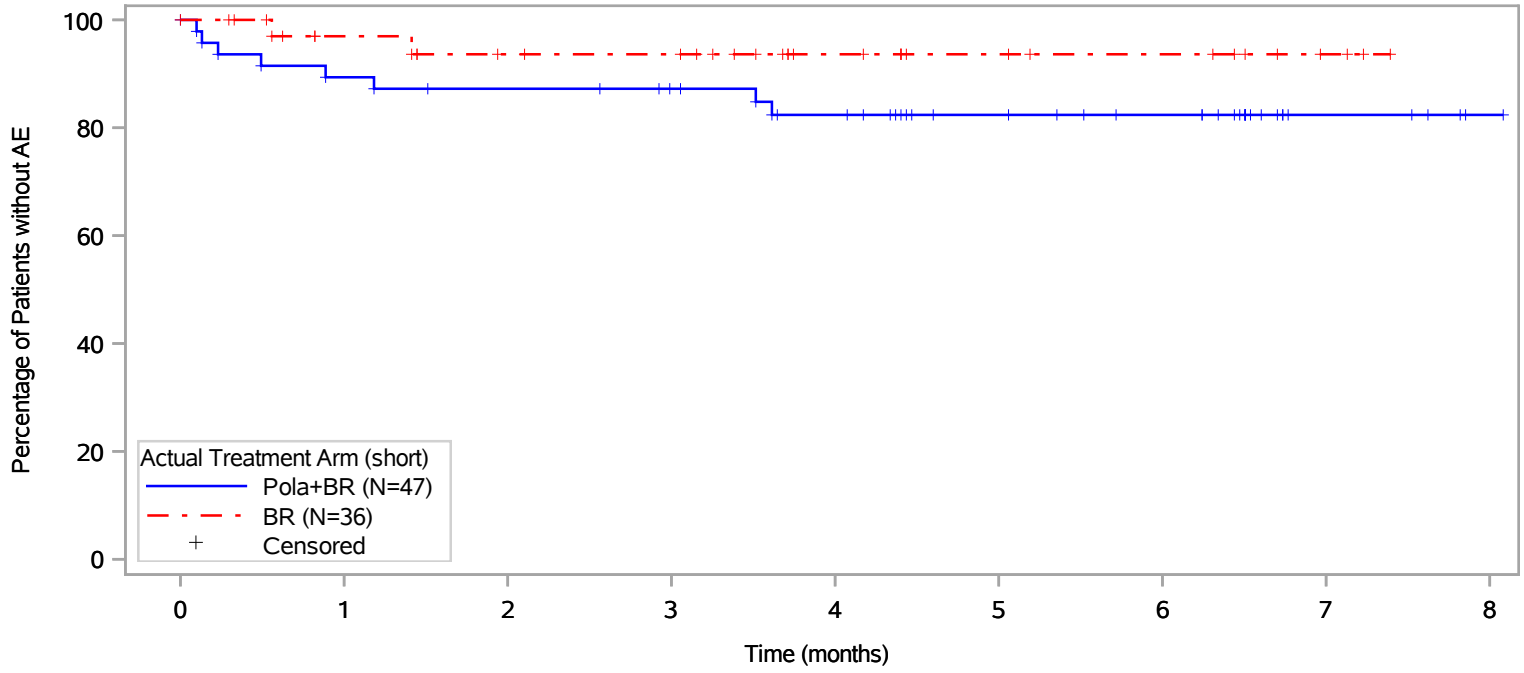
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	45	42	39	33	25	21	5	1
BR (N=36)	36	30	26	22	13	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	6	13	16	32	36
BR (N=36)	0	6	9	12	21	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	42	40	37	33	25	21	5	1
BR (N=36)	36	29	25	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	6	14	18	34	38
BR (N=36)	0	6	9	10	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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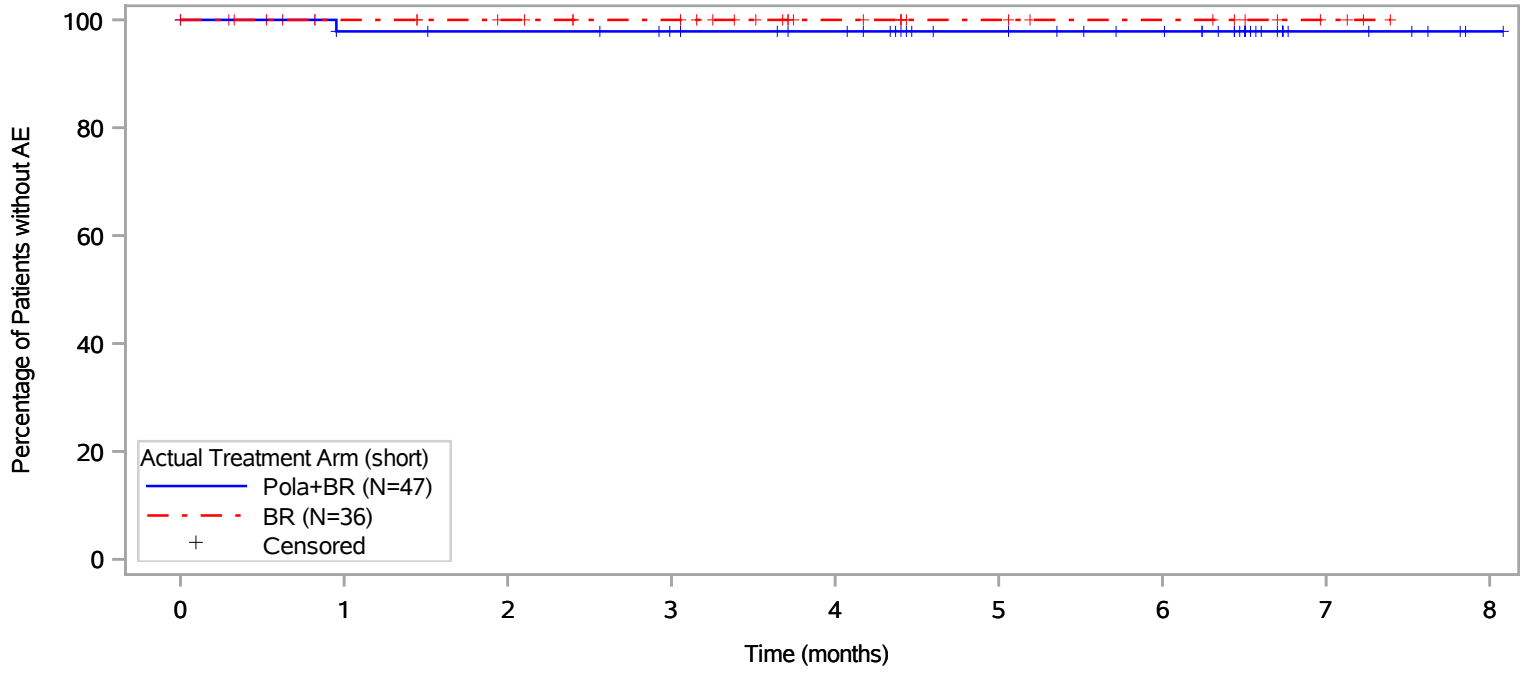
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOCALCAEMIA



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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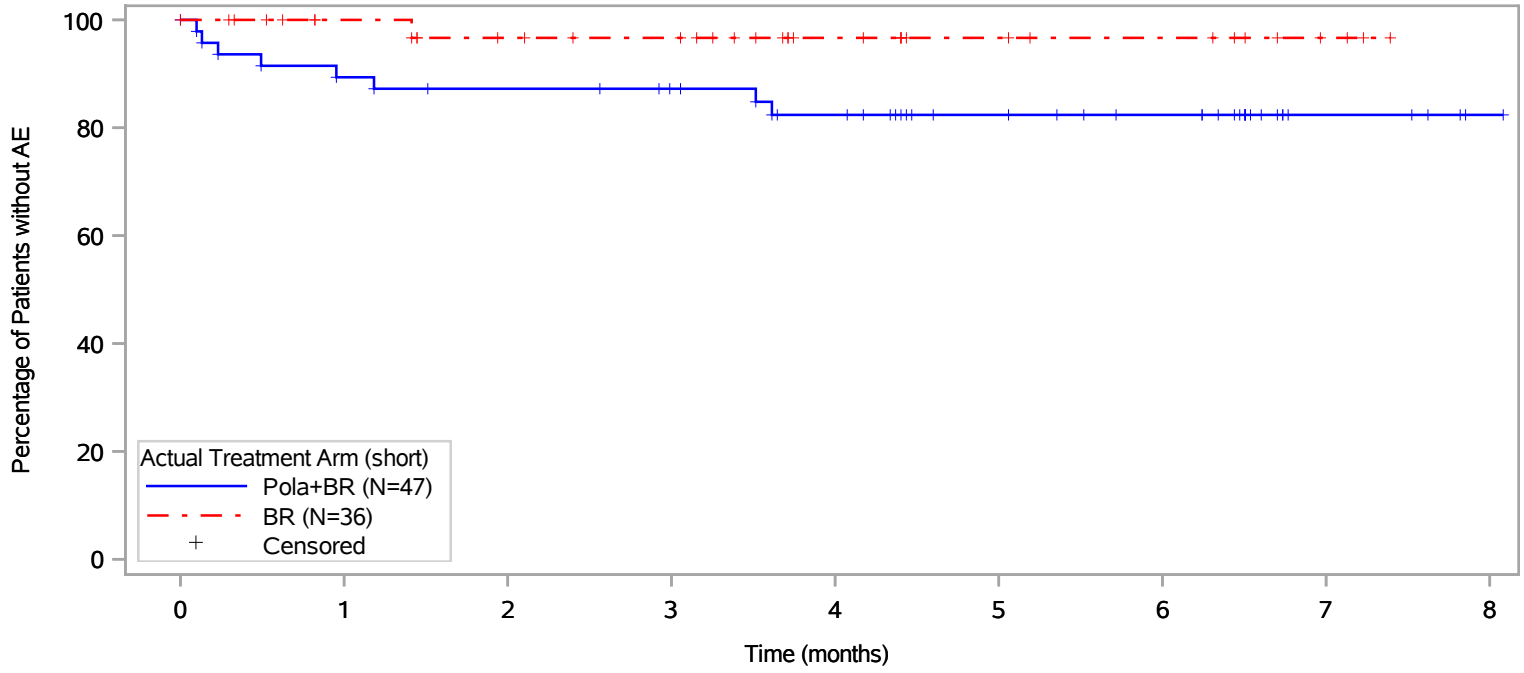
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA

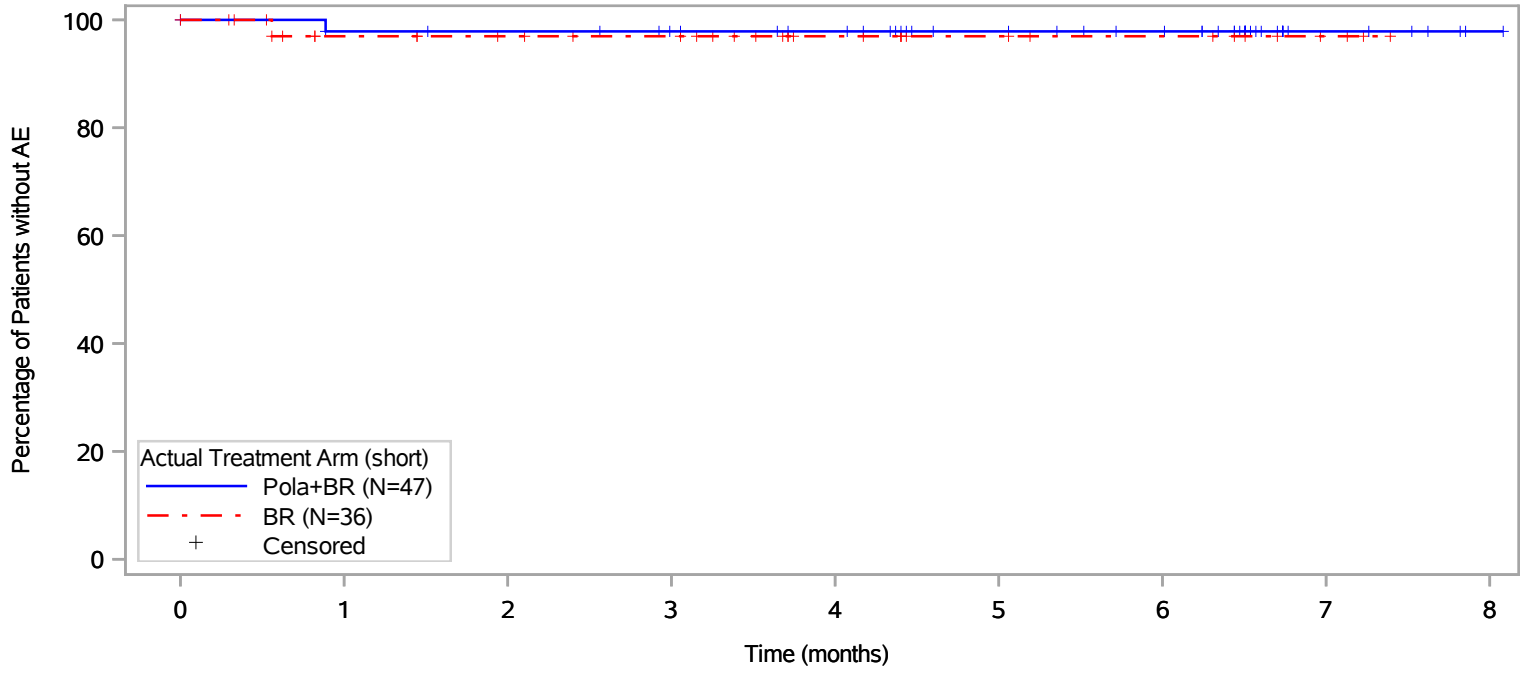


Patients at risk									
Pola+BR (N=47)	47	42	40	37	33	25	21	5	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	6	14	18	34	38
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOPHOSPHATAEMIA

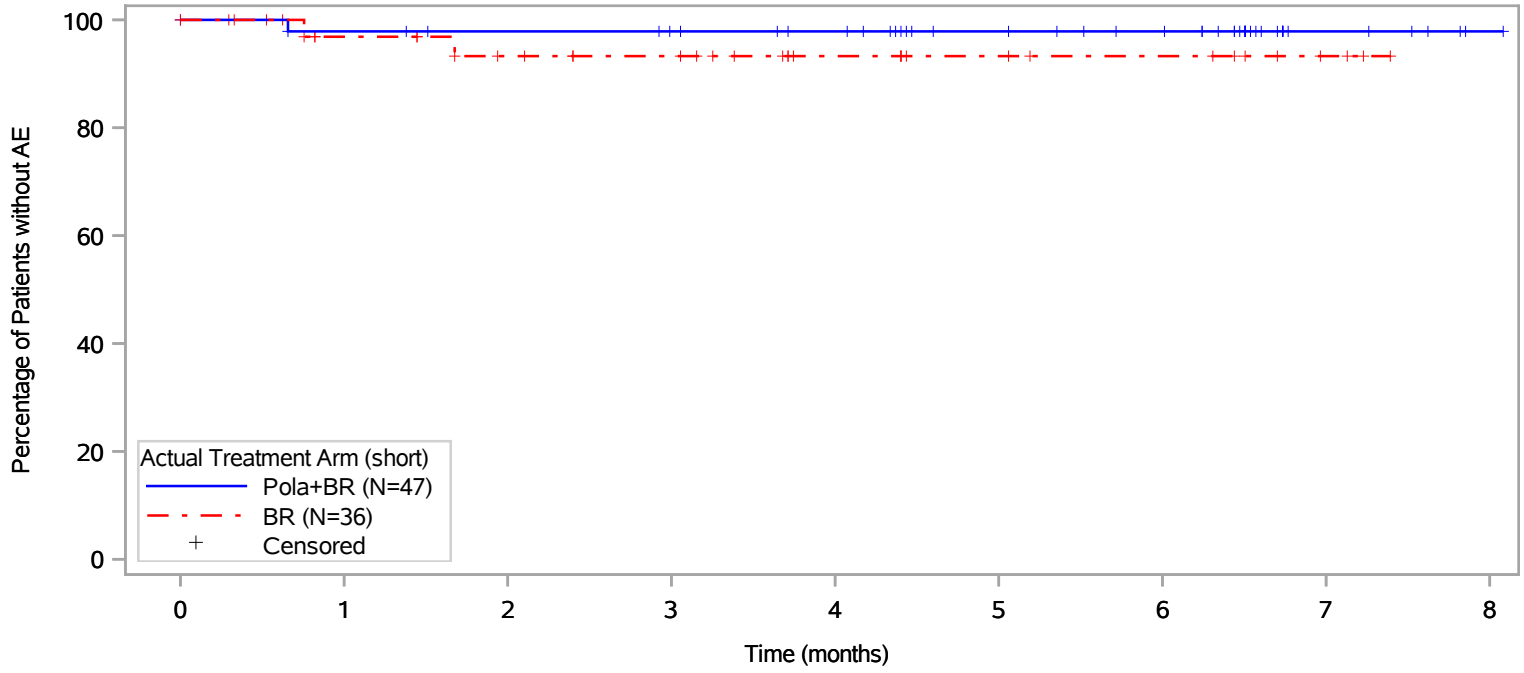


Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	46	44	42	39	31	27	6	1
BR (N=36)	36	29	25	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	20	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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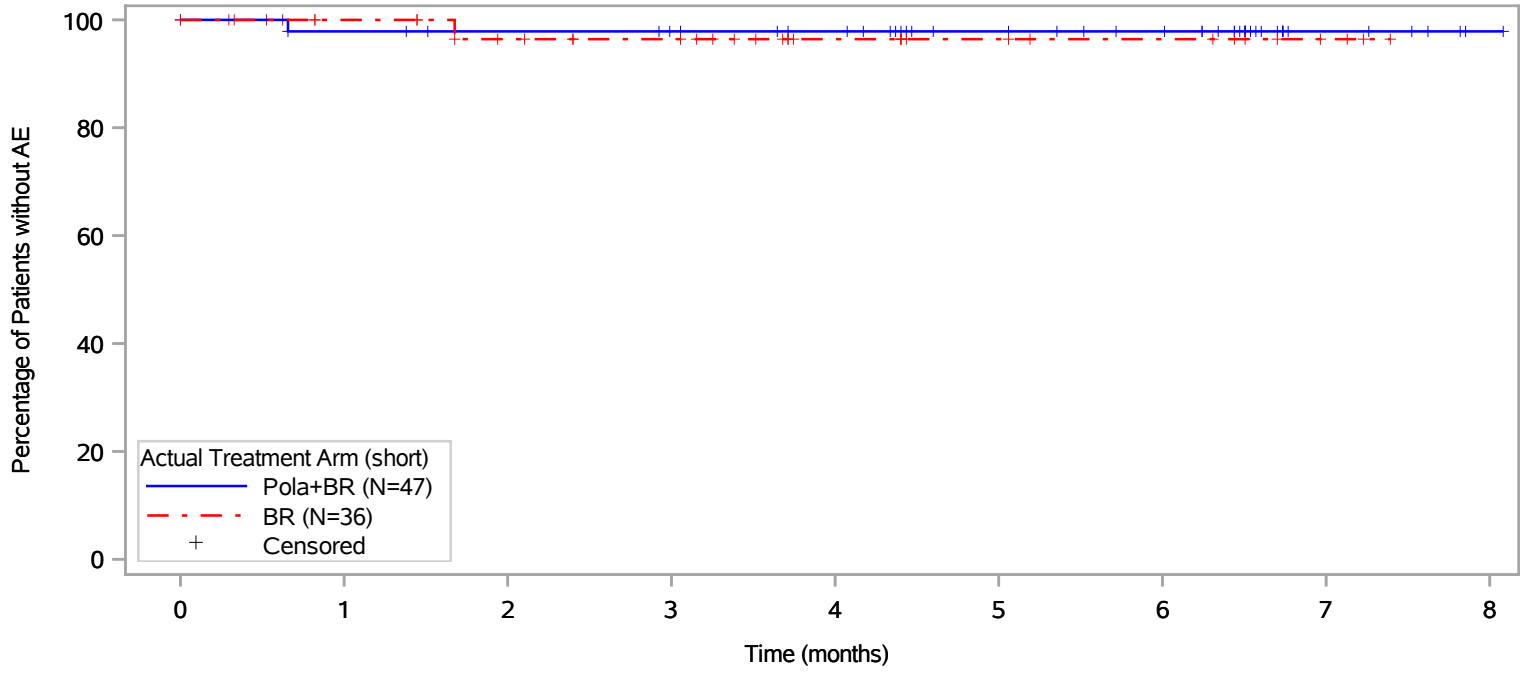
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN

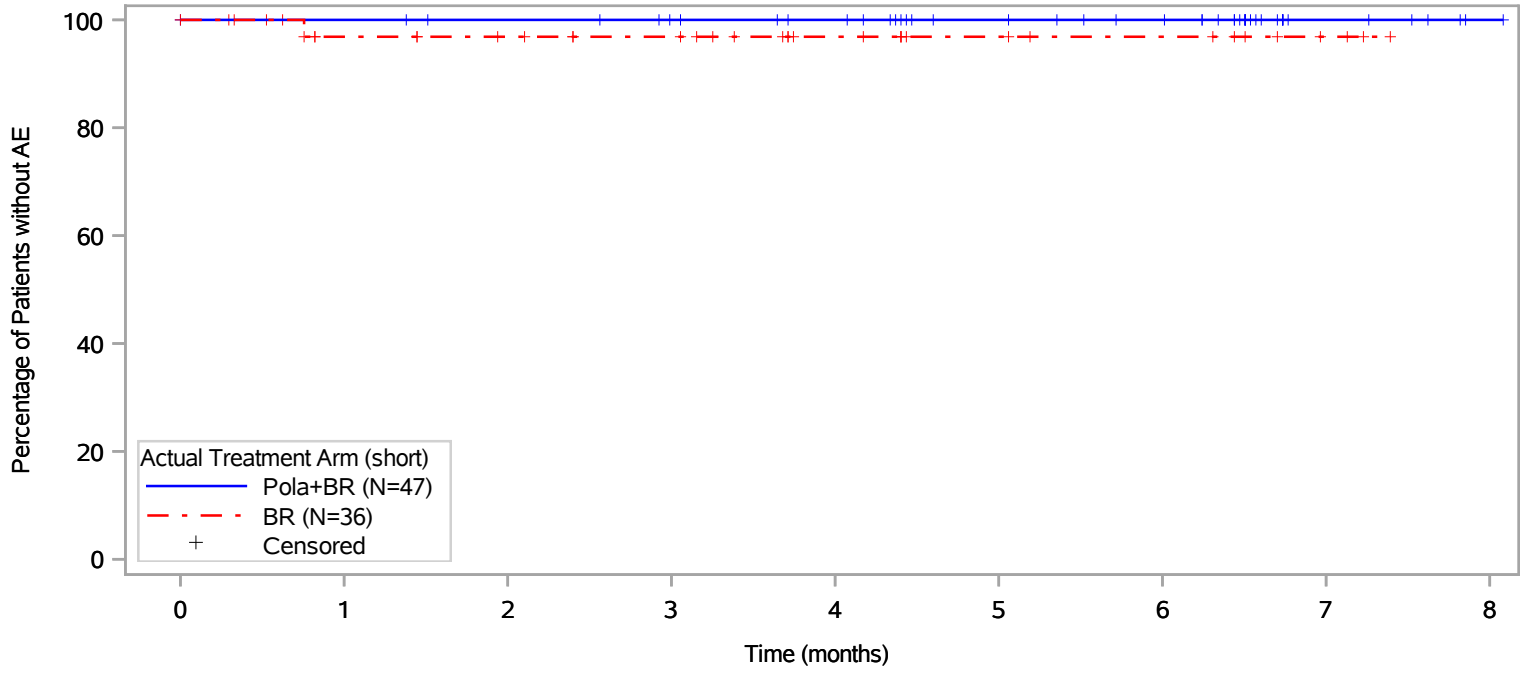


Patients at risk									
Pola+BR (N=47)	47	46	44	42	39	31	27	6	1
BR (N=36)	36	30	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, INTERVERTEBRAL DISC PROTRUSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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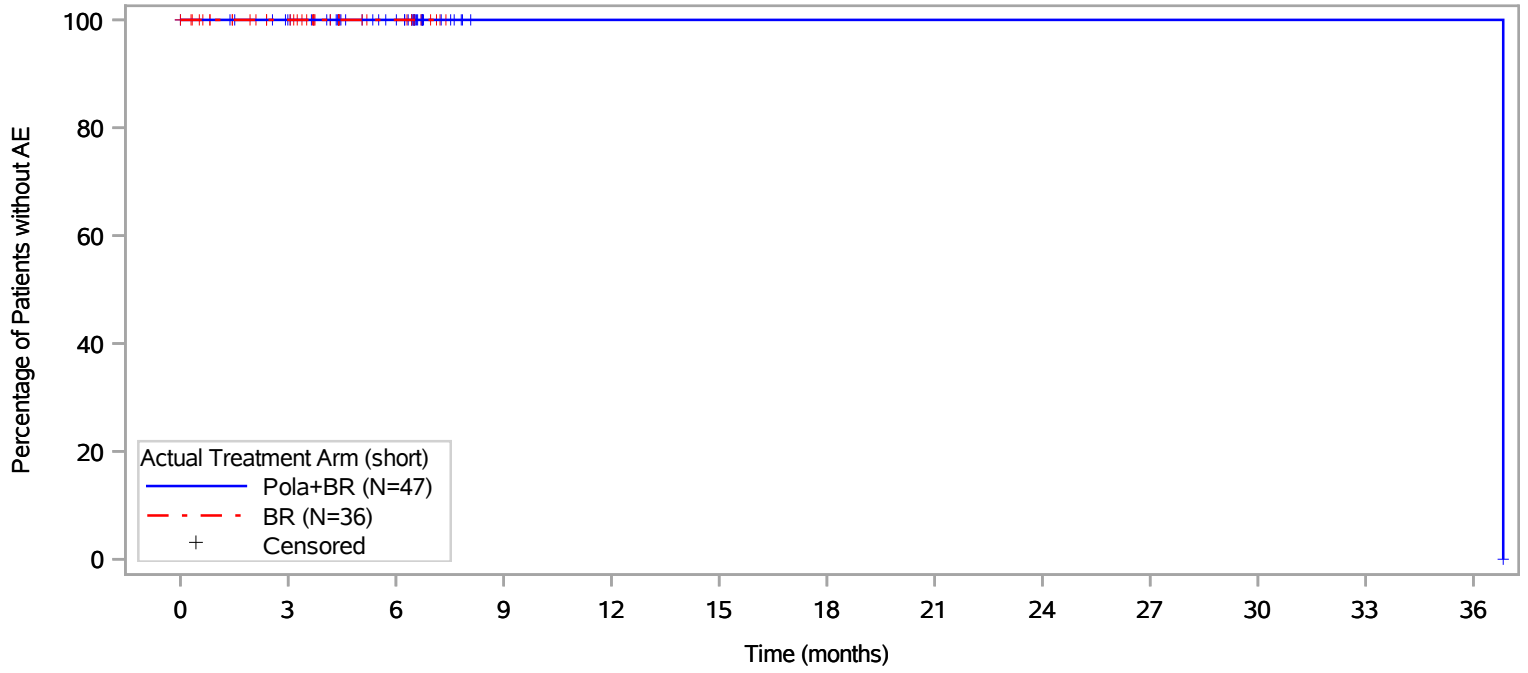
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



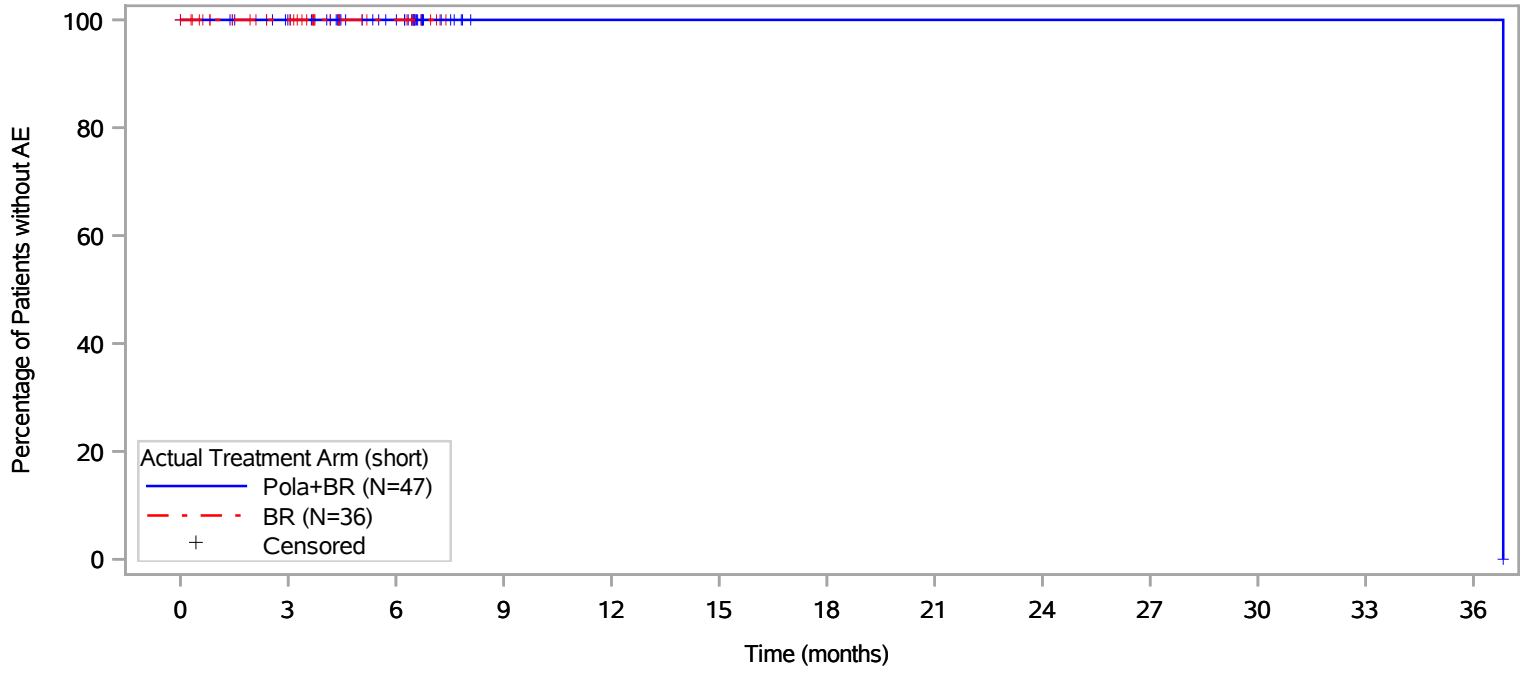
Patients at risk													
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=47)	0	5	20	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MALIGNANT MELANOMA



Patients at risk													
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=47)	0	5	20	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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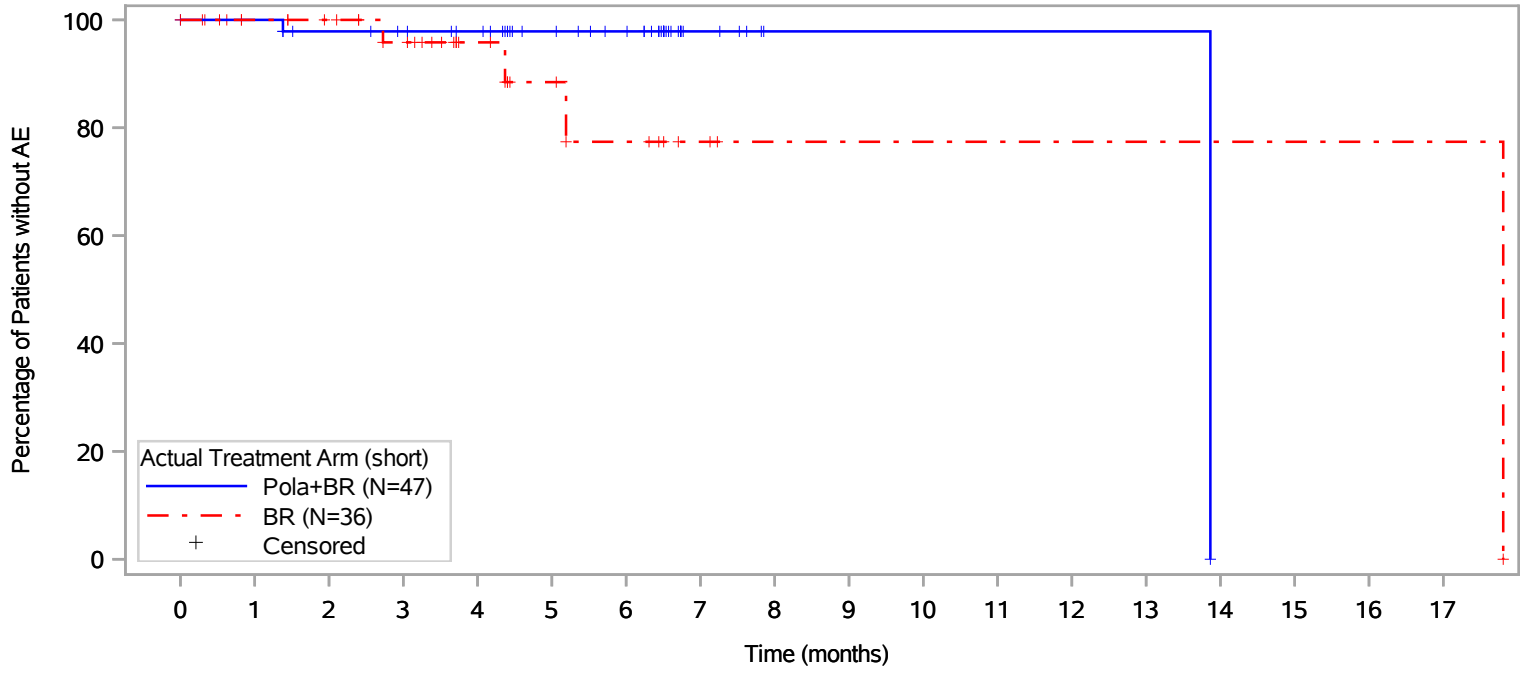
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk																		
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1	1	1	1	1	1	NE	NE	NE	NE
BR (N=36)	36	30	27	23	14	9	7	3	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45	45	45	45	45	45	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	25	26	30	32	32	32	32	32	32	32	32	32	32

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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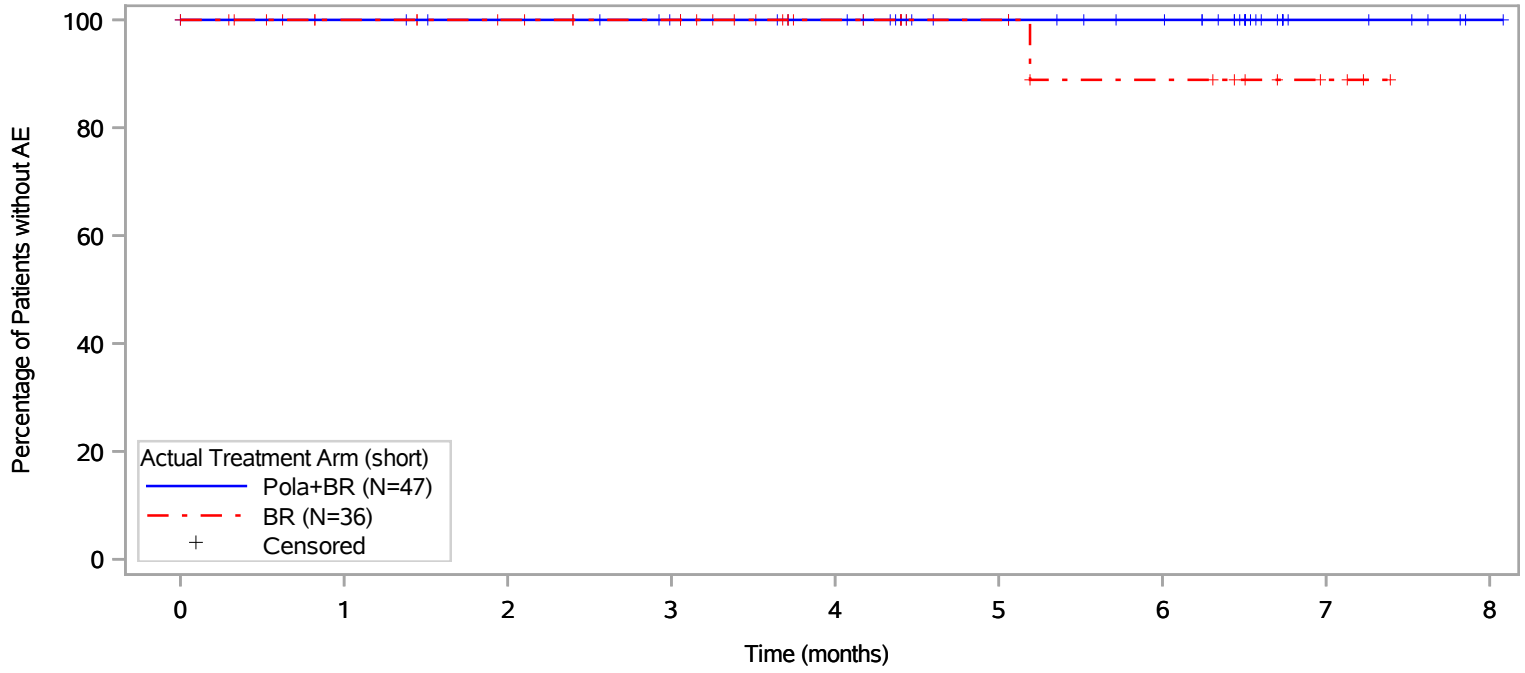
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, CEREBRAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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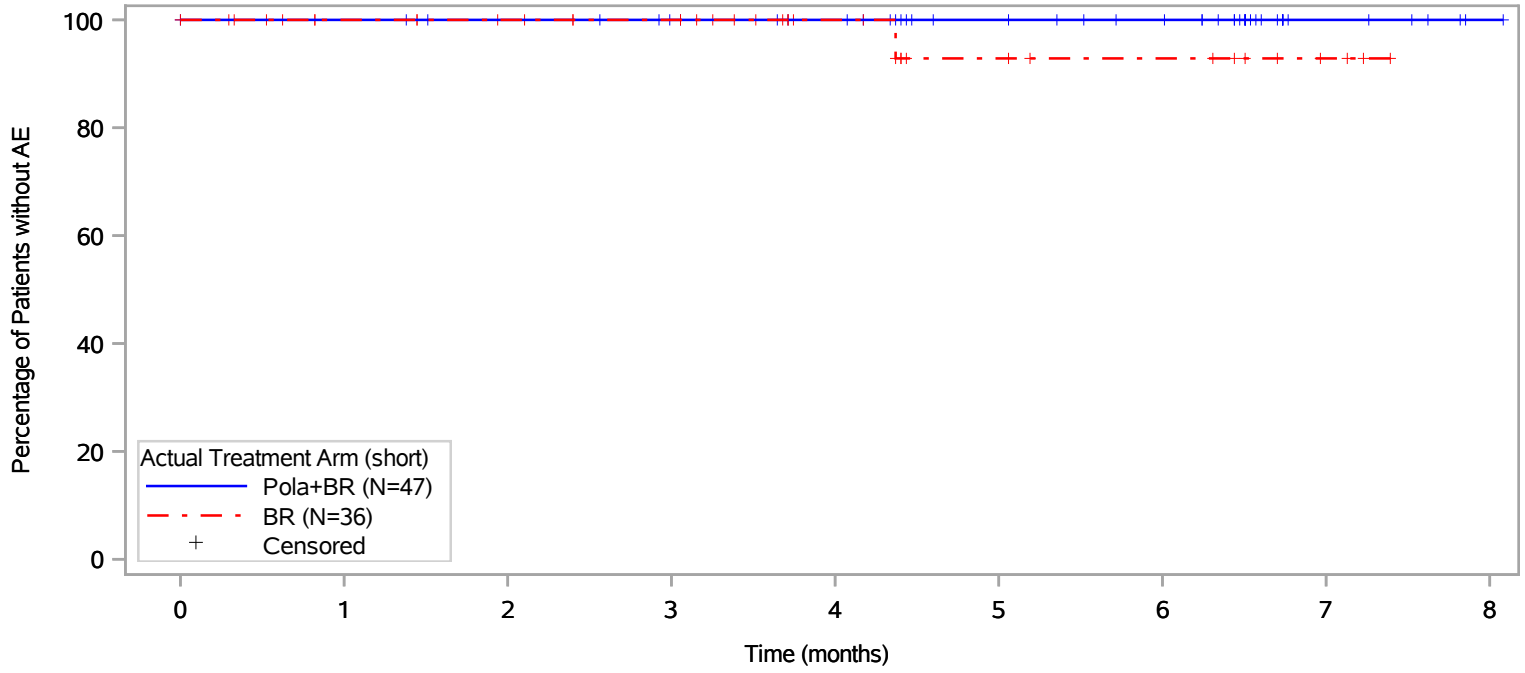
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, CEREBROVASCULAR ACCIDENT



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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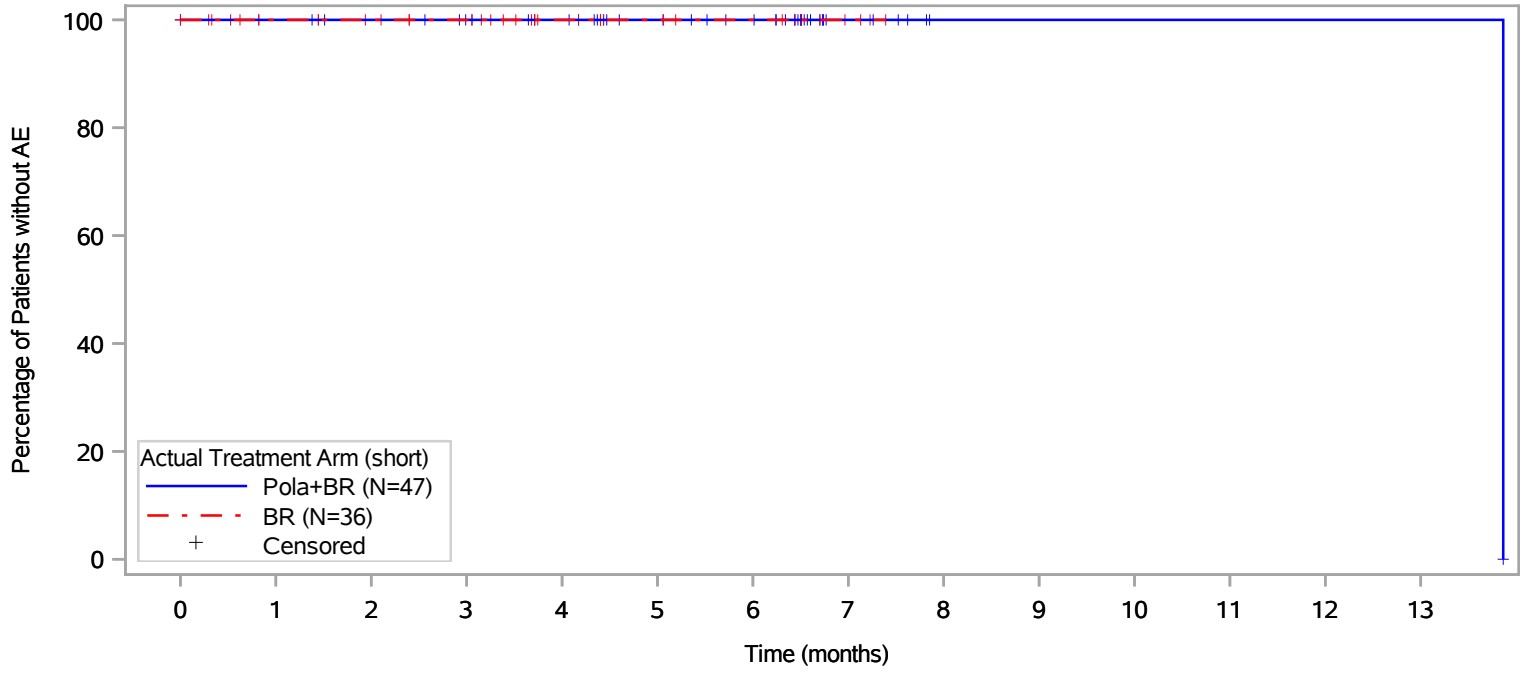
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HAEMORRHAGE INTRACRANIAL



Patients at risk														
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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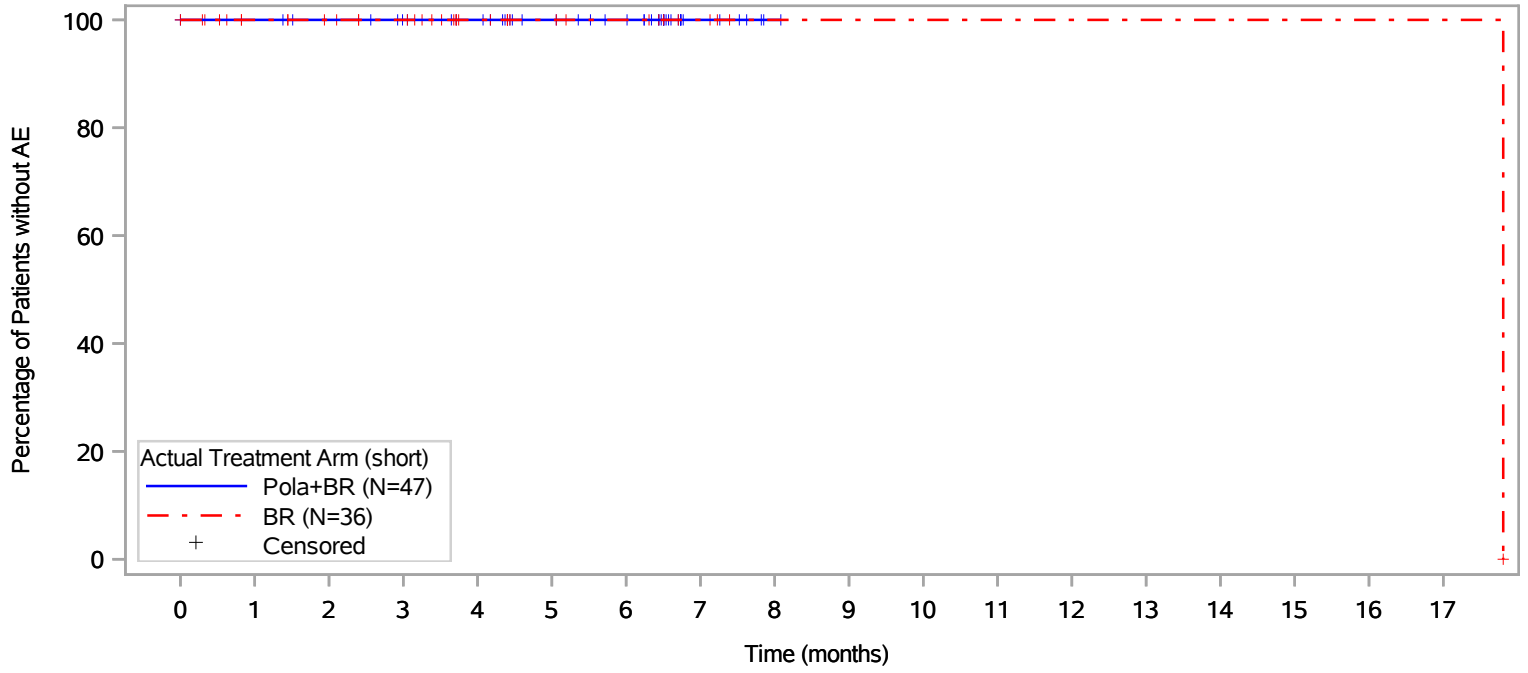
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, LEUKOENCEPHALOPATHY



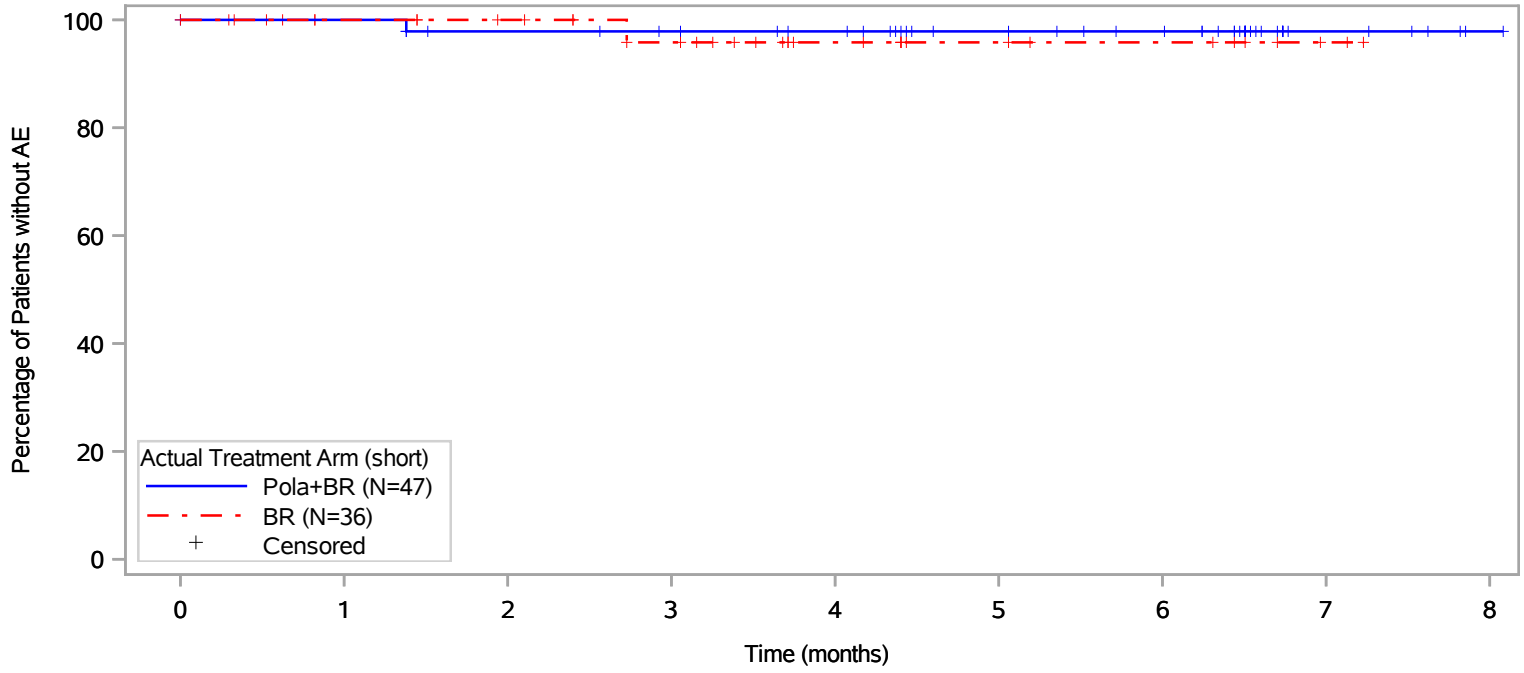
Patients at risk																		
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	32	35	35	35	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, SYNCOPE



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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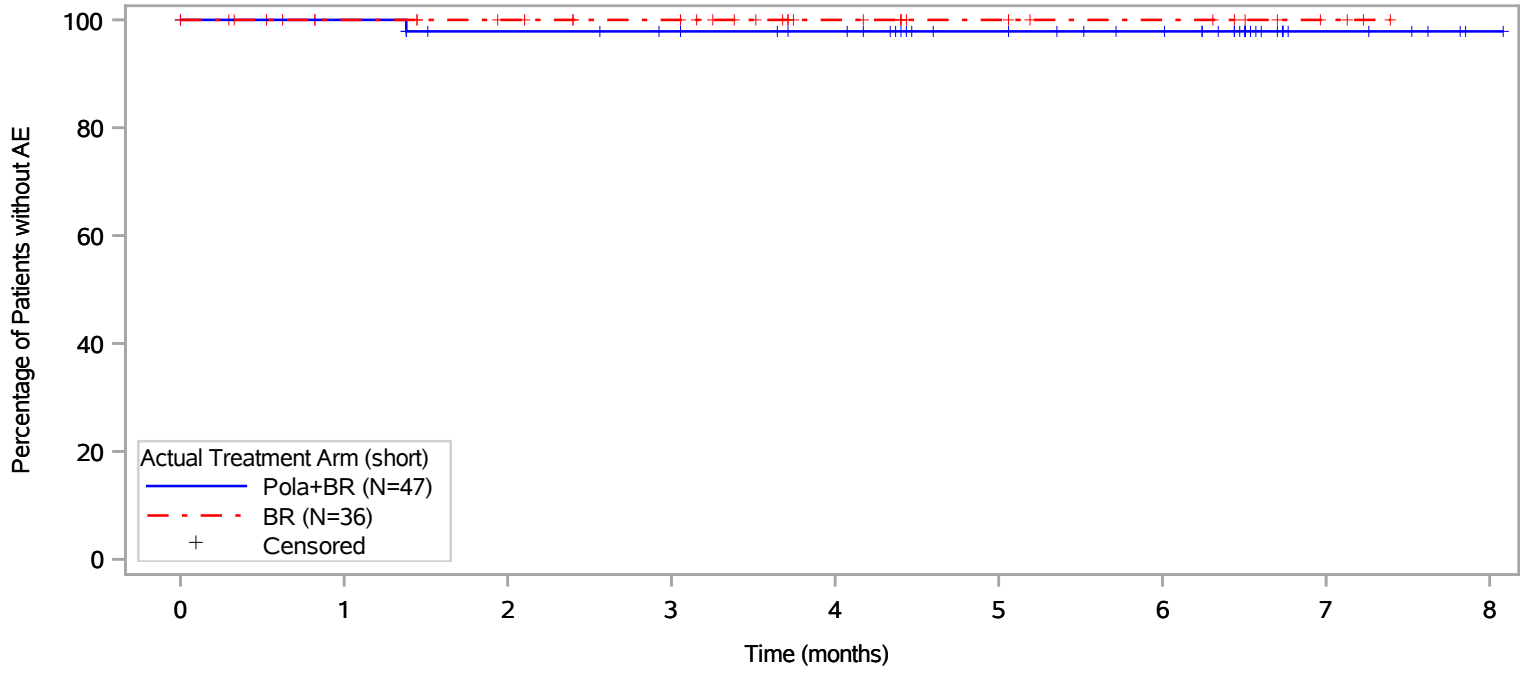
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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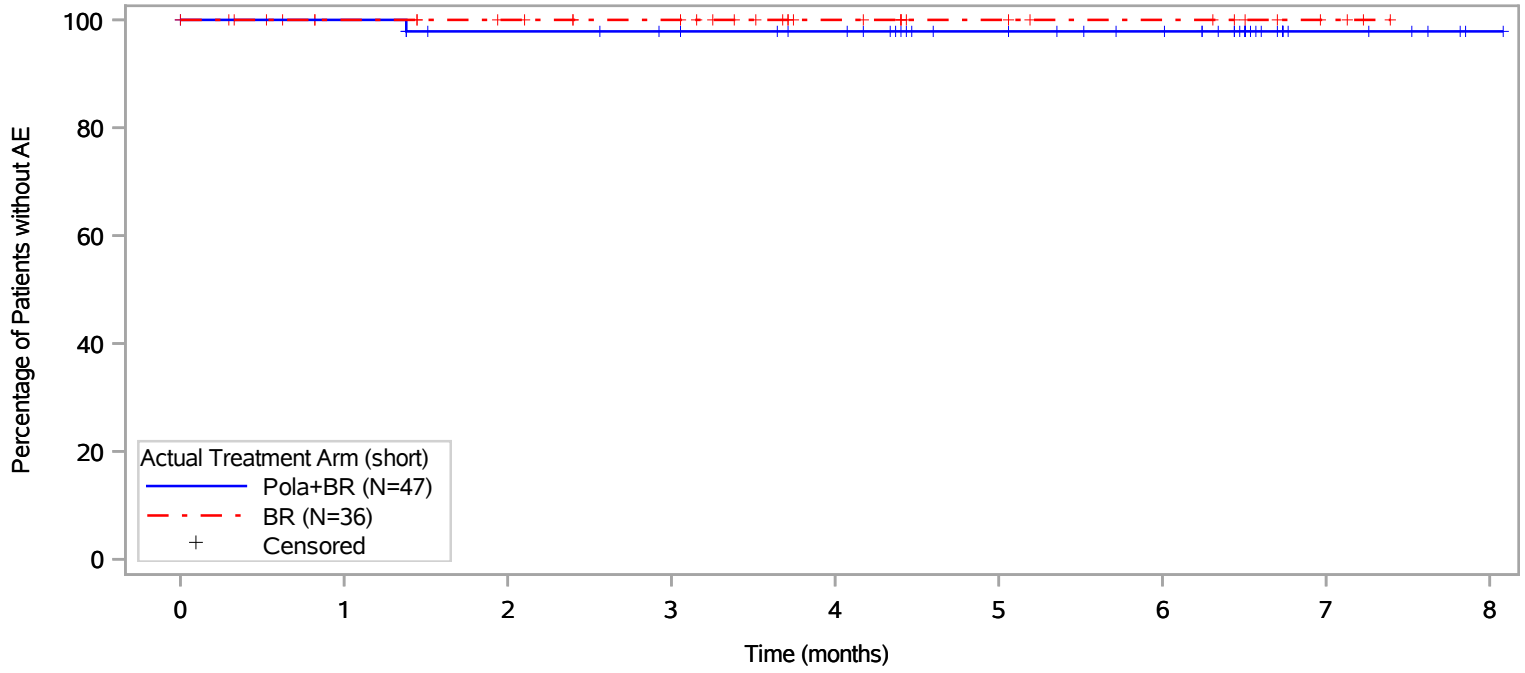
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, CONFUSIONAL STATE



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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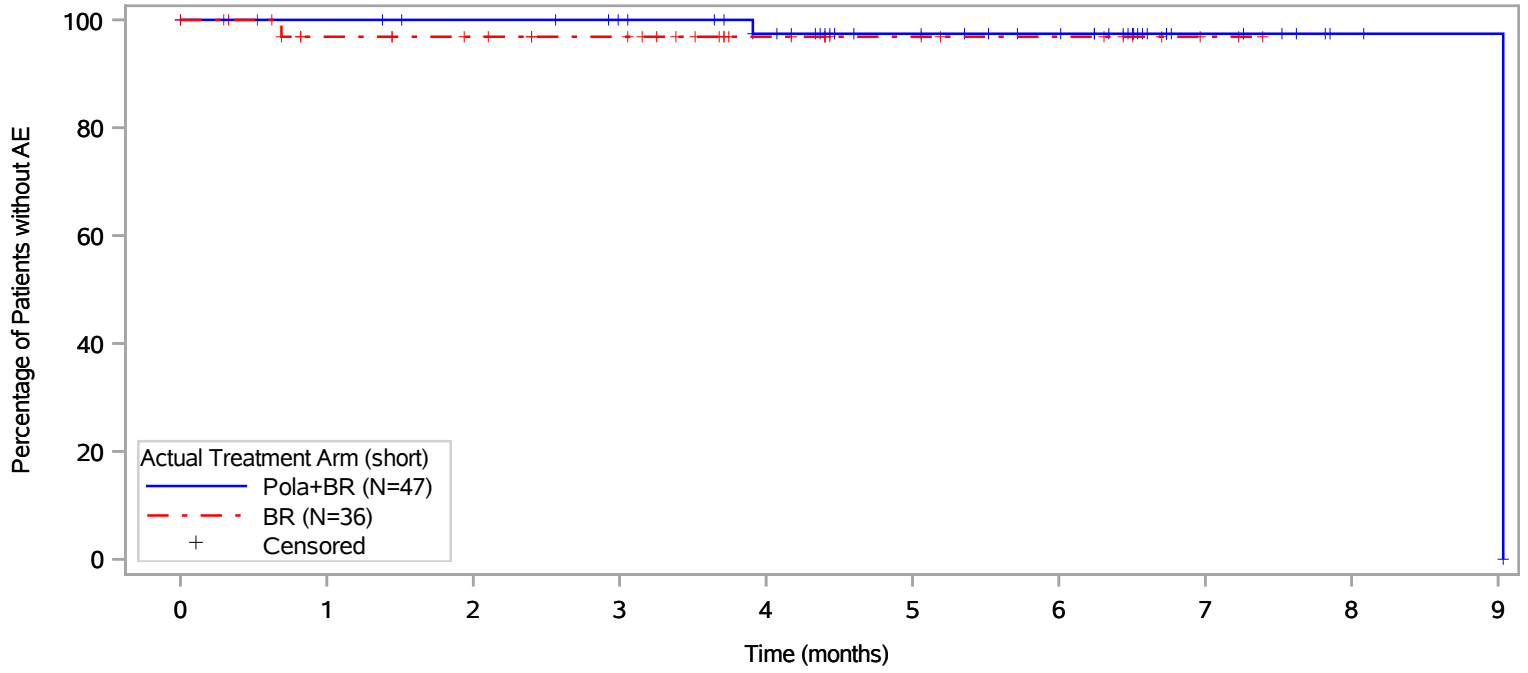
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk										
Pola+BR (N=47)	47	47	45	42	38	30	26	7	2	1
BR (N=36)	36	29	26	23	14	9	7	2	NE	NE
Patients censored										
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44	45
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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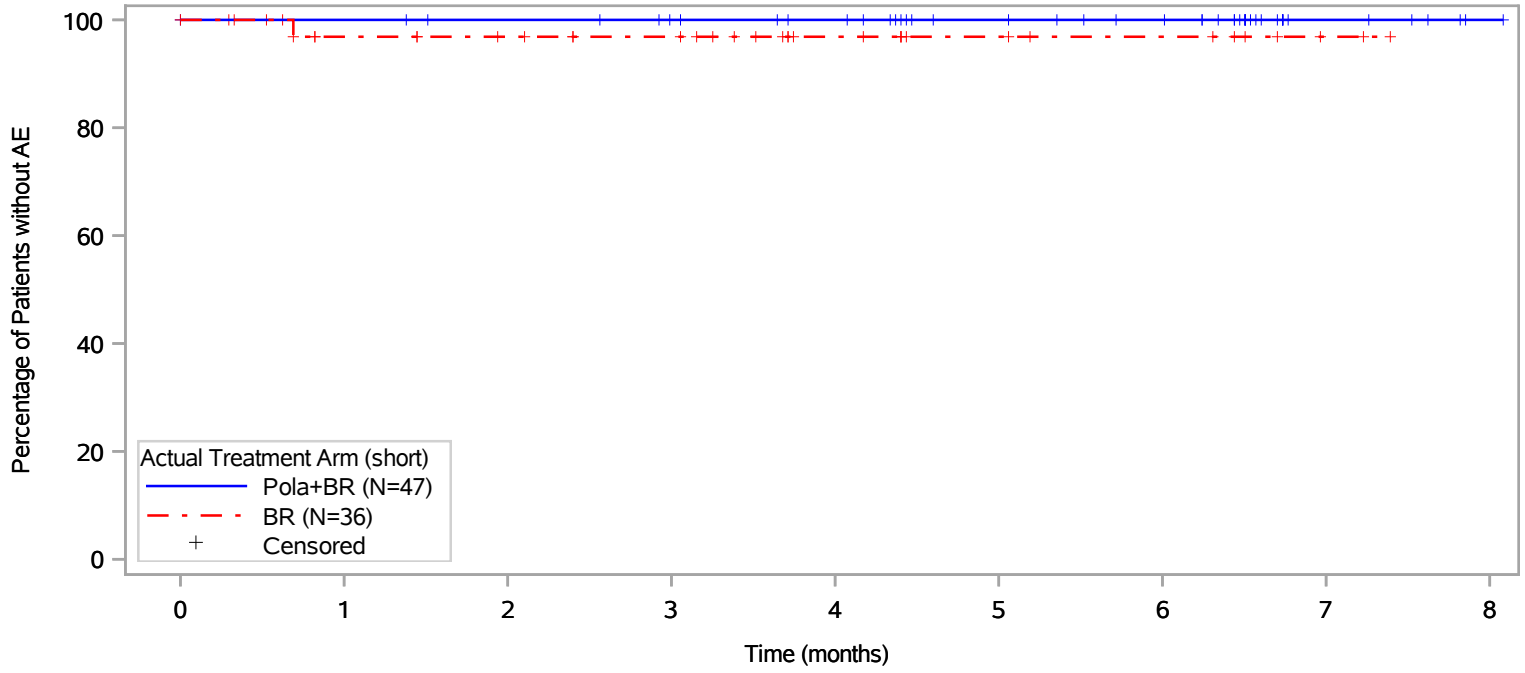
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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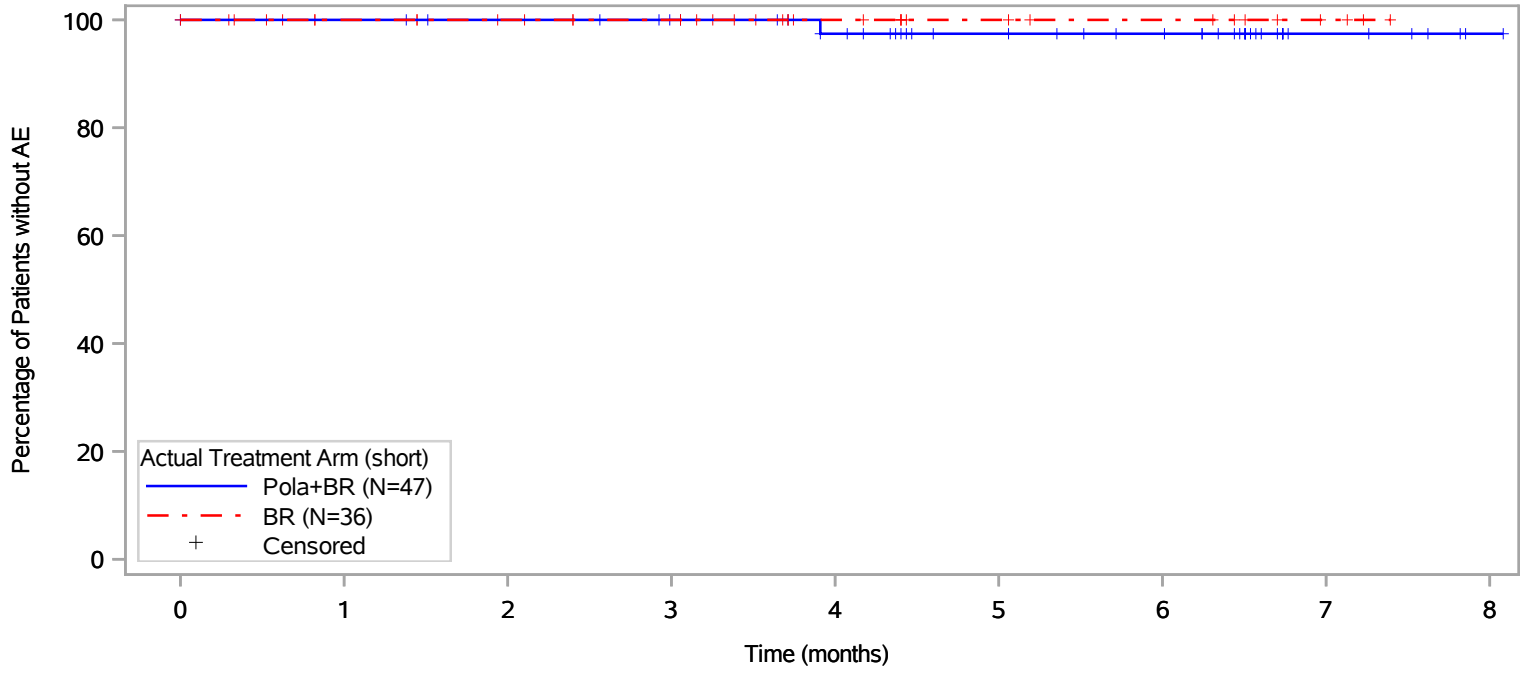
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RENAL AND URINARY DISORDERS, HAEMATURIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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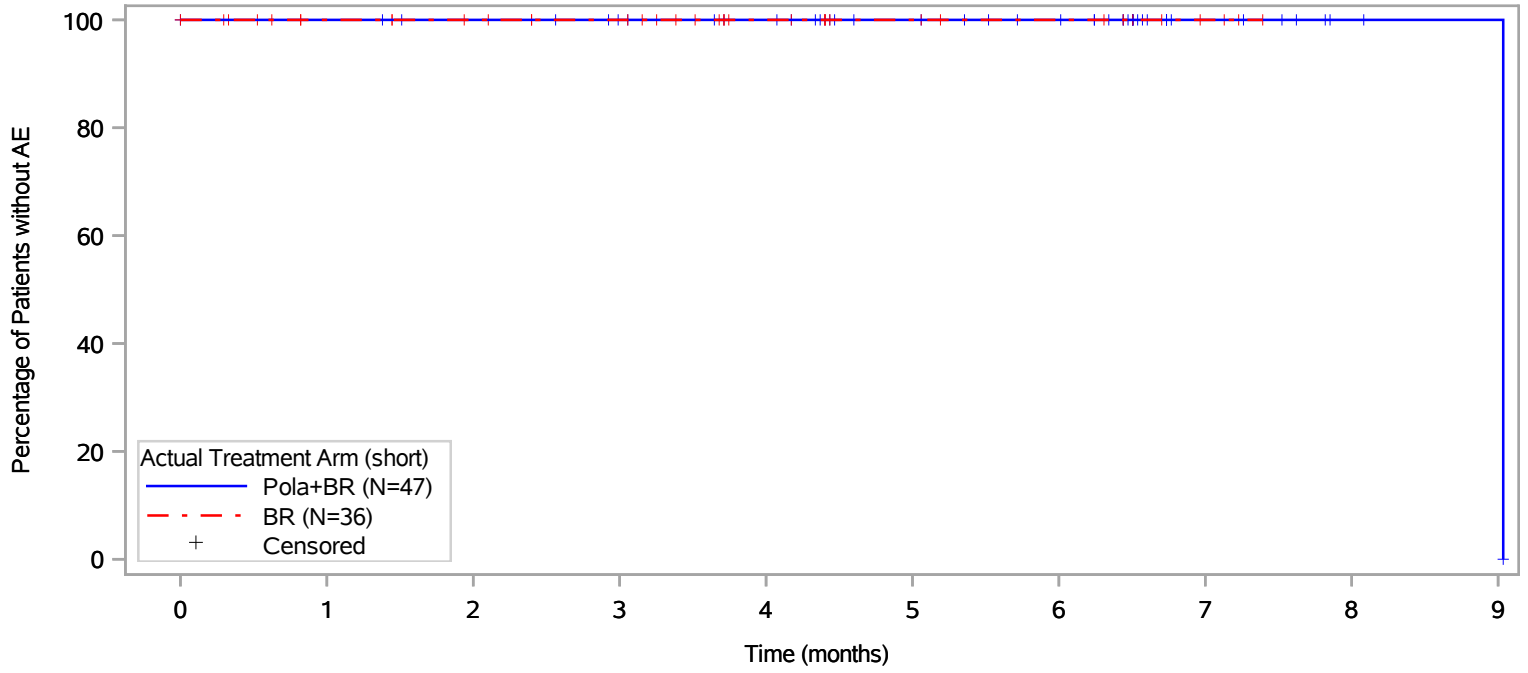
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk										
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE
Patients censored										
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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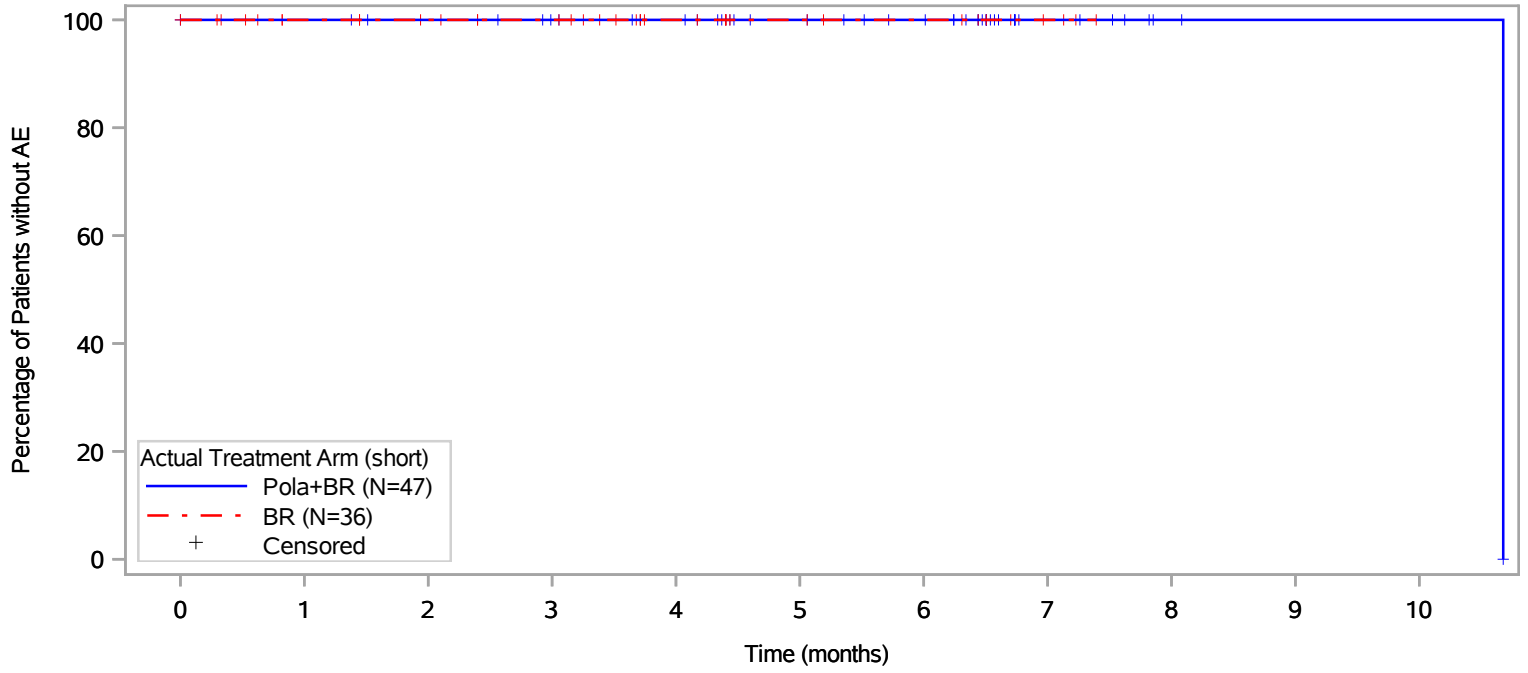
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE



Patients at risk											
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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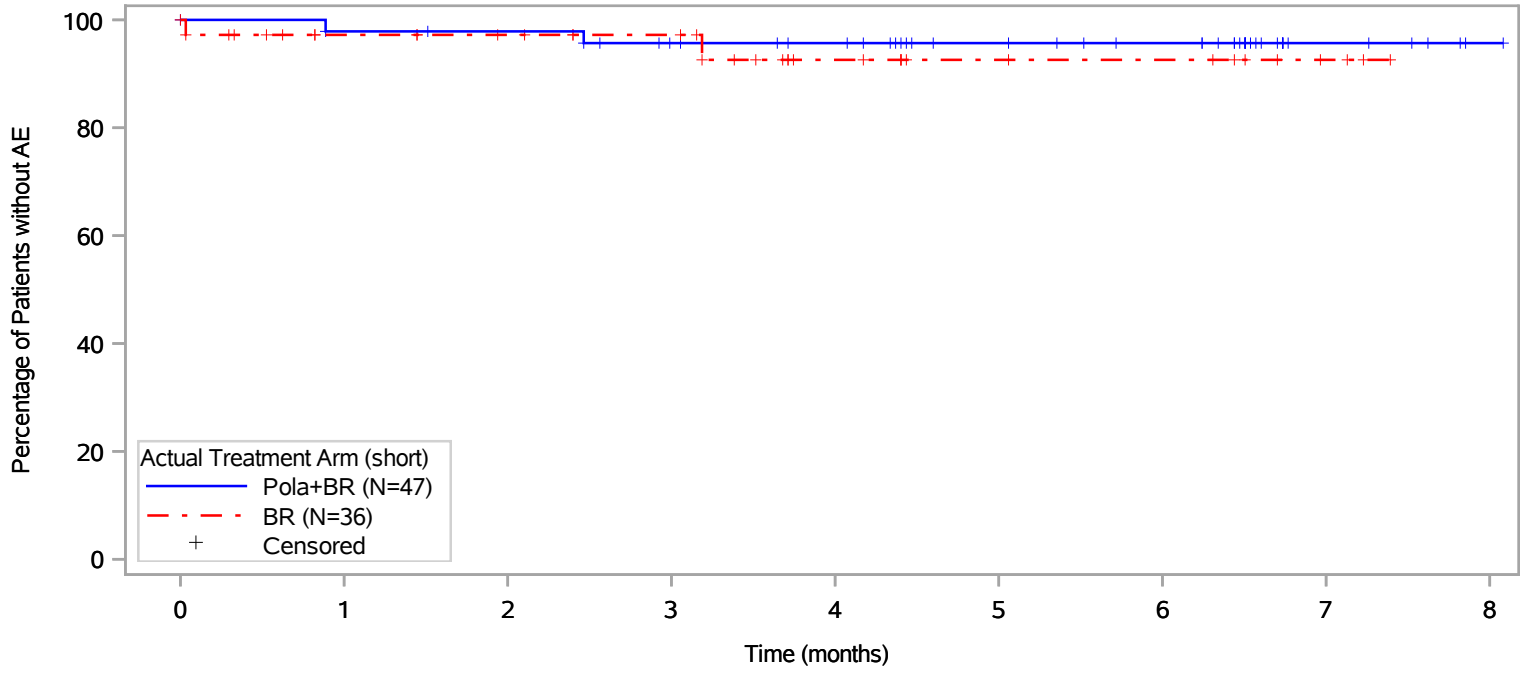
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All

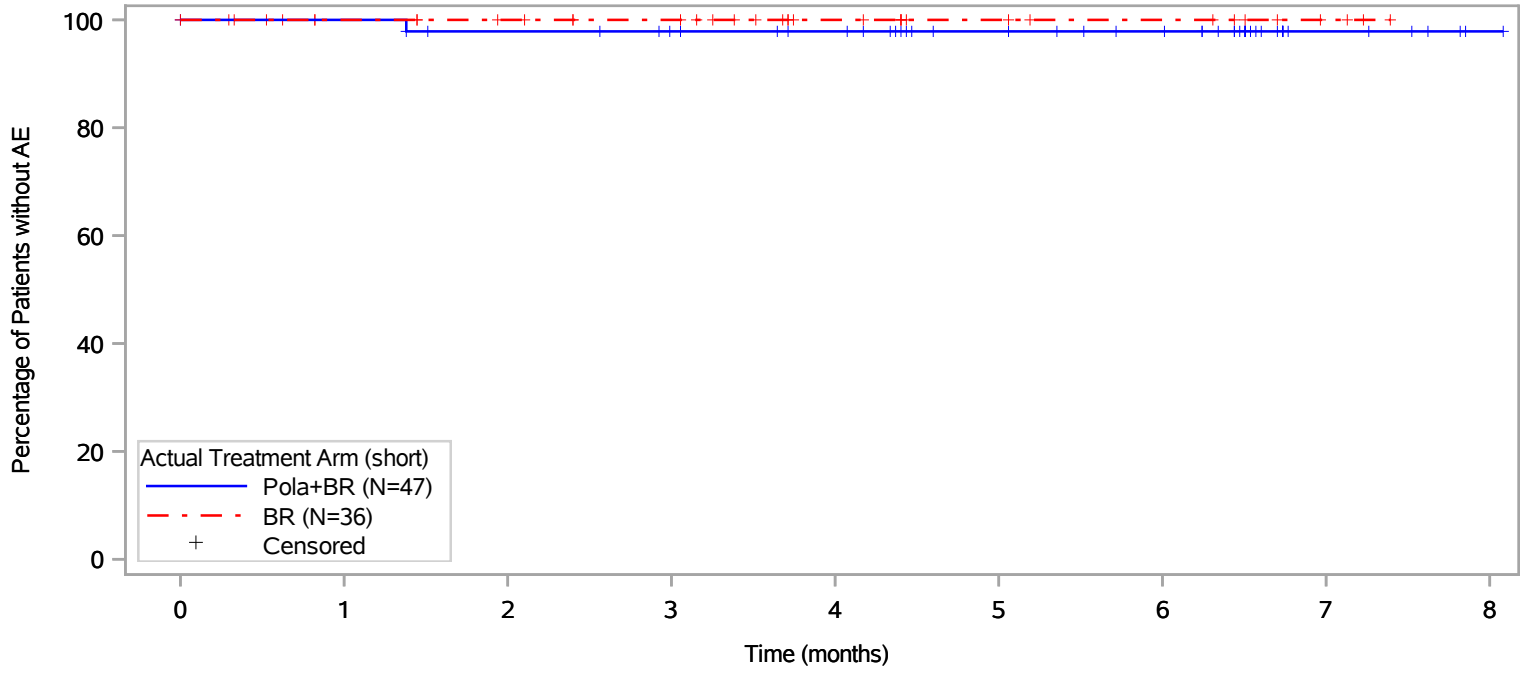


Patients at risk									
Pola+BR (N=47)	47	46	45	41	38	30	26	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	39	44
BR (N=36)	0	6	9	12	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HAEMOPTYSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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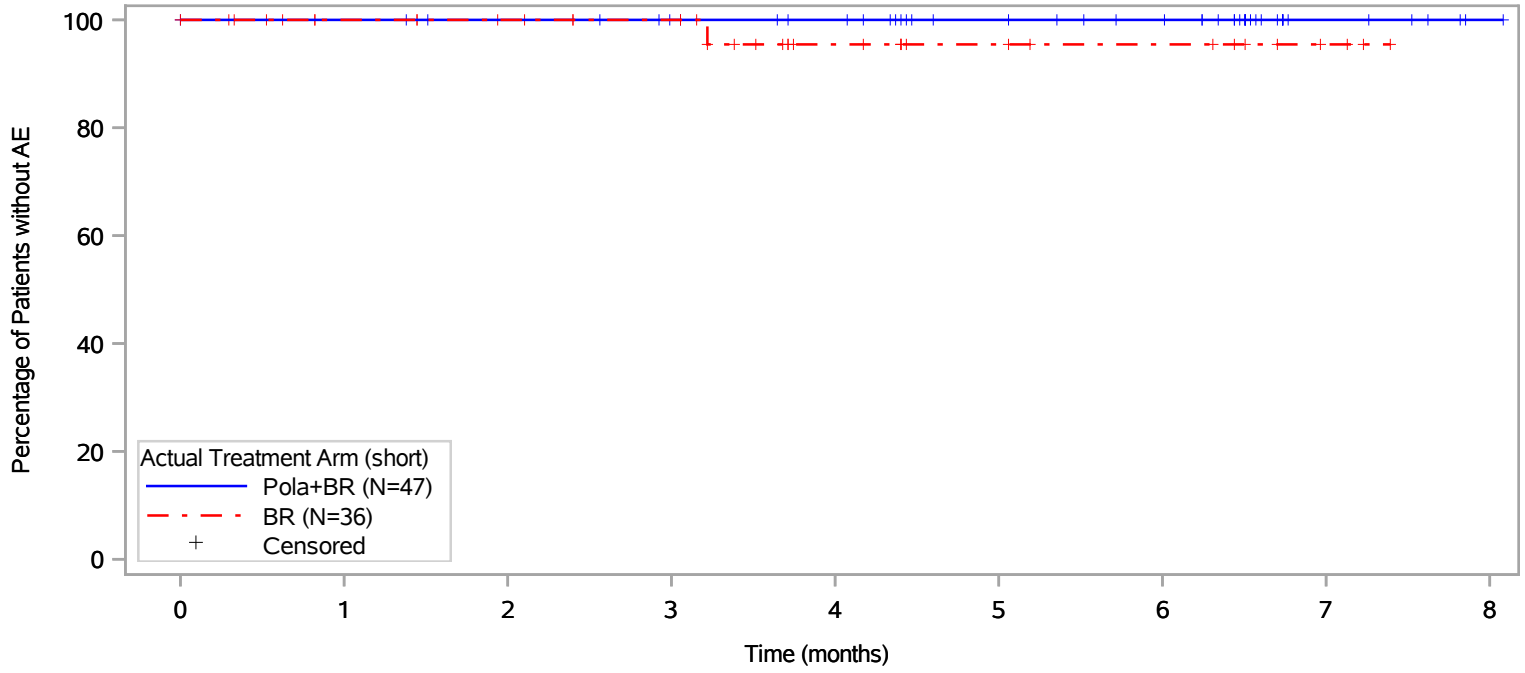
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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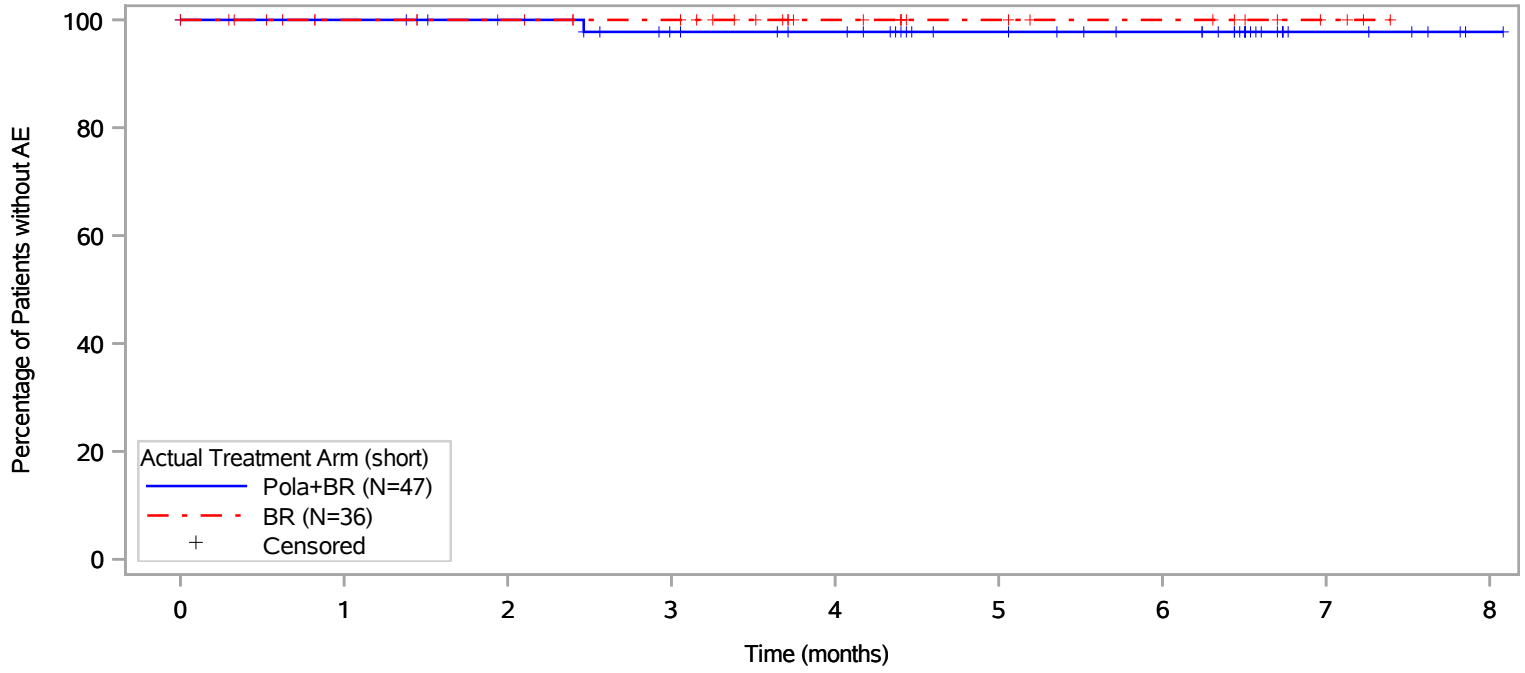
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, INTERSTITIAL LUNG DISEASE



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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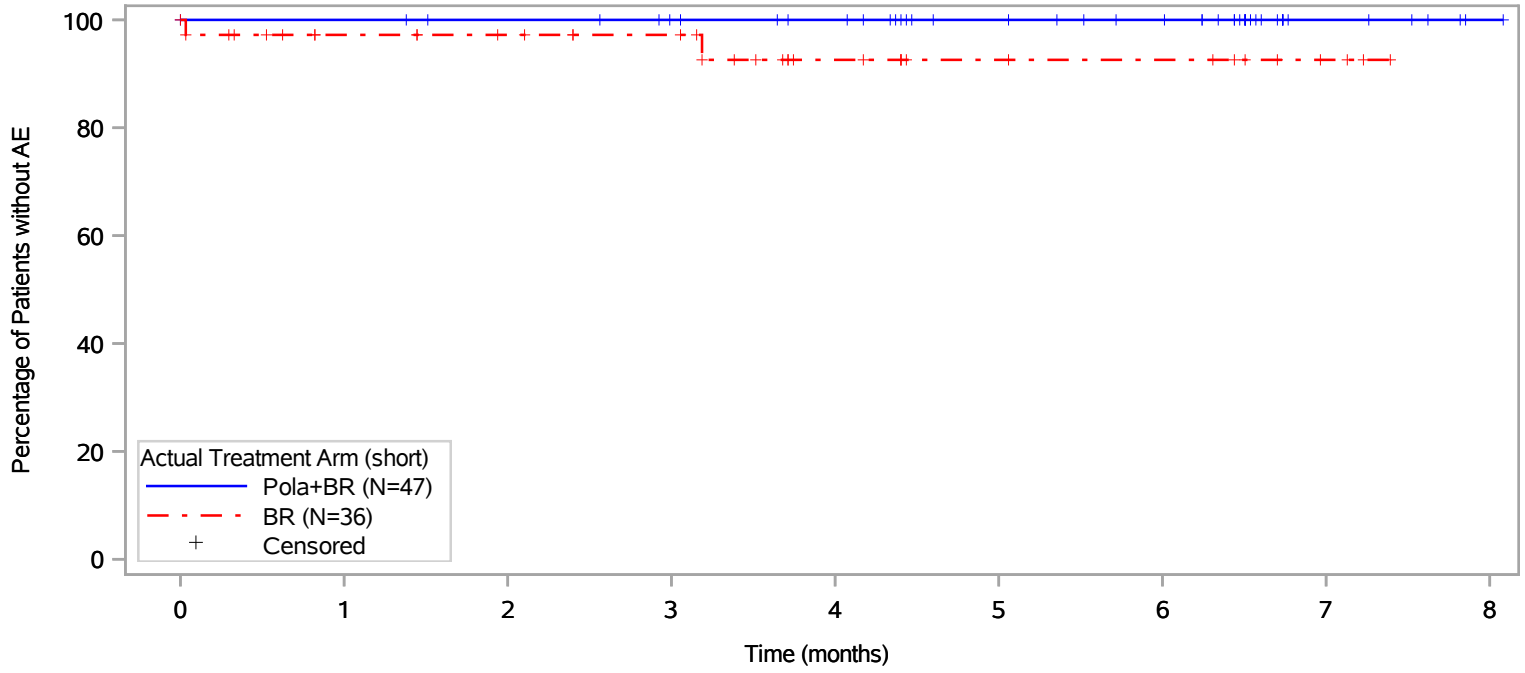
02DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION

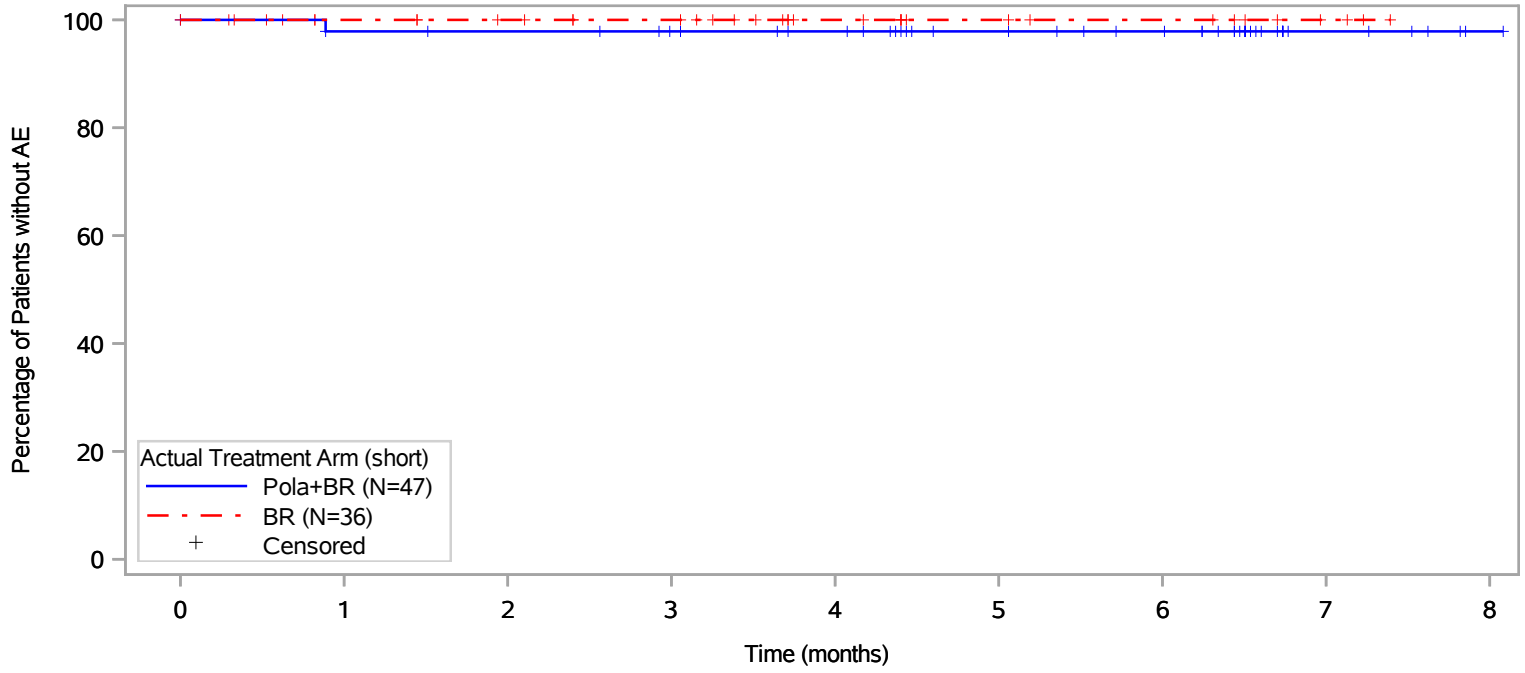


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY EMBOLISM

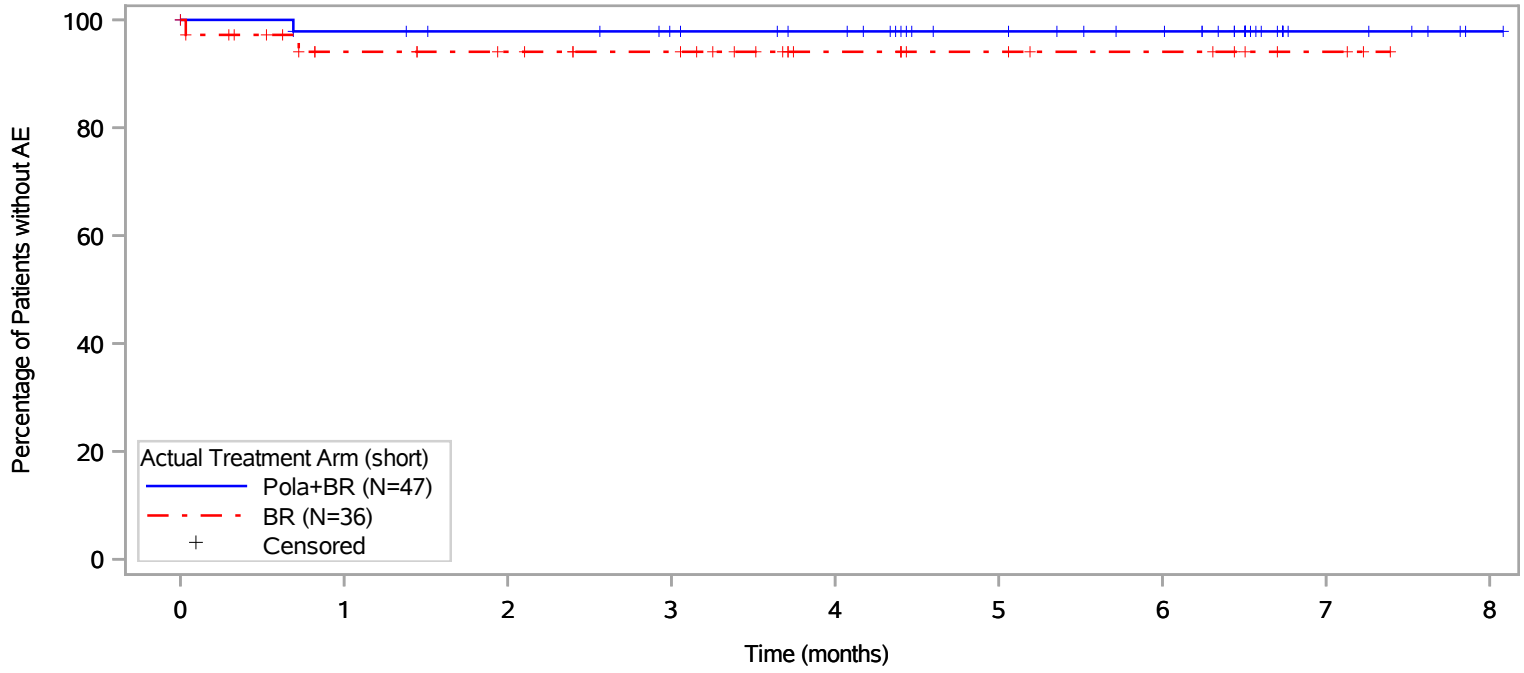


Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	28	25	22	13	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	25	27	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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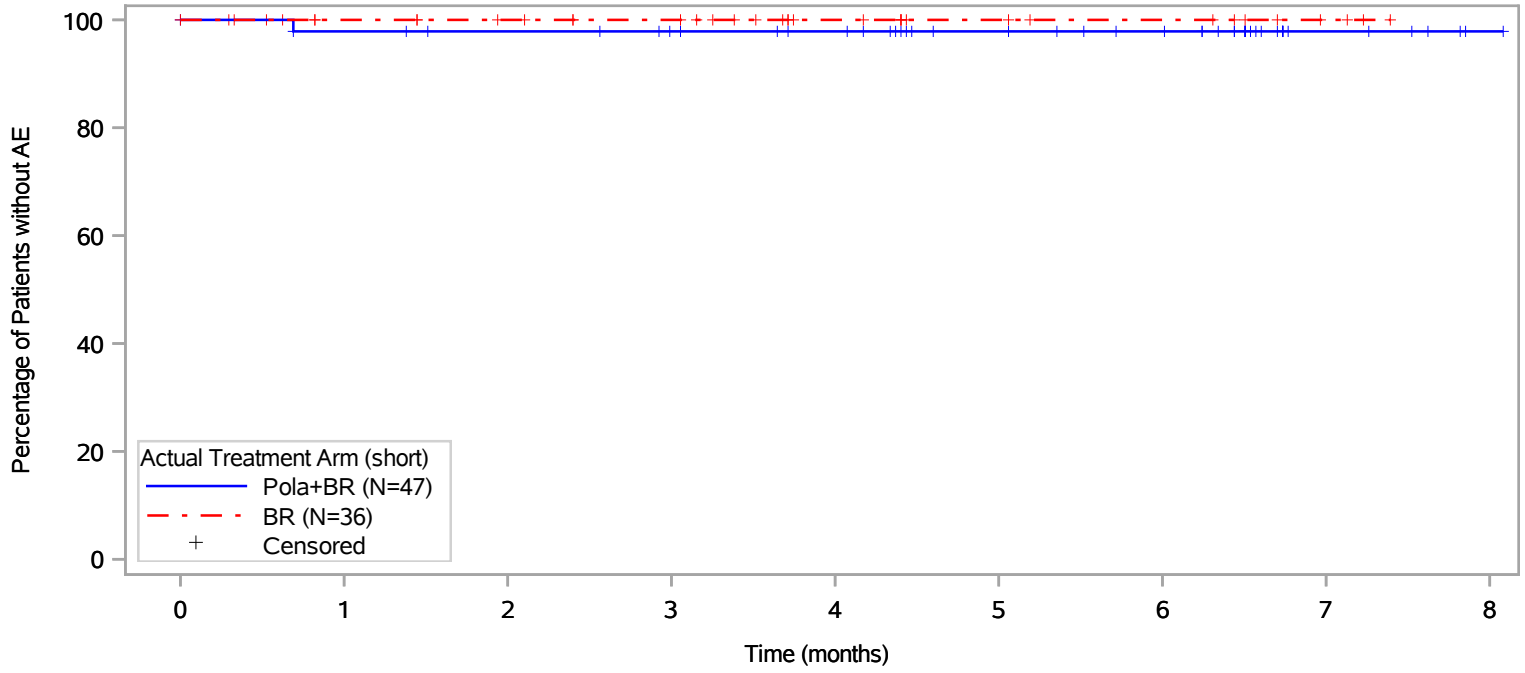
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DRUG ERUPTION



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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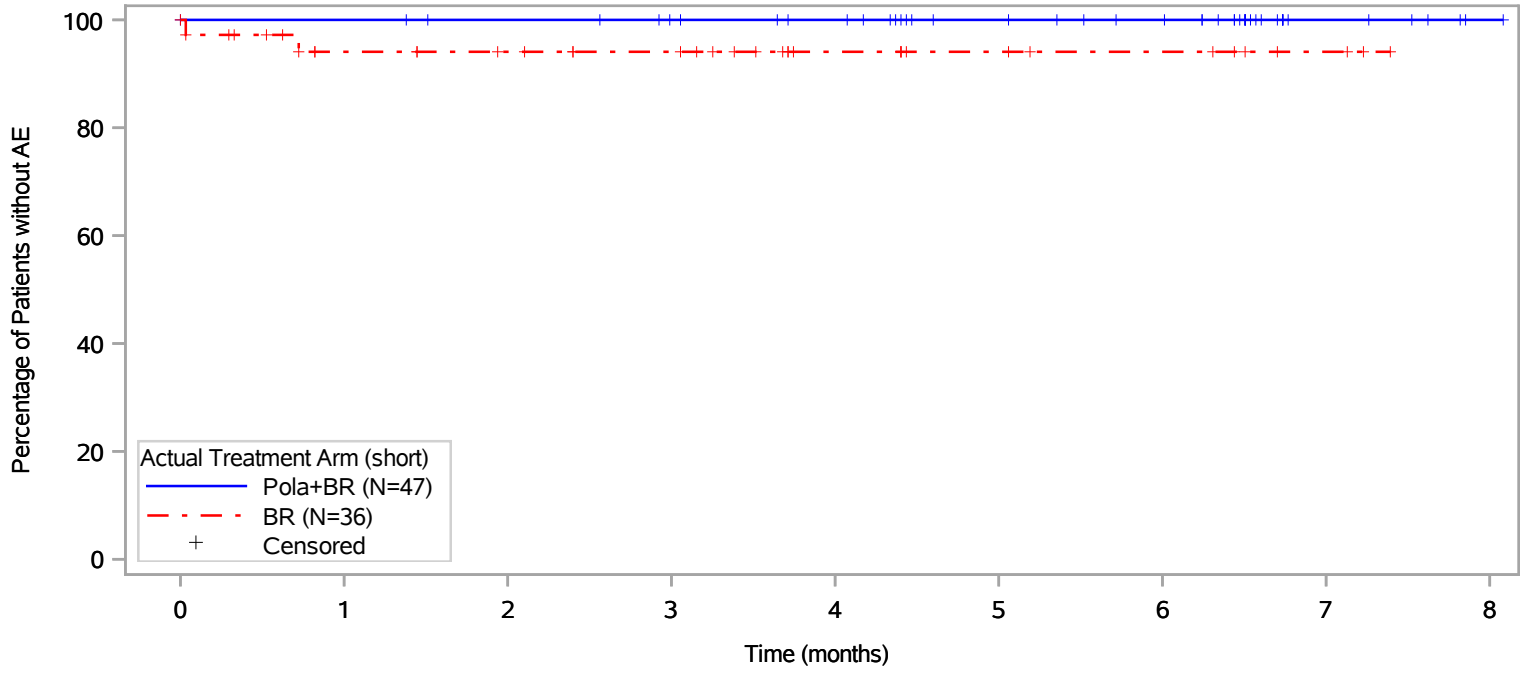
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	28	25	22	13	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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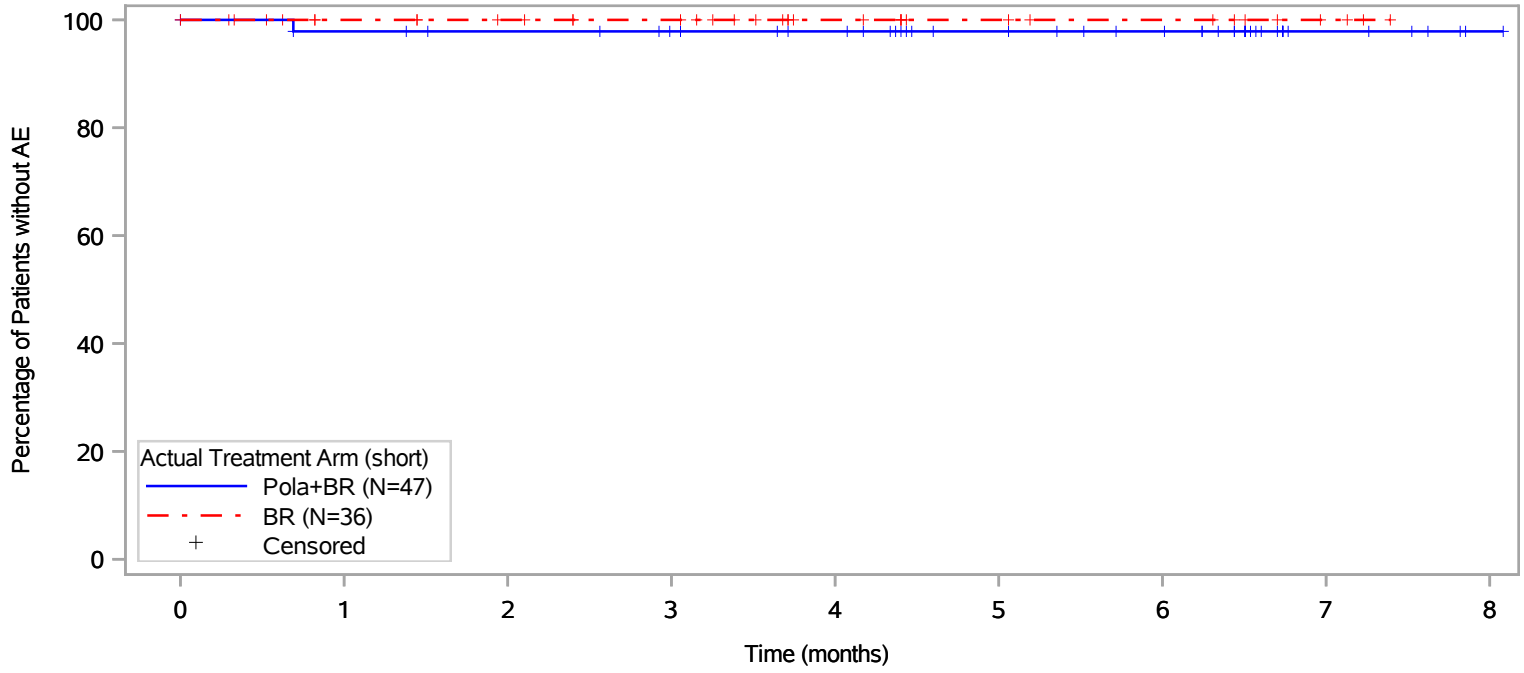
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, URTICARIA

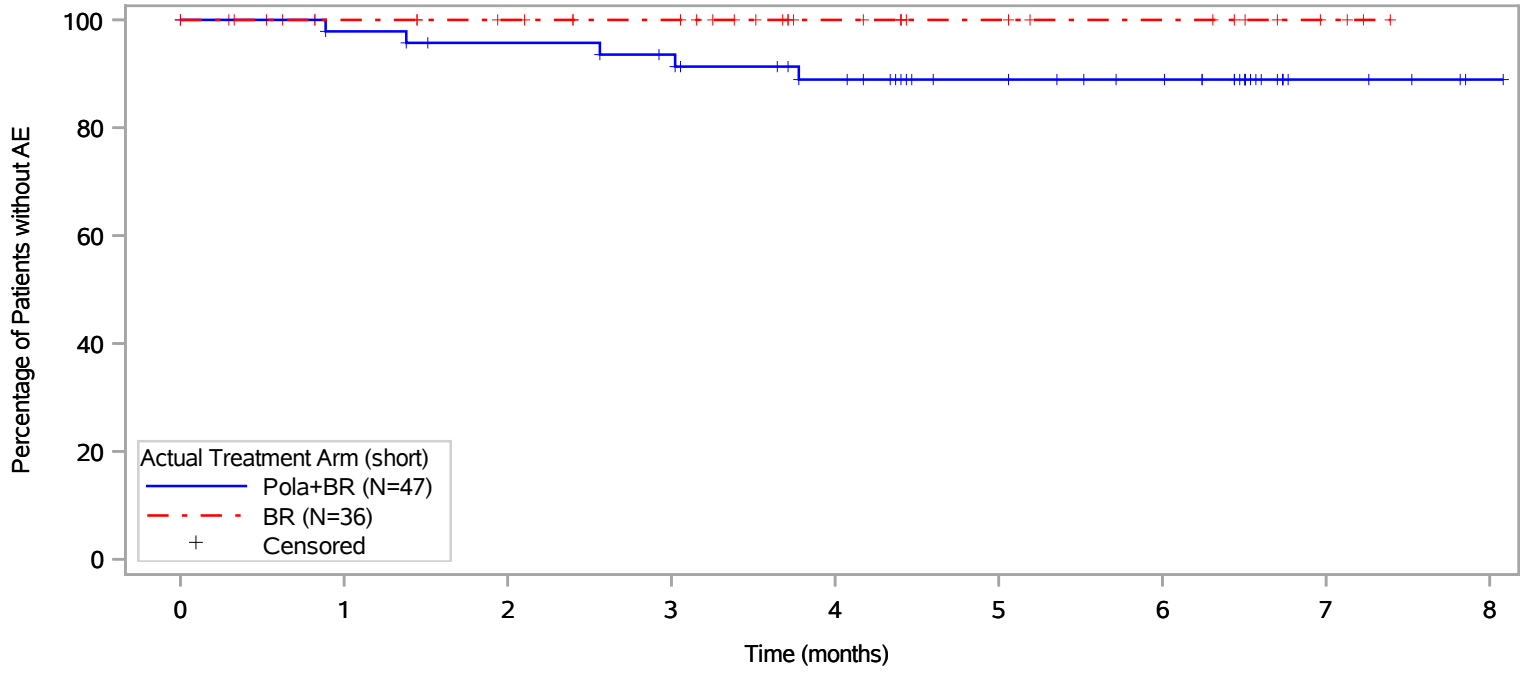


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR345AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 2:28

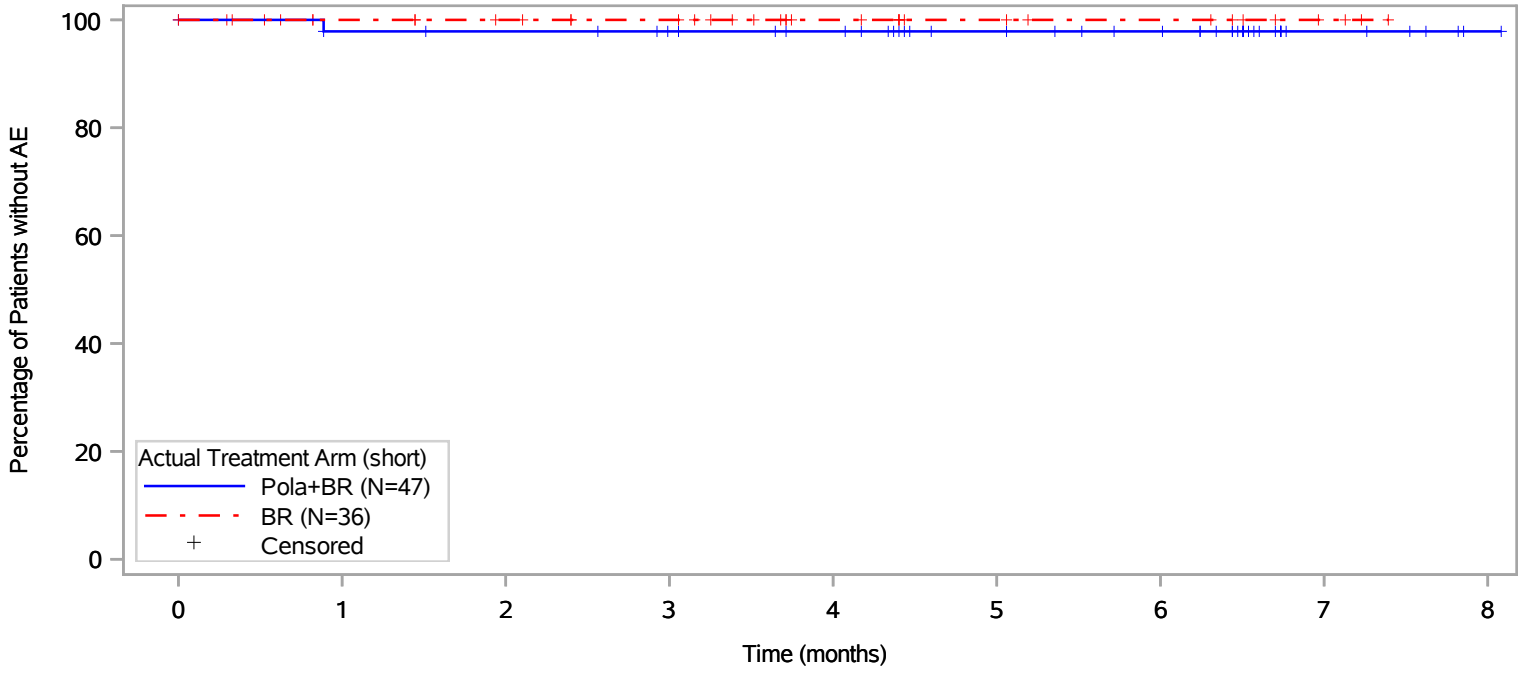
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	46	44	42	37	29	25	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	2	5	13	17	37	41
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DEEP VEIN THROMBOSIS



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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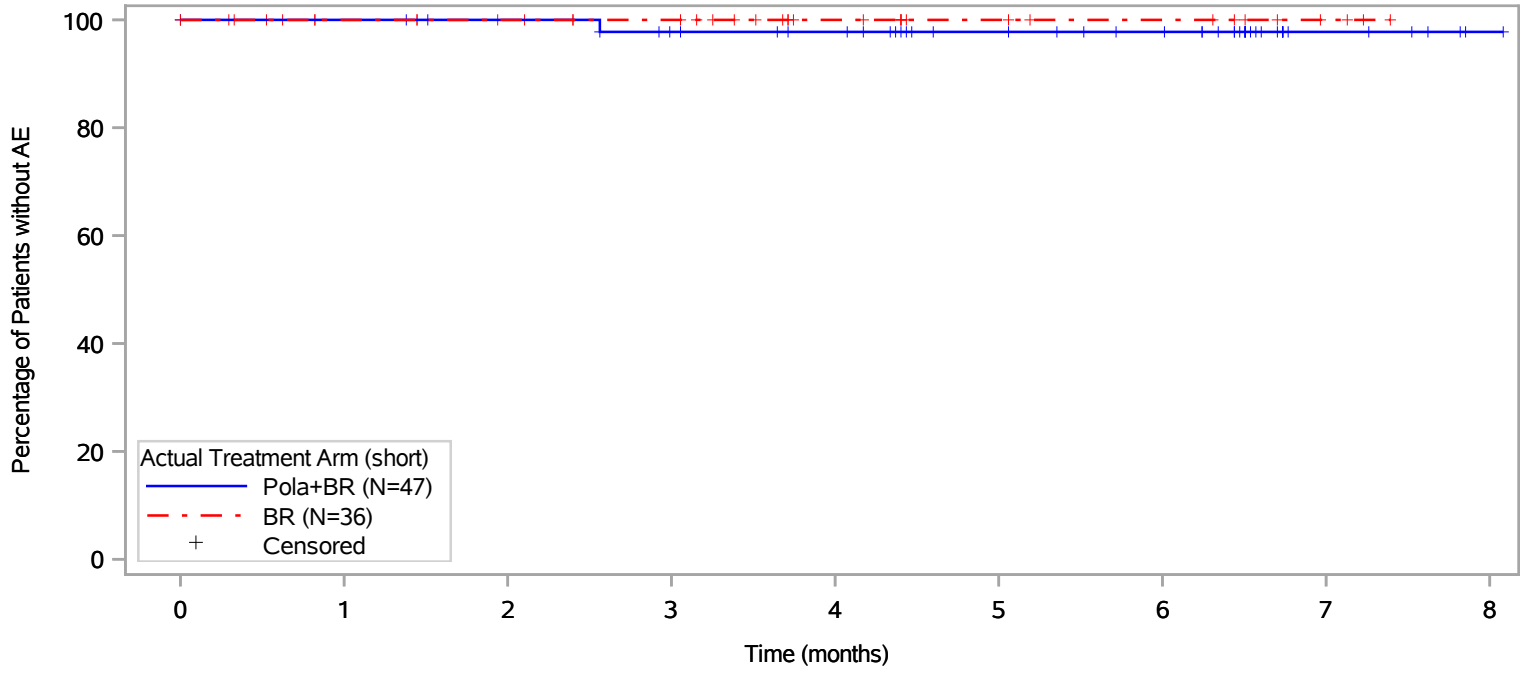
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DISTRIBUTIVE SHOCK



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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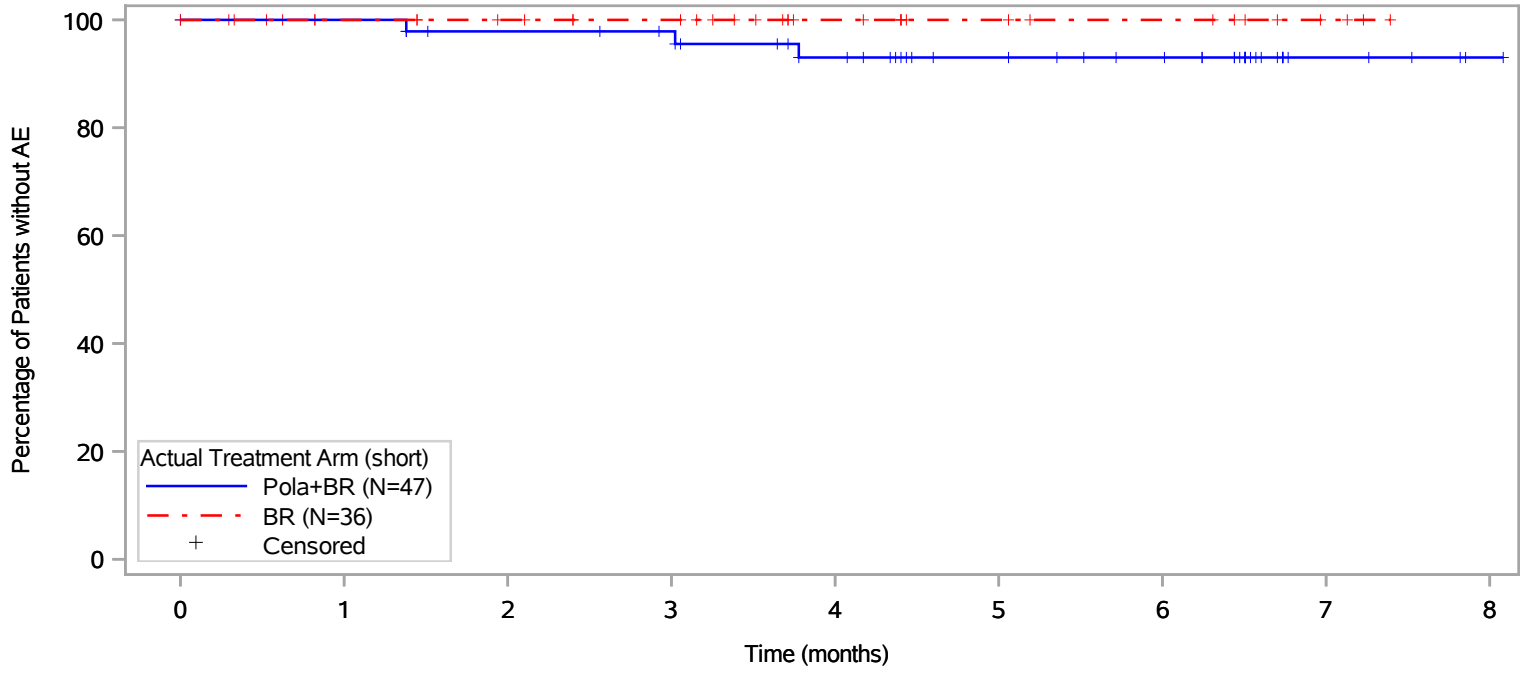
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION



Patients at risk									
Pola+BR (N=47)	47	47	44	42	37	29	25	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	39	43
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			47	100.0	24	51.1	23	48.9	36	100.0	15	41.7	21	58.3	0.8947	1.16	0.60	2.24		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		47	100.0	13	27.7	34	72.3	36	100.0	5	13.9	31	86.1	0.3468	1.65	0.58	4.69		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		47	100.0	2	4.3	45	95.7	36	100.0	2	5.6	34	94.4	0.3862	0.48	0.06	3.61		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		47	100.0	3	6.4	44	93.6	36	100.0	1	2.8	35	97.2	0.5360	2.45	0.25	23.66		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2410	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		47	100.0	12	25.5	35	74.5	36	100.0	7	19.4	29	80.6	0.7476	1.40	0.55	3.62		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4302	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		47	100.0	9	19.1	38	80.9	36	100.0	3	8.3	33	91.7	0.3458	2.21	0.60	8.19		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.7329	1.54	0.14	17.41		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FLUTTER		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2134	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			47	100.0	9	19.1	38	80.9	36	100.0	4	11.1	32	88.9	0.6368	1.48	0.45	4.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		47	100.0	3	6.4	44	93.6	36	100.0	1	2.8	35	97.2	0.6110	1.88	0.19	18.26		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3310	0.39	0.04	4.34		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4960	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ILEUS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4472	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.8283	1.55	0.14	17.53		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7135	0.68	0.04	11.35		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			47	100.0	9	19.1	38	80.9	36	100.0	6	16.7	30	83.3	0.2791	0.54	0.17	1.69		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2327	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		47	100.0	4	8.5	43	91.5	36	100.0	1	2.8	35	97.2	0.3797	2.46	0.27	22.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.6230	0.47	0.03	8.04		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UROSEPSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INVESTIGATIONS			47	100.0	14	29.8	33	70.2	36	100.0	5	13.9	31	86.1	0.3090	1.24	0.43	3.59		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PRESSURE INCREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	FIBRIN D DIMER INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	HAEMOGLOBIN DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		47	100.0	6	12.8	41	87.2	36	100.0	5	13.9	31	86.1	0.7014	0.51	0.14	1.81		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MORAXELLA TEST POSITIVE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		47	100.0	10	21.3	37	78.7	36	100.0	2	5.6	34	94.4	0.2061	2.27	0.50	10.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NITRITE URINE PRESENT		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		47	100.0	3	6.4	44	93.6	36	100.0	1	2.8	35	97.2	0.5850	1.76	0.18	17.12		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		47	100.0	7	14.9	40	85.1	36	100.0	1	2.8	35	97.2	0.2001	3.47	0.43	28.21		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			47	100.0	7	14.9	40	85.1	36	100.0	2	5.6	34	94.4	0.2495	2.24	0.46	10.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		47	100.0	7	14.9	40	85.1	36	100.0	1	2.8	35	97.2	0.1006	4.35	0.53	35.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7659	0.78	0.05	12.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3427	0.33	0.03	3.71		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7658	0.77	0.05	12.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7123	0.71	0.04	11.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SYNCOPE		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7123	0.71	0.04	11.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.6161	0.48	0.03	7.93		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HAEMATURIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	2	5.6	34	94.4	0.6028	0.62	0.09	4.48		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0732	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3684	0.43	0.04	4.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		47	100.0	0	-	47	100.0	36	100.0	2	5.6	34	94.4	0.0933	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			47	100.0	4	8.5	43	91.5	36	100.0	0	-	36	100.0	0.1338	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		47	100.0	3	6.4	44	93.6	36	100.0	0	-	36	100.0	0.2062	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 20:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	29	61.7	16	55.2	13	44.8	20	55.6	8	40.0	12	60.0	0.6247	1.54	0.64	3.68		Convergence criterion (GCONV=1E-8) satisfied.	0.2679
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	18	38.3	8	44.4	10	55.6	16	44.4	7	43.8	9	56.3	0.6593	0.77	0.27	2.17		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	29	61.7	10	34.5	19	65.5	20	55.6	3	15.0	17	85.0	0.2391	2.22	0.60	8.20		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	2	12.5	14	87.5	0.7432	0.73	0.10	5.22		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.2023	0.28	0.02	3.25		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	1	5.0	19	95.0	0.8223	1.88	0.17	20.82		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	29	61.7	8	27.6	21	72.4	20	55.6	4	20.0	16	80.0	0.6536	1.88	0.55	6.39		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	18	38.3	4	22.2	14	77.8	16	44.4	3	18.8	13	81.3	0.9874	0.97	0.21	4.40		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	29	61.7	5	17.2	24	82.8	20	55.6	2	10.0	18	90.0	0.6405	2.04	0.40	10.56		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	18	38.3	4	22.2	14	77.8	16	44.4	1	6.3	15	93.8	0.3333	2.76	0.31	24.74		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7774	0.65	0.04	10.94		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	29	61.7	6	20.7	23	79.3	20	55.6	1	5.0	19	95.0	0.1982	4.59	0.54	38.83		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	18	38.3	3	16.7	15	83.3	16	44.4	3	18.8	13	81.3	0.6162	0.61	0.12	3.06		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.7264	0.58	0.04	9.30		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	18	38.3	0	-	18	100.0	16	44.4	2	12.5	14	87.5	0.1005	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4720	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7774	0.96	0.06	15.37		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	29	61.7	4	13.8	25	86.2	20	55.6	1	5.0	19	95.0	0.5619	1.83	0.20	16.85		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	18	38.3	5	27.8	13	72.2	16	44.4	5	31.3	11	68.8	0.0757	0.25	0.05	1.31		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2568	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2947	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.6611	1.88	0.17	21.09		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	29	61.7	10	34.5	19	65.5	20	55.6	2	10.0	18	90.0	0.0841	2.60	0.55	12.28		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	18	38.3	4	22.2	14	77.8	16	44.4	3	18.8	13	81.3	0.4168	0.32	0.05	1.94		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1644	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2733	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	29	61.7	5	17.2	24	82.8	20	55.6	2	10.0	18	90.0	0.4552	1.26	0.23	6.96		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	3	18.8	13	81.3	0.0956	0.08	0.00	1.39		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	MORAXELLA TEST POSITIVE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	29	61.7	9	31.0	20	69.0	20	55.6	1	5.0	19	95.0	0.1249	3.64	0.46	28.92		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.6009	0.71	0.04	11.79		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5982	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2824	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.7646	0.65	0.04	10.47		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	29	61.7	6	20.7	23	79.3	20	55.6	0	-	20	100.0	0.0955	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.6457	0.68	0.04	11.61		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	29	61.7	6	20.7	23	79.3	20	55.6	2	10.0	18	90.0	0.4063	1.80	0.36	9.09		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	29	61.7	6	20.7	23	79.3	20	55.6	1	5.0	19	95.0	0.1794	3.39	0.40	28.57		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7729	0.65	0.04	10.94		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6653	0.78	0.05	12.57		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6653	0.78	0.05	12.57		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.2147	0.26	0.02	2.96		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	29	61.7	0	-	29	100.0	20	55.6	2	10.0	18	90.0	0.0504	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	2	12.5	14	87.5	0.4028	0.38	0.03	4.22		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	18	38.3	0	-	18	100.0	16	44.4	2	12.5	14	87.5	0.1063	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3309	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2446	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3309	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 20:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	29	61.7	14	48.3	15	51.7	24	66.7	10	41.7	14	58.3	0.6451	0.94	0.40	2.19		Convergence criterion (GCONV=1E-8) satisfied.	0.6158
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	18	38.3	10	55.6	8	44.4	12	33.3	5	41.7	7	58.3	0.5000	1.44	0.48	4.29		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	29	61.7	8	27.6	21	72.4	24	66.7	3	12.5	21	87.5	0.4958	1.50	0.39	5.80		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	18	38.3	5	27.8	13	72.2	12	33.3	2	16.7	10	83.3	0.5311	1.67	0.32	8.66		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.4713	0.42	0.02	7.28		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.6862	0.55	0.03	8.90		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7987	0.96	0.06	15.35		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2558	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.2307	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	29	61.7	5	17.2	24	82.8	24	66.7	6	25.0	18	75.0	0.2527	0.59	0.18	2.01		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	18	38.3	7	38.9	11	61.1	12	33.3	1	8.3	11	91.7	0.0704	6.44	0.79	52.73		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4275	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	29	61.7	5	17.2	24	82.8	24	66.7	1	4.2	23	95.8	0.2605	4.40	0.51	38.13		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	18	38.3	4	22.2	14	77.8	12	33.3	2	16.7	10	83.3	0.8768	1.12	0.20	6.12		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.6878	1.76	0.15	20.44		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2509	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.1943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	29	61.7	6	20.7	23	79.3	24	66.7	3	12.5	21	87.5	0.8713	1.31	0.32	5.39		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	18	38.3	3	16.7	15	83.3	12	33.3	1	8.3	11	91.7	0.6166	1.75	0.18	16.90		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	29	61.7	3	10.3	26	89.7	24	66.7	1	4.2	23	95.8	0.6208	1.98	0.20	19.52		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.7489	0.65	0.04	10.45		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.8135	1.81	0.16	20.74		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7077	0.74	0.04	12.88		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	29	61.7	6	20.7	23	79.3	24	66.7	3	12.5	21	87.5	0.7329	0.68	0.15	3.14		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	18	38.3	3	16.7	15	83.3	12	33.3	3	25.0	9	75.0	0.1761	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.7673	1.13	0.10	13.15		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2745	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.6524	0.48	0.03	8.48		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	29	61.7	10	34.5	19	65.5	24	66.7	2	8.3	22	91.7	0.1298	1.82	0.37	8.86		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	18	38.3	4	22.2	14	77.8	12	33.3	3	25.0	9	75.0	0.8015	1.02	0.22	4.63		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	29	61.7	4	13.8	25	86.2	24	66.7	2	8.3	22	91.7	0.6890	0.68	0.11	4.27		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	18	38.3	2	11.1	16	88.9	12	33.3	3	25.0	9	75.0	0.3165	0.45	0.08	2.73		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	MORAXELLA TEST POSITIVE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	29	61.7	6	20.7	23	79.3	24	66.7	0	-	24	100.0	0.0846	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	18	38.3	4	22.2	14	77.8	12	33.3	2	16.7	10	83.3	0.9784	1.03	0.17	6.25		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	29	61.7	3	10.3	26	89.7	24	66.7	0	-	24	100.0	0.1618	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	29	61.7	4	13.8	25	86.2	24	66.7	0	-	24	100.0	0.1789	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	18	38.3	3	16.7	15	83.3	12	33.3	1	8.3	11	91.7	0.6602	1.99	0.20	19.30		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	29	61.7	4	13.8	25	86.2	24	66.7	1	4.2	23	95.8	0.3401	2.44	0.27	22.47		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	18	38.3	3	16.7	15	83.3	12	33.3	1	8.3	11	91.7	0.5425	2.00	0.21	19.24		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	29	61.7	4	13.8	25	86.2	24	66.7	0	-	24	100.0	0.0971	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	18	38.3	3	16.7	15	83.3	12	33.3	1	8.3	11	91.7	0.5425	2.00	0.21	19.24		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7761	0.89	0.06	14.36		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.8013	0.64	0.04	10.89		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.8480	1.35	0.12	15.66		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.7887	0.72	0.05	11.53		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.3190	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2735	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2735	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 20:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	19.1	4	44.4	5	55.6	13	36.1	5	38.5	8	61.5	0.6731	0.75	0.20	2.84		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	38	80.9	20	52.6	18	47.4	23	63.9	10	43.5	13	56.5	0.7643	1.22	0.56	2.64		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	38	80.9	12	31.6	26	68.4	23	63.9	5	21.7	18	78.3	0.6301	1.32	0.46	3.77		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	2	8.7	21	91.3	0.3101	0.39	0.05	2.83		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	1	4.3	22	95.7	0.6699	1.87	0.19	18.11		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2901	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	19.1	2	22.2	7	77.8	13	36.1	3	23.1	10	76.9	0.6746	0.68	0.11	4.18		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	38	80.9	10	26.3	28	73.7	23	63.9	4	17.4	19	82.6	0.5473	1.70	0.53	5.52		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	19.1	2	22.2	7	77.8	13	36.1	1	7.7	12	92.3	0.4861	2.29	0.21	25.40		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	2	8.7	21	91.3	0.4745	1.93	0.40	9.38		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.7077	0.58	0.04	9.41		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	9	19.1	3	33.3	6	66.7	13	36.1	2	15.4	11	84.6	0.6289	1.55	0.26	9.40		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	38	80.9	6	15.8	32	84.2	23	63.9	2	8.7	21	91.3	0.6848	1.47	0.29	7.49		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	0	-	23	100.0	0.2249	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.8671	1.27	0.08	20.38		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1391	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5734	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5734	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	19.1	3	33.3	6	66.7	13	36.1	4	30.8	9	69.2	0.1569	0.23	0.02	2.10		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	38	80.9	6	15.8	32	84.2	23	63.9	2	8.7	21	91.3	0.9423	1.04	0.20	5.50		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	1	4.3	22	95.7	0.7945	1.29	0.13	13.01		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	38	80.9	14	36.8	24	63.2	23	63.9	5	21.7	18	78.3	0.5986	1.19	0.41	3.45		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	38	80.9	6	15.8	32	84.2	23	63.9	5	21.7	18	78.3	0.4203	0.49	0.14	1.75		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	MORAXELLA TEST POSITIVE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	38	80.9	10	26.3	28	73.7	23	63.9	2	8.7	21	91.3	0.3208	2.27	0.50	10.40		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	1	4.3	22	95.7	0.7062	1.54	0.16	14.80		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	1	4.3	22	95.7	0.2713	3.35	0.41	27.27		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	2	8.7	21	91.3	0.3909	1.94	0.40	9.39		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	1	4.3	22	95.7	0.1661	3.85	0.47	31.34		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6437	0.58	0.04	9.24		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	2	8.7	21	91.3	0.2622	0.29	0.03	3.21		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6795	0.64	0.04	10.22		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6148	0.57	0.04	9.12		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6148	0.57	0.04	9.12		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	2	8.7	21	91.3	0.4537	0.49	0.07	3.53		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	2	8.7	21	91.3	0.0444	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.8671	1.27	0.08	20.38		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	0	-	23	100.0	0.1665	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	0	-	23	100.0	0.2410	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 20:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	34	72.3	15	44.1	19	55.9	24	66.7	10	41.7	14	58.3	0.5351	0.89	0.39	2.02		Convergence criterion (GCONV=1E-8) satisfied.	0.2241
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	13	27.7	9	69.2	4	30.8	12	33.3	5	41.7	7	58.3	0.2152	1.99	0.66	5.99		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	34	72.3	7	20.6	27	79.4	24	66.7	5	20.8	19	79.2	0.5189	0.72	0.22	2.33		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	13	27.7	6	46.2	7	53.8	12	33.3	0	-	12	100.0	0.0165	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.1479	0.23	0.02	2.76		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.5863	2.32	0.24	22.47		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.2519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	34	72.3	7	20.6	27	79.4	24	66.7	4	16.7	20	83.3	0.9259	1.36	0.39	4.74		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	13	27.7	5	38.5	8	61.5	12	33.3	3	25.0	9	75.0	0.6351	1.52	0.36	6.43		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4363	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	34	72.3	4	11.8	30	88.2	24	66.7	2	8.3	22	91.7	0.8742	1.38	0.25	7.65		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	13	27.7	5	38.5	8	61.5	12	33.3	1	8.3	11	91.7	0.2118	4.12	0.48	35.33		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.9304	0.80	0.05	13.13		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	34	72.3	7	20.6	27	79.4	24	66.7	4	16.7	20	83.3	0.9382	1.07	0.31	3.72		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2335	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8450	1.30	0.12	14.57		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.3002	0.38	0.03	4.21		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1510	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8510	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8510	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	34	72.3	8	23.5	26	76.5	24	66.7	4	16.7	20	83.3	0.3469	0.53	0.14	2.02		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	13	27.7	1	7.7	12	92.3	12	33.3	2	16.7	10	83.3	0.4626	0.41	0.04	4.62		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.7009	1.63	0.17	16.03		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	34	72.3	13	38.2	21	61.8	24	66.7	3	12.5	21	87.5	0.1641	1.87	0.51	6.85		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	13	27.7	1	7.7	12	92.3	12	33.3	2	16.7	10	83.3	0.4430	0.18	0.01	2.46		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	34	72.3	6	17.6	28	82.4	24	66.7	3	12.5	21	87.5	0.7886	0.85	0.19	3.67		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	2	16.7	10	83.3	0.1231	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	MORAXELLA TEST POSITIVE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	34	72.3	9	26.5	25	73.5	24	66.7	2	8.3	22	91.7	0.4568	1.03	0.21	5.05		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.6165	1.65	0.17	16.14		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	34	72.3	7	20.6	27	79.4	24	66.7	1	4.2	23	95.8	0.2629	2.95	0.36	24.06		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	34	72.3	3	8.8	31	91.2	24	66.7	2	8.3	22	91.7	0.9485	0.92	0.15	5.59		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	13	27.7	4	30.8	9	69.2	12	33.3	0	-	12	100.0	0.0669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	34	72.3	3	8.8	31	91.2	24	66.7	1	4.2	23	95.8	0.5049	1.69	0.17	16.49		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	13	27.7	4	30.8	9	69.2	12	33.3	0	-	12	100.0	0.0669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.3367	0.32	0.03	3.66		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.7591	0.79	0.05	12.67		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.6823	0.71	0.04	11.32		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.6823	0.71	0.04	11.32		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	13	27.7	2	15.4	11	84.6	12	33.3	1	8.3	11	91.7	0.7866	1.41	0.13	15.75		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.3502	0.42	0.04	4.67		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	34	72.3	0	-	34	100.0	24	66.7	2	8.3	22	91.7	0.0853	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.2264	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.2264	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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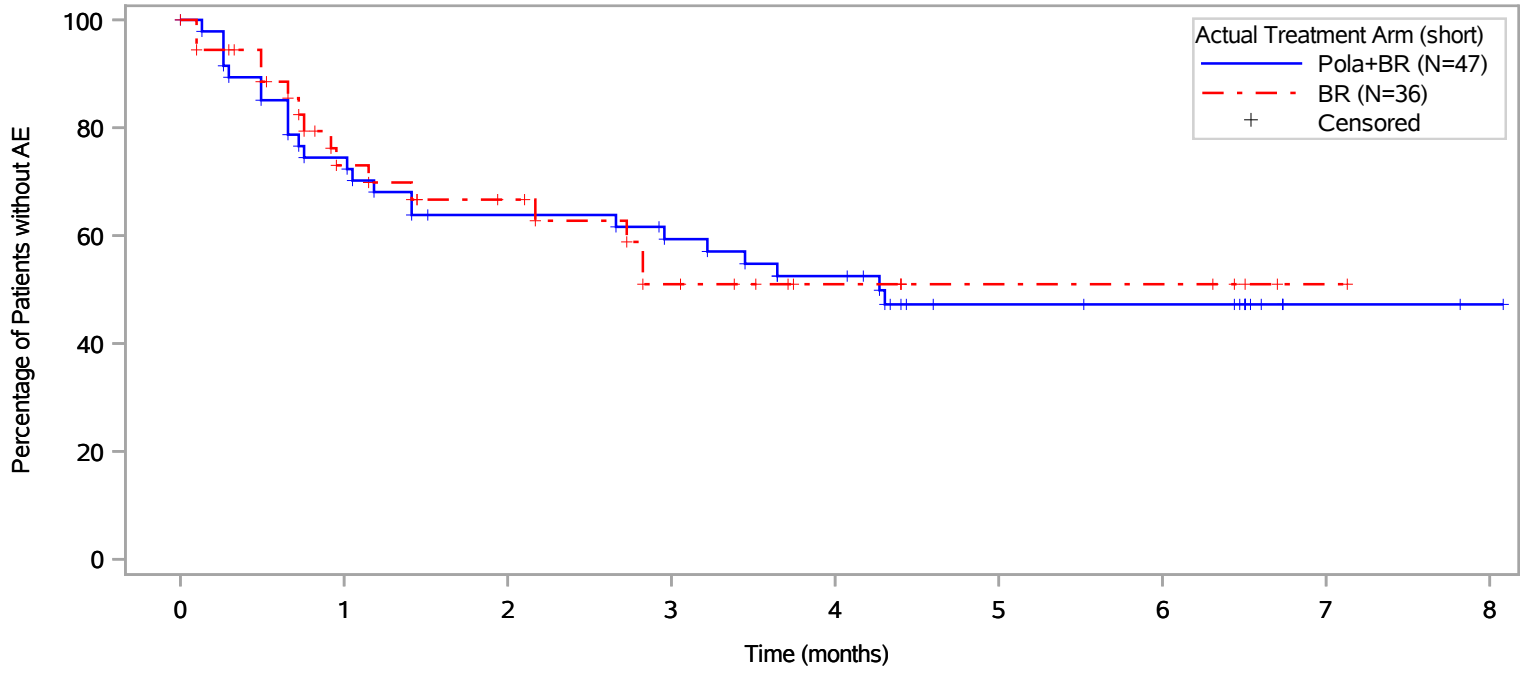
30NOV2022 20:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	35	29	26	22	14	13	2	1
BR (N=36)	36	23	18	13	8	5	5	1	NE
Patients censored									
Pola+BR (N=47)	0	0	1	2	3	9	10	21	22
BR (N=36)	0	4	7	8	13	16	16	20	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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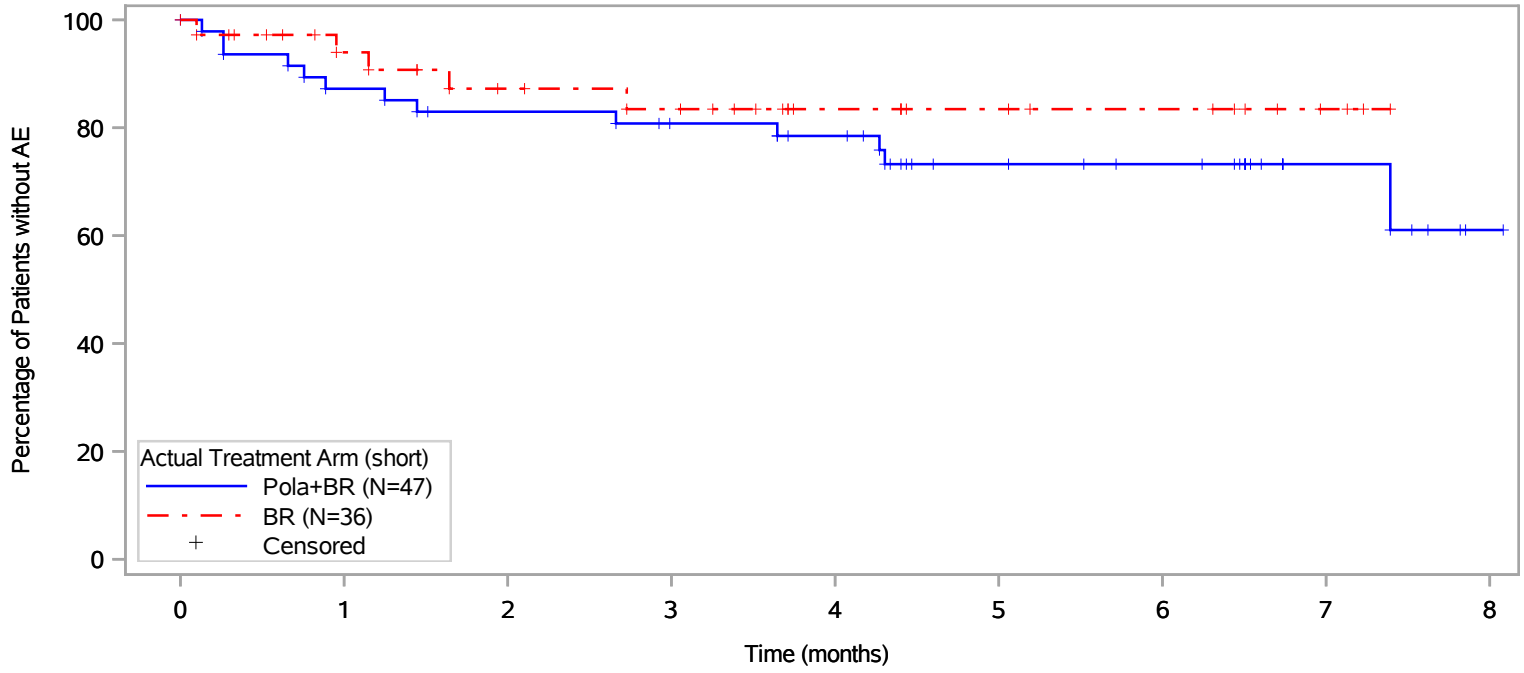
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA

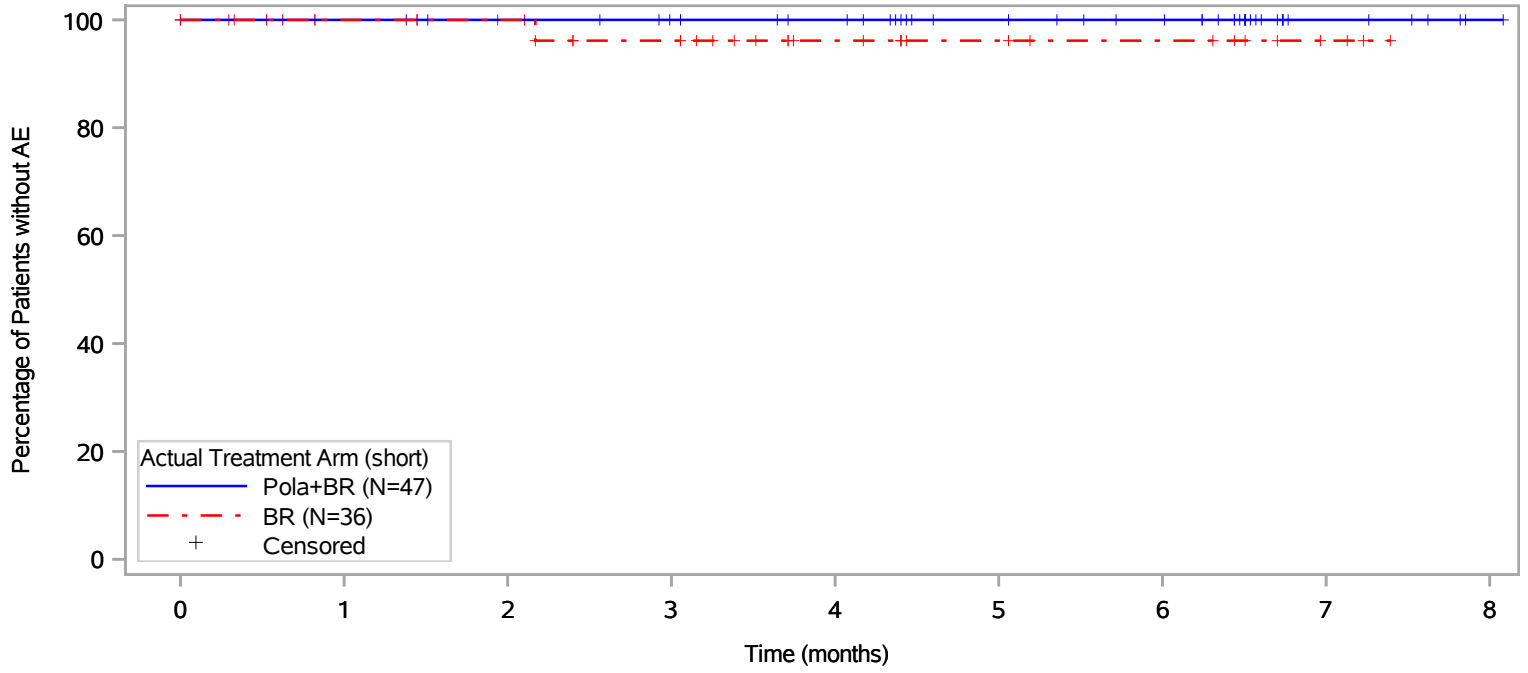


Patients at risk									
Pola+BR (N=47)	47	41	38	35	32	23	20	6	1
BR (N=36)	36	29	24	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	5	12	15	29	33
BR (N=36)	0	5	8	9	17	21	23	28	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE BONE MARROW APLASIA

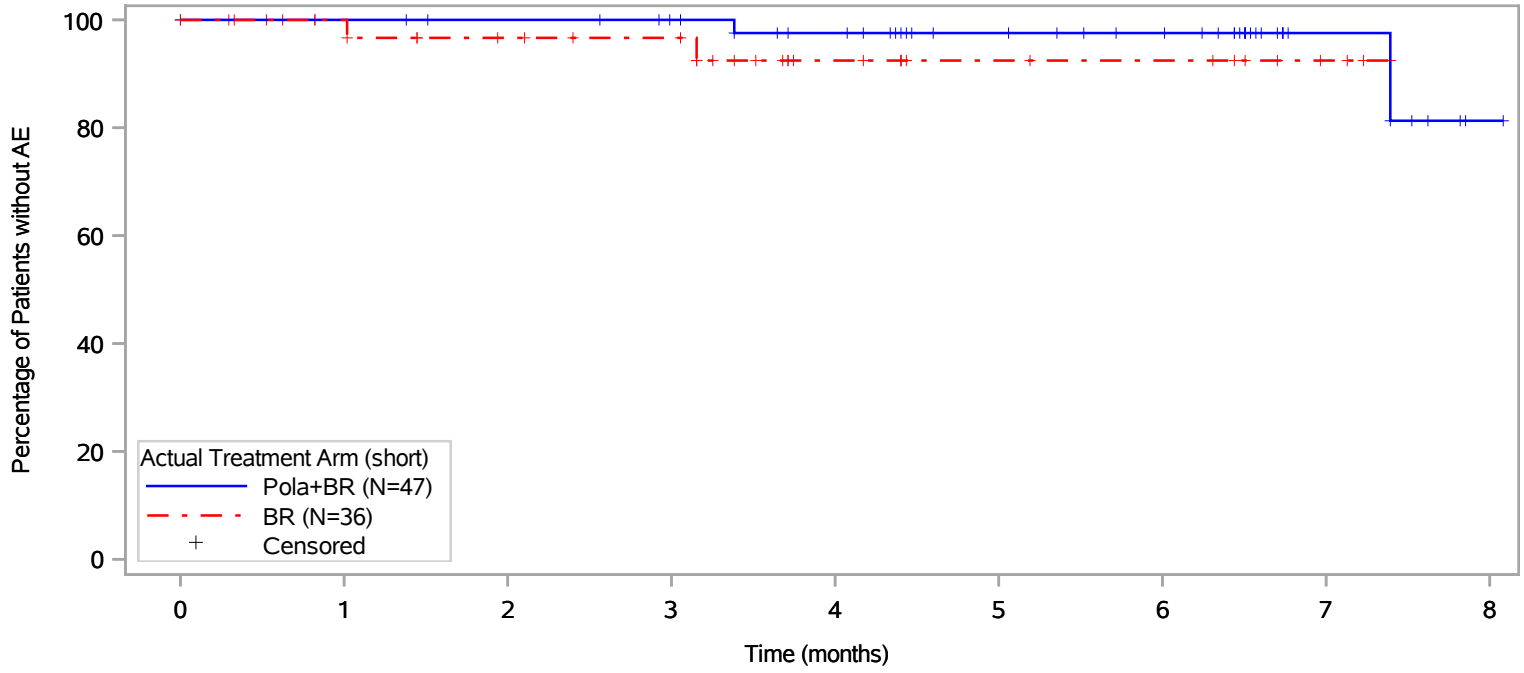


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	6	1
BR (N=36)	36	30	26	24	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	44
BR (N=36)	0	6	9	11	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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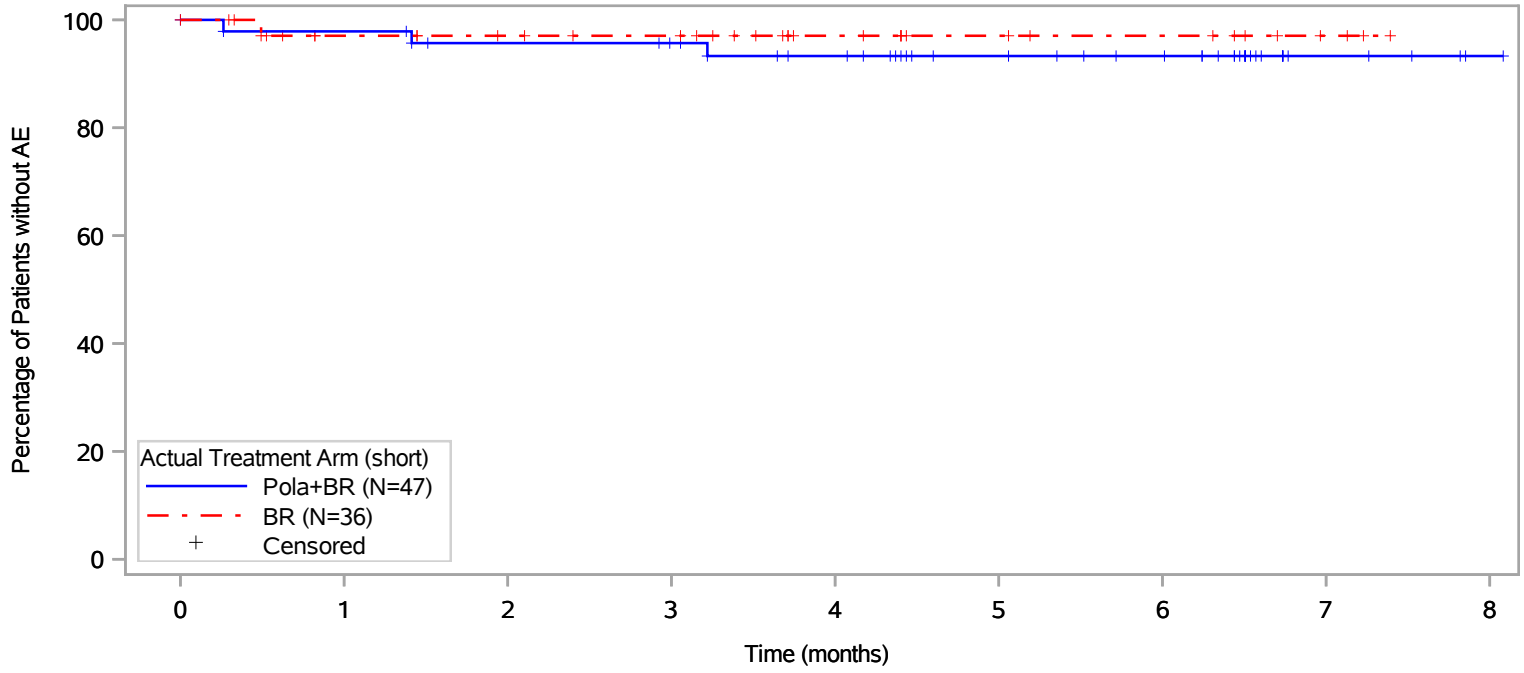
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=47)	47	46	43	41	37	29	25	5	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	39	43
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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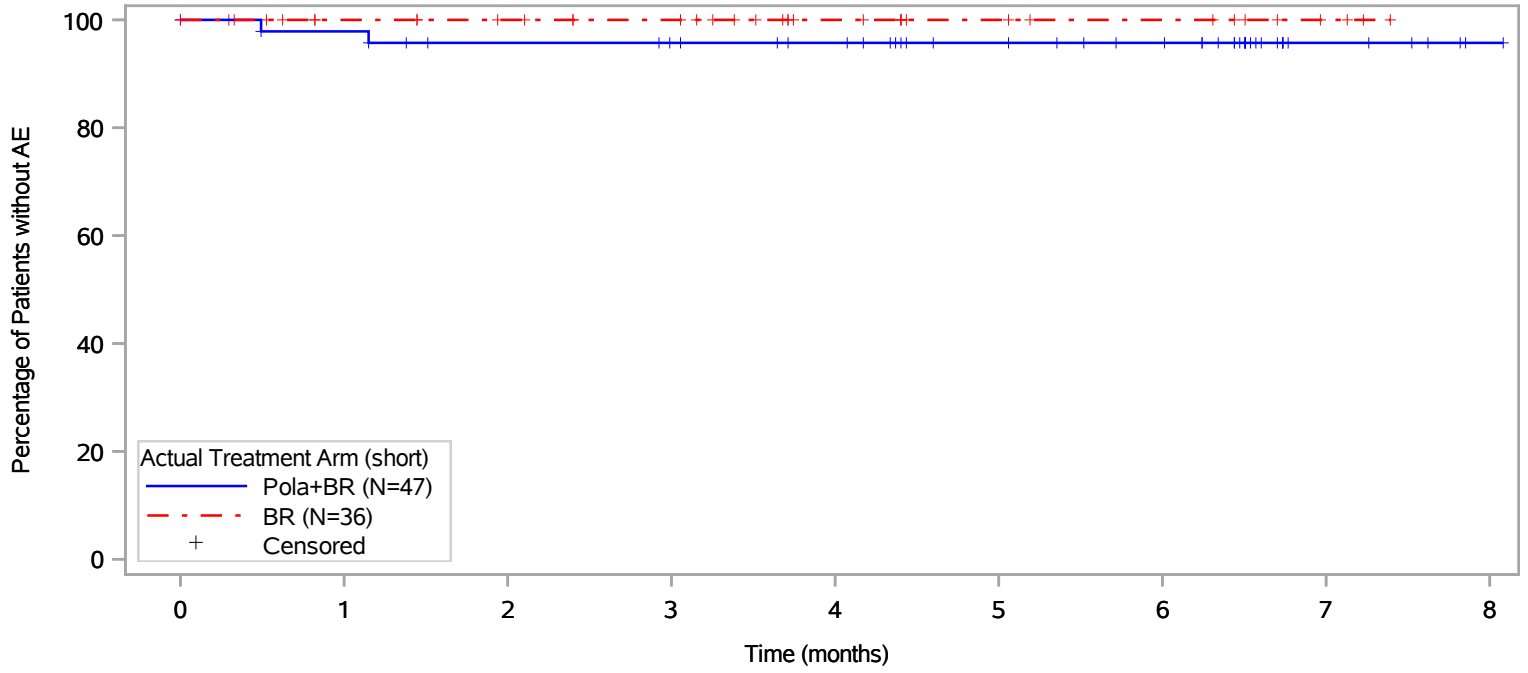
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA

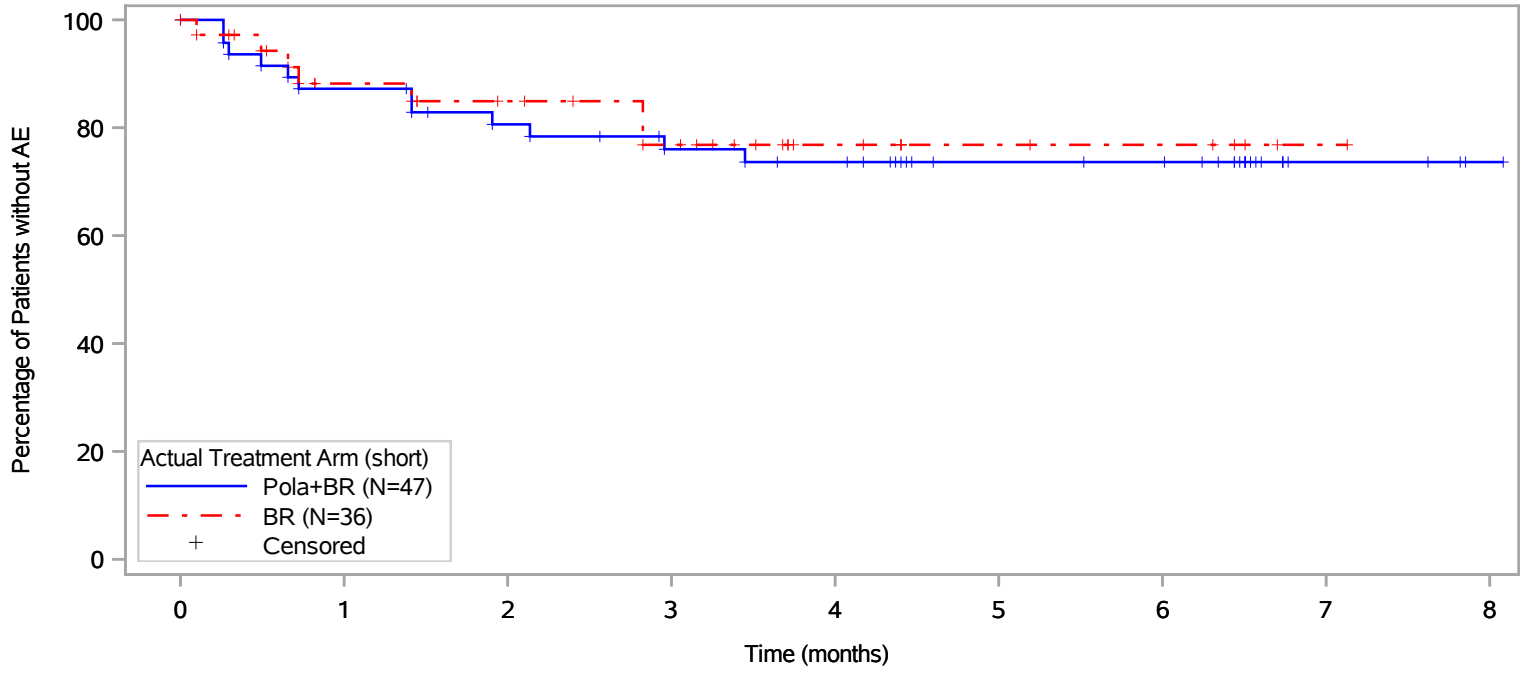


Patients at risk									
Pola+BR (N=47)	47	46	43	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	18	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk									
Pola+BR (N=47)	47	41	36	32	30	22	21	4	1
BR (N=36)	36	27	23	19	10	6	5	1	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	5	13	14	31	34
BR (N=36)	0	5	8	10	19	23	24	28	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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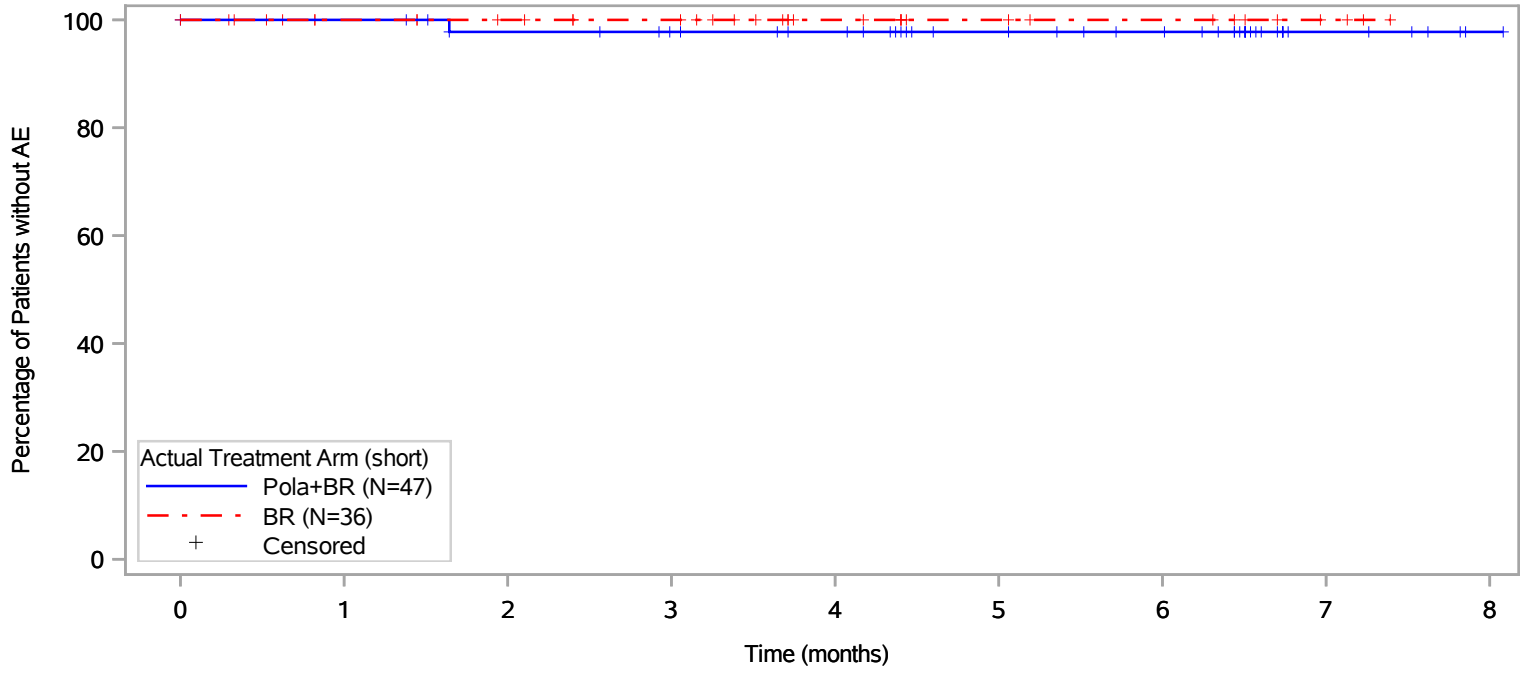
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA

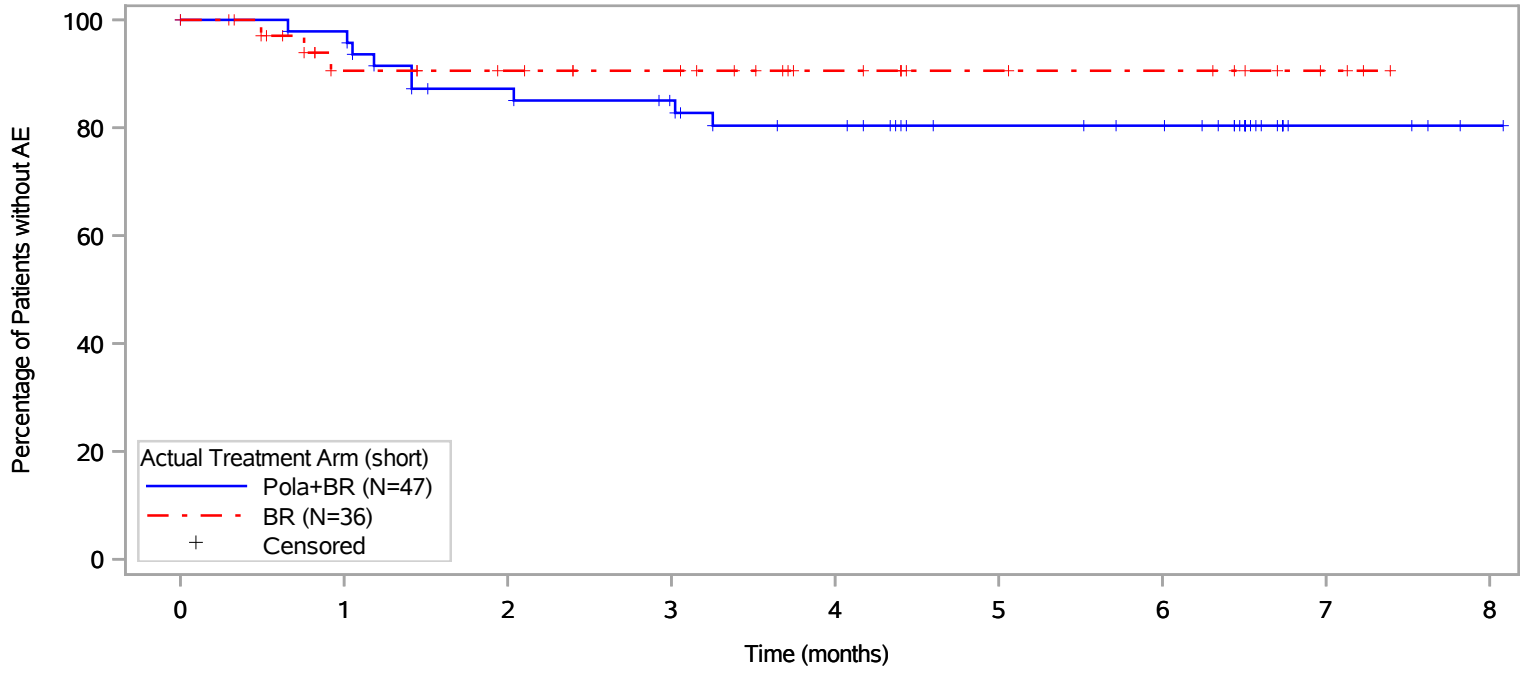


Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

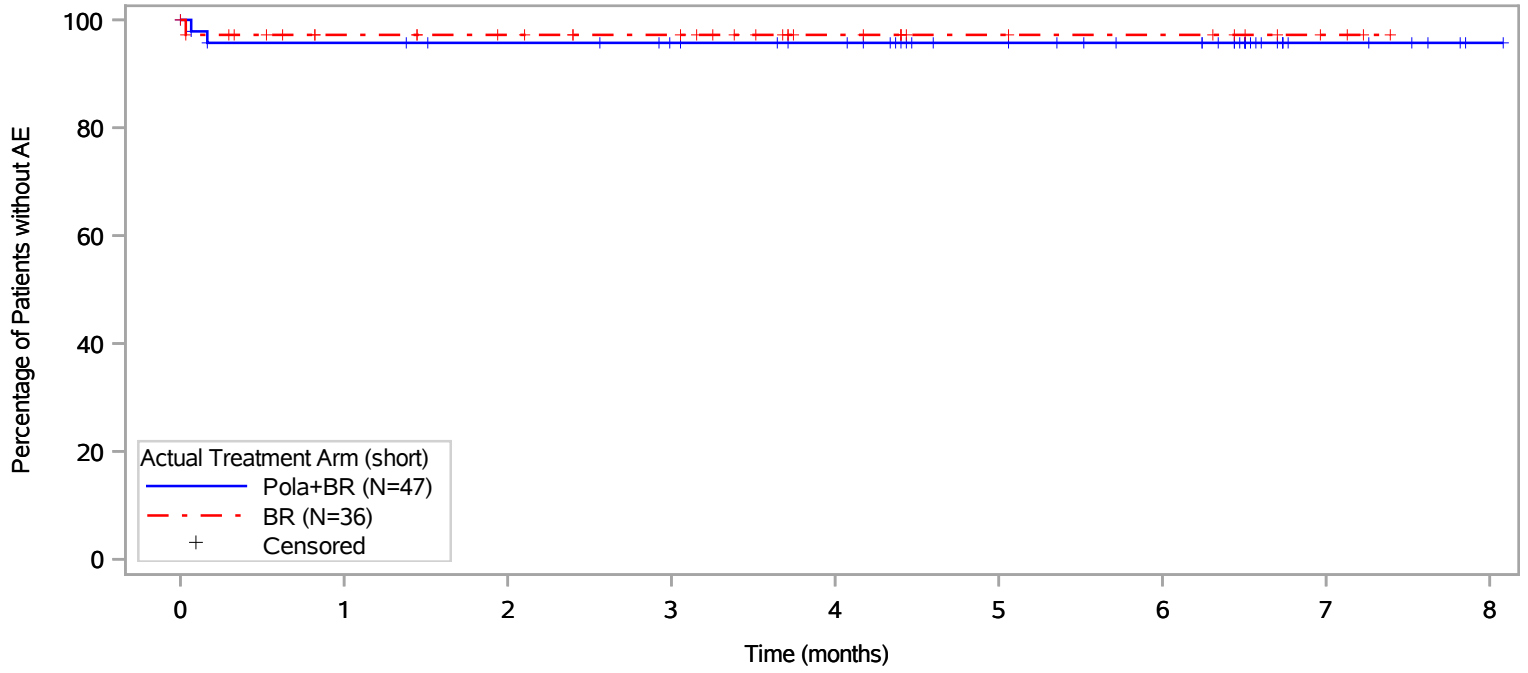
BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk									
Pola+BR (N=47)	47	46	40	37	33	26	24	4	1
BR (N=36)	36	27	24	21	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	5	12	14	34	37
BR (N=36)	0	6	9	12	19	24	25	30	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

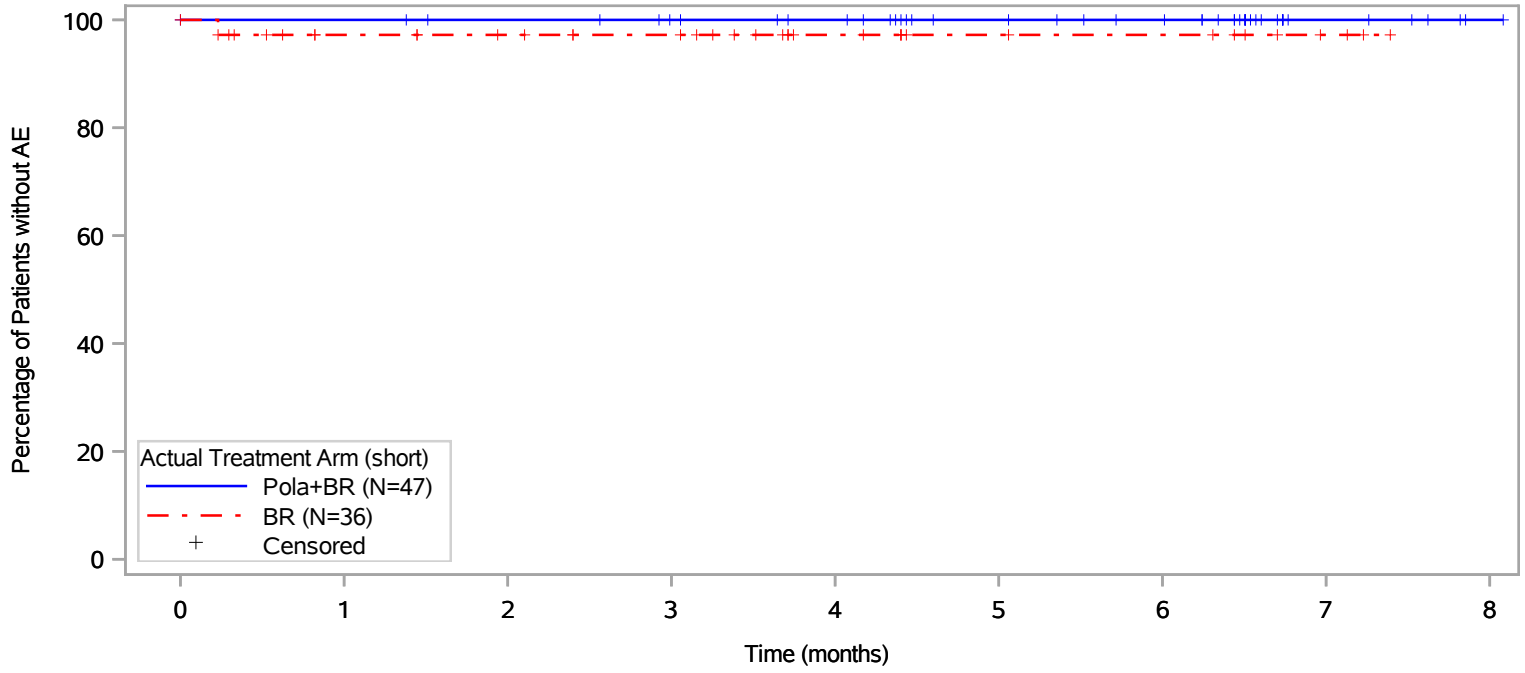
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	29	25	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

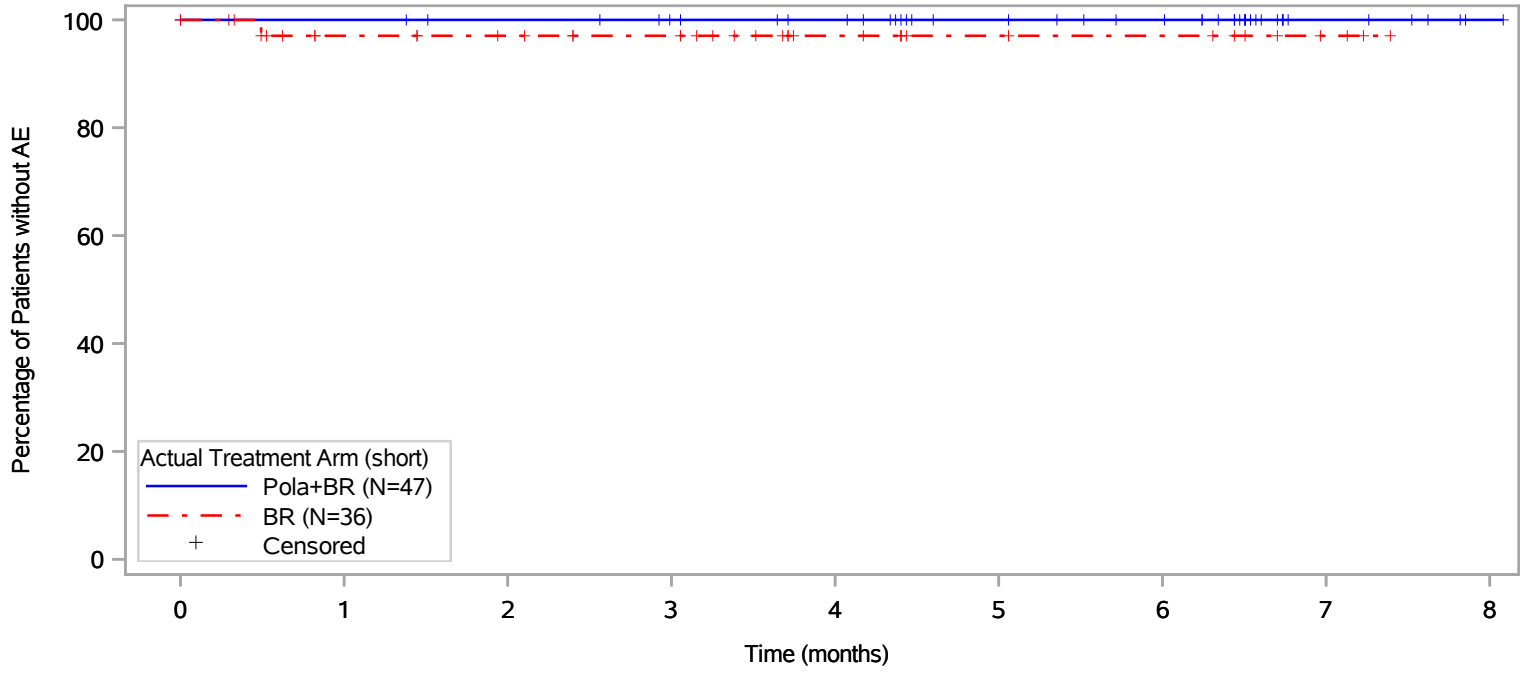
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FLUTTER



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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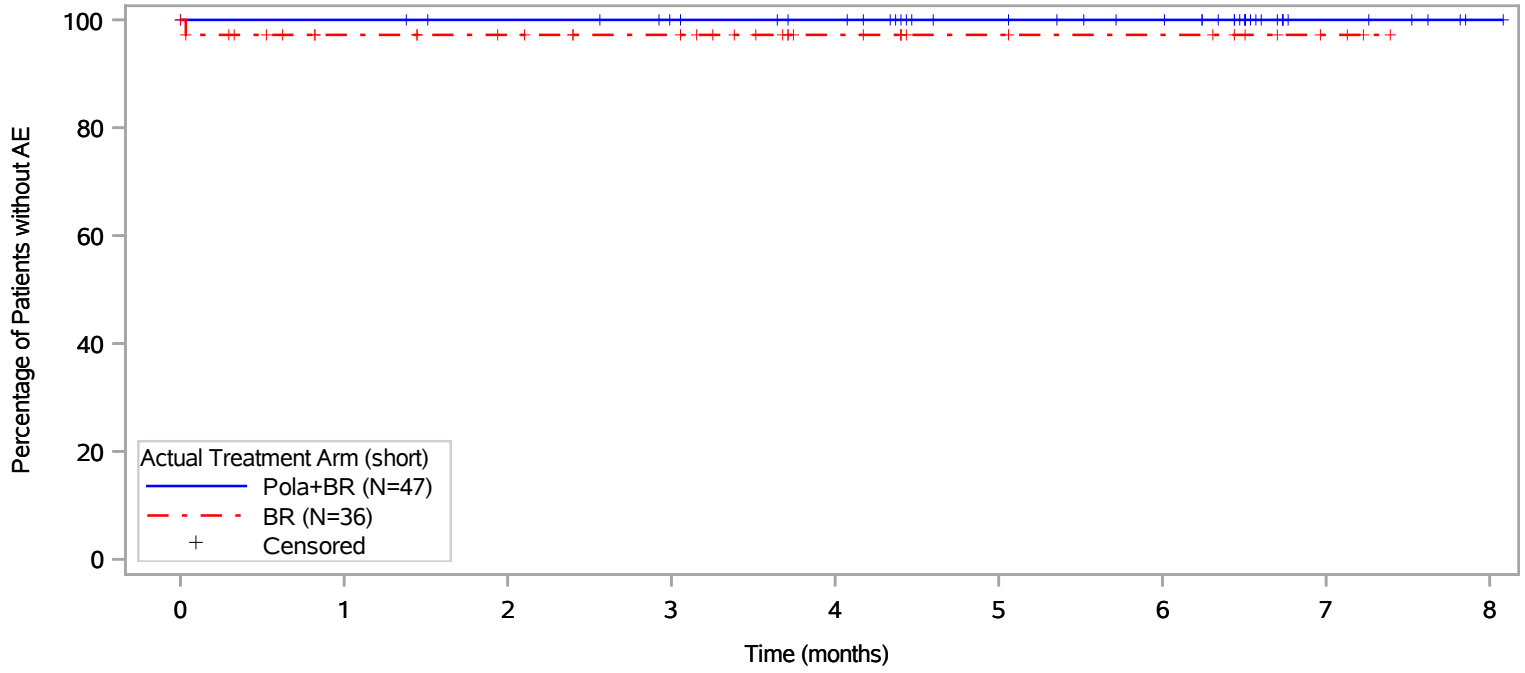
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SUPRAVENTRICULAR TACHYCARDIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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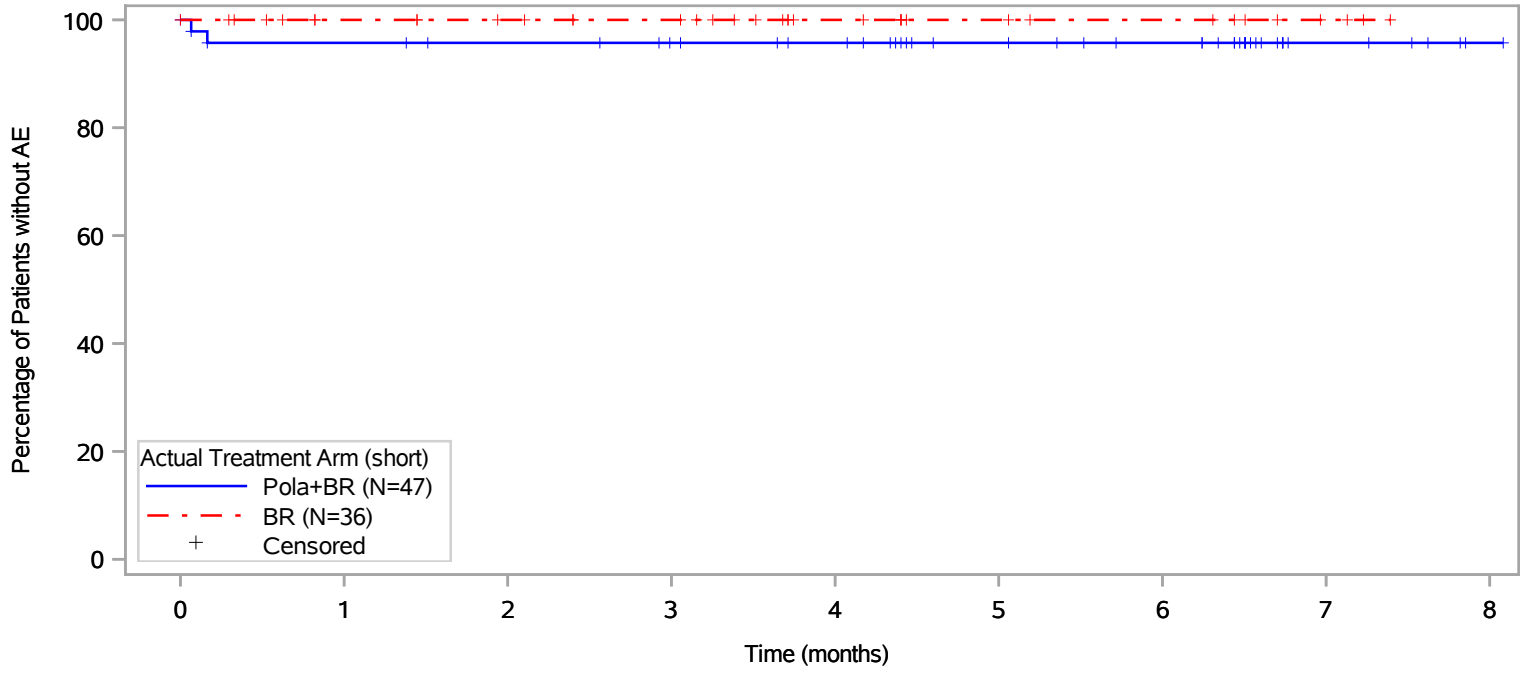
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	29	25	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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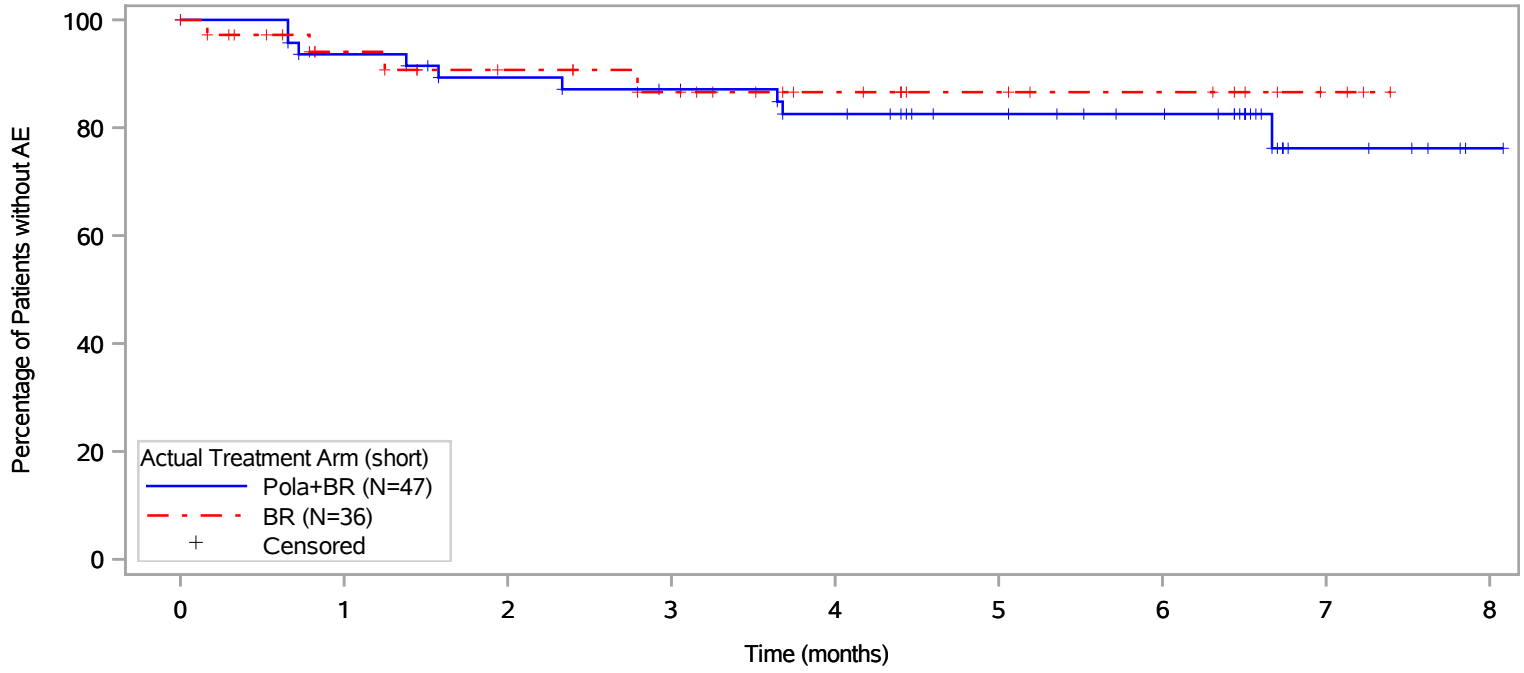
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	44	41	39	36	30	26	6	1
BR (N=36)	36	28	24	21	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	2	3	9	13	32	37
BR (N=36)	0	6	9	11	17	22	24	29	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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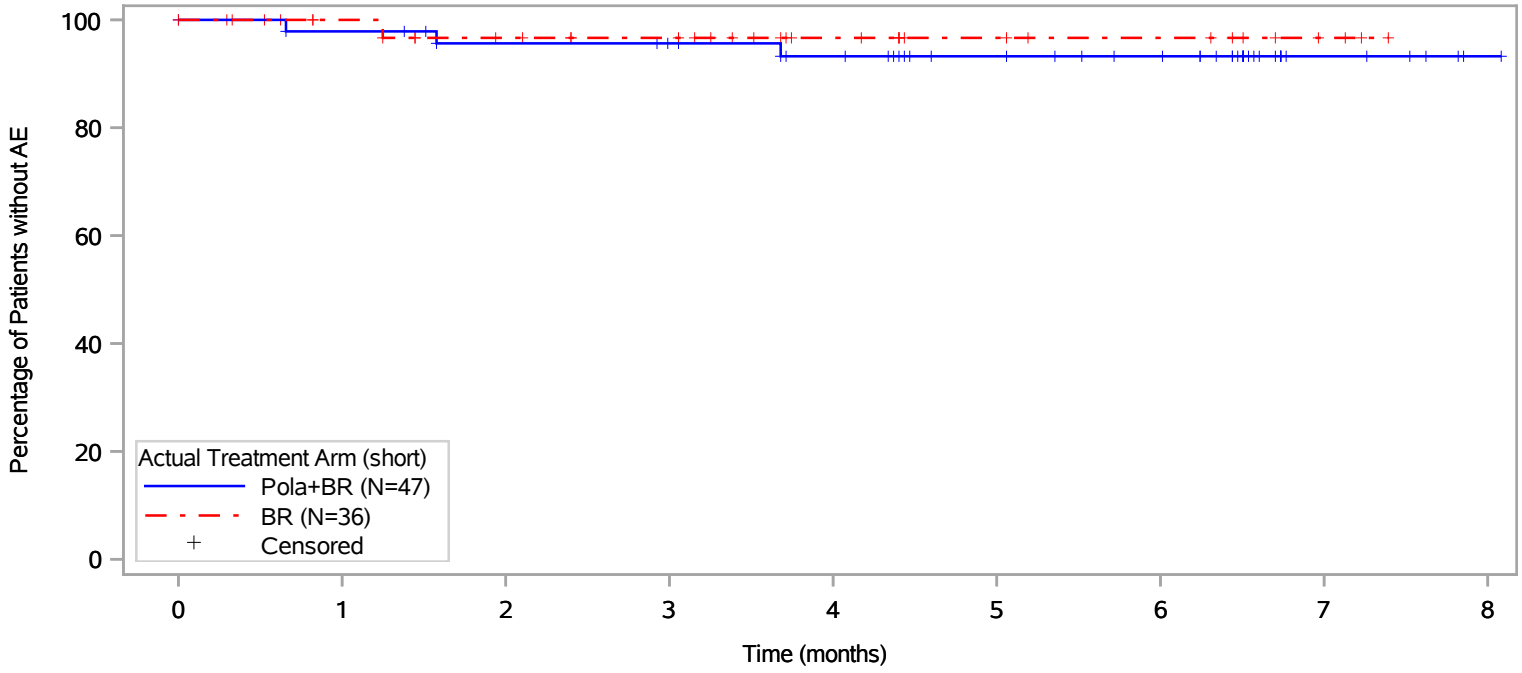
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=47)	47	46	43	41	38	31	27	6	1
BR (N=36)	36	30	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	6	13	17	38	43
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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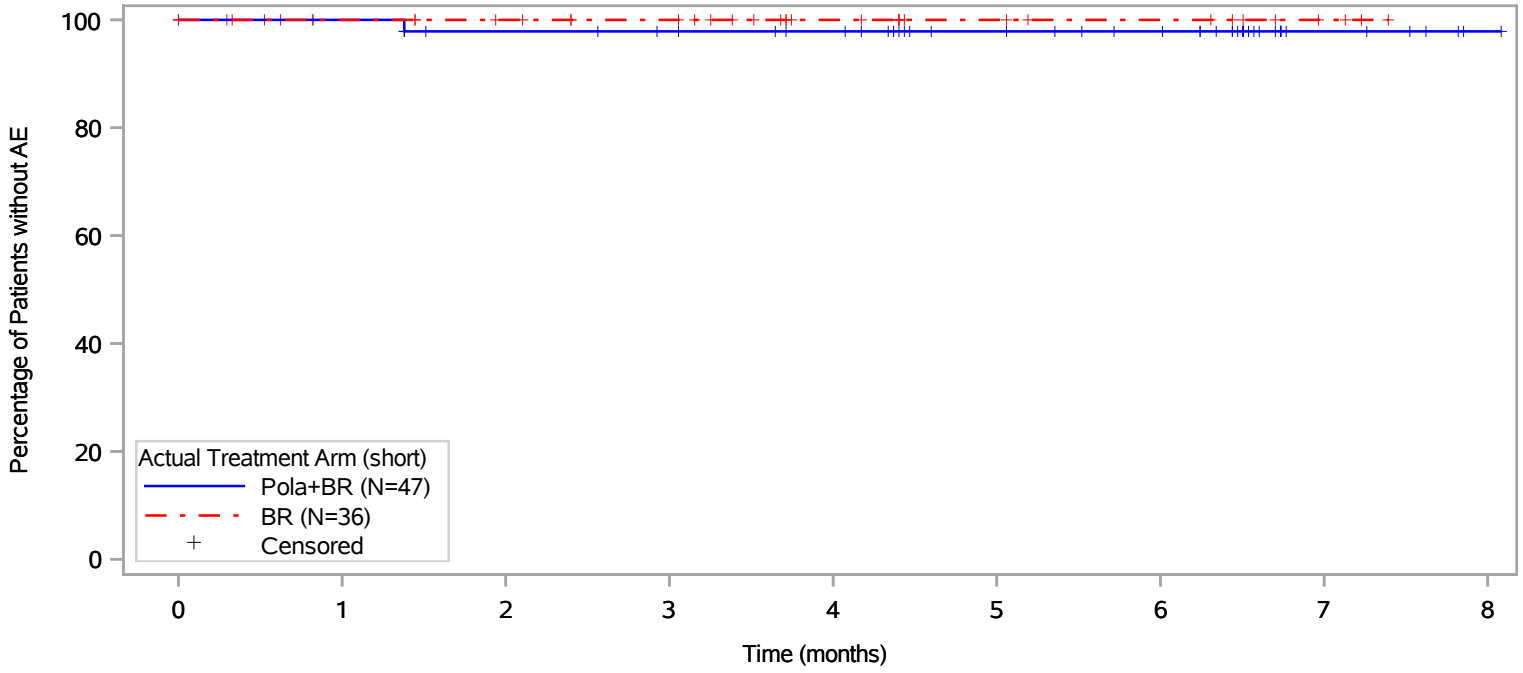
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN UPPER



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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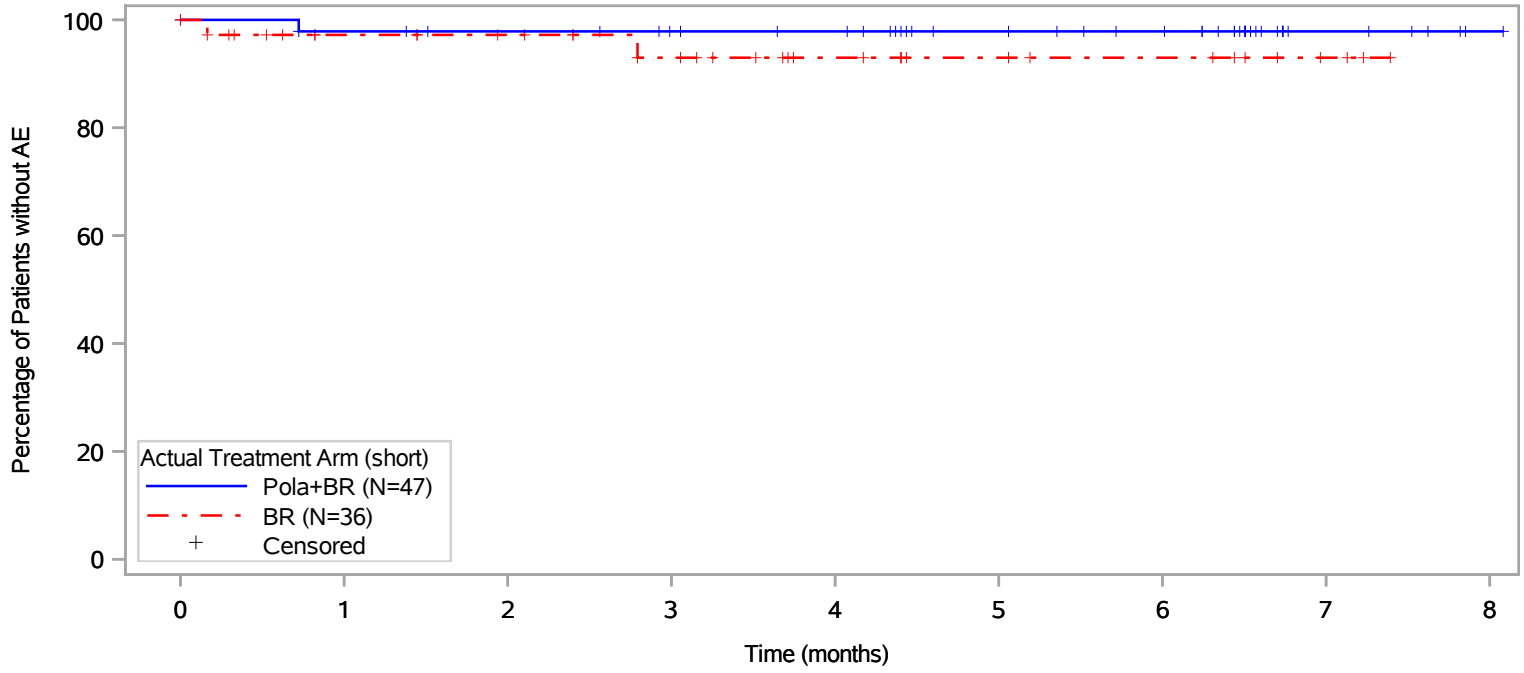
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	39	31	27	6	1
BR (N=36)	36	29	26	22	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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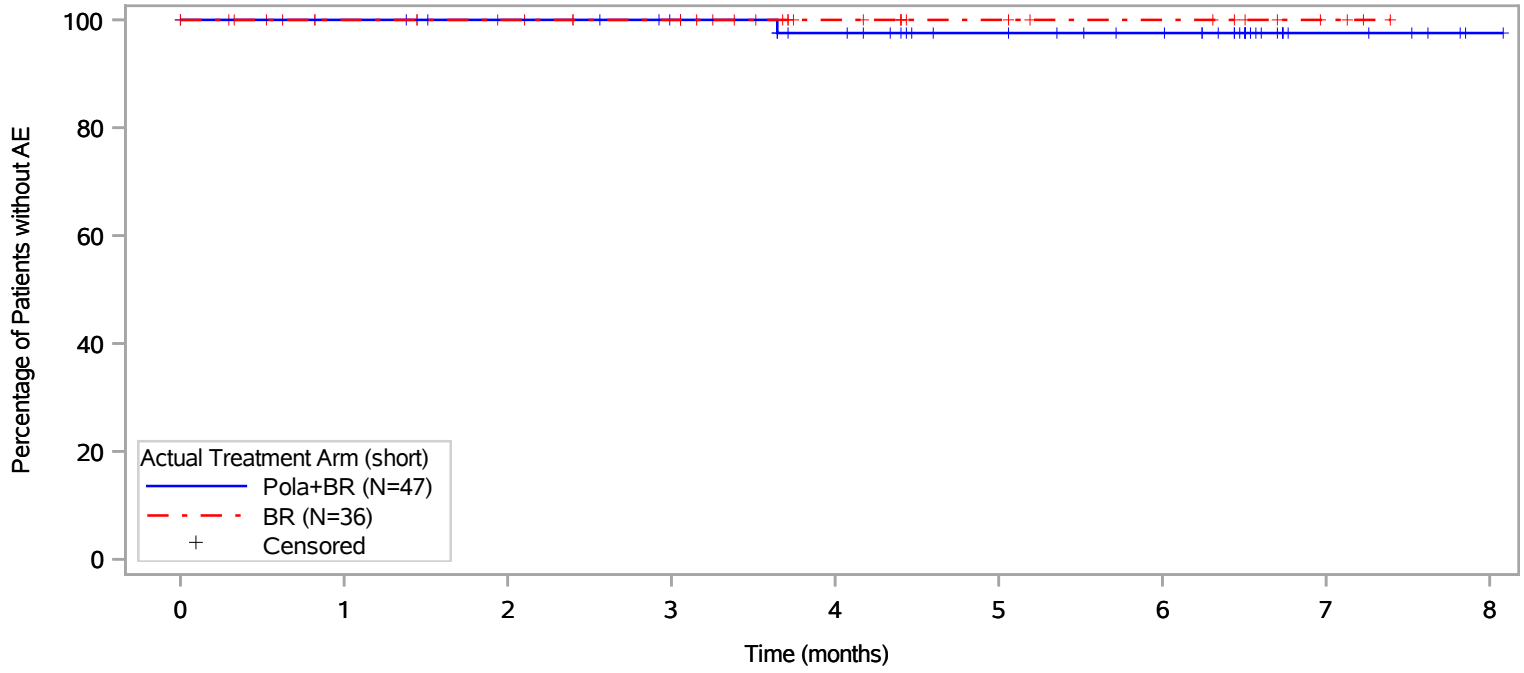
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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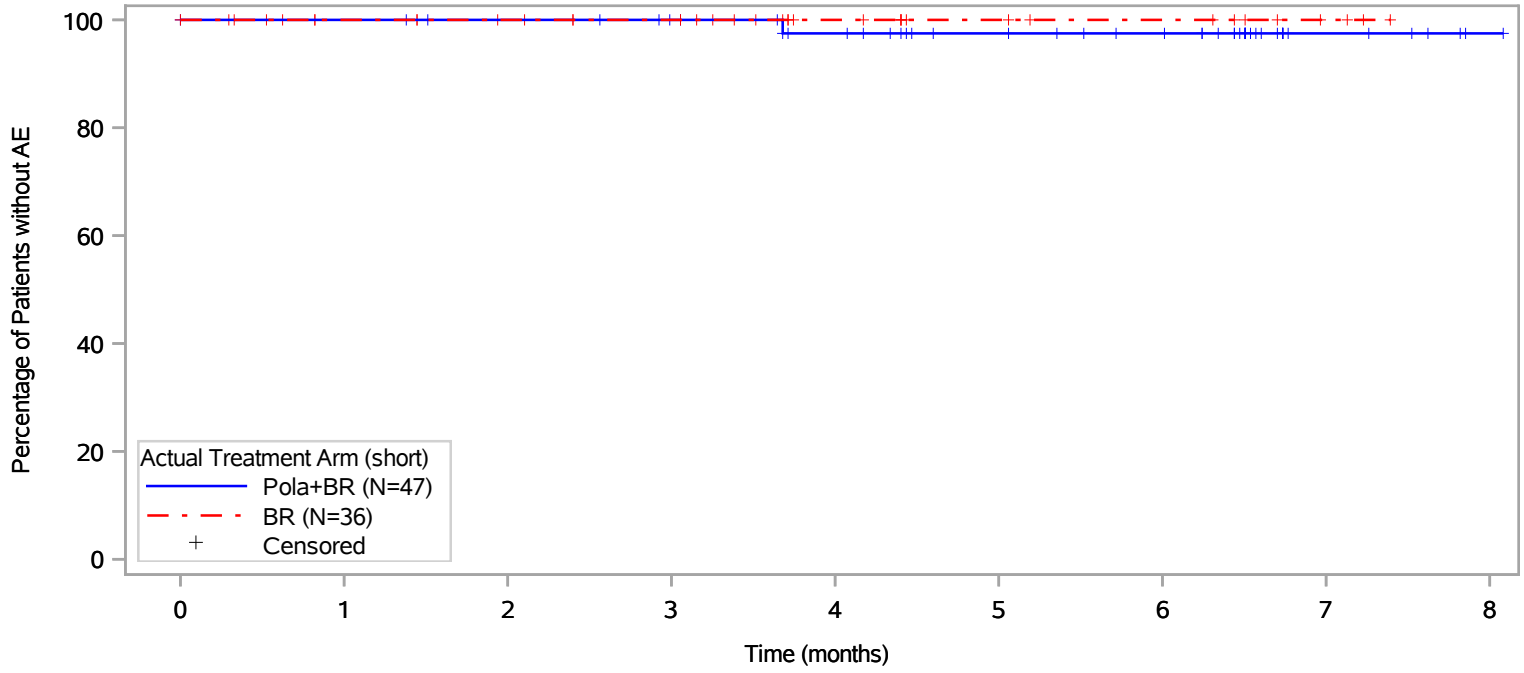
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTROINTESTINAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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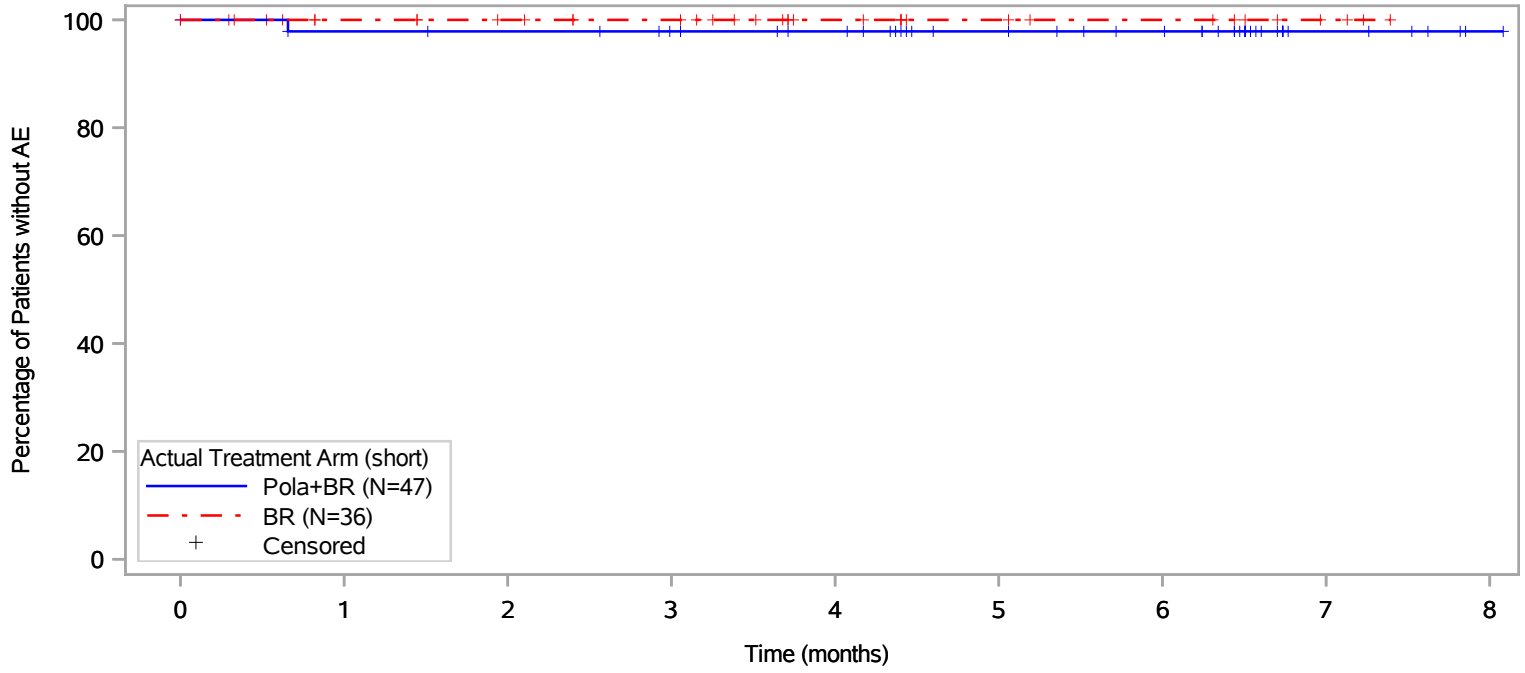
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ILEUS



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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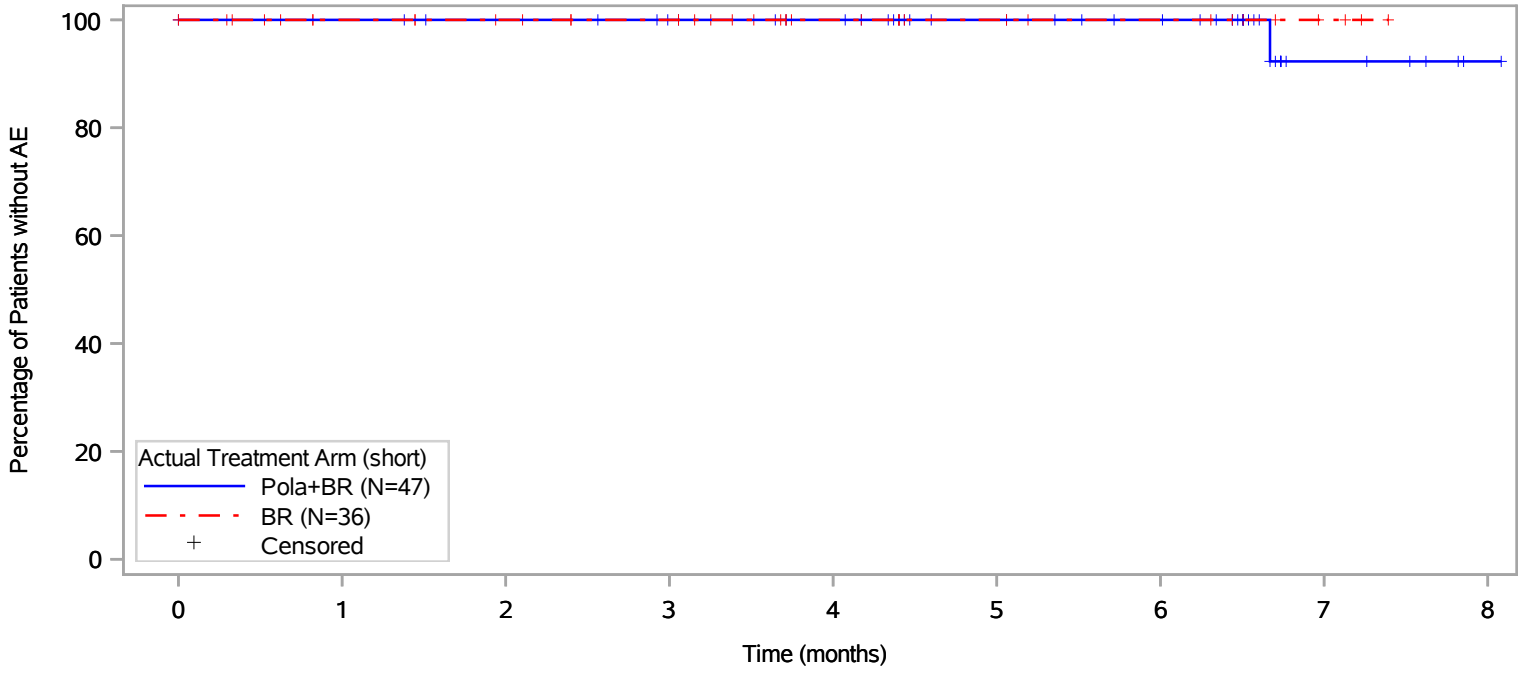
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, OBSTRUCTION GASTRIC



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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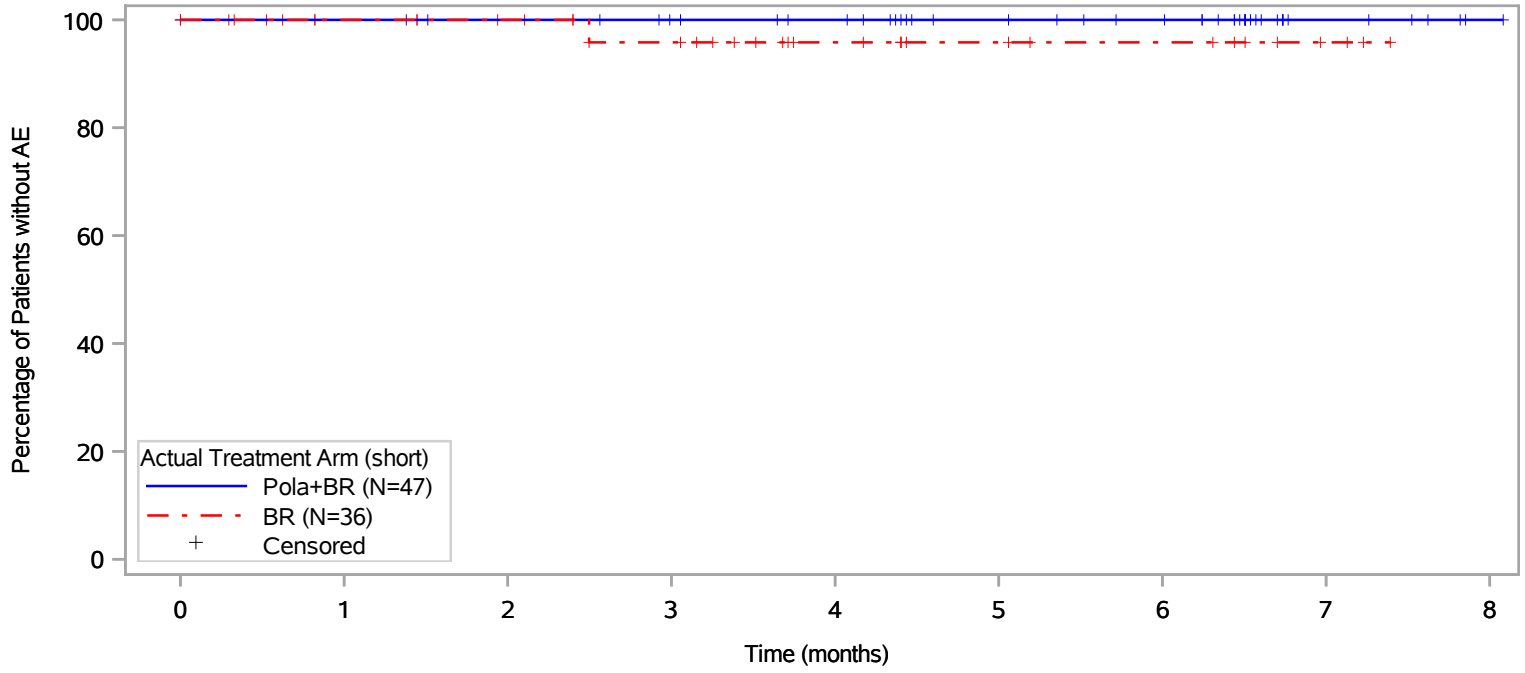
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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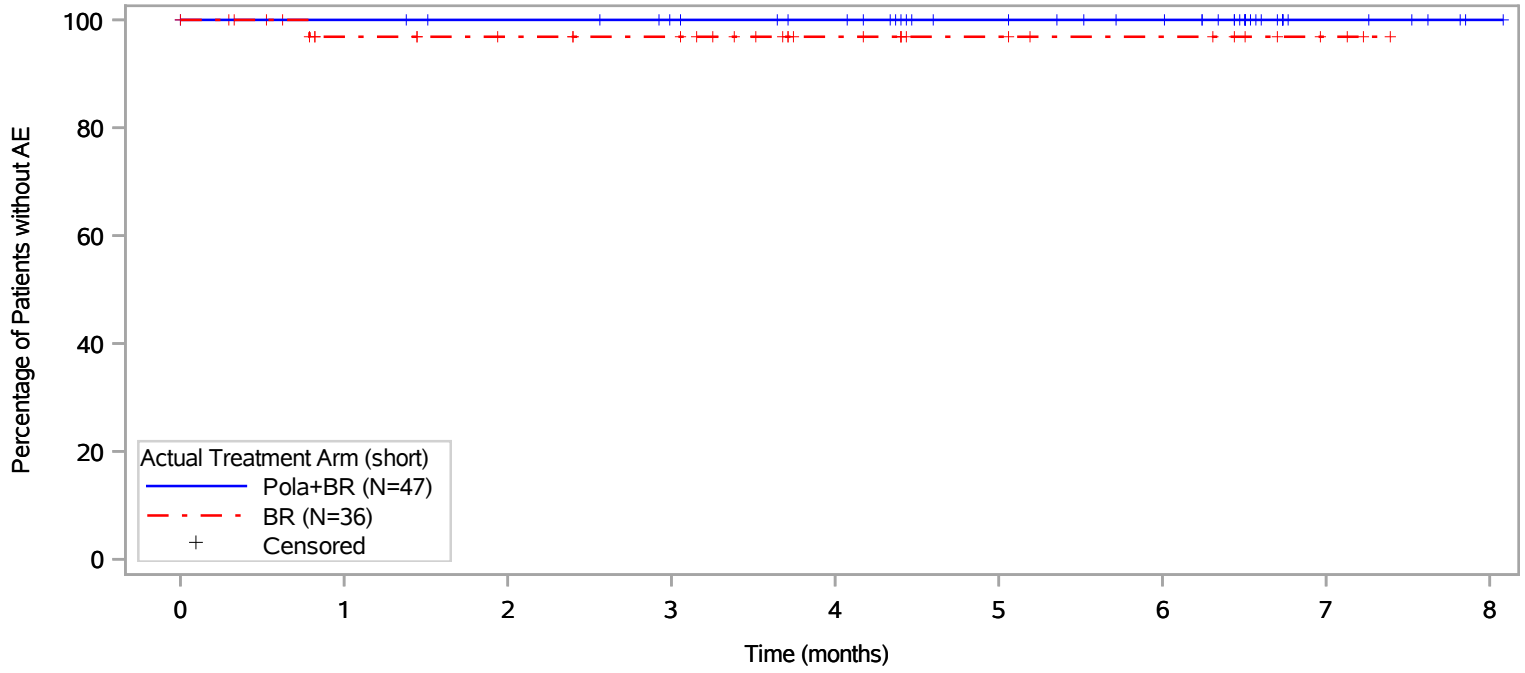
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, UPPER GASTROINTESTINAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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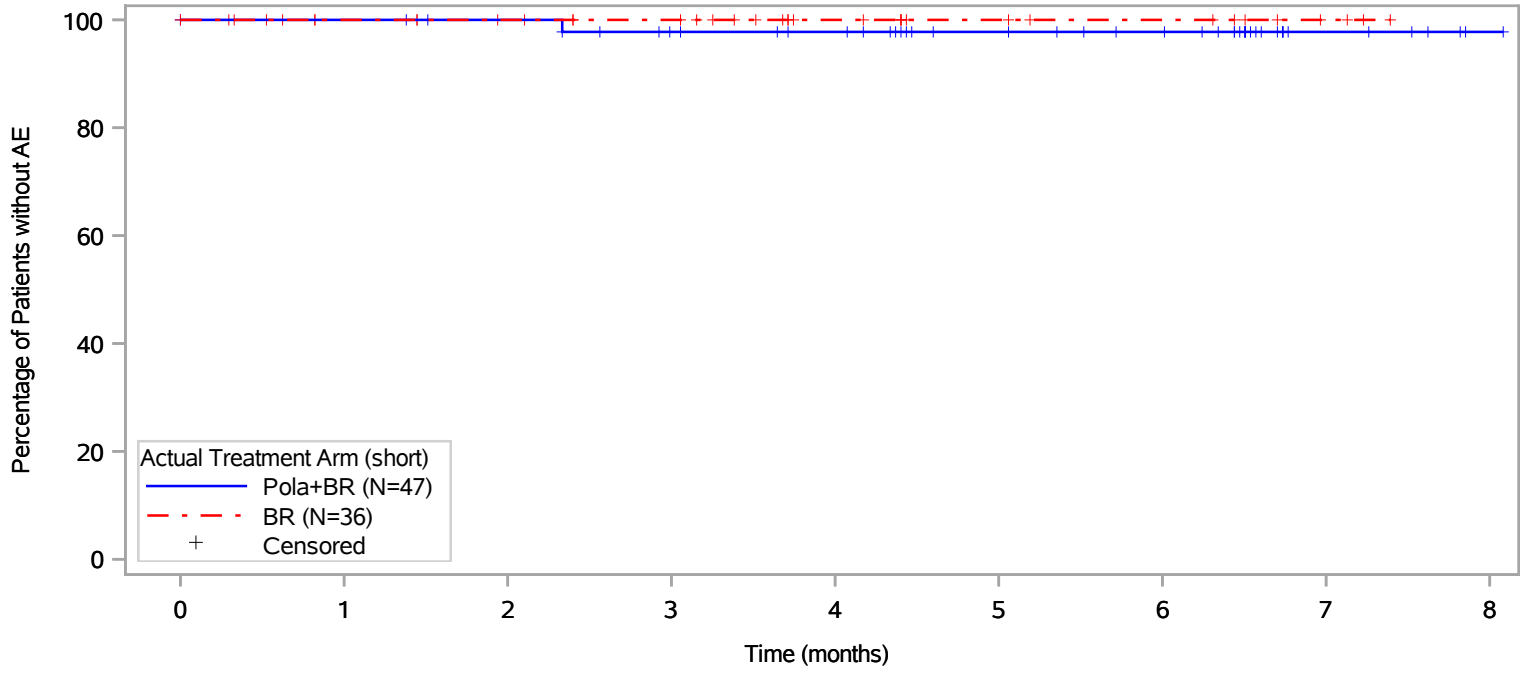
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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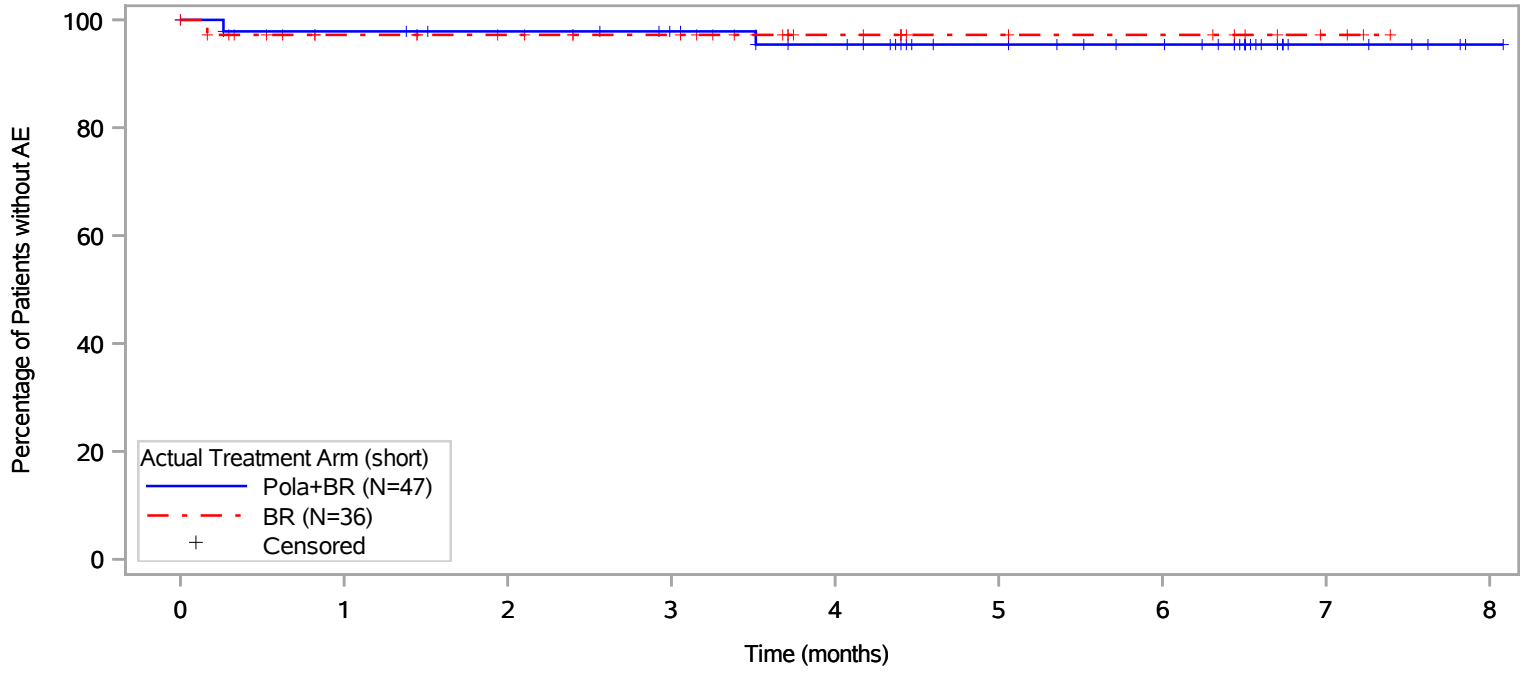
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	39	44
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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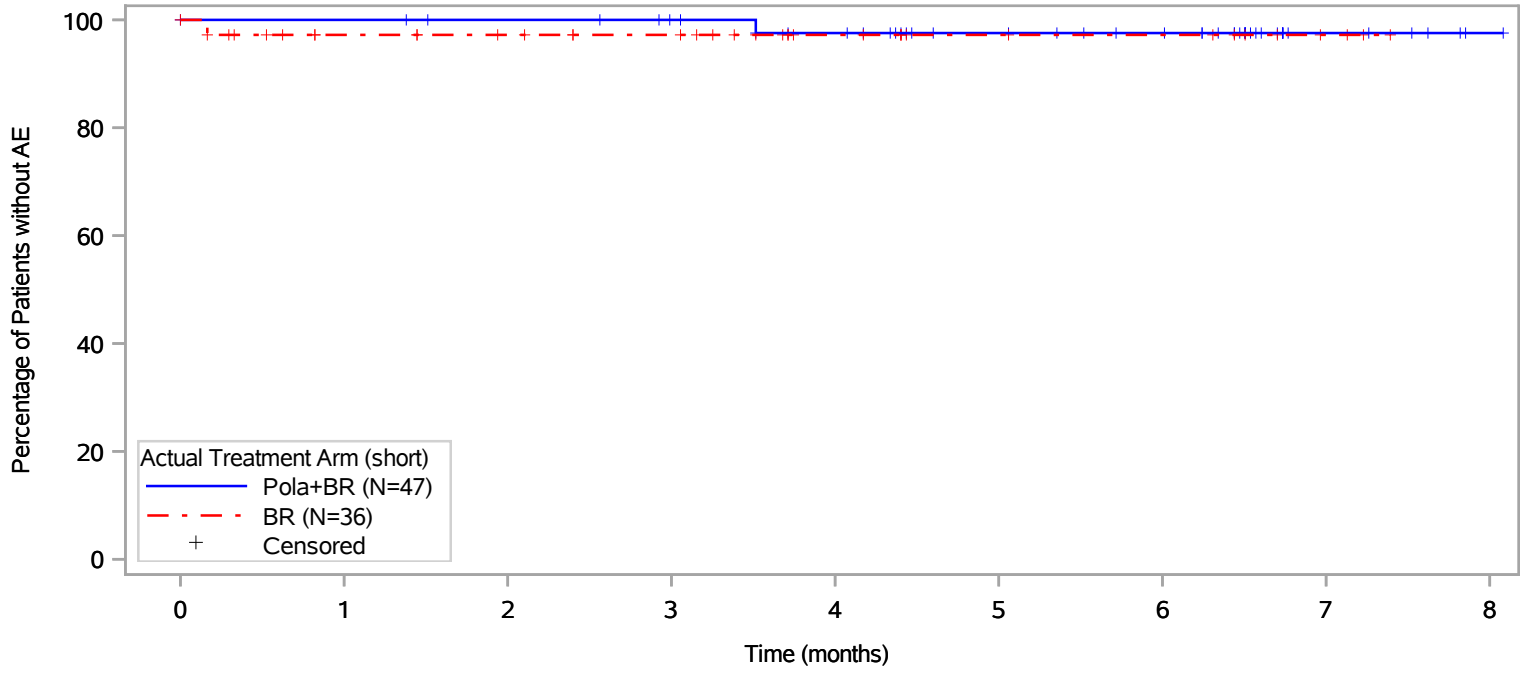
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE

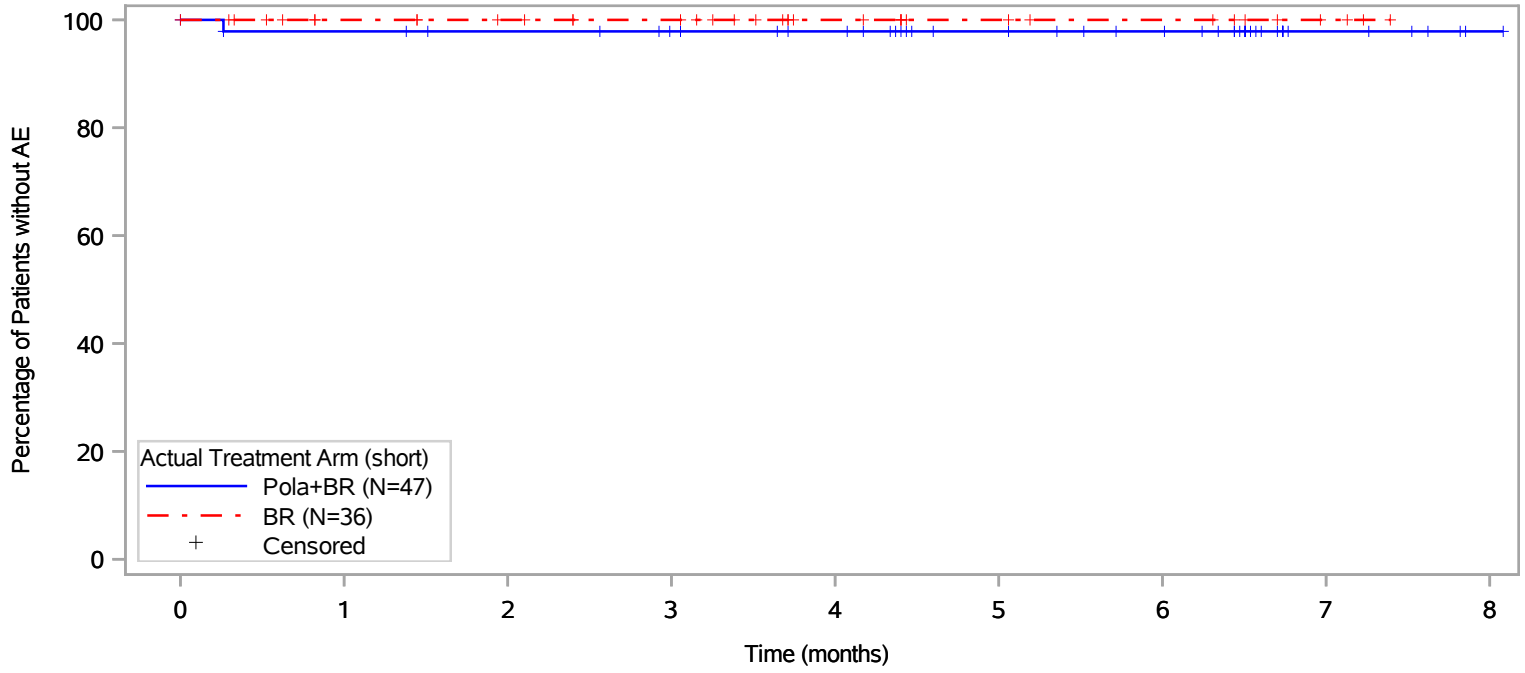


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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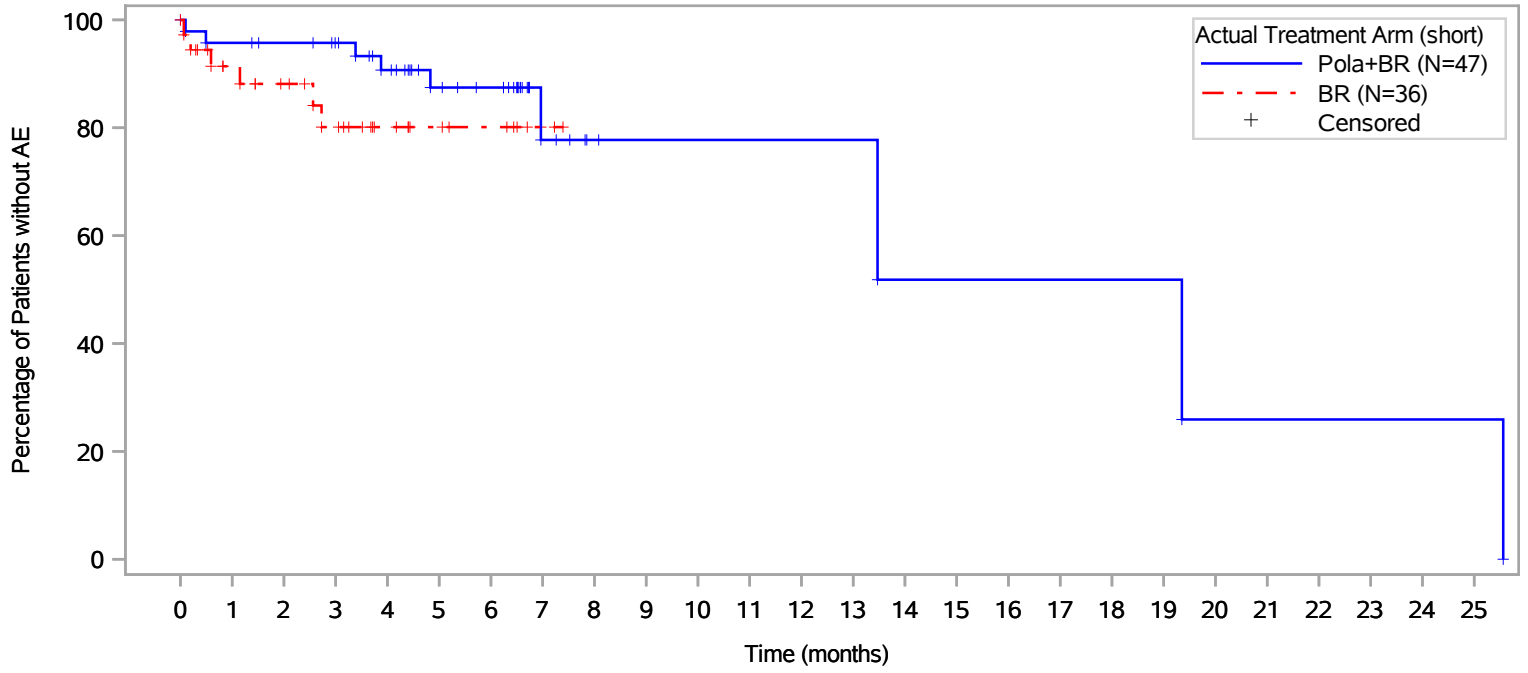
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk																										
Pola+BR (N=47)	47	45	43	40	35	27	24	8	4	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=36)	36	28	24	20	13	9	7	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	2	5	8	15	18	33	37	38	38	38	38	38	38	38	38	38	38	38	38	38	38	38	38	38
BR (N=36)	0	5	8	10	17	21	23	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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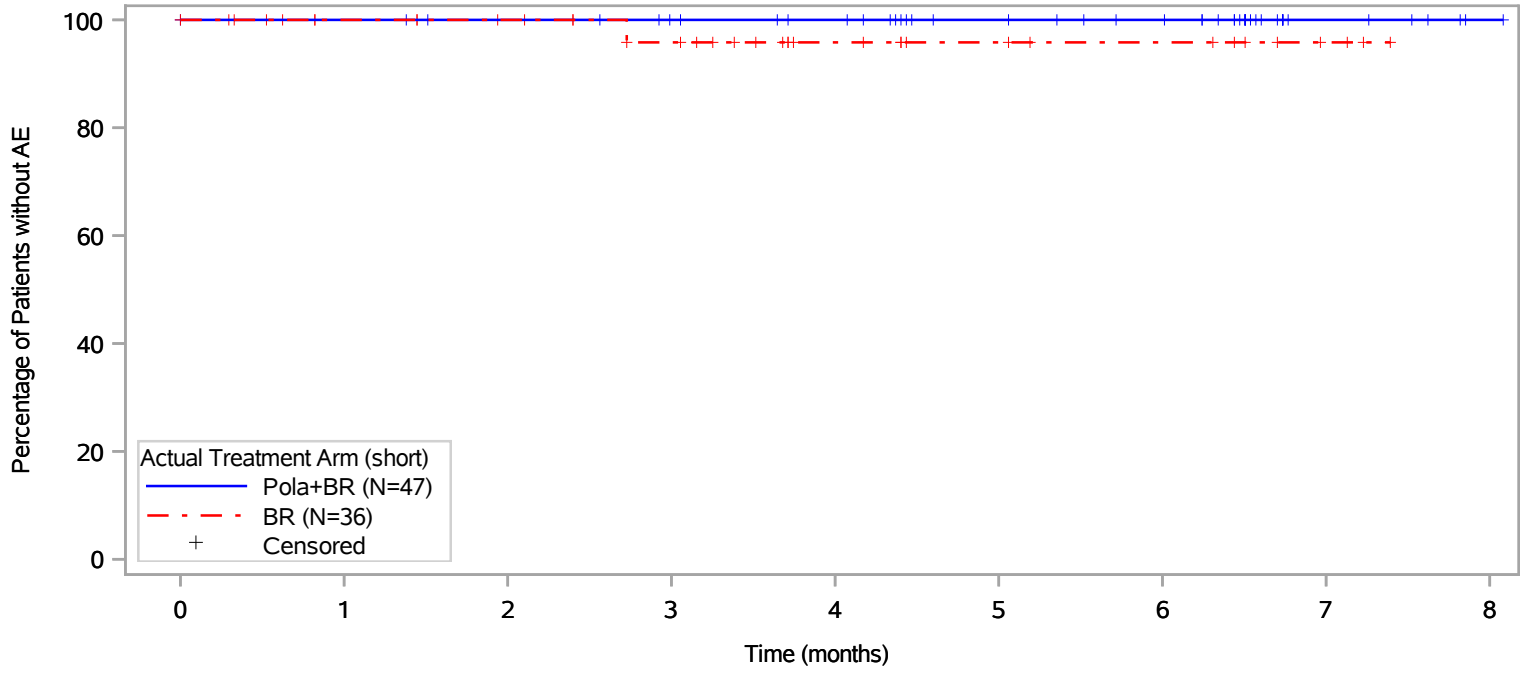
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, CYTOMEGALOVIRUS INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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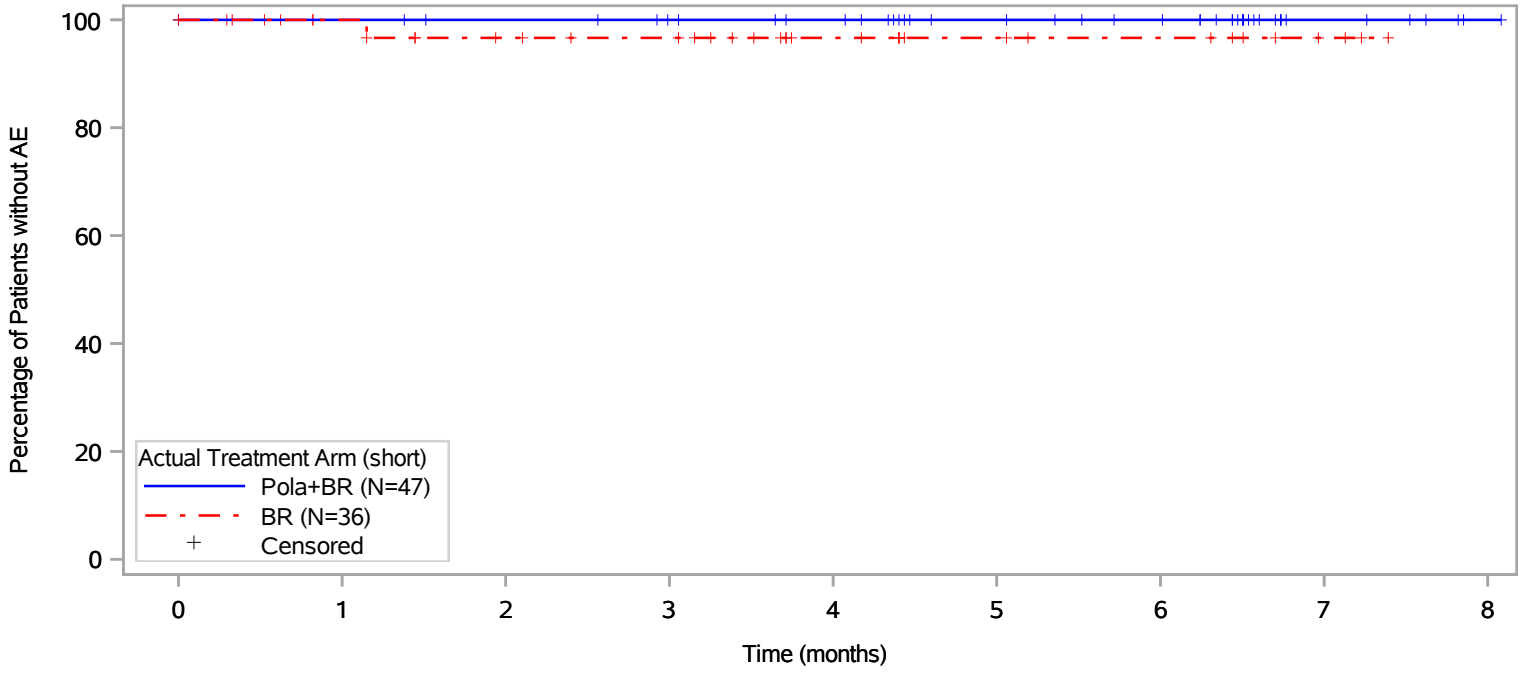
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, DEVICE RELATED INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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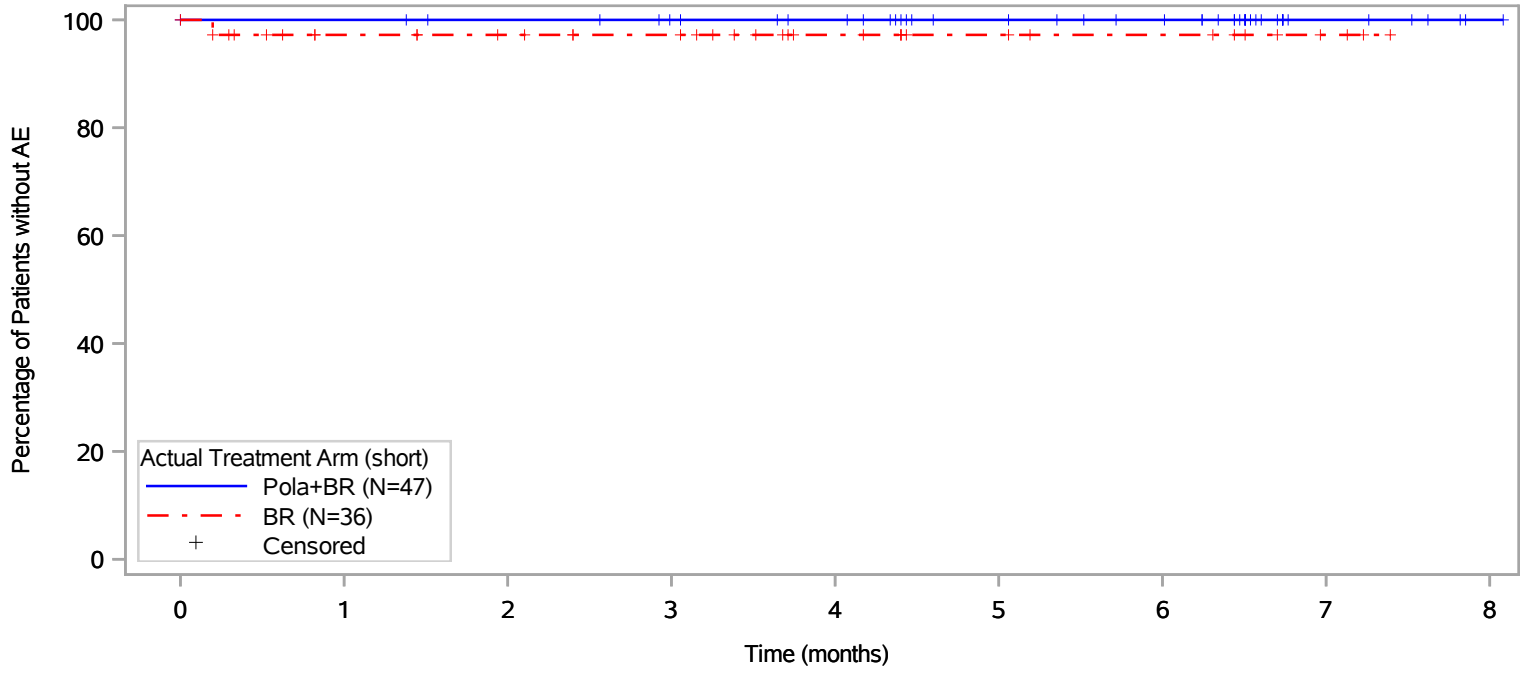
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ENTEROCOLITIS VIRAL



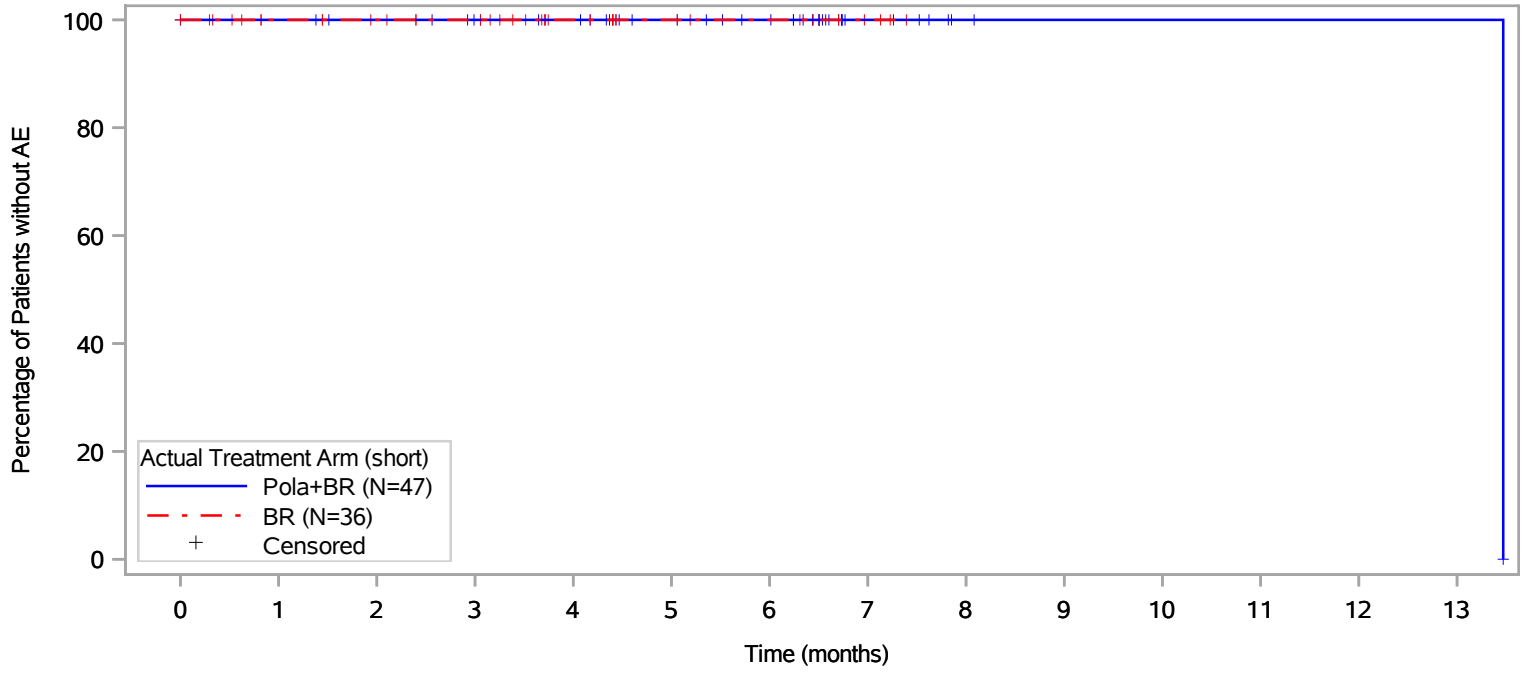
Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, GASTROINTESTINAL BACTERIAL INFECTION

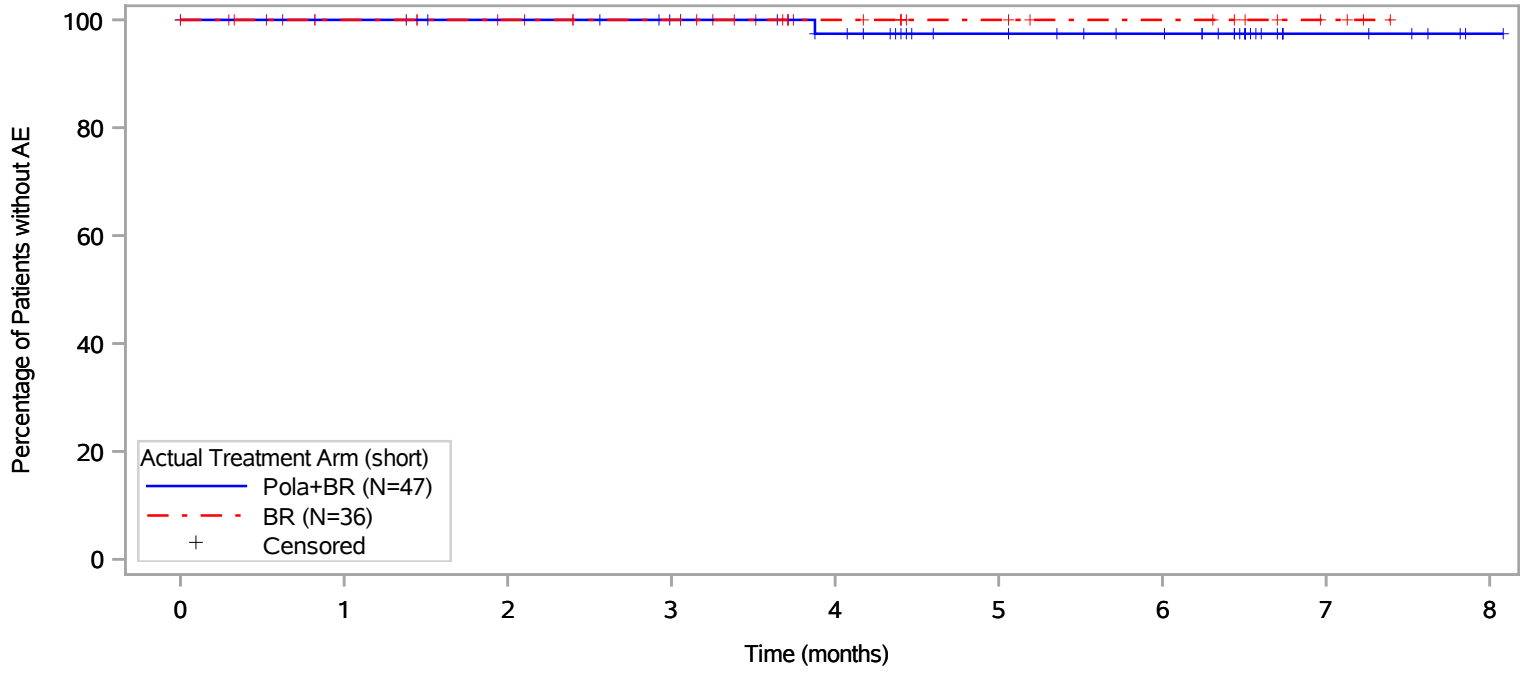


Patients at risk														
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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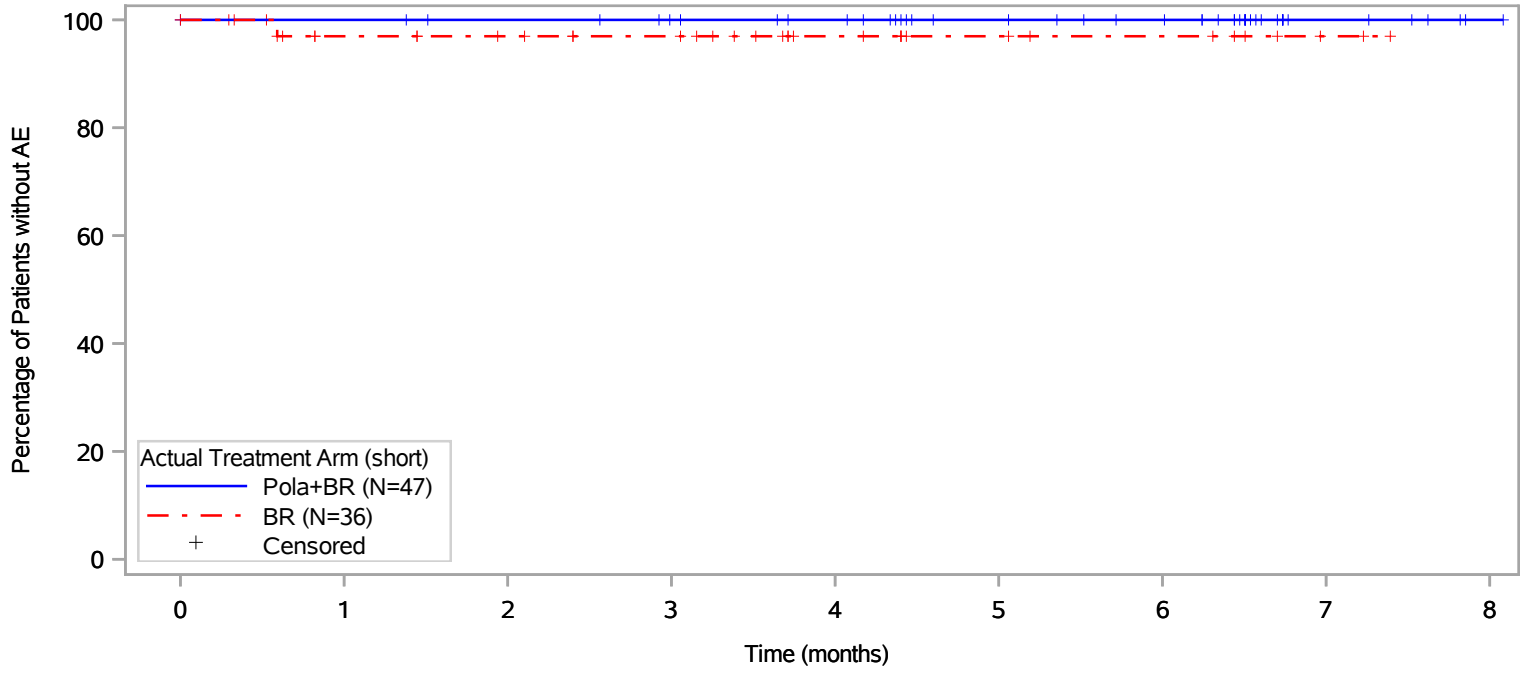
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, LOWER RESPIRATORY TRACT INFECTION

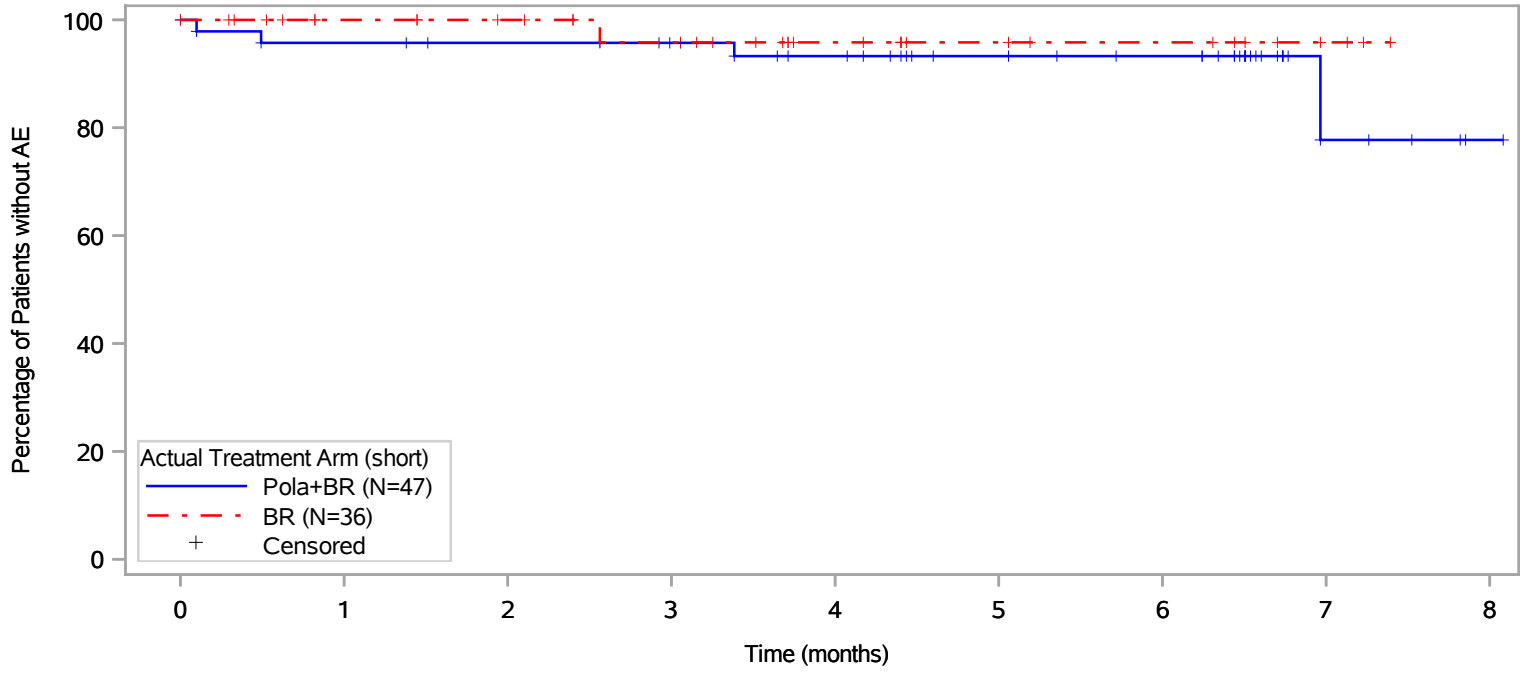


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=47)	47	45	43	40	36	29	26	5	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	18	38	42
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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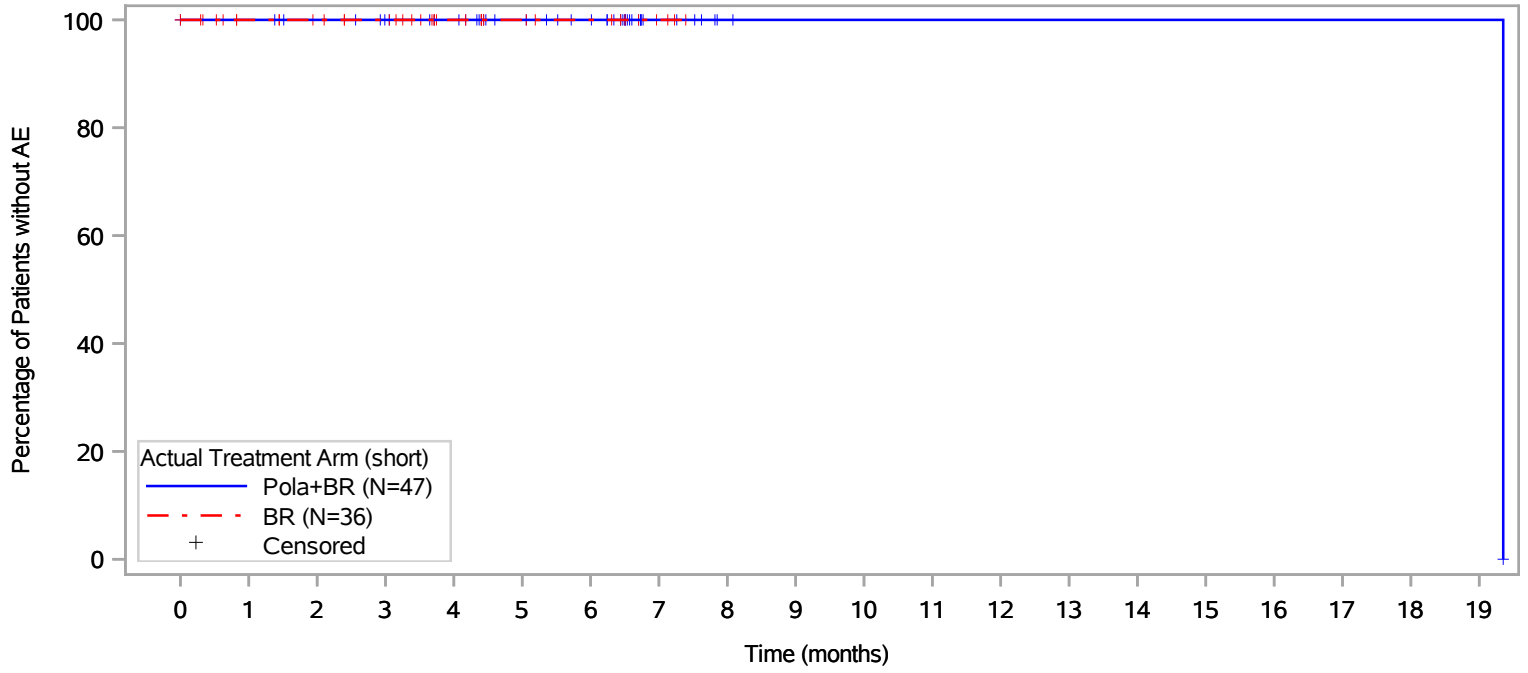
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA PNEUMOCOCCAL



Patients at risk																				
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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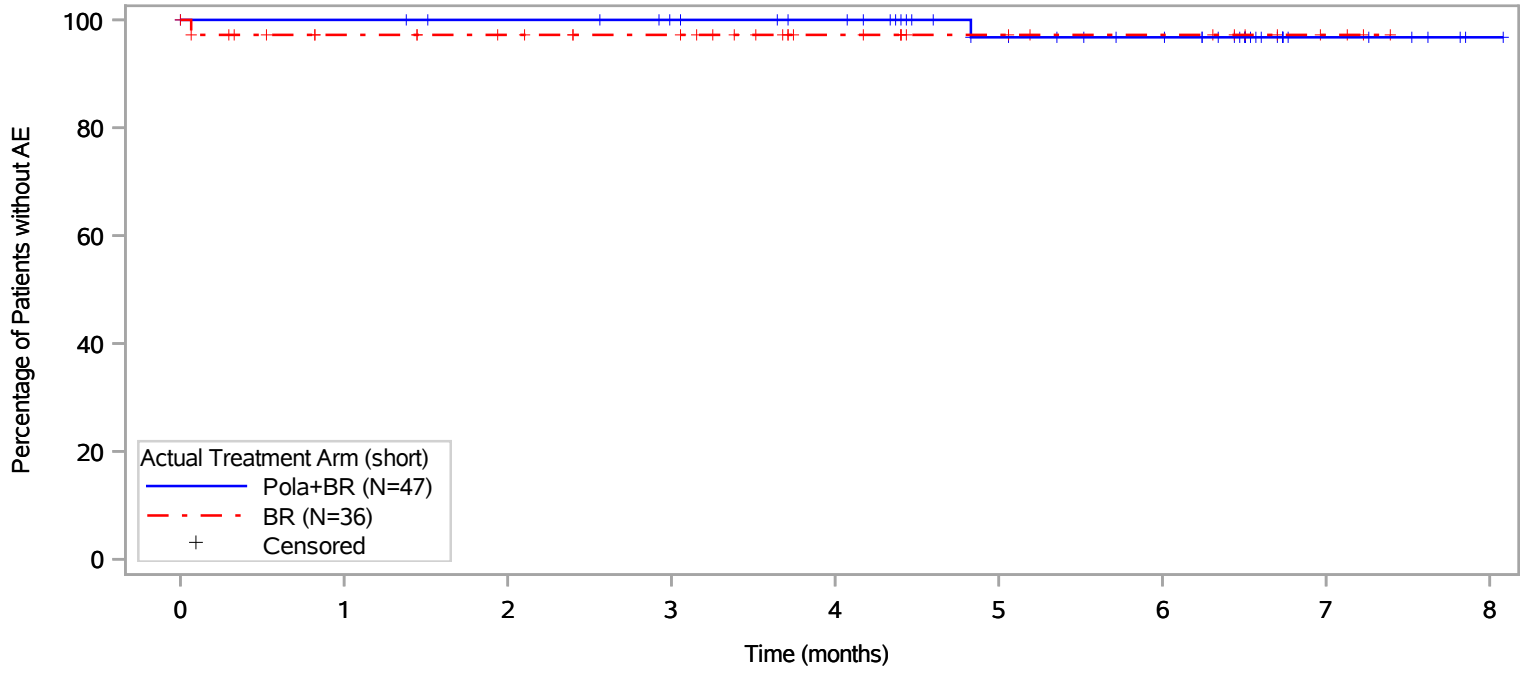
02DEC2022 3:43

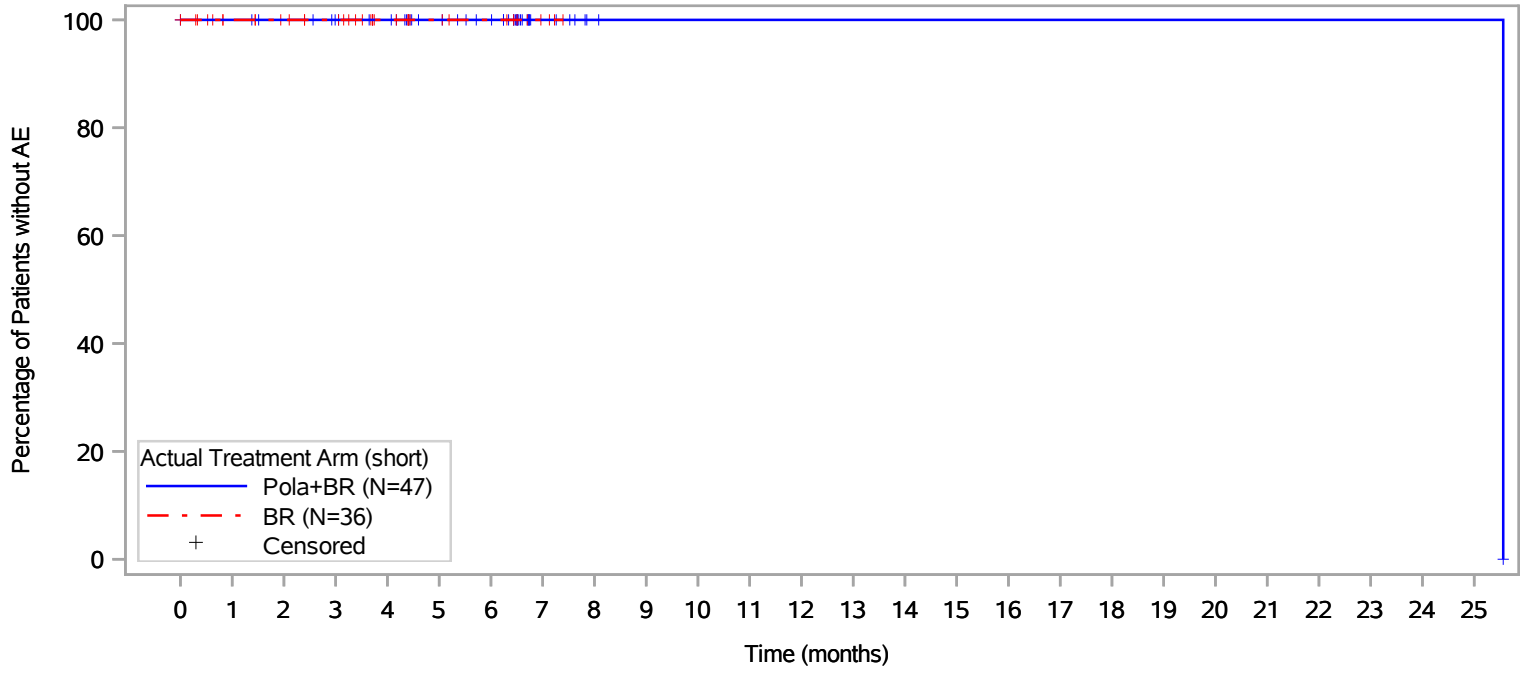
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	5	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UROSEPSIS

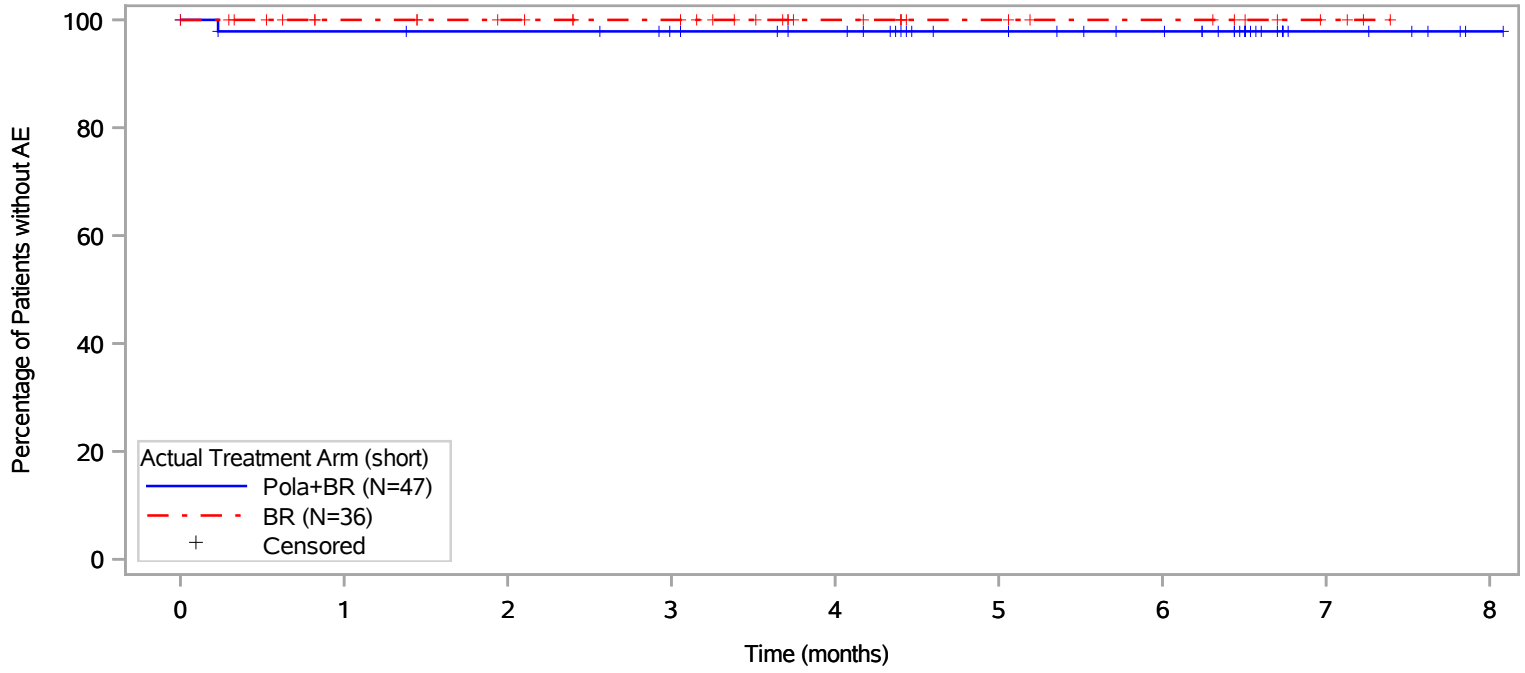


Patients at risk																										
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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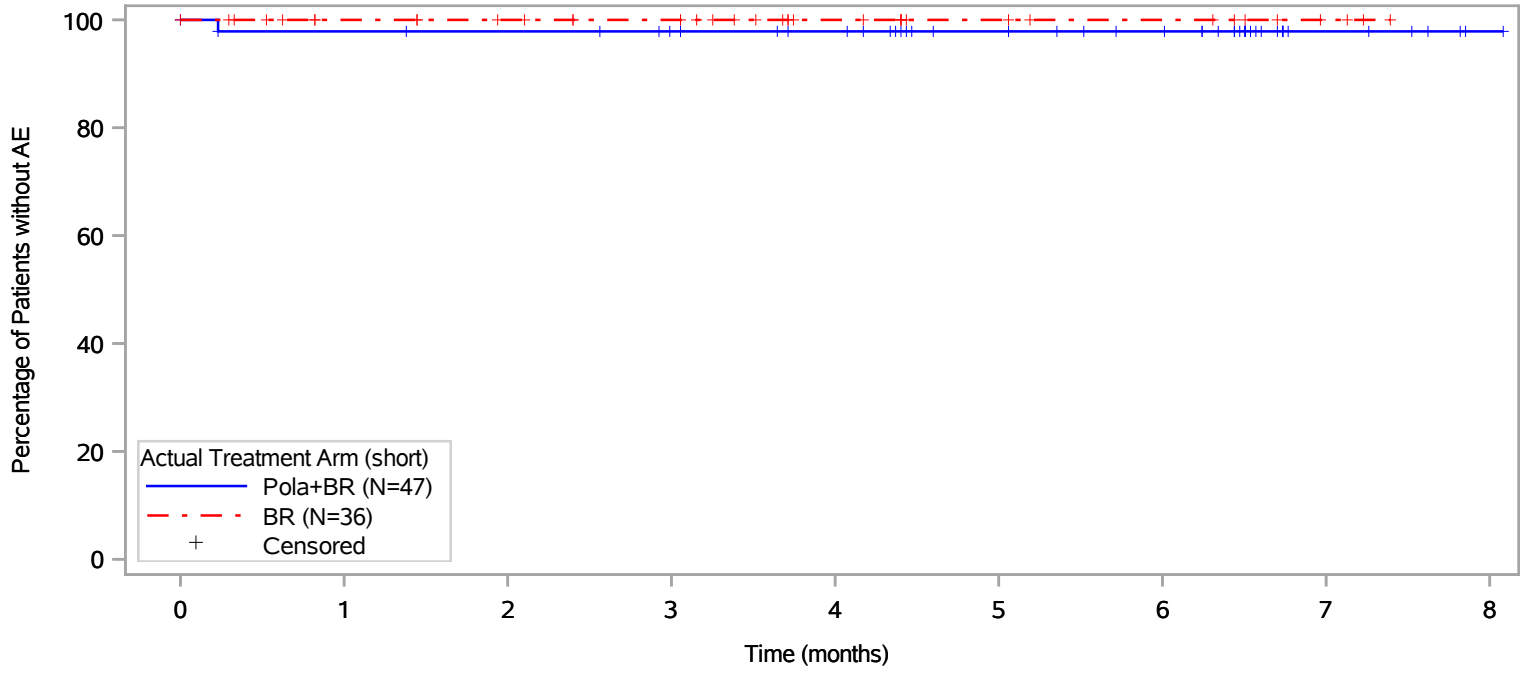
02DEC2022 3:43

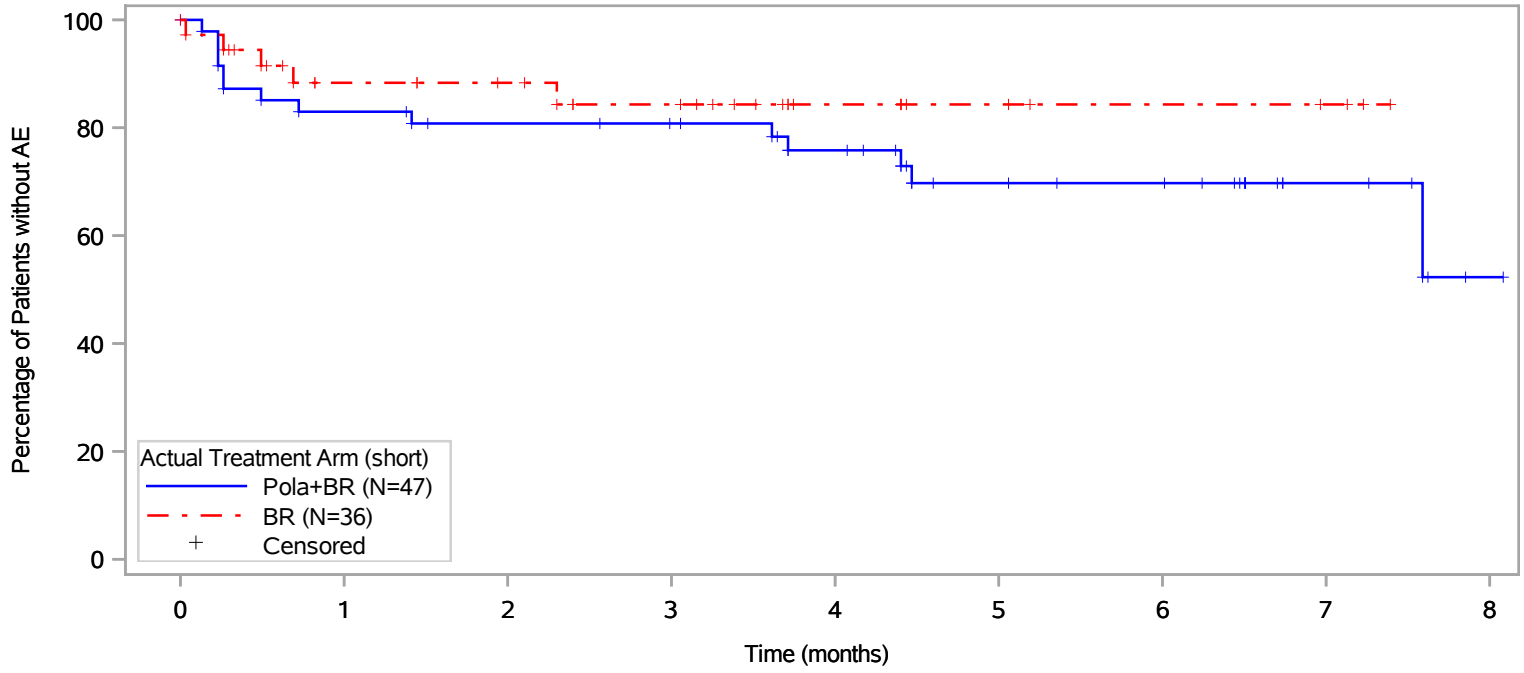
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FEMUR FRACTURE



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk									
Pola+BR (N=47)	47	39	36	34	29	20	18	6	1
BR (N=36)	36	26	23	19	10	6	4	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	16	28	32
BR (N=36)	0	6	9	12	21	25	27	28	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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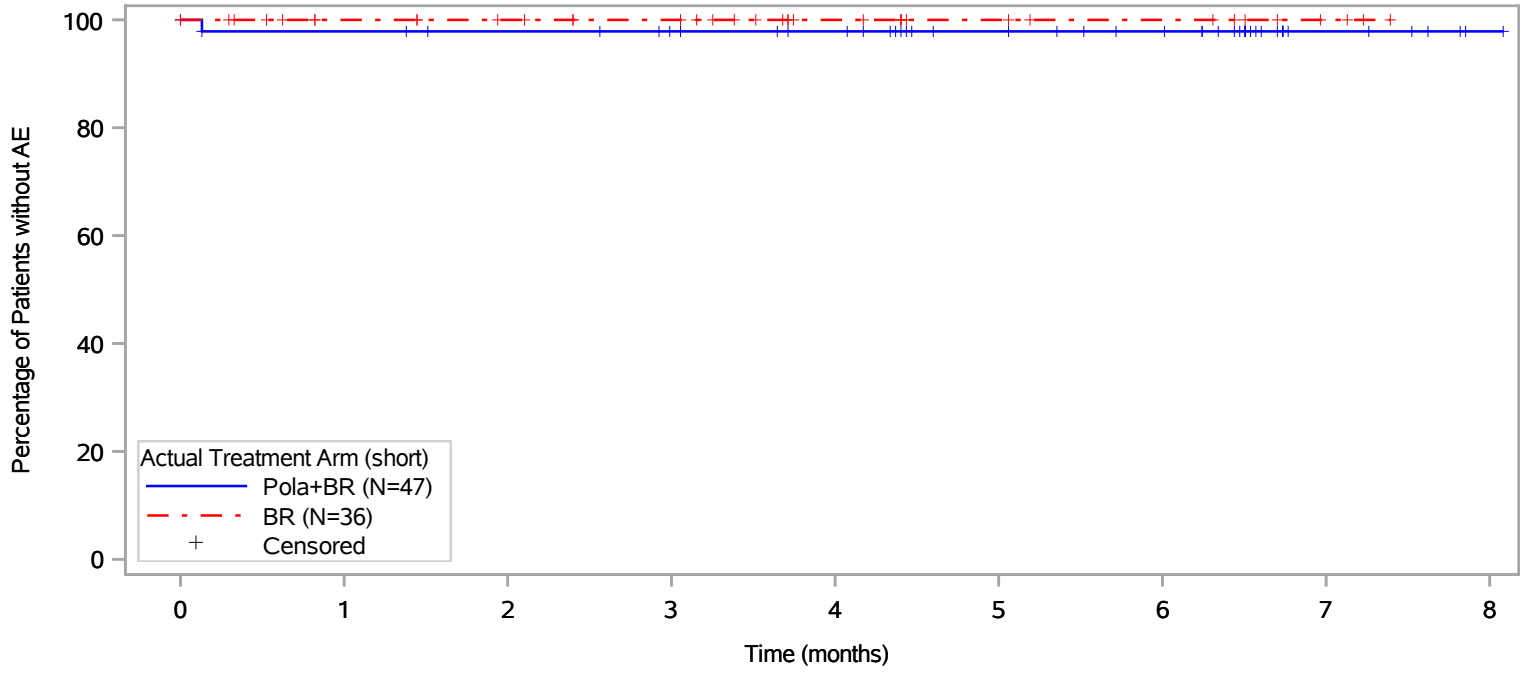
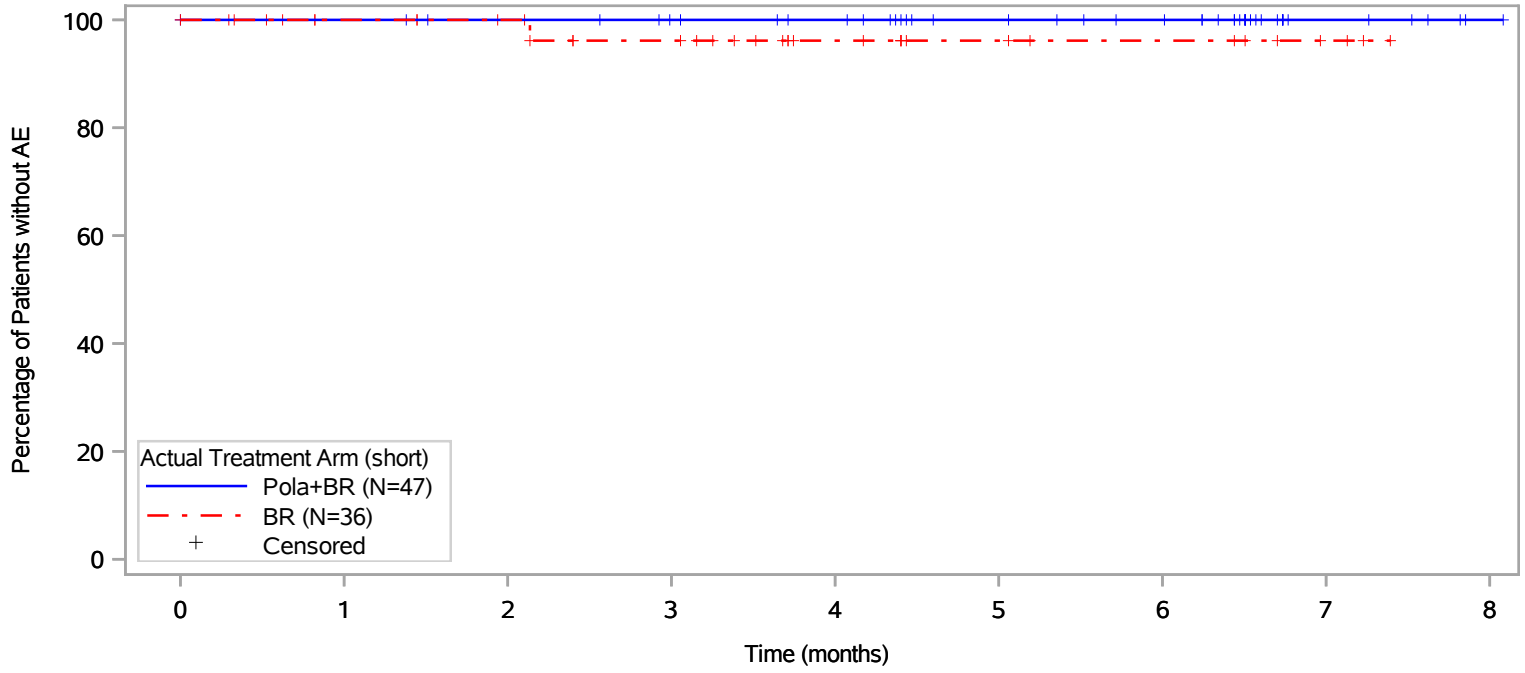
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

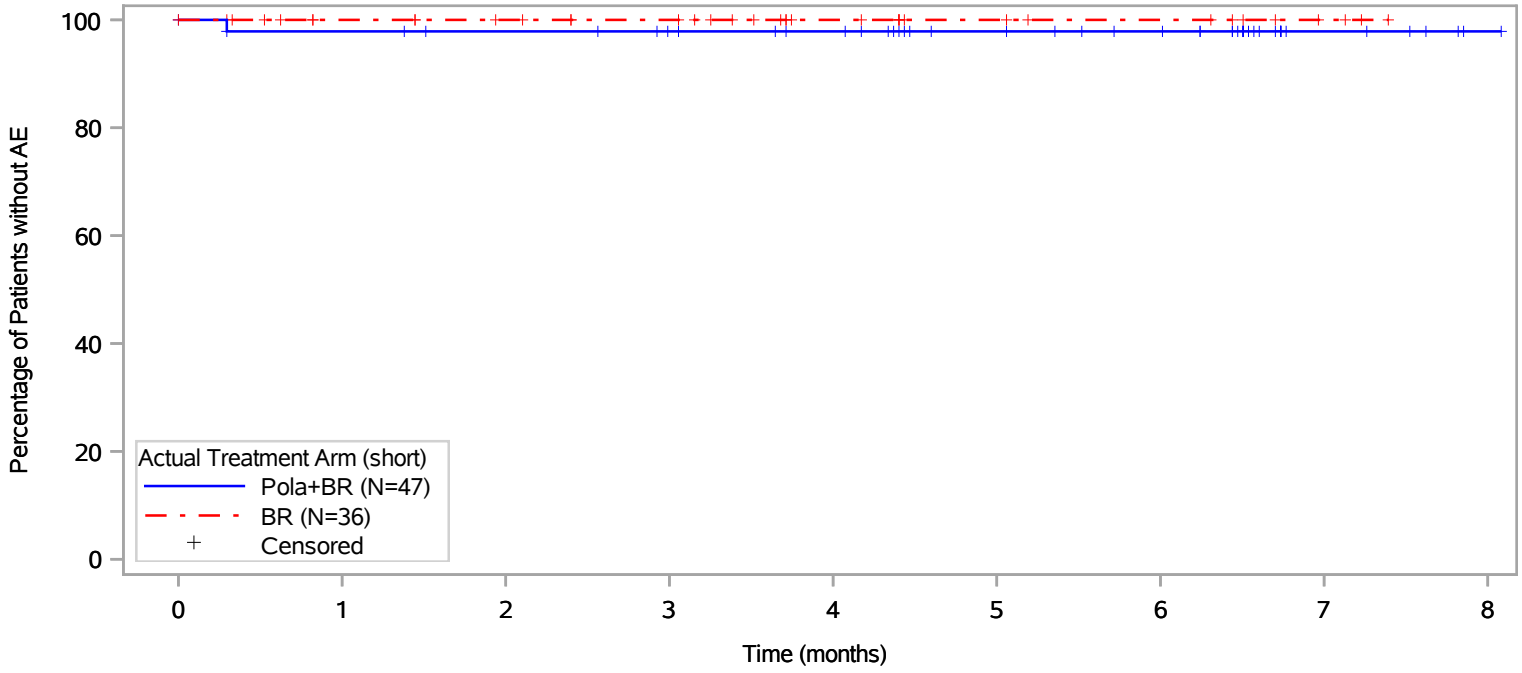
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PRESSURE INCREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

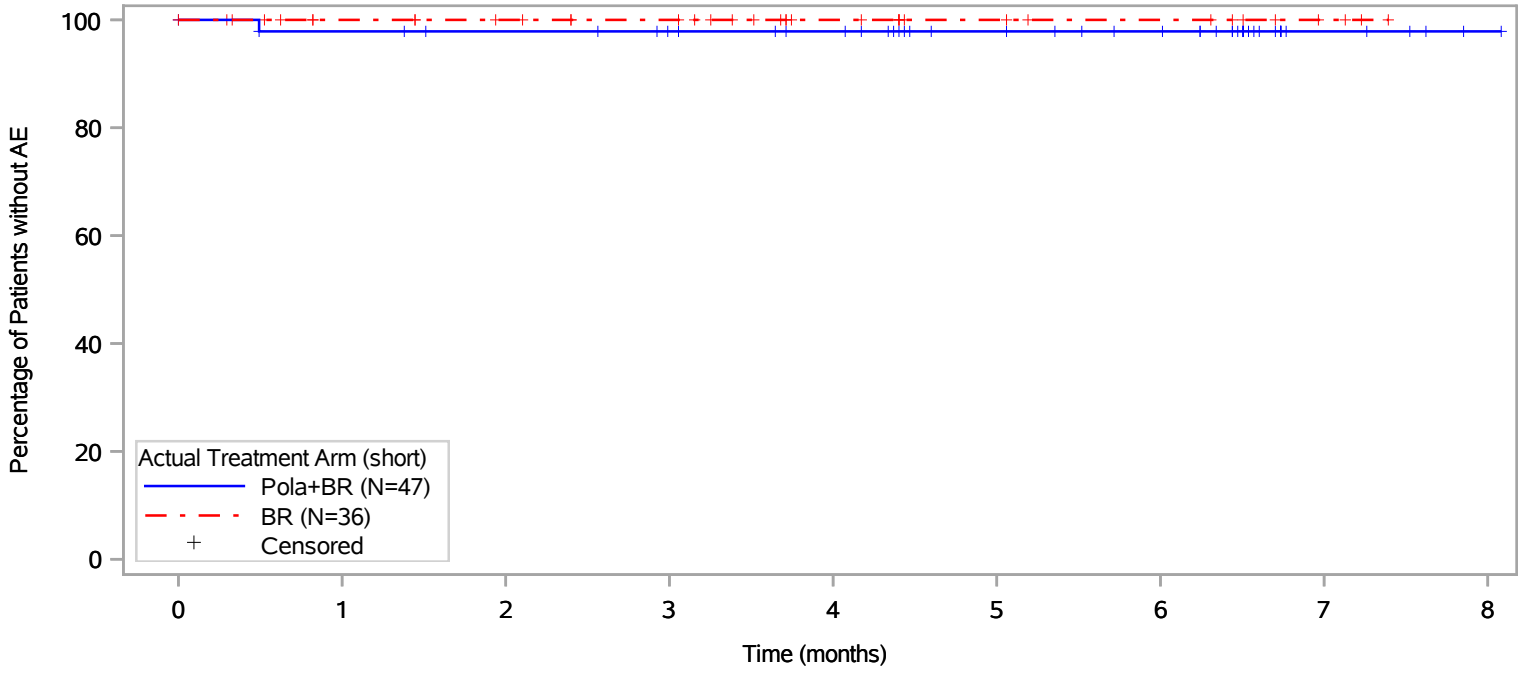
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, FIBRIN D DIMER INCREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GAMMA-GLUTAMYLTRANSFERASE INCREASED

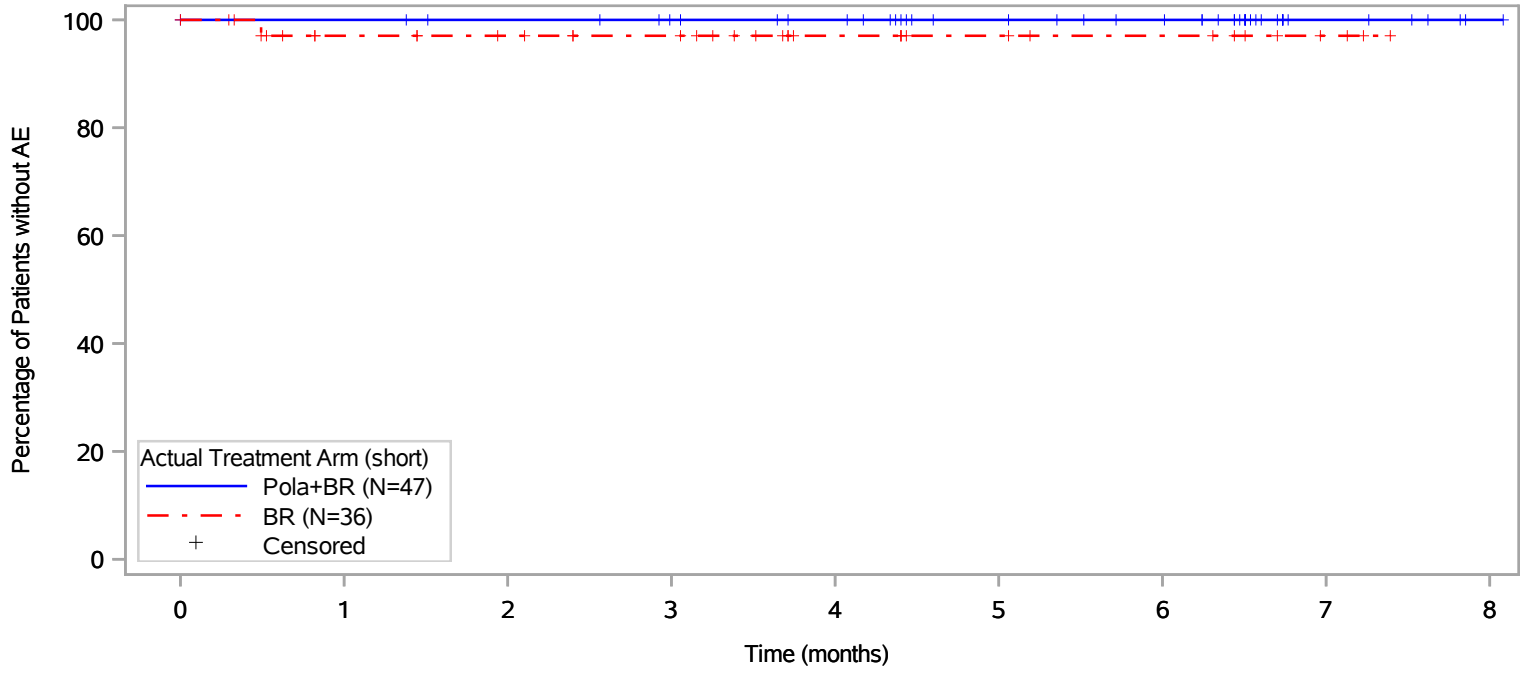


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

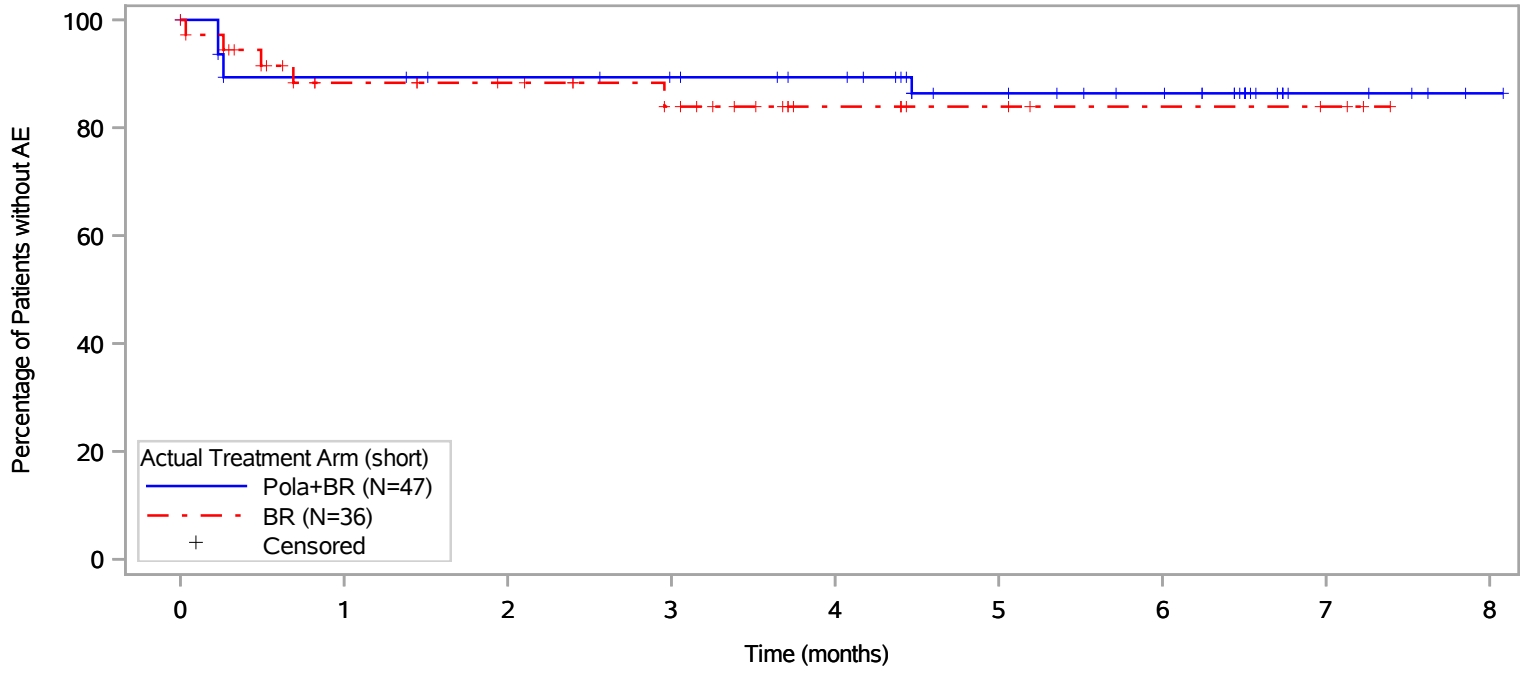
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, HAEMOGLOBIN DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

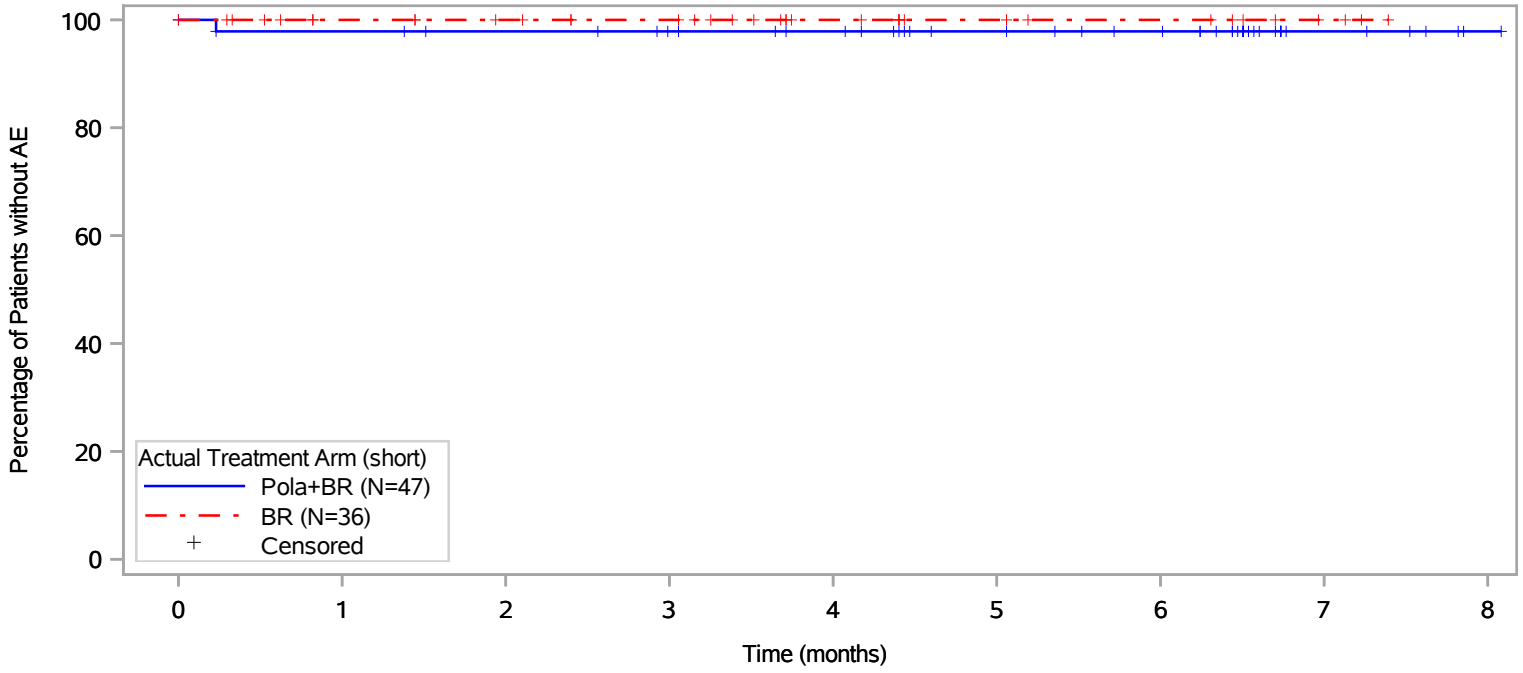
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	42	40	38	35	27	23	5	1
BR (N=36)	36	26	23	19	10	6	4	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	18	36	40
BR (N=36)	0	6	9	12	21	25	27	28	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE PERCENTAGE DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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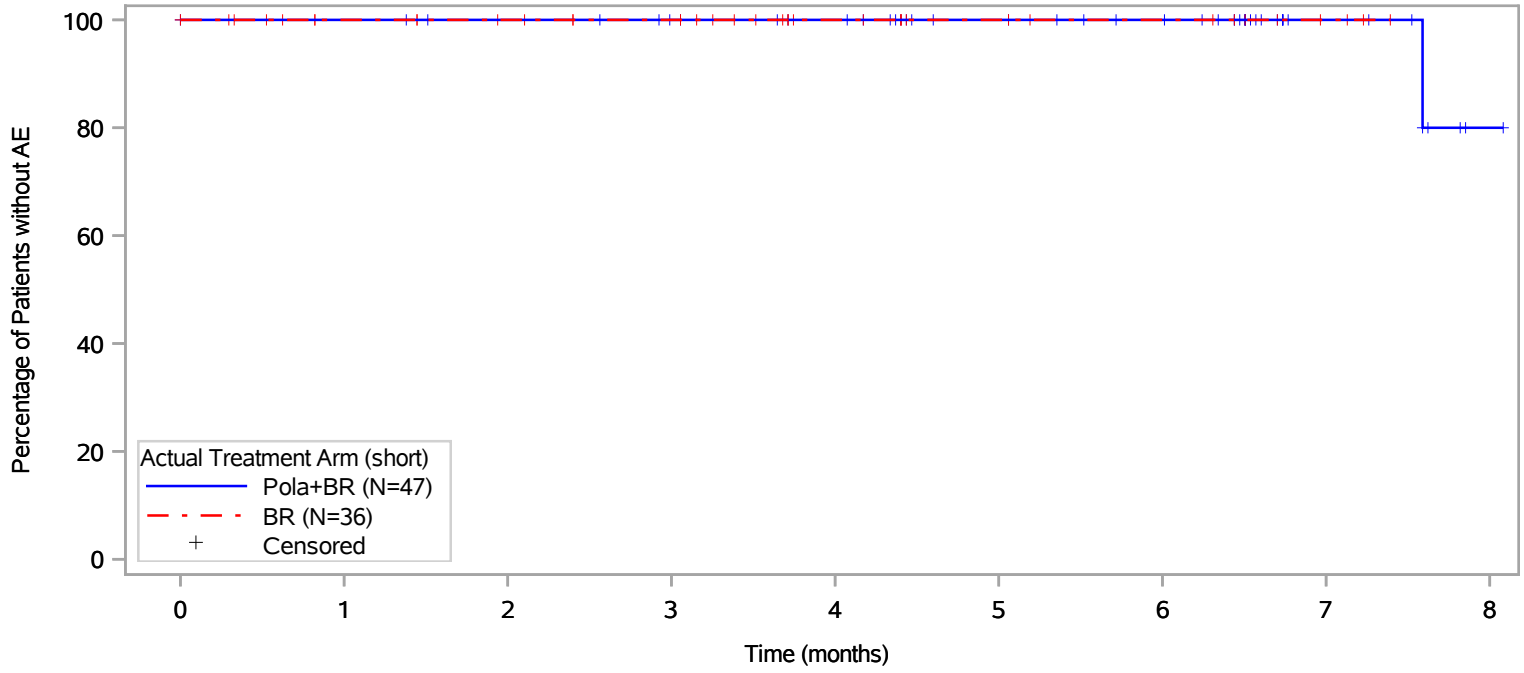
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MORAXELLA TEST POSITIVE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	7	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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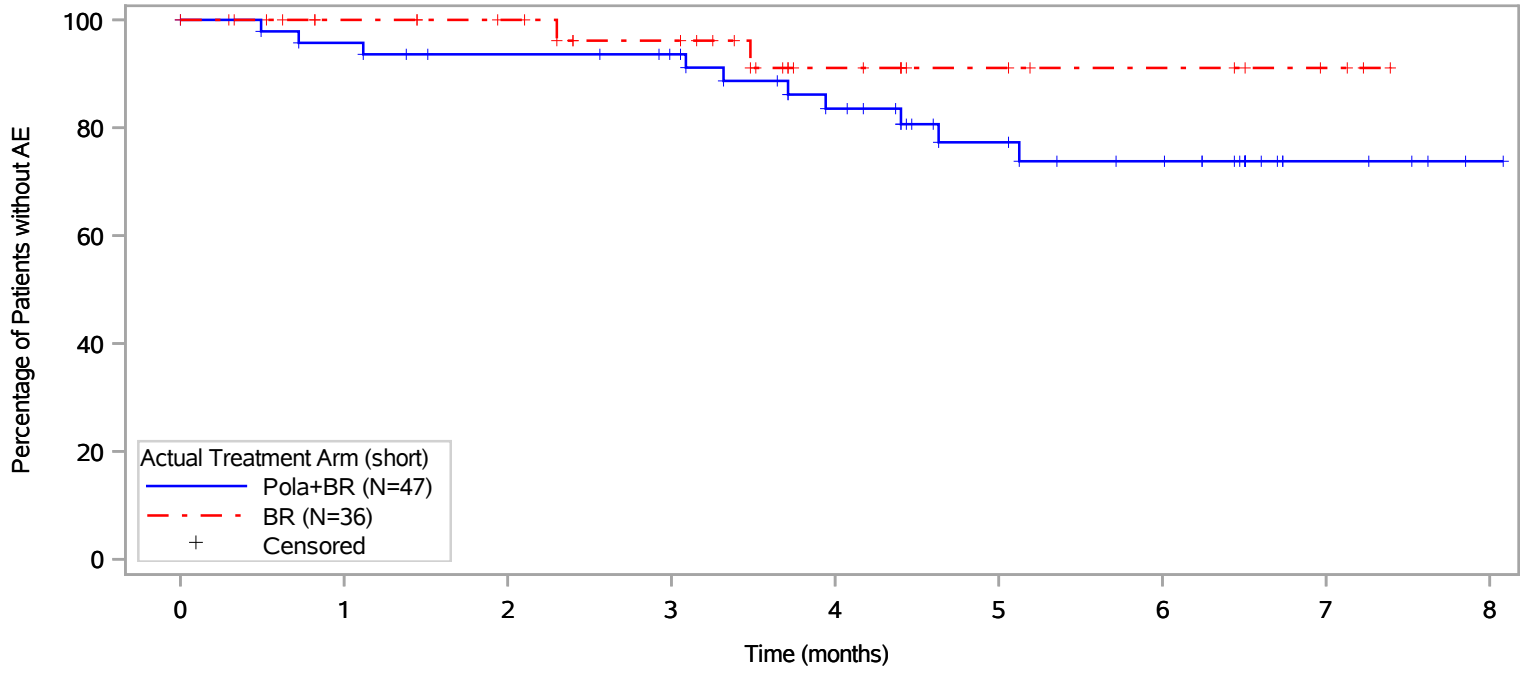
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	45	42	39	32	23	19	5	1
BR (N=36)	36	30	27	23	13	8	6	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	18	32	36
BR (N=36)	0	6	9	12	21	26	28	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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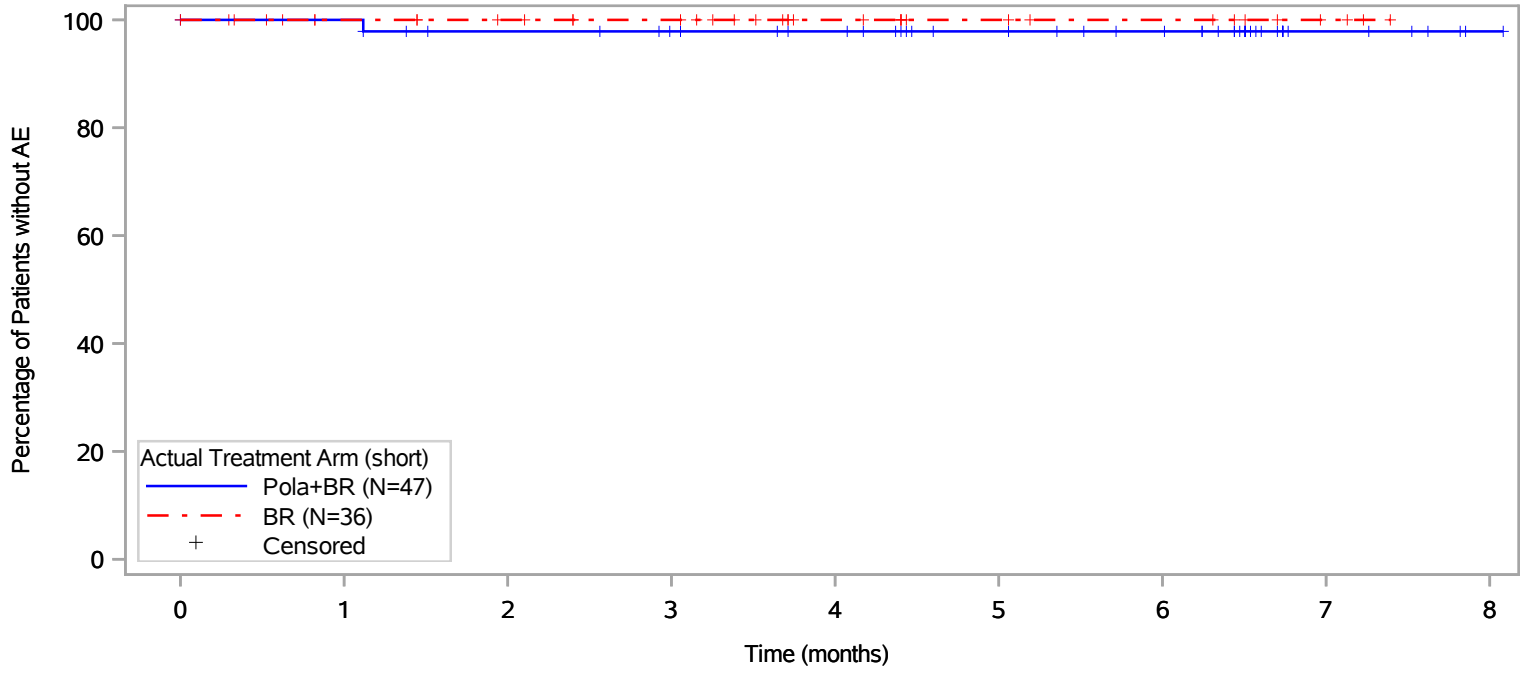
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL PERCENTAGE DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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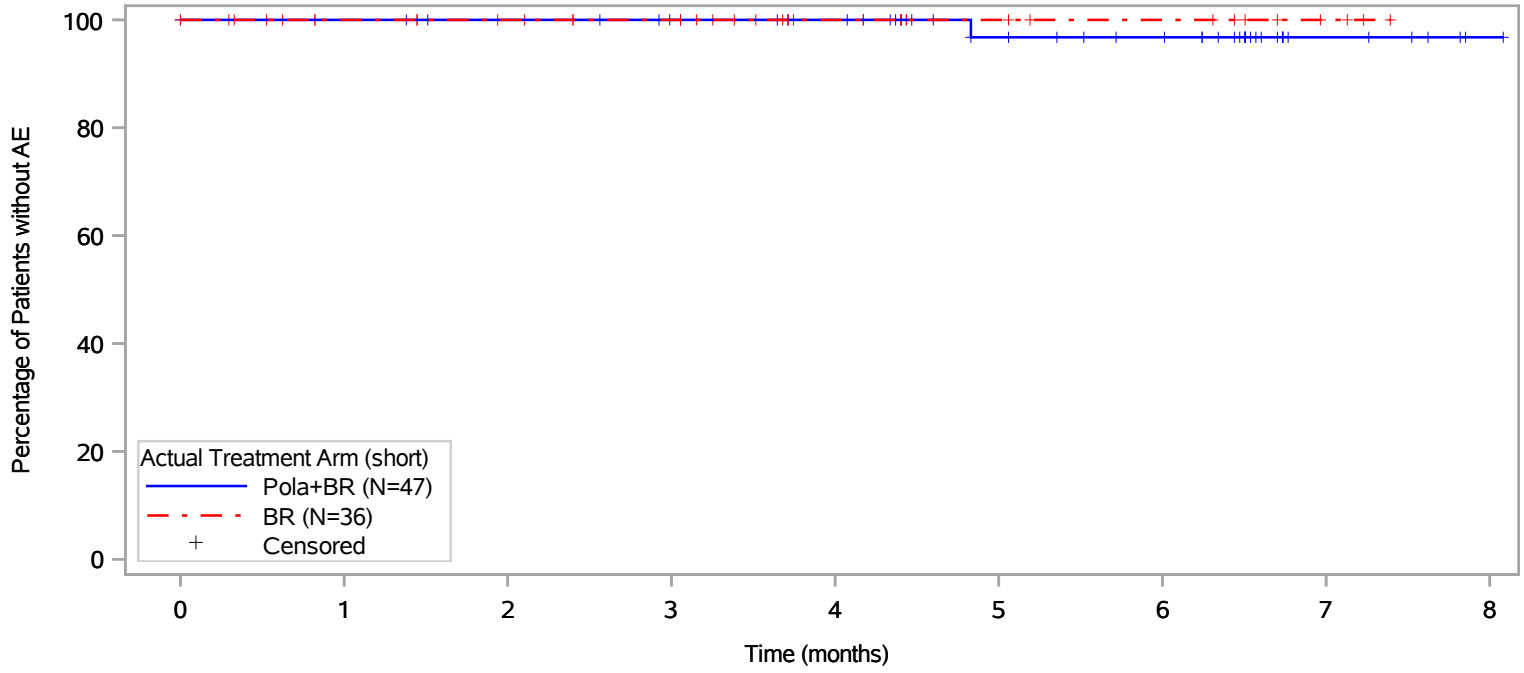
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NITRITE URINE PRESENT



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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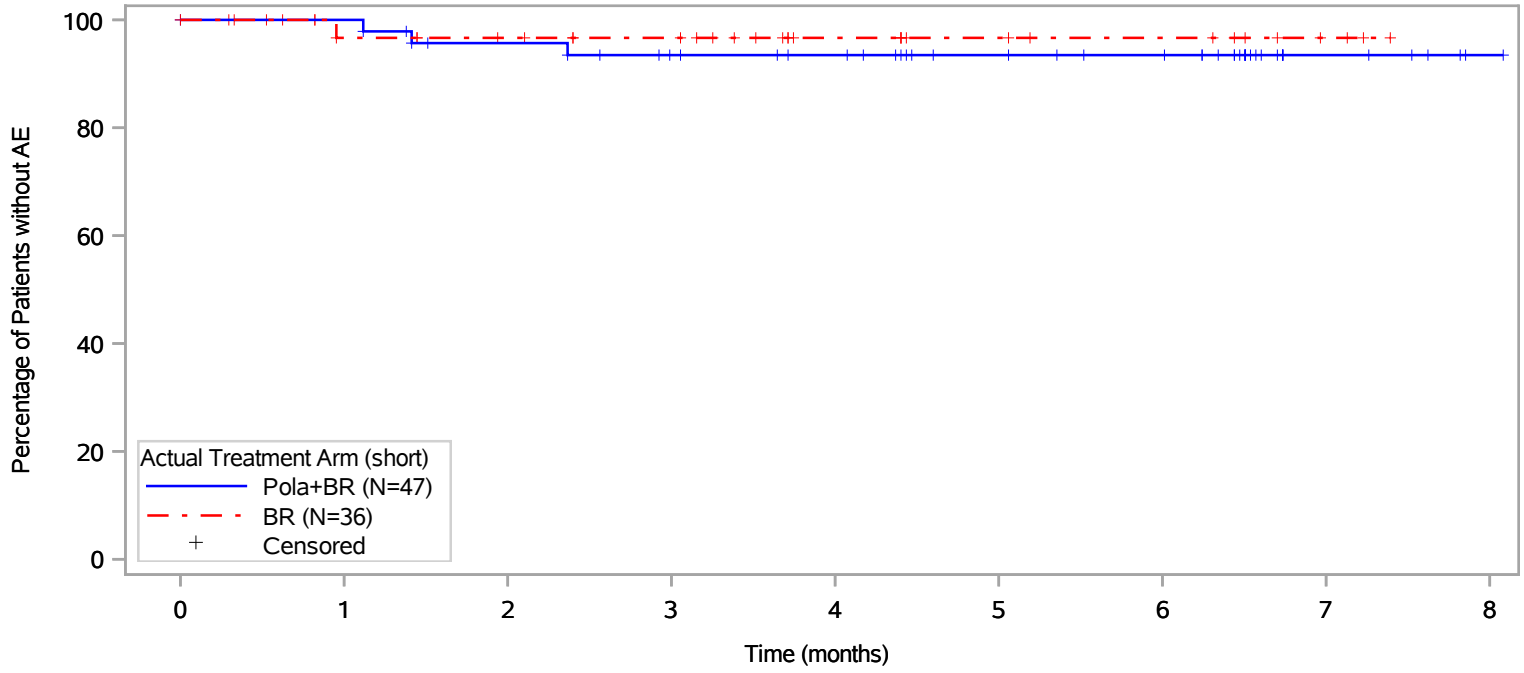
02DEC2022 3:43

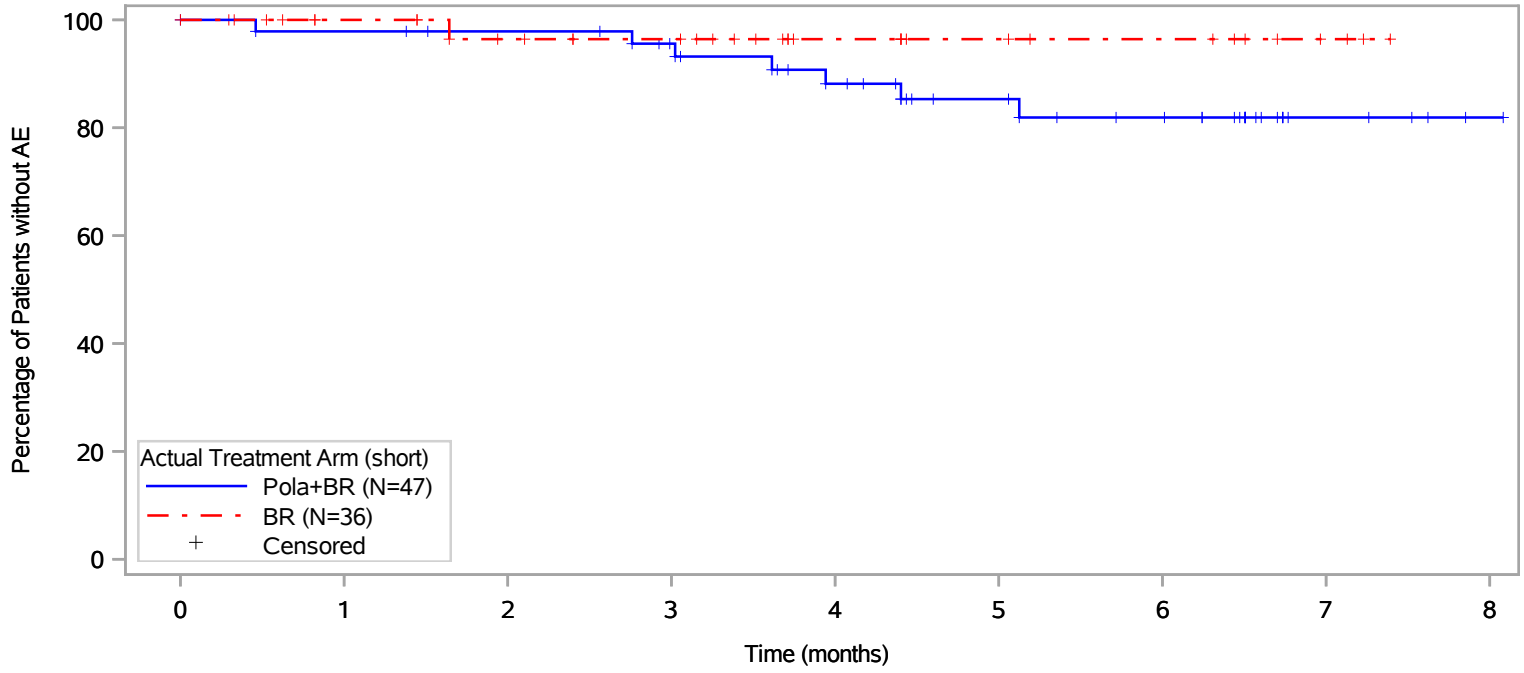
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	43	39	36	29	26	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	18	38	43
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	44	40	34	26	22	5	1
BR (N=36)	36	30	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	18	35	39
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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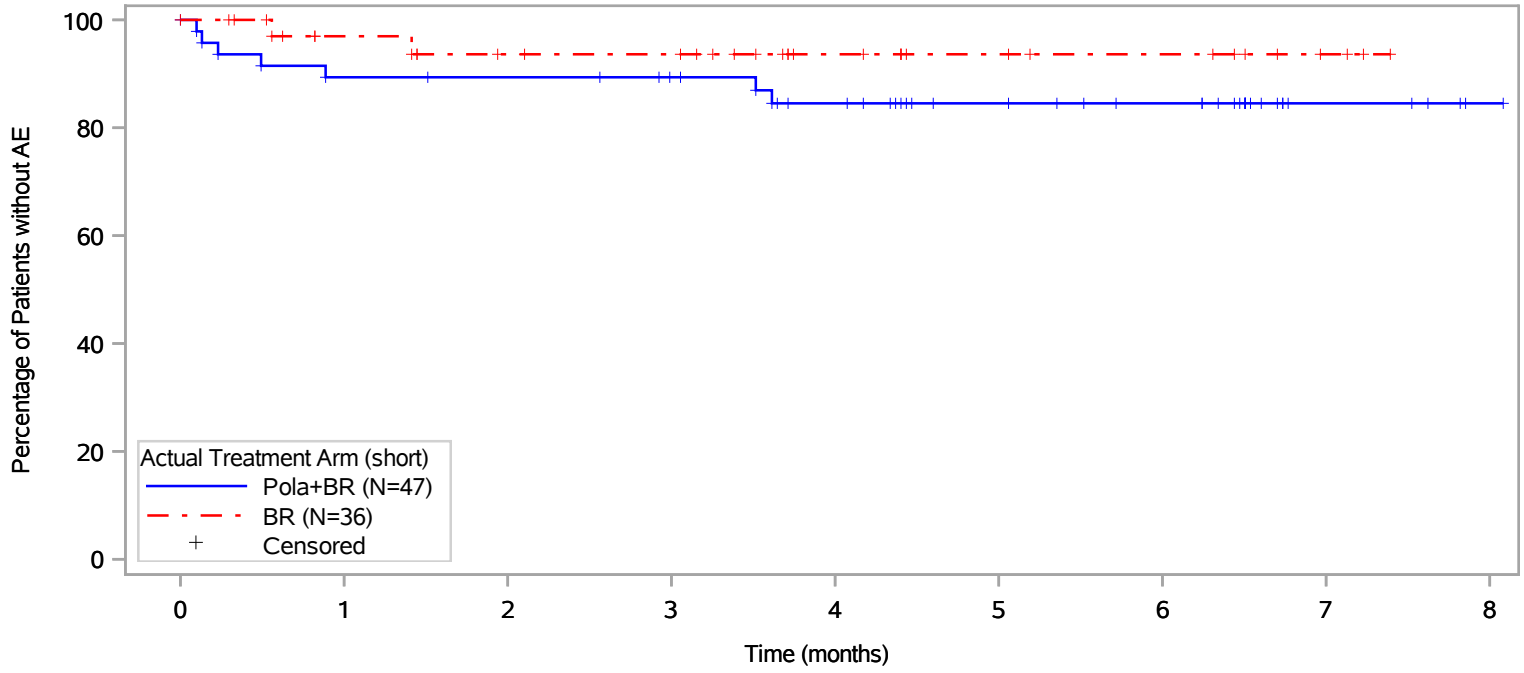
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	42	41	38	33	25	21	5	1
BR (N=36)	36	29	25	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	35	39
BR (N=36)	0	6	9	10	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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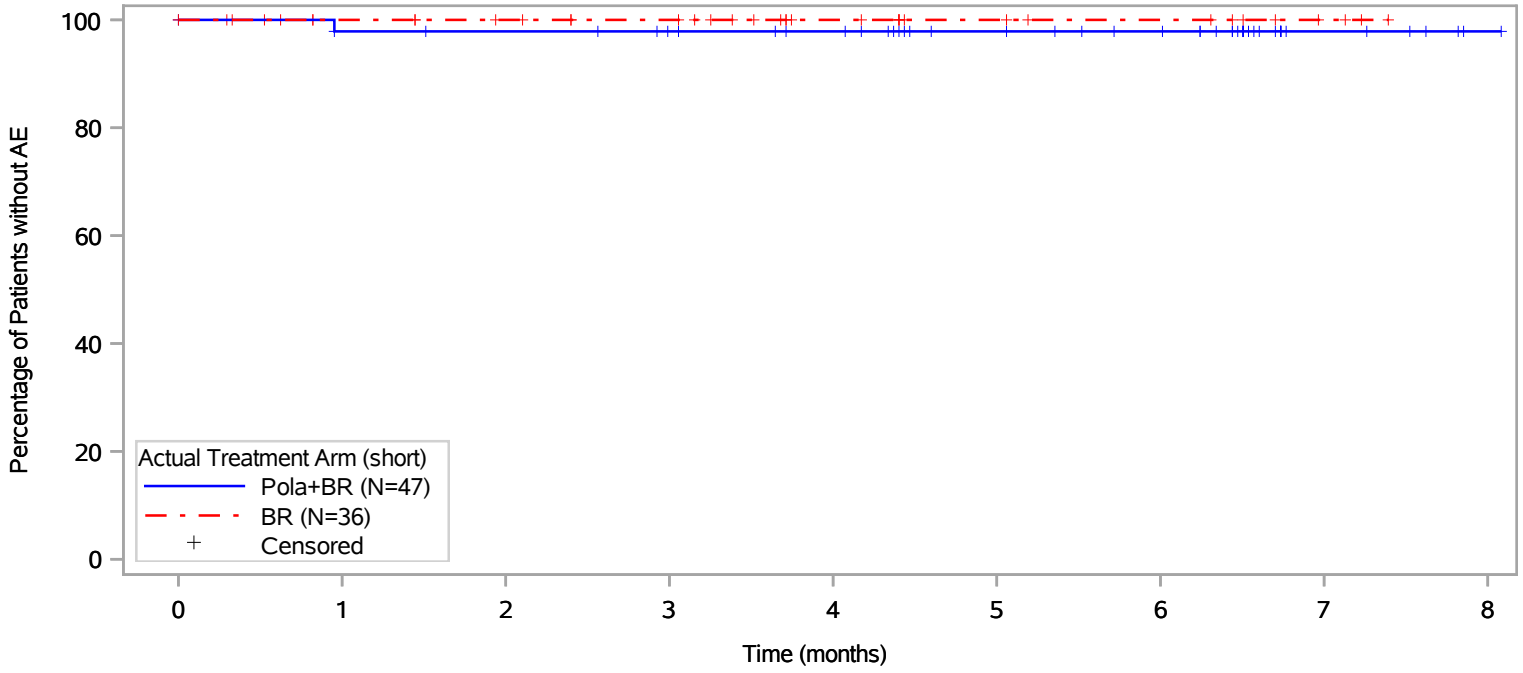
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOCALCAEMIA



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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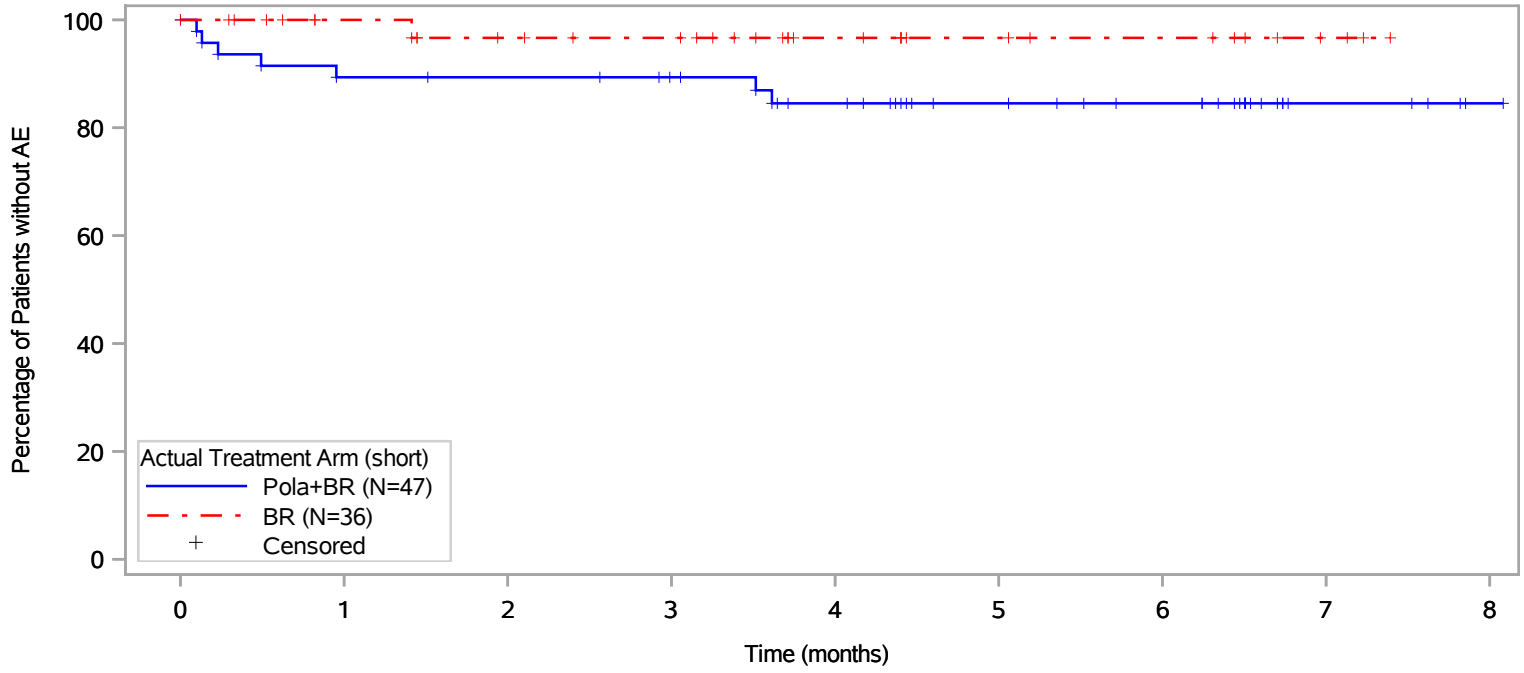
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk									
Pola+BR (N=47)	47	42	41	38	33	25	21	5	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	35	39
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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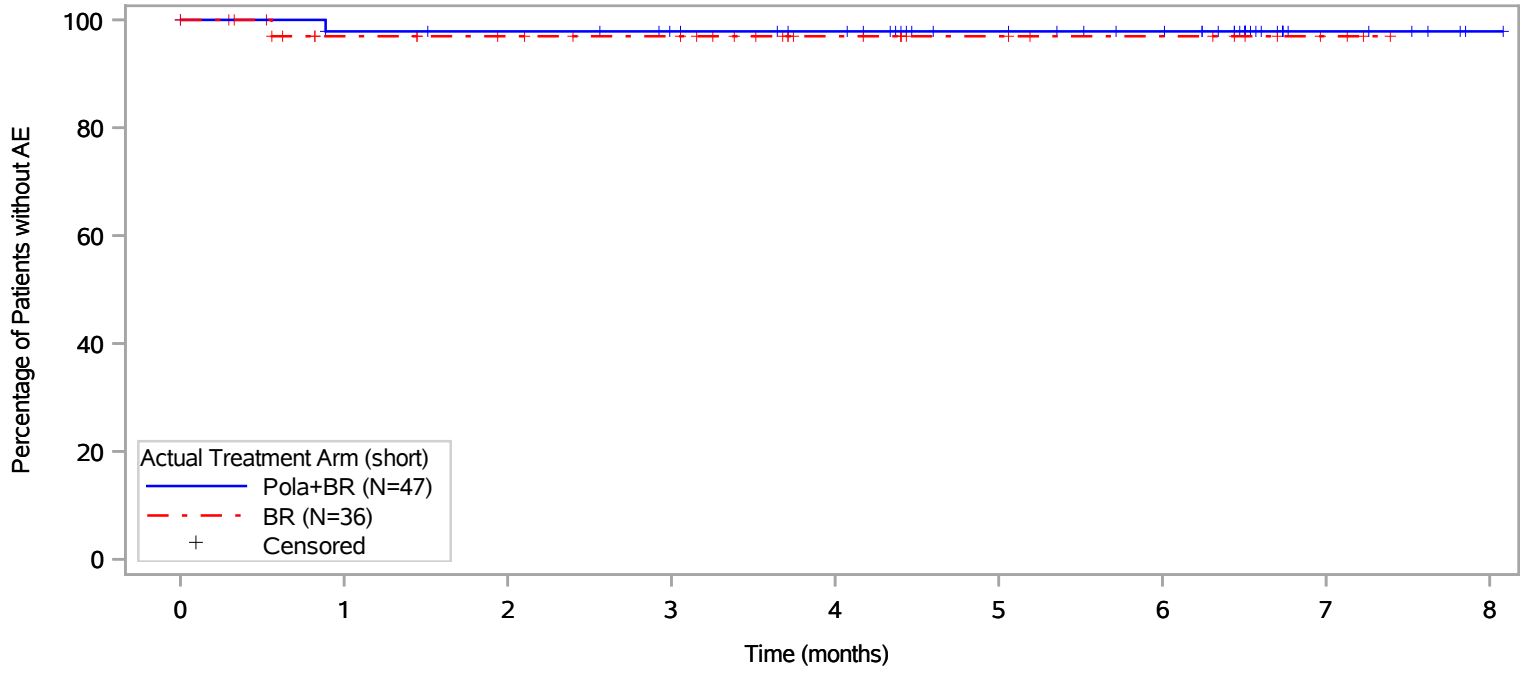
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOPHOSPHATAEMIA



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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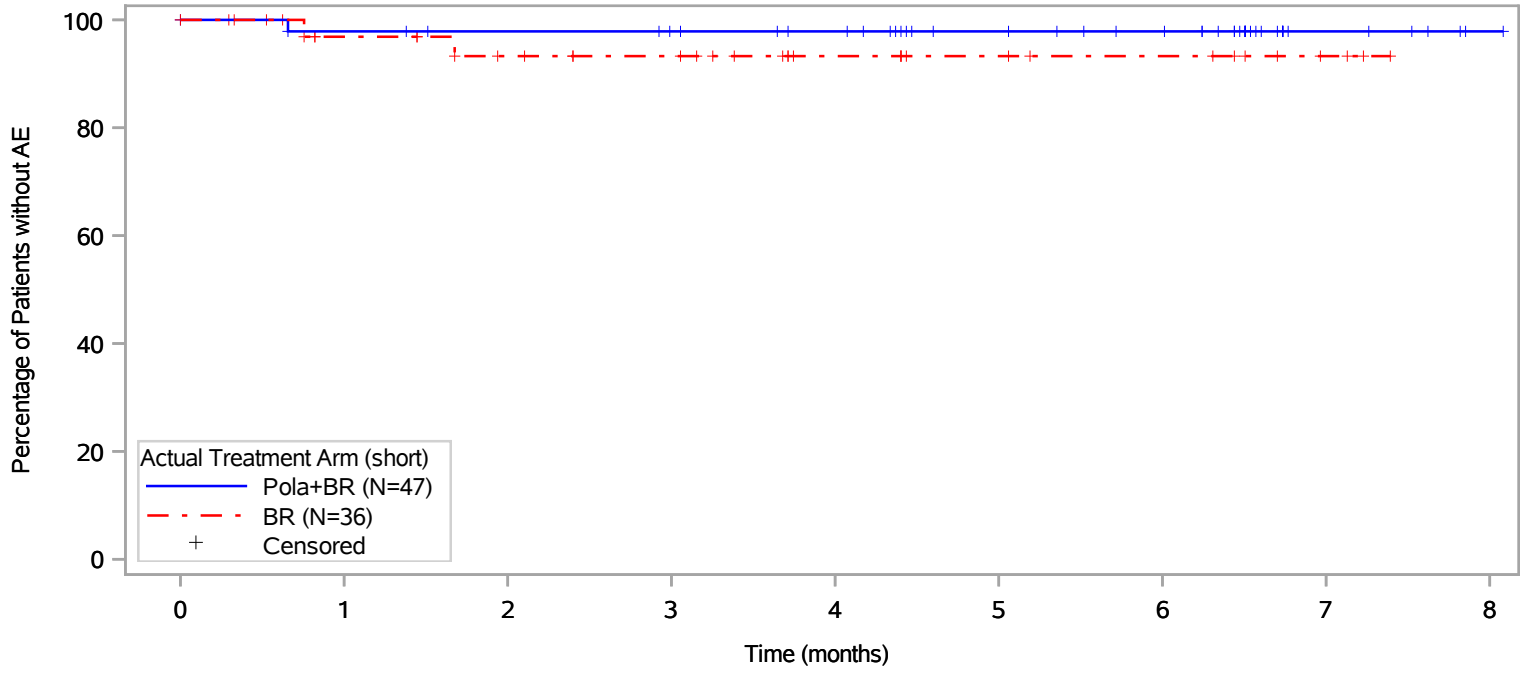
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



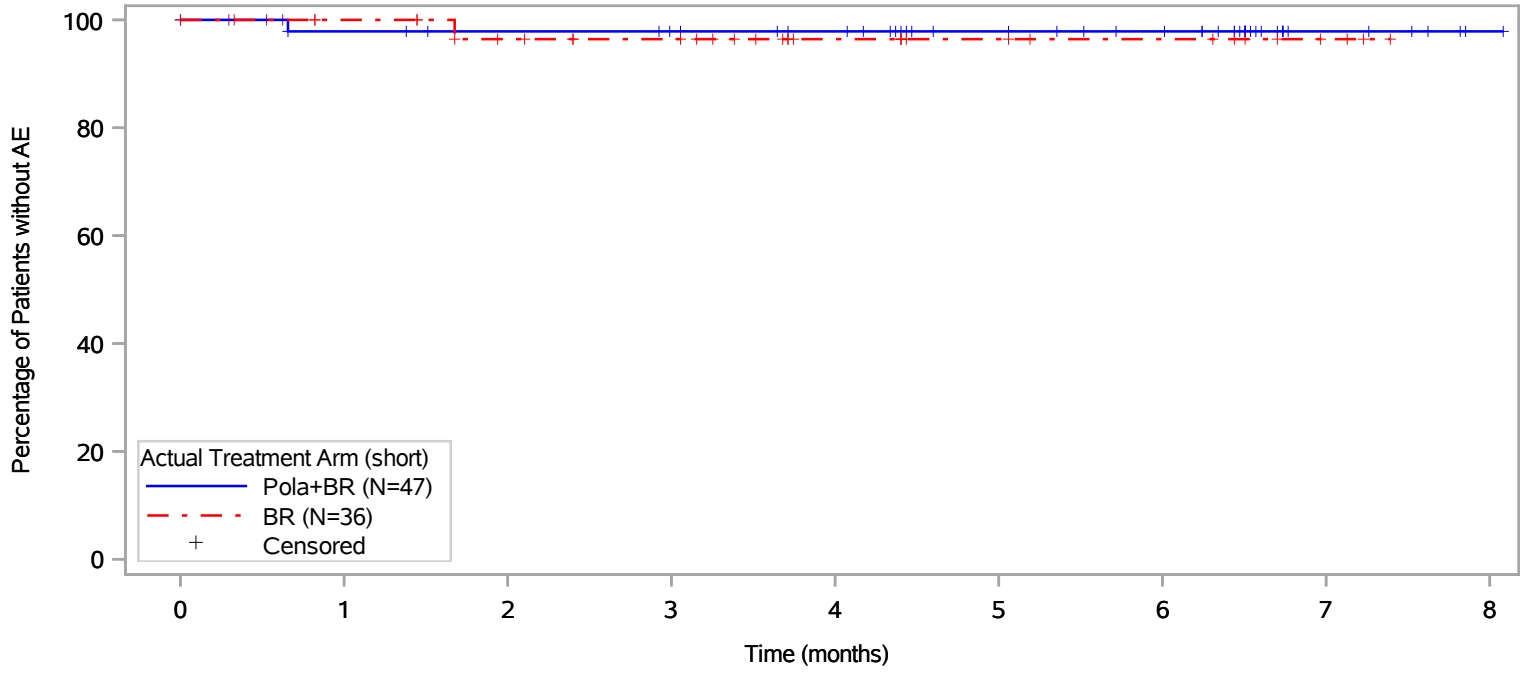
Patients at risk									
Pola+BR (N=47)	47	46	44	42	39	31	27	6	1
BR (N=36)	36	29	25	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	20	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN



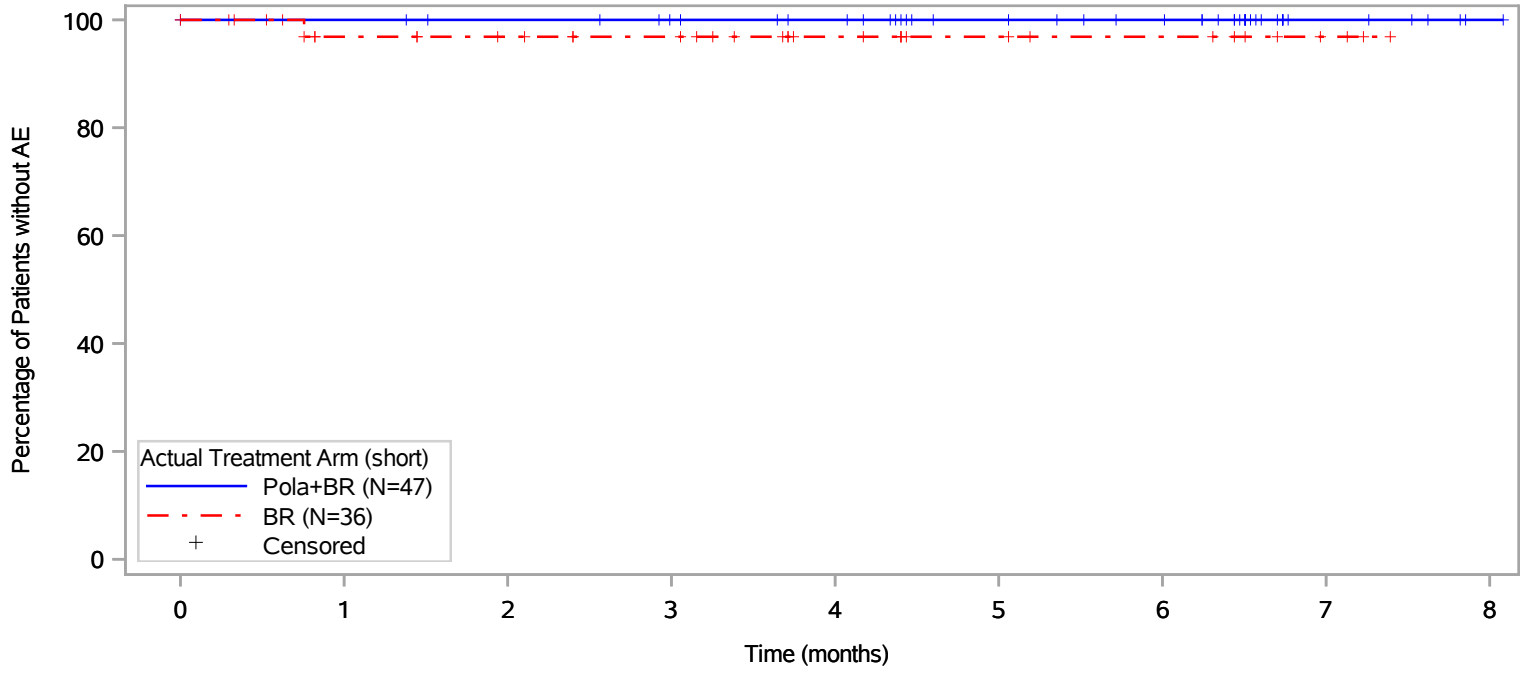
Patients at risk									
Pola+BR (N=47)	47	46	44	42	39	31	27	6	1
BR (N=36)	36	30	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, INTERVERTEBRAL DISC PROTRUSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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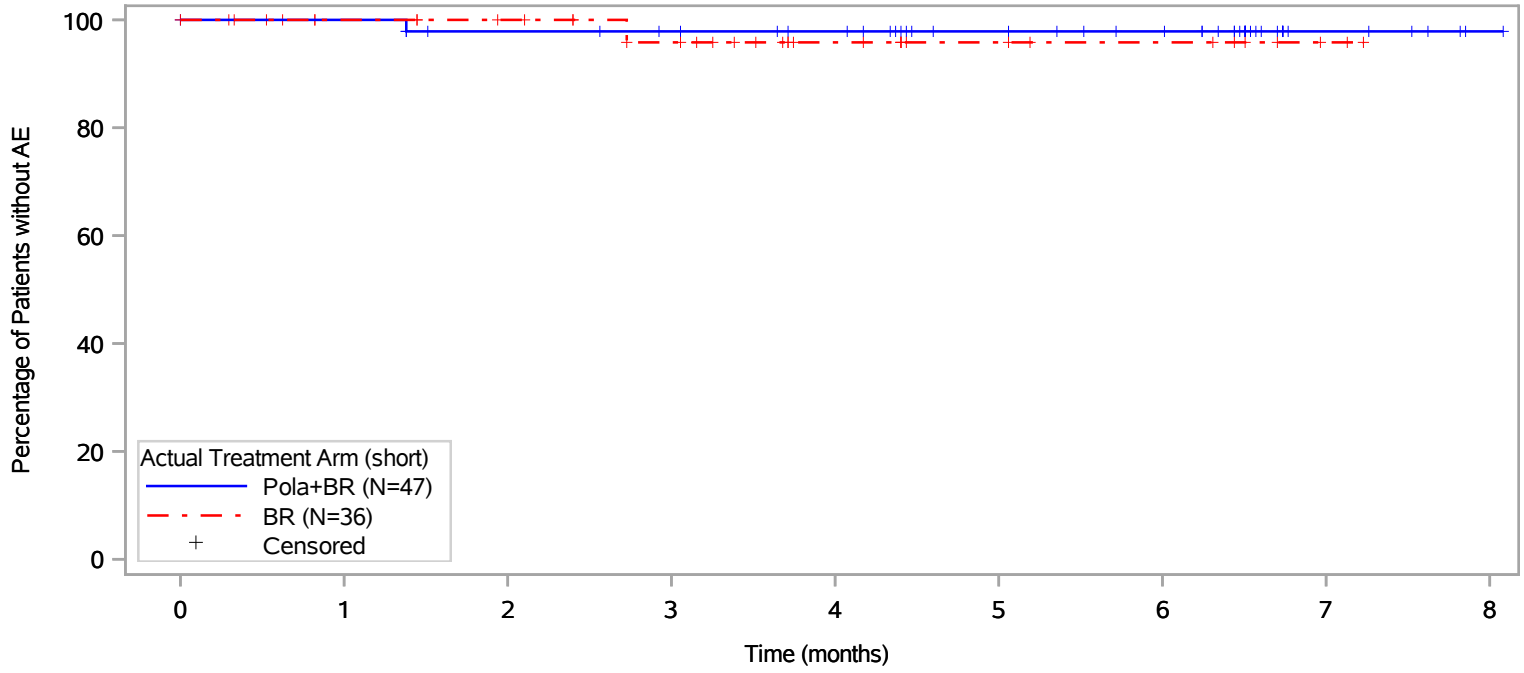
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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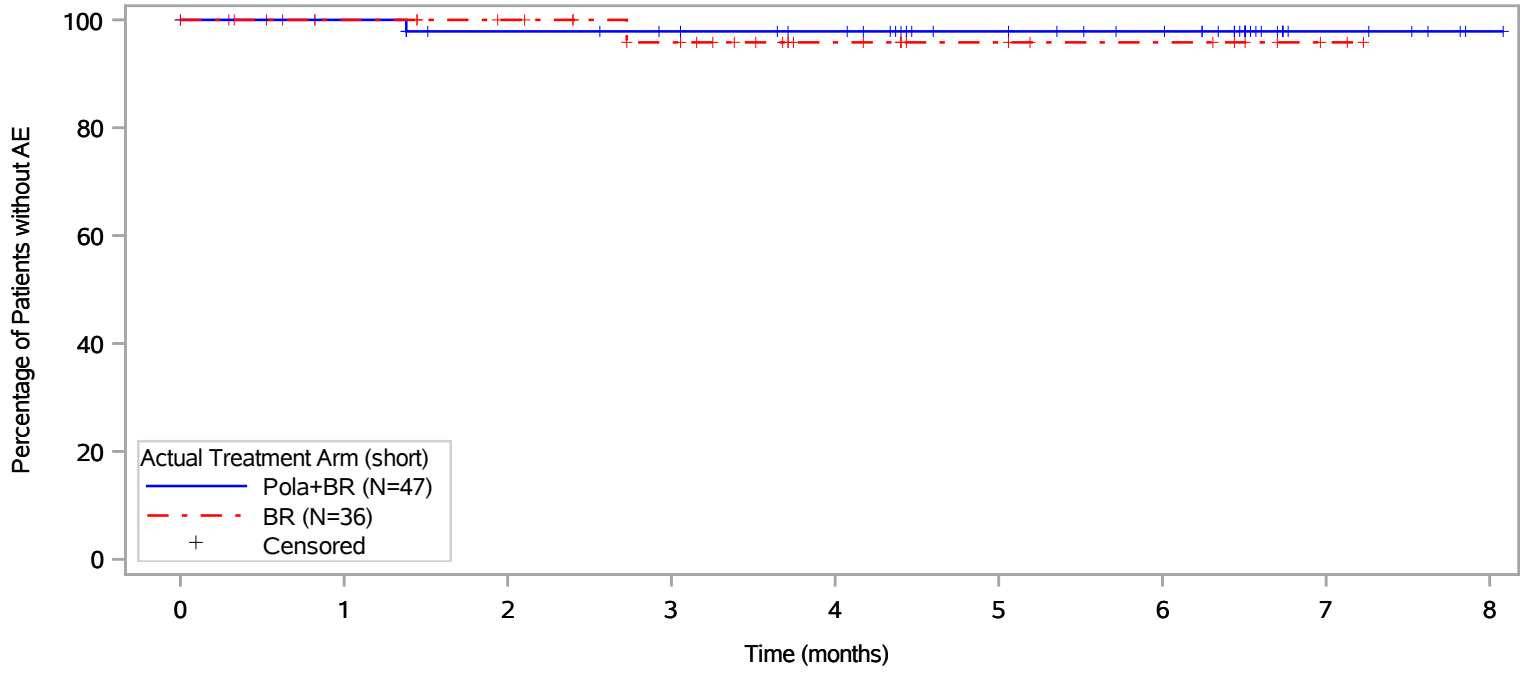
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, SYNCOPE



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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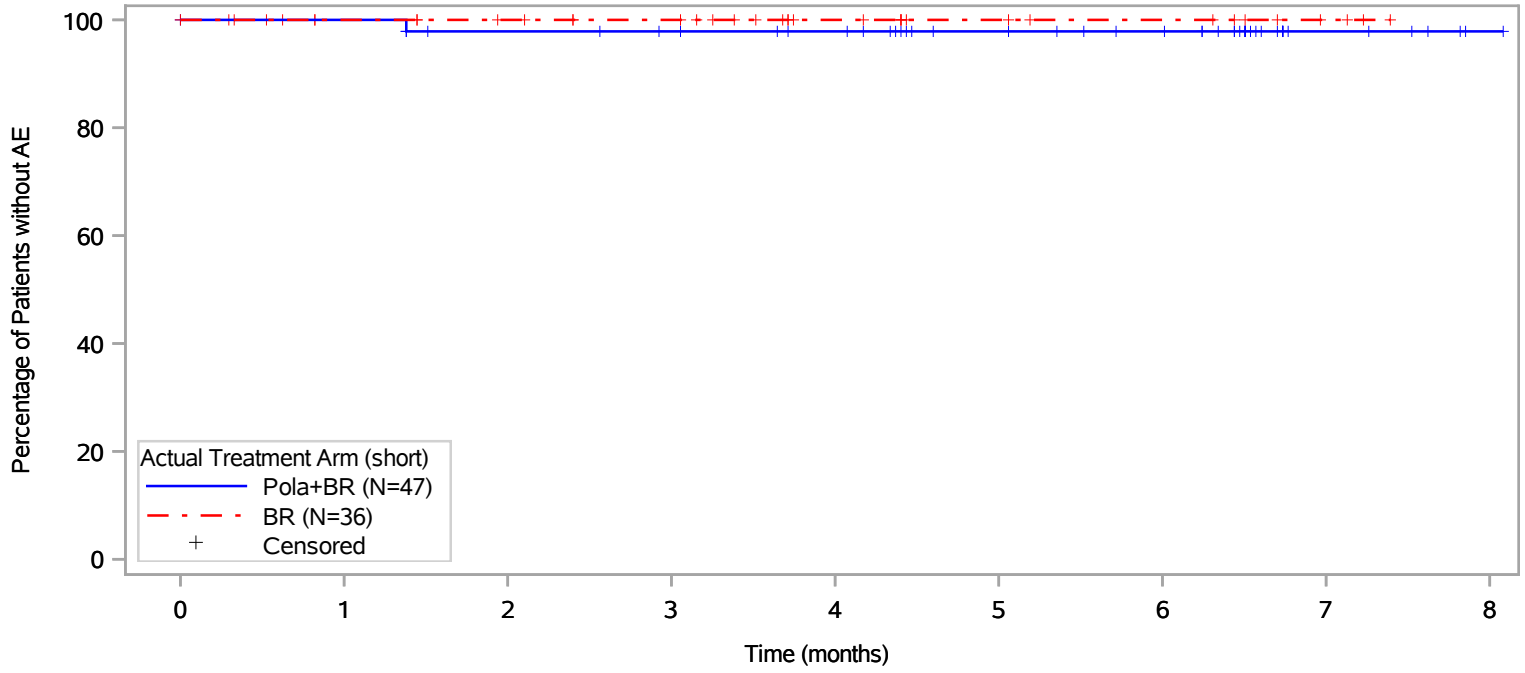
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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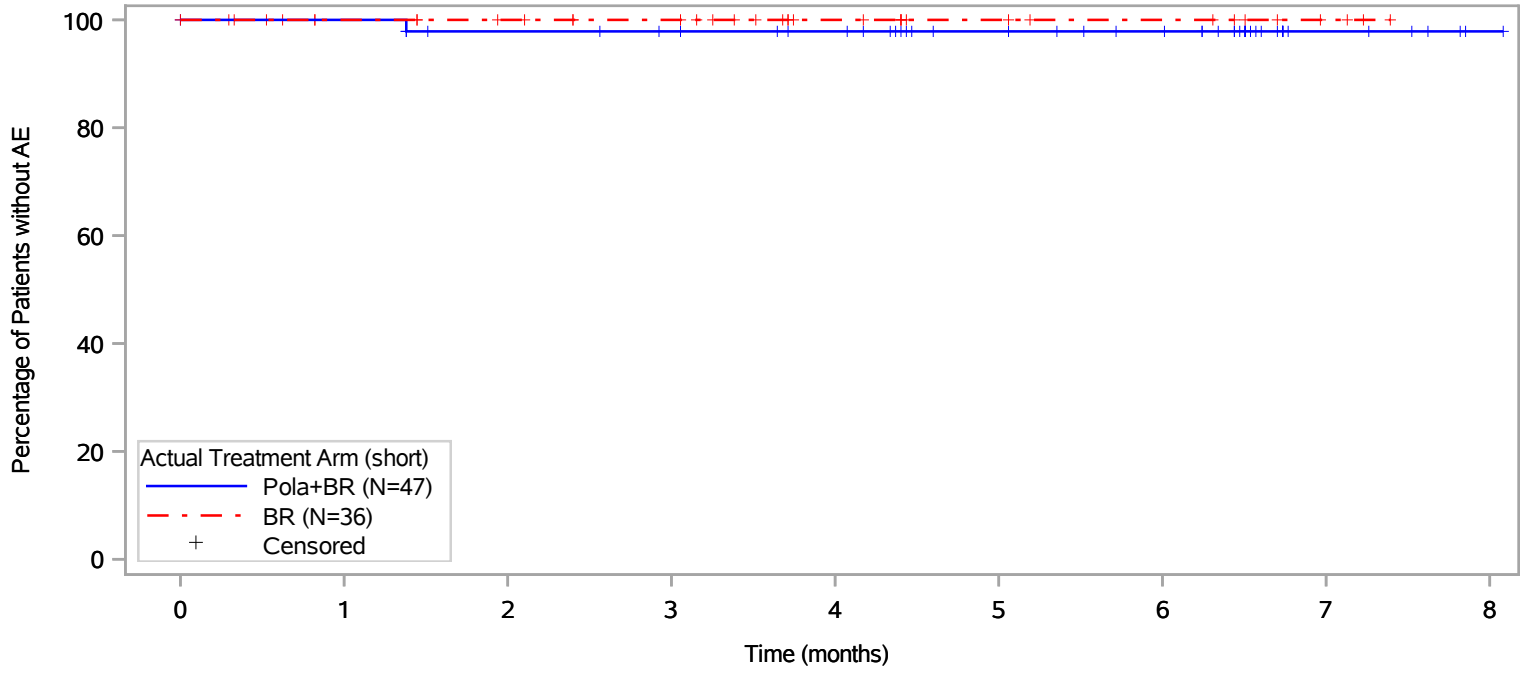
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, CONFUSIONAL STATE



Patients at risk									
Pola+BR (N=47)	47	47	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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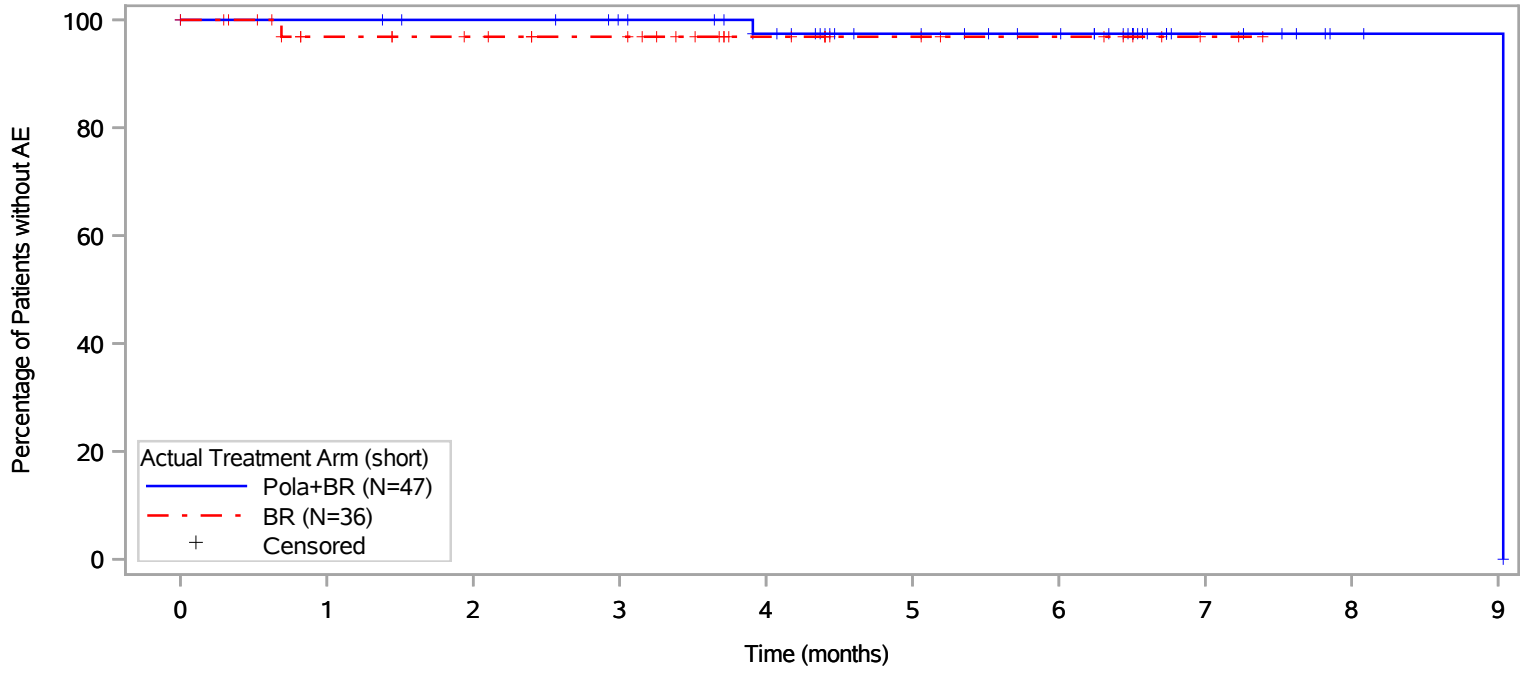
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk										
Pola+BR (N=47)	47	47	45	42	38	30	26	7	2	1
BR (N=36)	36	29	26	23	14	9	7	2	NE	NE
Patients censored										
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44	45
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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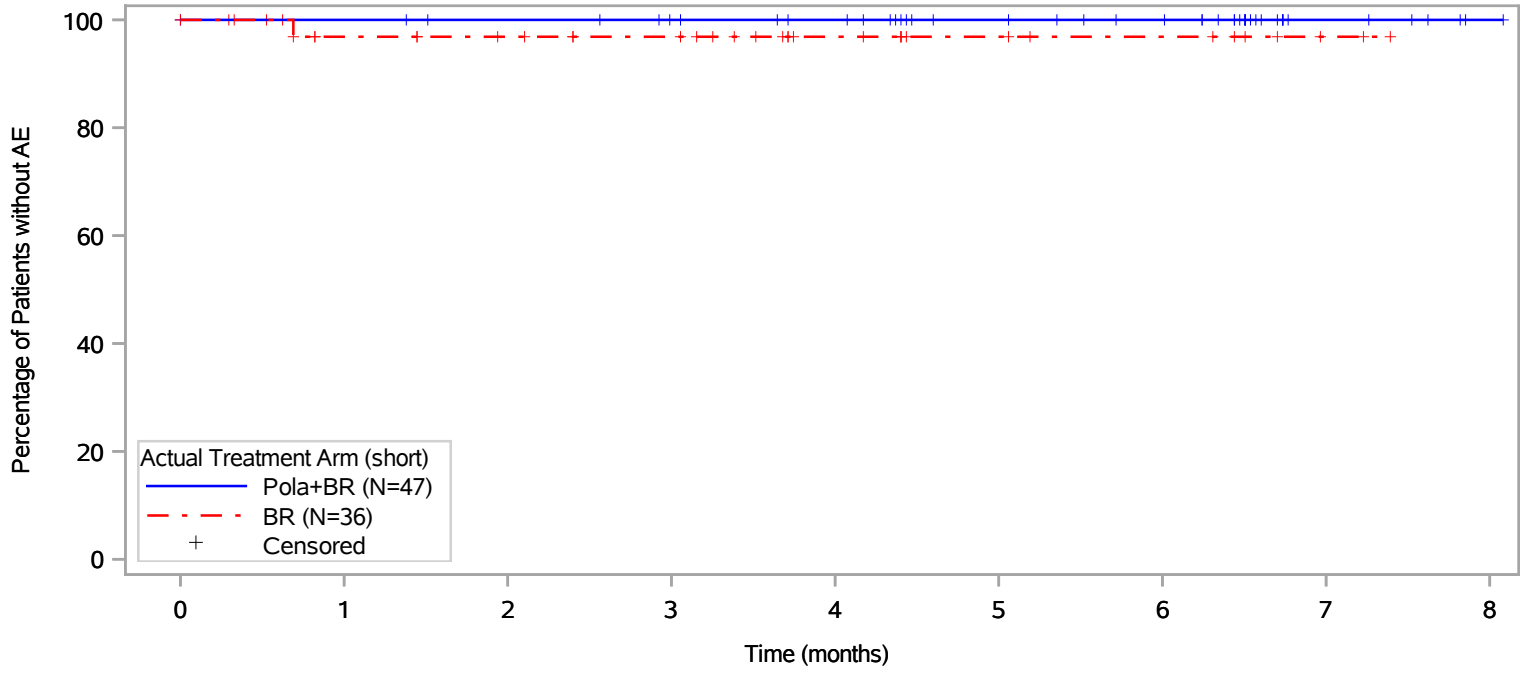
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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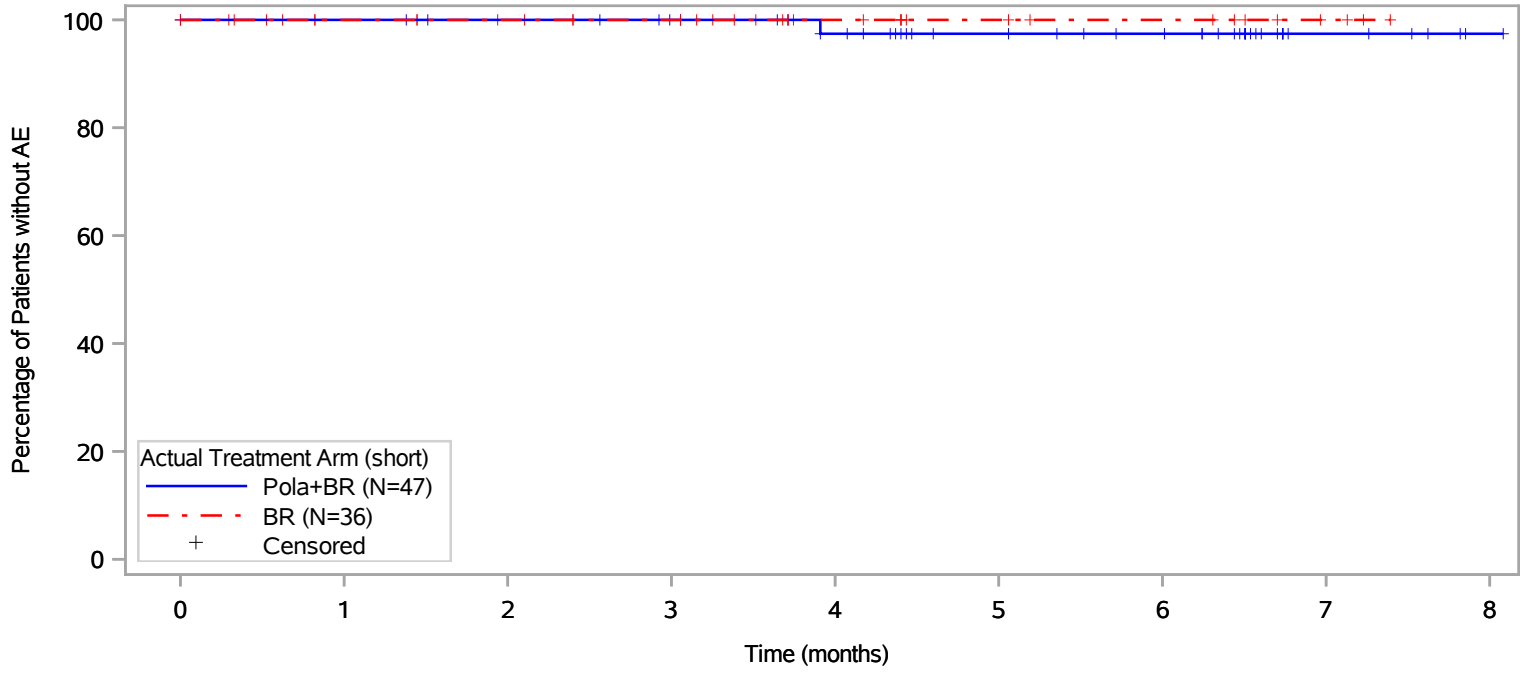
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HAEMATURIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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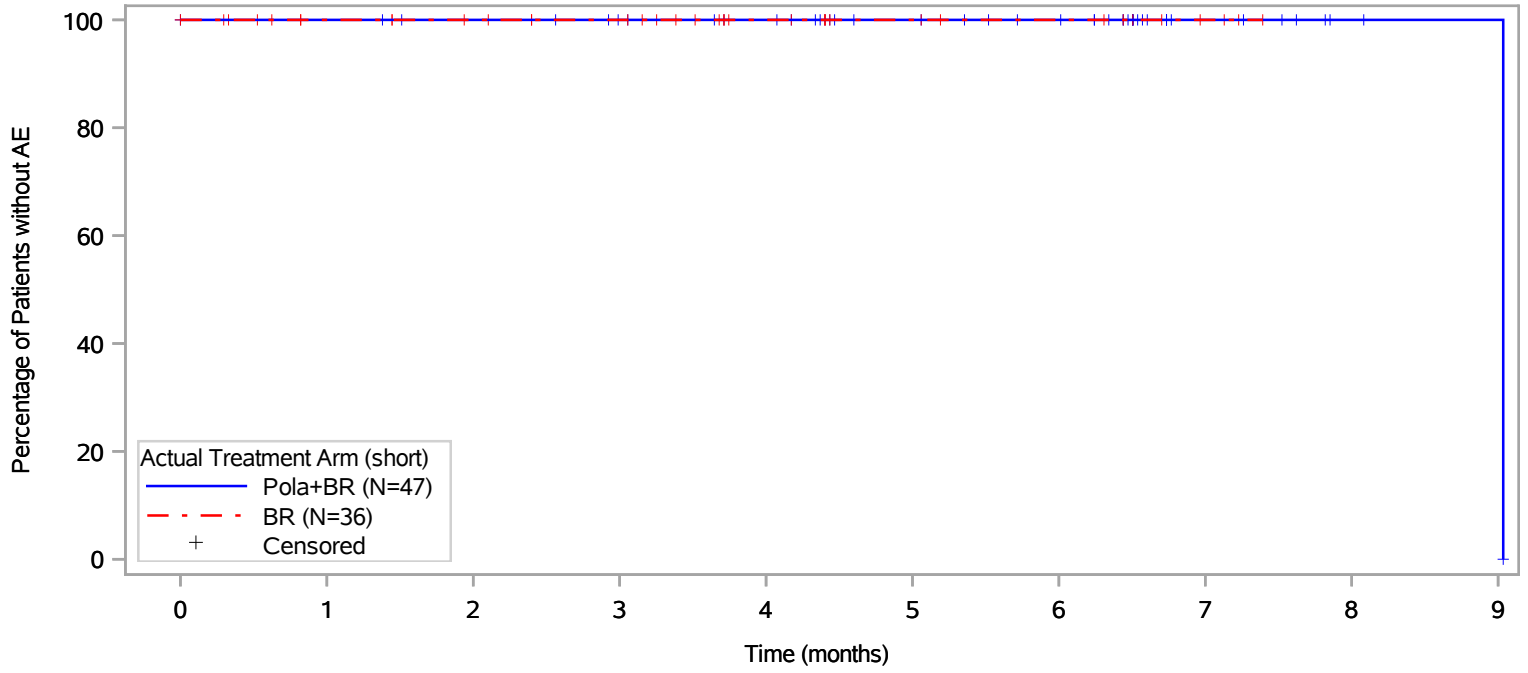
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk										
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE
Patients censored										
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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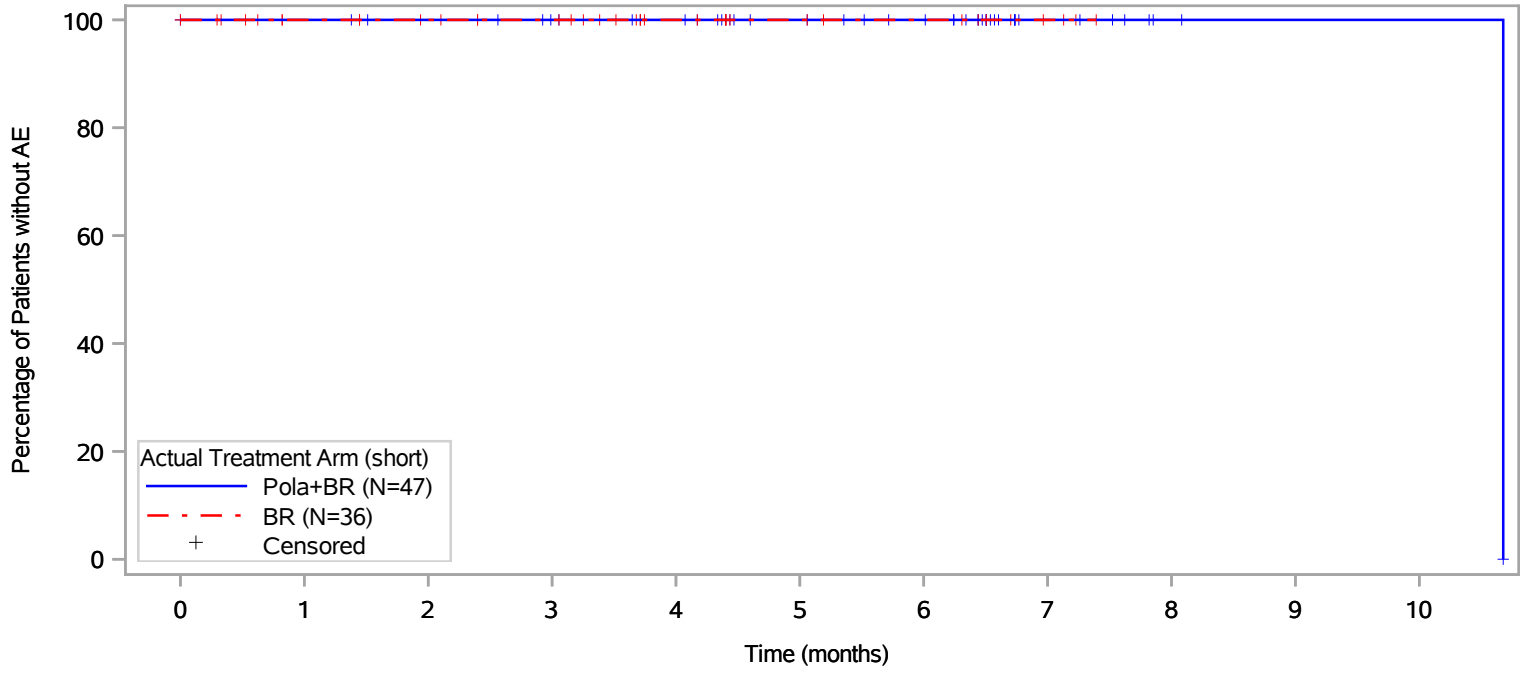
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE

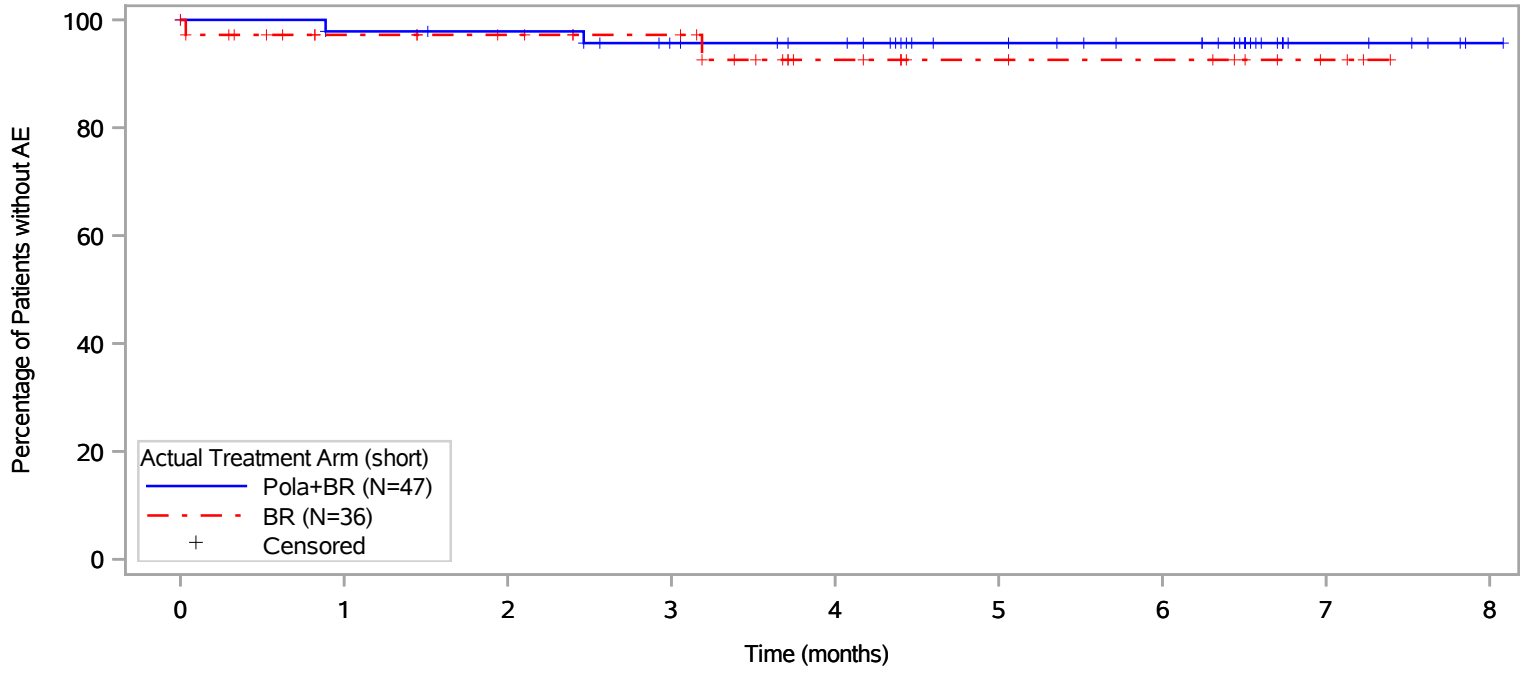


Patients at risk											
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	46	45	41	38	30	26	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	39	44
BR (N=36)	0	6	9	12	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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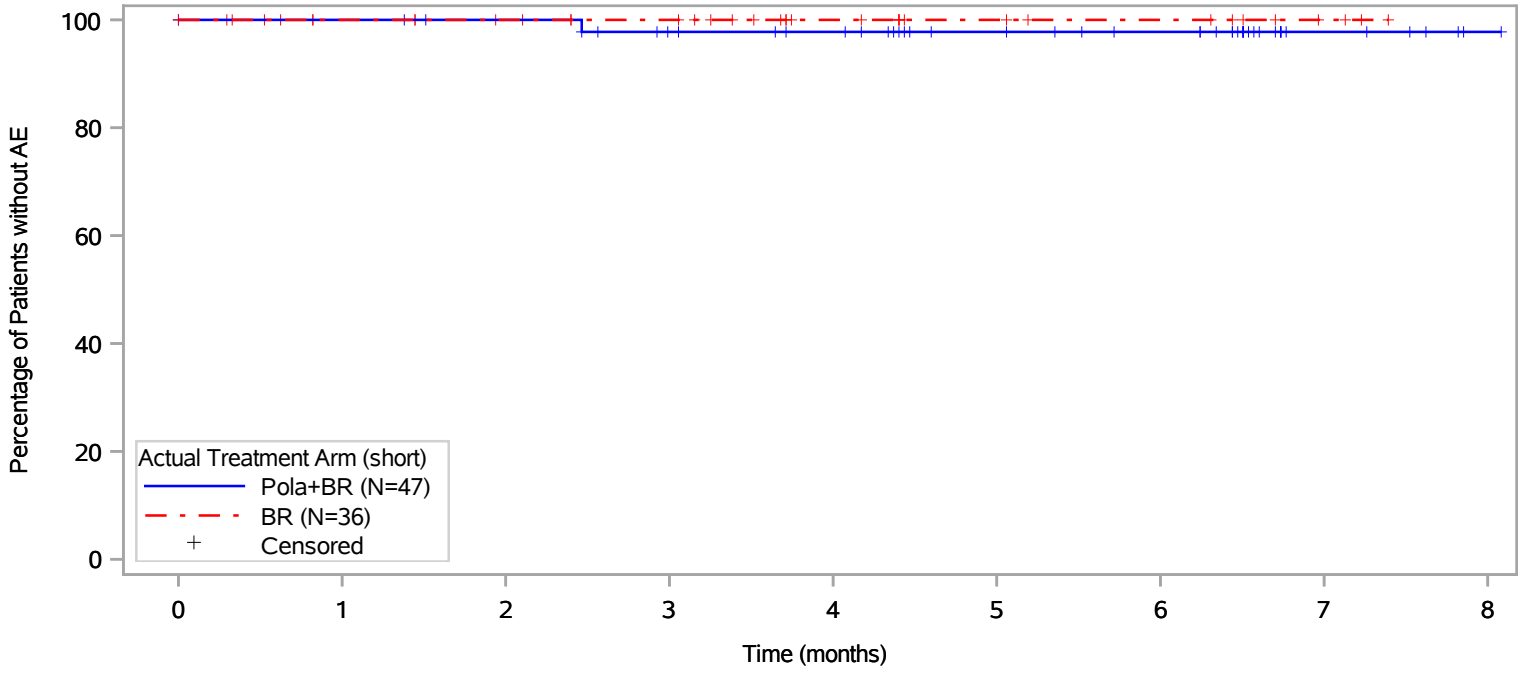
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, INTERSTITIAL LUNG DISEASE



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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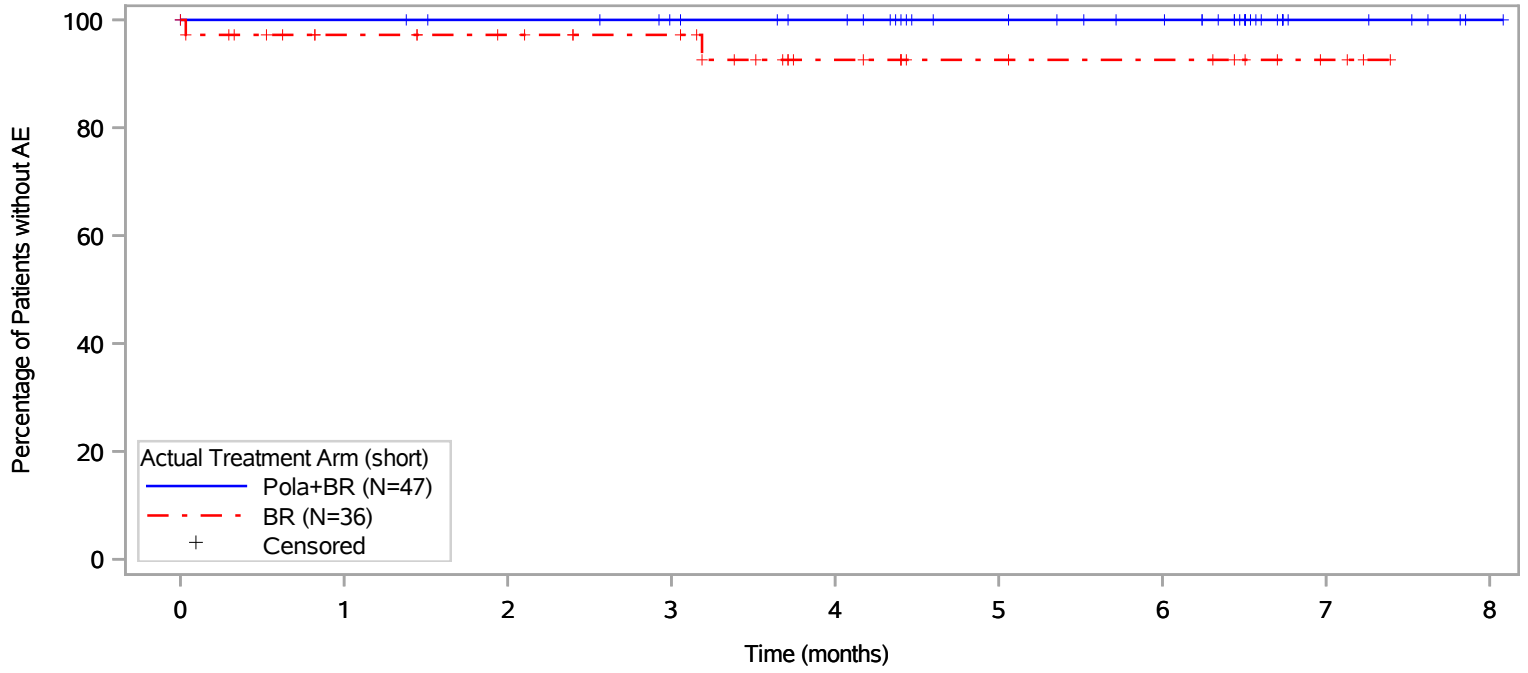
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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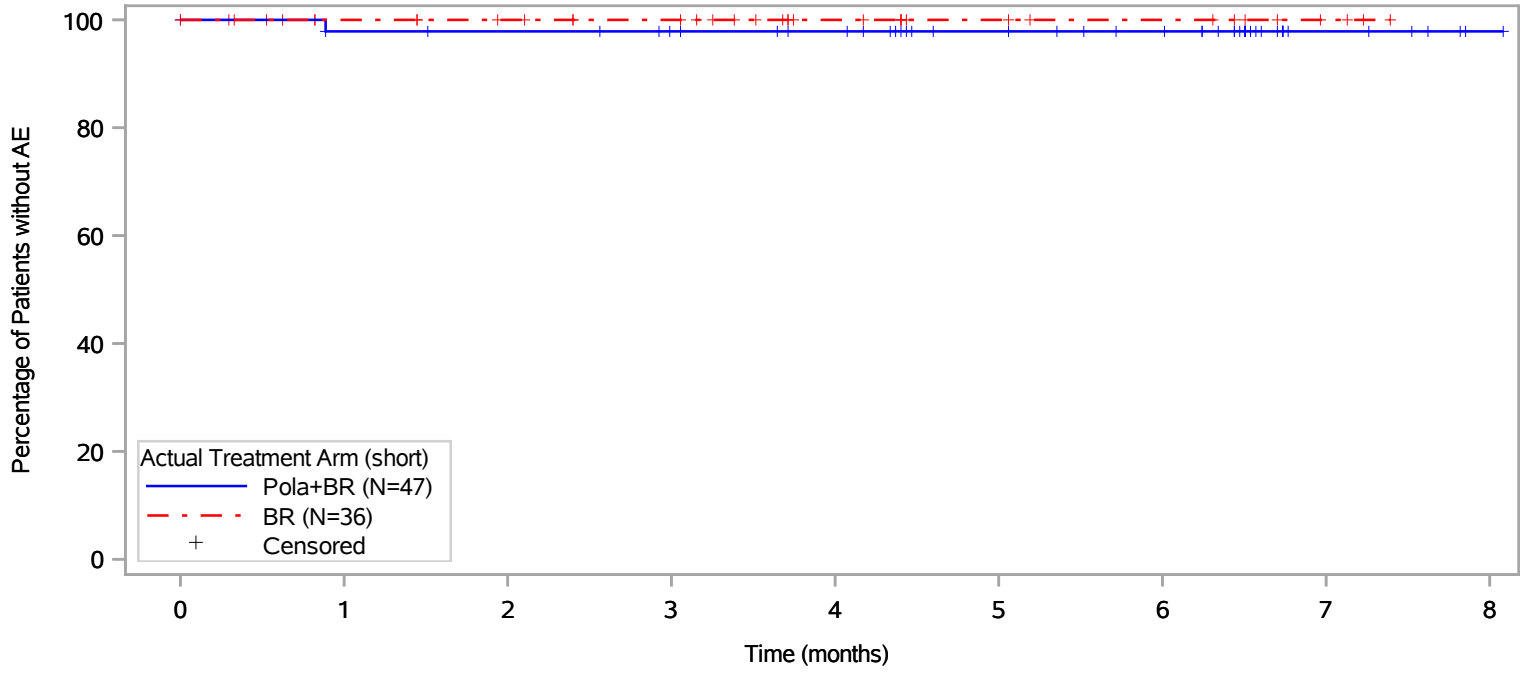
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY EMBOLISM



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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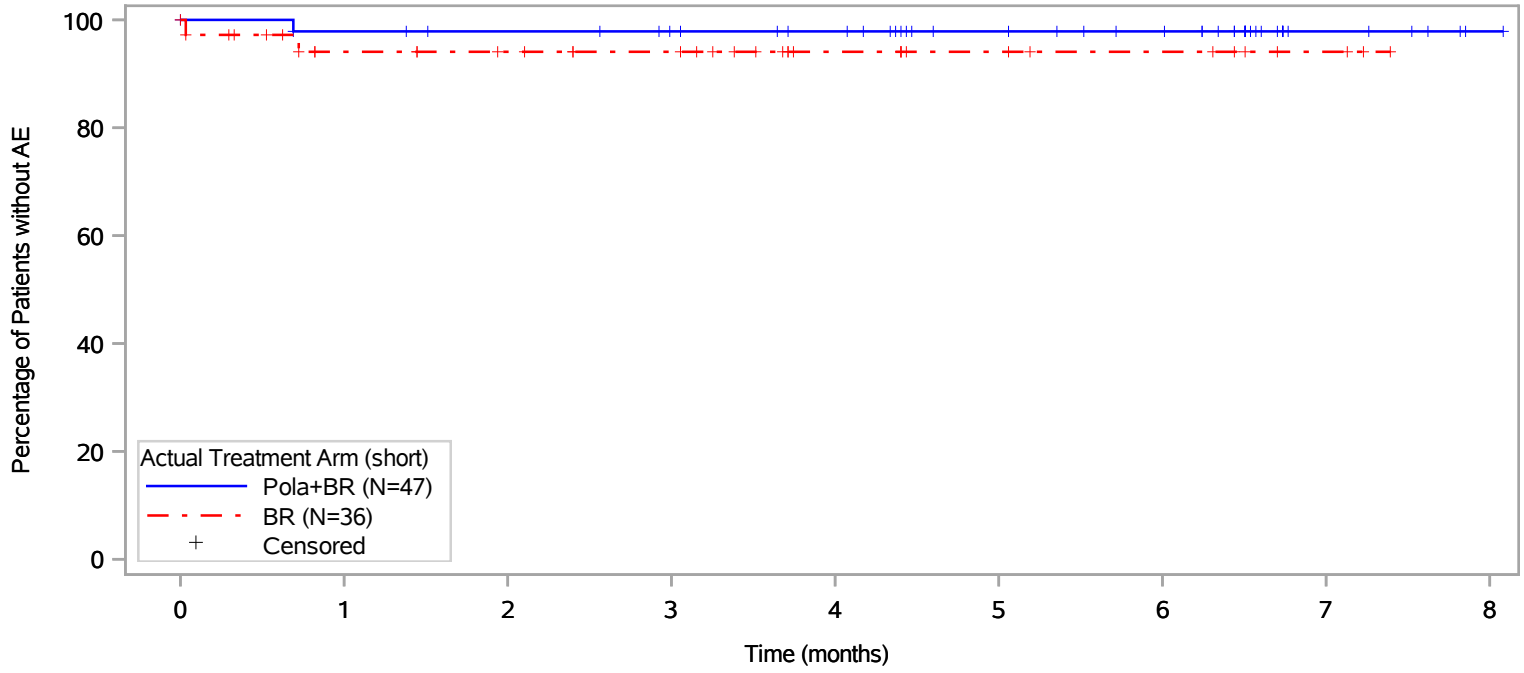
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	28	25	22	13	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	25	27	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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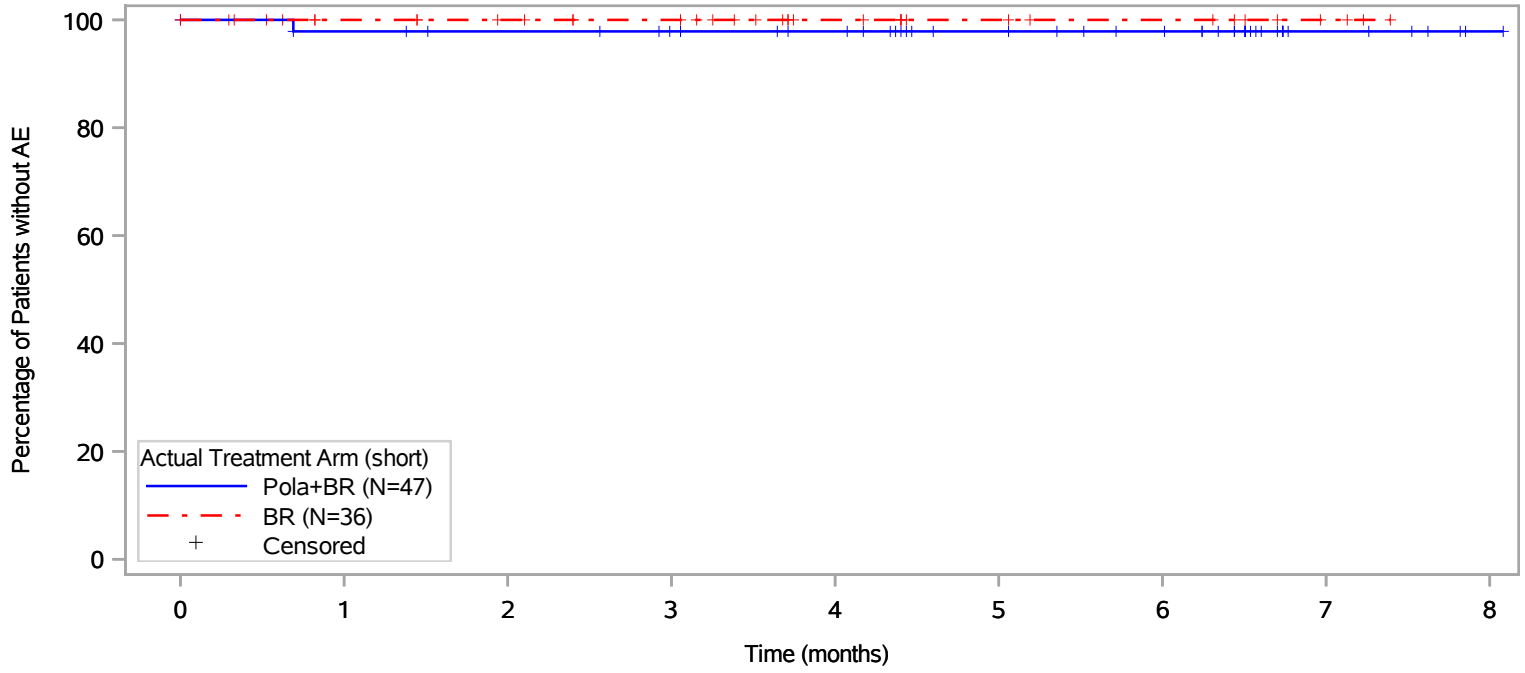
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DRUG ERUPTION



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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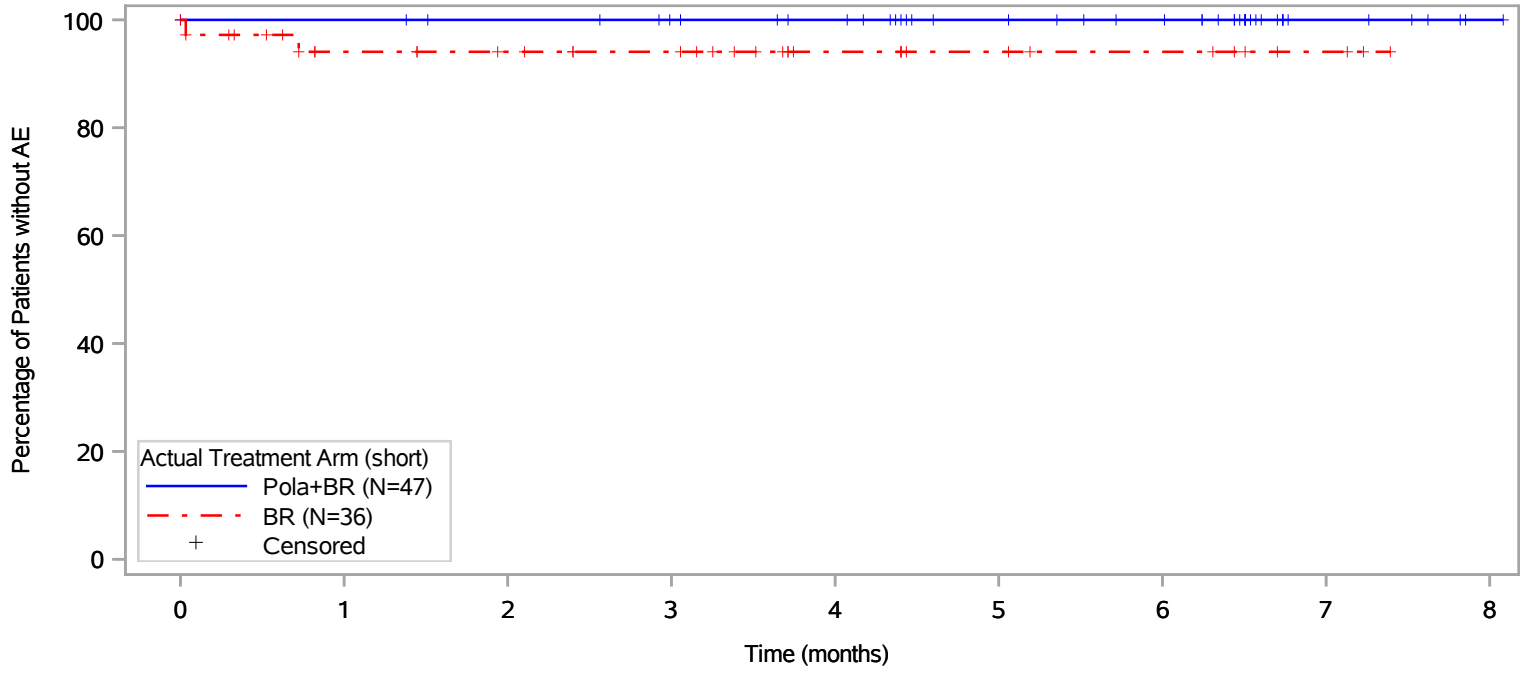
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	28	25	22	13	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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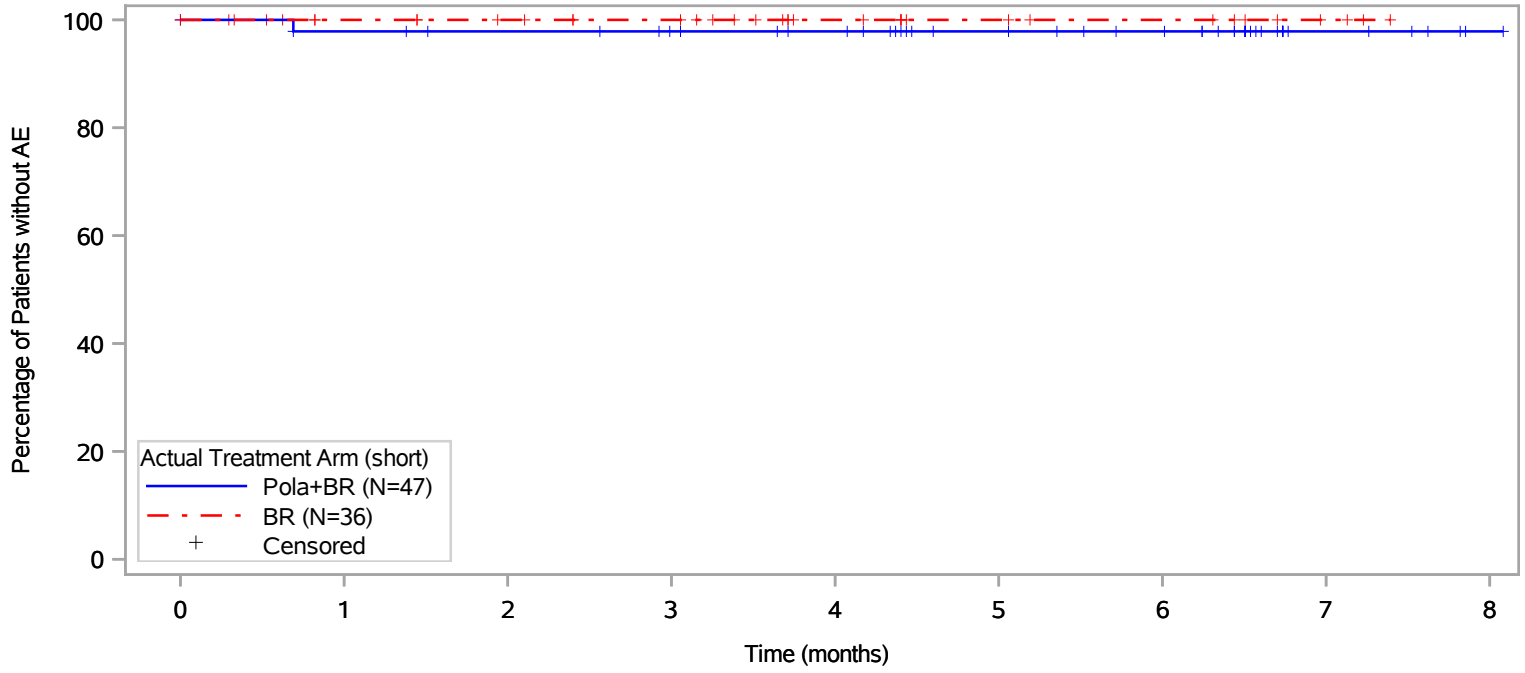
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, URTICARIA

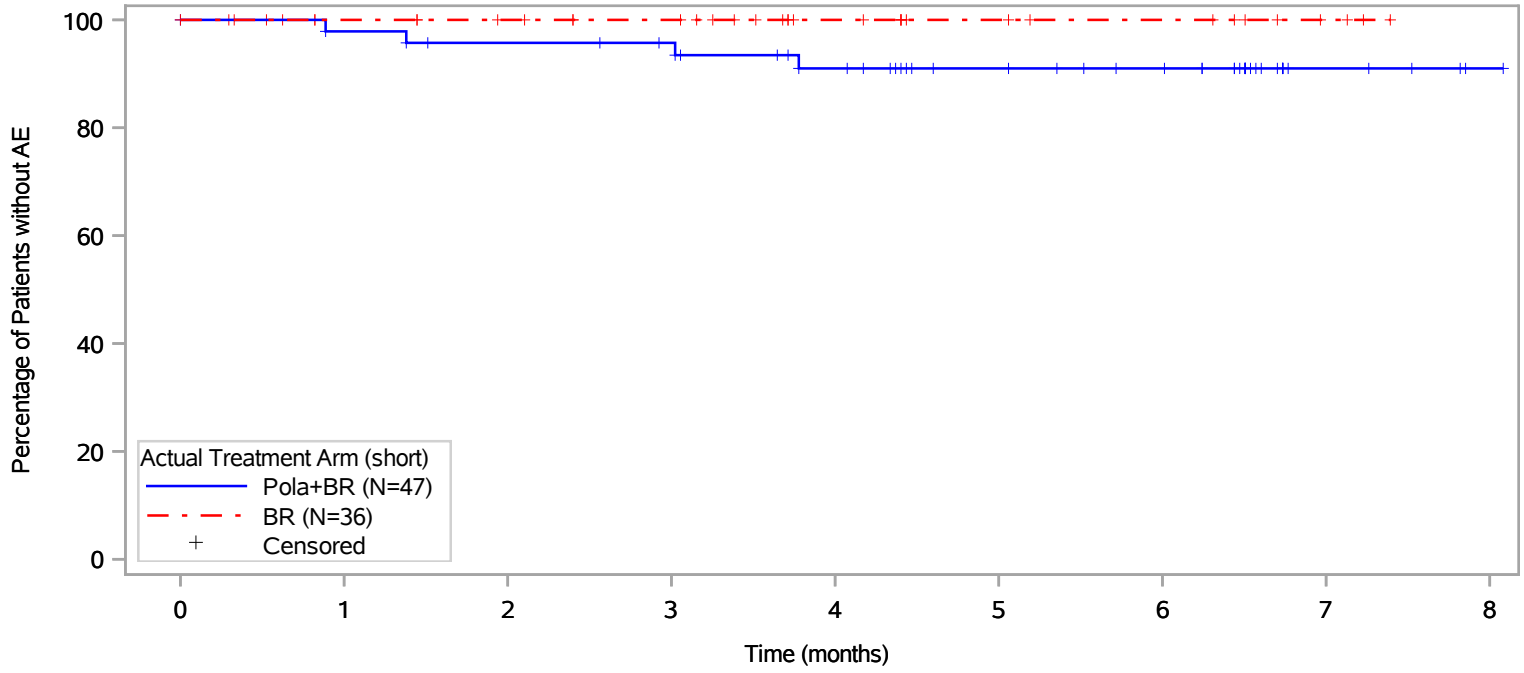


Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

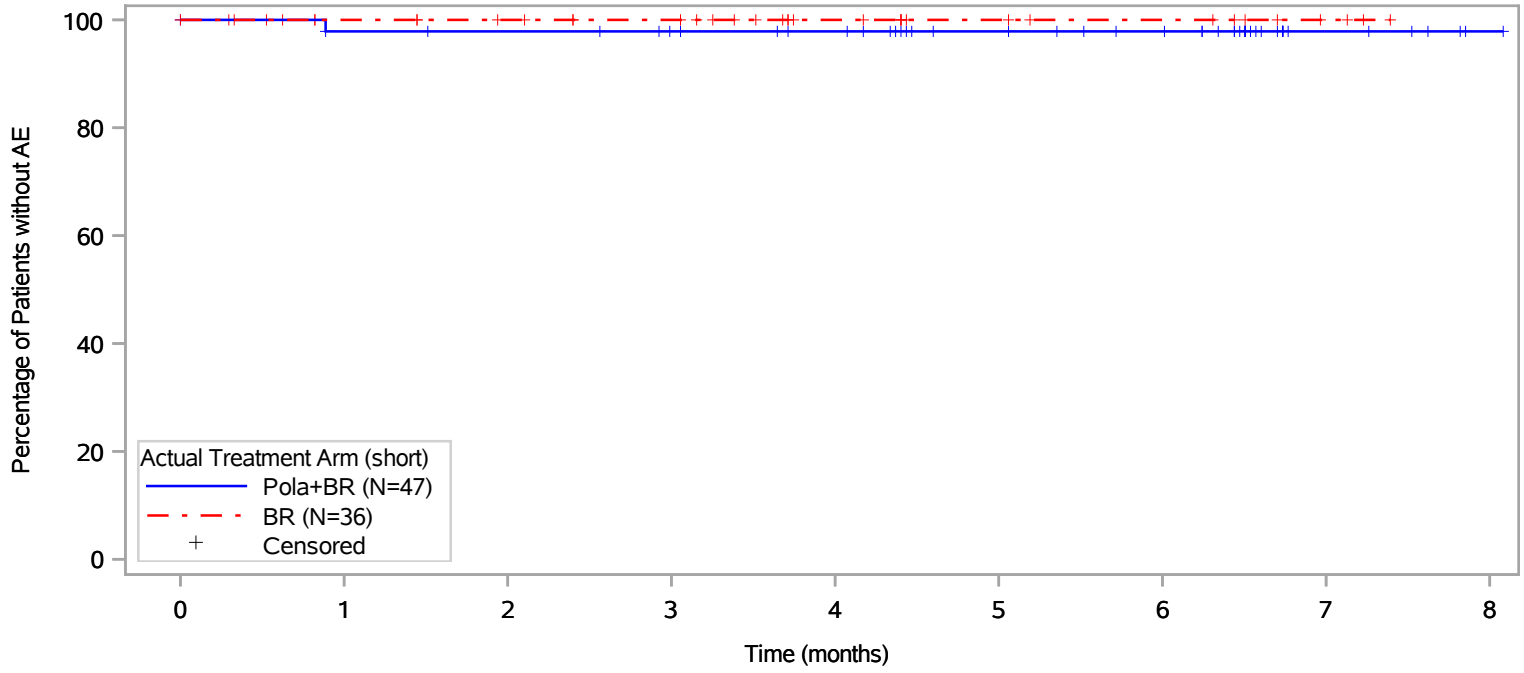
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	46	44	42	37	29	25	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	6	14	18	38	42
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DEEP VEIN THROMBOSIS

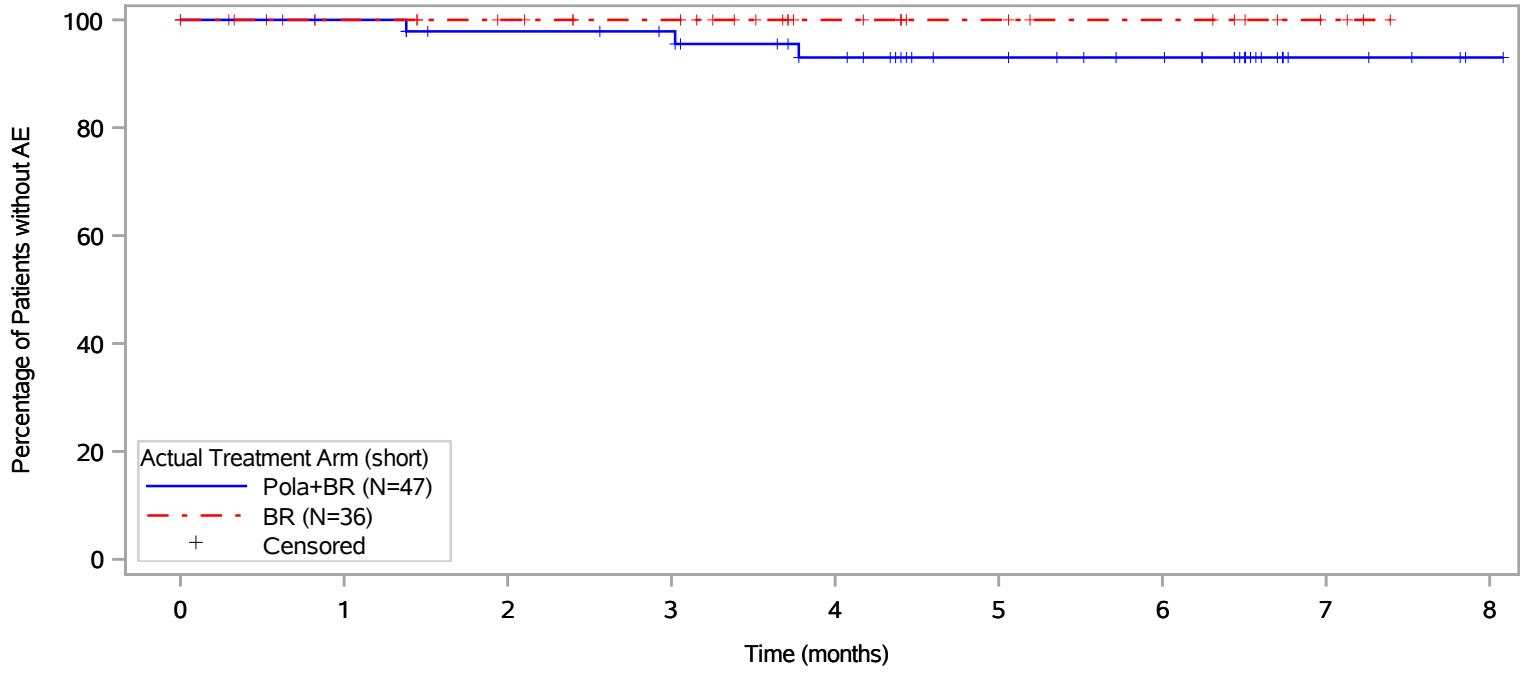


Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION



Patients at risk									
Pola+BR (N=47)	47	47	44	42	37	29	25	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	39	43
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR3AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 3:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			47	100.0	12	25.5	35	74.5	36	100.0	8	22.2	28	77.8	0.7885	1.27	0.50	3.25		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.2713	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.3040	0.36	0.03	3.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2199	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.6852	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		47	100.0	7	14.9	40	85.1	36	100.0	4	11.1	32	88.9	0.9086	1.29	0.38	4.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		47	100.0	6	12.8	41	87.2	36	100.0	4	11.1	32	88.9	0.5532	0.73	0.19	2.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.2049	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2049	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			47	100.0	5	10.6	42	89.4	36	100.0	1	2.8	35	97.2	0.2770	3.19	0.37	27.72		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2889	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			47	100.0	11	23.4	36	76.6	36	100.0	3	8.3	33	91.7	0.2781	1.71	0.47	6.26		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		47	100.0	4	8.5	43	91.5	36	100.0	2	5.6	34	94.4	0.7061	0.97	0.17	5.51		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		47	100.0	5	10.6	42	89.4	36	100.0	0	-	36	100.0	0.0974	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		47	100.0	4	8.5	43	91.5	36	100.0	0	-	36	100.0	0.1734	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	TRANSAMINASES INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	URINE OUTPUT DECREASED		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2327	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		47	100.0	5	10.6	42	89.4	36	100.0	1	2.8	35	97.2	0.3614	2.45	0.28	21.09		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2554	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.2554	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1722	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1722	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR4AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 21:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	29	61.7	7	24.1	22	75.9	20	55.6	6	30.0	14	70.0	0.5143	0.90	0.30	2.73		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	18	38.3	5	27.8	13	72.2	16	44.4	2	12.5	14	87.5	0.1860	3.72	0.43	31.96		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.3778	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.2713	0.40	0.04	4.42		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.2421	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6063	0.37	0.02	5.93		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	29	61.7	4	13.8	25	86.2	20	55.6	4	20.0	16	80.0	0.4022	0.82	0.20	3.28		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	0	-	16	100.0	0.1335	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	29	61.7	3	10.3	26	89.7	20	55.6	3	15.0	17	85.0	0.2755	0.44	0.07	2.68		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	1	6.3	15	93.8	0.7867	1.30	0.12	14.34		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1915	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1915	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3159	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	18	38.3	3	16.7	15	83.3	16	44.4	1	6.3	15	93.8	0.5017	2.11	0.21	20.75		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.3159	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	29	61.7	9	31.0	20	69.0	20	55.6	2	10.0	18	90.0	0.3889	1.55	0.32	7.43		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS		>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.6554	2.93	0.18	48.58		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	29	61.7	2	6.9	27	93.1	20	55.6	2	10.0	18	90.0	0.5679	0.43	0.06	3.17		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.1757	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	29	61.7	4	13.8	25	86.2	20	55.6	0	-	20	100.0	0.1523	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4070	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	29	61.7	4	13.8	25	86.2	20	55.6	0	-	20	100.0	0.2131	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	29	61.7	4	13.8	25	86.2	20	55.6	0	-	20	100.0	0.1618	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.7636	0.78	0.05	12.73		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1317	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1317	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR4AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 21:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	29	61.7	6	20.7	23	79.3	24	66.7	6	25.0	18	75.0	0.6906	0.92	0.27	3.05		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	18	38.3	6	33.3	12	66.7	12	33.3	2	16.7	10	83.3	0.3495	2.19	0.43	10.98		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.3948	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	29	61.7	0	-	29	100.0	24	66.7	2	8.3	22	91.7	0.0638	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1742	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	3	12.5	21	87.5	0.2778	0.51	0.09	3.09		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	18	38.3	5	27.8	13	72.2	12	33.3	1	8.3	11	91.7	0.2658	3.28	0.38	28.15		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	29	61.7	4	13.8	25	86.2	24	66.7	2	8.3	22	91.7	0.8530	1.32	0.24	7.31		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	2	16.7	10	83.3	0.2941	0.30	0.03	3.28		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	29	61.7	5	17.2	24	82.8	24	66.7	1	4.2	23	95.8	0.2673	3.49	0.40	30.74		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.3007	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	29	61.7	7	24.1	22	75.9	24	66.7	3	12.5	21	87.5	0.5729	1.00	0.25	4.03		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS		<3	18	38.3	4	22.2	14	77.8	12	33.3	0	-	12	100.0	0.2003	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	29	61.7	3	10.3	26	89.7	24	66.7	2	8.3	22	91.7	0.8873	0.69	0.10	4.52		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	29	61.7	4	13.8	25	86.2	24	66.7	0	-	24	100.0	0.1402	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	18	38.3	3	16.7	15	83.3	12	33.3	0	-	12	100.0	0.2003	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2399	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	29	61.7	5	17.2	24	82.8	24	66.7	1	4.2	23	95.8	0.3749	2.28	0.26	19.92		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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30NOV2022 21:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	38	80.9	11	28.9	27	71.1	23	63.9	7	30.4	16	69.6	0.7496	0.94	0.36	2.45		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3281	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	2	8.7	21	91.3	0.2370	0.30	0.03	3.28		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2734	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5915	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	38	80.9	6	15.8	32	84.2	23	63.9	4	17.4	19	82.6	0.6756	0.88	0.25	3.10		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	38	80.9	6	15.8	32	84.2	23	63.9	4	17.4	19	82.6	0.4090	0.60	0.16	2.27		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.8403	1.33	0.08	21.29		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	0	-	23	100.0	0.1709	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3419	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5571	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS		Non-Europe	38	80.9	11	28.9	27	71.1	23	63.9	2	8.7	21	91.3	0.2073	2.40	0.52	11.04		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	2	8.7	21	91.3	0.9025	0.93	0.16	5.22		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	0	-	23	100.0	0.1217	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	0	-	23	100.0	0.2047	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	0	-	23	100.0	0.1279	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	34	72.3	7	20.6	27	79.4	24	66.7	8	33.3	16	66.7	0.3070	0.65	0.22	1.90		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	13	27.7	5	38.5	8	61.5	12	33.3	0	-	12	100.0	0.0366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.5104	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.2848	0.36	0.03	3.95		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.6261	0.35	0.02	5.57		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	34	72.3	4	11.8	30	88.2	24	66.7	4	16.7	20	83.3	0.3887	0.67	0.17	2.66		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	13	27.7	3	23.1	10	76.9	12	33.3	0	-	12	100.0	0.1276	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	34	72.3	4	11.8	30	88.2	24	66.7	4	16.7	20	83.3	0.1529	0.42	0.09	1.90		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2335	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.1990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	34	72.3	4	11.8	30	88.2	24	66.7	0	-	24	100.0	0.1496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8743	0.75	0.05	12.16		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	34	72.3	8	23.5	26	76.5	24	66.7	2	8.3	22	91.7	0.2835	1.89	0.40	8.99		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS		Female	13	27.7	3	23.1	10	76.9	12	33.3	1	8.3	11	91.7	0.7236	1.29	0.11	14.69		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	34	72.3	4	11.8	30	88.2	24	66.7	1	4.2	23	95.8	0.3787	1.89	0.21	17.33		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	34	72.3	5	14.7	29	85.3	24	66.7	0	-	24	100.0	0.1125	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	34	72.3	3	8.8	31	91.2	24	66.7	0	-	24	100.0	0.2412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	34	72.3	4	11.8	30	88.2	24	66.7	1	4.2	23	95.8	0.6564	1.53	0.17	13.88		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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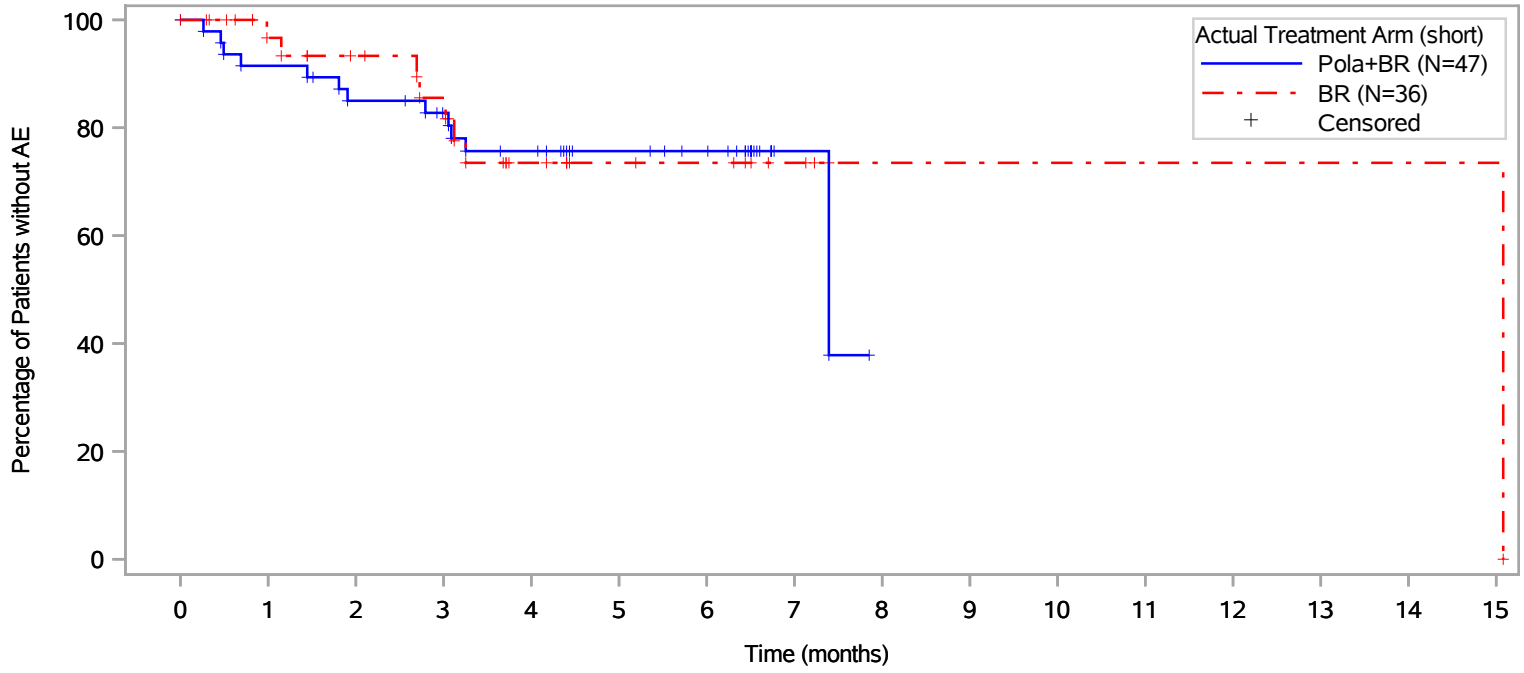
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk																
Pola+BR (N=47)	47	43	39	35	31	24	21	2	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	29	25	22	14	9	8	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=47)	0	0	1	4	5	12	15	34	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	10	15	20	21	25	28	28	28	28	28	28	28	28

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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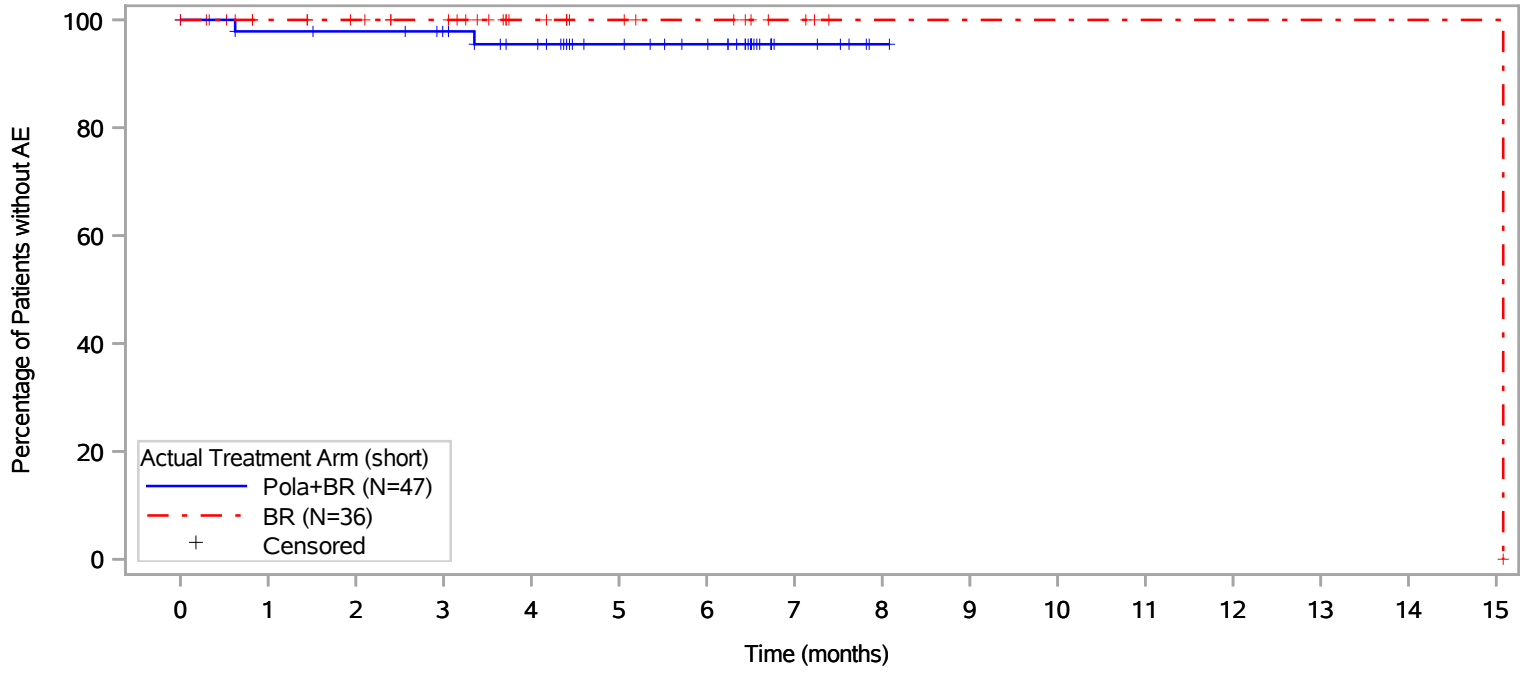
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk																
Pola+BR (N=47)	47	46	45	42	38	30	26	6	1	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=47)	0	0	1	4	7	15	19	39	44	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	32	35	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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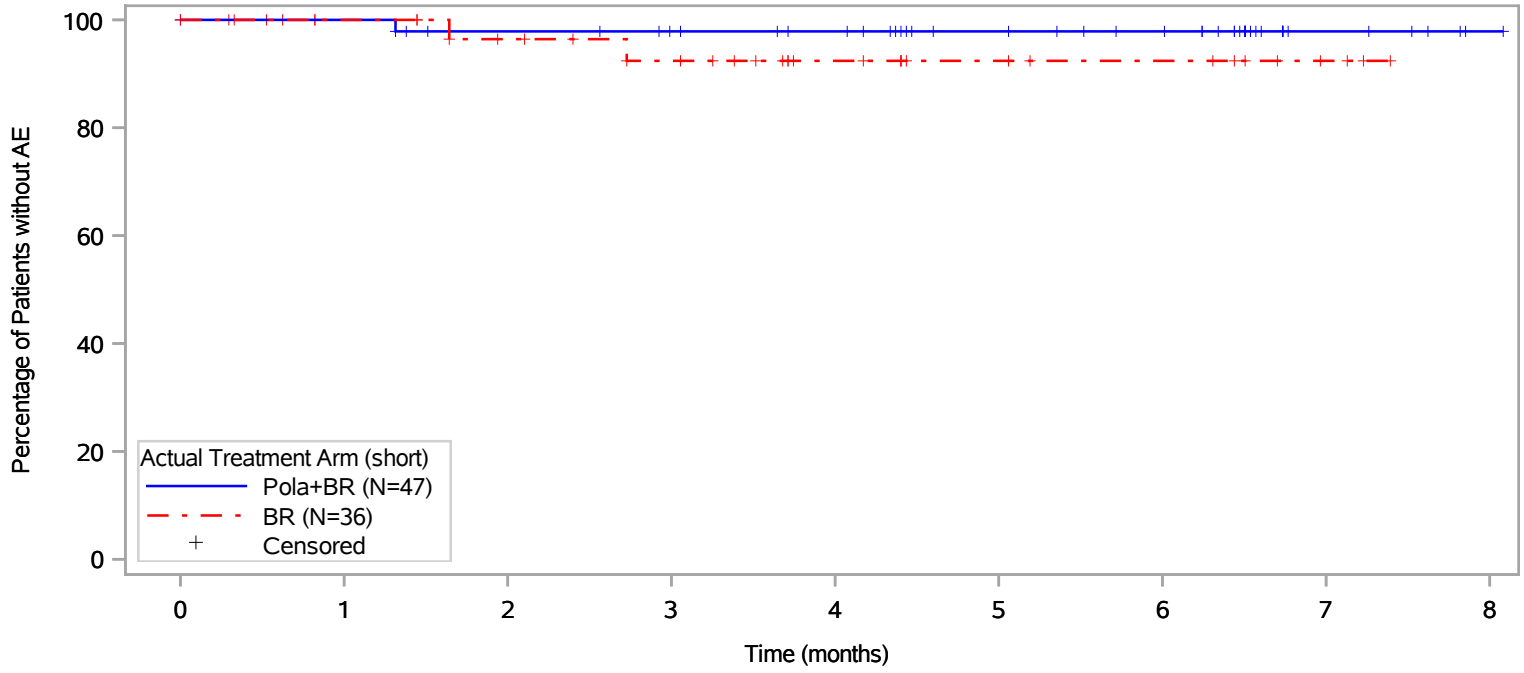
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=47)	47	47	44	41	38	30	26	6	1
BR (N=36)	36	30	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	11	19	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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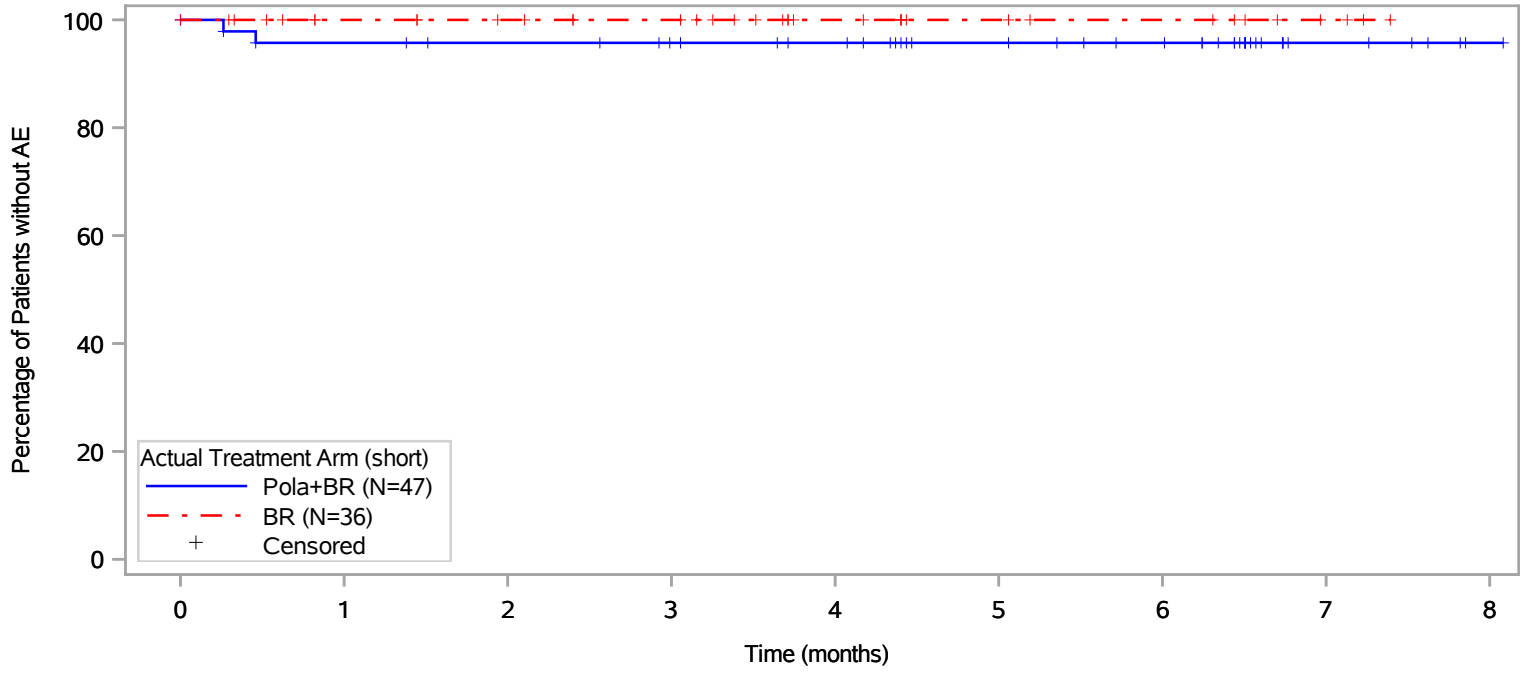
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA



Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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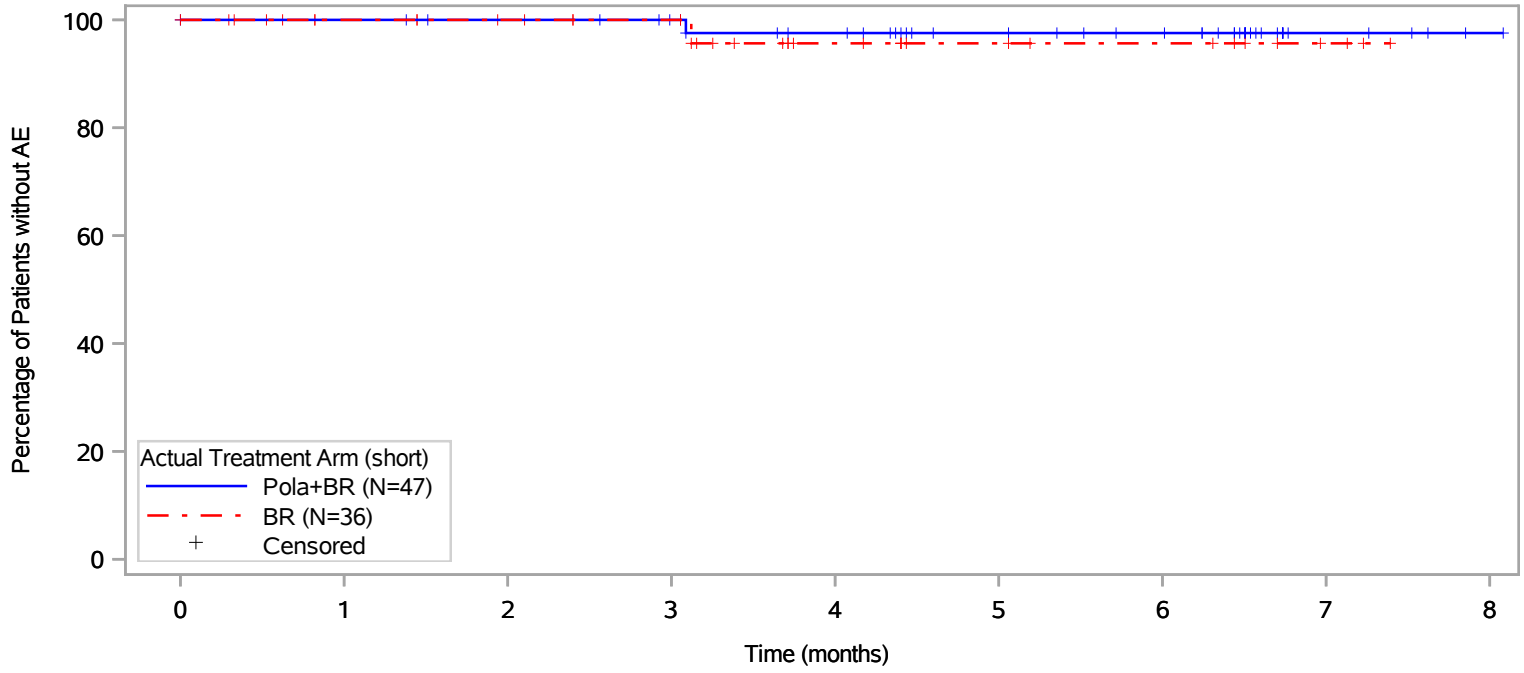
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, MYELOSUPPRESSION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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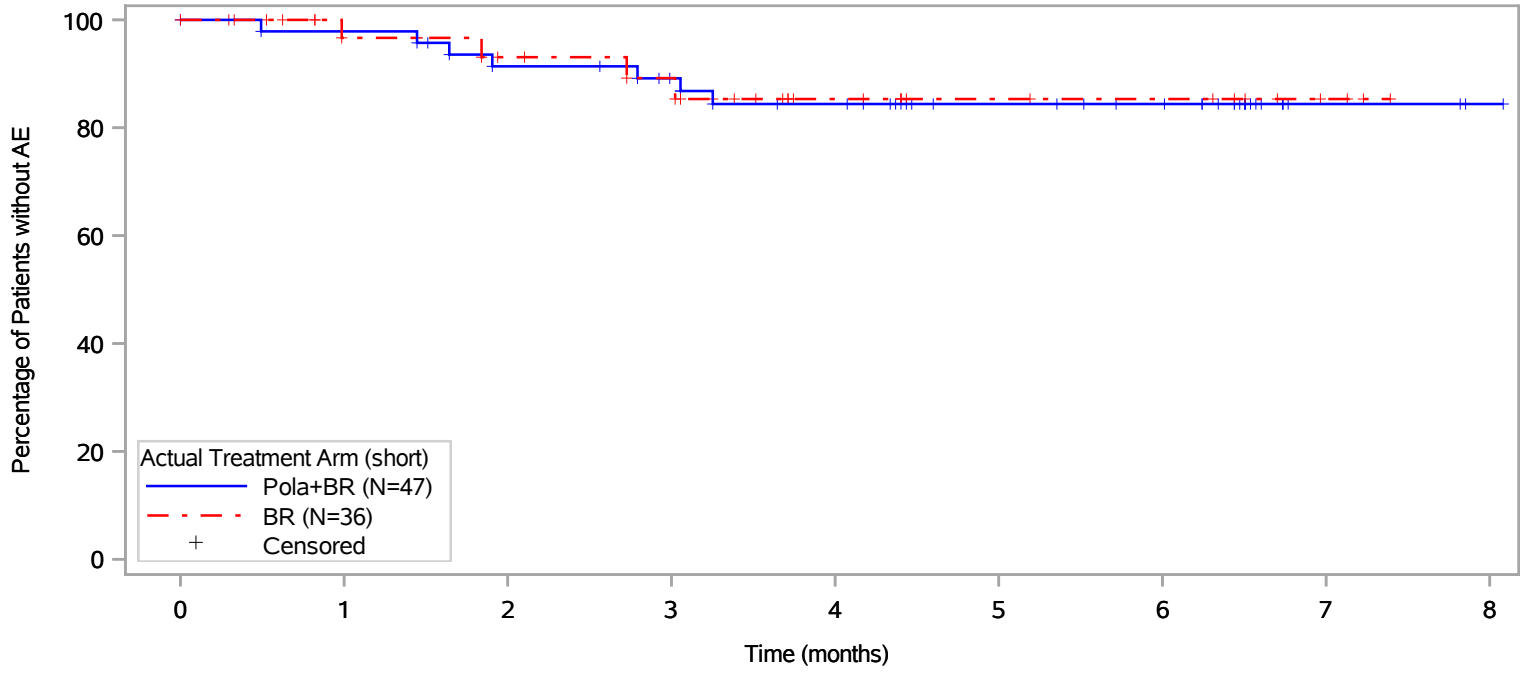
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA

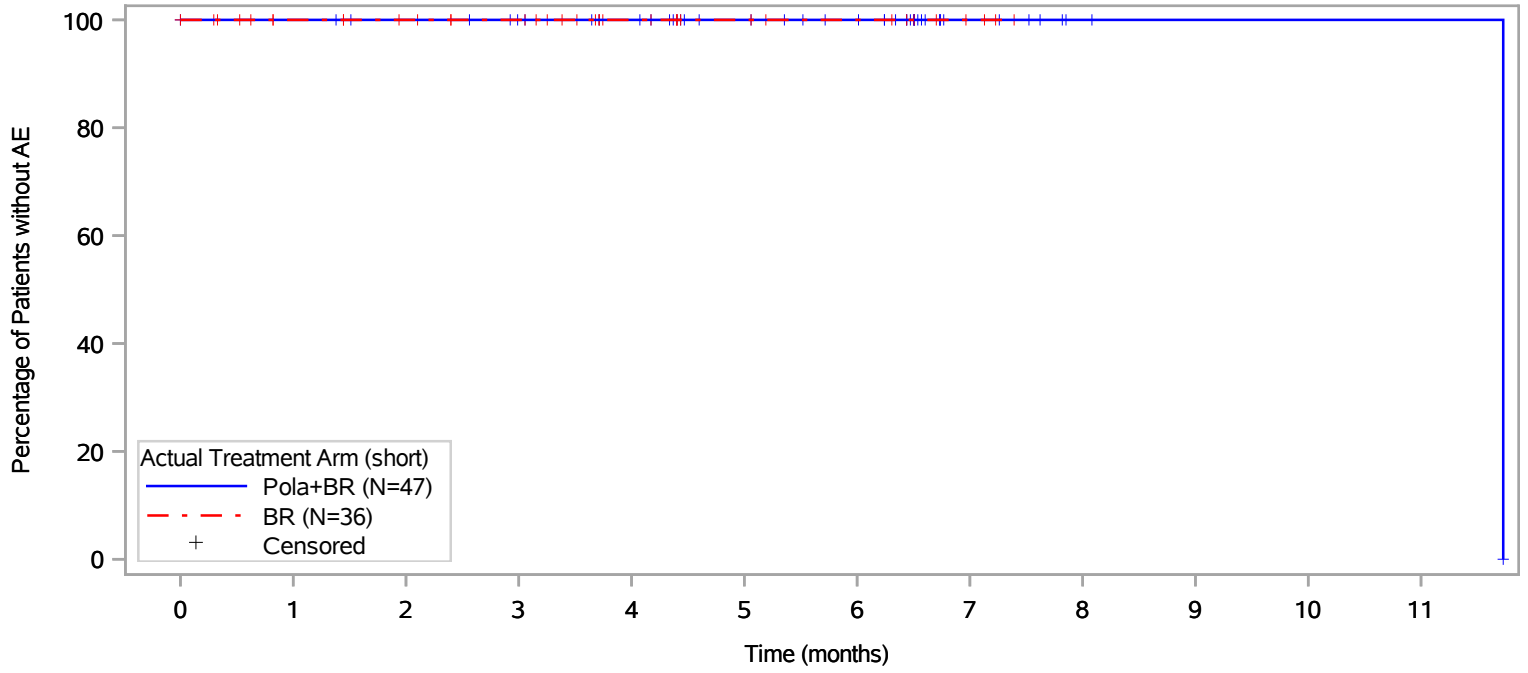


Patients at risk									
Pola+BR (N=47)	47	46	42	38	34	26	23	3	1
BR (N=36)	36	29	25	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	6	14	17	37	39
BR (N=36)	0	6	9	10	18	23	24	29	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA



Patients at risk												
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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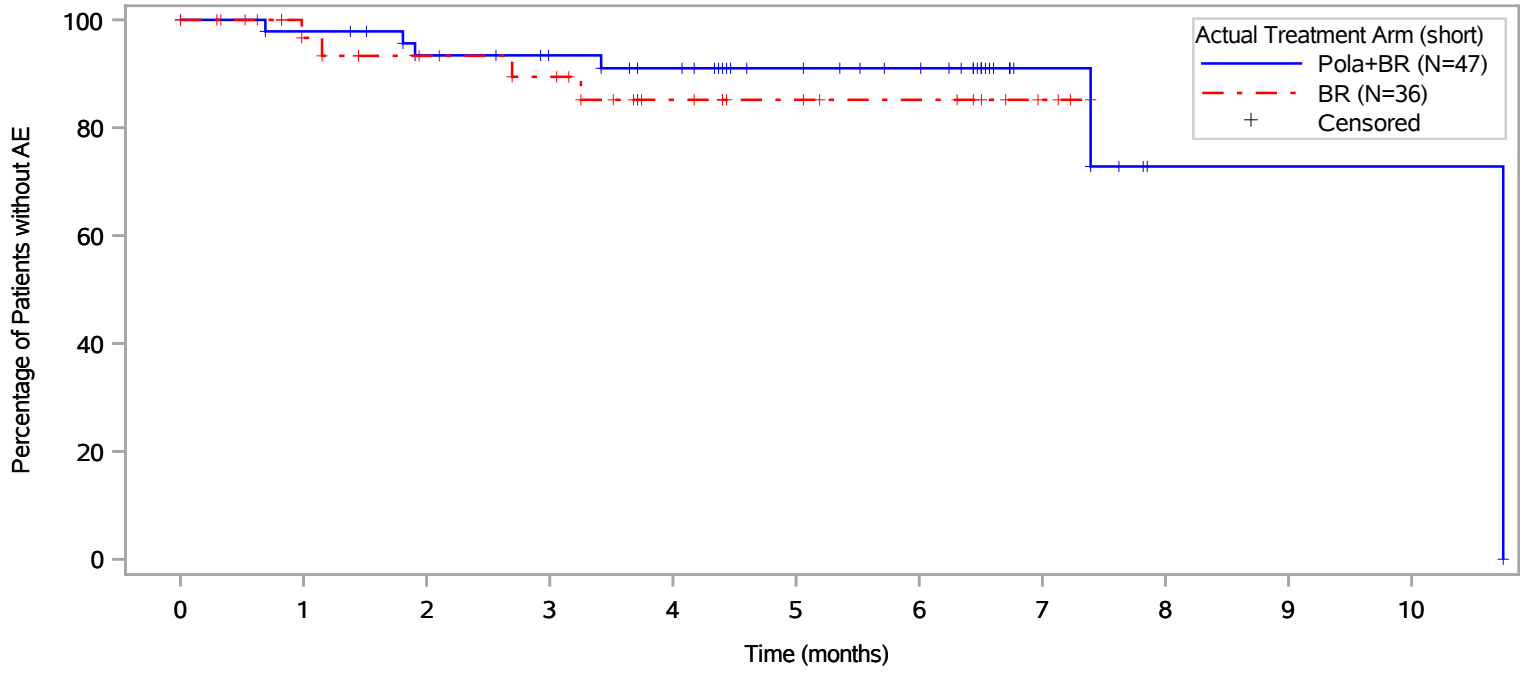
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk											
Pola+BR (N=47)	47	46	42	39	36	28	24	5	1	1	1
BR (N=36)	36	29	25	23	15	10	8	3	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	0	2	5	7	15	19	38	41	41	41
BR (N=36)	0	6	9	10	17	22	24	29	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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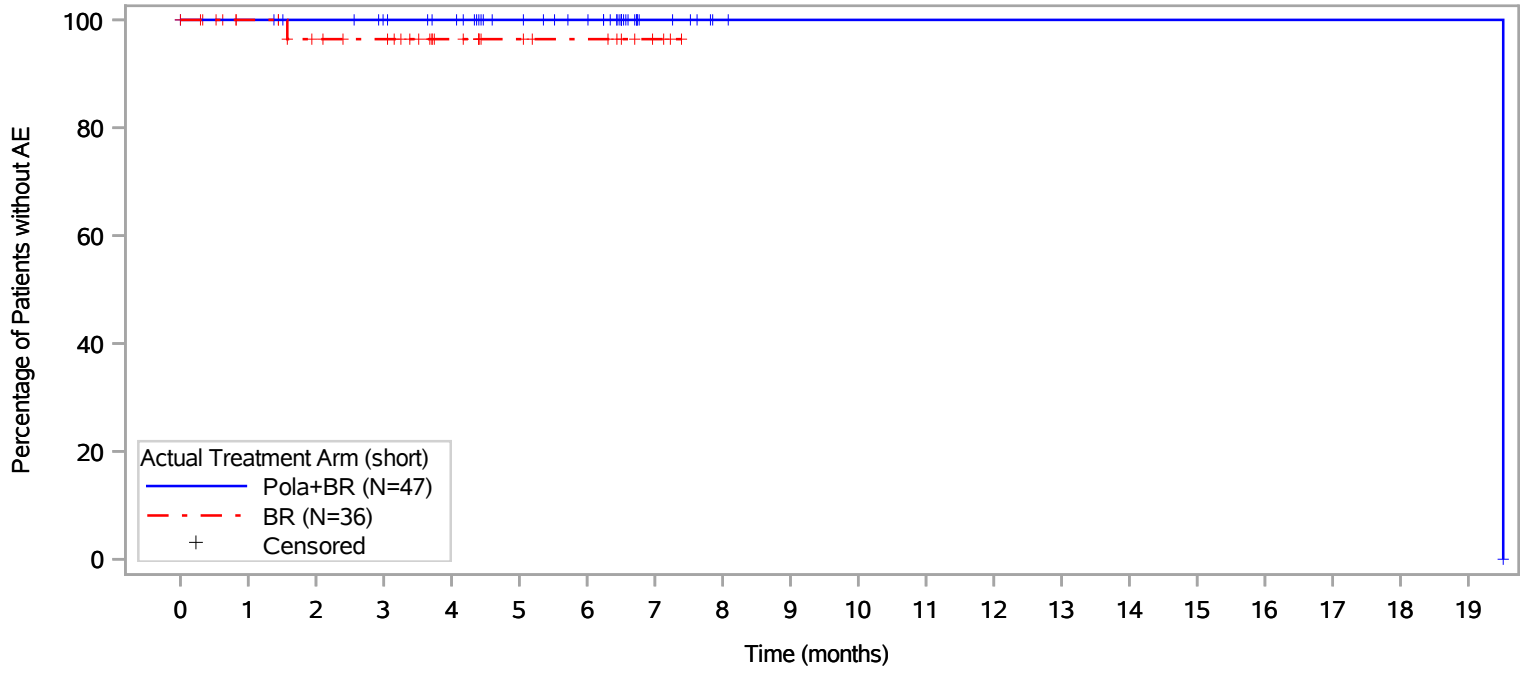
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk																				
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	26	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	11	20	25	27	32	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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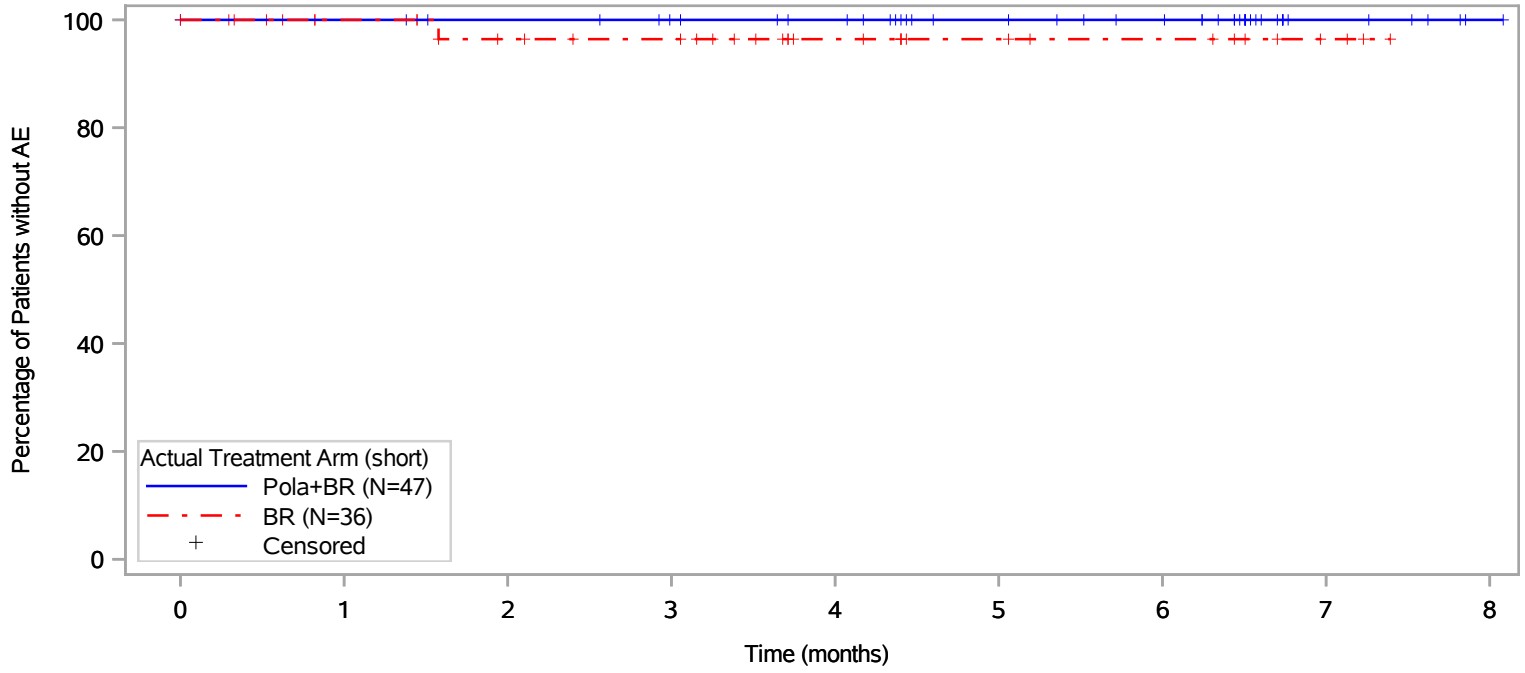
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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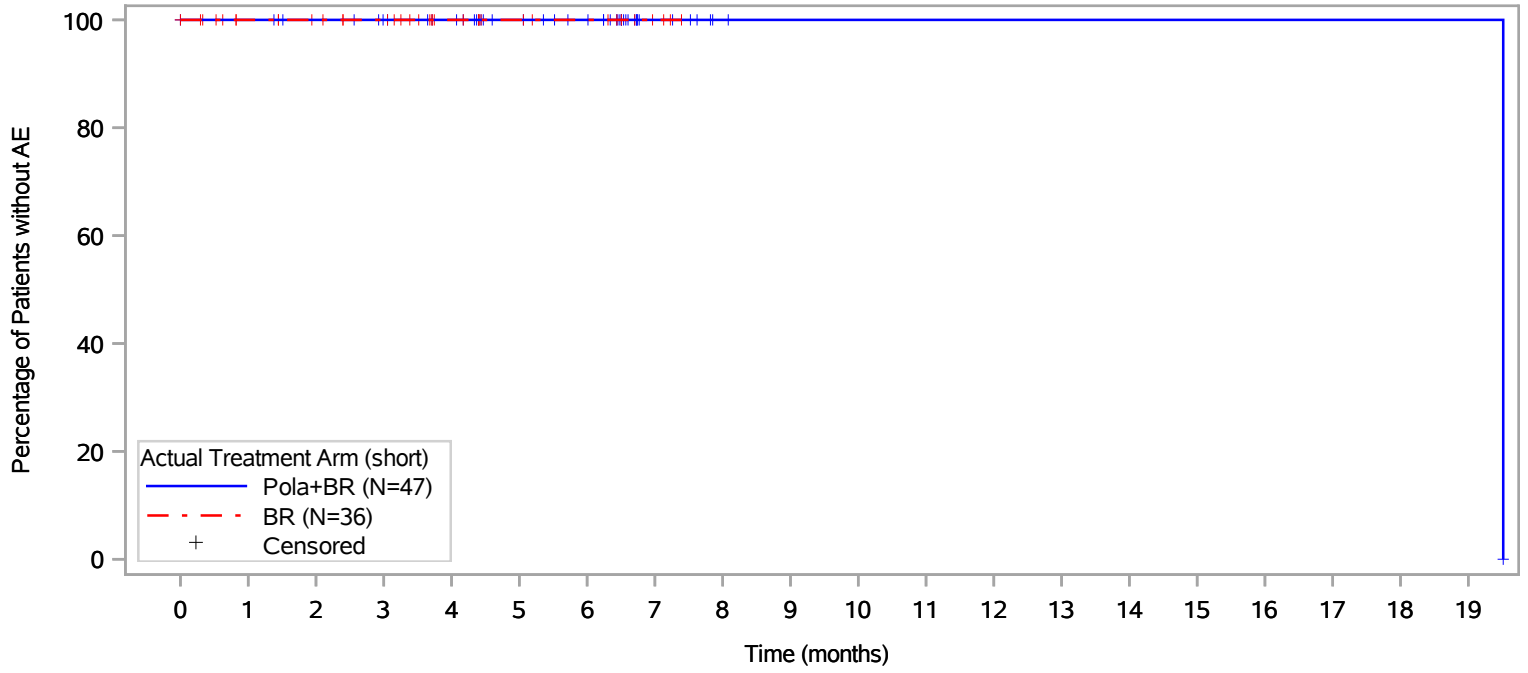
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk																				
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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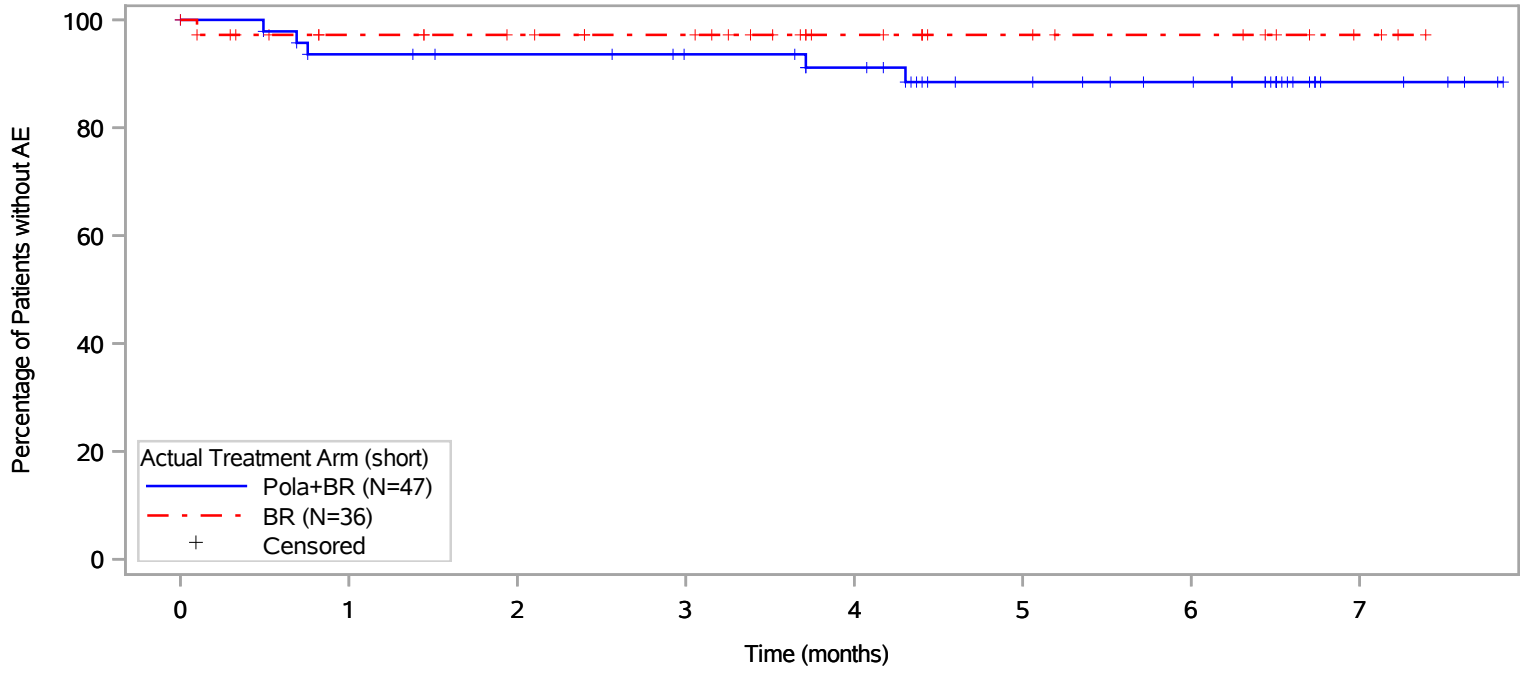
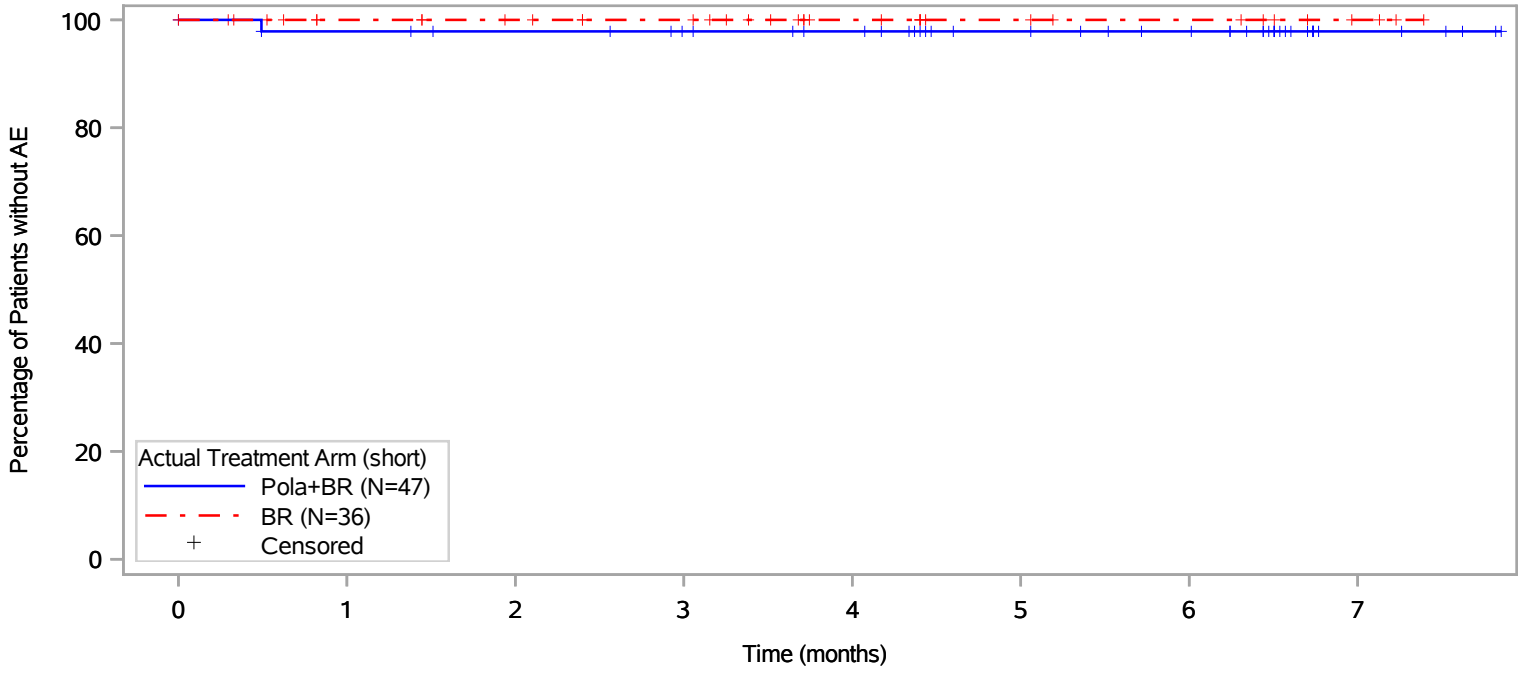
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk								
Pola+BR (N=47)	47	44	42	39	36	28	24	5
BR (N=36)	36	30	27	24	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	7	14	18	37
BR (N=36)	0	5	8	11	20	25	27	32

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HUMAN ANAPLASMOSIS



Patients at risk								
Pola+BR (N=47)	47	46	44	41	38	30	26	5
BR (N=36)	36	30	27	24	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	16	20	41
BR (N=36)	0	6	9	12	21	26	28	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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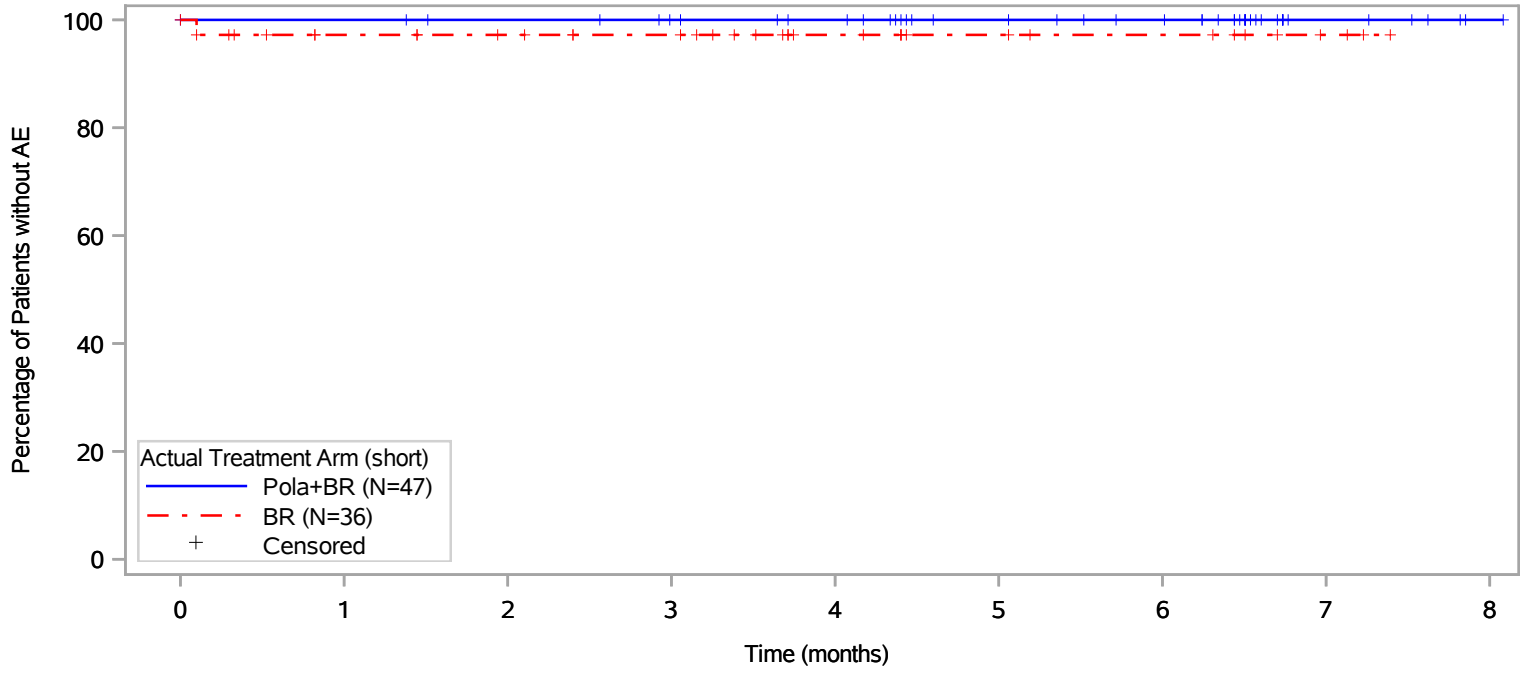
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NEUTROPENIC SEPSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	5	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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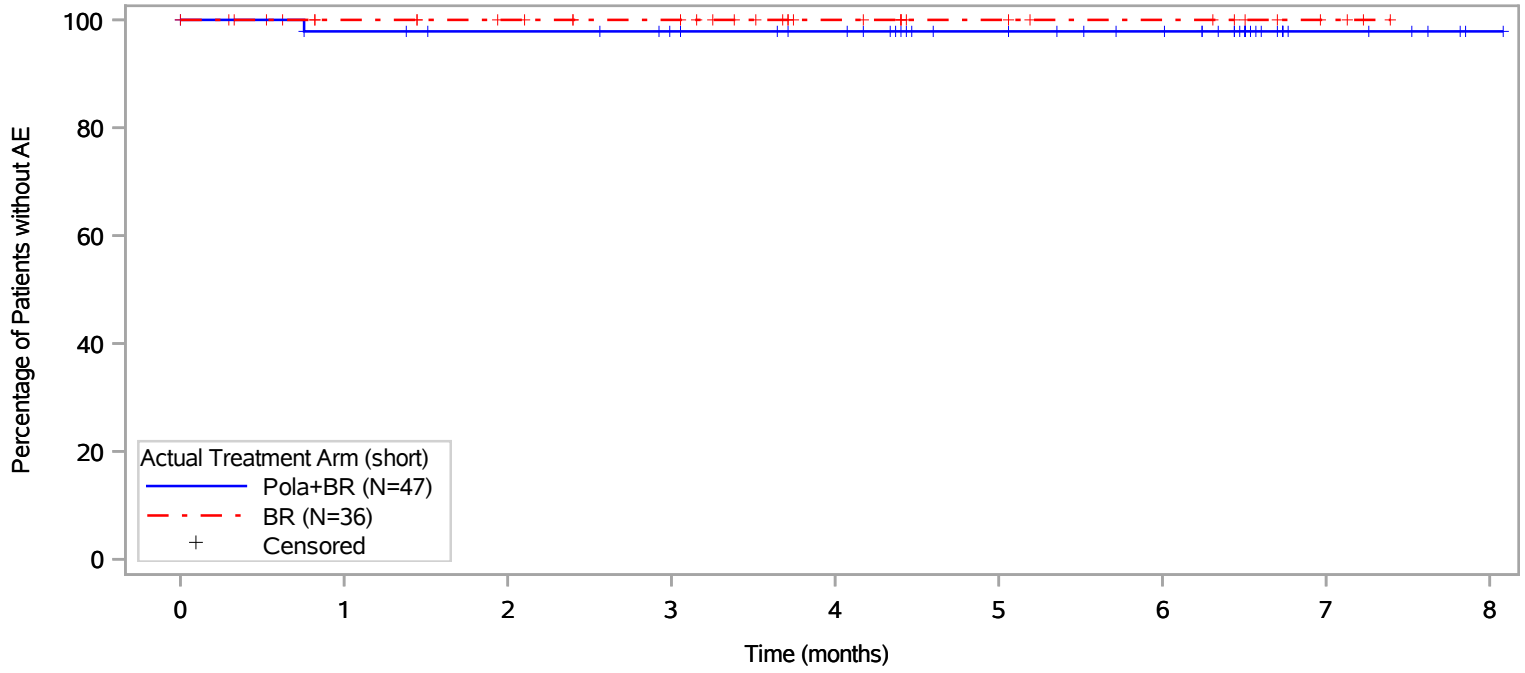
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMOCYSTIS JIROVECII PNEUMONIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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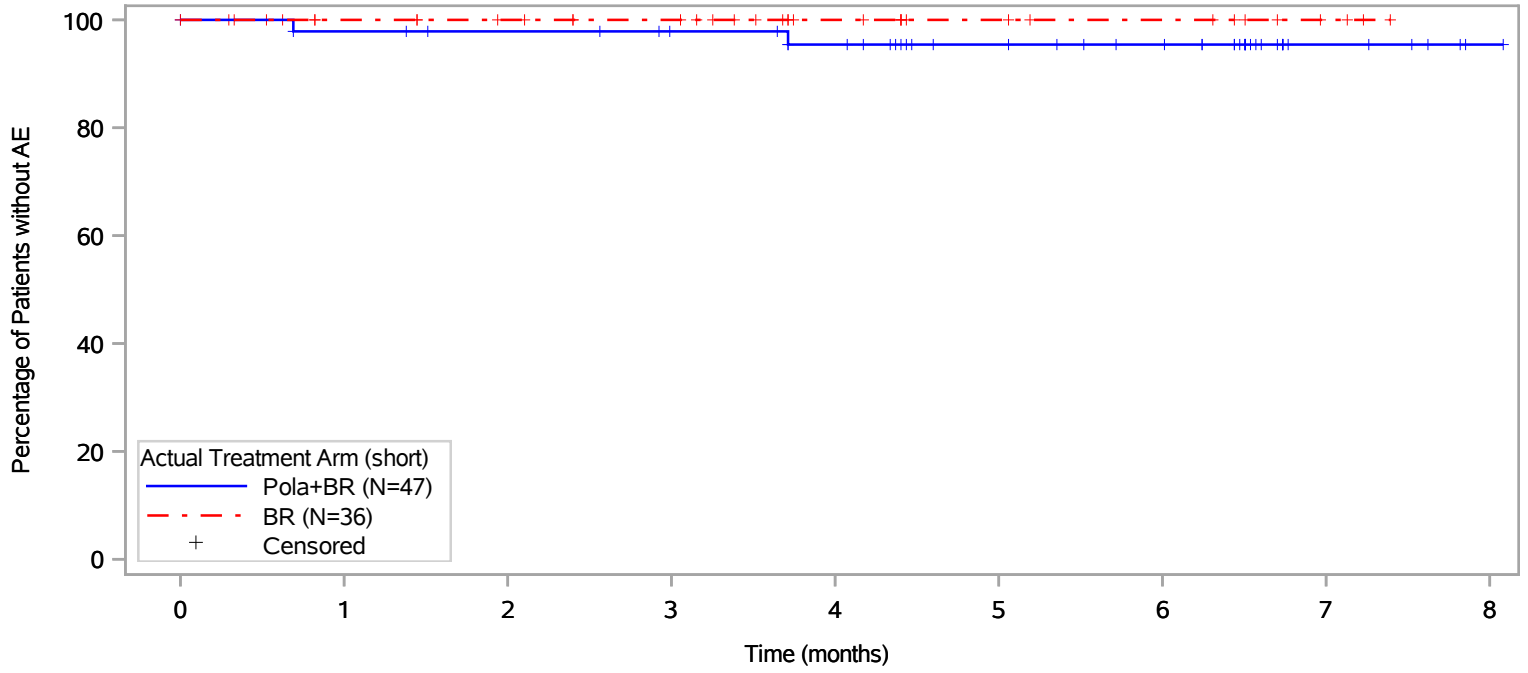
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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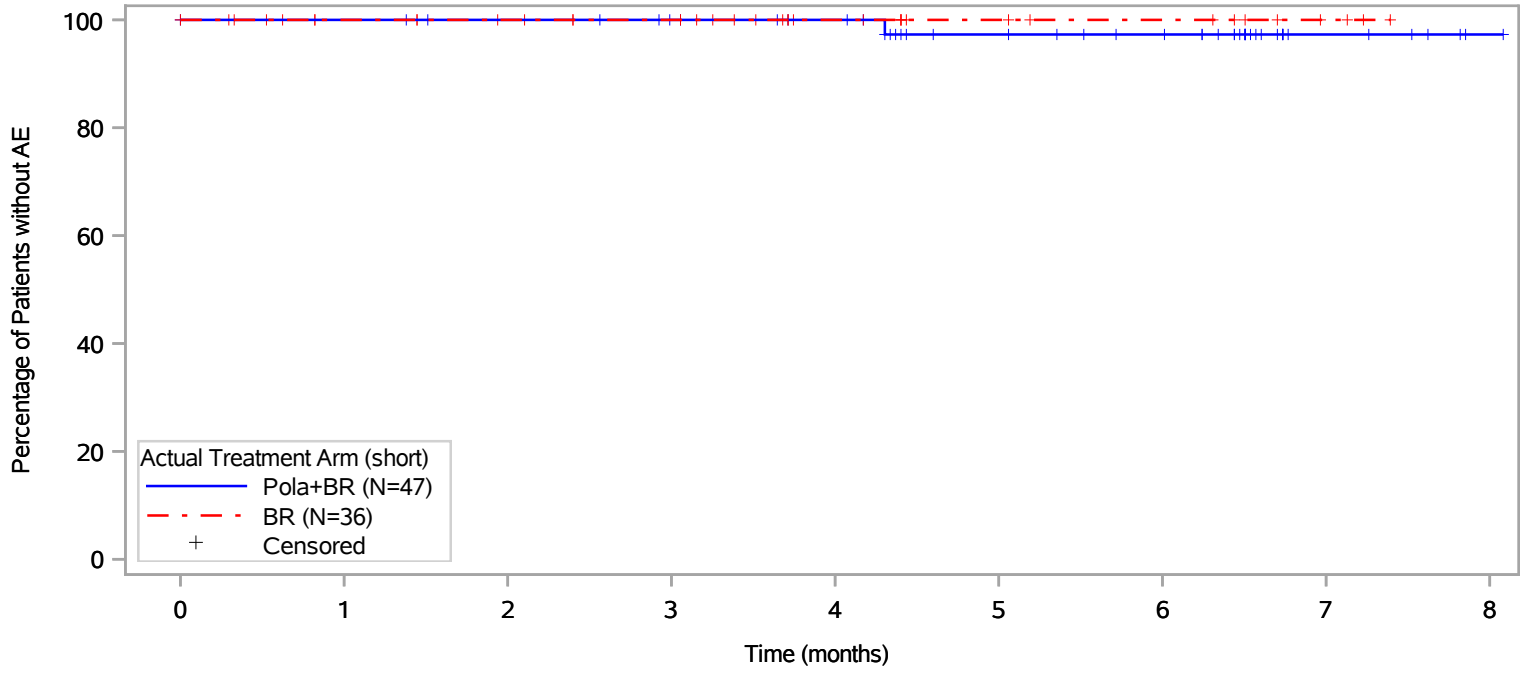
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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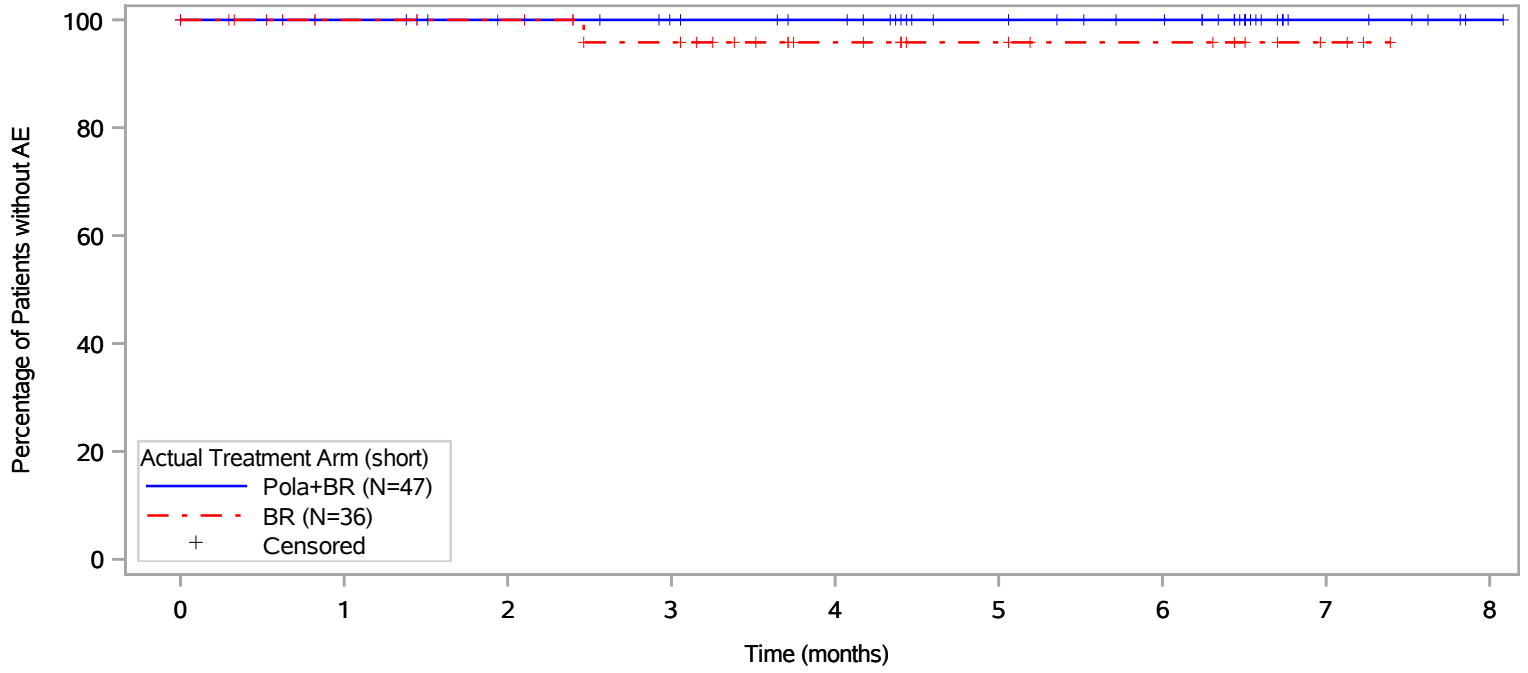
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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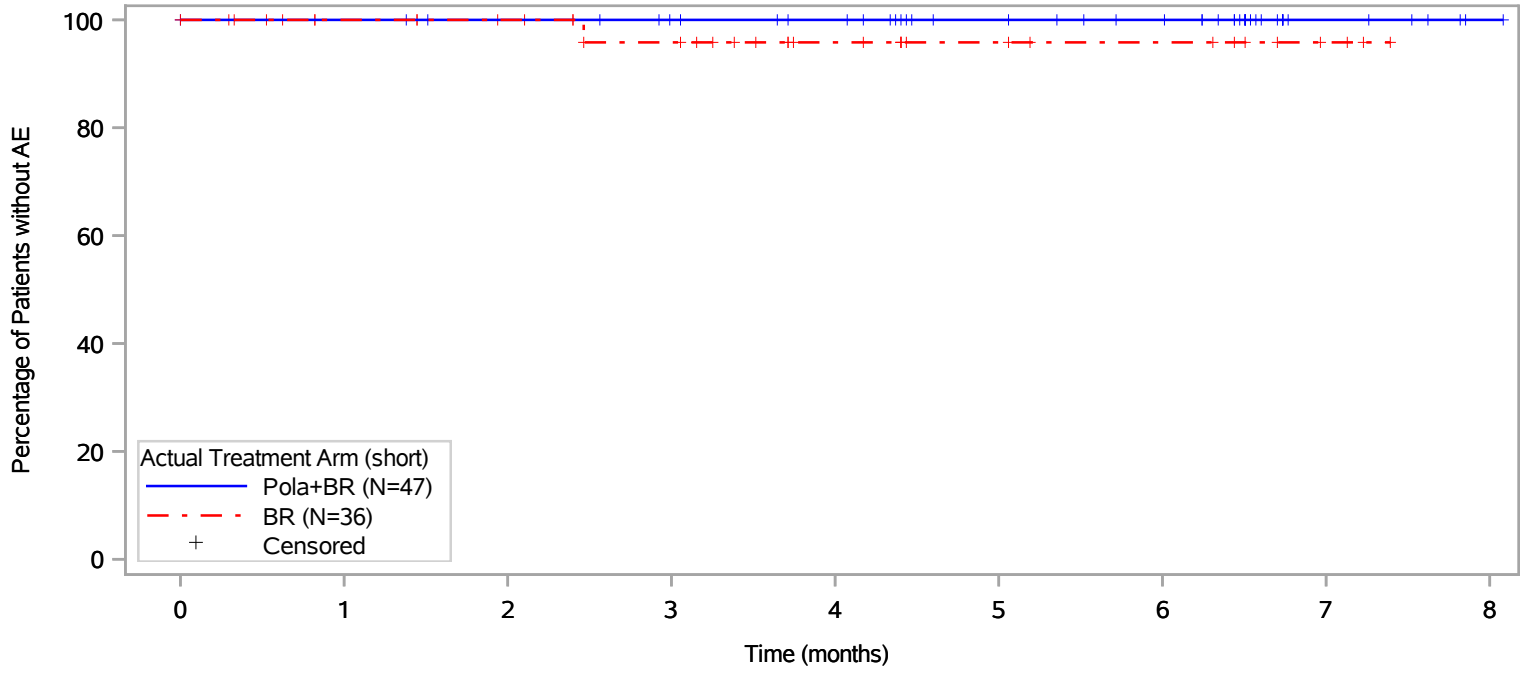
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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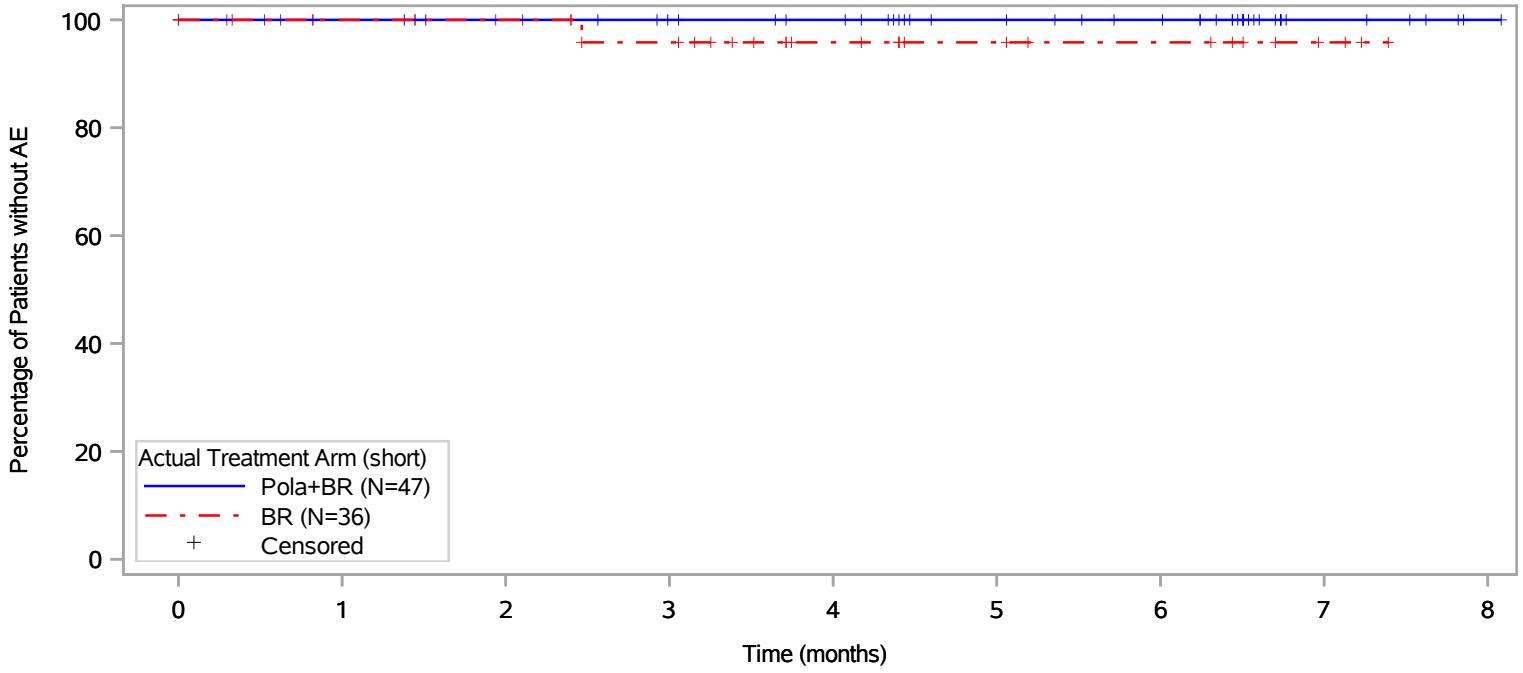
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, HEAD INJURY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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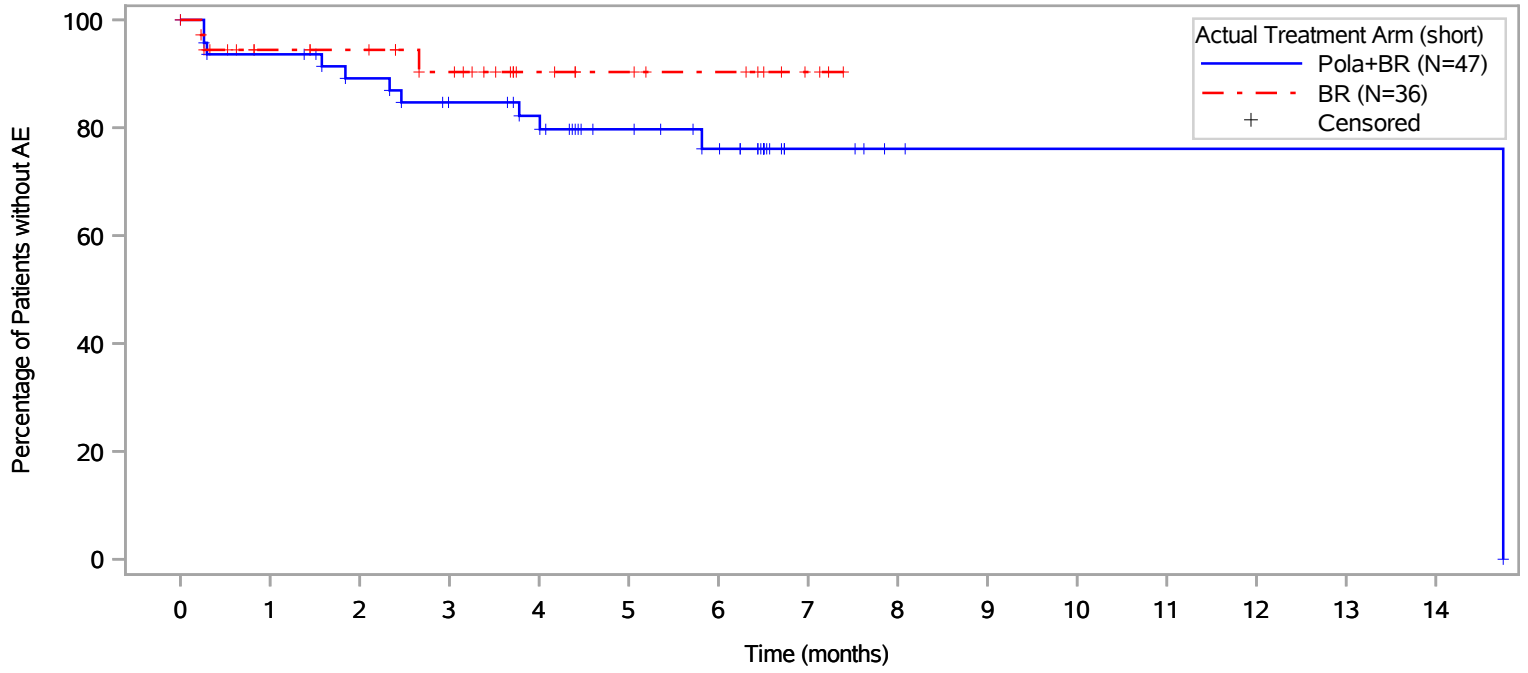
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk															
Pola+BR (N=47)	47	44	40	36	33	25	21	5	2	1	1	1	1	1	1
BR (N=36)	36	28	26	22	13	10	8	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	4	6	13	16	32	35	36	36	36	36	36	36
BR (N=36)	0	6	8	11	20	23	25	30	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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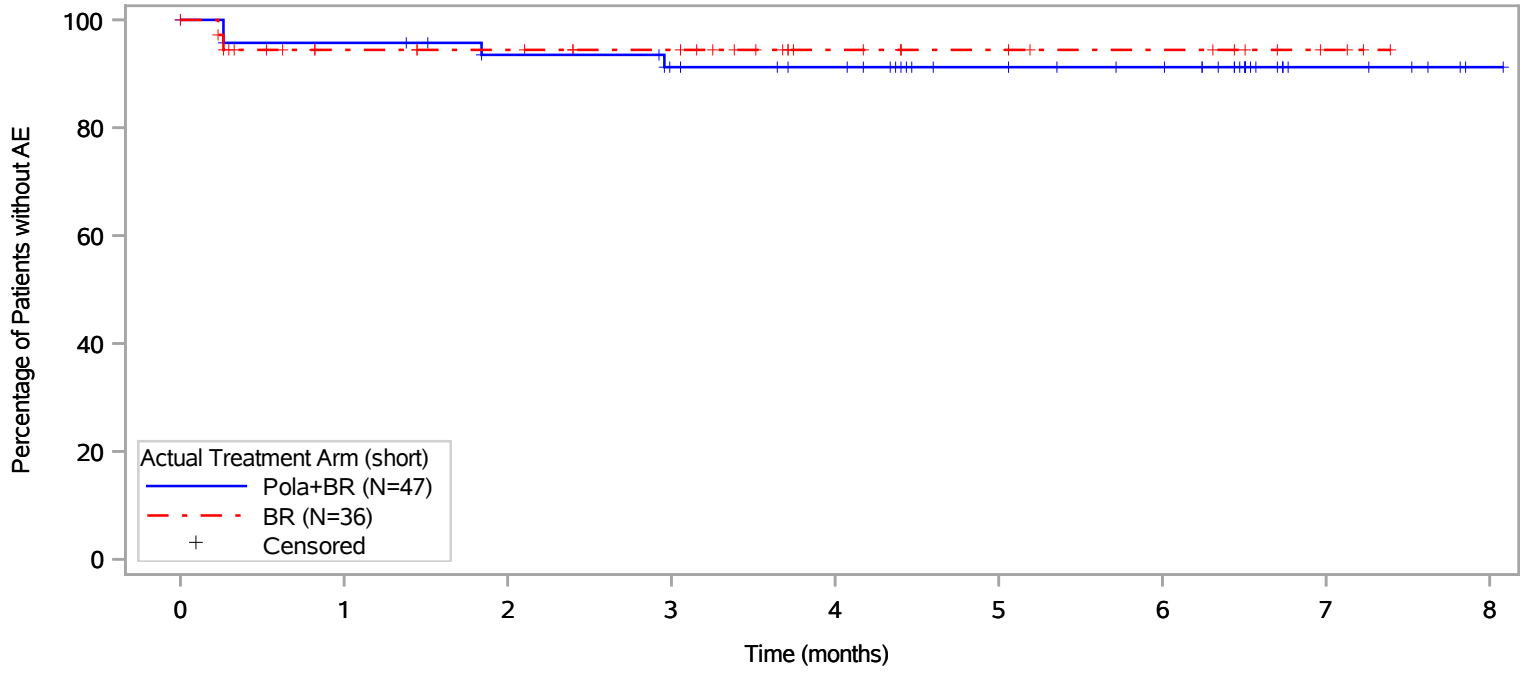
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	45	42	39	36	28	25	6	1
BR (N=36)	36	28	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	18	37	42
BR (N=36)	0	6	8	11	20	24	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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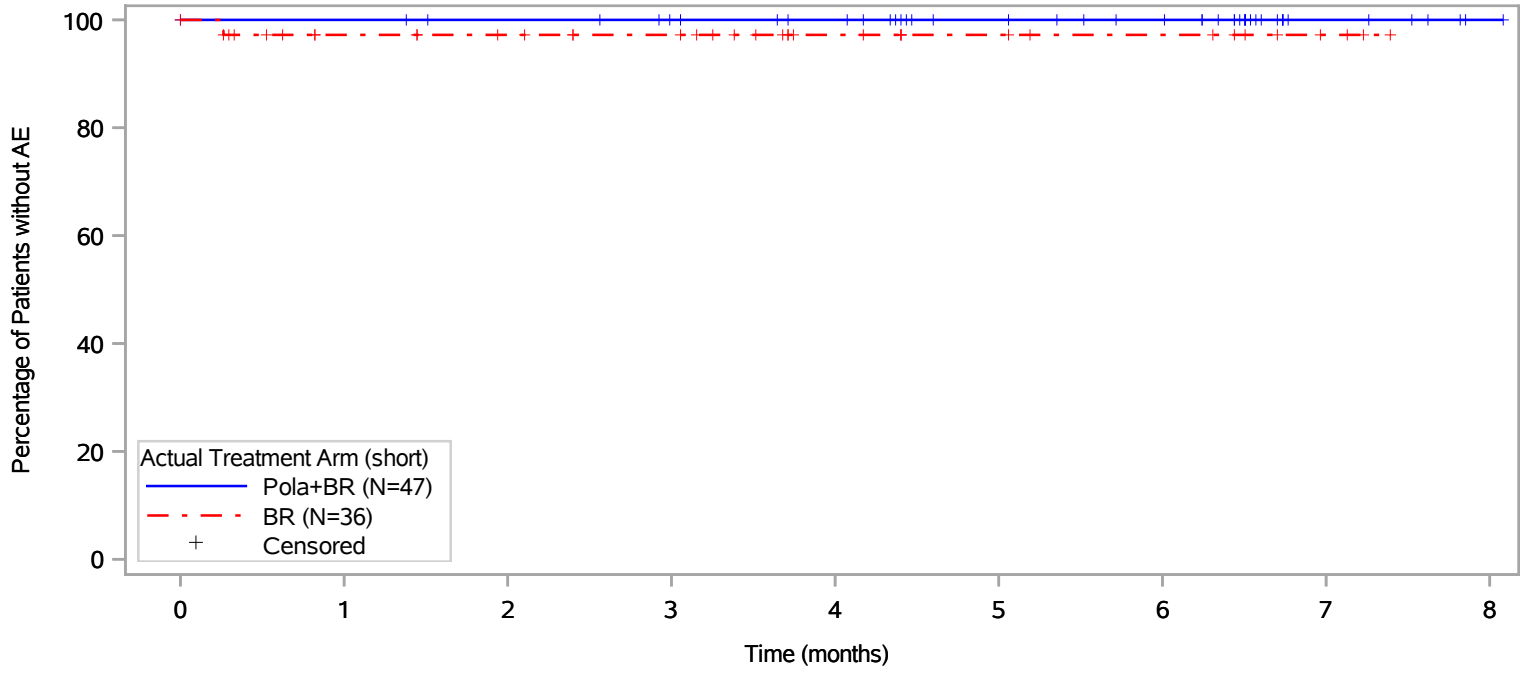
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE PERCENTAGE DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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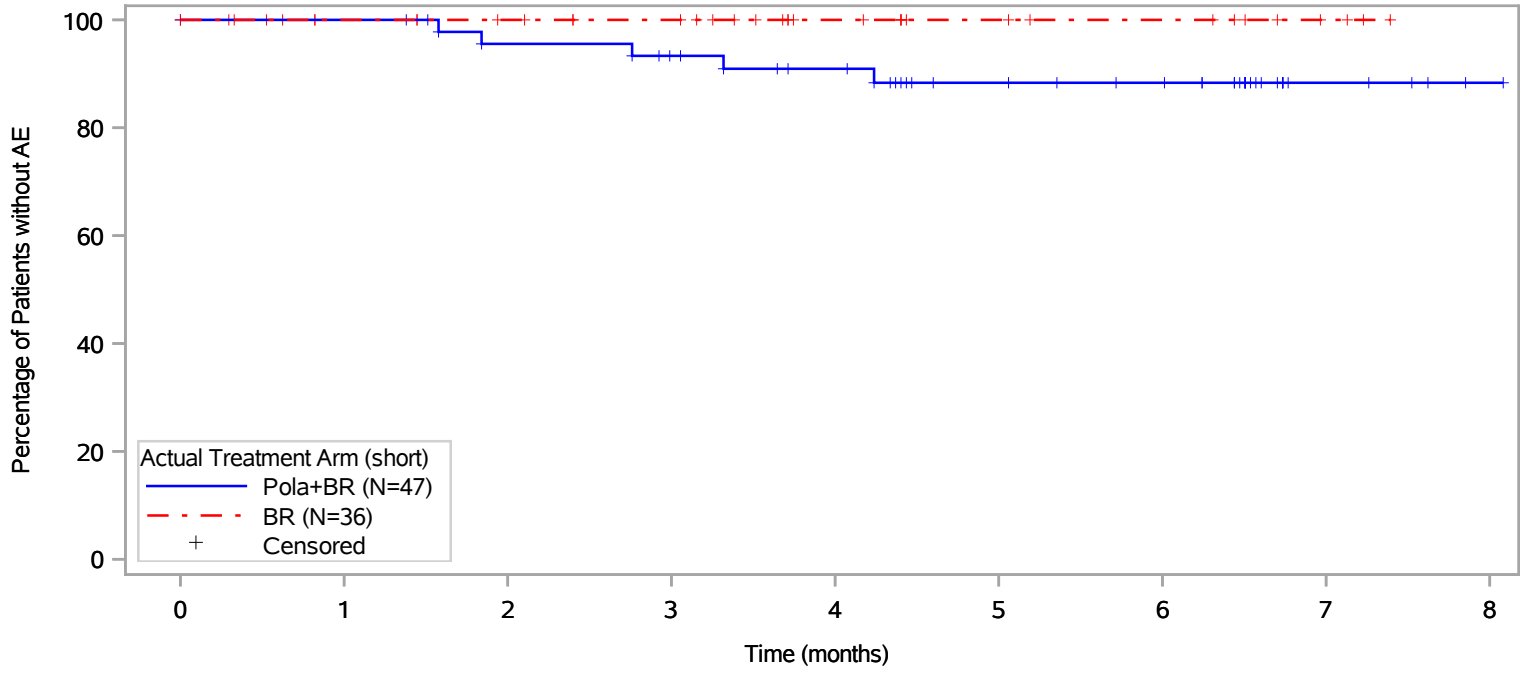
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	43	40	36	28	25	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	17	37	41
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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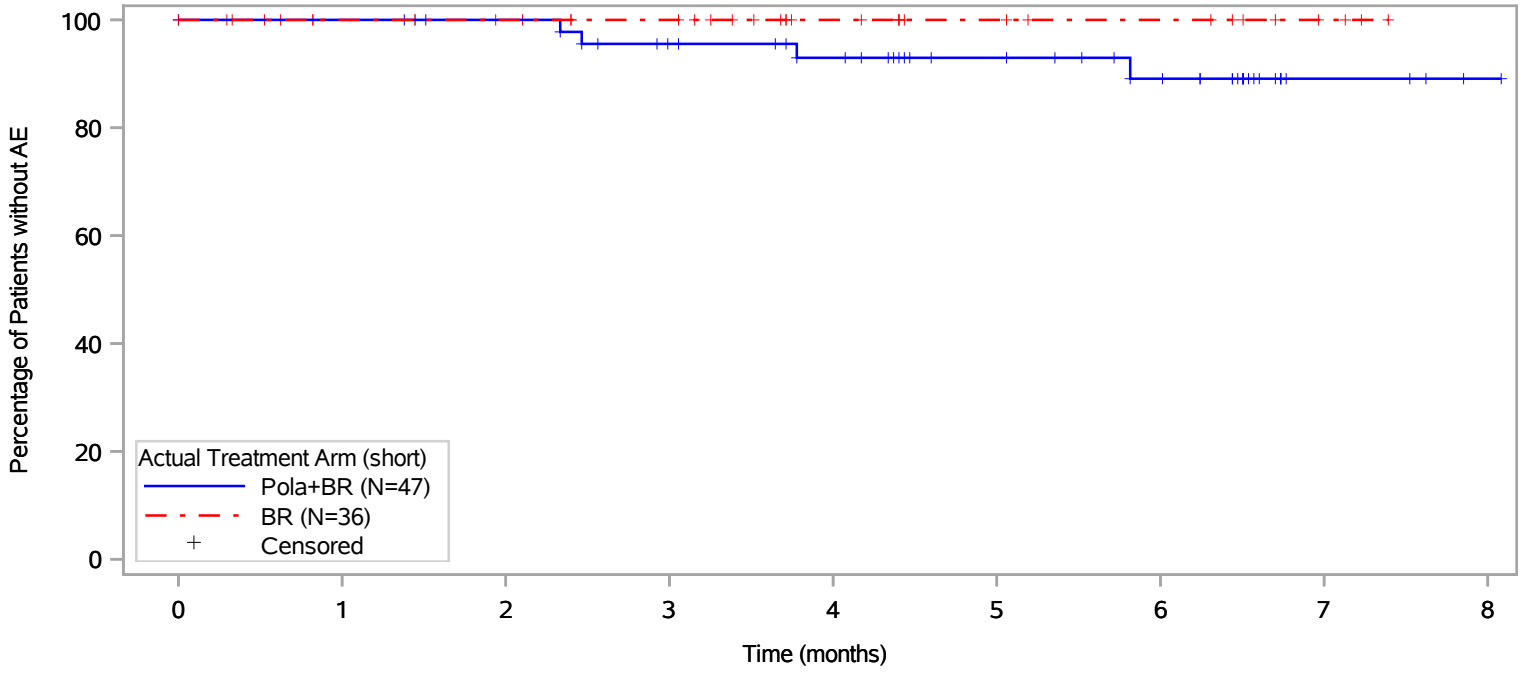
02DEC2022 4:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	40	36	28	23	4	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	42
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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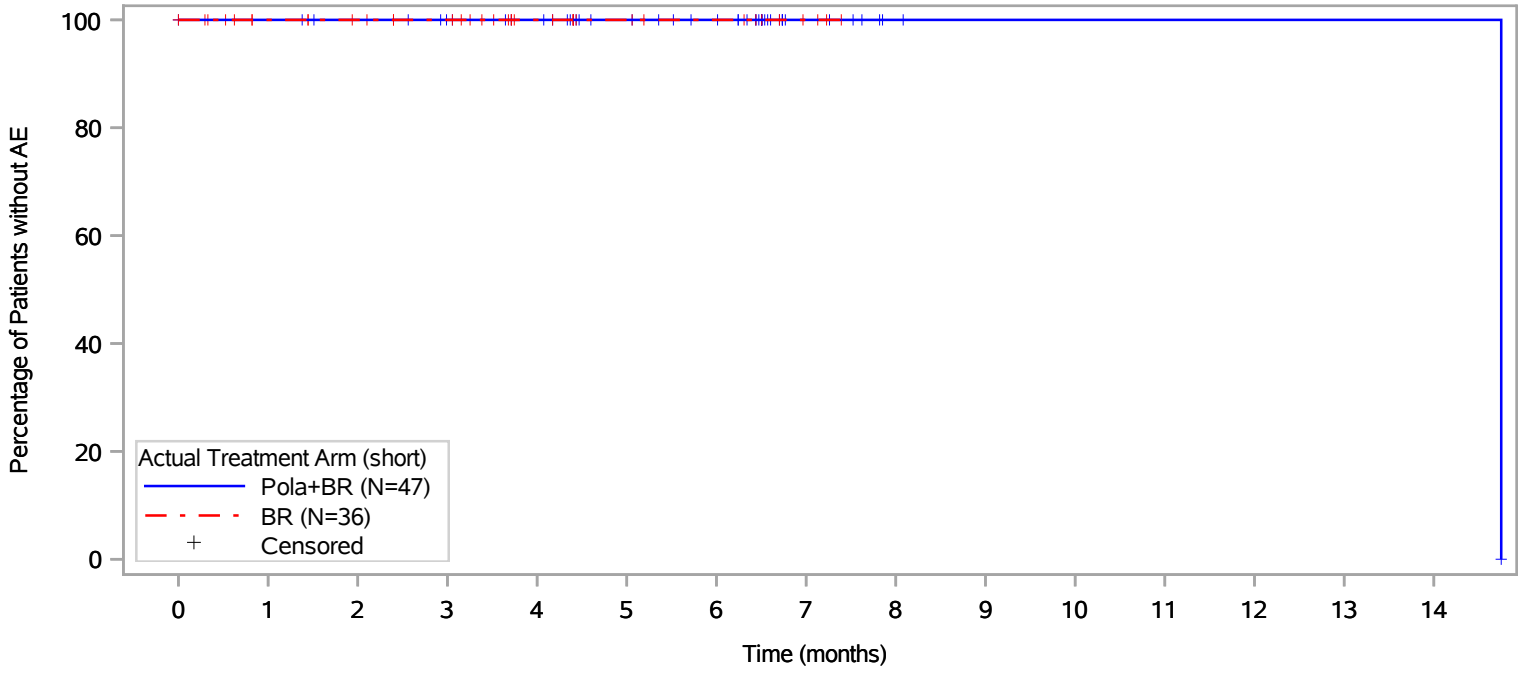
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, TRANSAMINASES INCREASED



Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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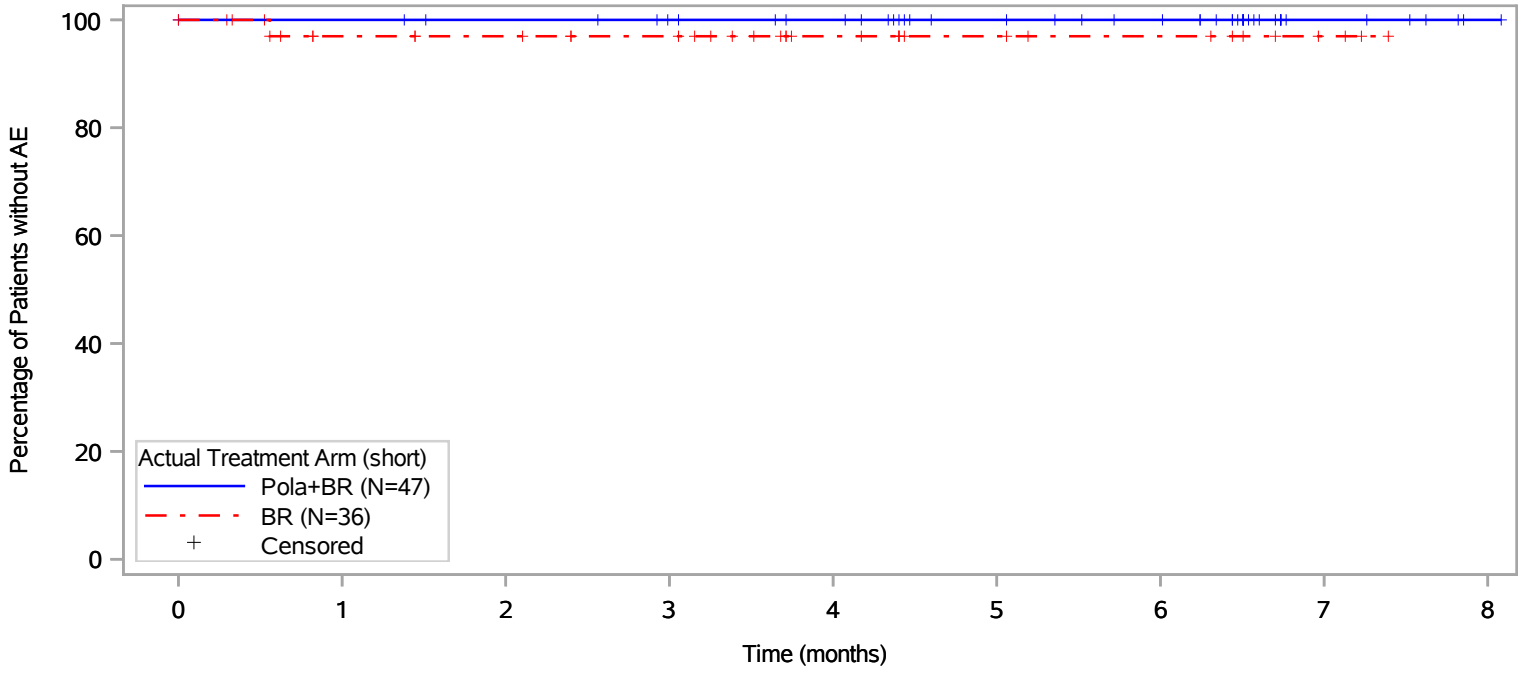
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, URINE OUTPUT DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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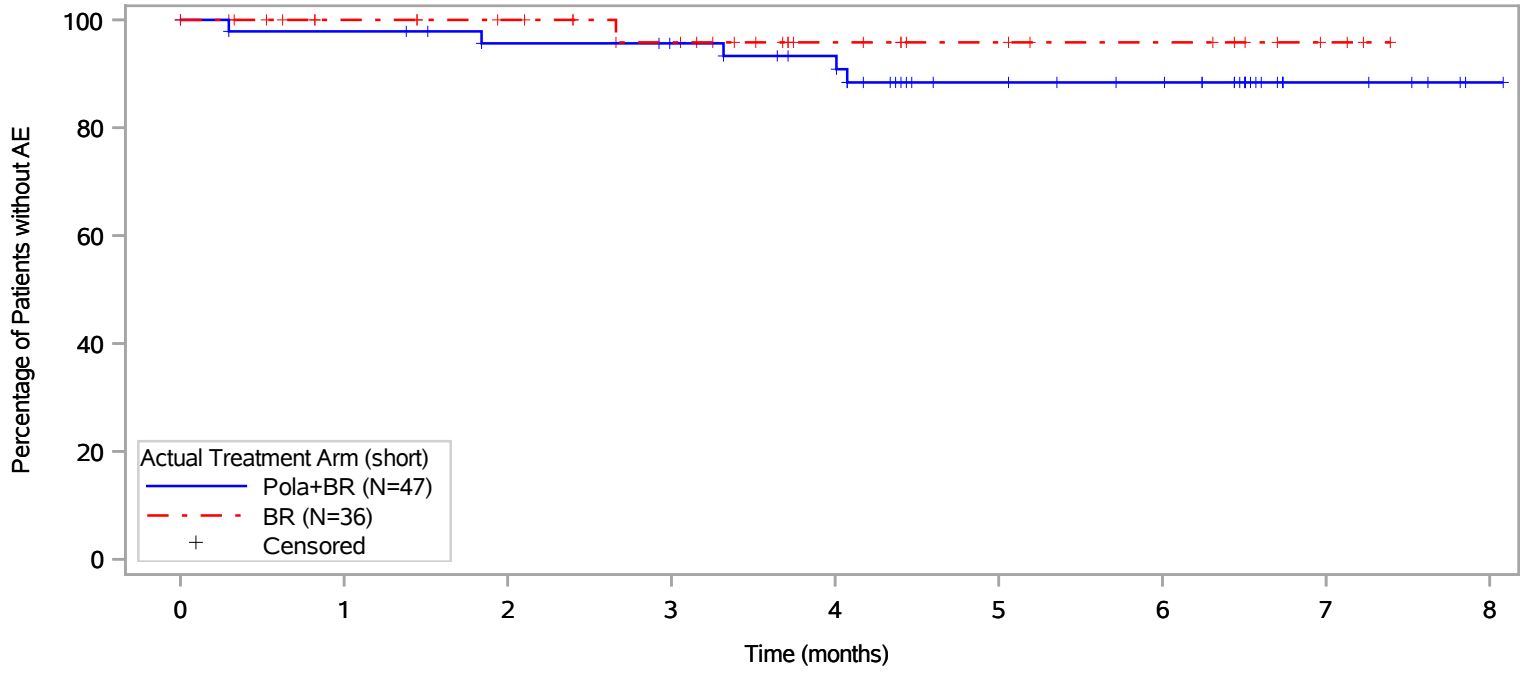
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	46	43	41	38	28	25	6	1
BR (N=36)	36	30	27	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	6	14	17	36	41
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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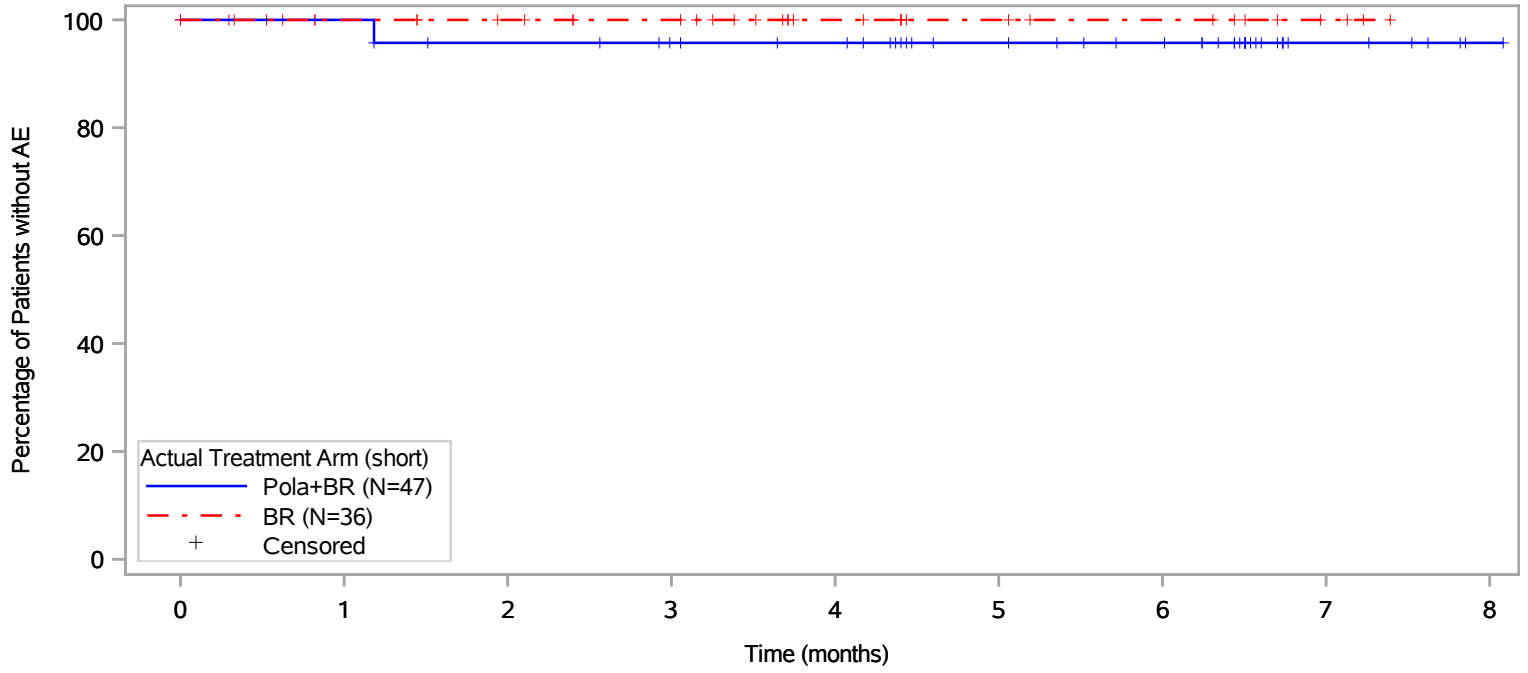
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All

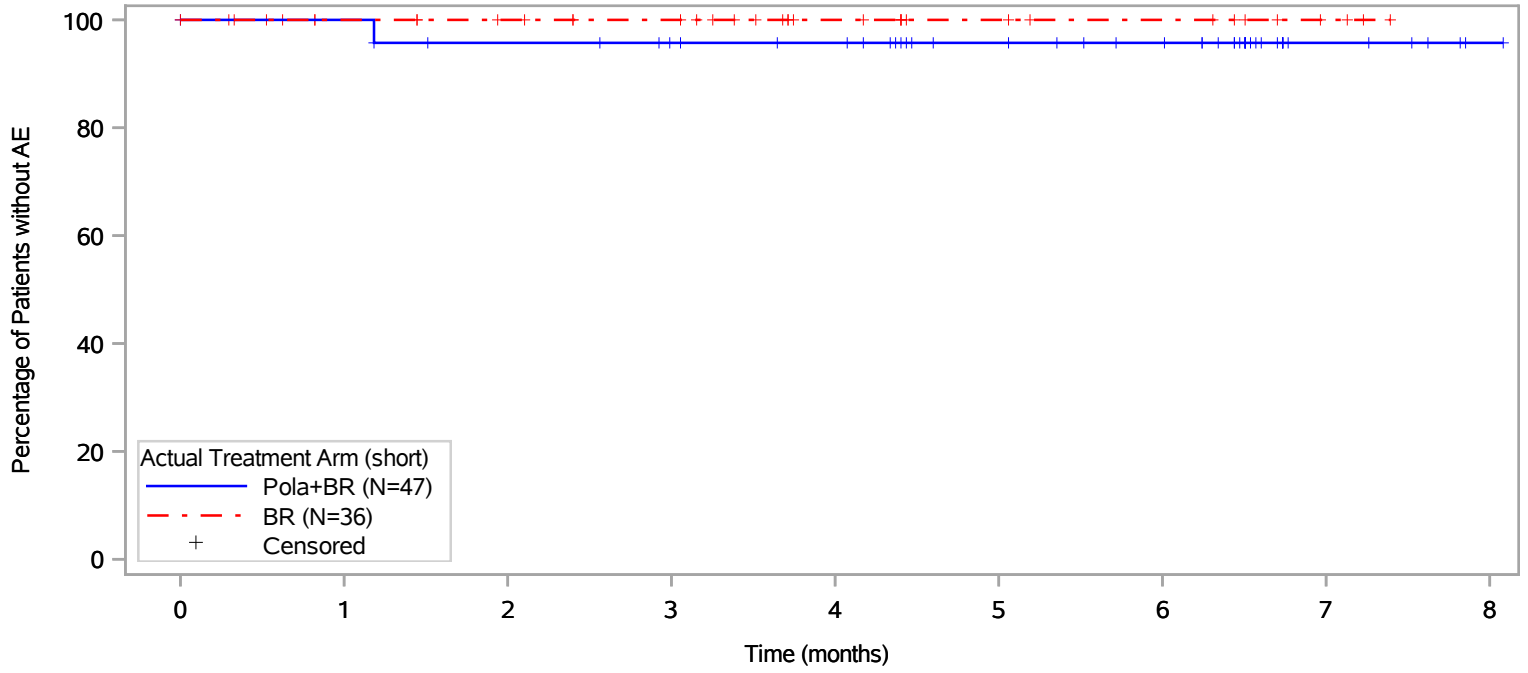


Patients at risk									
Pola+BR (N=47)	47	47	44	41	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	6	14	18	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk									
Pola+BR (N=47)	47	47	44	41	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	6	14	18	39	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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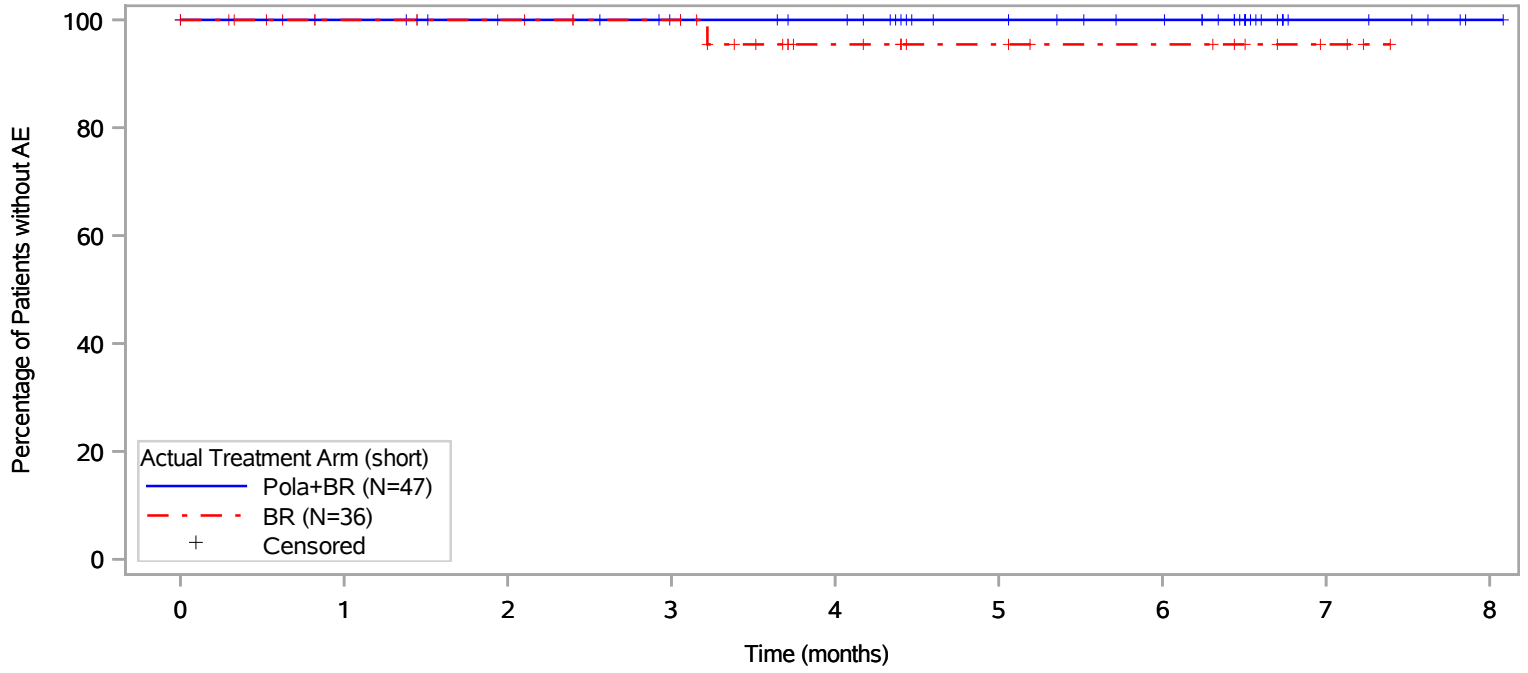
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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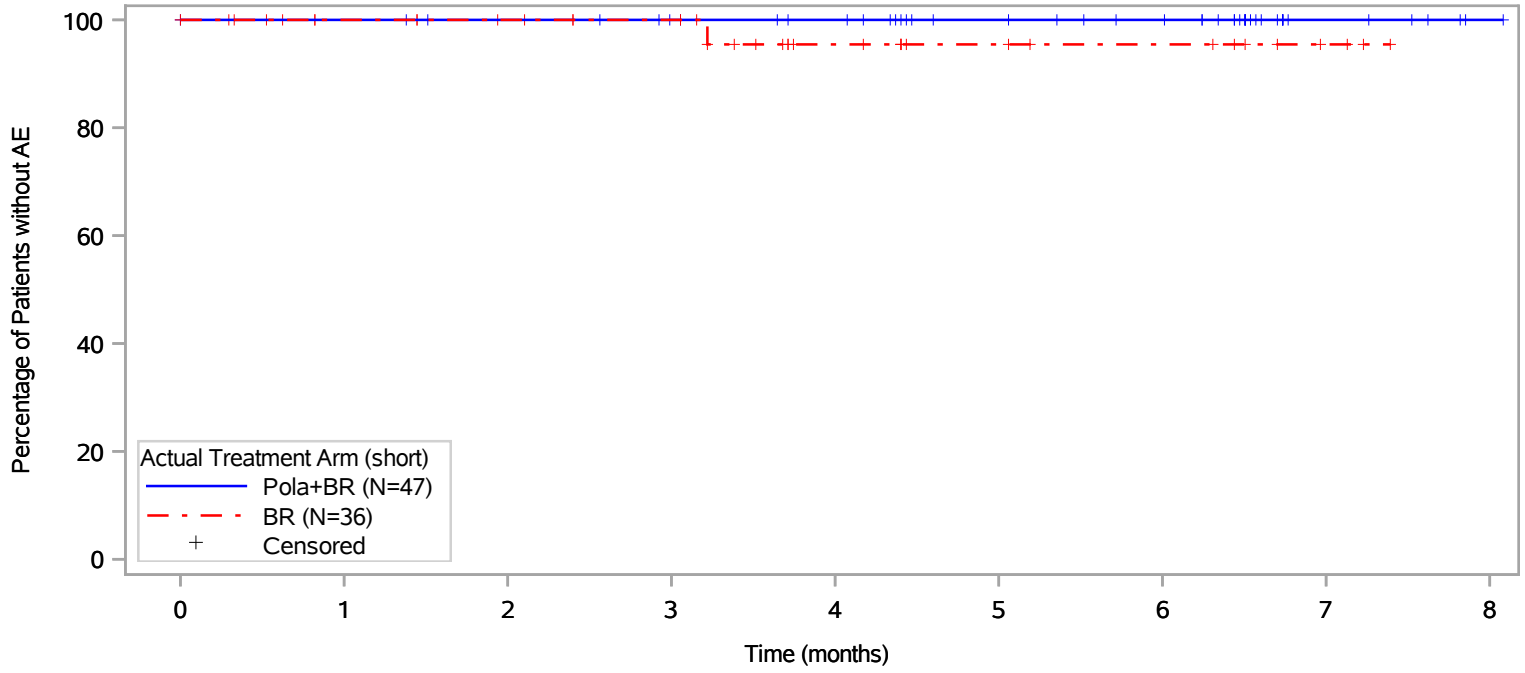
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR4AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 4:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
CARDIAC DISORDERS			47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	CARDIAC FAILURE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			47	100.0	2	4.3	45	95.7	36	100.0	3	8.3	33	91.7	0.0880	0.18	0.02	1.74		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.6658	0.61	0.04	10.54		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1623	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	3	8.3	33	91.7	0.2123	0.23	0.02	2.65		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR5AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
CARDIAC DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1644	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1644	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.1844	0.24	0.02	2.73		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6018	0.63	0.04	10.88		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	2	12.5	14	87.5	0.7505	0.55	0.03	10.01		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR5AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
CARDIAC DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	29	61.7	0	-	29	100.0	24	66.7	3	12.5	21	87.5	0.0226	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	3	12.5	21	87.5	0.2010	0.24	0.02	2.80		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.0578	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1052	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTGR5AE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		p-value (likelihood ratio)
CARDIAC DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1573	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1573	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	2	15.4	11	84.6	0.4736	0.42	0.04	4.85	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.1167	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.9114	0.85	0.05	14.99	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1167	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	2	15.4	11	84.6	0.1573	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.0455	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.0455	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.1573	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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30NOV2022 22:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
CARDIAC DISORDERS		Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	34	72.3	2	5.9	32	94.1	24	66.7	2	8.3	22	91.7	0.1886	0.22	0.02	2.57		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.5913	0.56	0.03	9.72		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1287	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.6864	0.56	0.03	10.06		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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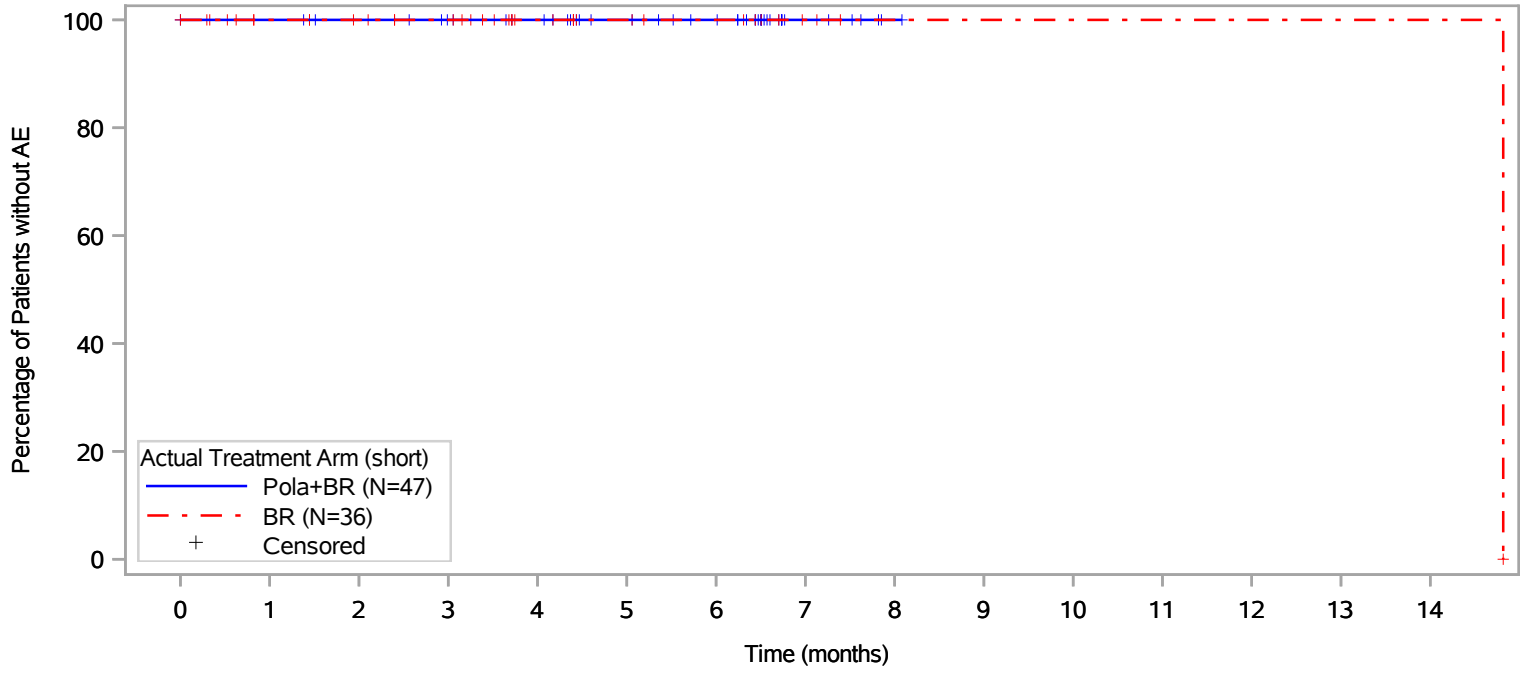
30NOV2022 22:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	33	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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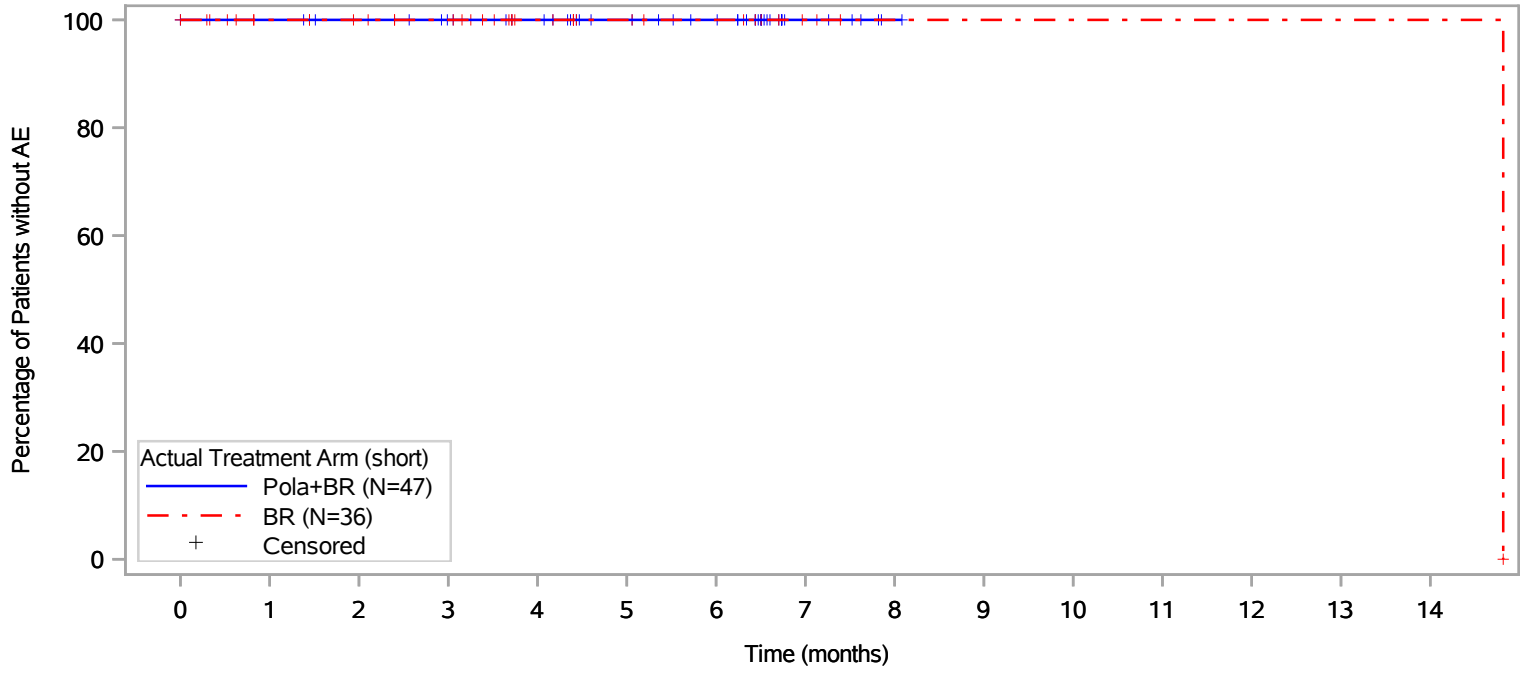
02DEC2022 5:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, CARDIAC FAILURE

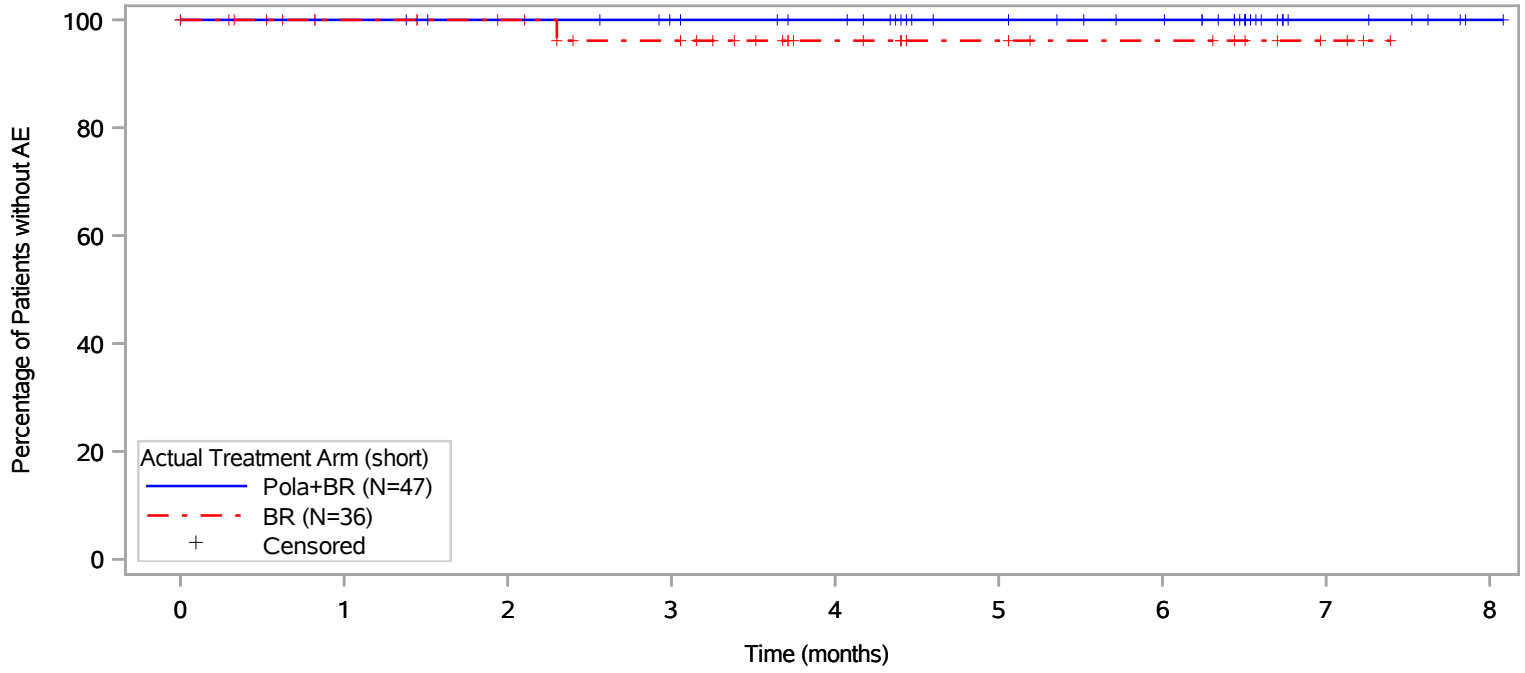


Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	33	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All

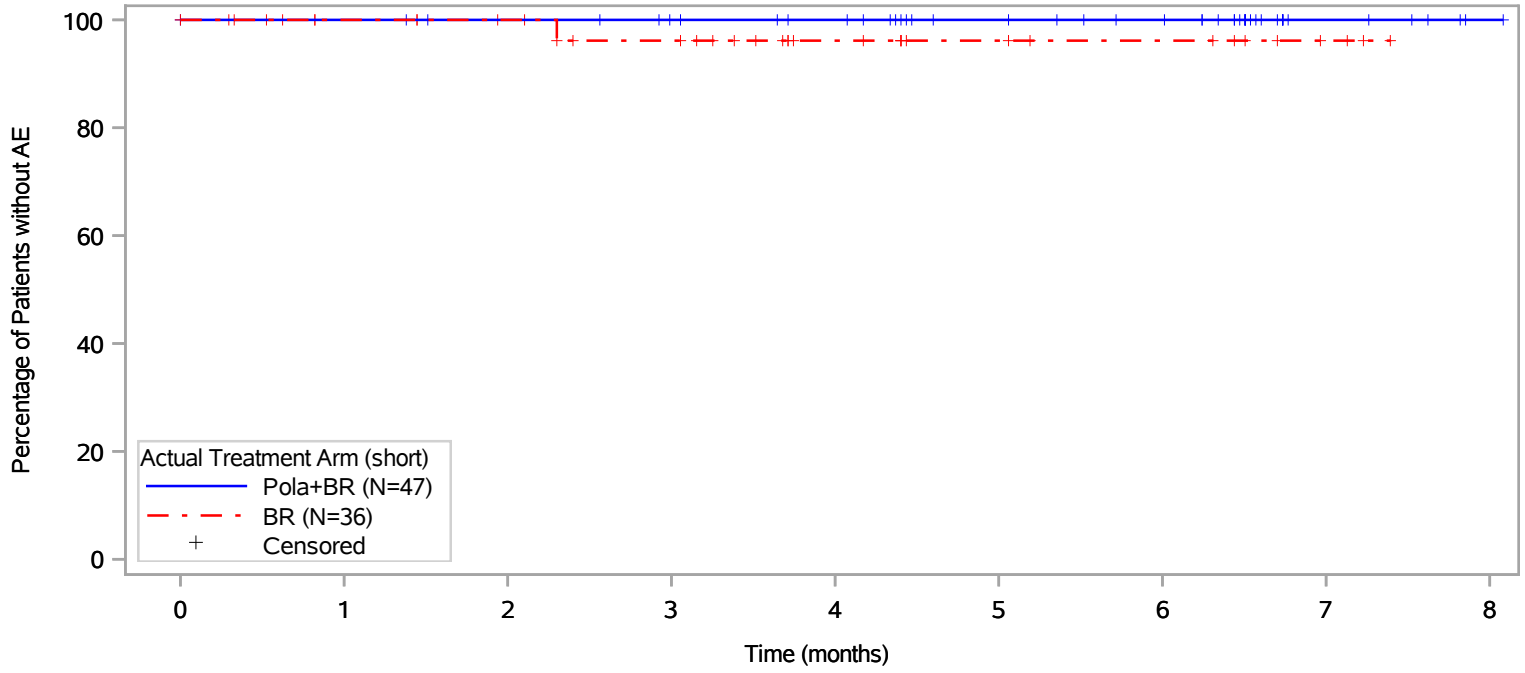


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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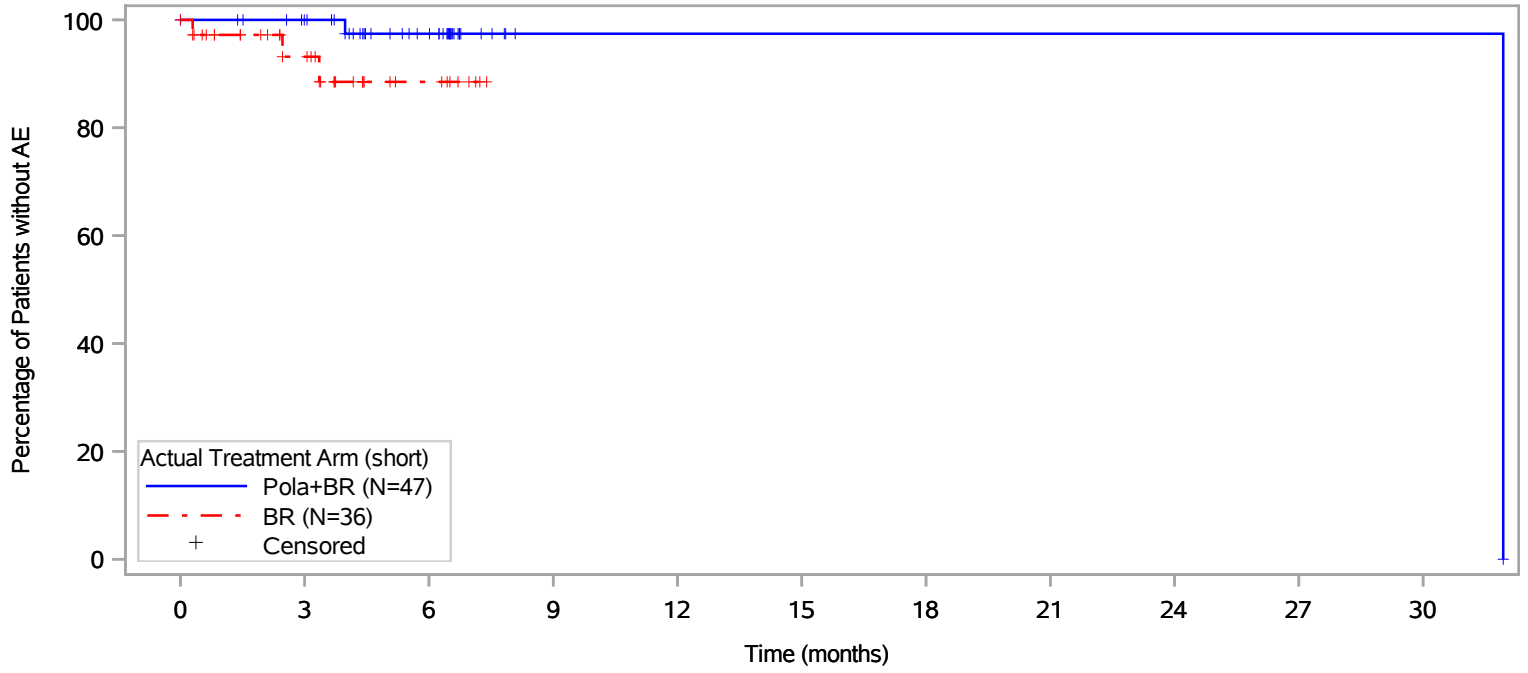
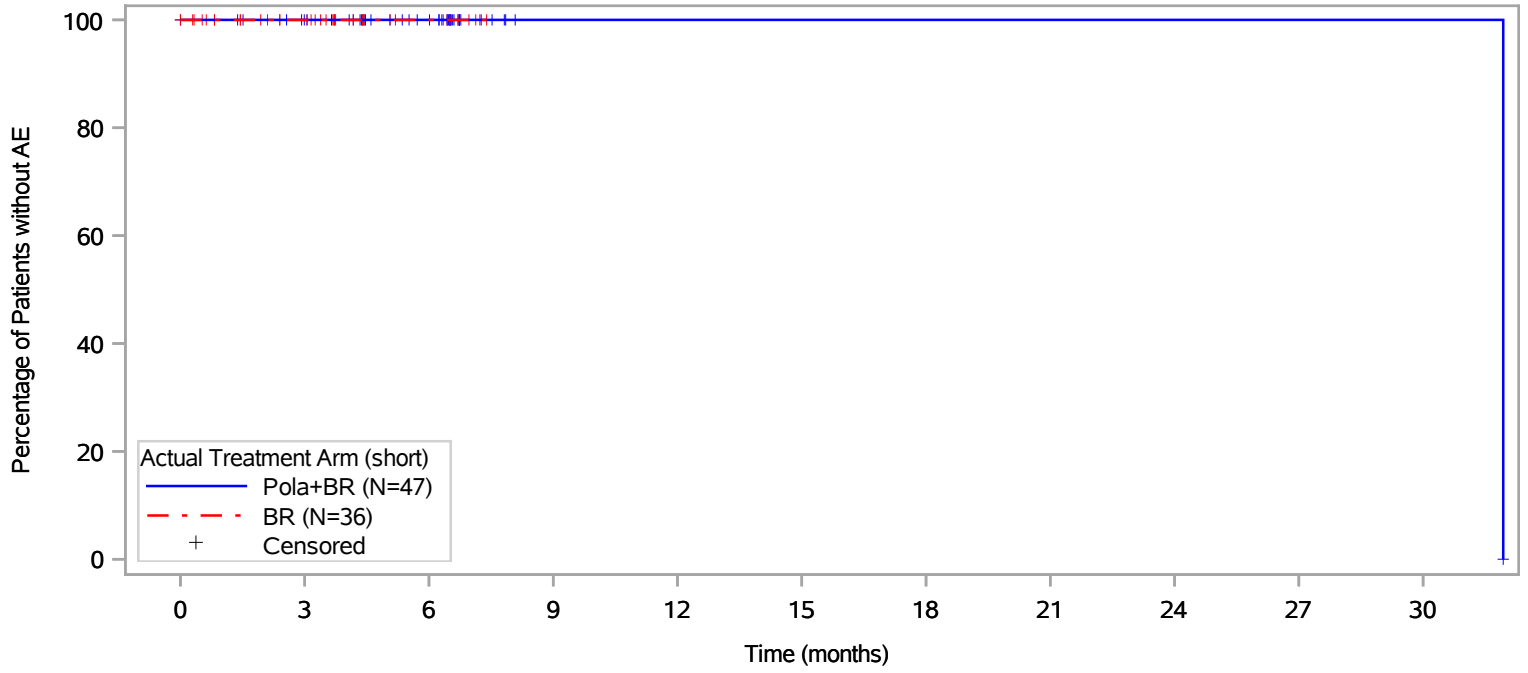
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk											
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1
BR (N=36)	36	23	8	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	5	19	45	45	45	45	45	45	45	45
BR (N=36)	0	11	25	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk											
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	5	20	46	46	46	46	46	46	46	46
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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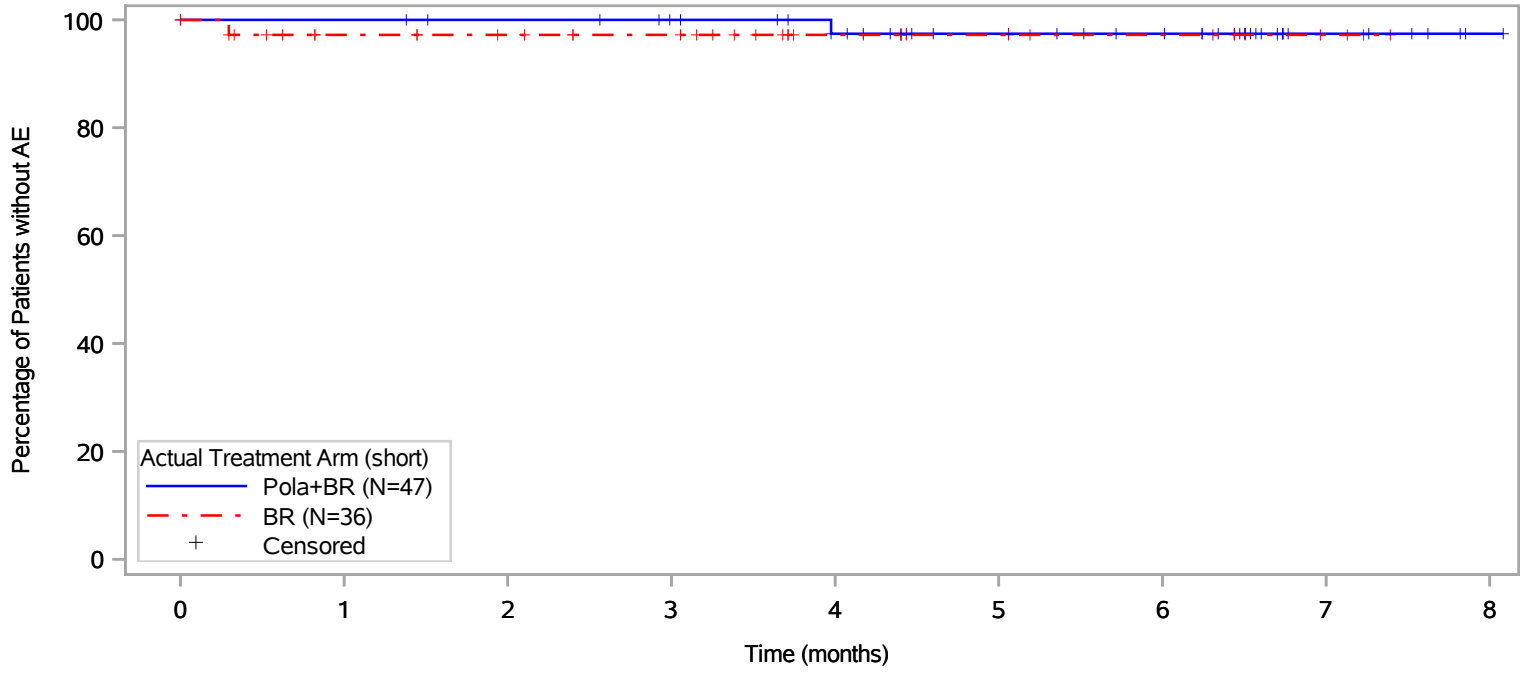
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	5	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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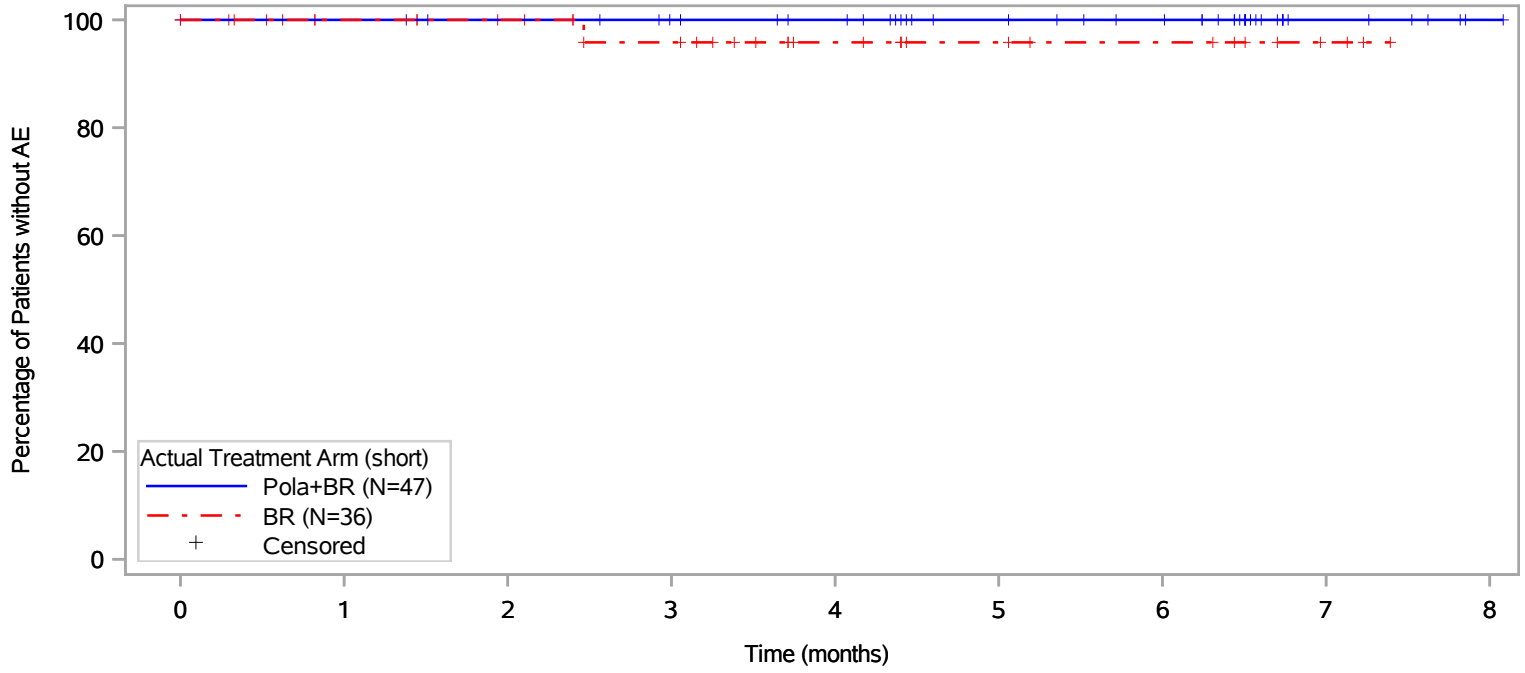
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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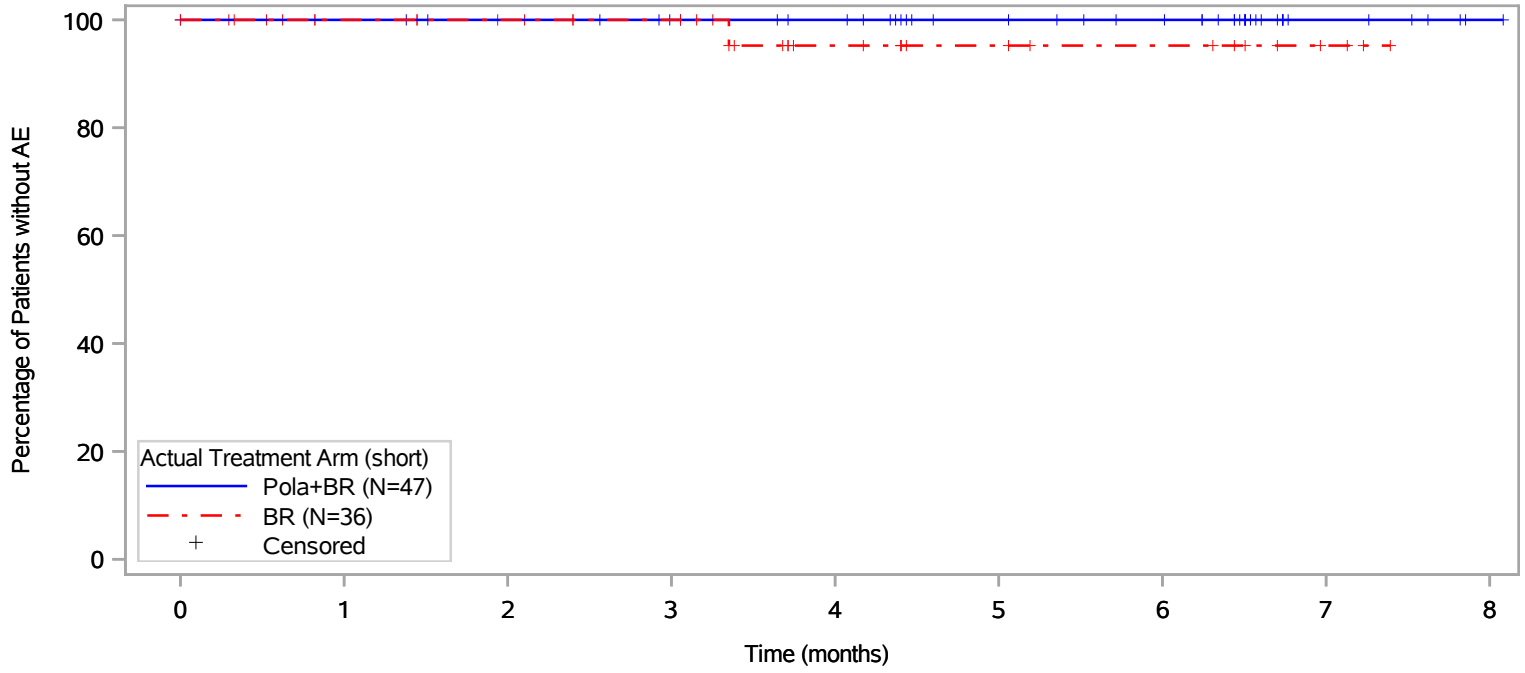
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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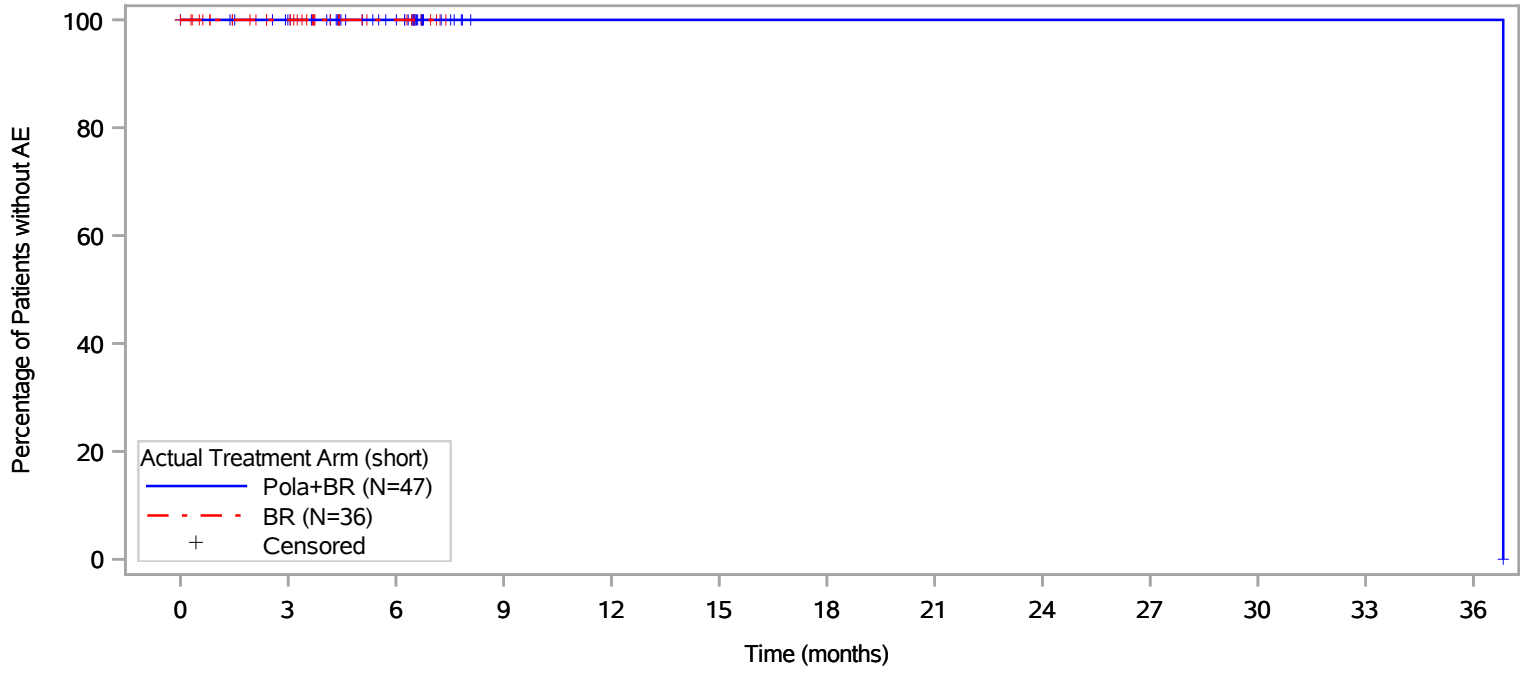
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk													
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=47)	0	5	20	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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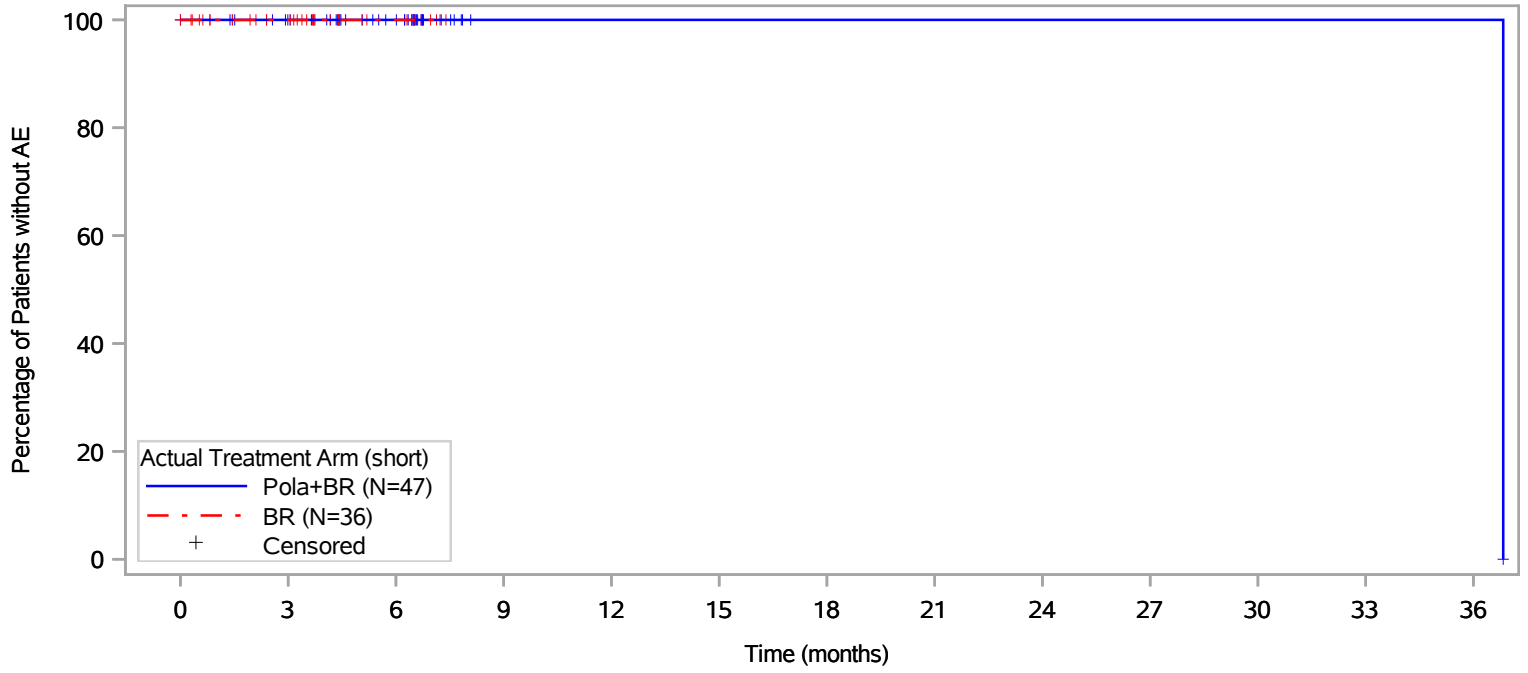
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MALIGNANT MELANOMA



Patients at risk													
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=47)	0	5	20	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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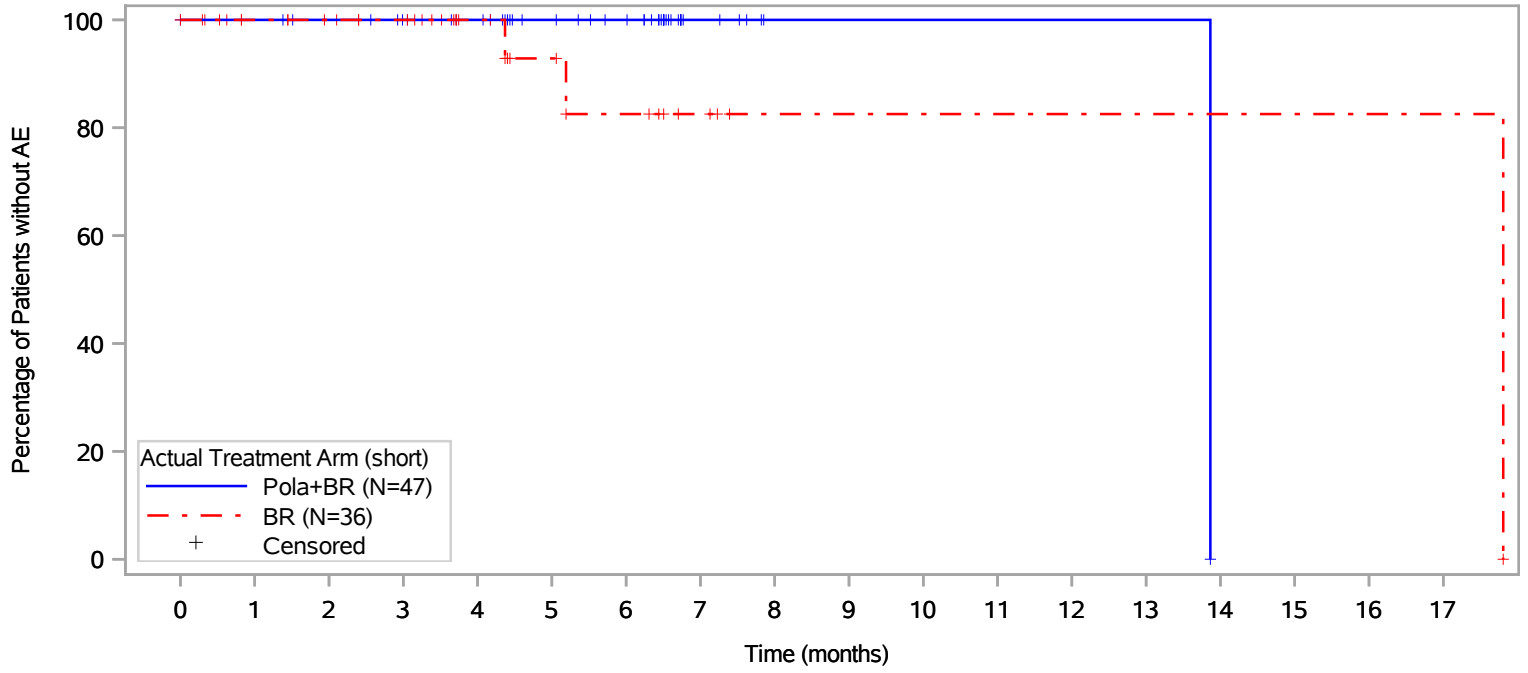
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk																		
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	1	1	1	1	1	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	46	46	46	46	46	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	25	26	30	33	33	33	33	33	33	33	33	33	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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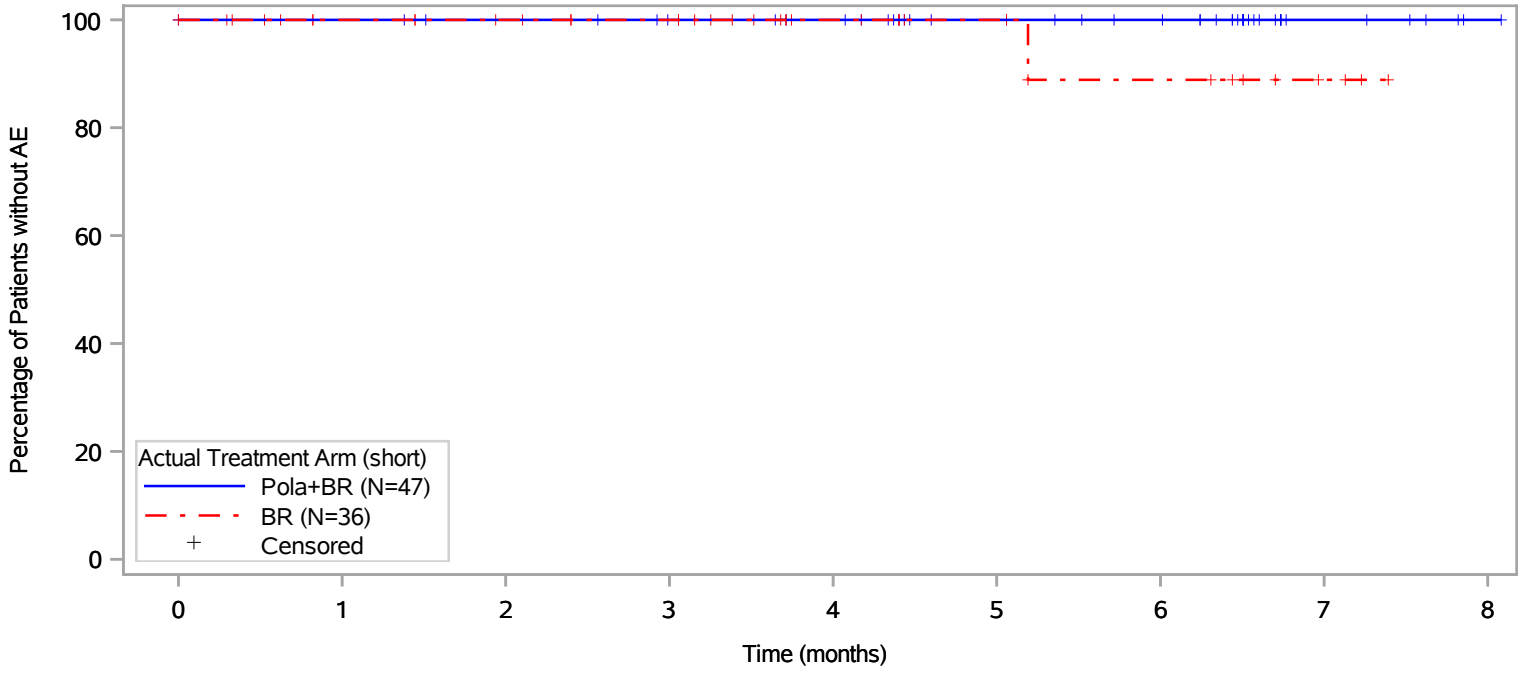
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, CEREBRAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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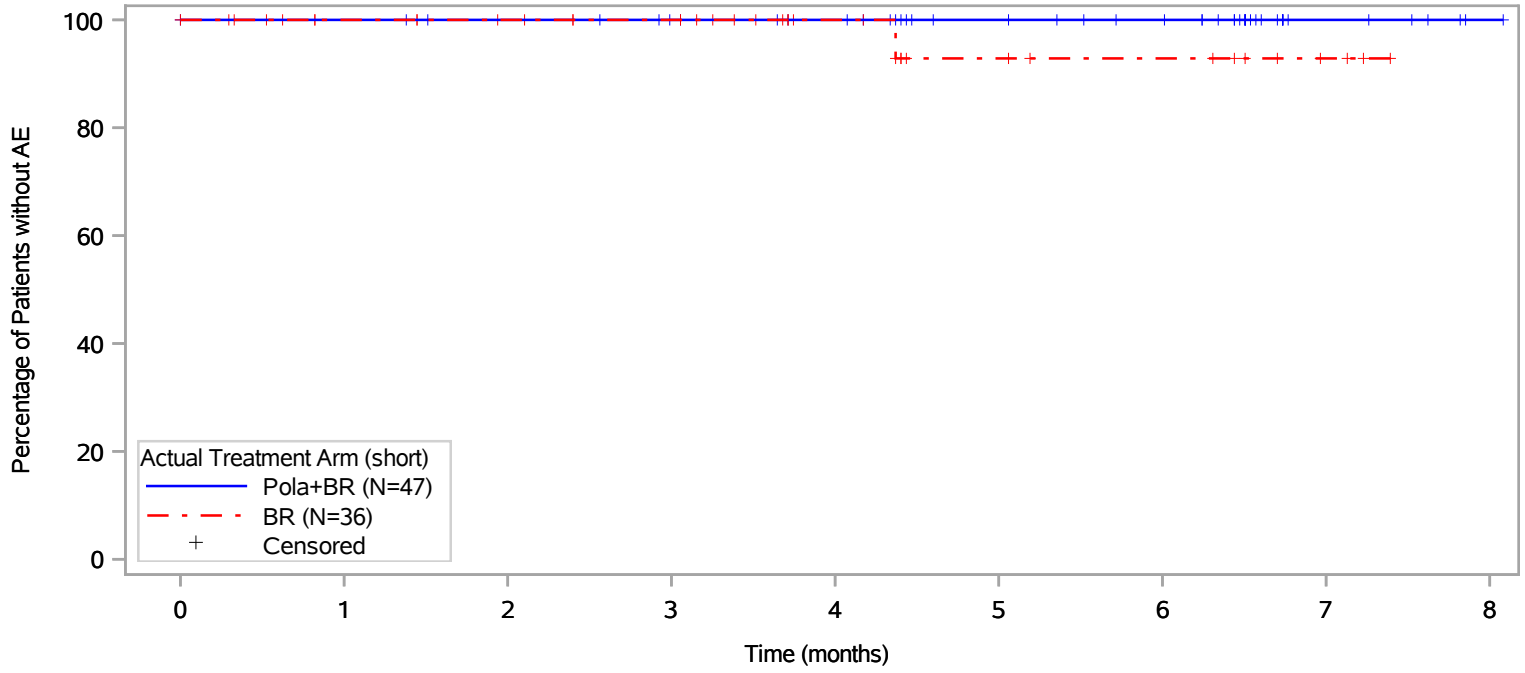
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, CEREBROVASCULAR ACCIDENT



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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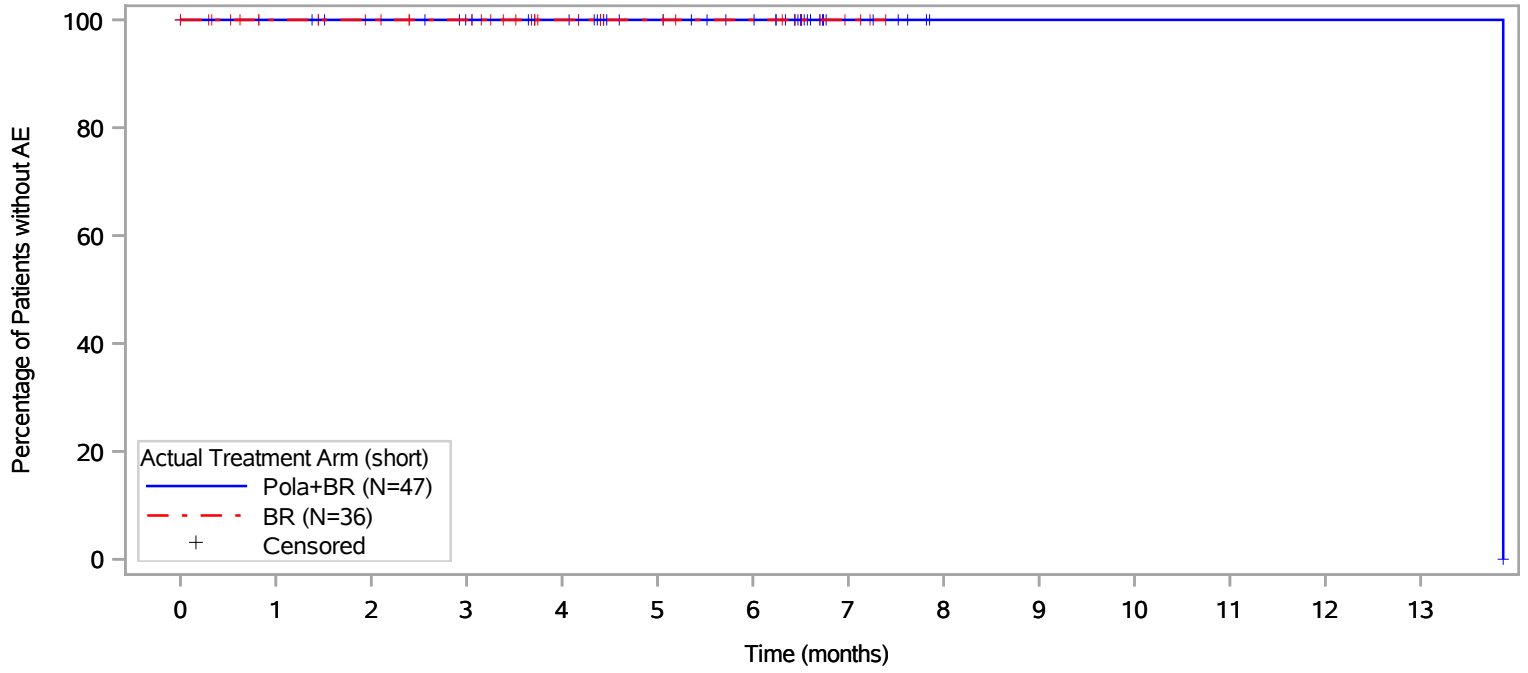
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HAEMORRHAGE INTRACRANIAL



Patients at risk														
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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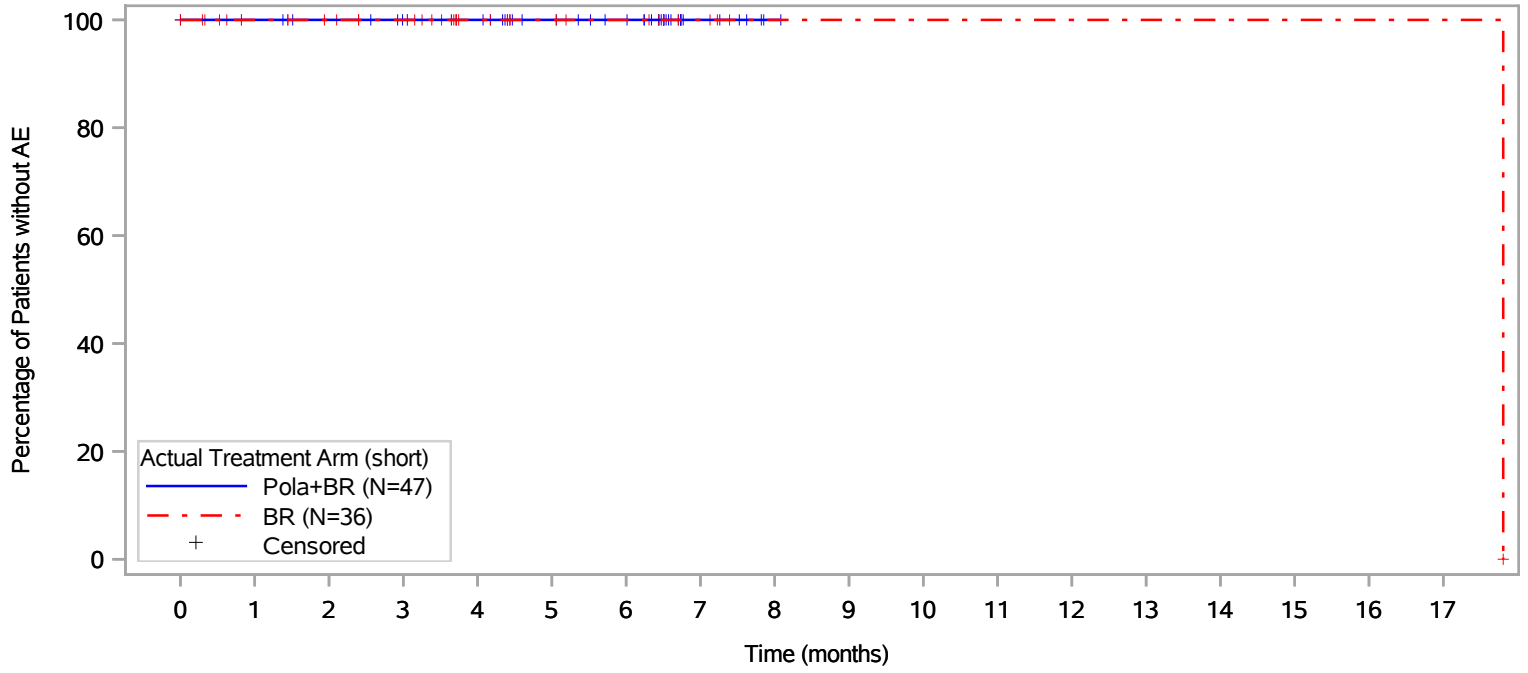
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, LEUKOENCEPHALOPATHY



Patients at risk																		
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	32	35	35	35	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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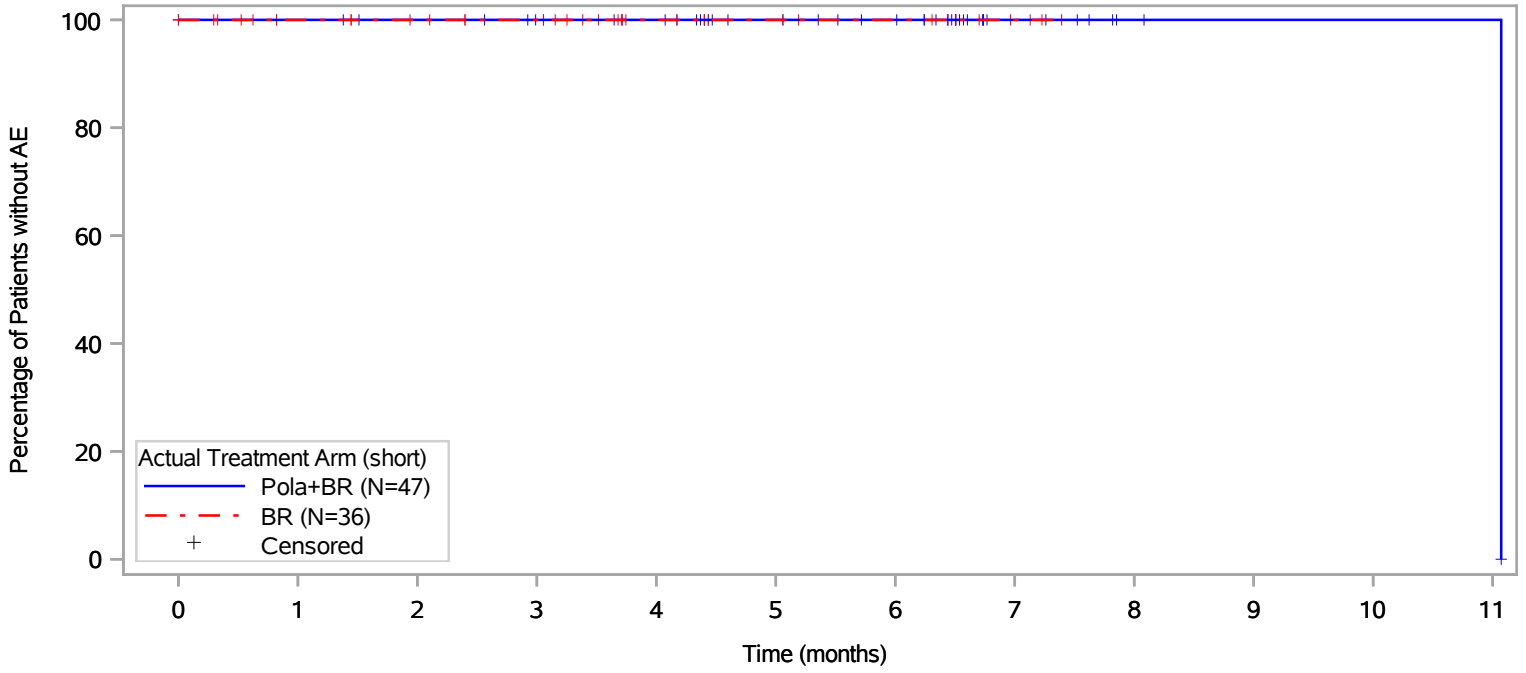
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk												
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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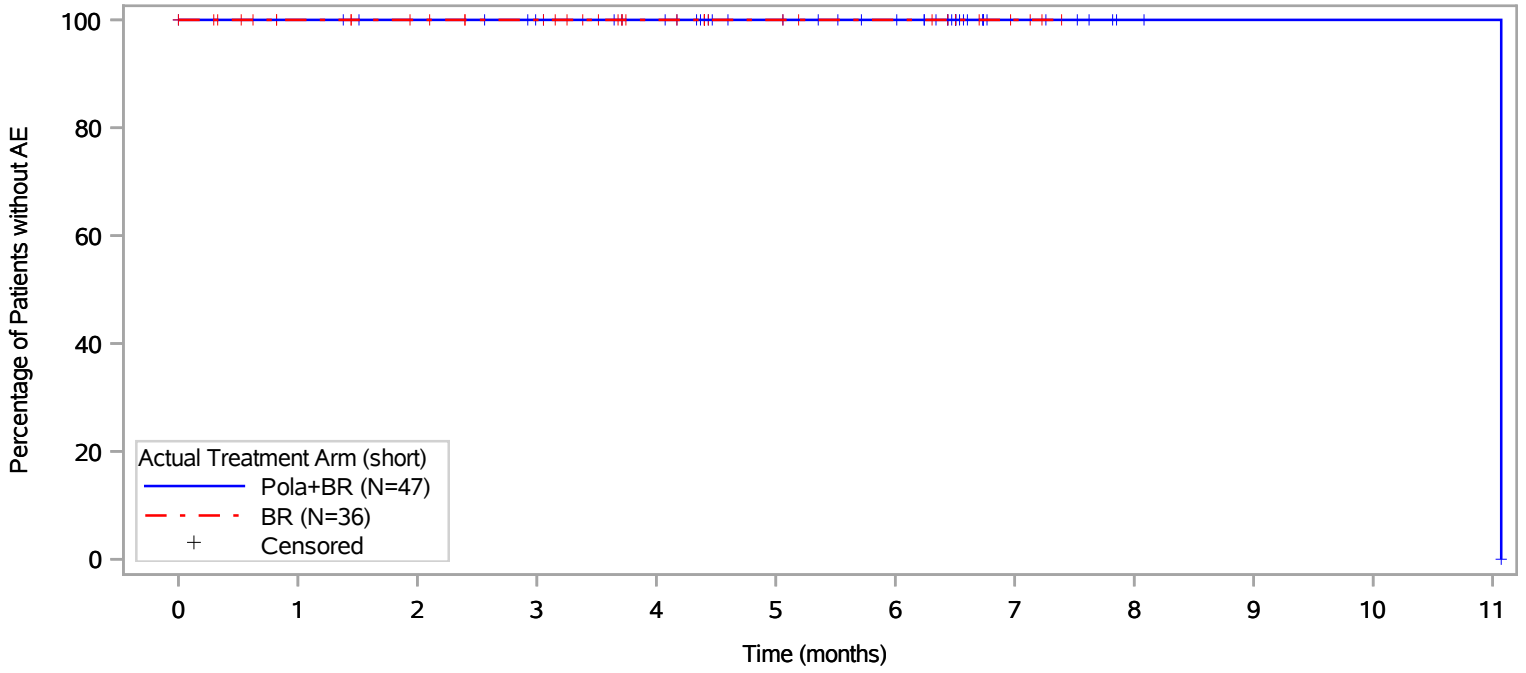
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE



Patients at risk												
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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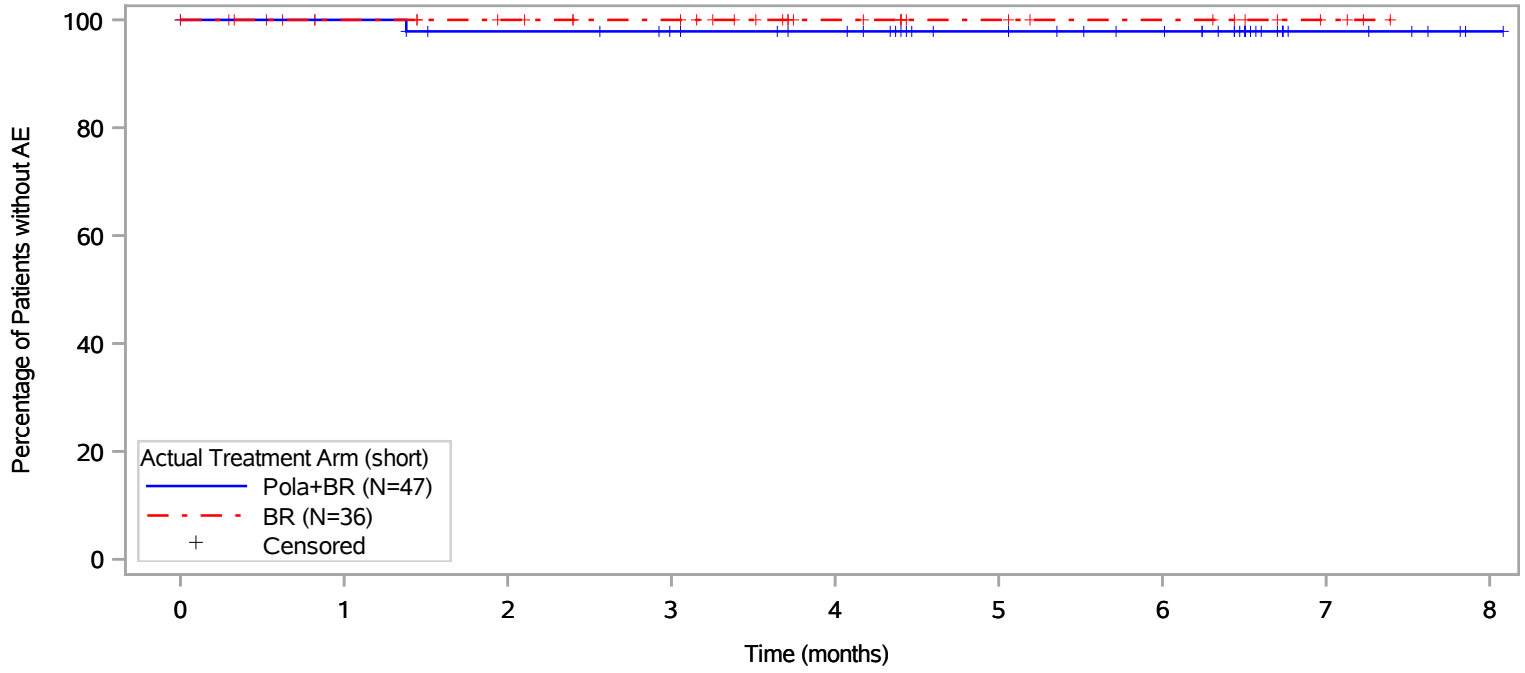
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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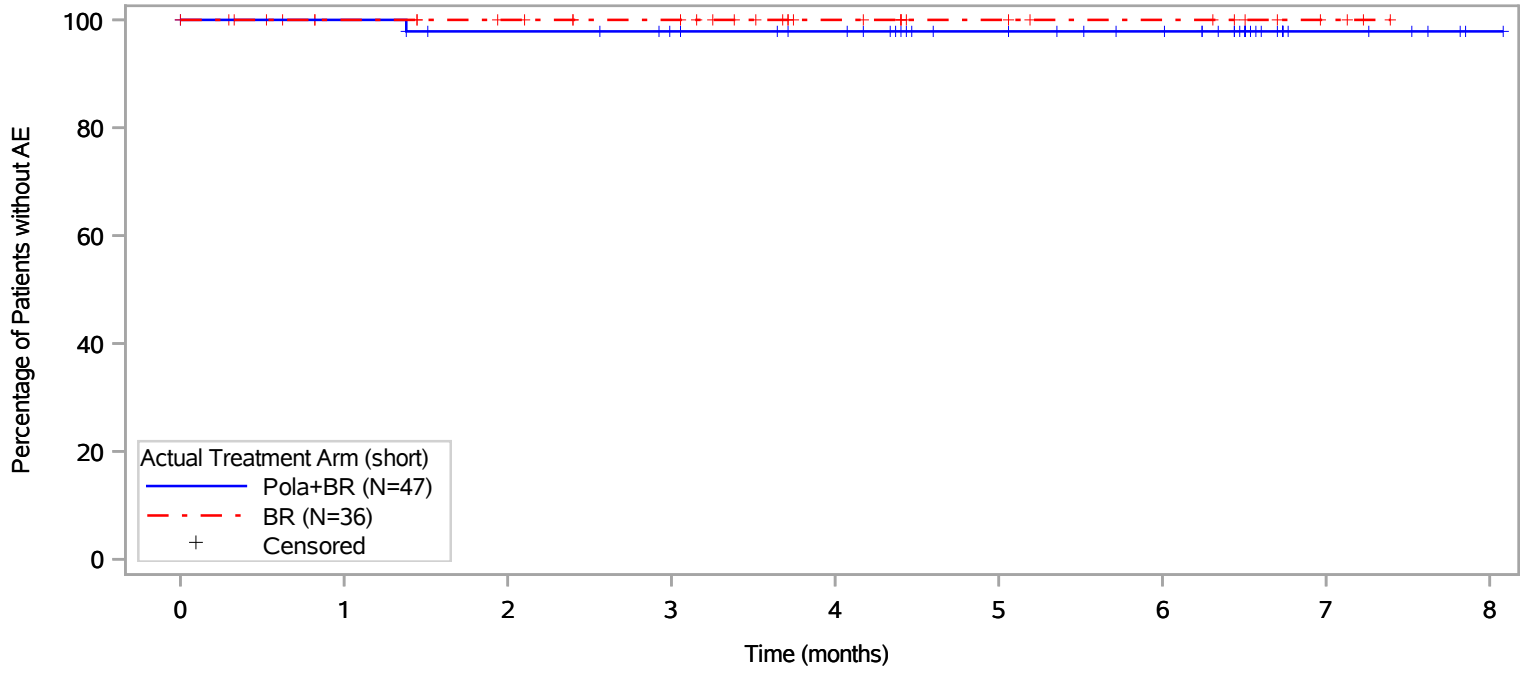
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HAEMOPTYSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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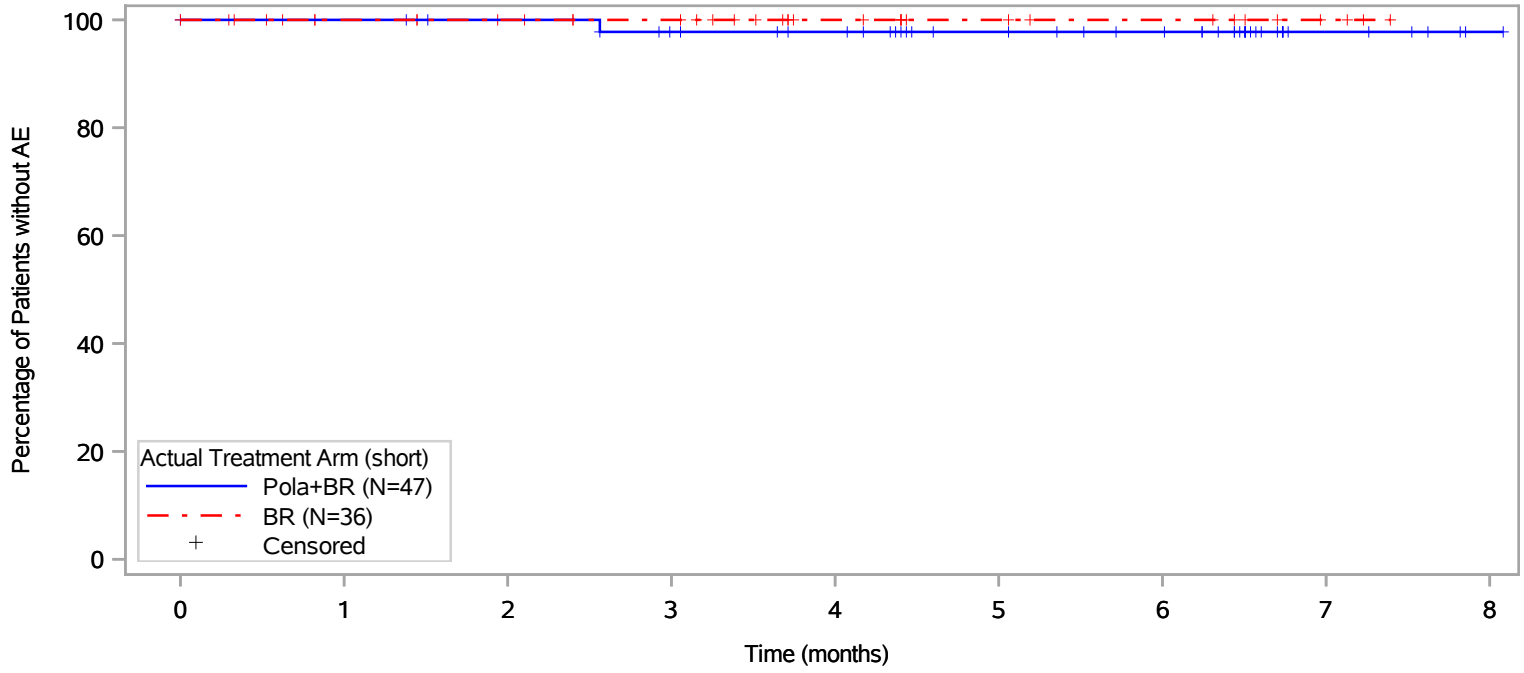
02DEC2022 5:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All

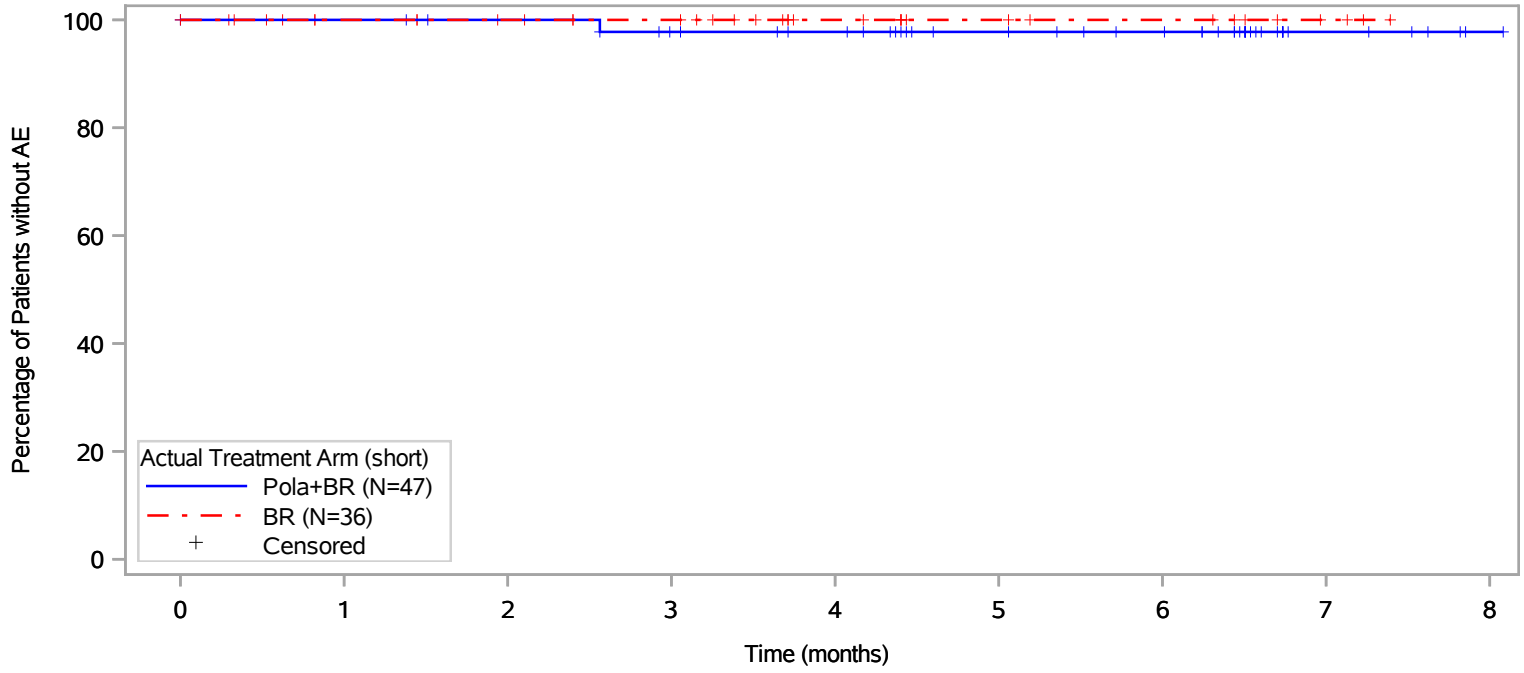


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR5AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 5:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DISTRIBUTIVE SHOCK



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTGR5AE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 5:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			47	100.0	8	17.0	39	83.0	36	100.0	3	8.3	33	91.7	0.2514	2.51	0.53	11.96		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.8425	0.90	0.08	10.72		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		47	100.0	4	8.5	43	91.5	36	100.0	2	5.6	34	94.4	0.4840	2.51	0.28	22.71		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4539	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.0655	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		47	100.0	3	6.4	44	93.6	36	100.0	1	2.8	35	97.2	0.8334	1.32	0.13	13.61		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.8422	0.95	0.06	15.13		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FLUTTER		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	CARDIAC FAILURE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			47	100.0	6	12.8	41	87.2	36	100.0	4	11.1	32	88.9	0.6337	0.80	0.21	3.02		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4960	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2049	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.4960	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4472	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			47	100.0	5	10.6	42	89.4	36	100.0	1	2.8	35	97.2	0.2241	3.91	0.45	33.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1883	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		47	100.0	5	10.6	42	89.4	36	100.0	0	-	36	100.0	0.0600	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			47	100.0	13	27.7	34	72.3	36	100.0	9	25.0	27	75.0	0.3231	0.64	0.26	1.59		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2107	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2327	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		47	100.0	6	12.8	41	87.2	36	100.0	3	8.3	33	91.7	0.7074	1.23	0.30	4.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.5628	0.48	0.03	7.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1623	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UROSEPSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INJURY, POISONING AND PROCEDURAL COMPLICATIONS			47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7506	0.58	0.03	9.63		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.3815	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1709	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			47	100.0	3	6.4	44	93.6	36	100.0	0	-	36	100.0	0.4472	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MORAXELLA TEST POSITIVE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4472	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	TRANSAMINASES INCREASED		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7904	0.63	0.04	10.35		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			47	100.0	1	2.1	46	97.9	36	100.0	3	8.3	33	91.7	0.2123	0.23	0.02	2.65		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.6161	0.48	0.03	7.93		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HAEMATURIA		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			47	100.0	3	6.4	44	93.6	36	100.0	2	5.6	34	94.4	0.8485	0.89	0.15	5.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4243	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.1722	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.6848	0.65	0.04	10.99		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.3123	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4849	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	29	61.7	5	17.2	24	82.8	20	55.6	2	10.0	18	90.0	0.8054	1.38	0.26	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	18	38.3	3	16.7	15	83.3	16	44.4	1	6.3	15	93.8	0.1602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.5915	0.62	0.04	10.25		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	1	5.0	19	95.0	0.9632	1.17	0.10	13.15		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.3171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1422	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4884	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	29	61.7	0	-	29	100.0	20	55.6	2	10.0	18	90.0	0.0534	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	29	61.7	2	6.9	27	93.1	20	55.6	1	5.0	19	95.0	0.9955	1.14	0.10	13.39		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	29	61.7	3	10.3	26	89.7	20	55.6	2	10.0	18	90.0	0.8352	1.04	0.17	6.40		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	18	38.3	3	16.7	15	83.3	16	44.4	2	12.5	14	87.5	0.7345	0.63	0.09	4.58		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1915	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4720	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	29	61.7	3	10.3	26	89.7	20	55.6	1	5.0	19	95.0	0.5539	2.41	0.25	23.67		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2276	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1644	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	29	61.7	3	10.3	26	89.7	20	55.6	0	-	20	100.0	0.1537	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2276	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	29	61.7	5	17.2	24	82.8	20	55.6	3	15.0	17	85.0	0.8529	0.81	0.19	3.48		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	18	38.3	8	44.4	10	55.6	16	44.4	6	37.5	10	62.5	0.2803	0.50	0.15	1.68		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2043	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2568	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3954	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	29	61.7	4	13.8	25	86.2	20	55.6	2	10.0	18	90.0	0.8616	1.16	0.21	6.50		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	1	6.3	15	93.8	0.6611	1.88	0.17	21.09		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.6457	0.44	0.03	7.45		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.8617	0.80	0.05	12.75		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2278	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.4720	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4720	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.7729	0.65	0.04	10.94		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	2	12.5	14	87.5	0.7505	0.55	0.03	10.01		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.0393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.2147	0.26	0.02	2.96		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	18	38.3	2	11.1	16	88.9	16	44.4	0	-	16	100.0	0.2678	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.1317	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4533	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 23:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	29	61.7	4	13.8	25	86.2	24	66.7	2	8.3	22	91.7	0.3453	2.92	0.32	26.73		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	18	38.3	4	22.2	14	77.8	12	33.3	1	8.3	11	91.7	0.4183	2.36	0.26	21.19		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.6171				*	WARNING: Iteration limit reached without convergence.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.6862	0.55	0.03	8.90		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	1	4.2	23	95.8	0.2697	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	1	8.3	11	91.7	0.9182	1.10	0.10	12.20		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.3372	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.5498	0.39	0.02	6.73		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.8815	1.17	0.07	18.65		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2509	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	29	61.7	4	13.8	25	86.2	24	66.7	2	8.3	22	91.7	0.7169	0.82	0.13	5.15		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	18	38.3	2	11.1	16	88.9	12	33.3	2	16.7	10	83.3	0.9010	1.14	0.10	12.70		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	29	61.7	3	10.3	26	89.7	24	66.7	0	-	24	100.0	0.1363	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	18	38.3	2	11.1	16	88.9	12	33.3	1	8.3	11	91.7	0.8134	1.39	0.13	15.34		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	29	61.7	3	10.3	26	89.7	24	66.7	0	-	24	100.0	0.1363	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.2517	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	29	61.7	10	34.5	19	65.5	24	66.7	6	25.0	18	75.0	0.7424	0.82	0.28	2.41		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	18	38.3	3	16.7	15	83.3	12	33.3	3	25.0	9	75.0	0.1761	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	29	61.7	4	13.8	25	86.2	24	66.7	2	8.3	22	91.7	0.7077	1.12	0.20	6.32		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	18	38.3	2	11.1	16	88.9	12	33.3	1	8.3	11	91.7	0.8809	1.37	0.12	15.45		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.5456	0.55	0.03	8.94		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7648	0.58	0.03	10.17		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.3630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS		<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.8013	0.64	0.04	10.89		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	3	12.5	21	87.5	0.2010	0.24	0.02	2.80		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.0578	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.1052	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.5553	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	29	61.7	3	10.3	26	89.7	24	66.7	1	4.2	23	95.8	0.6579	1.87	0.19	18.80		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.1923	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.6524	0.68	0.04	12.16		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 23:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	2	8.7	21	91.3	0.7028	1.39	0.28	6.98		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.4186	0.38	0.02	6.47		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	1	4.3	22	95.7	0.6486	1.78	0.19	16.19		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1391	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4936	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	2	8.7	21	91.3	0.0434	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	1	4.3	22	95.7	0.9161	1.17	0.12	11.72		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	9	19.1	3	33.3	6	66.7	13	36.1	2	15.4	11	84.6	0.2778	3.27	0.34	31.46		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	2	8.7	21	91.3	0.3045	0.36	0.05	2.74		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5577	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	1	4.3	22	95.7	0.4497	2.48	0.28	22.29		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	0	-	23	100.0	0.1309	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	19.1	4	44.4	5	55.6	13	36.1	6	46.2	7	53.8	0.1287	0.30	0.06	1.54		Convergence criterion (GCONV=1E-8) satisfied.	0.0774
INFECTIONS AND INFESTATIONS		Non-Europe	38	80.9	9	23.7	29	76.3	23	63.9	3	13.0	20	87.0	0.7310	1.25	0.33	4.79		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1681	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	1	7.7	12	92.3	0.9301	1.13	0.07	18.50		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	2	8.7	21	91.3	0.8377	1.15	0.22	6.05		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5571	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4366	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS		Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	0	-	23	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.6776	0.55	0.03	8.94		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	2	15.4	11	84.6	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5514	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	2	8.7	21	91.3	0.6573	0.67	0.11	4.07		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4682	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5509	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.3655	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_soc_sgl_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30NOV2022 23:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	34	72.3	5	14.7	29	85.3	24	66.7	3	12.5	21	87.5	0.7140	1.44	0.27	7.56		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	13	27.7	3	23.1	10	76.9	12	33.3	0	-	12	100.0	0.1339	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8085	0.90	0.08	10.50		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	34	72.3	2	5.9	32	94.1	24	66.7	2	8.3	22	91.7	0.9702	1.15	0.10	12.83		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2212	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.0577	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.4609	0.43	0.02	7.69		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2644	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	2	16.7	10	83.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	34	72.3	5	14.7	29	85.3	24	66.7	3	12.5	21	87.5	0.6001	0.76	0.16	3.49		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1990	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.5448	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1510	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	34	72.3	4	11.8	30	88.2	24	66.7	1	4.2	23	95.8	0.3596	2.99	0.33	27.02		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	34	72.3	4	11.8	30	88.2	24	66.7	0	-	24	100.0	0.0988	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	34	72.3	11	32.4	23	67.6	24	66.7	6	25.0	18	75.0	0.4161	0.66	0.22	1.95		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	13	27.7	2	15.4	11	84.6	12	33.3	3	25.0	9	75.0	0.4664	0.51	0.08	3.13		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2032	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2340	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	34	72.3	4	11.8	30	88.2	24	66.7	3	12.5	21	87.5	0.6598	0.73	0.16	3.33		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.1963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1287	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS		Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.7892	0.61	0.04	10.21		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	34	72.3	1	2.9	33	97.1	24	66.7	2	8.3	22	91.7	0.6864	0.56	0.03	10.06		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5775	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	13	27.7	3	23.1	10	76.9	12	33.3	1	8.3	11	91.7	0.5357	2.01	0.21	19.59		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	34	72.3	0	-	34	100.0	24	66.7	1	4.2	23	95.8	0.1432	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8091	0.69	0.04	12.04		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	34	72.3	2	5.9	32	94.1	24	66.7	0	-	24	100.0	0.3471	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4862	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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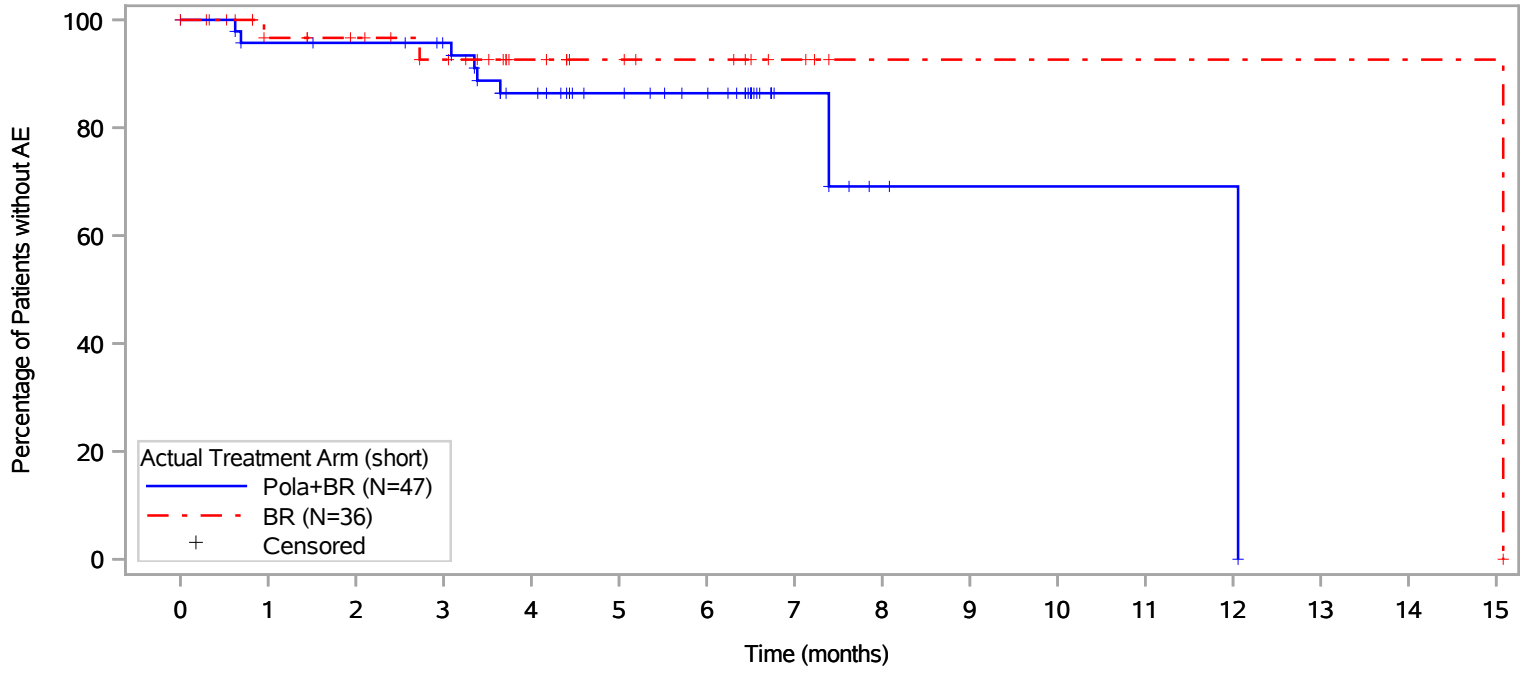
30NOV2022 23:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk																
Pola+BR (N=47)	47	45	44	41	35	28	24	5	2	1	1	1	1	NE	NE	NE
BR (N=36)	36	29	26	23	15	10	8	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=47)	0	0	1	4	6	13	17	36	38	39	39	39	39	NE	NE	NE
BR (N=36)	0	6	9	11	19	24	26	30	33	33	33	33	33	33	33	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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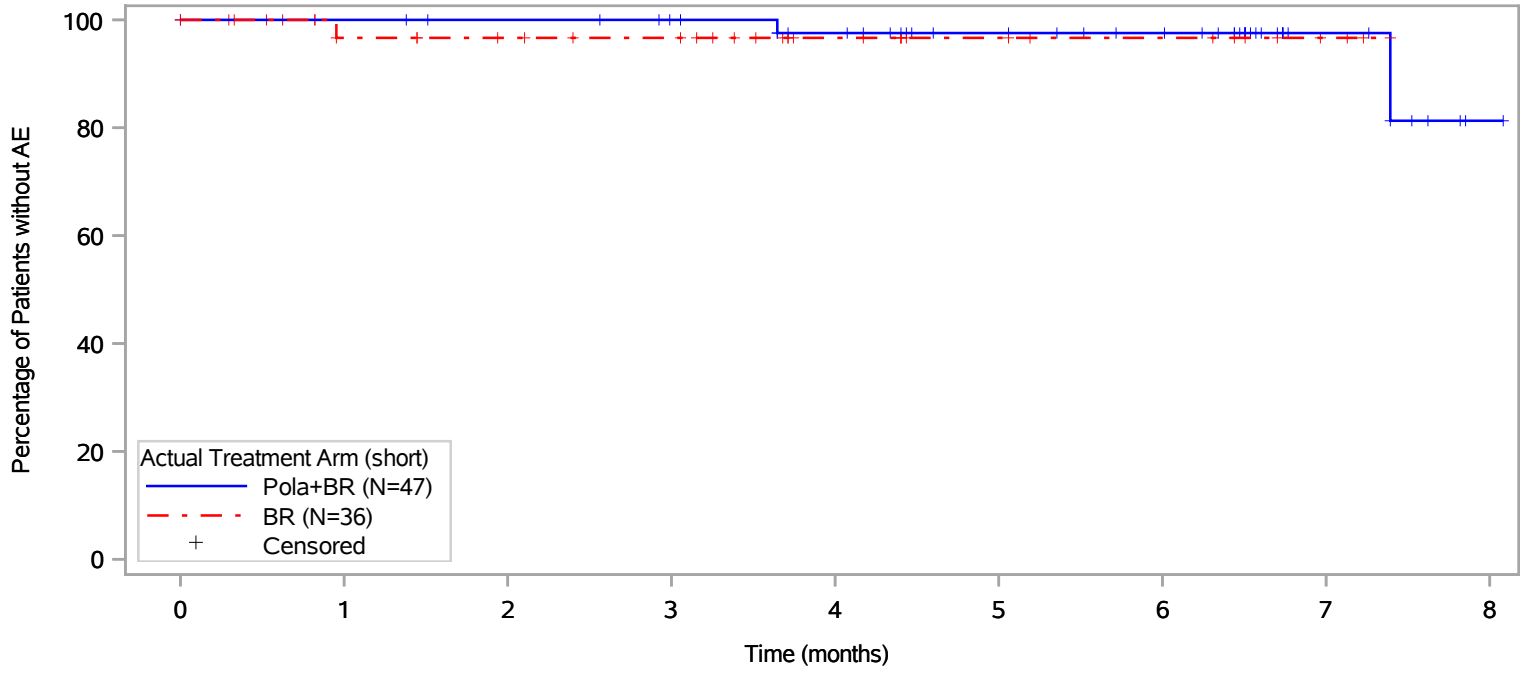
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	7	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	39	44
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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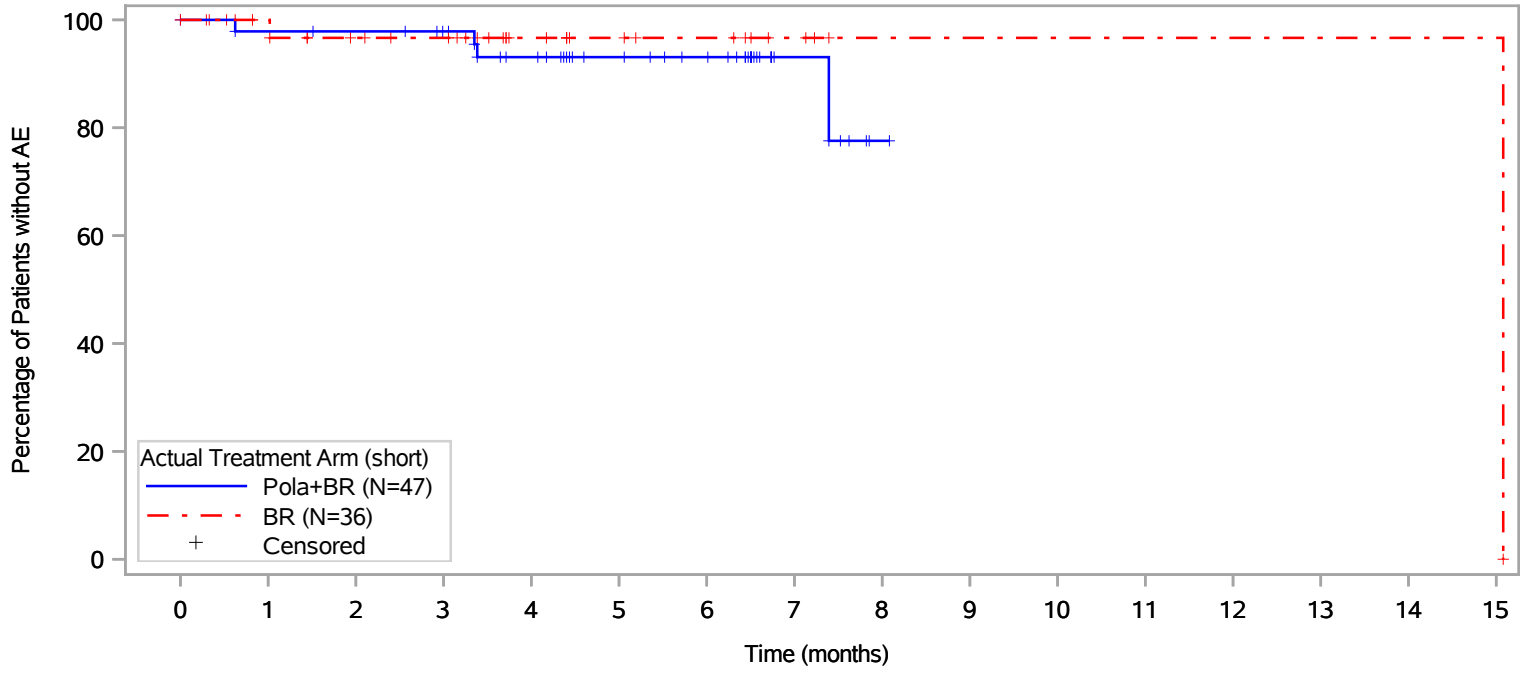
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA

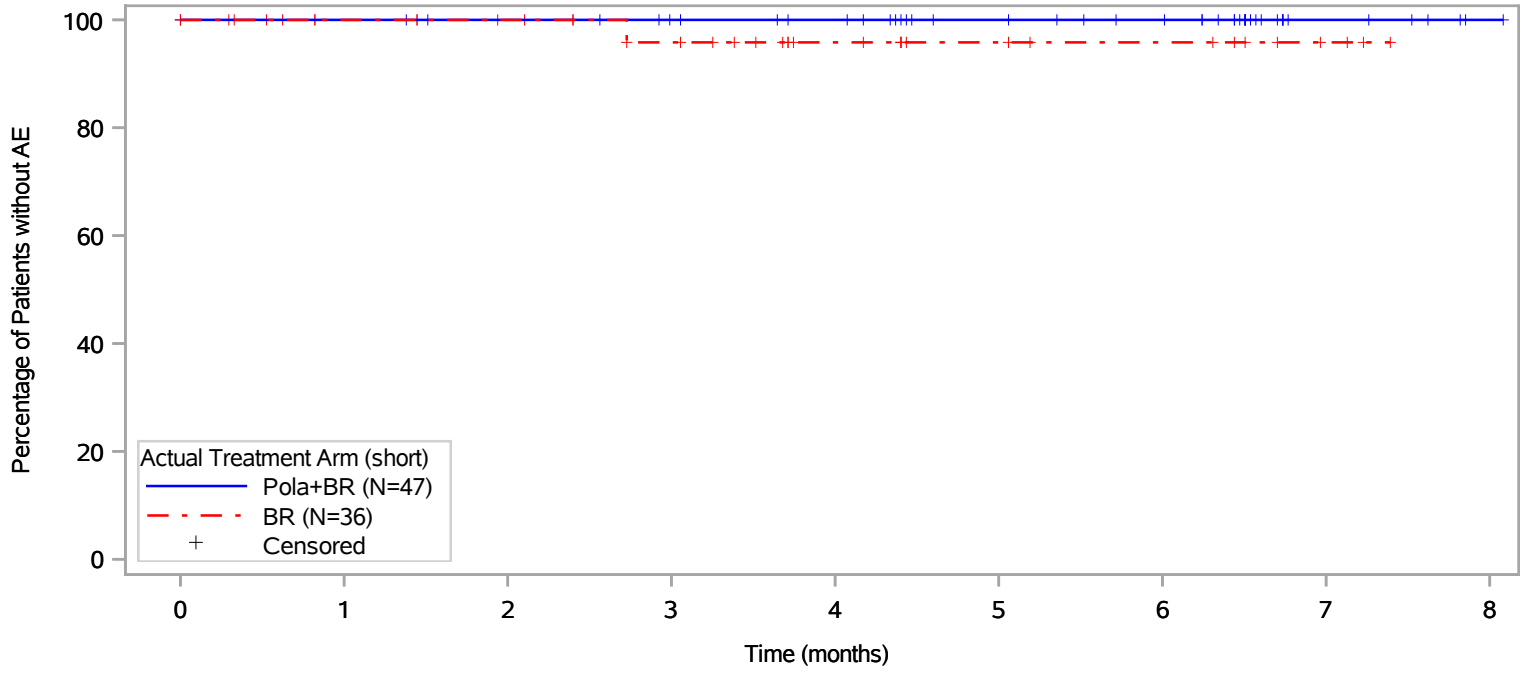


Patients at risk																
Pola+BR (N=47)	47	46	45	42	37	29	25	6	1	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	26	24	15	10	8	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=47)	0	0	1	4	7	15	19	38	42	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	11	20	25	27	31	34	34	34	34	34	34	34	34

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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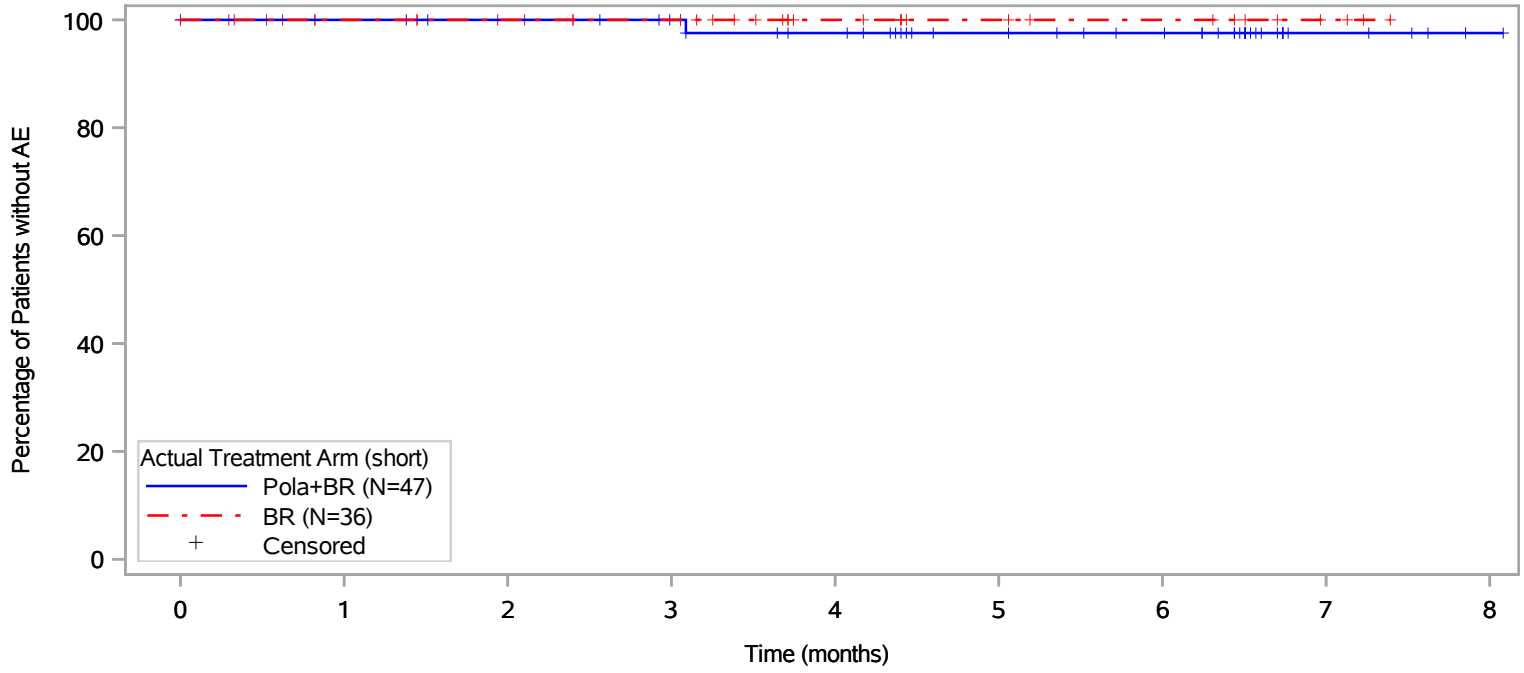
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, MYELOSUPPRESSION

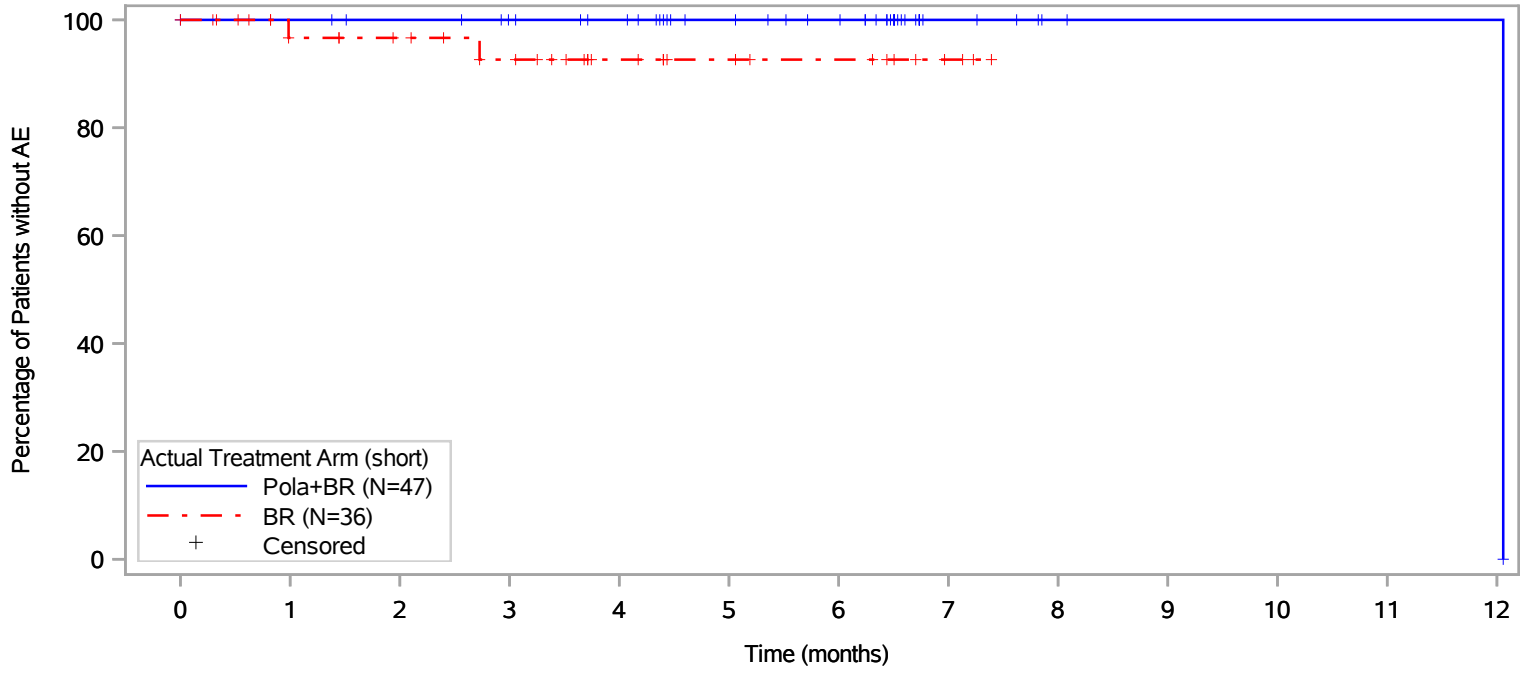


Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA

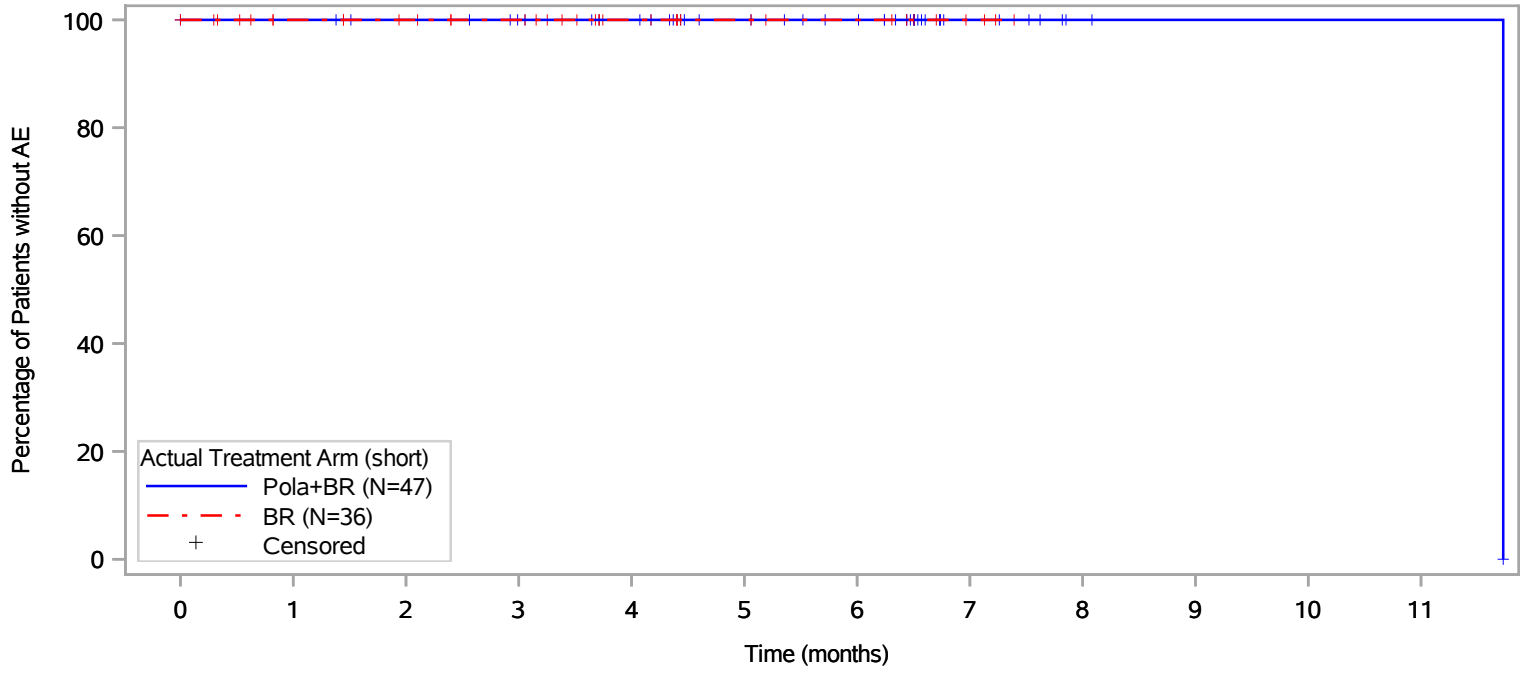


Patients at risk													
Pola+BR (N=47)	47	47	45	42	39	31	27	6	2	1	1	1	1
BR (N=36)	36	29	26	23	15	10	8	3	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45	46	46	46	46
BR (N=36)	0	6	9	11	19	24	26	31	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA



Patients at risk												
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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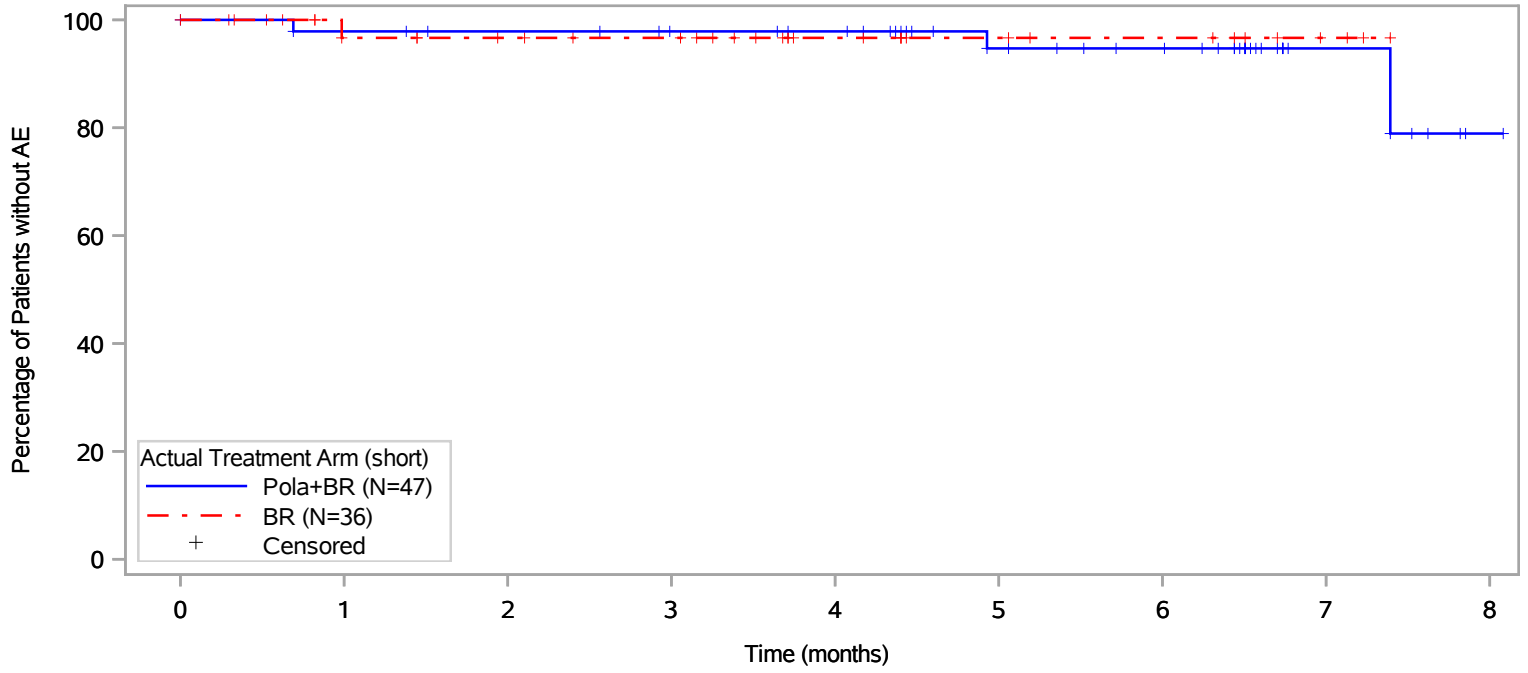
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	39	30	26	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	39	43
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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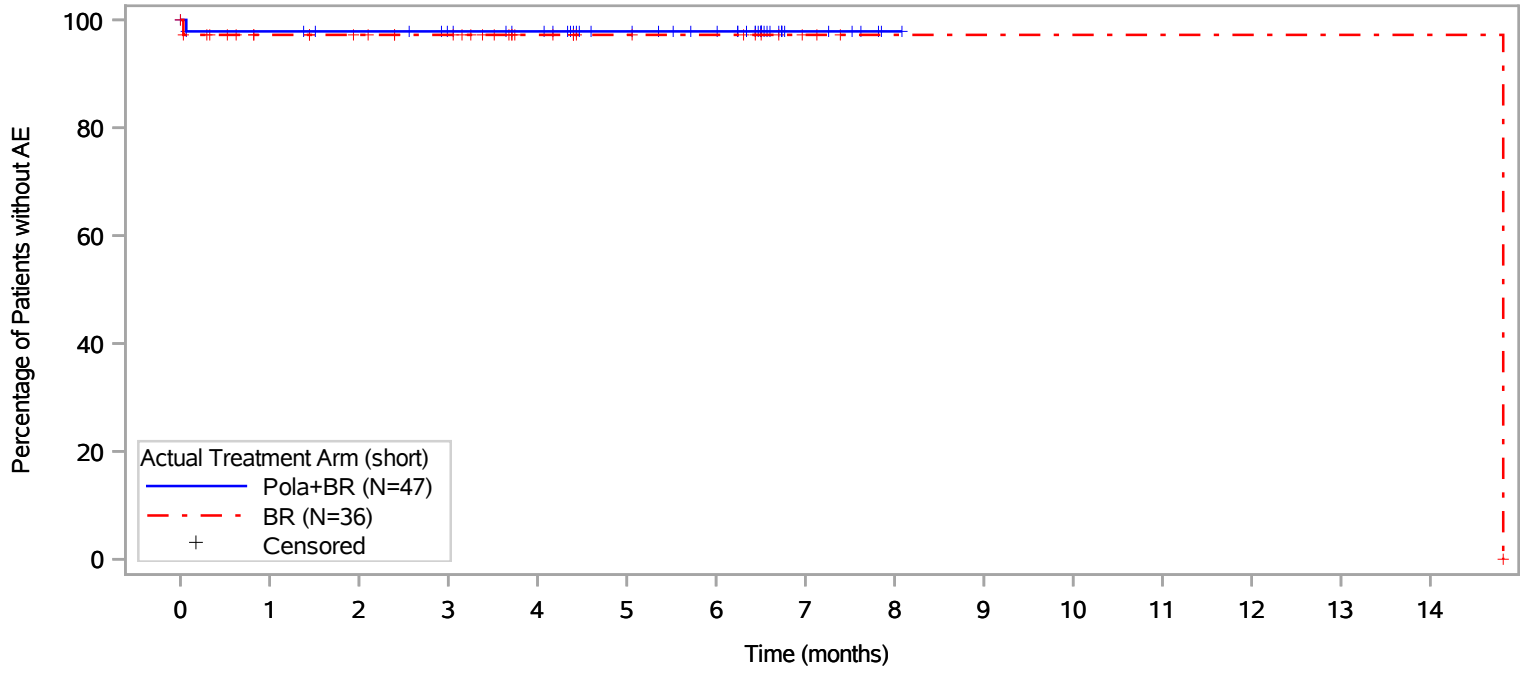
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk															
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1	NE	NE	NE	NE	NE	NE
BR (N=36)	36	29	26	23	14	9	8	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	27	32	34	34	34	34	34	34	34

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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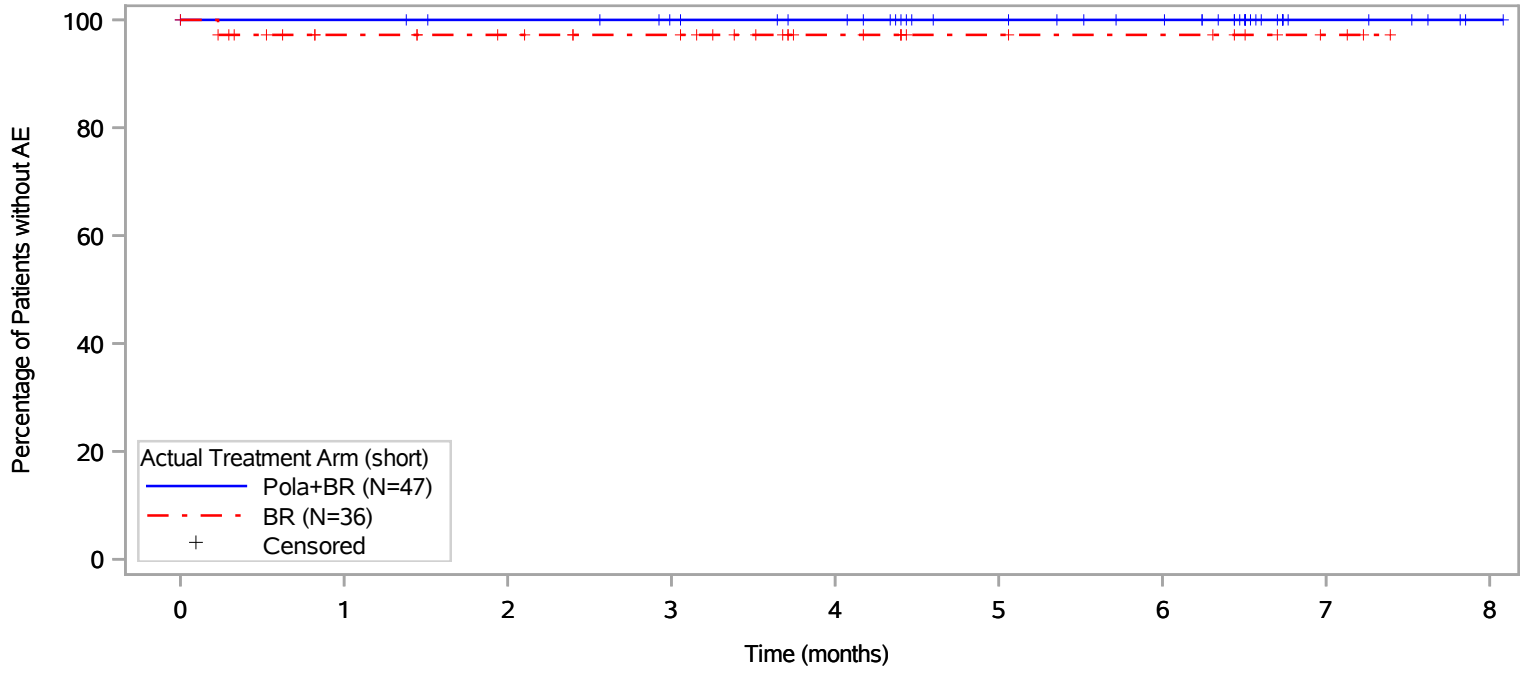
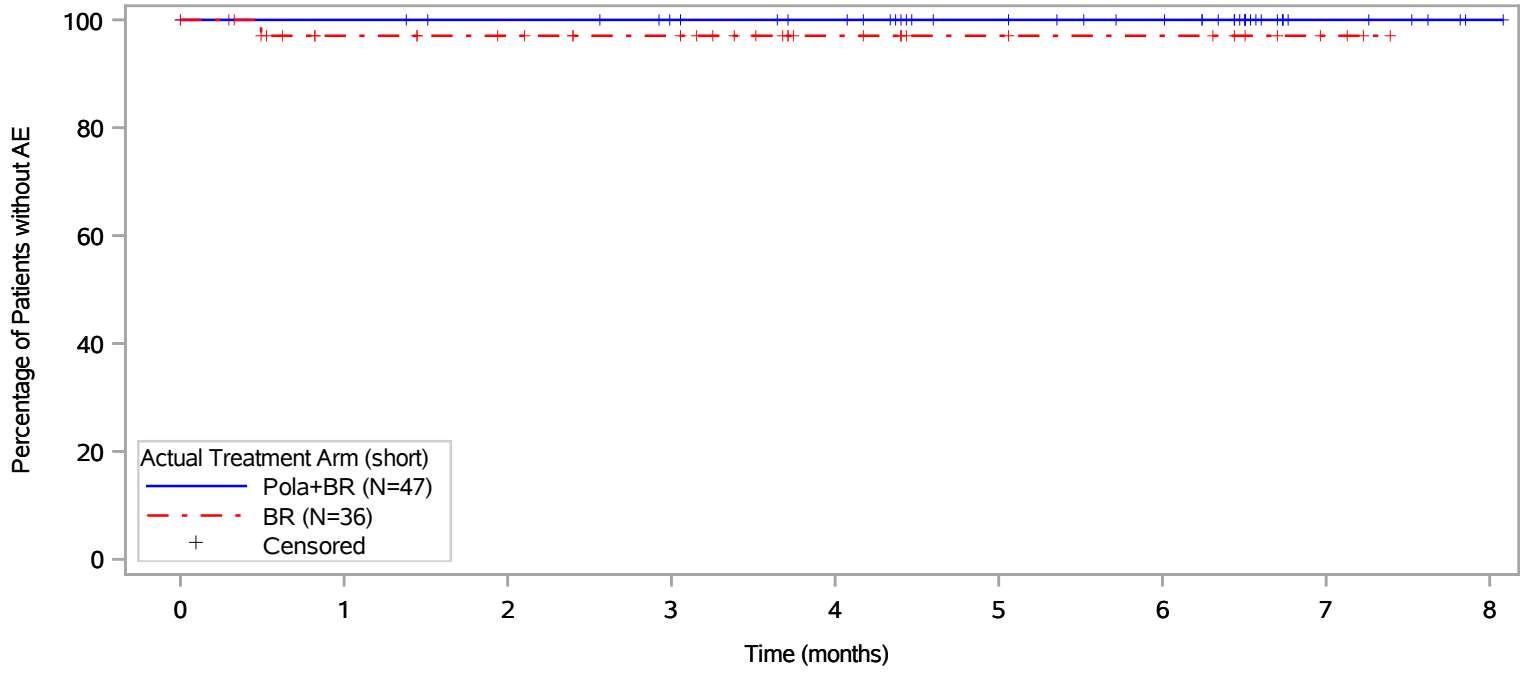
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

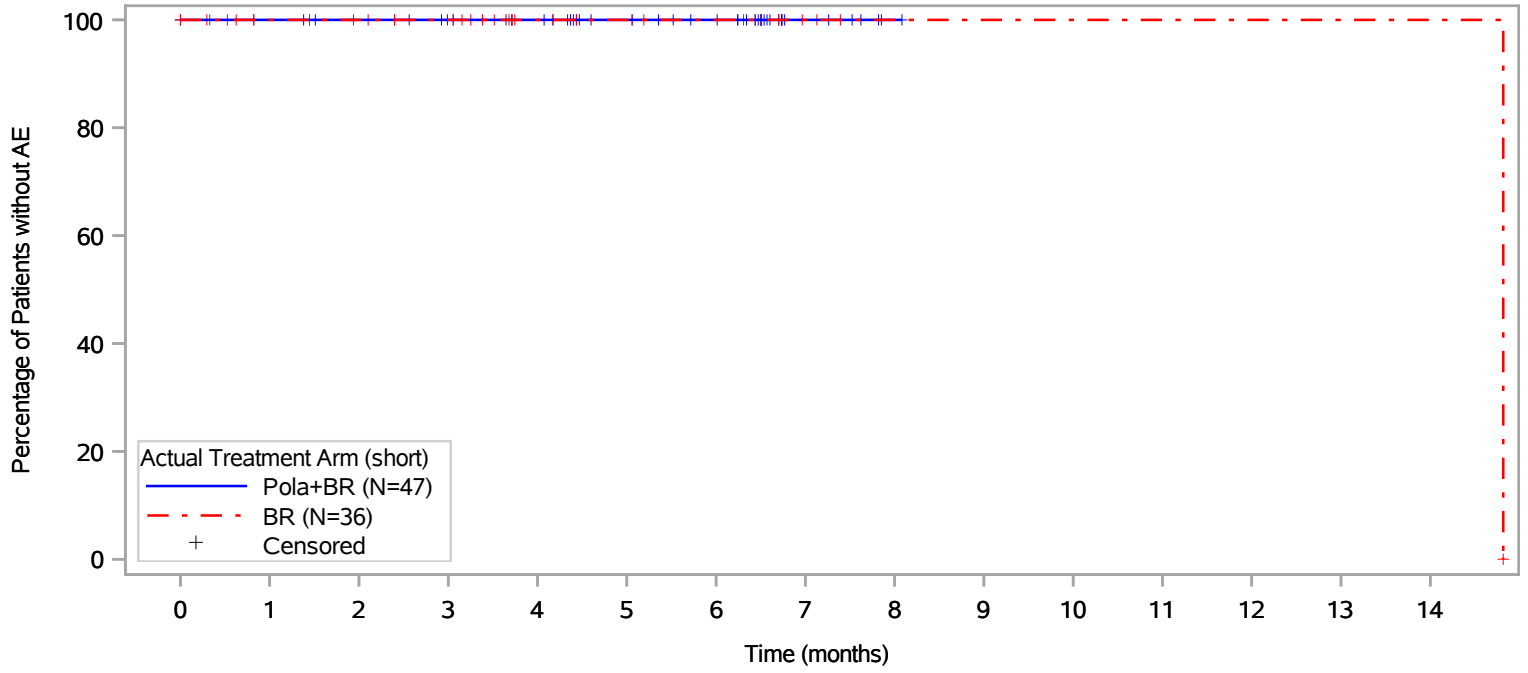
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FLUTTER



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

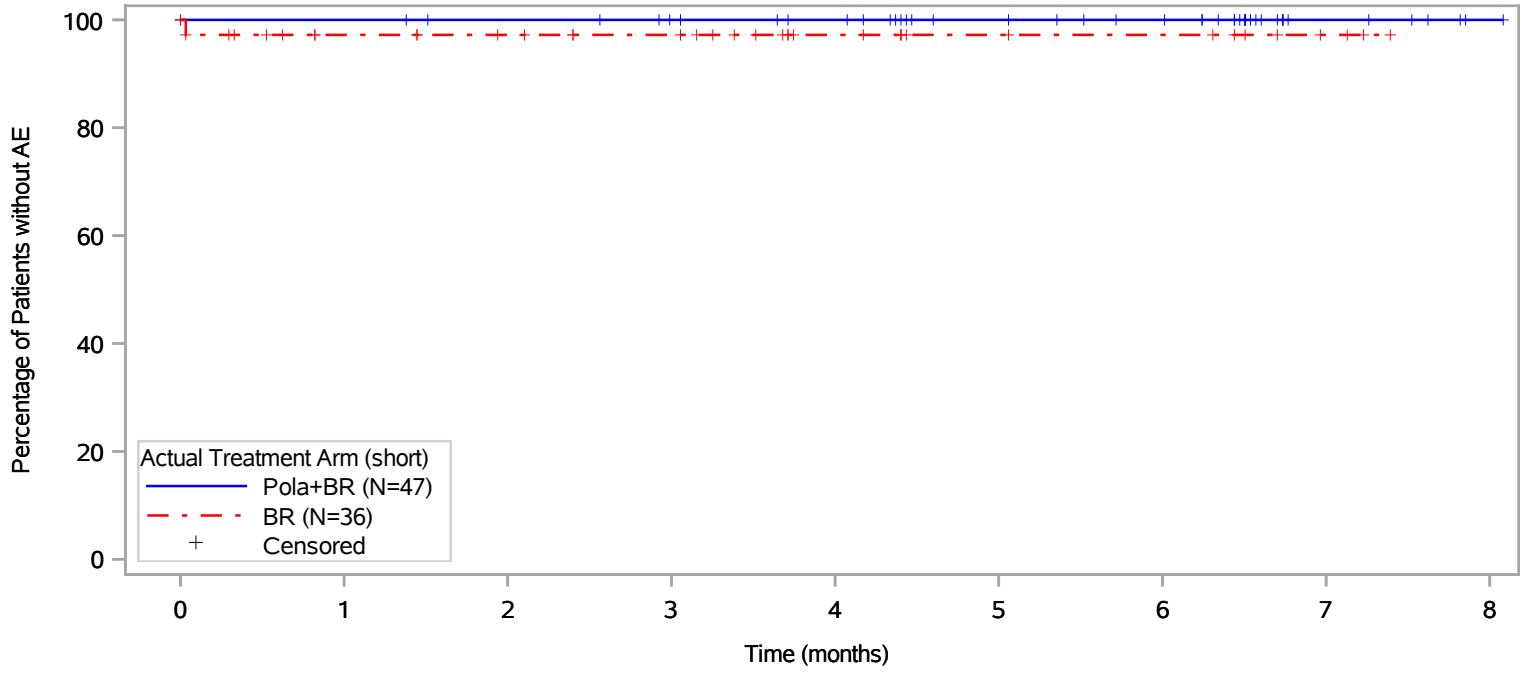
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, CARDIAC FAILURE



Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	33	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SUPRAVENTRICULAR TACHYCARDIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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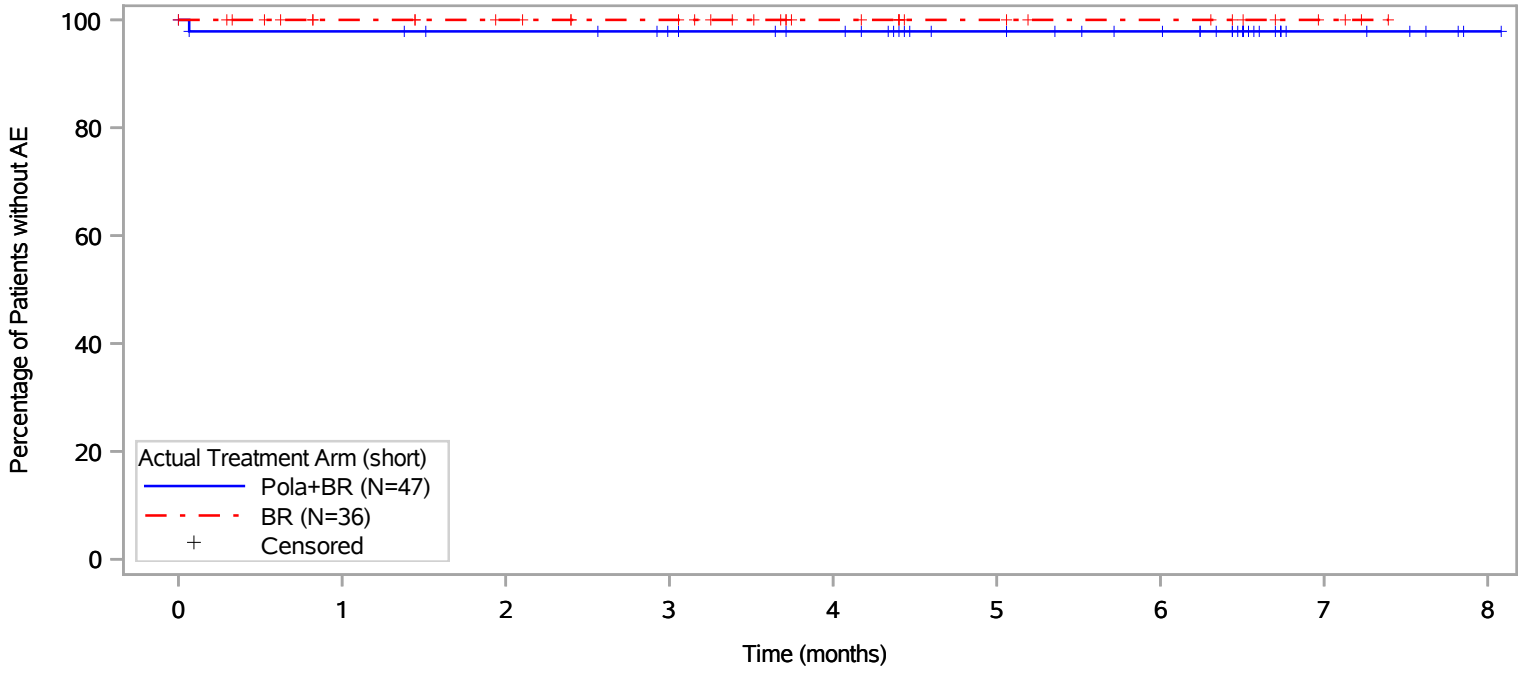
02DEC2022 6:23

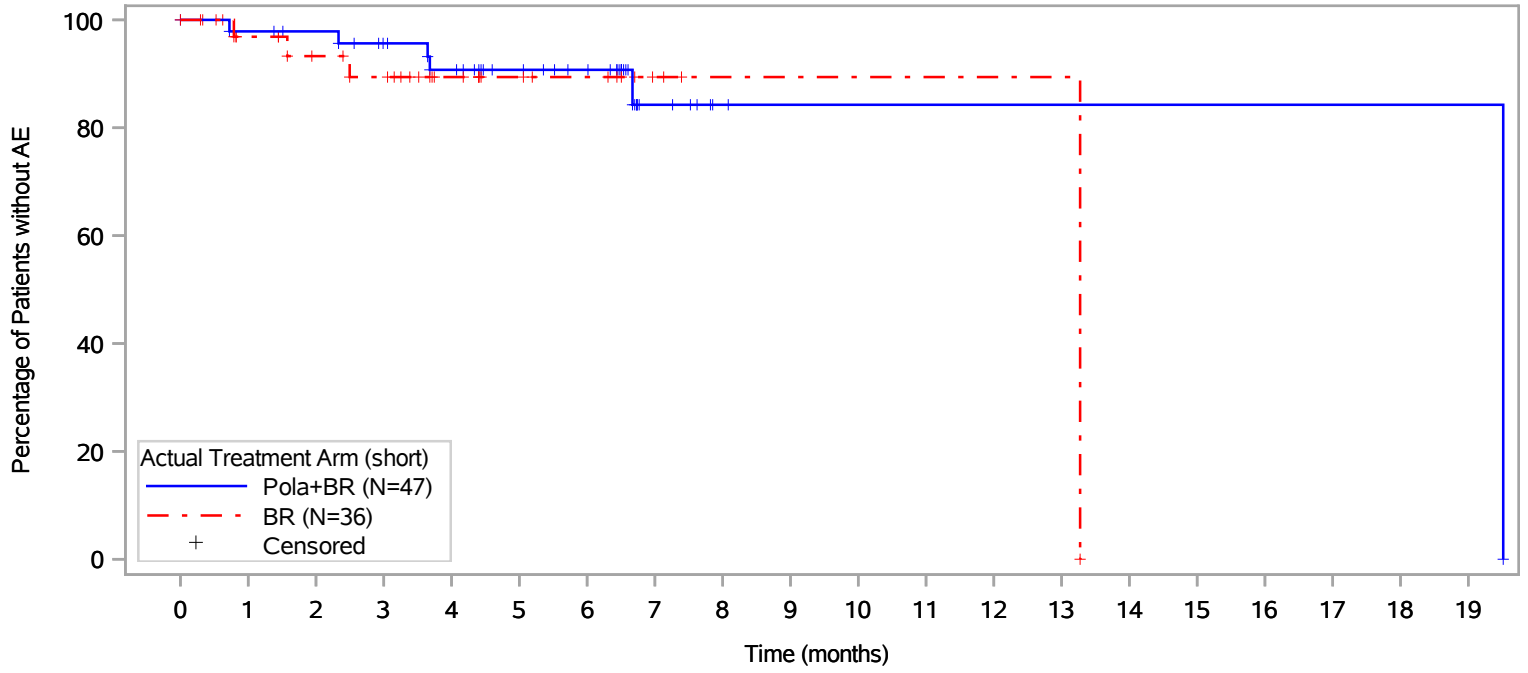
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

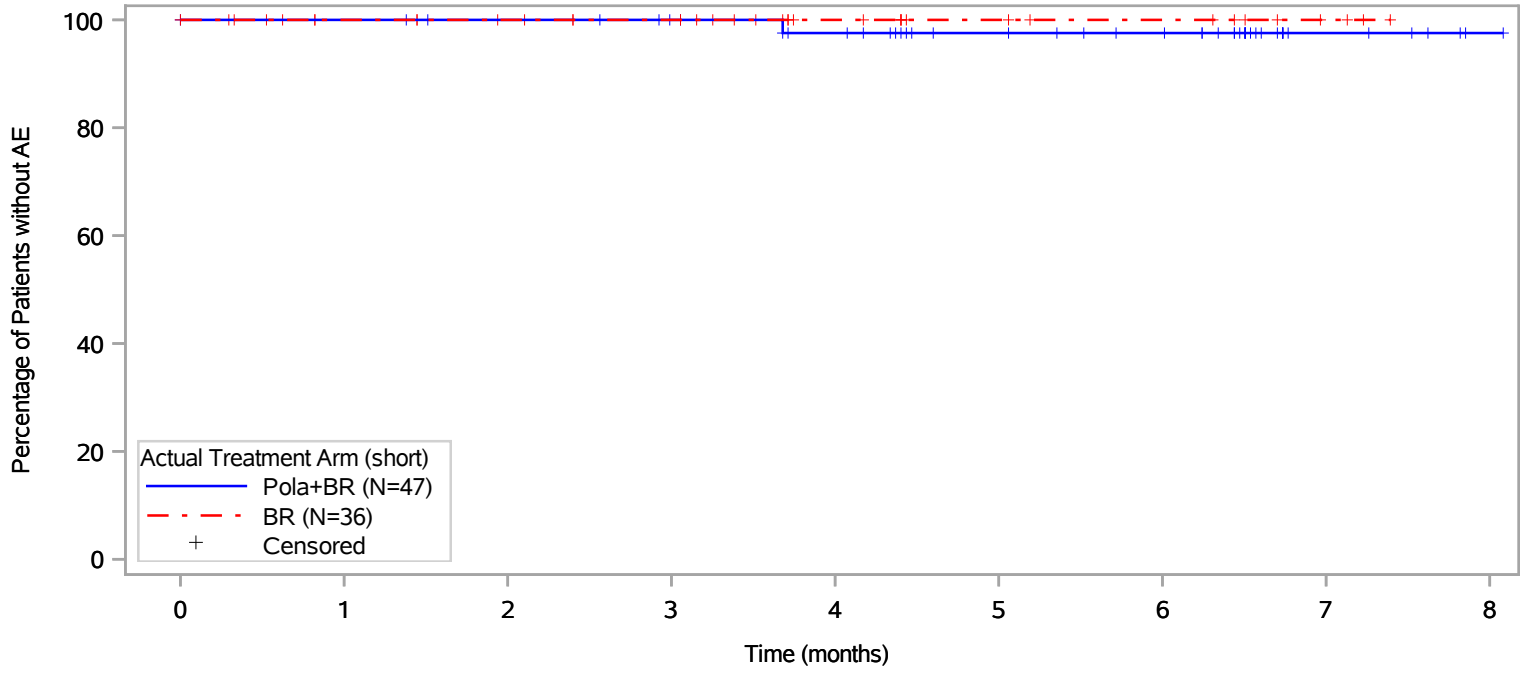
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk																				
Pola+BR (N=47)	47	46	44	40	37	30	26	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	29	25	23	15	10	8	3	1	1	1	1	1	1	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	6	13	17	35	40	41	41	41	41	41	41	41	41	41	41	41
BR (N=36)	0	6	9	10	18	23	25	30	32	32	32	32	32	32	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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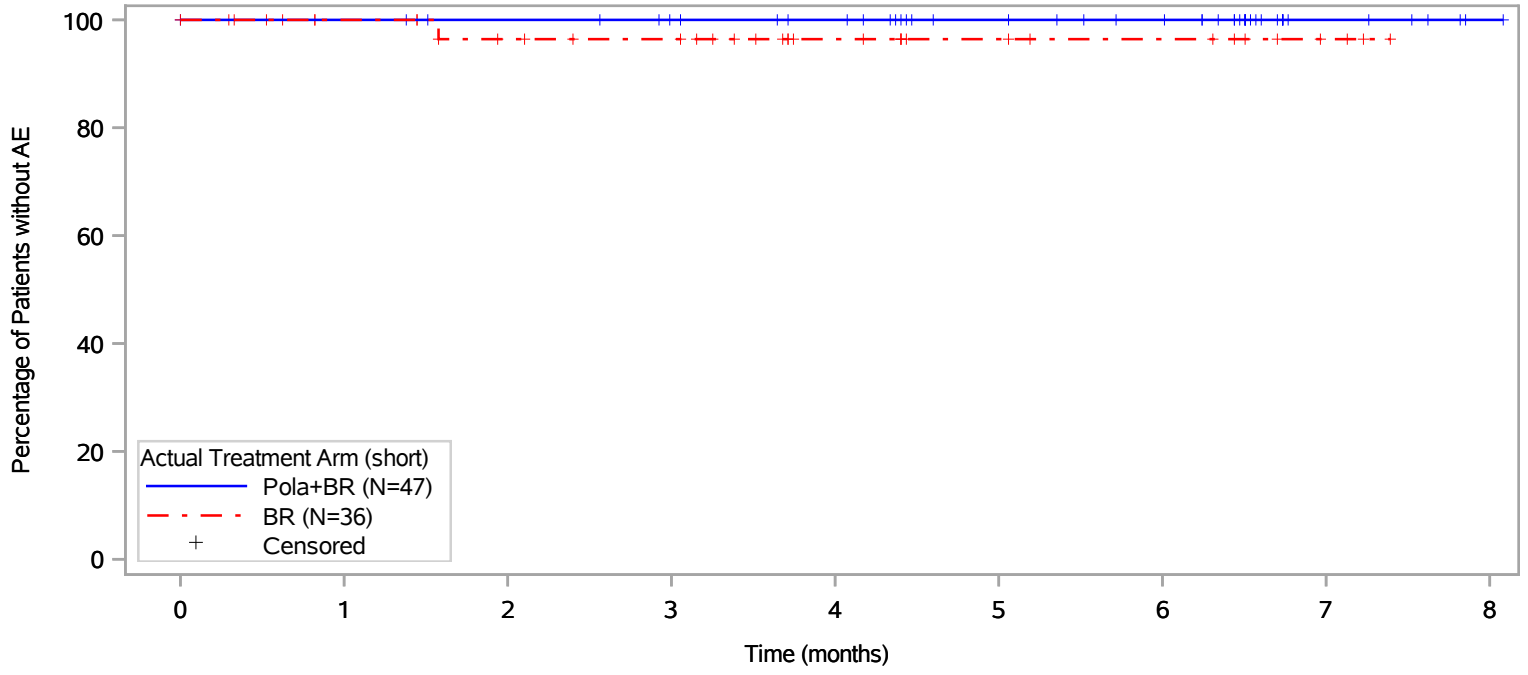
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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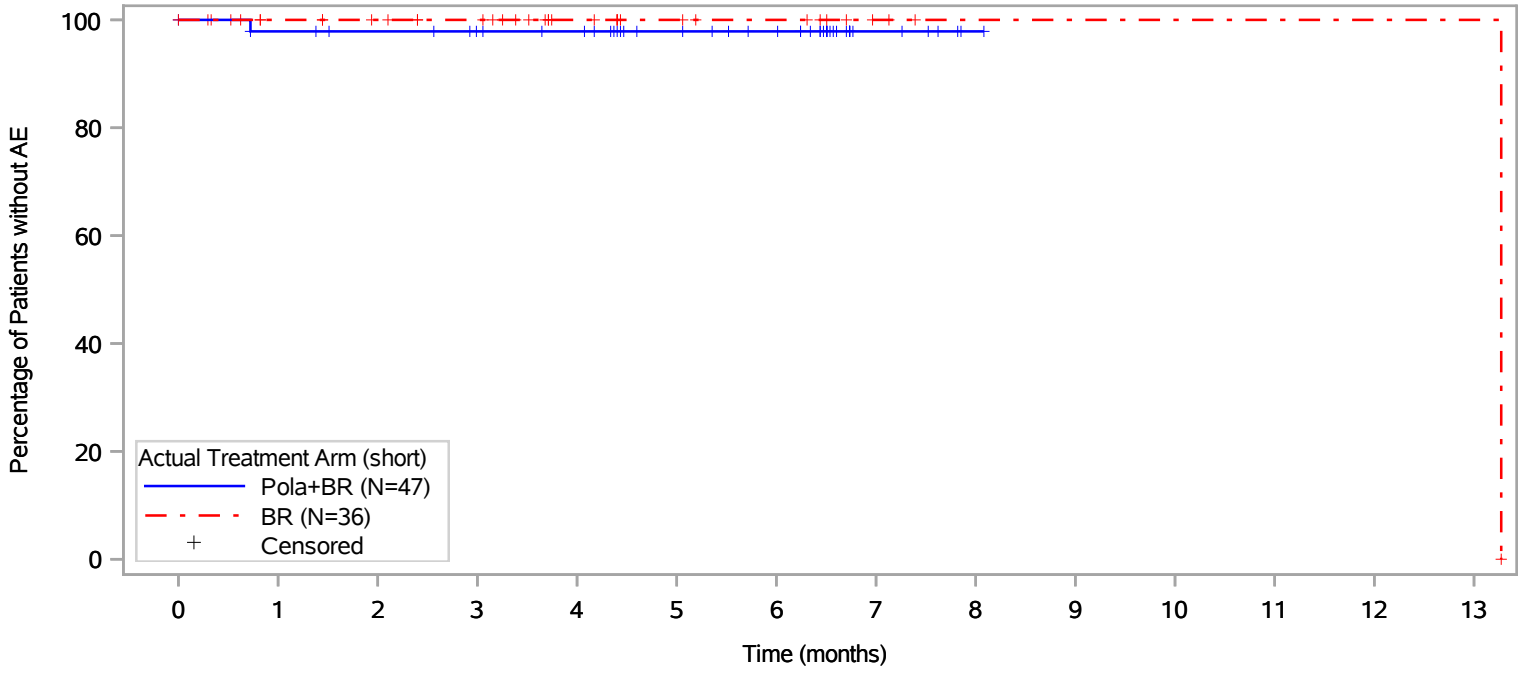
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



Patients at risk														
Pola+BR (N=47)	47	46	44	41	39	31	27	6	1	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	3	1	1	1	1	1	1
Patients censored														
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	33	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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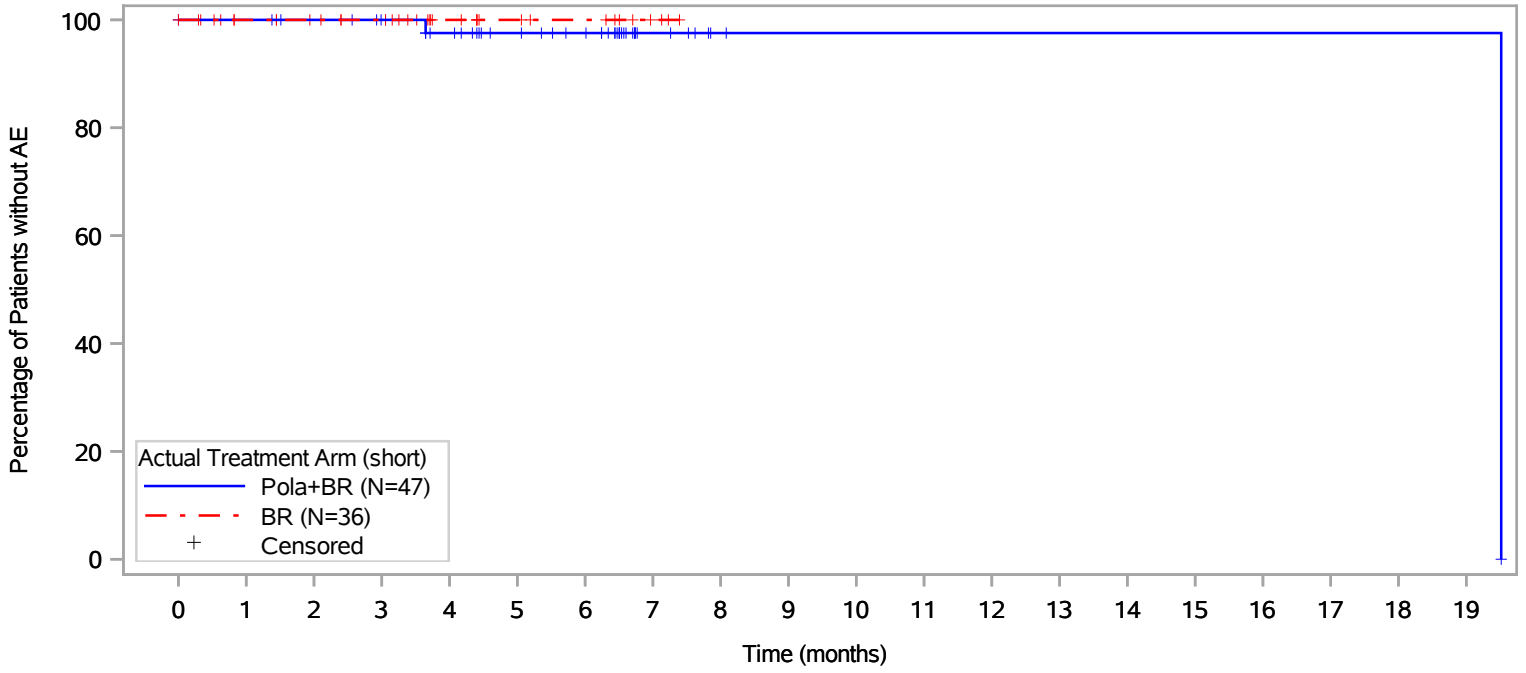
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

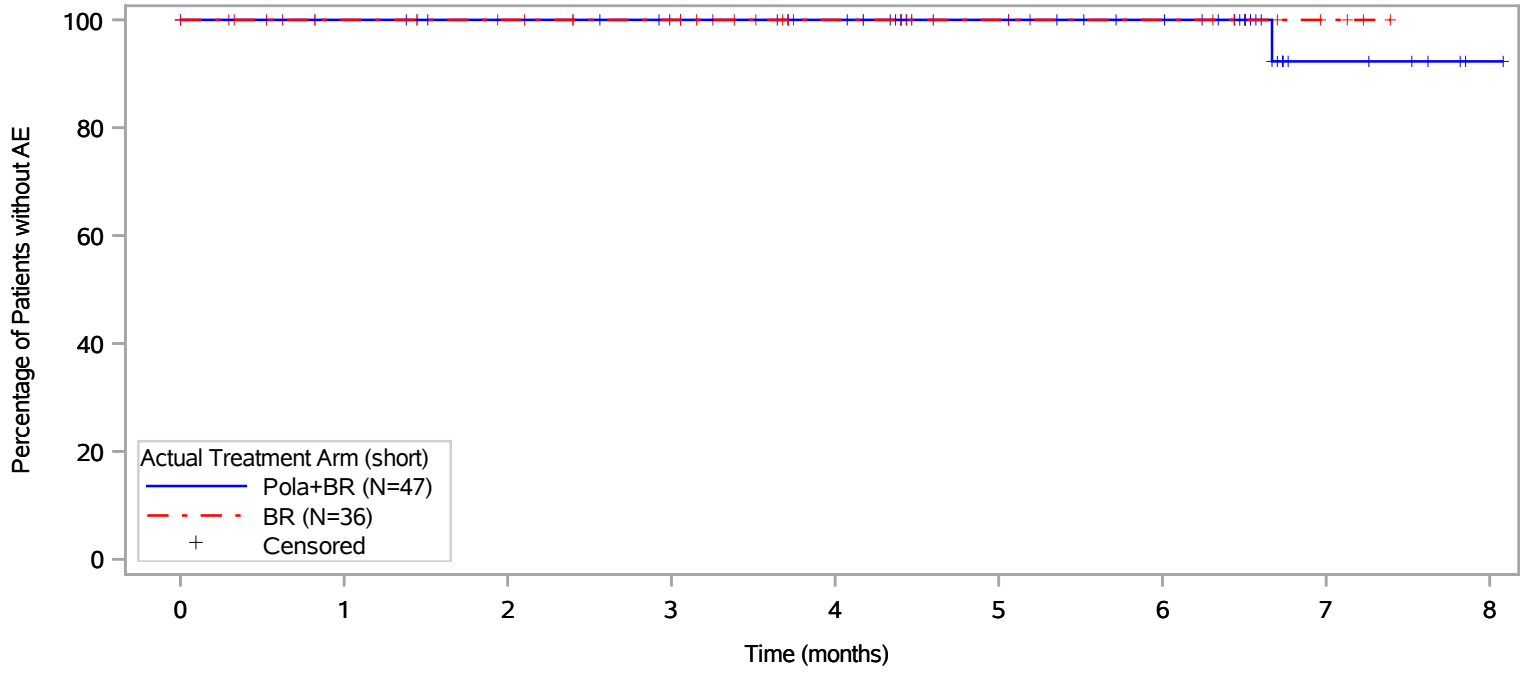
GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk																				
Pola+BR (N=47)	47	47	45	42	38	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	8	15	19	39	44	45	45	45	45	45	45	45	45	45	45	45
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

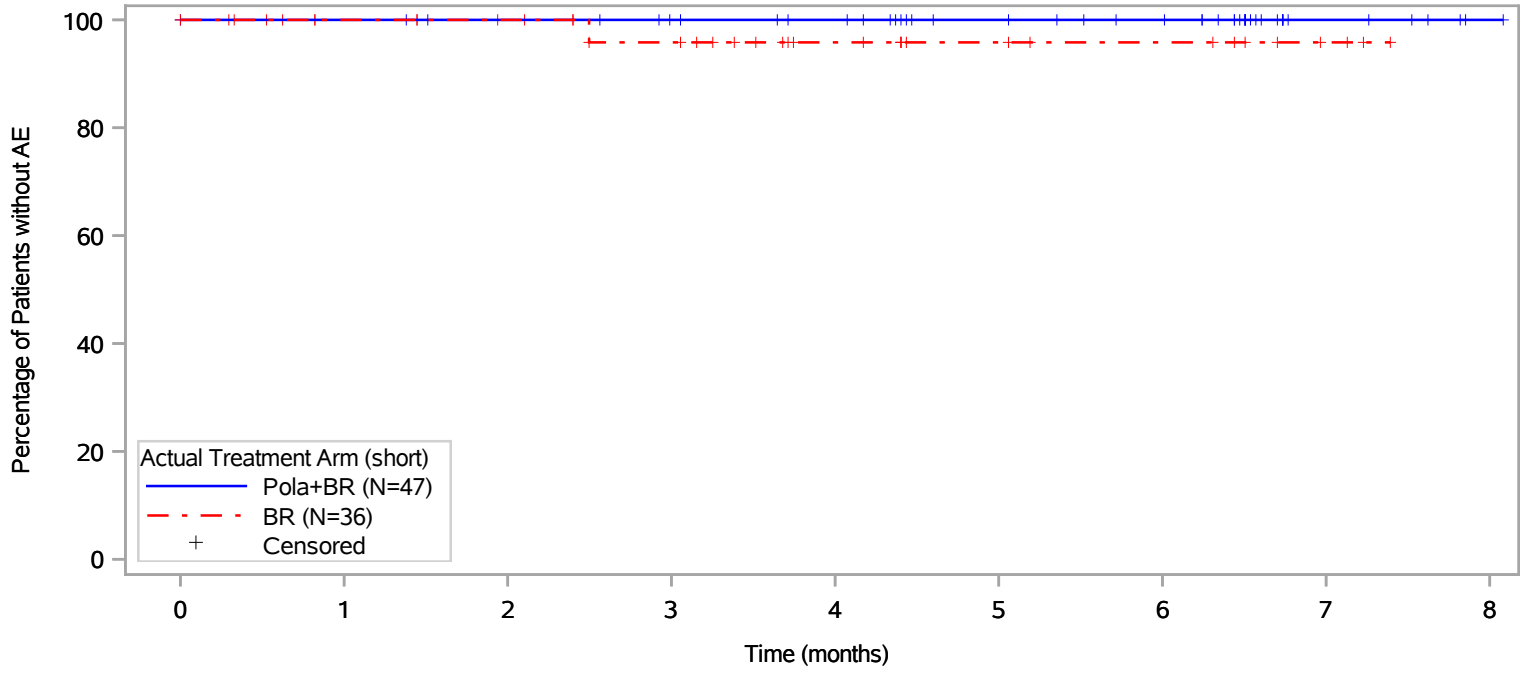
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, OBSTRUCTION GASTRIC



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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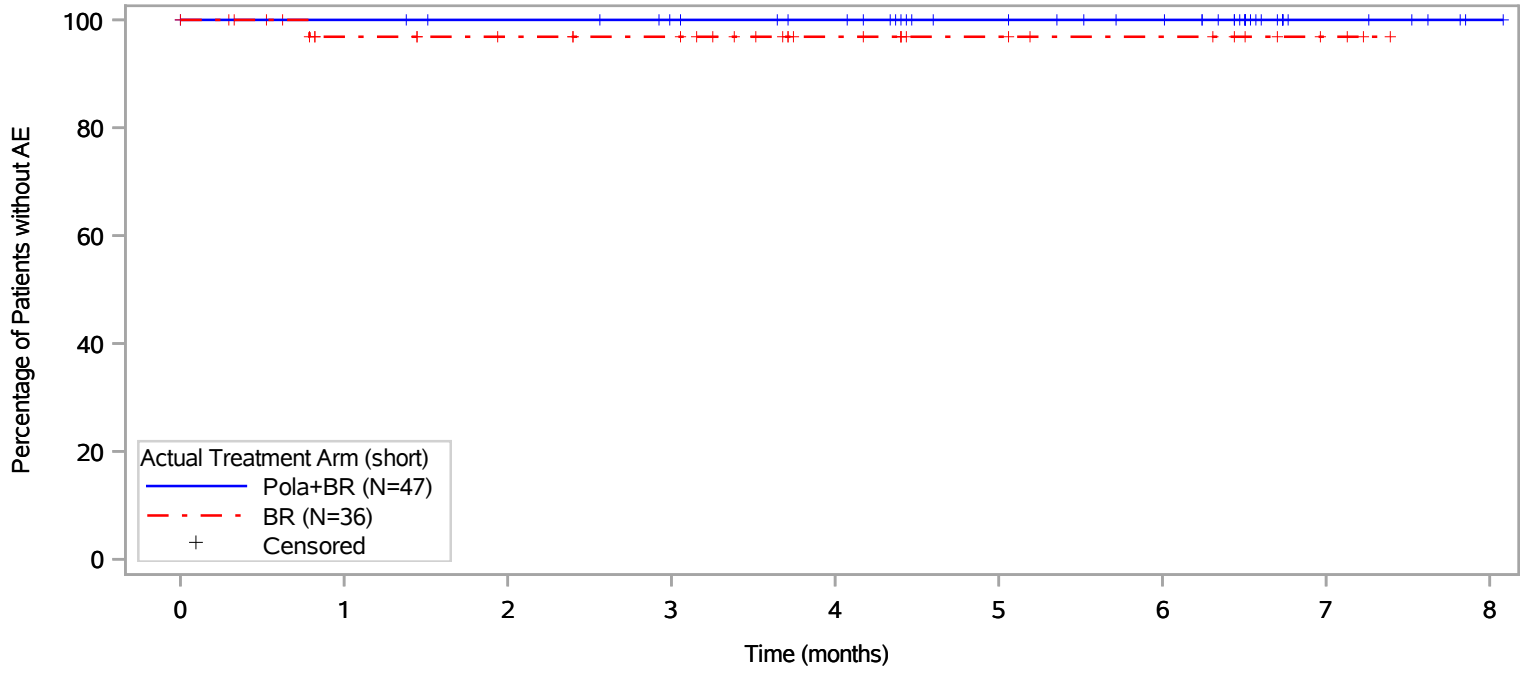
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, UPPER GASTROINTESTINAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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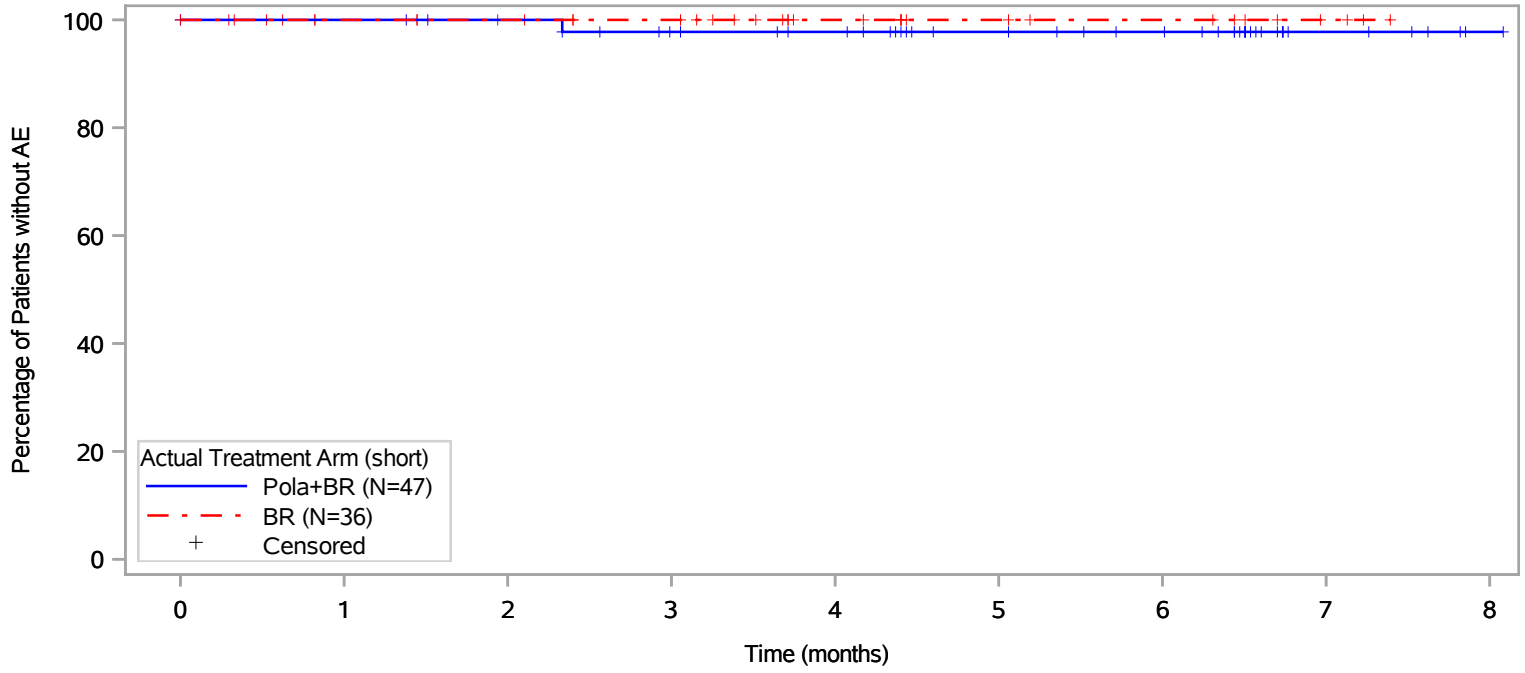
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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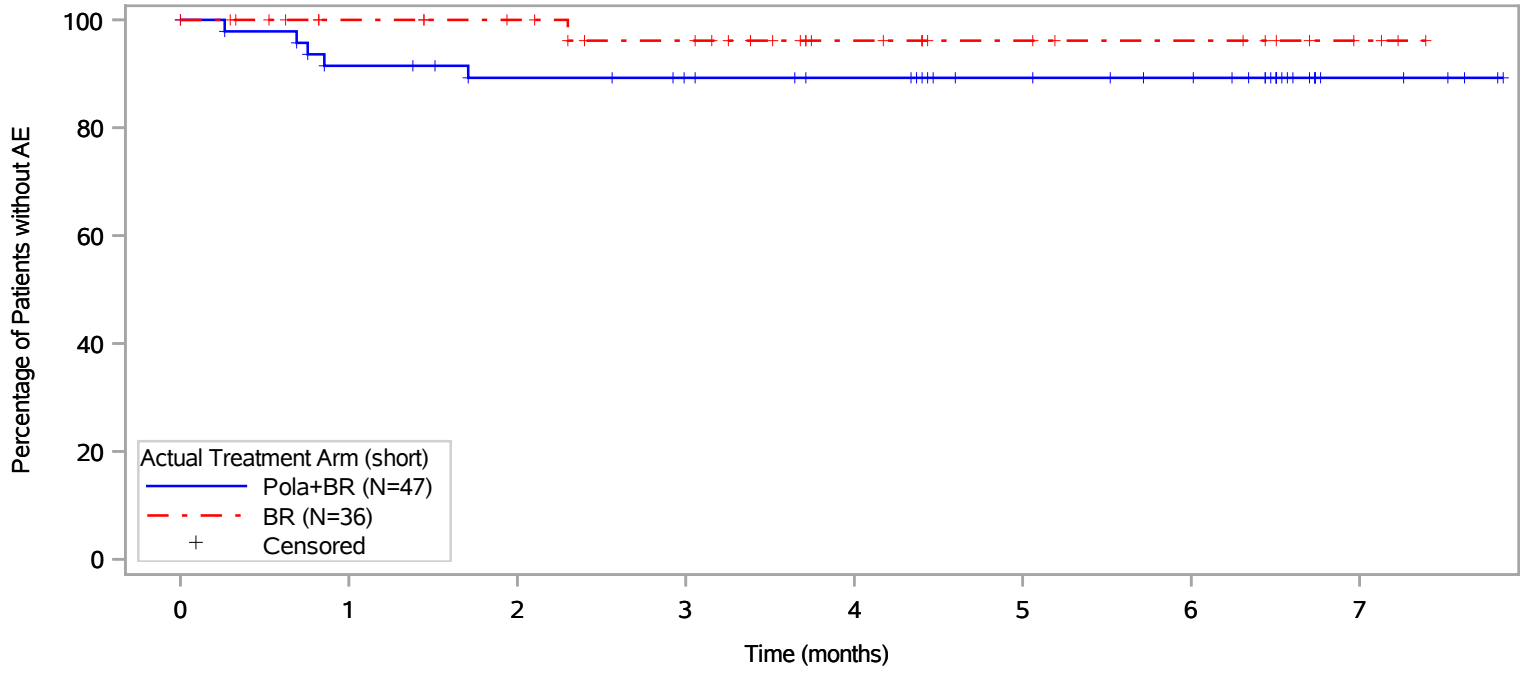
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All

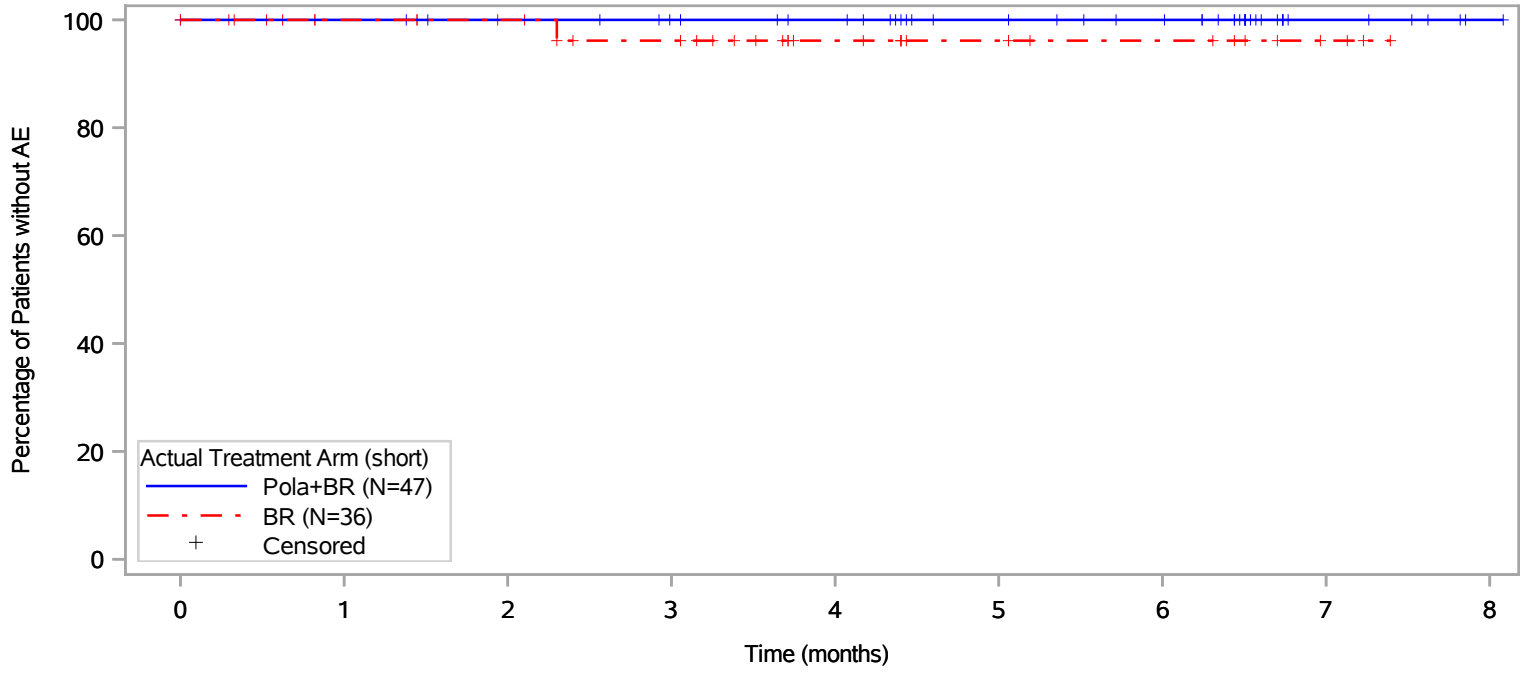


Patients at risk								
Pola+BR (N=47)	47	43	40	37	34	28	25	5
BR (N=36)	36	30	27	24	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	14	17	37
BR (N=36)	0	6	9	11	20	25	27	32

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME

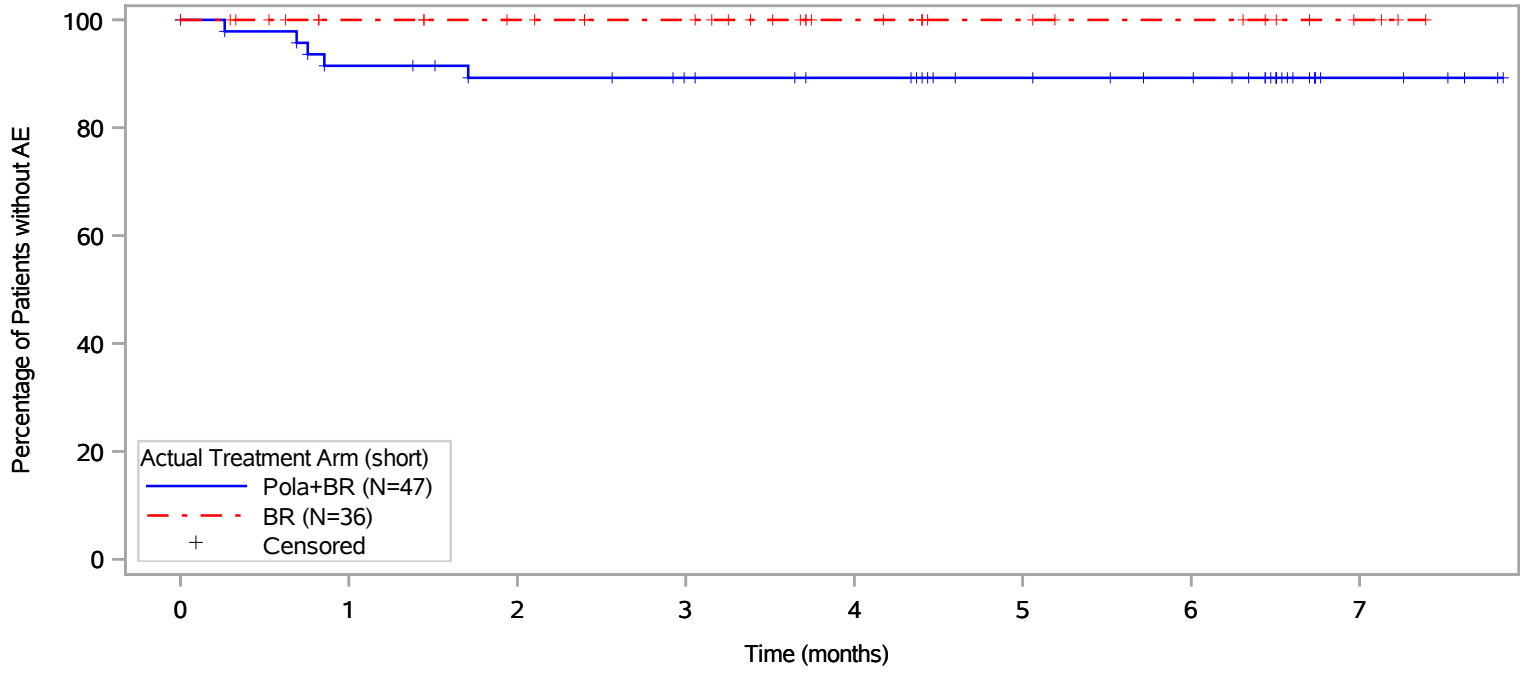


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

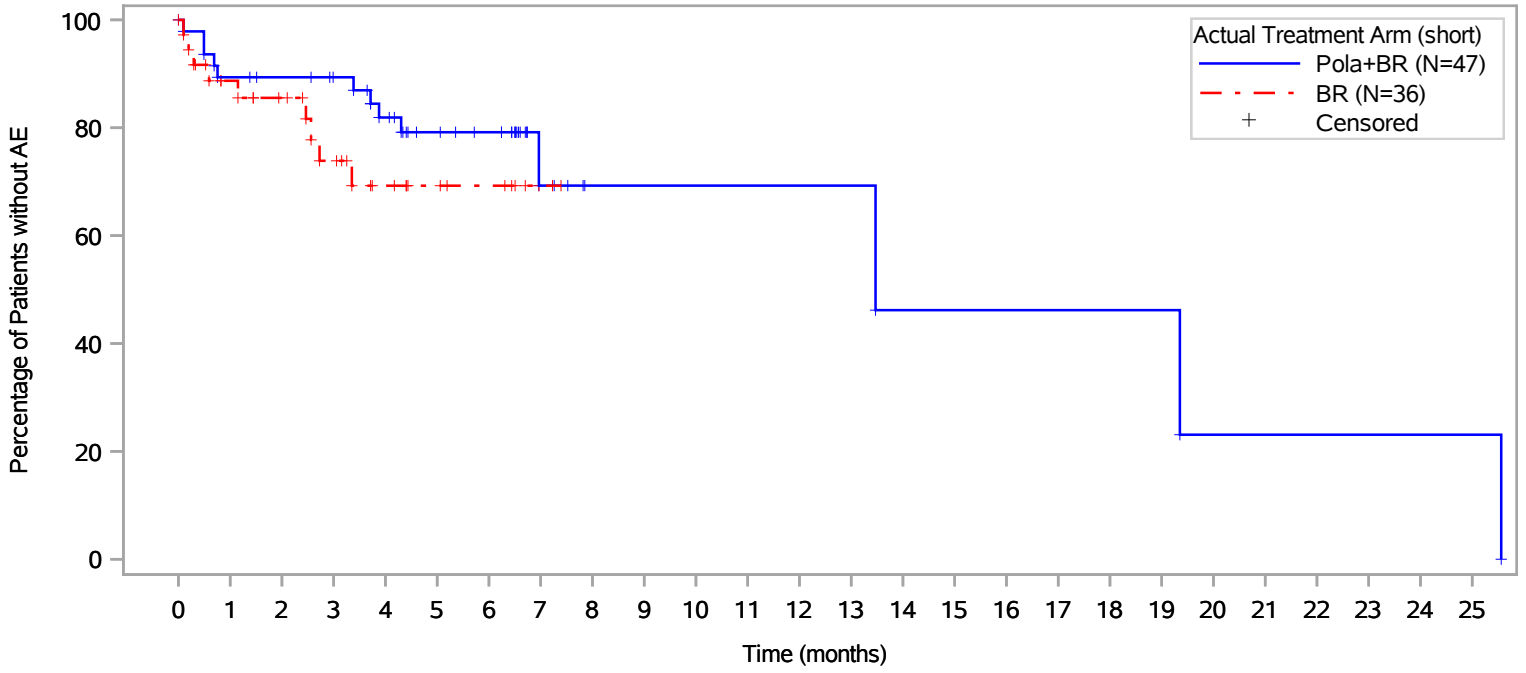
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk								
Pola+BR (N=47)	47	43	40	37	34	28	25	5
BR (N=36)	36	30	27	24	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	14	17	37
BR (N=36)	0	6	9	12	21	26	28	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All

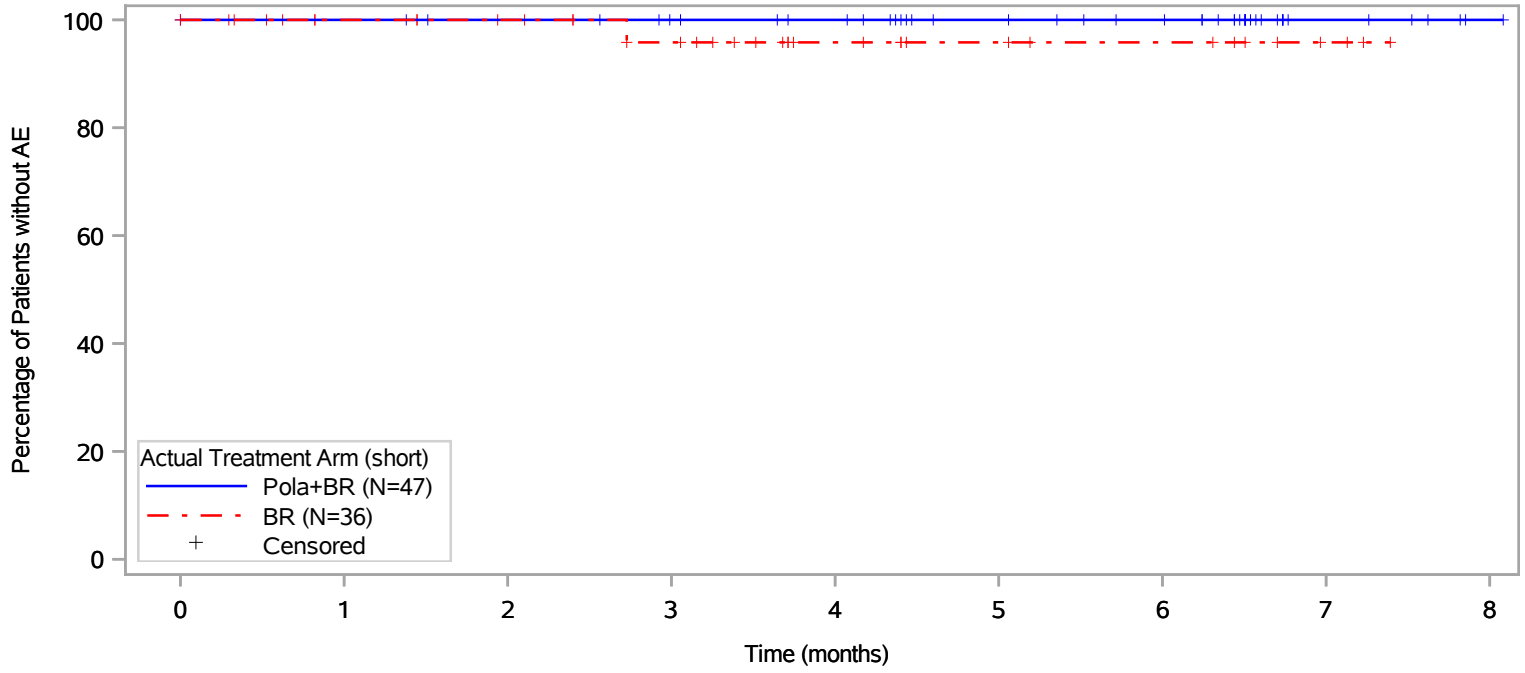


Patients at risk																										
Pola+BR (N=47)	47	42	40	37	32	25	22	7	3	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=36)	36	28	24	19	13	9	7	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	2	5	7	13	16	30	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34
BR (N=36)	0	4	7	9	14	18	20	25	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, CYTOMEGALOVIRUS INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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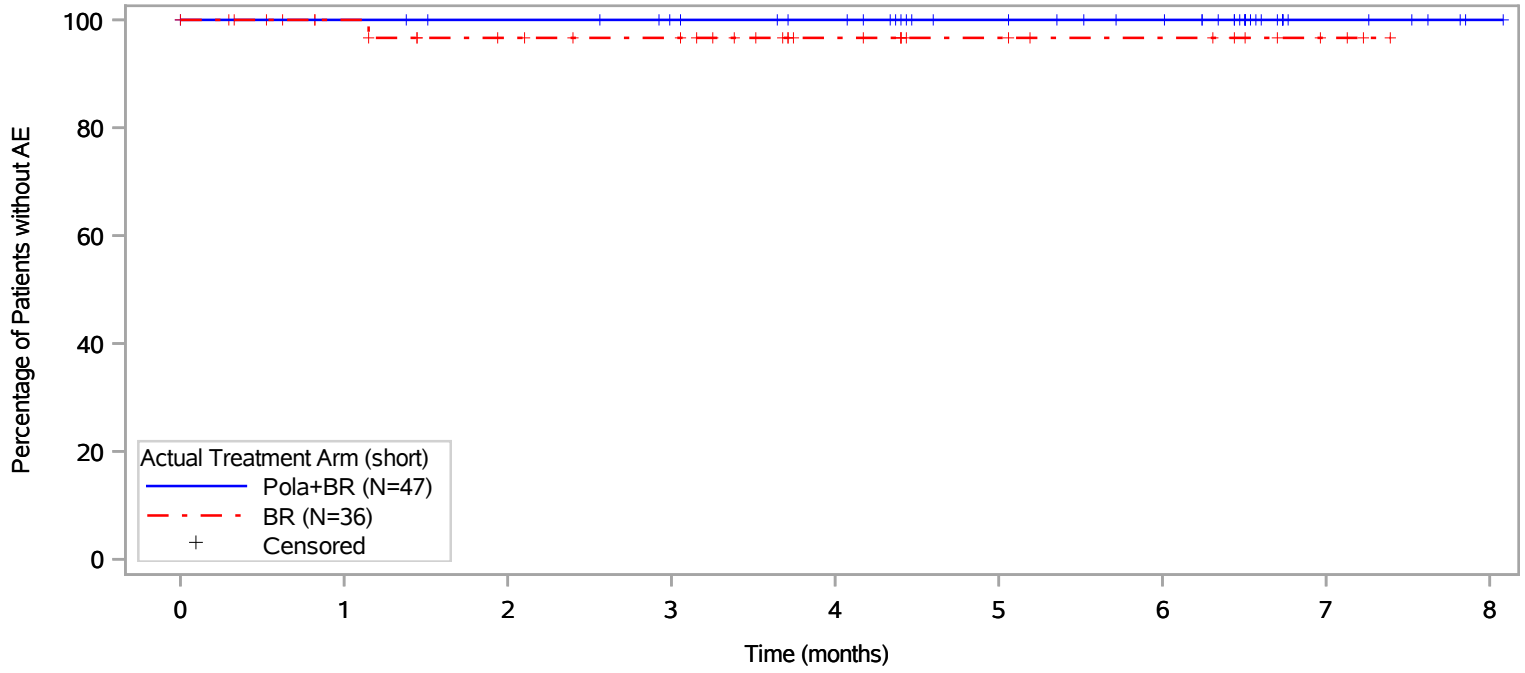
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, DEVICE RELATED INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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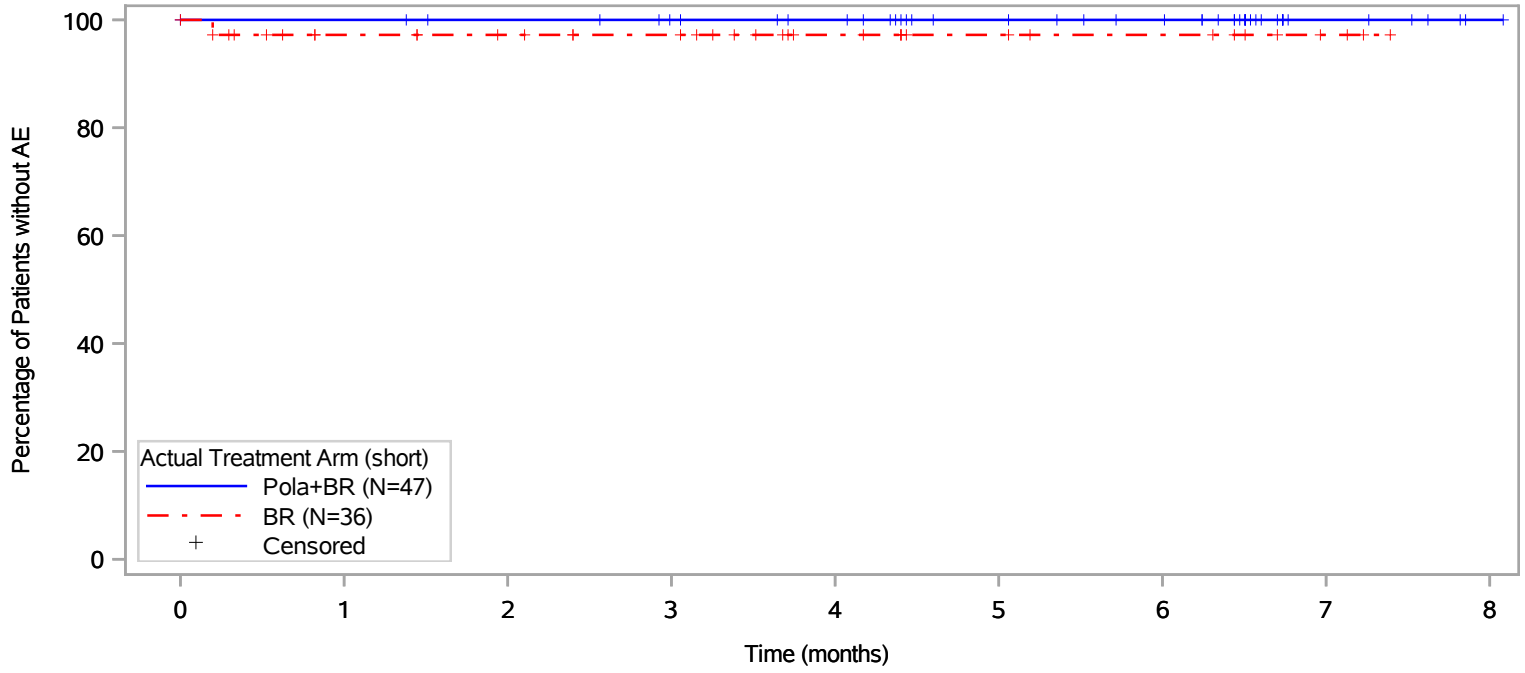
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ENTEROCOLITIS VIRAL



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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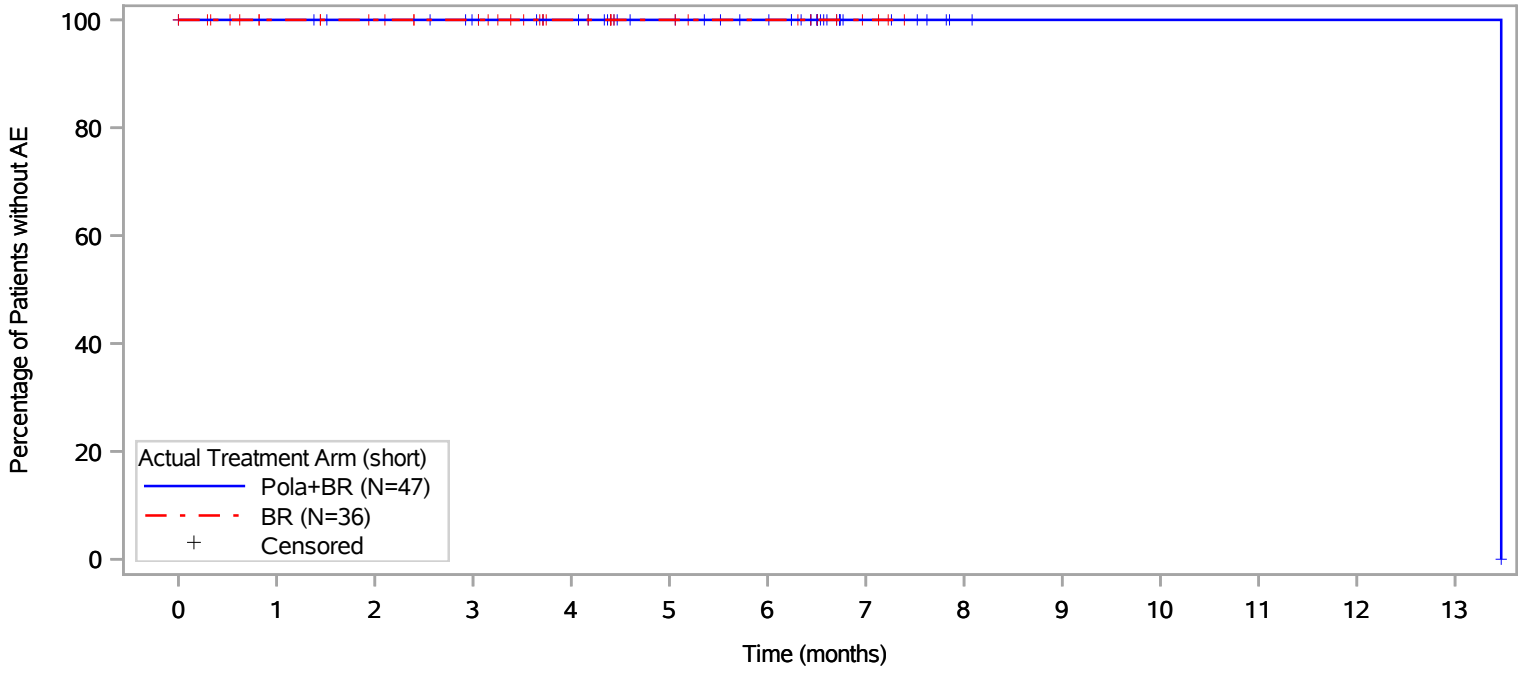
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

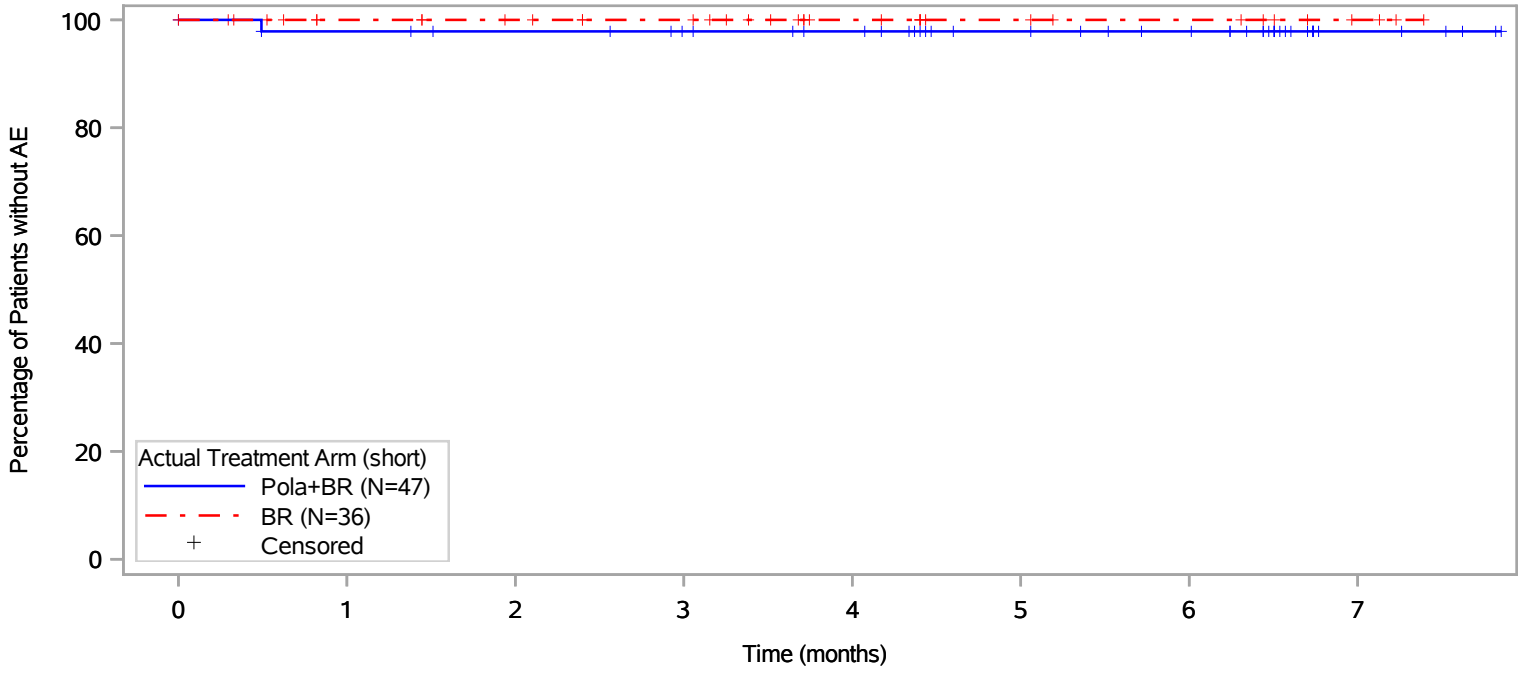
INFECTIONS AND INFESTATIONS, GASTROINTESTINAL BACTERIAL INFECTION



Patients at risk														
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HUMAN ANAPLASMOSIS



Patients at risk								
Pola+BR (N=47)	47	46	44	41	38	30	26	5
BR (N=36)	36	30	27	24	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	5	8	16	20	41
BR (N=36)	0	6	9	12	21	26	28	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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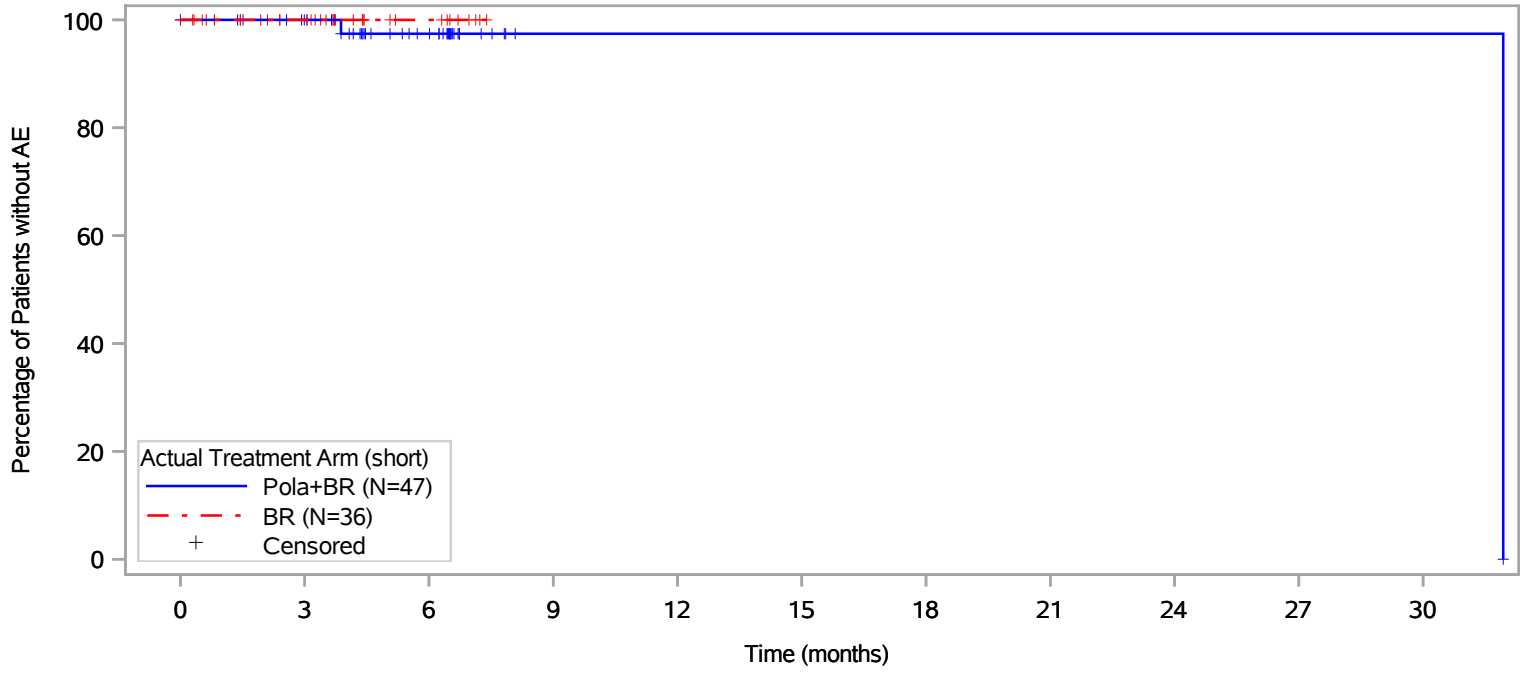
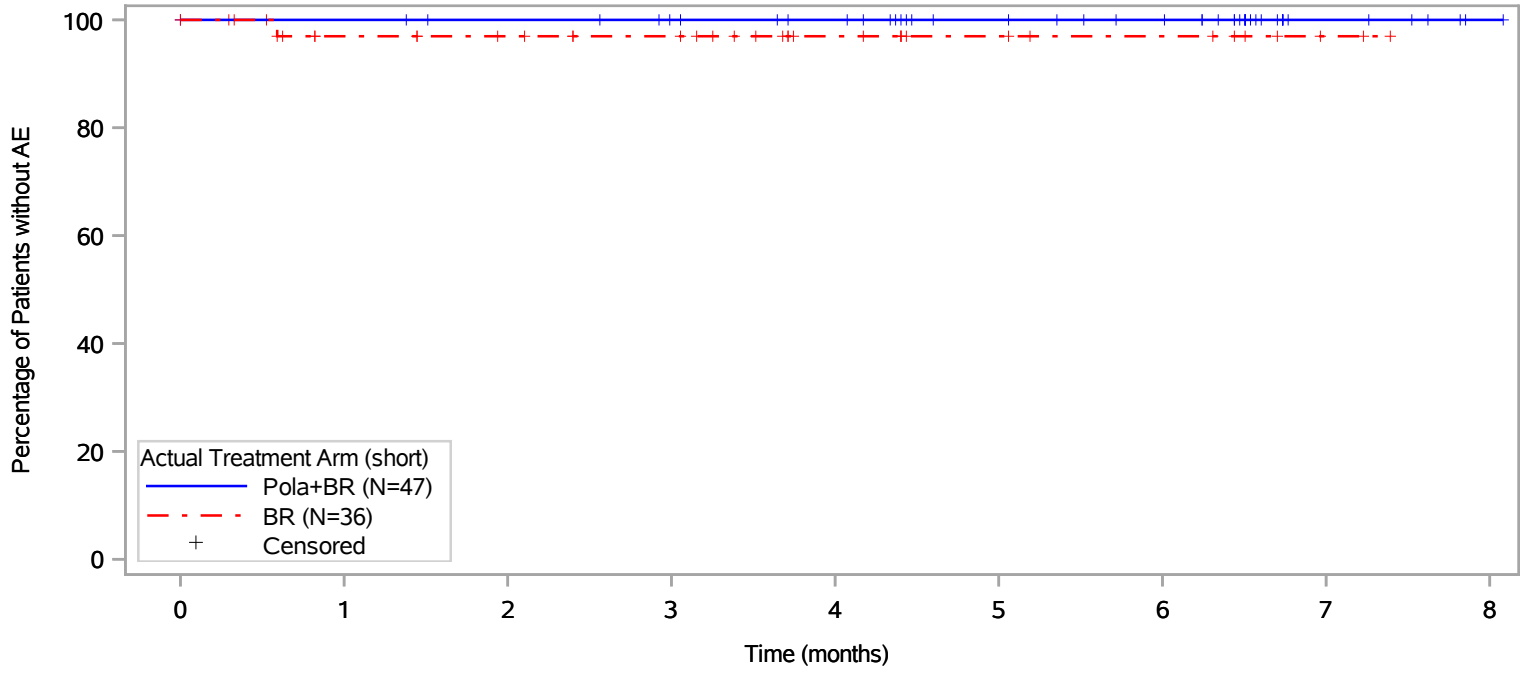
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk											
Pola+BR (N=47)	47	42	26	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	5	20	45	45	45	45	45	45	45	45
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, LOWER RESPIRATORY TRACT INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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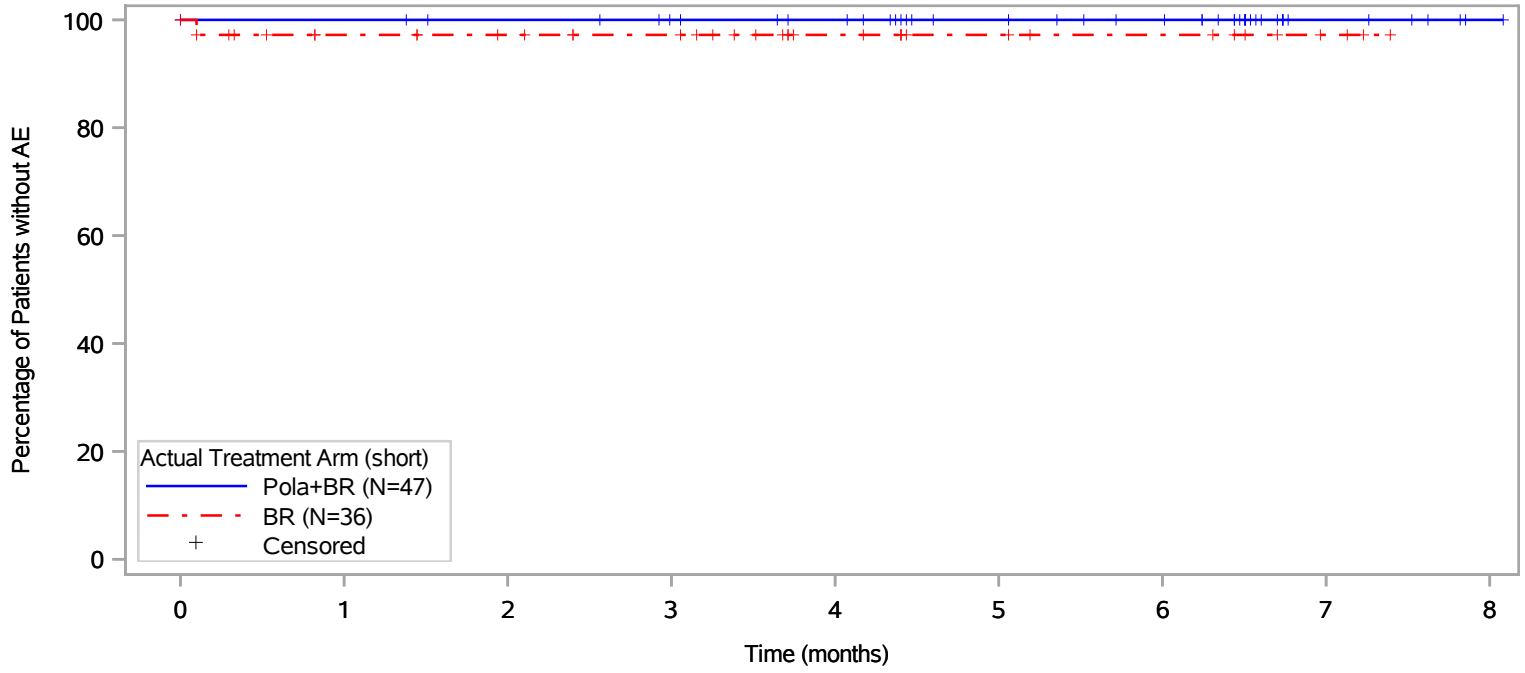
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NEUTROPENIC SEPSIS

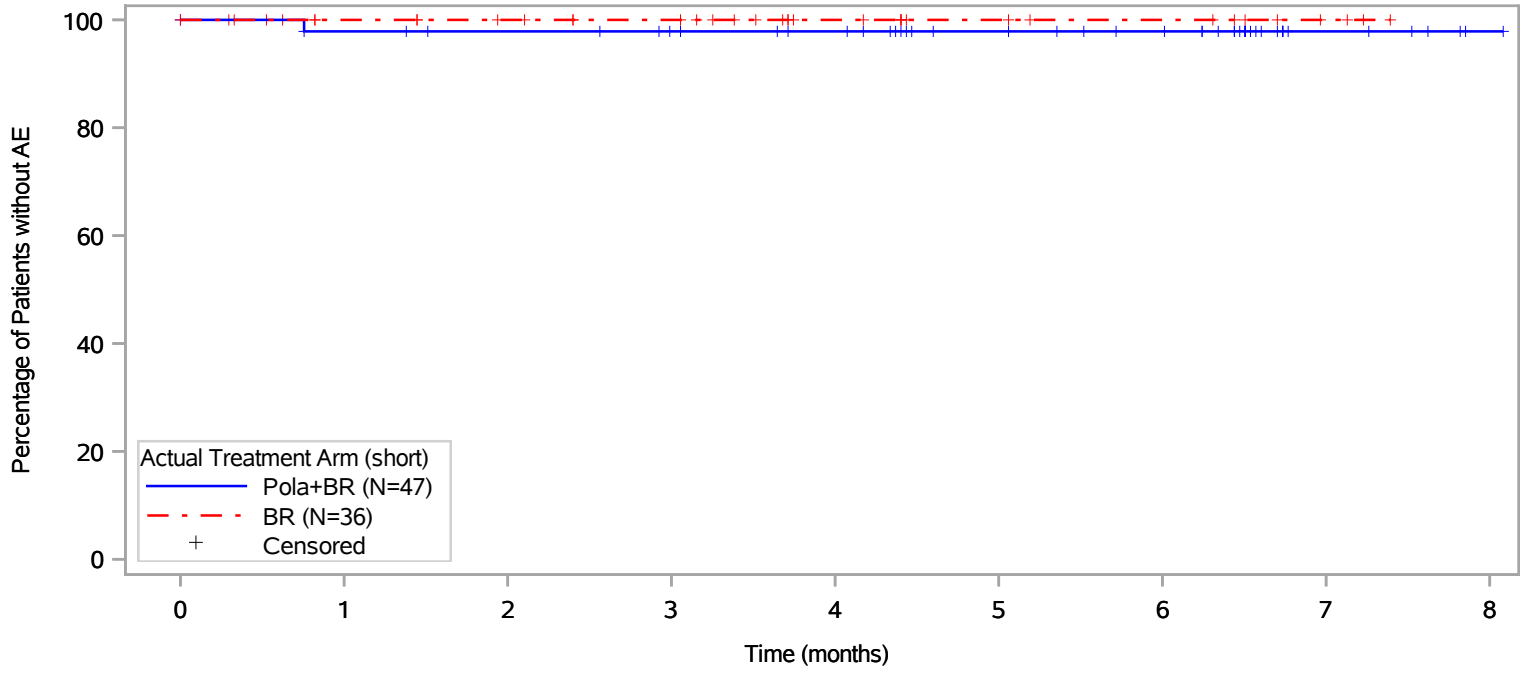


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	5	8	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

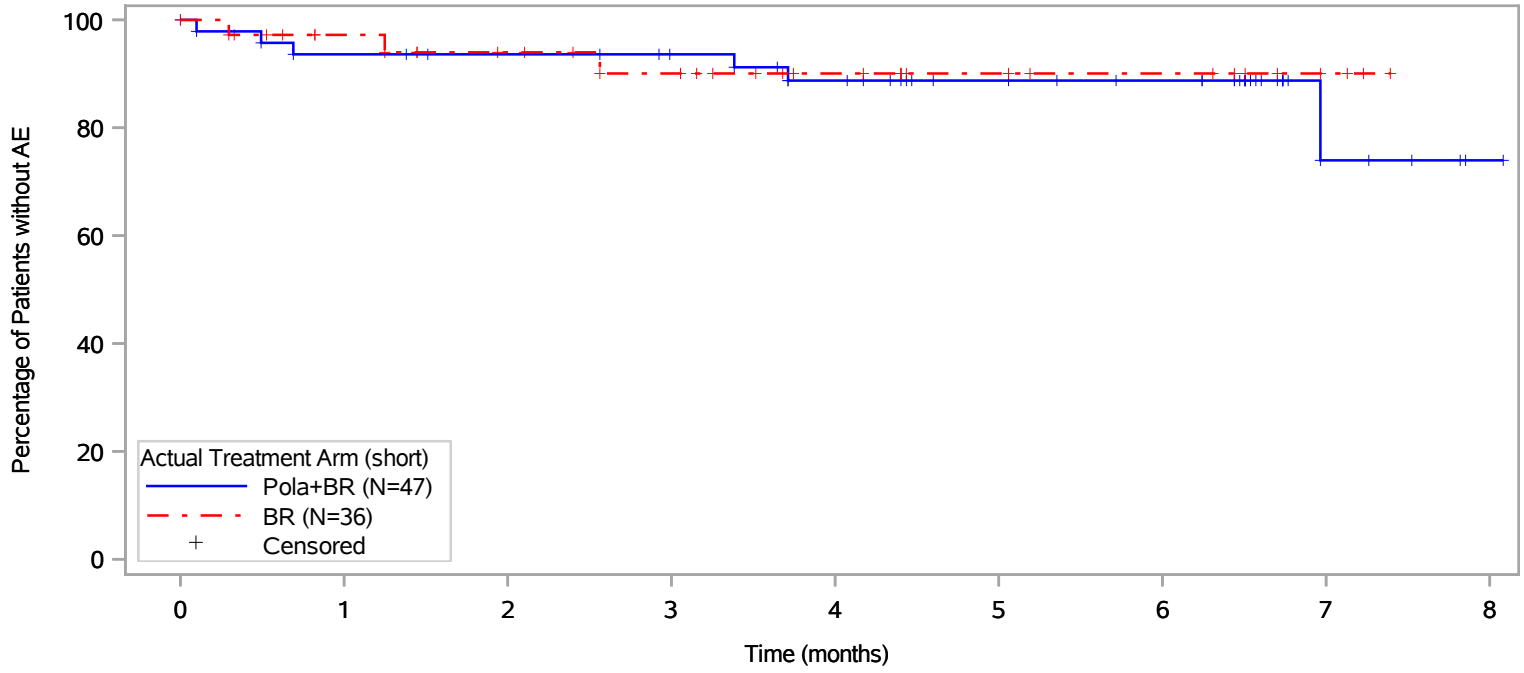
INFECTIONS AND INFESTATIONS, PNEUMOCYSTIS JIROVECII PNEUMONIA



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=47)	47	44	42	39	35	28	25	5	1
BR (N=36)	36	30	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	14	17	36	40
BR (N=36)	0	5	8	10	18	23	25	30	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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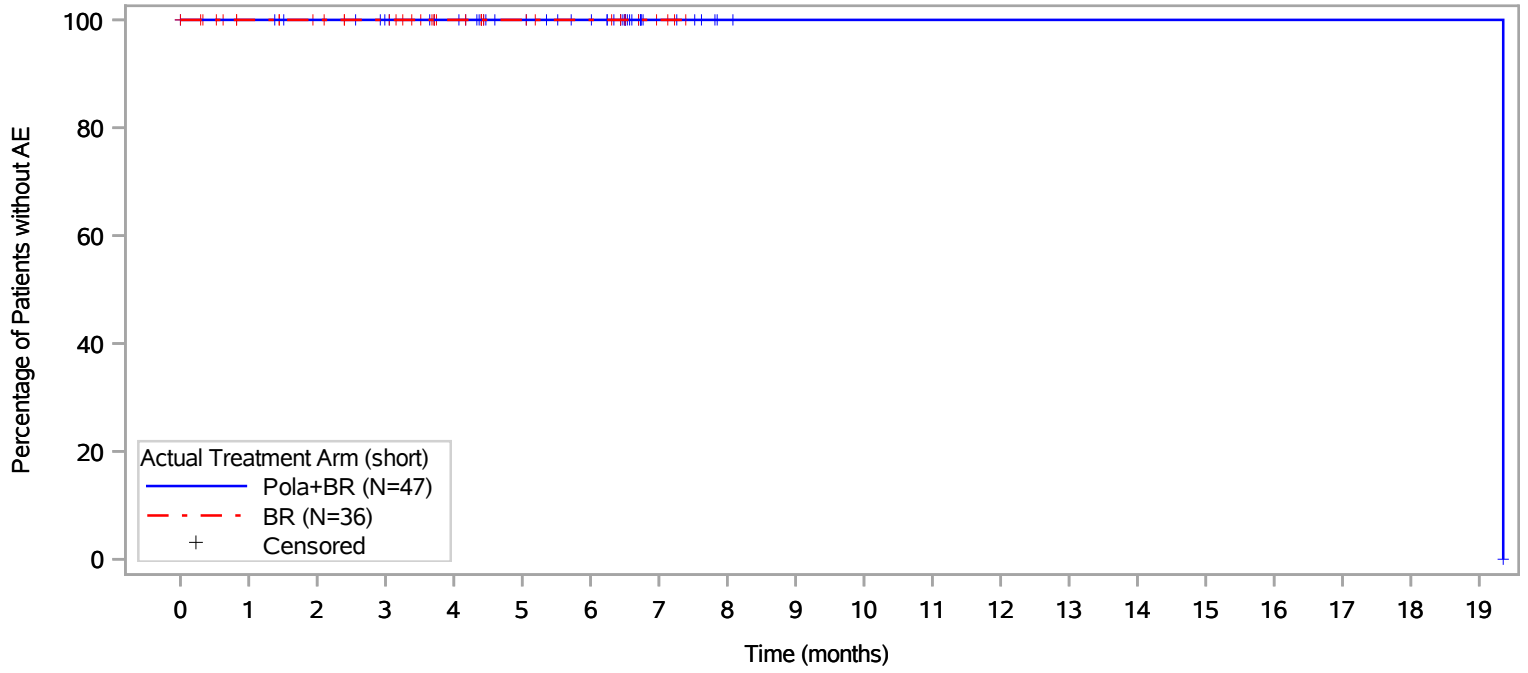
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

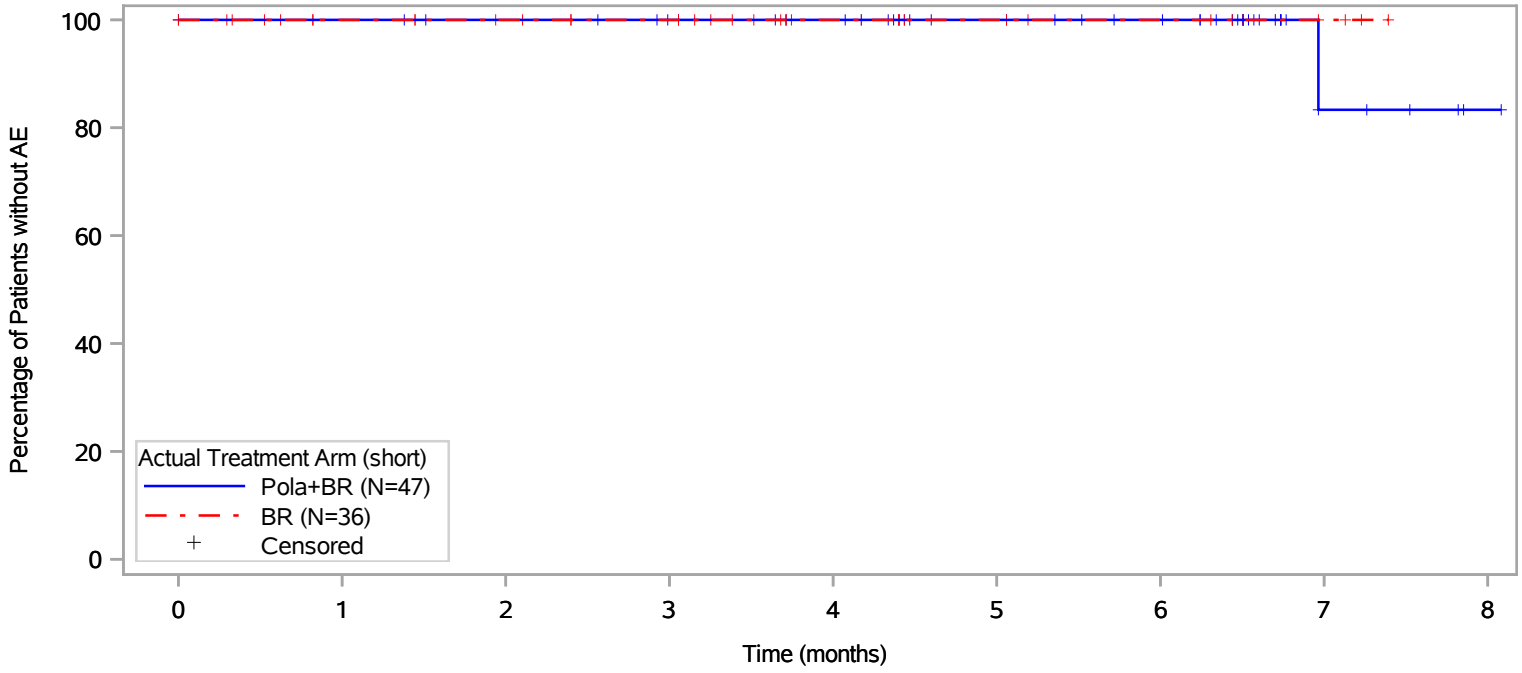
INFECTIONS AND INFESTATIONS, PNEUMONIA PNEUMOCOCCAL



Patients at risk																				
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, RHINOVIRUS INFECTION



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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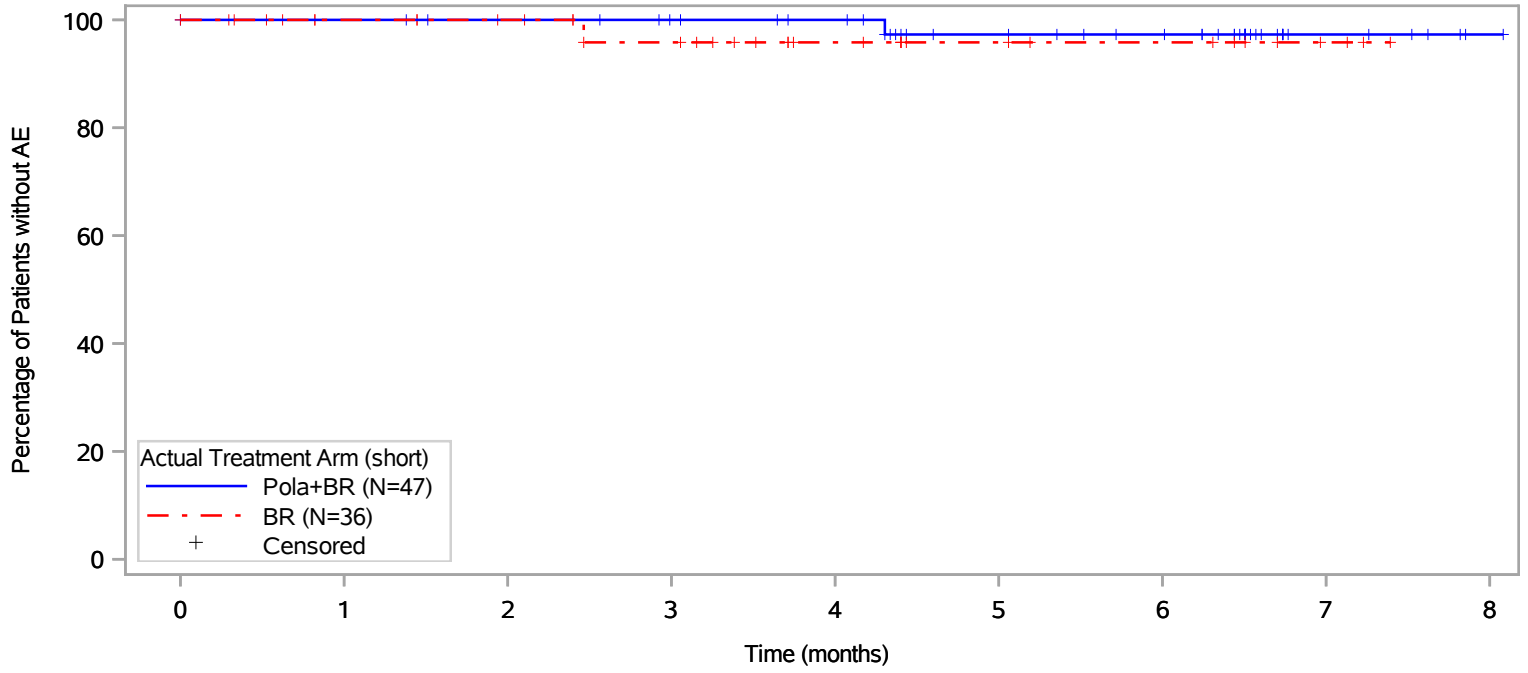
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	40	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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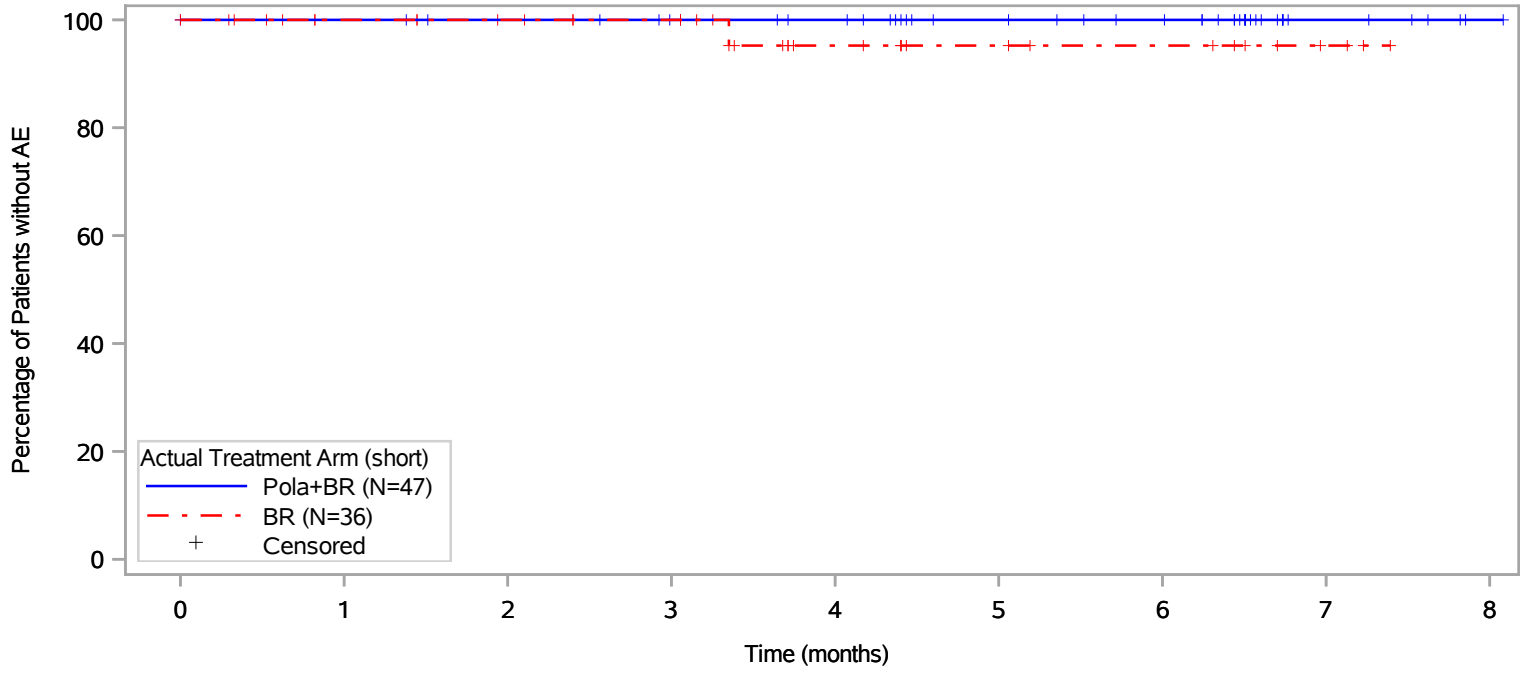
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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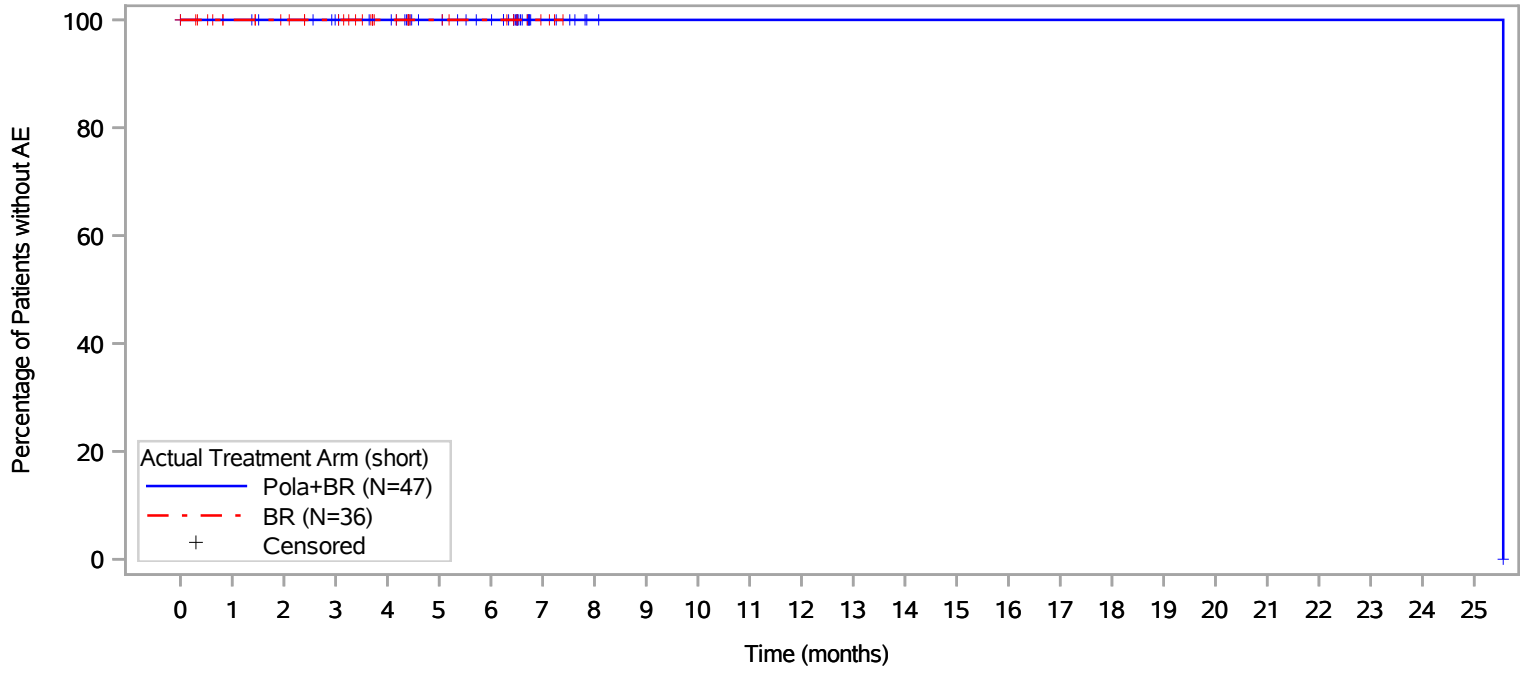
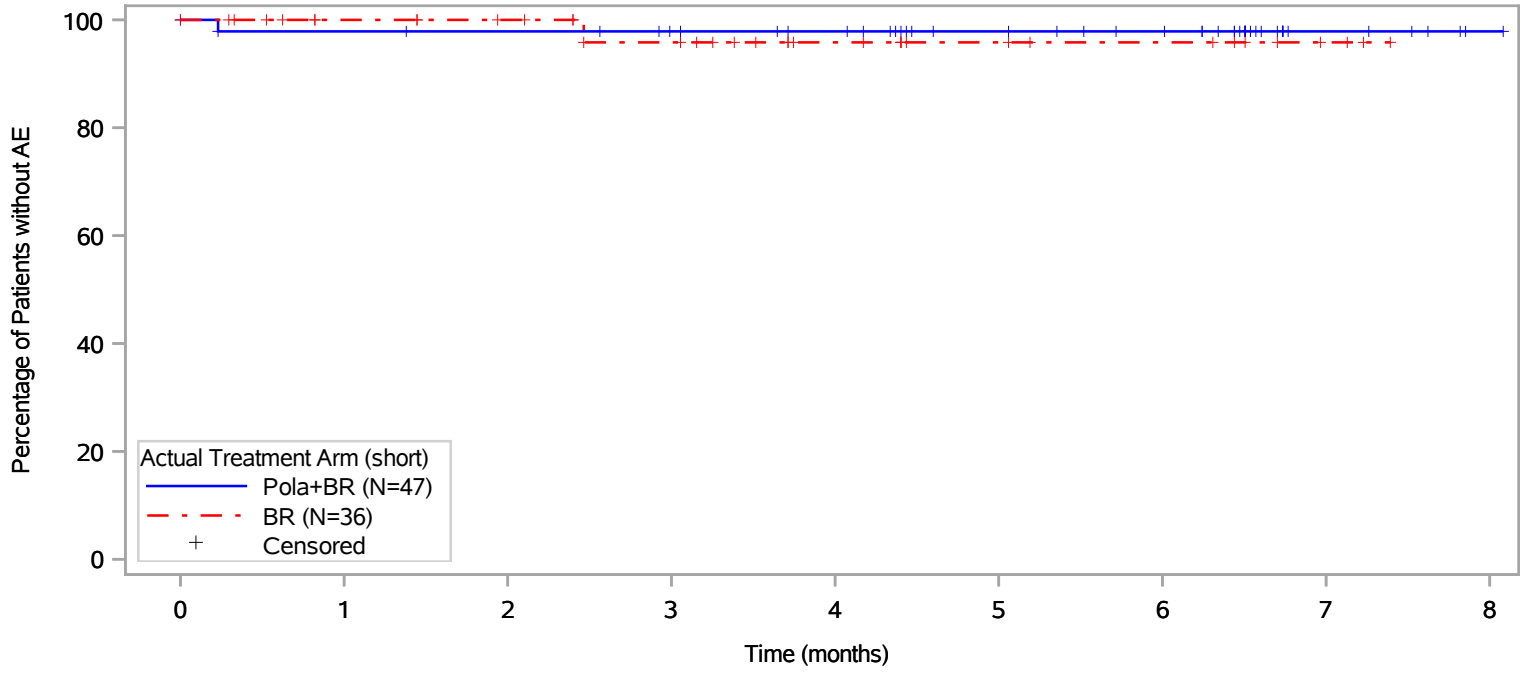
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UROSEPSIS



Patients at risk																										
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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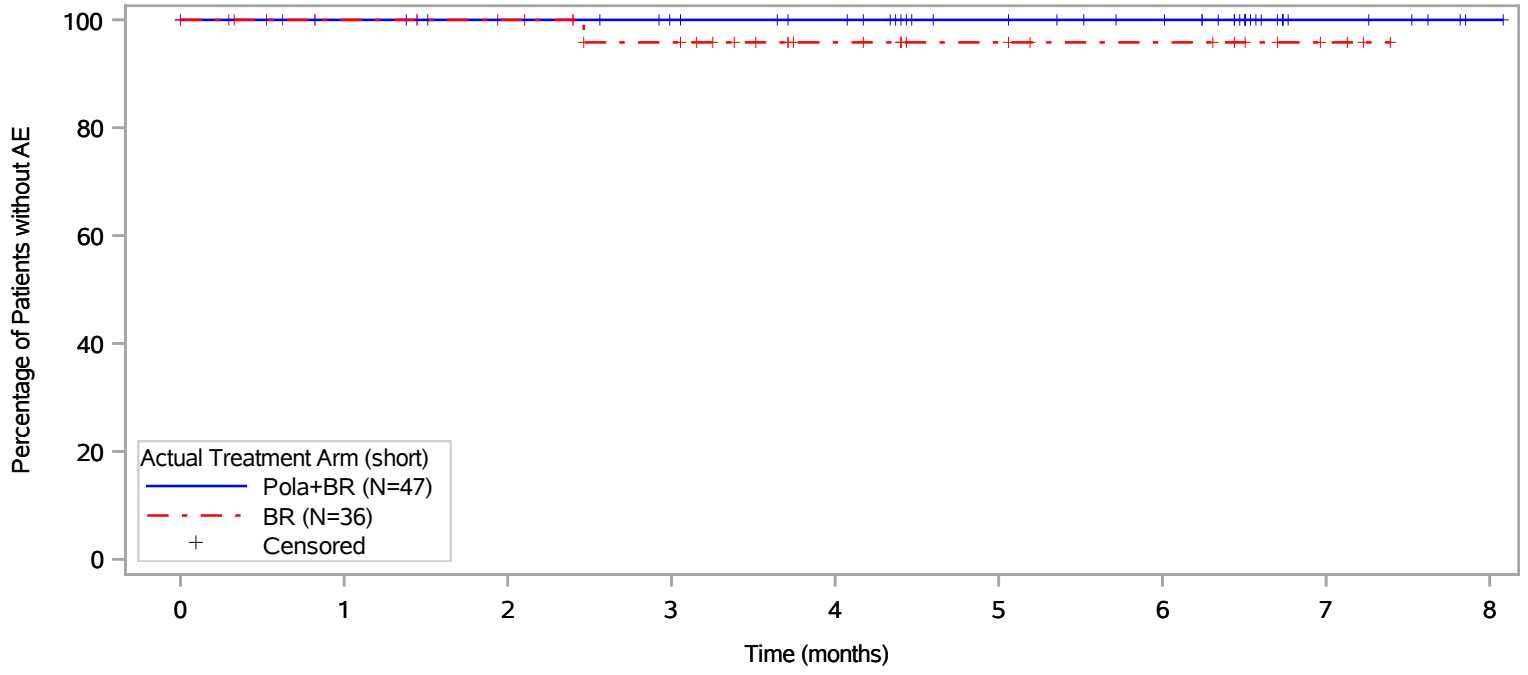
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL

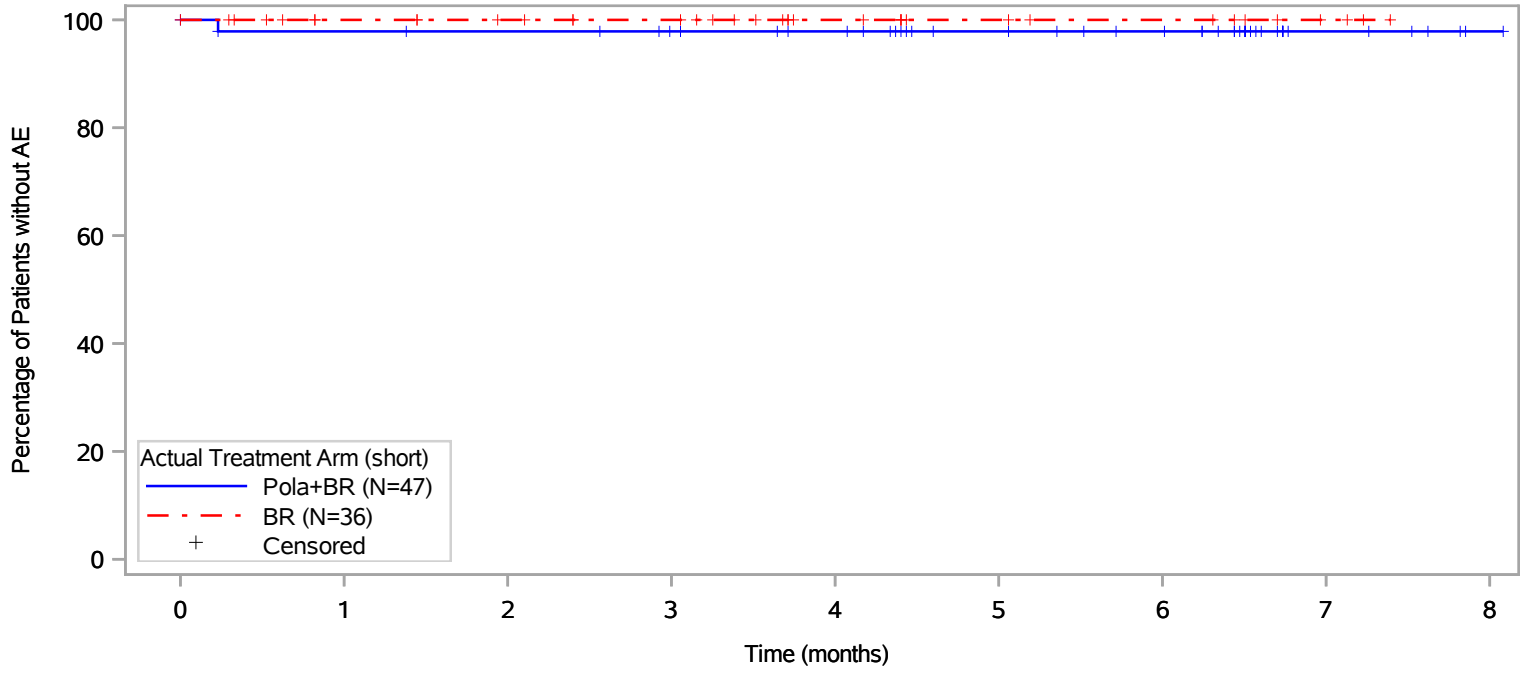


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:23

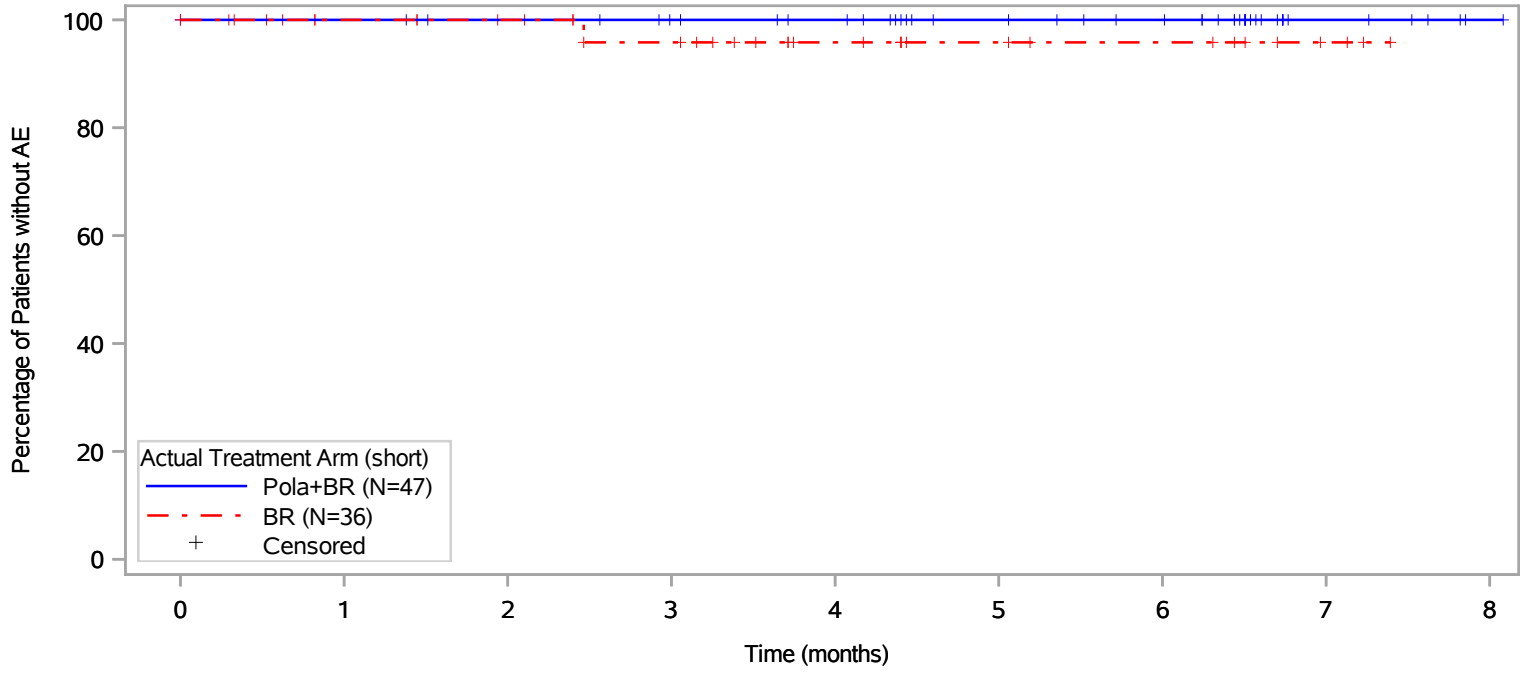
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FEMUR FRACTURE



Patients at risk									
Pola+BR (N=47)	47	46	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, HEAD INJURY



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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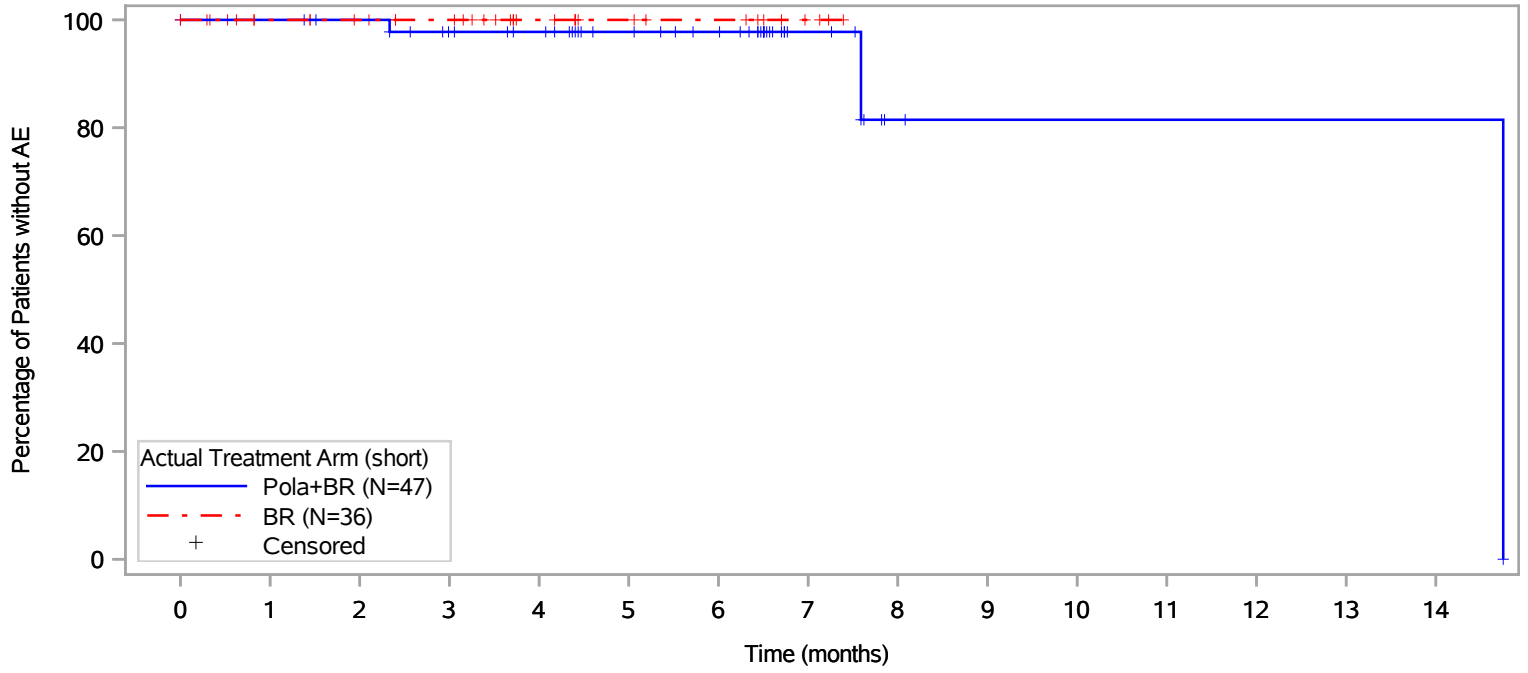
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk															
Pola+BR (N=47)	47	47	45	41	38	30	26	8	2	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	38	43	44	44	44	44	44	44
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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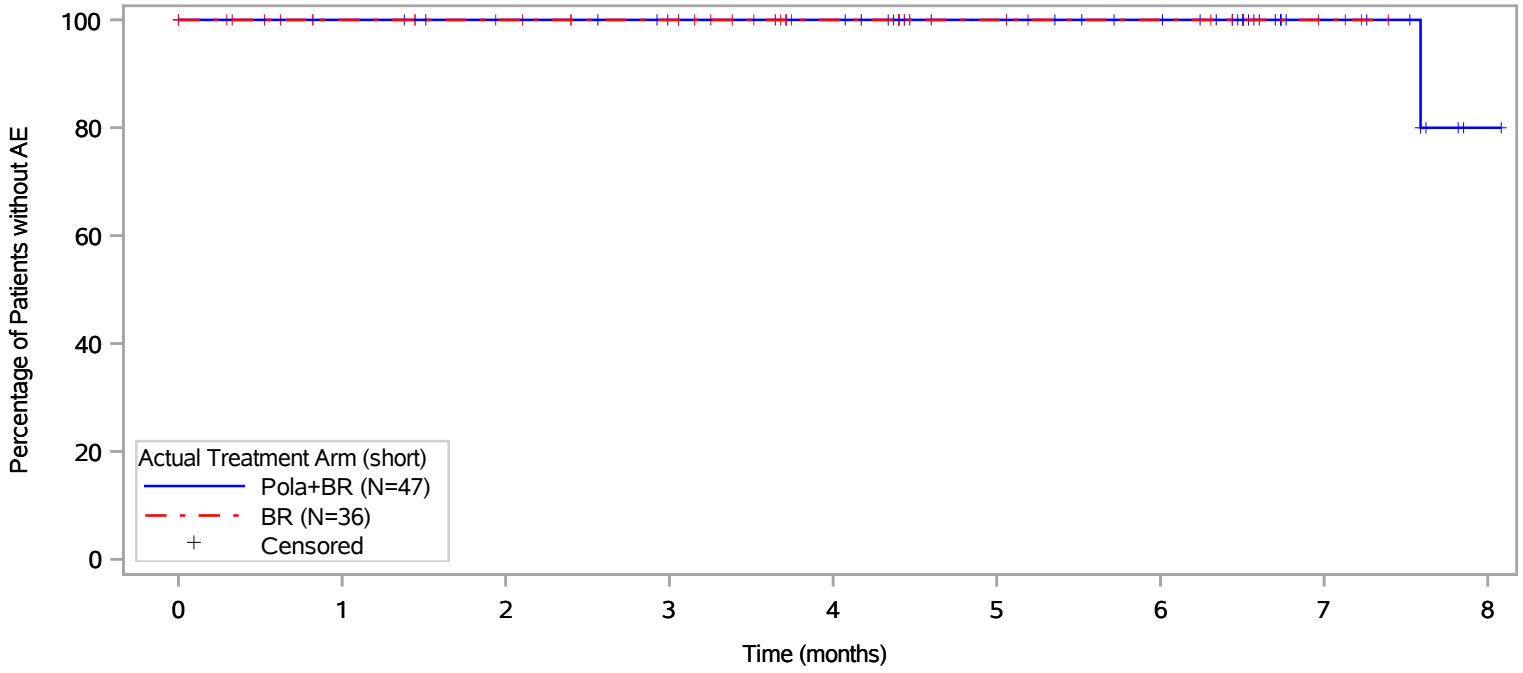
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MORAXELLA TEST POSITIVE

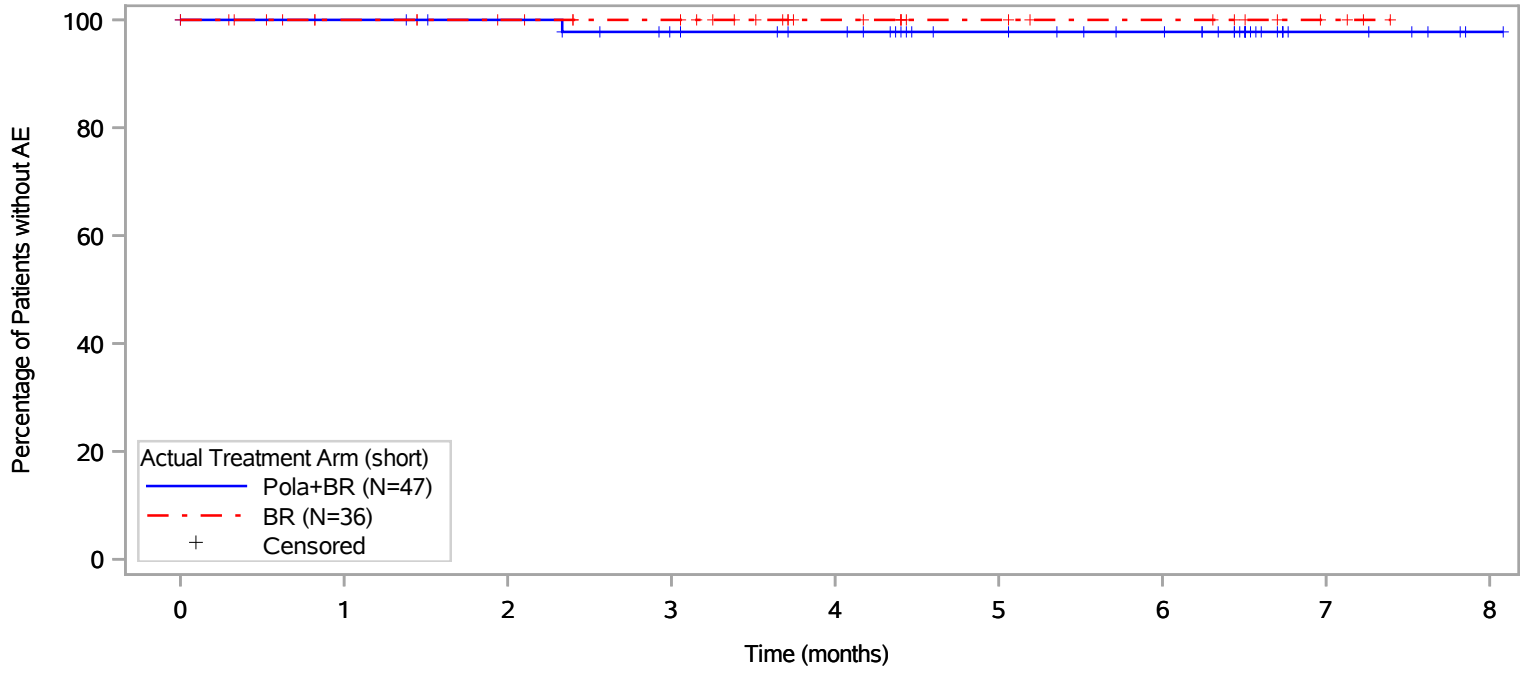


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	7	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:23

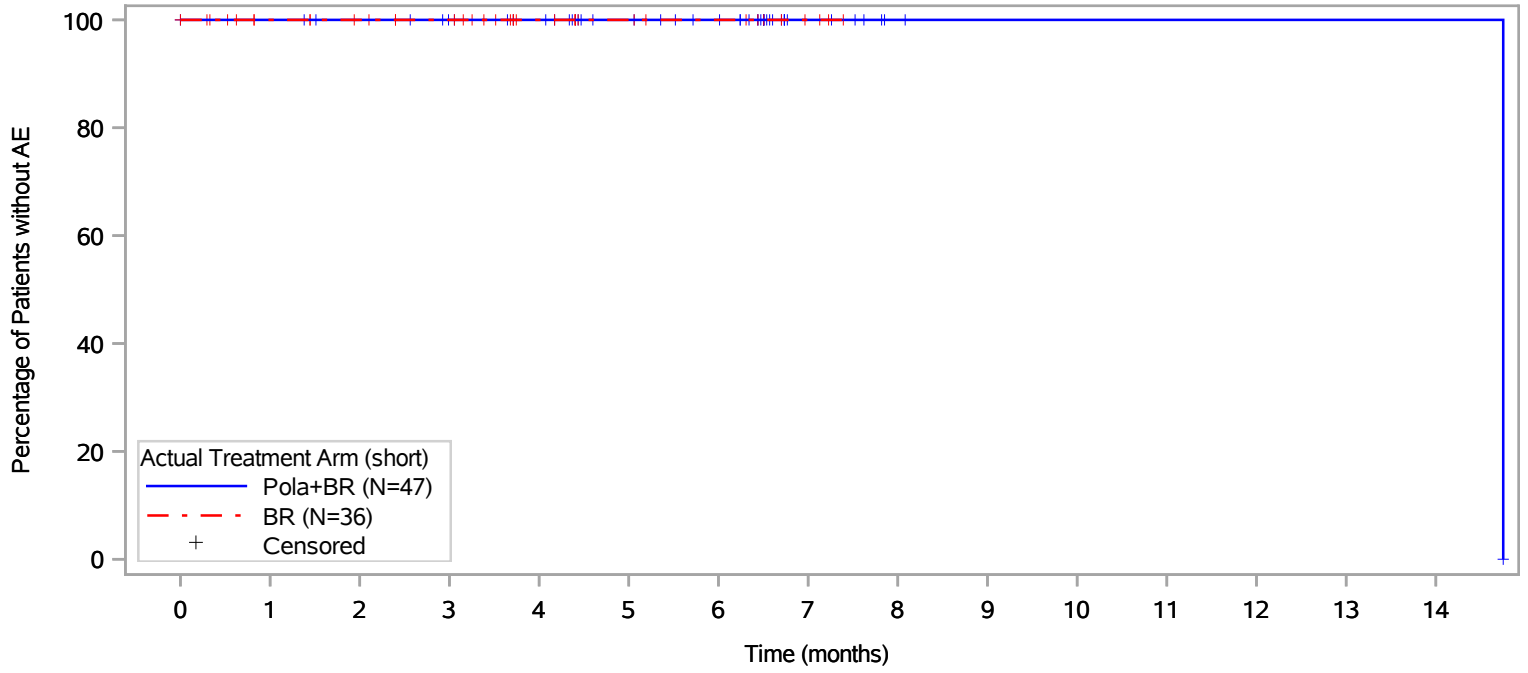
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, TRANSAMINASES INCREASED



Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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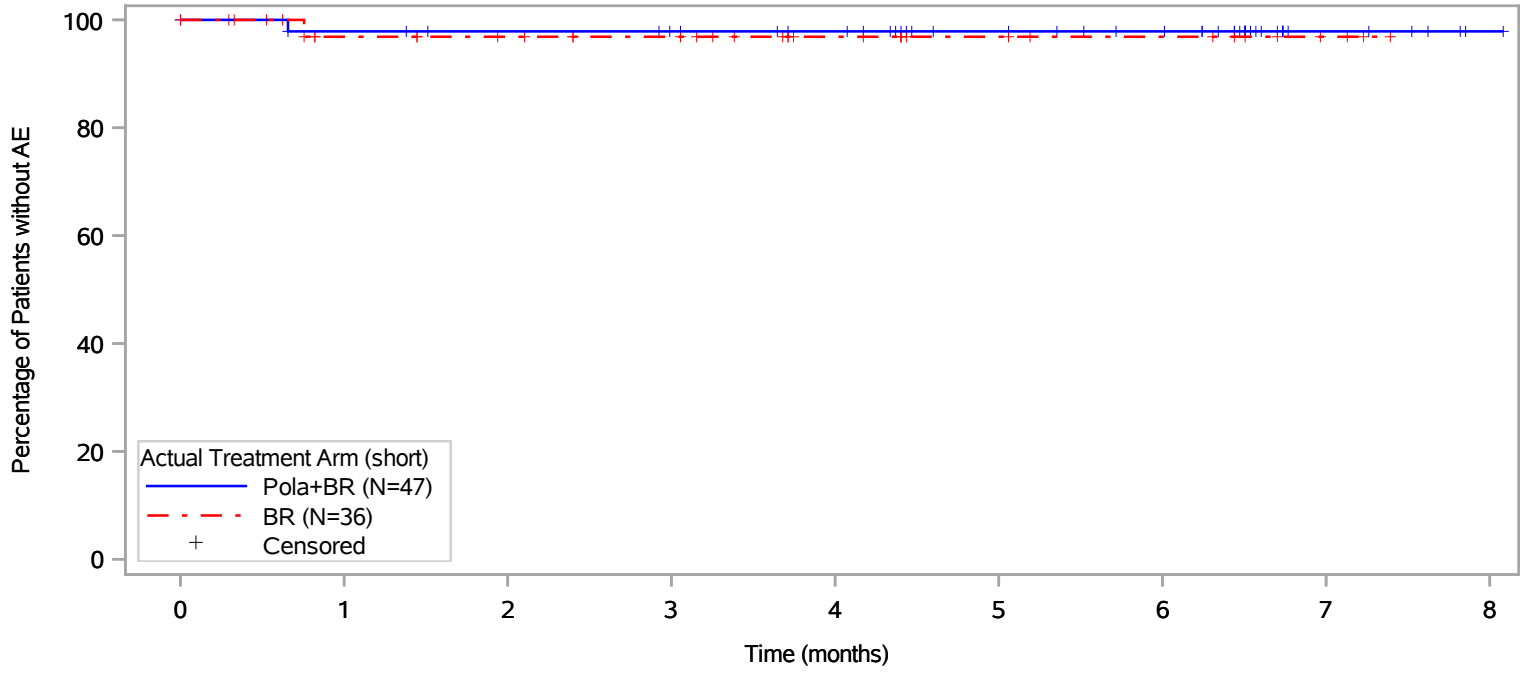
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All

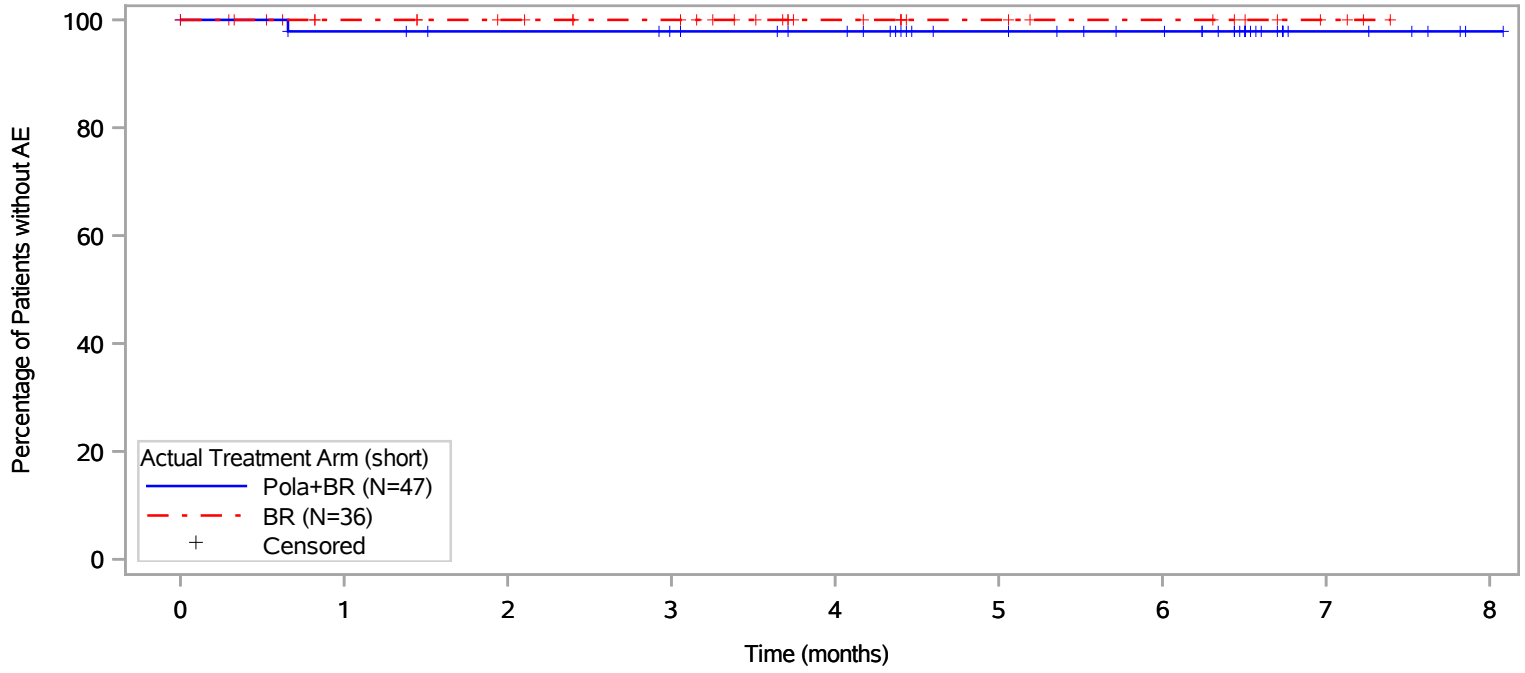


Patients at risk									
Pola+BR (N=47)	47	46	44	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN

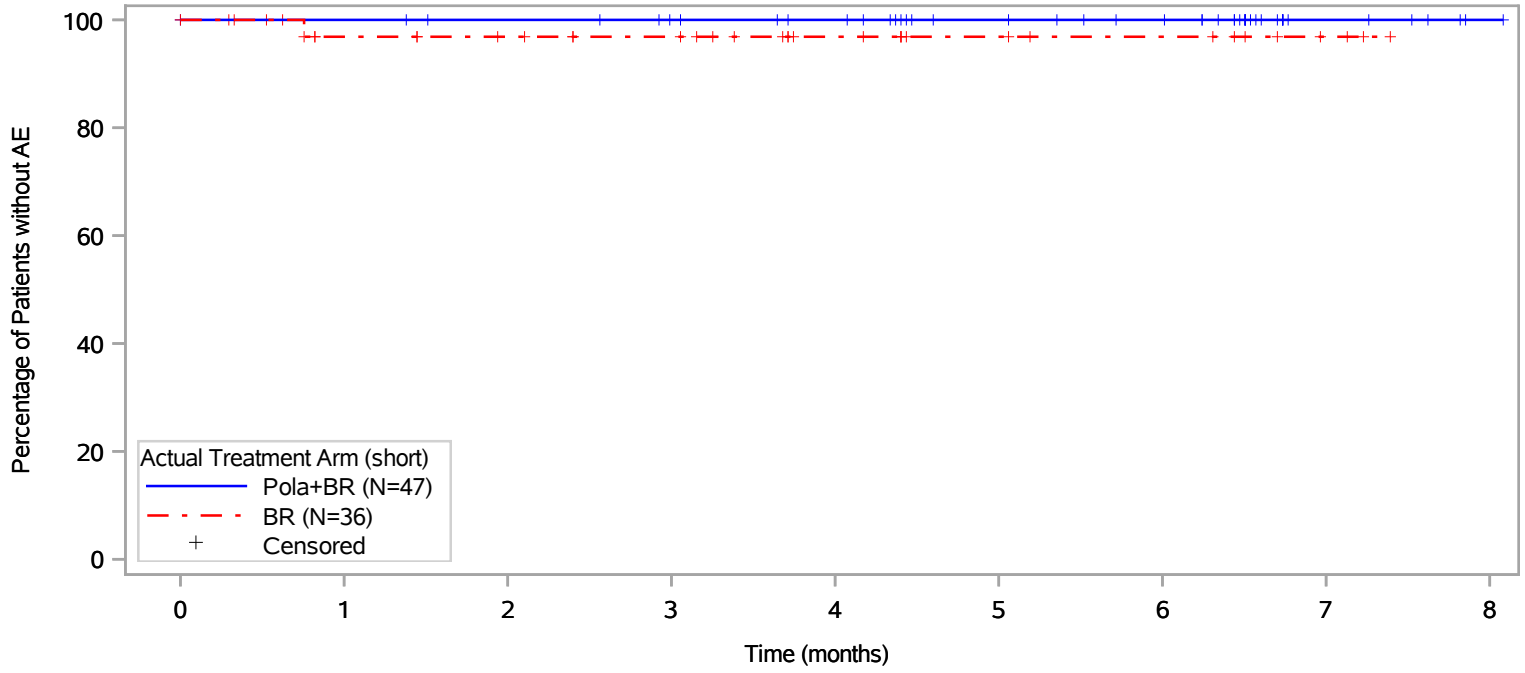


Patients at risk									
Pola+BR (N=47)	47	46	44	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, INTERVERTEBRAL DISC PROTRUSION

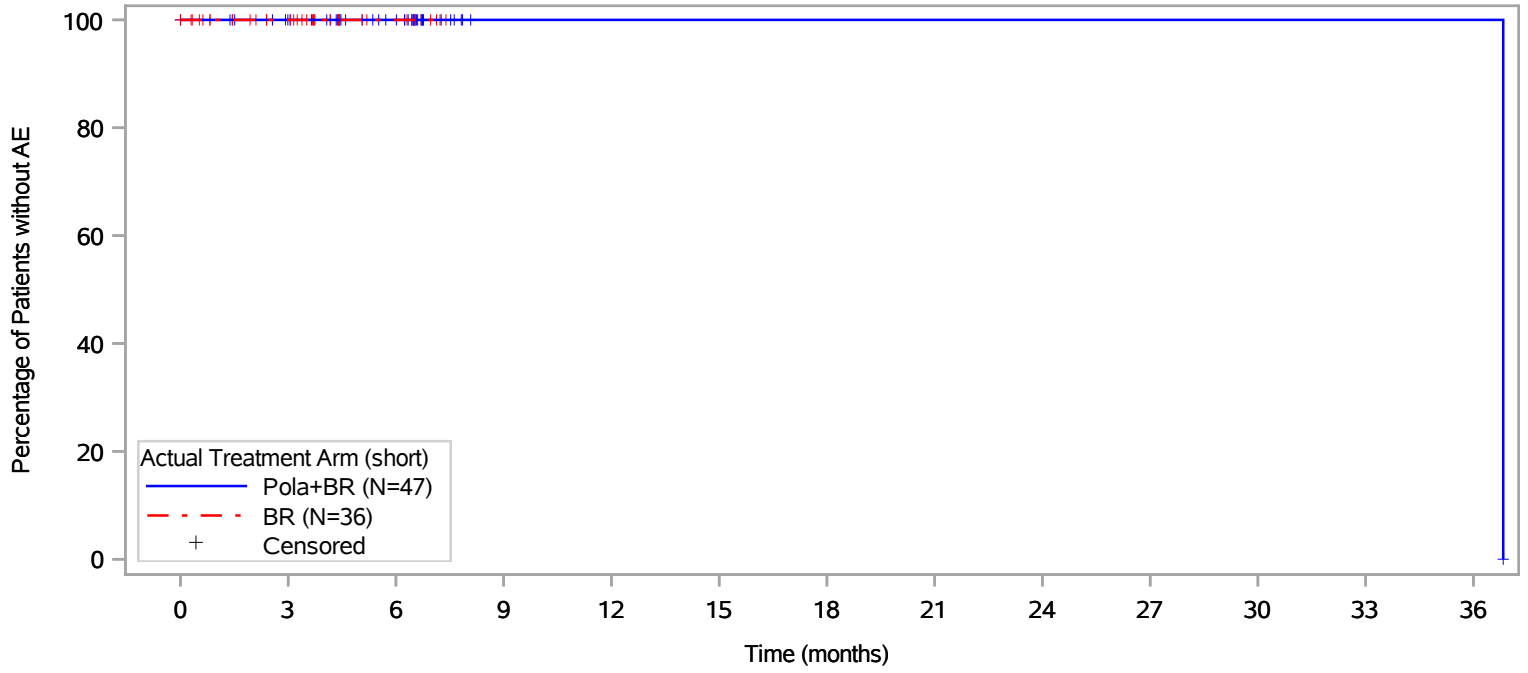


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All

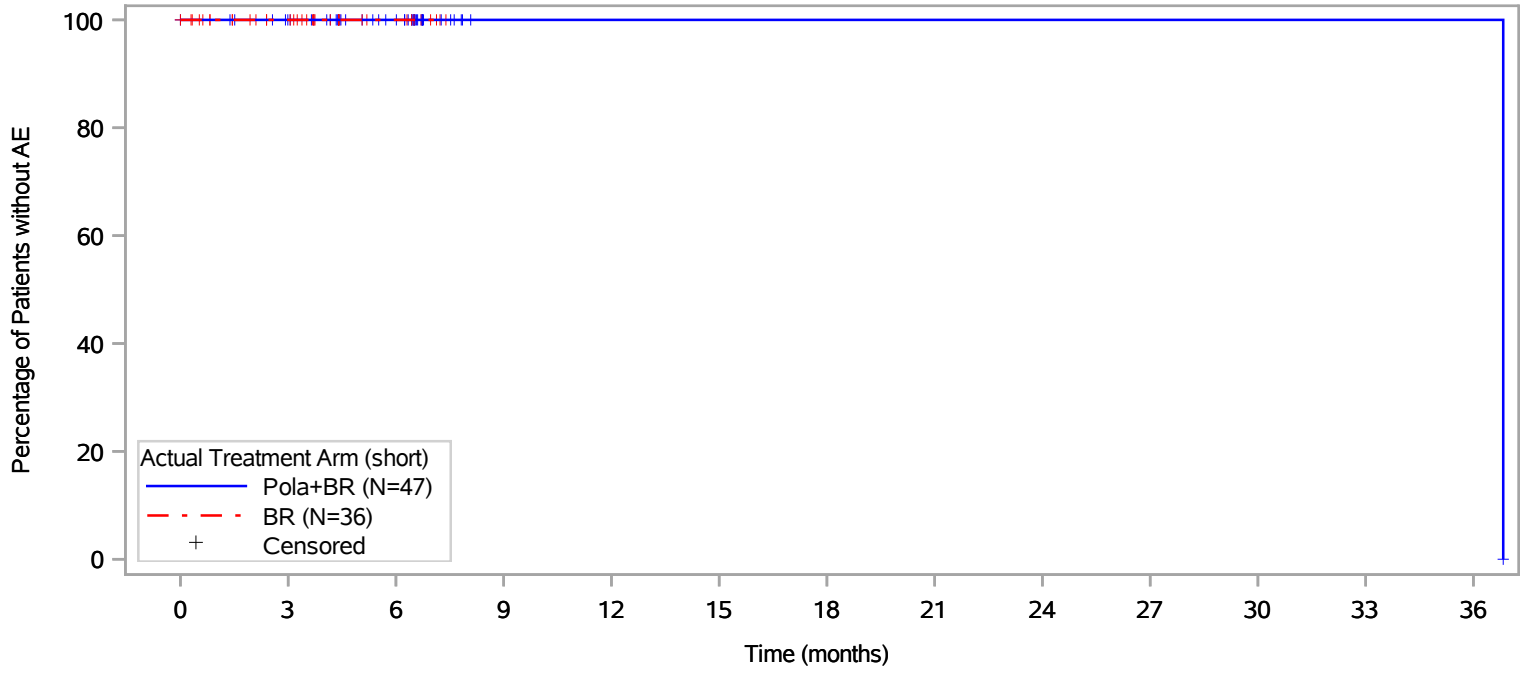


Patients at risk													
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=47)	0	5	20	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MALIGNANT MELANOMA



Patients at risk													
Pola+BR (N=47)	47	42	27	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	24	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=47)	0	5	20	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	12	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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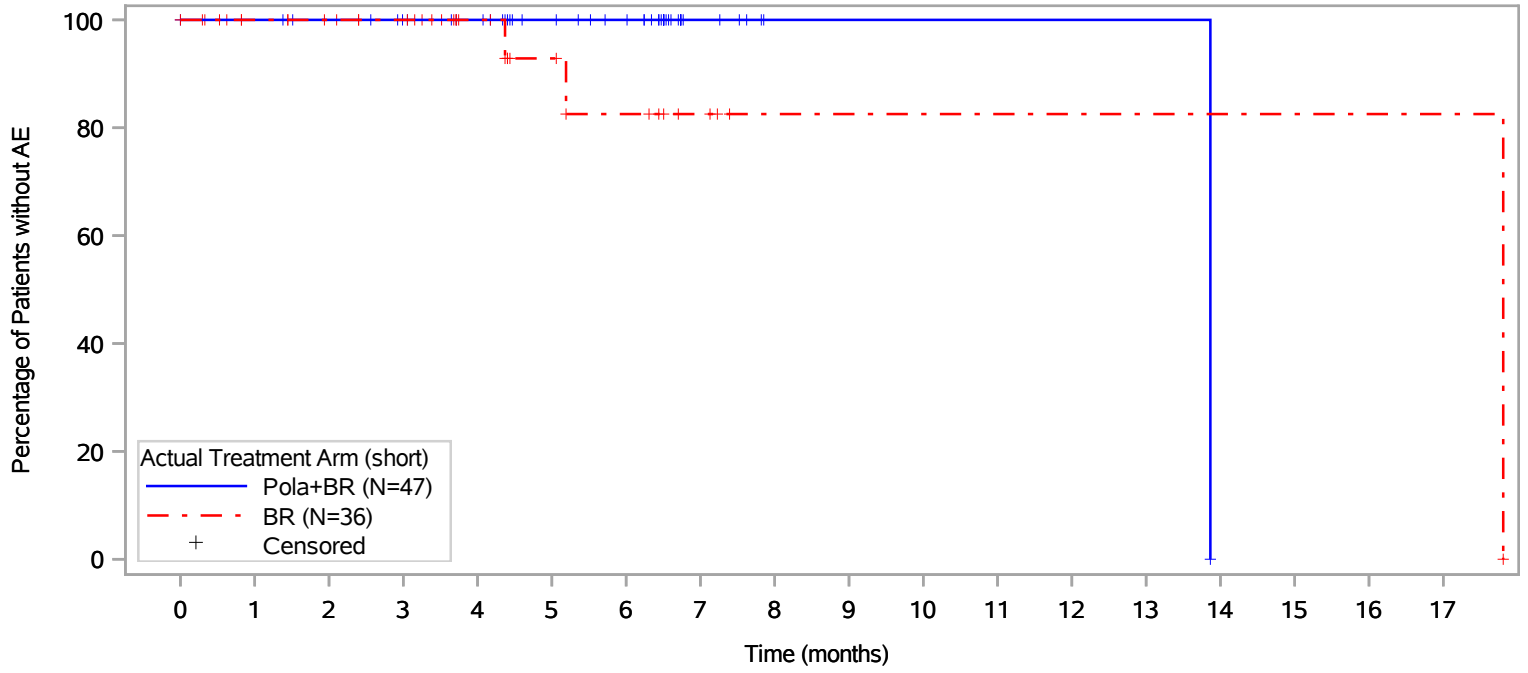
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All

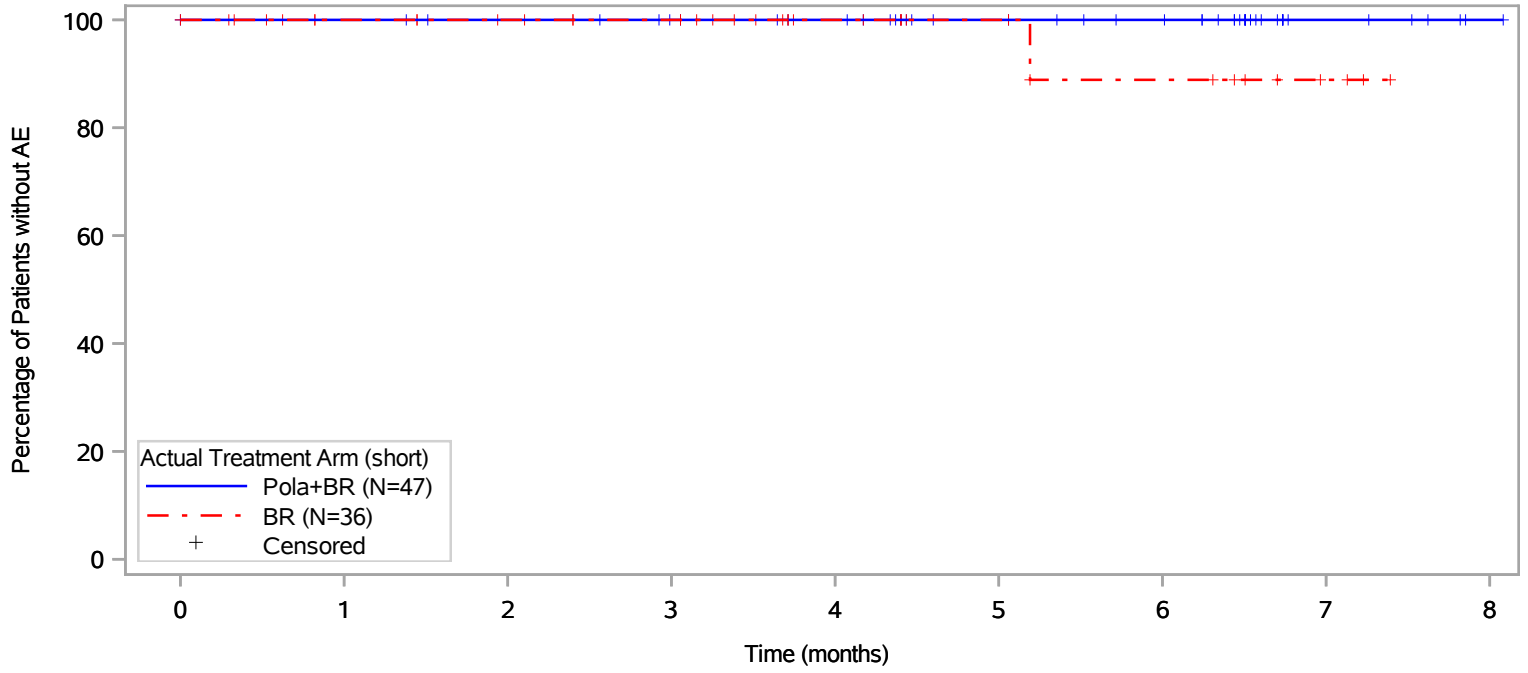


Patients at risk																		
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	1	1	1	1	1	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	46	46	46	46	46	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	25	26	30	33	33	33	33	33	33	33	33	33	33

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, CEREBRAL HAEMORRHAGE

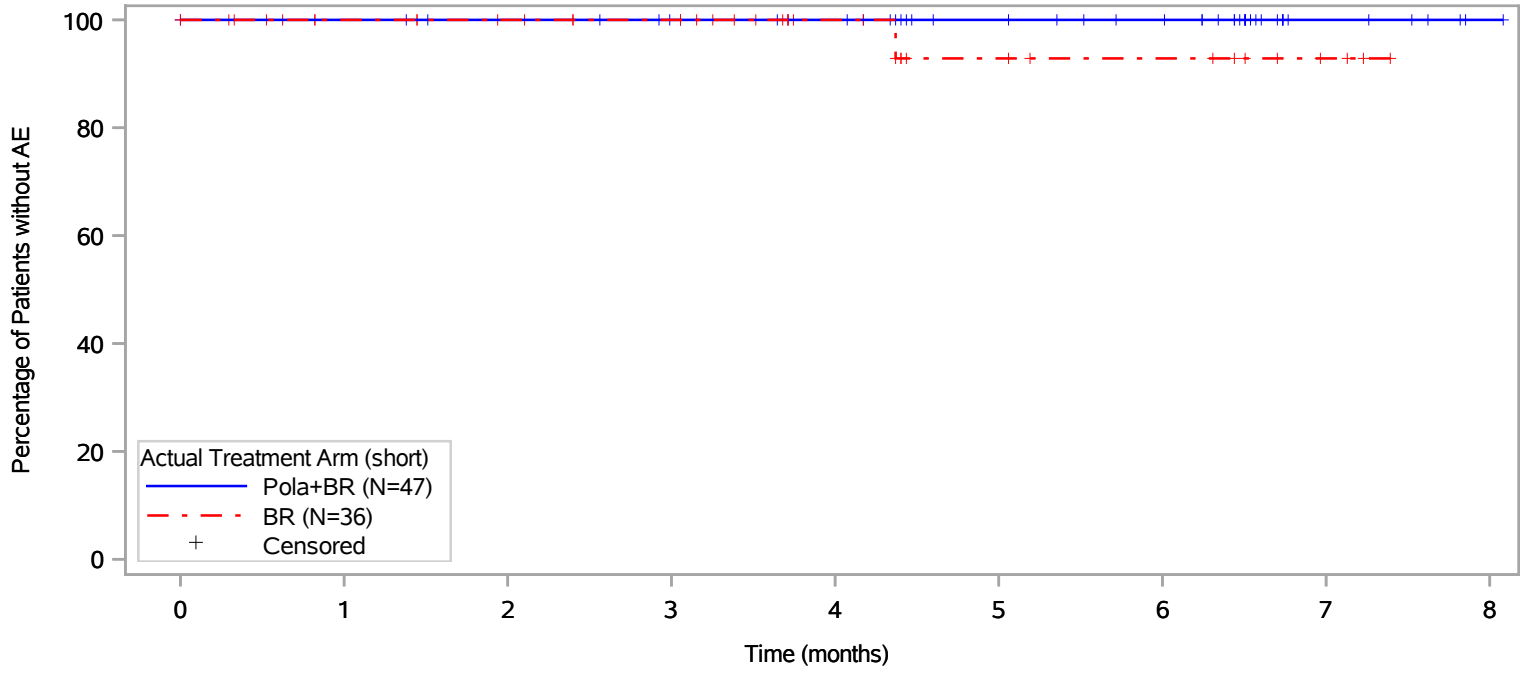


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, CEREBROVASCULAR ACCIDENT



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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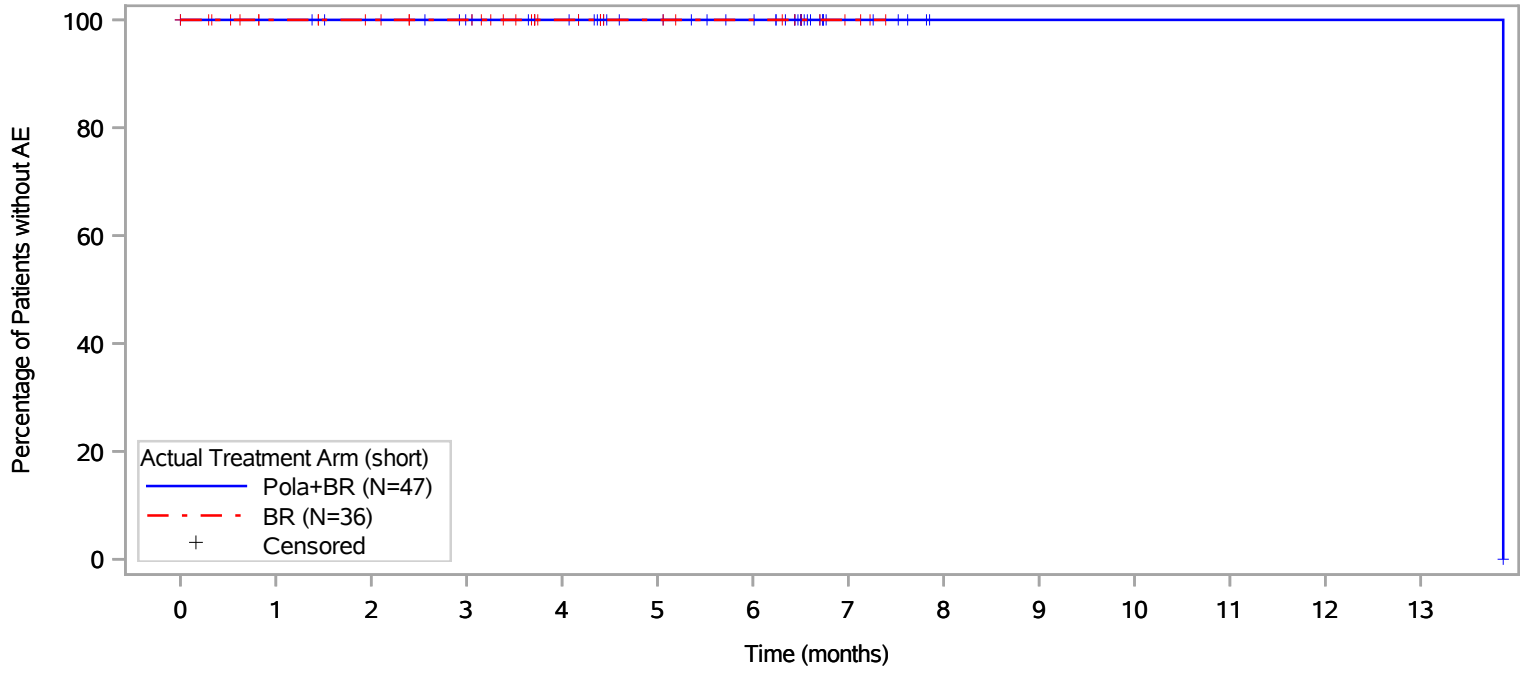
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HAEMORRHAGE INTRACRANIAL



Patients at risk														
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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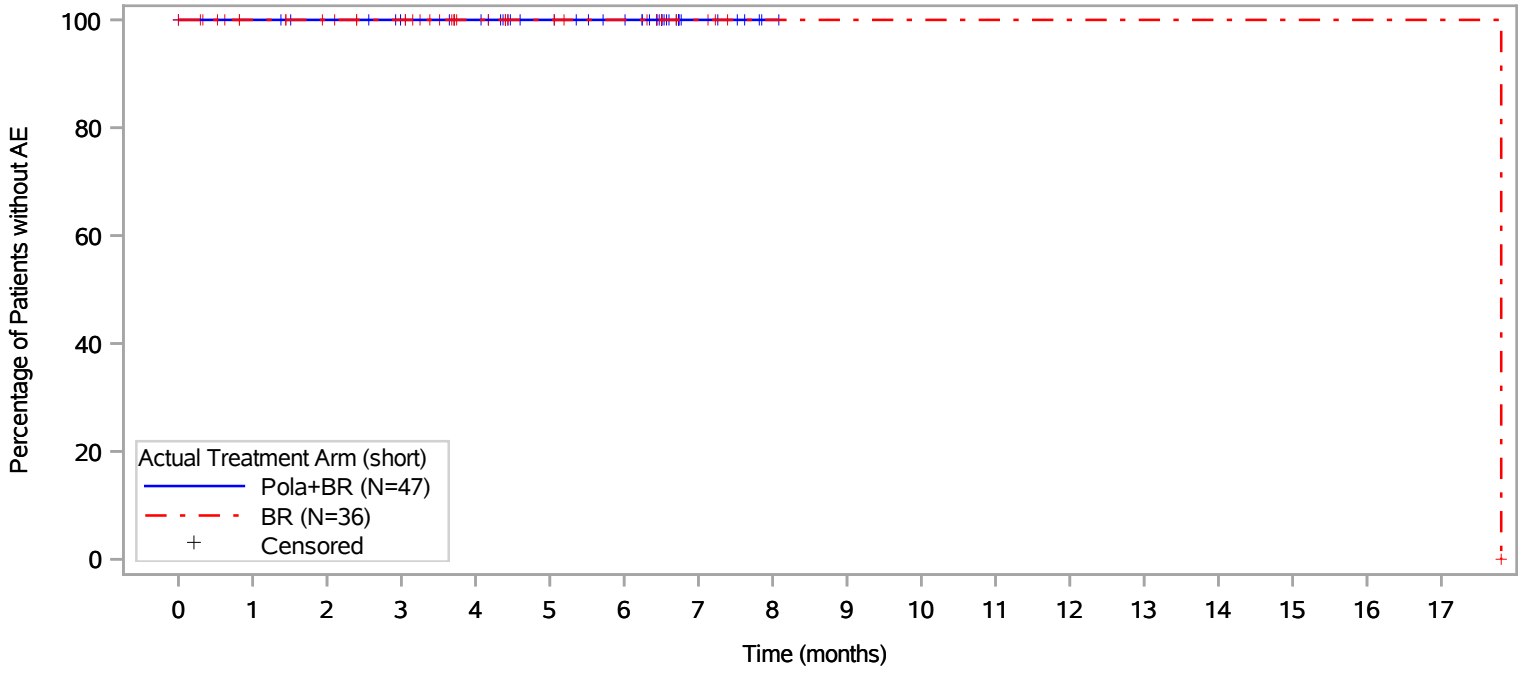
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, LEUKOENCEPHALOPATHY



Patients at risk																		
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	36	30	27	24	15	10	8	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=36)	0	6	9	12	21	26	28	32	35	35	35	35	35	35	35	35	35	35

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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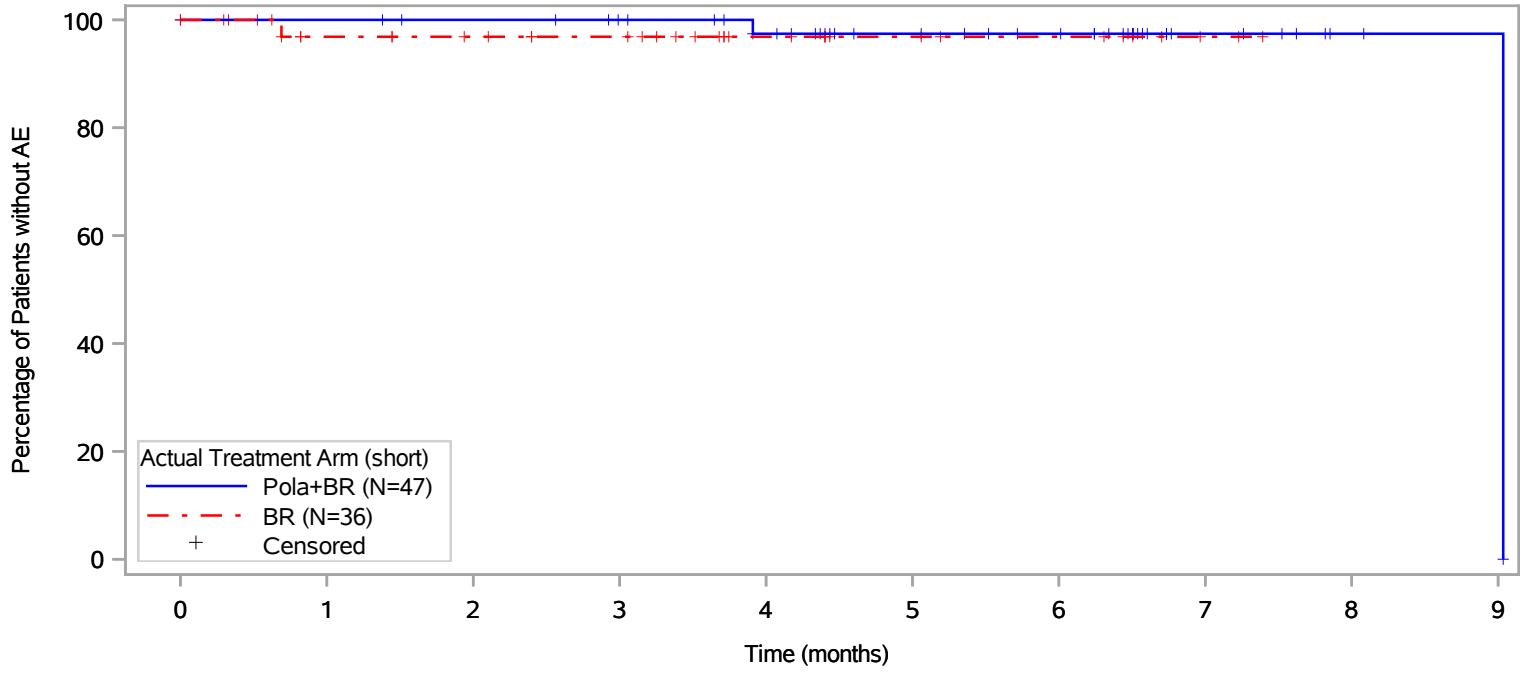
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk										
Pola+BR (N=47)	47	47	45	42	38	30	26	7	2	1
BR (N=36)	36	29	26	23	14	9	7	2	NE	NE
Patients censored										
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44	45
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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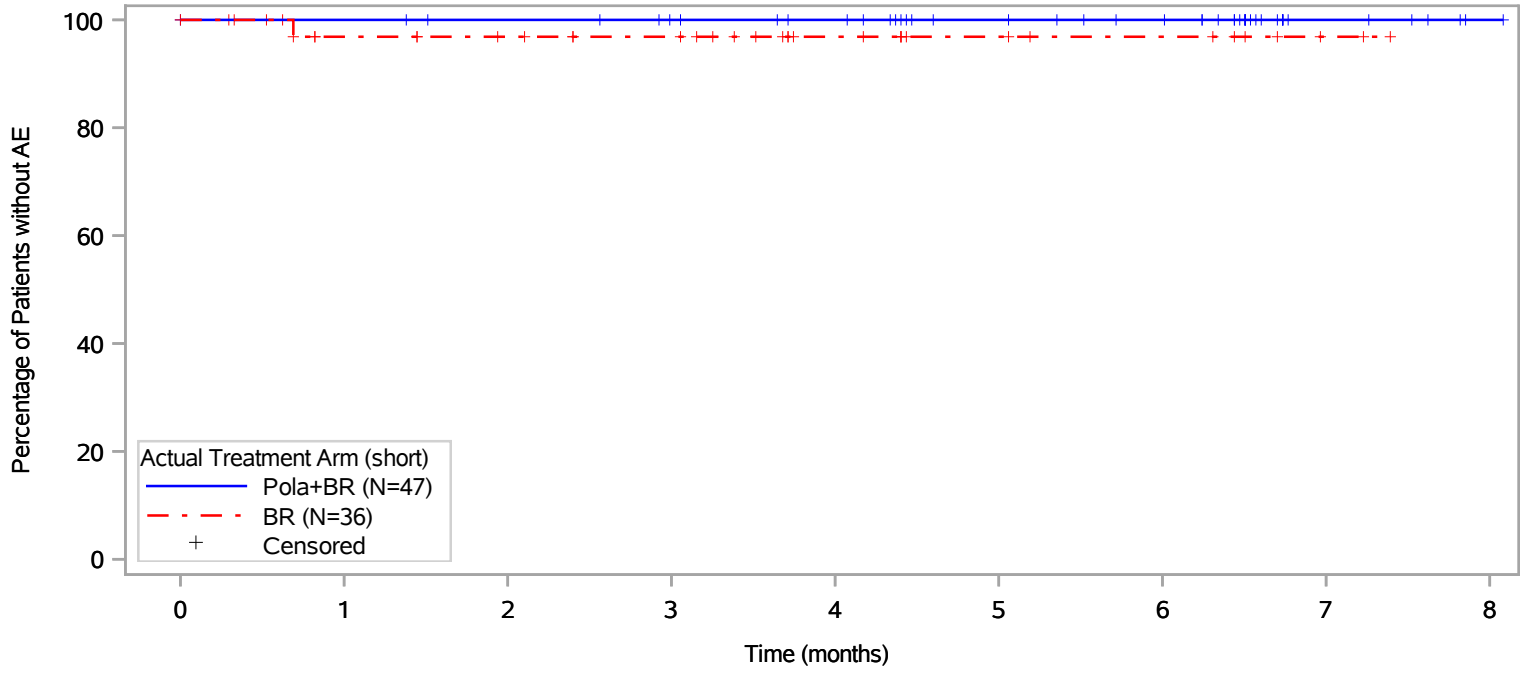
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



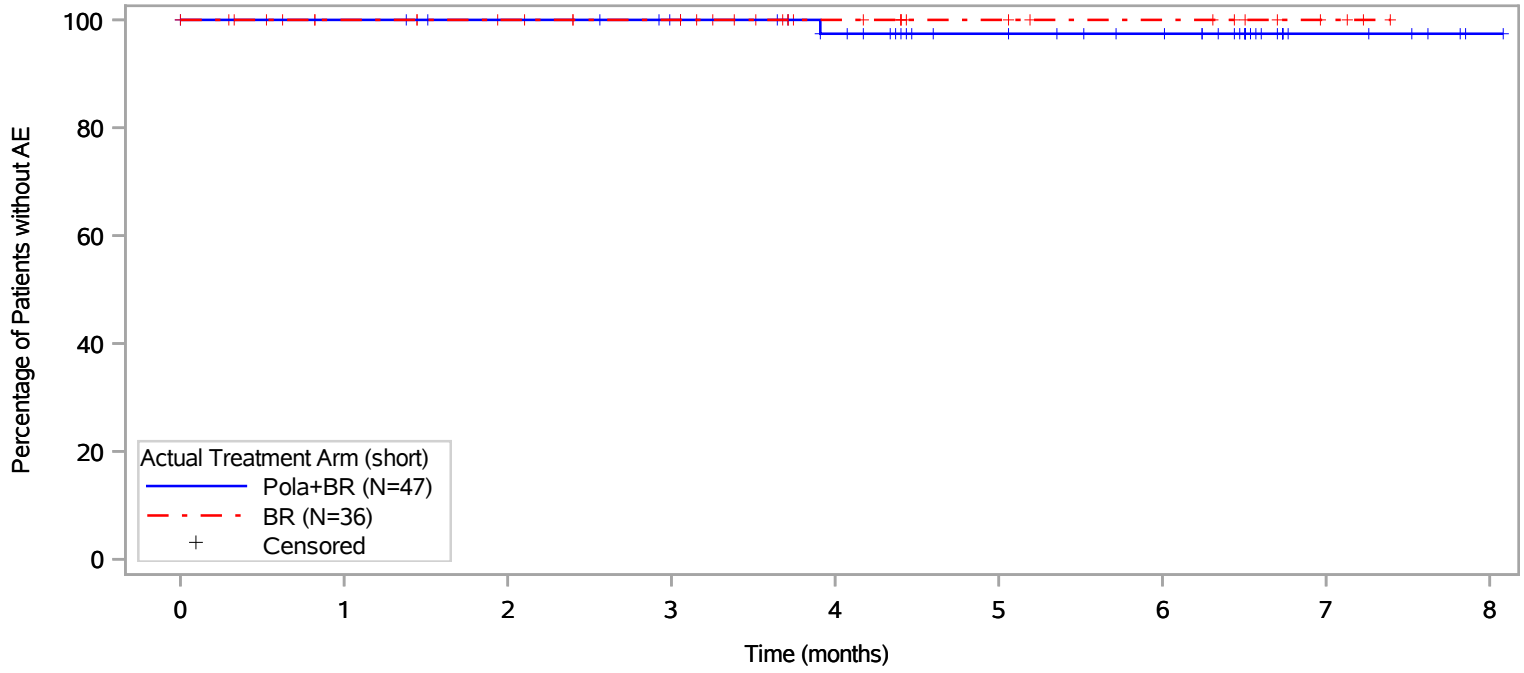
Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

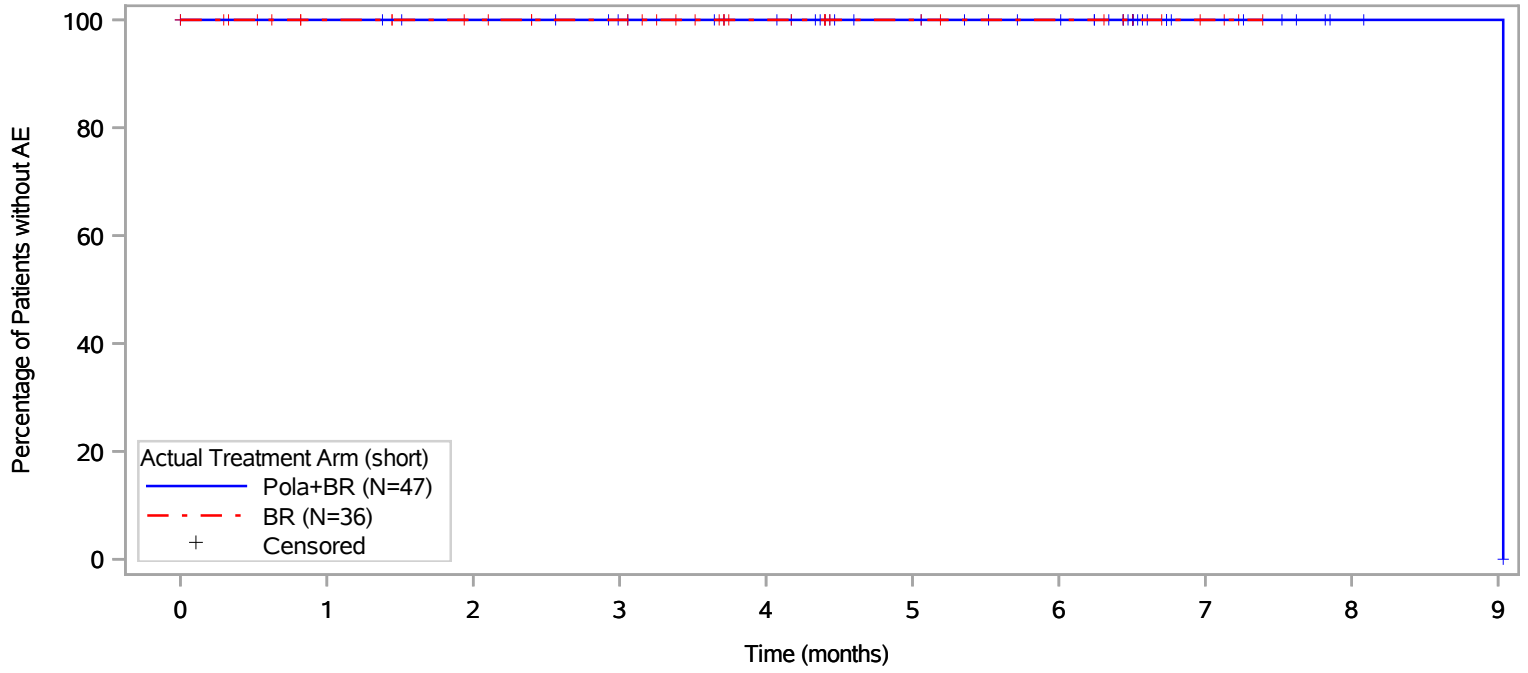
RENAL AND URINARY DISORDERS, HAEMATURIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk										
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE
Patients censored										
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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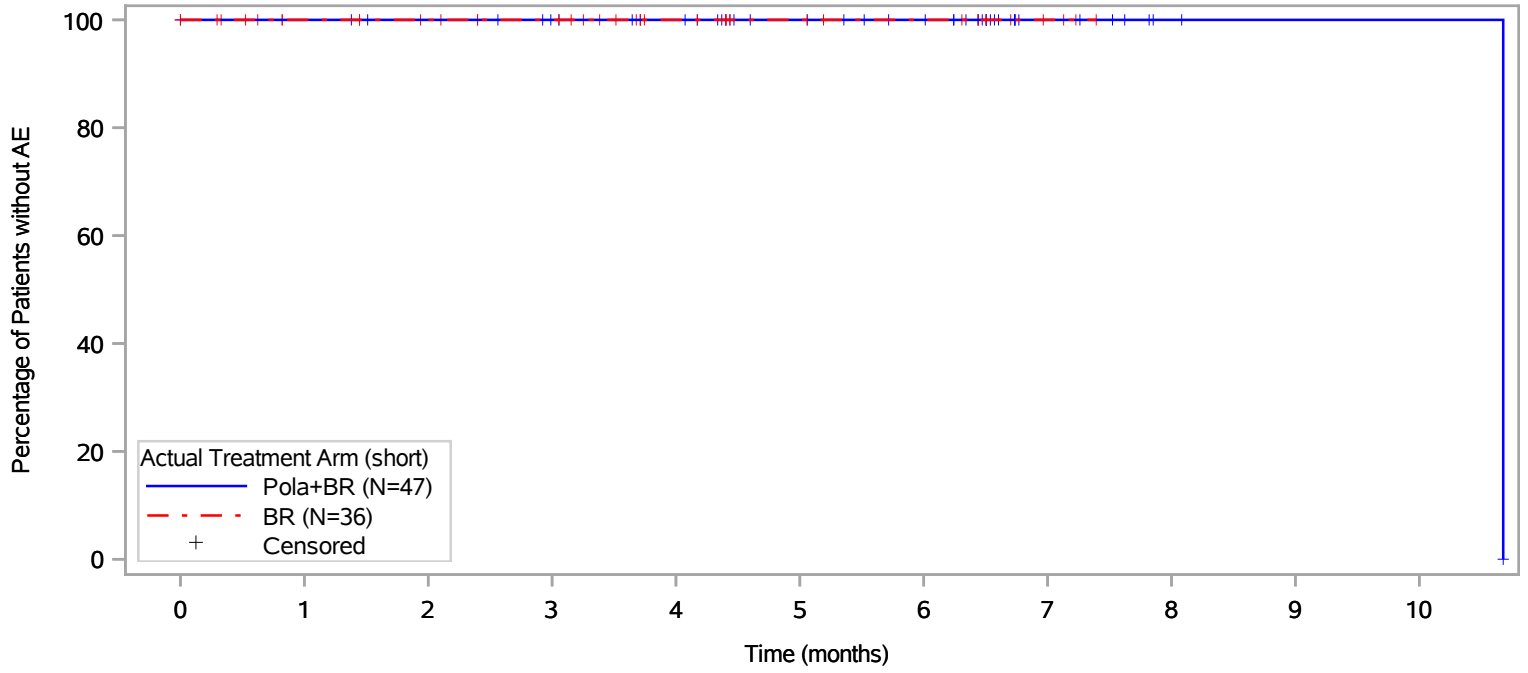
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE



Patients at risk											
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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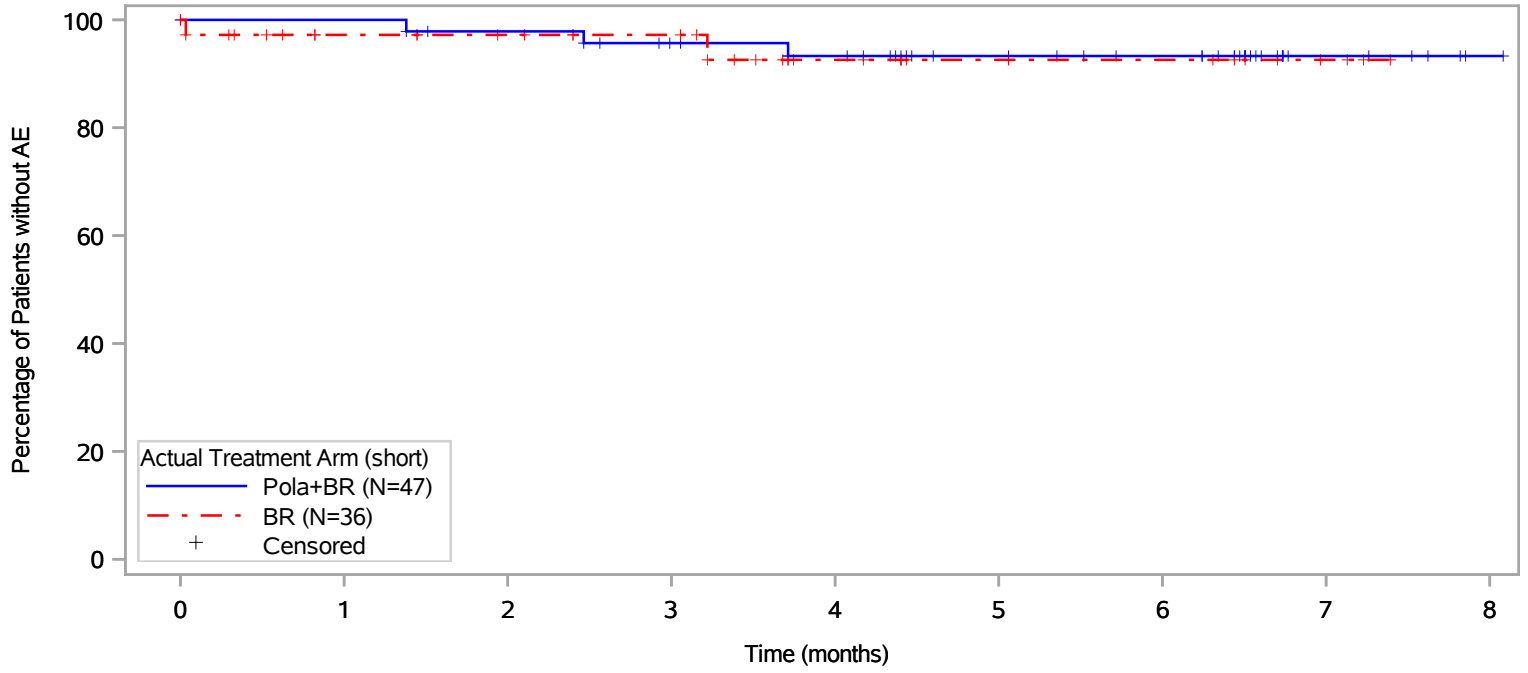
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	6	14	18	38	43
BR (N=36)	0	6	9	12	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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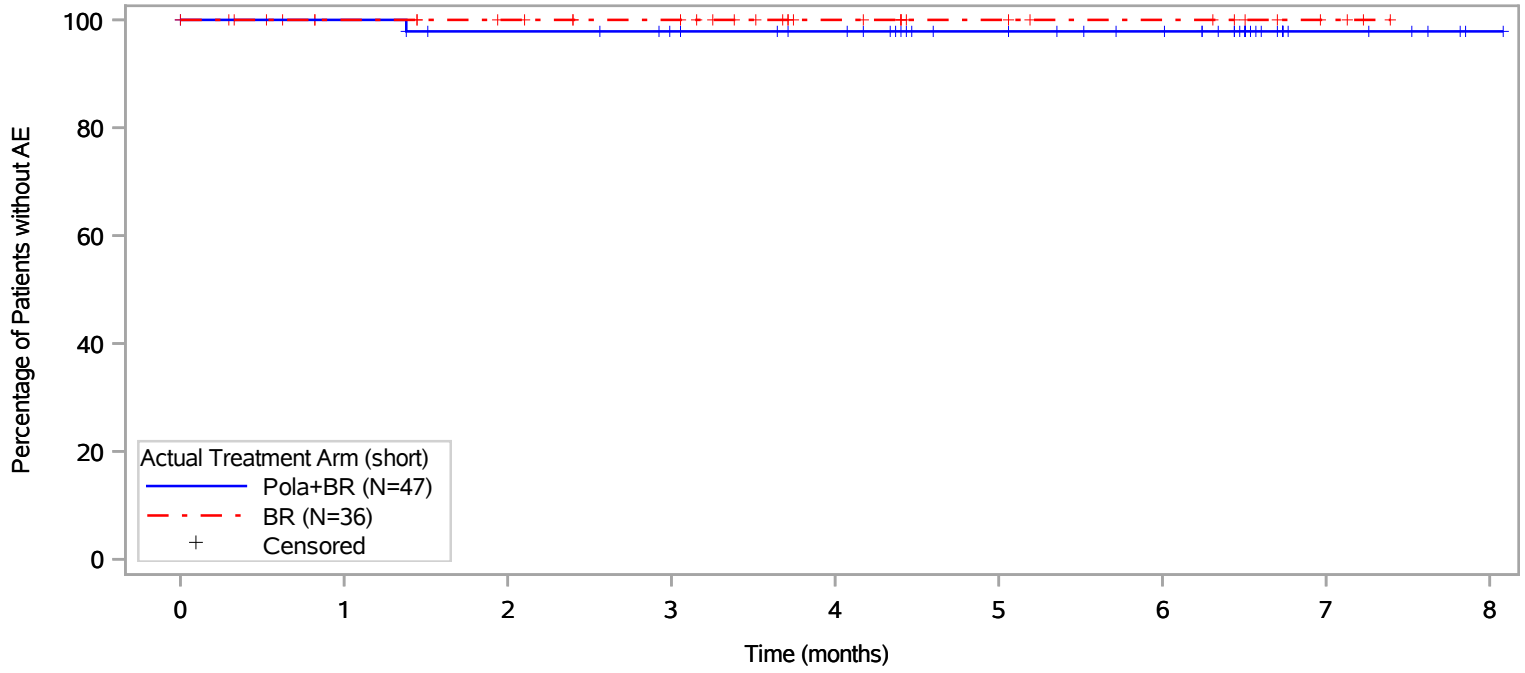
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

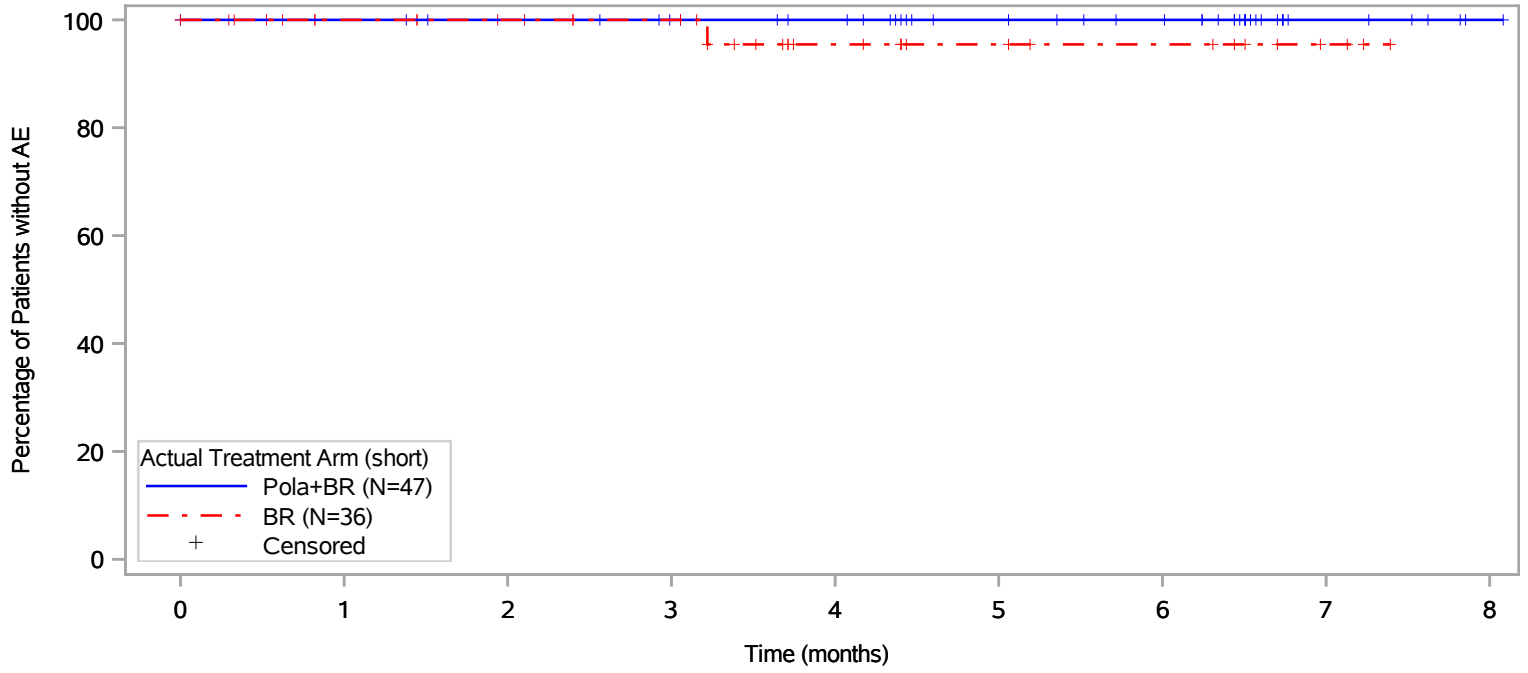
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HAEMOPTYSIS



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

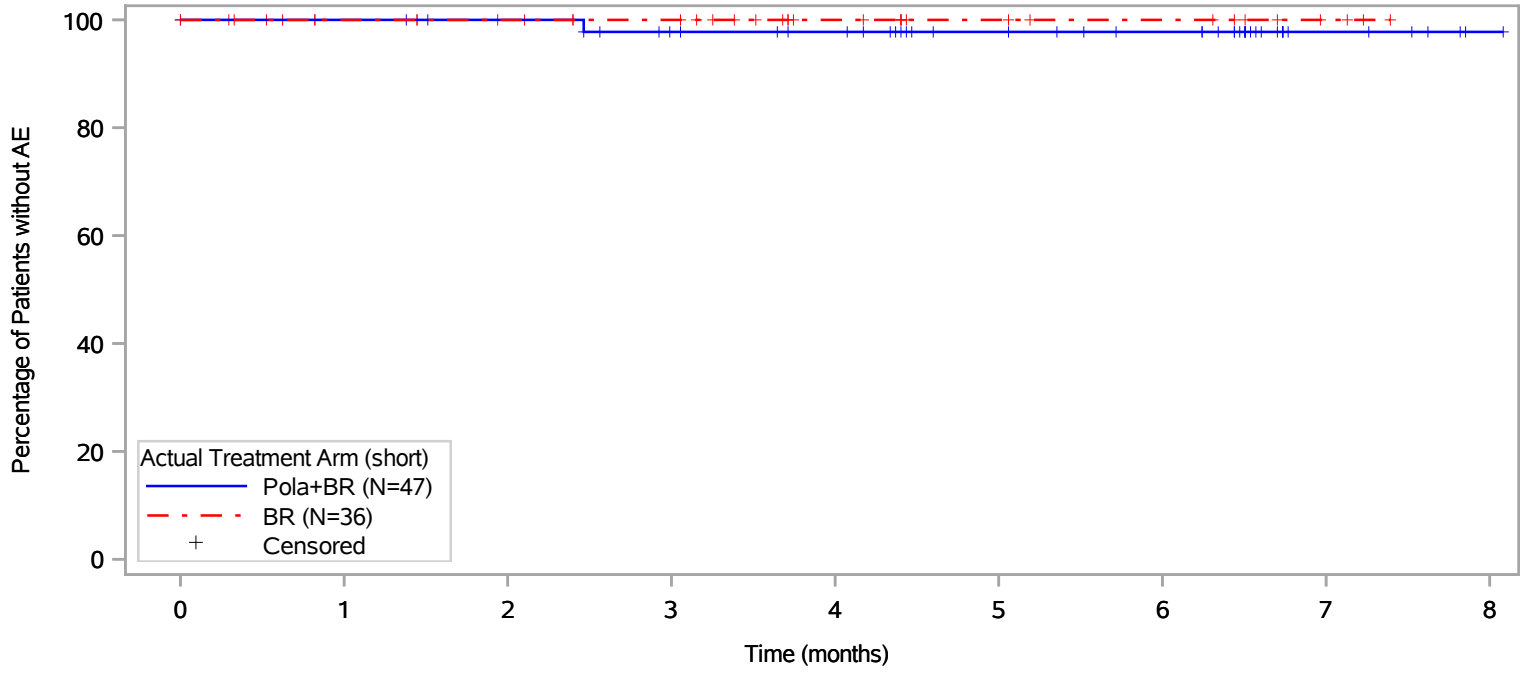
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, INTERSTITIAL LUNG DISEASE



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
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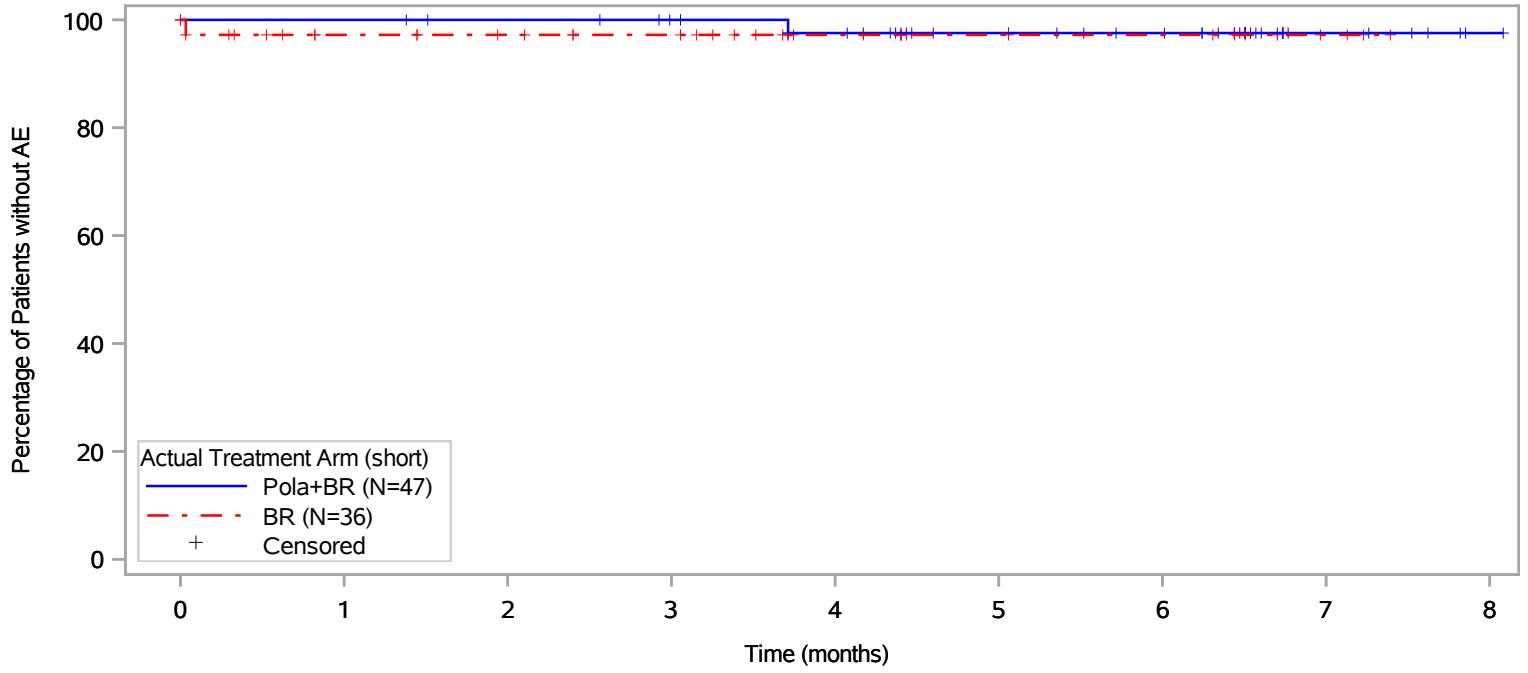
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION

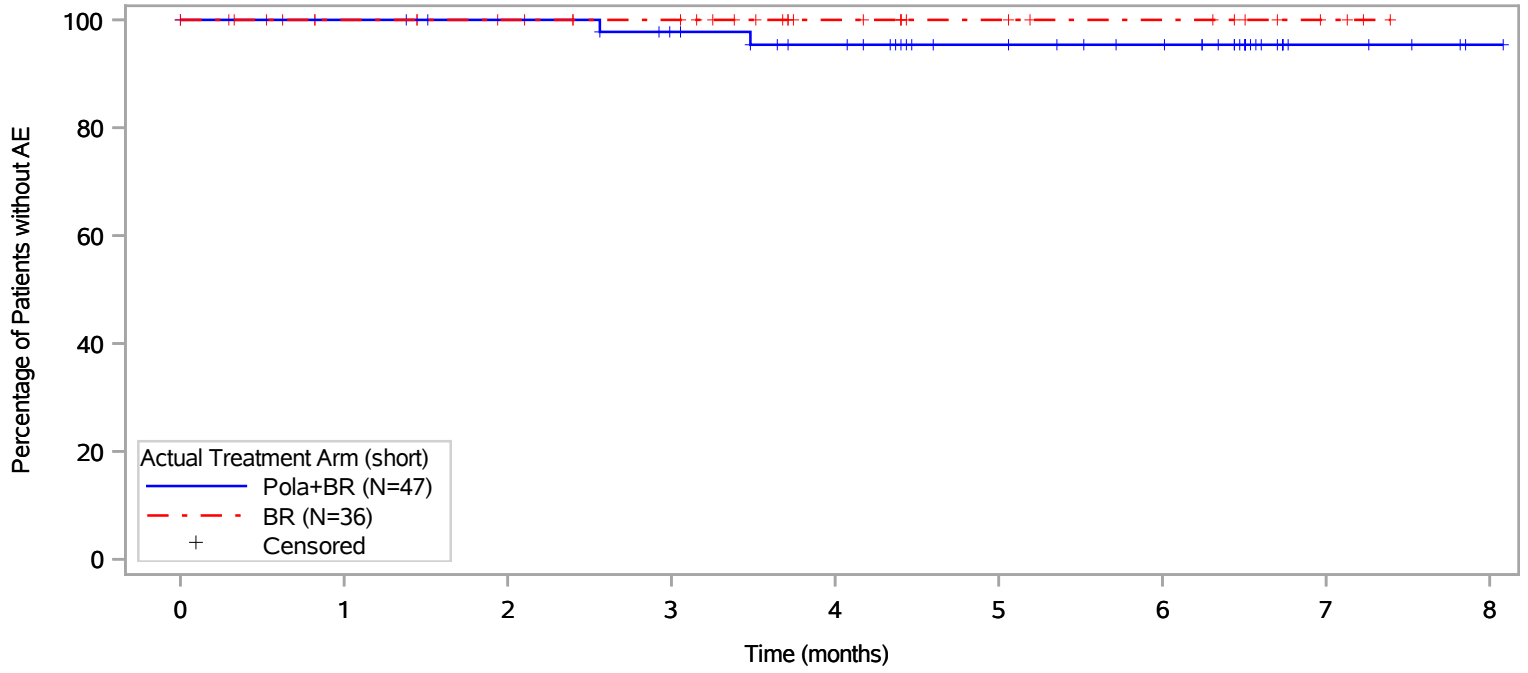


Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	44
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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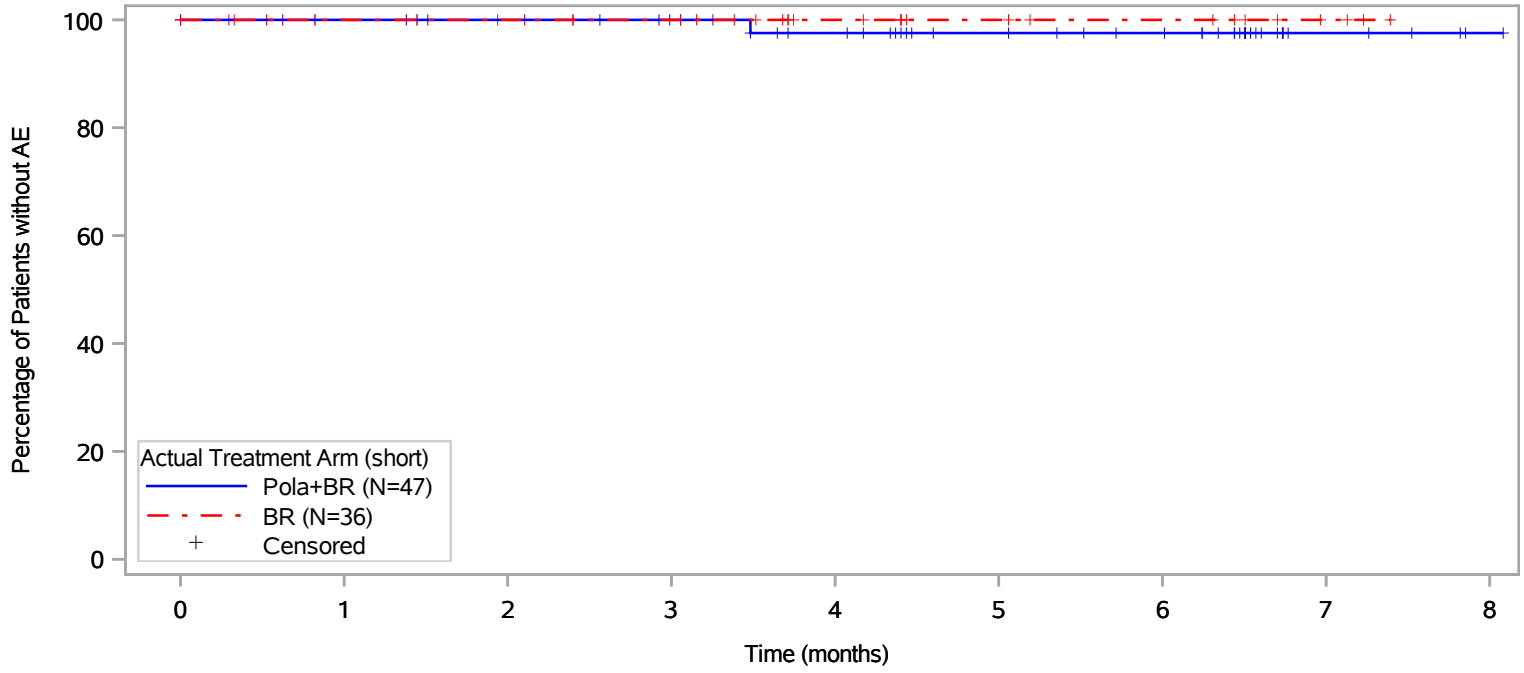
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DEEP VEIN THROMBOSIS

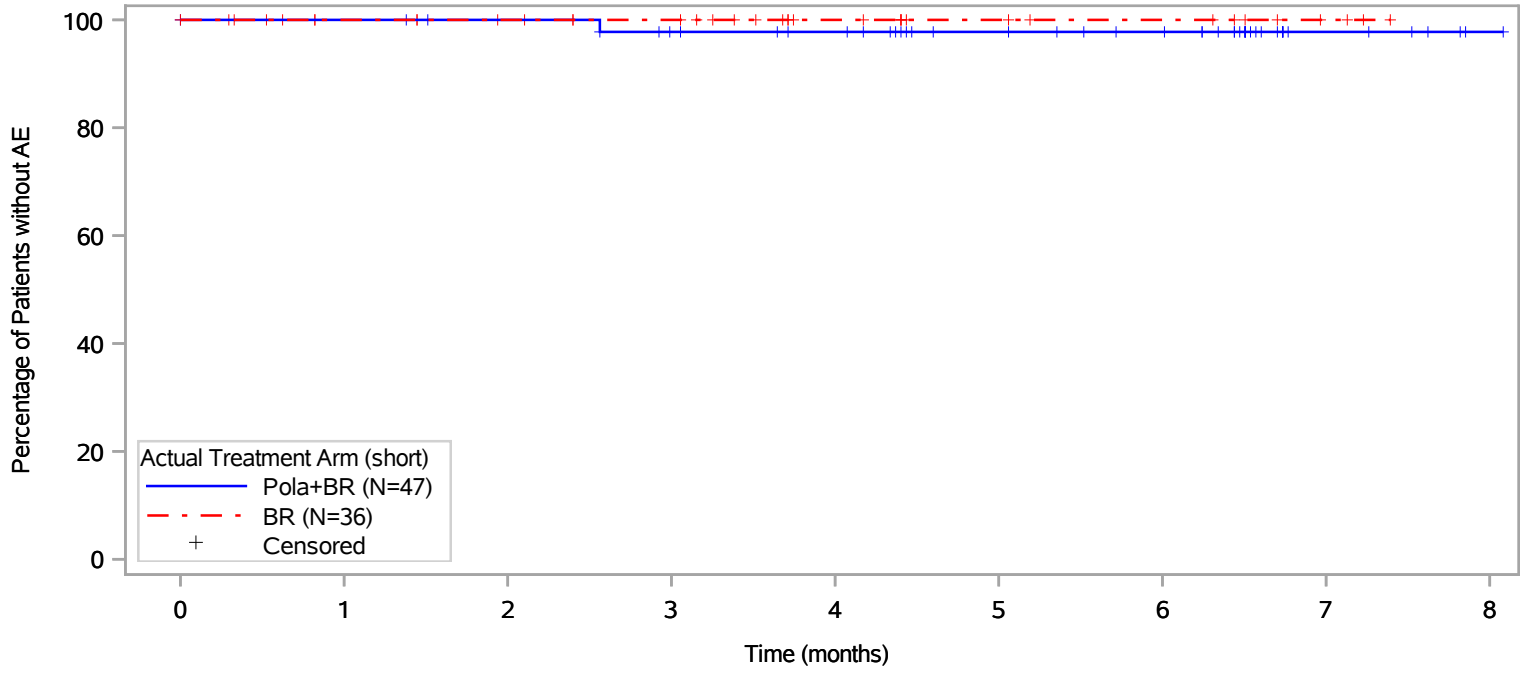


Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_soc_TTSAE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DISTRIBUTIVE SHOCK



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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02DEC2022 6:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

All

			Pola+BR (N=47)				BR (N=36)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS			47	100.0	5	10.6	36	100.0	3	8.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		47	100.0	0	-	36	100.0	1	2.8
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		47	100.0	2	4.3	36	100.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		47	100.0	1	2.1	36	100.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		47	100.0	4	8.5	36	100.0	2	5.6
INFECTIONS AND INFESTATIONS			47	100.0	2	4.3	36	100.0	2	5.6
INFECTIONS AND INFESTATIONS	PNEUMONIA		47	100.0	2	4.3	36	100.0	1	2.8
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		47	100.0	0	-	36	100.0	1	2.8
INVESTIGATIONS			47	100.0	2	4.3	36	100.0	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		47	100.0	1	2.1	36	100.0	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED		47	100.0	1	2.1	36	100.0	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			47	100.0	0	-	36	100.0	1	2.8
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		47	100.0	0	-	36	100.0	1	2.8
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			47	100.0	2	4.3	36	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		47	100.0	1	2.1	36	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		47	100.0	1	2.1	36	100.0	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 18:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=47)				BR (N=36)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	29	61.7	2	6.9	20	55.6	2	10.0
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	18	38.3	3	16.7	16	44.4	1	6.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	29	61.7	0	-	20	55.6	1	5.0
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	18	38.3	0	-	16	44.4	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	29	61.7	1	3.4	20	55.6	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	18	38.3	1	5.6	16	44.4	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	29	61.7	0	-	20	55.6	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	18	38.3	1	5.6	16	44.4	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	29	61.7	2	6.9	20	55.6	1	5.0
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	18	38.3	2	11.1	16	44.4	1	6.3
INFECTIONS AND INFESTATIONS		< 65	29	61.7	2	6.9	20	55.6	2	10.0
INFECTIONS AND INFESTATIONS		>= 65	18	38.3	0	-	16	44.4	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	29	61.7	2	6.9	20	55.6	1	5.0
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	18	38.3	0	-	16	44.4	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	29	61.7	0	-	20	55.6	1	5.0
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	18	38.3	0	-	16	44.4	0	-
INVESTIGATIONS		< 65	29	61.7	1	3.4	20	55.6	0	-
INVESTIGATIONS		>= 65	18	38.3	1	5.6	16	44.4	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	29	61.7	1	3.4	20	55.6	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	18	38.3	0	-	16	44.4	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	29	61.7	0	-	20	55.6	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	18	38.3	1	5.6	16	44.4	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	29	61.7	0	-	20	55.6	1	5.0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	18	38.3	0	-	16	44.4	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	29	61.7	0	-	20	55.6	1	5.0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	18	38.3	0	-	16	44.4	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	29	61.7	1	3.4	20	55.6	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	18	38.3	1	5.6	16	44.4	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	29	61.7	0	-	20	55.6	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	18	38.3	1	5.6	16	44.4	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	29	61.7	1	3.4	20	55.6	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	18	38.3	0	-	16	44.4	0	-

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 18:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=47)				BR (N=36)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	29	61.7	3	10.3	24	66.7	2	8.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	18	38.3	2	11.1	12	33.3	1	8.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	29	61.7	0	-	24	66.7	1	4.2
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	18	38.3	0	-	12	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	29	61.7	1	3.4	24	66.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	18	38.3	1	5.6	12	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	29	61.7	1	3.4	24	66.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	18	38.3	0	-	12	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	29	61.7	2	6.9	24	66.7	1	4.2
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	18	38.3	2	11.1	12	33.3	1	8.3
INFECTIONS AND INFESTATIONS		>=3	29	61.7	2	6.9	24	66.7	2	8.3
INFECTIONS AND INFESTATIONS		<3	18	38.3	0	-	12	33.3	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	29	61.7	2	6.9	24	66.7	1	4.2
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	18	38.3	0	-	12	33.3	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	29	61.7	0	-	24	66.7	1	4.2
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	18	38.3	0	-	12	33.3	0	-
INVESTIGATIONS		>=3	29	61.7	2	6.9	24	66.7	0	-
INVESTIGATIONS		<3	18	38.3	0	-	12	33.3	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	29	61.7	1	3.4	24	66.7	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	18	38.3	0	-	12	33.3	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	29	61.7	1	3.4	24	66.7	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	18	38.3	0	-	12	33.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	29	61.7	0	-	24	66.7	1	4.2
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	18	38.3	0	-	12	33.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	29	61.7	0	-	24	66.7	1	4.2
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	18	38.3	0	-	12	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	29	61.7	2	6.9	24	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	18	38.3	0	-	12	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	29	61.7	1	3.4	24	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	18	38.3	0	-	12	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	29	61.7	1	3.4	24	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	18	38.3	0	-	12	33.3	0	-

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24JAN2023 18:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=47)				BR (N=36)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	19.1	1	11.1	13	36.1	1	7.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	38	80.9	4	10.5	23	63.9	2	8.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Europe	9	19.1	0	-	13	36.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	38	80.9	0	-	23	63.9	1	4.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	19.1	0	-	13	36.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	38	80.9	2	5.3	23	63.9	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	19.1	0	-	13	36.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	38	80.9	1	2.6	23	63.9	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	19.1	1	11.1	13	36.1	1	7.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	38	80.9	3	7.9	23	63.9	1	4.3
INFECTIONS AND INFESTATIONS		Europe	9	19.1	0	-	13	36.1	1	7.7
INFECTIONS AND INFESTATIONS		Non-Europe	38	80.9	2	5.3	23	63.9	1	4.3
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	19.1	0	-	13	36.1	1	7.7
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	38	80.9	2	5.3	23	63.9	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	9	19.1	0	-	13	36.1	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	38	80.9	0	-	23	63.9	1	4.3
INVESTIGATIONS		Europe	9	19.1	0	-	13	36.1	0	-
INVESTIGATIONS		Non-Europe	38	80.9	2	5.3	23	63.9	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	9	19.1	0	-	13	36.1	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	38	80.9	1	2.6	23	63.9	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	19.1	0	-	13	36.1	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	38	80.9	1	2.6	23	63.9	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	9	19.1	0	-	13	36.1	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	38	80.9	0	-	23	63.9	1	4.3
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Europe	9	19.1	0	-	13	36.1	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	38	80.9	0	-	23	63.9	1	4.3
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	19.1	0	-	13	36.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	38	80.9	2	5.3	23	63.9	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	19.1	0	-	13	36.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	38	80.9	1	2.6	23	63.9	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Europe	9	19.1	0	-	13	36.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	38	80.9	1	2.6	23	63.9	0	-

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 18:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=47)				BR (N=36)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	34	72.3	4	11.8	24	66.7	3	12.5
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	13	27.7	1	7.7	12	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	34	72.3	0	-	24	66.7	1	4.2
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	13	27.7	0	-	12	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	34	72.3	1	2.9	24	66.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	13	27.7	1	7.7	12	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	34	72.3	1	2.9	24	66.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	13	27.7	0	-	12	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	34	72.3	3	8.8	24	66.7	2	8.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	13	27.7	1	7.7	12	33.3	0	-
INFECTIONS AND INFESTATIONS		Male	34	72.3	1	2.9	24	66.7	2	8.3
INFECTIONS AND INFESTATIONS		Female	13	27.7	1	7.7	12	33.3	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	34	72.3	1	2.9	24	66.7	1	4.2
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	13	27.7	1	7.7	12	33.3	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	34	72.3	0	-	24	66.7	1	4.2
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	13	27.7	0	-	12	33.3	0	-
INVESTIGATIONS		Male	34	72.3	2	5.9	24	66.7	0	-
INVESTIGATIONS		Female	13	27.7	0	-	12	33.3	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	34	72.3	1	2.9	24	66.7	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	13	27.7	0	-	12	33.3	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	34	72.3	1	2.9	24	66.7	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	13	27.7	0	-	12	33.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	34	72.3	0	-	24	66.7	1	4.2
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	13	27.7	0	-	12	33.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	34	72.3	0	-	24	66.7	1	4.2
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	13	27.7	0	-	12	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	34	72.3	0	-	24	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	13	27.7	2	15.4	12	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	34	72.3	0	-	24	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	13	27.7	1	7.7	12	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	34	72.3	0	-	24	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	13	27.7	1	7.7	12	33.3	0	-

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24JAN2023 18:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.6583	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.6310	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.6232	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.6434	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.6265	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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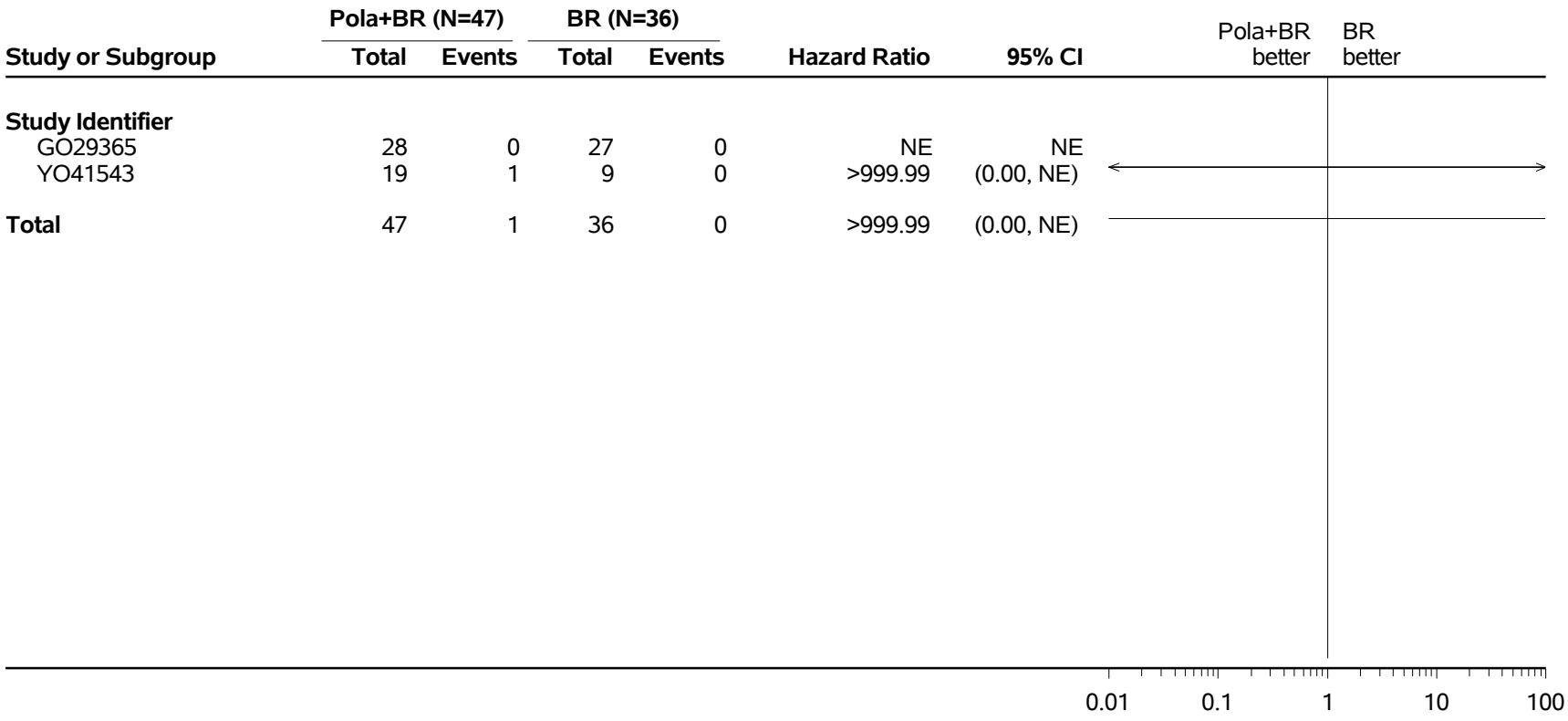
06APR2023 19:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	0	27	0	NE	NE
YO41543	19	1	9	0	>999.99	(0.00, NE)
Total	47	1	36	0	>999.99	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTADAP_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 25OCT2023 8:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi^2	Df	P-value	I^2 (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	1	5.3	18	94.7	9	25.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.6583	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9988

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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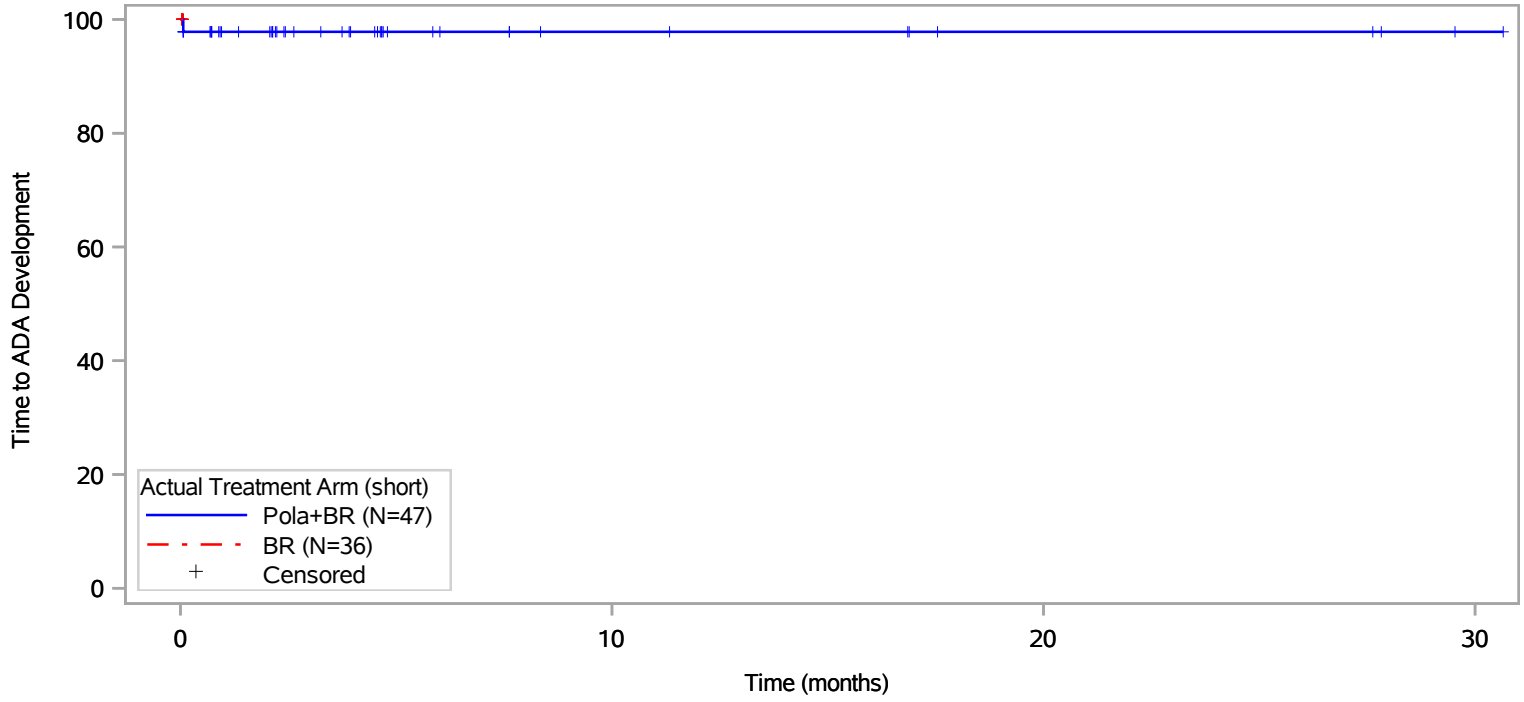
25OCT2023 8:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=47)	47	24	12	8	7	7	4	4	4	4	1
BR (N=36)	36	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	22	34	38	39	39	42	42	42	42	45
BR (N=36)	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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06APR2023 19:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

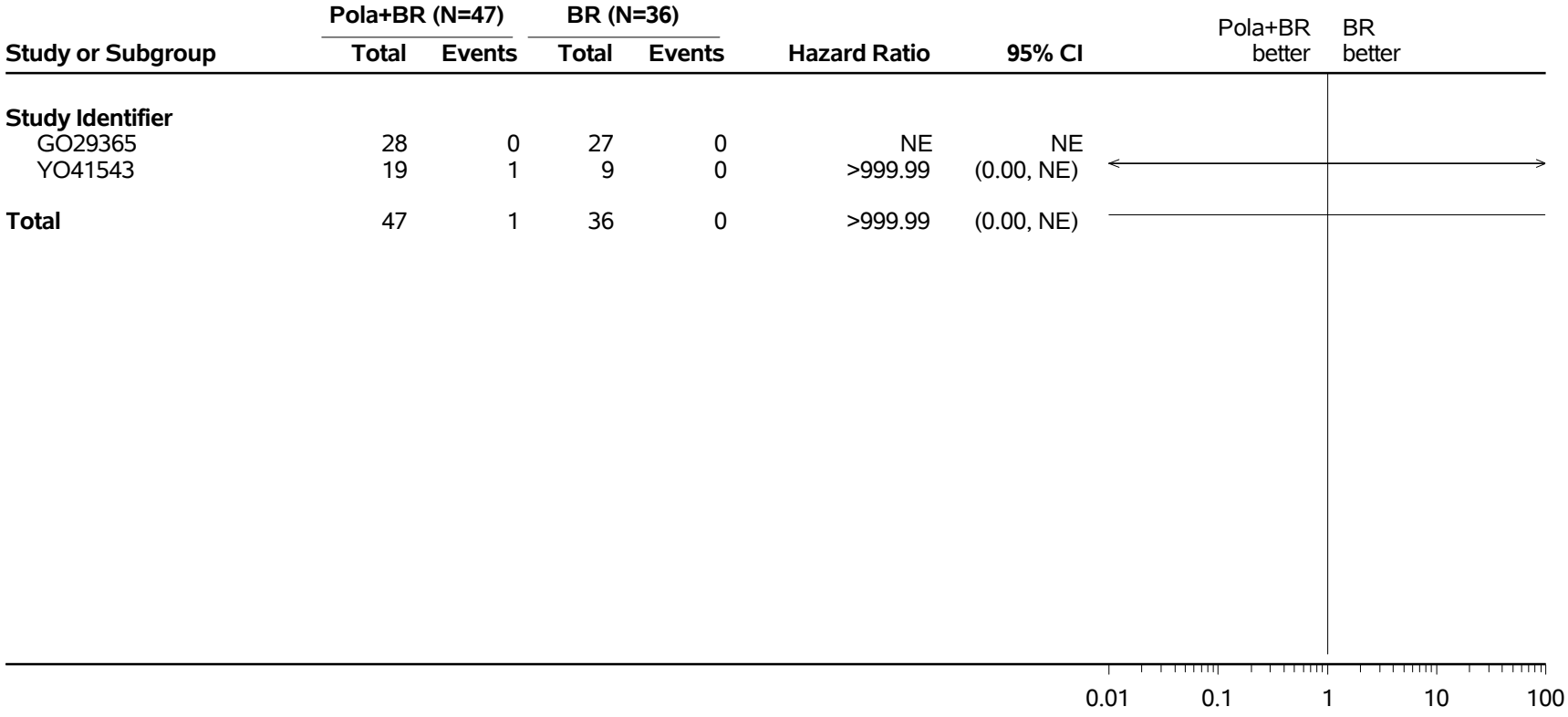
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.4572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTALOPE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 9:45

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	0	27	0	NE	NE
YO41543	19	1	9	0	>999.99	(0.00, NE)
Total	47	1	36	0	>999.99	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTALOPE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 20:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR													
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	1	5.3	18	94.7	9	25.0	0	-	9	100.0	0.4913	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4093	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9984

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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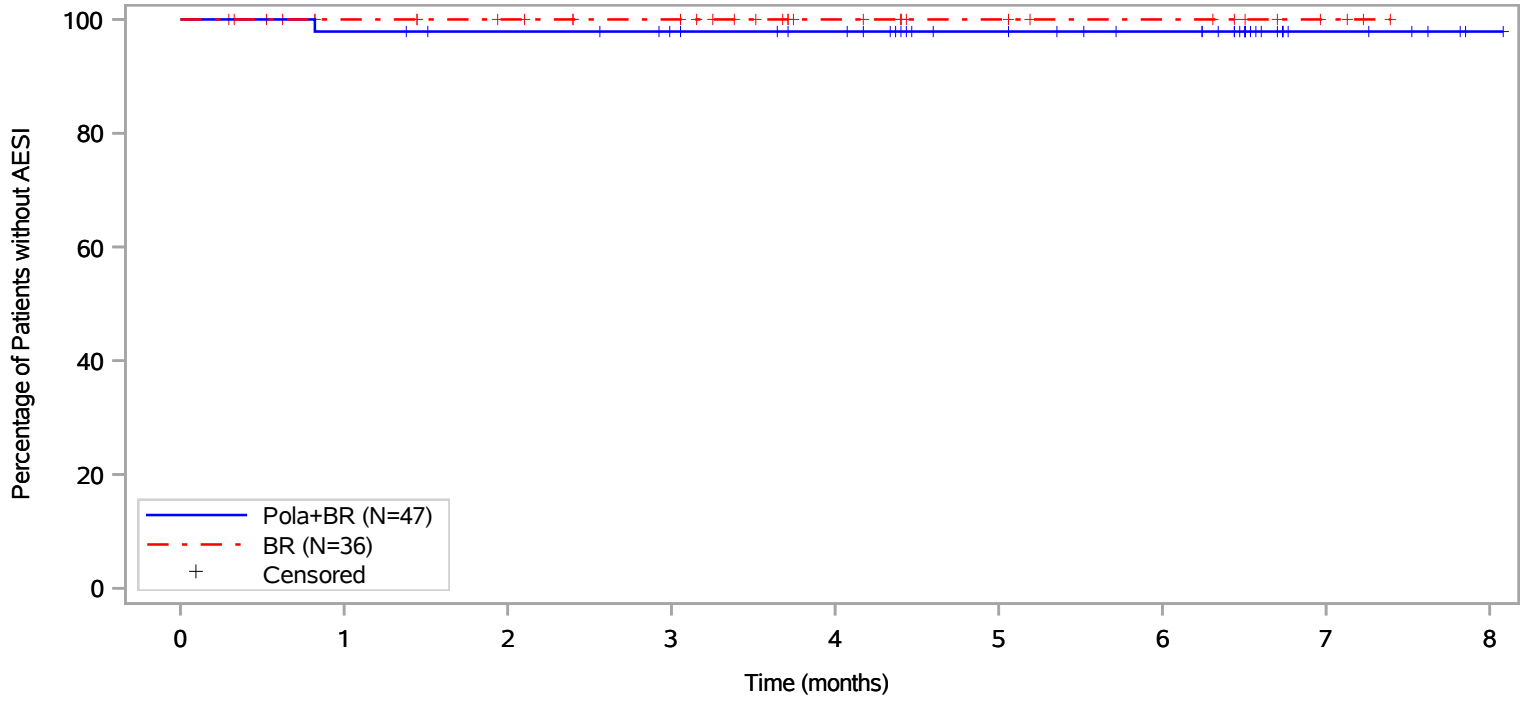
17DEC2022 21:53

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	46	44	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTALOPE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:48

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTALOPE35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 22:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTALOPE35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
16DEC2022 16:12

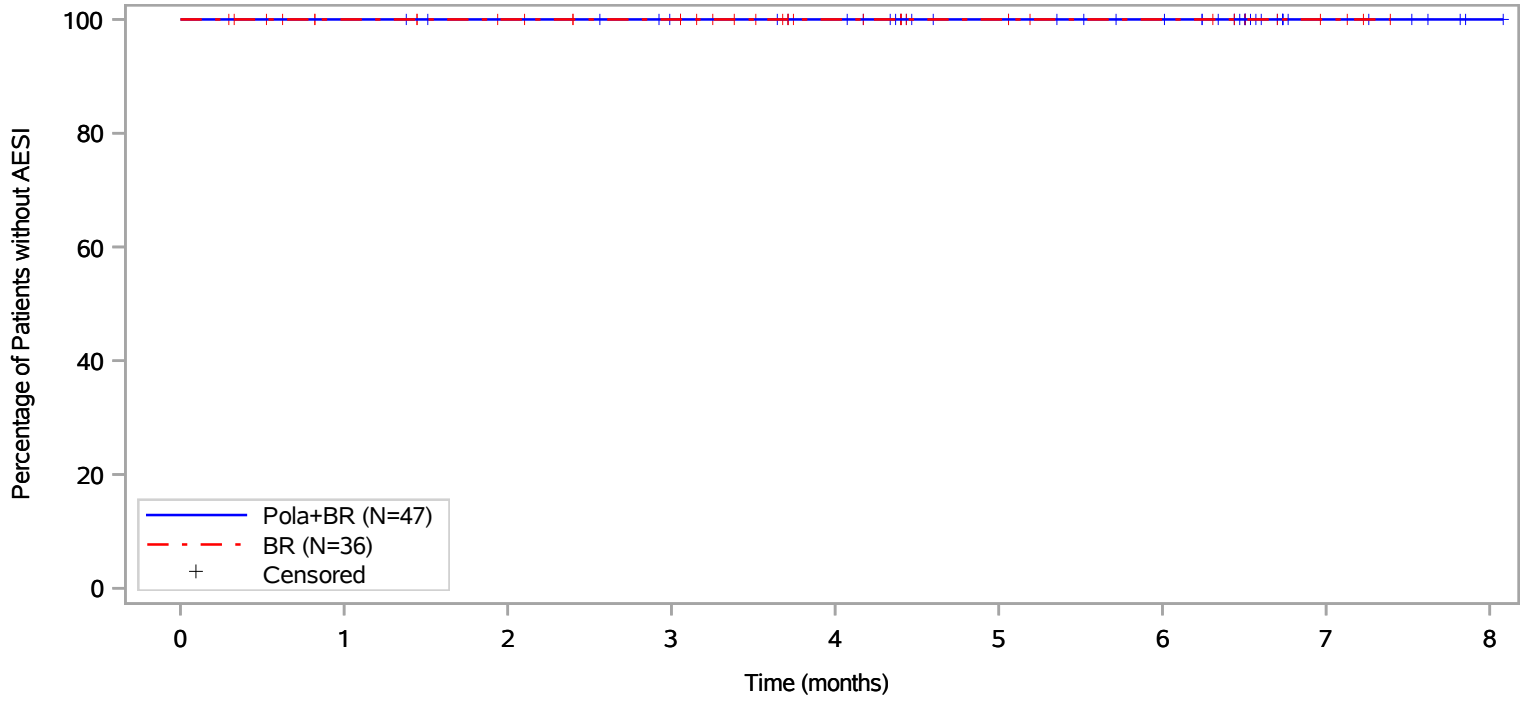
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTALOPE35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 21:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_TTALOPE35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 23:57

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTALOPES_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:53

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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16DEC2022 18:49

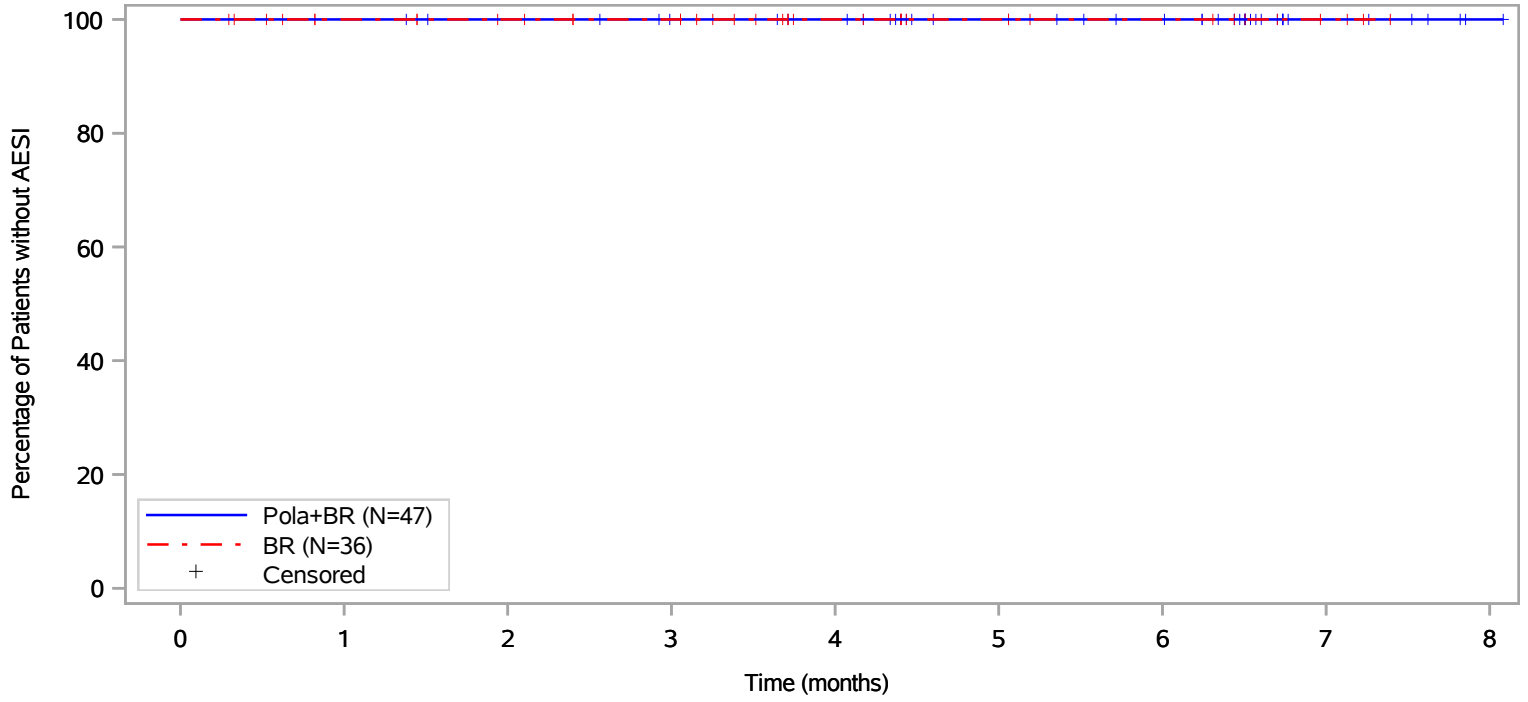
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTALOPES_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 15:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Alopecia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTALOPES_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 2:16

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	28	59.6	19	40.4	36	100.0	9	25.0	27	75.0	0.0303	2.17	1.02	4.63		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	20	58.8	14	41.2	24	66.7	6	25.0	18	75.0	0.0847	2.17	0.87	5.43		Convergence criterion (GCONV=1E-8) satisfied.	0.9859
	Female	13	27.7	8	61.5	5	38.5	12	33.3	3	25.0	9	75.0	0.1888	2.03	0.53	7.83		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	21	72.4	8	27.6	20	55.6	5	25.0	15	75.0	0.0164	3.09	1.15	8.34		Convergence criterion (GCONV=1E-8) satisfied.	0.3088
	>= 65	18	38.3	7	38.9	11	61.1	16	44.4	4	25.0	12	75.0	0.8622	1.32	0.36	4.83		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	17	58.6	12	41.4	24	66.7	6	25.0	18	75.0	0.1513	1.71	0.66	4.43		Convergence criterion (GCONV=1E-8) satisfied.	0.5458
	<3	18	38.3	11	61.1	7	38.9	12	33.3	3	25.0	9	75.0	0.1100	2.75	0.76	9.97		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	4	44.4	5	55.6	13	36.1	0	-	13	100.0	0.0487	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	24	63.2	14	36.8	23	63.9	9	39.1	14	60.9	0.2283	1.60	0.74	3.46		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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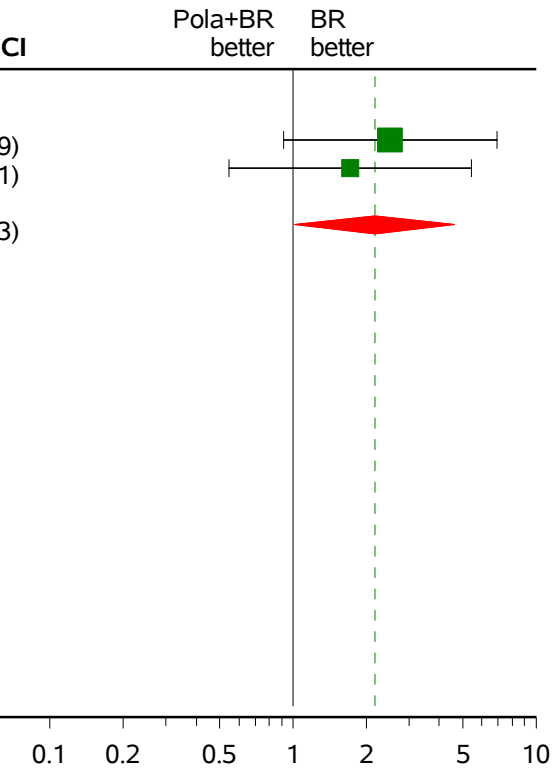
01DEC2022 1:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=47) Total	Pola+BR (N=47) Events	BR (N=36) Total	BR (N=36) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	28	16	27	5	2.51	(0.91, 6.89)
YO41543	19	12	9	4	1.72	(0.55, 5.41)
Total	47	28	36	9	2.17	(1.02, 4.63)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	16	57.1	12	42.9	27	75.0	5	18.5	22	81.5	0.0649	2.51	0.91	6.89		Convergence criterion (GCONV=1E-8) satisfied.	56.2						
	YO41543	19	40.4	12	63.2	7	36.8	9	25.0	4	44.4	5	55.6	0.3472	1.72	0.55	5.41		Convergence criterion (GCONV=1E-8) satisfied.	43.8						
	Total	47	100.0	28	59.6	19	40.4	36	100.0	9	25.0	27	75.0	0.0303	2.17	1.02	4.63		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.24	1	0.6263	0.00	2.01	0.0446

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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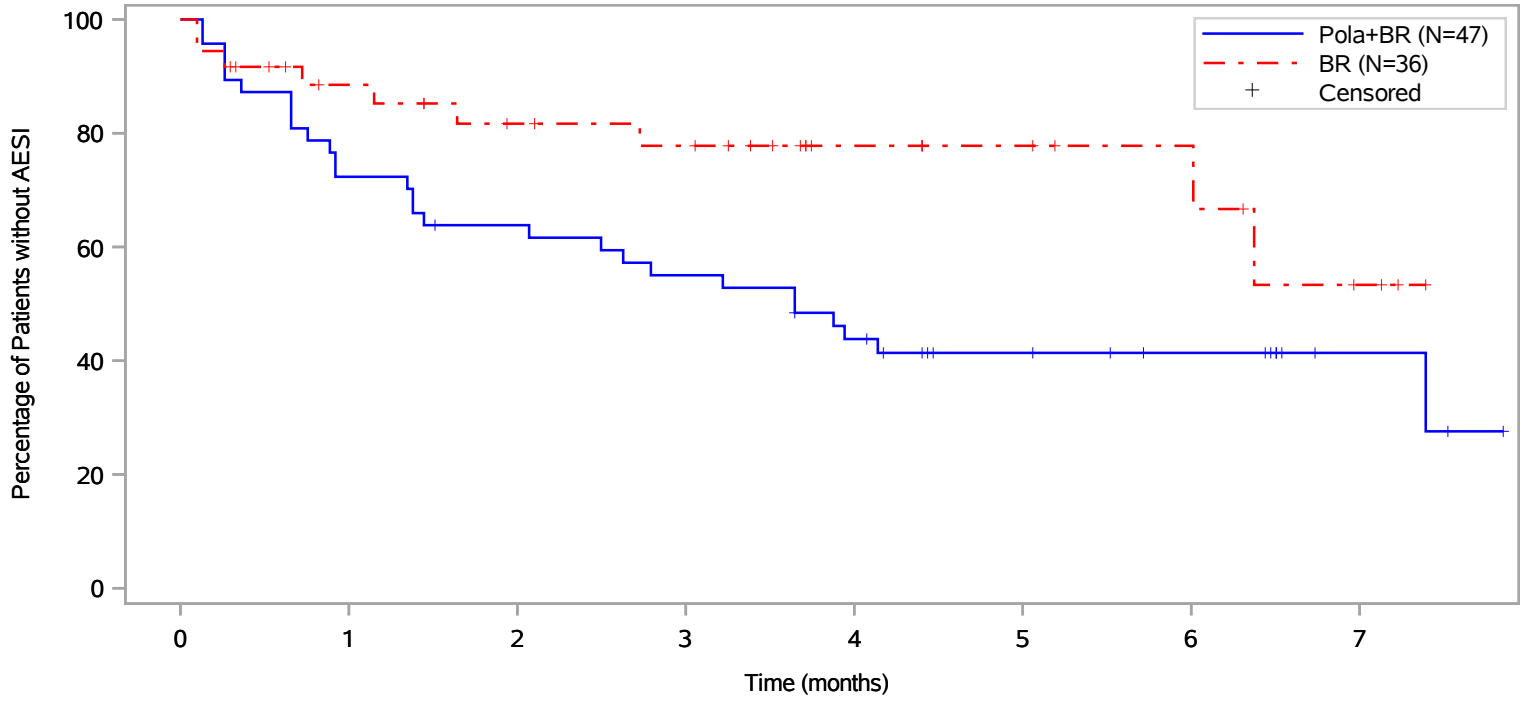
16DEC2022 10:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=47)	47	34	29	25	19	13	10	3
BR (N=36)	36	27	22	20	12	9	7	3
Patients censored								
Pola+BR (N=47)	0	0	1	1	2	7	10	17
BR (N=36)	0	5	8	9	17	20	22	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

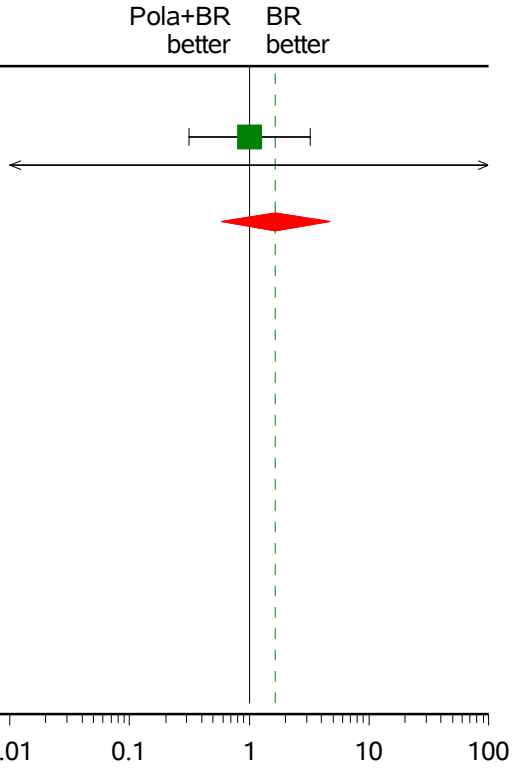
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	13	27.7	34	72.3	36	100.0	5	13.9	31	86.1	0.3468	1.65	0.58	4.69		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	7	20.6	27	79.4	24	66.7	5	20.8	19	79.2	0.5189	0.72	0.22	2.33		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	6	46.2	7	53.8	12	33.3	0	-	12	100.0	0.0165	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	10	34.5	19	65.5	20	55.6	3	15.0	17	85.0	0.2391	2.22	0.60	8.20		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	2	12.5	14	87.5	0.7432	0.73	0.10	5.22		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	8	27.6	21	72.4	24	66.7	3	12.5	21	87.5	0.4958	1.50	0.39	5.80		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	5	27.8	13	72.2	12	33.3	2	16.7	10	83.3	0.5311	1.67	0.32	8.66		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	12	31.6	26	68.4	23	63.9	5	21.7	18	78.3	0.6301	1.32	0.46	3.77		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTANEIM35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:34

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	7	27	5	1.00	(0.31, 3.21)
YO41543	19	6	9	0	>999.99	(0.00, NE)
Total	47	13	36	5	1.65	(0.58, 4.69)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	7	25.0	21	75.0	27	75.0	5	18.5	22	81.5	0.9956	1.00	0.31	3.21		Convergence criterion (GCONV=1E-8) satisfied.		100.0						
	YO41543	19	40.4	6	31.6	13	68.4	9	25.0	0	-	9	100.0	0.0825	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		0.0						
	Total	47	100.0	13	27.7	34	72.3	36	100.0	5	13.9	31	86.1	0.3468	1.65	0.58	4.69		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.71	1	0.4008	0.00	0.94	0.3452

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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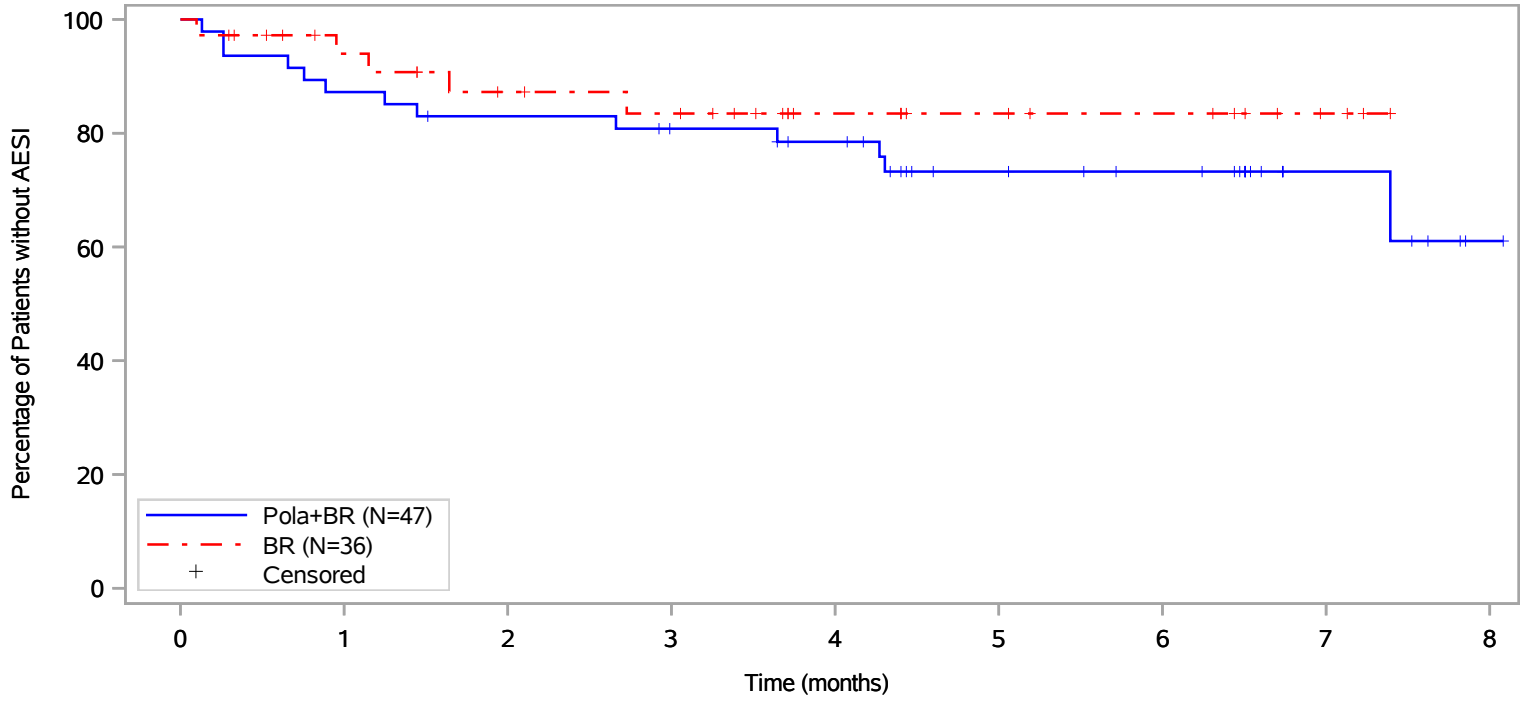
15DEC2022 20:13

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	41	38	35	32	23	20	6	1
BR (N=36)	36	29	24	22	14	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	1	3	5	12	15	29	33
BR (N=36)	0	5	8	9	17	21	23	28	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 22:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.8425	0.90	0.08	10.72		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8085	0.90	0.08	10.50		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.5915	0.62	0.04	10.25		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.6171				*	WARNING: Iteration limit reached without convergence.	-
	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.6862	0.55	0.03	8.90		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.4186	0.38	0.02	6.47		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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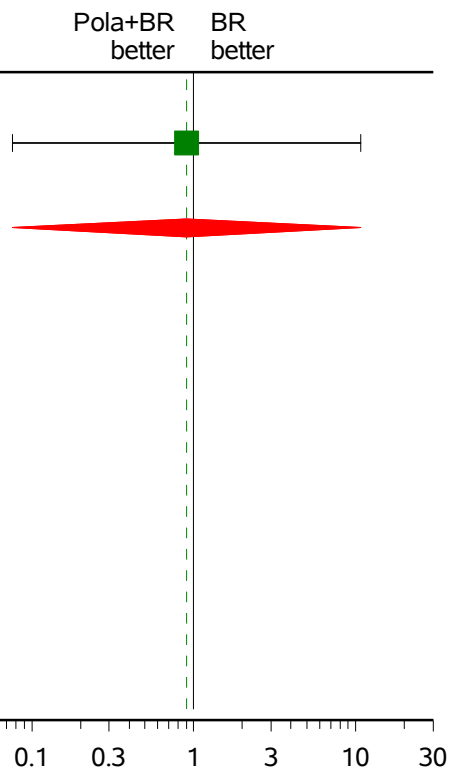
02DEC2022 20:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	2	27	1	0.90	(0.08, 10.72)
YO41543	19	0	9	0	NE	NE
Total	47	2	36	1	0.90	(0.08, 10.72)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..CE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTANEIMS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 15:20

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	2	7.1	26	92.9	27	75.0	1	3.7	26	96.3	0.9360	0.90	0.08	10.72		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.8425	0.90	0.08	10.72		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	-0.08	0.9360

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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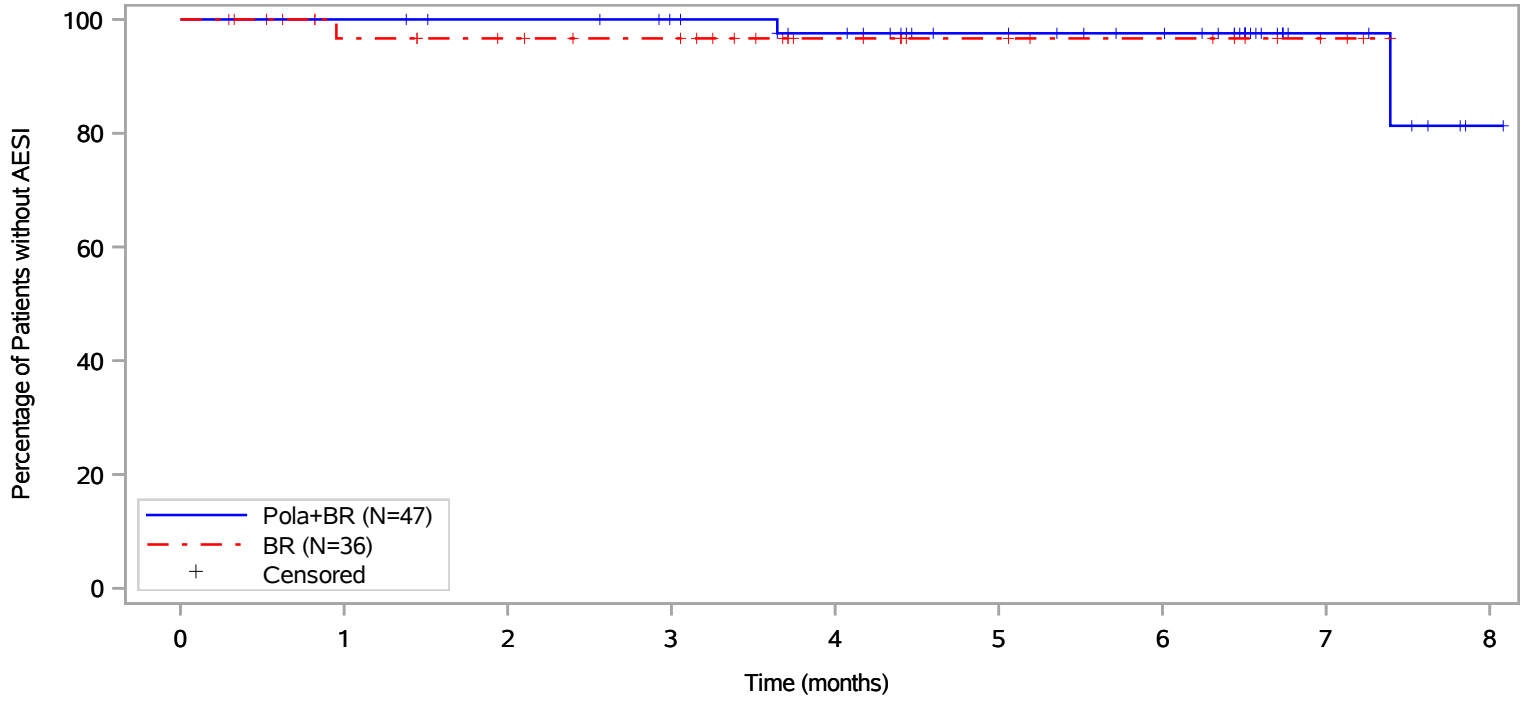
15DEC2022 20:05

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Anemia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	38	31	27	7	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	15	19	39	44
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTANEIMS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 0:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	2	4.3	45	95.7	36	100.0	5	13.9	31	86.1	0.0485	0.21	0.04	1.10		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	2	5.9	32	94.1	24	66.7	4	16.7	20	83.3	0.0790	0.22	0.04	1.23		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	2	10.0	18	90.0	0.1945	0.19	0.02	2.32		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	3	18.8	13	81.3	0.1367	0.21	0.02	2.08		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	2	6.9	27	93.1	24	66.7	3	12.5	21	87.5	0.2479	0.31	0.05	1.91		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	2	16.7	10	83.3	0.0697	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	4	17.4	19	82.6	0.0557	0.22	0.04	1.20		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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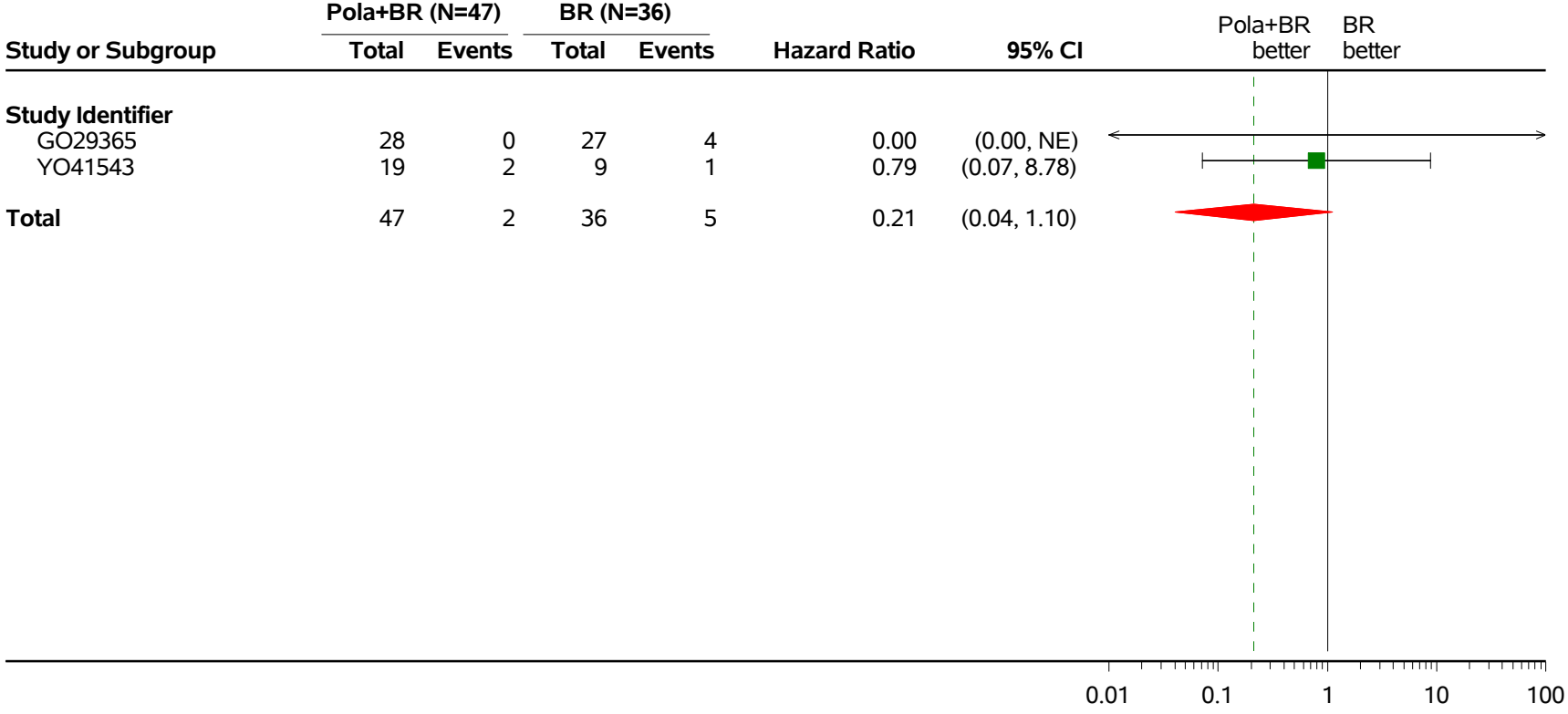
01DEC2022 20:16

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=47) Total	Pola+BR (N=47) Events	BR (N=36) Total	BR (N=36) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	28	0	27	4	0.00	(0.00, NE)
YO41543	19	2	9	1	0.79	(0.07, 8.78)
Total	47	2	36	5	0.21	(0.04, 1.10)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTCTAAR_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 20:41

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	4	14.8	23	85.2	0.0232	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	YO41543	19	40.4	2	10.5	17	89.5	9	25.0	1	11.1	8	88.9	0.8488	0.79	0.07	8.78		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	47	100.0	2	4.3	45	95.7	36	100.0	5	13.9	31	86.1	0.0485	0.21	0.04	1.10		Convergence criterion (GCONV=1E-8) satisfied.	100.0	1.17	1	0.2790	14.68	-1.85	0.0650

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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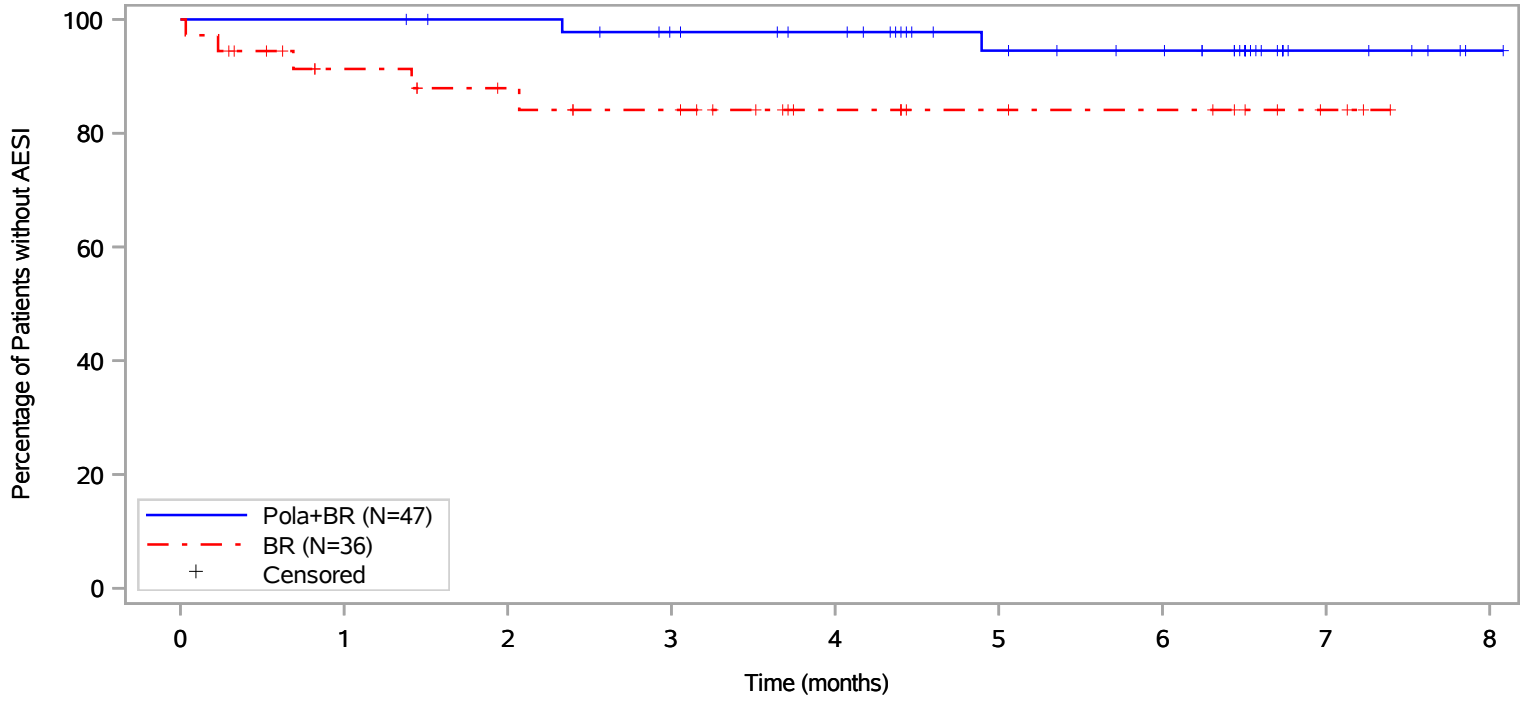
17DEC2022 22:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	29	26	6	1
BR (N=36)	36	27	23	20	13	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	19	39	44
BR (N=36)	0	6	9	11	18	22	23	28	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 21:53

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

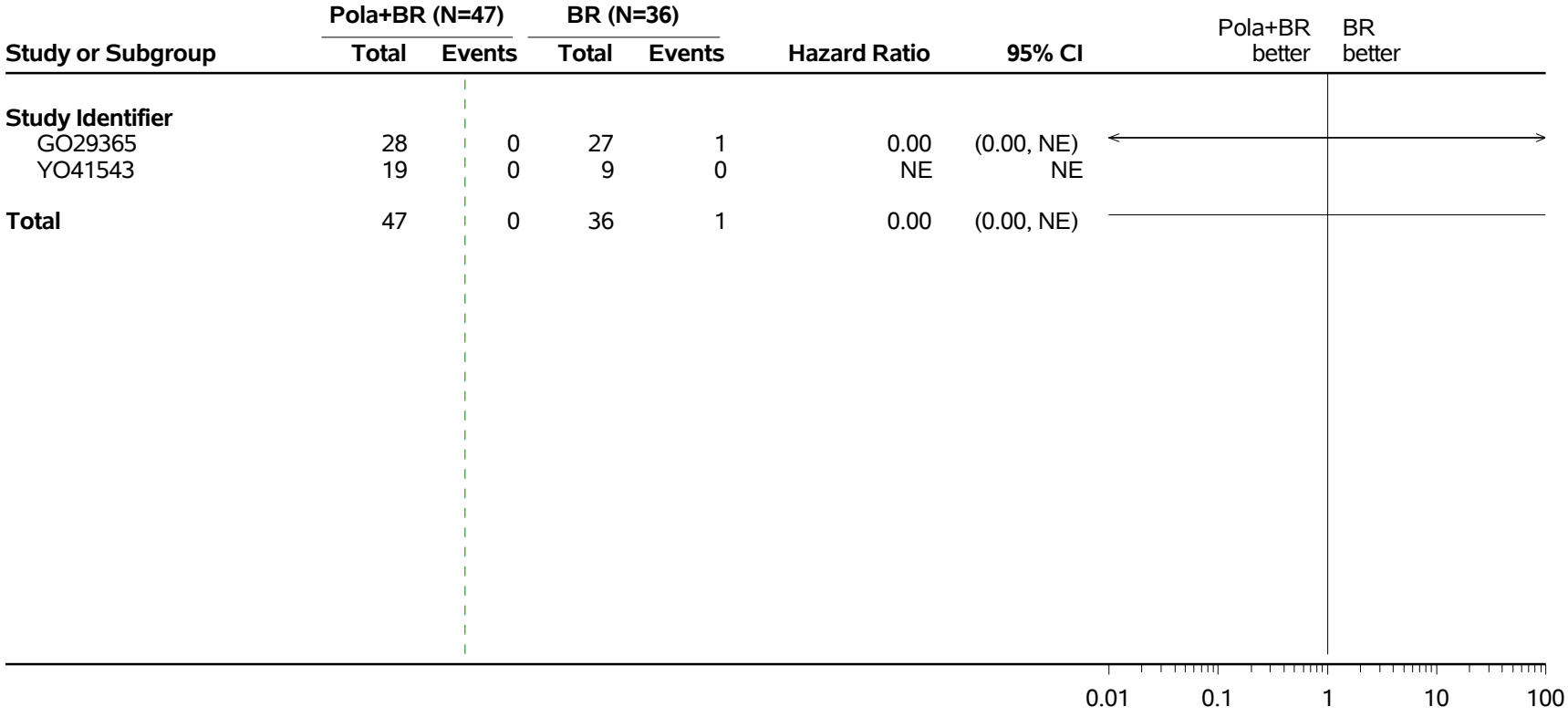
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTCTAAR35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 10:04

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	0	27	1	0.00	(0.00, NE)
YO41543	19	0	9	0	NE	NE
Total	47	0	36	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9983

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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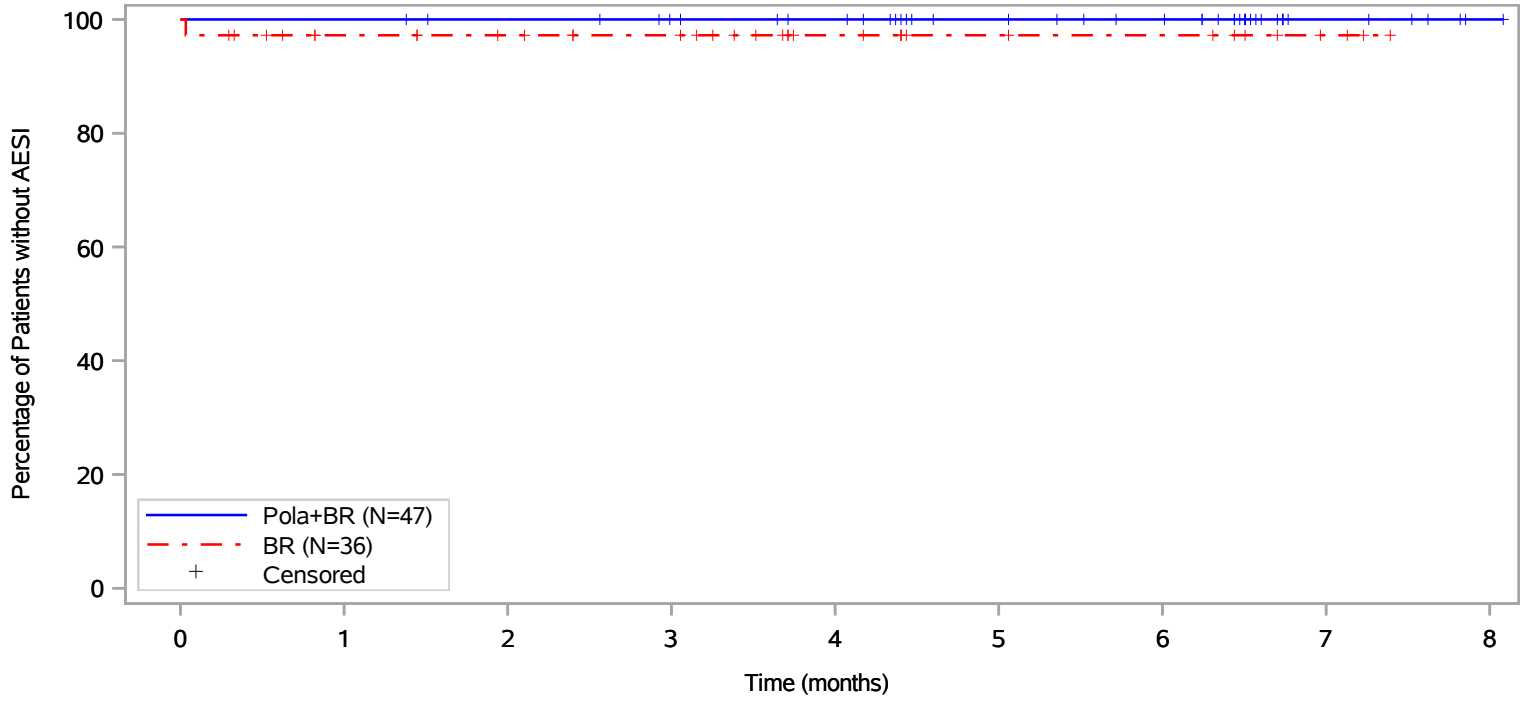
17DEC2022 21:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 0:03

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2717	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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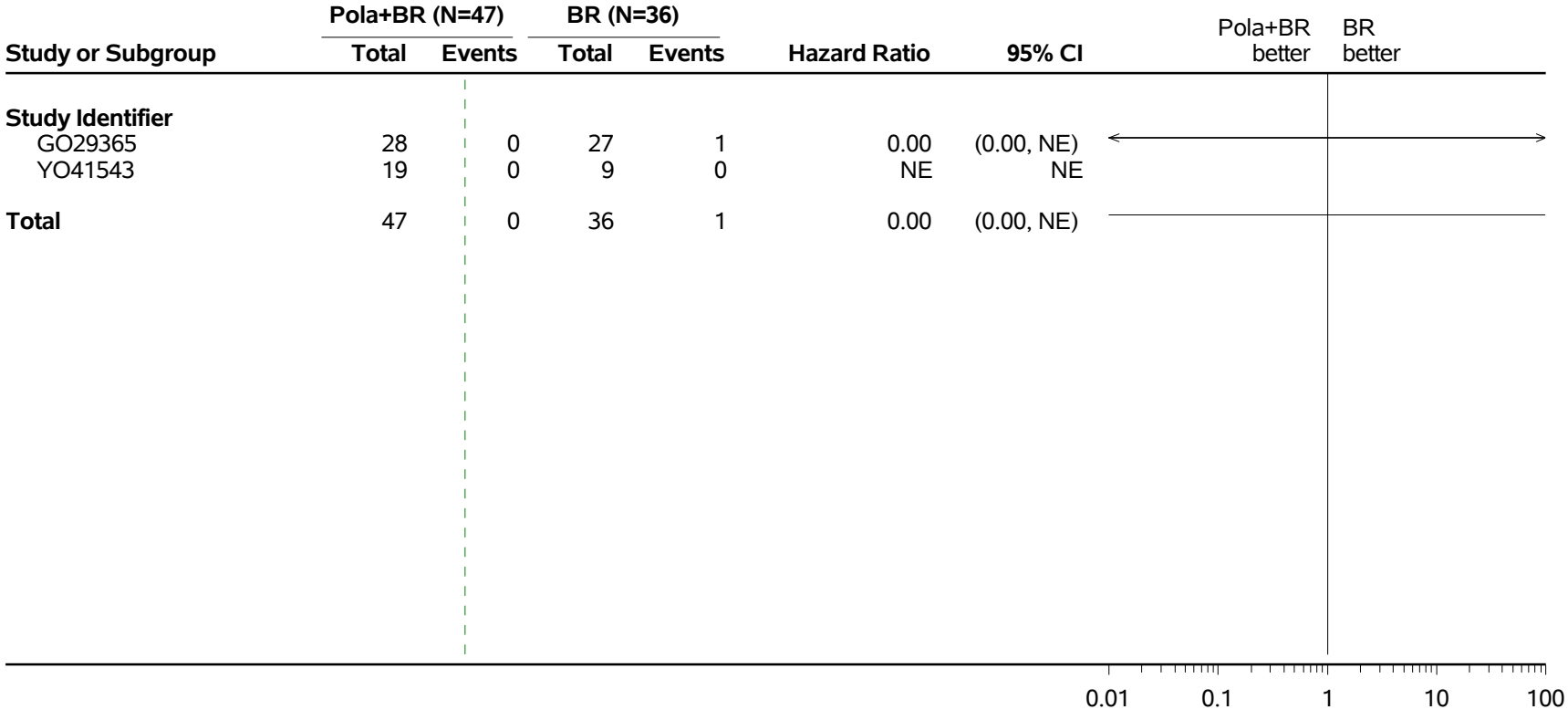
25JAN2023 10:16

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	0	27	1	0.00	(0.00, NE)
YO41543	19	0	9	0	NE	NE
Total	47	0	36	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	Total	47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2532	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		100.0	NE	NE	NE	NE	0.00	0.9983

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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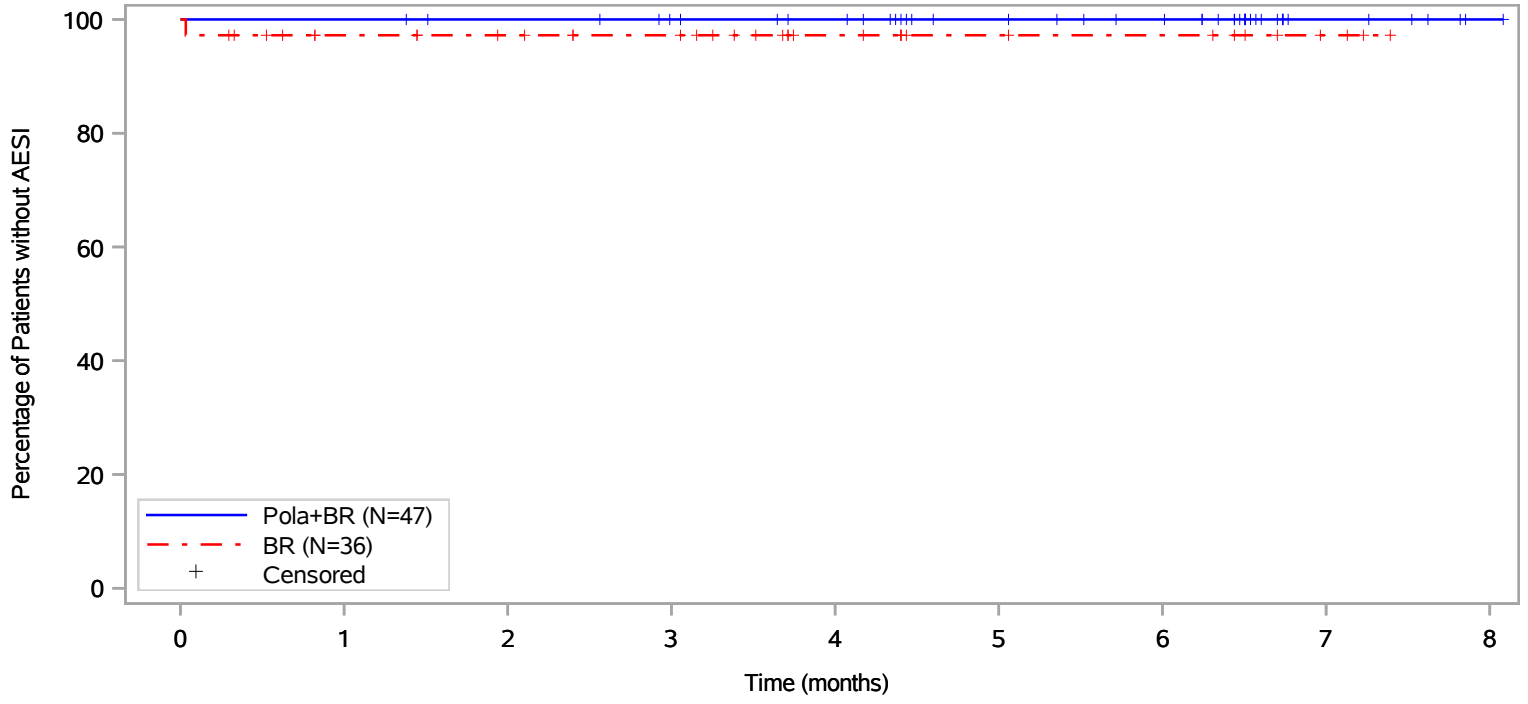
17DEC2022 15:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTCTAARS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 2:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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01DEC2022 22:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTDDIN_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 17:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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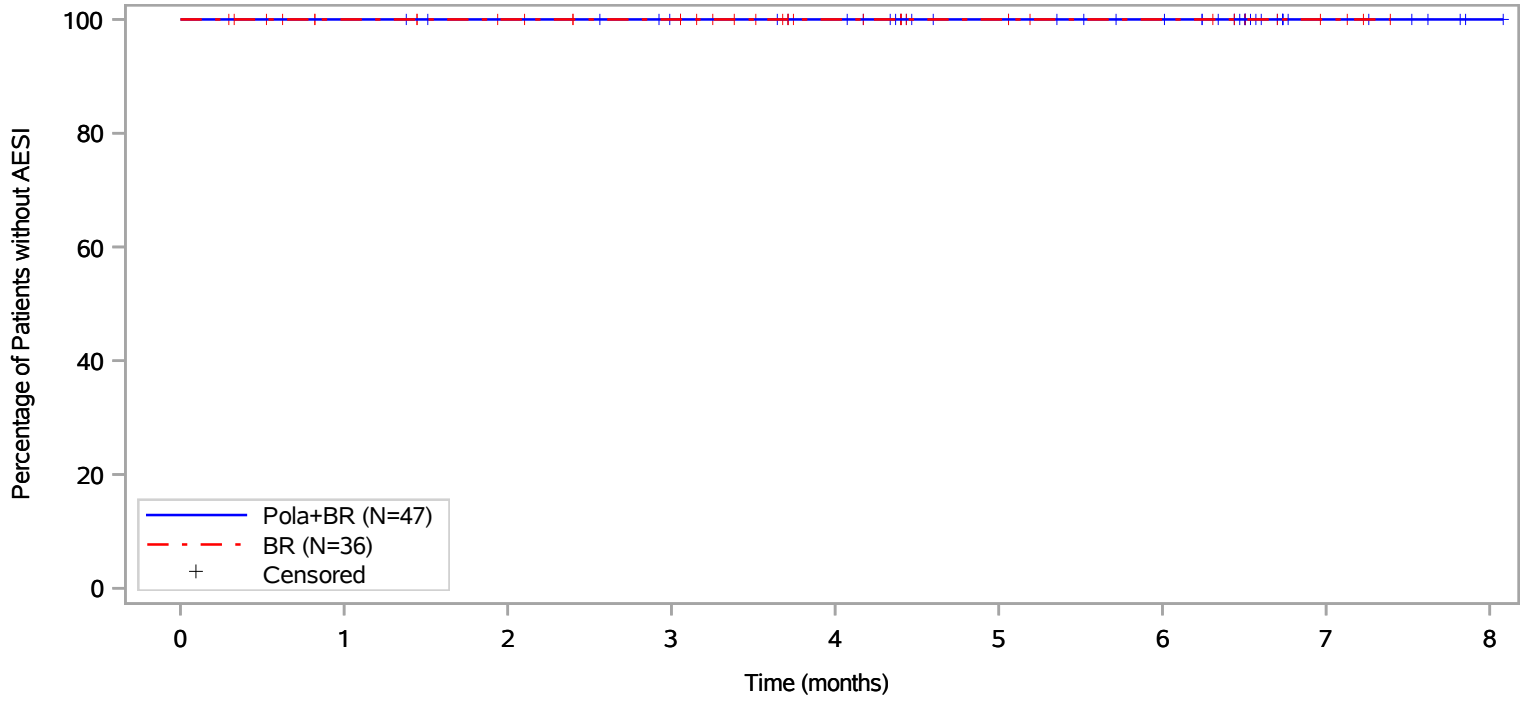
17DEC2022 22:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Drug Drug Interaction
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 22:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

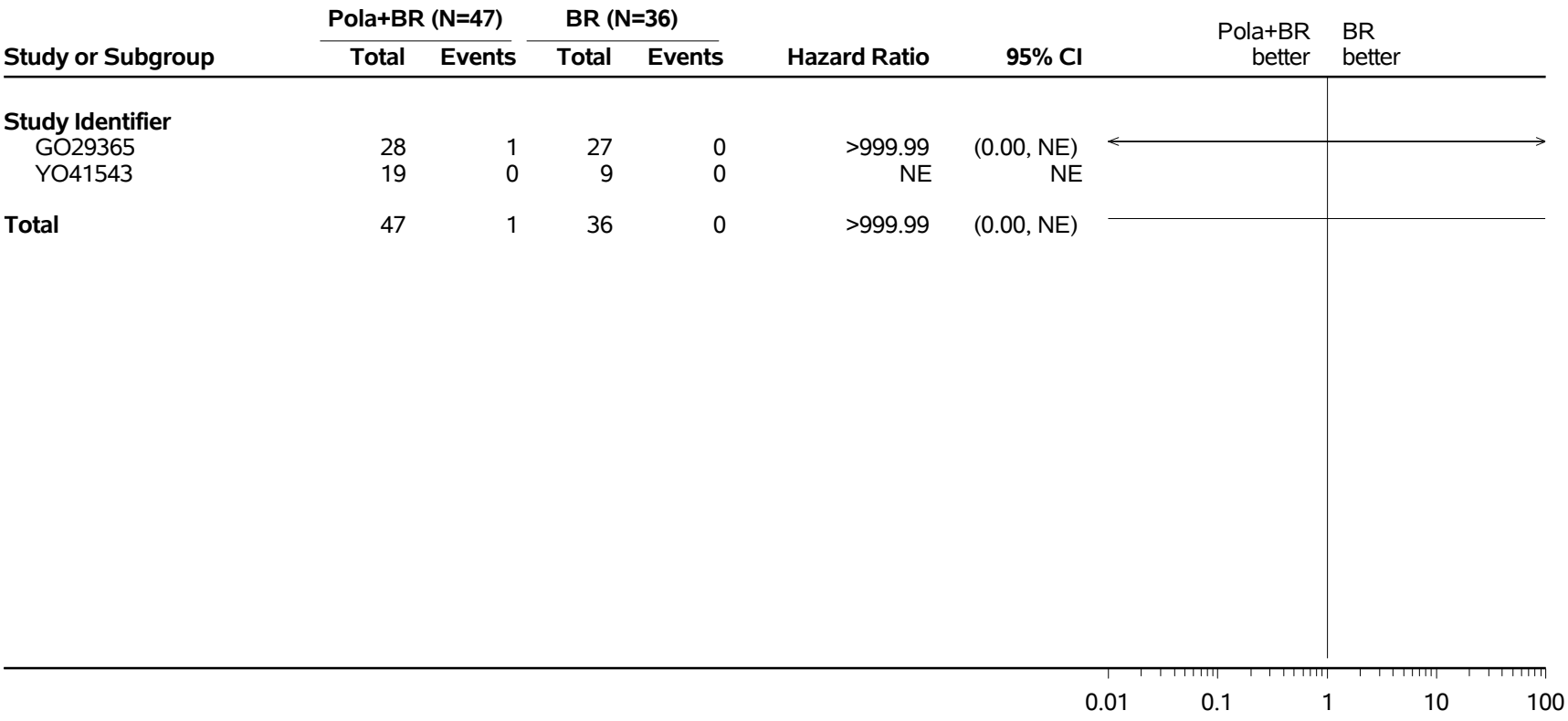
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.6336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTDYSGUE_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 10:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	1	27	0	>999.99	(0.00, NE)
YO41543	19	0	9	0	NE	NE
Total	47	1	36	0	>999.99	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTDYSGUE_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 21:51

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR													
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	0.5637	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.5701	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9987

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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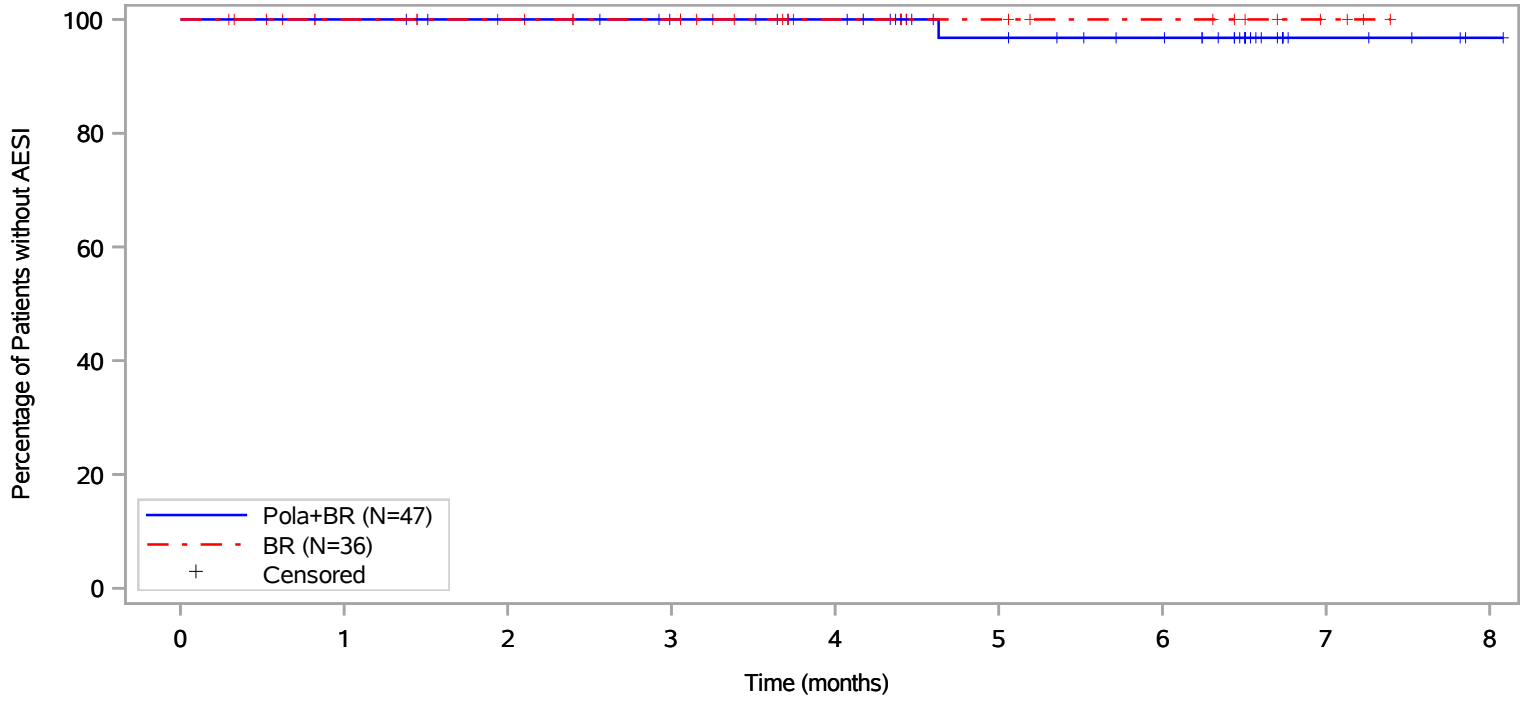
17DEC2022 22:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	30	26	5	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 22:06

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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02DEC2022 22:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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17DEC2022 15:29

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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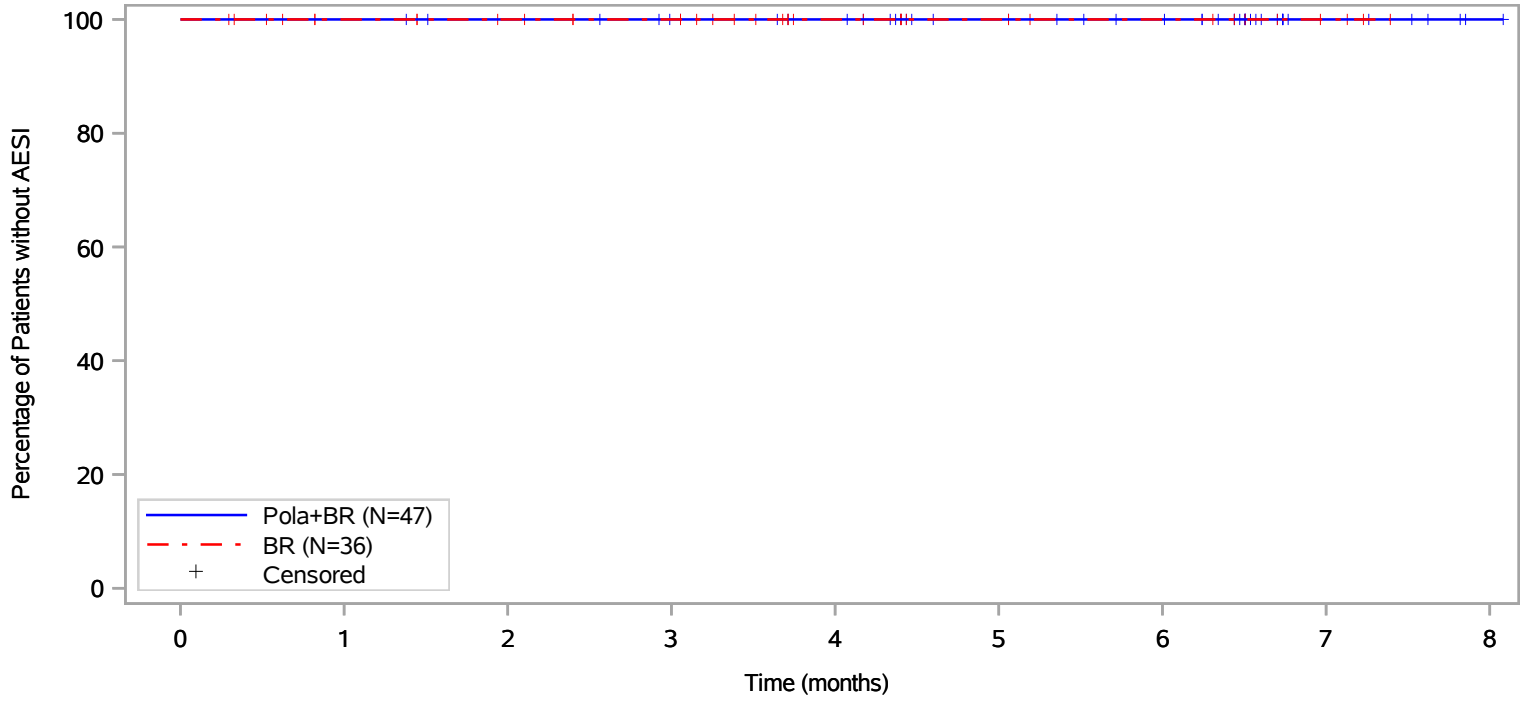
17DEC2022 21:59

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_km_TTDYSGUE35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 0:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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02DEC2022 22:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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16DEC2022 20:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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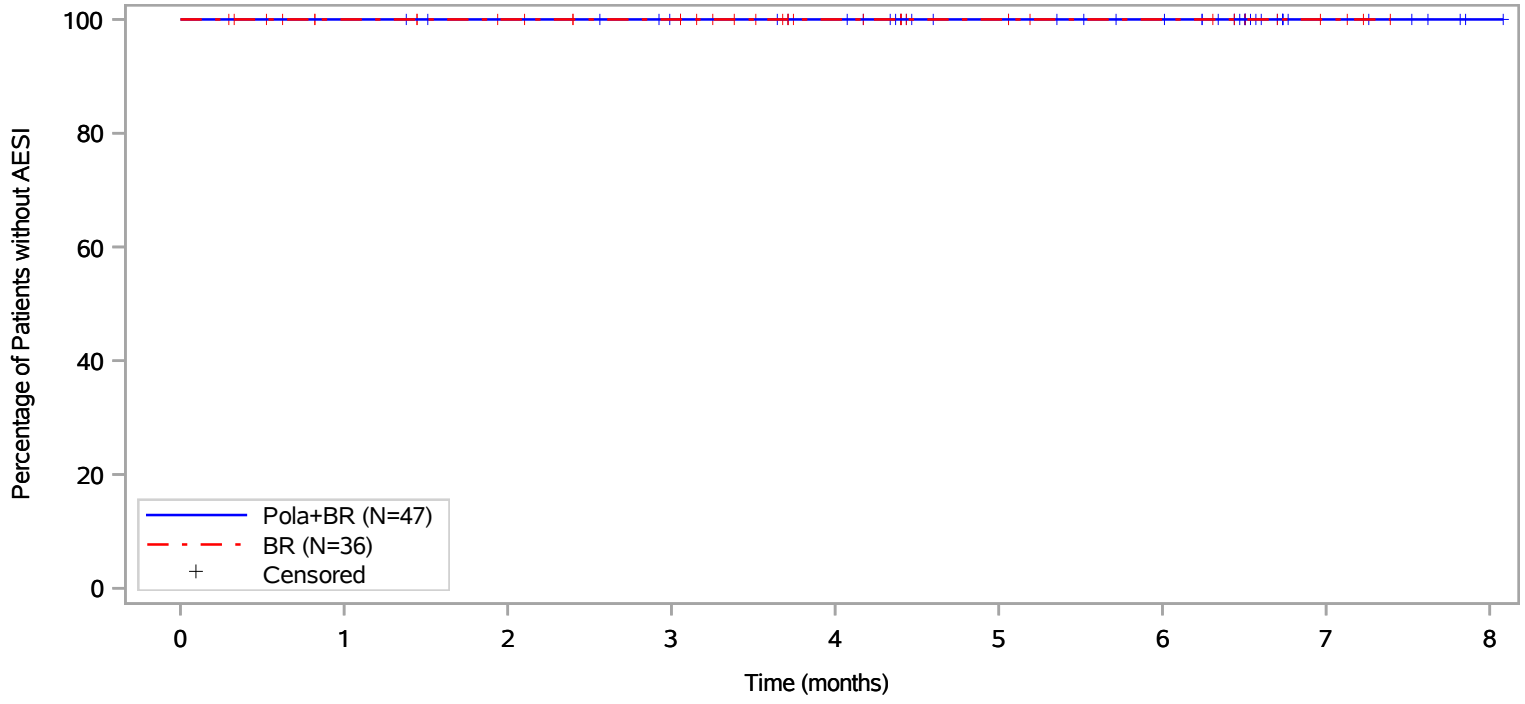
17DEC2022 15:59

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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04DEC2022 2:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	20	42.6	27	57.4	36	100.0	15	41.7	21	58.3	0.5445	0.83	0.42	1.64		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	15	44.1	19	55.9	24	66.7	10	41.7	14	58.3	0.7791	0.81	0.36	1.85		Convergence criterion (GCONV=1E-8) satisfied.	0.6250
	Female	13	27.7	5	38.5	8	61.5	12	33.3	5	41.7	7	58.3	0.5243	0.68	0.19	2.39		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	11	37.9	18	62.1	20	55.6	9	45.0	11	55.0	0.3049	0.64	0.26	1.58		Convergence criterion (GCONV=1E-8) satisfied.	0.4678
	>= 65	18	38.3	9	50.0	9	50.0	16	44.4	6	37.5	10	62.5	0.7749	1.15	0.40	3.28		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	12	41.4	17	58.6	24	66.7	9	37.5	15	62.5	0.7363	0.87	0.36	2.10		Convergence criterion (GCONV=1E-8) satisfied.	0.8313
	<3	18	38.3	8	44.4	10	55.6	12	33.3	6	50.0	6	50.0	0.6048	0.77	0.26	2.23		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	3	33.3	6	66.7	13	36.1	4	30.8	9	69.2	0.6773	0.72	0.16	3.32		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	17	44.7	21	55.3	23	63.9	11	47.8	12	52.2	0.5023	0.79	0.37	1.70		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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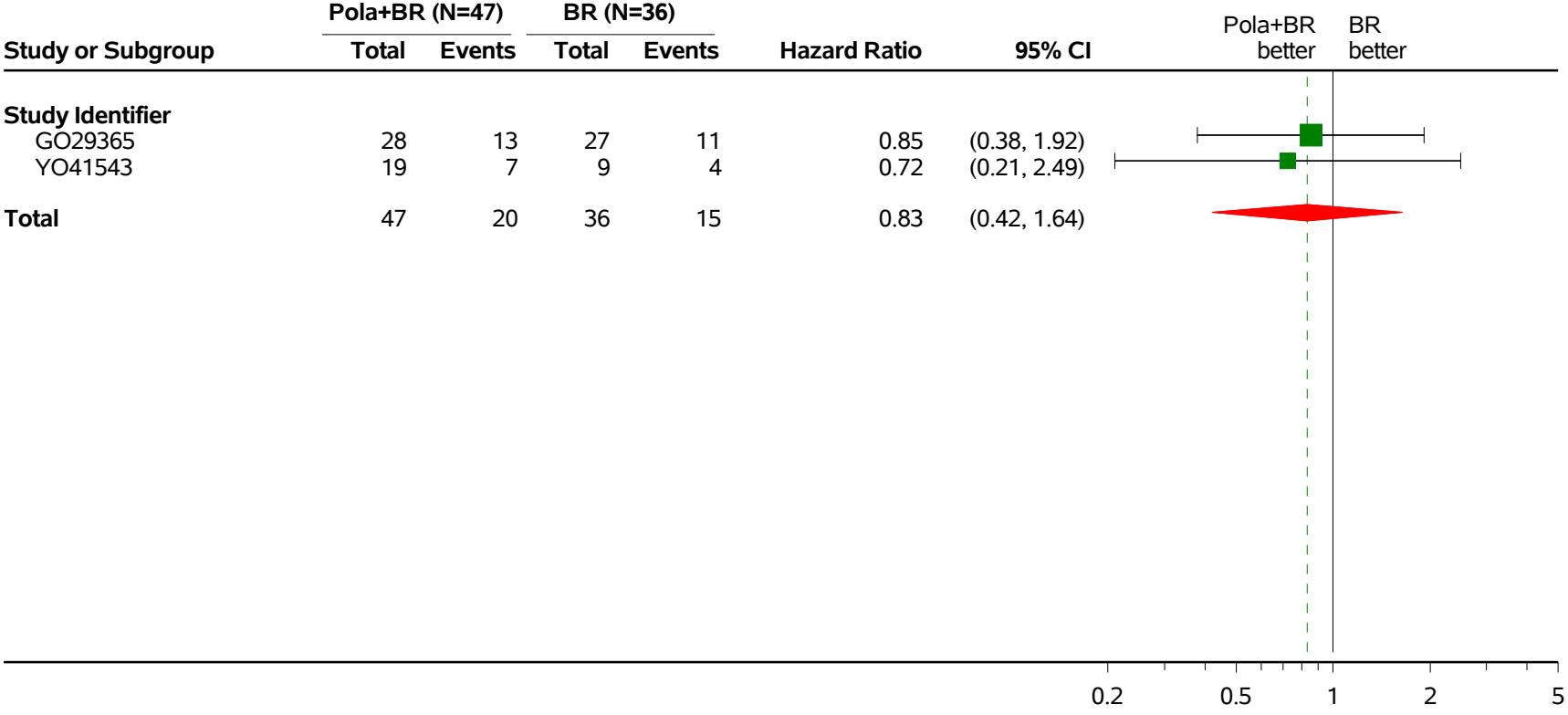
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	13	27	11	0.85	(0.38, 1.92)
YO41543	19	7	9	4	0.72	(0.21, 2.49)
Total	47	20	36	15	0.83	(0.42, 1.64)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	13	46.4	15	53.6	27	75.0	11	40.7	16	59.3	0.7035	0.85	0.38	1.92		Convergence criterion (GCONV=1E-8) satisfied.	69.9						
	YO41543	19	40.4	7	36.8	12	63.2	9	25.0	4	44.4	5	55.6	0.6051	0.72	0.21	2.49		Convergence criterion (GCONV=1E-8) satisfied.	30.1						
	Total	47	100.0	20	42.6	27	57.4	36	100.0	15	41.7	21	58.3	0.5445	0.83	0.42	1.64		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.05	1	0.8172	0.00	-0.54	0.5926

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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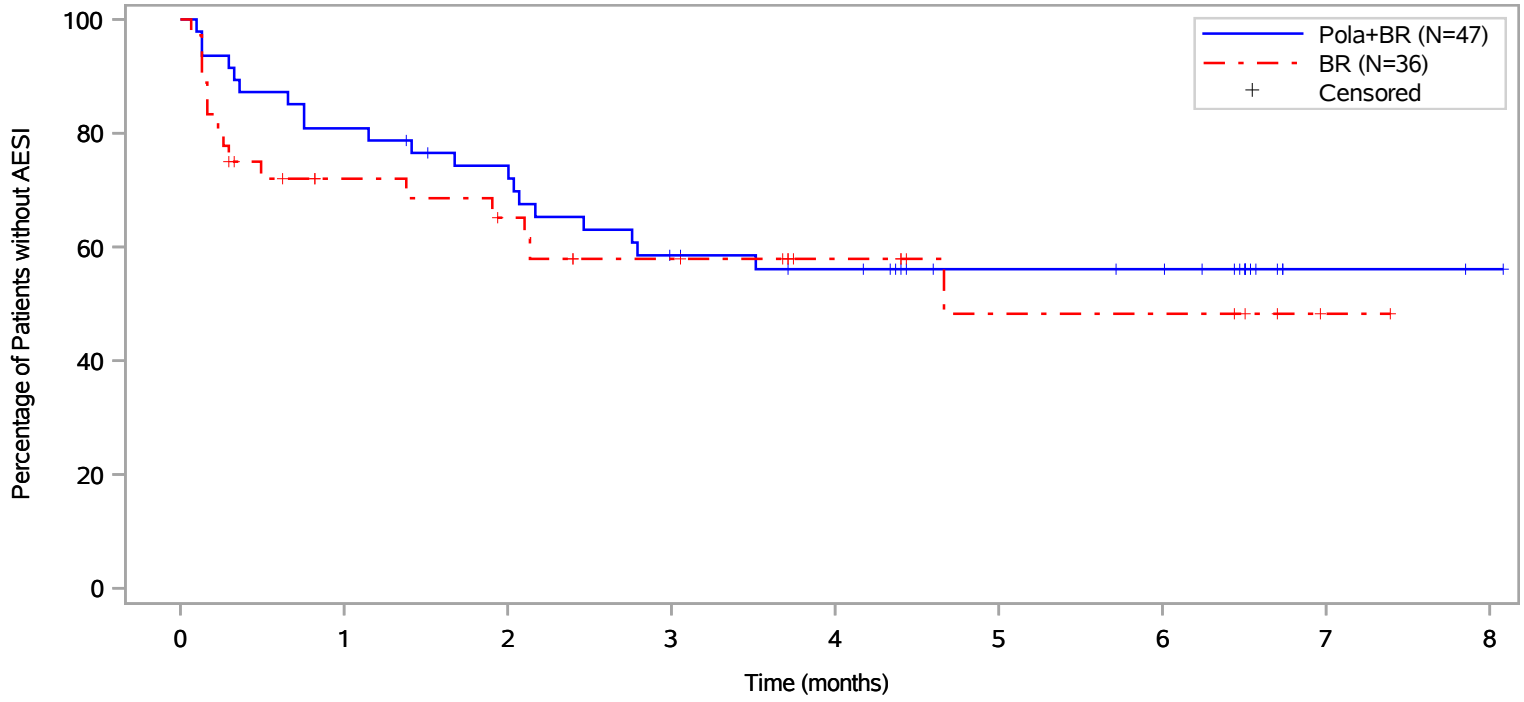
17DEC2022 20:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	38	33	25	22	16	15	2	1
BR (N=36)	36	21	18	14	9	5	5	1	NE
Patients censored									
Pola+BR (N=47)	0	0	2	3	5	11	12	25	26
BR (N=36)	0	5	6	8	13	16	16	20	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 21:13

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7135	0.68	0.04	11.35		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.8510	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	1	5.0	19	95.0	0.2285	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	1	4.2	23	95.8	0.7077	0.74	0.04	12.88		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.5734	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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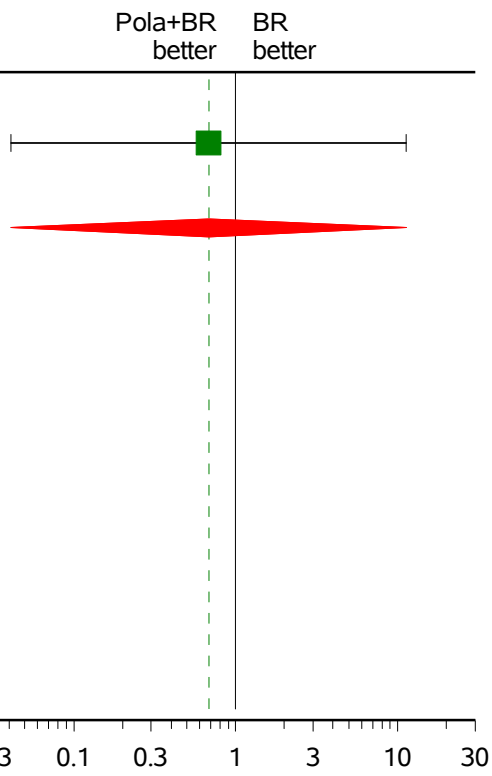
02DEC2022 21:21

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	1	27	1	0.68	(0.04, 11.35)
YO41543	19	0	9	0	NE	NE
Total	47	1	36	1	0.68	(0.04, 11.35)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	1	3.7	26	96.3	0.7873	0.68	0.04	11.35		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.7135	0.68	0.04	11.35		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	-0.27	0.7885

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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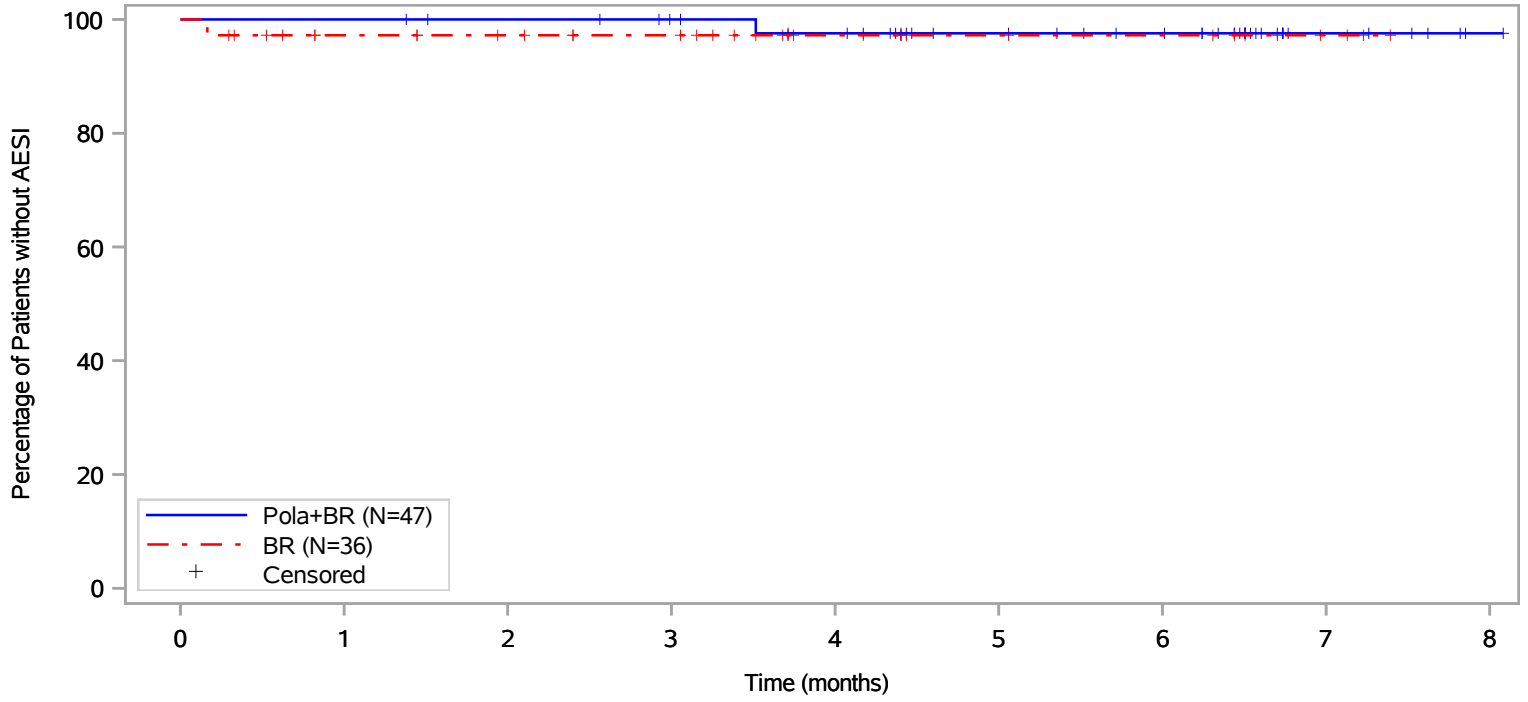
15DEC2022 21:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	14	9	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	40	45
BR (N=36)	0	6	9	12	21	26	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 23:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTFAAS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTFAAS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
15DEC2022 19:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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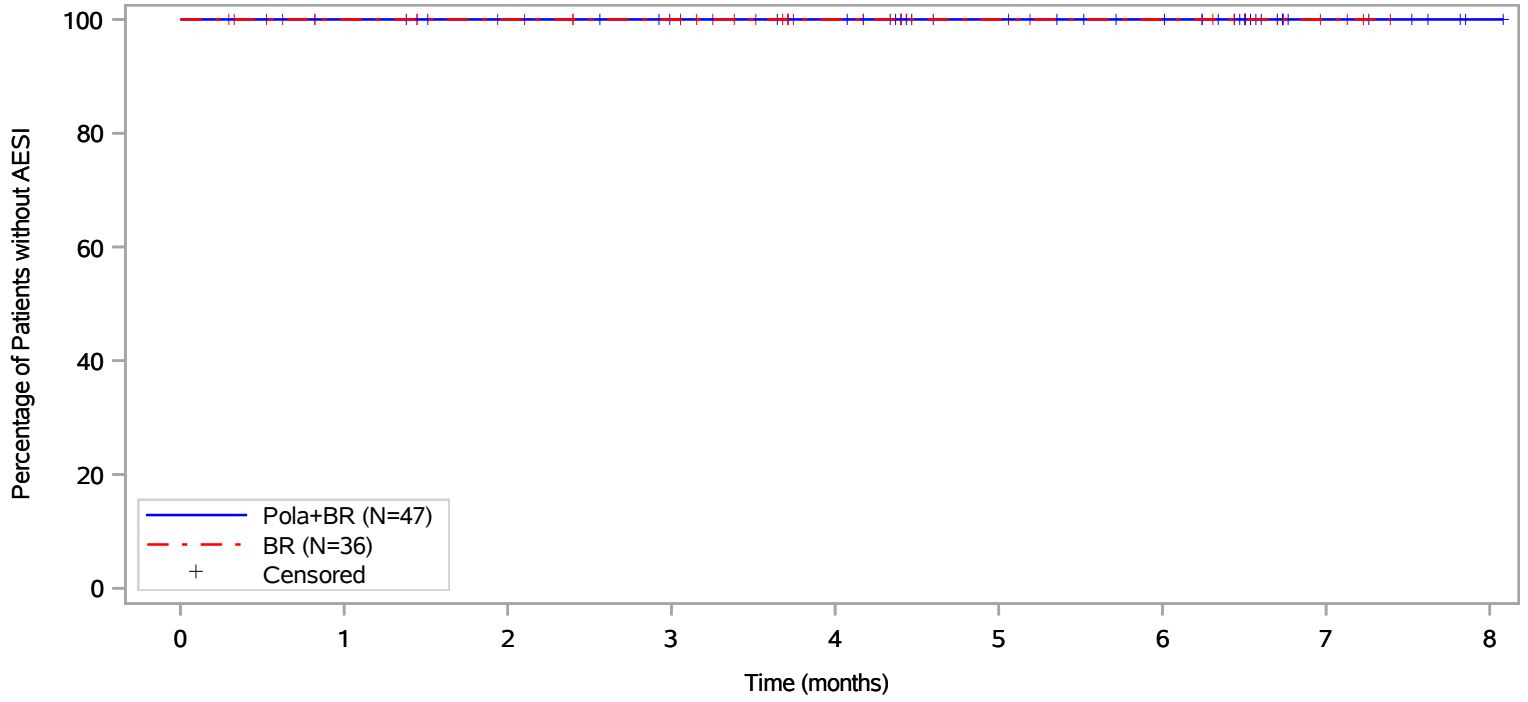
15DEC2022 21:59

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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04DEC2022 1:31

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

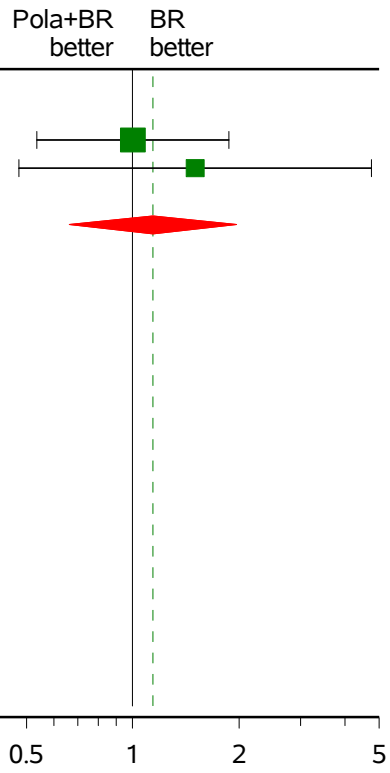
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		47	100.0	36	76.6	11	23.4	36	100.0	22	61.1	14	38.9	0.7272	1.14	0.66	1.97	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	26	76.5	8	23.5	24	66.7	14	58.3	10	41.7	0.5935	1.25	0.64	2.44	Convergence criterion (GCONV=1E-8) satisfied.	0.6171
	Female	13	27.7	10	76.9	3	23.1	12	33.3	8	66.7	4	33.3	0.8024	0.90	0.35	2.30	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	23	79.3	6	20.7	20	55.6	11	55.0	9	45.0	0.3477	1.49	0.71	3.15	Convergence criterion (GCONV=1E-8) satisfied.	0.1863
	>= 65	18	38.3	13	72.2	5	27.8	16	44.4	11	68.8	5	31.3	0.5795	0.73	0.32	1.70	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	20	69.0	9	31.0	24	66.7	15	62.5	9	37.5	0.7292	0.96	0.47	1.93	Convergence criterion (GCONV=1E-8) satisfied.	0.3505
	<3	18	38.3	16	88.9	2	11.1	12	33.3	7	58.3	5	41.7	0.2935	1.58	0.63	3.95	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	7	77.8	2	22.2	13	36.1	6	46.2	7	53.8	0.4130	1.58	0.53	4.72	Convergence criterion (GCONV=1E-8) satisfied.	0.4672
	Non-Europe	38	80.9	29	76.3	9	23.7	23	63.9	16	69.6	7	30.4	0.8811	0.97	0.52	1.81	Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGASTOX_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30MAR2023 9:45

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	24	27	18	1.00	(0.53, 1.88)
YO41543	19	12	9	4	1.50	(0.48, 4.75)
Total	47	36	36	22	1.14	(0.66, 1.97)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGASTOX_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 30MAR2023 15:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	24	85.7	4	14.3	27	75.0	18	66.7	9	33.3	0.9981	1.00	0.53	1.88		Convergence criterion (GCONV=1E-8) satisfied.	77.0							
	YO41543	19	40.4	12	63.2	7	36.8	9	25.0	4	44.4	5	55.6	0.4838	1.50	0.48	4.75		Convergence criterion (GCONV=1E-8) satisfied.	23.0							
	Total	47	100.0	36	76.6	11	23.4	36	100.0	22	61.1	14	38.9	0.7272	1.14	0.66	1.97		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.39	1	0.5316	0.00		0.48	0.6291

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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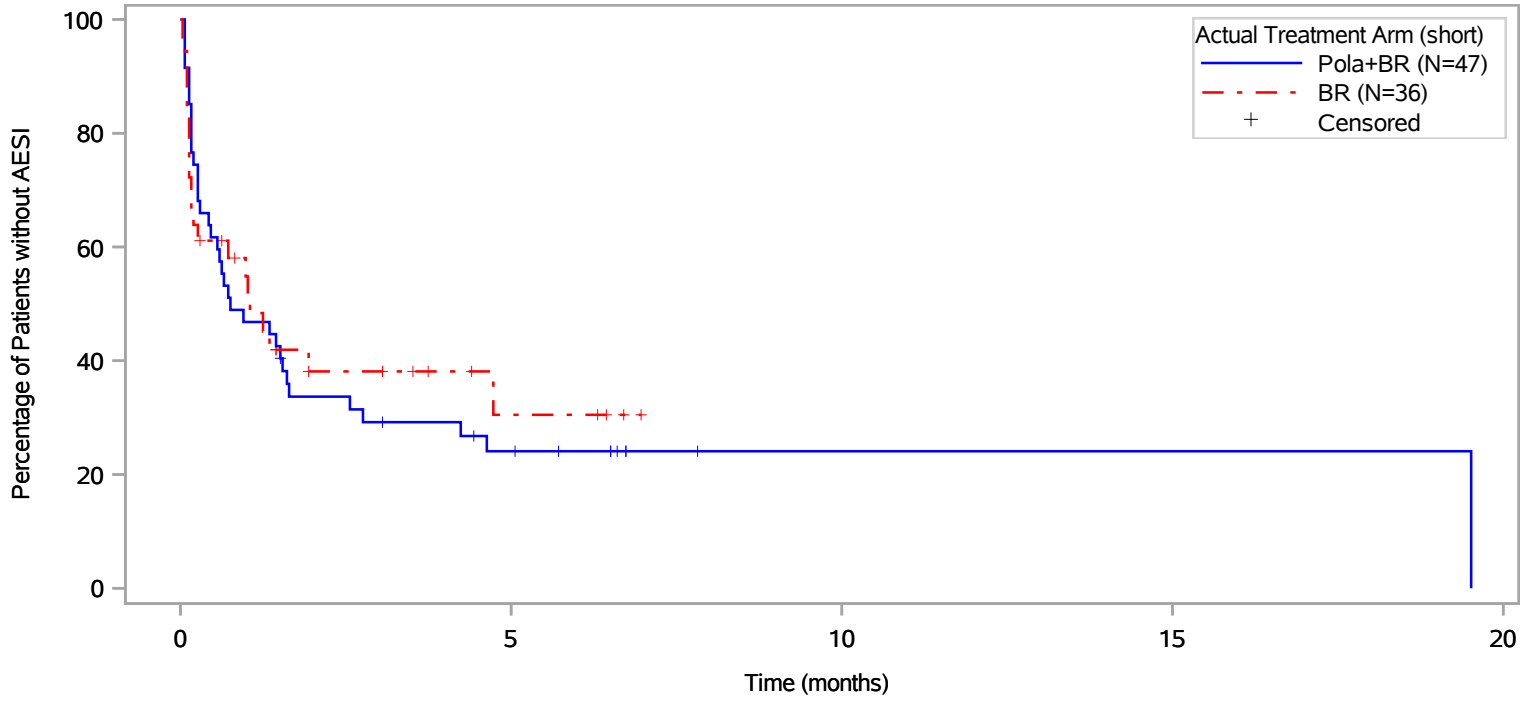
03APR2023 13:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=47)	47	22	15	13	12	9	7	2	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	17	9	9	6	4	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	1	1	2	3	5	10	11	11	11	11	11	11	11	11	11	11	11	11
BR (N=36)	0	3	6	6	9	10	10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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30MAR2023 12:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

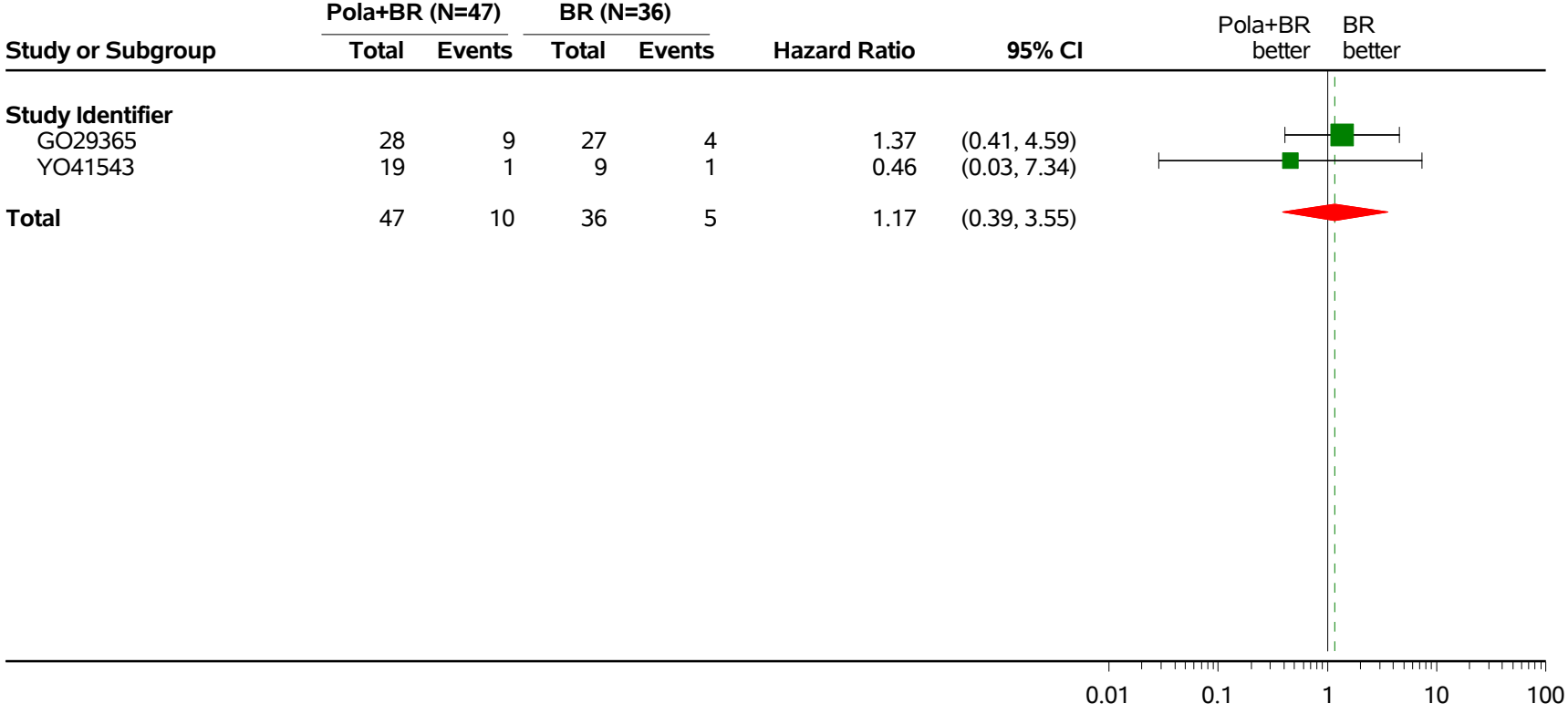
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	10	21.3	37	78.7	36	100.0	5	13.9	31	86.1	0.9260	1.17	0.39	3.55		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	8	23.5	26	76.5	24	66.7	5	20.8	19	79.2	0.6288	0.85	0.26	2.72		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2335	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	6	20.7	23	79.3	20	55.6	2	10.0	18	90.0	0.4581	2.33	0.46	11.85		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	4	22.2	14	77.8	16	44.4	3	18.8	13	81.3	0.5894	0.59	0.12	2.97		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	7	24.1	22	75.9	24	66.7	4	16.7	20	83.3	0.7669	0.96	0.26	3.54		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	3	16.7	15	83.3	12	33.3	1	8.3	11	91.7	0.6166	1.75	0.18	16.90		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	3	33.3	6	66.7	13	36.1	2	15.4	11	84.6	0.6289	1.55	0.26	9.40		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	7	18.4	31	81.6	23	63.9	3	13.0	20	87.0	0.9271	1.00	0.24	4.12		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGASTOX35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30MAR2023 11:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)				
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**	
Study Identifier							
GO29365	28	9	27	4	1.37	(0.41, 4.59)	
YO41543	19	1	9	1	0.46	(0.03, 7.34)	
Total	47	10	36	5	1.17	(0.39, 3.55)	



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	9	32.1	19	67.9	27	75.0	4	14.8	23	85.2	0.6109	1.37	0.41	4.59		Convergence criterion (GCONV=1E-8) satisfied.	84.0						
	YO41543	19	40.4	1	5.3	18	94.7	9	25.0	1	11.1	8	88.9	0.5722	0.46	0.03	7.34		Convergence criterion (GCONV=1E-8) satisfied.	16.0						
	Total	47	100.0	10	21.3	37	78.7	36	100.0	5	13.9	31	86.1	0.9260	1.17	0.39	3.55		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.50	1	0.4785	0.00	0.29	0.7753

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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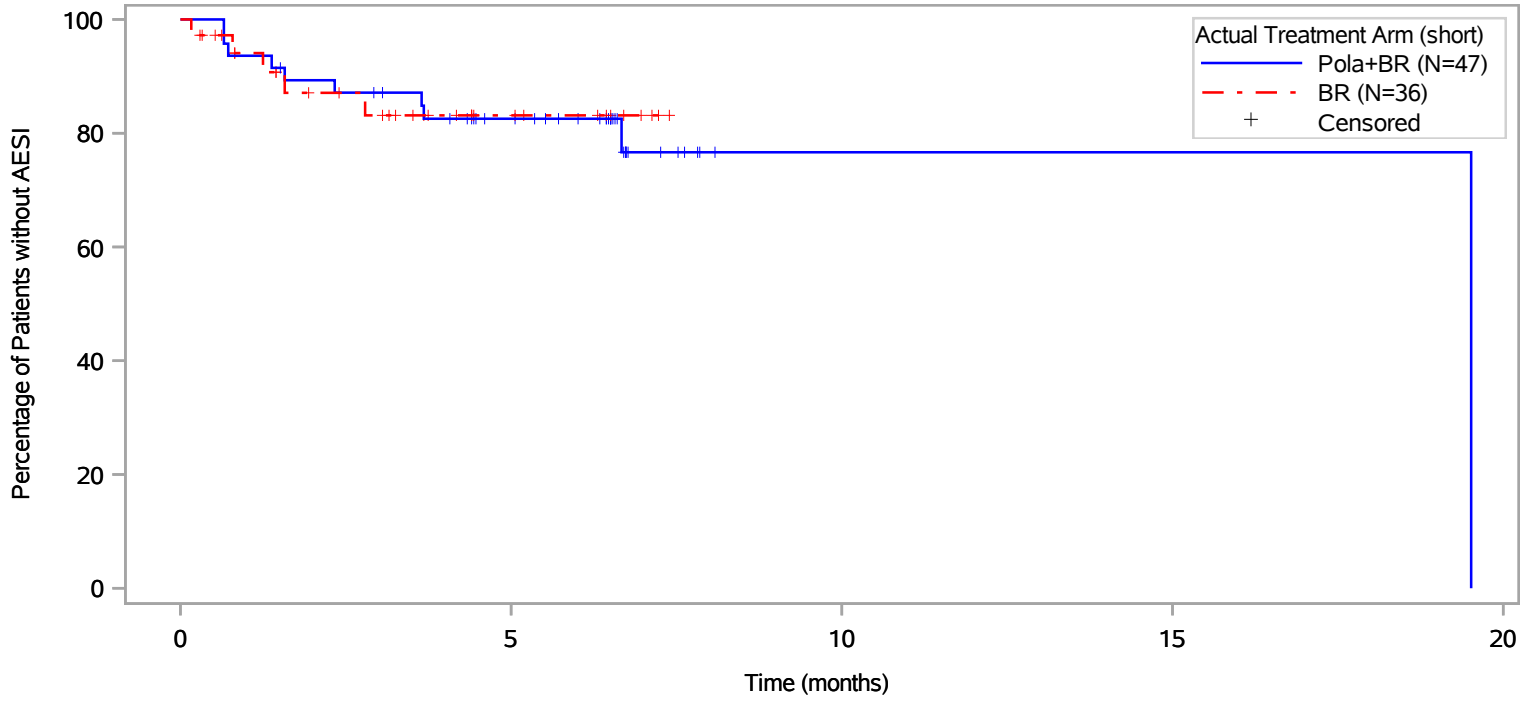
03APR2023 13:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=47)	47	44	41	39	36	30	26	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	28	23	21	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	1	2	3	9	13	31	36	37	37	37	37	37	37	37	37	37	37	37
BR (N=36)	0	6	9	10	16	21	23	28	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_km_TTGASTOX35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
30MAR2023 13:56

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

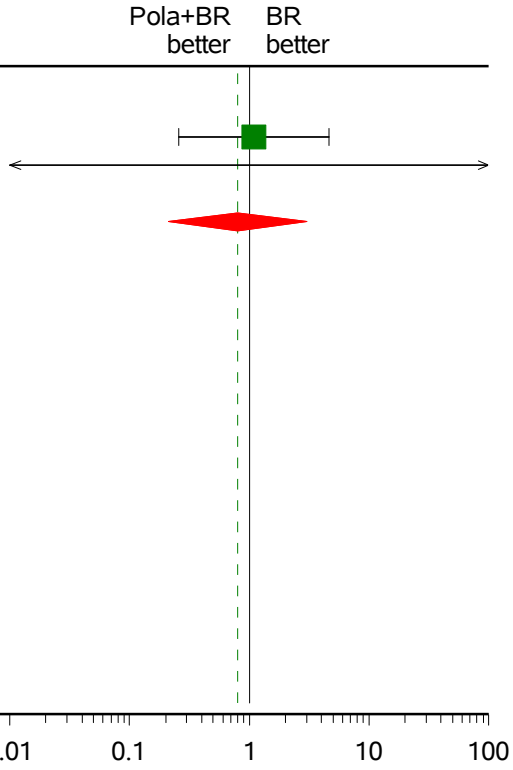
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	6	12.8	41	87.2	36	100.0	4	11.1	32	88.9	0.6337	0.80	0.21	3.02		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	5	14.7	29	85.3	24	66.7	3	12.5	21	87.5	0.6001	0.76	0.16	3.49		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.3938	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	3	10.3	26	89.7	20	55.6	2	10.0	18	90.0	0.8352	1.04	0.17	6.40		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	2	12.5	14	87.5	0.7345	0.63	0.09	4.58		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	4	13.8	25	86.2	24	66.7	2	8.3	22	91.7	0.7169	0.82	0.13	5.15		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	2	11.1	16	88.9	12	33.3	2	16.7	10	83.3	0.9010	1.14	0.10	12.70		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	3	33.3	6	66.7	13	36.1	2	15.4	11	84.6	0.2778	3.27	0.34	31.46		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	3	7.9	35	92.1	23	63.9	2	8.7	21	91.3	0.3045	0.36	0.05	2.74		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGASTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30MAR2023 10:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=47) Total	Pola+BR (N=47) Events	BR (N=36) Total	BR (N=36) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	28	6	27	3	1.09	(0.26, 4.63)
YO41543	19	0	9	1	0.00	(0.00, NE)
Total	47	6	36	4	0.80	(0.21, 3.02)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGASTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 30MAR2023 15:41

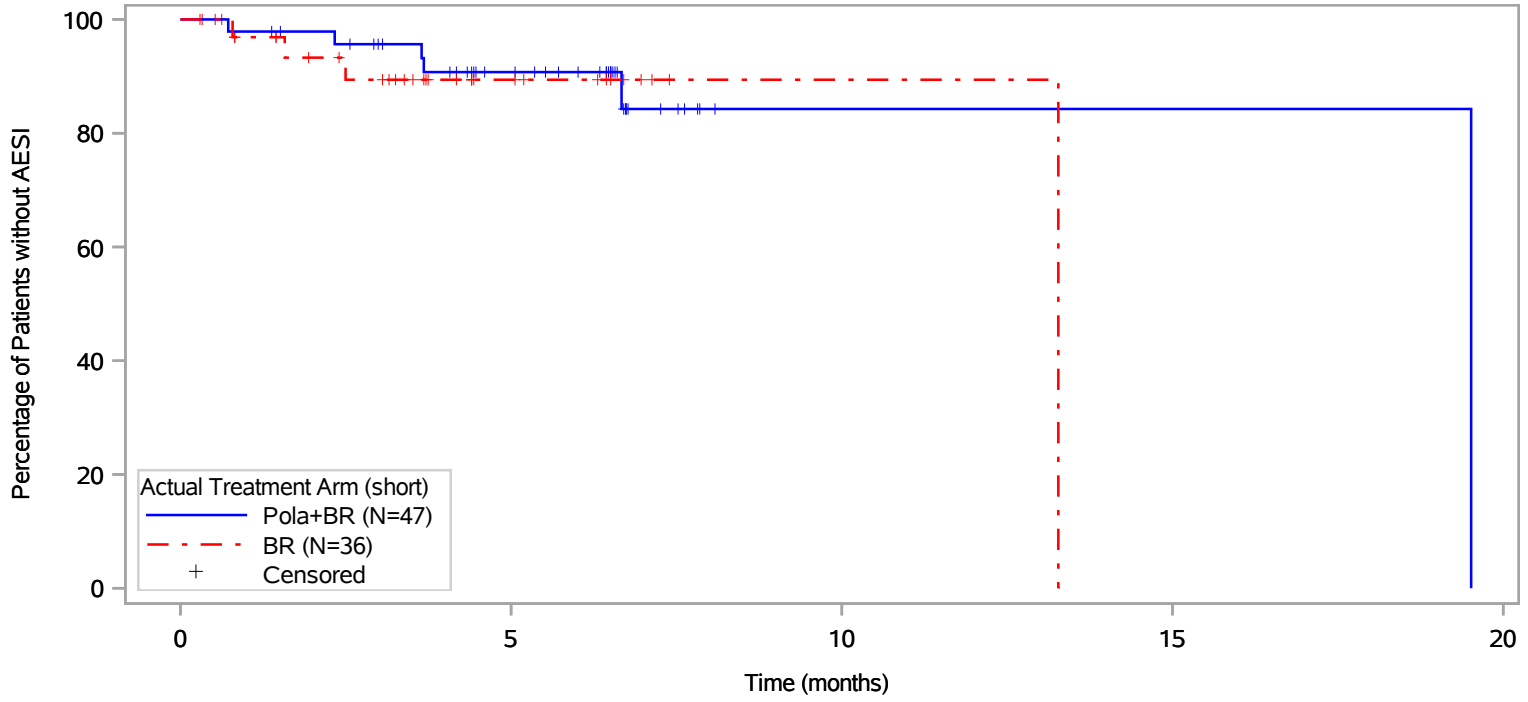
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	6	21.4	22	78.6	27	75.0	3	11.1	24	88.9	0.9022	1.09	0.26	4.63		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	47	100.0	6	12.8	41	87.2	36	100.0	4	11.1	32	88.9	0.6337	0.80	0.21	3.02		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.18	1	0.6686	0.00	-0.33	0.7405

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTGASTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
03APR2023 13:36

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=47)	47	46	44	40	37	30	26	7	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	29	25	23	15	10	8	3	1	1	1	1	1	1	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	2	5	6	13	17	35	40	41	41	41	41	41	41	41	41	41	41	41
BR (N=36)	0	6	9	10	18	23	25	30	32	32	32	32	32	32	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_TTGASTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
30MAR2023 13:04

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGENCAR_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 10:55

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGENCAR_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 17:00

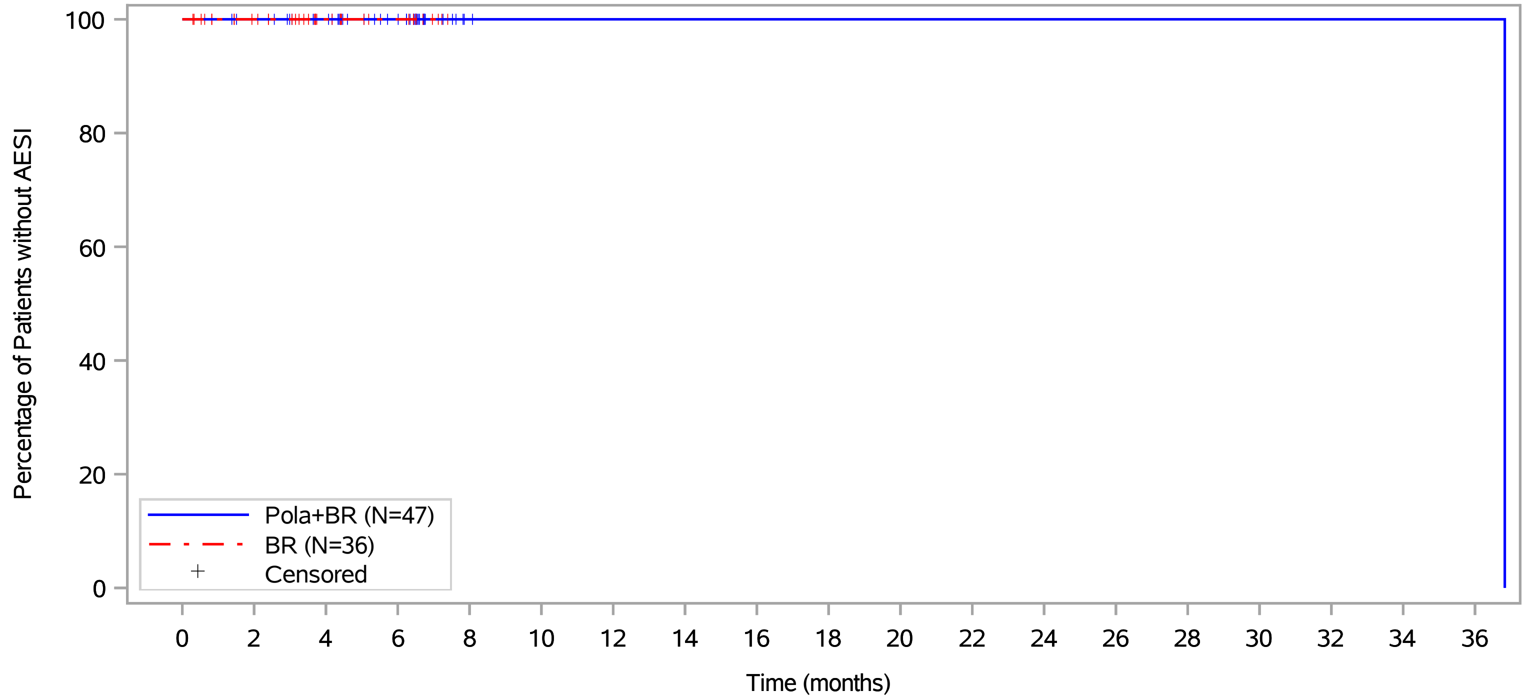
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTGENCAR_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 22:32

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk																																					
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																					
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTGENCAR_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:19

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGENCAR35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 11:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGENCAR35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 15:08

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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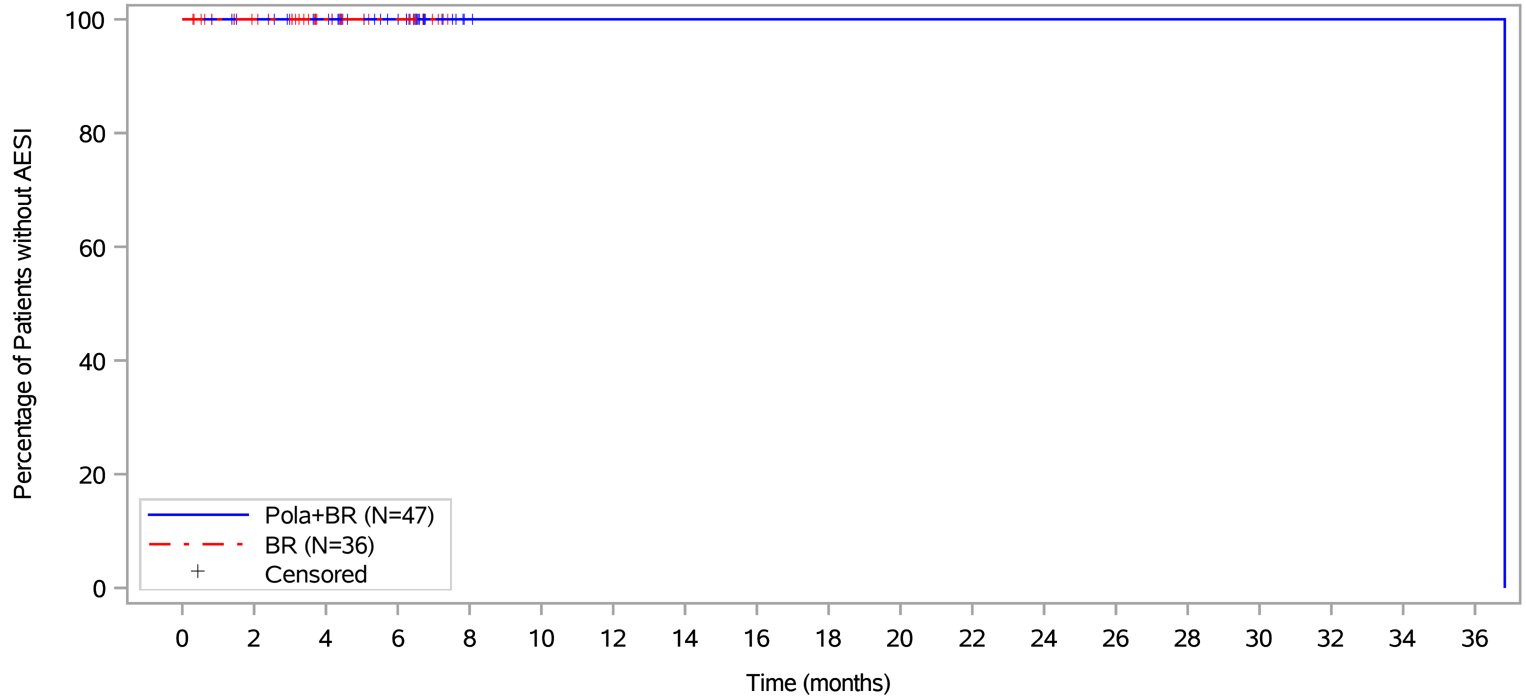
17DEC2022 22:16

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk																																					
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																					
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_km_TTGENCAR35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 0:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTGENCARS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 11:06

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTGENCARS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
16DEC2022 21:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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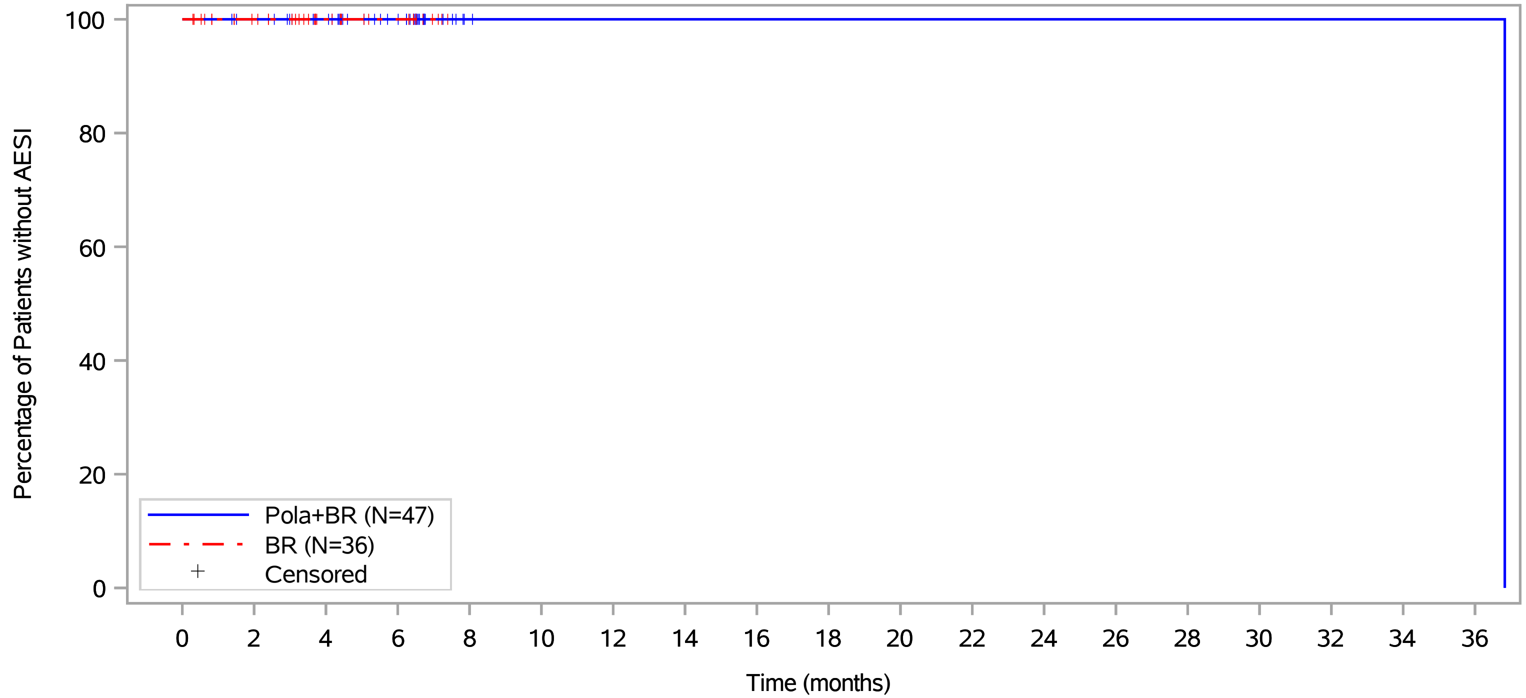
17DEC2022 16:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk
Pola+BR (N=47) 47 47 45 42 39 31 27 7 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
BR (N=36) 36 30 27 24 15 10 8 3 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE
Patients censored
Pola+BR (N=47) 0 0 2 5 8 16 20 40 45 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46 46
BR (N=36) 0 6 9 12 21 26 28 33 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_TTGENCARS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 2:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

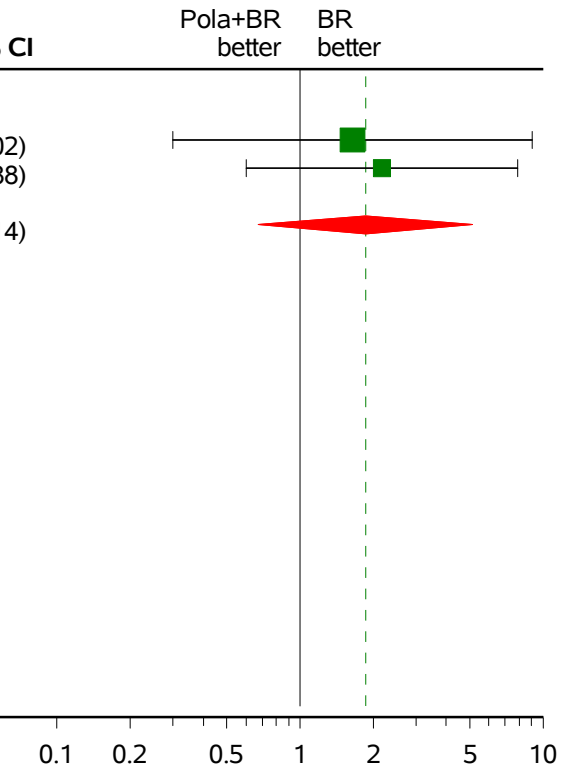
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	16	34.0	31	66.0	36	100.0	5	13.9	31	86.1	0.1558	1.86	0.67	5.14		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	9	26.5	25	73.5	24	66.7	4	16.7	20	83.3	0.5794	1.05	0.31	3.48		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	7	53.8	6	46.2	12	33.3	1	8.3	11	91.7	0.1103	5.17	0.62	43.20		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	13	44.8	16	55.2	20	55.6	4	20.0	16	80.0	0.2564	1.76	0.56	5.51		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	1	6.3	15	93.8	0.4522	2.16	0.22	20.99		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	10	34.5	19	65.5	24	66.7	4	16.7	20	83.3	0.3123	1.63	0.51	5.27		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	6	33.3	12	66.7	12	33.3	1	8.3	11	91.7	0.2923	3.72	0.43	32.18		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	16	42.1	22	57.9	23	63.9	5	21.7	18	78.3	0.3156	1.70	0.61	4.68		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHEPAT_L3PLUS_ARMCDPLUSSE_29365_41543.xls
01DEC2022 4:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=47) Total	Pola+BR (N=47) Events	BR (N=36) Total	BR (N=36) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	28	5	27	2	1.65	(0.30, 9.02)
YO41543	19	11	9	3	2.18	(0.60, 7.88)
Total	47	16	36	5	1.86	(0.67, 5.14)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTHEPAT_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 19:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	5	17.9	23	82.1	27	75.0	2	7.4	25	92.6	0.5608	1.65	0.30	9.02		Convergence criterion (GCONV=1E-8) satisfied.		36.4						
	YO41543	19	40.4	11	57.9	8	42.1	9	25.0	3	33.3	6	66.7	0.2250	2.18	0.60	7.88		Convergence criterion (GCONV=1E-8) satisfied.		63.6						
	Total	47	100.0	16	34.0	31	66.0	36	100.0	5	13.9	31	86.1	0.1558	1.86	0.67	5.14		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.08	1	0.7817	0.00	1.20	0.2318

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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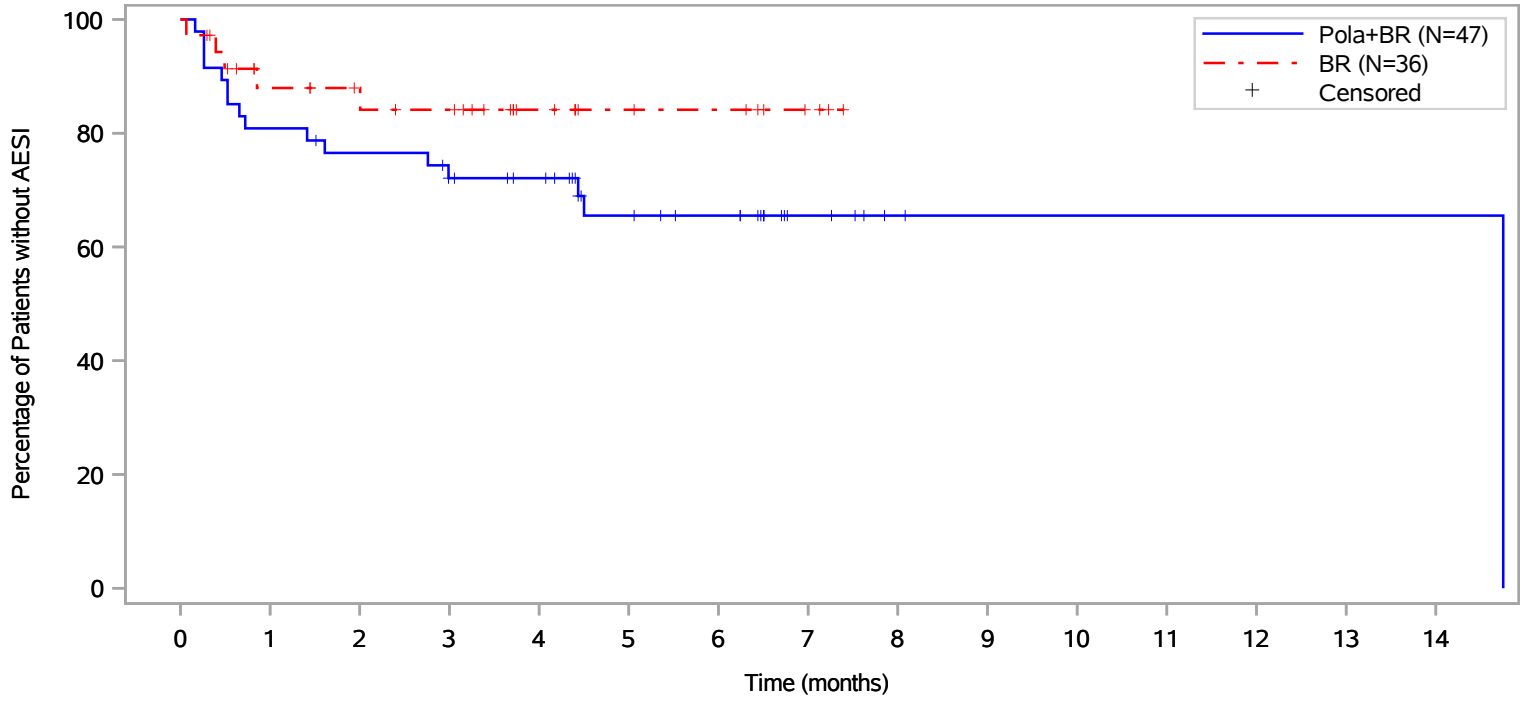
15DEC2022 19:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk															
Pola+BR (N=47)	47	38	35	31	28	19	16	6	2	1	1	1	1	1	1
BR (N=36)	36	26	23	21	13	8	7	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	1	3	6	13	16	26	30	31	31	31	31	31	31
BR (N=36)	0	6	9	10	18	23	24	28	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 21:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4108	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	2	6.9	27	93.1	20	55.6	0	-	20	100.0	0.4183	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	2	11.1	16	88.9	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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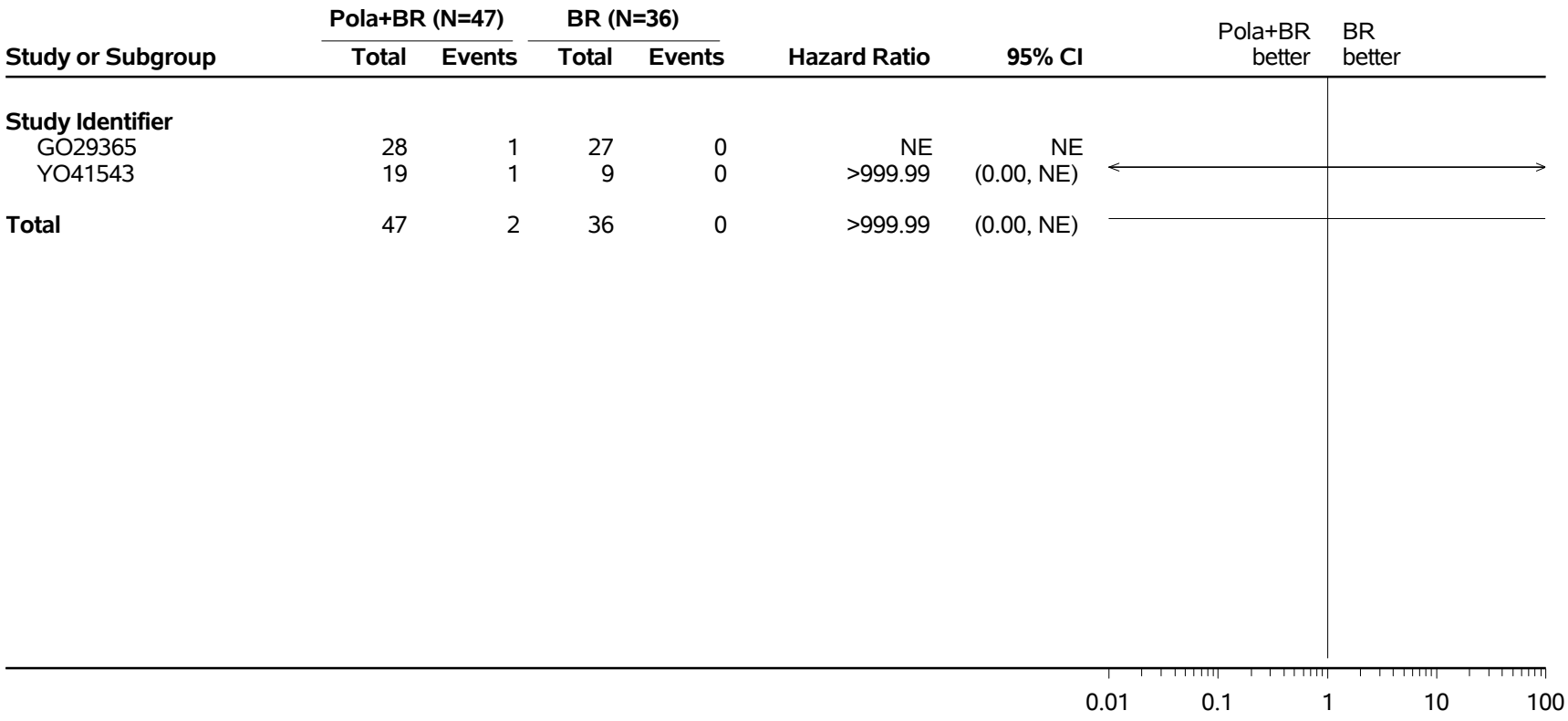
25JAN2023 11:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	1	27	0	NE	NE
YO41543	19	1	9	0	>999.99	(0.00, NE)
Total	47	2	36	0	>999.99	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	YO41543	19	40.4	1	5.3	18	94.7	9	25.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		100.0						
	Total	47	100.0	2	4.3	45	95.7	36	100.0	0	-	36	100.0	0.3950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		100.0	NE	NE	NE	NE	0.00	0.9984

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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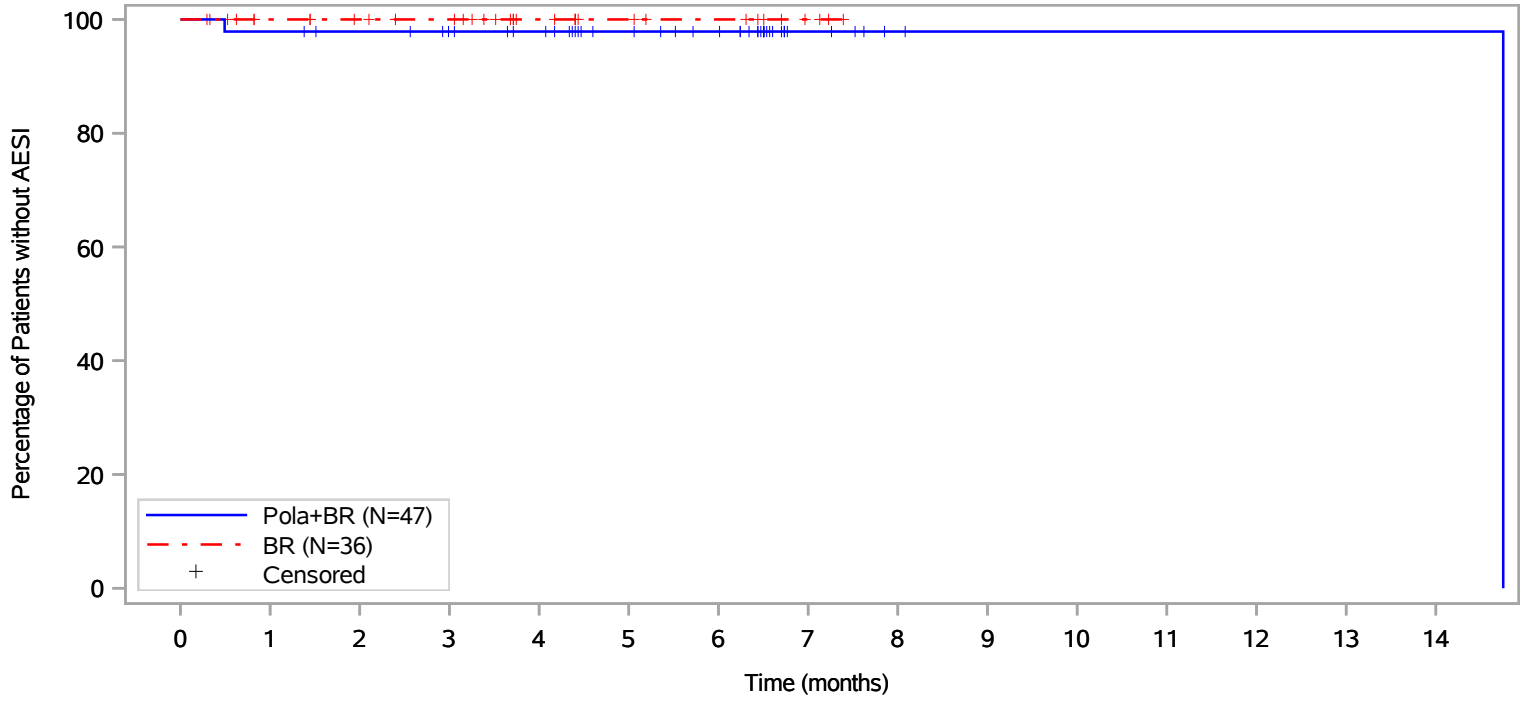
15DEC2022 21:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk															
Pola+BR (N=47)	47	46	44	41	38	30	26	6	2	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	40	44	45	45	45	45	45	45
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_TTHEPAT35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 23:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	1	5.6	17	94.4	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHEPATS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 11:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTHEPATS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
15DEC2022 18:04

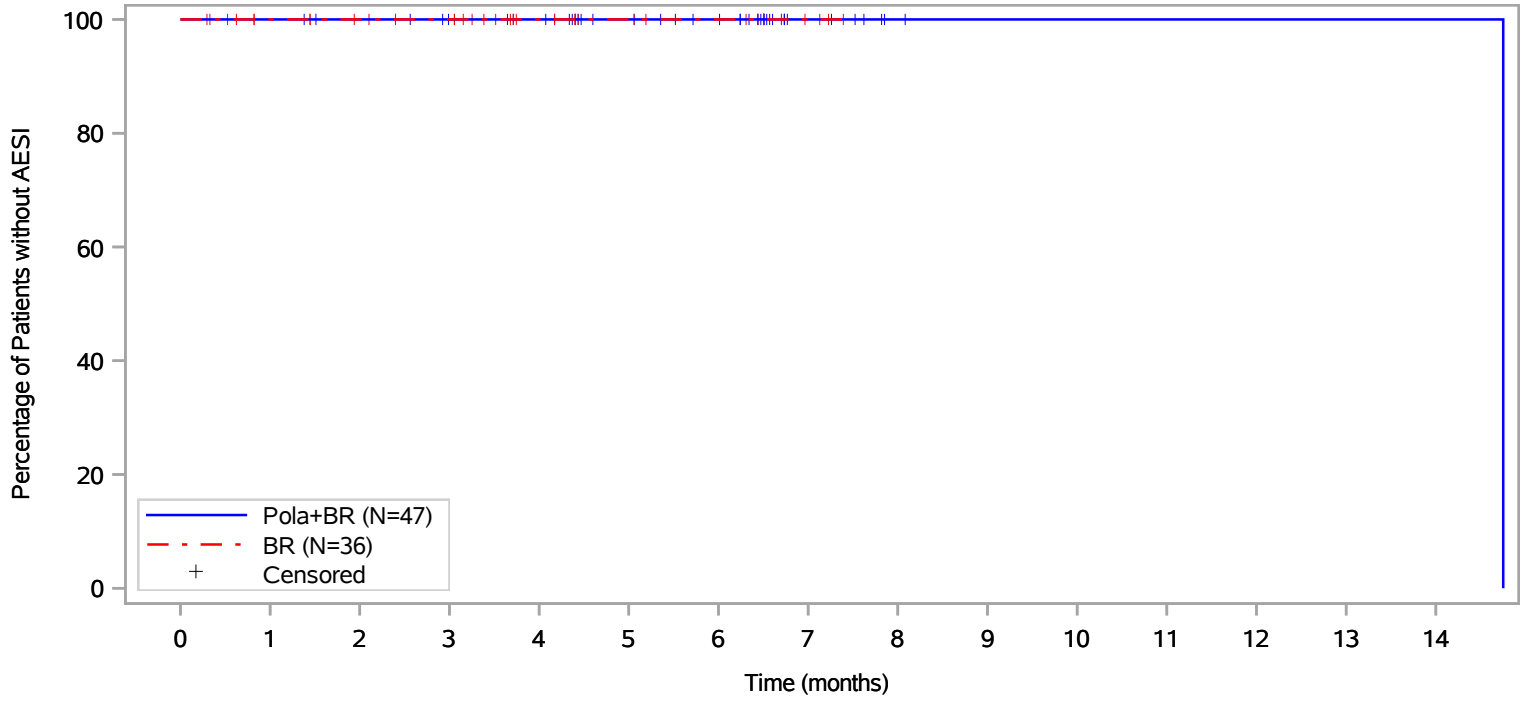
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTHEPATS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
15DEC2022 21:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk															
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1	1	1	1	1
BR (N=36)	36	30	27	24	15	10	8	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46	46	46	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTHEPATS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 1:19

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

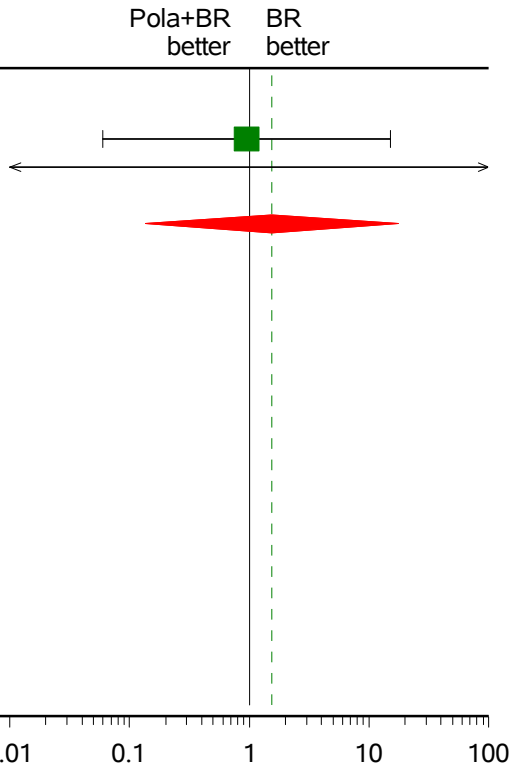
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.7329	1.54	0.14	17.41		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.7889	1.42	0.12	16.05		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.4063	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	1	6.3	15	93.8	0.9154	0.90	0.06	14.39		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.1943	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	2	5.3	36	94.7	23	63.9	0	-	23	100.0	0.2680	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHYPGL_L3PLUS_ARMCDPLUSSE_29365_41543.xls
01DEC2022 5:21

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=47) Total	Pola+BR (N=47) Events	BR (N=36) Total	BR (N=36) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	28	1	27	1	0.95	(0.06, 15.13)
YO41543	19	1	9	0	>999.99	(0.00, NE)
Total	47	2	36	1	1.54	(0.14, 17.41)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTHYPGL_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 11:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	1	3.7	26	96.3	0.9688	0.95	0.06	15.13		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	1	5.3	18	94.7	9	25.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	47	100.0	2	4.3	45	95.7	36	100.0	1	2.8	35	97.2	0.7329	1.54	0.14	17.41		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.12	1	0.7312	0.00	0.35	0.7281

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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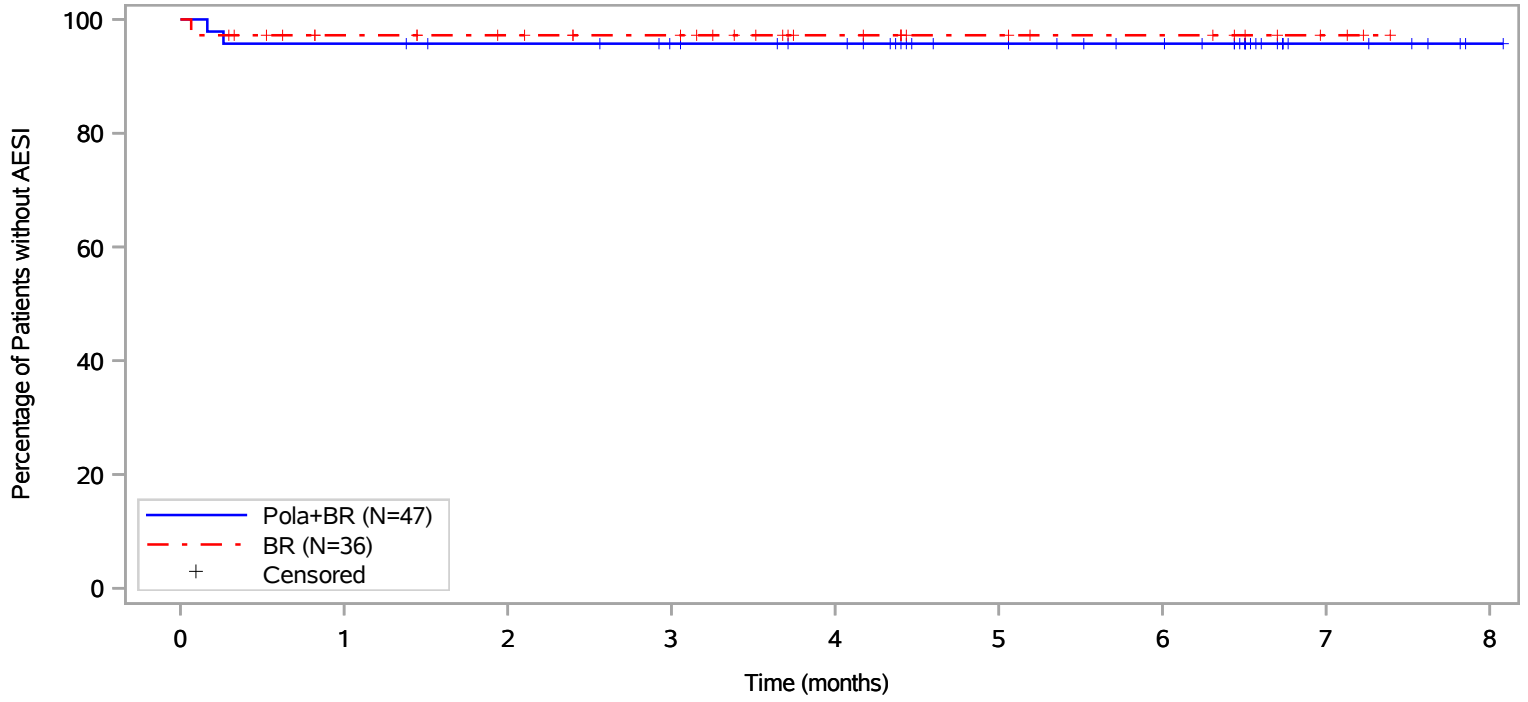
17DEC2022 20:59

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	45	43	40	37	29	25	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTHYPGL_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHYPGL35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:29

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTHYPGL35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
16DEC2022 10:25

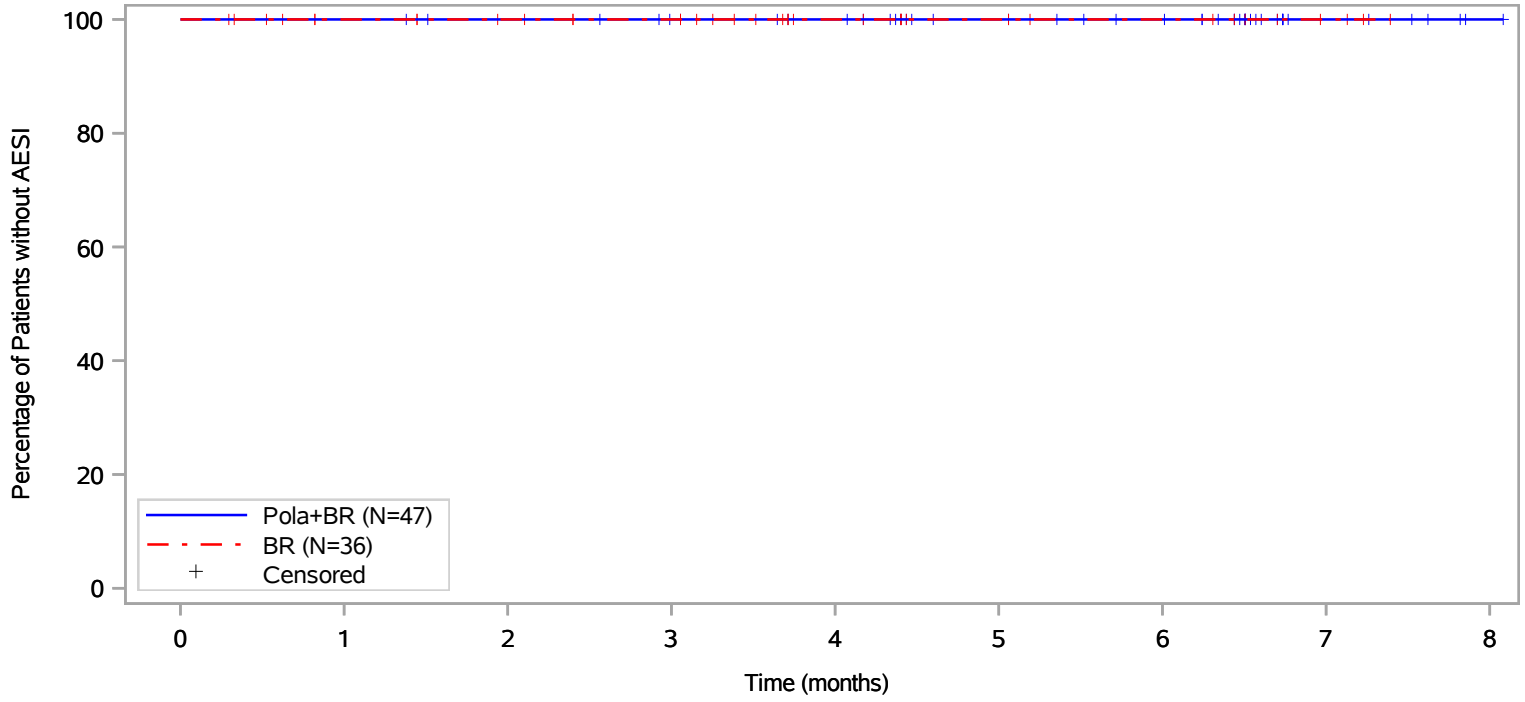
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTHYPGL35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
15DEC2022 21:45

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_TTHYPGL35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 23:29

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTHYPGLS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:14

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTHYPGLS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
16DEC2022 10:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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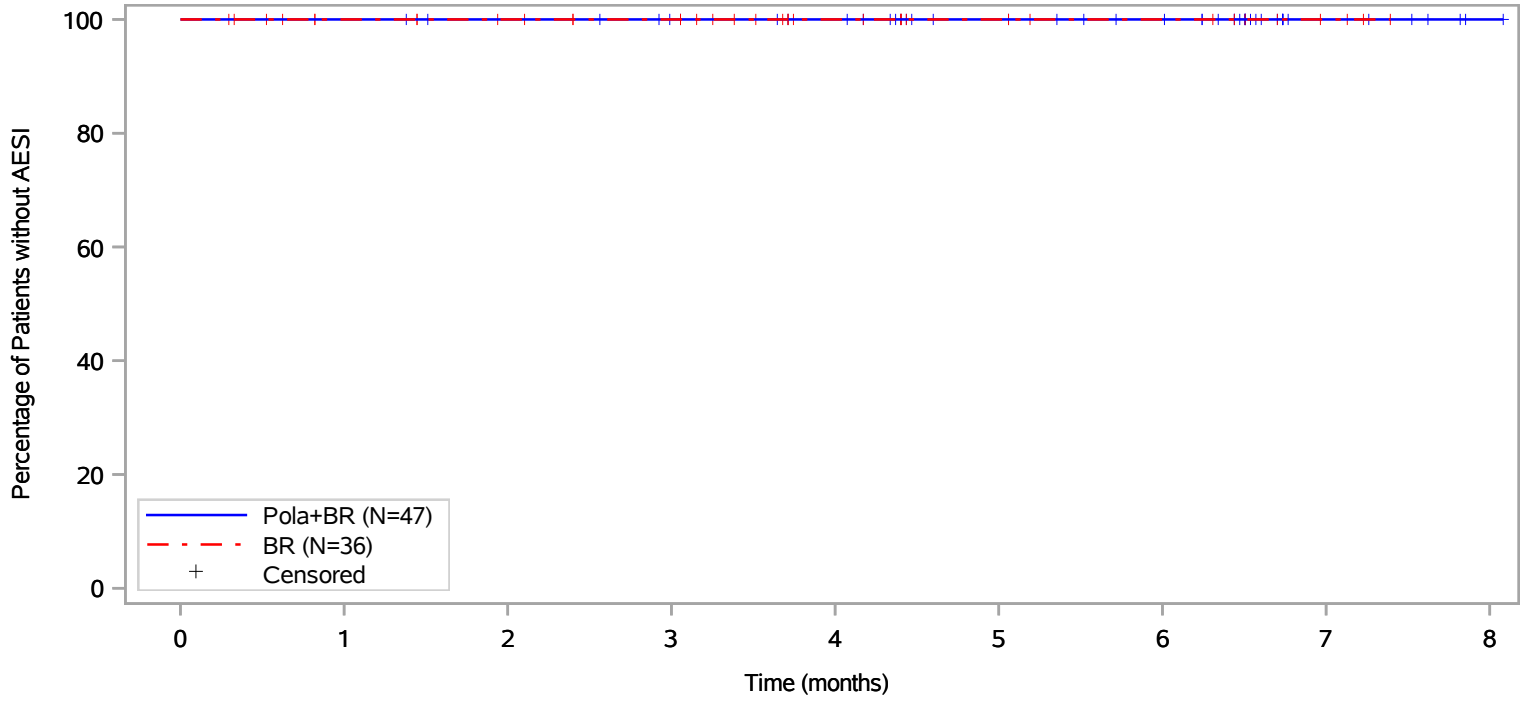
15DEC2022 22:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 1:39

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

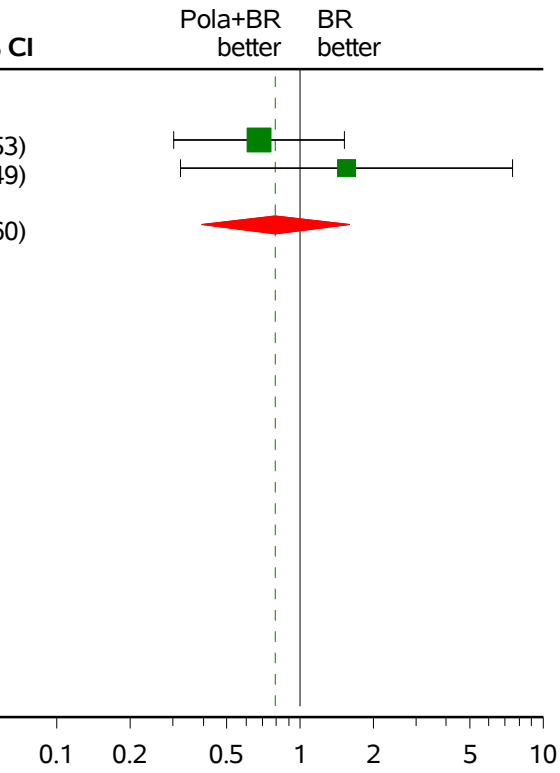
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	21	44.7	26	55.3	36	100.0	14	38.9	22	61.1	0.4501	0.79	0.39	1.60		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	15	44.1	19	55.9	24	66.7	9	37.5	15	62.5	0.4241	0.75	0.32	1.79		Convergence criterion (GCONV=1E-8) satisfied.	0.9583
	Female	13	27.7	6	46.2	7	53.8	12	33.3	5	41.7	7	58.3	0.8413	0.88	0.27	2.91		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	11	37.9	18	62.1	20	55.6	6	30.0	14	70.0	0.7362	0.84	0.30	2.38		Convergence criterion (GCONV=1E-8) satisfied.	0.5635
	>= 65	18	38.3	10	55.6	8	44.4	16	44.4	8	50.0	8	50.0	0.5165	0.67	0.25	1.77		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	16	55.2	13	44.8	24	66.7	10	41.7	14	58.3	0.7595	0.92	0.40	2.09		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	5	27.8	13	72.2	12	33.3	4	33.3	8	66.7	0.3484	0.52	0.13	2.10		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	5	55.6	4	44.4	13	36.1	7	53.8	6	46.2	0.4665	0.65	0.20	2.09		Convergence criterion (GCONV=1E-8) satisfied.	0.7039
	Non-Europe	38	80.9	16	42.1	22	57.9	23	63.9	7	30.4	16	69.6	0.8785	0.94	0.37	2.35		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTINECT_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30MAR2023 9:22

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	14	27	12	0.68	(0.30, 1.53)
YO41543	19	7	9	2	1.55	(0.32, 7.49)
Total	47	21	36	14	0.79	(0.39, 1.60)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTINECT_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 30MAR2023 15:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	14	50.0	14	50.0	27	75.0	12	44.4	15	55.6	0.3454	0.68	0.30	1.53		Convergence criterion (GCONV=1E-8) satisfied.		79.0						
	YO41543	19	40.4	7	36.8	12	63.2	9	25.0	2	22.2	7	77.8	0.5803	1.55	0.32	7.49		Convergence criterion (GCONV=1E-8) satisfied.		21.0						
	Total	47	100.0	21	44.7	26	55.3	36	100.0	14	38.9	22	61.1	0.4501	0.79	0.39	1.60		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.84	1	0.3582	0.00	-0.65	0.5147

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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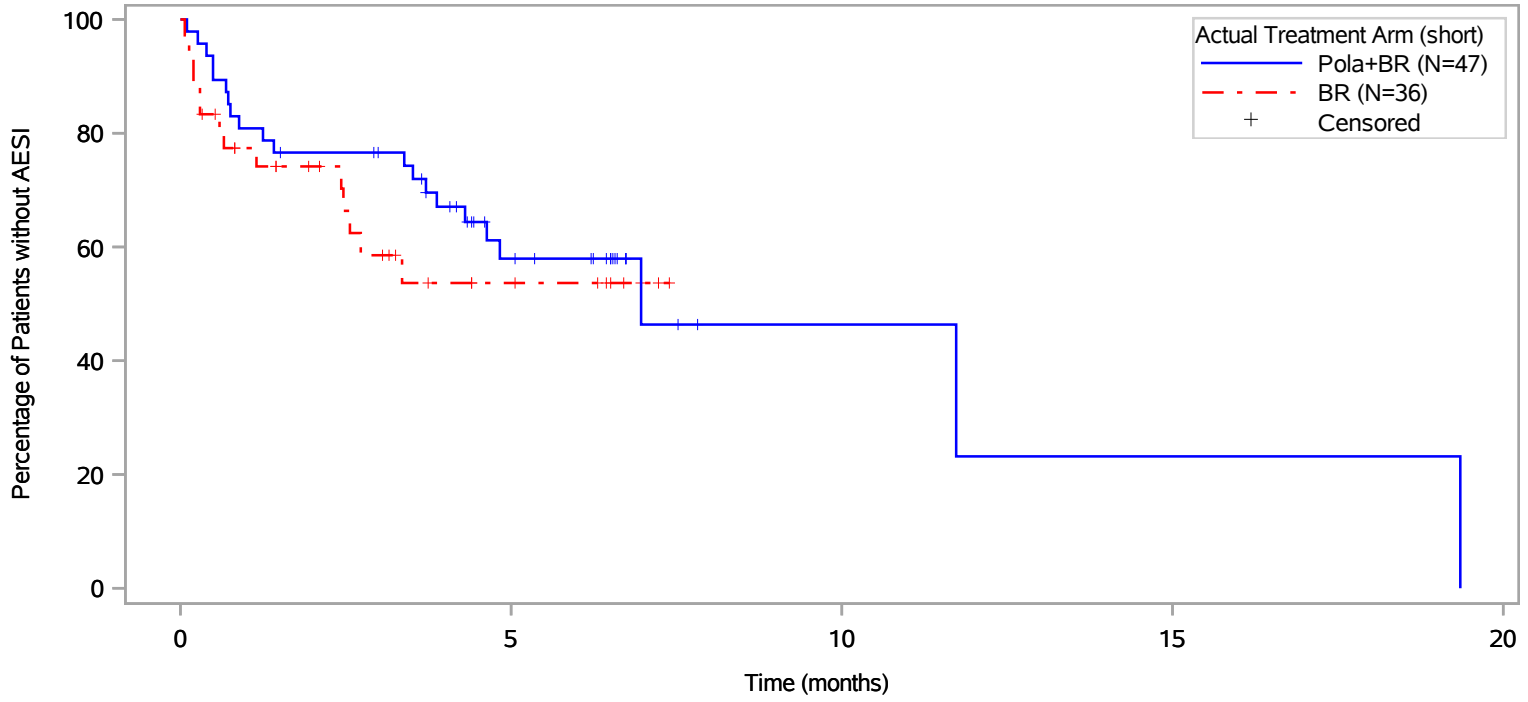
03APR2023 13:20

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=47)	47	38	35	33	27	18	16	4	2	2	2	2	1	1	1	1	1	1	1	1
BR (N=36)	36	24	20	15	10	8	7	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=47)	0	0	1	3	5	11	13	24	26	26	26	26	26	26	26	26	26	26	26	26
BR (N=36)	0	4	7	8	12	14	15	20	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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30MAR2023 11:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	14	29.8	33	70.2	36	100.0	9	25.0	27	75.0	0.3981	0.68	0.28	1.66		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	12	35.3	22	64.7	24	66.7	6	25.0	18	75.0	0.5073	0.71	0.25	2.03		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	2	15.4	11	84.6	12	33.3	3	25.0	9	75.0	0.4580	0.51	0.09	3.07		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	6	20.7	23	79.3	20	55.6	3	15.0	17	85.0	0.9983	0.91	0.22	3.74		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	8	44.4	10	55.6	16	44.4	6	37.5	10	62.5	0.2803	0.50	0.15	1.68		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	11	37.9	18	62.1	24	66.7	6	25.0	18	75.0	0.8852	0.89	0.31	2.55		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	3	16.7	15	83.3	12	33.3	3	25.0	9	75.0	0.1761	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	4	44.4	5	55.6	13	36.1	6	46.2	7	53.8	0.1287	0.30	0.06	1.54		Convergence criterion (GCONV=1E-8) satisfied.	0.0562
	Non-Europe	38	80.9	10	26.3	28	73.7	23	63.9	3	13.0	20	87.0	0.6219	1.38	0.37	5.17		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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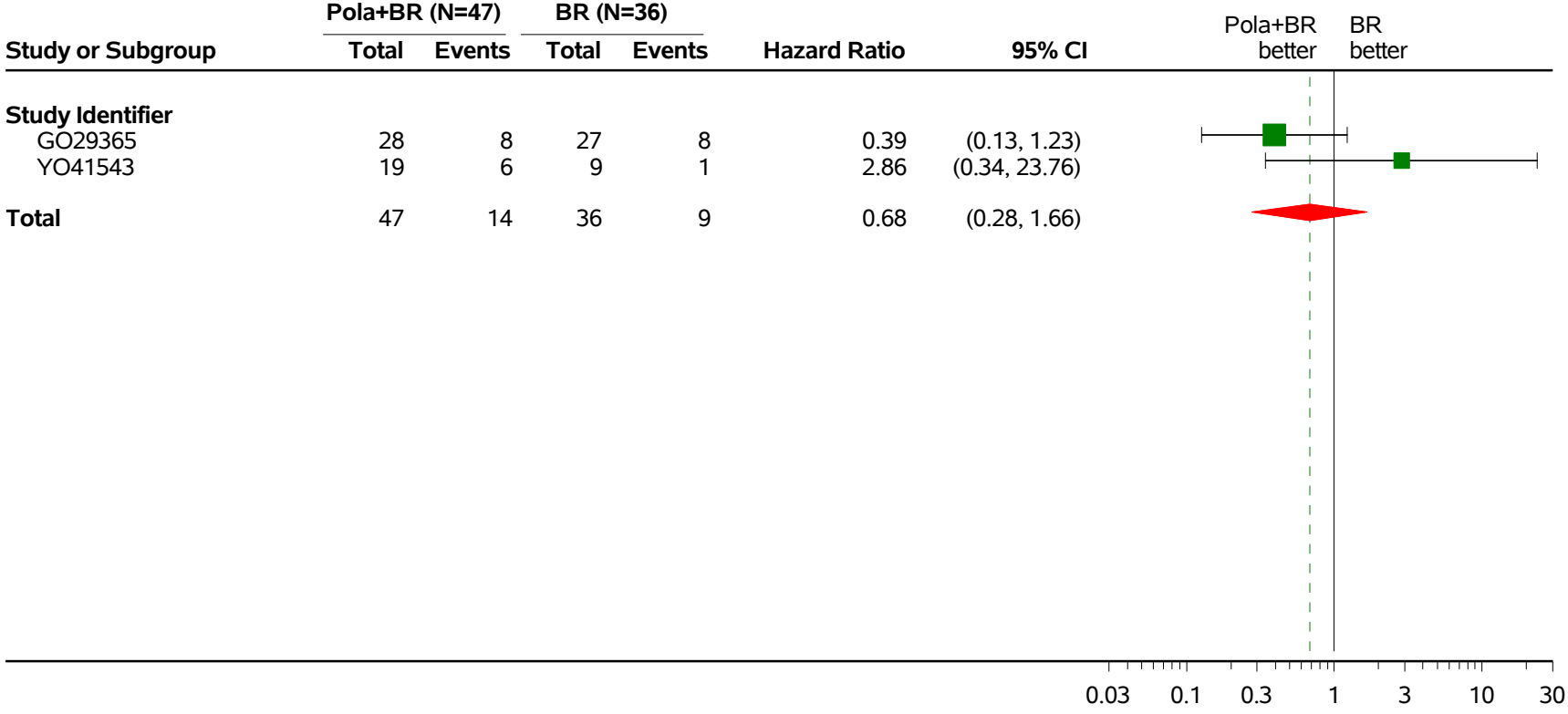
30MAR2023 11:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	8	27	8	0.39	(0.13, 1.23)
YO41543	19	6	9	1	2.86	(0.34, 23.76)
Total	47	14	36	9	0.68	(0.28, 1.66)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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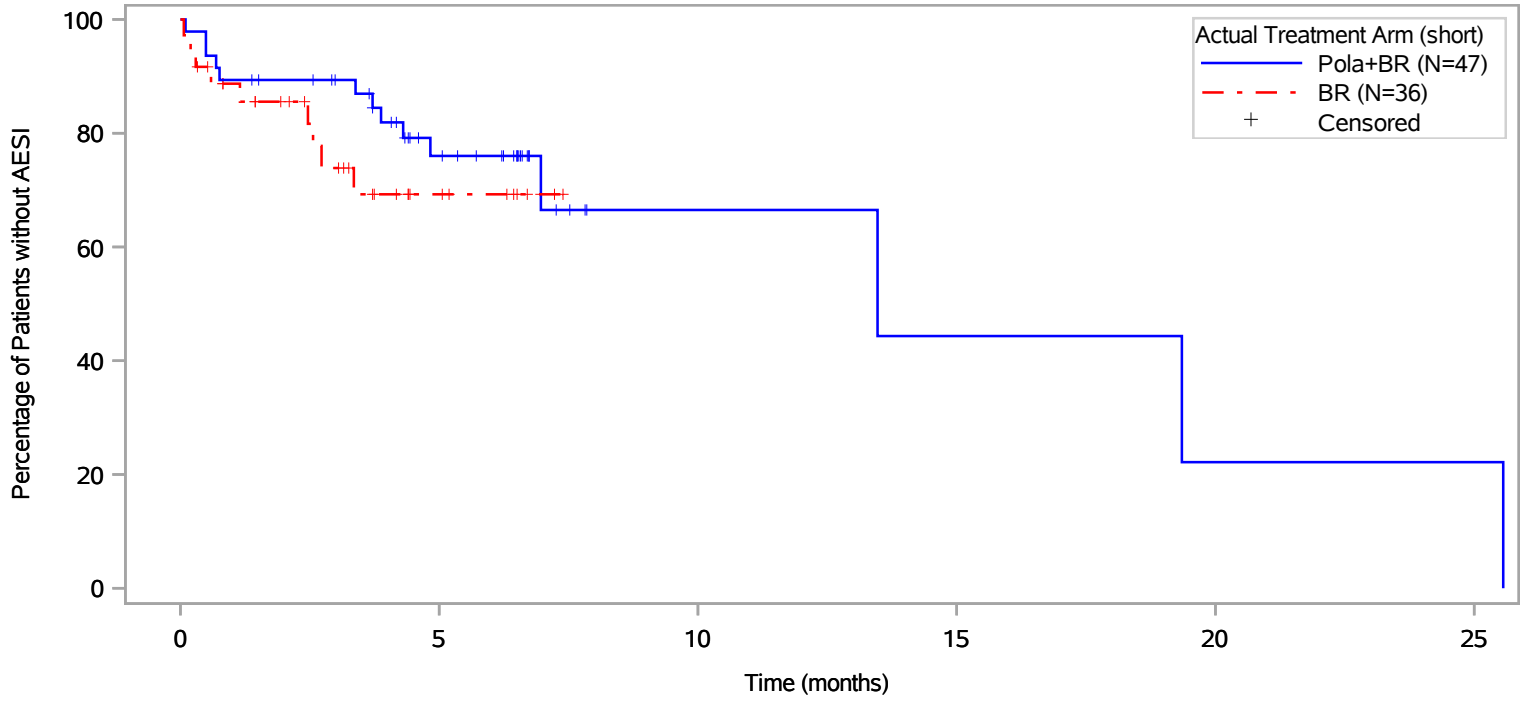
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	8	28.6	20	71.4	27	75.0	8	29.6	19	70.4	0.0964	0.39	0.13	1.23		Convergence criterion (GCONV=1E-8) satisfied.	77.7						
	YO41543	19	40.4	6	31.6	13	68.4	9	25.0	1	11.1	8	88.9	0.3089	2.86	0.34	23.76		Convergence criterion (GCONV=1E-8) satisfied.	22.3						
	Total	47	100.0	14	29.8	33	70.2	36	100.0	9	25.0	27	75.0	0.3981	0.68	0.28	1.66		Convergence criterion (GCONV=1E-8) satisfied.	100.0	2.66	1	0.1031	62.35	-0.84	0.4001

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTINECT35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
03APR2023 13:44

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk																										
Pola+BR (N=47)	47	42	40	37	32	24	21	7	3	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=36)	36	28	24	19	13	9	7	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	2	5	7	13	16	29	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33	33
BR (N=36)	0	4	7	9	14	18	20	25	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_TTINECT35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
30MAR2023 13:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

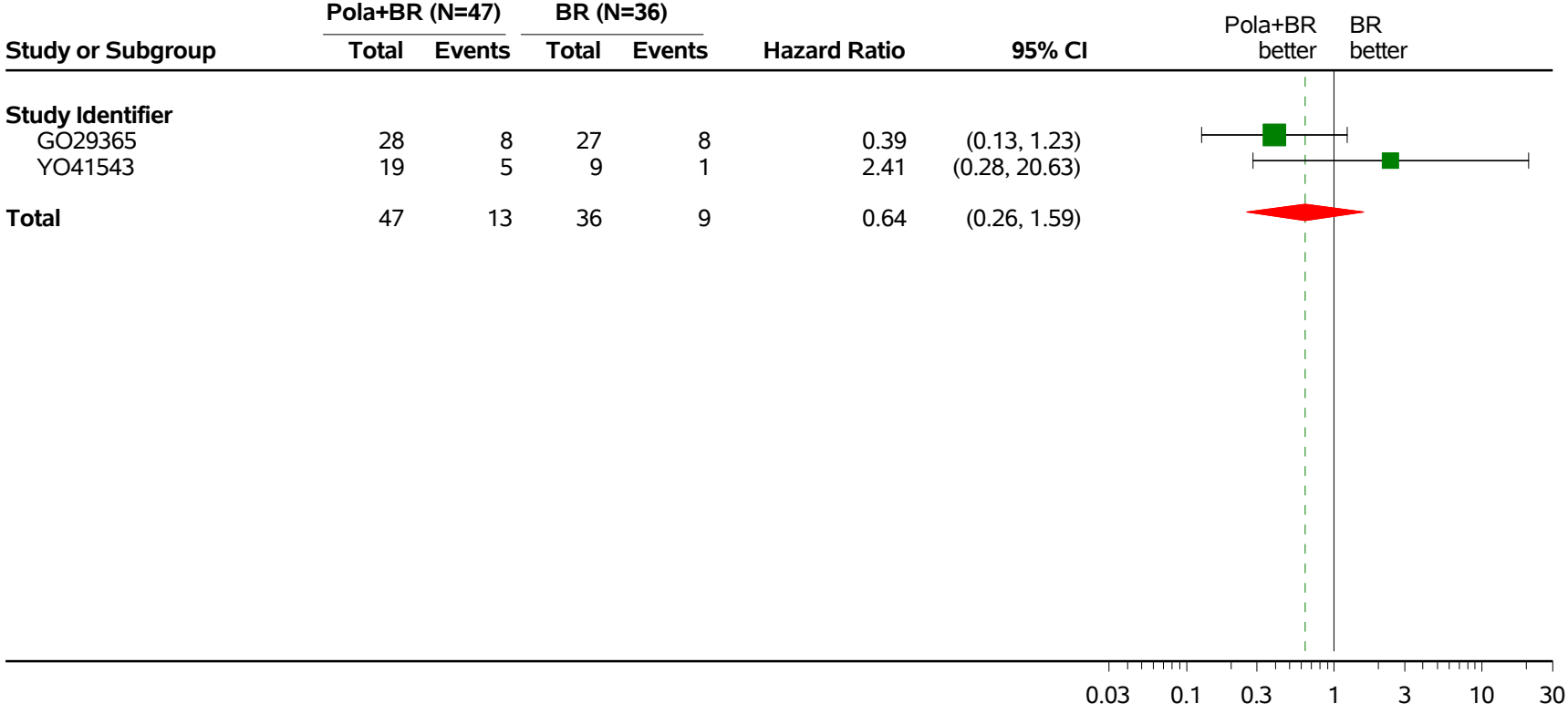
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	13	27.7	34	72.3	36	100.0	9	25.0	27	75.0	0.3231	0.64	0.26	1.59		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	11	32.4	23	67.6	24	66.7	6	25.0	18	75.0	0.4161	0.66	0.22	1.95		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	2	15.4	11	84.6	12	33.3	3	25.0	9	75.0	0.4664	0.51	0.08	3.13		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	5	17.2	24	82.8	20	55.6	3	15.0	17	85.0	0.8529	0.81	0.19	3.48		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	8	44.4	10	55.6	16	44.4	6	37.5	10	62.5	0.2803	0.50	0.15	1.68		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	10	34.5	19	65.5	24	66.7	6	25.0	18	75.0	0.7424	0.82	0.28	2.41		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	3	16.7	15	83.3	12	33.3	3	25.0	9	75.0	0.1761	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	4	44.4	5	55.6	13	36.1	6	46.2	7	53.8	0.1287	0.30	0.06	1.54		Convergence criterion (GCONV=1E-8) satisfied.	0.0774
	Non-Europe	38	80.9	9	23.7	29	76.3	23	63.9	3	13.0	20	87.0	0.7310	1.25	0.33	4.79		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTINECTS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
30MAR2023 10:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	8	27	8	0.39	(0.13, 1.23)
YO41543	19	5	9	1	2.41	(0.28, 20.63)
Total	47	13	36	9	0.64	(0.26, 1.59)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..CE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTINECTS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 30MAR2023 15:33

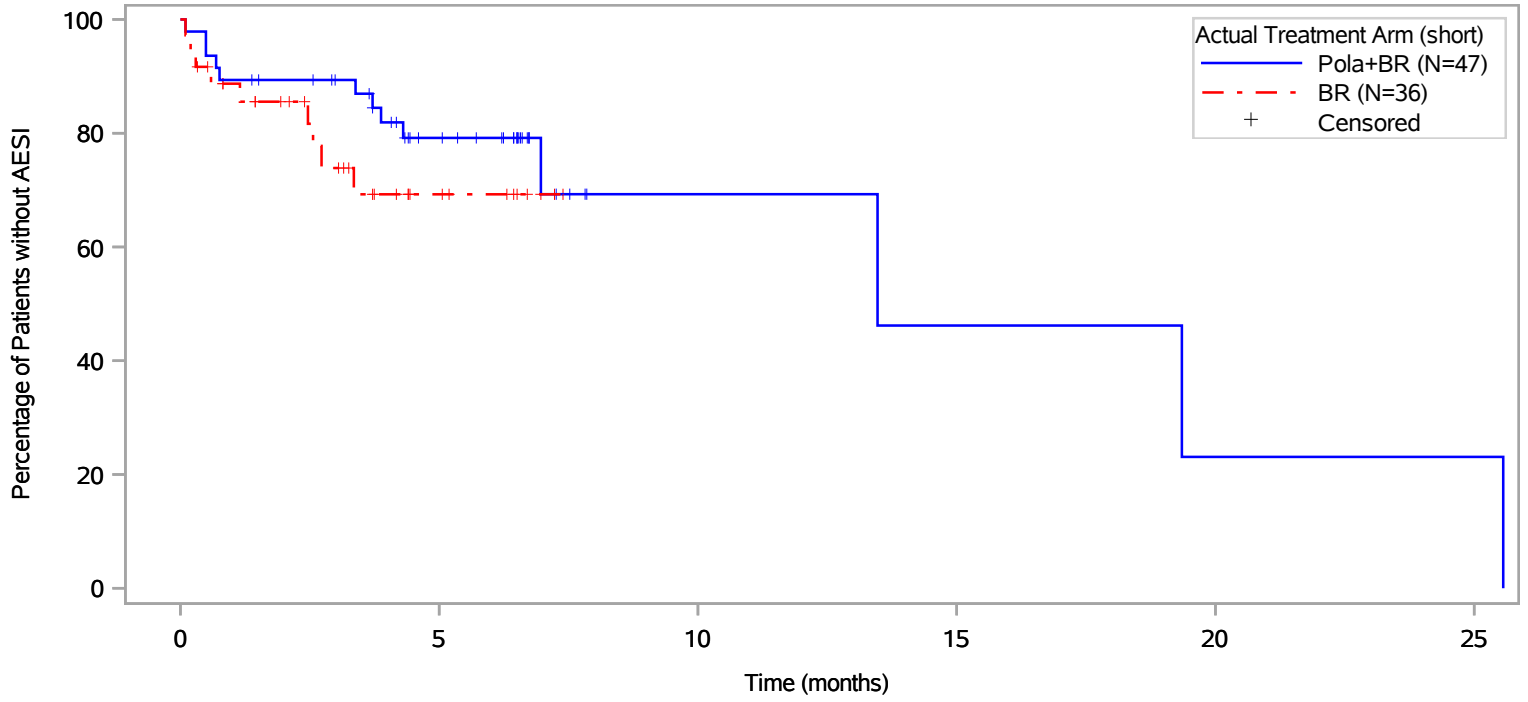
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	8	28.6	20	71.4	27	75.0	8	29.6	19	70.4	0.0964	0.39	0.13	1.23		Convergence criterion (GCONV=1E-8) satisfied.	78.2							
	YO41543	19	40.4	5	26.3	14	73.7	9	25.0	1	11.1	8	88.9	0.4074	2.41	0.28	20.63		Convergence criterion (GCONV=1E-8) satisfied.	21.8							
	Total	47	100.0	13	27.7	34	72.3	36	100.0	9	25.0	27	75.0	0.3231	0.64	0.26	1.59		Convergence criterion (GCONV=1E-8) satisfied.	100.0	2.16	1	0.1414	53.76		-0.96	0.3353

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTINECTS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
03APR2023 13:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk																										
Pola+BR (N=47)	47	42	40	37	32	25	22	7	3	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=36)	36	28	24	19	13	9	7	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=47)	0	0	2	5	7	13	16	30	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34	34
BR (N=36)	0	4	7	9	14	18	20	25	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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30MAR2023 12:34

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

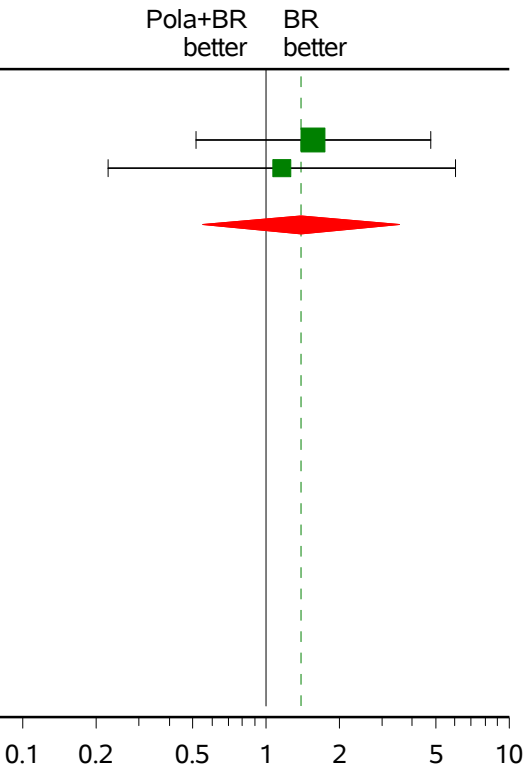
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	14	29.8	33	70.2	36	100.0	7	19.4	29	80.6	0.5145	1.39	0.55	3.52		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	12	35.3	22	64.7	24	66.7	3	12.5	21	87.5	0.1082	2.74	0.75	9.99		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	2	15.4	11	84.6	12	33.3	4	33.3	8	66.7	0.2112	0.35	0.06	2.01		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	9	31.0	20	69.0	20	55.6	4	20.0	16	80.0	0.6541	1.37	0.41	4.58		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	5	27.8	13	72.2	16	44.4	3	18.8	13	81.3	0.6380	1.42	0.33	6.20		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	9	31.0	20	69.0	24	66.7	5	20.8	19	79.2	0.6887	1.25	0.40	3.90		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	5	27.8	13	72.2	12	33.3	2	16.7	10	83.3	0.5829	1.59	0.30	8.25		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	4	44.4	5	55.6	13	36.1	4	30.8	9	69.2	0.7872	1.22	0.29	5.02		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	10	26.3	28	73.7	23	63.9	3	13.0	20	87.0	0.3333	1.85	0.50	6.82		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTIRR_L3PLUS_ARMCDPLUSSE_29365_41543.xls
01DEC2022 3:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=47) Total	Pola+BR (N=47) Events	BR (N=36) Total	BR (N=36) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	28	9	27	5	1.56	(0.51, 4.76)
YO41543	19	5	9	2	1.16	(0.22, 6.05)
Total	47	14	36	7	1.39	(0.55, 3.52)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTIRR_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 18:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	9	32.1	19	67.9	27	75.0	5	18.5	22	81.5	0.4279	1.56	0.51	4.76		Convergence criterion (GCONV=1E-8) satisfied.		68.7						
	YO41543	19	40.4	5	26.3	14	73.7	9	25.0	2	22.2	7	77.8	0.8583	1.16	0.22	6.05		Convergence criterion (GCONV=1E-8) satisfied.		31.3						
	Total	47	100.0	14	29.8	33	70.2	36	100.0	7	19.4	29	80.6	0.5145	1.39	0.55	3.52		Convergence criterion (GCONV=1E-8) satisfied.		100.0	0.09	1	0.7665	0.00	0.69	0.4880

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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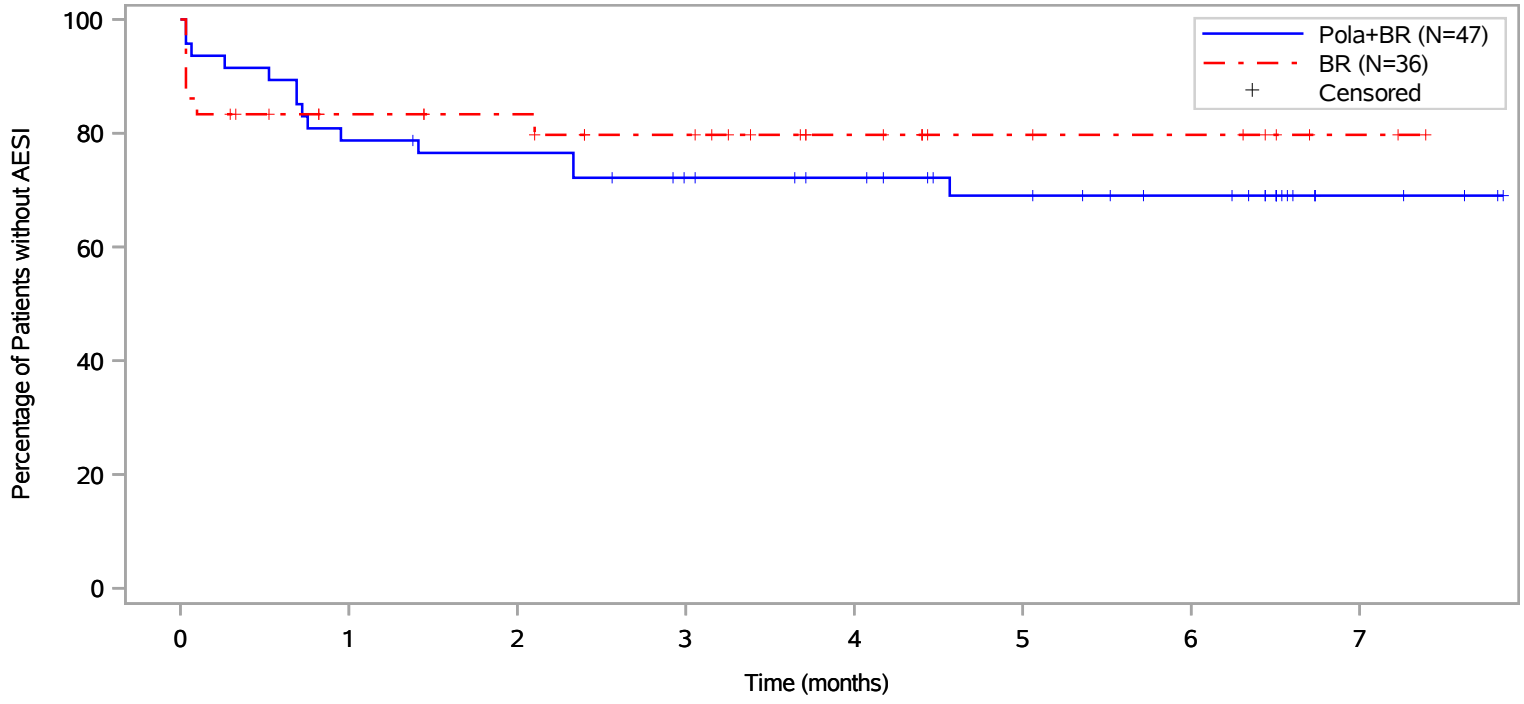
16DEC2022 11:41

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=47)	47	37	35	30	27	22	18	4
BR (N=36)	36	25	23	19	12	7	6	2
Patients censored								
Pola+BR (N=47)	0	0	1	4	7	11	15	29
BR (N=36)	0	5	7	10	17	22	23	27

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:56

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

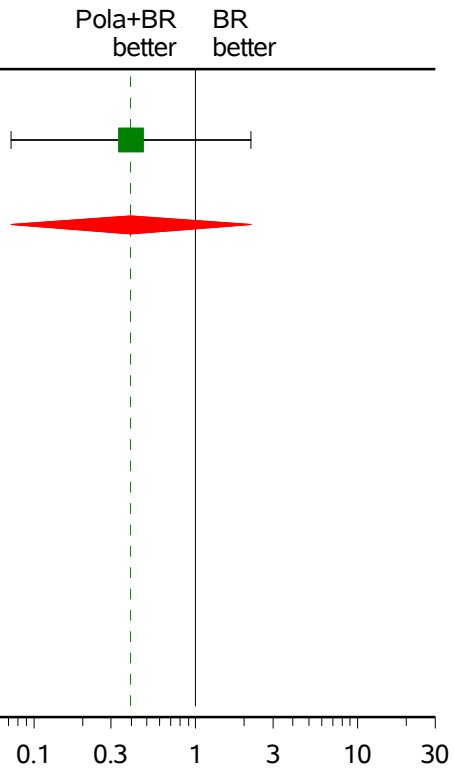
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	2	4.3	45	95.7	36	100.0	4	11.1	32	88.9	0.1801	0.40	0.07	2.19		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8551	1.58	0.14	17.51		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	3	25.0	9	75.0	0.0497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6950	0.83	0.05	13.46		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	3	18.8	13	81.3	0.1943	0.25	0.03	2.46		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	3	12.5	21	87.5	0.1700	0.32	0.03	3.18		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.7646	0.68	0.04	10.86		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	2	22.2	7	77.8	13	36.1	3	23.1	10	76.9	0.7500	0.75	0.12	4.52		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTIRR35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:59

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	2	27	4	0.40	(0.07, 2.19)
YO41543	19	0	9	0	NE	NE
Total	47	2	36	4	0.40	(0.07, 2.19)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTIRR35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 18:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	2	7.1	26	92.9	27	75.0	4	14.8	23	85.2	0.2737	0.40	0.07	2.19		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	2	4.3	45	95.7	36	100.0	4	11.1	32	88.9	0.1801	0.40	0.07	2.19		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	-1.06	0.2900

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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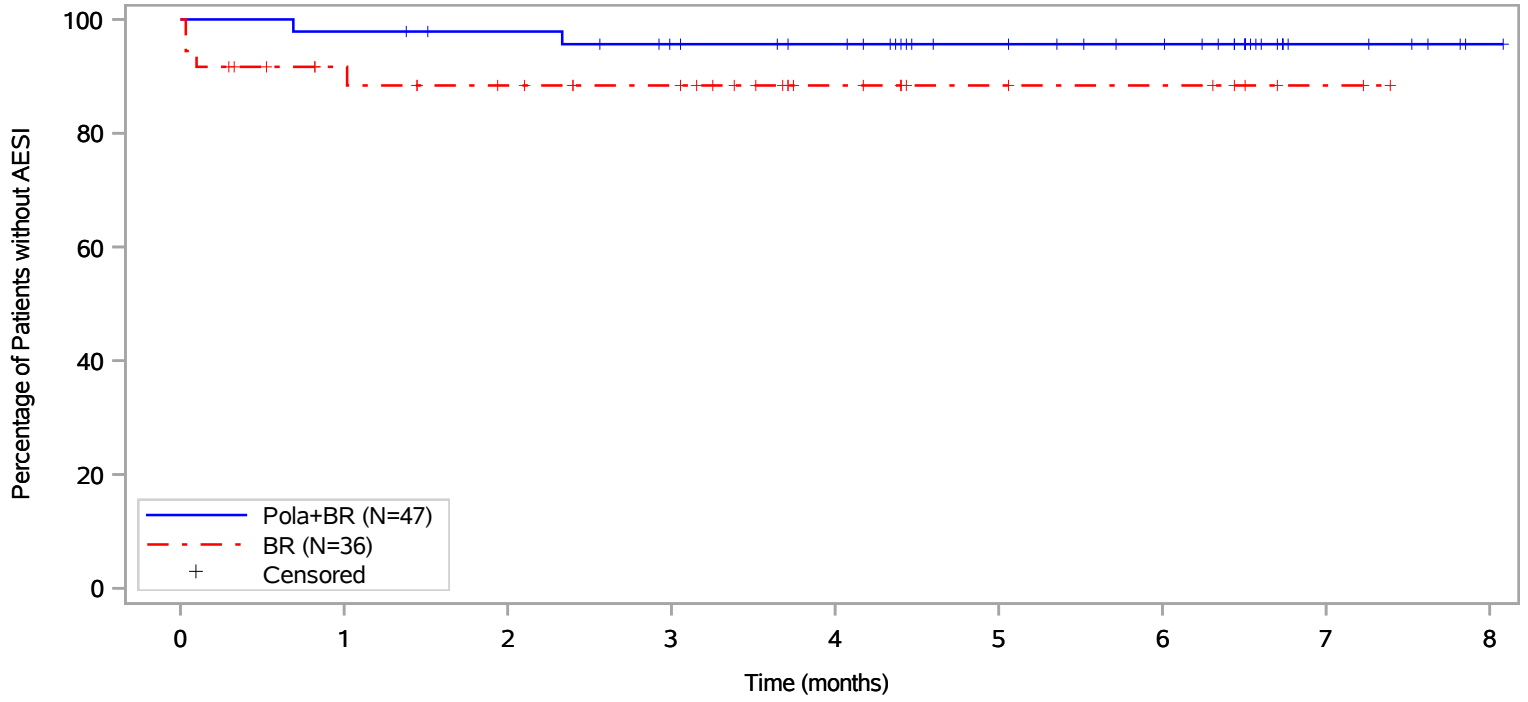
15DEC2022 18:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	46	44	40	37	29	25	6	1
BR (N=36)	36	28	24	21	12	7	6	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	39	44
BR (N=36)	0	5	8	11	20	25	26	30	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 23:05

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	3	8.3	33	91.7	0.1486	0.26	0.03	2.55		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	3	25.0	9	75.0	0.0497	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.6950	0.83	0.05	13.46		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	2	12.5	14	87.5	0.1063	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	2	8.3	22	91.7	0.3681	0.49	0.04	5.50		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	1	8.3	11	91.7	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	1	11.1	8	88.9	13	36.1	2	15.4	11	84.6	0.6040	0.53	0.05	5.98		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	1	4.3	22	95.7	0.1987	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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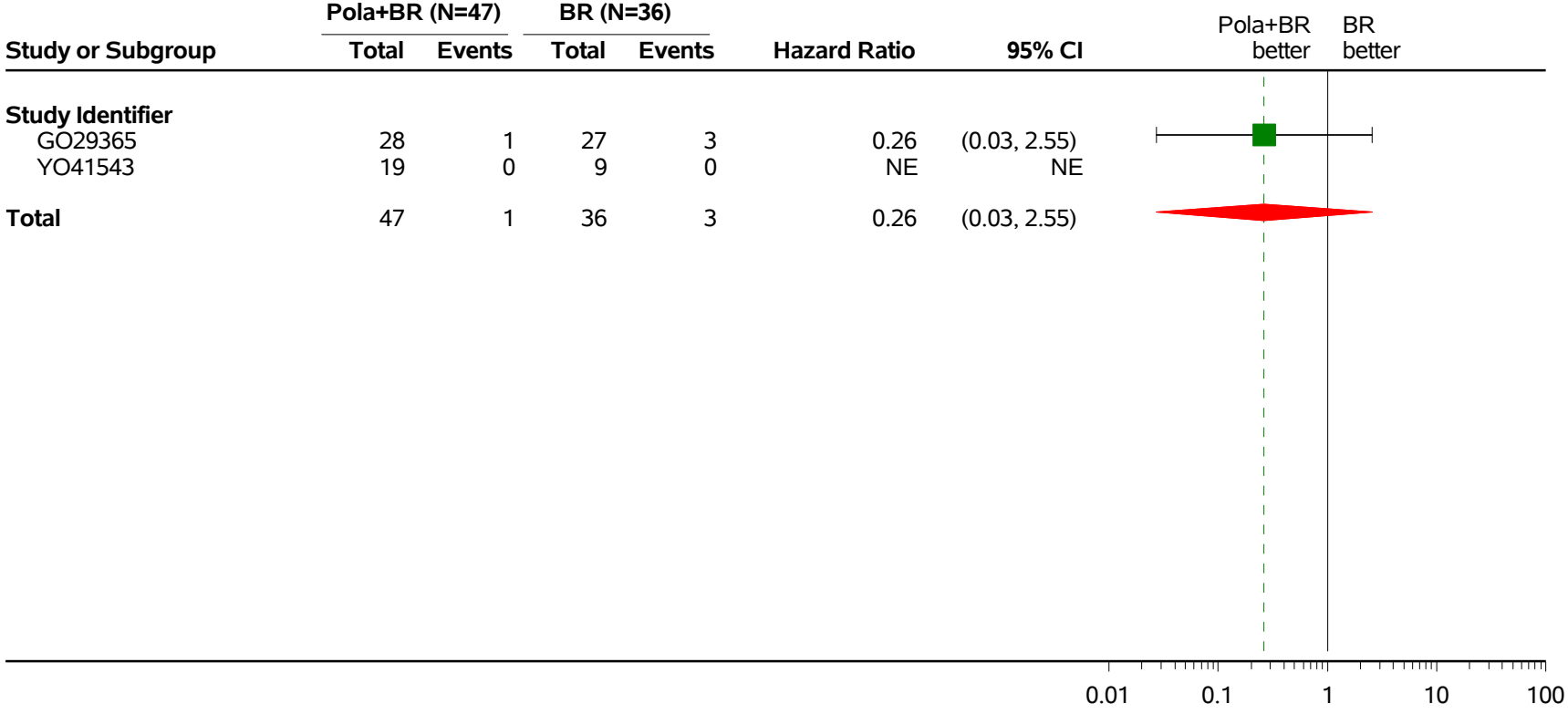
02DEC2022 20:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	1	27	3	0.26	(0.03, 2.55)
YO41543	19	0	9	0	NE	NE
Total	47	1	36	3	0.26	(0.03, 2.55)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTIRRS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 17:20

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	3	11.1	24	88.9	0.2160	0.26	0.03	2.55		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	3	8.3	33	91.7	0.1486	0.26	0.03	2.55		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	-1.15	0.2494

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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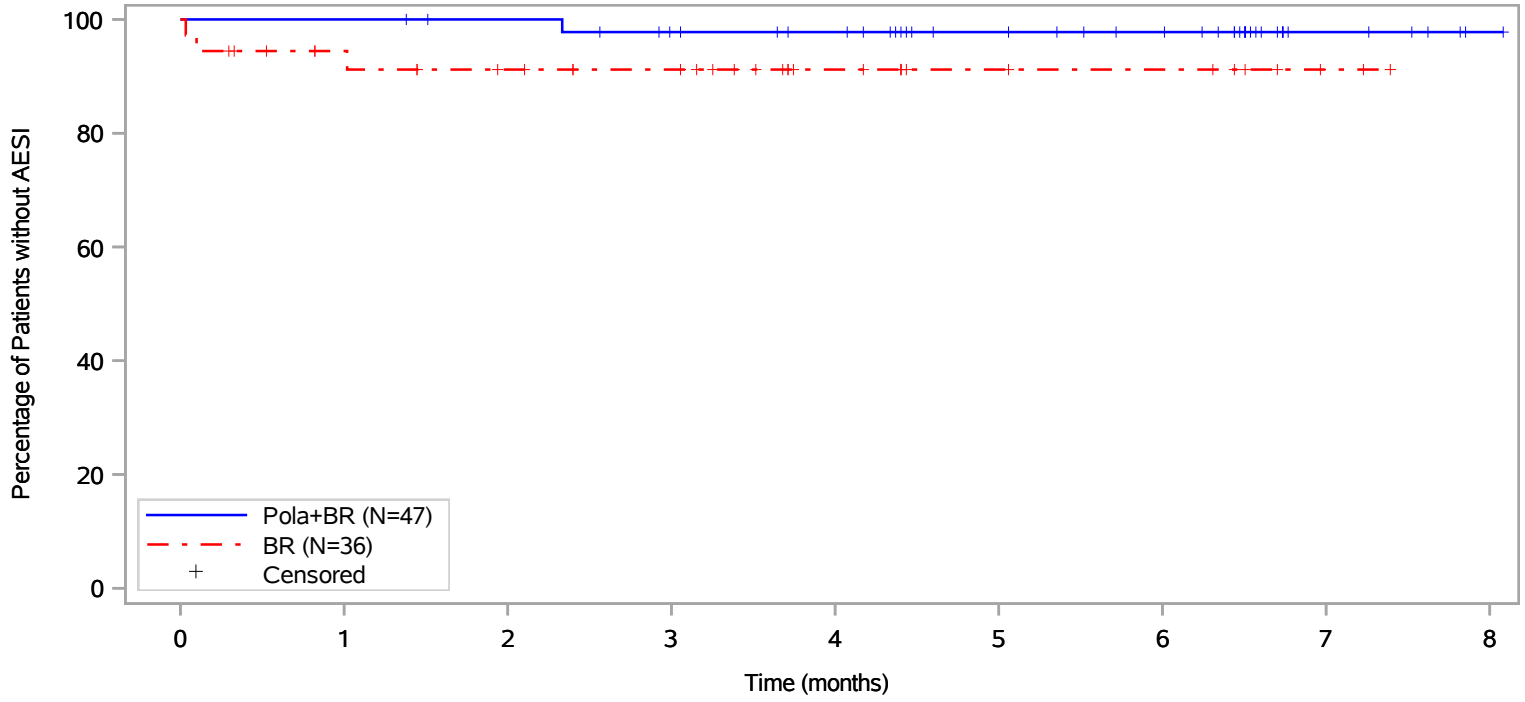
15DEC2022 21:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	29	25	22	13	8	7	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	5	8	11	20	25	26	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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04DEC2022 1:14

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	35	74.5	12	25.5	36	100.0	20	55.6	16	44.4	0.5169	0.96	0.53	1.74		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	24	70.6	10	29.4	24	66.7	13	54.2	11	45.8	0.8449	0.89	0.43	1.85		Convergence criterion (GCONV=1E-8) satisfied.	0.8280
	Female	13	27.7	11	84.6	2	15.4	12	33.3	7	58.3	5	41.7	0.4230	1.13	0.39	3.31		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	24	82.8	5	17.2	20	55.6	12	60.0	8	40.0	0.2369	1.19	0.56	2.56		Convergence criterion (GCONV=1E-8) satisfied.	0.4939
	>= 65	18	38.3	11	61.1	7	38.9	16	44.4	8	50.0	8	50.0	0.6053	0.71	0.27	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	22	75.9	7	24.1	24	66.7	13	54.2	11	45.8	0.7210	0.89	0.42	1.88		Convergence criterion (GCONV=1E-8) satisfied.	0.6178
	<3	18	38.3	13	72.2	5	27.8	12	33.3	7	58.3	5	41.7	0.6635	1.03	0.39	2.75		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	3	33.3	6	66.7	13	36.1	6	46.2	7	53.8	0.2876	0.47	0.11	1.94		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	32	84.2	6	15.8	23	63.9	14	60.9	9	39.1	0.5338	1.05	0.53	2.07		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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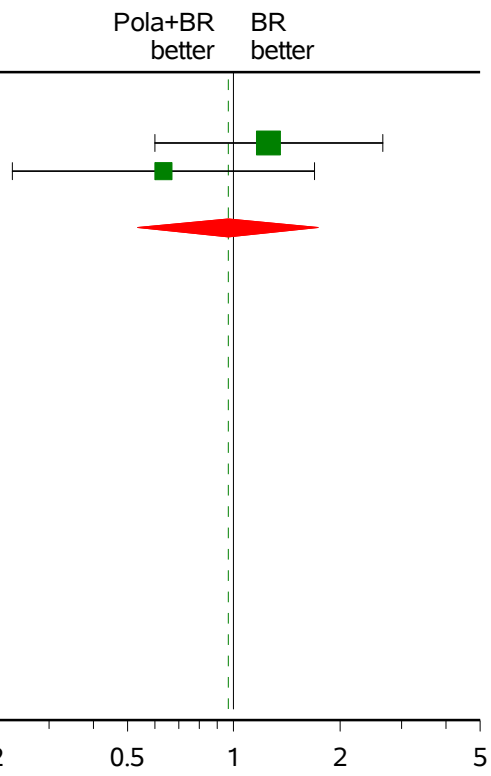
01DEC2022 0:11

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	19	27	12	1.26	(0.60, 2.64)
YO41543	19	16	9	8	0.63	(0.24, 1.69)
Total	47	35	36	20	0.96	(0.53, 1.74)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	19	67.9	9	32.1	27	75.0	12	44.4	15	55.6	0.5476	1.26	0.60	2.64		Convergence criterion (GCONV=1E-8) satisfied.		63.7						
	YO41543	19	40.4	16	84.2	3	15.8	9	25.0	8	88.9	1	11.1	0.3607	0.63	0.24	1.69		Convergence criterion (GCONV=1E-8) satisfied.		36.3						
	Total	47	100.0	35	74.5	12	25.5	36	100.0	20	55.6	16	44.4	0.5169	0.96	0.53	1.74		Convergence criterion (GCONV=1E-8) satisfied.		100.0	1.19	1	0.2760	15.72	-0.12	0.9030

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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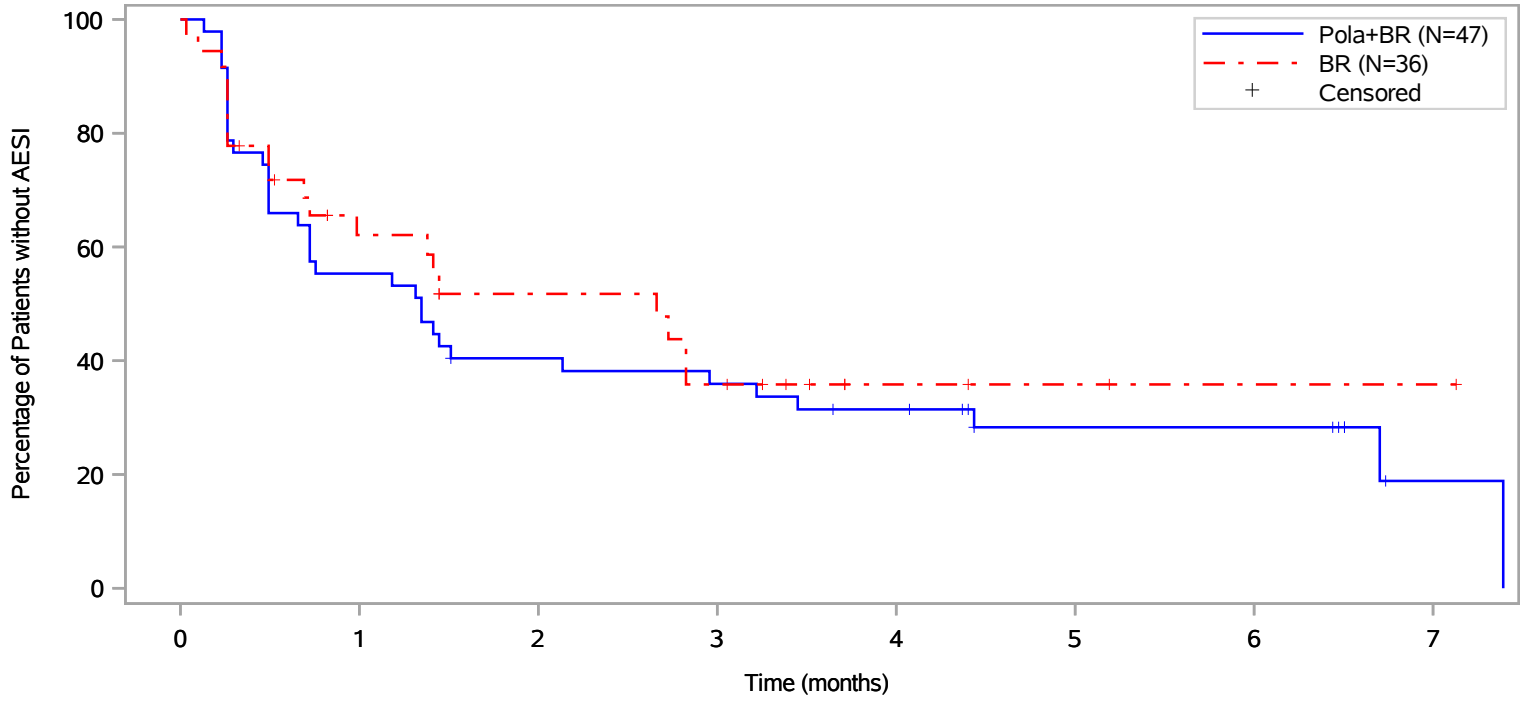
16DEC2022 12:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=47)	47	26	18	16	13	8	8	1
BR (N=36)	36	18	13	9	3	2	1	1
Patients censored								
Pola+BR (N=47)	0	0	1	1	2	6	6	12
BR (N=36)	0	5	7	7	13	14	15	15

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 20:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		47	100.0	31	66.0	16	34.0	36	100.0	16	44.4	20	55.6	0.3600	1.20	0.64	2.26	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	23	67.6	11	32.4	24	66.7	11	45.8	13	54.2	0.5510	1.19	0.56	2.52	Convergence criterion (GCONV=1E-8) satisfied.	0.6574
	Female	13	27.7	8	61.5	5	38.5	12	33.3	5	41.7	7	58.3	0.6720	1.09	0.32	3.74	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	21	72.4	8	27.6	20	55.6	9	45.0	11	55.0	0.2253	1.50	0.65	3.43	Convergence criterion (GCONV=1E-8) satisfied.	0.6068
	>= 65	18	38.3	10	55.6	8	44.4	16	44.4	7	43.8	9	56.3	0.8968	1.02	0.37	2.82	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	19	65.5	10	34.5	24	66.7	11	45.8	13	54.2	0.8160	0.90	0.40	2.02	Convergence criterion (GCONV=1E-8) satisfied.	0.2993
	<3	18	38.3	12	66.7	6	33.3	12	33.3	5	41.7	7	58.3	0.2410	1.88	0.66	5.40	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	2	22.2	7	77.8	13	36.1	4	30.8	9	69.2	0.3701	0.46	0.08	2.59	Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	29	76.3	9	23.7	23	63.9	12	52.2	11	47.8	0.3863	1.31	0.65	2.65	Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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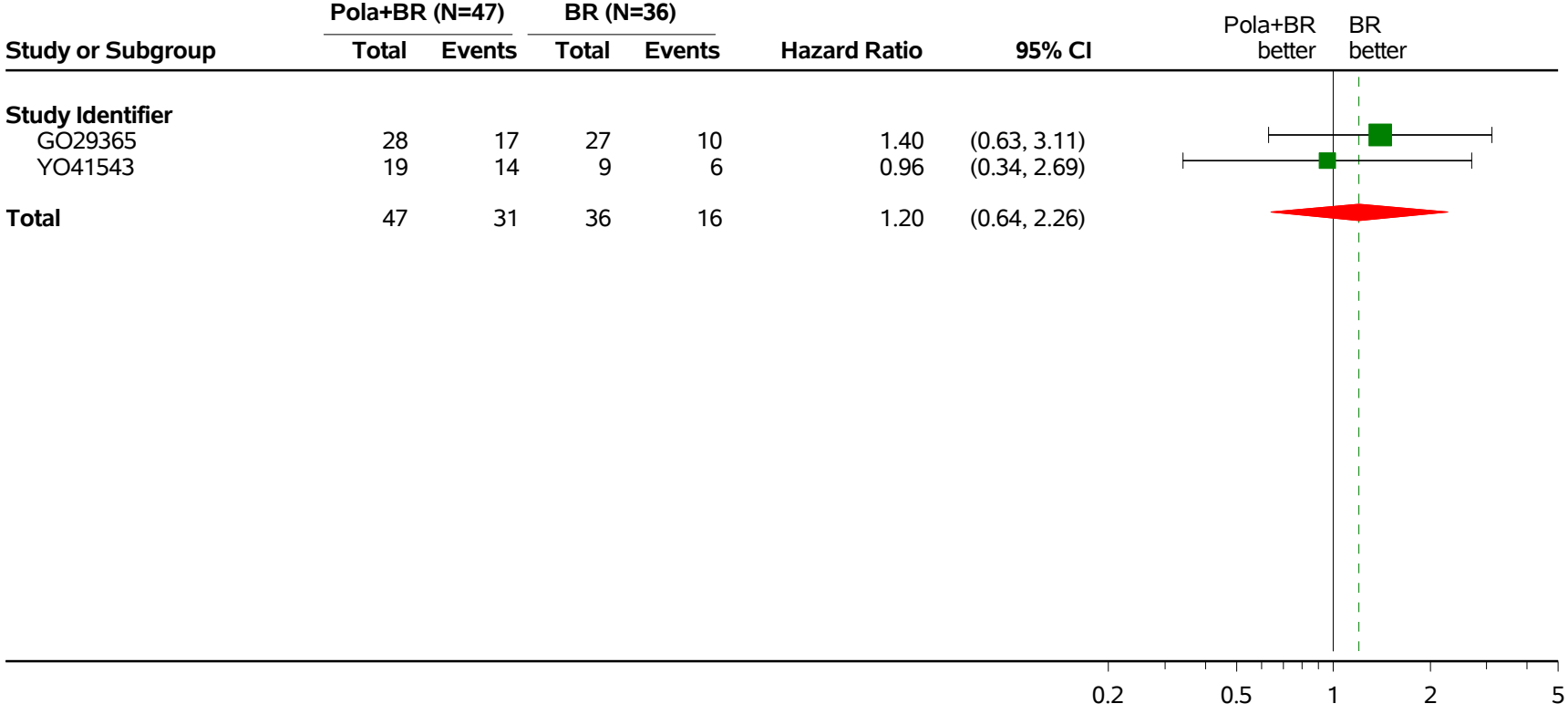
02DEC2022 20:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	17	27	10	1.40	(0.63, 3.11)
YO41543	19	14	9	6	0.96	(0.34, 2.69)
Total	47	31	36	16	1.20	(0.64, 2.26)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	17	60.7	11	39.3	27	75.0	10	37.0	17	63.0	0.4094	1.40	0.63	3.11		Convergence criterion (GCONV=1E-8) satisfied.	62.4							
	YO41543	19	40.4	14	73.7	5	26.3	9	25.0	6	66.7	3	33.3	0.9346	0.96	0.34	2.69		Convergence criterion (GCONV=1E-8) satisfied.	37.6							
	Total	47	100.0	31	66.0	16	34.0	36	100.0	16	44.4	20	55.6	0.3600	1.20	0.64	2.26		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.32	1	0.5693	0.00		0.58	0.5644

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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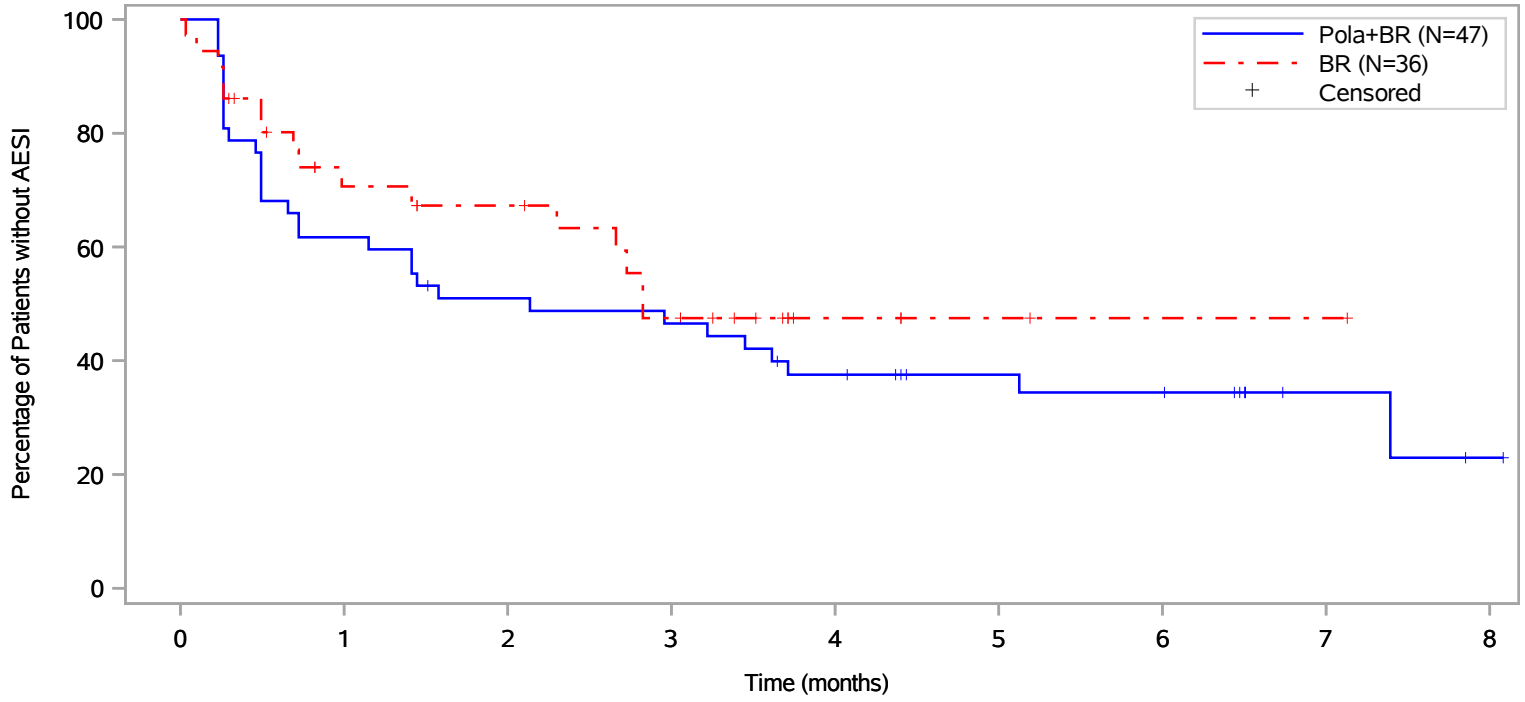
15DEC2022 19:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	29	23	21	16	12	11	3	1
BR (N=36)	36	21	18	12	4	2	1	1	NE
Patients censored									
Pola+BR (N=47)	0	0	1	1	2	6	6	14	15
BR (N=36)	0	5	7	8	16	18	19	19	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_km_TTNIFNEU35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:31

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

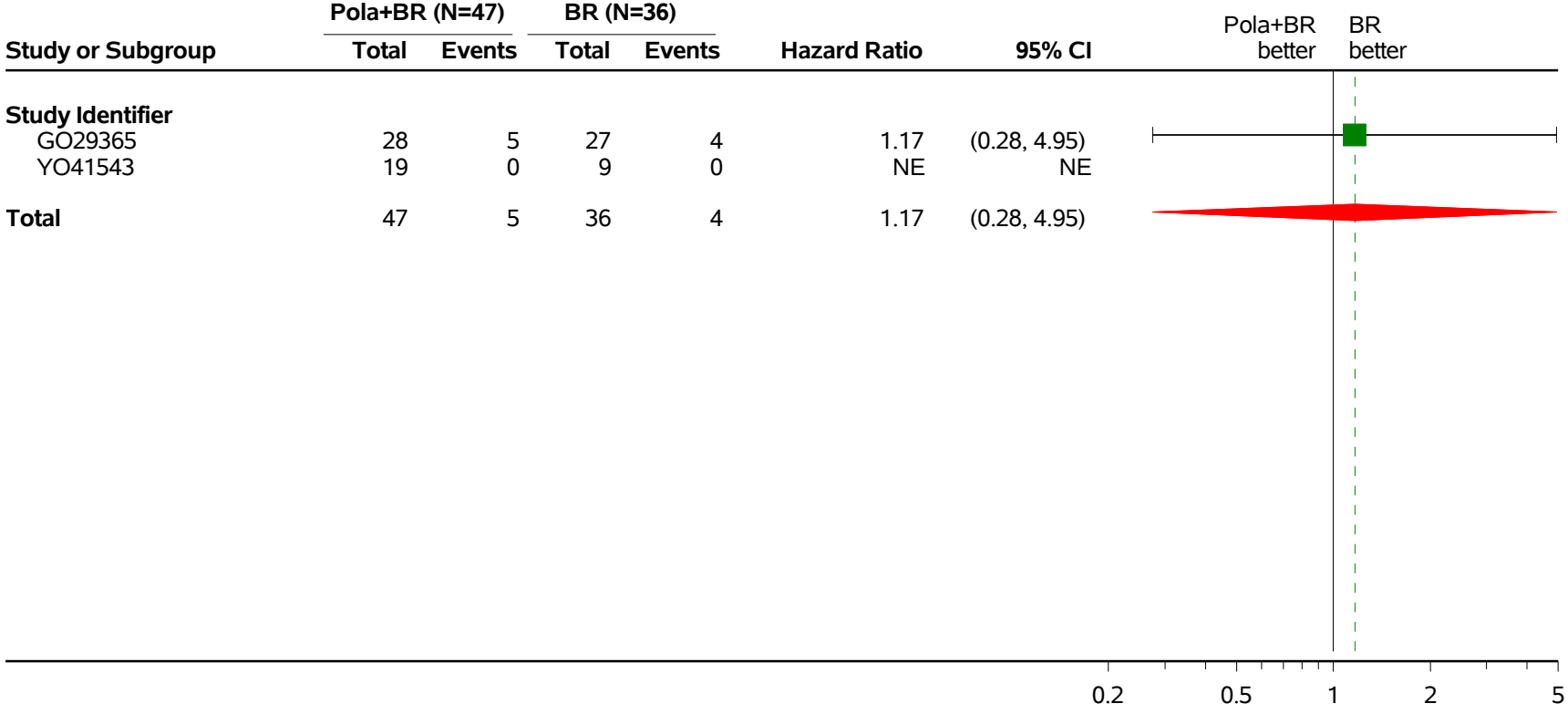
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	5	10.6	42	89.4	36	100.0	4	11.1	32	88.9	0.9886	1.17	0.28	4.95		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	3	8.8	31	91.2	24	66.7	3	12.5	21	87.5	0.8527	0.99	0.16	5.98		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	2	15.4	11	84.6	12	33.3	1	8.3	11	91.7	0.7176	1.70	0.15	18.97		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	2	6.9	27	93.1	20	55.6	2	10.0	18	90.0	0.4386	0.60	0.08	4.31		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	3	16.7	15	83.3	16	44.4	2	12.5	14	87.5	0.5346	2.09	0.21	21.00		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	3	10.3	26	89.7	24	66.7	3	12.5	21	87.5	0.9676	1.28	0.21	7.80		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	2	11.1	16	88.9	12	33.3	1	8.3	11	91.7	0.9182	1.10	0.10	12.20		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	2	15.4	11	84.6	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	5	13.2	33	86.8	23	63.9	2	8.7	21	91.3	0.8365	0.90	0.16	5.03		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTNIFNEUS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	5	27	4	1.17	(0.28, 4.95)
YO41543	19	0	9	0	NE	NE
Total	47	5	36	4	1.17	(0.28, 4.95)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTNIFNEUS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 13:56

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	5	17.9	23	82.1	27	75.0	4	14.8	23	85.2	0.8346	1.17	0.28	4.95		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	5	10.6	42	89.4	36	100.0	4	11.1	32	88.9	0.9886	1.17	0.28	4.95		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.21	0.8347

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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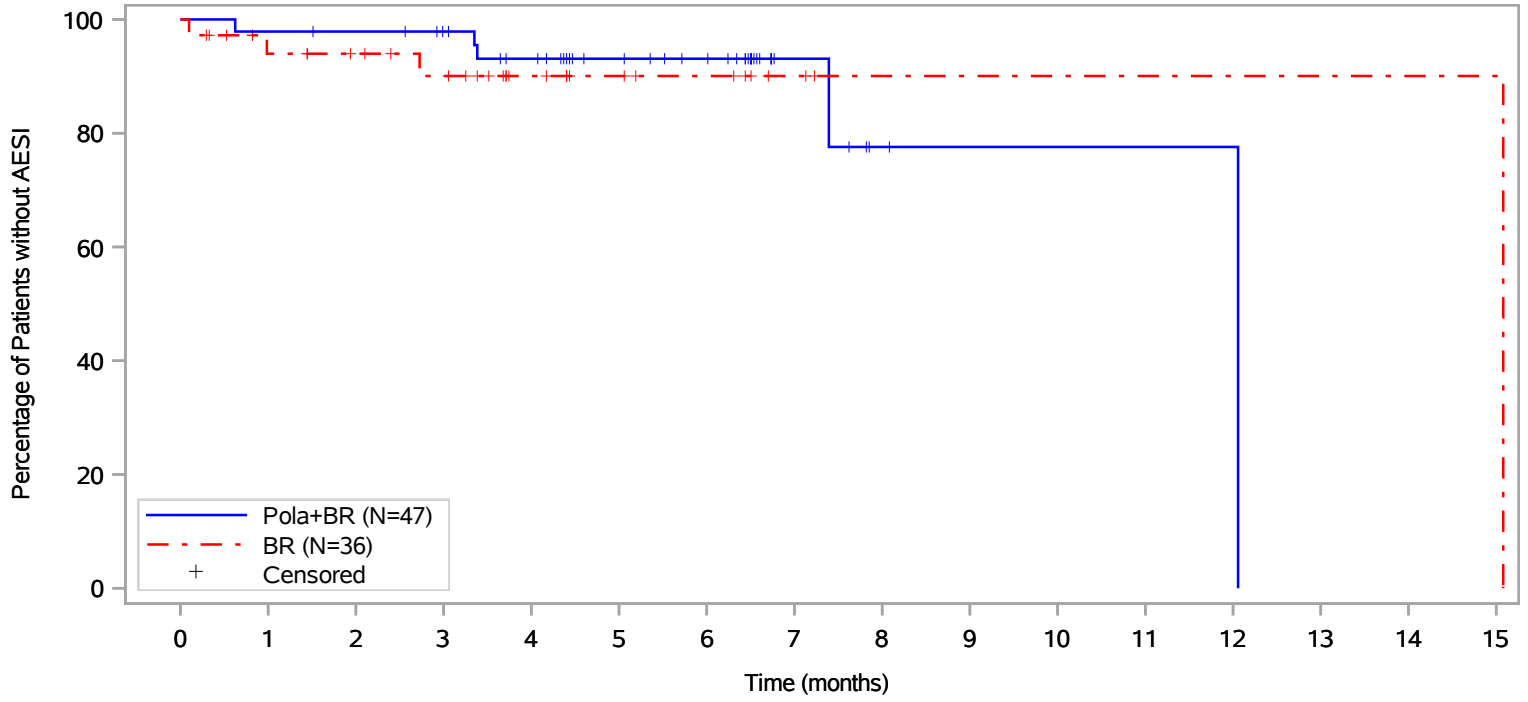
15DEC2022 18:41

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk																
Pola+BR (N=47)	47	46	45	42	37	29	25	6	2	1	1	1	1	NE	NE	NE
BR (N=36)	36	29	26	23	15	10	8	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=47)	0	0	1	4	7	15	19	38	41	42	42	42	42	NE	NE	NE
BR (N=36)	0	5	8	10	18	23	25	29	32	32	32	32	32	32	32	32

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 0:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

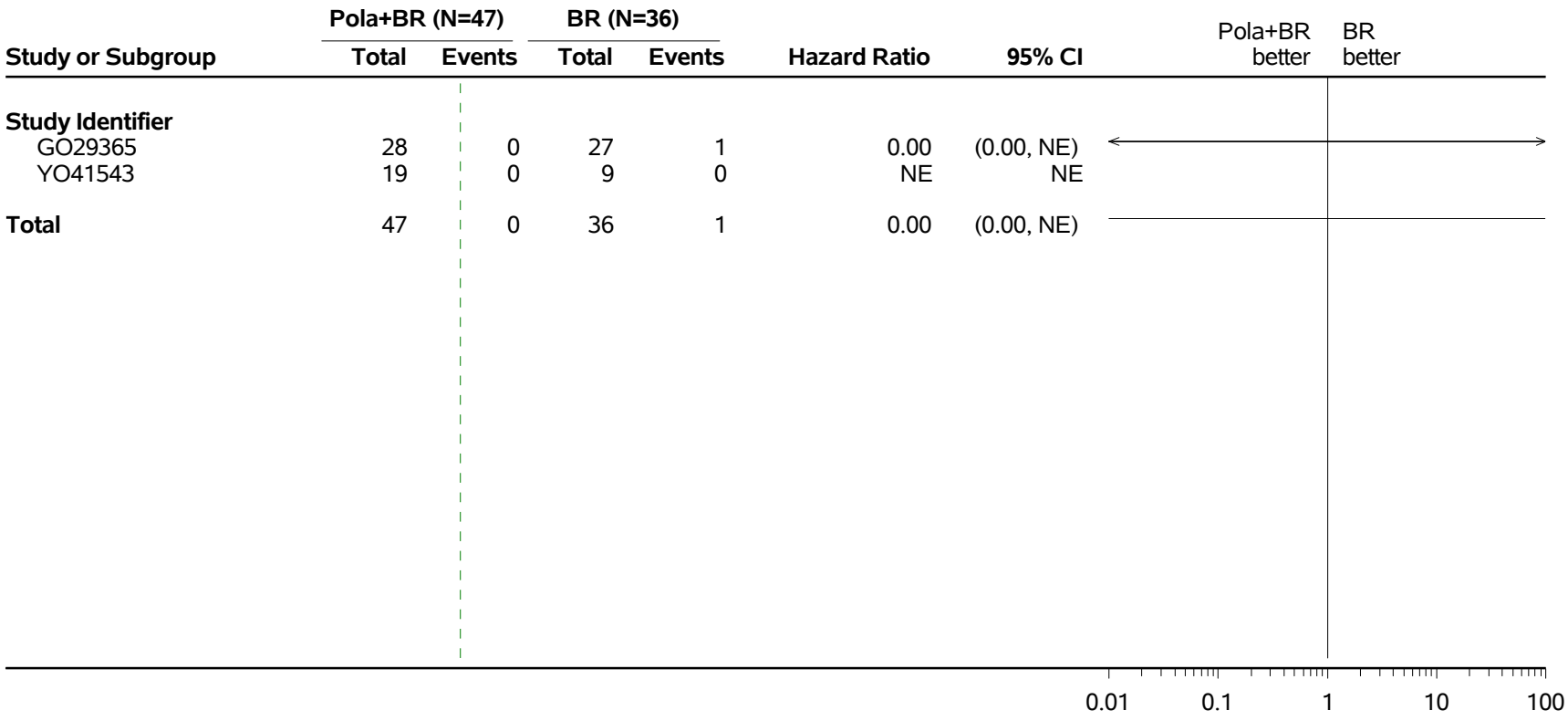
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2733	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2509	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTOCUTOX_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 11:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=47) Total	Pola+BR (N=47) Events	BR (N=36) Total	BR (N=36) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	28	0	27	1	0.00	(0.00, NE)
YO41543	19	0	9	0	NE	NE
Total	47	0	36	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTOCUTOX_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 21:21

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	0	-	47	100.0	36	100.0	1	2.8	35	97.2	0.2397	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9984

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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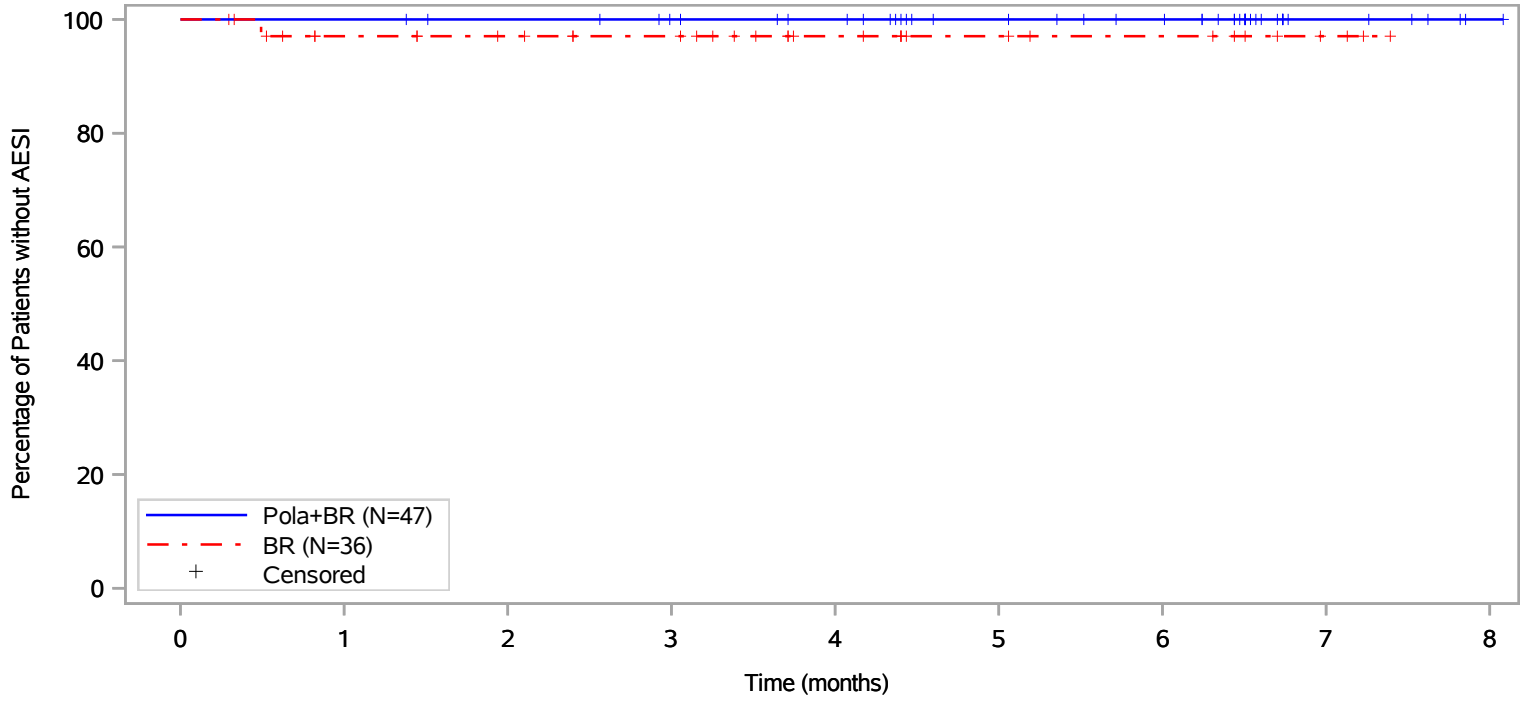
17DEC2022 22:09

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	29	26	23	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTOCUTOX_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:59

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTOCUTOX35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 22:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_fp_hr_TTOCUTOX35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 15:13

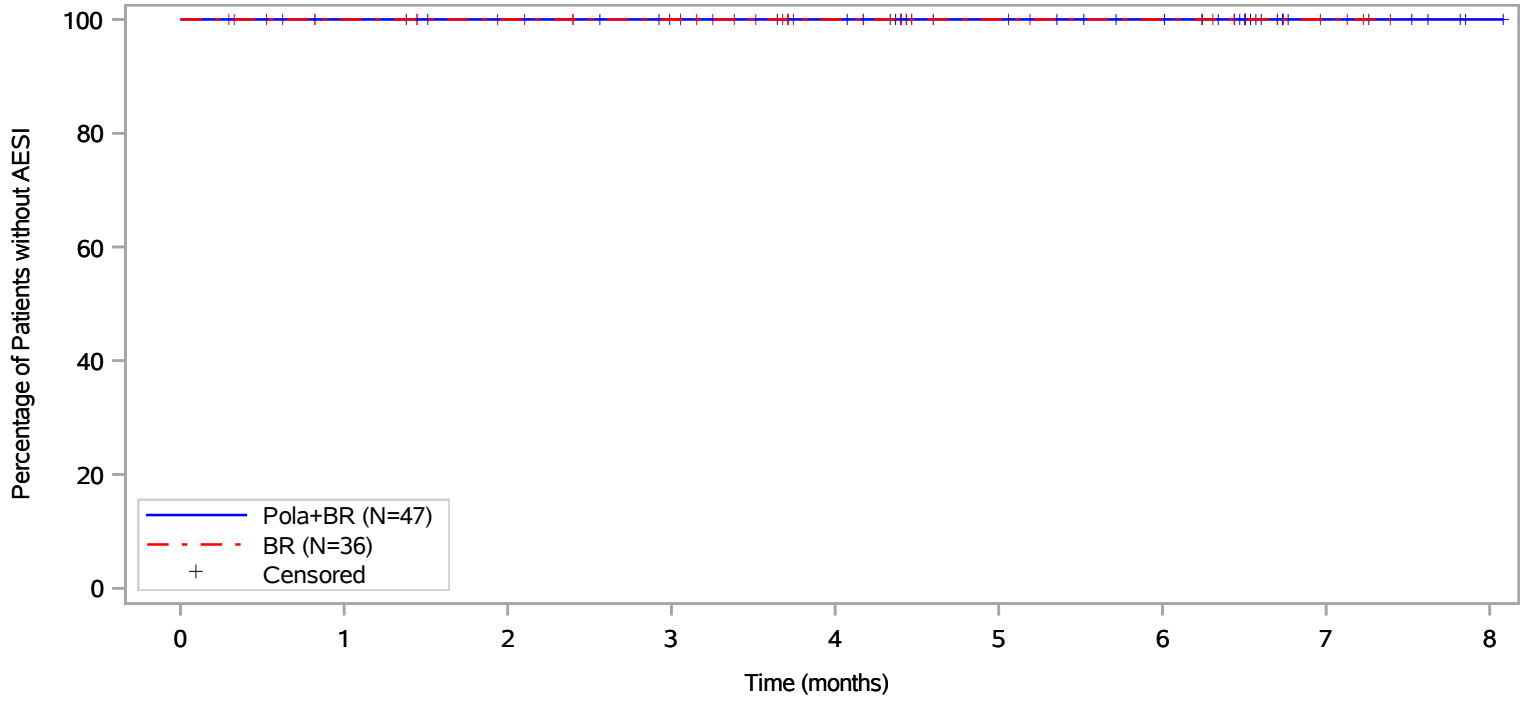
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTOCUTOX35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 21:52

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_km_TTOCUTOX35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 0:11

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Ocular Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTOCUTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 22:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Ocular Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTOCUTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
16DEC2022 20:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Ocular Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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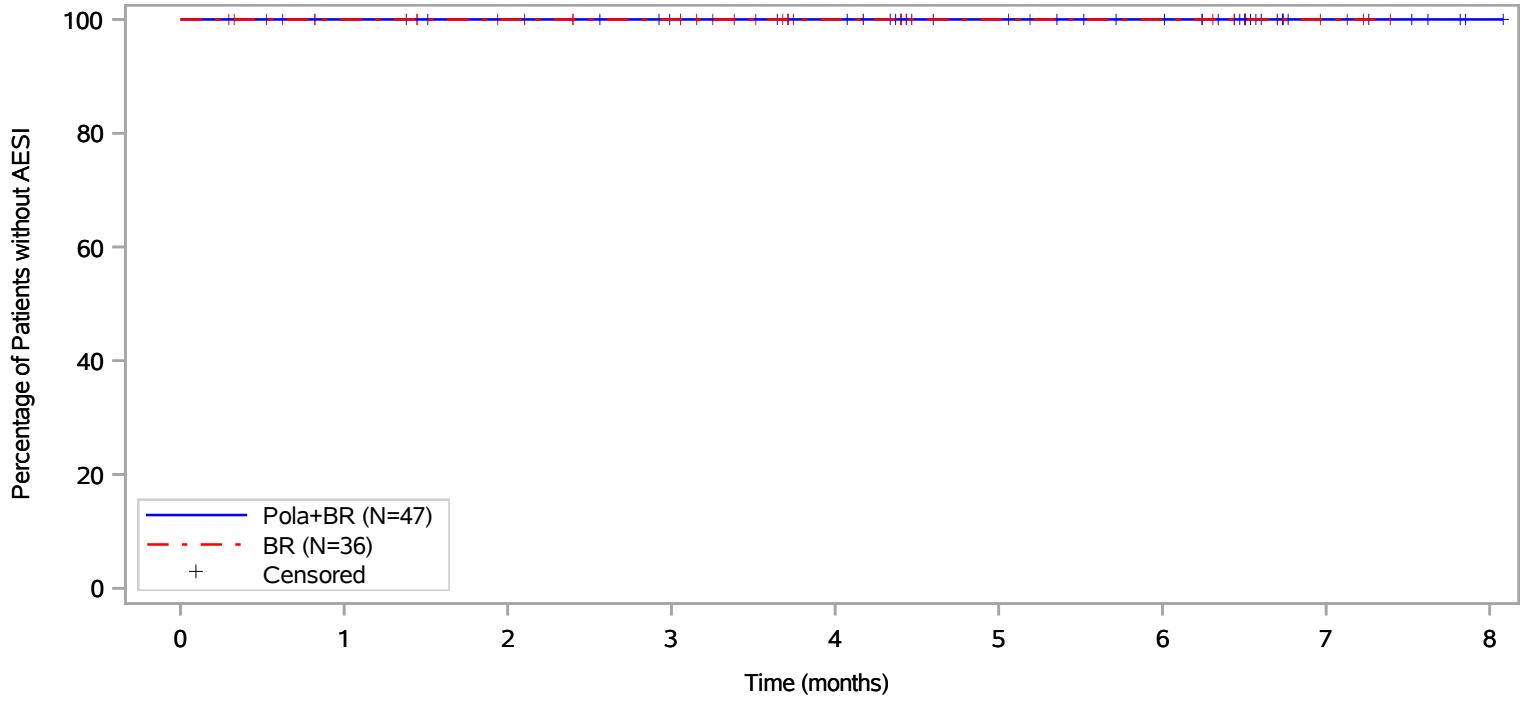
17DEC2022 15:53

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Ocular Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_TTOCUTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 2:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

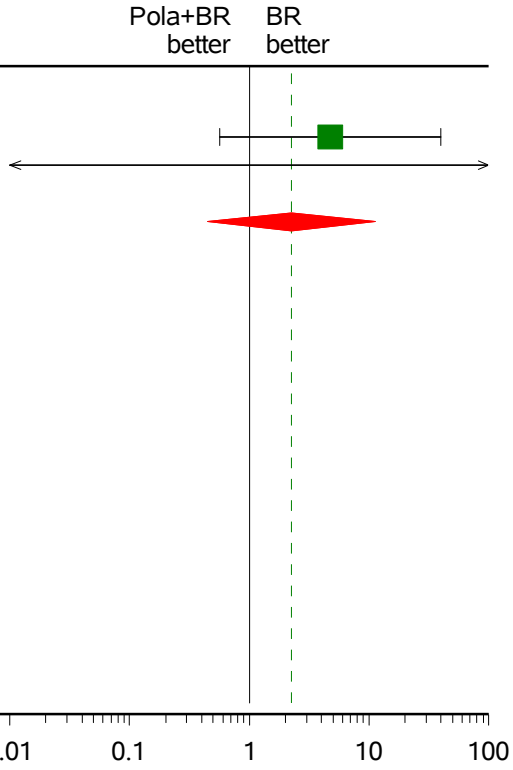
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	6	12.8	41	87.2	36	100.0	2	5.6	34	94.4	0.4227	2.25	0.45	11.33		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	5	14.7	29	85.3	24	66.7	1	4.2	23	95.8	0.2654	4.10	0.48	35.29		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	1	8.3	11	91.7	0.7858	0.65	0.04	10.72		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	4	13.8	25	86.2	20	55.6	0	-	20	100.0	0.1255	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	2	12.5	14	87.5	0.7609	0.70	0.10	5.02		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	3	10.3	26	89.7	24	66.7	2	8.3	22	91.7	0.9558	1.17	0.19	7.31		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	3	16.7	15	83.3	12	33.3	0	-	12	100.0	0.1759	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	2	22.2	7	77.8	13	36.1	0	-	13	100.0	0.1198	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	2	8.7	21	91.3	0.9632	1.09	0.19	6.05		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPAIN_L3PLUS_ARMCDPLUSSE_29365_41543.xls
01DEC2022 8:17

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	6	27	1	4.75	(0.57, 39.77)
YO41543	19	0	9	1	0.00	(0.00, NE)
Total	47	6	36	2	2.25	(0.45, 11.33)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPAIN_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 19:13

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	6	21.4	22	78.6	27	75.0	1	3.7	26	96.3	0.1132	4.75	0.57	39.77		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	47	100.0	6	12.8	41	87.2	36	100.0	2	5.6	34	94.4	0.4227	2.25	0.45	11.33		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.47	1	0.4915	0.00	0.99	0.3238

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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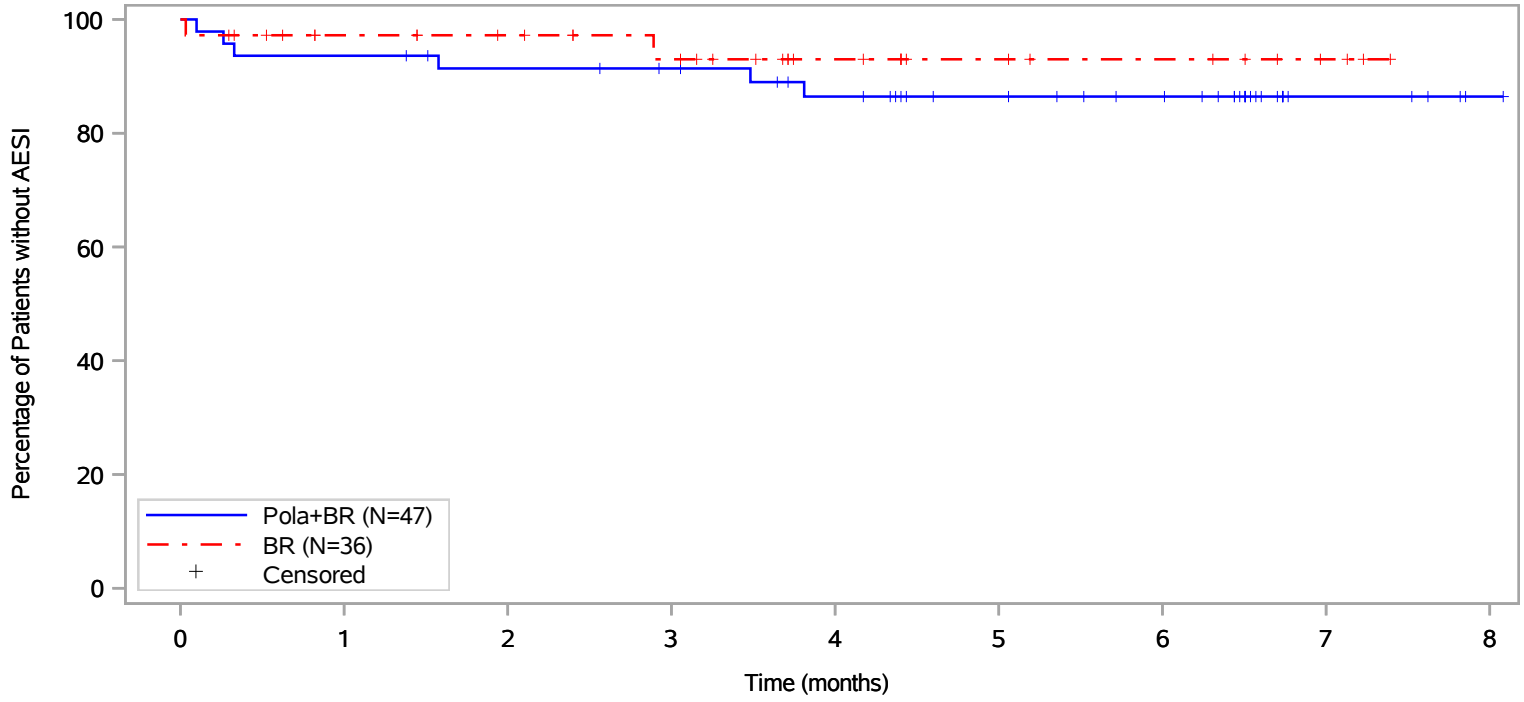
17DEC2022 21:45

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	44	41	39	34	28	24	5	1
BR (N=36)	36	29	26	22	14	9	7	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	13	17	36	40
BR (N=36)	0	6	9	12	20	25	27	31	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 21:41

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPAIN35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 22:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPAIN35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
16DEC2022 14:54

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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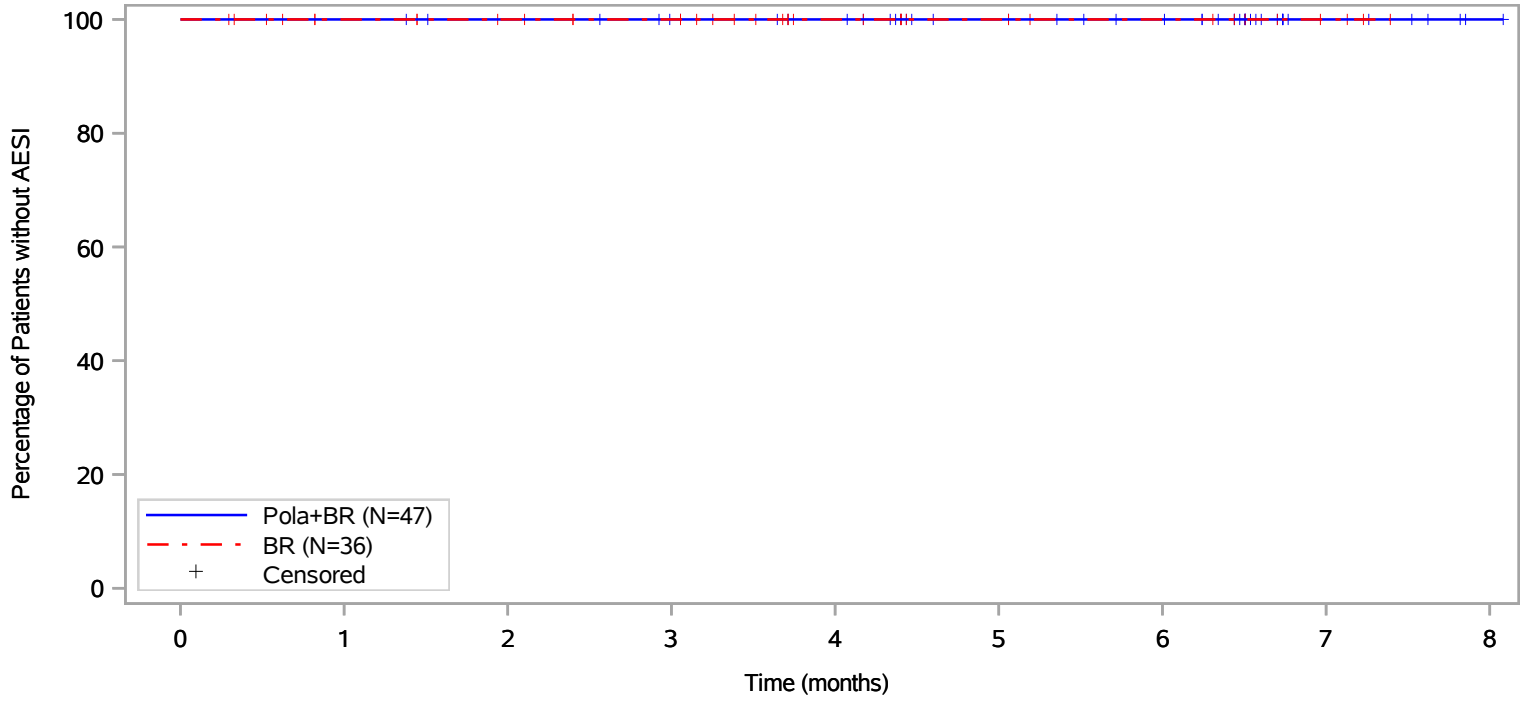
17DEC2022 21:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPAIN35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 23:52

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPAINS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPAINS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
16DEC2022 18:04

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE						
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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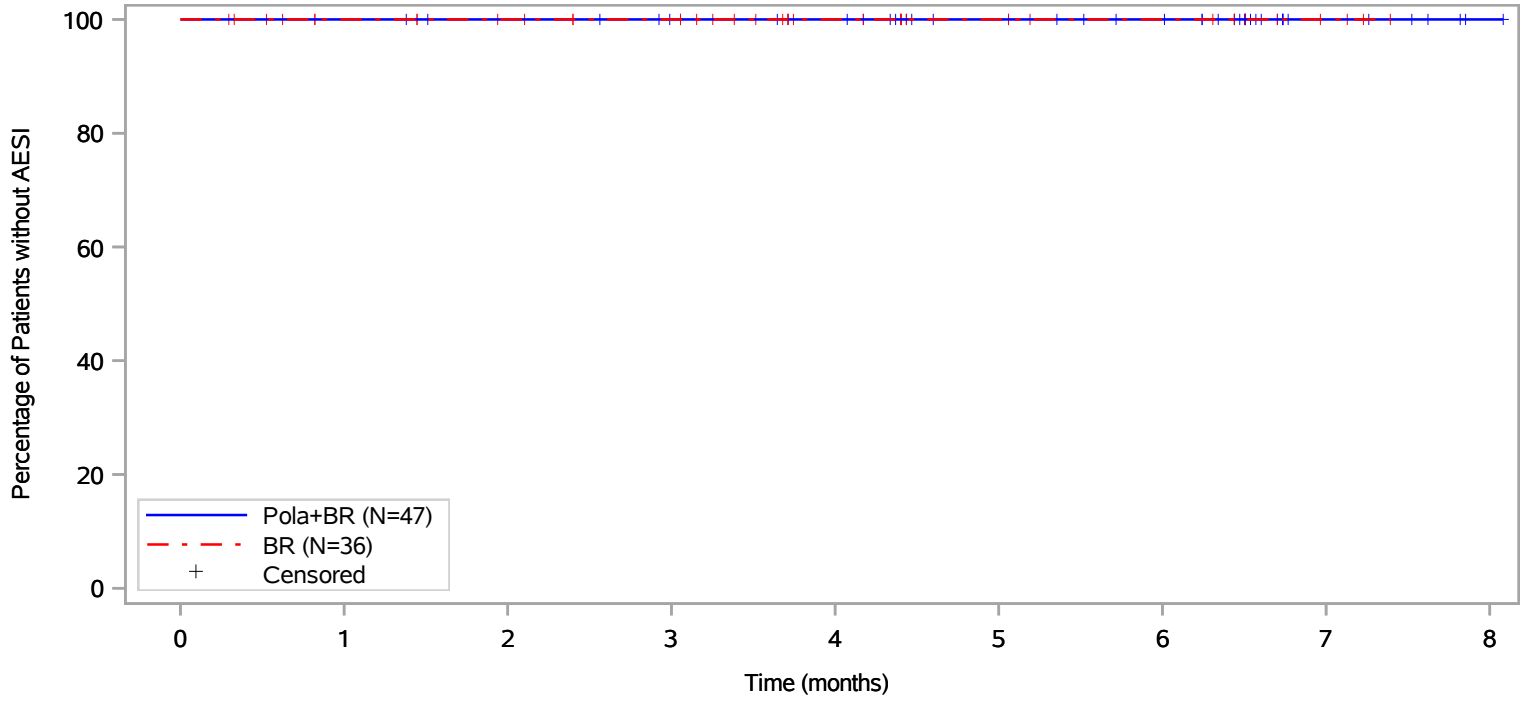
17DEC2022 15:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 2:08

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

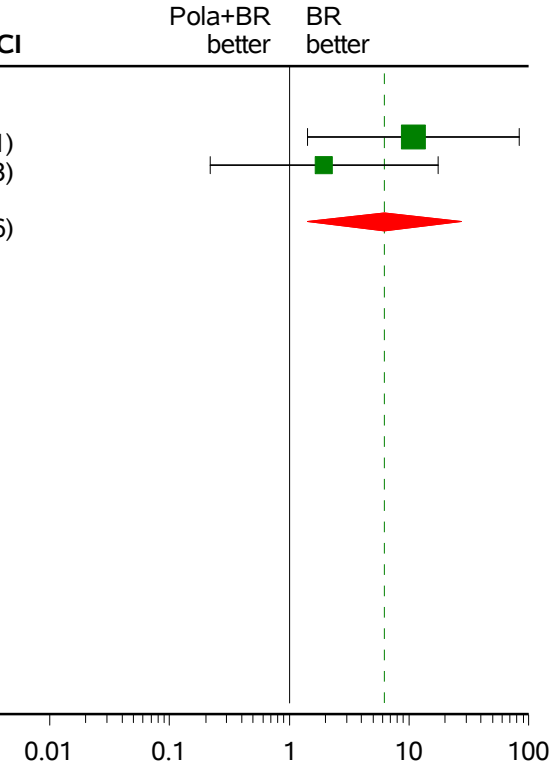
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	16	34.0	31	66.0	36	100.0	2	5.6	34	94.4	0.0083	6.25	1.43	27.36		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	11	32.4	23	67.6	24	66.7	2	8.3	22	91.7	0.0797	3.82	0.83	17.50		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	5	38.5	8	61.5	12	33.3	0	-	12	100.0	0.0337	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	8	27.6	21	72.4	20	55.6	1	5.0	19	95.0	0.0847	5.62	0.69	45.74		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	8	44.4	10	55.6	16	44.4	1	6.3	15	93.8	0.0310	7.03	0.88	56.43		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	11	37.9	18	62.1	24	66.7	2	8.3	22	91.7	0.0521	4.57	1.00	20.98		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	5	27.8	13	72.2	12	33.3	0	-	12	100.0	0.0619	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	1	11.1	8	88.9	13	36.1	0	-	13	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	15	39.5	23	60.5	23	63.9	2	8.7	21	91.3	0.0296	5.01	1.14	22.01		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPHENEU_L3PLUS_ARMCDPLUSSE_29365_41543.xls
01DEC2022 0:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	12	27	1	10.88	(1.41, 83.81)
YO41543	19	4	9	1	1.95	(0.22, 17.43)
Total	47	16	36	2	6.25	(1.43, 27.36)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	12	42.9	16	57.1	27	75.0	1	3.7	26	96.3	0.0041	10.88	1.41	83.81		Convergence criterion (GCONV=1E-8) satisfied.		53.5						
	YO41543	19	40.4	4	21.1	15	78.9	9	25.0	1	11.1	8	88.9	0.5439	1.95	0.22	17.43		Convergence criterion (GCONV=1E-8) satisfied.		46.5						
	Total	47	100.0	16	34.0	31	66.0	36	100.0	2	5.6	34	94.4	0.0083	6.25	1.43	27.36		Convergence criterion (GCONV=1E-8) satisfied.		100.0	1.37	1	0.2416	27.07	2.43	0.0150

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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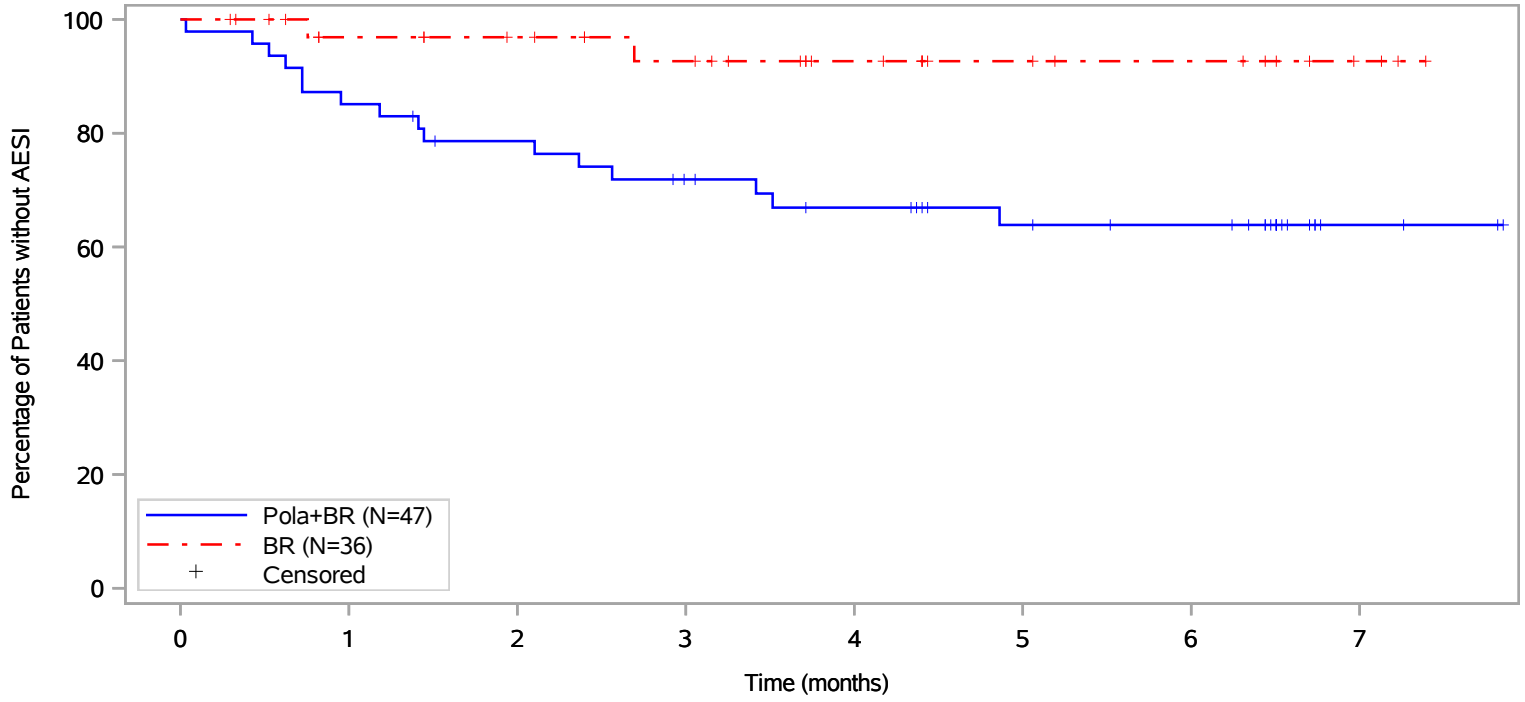
16DEC2022 9:50

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=47)	47	40	35	30	26	21	19	3
BR (N=36)	36	29	26	22	15	10	8	3
Patients censored								
Pola+BR (N=47)	0	0	2	4	6	10	12	28
BR (N=36)	0	6	9	12	19	24	26	31

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:32

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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02DEC2022 20:26

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: .._FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPHENEU35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
15DEC2022 14:41

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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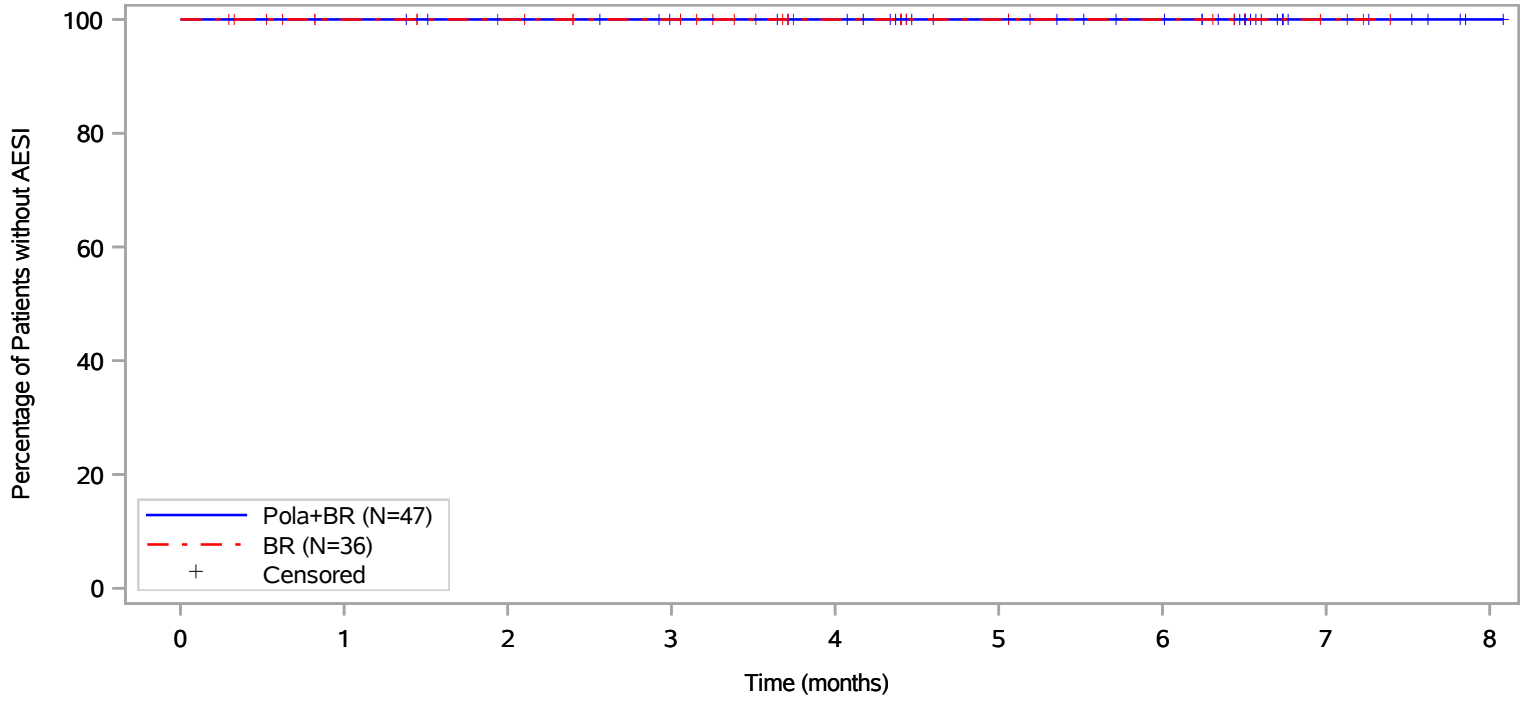
15DEC2022 19:40

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPHENEU35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPHENEUS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:13

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPHENEUS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
15DEC2022 14:39

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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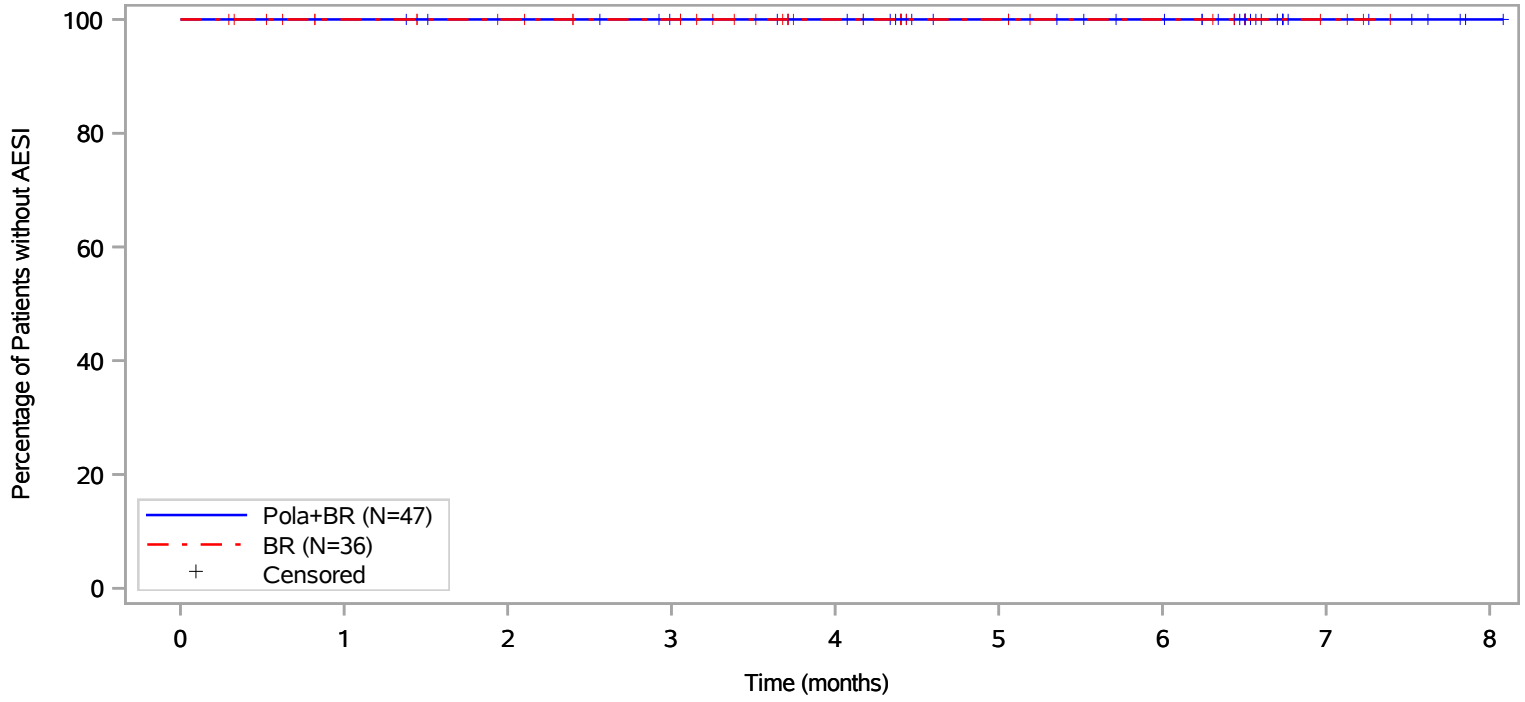
15DEC2022 19:02

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 0:48

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

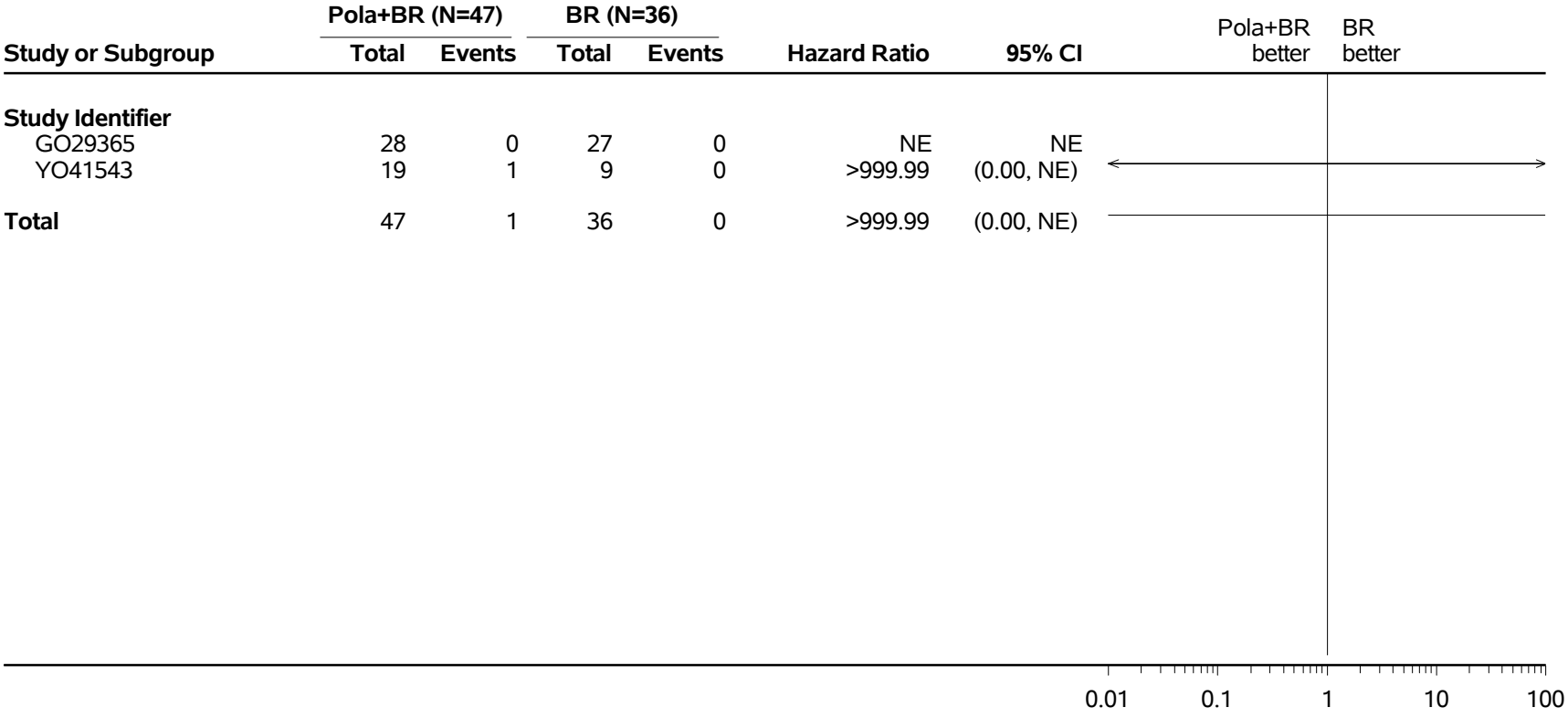
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPULTOX_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 12:08

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

Study or Subgroup	Pola+BR (N=47) Total	Pola+BR (N=47) Events	BR (N=36) Total	BR (N=36) Events	Hazard Ratio	95% CI
Study Identifier						
GO29365	28	0	27	0	NE	NE
YO41543	19	1	9	0	>999.99	(0.00, NE)
Total	47	1	36	0	>999.99	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	1	5.3	18	94.7	9	25.0	0	-	9	100.0	0.5329	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9985

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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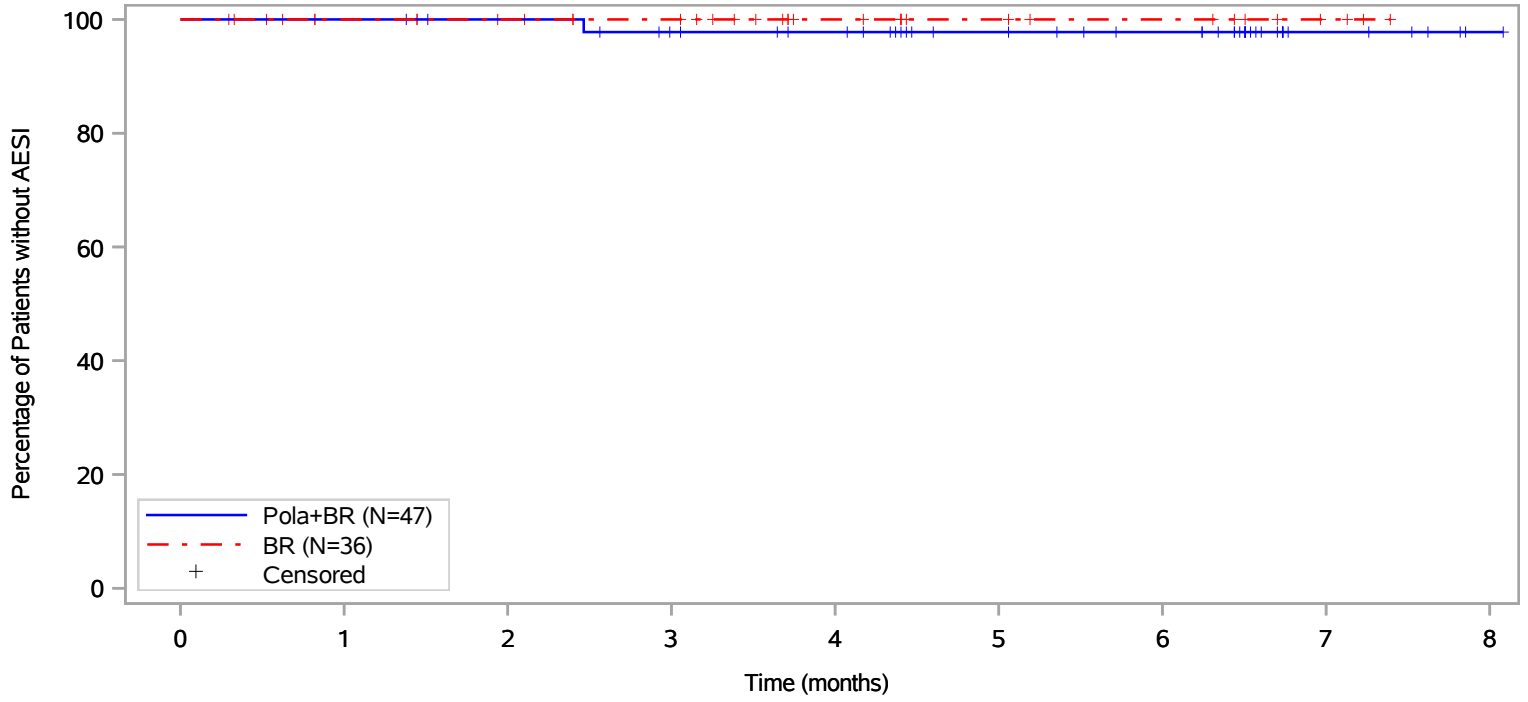
17DEC2022 21:37

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTPULTOX_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:35

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

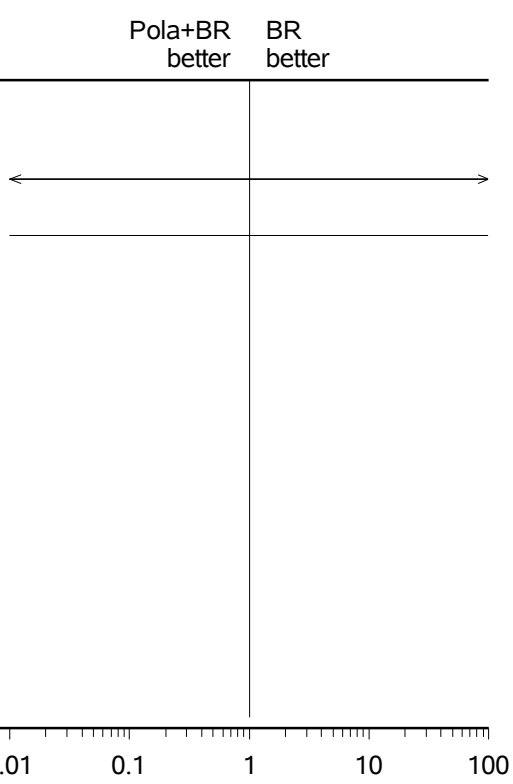
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPULTOX35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 12:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	0	27	0	NE	NE
YO41543	19	1	9	0	>999.99	(0.00, NE)
Total	47	1	36	0	>999.99	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	1	5.3	18	94.7	9	25.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9985

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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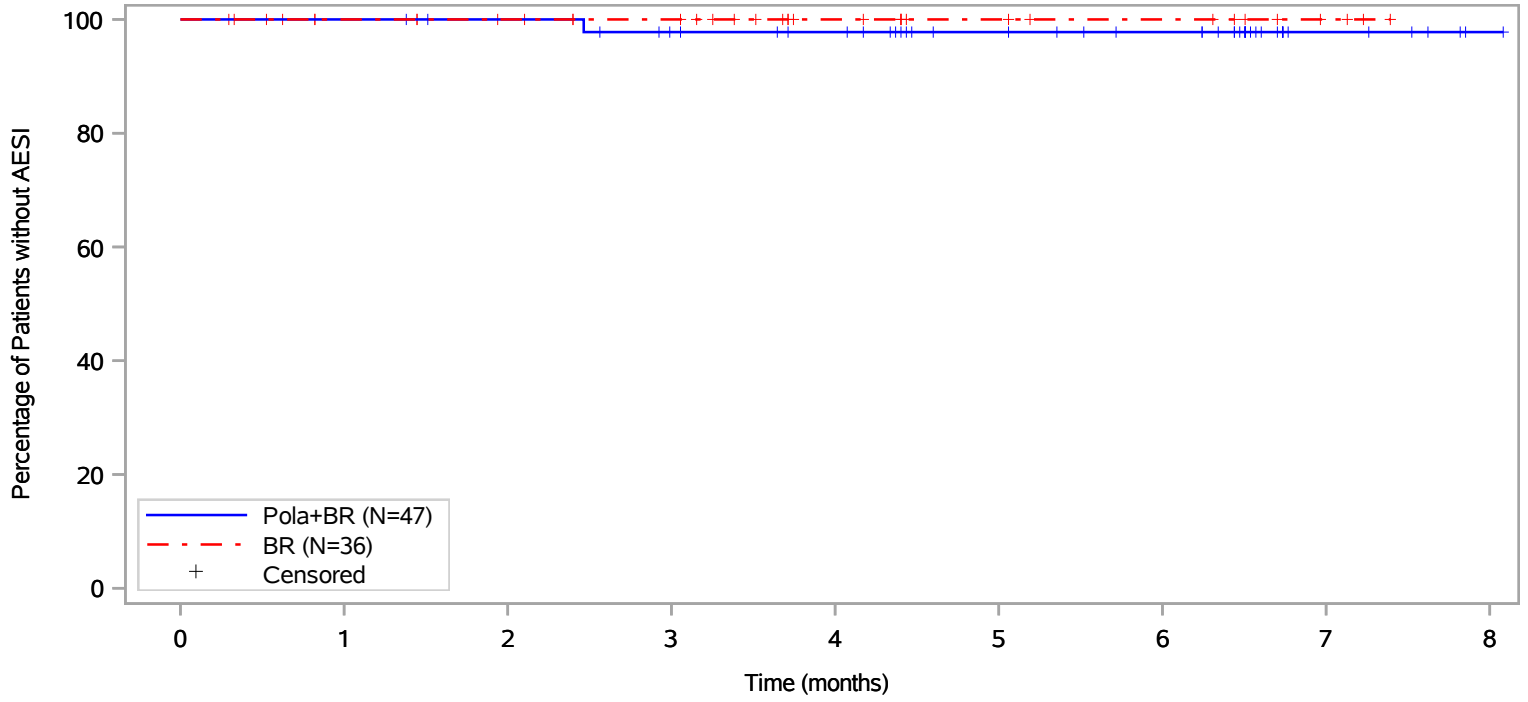
17DEC2022 21:06

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 23:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

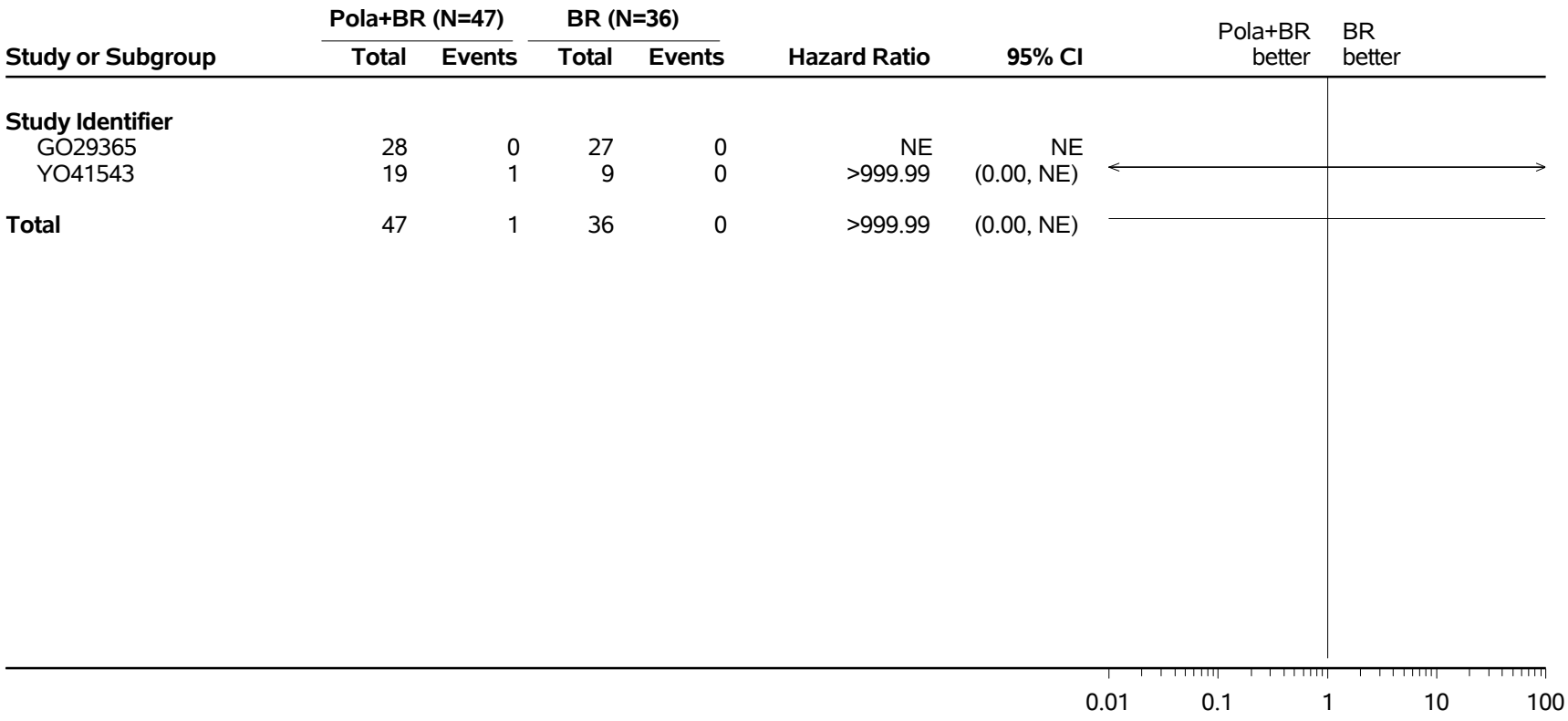
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	1	7.7	12	92.3	12	33.3	0	-	12	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	0.5032	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	1	3.4	28	96.6	24	66.7	0	-	24	100.0	0.4715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTPULTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
25JAN2023 12:29

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	0	27	0	NE	NE
YO41543	19	1	9	0	>999.99	(0.00, NE)
Total	47	1	36	0	>999.99	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTPULTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 13:31

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	1	5.3	18	94.7	9	25.0	0	-	9	100.0	0.5329	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	0	-	36	100.0	0.4652	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9985

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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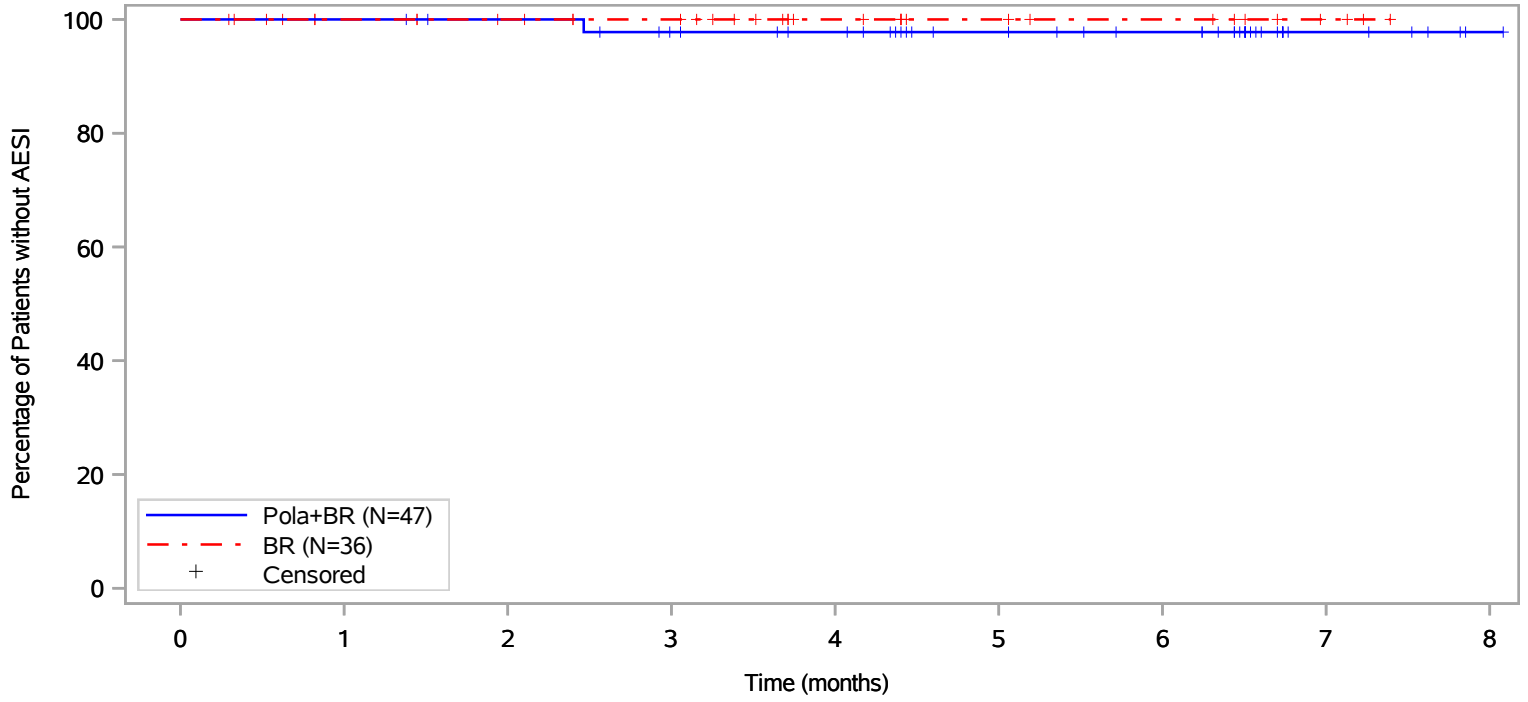
17DEC2022 15:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	41	38	30	26	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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04DEC2022 2:00

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

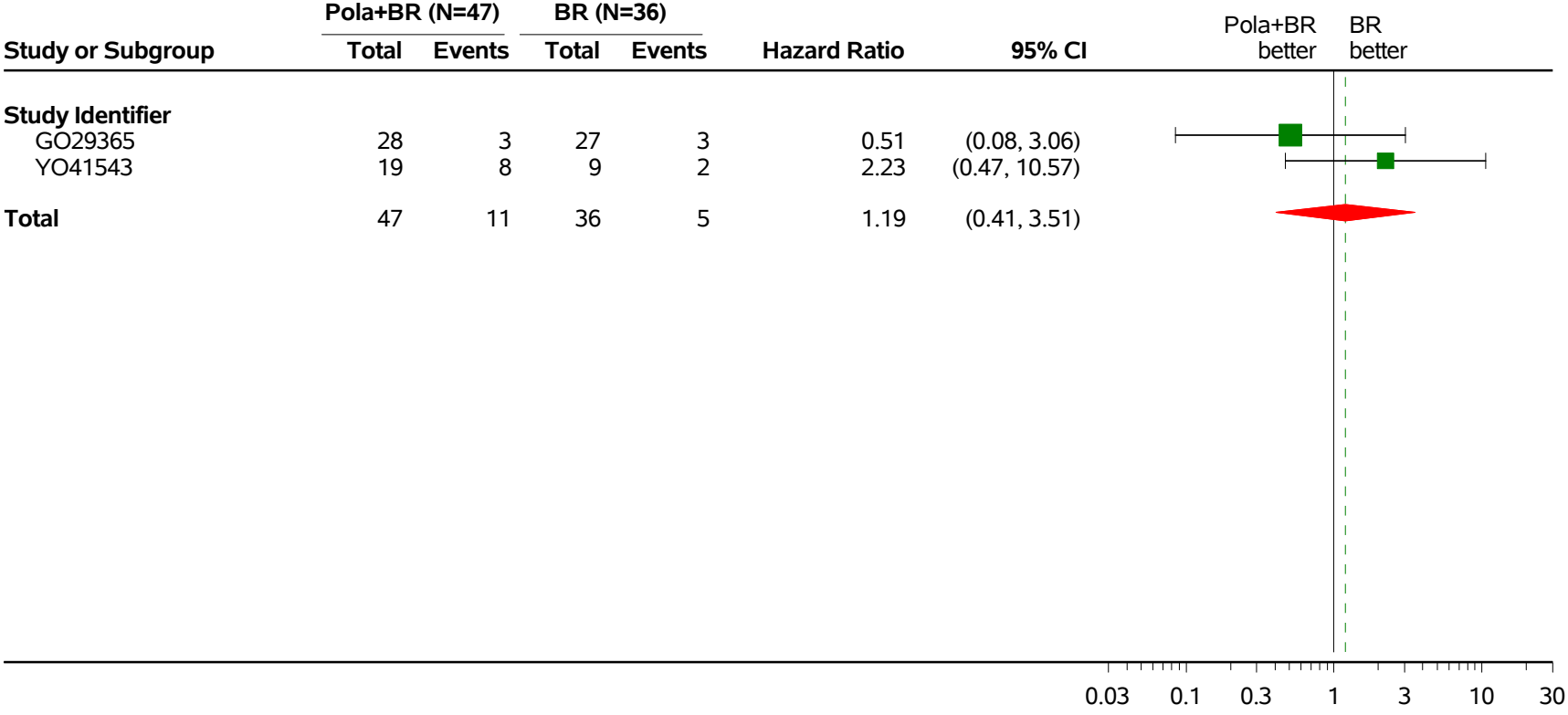
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	11	23.4	36	76.6	36	100.0	5	13.9	31	86.1	0.6497	1.19	0.41	3.51		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	10	29.4	24	70.6	24	66.7	2	8.3	22	91.7	0.1515	2.45	0.53	11.44		Convergence criterion (GCONV=1E-8) satisfied.	
	Female	13	27.7	1	7.7	12	92.3	12	33.3	3	25.0	9	75.0	0.0983	0.18	0.02	1.71		Convergence criterion (GCONV=1E-8) satisfied.	-
Age (years)	< 65	29	61.7	9	31.0	20	69.0	20	55.6	1	5.0	19	95.0	0.0778	4.24	0.52	34.19		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 65	18	38.3	2	11.1	16	88.9	16	44.4	4	25.0	12	75.0	0.1374	0.33	0.06	1.83		Convergence criterion (GCONV=1E-8) satisfied.	-
IPI at study entry	>=3	29	61.7	7	24.1	22	75.9	24	66.7	4	16.7	20	83.3	0.8779	0.92	0.27	3.16		Convergence criterion (GCONV=1E-8) satisfied.	
	<3	18	38.3	4	22.2	14	77.8	12	33.3	1	8.3	11	91.7	0.5290	2.18	0.23	21.06		Convergence criterion (GCONV=1E-8) satisfied.	-
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	2	15.4	11	84.6	0.1780	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
	Non-Europe	38	80.9	11	28.9	27	71.1	23	63.9	3	13.0	20	87.0	0.3452	1.85	0.51	6.73		Convergence criterion (GCONV=1E-8) satisfied.	-

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTRENTOX_L3PLUS_ARMCDPLUSSE_29365_41543.xls
01DEC2022 6:06

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	3	27	3	0.51	(0.08, 3.06)
YO41543	19	8	9	2	2.23	(0.47, 10.57)
Total	47	11	36	5	1.19	(0.41, 3.51)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	3	10.7	25	89.3	27	75.0	3	11.1	24	88.9	0.4526	0.51	0.08	3.06		Convergence criterion (GCONV=1E-8) satisfied.		42.9						
	YO41543	19	40.4	8	42.1	11	57.9	9	25.0	2	22.2	7	77.8	0.2984	2.23	0.47	10.57		Convergence criterion (GCONV=1E-8) satisfied.		57.1						
	Total	47	100.0	11	23.4	36	76.6	36	100.0	5	13.9	31	86.1	0.6497	1.19	0.41	3.51		Convergence criterion (GCONV=1E-8) satisfied.		100.0	1.49	1	0.2222	32.89	0.32	0.7475

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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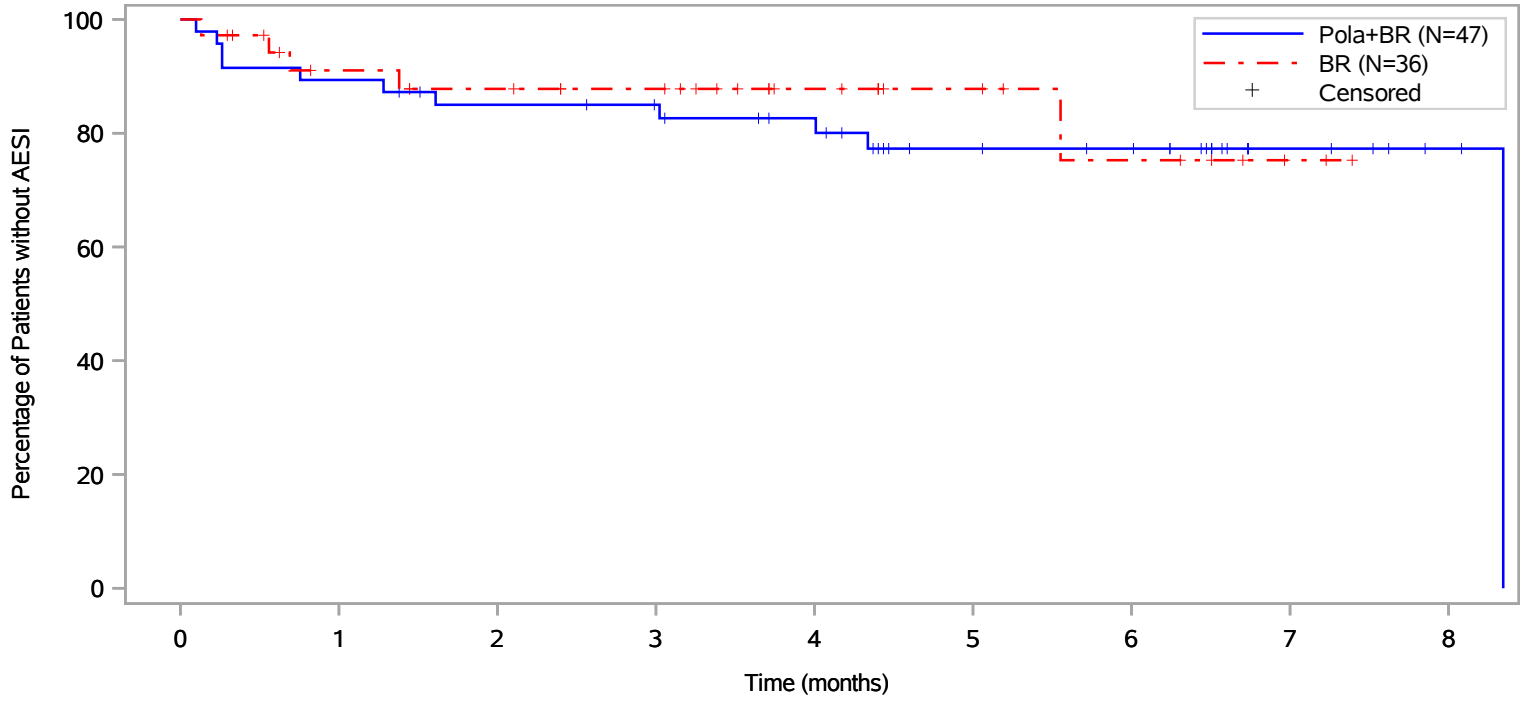
17DEC2022 21:15

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	42	38	36	32	23	21	6	2
BR (N=36)	36	28	25	22	14	9	6	2	NE
Patients censored									
Pola+BR (N=47)	0	0	2	4	7	14	16	31	35
BR (N=36)	0	5	7	10	18	23	25	29	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 21:24

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.0864	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	1	2.9	33	97.1	24	66.7	1	4.2	23	95.8	0.2240	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	1	5.0	19	95.0	0.2167	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	1	4.2	23	95.8	0.2399	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	1	4.3	22	95.7	0.1786	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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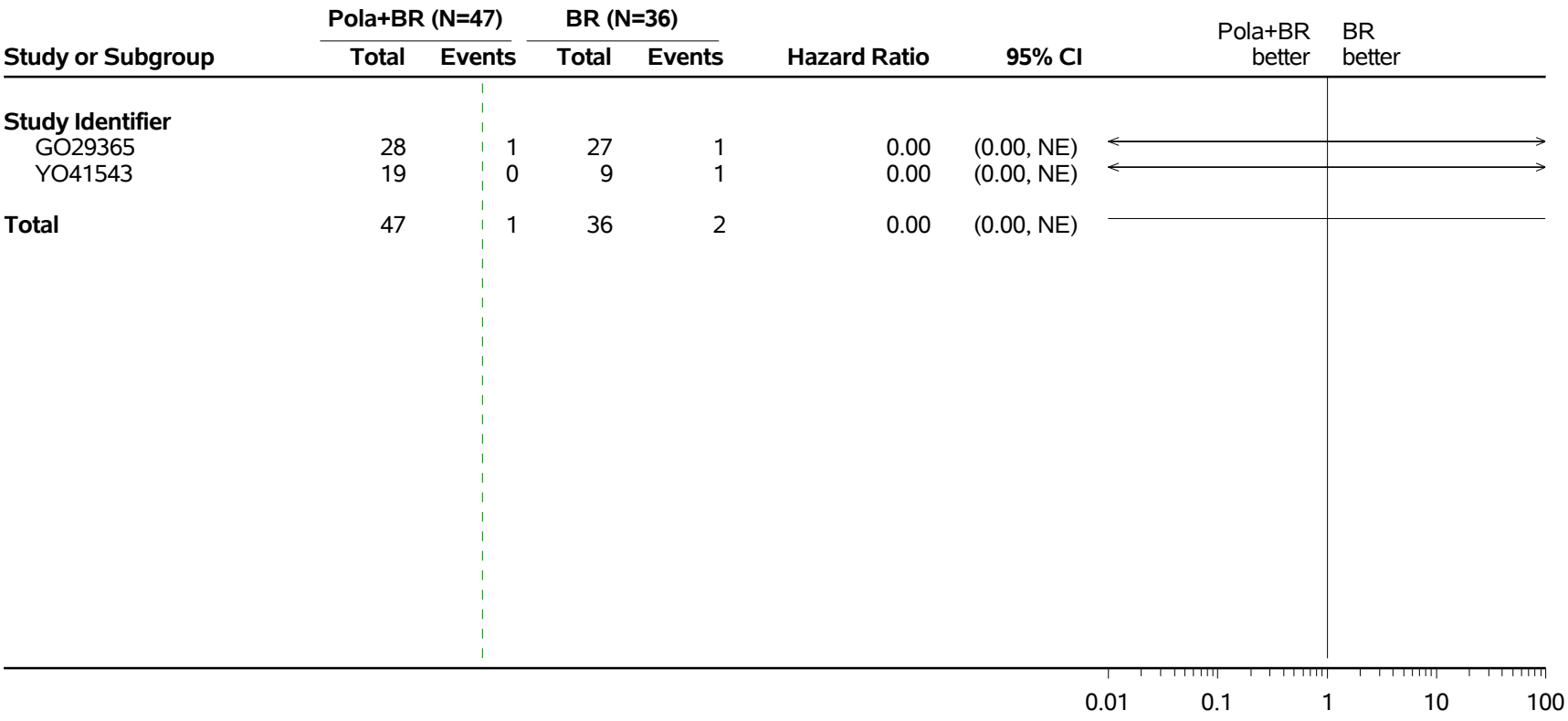
02DEC2022 21:38

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	1	27	1	0.00	(0.00, NE)
YO41543	19	0	9	1	0.00	(0.00, NE)
Total	47	1	36	2	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	57.1						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	42.9						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	2	5.6	34	94.4	0.0864	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.00	1	0.9999	0.00	0.00	0.9964

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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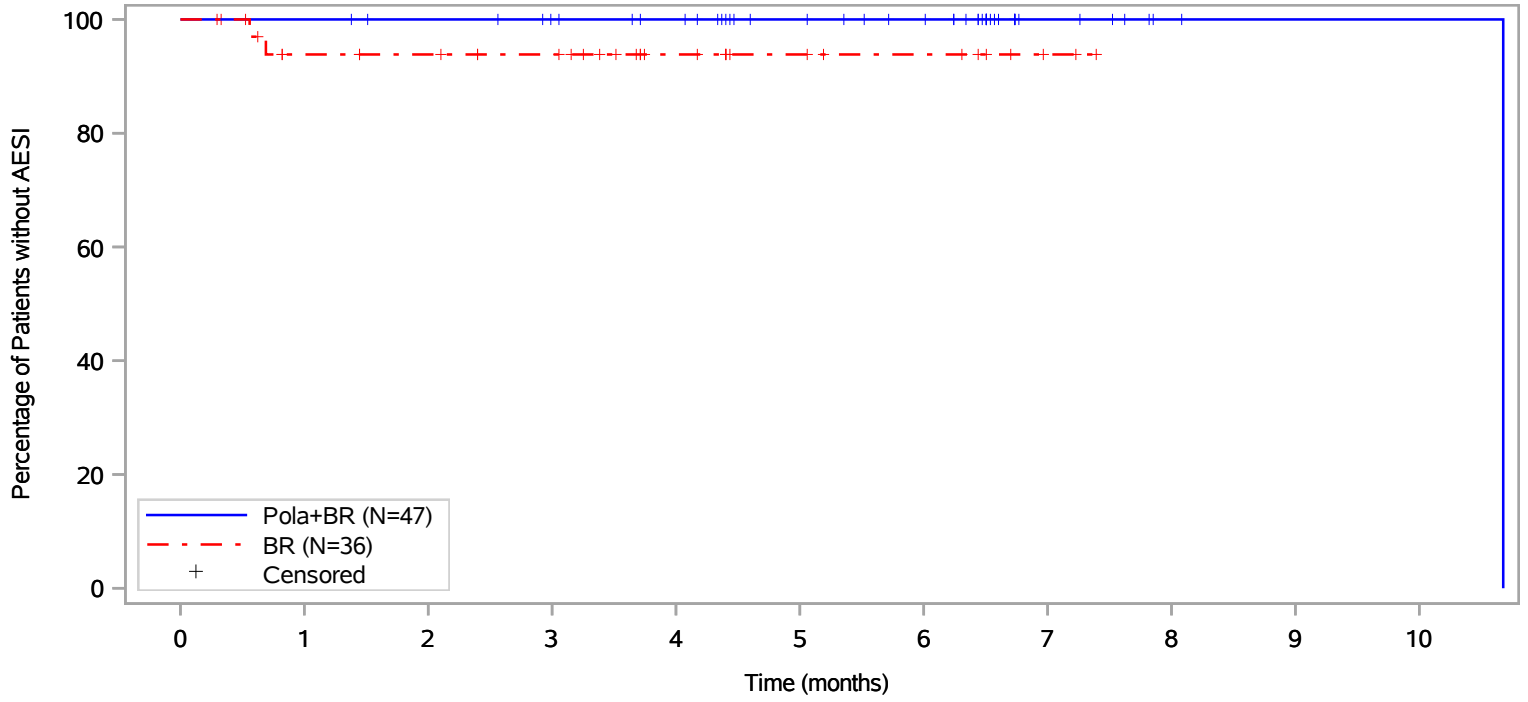
15DEC2022 21:58

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1
BR (N=36)	36	28	26	23	14	9	7	2	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46
BR (N=36)	0	6	8	11	20	25	27	32	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_km_TTRENTOX35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 23:36

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

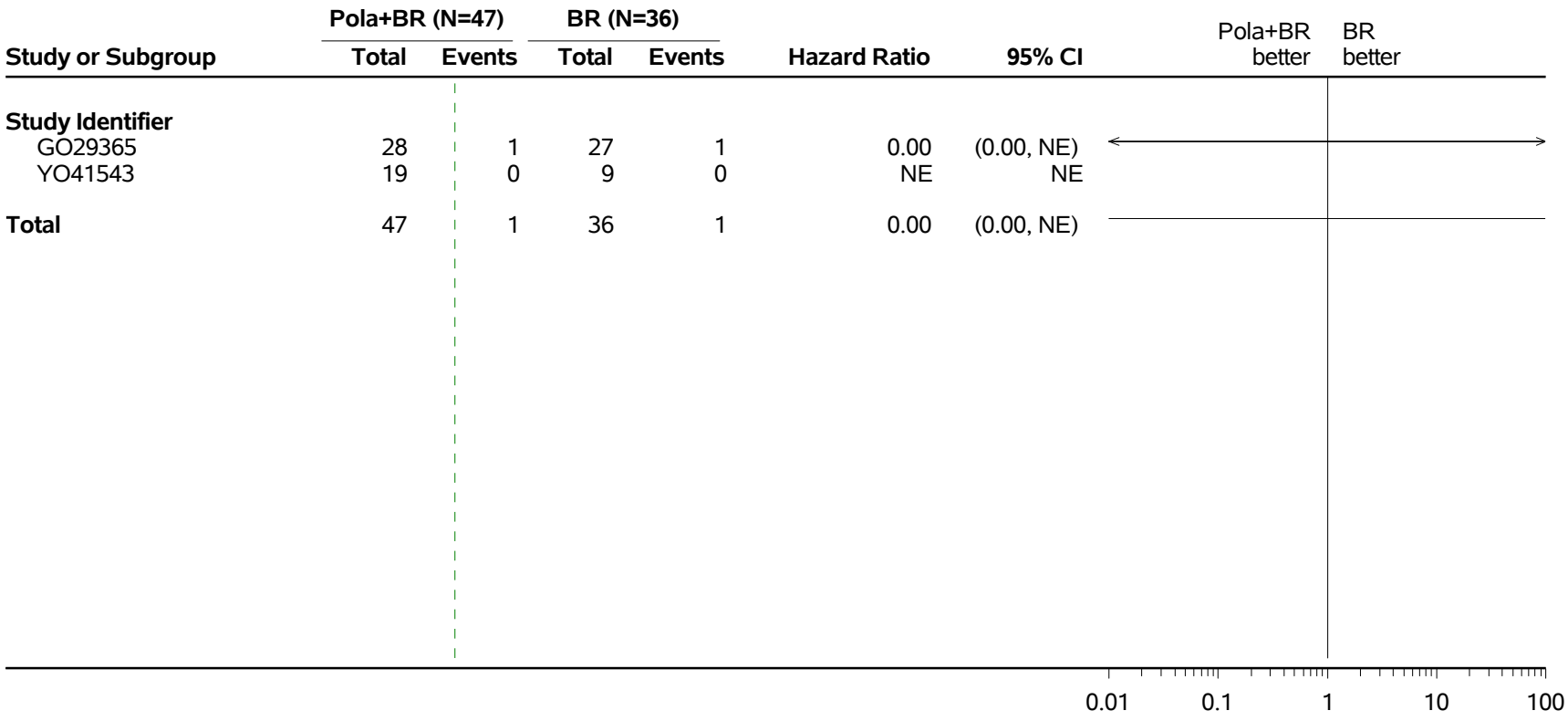
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	1	2.9	33	97.1	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	1	8.3	11	91.7	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	1	3.4	28	96.6	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	1	6.3	15	93.8	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	1	5.6	17	94.4	12	33.3	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	1	2.6	37	97.4	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTRENTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 21:20

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	1	27	1	0.00	(0.00, NE)
YO41543	19	0	9	0	NE	NE
Total	47	1	36	1	0.00	(0.00, NE)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTRENTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 16DEC2022 11:51

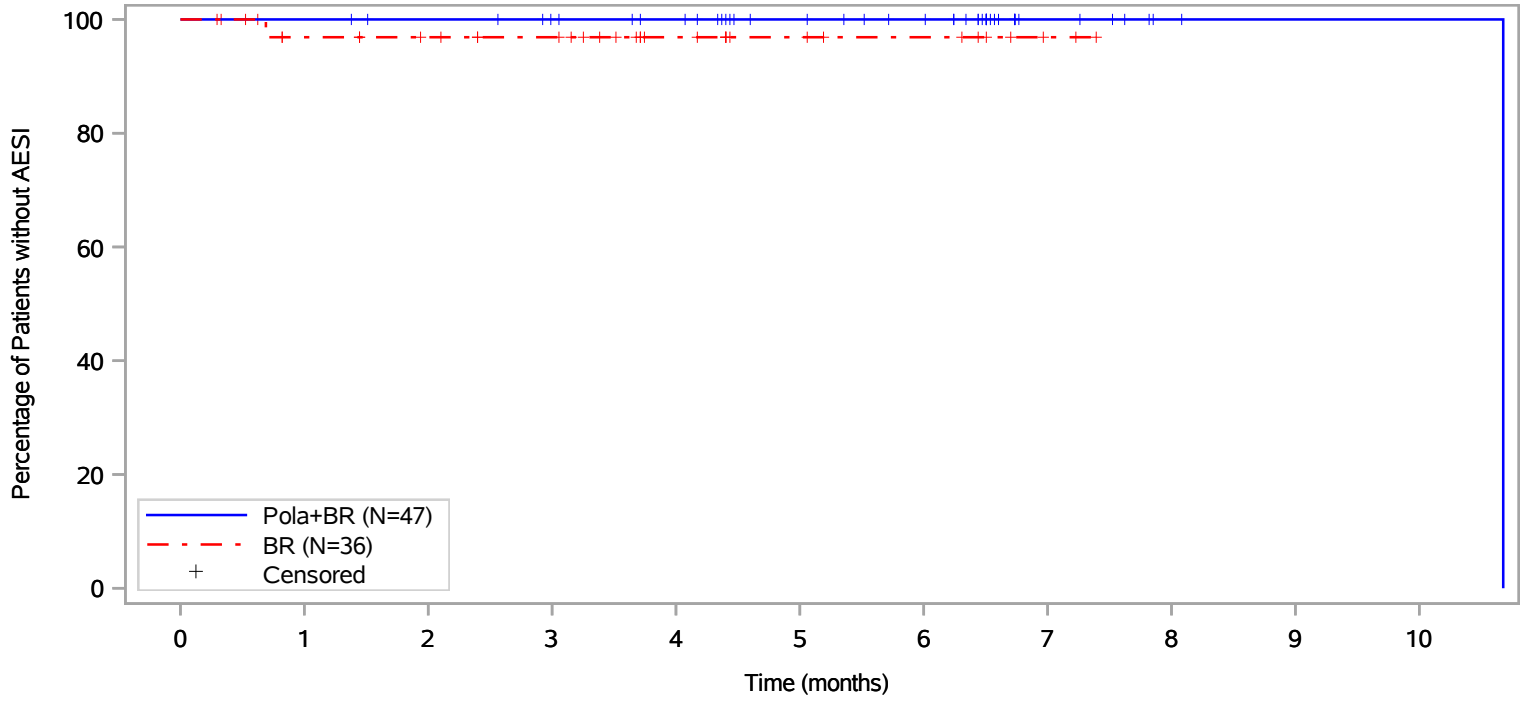
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	1	3.6	27	96.4	27	75.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	1	2.1	46	97.9	36	100.0	1	2.8	35	97.2	0.2255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	100.0	NE	NE	NE	NE	0.00	0.9984

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTRENTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
15DEC2022 22:21

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=47)	47	47	45	42	39	31	27	7	2	1	1
BR (N=36)	36	29	26	23	14	9	7	2	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	0	2	5	8	16	20	40	45	46	46
BR (N=36)	0	6	9	12	21	26	28	33	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output/g_km_TTRENTOXS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 1:46

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTREPROD_L3PLUS_ARMCDPLUSSE_29365_41543.xls
01DEC2022 4:33

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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16DEC2022 9:39

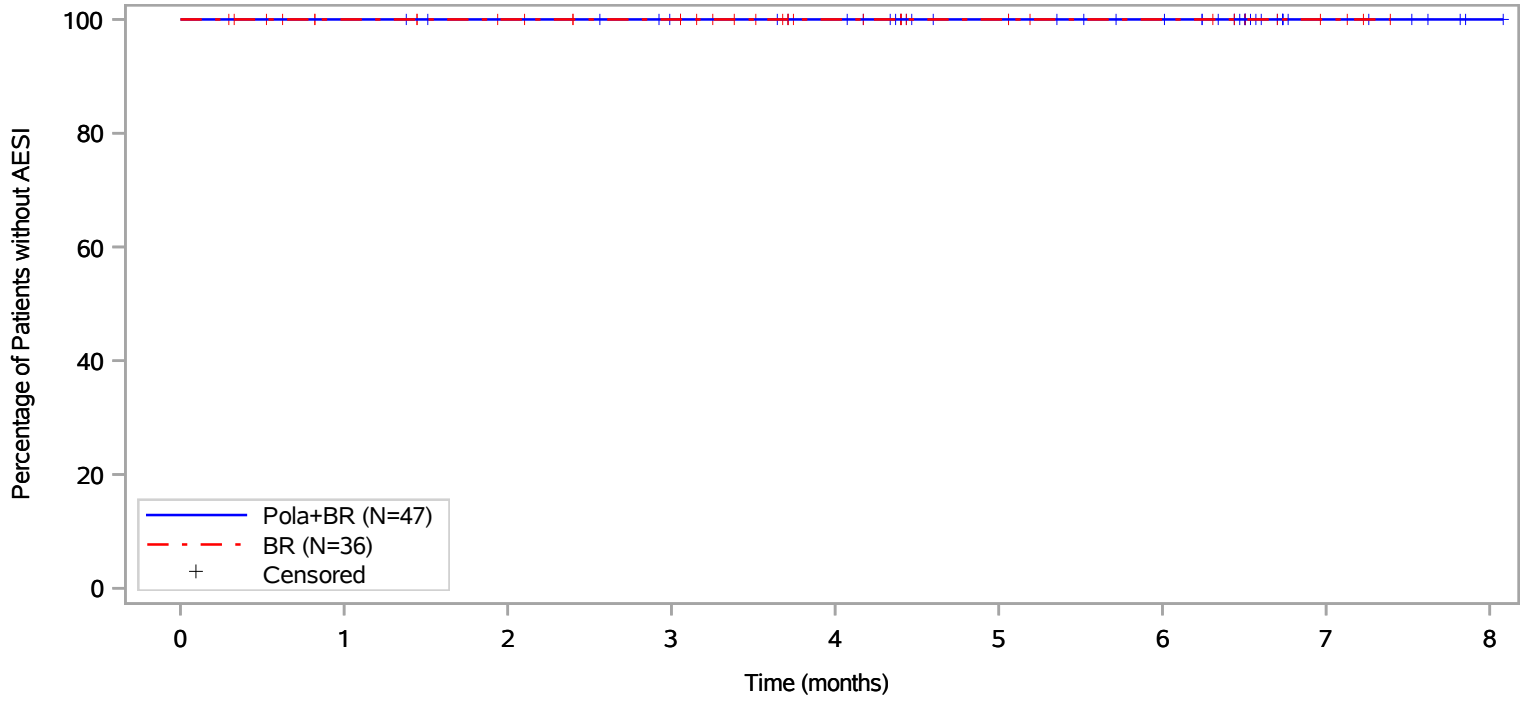
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTREPROD_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 7:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Reproductive Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTREPROD_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 21:08

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTSTIAMP_L3PLUS_ARMCDPLUSSE_29365_41543.xls
04DEC2022 14:10

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
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17DEC2022 17:28

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE						
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE	NE	NE	NE	NE	NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
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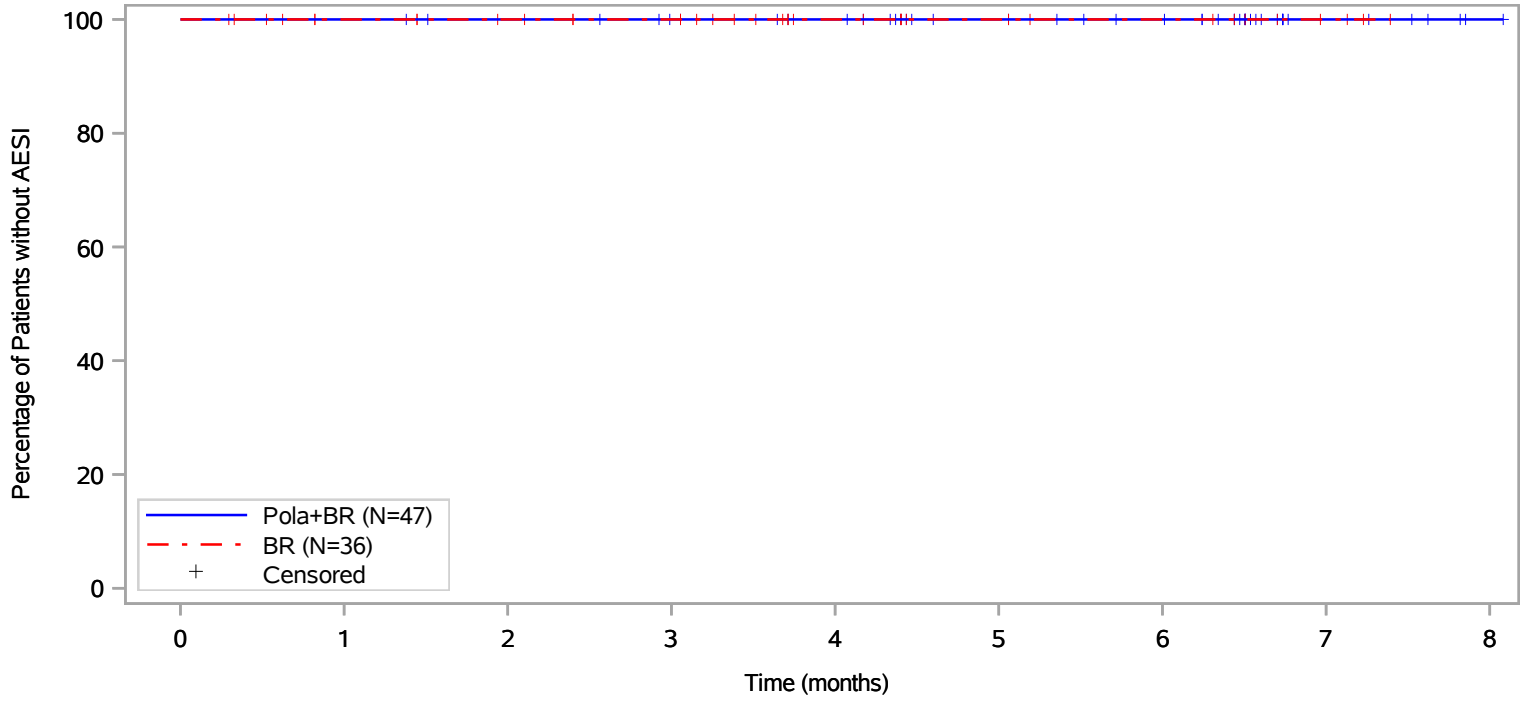
17DEC2022 22:47

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 14:23

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

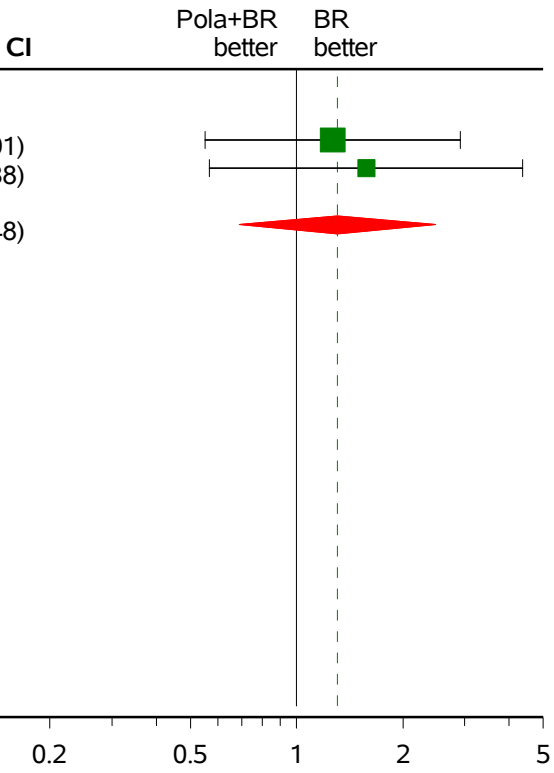
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	30	63.8	17	36.2	36	100.0	14	38.9	22	61.1	0.3312	1.31	0.69	2.48		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	19	55.9	15	44.1	24	66.7	8	33.3	16	66.7	0.4808	1.21	0.52	2.80		Convergence criterion (GCONV=1E-8) satisfied.	0.6268
	Female	13	27.7	11	84.6	2	15.4	12	33.3	6	50.0	6	50.0	0.2700	1.80	0.63	5.15		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	21	72.4	8	27.6	20	55.6	8	40.0	12	60.0	0.1695	1.72	0.75	3.92		Convergence criterion (GCONV=1E-8) satisfied.	0.3580
	>= 65	18	38.3	9	50.0	9	50.0	16	44.4	6	37.5	10	62.5	0.8477	0.90	0.32	2.54		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	19	65.5	10	34.5	24	66.7	7	29.2	17	70.8	0.0992	1.95	0.81	4.71		Convergence criterion (GCONV=1E-8) satisfied.	0.1232
	<3	18	38.3	11	61.1	7	38.9	12	33.3	7	58.3	5	41.7	0.4064	0.65	0.25	1.73		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	2	22.2	7	77.8	13	36.1	3	23.1	10	76.9	0.8681	0.86	0.14	5.16		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	28	73.7	10	26.3	23	63.9	11	47.8	12	52.2	0.3554	1.38	0.69	2.79		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTTHROM_L3PLUS_ARMCDPLUSSE_29365_41543.xls
01DEC2022 2:18

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	15	27	9	1.27	(0.55, 2.91)
YO41543	19	15	9	5	1.58	(0.57, 4.38)
Total	47	30	36	14	1.31	(0.69, 2.48)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTTHROM_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 16:05

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	15	53.6	13	46.4	27	75.0	9	33.3	18	66.7	0.5758	1.27	0.55	2.91		Convergence criterion (GCONV=1E-8) satisfied.	60.2						
	YO41543	19	40.4	15	78.9	4	21.1	9	25.0	5	55.6	4	44.4	0.3785	1.58	0.57	4.38		Convergence criterion (GCONV=1E-8) satisfied.	39.8						
	Total	47	100.0	30	63.8	17	36.2	36	100.0	14	38.9	22	61.1	0.3312	1.31	0.69	2.48		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.13	1	0.7141	0.00	0.82	0.4117

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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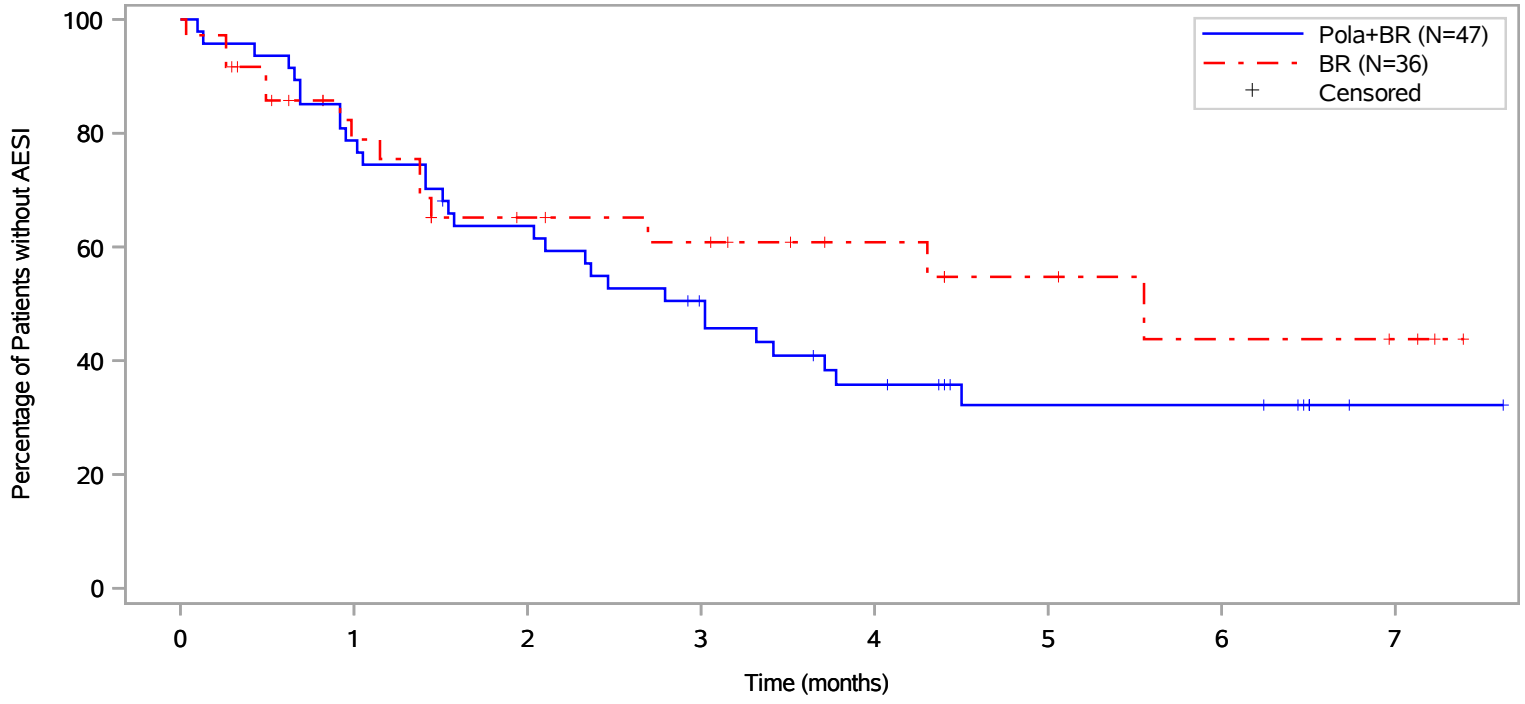
16DEC2022 10:27

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=47)	47	37	29	21	14	9	9	1
BR (N=36)	36	23	16	14	10	6	4	3
Patients censored								
Pola+BR (N=47)	0	0	1	3	4	8	8	16
BR (N=36)	0	6	9	10	14	17	18	19

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:45

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

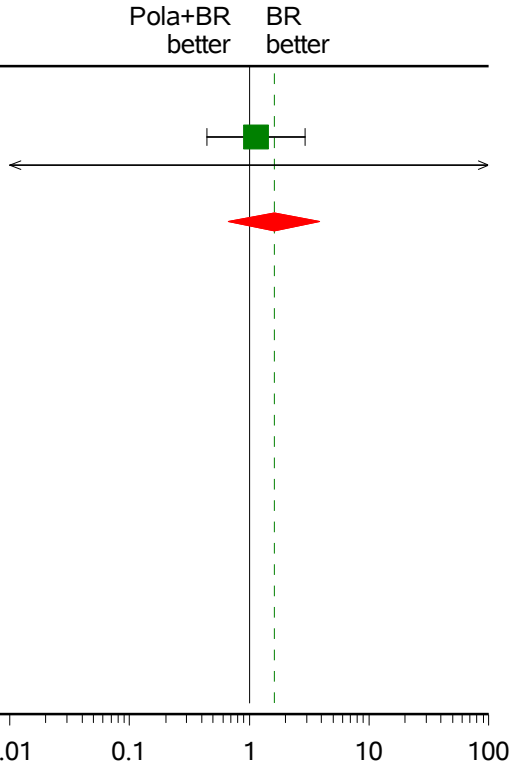
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	19	40.4	28	59.6	36	100.0	7	19.4	29	80.6	0.3225	1.61	0.67	3.88		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	13	38.2	21	61.8	24	66.7	6	25.0	18	75.0	0.9512	1.06	0.40	2.84		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	6	46.2	7	53.8	12	33.3	1	8.3	11	91.7	0.1167	4.86	0.58	40.43		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	12	41.4	17	58.6	20	55.6	4	20.0	16	80.0	0.4562	1.64	0.52	5.20		Convergence criterion (GCONV=1E-8) satisfied.	0.8677
	>= 65	18	38.3	7	38.9	11	61.1	16	44.4	3	18.8	13	81.3	0.5203	1.48	0.38	5.76		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	12	41.4	17	58.6	24	66.7	3	12.5	21	87.5	0.1180	3.03	0.84	10.88		Convergence criterion (GCONV=1E-8) satisfied.	0.1053
	<3	18	38.3	7	38.9	11	61.1	12	33.3	4	33.3	8	66.7	0.6450	0.70	0.20	2.52		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	2	22.2	7	77.8	13	36.1	1	7.7	12	92.3	0.4861	2.29	0.21	25.40		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	17	44.7	21	55.3	23	63.9	6	26.1	17	73.9	0.5778	1.26	0.49	3.25		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTTHROM35_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:43

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	13	27	7	1.14	(0.45, 2.90)
YO41543	19	6	9	0	>999.99	(0.00, NE)
Total	47	19	36	7	1.61	(0.67, 3.88)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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Output: ..E_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTTHROM35_L3PLUS_ARMCDPLUSSE_29365_41543.pdf 15DEC2022 16:08

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	13	46.4	15	53.6	27	75.0	7	25.9	20	74.1	0.7883	1.14	0.45	2.90		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	6	31.6	13	68.4	9	25.0	0	-	9	100.0	0.0898	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	47	100.0	19	40.4	28	59.6	36	100.0	7	19.4	29	80.6	0.3225	1.61	0.67	3.88		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.54	1	0.4641	0.00	1.07	0.2847

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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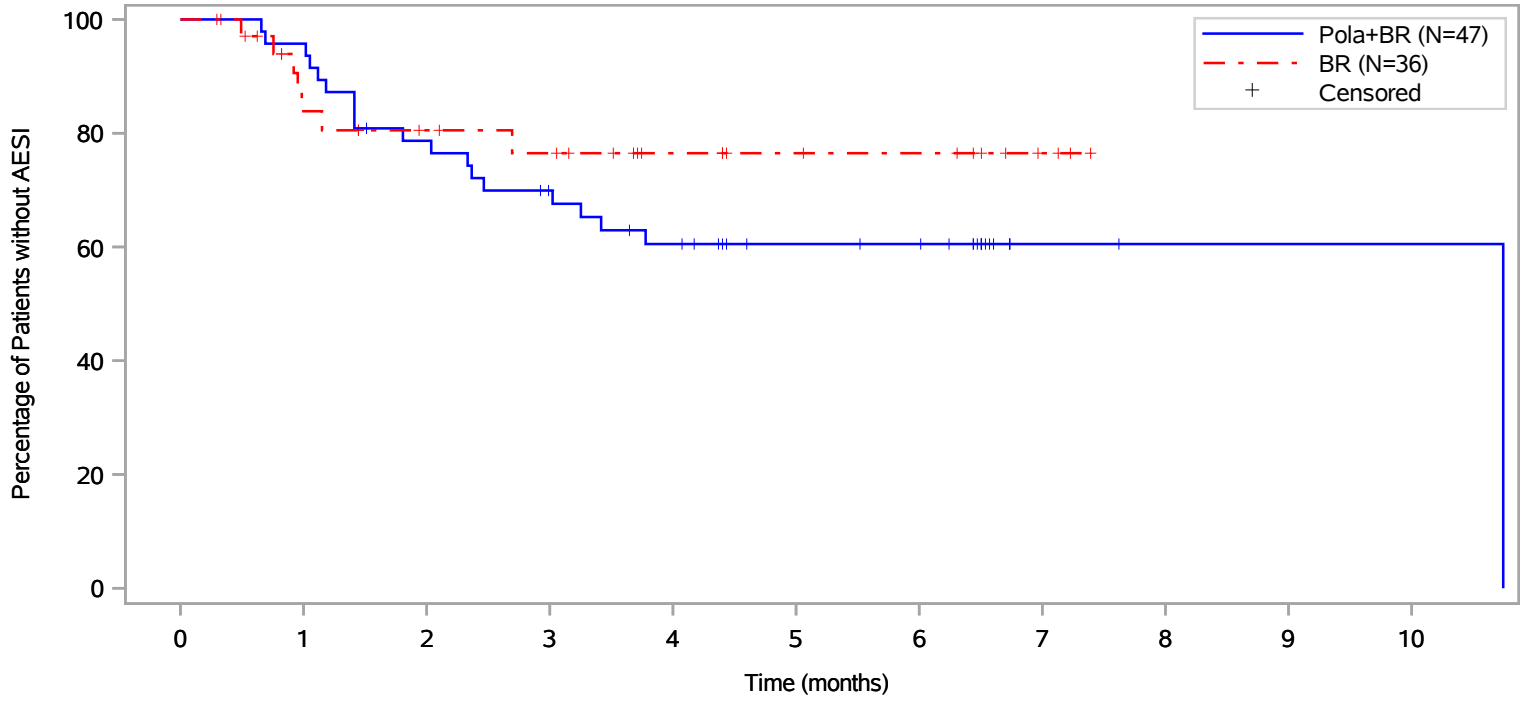
15DEC2022 16:49

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=47)	47	45	36	30	25	19	18	2	1	1	1
BR (N=36)	36	25	21	19	13	9	8	3	NE	NE	NE
Patients censored											
Pola+BR (N=47)	0	0	1	3	4	10	11	27	28	28	28
BR (N=36)	0	6	9	10	16	20	21	26	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 22:50

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

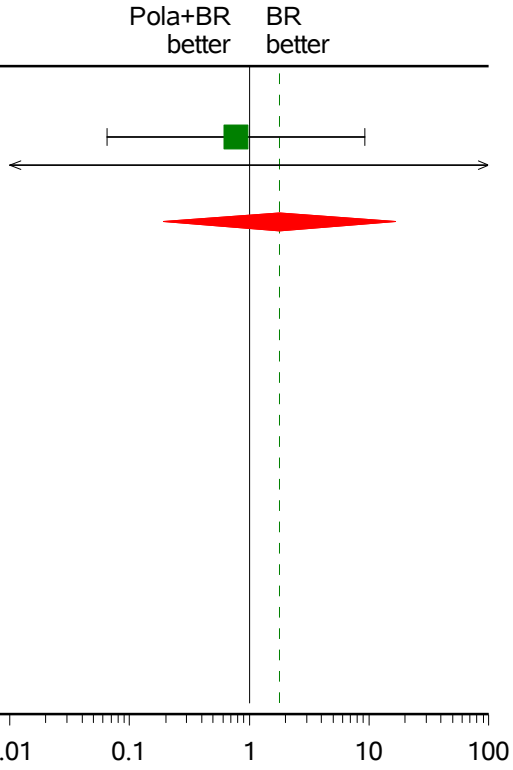
		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	4	8.5	43	91.5	36	100.0	1	2.8	35	97.2	0.5828	1.79	0.19	16.76		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	2	5.9	32	94.1	24	66.7	1	4.2	23	95.8	0.8855	0.80	0.07	9.74		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	2	15.4	11	84.6	12	33.3	0	-	12	100.0	0.2644	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	3	10.3	26	89.7	20	55.6	1	5.0	19	95.0	0.7101	1.55	0.15	15.55		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	1	5.6	17	94.4	16	44.4	0	-	16	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	2	6.9	27	93.1	24	66.7	0	-	24	100.0	0.3372	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	2	11.1	16	88.9	12	33.3	1	8.3	11	91.7	0.9866	0.98	0.09	11.08		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	4	10.5	34	89.5	23	63.9	1	4.3	22	95.7	0.6685	1.62	0.18	14.91		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTTHROMS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
02DEC2022 20:34

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

	Pola+BR (N=47)		BR (N=36)			
Study or Subgroup	**Total**	**Events**	**Total**	**Events**	**Hazard Ratio**	**95% CI**
Study Identifier						
GO29365	28	2	27	1	0.77	(0.06, 9.23)
YO41543	19	2	9	0	>999.99	(0.00, NE)
Total	47	4	36	1	1.79	(0.19, 16.76)



* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022
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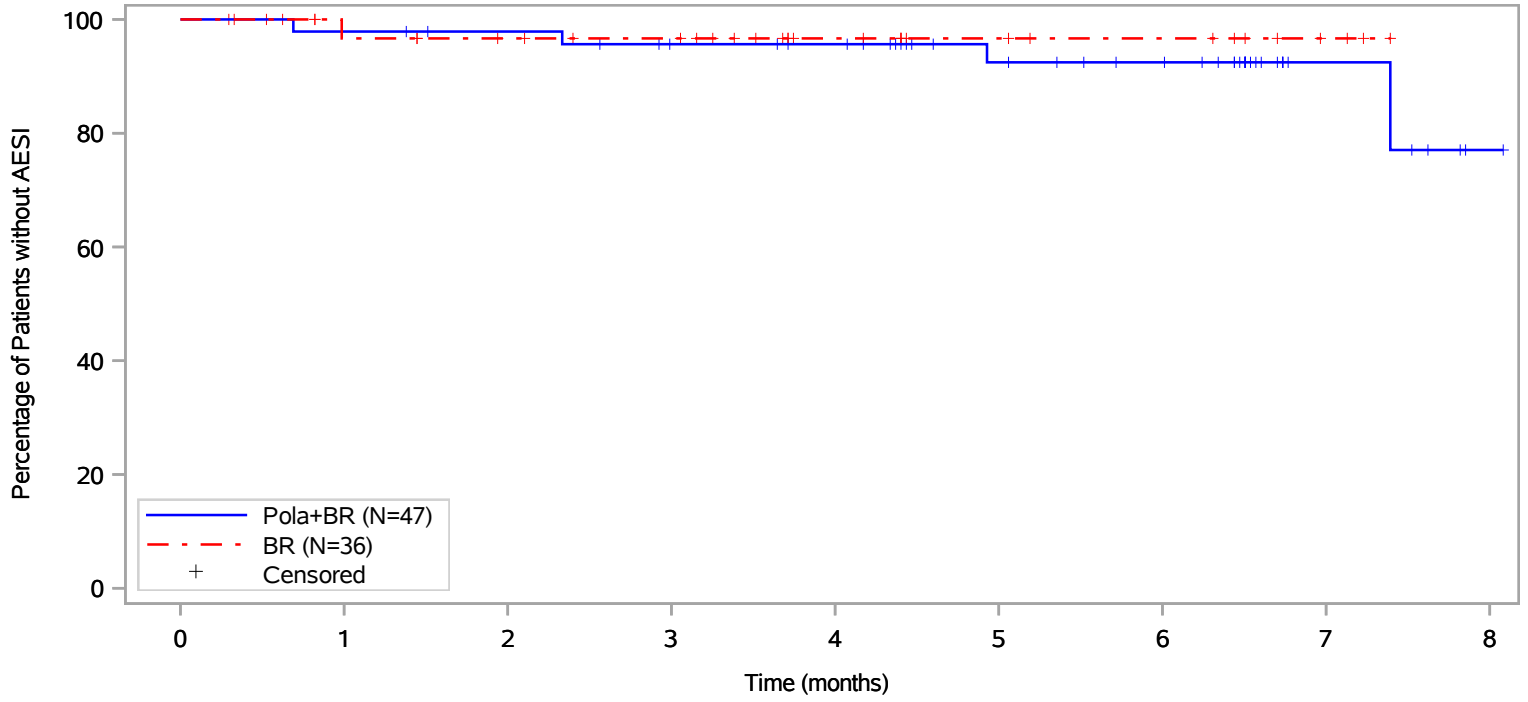
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR											
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Weight	Heterogeneity				Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	Weight (%)	Chi²	Df	P-value	I² (%)	Z	P-value
Study Identifier	GO29365	28	59.6	2	7.1	26	92.9	27	75.0	1	3.7	26	96.3	0.8378	0.77	0.06	9.23		Convergence criterion (GCONV=1E-8) satisfied.	100.0						
	YO41543	19	40.4	2	10.5	17	89.5	9	25.0	0	-	9	100.0	0.3468	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	0.0						
	Total	47	100.0	4	8.5	43	91.5	36	100.0	1	2.8	35	97.2	0.5828	1.79	0.19	16.76		Convergence criterion (GCONV=1E-8) satisfied.	100.0	0.44	1	0.5059	0.00	0.51	0.6090

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTTHROMS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
15DEC2022 20:42

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	46	44	40	38	29	25	6	1
BR (N=36)	36	29	26	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	7	15	19	38	42
BR (N=36)	0	6	9	11	20	25	27	32	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTTHROMS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
04DEC2022 1:01

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	34	72.3	0	-	34	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	13	27.7	0	-	13	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	29	61.7	0	-	29	100.0	20	55.6	0	-	20	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	18	38.3	0	-	18	100.0	16	44.4	0	-	16	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	29	61.7	0	-	29	100.0	24	66.7	0	-	24	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	18	38.3	0	-	18	100.0	12	33.3	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	19.1	0	-	9	100.0	13	36.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	38	80.9	0	-	38	100.0	23	63.9	0	-	23	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Study was included as a covariate in the Cox regression model.
Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ttae_sg1_TTTLS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
01DEC2022 21:30

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..41077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_fp_hr.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output/g_fp_hr_TTTLS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
16DEC2022 22:12

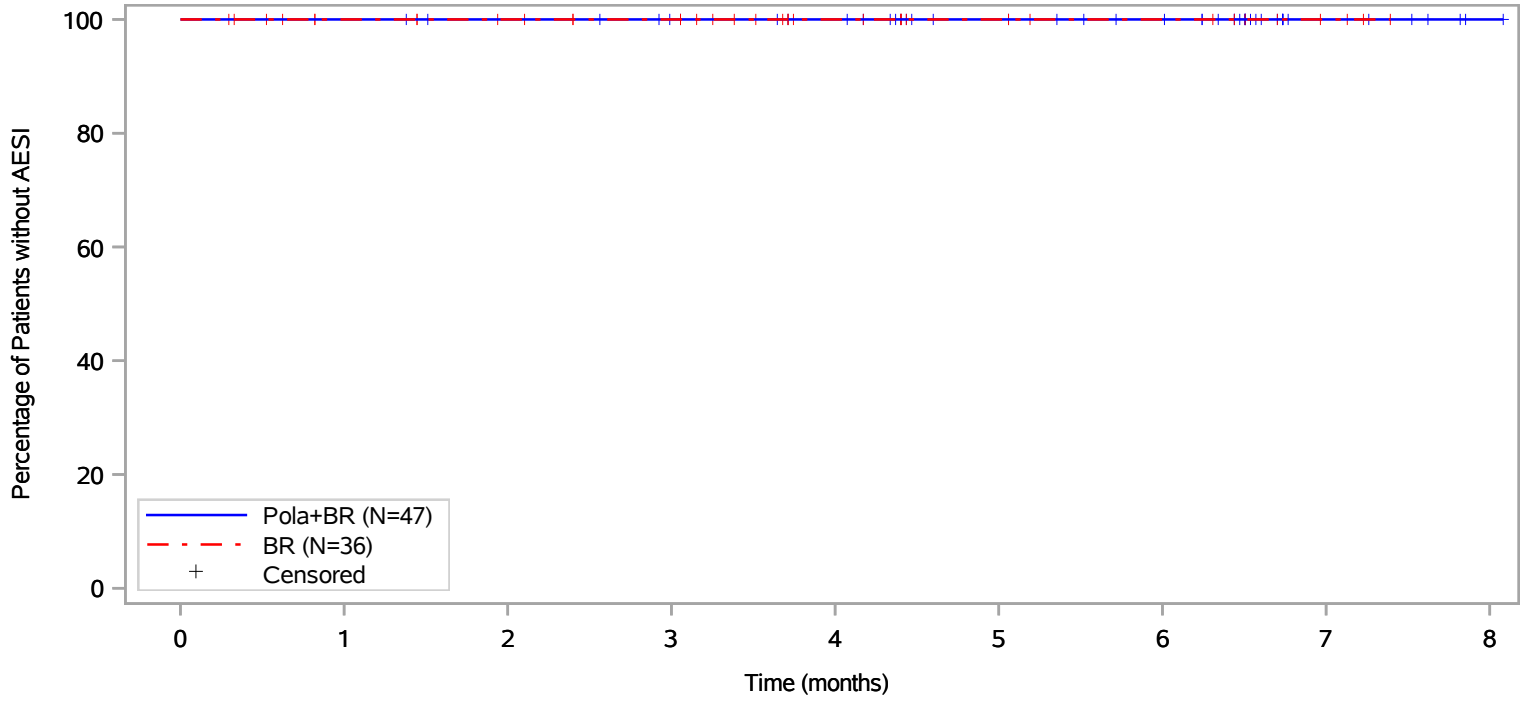
POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Hazard Ratio and Heterogeneity Statistics

		Pola+BR (N=47)						BR (N=36)						Pola + BR vs. BR												
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio						Weight	Heterogeneity					Test for overall effect	
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status		Weight (%)	Chi²	Df	P-value	I² (%)		Z	P-value
Study Identifier	GO29365	28	59.6	0	-	28	100.0	27	75.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	YO41543	19	40.4	0	-	19	100.0	9	25.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE							
	Total	47	100.0	0	-	47	100.0	36	100.0	0	-	36	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		NE	NE	NE	NE	NE		NE	NE

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fp_hr.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_fp_hr_TTTLS_L3PLUS_ARMCDPLUSSE_29365_41543.xls
17DEC2022 22:25

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=47)	47	47	45	42	39	31	27	6	1
BR (N=36)	36	30	27	24	15	10	8	3	NE
Patients censored									
Pola+BR (N=47)	0	0	2	5	8	16	20	41	46
BR (N=36)	0	6	9	12	21	26	28	33	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output/g_km_TTTLS_L3PLUS_ARMCDPLUSSE_29365_41543.pdf
03DEC2022 22:12

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=47)															BR (N=36)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																														
All	835	641	76.8	5	0.6	150	18.0	3	0.4	34	4.1	2	0.2	0	0.0	376	242	64.4	5	1.3	109	29.0	6	1.6	9	2.4	5	1.3	0	0.0
Grade 1	419	324	77.3	0	0.0	71	16.9	0	0.0	23	5.5	1	0.2	0	0.0	170	119	70.0	3	1.8	44	25.9	0	0.0	3	1.8	1	0.6	0	0.0
Grade 2	208	153	73.6	2	1.0	45	21.6	0	0.0	7	3.4	1	0.5	0	0.0	112	64	57.1	0	0.0	38	33.9	0	0.0	6	5.4	4	3.6	0	0.0
Grade 3	147	116	78.9	3	2.0	26	17.7	0	0.0	2	1.4	0	0.0	0	0.0	67	51	76.1	1	1.5	15	22.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	58	48	82.8	0	0.0	8	13.8	0	0.0	2	3.4	0	0.0	0	0.0	21	8	38.1	1	4.8	12	57.1	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	6	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0
AEs Grade >=3																														
All	208	164	78.8	3	1.4	34	16.3	3	1.4	4	1.9	0	0.0	0	0.0	94	59	62.8	2	2.1	27	28.7	6	6.4	0	0.0	0	0.0	0	0.0
Grade 3	147	116	78.9	3	2.0	26	17.7	0	0.0	2	1.4	0	0.0	0	0.0	67	51	76.1	1	1.5	15	22.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	58	48	82.8	0	0.0	8	13.8	0	0.0	2	3.4	0	0.0	0	0.0	21	8	38.1	1	4.8	12	57.1	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	6	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0
AEs Grade 3																														
All	147	116	78.9	3	2.0	26	17.7	0	0.0	2	1.4	0	0.0	0	0.0	67	51	76.1	1	1.5	15	22.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	147	116	78.9	3	2.0	26	17.7	0	0.0	2	1.4	0	0.0	0	0.0	67	51	76.1	1	1.5	15	22.4	0	0.0	0	0.0	0	0.0	0	0.0
AEs Grade 4																														
All	58	48	82.8	0	0.0	8	13.8	0	0.0	2	3.4	0	0.0	0	0.0	21	8	38.1	1	4.8	12	57.1	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	58	48	82.8	0	0.0	8	13.8	0	0.0	2	3.4	0	0.0	0	0.0	21	8	38.1	1	4.8	12	57.1	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																														
All	38	29	76.3	0	0.0	5	13.2	3	7.9	1	2.6	0	0.0	0	0.0	33	17	51.5	1	3.0	9	27.3	6	18.2	0	0.0	0	0.0	0	0.0
Grade 1	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	18	16	88.9	0	0.0	2	11.1	0	0.0	0	0.0	0	0.0	0	0.0	16	11	68.8	0	0.0	5	31.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	11	7	63.6	0	0.0	3	27.3	0	0.0	1	9.1	0	0.0	0	0.0	9	4	44.4	1	11.1	4	44.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	6	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ae_resolved.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output/t_s_ae_resolved_L3PLUS_ARMCDPLUSSE_29365_41543.xls
18APR2023 16:36

POPULATION: Safety Population, Arms C,D (Study 365)+Polarose, Third-line or beyond (3L+) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=47)															BR (N=36)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Neutropenia Including Febrile Neutropenia																														
All	151	134	88.7	2	1.3	15	9.9	0	0.0	0	0.0	0	0.0	0	0.0	69	59	85.5	0	0.0	9	13.0	0	0.0	1	1.4	0	0.0	0	0.0
Grade 1	18	17	94.4	0	0.0	1	5.6	0	0.0	0	0.0	0	0.0	0	0.0	15	13	86.7	0	0.0	2	13.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	37	34	91.9	1	2.7	2	5.4	0	0.0	0	0.0	0	0.0	0	0.0	18	15	83.3	0	0.0	2	11.1	0	0.0	1	5.6	0	0.0	0	0.0
Grade 3	60	52	86.7	1	1.7	7	11.7	0	0.0	0	0.0	0	0.0	0	0.0	26	24	92.3	0	0.0	2	7.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	36	31	86.1	0	0.0	5	13.9	0	0.0	0	0.0	0	0.0	0	0.0	10	7	70.0	0	0.0	3	30.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Neutropenia Including Febrile Neutropenia																														
All	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral Neuropathy																														
All	24	17	70.8	0	0.0	6	25.0	0	0.0	1	4.2	0	0.0	0	0.0	2	1	50.0	0	0.0	0	0.0	0	0.0	1	50.0	0	0.0	0	0.0
Grade 1	19	14	73.7	0	0.0	4	21.1	0	0.0	1	5.3	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
Grade 2	5	3	60.0	0	0.0	2	40.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Peripheral Neuropathy																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Anemia																														
All	48	37	77.1	0	0.0	8	16.7	0	0.0	3	6.3	0	0.0	0	0.0	13	7	53.8	0	0.0	4	30.8	0	0.0	2	15.4	0	0.0	0	0.0
Grade 1	10	8	80.0	0	0.0	1	10.0	0	0.0	1	10.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	19	15	78.9	0	0.0	3	15.8	0	0.0	1	5.3	0	0.0	0	0.0	5	2	40.0	0	0.0	1	20.0	0	0.0	2	40.0	0	0.0	0	0.0
Grade 3	19	14	73.7	0	0.0	4	21.1	0	0.0	1	5.3	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Anemia																														
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Thrombocytopenia																														
All	67	52	77.6	3	4.5	11	16.4	0	0.0	1	1.5	0	0.0	0	0.0	26	14	53.8	3	11.5	8	30.8	0	0.0	1	3.8	0	0.0	0	0.0
Grade 1	22	21	95.5	0	0.0	1	4.5	0	0.0	0	0.0	0	0.0	0	0.0	10	4	40.0	2	20.0	4	40.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	15	10	66.7	1	6.7	4	26.7	0	0.0	0	0.0	0	0.0	0	0.0	6	5	83.3	0	0.0	0	0.0	0	0.0	1	16.7	0	0.0	0	0.0
Grade 3	16	9	56.3	2	12.5	5	31.3	0	0.0	0	0.0	0	0.0	0	0.0	6	5	83.3	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	14	12	85.7	0	0.0	1	7.1	0	0.0	1	7.1	0	0.0	0	0.0	4	0	0.0	0	0.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Thrombocytopenia																														
All	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Infections and Infestations																														
All	32	24	75.0	0	0.0	6	18.8	1	3.1	1	3.1	0	0.0	0	0.0	20	12	60.0	0	0.0	5	25.0	3	15.0	0	0.0	0	0.0	0	0.0
Grade 1	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	12	10	83.3	0	0.0	2	16.7	0	0.0	0	0.0	0	0.0	0	0.0	8	5	62.5	0	0.0	3	37.5	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	7	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	5	2	40.0	0	0.0	2	40.0	0	0.0	1	20.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0
Serious Infections and Infestations																														
All	13	9	69.2	0	0.0	2	15.4	1	7.7	1	7.7	0	0.0	0	0.0	11	6	54.5	0	0.0	2	18.2	3	27.3	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	6	6	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	4	66.7	0	0.0	2	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	5	2	40.0	0	0.0	2	40.0	0	0.0	1	20.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0
Infusion Related Reactions																														
All	26	23	88.5	0	0.0	2	7.7	0	0.0	1	3.8	0	0.0	0	0.0	19	16	84.2	0	0.0	3	15.8	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	12	10	83.3	0	0.0	2	16.7	0	0.0	0	0.0	0	0.0	0	0.0	11	9	81.8	0	0.0	2	18.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	11	10	90.9	0	0.0	0	0.0	0	0.0	1	9.1	0	0.0	0	0.0	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Infusion Related Reactions																														
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hepatic Toxicity																														
All	41	27	65.9	0	0.0	9	22.0	0	0.0	5	12.2	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	27	19	70.4	0	0.0	5	18.5	0	0.0	3	11.1	0	0.0	0	0.0	4	2	50.0	0	0.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	13	7	53.8	0	0.0	4	30.8	0	0.0	2	15.4	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hepatic Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Fatigue and Asthenia																														
All	25	12	48.0	0	0.0	11	44.0	0	0.0	2	8.0	0	0.0	0	0.0	19	9	47.4	1	5.3	9	47.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	18	9	50.0	0	0.0	7	38.9	0	0.0	2	11.1	0	0.0	0	0.0	15	7	46.7	1	6.7	7	46.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	6	3	50.0	0	0.0	3	50.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Fatigue and Asthenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Hyperglycemias																																
All	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hyperglycemias																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Renal Toxicity																																
All	17	13	76.5	0	0.0	3	17.6	0	0.0	1	5.9	0	0.0	0	0.0	7	3	42.9	0	0.0	4	57.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	15	12	80.0	0	0.0	2	13.3	0	0.0	1	6.7	0	0.0	0	0.0	4	2	50.0	0	0.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Renal Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Gastrointestinal Toxicity																																
All	115	86	74.8	0	0.0	22	19.1	0	0.0	6	5.2	1	0.9	0	0.0	59	40	67.8	1	1.7	17	28.8	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0
Grade 1	71	56	78.9	0	0.0	10	14.1	0	0.0	5	7.0	0	0.0	0	0.0	29	22	75.9	0	0.0	7	24.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	36	25	69.4	0	0.0	9	25.0	0	0.0	1	2.8	1	2.8	0	0.0	24	16	66.7	0	0.0	7	29.2	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0
Grade 3	8	5	62.5	0	0.0	3	37.5	0	0.0	0	0.0	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Gastrointestinal Toxicity																																
All	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	1	33.3	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pulmonary Toxicity																																
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Pulmonary Toxicity																																
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Joint Pains, Arthralgia, Skeletal Pain																																
All	6	4	66.7	0	0.0	2	33.3	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Joint Pains, Arthralgia, Skeletal Pain																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Alopecia																																
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Alopecia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Cardiac Toxicity and Arrhythmias																																
All	2	1	50.0	0	0.0	0	0.0	0	0.0	1	50.0	0	0.0	0	0.0	10	7	70.0	0	0.0	3	30.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Cardiac Toxicity and Arrhythmias																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dysgeusia																																
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Dysgeusia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Demographics and Baseline Characteristics

	Pola+BR (N=11)	BR (N=12)	All (N=23)
Age (Years)			
n	11	12	23
Mean (SD)	70.7 (10.2)	75.7 (4.2)	73.3 (7.9)
Median	72	75	74
Min - Max	56 - 86	70 - 83	56 - 86
Age Group (Years)			
n	11	12	23
41 - 64	3 (27.3%)	0	3 (13.0%)
>= 65	8 (72.7%)	12 (100%)	20 (87.0%)
Sex			
n	11	12	23
Male	7 (63.6%)	7 (58.3%)	14 (60.9%)
Female	4 (36.4%)	5 (41.7%)	9 (39.1%)
Race			
n	11	12	23
Asian	2 (18.2%)	2 (16.7%)	4 (17.4%)
White	8 (72.7%)	10 (83.3%)	18 (78.3%)
Unknown	1 (9.1%)	0	1 (4.3%)
Ethnicity			
n	11	12	23
Hispanic or Latino	0	1 (8.3%)	1 (4.3%)
Not Hispanic or Latino	10 (90.9%)	11 (91.7%)	21 (91.3%)
Not reported	1 (9.1%)	0	1 (4.3%)
Weight (kg) at Baseline			
n	11	12	23
Mean (SD)	71.43 (23.76)	71.59 (13.19)	71.51 (18.54)
Median	67	70.9	67.7

Min - Max	48.0 - 132.9	48.0 - 90.0	48.0 - 132.9
Height (cm) at Baseline			
n	11	12	23
Mean (SD)	167.9 (14.12)	162.7 (9.01)	165.2 (11.76)
Median	167	164.3	165
Min - Max	146.3 - 195.6	145.0 - 174.0	145.0 - 195.6
ECOG score at Baseline			
n	11	12	23
0	3 (27.3%)	6 (50.0%)	9 (39.1%)
1	5 (45.5%)	4 (33.3%)	9 (39.1%)
2	3 (27.3%)	2 (16.7%)	5 (21.7%)
Bulky disease at Baseline			
n	11	12	23
Yes	3 (27.3%)	1 (8.3%)	4 (17.4%)
No	8 (72.7%)	11 (91.7%)	19 (82.6%)
Primary Reason for Stem Cell Transplant Ineligibility			
n	11	12	23
Age	7 (63.6%)	11 (91.7%)	18 (78.3%)
Co-Morbidities	1 (9.1%)	0	1 (4.3%)
Patient Refused Transplant	2 (18.2%)	0	2 (8.7%)
Performance Status	0	1 (8.3%)	1 (4.3%)
Other	1 (9.1%)	0	1 (4.3%)
Duration of response to prior therapy (IxRS)			
n	11	12	23
<=12 Months	5 (45.5%)	10 (83.3%)	15 (65.2%)
>12 Months	6 (54.5%)	2 (16.7%)	8 (34.8%)
Duration of response to prior therapy (CRF)			
n	11	12	23
<=12 Months	5 (45.5%)	11 (91.7%)	16 (69.6%)
>12 Months	6 (54.5%)	1 (8.3%)	7 (30.4%)

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_dm.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_dm_L2_365_ARMCD_IT_29365_41543.xls
08DEC2022 17:42

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of Patients who discontinued Study or Treatment

Status / Primary Reason for Discontinuation	Pola+BR (N=11)	BR (N=12)	All (N=23)
Number of Patients Randomized	11 (100.0%)	12 (100.0%)	23 (100.0%)
Number of Patients Treated	11 (100.0%)	12 (100.0%)	23 (100.0%)
Discontinued Study*			
Total	7 (63.6%)	12 (100.0%)	19 (82.6%)
Death	5 (45.5%)	9 (75.0%)	14 (60.9%)
Withdrawal by Subject	2 (18.2%)	3 (25.0%)	5 (21.7%)
Discontinued Polatuzumab Vedotin Treatment or Placebo**			
Total	6 (54.5%)	0	6 (26.1%)
Adverse Event	5 (45.5%)	0	5 (21.7%)
Withdrawal by Subject	1 (9.1%)	0	1 (4.3%)
Discontinued Bendamustine Treatment**			
Total	7 (63.6%)	8 (66.7%)	15 (65.2%)
Adverse Event	6 (54.5%)	1 (8.3%)	7 (30.4%)
Progressive Disease	0	4 (33.3%)	4 (17.4%)
Death	0	1 (8.3%)	1 (4.3%)
Lack of Efficacy	0	1 (8.3%)	1 (4.3%)
Withdrawal by Subject	1 (9.1%)	1 (8.3%)	2 (8.7%)
Discontinued Rituximab or Obinutuzumab Treatment**			
Total	6 (54.5%)	8 (66.7%)	14 (60.9%)
Adverse Event	5 (45.5%)	1 (8.3%)	6 (26.1%)
Progressive Disease	0	4 (33.3%)	4 (17.4%)
Death	0	1 (8.3%)	1 (4.3%)
Lack of Efficacy	0	1 (8.3%)	1 (4.3%)
Withdrawal by Subject	1 (9.1%)	1 (8.3%)	2 (8.7%)

* Percentages are based on the number of patients randomized.
** Percentages are based on the number of patients treated.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ds.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_ds_L2_365_ARMCD_IT_29365_41543.xls
08DEC2022 12:57

POPULATION: Intent-to-Treat Patients, Study GO29365, Arms C,D, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Number of Centers/Countries/Geographical Regions with <10, >=10 Patients per Arm

	Center				Country				Geographical region			
	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients
Overall	18	100.0	23	100.0	10	100.0	23	100.0	4	100.0	23	100.0
with <10 patients per arm	18	100.0	23	100.0	10	100.0	23	100.0	4	100.0	23	100.0
with >=10 patients per arm	0	-	0	-	0	-	0	-	0	-	0	-

'<10 patients' category if at least one treatment arm has <10 patients; '>=10 patients' category if all treatment arms have >=10 patients.
Geographical regions: Asia/Pacific, Eastern Europe, North America, Western Europe.
'n': Number of centers/countries/regions; "%": Percent of centers/countries/regions compared to overall number of centers/countries/regions
'n of patients randomized': Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)
'% randomized patients': Percent of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_center.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_center_L2_ARMCD_365_IT_29365_41543.xls
08DEC2022 0:42

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Second-line (2L) Patients
ENDPOINT: Concordance of Stratification Factors by eCRF and IxRS
MODEL: Descriptive
STUDIES: GO29365, YO41543
Stratification Factor: Duration of Response to prior therapy

	Pola+BR (N=11)			BR (N=12)		
	eCRF			eCRF		
	<=12 Months	>12 Months	Total	<=12 Months	>12 Months	Total
IxRS						
<=12 Months	5 (45.5%)	0	5 (45.5%)	10 (83.3%)	0	10 (83.3%)
>12 Months	0	6 (54.5%)	6 (54.5%)	1 (8.3%)	1 (8.3%)	2 (16.7%)
Total	5	6	11	11	1	12

Percentages are based on N in the column headings.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_strat.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_strat_L2_365_ARMCD_IT_29365_41543.xls
08DEC2022 12:57

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: POLATUZUMAB VEDOTIN

	Pola+BR (N=11)
Treatment Duration (Months)	
n	11
Mean (SD)	2.71 (1.77)
Median	3.19
Interquartile Range	1.35 - 3.65
Min - Max	0.0 - 5.9
Number of Cycles	
n	11
Mean (SD)	4.4 (2.0)
Median	5
Interquartile Range	3.0 - 6.0
Min - Max	1 - 6
Total Cumulative Dose (mg)	
n	11
Mean (SD)	549.3 (316.4)
Median	518.4
Interquartile Range	318.6 - 660.0
Min - Max	121 - 1183
Dose intensity (%) adjusted for dose reduction and delay	
n	11
Mean (SD)	91.5 (12.7)
Median	95.5
Interquartile Range	87.3 - 100.3
Min - Max	58 - 102

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas

Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_ex_L2_ARMCDSE_365_29365_41543.xls
20APR2023 11:13

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: BENDAMUSTINE

	Pola+BR (N=11)	BR (N=12)
Treatment Duration (Months)		
n	11	12
Mean (SD)	2.59 (1.53)	2.17 (1.35)
Median	3.22	2.12
Interquartile Range	1.38 - 3.68	0.71 - 3.48
Min - Max	0.0 - 4.3	0.7 - 3.9
Number of Cycles		
n	11	12
Mean (SD)	4.3 (2.0)	4.0 (1.8)
Median	5	4
Interquartile Range	3.0 - 6.0	2.0 - 6.0
Min - Max	1 - 6	2 - 6
Total Cumulative Dose (mg)		
n	11	12
Mean (SD)	1319.4 (637.1)	1249.3 (583.0)
Median	1533.6	1134
Interquartile Range	880.2 - 1800.0	642.8 - 1785.6
Min - Max	329 - 2161	580 - 2171
Dose intensity (%) adjusted for dose reduction and delay		
n	11	12
Mean (SD)	89.2 (13.4)	96.8 (6.5)
Median	94.7	97.3
Interquartile Range	85.1 - 98.2	95.4 - 101.1
Min - Max	53 - 100	78 - 103

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_ex_L2_ARMCDSE_365_29365_41543.xls
20APR2023 11:13

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: RITUXIMAB

	Pola+BR (N=11)	BR (N=12)
Treatment Duration (Months)		
n	11	12
Mean (SD)	2.73 (1.78)	2.17 (1.34)
Median	3.22	2.1
Interquartile Range	1.38 - 3.68	0.71 - 3.49
Min - Max	0.0 - 5.9	0.7 - 3.9
Number of Cycles		
n	11	12
Mean (SD)	4.4 (2.0)	4.0 (1.8)
Median	5	4
Interquartile Range	3.0 - 6.0	2.0 - 6.0
Min - Max	1 - 6	2 - 6
Total Cumulative Dose (mg)		
n	11	12
Mean (SD)	2937.7 (1413.3)	2596.0 (1217.0)
Median	3338	2362.5
Interquartile Range	1833.9 - 3911.6	1337.0 - 3739.5
Min - Max	686 - 5006	1200 - 4522
Dose intensity (%) adjusted for dose reduction and delay		
n	11	12
Mean (SD)	92.2 (8.9)	96.3 (6.0)
Median	94.6	97.3
Interquartile Range	88.2 - 100.0	95.2 - 99.5
Min - Max	73 - 100	79 - 103

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_ex_L2_ARMCDSE_365_29365_41543.xls
20APR2023 11:13

POPULATION: Safety Population, Arms C,D, Study GO29365, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=11)	BR (N=12)	All (N=23)
n	11	12	23
Median	129	95	116

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 30 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_fu_D30_L2_365_ARMCDSE_29365_41543.xls
08DEC2022 17:09

POPULATION: Safety Population, Arms C,D, Study GO29365, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=11)	BR (N=12)	All (N=23)
n	11	12	23
Median	189	134.5	148

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 90 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_fu_D90_L2_365_ARMCDSE_29365_41543.xls
08DEC2022 17:23

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of New Anti-Lymphoma Therapy

	Pola+BR (N=11)	BR (N=12)
Total number of patients with at least one NALT treatment	1 (9.1%)	4 (33.3%)
Total number of NALT treatments	1	5
Total number of patients with at least one NALT treatment before PFS event	1 (9.1%)	1 (8.3%)
Total number of patients with at least one NALT treatment at or after PFS event	0	2 (16.7%)
Total number of patients with at least one NALT treatment and without PFS event	0	1 (8.3%)
Radiotherapy		
Total number of patients with at least one treatment	0	0
Total number of treatments	0	0
Systemic therapy		
Total number of patients with at least one treatment	1 (9.1%)	4 (33.3%)
Total number of treatments	1	5
Total number of patients received stem cell transplants	0	0
Autologous transplant	0	0
Allogeneic transplant	0	0
Unknown	0	0
Total number of patients received CAR-T	0	0
Total number of patients received unknown treatment	0	0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_nalt.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_nalt_L2_365_ARMCD_IT_29365_41543.xls
01FEB2023 19:02

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median observation time(of follow up)

Overall Survival

	Pola+BR (N=11)	BR (N=12)	All (N=23)
Patients with event (%)	6 (54.5%)	3 (25.0%)	9 (39.1%)
Latest contributing event			
Alive	6	3	9
Patients without event (%)	5 (45.5%)	9 (75.0%)	14 (60.9%)
Time to event (months)			
Median	64.5	NE	58.6
95% CI	(19.6, NE)	(5.3, NE)	(19.6, 65.9)
25% and 75%-ile	19.6 - 65.9	5.3 - NE	19.6 - 65.9
Range	1 - 67	1 - 25*	1 - 67

Summaries of Duration of Follow-up (median, percentiles) are based on reverse Kaplan-Meier estimates.
* Censored observation.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_obs_time.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_obs_time_OSDFU_L2_365_ARMCD_IT_29365_41543.xls
08DEC2022 3:09

POPULATION: Safety Population, Arms C,D, Study GO29365, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Deaths and Primary Reason for Death

	Pola+BR (N=11)		BR (N=12)		All (N=23)	
	n	%	n	%	n	%
All Deaths	5	45.5	9	75.0	14	60.9
Adverse Event	4	36.4	3	25.0	7	30.4
Progressive Disease	1	9.1	6	50.0	7	30.4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_death.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_death_L2_365_ARMCDSE_29365_41543.xls
08DEC2022 18:17

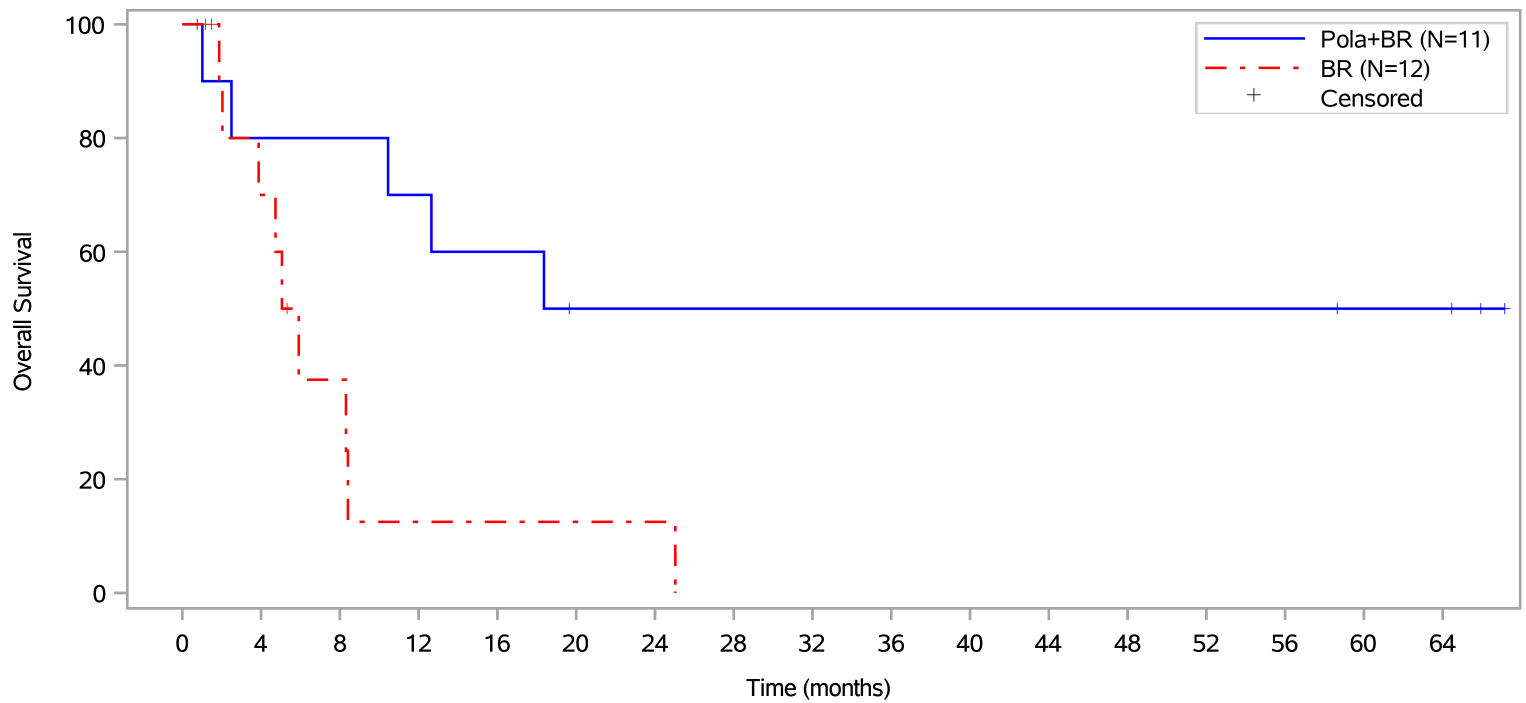
POPULATION: Intent-to-Treat Patients, Arms C,D, Second-line (2L) Patients, Study GO29365
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=11)											BR (N=12)											Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		11	100.0	5	45.5	6	54.5	10.4	1.0	NE	NE	10.4	NE	12	100.0	9	75.0	3	25.0	3.9	1.9	5.9	5.5	3.9	8.4	0.0530	0.21	0.04	1.11		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_eff_tte_gh_str_OS_365_L2_ARMCD_IT_29365_41543.xls
20JAN2023 16:34

POPULATION: Intent-to-Treat Patients, Arms C,D, Second-line (2L) Patients, Study GO29365
ENDPOINT: Overall Survival
STUDIES: GO29365, YO41543



Patients at risk																																		
Pola+BR (N=11)	11	9	8	8	8	8	7	6	6	6	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3	3	3	1
BR (N=12)	12	9	7	3	3	1	1	1	1	1	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																		
Pola+BR (N=11)	0	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3	3	3	5
BR (N=12)	0	2	2	3	3	3	3	3	3	3	3	3	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..alysis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_OS_365_L2_ARMCD_IT_29365_41543.pdf
28NOV2022 15:15

POPULATION: Intent-to-Treat Patients, Arms C,D, Second-line (2L) Patients, Study GO29365
ENDPOINT: Overall Survival
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=11)												BR (N=12)											Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		11	100.0	5	45.5	6	54.5	10.4	1.0	NE	NE	10.4	NE	12	100.0	9	75.0	3	25.0	3.9	1.9	5.9	5.5	3.9	8.4	0.0127	0.24	0.07	0.79	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	4	57.1	3	42.9	2.5	1.0	18.4	15.5	2.5	NE	7	58.3	5	71.4	2	28.6	2.0	1.9	8.4	6.7	2.0	NE	0.3422	0.52	0.13	2.04	Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	NE	10.4	NE	NE	10.4	NE	5	41.7	4	80.0	1	20.0	4.3	3.9	5.9	5.3	3.9	NE	0.0067	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	1.0	1.0	NE	NE	1.0	NE	0	0.0	0	-	0	-	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-
	>= 65	8	72.7	4	50.0	4	50.0	10.4	2.5	NE	18.4	10.4	NE	12	100.0	9	75.0	3	25.0	3.9	1.9	5.9	5.5	3.9	8.4	0.0198	0.25	0.07	0.86	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	4	66.7	2	33.3	2.5	1.0	18.4	12.6	1.0	NE	10	83.3	8	80.0	2	20.0	3.0	1.9	5.1	4.9	2.0	8.4	0.3410	0.55	0.16	1.91	Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	1	20.0	4	80.0	NE	10.4	NE	NE	10.4	NE	2	16.7	1	50.0	1	50.0	5.9	NE	NE	5.9	NE	NE	0.0253	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	14.4	10.4	NE	NE	10.4	NE	3	25.0	3	100.0	0	-	3.9	3.9	NE	4.7	3.9	NE	0.2119	0.32	0.05	2.03	Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	3	50.0	3	50.0	2.5	1.0	NE	NE	2.5	NE	9	75.0	6	66.7	3	33.3	2.0	1.9	8.3	5.9	2.0	NE	0.0980	0.27	0.05	1.40	Convergence criterion (GCONV=1E-8) satisfied.	
Duration of response to prior therapy	<=12 Months	5	45.5	2	40.0	3	60.0	1.8	1.0	NE	NE	1.0	NE	10	83.3	7	70.0	3	30.0	3.0	1.9	5.9	5.3	2.0	8.4	0.3526	0.47	0.09	2.39	Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	6	54.5	3	50.0	3	50.0	12.6	10.4	NE	NE	12.6	NE	2	16.7	2	100.0	0	-	5.1	5.1	NE	6.7	5.1	NE	0.0039	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Refractory to last prior anti-lymphoma therapy**	Yes	3	27.3	1	33.3	2	66.7	1.0	1.0	NE	NE	1.0	NE	10	83.3	7	70.0	3	30.0	3.0	1.9	5.9	5.3	2.0	8.4	0.4799	0.47	0.05	4.06	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	8	72.7	4	50.0	4	50.0	11.5	2.5	NE	NE	10.4	NE	2	16.7	2	100.0	0	-	5.5	5.1	NE	6.7	5.1	NE	0.0289	0.11	0.01	1.21	Convergence criterion (GCONV=1E-8) satisfied.	
Prior Bone Marrow Transplant	No	11	100.0	5	45.5	6	54.5	10.4	1.0	NE	NE	10.4	NE	12	100.0	9	75.0	3	25.0	3.9	1.9	5.9	5.5	3.9	8.4	0.0127	0.24	0.07	0.79	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_eff_tte_gh_sg_OS_365_L2_ARMCD_IT_29365_41543.xls
20JAN2023 16:47

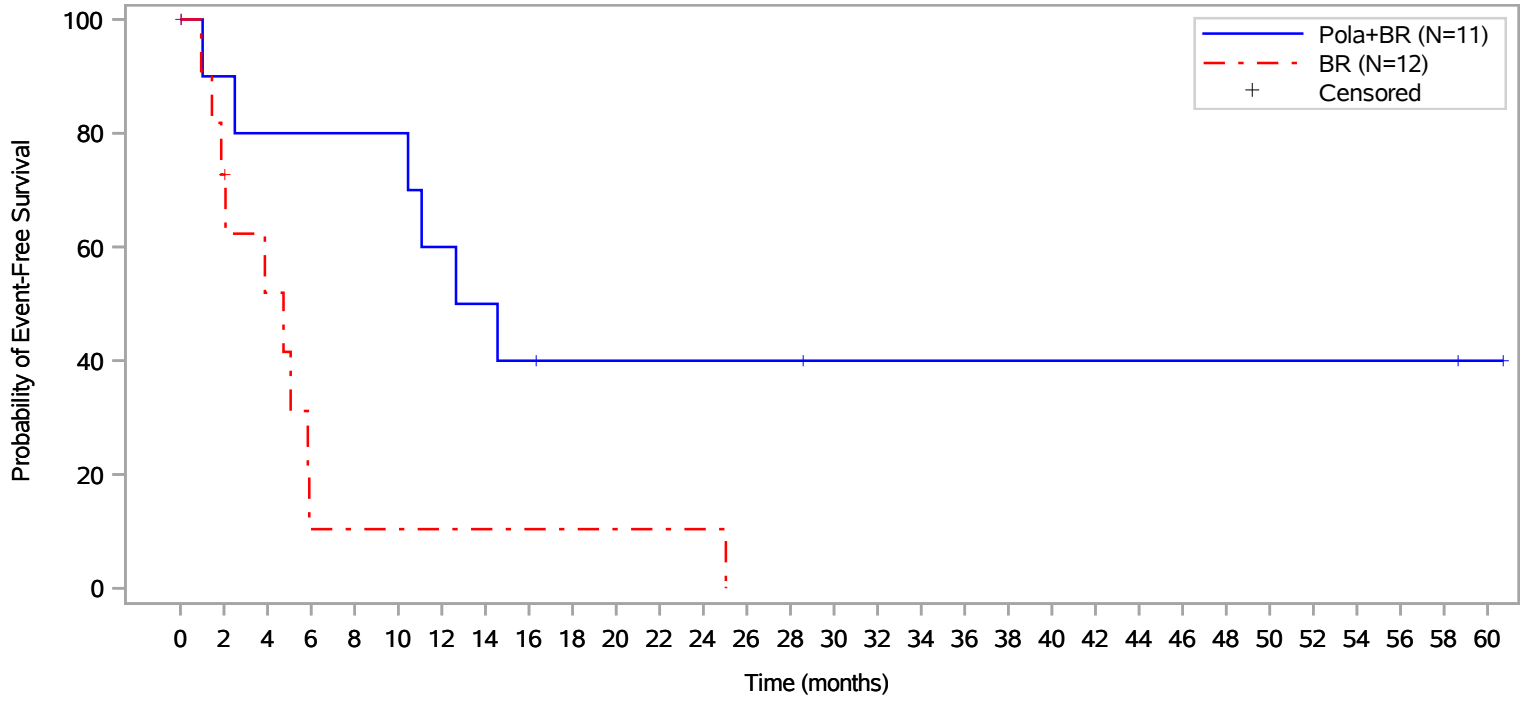
POPULATION: Intent-to-Treat Patients, Arms C,D, Second-line (2L) Patients, Study GO29365
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=11)											BR (N=12)											Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		11	100.0	6	54.5	5	45.5	10.4	1.0	14.6	13.6	10.4	NE	12	100.0	10	83.3	2	16.7	1.9	1.0	4.7	4.7	1.9	5.8	0.0278	0.18	0.04	0.93		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_eff_tte_gh_str_PFSIRC_365_L2_ARMCD_IT_29365_41543.xls
20JAN2023 16:01

POPULATION: Intent-to-Treat Patients, Arms C,D, Second-line (2L) Patients, Study GO29365
ENDPOINT: Progression-Free Survival (PFS) - IRC
STUDIES: GO29365, YO41543



Patients at risk																																		
Pola+BR (N=11)	11	9	8	8	8	8	6	5	4	3	3	3	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1
BR (N=12)	12	8	5	1	1	1	1	1	1	1	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																	
Pola+BR (N=11)	0	1	1	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4
BR (N=12)	0	1	2	2	2	2	2	2	2	2	2	2	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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28NOV2022 14:39

POPULATION: Intent-to-Treat Patients, Arms C,D, Second-line (2L) Patients, Study GO29365
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=11)												BR (N=12)										Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		11	100.0	6	54.5	5	45.5	10.4	1.0	14.6	13.6	10.4	NE	12	100.0	10	83.3	2	16.7	1.9	1.0	4.7	4.7	1.9	5.8	0.0087	0.25	0.09	0.75	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	5	71.4	2	28.6	2.5	1.0	12.6	11.9	2.5	14.6	7	58.3	5	71.4	2	28.6	1.9	1.0	5.1	2.1	1.9	NE	0.3956	0.58	0.16	2.07	Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	NE	10.4	NE	NE	10.4	NE	5	41.7	5	100.0	0	-	3.9	1.4	5.8	4.7	1.4	NE	0.0049	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	2	66.7	1	33.3	1.0	1.0	NE	14.6	1.0	NE	0	0.0	0	-	0	-	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	-
	>= 65	8	72.7	4	50.0	4	50.0	10.4	2.5	NE	12.6	10.4	NE	12	100.0	10	83.3	2	16.7	1.9	1.0	4.7	4.7	1.9	5.8	0.0096	0.22	0.06	0.75	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	4	66.7	2	33.3	2.5	1.0	12.6	11.1	1.0	NE	10	83.3	9	90.0	1	10.0	1.9	1.0	4.7	3.9	1.9	5.1	0.2273	0.48	0.14	1.62	Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	2	40.0	3	60.0	14.6	10.4	NE	NE	10.4	NE	2	16.7	1	50.0	1	50.0	5.9	NE	NE	5.9	NE	NE	0.0253	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	10.8	10.4	NE	NE	10.4	NE	3	25.0	3	100.0	0	-	3.9	3.9	NE	4.7	3.9	NE	0.2119	0.32	0.05	2.05	Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	4	66.7	2	33.3	2.5	1.0	14.6	13.6	2.5	NE	9	75.0	7	77.8	2	22.2	1.7	1.0	5.1	2.1	1.4	5.8	0.0394	0.21	0.04	1.05	Convergence criterion (GCONV=1E-8) satisfied.	
Duration of response to prior therapy	<=12 Months	5	45.5	2	40.0	3	60.0	1.8	1.0	NE	NE	1.0	NE	10	83.3	8	80.0	2	20.0	1.9	1.0	3.9	3.9	1.9	5.9	0.2019	0.37	0.08	1.80	Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	6	54.5	4	66.7	2	33.3	11.1	10.4	14.6	13.6	11.1	NE	2	16.7	2	100.0	0	-	5.1	5.1	NE	5.5	5.1	NE	0.0039	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Refractory to last prior anti-lymphoma therapy**	Yes	3	27.3	1	33.3	2	66.7	1.0	1.0	NE	NE	1.0	NE	10	83.3	8	80.0	2	20.0	1.9	1.0	3.9	3.9	1.9	5.9	0.3793	0.40	0.05	3.33	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	8	72.7	5	62.5	3	37.5	10.8	2.5	14.6	13.6	10.4	NE	2	16.7	2	100.0	0	-	5.1	5.1	NE	5.5	5.1	NE	0.0289	0.11	0.01	1.21	Convergence criterion (GCONV=1E-8) satisfied.	
Prior Bone Marrow Transplant	No	11	100.0	6	54.5	5	45.5	10.4	1.0	14.6	13.6	10.4	NE	12	100.0	10	83.3	2	16.7	1.9	1.0	4.7	4.7	1.9	5.8	0.0087	0.25	0.09	0.75	Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_eff_tte_gh_sg_PFSIRC_365_L2_ARMCD_IT_29365_41543.xls
20JAN2023 16:20

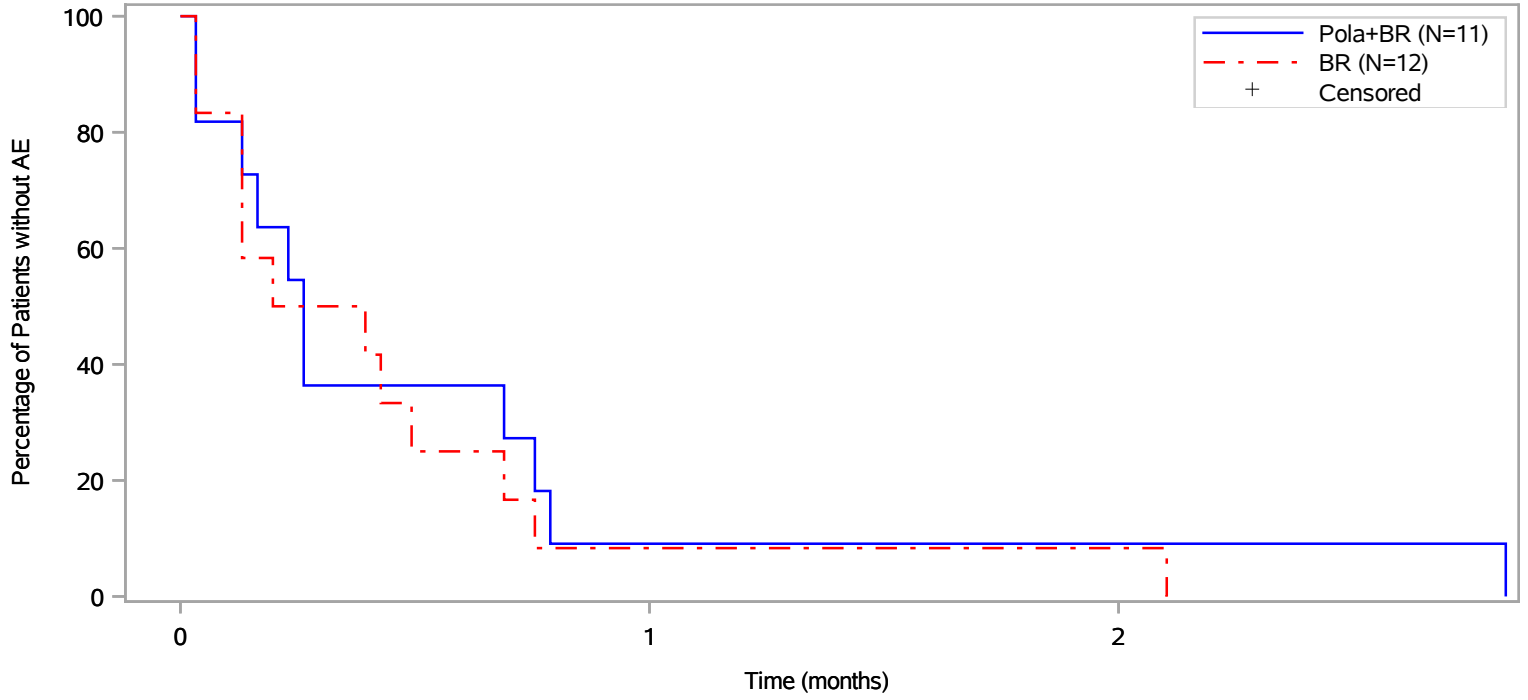
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	11	100.0	0	-	12	100.0	12	100.0	0	-	0.5763	0.78	0.32	1.89		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	7	100.0	0	-	7	58.3	7	100.0	0	-	0.2606	0.50	0.15	1.69		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	4	100.0	0	-	5	41.7	5	100.0	0	-	0.6049	1.46	0.35	6.07		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	3	100.0	0	-	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	8	100.0	0	-	12	100.0	12	100.0	0	-	0.7556	1.17	0.44	3.10		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	6	100.0	0	-	10	83.3	10	100.0	0	-	0.5688	1.38	0.45	4.23		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	5	100.0	0	-	2	16.7	2	100.0	0	-	0.6519	0.64	0.09	4.44		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	5	100.0	0	-	3	25.0	3	100.0	0	-	0.4928	0.58	0.12	2.81		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	6	100.0	0	-	9	75.0	9	100.0	0	-	0.2416	2.02	0.61	6.65		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTAE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 18:24

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543



Patients at risk			
Pola+BR (N=11)	11	1	1
BR (N=12)	12	1	1
Patients censored			
Pola+BR (N=11)	0	0	0
BR (N=12)	0	0	0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..lysis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTAE_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 16:50

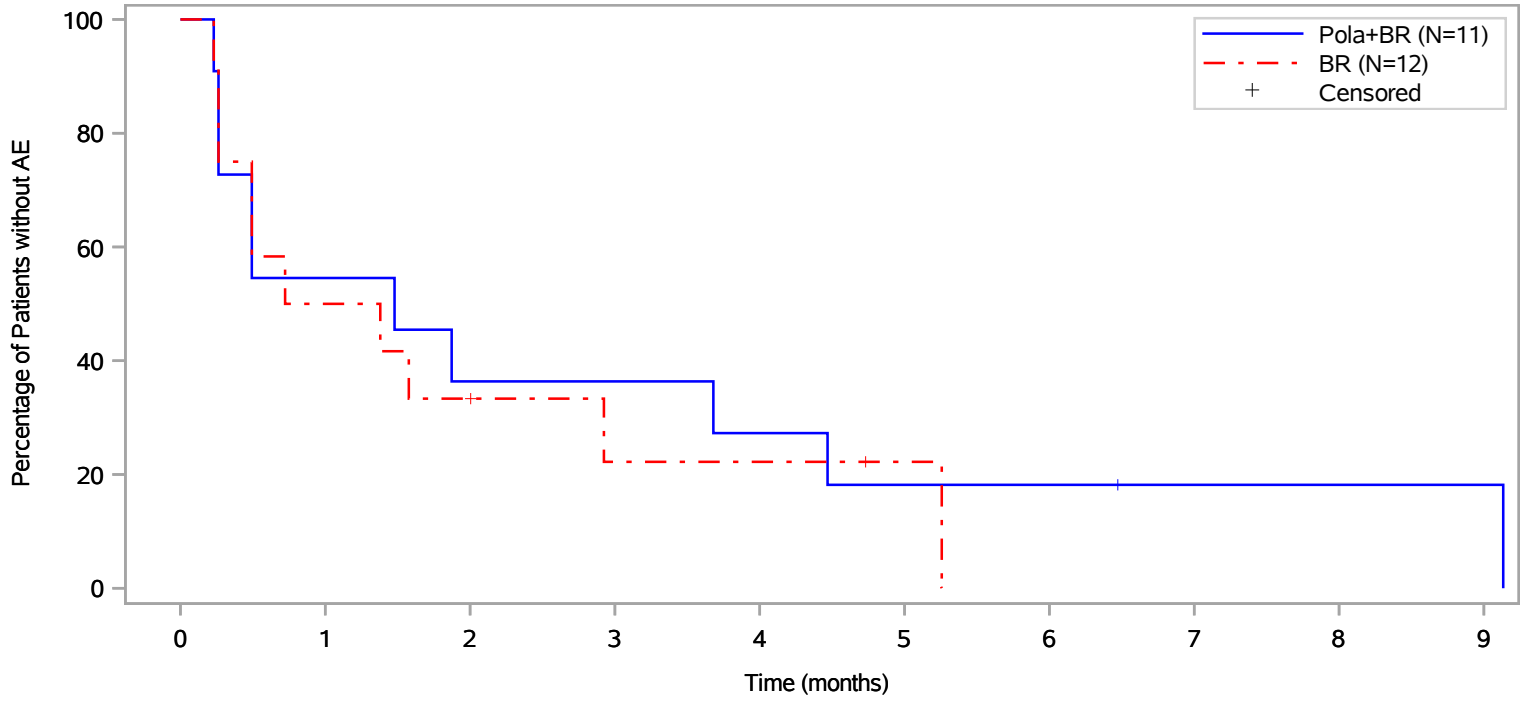
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	10	90.9	1	9.1	12	100.0	10	83.3	2	16.7	0.6960	0.83	0.32	2.13		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	6	85.7	1	14.3	7	58.3	6	85.7	1	14.3	0.1741	0.40	0.10	1.55		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	4	100.0	0	-	5	41.7	4	80.0	1	20.0	0.6788	1.42	0.27	7.36		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	8	100.0	0	-	12	100.0	10	83.3	2	16.7	0.9911	1.01	0.37	2.76		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	6	100.0	0	-	10	83.3	8	80.0	2	20.0	0.5875	1.38	0.43	4.42		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	4	80.0	1	20.0	2	16.7	2	100.0	0	-	0.4289	0.46	0.06	3.31		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	4	80.0	1	20.0	3	25.0	2	66.7	1	33.3	0.9656	0.96	0.16	5.90		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	6	100.0	0	-	9	75.0	8	88.9	1	11.1	0.8811	1.09	0.34	3.51		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGR345AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 19:09

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543



Patients at risk										
Pola+BR (N=11)	11	6	4	4	3	2	2	1	1	1
BR (N=12)	12	6	4	2	2	1	NE	NE	NE	NE
Patients censored										
Pola+BR (N=11)	0	0	0	0	0	0	0	1	1	1
BR (N=12)	0	0	0	1	1	2	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 18:14

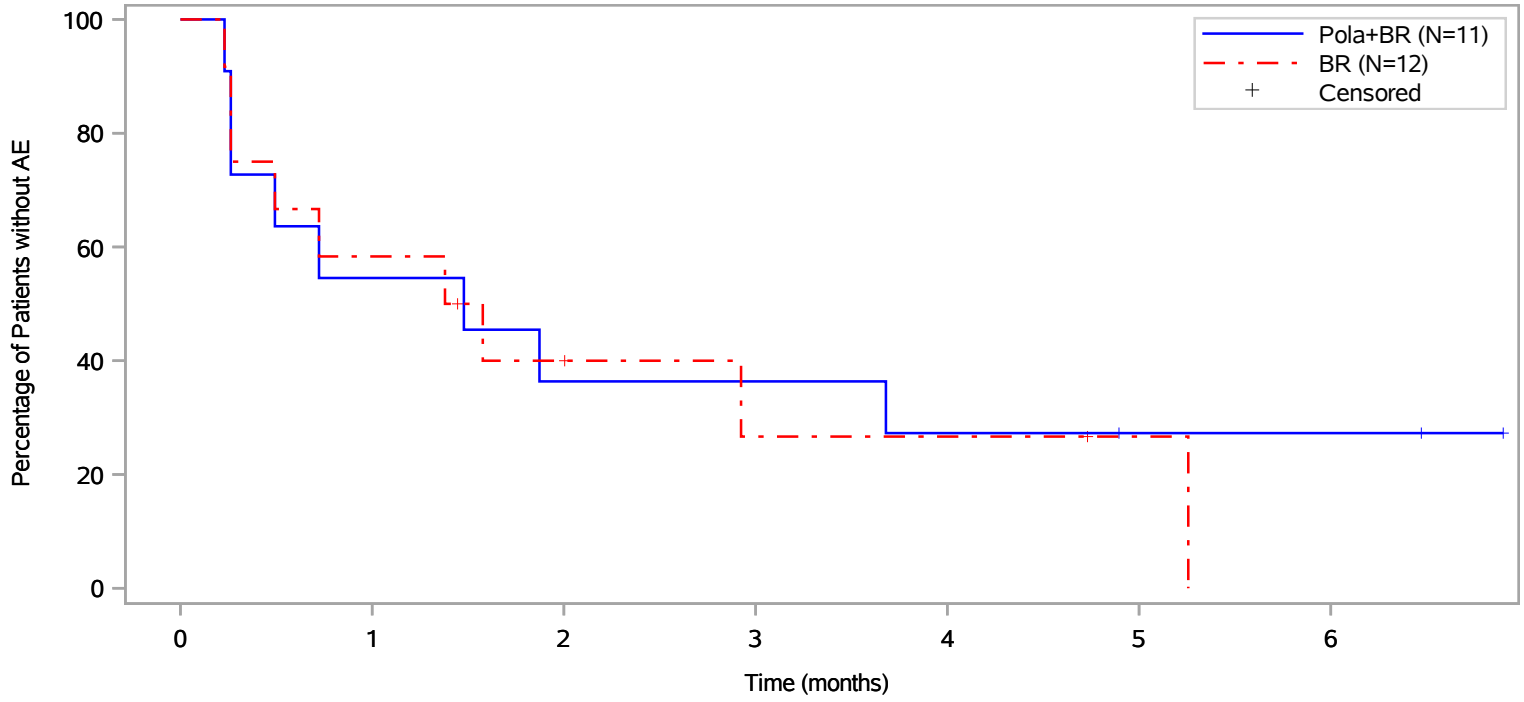
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	8	72.7	3	27.3	12	100.0	9	75.0	3	25.0	0.7231	0.84	0.31	2.25		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	5	71.4	2	28.6	7	58.3	6	85.7	1	14.3	0.1741	0.40	0.10	1.55		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	3	75.0	1	25.0	5	41.7	3	60.0	2	40.0	0.3839	2.06	0.39	10.82		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	6	75.0	2	25.0	12	100.0	9	75.0	3	25.0	0.9795	0.99	0.34	2.85		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	5	83.3	1	16.7	10	83.3	7	70.0	3	30.0	0.7034	1.28	0.36	4.48		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	3	60.0	2	40.0	2	16.7	2	100.0	0	-	0.4289	0.46	0.06	3.31		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	3	60.0	2	40.0	3	25.0	2	66.7	1	33.3	0.9656	0.96	0.16	5.90		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	5	83.3	1	16.7	9	75.0	7	77.8	2	22.2	0.9462	1.04	0.30	3.61		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGR3AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 19:51

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	6	4	4	3	2	2
BR (N=12)	12	7	4	2	2	1	NE
Patients censored							
Pola+BR (N=11)	0	0	0	0	0	1	1
BR (N=12)	0	0	1	2	2	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 18:05

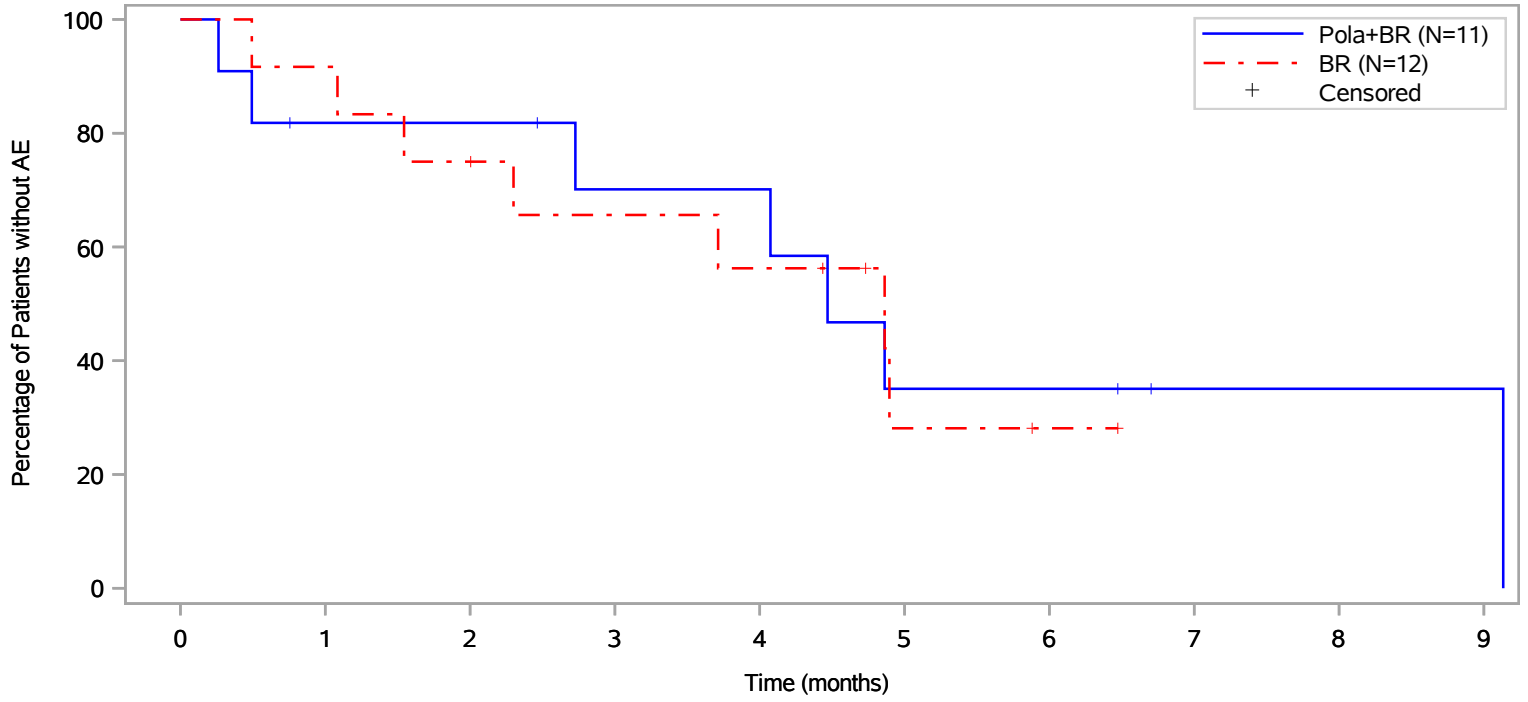
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	7	63.6	4	36.4	12	100.0	7	58.3	5	41.7	0.9037	0.93	0.31	2.83		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	4	57.1	3	42.9	7	58.3	5	71.4	2	28.6	0.6766	0.75	0.19	2.95		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	3	75.0	1	25.0	5	41.7	2	40.0	3	60.0	0.7127	1.46	0.19	11.18		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	5	62.5	3	37.5	12	100.0	7	58.3	5	41.7	0.8785	0.91	0.26	3.13		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	4	66.7	2	33.3	10	83.3	7	70.0	3	30.0	0.3443	1.89	0.50	7.19		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	3	60.0	2	40.0	2	16.7	0	-	2	100.0	0.4208	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	3	25.0	2	66.7	1	33.3	0.2220	0.25	0.02	2.79		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	5	83.3	1	16.7	9	75.0	5	55.6	4	44.4	0.2431	2.18	0.57	8.30		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGR4AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 20:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543



Patients at risk										
Pola+BR (N=11)	11	8	8	6	6	3	3	1	1	1
BR (N=12)	12	11	9	7	6	2	1	NE	NE	NE
Patients censored										
Pola+BR (N=11)	0	1	1	2	2	2	2	4	4	4
BR (N=12)	0	0	0	1	1	3	4	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTGR4AE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 6:46

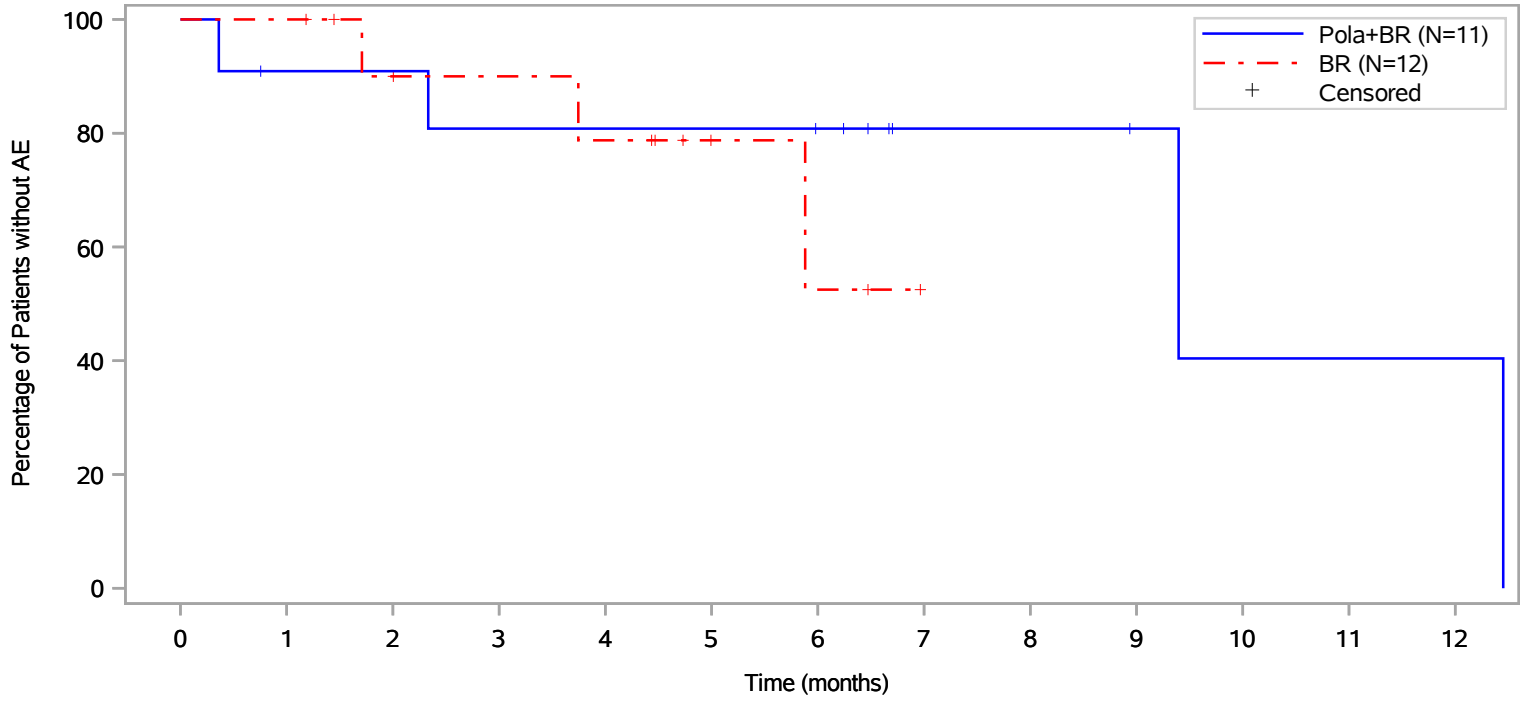
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	4	36.4	7	63.6	12	100.0	3	25.0	9	75.0	0.5171	0.55	0.09	3.42		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	3	42.9	4	57.1	7	58.3	1	14.3	6	85.7	0.5703	1.98	0.18	22.01		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	5	41.7	2	40.0	3	60.0	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	3	25.0	9	75.0	0.3199	0.33	0.03	3.28		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	3	50.0	3	50.0	10	83.3	2	20.0	8	80.0	0.5602	1.78	0.25	12.67		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.0253				*	WARNING: Iteration limit reached without convergence.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	2	22.2	7	77.8	0.9864	1.02	0.14	7.56		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGR5AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 21:15

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543



Patients at risk													
Pola+BR (N=11)	11	9	9	8	8	8	7	3	3	2	1	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	1	1	1	1	2	6	6	7	7	7	7
BR (N=12)	0	0	2	3	3	7	7	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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01DEC2022 7:21

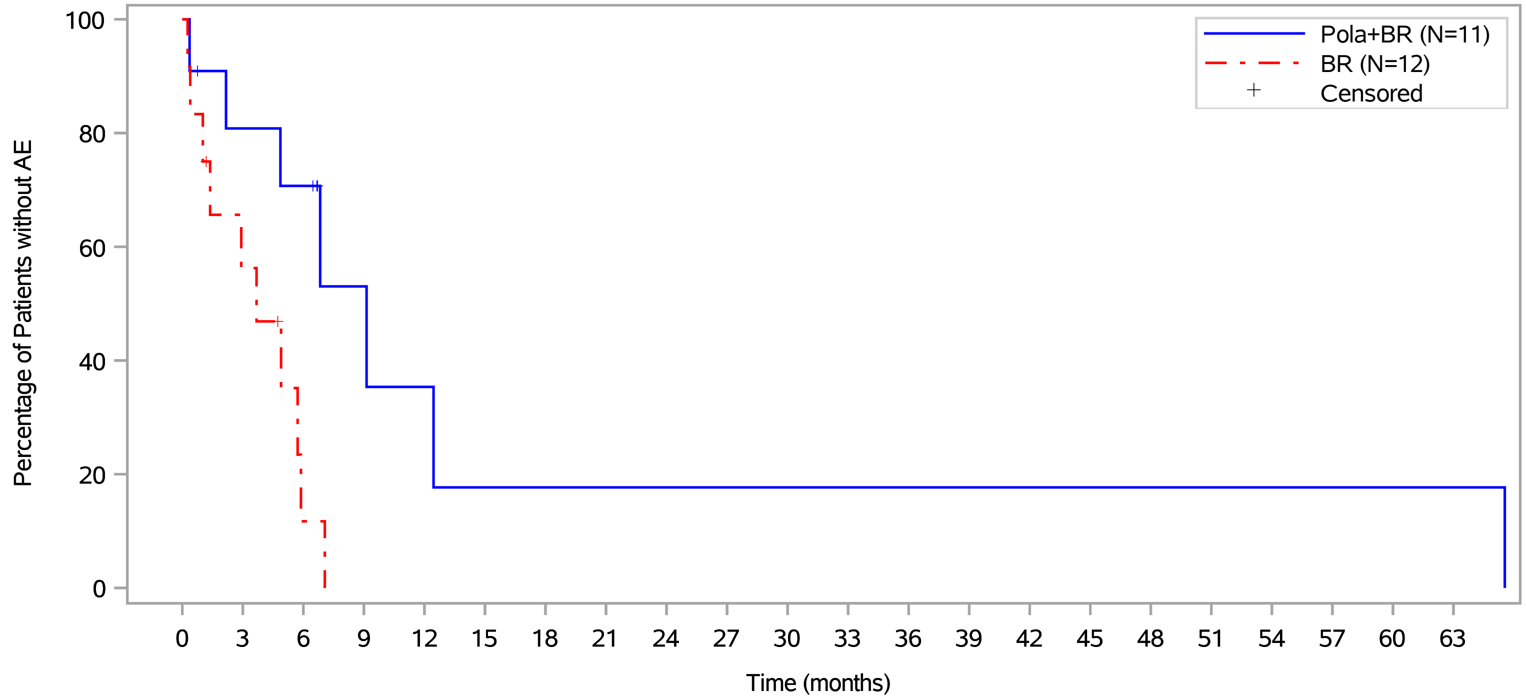
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	7	63.6	4	36.4	12	100.0	10	83.3	2	16.7	0.0123	0.24	0.07	0.80		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	5	71.4	2	28.6	7	58.3	6	85.7	1	14.3	0.2828	0.50	0.14	1.80		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	2	50.0	2	50.0	5	41.7	4	80.0	1	20.0	0.0101	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	5	62.5	3	37.5	12	100.0	10	83.3	2	16.7	0.0042	0.13	0.03	0.64		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	5	83.3	1	16.7	10	83.3	8	80.0	2	20.0	0.1678	0.39	0.10	1.55		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	2	40.0	3	60.0	2	16.7	2	100.0	0	-	0.0574	0.13	0.01	1.51		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	3	25.0	2	66.7	1	33.3	0.3834	0.36	0.03	4.01		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	5	83.3	1	16.7	9	75.0	8	88.9	1	11.1	0.1082	0.34	0.09	1.34		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTSAE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 22:05

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543



Patients at risk
Pola+BR (N=11) 11 9 9 8 8 7 7 3 3 3 2 2 2 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
BR (N=12) 12 10 7 6 5 3 1 1 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE
Patients censored
Pola+BR (N=11) 0 1 1 1 1 1 1 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4
BR (N=12) 0 0 1 1 1 2 2 2 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 7:33

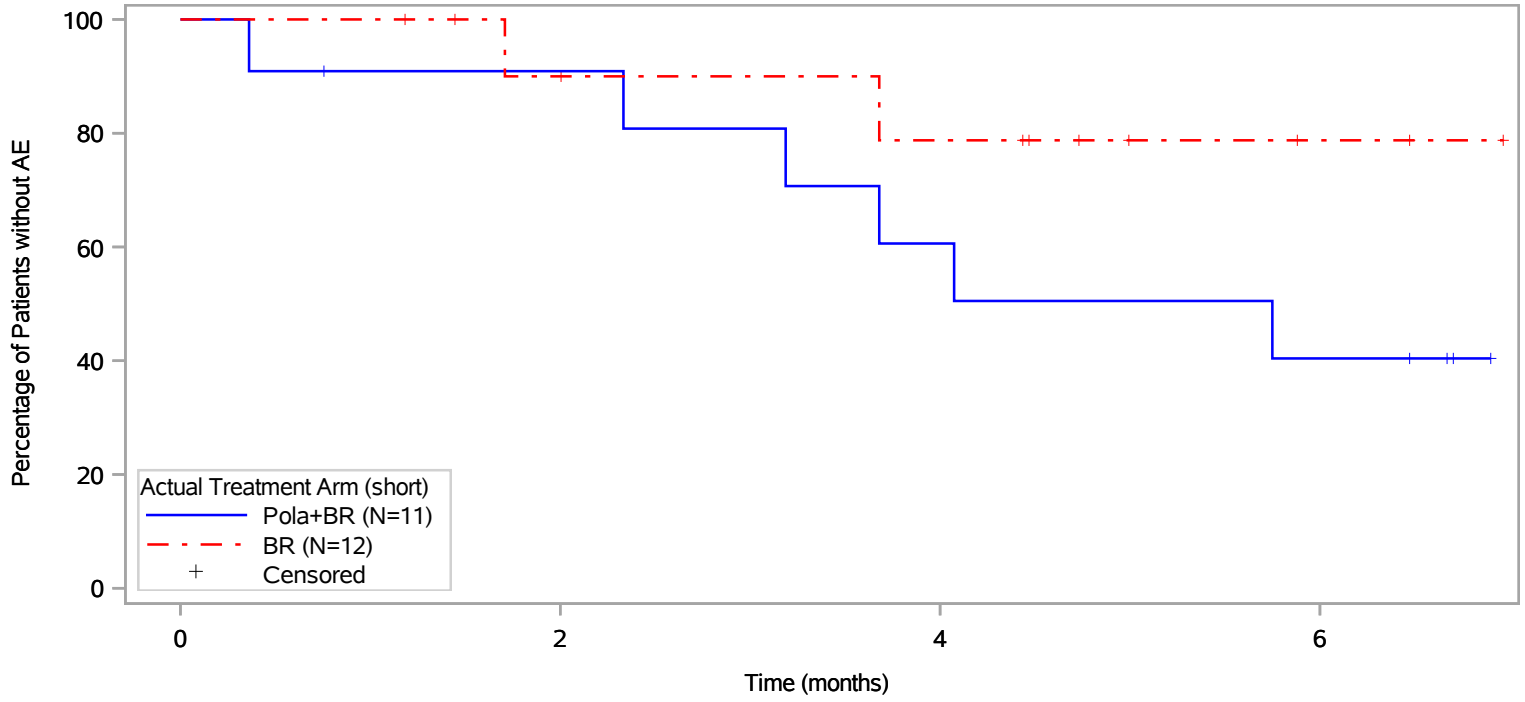
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	6	54.5	5	45.5	12	100.0	2	16.7	10	83.3	0.1516	3.09	0.61	15.61		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	5	71.4	2	28.6	7	58.3	1	14.3	6	85.7	0.0654	6.01	0.69	52.18		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	5	41.7	1	20.0	4	80.0	0.8084	0.71	0.04	11.79		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	2	16.7	10	83.3	0.2746	2.51	0.46	13.84		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	5	83.3	1	16.7	10	83.3	2	20.0	8	80.0	0.0298	5.16	0.99	26.84		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.7276	0.61	0.04	9.93		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	5	83.3	1	16.7	9	75.0	1	11.1	8	88.9	0.0508	6.47	0.75	55.71		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTWDAE_L2_ARMCDSE_365_29365_41543.xls
24JAN2023 17:02

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	9	9	8	6	5	4
BR (N=12)	12	12	9	8	7	3	2
Patients censored							
Pola+BR (N=11)	0	1	1	1	1	1	1
BR (N=12)	0	0	2	3	3	7	8

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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24JAN2023 18:49

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			11	100.0	10	90.9	1	9.1	12	100.0	9	75.0	3	25.0	0.5091	1.36	0.54	3.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		11	100.0	5	45.5	6	54.5	12	100.0	5	41.7	7	58.3	0.9639	1.03	0.29	3.61		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		11	100.0	1	9.1	10	90.9	12	100.0	2	16.7	10	83.3	0.6015	0.53	0.05	5.88		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		11	100.0	5	45.5	6	54.5	12	100.0	5	41.7	7	58.3	0.9802	1.02	0.29	3.53		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		11	100.0	5	45.5	6	54.5	12	100.0	3	25.0	9	75.0	0.4204	1.79	0.43	7.51		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.9437	0.90	0.06	14.64		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	EAR CONGESTION		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	EAR PAIN		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			11	100.0	8	72.7	3	27.3	12	100.0	8	66.7	4	33.3	0.5202	1.39	0.51	3.79		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.9486	1.10	0.07	17.52		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.9458	1.10	0.07	17.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1682	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ASCITES		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1869	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1777	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		11	100.0	5	45.5	6	54.5	12	100.0	2	16.7	10	83.3	0.1163	3.45	0.67	17.91		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DYSPEPSIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DYSPHAGIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	FAECES SOFT		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	NAUSEA		11	100.0	5	45.5	6	54.5	12	100.0	6	50.0	6	50.0	0.7786	0.84	0.26	2.77		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	STOMATITIS		11	100.0	2	18.2	9	81.8	12	100.0	1	8.3	11	91.7	0.5377	2.09	0.19	23.10		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		11	100.0	3	27.3	8	72.7	12	100.0	1	8.3	11	91.7	0.2298	3.66	0.38	35.21		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			11	100.0	7	63.6	4	36.4	12	100.0	10	83.3	2	16.7	0.3089	0.59	0.21	1.66		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA		11	100.0	2	18.2	9	81.8	12	100.0	3	25.0	9	75.0	0.5975	0.62	0.10	3.77		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.9126	1.17	0.07	18.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1663	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		11	100.0	3	27.3	8	72.7	12	100.0	5	41.7	7	58.3	0.4502	0.58	0.14	2.45		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA		11	100.0	2	18.2	9	81.8	12	100.0	1	8.3	11	91.7	0.5330	2.11	0.19	23.41		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1879	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.8860	1.22	0.08	19.67		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		11	100.0	5	45.5	6	54.5	12	100.0	3	25.0	9	75.0	0.4926	1.66	0.38	7.20		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			11	100.0	7	63.6	4	36.4	12	100.0	8	66.7	4	33.3	0.1260	0.41	0.13	1.32		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYSTITIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION		11	100.0	3	27.3	8	72.7	12	100.0	0	-	12	100.0	0.2278	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LARYNGITIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ORAL HERPES		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1663	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		11	100.0	4	36.4	7	63.6	12	100.0	1	8.3	11	91.7	0.5301	2.12	0.19	23.51		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INFECTIONS AND INFESTATIONS	RHINITIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SINUSITIS		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			11	100.0	2	18.2	9	81.8	12	100.0	2	16.7	10	83.3	0.9198	1.11	0.16	7.86		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2850	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			11	100.0	2	18.2	9	81.8	12	100.0	4	33.3	8	66.7	0.3110	0.43	0.08	2.33		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD CREATININE INCREASED		11	100.0	1	9.1	10	90.9	12	100.0	2	16.7	10	83.3	0.4542	0.41	0.04	4.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LIPASE INCREASED		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1321	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	OXYGEN SATURATION DECREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.9624	0.94	0.06	14.98		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.8194	0.72	0.04	12.57		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			11	100.0	4	36.4	7	63.6	12	100.0	5	41.7	7	58.3	0.9742	1.02	0.27	3.82		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		11	100.0	4	36.4	7	63.6	12	100.0	2	16.7	10	83.3	0.2857	2.45	0.45	13.45		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3657	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		11	100.0	2	18.2	9	81.8	12	100.0	1	8.3	11	91.7	0.6563	1.72	0.15	19.24			Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.8380	0.75	0.04	12.60			Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4497	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1780	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			11	100.0	3	27.3	8	72.7	12	100.0	6	50.0	6	50.0	0.3053	0.49	0.12	1.97			Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3657	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.9755	1.04	0.07	16.71			Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1663	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3657	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			11	100.0	1	9.1	10	90.9	12	100.0	2	16.7	10	83.3	0.0376	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173					*	WARNING: Iteration limit reached without convergence.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.4795	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			11	100.0	5	45.5	6	54.5	12	100.0	4	33.3	8	66.7	0.6377	1.37	0.37	5.14			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DIZZINESS		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.9241	1.14	0.07	18.31			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4292	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HYPOTONIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEURALGIA		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2888	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL		11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.1351	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	PARAESTHESIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY		11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.1490	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3657	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SYNCOPE		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2888	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS			11	100.0	3	27.3	8	72.7	12	100.0	3	25.0	9	75.0	0.8475	1.17	0.24	5.81			Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	ANXIETY		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.9486	1.10	0.07	17.57			Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	DEPRESSED MOOD		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	INSOMNIA		11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.1088	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	MOOD ALTERED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.3657	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ANURIA		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3657	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			11	100.0	6	54.5	5	45.5	12	100.0	8	66.7	4	33.3	0.3461	0.60	0.20	1.77			Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH		11	100.0	2	18.2	9	81.8	12	100.0	4	33.3	8	66.7	0.1379	0.29	0.05	1.64			Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2918	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.5127	>999.99	0.00	NE			Convergence criterion (GCONV=1E-8) satisfied.	NE

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS		11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.1435	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH		11	100.0	2	18.2	9	81.8	12	100.0	2	16.7	10	83.3	0.9664	1.04	0.15	7.45		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1537	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			11	100.0	3	27.3	8	72.7	12	100.0	5	41.7	7	58.3	0.4453	0.57	0.14	2.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		11	100.0	1	9.1	10	90.9	12	100.0	2	16.7	10	83.3	0.5154	0.46	0.04	5.11		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		11	100.0	1	9.1	10	90.9	12	100.0	2	16.7	10	83.3	0.6417	0.57	0.05	6.29		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			11	100.0	3	27.3	8	72.7	12	100.0	6	50.0	6	50.0	0.2950	0.48	0.12	1.96		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		11	100.0	2	18.2	9	81.8	12	100.0	1	8.3	11	91.7	0.4586	2.41	0.22	26.63		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		11	100.0	0	-	11	100.0	12	100.0	3	25.0	9	75.0	0.0860	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTAE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 22:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	8	72.7	8	100.0	0	-	12	100.0	9	75.0	3	25.0	0.2217	1.83	0.69	4.86		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	5	41.7	7	58.3	0.9923	0.99	0.24	4.18		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2286	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	8	72.7	5	62.5	3	37.5	12	100.0	5	41.7	7	58.3	0.5542	1.45	0.42	5.06		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	3	25.0	9	75.0	0.4100	1.86	0.42	8.33		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
CARDIAC DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
EAR AND LABYRINTH DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR PAIN	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
EAR AND LABYRINTH DISORDERS	EAR PAIN	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS		>= 65	8	72.7	7	87.5	1	12.5	12	100.0	8	66.7	4	33.3	0.1772	2.06	0.71	5.99		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.7600	1.54	0.10	24.55		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.7863	1.46	0.09	23.41		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2286	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	ASCITES	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2441	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2424	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	2	16.7	10	83.3	0.0882	3.96	0.72	21.78		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FAECES SOFT	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	FAECES SOFT	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.3613	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	NAUSEA	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	6	50.0	6	50.0	0.8925	0.92	0.26	3.26		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	STOMATITIS	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	1	8.3	11	91.7	0.3797	2.80	0.25	31.00		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	1	8.3	11	91.7	0.3399	3.04	0.28	33.56		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	8	72.7	6	75.0	2	25.0	12	100.0	10	83.3	2	16.7	0.5221	0.70	0.23	2.10		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	3	25.0	9	75.0	0.8525	0.84	0.14	5.16		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2297	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	5	41.7	7	58.3	0.3605	0.47	0.09	2.46		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4250	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	1	8.3	11	91.7	0.3791	2.81	0.25	31.13		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2537	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4250	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	3	25.0	9	75.0	0.3850	1.97	0.42	9.30		Convergence criterion (GCONV=1E-8) satisfied.	

INFECTIONS AND INFESTATIONS		< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS		>= 65	8	72.7	5	62.5	3	37.5	12	100.0	8	66.7	4	33.3	0.0811	0.30	0.08	1.23		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYSTITIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	CYSTITIS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	0	-	12	100.0	0.1763	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LARYNGITIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	LARYNGITIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL HERPES	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	ORAL HERPES	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2297	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	1	8.3	11	91.7	0.8359	1.34	0.08	21.61		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	RHINITIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	RHINITIS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	SINUSITIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3496	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	8	72.7	2	25.0	6	75.0	12	100.0	2	16.7	10	83.3	0.6464	1.58	0.22	11.20		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2100	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3545	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3496	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	4	33.3	8	66.7	0.2485	0.30	0.03	2.66		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2100	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	LIPASE INCREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.1881	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OXYGEN SATURATION DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	OXYGEN SATURATION DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.8757	1.25	0.08	19.97		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4450	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS		>= 65	8	72.7	3	37.5	5	62.5	12	100.0	5	41.7	7	58.3	0.9789	1.02	0.24	4.28		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	2	16.7	10	83.3	0.3168	2.43	0.40	14.57		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4250	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.8623	1.28	0.08	20.52		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2393	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	8	72.7	2	25.0	6	75.0	12	100.0	6	50.0	6	50.0	0.3255	0.45	0.09	2.28		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4250	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.8055	1.41	0.09	22.64		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2341	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4250	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	2	16.7	10	83.3	0.0559	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS		>= 65	8	72.7	4	50.0	4	50.0	12	100.0	4	33.3	8	66.7	0.4732	1.65	0.41	6.65		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.7362	1.60	0.10	25.68		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOTONIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	HYPOTONIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NERVOUS SYSTEM DISORDERS	NEURALGIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	NEURALGIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3496	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	0	-	12	100.0	0.0783	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2100	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4250	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3496	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
PSYCHIATRIC DISORDERS		>= 65	8	72.7	2	25.0	6	75.0	12	100.0	3	25.0	9	75.0	0.9905	0.99	0.16	5.94		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
PSYCHIATRIC DISORDERS	ANXIETY	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.7689	1.51	0.09	24.30		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
PSYCHIATRIC DISORDERS	INSOMNIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.1904	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	MOOD ALTERED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
PSYCHIATRIC DISORDERS	MOOD ALTERED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RENAL AND URINARY DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.4250	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ANURIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RENAL AND URINARY DISORDERS	ANURIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4250	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	8	72.7	4	50.0	4	50.0	12	100.0	8	66.7	4	33.3	0.2069	0.46	0.13	1.58		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	4	33.3	8	66.7	0.2669	0.39	0.07	2.18		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	2	16.7	10	83.3	0.7210	0.65	0.06	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2125	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	8	72.7	3	37.5	5	62.5	12	100.0	5	41.7	7	58.3	0.7644	0.80	0.19	3.39		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	2	16.7	10	83.3	0.6888	0.61	0.06	6.83		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	2	16.7	10	83.3	0.8130	0.75	0.07	8.27		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.1904	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
VASCULAR DISORDERS		>= 65	8	72.7	2	25.0	6	75.0	12	100.0	6	50.0	6	50.0	0.3904	0.50	0.10	2.53		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3496	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	1	8.3	11	91.7	0.2812	3.46	0.31	38.30		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	8	72.7	0	-	8	100.0	12	100.0	3	25.0	9	75.0	0.1323	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTAE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 22:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	6	54.5	6	100.0	0	-	10	83.3	7	70.0	3	30.0	0.2063	2.04	0.66	6.29		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	45.5	4	80.0	1	20.0	2	16.7	2	100.0	0	-	0.7649	1.30	0.23	7.26		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	6	54.5	3	50.0	3	50.0	10	83.3	4	40.0	6	60.0	0.4980	1.69	0.37	7.79		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.5596	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	2	20.0	8	80.0	0.9597	0.94	0.09	10.39		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	6	54.5	3	50.0	3	50.0	10	83.3	5	50.0	5	50.0	0.7840	1.23	0.28	5.30		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	6	54.5	3	50.0	3	50.0	10	83.3	3	30.0	7	70.0	0.4047	1.95	0.39	9.71		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR PAIN	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR PAIN	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	6	54.5	4	66.7	2	33.3	10	83.3	6	60.0	4	40.0	0.4796	1.62	0.42	6.28		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	5	45.5	4	80.0	1	20.0	2	16.7	2	100.0	0	-	0.8491	0.83	0.13	5.47		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.6660	1.83	0.11	29.27		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.3251	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.5050	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	6	54.5	2	33.3	4	66.7	10	83.3	0	-	10	100.0	0.0559	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	5	45.5	3	60.0	2	40.0	2	16.7	2	100.0	0	-	0.5493	0.58	0.10	3.52		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FAECES SOFT	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FAECES SOFT	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	4	40.0	6	60.0	0.3576	0.37	0.04	3.33		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	<3	5	45.5	4	80.0	1	20.0	2	16.7	2	100.0	0	-	0.7015	0.70	0.12	4.26		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	>=3	6	54.5	2	33.3	4	66.7	10	83.3	0	-	10	100.0	0.0530	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	5	45.5	3	60.0	2	40.0	2	16.7	0	-	2	100.0	0.2119	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	6	54.5	4	66.7	2	33.3	10	83.3	8	80.0	2	20.0	0.5125	0.64	0.17	2.47		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	5	45.5	3	60.0	2	40.0	2	16.7	2	100.0	0	-	0.3830	0.43	0.06	3.06		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>=3	6	54.5	2	33.3	4	66.7	10	83.3	3	30.0	7	70.0	0.9841	1.02	0.17	6.27		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.0253				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2791	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	6	54.5	1	16.7	5	83.3	10	83.3	4	40.0	6	60.0	0.4556	0.44	0.05	4.00		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.8132	0.75	0.07	8.42		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.6240	0.55	0.05	6.21		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.3074	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.5050	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	6	54.5	2	33.3	4	66.7	10	83.3	2	20.0	8	80.0	0.6873	1.50	0.21	10.79		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	5	45.5	3	60.0	2	40.0	2	16.7	1	50.0	1	50.0	0.9814	1.03	0.09	11.48		Convergence criterion (GCONV=1E-8) satisfied.	

INFECTIONS AND INFESTATIONS		>=3	6	54.5	4	66.7	2	33.3	10	83.3	6	60.0	4	40.0	0.7092	0.76	0.18	3.16		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	45.5	3	60.0	2	40.0	2	16.7	2	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYSTITIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYSTITIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LARYNGITIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LARYNGITIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL HERPES	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2791	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL HERPES	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	6	54.5	3	50.0	3	50.0	10	83.3	1	10.0	9	90.0	0.2686	3.57	0.32	39.73		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINITIS	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINITIS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.6660	1.83	0.11	29.27		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.5596	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	3	30.0	7	70.0	0.6484	0.59	0.06	5.74		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.3497	0.28	0.02	4.71		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OXYGEN SATURATION DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OXYGEN SATURATION DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	6	54.5	3	50.0	3	50.0	10	83.3	3	30.0	7	70.0	0.2545	2.49	0.49	12.66		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	2	100.0	0	-	0.1230	0.18	0.02	2.05		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	6	54.5	3	50.0	3	50.0	10	83.3	1	10.0	9	90.0	0.0665	6.48	0.66	63.50		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.5596	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.5050	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.6949	1.73	0.11	27.89		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.5050	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	5	50.0	5	50.0	0.2749	0.32	0.04	2.77		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.8132	0.75	0.07	8.42		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2945	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.5050	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.6660	1.83	0.11	29.27		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2945	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	6	54.5	1	16.7	5	83.3	10	83.3	2	20.0	8	80.0	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	6	54.5	2	33.3	4	66.7	10	83.3	2	20.0	8	80.0	0.5525	1.80	0.25	12.86		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	5	45.5	3	60.0	2	40.0	2	16.7	2	100.0	0	-	0.1230	0.18	0.02	2.05		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOTONIA	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOTONIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NERVOUS SYSTEM DISORDERS	NEURALGIA	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEURALGIA	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1336	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		>=3	6	54.5	2	33.3	4	66.7	10	83.3	2	20.0	8	80.0	0.3500	2.47	0.35	17.66		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.5596	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.6171	2.00	0.13	31.97		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	MOOD ALTERED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	MOOD ALTERED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.5050	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ANURIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.5050	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ANURIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	6	54.5	4	66.7	2	33.3	10	83.3	6	60.0	4	40.0	0.9087	0.93	0.26	3.37		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	45.5	2	40.0	3	60.0	2	16.7	2	100.0	0	-	0.4289	0.46	0.06	3.31		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>=3	6	54.5	1	16.7	5	83.3	10	83.3	3	30.0	7	70.0	0.4719	0.44	0.05	4.32		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.9814	1.03	0.09	11.48		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2945	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	6	54.5	2	33.3	4	66.7	10	83.3	5	50.0	5	50.0	0.7512	0.77	0.15	4.02		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.3074	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	6	54.5	1	16.7	5	83.3	10	83.3	2	20.0	8	80.0	0.9844	0.98	0.09	10.81		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	5	50.0	5	50.0	0.0539	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	5	45.5	3	60.0	2	40.0	2	16.7	1	50.0	1	50.0	0.7709	1.40	0.14	13.66		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.3139	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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30NOV2022 22:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	45.5	4	80.0	1	20.0	3	25.0	2	66.7	1	33.3	0.8070	1.24	0.22	6.90		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	6	54.5	6	100.0	0	-	9	75.0	7	77.8	2	22.2	0.6463	1.30	0.43	3.93		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	1	33.3	2	66.7	0.5768	1.98	0.17	22.61		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	4	44.4	5	55.6	0.7331	0.77	0.16	3.57		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	2	22.2	7	77.8	0.7599	0.69	0.06	7.61		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	3	33.3	6	66.7	0.6269	1.49	0.29	7.57		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	1	33.3	2	66.7	0.7222	1.54	0.14	17.22		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	2	22.2	7	77.8	0.4641	1.93	0.32	11.60		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR PAIN	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR PAIN	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	5	45.5	3	60.0	2	40.0	3	25.0	2	66.7	1	33.3	0.8321	1.22	0.19	7.80		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	6	54.5	5	83.3	1	16.7	9	75.0	6	66.7	3	33.3	0.1200	2.86	0.72	11.26		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.8055	1.41	0.09	22.64		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.7919	1.45	0.09	23.18		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.2402	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.2400	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	2	22.2	7	77.8	0.0466	4.92	0.88	27.65		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FAECES SOFT	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FAECES SOFT	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	1	33.3	2	66.7	0.9412	1.09	0.10	12.22		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	5	55.6	4	44.4	0.7728	0.81	0.19	3.40		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	1	11.1	8	88.9	0.3952	2.72	0.25	30.22		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.7276	0.61	0.04	9.93		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	0	-	9	100.0	0.0697	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	45.5	2	40.0	3	60.0	3	25.0	2	66.7	1	33.3	0.1645	0.18	0.01	2.46		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	6	54.5	5	83.3	1	16.7	9	75.0	8	88.9	1	11.1	0.5720	1.41	0.42	4.73		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	2	66.7	1	33.3	0.0559	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	1	11.1	8	88.9	0.3640	2.98	0.25	35.01		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	Europe	5	45.5	0	-	5	100.0	3	25.0	2	66.7	1	33.3	0.0559	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	5	55.6	4	44.4	0.4050	0.50	0.10	2.62		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.7551	1.55	0.10	24.78		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.2558	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.6949	1.73	0.11	27.89		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	1	33.3	2	66.7	0.9160	1.15	0.09	14.29		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	2	22.2	7	77.8	0.3012	2.51	0.41	15.30		Convergence criterion (GCONV=1E-8) satisfied.	

INFECTIONS AND INFESTATIONS		Europe	5	45.5	3	60.0	2	40.0	3	25.0	2	66.7	1	33.3	0.4335	0.39	0.04	4.39		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	6	66.7	3	33.3	0.2381	0.44	0.11	1.79		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYSTITIS	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYSTITIS	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Europe	5	45.5	3	60.0	2	40.0	3	25.0	0	-	3	100.0	0.3021	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LARYNGITIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LARYNGITIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL HERPES	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL HERPES	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	1	11.1	8	88.9	0.4014	2.70	0.24	30.08		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	RHINITIS	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINITIS	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	1	11.1	8	88.9	0.2436	3.81	0.34	42.50		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	4	44.4	5	55.6	0.3777	0.47	0.09	2.60		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	2	22.2	7	77.8	0.6288	0.56	0.05	6.18		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OXYGEN SATURATION DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OXYGEN SATURATION DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.9372	1.12	0.07	17.96		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	1.0000	1.00	0.06	16.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.1803	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	5	55.6	4	44.4	0.4036	1.76	0.46	6.73		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	2	22.2	7	77.8	0.0816	4.20	0.74	23.89		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	1	11.1	8	88.9	0.5512	2.05	0.18	23.05		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.9864	1.02	0.06	16.95		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	2	66.7	1	33.3	0.3943	0.37	0.03	4.08		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	4	44.4	5	55.6	0.6212	0.65	0.12	3.62		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.6660	0.55	0.03	8.78		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	3	33.3	6	66.7	0.1742	2.74	0.60	12.40		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOTONIA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOTONIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NERVOUS SYSTEM DISORDERS	NEURALGIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEURALGIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	0	-	9	100.0	0.0922	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.9191	0.87	0.05	13.95		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	2	22.2	7	77.8	0.6595	1.55	0.22	11.03		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.8236	1.37	0.09	21.95		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2059	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	MOOD ALTERED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	MOOD ALTERED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ANURIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ANURIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4292	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	3	100.0	0	-	0.0101	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	6	54.5	5	83.3	1	16.7	9	75.0	5	55.6	4	44.4	0.3709	1.76	0.50	6.14		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Europe	5	45.5	1	20.0	4	80.0	3	25.0	2	66.7	1	33.3	0.0701	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	2	22.2	7	77.8	0.3944	0.36	0.03	4.10		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	0	-	9	100.0	0.0919	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	2	22.2	7	77.8	0.6496	1.58	0.22	11.59		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Europe	5	45.5	0	-	5	100.0	3	25.0	2	66.7	1	33.3	0.0701	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	5	55.6	4	44.4	0.2980	0.42	0.08	2.26		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	2	22.2	7	77.8	0.7142	0.64	0.06	7.13		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	2	22.2	7	77.8	0.8125	0.75	0.07	8.26		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	5	45.5	2	40.0	3	60.0	3	25.0	2	66.7	1	33.3	0.6189	0.61	0.08	4.46		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	4	44.4	5	55.6	0.3374	0.35	0.04	3.29		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.7230	1.64	0.10	26.35		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.2186	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTAE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 22:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	63.6	6	85.7	1	14.3	7	58.3	6	85.7	1	14.3	0.4109	0.58	0.16	2.16		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	4	36.4	4	100.0	0	-	5	41.7	3	60.0	2	40.0	0.1252	3.83	0.63	23.40		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	7	63.6	3	42.9	4	57.1	7	58.3	3	42.9	4	57.1	0.7463	0.76	0.15	3.92		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	4	36.4	2	50.0	2	50.0	5	41.7	2	40.0	3	60.0	0.6869	1.49	0.21	10.70		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	2	28.6	5	71.4	0.5992	0.53	0.05	5.86		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	3	42.9	4	57.1	0.6652	0.67	0.11	4.05		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	4	36.4	3	75.0	1	25.0	5	41.7	2	40.0	3	60.0	0.4688	1.95	0.31	12.28		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	7	63.6	3	42.9	4	57.1	7	58.3	2	28.6	5	71.4	0.7362	1.36	0.23	8.22		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	4	36.4	2	50.0	2	50.0	5	41.7	1	20.0	4	80.0	0.3834	2.81	0.25	31.68		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.9191	0.87	0.05	13.95		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR CONGESTION	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	EAR PAIN	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	EAR PAIN	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	7	63.6	4	57.1	3	42.9	7	58.3	4	57.1	3	42.9	0.8399	1.16	0.28	4.84		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	4	36.4	4	100.0	0	-	5	41.7	4	80.0	1	20.0	0.4859	1.67	0.39	7.17		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL RIGIDITY	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	Male	7	63.6	0	-	7	100.0	7	58.3	2	28.6	5	71.4	0.1761	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	APHTHOUS ULCER	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	Male	7	63.6	0	-	7	100.0	7	58.3	2	28.6	5	71.4	0.1917	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	7	63.6	3	42.9	4	57.1	7	58.3	1	14.3	6	85.7	0.1939	4.05	0.41	39.52		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	4	36.4	2	50.0	2	50.0	5	41.7	1	20.0	4	80.0	0.4261	2.57	0.23	28.71		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FAECES SOFT	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FAECES SOFT	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GINGIVAL PAIN	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	Male	7	63.6	2	28.6	5	71.4	7	58.3	3	42.9	4	57.1	0.5000	0.54	0.09	3.28		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Female	4	36.4	3	75.0	1	25.0	5	41.7	3	60.0	2	40.0	0.7441	1.31	0.26	6.55		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	1.0000	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	4	36.4	2	50.0	2	50.0	5	41.7	1	20.0	4	80.0	0.4666	2.38	0.21	26.32		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	7	63.6	4	57.1	3	42.9	7	58.3	6	85.7	1	14.3	0.1243	0.34	0.08	1.42		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	4	36.4	3	75.0	1	25.0	5	41.7	4	80.0	1	20.0	0.6810	1.39	0.29	6.60		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	2	28.6	5	71.4	0.8791	0.86	0.12	6.36		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DISCOMFORT	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	7	63.6	1	14.3	6	85.7	7	58.3	3	42.9	4	57.1	0.3198	0.33	0.03	3.23		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	4	36.4	2	50.0	2	50.0	5	41.7	2	40.0	3	60.0	0.8087	0.78	0.11	5.67		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INFLUENZA LIKE ILLNESS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MUCOSAL INFLAMMATION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Female	4	36.4	2	50.0	2	50.0	5	41.7	1	20.0	4	80.0	0.5203	2.16	0.20	23.87		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PERIPHERAL SWELLING	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	0	-	7	100.0	0.2253	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	4	36.4	3	75.0	1	25.0	5	41.7	3	60.0	2	40.0	0.4439	1.92	0.35	10.53		Convergence criterion (GCONV=1E-8) satisfied.	

INFECTIONS AND INFESTATIONS		Male	7	63.6	5	71.4	2	28.6	7	58.3	4	57.1	3	42.9	0.7703	0.81	0.20	3.32		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	4	36.4	2	50.0	2	50.0	5	41.7	4	80.0	1	20.0	0.0615	0.15	0.02	1.41		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYSTITIS	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYSTITIS	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Female	4	36.4	2	50.0	2	50.0	5	41.7	0	-	5	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LARYNGITIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LARYNGITIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL HERPES	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL HERPES	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	OROPHARYNGEAL CANDIDIASIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	63.6	3	42.9	4	57.1	7	58.3	0	-	7	100.0	0.1803	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	4	36.4	1	25.0	3	75.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	RHINITIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINITIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	STAPHYLOCOCCAL INFECTION	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173				*	WARNING: Iteration limit reached without convergence.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.9191	1.15	0.07	18.59		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	4	36.4	1	25.0	3	75.0	5	41.7	1	20.0	4	80.0	0.8563	1.29	0.08	20.65		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	CONTUSION	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	EYE CONTUSION	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SPINAL COMPRESSION FRACTURE	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	7	63.6	2	28.6	5	71.4	7	58.3	3	42.9	4	57.1	0.5125	0.55	0.09	3.33		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	2	28.6	5	71.4	0.4766	0.43	0.04	4.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OXYGEN SATURATION DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OXYGEN SATURATION DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.7487	0.62	0.03	11.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	7	63.6	3	42.9	4	57.1	7	58.3	3	42.9	4	57.1	0.6964	1.38	0.27	6.97		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	4	36.4	1	25.0	3	75.0	5	41.7	2	40.0	3	60.0	0.6649	0.59	0.05	6.55		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	7	63.6	3	42.9	4	57.1	7	58.3	1	14.3	6	85.7	0.2533	3.48	0.36	33.76		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	4	36.4	1	25.0	3	75.0	5	41.7	1	20.0	4	80.0	0.9191	1.15	0.07	18.59		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FLUID IMBALANCE	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	1	14.3	6	85.7	0.7027	1.60	0.14	18.24		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.8597	0.77	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	7	63.6	2	28.6	5	71.4	7	58.3	4	57.1	3	42.9	0.3020	0.42	0.07	2.32		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	4	36.4	1	25.0	3	75.0	5	41.7	2	40.0	3	60.0	0.7087	0.63	0.06	7.07		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL DISCOMFORT	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	1.0000	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYOPATHY	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN JAW	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	7	63.6	3	42.9	4	57.1	7	58.3	3	42.9	4	57.1	0.9561	0.96	0.19	4.78		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	4	36.4	2	50.0	2	50.0	5	41.7	1	20.0	4	80.0	0.4666	2.38	0.21	26.32		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DECREASED VIBRATORY SENSE	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	FACIAL PARALYSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOTONIA	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOTONIA	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NERVOUS SYSTEM DISORDERS	NEURALGIA	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEURALGIA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Male	7	63.6	2	28.6	5	71.4	7	58.3	0	-	7	100.0	0.1385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	RESTLESS LEGS SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Male	7	63.6	3	42.9	4	57.1	7	58.3	2	28.6	5	71.4	0.4790	1.89	0.31	11.38		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.9566	1.08	0.07	17.31		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSED MOOD	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	0	-	7	100.0	0.1033	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	MOOD ALTERED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	MOOD ALTERED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	POOR QUALITY SLEEP	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ANURIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ANURIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	7	63.6	5	71.4	2	28.6	7	58.3	5	71.4	2	28.6	0.6011	0.70	0.19	2.65		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	4	36.4	1	25.0	3	75.0	5	41.7	3	60.0	2	40.0	0.3000	0.32	0.03	3.11		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Male	7	63.6	1	14.3	6	85.7	7	58.3	2	28.6	5	71.4	0.3108	0.30	0.03	3.51		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Female	4	36.4	1	25.0	3	75.0	5	41.7	2	40.0	3	60.0	0.3834	0.36	0.03	4.01		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HICCUPS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	LUNG INFILTRATION	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Male	7	63.6	2	28.6	5	71.4	7	58.3	0	-	7	100.0	0.1278	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Male	7	63.6	1	14.3	6	85.7	7	58.3	2	28.6	5	71.4	0.5740	0.51	0.05	5.66		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	TACHYPNOEA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER RESPIRATORY TRACT INFLAMMATION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	3	42.9	4	57.1	0.3022	0.32	0.03	3.11		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	4	36.4	2	50.0	2	50.0	5	41.7	2	40.0	3	60.0	0.9783	1.03	0.14	7.43		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	4	36.4	1	25.0	3	75.0	5	41.7	1	20.0	4	80.0	0.9819	0.97	0.06	15.83		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	7	63.6	0	-	7	100.0	7	58.3	2	28.6	5	71.4	0.1761	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.2801	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	SOLAR LENTIGO	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	2	28.6	5	71.4	0.5079	0.45	0.04	5.02		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	4	36.4	2	50.0	2	50.0	5	41.7	4	80.0	1	20.0	0.6525	0.66	0.10	4.12		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	AXILLARY VEIN THROMBOSIS	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	4	36.4	2	50.0	2	50.0	5	41.7	0	-	5	100.0	0.0888	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	4	36.4	0	-	4	100.0	5	41.7	2	40.0	3	60.0	0.1475	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PERIPHERAL VENOUS DISEASE	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	PHLEBITIS SUPERFICIAL	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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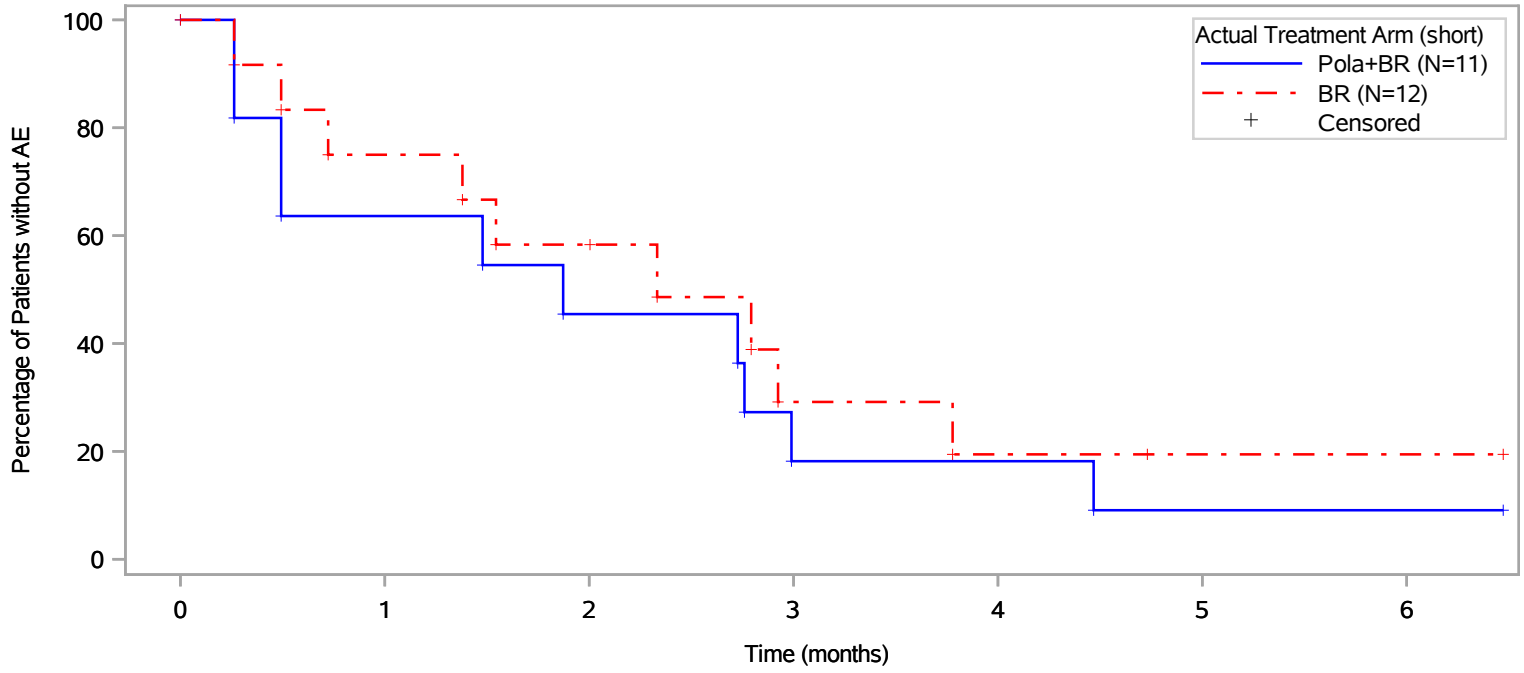
30NOV2022 22:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=11)	11	7	5	2	2	1	1
BR (N=12)	12	9	7	3	2	1	1
Patients censored							
Pola+BR (N=11)	0	0	0	0	0	0	0
BR (N=12)	0	0	0	1	1	2	2

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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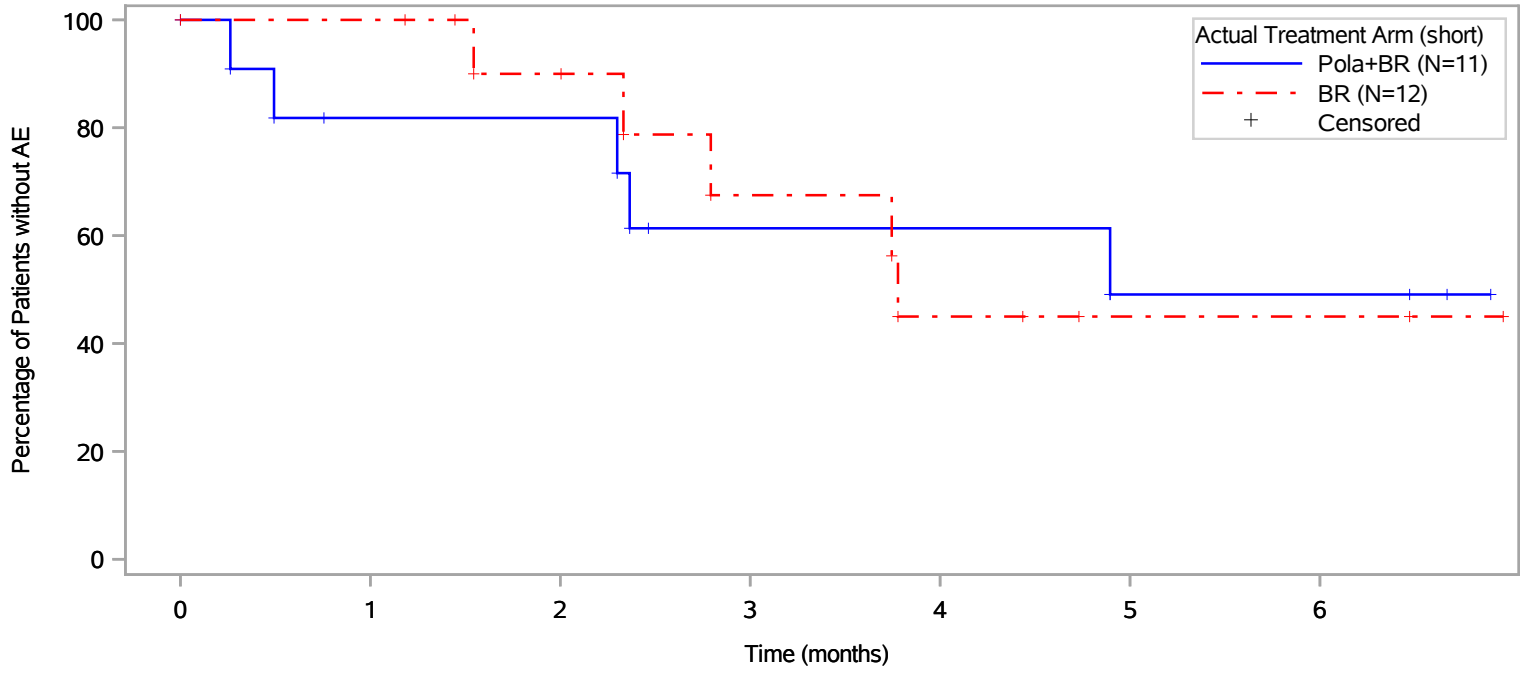
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk							
Pola+BR (N=11)	11	8	8	5	5	3	3
BR (N=12)	12	12	9	6	4	2	2
Patients censored							
Pola+BR (N=11)	0	1	1	2	2	3	3
BR (N=12)	0	0	2	3	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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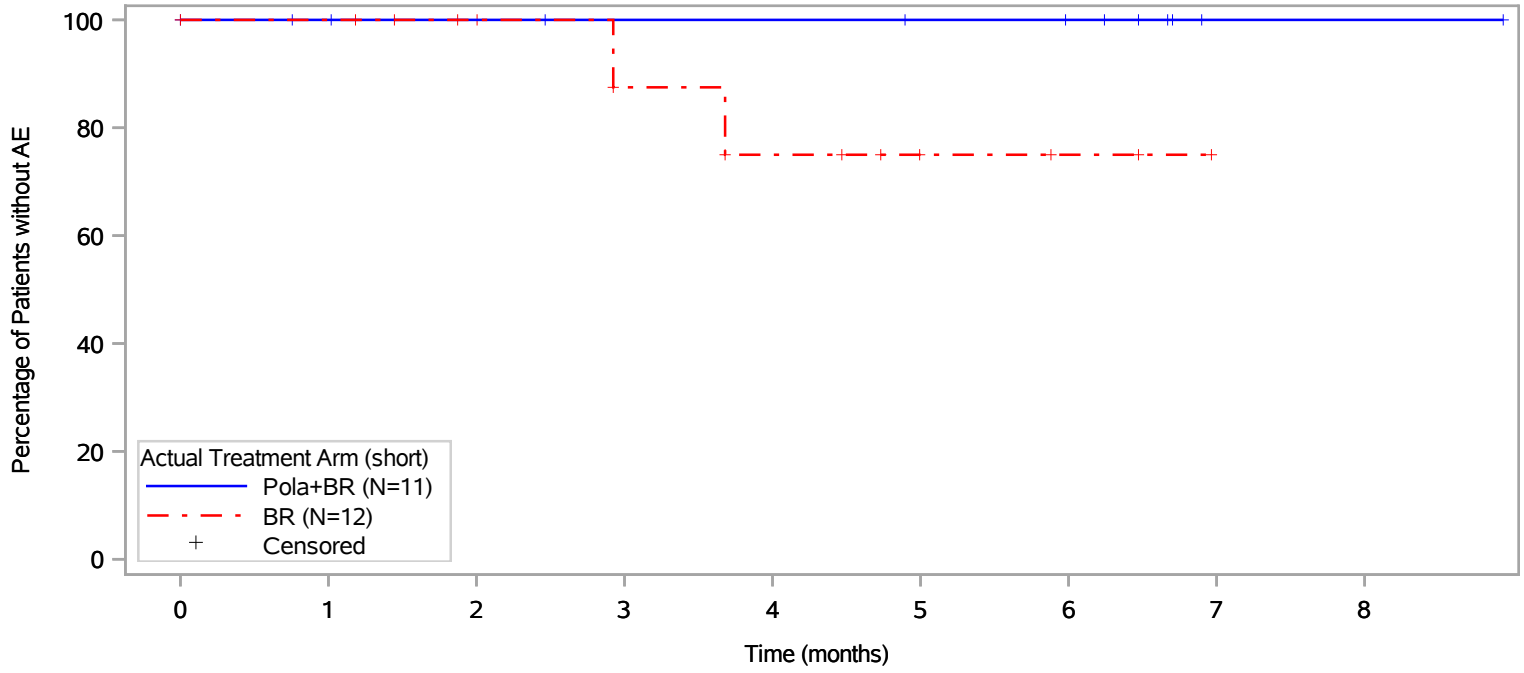
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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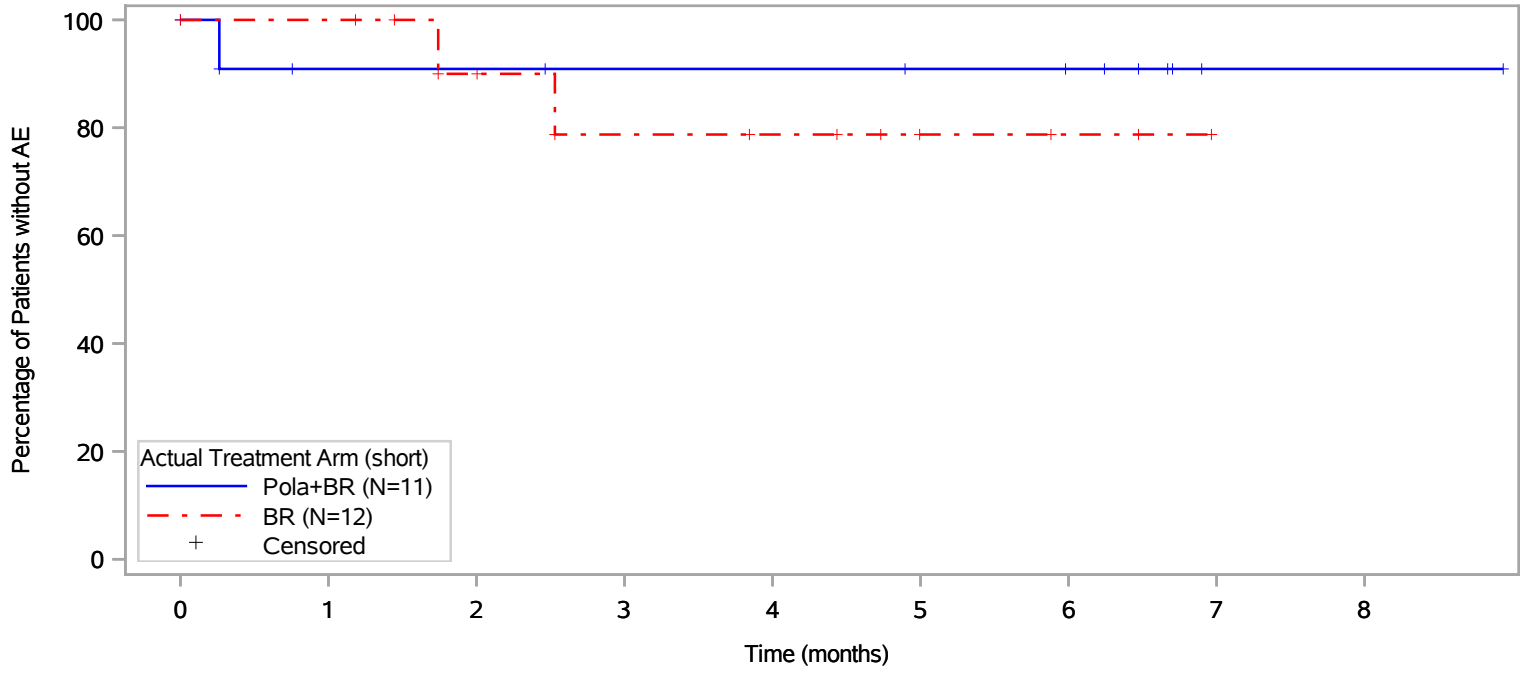
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk								
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	2	3	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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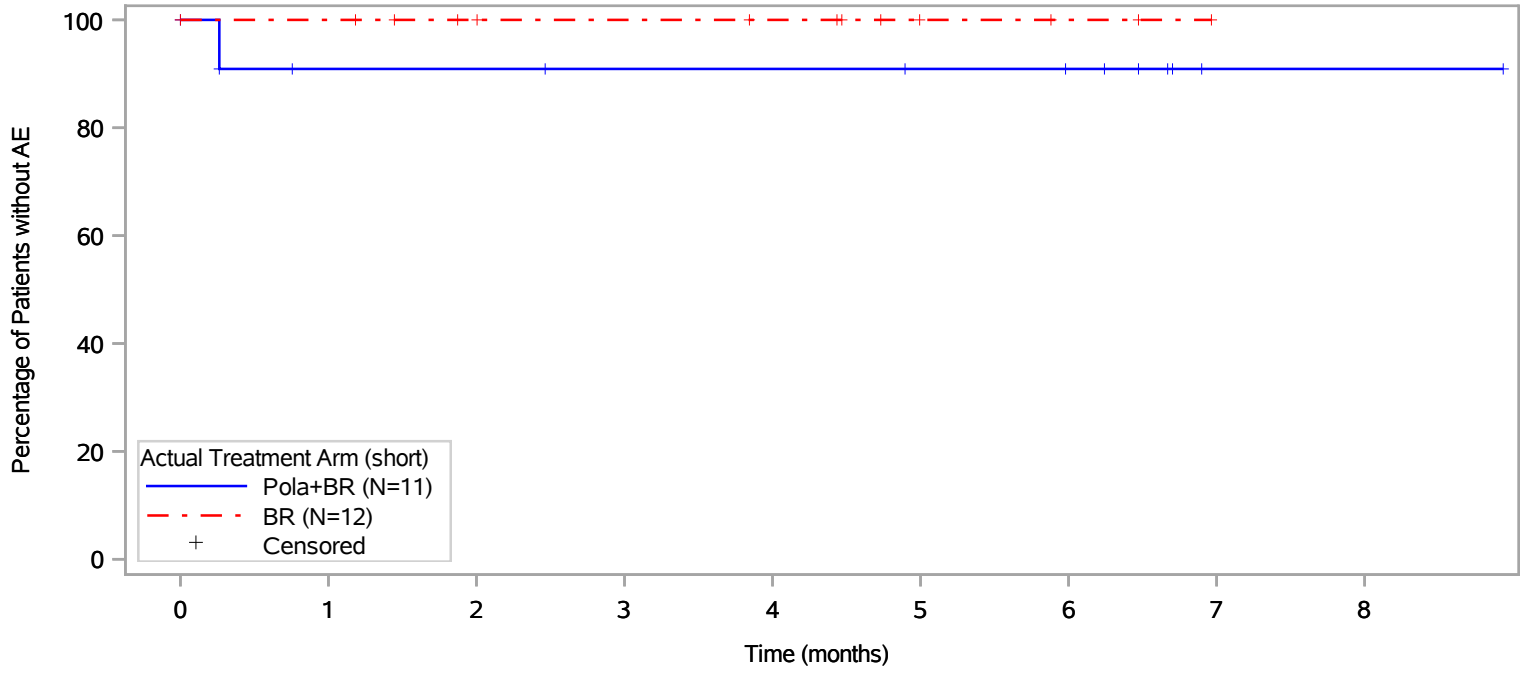
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA



Patients at risk								
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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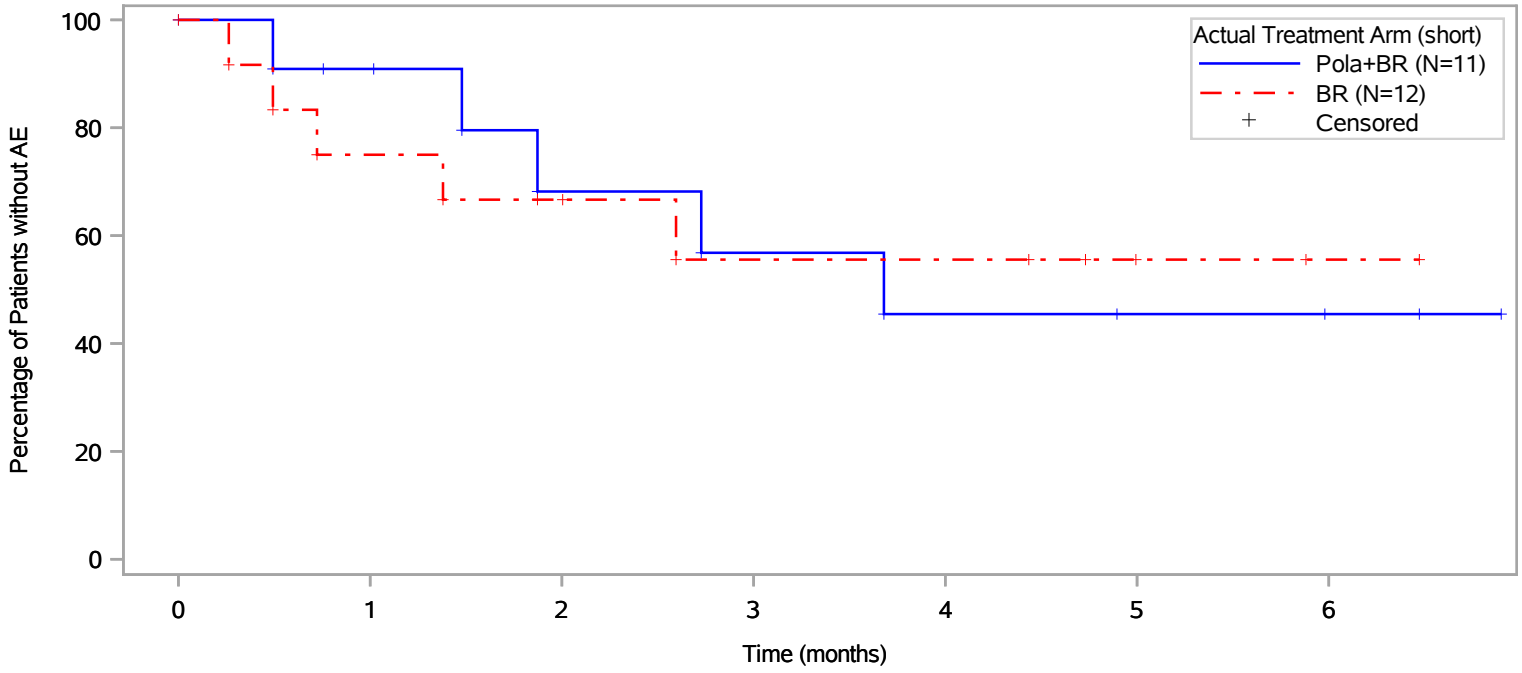
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk							
Pola+BR (N=11)	11	9	6	5	4	3	2
BR (N=12)	12	9	7	5	5	2	1
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	3	4
BR (N=12)	0	0	1	2	2	5	6

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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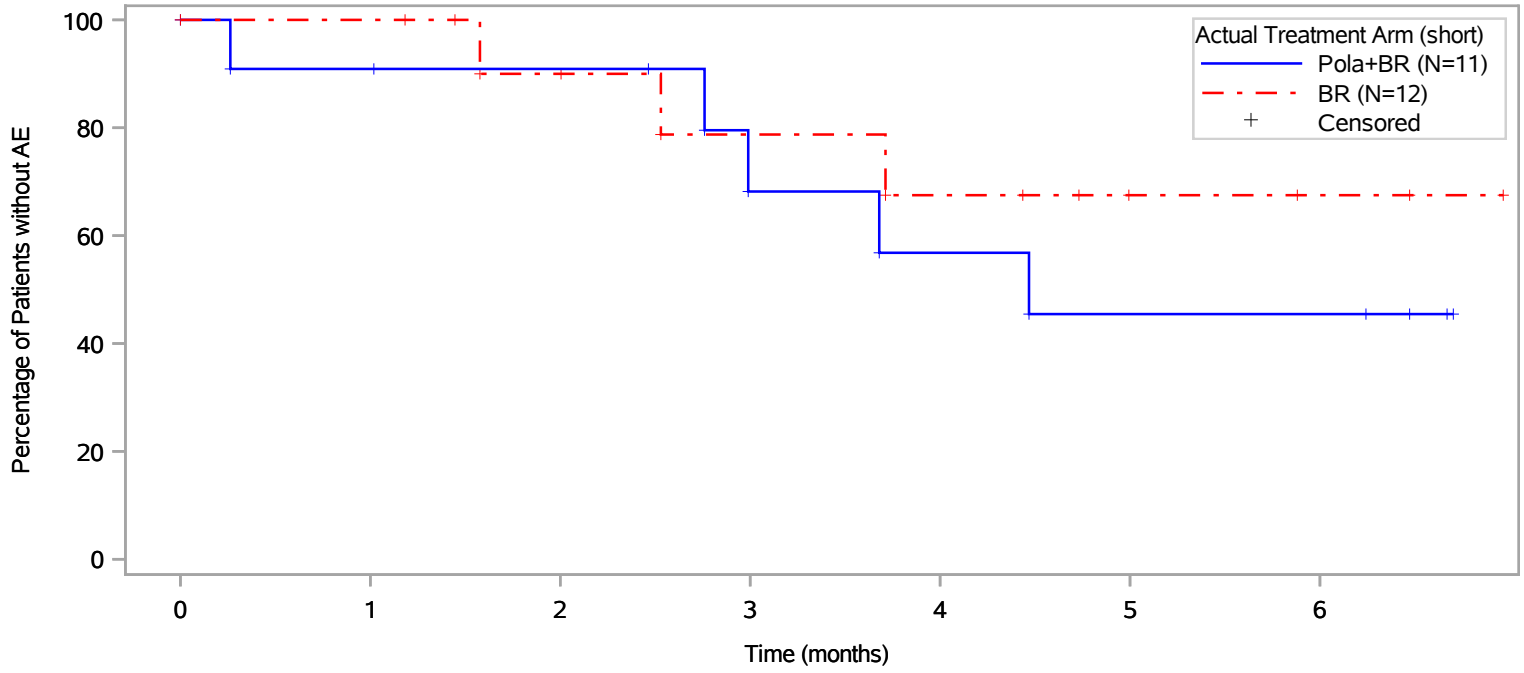
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk							
Pola+BR (N=11)	11	10	9	6	5	4	4
BR (N=12)	12	12	9	7	6	3	2
Patients censored							
Pola+BR (N=11)	0	0	1	2	2	2	2
BR (N=12)	0	0	2	3	3	6	7

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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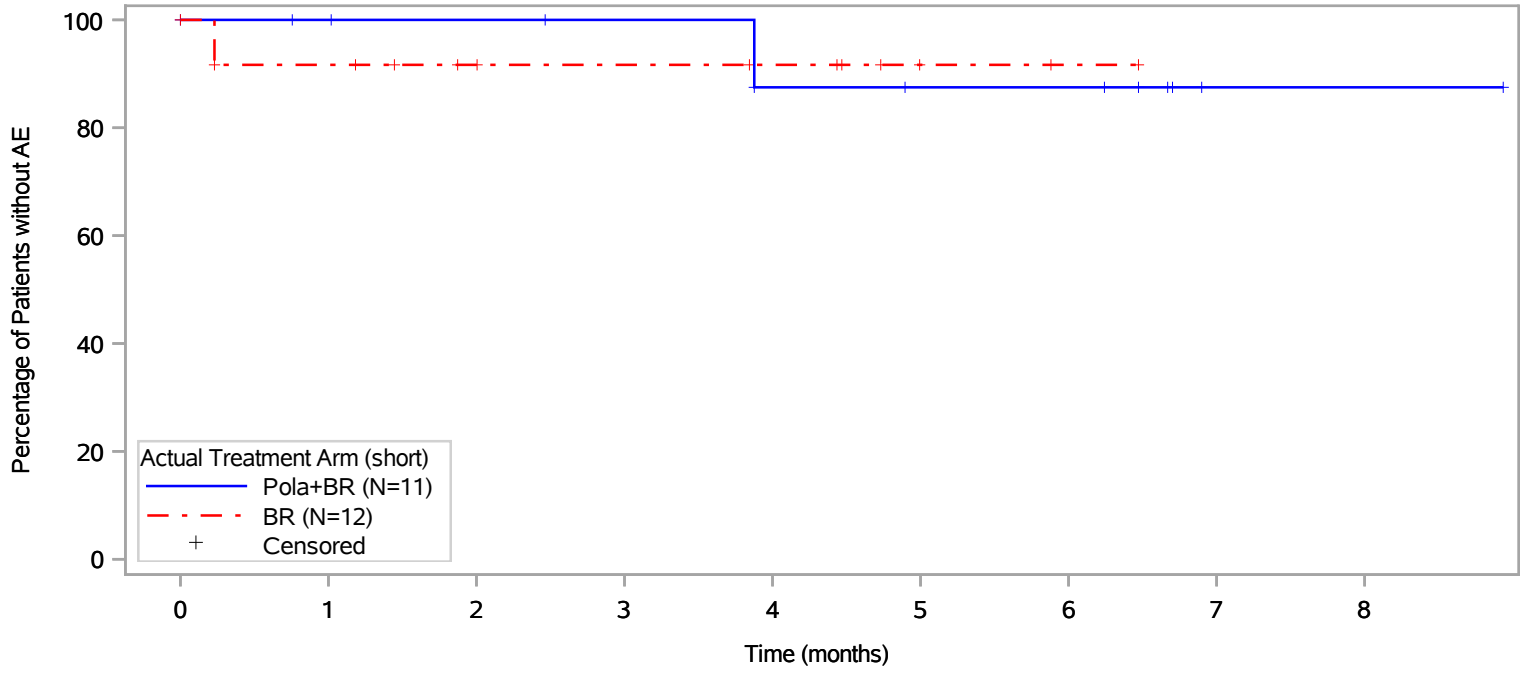
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	11	8	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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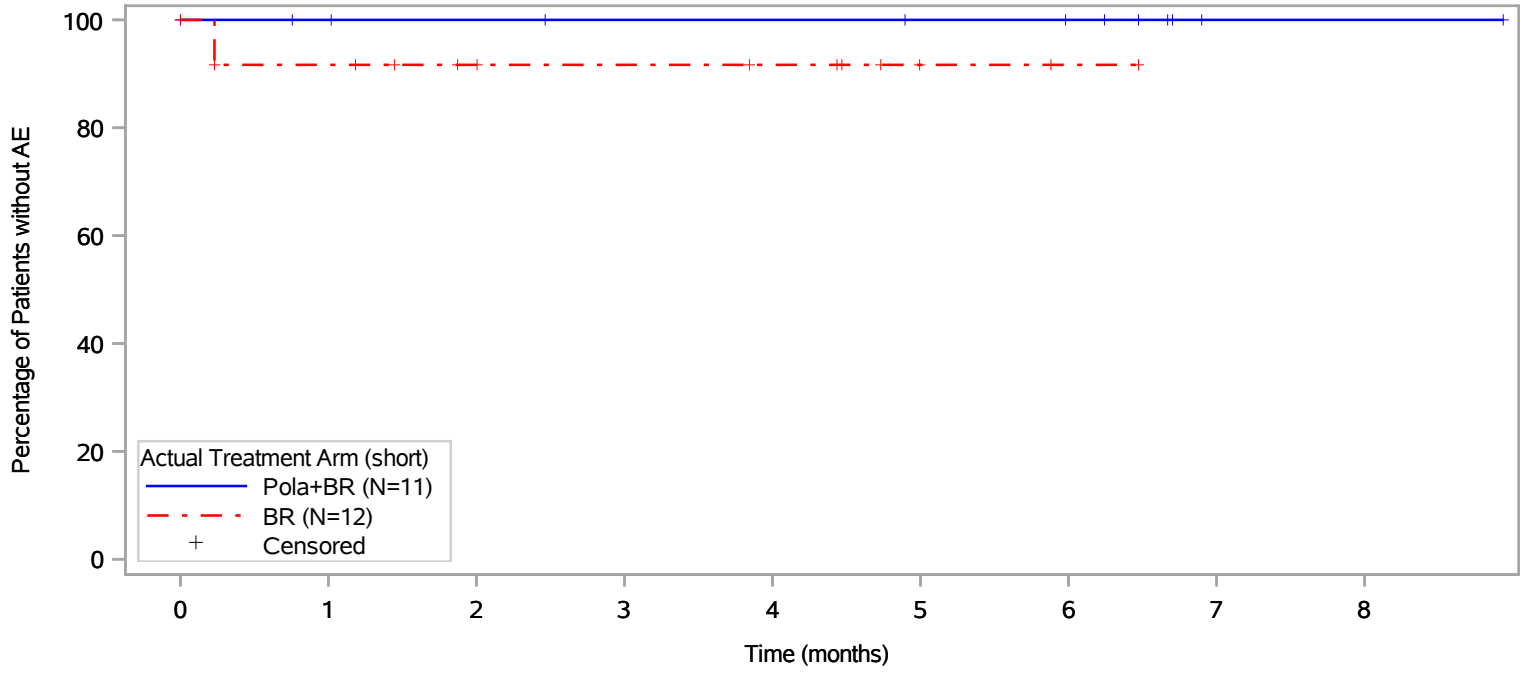
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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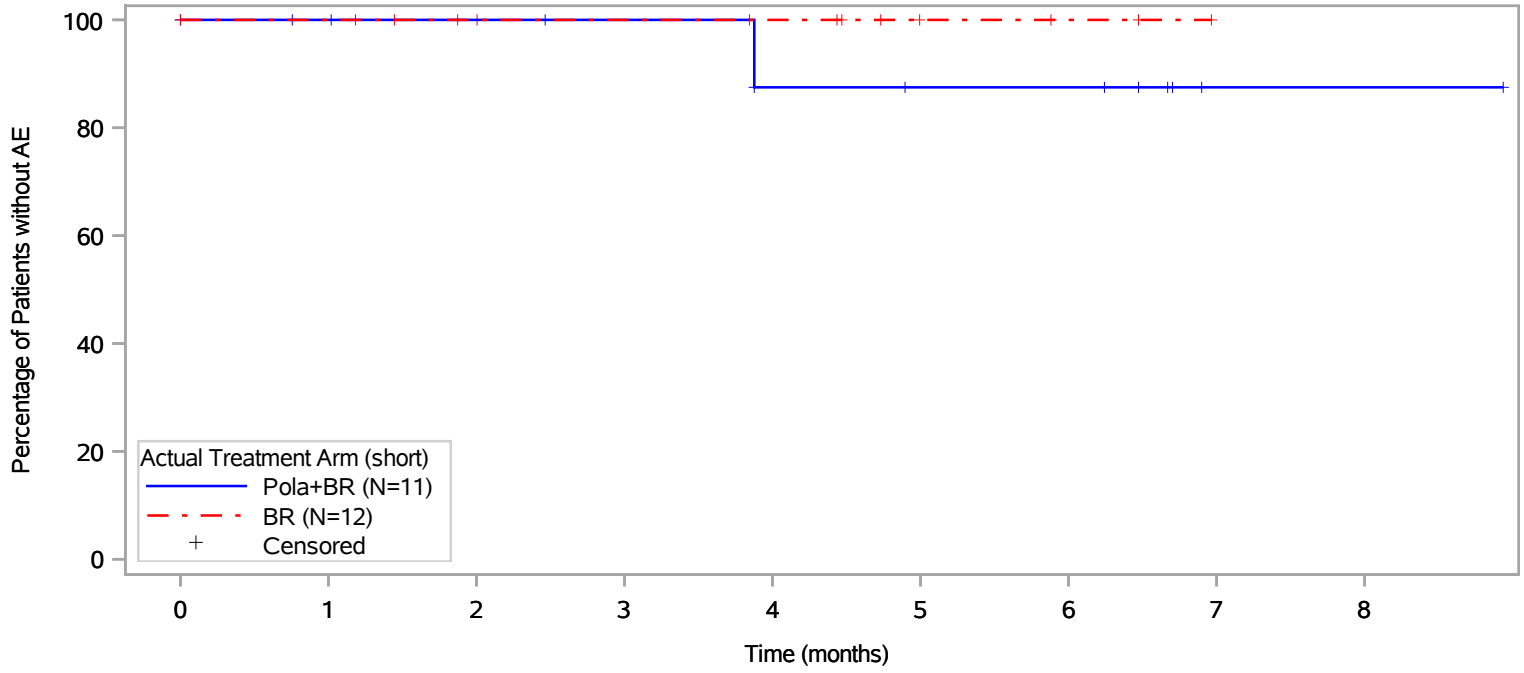
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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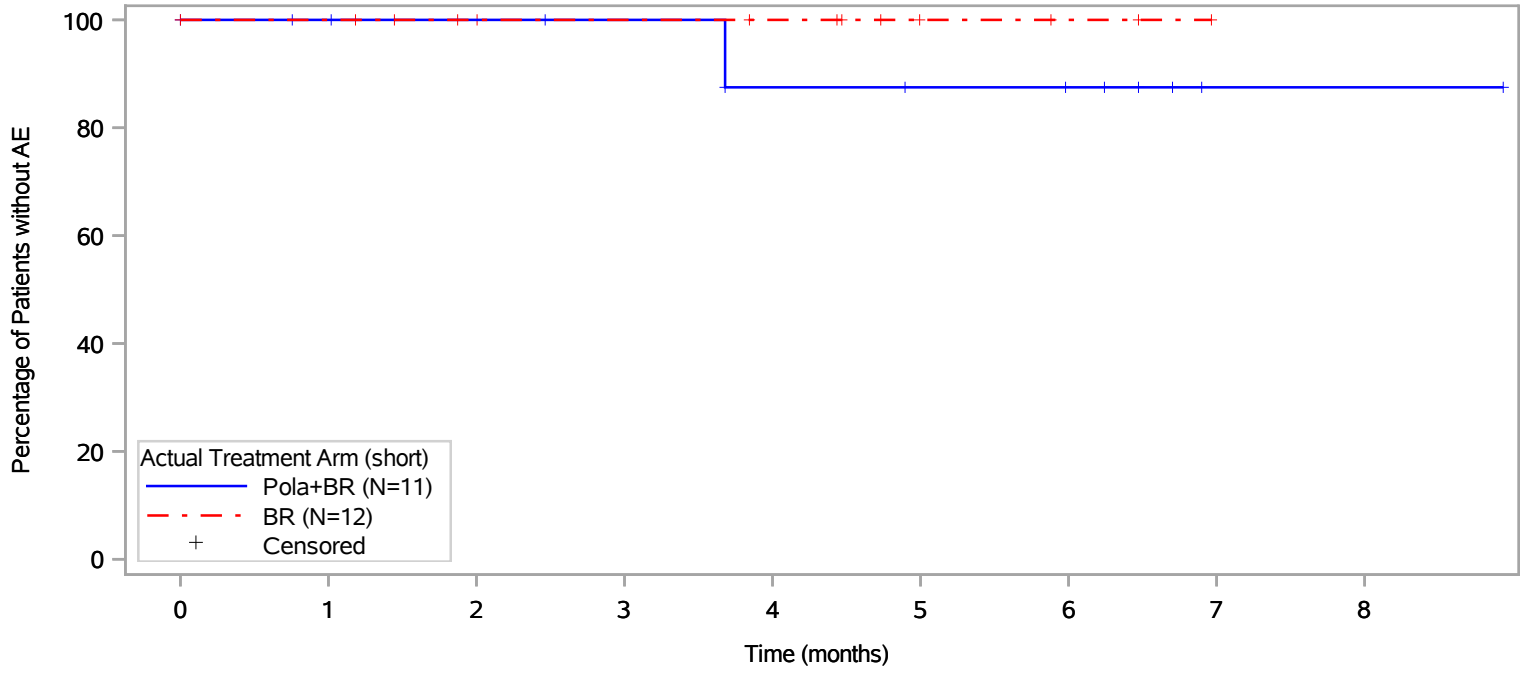
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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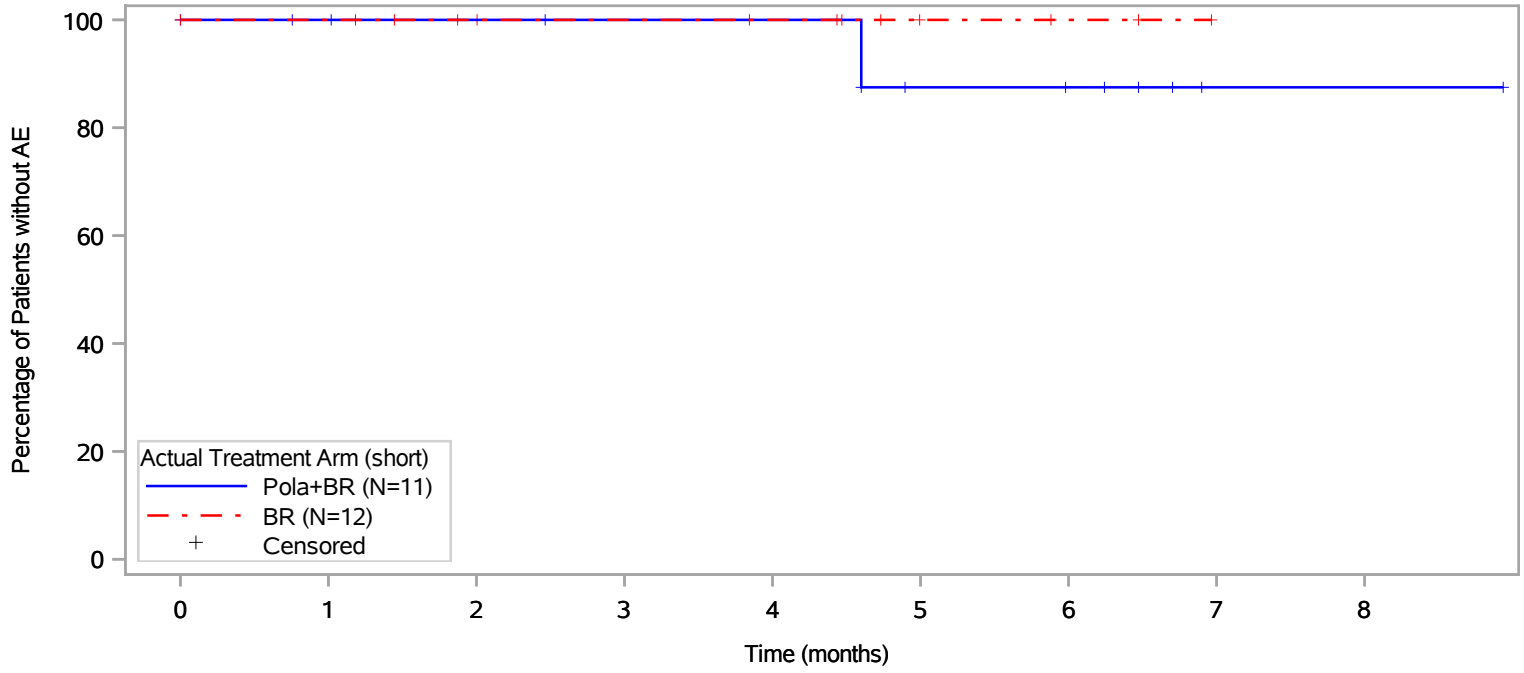
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, EAR CONGESTION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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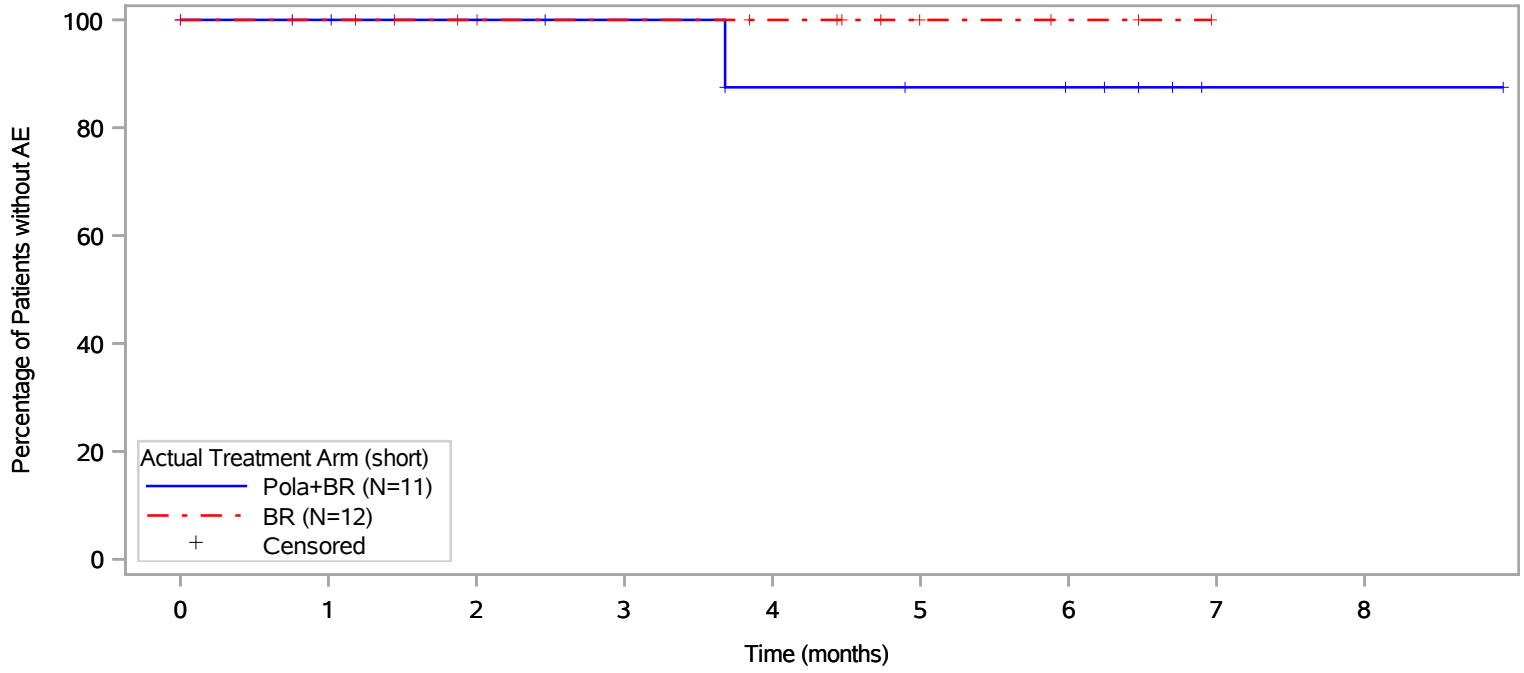
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, EAR PAIN



Patients at risk								
Pola+BR (N=11)	11	10	9	8	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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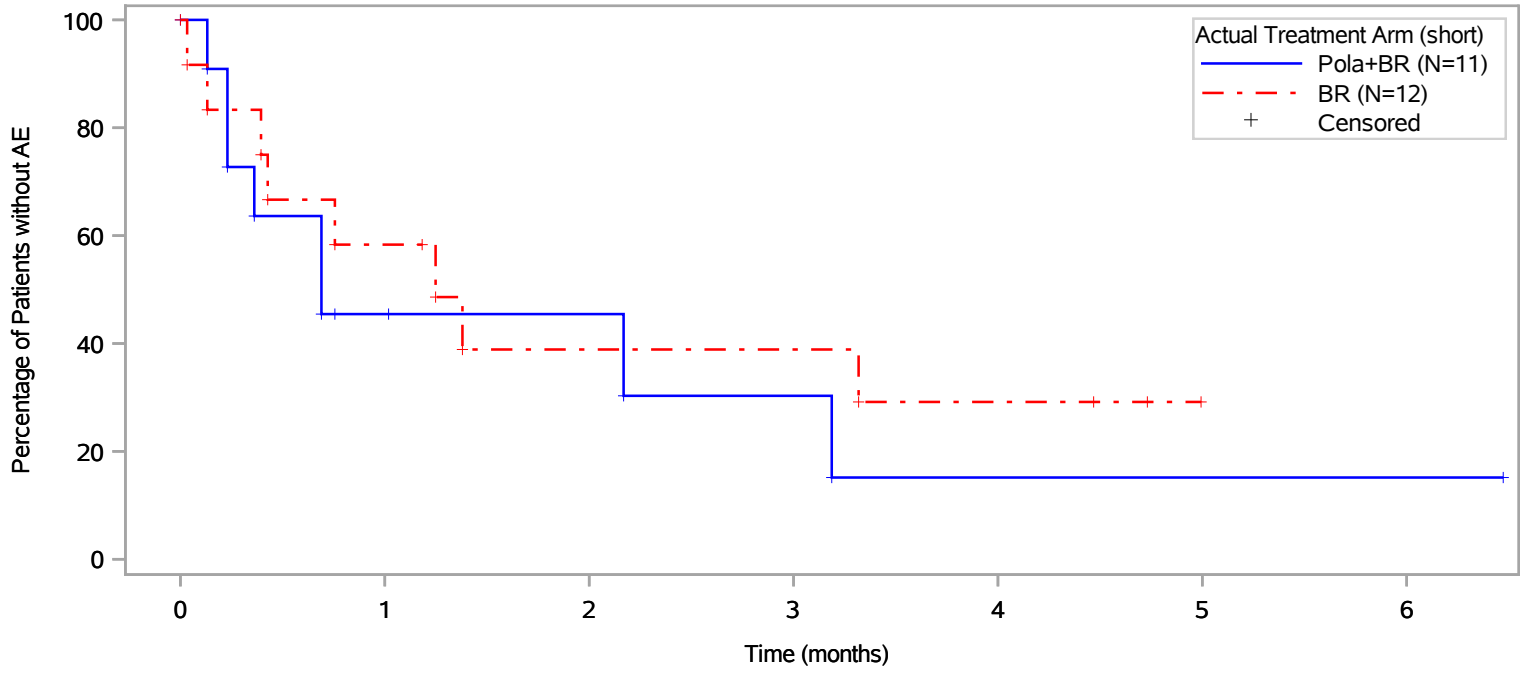
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk							
Pola+BR (N=11)	11	4	3	2	1	1	1
BR (N=12)	12	7	4	4	3	NE	NE
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	2	2
BR (N=12)	0	0	1	1	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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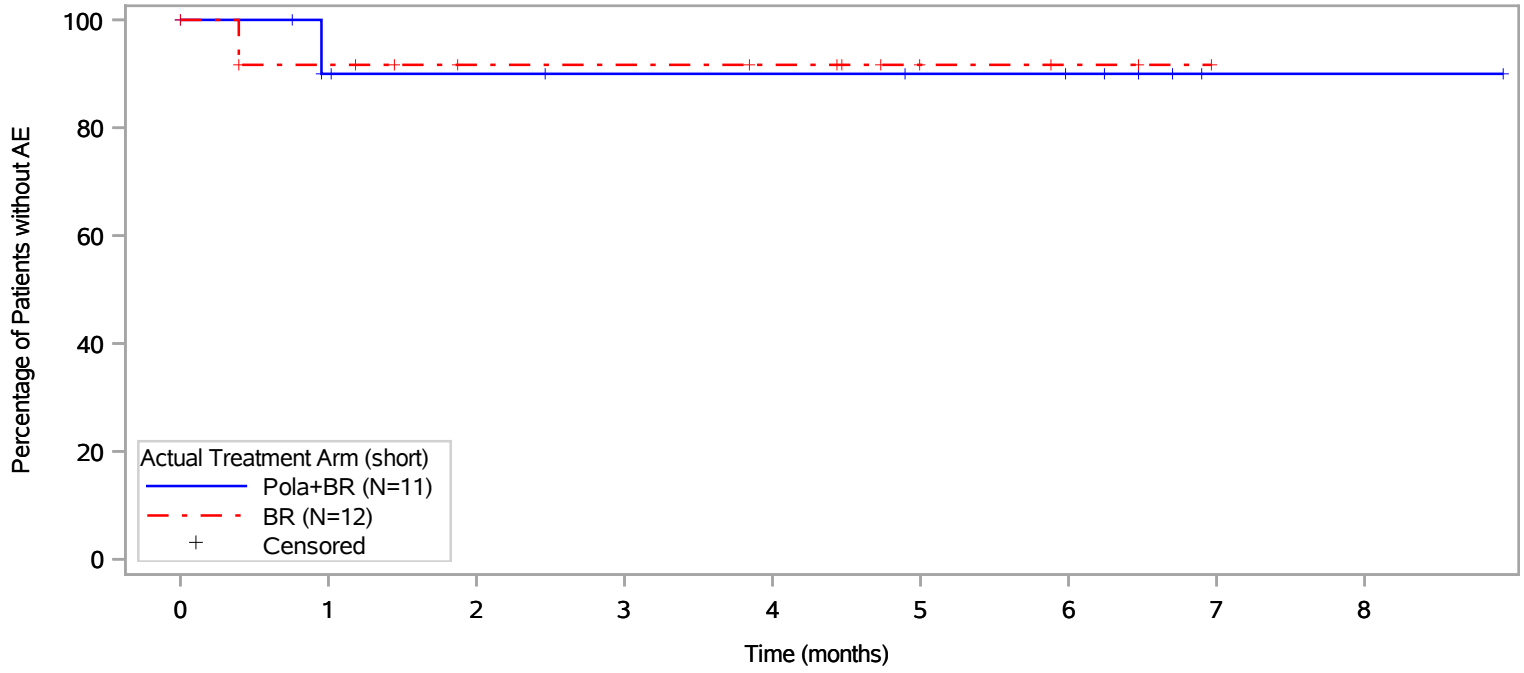
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN

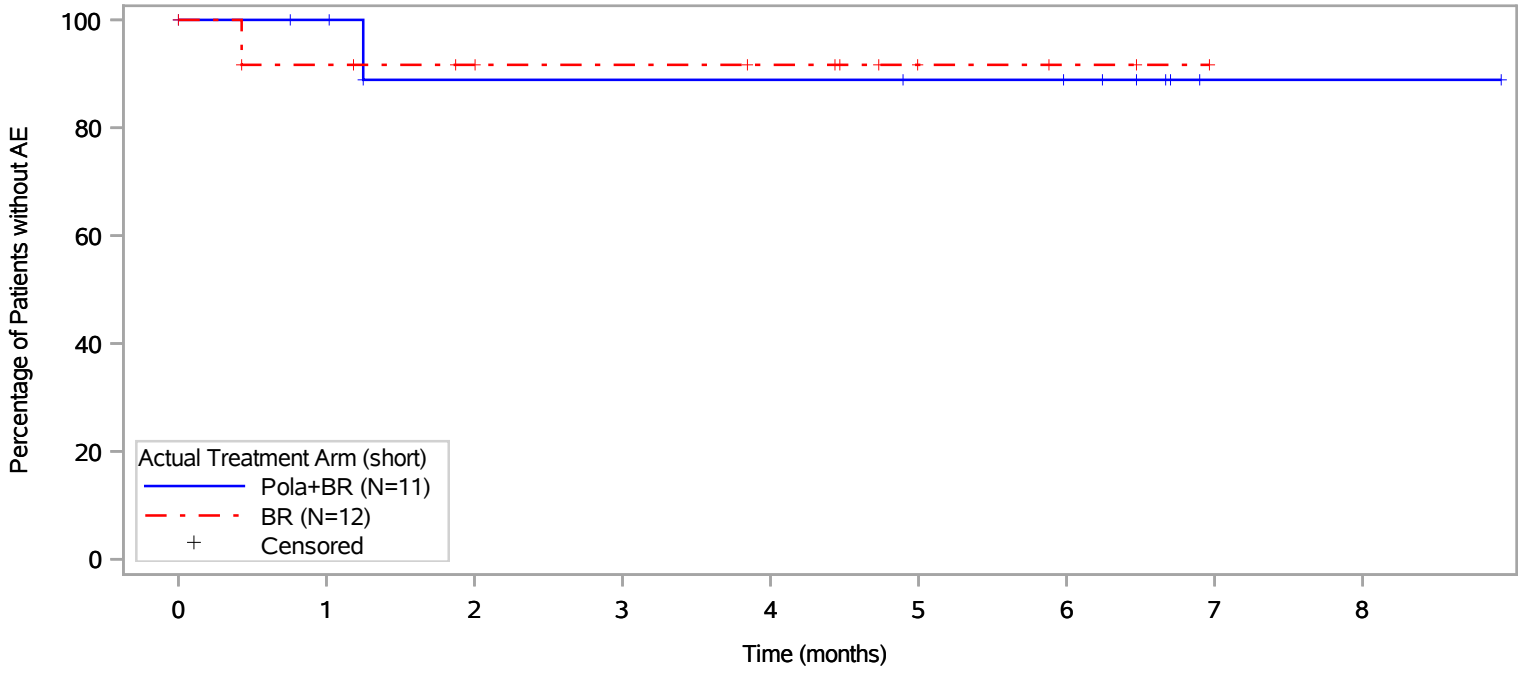


Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	5	1	1
BR (N=12)	12	11	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN UPPER



Patients at risk									
Pola+BR (N=11)	11	10	8	8	8	7	6	1	1
BR (N=12)	12	11	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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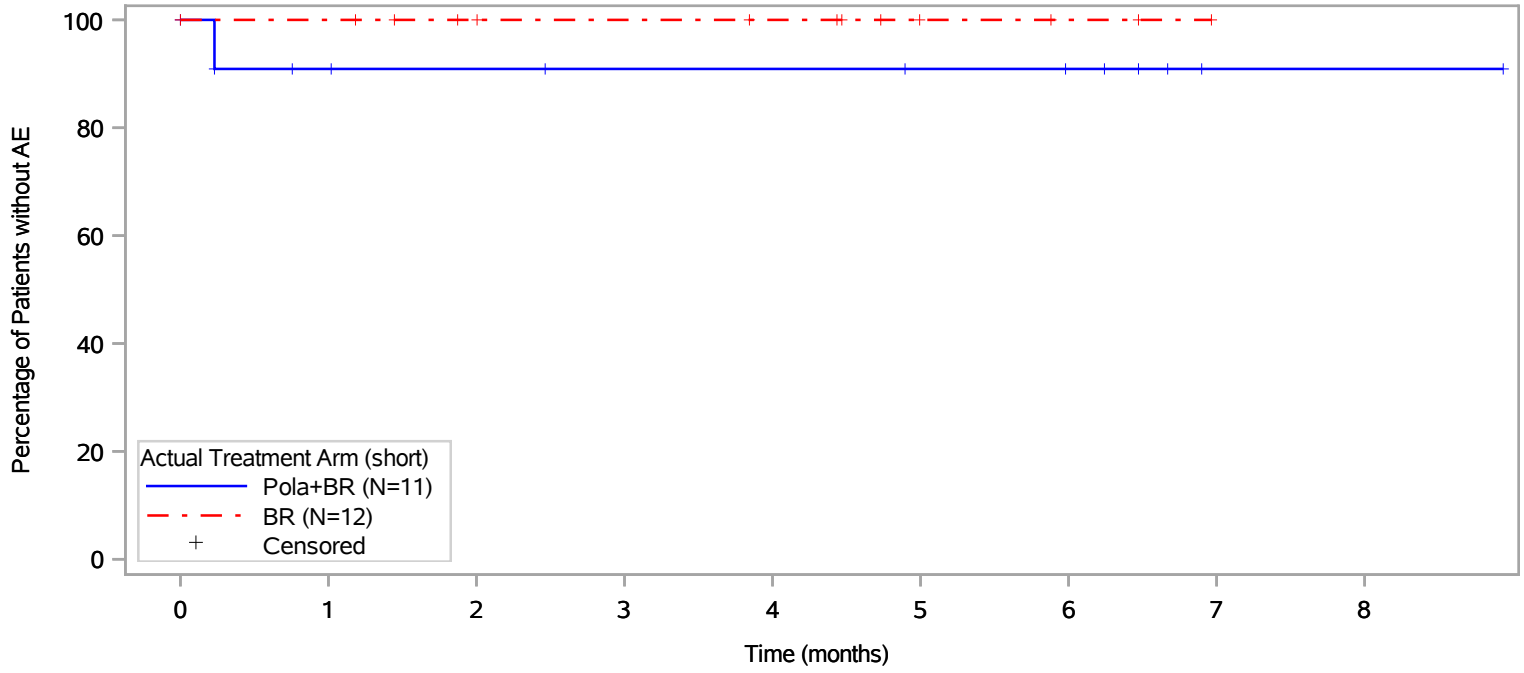
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL RIGIDITY



Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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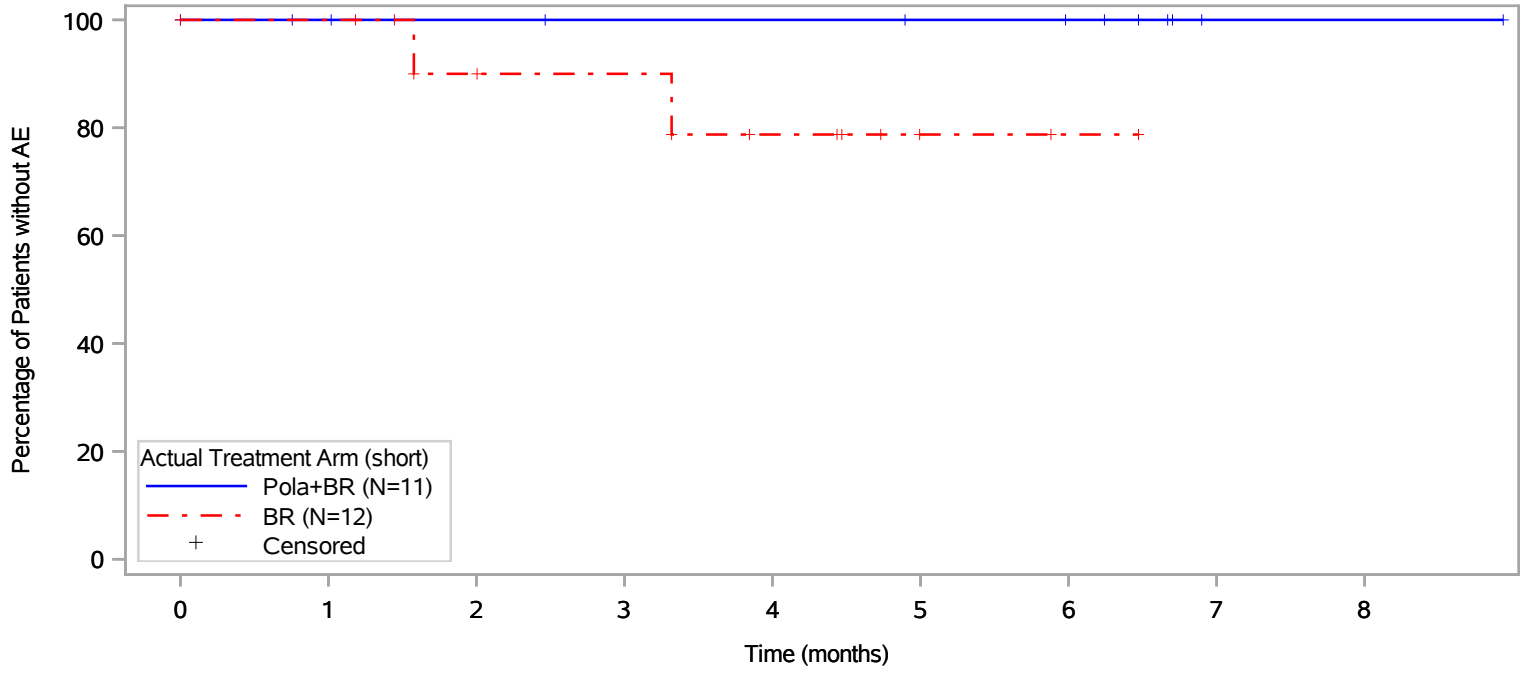
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, APHTHOUS ULCER



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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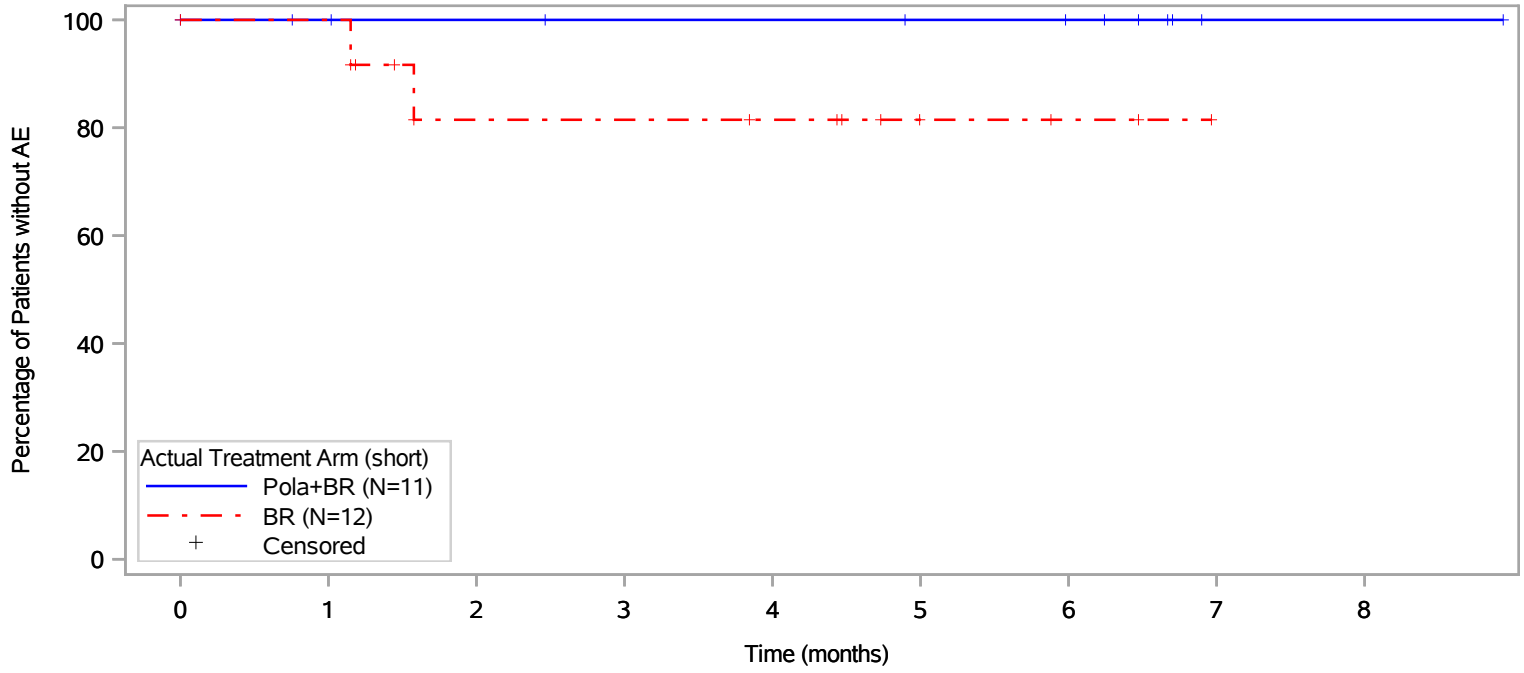
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ASCITES



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	2	3	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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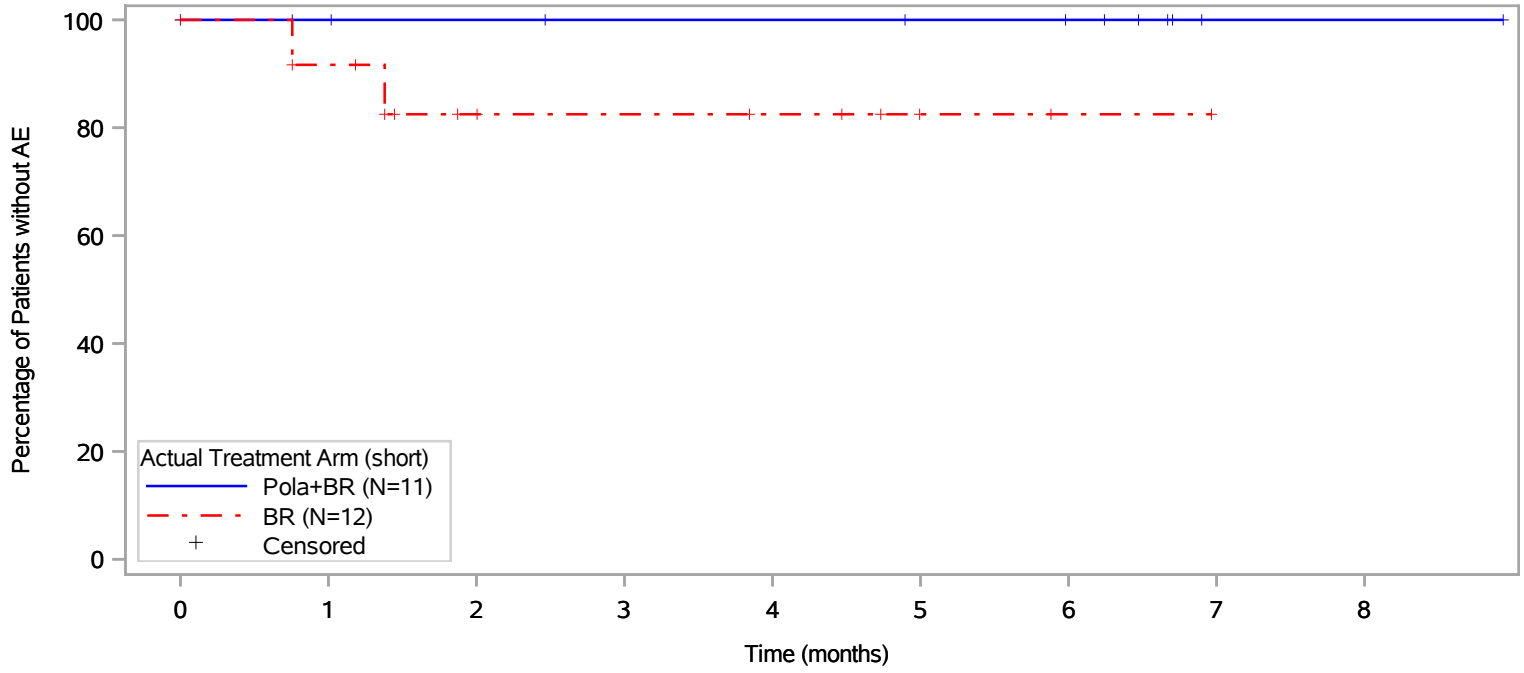
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	7	6	5	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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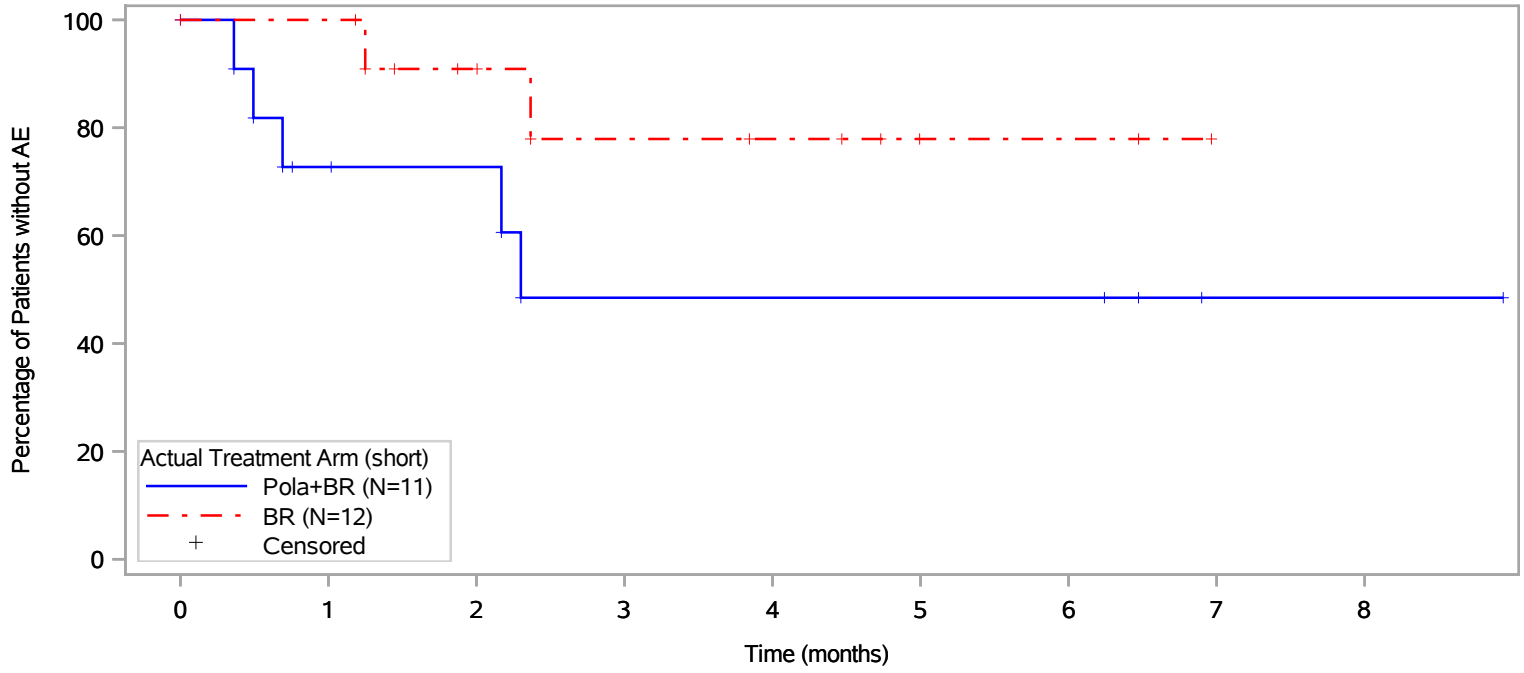
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



Patients at risk									
Pola+BR (N=11)	11	7	6	4	4	4	4	1	1
BR (N=12)	12	12	8	6	5	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	2	2	5	5
BR (N=12)	0	0	3	4	5	8	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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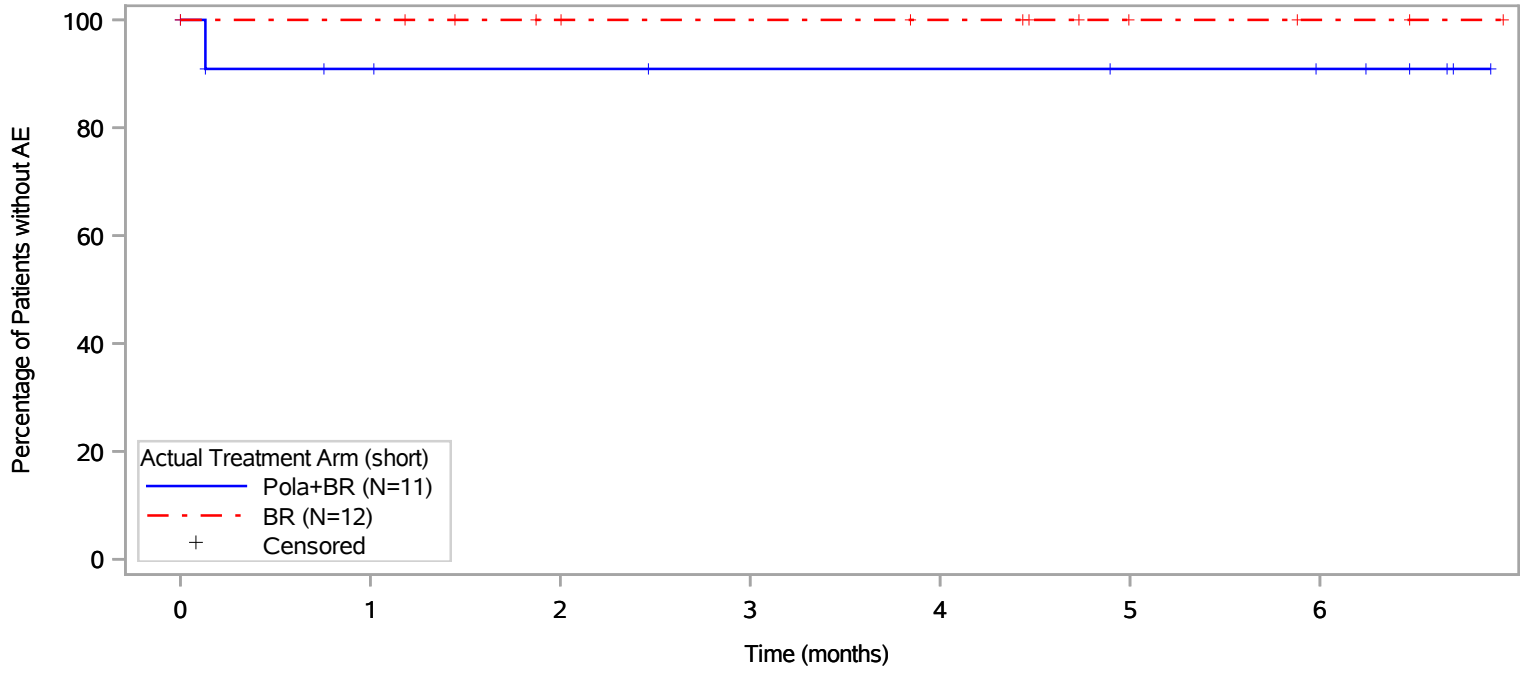
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DYSPEPSIA



Patients at risk							
Pola+BR (N=11)	11	9	8	7	7	6	5
BR (N=12)	12	12	9	8	7	3	2
Patients censored							
Pola+BR (N=11)	0	1	2	3	3	4	5
BR (N=12)	0	0	3	4	5	9	10

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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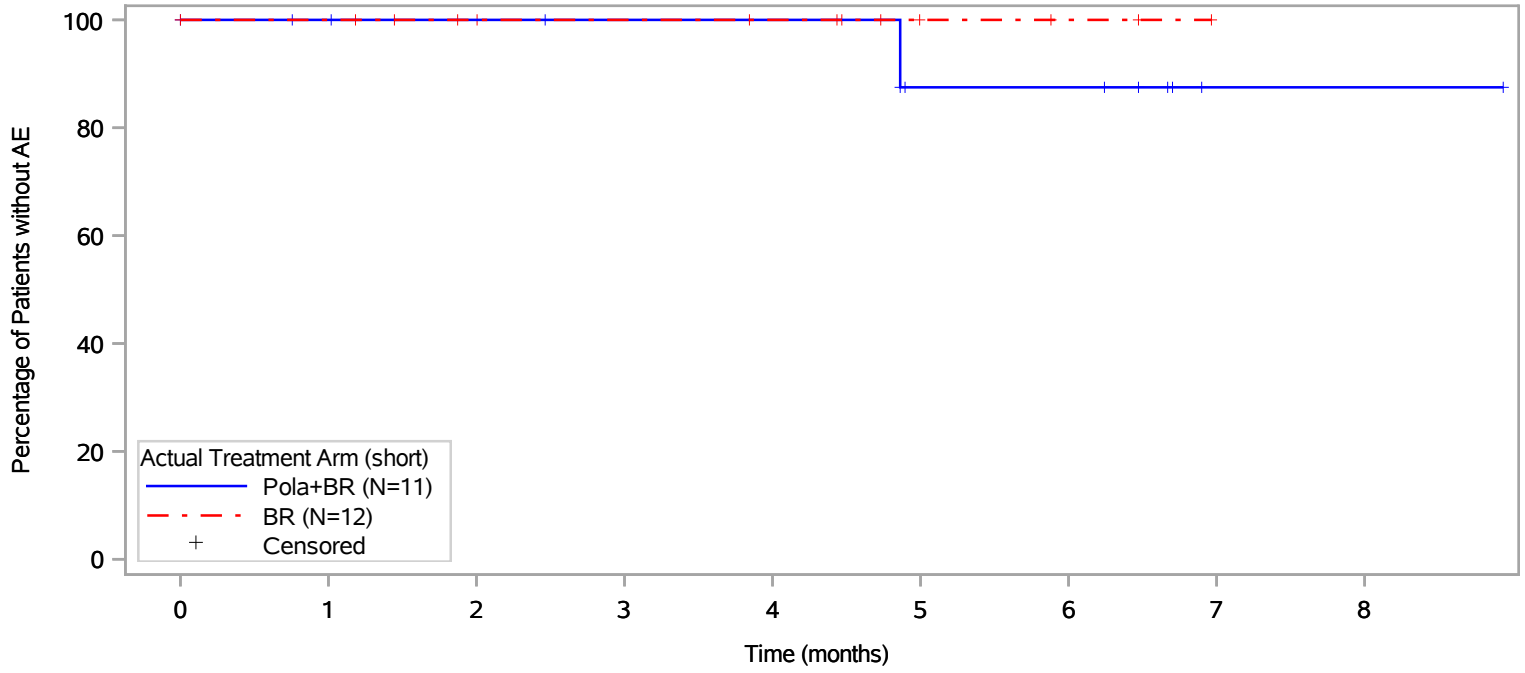
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DYSPHAGIA

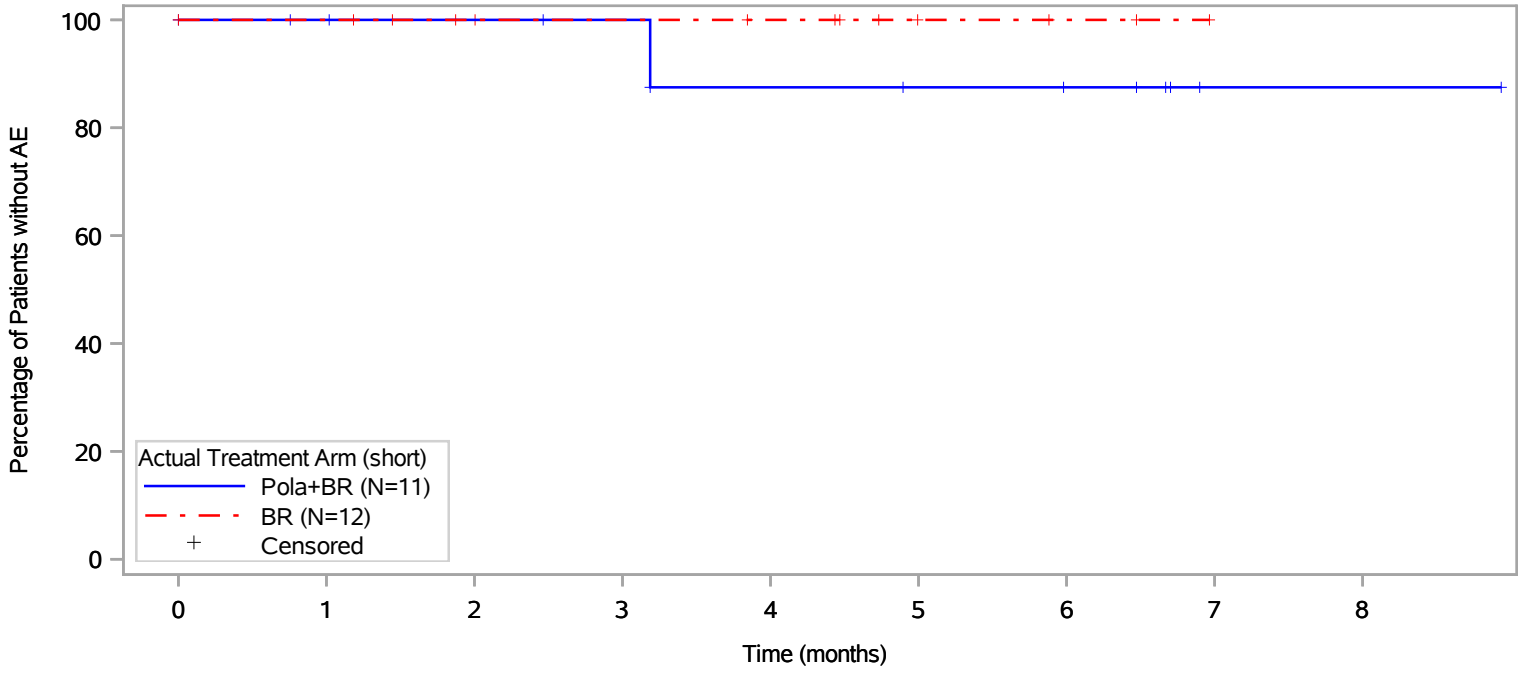


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, FAECES SOFT



Patients at risk								
Pola+BR (N=11)	11	10	9	8	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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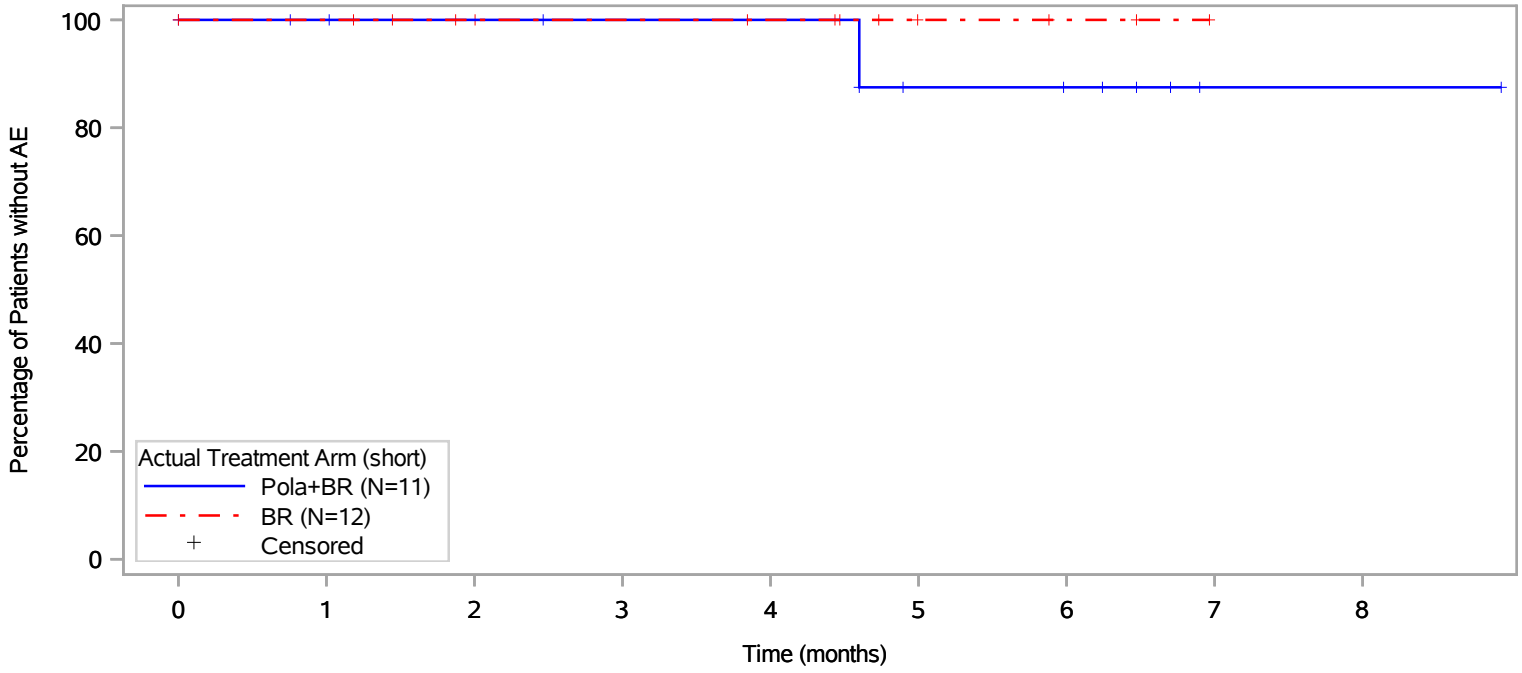
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GINGIVAL PAIN

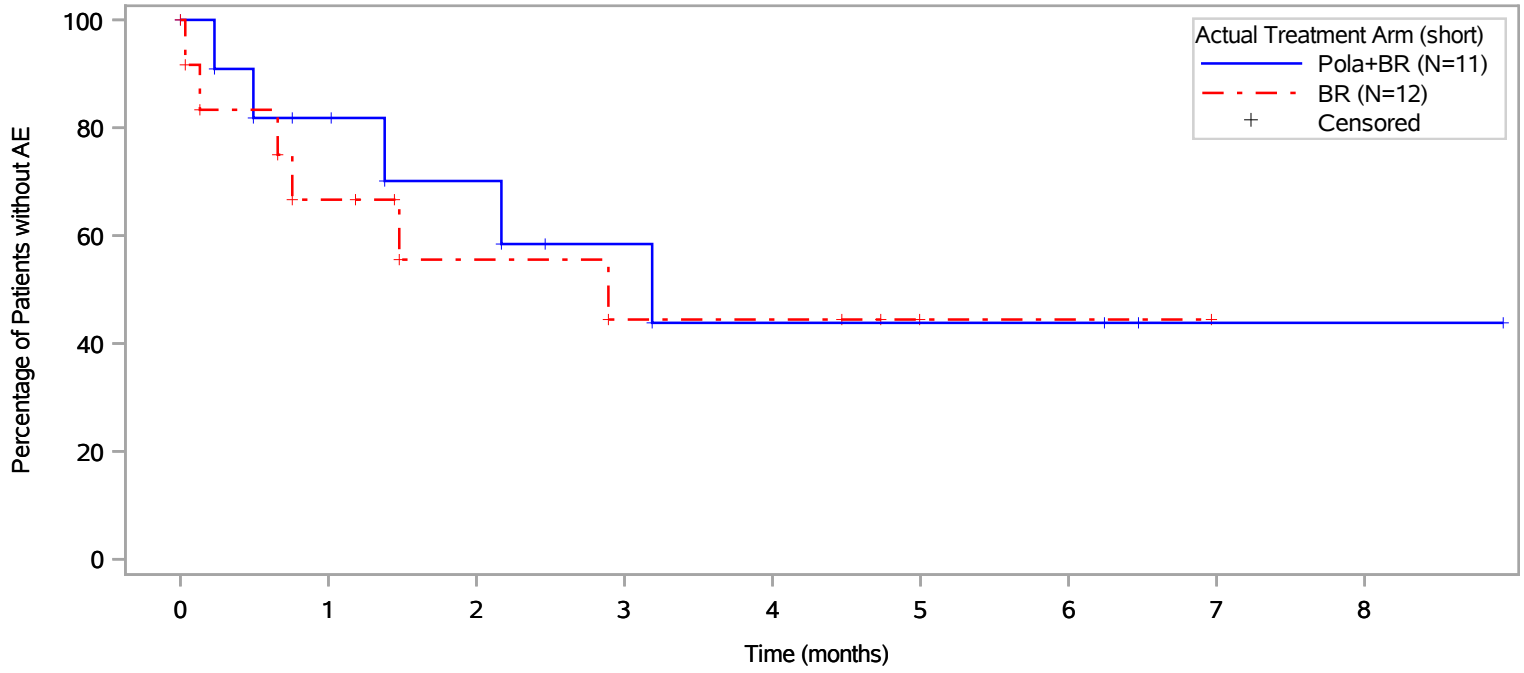


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, NAUSEA

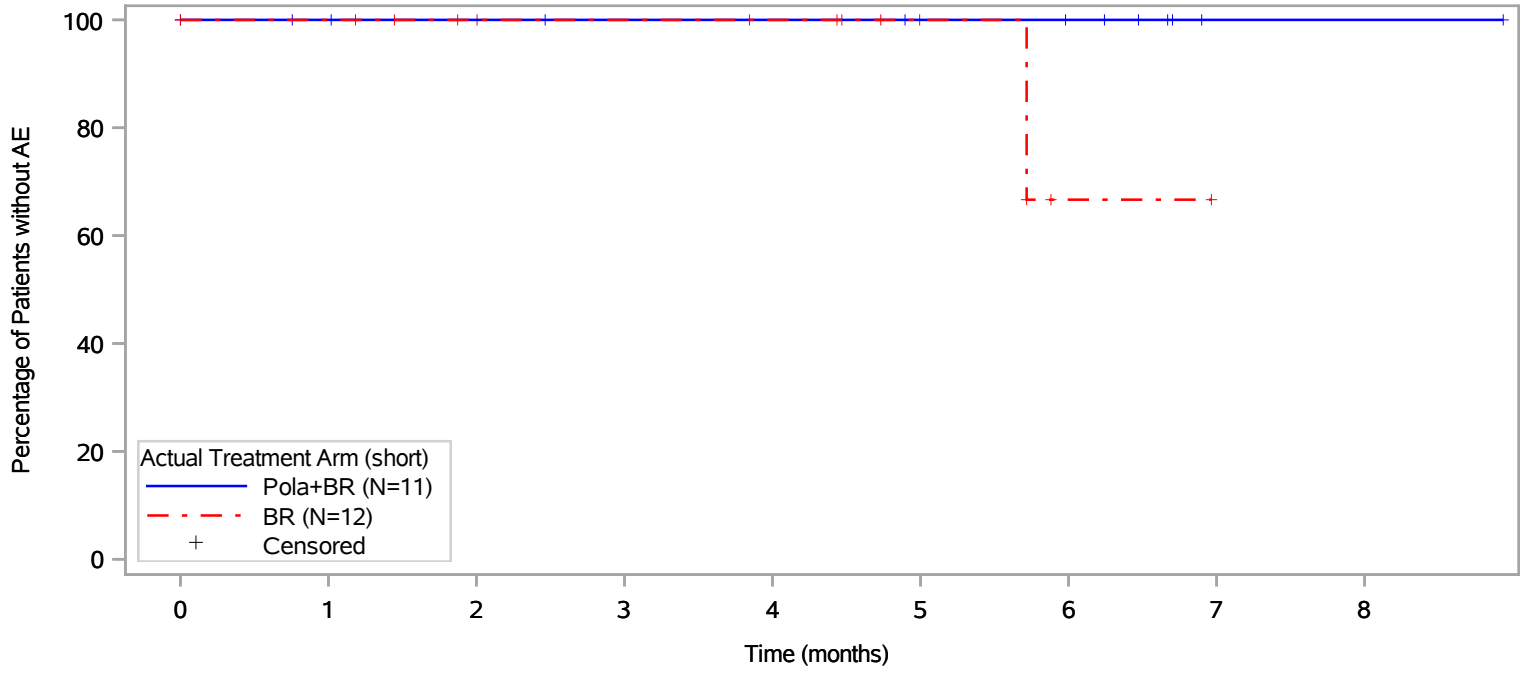


Patients at risk									
Pola+BR (N=11)	11	8	6	4	3	3	3	1	1
BR (N=12)	12	8	5	4	4	1	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	3	5	5
BR (N=12)	0	0	2	2	2	5	5	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SMALL INTESTINAL OBSTRUCTION

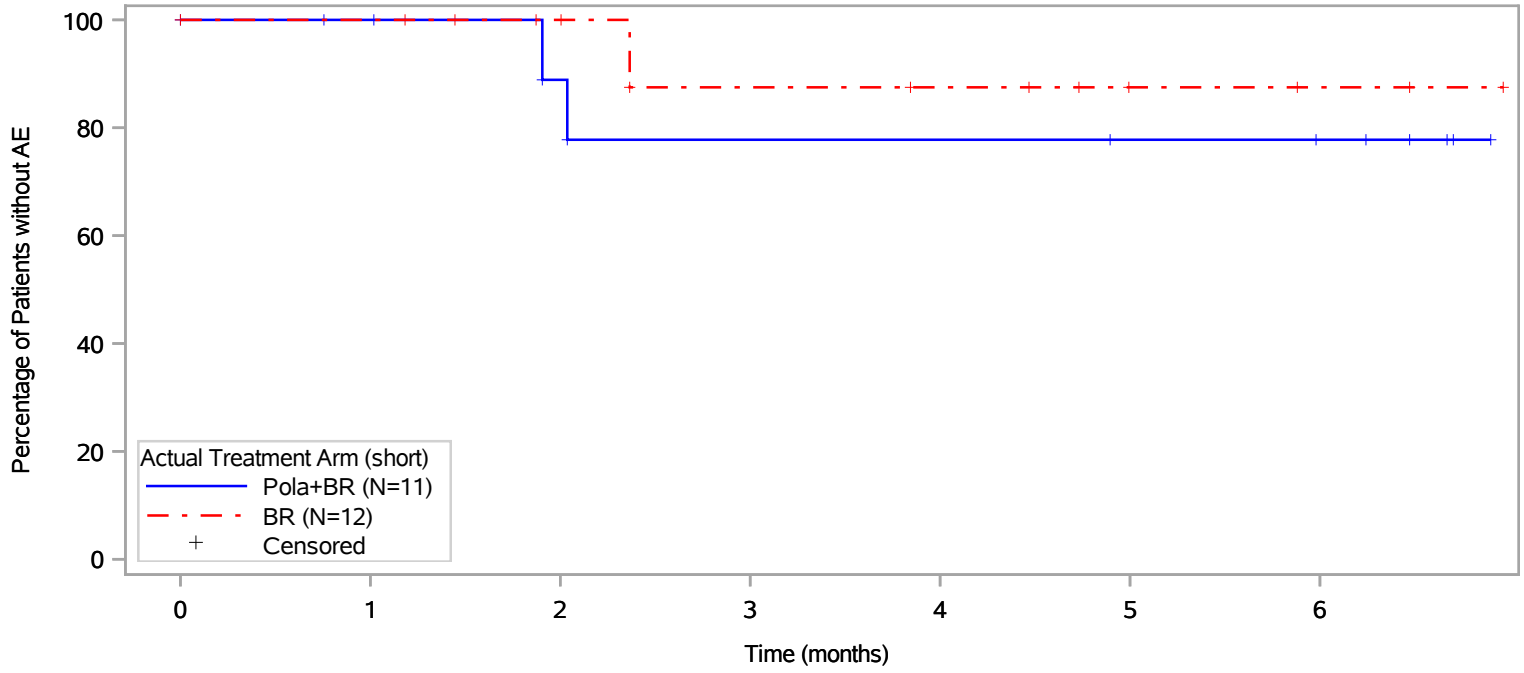


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, STOMATITIS



Patients at risk							
Pola+BR (N=11)	11	10	8	7	7	6	5
BR (N=12)	12	12	9	7	6	3	2
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	3	4
BR (N=12)	0	0	3	4	5	8	9

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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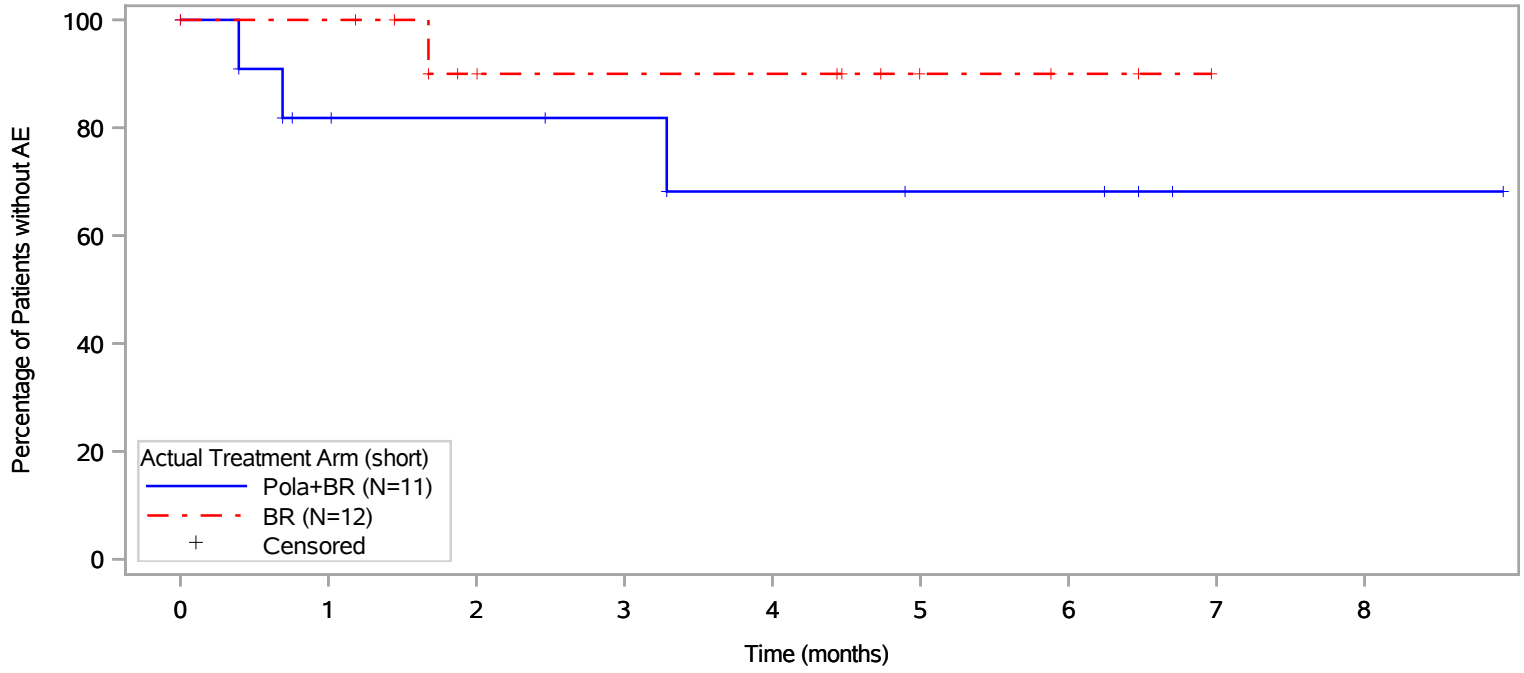
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=11)	11	8	7	6	5	4	4	1	1
BR (N=12)	12	12	8	7	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	7	7
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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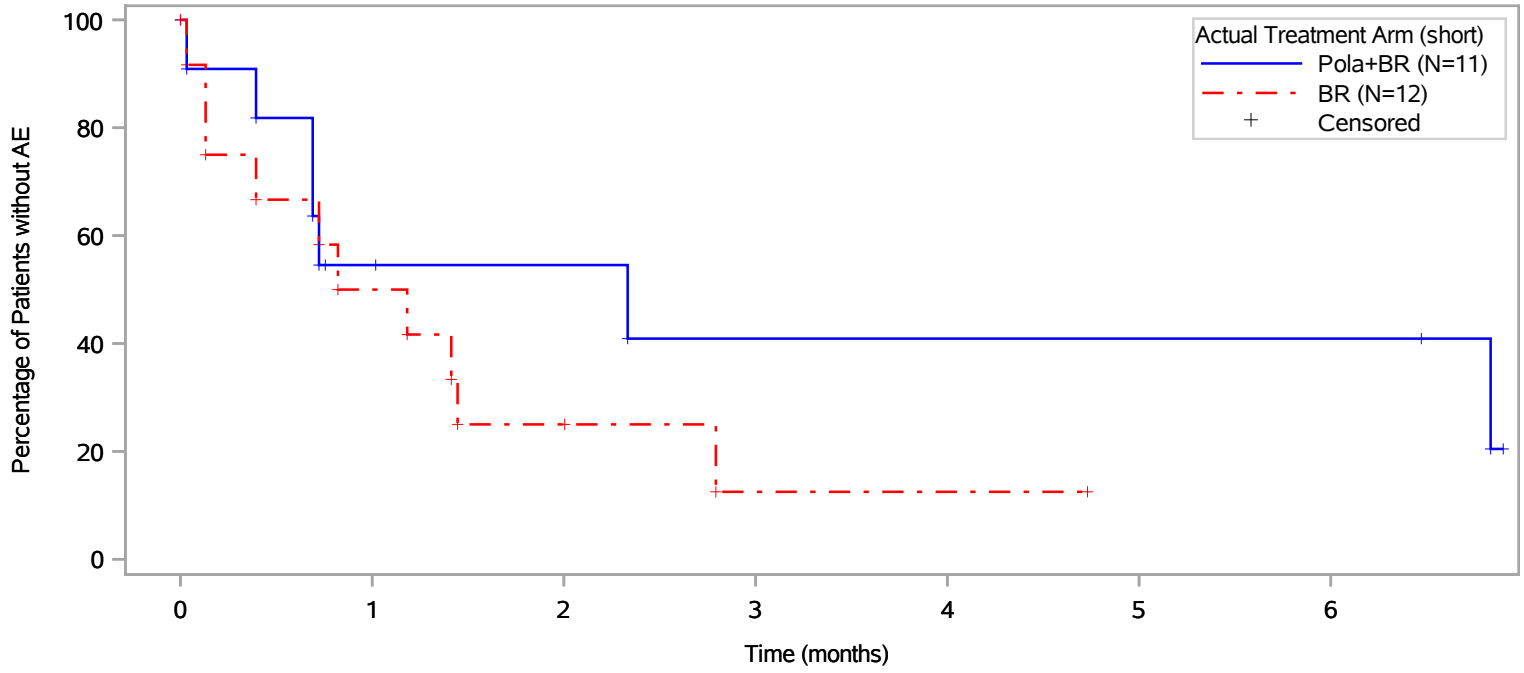
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk							
Pola+BR (N=11)	11	5	4	3	3	3	3
BR (N=12)	12	6	3	1	1	NE	NE
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	2	2
BR (N=12)	0	0	0	1	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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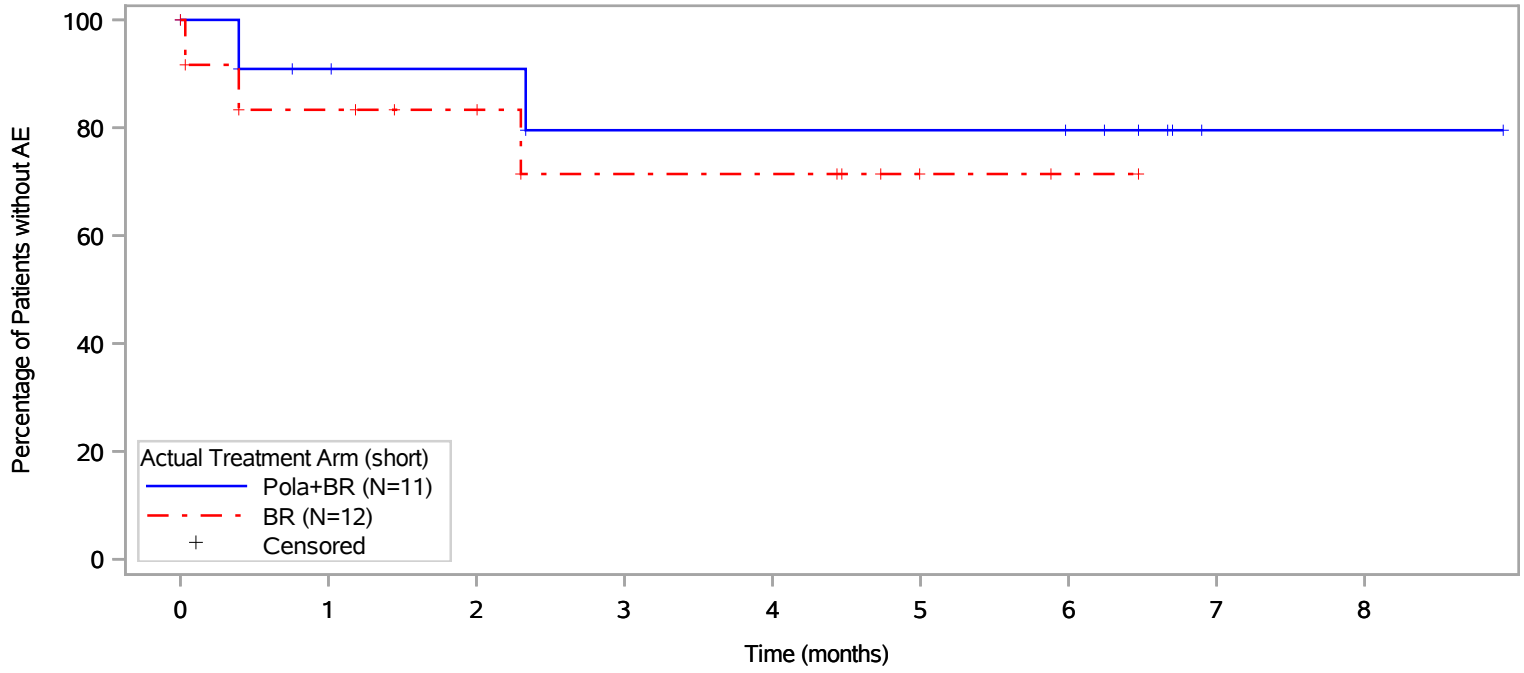
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, ASTHENIA



Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	7	6	1	1
BR (N=12)	12	10	8	6	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	2	3	8	8
BR (N=12)	0	0	2	3	3	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
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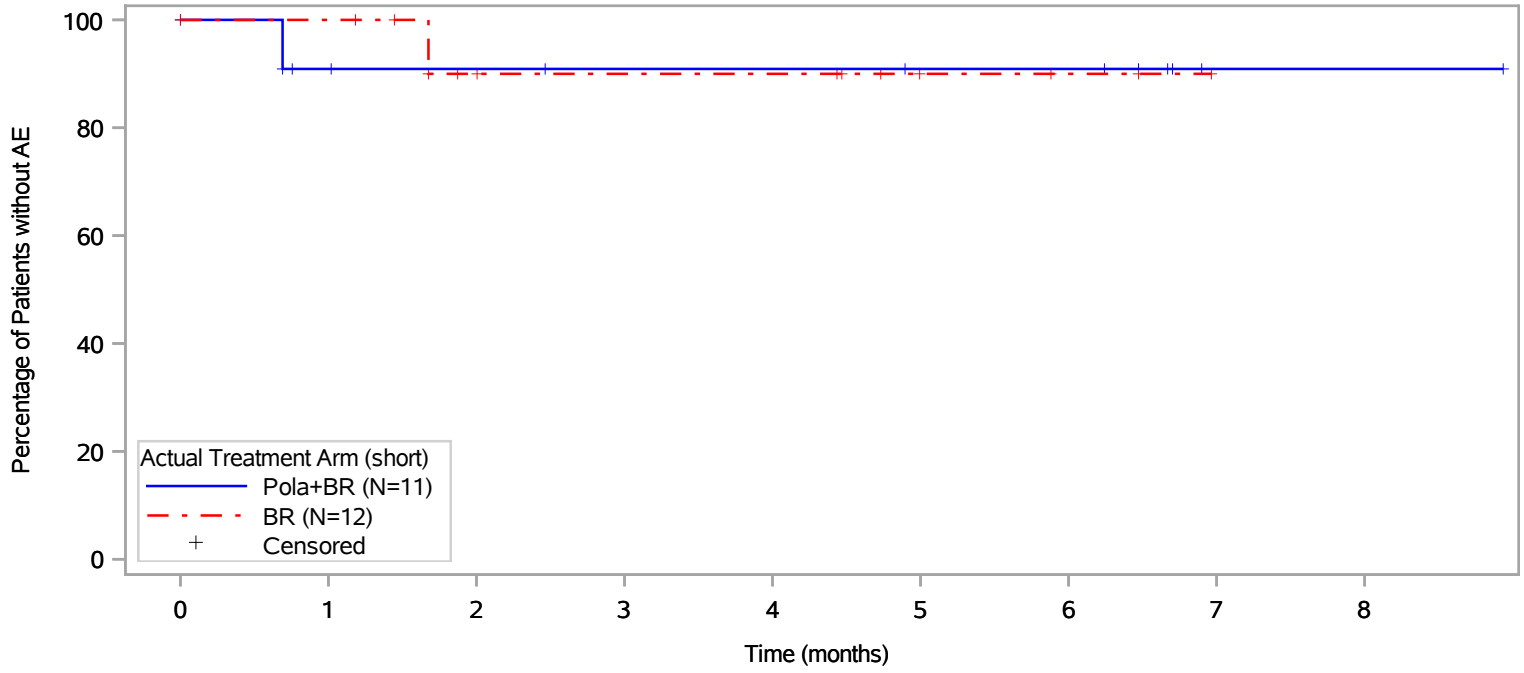
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHILLS



Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	6	1	1
BR (N=12)	12	12	8	7	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
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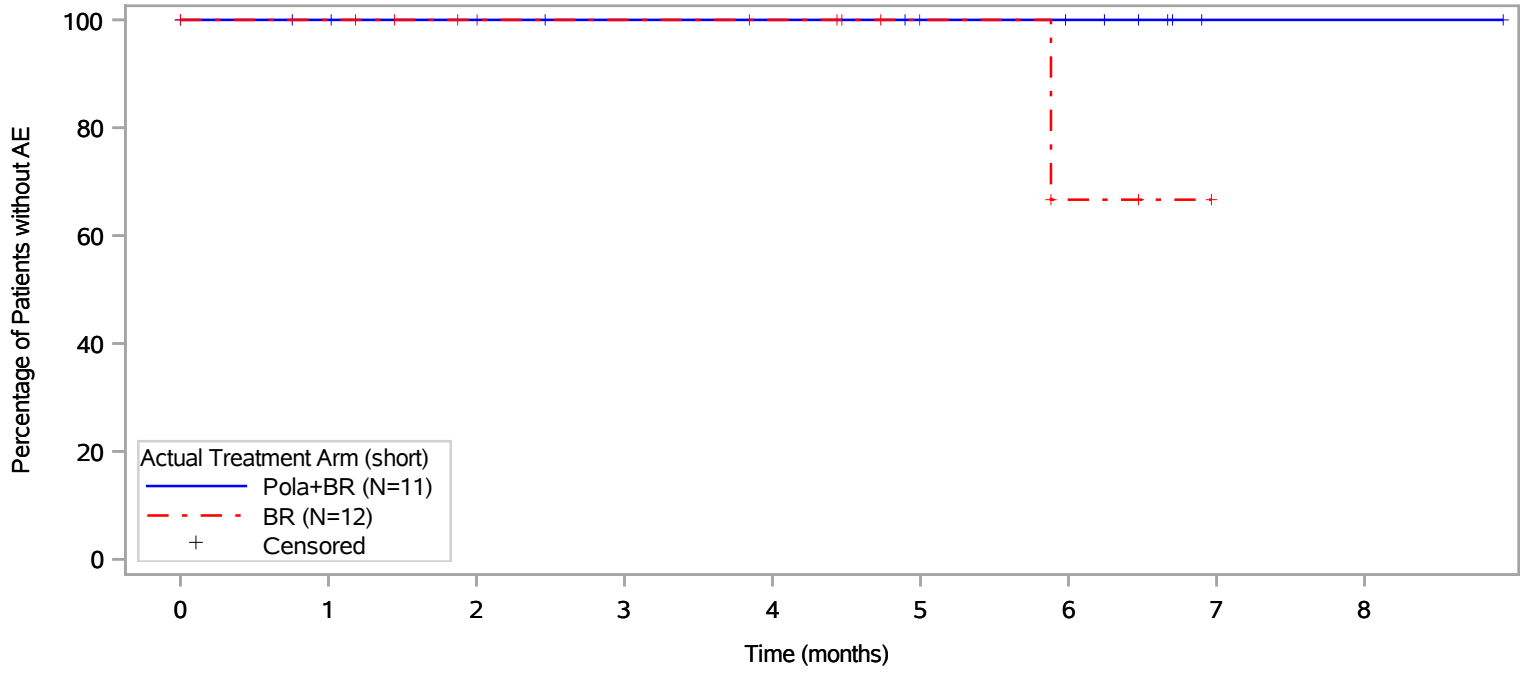
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DEATH



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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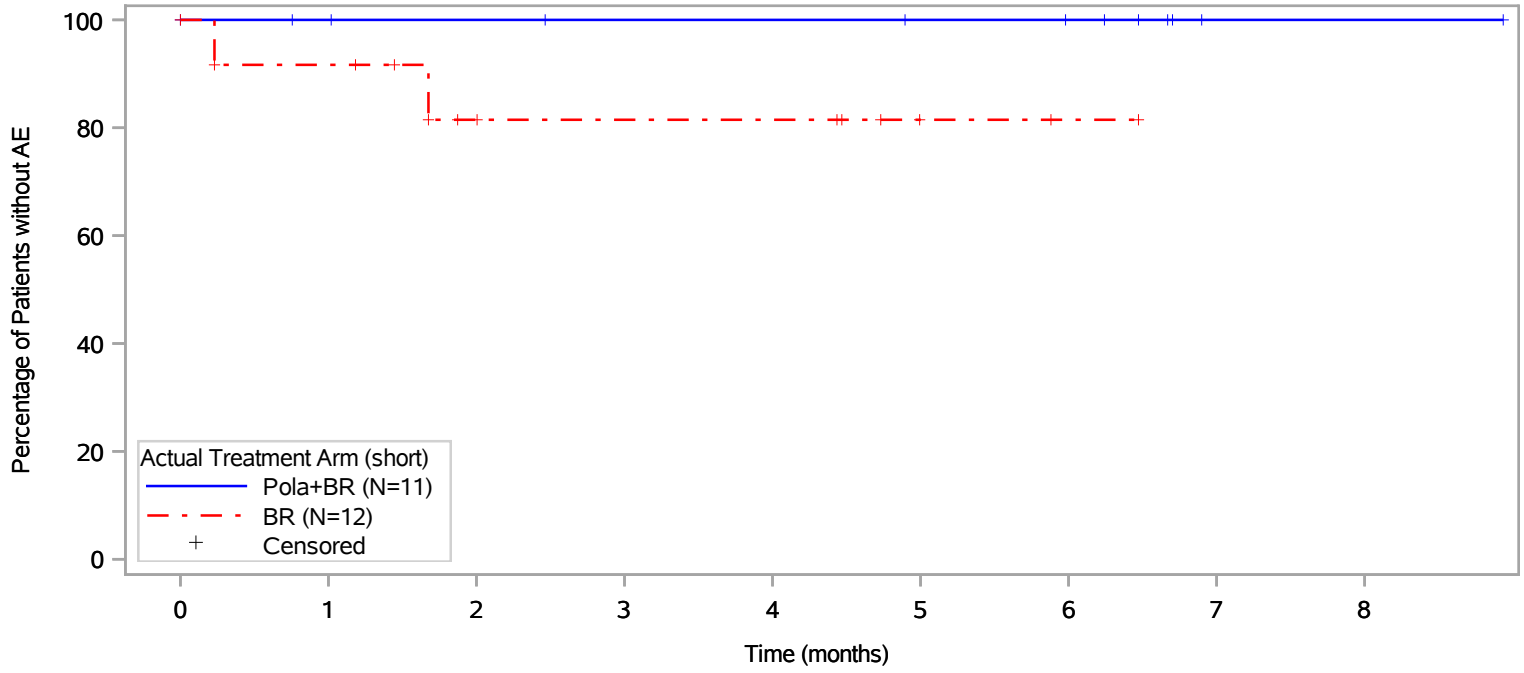
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DISCOMFORT



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	7	6	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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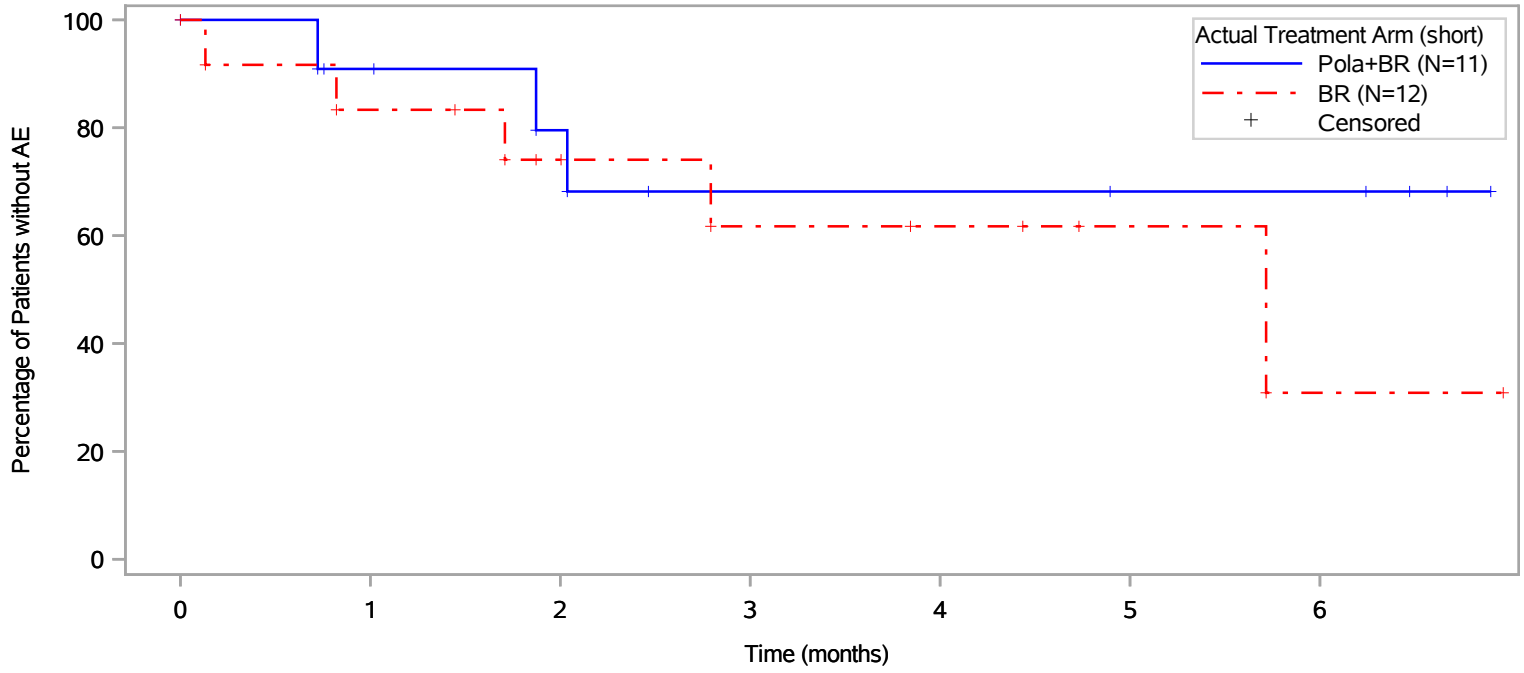
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE



Patients at risk							
Pola+BR (N=11)	11	9	7	5	5	4	4
BR (N=12)	12	10	7	5	4	2	1
Patients censored							
Pola+BR (N=11)	0	1	2	3	3	4	4
BR (N=12)	0	0	2	3	4	6	6

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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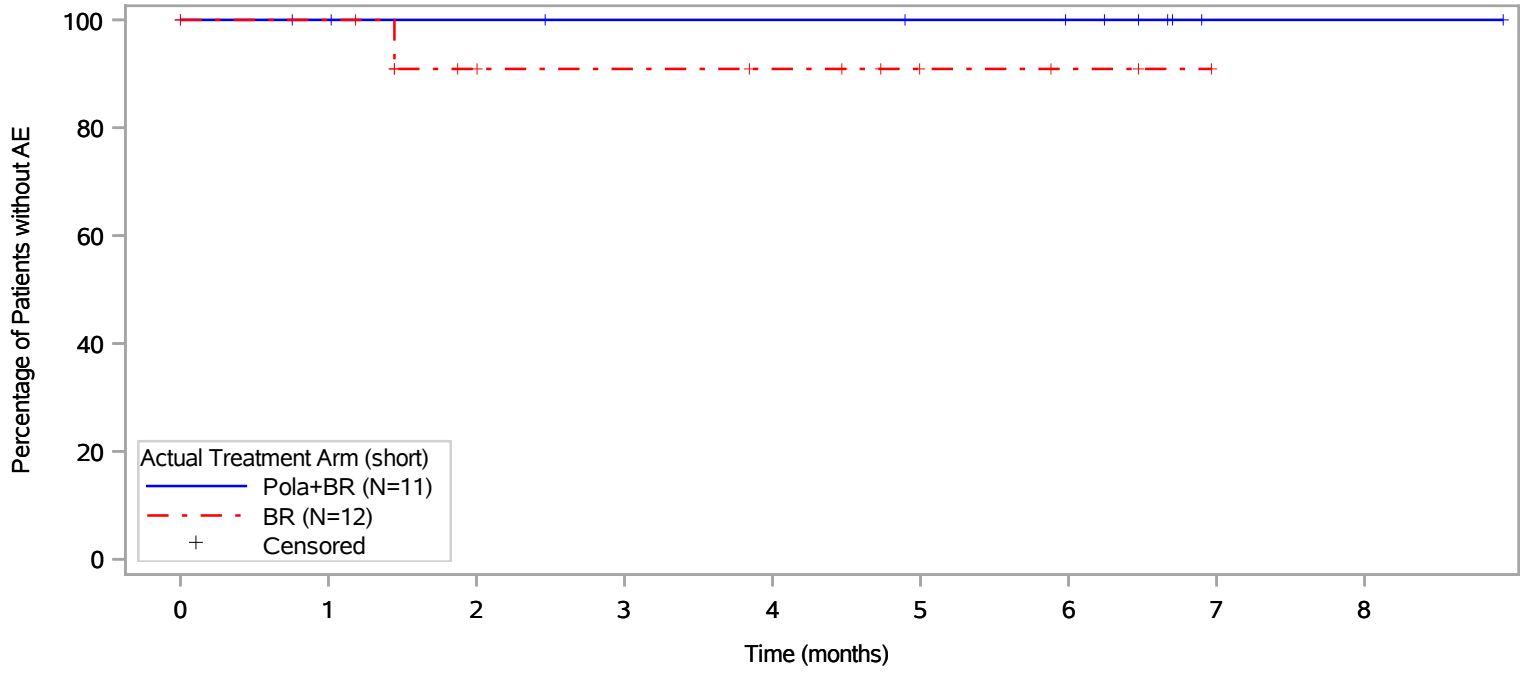
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, INFLUENZA LIKE ILLNESS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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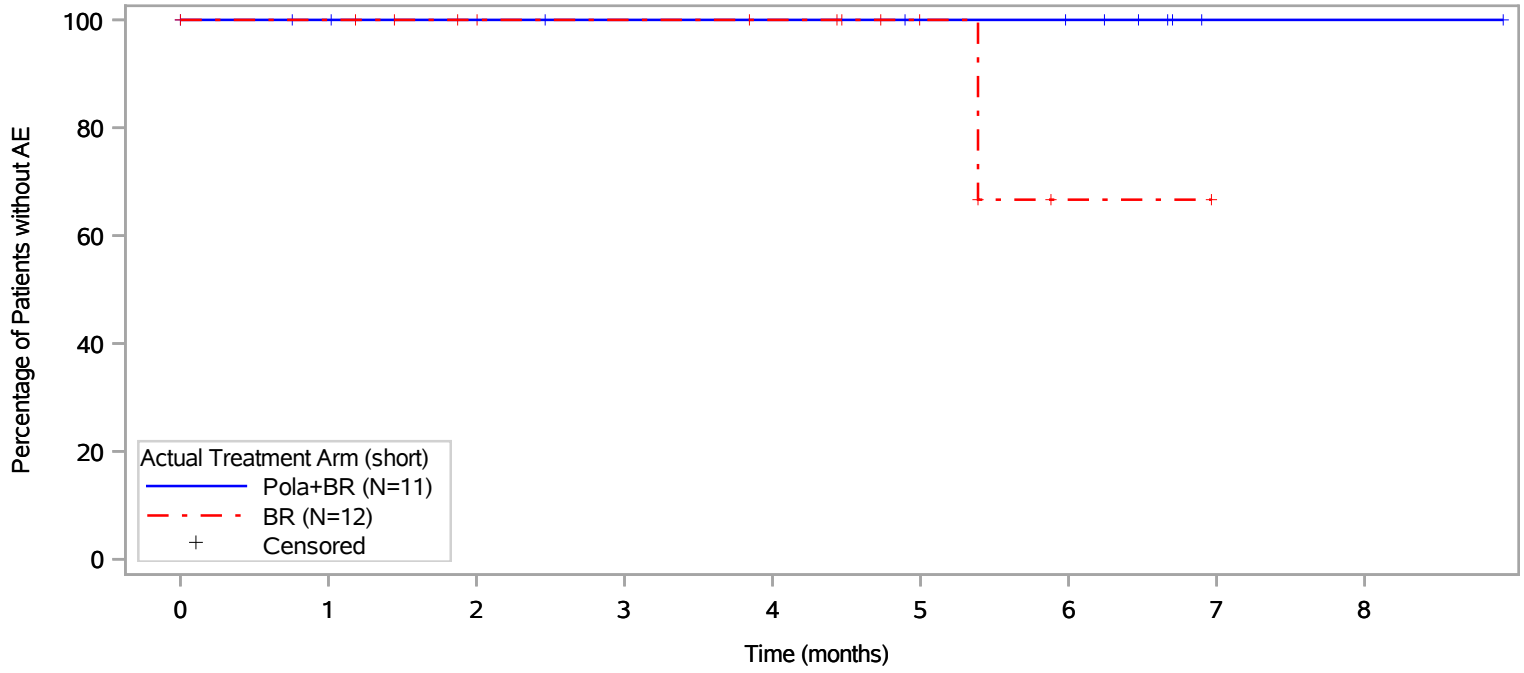
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MUCOSAL INFLAMMATION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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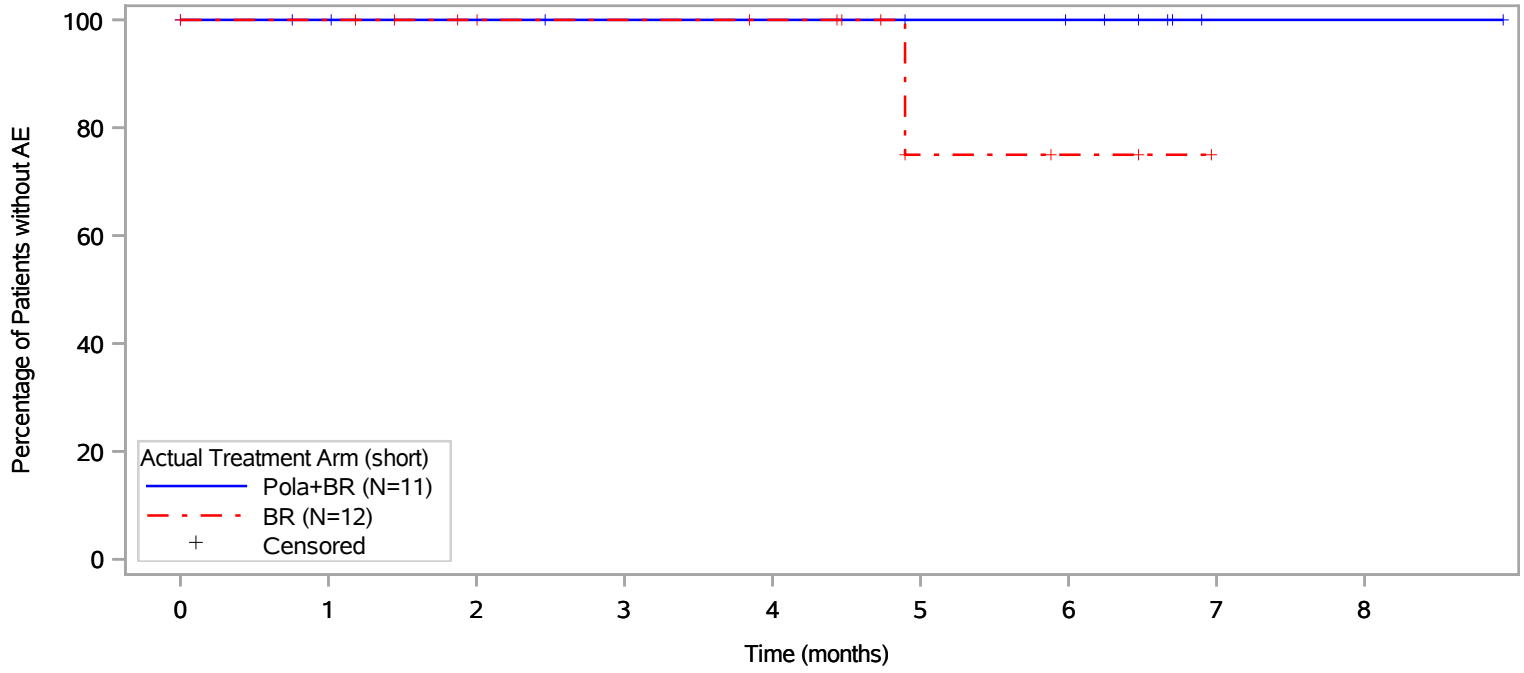
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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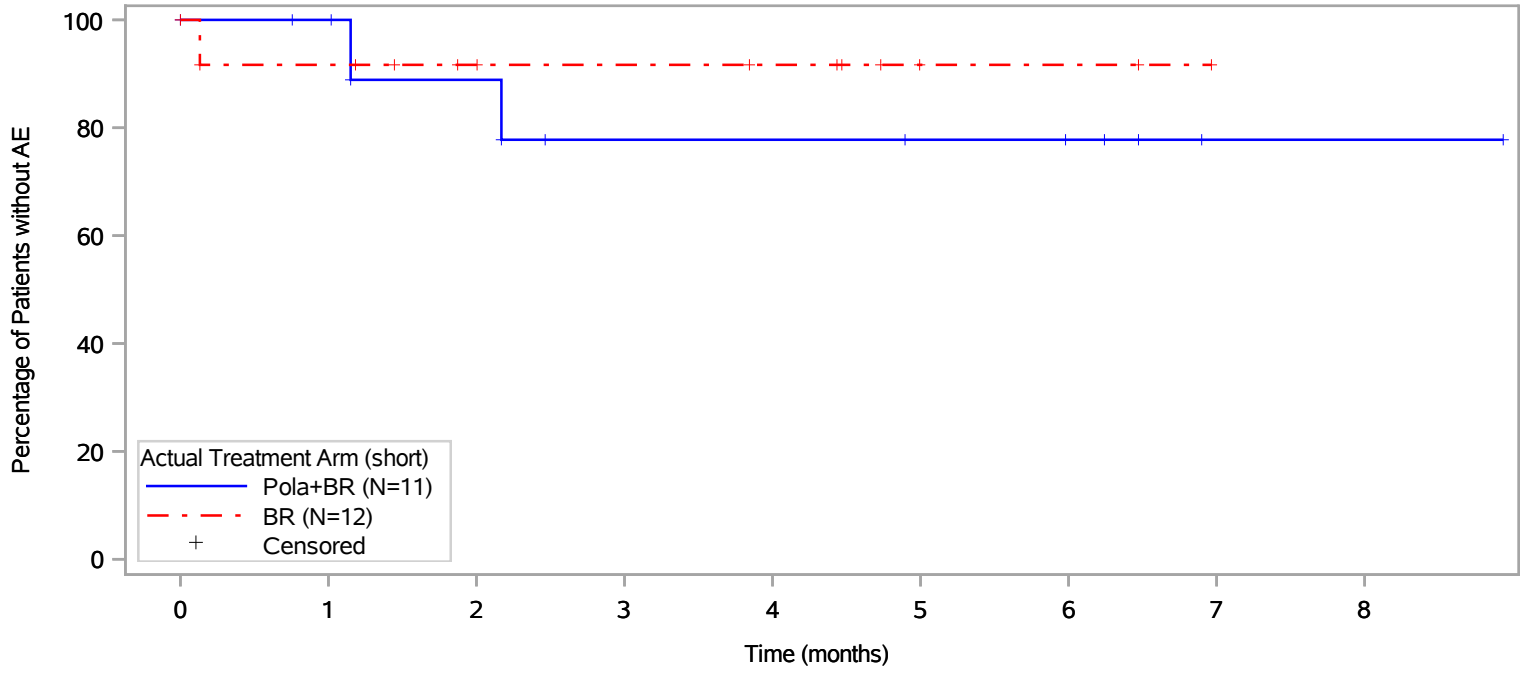
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA



Patients at risk									
Pola+BR (N=11)	11	10	8	6	6	5	4	1	1
BR (N=12)	12	11	8	7	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	8	8
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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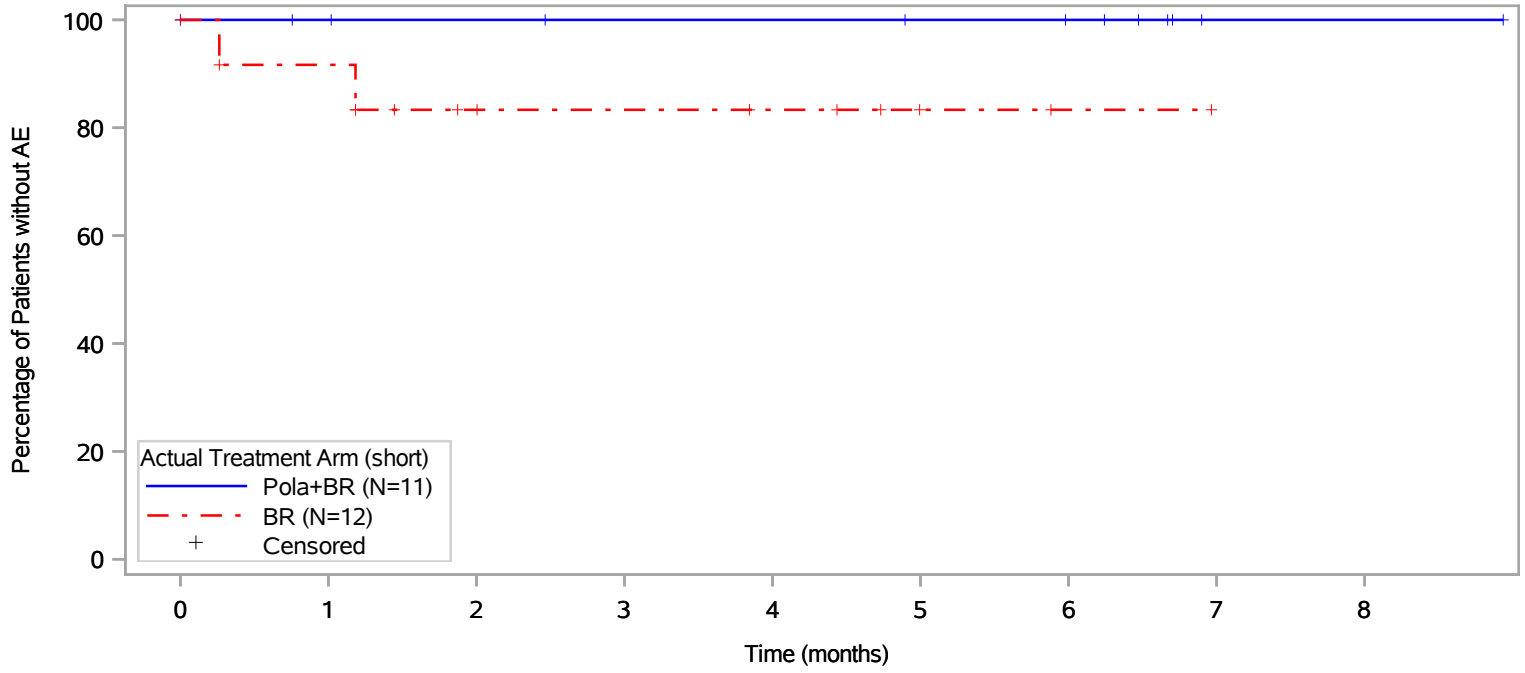
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	7	6	5	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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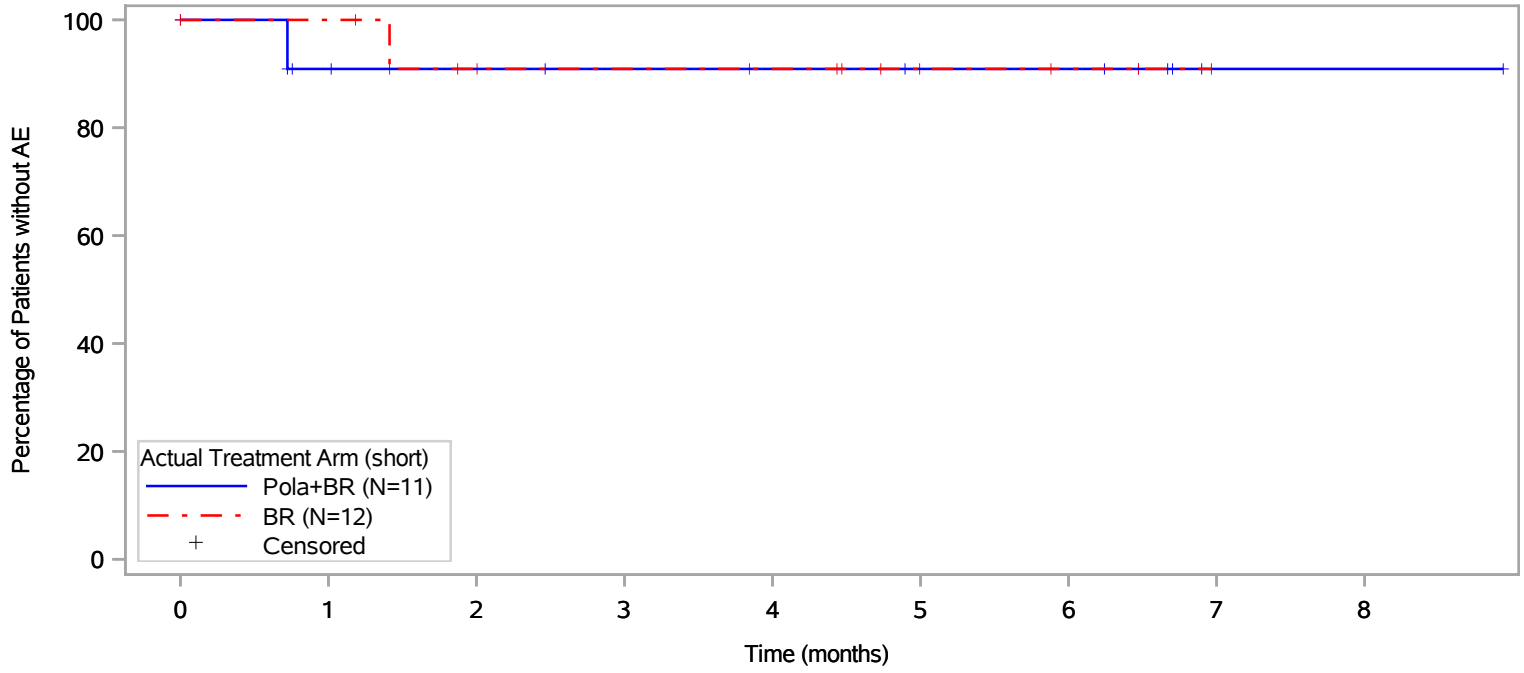
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PAIN

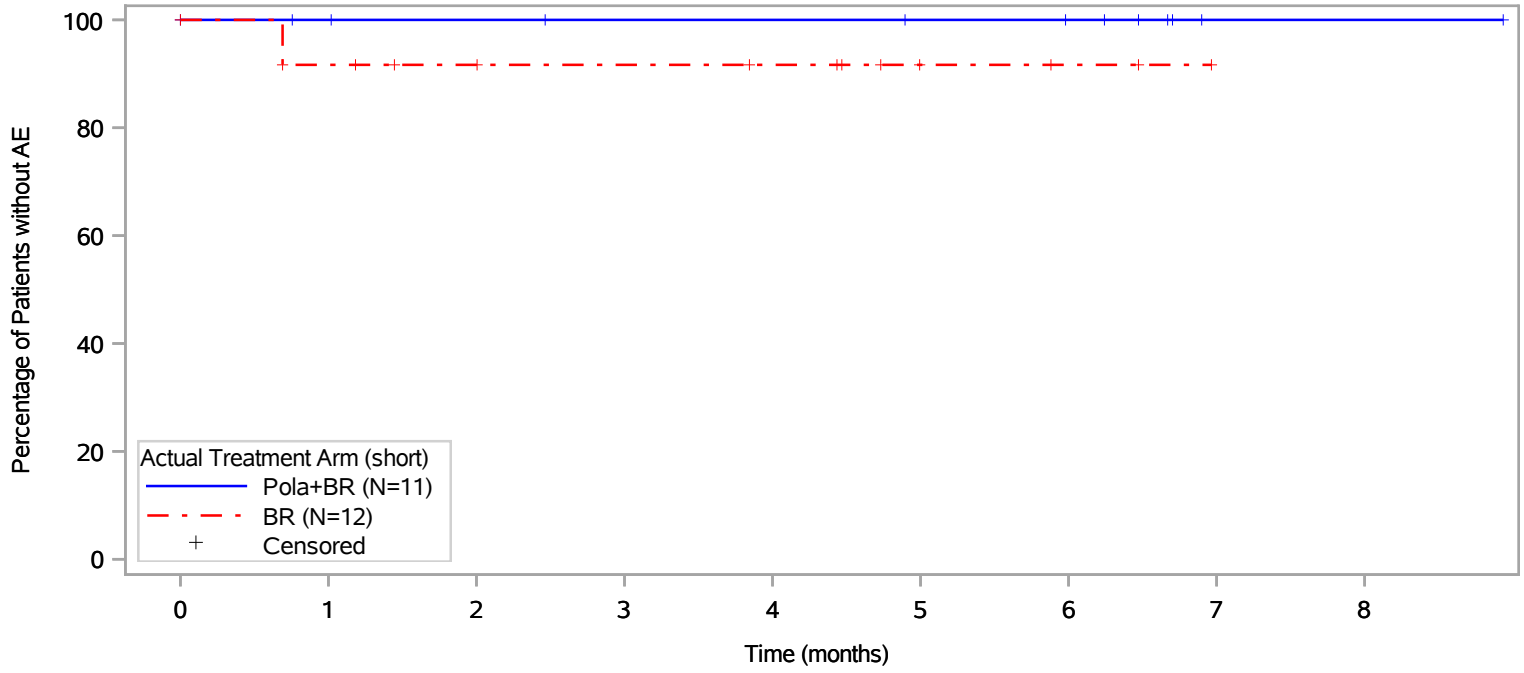


Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PERIPHERAL SWELLING



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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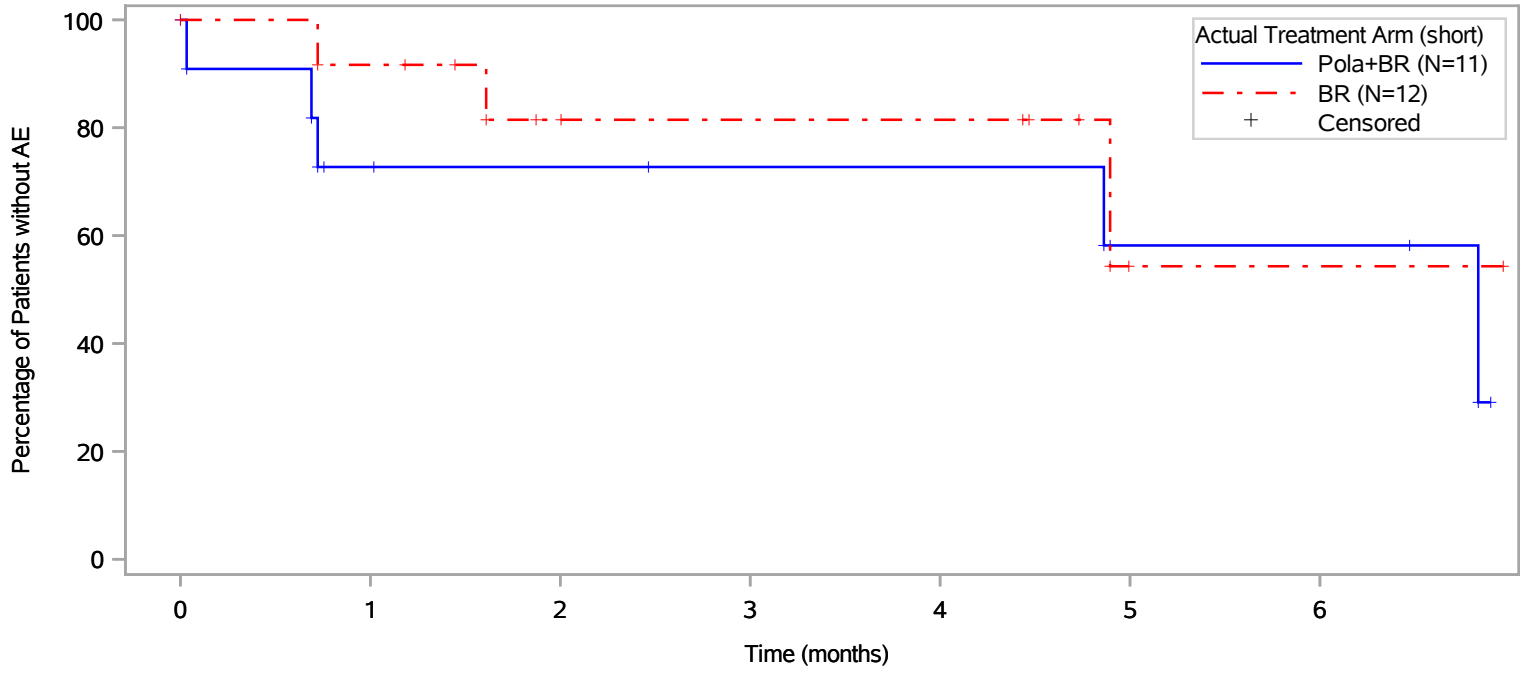
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk							
Pola+BR (N=11)	11	7	6	5	5	3	3
BR (N=12)	12	11	7	6	6	1	1
Patients censored							
Pola+BR (N=11)	0	1	2	3	3	4	4
BR (N=12)	0	0	3	4	4	8	8

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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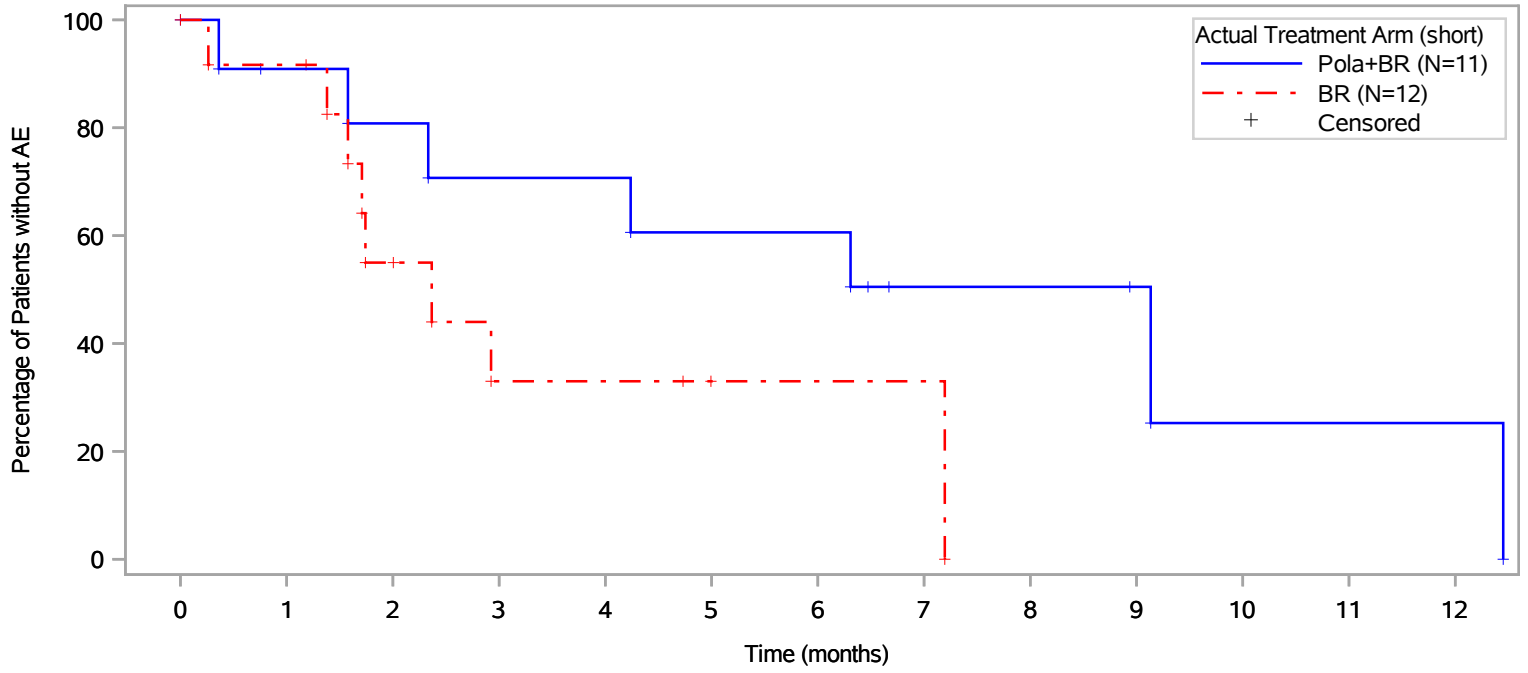
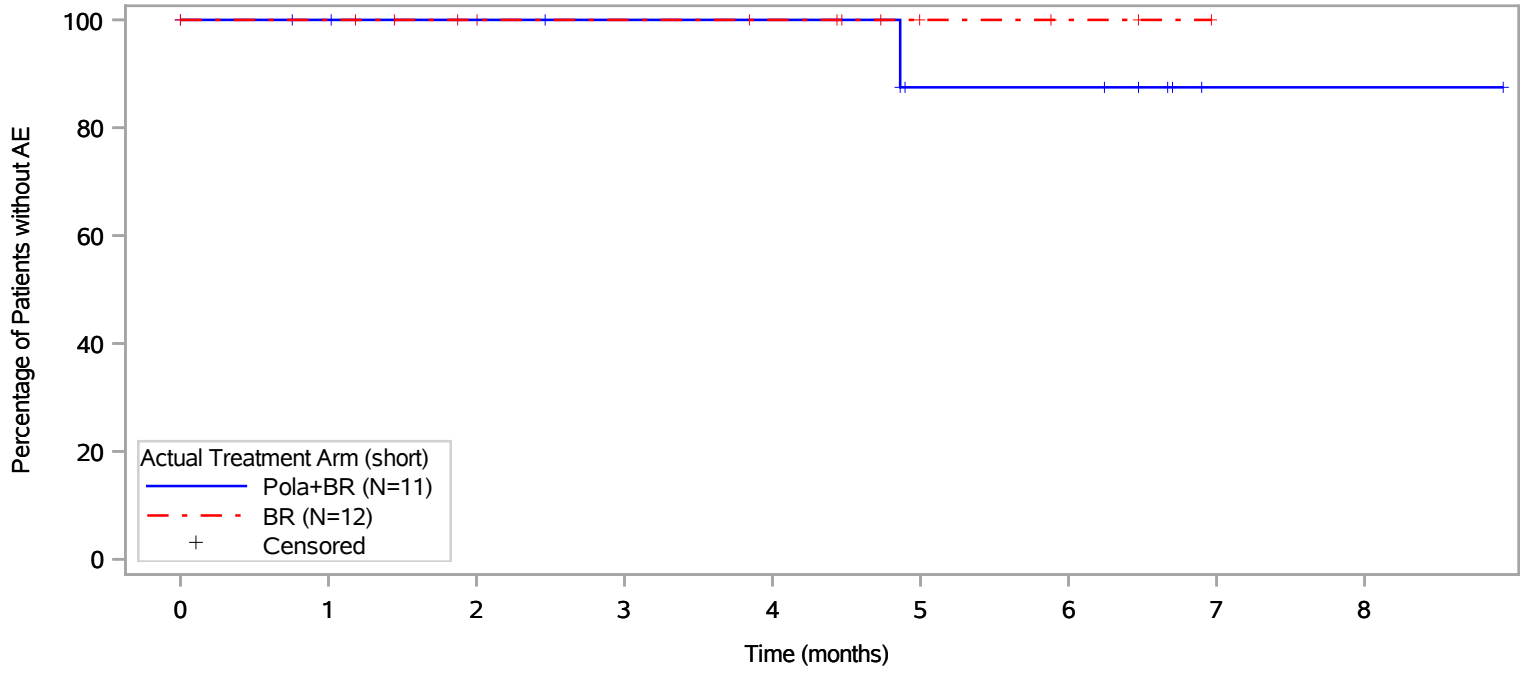
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk													
Pola+BR (N=11)	11	9	8	7	7	6	6	3	3	2	1	1	1
BR (N=12)	12	11	6	3	3	1	1	1	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	1	1	1	1	1	3	3	4	4	4	4
BR (N=12)	0	0	1	2	2	4	4	4	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CEREBRAL TOXOPLASMOSIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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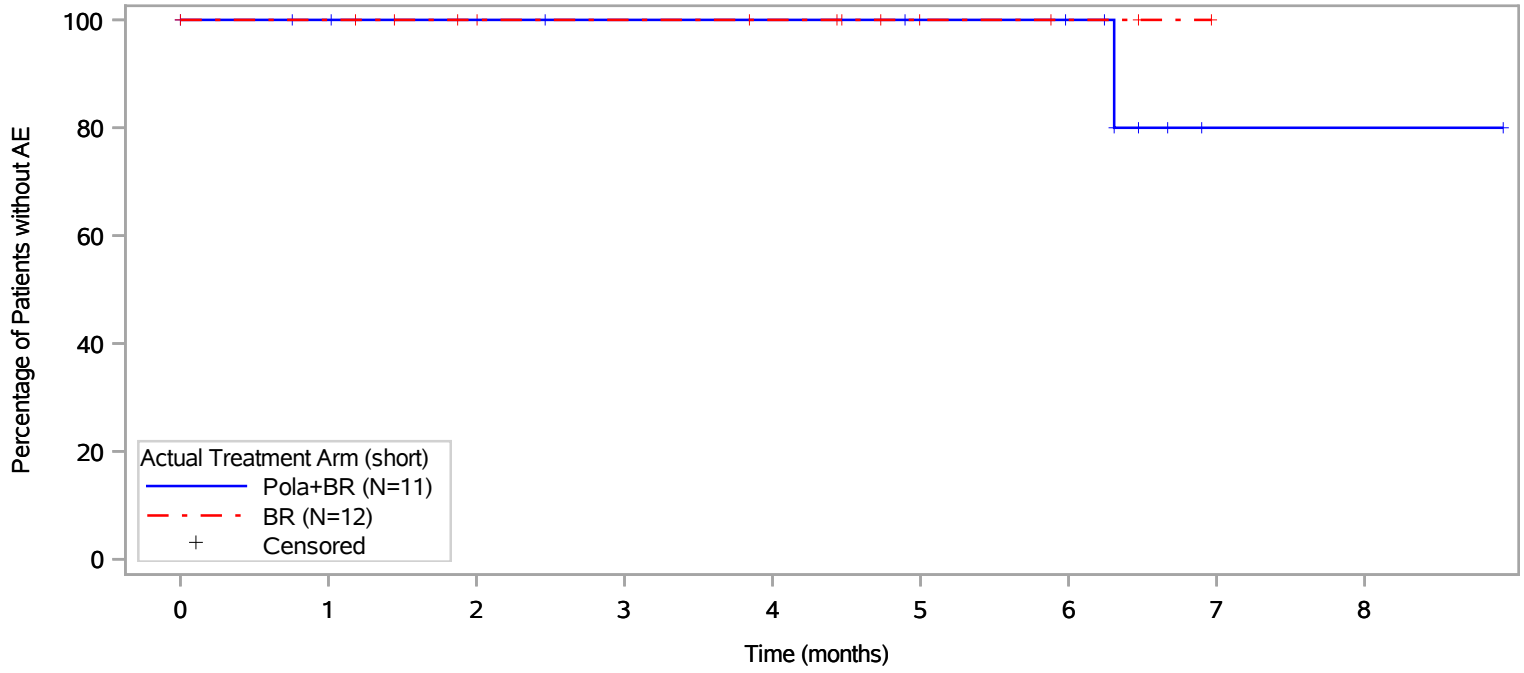
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CYSTITIS



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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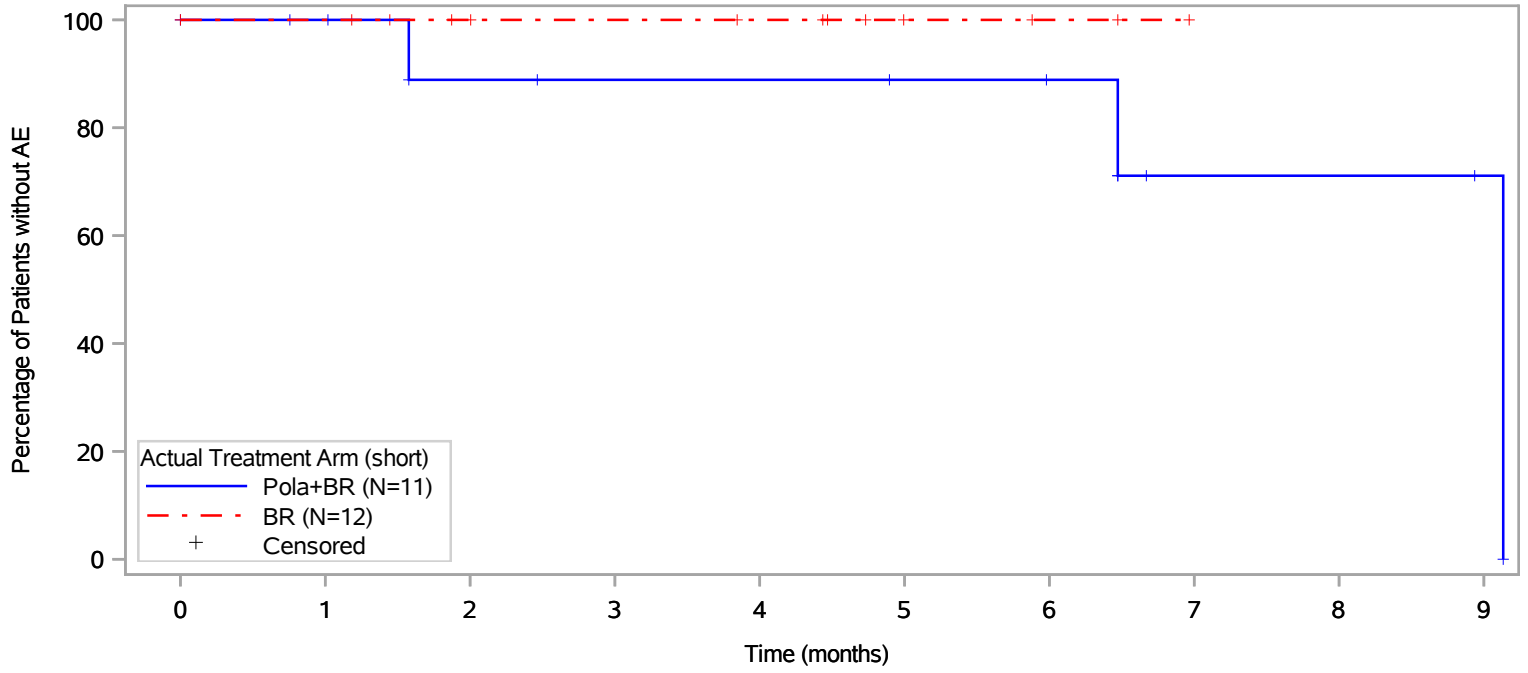
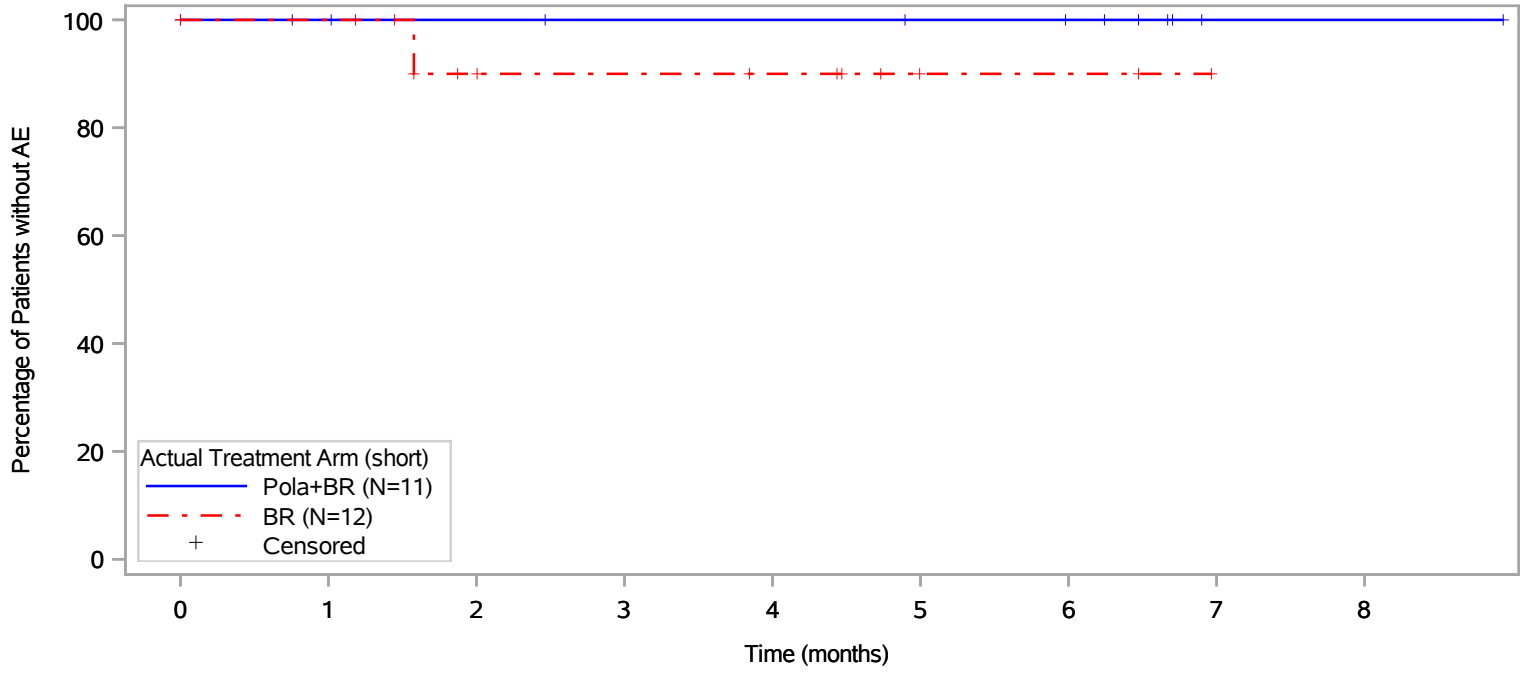
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES VIRUS INFECTION



Patients at risk										
Pola+BR (N=11)	11	10	8	7	7	6	5	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored										
Pola+BR (N=11)	0	1	2	3	3	4	5	7	7	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	7	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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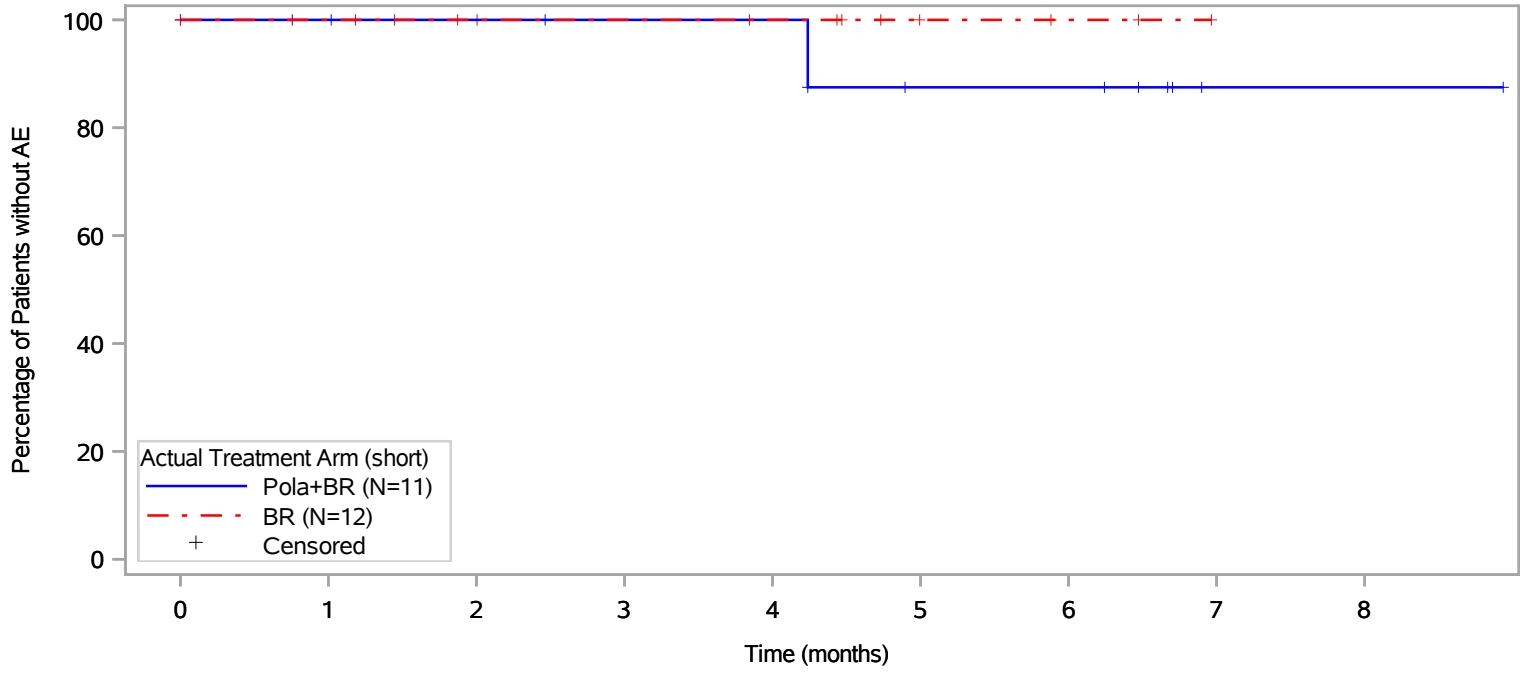
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, LARYNGITIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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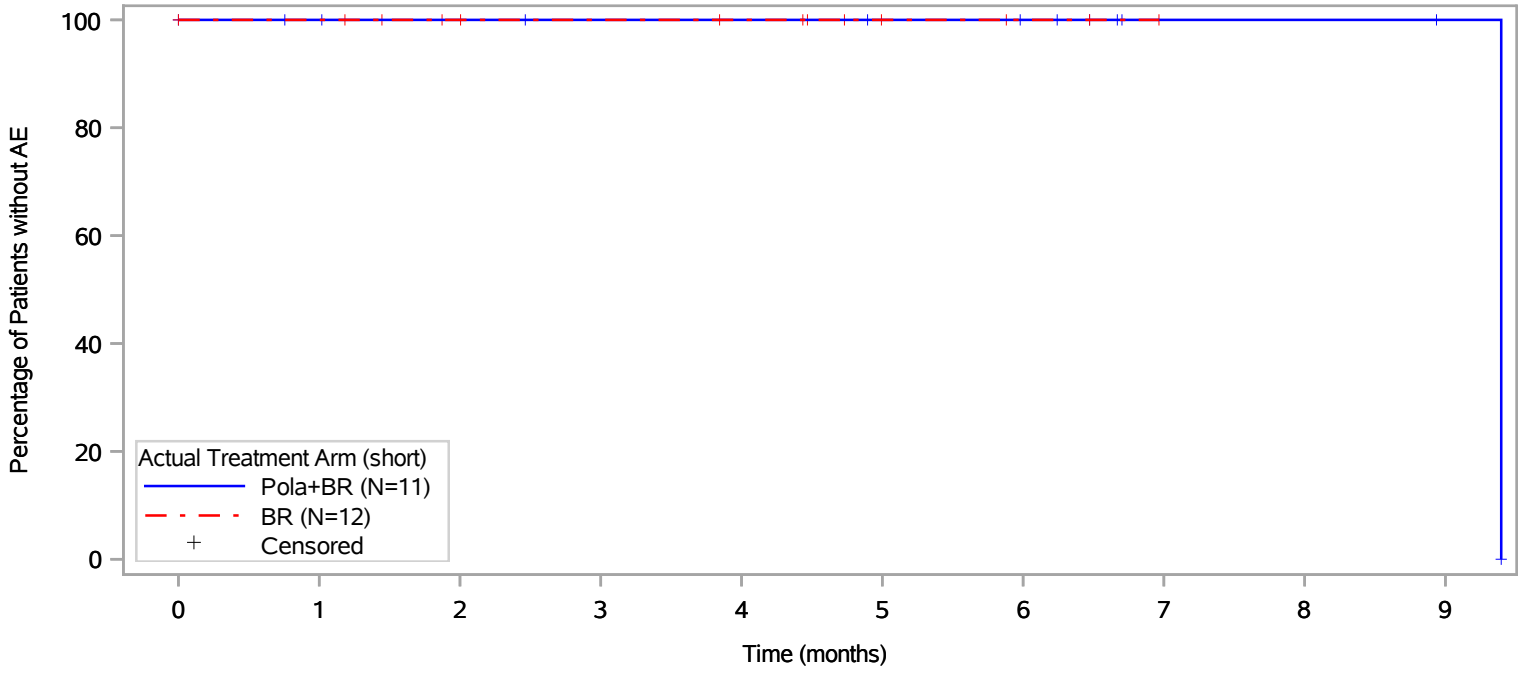
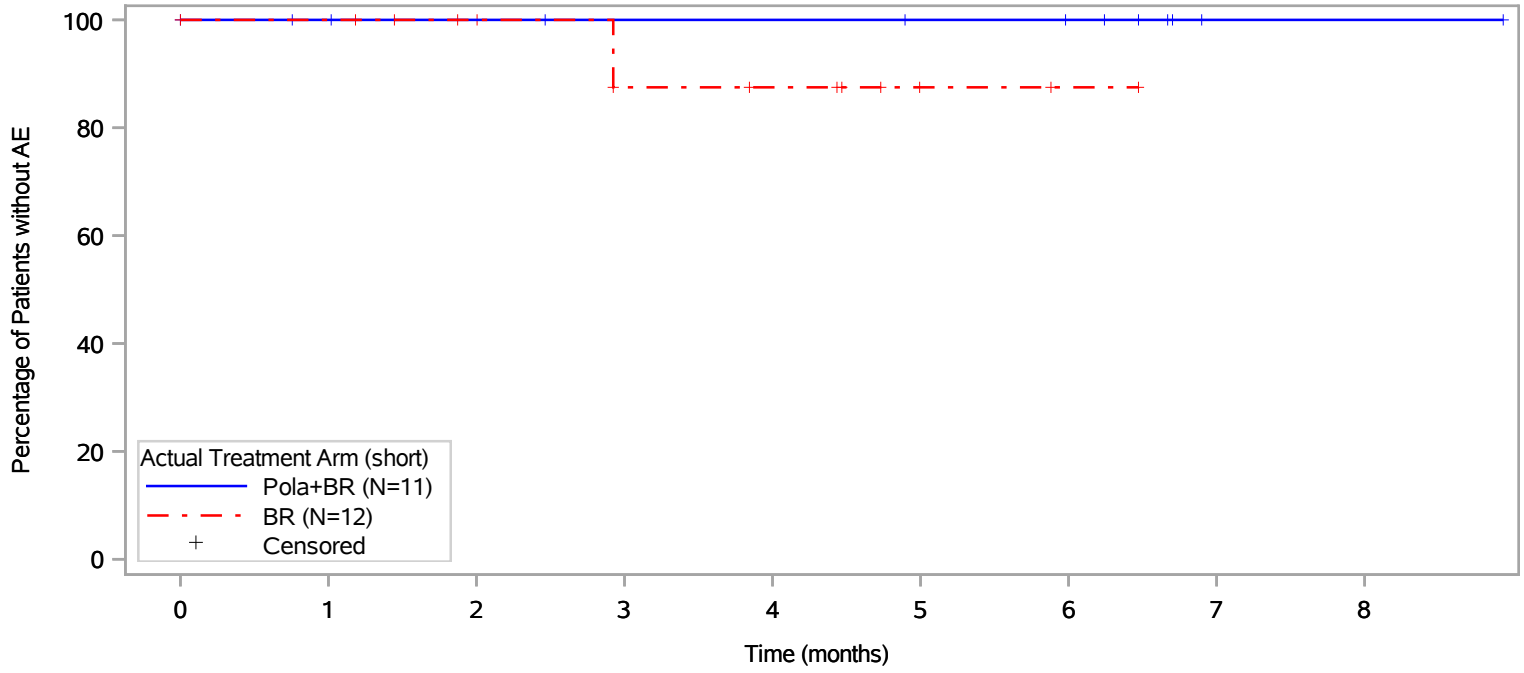
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MENINGOENCEPHALITIS HERPETIC



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NASOPHARYNGITIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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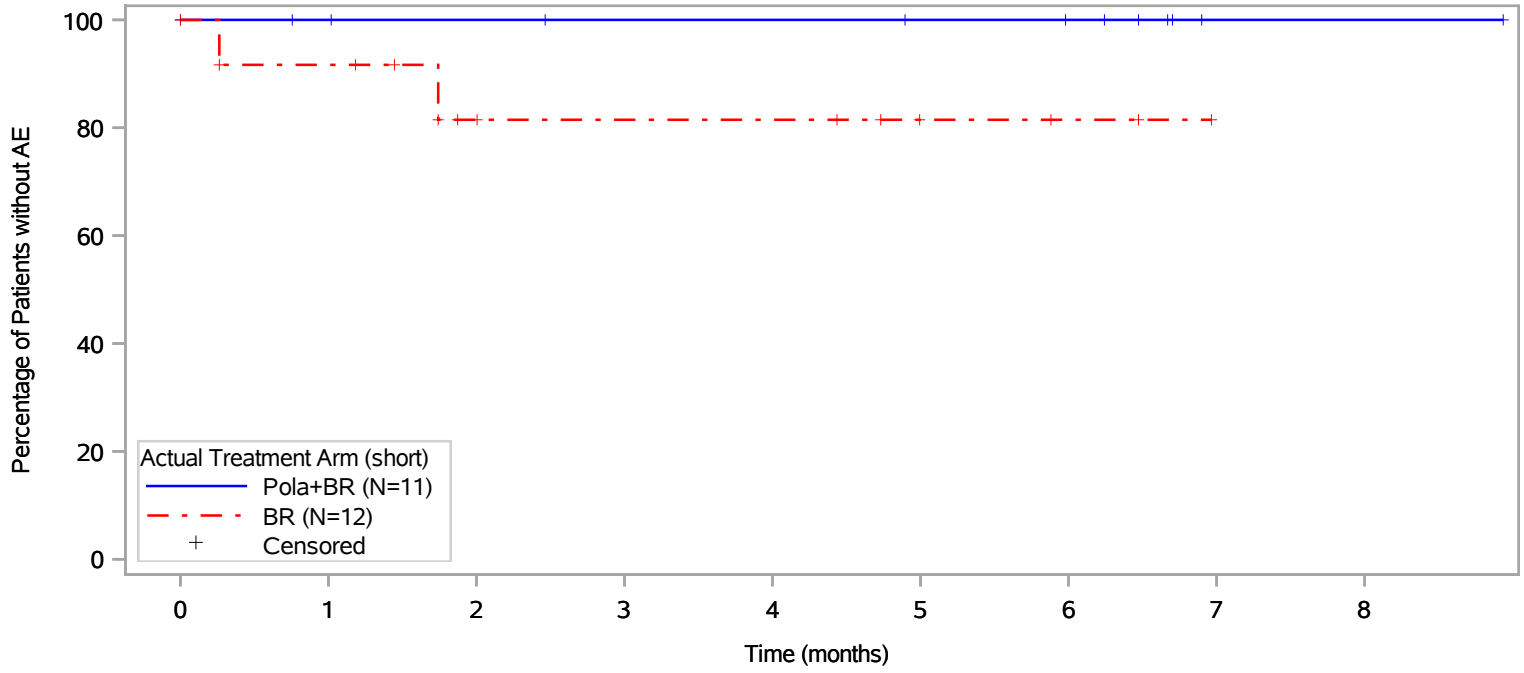
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ORAL HERPES



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	7	6	6	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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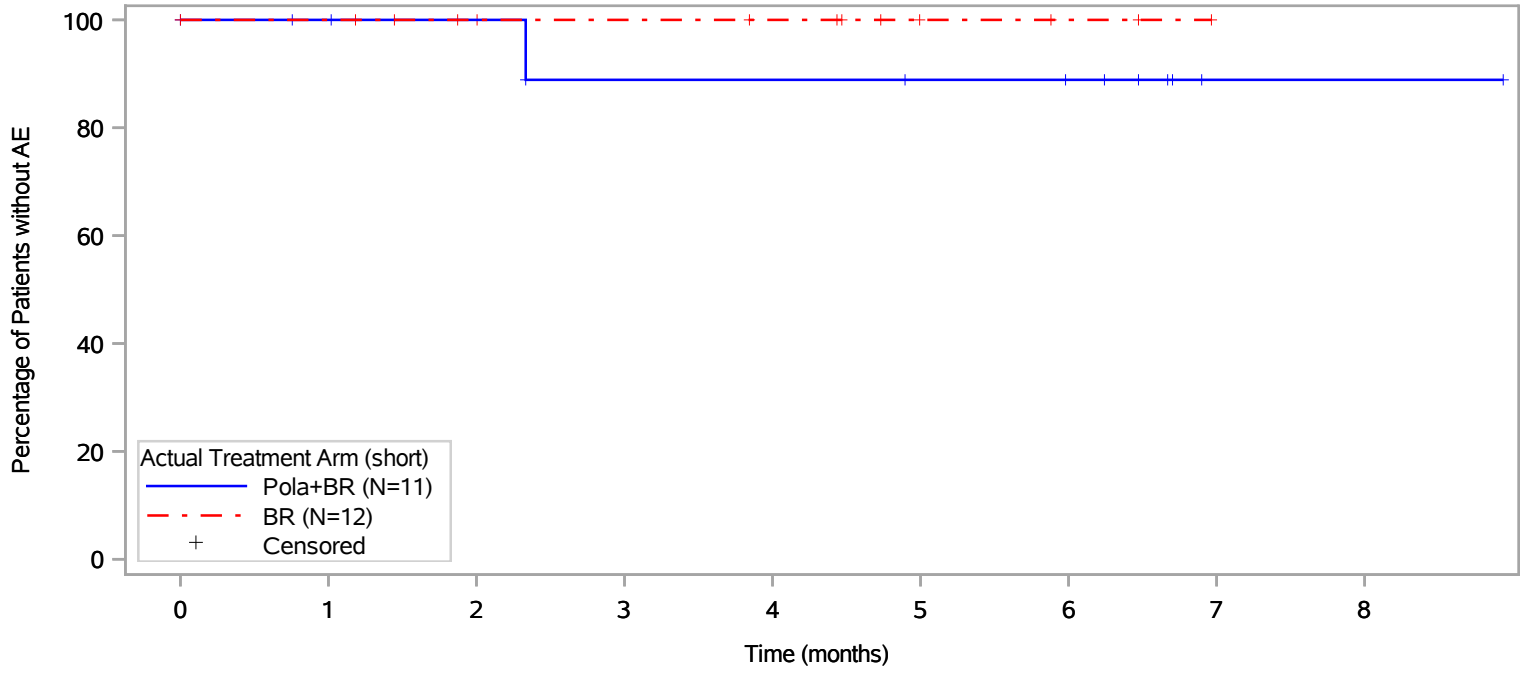
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, OROPHARYNGEAL CANDIDIASIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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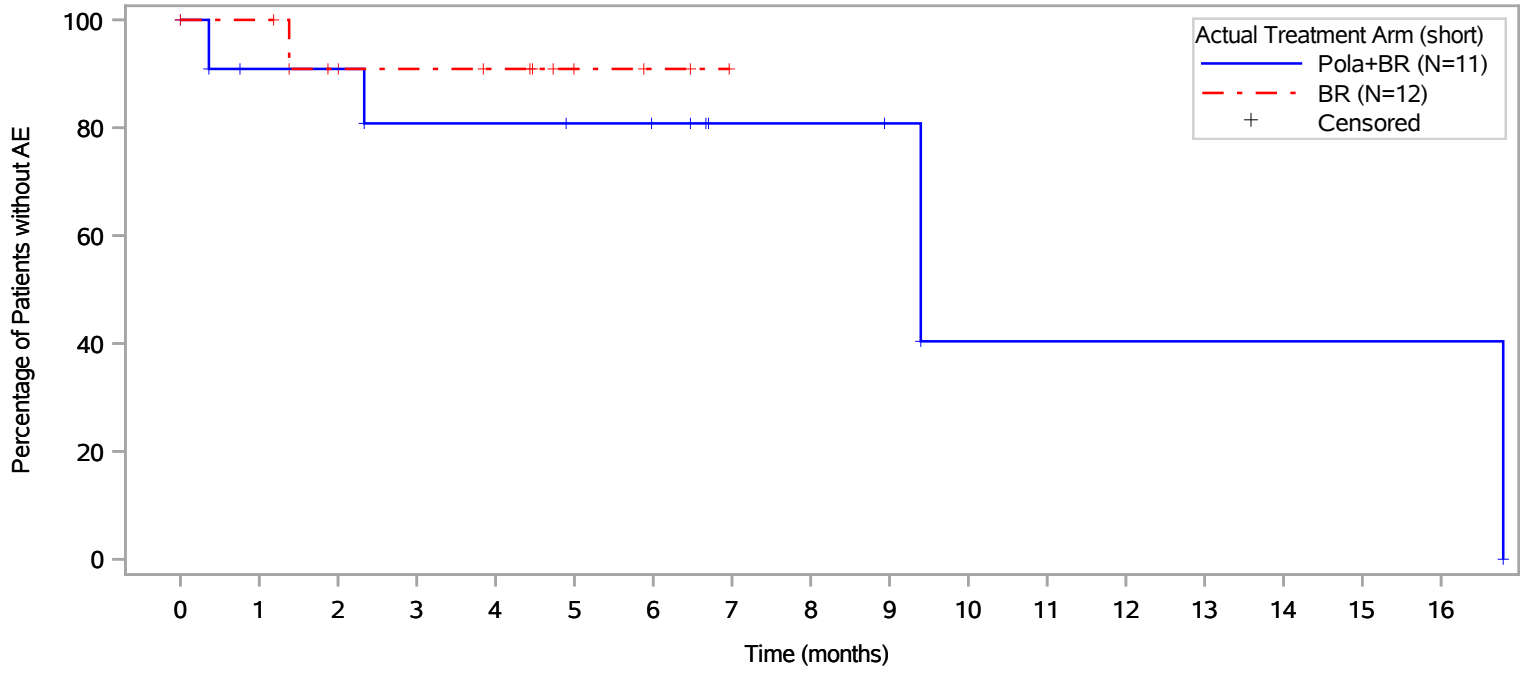
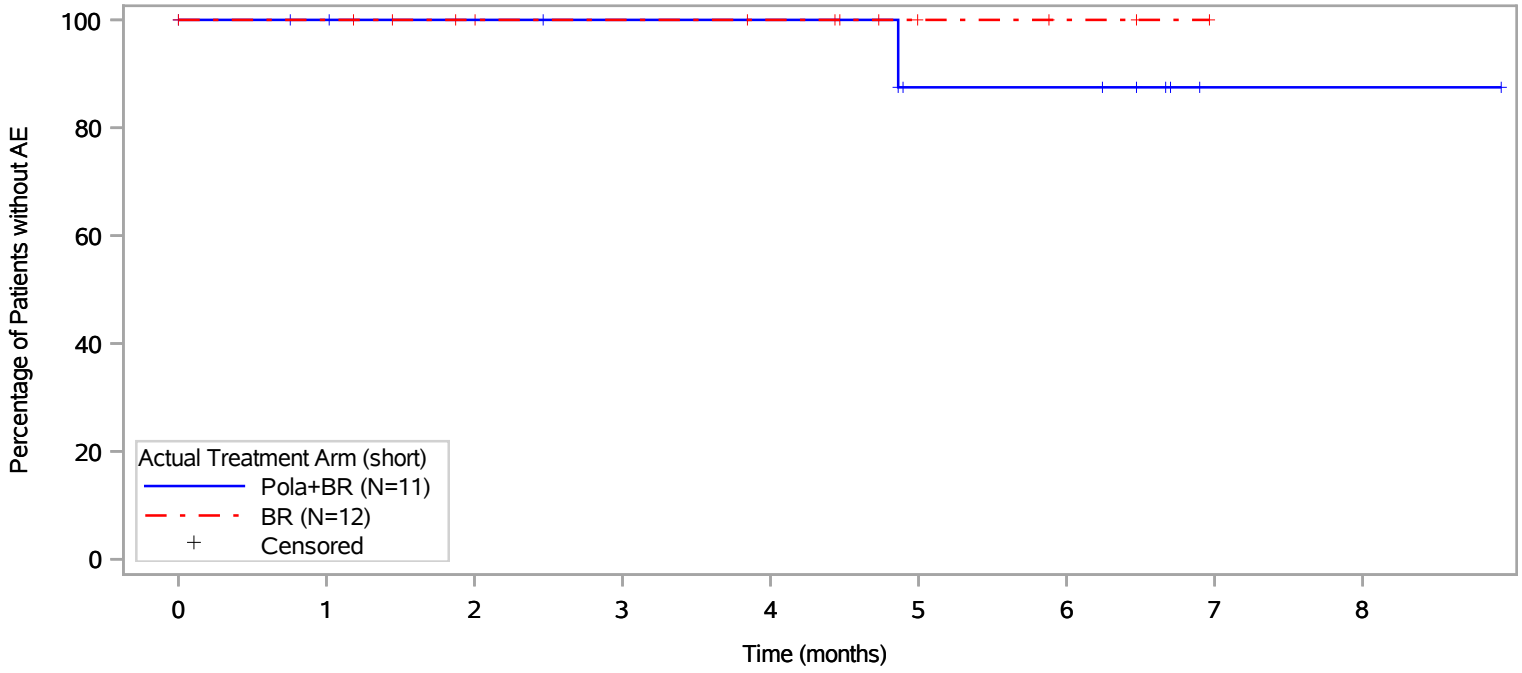
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk																	
Pola+BR (N=11)	11	9	9	8	8	7	6	3	3	2	1	1	1	1	1	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																	
Pola+BR (N=11)	0	1	1	1	1	2	3	6	6	7	7	7	7	7	7	7	7
BR (N=12)	0	0	2	3	4	8	9	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA CYTOMEGALOVIRAL



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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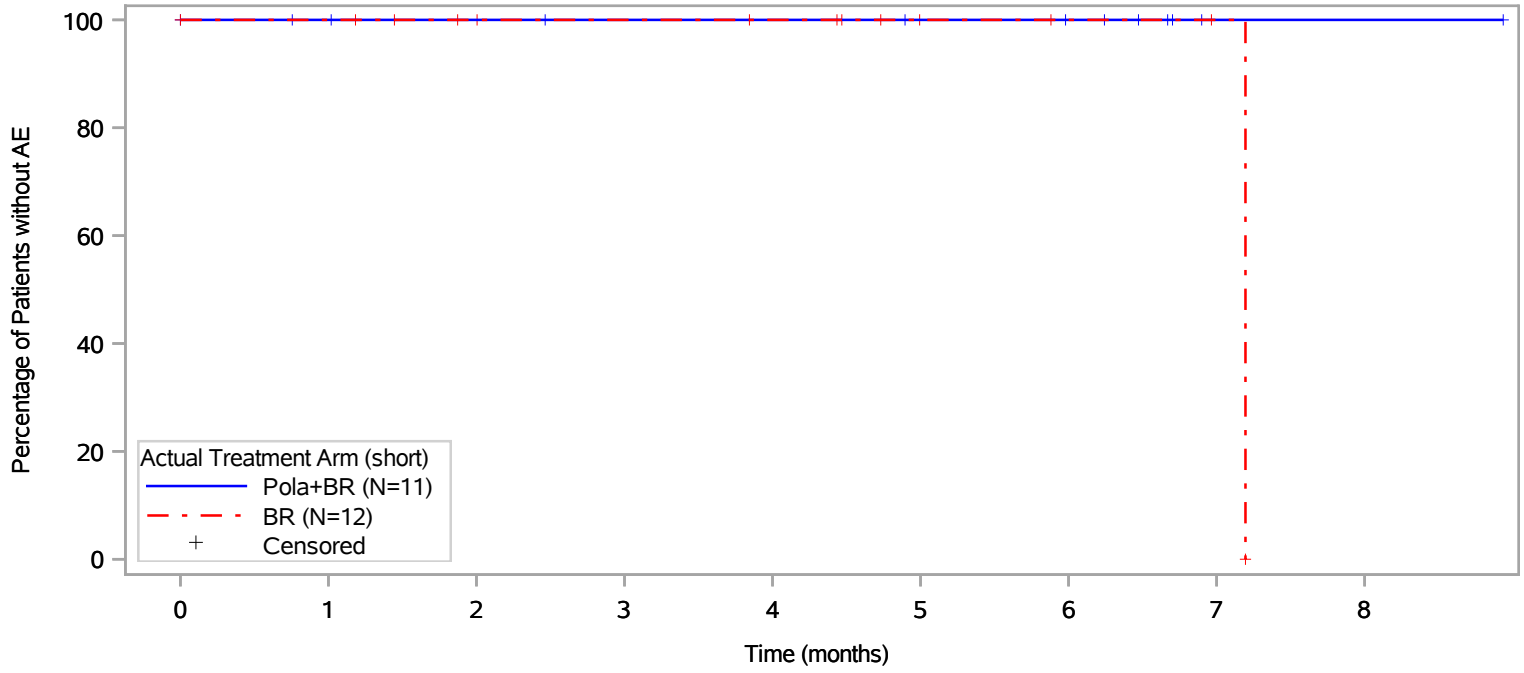
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, POST PROCEDURAL INFECTION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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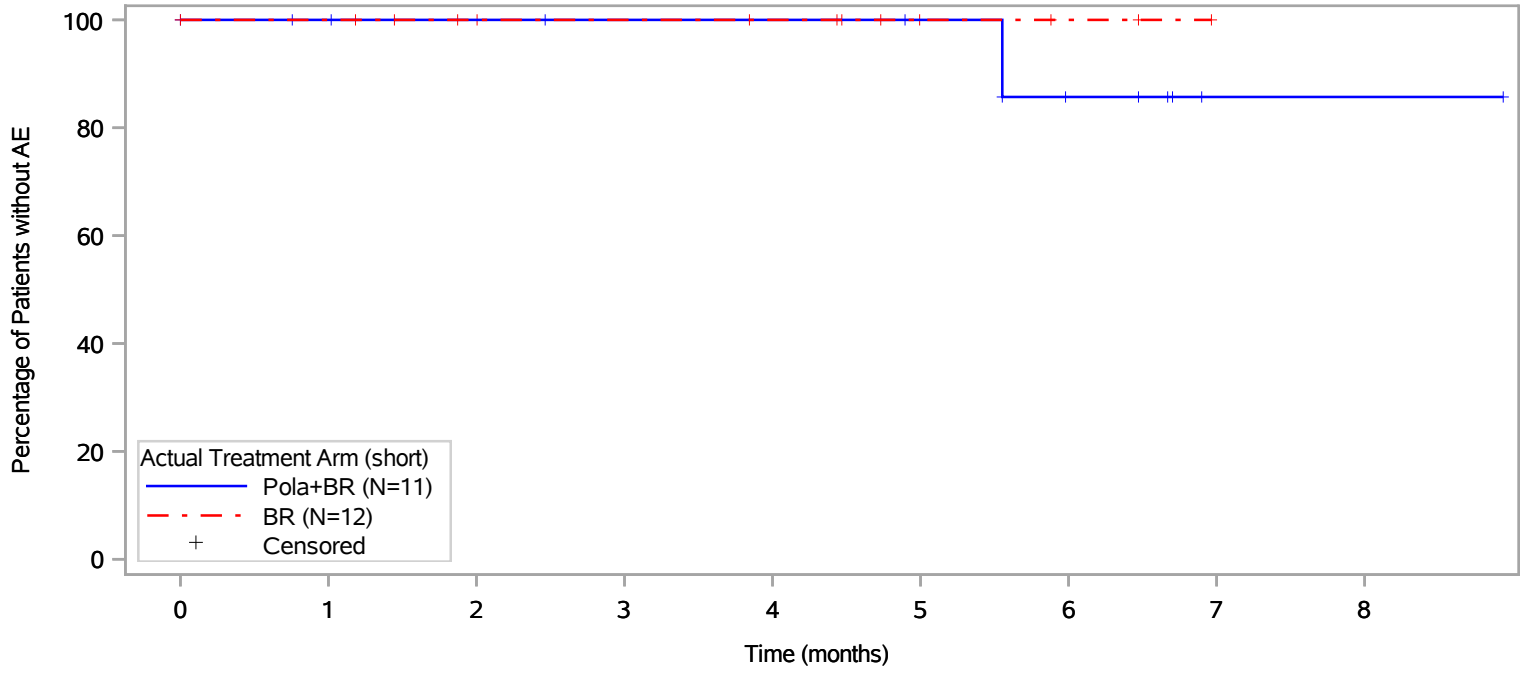
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, RHINITIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
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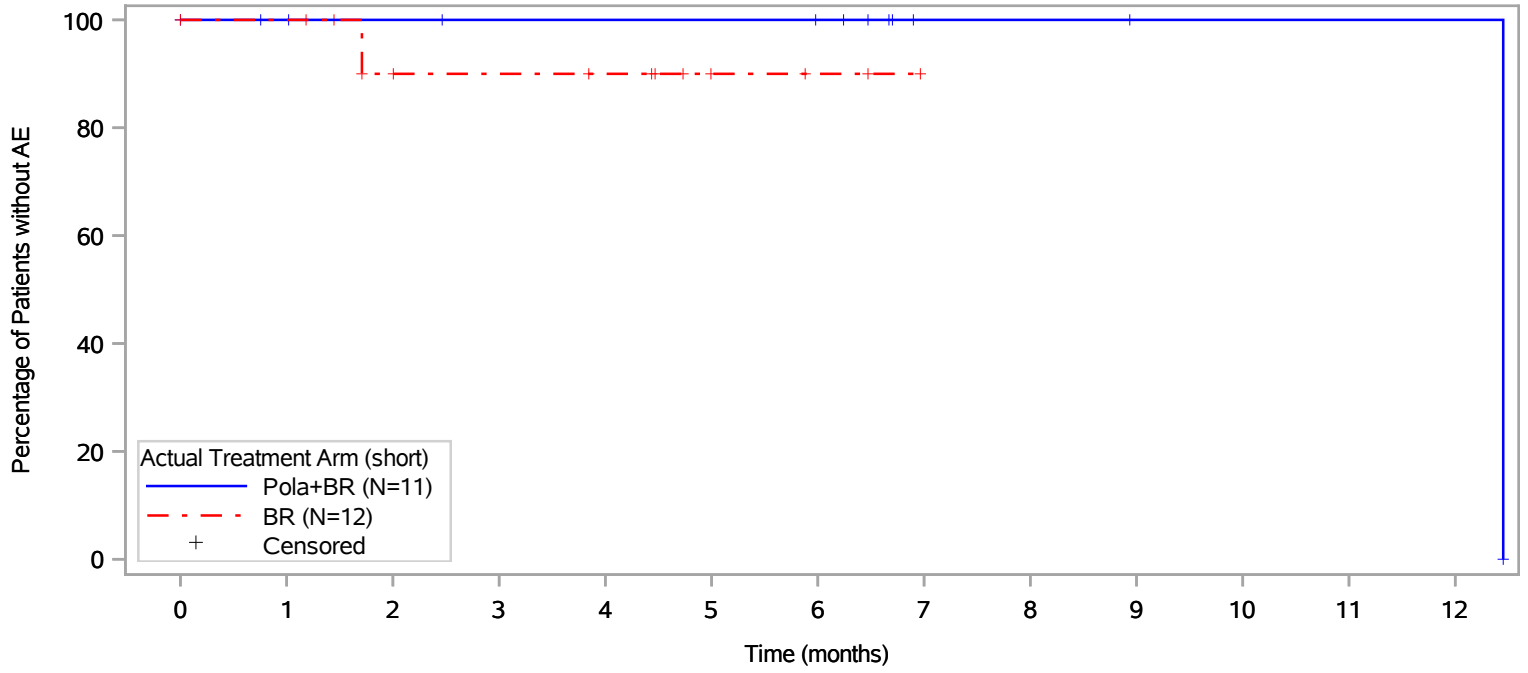
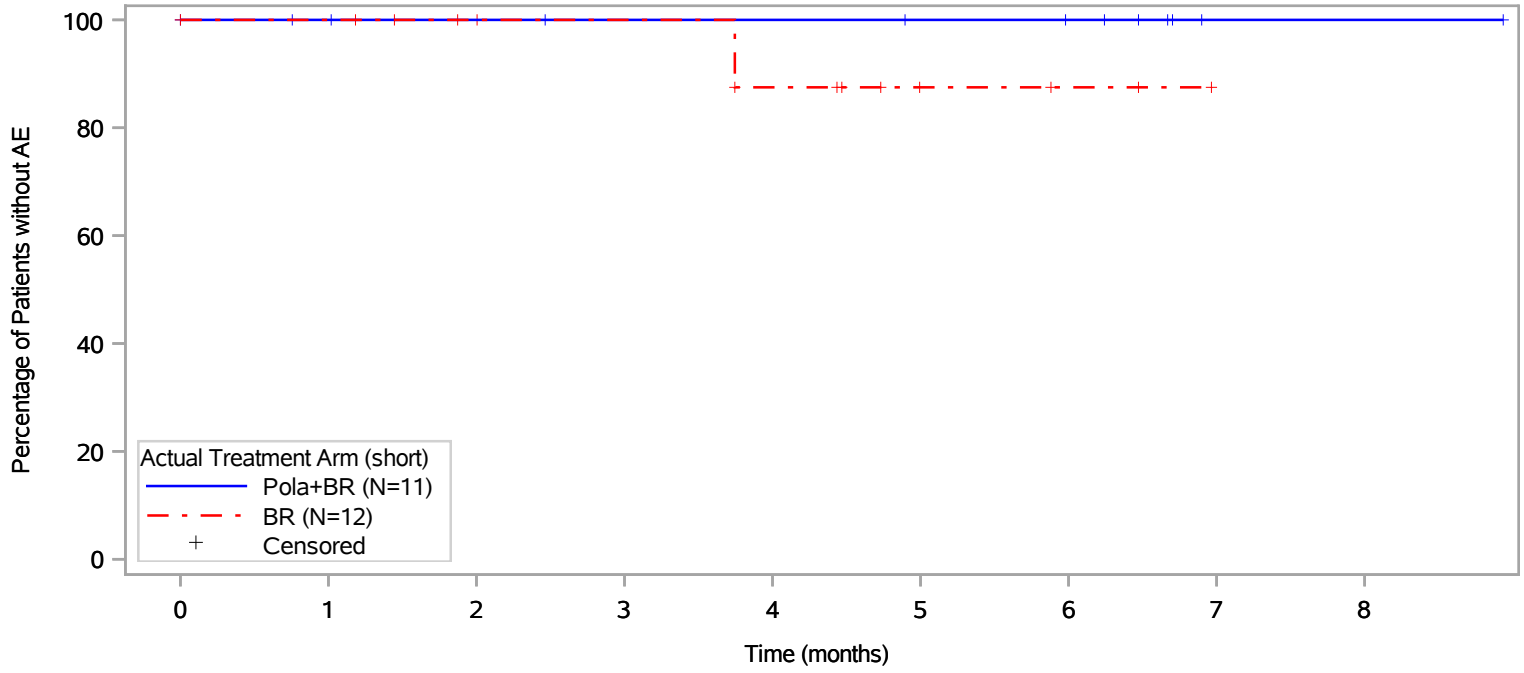
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk													
Pola+BR (N=11)	11	10	9	8	8	8	7	2	2	1	1	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	2	3	3	3	4	9	9	10	10	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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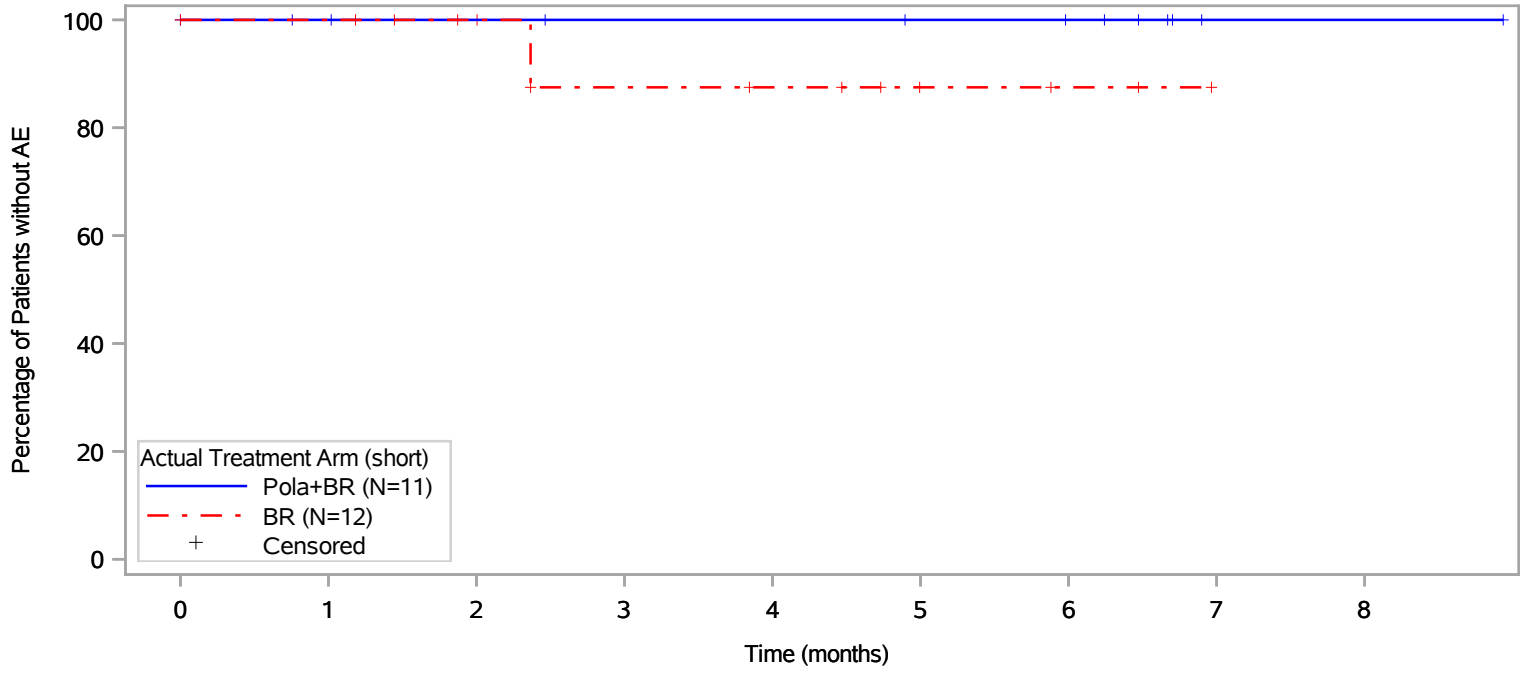
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SINUSITIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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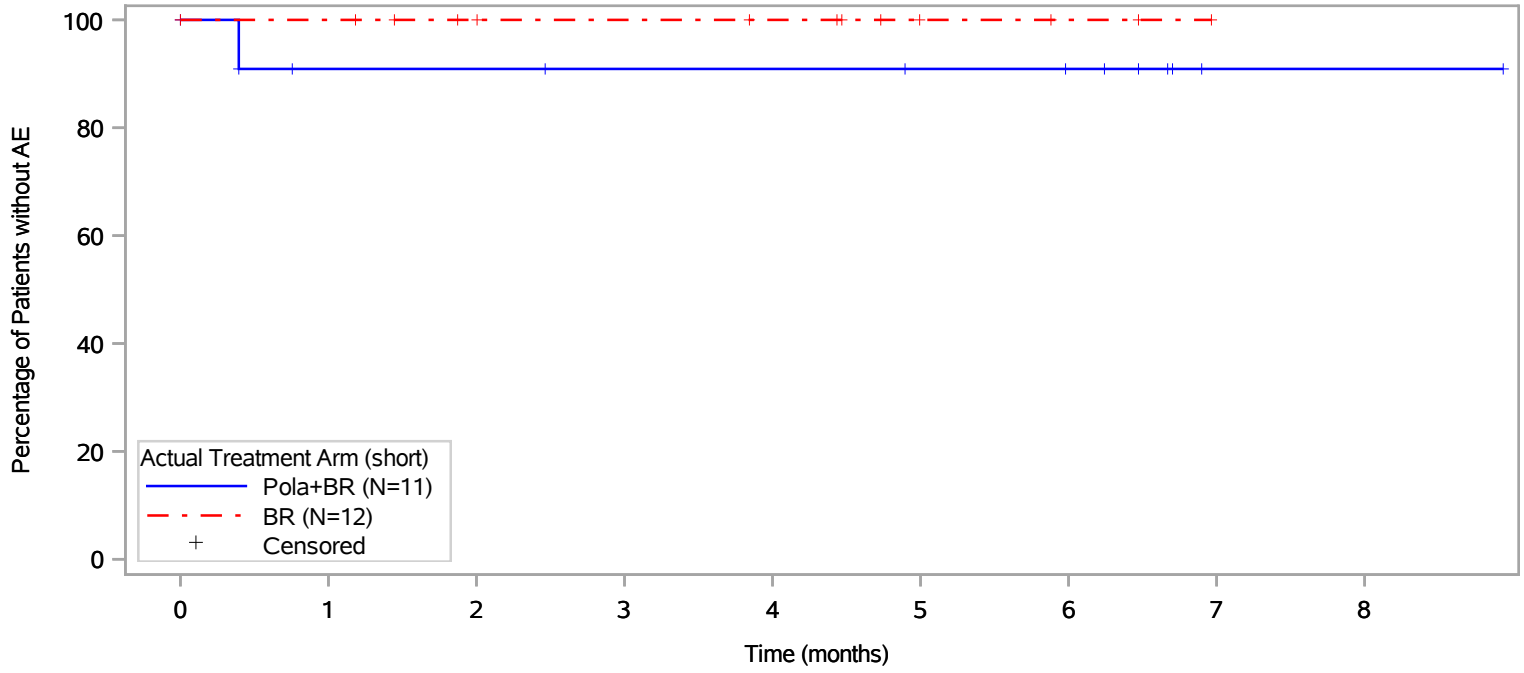
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, STAPHYLOCOCCAL INFECTION

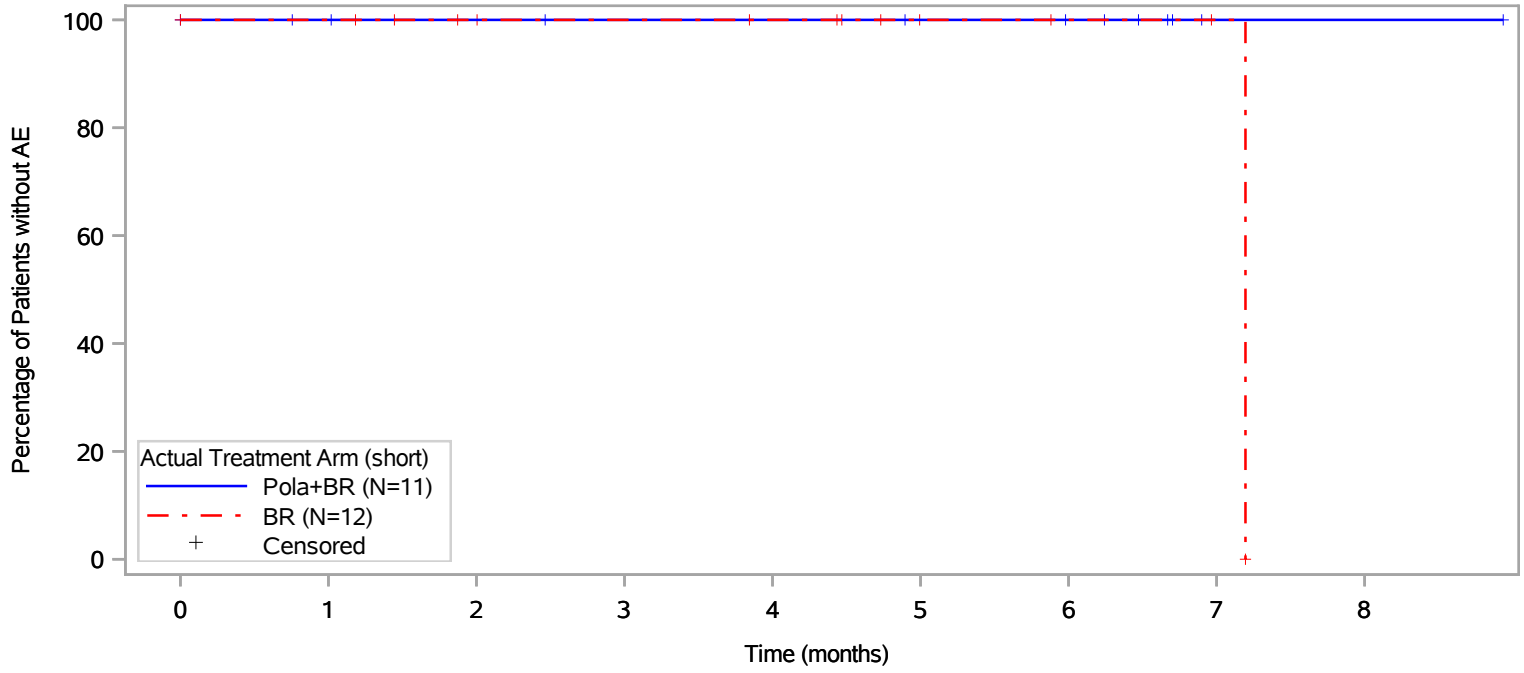


Patients at risk									
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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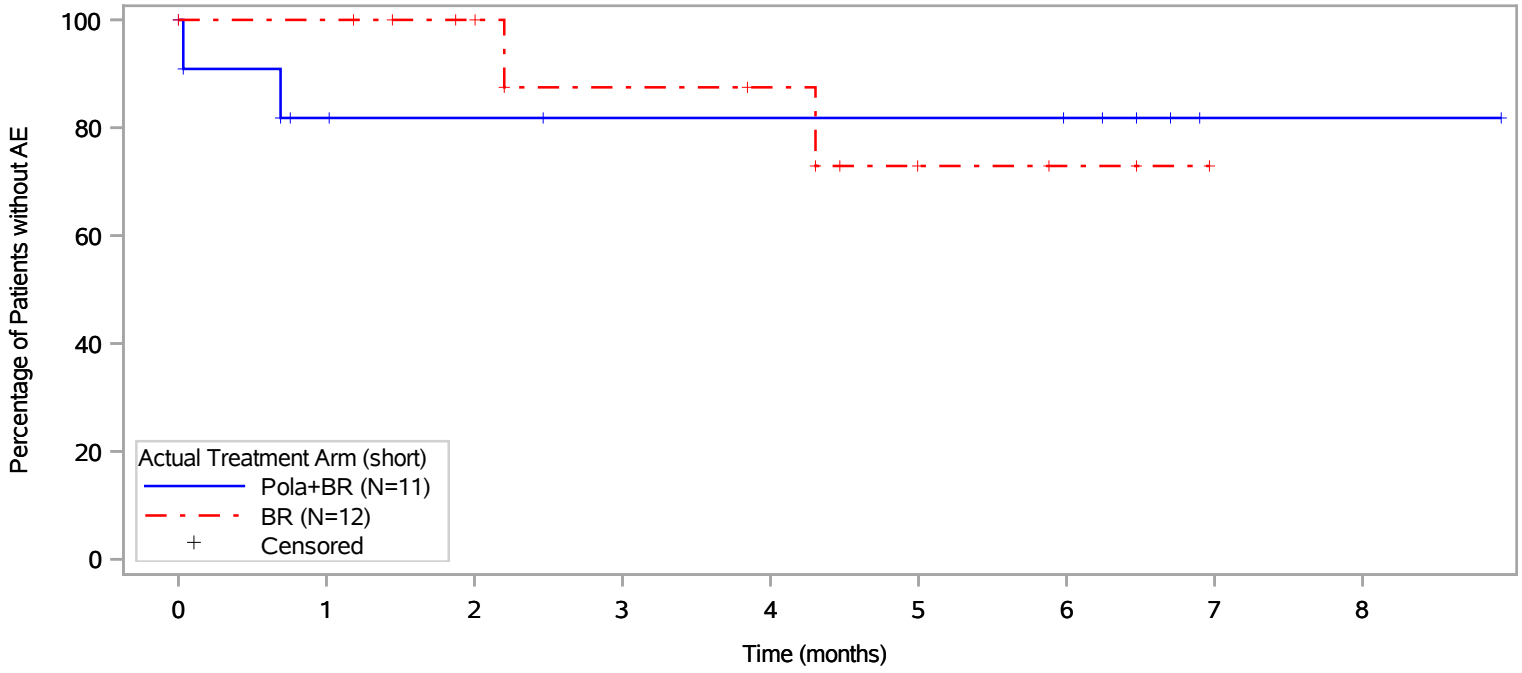
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=11)	11	8	7	6	6	6	5	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	4	8	8
BR (N=12)	0	0	3	4	5	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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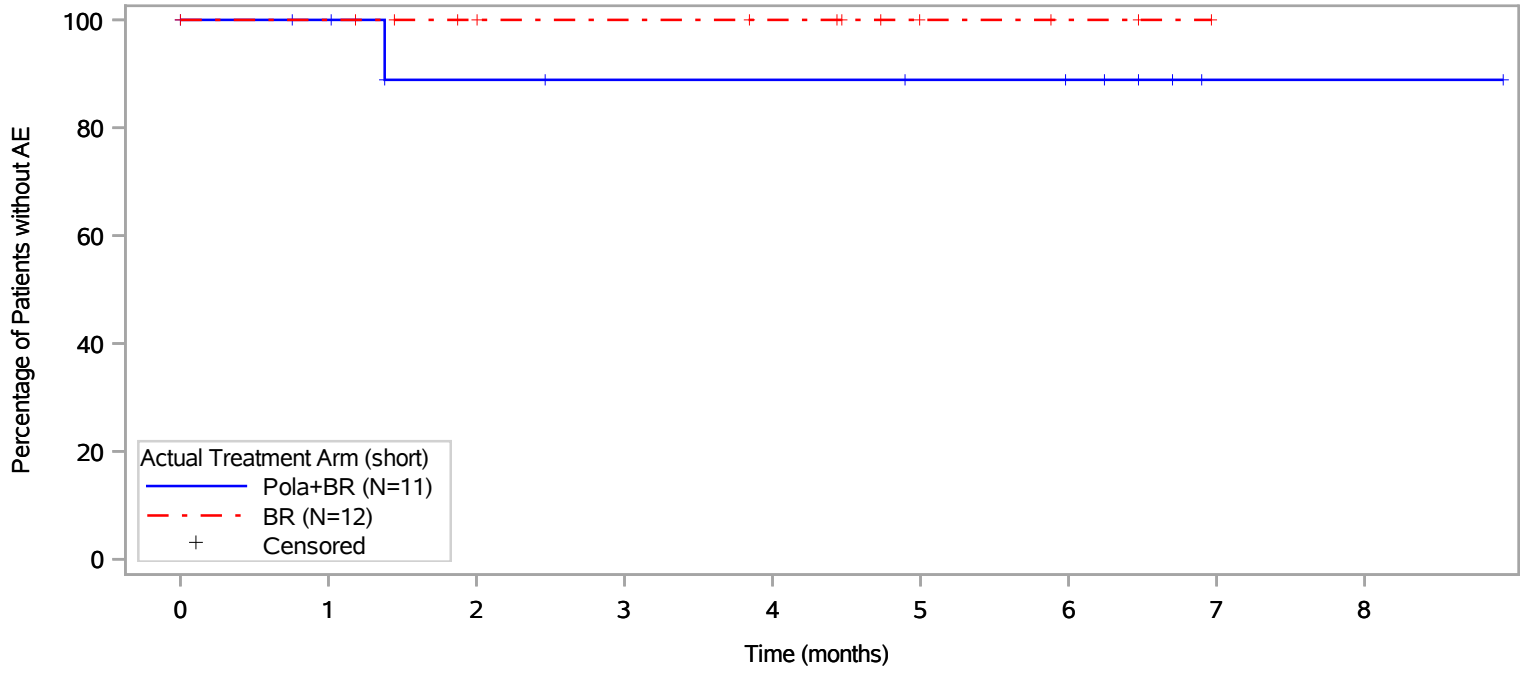
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, CONTUSION



Patients at risk									
Pola+BR (N=11)	11	10	8	7	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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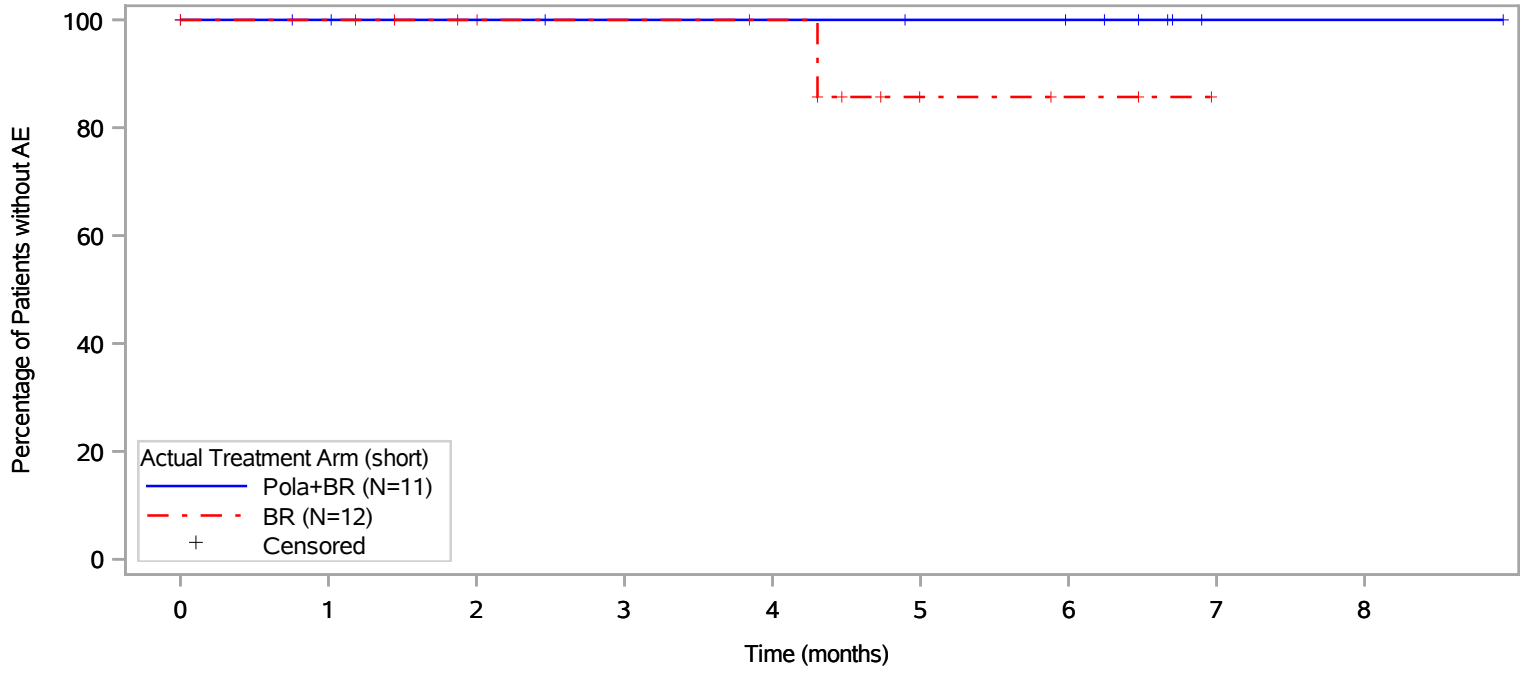
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, EYE CONTUSION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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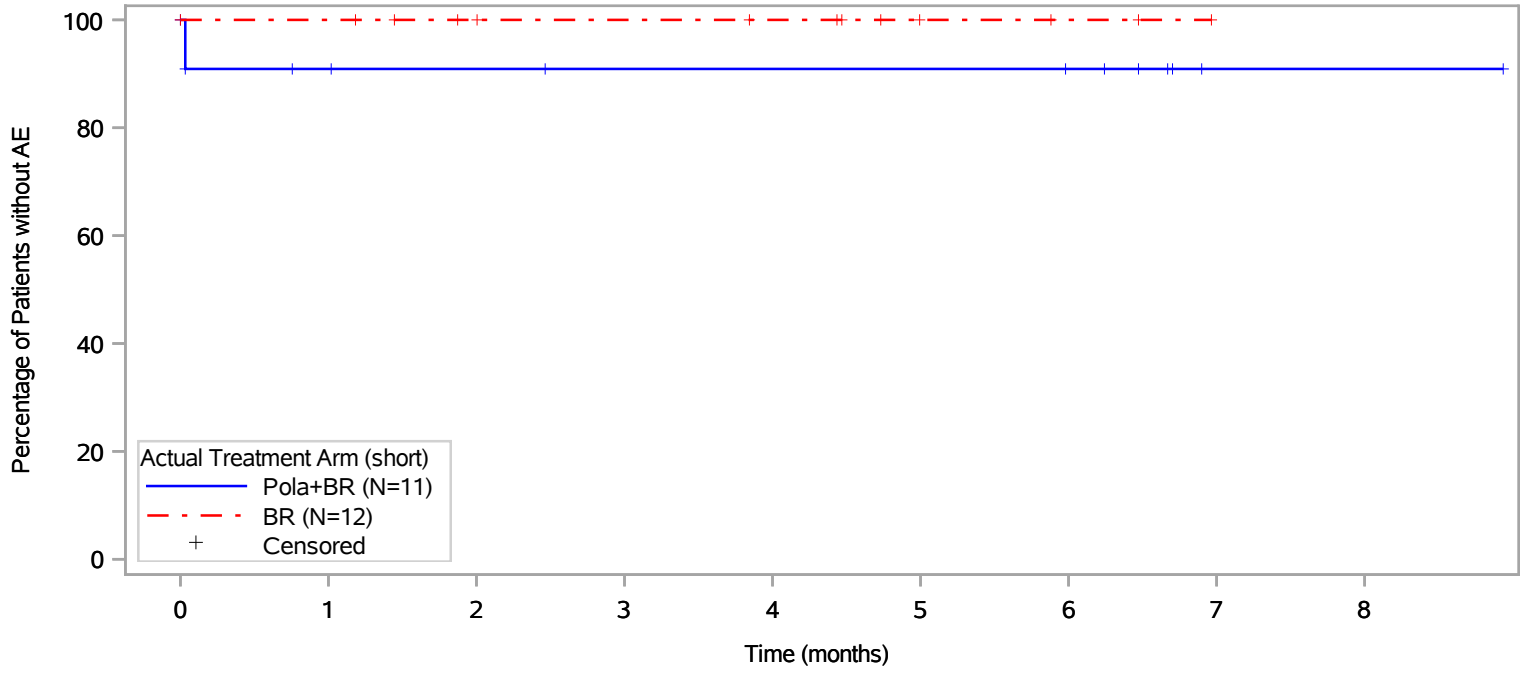
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL

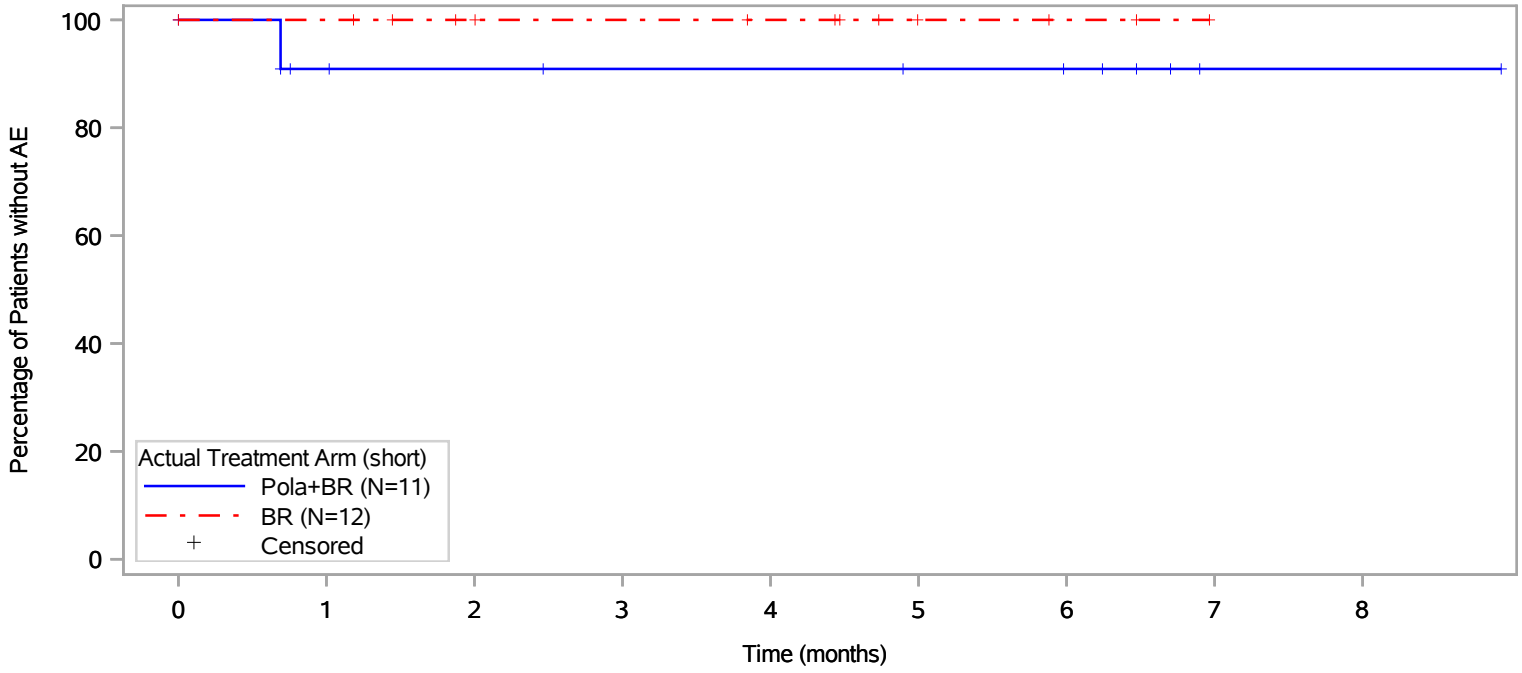


Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, INFUSION RELATED REACTION



Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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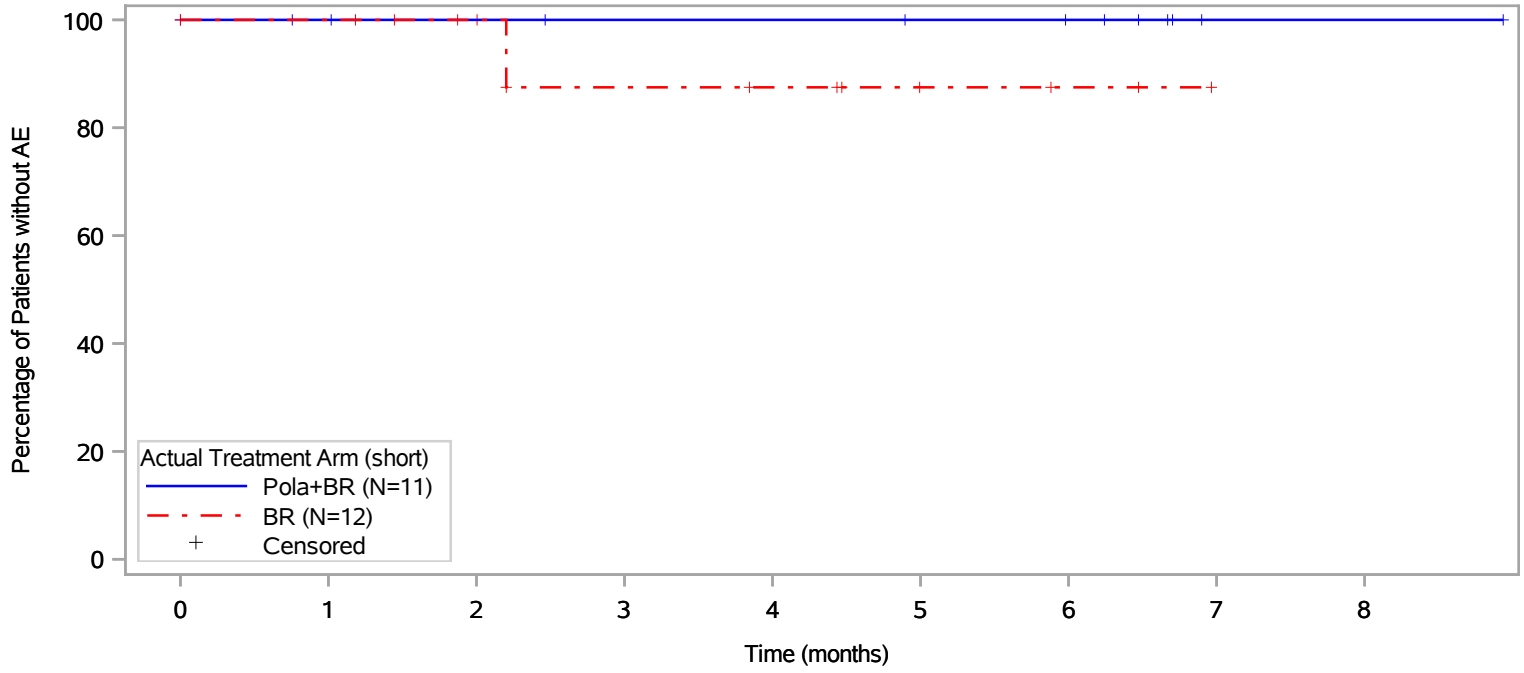
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, SPINAL COMPRESSION FRACTURE

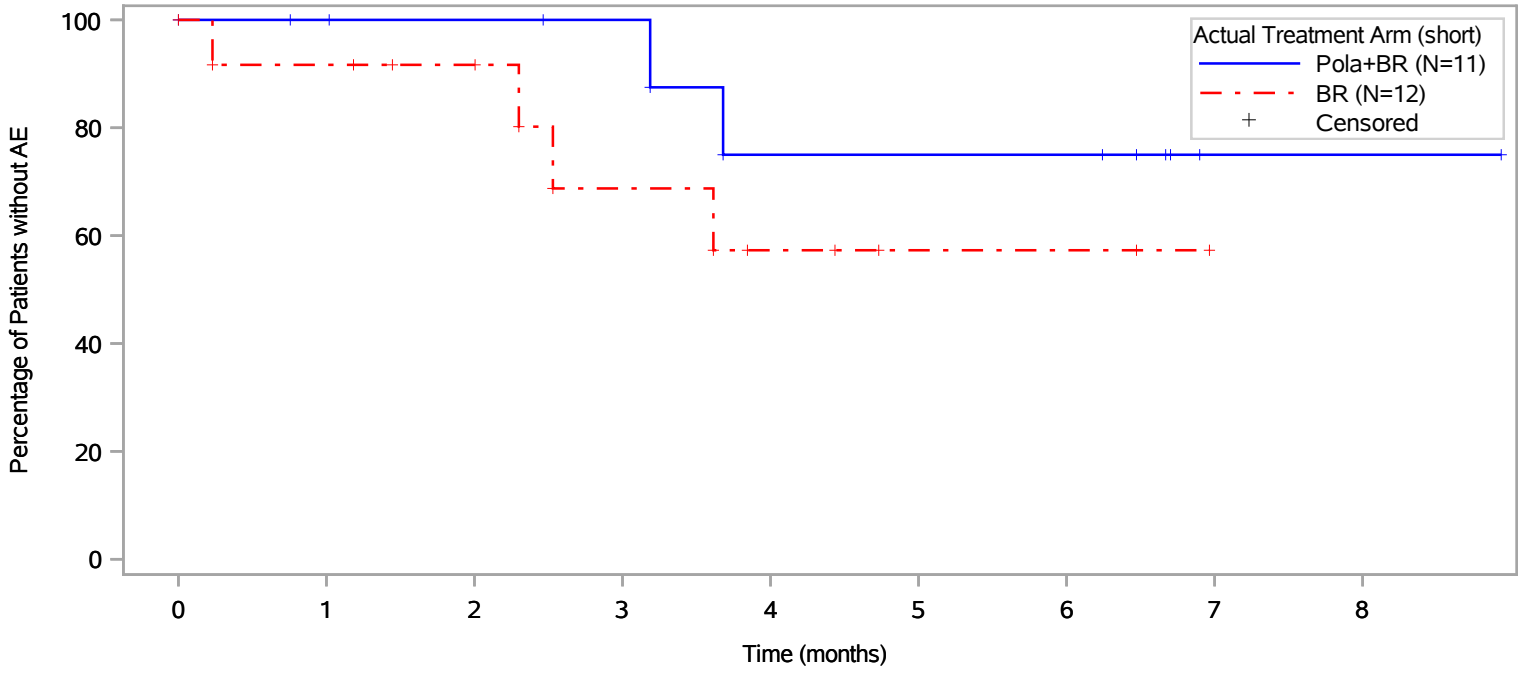


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

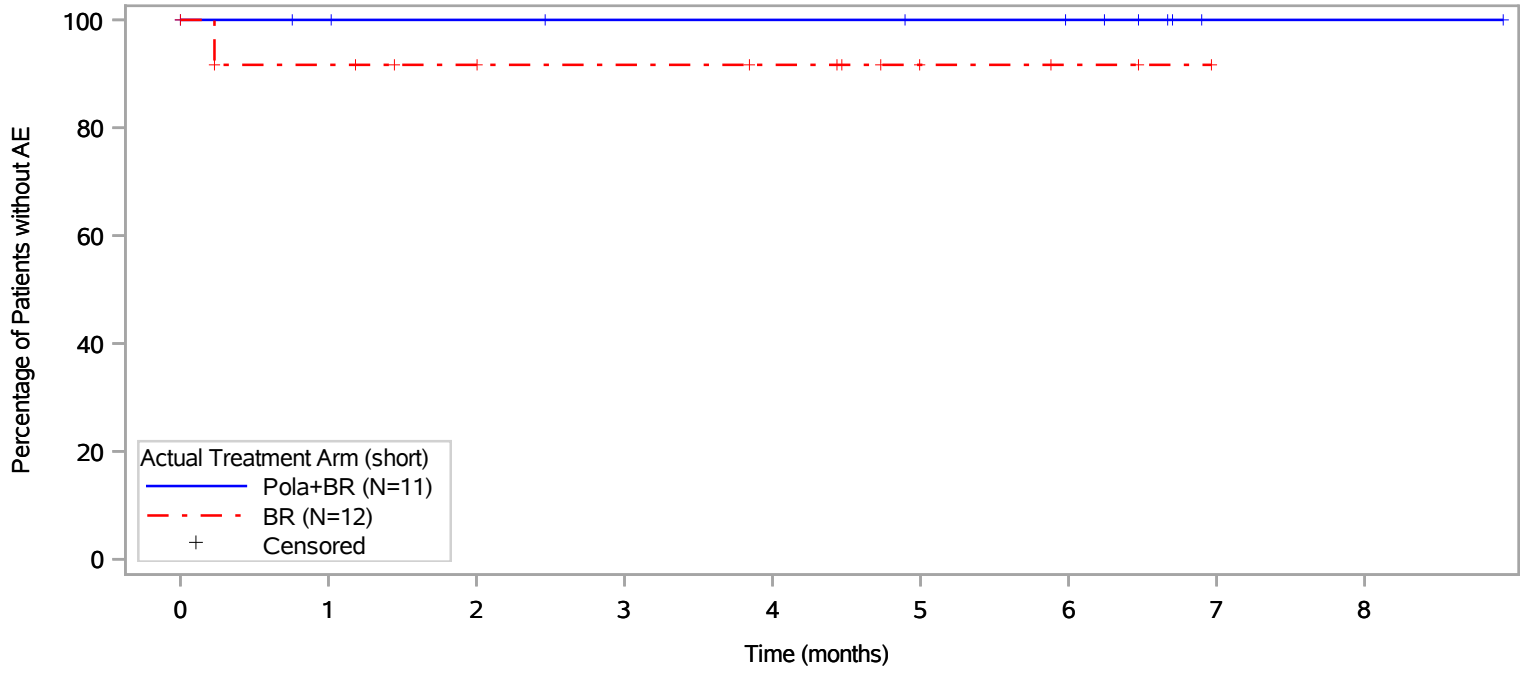


Patients at risk									
Pola+BR (N=11)	11	10	9	8	6	6	6	1	1
BR (N=12)	12	11	9	6	4	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	3	8	8
BR (N=12)	0	0	2	3	4	6	6	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALKALINE PHOSPHATASE INCREASED

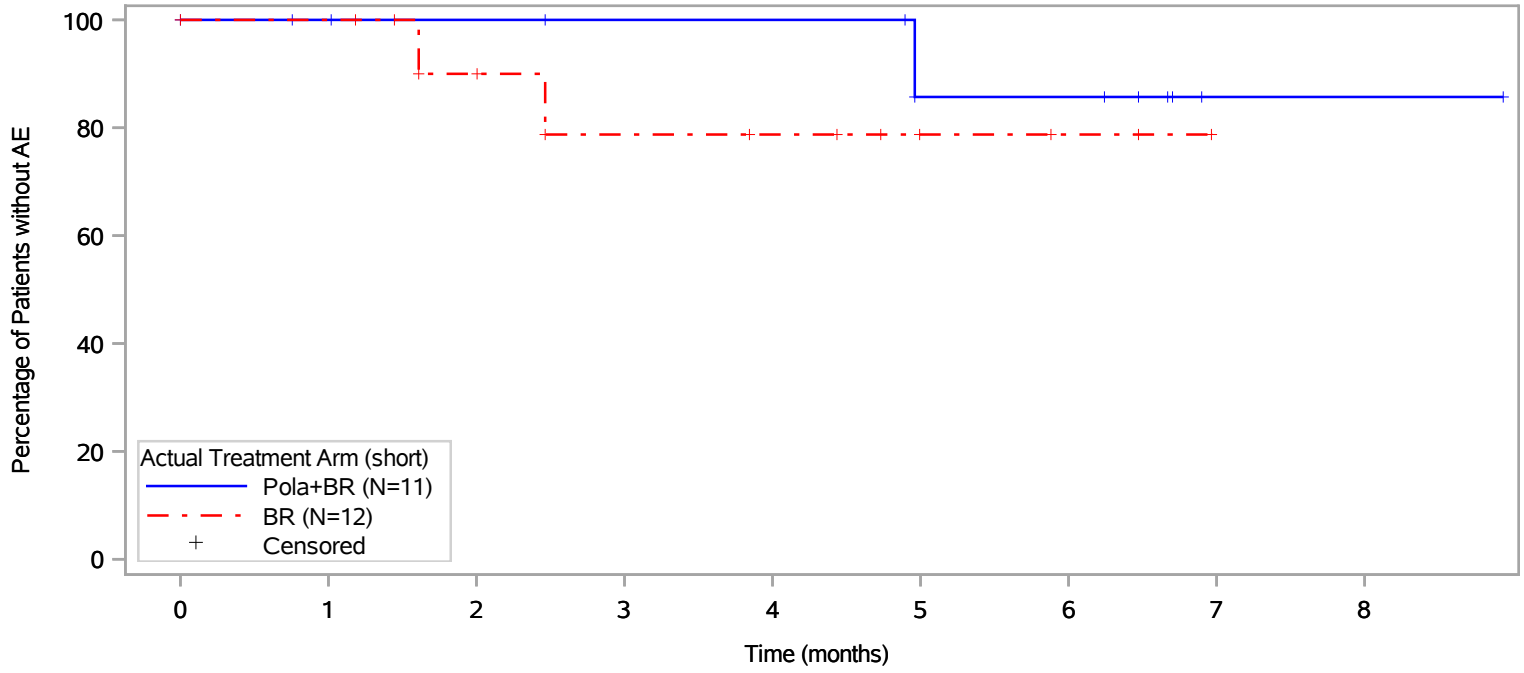


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD CREATININE INCREASED

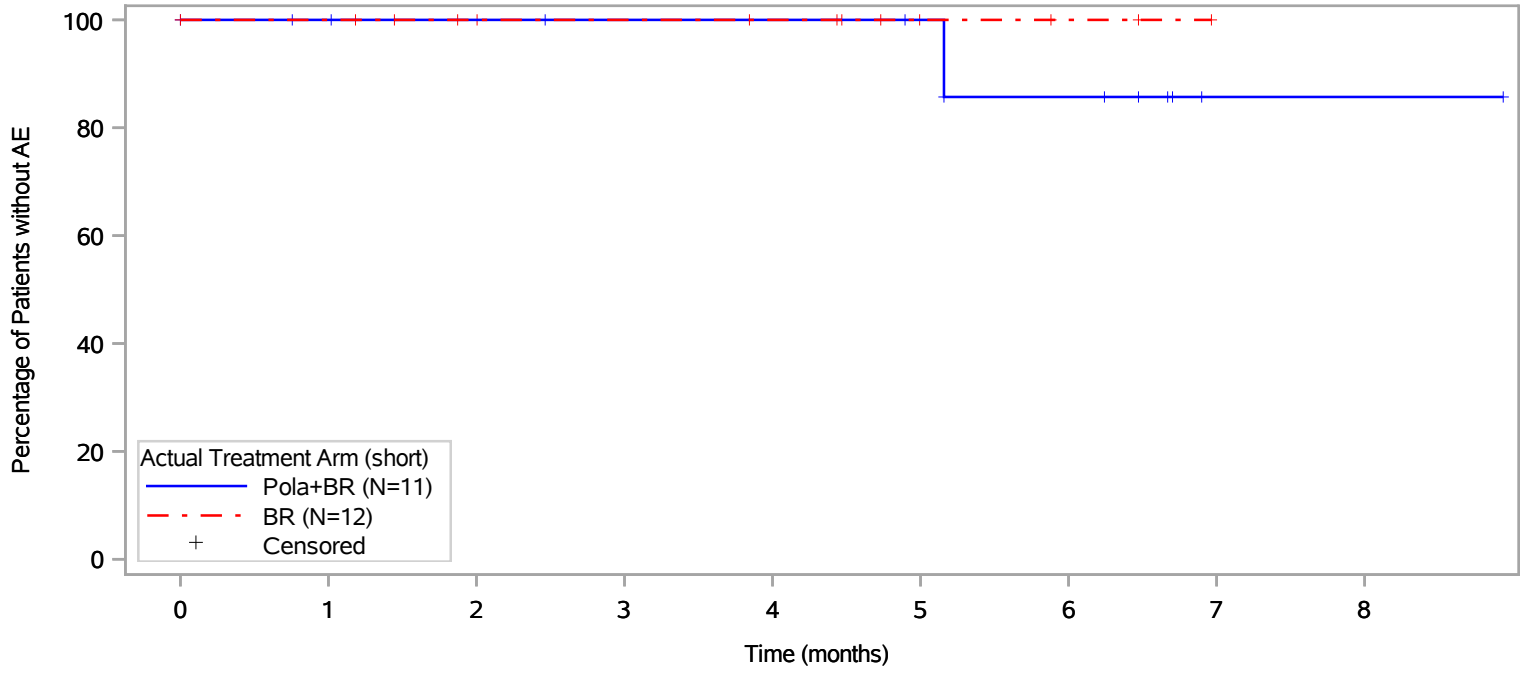


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	2	3	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PHOSPHORUS DECREASED

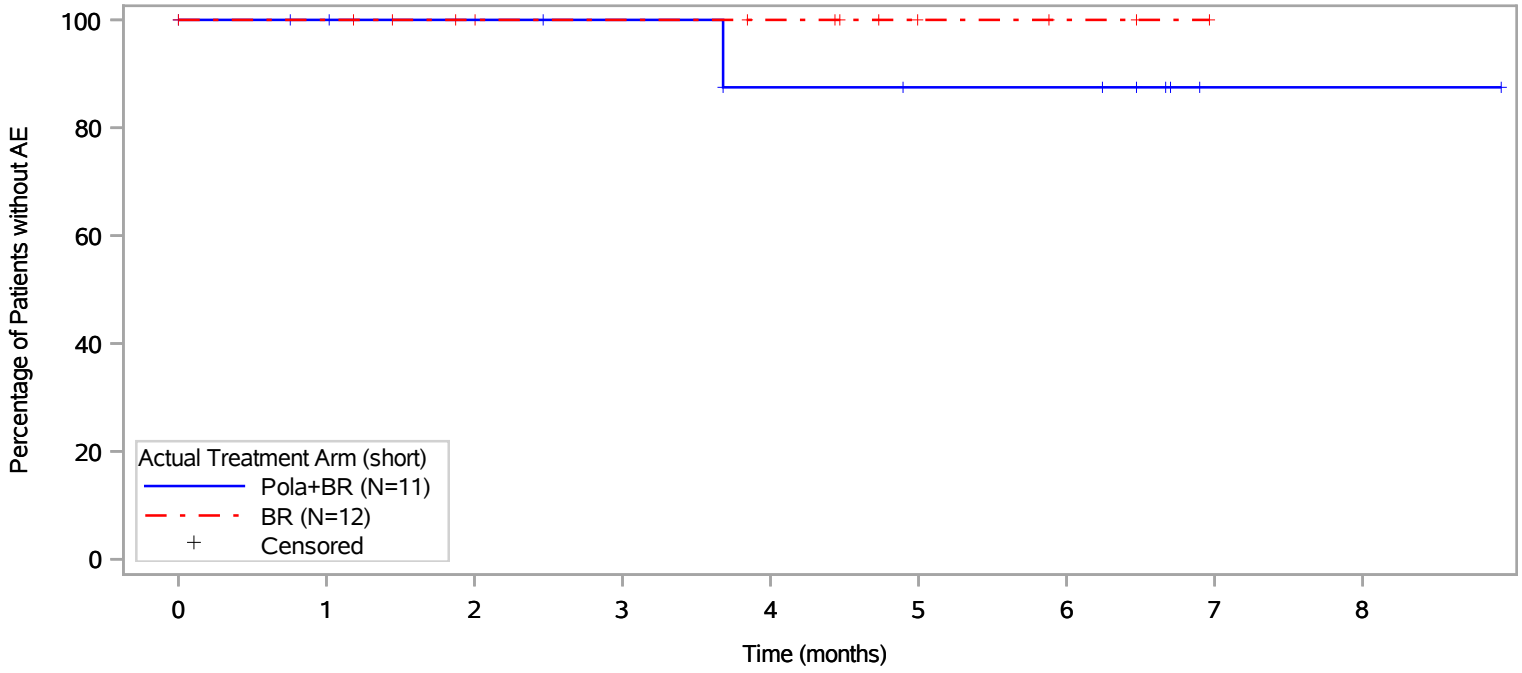


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED

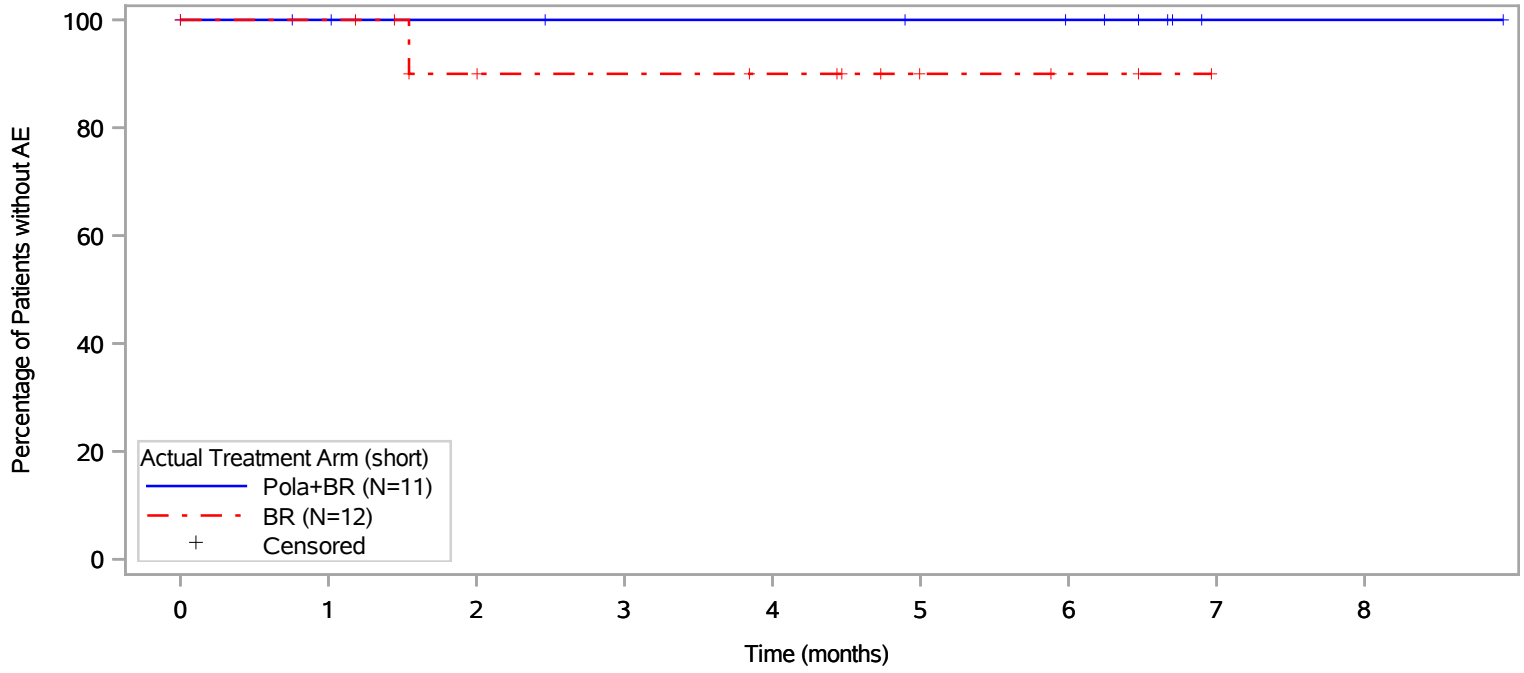


Patients at risk								
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, C-REACTIVE PROTEIN INCREASED

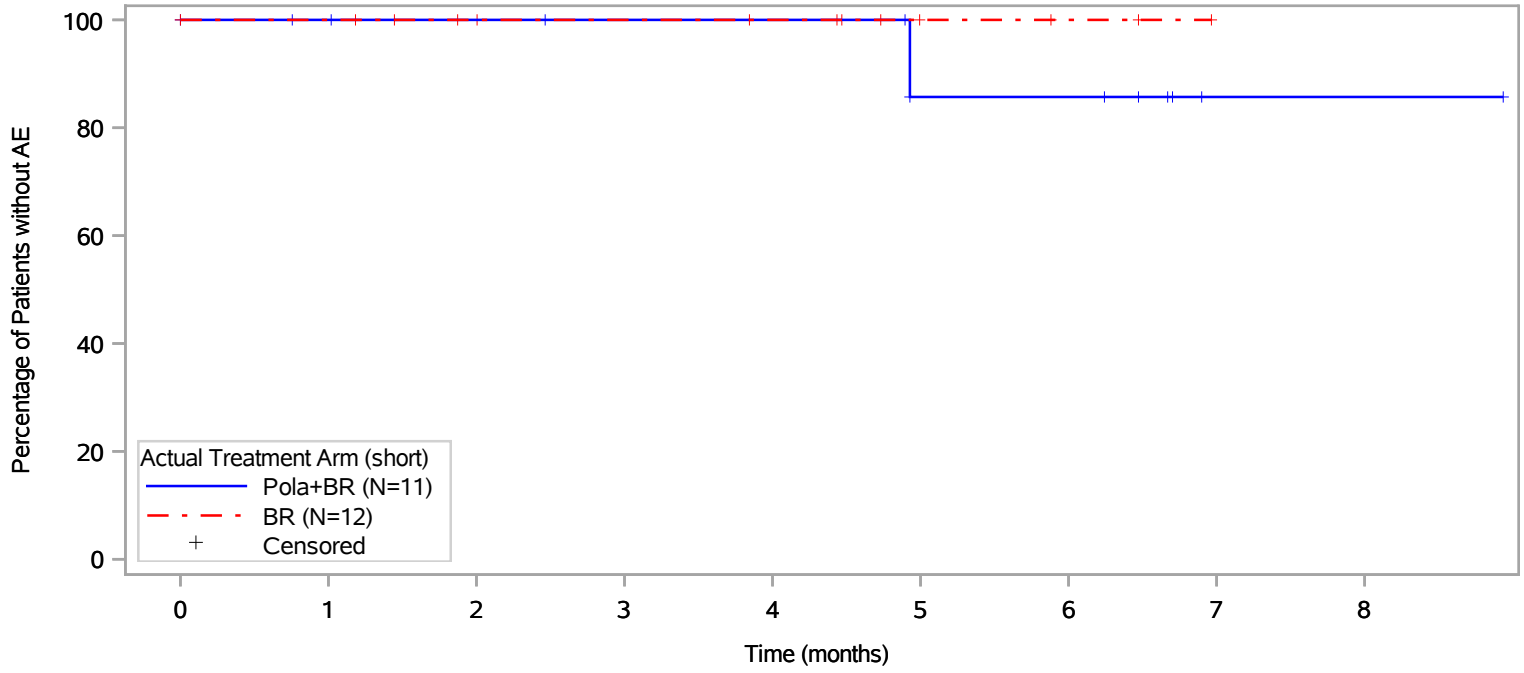


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYTOMEGALOVIRUS TEST POSITIVE

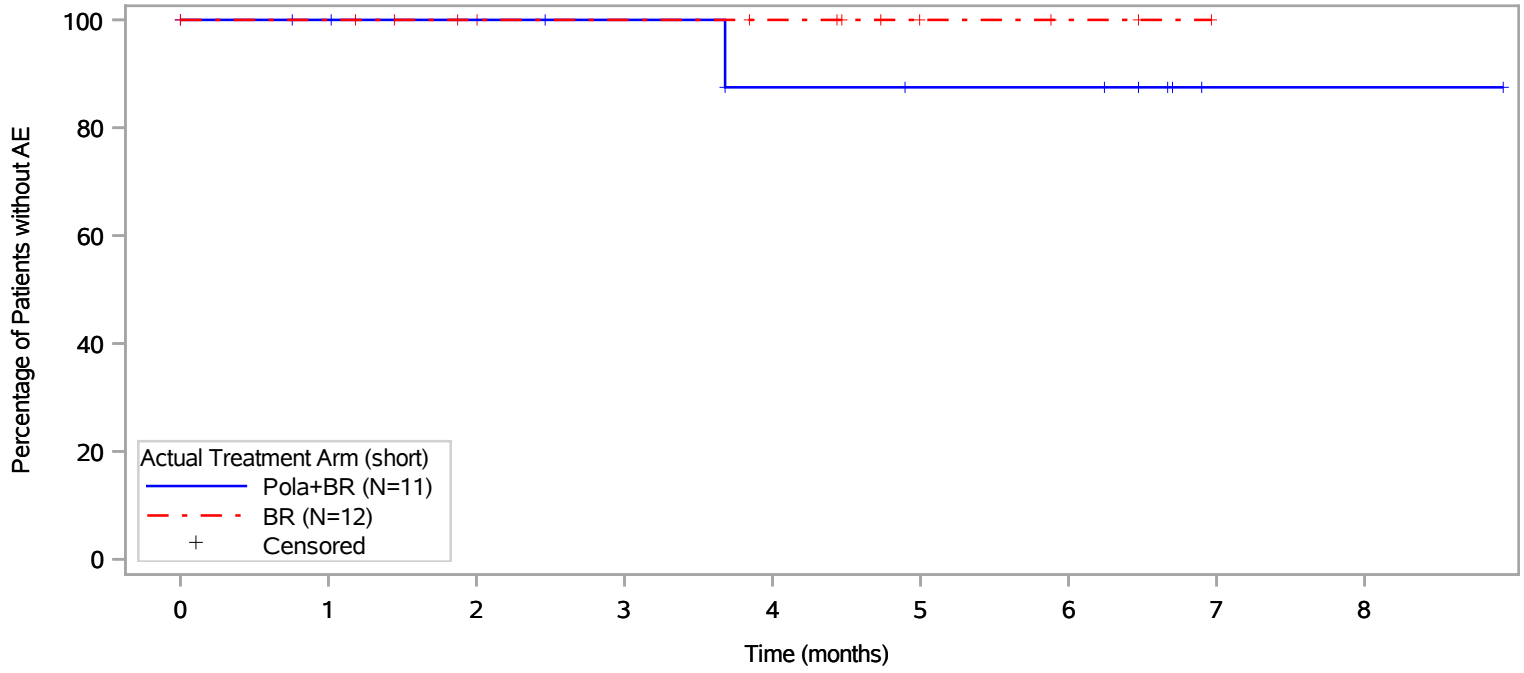


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LIPASE INCREASED

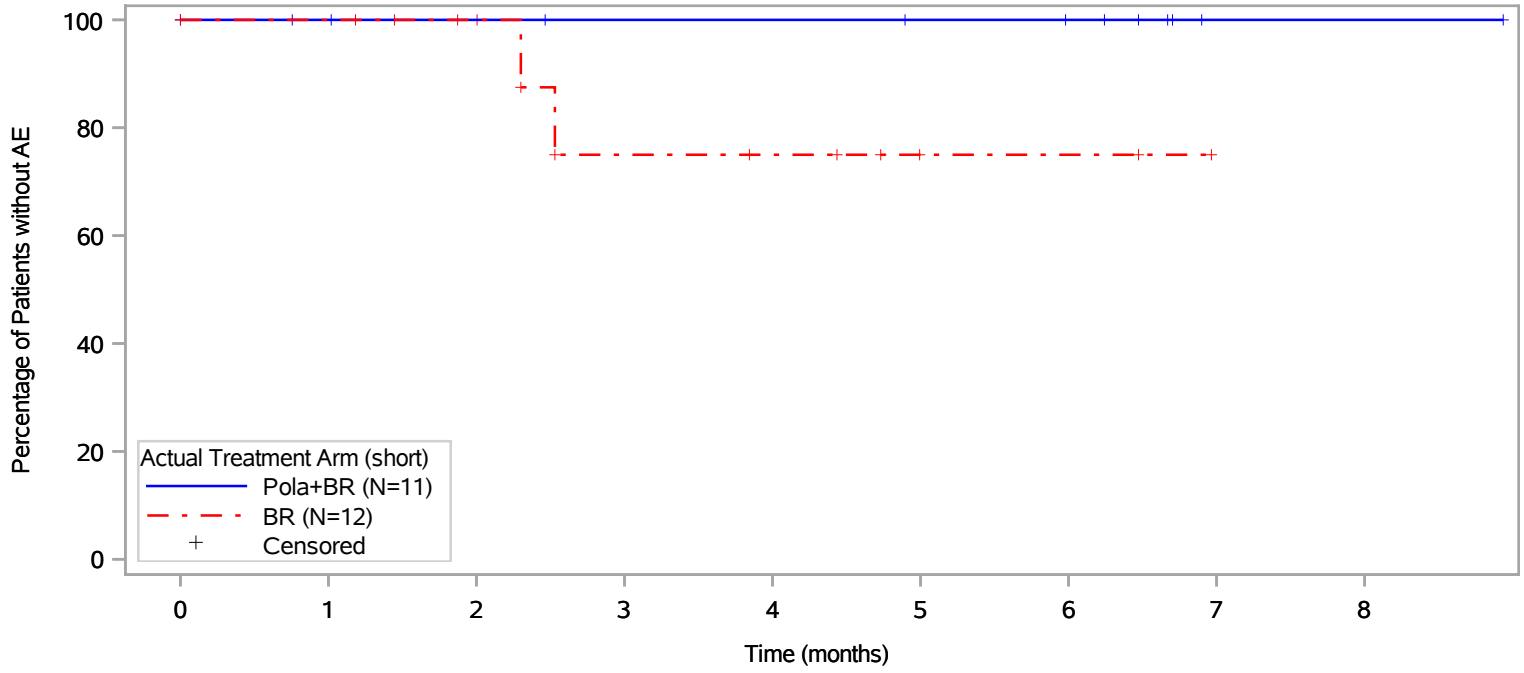


Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED

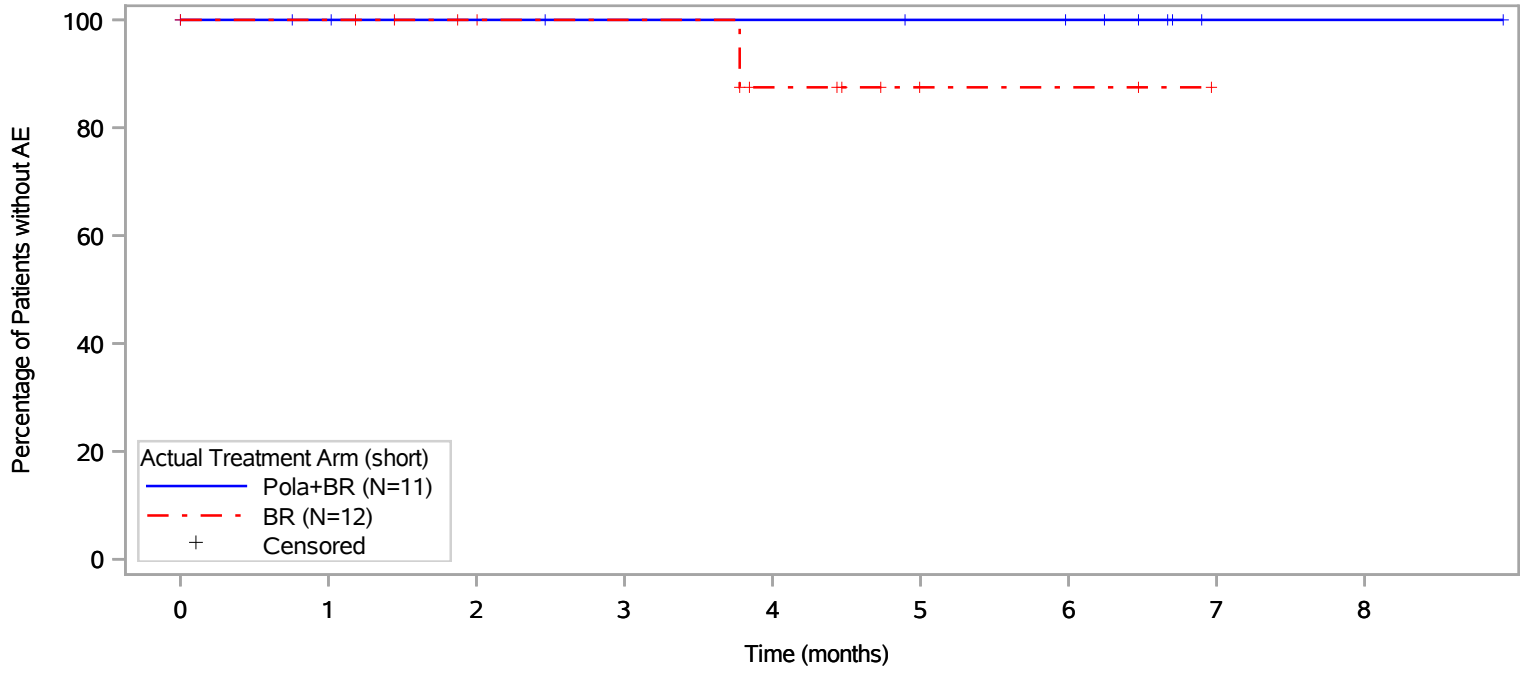


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	6	5	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

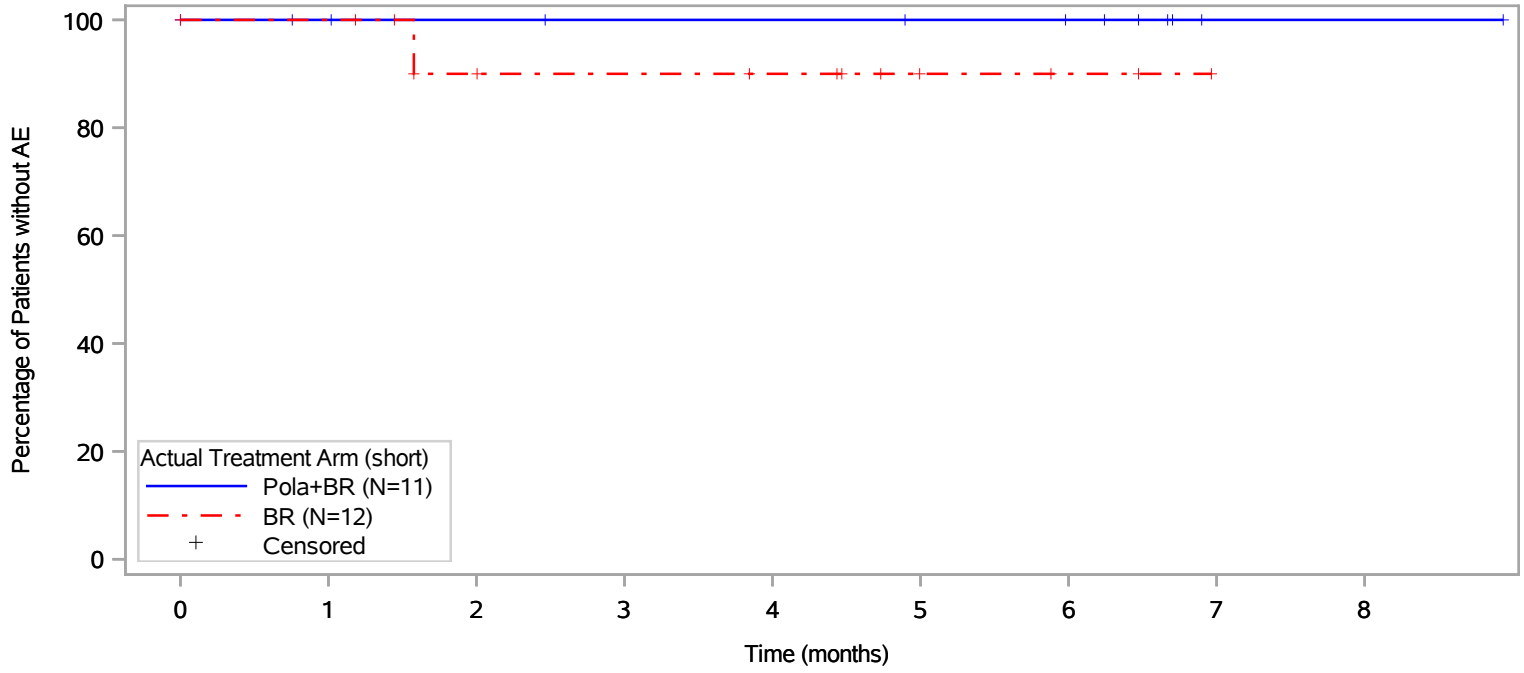


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, OXYGEN SATURATION DECREASED

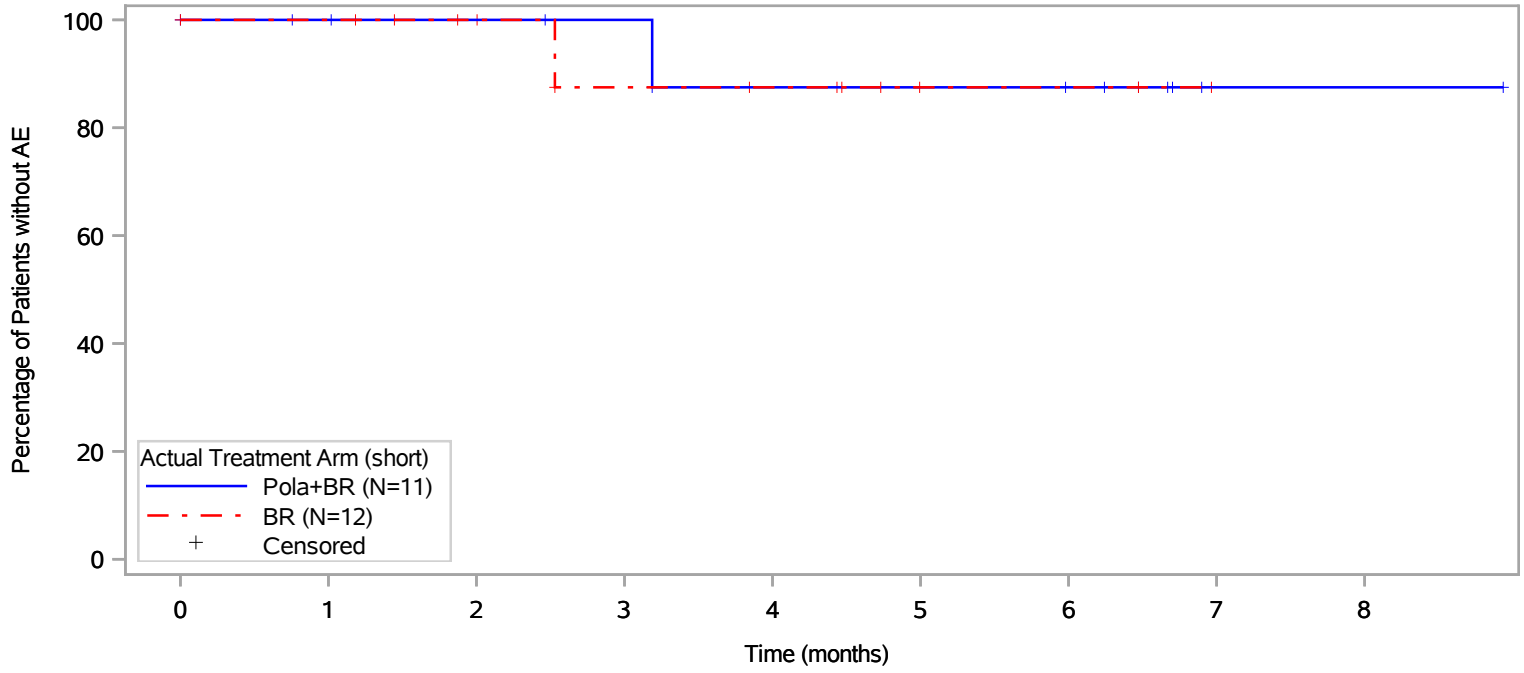


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

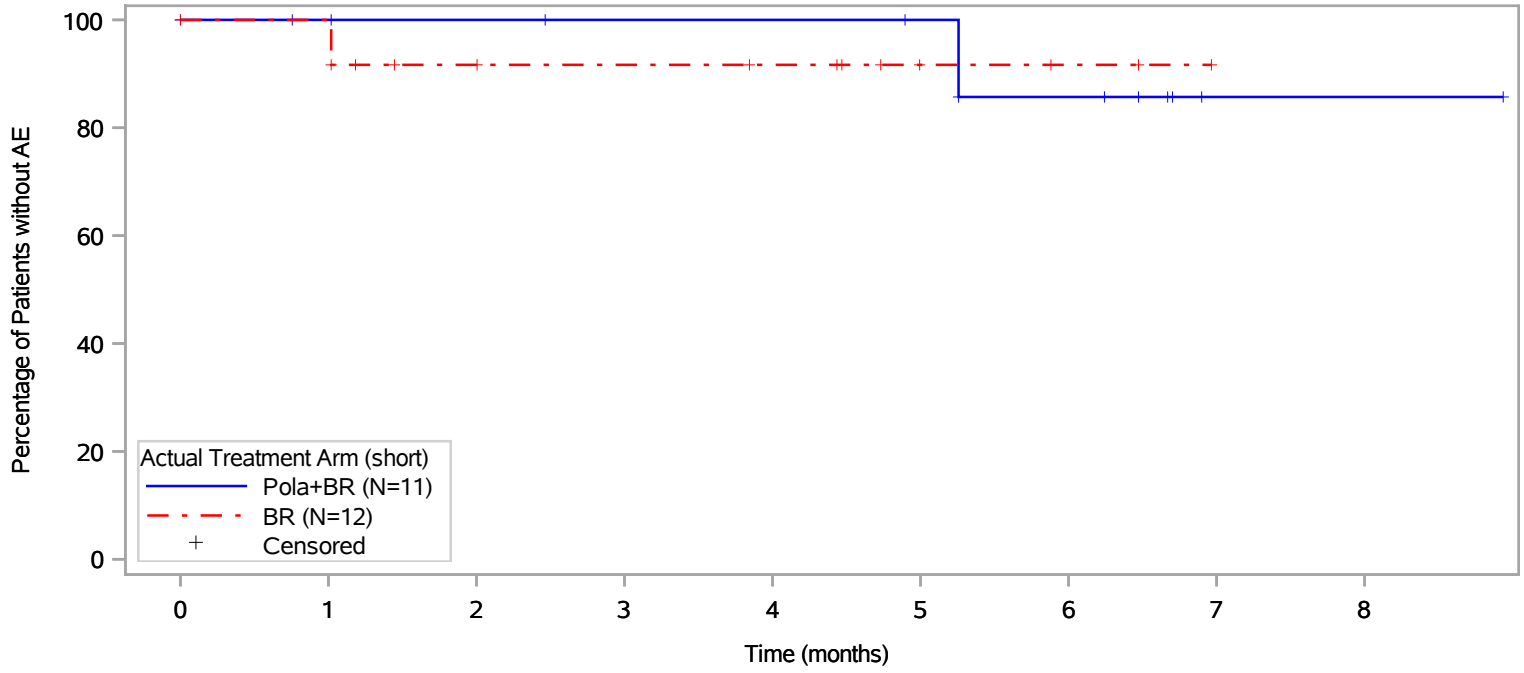


Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	7	6	1	1
BR (N=12)	12	12	9	7	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	4	9	9
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED

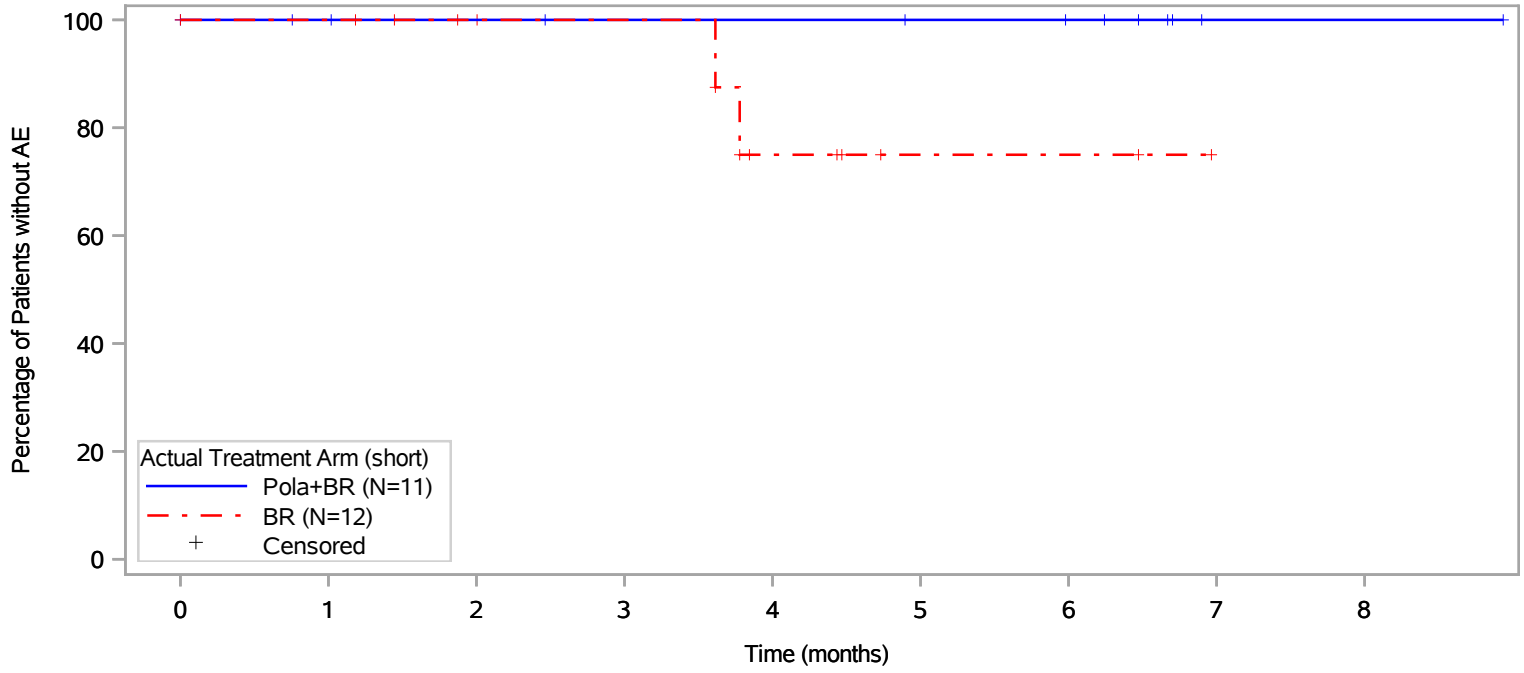


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED

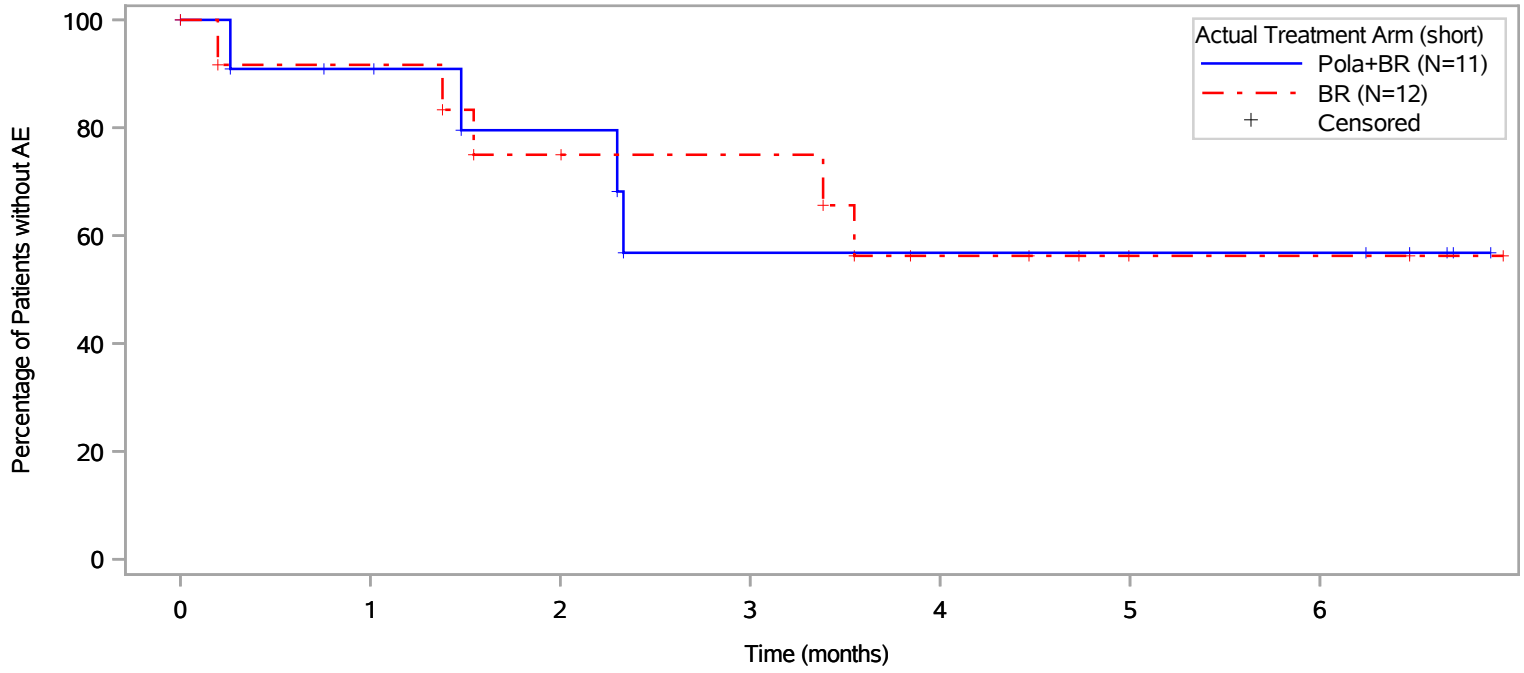


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	5	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All

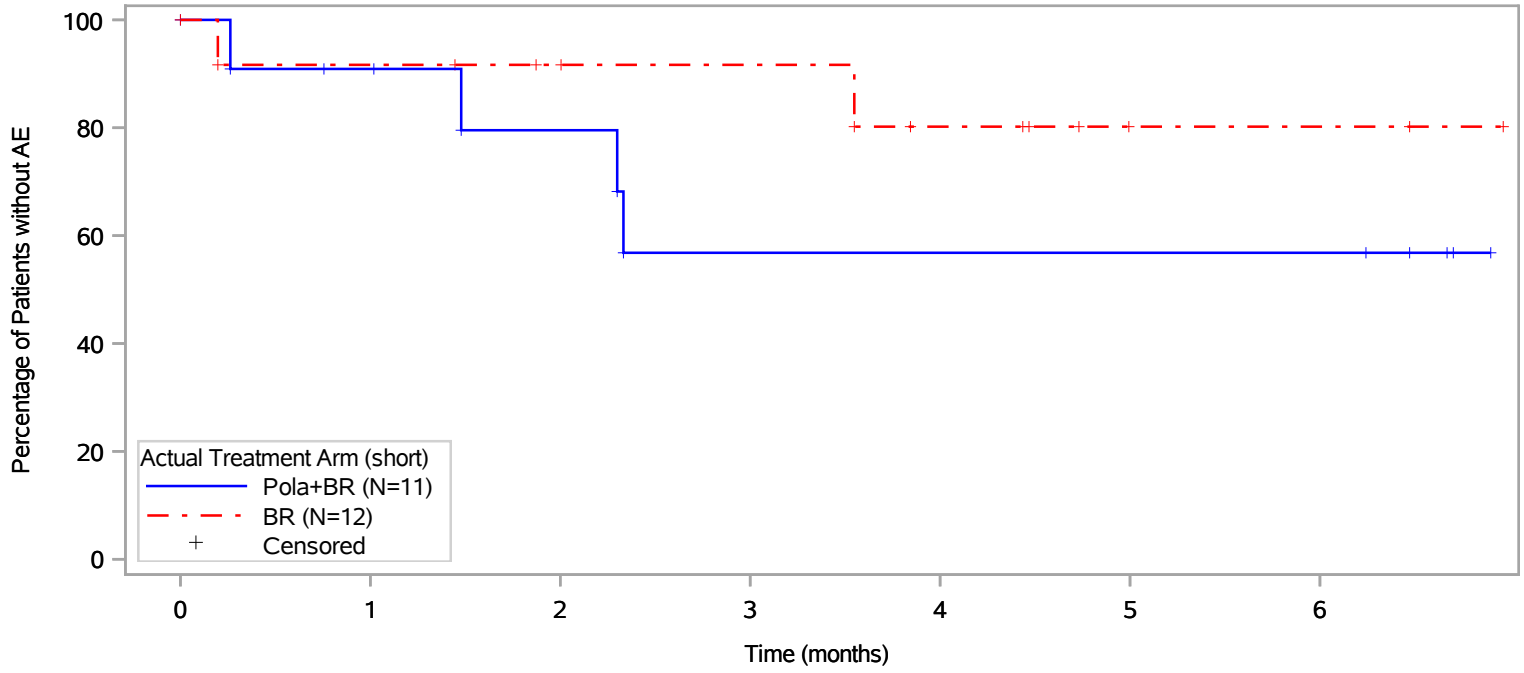


Patients at risk							
Pola+BR (N=11)	11	9	7	5	5	5	5
BR (N=12)	12	11	9	8	5	2	2
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	2	2
BR (N=12)	0	0	0	1	2	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE

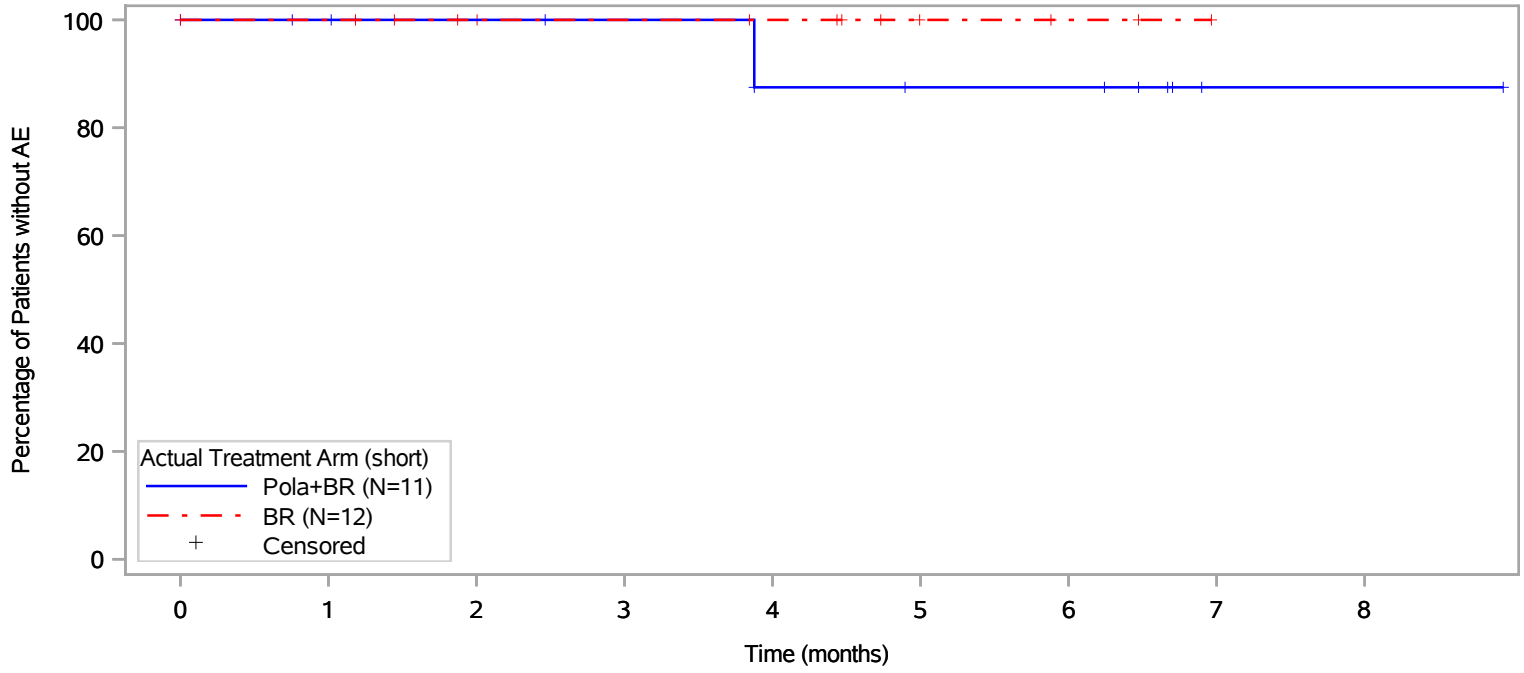


Patients at risk							
Pola+BR (N=11)	11	9	7	5	5	5	5
BR (N=12)	12	11	9	8	6	2	2
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	2	2
BR (N=12)	0	0	2	3	4	8	8

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, DEHYDRATION



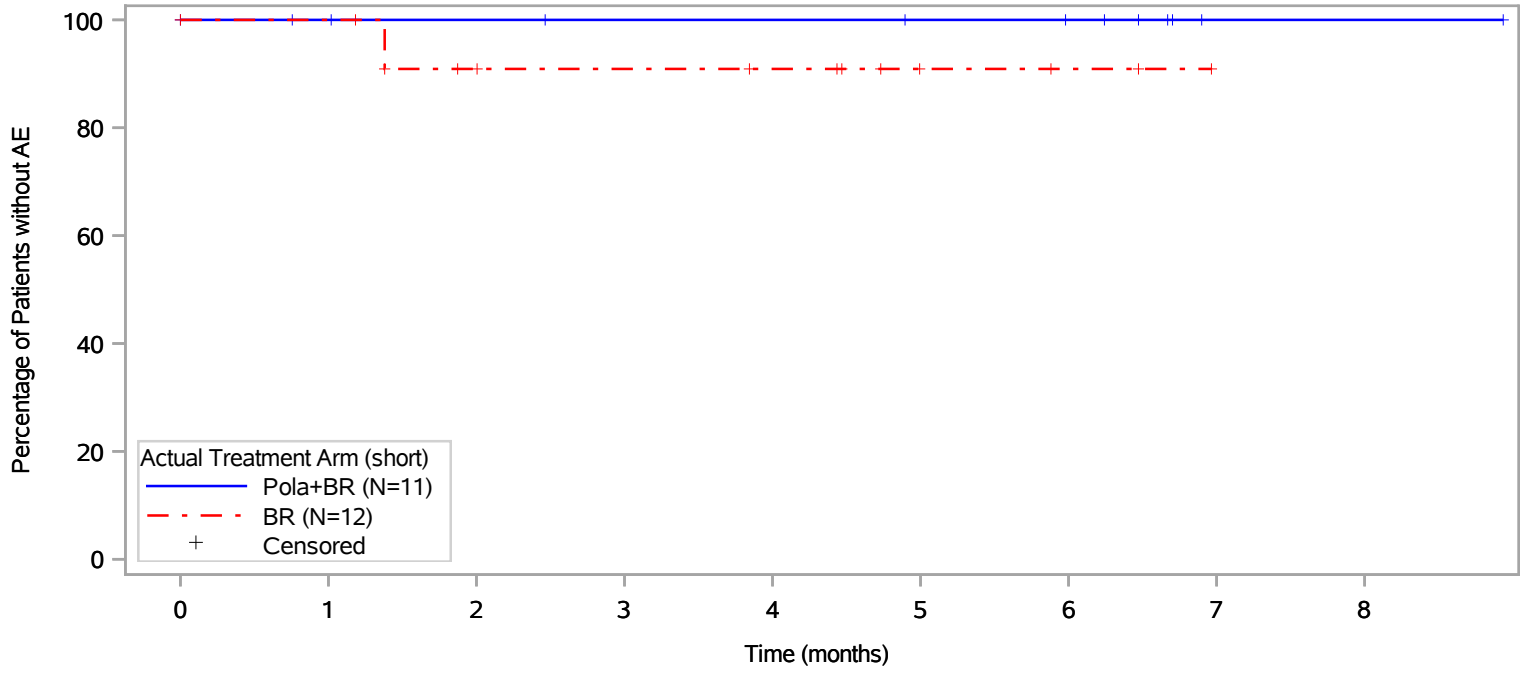
Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, FLUID IMBALANCE



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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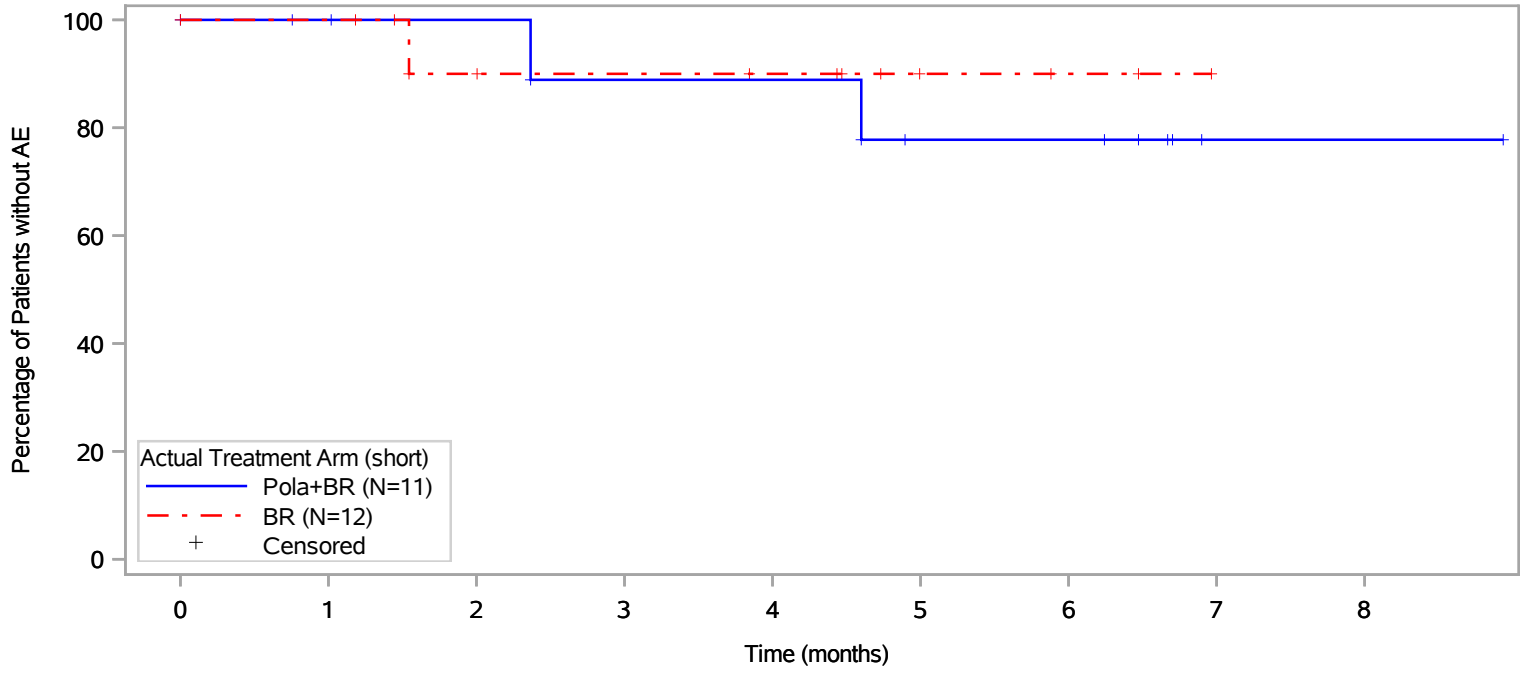
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	3	8	8
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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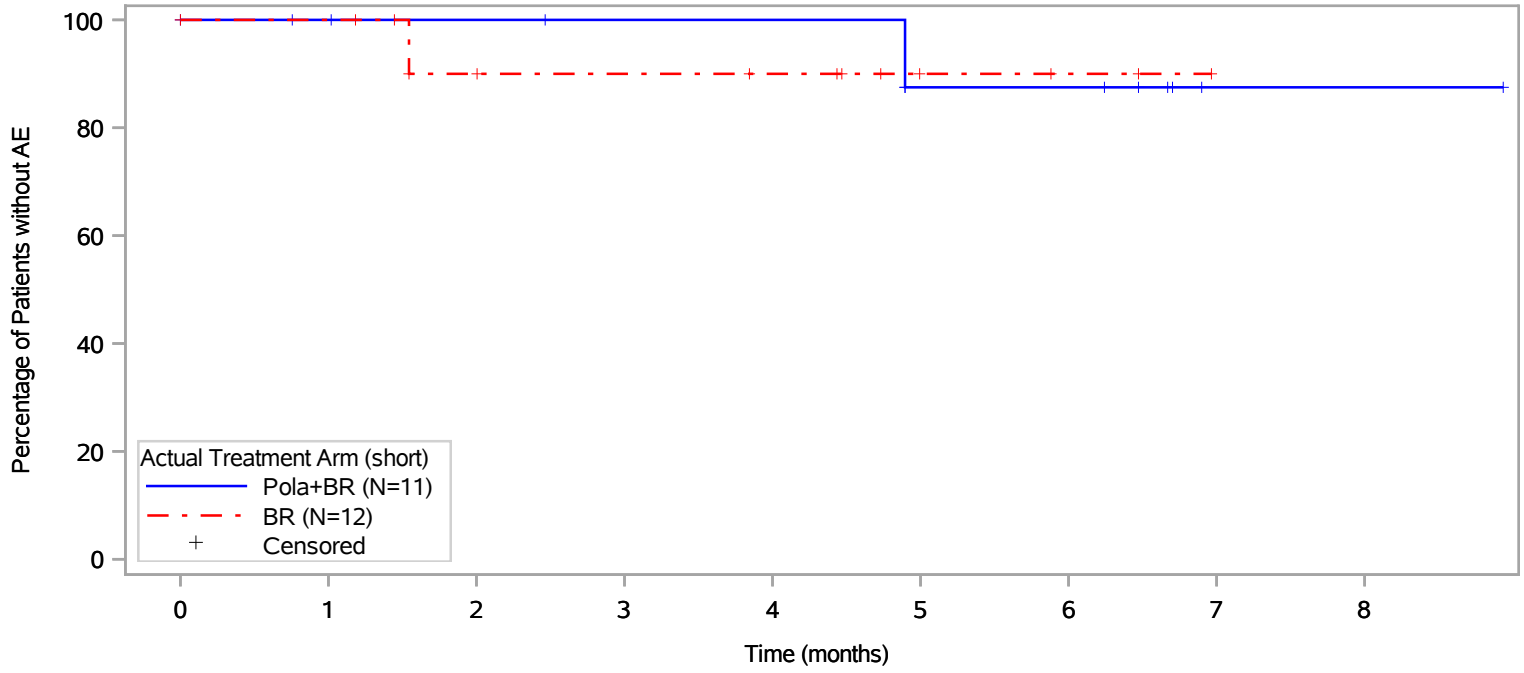
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOCALCAEMIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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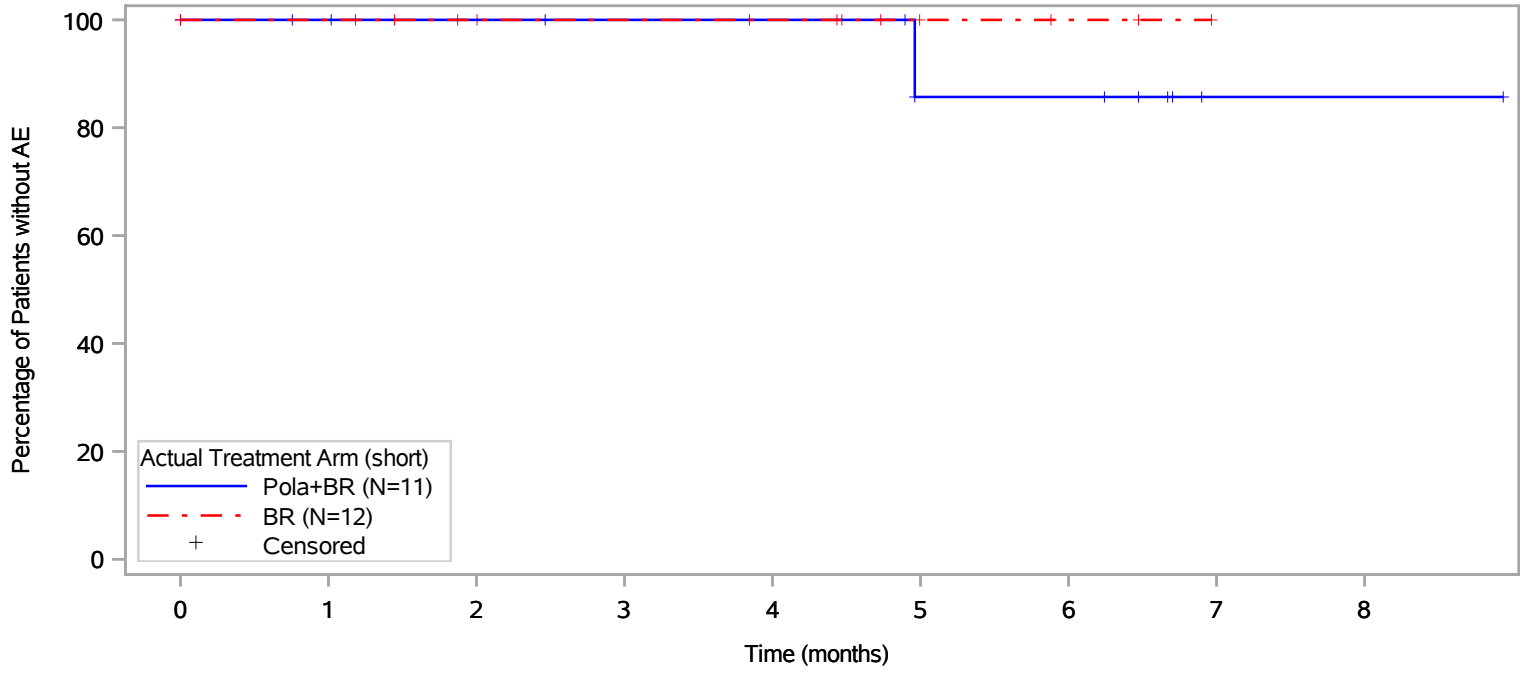
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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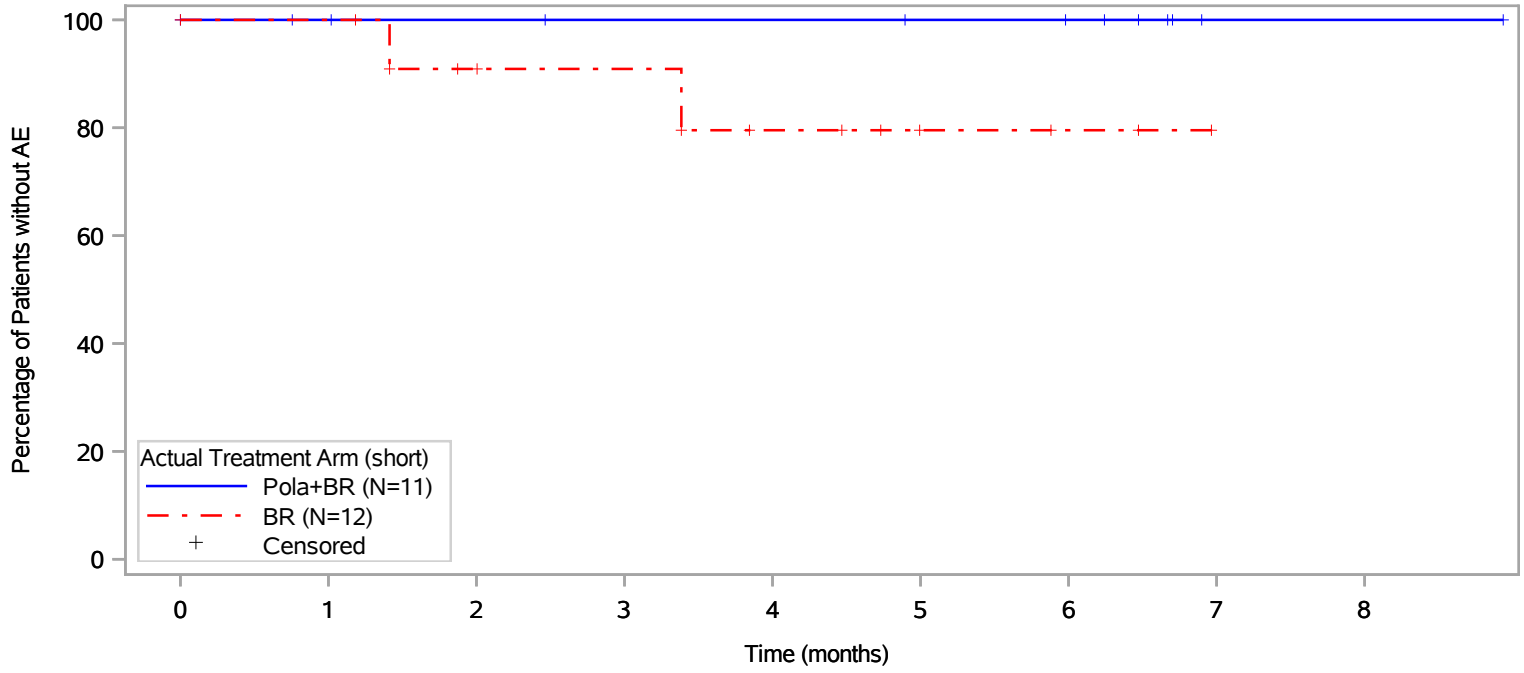
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOMAGNESAEMIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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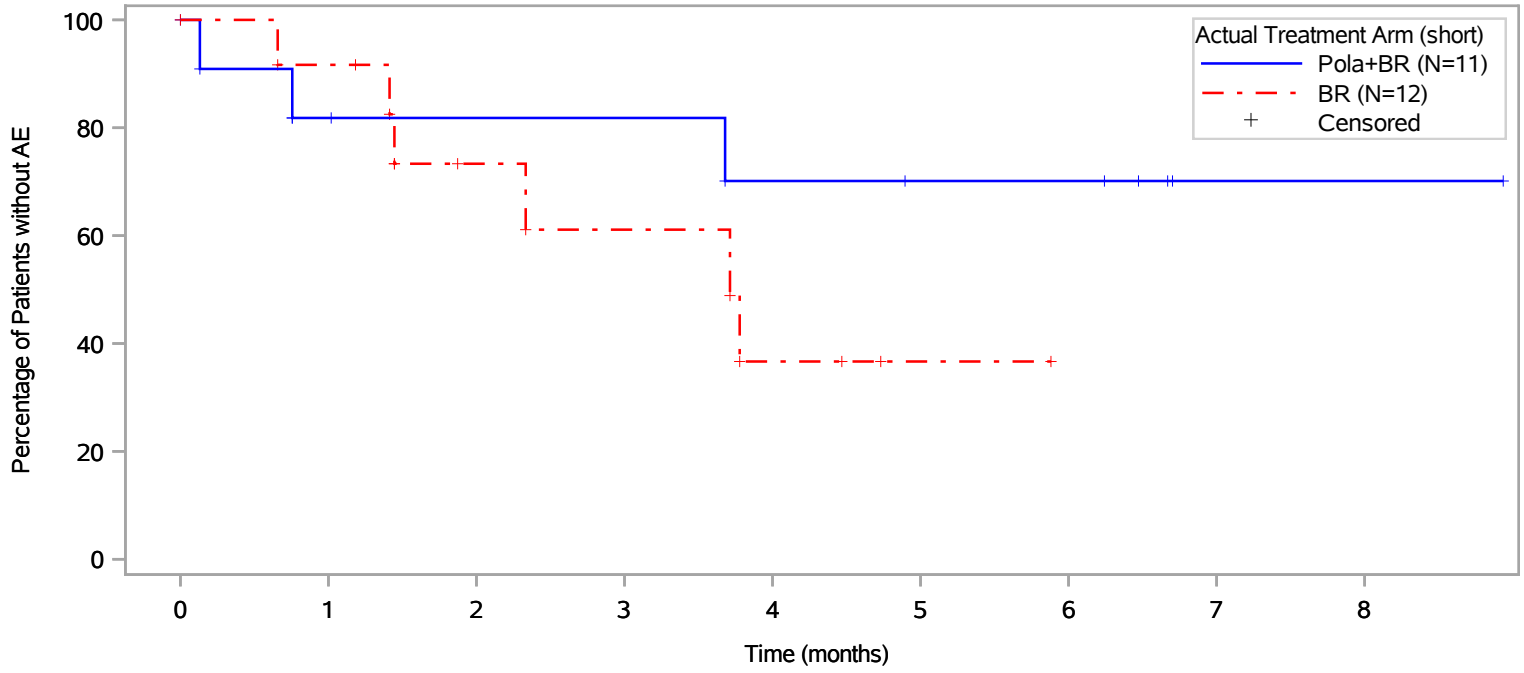
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	8	7	7	6	5	5	1	1
BR (N=12)	12	11	6	5	3	1	NE	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	3	7	7
BR (N=12)	0	0	3	3	3	5	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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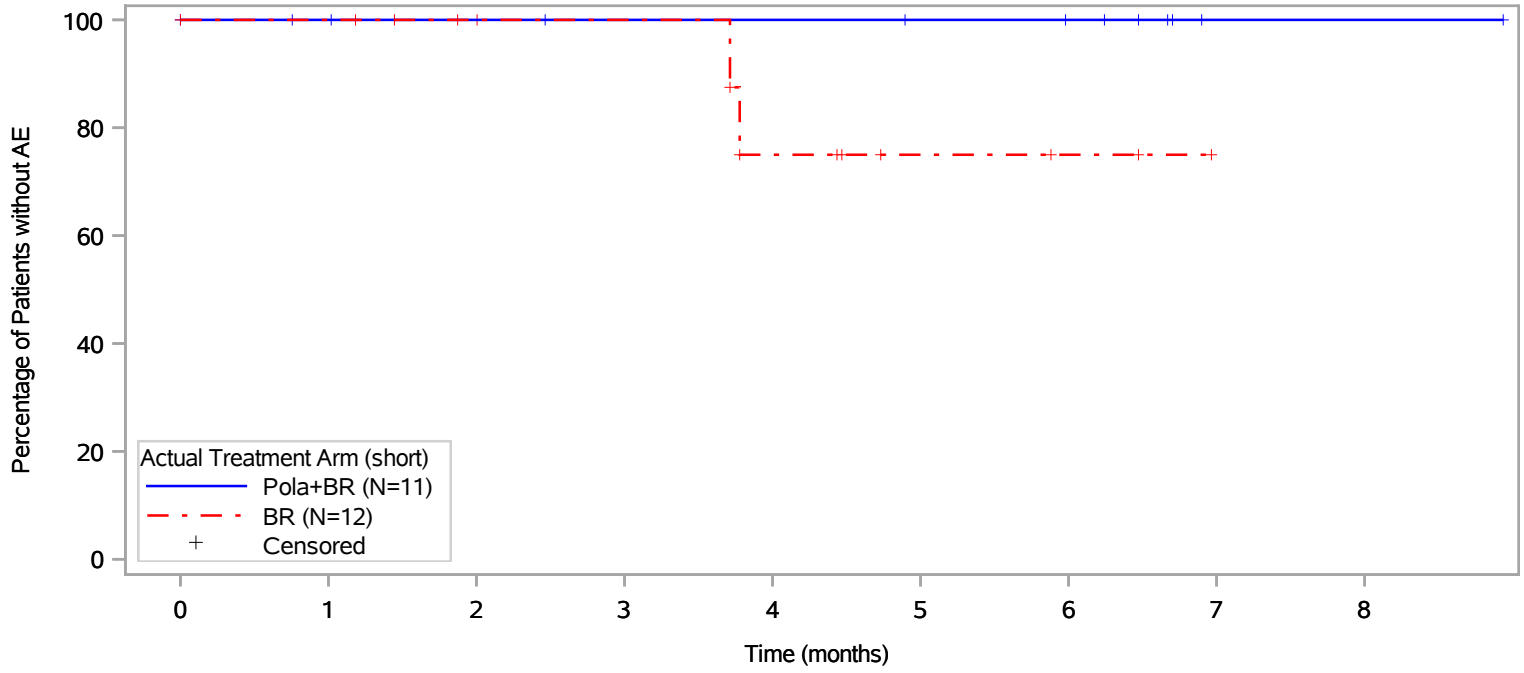
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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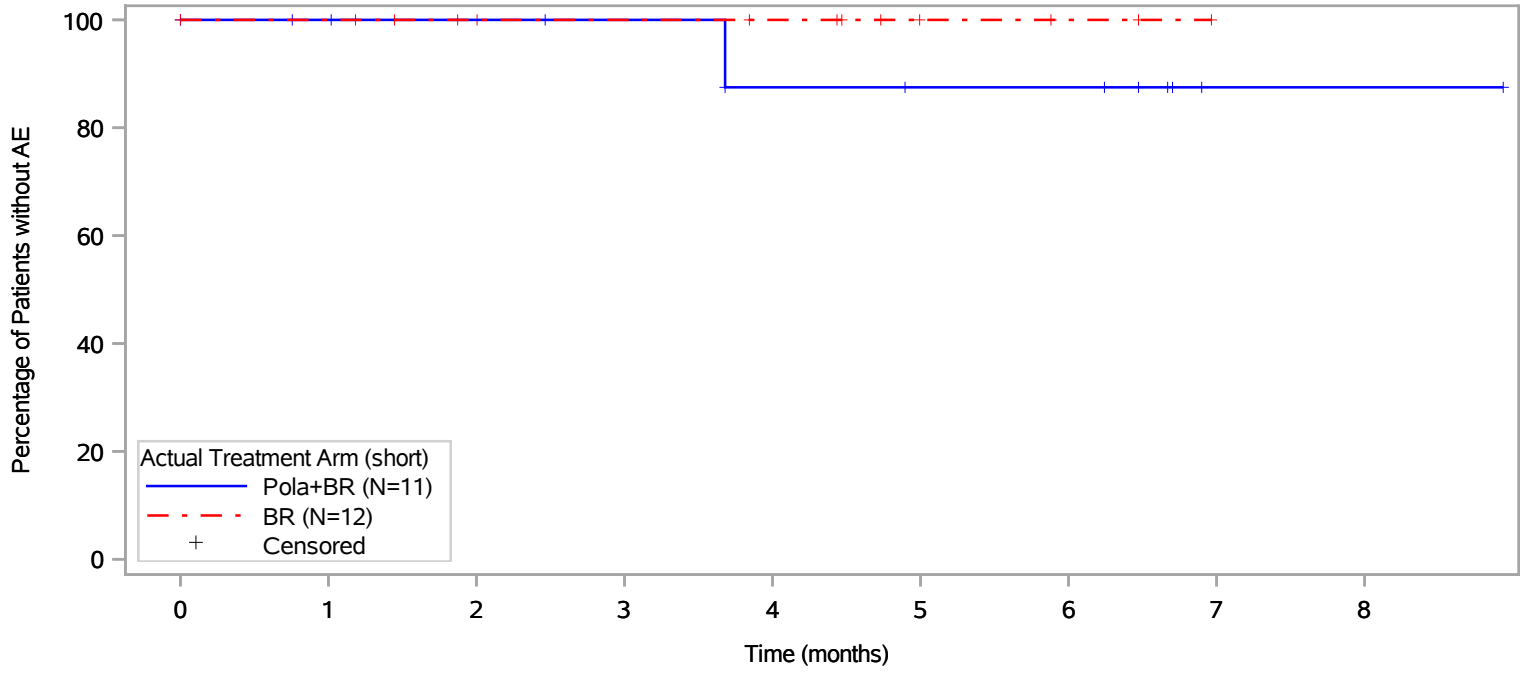
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCLE ATROPHY



Patients at risk								
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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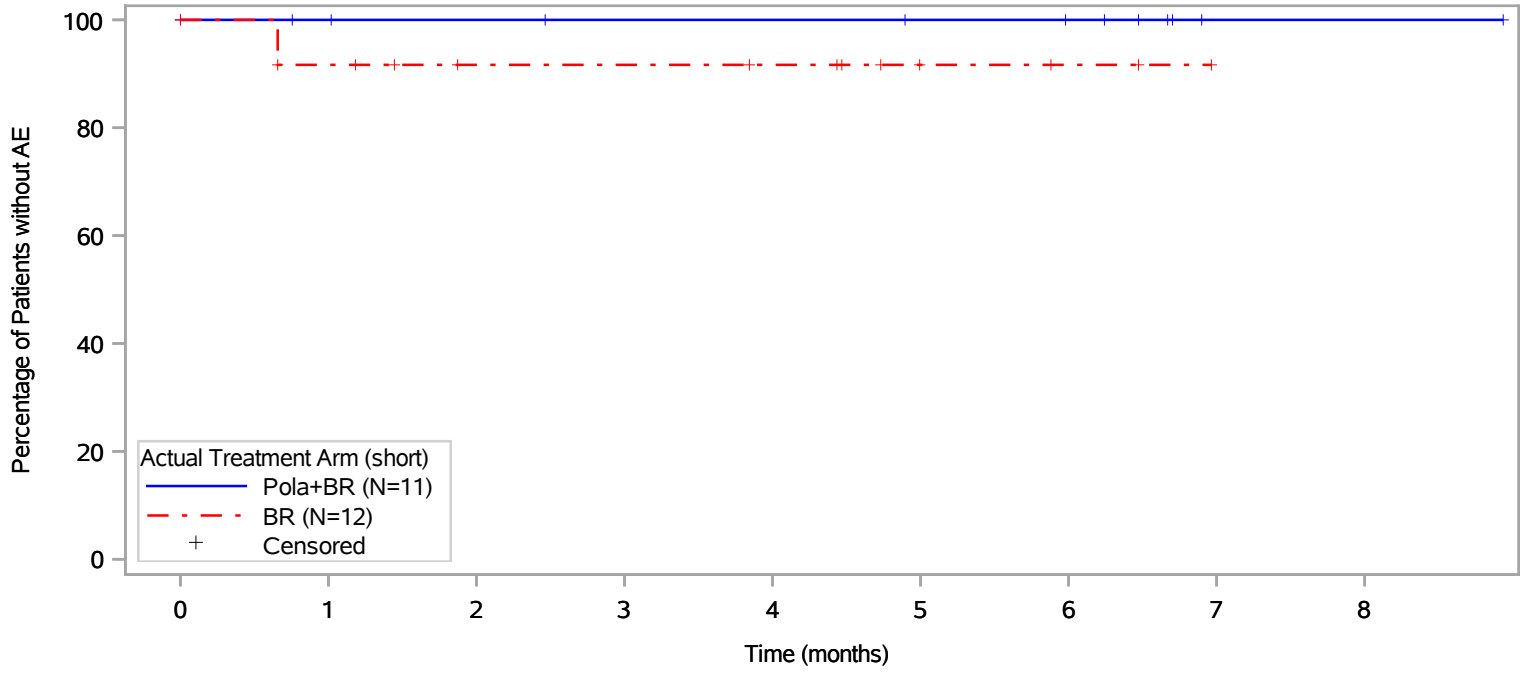
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULAR WEAKNESS



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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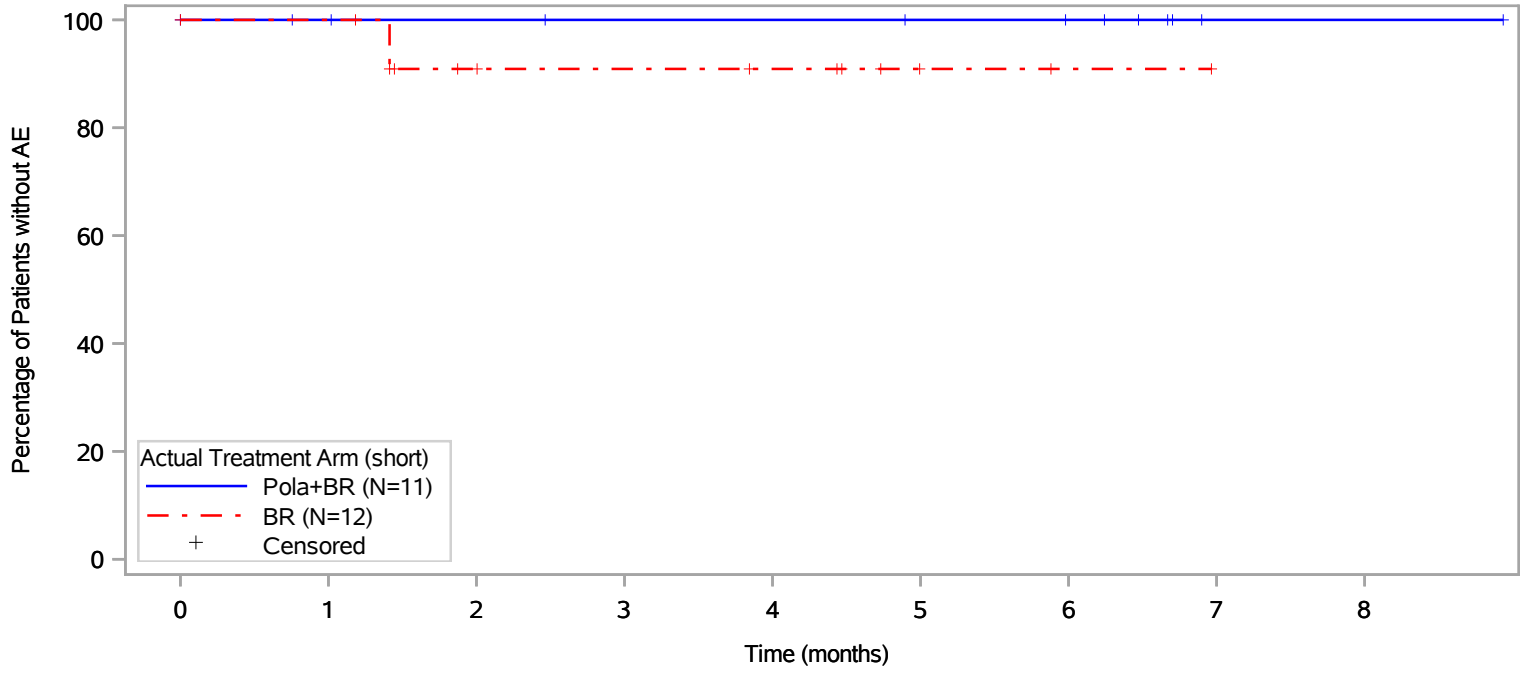
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULOSKELETAL DISCOMFORT



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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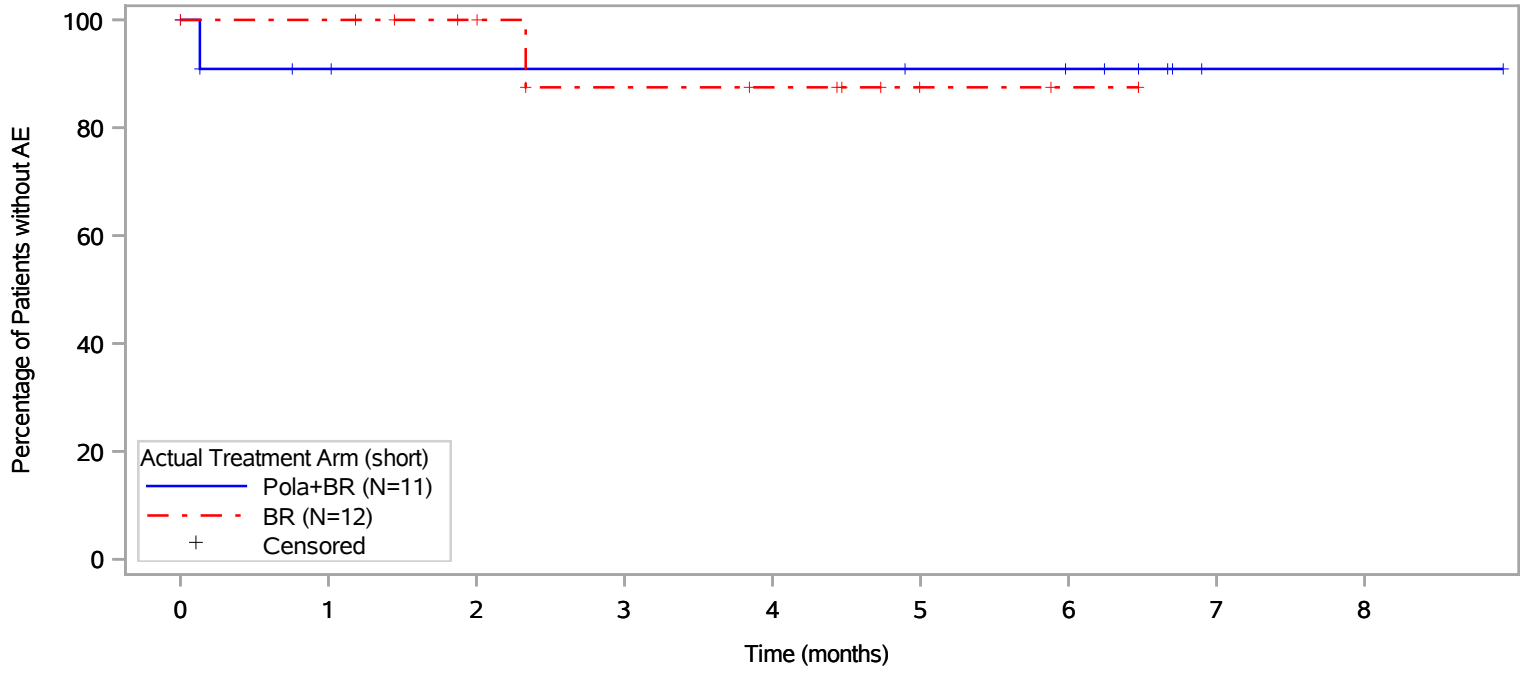
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MYALGIA



Patients at risk									
Pola+BR (N=11)	11	9	8	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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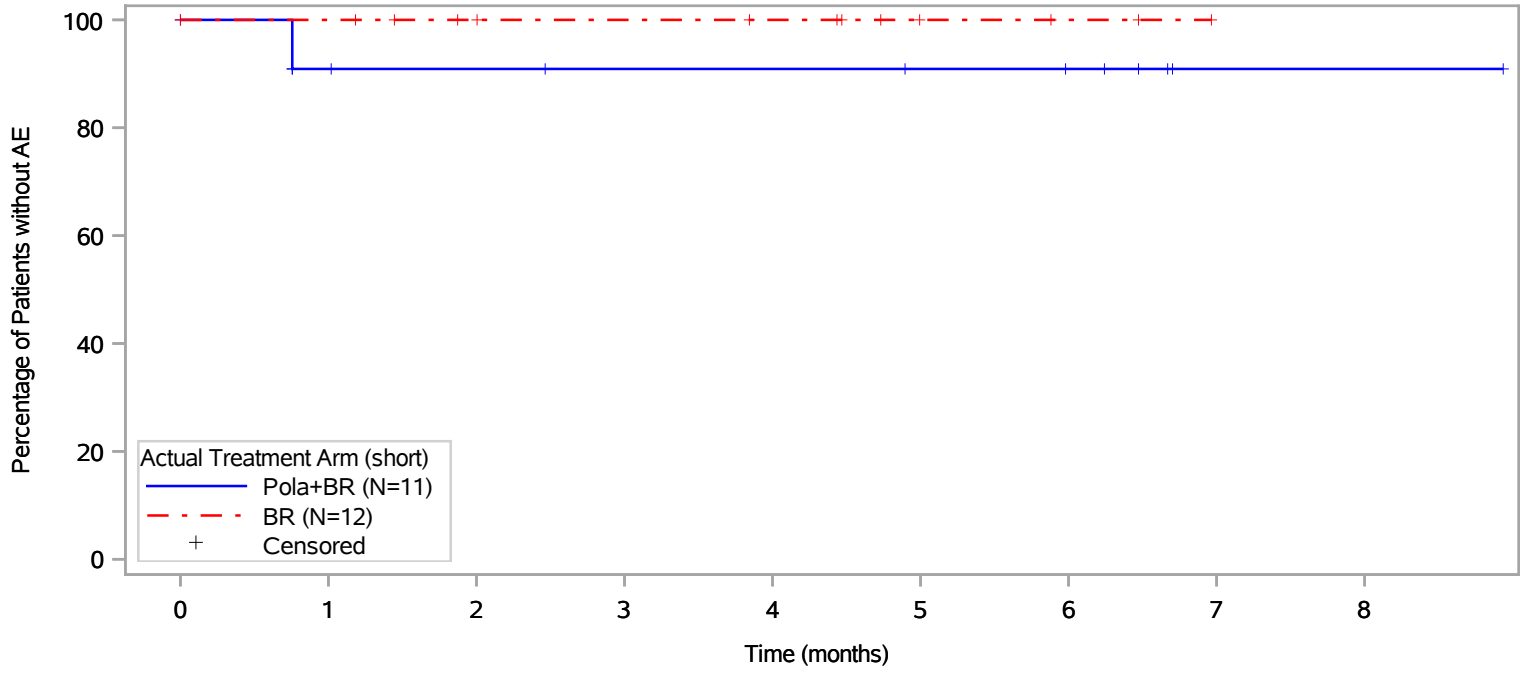
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MYOPATHY



Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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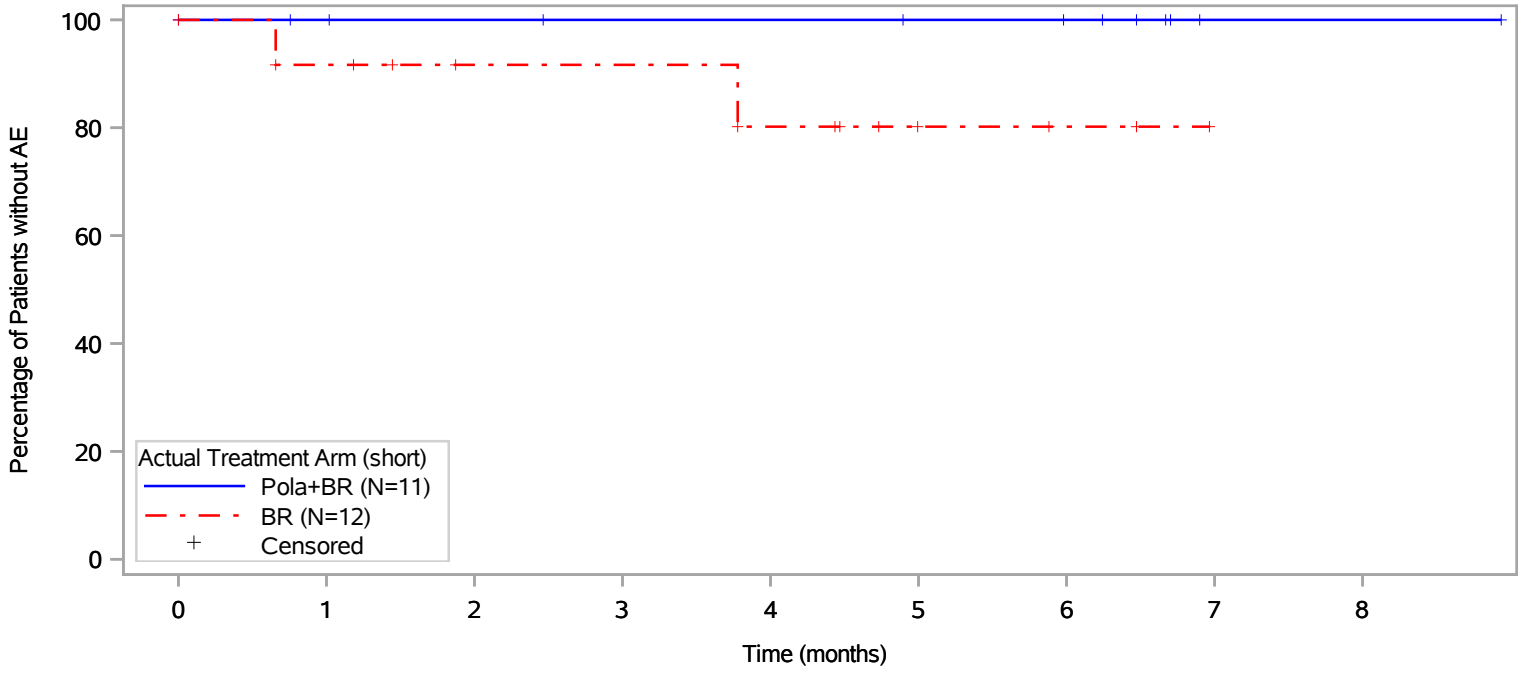
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, PAIN IN EXTREMITY



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	3	3	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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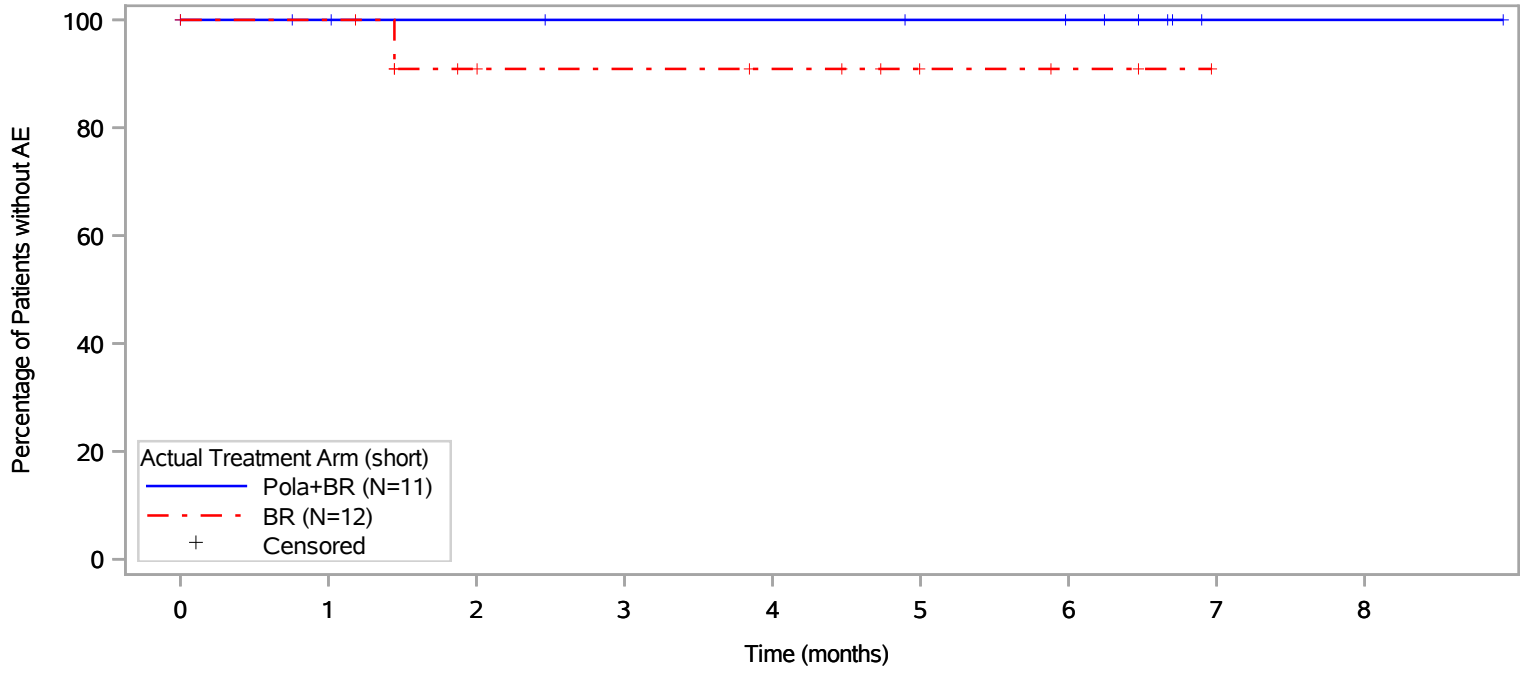
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, PAIN IN JAW



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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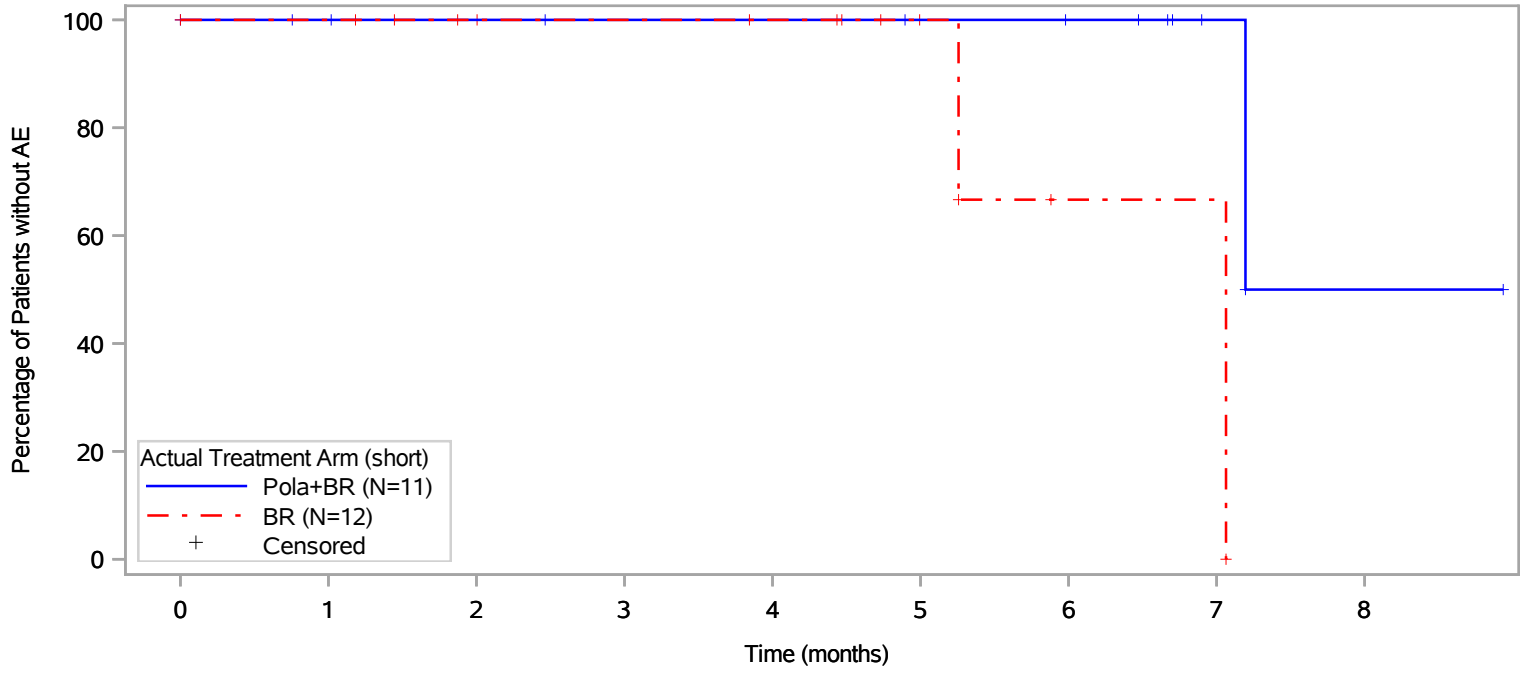
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	1
BR (N=12)	12	12	9	8	7	3	1	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	10	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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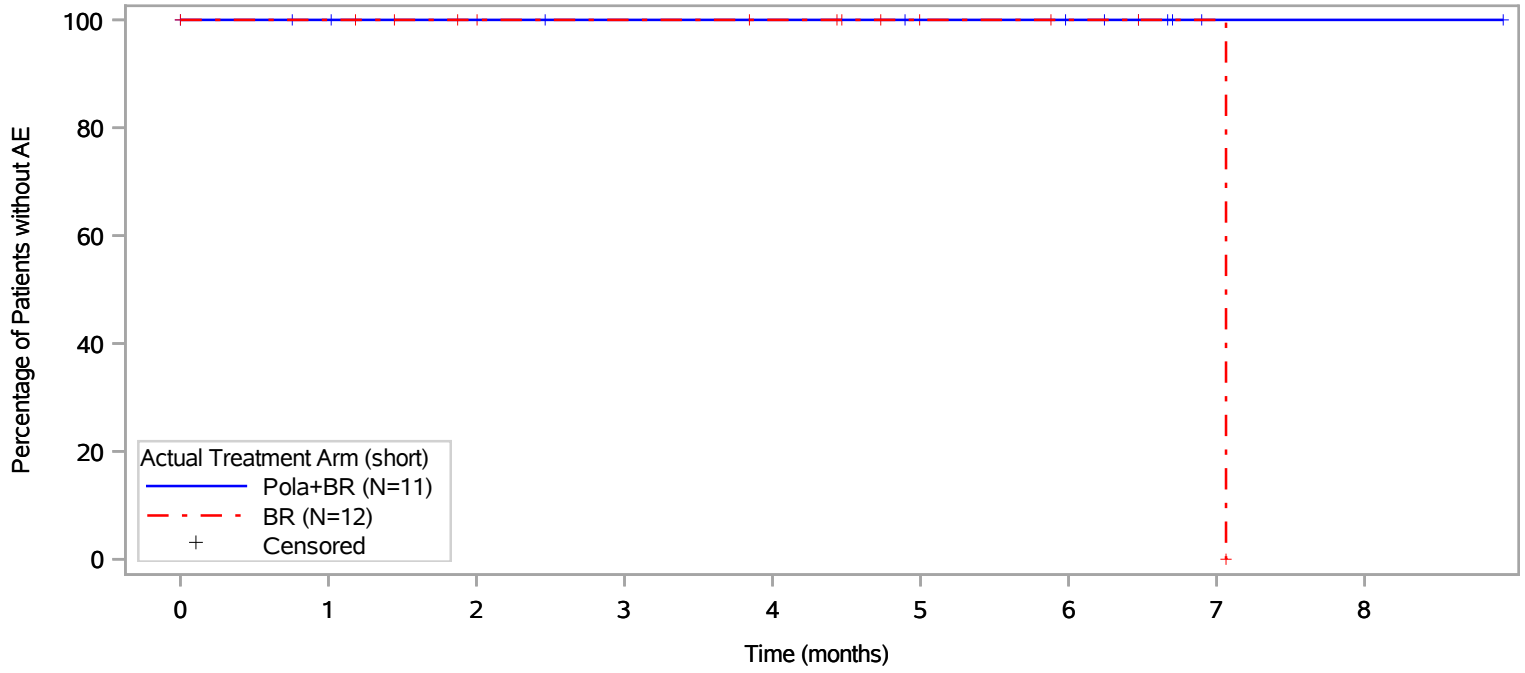
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), EPIGLOTTIC CANCER

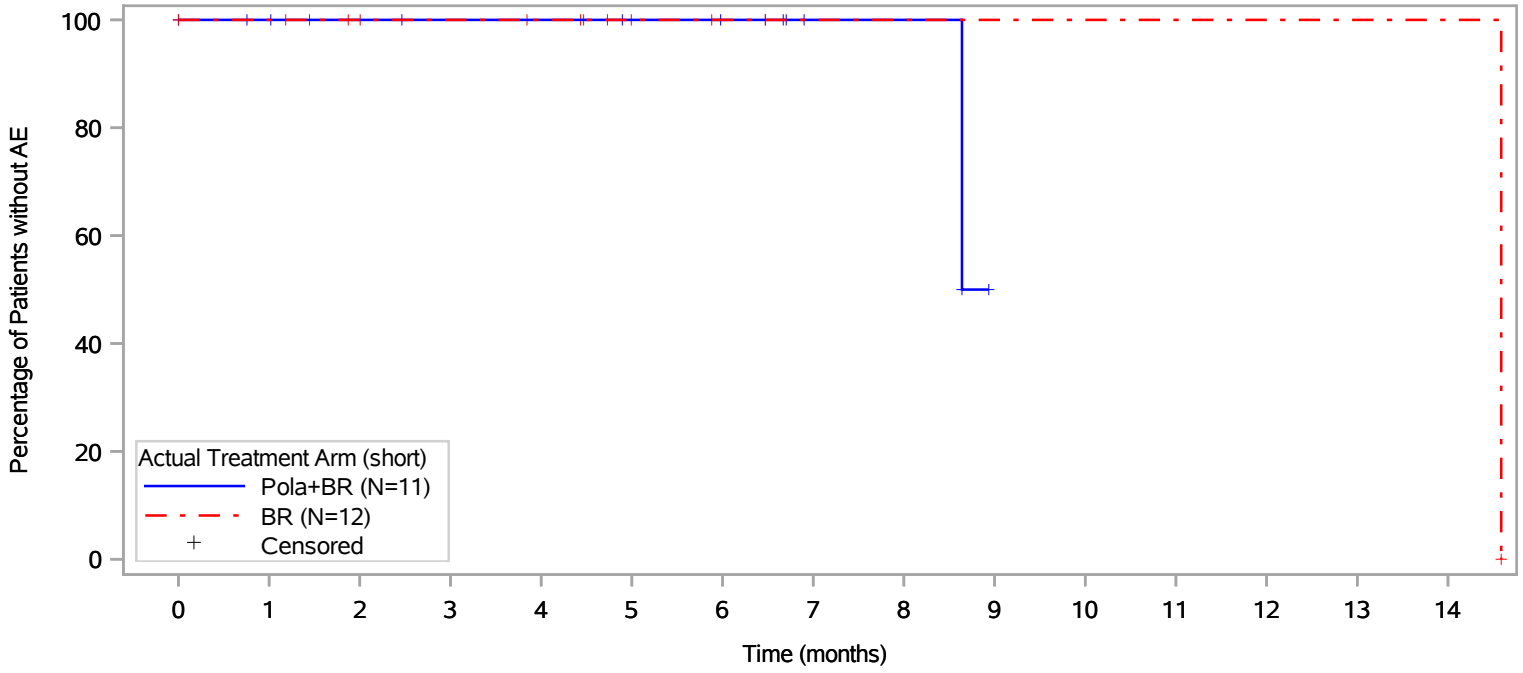


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



Patients at risk															
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	NE	NE	NE	NE	NE	NE
BR (N=12)	12	12	9	8	7	3	2	1	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	NE	NE	NE	NE	NE	NE
BR (N=12)	0	0	3	4	5	9	10	11	11	11	11	11	11	11	11

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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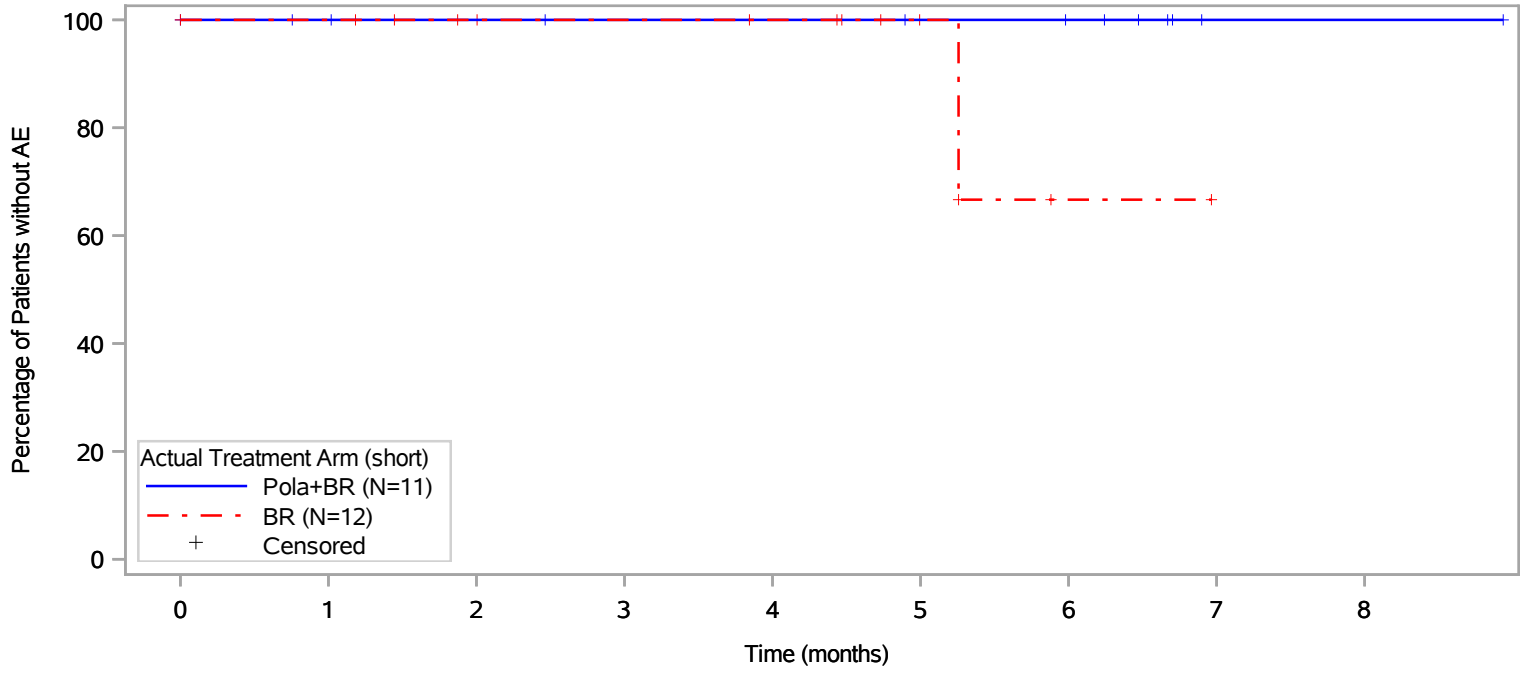
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), PAPILLARY THYROID CANCER



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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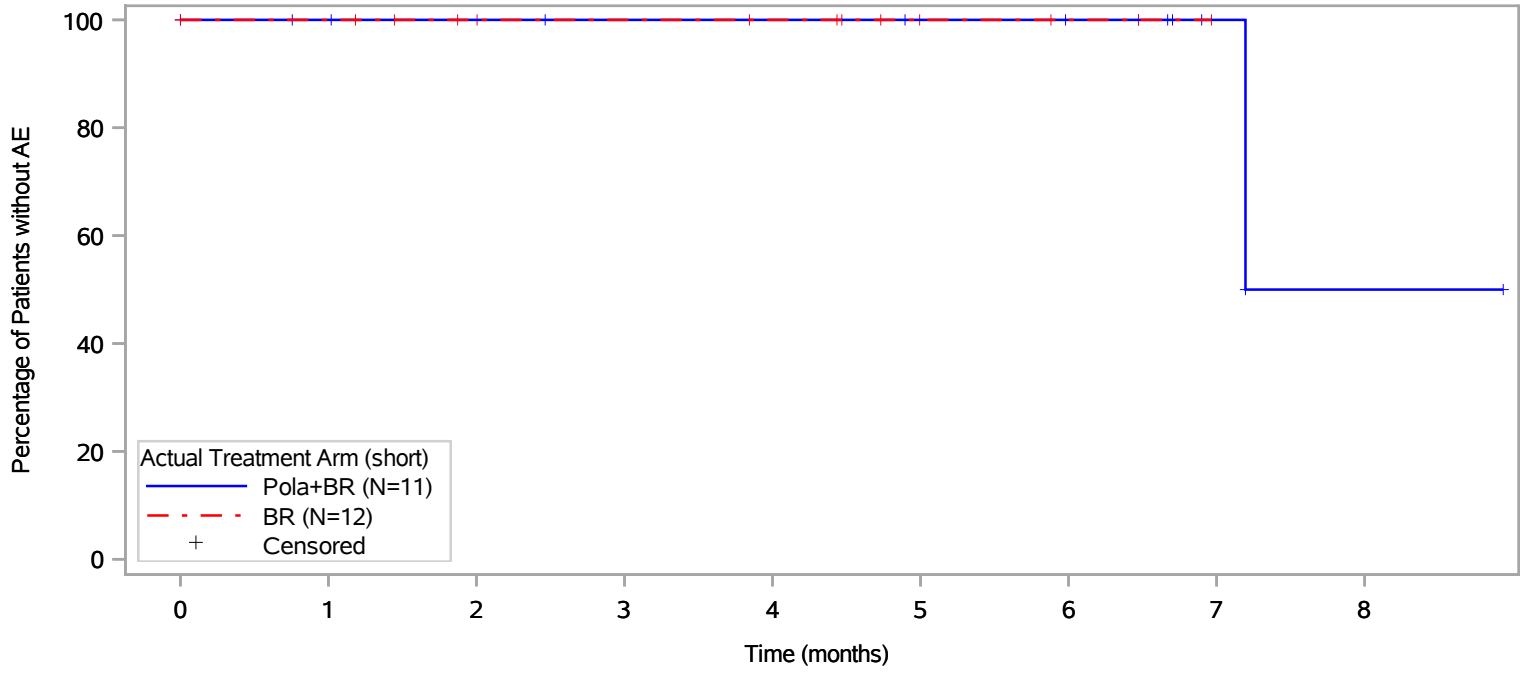
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), SQUAMOUS CELL CARCINOMA



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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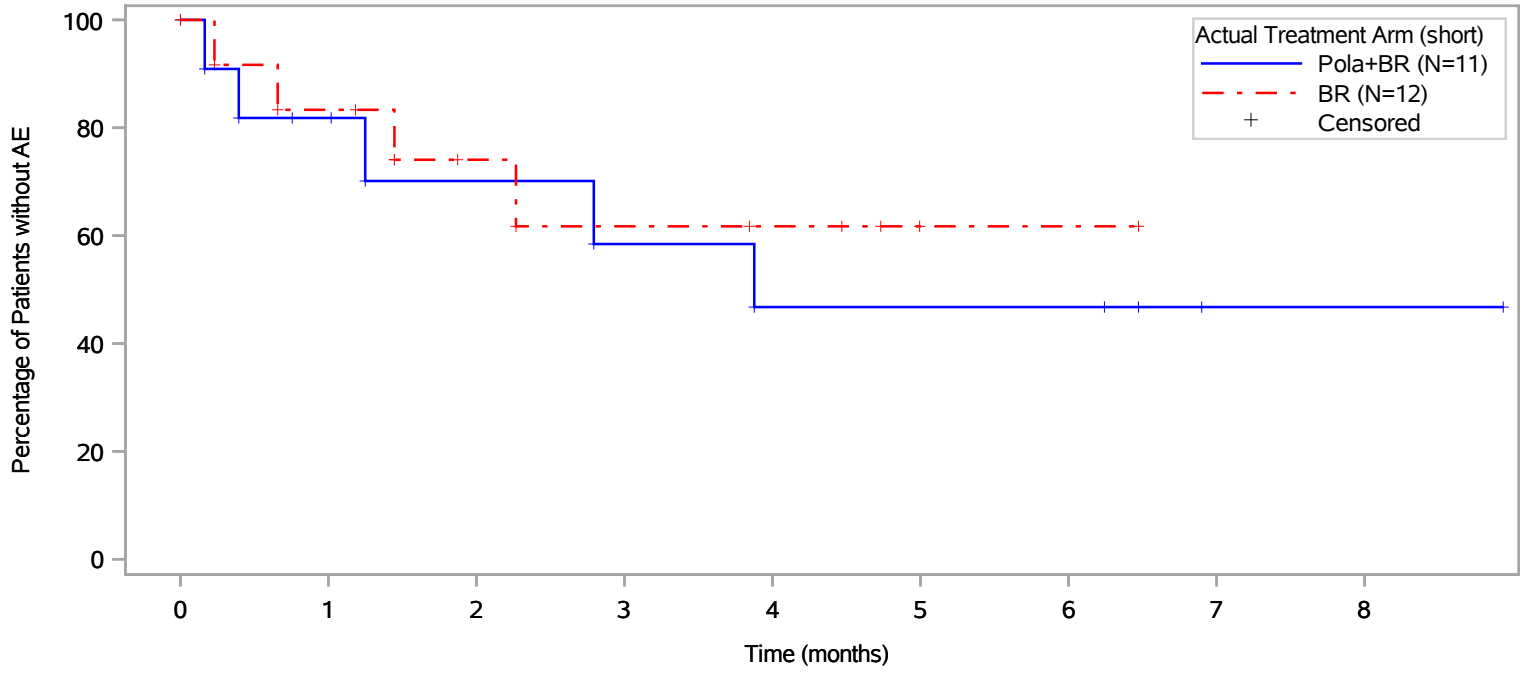
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	8	6	5	4	4	4	1	1
BR (N=12)	12	10	6	5	4	1	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	2	2	5	5
BR (N=12)	0	0	3	3	4	7	7	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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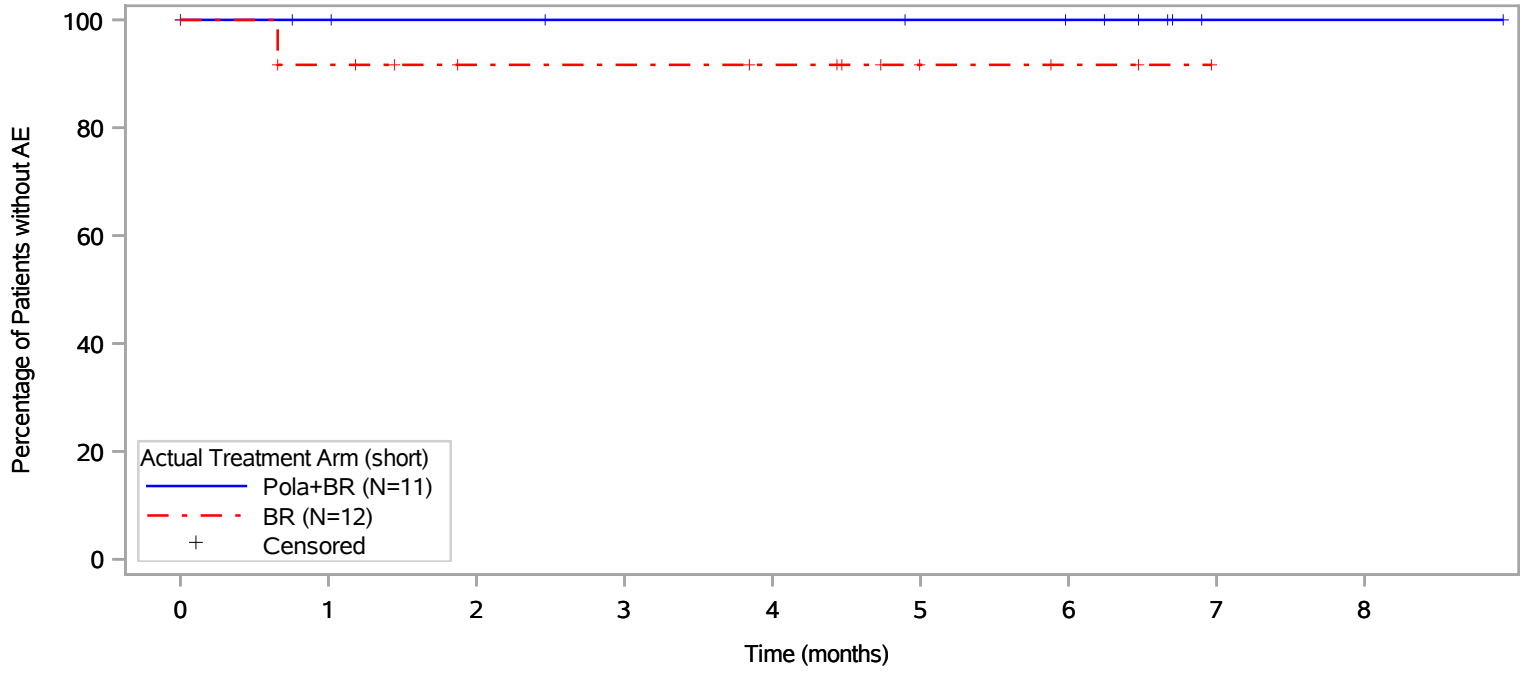
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

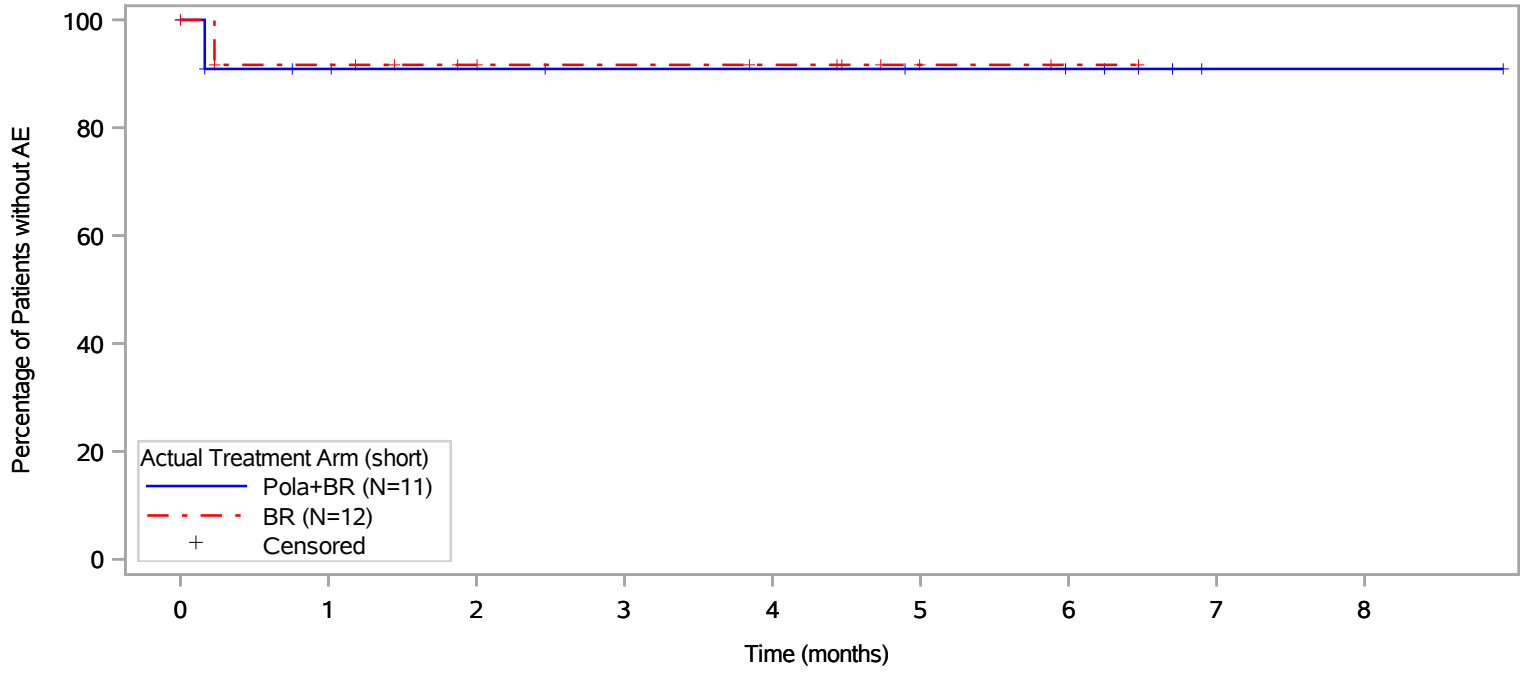
NERVOUS SYSTEM DISORDERS, DECREASED VIBRATORY SENSE



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, DIZZINESS



Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	5	1	1
BR (N=12)	12	11	8	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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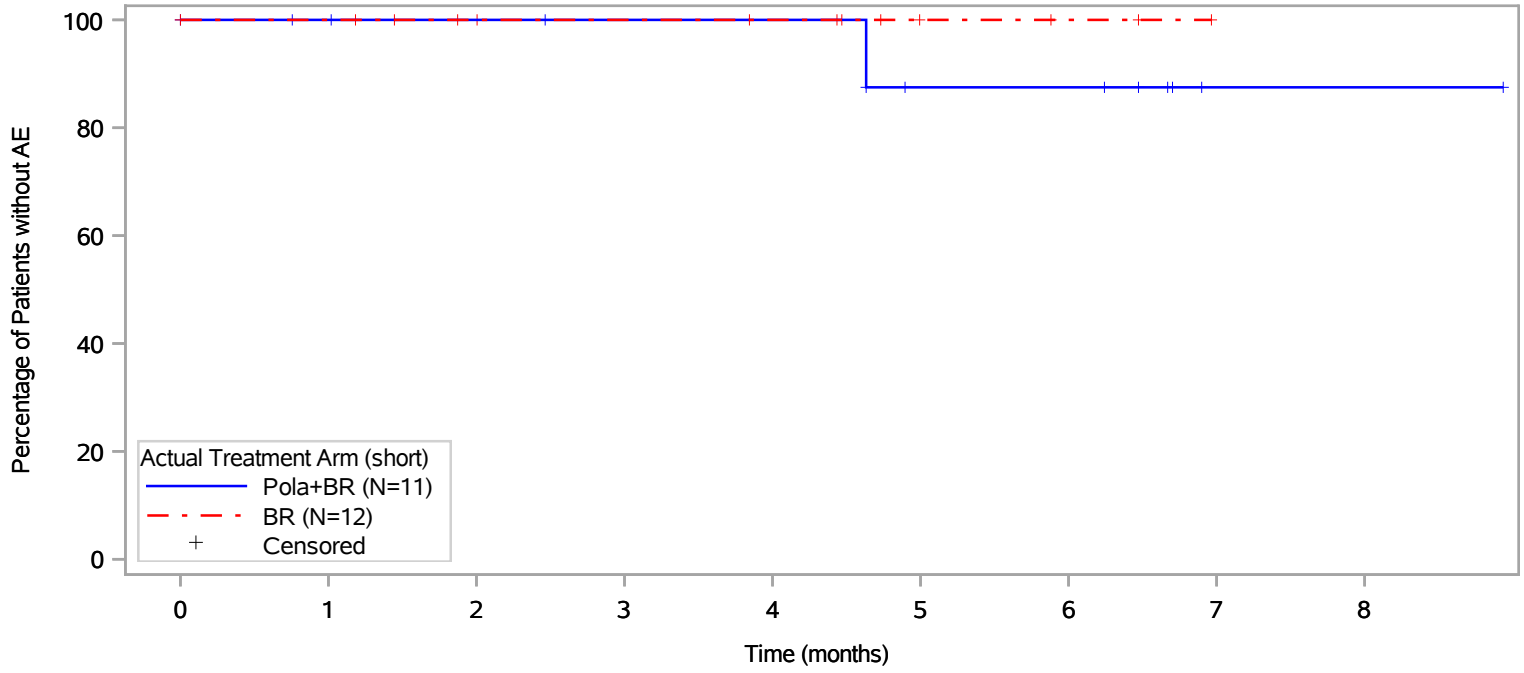
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, FACIAL PARALYSIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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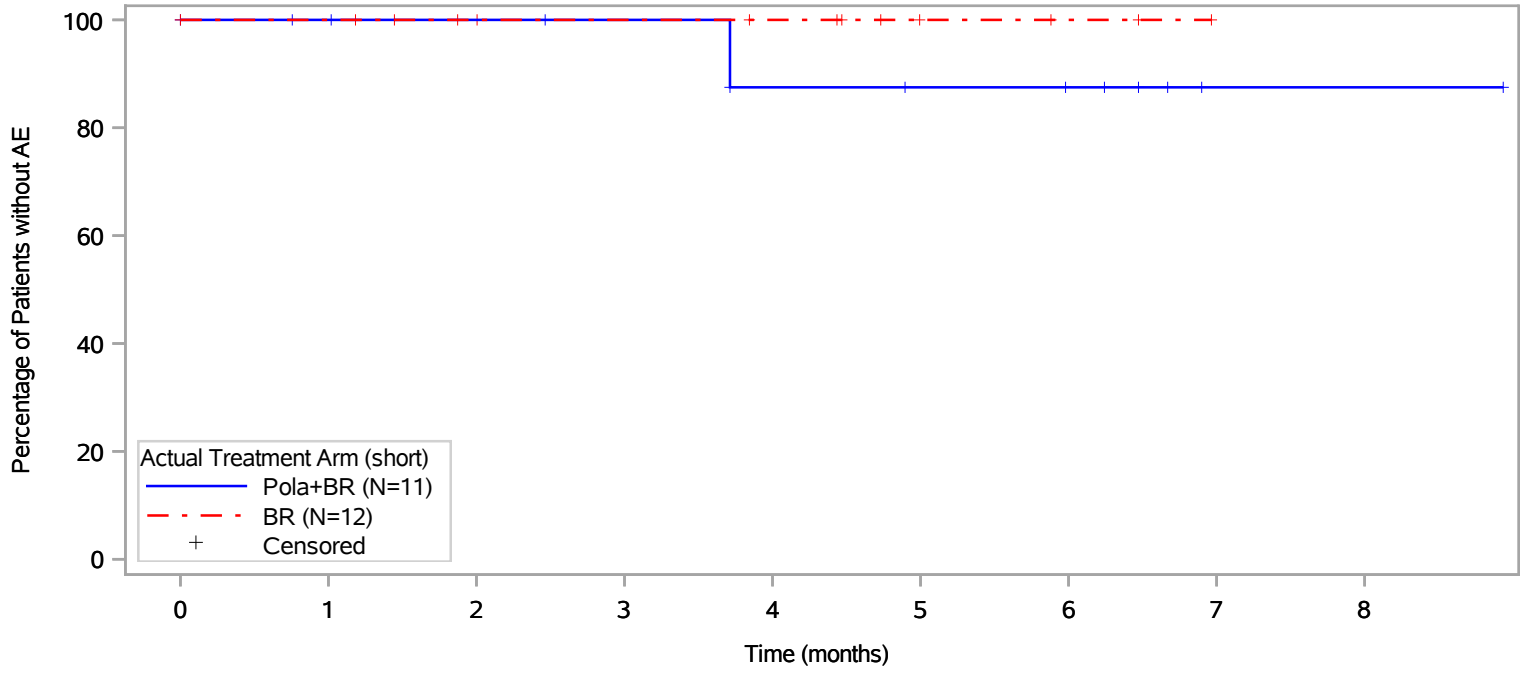
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, HYPOTONIA



Patients at risk								
Pola+BR (N=11)	11	10	9	8	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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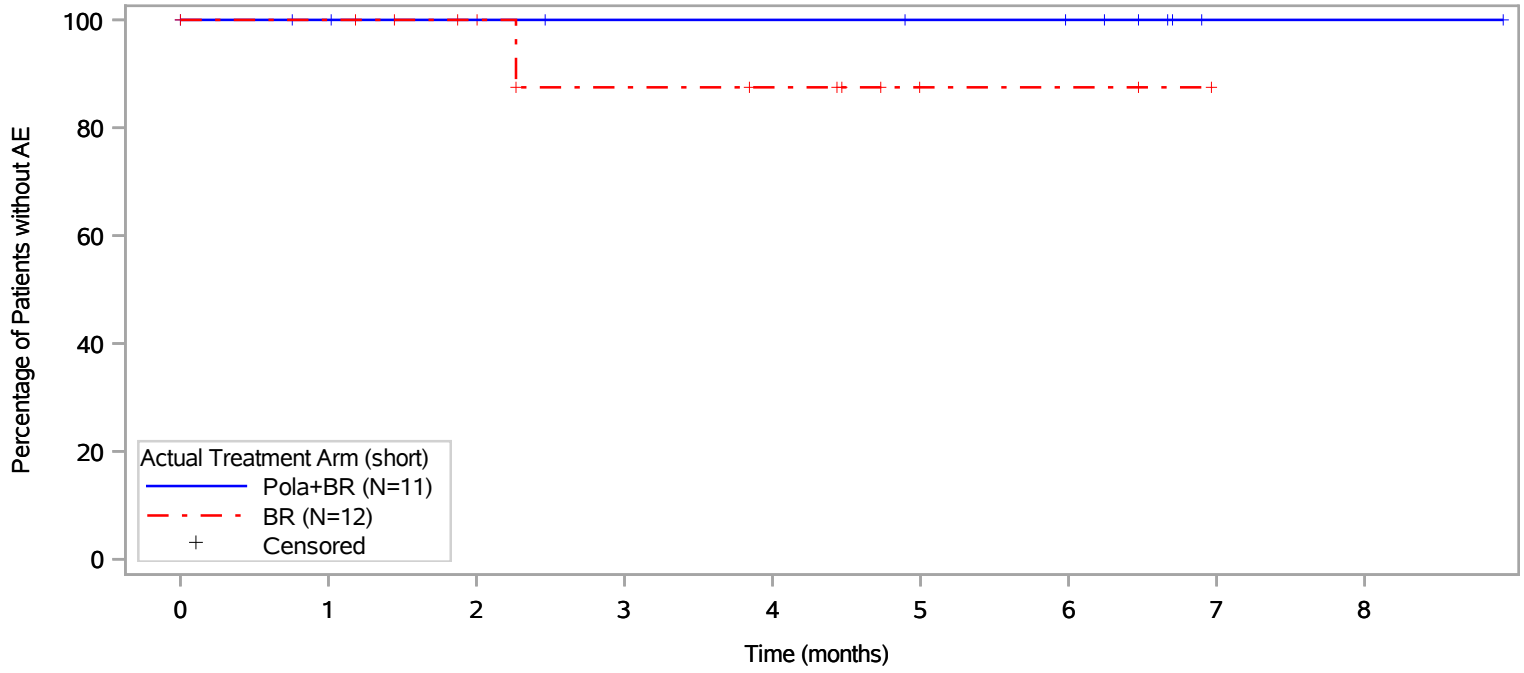
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, NEURALGIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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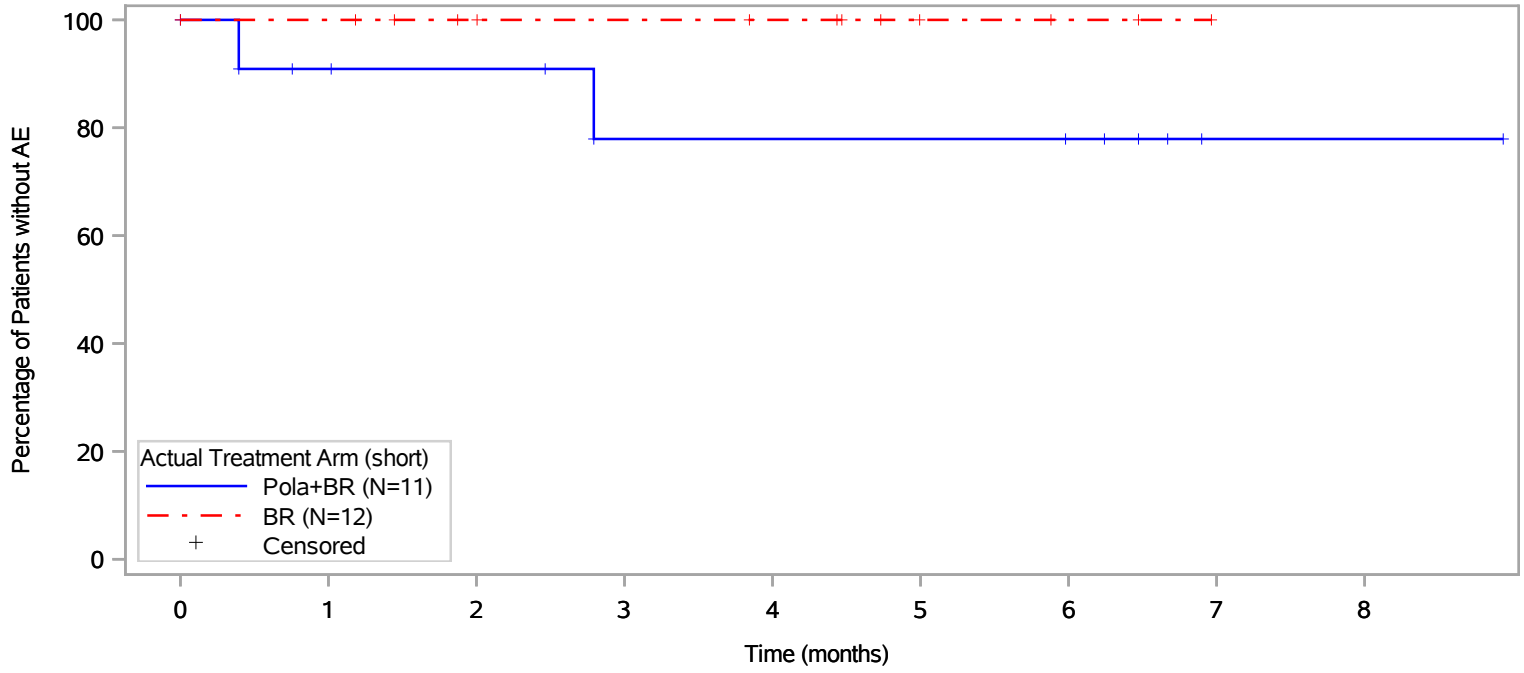
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, NEUROPATHY PERIPHERAL



Patients at risk									
Pola+BR (N=11)	11	9	8	6	6	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	4	8	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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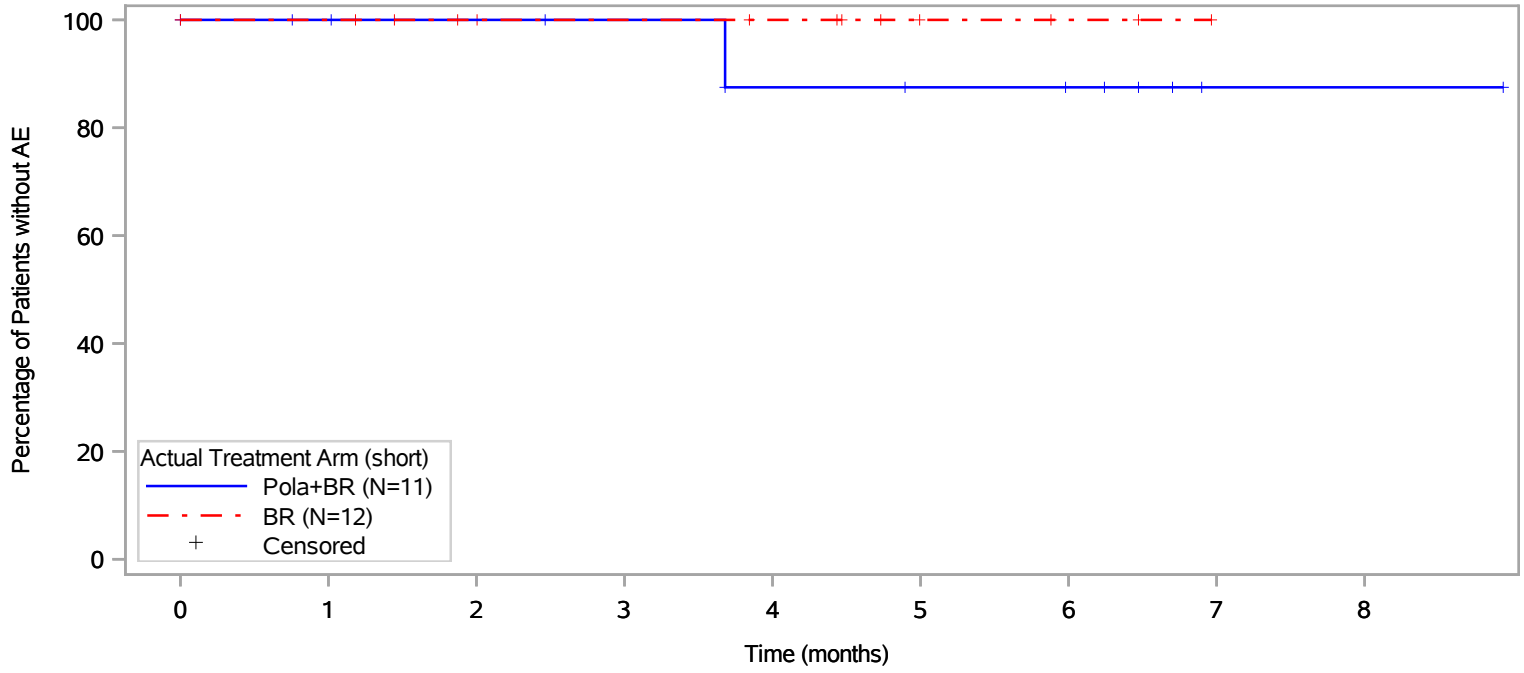
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, PARAESTHESIA



Patients at risk								
Pola+BR (N=11)	11	10	9	8	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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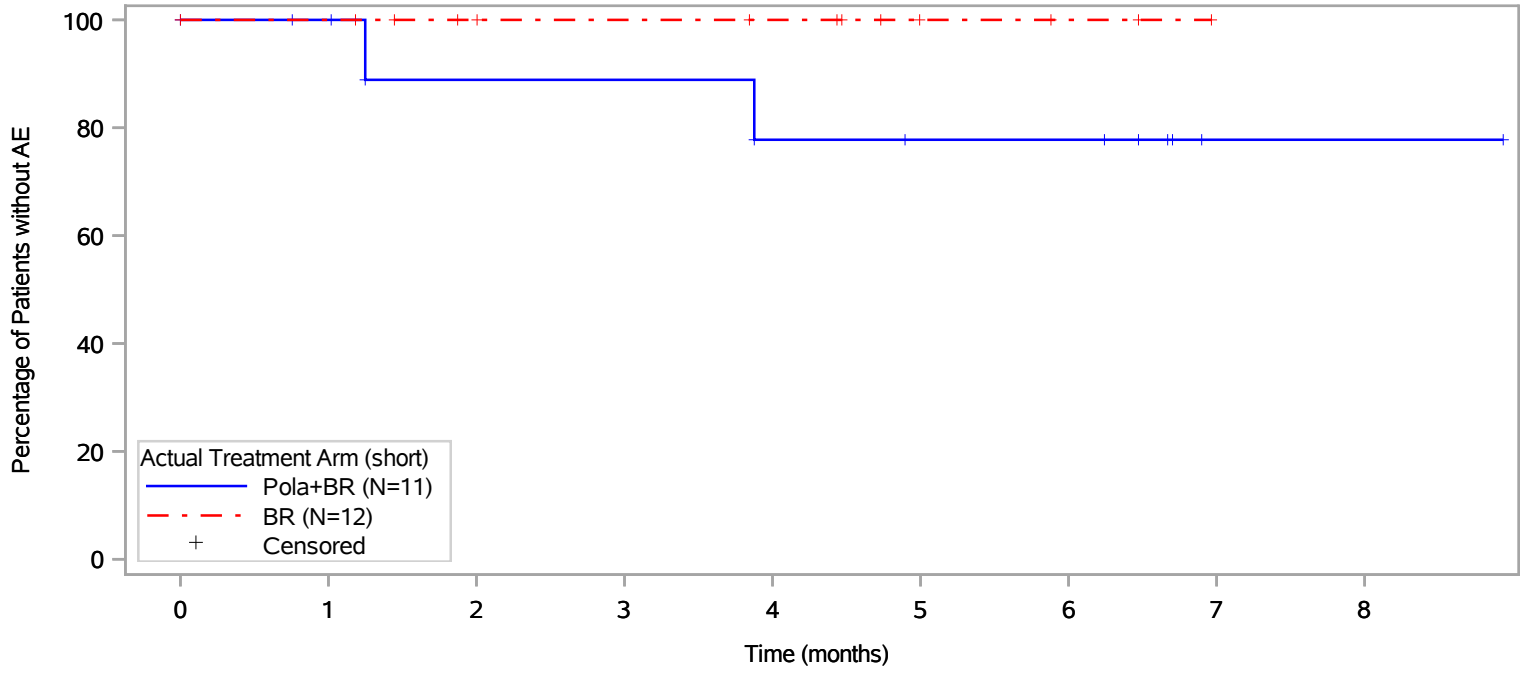
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, PERIPHERAL SENSORY NEUROPATHY



Patients at risk									
Pola+BR (N=11)	11	10	8	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	3	8	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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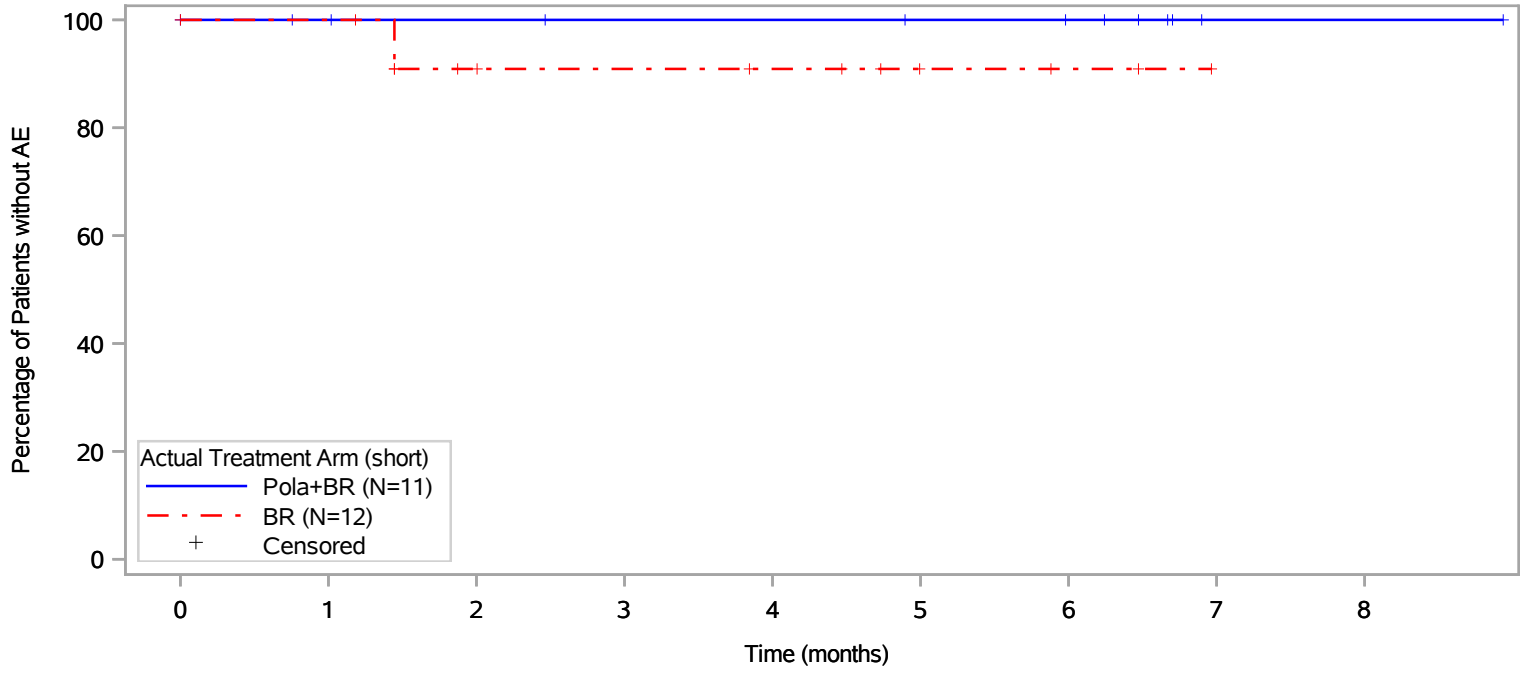
01DEC2022 20:20

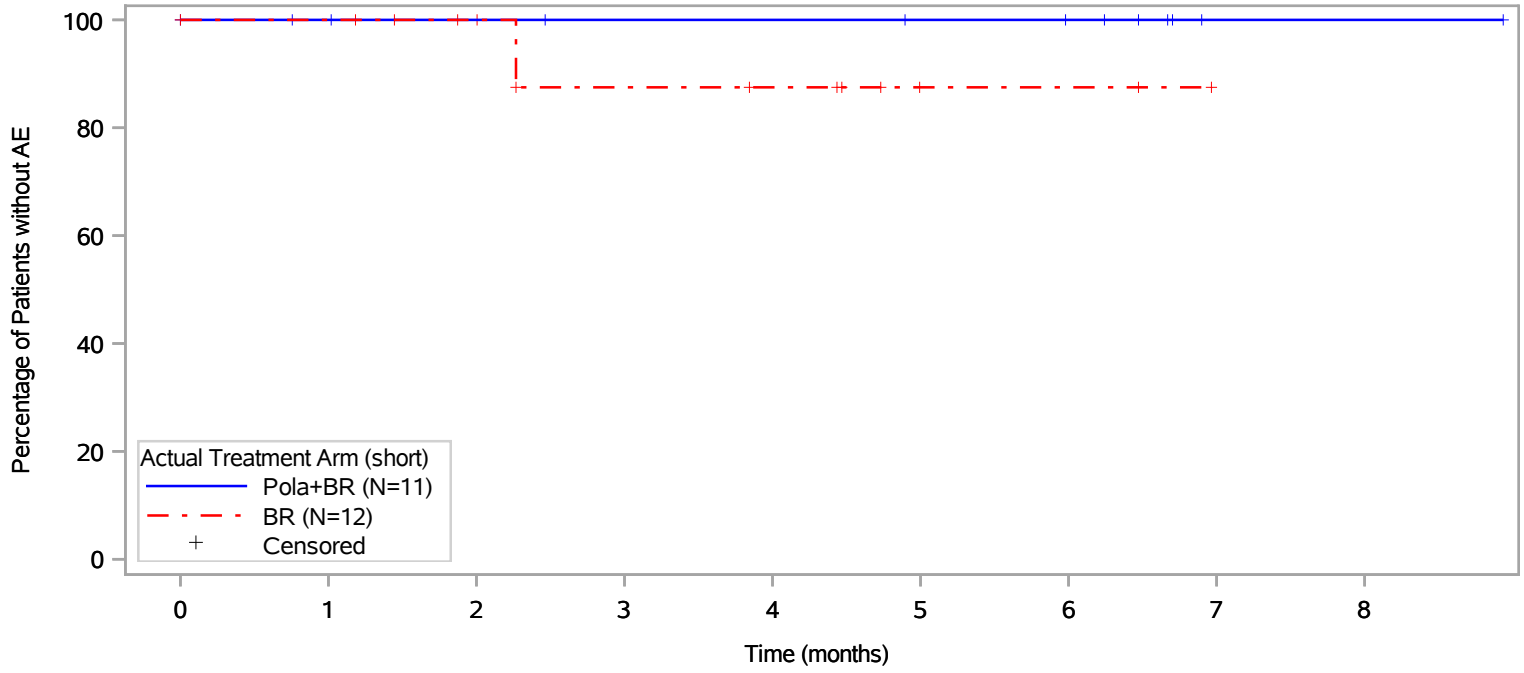
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, RESTLESS LEGS SYNDROME



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, SYNCOPE

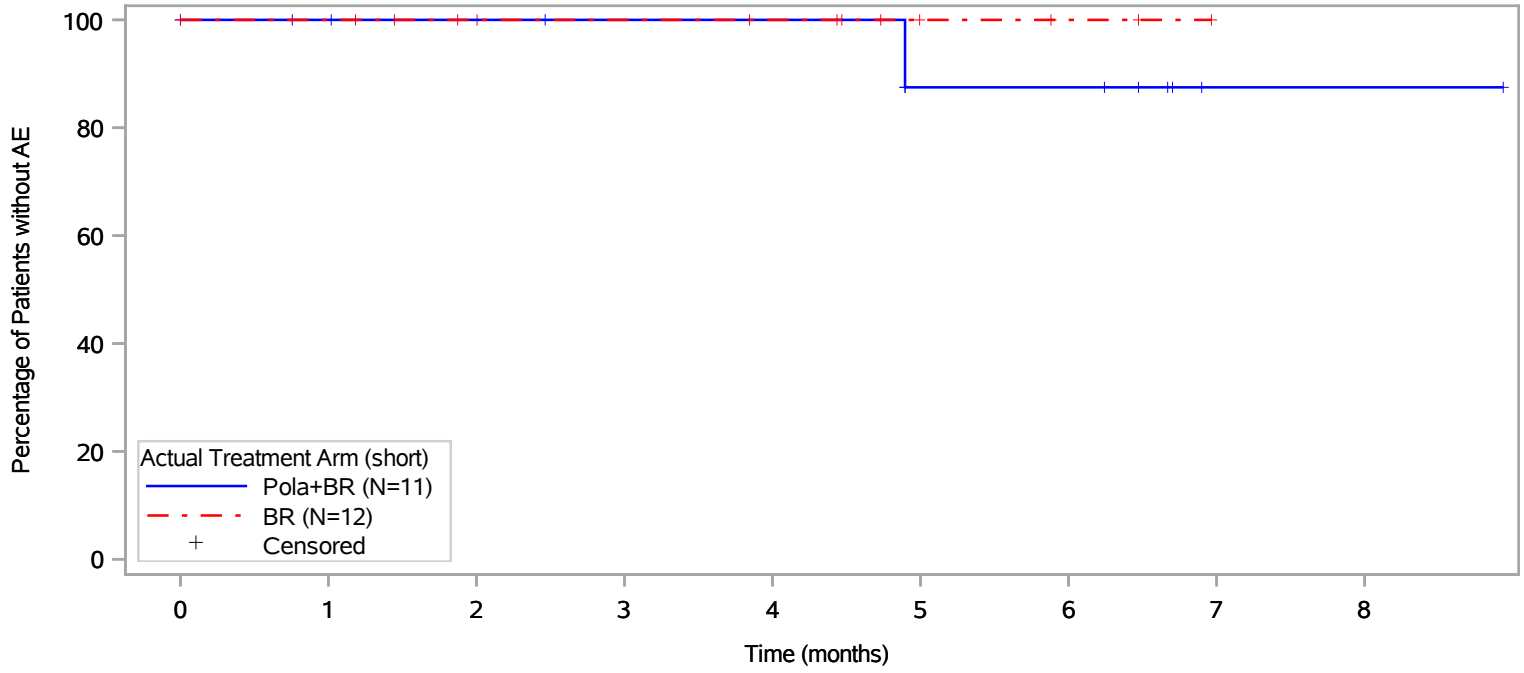


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, VOCAL CORD PARALYSIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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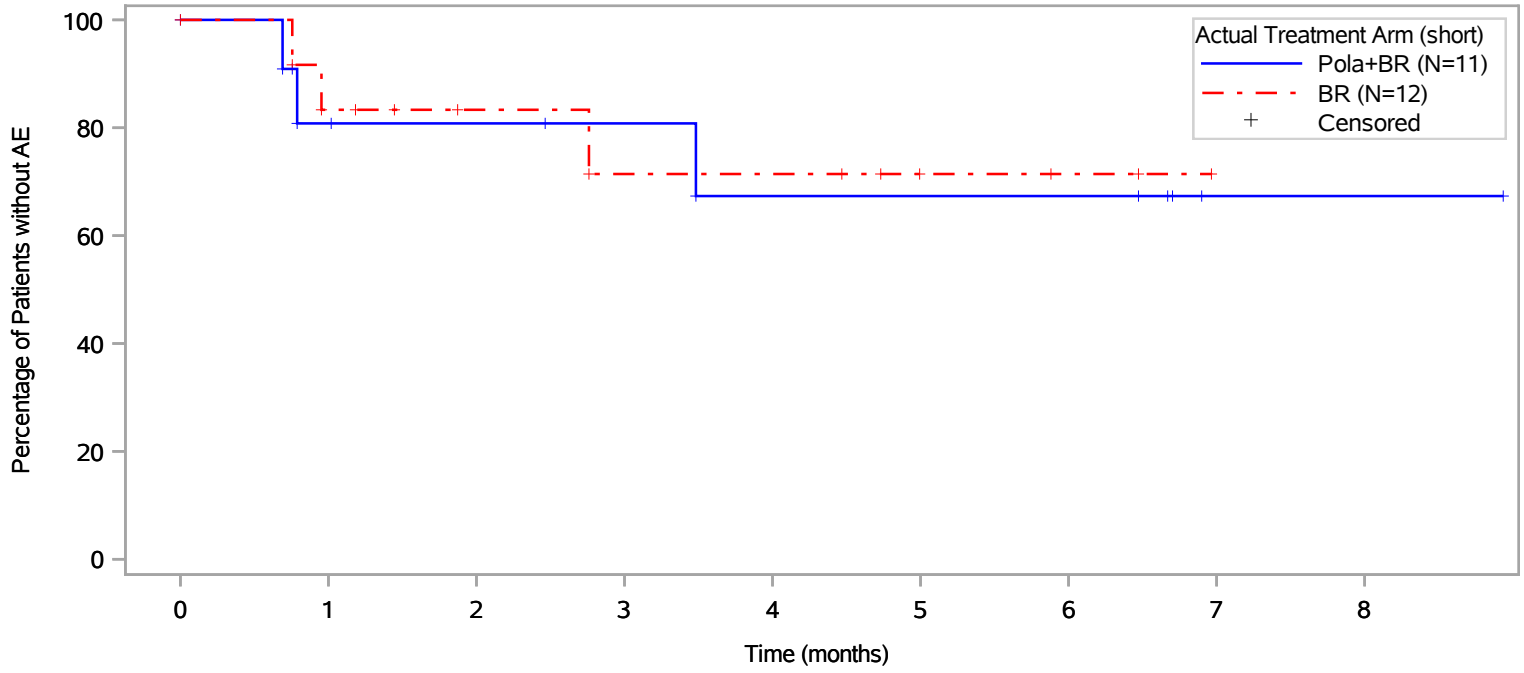
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	8	7	6	5	5	5	1	1
BR (N=12)	12	10	7	6	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	3	7	7
BR (N=12)	0	0	3	3	3	6	7	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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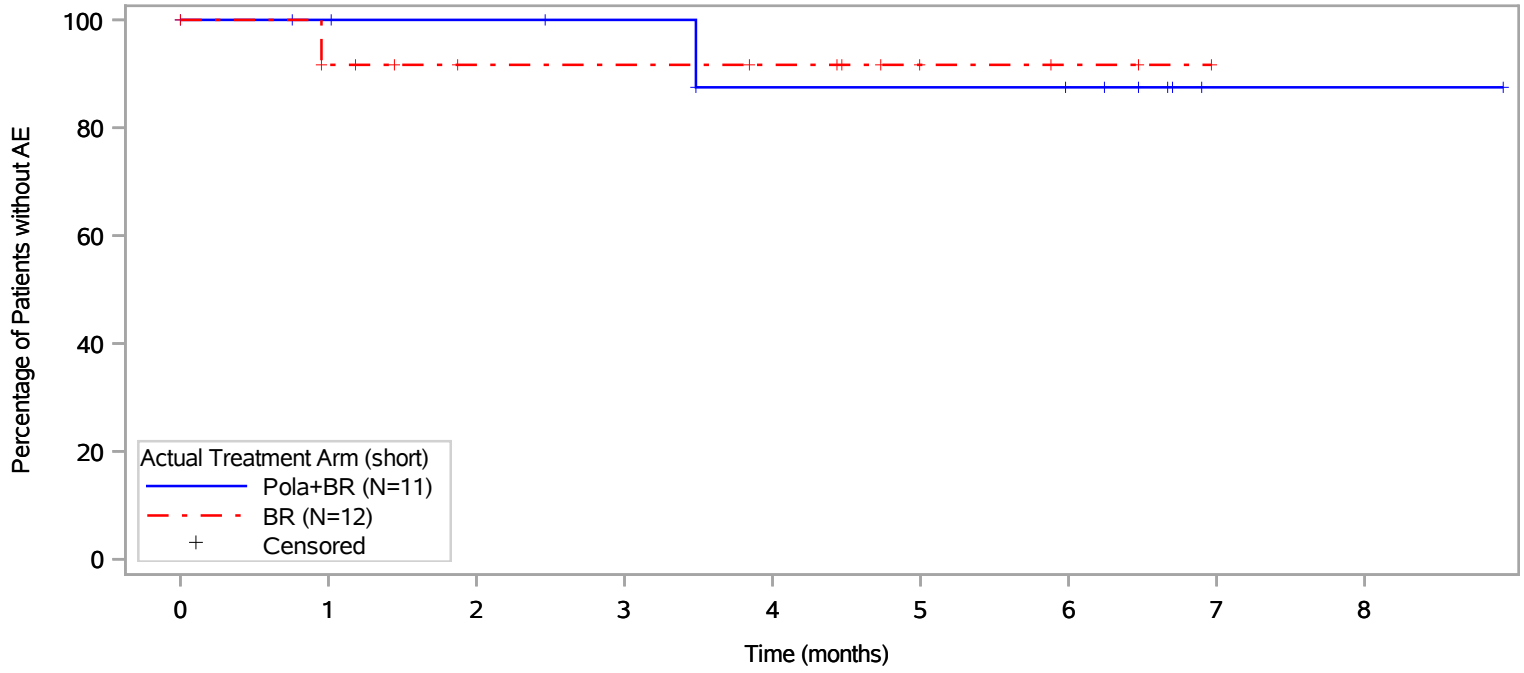
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, ANXIETY



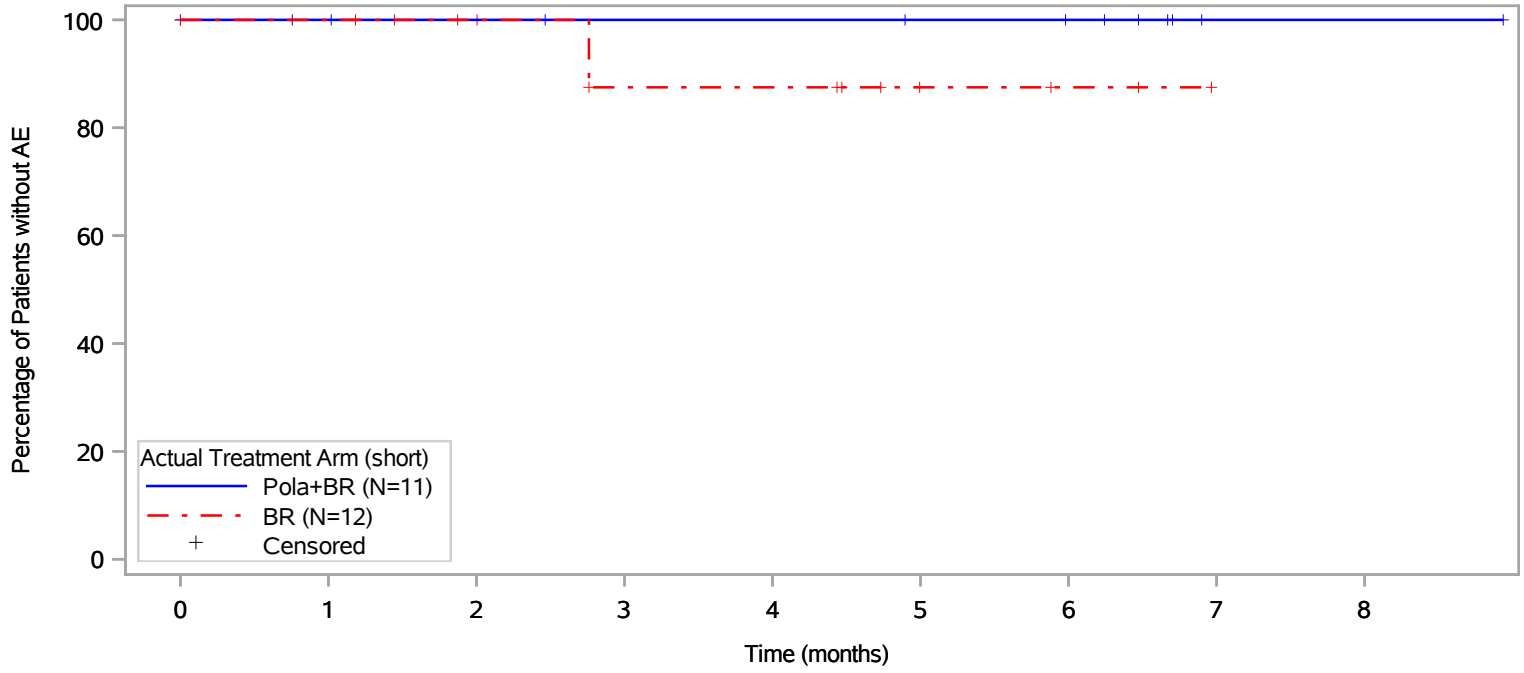
Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	7	6	1	1
BR (N=12)	12	11	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	4	9	9
BR (N=12)	0	0	3	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

PSYCHIATRIC DISORDERS, DEPRESSED MOOD



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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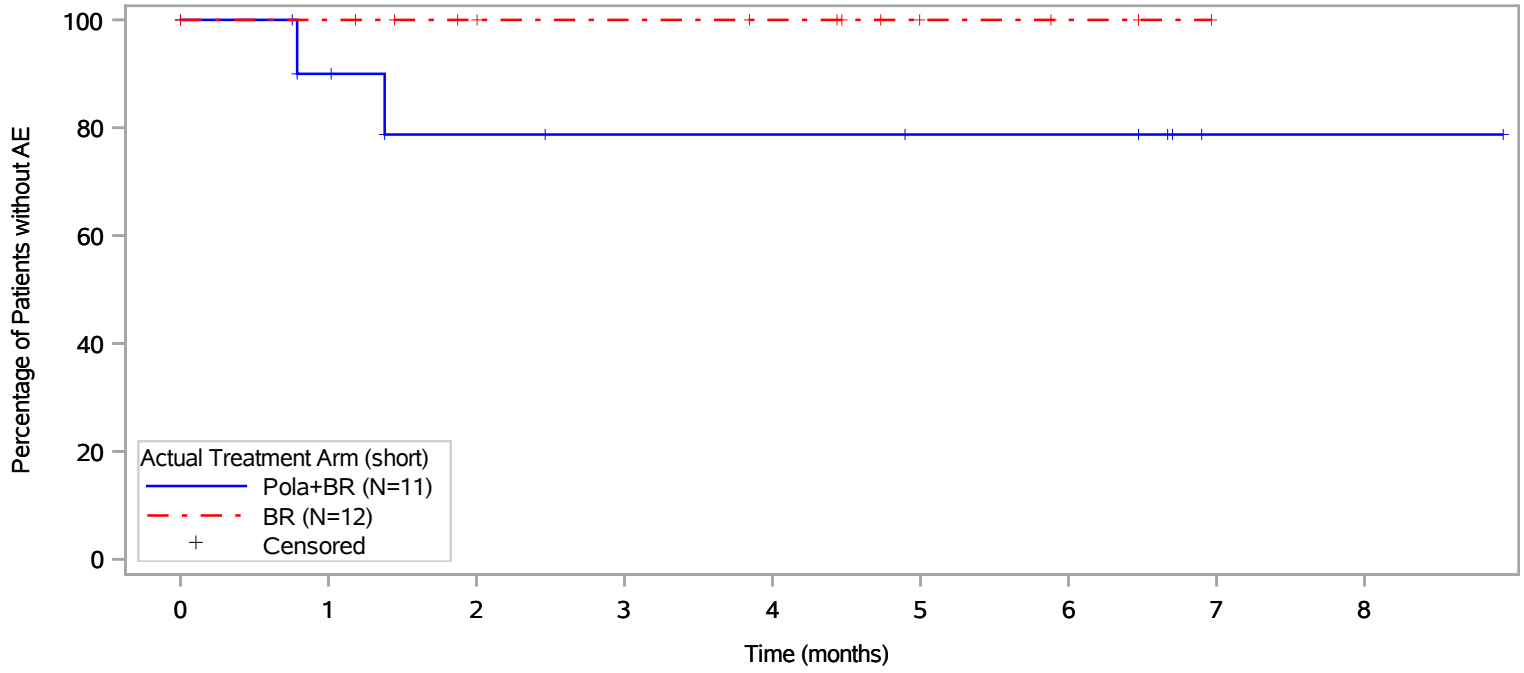
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, INSOMNIA



Patients at risk									
Pola+BR (N=11)	11	9	7	6	6	5	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	8	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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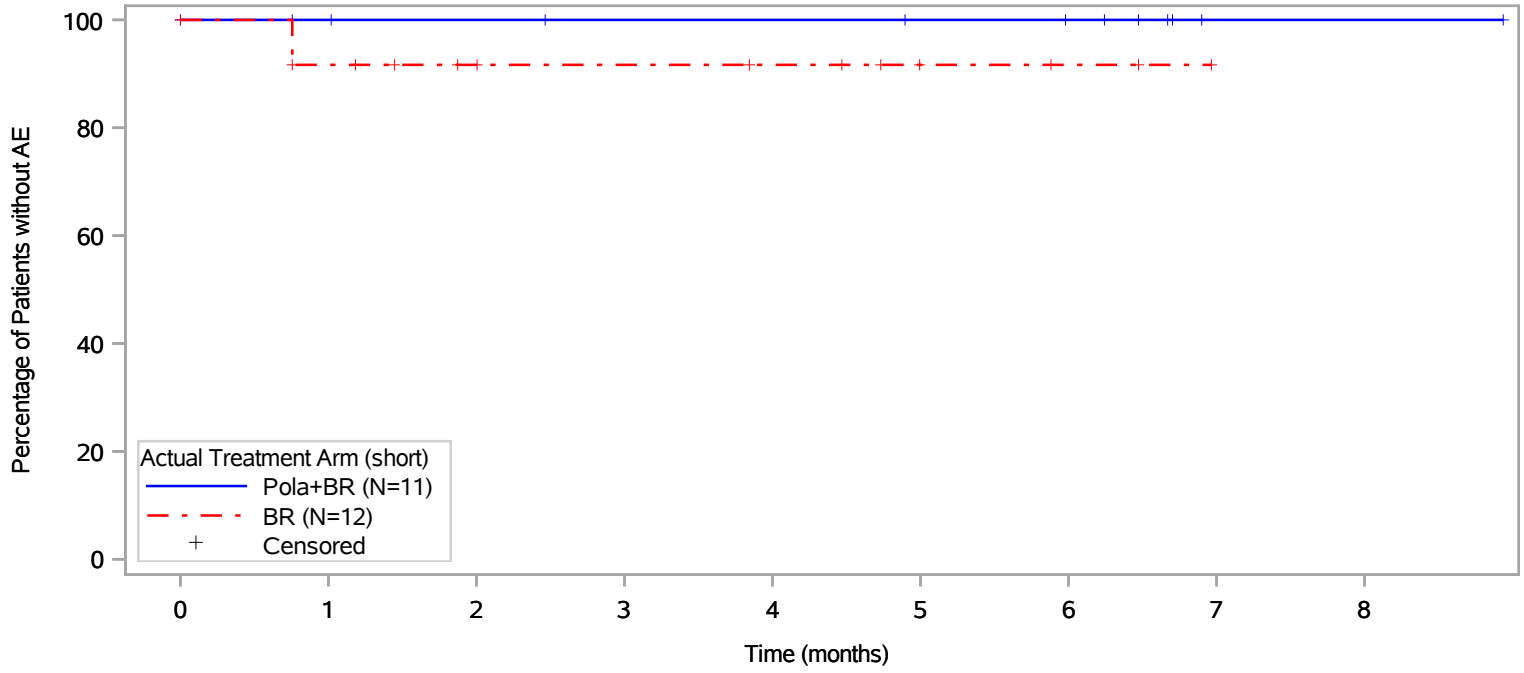
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, MOOD ALTERED



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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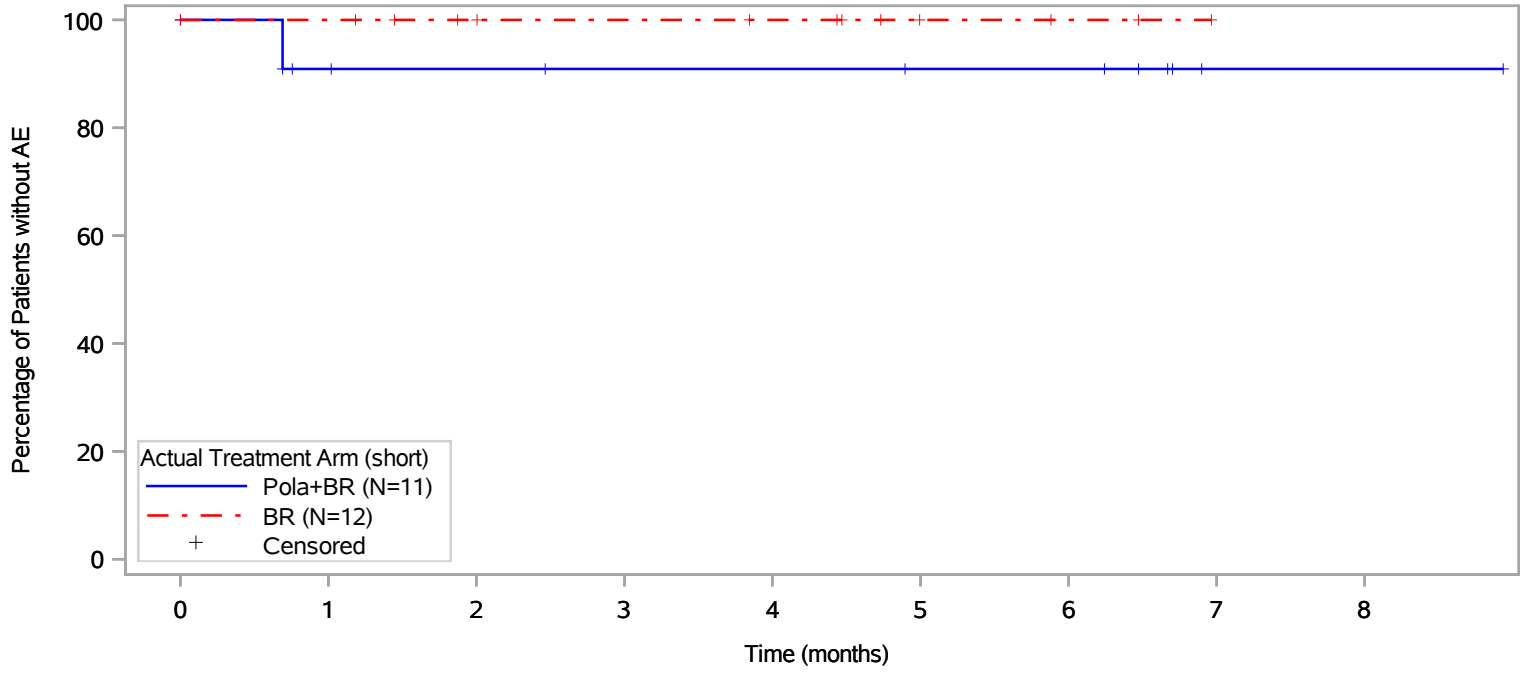
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, POOR QUALITY SLEEP



Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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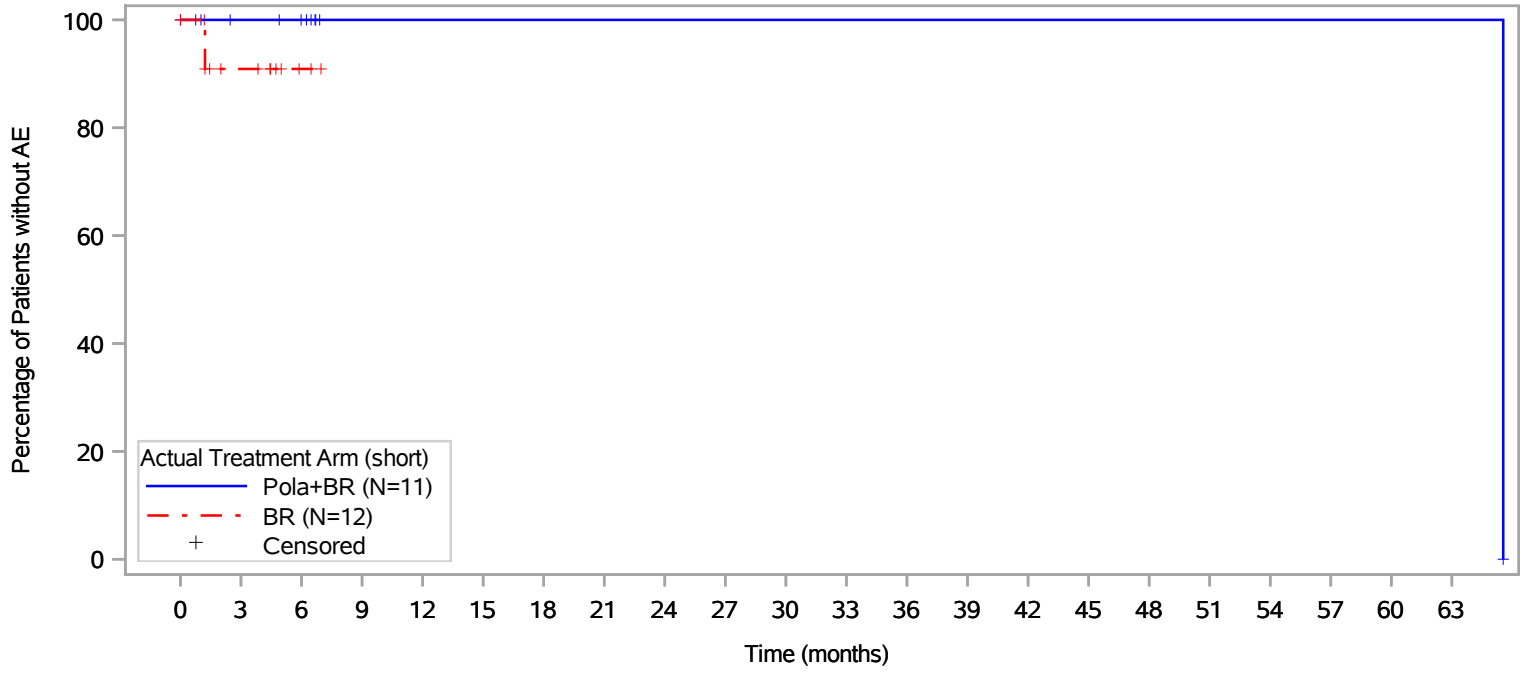
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk																							
Pola+BR (N=11)	11	8	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=12)	12	8	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=11)	0	3	5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BR (N=12)	0	3	9	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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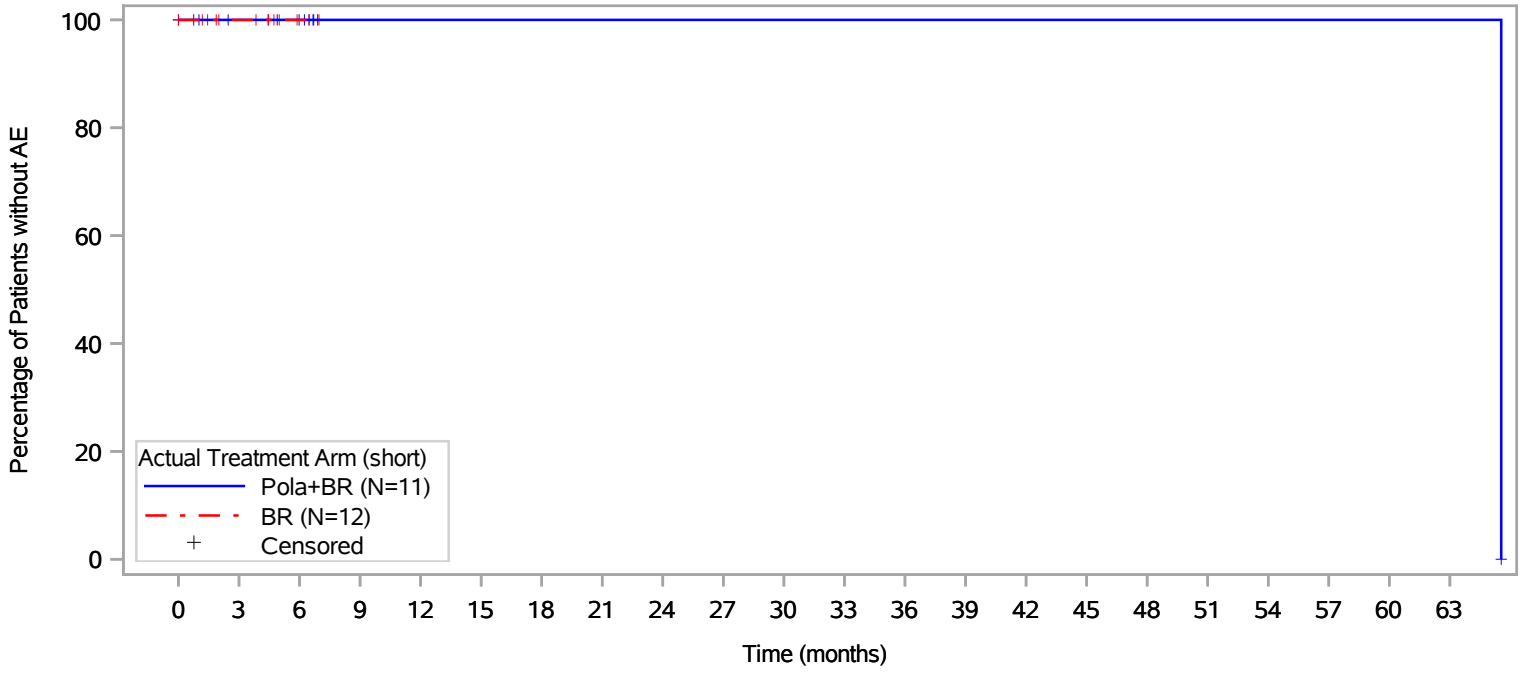
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk																							
Pola+BR (N=11)	11	8	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=12)	12	8	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=11)	0	3	5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BR (N=12)	0	4	10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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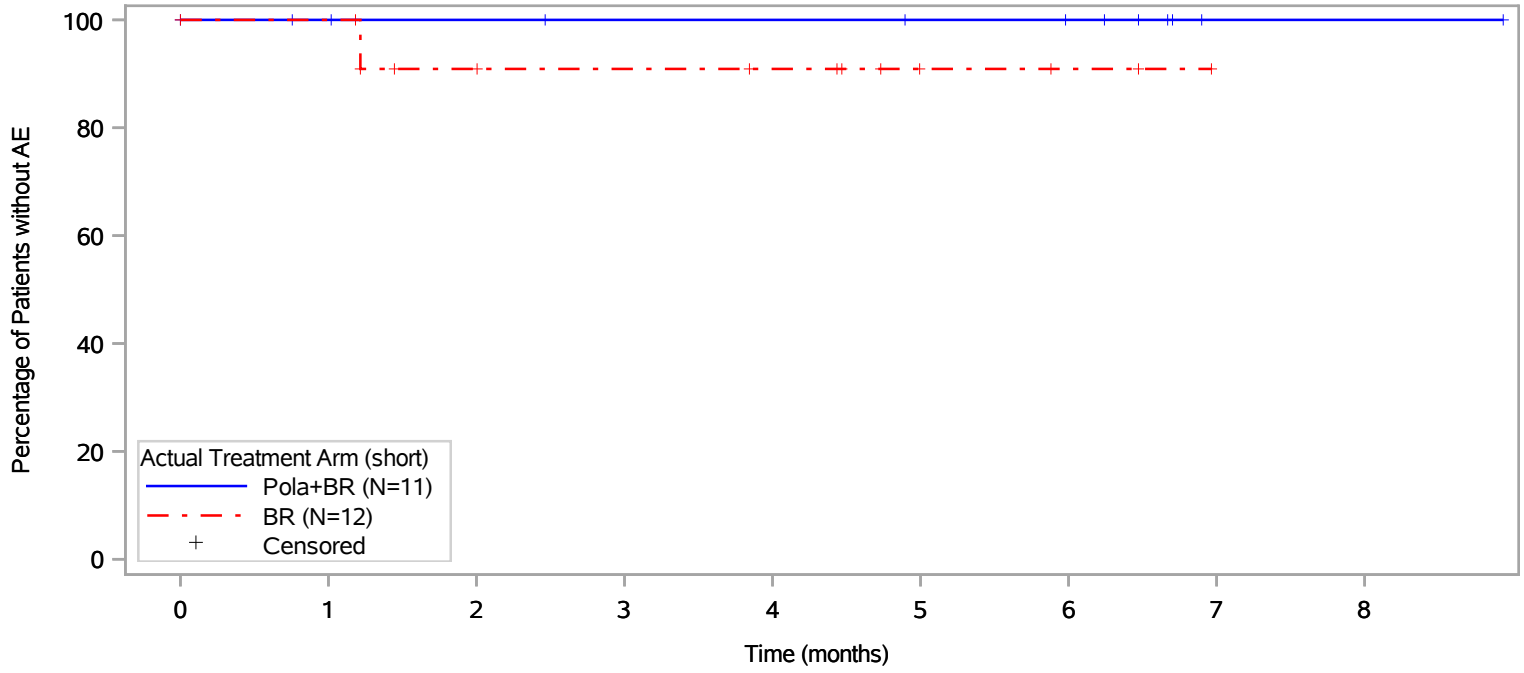
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ANURIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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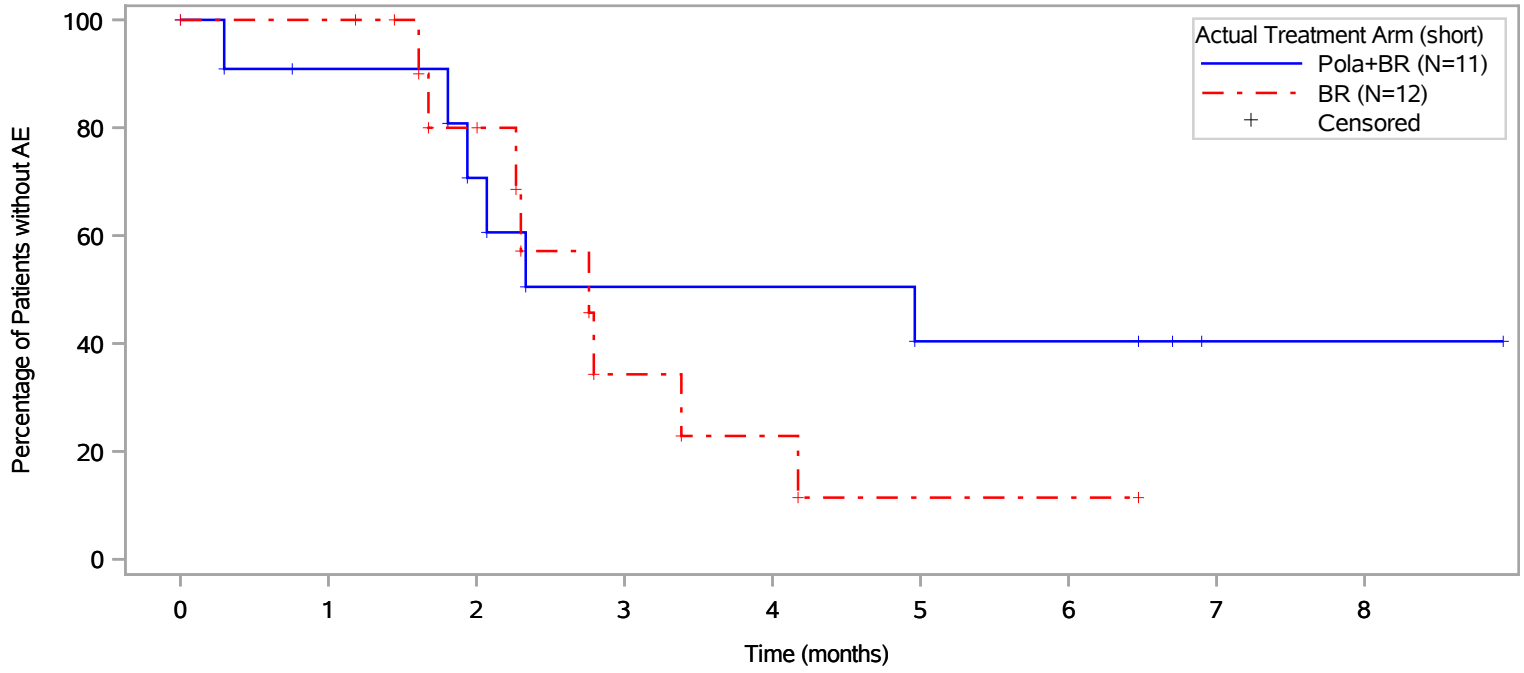
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	9	7	5	5	4	4	1	1
BR (N=12)	12	12	8	3	2	1	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	1	1	1	1	1	4	4
BR (N=12)	0	0	2	3	3	3	3	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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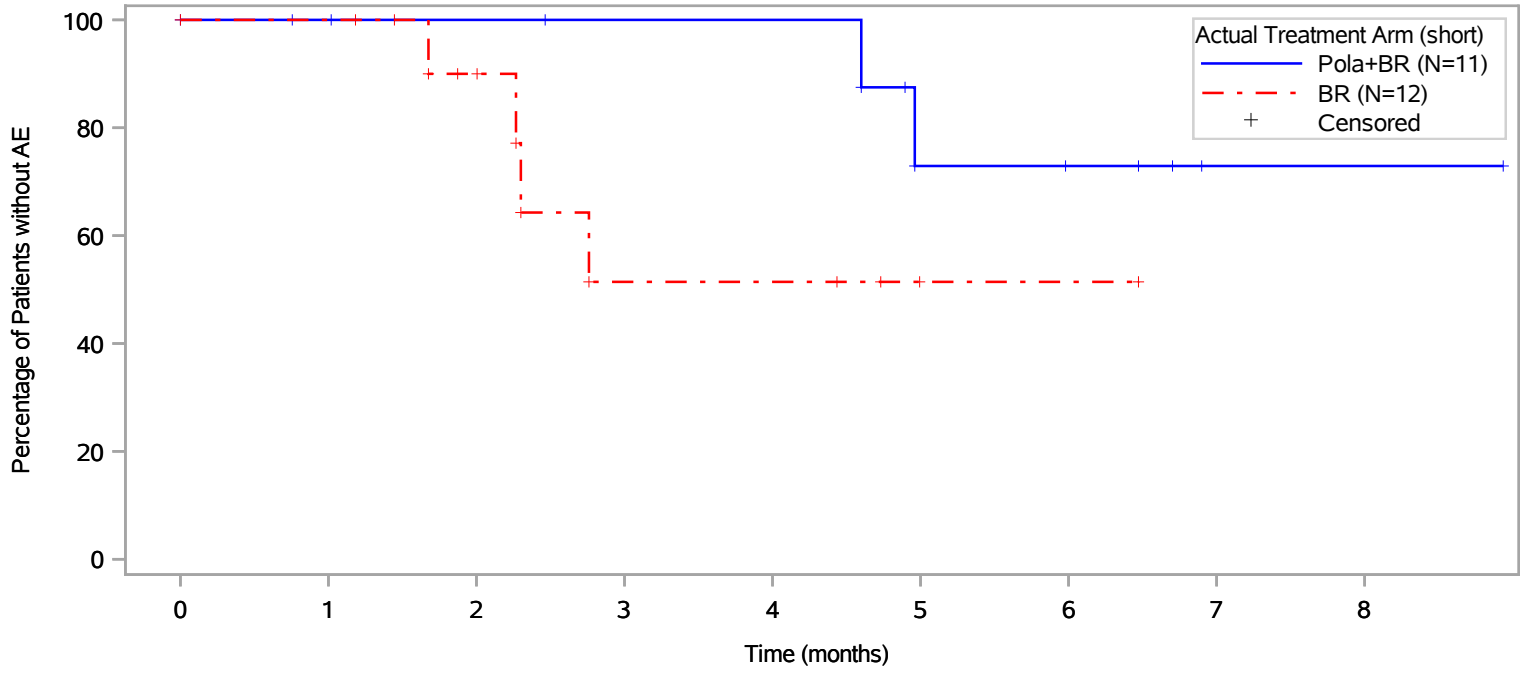
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, COUGH



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	5	4	1	1
BR (N=12)	12	12	8	4	4	1	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	8	8
BR (N=12)	0	0	3	4	4	7	7	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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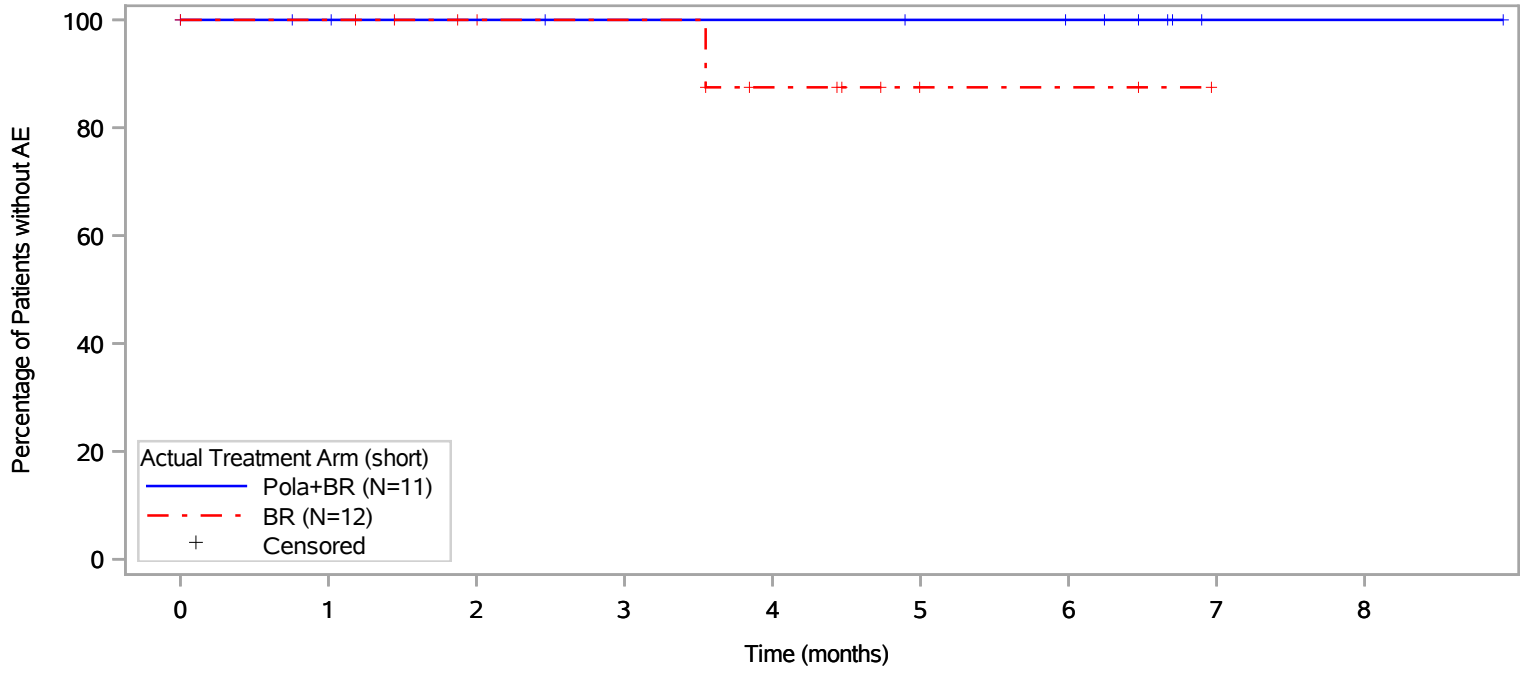
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPNOEA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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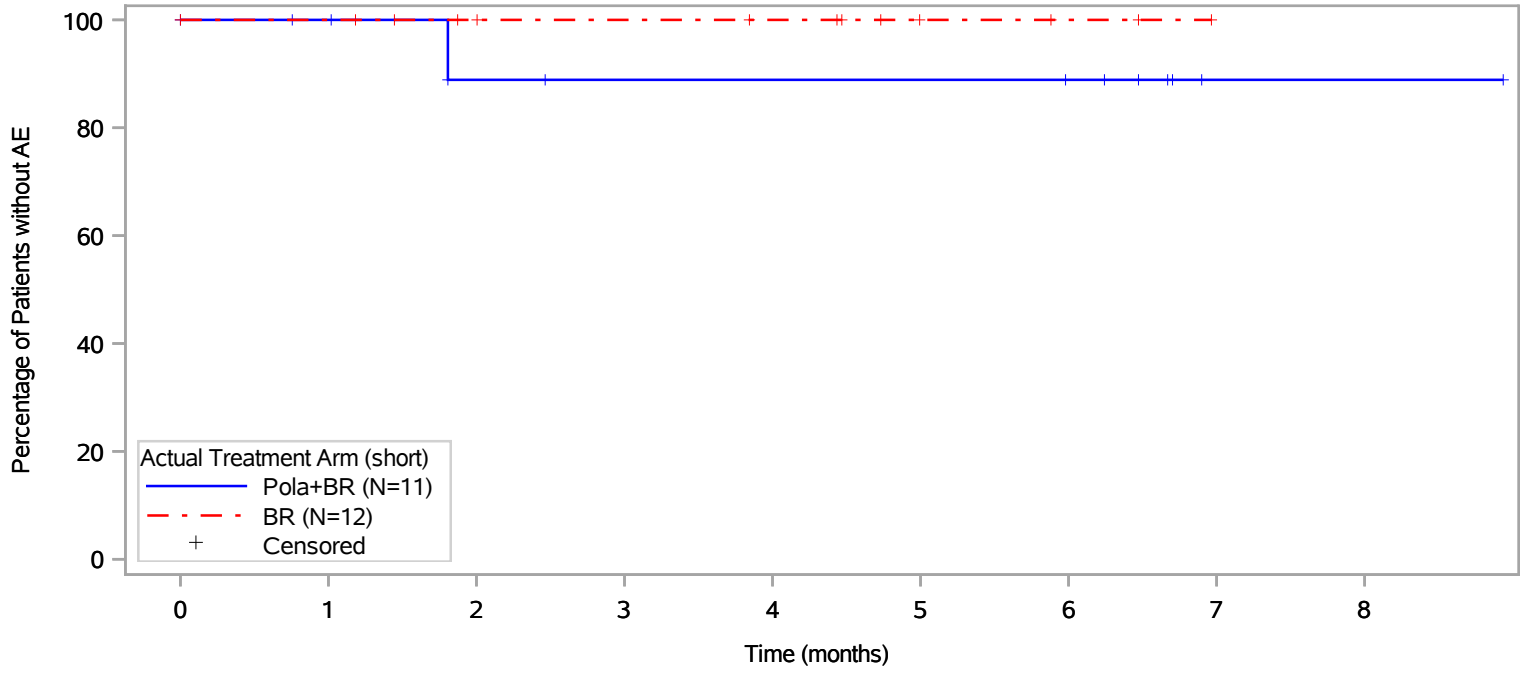
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPNOEA EXERTIONAL



Patients at risk									
Pola+BR (N=11)	11	10	8	7	7	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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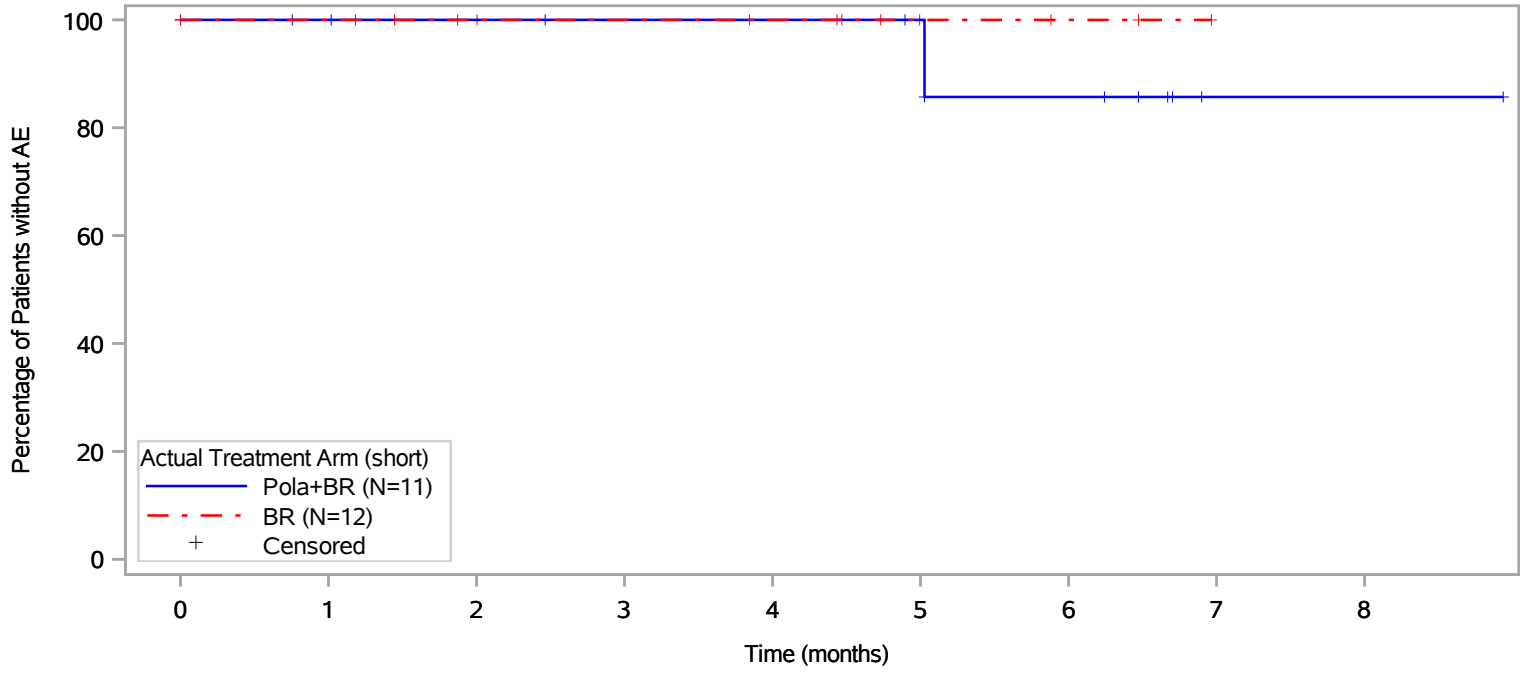
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HICCUPS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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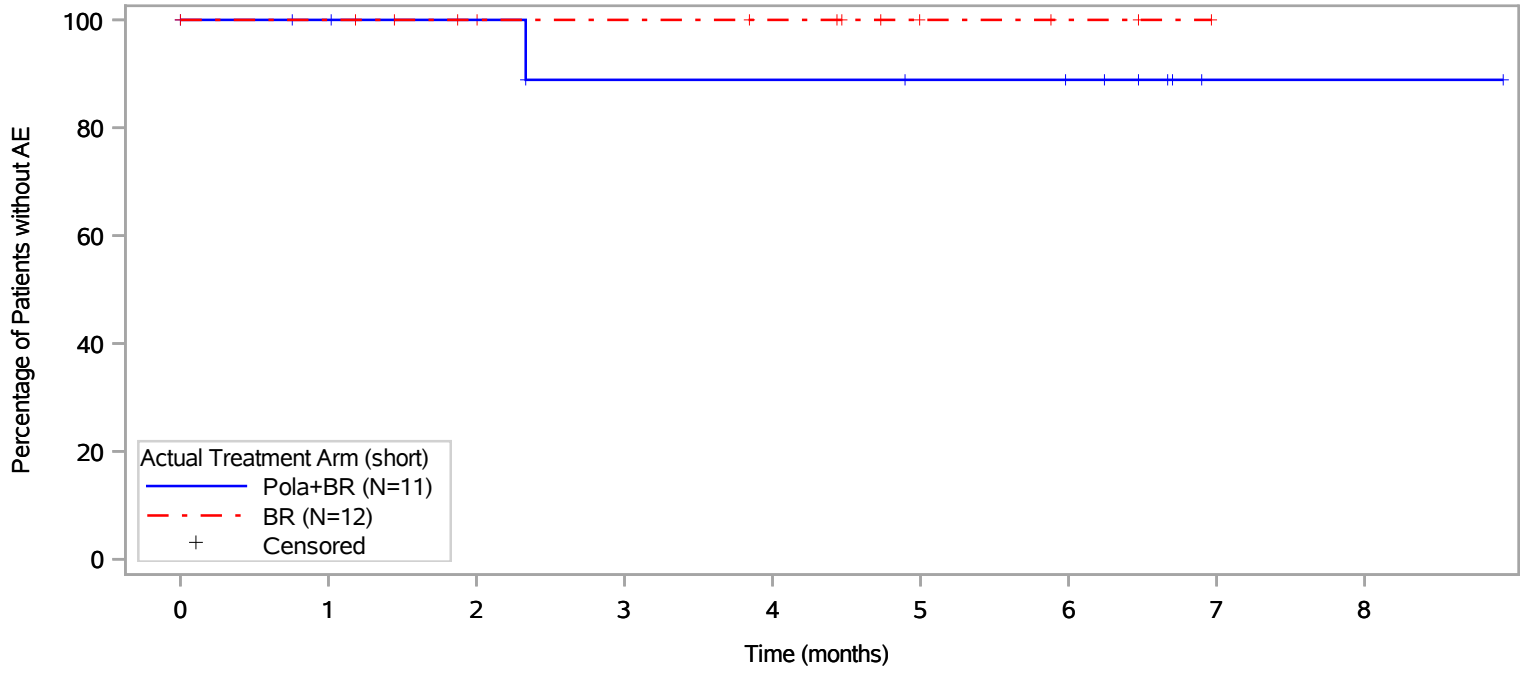
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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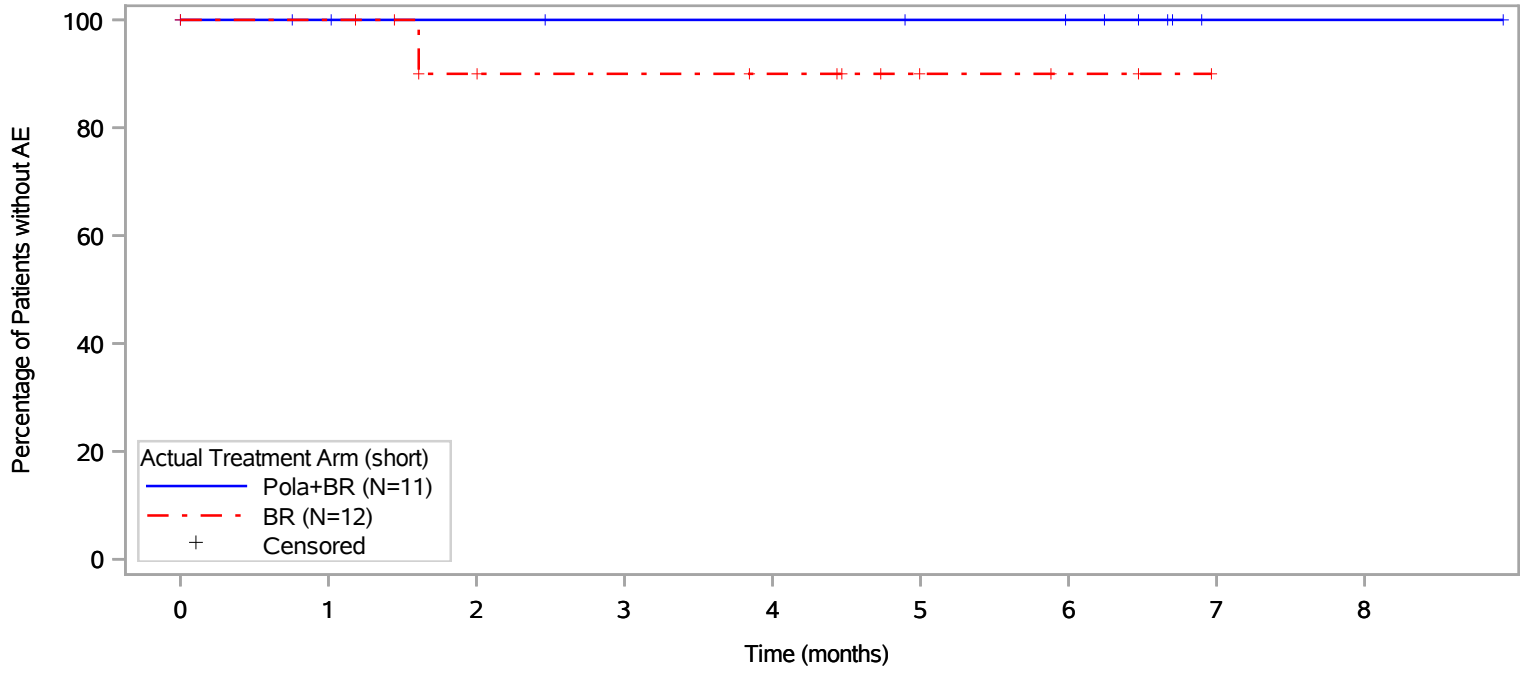
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, LUNG INFILTRATION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
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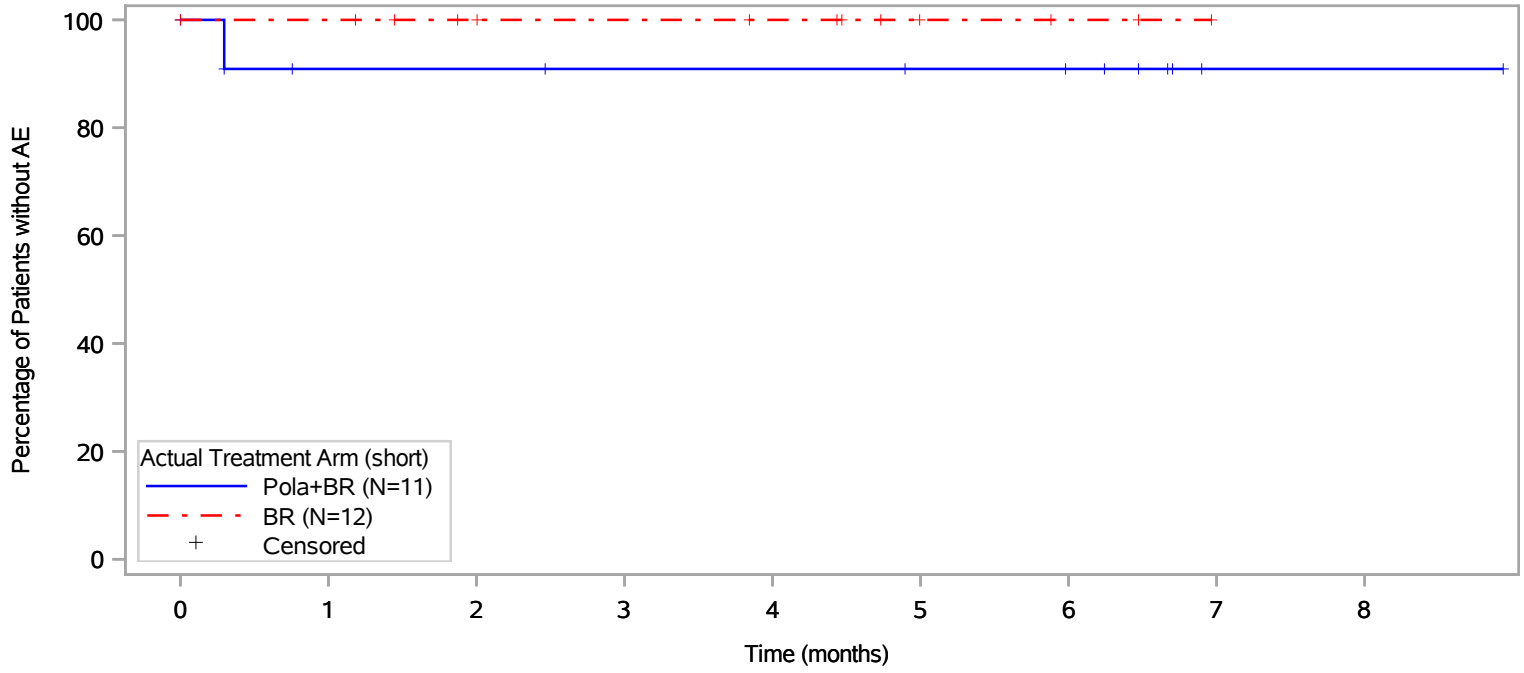
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION



Patients at risk								
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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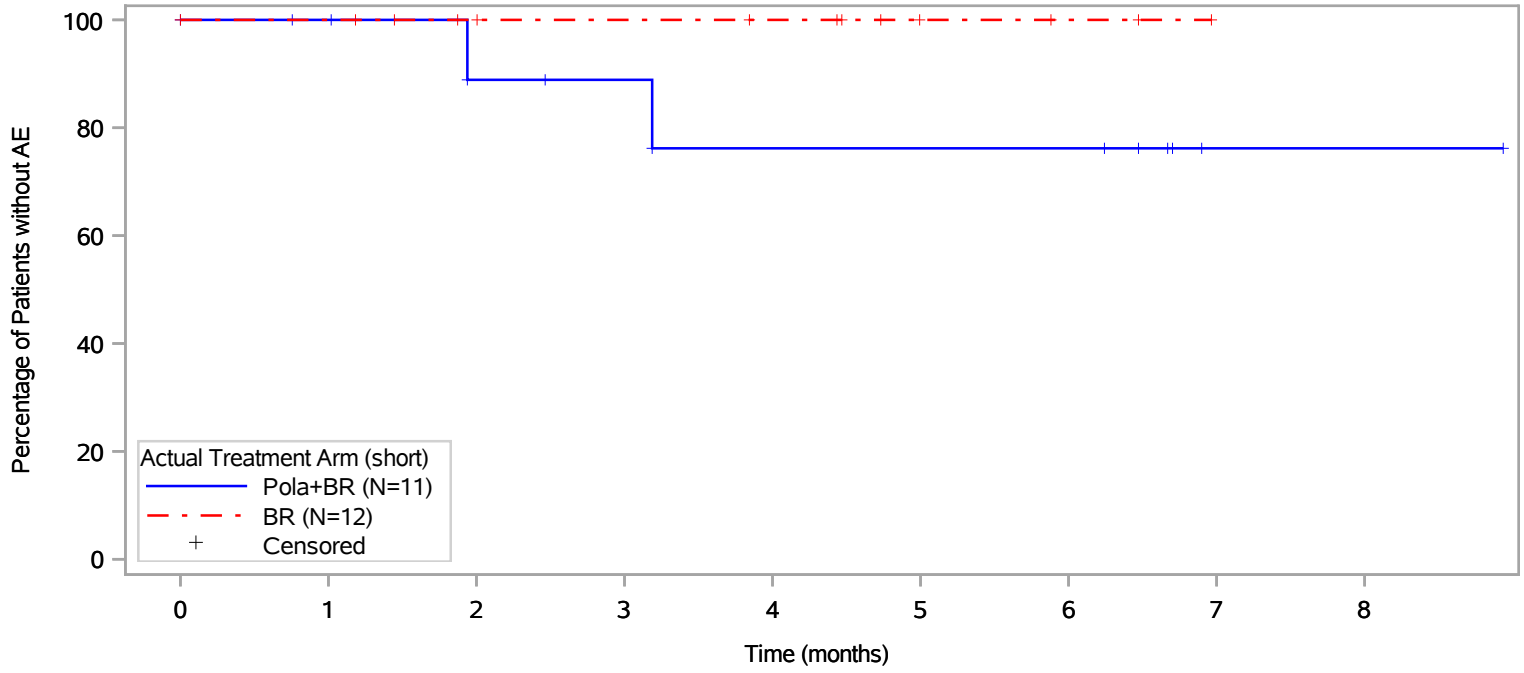
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PNEUMONITIS



Patients at risk									
Pola+BR (N=11)	11	10	8	7	6	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	3	8	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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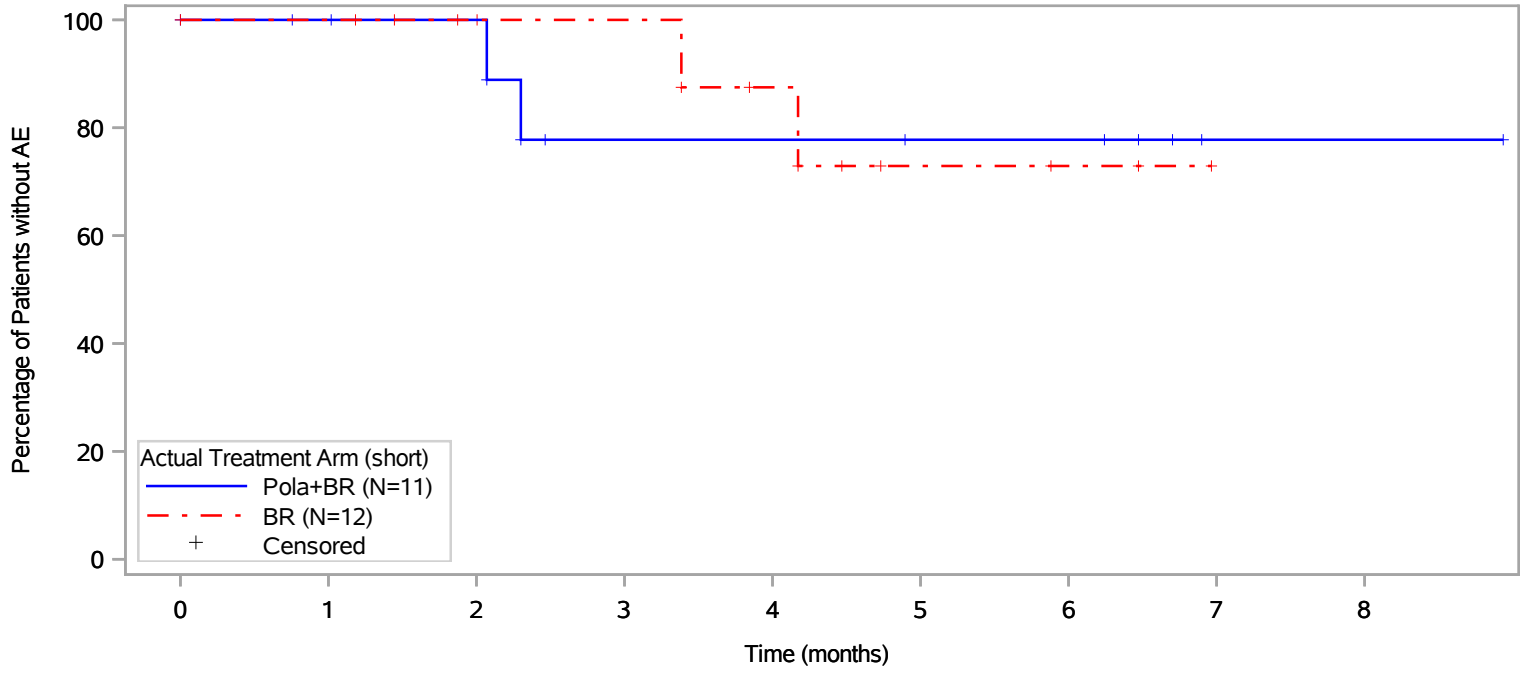
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PRODUCTIVE COUGH



Patients at risk									
Pola+BR (N=11)	11	10	9	6	6	5	5	1	1
BR (N=12)	12	12	9	8	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	8	8
BR (N=12)	0	0	3	4	5	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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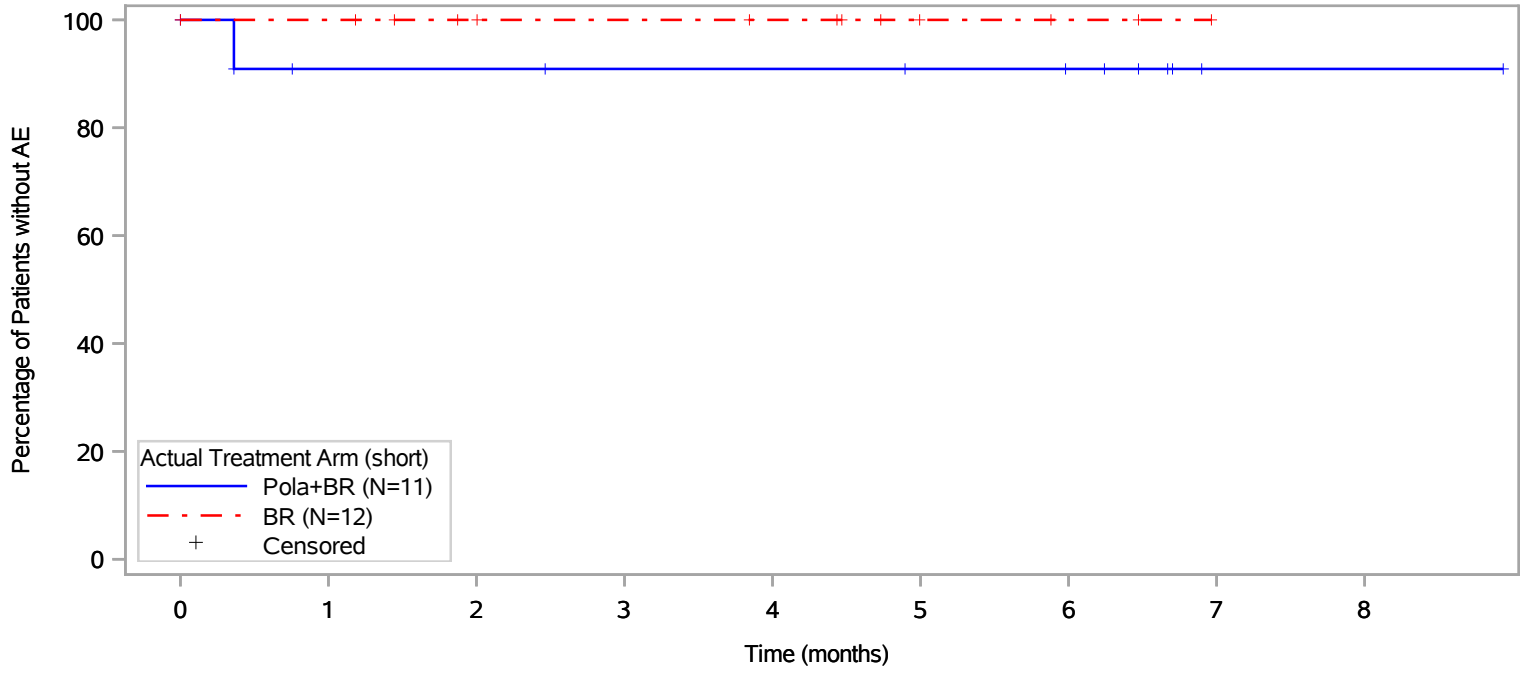
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY OEDEMA



Patients at risk									
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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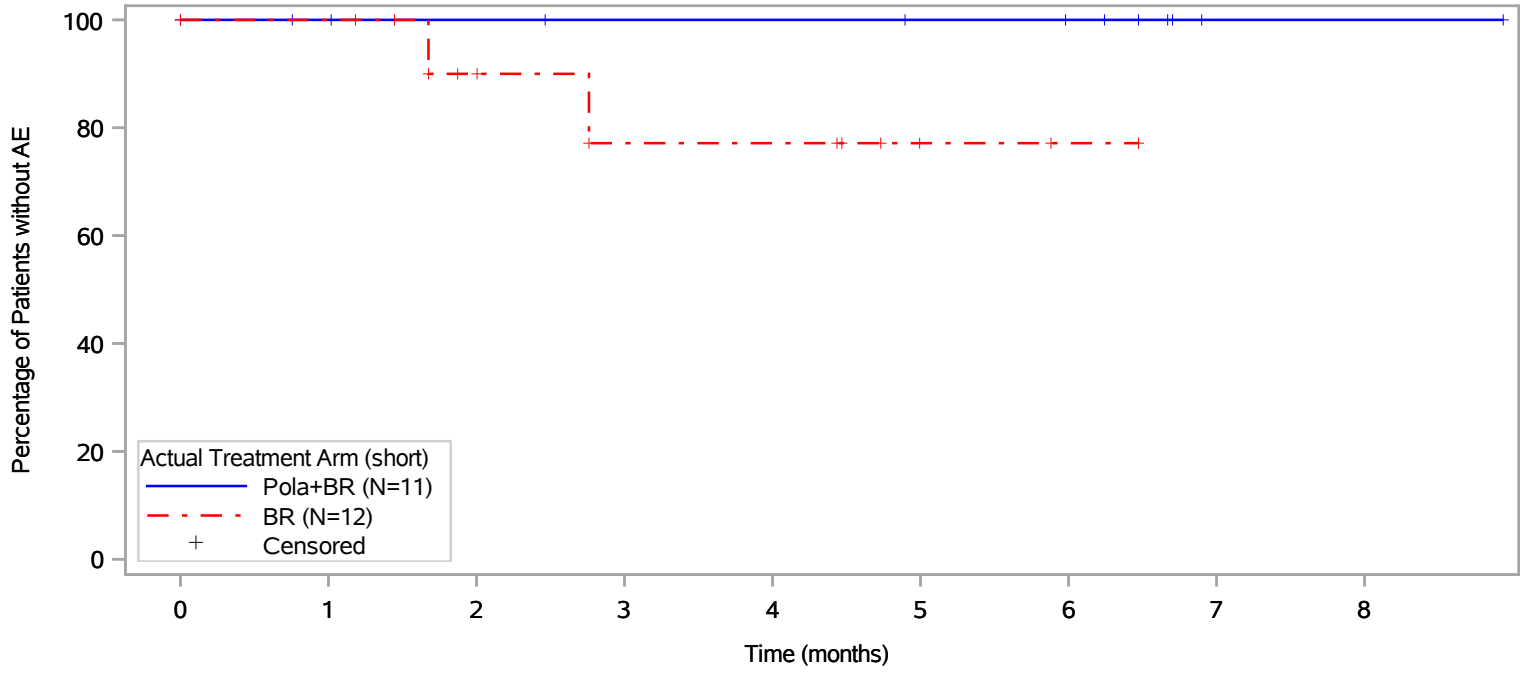
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, RHINORRHOEA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	6	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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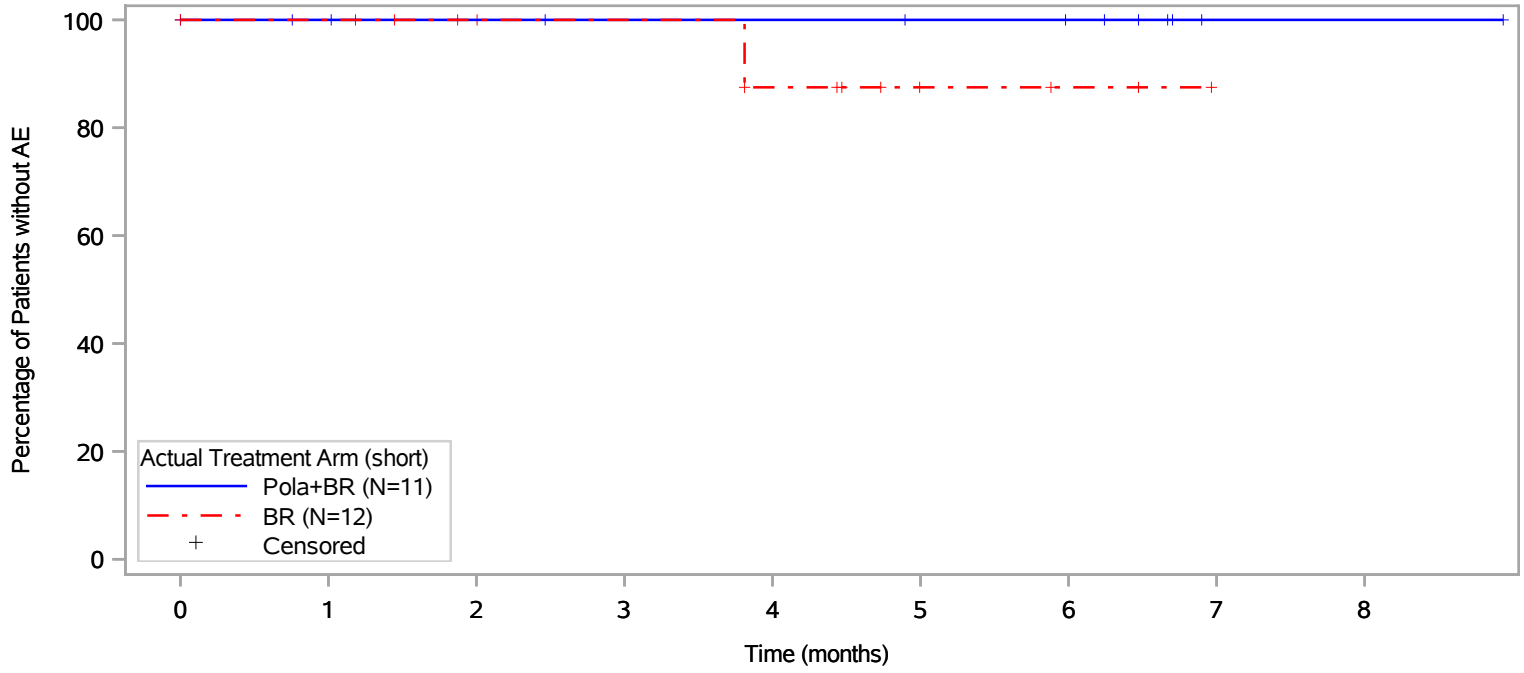
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, TACHYPNOEA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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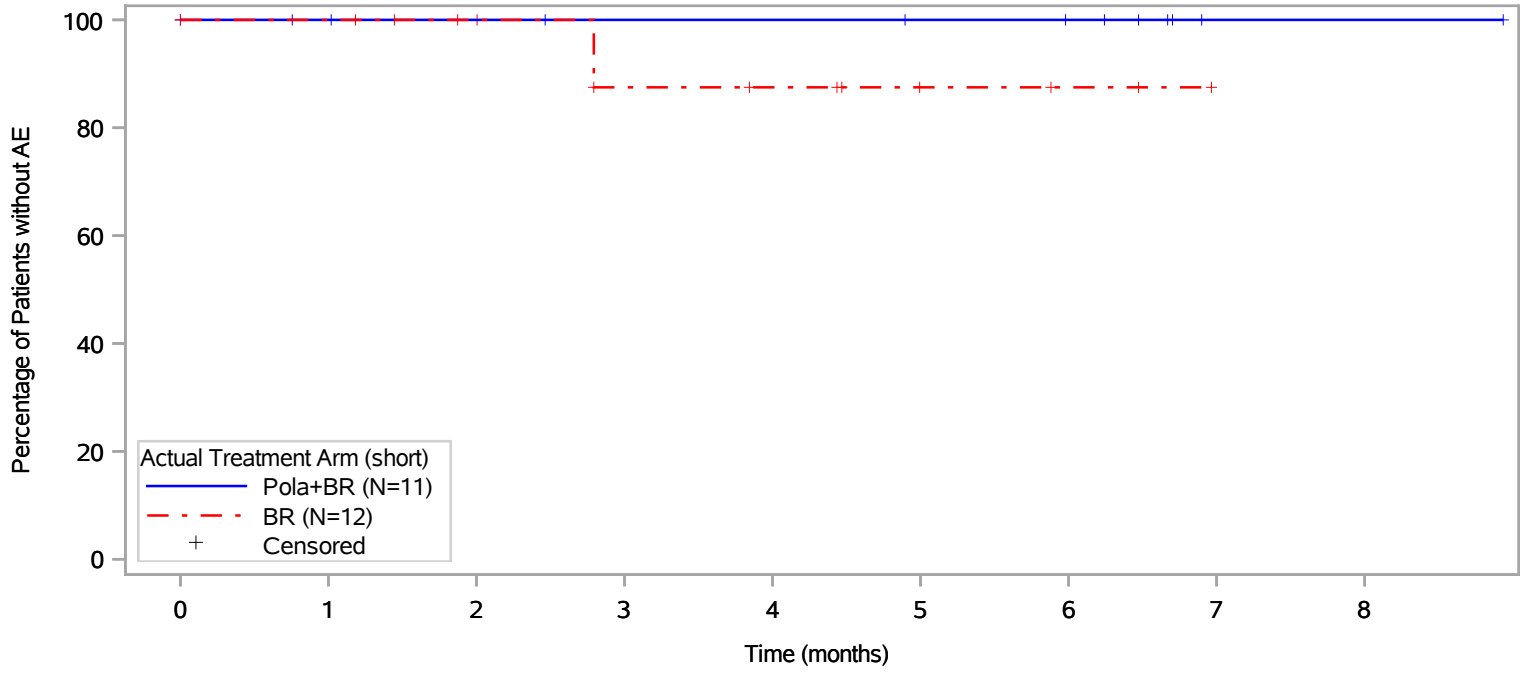
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, UPPER RESPIRATORY TRACT INFLAMMATION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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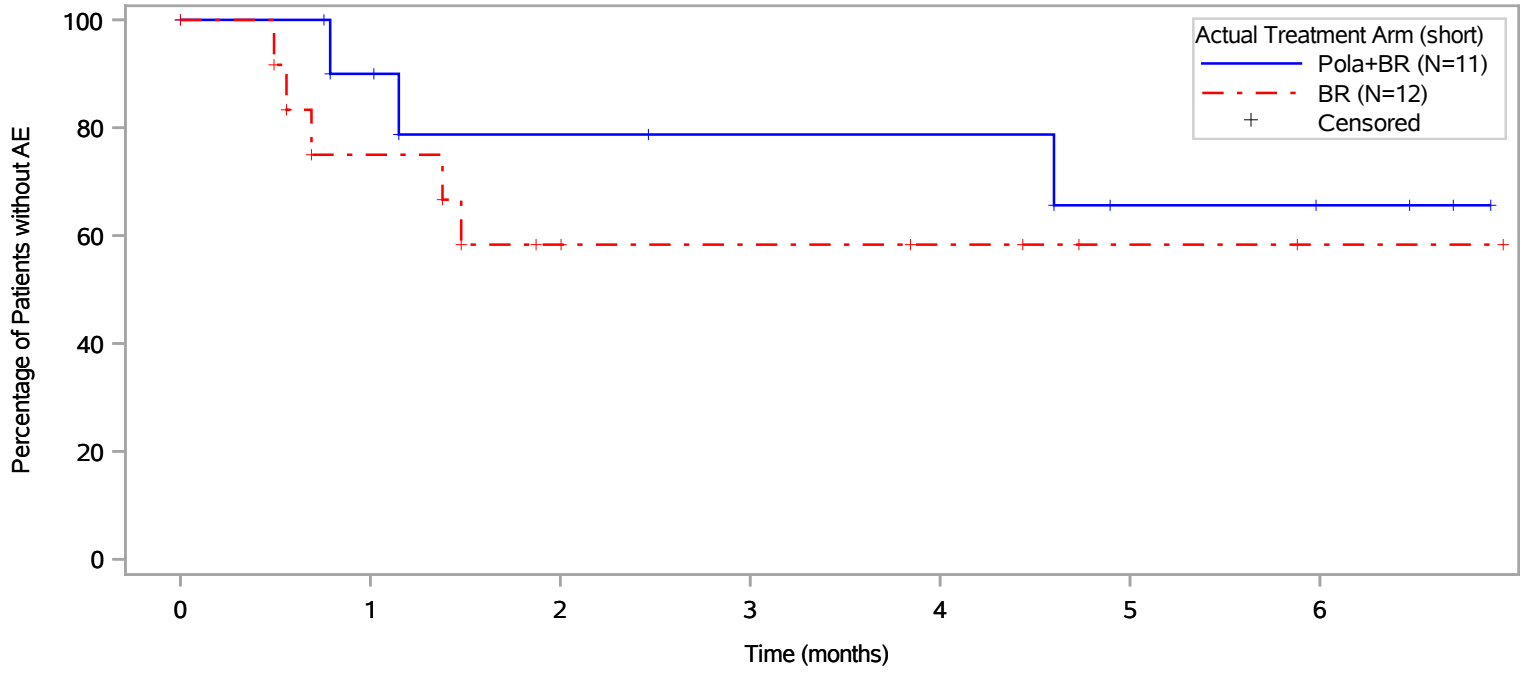
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk							
Pola+BR (N=11)	11	9	7	6	6	4	3
BR (N=12)	12	9	6	5	4	2	1
Patients censored							
Pola+BR (N=11)	0	1	2	3	3	4	5
BR (N=12)	0	0	1	2	3	5	6

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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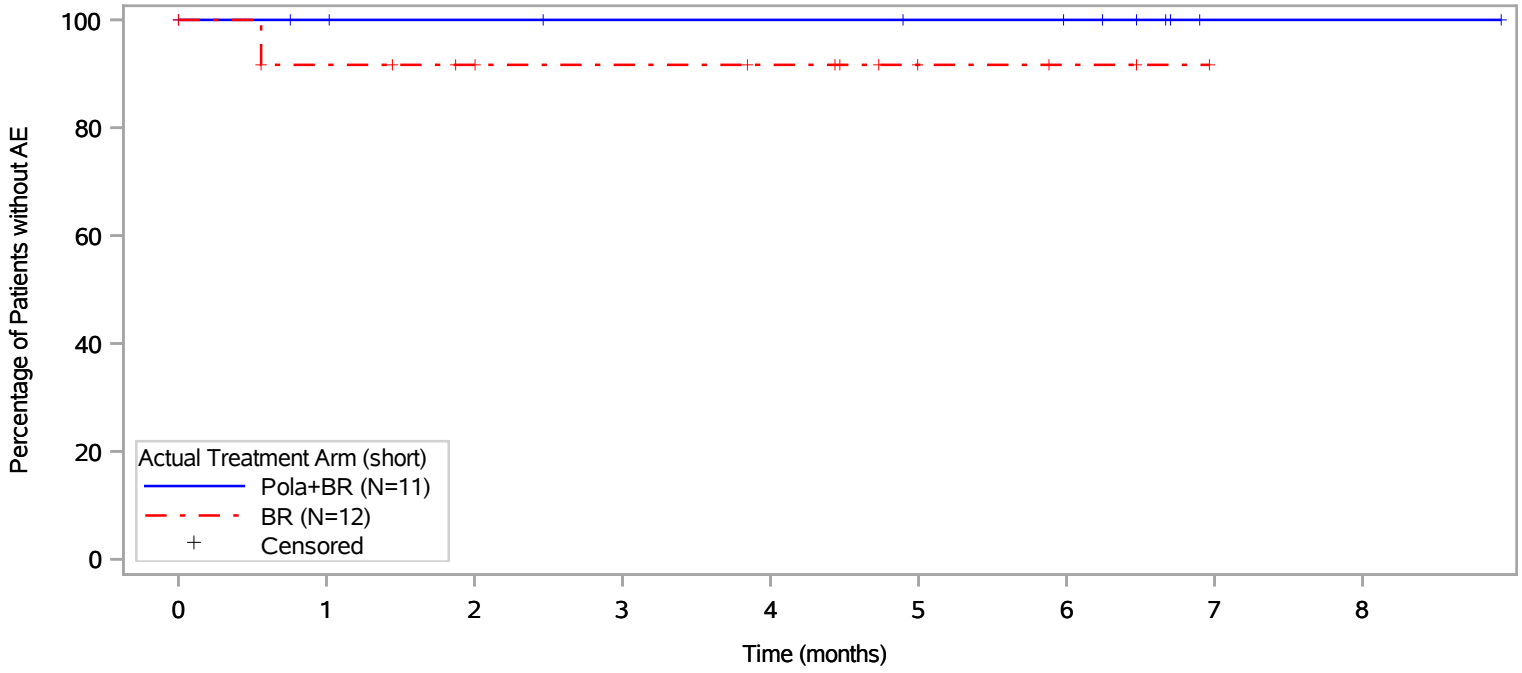
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, ALOPECIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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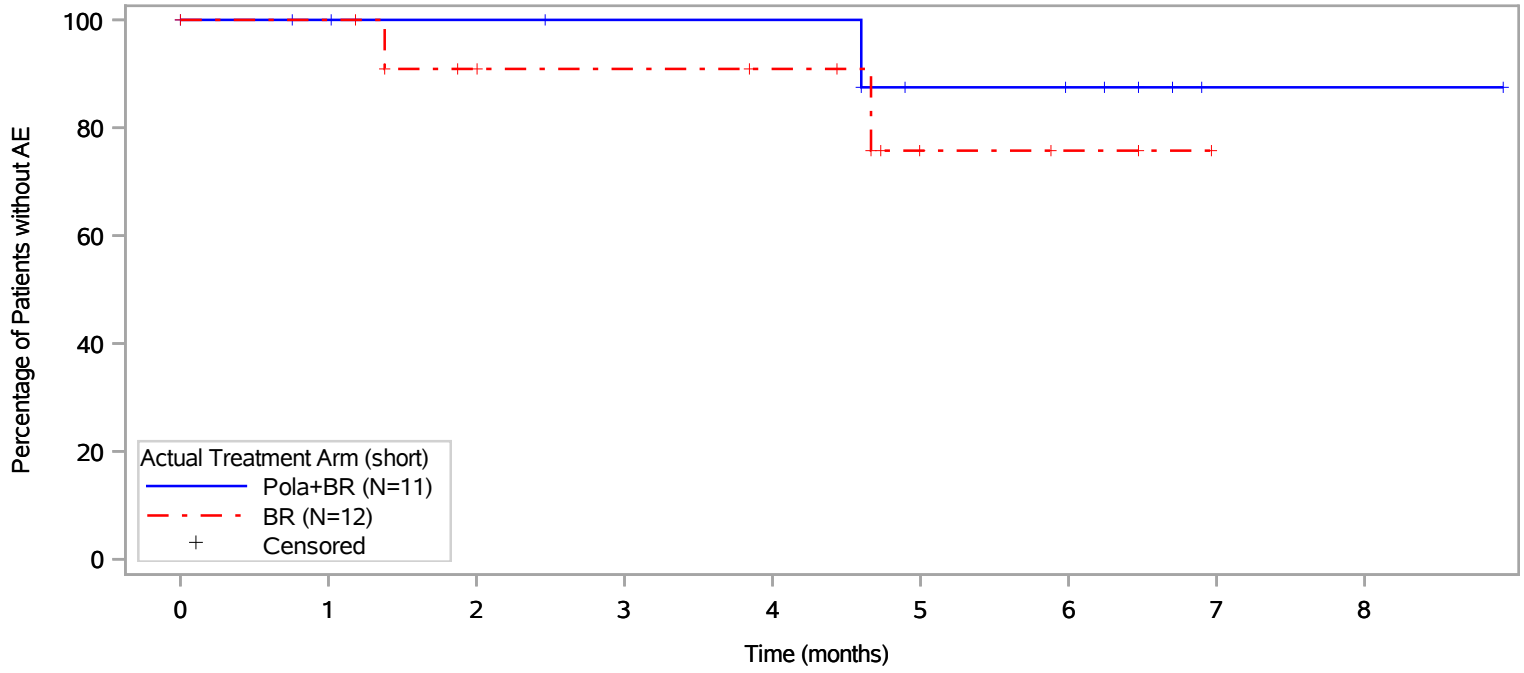
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	2	3	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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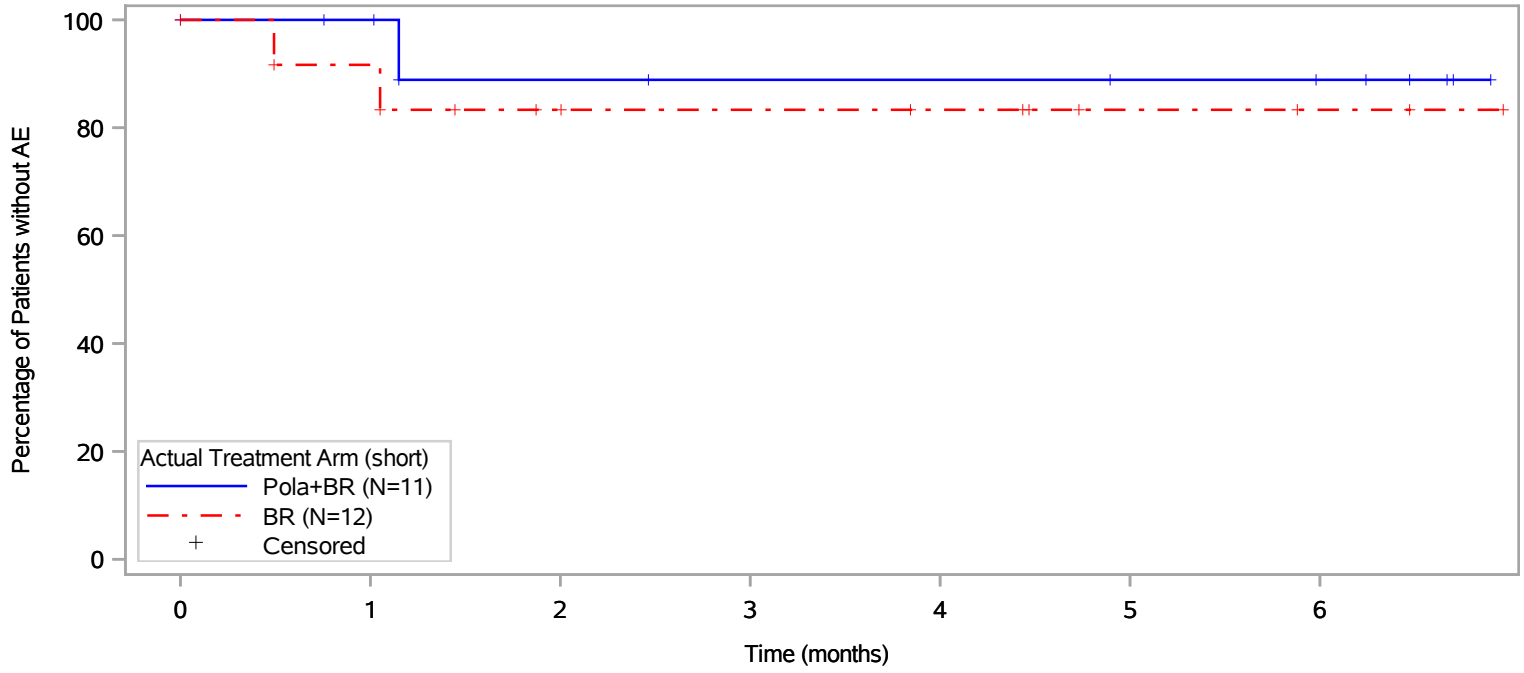
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk							
Pola+BR (N=11)	11	10	8	7	7	6	5
BR (N=12)	12	11	8	7	6	3	2
Patients censored							
Pola+BR (N=11)	0	1	2	3	3	4	5
BR (N=12)	0	0	2	3	4	7	8

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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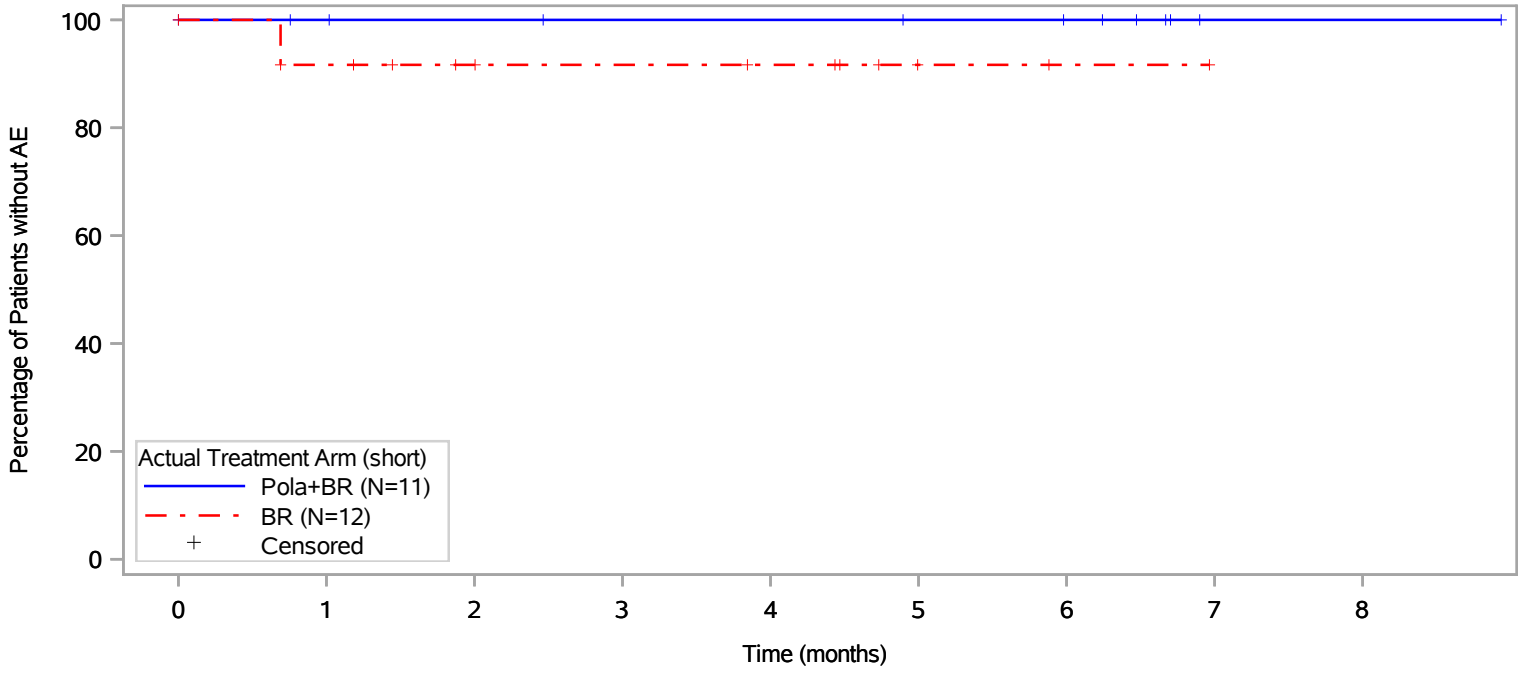
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH MACULO-PAPULAR



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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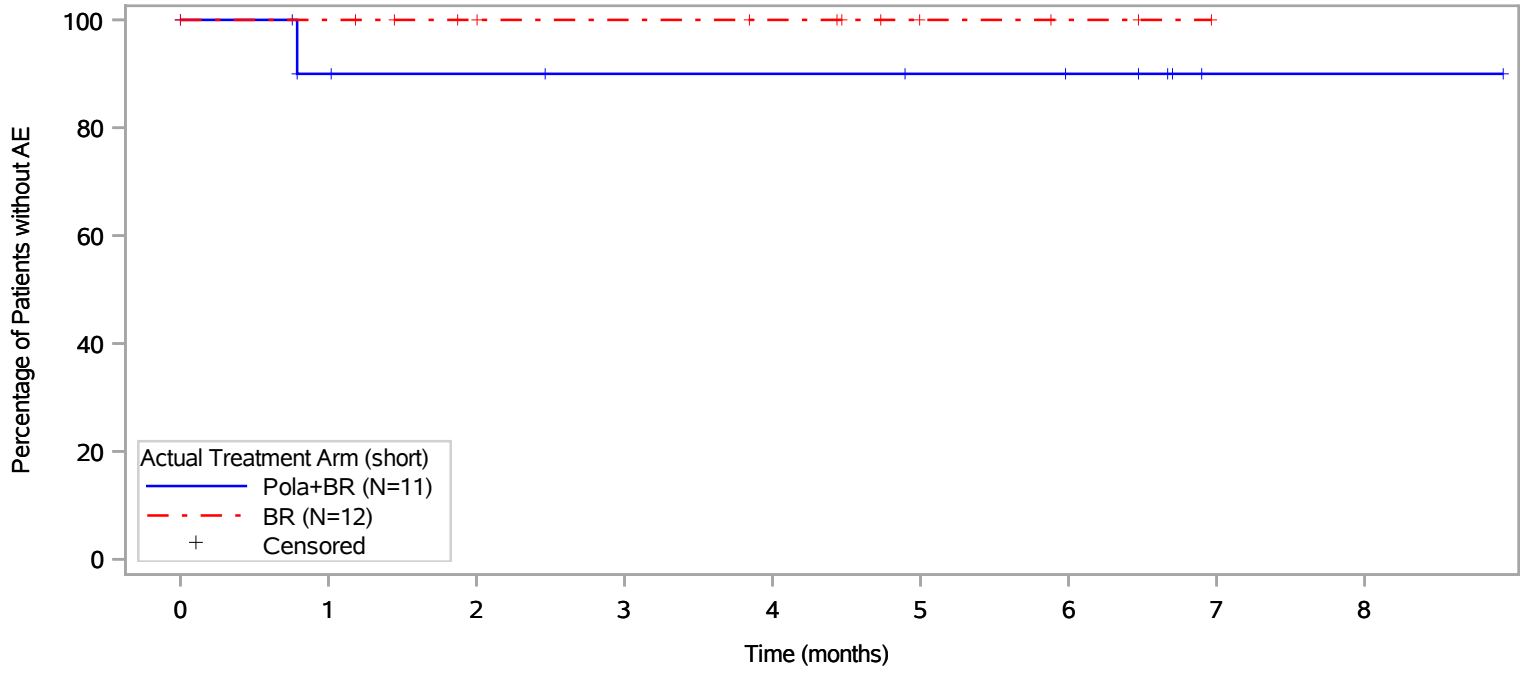
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, SOLAR LENTIGO



Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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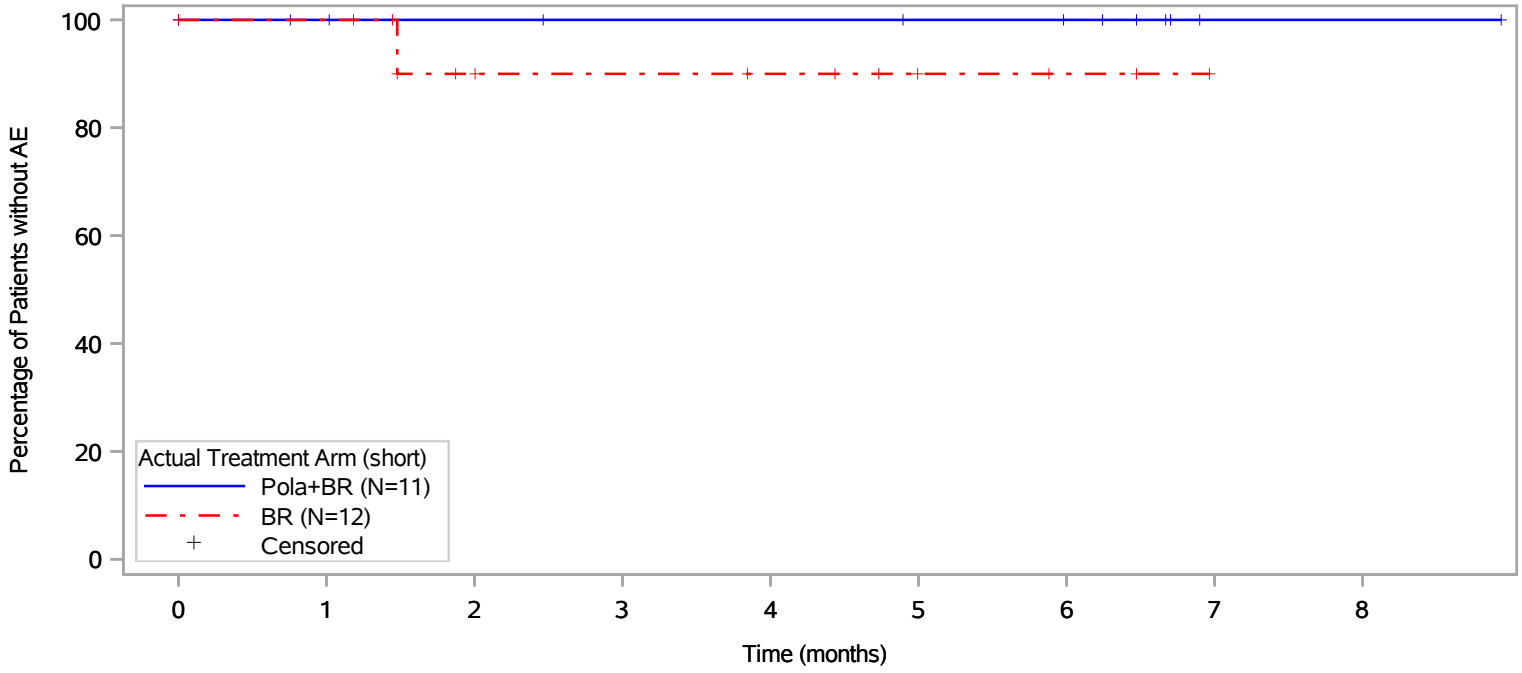
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, URTICARIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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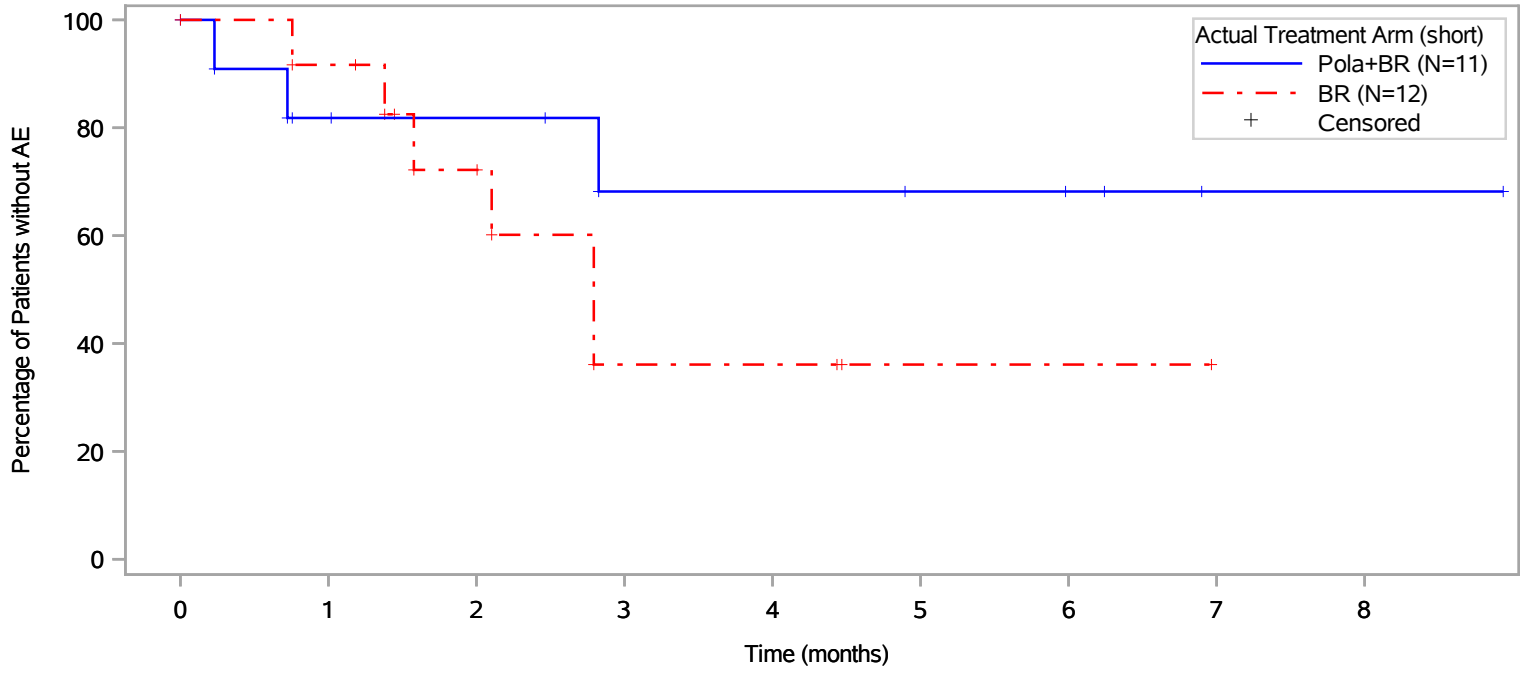
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	8	7	5	5	4	3	1	1
BR (N=12)	12	11	7	3	3	1	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	7	7
BR (N=12)	0	0	2	3	3	5	5	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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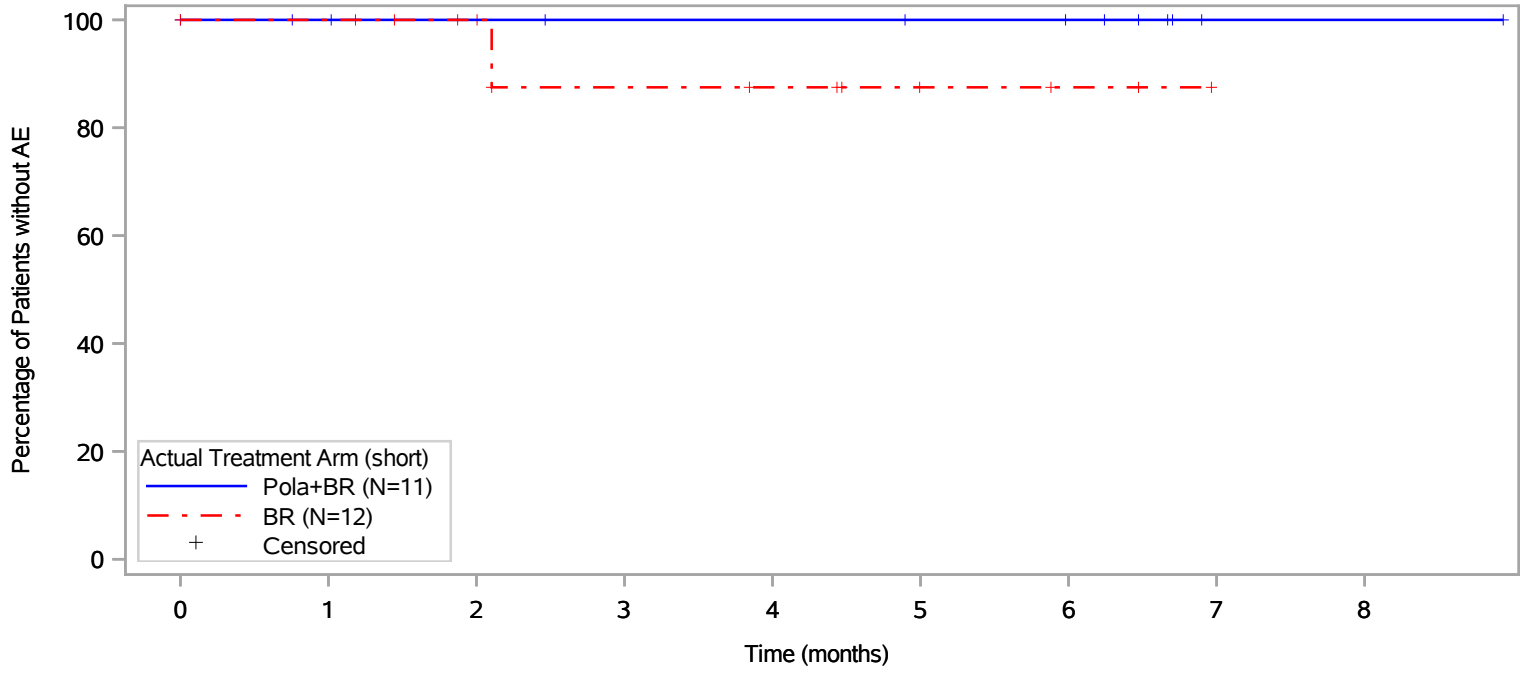
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, AXILLARY VEIN THROMBOSIS

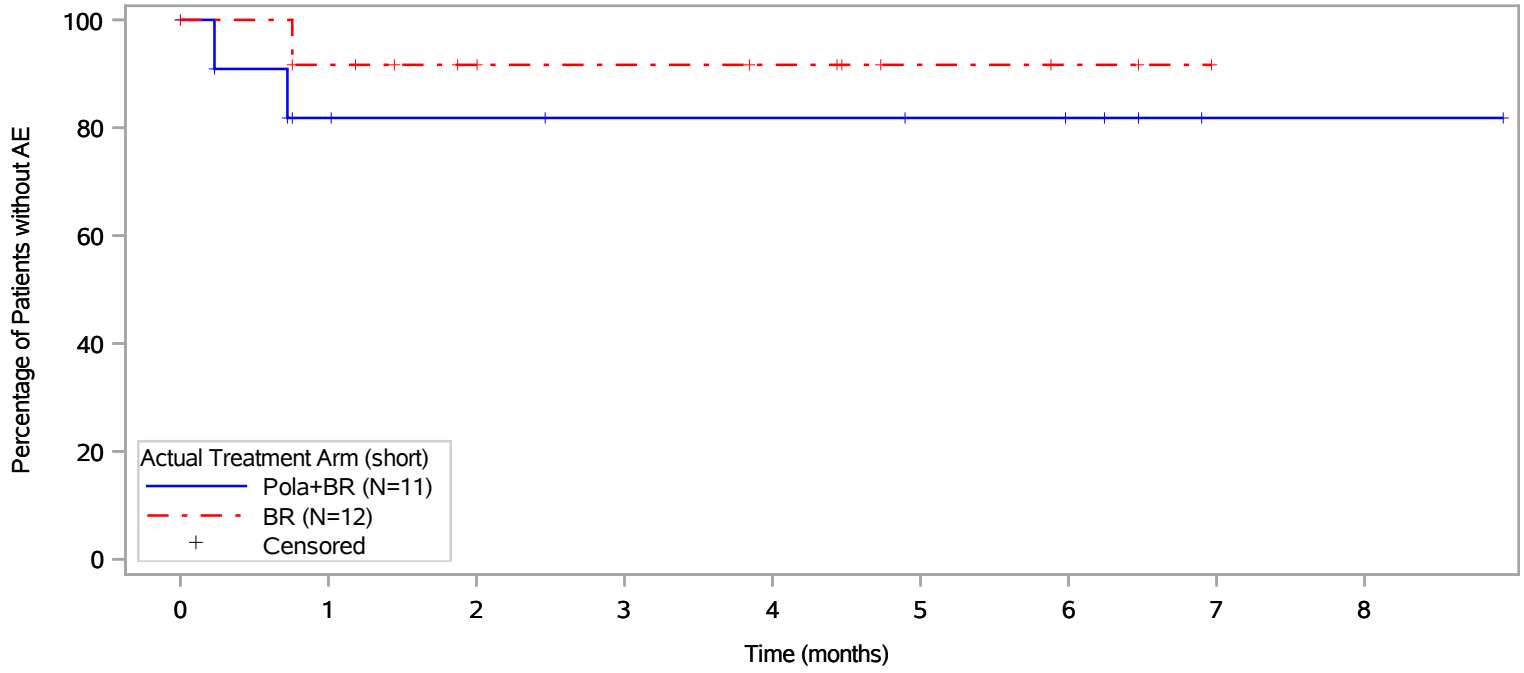


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION



Patients at risk									
Pola+BR (N=11)	11	8	7	6	6	5	4	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	8	8
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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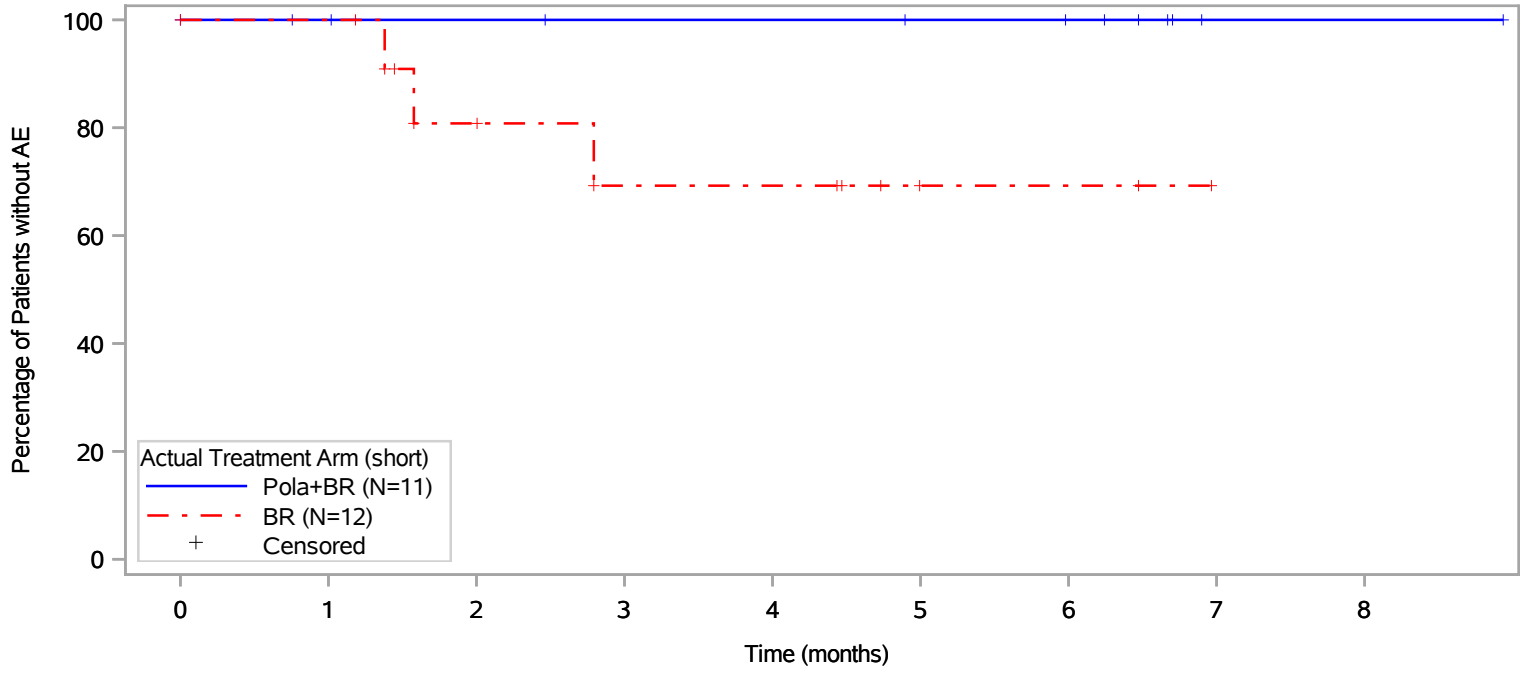
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	6	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	3	7	7	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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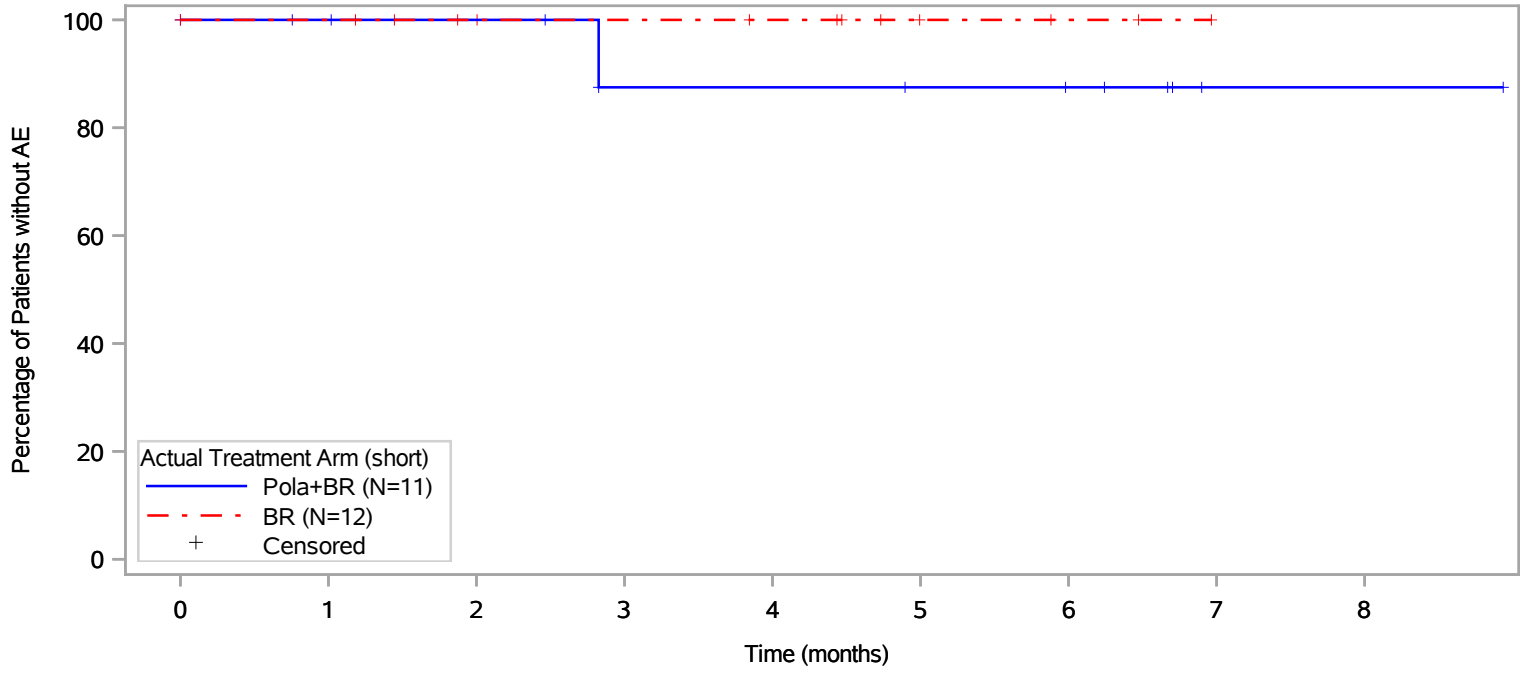
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, PERIPHERAL VENOUS DISEASE



Patients at risk									
Pola+BR (N=11)	11	10	9	7	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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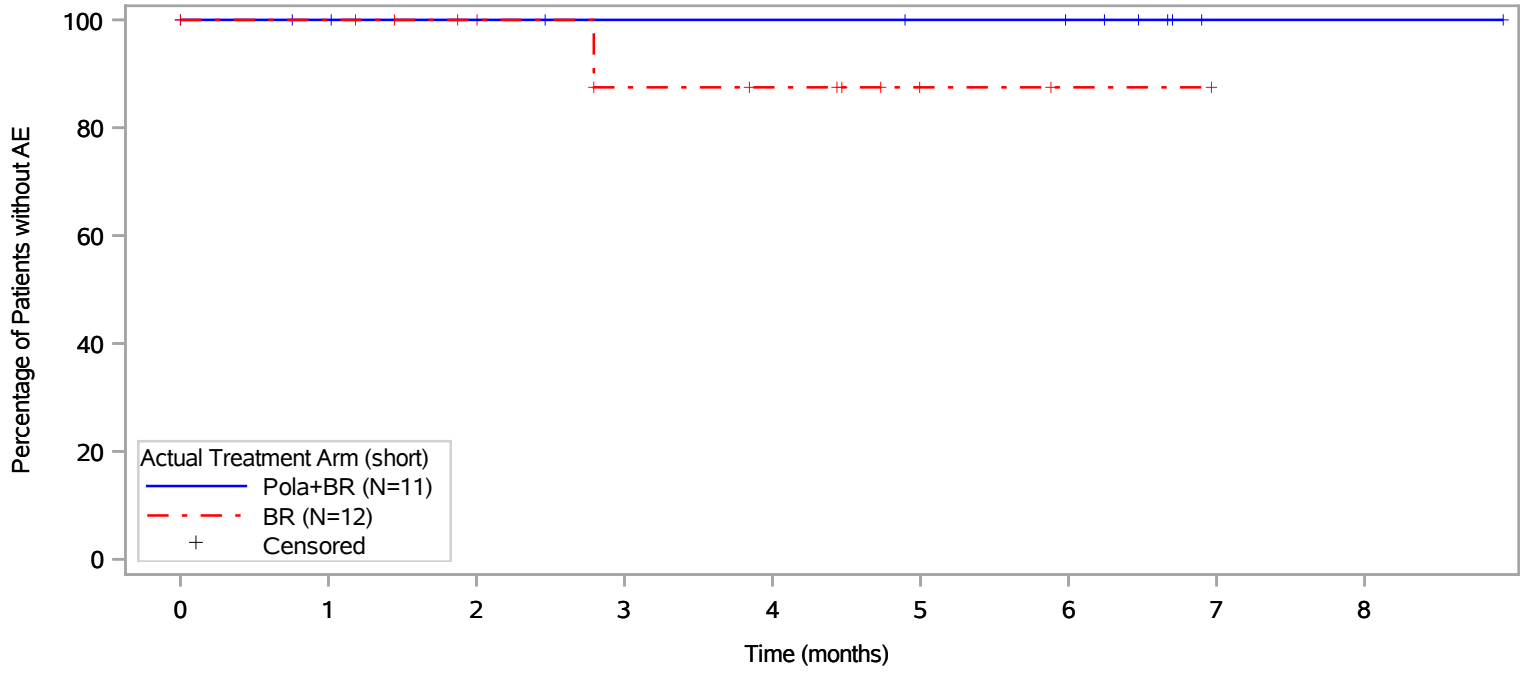
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, PHLEBITIS SUPERFICIAL



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			11	100.0	8	72.7	3	27.3	12	100.0	7	58.3	5	41.7	0.5568	1.36	0.48	3.84		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		11	100.0	4	36.4	7	63.6	12	100.0	2	16.7	10	83.3	0.3441	2.22	0.41	12.15		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		11	100.0	5	45.5	6	54.5	12	100.0	5	41.7	7	58.3	0.9802	1.02	0.29	3.53		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		11	100.0	3	27.3	8	72.7	12	100.0	3	25.0	9	75.0	0.9552	0.96	0.19	4.75		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			11	100.0	0	-	11	100.0	12	100.0	3	25.0	9	75.0	0.0255	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			11	100.0	4	36.4	7	63.6	12	100.0	4	33.3	8	66.7	0.1880	0.33	0.06	1.86		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			11	100.0	1	9.1	10	90.9	12	100.0	4	33.3	8	66.7	0.1191	0.21	0.02	1.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LIPASE INCREASED		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1321	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.8194	0.72	0.04	12.57		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			11	100.0	1	9.1	10	90.9	12	100.0	2	16.7	10	83.3	0.0376	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.1599	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1168	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.1303	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.1303	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR345AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 23:03

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	8	72.7	7	87.5	1	12.5	12	100.0	7	58.3	5	41.7	0.2727	1.80	0.62	5.25		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	2	16.7	10	83.3	0.3634	2.24	0.37	13.45		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	8	72.7	5	62.5	3	37.5	12	100.0	5	41.7	7	58.3	0.5542	1.45	0.42	5.06		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	3	25.0	9	75.0	0.7529	1.29	0.26	6.43		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	8	72.7	0	-	8	100.0	12	100.0	3	25.0	9	75.0	0.0545	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS		>= 65	8	72.7	3	37.5	5	62.5	12	100.0	4	33.3	8	66.7	0.1498	0.22	0.02	2.06		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-

INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS		>= 65	8	72.7	0	-	8	100.0	12	100.0	4	33.3	8	66.7	0.0658	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	LIPASE INCREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	LIPASE INCREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.1881	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	WEIGHT DECREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	WEIGHT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4450	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
METABOLISM AND NUTRITION DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	2	16.7	10	83.3	0.0559	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.

NERVOUS SYSTEM DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RENAL AND URINARY DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.1759	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
VASCULAR DISORDERS		>= 65	8	72.7	2	25.0	6	75.0	12	100.0	0	-	12	100.0	0.0732	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	0	-	12	100.0	0.0732	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical studies/RO5541077/CDPT7898/GO29365/data analysis/ACE FINAL CSR Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR345AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 23:03

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	6	54.5	6	100.0	0	-	10	83.3	6	60.0	4	40.0	0.1240	2.44	0.76	7.87		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.9814	1.03	0.09	11.48		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	6	54.5	3	50.0	3	50.0	10	83.3	2	20.0	8	80.0	0.2705	2.64	0.44	15.82		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	6	54.5	3	50.0	3	50.0	10	83.3	5	50.0	5	50.0	0.7840	1.23	0.28	5.30		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	6	54.5	3	50.0	3	50.0	10	83.3	3	30.0	7	70.0	0.4047	1.95	0.39	9.71		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2087	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.0253				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.0253				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	6	54.5	2	33.3	4	66.7	10	83.3	3	30.0	7	70.0	0.4412	0.41	0.04	4.26		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	3	30.0	7	70.0	0.1719	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.3497	0.28	0.02	4.71		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	6	54.5	1	16.7	5	83.3	10	83.3	2	20.0	8	80.0	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NERVOUS SYSTEM DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	6	54.5	2	33.3	4	66.7	10	83.3	0	-	10	100.0	0.0753	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2457	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical studies/RO5541077/CDPT7898/GO29365/data analysis/ACE FINAL CSR Pooled/prod/program/t s ttae soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR345AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 23:03

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	45.5	3	60.0	2	40.0	3	25.0	2	66.7	1	33.3	0.9656	0.96	0.16	5.90		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	6	54.5	5	83.3	1	16.7	9	75.0	5	55.6	4	44.4	0.4554	1.61	0.46	5.69		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	0	-	3	100.0	0.2087	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	2	22.2	7	77.8	0.8093	1.27	0.18	9.09		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	3	33.3	6	66.7	0.6269	1.49	0.29	7.57		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.7766	0.67	0.04	10.77		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	2	22.2	7	77.8	0.8890	1.15	0.16	8.21		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	3	33.3	6	66.7	0.0649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	3	33.3	6	66.7	0.4845	0.53	0.08	3.27		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	4	44.4	5	55.6	0.1360	0.21	0.02	1.96		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	1.0000	1.00	0.06	16.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.1803	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NERVOUS SYSTEM DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	0	-	9	100.0	0.1161	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.1630	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical studies/RO5541077/CDPT7898/GO29365/data analysis/ACE FINAL CSR Pooled/prod/program/t s ttae soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR345AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 23:03

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	63.6	5	71.4	2	28.6	7	58.3	5	71.4	2	28.6	0.8698	0.90	0.25	3.26		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	4	36.4	3	75.0	1	25.0	5	41.7	2	40.0	3	60.0	0.3549	2.45	0.35	17.03		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	2	28.6	5	71.4	0.8914	0.87	0.12	6.29		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	4	36.4	2	50.0	2	50.0	5	41.7	0	-	5	100.0	0.1081	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	3	42.9	4	57.1	0.6652	0.67	0.11	4.05		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	4	36.4	3	75.0	1	25.0	5	41.7	2	40.0	3	60.0	0.4688	1.95	0.31	12.28		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	2	28.6	5	71.4	0.9021	0.88	0.12	6.44		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	4	36.4	1	25.0	3	75.0	5	41.7	1	20.0	4	80.0	0.9191	1.15	0.07	18.59		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	7	63.6	0	-	7	100.0	7	58.3	2	28.6	5	71.4	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	7	63.6	3	42.9	4	57.1	7	58.3	1	14.3	6	85.7	0.7027	1.60	0.14	18.24		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	4	36.4	1	25.0	3	75.0	5	41.7	3	60.0	2	40.0	0.0401	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	7	63.6	1	14.3	6	85.7	7	58.3	3	42.9	4	57.1	0.1877	0.24	0.02	2.37		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.7487	0.62	0.03	11.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

NERVOUS SYSTEM DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	7	63.6	2	28.6	5	71.4	7	58.3	0	-	7	100.0	0.1803	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	2	28.6	5	71.4	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	4	36.4	2	50.0	2	50.0	5	41.7	0	-	5	100.0	0.0888	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	4	36.4	2	50.0	2	50.0	5	41.7	0	-	5	100.0	0.0888	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical studies/RO5541077/CDPT7898/GO29365/data analysis/ACE FINAL CSR Pooled/prod/program/t s ttae soc.sas
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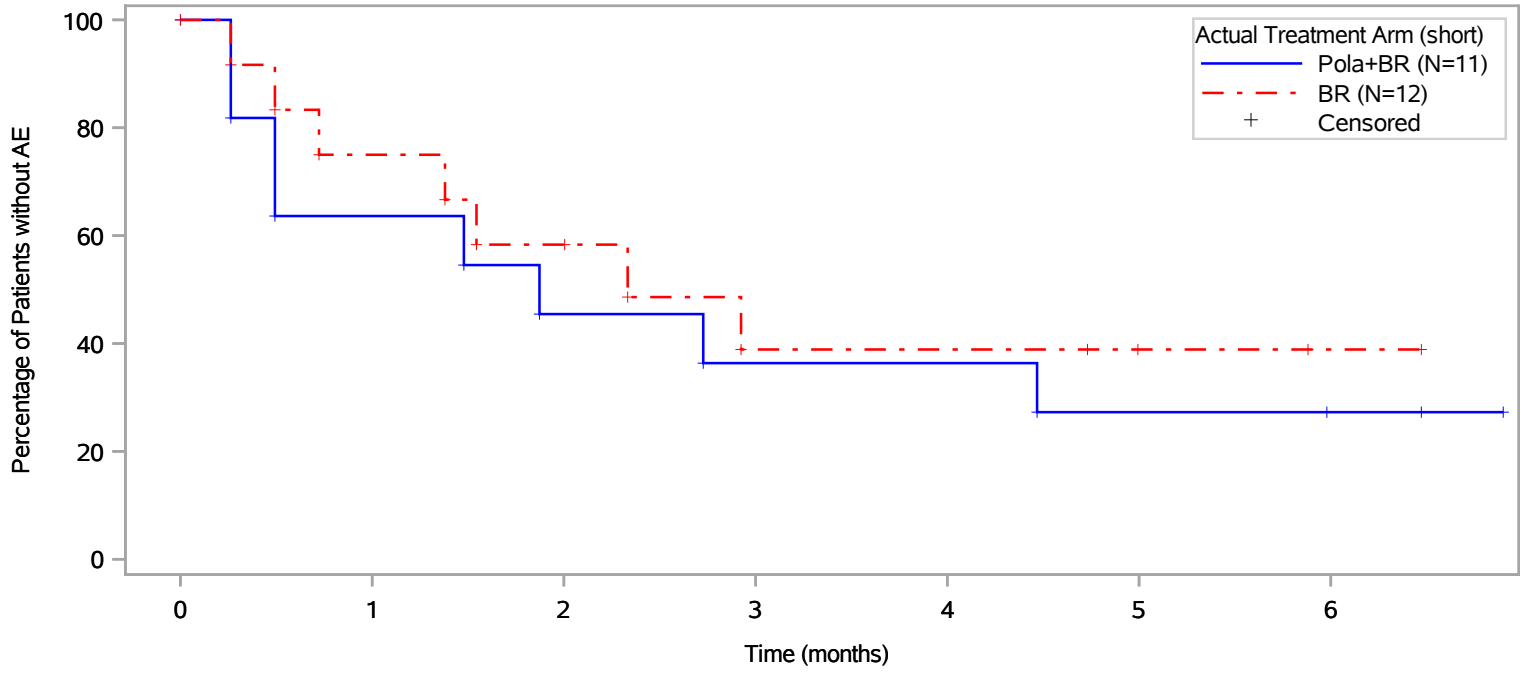
30NOV2022 23:03

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=11)	11	7	5	4	4	3	2
BR (N=12)	12	9	7	4	4	2	1
Patients censored							
Pola+BR (N=11)	0	0	0	0	0	0	1
BR (N=12)	0	0	0	1	1	3	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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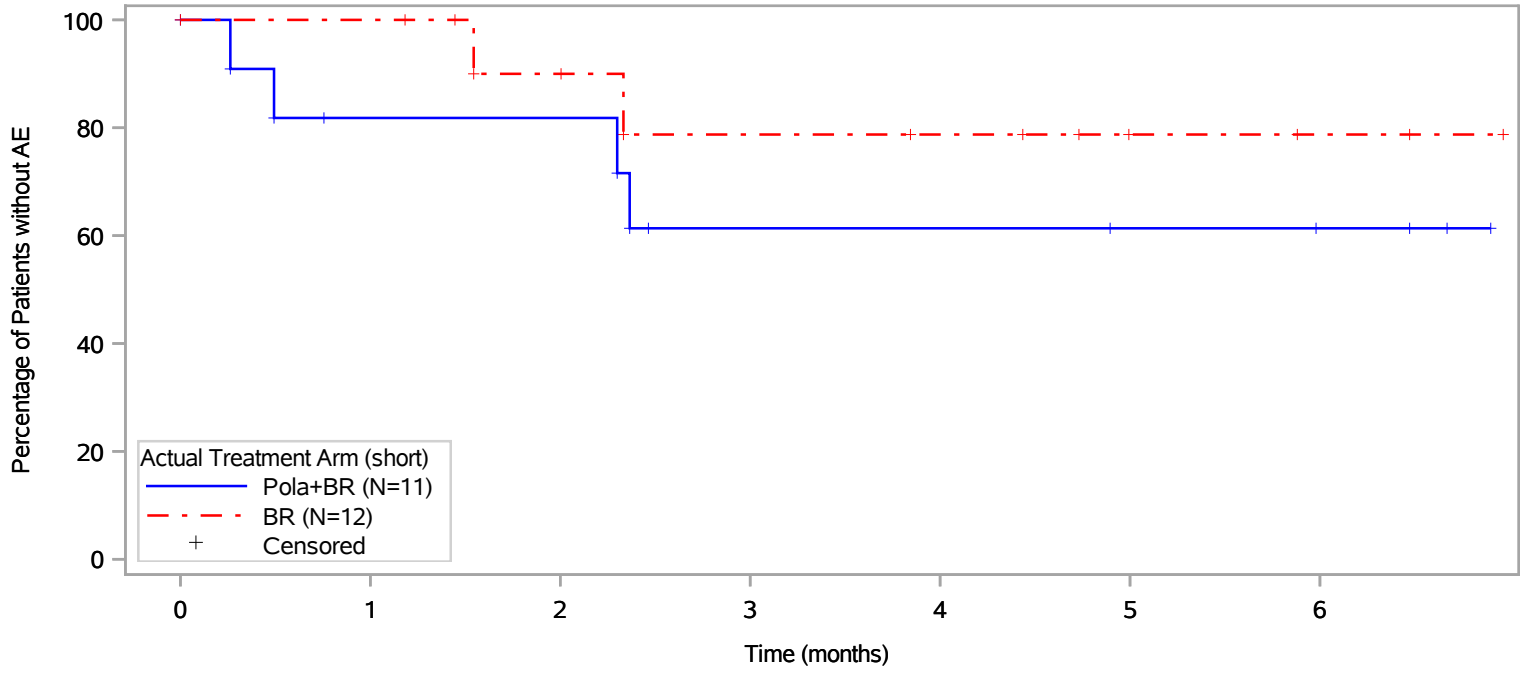
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA

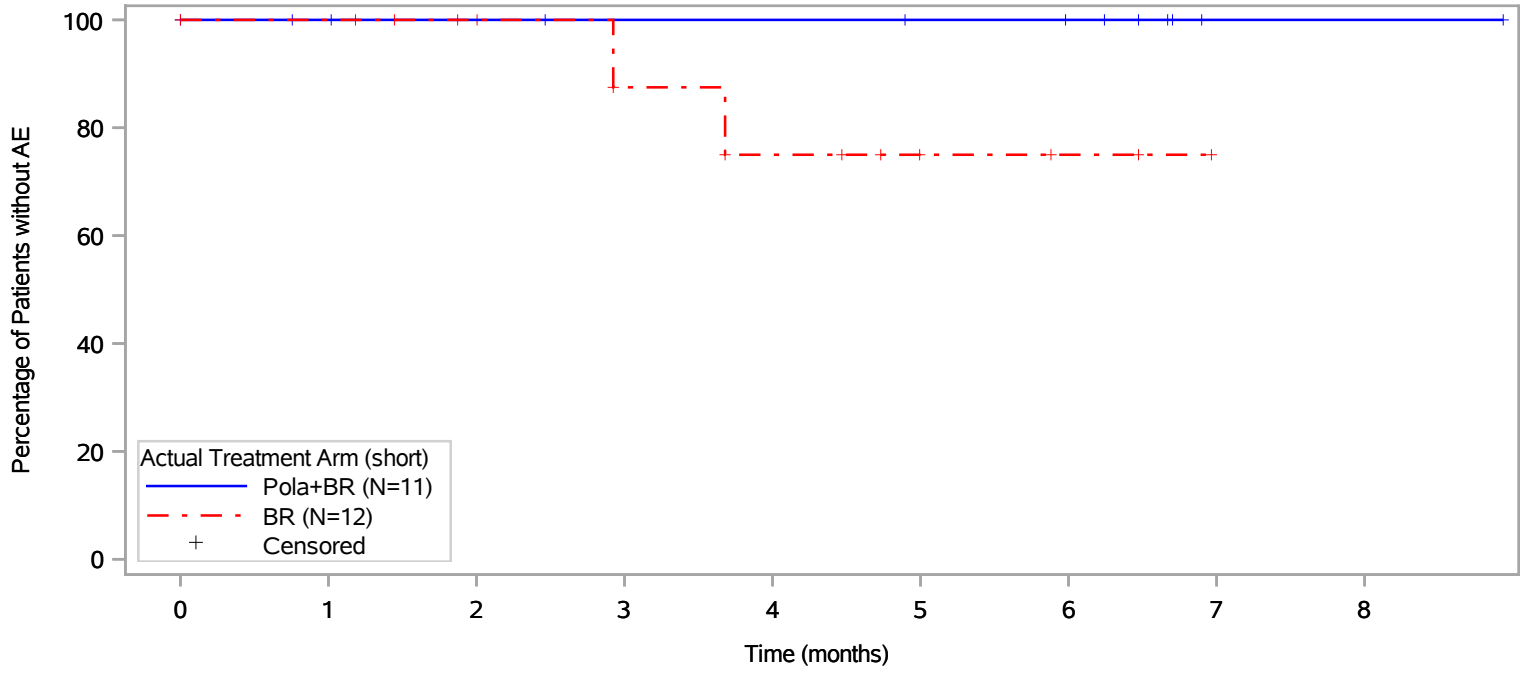


Patients at risk							
Pola+BR (N=11)	11	8	8	5	5	4	3
BR (N=12)	12	12	9	7	6	3	2
Patients censored							
Pola+BR (N=11)	0	1	1	2	2	3	4
BR (N=12)	0	0	2	3	4	7	8

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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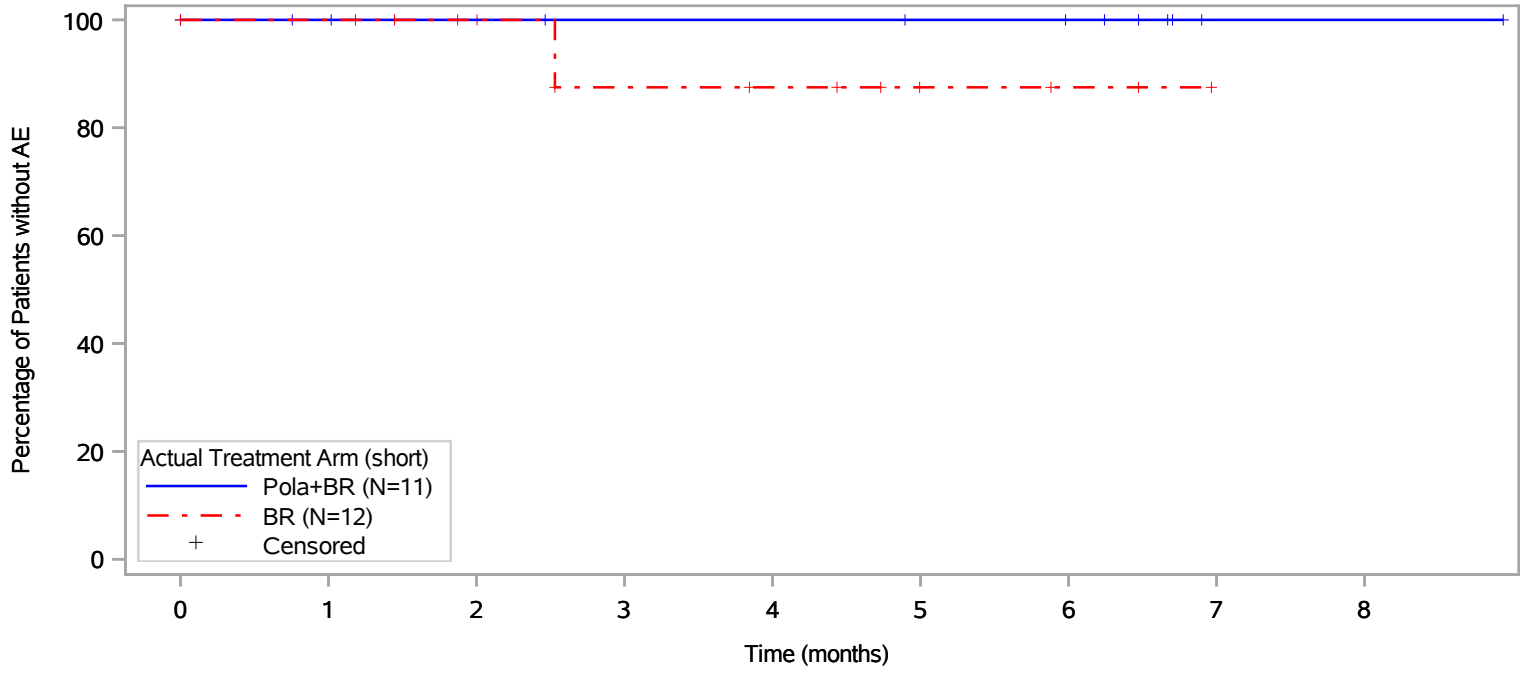
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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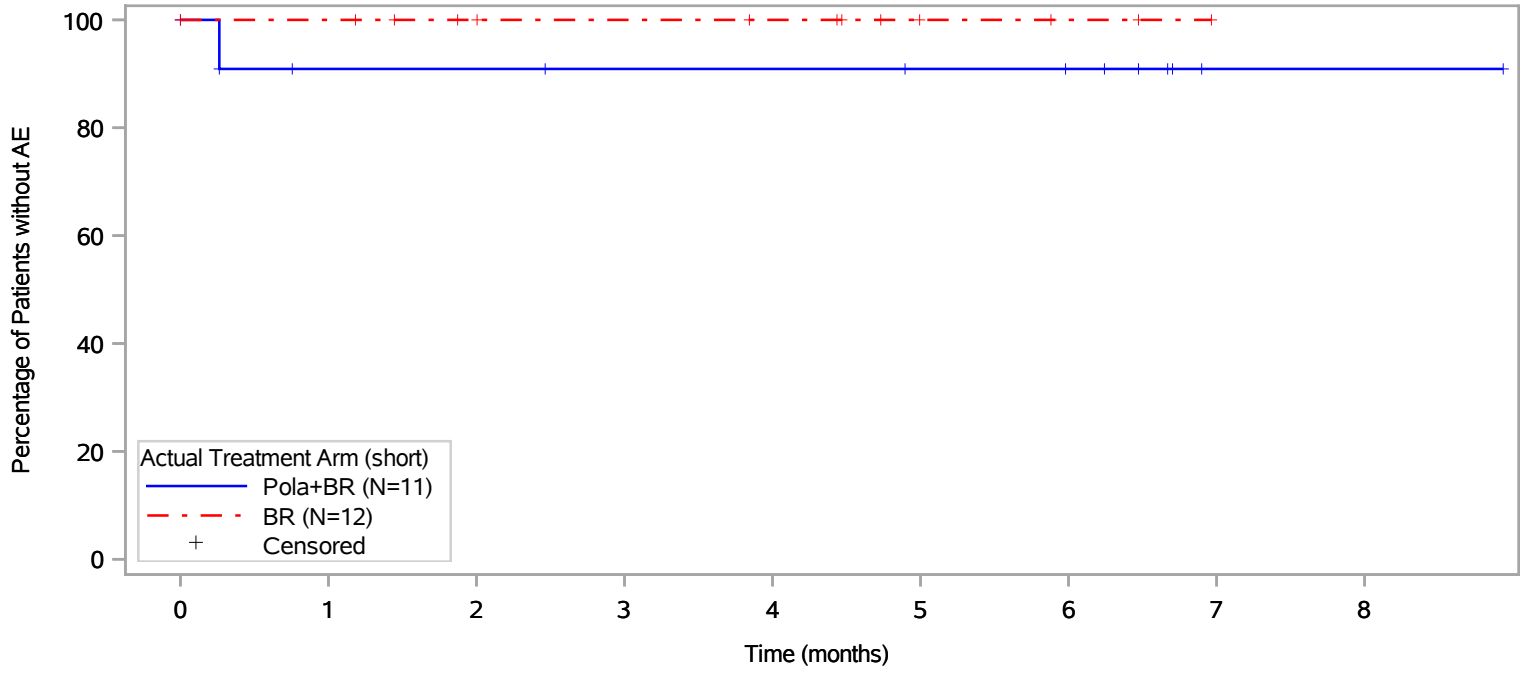
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA



Patients at risk								
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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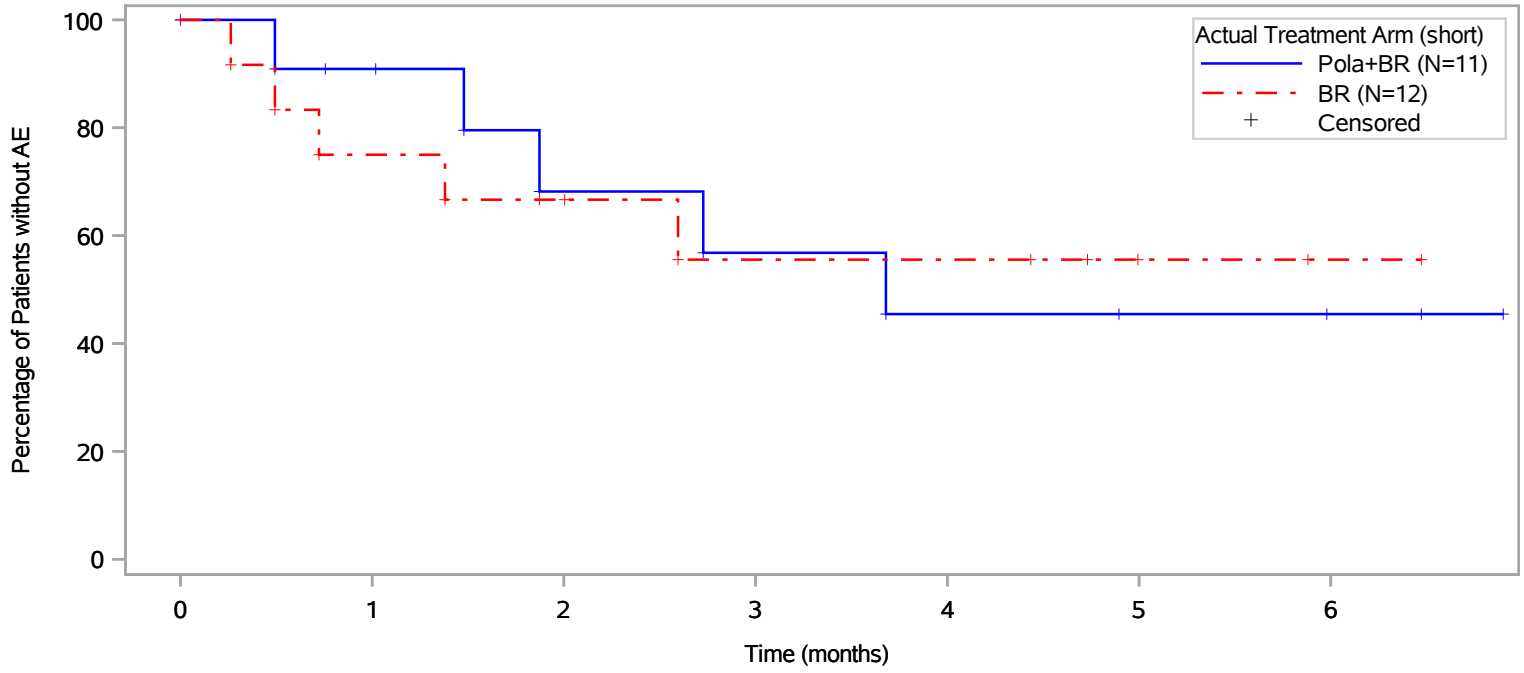
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk							
Pola+BR (N=11)	11	9	6	5	4	3	2
BR (N=12)	12	9	7	5	5	2	1
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	3	4
BR (N=12)	0	0	1	2	2	5	6

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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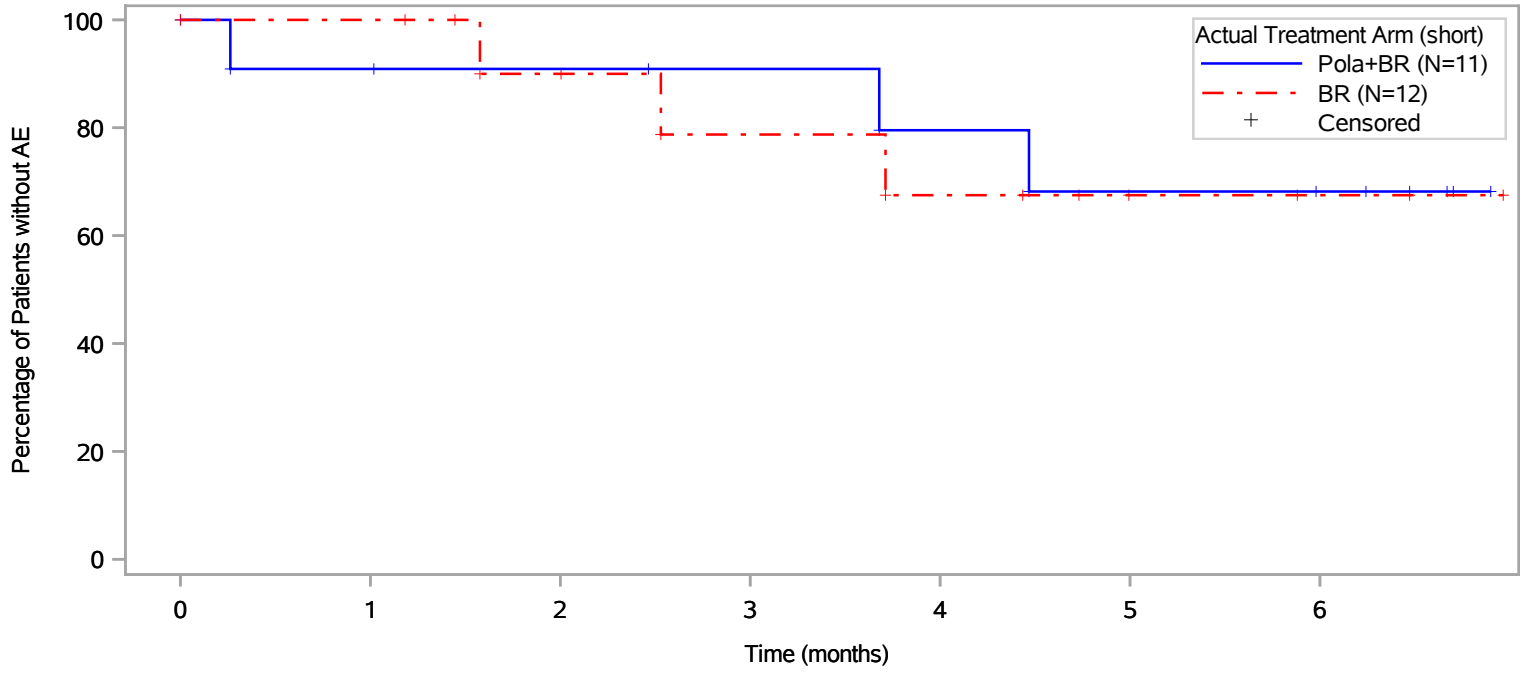
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

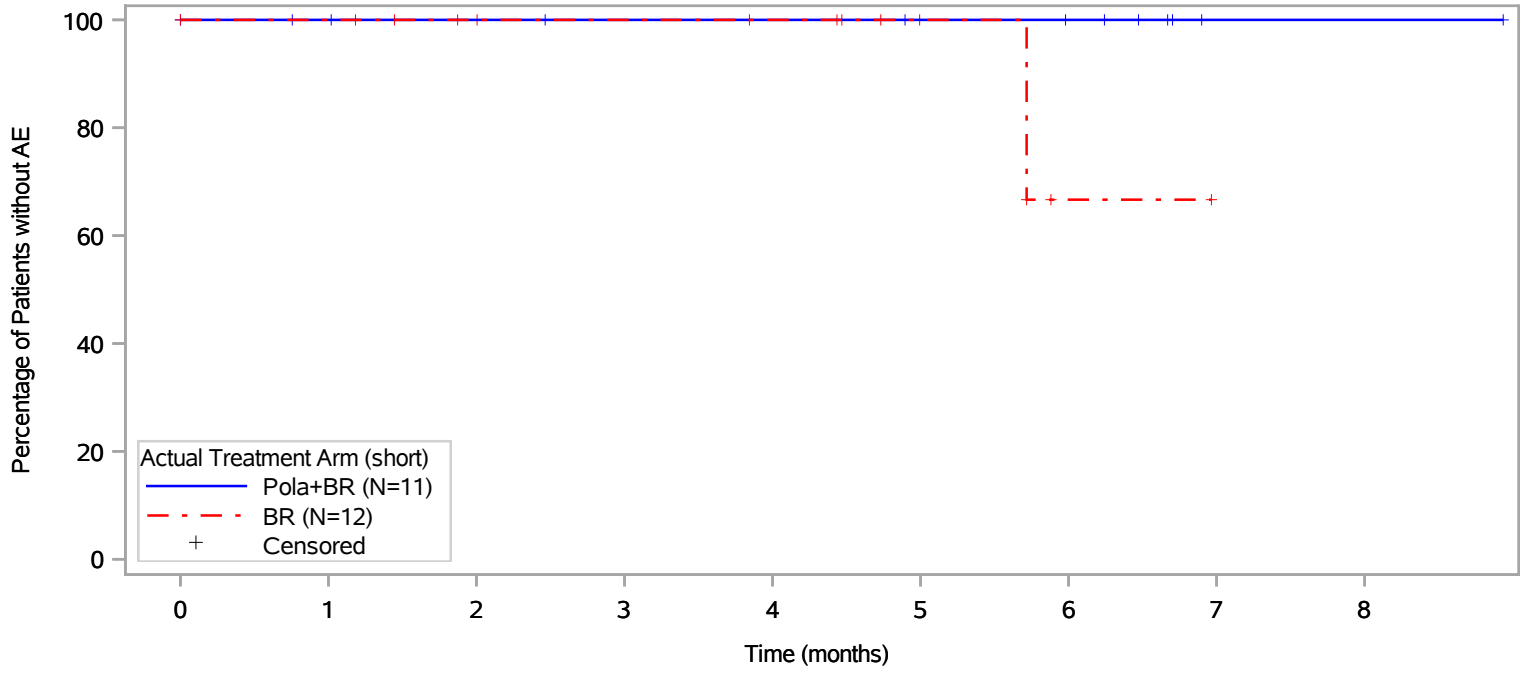
BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk							
Pola+BR (N=11)	11	10	9	8	7	6	5
BR (N=12)	12	12	9	7	6	3	2
Patients censored							
Pola+BR (N=11)	0	0	1	2	2	2	3
BR (N=12)	0	0	2	3	3	6	7

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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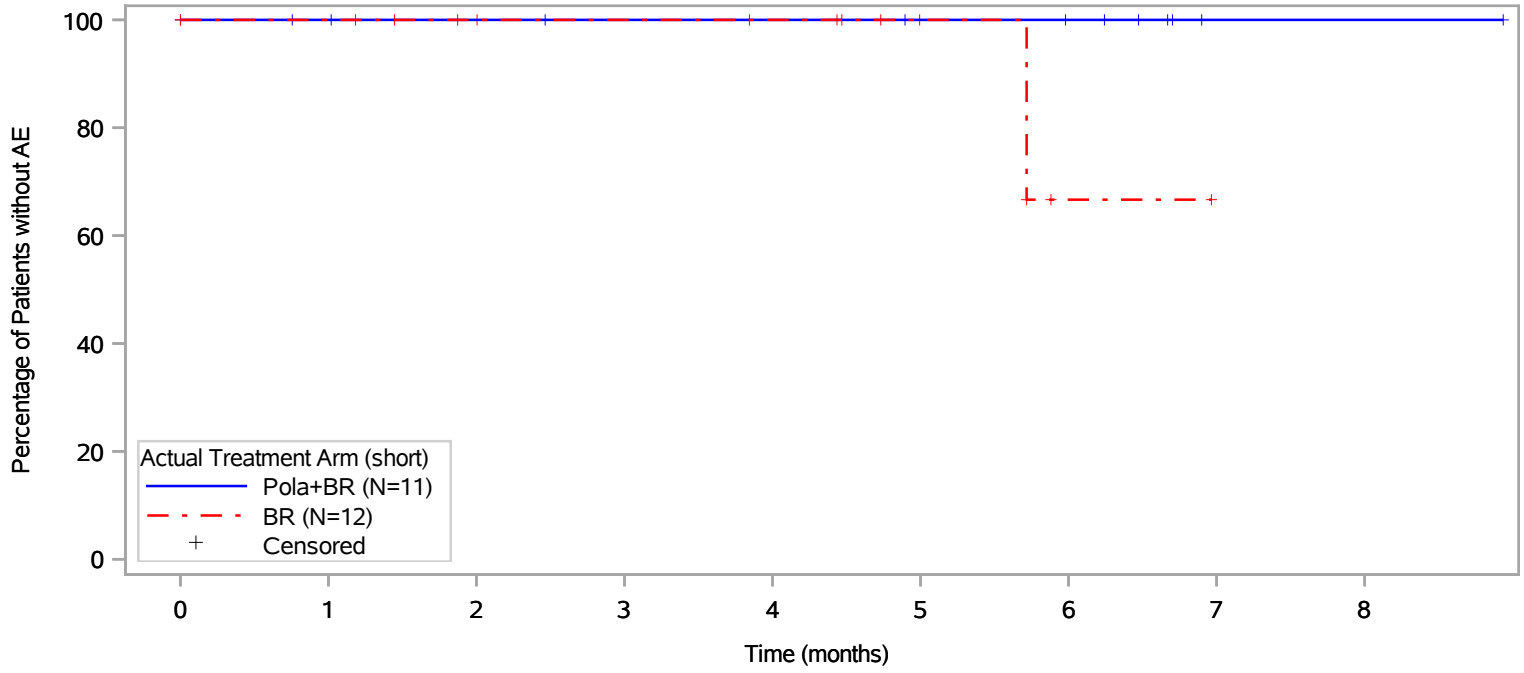
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SMALL INTESTINAL OBSTRUCTION



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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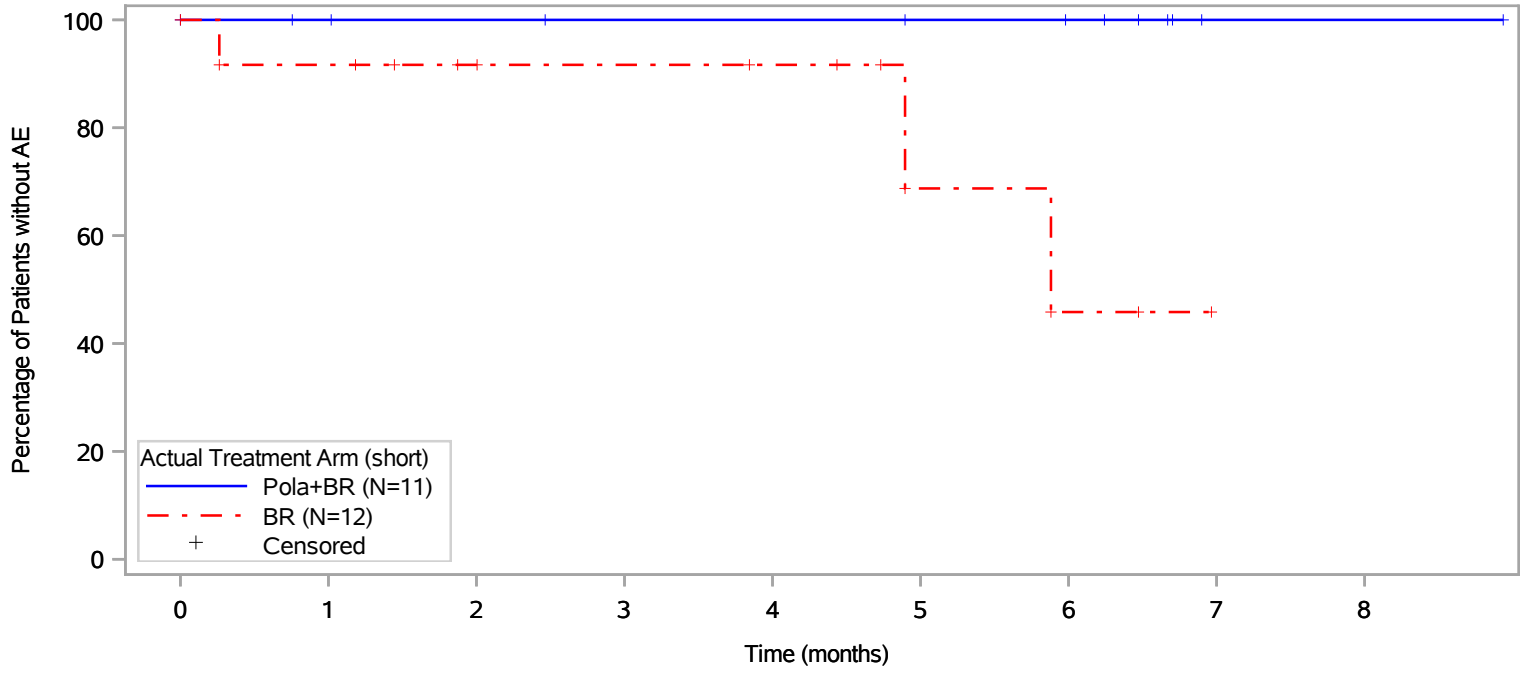
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	7	7	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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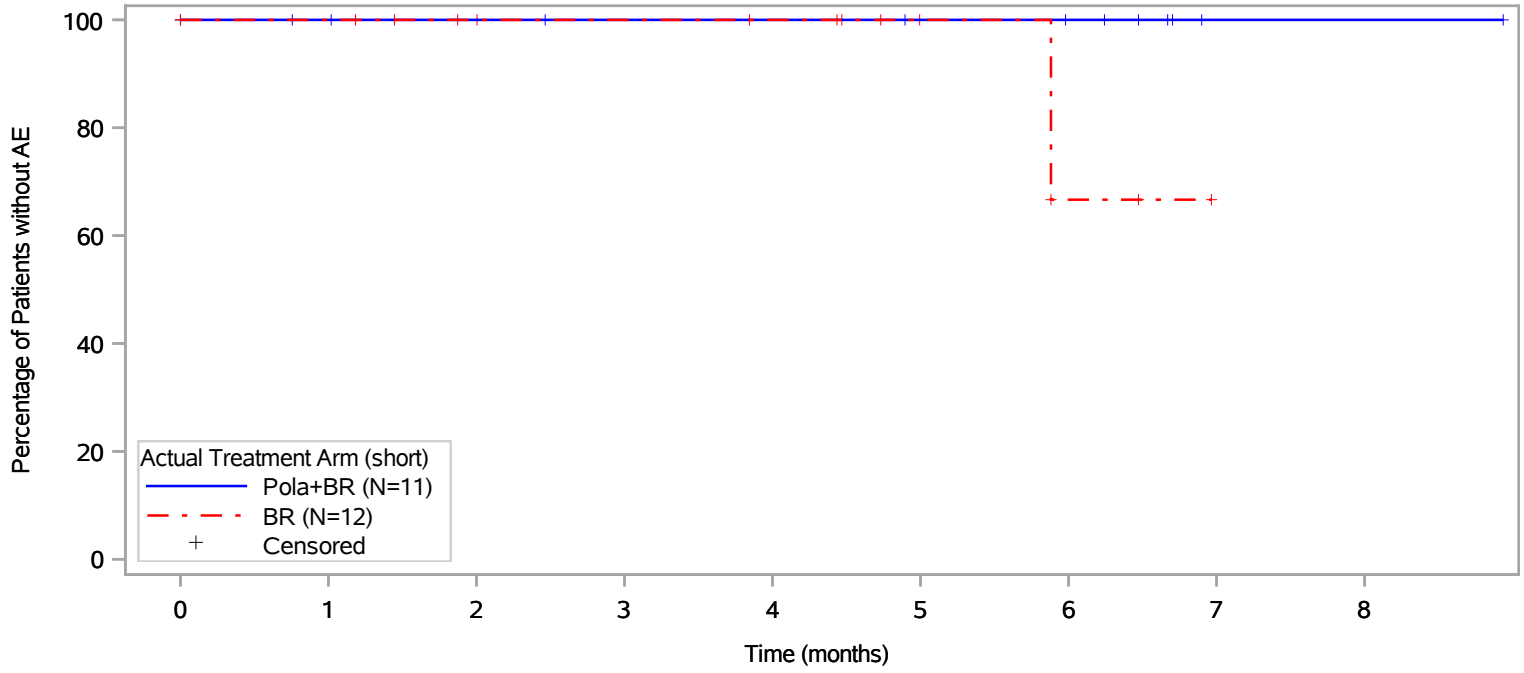
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DEATH



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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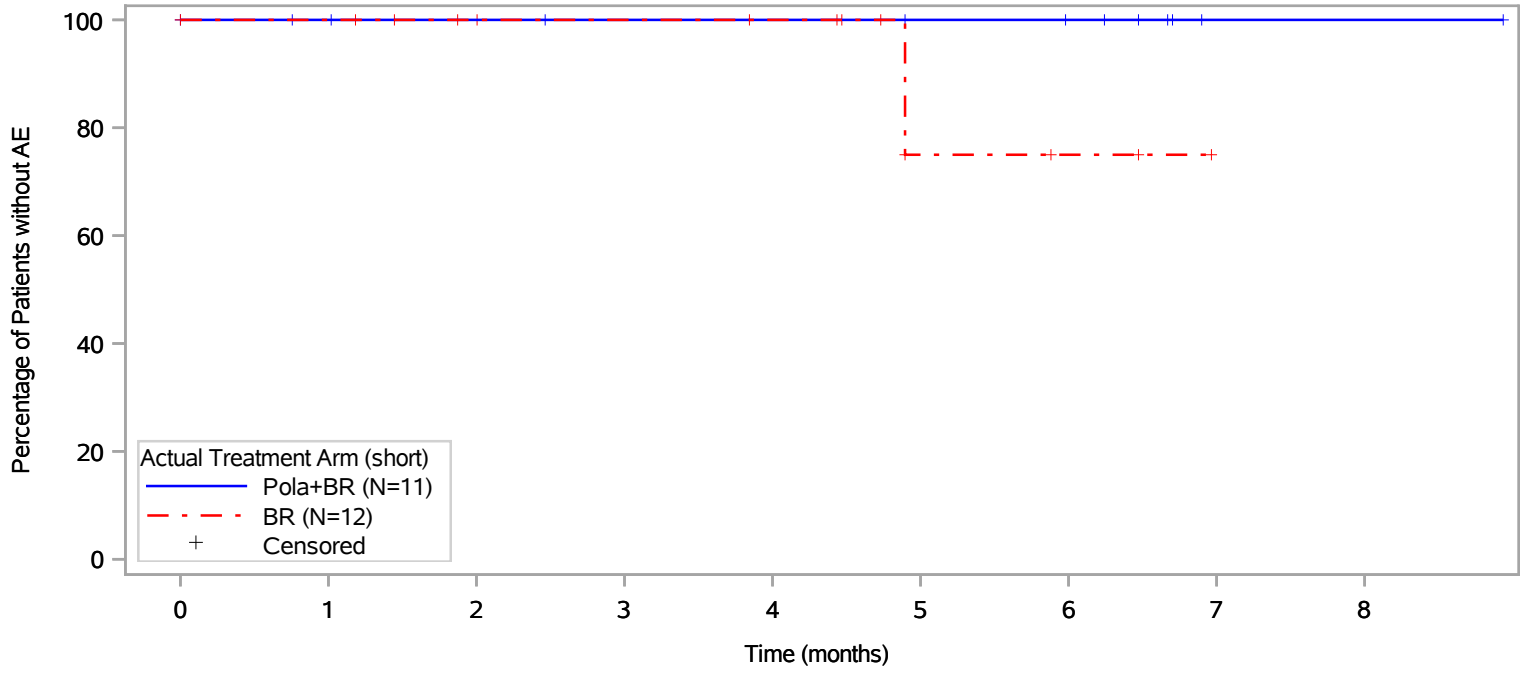
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME

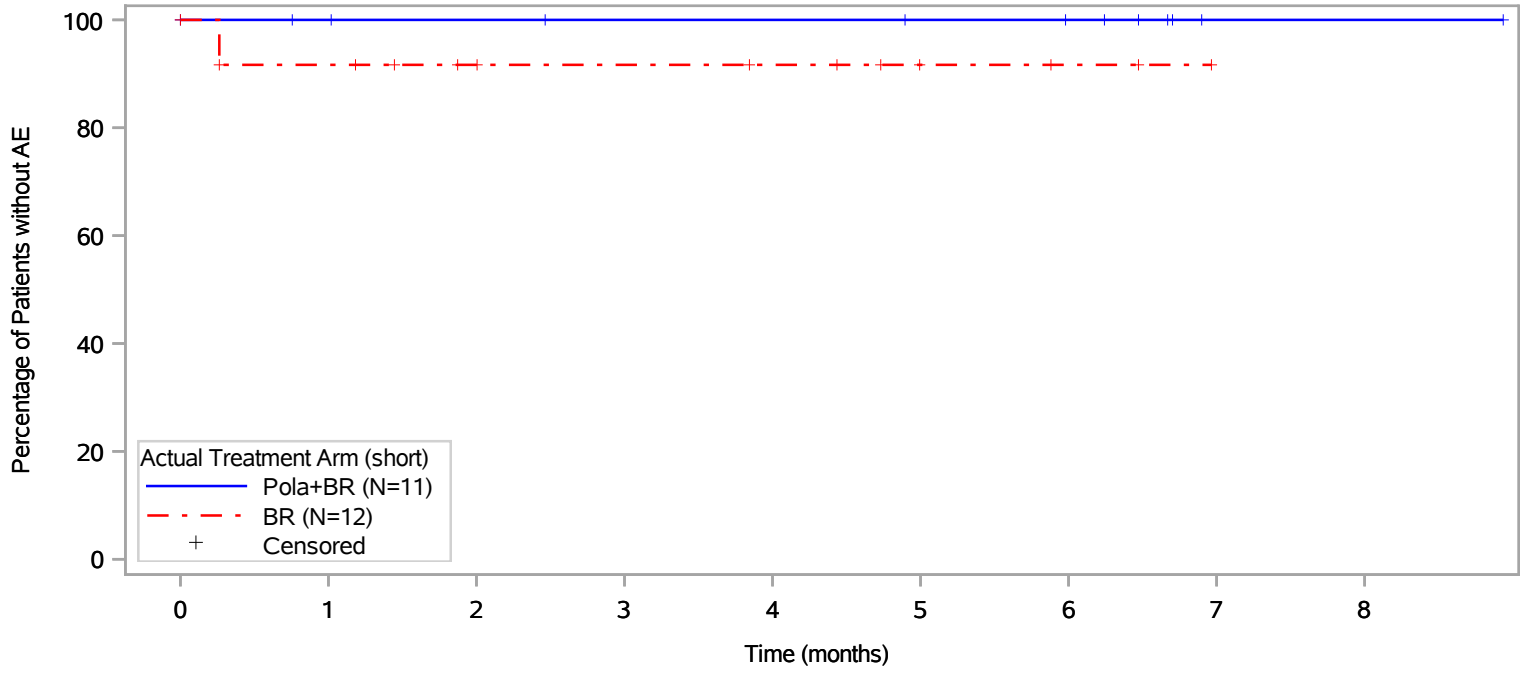


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

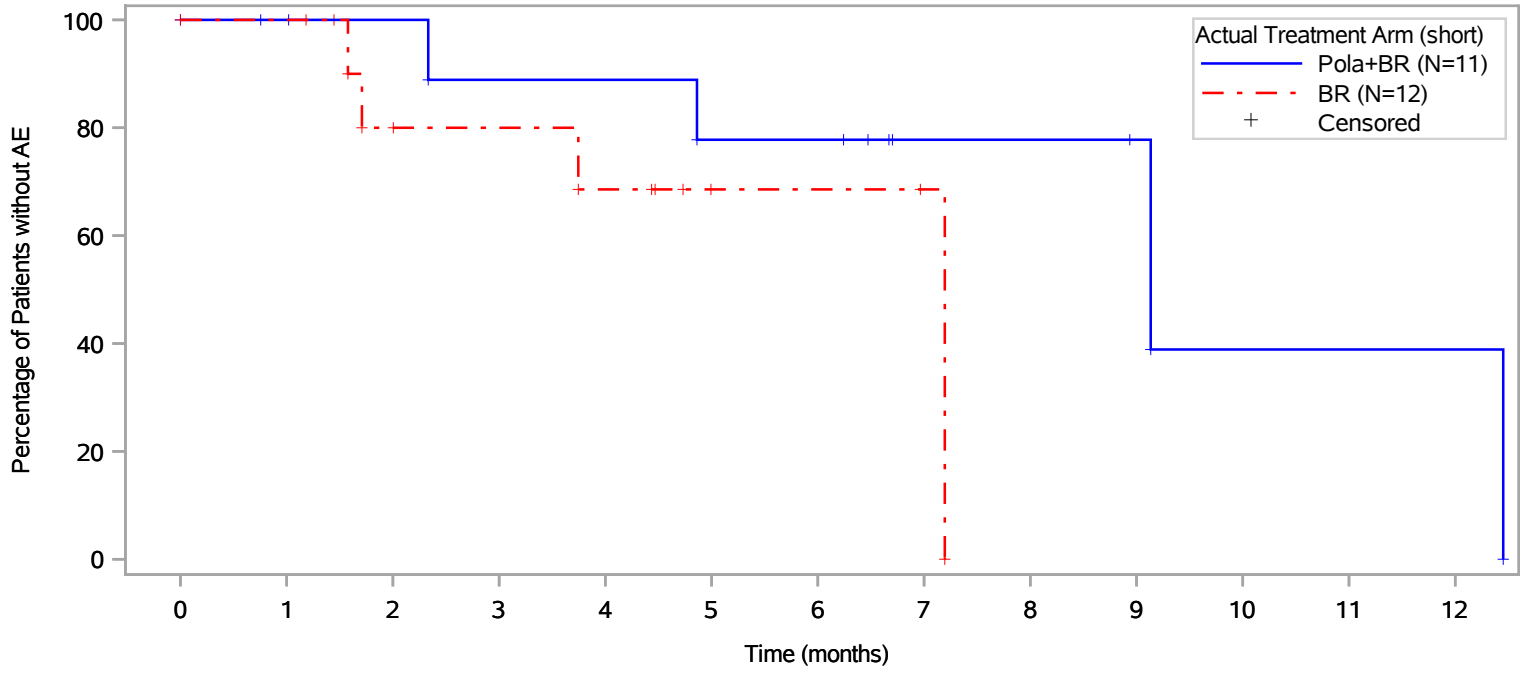
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk													
Pola+BR (N=11)	11	10	9	8	8	7	7	3	3	2	1	1	1
BR (N=12)	12	12	8	7	6	2	2	1	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	2	2	2	2	2	6	6	7	7	7	7
BR (N=12)	0	0	2	3	3	7	7	8	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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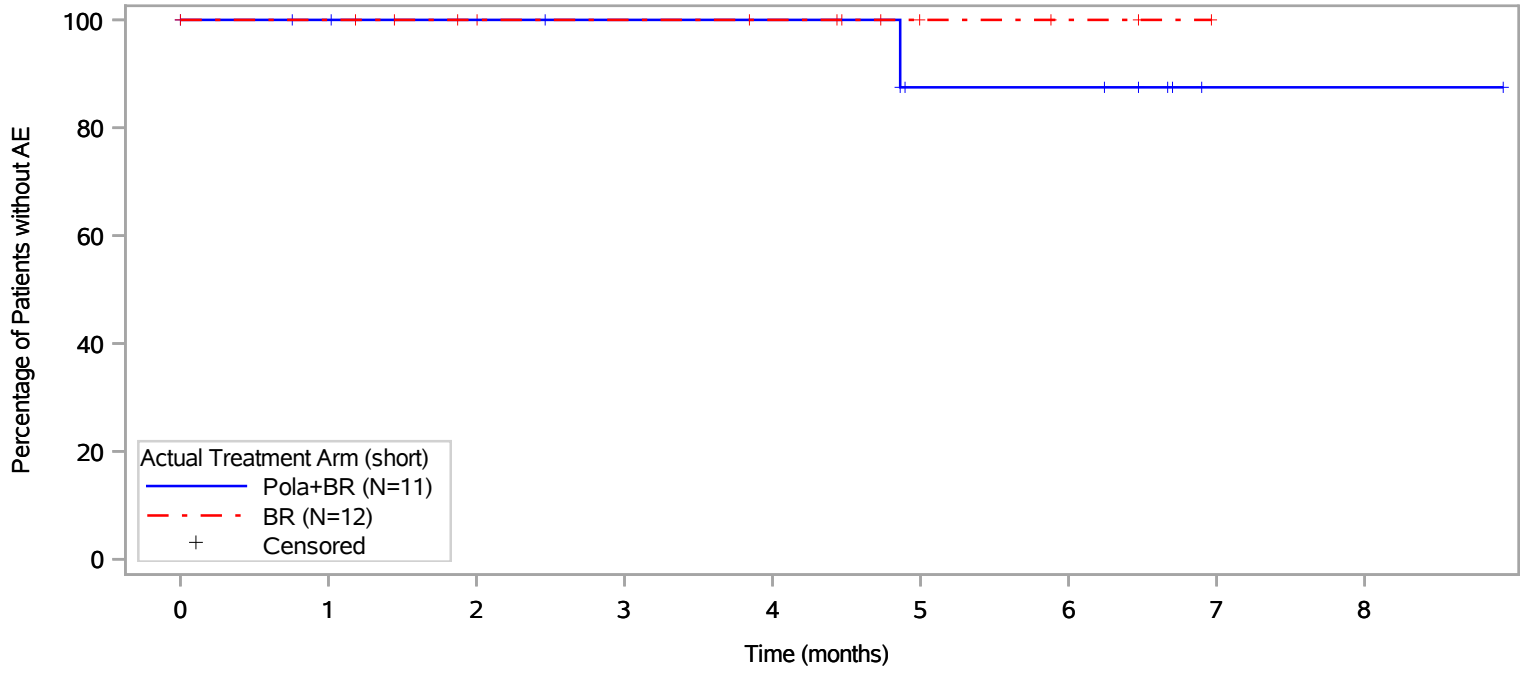
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CEREBRAL TOXOPLASMOSIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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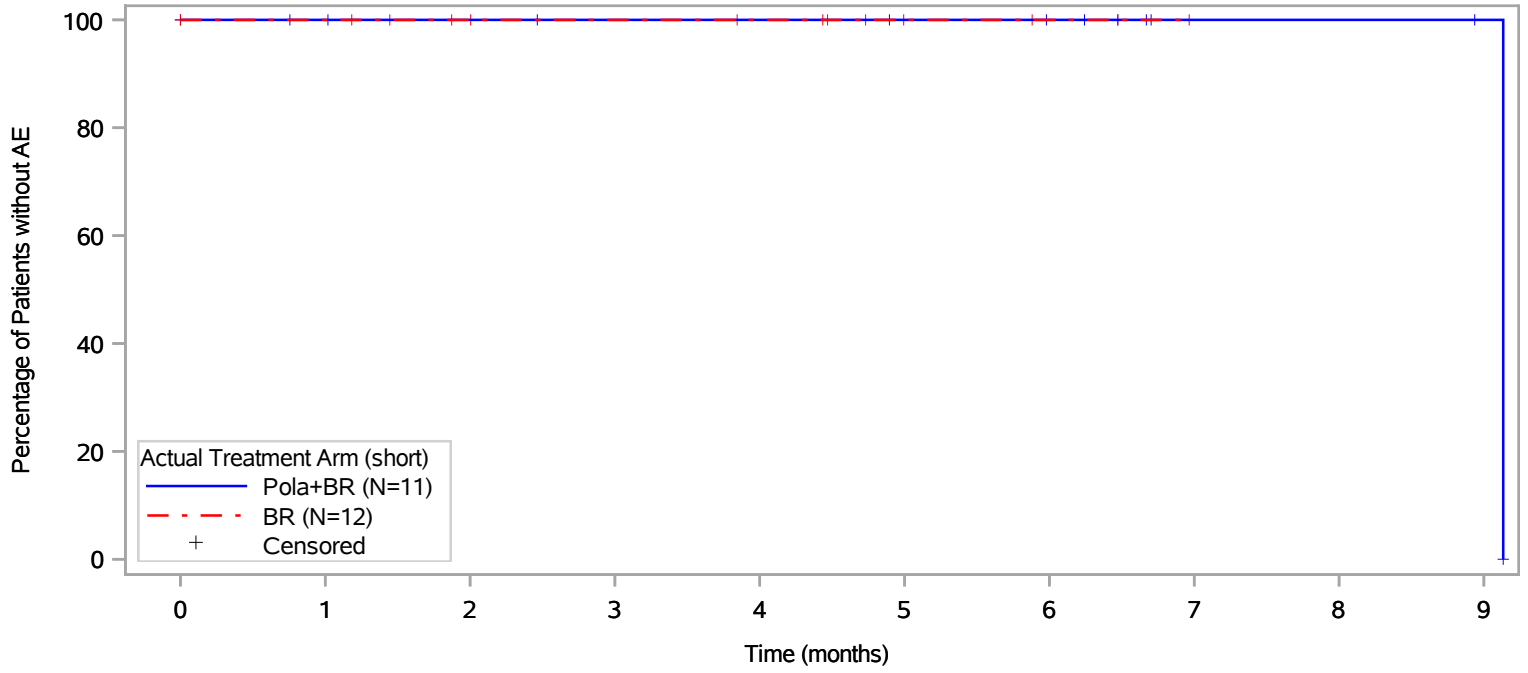
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES VIRUS INFECTION

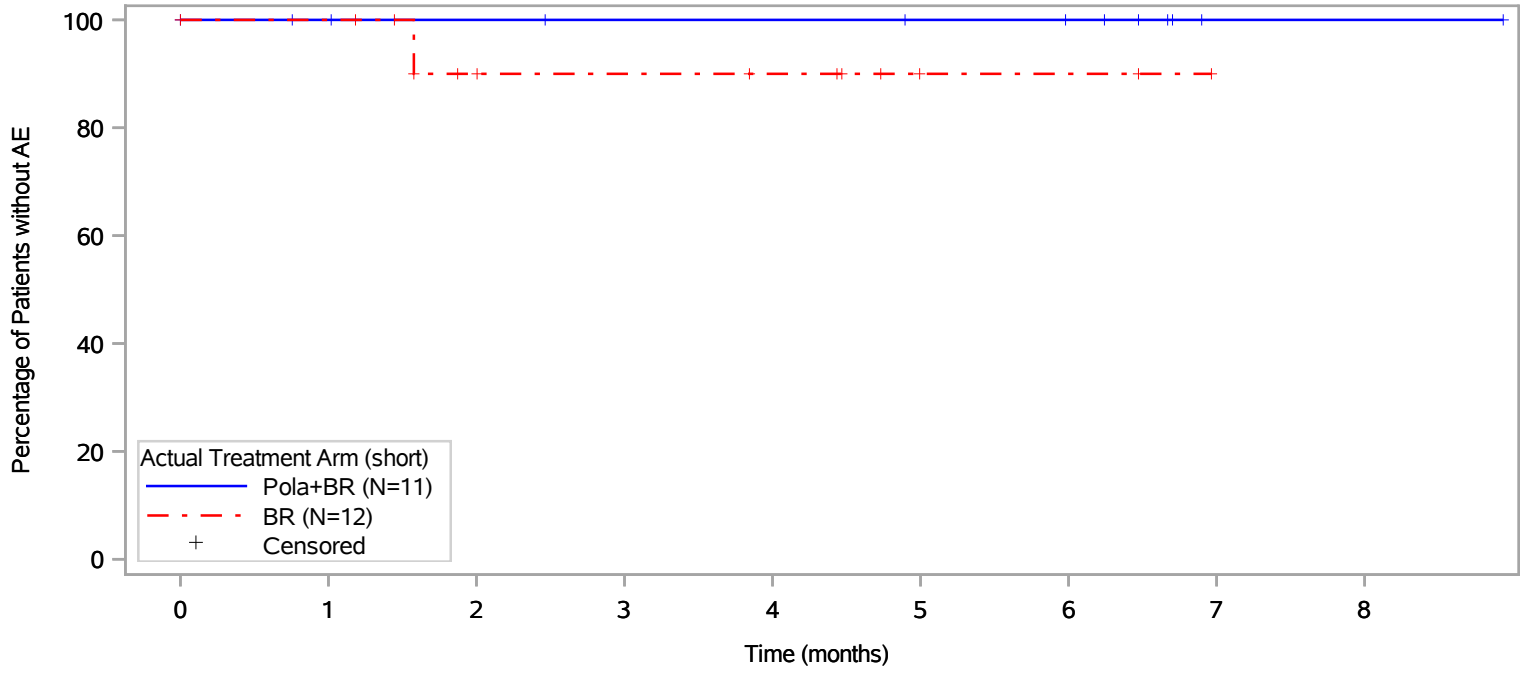


Patients at risk										
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored										
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER

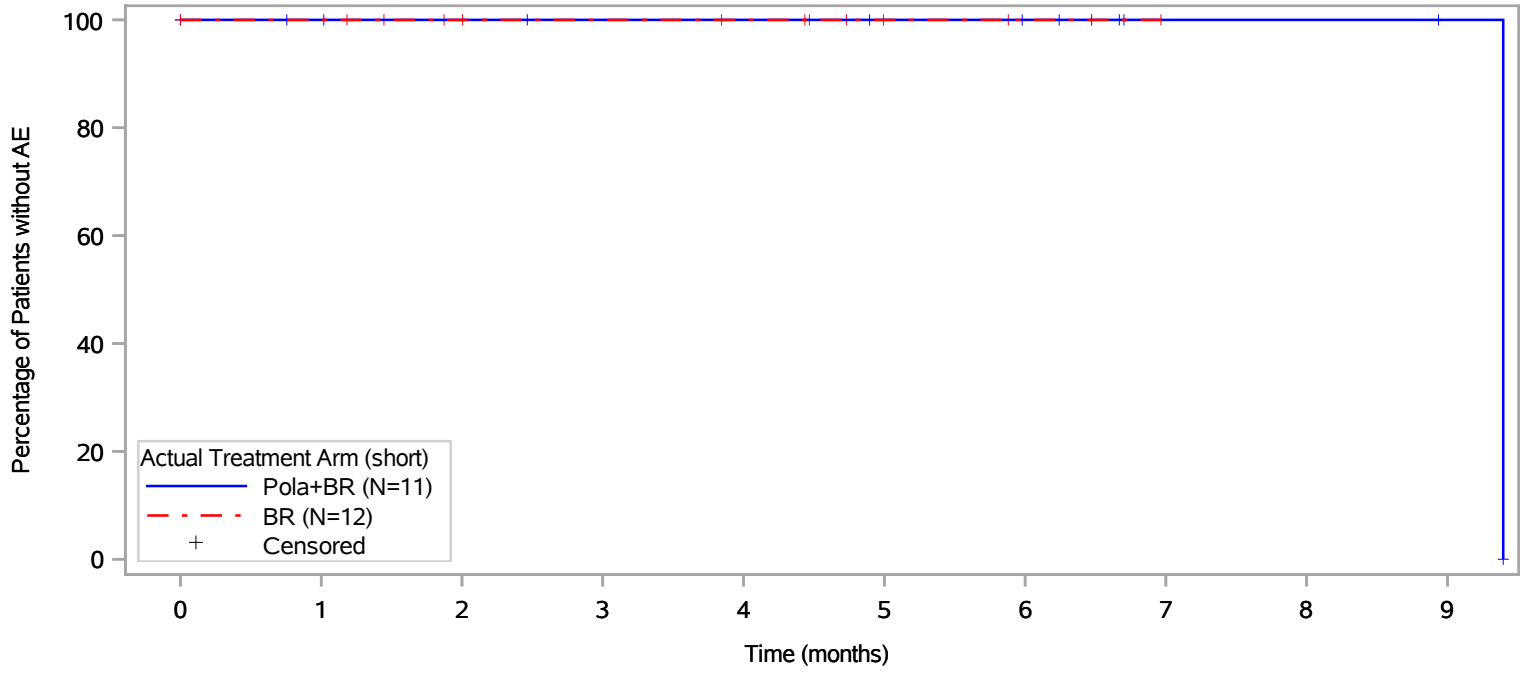


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	7	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

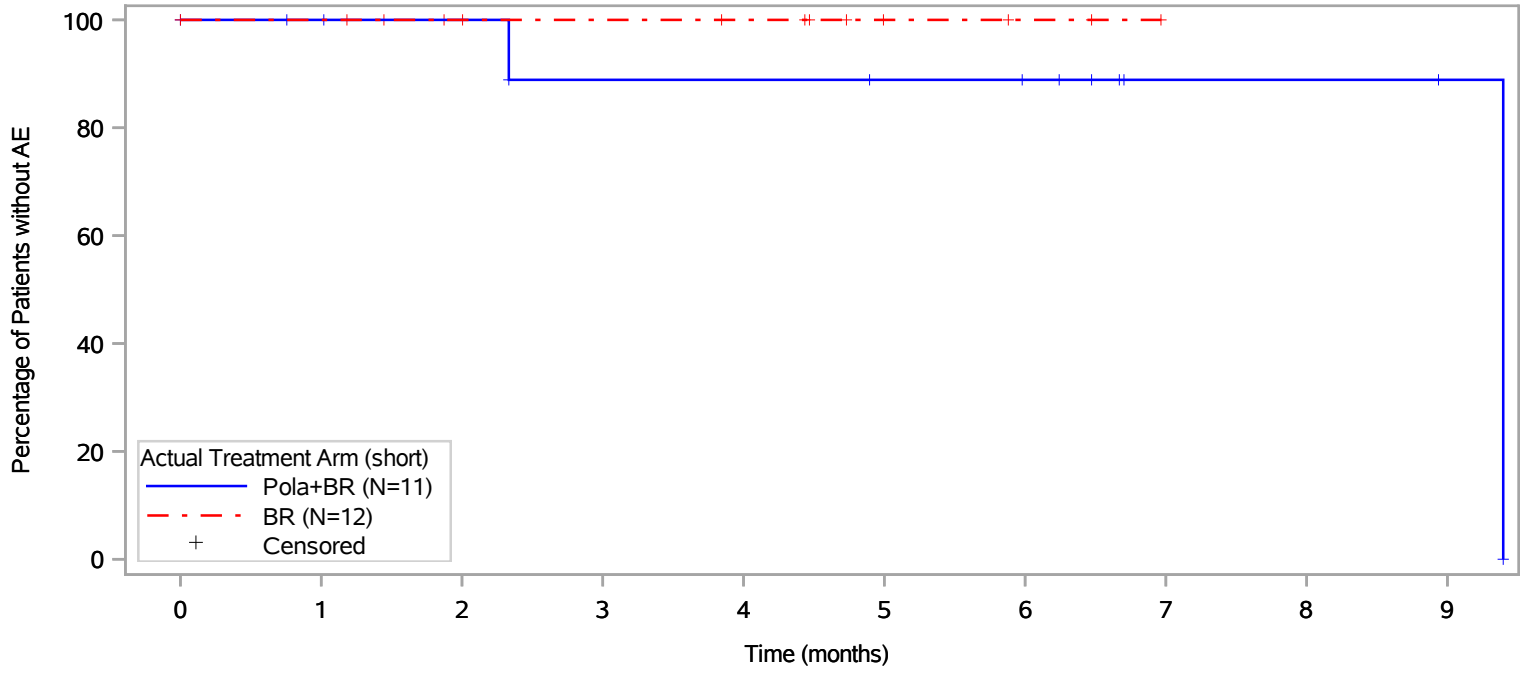
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MENINGOENCEPHALITIS HERPETIC



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA

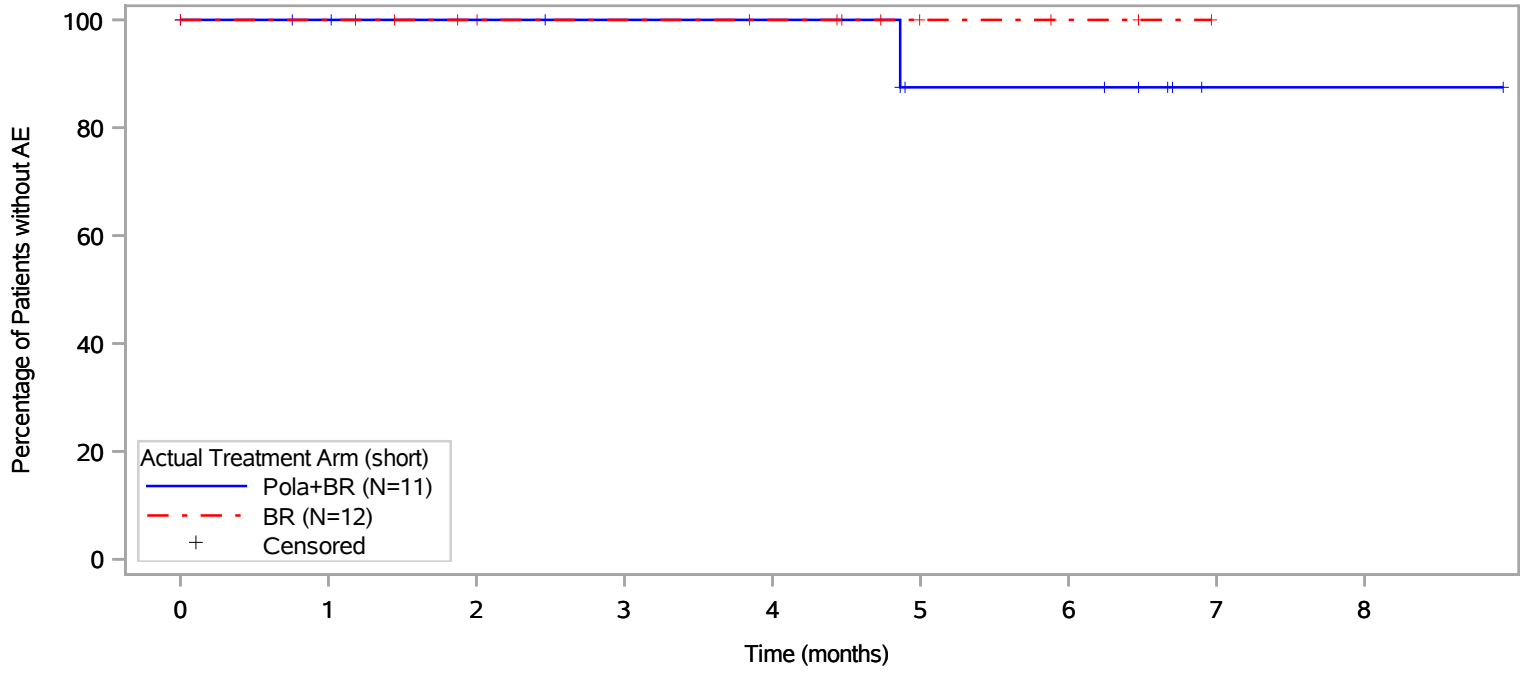


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	8	8	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA CYTOMEGALOVIRAL

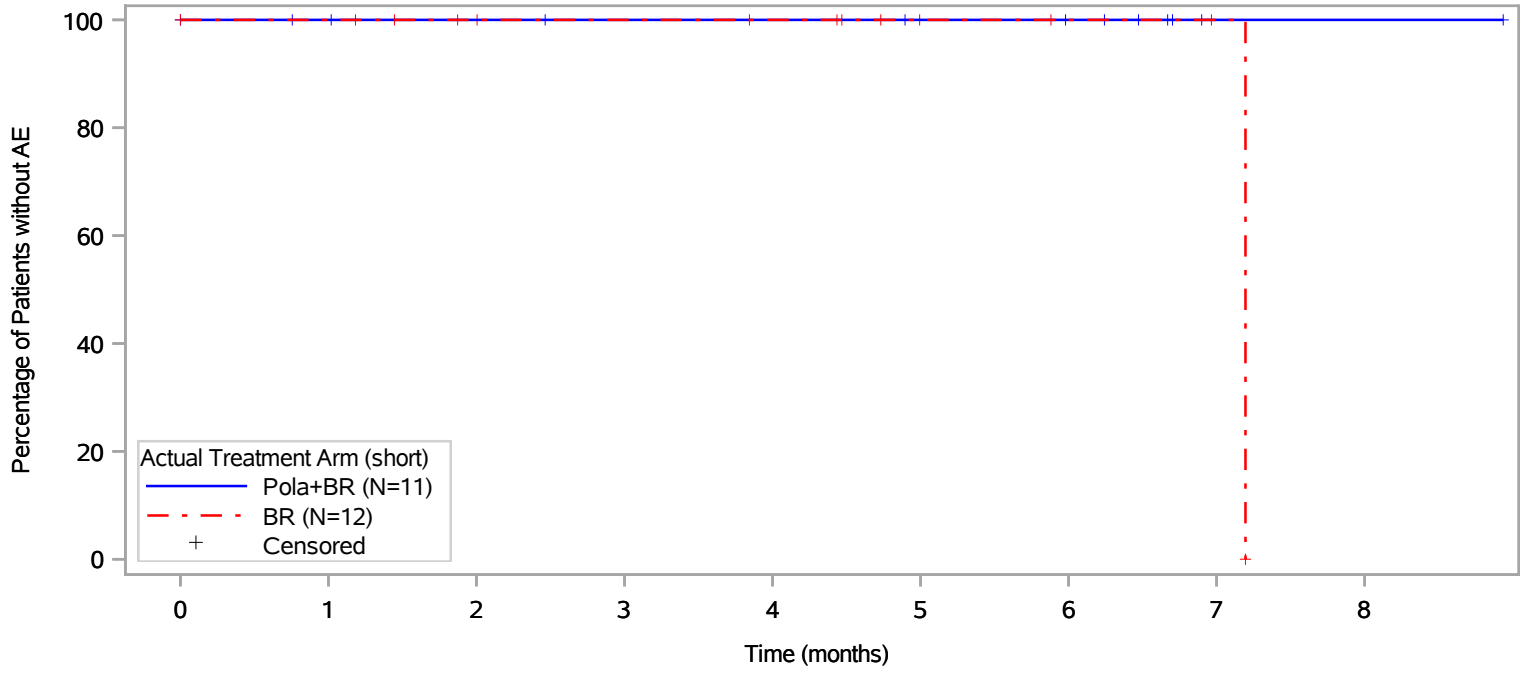


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, POST PROCEDURAL INFECTION

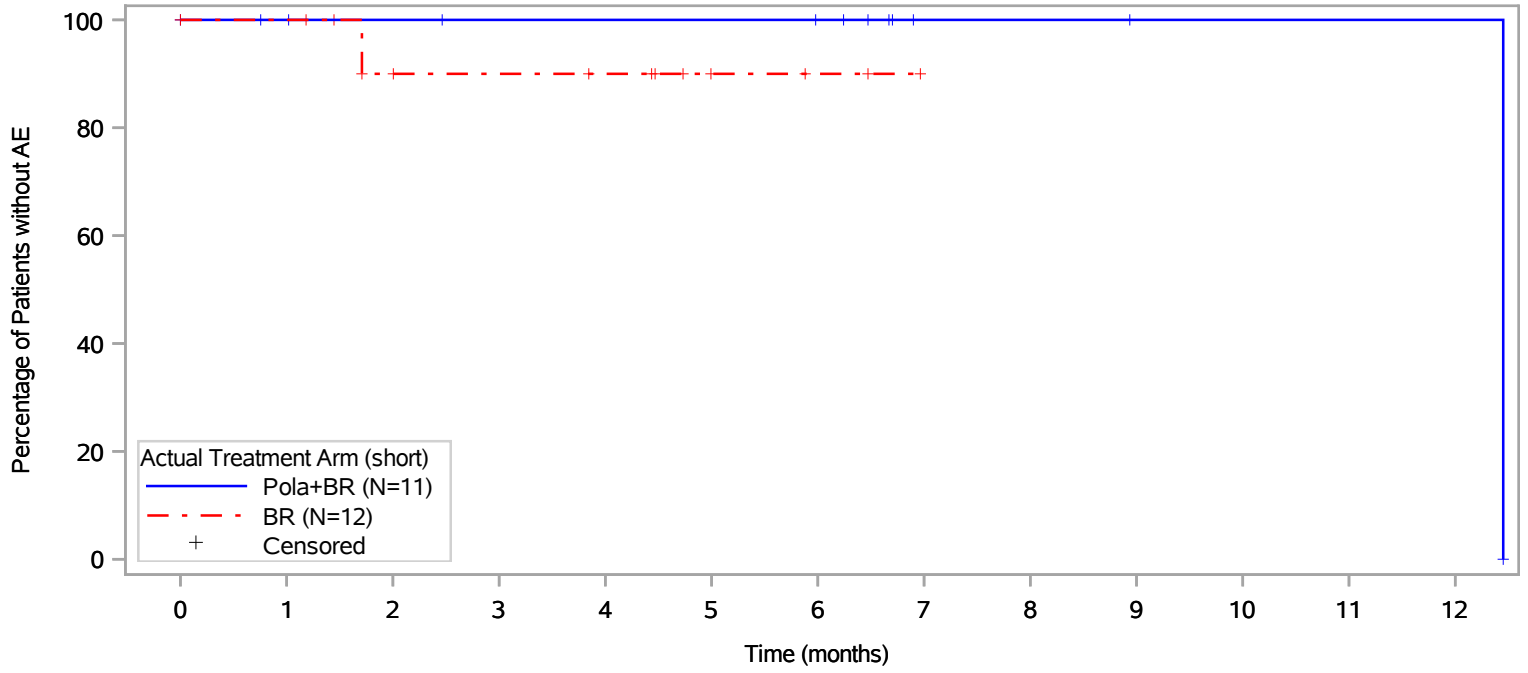


Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS

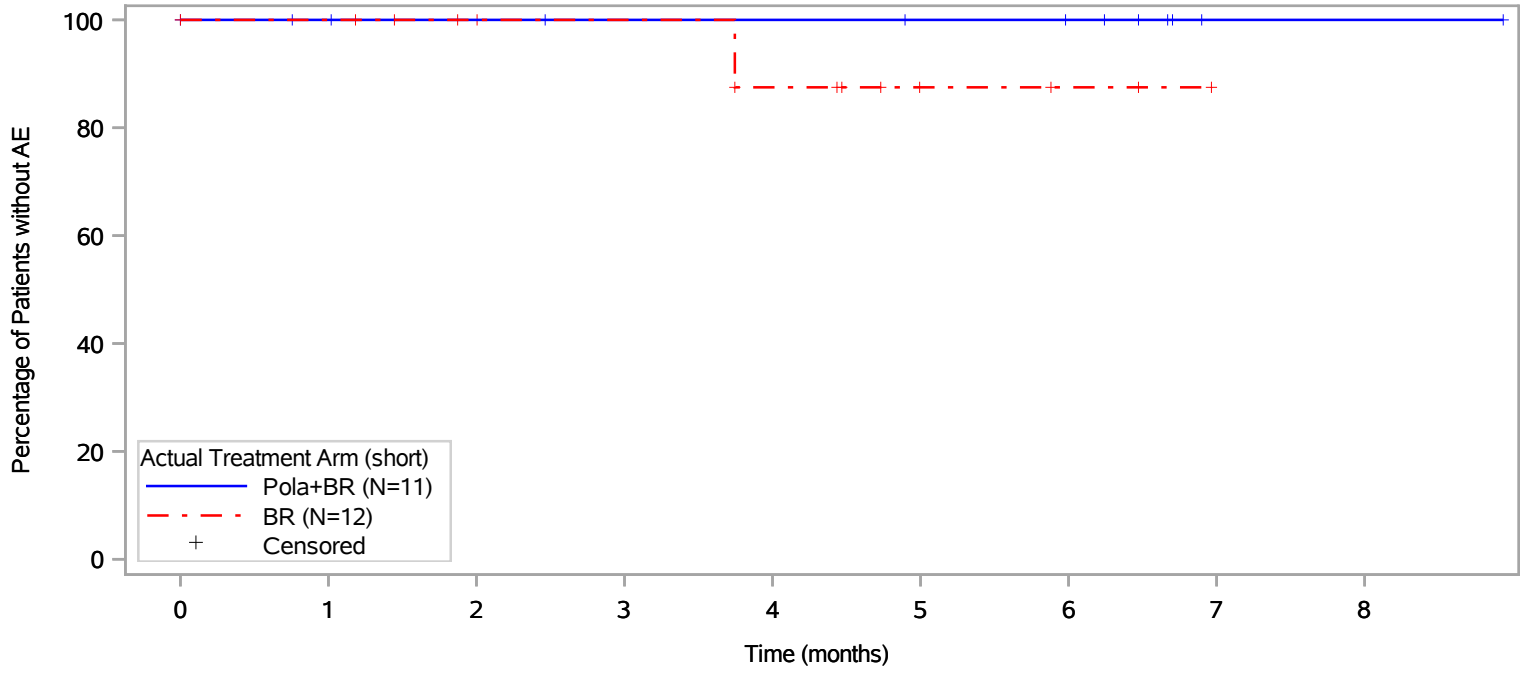


Patients at risk													
Pola+BR (N=11)	11	10	9	8	8	8	7	2	2	1	1	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	2	3	3	3	4	9	9	10	10	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK

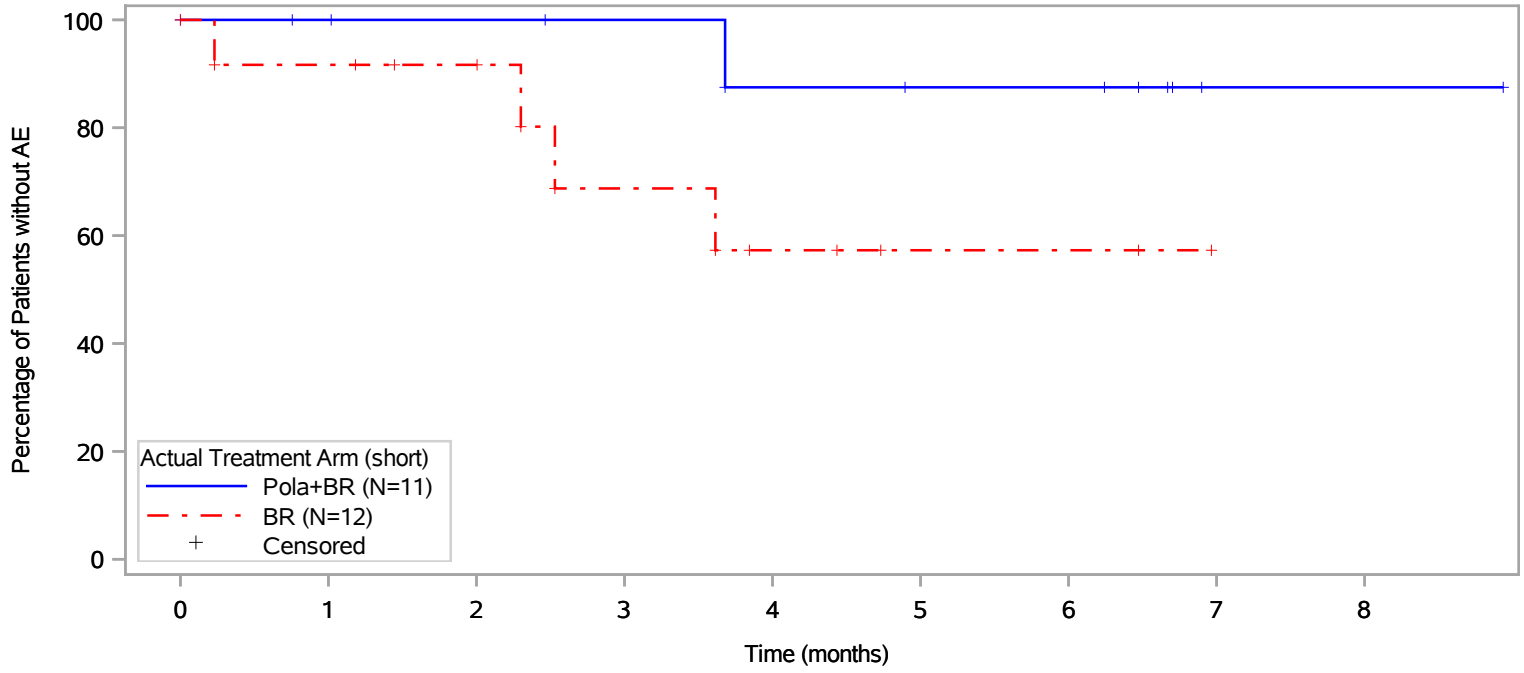


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

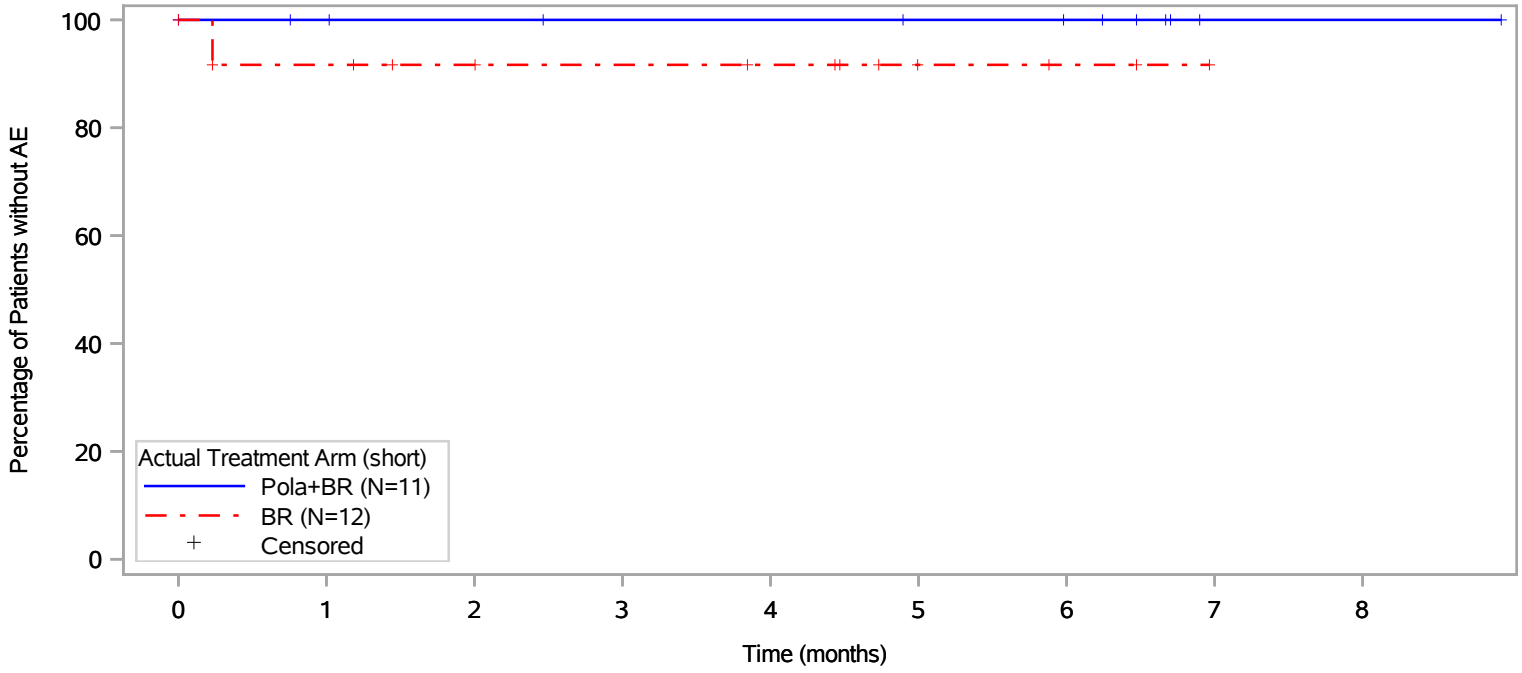
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	11	9	6	4	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	2	3	4	6	6	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALKALINE PHOSPHATASE INCREASED

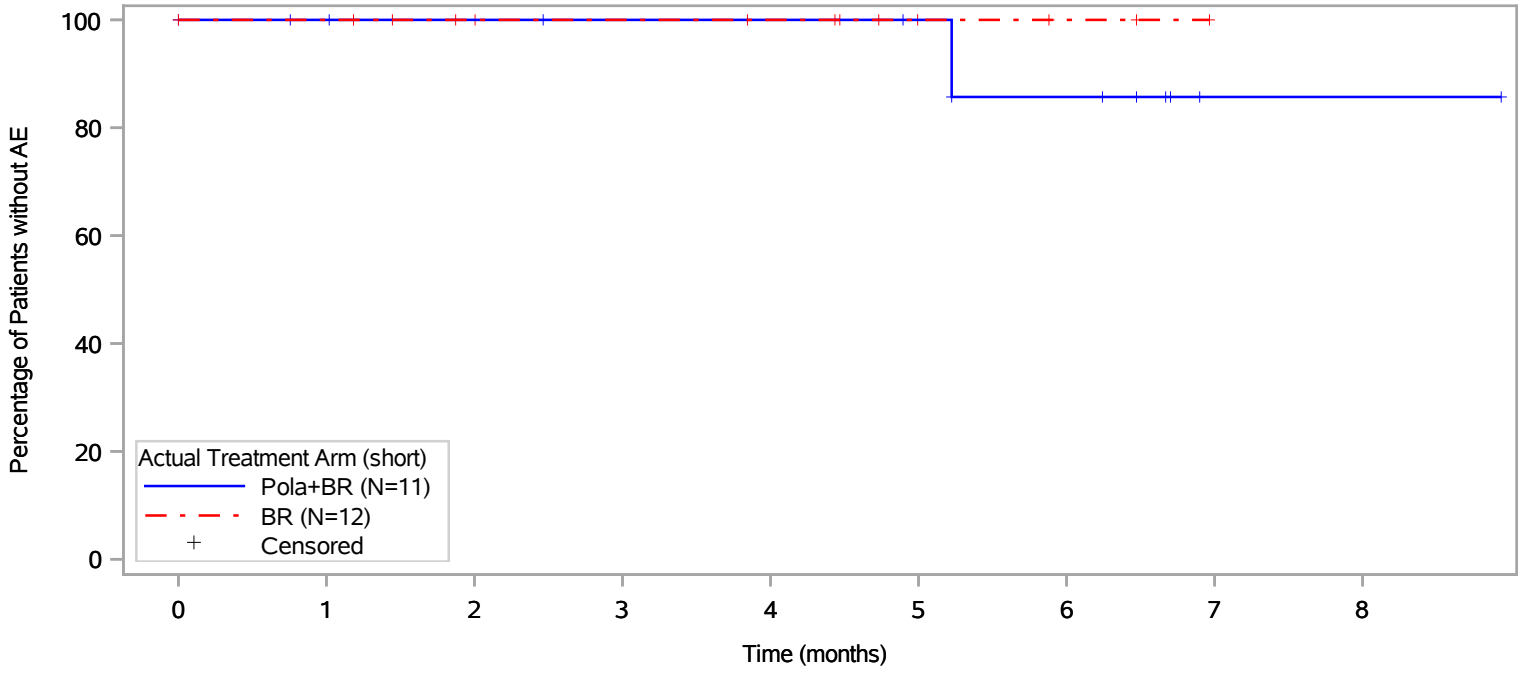


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PHOSPHORUS DECREASED

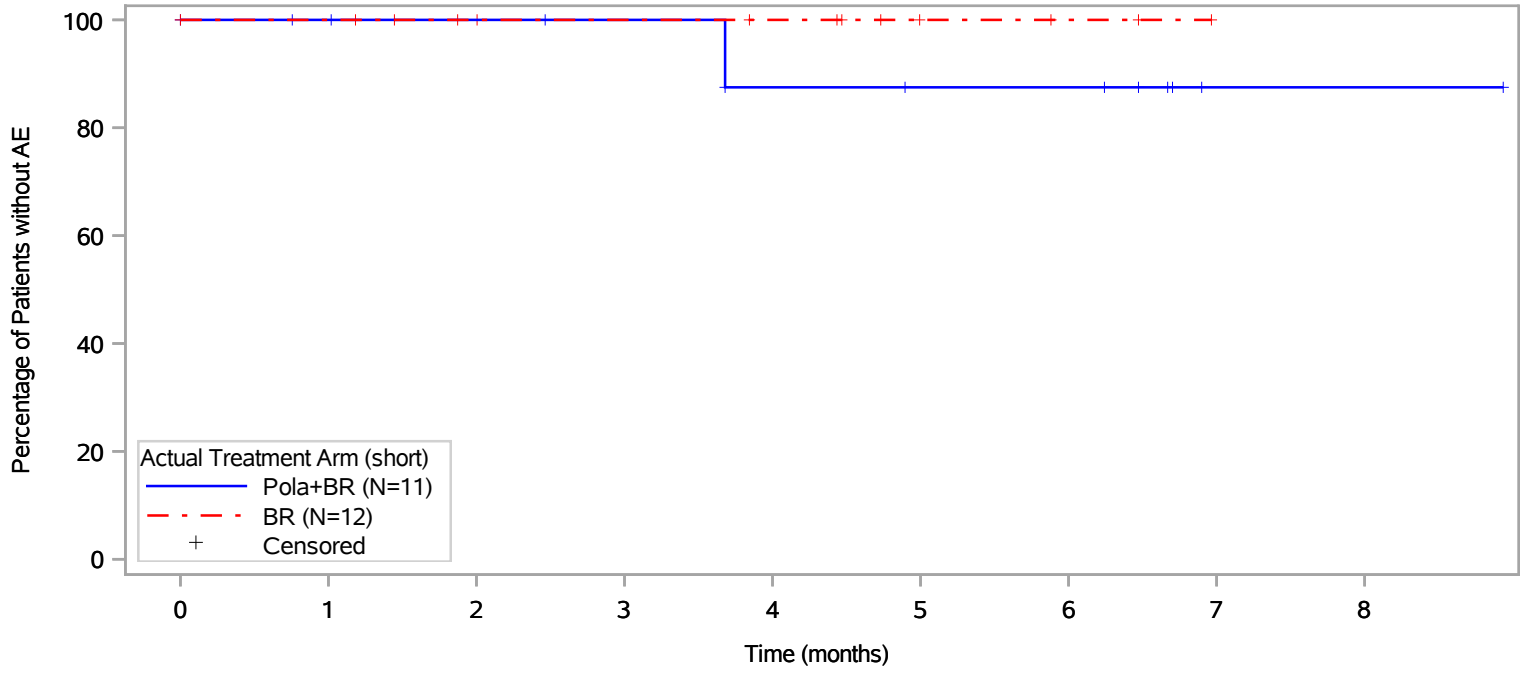


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED

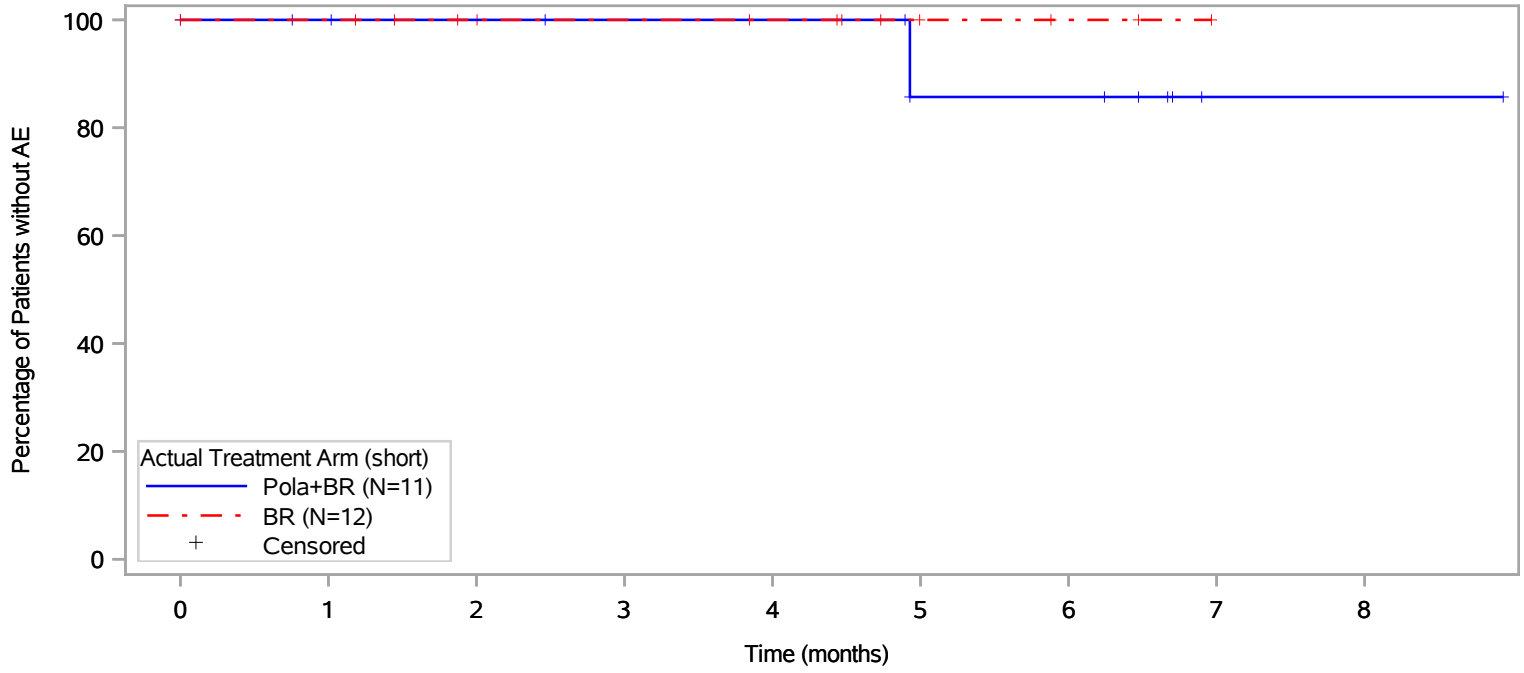


Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYTOMEGALOVIRUS TEST POSITIVE

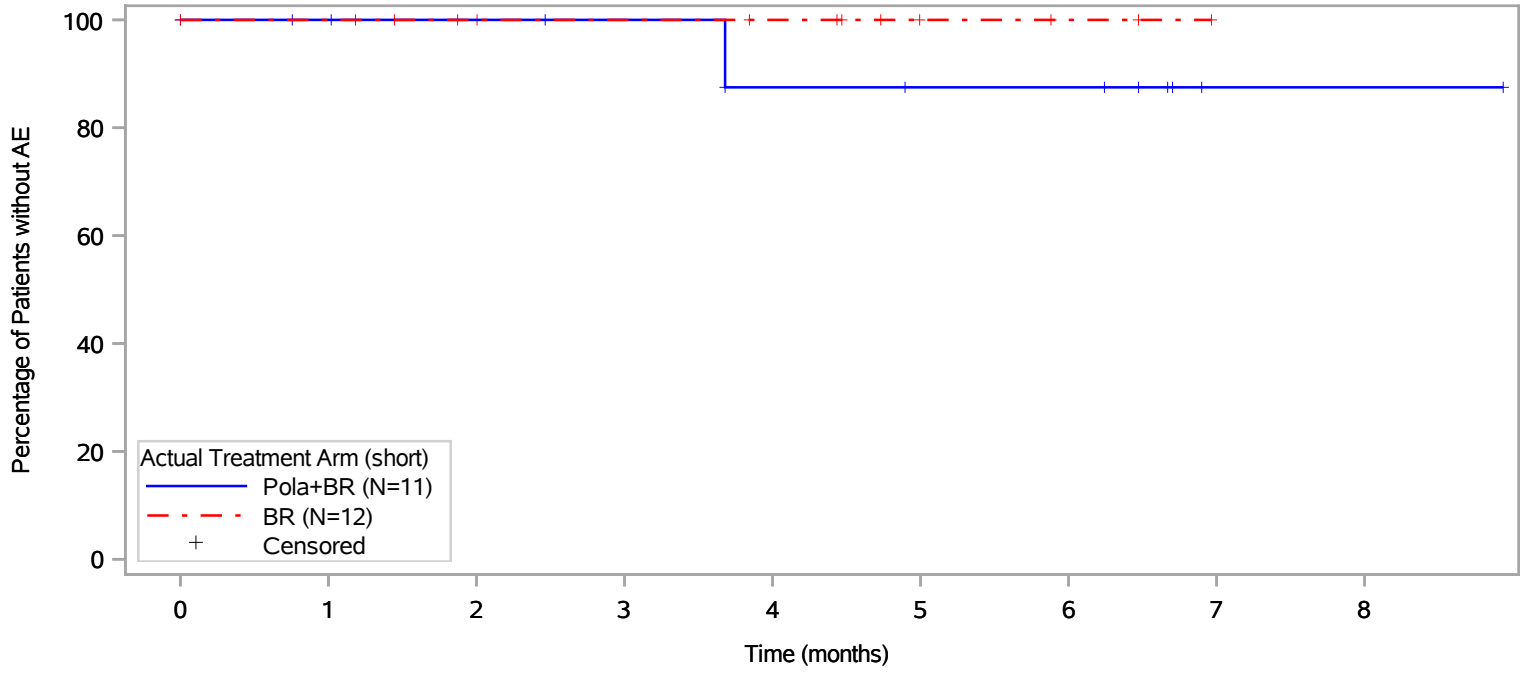


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LIPASE INCREASED

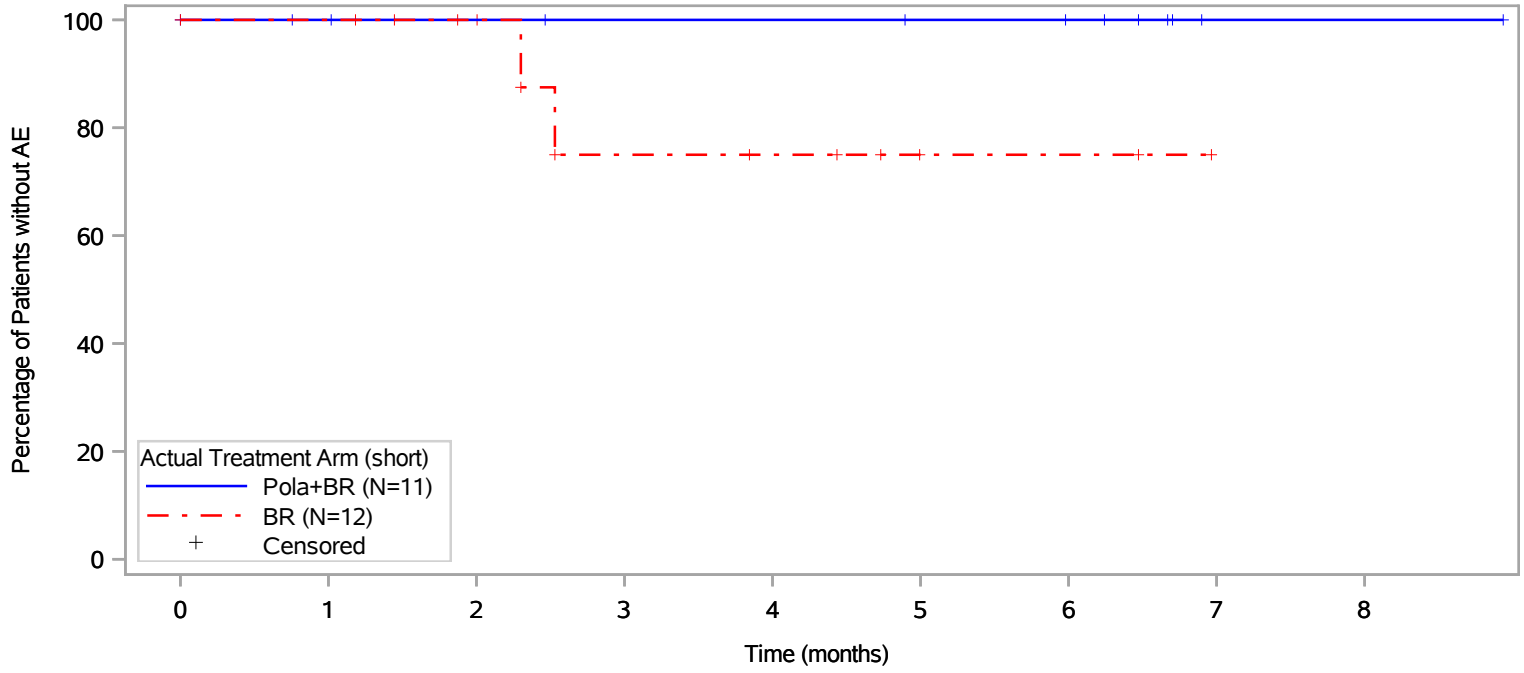


Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED

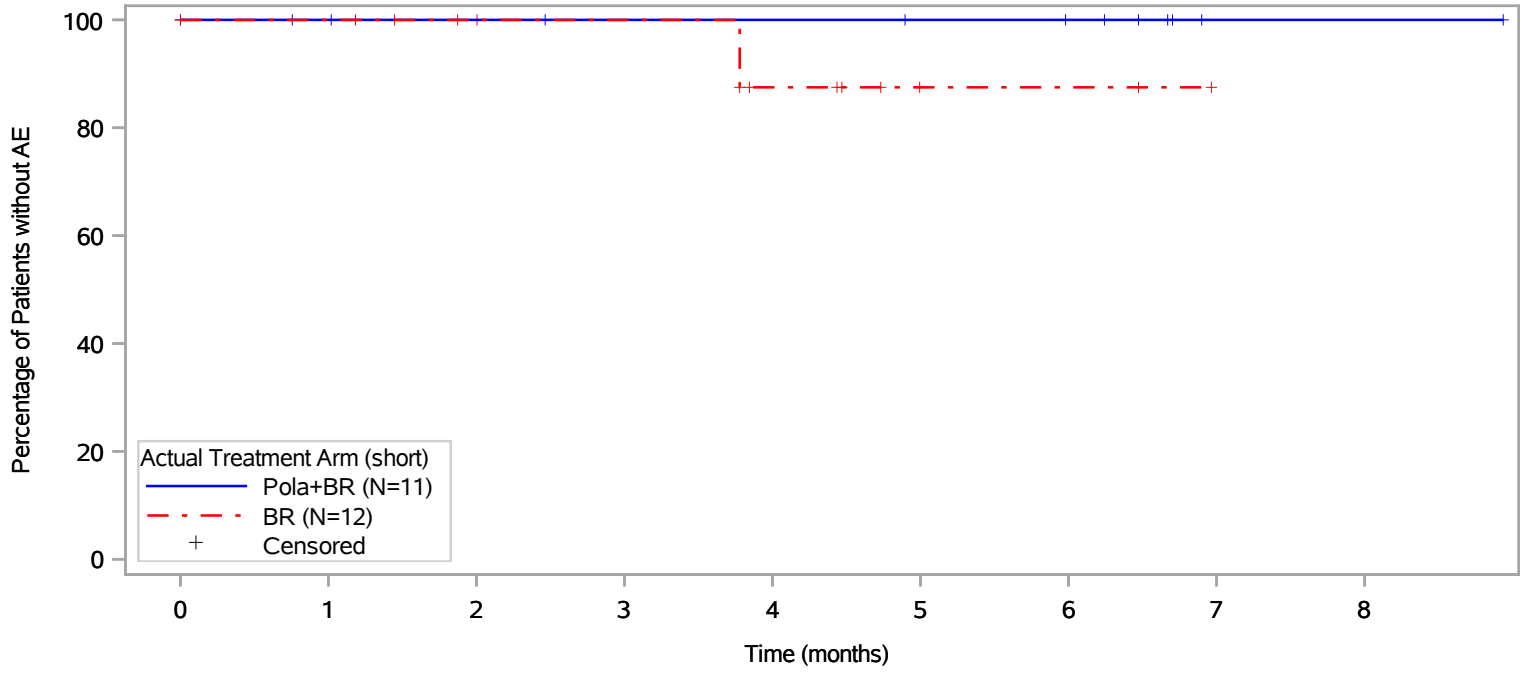


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	6	5	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

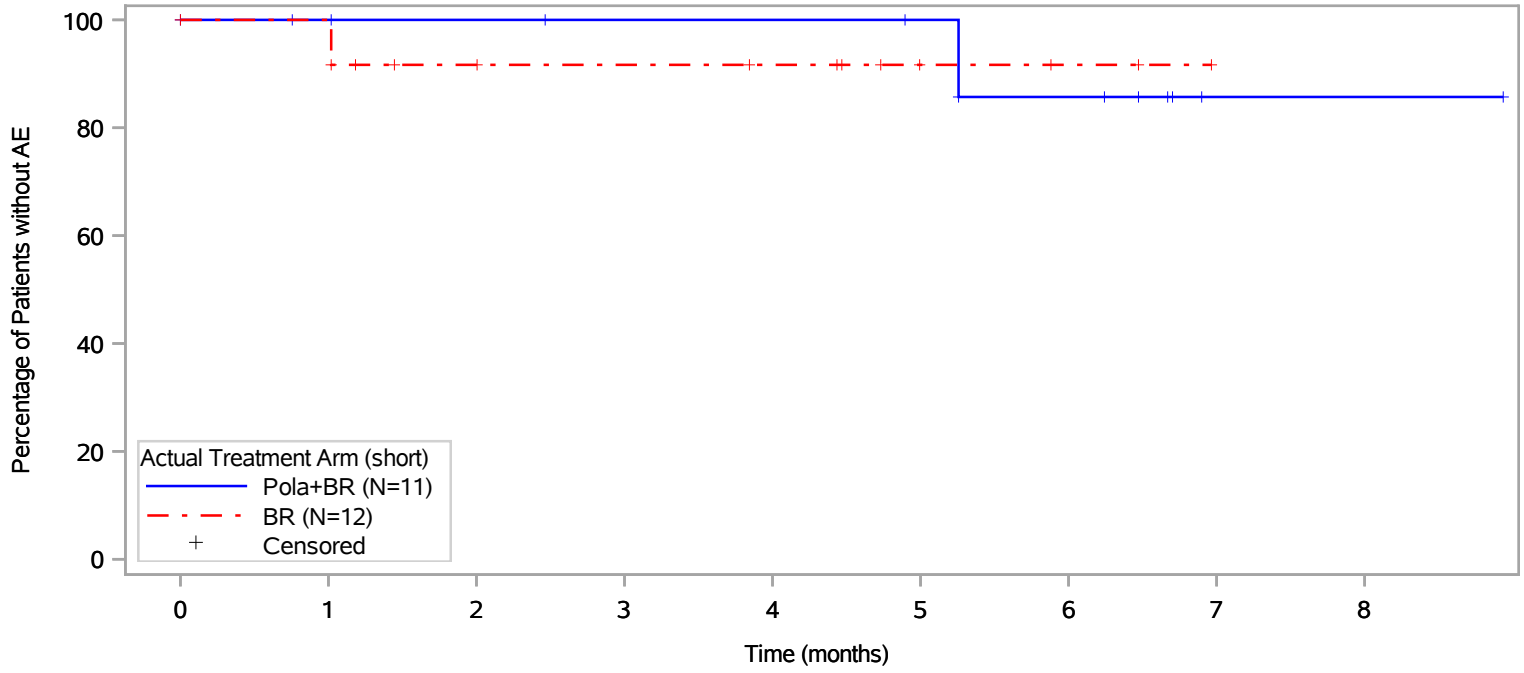


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

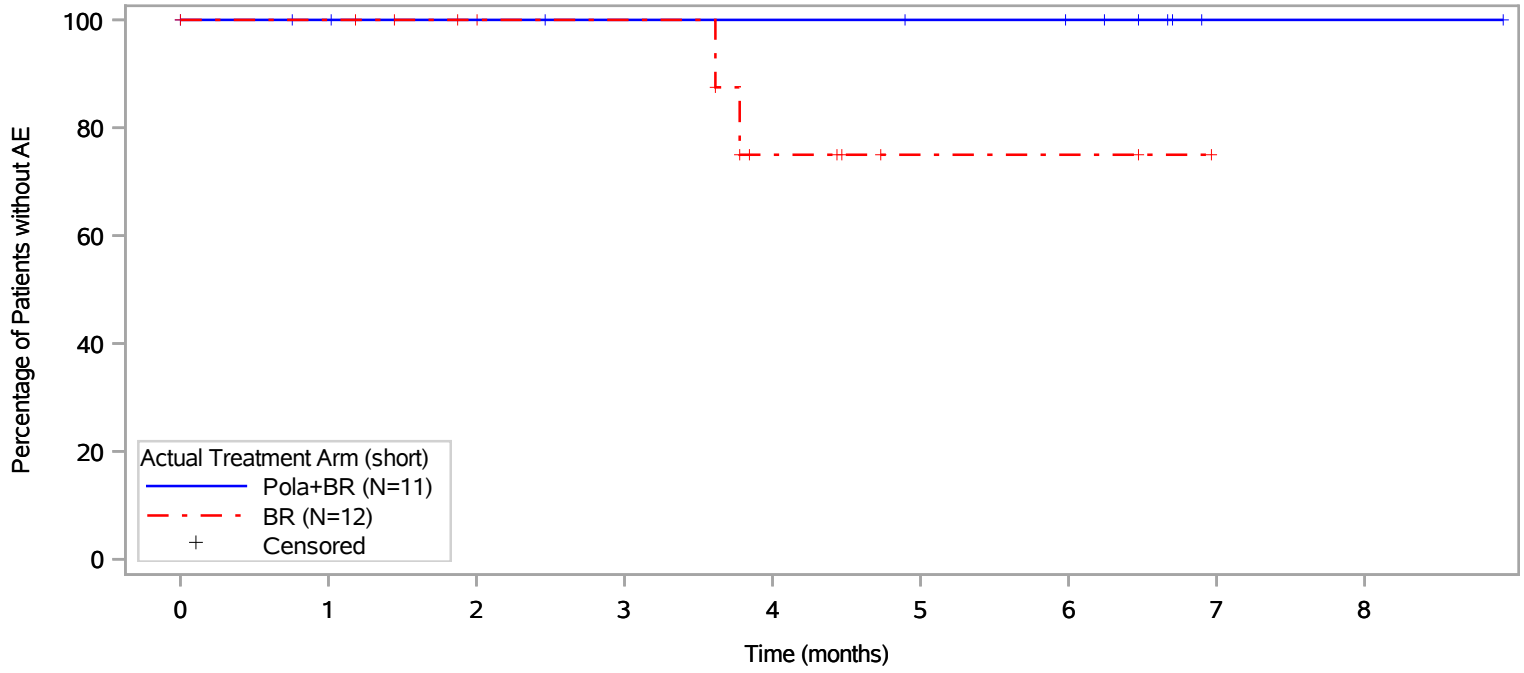
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED

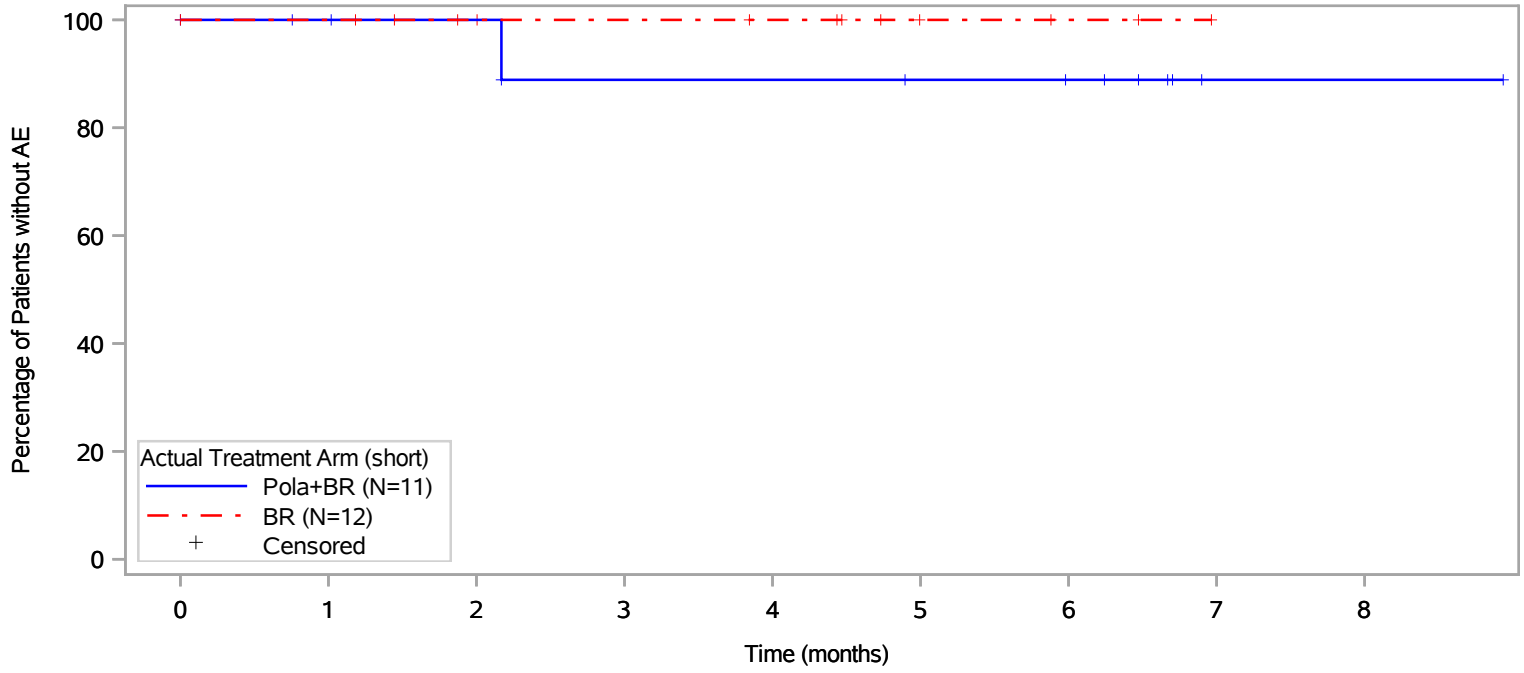


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	5	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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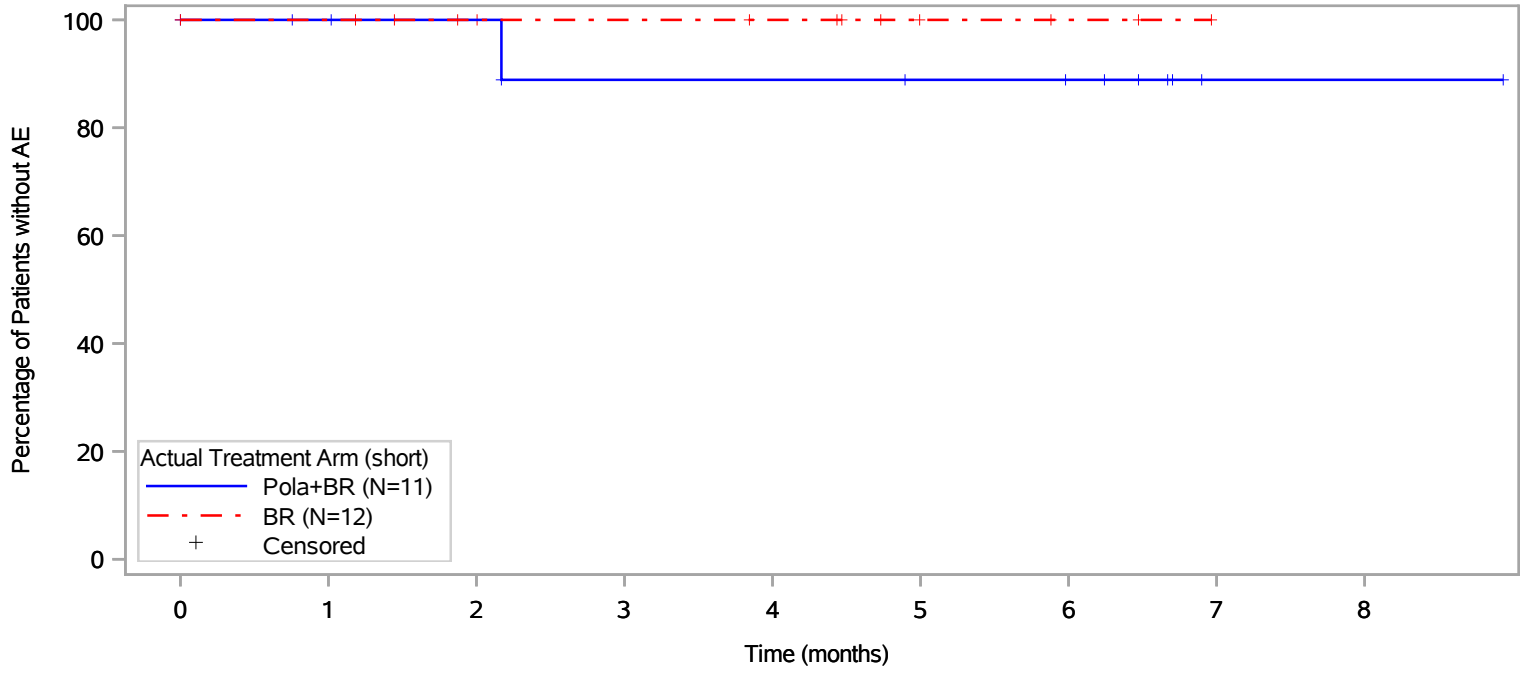
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE

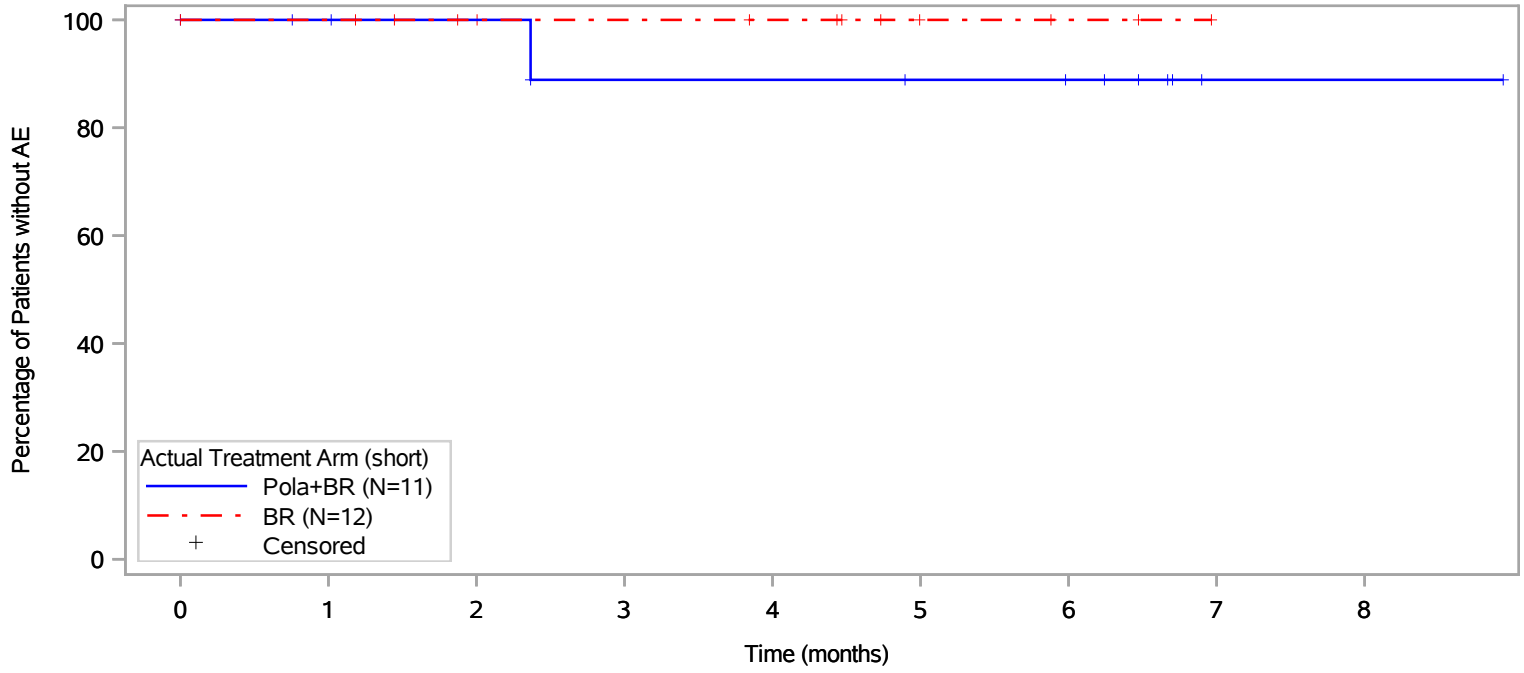


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA

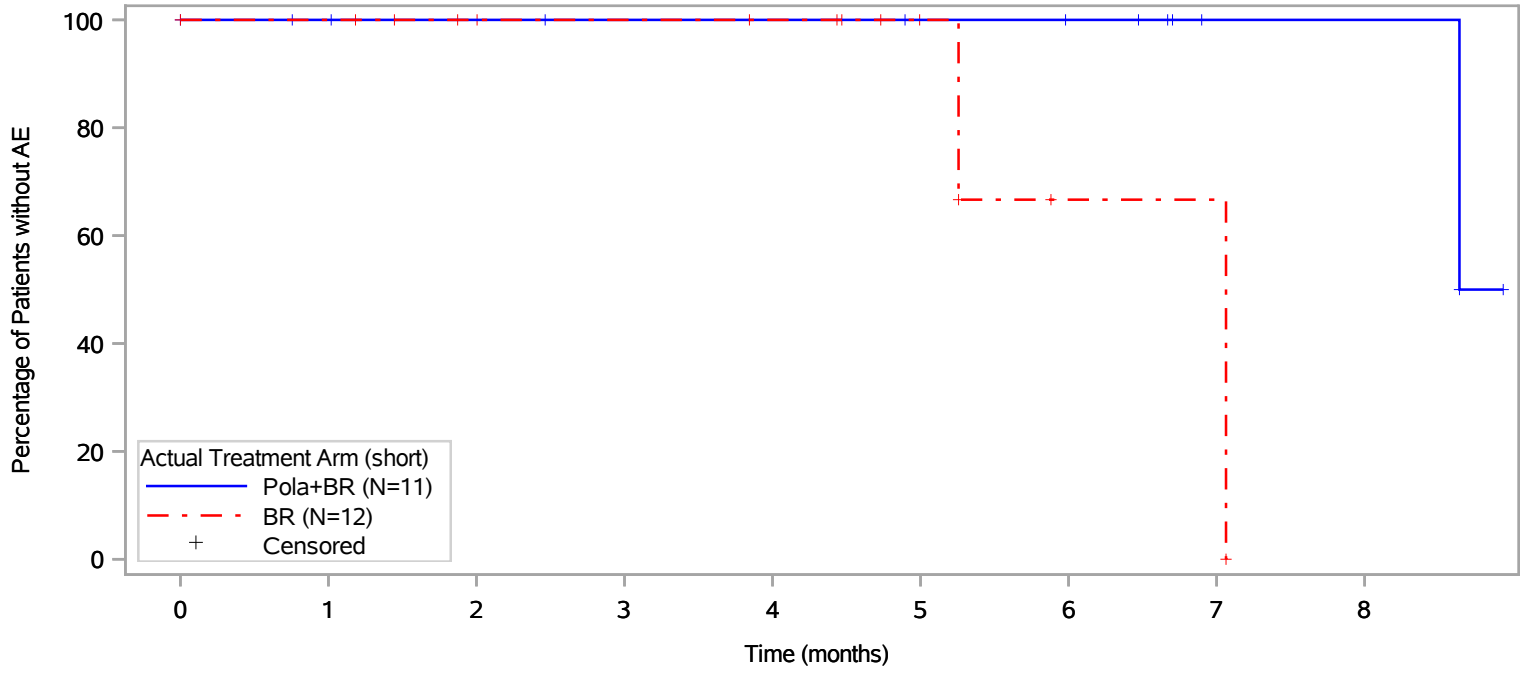


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2
BR (N=12)	12	12	9	8	7	3	1	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	10	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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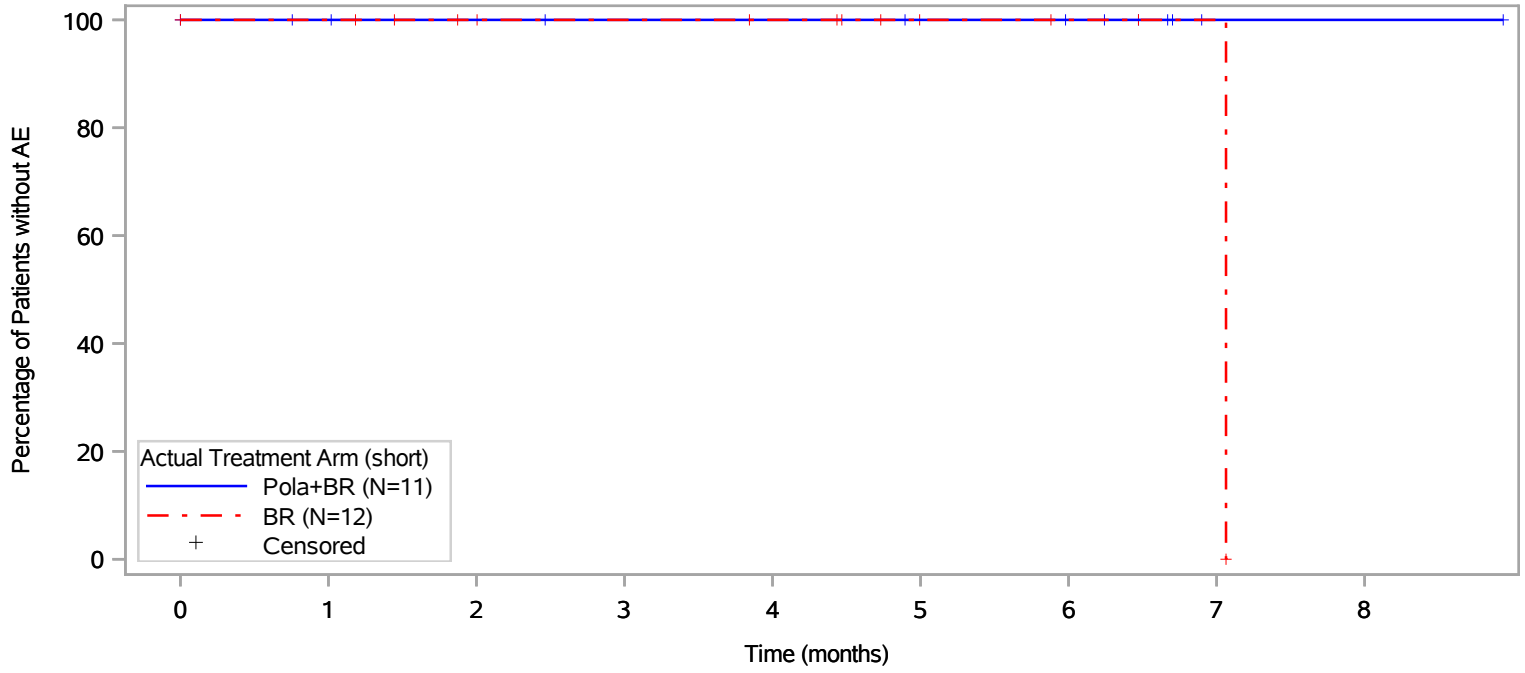
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), EPIGLOTTIC CANCER



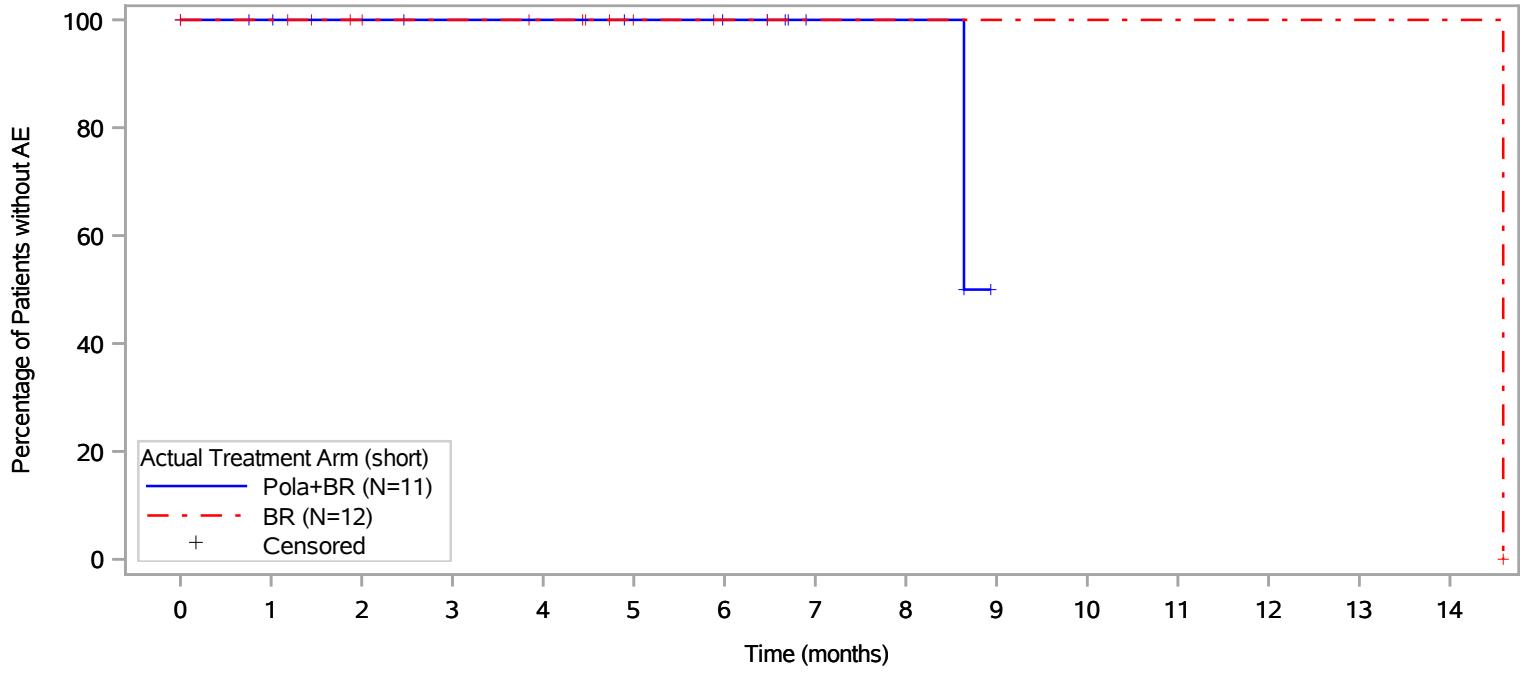
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



Patients at risk															
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	NE	NE	NE	NE	NE	NE
BR (N=12)	12	12	9	8	7	3	2	1	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	NE	NE	NE	NE	NE	NE
BR (N=12)	0	0	3	4	5	9	10	11	11	11	11	11	11	11	11

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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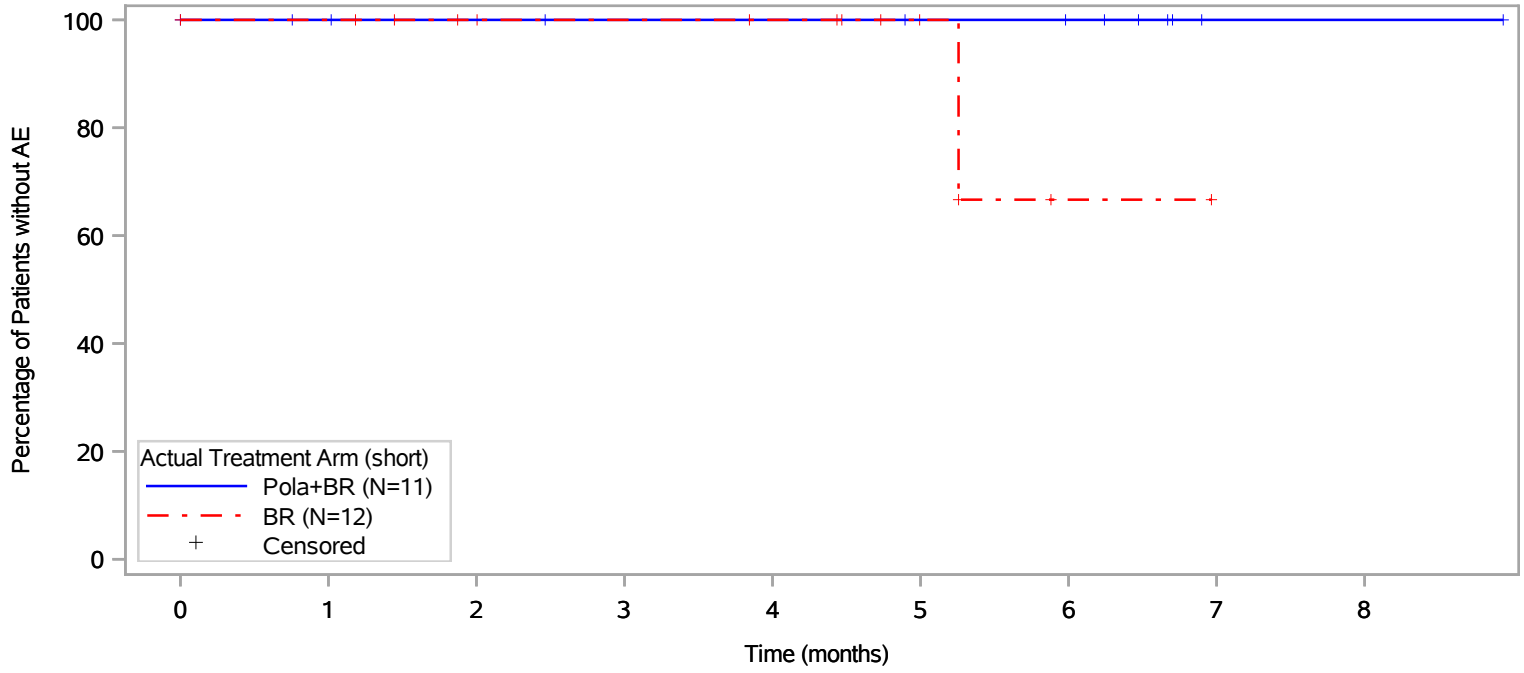
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), PAPILLARY THYROID CANCER



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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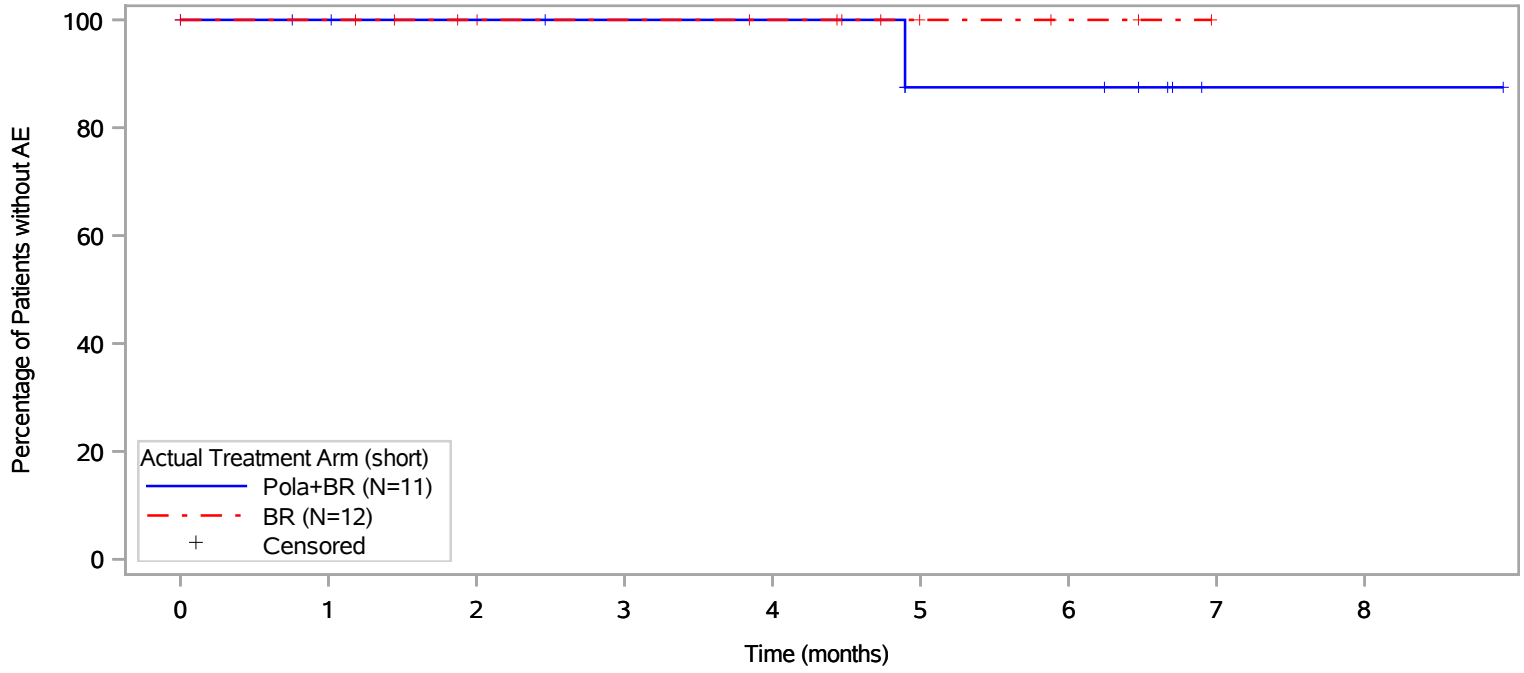
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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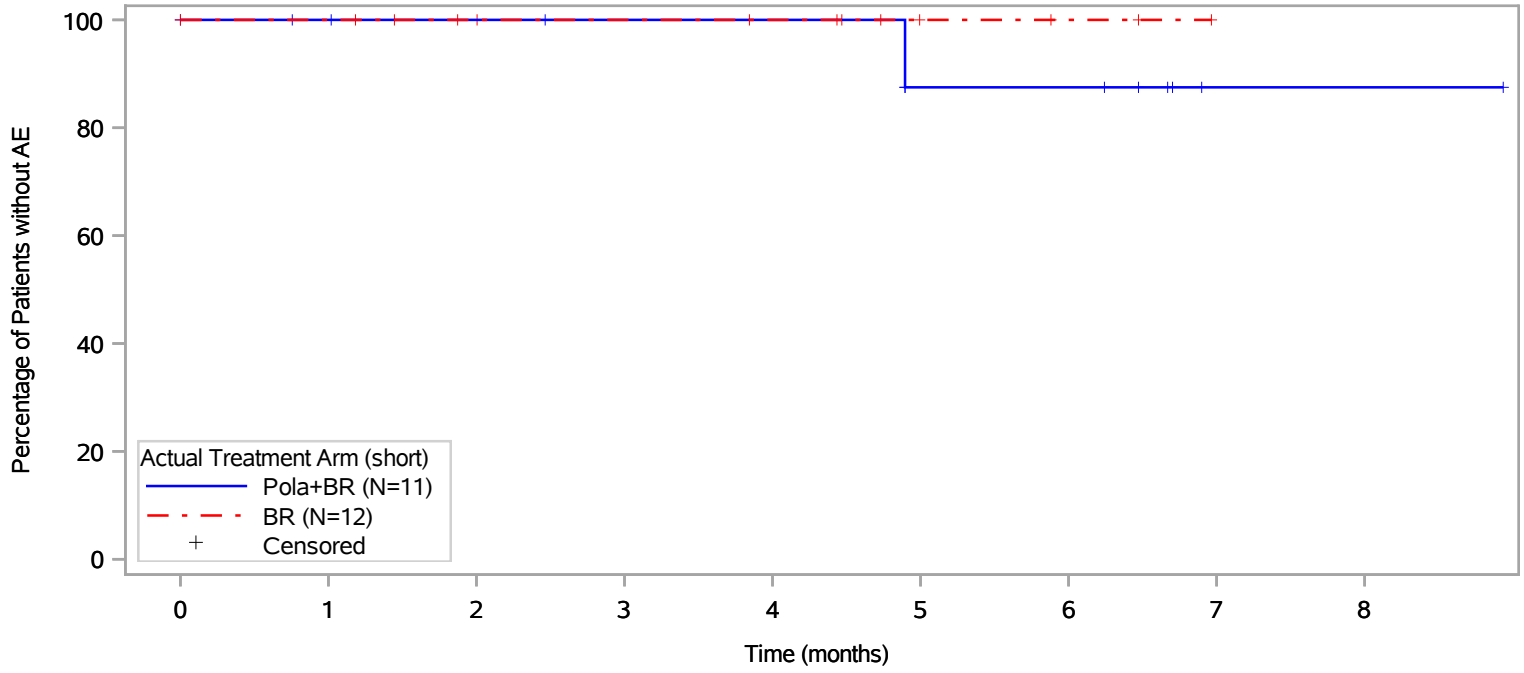
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, VOCAL CORD PARALYSIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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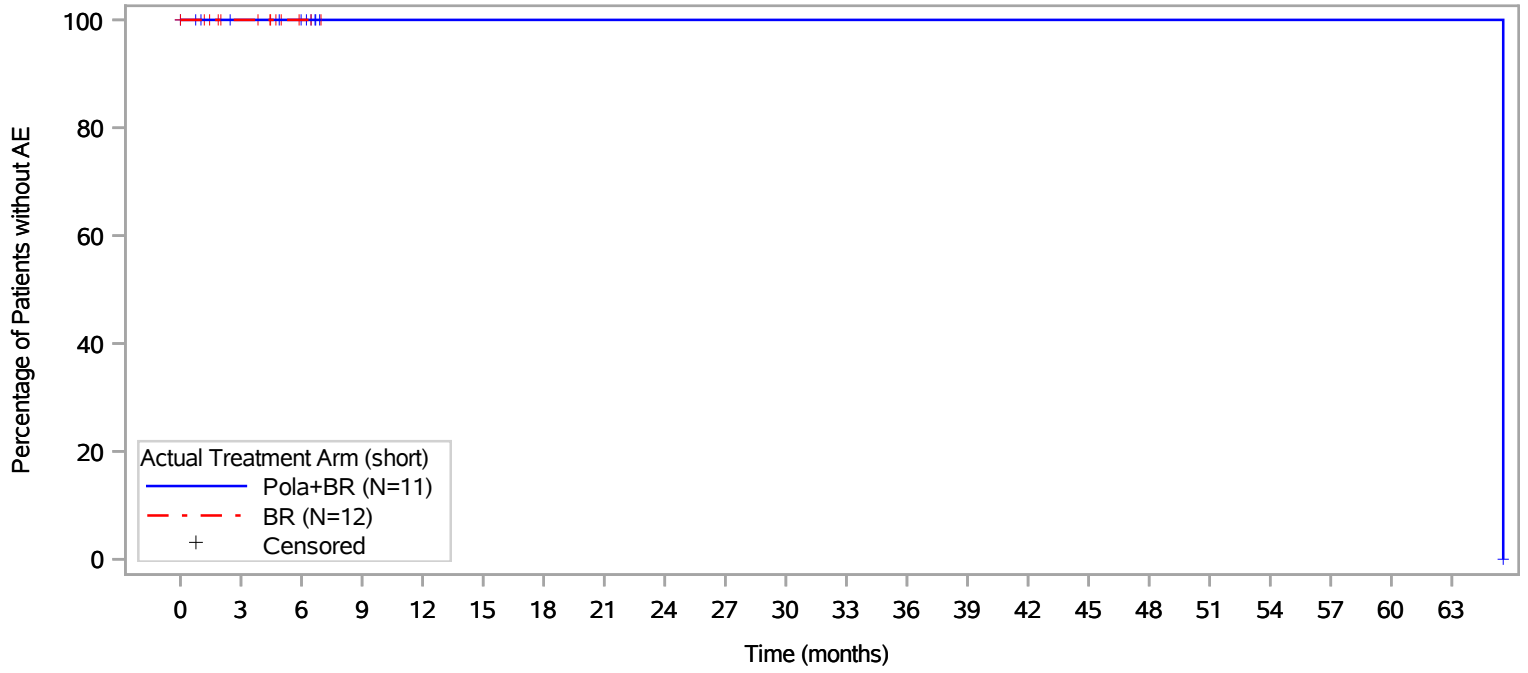
02DEC2022 1:40

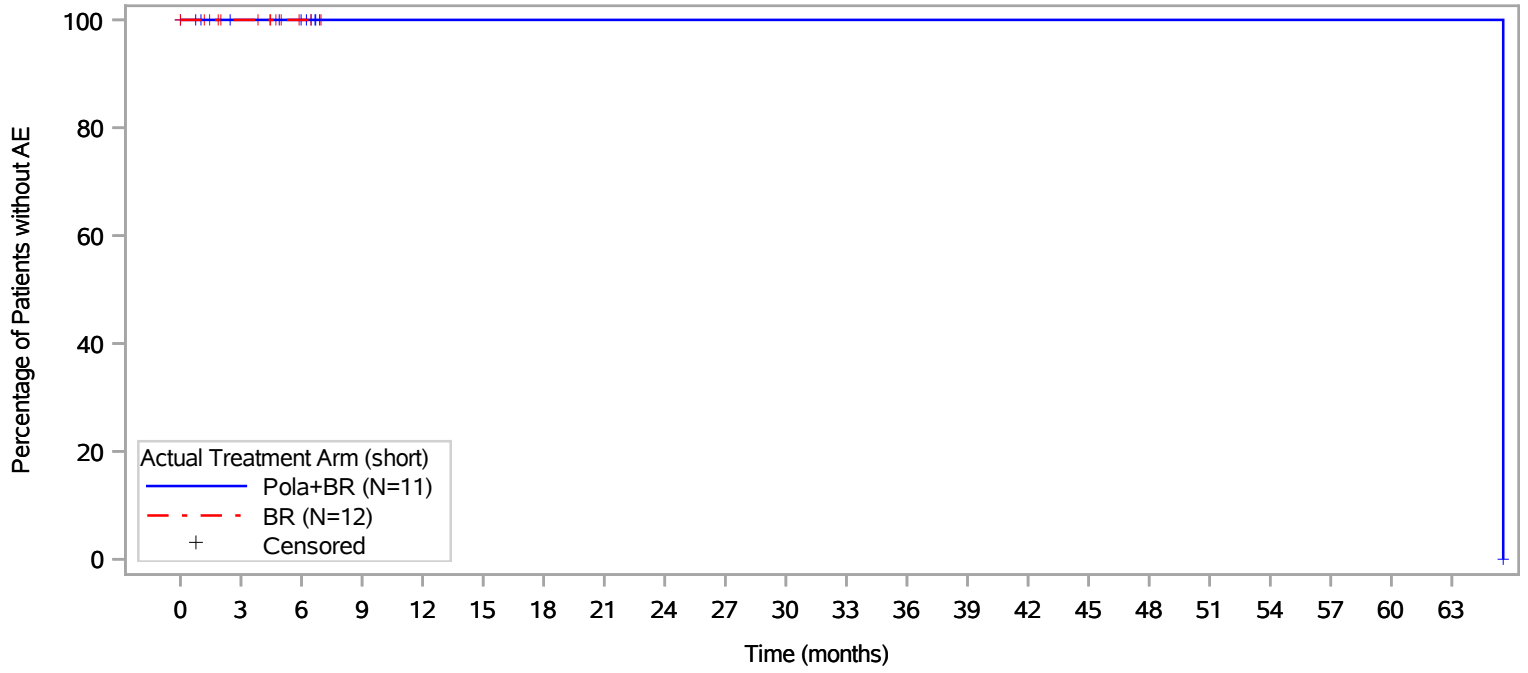
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk																							
Pola+BR (N=11)	11	8	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=12)	12	8	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=11)	0	3	5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BR (N=12)	0	4	10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk																							
Pola+BR (N=11)	11	8	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=12)	12	8	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=11)	0	3	5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BR (N=12)	0	4	10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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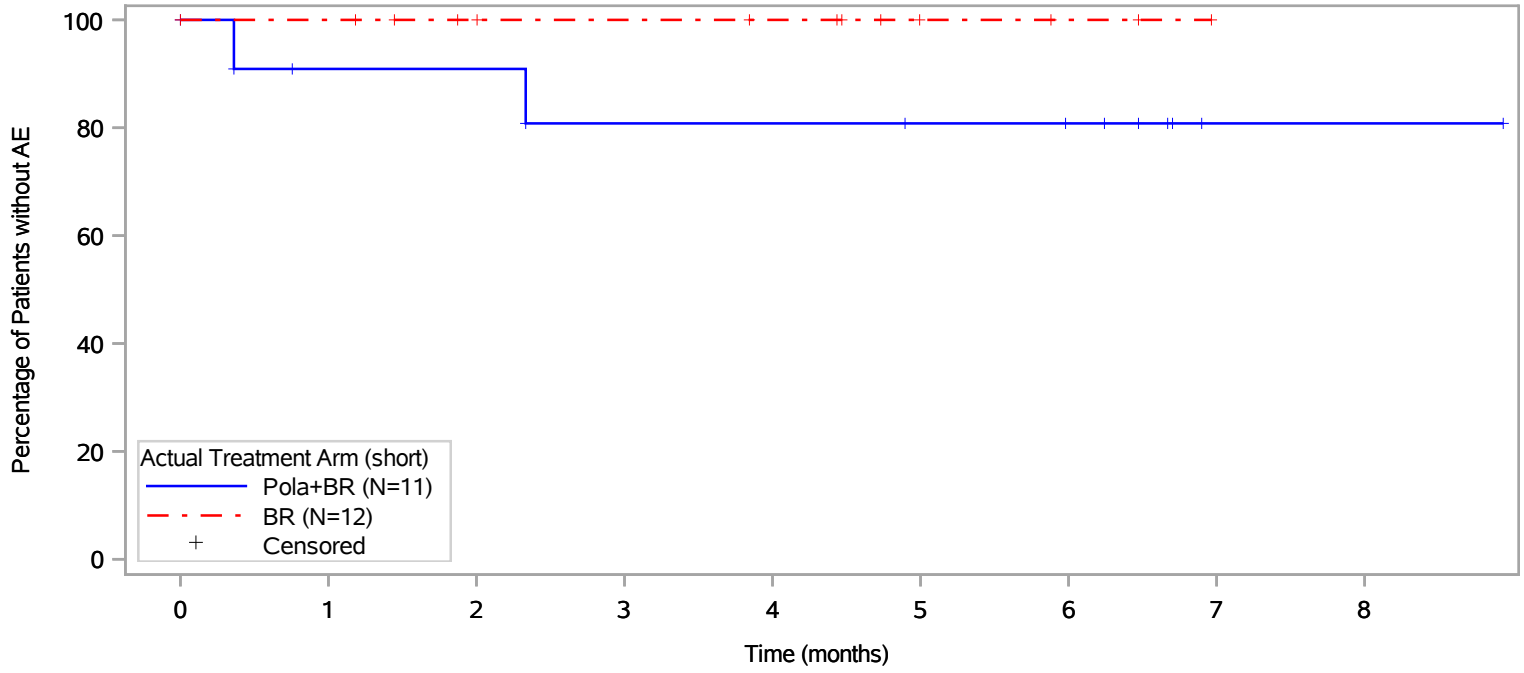
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	1	1	1	2	3	8	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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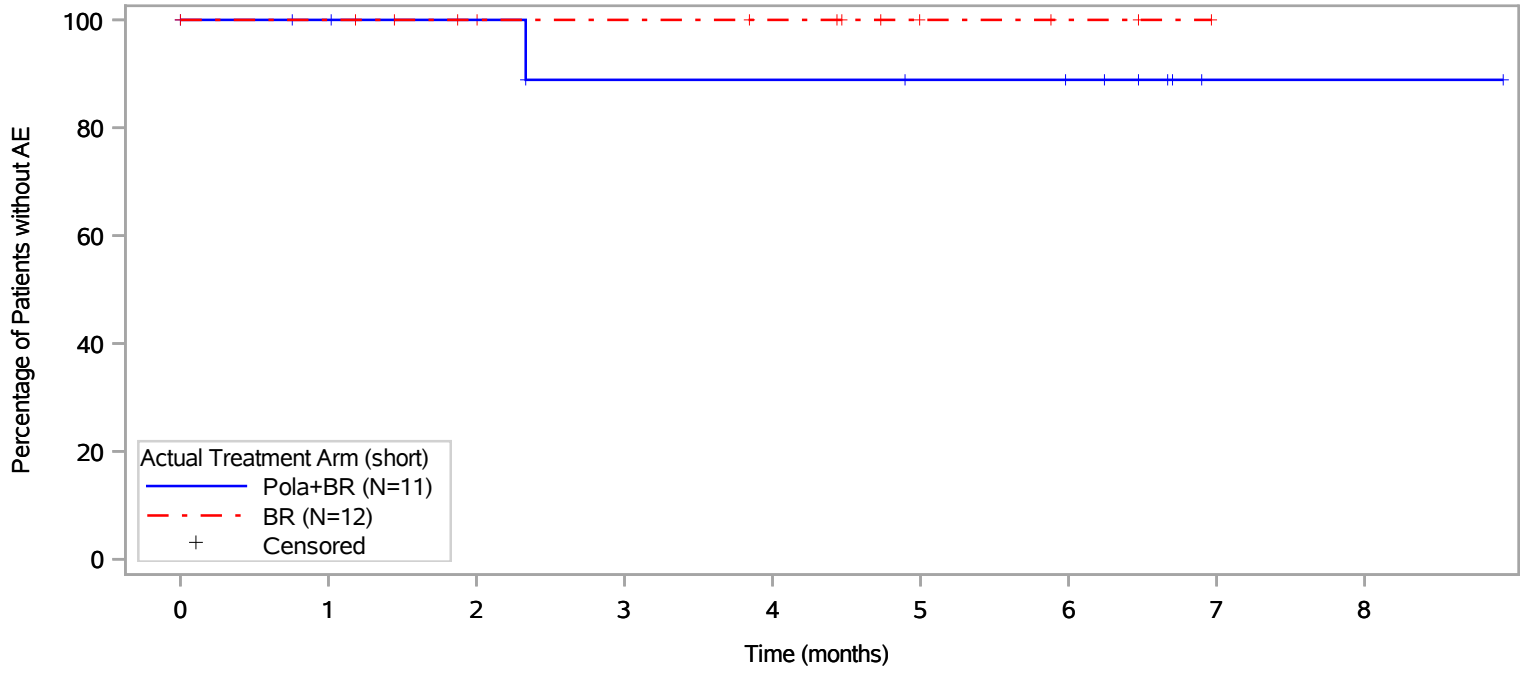
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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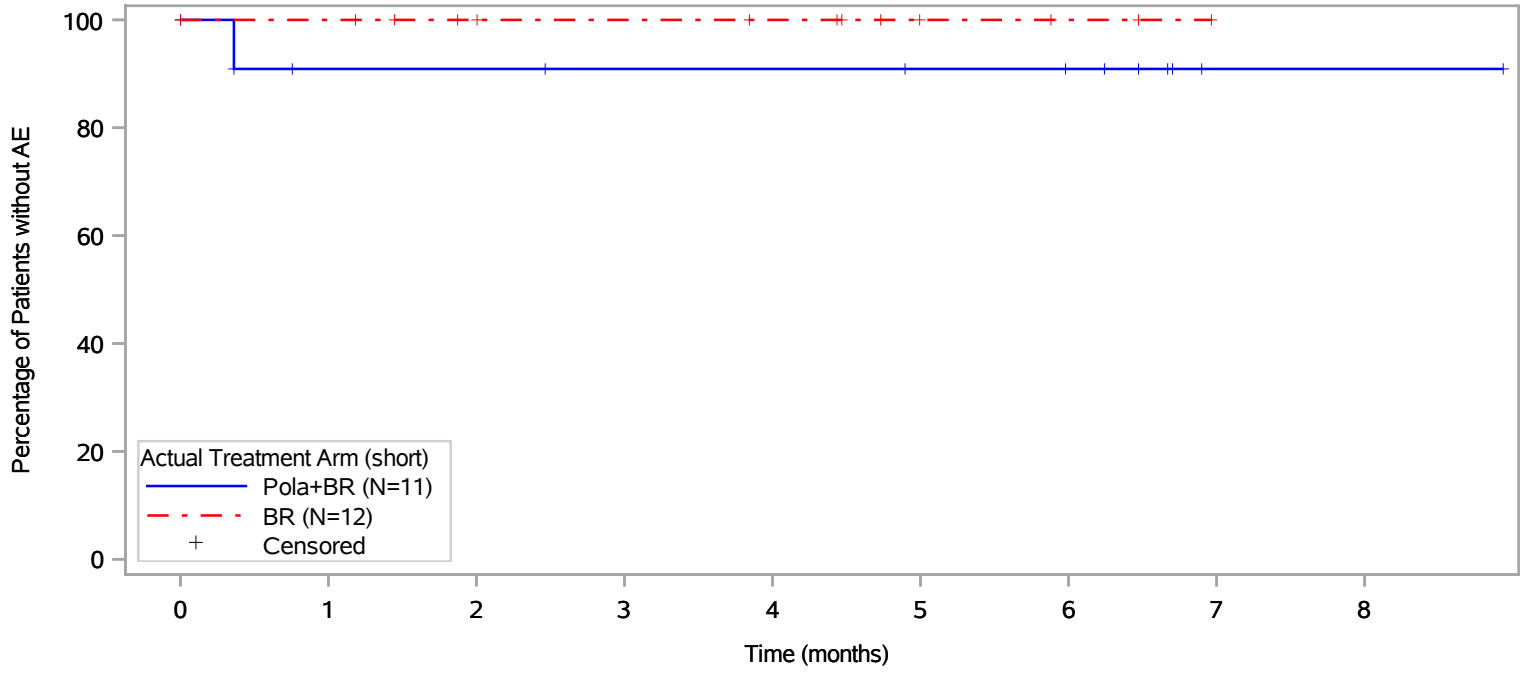
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

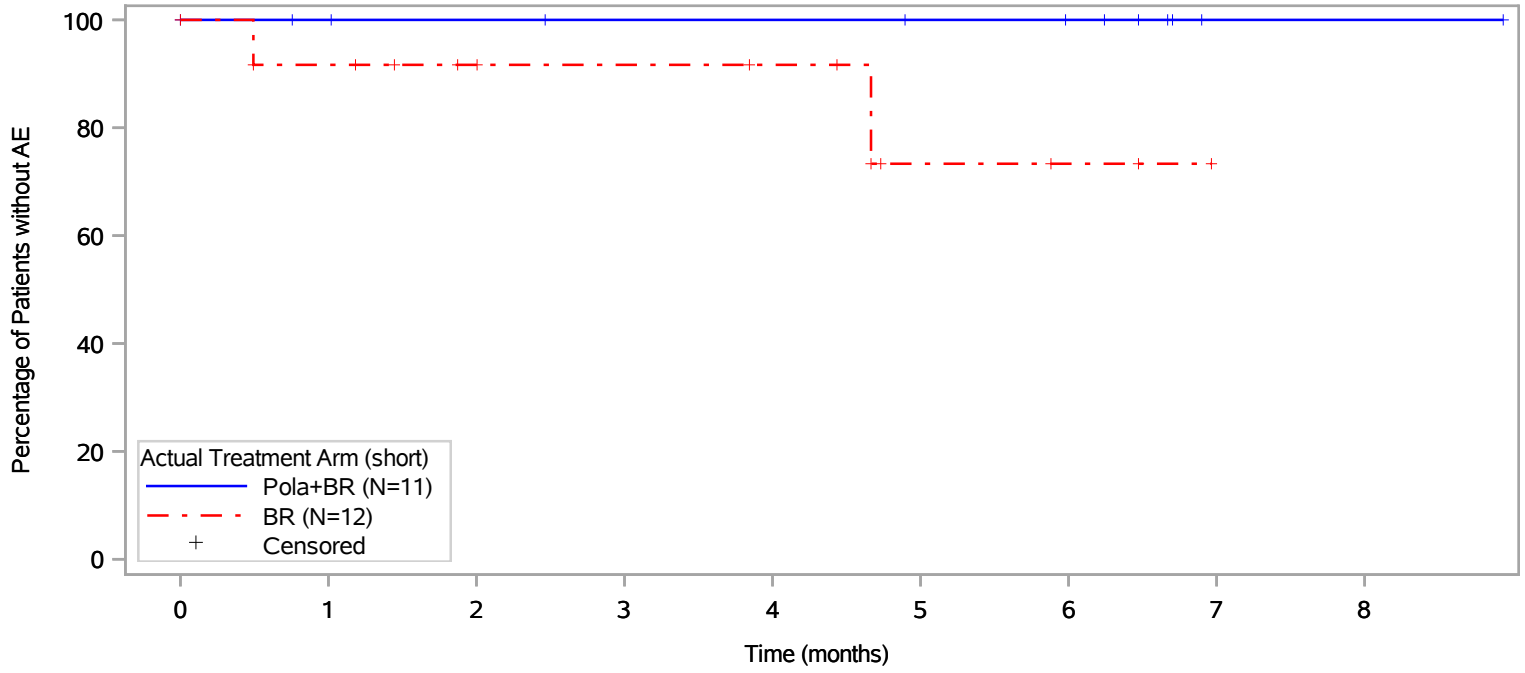
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY OEDEMA



Patients at risk								
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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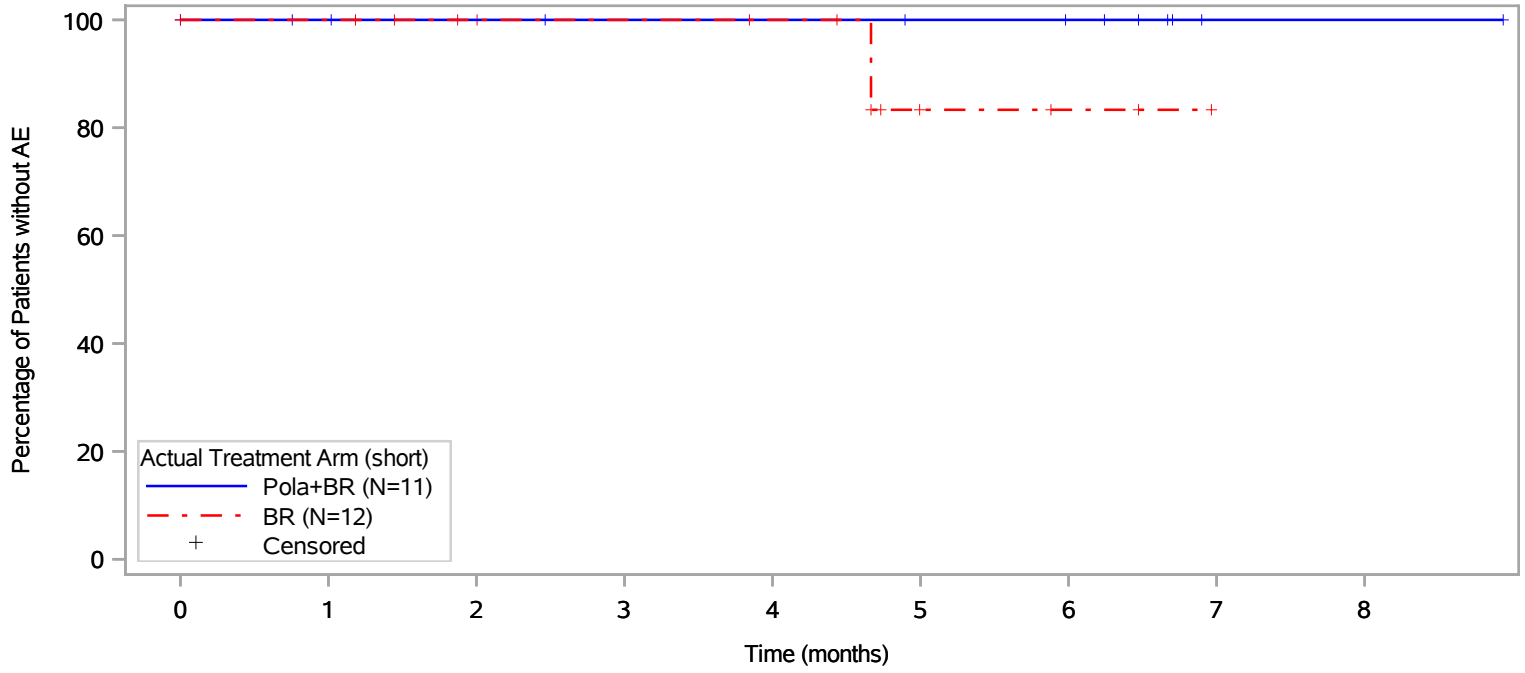
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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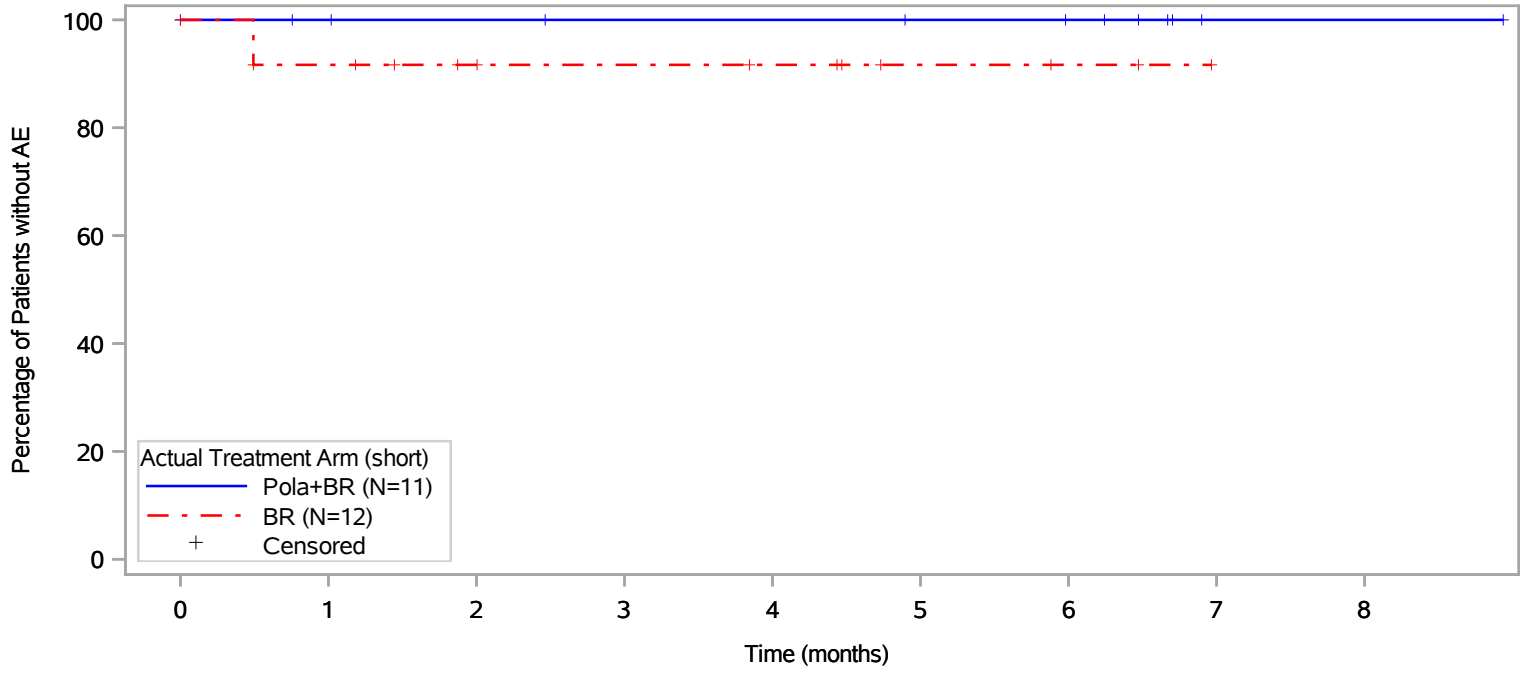
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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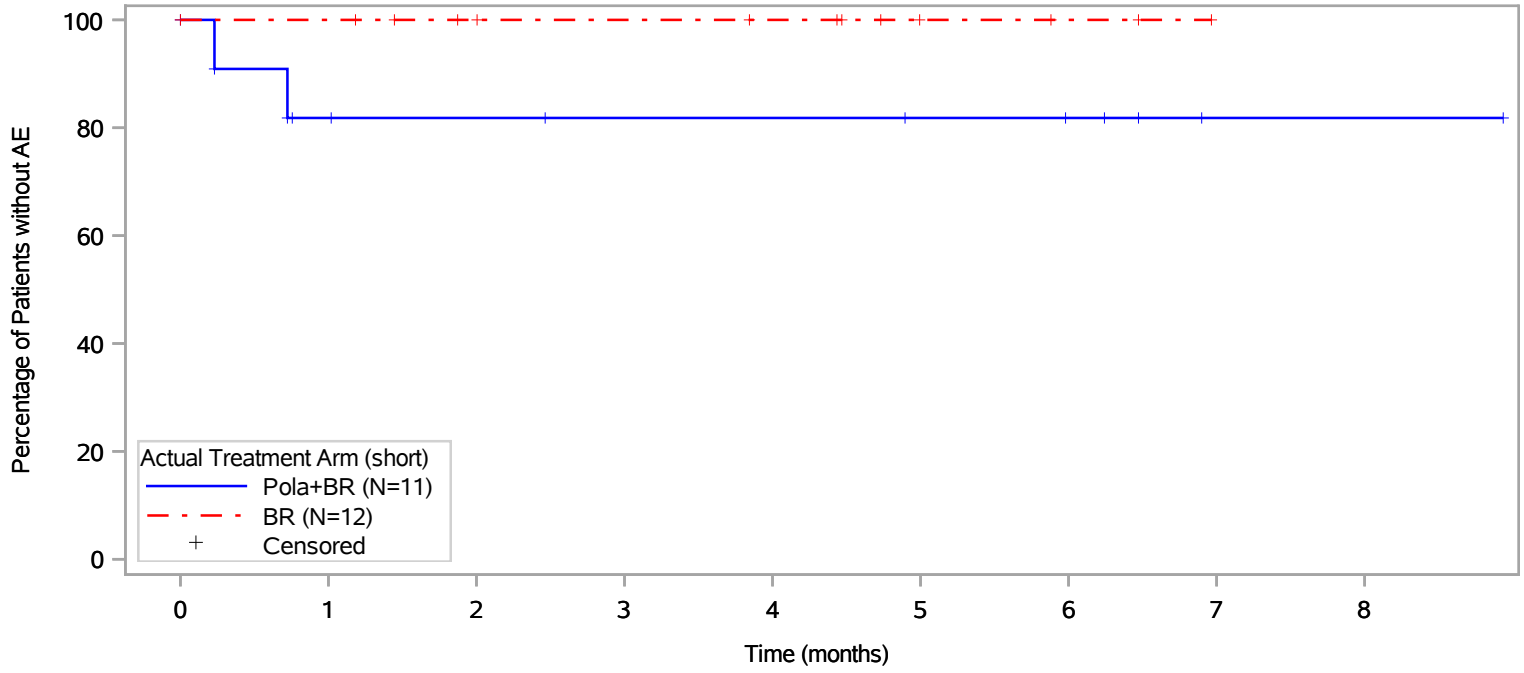
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All

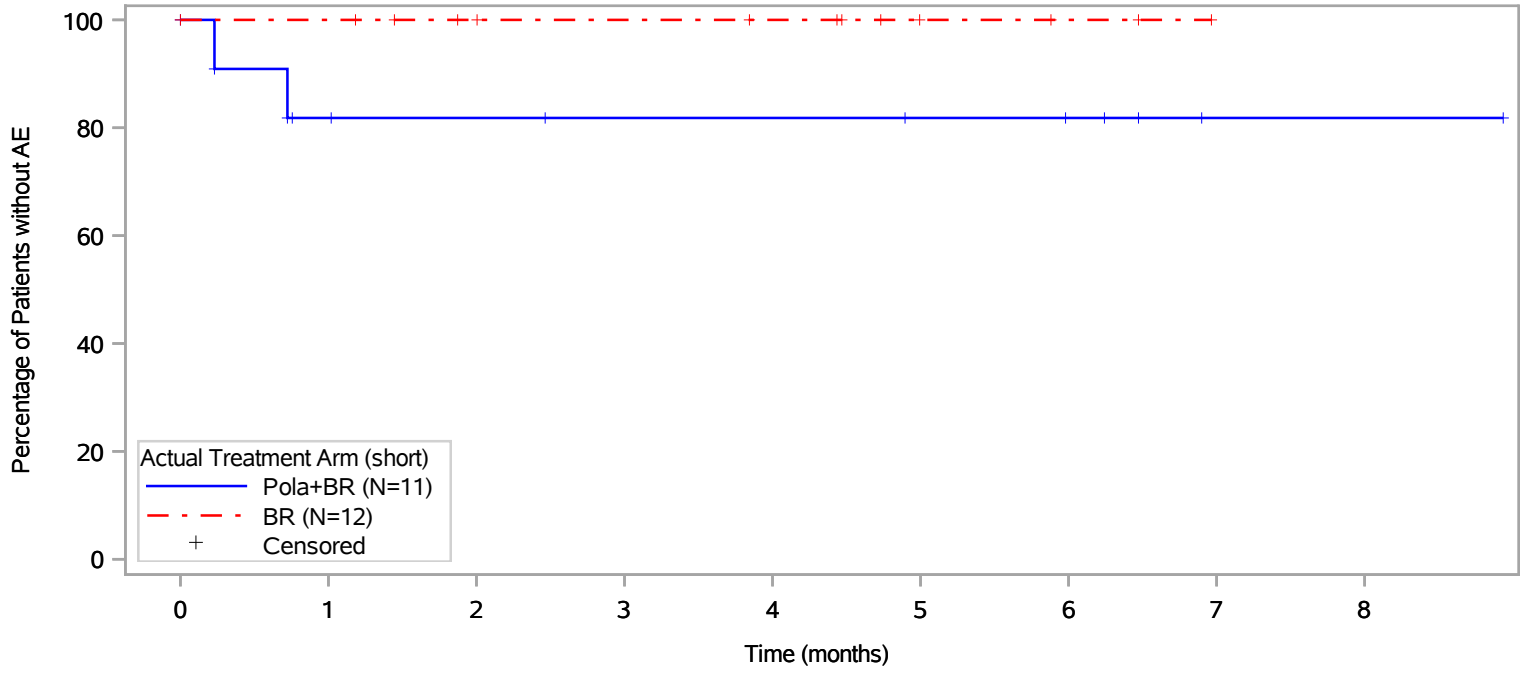


Patients at risk									
Pola+BR (N=11)	11	8	7	6	6	5	4	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	8	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION



Patients at risk								
Pola+BR (N=11)	11	8	7	6	6	5	4	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	8	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 1:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			11	100.0	6	54.5	5	45.5	12	100.0	5	41.7	7	58.3	0.5322	1.47	0.44	4.92		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		11	100.0	4	36.4	7	63.6	12	100.0	1	8.3	11	91.7	0.1517	4.34	0.48	38.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		11	100.0	4	36.4	7	63.6	12	100.0	3	25.0	9	75.0	0.6416	1.43	0.32	6.45		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		11	100.0	2	18.2	9	81.8	12	100.0	1	8.3	11	91.7	0.5724	1.97	0.18	21.79		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			11	100.0	1	9.1	10	90.9	12	100.0	2	16.7	10	83.3	0.4014	0.36	0.03	4.26		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INVESTIGATIONS			11	100.0	1	9.1	10	90.9	12	100.0	3	25.0	9	75.0	0.2772	0.31	0.03	2.95		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LIPASE INCREASED		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.8194	0.72	0.04	12.57		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.0768	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.1303	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.1303	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR3AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 23:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	8	72.7	5	62.5	3	37.5	12	100.0	5	41.7	7	58.3	0.3706	1.76	0.50	6.20		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	1	8.3	11	91.7	0.1630	4.37	0.45	42.05		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	3	25.0	9	75.0	0.3634	1.99	0.44	9.00		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	1	8.3	11	91.7	0.4071	2.66	0.24	29.39		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS		>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.1937	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	
INVESTIGATIONS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS		>= 65	8	72.7	0	-	8	100.0	12	100.0	3	25.0	9	75.0	0.1320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	LIPASE INCREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	WEIGHT DECREASED	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	WEIGHT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4450	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
METABOLISM AND NUTRITION DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.1060	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NERVOUS SYSTEM DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RENAL AND URINARY DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
RENAL AND URINARY DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
VASCULAR DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
VASCULAR DISORDERS		>= 65	8	72.7	2	25.0	6	75.0	12	100.0	0	-	12	100.0	0.0732	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
VASCULAR DISORDERS	HYPERTENSION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE
VASCULAR DISORDERS	HYPERTENSION	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	0	-	12	100.0	0.0732	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR3AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 23:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	6	54.5	5	83.3	1	16.7	10	83.3	4	40.0	6	60.0	0.0975	3.05	0.77	12.00		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.5596	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	6	54.5	3	50.0	3	50.0	10	83.3	1	10.0	9	90.0	0.1160	5.11	0.53	49.25		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	6	54.5	3	50.0	3	50.0	10	83.3	3	30.0	7	70.0	0.3933	2.01	0.39	10.30		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	6	54.5	2	33.3	4	66.7	10	83.3	1	10.0	9	90.0	0.2701	3.55	0.32	39.19		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS		<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2945	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	45.5	1	20.0	4	80.0	2	16.7	1	50.0	1	50.0	0.3497	0.28	0.02	4.71		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR3AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 23:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	45.5	3	60.0	2	40.0	3	25.0	2	66.7	1	33.3	0.9656	0.96	0.16	5.90		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	3	33.3	6	66.7	0.5829	1.57	0.31	7.95		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	0	-	3	100.0	0.2087	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	1	11.1	8	88.9	0.4451	2.48	0.22	27.52		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	45.5	2	40.0	3	60.0	3	25.0	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	1	11.1	8	88.9	0.3399	3.04	0.27	33.67		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.9372	1.12	0.07	17.96		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	2	22.2	7	77.8	0.4904	0.43	0.04	5.01		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	
INVESTIGATIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	3	33.3	6	66.7	0.3553	0.36	0.04	3.48		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	1.0000	1.00	0.06	16.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.1803	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR3AE_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 23:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	63.6	4	57.1	3	42.9	7	58.3	4	57.1	3	42.9	0.9994	1.00	0.24	4.20		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	4	36.4	2	50.0	2	50.0	5	41.7	1	20.0	4	80.0	0.2797	3.51	0.31	39.60		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	1	14.3	6	85.7	0.7087	1.58	0.14	17.60		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	4	36.4	2	50.0	2	50.0	5	41.7	0	-	5	100.0	0.1081	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	2	28.6	5	71.4	0.9863	1.02	0.14	7.25		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	4	36.4	2	50.0	2	50.0	5	41.7	1	20.0	4	80.0	0.4261	2.57	0.23	28.71		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	1.0000	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	4	36.4	0	-	4	100.0	5	41.7	2	40.0	3	60.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173				*	WARNING: Iteration limit reached without convergence.	
INVESTIGATIONS		Male	7	63.6	1	14.3	6	85.7	7	58.3	2	28.6	5	71.4	0.5079	0.45	0.04	5.02		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PHOSPHORUS DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.7487	0.62	0.03	11.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	PAPILLARY THYROID CANCER	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	4	36.4	2	50.0	2	50.0	5	41.7	0	-	5	100.0	0.0888	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	4	36.4	2	50.0	2	50.0	5	41.7	0	-	5	100.0	0.0888	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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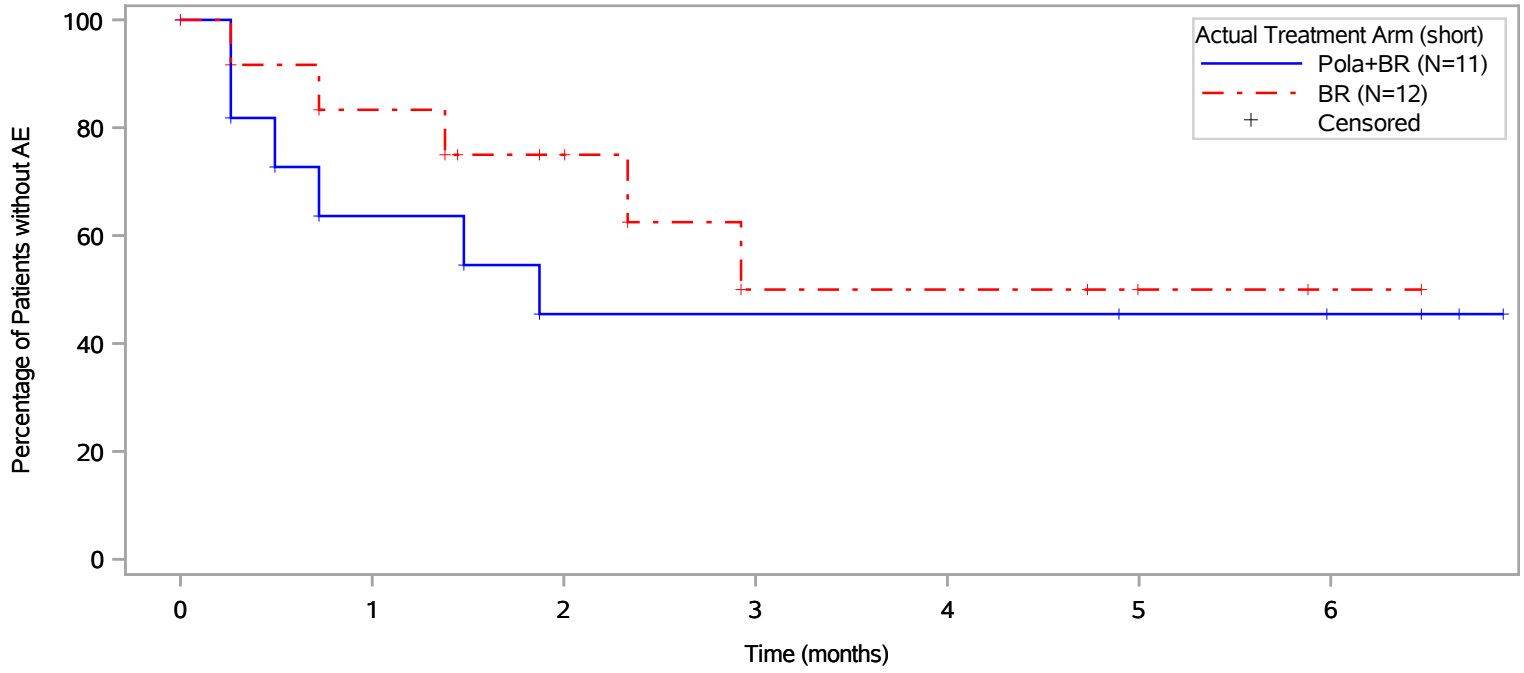
30NOV2022 23:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=11)	11	7	5	5	5	4	3
BR (N=12)	12	10	7	4	4	2	1
Patients censored							
Pola+BR (N=11)	0	0	0	0	0	1	2
BR (N=12)	0	0	2	3	3	5	6

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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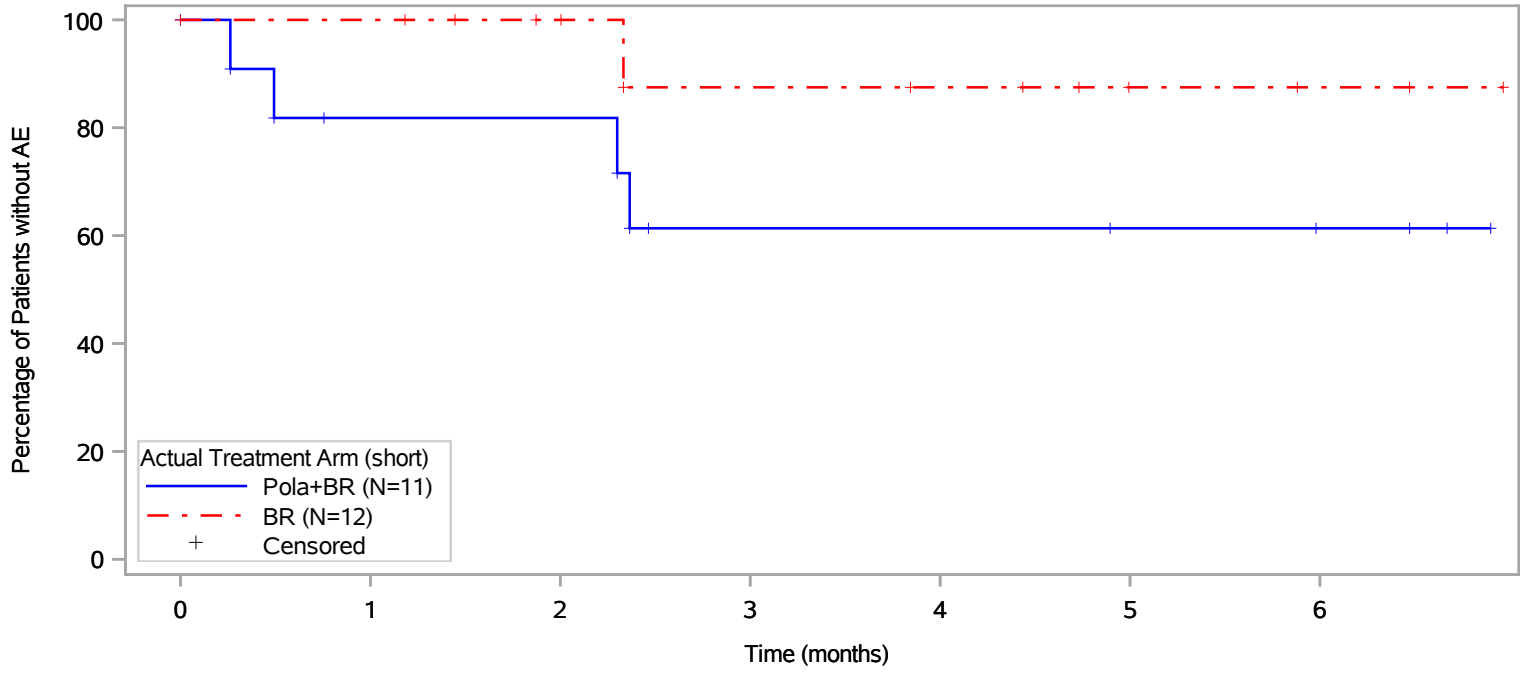
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk							
Pola+BR (N=11)	11	8	8	5	5	4	3
BR (N=12)	12	12	9	7	6	3	2
Patients censored							
Pola+BR (N=11)	0	1	1	2	2	3	4
BR (N=12)	0	0	3	4	5	8	9

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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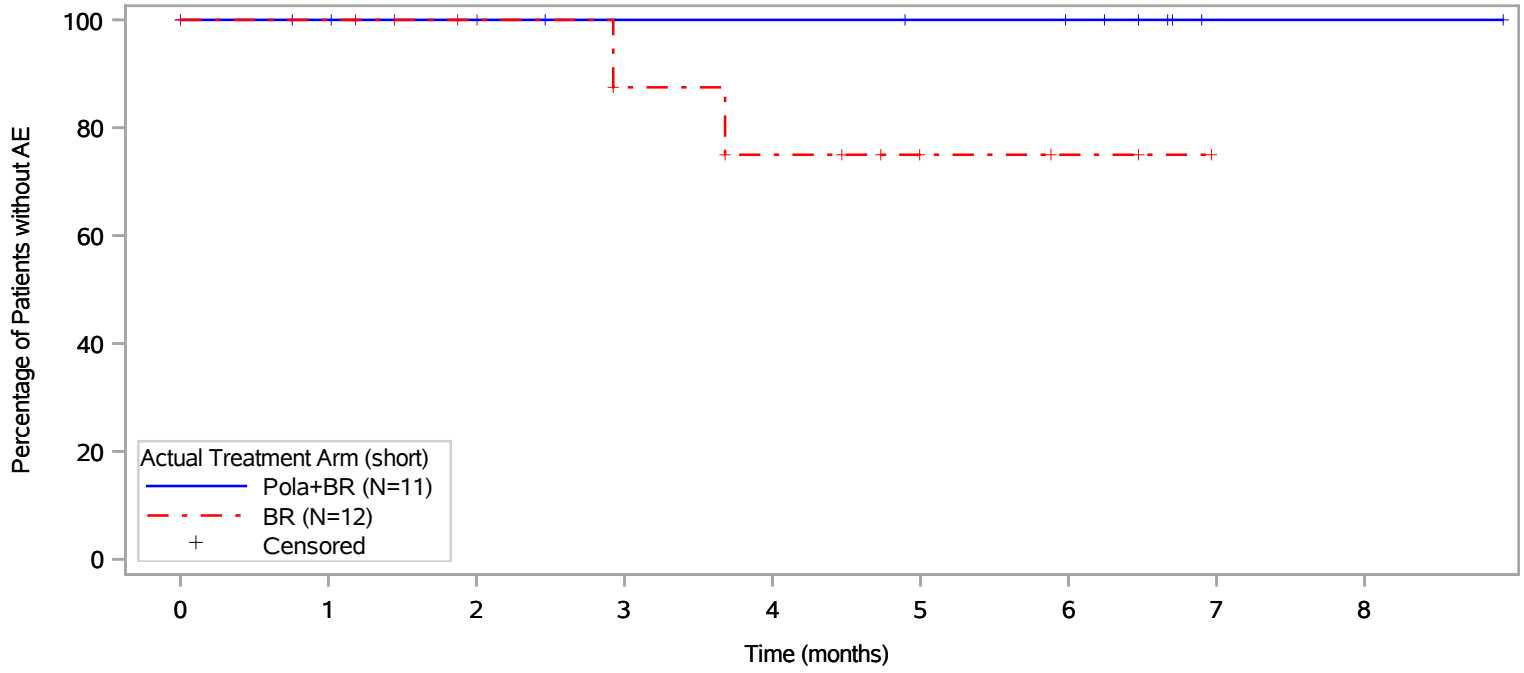
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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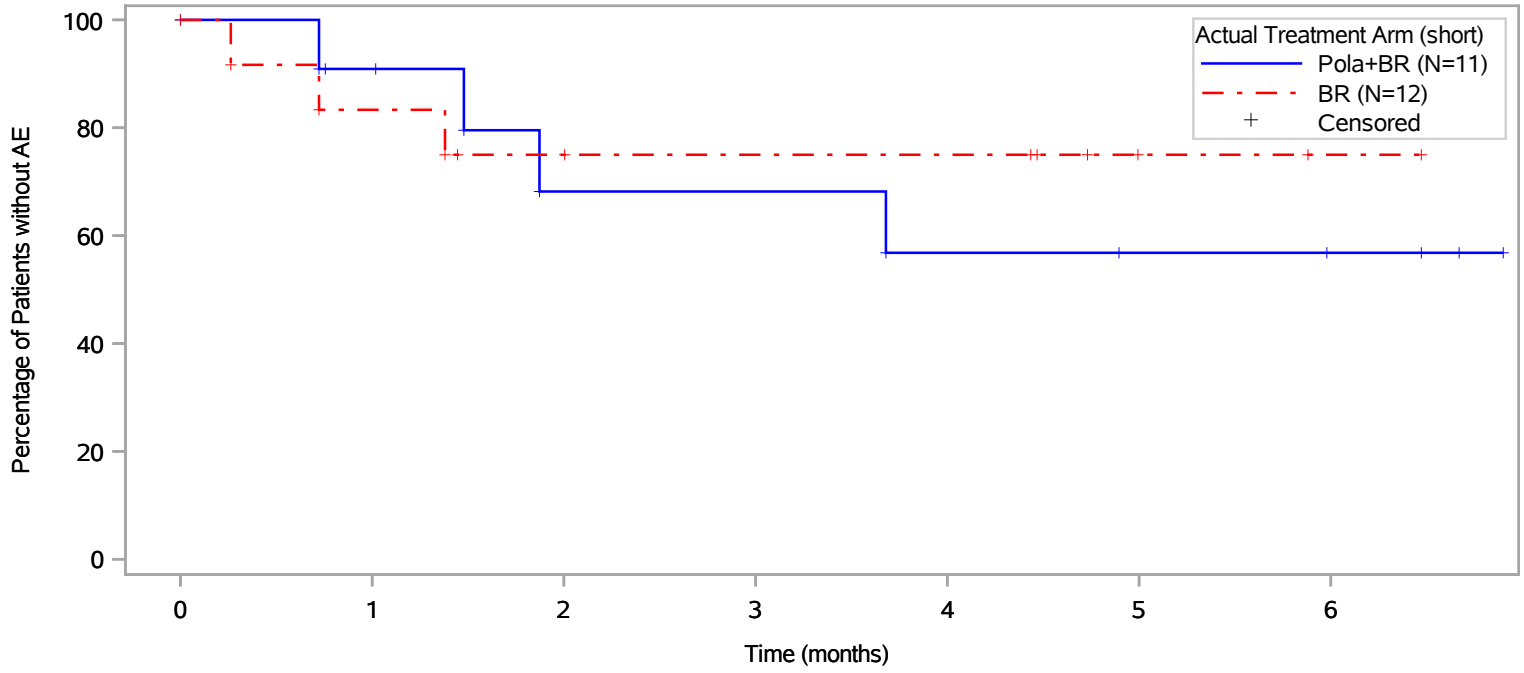
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk							
Pola+BR (N=11)	11	9	6	6	5	4	3
BR (N=12)	12	10	7	6	6	2	1
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	3	4
BR (N=12)	0	0	2	3	3	7	8

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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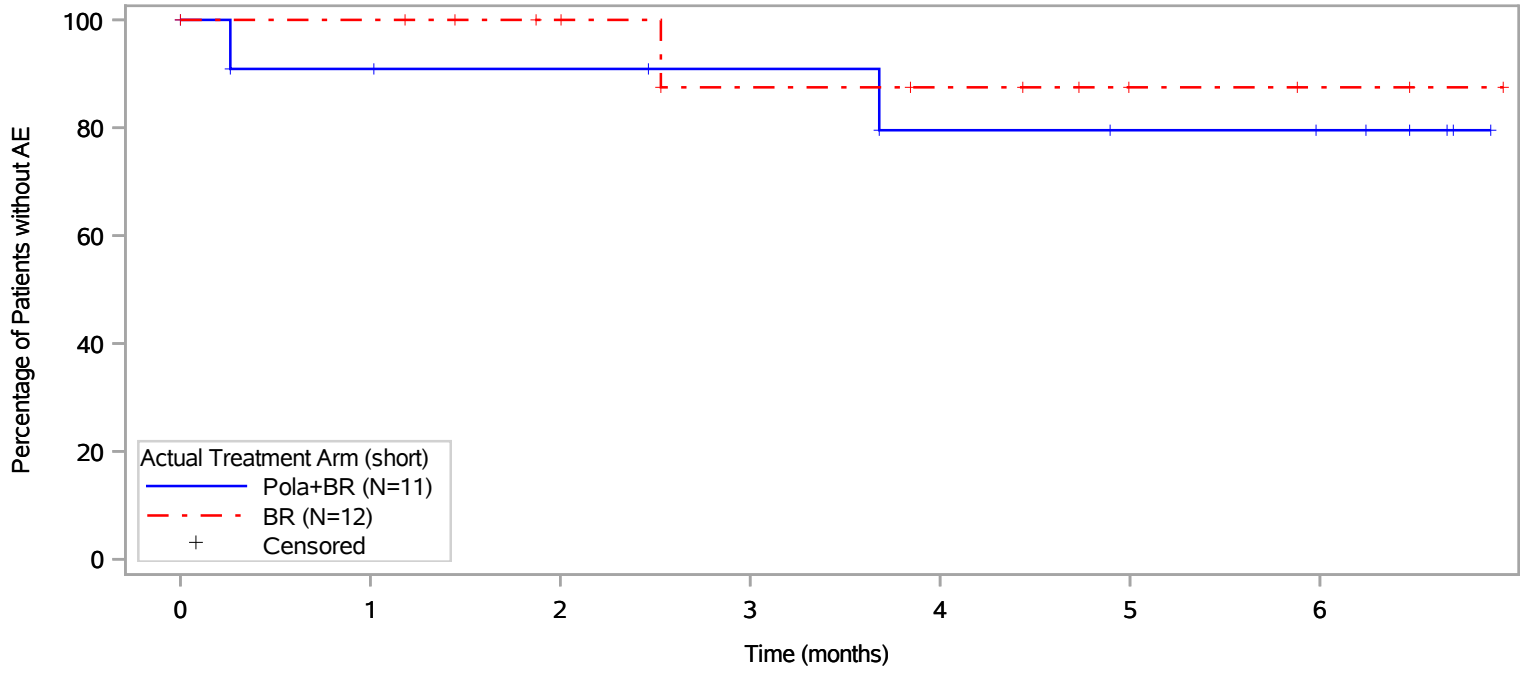
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk							
Pola+BR (N=11)	11	10	9	8	7	6	5
BR (N=12)	12	12	9	7	6	3	2
Patients censored							
Pola+BR (N=11)	0	0	1	2	2	3	4
BR (N=12)	0	0	3	4	5	8	9

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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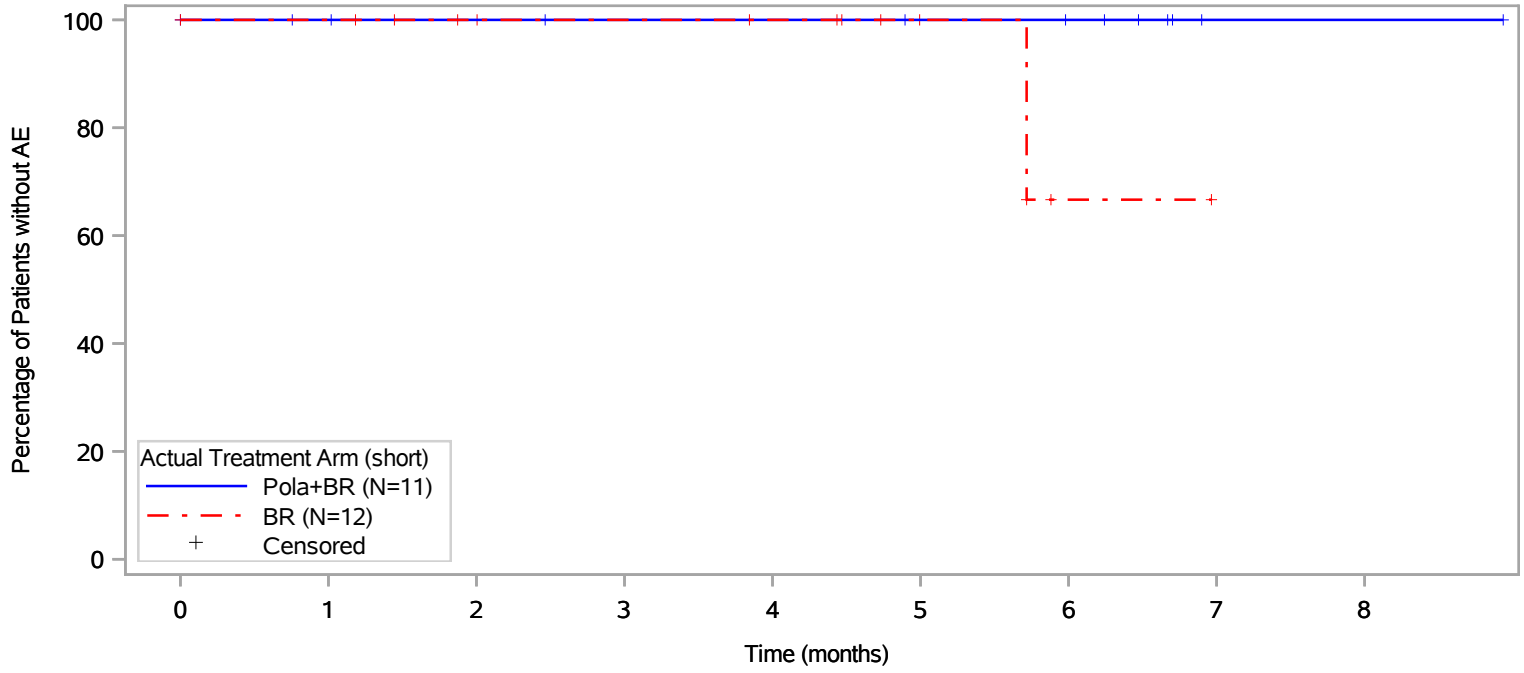
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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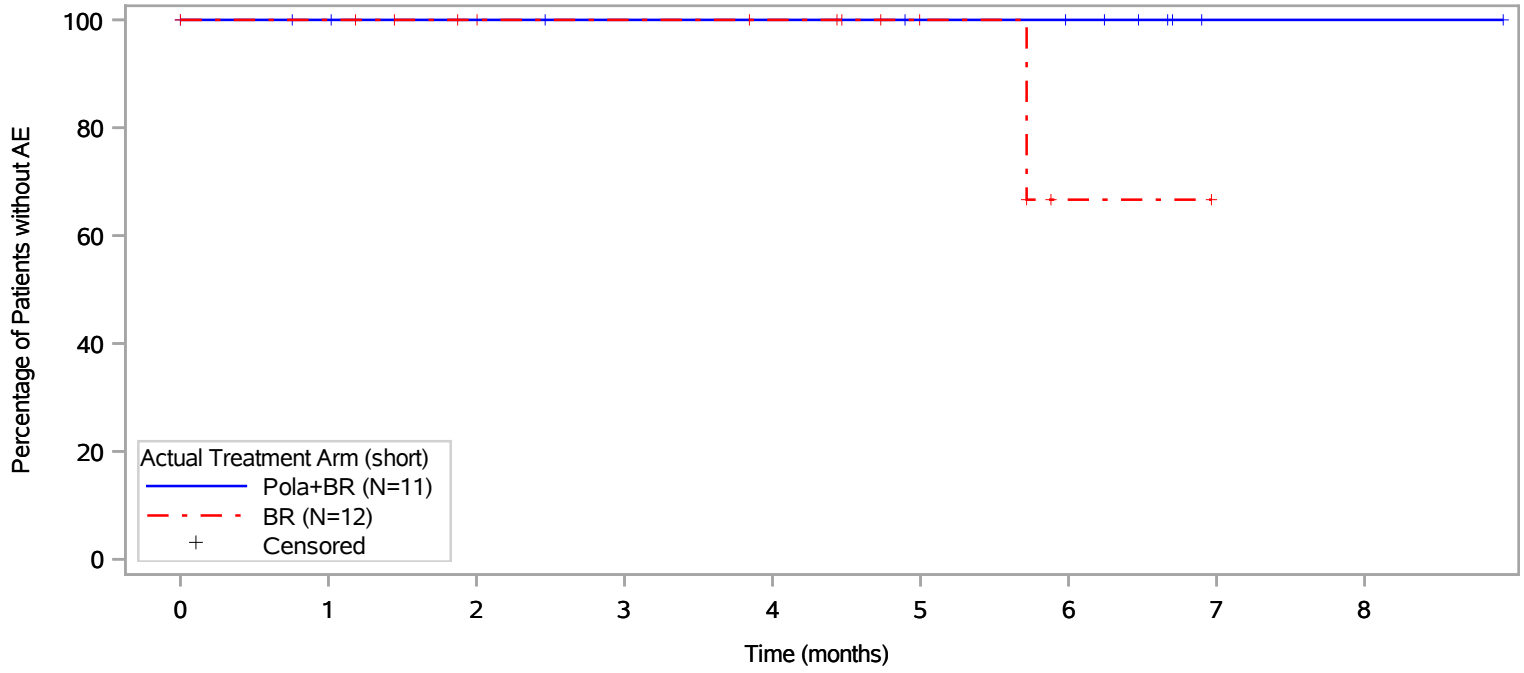
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SMALL INTESTINAL OBSTRUCTION



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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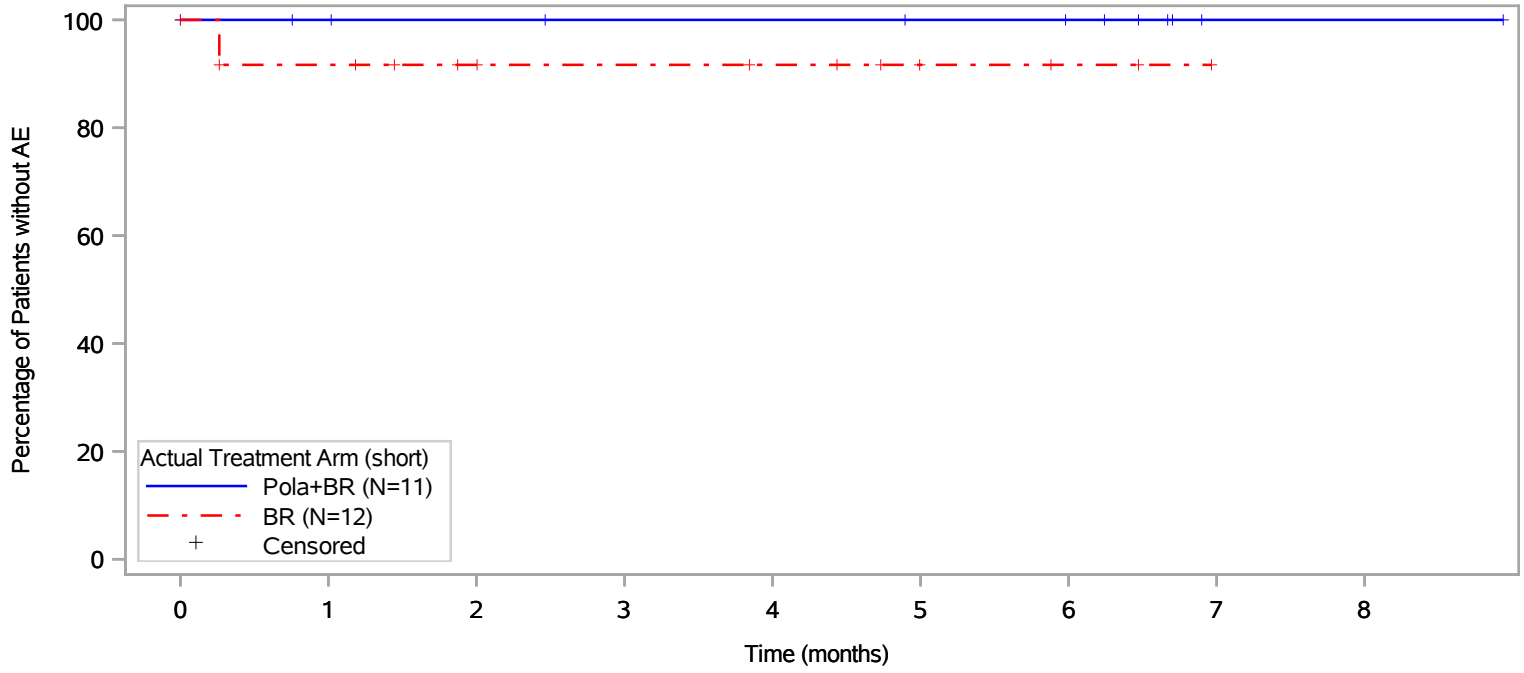
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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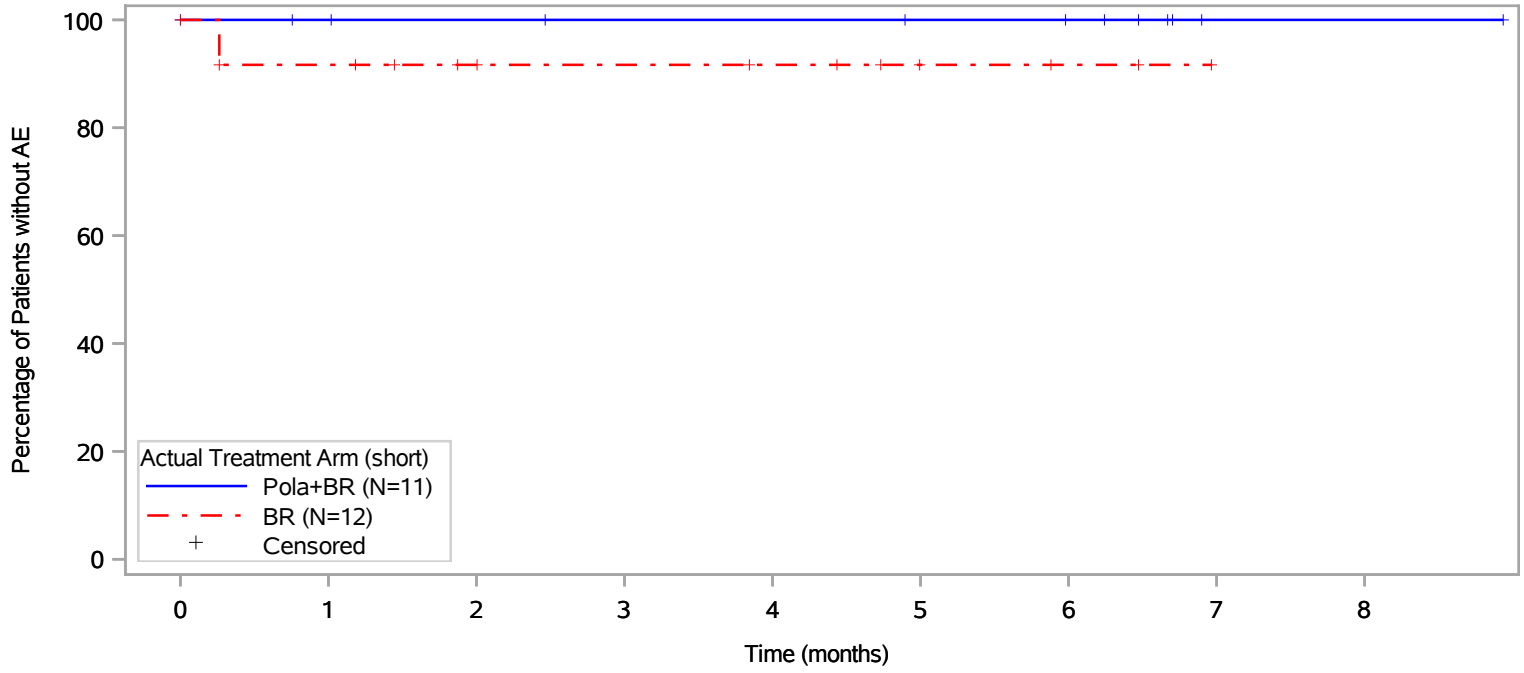
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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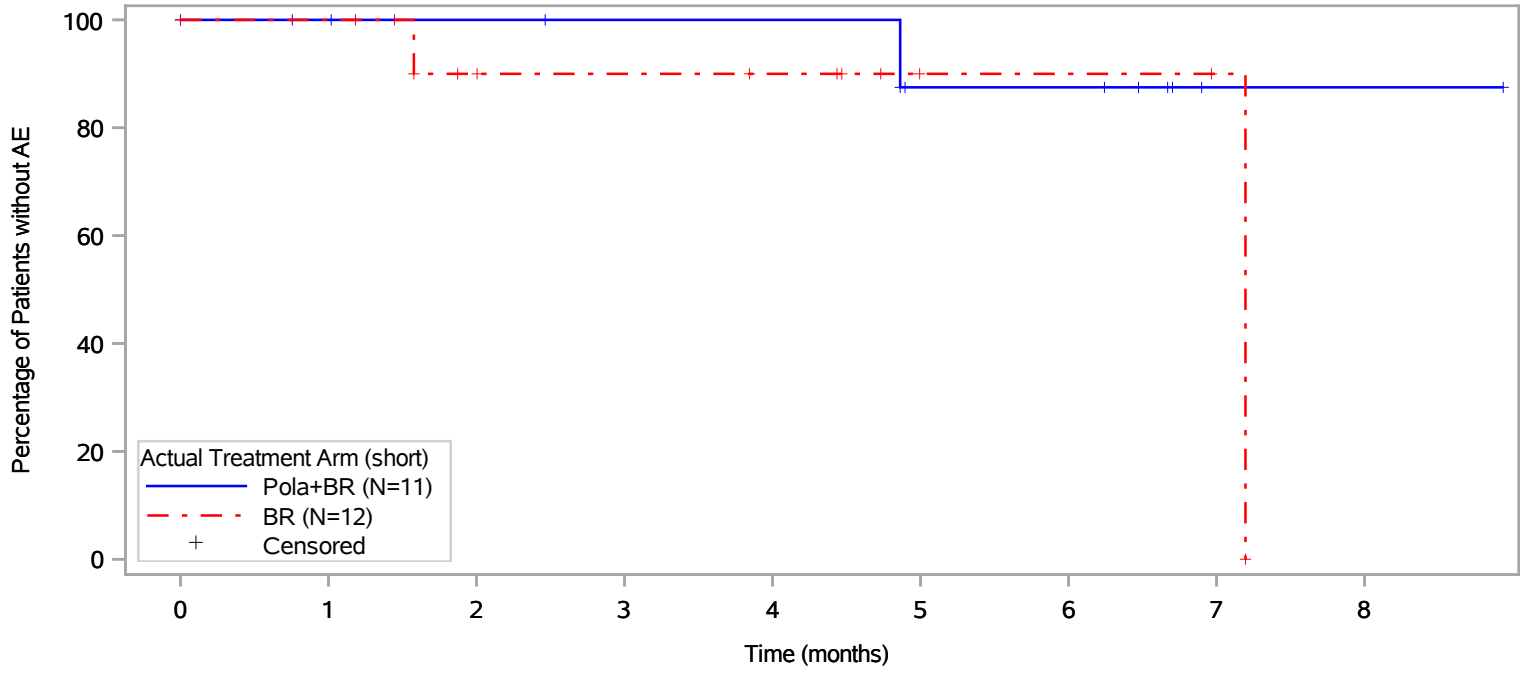
02DEC2022 2:59

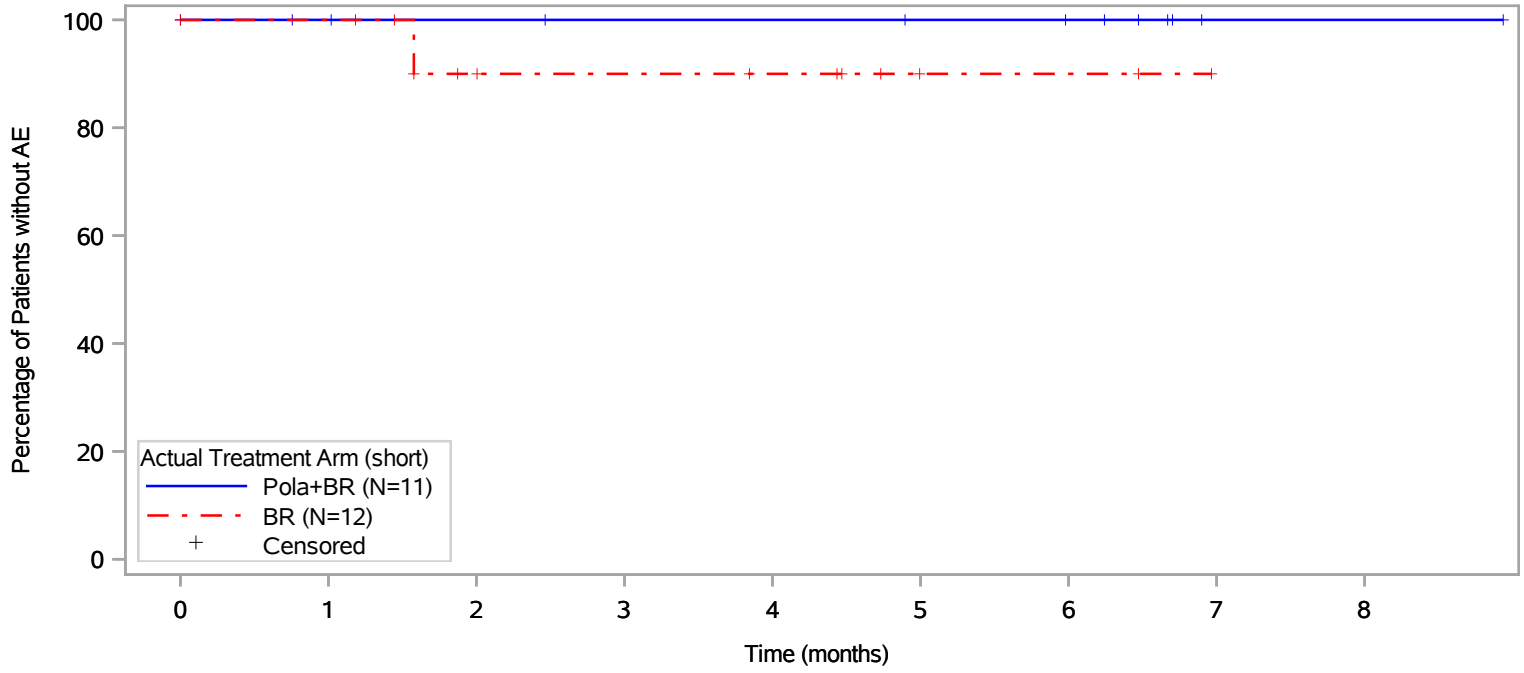
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	8	7	6	2	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	9	10	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	7	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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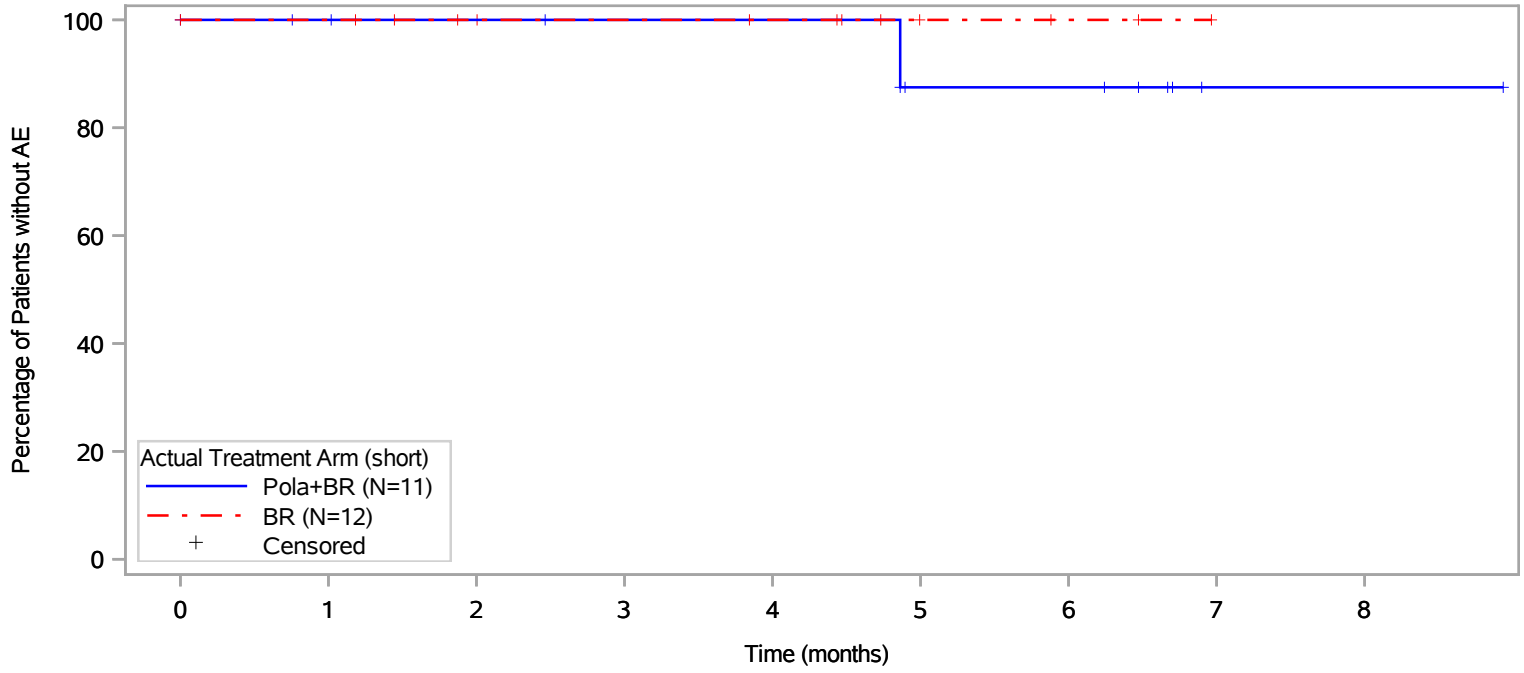
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA CYTOMEGALOVIRAL



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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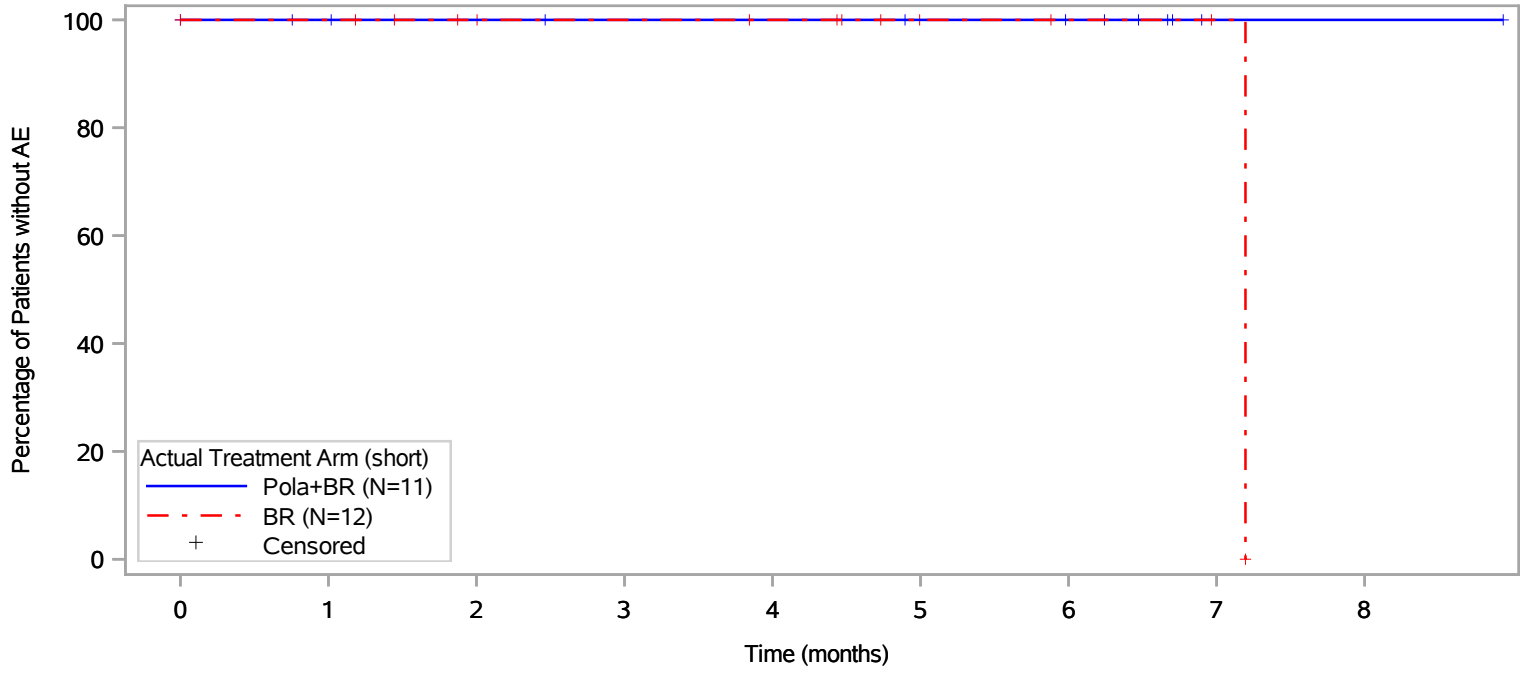
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, POST PROCEDURAL INFECTION



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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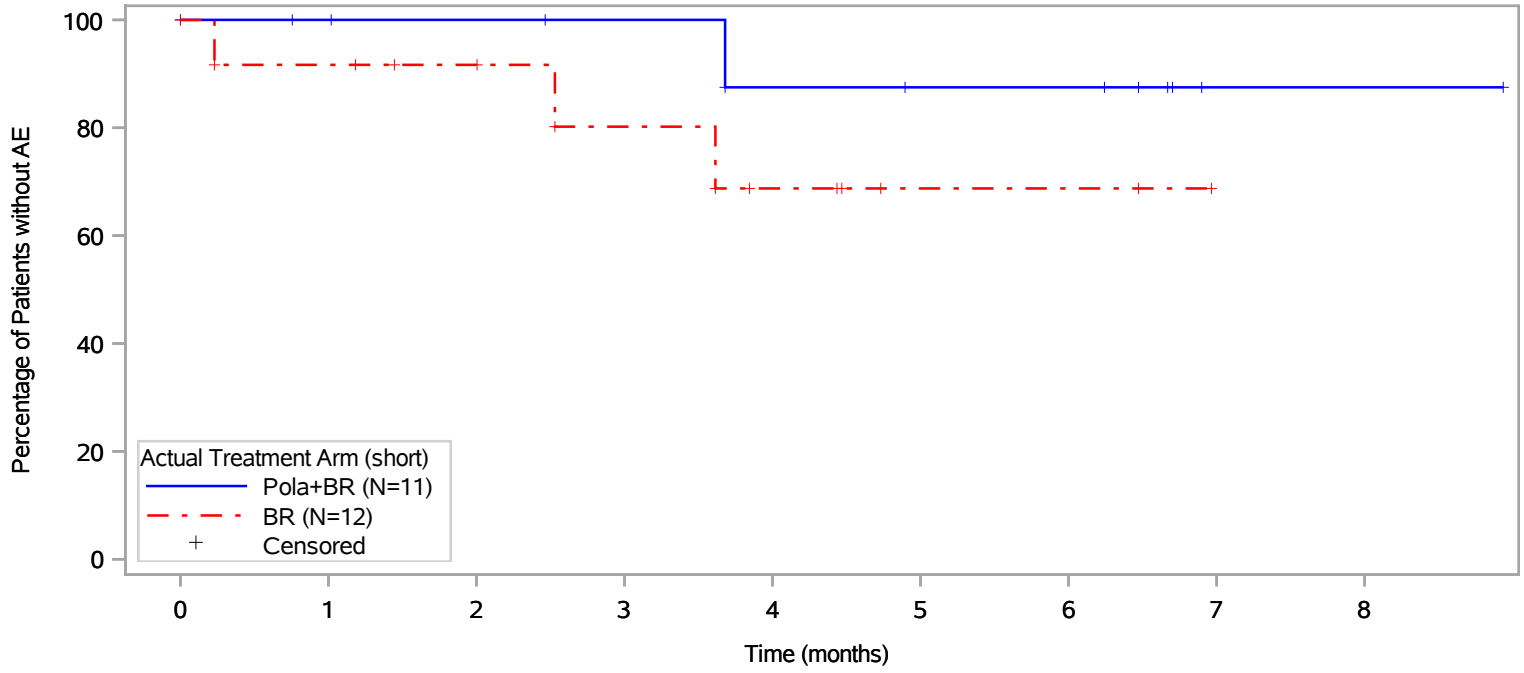
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	11	9	7	5	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	2	3	4	7	7	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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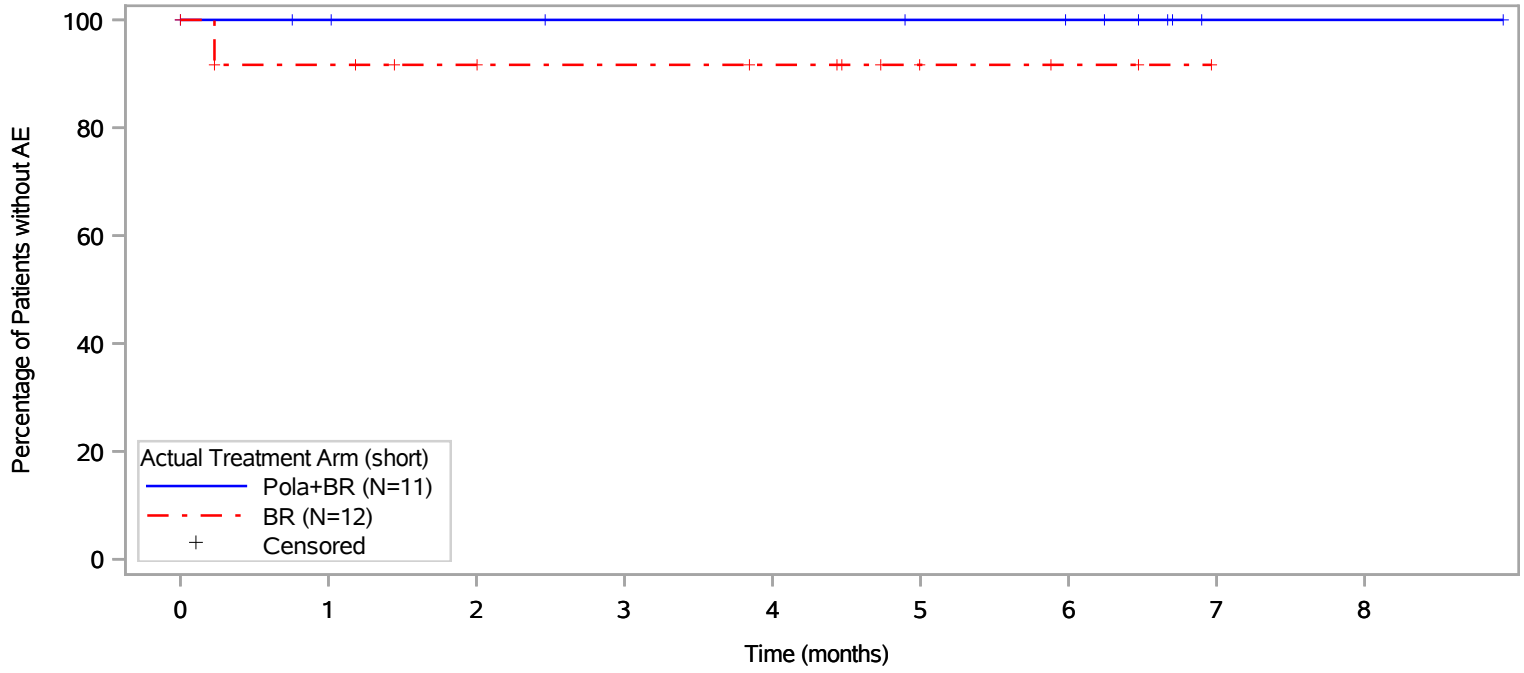
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALKALINE PHOSPHATASE INCREASED

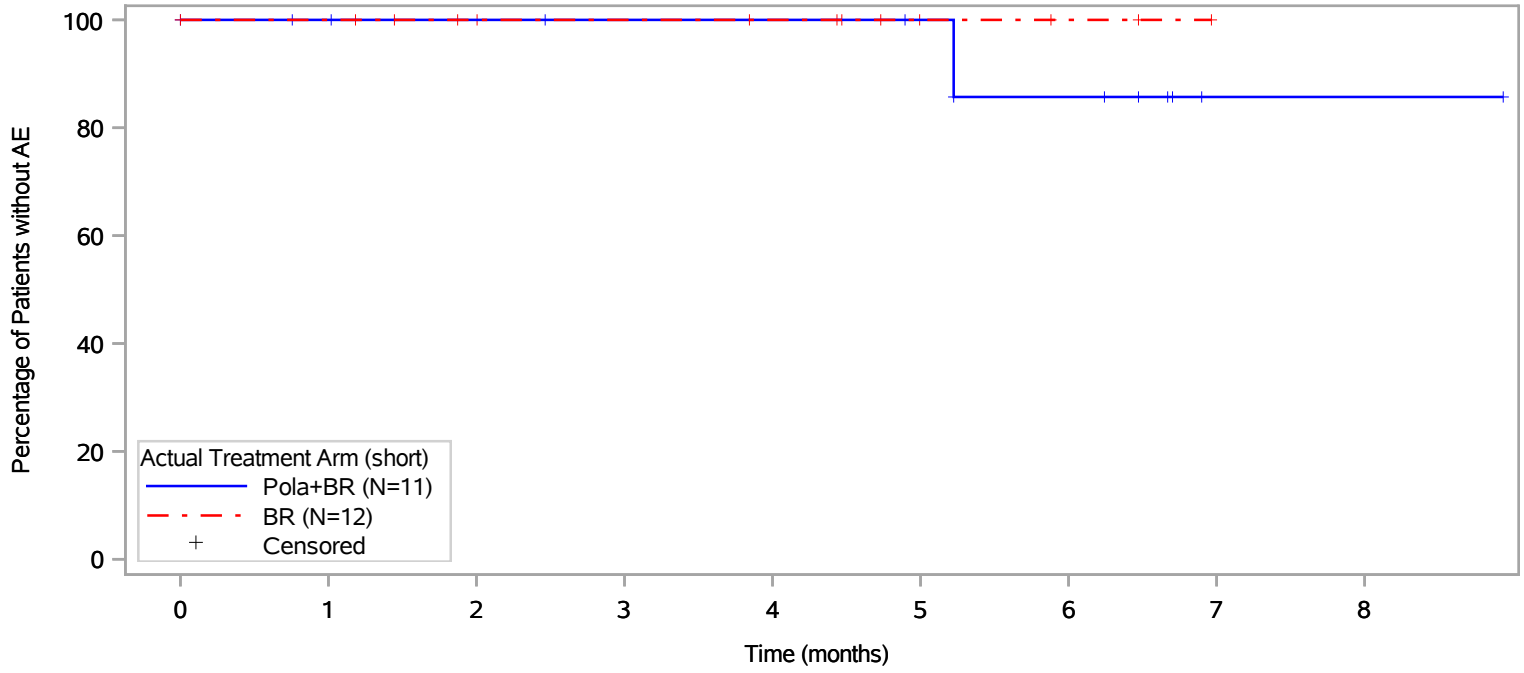


Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PHOSPHORUS DECREASED

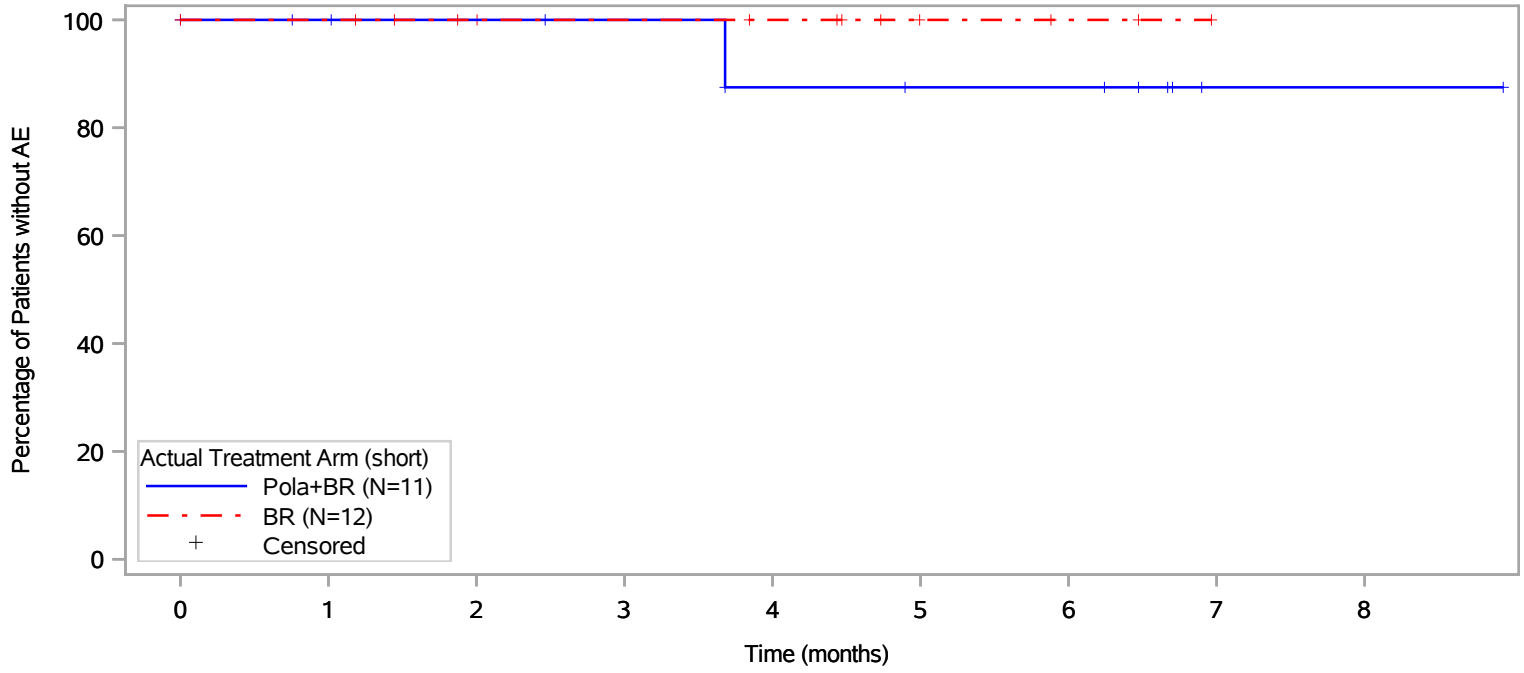


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED

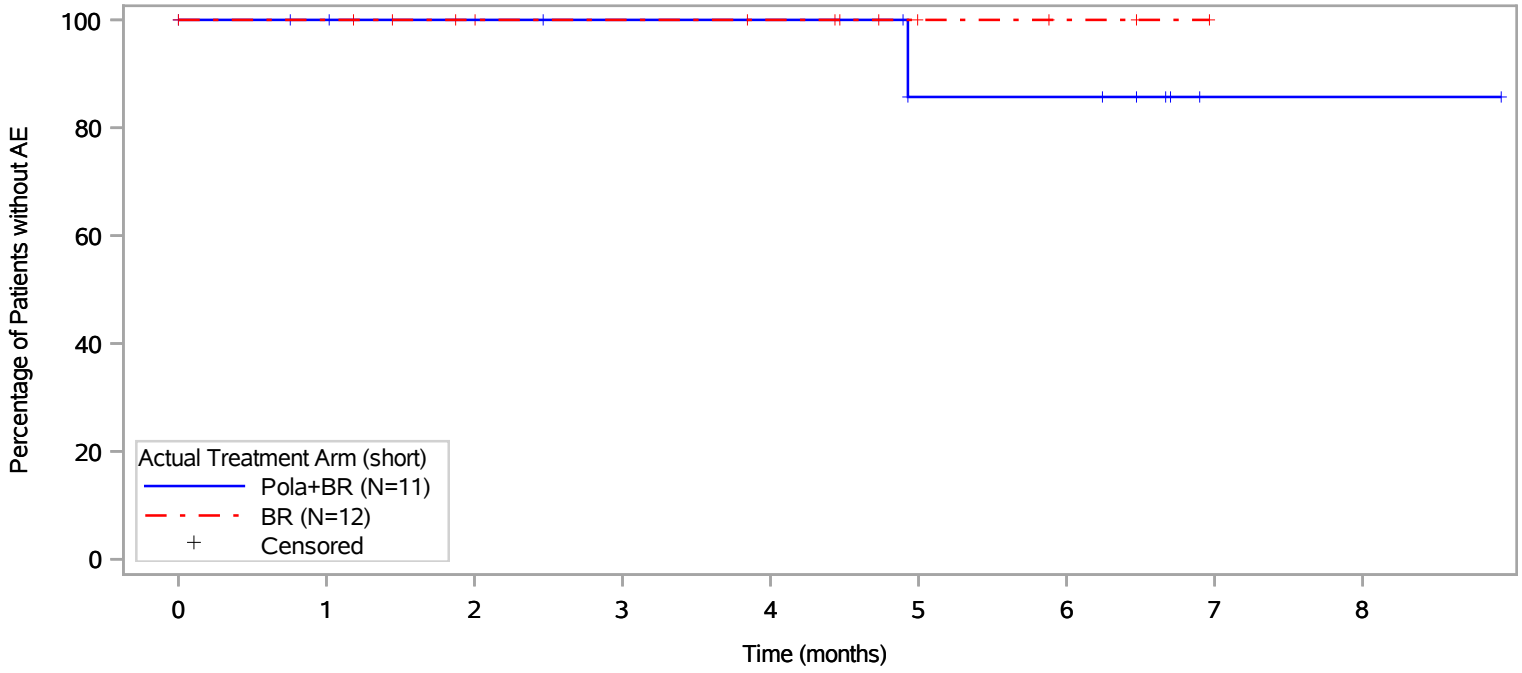


Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYTOMEGALOVIRUS TEST POSITIVE

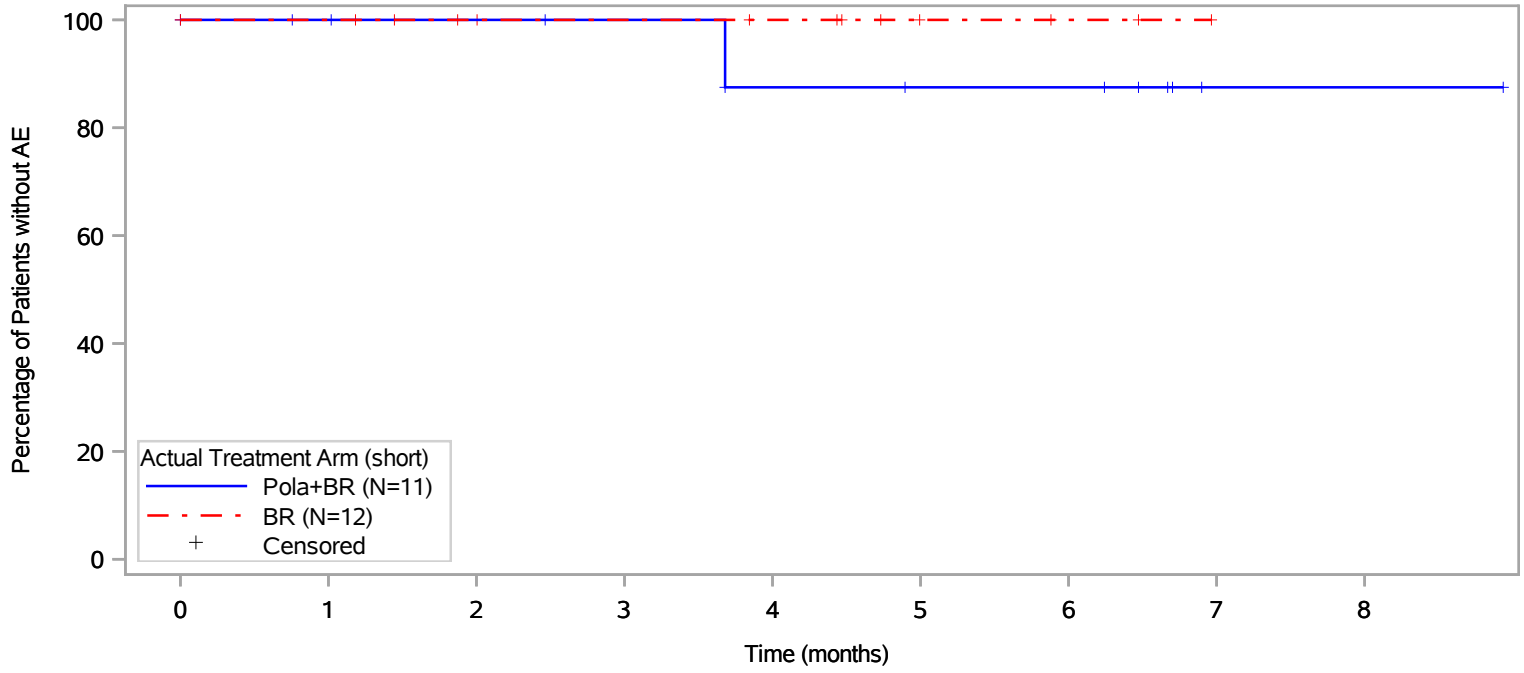


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LIPASE INCREASED



Patients at risk									
Pola+BR (N=11)	11	10	9	8	7	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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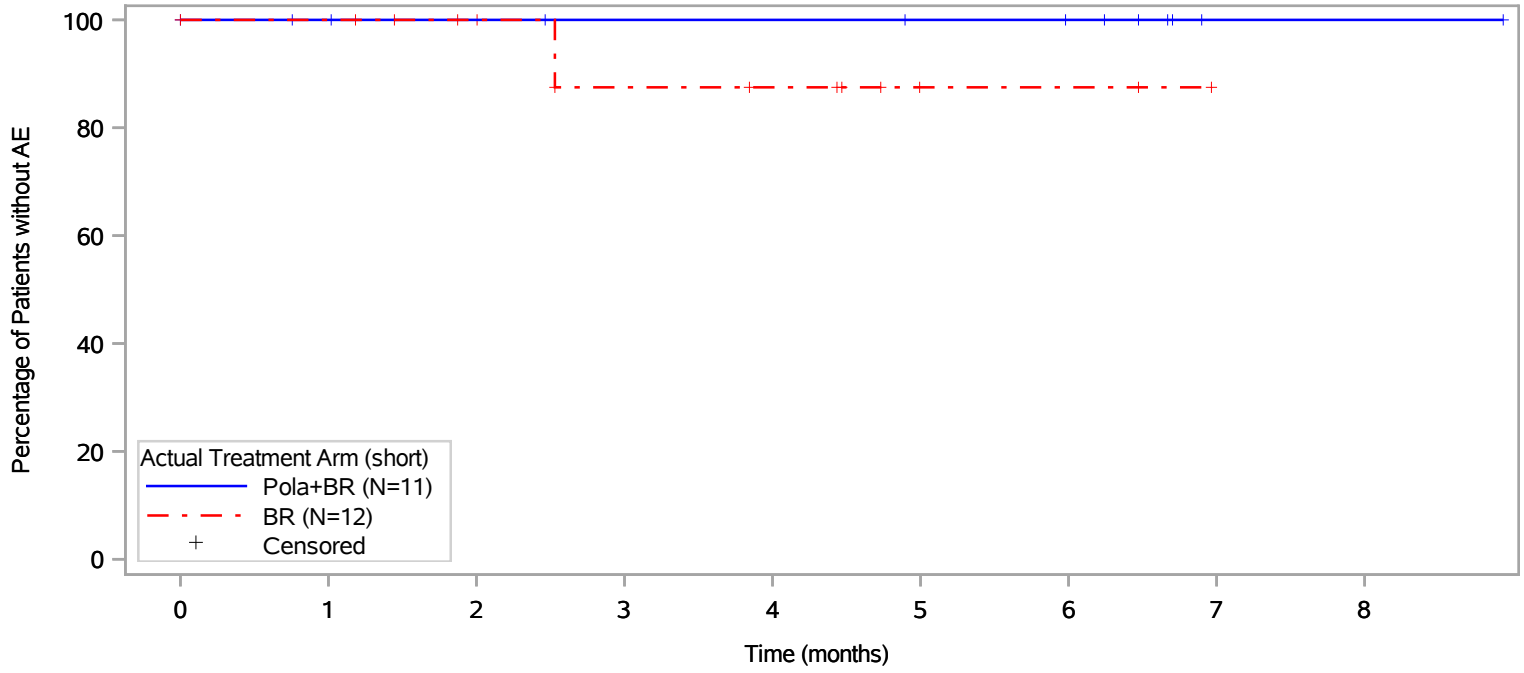
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED

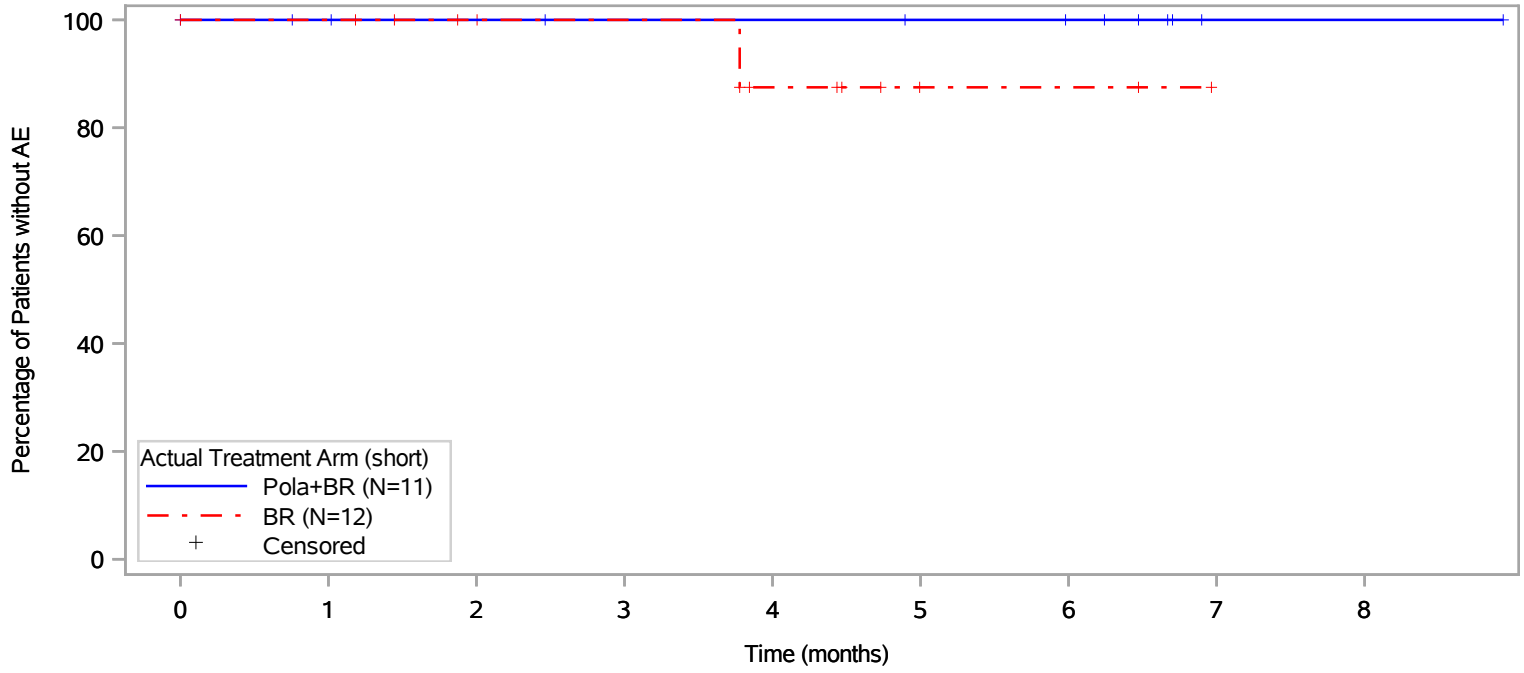


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

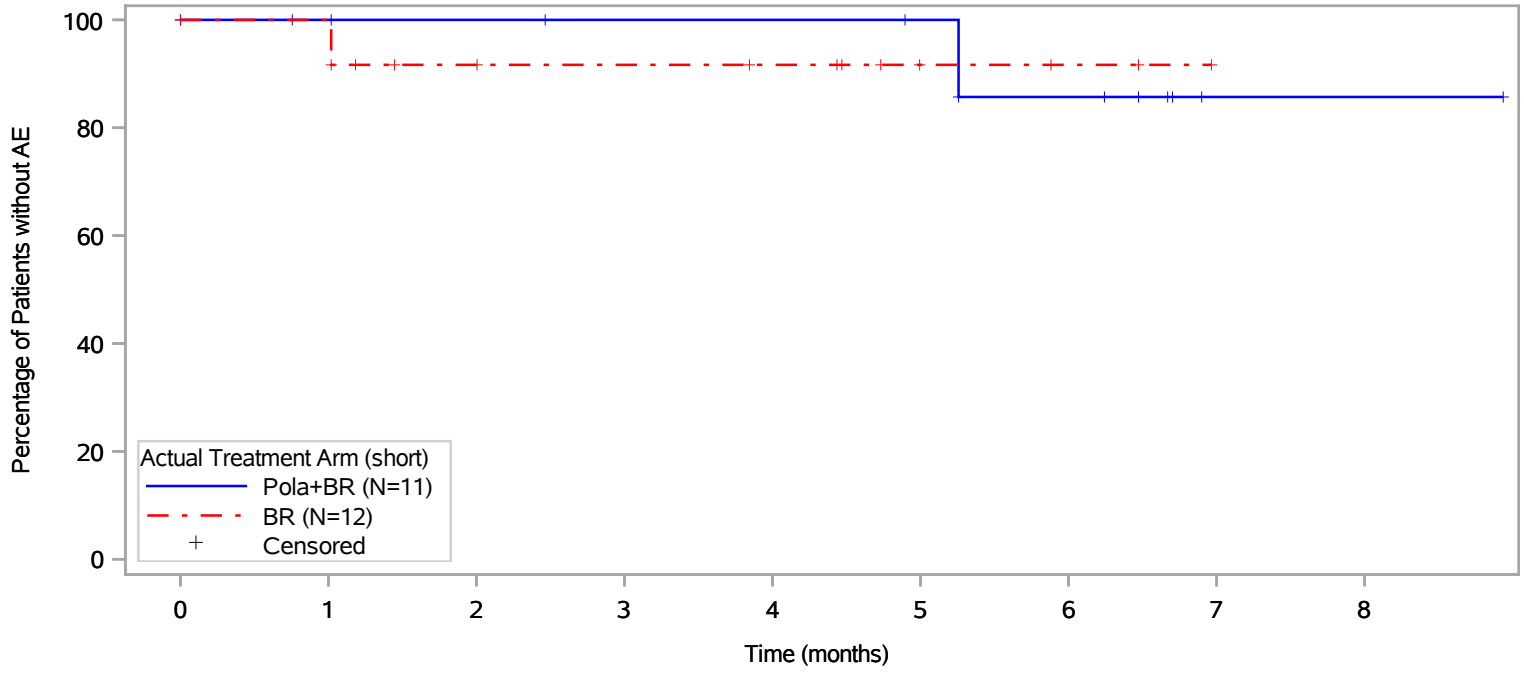


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED

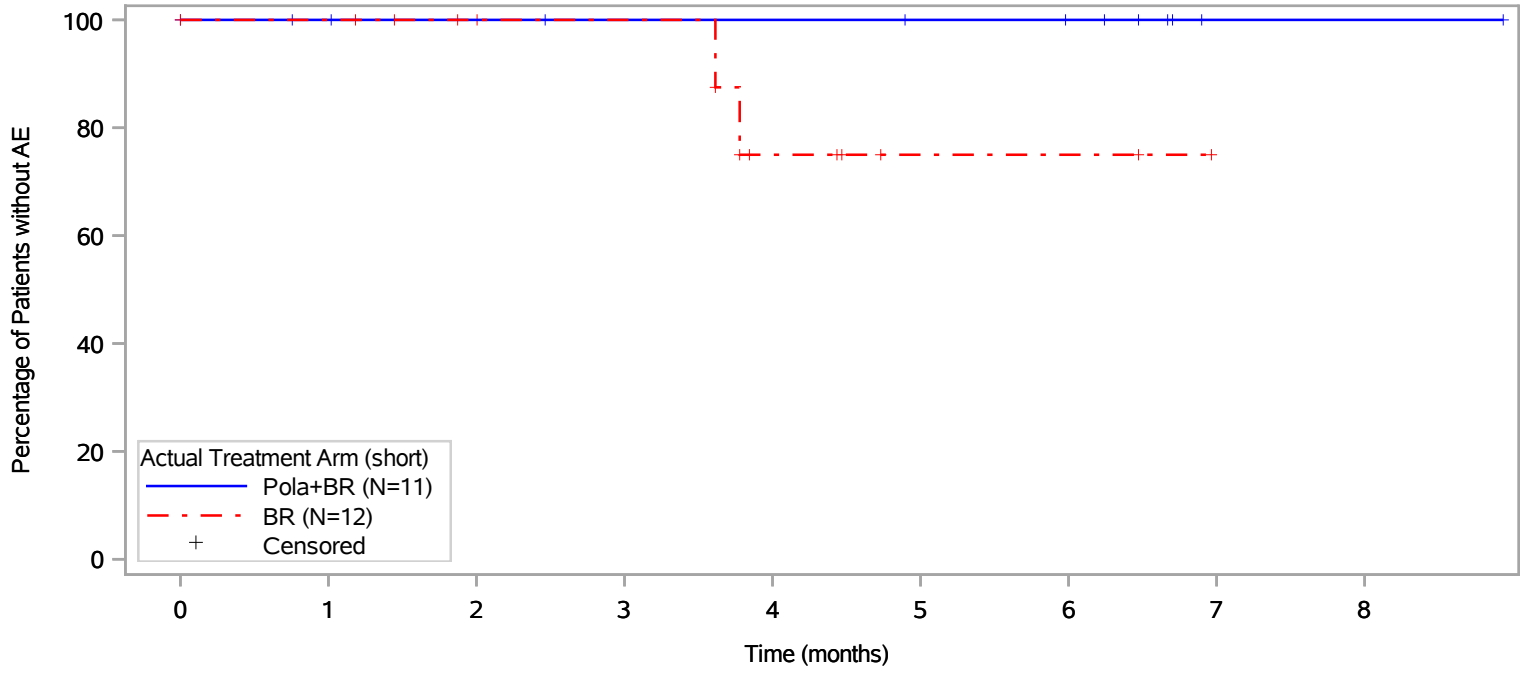


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	5	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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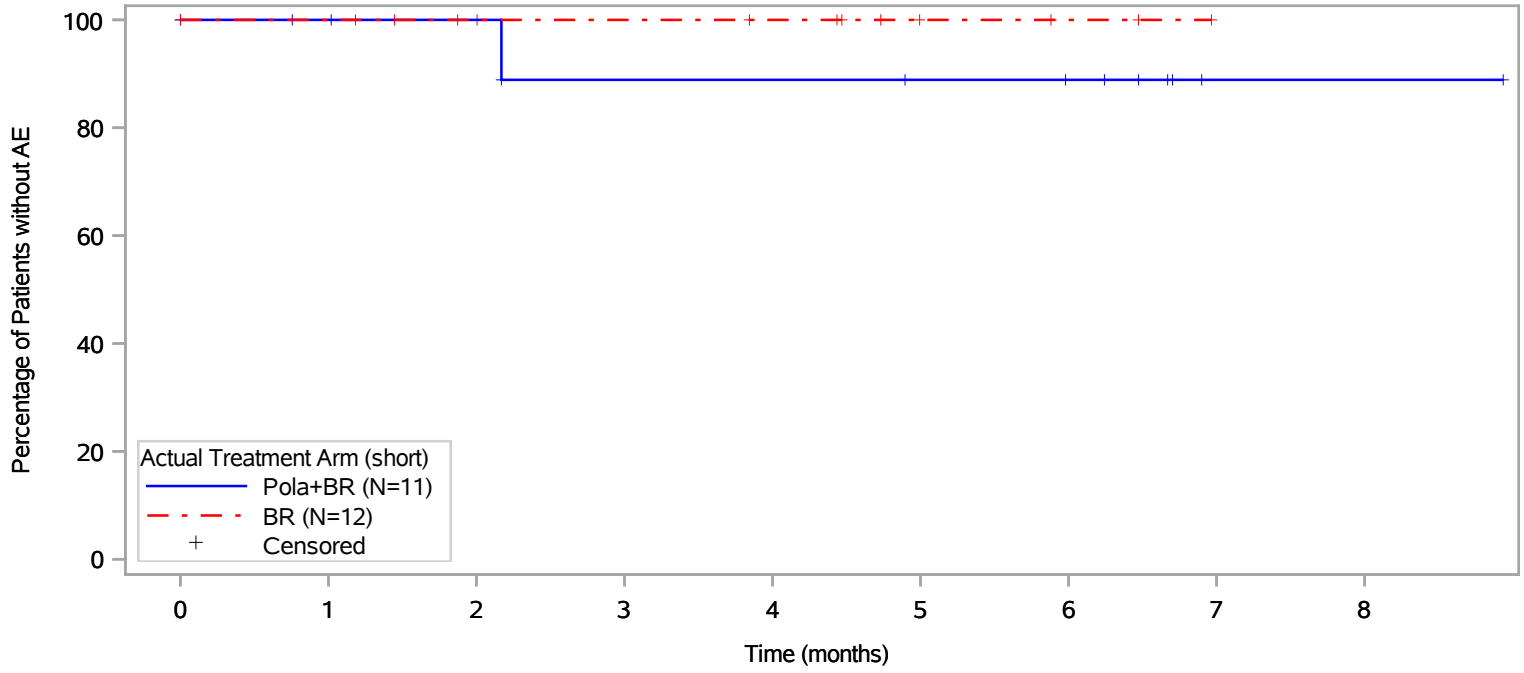
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



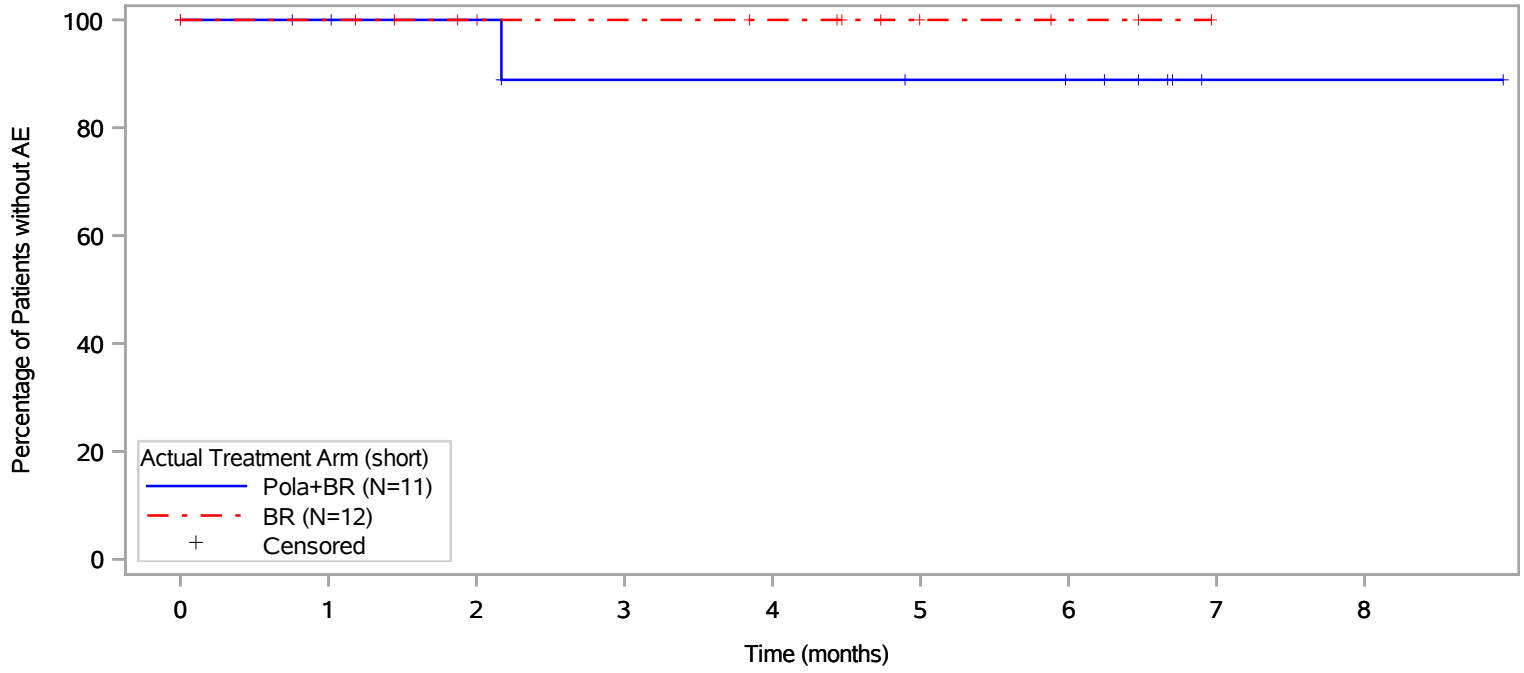
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE



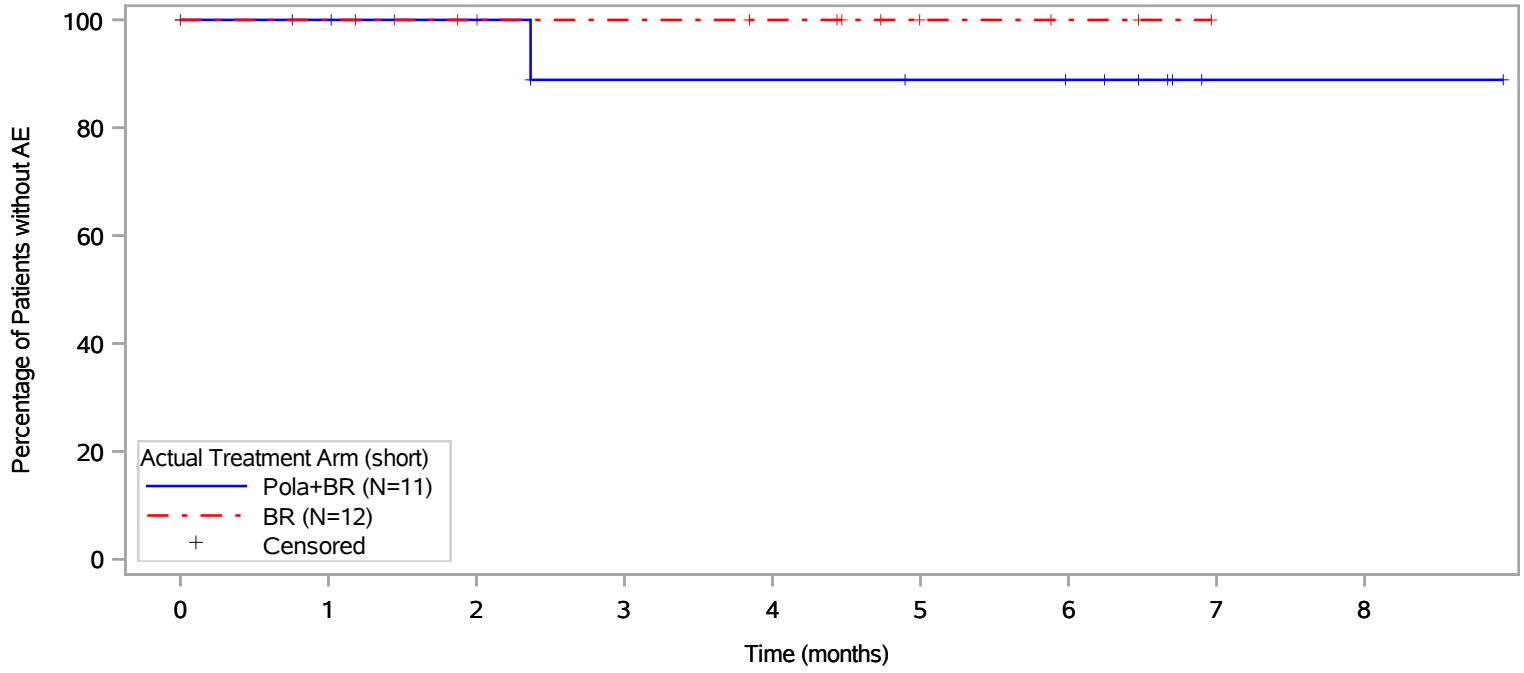
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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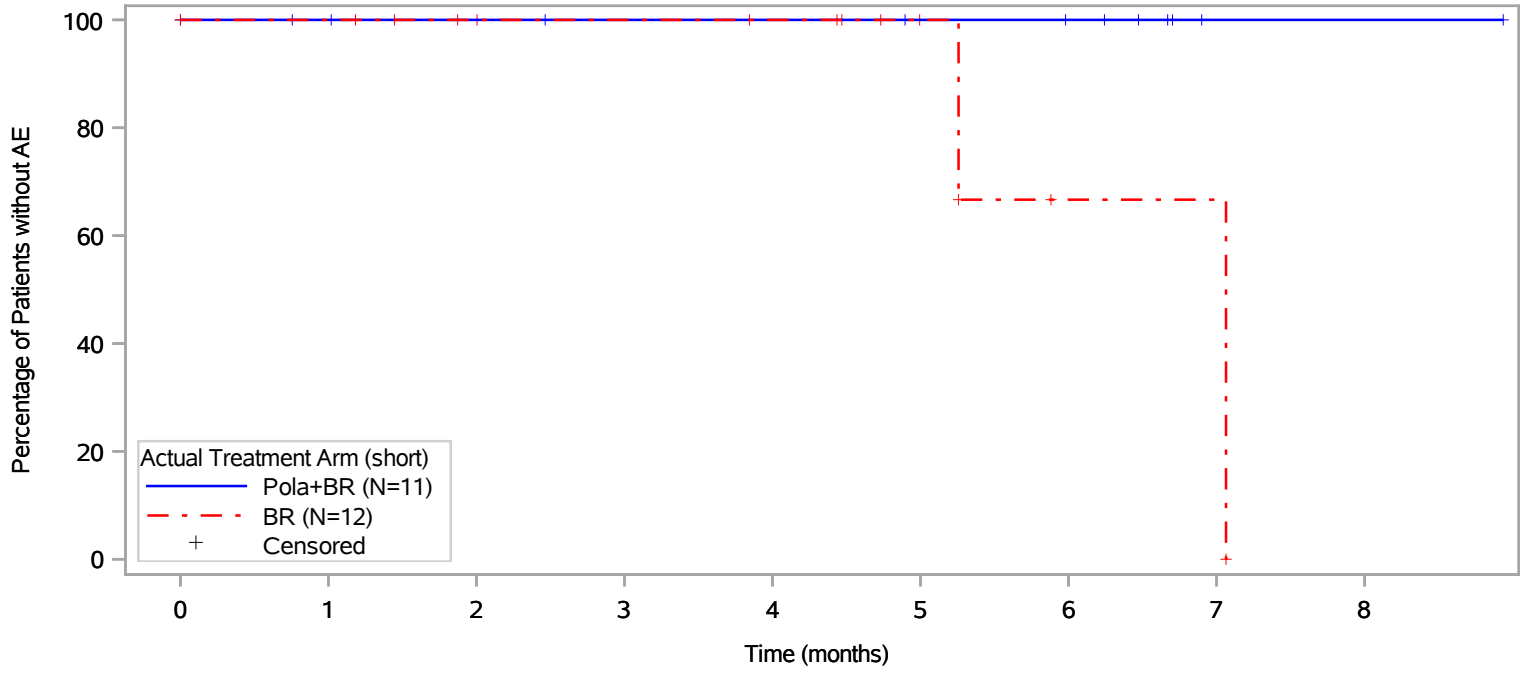
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



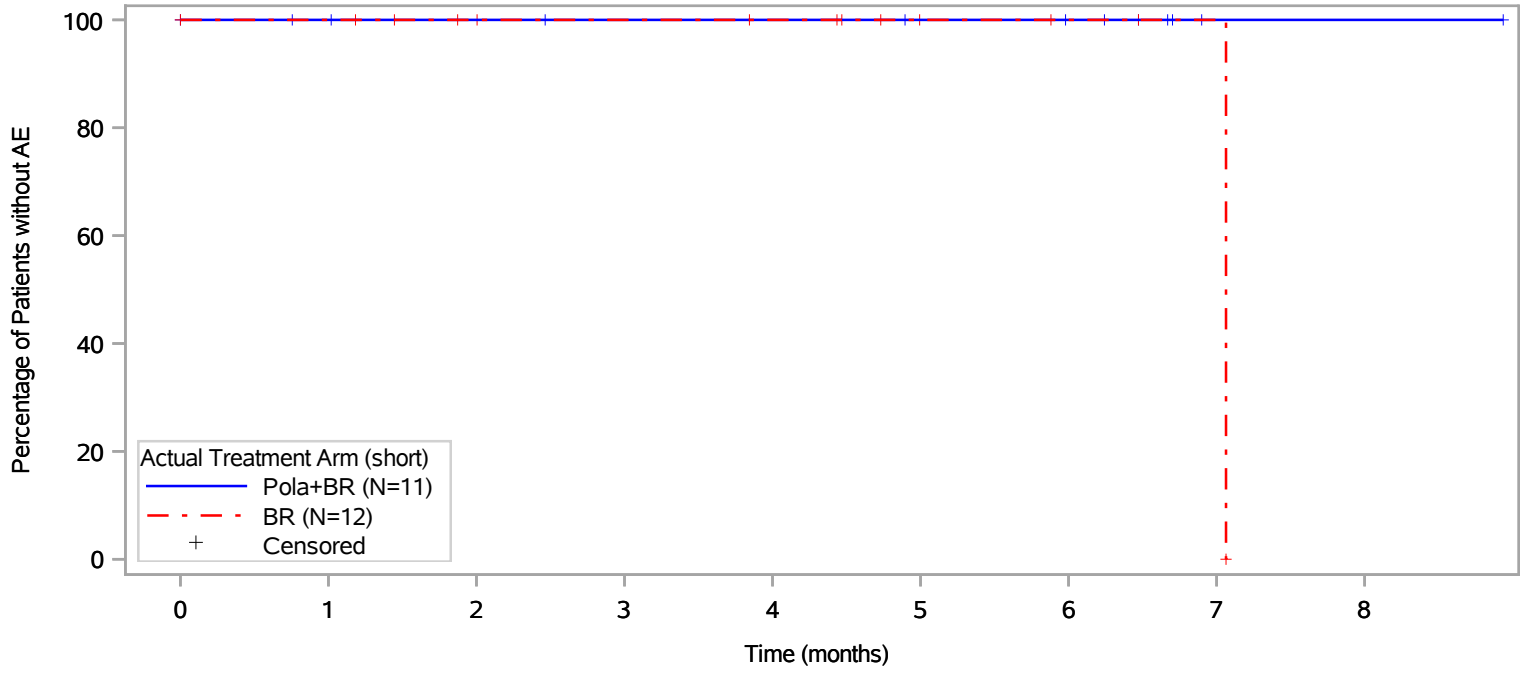
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	10	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), EPIGLOTTIC CANCER



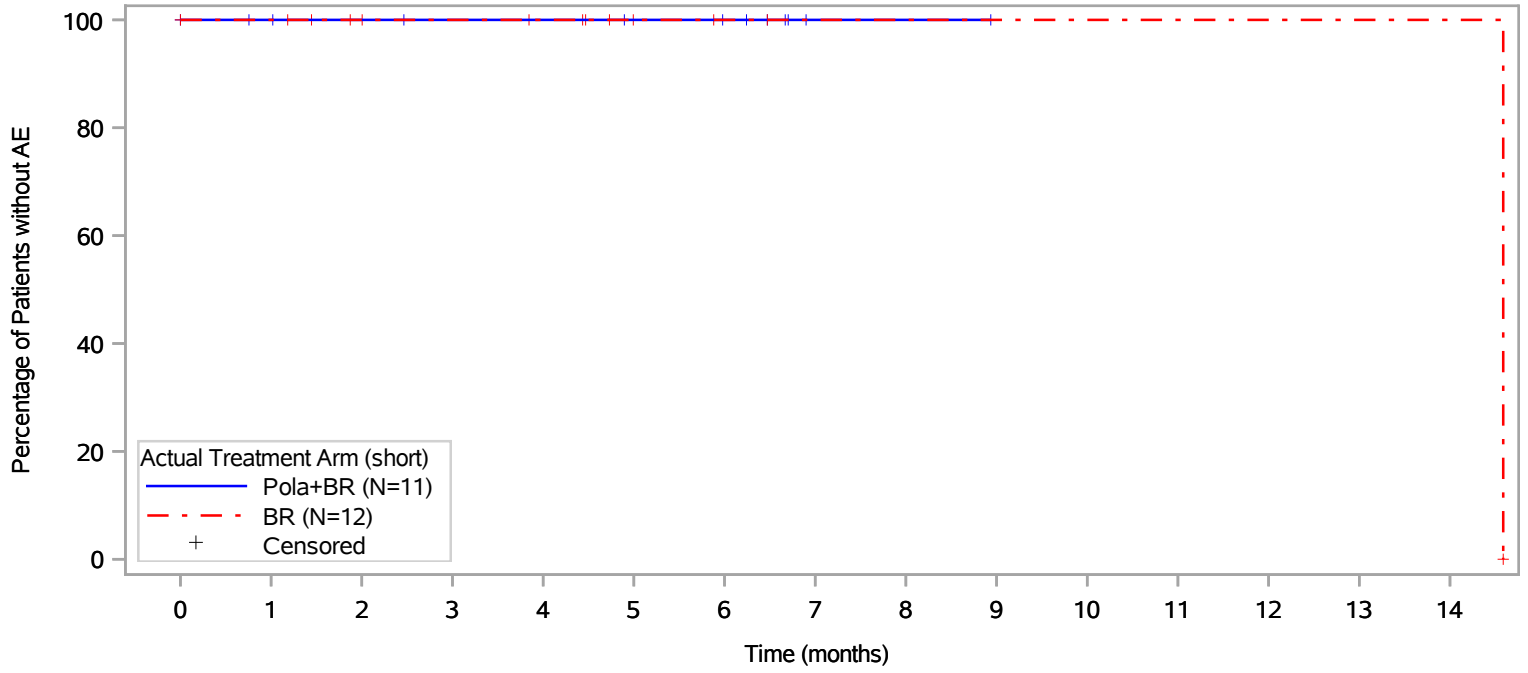
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



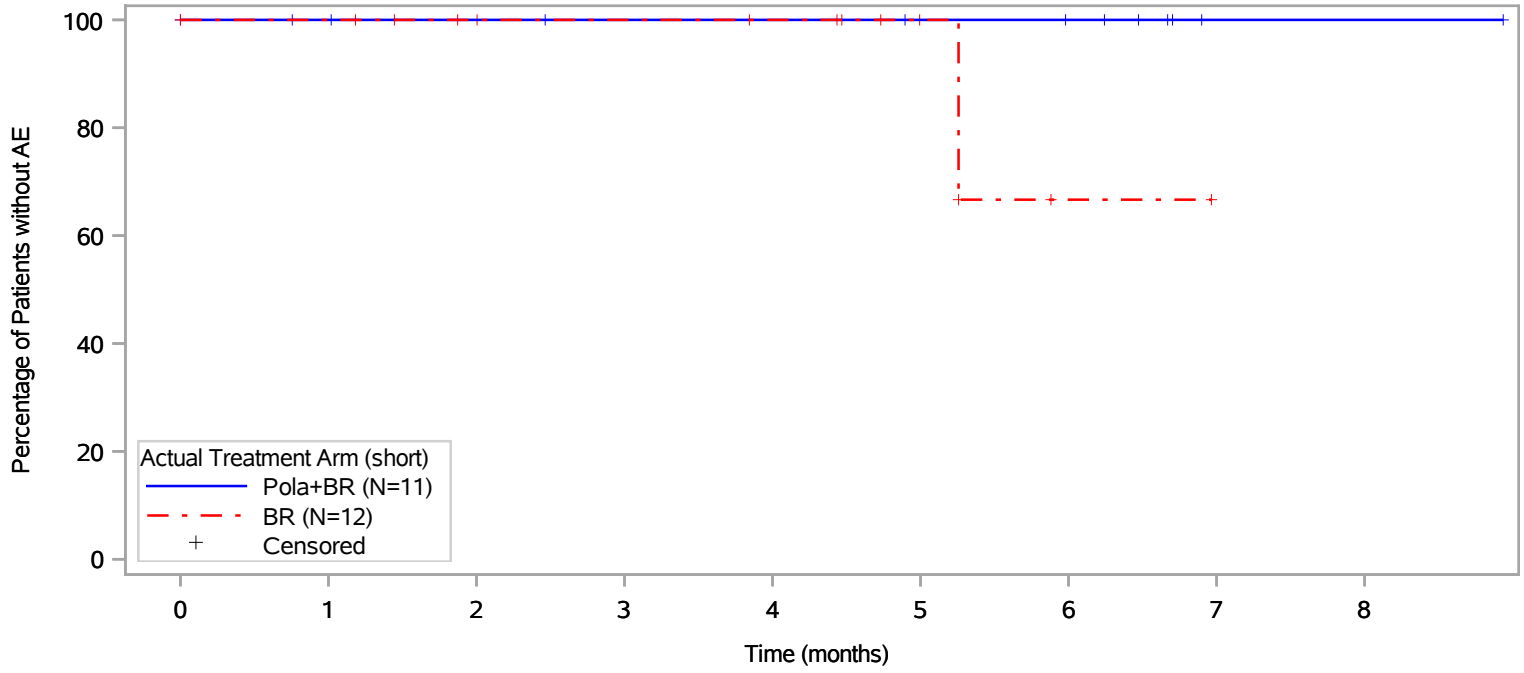
Patients at risk															
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1	NE	NE	NE	NE	NE	NE
BR (N=12)	12	12	9	8	7	3	2	1	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10	NE	NE	NE	NE	NE	NE
BR (N=12)	0	0	3	4	5	9	10	11	11	11	11	11	11	11	11

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), PAPILLARY THYROID CANCER

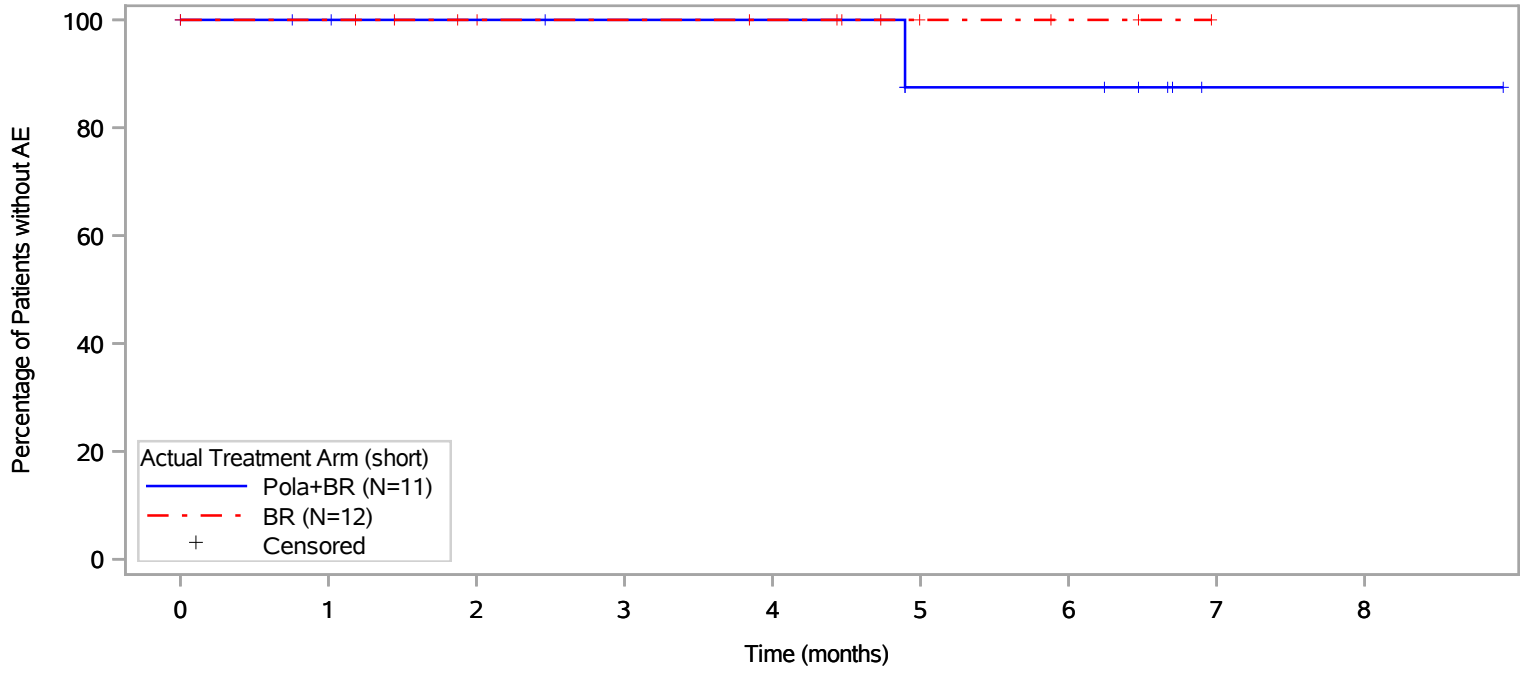


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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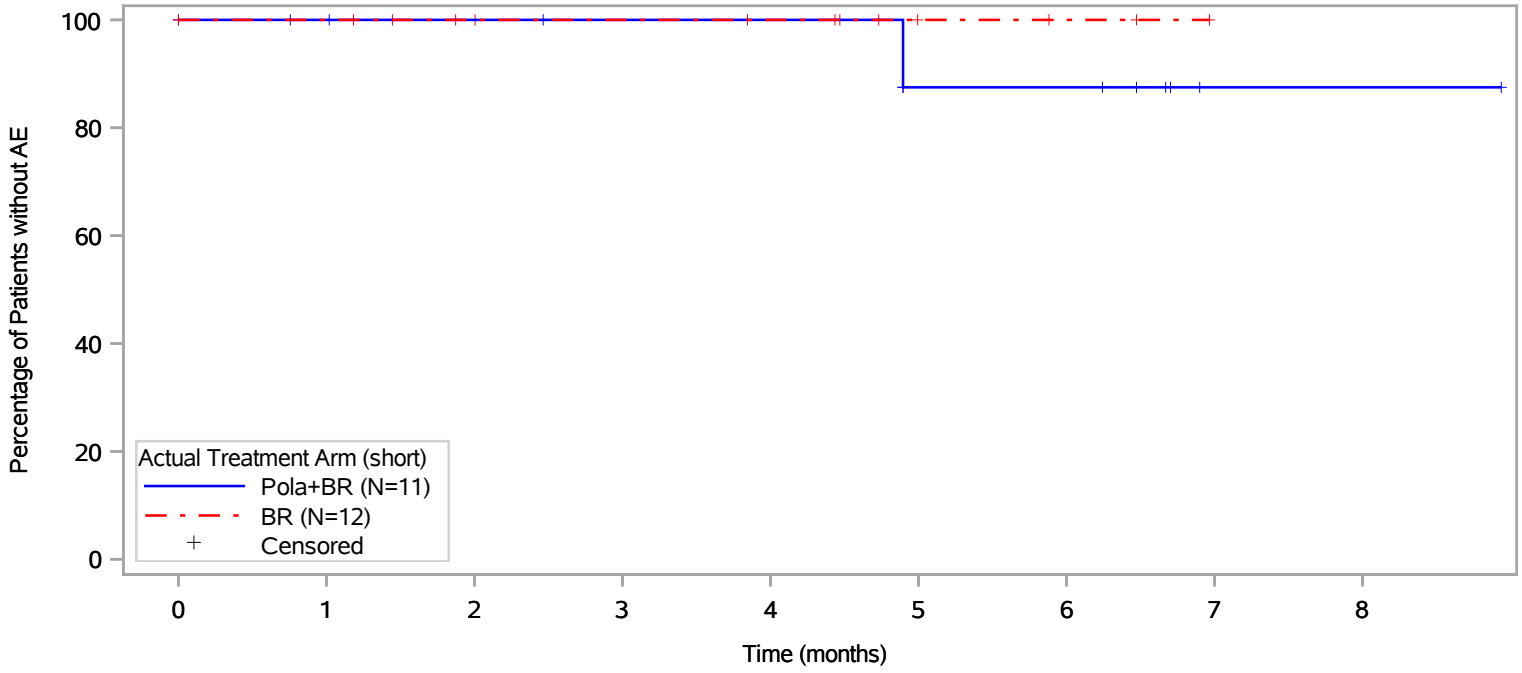
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, VOCAL CORD PARALYSIS

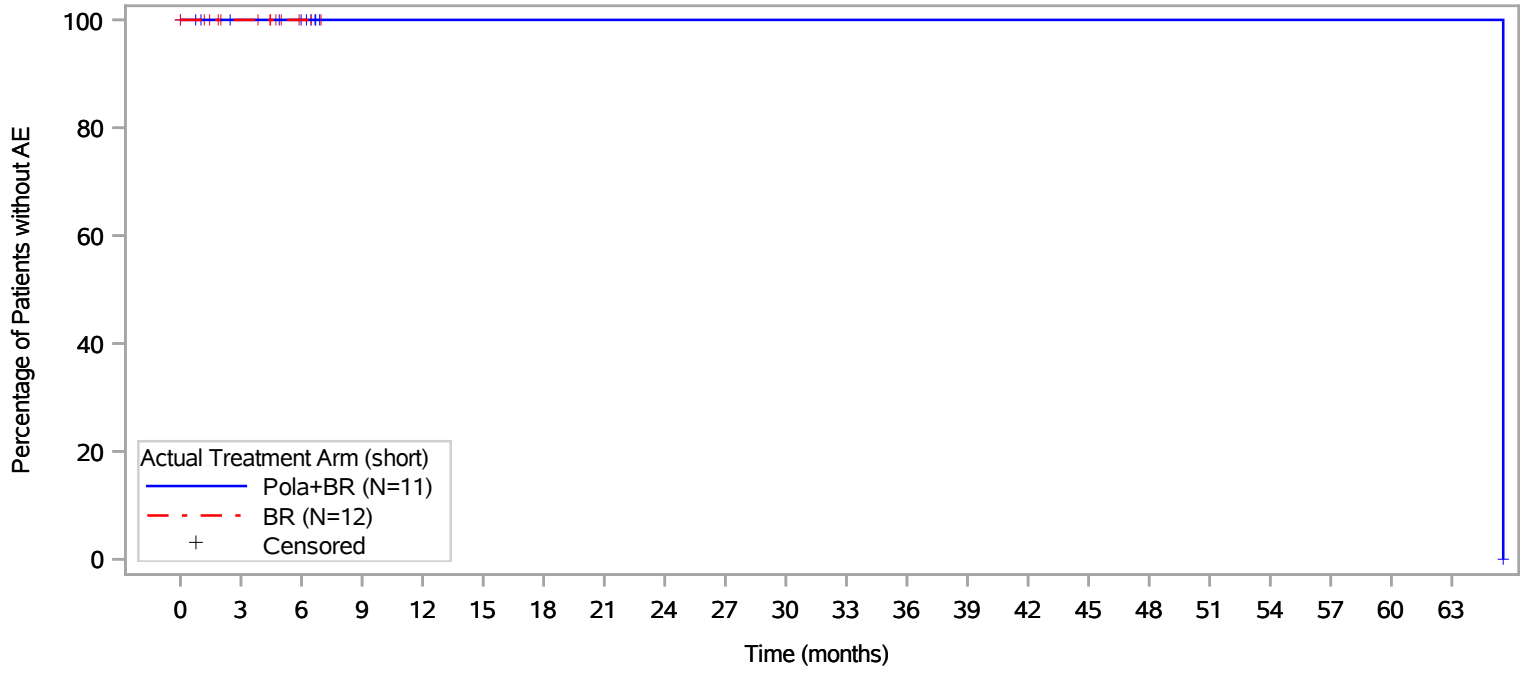


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All

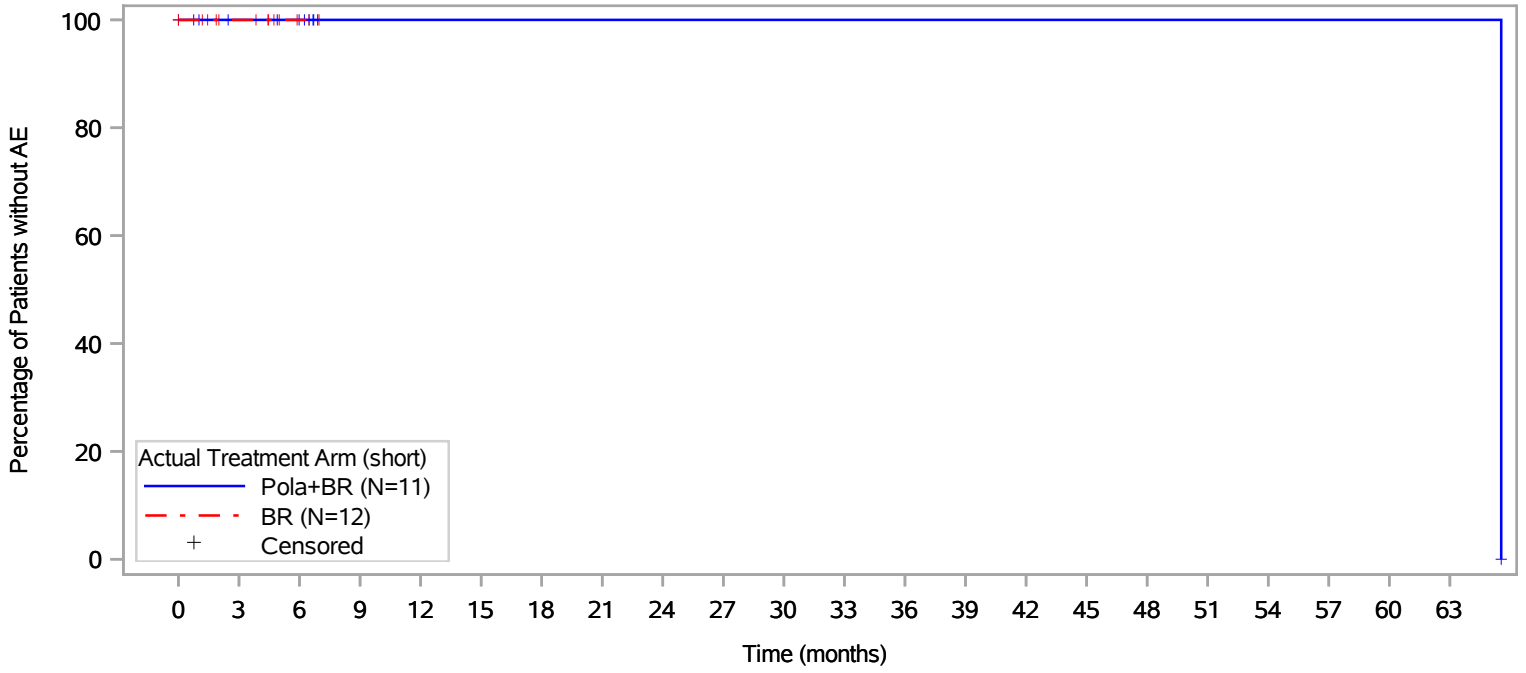


Patients at risk																							
Pola+BR (N=11)	11	8	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=12)	12	8	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=11)	0	3	5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BR (N=12)	0	4	10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



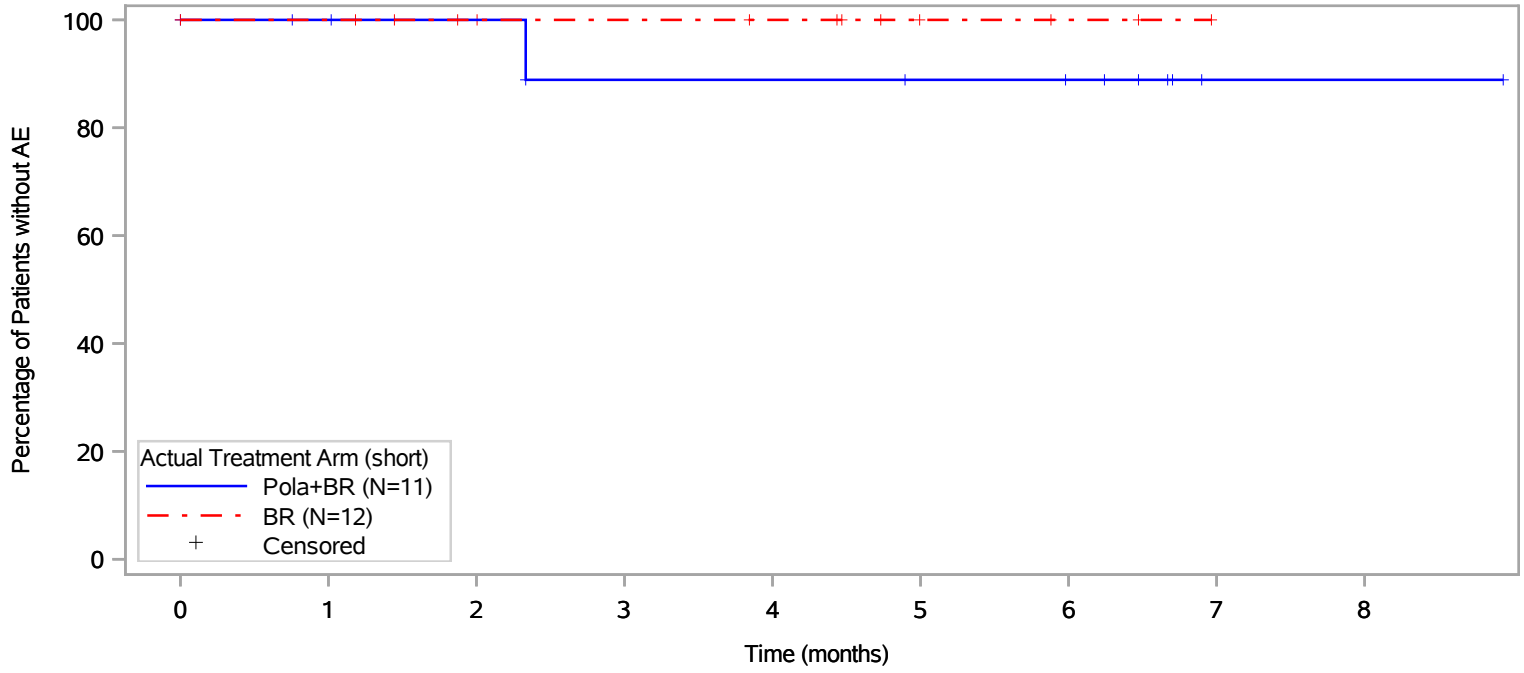
Patients at risk																							
Pola+BR (N=11)	11	8	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=12)	12	8	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=11)	0	3	5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BR (N=12)	0	4	10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
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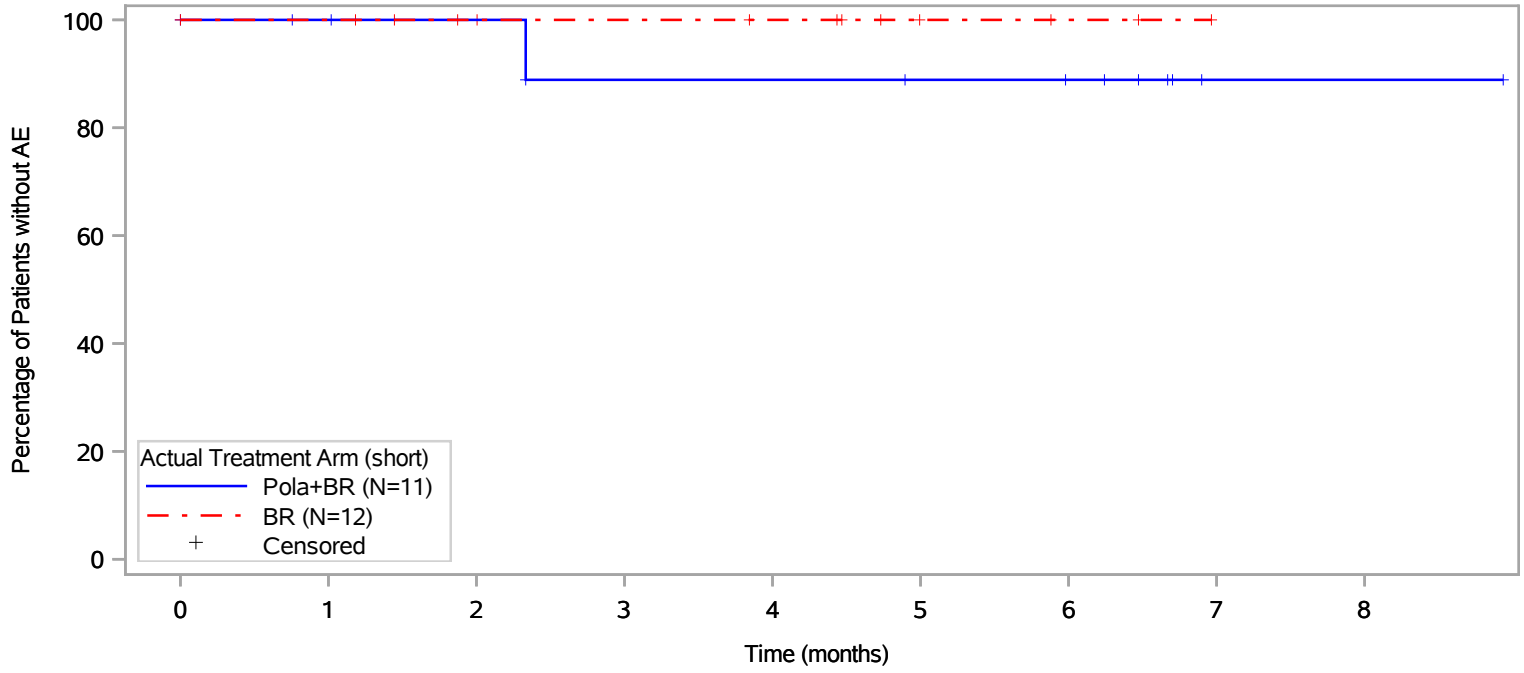
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



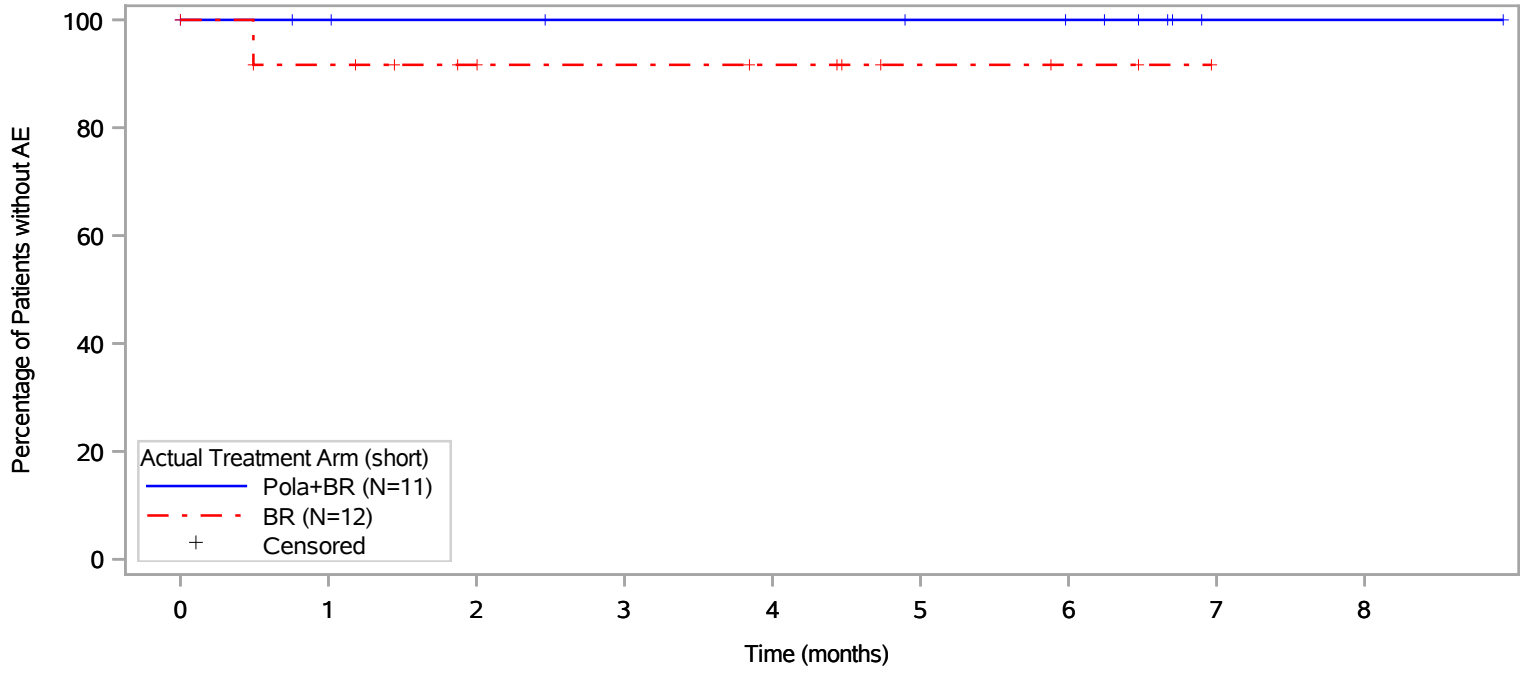
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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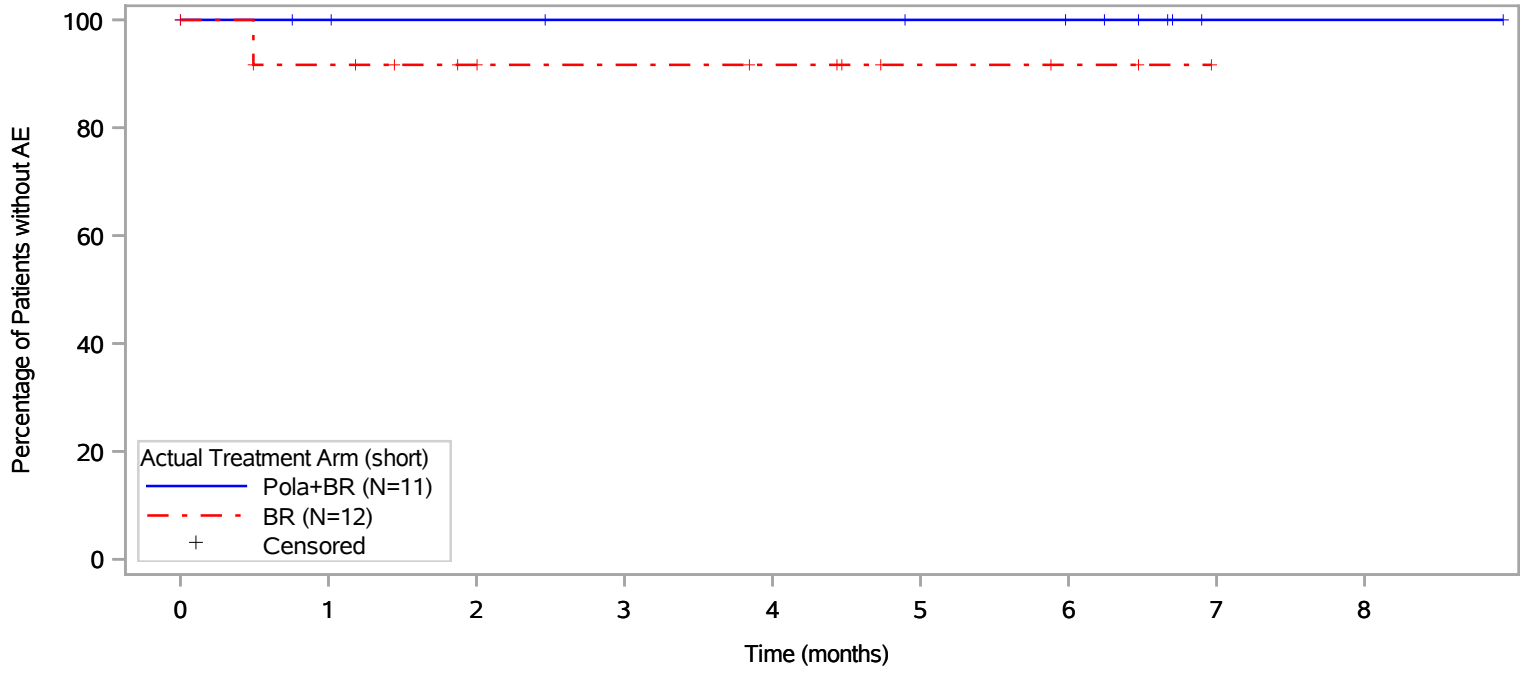
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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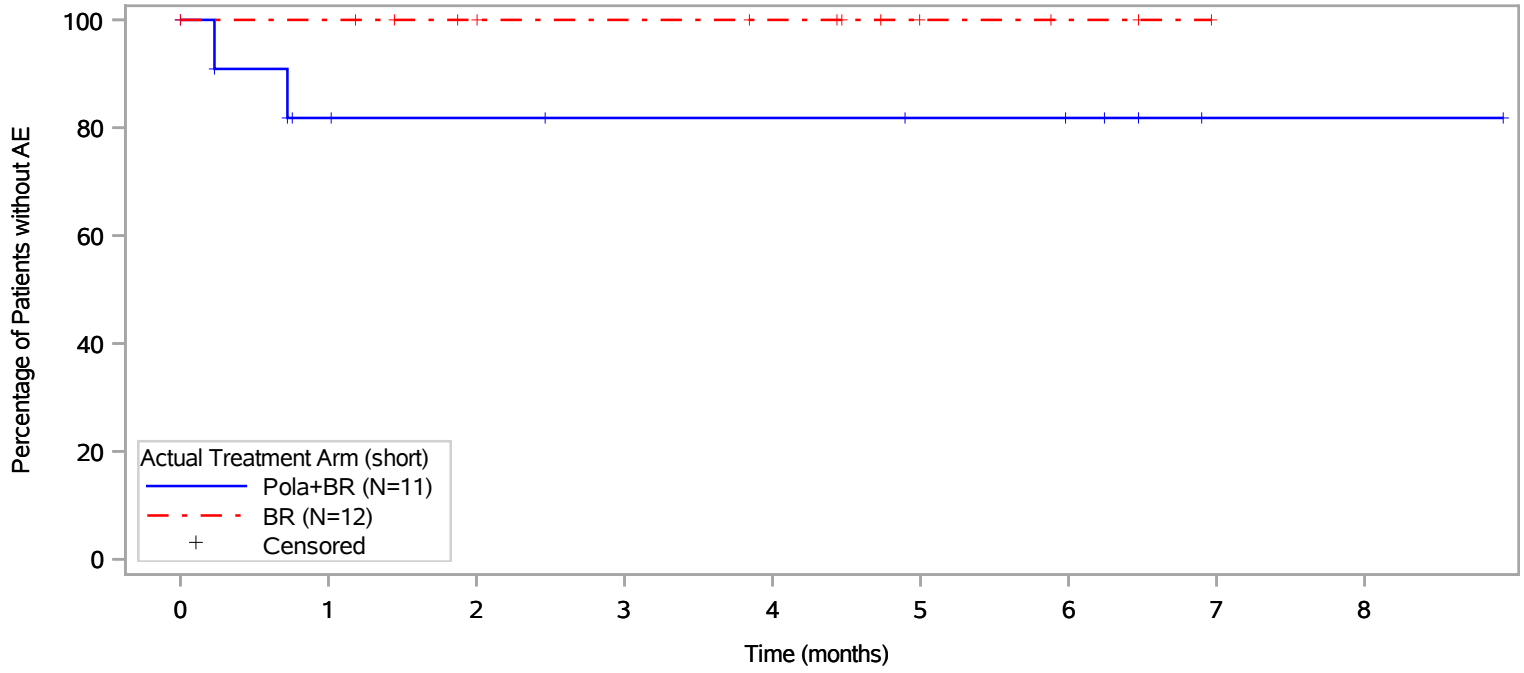
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	8	7	6	6	5	4	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	8	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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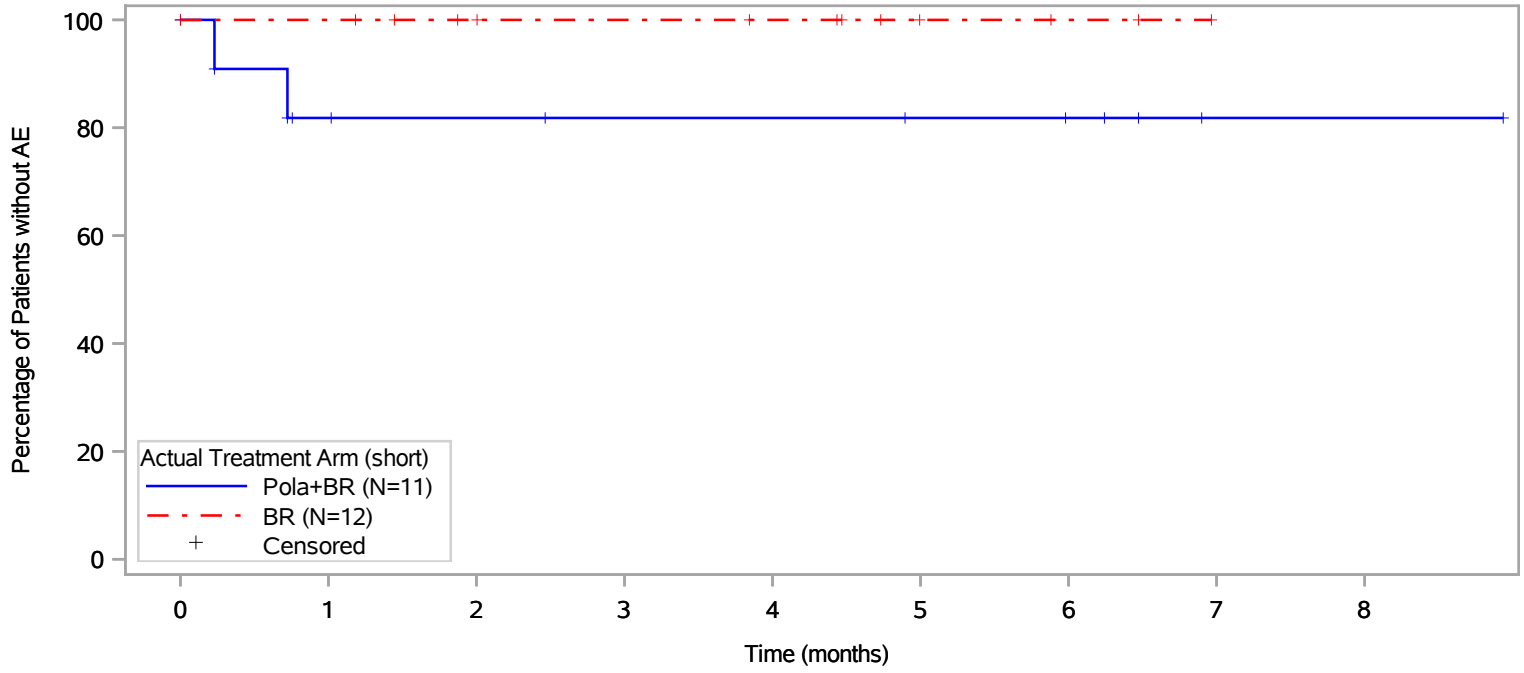
02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION



Patients at risk									
Pola+BR (N=11)	11	8	7	6	6	5	4	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	8	8
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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02DEC2022 2:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			11	100.0	5	45.5	6	54.5	12	100.0	6	50.0	6	50.0	0.9124	0.94	0.28	3.09		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		11	100.0	3	27.3	8	72.7	12	100.0	4	33.3	8	66.7	0.7602	0.79	0.17	3.58		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		11	100.0	1	9.1	10	90.9	12	100.0	3	25.0	9	75.0	0.2581	0.29	0.03	2.83		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			11	100.0	2	18.2	9	81.8	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR4AE_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 0:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	8	72.7	4	50.0	4	50.0	12	100.0	6	50.0	6	50.0	0.8963	1.09	0.30	3.89		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	4	33.3	8	66.7	0.8656	1.14	0.25	5.16		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	3	25.0	9	75.0	0.3929	0.38	0.04	3.74		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3496	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3496	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR4AE_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 0:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	6	54.5	4	66.7	2	33.3	10	83.3	6	60.0	4	40.0	0.3093	1.98	0.52	7.53		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	6	54.5	2	33.3	4	66.7	10	83.3	4	40.0	6	60.0	0.8802	1.14	0.20	6.46		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	3	30.0	7	70.0	0.6247	0.57	0.06	5.53		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR4AE_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 0:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	2	66.7	1	33.3	0.2220	0.25	0.02	2.79		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	4	44.4	5	55.6	0.4673	1.67	0.41	6.81		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.5151	0.41	0.03	6.62		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	3	33.3	6	66.7	0.9530	1.06	0.17	6.52		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	2	22.2	7	77.8	0.6139	0.54	0.05	6.09		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR4AE_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 0:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	63.6	3	42.9	4	57.1	7	58.3	4	57.1	3	42.9	0.6796	0.73	0.16	3.29		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	4	36.4	2	50.0	2	50.0	5	41.7	2	40.0	3	60.0	0.7127	1.46	0.19	11.18		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	3	42.9	4	57.1	0.2712	0.30	0.03	2.92		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	4	36.4	2	50.0	2	50.0	5	41.7	1	20.0	4	80.0	0.4068	2.78	0.23	33.65		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	2	28.6	5	71.4	0.4642	0.41	0.04	4.74		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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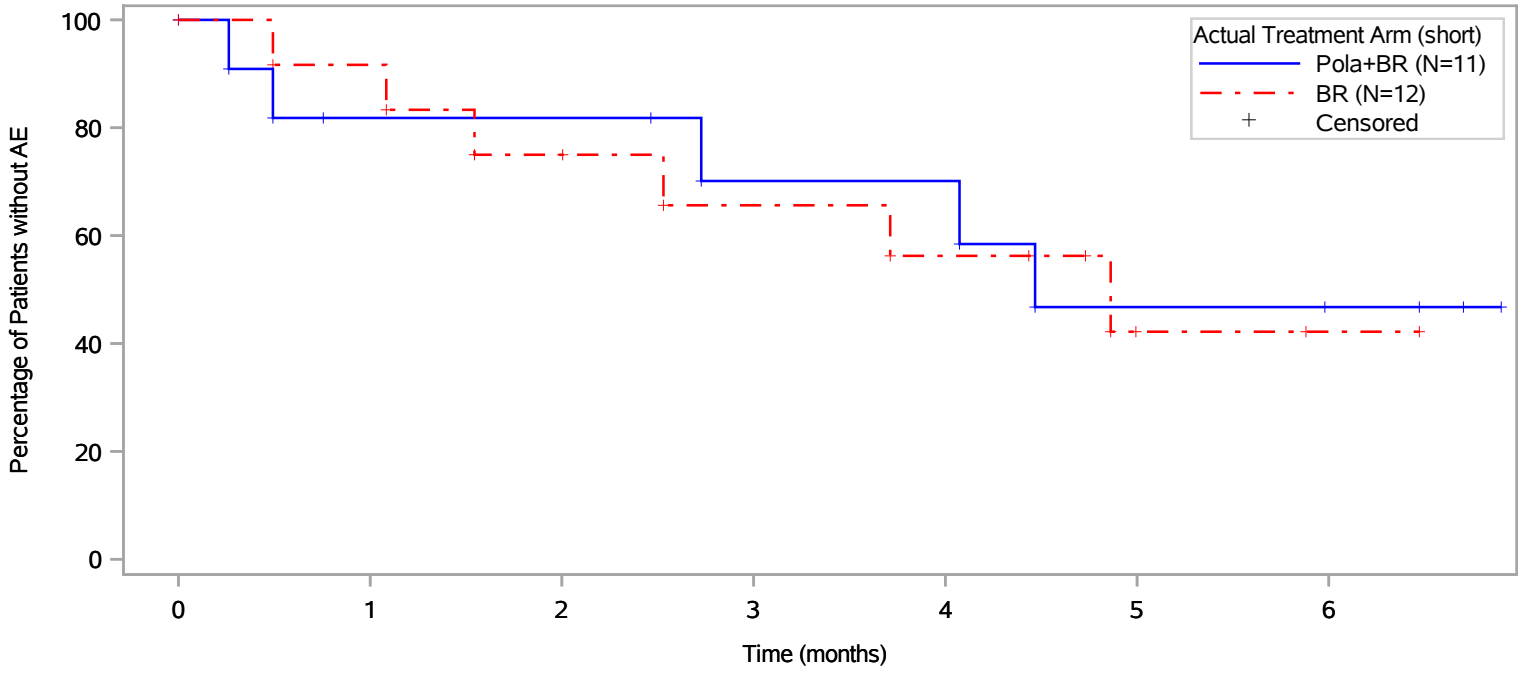
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=11)	11	8	8	6	6	4	3
BR (N=12)	12	11	9	7	6	2	1
Patients censored							
Pola+BR (N=11)	0	1	1	2	2	2	3
BR (N=12)	0	0	0	1	1	4	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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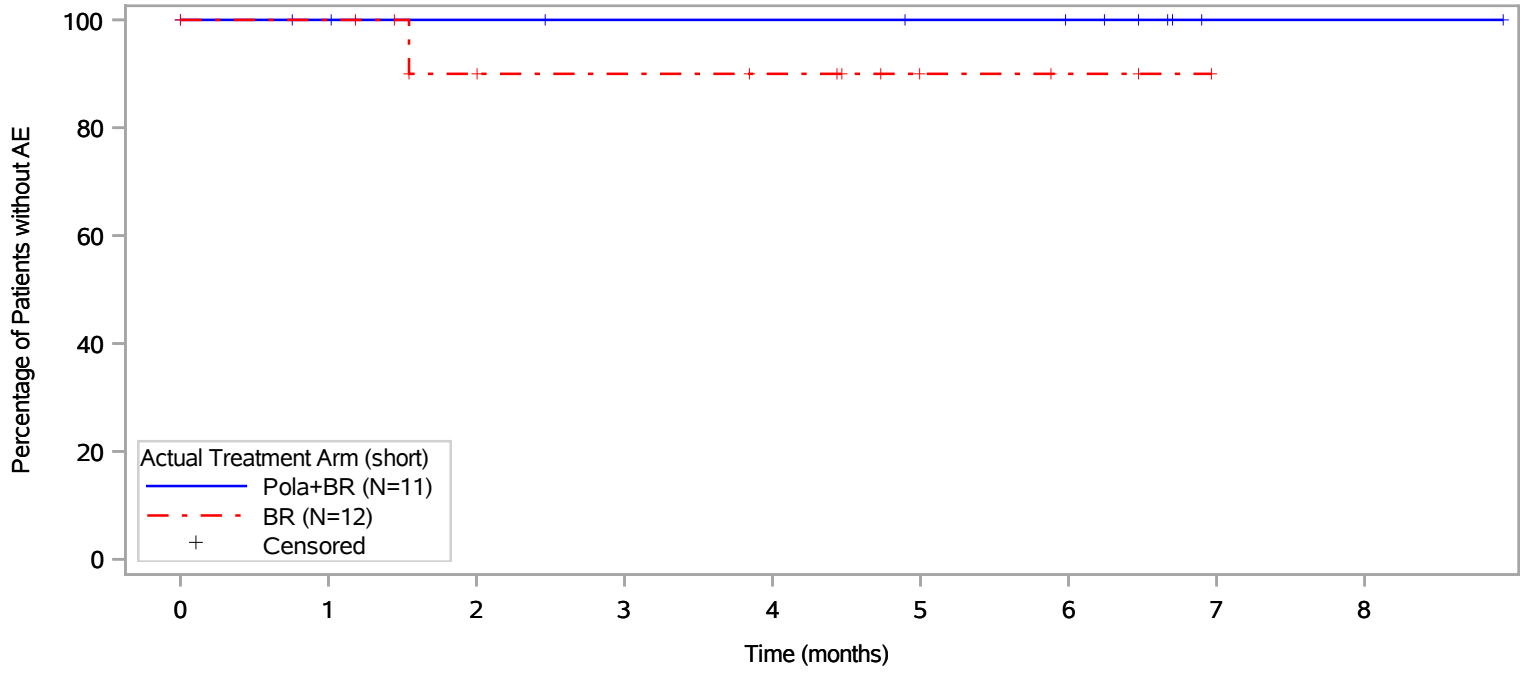
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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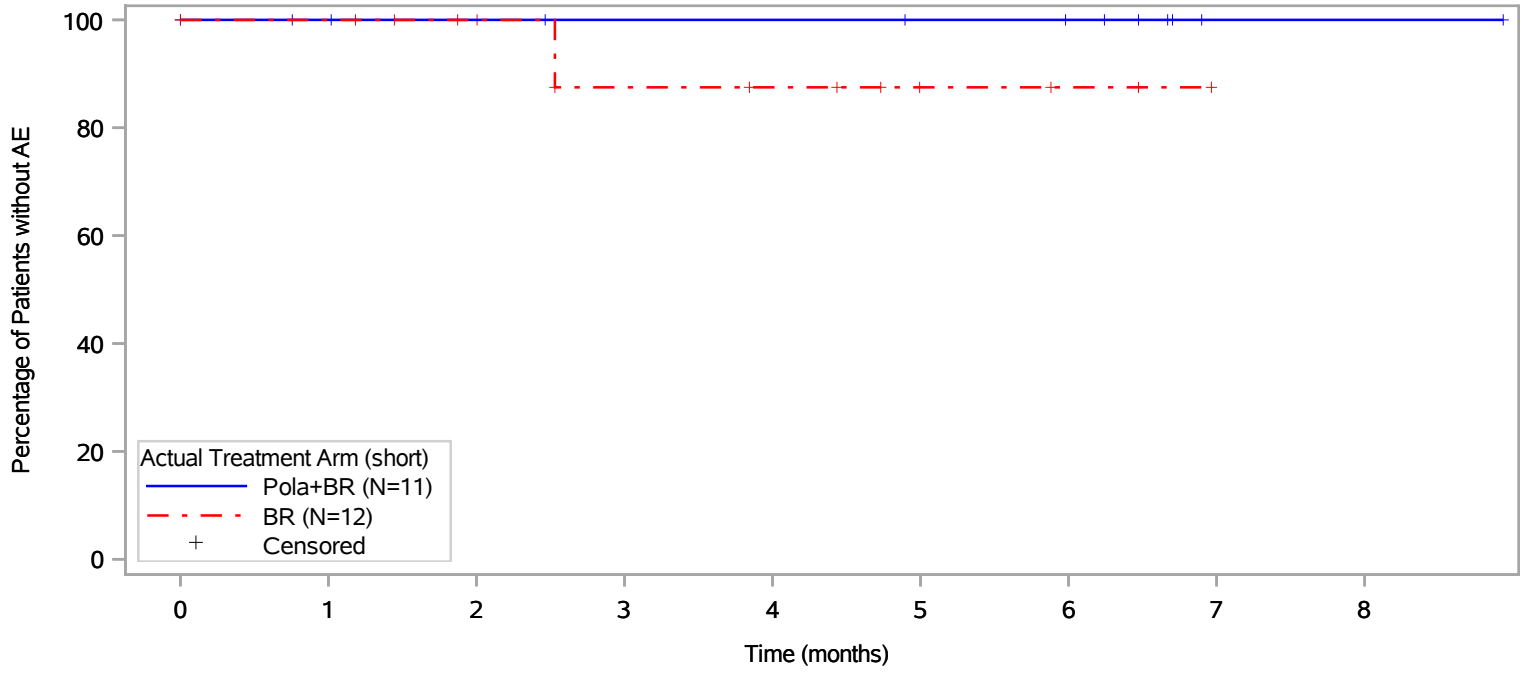
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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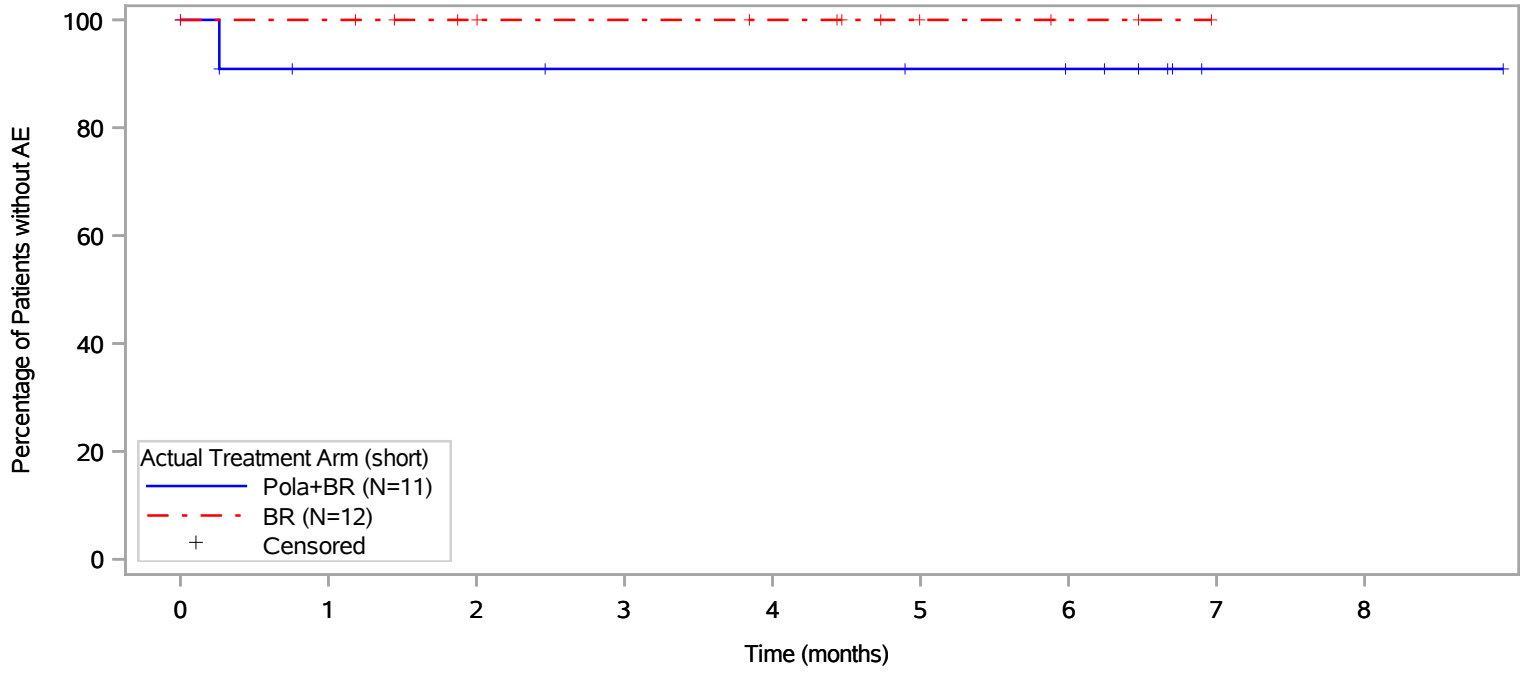
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA



Patients at risk								
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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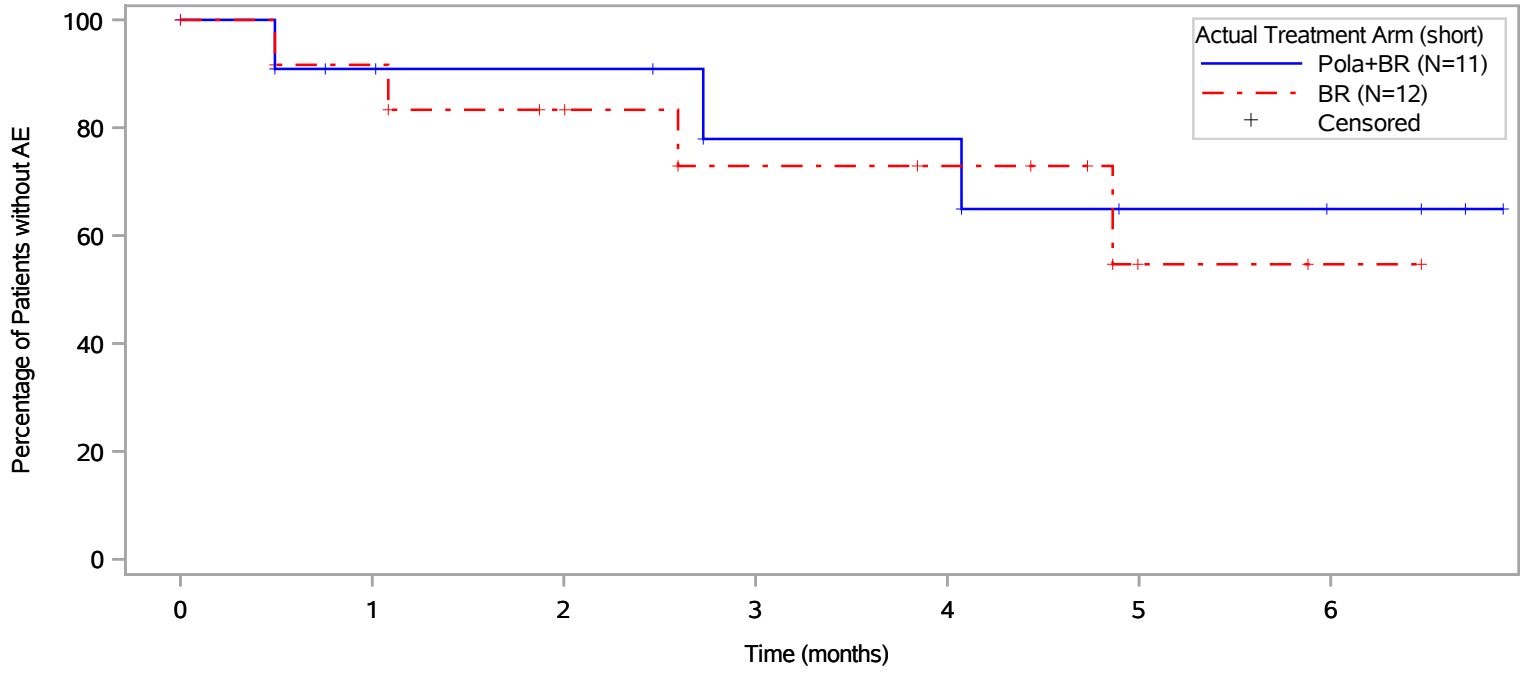
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk							
Pola+BR (N=11)	11	9	8	6	6	4	3
BR (N=12)	12	11	9	7	6	2	1
Patients censored							
Pola+BR (N=11)	0	1	2	3	3	4	5
BR (N=12)	0	0	1	2	3	6	7

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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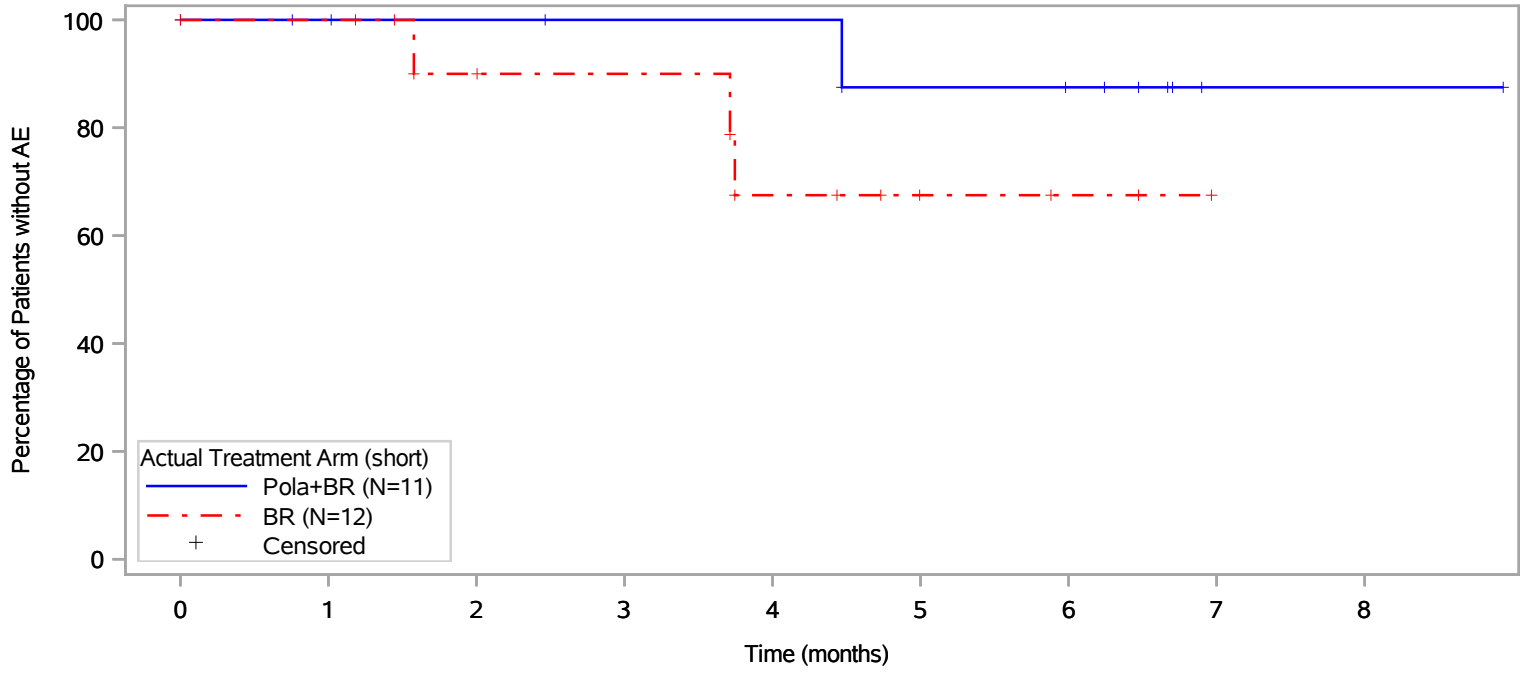
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	4	9	9
BR (N=12)	0	0	2	3	3	6	7	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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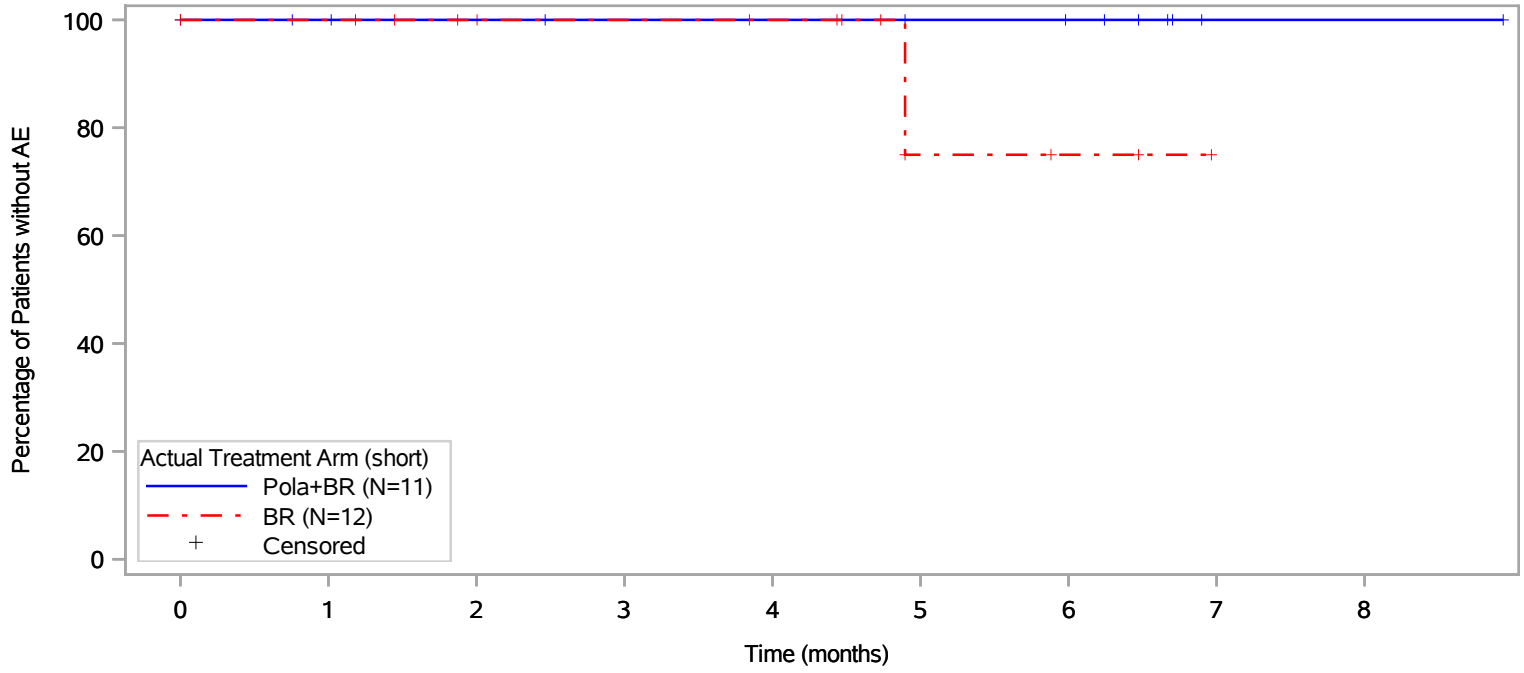
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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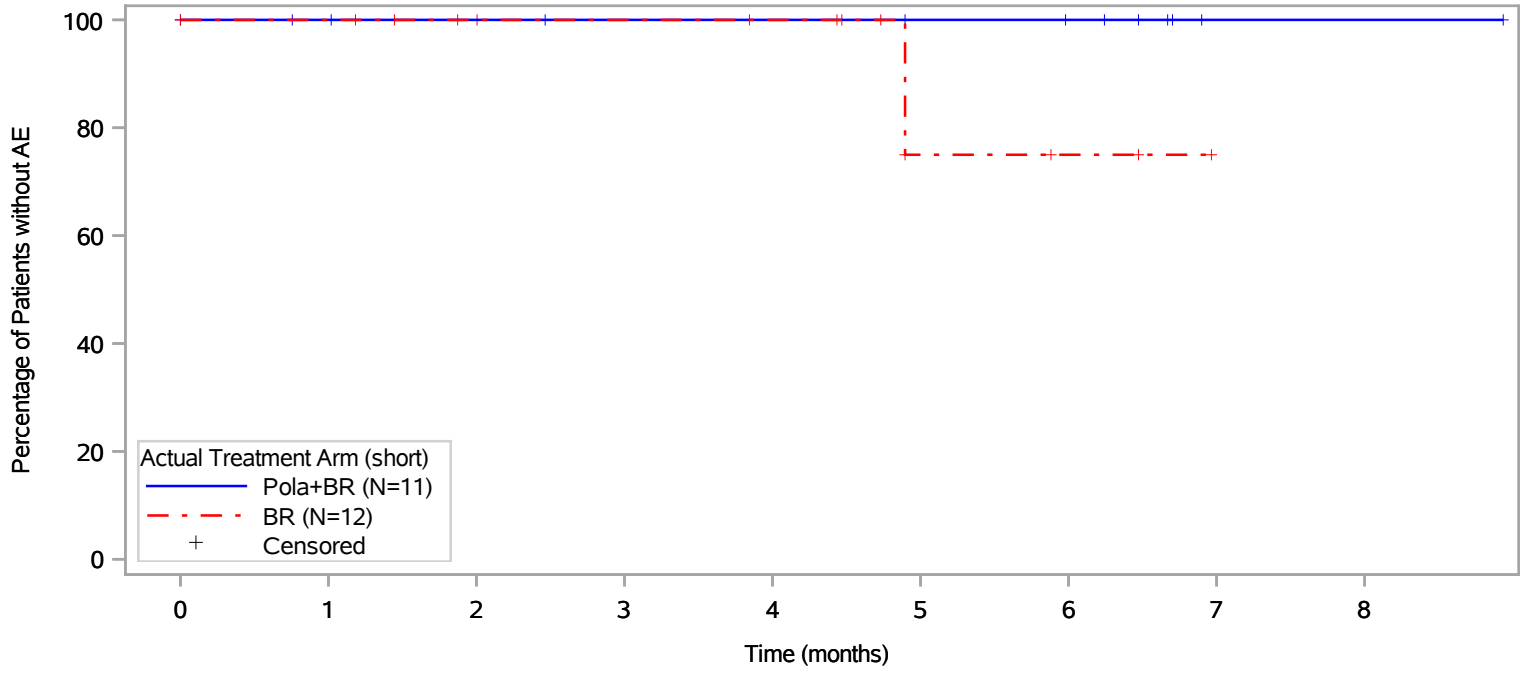
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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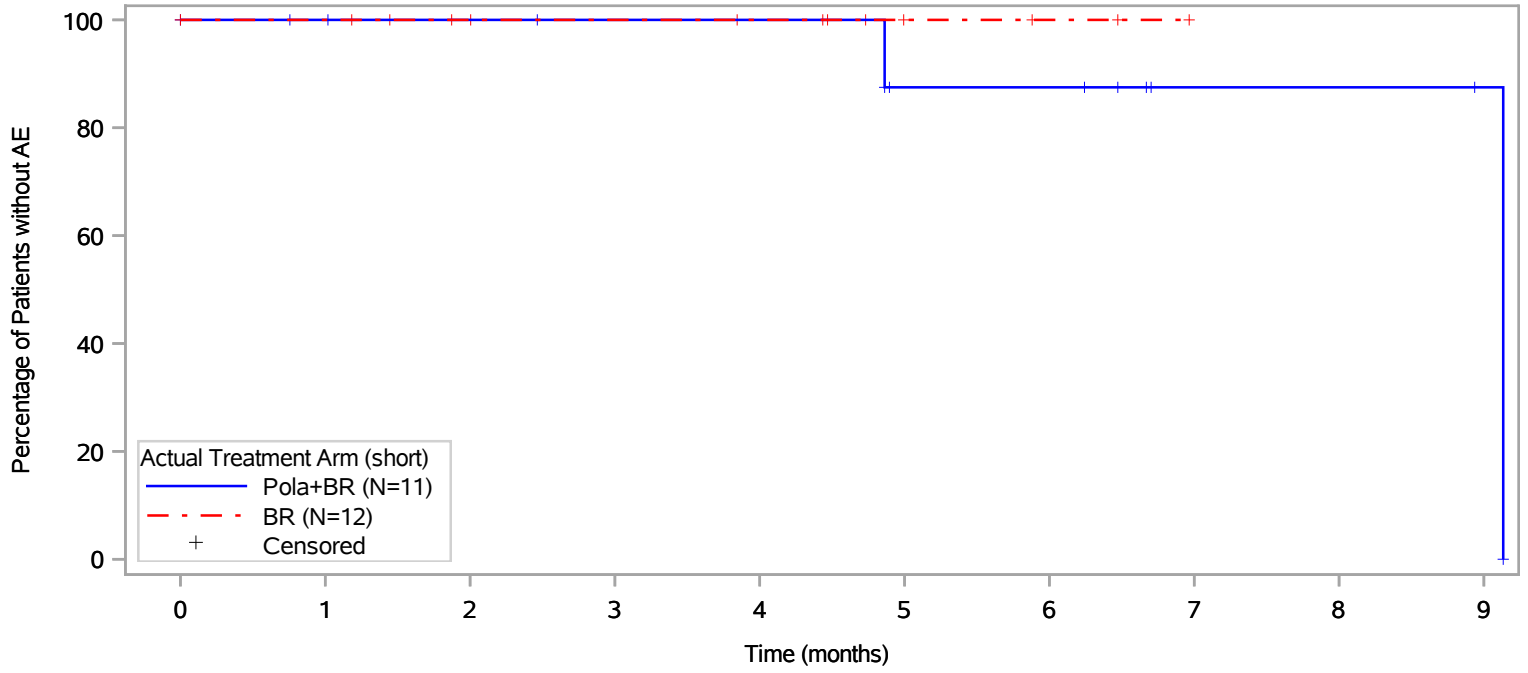
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All

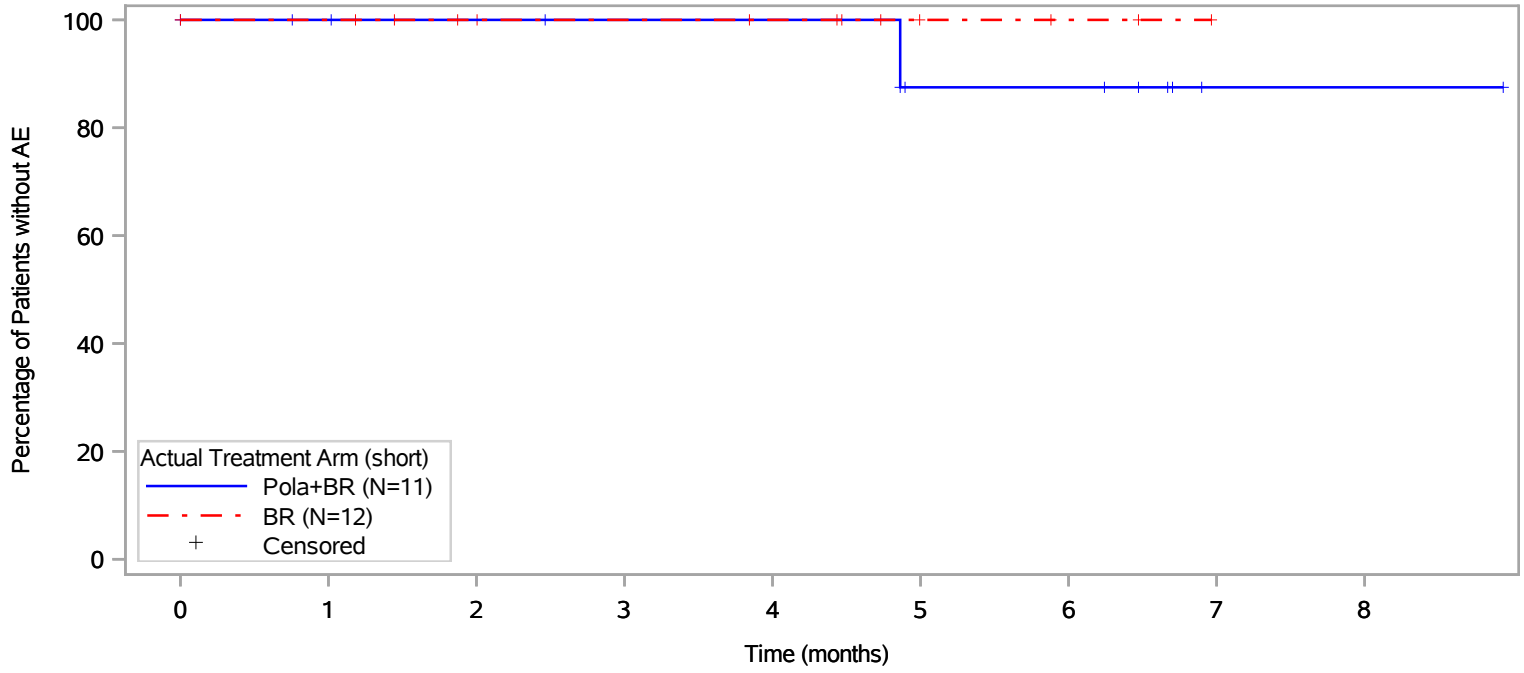


Patients at risk										
Pola+BR (N=11)	11	10	9	8	8	6	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored										
Pola+BR (N=11)	0	1	2	3	3	4	4	8	8	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR4AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 4:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CEREBRAL TOXOPLASMOSIS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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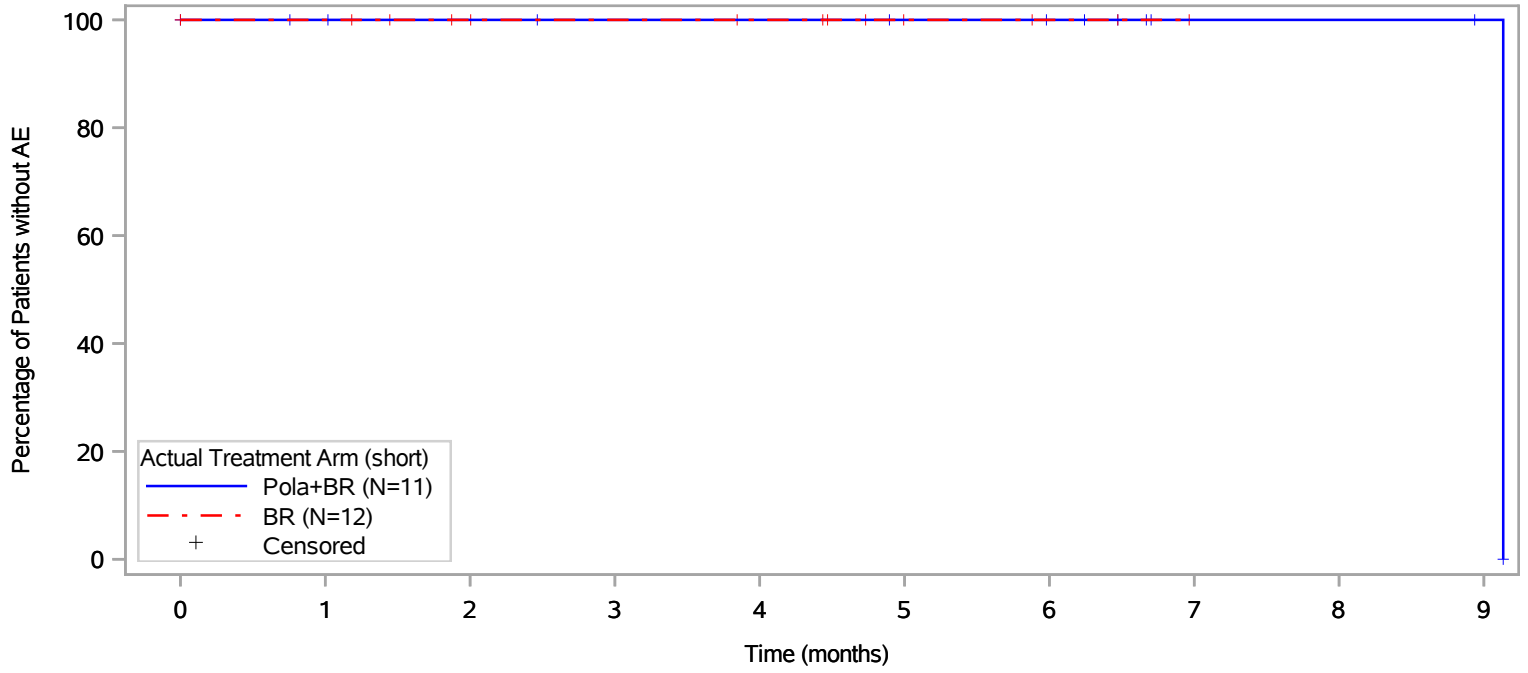
02DEC2022 4:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES VIRUS INFECTION



Patients at risk										
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored										
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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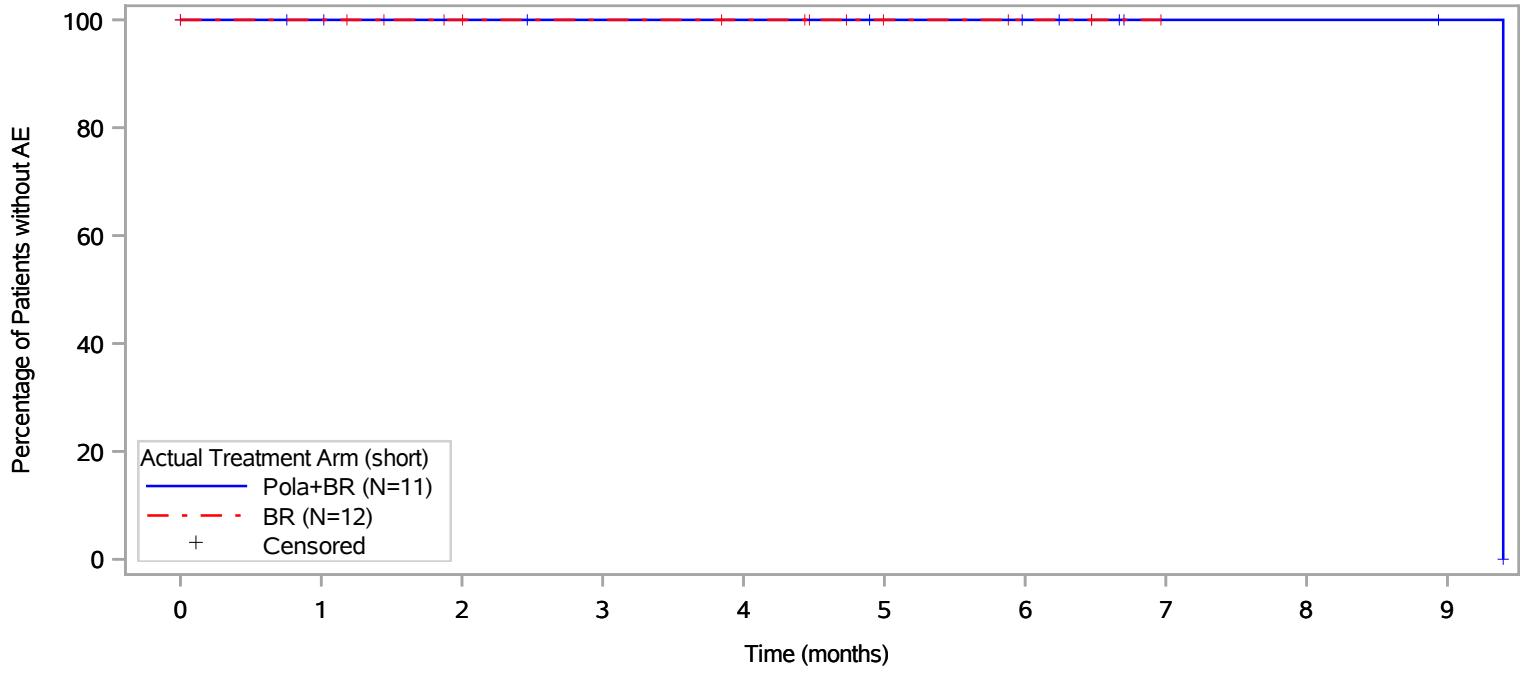
02DEC2022 4:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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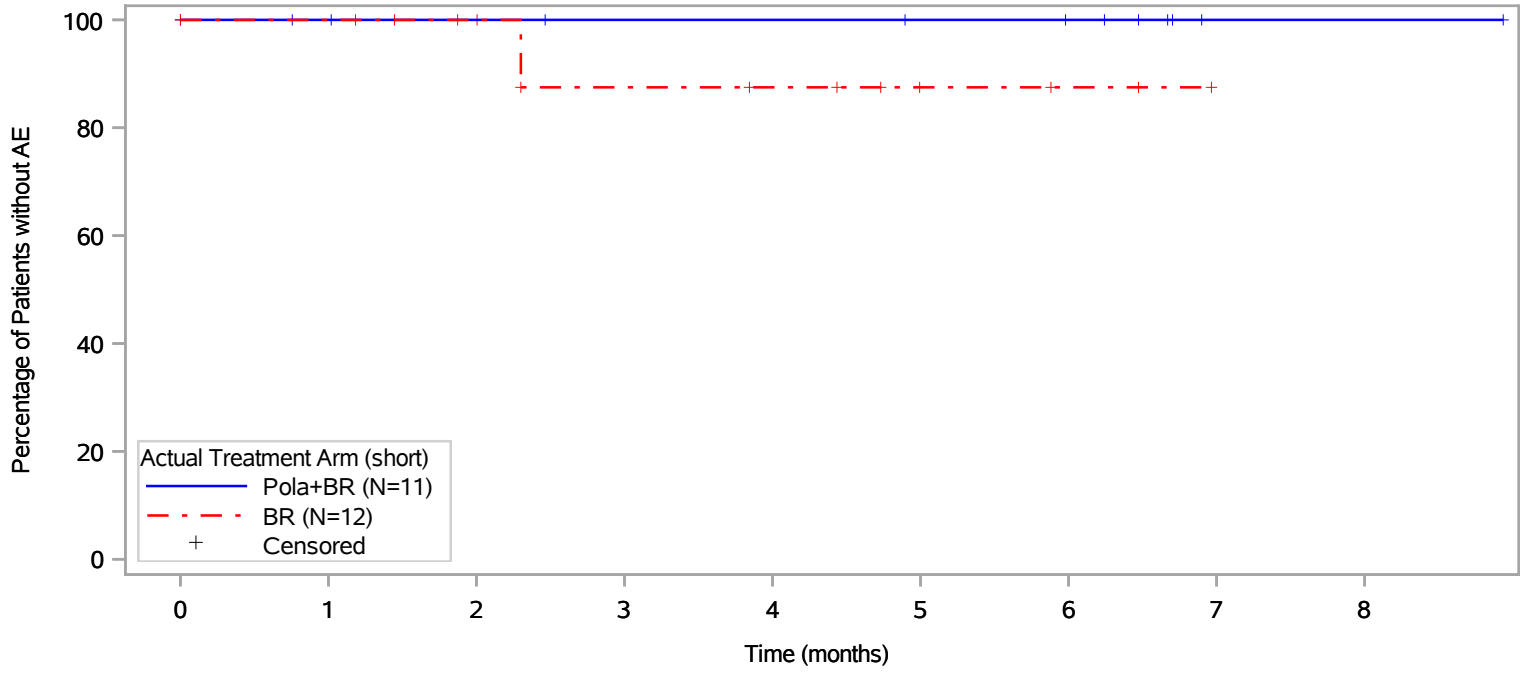
02DEC2022 4:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

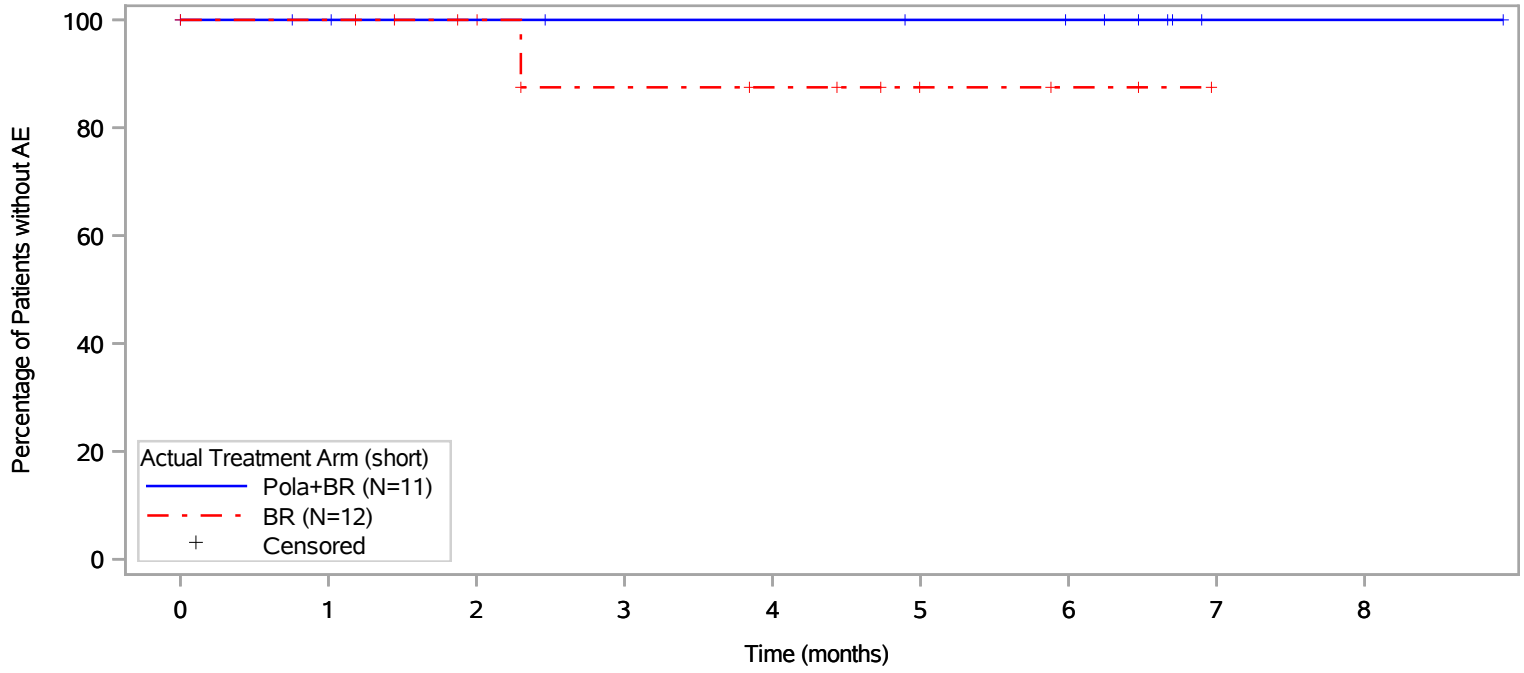


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR4AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 4:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



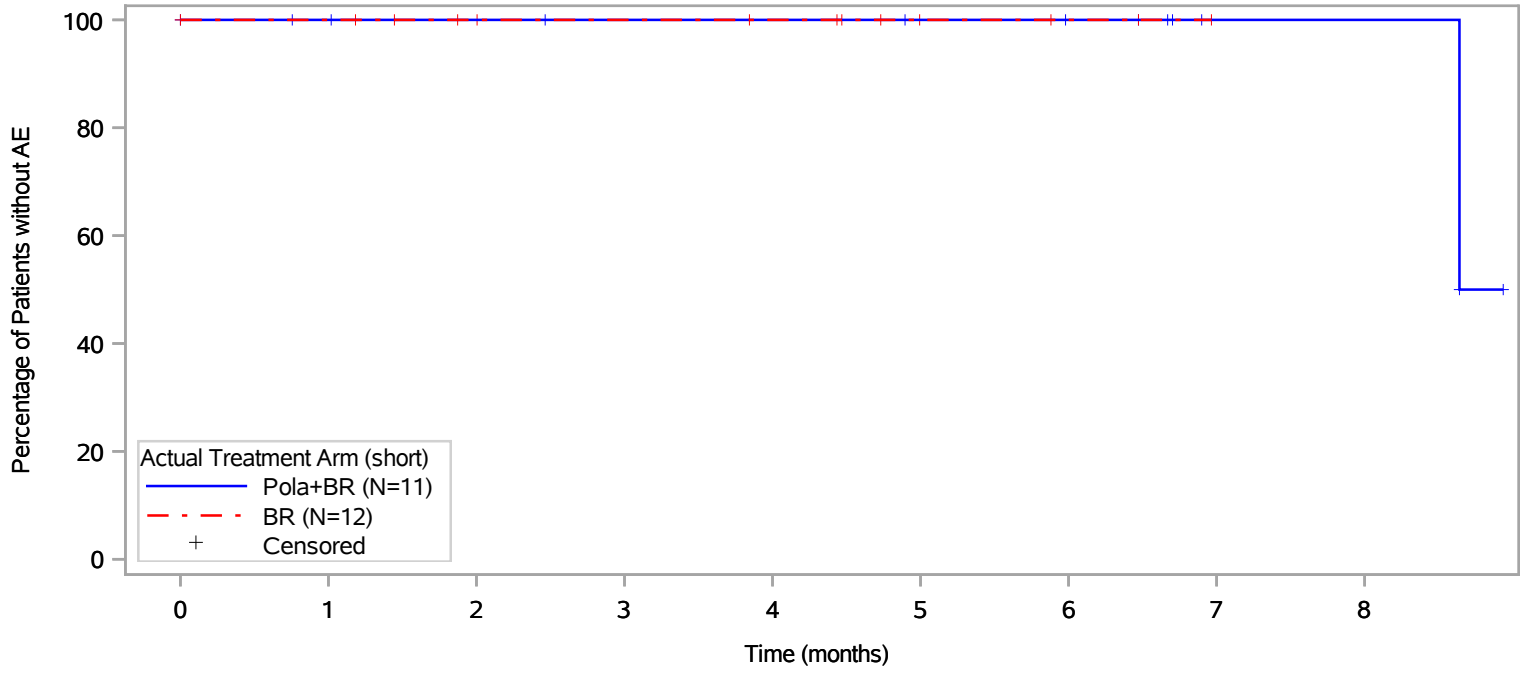
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR4AE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 4:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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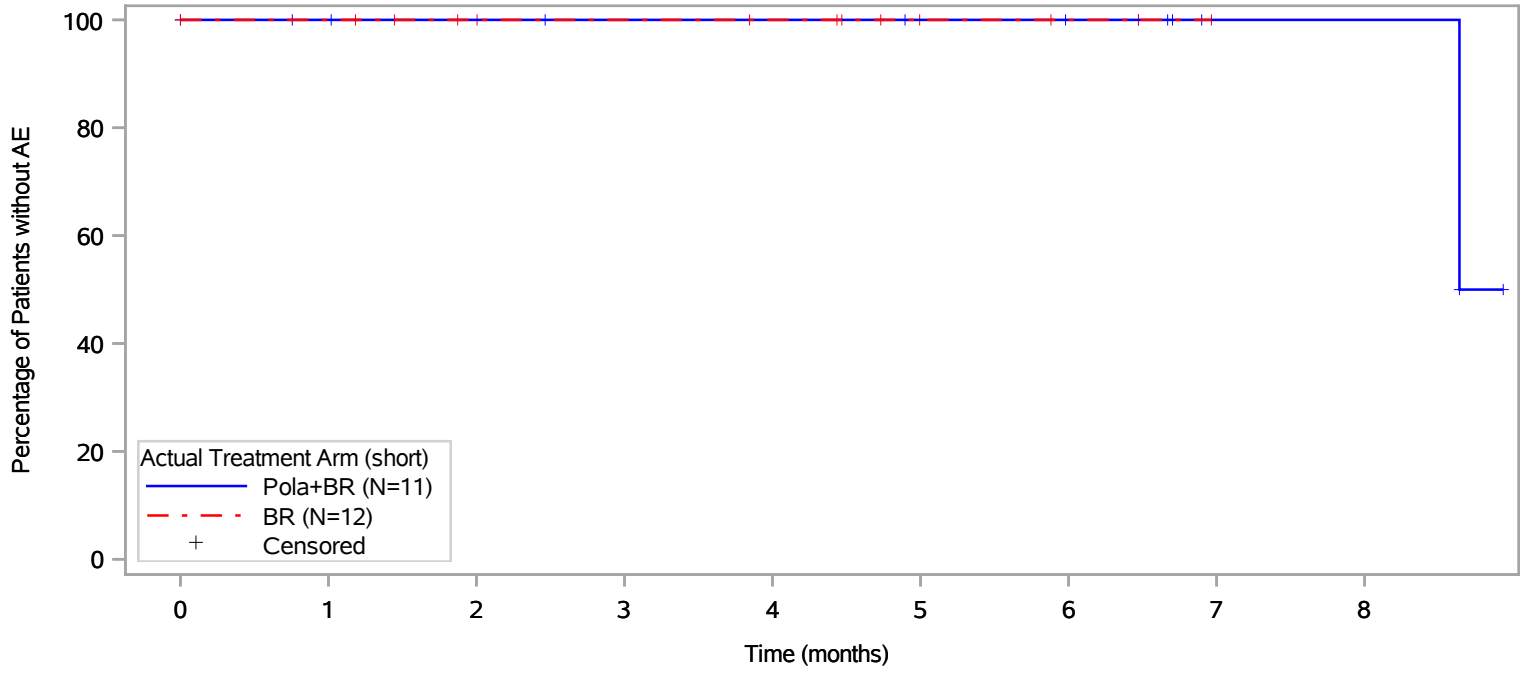
02DEC2022 4:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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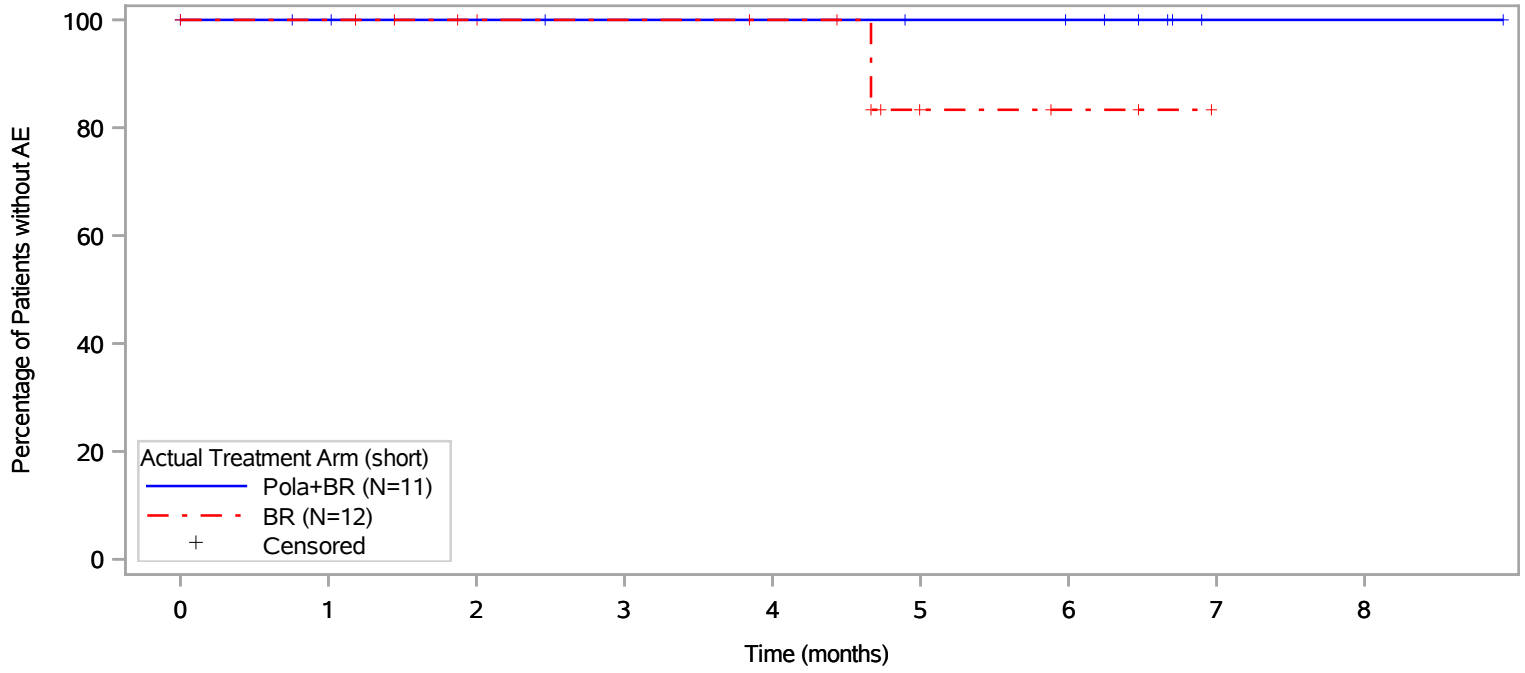
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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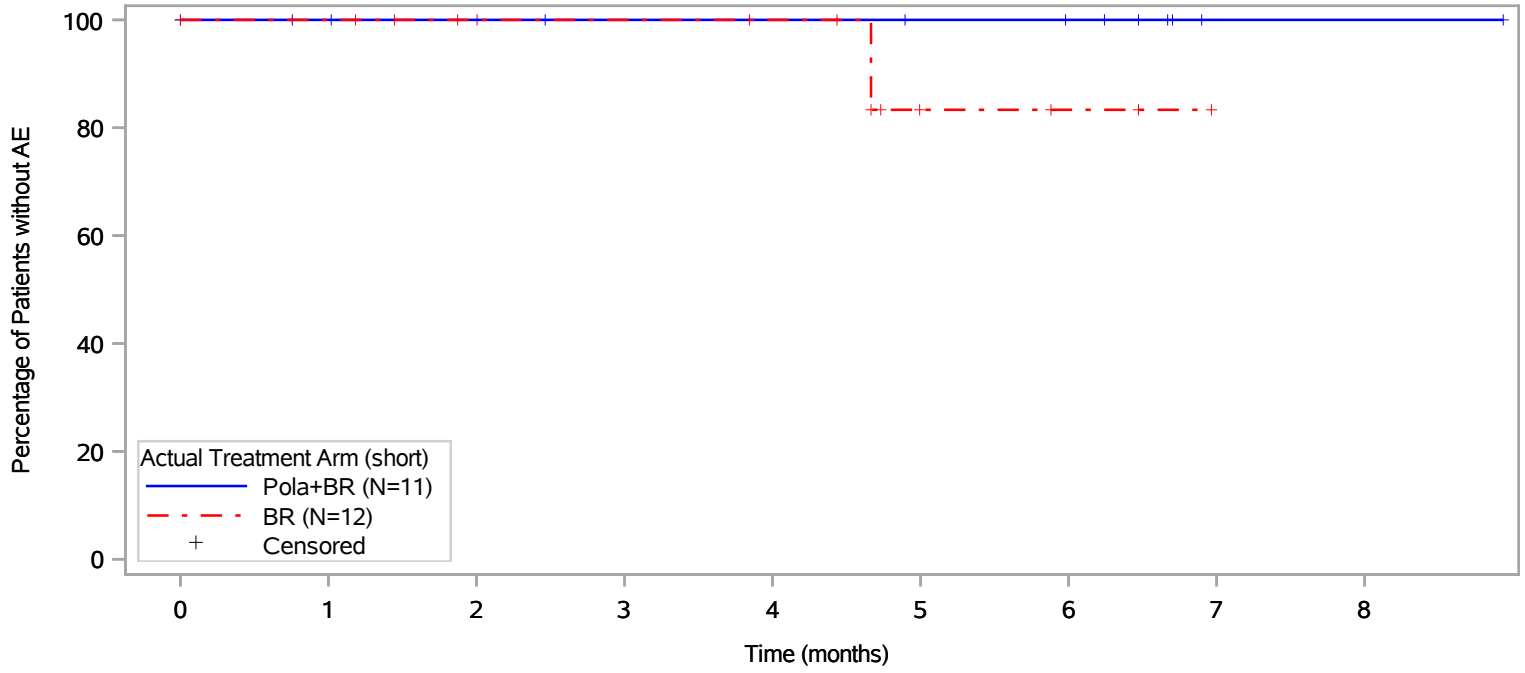
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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02DEC2022 4:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			11	100.0	3	27.3	8	72.7	12	100.0	2	16.7	10	83.3	0.5609	0.50	0.04	5.50		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR5AE_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 1:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS		>= 65	8	72.7	3	37.5	5	62.5	12	100.0	2	16.7	10	83.3	0.7205	0.65	0.06	7.15		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR5AE_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 1:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.0253				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.0253				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS		>=3	6	54.5	2	33.3	4	66.7	10	83.3	2	20.0	8	80.0	0.9358	0.91	0.08	10.04		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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01DEC2022 1:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	1	11.1	8	88.9	0.9055	1.18	0.07	19.10		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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01DEC2022 1:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	7	63.6	2	28.6	5	71.4	7	58.3	1	14.3	6	85.7	0.9885	0.98	0.06	15.89		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	4	36.4	1	25.0	3	75.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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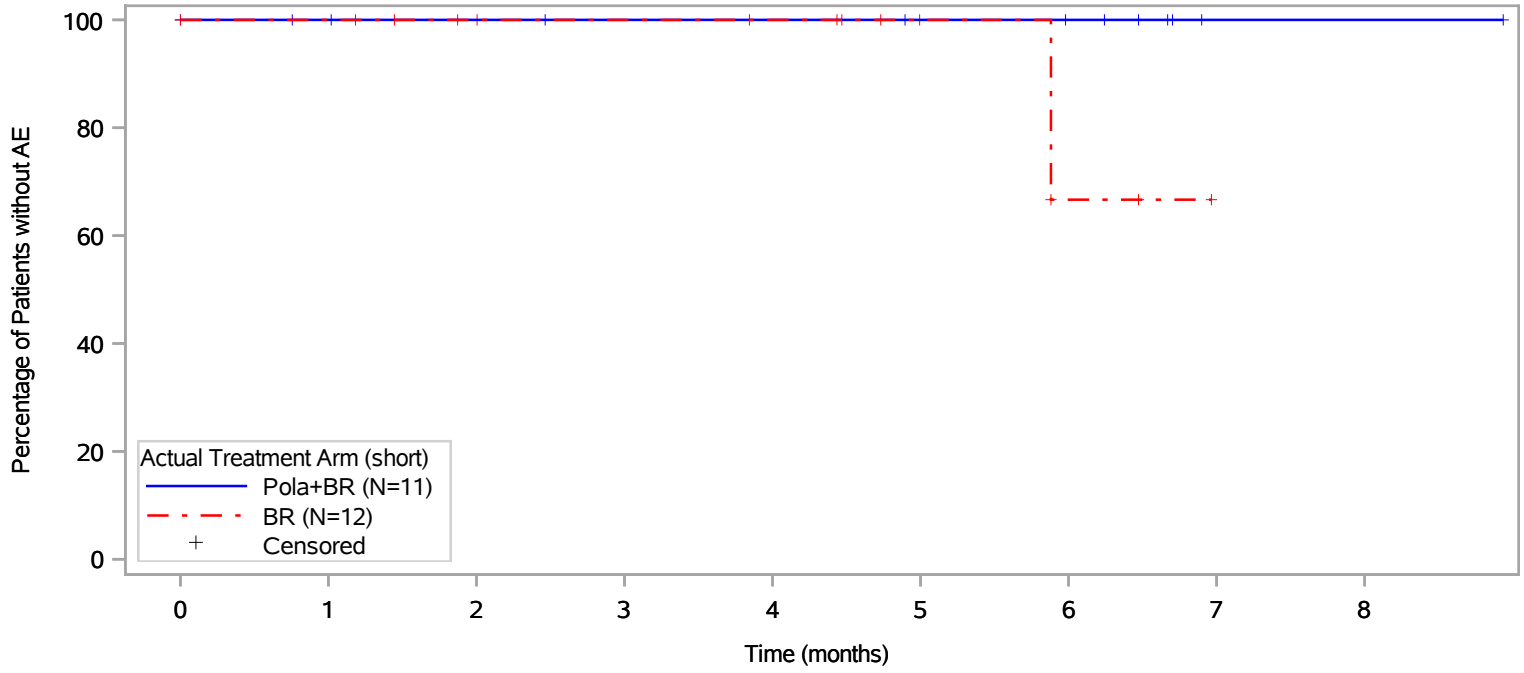
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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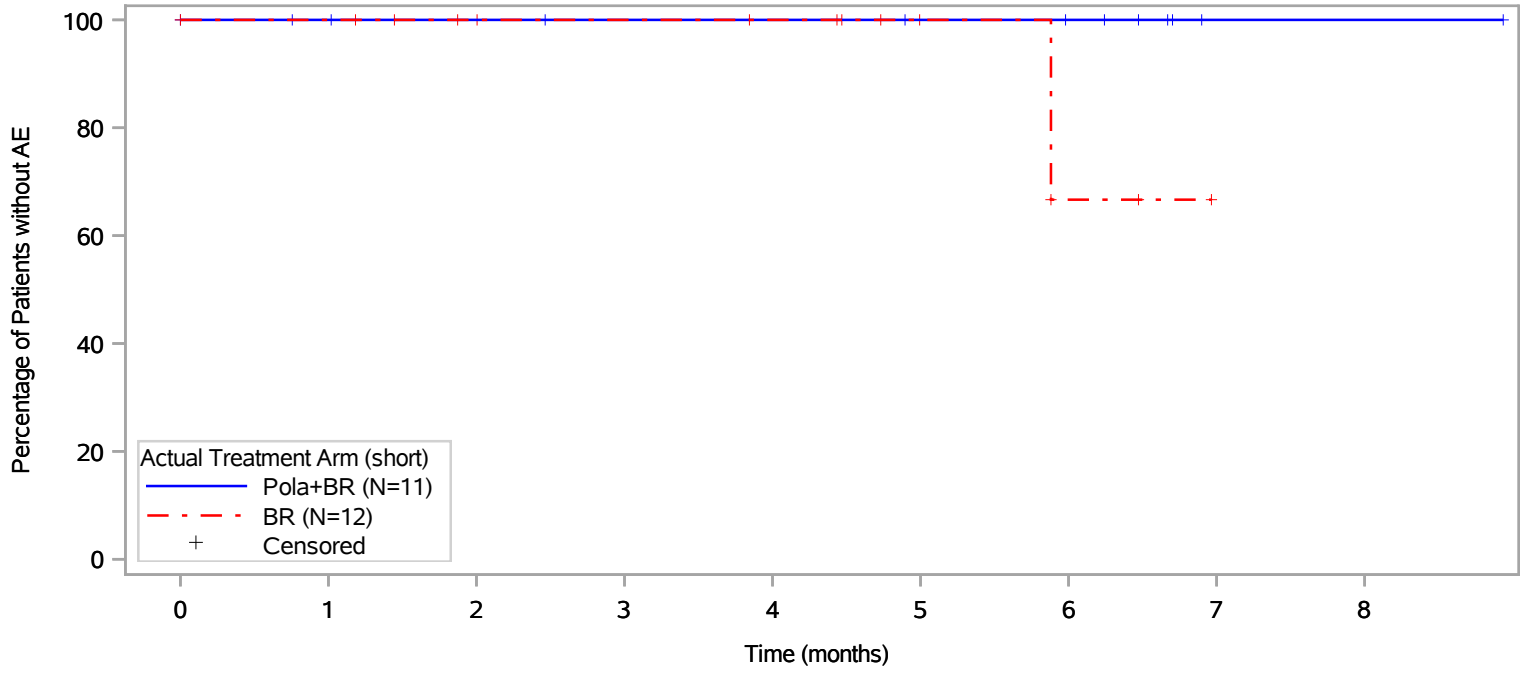
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DEATH



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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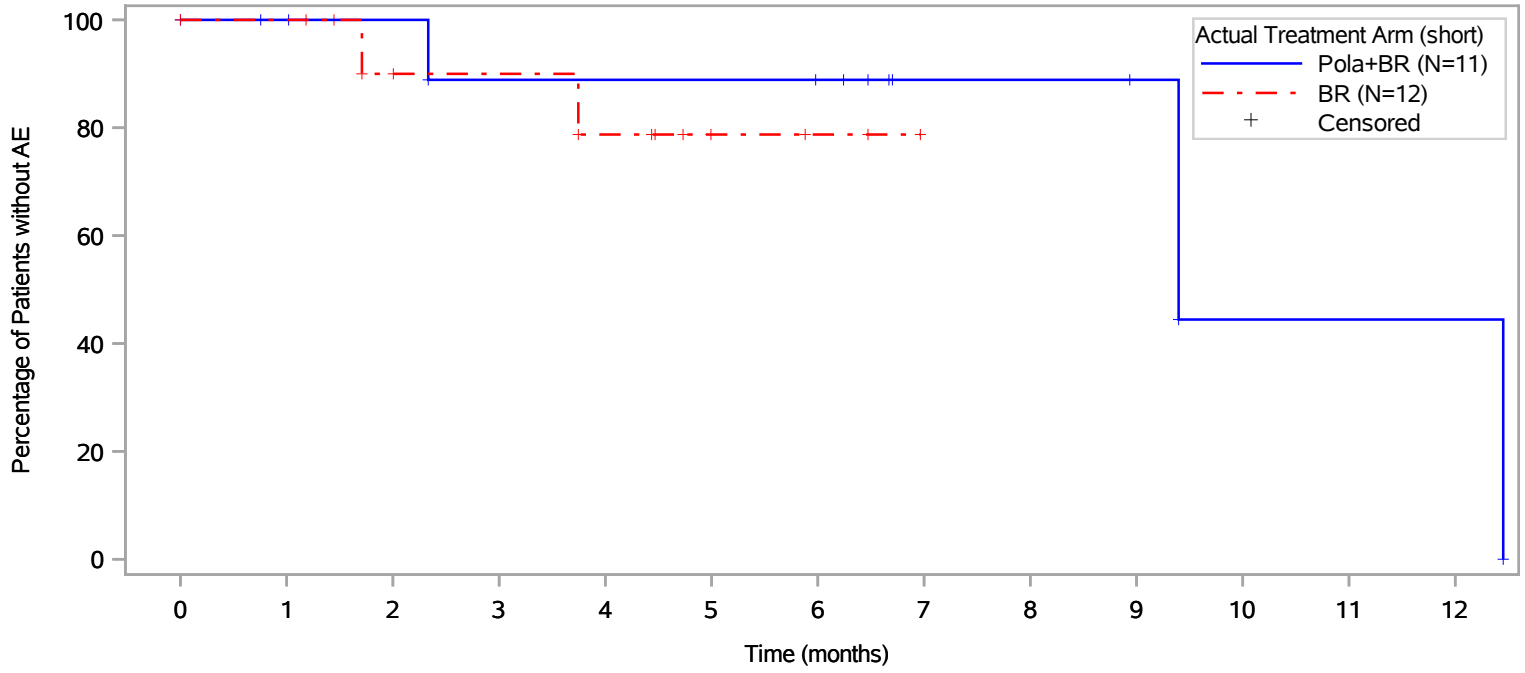
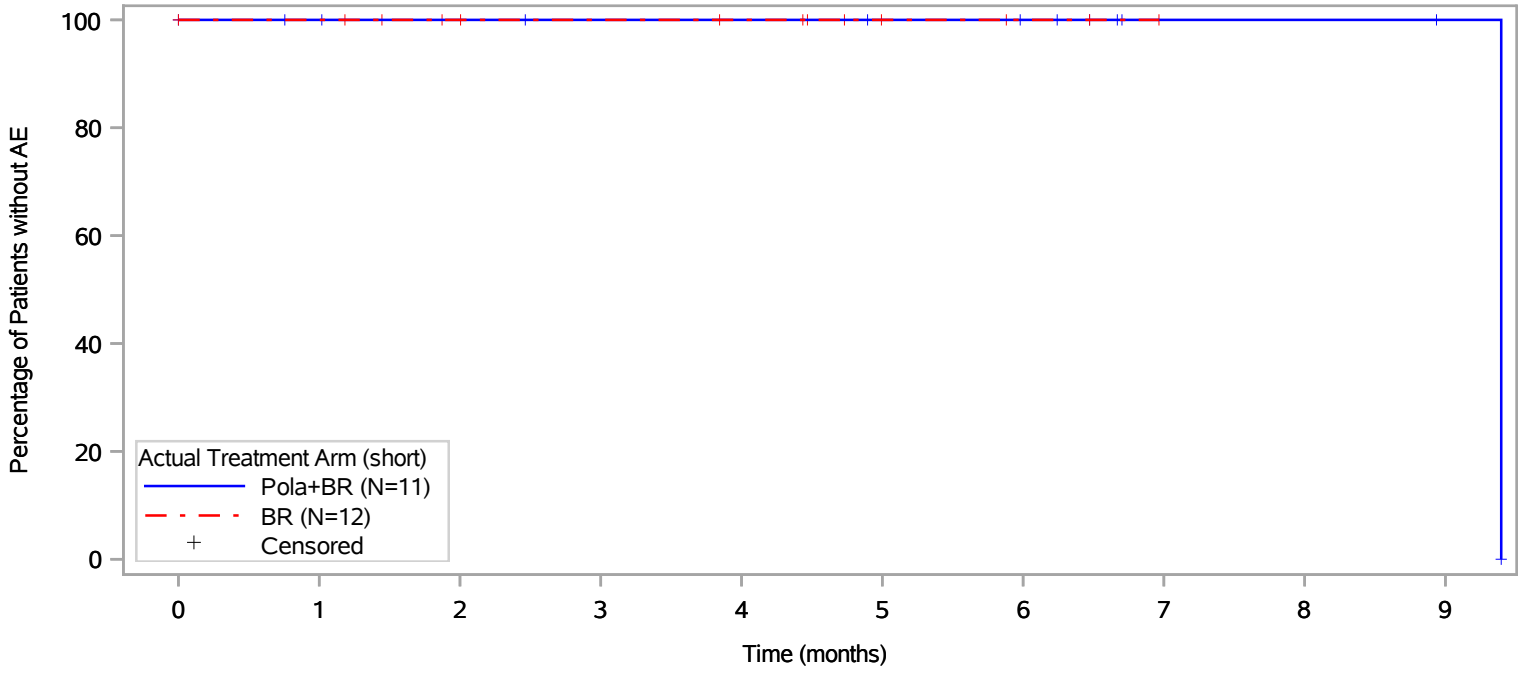
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk													
Pola+BR (N=11)	11	10	9	8	8	8	7	3	3	2	1	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	2	2	2	2	3	7	7	8	8	8	8
BR (N=12)	0	0	2	3	3	7	8	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MENINGOENCEPHALITIS HERPETIC



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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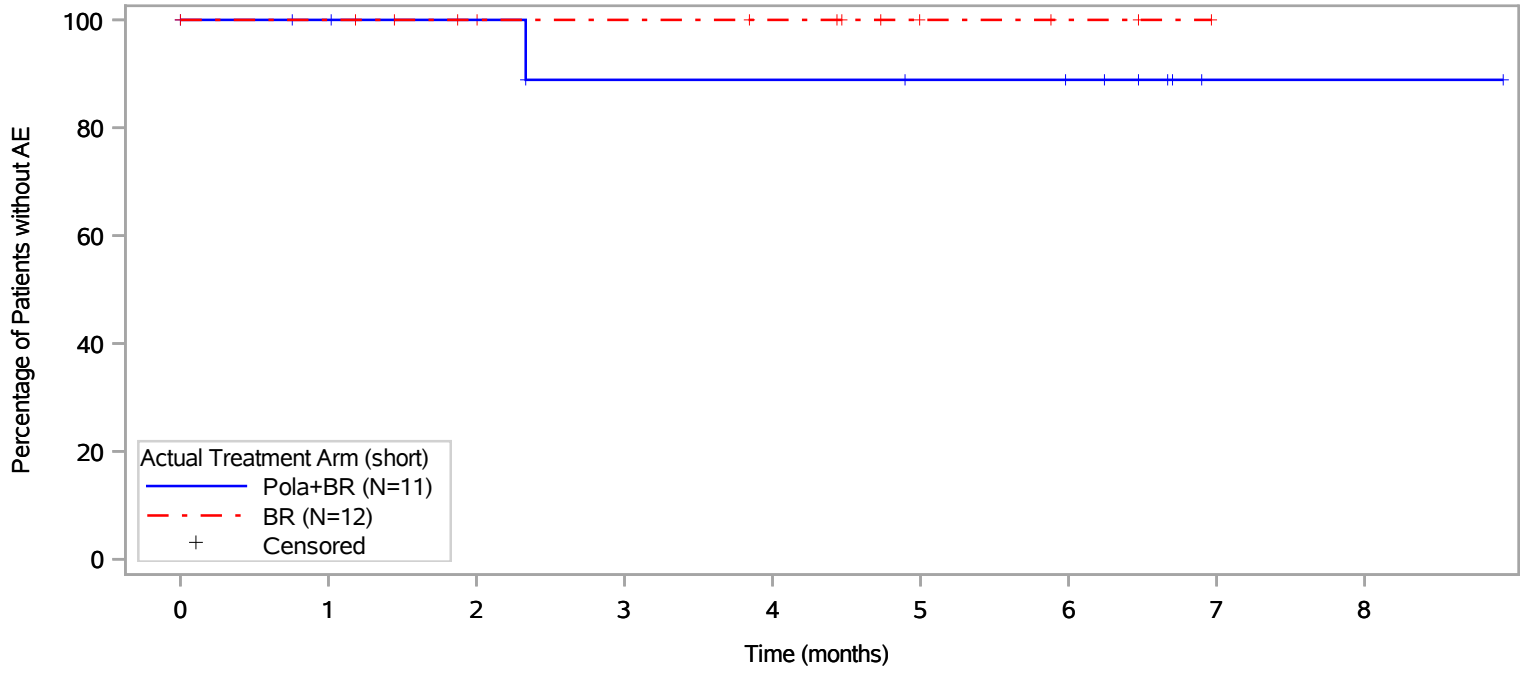
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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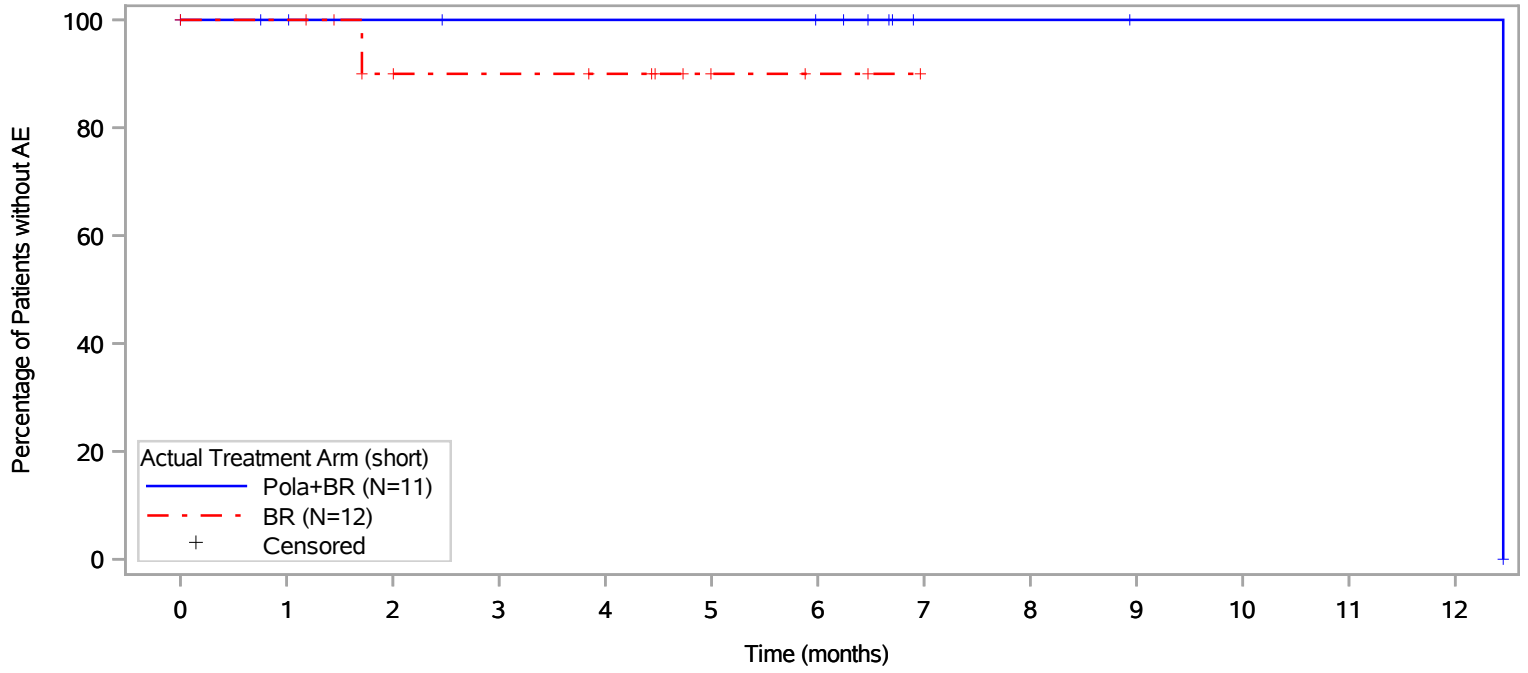
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk													
Pola+BR (N=11)	11	10	9	8	8	8	7	2	2	1	1	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	2	3	3	3	4	9	9	10	10	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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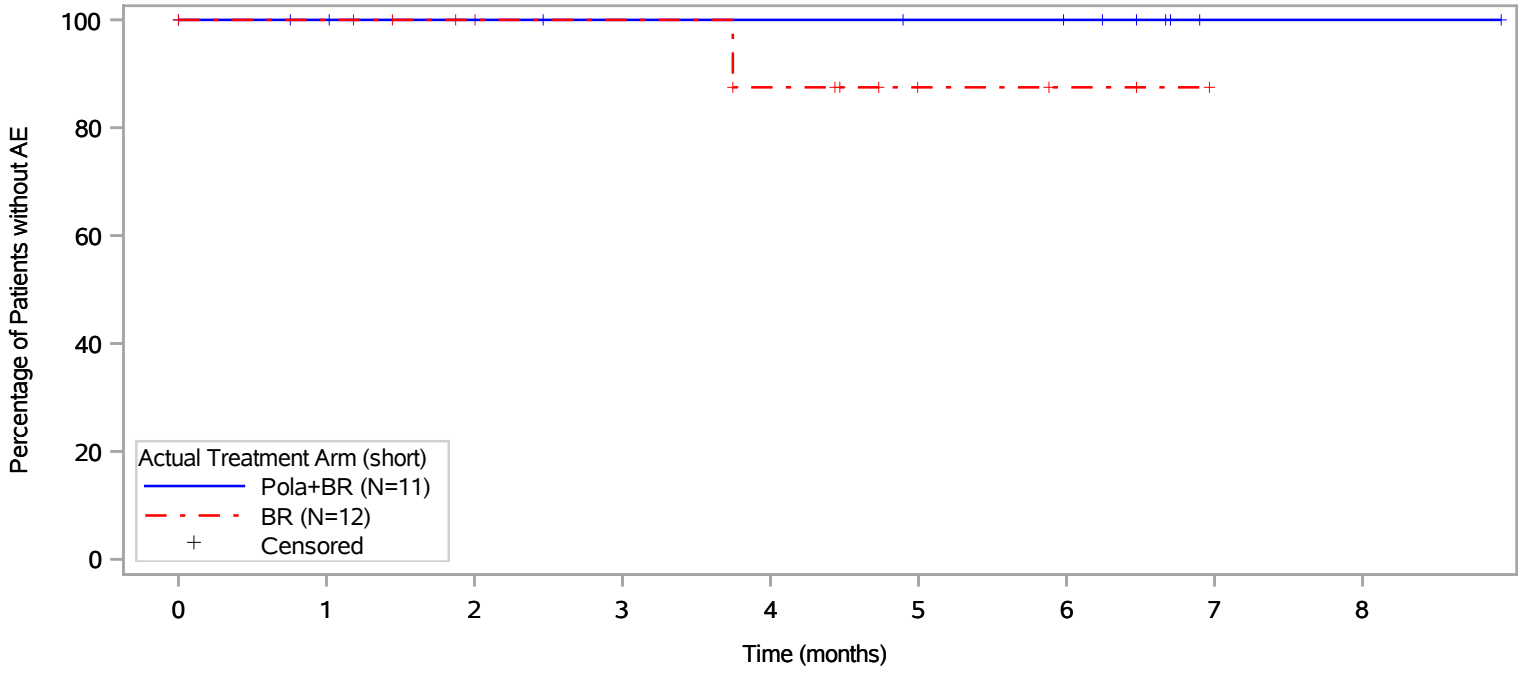
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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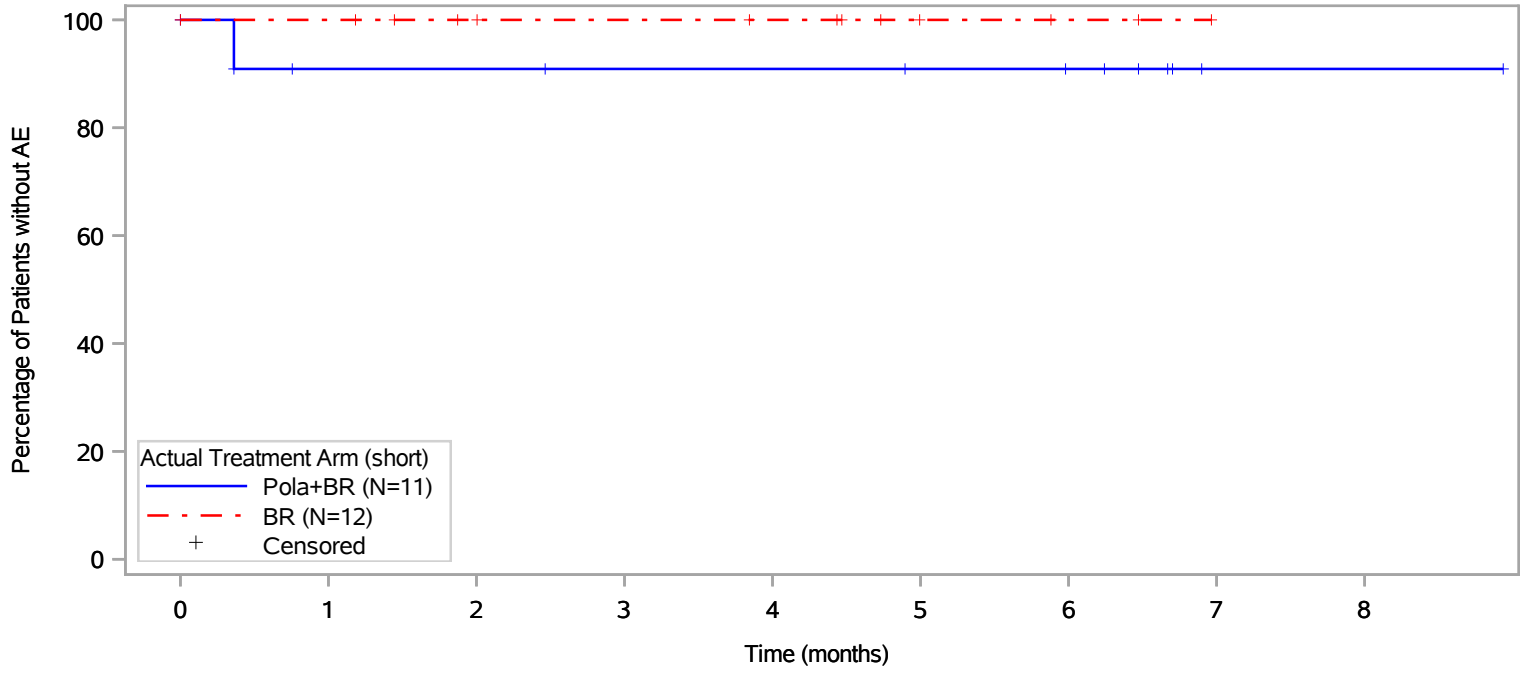
02DEC2022 5:07

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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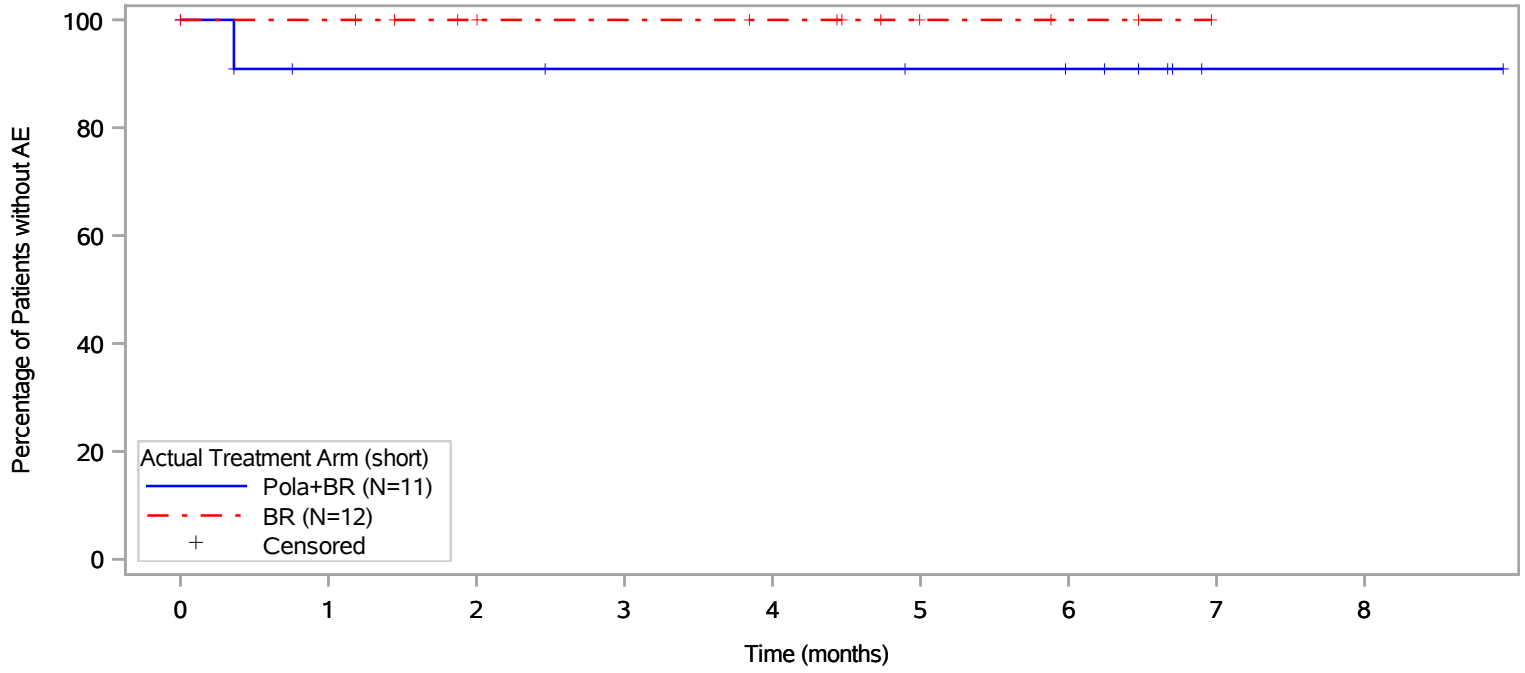
02DEC2022 5:07

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY OEDEMA



Patients at risk									
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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02DEC2022 5:07

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.0822	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ASCITES		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			11	100.0	1	9.1	10	90.9	12	100.0	3	25.0	9	75.0	0.0871	0.17	0.02	1.67		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			11	100.0	5	45.5	6	54.5	12	100.0	4	33.3	8	66.7	0.2265	0.35	0.06	2.04		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		11	100.0	2	18.2	9	81.8	12	100.0	1	8.3	11	91.7	0.9767	1.04	0.06	16.81		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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01DEC2022 1:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.1367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	ASCITES	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4450	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	3	25.0	9	75.0	0.1477	0.21	0.02	2.11		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS		>= 65	8	72.7	4	50.0	4	50.0	12	100.0	4	33.3	8	66.7	0.1600	0.21	0.02	2.15		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	8	72.7	2	25.0	6	75.0	12	100.0	1	8.3	11	91.7	0.8359	1.34	0.08	21.61		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	

INFECTIONS AND INFESTATIONS	SEPSIS	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.4028	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS		>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4450	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4450	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2850	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.3173				*	WARNING: Iteration limit reached without convergence.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RENAL AND URINARY DISORDERS		>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTSAE_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 1:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2087	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.5271	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	2	20.0	8	80.0	0.5193	0.45	0.04	5.33		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.0253				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.0253				*	WARNING: Iteration limit reached without convergence.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	6	54.5	3	50.0	3	50.0	10	83.3	4	40.0	6	60.0	0.2804	0.29	0.03	2.99		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	6	54.5	2	33.3	4	66.7	10	83.3	1	10.0	9	90.0	0.6641	1.84	0.11	29.79		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INFECTIONS AND INFESTATIONS	SEPSIS	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	0.1967	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTSAE_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 1:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.1489	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	3	33.3	6	66.7	0.0649	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	5	45.5	2	40.0	3	60.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	3	33.3	6	66.7	0.6220	0.63	0.10	3.94		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.8686	1.26	0.08	20.61		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3173				*	WARNING: Iteration limit reached without convergence.	

INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTSAE_L2_ARMCDSE_365_29365_41543.xls
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POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ASCITES	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ASCITES	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SMALL INTESTINAL OBSTRUCTION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	7	63.6	1	14.3	6	85.7	7	58.3	2	28.6	5	71.4	0.4328	0.39	0.03	4.44		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	DEATH	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173				*	WARNING: Iteration limit reached without convergence.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	7	63.6	4	57.1	3	42.9	7	58.3	1	14.3	6	85.7	0.7027	1.60	0.14	18.24		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	4	36.4	1	25.0	3	75.0	5	41.7	3	60.0	2	40.0	0.0575	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CEREBRAL TOXOPLASMOSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES VIRUS INFECTION	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MENINGOENCEPHALITIS HERPETIC	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	63.6	2	28.6	5	71.4	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA CYTOMEGALOVIRAL	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	POST PROCEDURAL INFECTION	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173				*	WARNING: Iteration limit reached without convergence.	

INFECTIONS AND INFESTATIONS	SEPSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3545	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3545	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	EPIGLOTTIC CANCER	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MYELODYSPLASTIC SYNDROME	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	SQUAMOUS CELL CARCINOMA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	VOCAL CORD PARALYSIS	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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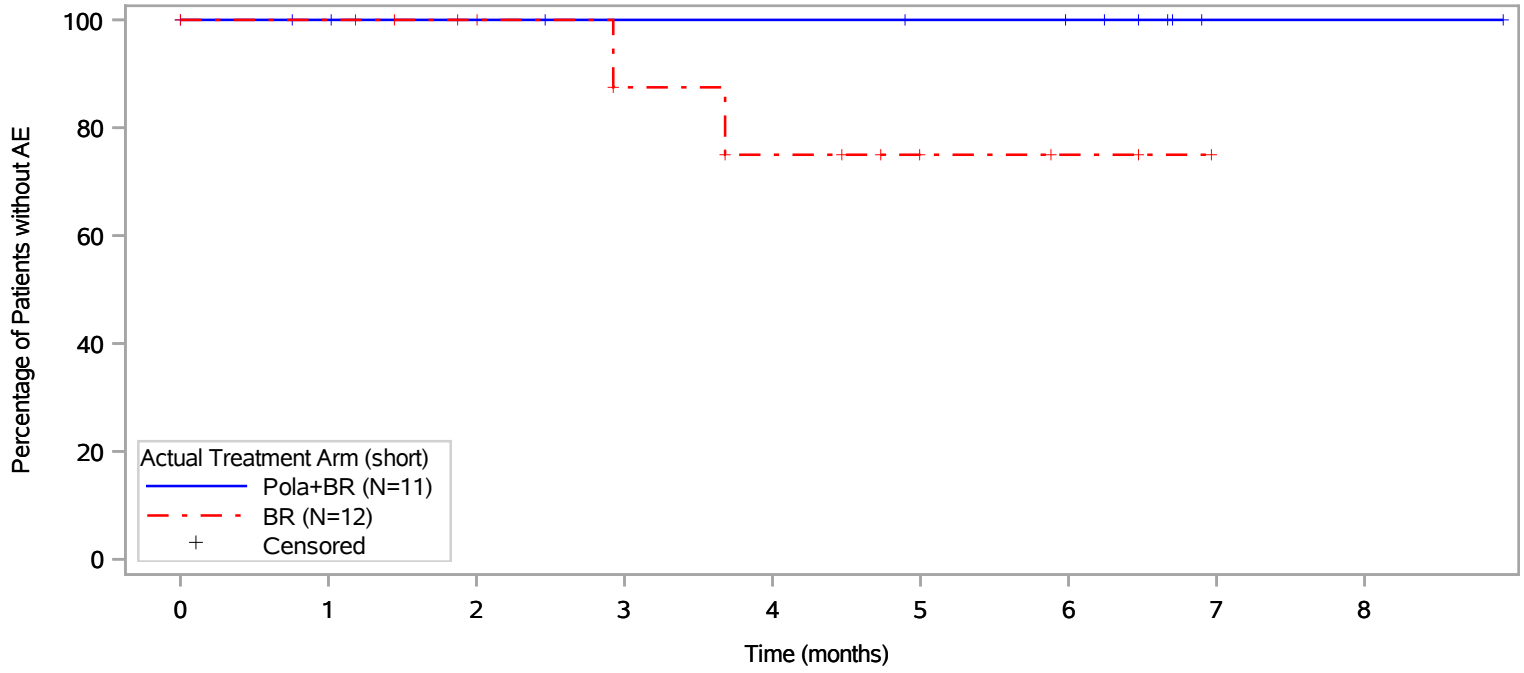
01DEC2022 1:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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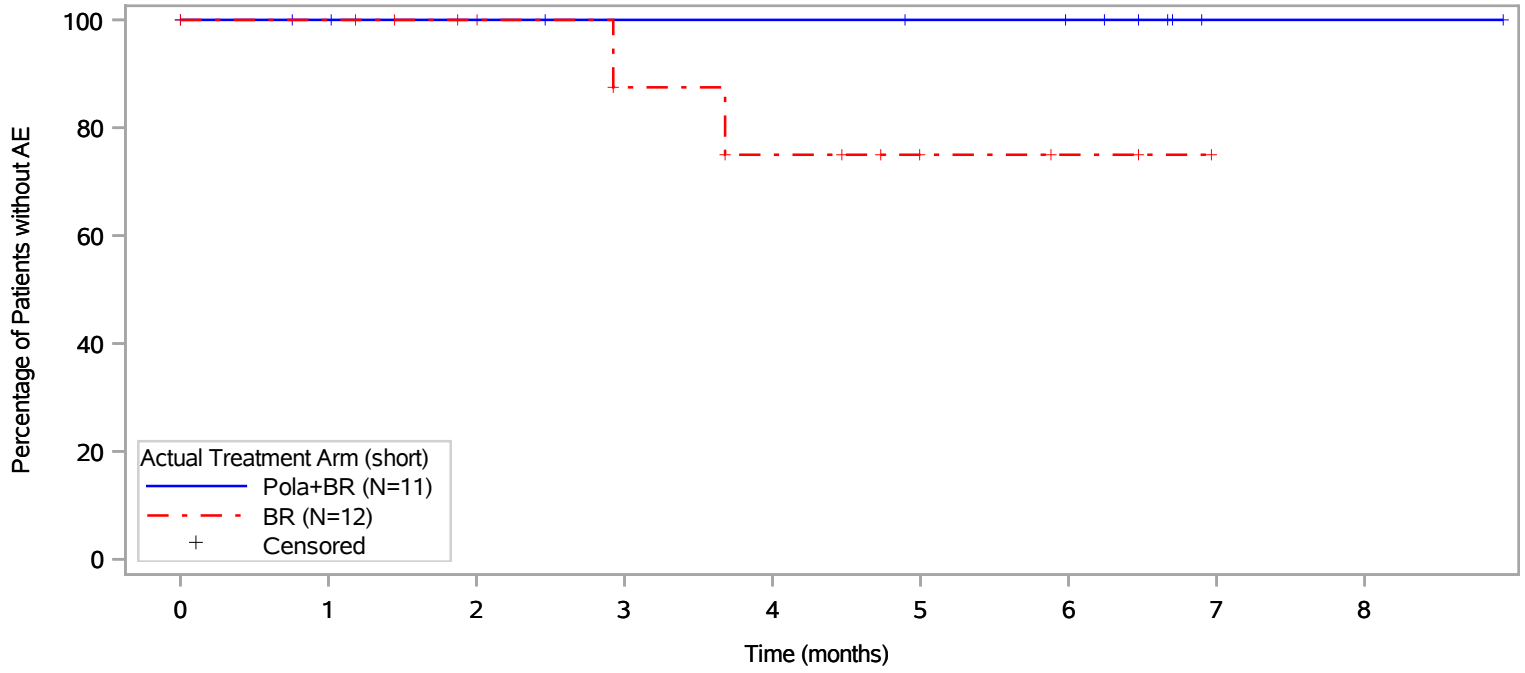
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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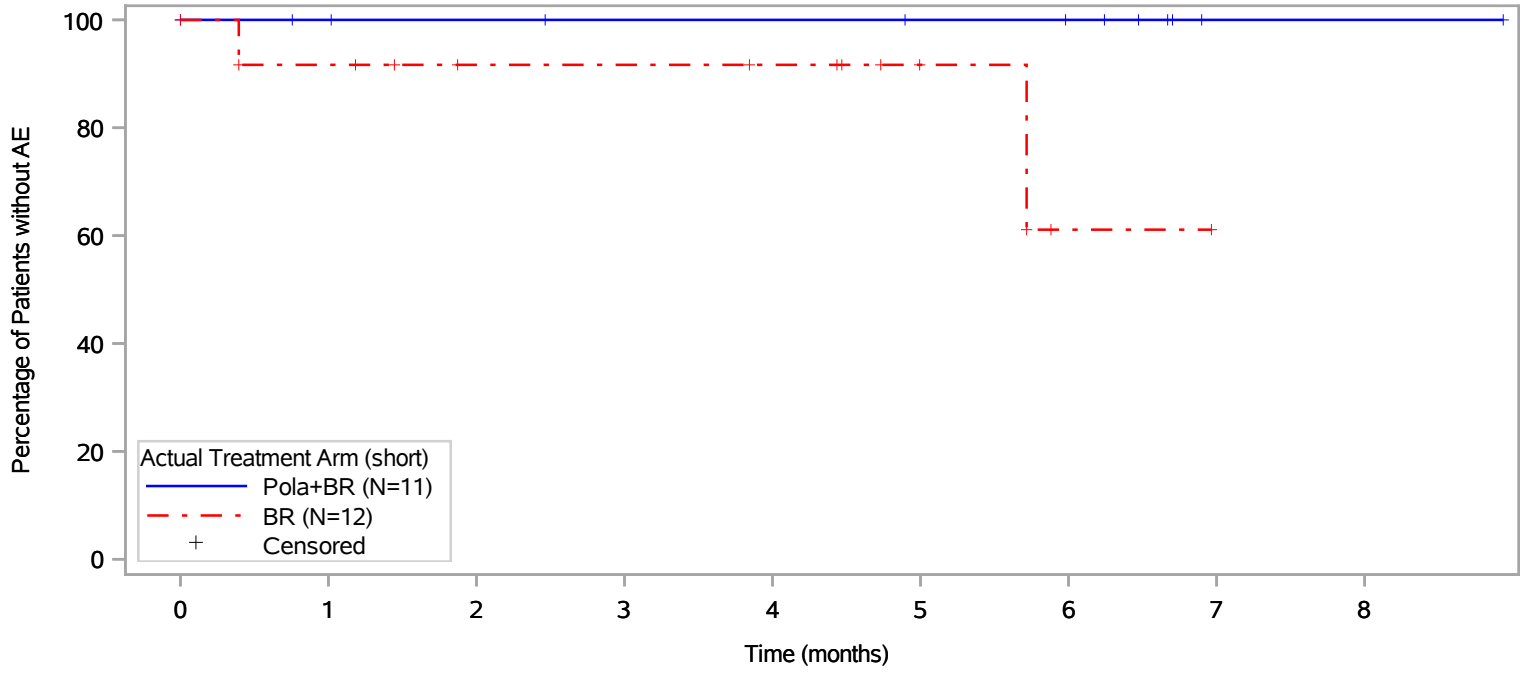
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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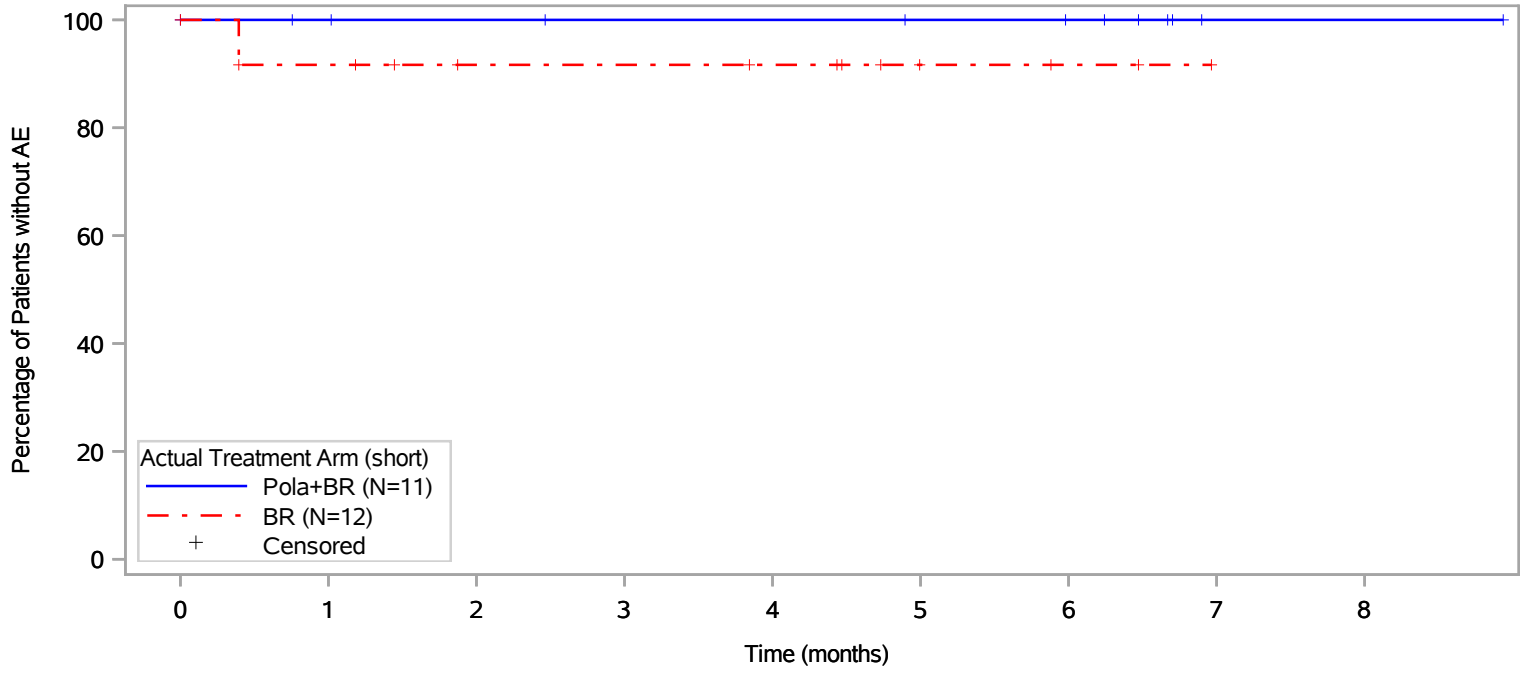
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

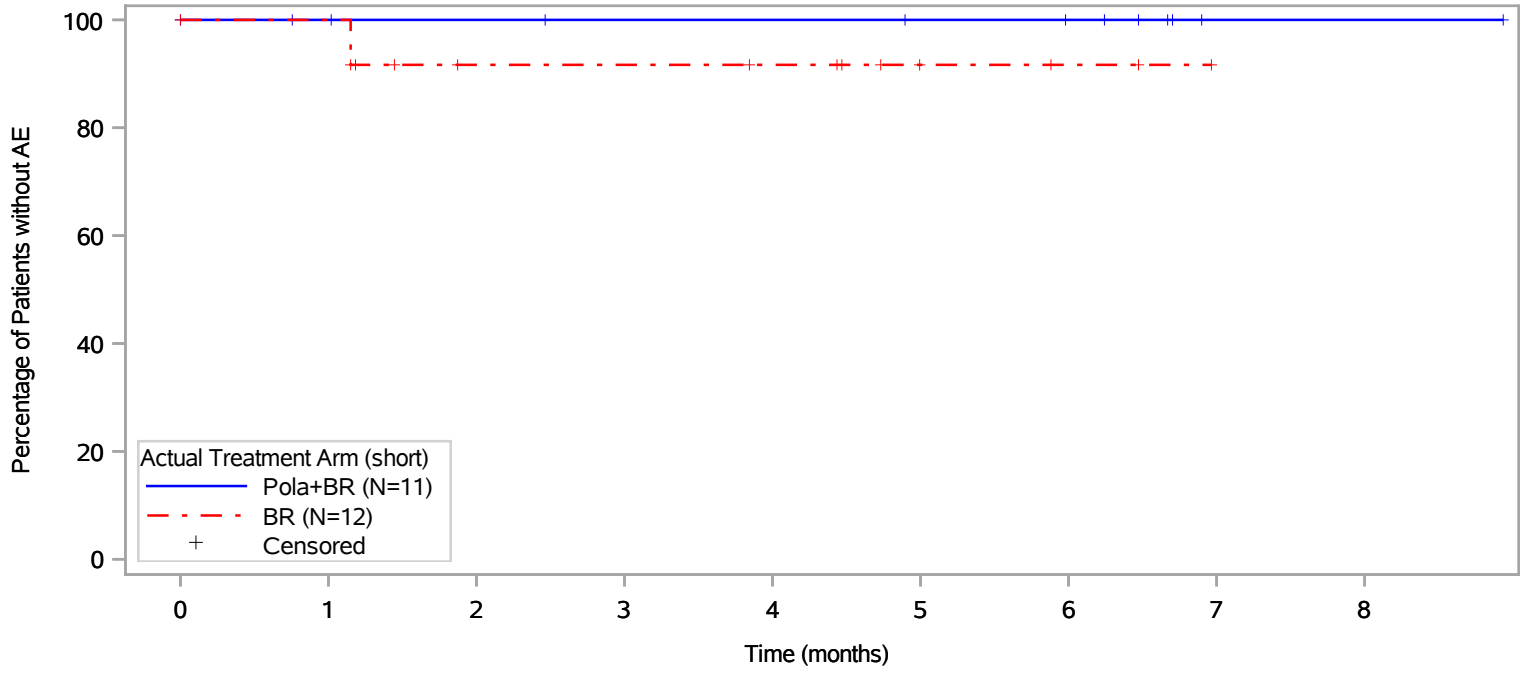
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ASCITES



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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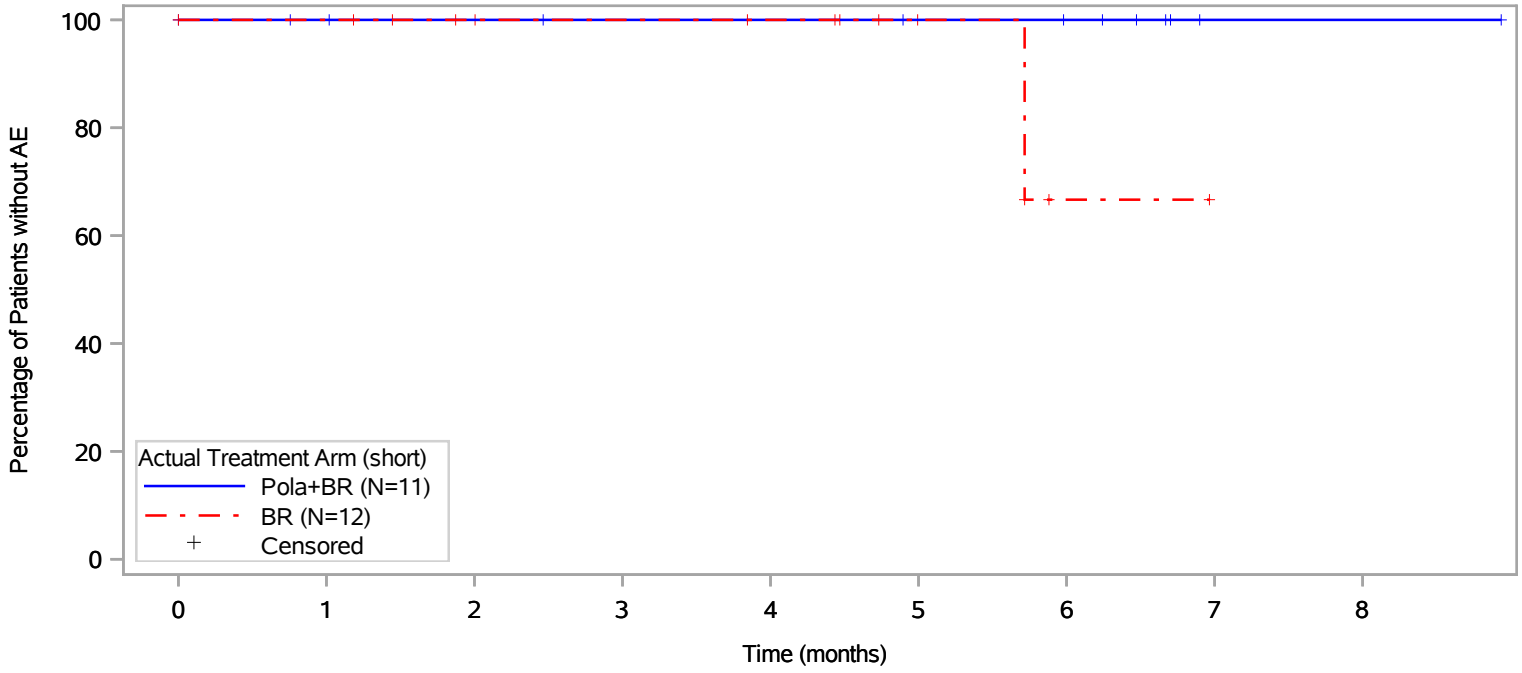
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SMALL INTESTINAL OBSTRUCTION



Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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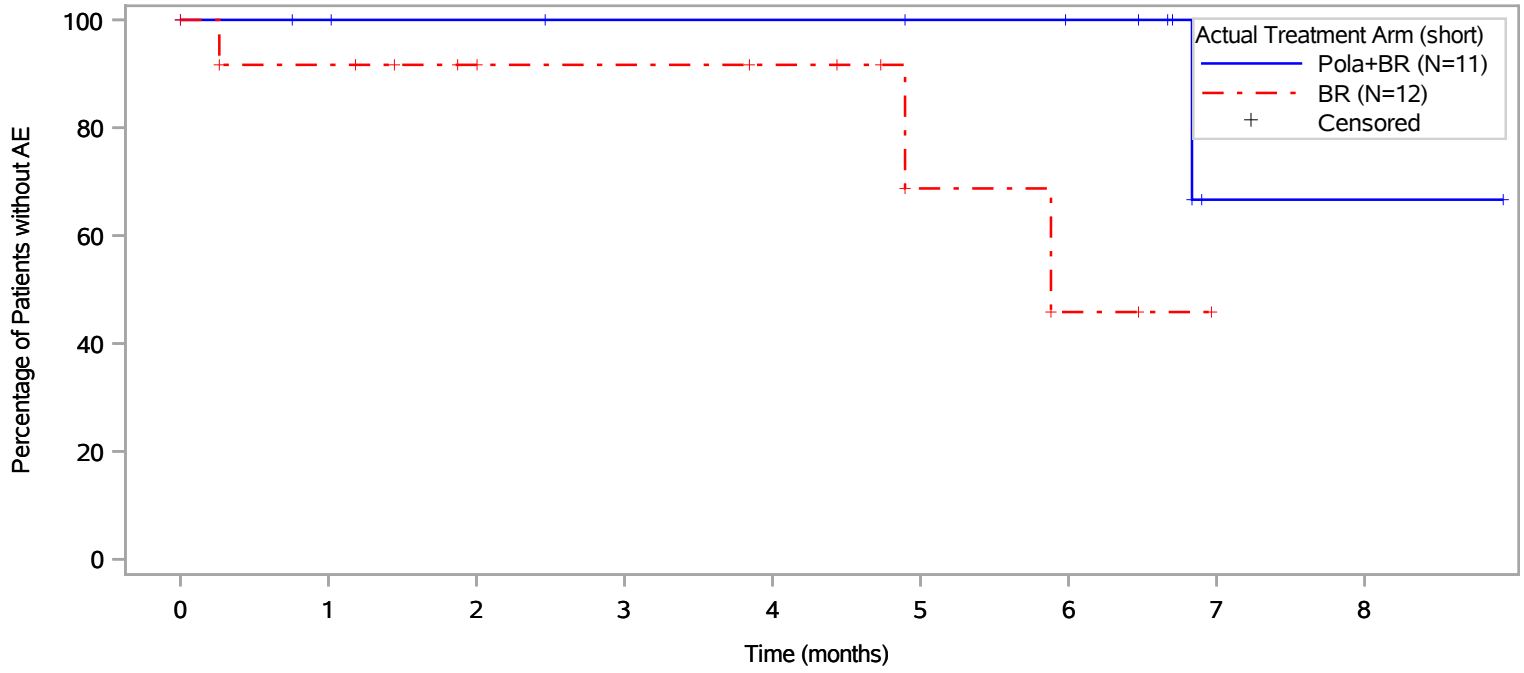
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	7	7	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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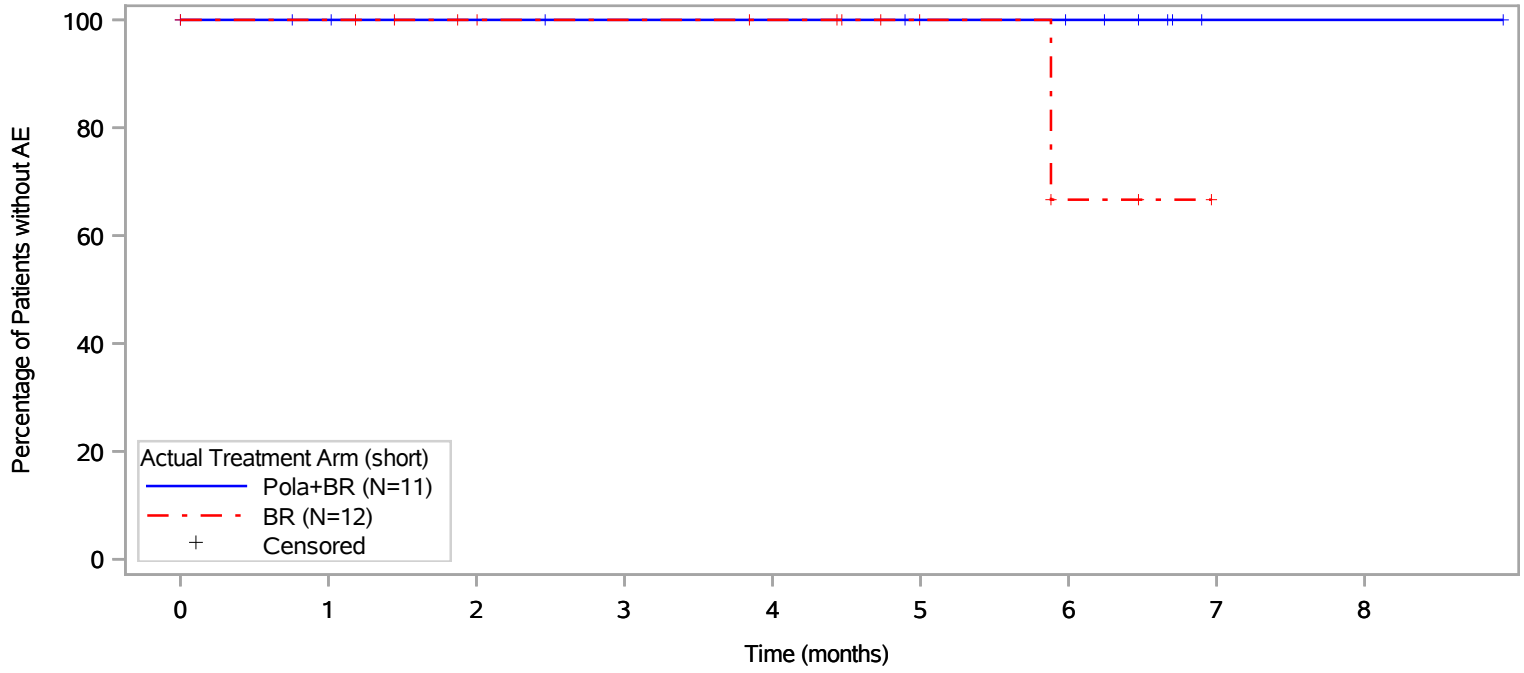
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, DEATH



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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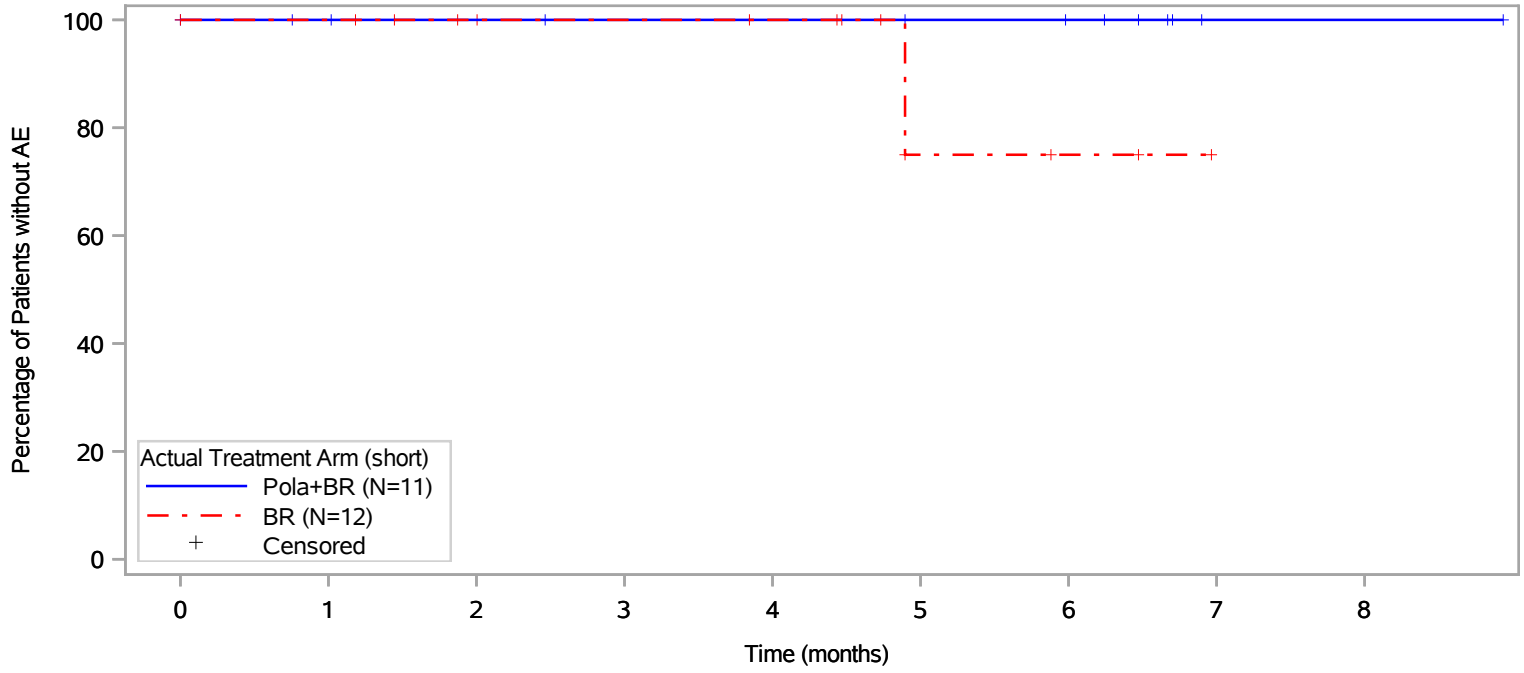
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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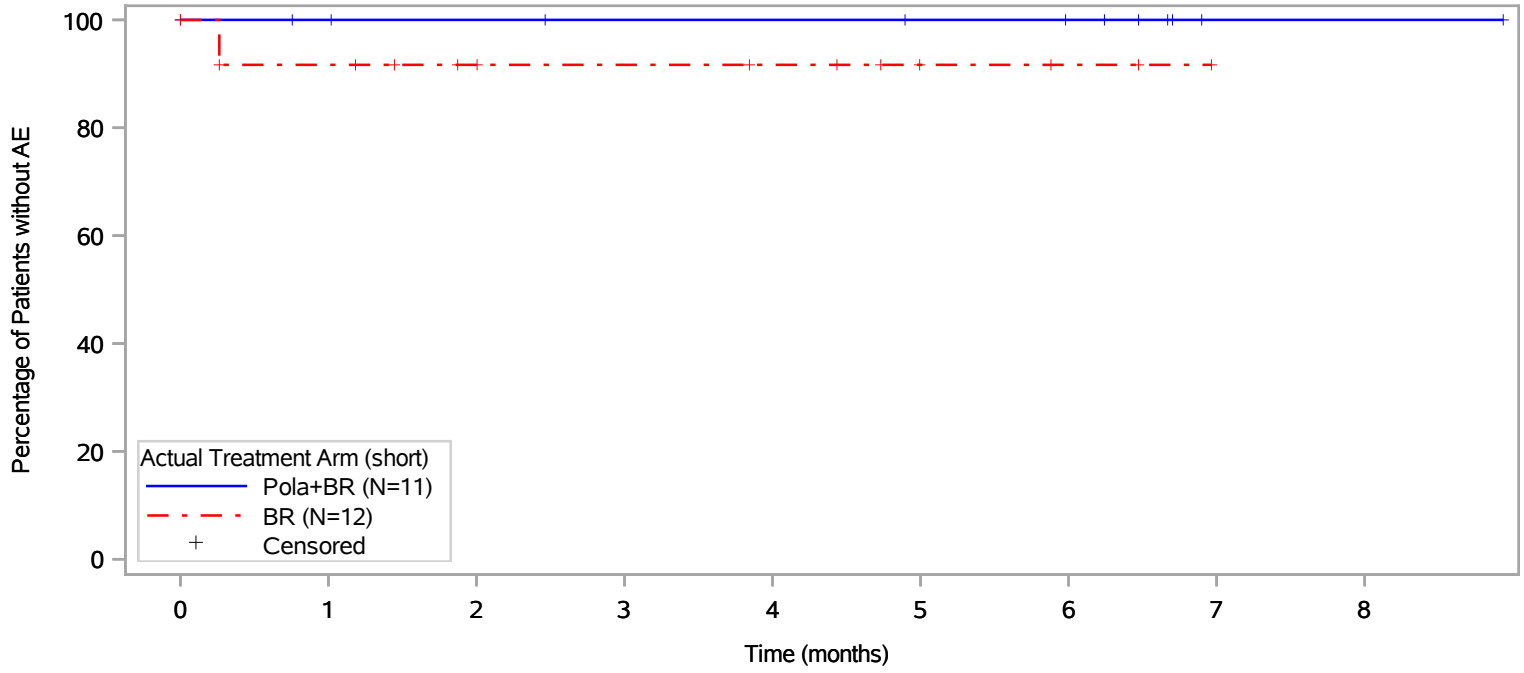
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL

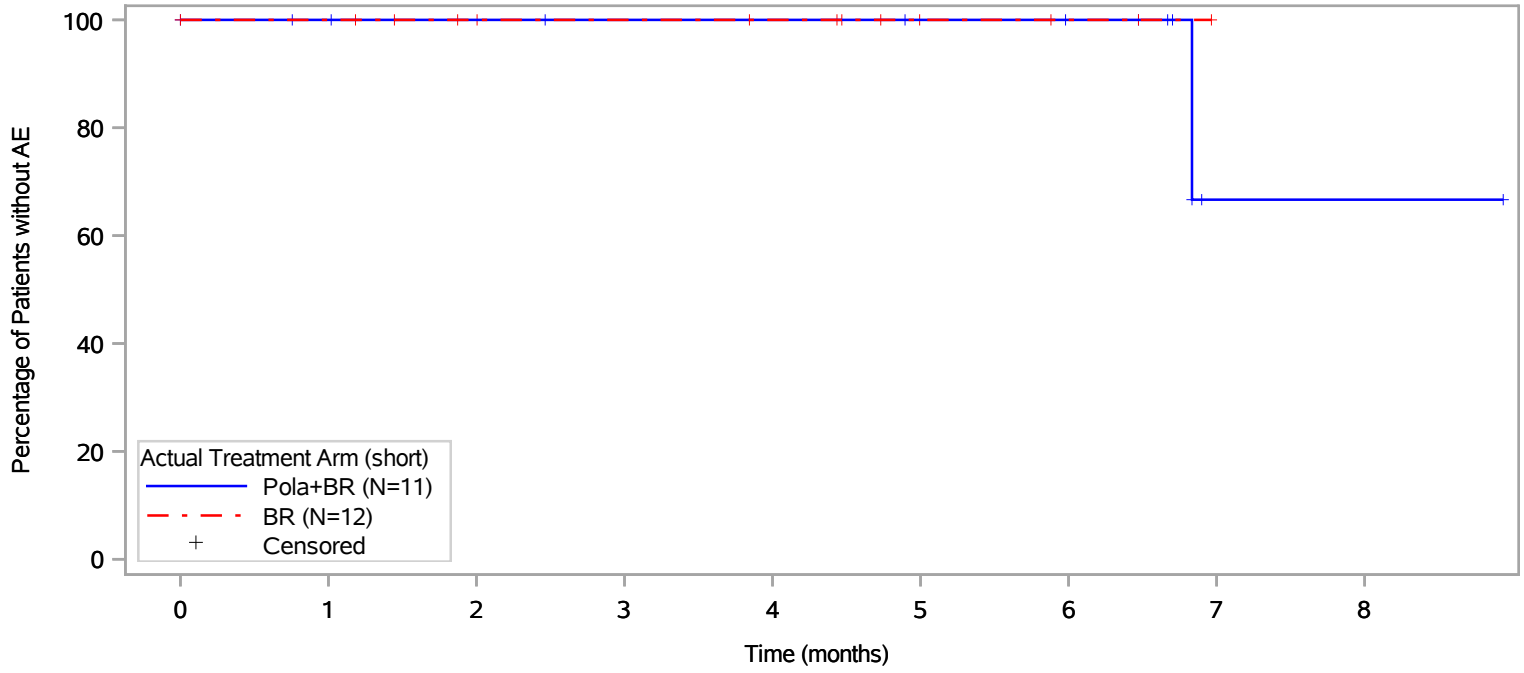


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA

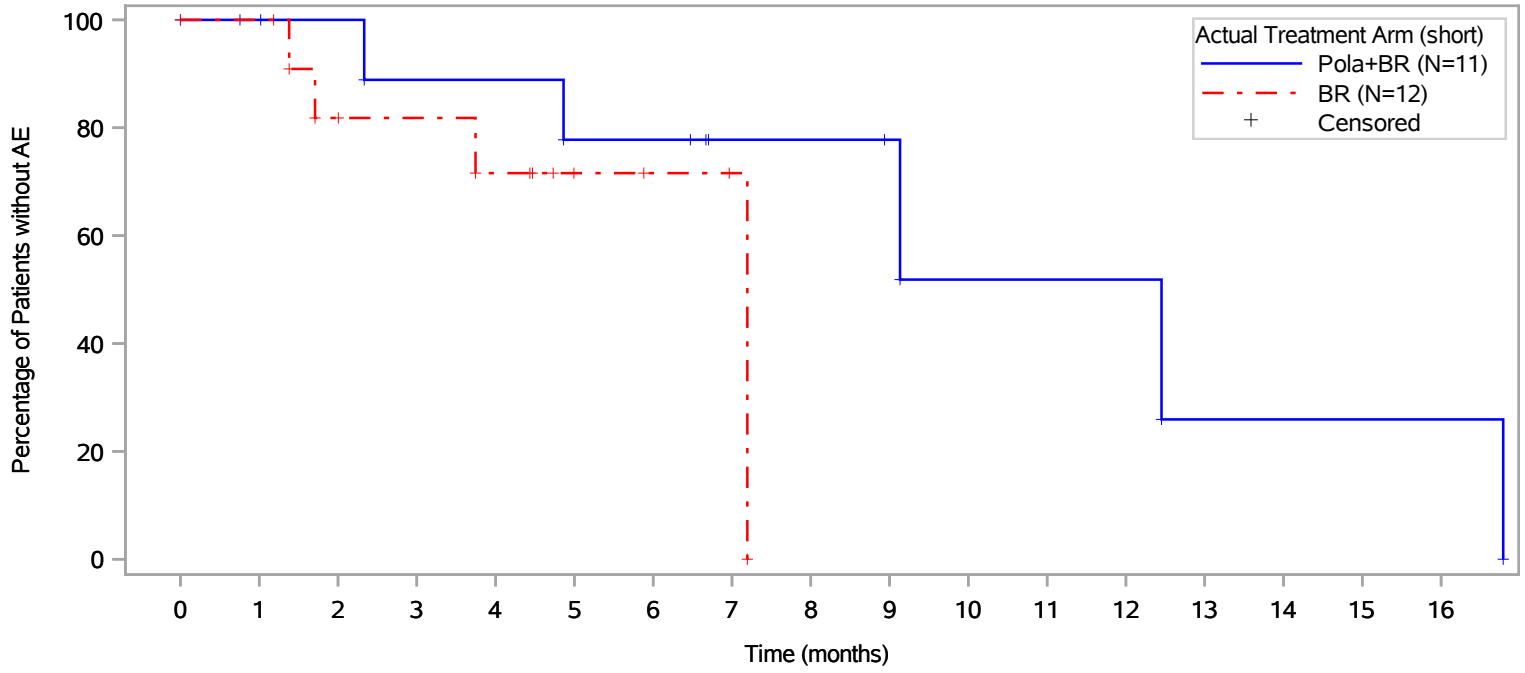


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All

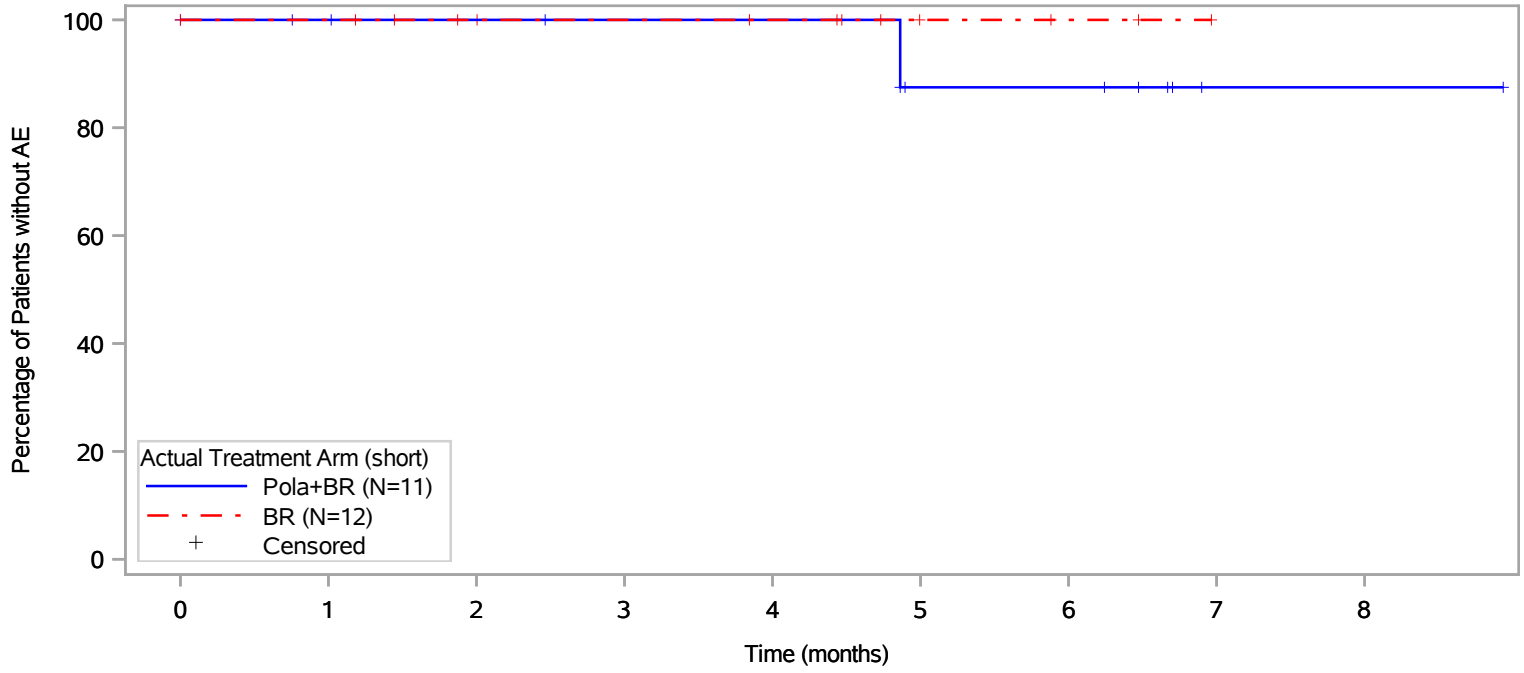


Patients at risk																	
Pola+BR (N=11)	11	10	9	8	8	7	7	4	4	3	2	2	2	1	1	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																	
Pola+BR (N=11)	0	1	2	2	2	2	2	5	5	6	6	6	6	6	6	6	6
BR (N=12)	0	0	1	2	2	6	7	8	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CEREBRAL TOXOPLASMOSIS

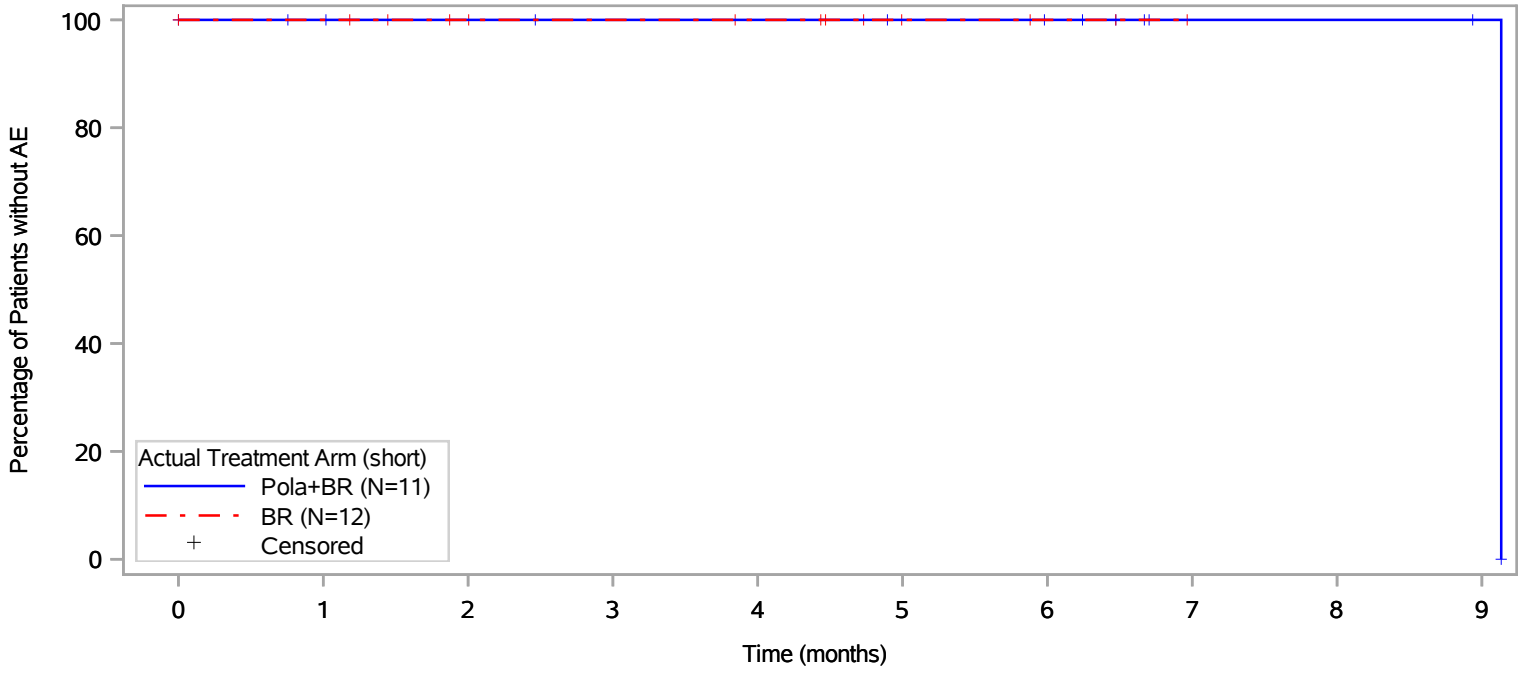


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES VIRUS INFECTION



Patients at risk										
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored										
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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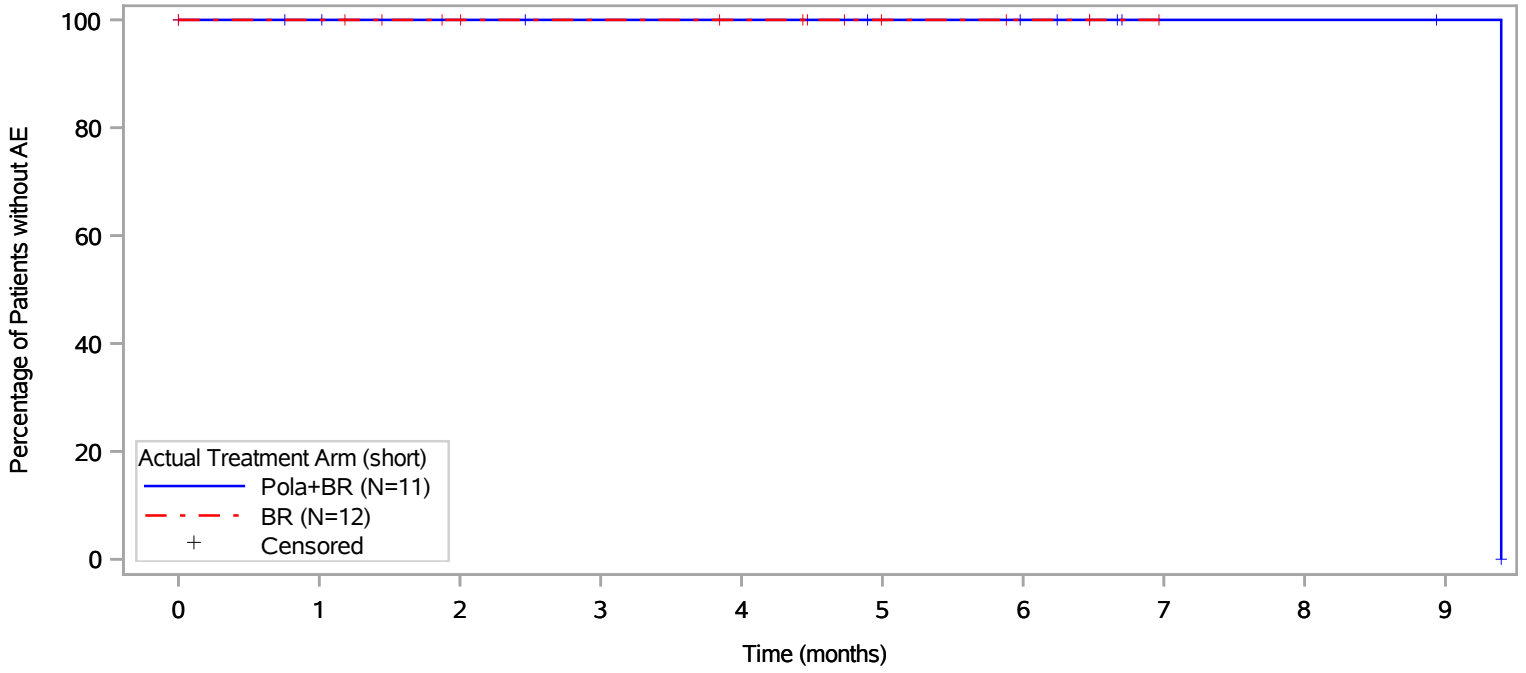
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MENINGOENCEPHALITIS HERPETIC

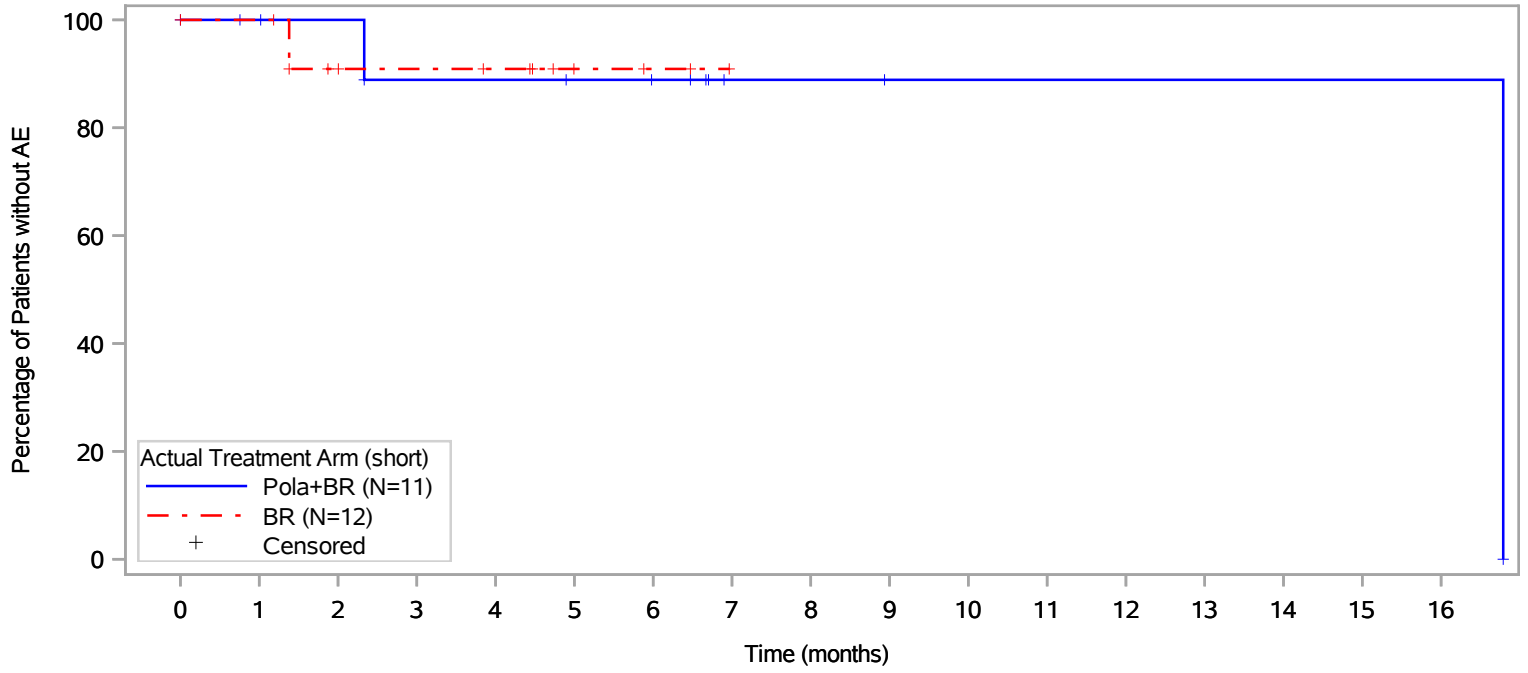


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA

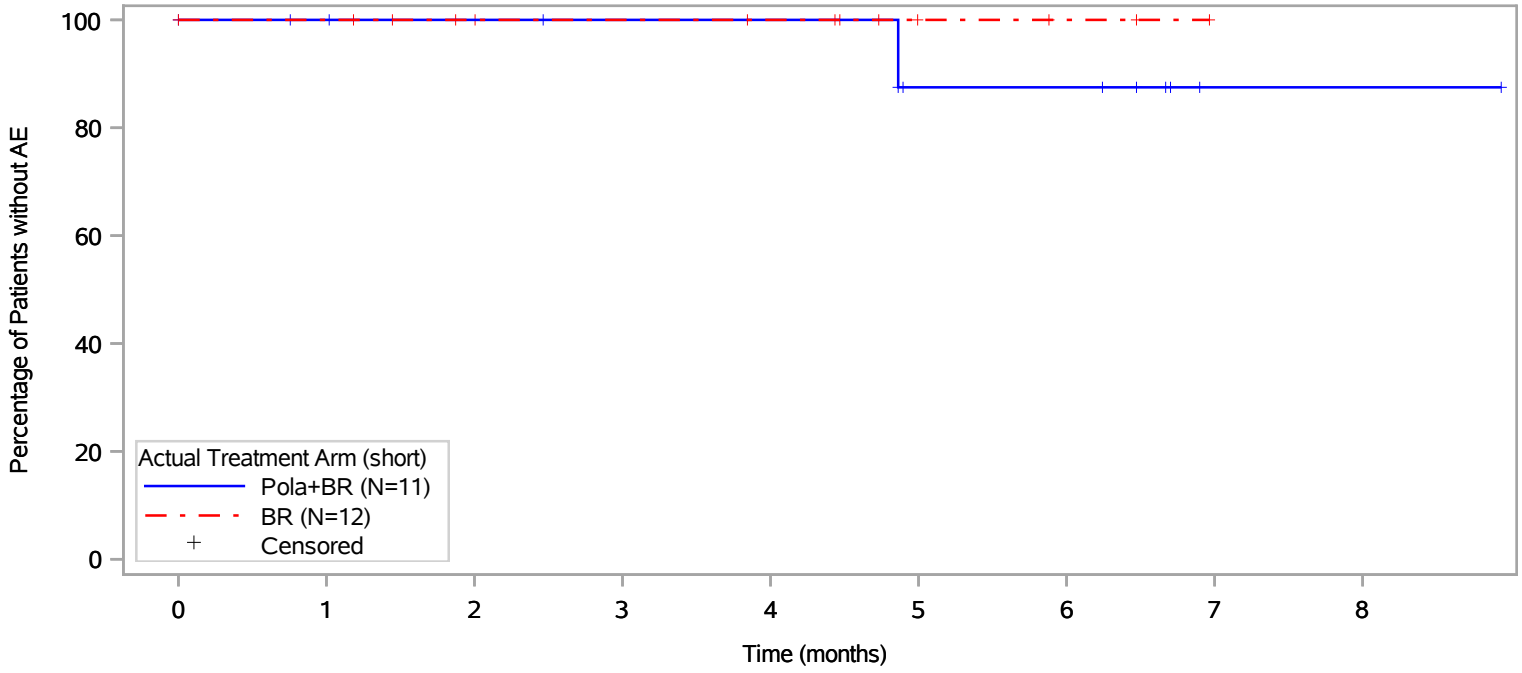


Patients at risk																	
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	1	1	1	1	1	1	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																	
Pola+BR (N=11)	0	1	2	2	2	3	4	8	8	9	9	9	9	9	9	9	9
BR (N=12)	0	0	2	3	4	8	9	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA CYTOMEGALOVIRAL

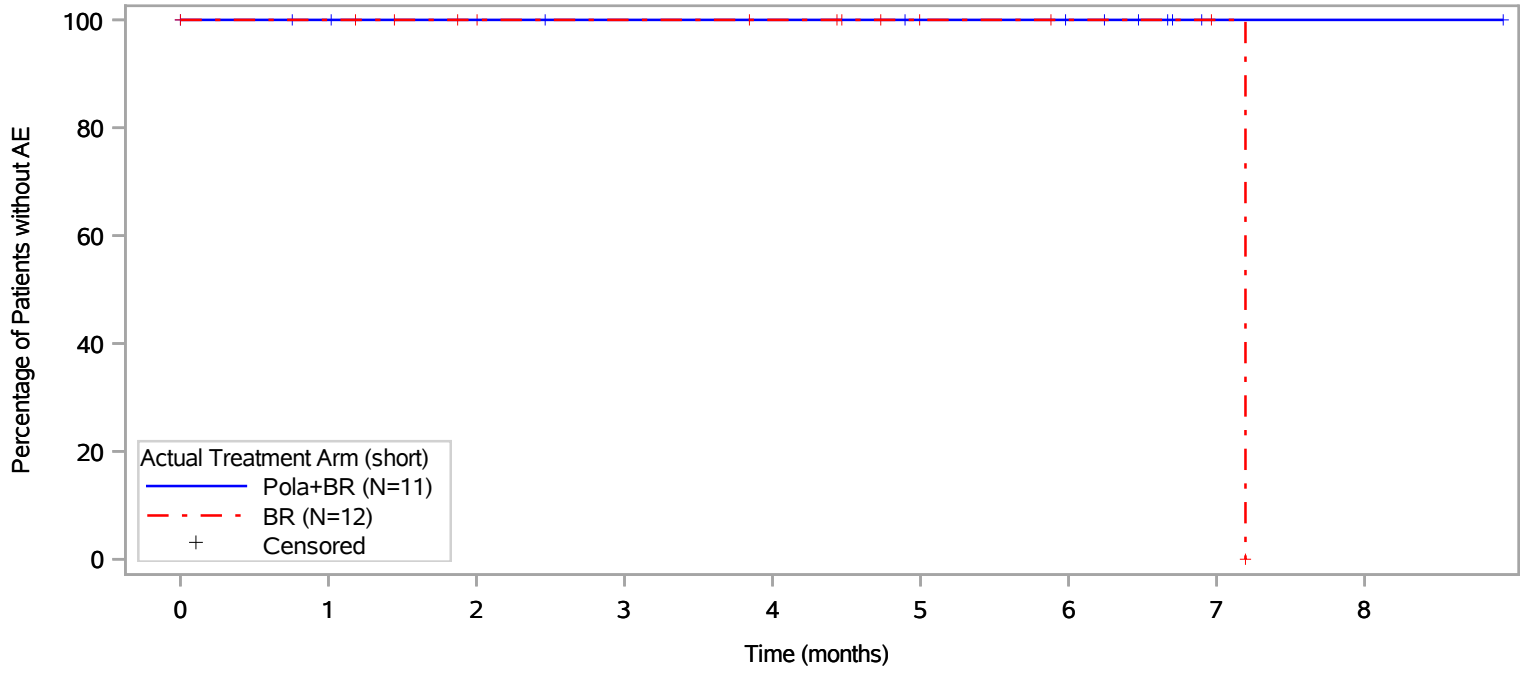


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, POST PROCEDURAL INFECTION

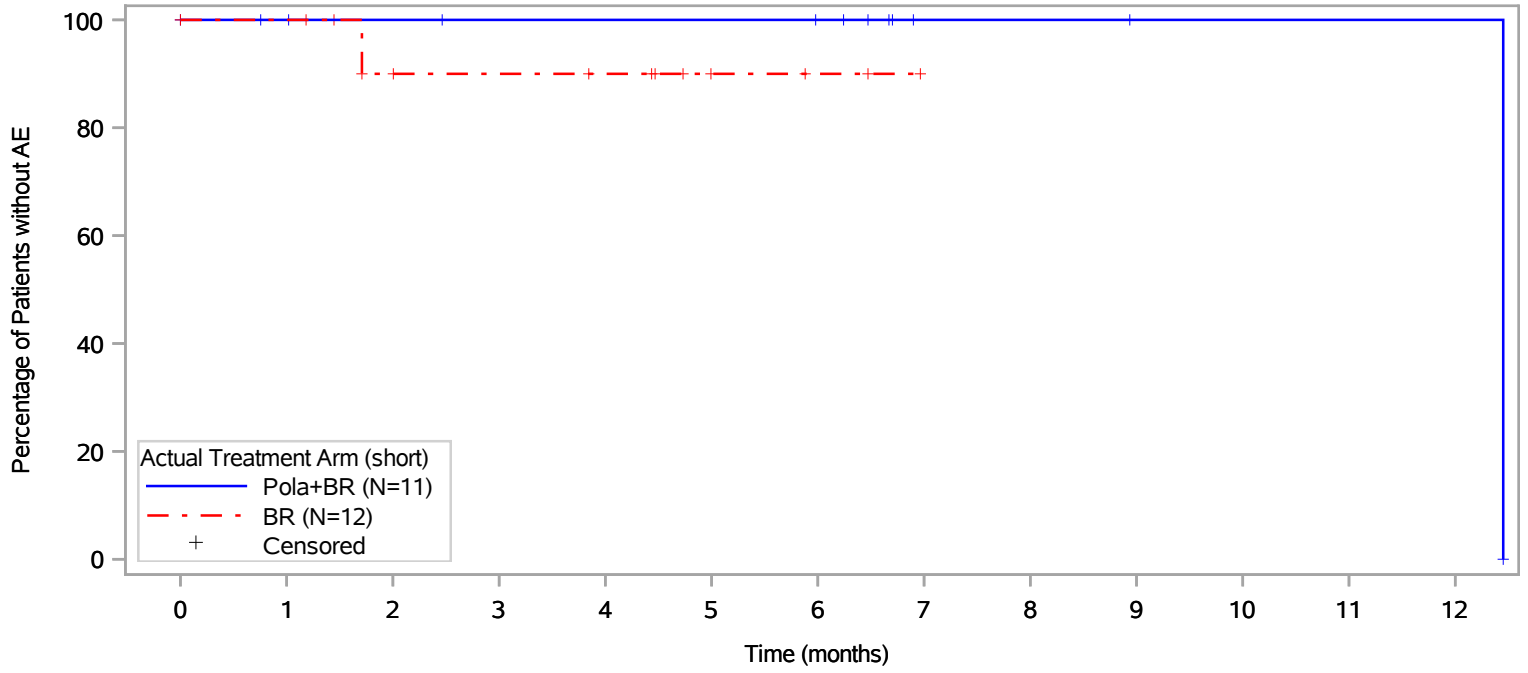


Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

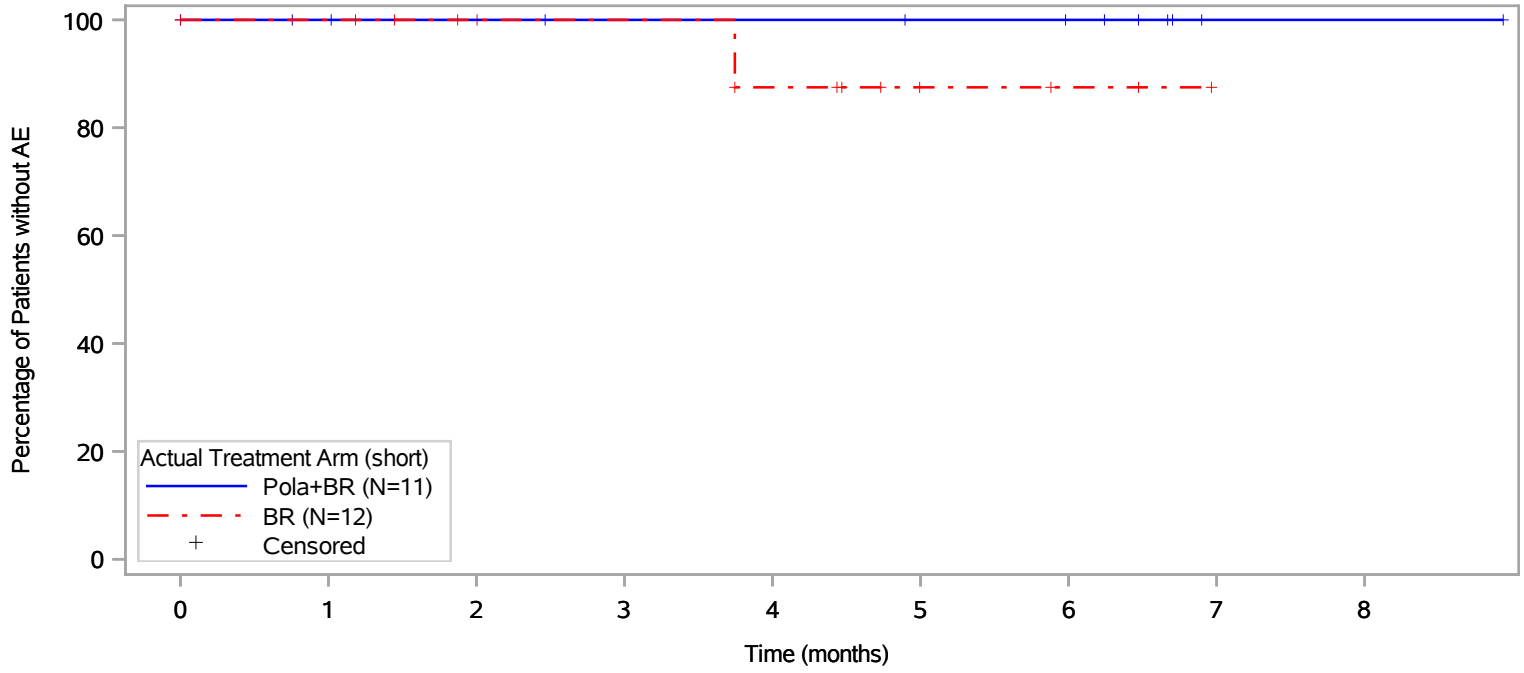
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk													
Pola+BR (N=11)	11	10	9	8	8	8	7	2	2	1	1	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	2	3	3	3	4	9	9	10	10	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK

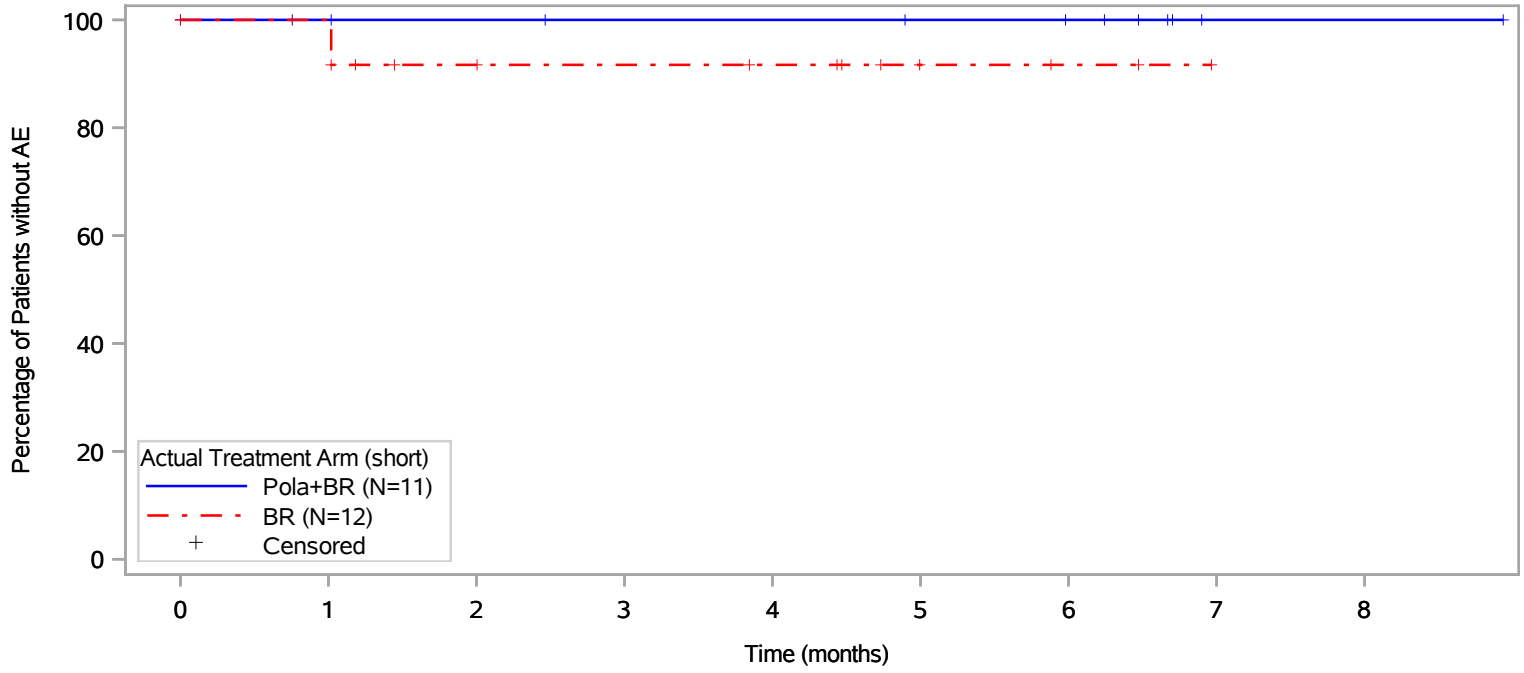


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

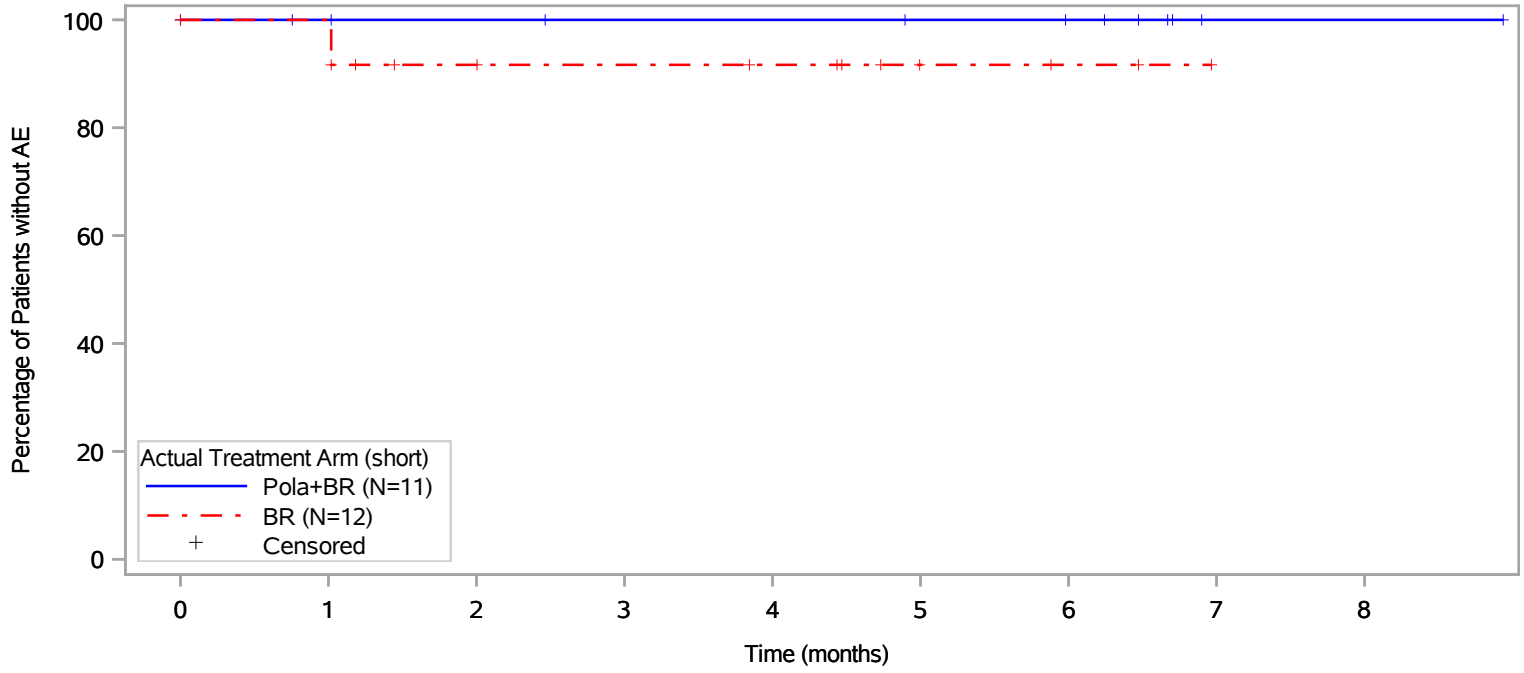


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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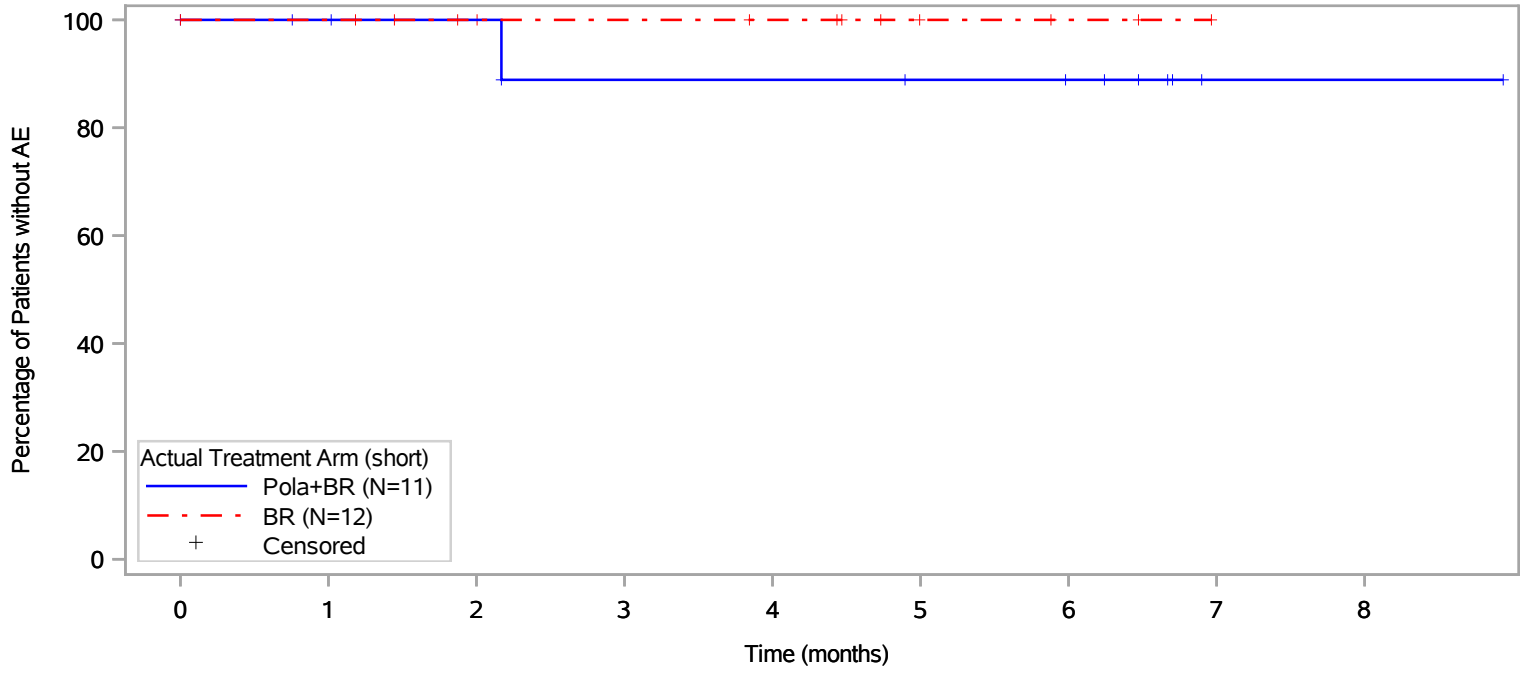
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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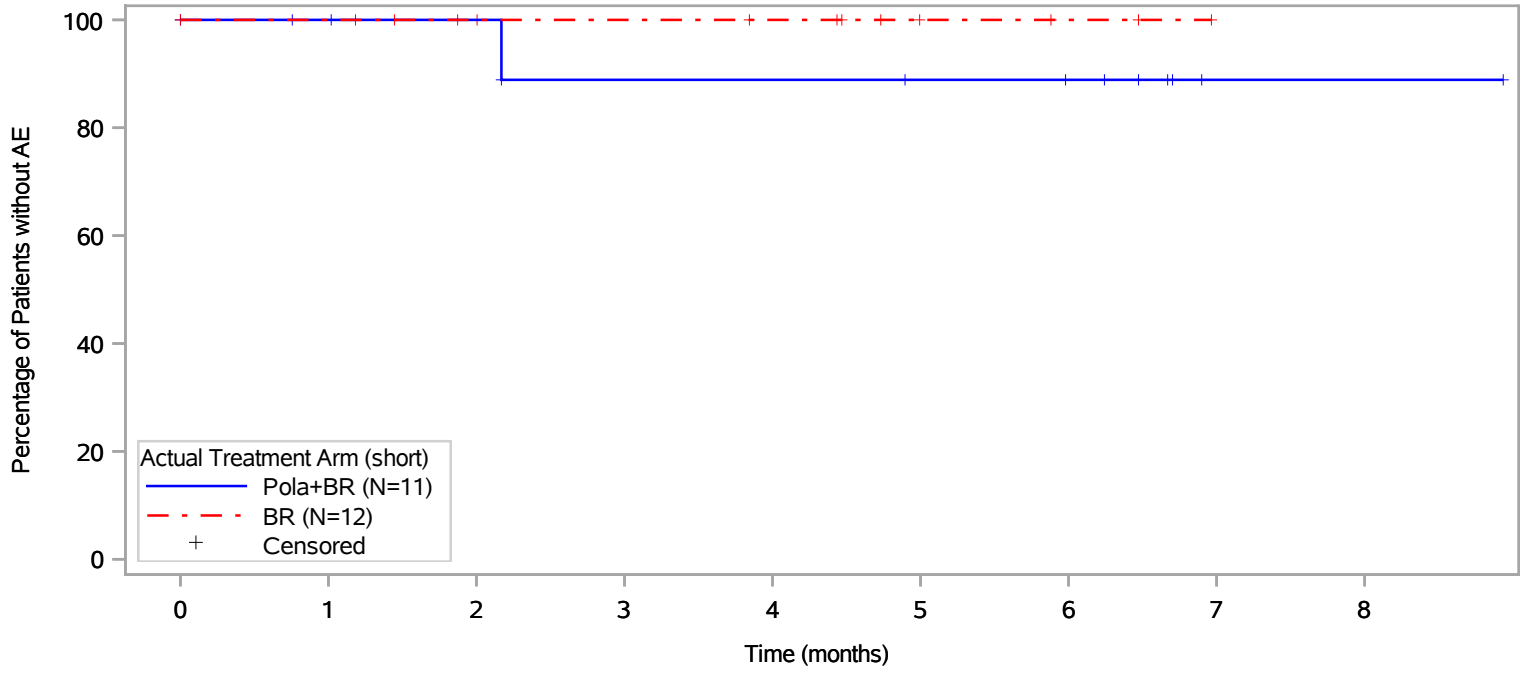
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE



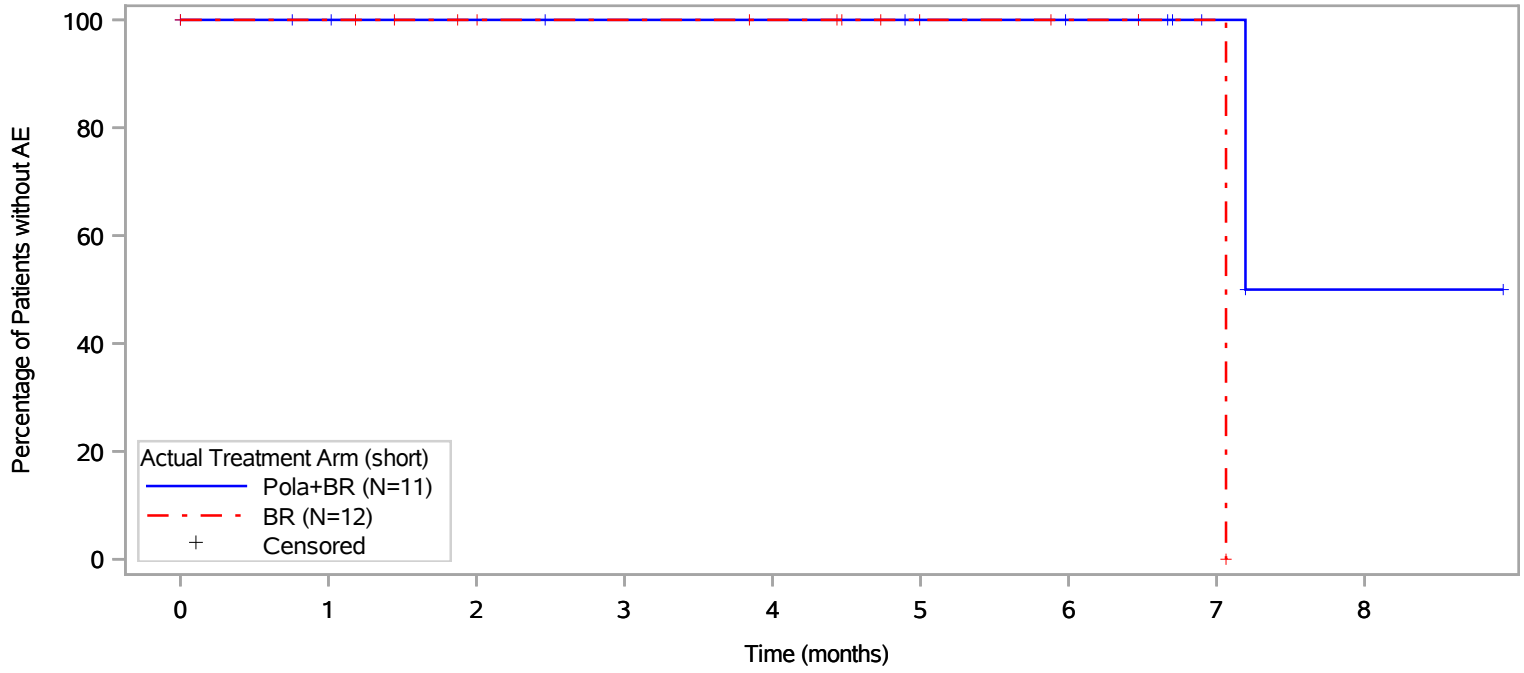
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All



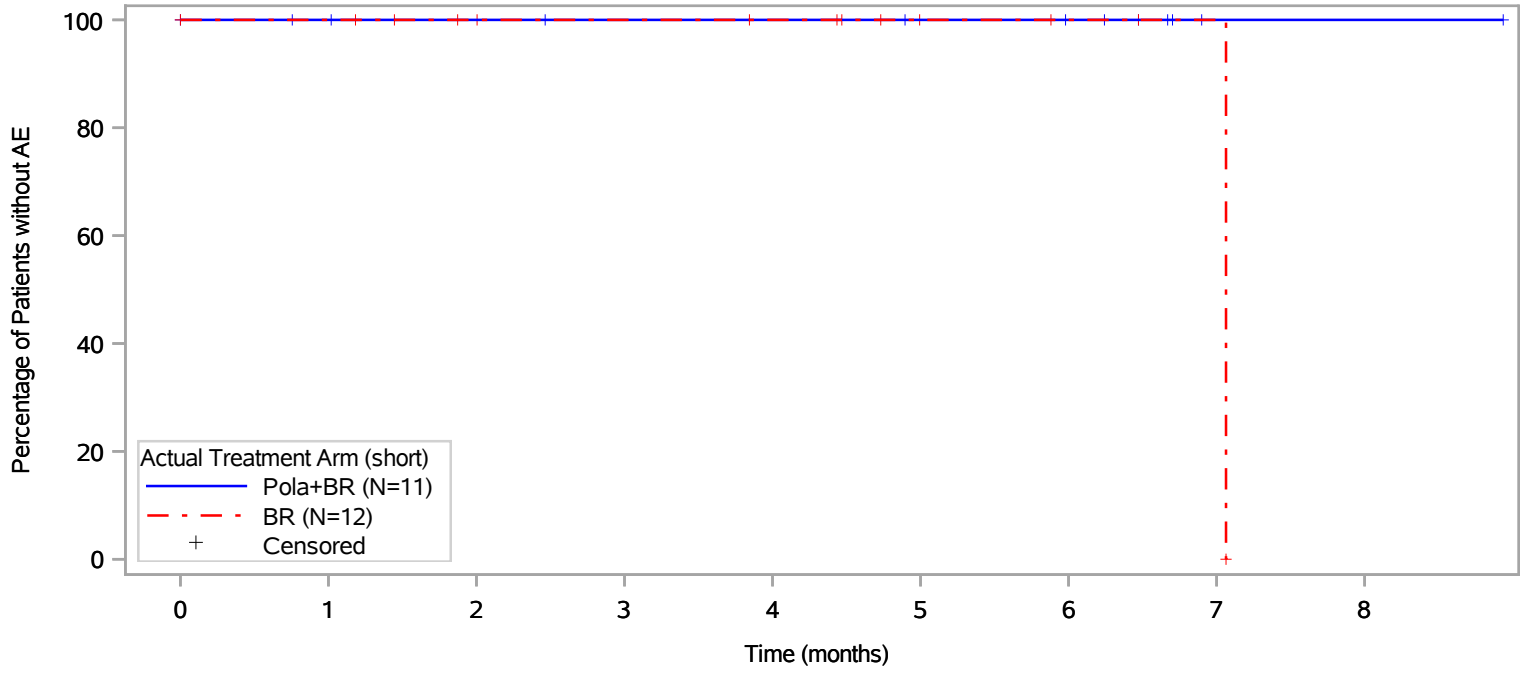
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), EPIGLOTTIC CANCER



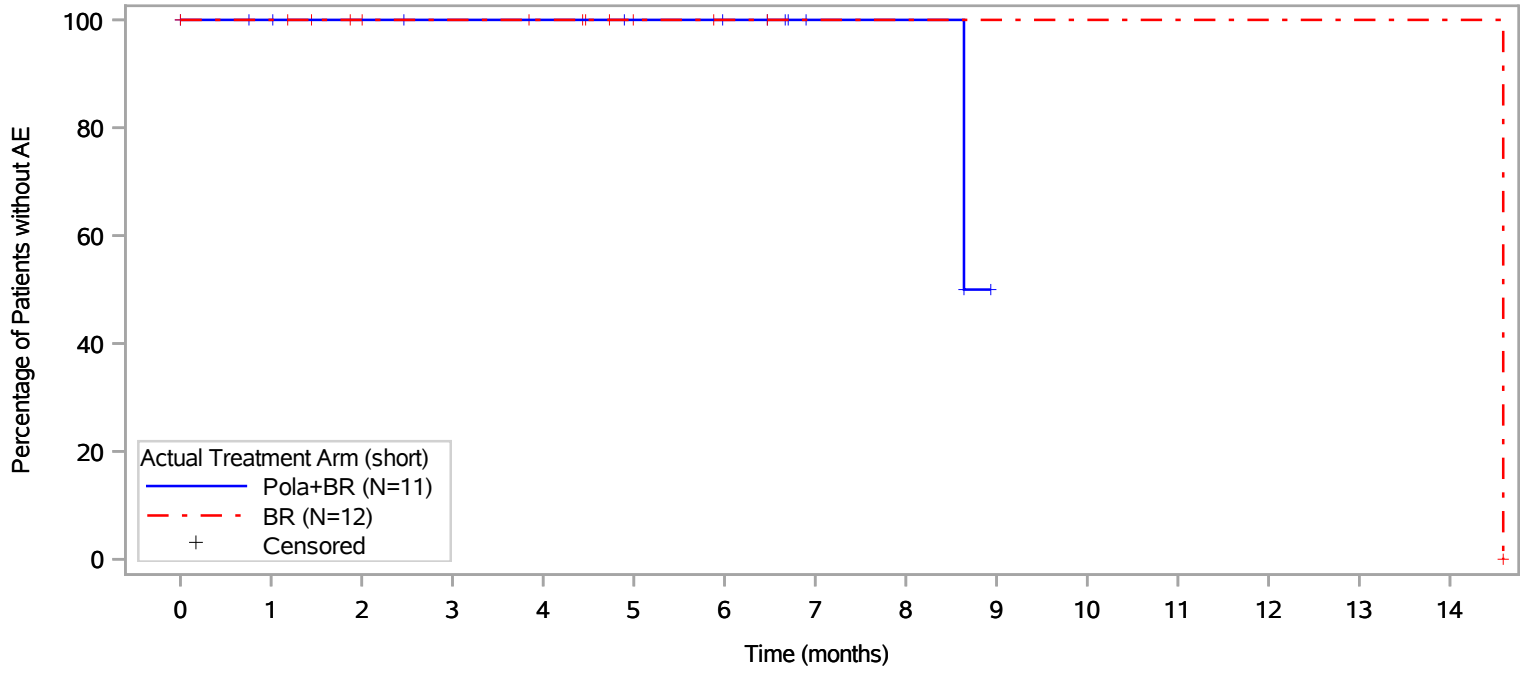
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MYELODYSPLASTIC SYNDROME



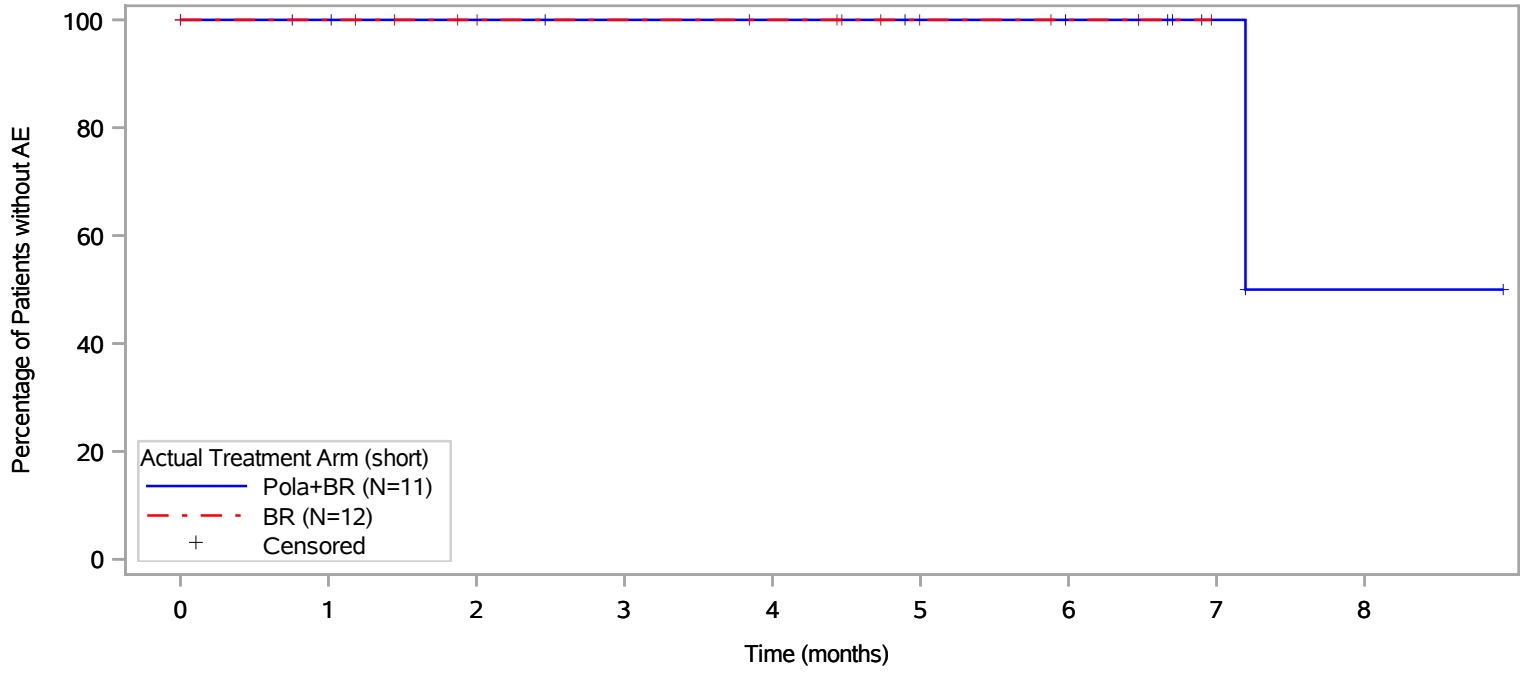
Patients at risk															
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2	NE	NE	NE	NE	NE	NE
BR (N=12)	12	12	9	8	7	3	2	1	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9	NE	NE	NE	NE	NE	NE
BR (N=12)	0	0	3	4	5	9	10	11	11	11	11	11	11	11	11

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), SQUAMOUS CELL CARCINOMA

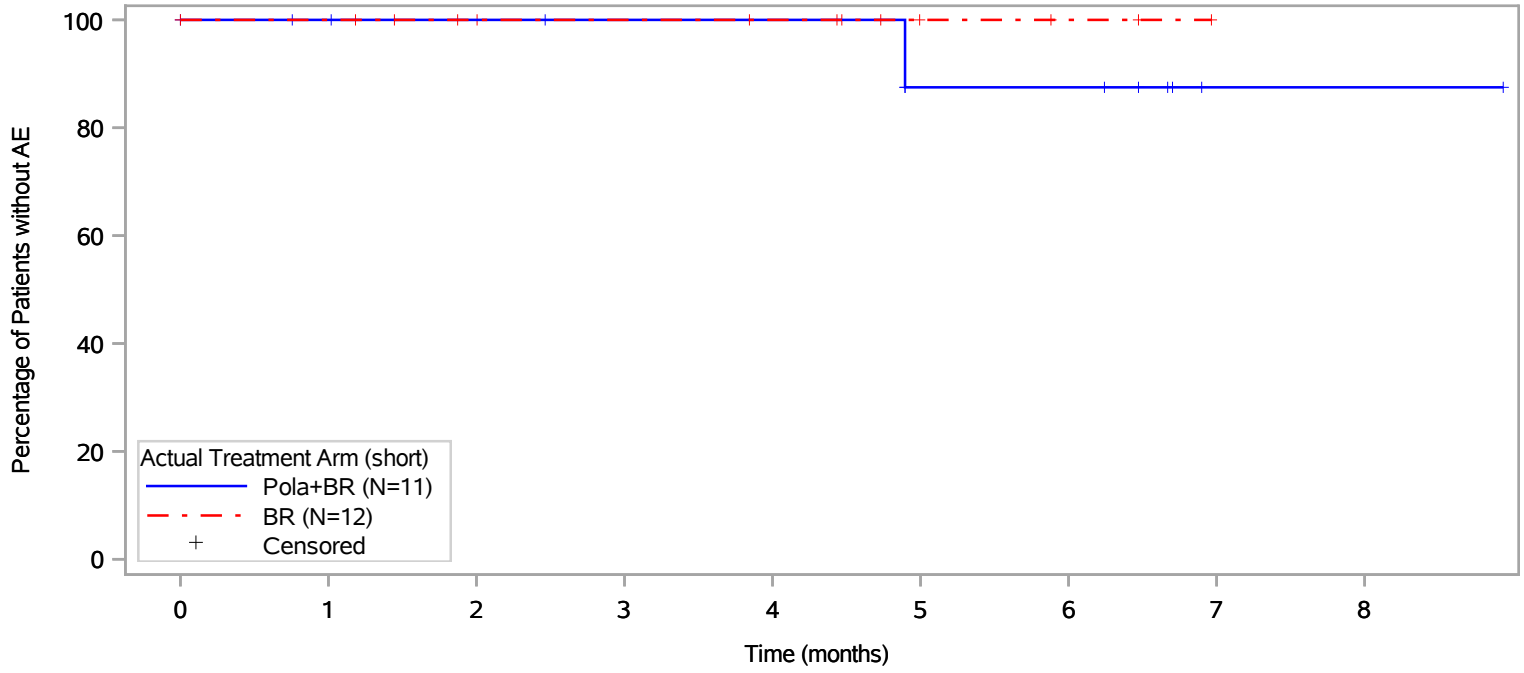


Patients at risk								
Pola+BR (N=11)	11	10	9	8	8	7	6	2	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



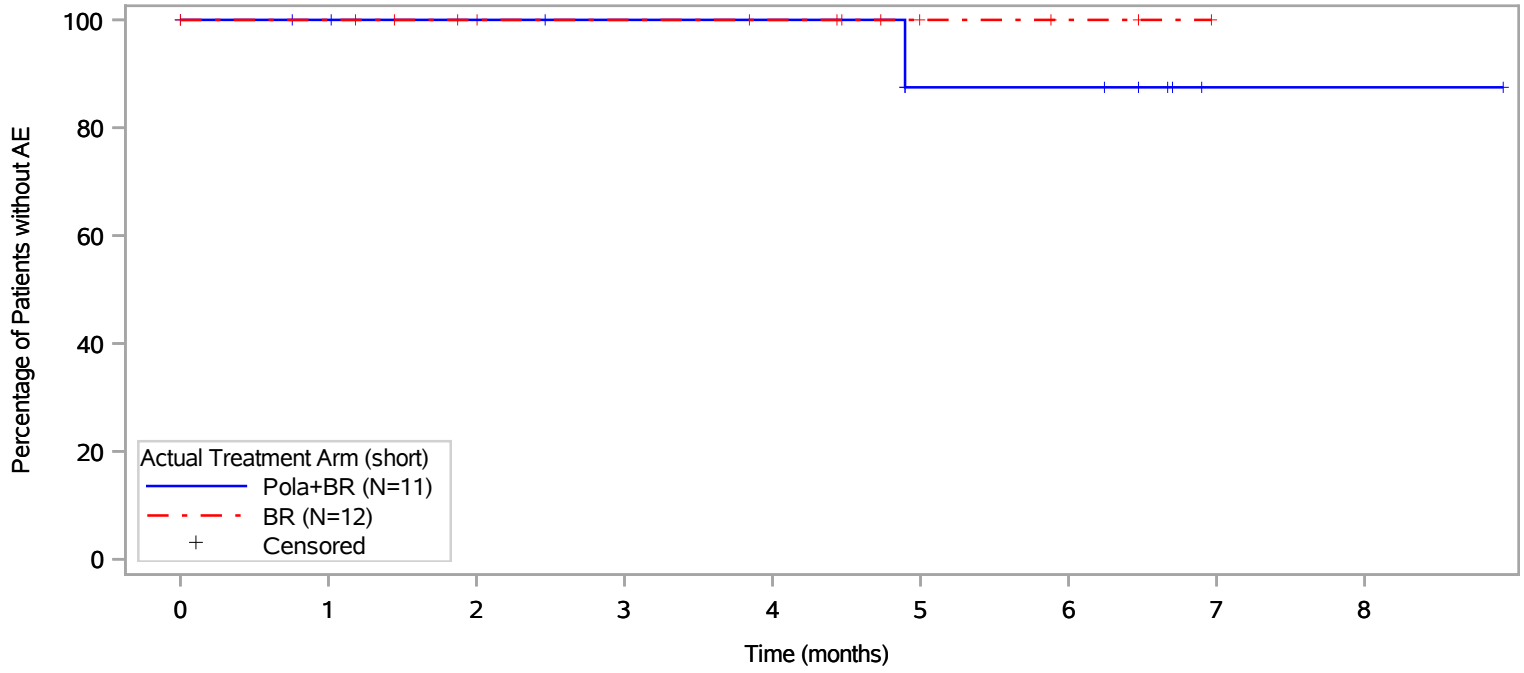
Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, VOCAL CORD PARALYSIS

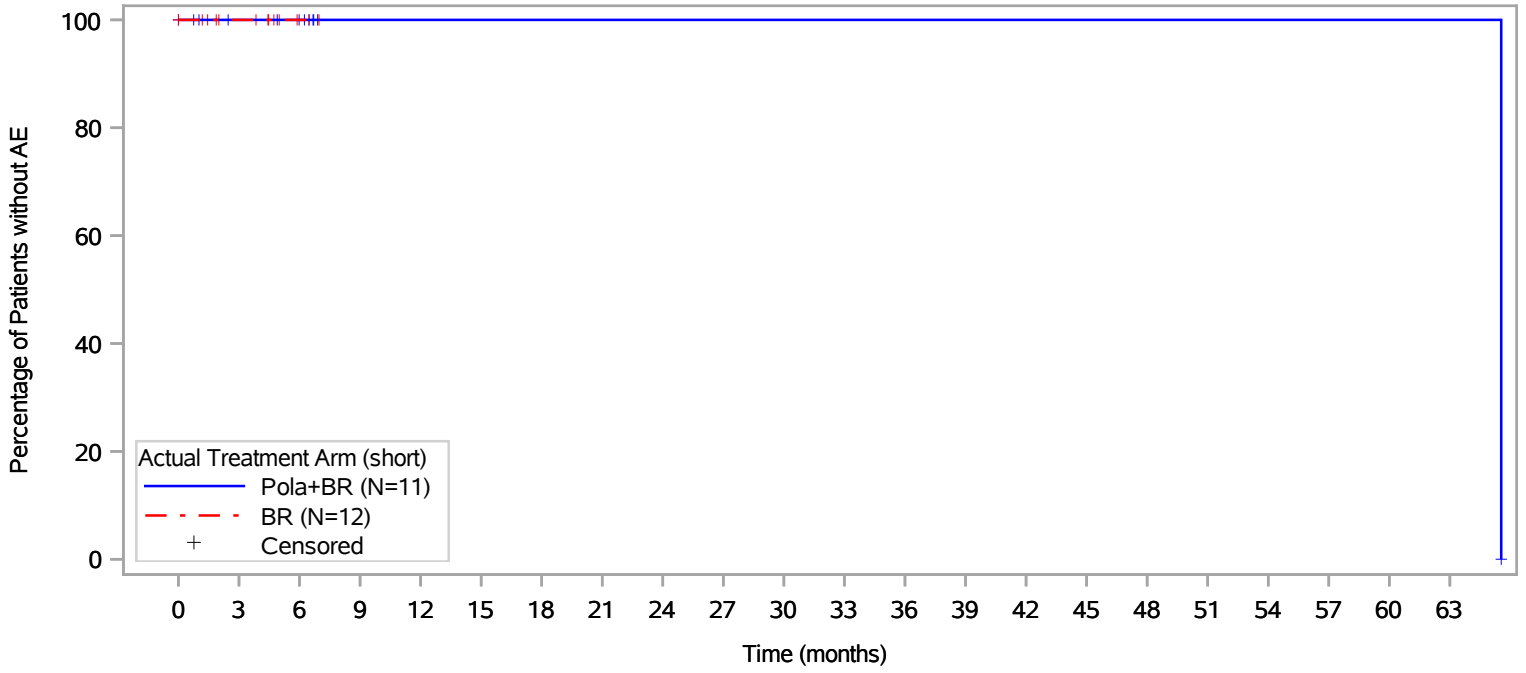


Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



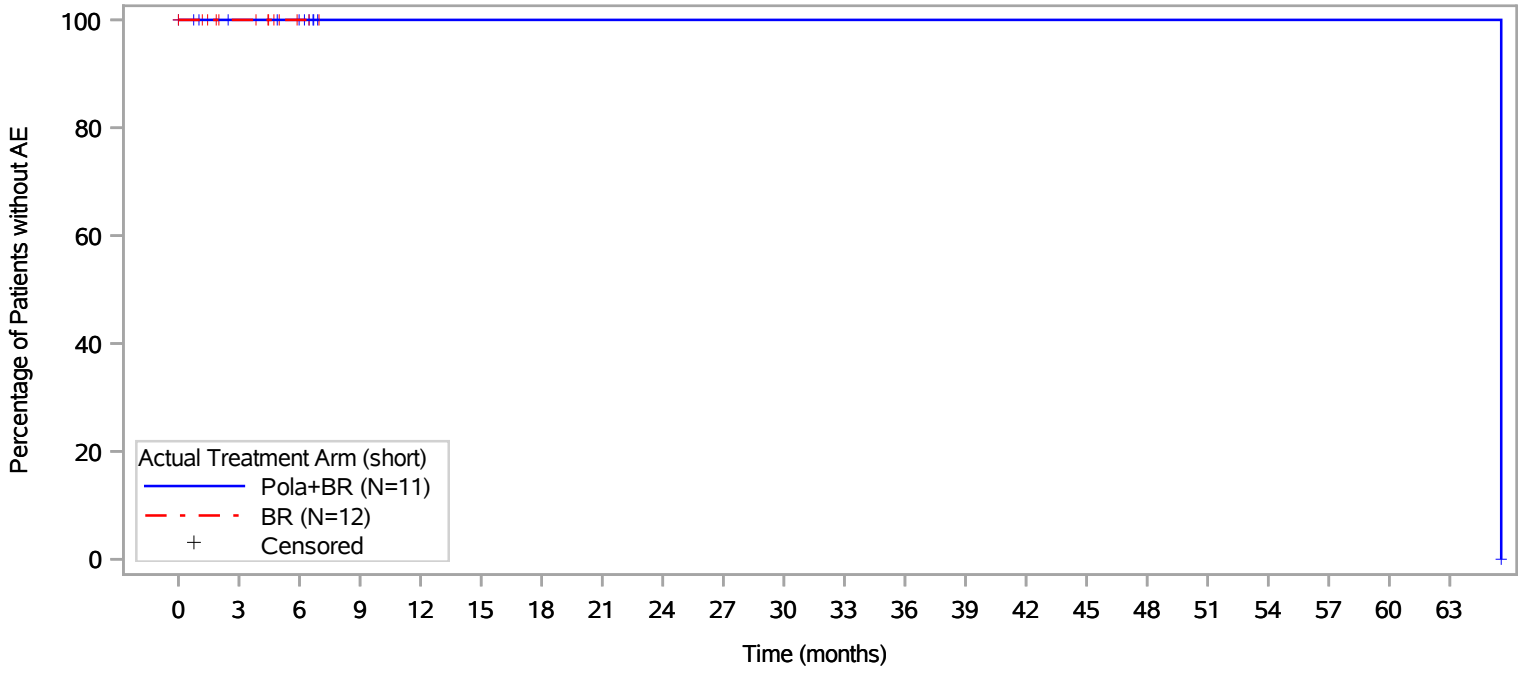
Patients at risk																							
Pola+BR (N=11)	11	8	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=12)	12	8	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=11)	0	3	5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BR (N=12)	0	4	10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



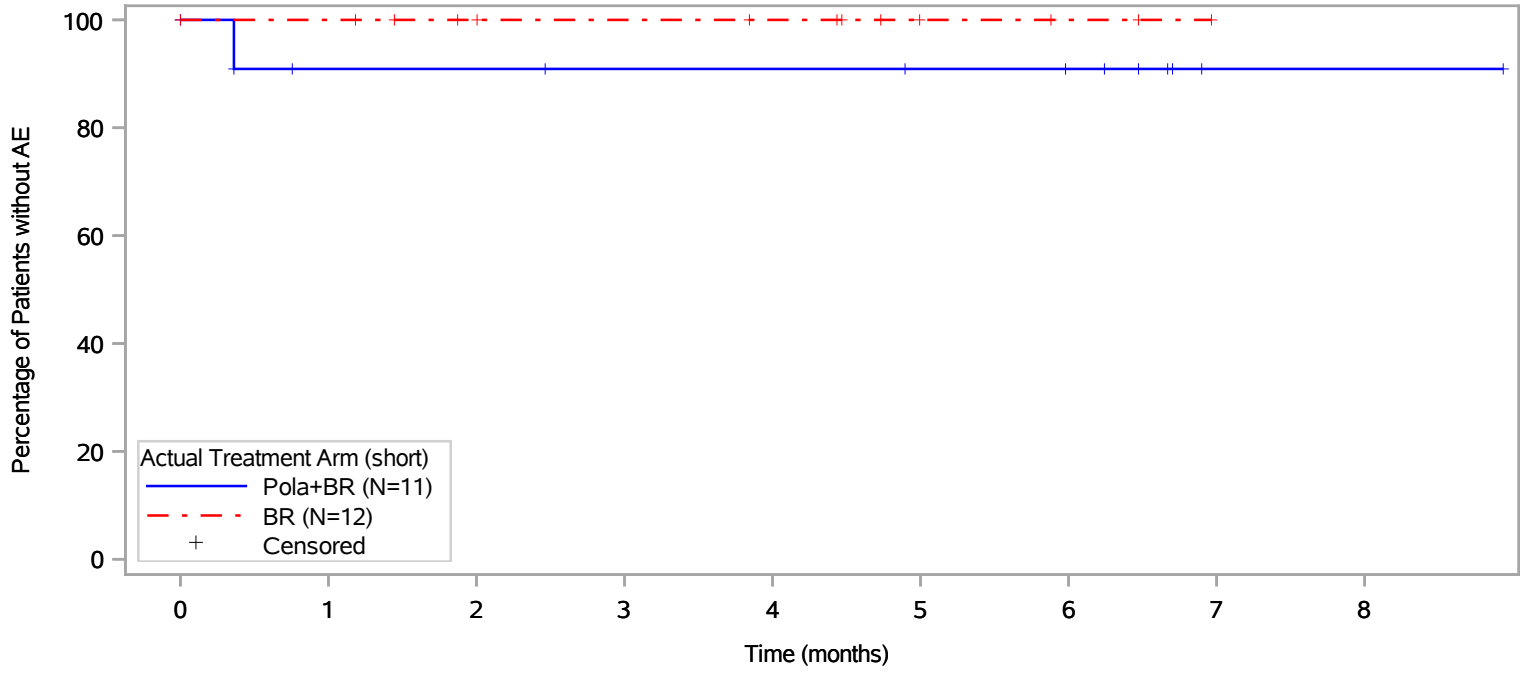
Patients at risk																							
Pola+BR (N=11)	11	8	6	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=12)	12	8	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																							
Pola+BR (N=11)	0	3	5	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
BR (N=12)	0	4	10	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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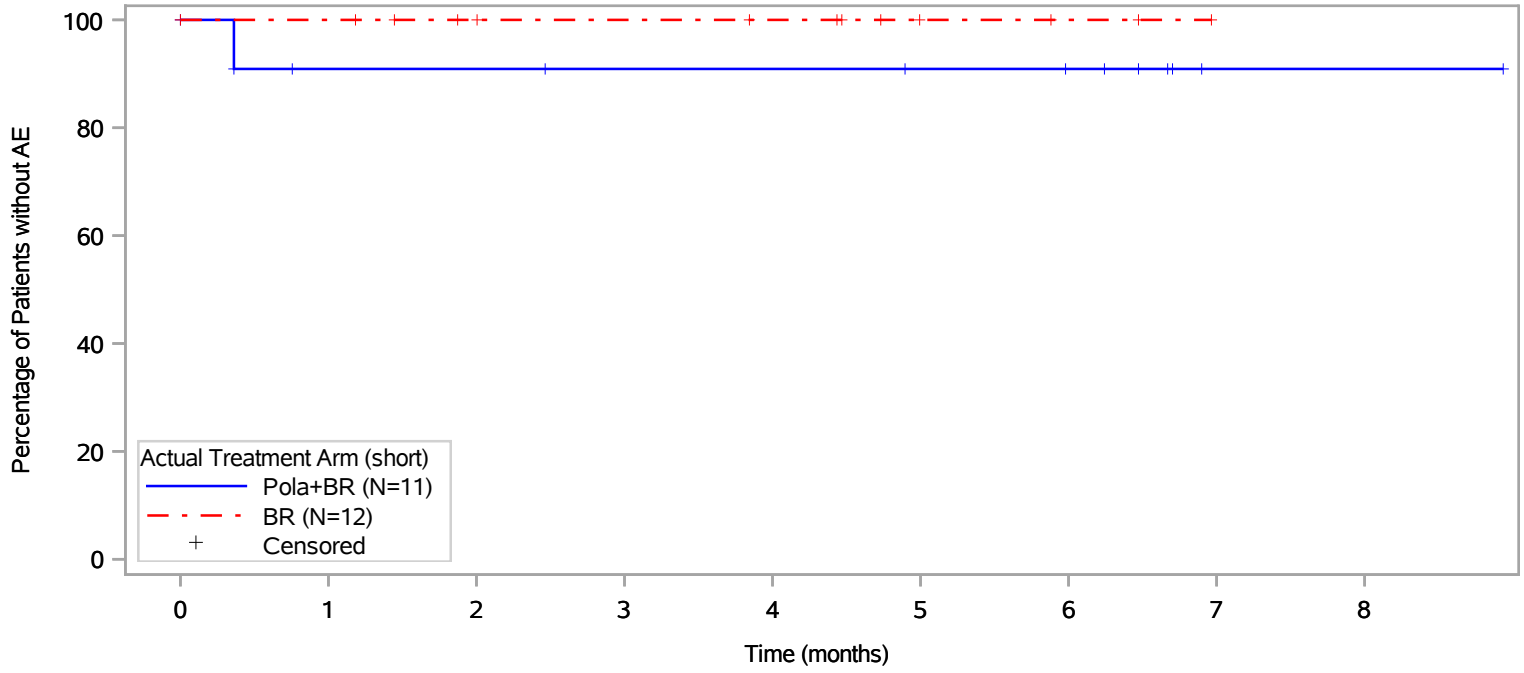
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY OEDEMA



Patients at risk								
Pola+BR (N=11)	11	9	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored								
Pola+BR (N=11)	0	1	1	2	2	3	4	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

All

			Pola+BR (N=11)				BR (N=12)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS			11	100.0	2	18.2	12	100.0	1	8.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		11	100.0	0	-	12	100.0	1	8.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		11	100.0	2	18.2	12	100.0	0	-
INFECTIONS AND INFESTATIONS			11	100.0	1	9.1	12	100.0	1	8.3
INFECTIONS AND INFESTATIONS	PNEUMONIA		11	100.0	1	9.1	12	100.0	0	-
INFECTIONS AND INFESTATIONS	SEPSIS		11	100.0	0	-	12	100.0	1	8.3
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			11	100.0	1	9.1	12	100.0	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY		11	100.0	1	9.1	12	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			11	100.0	2	18.2	12	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS		11	100.0	1	9.1	12	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA		11	100.0	1	9.1	12	100.0	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=11)				BR (N=12)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	3	27.3	0	-	0	0.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	8	72.7	2	25.0	12	100.0	1	8.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	3	27.3	0	-	0	0.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	8	72.7	0	-	12	100.0	1	8.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	3	27.3	0	-	0	0.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	8	72.7	2	25.0	12	100.0	0	-
INFECTIONS AND INFESTATIONS		< 65	3	27.3	0	-	0	0.0	0	-
INFECTIONS AND INFESTATIONS		>= 65	8	72.7	1	12.5	12	100.0	1	8.3
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	3	27.3	0	-	0	0.0	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	8	72.7	1	12.5	12	100.0	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	3	27.3	0	-	0	0.0	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	8	72.7	0	-	12	100.0	1	8.3
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	3	27.3	1	33.3	0	0.0	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	8	72.7	0	-	12	100.0	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	< 65	3	27.3	1	33.3	0	0.0	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	>= 65	8	72.7	0	-	12	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	3	27.3	1	33.3	0	0.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	8	72.7	1	12.5	12	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	< 65	3	27.3	0	-	0	0.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	>= 65	8	72.7	1	12.5	12	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	< 65	3	27.3	1	33.3	0	0.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>= 65	8	72.7	0	-	12	100.0	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=11)				BR (N=12)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	6	54.5	2	33.3	10	83.3	1	10.0
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	45.5	0	-	2	16.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	6	54.5	0	-	10	83.3	1	10.0
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	5	45.5	0	-	2	16.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	6	54.5	2	33.3	10	83.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	5	45.5	0	-	2	16.7	0	-
INFECTIONS AND INFESTATIONS		>=3	6	54.5	1	16.7	10	83.3	1	10.0
INFECTIONS AND INFESTATIONS		<3	5	45.5	0	-	2	16.7	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	6	54.5	1	16.7	10	83.3	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	45.5	0	-	2	16.7	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	6	54.5	0	-	10	83.3	1	10.0
INFECTIONS AND INFESTATIONS	SEPSIS	<3	5	45.5	0	-	2	16.7	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	6	54.5	0	-	10	83.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	5	45.5	1	20.0	2	16.7	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	>=3	6	54.5	0	-	10	83.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	<3	5	45.5	1	20.0	2	16.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	6	54.5	2	33.3	10	83.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	45.5	0	-	2	16.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	>=3	6	54.5	1	16.7	10	83.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	<3	5	45.5	0	-	2	16.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	>=3	6	54.5	1	16.7	10	83.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	<3	5	45.5	0	-	2	16.7	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=11)				BR (N=12)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	5	45.5	1	20.0	3	25.0	1	33.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	6	54.5	1	16.7	9	75.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	5	45.5	0	-	3	25.0	1	33.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	6	54.5	0	-	9	75.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	5	45.5	1	20.0	3	25.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	6	54.5	1	16.7	9	75.0	0	-
INFECTIONS AND INFESTATIONS		Europe	5	45.5	0	-	3	25.0	0	-
INFECTIONS AND INFESTATIONS		Non-Europe	6	54.5	1	16.7	9	75.0	1	11.1
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	5	45.5	0	-	3	25.0	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	6	54.5	1	16.7	9	75.0	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	5	45.5	0	-	3	25.0	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	6	54.5	0	-	9	75.0	1	11.1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	5	45.5	0	-	3	25.0	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	6	54.5	1	16.7	9	75.0	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Europe	5	45.5	0	-	3	25.0	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Non-Europe	6	54.5	1	16.7	9	75.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	5	45.5	0	-	3	25.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	6	54.5	2	33.3	9	75.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Europe	5	45.5	0	-	3	25.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Non-Europe	6	54.5	1	16.7	9	75.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Europe	5	45.5	0	-	3	25.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Non-Europe	6	54.5	1	16.7	9	75.0	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=11)				BR (N=12)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	63.6	1	14.3	7	58.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	4	36.4	1	25.0	5	41.7	1	20.0
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	7	63.6	0	-	7	58.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	4	36.4	0	-	5	41.7	1	20.0
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	7	63.6	1	14.3	7	58.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	4	36.4	1	25.0	5	41.7	0	-
INFECTIONS AND INFESTATIONS		Male	7	63.6	1	14.3	7	58.3	1	14.3
INFECTIONS AND INFESTATIONS		Female	4	36.4	0	-	5	41.7	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	63.6	1	14.3	7	58.3	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	4	36.4	0	-	5	41.7	0	-
INFECTIONS AND INFESTATIONS	SEPSIS	Male	7	63.6	0	-	7	58.3	1	14.3
INFECTIONS AND INFESTATIONS	SEPSIS	Female	4	36.4	0	-	5	41.7	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	7	63.6	1	14.3	7	58.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	4	36.4	0	-	5	41.7	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Male	7	63.6	1	14.3	7	58.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE ATROPHY	Female	4	36.4	0	-	5	41.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	7	63.6	2	28.6	7	58.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	4	36.4	0	-	5	41.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Male	7	63.6	1	14.3	7	58.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMONITIS	Female	4	36.4	0	-	5	41.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Male	7	63.6	1	14.3	7	58.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY OEDEMA	Female	4	36.4	0	-	5	41.7	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	1	14.3	6	85.7	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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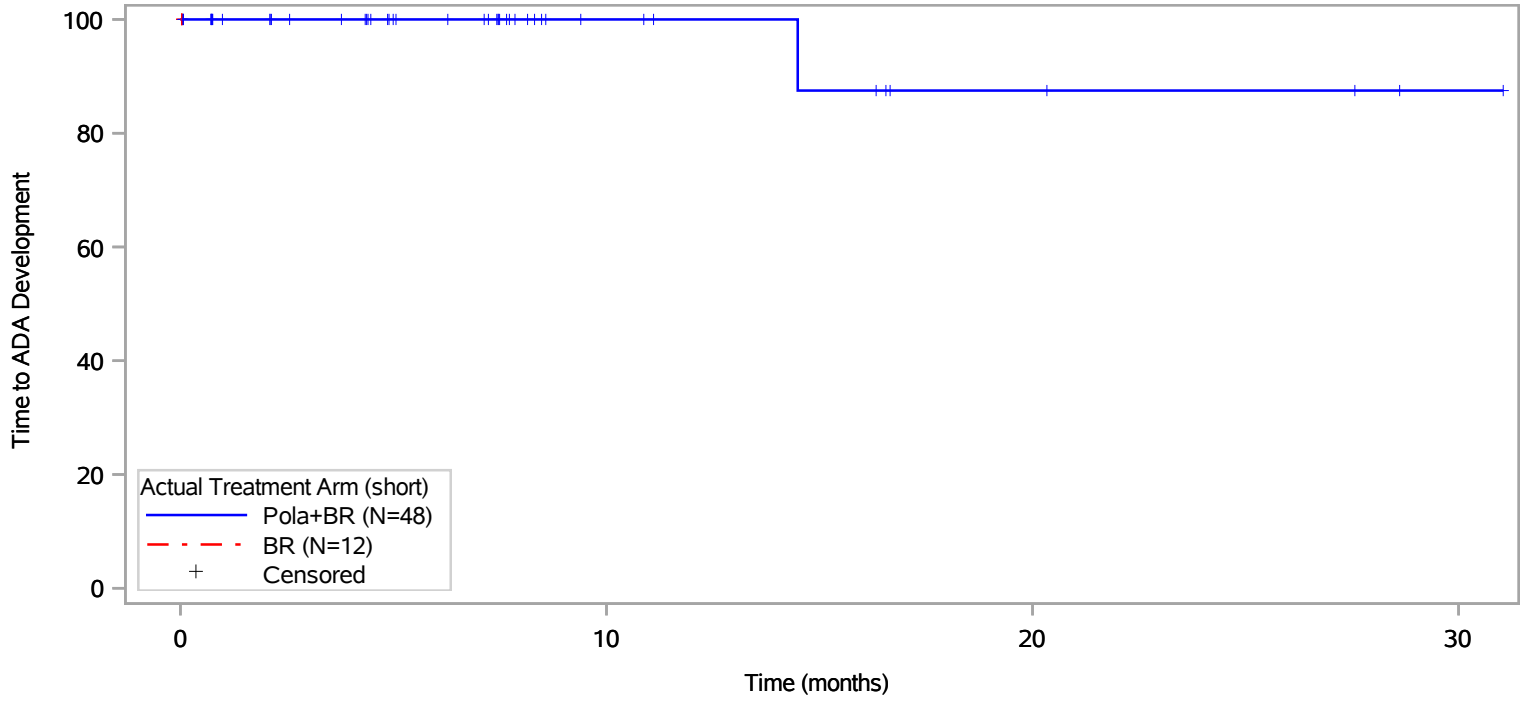
06APR2023 19:04

POPULATION: Safety-Evaluable Patients, Study GO29365, Second-line (2L) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=48)	48	34	25	11	8	7	4	3	3	3	1
BR (N=12)	12	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=48)	0	14	23	37	40	40	43	44	44	44	46
BR (N=12)	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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06APR2023 19:45

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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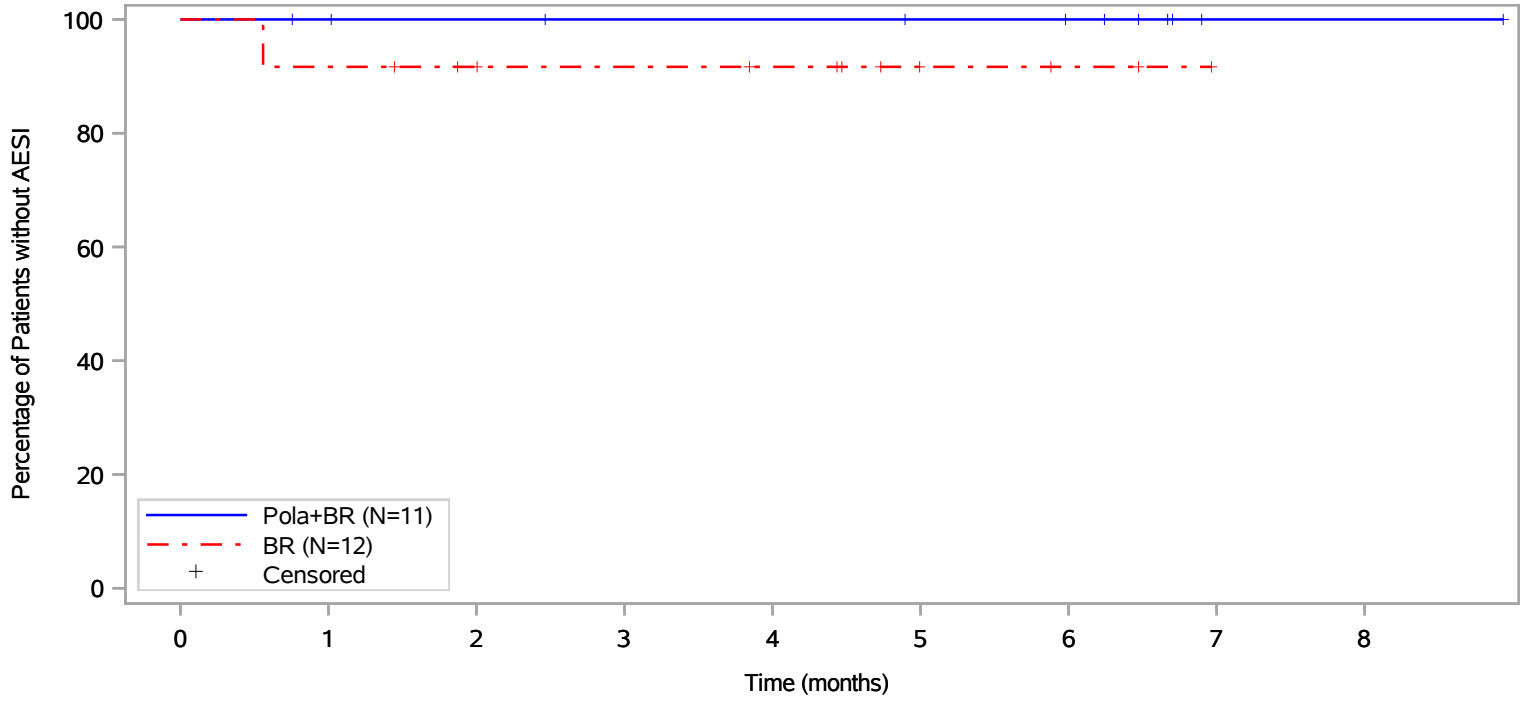
25JAN2023 17:05

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Alopecia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 16:54

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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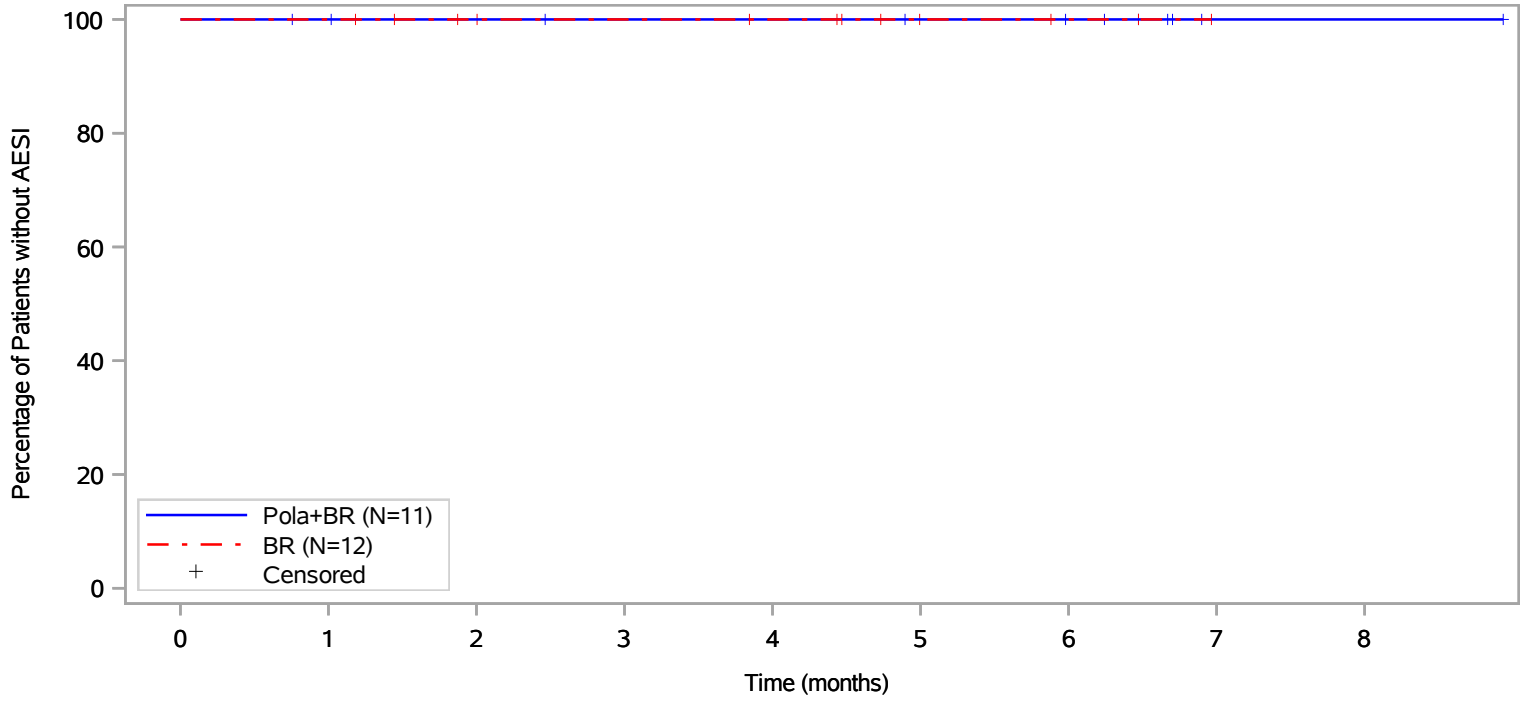
02DEC2022 21:57

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTALOPE35_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 16:56

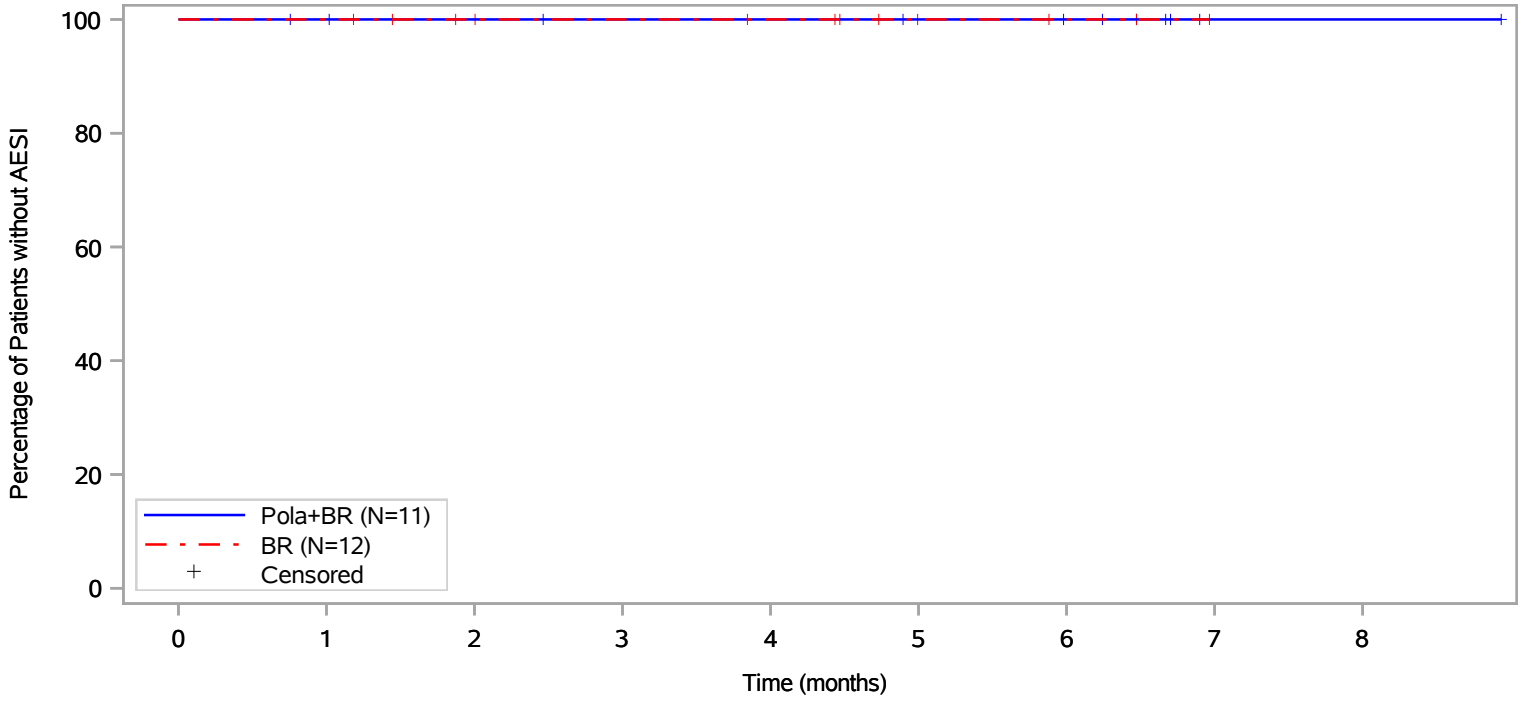
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTALOPES_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 21:56

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Alopecia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTALOPES_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 8:53

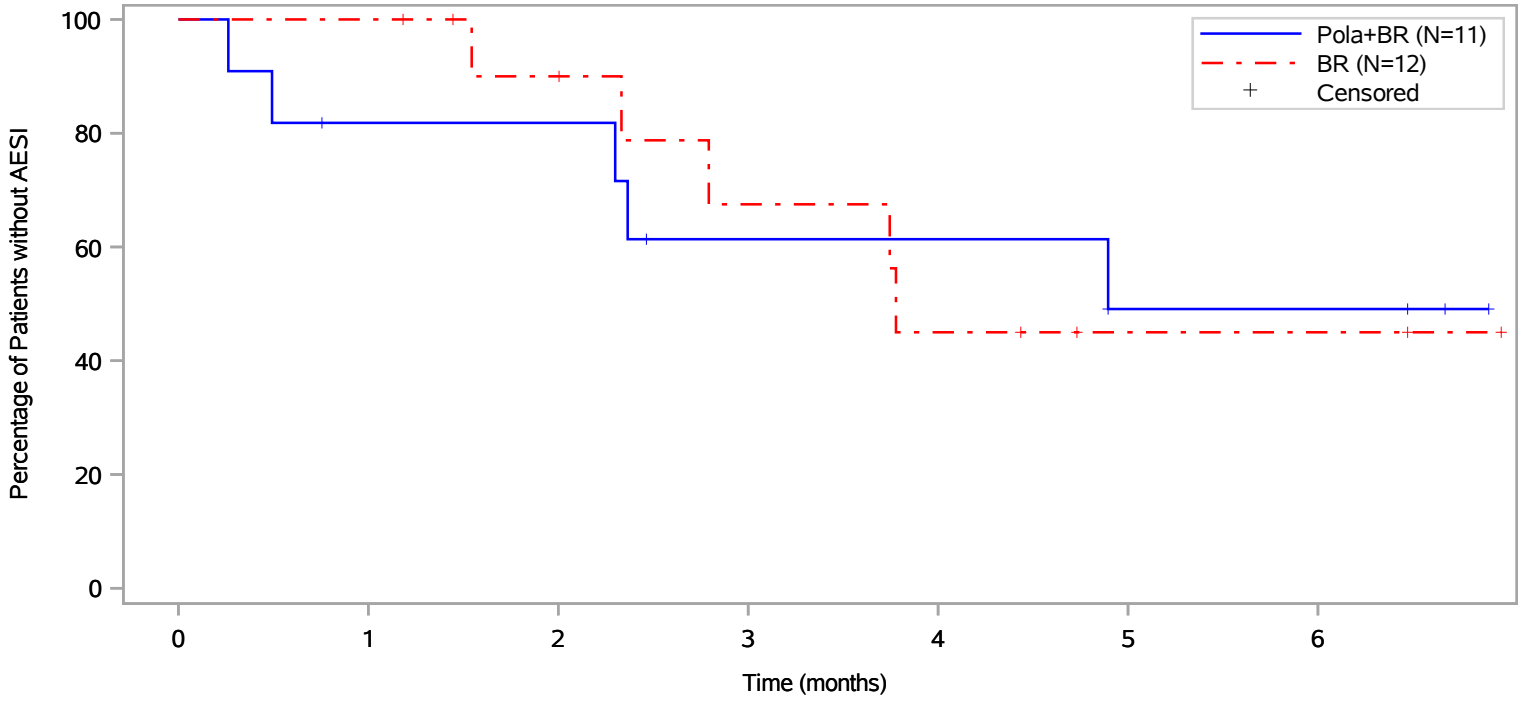
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	5	45.5	6	54.5	12	100.0	5	41.7	7	58.3	0.9639	1.03	0.29	3.61		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	3	42.9	4	57.1	7	58.3	3	42.9	4	57.1	0.7463	0.76	0.15	3.92		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	2	50.0	2	50.0	5	41.7	2	40.0	3	60.0	0.6869	1.49	0.21	10.70		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	5	41.7	7	58.3	0.9923	0.99	0.24	4.18		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	3	50.0	3	50.0	10	83.3	4	40.0	6	60.0	0.4980	1.69	0.37	7.79		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.5596	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	3	25.0	1	33.3	2	66.7	0.5768	1.98	0.17	22.61		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	4	44.4	5	55.6	0.7331	0.77	0.16	3.57		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTANEIM_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 1:02

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Anemia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	8	8	5	5	3	3
BR (N=12)	12	12	9	6	4	2	2
Patients censored							
Pola+BR (N=11)	0	1	1	2	2	3	3
BR (N=12)	0	0	2	3	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTANEIM_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:05

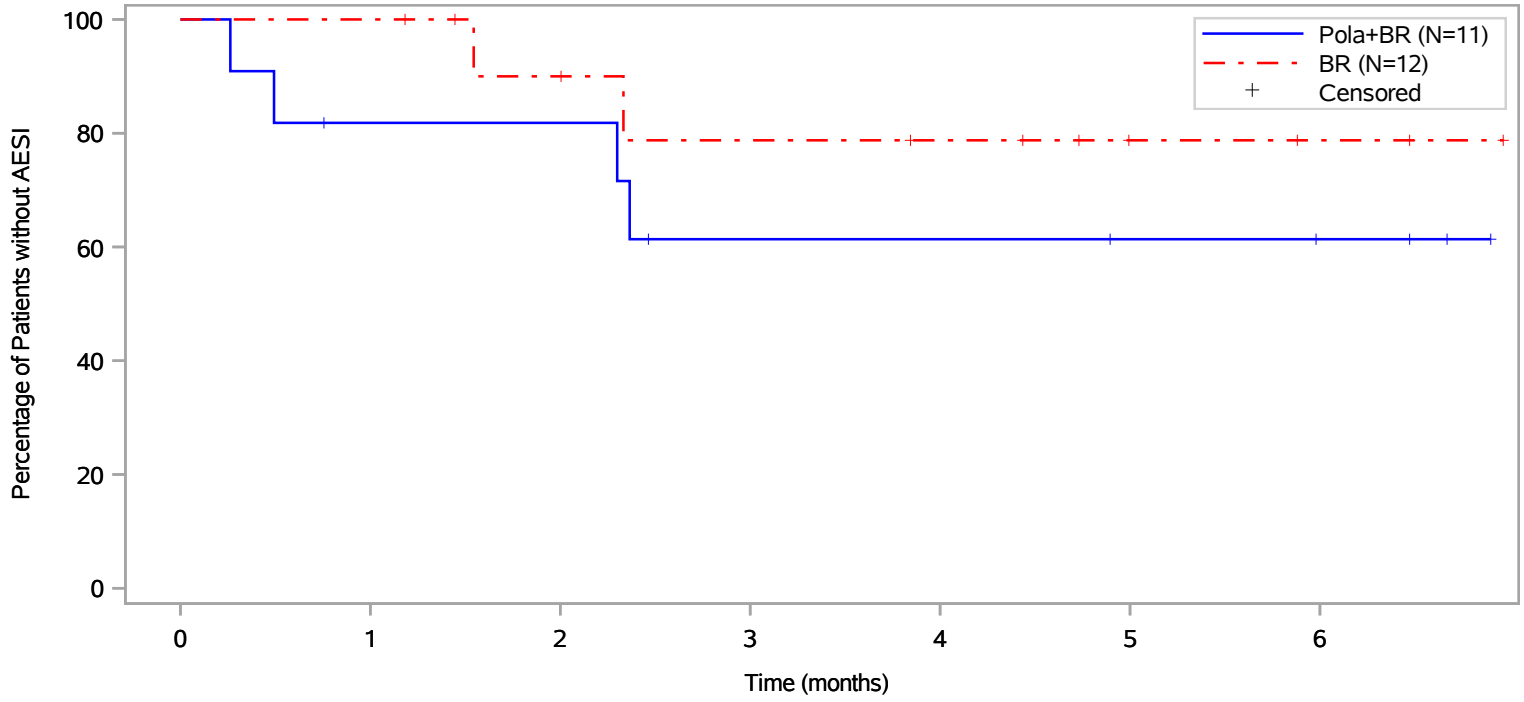
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	4	36.4	7	63.6	12	100.0	2	16.7	10	83.3	0.3441	2.22	0.41	12.15		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	2	28.6	5	71.4	7	58.3	2	28.6	5	71.4	0.8914	0.87	0.12	6.29		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	2	50.0	2	50.0	5	41.7	0	-	5	100.0	0.1081	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	2	16.7	10	83.3	0.3634	2.24	0.37	13.45		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	3	50.0	3	50.0	10	83.3	2	20.0	8	80.0	0.2705	2.64	0.44	15.82		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	3	25.0	0	-	3	100.0	0.2087	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	2	22.2	7	77.8	0.8093	1.27	0.18	9.09		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTANEIM35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:29

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	8	8	5	5	4	3
BR (N=12)	12	12	9	7	6	3	2
Patients censored							
Pola+BR (N=11)	0	1	1	2	2	3	4
BR (N=12)	0	0	2	3	4	7	8

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTANEIM35_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 9:33

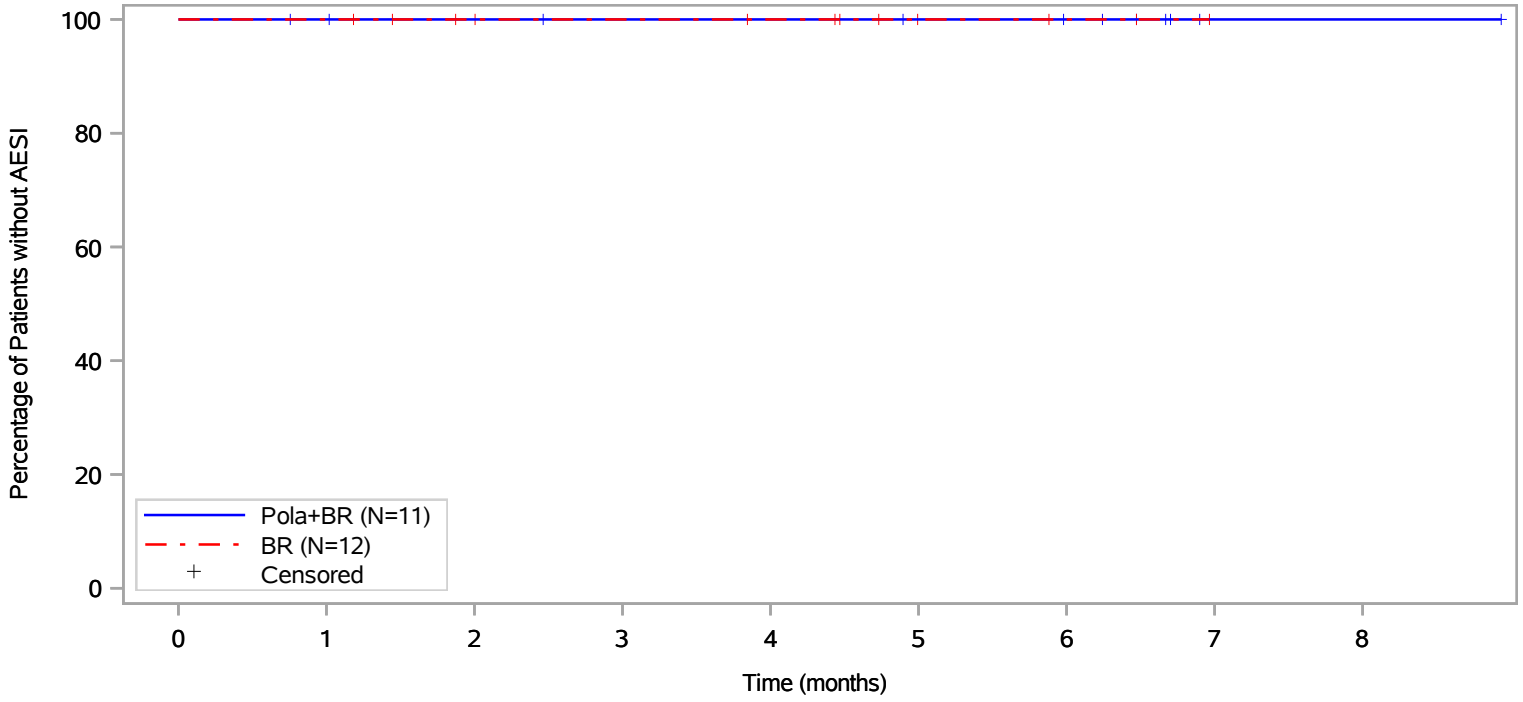
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTANEIMS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:24

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Anemia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTANEIMS_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 7:04

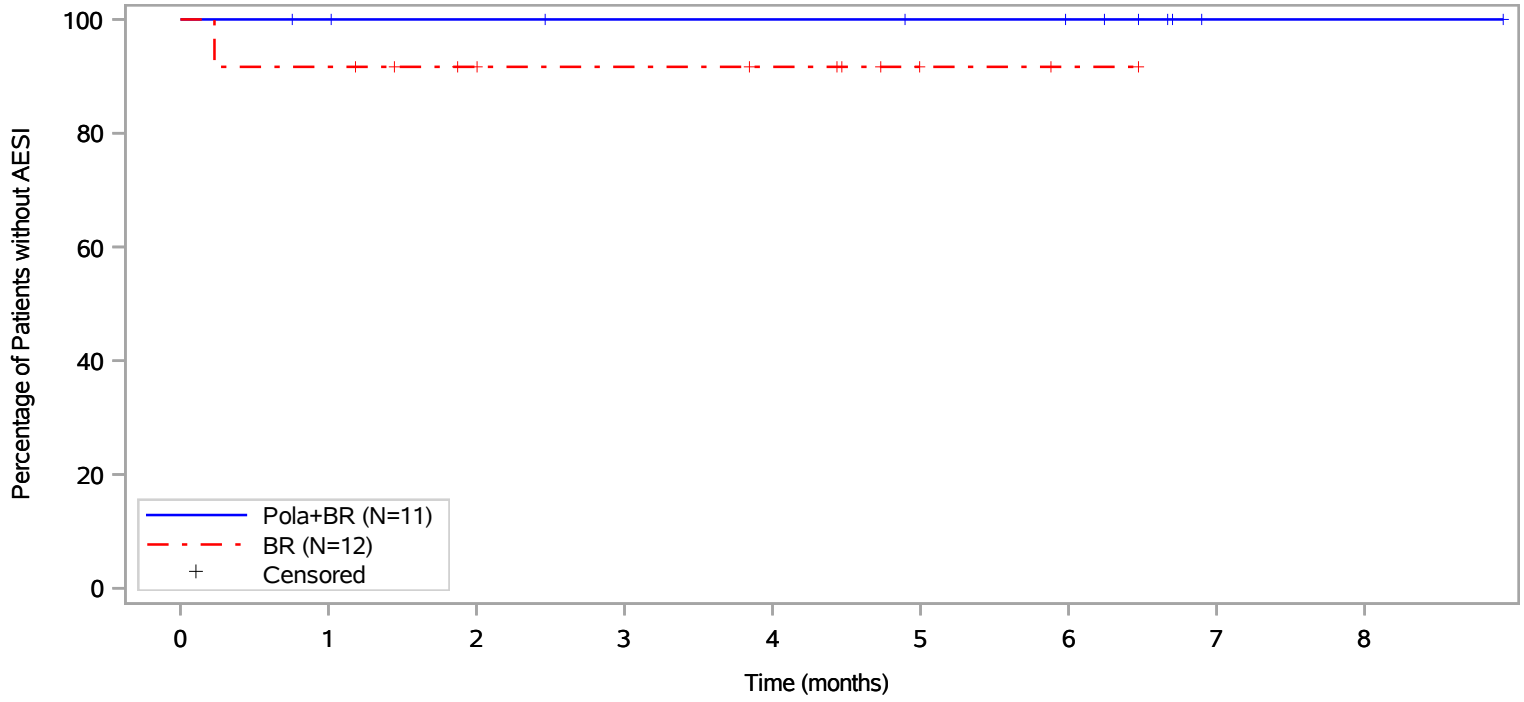
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3384	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTCTAAR_L2_ARMCDSE_365_29365_41543.xls
25JAN2023 17:13

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	7	6	2	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTCTAAR_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:16

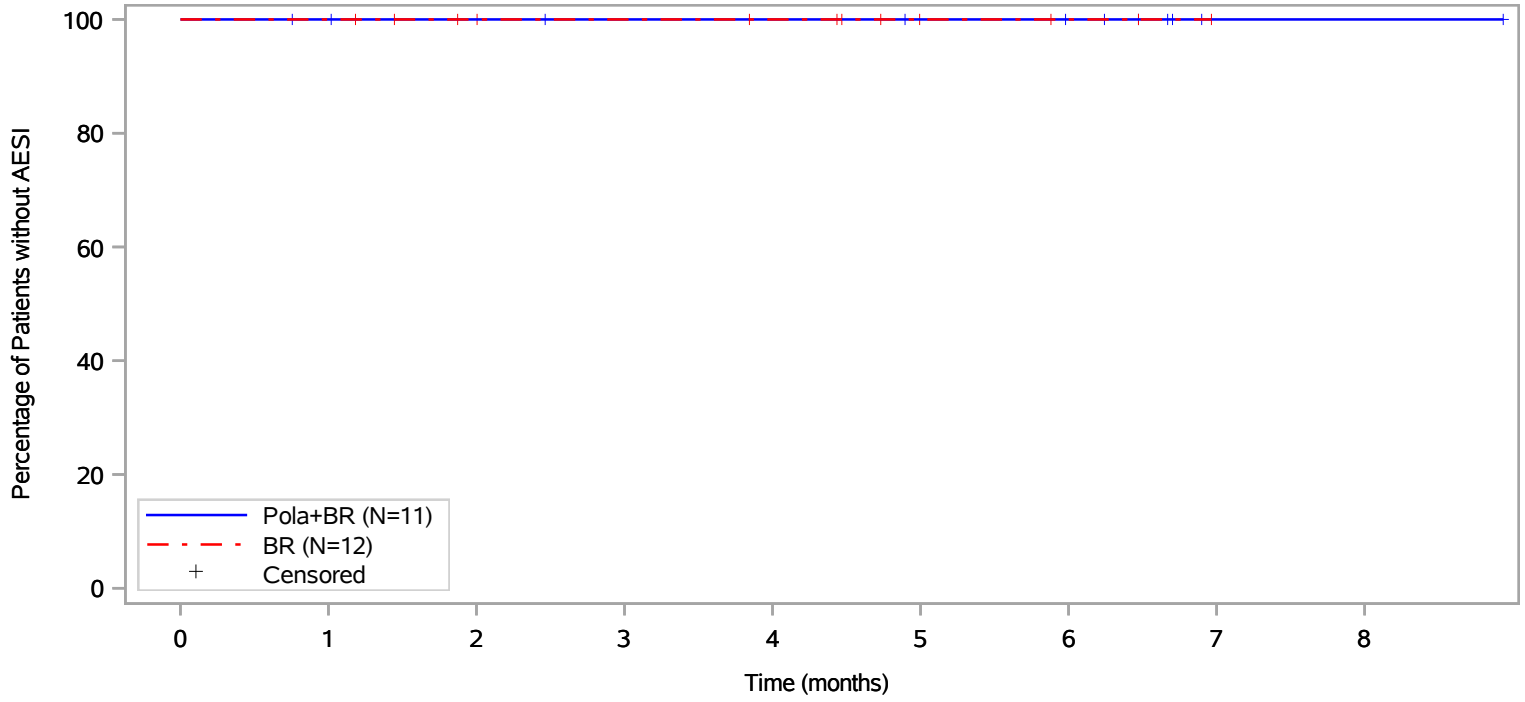
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTCTAAR35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 22:08

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTCTAAR35_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 14:07

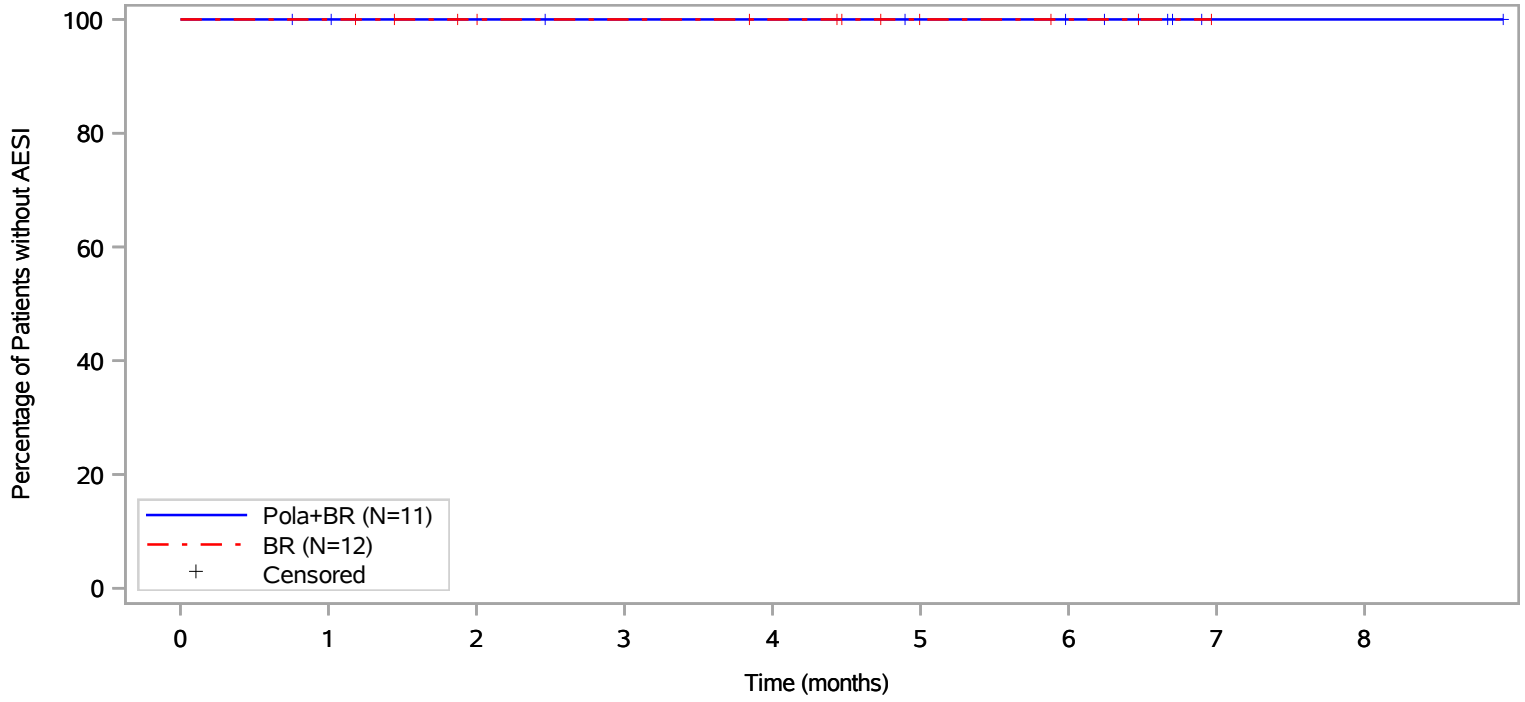
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTCTAARS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 22:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTCTAARS_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 9:02

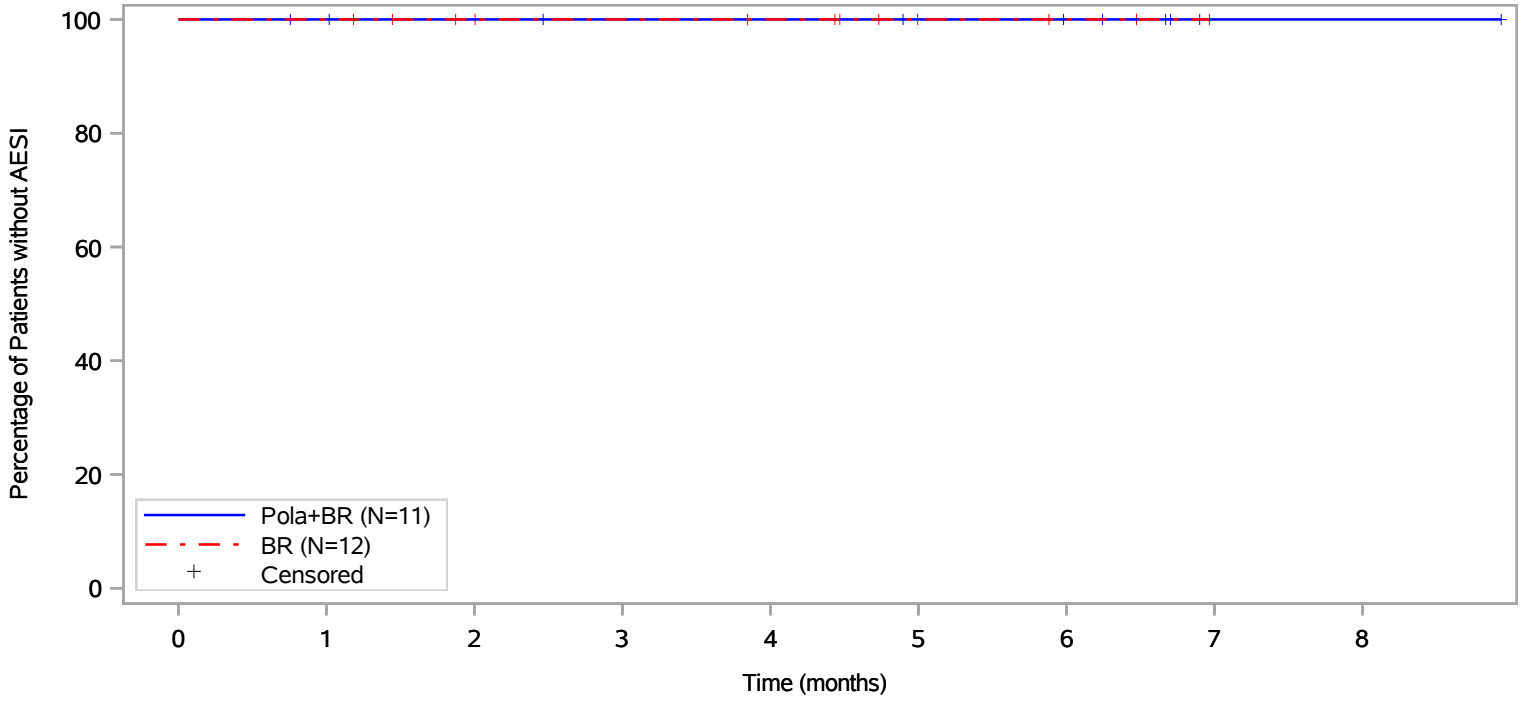
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTDDIN_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 22:03

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Drug Drug Interaction
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTDDIN_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 23:22

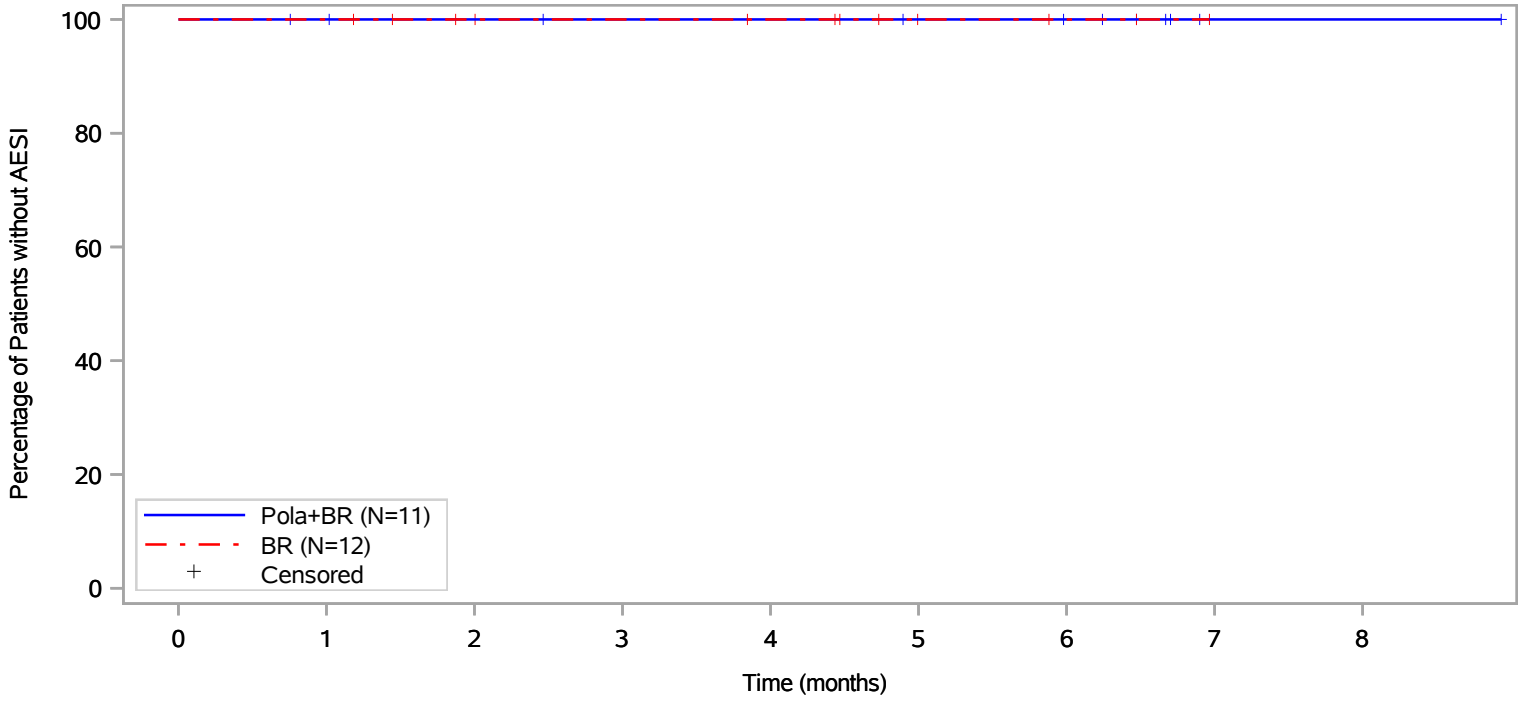
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTDYSGUE_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 20:51

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTDYSGUE_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 22:43

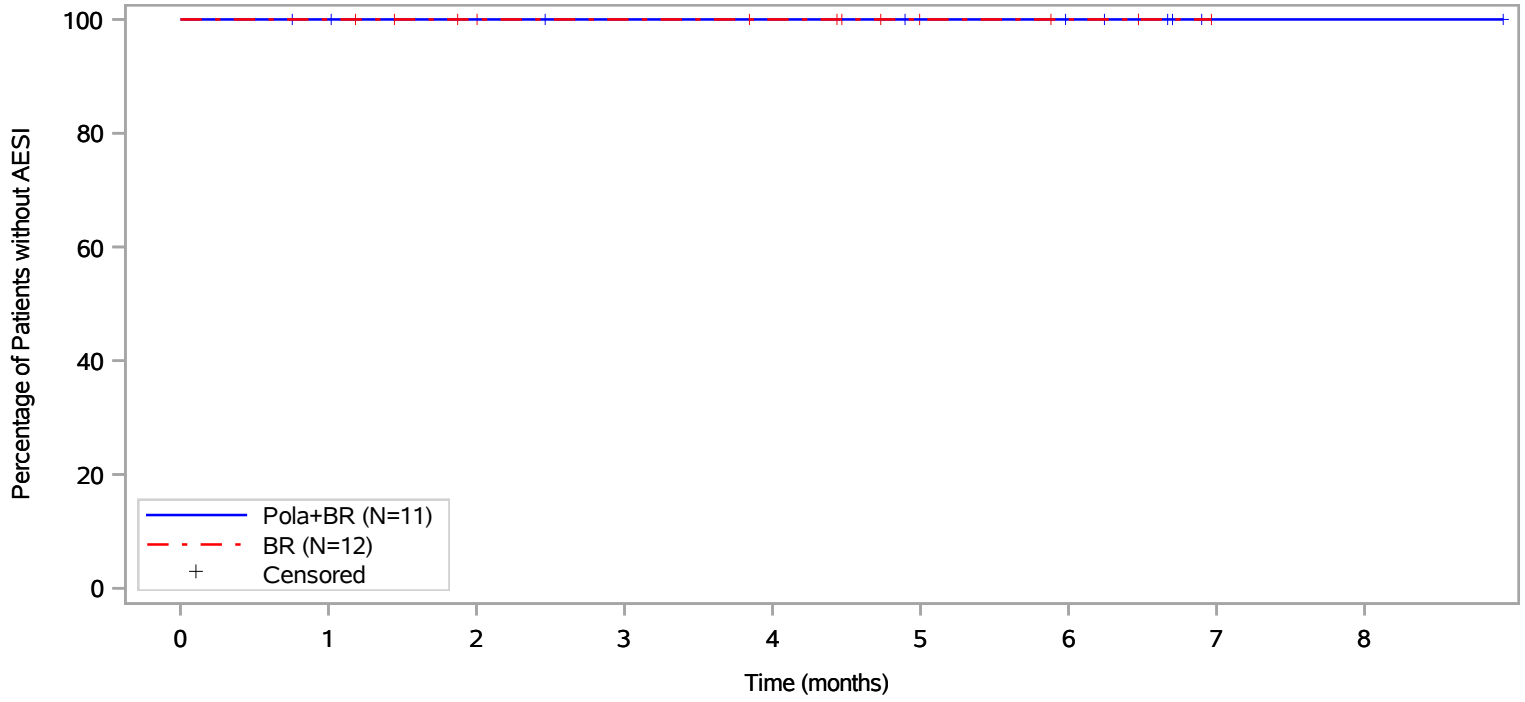
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTDYSGUE35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 22:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTDYSGUE35_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:27

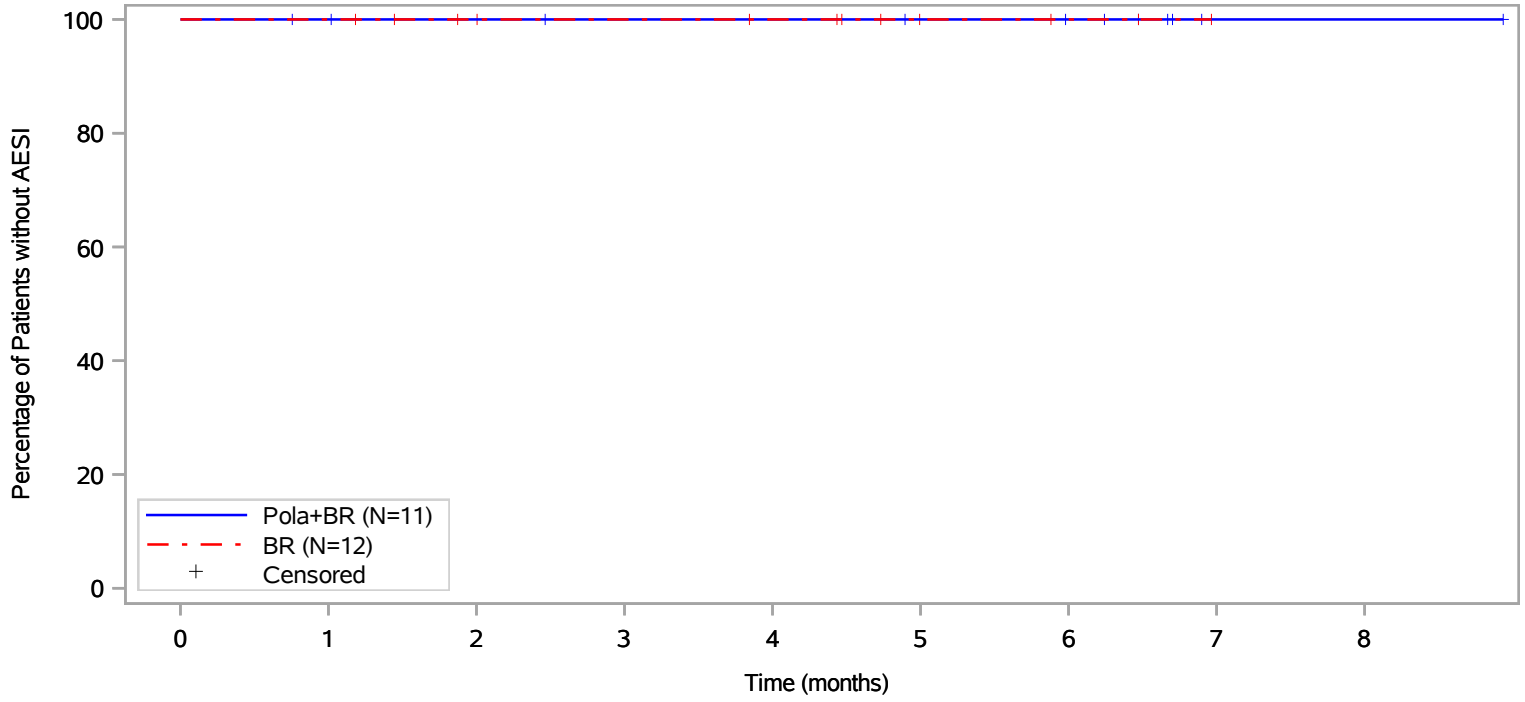
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTDYSGUES_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 22:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTDYSGUES_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 11:55

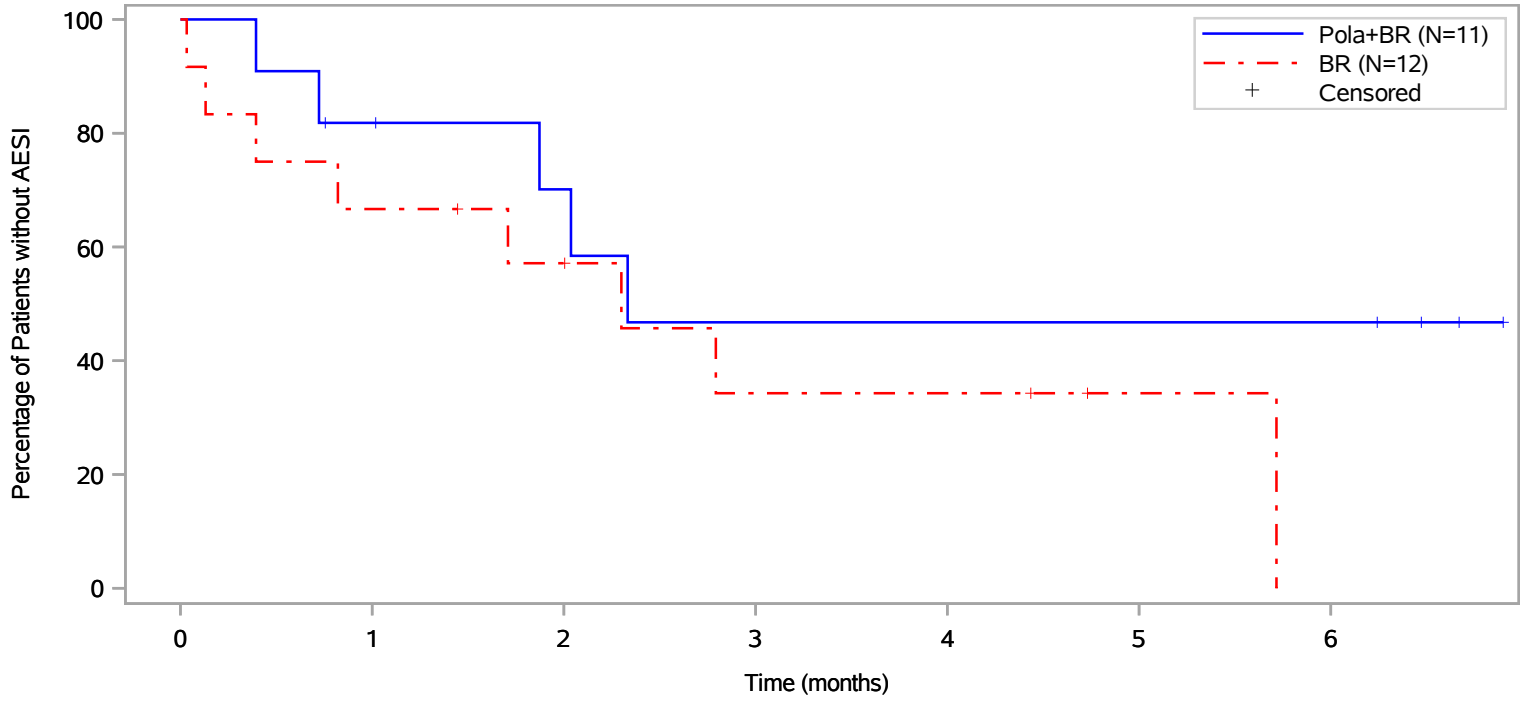
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	5	45.5	6	54.5	12	100.0	8	66.7	4	33.3	0.2670	0.53	0.17	1.66		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	3	42.9	4	57.1	7	58.3	5	71.4	2	28.6	0.3106	0.48	0.11	2.05		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	2	50.0	2	50.0	5	41.7	3	60.0	2	40.0	0.5614	0.59	0.10	3.61		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	8	66.7	4	33.3	0.3169	0.54	0.16	1.84		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	3	50.0	3	50.0	10	83.3	7	70.0	3	30.0	0.5497	0.66	0.17	2.60		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.8132	0.75	0.07	8.42		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	2	66.7	1	33.3	0.2854	0.29	0.03	3.23		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	6	66.7	3	33.3	0.9674	0.97	0.27	3.53		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTFAA_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 4:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	8	6	4	4	4	4
BR (N=12)	12	8	6	3	3	1	NE
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	2	2
BR (N=12)	0	0	1	2	2	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTFAA_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:33

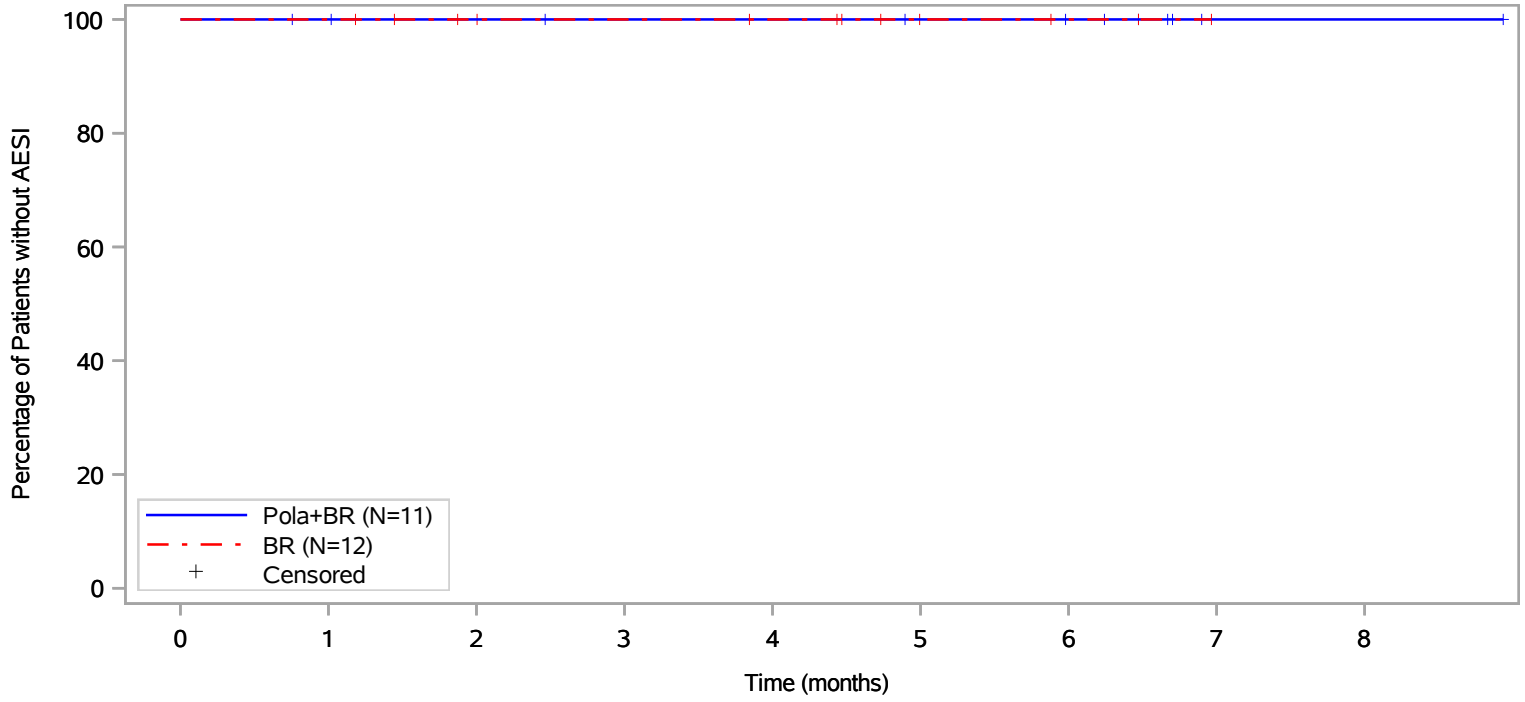
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTFAA35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 21:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTFAA35_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 11:31

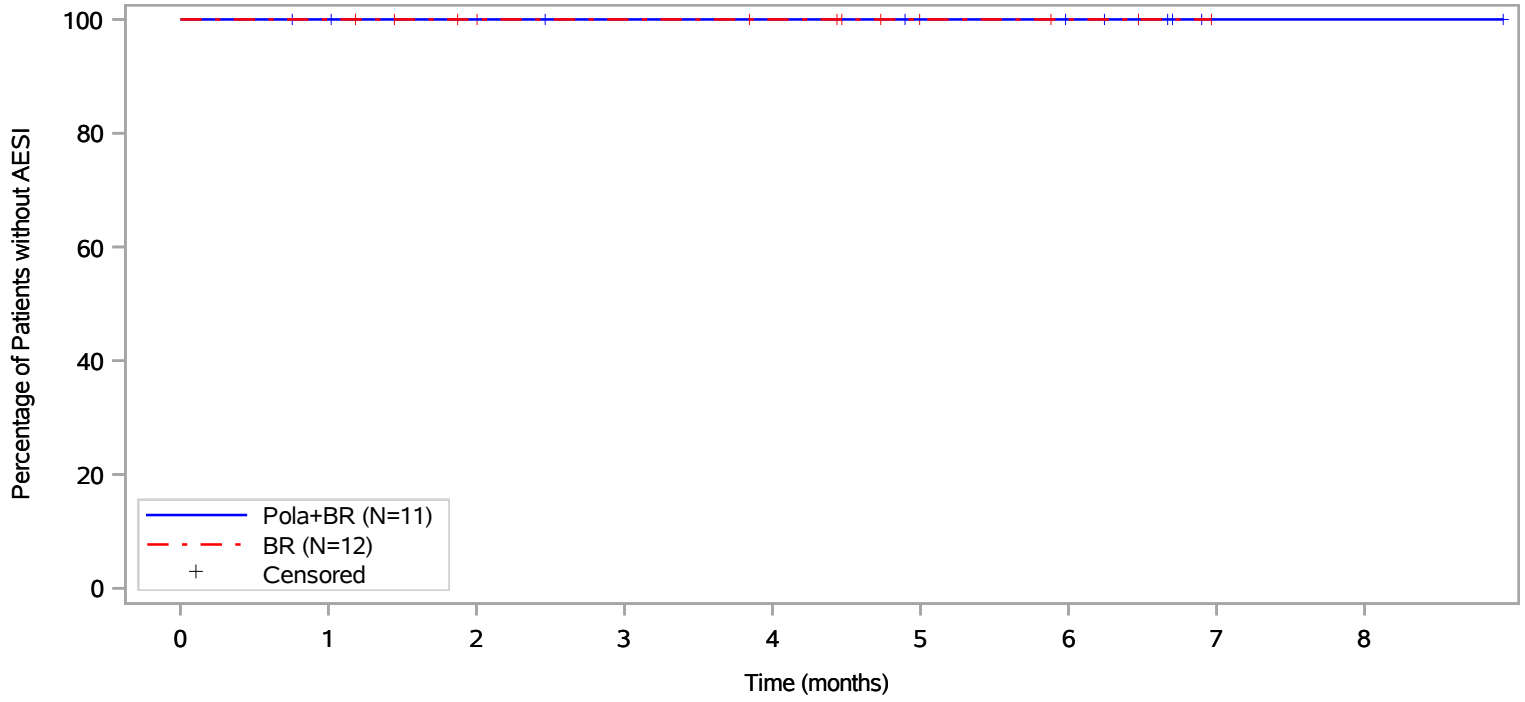
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTFAAS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 21:13

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTFAAS_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:37

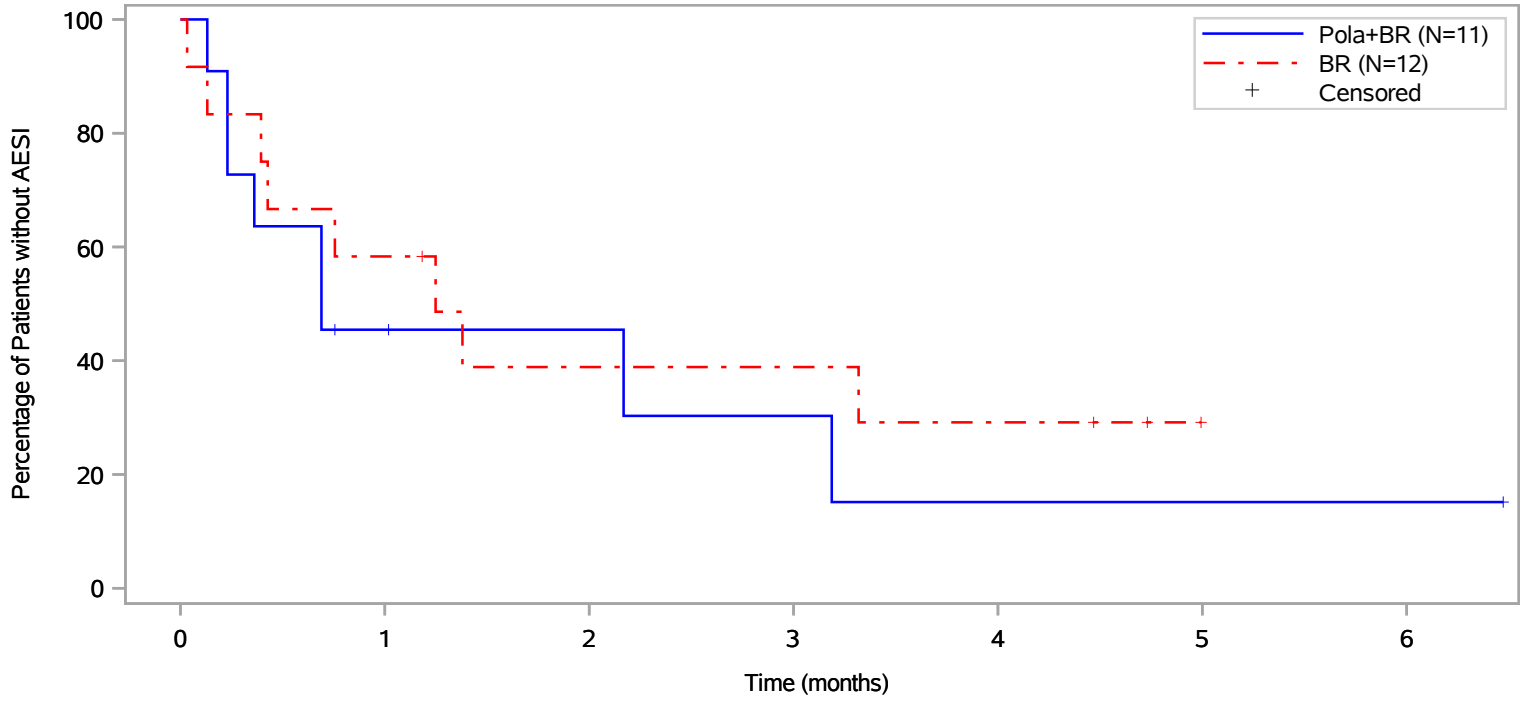
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	8	72.7	3	27.3	12	100.0	8	66.7	4	33.3	0.5202	1.39	0.51	3.79		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	4	57.1	3	42.9	7	58.3	4	57.1	3	42.9	0.8399	1.16	0.28	4.84		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	4	100.0	0	-	5	41.7	4	80.0	1	20.0	0.4859	1.67	0.39	7.17		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	7	87.5	1	12.5	12	100.0	8	66.7	4	33.3	0.1772	2.06	0.71	5.99		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	4	66.7	2	33.3	10	83.3	6	60.0	4	40.0	0.4796	1.62	0.42	6.28		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	4	80.0	1	20.0	2	16.7	2	100.0	0	-	0.8491	0.83	0.13	5.47		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	3	60.0	2	40.0	3	25.0	2	66.7	1	33.3	0.8321	1.22	0.19	7.80		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	5	83.3	1	16.7	9	75.0	6	66.7	3	33.3	0.1200	2.86	0.72	11.26		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGASTOX_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 6:25

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	4	3	2	1	1	1
BR (N=12)	12	7	4	4	3	NE	NE
Patients censored							
Pola+BR (N=11)	0	1	2	2	2	2	2
BR (N=12)	0	0	1	1	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTGASTOX_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:42

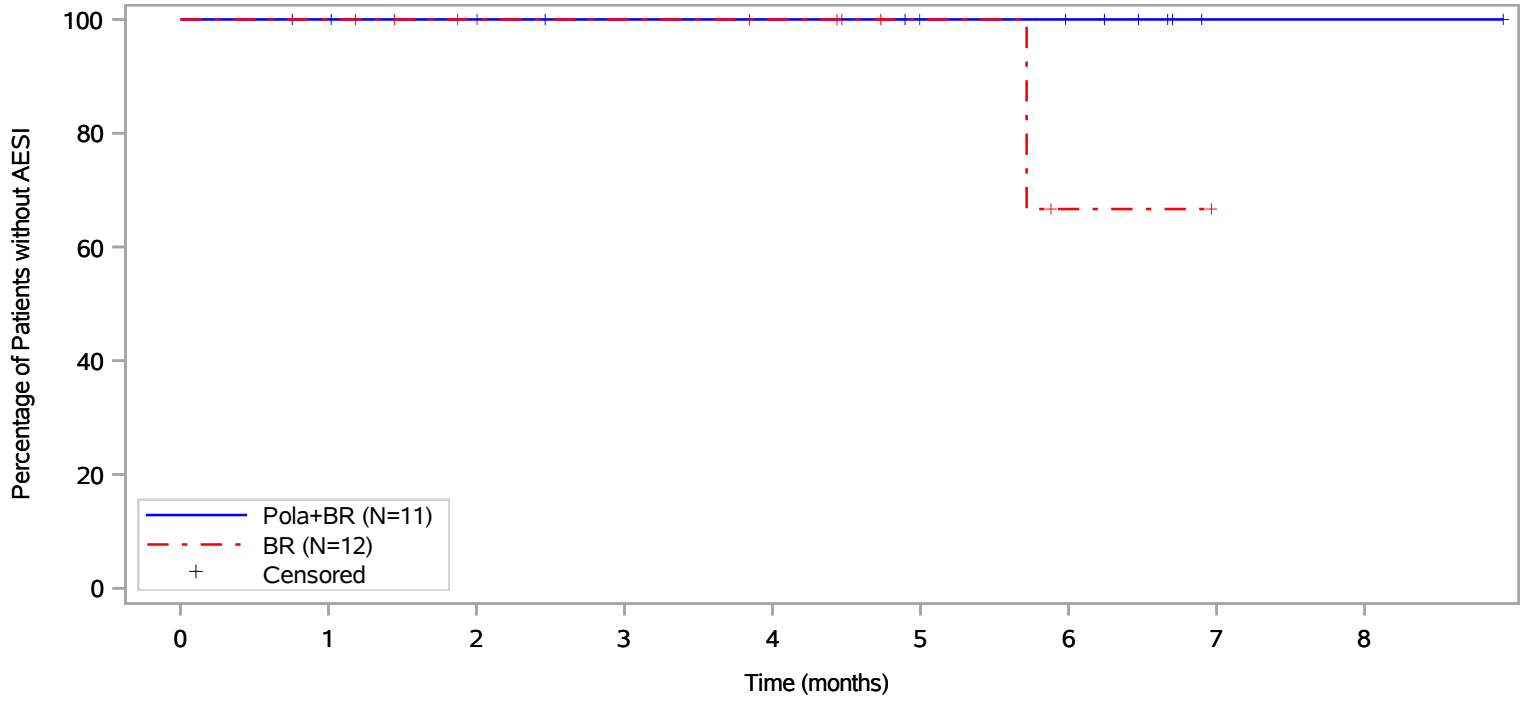
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGASTOX35_L2_ARMCDSE_365_29365_41543.xls
25JAN2023 17:44

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTGASTOX35_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 12:30

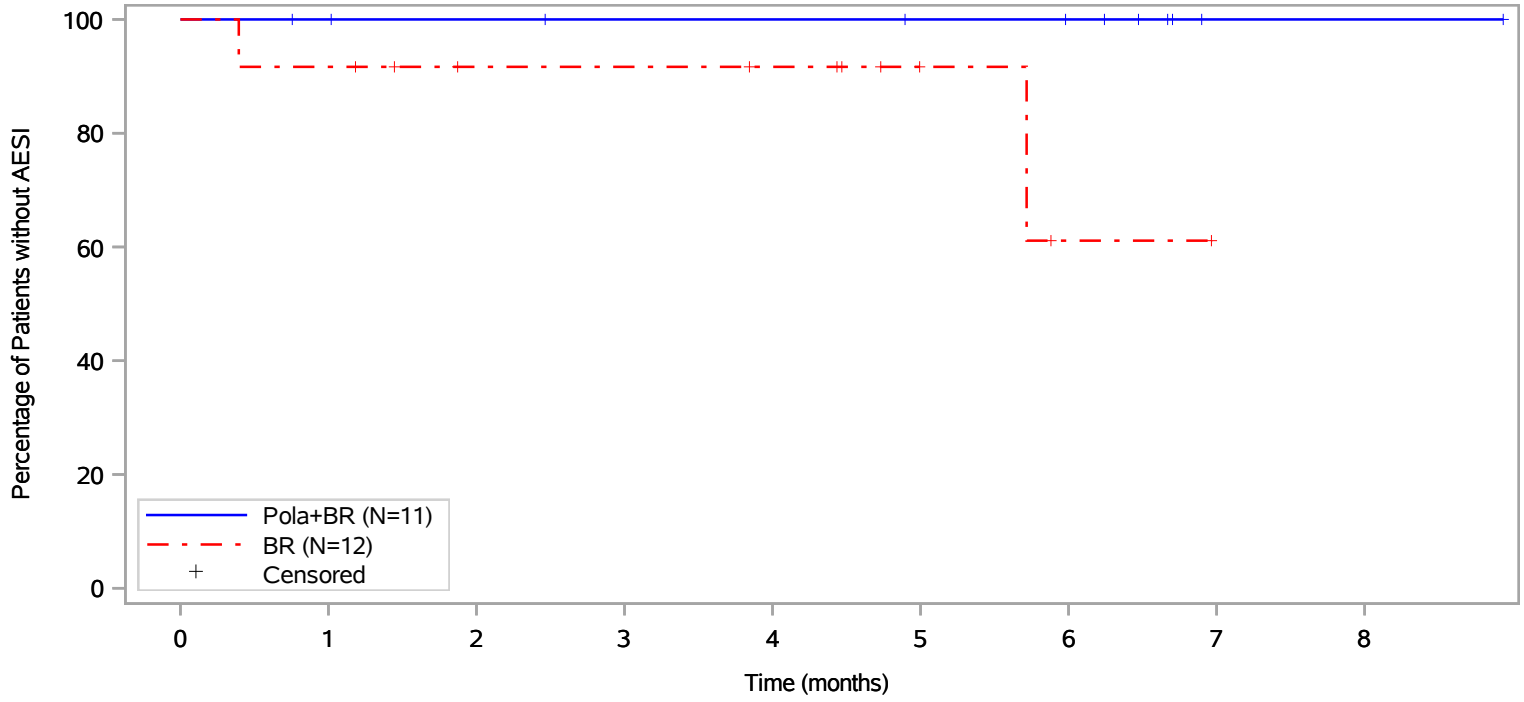
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.0822	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.1367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	2	20.0	8	80.0	0.2087	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	2	22.2	7	77.8	0.1489	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGASTOXS_L2_ARMCDSE_365_29365_41543.xls
25JAN2023 17:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	8	8	7	3	1	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTGASTOXS_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 8:32

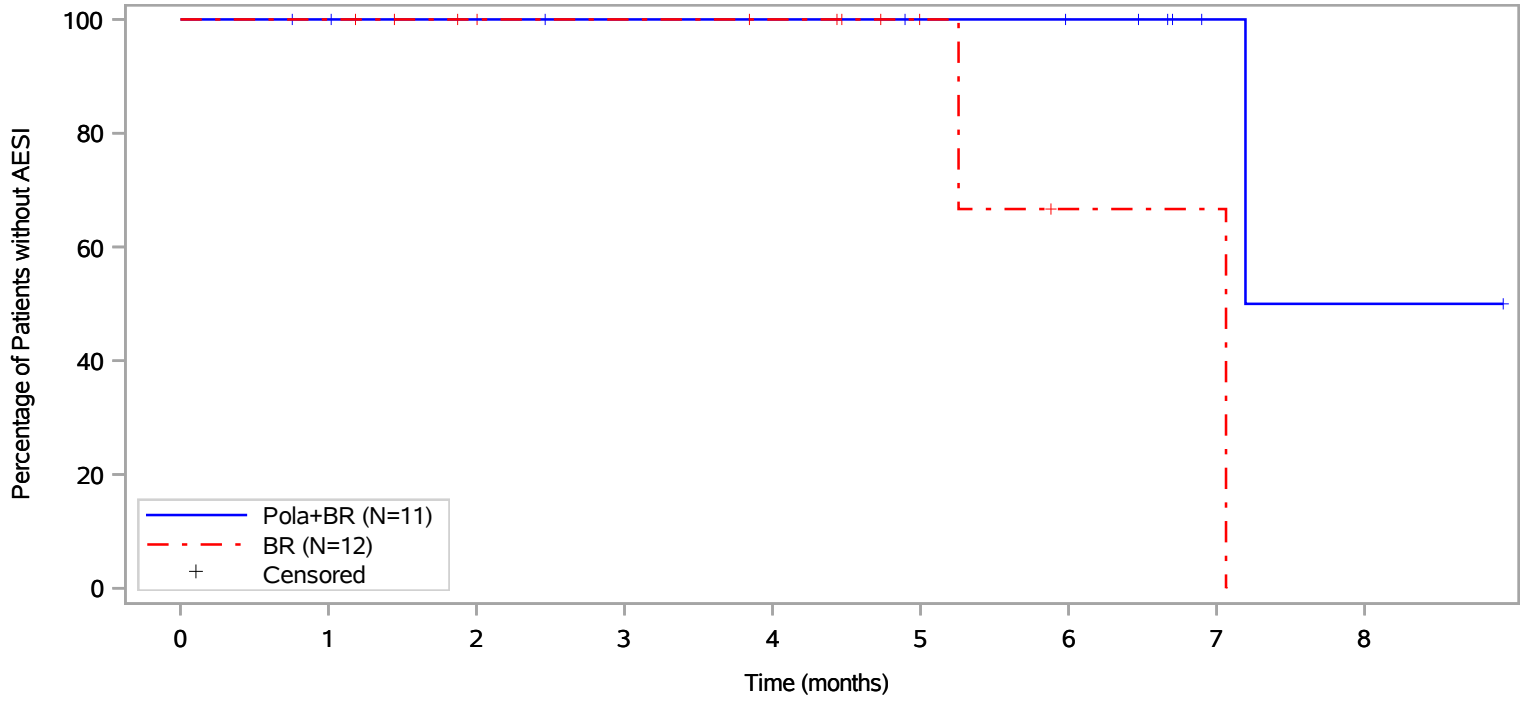
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	1	9.1	10	90.9	12	100.0	2	16.7	10	83.3	0.0376	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	2	16.7	10	83.3	0.0559	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	2	20.0	8	80.0	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGENCAR_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 21:42

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	1
BR (N=12)	12	12	9	8	7	3	1	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	10	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTGENCAR_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 23:12

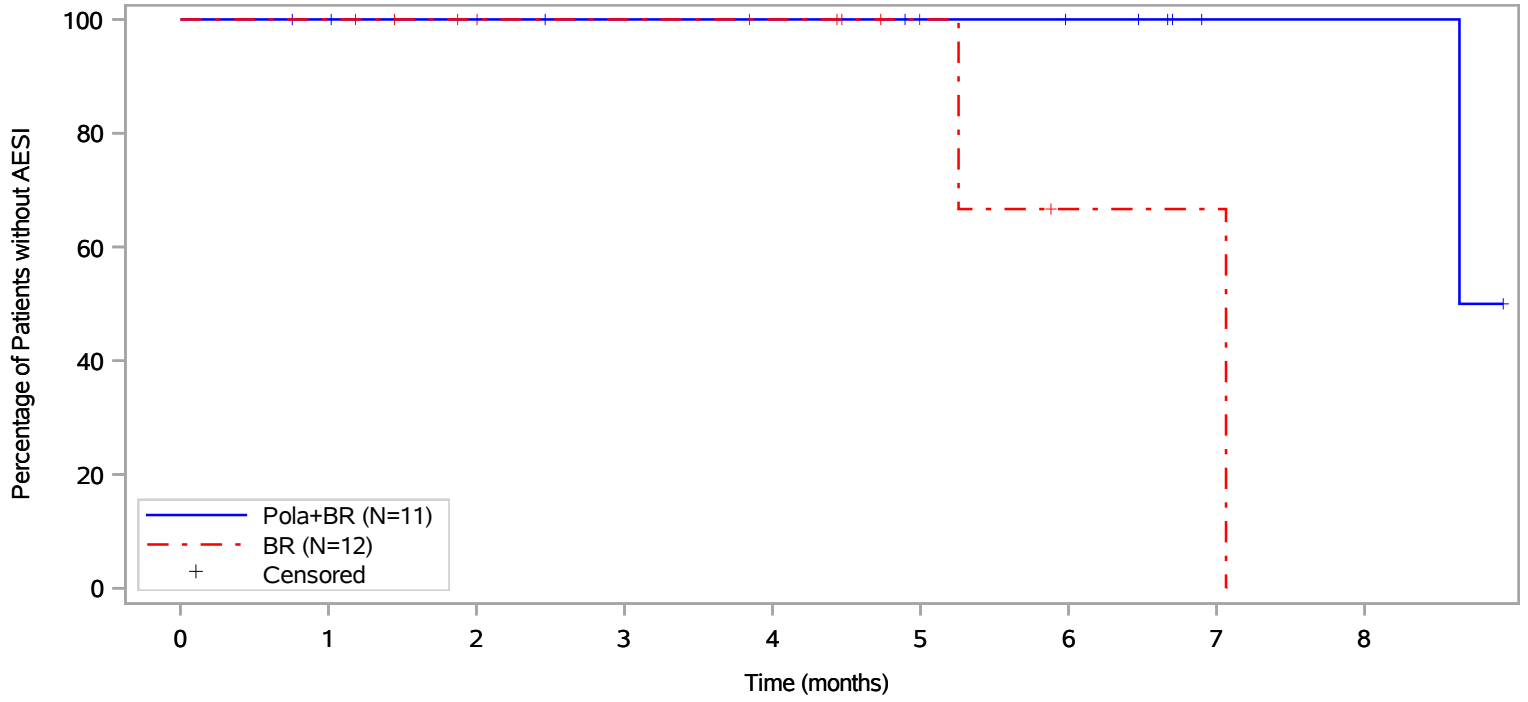
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	1	9.1	10	90.9	12	100.0	2	16.7	10	83.3	0.0376	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	2	16.7	10	83.3	0.0559	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	2	20.0	8	80.0	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGENCAR35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 22:36

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	2
BR (N=12)	12	12	9	8	7	3	1	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	10	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTGENCAR35_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:54

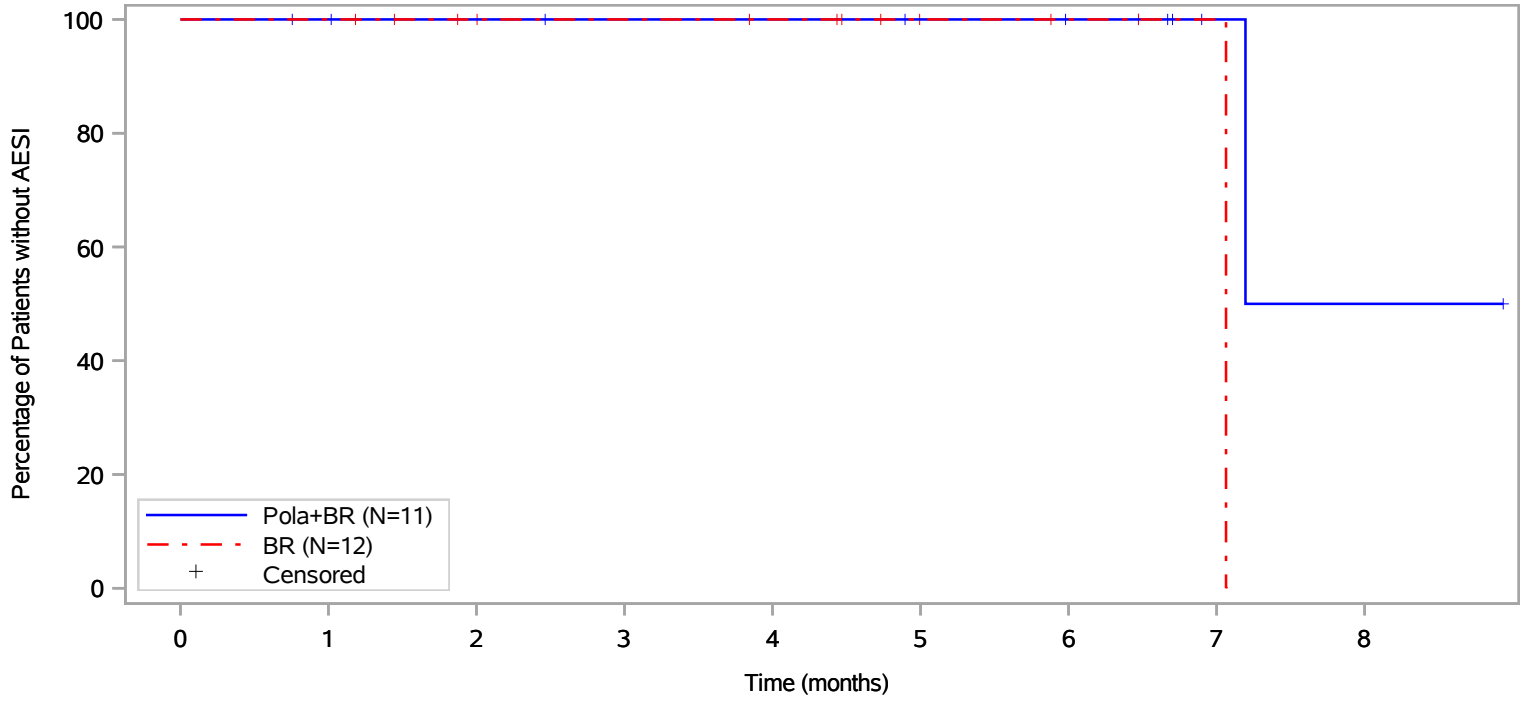
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.3173				*	WARNING: Iteration limit reached without convergence.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGENCARS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 22:30

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	2	1
BR (N=12)	12	12	9	8	7	3	2	1	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTGENCARS_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 9:34

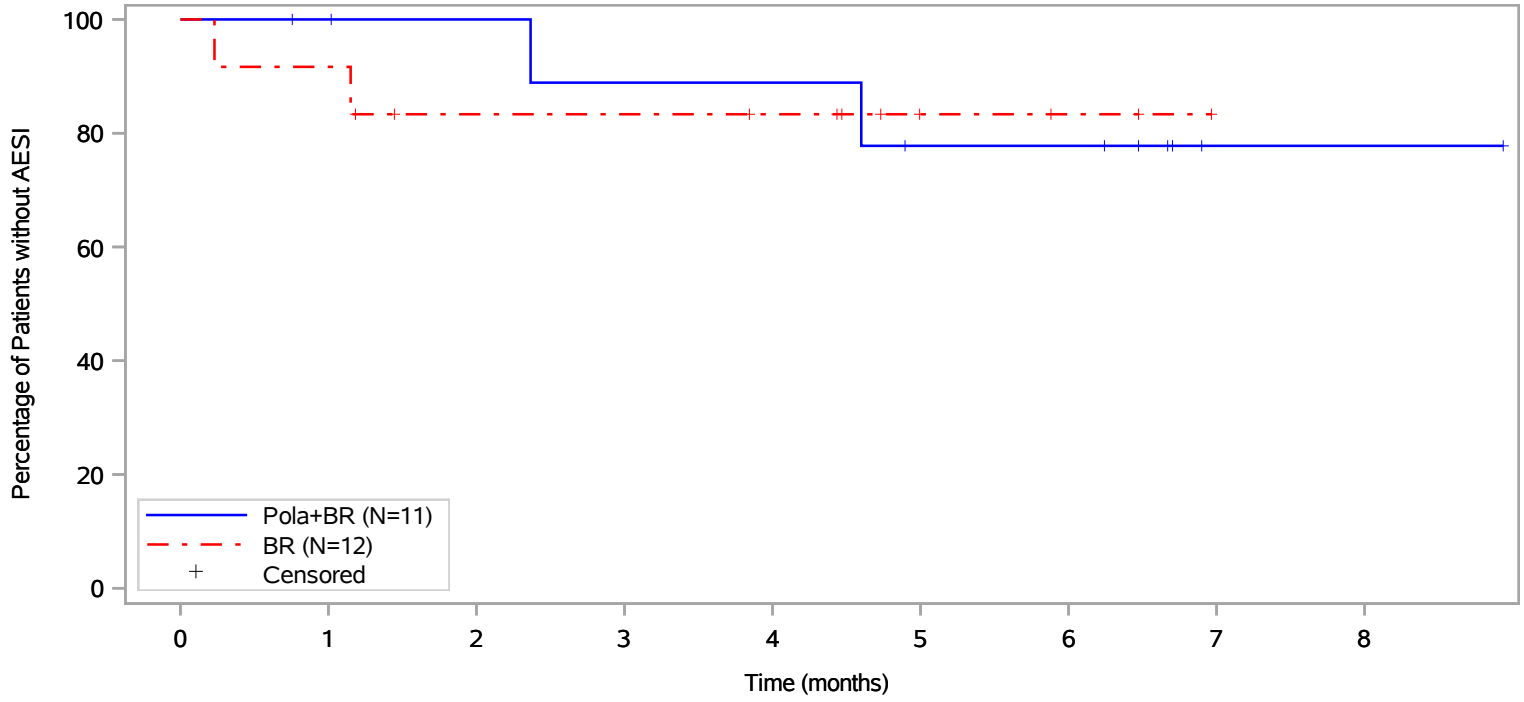
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	2	18.2	9	81.8	12	100.0	2	16.7	10	83.3	0.9413	0.93	0.13	6.70		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	2	28.6	5	71.4	7	58.3	2	28.6	5	71.4	0.8573	0.83	0.11	6.07		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	2	16.7	10	83.3	0.7643	0.69	0.06	7.69		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	2	20.0	8	80.0	0.9206	0.88	0.08	9.83		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	2	22.2	7	77.8	0.8839	1.16	0.16	8.42		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHEPAT_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 3:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	6	6	1	1
BR (N=12)	12	11	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	3	8	8
BR (N=12)	0	0	2	2	3	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTHEPAT_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:16

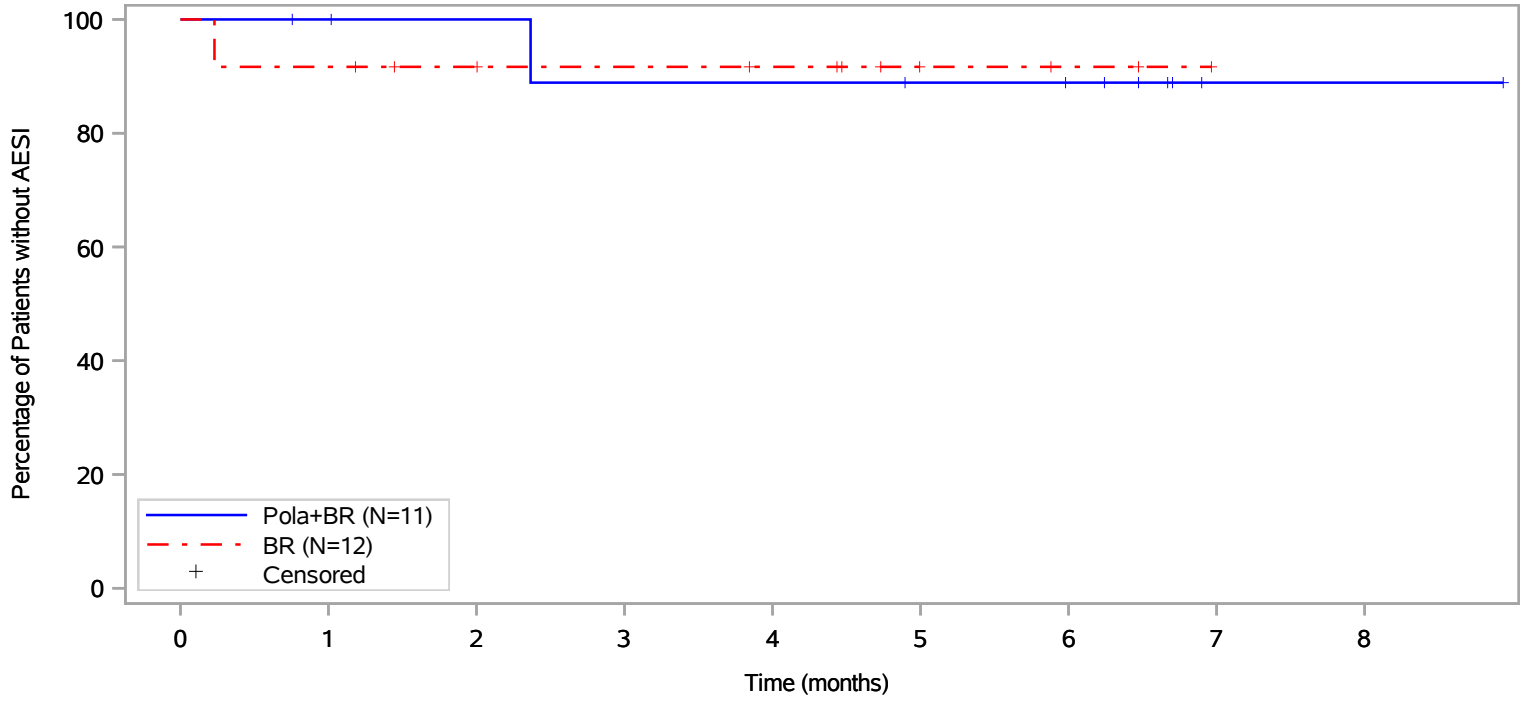
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	1	9.1	10	90.9	12	100.0	1	8.3	11	91.7	0.9913	0.98	0.06	15.80		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	1	14.3	6	85.7	7	58.3	1	14.3	6	85.7	0.9372	0.89	0.06	14.36		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.8488	1.31	0.08	21.07		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.7439	1.58	0.10	25.30		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	1	11.1	8	88.9	0.8864	1.22	0.08	19.86		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHEPAT35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	11	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	3	4	9	9
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTHEPAT35_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:23

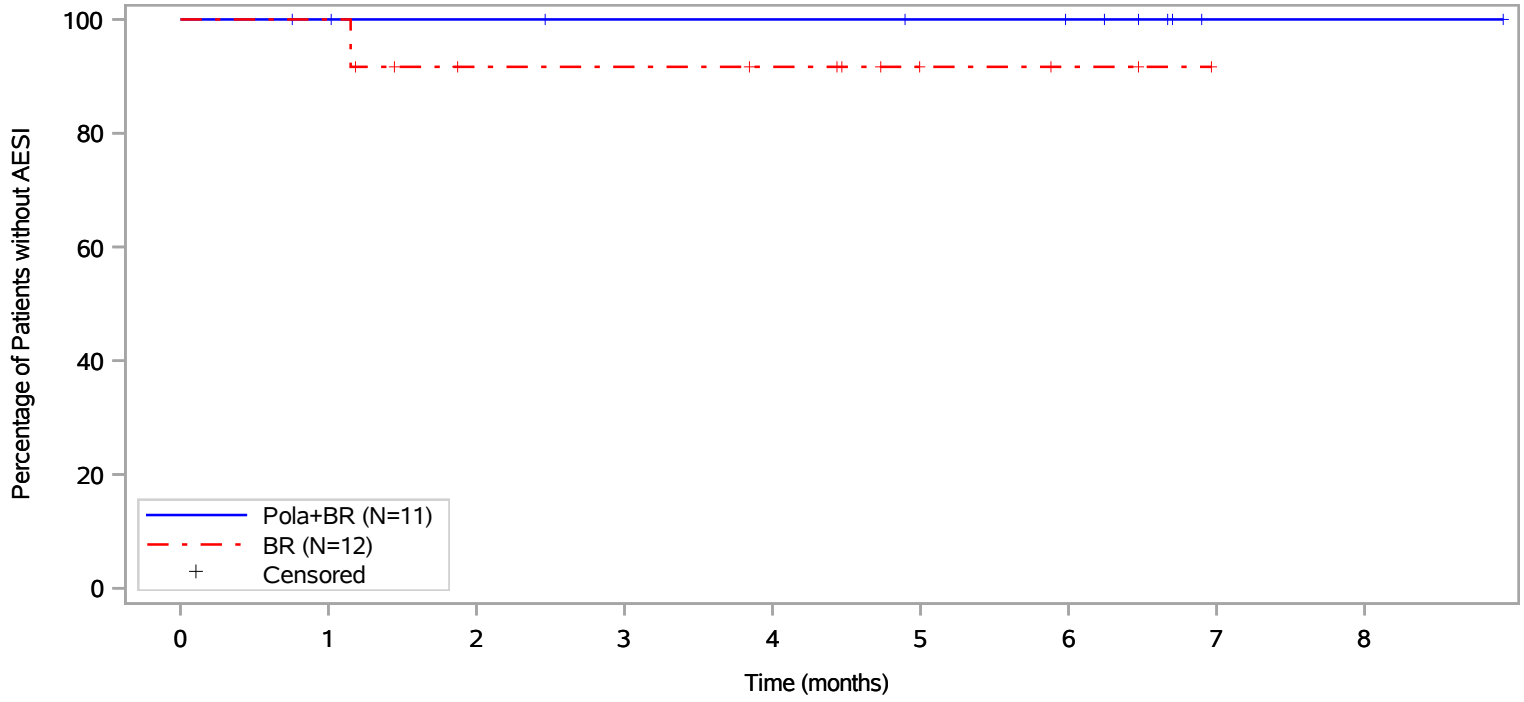
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	1	8.3	11	91.7	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	1	8.3	11	91.7	0.4450	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.5271	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.4561	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHEPATS_L2_ARMCDSE_365_29365_41543.xls
25JAN2023 18:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	8	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTHEPATS_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:28

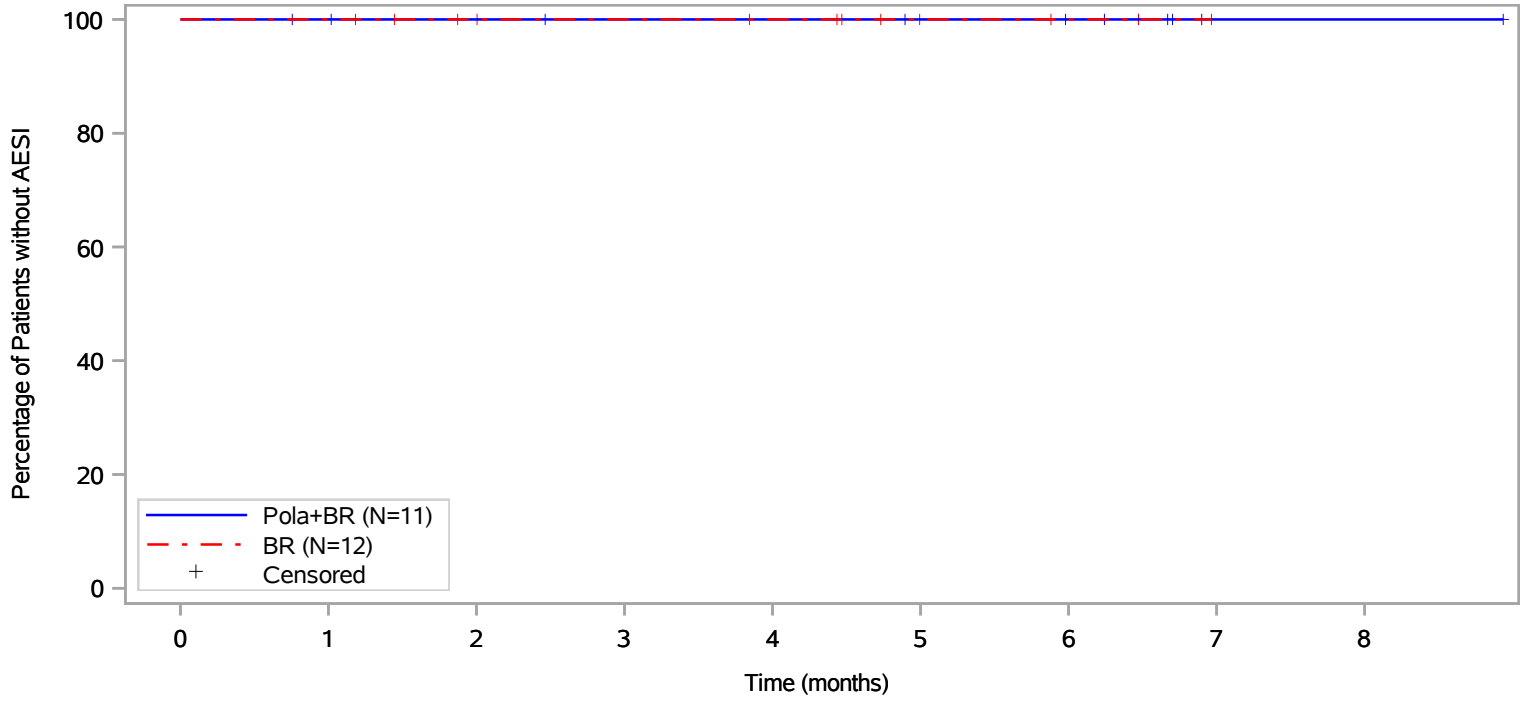
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHYPGL_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 5:02

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTHYPGL_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:34

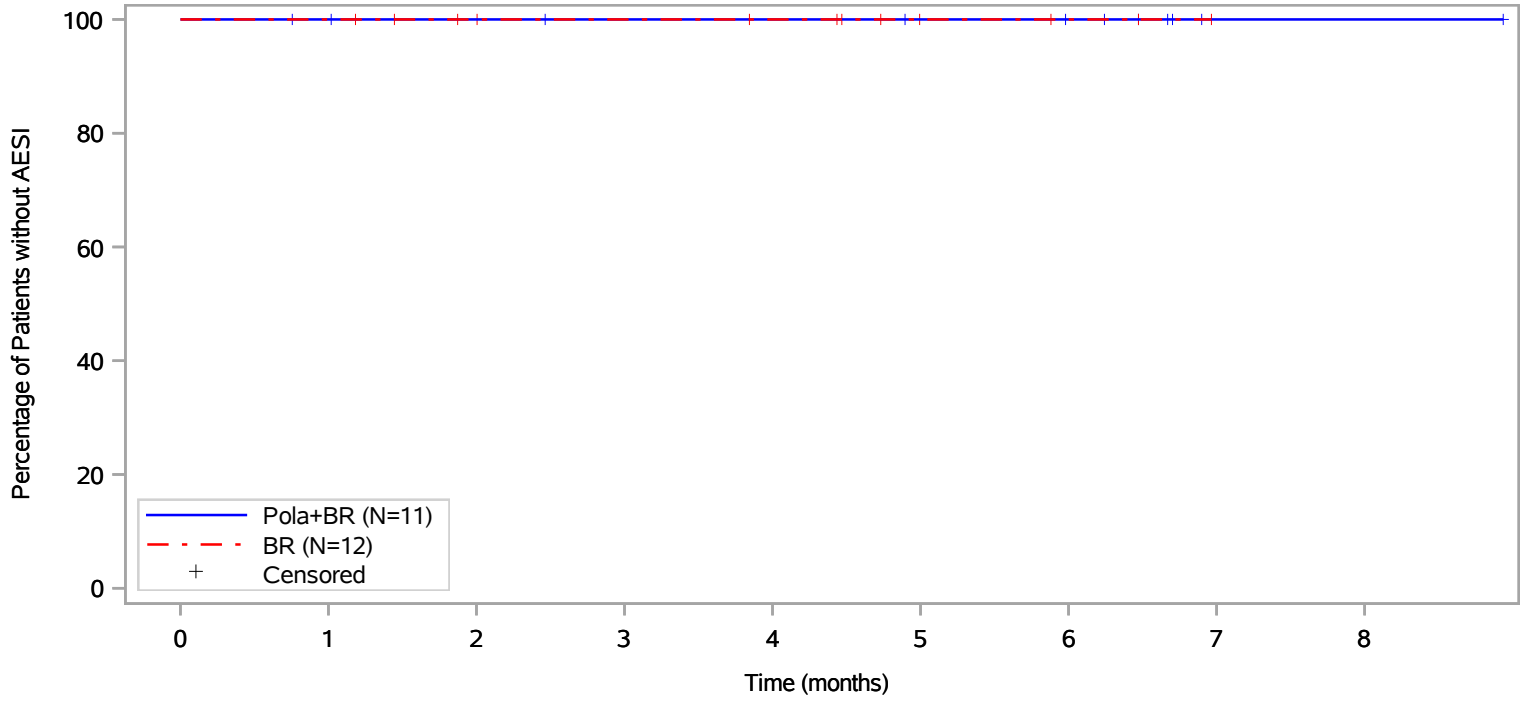
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHYPGL35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 21:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTHYPGL35_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:38

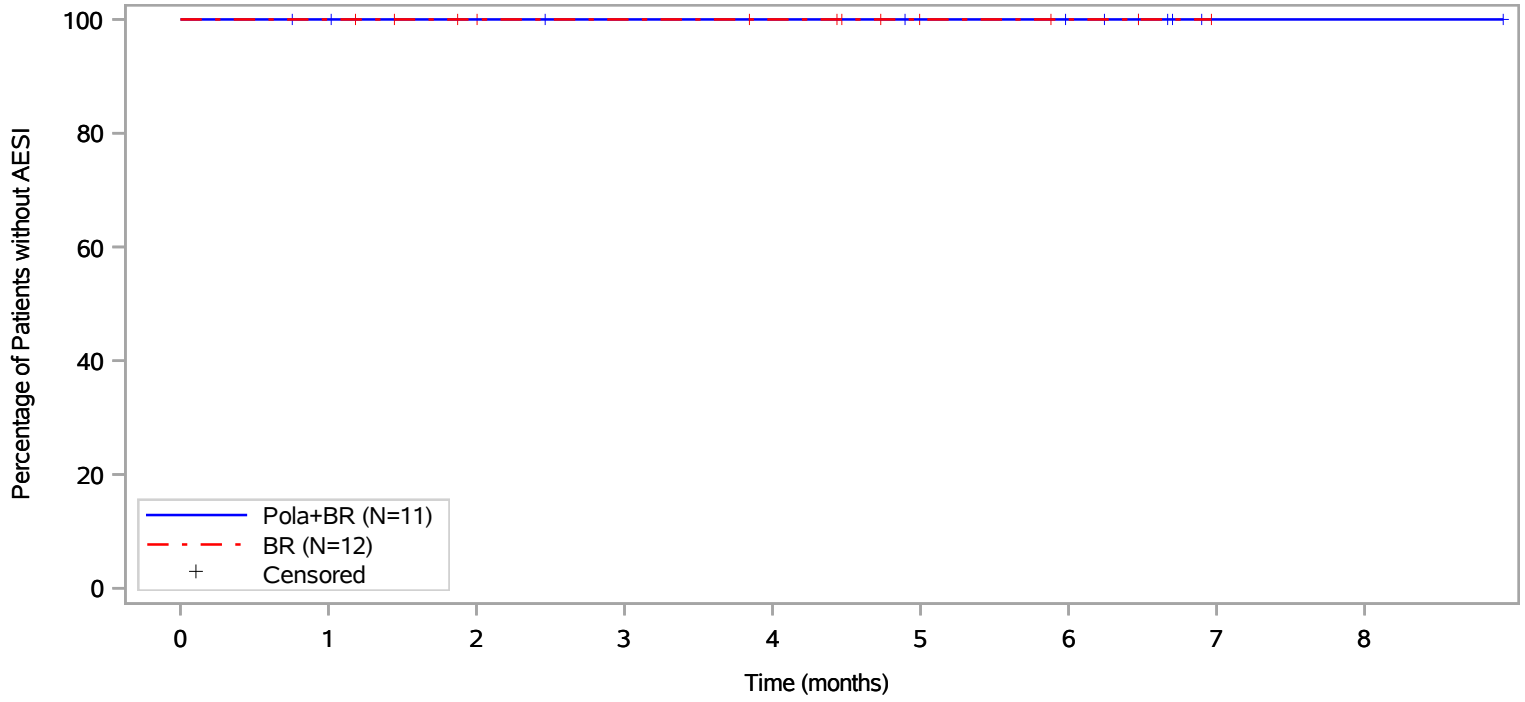
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHYPGLS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 21:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTHYPGLS_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 8:14

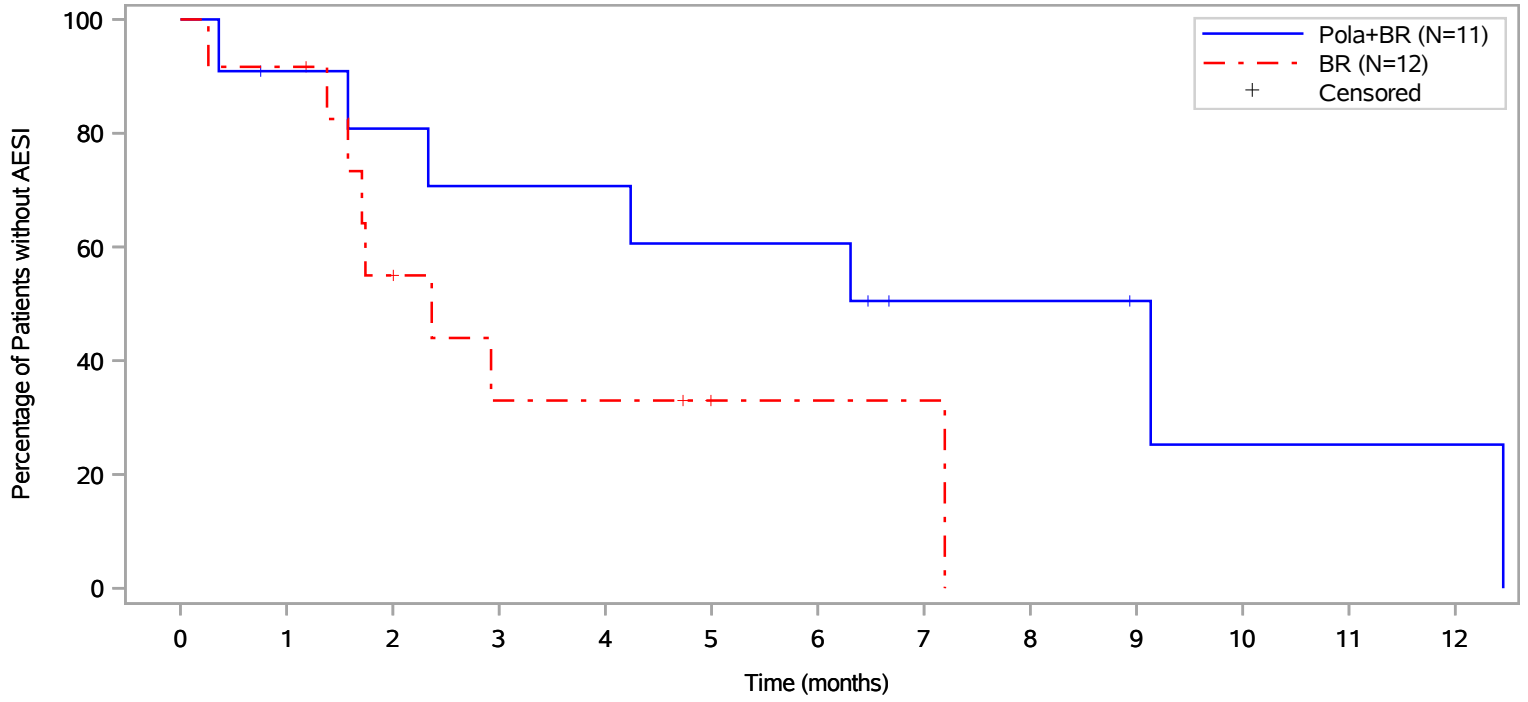
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	7	63.6	4	36.4	12	100.0	8	66.7	4	33.3	0.1260	0.41	0.13	1.32		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	5	71.4	2	28.6	7	58.3	4	57.1	3	42.9	0.7703	0.81	0.20	3.32		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	2	50.0	2	50.0	5	41.7	4	80.0	1	20.0	0.0615	0.15	0.02	1.41		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	2	66.7	1	33.3	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	5	62.5	3	37.5	12	100.0	8	66.7	4	33.3	0.0811	0.30	0.08	1.23		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	4	66.7	2	33.3	10	83.3	6	60.0	4	40.0	0.7092	0.76	0.18	3.16		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	3	60.0	2	40.0	2	16.7	2	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	3	60.0	2	40.0	3	25.0	2	66.7	1	33.3	0.4335	0.39	0.04	4.39		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	6	66.7	3	33.3	0.2381	0.44	0.11	1.79		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTINECT_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 2:35

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk													
Pola+BR (N=11)	11	9	8	7	7	6	6	3	3	2	1	1	1
BR (N=12)	12	11	6	3	3	1	1	1	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	1	1	1	1	1	3	3	4	4	4	4
BR (N=12)	0	0	1	2	2	4	4	4	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTINECT_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:01

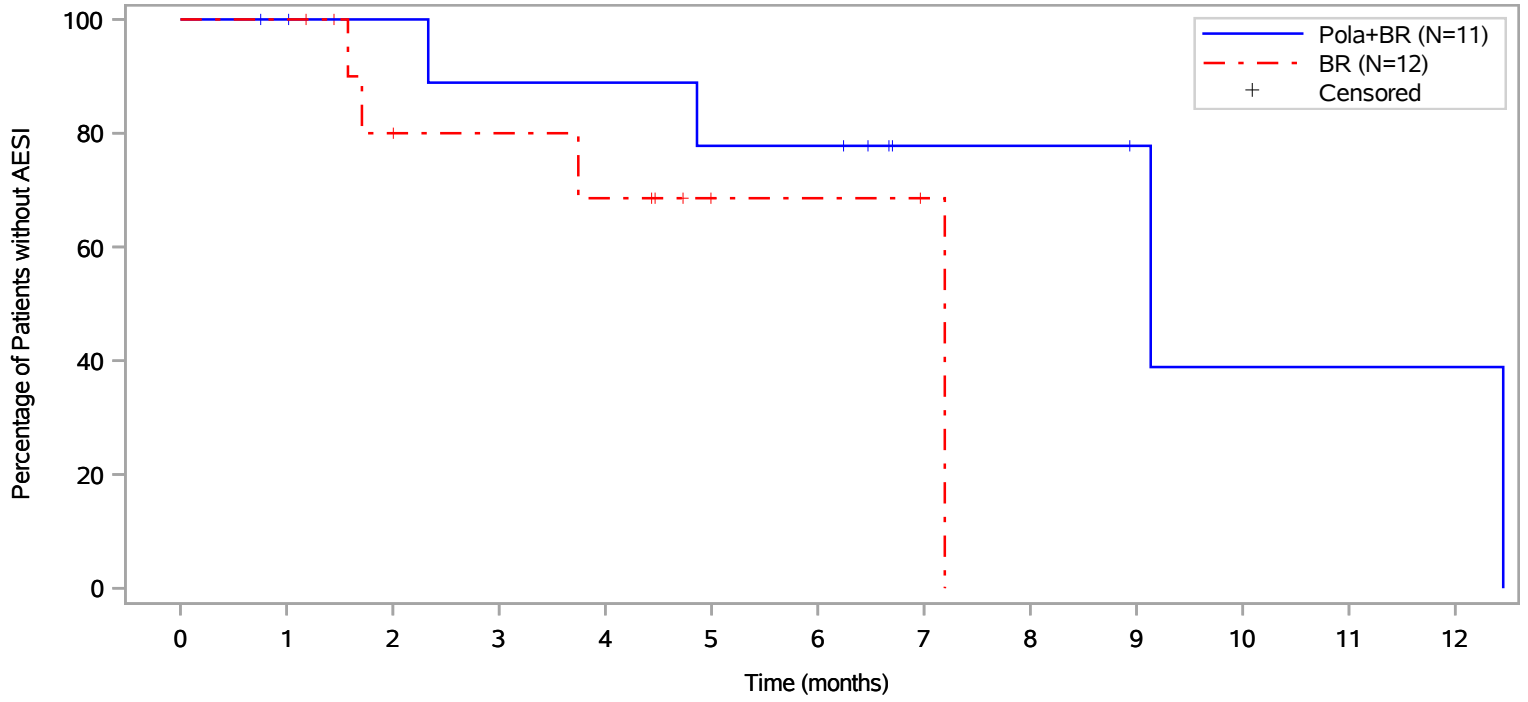
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	4	36.4	7	63.6	12	100.0	4	33.3	8	66.7	0.1880	0.33	0.06	1.86		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	3	42.9	4	57.1	7	58.3	1	14.3	6	85.7	0.7027	1.60	0.14	18.24		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	5	41.7	3	60.0	2	40.0	0.0401	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	4	33.3	8	66.7	0.1498	0.22	0.02	2.06		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	2	33.3	4	66.7	10	83.3	3	30.0	7	70.0	0.4412	0.41	0.04	4.26		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	3	33.3	6	66.7	0.4845	0.53	0.08	3.27		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTINECT35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:45

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk													
Pola+BR (N=11)	11	10	9	8	8	7	7	3	3	2	1	1	1
BR (N=12)	12	12	8	7	6	2	2	1	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=11)	0	1	2	2	2	2	2	6	6	7	7	7	7
BR (N=12)	0	0	2	3	3	7	7	8	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTINECT35_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 10:20

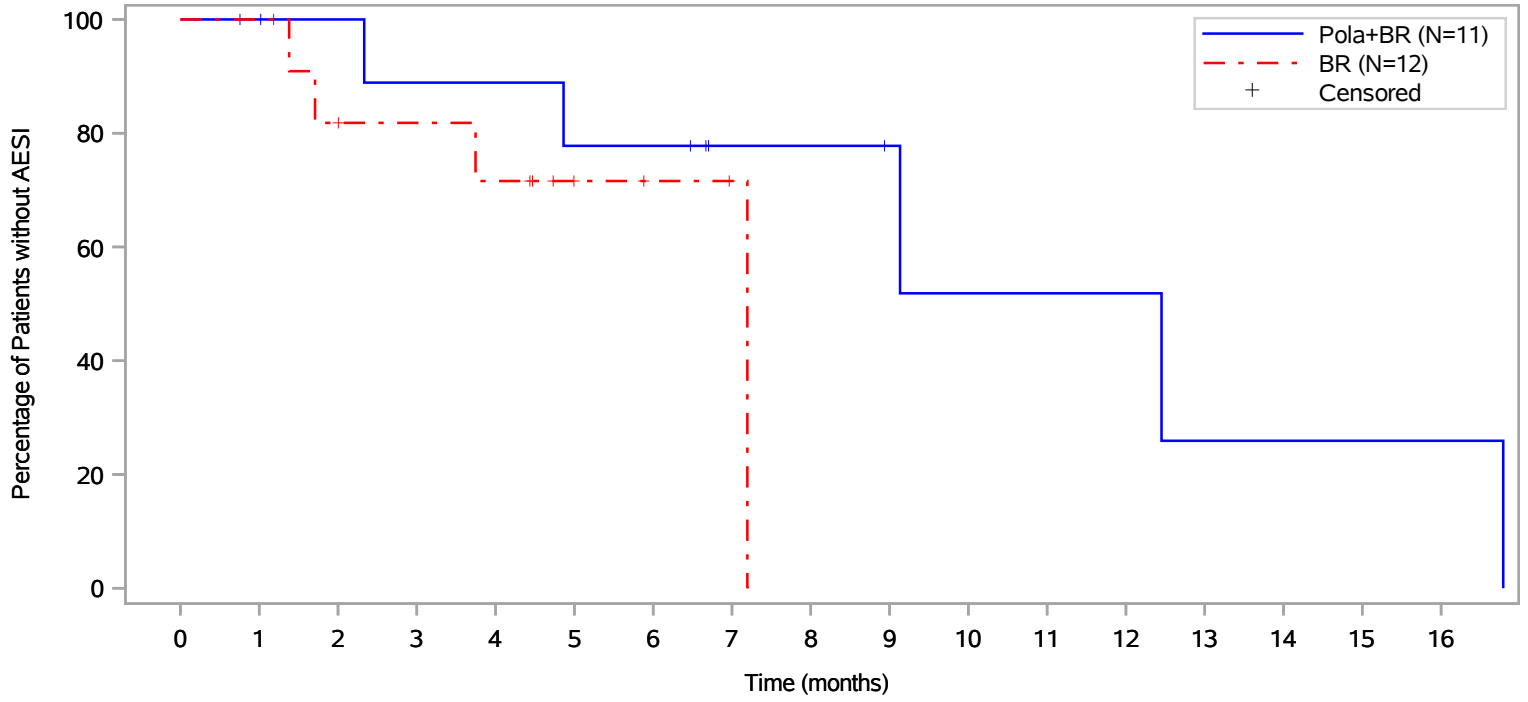
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	5	45.5	6	54.5	12	100.0	4	33.3	8	66.7	0.2265	0.35	0.06	2.04		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	4	57.1	3	42.9	7	58.3	1	14.3	6	85.7	0.7027	1.60	0.14	18.24		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	5	41.7	3	60.0	2	40.0	0.0575	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	4	33.3	8	66.7	0.1600	0.21	0.02	2.15		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	3	50.0	3	50.0	10	83.3	4	40.0	6	60.0	0.2804	0.29	0.03	2.99		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	2	40.0	3	60.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	3	33.3	6	66.7	0.6220	0.63	0.10	3.94		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTINECTS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:45

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk																	
Pola+BR (N=11)	11	10	9	8	8	7	7	4	4	3	2	2	2	1	1	1	1
BR (N=12)	12	12	9	8	7	3	2	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																	
Pola+BR (N=11)	0	1	2	2	2	2	2	5	5	6	6	6	6	6	6	6	6
BR (N=12)	0	0	1	2	2	6	7	8	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTINECTS_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:54

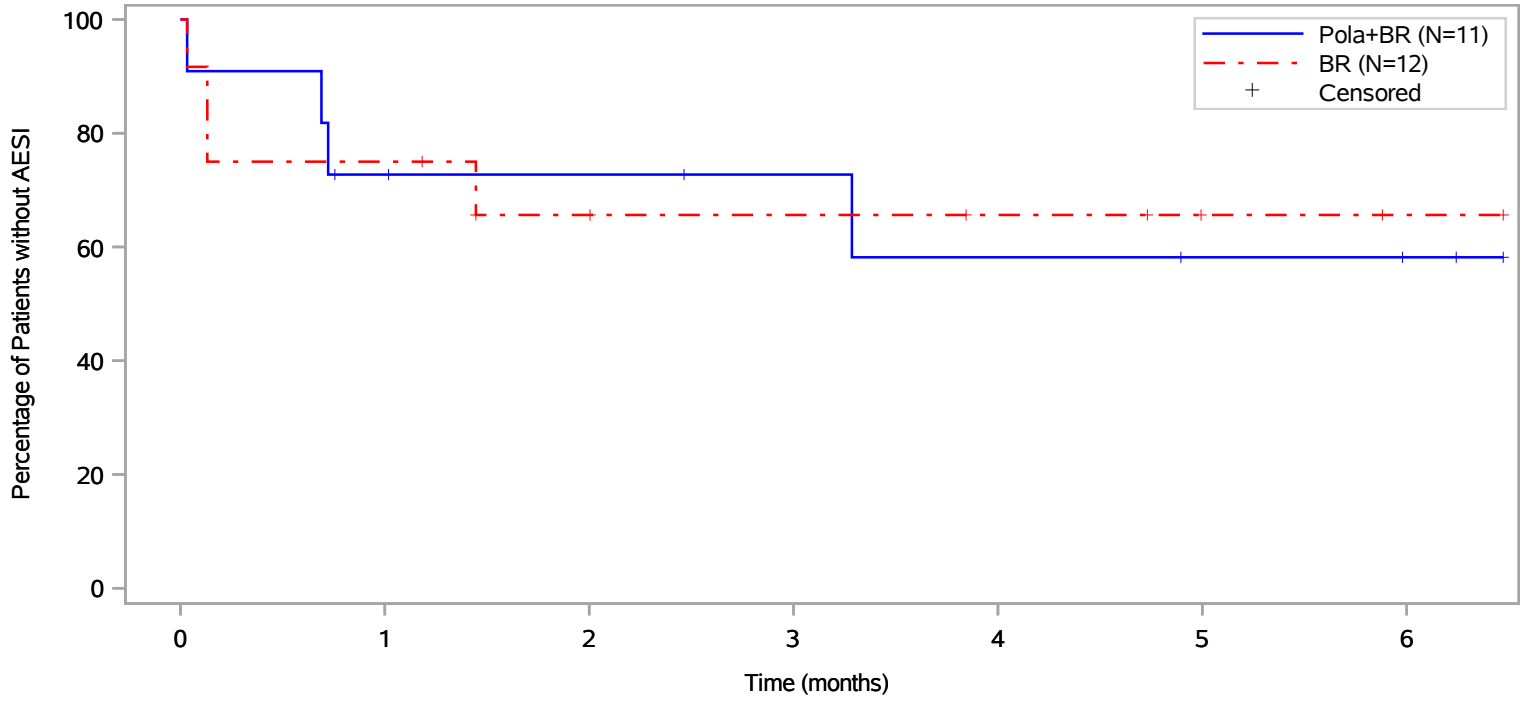
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	4	36.4	7	63.6	12	100.0	4	33.3	8	66.7	0.9222	1.07	0.26	4.37		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	4	57.1	3	42.9	0.0231	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	4	100.0	0	-	5	41.7	0	-	5	100.0	0.0034	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	4	33.3	8	66.7	0.5188	1.58	0.39	6.48		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	3	30.0	7	70.0	0.6169	0.56	0.05	5.71		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	3	60.0	2	40.0	2	16.7	1	50.0	1	50.0	0.7709	1.40	0.14	13.66		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	3	25.0	1	33.3	2	66.7	0.9412	1.09	0.10	12.22		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	3	33.3	6	66.7	0.8984	1.13	0.18	6.96		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTIRR_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 3:03

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	7	6	5	4	3	2
BR (N=12)	12	9	6	5	4	2	1
Patients censored							
Pola+BR (N=11)	0	1	2	3	3	4	5
BR (N=12)	0	0	2	3	4	6	7

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTIRR_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:08

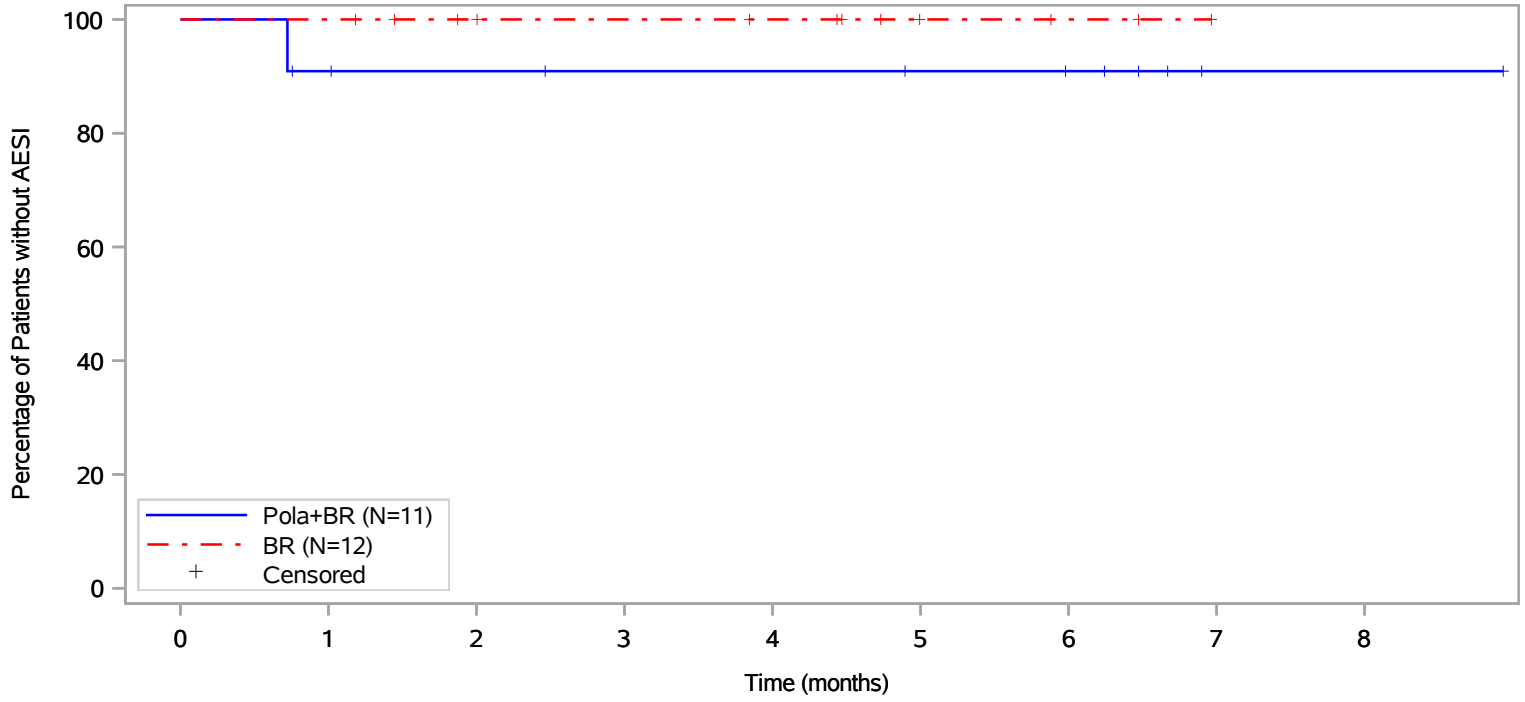
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	0.2963	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	0.2636	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTIRR35_L2_ARMCDSE_365_29365_41543.xls
25JAN2023 18:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	9	8	7	7	6	5	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	9	9
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTIRR35_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 10:38

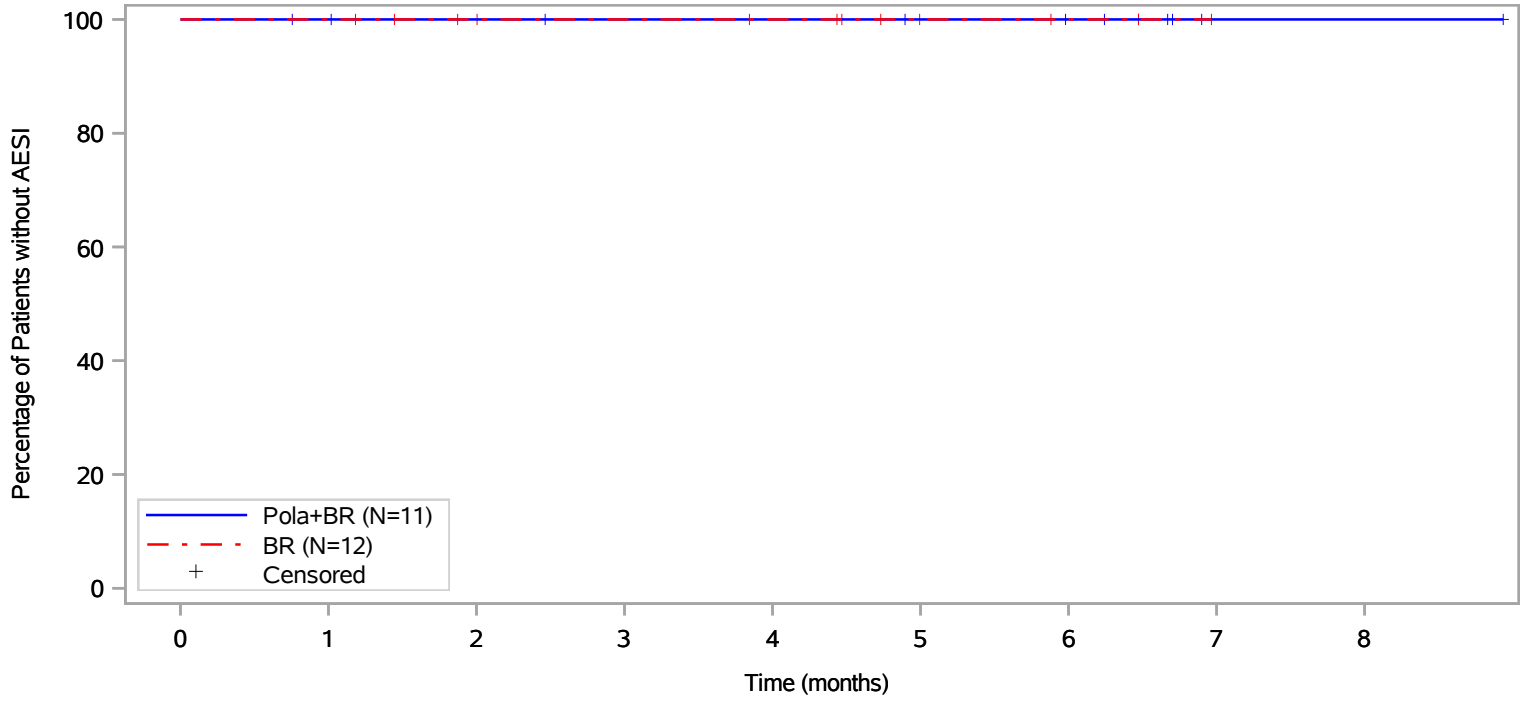
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTIRRS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:52

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTIRRS_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:06

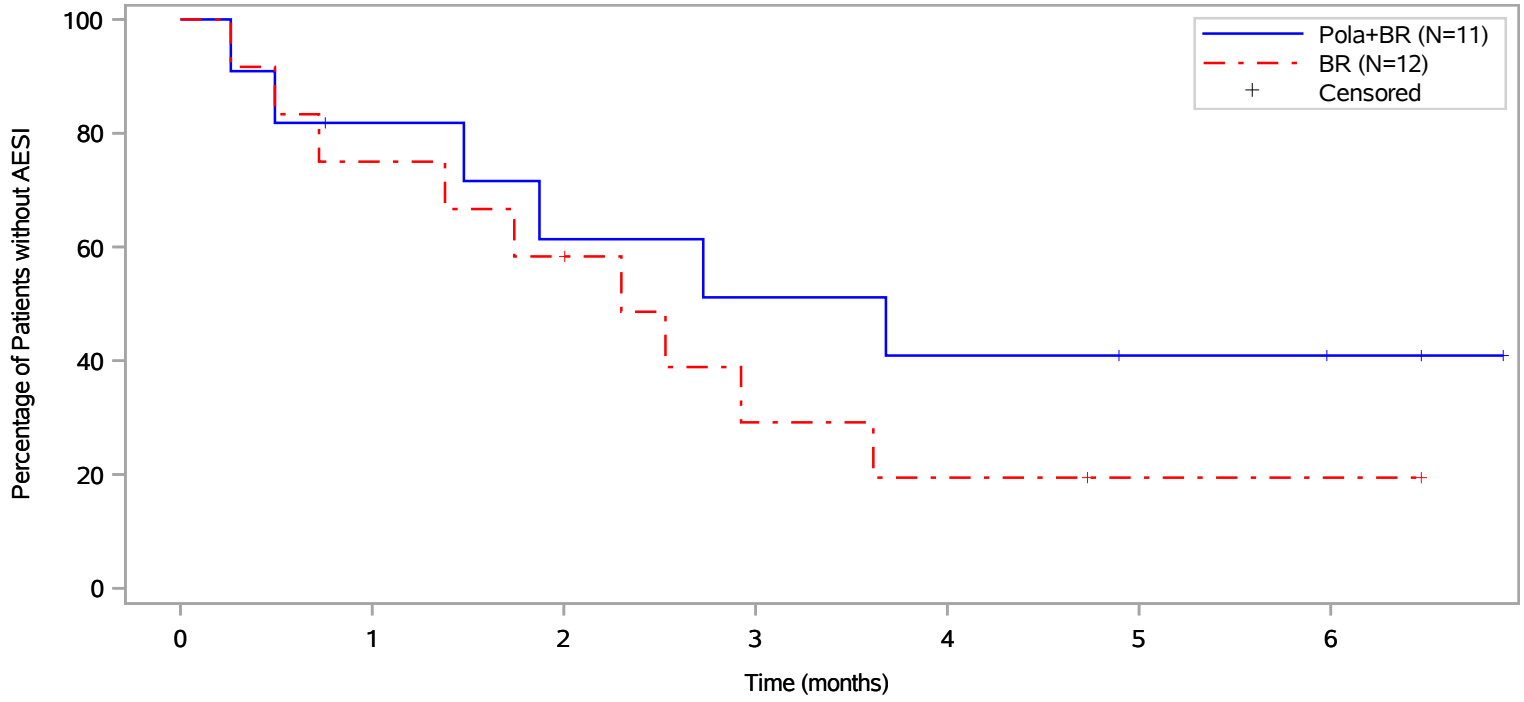
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	6	54.5	5	45.5	12	100.0	9	75.0	3	25.0	0.3283	0.60	0.21	1.70		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	3	42.9	4	57.1	7	58.3	6	85.7	1	14.3	0.2195	0.42	0.10	1.74		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	3	75.0	1	25.0	5	41.7	3	60.0	2	40.0	0.9447	1.06	0.20	5.50		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	5	62.5	3	37.5	12	100.0	9	75.0	3	25.0	0.5292	0.70	0.23	2.12		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	4	66.7	2	33.3	10	83.3	7	70.0	3	30.0	0.6977	1.28	0.36	4.50		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	2	40.0	3	60.0	2	16.7	2	100.0	0	-	0.0574	0.13	0.01	1.51		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	3	25.0	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	7	77.8	2	22.2	0.7379	0.81	0.23	2.82		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTNIFNEU_L2_ARMCDSE_365_29365_41543.xls
30NOV2022 23:46

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	8	6	5	4	3	2
BR (N=12)	12	9	7	3	2	1	1
Patients censored							
Pola+BR (N=11)	0	1	1	1	1	2	3
BR (N=12)	0	0	0	1	1	2	2

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTNIFNEU_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 20:22

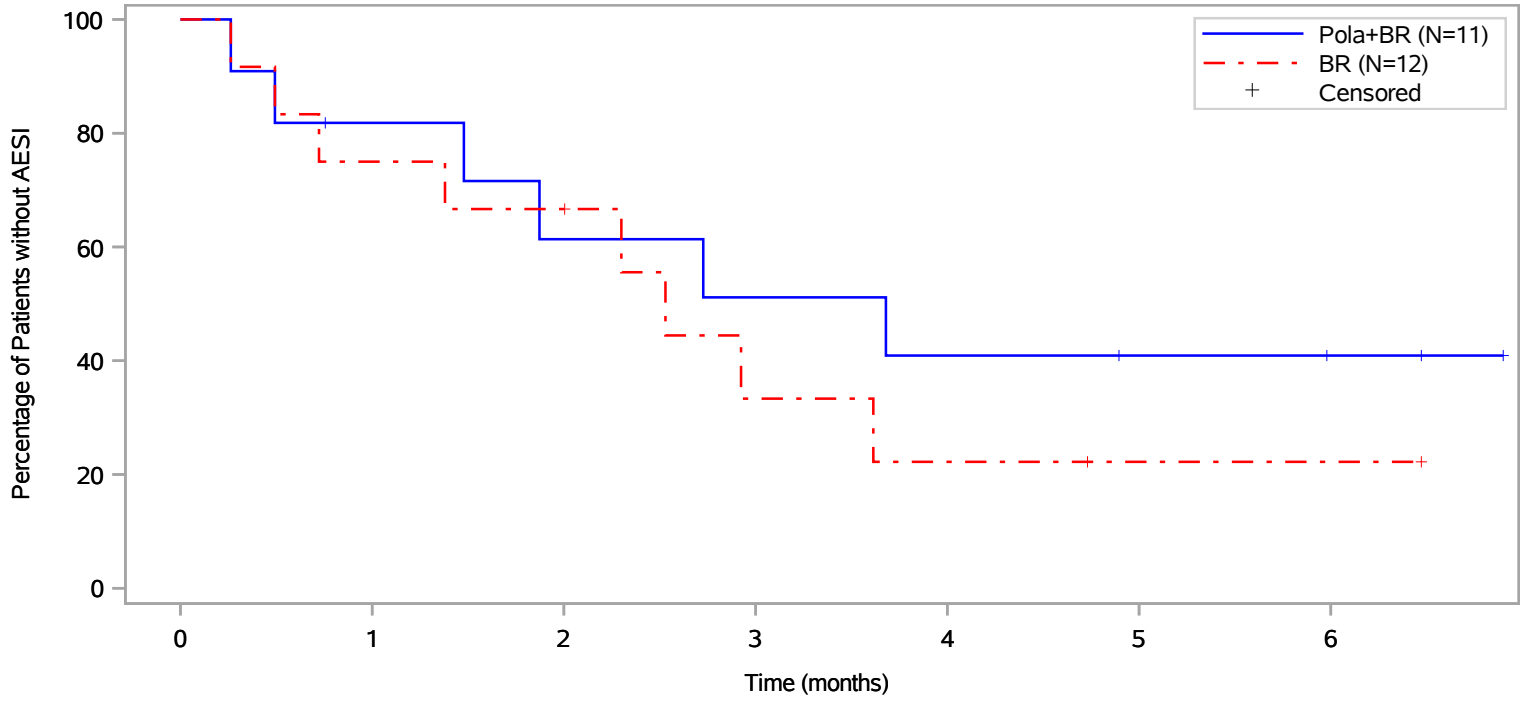
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	6	54.5	5	45.5	12	100.0	8	66.7	4	33.3	0.4588	0.67	0.23	1.96		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	3	42.9	4	57.1	7	58.3	5	71.4	2	28.6	0.3459	0.50	0.11	2.17		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	3	75.0	1	25.0	5	41.7	3	60.0	2	40.0	0.9447	1.06	0.20	5.50		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	5	62.5	3	37.5	12	100.0	8	66.7	4	33.3	0.6760	0.79	0.25	2.43		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	4	66.7	2	33.3	10	83.3	6	60.0	4	40.0	0.5440	1.49	0.41	5.45		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	2	40.0	3	60.0	2	16.7	2	100.0	0	-	0.0574	0.13	0.01	1.51		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	3	25.0	2	66.7	1	33.3	0.3479	0.40	0.05	2.91		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	6	66.7	3	33.3	0.9288	0.94	0.26	3.43		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTNIFNEU35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 19:50

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	8	6	5	4	3	2
BR (N=12)	12	9	7	3	2	1	1
Patients censored							
Pola+BR (N=11)	0	1	1	1	1	2	3
BR (N=12)	0	0	1	2	2	3	3

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTNIFNEU35_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:12

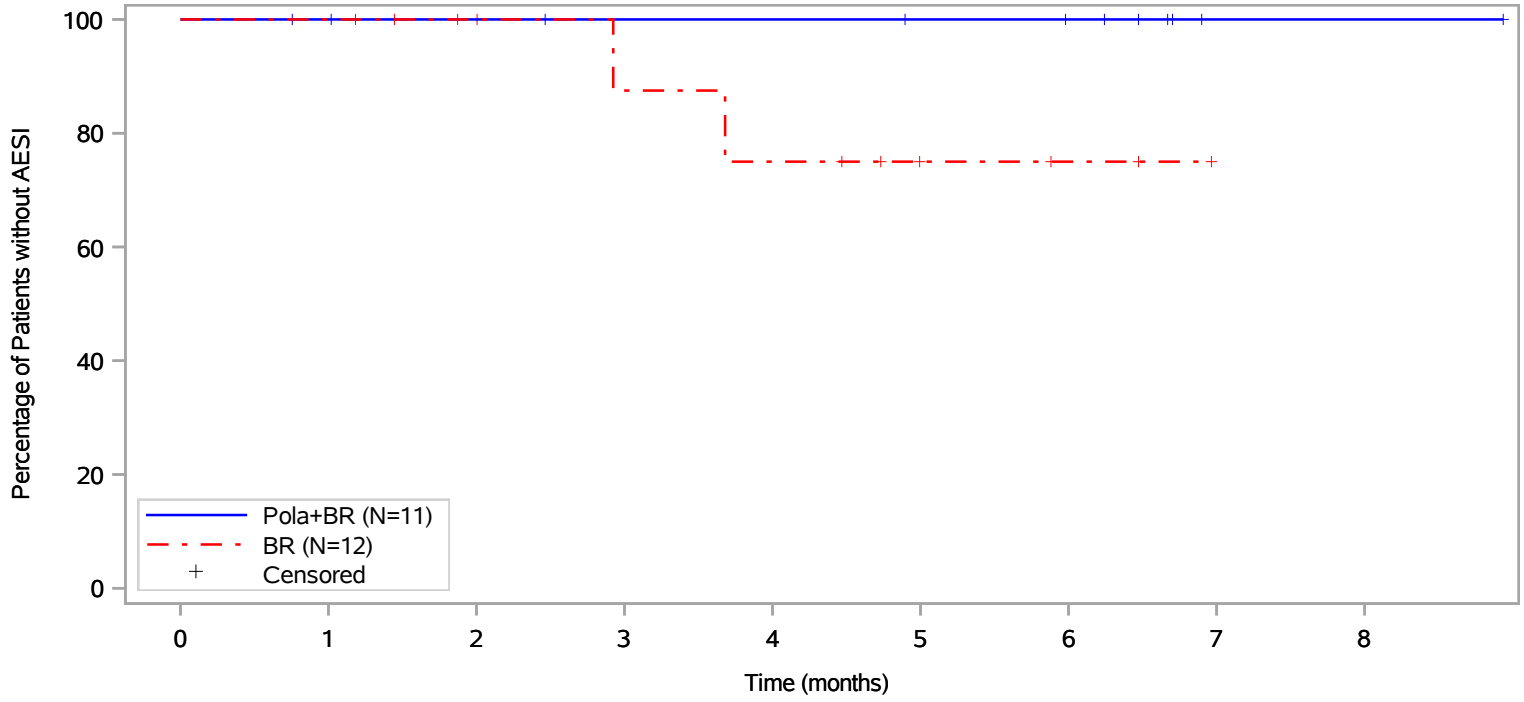
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	2	16.7	10	83.3	0.1435	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	1	14.3	6	85.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	1	20.0	4	80.0	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	2	16.7	10	83.3	0.2051	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	1	10.0	9	90.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	1	33.3	2	66.7	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	1	11.1	8	88.9	0.3711	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTNIFNEUS_L2_ARMCDSE_365_29365_41543.xls
25JAN2023 18:15

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	7	6	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	4	7	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 21:16

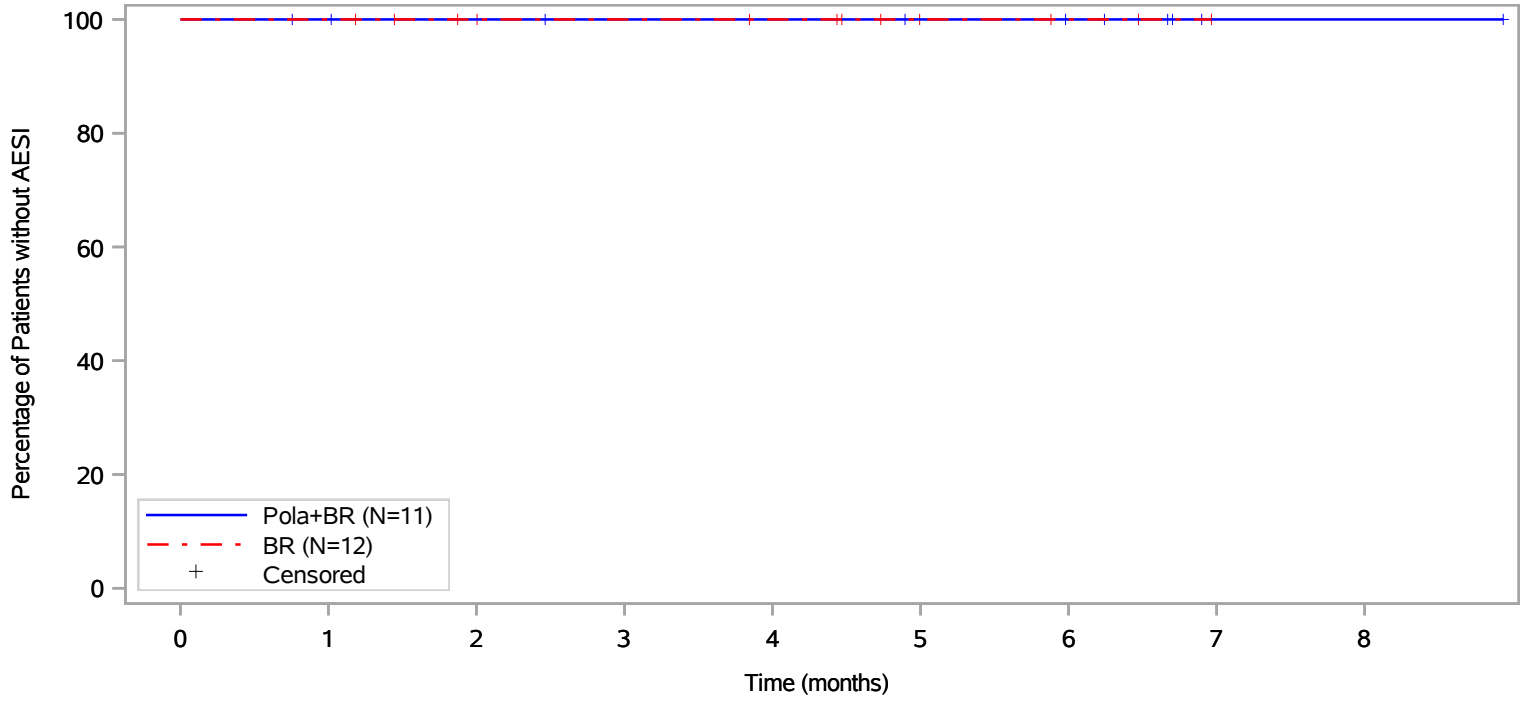
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTOCUTOX_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 20:26

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Ocular Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTOCUTOX_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:23

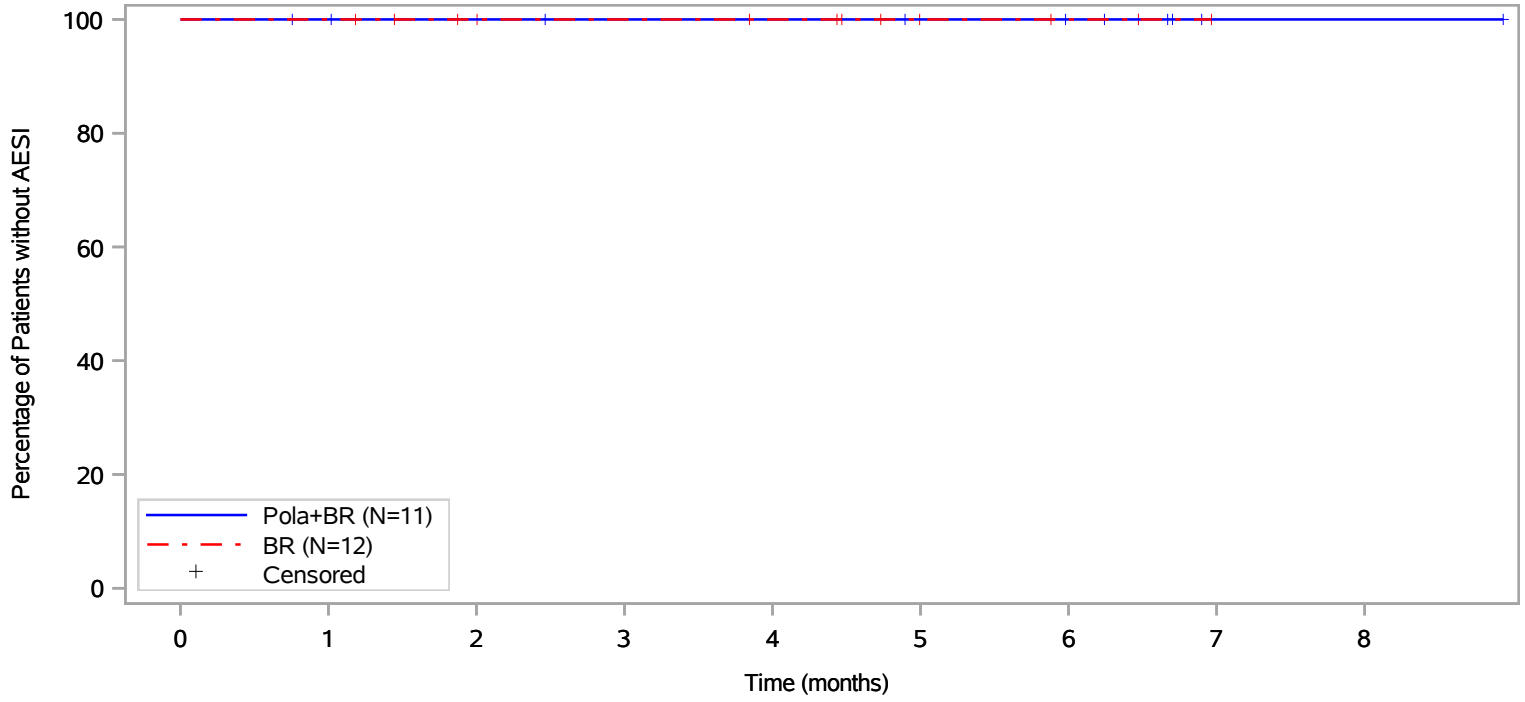
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPAIN_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 7:50

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..sis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPAIN_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:35

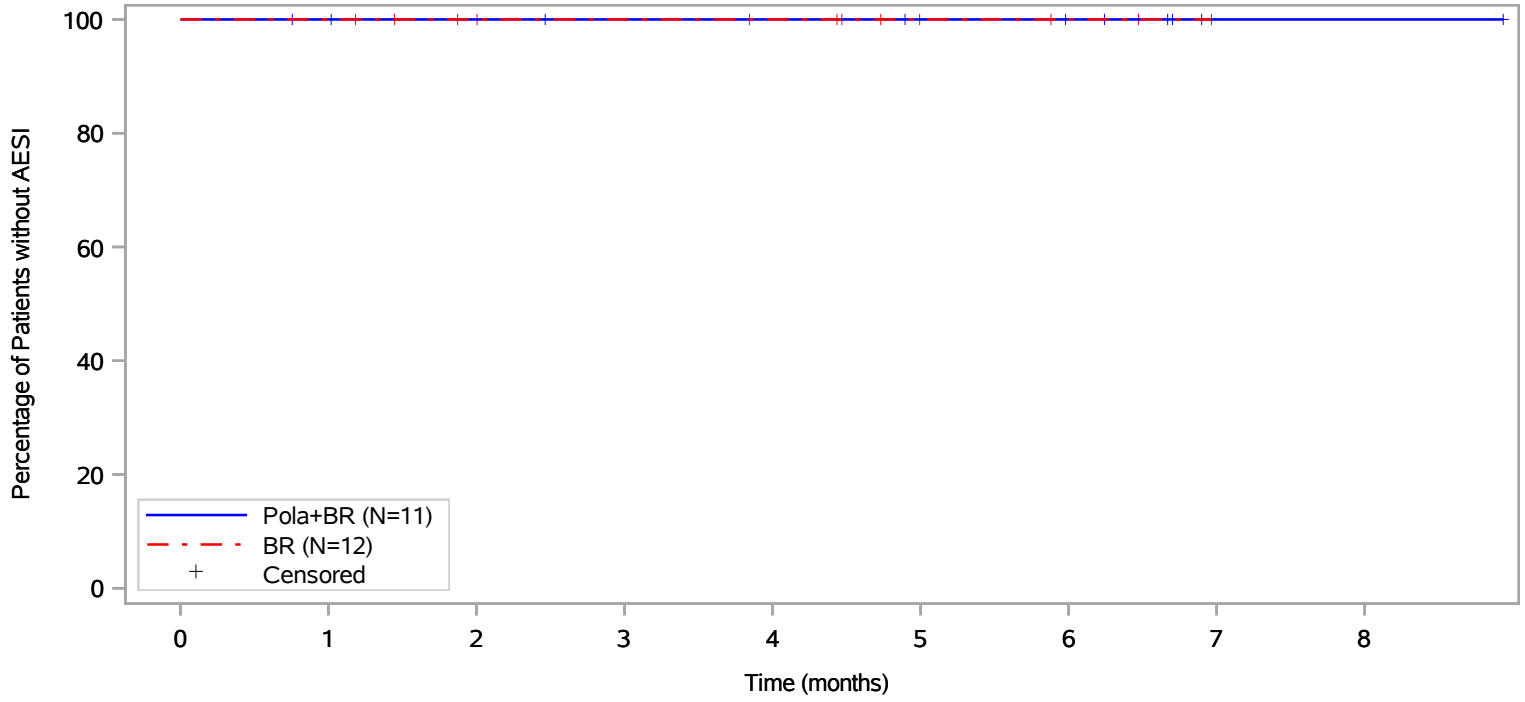
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPAIN35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 21:49

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPAIN35_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 13:15

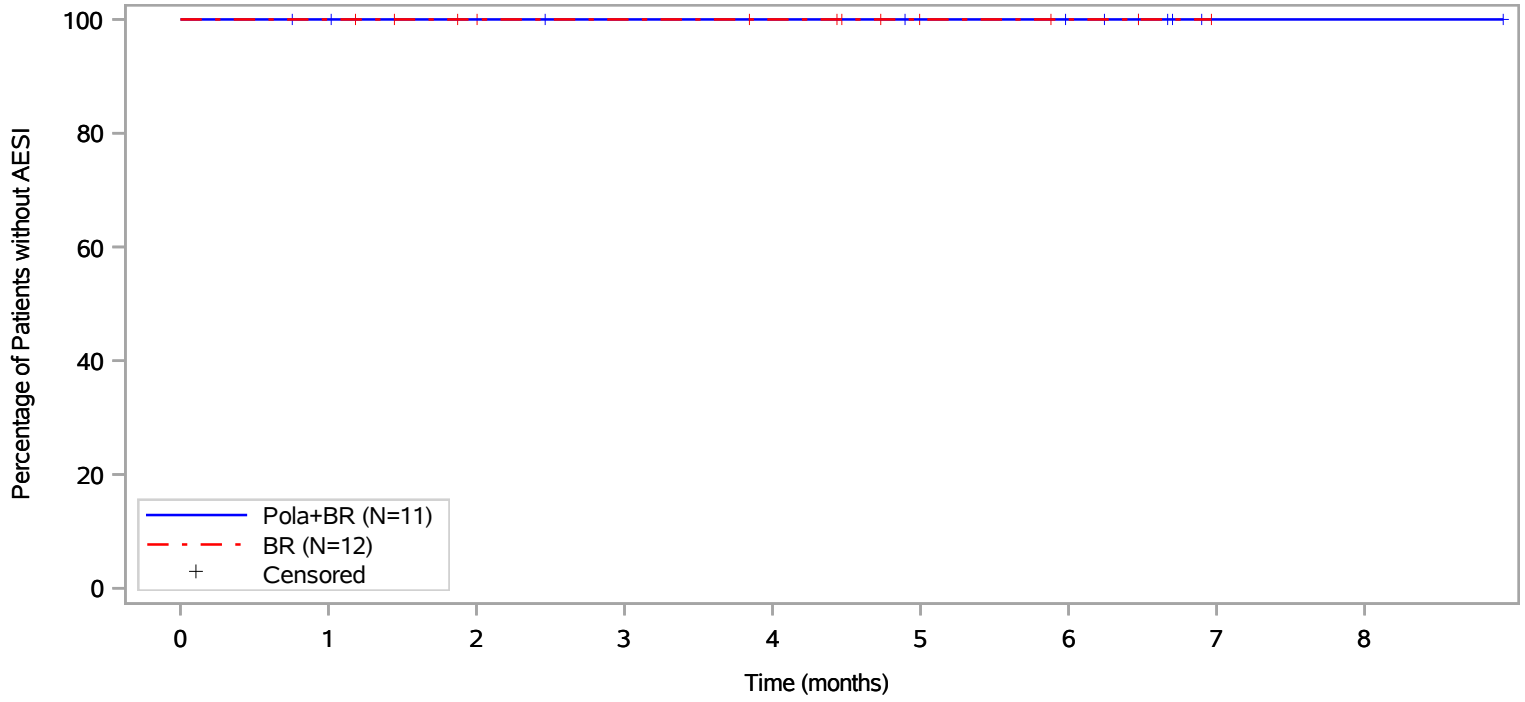
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPAINS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 21:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPAINS_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 16:44

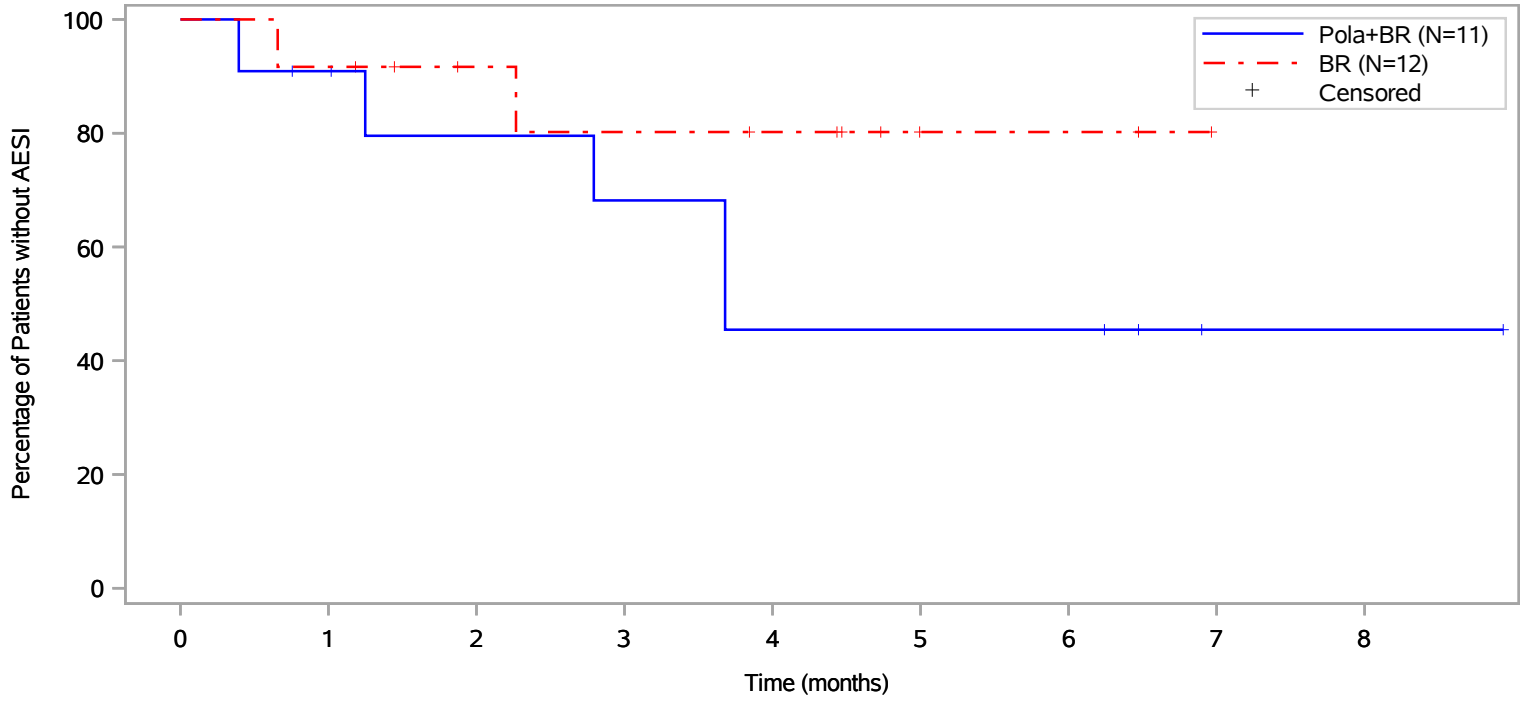
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	5	45.5	6	54.5	12	100.0	2	16.7	10	83.3	0.1837	2.93	0.56	15.39		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	3	42.9	4	57.1	7	58.3	1	14.3	6	85.7	0.2416	3.55	0.37	34.24		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	2	50.0	2	50.0	5	41.7	1	20.0	4	80.0	0.6195	1.82	0.16	20.20		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	2	16.7	10	83.3	0.1555	3.20	0.59	17.51		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	2	33.3	4	66.7	10	83.3	1	10.0	9	90.0	0.2080	4.17	0.37	46.44		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	3	60.0	2	40.0	2	16.7	1	50.0	1	50.0	0.8467	0.78	0.07	9.20		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	4	66.7	2	33.3	9	75.0	2	22.2	7	77.8	0.1553	3.32	0.58	18.90		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPHENEU_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 0:23

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	9	7	6	4	4	4	1	1
BR (N=12)	12	11	8	7	6	2	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	2	2	2	2	5	5
BR (N=12)	0	0	3	3	4	8	8	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPHENEU_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:44

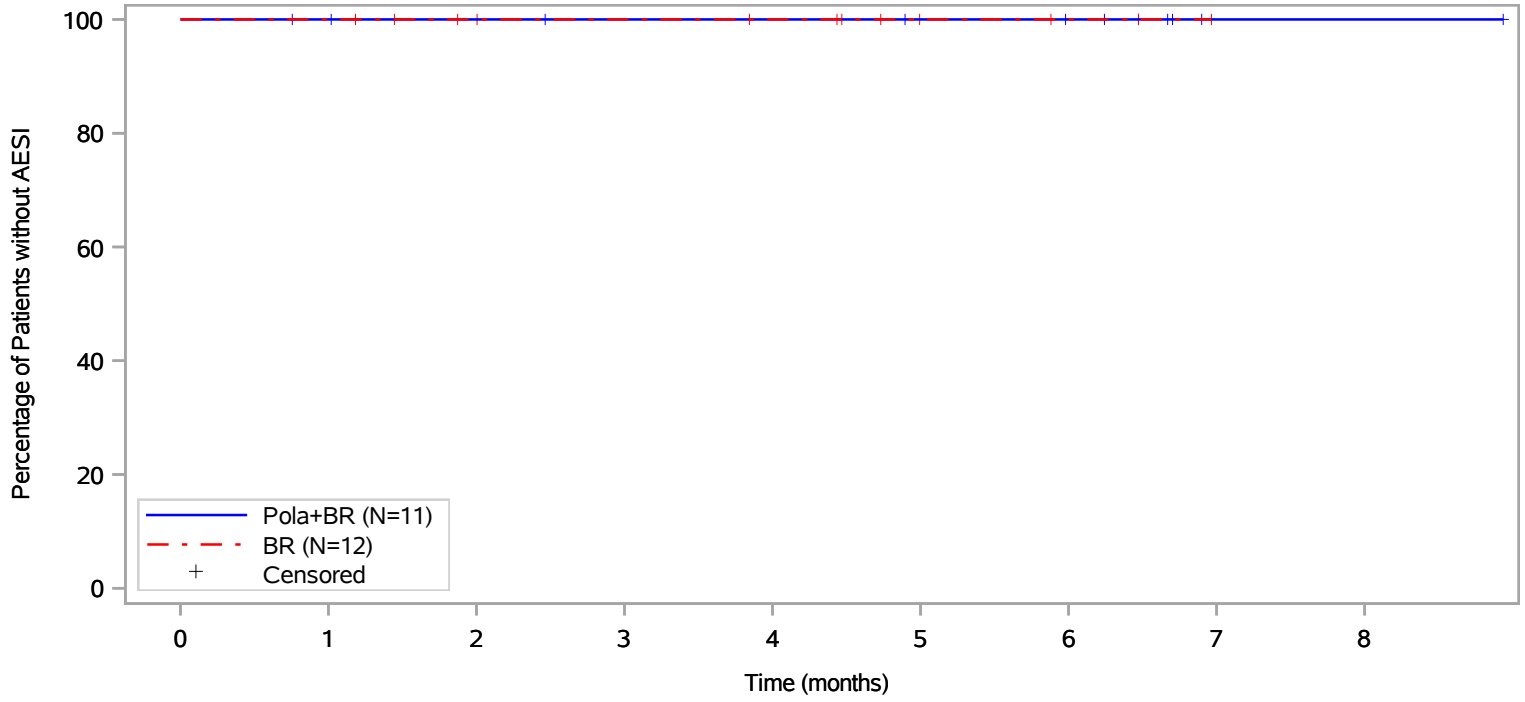
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPHENEU35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:13

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPHENEU35_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:49

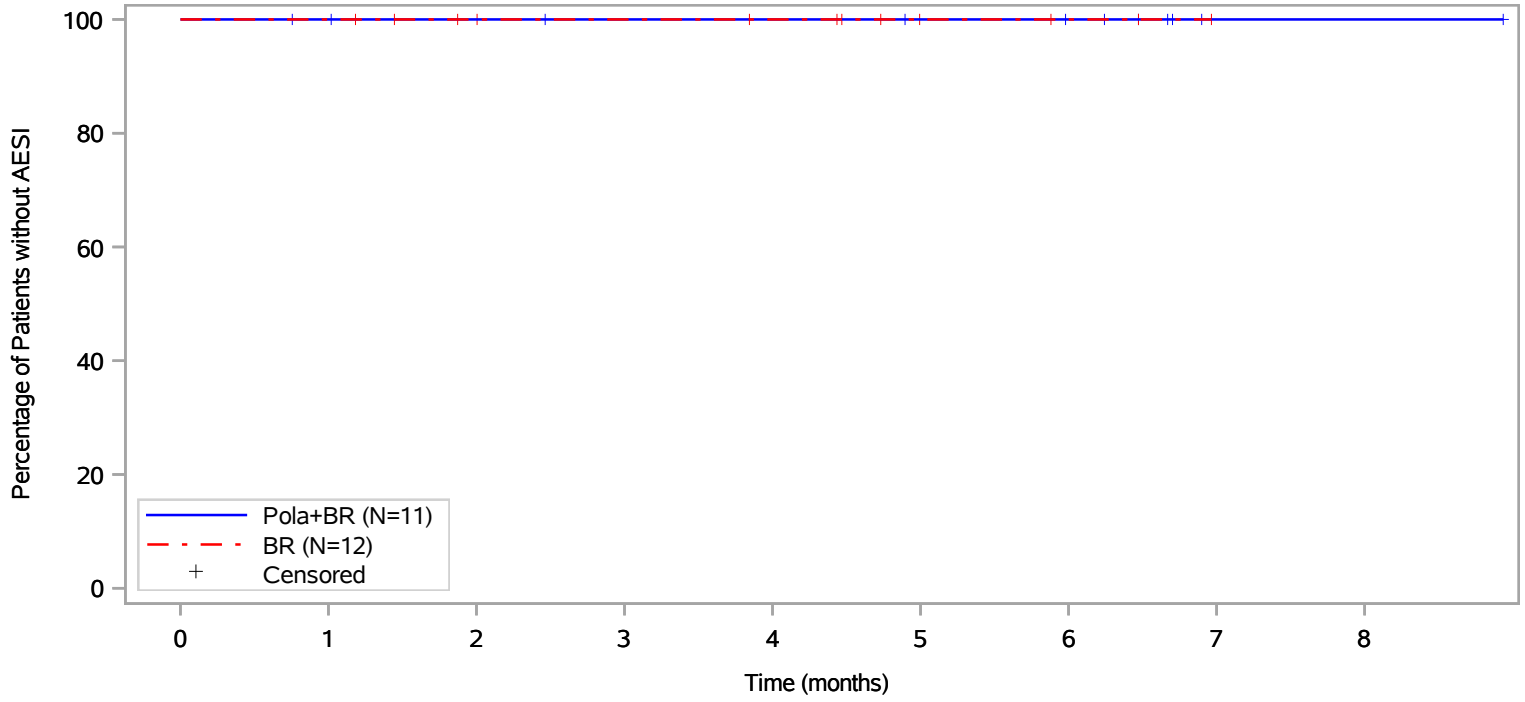
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPHENEUS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:06

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPHENEUS_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 6:55

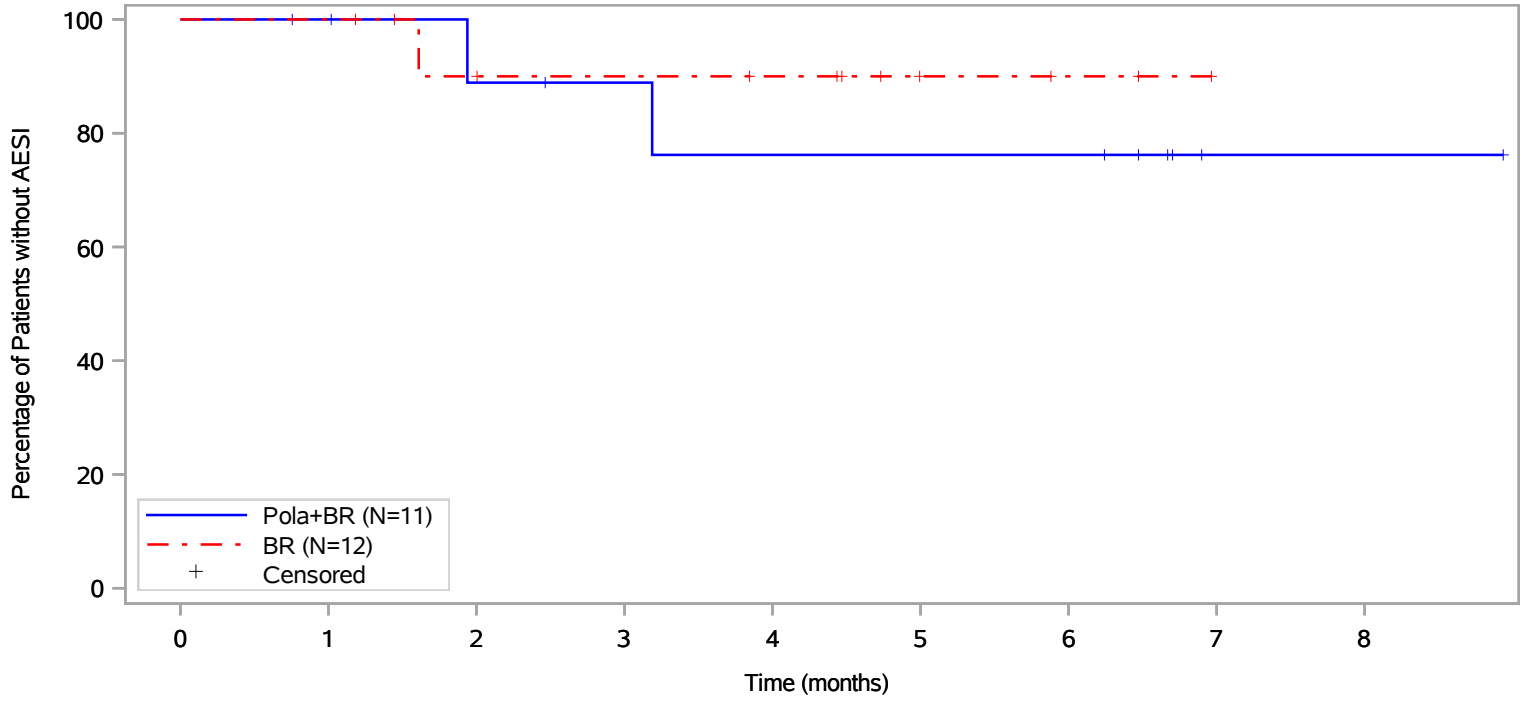
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	2	18.2	9	81.8	12	100.0	1	8.3	11	91.7	0.5176	2.17	0.20	23.92		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	2	28.6	5	71.4	7	58.3	1	14.3	6	85.7	0.4741	2.34	0.21	25.95		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	1	8.3	11	91.7	0.8191	1.38	0.09	22.07		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	1	10.0	9	90.0	0.6171	2.00	0.13	31.97		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	1	11.1	8	88.9	0.3761	2.83	0.26	31.32		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPULTOX_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 7:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	8	7	6	6	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	3	3	8	8
BR (N=12)	0	0	2	3	4	8	9	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPULTOX_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:53

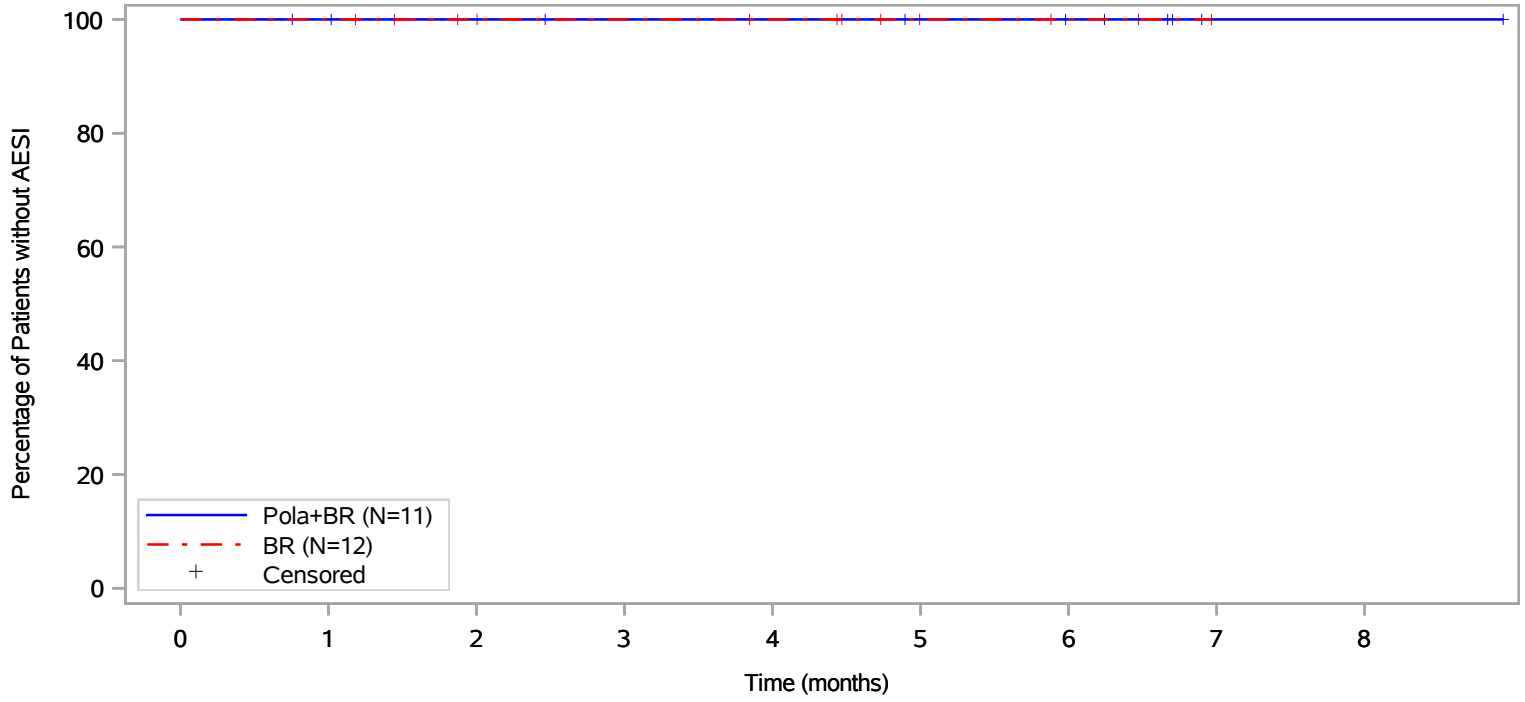
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPULTOX35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 21:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPULTOX35_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:01

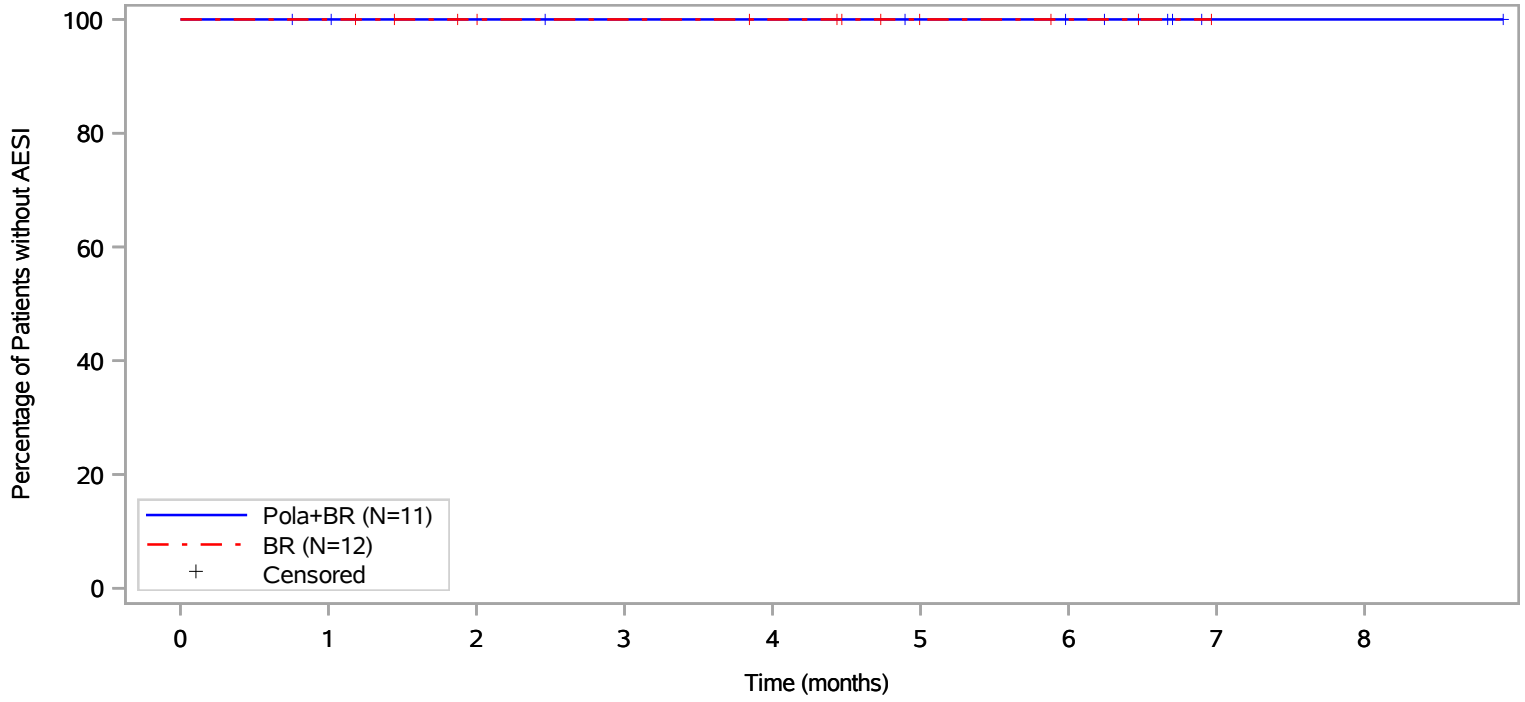
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPULTOXS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 21:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPULTOXS_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 13:31

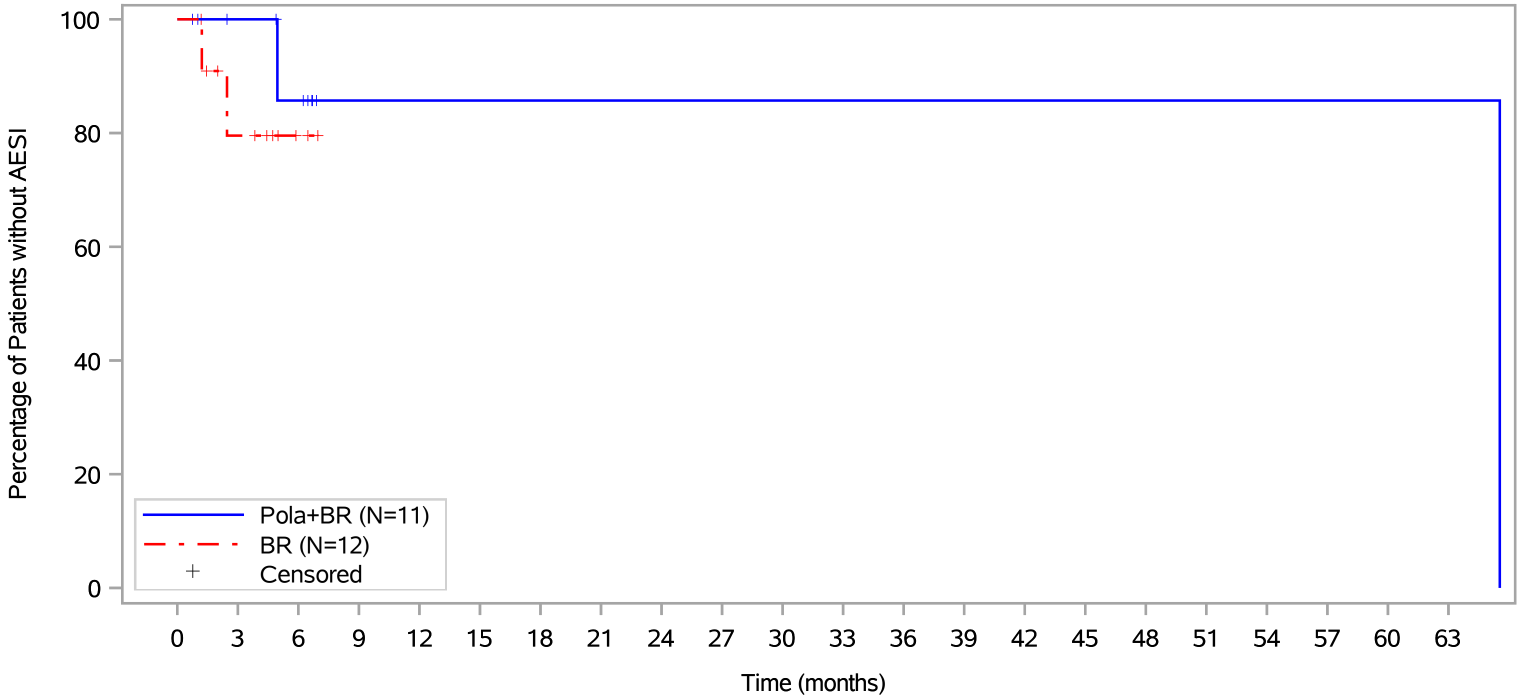
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	2	18.2	9	81.8	12	100.0	2	16.7	10	83.3	0.4705	0.42	0.04	4.75		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	1	14.3	6	85.7	7	58.3	2	28.6	5	71.4	0.4766	0.43	0.04	4.78		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	2	16.7	10	83.3	0.2200	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	2	20.0	8	80.0	0.2931	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	1	20.0	4	80.0	2	16.7	0	-	2	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	2	22.2	7	77.8	0.6541	0.58	0.05	6.47		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTRENTOX_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 5:43

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk
Pola+BR (N=11) 11 10 9 8 8 6 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
BR (N=12) 12 12 9 7 6 3 2 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE
Patients censored
Pola+BR (N=11) 0 1 2 3 3 4 4 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9
BR (N=12) 0 0 2 3 4 7 8 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTRENTOX_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:09

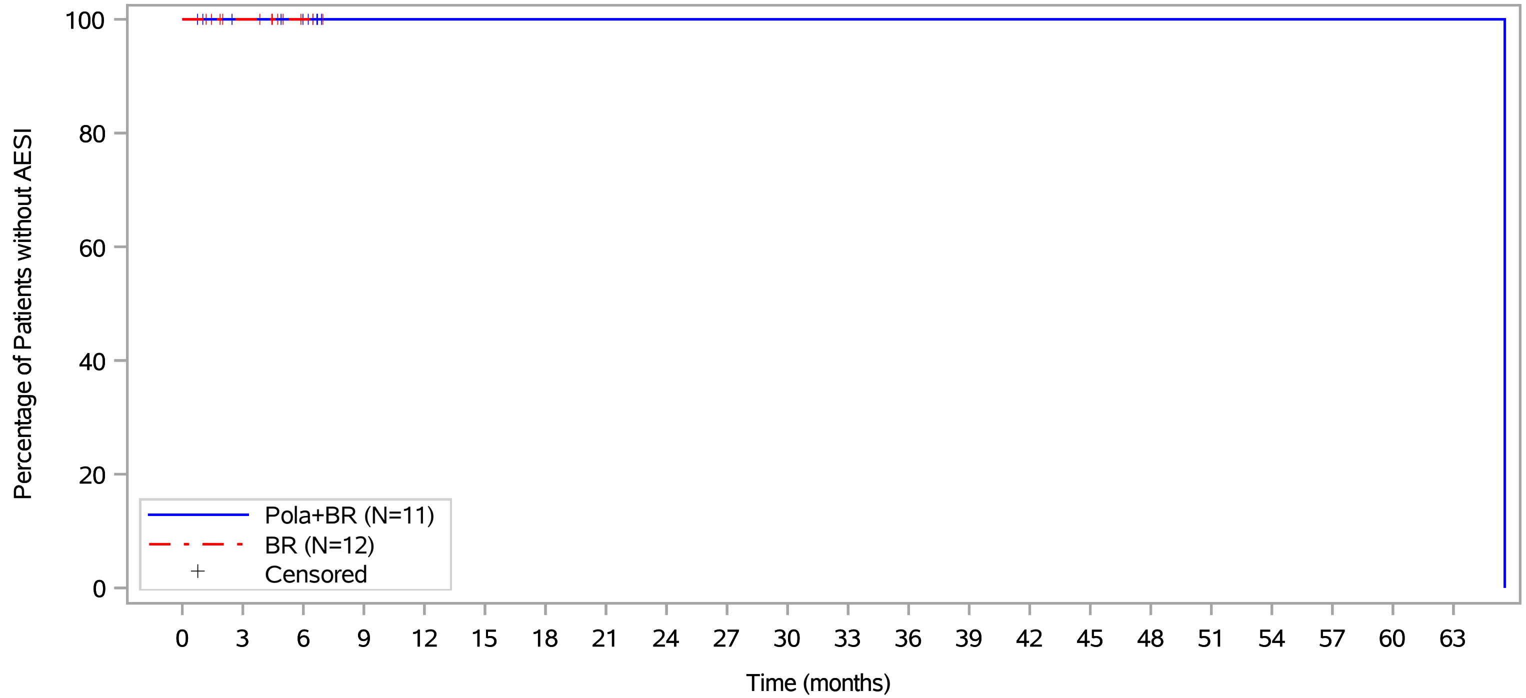
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTRENTOX35_L2_ARMCDSE_365_29365_41543.xls
25JAN2023 18:25

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk
Pola+BR (N=11) 11 10 9 8 8 7 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
BR (N=12) 12 12 9 8 7 3 2 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE
Patients censored
Pola+BR (N=11) 0 1 2 3 3 4 5 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10
BR (N=12) 0 0 3 4 5 9 10 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTRENTOX35_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:15

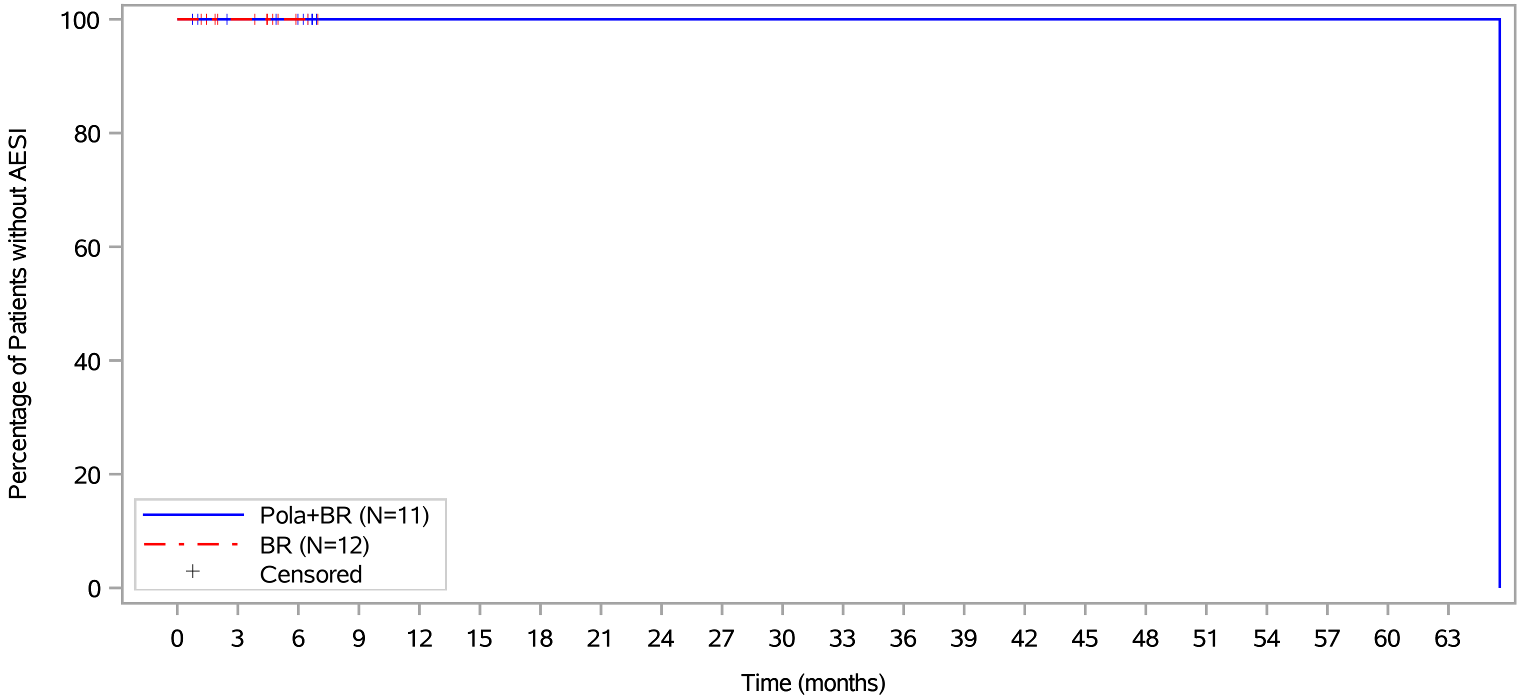
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	1	9.1	10	90.9	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	1	12.5	7	87.5	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	1	16.7	5	83.3	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	1	16.7	5	83.3	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTRENTOXS_L2_ARMCDSE_365_29365_41543.xls
25JAN2023 18:28

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk
Pola+BR (N=11) 11 10 9 8 8 7 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
BR (N=12) 12 12 9 8 7 3 2 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE
Patients censored
Pola+BR (N=11) 0 1 2 3 3 4 5 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10 10
BR (N=12) 0 0 3 4 5 9 10 NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTRENTOXS_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:18

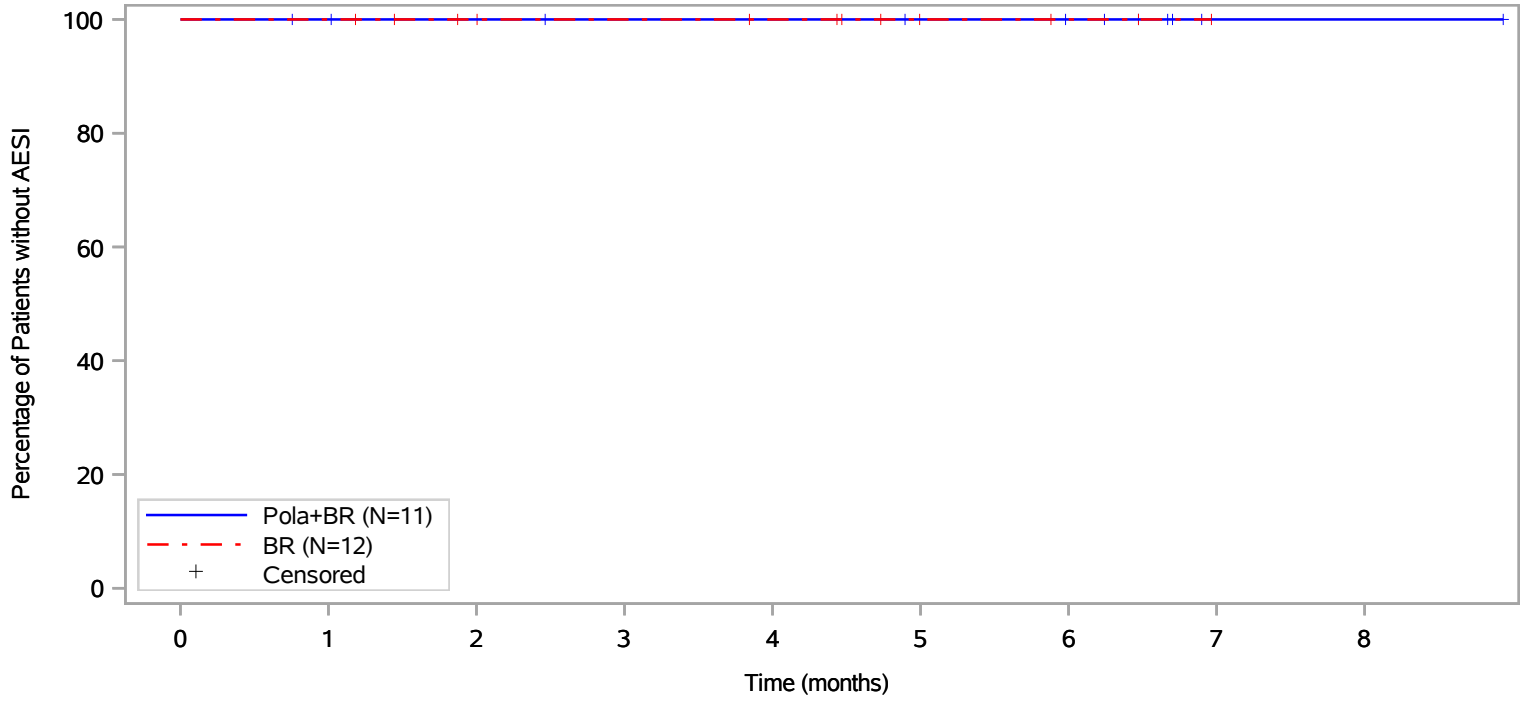
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTREPROD_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 4:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Reproductive Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTREPROD_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:24

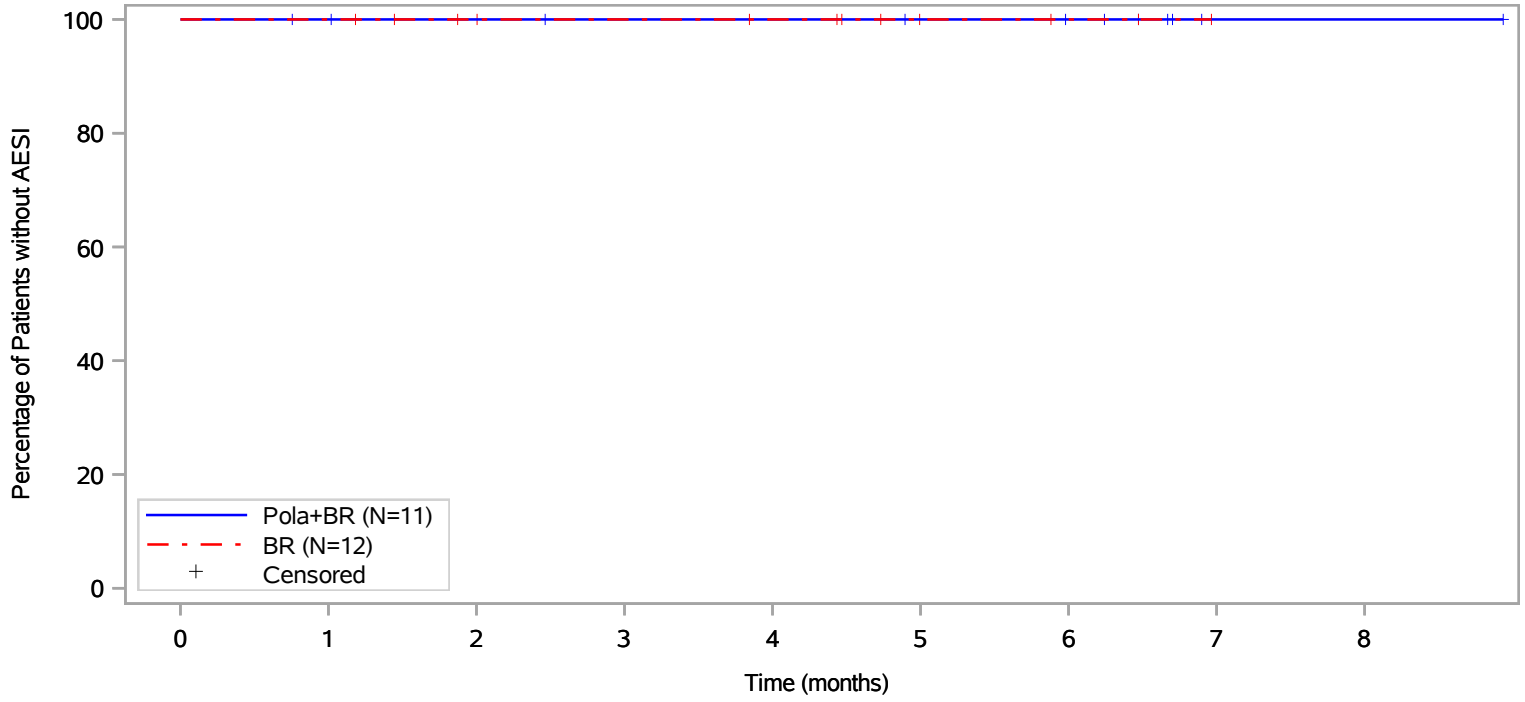
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTSTIAMP_L2_ARMCDSE_365_29365_41543.xls
04DEC2022 13:54

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTSTIAMP_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 14:16

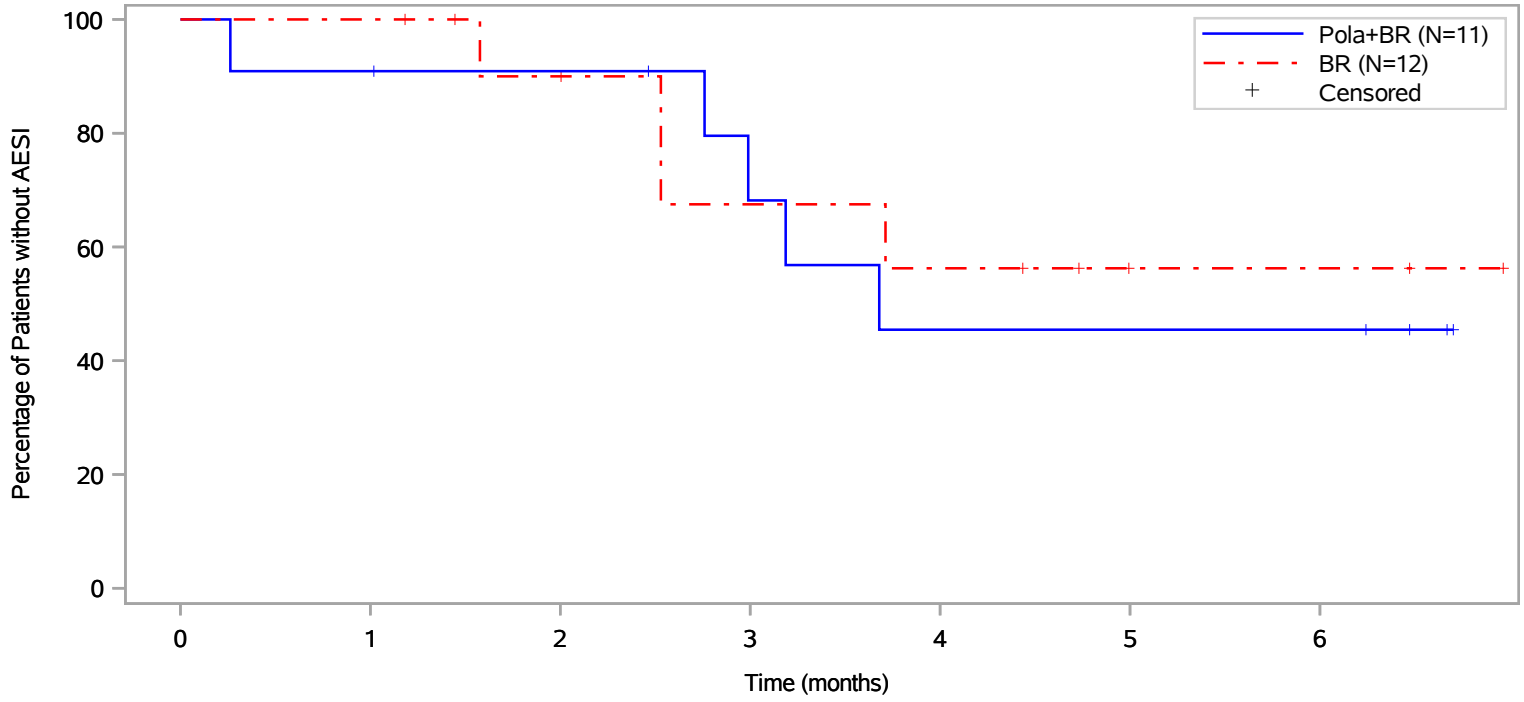
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	5	45.5	6	54.5	12	100.0	4	33.3	8	66.7	0.6938	1.31	0.35	4.94		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	3	42.9	4	57.1	7	58.3	2	28.6	5	71.4	0.6707	1.47	0.24	8.85		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	2	50.0	2	50.0	5	41.7	2	40.0	3	60.0	0.9770	1.03	0.14	7.42		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	1	33.3	2	66.7	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	4	50.0	4	50.0	12	100.0	4	33.3	8	66.7	0.6403	1.40	0.34	5.70		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	3	50.0	3	50.0	10	83.3	3	30.0	7	70.0	0.3129	2.26	0.44	11.52		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	2	40.0	3	60.0	2	16.7	1	50.0	1	50.0	0.6240	0.55	0.05	6.21		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	2	40.0	3	60.0	3	25.0	1	33.3	2	66.7	0.7222	1.54	0.14	17.22		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	3	50.0	3	50.0	9	75.0	3	33.3	6	66.7	0.8510	1.17	0.23	6.08		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTTHROM_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 1:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	10	9	6	4	4	4
BR (N=12)	12	12	9	6	5	2	2
Patients censored							
Pola+BR (N=11)	0	0	1	2	2	2	2
BR (N=12)	0	0	2	3	3	6	6

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTTHROM_L2_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:38

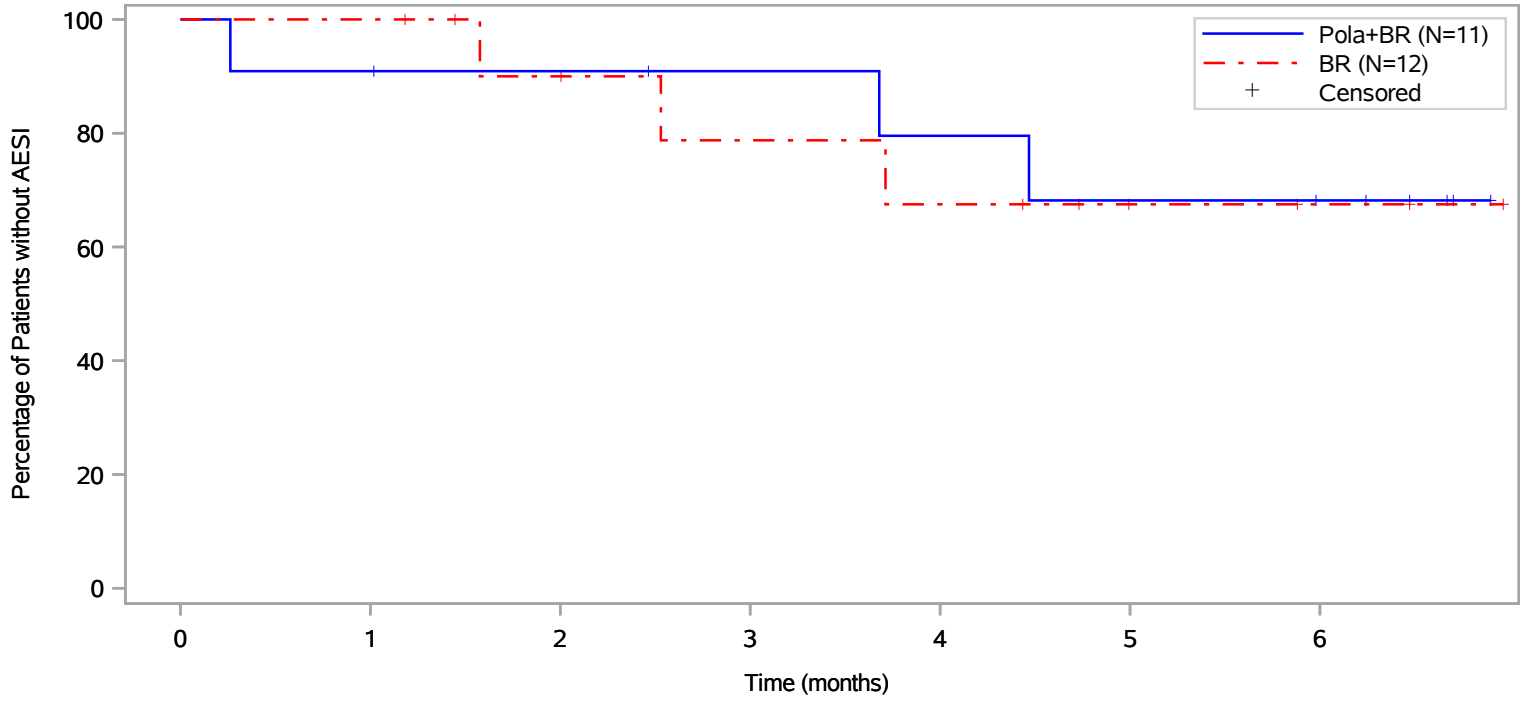
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	3	27.3	8	72.7	12	100.0	3	25.0	9	75.0	0.9552	0.96	0.19	4.75		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	2	28.6	5	71.4	7	58.3	2	28.6	5	71.4	0.9021	0.88	0.12	6.44		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	1	25.0	3	75.0	5	41.7	1	20.0	4	80.0	0.9191	1.15	0.07	18.59		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	3	37.5	5	62.5	12	100.0	3	25.0	9	75.0	0.7529	1.29	0.26	6.43		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	3	50.0	3	50.0	10	83.3	3	30.0	7	70.0	0.4047	1.95	0.39	9.71		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	1	20.0	4	80.0	3	25.0	1	33.3	2	66.7	0.7766	0.67	0.04	10.77		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	2	33.3	4	66.7	9	75.0	2	22.2	7	77.8	0.8890	1.15	0.16	8.21		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTTHROM35_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:36

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=11)	11	10	9	8	7	6	5
BR (N=12)	12	12	9	7	6	3	2
Patients censored							
Pola+BR (N=11)	0	0	1	2	2	2	3
BR (N=12)	0	0	2	3	3	6	7

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTTHROM35_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 9:56

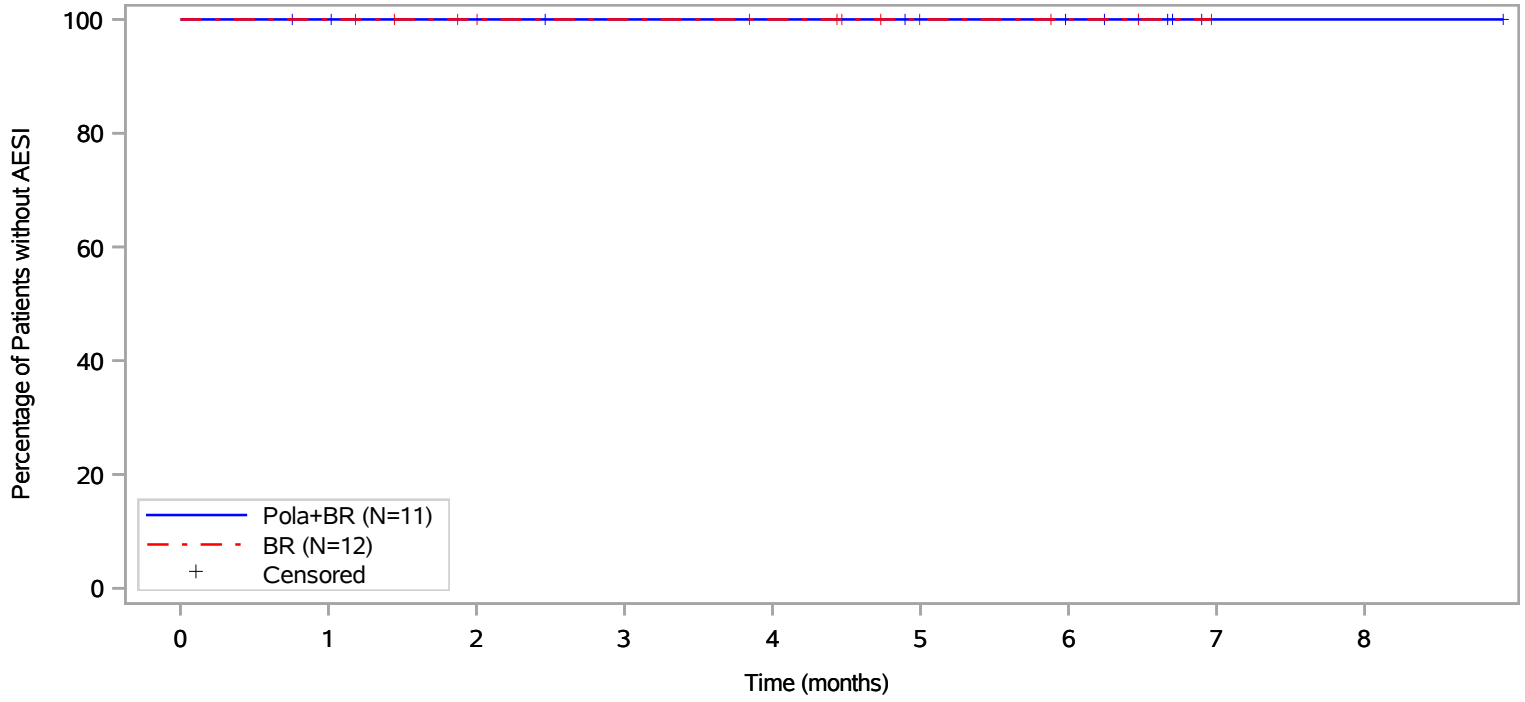
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTTHROMS_L2_ARMCDSE_365_29365_41543.xls
02DEC2022 20:32

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Serious Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..s/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTTHROMS_L2_ARMCDSE_365_29365_41543.pdf
02DEC2022 7:12

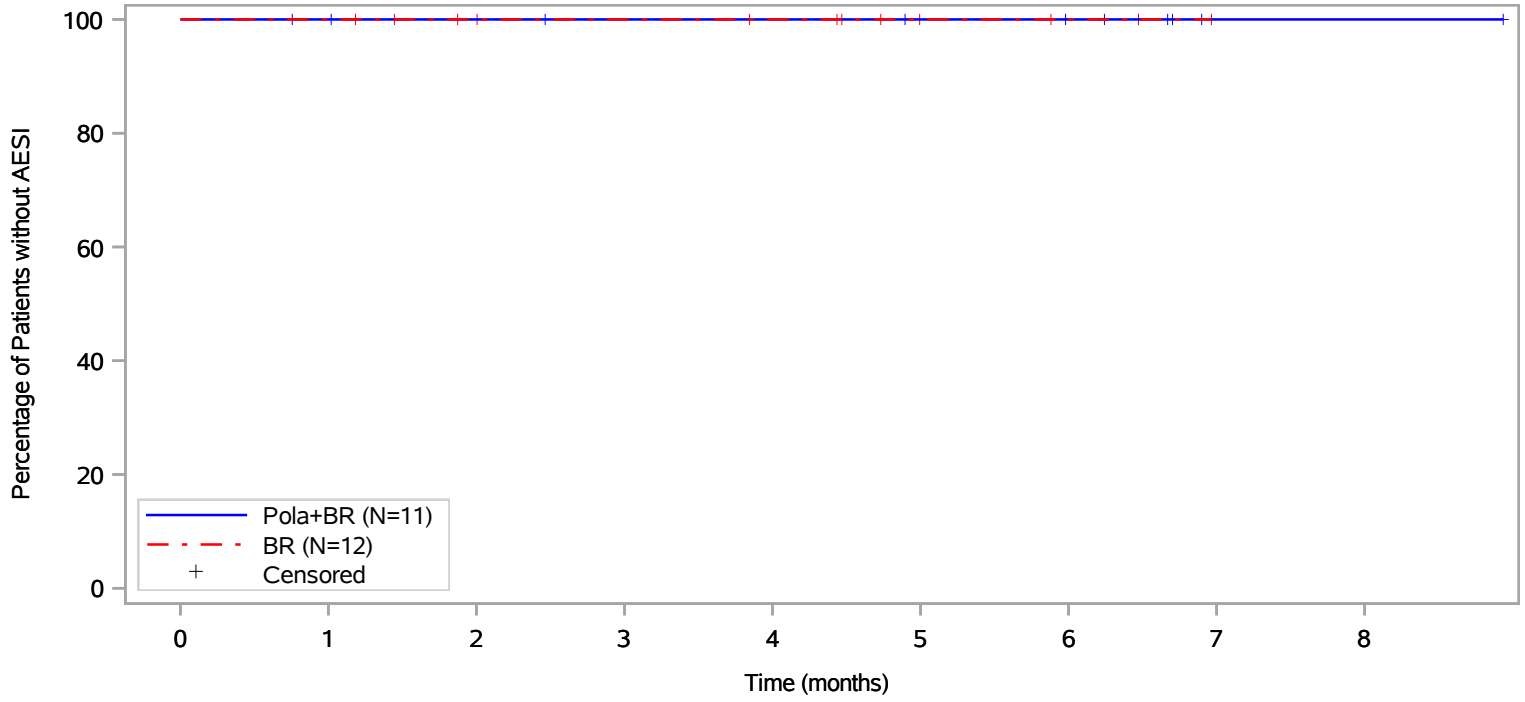
POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=11)						BR (N=12)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		11	100.0	0	-	11	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	63.6	0	-	7	100.0	7	58.3	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	4	36.4	0	-	4	100.0	5	41.7	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	3	27.3	0	-	3	100.0	0	0.0	0	-	0	-	NE	NE	NE	NE		NE	-
	>= 65	8	72.7	0	-	8	100.0	12	100.0	0	-	12	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	6	54.5	0	-	6	100.0	10	83.3	0	-	10	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	45.5	0	-	5	100.0	2	16.7	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	5	45.5	0	-	5	100.0	3	25.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	6	54.5	0	-	6	100.0	9	75.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTTLS_L2_ARMCDSE_365_29365_41543.xls
01DEC2022 21:15

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=11)	11	10	9	8	8	7	6	1	1
BR (N=12)	12	12	9	8	7	3	2	NE	NE
Patients censored									
Pola+BR (N=11)	0	1	2	3	3	4	5	10	10
BR (N=12)	0	0	3	4	5	9	10	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTTLS_L2_ARMCDSE_365_29365_41543.pdf
01DEC2022 23:06

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=11)															BR (N=12)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																													
All	153	115	75.2	0	0.0	30	19.6	2	1.3	1	0.7	5	3.3	0	0.0	151	83	55.0	0	0.0	56	37.1	3	2.0	4	2.6	5	3.3	0	0.0
Grade 1	75	55	73.3	0	0.0	14	18.7	0	0.0	1	1.3	5	6.7	0	0.0	69	44	63.8	0	0.0	20	29.0	0	0.0	2	2.9	3	4.3	0	0.0
Grade 2	41	31	75.6	0	0.0	10	24.4	0	0.0	0	0.0	0	0.0	0	0.0	45	22	48.9	0	0.0	19	42.2	0	0.0	2	4.4	2	4.4	0	0.0
Grade 3	27	22	81.5	0	0.0	5	18.5	0	0.0	0	0.0	0	0.0	0	0.0	21	10	47.6	0	0.0	11	52.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	8	7	87.5	0	0.0	1	12.5	0	0.0	0	0.0	0	0.0	0	0.0	13	7	53.8	0	0.0	6	46.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0
AEs Grade >=3																													
All	37	29	78.4	0	0.0	6	16.2	2	5.4	0	0.0	0	0.0	0	0.0	37	17	45.9	0	0.0	17	45.9	3	8.1	0	0.0	0	0.0	0	0.0
Grade 3	27	22	81.5	0	0.0	5	18.5	0	0.0	0	0.0	0	0.0	0	0.0	21	10	47.6	0	0.0	11	52.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	8	7	87.5	0	0.0	1	12.5	0	0.0	0	0.0	0	0.0	0	0.0	13	7	53.8	0	0.0	6	46.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0
AEs Grade 3																													
All	27	22	81.5	0	0.0	5	18.5	0	0.0	0	0.0	0	0.0	0	0.0	21	10	47.6	0	0.0	11	52.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	27	22	81.5	0	0.0	5	18.5	0	0.0	0	0.0	0	0.0	0	0.0	21	10	47.6	0	0.0	11	52.4	0	0.0	0	0.0	0	0.0	0	0.0
AEs Grade 4																													
All	8	7	87.5	0	0.0	1	12.5	0	0.0	0	0.0	0	0.0	0	0.0	13	7	53.8	0	0.0	6	46.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	8	7	87.5	0	0.0	1	12.5	0	0.0	0	0.0	0	0.0	0	0.0	13	7	53.8	0	0.0	6	46.2	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																													
All	6	3	50.0	0	0.0	1	16.7	2	33.3	0	0.0	0	0.0	0	0.0	12	2	16.7	0	0.0	7	58.3	3	25.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ae_resolved.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ae_resolved_L2_ARMCDSE_365_29365_41543.xls
29NOV2022 8:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Second-line (2L) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=11)															BR (N=12)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Neutropenia Including Febrile Neutropenia																													
All	16	15	93.8	0	0.0	1	6.3	0	0.0	0	0.0	0	0.0	0	0.0	21	14	66.7	0	0.0	7	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	9	9	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	11	6	54.5	0	0.0	5	45.5	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	6	5	83.3	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0	8	6	75.0	0	0.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Neutropenia Including Febrile Neutropenia																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral Neuropathy																													
All	7	6	85.7	0	0.0	1	14.3	0	0.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	1	33.3	0	0.0	0	0.0	2	66.7	0	0.0
Grade 1	5	4	80.0	0	0.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0
Grade 2	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Peripheral Neuropathy																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Anemia																													
All	5	3	60.0	0	0.0	2	40.0	0	0.0	0	0.0	0	0.0	0	0.0	6	2	33.3	0	0.0	4	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	4	2	50.0	0	0.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Anemia																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Thrombocytopenia																													
All	7	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Serious Thrombocytopenia																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infections and Infestations																													
All	11	7	63.6	0	0.0	3	27.3	1	9.1	0	0.0	0	0.0	0	0.0	9	5	55.6	0	0.0	2	22.2	2	22.2	0	0.0	0	0.0	0	0.0
Grade 1	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
Serious Infections and Infestations																													
All	3	2	66.7	0	0.0	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	1	33.3	2	66.7	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
Infusion Related Reactions																													
All	8	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	4	66.7	0	0.0	2	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	6	6	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	4	66.7	0	0.0	2	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Infusion Related Reactions																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hepatic Toxicity																													
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	4	0	0.0	0	0.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hepatic Toxicity																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Reproductive Toxicity																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Reproductive Toxicity																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Fatigue and Asthenia																													
All	7	3	42.9	0	0.0	4	57.1	0	0.0	0	0.0	0	0.0	0	0.0	10	4	40.0	0	0.0	5	50.0	0	0.0	1	10.0	0	0.0	0	0.0
Grade 1	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	6	3	50.0	0	0.0	3	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	4	1	25.0	0	0.0	3	75.0	0	0.0	0	0.0	0	0.0	0	0.0	4	1	25.0	0	0.0	2	50.0	0	0.0	1	25.0	0	0.0	0	0.0
Serious Fatigue and Asthenia																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hyperglycemias																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hyperglycemias																													
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Renal Toxicity																																
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Renal Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Gastrointestinal Toxicity																																
All	32	26	81.3	0	0.0	4	12.5	0	0.0	1	3.1	1	3.1	0	0.0	22	15	68.2	0	0.0	5	22.7	0	0.0	1	4.5	1	4.5	0	0.0		
Grade 1	23	19	82.6	0	0.0	2	8.7	0	0.0	1	4.3	1	4.3	0	0.0	11	8	72.7	0	0.0	2	18.2	0	0.0	1	9.1	0	0.0	0	0.0		
Grade 2	9	7	77.8	0	0.0	2	22.2	0	0.0	0	0.0	0	0.0	0	0.0	10	6	60.0	0	0.0	3	30.0	0	0.0	0	0.0	1	10.0	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Gastrointestinal Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Pulmonary Toxicity																																
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0		
Grade 1	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0		
Serious Pulmonary Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Joint Pains, Arthralgia, Skeletal Pain																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Joint Pains, Arthralgia, Skeletal Pain																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Alopecia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Alopecia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Cardiac Toxicity and Arrhythmias																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0		
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0		
Serious Cardiac Toxicity and Arrhythmias																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Dysgeusia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Dysgeusia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ae_resolved.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ae_resolved_aesi_L2_ARMCDSE_365_29365_41543.xls
29NOV2022 9:18

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Demographics and Baseline Characteristics

	Pola+BR (N=29)	BR (N=28)	All (N=57)
Age (Years)			
n	29	28	57
Mean (SD)	62.4 (11.5)	62.6 (12.9)	62.5 (12.1)
Median	65	64.5	65
Min - Max	33 - 81	30 - 84	30 - 84
Age Group (Years)			
n	29	28	57
18 - 40	3 (10.3%)	2 (7.1%)	5 (8.8%)
41 - 64	11 (37.9%)	12 (42.9%)	23 (40.4%)
>= 65	15 (51.7%)	14 (50.0%)	29 (50.9%)
Sex			
n	29	28	57
Male	21 (72.4%)	18 (64.3%)	39 (68.4%)
Female	8 (27.6%)	10 (35.7%)	18 (31.6%)
Race			
n	29	28	57
American Indian or Alaska Native	0	1 (3.6%)	1 (1.8%)
Asian	4 (13.8%)	2 (7.1%)	6 (10.5%)
Black or African American	3 (10.3%)	0	3 (5.3%)
White	18 (62.1%)	21 (75.0%)	39 (68.4%)
Unknown	4 (13.8%)	4 (14.3%)	8 (14.0%)
Ethnicity			
n	29	28	57
Hispanic or Latino	1 (3.4%)	0	1 (1.8%)
Not Hispanic or Latino	25 (86.2%)	25 (89.3%)	50 (87.7%)
Not reported	2 (6.9%)	1 (3.6%)	3 (5.3%)
Unknown	1 (3.4%)	2 (7.1%)	3 (5.3%)
Weight (kg) at Baseline			

n	29	28	57
Mean (SD)	78.39 (17.38)	69.41 (14.35)	73.98 (16.46)
Median	78	71.7	74.5
Min - Max	45.5 - 107.0	40.4 - 93.5	40.4 - 107.0
Height (cm) at Baseline			
n	28	27	55
Mean (SD)	170.7 (11.18)	169.8 (10.23)	170.3 (10.63)
Median	172.6	170	170.2
Min - Max	145.4 - 191.0	147.0 - 185.0	145.4 - 191.0
ECOG score at Baseline			
n	29	28	57
0	9 (31.0%)	11 (39.3%)	20 (35.1%)
1	16 (55.2%)	10 (35.7%)	26 (45.6%)
2	3 (10.3%)	6 (21.4%)	9 (15.8%)
Unknown	1 (3.4%)	1 (3.6%)	2 (3.5%)
Bulky disease at Baseline			
n	29	28	57
Yes	7 (24.1%)	13 (46.4%)	20 (35.1%)
No	22 (75.9%)	15 (53.6%)	37 (64.9%)
Primary Reason for Stem Cell Transplant Ineligibility			
n	29	28	57
Age	6 (20.7%)	8 (28.6%)	14 (24.6%)
Co-Morbidities	0	1 (3.6%)	1 (1.8%)
Failed Prior Transplant	10 (34.5%)	6 (21.4%)	16 (28.1%)
Insufficient Response to Salvage Therapy	12 (41.4%)	9 (32.1%)	21 (36.8%)
Patient Refused Transplant	0	2 (7.1%)	2 (3.5%)
Performance Status	0	1 (3.6%)	1 (1.8%)
Other	1 (3.4%)	1 (3.6%)	2 (3.5%)
Duration of response to prior therapy (IxRS)			
n	29	28	57
<=12 Months	27 (93.1%)	23 (82.1%)	50 (87.7%)
>12 Months	2 (6.9%)	5 (17.9%)	7 (12.3%)
Duration of response to prior therapy (CRF)			
n	29	28	57
<=12 Months	27 (93.1%)	23 (82.1%)	50 (87.7%)
>12 Months	2 (6.9%)	5 (17.9%)	7 (12.3%)

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_dm.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_dm_L3PLUS_365_ARMCD_IT_29365_41543.xls
08DEC2022 17:46

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of Patients who discontinued Study or Treatment

Status / Primary Reason for Discontinuation	Pola+BR (N=29)	BR (N=28)	All (N=57)
Number of Patients Randomized	29 (100.0%)	28 (100.0%)	57 (100.0%)
Number of Patients Treated	28 (96.6%)	27 (96.4%)	55 (96.5%)
Discontinued Study*			
Total	27 (93.1%)	26 (92.9%)	53 (93.0%)
Death	21 (72.4%)	21 (75.0%)	42 (73.7%)
Withdrawal by Subject	4 (13.8%)	3 (10.7%)	7 (12.3%)
Physician decision	0	2 (7.1%)	2 (3.5%)
Other	2 (6.9%)	0	2 (3.5%)
Discontinued Polatuzumab Vedotin Treatment or Placebo**			
Total	15 (53.6%)	0	15 (27.3%)
Adverse Event	7 (25.0%)	0	7 (12.7%)
Progressive Disease	6 (21.4%)	0	6 (10.9%)
Lack of Efficacy	1 (3.6%)	0	1 (1.8%)
Other	1 (3.6%)	0	1 (1.8%)
Discontinued Bendamustine Treatment**			
Total	14 (50.0%)	22 (81.5%)	36 (65.5%)
Adverse Event	7 (25.0%)	3 (11.1%)	10 (18.2%)
Progressive Disease	6 (21.4%)	17 (63.0%)	23 (41.8%)
Lack of Efficacy	1 (3.6%)	0	1 (1.8%)
Physician decision	0	1 (3.7%)	1 (1.8%)
Other	0	1 (3.7%)	1 (1.8%)
Discontinued Rituximab or Obinutuzumab Treatment**			
Total	15 (53.6%)	23 (85.2%)	38 (69.1%)
Adverse Event	7 (25.0%)	3 (11.1%)	10 (18.2%)
Progressive Disease	6 (21.4%)	17 (63.0%)	23 (41.8%)
Lack of Efficacy	1 (3.6%)	0	1 (1.8%)
Physician decision	0	2 (7.4%)	2 (3.6%)
Other	1 (3.6%)	1 (3.7%)	2 (3.6%)

* Percentages are based on the number of patients randomized.
** Percentages are based on the number of patients treated.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ds.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_ds_L3PLUS_365_ARMCD_IT_29365_41543.xls
08DEC2022 13:07

POPULATION: Intent-to-Treat Patients, Study GO29365, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Number of Centers/Countries/Geographical Regions with <10, >=10 Patients per Arm

	Center				Country				Geographical region			
	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients
Overall	29	100.0	57	100.0	11	100.0	57	100.0	4	100.0	57	100.0
with <10 patients per arm	29	100.0	57	100.0	11	100.0	57	100.0	4	100.0	57	100.0
with >=10 patients per arm	0	-	0	-	0	-	0	-	0	-	0	-

'<10 patients' category if at least one treatment arm has <10 patients; '>=10 patients' category if all treatment arms have >=10 patients.
Geographical regions: Asia/Pacific, Eastern Europe, North America, Western Europe.
'n': Number of centers/countries/regions; "%": Percent of centers/countries/regions compared to overall number of centers/countries/regions
'n of patients randomized': Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)
'% randomized patients': Percent of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_center.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_center_L3PLUS_ARMCD_365_IT_29365_41543.xls
08DEC2022 0:45

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Third-line or beyond (3L+) Patients
ENDPOINT: Concordance of Stratification Factors by eCRF and IxRS
MODEL: Descriptive
STUDIES: GO29365, YO41543
Stratification Factor: Duration of Response to prior therapy

	Pola+BR (N=29)			BR (N=28)		
	eCRF			eCRF		
	<=12 Months	>12 Months	Total	<=12 Months	>12 Months	Total
IxRS						
<=12 Months	26 (89.7%)	1 (3.4%)	27 (93.1%)	23 (82.1%)	0	23 (82.1%)
>12 Months	1 (3.4%)	1 (3.4%)	2 (6.9%)	0	5 (17.9%)	5 (17.9%)
Total	27	2	29	23	5	28

Percentages are based on N in the column headings.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_strat.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_strat_L3PLUS_365_ARMCD_IT_29365_41543.xls
08DEC2022 13:07

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: POLATUZUMAB VEDOTIN

	Pola+BR (N=28)
Treatment Duration (Months)	
n	28
Mean (SD)	2.72 (1.45)
Median	3.29
Interquartile Range	1.35 - 3.69
Min - Max	0.0 - 5.0
Number of Cycles	
n	28
Mean (SD)	4.5 (1.7)
Median	5
Interquartile Range	3.0 - 6.0
Min - Max	1 - 6
Total Cumulative Dose (mg)	
n	28
Mean (SD)	610.5 (249.1)
Median	679
Interquartile Range	399.4 - 789.6
Min - Max	86 - 972
Dose intensity (%) adjusted for dose reduction and delay	
n	28
Mean (SD)	92.3 (12.3)
Median	94.3
Interquartile Range	83.1 - 101.9
Min - Max	67 - 113

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas

Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_ex_L3PLUS_ARMCDSE_365_29365_41543.xls
20APR2023 11:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: BENDAMUSTINE

	Pola+BR (N=28)	BR (N=27)
Treatment Duration (Months)		
n	28	27
Mean (SD)	2.74 (1.45)	1.48 (1.50)
Median	3.32	1.16
Interquartile Range	1.38 - 3.69	0.04 - 2.17
Min - Max	0.0 - 5.1	0.0 - 4.4
Number of Cycles		
n	28	27
Mean (SD)	4.5 (1.7)	2.8 (1.8)
Median	5	2
Interquartile Range	3.0 - 6.0	1.0 - 4.0
Min - Max	1 - 6	1 - 6
Total Cumulative Dose (mg)		
n	28	27
Mean (SD)	1486.7 (595.1)	873.9 (556.7)
Median	1533.6	712.8
Interquartile Range	1046.4 - 2040.0	360.0 - 1204.0
Min - Max	252 - 2268	236 - 1940
Dose intensity (%) adjusted for dose reduction and delay		
n	28	27
Mean (SD)	90.8 (12.5)	90.1 (10.9)
Median	95.7	95.5
Interquartile Range	84.2 - 100.1	81.8 - 96.1
Min - Max	61 - 102	64 - 102

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_ex_L3PLUS_ARMCDSE_365_29365_41543.xls
20APR2023 11:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: RITUXIMAB

	Pola+BR (N=28)	BR (N=27)
Treatment Duration (Months)		
n	28	27
Mean (SD)	2.75 (1.45)	1.47 (1.51)
Median	3.32	1.15
Interquartile Range	1.48 - 3.72	0.01 - 2.17
Min - Max	0.0 - 5.1	0.0 - 4.4
Number of Cycles		
n	28	27
Mean (SD)	4.5 (1.7)	2.8 (1.8)
Median	5	2
Interquartile Range	3.0 - 6.0	1.0 - 4.0
Min - Max	1 - 6	1 - 6
Total Cumulative Dose (mg)		
n	28	27
Mean (SD)	3162.1 (1260.5)	1890.2 (1250.4)
Median	3273.9	1485
Interquartile Range	2167.6 - 4227.0	750.0 - 2665.5
Min - Max	525 - 4770	491 - 4500
Dose intensity (%) adjusted for dose reduction and delay		
n	28	27
Mean (SD)	92.0 (10.1)	92.9 (8.8)
Median	94.8	96.7
Interquartile Range	83.2 - 100.0	85.4 - 100.0
Min - Max	71 - 105	74 - 102

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_ex_L3PLUS_ARMCDSE_365_29365_41543.xls
20APR2023 11:19

POPULATION: Safety Population, Arms C,D, Study GO29365, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=28)	BR (N=27)	All (N=55)
n	28	27	55
Median	132	66	93

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 30 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_fu_D30_L3PLUS_365_ARMCDSE_29365_41543.xls
08DEC2022 17:12

POPULATION: Safety Population, Arms C,D, Study GO29365, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=28)	BR (N=27)	All (N=55)
n	28	27	55
Median	188.5	111	133

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 90 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_fu_D90_L3PLUS_365_ARMCDSE_29365_41543.xls
08DEC2022 17:26

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of New Anti-Lymphoma Therapy

	Pola+BR (N=29)	BR (N=28)
Total number of patients with at least one NALT treatment	16 (55.2%)	12 (42.9%)
Total number of NALT treatments	37	18
Total number of patients with at least one NALT treatment before PFS event	6 (20.7%)	2 (7.1%)
Total number of patients with at least one NALT treatment at or after PFS event	8 (27.6%)	7 (25.0%)
Total number of patients with at least one NALT treatment and without PFS event	2 (6.9%)	3 (10.7%)
Radiotherapy		
Total number of patients with at least one treatment	3 (10.3%)	1 (3.6%)
Total number of treatments	3	1
Systemic therapy		
Total number of patients with at least one treatment	15 (51.7%)	11 (39.3%)
Total number of treatments	34	17
Total number of patients received stem cell transplants	1 (3.4%)	1 (3.6%)
Autologous transplant	0	0
Allogeneic transplant	0	1 (3.6%)
Unknown	1 (3.4%)	0
Total number of patients received CAR-T	2 (6.9%)	0
Total number of patients received unknown treatment	0	0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_nalt.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_nalt_L3PLUS_365_ARMCD_IT_29365_41543.xls
01FEB2023 19:16

POPULATION: Intent-to-Treat Patients, Arms C,D, Study GO29365, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median observation time(of follow up)

Overall Survival

	Pola+BR (N=29)	BR (N=28)	All (N=57)
Patients with event (%)	8 (27.6%)	7 (25.0%)	15 (26.3%)
Latest contributing event			
Alive	8	7	15
Patients without event (%)	21 (72.4%)	21 (75.0%)	42 (73.7%)
Time to event (months)			
Median	59.9	59.4	59.4
95% CI	(20.1, 61.1)	(26.3, NE)	(26.3, 60.4)
25% and 75%-ile	20.1 - 61.1	26.3 - 60.4	20.1 - 60.4
Range	0 - 64	0* - 60	0* - 64

Summaries of Duration of Follow-up (median, percentiles) are based on reverse Kaplan-Meier estimates.
* Censored observation.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_obs_time.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_obs_time_OSDFU_L3PLUS_365_ARMCD_IT_29365_41543.xls
08DEC2022 3:12

POPULATION: Safety Population, Arms C,D, Study GO29365, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Deaths and Primary Reason for Death

	Pola+BR (N=28)		BR (N=27)		All (N=55)	
	n	%	n	%	n	%
All Deaths	21	75.0	21	77.8	42	76.4
Adverse Event	7	25.0	7	25.9	14	25.5
Progressive Disease	14	50.0	14	51.9	28	50.9

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_death.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_death_L3PLUS_365_ARMCDSE_29365_41543.xls
08DEC2022 18:21

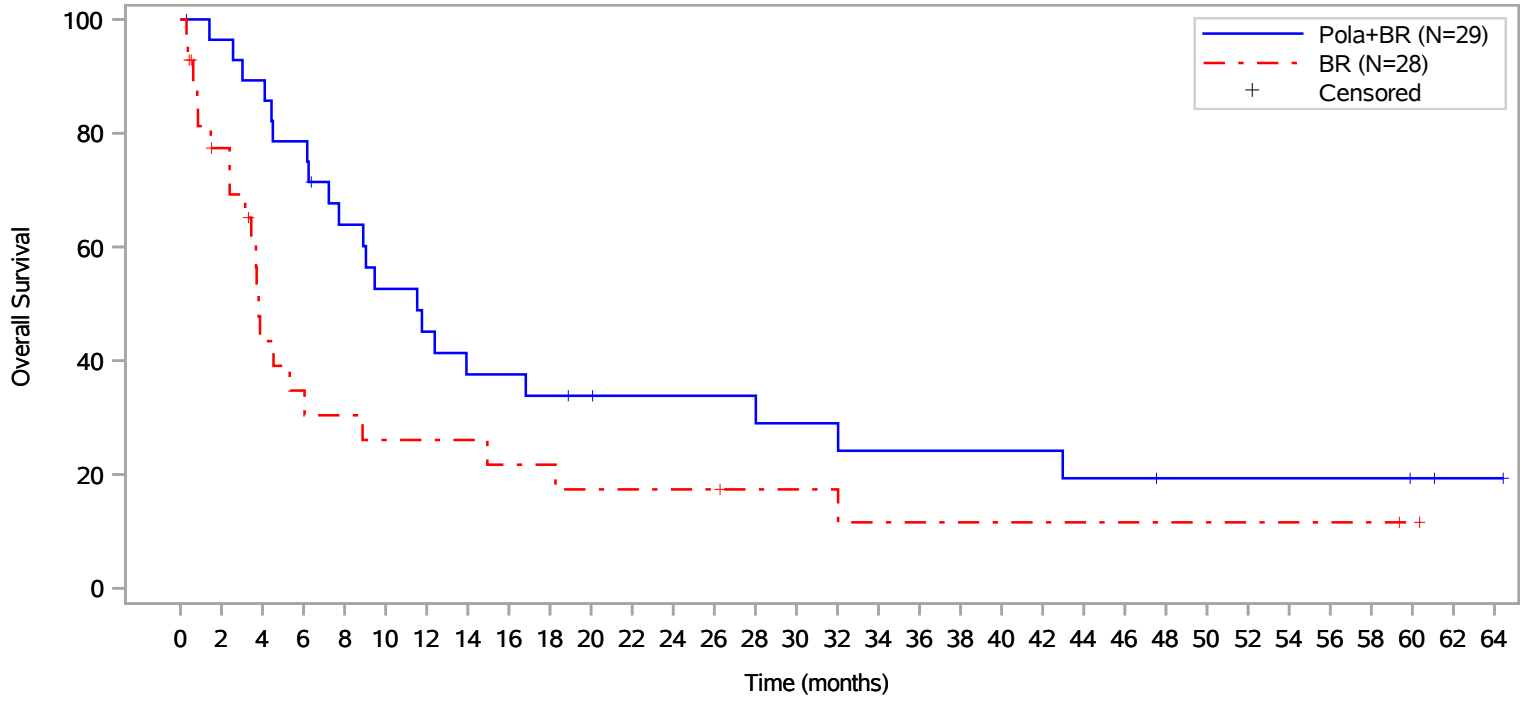
POPULATION: Intent-to-Treat Patients, Arms C,D, Third-line or beyond (3L+) Patients, Study GO29365
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=29)											BR (N=28)											Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		29	100.0	21	72.4	8	27.6	6.2	4.1	9.0	11.5	7.7	28.0	28	100.0	21	75.0	7	25.0	2.4	0.8	3.7	3.8	3.2	6.0	0.0051	0.41	0.22	0.78		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_eff_tte_gh_str_OS_365_L3PLUS_ARMCD_IT_29365_41543.xls
20JAN2023 16:39

POPULATION: Intent-to-Treat Patients, Arms C,D, Third-line or beyond (3L+) Patients, Study GO29365
ENDPOINT: Overall Survival
STUDIES: GO29365, YO41543



Patients at risk																															
Pola+BR (N=29)	29	27	25	22	17	14	12	10	10	9	8	7	7	7	7	6	6	5	5	5	5	5	4	4	3	3	3	3	3	2	1	1
BR (N=28)	28	19	10	8	7	6	6	6	5	5	4	4	4	4	3	3	3	2	2	2	2	2	2	2	2	2	2	2	2	1	NE	NE
Patients censored																															
Pola+BR (N=29)	0	1	1	1	2	2	2	2	2	2	3	4	4	4	4	4	4	4	4	4	4	4	4	4	5	5	5	5	5	5	6	7	7
BR (N=28)	0	3	4	4	4	4	4	4	4	4	4	4	4	4	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	6	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_OS_365_L3PLUS_ARMCD_IT_29365_41543.pdf
28NOV2022 15:18

POPULATION: Intent-to-Treat Patients, Arms C,D, Third-line or beyond (3L+) Patients, Study GO29365
ENDPOINT: Overall Survival
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=29)												BR (N=28)										log-rank	Pola + BR vs. BR				
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		29	100.0	21	72.4	8	27.6	6.2	4.1	9.0	11.5	7.7	28.0	28	100.0	21	75.0	7	25.0	2.4	0.8	3.7	3.8	3.2	6.0	0.0308	0.51	0.28	0.95	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	21	72.4	16	76.2	5	23.8	5.4	4.1	11.5	11.6	6.2	32.0	18	64.3	15	83.3	3	16.7	2.4	0.8	3.7	3.7	2.4	8.9	0.0658	0.51	0.25	1.08	Convergence criterion (GCONV=1E-8) satisfied.	0.9323
	Female	8	27.6	5	62.5	3	37.5	6.7	1.4	28.0	9.5	6.2	NE	10	35.7	6	60.0	4	40.0	3.7	0.4	5.3	3.8	0.6	14.9	0.2296	0.48	0.14	1.62	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	14	48.3	10	71.4	4	28.6	4.4	3.0	9.5	9.5	4.4	28.0	14	50.0	10	71.4	4	28.6	2.4	0.8	3.9	3.8	2.4	8.9	0.1166	0.50	0.20	1.21	Convergence criterion (GCONV=1E-8) satisfied.	0.9624
	>= 65	15	51.7	11	73.3	4	26.7	7.7	4.9	13.9	13.9	7.7	43.0	14	50.0	11	78.6	3	21.4	1.5	0.6	3.7	3.7	1.5	14.9	0.1502	0.54	0.23	1.26	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	16	55.2	12	75.0	4	25.0	6.2	2.6	9.5	9.5	6.2	16.8	19	67.9	16	84.2	3	15.8	1.5	0.6	3.7	3.7	2.4	4.5	0.0053	0.34	0.15	0.75	Convergence criterion (GCONV=1E-8) satisfied.	0.1064
	<3	13	44.8	9	69.2	4	30.8	8.9	4.1	12.4	12.4	8.9	32.0	9	32.1	5	55.6	4	44.4	3.8	0.8	14.9	14.9	3.8	NE	0.9981	1.00	0.33	2.99	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	31.0	8	88.9	1	11.1	7.7	4.4	9.5	9.0	7.7	12.4	14	50.0	11	78.6	3	21.4	1.5	0.6	3.8	3.8	1.5	14.9	0.1990	0.55	0.22	1.39	Convergence criterion (GCONV=1E-8) satisfied.	0.9706
	Non-Europe	20	69.0	13	65.0	7	35.0	4.5	3.0	11.8	13.9	6.2	32.0	14	50.0	10	71.4	4	28.6	2.4	0.9	3.9	3.9	2.4	32.0	0.1598	0.55	0.24	1.28	Convergence criterion (GCONV=1E-8) satisfied.	
Duration of response to prior therapy	<=12 Months	27	93.1	20	74.1	7	25.9	6.2	4.1	9.0	9.5	7.2	28.0	23	82.1	18	78.3	5	21.7	1.5	0.6	3.7	3.7	2.4	4.5	0.0042	0.39	0.20	0.76	Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	2	6.9	1	50.0	1	50.0	13.9	13.9	NE	NE	13.9	NE	5	17.9	3	60.0	2	40.0	6.0	3.2	NE	18.3	3.2	NE	0.7709	0.71	0.07	6.97	Convergence criterion (GCONV=1E-8) satisfied.	
Refractory to last prior anti-lymphoma therapy**	Yes	27	93.1	21	77.8	6	22.2	6.2	4.1	9.0	9.5	7.2	16.8	23	82.1	19	82.6	4	17.4	1.5	0.6	3.4	3.7	2.4	4.5	0.0036	0.40	0.21	0.75	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	2	6.9	0	-	2	100.0	NE	NE	NE	NE	NE	NE	5	17.9	2	40.0	3	60.0	12.2	6.0	NE	NE	6.0	NE	0.2807	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
Prior Bone Marrow Transplant	Yes	10	34.5	6	60.0	4	40.0	9.5	4.5	16.8	13.9	9.5	NE	6	21.4	3	50.0	3	50.0	3.8	3.2	NE	5.3	3.8	NE	0.6571	0.73	0.18	2.95	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	19	65.5	15	78.9	4	21.1	4.4	2.8	8.9	9.0	6.2	28.0	22	78.6	18	81.8	4	18.2	1.5	0.6	3.7	3.7	2.4	6.0	0.0412	0.48	0.24	0.98	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* Indicates convergence problem, Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_eff_tte_gh_sg_OS_365_L3PLUS_ARMCD_IT_29365_41543.xls
20JAN2023 16:53

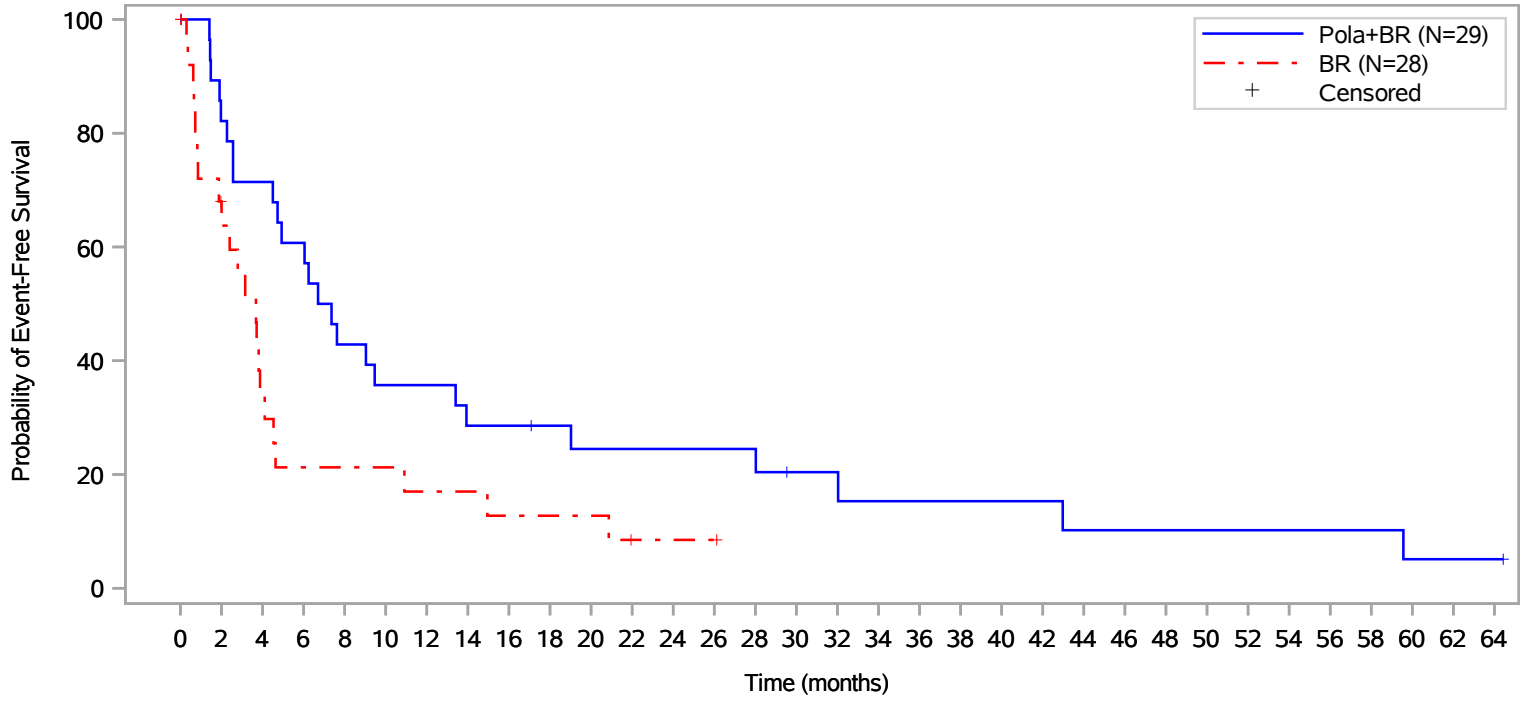
POPULATION: Intent-to-Treat Patients, Arms C,D, Third-line or beyond (3L+) Patients, Study GO29365
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=29)											BR (N=28)											Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		29	100.0	25	86.2	4	13.8	2.6	1.9	6.2	7.0	4.7	13.4	28	100.0	22	78.6	6	21.4	0.9	0.7	2.8	3.7	1.9	4.1	0.0012	0.36	0.19	0.68		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_eff_tte_gh_str_PFSIRC_365_L3PLUS_ARMCD_IT_29365_41543.xls
20JAN2023 16:09

POPULATION: Intent-to-Treat Patients, Arms C,D, Third-line or beyond (3L+) Patients, Study GO29365
ENDPOINT: Progression-Free Survival (PFS) - IRC
STUDIES: GO29365, YO41543



Patients at risk																																		
Pola+BR (N=29)	29	23	20	17	12	10	10	8	8	7	6	6	6	6	6	4	4	3	3	3	3	3	2	2	2	2	2	2	2	2	1	1	1
BR (N=28)	28	16	8	5	5	5	4	4	3	3	3	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																	
Pola+BR (N=29)	0	1	1	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
BR (N=28)	0	4	4	4	4	4	4	4	4	4	4	5	5	5	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_PFSIRC_365_L3PLUS_ARMCD_IT_29365_41543.pdf
28NOV2022 14:41

POPULATION: Intent-to-Treat Patients, Arms C,D, Third-line or beyond (3L+) Patients, Study GO29365
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=29)												BR (N=28)										log-rank	Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		29	100.0	25	86.2	4	13.8	2.6	1.9	6.2	7.0	4.7	13.4	28	100.0	22	78.6	6	21.4	0.9	0.7	2.8	3.7	1.9	4.1	0.0215	0.50	0.27	0.91	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	21	72.4	18	85.7	3	14.3	4.6	2.6	6.7	7.0	4.7	13.9	18	64.3	16	88.9	2	11.1	0.9	0.7	2.8	2.8	1.9	4.5	0.0167	0.43	0.21	0.87	Convergence criterion (GCONV=1E-8) satisfied.	0.5685
	Female	8	27.6	7	87.5	1	12.5	1.7	1.4	9.5	5.9	1.4	28.0	10	35.7	6	60.0	4	40.0	0.6	0.4	4.1	3.8	0.6	14.9	0.4891	0.66	0.20	2.17	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	14	48.3	11	78.6	3	21.4	2.6	1.9	7.4	7.4	2.6	28.0	14	50.0	10	71.4	4	28.6	1.8	0.7	3.8	3.2	2.4	4.1	0.1679	0.53	0.21	1.33	Convergence criterion (GCONV=1E-8) satisfied.	0.9149
	>= 65	15	51.7	14	93.3	1	6.7	4.5	1.4	6.7	6.7	4.7	13.9	14	50.0	12	85.7	2	14.3	0.9	0.6	3.7	3.7	0.9	4.6	0.0740	0.48	0.22	1.09	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	16	55.2	14	87.5	2	12.5	2.6	1.4	6.0	6.0	4.5	13.4	19	67.9	16	84.2	3	15.8	0.8	0.4	2.8	3.0	0.9	3.9	0.0146	0.40	0.19	0.85	Convergence criterion (GCONV=1E-8) satisfied.	0.4288
	<3	13	44.8	11	84.6	2	15.4	2.6	1.9	7.6	7.6	2.6	32.0	9	32.1	6	66.7	3	33.3	2.0	0.7	4.6	4.6	2.0	NE	0.4980	0.69	0.24	2.01	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	31.0	8	88.9	1	11.1	6.2	2.6	9.0	7.4	6.2	9.5	14	50.0	11	78.6	3	21.4	0.8	0.6	3.8	3.8	0.8	4.6	0.1533	0.50	0.19	1.32	Convergence criterion (GCONV=1E-8) satisfied.	0.8193
	Non-Europe	20	69.0	17	85.0	3	15.0	2.0	1.5	6.0	6.0	2.3	19.0	14	50.0	11	78.6	3	21.4	1.9	0.7	2.8	2.8	1.9	4.1	0.1180	0.53	0.24	1.19	Convergence criterion (GCONV=1E-8) satisfied.	
Duration of response to prior therapy	<=12 Months	27	93.1	24	88.9	3	11.1	2.6	1.9	6.0	6.5	4.5	9.5	23	82.1	19	82.6	4	17.4	0.8	0.6	2.4	2.4	0.8	3.8	0.0011	0.35	0.18	0.68	Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	2	6.9	1	50.0	1	50.0	13.9	13.9	NE	NE	13.9	NE	5	17.9	3	60.0	2	40.0	4.6	3.2	NE	10.9	3.2	NE	0.5877	0.54	0.05	5.29	Convergence criterion (GCONV=1E-8) satisfied.	
Refractory to last prior anti-lymphoma therapy**	Yes	27	93.1	23	85.2	4	14.8	2.6	1.9	6.0	6.5	4.5	9.5	23	82.1	20	87.0	3	13.0	0.8	0.6	2.4	2.8	0.8	3.8	0.0008	0.35	0.18	0.68	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	2	6.9	2	100.0	0	-	19.0	19.0	NE	39.3	19.0	NE	5	17.9	2	40.0	3	60.0	7.8	4.6	NE	NE	4.6	NE	0.7822	0.71	0.06	8.02	Convergence criterion (GCONV=1E-8) satisfied.	
Prior Bone Marrow Transplant	Yes	10	34.5	8	80.0	2	20.0	4.5	2.0	13.4	11.4	4.5	NE	6	21.4	3	50.0	3	50.0	3.8	3.2	NE	4.1	3.2	NE	0.9922	1.01	0.26	3.94	Convergence criterion (GCONV=1E-8) satisfied.	0.1792
	No	19	65.5	17	89.5	2	10.5	2.6	1.4	6.0	6.1	2.6	9.0	22	78.6	19	86.4	3	13.6	0.7	0.6	2.4	2.4	0.8	3.9	0.0089	0.40	0.20	0.81	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* Indicates convergence problem, Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_eff_tte_gh_sg_PFSIRC_365_L3PLUS_ARMCD_IT_29365_41543.xls
20JAN2023 16:26

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)				BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	28	100.0	27	100.0	26	96.3	1	3.7	0.0353	0.52	0.29	0.96		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	20	100.0	18	66.7	17	94.4	1	5.6	0.3020	0.68	0.33	1.41		Convergence criterion (GCONV=1E-8) satisfied.	0.2391
	Female	8	28.6	8	100.0	9	33.3	9	100.0	0	-	0.0042	0.12	0.02	0.61		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	13	100.0	13	48.1	12	92.3	1	7.7	0.5231	0.76	0.33	1.76		Convergence criterion (GCONV=1E-8) satisfied.	0.0647
	>= 65	15	53.6	15	100.0	14	51.9	14	100.0	0	-	0.0143	0.30	0.11	0.81		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	15	100.0	18	66.7	18	100.0	0	-	0.0662	0.46	0.20	1.07		Convergence criterion (GCONV=1E-8) satisfied.	0.4971
	<3	13	46.4	13	100.0	9	33.3	8	88.9	1	11.1	0.6087	0.78	0.30	2.02		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	9	100.0	13	48.1	12	92.3	1	7.7	0.1281	0.45	0.15	1.28		Convergence criterion (GCONV=1E-8) satisfied.	0.8747
	Non-Europe	19	67.9	19	100.0	14	51.9	14	100.0	0	-	0.1631	0.58	0.27	1.25		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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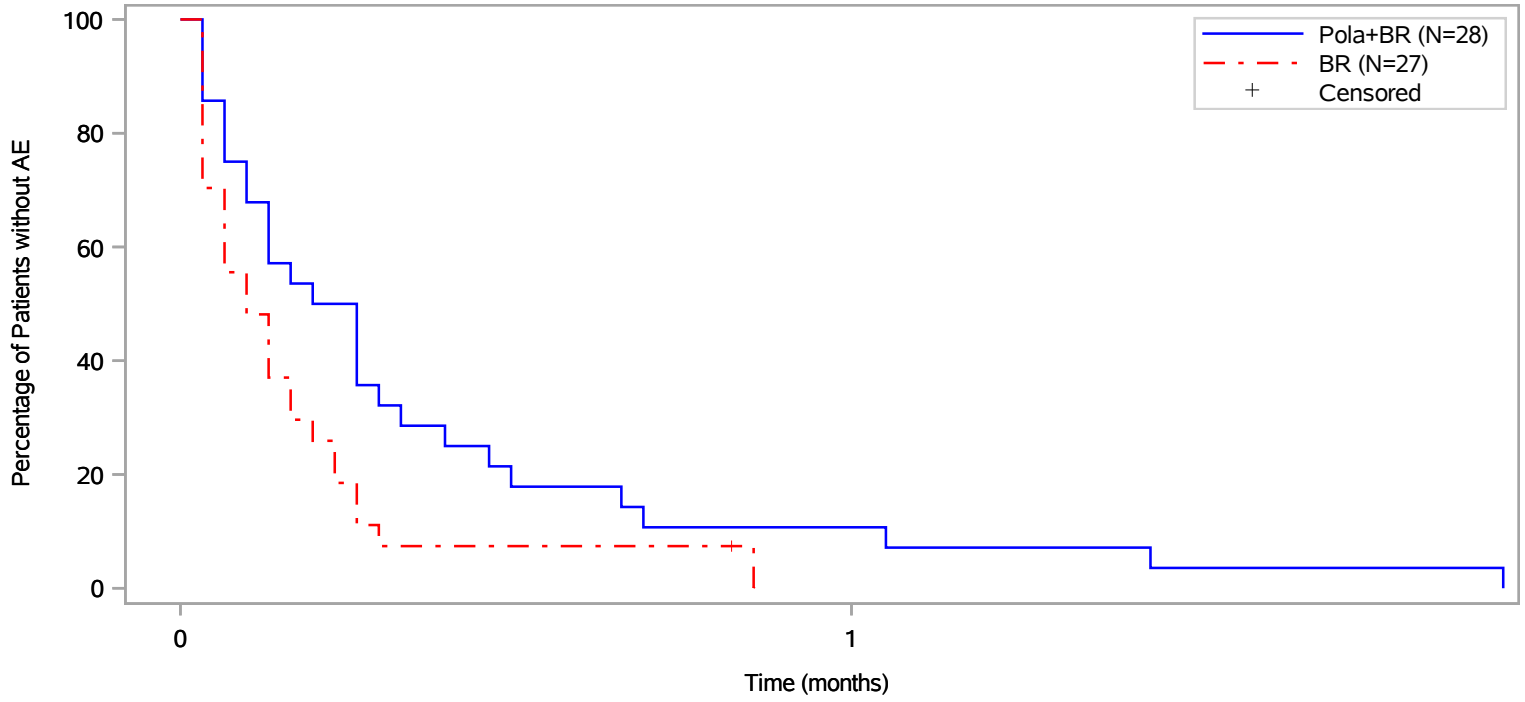
30NOV2022 18:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543



Patients at risk		
Pola+BR (N=28)	28	3
BR (N=27)	27	NE
Patients censored		
Pola+BR (N=28)	0	0
BR (N=27)	0	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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01DEC2022 5:56

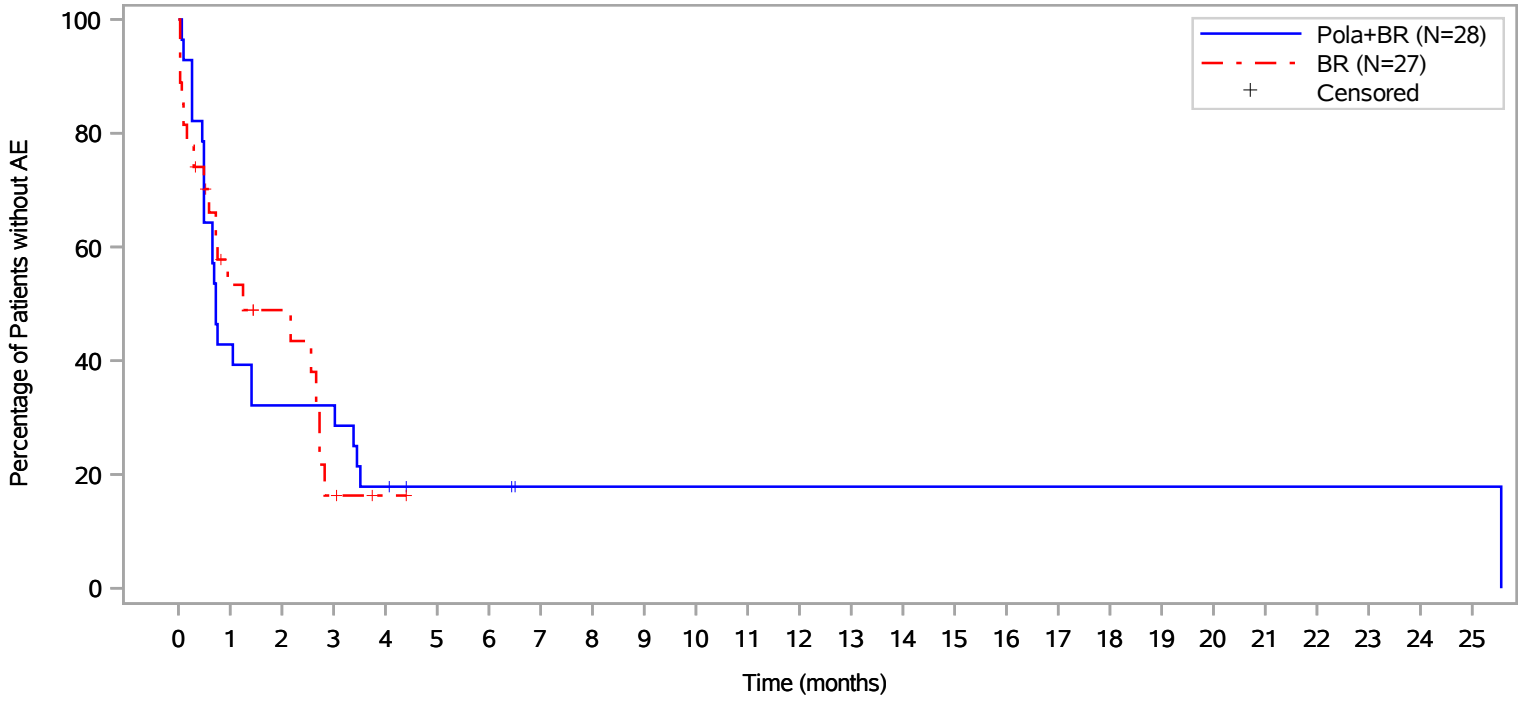
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	24	85.7	4	14.3	27	100.0	19	70.4	8	29.6	0.9713	0.99	0.53	1.85		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	16	80.0	4	20.0	18	66.7	14	77.8	4	22.2	0.4464	0.75	0.35	1.59		Convergence criterion (GCONV=1E-8) satisfied.	0.1448
	Female	8	28.6	8	100.0	0	-	9	33.3	5	55.6	4	44.4	0.2163	2.03	0.65	6.36		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	11	84.6	2	15.4	13	48.1	8	61.5	5	38.5	0.1775	1.90	0.74	4.92		Convergence criterion (GCONV=1E-8) satisfied.	0.0578
	>= 65	15	53.6	13	86.7	2	13.3	14	51.9	11	78.6	3	21.4	0.1121	0.48	0.20	1.20		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	14	93.3	1	6.7	18	66.7	13	72.2	5	27.8	0.8654	0.93	0.41	2.13		Convergence criterion (GCONV=1E-8) satisfied.	0.8487
	<3	13	46.4	10	76.9	3	23.1	9	33.3	6	66.7	3	33.3	0.8062	1.14	0.41	3.20		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	7	77.8	2	22.2	13	48.1	9	69.2	4	30.8	0.5250	0.71	0.24	2.06		Convergence criterion (GCONV=1E-8) satisfied.	0.4468
	Non-Europe	19	67.9	17	89.5	2	10.5	14	51.9	10	71.4	4	28.6	0.7112	1.17	0.52	2.64		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 19:25

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543



Patients at risk																											
Pola+BR (N=28)	28	12	9	9	5	3	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	12	9	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																											
Pola+BR (N=28)	0	0	0	0	0	2	2	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
BR (N=27)	0	3	5	5	7	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 18:15

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	22	78.6	6	21.4	27	100.0	18	66.7	9	33.3	0.6264	0.85	0.44	1.63		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	15	75.0	5	25.0	18	66.7	13	72.2	5	27.8	0.3822	0.70	0.32	1.55		Convergence criterion (GCONV=1E-8) satisfied.	0.3785
	Female	8	28.6	7	87.5	1	12.5	9	33.3	5	55.6	4	44.4	0.6569	1.30	0.41	4.14		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	10	76.9	3	23.1	13	48.1	7	53.8	6	46.2	0.2846	1.72	0.63	4.70		Convergence criterion (GCONV=1E-8) satisfied.	0.0597
	>= 65	15	53.6	12	80.0	3	20.0	14	51.9	11	78.6	3	21.4	0.0450	0.39	0.15	1.01		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	12	80.0	3	20.0	18	66.7	12	66.7	6	33.3	0.4089	0.69	0.28	1.68		Convergence criterion (GCONV=1E-8) satisfied.	0.5375
	<3	13	46.4	10	76.9	3	23.1	9	33.3	6	66.7	3	33.3	0.8062	1.14	0.41	3.20		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	7	77.8	2	22.2	13	48.1	8	61.5	5	38.5	0.6660	0.79	0.26	2.35		Convergence criterion (GCONV=1E-8) satisfied.	0.9419
	Non-Europe	19	67.9	15	78.9	4	21.1	14	51.9	10	71.4	4	28.6	0.6911	0.84	0.37	1.95		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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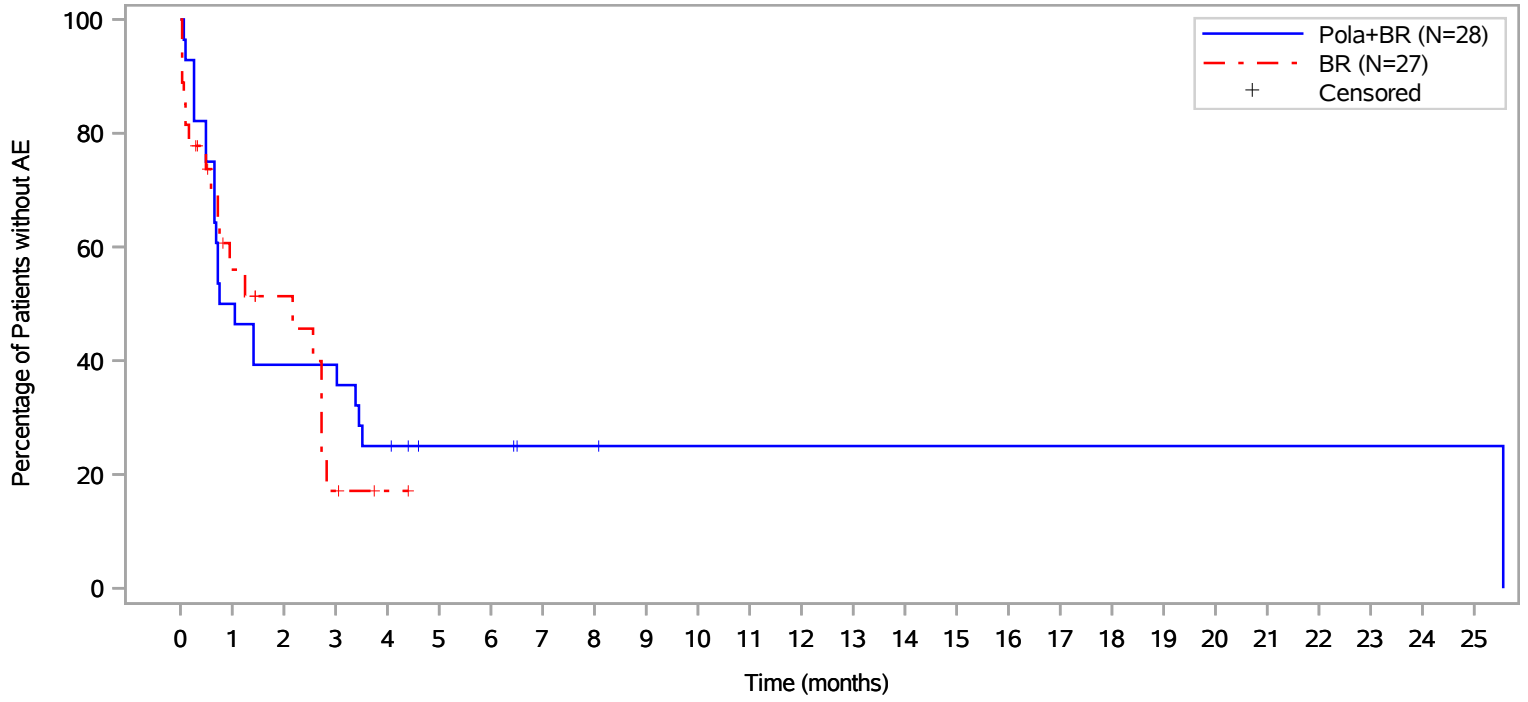
30NOV2022 20:05

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543



Patients at risk																										
Pola+BR (N=28)	28	14	11	11	7	4	4	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	12	9	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	0	0	0	3	3	5	5	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6	6
BR (N=27)	0	4	6	6	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 18:06

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	15	53.6	13	46.4	27	100.0	10	37.0	17	63.0	0.8730	1.07	0.47	2.42		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	10	50.0	10	50.0	18	66.7	8	44.4	10	55.6	0.6605	0.81	0.31	2.11		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	5	62.5	3	37.5	9	33.3	2	22.2	7	77.8	0.4418	1.93	0.35	10.54		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	7	53.8	6	46.2	13	48.1	5	38.5	8	61.5	0.8419	1.13	0.34	3.70		Convergence criterion (GCONV=1E-8) satisfied.	0.8004
	>= 65	15	53.6	8	53.3	7	46.7	14	51.9	5	35.7	9	64.3	0.9033	0.93	0.29	2.98		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	9	60.0	6	40.0	18	66.7	8	44.4	10	55.6	0.7397	0.84	0.31	2.28		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	6	46.2	7	53.8	9	33.3	2	22.2	7	77.8	0.5014	1.74	0.34	9.01		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	2	22.2	7	77.8	13	48.1	4	30.8	9	69.2	0.8079	0.80	0.13	4.81		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	13	68.4	6	31.6	14	51.9	6	42.9	8	57.1	0.8593	1.09	0.40	2.98		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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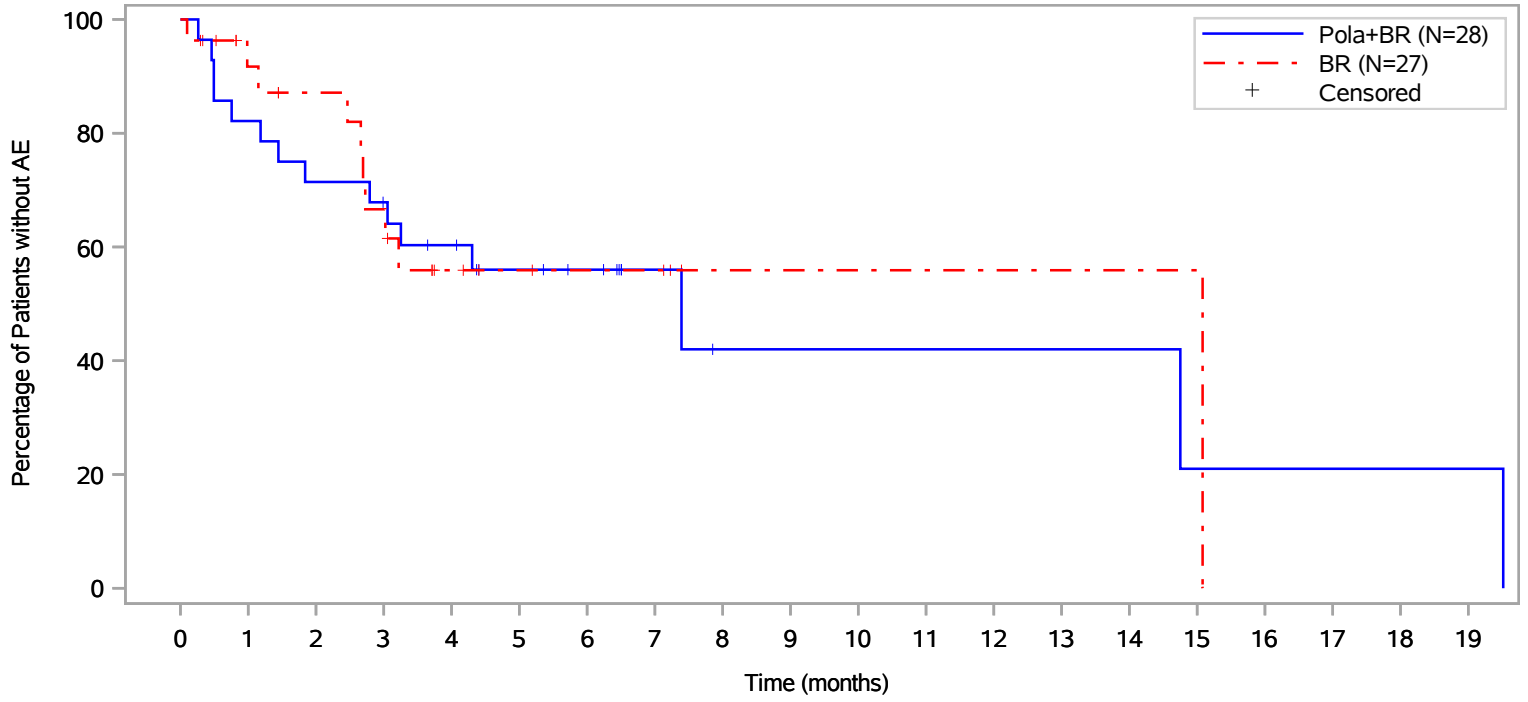
30NOV2022 20:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=28)	28	23	20	18	15	11	9	4	2	2	2	2	2	2	2	1	1	1	1	1
BR (N=27)	27	20	17	13	7	5	4	4	1	1	1	1	1	1	1	1	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	0	1	2	5	7	12	13	13	13	13	13	13	13	13	13	13	13	13
BR (N=27)	0	5	7	7	11	13	14	14	17	17	17	17	17	17	17	17	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 18:09

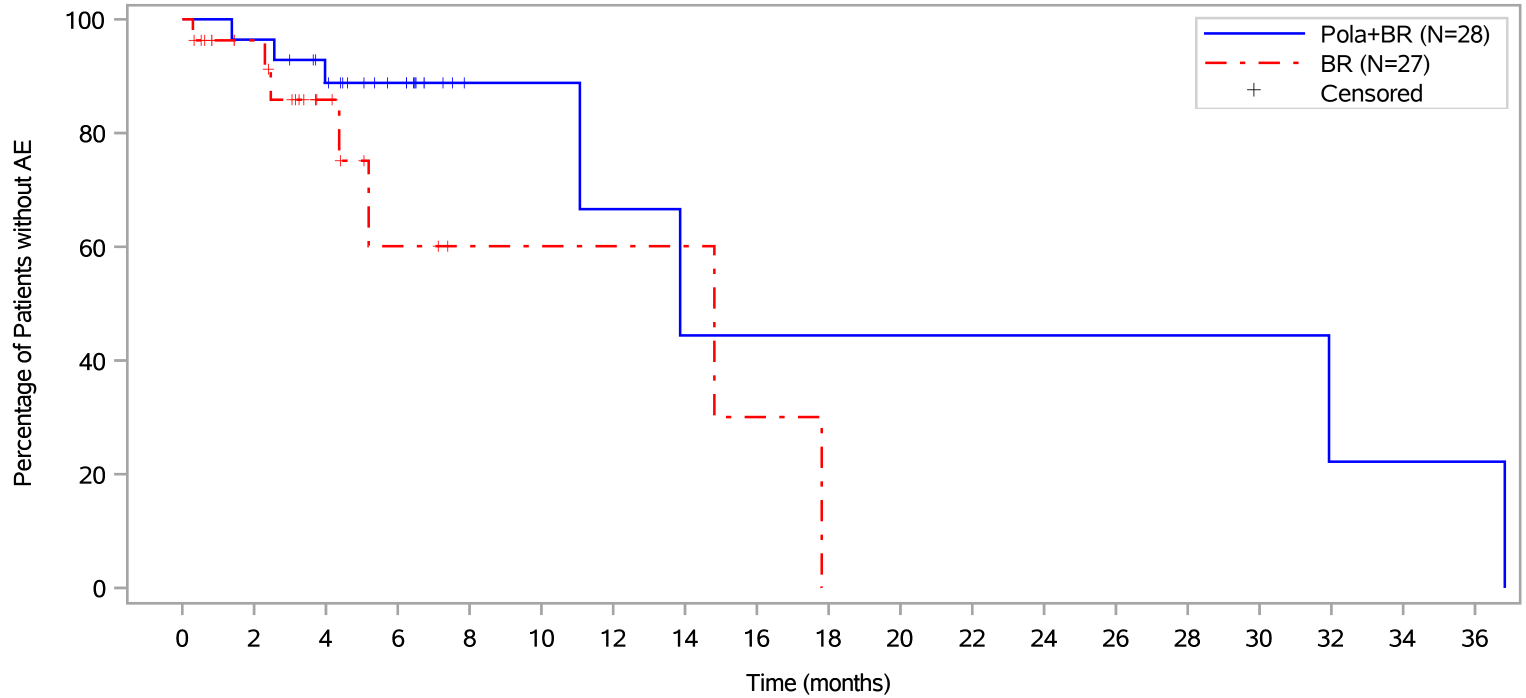
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	7	25.0	21	75.0	27	100.0	7	25.9	20	74.1	0.1209	0.41	0.13	1.31		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	6	30.0	14	70.0	18	66.7	4	22.2	14	77.8	0.2642	0.45	0.11	1.87		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	1	12.5	7	87.5	9	33.3	3	33.3	6	66.7	0.3963	0.37	0.03	4.07		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	3	23.1	10	76.9	13	48.1	3	23.1	10	76.9	0.2785	0.38	0.06	2.34		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	4	28.6	10	71.4	0.1372	0.29	0.05	1.63		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	4	26.7	11	73.3	18	66.7	5	27.8	13	72.2	0.1782	0.38	0.09	1.64		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	3	23.1	10	76.9	9	33.3	2	22.2	7	77.8	0.5850	0.58	0.08	4.24		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	2	22.2	7	77.8	13	48.1	5	38.5	8	61.5	0.0813	0.18	0.02	1.56		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	5	26.3	14	73.7	14	51.9	2	14.3	12	85.7	0.3971	0.43	0.06	3.22		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGR5AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 21:33

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543



Patients at risk																																					
Pola+BR (N=28)	28	28	27	25	22	18	15	7	4	4	4	4	3	3	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	1
BR (N=27)	27	21	19	16	9	6	4	4	2	2	2	2	2	2	2	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																					
Pola+BR (N=28)	0	0	0	1	3	7	10	18	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21	21
BR (N=27)	0	5	7	8	15	17	18	18	20	20	20	20	20	20	20	20	20	20	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 18:12

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	20	71.4	8	28.6	27	100.0	14	51.9	13	48.1	0.5672	0.81	0.40	1.66		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	15	75.0	5	25.0	18	66.7	9	50.0	9	50.0	0.9286	0.96	0.40	2.29		Convergence criterion (GCONV=1E-8) satisfied.	0.4117
	Female	8	28.6	5	62.5	3	37.5	9	33.3	5	55.6	4	44.4	0.2888	0.49	0.13	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	8	61.5	5	38.5	13	48.1	6	46.2	7	53.8	0.9269	0.95	0.31	2.87		Convergence criterion (GCONV=1E-8) satisfied.	0.6317
	>= 65	15	53.6	12	80.0	3	20.0	14	51.9	8	57.1	6	42.9	0.4757	0.71	0.28	1.83		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	11	73.3	4	26.7	18	66.7	9	50.0	9	50.0	0.6036	0.78	0.30	2.01		Convergence criterion (GCONV=1E-8) satisfied.	0.7319
	<3	13	46.4	9	69.2	4	30.8	9	33.3	5	55.6	4	44.4	0.6712	0.78	0.24	2.48		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	6	66.7	3	33.3	13	48.1	8	61.5	5	38.5	0.5127	0.69	0.22	2.13		Convergence criterion (GCONV=1E-8) satisfied.	0.4375
	Non-Europe	19	67.9	14	73.7	5	26.3	14	51.9	6	42.9	8	57.1	0.8600	0.91	0.33	2.50		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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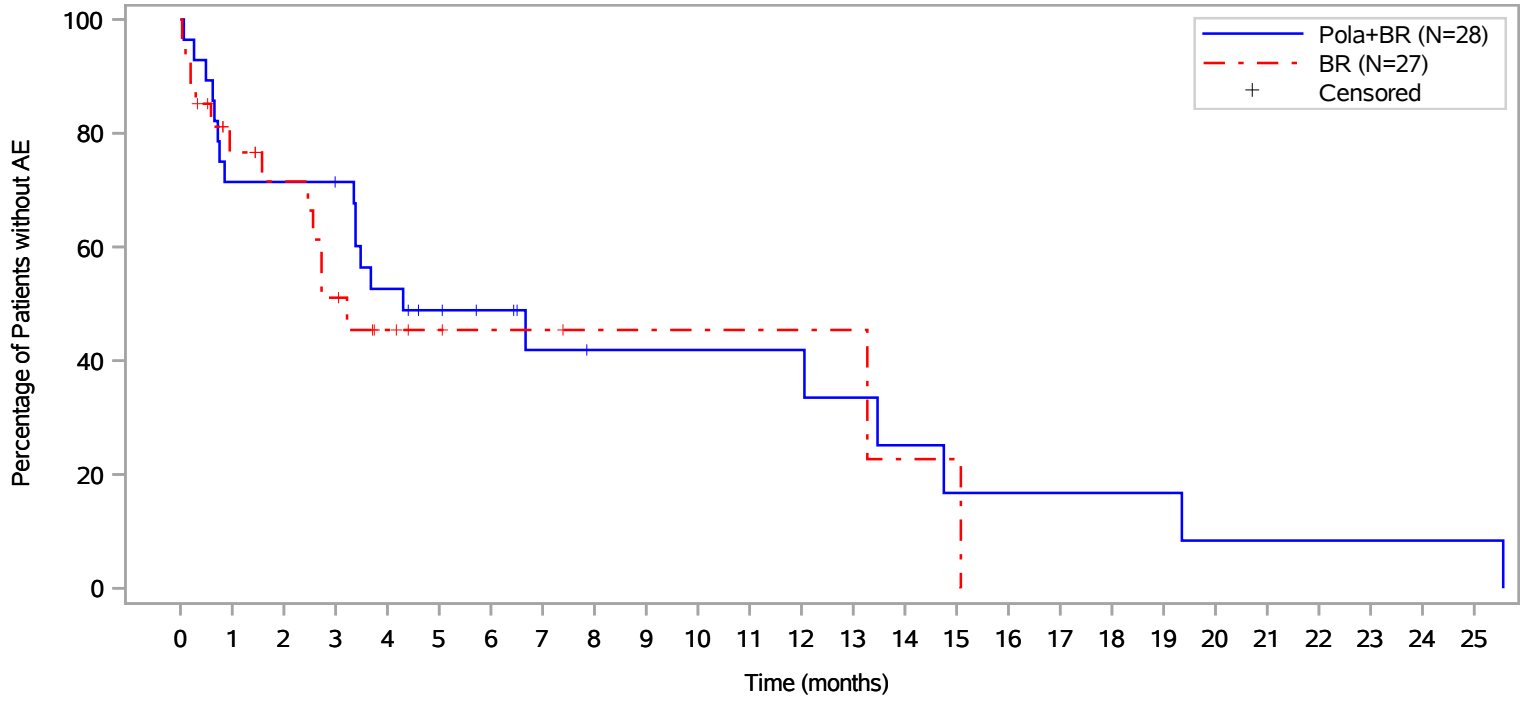
30NOV2022 22:24

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543



Patients at risk																										
Pola+BR (N=28)	28	20	20	19	14	11	9	6	5	5	5	5	5	4	3	2	2	2	2	2	1	1	1	1	1	1
BR (N=27)	27	17	14	10	6	4	3	3	2	2	2	2	2	2	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	0	1	1	3	5	7	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8
BR (N=27)	0	4	6	6	9	11	12	12	13	13	13	13	13	13	13	13	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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01DEC2022 7:35

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	7	25.0	21	75.0	27	100.0	3	11.1	24	88.9	0.4231	1.73	0.44	6.76		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	5	25.0	15	75.0	18	66.7	3	16.7	15	83.3	0.8125	1.19	0.28	5.08		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2263	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	3	23.1	10	76.9	13	48.1	2	15.4	11	84.6	0.8448	1.20	0.20	7.18		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	1	7.1	13	92.9	0.3266	2.92	0.31	27.23		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	5	33.3	10	66.7	18	66.7	2	11.1	16	88.9	0.3384	2.20	0.42	11.45		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.9381	1.10	0.10	12.15		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	1	11.1	8	88.9	13	48.1	2	15.4	11	84.6	0.6040	0.53	0.05	5.98		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	1	7.1	13	92.9	0.2246	3.44	0.41	28.77		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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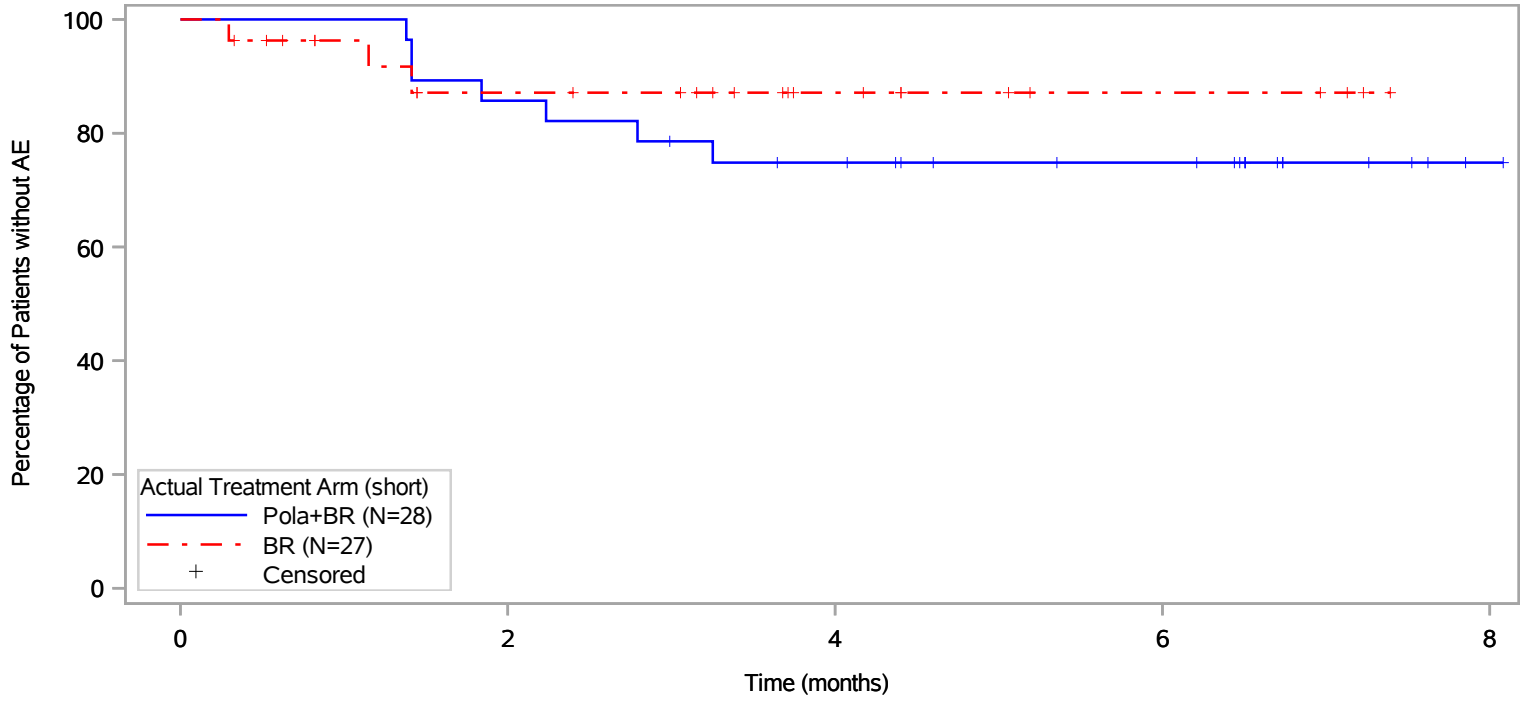
24JAN2023 17:13

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	24	21	19	15	14	5	1
BR (N=27)	27	21	17	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	2	6	7	16	20
BR (N=27)	0	5	7	8	15	18	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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24JAN2023 18:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			28	100.0	22	78.6	6	21.4	27	100.0	16	59.3	11	40.7	0.6430	1.17	0.60	2.26		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		28	100.0	16	57.1	12	42.9	27	100.0	5	18.5	22	81.5	0.0649	2.51	0.91	6.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		28	100.0	4	14.3	24	85.7	27	100.0	3	11.1	24	88.9	0.8199	1.22	0.22	6.74		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		28	100.0	4	14.3	24	85.7	27	100.0	3	11.1	24	88.9	0.9546	1.04	0.23	4.69		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		28	100.0	4	14.3	24	85.7	27	100.0	0	-	27	100.0	0.0521	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		28	100.0	16	57.1	12	42.9	27	100.0	10	37.0	17	63.0	0.5401	1.28	0.58	2.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		28	100.0	14	50.0	14	50.0	27	100.0	9	33.3	18	66.7	0.7009	1.18	0.51	2.74		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			28	100.0	2	7.1	26	92.9	27	100.0	7	25.9	20	74.1	0.0868	0.27	0.05	1.34		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		28	100.0	0	-	28	100.0	27	100.0	3	11.1	24	88.9	0.0536	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FLUTTER		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.1165	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	CARDIAC FAILURE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SINUS TACHYCARDIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYARRHYTHMIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.9209	0.90	0.13	6.49		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS			28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	TINNITUS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EYE DISORDERS			28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EYE DISORDERS	ASTHENOPIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			28	100.0	24	85.7	4	14.3	27	100.0	18	66.7	9	33.3	0.9981	1.00	0.53	1.88		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		28	100.0	3	10.7	25	89.3	27	100.0	3	11.1	24	88.9	0.7865	0.80	0.16	4.01		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER		28	100.0	4	14.3	24	85.7	27	100.0	1	3.7	26	96.3	0.2563	3.31	0.37	29.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		28	100.0	7	25.0	21	75.0	27	100.0	6	22.2	21	77.8	0.9310	0.95	0.32	2.86		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		28	100.0	11	39.3	17	60.7	27	100.0	9	33.3	18	66.7	0.6840	0.83	0.34	2.02		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DRY MOUTH		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.7164	0.59	0.03	10.28		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.4708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DYSPEPSIA		28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.7558	0.73	0.10	5.30		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DYSPHAGIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	FLATULENCE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTRITIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4617	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.1866	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	HAEMATEMESIS		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2165	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ILEUS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	LIP DRY		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	NAUSEA		28	100.0	7	25.0	21	75.0	27	100.0	10	37.0	17	63.0	0.2321	0.56	0.21	1.48		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	STOMATITIS		28	100.0	1	3.6	27	96.4	27	100.0	3	11.1	24	88.9	0.1162	0.19	0.02	1.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3447	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	TOOTHACHE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5316	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		28	100.0	4	14.3	24	85.7	27	100.0	4	14.8	23	85.2	0.8471	0.87	0.22	3.51		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			28	100.0	21	75.0	7	25.0	27	100.0	15	55.6	12	44.4	0.7187	1.13	0.58	2.21		Convergence criterion (GCONV=1E-8) satisfied.	NE

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA		28	100.0	2	7.1	26	92.9	27	100.0	3	11.1	24	88.9	0.4602	0.51	0.09	3.10		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.9446	0.91	0.06	14.51		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS		28	100.0	3	10.7	25	89.3	27	100.0	2	7.4	25	92.6	0.9952	1.01	0.16	6.22		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		28	100.0	11	39.3	17	60.7	27	100.0	9	33.3	18	66.7	0.8488	0.92	0.38	2.24		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4187	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3261	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.0999	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.7364	1.51	0.13	17.01		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		28	100.0	9	32.1	19	67.9	27	100.0	6	22.2	21	77.8	0.6917	1.23	0.44	3.47		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS			28	100.0	3	10.7	25	89.3	27	100.0	0	-	27	100.0	0.2033	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5097	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5316	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			28	100.0	14	50.0	14	50.0	27	100.0	12	44.4	15	55.6	0.3454	0.68	0.30	1.53		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	BRONCHITIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CELLULITIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8103	0.71	0.04	11.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.1060	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ERYSIPELAS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3447	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFLUENZA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2624	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		28	100.0	3	10.7	25	89.3	27	100.0	4	14.8	23	85.2	0.3990	0.53	0.12	2.38		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PYURIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3261	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.5978	0.48	0.03	7.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SINUSITIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.6276	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.7828	1.40	0.13	15.51		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UROSEPSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			28	100.0	2	7.1	26	92.9	27	100.0	6	22.2	21	77.8	0.0198	0.17	0.03	0.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.1655	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.1055	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.1655	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.1655	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			28	100.0	13	46.4	15	53.6	27	100.0	9	33.3	18	66.7	0.5827	0.78	0.32	1.90		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	AMYLASE INCREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3778	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2237	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALBUMIN DECREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD CALCIUM DECREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD CREATININE INCREASED		28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.4200	0.38	0.03	4.28		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD GLUCOSE DECREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3778	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD URINE PRESENT		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	HAEMOGLOBIN DECREASED		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.1291	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LIPASE INCREASED		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2030	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8761	0.80	0.05	12.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MONOCYTE COUNT DECREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MORAXELLA TEST POSITIVE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8761	0.80	0.05	12.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	OCCULT BLOOD POSITIVE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2994	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		28	100.0	3	10.7	25	89.3	27	100.0	1	3.7	26	96.3	0.5310	2.06	0.21	20.58		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	TRANSAMINASES INCREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	VITAMIN D DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		28	100.0	4	14.3	24	85.7	27	100.0	2	7.4	25	92.6	0.9298	1.08	0.19	6.02		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.3927	0.36	0.03	4.06		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			28	100.0	14	50.0	14	50.0	27	100.0	13	48.1	14	51.9	0.6847	0.85	0.40	1.84		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		28	100.0	6	21.4	22	78.6	27	100.0	6	22.2	21	77.8	0.6584	0.77	0.25	2.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3447	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.1183	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3261	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		28	100.0	3	10.7	25	89.3	27	100.0	1	3.7	26	96.3	0.3906	2.60	0.27	25.04		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.1874	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		28	100.0	3	10.7	25	89.3	27	100.0	3	11.1	24	88.9	0.8235	0.83	0.17	4.14		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA		28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.4318	0.39	0.04	4.37		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.6535	1.72	0.16	19.05		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			28	100.0	13	46.4	15	53.6	27	100.0	5	18.5	22	81.5	0.1797	2.03	0.71	5.80		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA		28	100.0	5	17.9	23	82.1	27	100.0	1	3.7	26	96.3	0.1520	4.24	0.49	36.49		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.8156	0.79	0.11	5.68		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.7437	1.49	0.13	16.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2194	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5316	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2094	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2193	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			28	100.0	15	53.6	13	46.4	27	100.0	7	25.9	20	74.1	0.0803	2.28	0.88	5.91		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0652	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DIZZINESS		28	100.0	4	14.3	24	85.7	27	100.0	2	7.4	25	92.6	0.6185	1.54	0.28	8.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DYSGEUSIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HEADACHE		28	100.0	3	10.7	25	89.3	27	100.0	2	7.4	25	92.6	0.7268	1.38	0.23	8.30		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HYPOSMIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL		28	100.0	7	25.0	21	75.0	27	100.0	1	3.7	26	96.3	0.0729	5.52	0.68	45.00		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	PARAESTHESIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3778	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY		28	100.0	4	14.3	24	85.7	27	100.0	0	-	27	100.0	0.0667	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SOMNOLENCE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SYNCOPE		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.7431	1.49	0.14	16.44		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	TREMOR		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5316	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS			28	100.0	5	17.9	23	82.1	27	100.0	3	11.1	24	88.9	0.6802	1.35	0.32	5.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	ANXIETY		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.6944	1.61	0.15	17.87		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	APATHY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	DEPRESSION		28	100.0	1	3.6	27	96.4	27	100.0	3	11.1	24	88.9	0.1712	0.23	0.02	2.26		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	INSOMNIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			28	100.0	3	10.7	25	89.3	27	100.0	2	7.4	25	92.6	0.7492	0.73	0.10	5.18		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8767	0.80	0.05	12.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HAEMATURIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

RENAL AND URINARY DISORDERS	MICTURITION URGENCY		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	POLLAKIURIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDERS			28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.1958	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			28	100.0	9	32.1	19	67.9	27	100.0	8	29.6	19	70.4	0.4531	0.69	0.26	1.83		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH		28	100.0	4	14.3	24	85.7	27	100.0	4	14.8	23	85.2	0.4786	0.60	0.14	2.50		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA		28	100.0	3	10.7	25	89.3	27	100.0	1	3.7	26	96.3	0.4960	2.17	0.22	21.30		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.0812	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3261	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.8699	0.82	0.07	9.44		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		28	100.0	1	3.6	27	96.4	27	100.0	4	14.8	23	85.2	0.0550	0.15	0.02	1.38		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.6276	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			28	100.0	8	28.6	20	71.4	27	100.0	6	22.2	21	77.8	0.8515	0.90	0.31	2.65		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		28	100.0	4	14.3	24	85.7	27	100.0	2	7.4	25	92.6	0.7256	1.36	0.24	7.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		28	100.0	1	3.6	27	96.4	27	100.0	3	11.1	24	88.9	0.2269	0.27	0.03	2.62		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SURGICAL AND MEDICAL PROCEDURES			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3778	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3778	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			28	100.0	4	14.3	24	85.7	27	100.0	6	22.2	21	77.8	0.2296	0.47	0.13	1.67		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS		28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.7336	0.71	0.10	5.11		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4275	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	FLUSHING		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HAEMATOMA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.7562	0.73	0.10	5.27		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTAE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 22:29

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	13	46.4	12	92.3	1	7.7	13	48.1	8	61.5	5	38.5	0.3197	1.59	0.63	3.96		Convergence criterion (GCONV=1E-8) satisfied.	0.3161
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	15	53.6	10	66.7	5	33.3	14	51.9	8	57.1	6	42.9	0.7445	0.85	0.33	2.22		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	13	46.4	10	76.9	3	23.1	13	48.1	3	23.1	10	76.9	0.0485	3.42	0.93	12.53		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	15	53.6	6	40.0	9	60.0	14	51.9	2	14.3	12	85.7	0.5340	1.68	0.32	8.72		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	2	15.4	11	84.6	0.5235	0.53	0.07	3.86		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.3124	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	13	46.4	3	23.1	10	76.9	13	48.1	3	23.1	10	76.9	0.8973	0.90	0.18	4.47		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	13	46.4	3	23.1	10	76.9	13	48.1	0	-	13	100.0	0.0788	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	13	46.4	8	61.5	5	38.5	13	48.1	6	46.2	7	53.8	0.5434	1.39	0.48	4.09		Convergence criterion (GCONV=1E-8) satisfied.	0.9813
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	15	53.6	8	53.3	7	46.7	14	51.9	4	28.6	10	71.4	0.6534	1.32	0.39	4.42		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	13	46.4	8	61.5	5	38.5	13	48.1	5	38.5	8	61.5	0.4599	1.52	0.50	4.68		Convergence criterion (GCONV=1E-8) satisfied.	0.6062
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	15	53.6	6	40.0	9	60.0	14	51.9	4	28.6	10	71.4	0.8810	0.91	0.25	3.23		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	2	15.4	11	84.6	0.1400	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	15	53.6	2	13.3	13	86.7	14	51.9	5	35.7	9	64.3	0.2663	0.39	0.07	2.17		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	2	14.3	12	85.7	0.0963	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYARRHYTHMIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYARRHYTHMIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.6346	1.79	0.16	20.30		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS	ASTHENOPIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS	ASTHENOPIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS		< 65	13	46.4	12	92.3	1	7.7	13	48.1	7	53.8	6	46.2	0.2304	1.77	0.69	4.53		Convergence criterion (GCONV=1E-8) satisfied.	0.1012
GASTROINTESTINAL DISORDERS		>= 65	15	53.6	12	80.0	3	20.0	14	51.9	11	78.6	3	21.4	0.3271	0.65	0.28	1.54		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	3	21.4	11	78.6	0.4548	0.51	0.08	3.08		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	< 65	13	46.4	2	15.4	11	84.6	13	48.1	1	7.7	12	92.3	0.6166	1.83	0.17	20.21		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2302	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	13	46.4	3	23.1	10	76.9	13	48.1	3	23.1	10	76.9	0.8068	0.82	0.16	4.07		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	3	21.4	11	78.6	0.9237	1.08	0.24	4.86		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	13	46.4	6	46.2	7	53.8	13	48.1	3	23.1	10	76.9	0.5867	1.47	0.36	5.92		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	15	53.6	5	33.3	10	66.7	14	51.9	6	42.9	8	57.1	0.2283	0.49	0.15	1.61		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.7755	1.42	0.13	15.86		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FLATULENCE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FLATULENCE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRITIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRITIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.1656	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	LIP DRY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	LIP DRY	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	< 65	13	46.4	3	23.1	10	76.9	13	48.1	4	30.8	9	69.2	0.5082	0.61	0.13	2.72		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	6	42.9	8	57.1	0.3405	0.54	0.15	1.96		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	3	23.1	10	76.9	0.1587	0.22	0.02	2.18		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TOOTHACHE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TOOTHACHE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	13	46.4	3	23.1	10	76.9	13	48.1	3	23.1	10	76.9	0.9965	1.00	0.20	4.99		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.8184	0.72	0.05	11.57		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	13	46.4	10	76.9	3	23.1	13	48.1	8	61.5	5	38.5	0.9535	1.03	0.40	2.65		Convergence criterion (GCONV=1E-8) satisfied.	0.8537
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	15	53.6	11	73.3	4	26.7	14	51.9	7	50.0	7	50.0	0.7081	1.20	0.46	3.14		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	3	23.1	10	76.9	0.2241	0.27	0.03	2.60		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	1.0000	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	1	7.1	13	92.9	0.5627	1.94	0.20	18.92		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	13	46.4	5	38.5	8	61.5	13	48.1	3	23.1	10	76.9	0.7394	1.28	0.30	5.37		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	15	53.6	6	40.0	9	60.0	14	51.9	6	42.9	8	57.1	0.6099	0.74	0.24	2.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2038	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	13	46.4	6	46.2	7	53.8	13	48.1	5	38.5	8	61.5	0.8746	1.10	0.33	3.62		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	1	7.1	13	92.9	0.4782	2.22	0.23	21.47		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.2594	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	13	46.4	5	38.5	8	61.5	13	48.1	4	30.8	9	69.2	0.7594	0.80	0.20	3.28		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	15	53.6	9	60.0	6	40.0	14	51.9	8	57.1	6	42.9	0.2422	0.55	0.20	1.51		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	BRONCHITIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	BRONCHITIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CELLULITIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CELLULITIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	2	15.4	11	84.6	0.1231	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ERYSIPELAS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ERYSIPELAS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFLUENZA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFLUENZA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.3879	0.36	0.03	4.07		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	2	14.3	12	85.7	0.7429	0.72	0.10	5.17		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PYURIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PYURIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.5636	0.44	0.03	7.45		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.4602	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.7919	0.69	0.04	11.04		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	3	23.1	10	76.9	0.0466	0.12	0.01	1.29		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	3	21.4	11	78.6	0.1596	0.22	0.02	2.18		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1380	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1380	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1380	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	13	46.4	5	38.5	8	61.5	13	48.1	3	23.1	10	76.9	0.9228	0.93	0.20	4.33		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	15	53.6	8	53.3	7	46.7	14	51.9	6	42.9	8	57.1	0.4417	0.65	0.22	1.96		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	AMYLASE INCREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	AMYLASE INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.1950	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CALCIUM DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CALCIUM DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	2	14.3	12	85.7	0.3748	0.35	0.03	3.92		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URINE PRESENT	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URINE PRESENT	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	HAEMOGLOBIN DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.1852	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONOCYTE COUNT DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONOCYTE COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OCCULT BLOOD POSITIVE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OCCULT BLOOD POSITIVE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.3072	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.8569	0.77	0.05	12.53		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	VITAMIN D DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	VITAMIN D DECREASED	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	1	7.1	13	92.9	0.4923	2.12	0.24	19.13		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	2	14.3	12	85.7	0.0963	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	13	46.4	8	61.5	5	38.5	13	48.1	7	53.8	6	46.2	0.9752	1.02	0.36	2.86		Convergence criterion (GCONV=1E-8) satisfied.	0.5937
METABOLISM AND NUTRITION DISORDERS		>= 65	15	53.6	6	40.0	9	60.0	14	51.9	6	42.9	8	57.1	0.6011	0.74	0.24	2.31		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	13	46.4	2	15.4	11	84.6	13	48.1	4	30.8	9	69.2	0.1817	0.32	0.06	1.83		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	2	14.3	12	85.7	0.5710	1.63	0.29	9.05		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	1.0000	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2289	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	3	23.1	10	76.9	0.5760	0.60	0.10	3.62		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.9016	0.84	0.05	13.43		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	1.0000	1.00	0.06	15.99		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	13	46.4	5	38.5	8	61.5	13	48.1	3	23.1	10	76.9	0.7144	1.31	0.30	5.68		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	15	53.6	8	53.3	7	46.7	14	51.9	2	14.3	12	85.7	0.1282	3.19	0.66	15.42		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	< 65	13	46.4	3	23.1	10	76.9	13	48.1	0	-	13	100.0	0.0882	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.7491	1.48	0.13	16.44		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.9539	0.92	0.05	15.61		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.8097	0.71	0.04	11.39		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.8278	1.30	0.12	14.40		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2033	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2124	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	13	46.4	8	61.5	5	38.5	13	48.1	3	23.1	10	76.9	0.1574	2.55	0.67	9.81		Convergence criterion (GCONV=1E-8) satisfied.	0.8053
NERVOUS SYSTEM DISORDERS		>= 65	15	53.6	7	46.7	8	53.3	14	51.9	4	28.6	10	71.4	0.3182	1.97	0.51	7.64		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.8510	0.77	0.05	12.40		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	1	7.1	13	92.9	0.4894	2.18	0.23	21.10		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	< 65	13	46.4	3	23.1	10	76.9	13	48.1	2	15.4	11	84.6	0.6781	1.46	0.24	8.88		Convergence criterion (GCONV=1E-8) satisfied.	-

NERVOUS SYSTEM DISORDERS	HEADACHE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2491	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOSMIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOSMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	< 65	13	46.4	3	23.1	10	76.9	13	48.1	0	-	13	100.0	0.0973	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	1	7.1	13	92.9	0.3458	2.77	0.31	25.05		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.2056	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.1902	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	< 65	13	46.4	2	15.4	11	84.6	13	48.1	1	7.7	12	92.3	0.6588	1.71	0.15	18.84		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	TREMOR	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	TREMOR	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.9016	0.84	0.05	13.43		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		>= 65	15	53.6	4	26.7	11	73.3	14	51.9	2	14.3	12	85.7	0.5764	1.62	0.29	8.86		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.7426	1.49	0.13	16.60		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	APATHY	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	APATHY	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	2	14.3	12	85.7	0.3687	0.35	0.03	3.87		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	13	46.4	2	15.4	11	84.6	13	48.1	1	7.7	12	92.3	0.9529	0.92	0.06	14.71		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.7571	0.65	0.04	10.41		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	POLLAKIURIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	POLLAKIURIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2178	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	13	46.4	4	30.8	9	69.2	13	48.1	5	38.5	8	61.5	0.2713	0.47	0.12	1.85		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	15	53.6	5	33.3	10	66.7	14	51.9	3	21.4	11	78.6	0.8723	1.13	0.27	4.78		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	< 65	13	46.4	2	15.4	11	84.6	13	48.1	2	15.4	11	84.6	0.6831	0.66	0.09	4.94		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	2	14.3	12	85.7	0.6580	0.64	0.09	4.63		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.7505	0.63	0.04	10.88		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2033	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	< 65	13	46.4	0	-	13	100.0	13	48.1	2	15.4	11	84.6	0.0836	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.2764	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	13	46.4	0	-	13	100.0	13	48.1	3	23.1	10	76.9	0.0344	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.6849	0.57	0.04	9.11		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	13	46.4	3	23.1	10	76.9	13	48.1	4	30.8	9	69.2	0.2775	0.43	0.09	2.04		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	15	53.6	5	33.3	10	66.7	14	51.9	2	14.3	12	85.7	0.4307	1.93	0.37	10.15		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	13	46.4	2	15.4	11	84.6	13	48.1	1	7.7	12	92.3	0.8029	1.36	0.12	15.49		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.7530	1.47	0.13	16.43		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.9262	0.88	0.05	14.11		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	15	53.6	0	-	15	100.0	14	51.9	2	14.3	12	85.7	0.1104	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	13	46.4	2	15.4	11	84.6	13	48.1	3	23.1	10	76.9	0.4760	0.53	0.09	3.17		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	15	53.6	2	13.3	13	86.7	14	51.9	3	21.4	11	78.6	0.3311	0.42	0.07	2.54		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.8541	1.25	0.11	13.83		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	FLUSHING	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	FLUSHING	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMATOMA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMATOMA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.9036	0.84	0.05	13.51		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.7307	0.62	0.04	9.89		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTAE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 22:29

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	15	53.6	13	86.7	2	13.3	18	66.7	10	55.6	8	44.4	0.4931	1.34	0.58	3.12		Convergence criterion (GCONV=1E-8) satisfied.	0.5592
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	13	46.4	9	69.2	4	30.8	9	33.3	6	66.7	3	33.3	0.9655	0.98	0.34	2.82		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	15	53.6	8	53.3	7	46.7	18	66.7	3	16.7	15	83.3	0.2601	2.13	0.56	8.14		Convergence criterion (GCONV=1E-8) satisfied.	0.8627
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	13	46.4	8	61.5	5	38.5	9	33.3	2	22.2	7	77.8	0.1985	2.68	0.56	12.77		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	2	11.1	16	88.9	0.7742	1.42	0.13	16.03		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.9353	1.10	0.10	12.20		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	2	11.1	16	88.9	0.9162	0.90	0.13	6.41		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.8475	1.27	0.11	13.99		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	15	53.6	3	20.0	12	80.0	18	66.7	0	-	18	100.0	0.0699	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	15	53.6	8	53.3	7	46.7	18	66.7	7	38.9	11	61.1	0.5870	0.74	0.25	2.17		Convergence criterion (GCONV=1E-8) satisfied.	0.1924
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	13	46.4	8	61.5	5	38.5	9	33.3	3	33.3	6	66.7	0.2203	2.26	0.59	8.63		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	15	53.6	8	53.3	7	46.7	18	66.7	4	22.2	14	77.8	0.2507	2.01	0.60	6.73		Convergence criterion (GCONV=1E-8) satisfied.	0.1565
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	13	46.4	6	46.2	7	53.8	9	33.3	5	55.6	4	44.4	0.4119	0.60	0.18	2.04		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	4	22.2	14	77.8	0.1958	0.26	0.03	2.34		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	3	33.3	6	66.7	0.3180	0.31	0.03	3.47		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1352	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1475	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYARRHYTHMIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYARRHYTHMIA	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.6465	0.57	0.05	6.44		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS	ASTHENOPIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS	ASTHENOPIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS		>=3	15	53.6	12	80.0	3	20.0	18	66.7	12	66.7	6	33.3	0.8019	0.90	0.39	2.07		Convergence criterion (GCONV=1E-8) satisfied.	0.6444
GASTROINTESTINAL DISORDERS		<3	13	46.4	12	92.3	1	7.7	9	33.3	6	66.7	3	33.3	0.7897	1.14	0.42	3.09		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	15	53.6	3	20.0	12	80.0	18	66.7	3	16.7	15	83.3	0.9400	0.94	0.19	4.73		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9791	0.96	0.06	15.41		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	<3	13	46.4	3	23.1	10	76.9	9	33.3	0	-	9	100.0	0.1487	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	15	53.6	3	20.0	12	80.0	18	66.7	4	22.2	14	77.8	0.7143	0.75	0.17	3.43		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	13	46.4	4	30.8	9	69.2	9	33.3	2	22.2	7	77.8	0.7966	1.25	0.23	6.83		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	4	22.2	14	77.8	0.3184	0.43	0.08	2.37		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	13	46.4	9	69.2	4	30.8	9	33.3	5	55.6	4	44.4	0.6578	0.78	0.25	2.39		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.5708	0.50	0.05	5.62		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FLATULENCE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FLATULENCE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRITIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRITIS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1506	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	LIP DRY	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	LIP DRY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	>=3	15	53.6	6	40.0	9	60.0	18	66.7	6	33.3	12	66.7	0.9389	1.05	0.33	3.30		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	<3	13	46.4	1	7.7	12	92.3	9	33.3	4	44.4	5	55.6	0.0416	0.14	0.02	1.27		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.3429	0.33	0.03	3.69		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3017	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TOOTHACHE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TOOTHACHE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	15	53.6	2	13.3	13	86.7	18	66.7	2	11.1	16	88.9	0.9907	1.01	0.14	7.22		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	13	46.4	2	15.4	11	84.6	9	33.3	2	22.2	7	77.8	0.7227	0.70	0.10	5.10		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	15	53.6	11	73.3	4	26.7	18	66.7	9	50.0	9	50.0	0.6812	1.21	0.49	2.95		Convergence criterion (GCONV=1E-8) satisfied.	0.6631
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	13	46.4	10	76.9	3	23.1	9	33.3	6	66.7	3	33.3	0.7204	0.83	0.29	2.37		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	3	16.7	15	83.3	0.5575	0.59	0.10	3.56		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9486	1.10	0.07	17.57		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.5191	0.46	0.04	5.13		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.3322	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	15	53.6	4	26.7	11	73.3	18	66.7	5	27.8	13	72.2	0.5697	0.68	0.18	2.62		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	13	46.4	7	53.8	6	46.2	9	33.3	4	44.4	5	55.6	0.9452	1.04	0.30	3.59		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4631	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.6553	1.73	0.15	19.75		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	15	53.6	4	26.7	11	73.3	18	66.7	2	11.1	16	88.9	0.4290	1.96	0.36	10.75		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	13	46.4	5	38.5	8	61.5	9	33.3	4	44.4	5	55.6	0.6268	0.72	0.19	2.70		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.3507	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	15	53.6	9	60.0	6	40.0	18	66.7	8	44.4	10	55.6	0.7237	0.84	0.31	2.26		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	13	46.4	5	38.5	8	61.5	9	33.3	4	44.4	5	55.6	0.3503	0.52	0.13	2.10		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	BRONCHITIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	BRONCHITIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CELLULITIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CELLULITIS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9053	0.85	0.05	13.55		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ERYSIPELAS	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ERYSIPELAS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3017	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFLUENZA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFLUENZA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.4631	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.2309	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.5189	0.46	0.04	5.14		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	2	22.2	7	77.8	0.6207	0.61	0.08	4.43		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PYURIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PYURIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.6666	0.55	0.03	8.94		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.7508	0.64	0.04	10.25		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	5	27.8	13	72.2	0.0318	0.13	0.01	1.14		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.4109	0.29	0.01	6.09		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1352	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	15	53.6	7	46.7	8	53.3	18	66.7	7	38.9	11	61.1	0.4210	0.64	0.21	1.93		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	13	46.4	6	46.2	7	53.8	9	33.3	2	22.2	7	77.8	0.6870	1.40	0.27	7.25		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	AMYLASE INCREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3352	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	AMYLASE INCREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1906	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CALCIUM DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CALCIUM DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1600	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3352	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URINE PRESENT	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URINE PRESENT	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	HAEMOGLOBIN DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	2	22.2	7	77.8	0.0800	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONOCYTE COUNT DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONOCYTE COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OCCULT BLOOD POSITIVE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3476	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OCCULT BLOOD POSITIVE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1506	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.6028	0.48	0.03	8.05		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	VITAMIN D DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	VITAMIN D DECREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	15	53.6	2	13.3	13	86.7	18	66.7	2	11.1	16	88.9	0.5658	0.56	0.07	4.19		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.3040	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.8583	0.78	0.05	12.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	15	53.6	7	46.7	8	53.3	18	66.7	9	50.0	9	50.0	0.6726	0.80	0.29	2.21		Convergence criterion (GCONV=1E-8) satisfied.	0.5665
METABOLISM AND NUTRITION DISORDERS		<3	13	46.4	7	53.8	6	46.2	9	33.3	4	44.4	5	55.6	0.8500	1.13	0.32	3.98		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	15	53.6	3	20.0	12	80.0	18	66.7	5	27.8	13	72.2	0.4432	0.57	0.13	2.43		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	13	46.4	3	23.1	10	76.9	9	33.3	1	11.1	8	88.9	0.5547	1.95	0.20	18.81		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1490	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	15	53.6	3	20.0	12	80.0	18	66.7	1	5.6	17	94.4	0.2973	3.13	0.33	30.23		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1454	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.5372	0.48	0.04	5.31		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.7870	1.39	0.13	15.34		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.7508	0.64	0.04	10.25		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.5439	2.07	0.19	22.97		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	15	53.6	7	46.7	8	53.3	18	66.7	4	22.2	14	77.8	0.6210	1.38	0.38	4.98		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	13	46.4	6	46.2	7	53.8	9	33.3	1	11.1	8	88.9	0.1540	4.14	0.50	34.54		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>=3	15	53.6	3	20.0	12	80.0	18	66.7	1	5.6	17	94.4	0.3809	2.66	0.27	25.85		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2298	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.6012	1.89	0.17	21.39		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.6926	0.58	0.04	9.22		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3352	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2491	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3017	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	15	53.6	8	53.3	7	46.7	18	66.7	7	38.9	11	61.1	0.7053	1.23	0.42	3.58		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	13	46.4	7	53.8	6	46.2	9	33.3	0	-	9	100.0	0.0181	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	>=3	15	53.6	3	20.0	12	80.0	18	66.7	2	11.1	16	88.9	0.7334	1.37	0.23	8.26		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4450	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.5928	0.52	0.05	5.82		Convergence criterion (GCONV=1E-8) satisfied.	-

NERVOUS SYSTEM DISORDERS	HEADACHE	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2298	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.2210	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOSMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOSMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>=3	15	53.6	4	26.7	11	73.3	18	66.7	1	5.6	17	94.4	0.2444	3.42	0.38	30.96		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	<3	13	46.4	3	23.1	10	76.9	9	33.3	0	-	9	100.0	0.1487	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3352	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1823	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2437	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	TREMOR	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	TREMOR	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		>=3	15	53.6	4	26.7	11	73.3	18	66.7	1	5.6	17	94.4	0.1693	4.14	0.46	37.21		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	2	22.2	7	77.8	0.2919	0.29	0.03	3.32		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1542	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	APATHY	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	APATHY	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSION	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9157	0.86	0.05	14.28		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSION	<3	13	46.4	0	-	13	100.0	9	33.3	2	22.2	7	77.8	0.0623	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.6719	1.67	0.15	18.56		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	POLLAKIURIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	POLLAKIURIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1645	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	15	53.6	5	33.3	10	66.7	18	66.7	4	22.2	14	77.8	0.9373	1.06	0.27	4.07		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	13	46.4	4	30.8	9	69.2	9	33.3	4	44.4	5	55.6	0.2770	0.46	0.11	1.91		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.3799	0.35	0.03	4.06		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	<3	13	46.4	3	23.1	10	76.9	9	33.3	2	22.2	7	77.8	0.8048	0.79	0.12	5.04		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.5574	2.03	0.18	22.62		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.0253	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.3558	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.3555	0.33	0.03	3.85		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	13	46.4	0	-	13	100.0	9	33.3	2	22.2	7	77.8	0.0677	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	15	53.6	5	33.3	10	66.7	18	66.7	3	16.7	15	83.3	0.5665	1.53	0.36	6.53		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	13	46.4	3	23.1	10	76.9	9	33.3	3	33.3	6	66.7	0.4033	0.51	0.10	2.56		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1874	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	13	46.4	2	15.4	11	84.6	9	33.3	2	22.2	7	77.8	0.4303	0.46	0.06	3.35		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.5751	0.51	0.05	5.66		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	6	33.3	12	66.7	0.0785	0.26	0.05	1.30		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2736	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.5191	0.46	0.04	5.13		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	FLUSHING	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	FLUSHING	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMATOMA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMATOMA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1402	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2736	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTAE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 22:29

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	32.1	5	55.6	4	44.4	13	48.1	6	46.2	7	53.8	0.6920	0.78	0.23	2.64	Convergence criterion (GCONV=1E-8) satisfied.	0.6691
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	67.9	17	89.5	2	10.5	14	51.9	10	71.4	4	28.6	0.7575	1.14	0.51	2.54	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	9	32.1	4	44.4	5	55.6	13	48.1	0	-	13	100.0	0.0487	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	19	67.9	12	63.2	7	36.8	14	51.9	5	35.7	9	64.3	0.4643	1.48	0.52	4.22	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	2	14.3	12	85.7	0.8479	0.85	0.15	4.72	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	2	14.3	12	85.7	0.8047	1.24	0.23	6.79	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	0	-	14	100.0	0.0846	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	32.1	3	33.3	6	66.7	13	48.1	5	38.5	8	61.5	0.5366	0.64	0.15	2.71	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	19	67.9	13	68.4	6	31.6	14	51.9	5	35.7	9	64.3	0.3401	1.66	0.58	4.80	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	32.1	2	22.2	7	77.8	13	48.1	3	23.1	10	76.9	0.8681	0.86	0.14	5.16	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	67.9	12	63.2	7	36.8	14	51.9	6	42.9	8	57.1	0.7442	1.18	0.44	3.17	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	9	32.1	2	22.2	7	77.8	13	48.1	3	23.1	10	76.9	0.7289	1.42	0.19	10.34	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	4	28.6	10	71.4	0.0078	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	2	14.3	12	85.7	0.0689	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	2	14.3	12	85.7	0.0715	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYARRHYTHMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYARRHYTHMIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	9	32.1	2	22.2	7	77.8	13	48.1	1	7.7	12	92.3	0.3646	2.94	0.26	33.68	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS	ASTHENOPIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS	ASTHENOPIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS		Europe	9	32.1	7	77.8	2	22.2	13	48.1	6	46.2	7	53.8	0.4130	1.58	0.53	4.72		Convergence criterion (GCONV=1E-8) satisfied.	0.2886
GASTROINTESTINAL DISORDERS		Non-Europe	19	67.9	17	89.5	2	10.5	14	51.9	12	85.7	2	14.3	0.4036	0.72	0.34	1.55		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	2	14.3	12	85.7	0.8959	0.89	0.15	5.39		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Europe	9	32.1	2	22.2	7	77.8	13	48.1	0	-	13	100.0	0.1198	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.8828	1.20	0.11	13.22		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.8160	1.39	0.09	22.20		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	5	35.7	9	64.3	0.5852	0.72	0.22	2.37		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	9	32.1	3	33.3	6	66.7	13	48.1	4	30.8	9	69.2	0.8077	0.83	0.18	3.73		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	19	67.9	8	42.1	11	57.9	14	51.9	5	35.7	9	64.3	0.7893	0.86	0.28	2.64		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.5841	0.46	0.03	7.93		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.8961	0.83	0.05	13.31		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.8078	0.71	0.04	11.36		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FLATULENCE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FLATULENCE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRITIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRITIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2451	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2753	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	LIP DRY	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	LIP DRY	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	2	15.4	11	84.6	0.6077	0.53	0.05	6.09		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	8	57.1	6	42.9	0.1493	0.46	0.16	1.35		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	3	21.4	11	78.6	0.0080	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TOOTHACHE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TOOTHACHE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	9	32.1	2	22.2	7	77.8	13	48.1	0	-	13	100.0	0.0800	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	4	28.6	10	71.4	0.1423	0.30	0.05	1.65		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	32.1	5	55.6	4	44.4	13	48.1	6	46.2	7	53.8	0.7528	0.82	0.24	2.80		Convergence criterion (GCONV=1E-8) satisfied.	0.5108
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	19	67.9	16	84.2	3	15.8	14	51.9	9	64.3	5	35.7	0.6281	1.23	0.54	2.79		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Europe	9	32.1	2	22.2	7	77.8	13	48.1	1	7.7	12	92.3	0.5142	2.19	0.20	24.42		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	2	14.3	12	85.7	0.0867	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.8006	0.70	0.04	11.21		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.7752	0.67	0.04	10.97		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.8482	1.26	0.11	13.99		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	3	23.1	10	76.9	0.3135	0.32	0.03	3.23		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	19	67.9	10	52.6	9	47.4	14	51.9	6	42.9	8	57.1	0.9922	1.01	0.36	2.79		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4669	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.3907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6434	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	2	14.3	12	85.7	0.0661	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.3625	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	9	32.1	2	22.2	7	77.8	13	48.1	2	15.4	11	84.6	0.7217	1.43	0.20	10.12		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	19	67.9	7	36.8	12	63.2	14	51.9	4	28.6	10	71.4	0.8761	1.10	0.32	3.77		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.3346	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	32.1	5	55.6	4	44.4	13	48.1	7	53.8	6	46.2	0.4665	0.65	0.20	2.09		Convergence criterion (GCONV=1E-8) satisfied.	0.9413
INFECTIONS AND INFESTATIONS		Non-Europe	19	67.9	9	47.4	10	52.6	14	51.9	5	35.7	9	64.3	0.6705	0.78	0.24	2.49		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	BRONCHITIS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	BRONCHITIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CELLULITIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CELLULITIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	2	14.3	12	85.7	0.0624	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ERYSIPELAS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ERYSIPELAS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4081	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFLUENZA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFLUENZA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4081	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.9301	1.13	0.07	18.50		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	3	21.4	11	78.6	0.1778	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PYURIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PYURIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.3907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Europe	9	32.1	2	22.2	7	77.8	13	48.1	1	7.7	12	92.3	0.5251	2.14	0.19	23.76		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	9	32.1	0	-	9	100.0	13	48.1	3	23.1	10	76.9	0.0917	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	3	21.4	11	78.6	0.0961	0.22	0.03	1.50		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1693	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6434	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	32.1	2	22.2	7	77.8	13	48.1	3	23.1	10	76.9	0.5880	0.61	0.10	3.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	67.9	11	57.9	8	42.1	14	51.9	6	42.9	8	57.1	0.5061	0.70	0.24	2.01		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	AMYLASE INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	AMYLASE INCREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2683	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CALCIUM DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CALCIUM DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7542	0.64	0.04	10.36		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URINE PRESENT	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URINE PRESENT	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	HAEMOGLOBIN DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7508	0.64	0.04	10.30		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONOCYTE COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONOCYTE COUNT DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7508	0.64	0.04	10.30		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OCCULT BLOOD POSITIVE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OCCULT BLOOD POSITIVE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	1	7.1	13	92.9	0.7535	1.45	0.14	14.94		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	VITAMIN D DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	VITAMIN D DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	2	14.3	12	85.7	0.6488	0.66	0.11	4.03		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7508	0.64	0.04	10.30		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	9	32.1	3	33.3	6	66.7	13	48.1	5	38.5	8	61.5	0.4765	0.59	0.14	2.54		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	19	67.9	11	57.9	8	42.1	14	51.9	8	57.1	6	42.9	0.9197	0.95	0.37	2.42		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Europe	9	32.1	2	22.2	7	77.8	13	48.1	2	15.4	11	84.6	0.9201	1.11	0.15	7.96		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	4	28.6	10	71.4	0.4905	0.61	0.15	2.49		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4081	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.3907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	1	7.1	13	92.9	0.5441	1.99	0.21	19.16		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2460	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	3	21.4	11	78.6	0.3295	0.42	0.07	2.53		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7407	0.63	0.04	10.06		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.8300	1.30	0.12	14.39		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	9	32.1	3	33.3	6	66.7	13	48.1	0	-	13	100.0	0.0417	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	19	67.9	10	52.6	9	47.4	14	51.9	5	35.7	9	64.3	0.9592	0.97	0.32	2.96		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Europe	9	32.1	2	22.2	7	77.8	13	48.1	0	-	13	100.0	0.1198	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	1	7.1	13	92.9	0.6103	1.80	0.18	17.62		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	2	14.3	12	85.7	0.6321	0.62	0.09	4.48		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.0455	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.6844	0.57	0.04	9.07		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2620	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2845	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	32.1	2	22.2	7	77.8	13	48.1	3	23.1	10	76.9	0.9477	1.07	0.15	7.85		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	19	67.9	13	68.4	6	31.6	14	51.9	4	28.6	10	71.4	0.1007	2.49	0.81	7.70		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.0190	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	2	14.3	12	85.7	0.8282	1.21	0.22	6.61		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

NERVOUS SYSTEM DISORDERS	HEADACHE	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	2	14.3	12	85.7	0.9601	1.05	0.17	6.34		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.3332	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOSMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOSMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	1	7.1	13	92.9	0.1826	3.82	0.46	31.90		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	0	-	14	100.0	0.1482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.6878	0.57	0.04	9.12		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	TREMOR	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	TREMOR	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Non-Europe	19	67.9	5	26.3	14	73.7	14	51.9	2	14.3	12	85.7	0.5836	1.58	0.30	8.23		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.8368	1.29	0.12	14.22		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	APATHY	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	APATHY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	2	14.3	12	85.7	0.2176	0.25	0.02	2.74		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	1	7.1	13	92.9	0.9189	1.13	0.10	12.55		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	POLLAKIURIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	POLLAKIURIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2546	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	32.1	2	22.2	7	77.8	13	48.1	3	23.1	10	76.9	0.8203	0.81	0.13	4.97		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	67.9	7	36.8	12	63.2	14	51.9	5	35.7	9	64.3	0.3874	0.60	0.18	1.94		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Europe	9	32.1	1	11.1	8	88.9	13	48.1	2	15.4	11	84.6	0.6478	0.57	0.05	6.41		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	2	14.3	12	85.7	0.5866	0.60	0.10	3.79		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.9664	0.95	0.08	10.88		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	2	14.3	12	85.7	0.0533	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.3907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.7752	0.67	0.04	10.97		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	4	28.6	10	71.4	0.0163	0.10	0.01	0.96		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.7630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	9	32.1	2	22.2	7	77.8	13	48.1	1	7.7	12	92.3	0.4973	2.26	0.20	25.15		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	5	35.7	9	64.3	0.2740	0.50	0.14	1.76		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	2	14.3	12	85.7	0.9978	1.00	0.18	5.65		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	2	14.3	12	85.7	0.2948	0.30	0.03	3.30		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	3	23.1	10	76.9	0.1191	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	3	21.4	11	78.6	0.6346	0.69	0.15	3.14		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.9650	0.95	0.08	10.66		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	FLUSHING	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	FLUSHING	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMATOMA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMATOMA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	2	14.3	12	85.7	0.5472	0.55	0.08	3.99		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTAE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 22:29

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	20	71.4	15	75.0	5	25.0	18	66.7	11	61.1	7	38.9	0.8787	0.94	0.42	2.09		Convergence criterion (GCONV=1E-8) satisfied.	0.2718
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	8	28.6	7	87.5	1	12.5	9	33.3	5	55.6	4	44.4	0.1312	2.44	0.74	8.05		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	20	71.4	11	55.0	9	45.0	18	66.7	5	27.8	13	72.2	0.4525	1.50	0.52	4.35		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	8	28.6	5	62.5	3	37.5	9	33.3	0	-	9	100.0	0.0252	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	3	16.7	15	83.3	0.5647	0.56	0.08	4.05		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2079	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	20	71.4	3	15.0	17	85.0	18	66.7	2	11.1	16	88.9	0.8986	1.12	0.19	6.76		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.9191	0.87	0.05	13.95		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPH NODE PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	20	71.4	3	15.0	17	85.0	18	66.7	0	-	18	100.0	0.0979	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	20	71.4	10	50.0	10	50.0	18	66.7	6	33.3	12	66.7	0.9067	1.06	0.37	3.03		Convergence criterion (GCONV=1E-8) satisfied.	0.5521
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	8	28.6	6	75.0	2	25.0	9	33.3	4	44.4	5	55.6	0.3916	1.75	0.48	6.39		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	20	71.4	7	35.0	13	65.0	18	66.7	6	33.3	12	66.7	0.7835	0.86	0.29	2.57		Convergence criterion (GCONV=1E-8) satisfied.	0.2947
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	8	28.6	7	87.5	1	12.5	9	33.3	3	33.3	6	66.7	0.3218	2.00	0.50	8.08		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	20	71.4	2	10.0	18	90.0	18	66.7	4	22.2	14	77.8	0.2685	0.40	0.07	2.17		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	3	33.3	6	66.7	0.1695	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	20	71.4	0	-	20	100.0	18	66.7	2	11.1	16	88.9	0.0995	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIOVENTRICULAR BLOCK FIRST DEGREE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYARRHYTHMIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYARRHYTHMIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.6409	1.76	0.16	19.38		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS		Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EYE DISORDERS	ASTHENOPIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EYE DISORDERS	ASTHENOPIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS		Male	20	71.4	17	85.0	3	15.0	18	66.7	12	66.7	6	33.3	0.9517	1.02	0.48	2.19		Convergence criterion (GCONV=1E-8) satisfied.	0.8587
GASTROINTESTINAL DISORDERS		Female	8	28.6	7	87.5	1	12.5	9	33.3	6	66.7	3	33.3	0.6301	0.76	0.24	2.36		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	20	71.4	2	10.0	18	90.0	18	66.7	2	11.1	16	88.9	0.8763	0.86	0.12	6.08		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.9055	0.85	0.05	13.65		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN LOWER	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Male	20	71.4	3	15.0	17	85.0	18	66.7	1	5.6	17	94.4	0.4444	2.36	0.24	22.69		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3496	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	20	71.4	5	25.0	15	75.0	18	66.7	5	27.8	13	72.2	0.7118	0.79	0.23	2.76		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	8	28.6	2	25.0	6	75.0	9	33.3	1	11.1	8	88.9	0.6761	1.66	0.15	18.61		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	20	71.4	7	35.0	13	65.0	18	66.7	6	33.3	12	66.7	0.6797	0.79	0.27	2.37		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	8	28.6	4	50.0	4	50.0	9	33.3	3	33.3	6	66.7	0.8888	0.89	0.18	4.52		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8415	0.75	0.04	12.70		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.7888	1.39	0.12	15.83		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPHAGIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	FLATULENCE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	FLATULENCE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRITIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRITIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.1866	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROOESOPHAGEAL REFLUX DISEASE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATEMESIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HAEMATOCHEZIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	HYPERCHLORHYDRIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	LIP DRY	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	LIP DRY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	Male	20	71.4	5	25.0	15	75.0	18	66.7	7	38.9	11	61.1	0.2921	0.54	0.17	1.73		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Female	8	28.6	2	25.0	6	75.0	9	33.3	3	33.3	6	66.7	0.5068	0.54	0.09	3.37		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.6310	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS ACUTE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	Male	20	71.4	0	-	20	100.0	18	66.7	3	16.7	15	83.3	0.0122	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TONGUE EXFOLIATION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	TOOTHACHE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	TOOTHACHE	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	20	71.4	2	10.0	18	90.0	18	66.7	3	16.7	15	83.3	0.5190	0.56	0.09	3.36		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	8	28.6	2	25.0	6	75.0	9	33.3	1	11.1	8	88.9	0.5937	1.90	0.17	21.00		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	20	71.4	15	75.0	5	25.0	18	66.7	9	50.0	9	50.0	0.3413	1.50	0.65	3.44		Convergence criterion (GCONV=1E-8) satisfied.	0.1841
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	8	28.6	6	75.0	2	25.0	9	33.3	6	66.7	3	33.3	0.3192	0.55	0.17	1.81		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.7716	1.43	0.13	15.85		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Female	8	28.6	0	-	8	100.0	9	33.3	2	22.2	7	77.8	0.1549	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.0374	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	AXILLARY PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.9389	0.90	0.06	14.34		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.9621	1.06	0.09	12.98		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.9387	0.90	0.06	14.59		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FACE OEDEMA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	20	71.4	6	30.0	14	70.0	18	66.7	5	27.8	13	72.2	0.8739	0.91	0.27	3.02		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	8	28.6	5	62.5	3	37.5	9	33.3	4	44.4	5	55.6	0.8275	0.86	0.22	3.30		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FEELING COLD	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	GAIT DISTURBANCE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	INJECTION SITE PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.2888	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	NON-CARDIAC CHEST PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Male	20	71.4	0	-	20	100.0	18	66.7	2	11.1	16	88.9	0.1004	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.2679	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	20	71.4	6	30.0	14	70.0	18	66.7	3	16.7	15	83.3	0.4664	1.67	0.42	6.67		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	8	28.6	3	37.5	5	62.5	9	33.3	3	33.3	6	66.7	0.7646	0.78	0.16	3.92		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.2922	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5525	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	AMYLOIDOSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	HYPOGAMMAGLOBULINAEMIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	SEASONAL ALLERGY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	20	71.4	11	55.0	9	45.0	18	66.7	8	44.4	10	55.6	0.4711	0.70	0.27	1.85		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	8	28.6	3	37.5	5	62.5	9	33.3	4	44.4	5	55.6	0.5693	0.65	0.14	2.92		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	BRONCHITIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	BRONCHITIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	CANDIDA INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CELLULITIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CELLULITIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.7907	0.69	0.04	11.03		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	2	11.1	16	88.9	0.1070	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ERYSIPELAS	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ERYSIPELAS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.6310	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFLUENZA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFLUENZA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2850	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NASOPHARYNGITIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ORAL CANDIDIASIS	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2253	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	4	22.2	14	77.8	0.1536	0.31	0.06	1.70		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA FUNGAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PYURIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PYURIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.2888	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SINUSITIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SINUSITIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8526	0.77	0.05	12.30		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	20	71.4	1	5.0	19	95.0	18	66.7	3	16.7	15	83.3	0.1297	0.20	0.02	1.98		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	8	28.6	1	12.5	7	87.5	9	33.3	3	33.3	6	66.7	0.0939	0.15	0.01	1.70		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FACIAL BONES FRACTURE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INFUSION RELATED REACTION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	Male	20	71.4	0	-	20	100.0	18	66.7	2	11.1	16	88.9	0.0947	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	LIMB INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN LACERATION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TOOTH FRACTURE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	TRANSFUSION REACTION	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	VASCULAR ACCESS SITE PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	20	71.4	9	45.0	11	55.0	18	66.7	5	27.8	13	72.2	0.9735	1.02	0.33	3.17		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	8	28.6	4	50.0	4	50.0	9	33.3	4	44.4	5	55.6	0.2742	0.43	0.09	2.02		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	AMYLASE INCREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	AMYLASE INCREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CALCIUM DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CALCIUM DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.7634	0.65	0.04	10.53		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URINE PRESENT	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URINE PRESENT	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CLOSTRIDIUM TEST POSITIVE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYTOMEGALOVIRUS TEST POSITIVE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	HAEMOGLOBIN DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	INTERNATIONAL NORMALISED RATIO INCREASED	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.2080	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8497	0.76	0.05	12.34		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONOCYTE COUNT DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONOCYTE COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8497	0.76	0.05	12.34		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	OCCULT BLOOD POSITIVE	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	OCCULT BLOOD POSITIVE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.6907	1.62	0.15	17.91		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	VITAMIN D DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	VITAMIN D DECREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	20	71.4	4	20.0	16	80.0	18	66.7	1	5.6	17	94.4	0.4889	2.14	0.24	19.53		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.3669	0.35	0.03	3.86		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	20	71.4	11	55.0	9	45.0	18	66.7	10	55.6	8	44.4	0.6701	0.83	0.35	1.98		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	8	28.6	3	37.5	5	62.5	9	33.3	3	33.3	6	66.7	0.9481	0.95	0.18	4.88		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	20	71.4	5	25.0	15	75.0	18	66.7	5	27.8	13	72.2	0.6610	0.76	0.22	2.65		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.9387	0.90	0.06	14.59		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DEHYDRATION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	ELECTROLYTE IMBALANCE	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	FOLATE DEFICIENCY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCALCAEMIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERMAGNESAEMIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.6676	1.68	0.15	18.60		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOGLYCAEMIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.4111	0.38	0.03	4.19		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	8	28.6	2	25.0	6	75.0	9	33.3	1	11.1	8	88.9	0.5539	2.04	0.18	22.90		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.4080	0.38	0.03	4.17		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOMAGNESAEMIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.9389	0.90	0.06	14.34		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	TYPE 2 DIABETES MELLITUS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	20	71.4	10	50.0	10	50.0	18	66.7	5	27.8	13	72.2	0.4794	1.49	0.49	4.53		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	8	28.6	3	37.5	5	62.5	9	33.3	0	-	9	100.0	0.1203	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Male	20	71.4	5	25.0	15	75.0	18	66.7	1	5.6	17	94.4	0.1635	4.10	0.48	35.28		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	20	71.4	2	10.0	18	90.0	18	66.7	2	11.1	16	88.9	0.8358	0.81	0.11	5.85		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.0374	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	GROIN PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.7570	1.46	0.13	16.08		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCLE SPASMS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.2227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULAR WEAKNESS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL CHEST PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MUSCULOSKELETAL PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	MYALGIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	NECK PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	PAIN IN EXTREMITY	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.1761	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	20	71.4	10	50.0	10	50.0	18	66.7	6	33.3	12	66.7	0.2265	1.93	0.65	5.69		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	8	28.6	5	62.5	3	37.5	9	33.3	1	11.1	8	88.9	0.1484	4.29	0.50	36.92		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	Male	20	71.4	3	15.0	17	85.0	18	66.7	1	5.6	17	94.4	0.4546	2.32	0.24	22.31		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8442	0.76	0.05	12.42		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.6310	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	Male	20	71.4	3	15.0	17	85.0	18	66.7	1	5.6	17	94.4	0.3633	2.75	0.28	26.78		Convergence criterion (GCONV=1E-8) satisfied.	-

NERVOUS SYSTEM DISORDERS	HEADACHE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOAESTHESIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.6310	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOGEUSIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HYPOSMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.6310	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HYPOSMIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Male	20	71.4	4	20.0	16	80.0	18	66.7	1	5.6	17	94.4	0.3802	2.60	0.29	23.63		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Female	8	28.6	3	37.5	5	62.5	9	33.3	0	-	9	100.0	0.0912	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Male	20	71.4	4	20.0	16	80.0	18	66.7	0	-	18	100.0	0.0655	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PERIPHERAL SENSORY NEUROPATHY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SOMNOLENCE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.7407	1.50	0.14	16.50		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	TREMOR	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	TREMOR	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Male	20	71.4	4	20.0	16	80.0	18	66.7	2	11.1	16	88.9	0.6641	1.46	0.26	8.05		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8961	1.20	0.08	19.26		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	ANXIETY	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.7986	0.70	0.04	11.18		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	ANXIETY	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.2888	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	APATHY	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	APATHY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	DEPRESSION	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.3002	0.30	0.03	3.34		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	DEPRESSION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	20	71.4	3	15.0	17	85.0	18	66.7	1	5.6	17	94.4	0.7508	1.47	0.13	16.36		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	MICTURITION URGENCY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	POLLAKIURIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4561	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	POLLAKIURIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL TUBULAR DISORDER	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.1866	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	ERECTILE DYSFUNCTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	GYNAECOMASTIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	20	71.4	4	20.0	16	80.0	18	66.7	5	27.8	13	72.2	0.4333	0.59	0.16	2.24		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	8	28.6	5	62.5	3	37.5	9	33.3	3	33.3	6	66.7	0.8495	0.87	0.19	3.86		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	ASPHYXIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Male	20	71.4	1	5.0	19	95.0	18	66.7	3	16.7	15	83.3	0.1988	0.25	0.03	2.44		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Female	8	28.6	3	37.5	5	62.5	9	33.3	1	11.1	8	88.9	0.5072	2.12	0.22	20.57		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPHONIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.2117	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8415	0.75	0.04	12.70		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Male	20	71.4	0	-	20	100.0	18	66.7	2	11.1	16	88.9	0.0761	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA EXERTIONAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	EPISTAXIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.4469	0.33	0.02	6.42		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	20	71.4	0	-	20	100.0	18	66.7	3	16.7	15	83.3	0.0271	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8012	0.69	0.04	12.04		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	RHINORRHOEA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	UPPER-AIRWAY COUGH SYNDROME	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	20	71.4	6	30.0	14	70.0	18	66.7	5	27.8	13	72.2	0.8415	0.89	0.27	2.93		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	8	28.6	2	25.0	6	75.0	9	33.3	1	11.1	8	88.9	0.8290	1.31	0.11	15.19		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	BUTTERFLY RASH	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DERMATITIS EXFOLIATIVE GENERALISED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRY SKIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	NIGHT SWEATS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PAPULE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	20	71.4	2	10.0	18	90.0	18	66.7	2	11.1	16	88.9	0.8175	0.79	0.11	5.67		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	20	71.4	1	5.0	19	95.0	18	66.7	3	16.7	15	83.3	0.2012	0.25	0.03	2.45		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH ERYTHEMATOUS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH MACULO-PAPULAR	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES		Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES		Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3545	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SURGICAL AND MEDICAL PROCEDURES	SINUS OPERATION	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3545	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	20	71.4	3	15.0	17	85.0	18	66.7	4	22.2	14	77.8	0.3856	0.52	0.11	2.34		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	2	22.2	7	77.8	0.3937	0.36	0.03	4.09		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.3287	0.32	0.03	3.58		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	FLUSHING	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	FLUSHING	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMATOMA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMATOMA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	20	71.4	2	10.0	18	90.0	18	66.7	2	11.1	16	88.9	0.7295	0.71	0.10	5.11		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	ORTHOSTATIC HYPOTENSION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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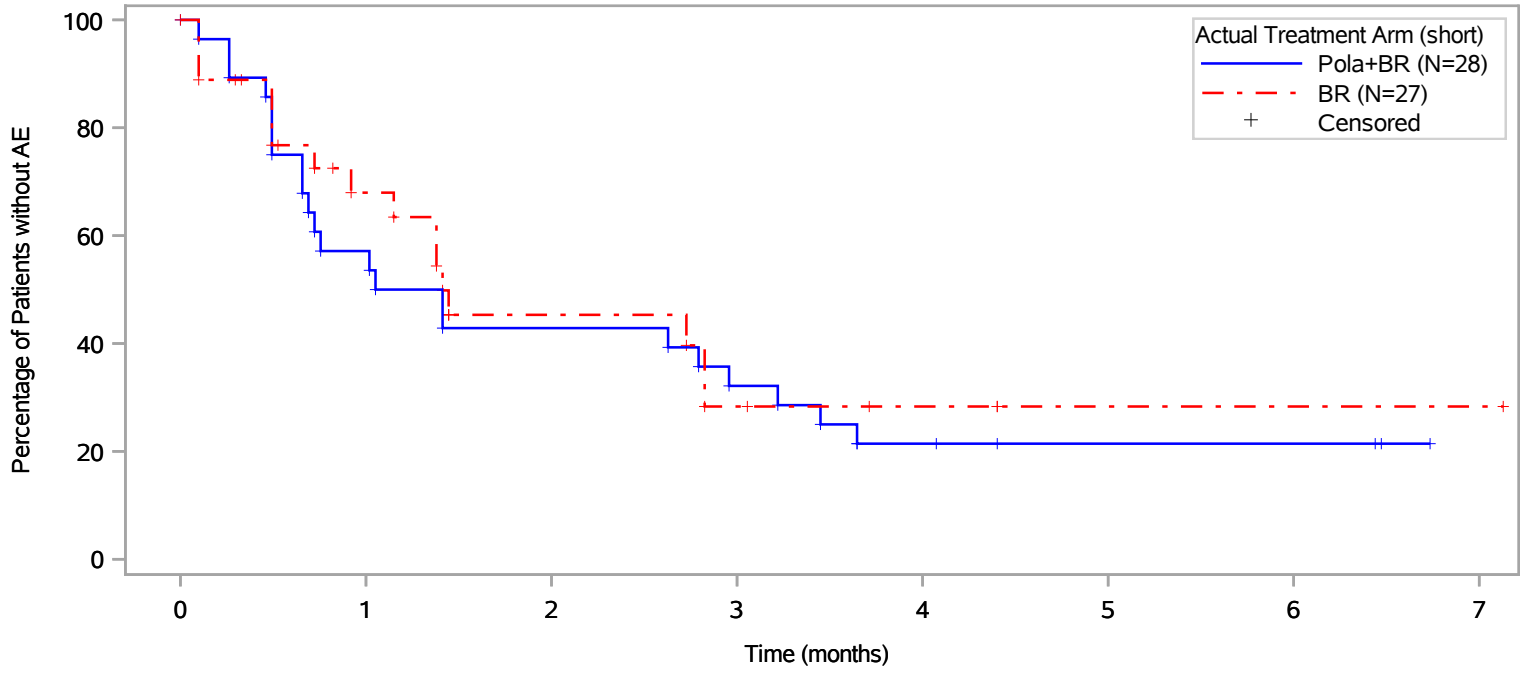
30NOV2022 22:29

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk								
Pola+BR (N=28)	28	16	12	9	5	3	3	NE
BR (N=27)	27	15	8	5	3	1	1	1
Patients censored								
Pola+BR (N=28)	0	0	0	0	1	3	3	NE
BR (N=27)	0	4	6	6	8	10	10	10

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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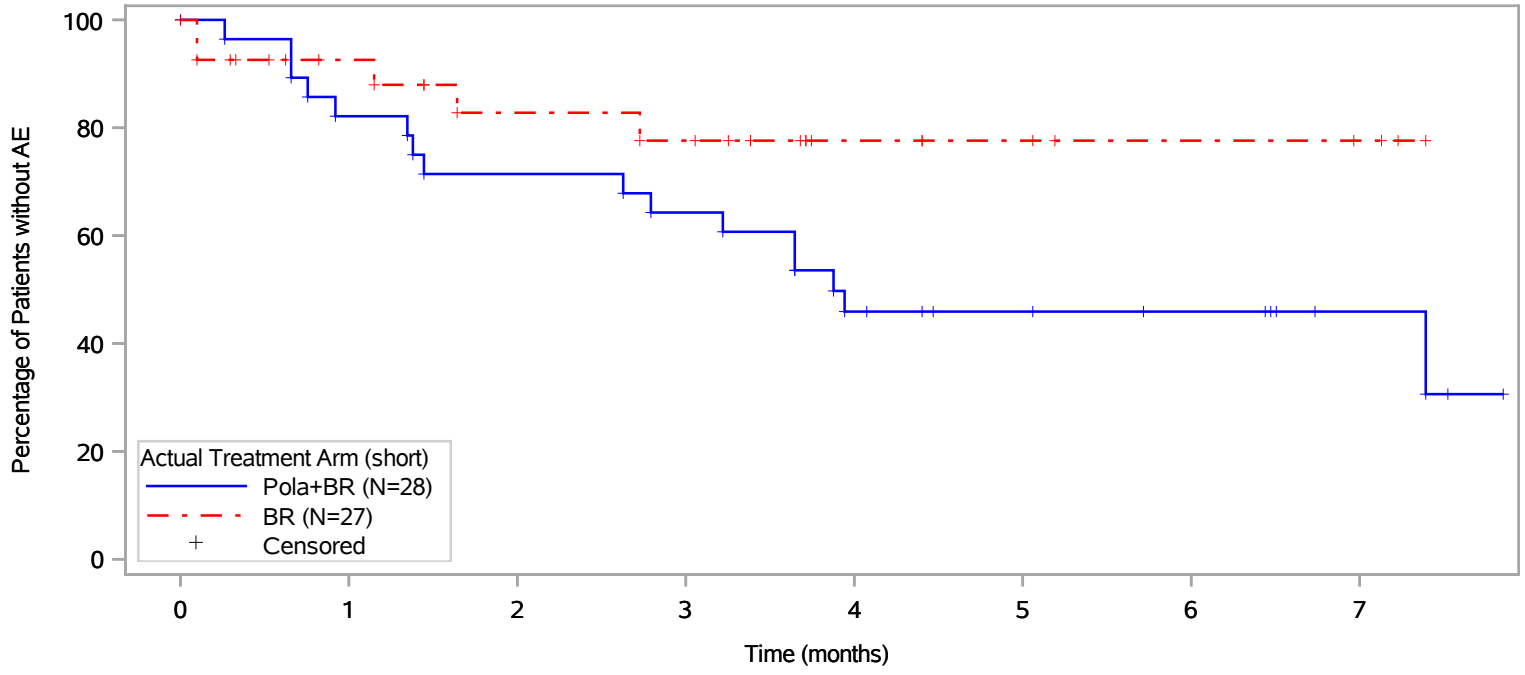
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk								
Pola+BR (N=28)	28	23	20	18	12	9	7	3
BR (N=27)	27	20	16	15	8	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	0	0	1	4	6	10
BR (N=27)	0	5	7	7	14	16	18	19

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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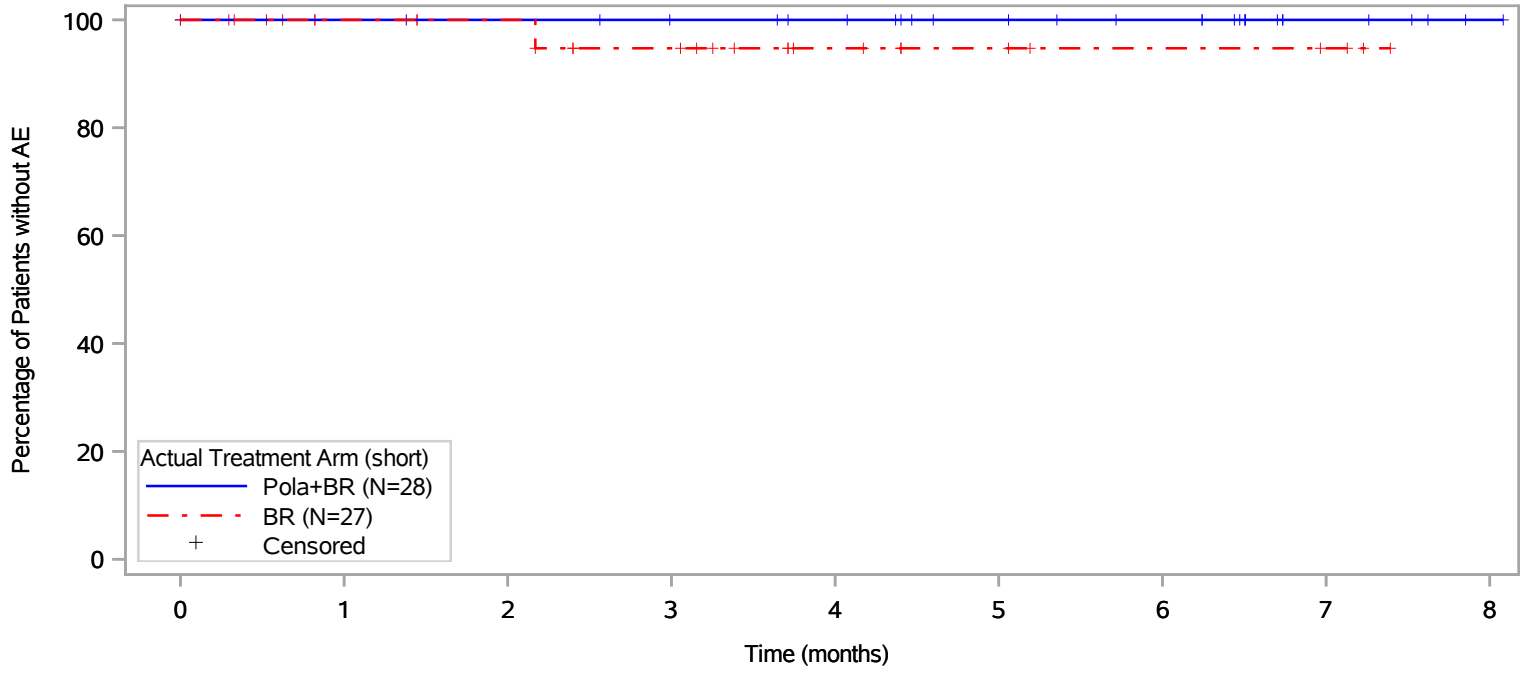
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE BONE MARROW APLASIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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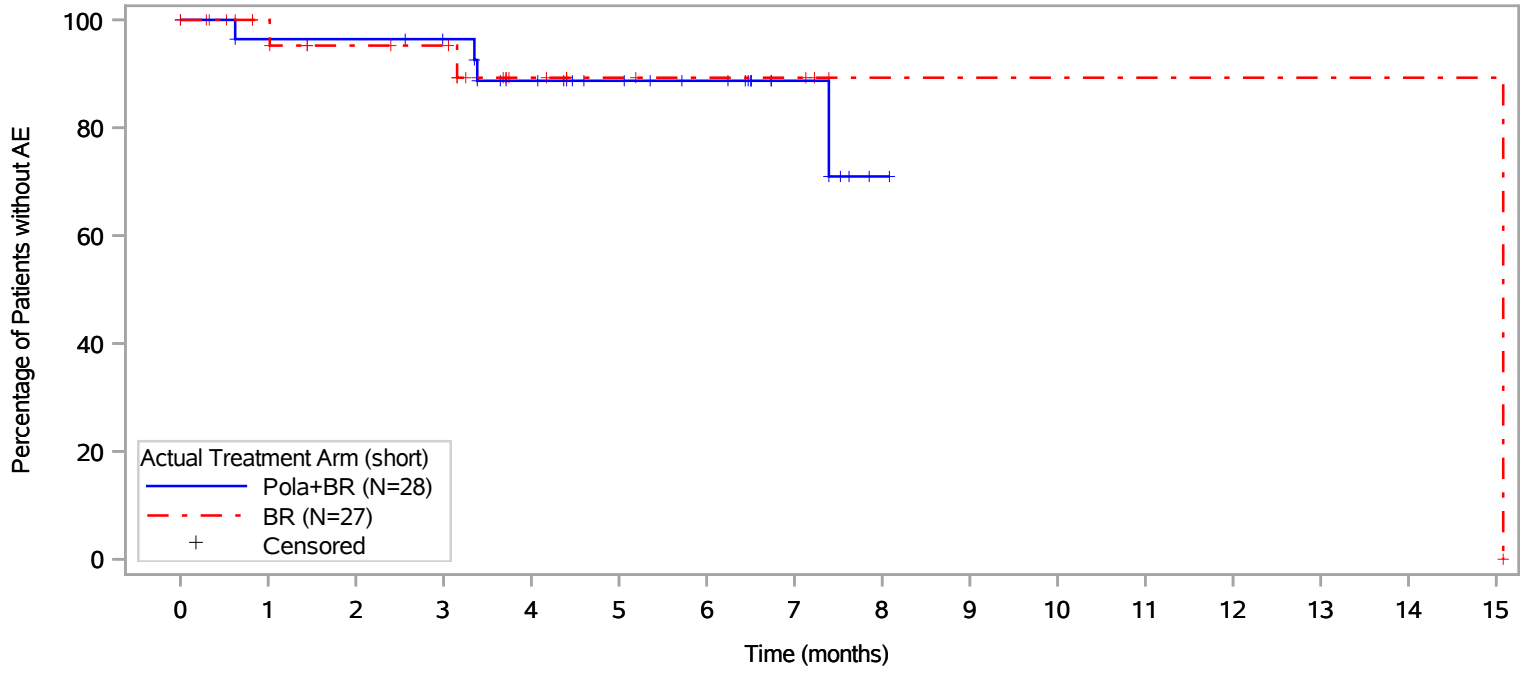
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk																
Pola+BR (N=28)	28	27	27	25	21	16	13	5	1	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	18	17	8	5	4	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=28)	0	0	0	2	4	9	12	20	23	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	9	17	20	21	21	24	24	24	24	24	24	24	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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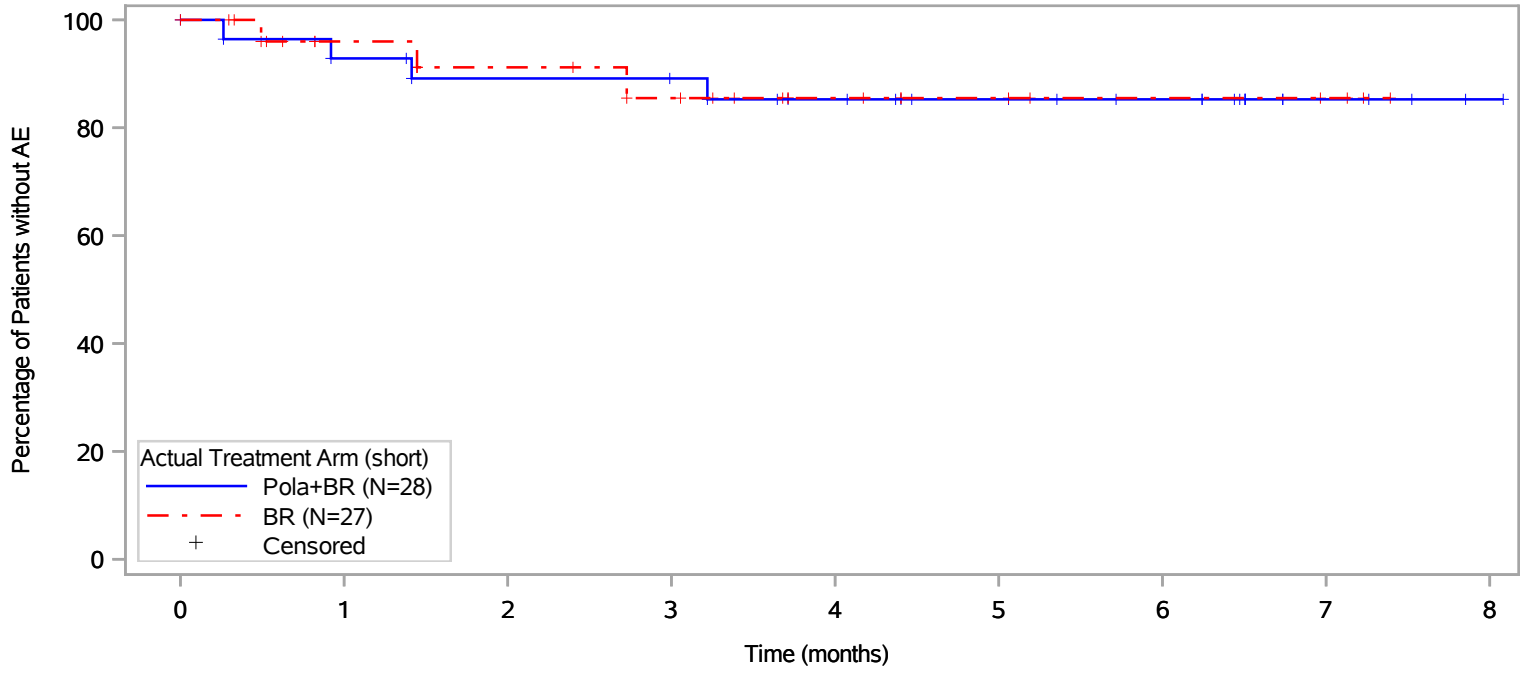
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA

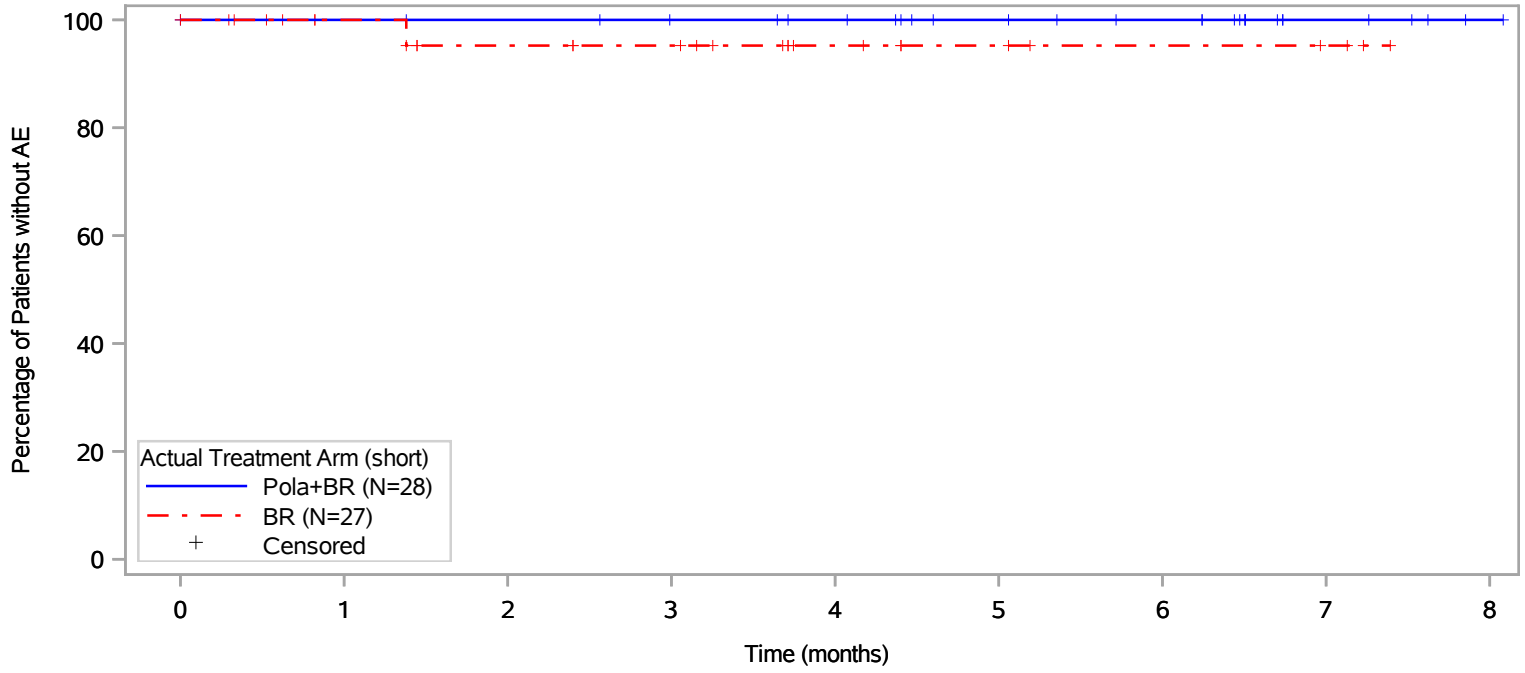


Patients at risk									
Pola+BR (N=28)	28	26	24	23	20	16	13	4	1
BR (N=27)	27	20	17	15	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	8	11	20	23
BR (N=27)	0	6	8	9	15	18	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPH NODE PAIN



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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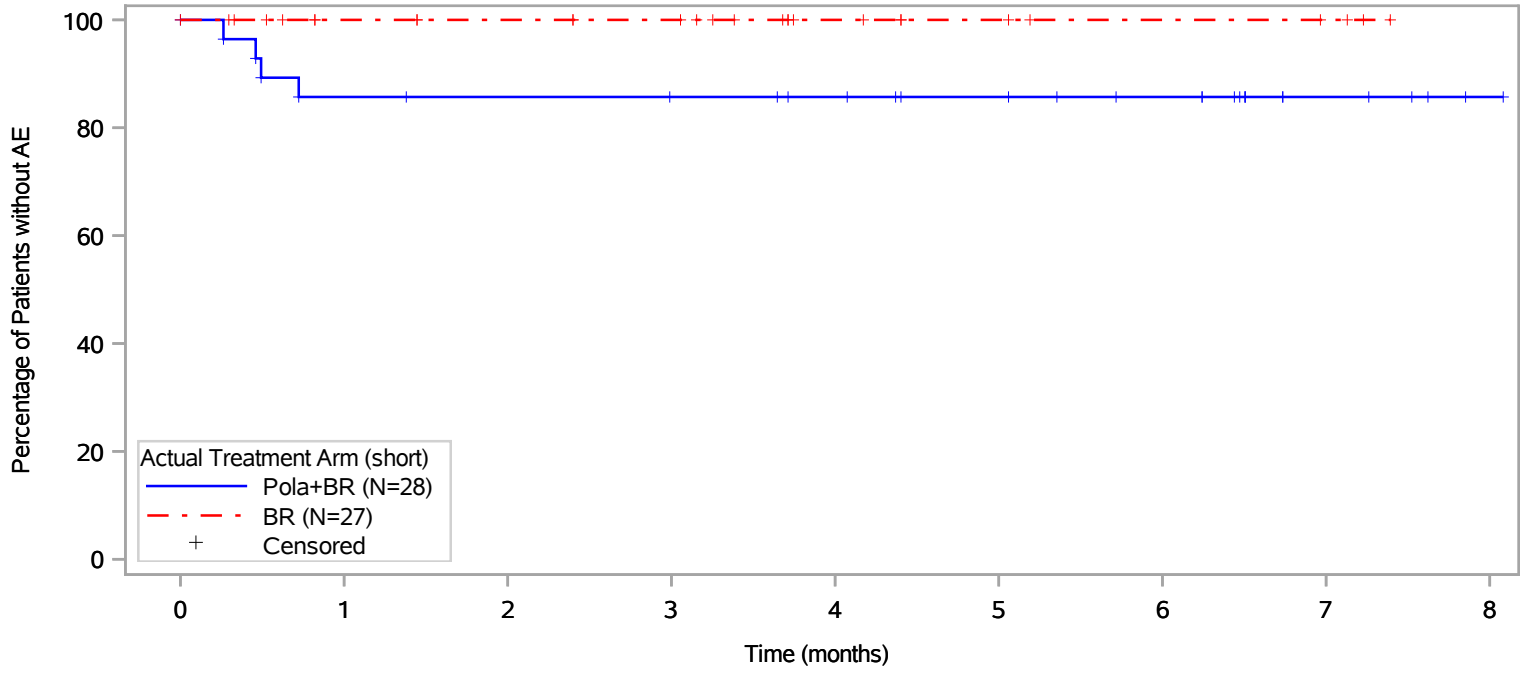
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA

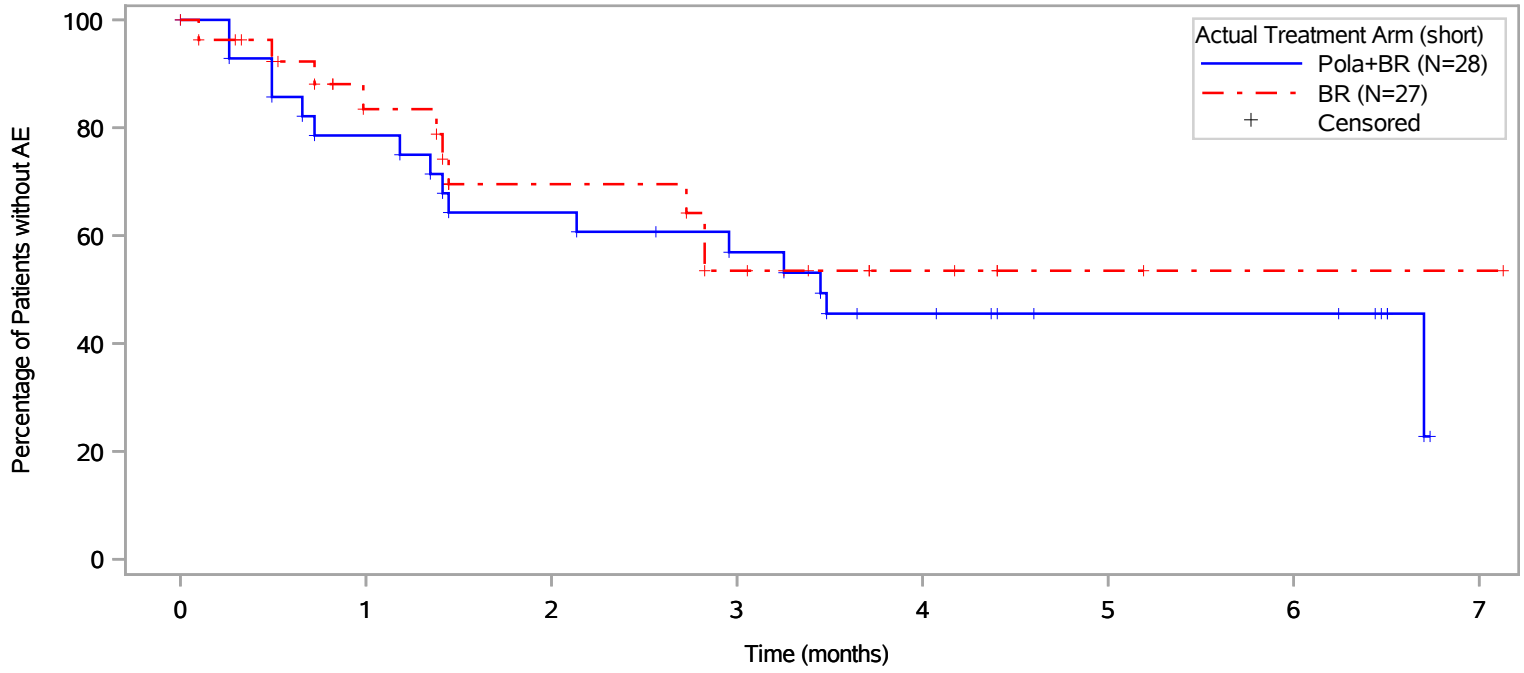


Patients at risk									
Pola+BR (N=28)	28	24	23	22	20	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	7	10	19	23
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk								
Pola+BR (N=28)	28	22	18	15	11	7	7	NE
BR (N=27)	27	18	13	10	5	2	1	1
Patients censored								
Pola+BR (N=28)	0	0	0	1	2	6	6	NE
BR (N=27)	0	5	7	7	12	15	16	16

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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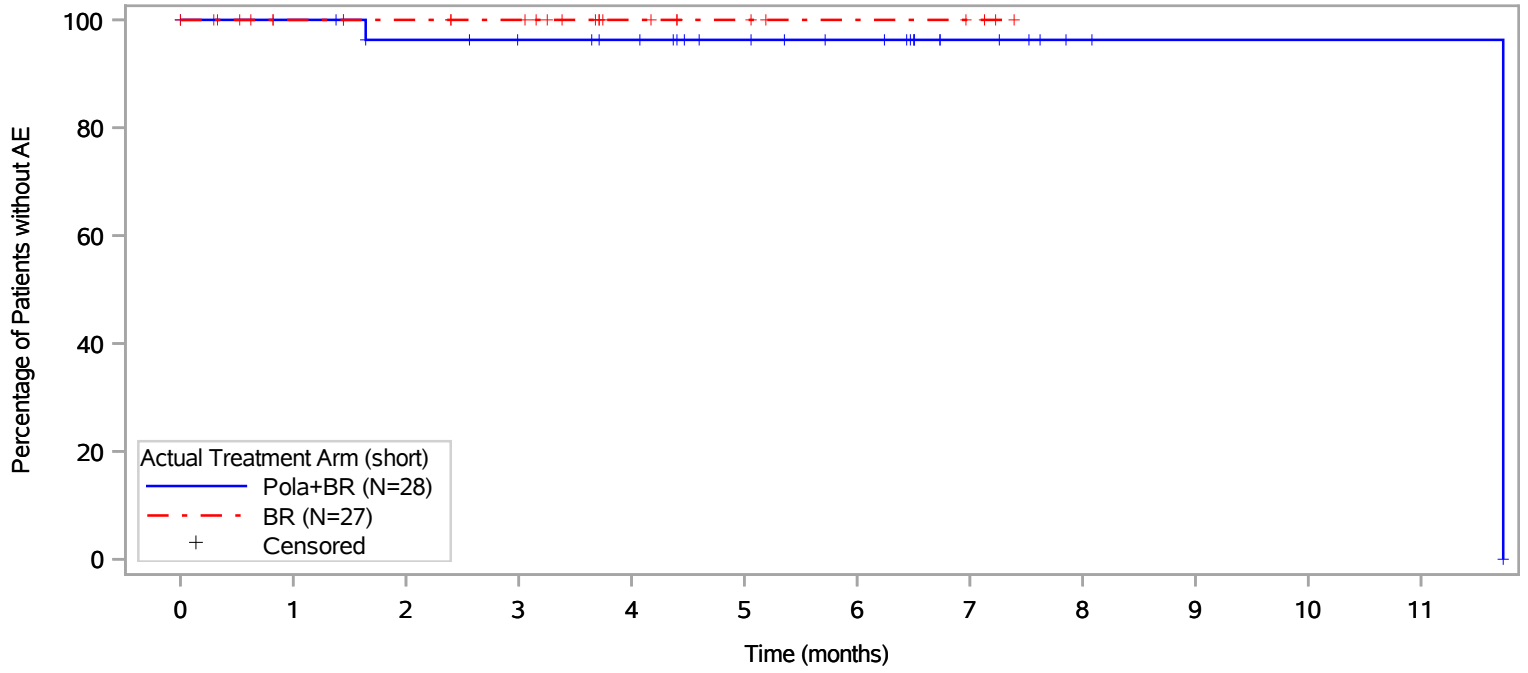
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA

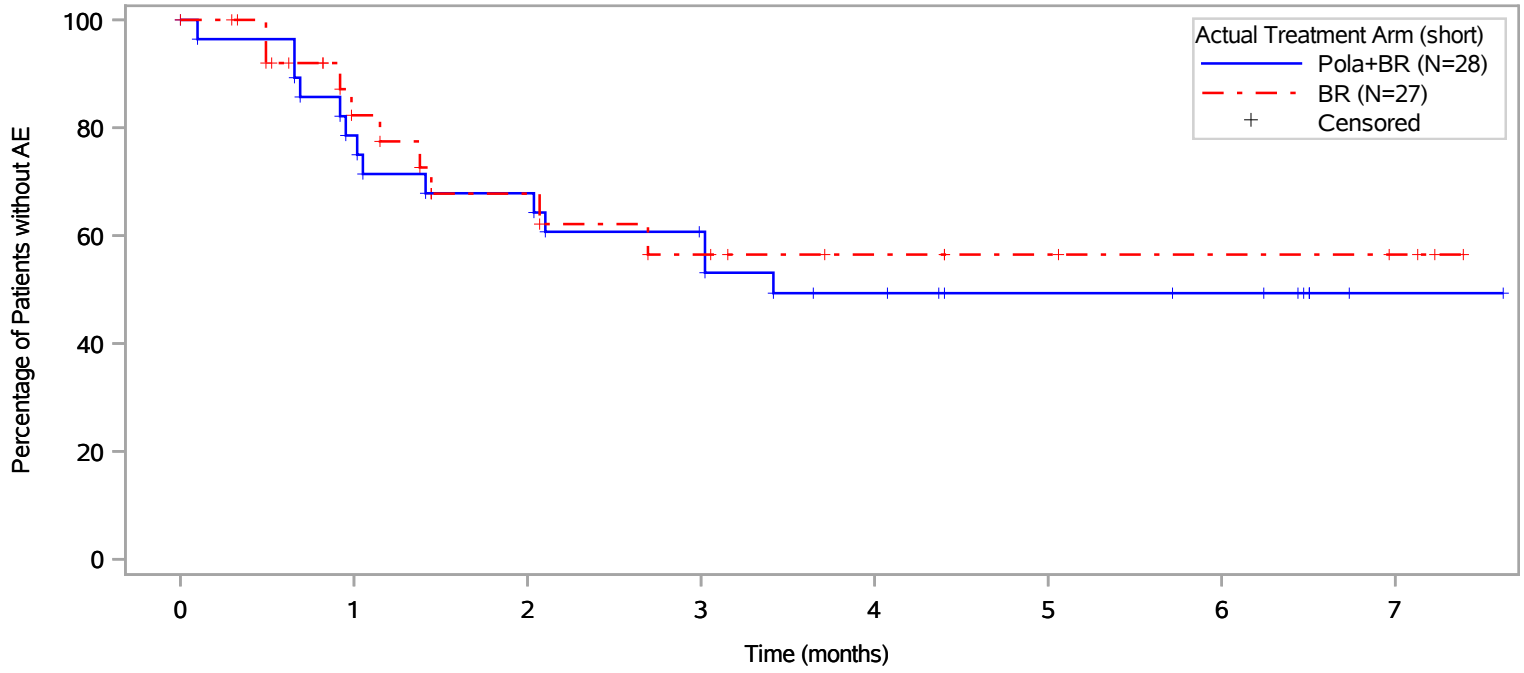


Patients at risk												
Pola+BR (N=28)	28	28	26	24	22	17	14	6	2	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=28)	0	0	1	3	5	10	13	21	25	26	26	26
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk								
Pola+BR (N=28)	28	22	19	16	12	9	8	1
BR (N=27)	27	17	12	10	7	5	4	3
Patients censored								
Pola+BR (N=28)	0	0	0	1	2	5	6	13
BR (N=27)	0	6	8	8	11	13	14	15

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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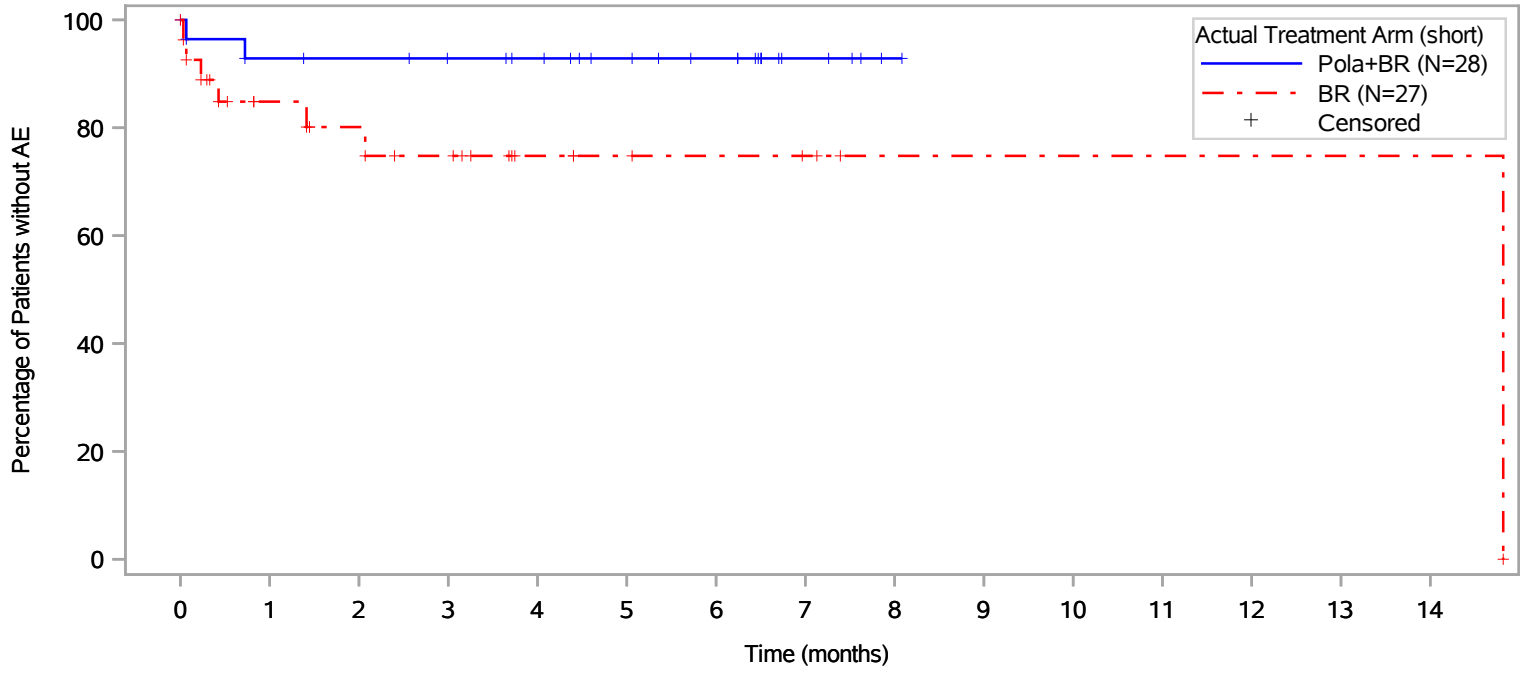
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk															
Pola+BR (N=28)	28	26	25	23	21	17	14	5	1	NE	NE	NE	NE	NE	NE
BR (N=27)	27	18	15	13	7	5	4	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	9	12	21	25	NE	NE	NE	NE	NE	NE
BR (N=27)	0	5	7	8	14	16	17	18	20	20	20	20	20	20	20

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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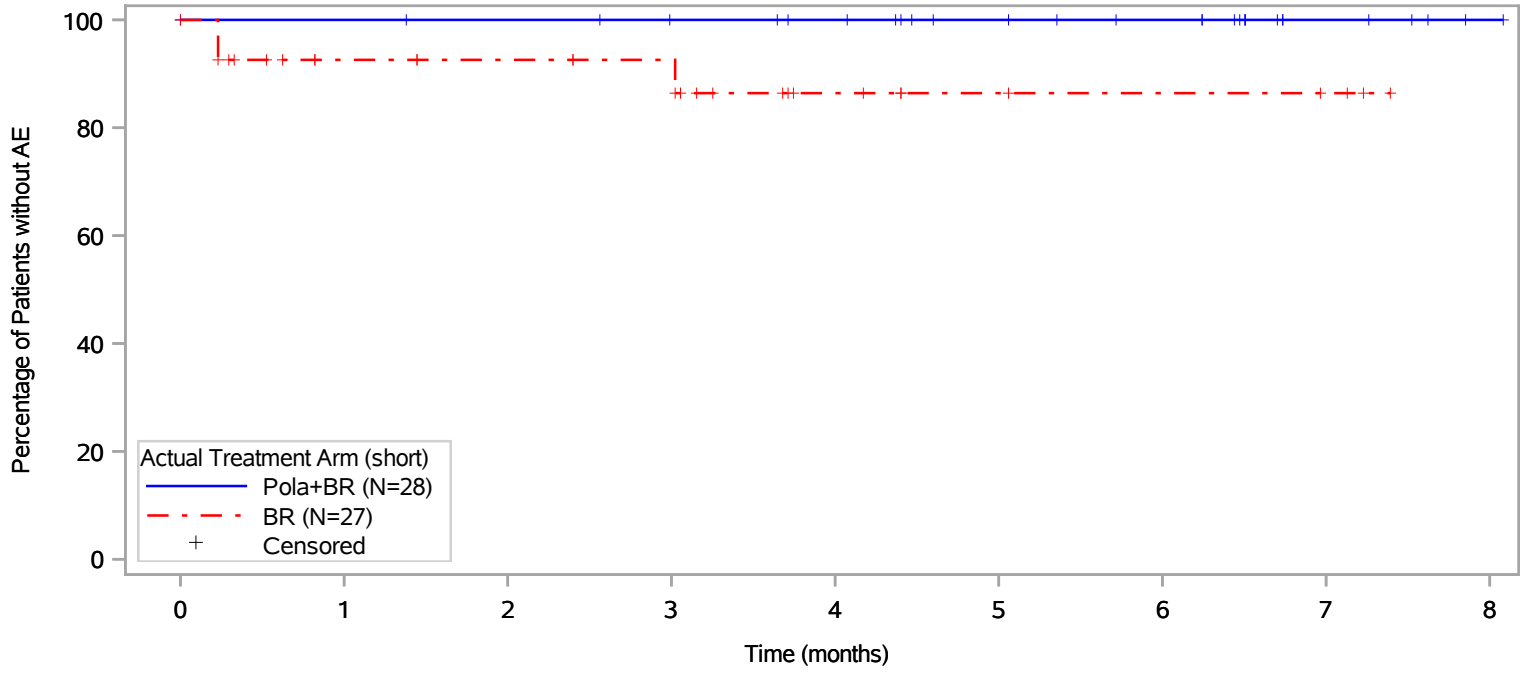
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	19	17	15	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	16	19	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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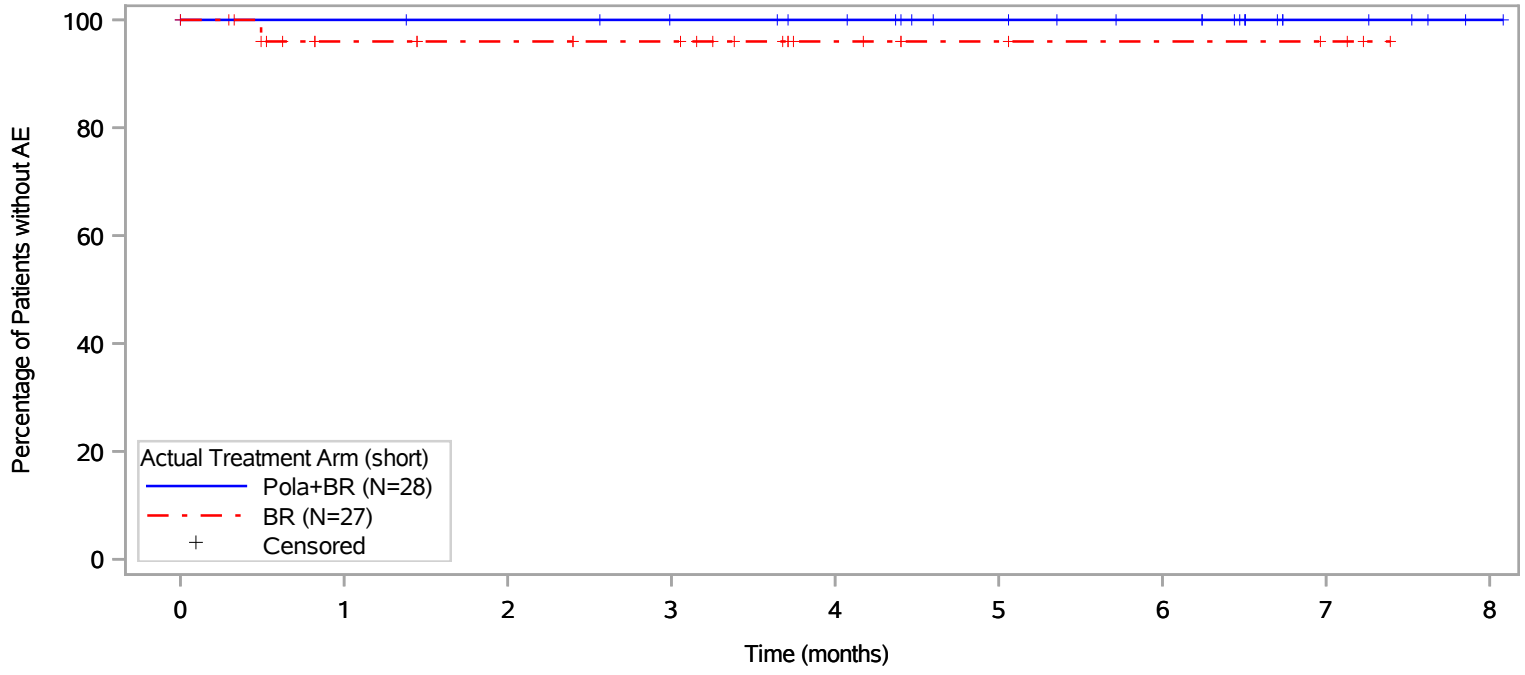
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FLUTTER



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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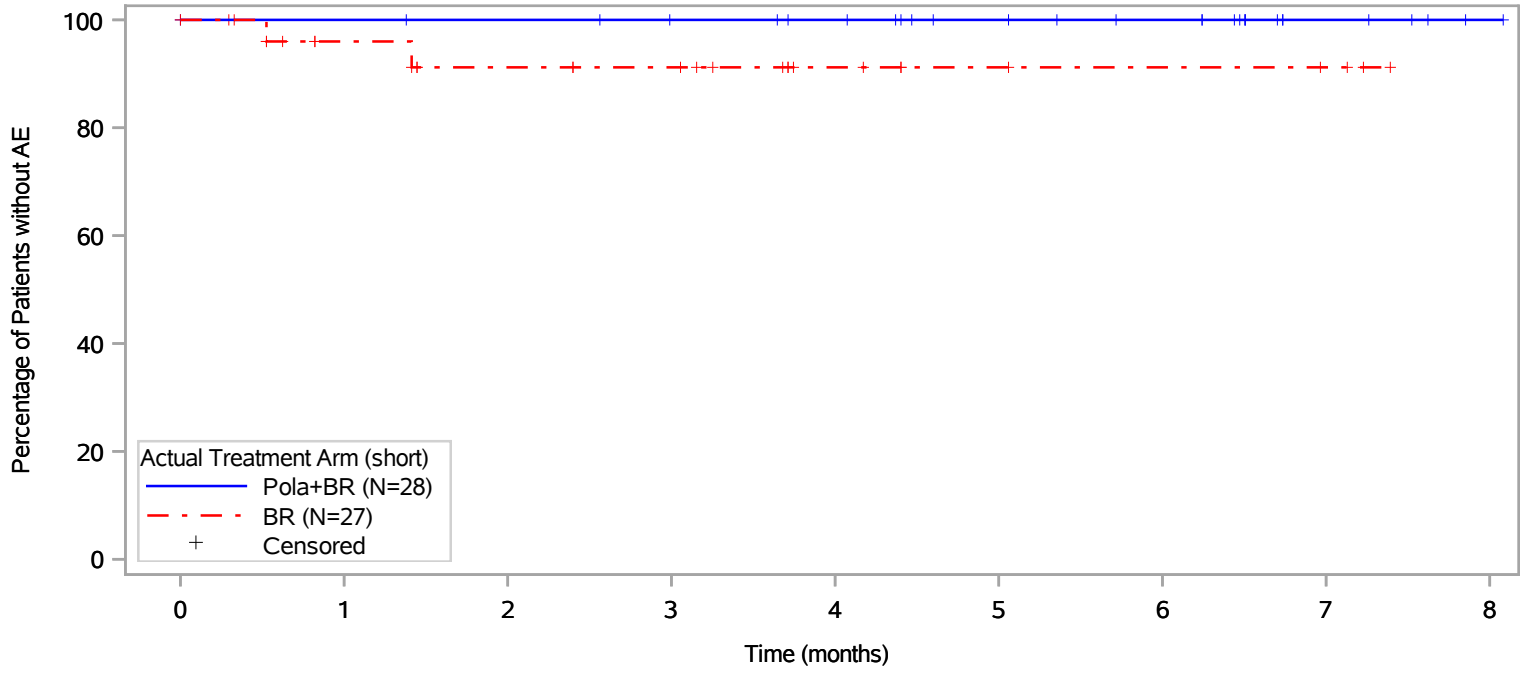
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

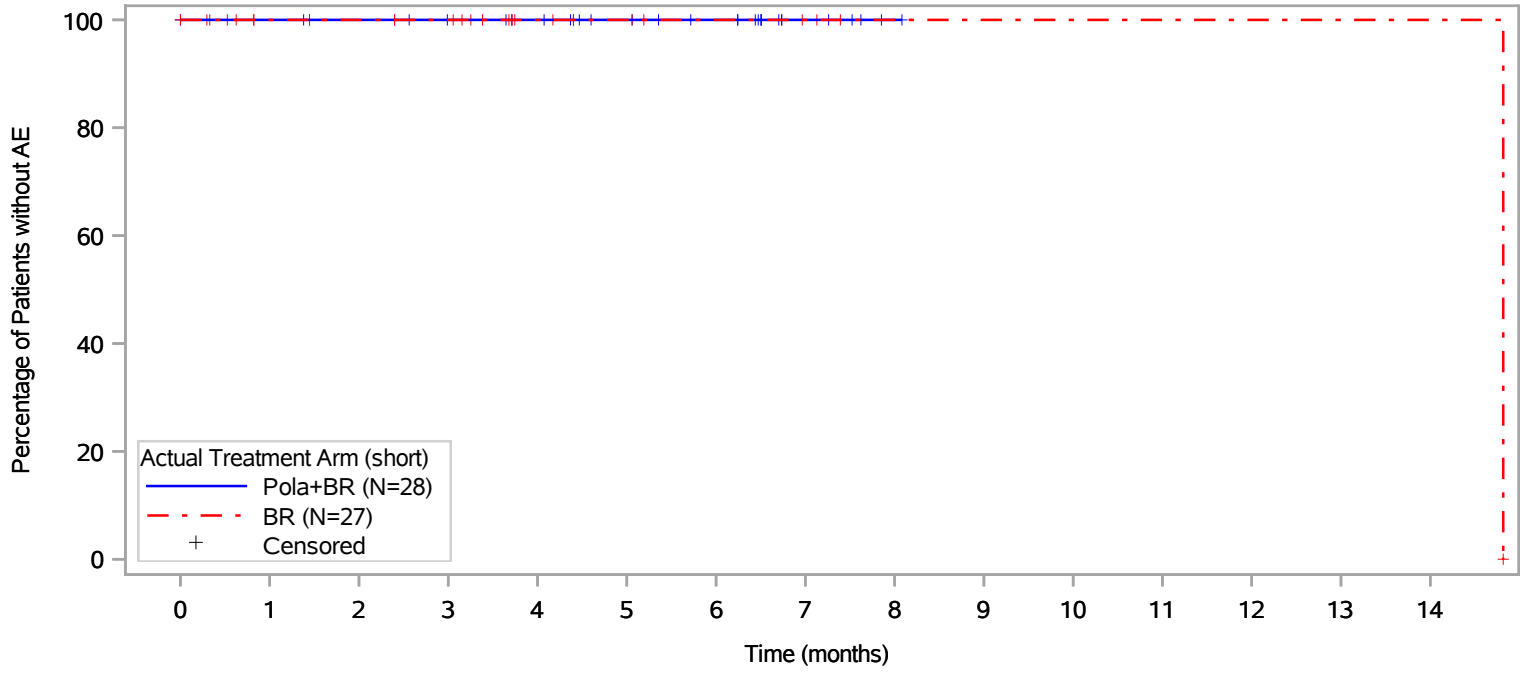
CARDIAC DISORDERS, ATRIOVENTRICULAR BLOCK FIRST DEGREE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	17	15	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, CARDIAC FAILURE



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	24	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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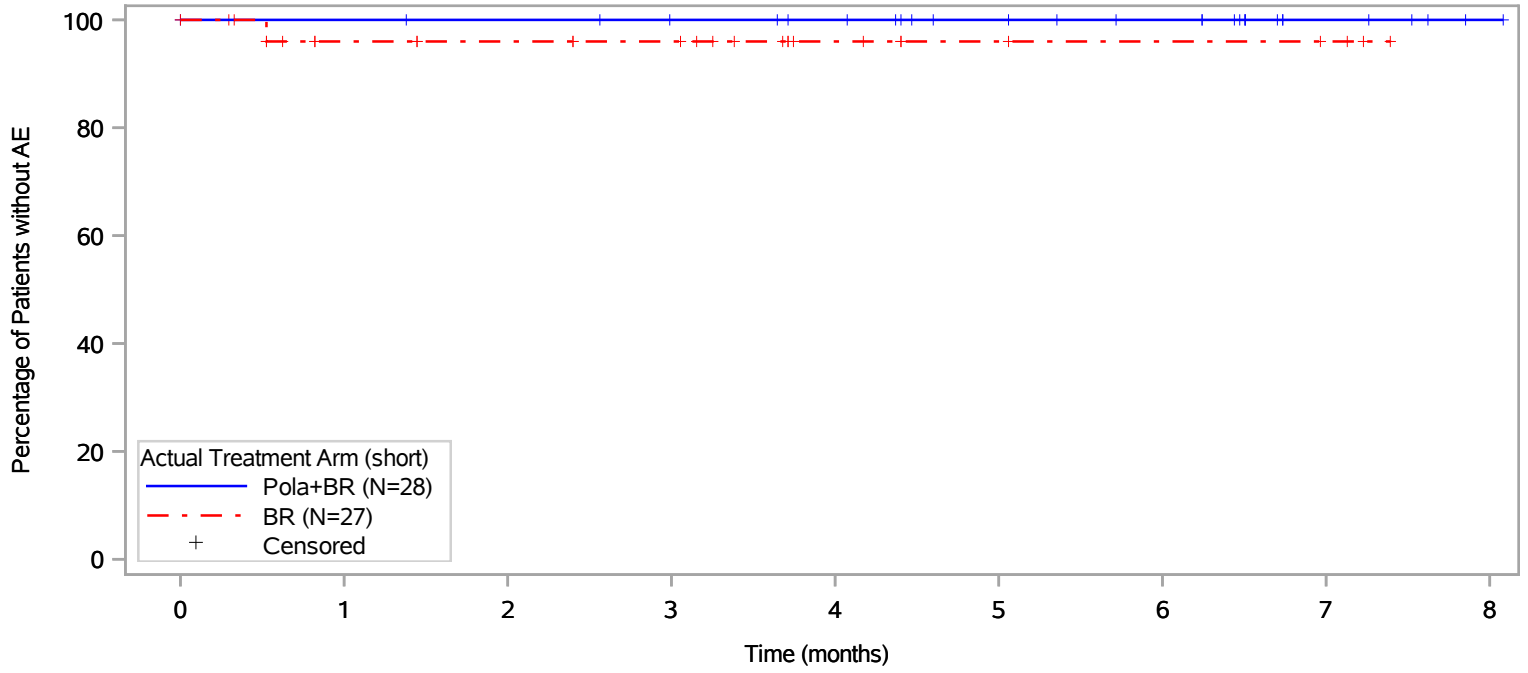
01DEC2022 21:22

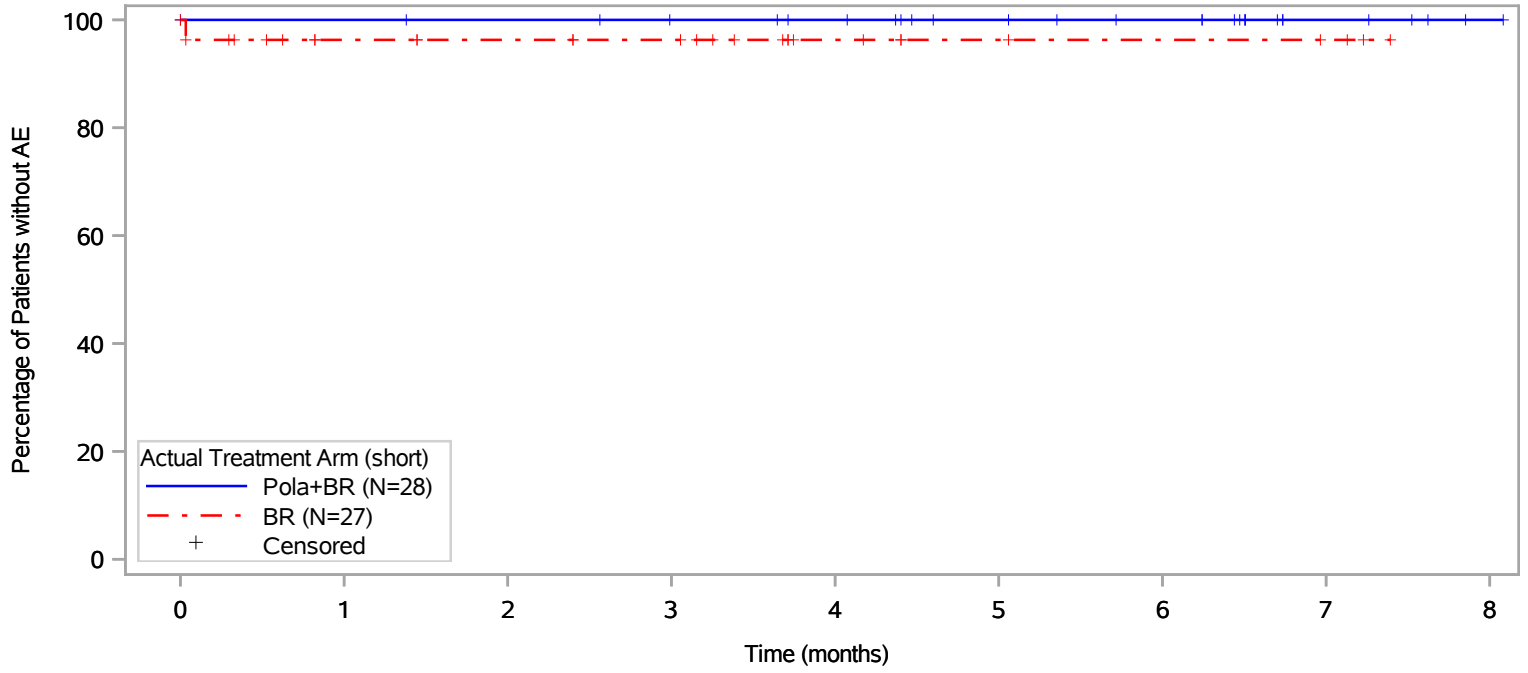
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SINUS TACHYCARDIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

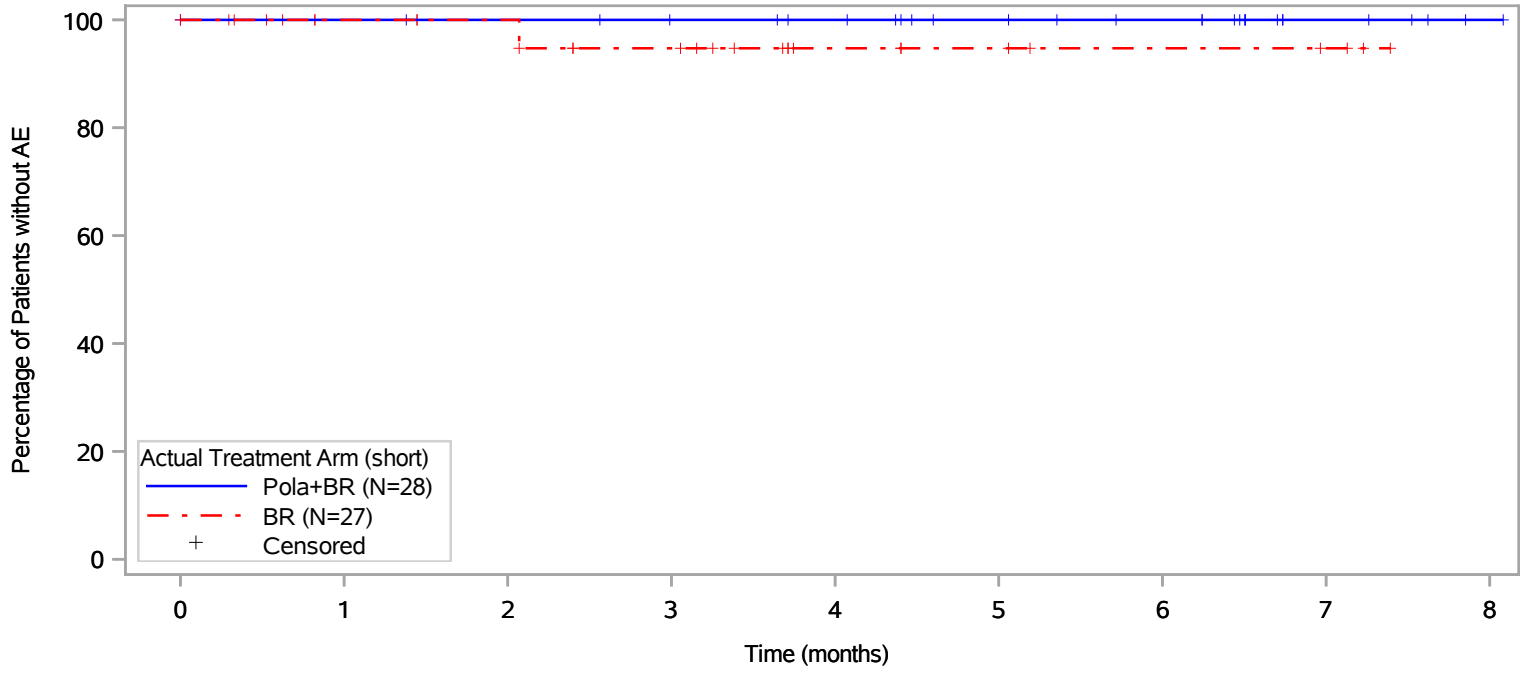
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SUPRAVENTRICULAR TACHYCARDIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYARRHYTHMIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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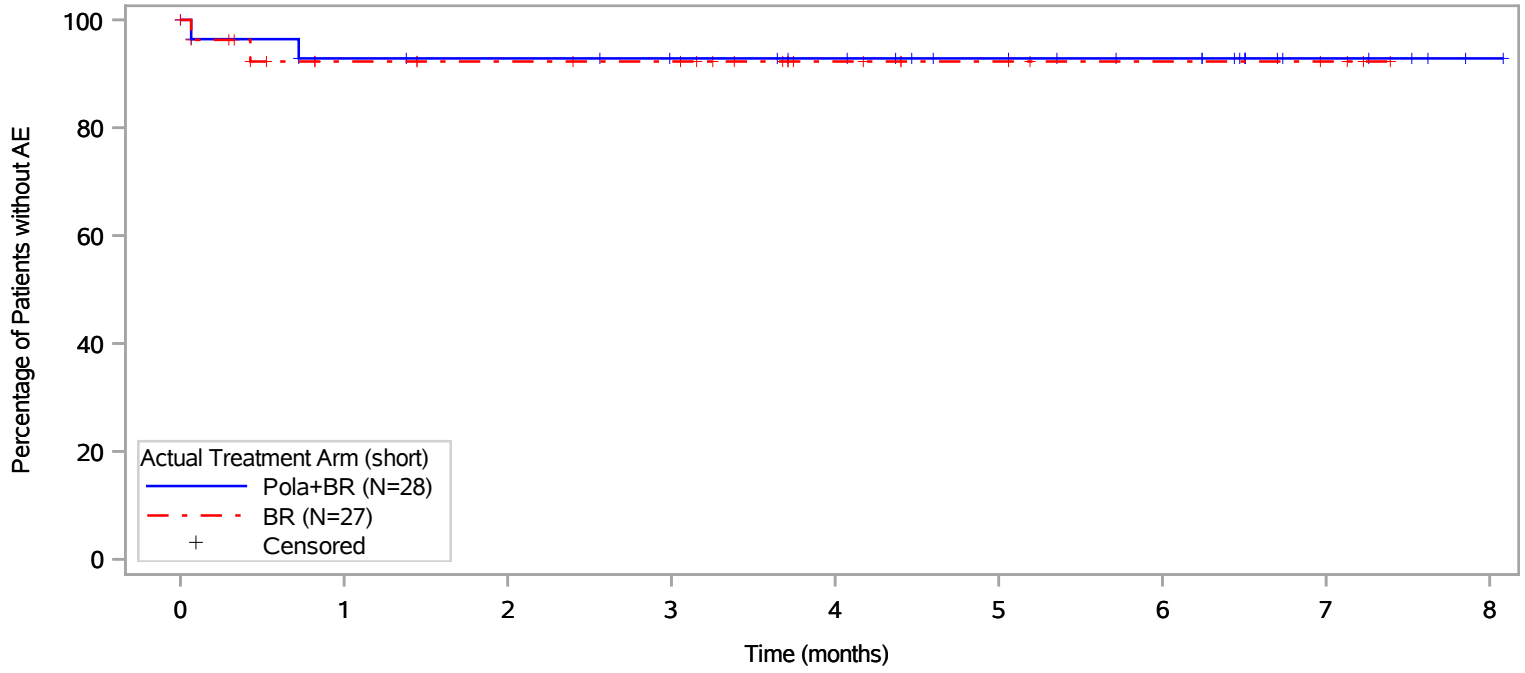
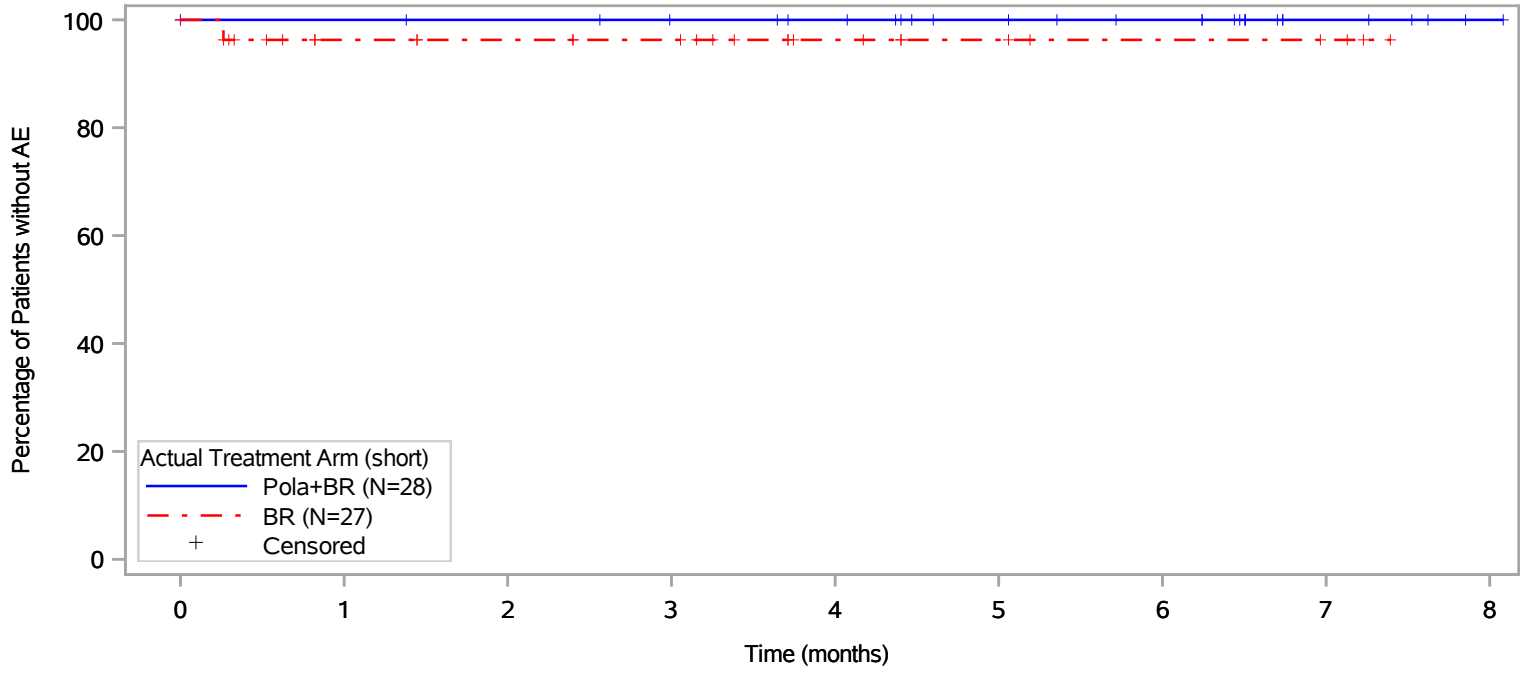
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=28)	28	26	25	23	21	17	14	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	21	25
BR (N=27)	0	5	7	8	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

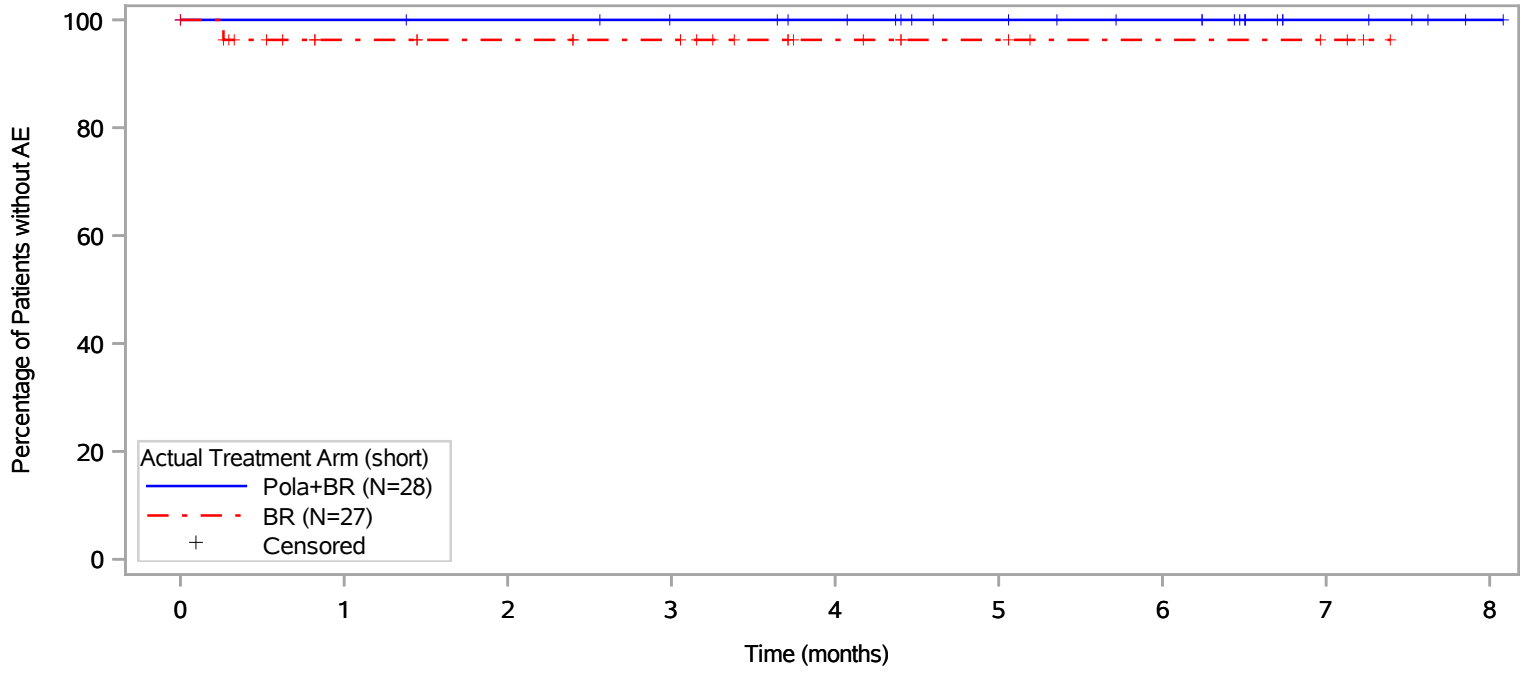
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, TINNITUS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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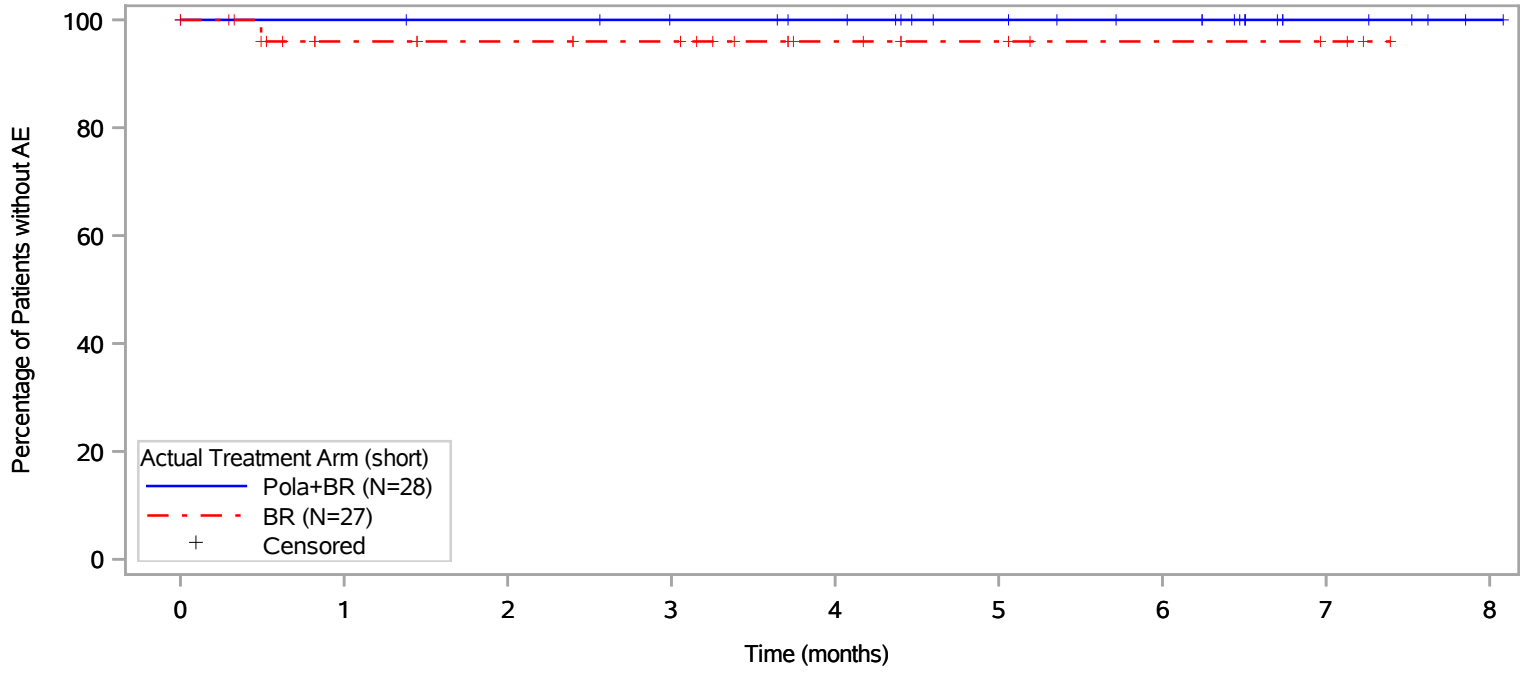
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

EYE DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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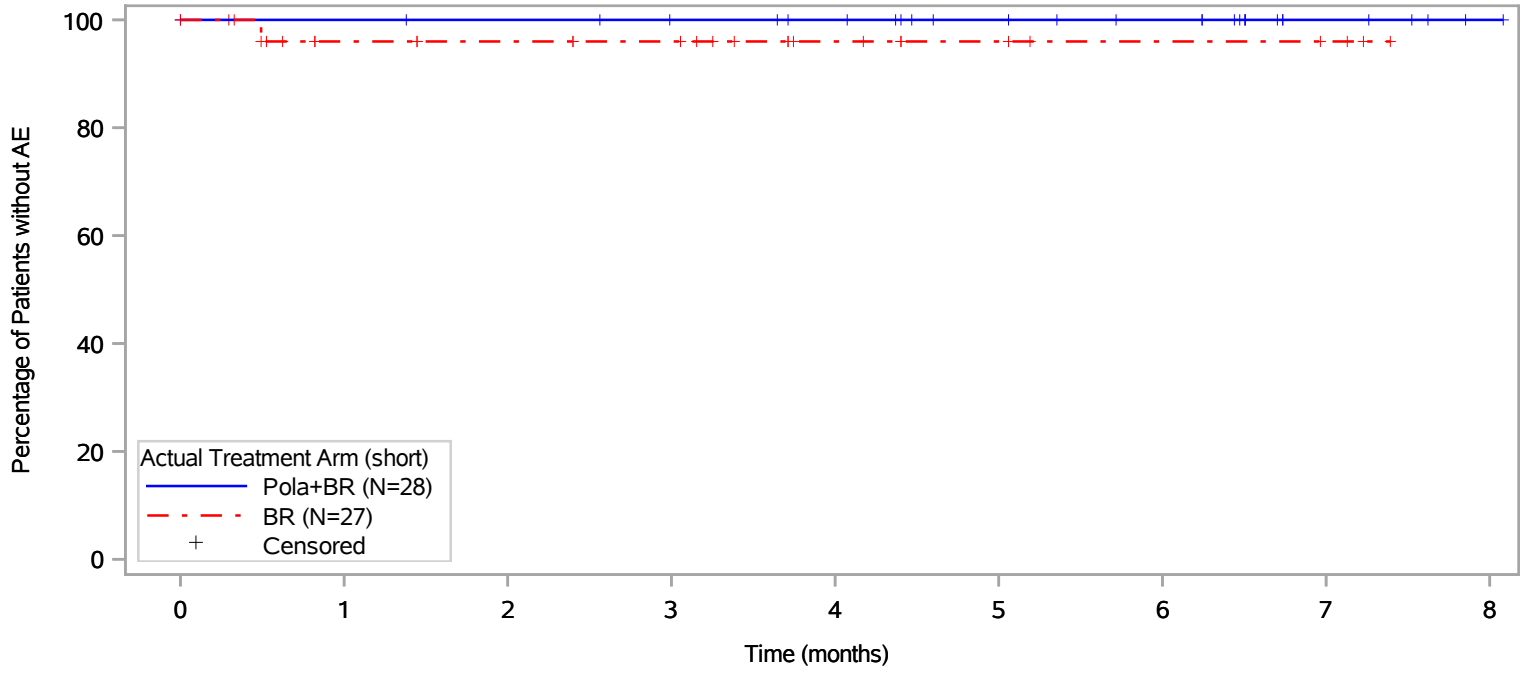
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EYE DISORDERS, ASTHENOPIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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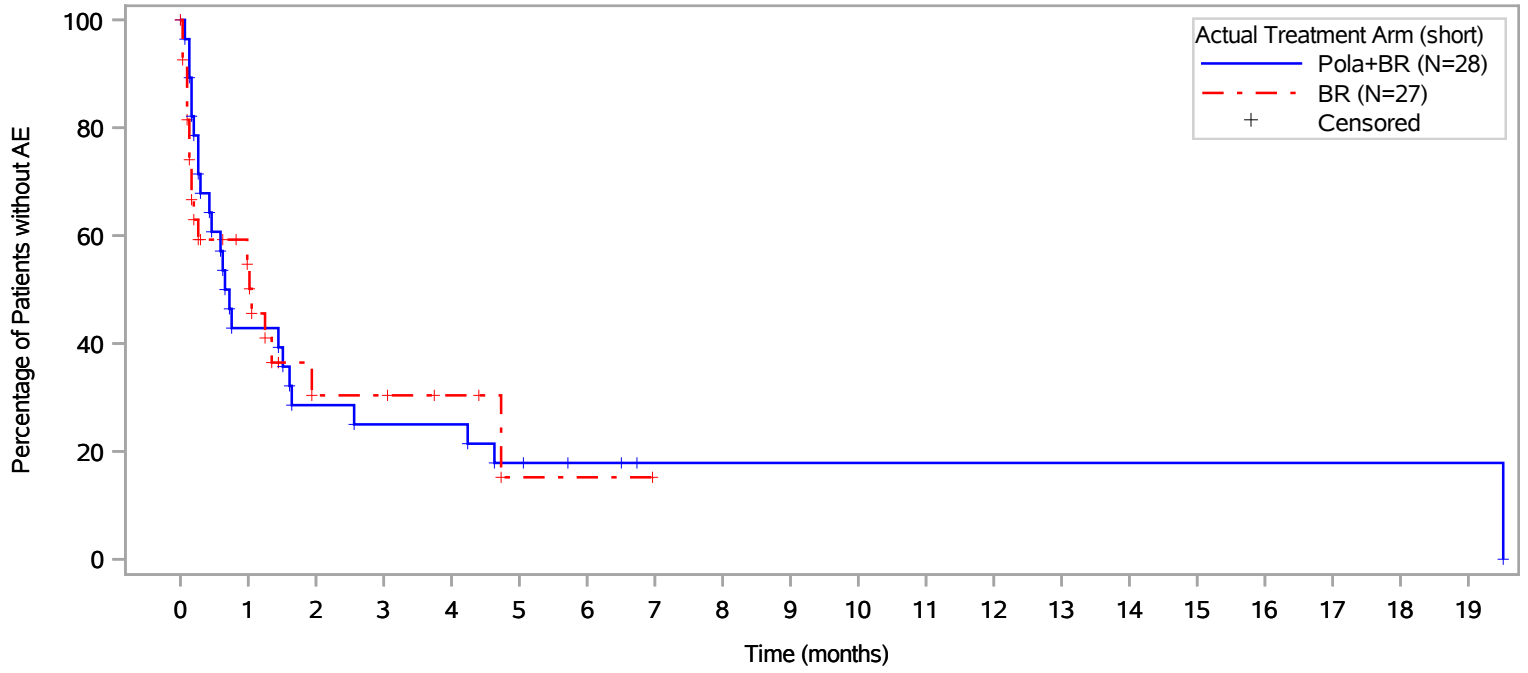
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk																				
Pola+BR (N=28)	28	12	8	7	7	5	3	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	12	5	5	3	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	0	0	0	0	2	4	4	4	4	4	4	4	4	4	4	4	4	4
BR (N=27)	0	3	5	5	7	8	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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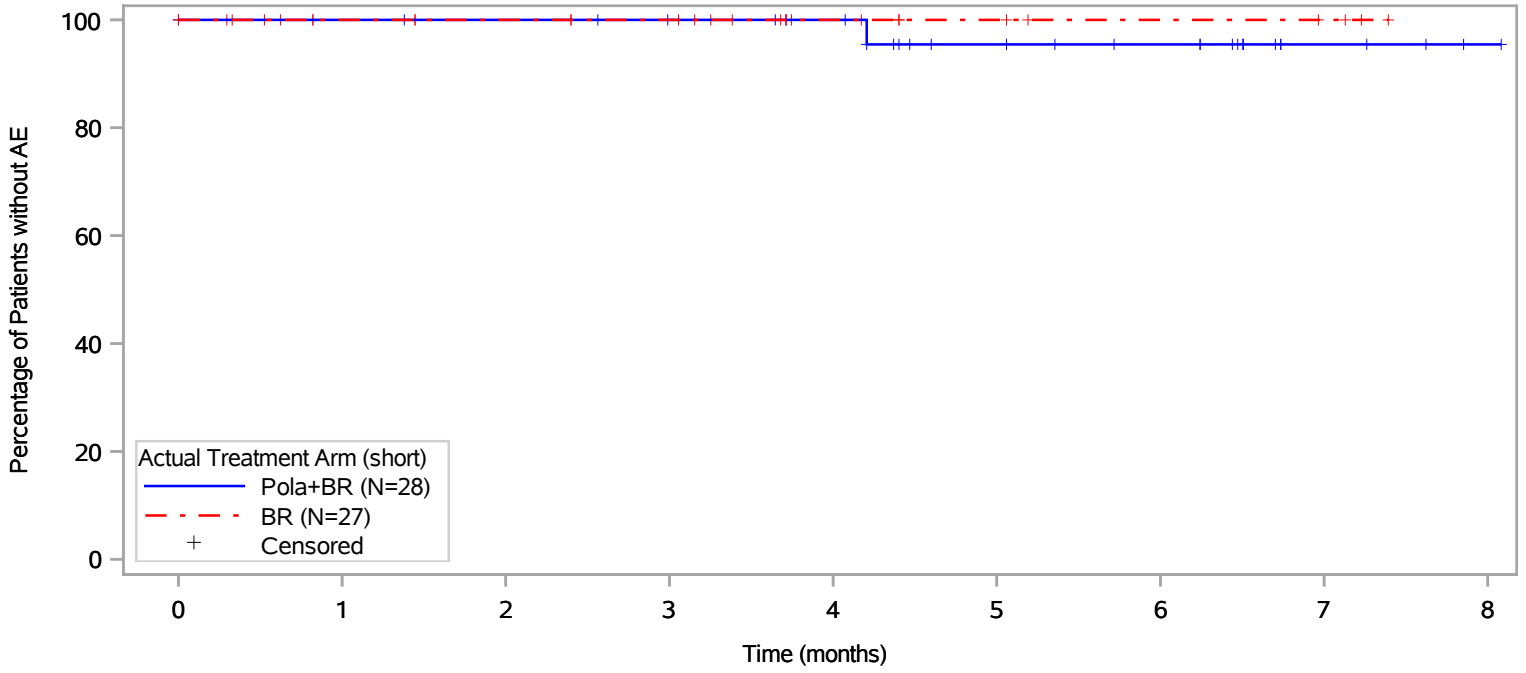
01DEC2022 21:22

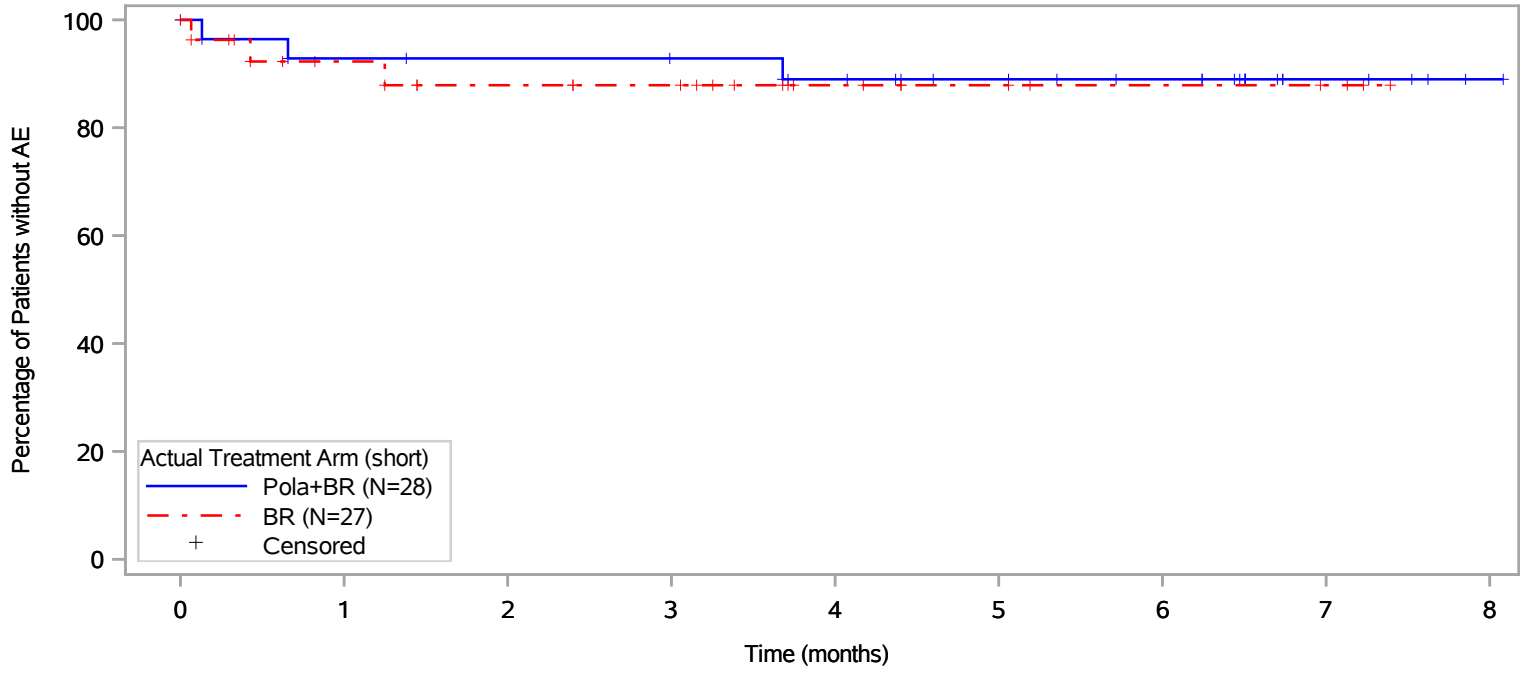
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL DISTENSION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=28)	28	26	25	24	22	18	15	5	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	3	7	10	20	24
BR (N=27)	0	4	6	8	15	18	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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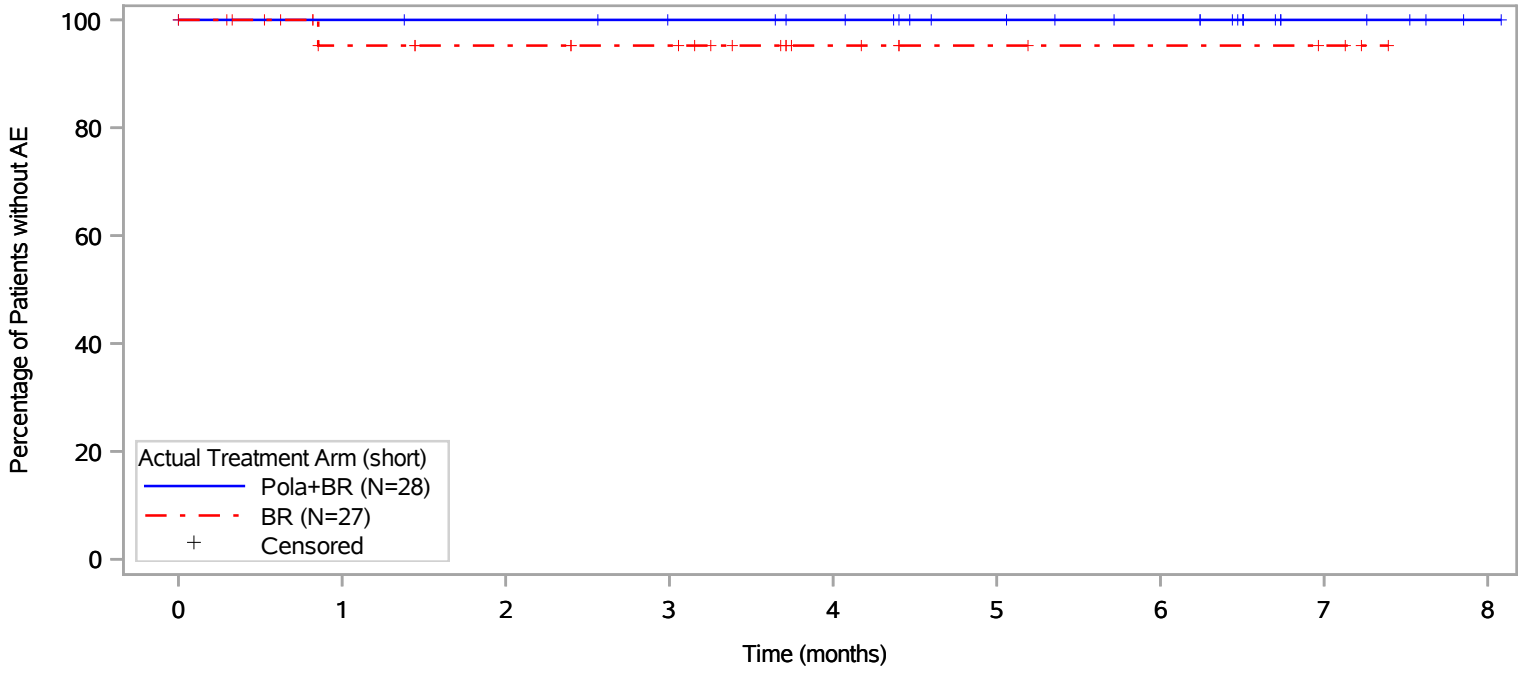
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

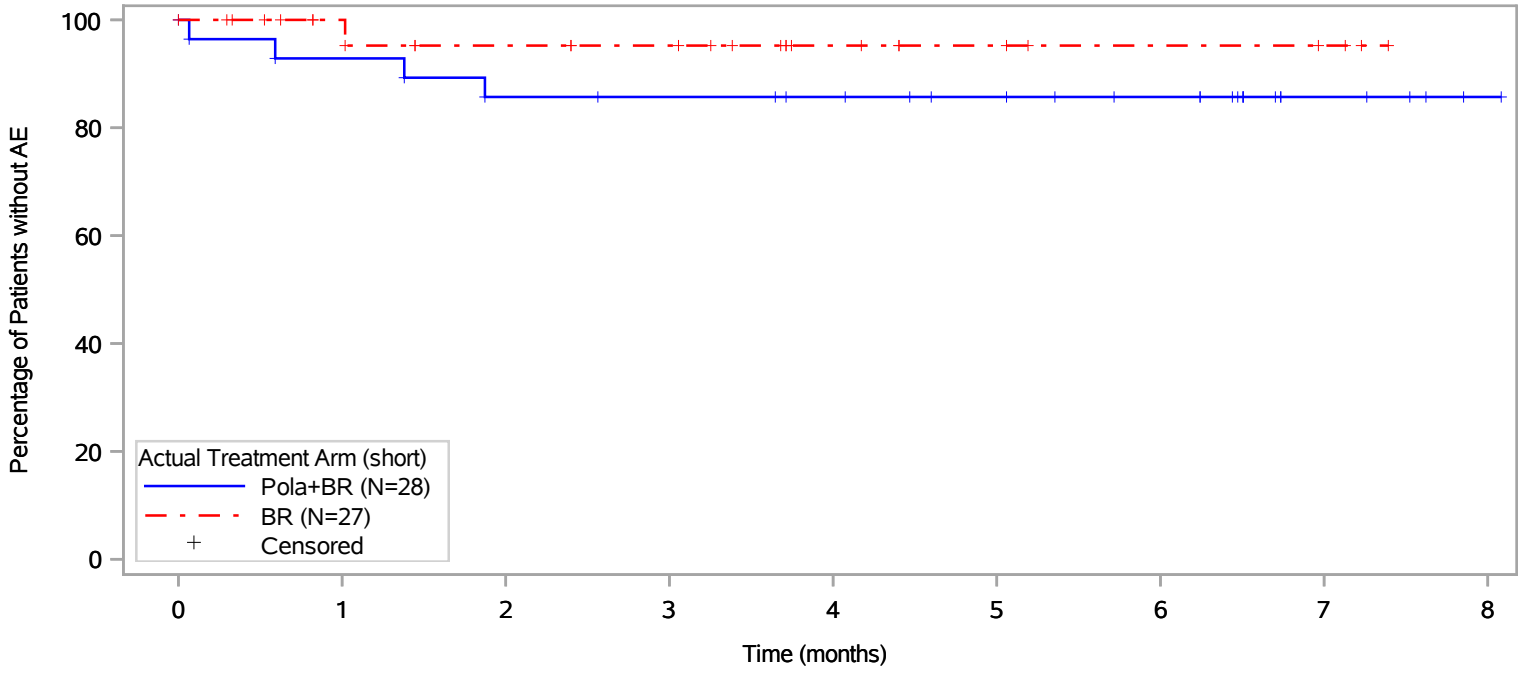
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN LOWER



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN UPPER



Patients at risk									
Pola+BR (N=28)	28	26	24	23	21	18	15	5	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	3	6	9	19	23
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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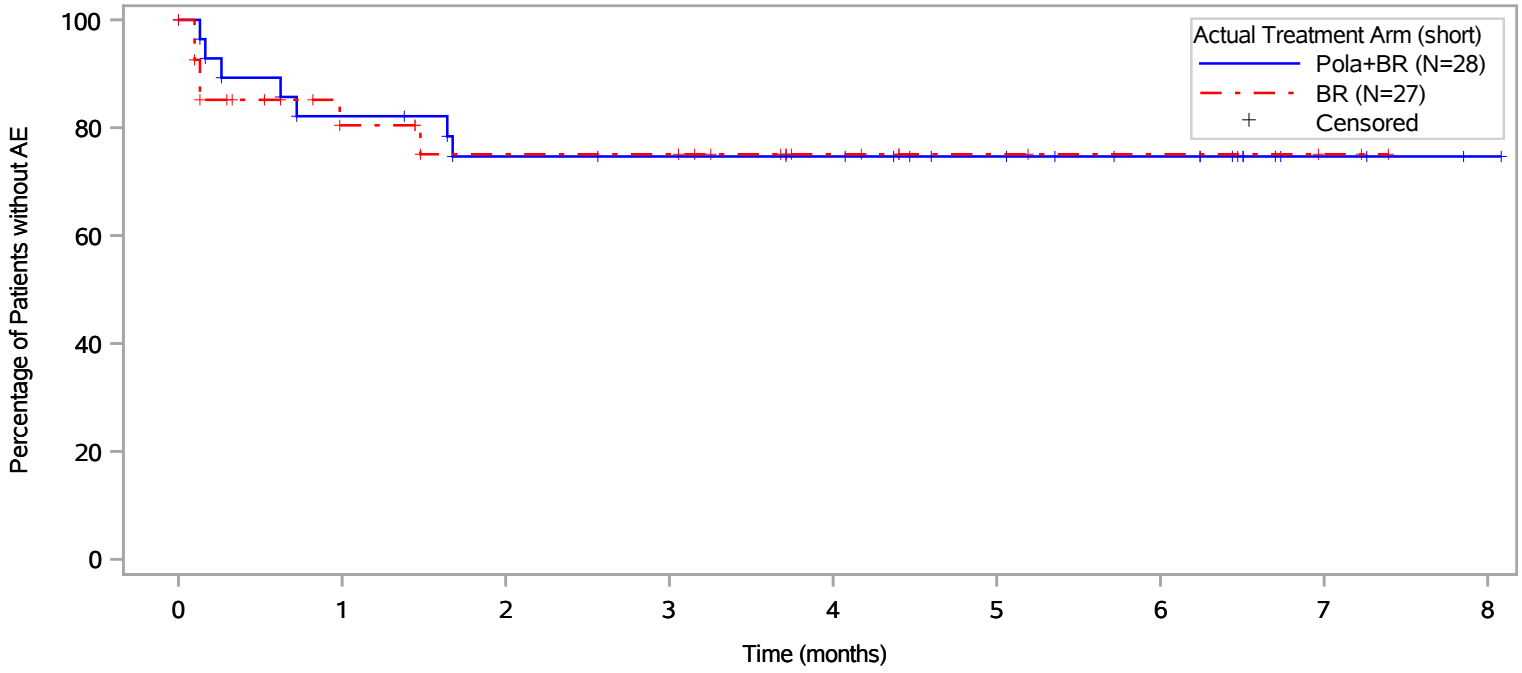
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk									
Pola+BR (N=28)	28	23	20	19	18	14	11	3	1
BR (N=27)	27	17	14	14	7	4	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	3	7	10	18	20
BR (N=27)	0	5	7	7	14	17	18	19	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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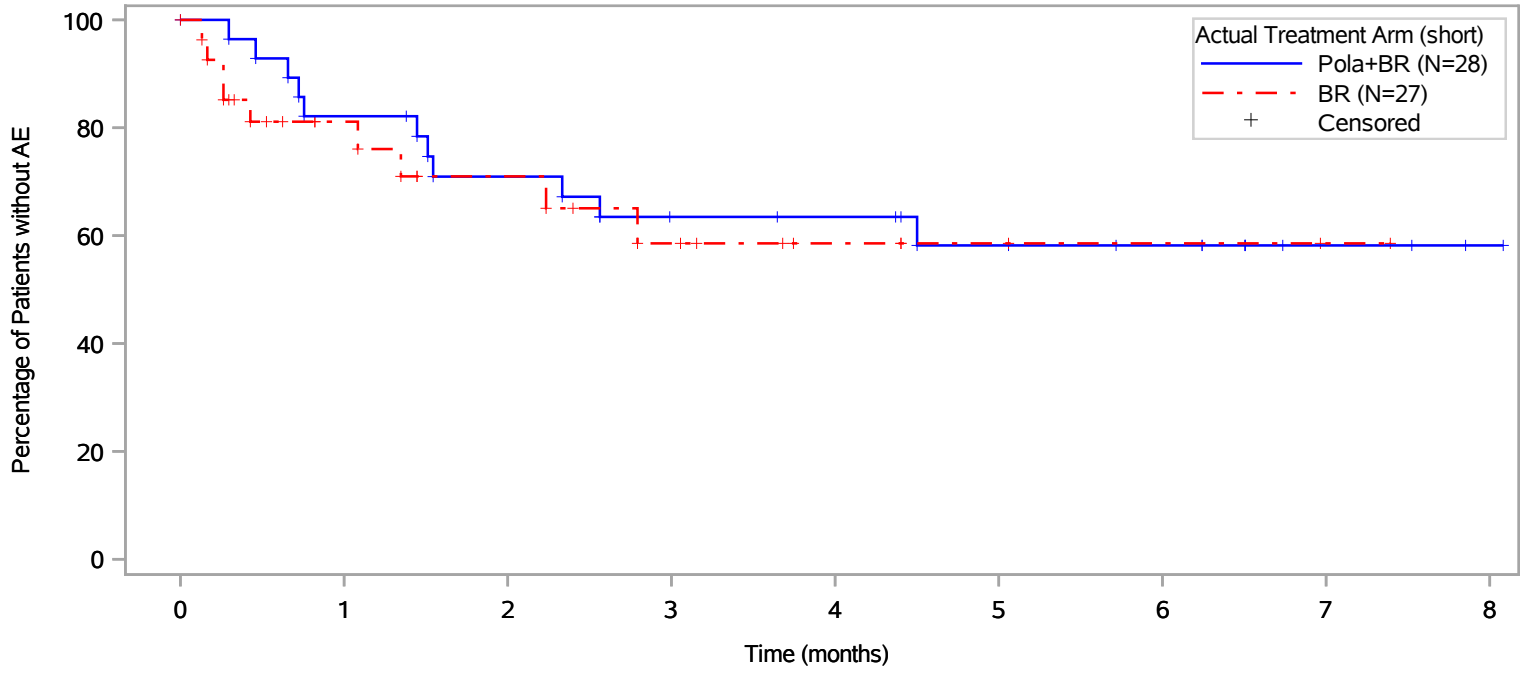
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



Patients at risk									
Pola+BR (N=28)	28	23	19	15	14	11	9	3	1
BR (N=27)	27	16	12	9	5	3	2	1	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	6	8	14	16
BR (N=27)	0	6	8	9	13	15	16	17	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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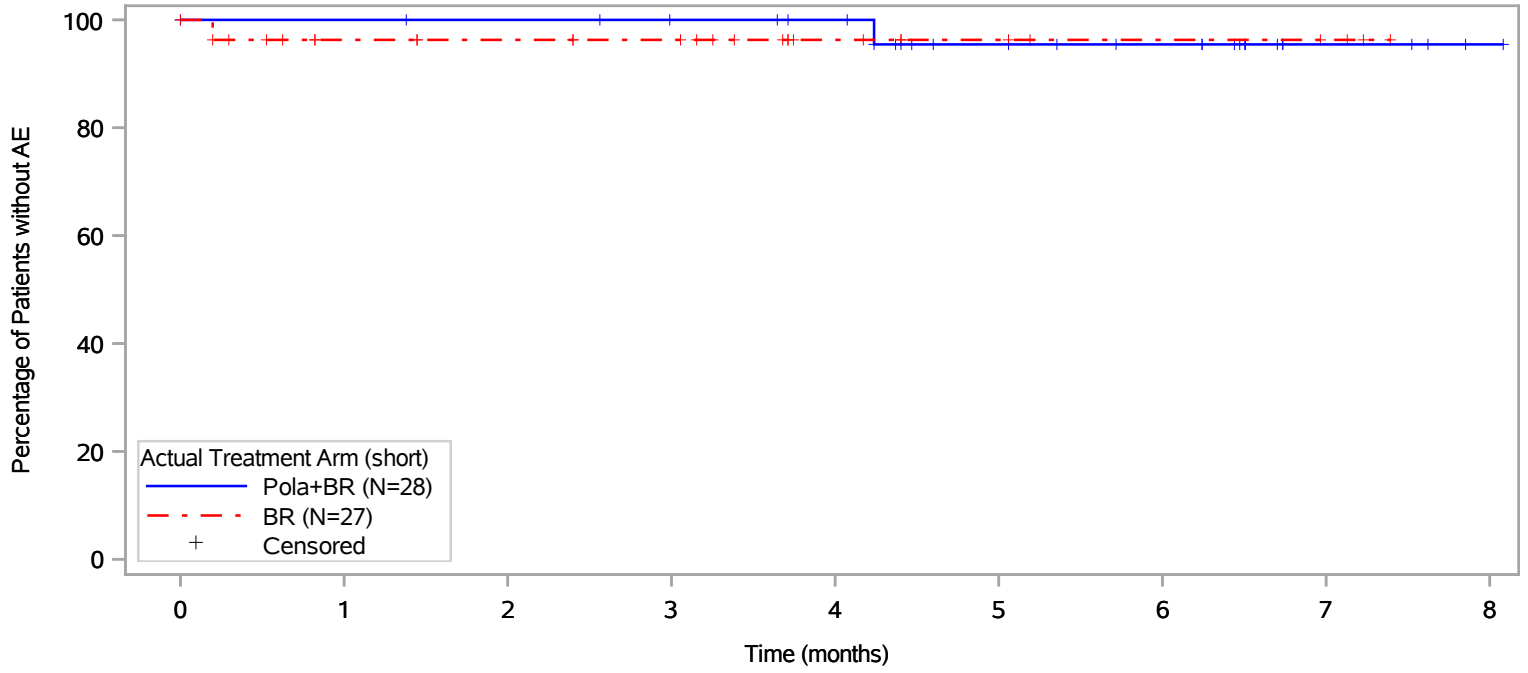
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DRY MOUTH



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	5	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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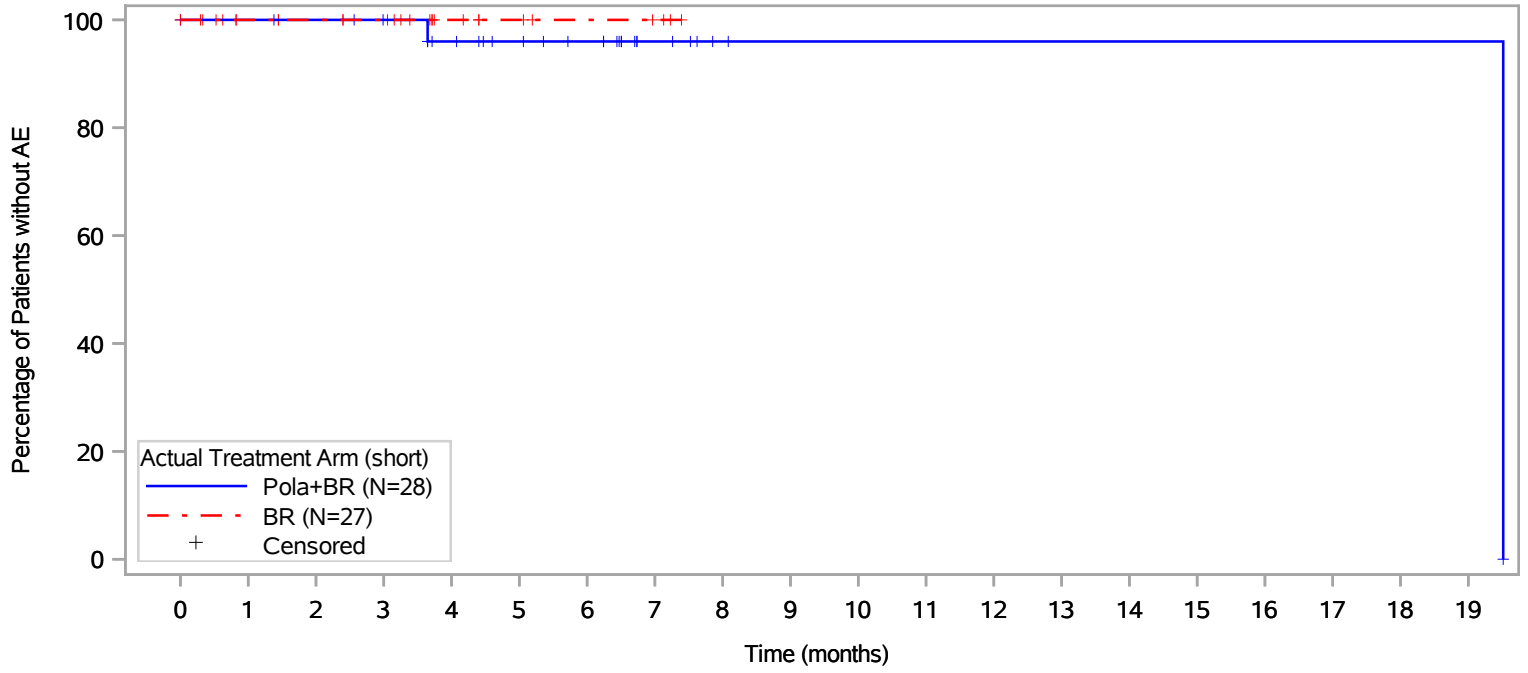
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

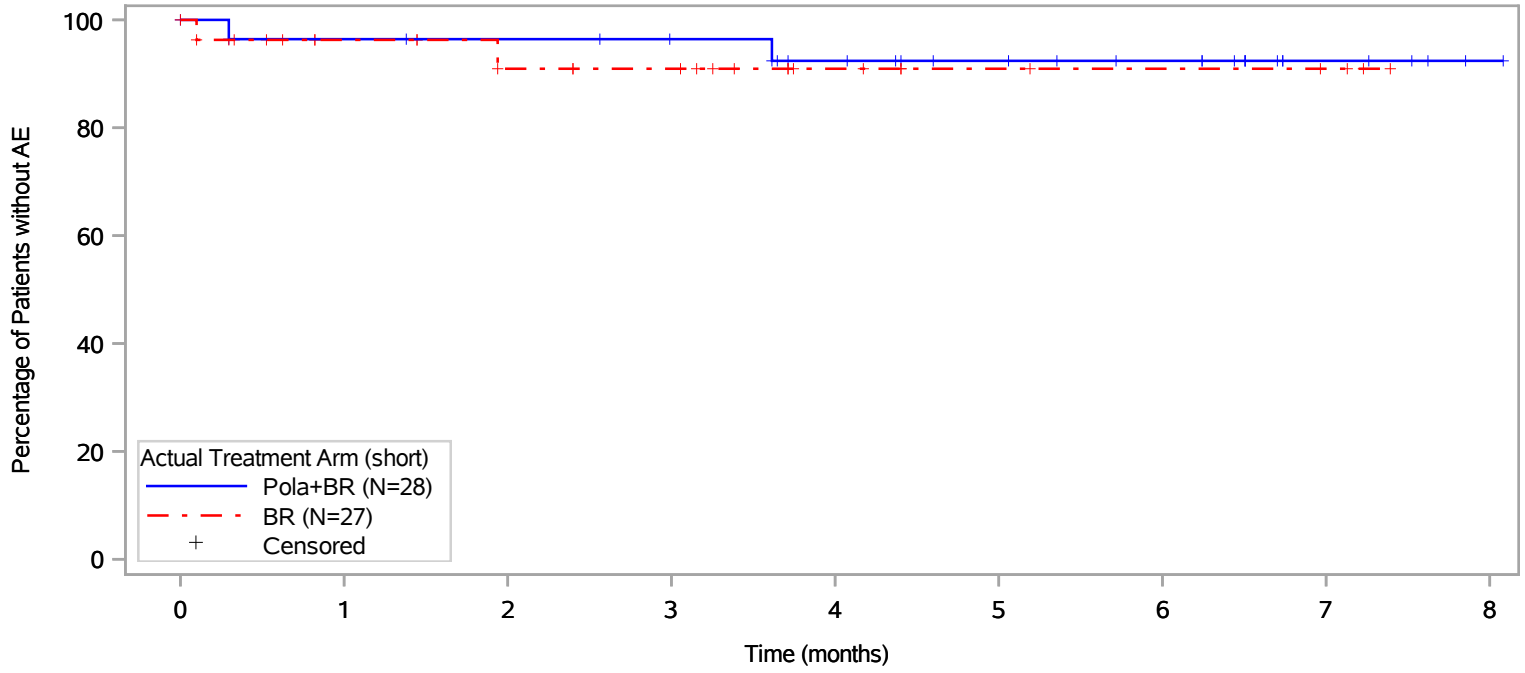
GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk																				
Pola+BR (N=28)	28	28	27	25	22	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	5	9	12	21	25	26	26	26	26	26	26	26	26	26	26	26
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DYSPEPSIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	21	17	14	5	1
BR (N=27)	27	20	17	15	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	21	25
BR (N=27)	0	6	8	10	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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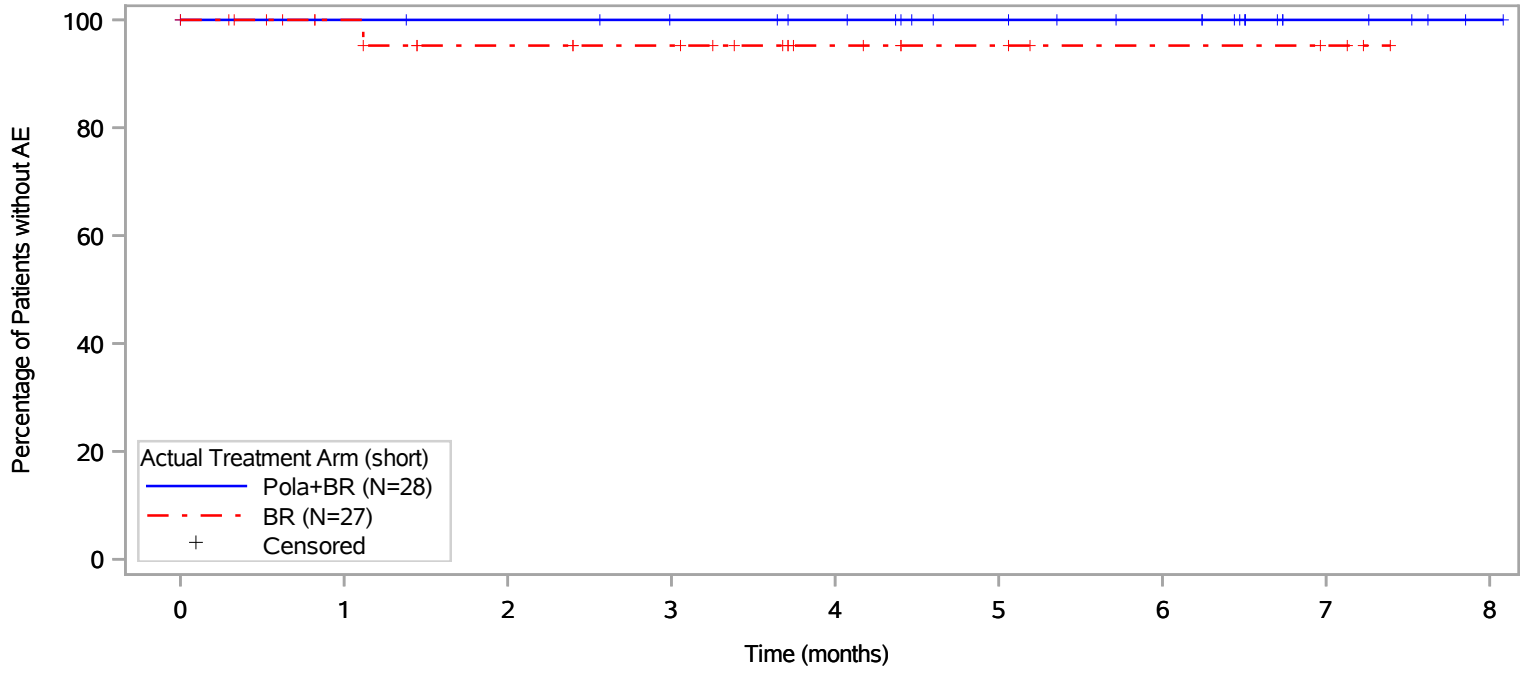
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DYSPHAGIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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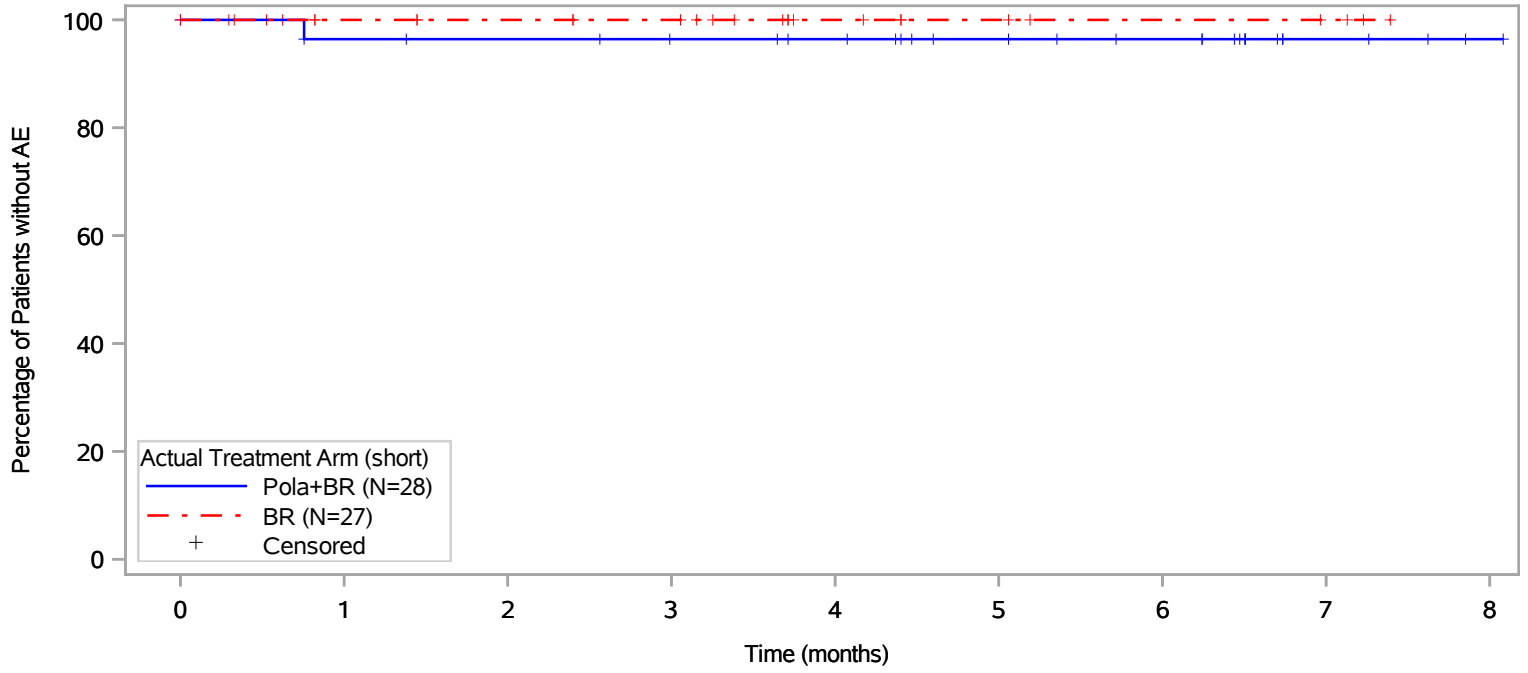
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, FLATULENCE



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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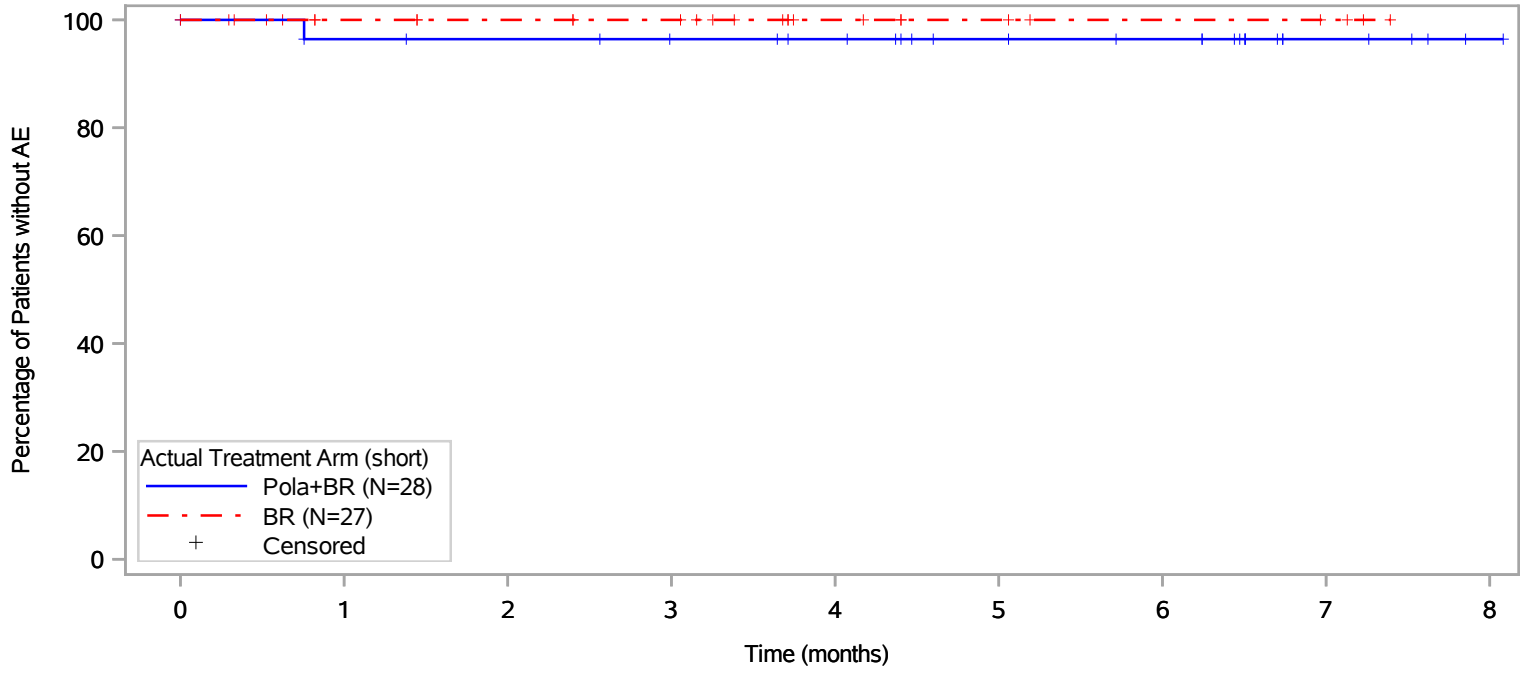
01DEC2022 21:22

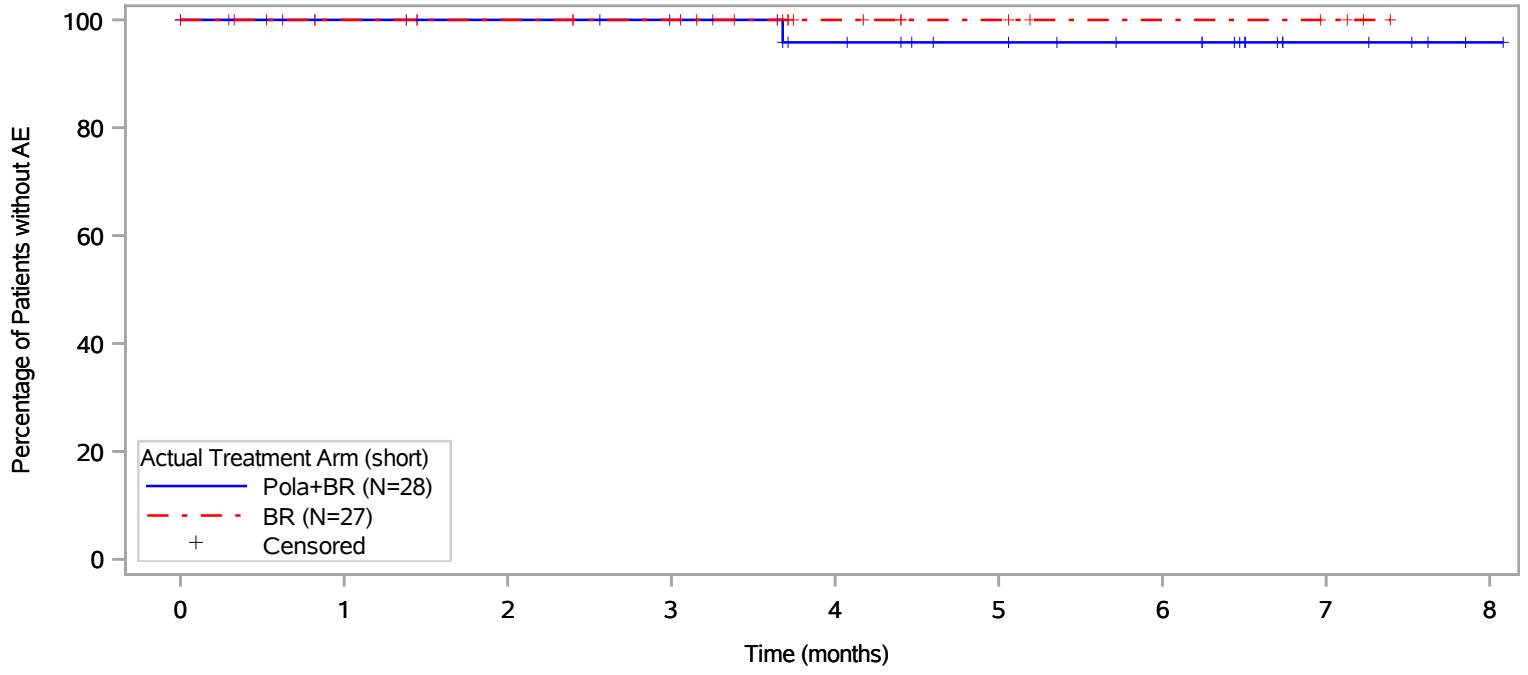
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTRITIS



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTROINTESTINAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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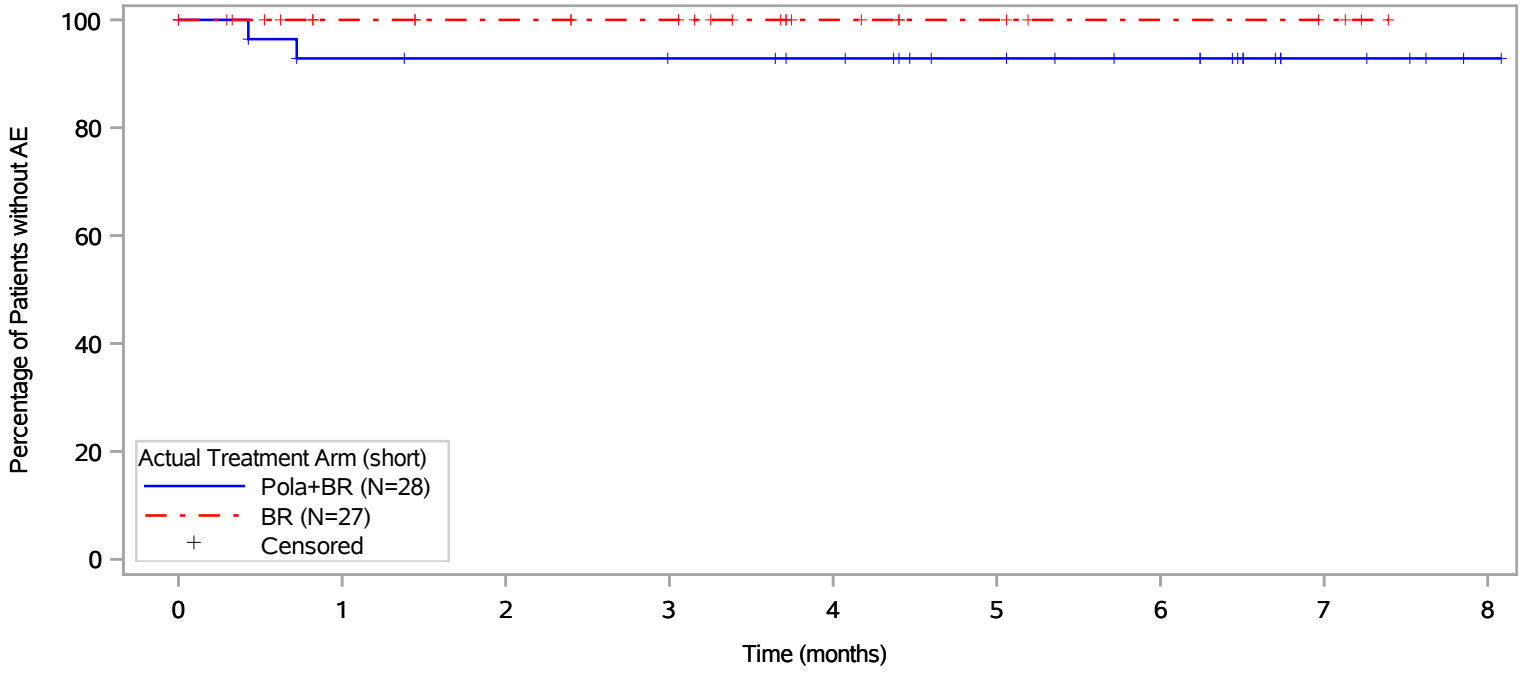
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTROOESOPHAGEAL REFLUX DISEASE



Patients at risk									
Pola+BR (N=28)	28	26	25	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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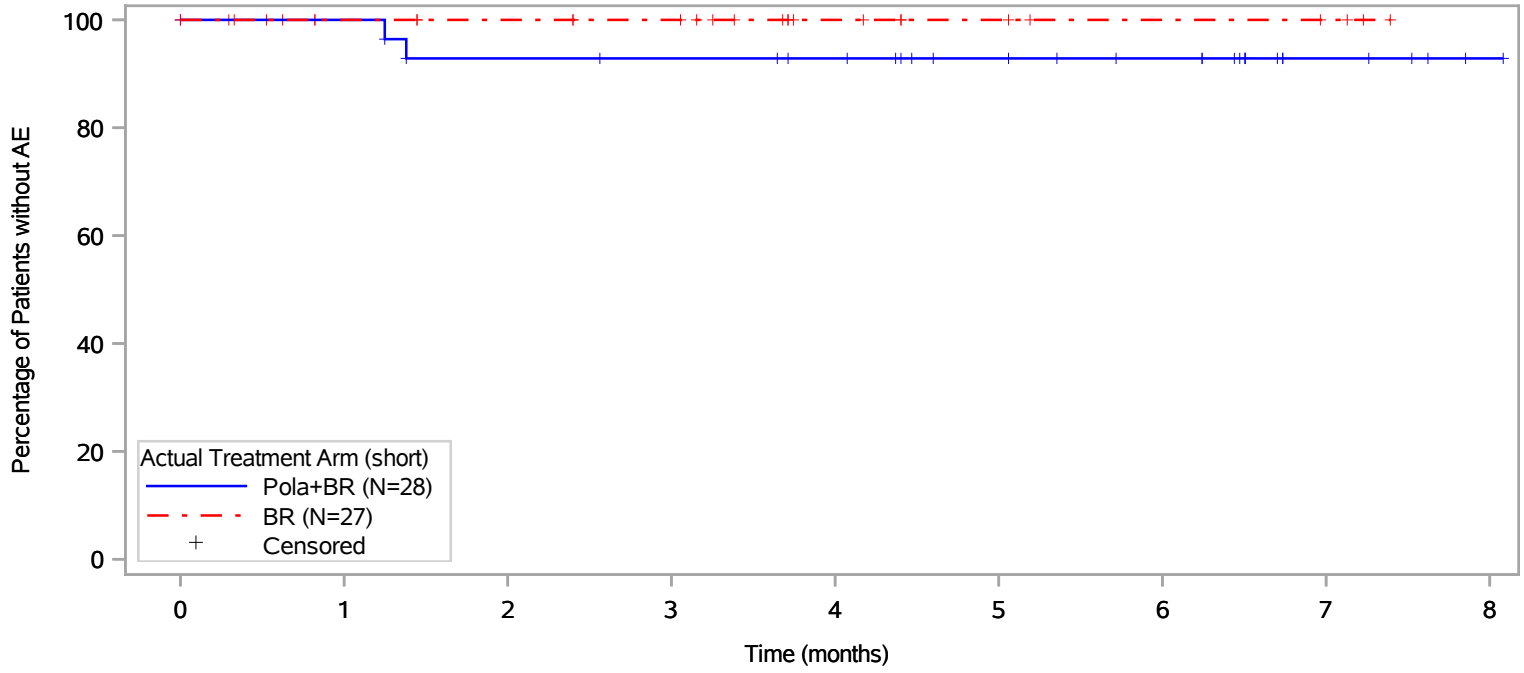
01DEC2022 21:22

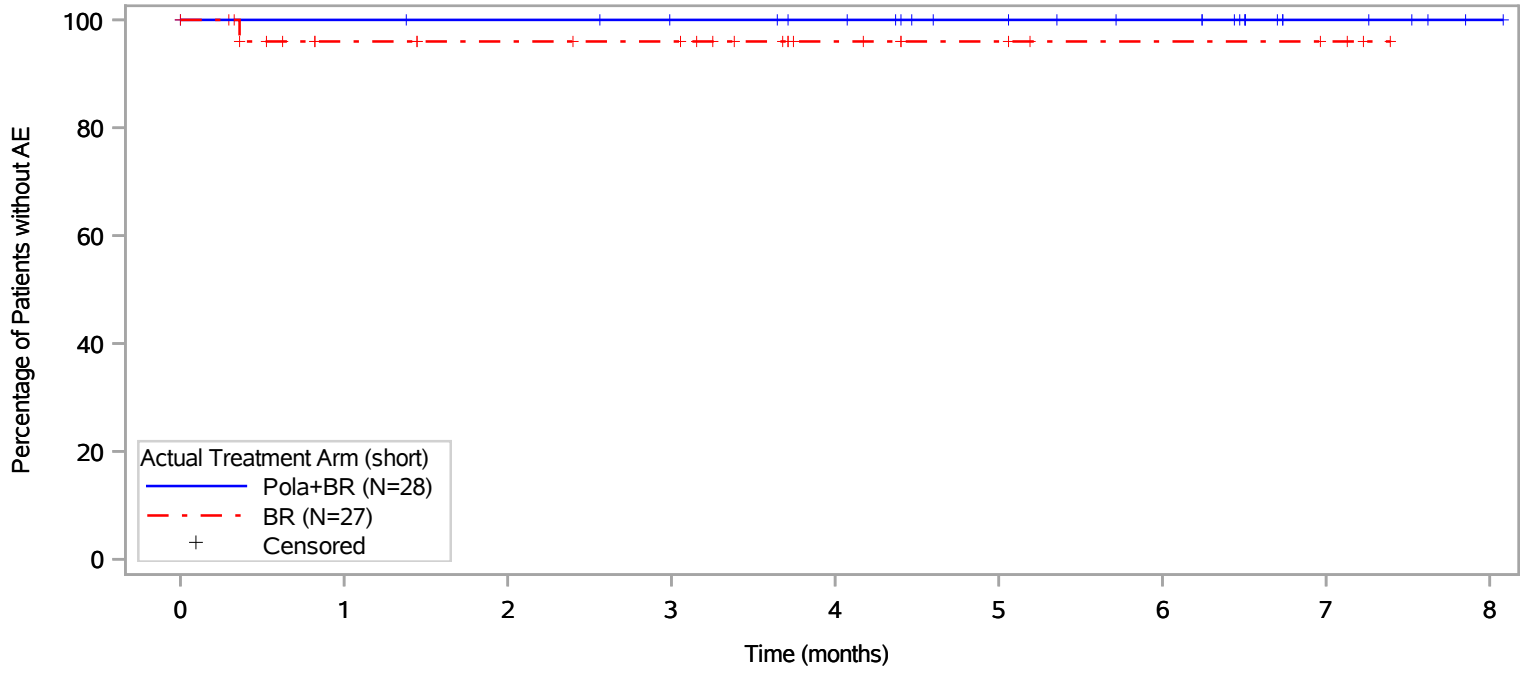
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, HAEMATEMESIS



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	3	8	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

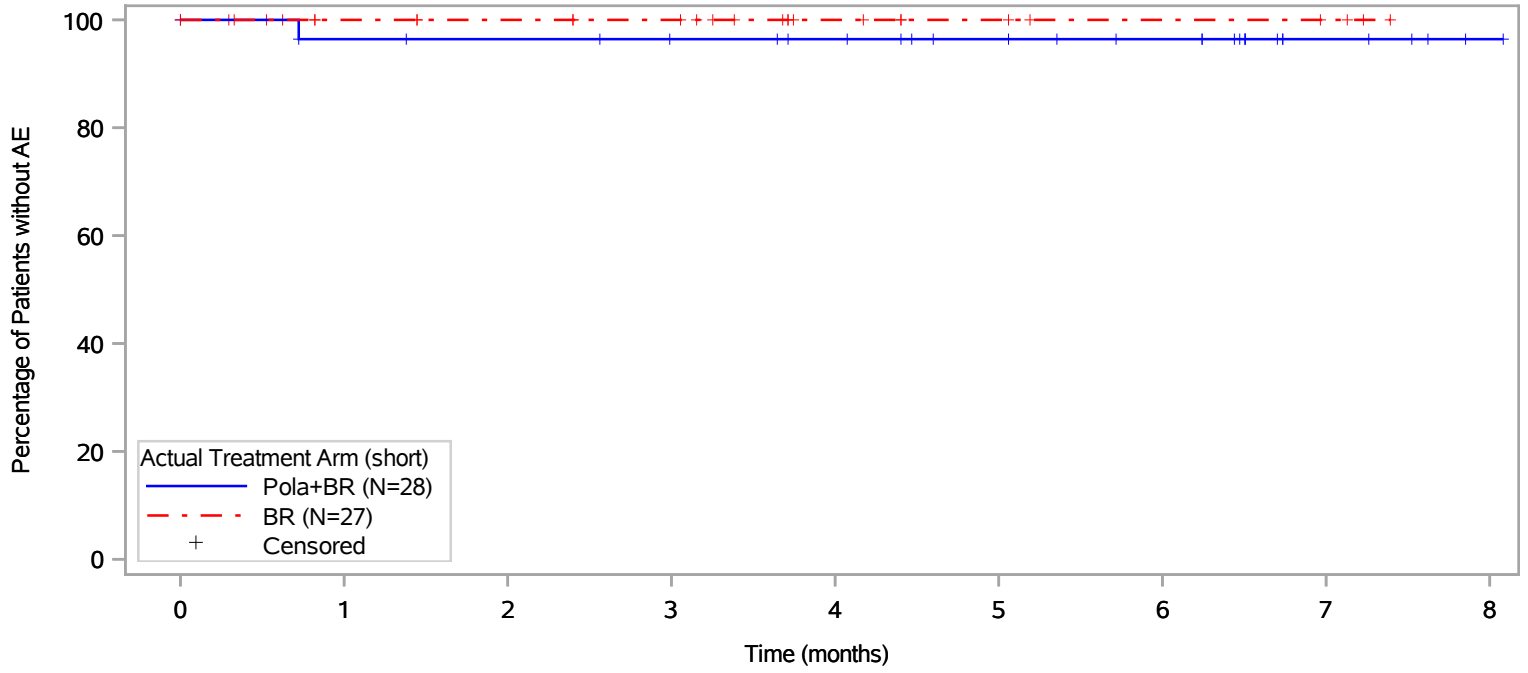
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, HAEMATOCHEZIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

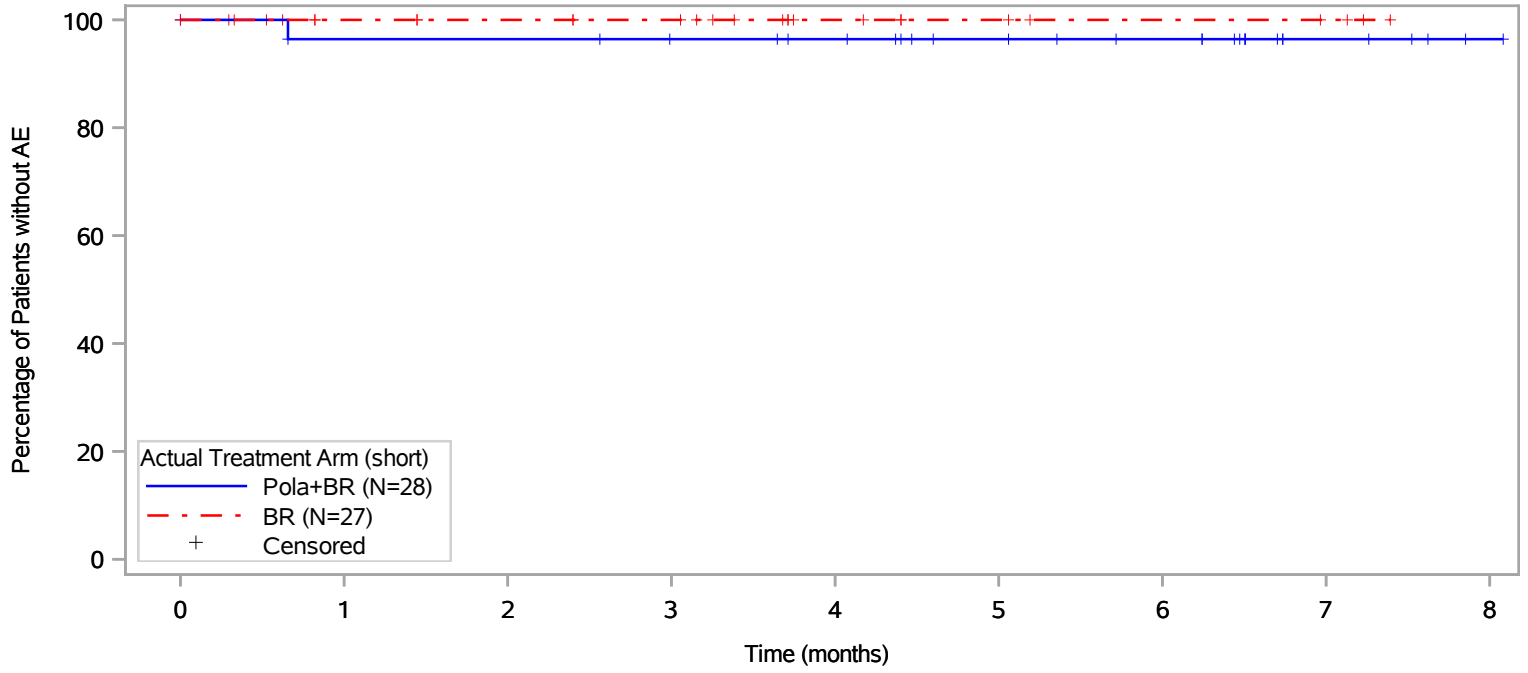
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, HYPERCHLORHYDRIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ILEUS

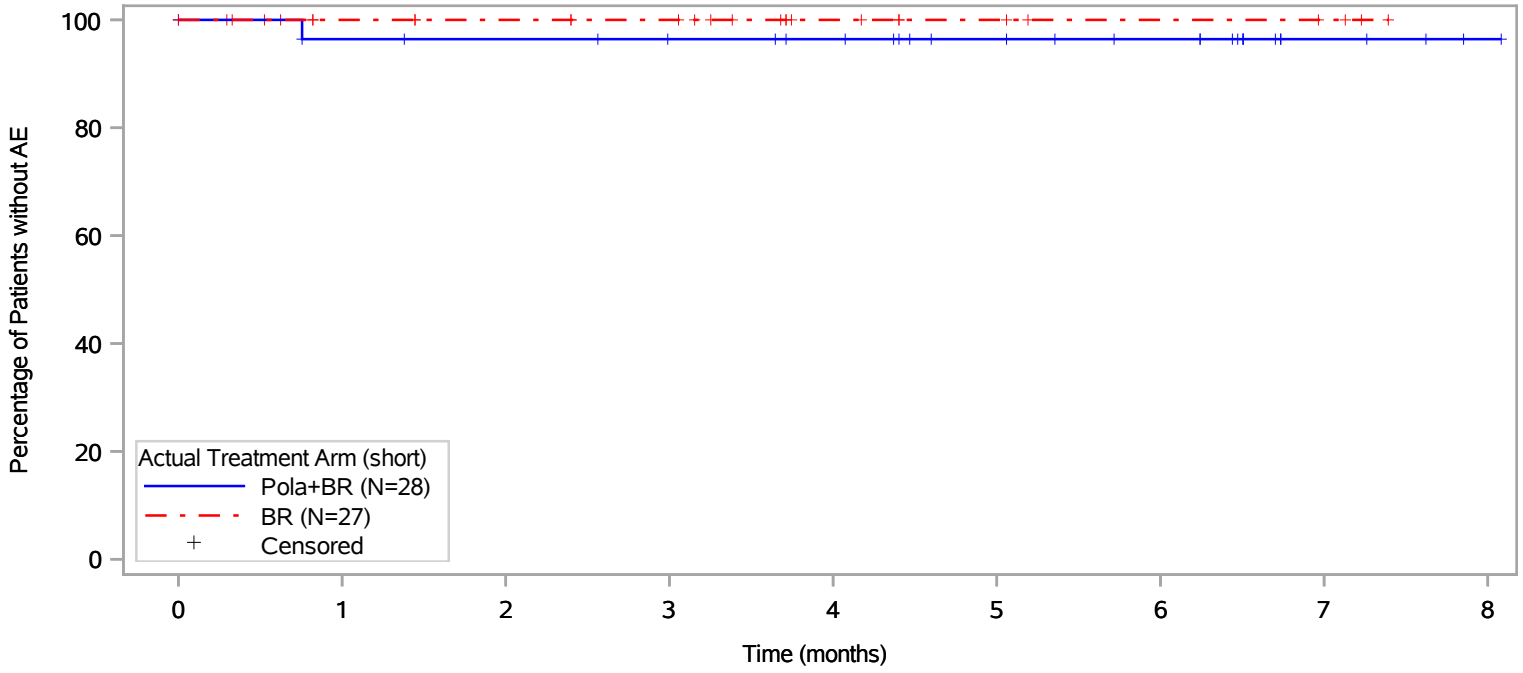


Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

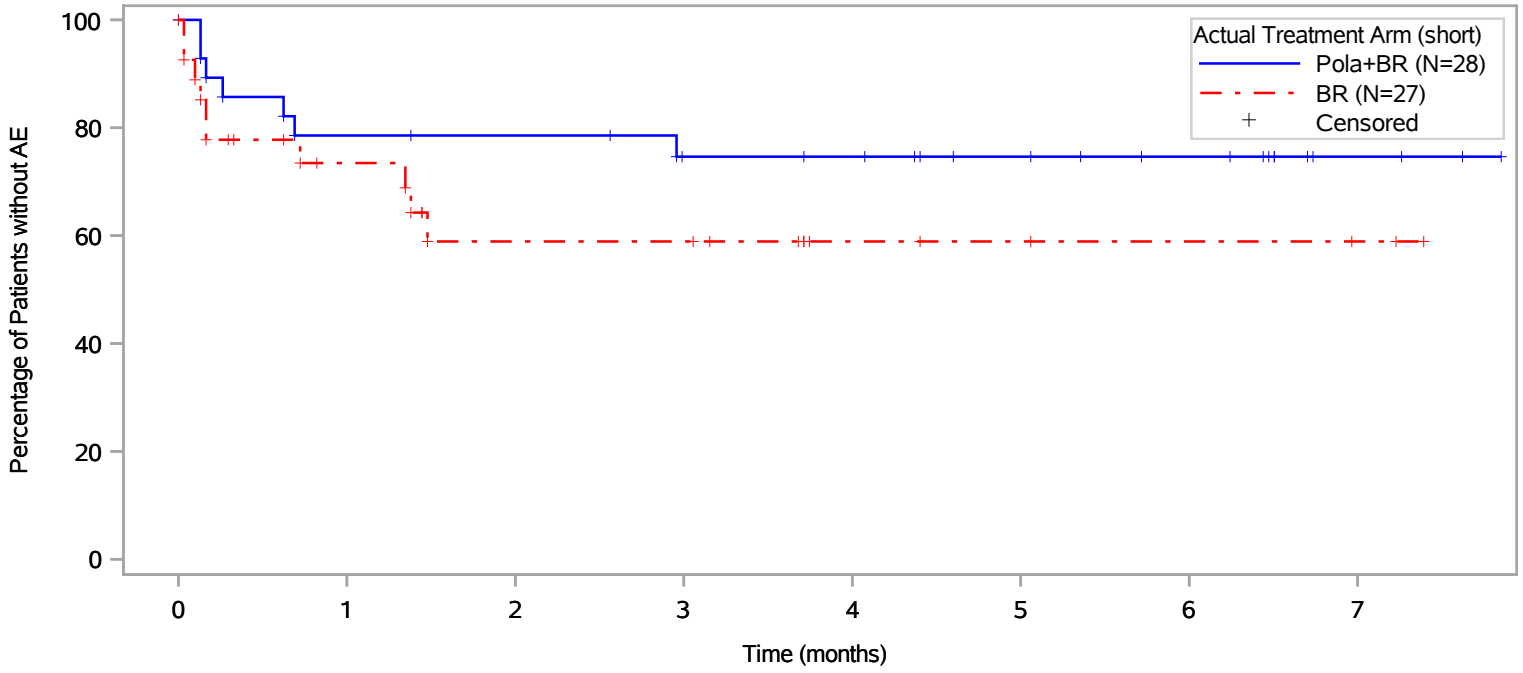
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, LIP DRY



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, NAUSEA



Patients at risk								
Pola+BR (N=28)	28	22	21	18	17	13	10	3
BR (N=27)	27	16	11	11	5	4	3	2
Patients censored								
Pola+BR (N=28)	0	0	1	3	4	8	11	18
BR (N=27)	0	4	6	6	12	13	14	15

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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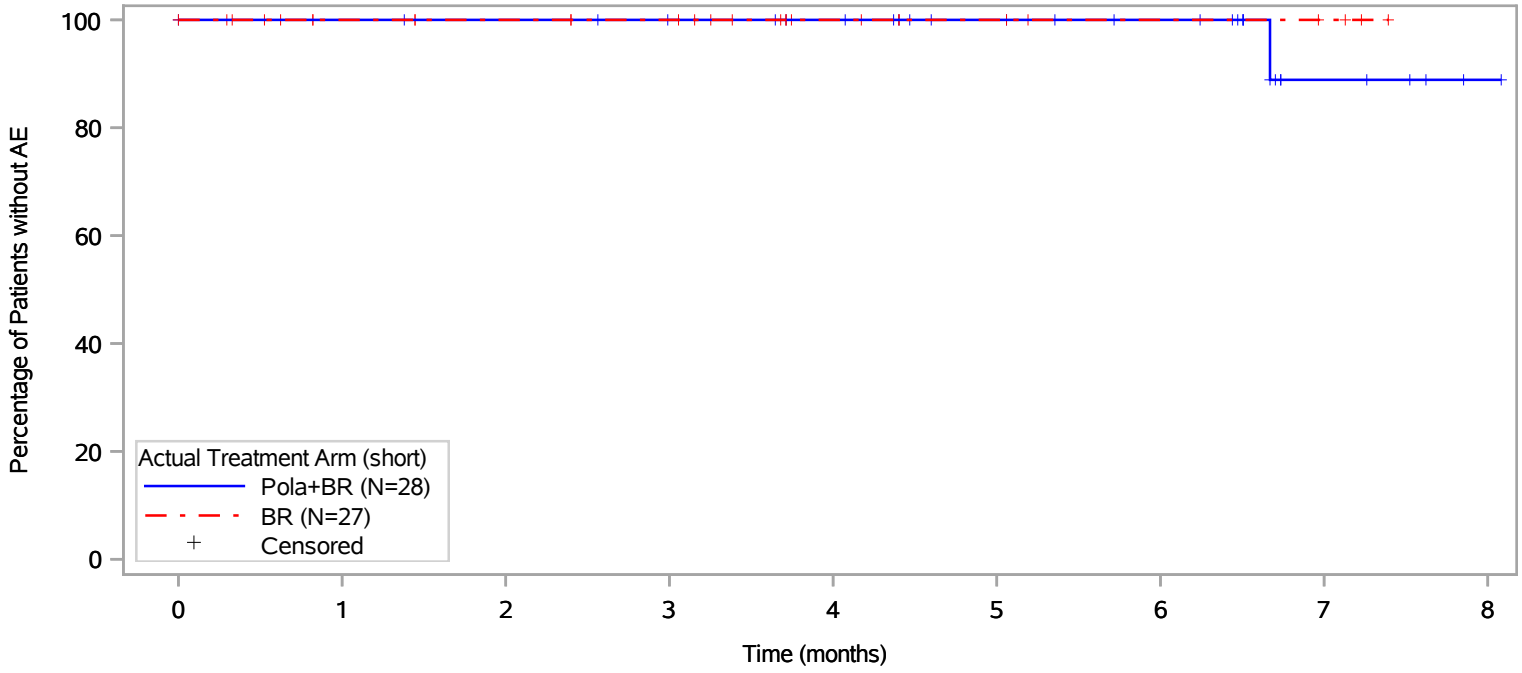
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, OBSTRUCTION GASTRIC



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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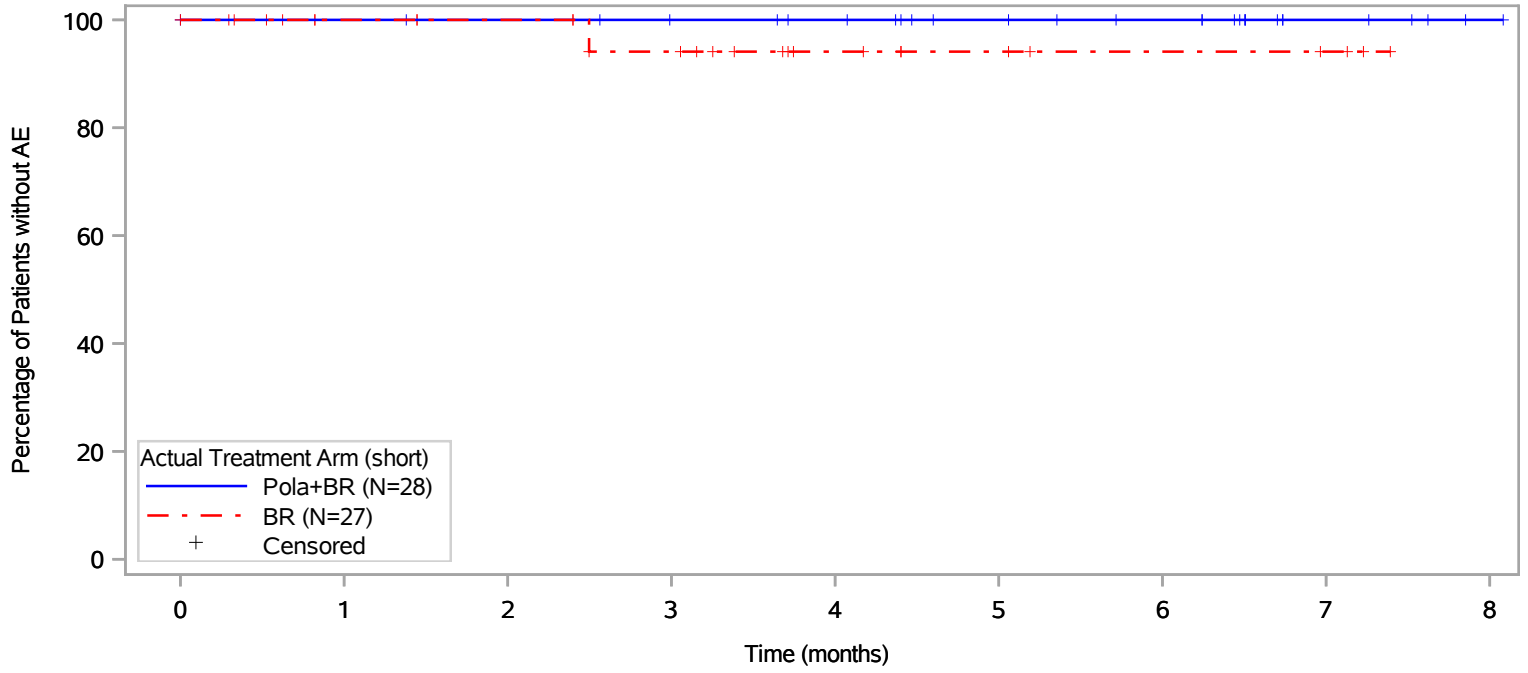
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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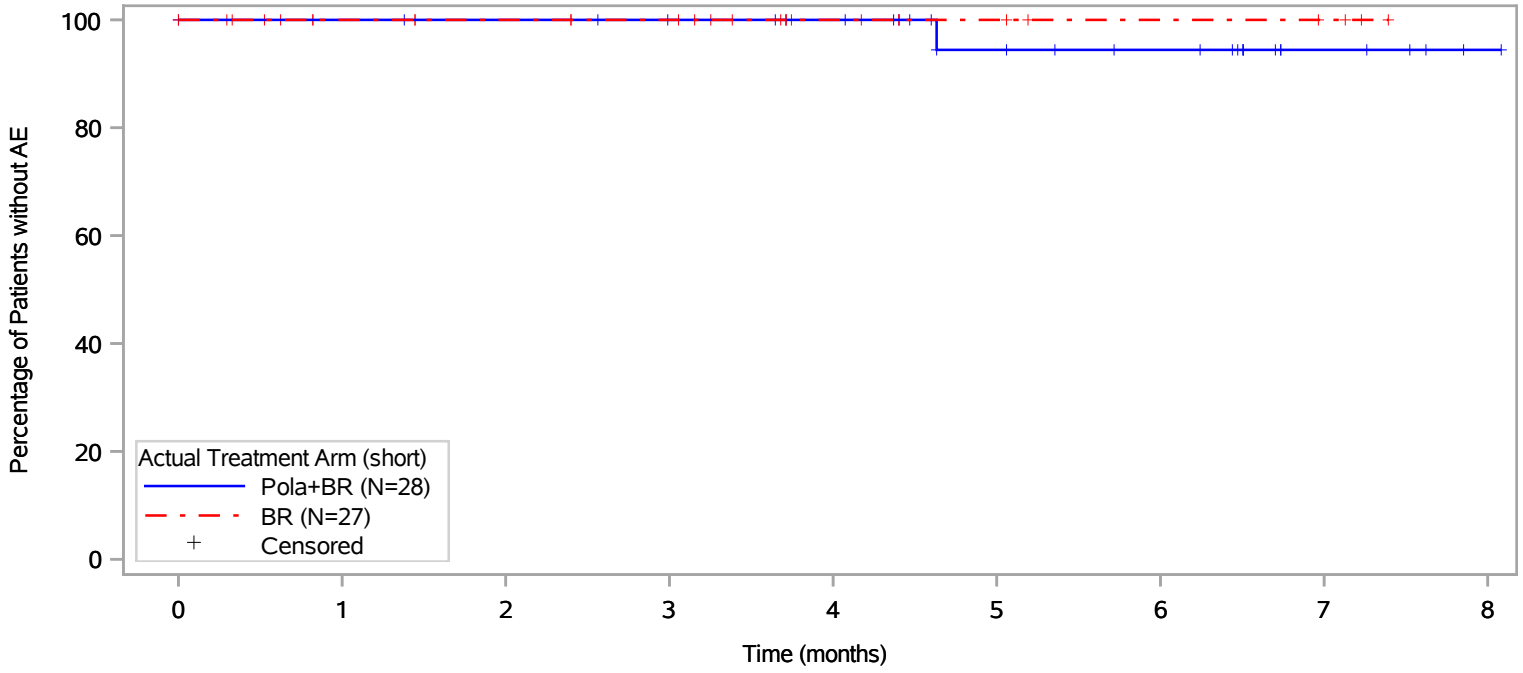
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS ACUTE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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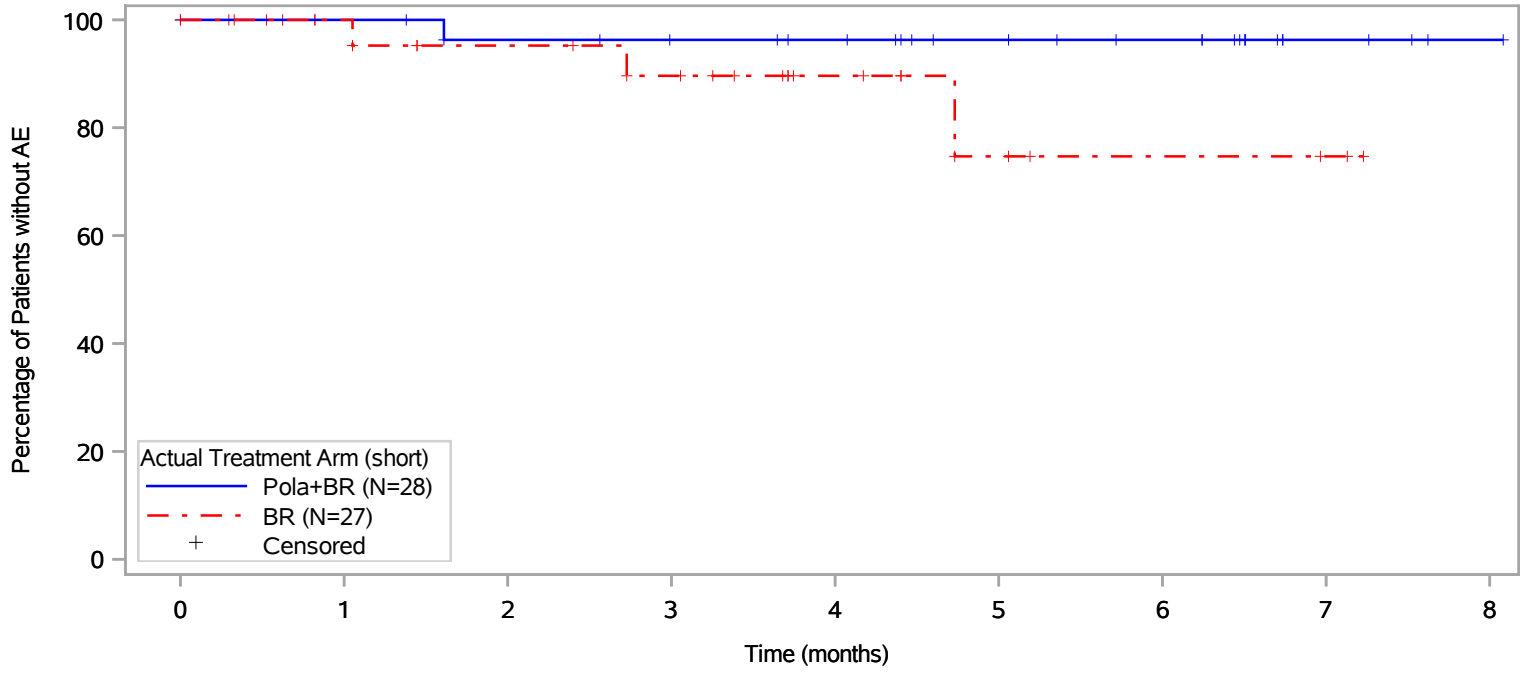
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, STOMATITIS



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	4	1
BR (N=27)	27	21	18	16	9	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	9	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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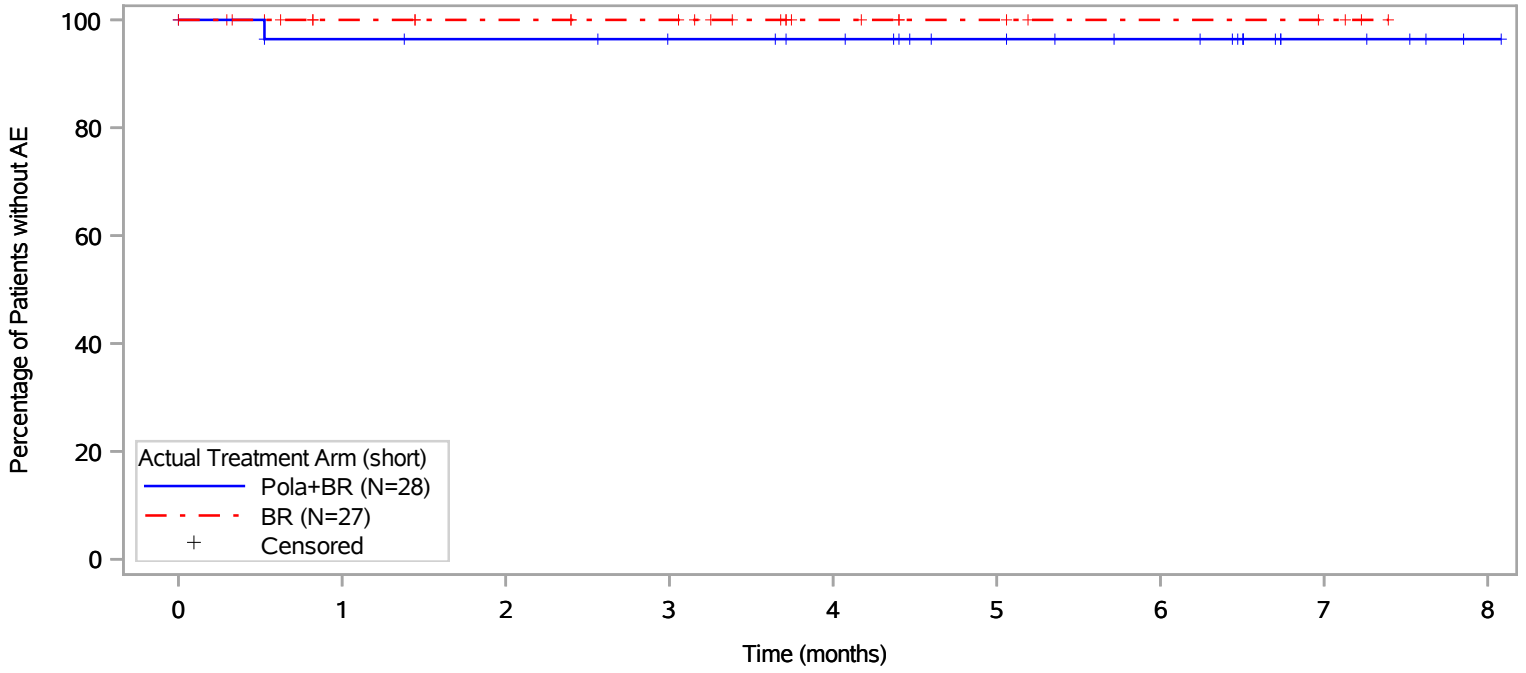
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

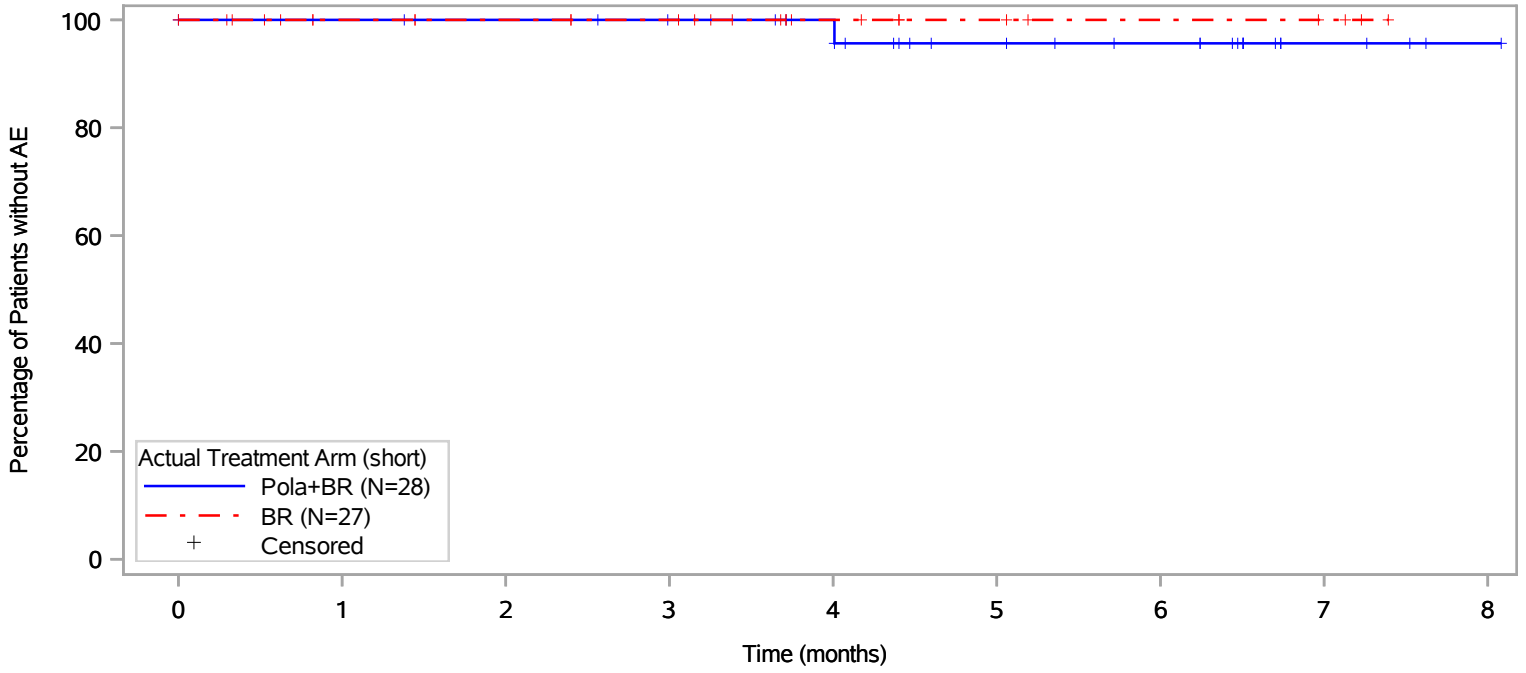
GASTROINTESTINAL DISORDERS, TONGUE EXFOLIATION



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

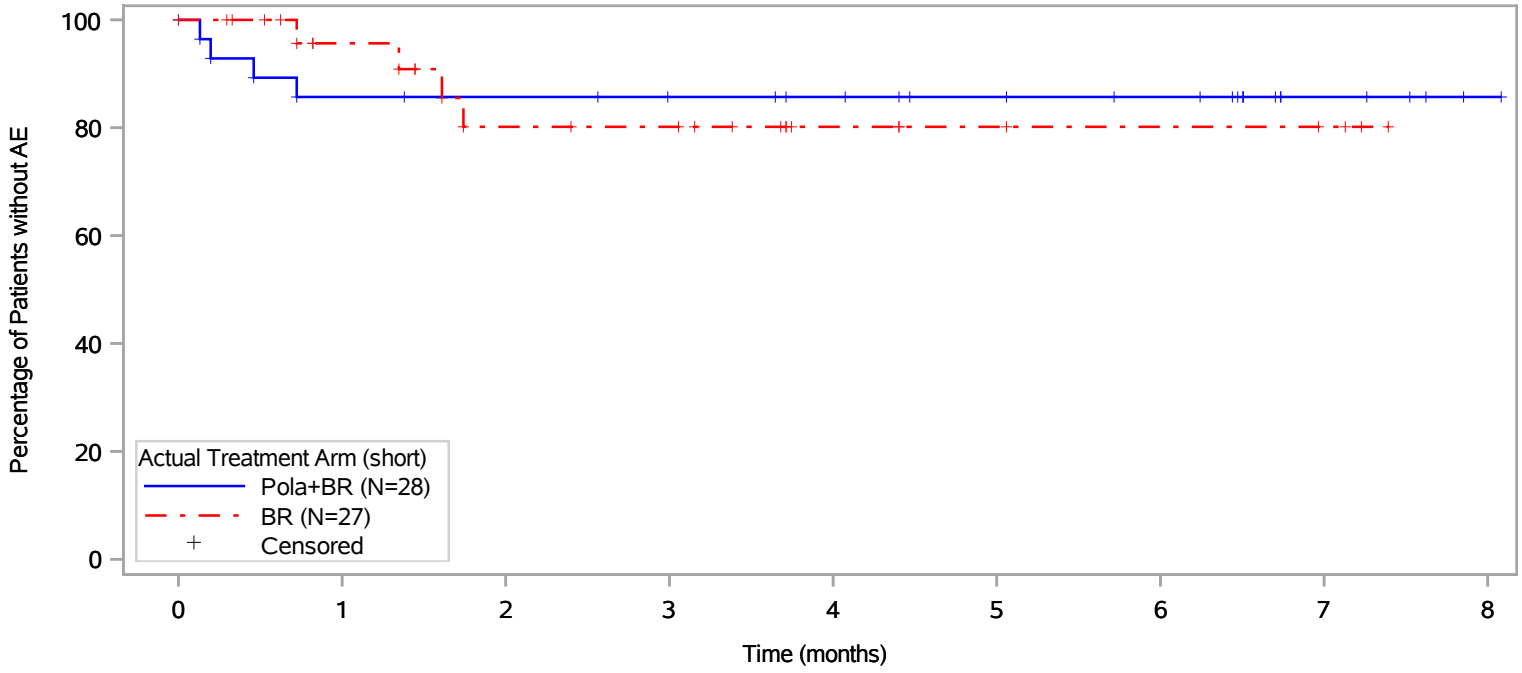
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, TOOTHACHE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=28)	28	24	23	21	19	16	14	5	1
BR (N=27)	27	20	15	14	7	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	8	10	19	23
BR (N=27)	0	6	8	9	16	18	19	20	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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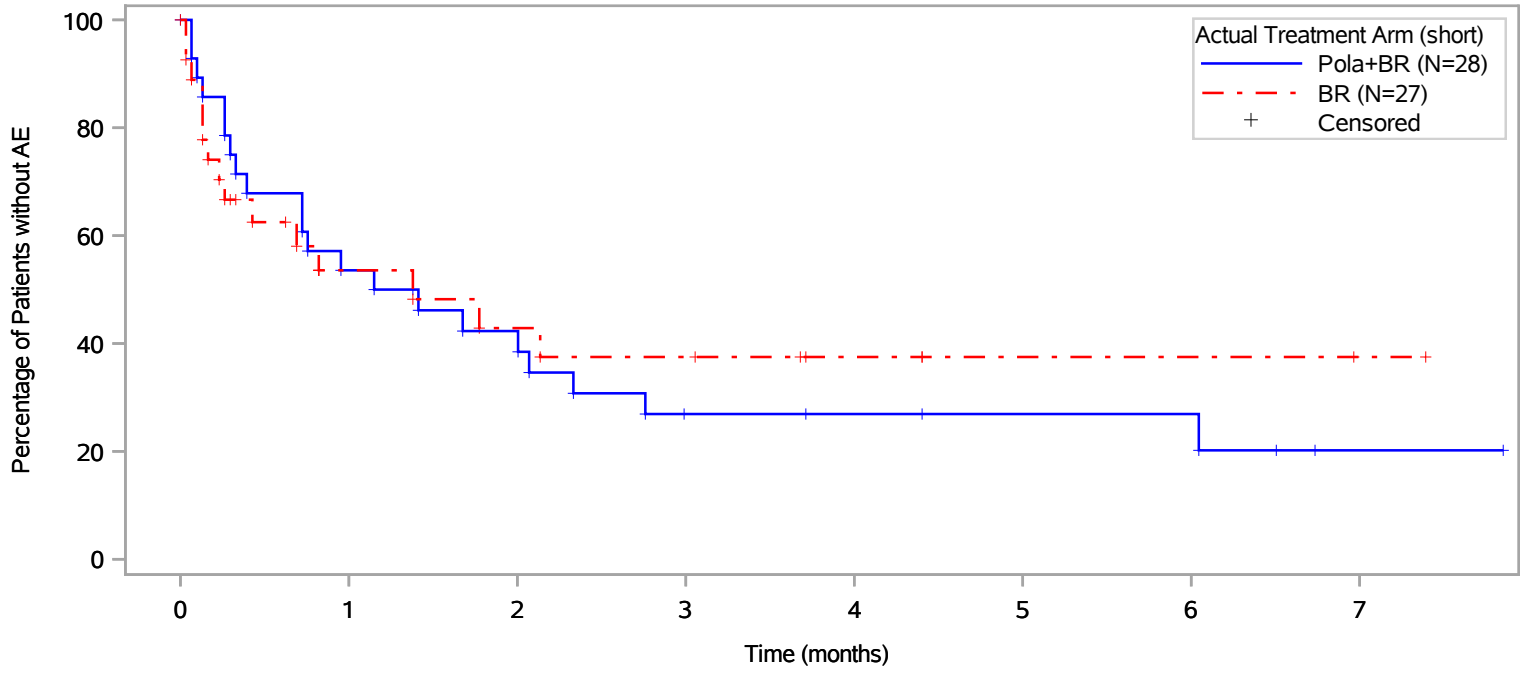
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk								
Pola+BR (N=28)	28	15	11	6	5	4	4	1
BR (N=27)	27	10	8	7	4	2	2	1
Patients censored								
Pola+BR (N=28)	0	0	1	2	3	4	4	6
BR (N=27)	0	5	5	5	8	10	10	11

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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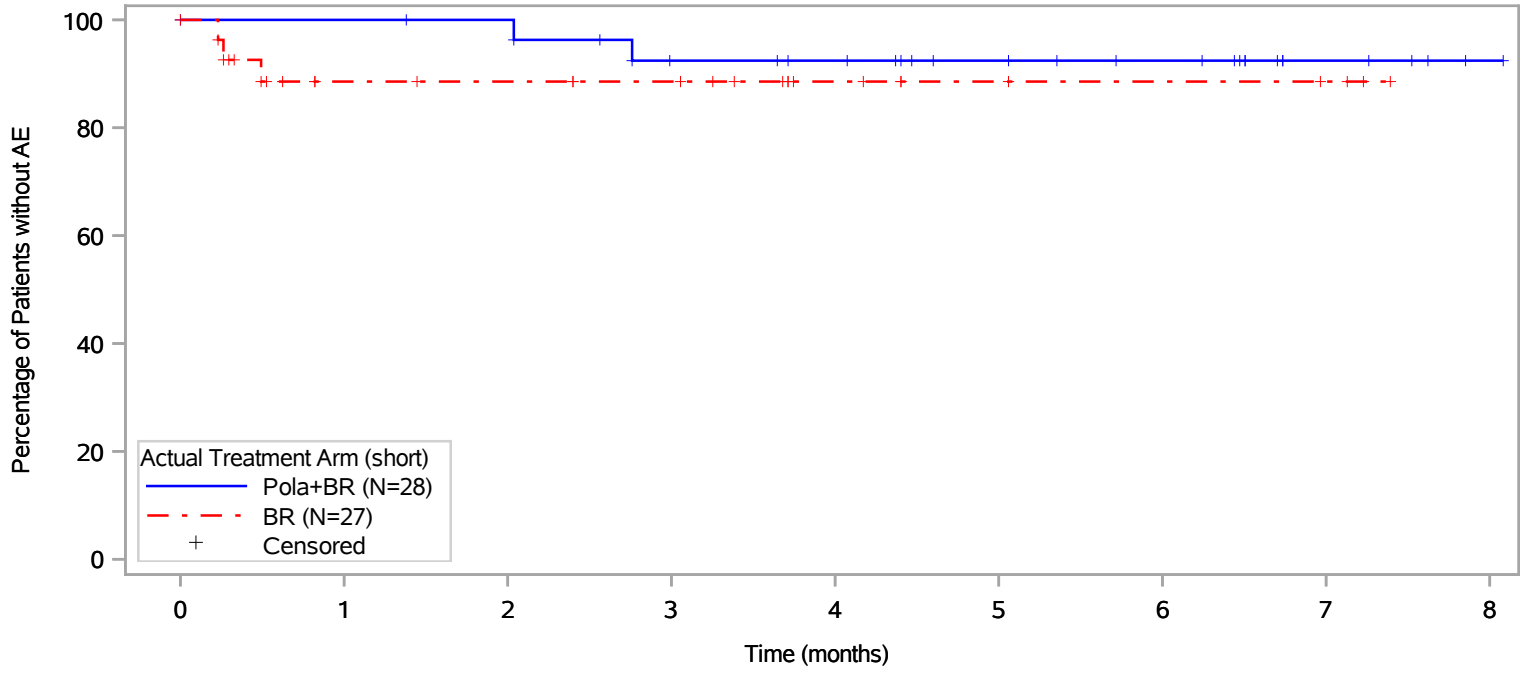
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, ASTHENIA



Patients at risk									
Pola+BR (N=28)	28	28	27	23	21	16	13	5	1
BR (N=27)	27	18	17	15	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	21	25
BR (N=27)	0	6	7	9	16	19	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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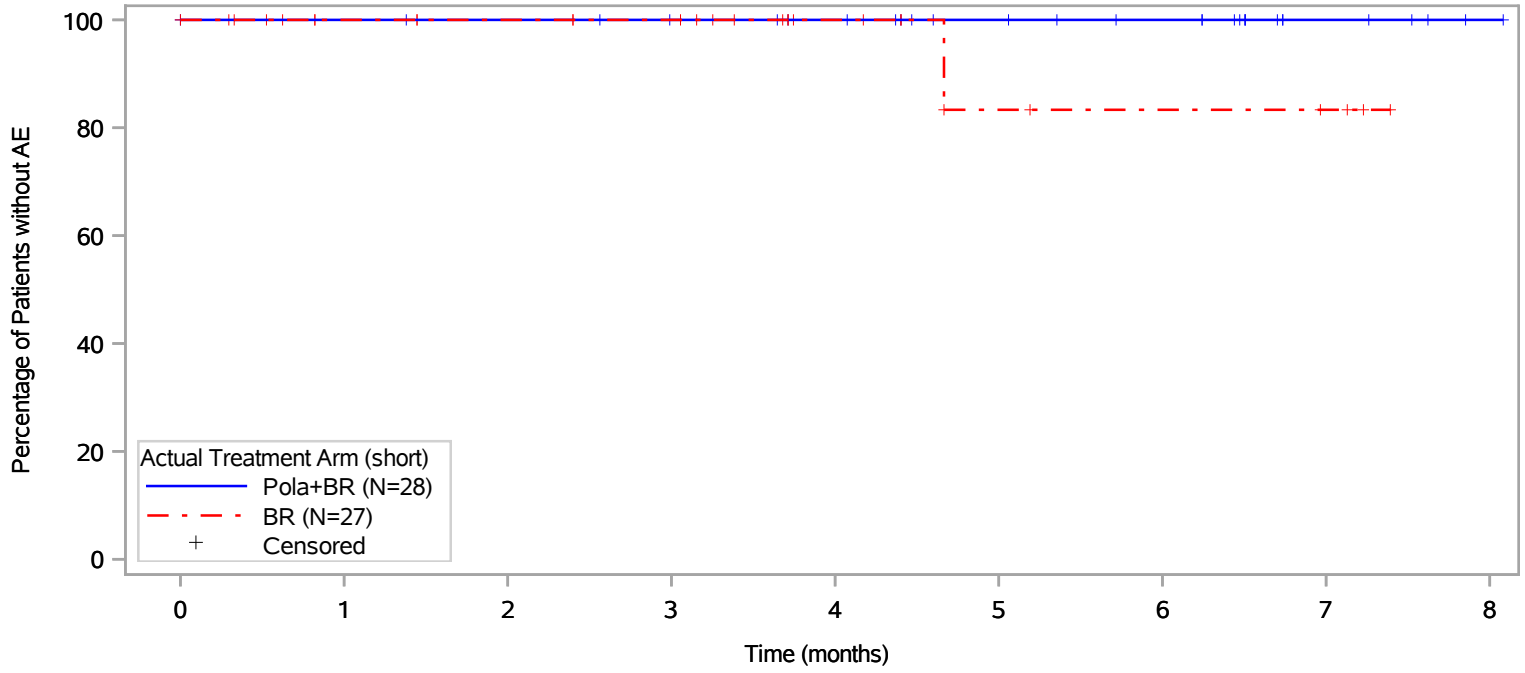
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, AXILLARY PAIN



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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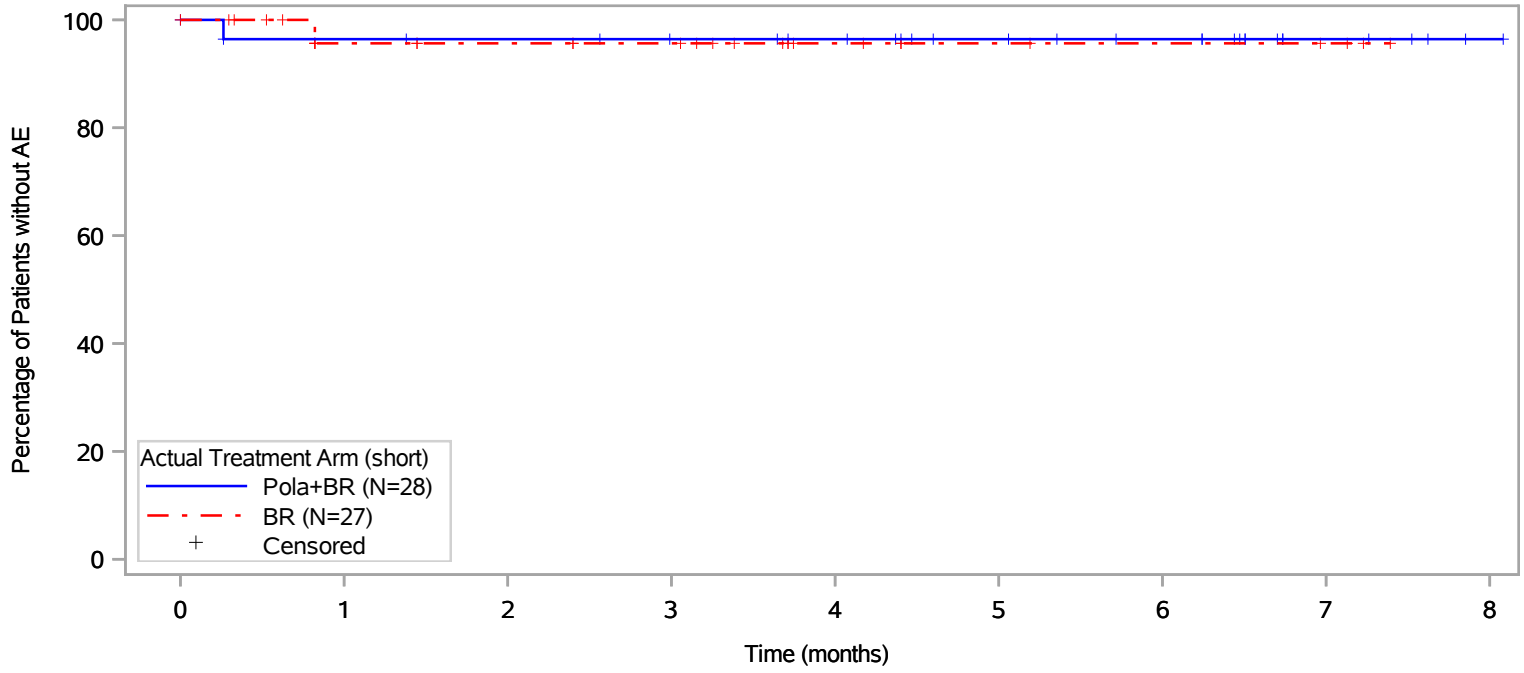
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHEST DISCOMFORT



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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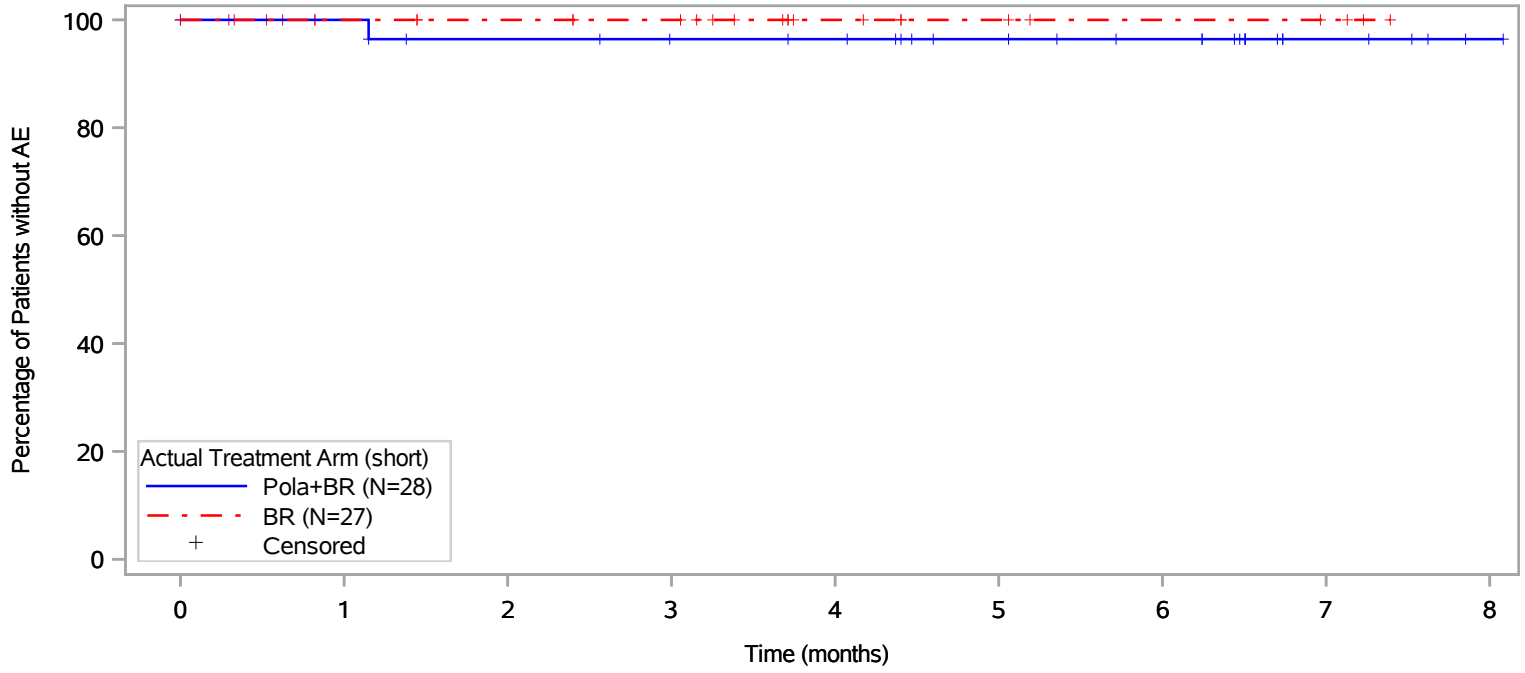
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHEST PAIN

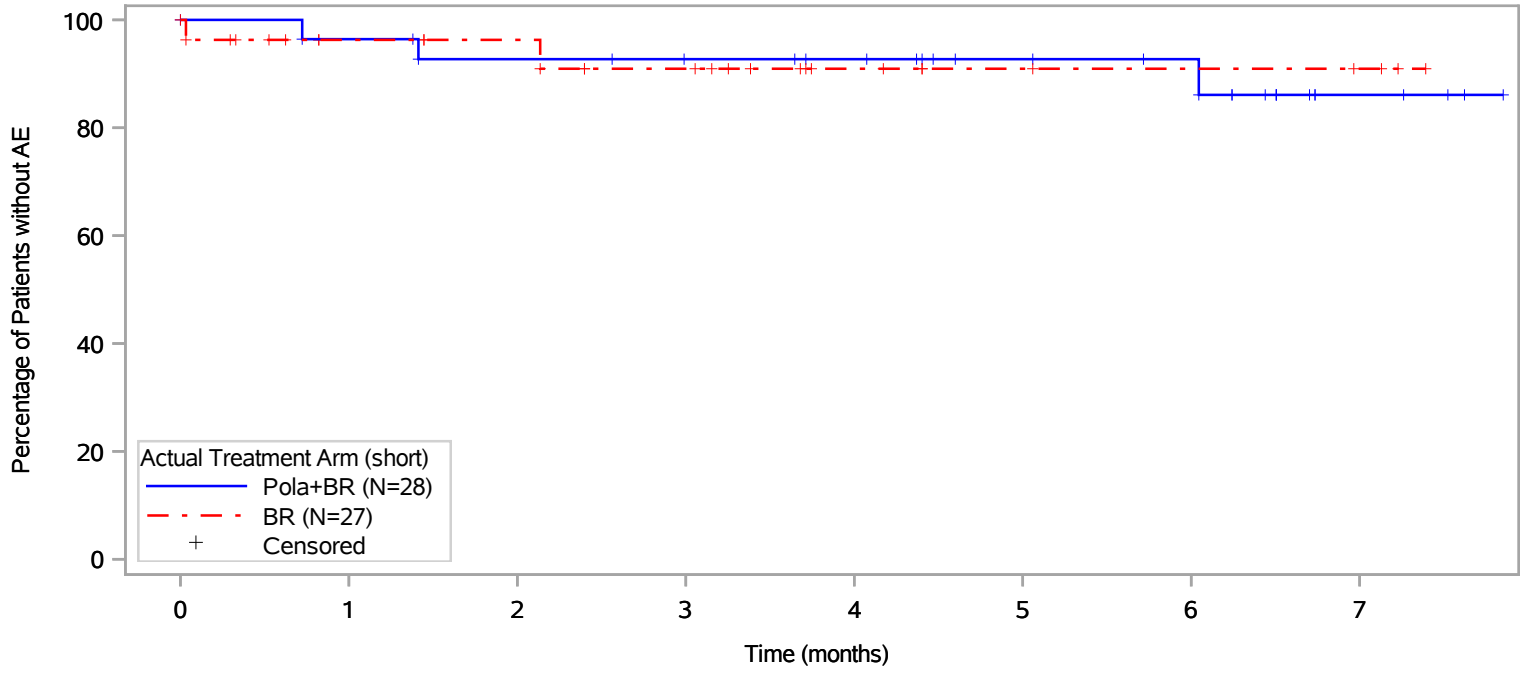


Patients at risk									
Pola+BR (N=28)	28	28	26	24	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHILLS

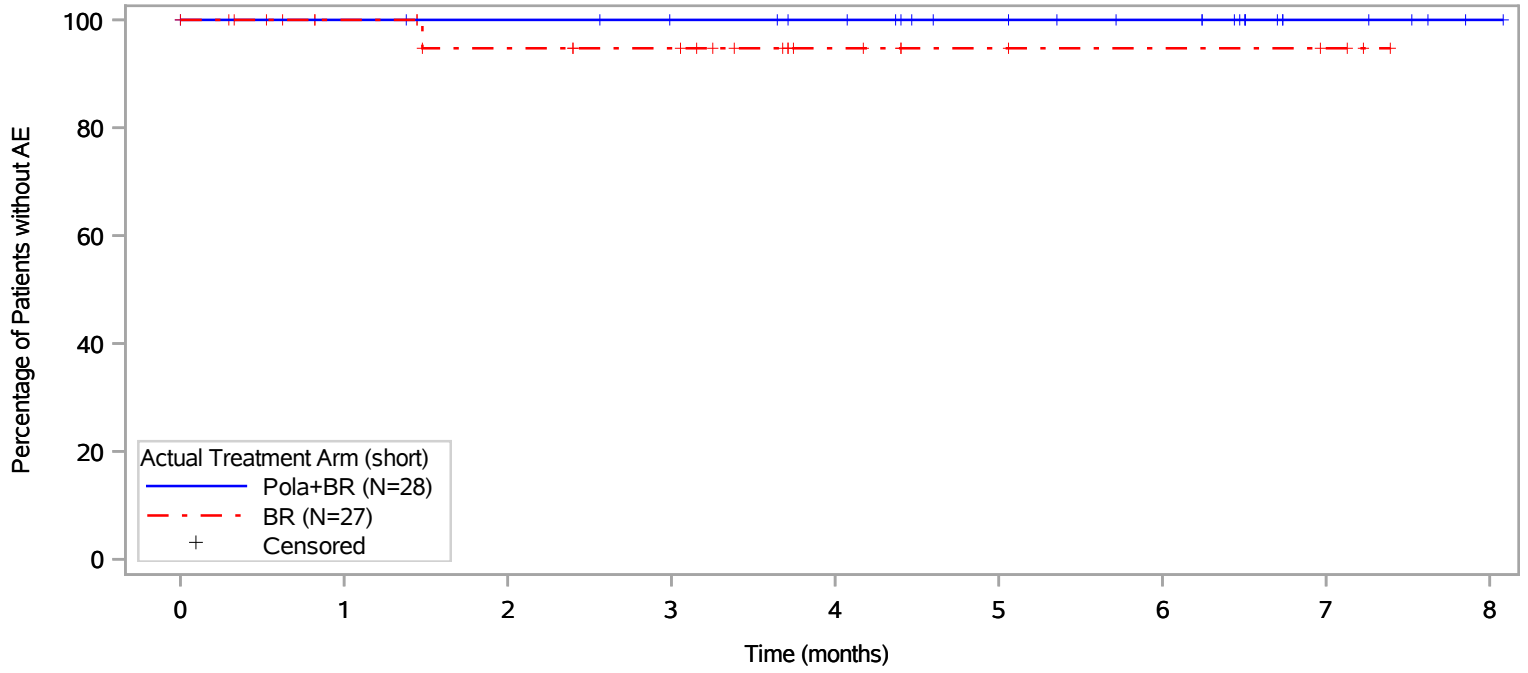


Patients at risk								
Pola+BR (N=28)	28	27	25	23	21	16	14	4
BR (N=27)	27	20	18	15	8	5	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	10	12	21
BR (N=27)	0	6	8	10	17	20	21	22

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FACE OEDEMA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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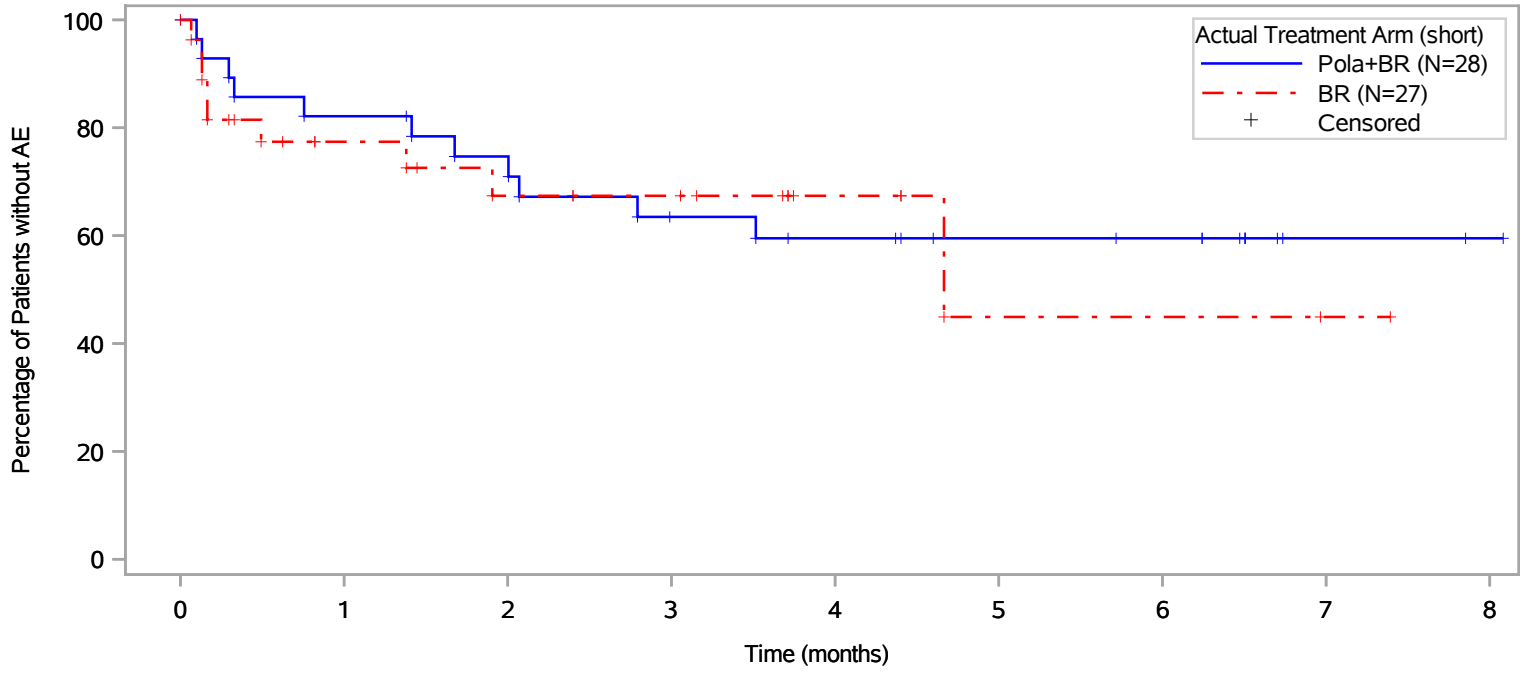
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE



Patients at risk									
Pola+BR (N=28)	28	23	20	16	14	11	10	2	1
BR (N=27)	27	16	13	11	5	2	2	1	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	3	6	7	15	16
BR (N=27)	0	5	6	8	14	16	16	17	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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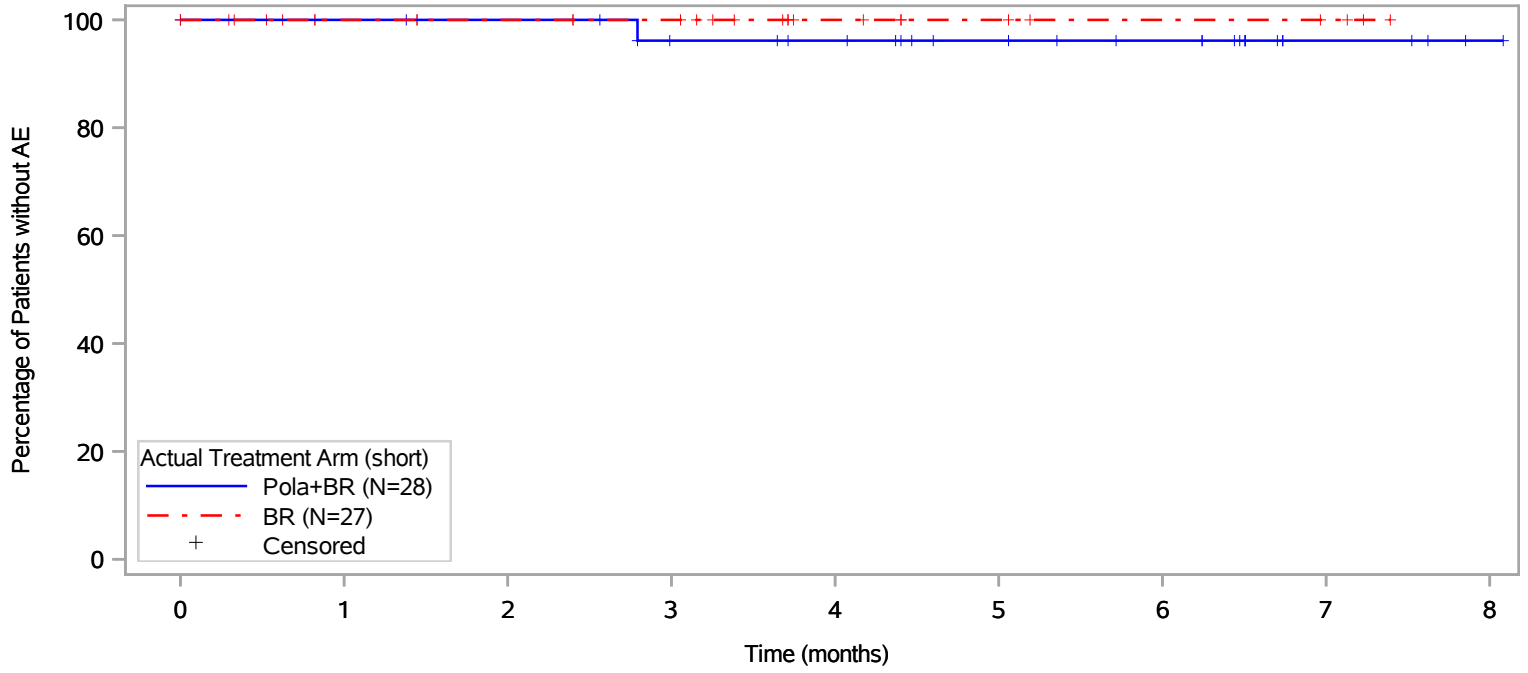
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FEELING COLD

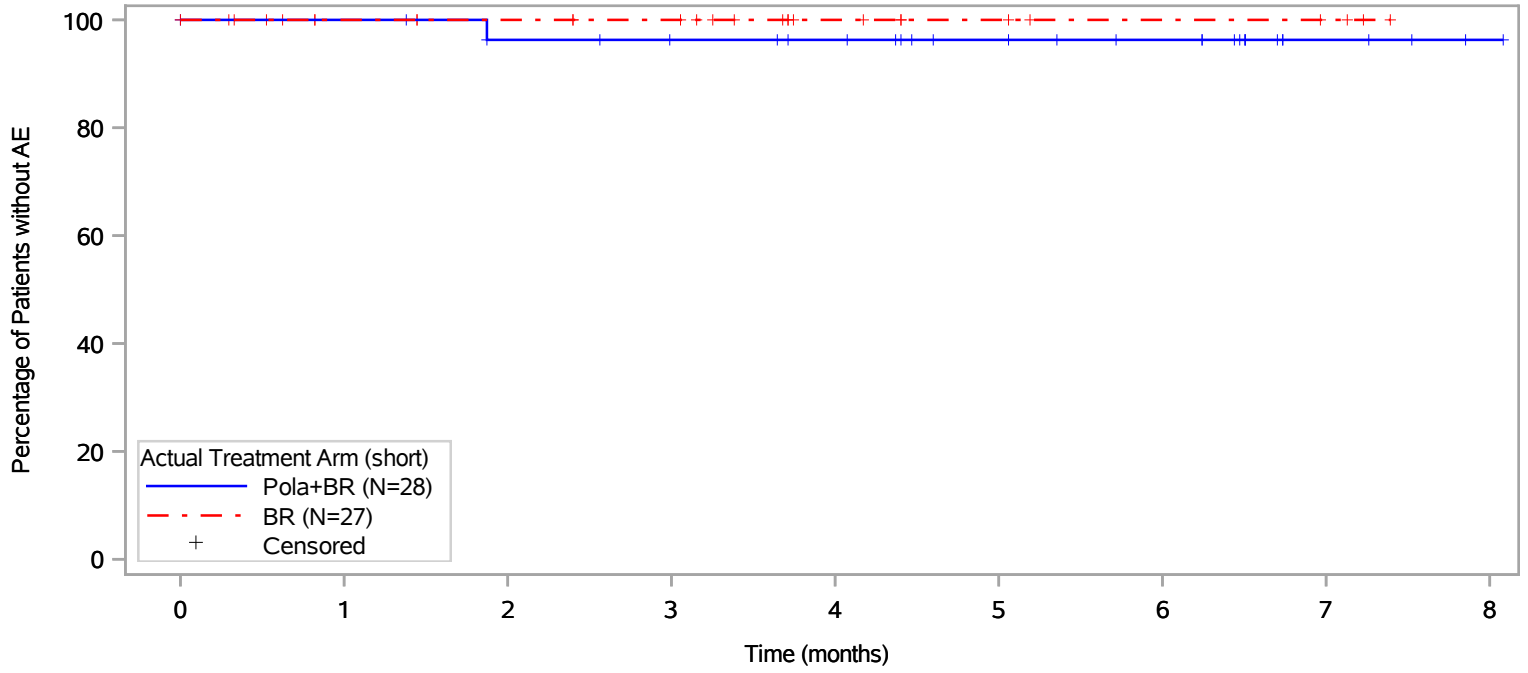


Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, GAIT DISTURBANCE

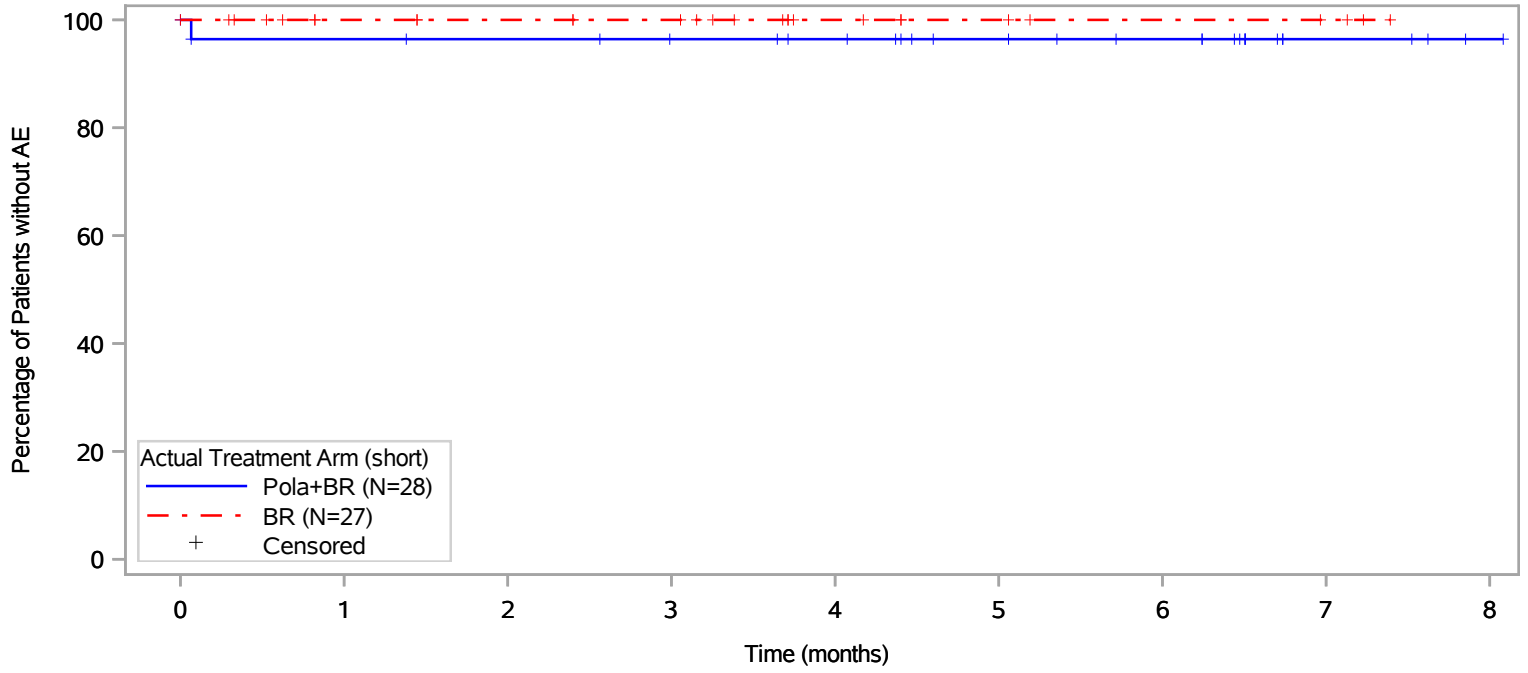


Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, INJECTION SITE PAIN

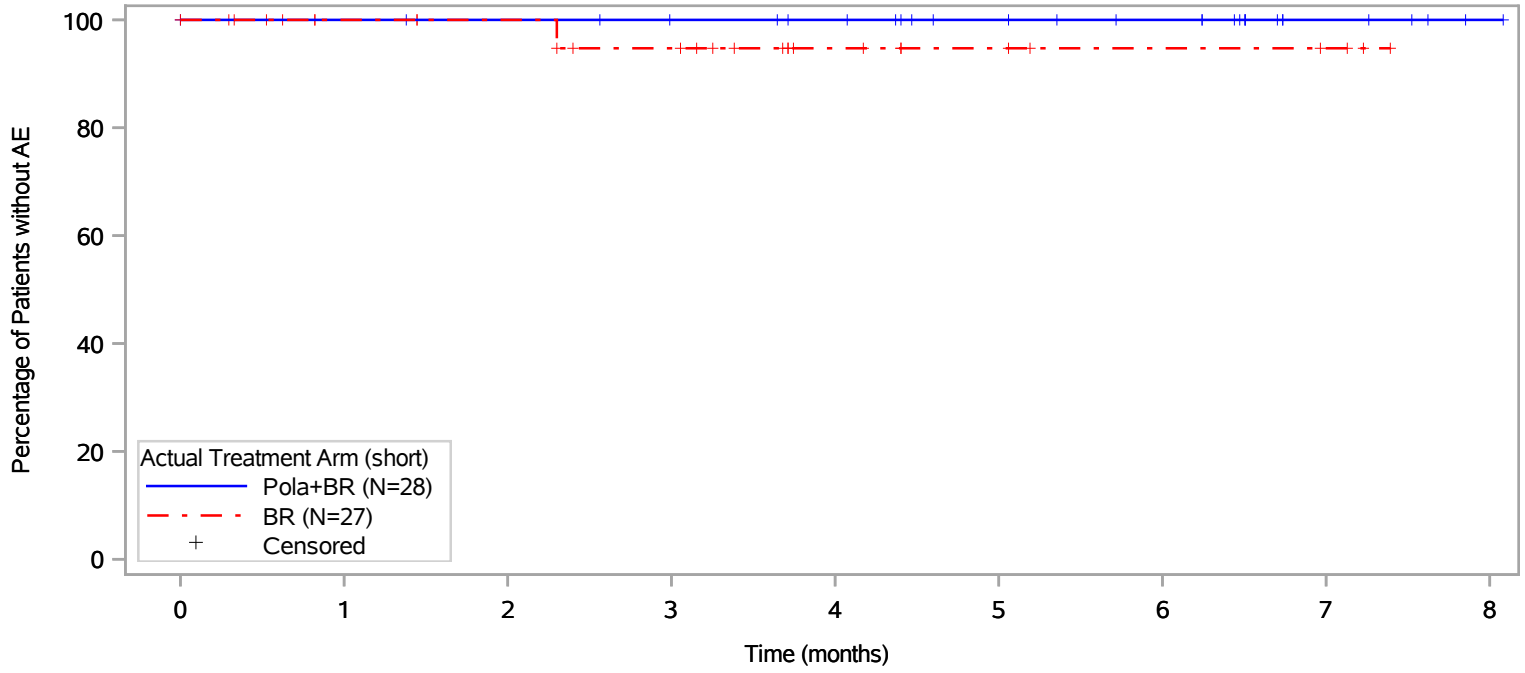


Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



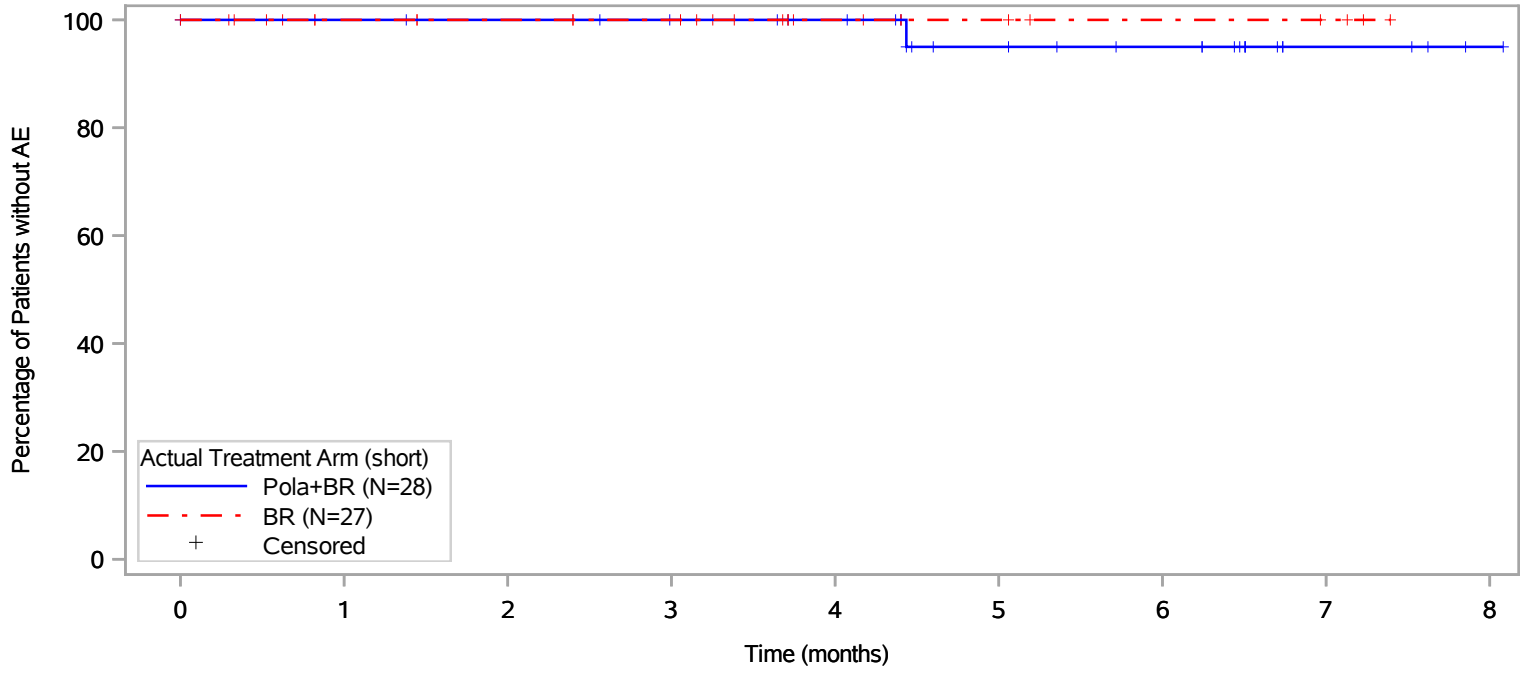
Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, NON-CARDIAC CHEST PAIN

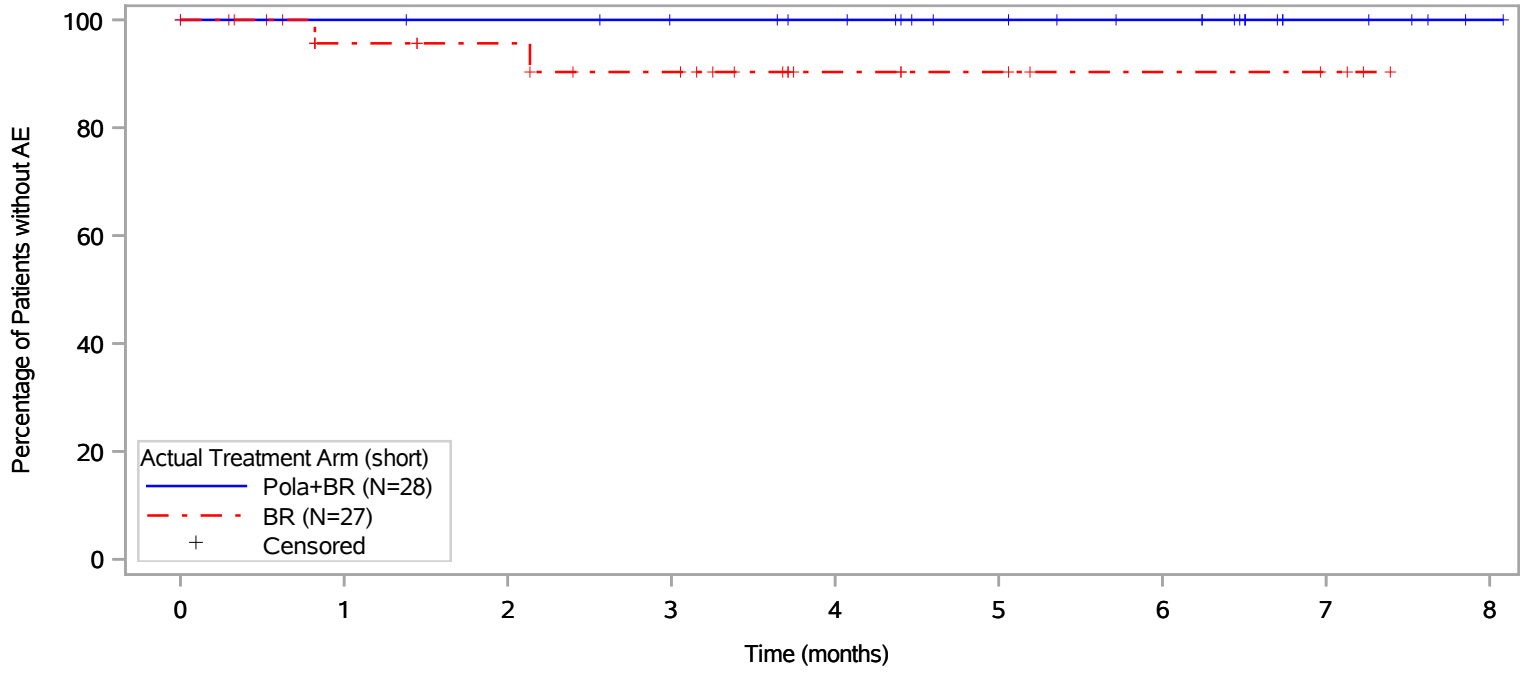


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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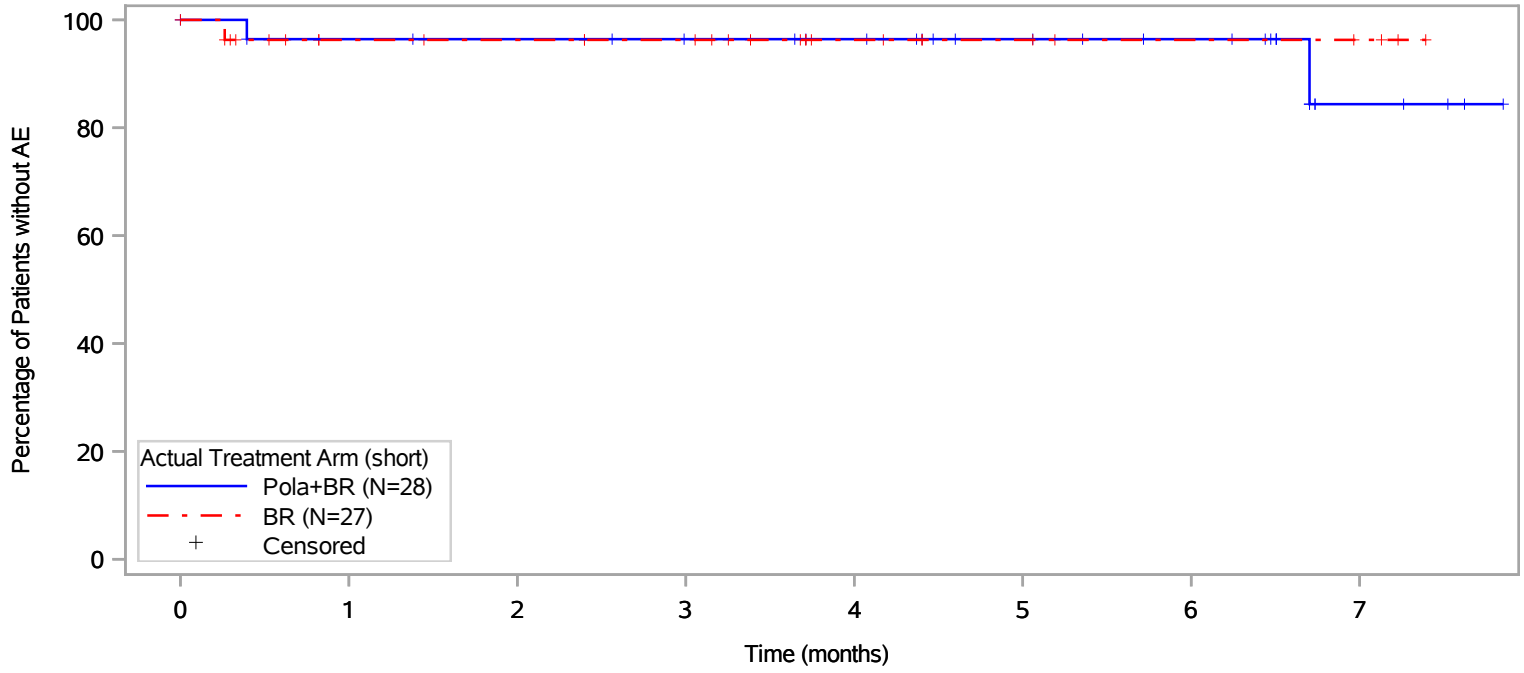
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL



Patients at risk								
Pola+BR (N=28)	28	27	26	24	22	17	14	4
BR (N=27)	27	20	19	17	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	10	13	22
BR (N=27)	0	6	7	9	17	20	22	23

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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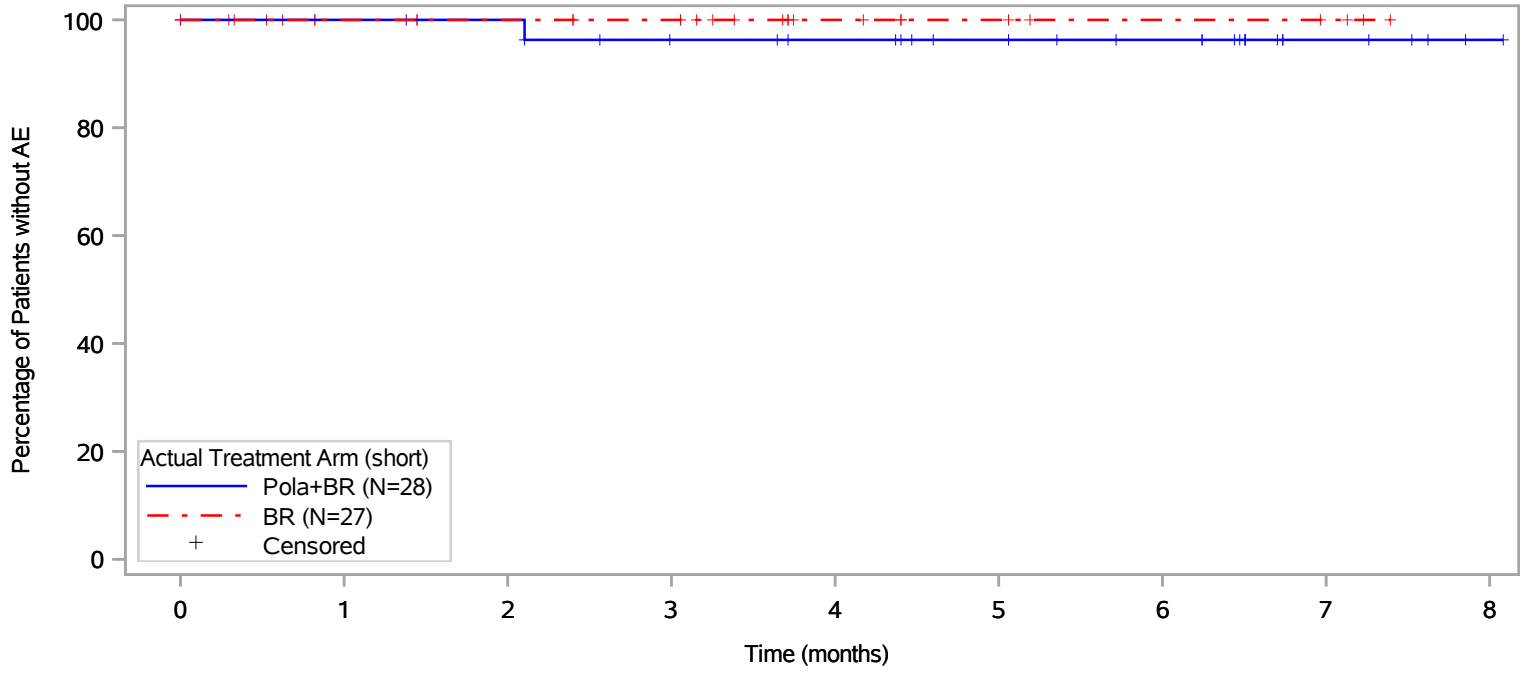
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PAIN

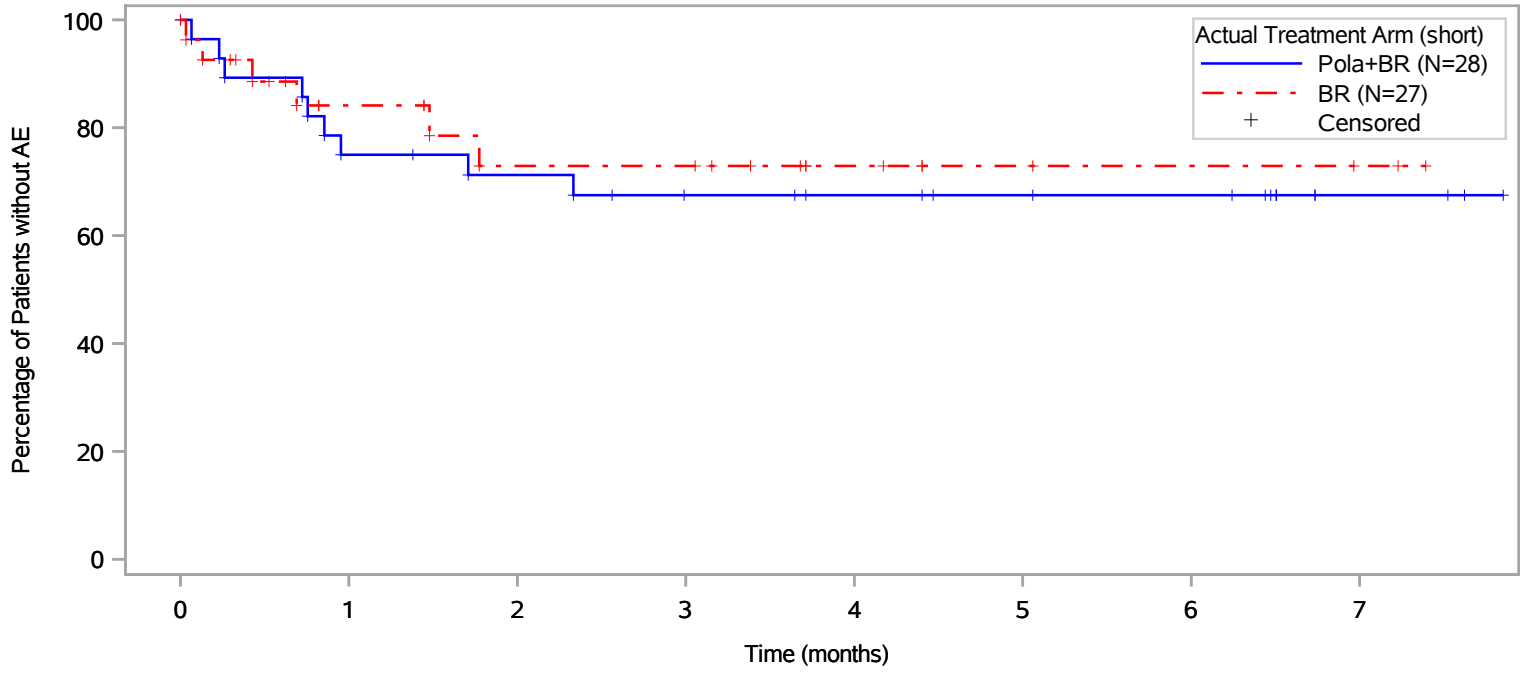


Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA

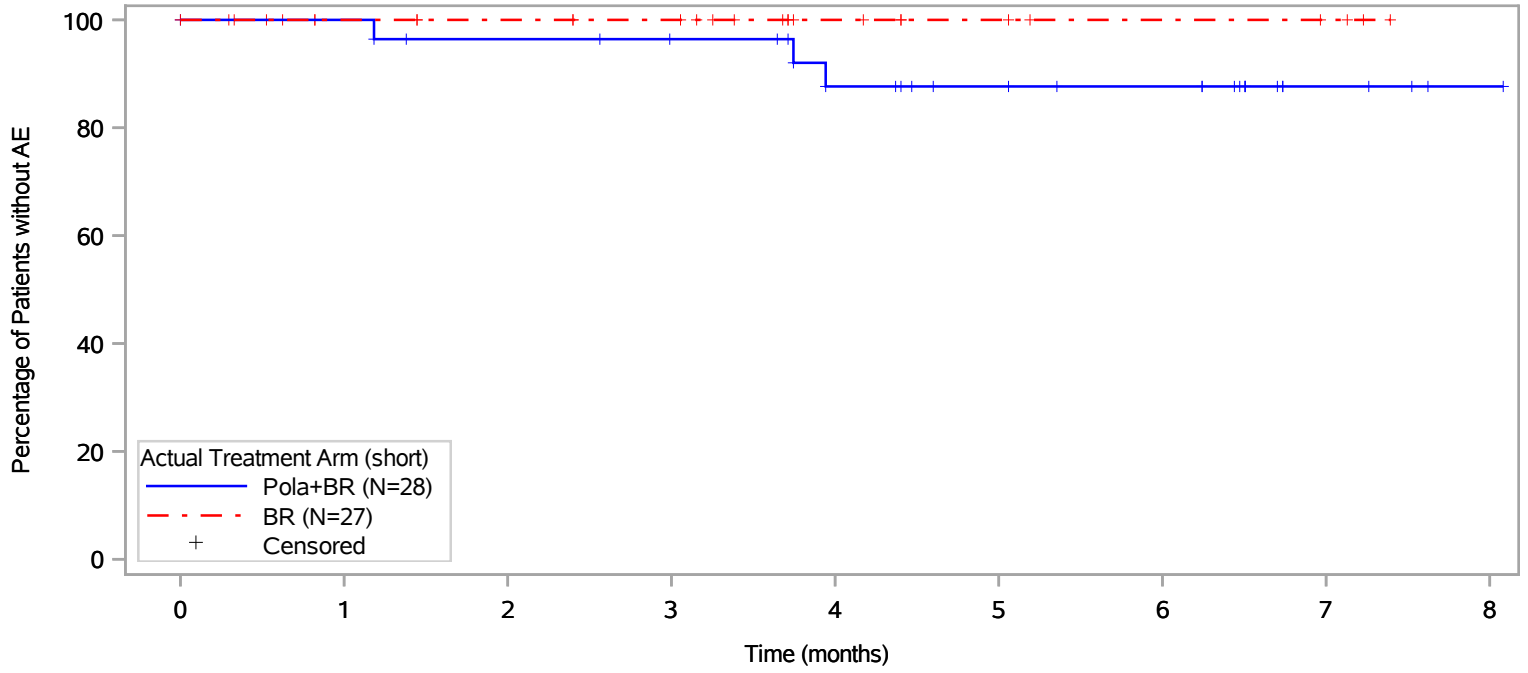


Patients at risk								
Pola+BR (N=28)	28	21	19	16	14	12	11	3
BR (N=27)	27	17	13	13	7	4	3	2
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	7	8	16
BR (N=27)	0	6	8	8	14	17	18	19

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

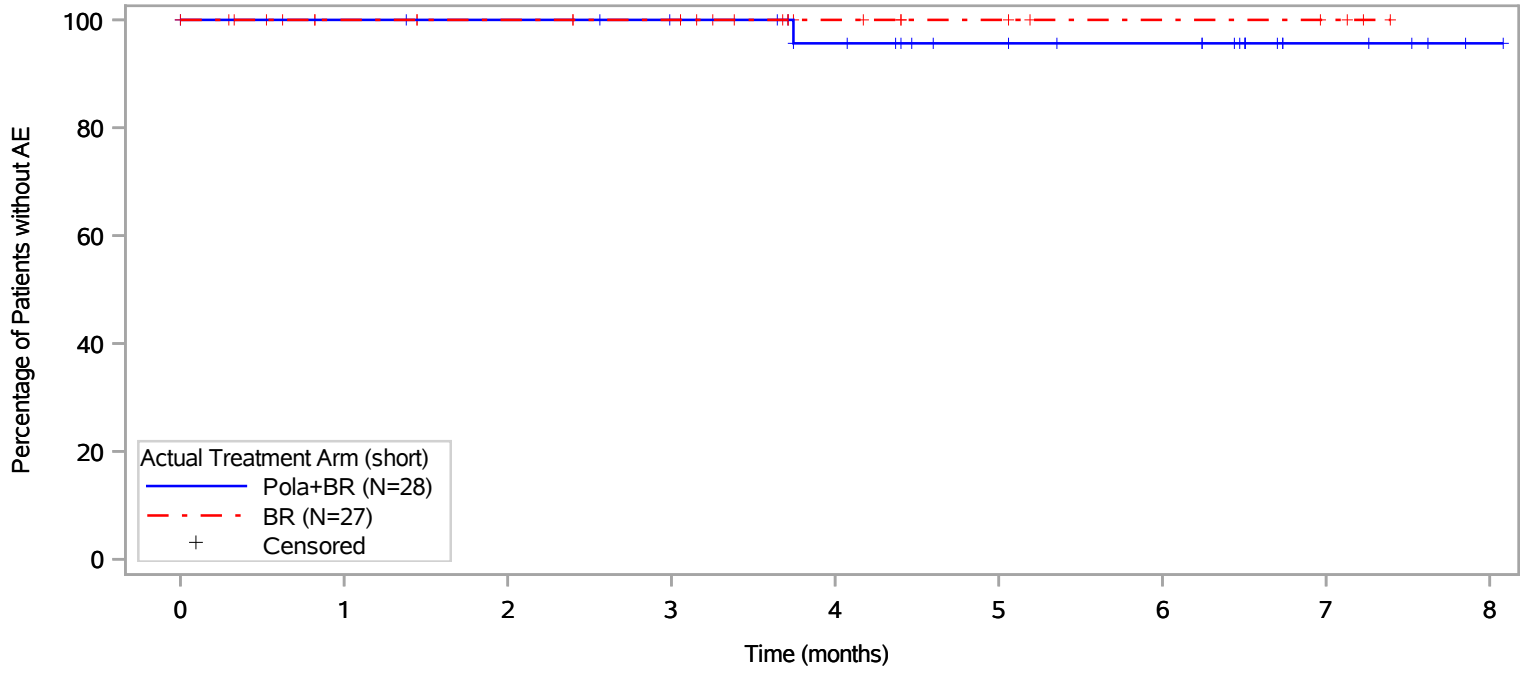
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	28	26	24	20	16	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	11	21	24
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, AMYLOIDOSIS

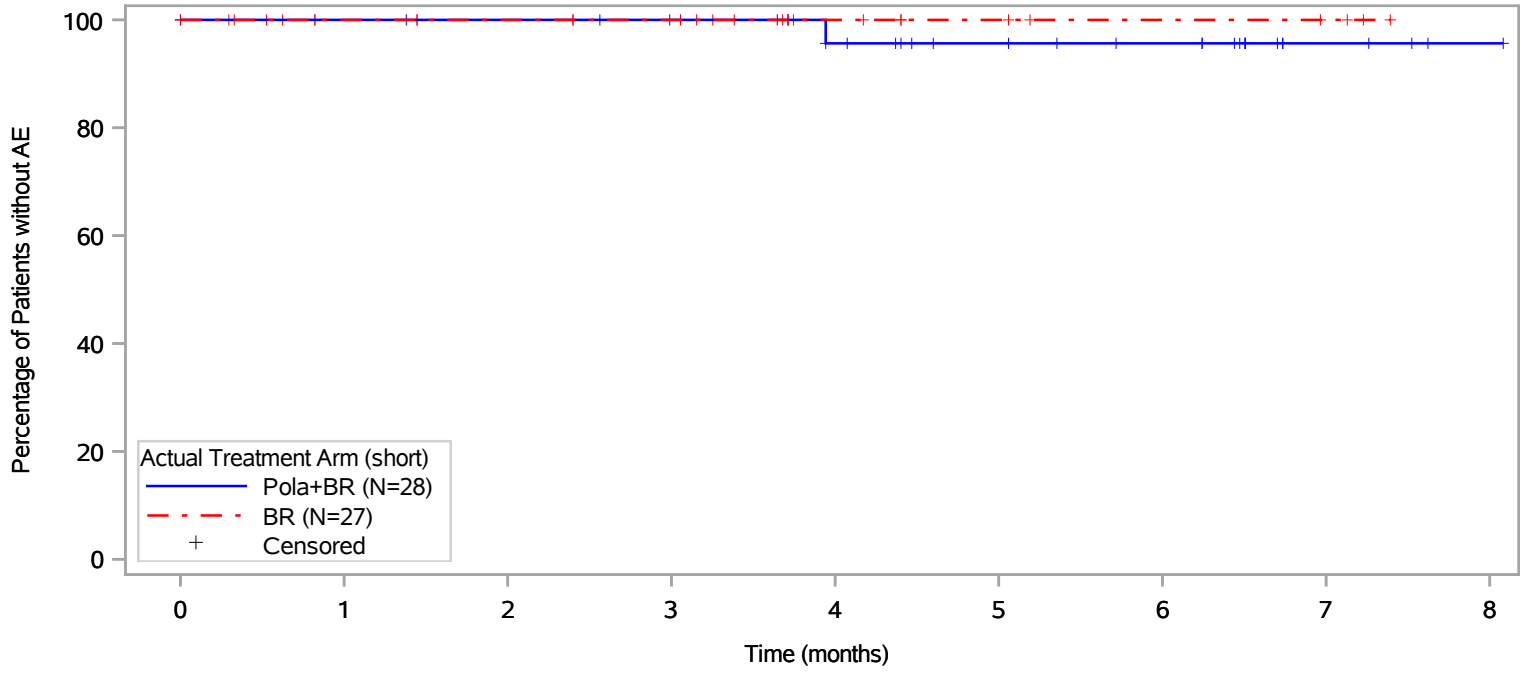


Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

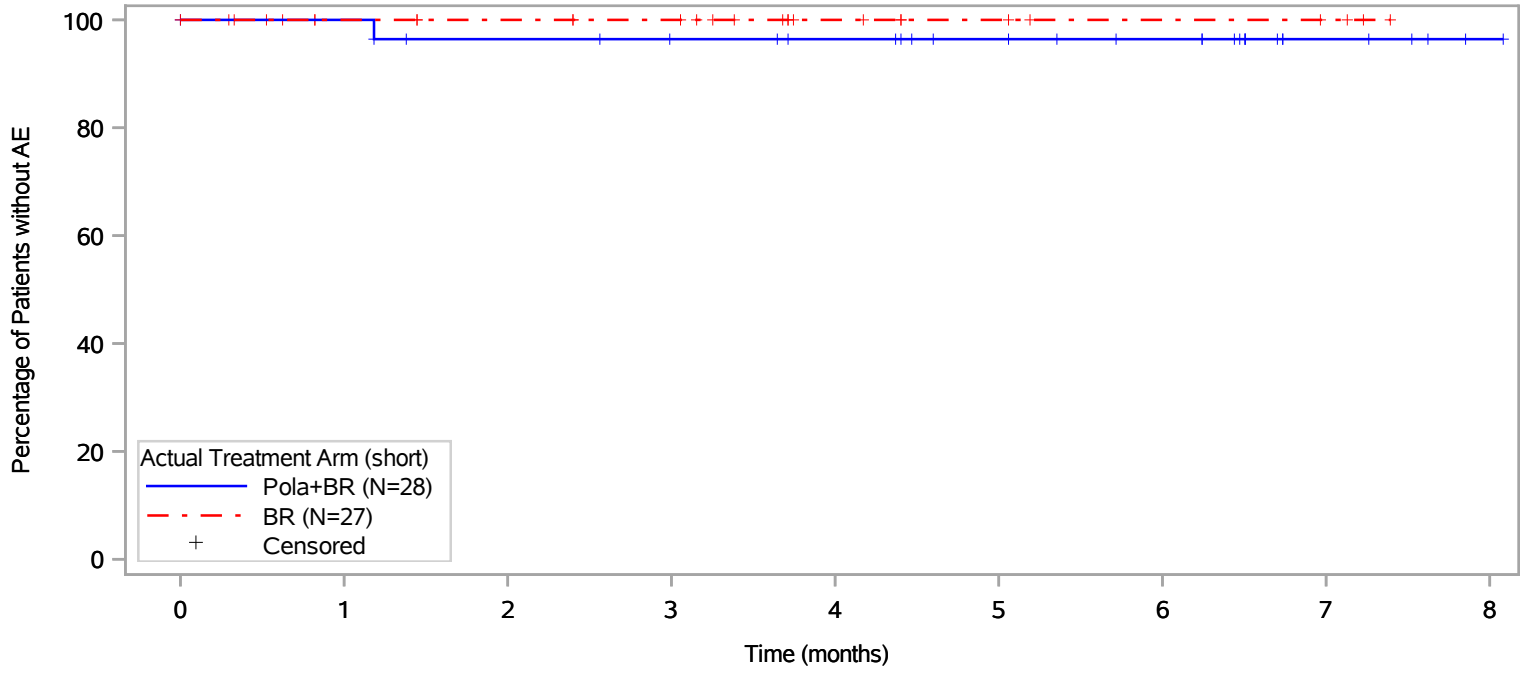
IMMUNE SYSTEM DISORDERS, HYPOGAMMAGLOBULINAEMIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, SEASONAL ALLERGY



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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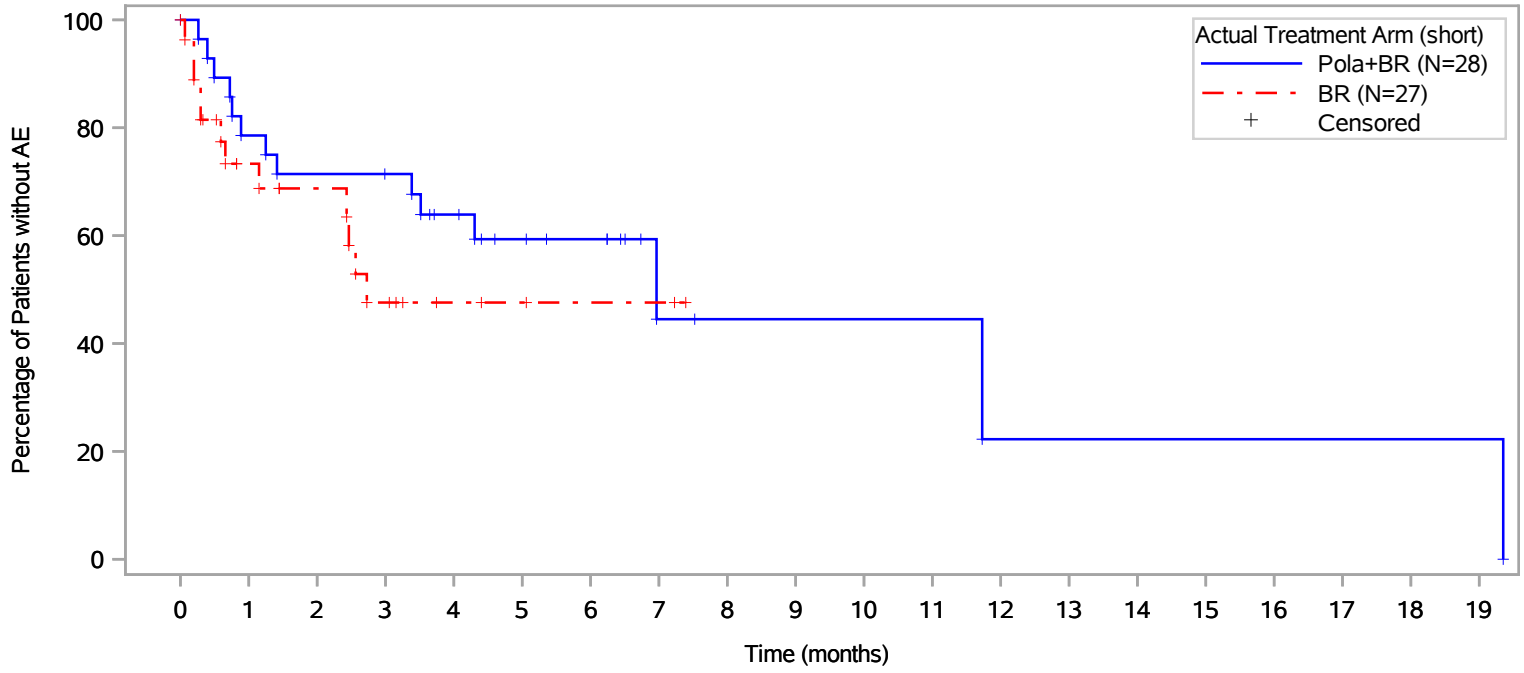
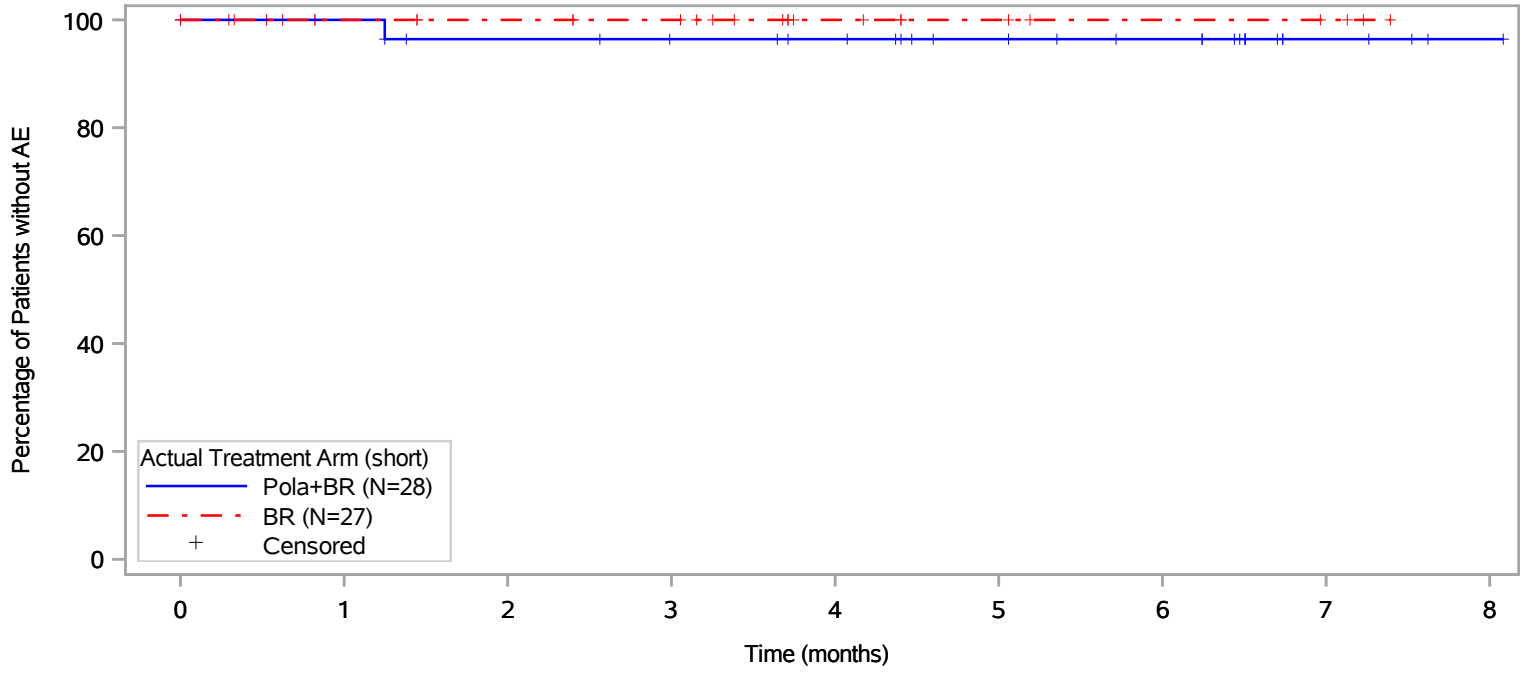
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk																				
Pola+BR (N=28)	28	22	20	19	15	11	9	3	2	2	2	2	1	1	1	1	1	1	1	1
BR (N=27)	27	16	13	9	5	4	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	0	1	3	6	8	13	14	14	14	14	14	14	14	14	14	14	14	14
BR (N=27)	0	4	6	6	10	11	12	13	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

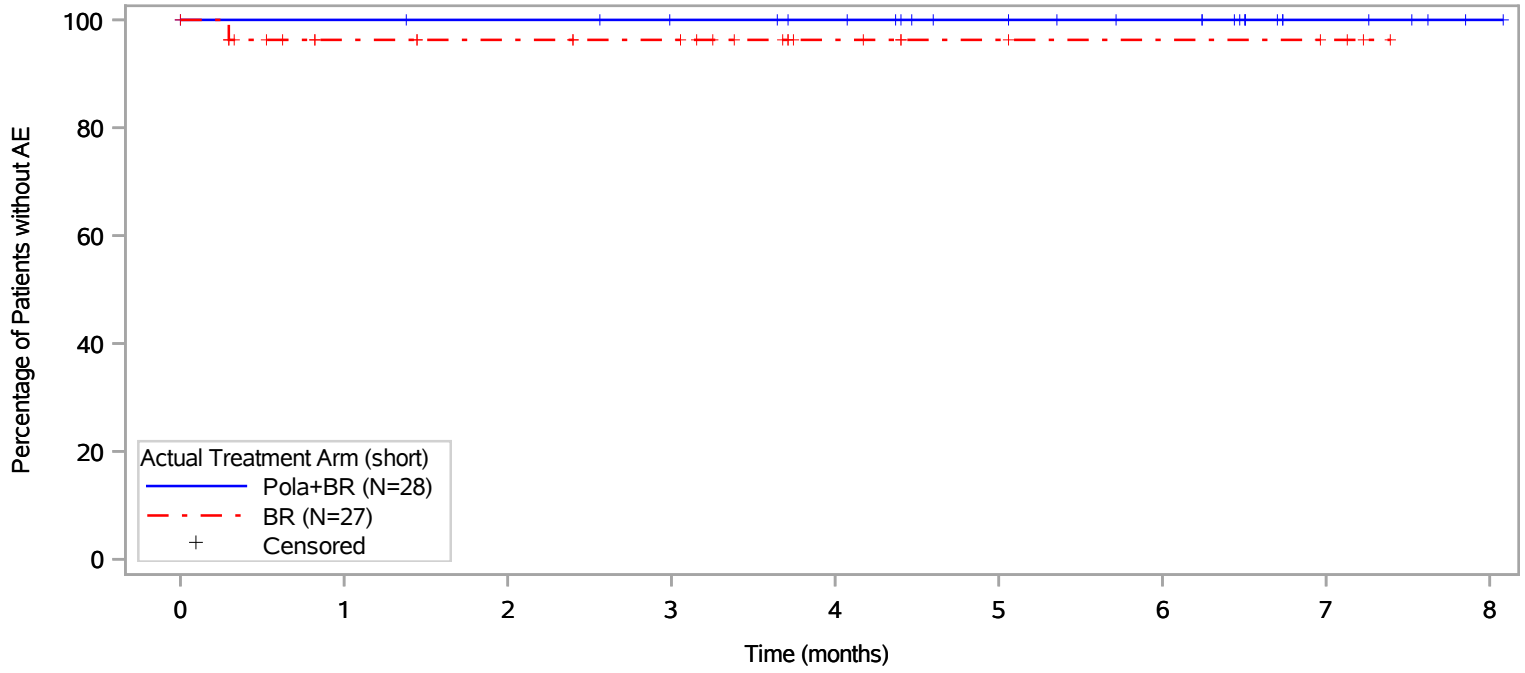
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, BRONCHITIS



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

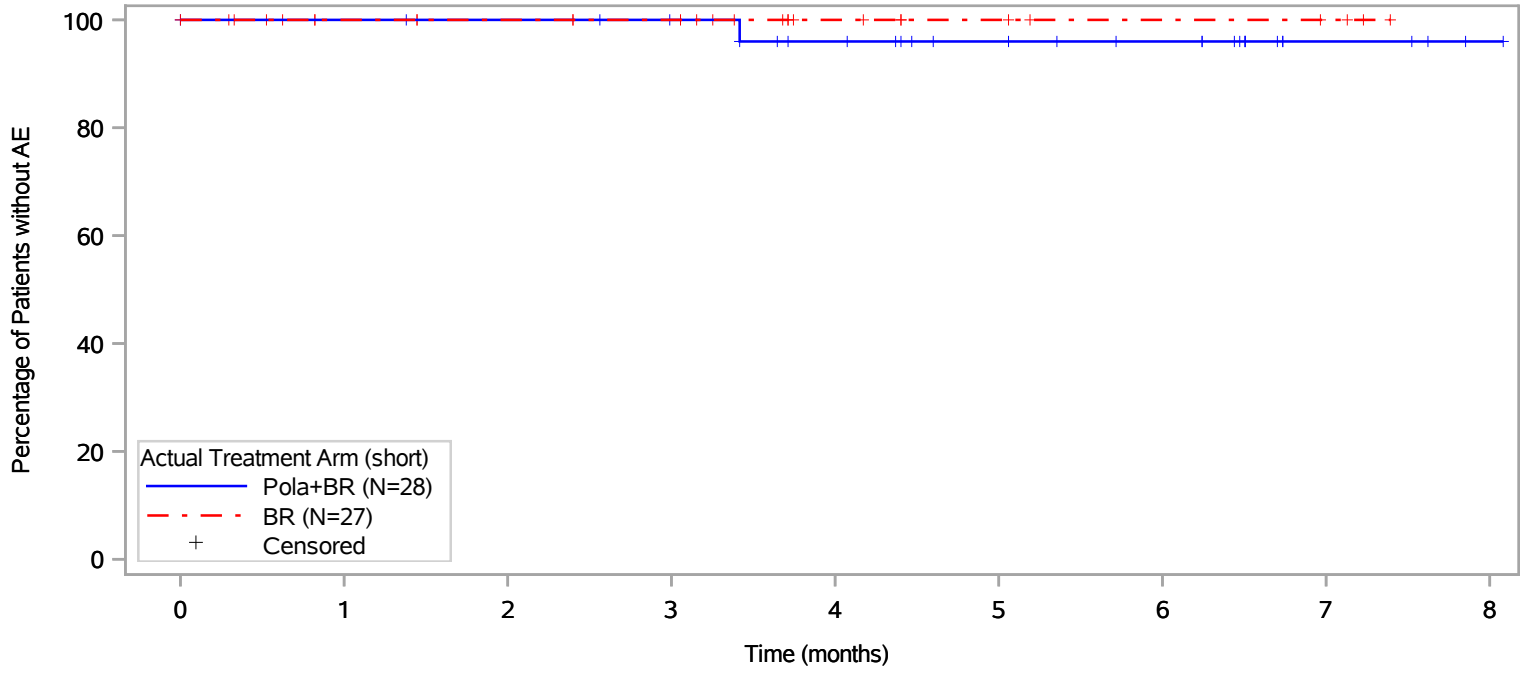
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CANDIDA INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CELLULITIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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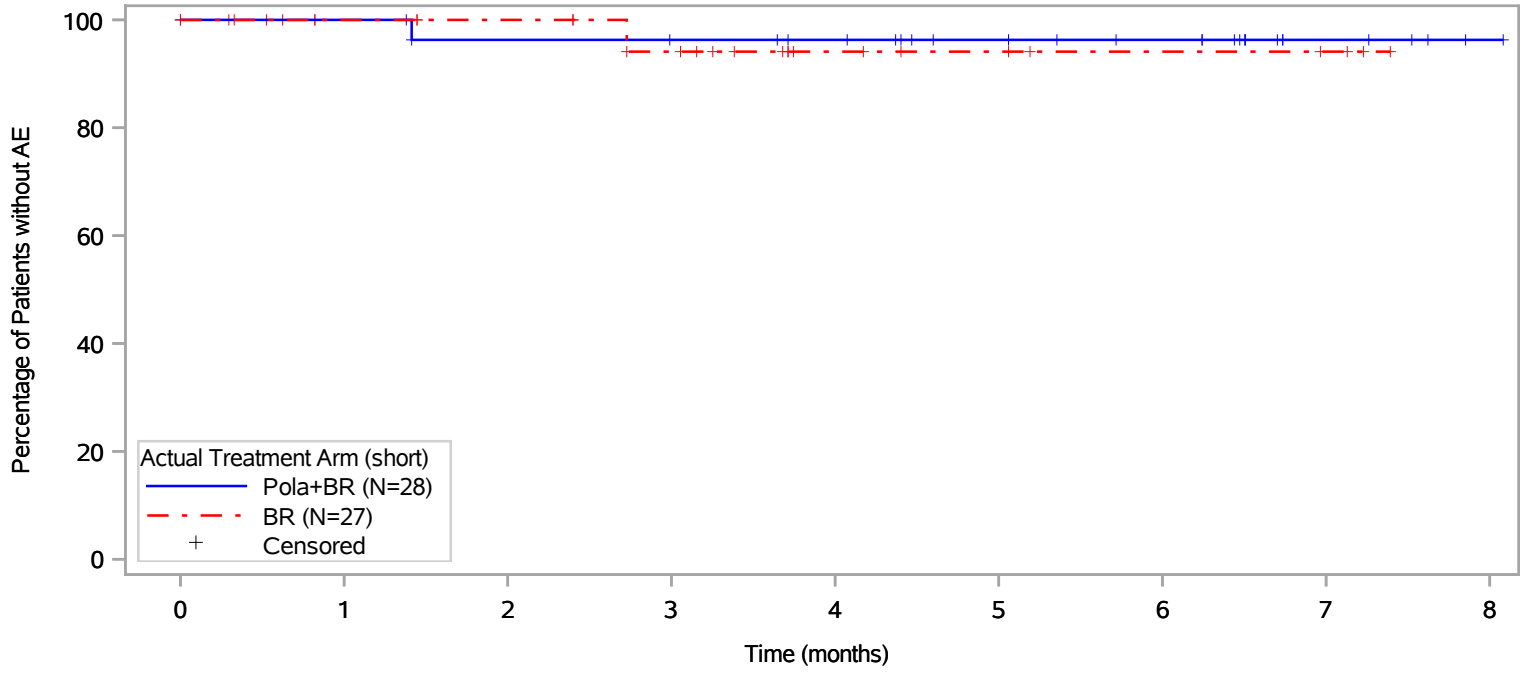
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CYTOMEGALOVIRUS INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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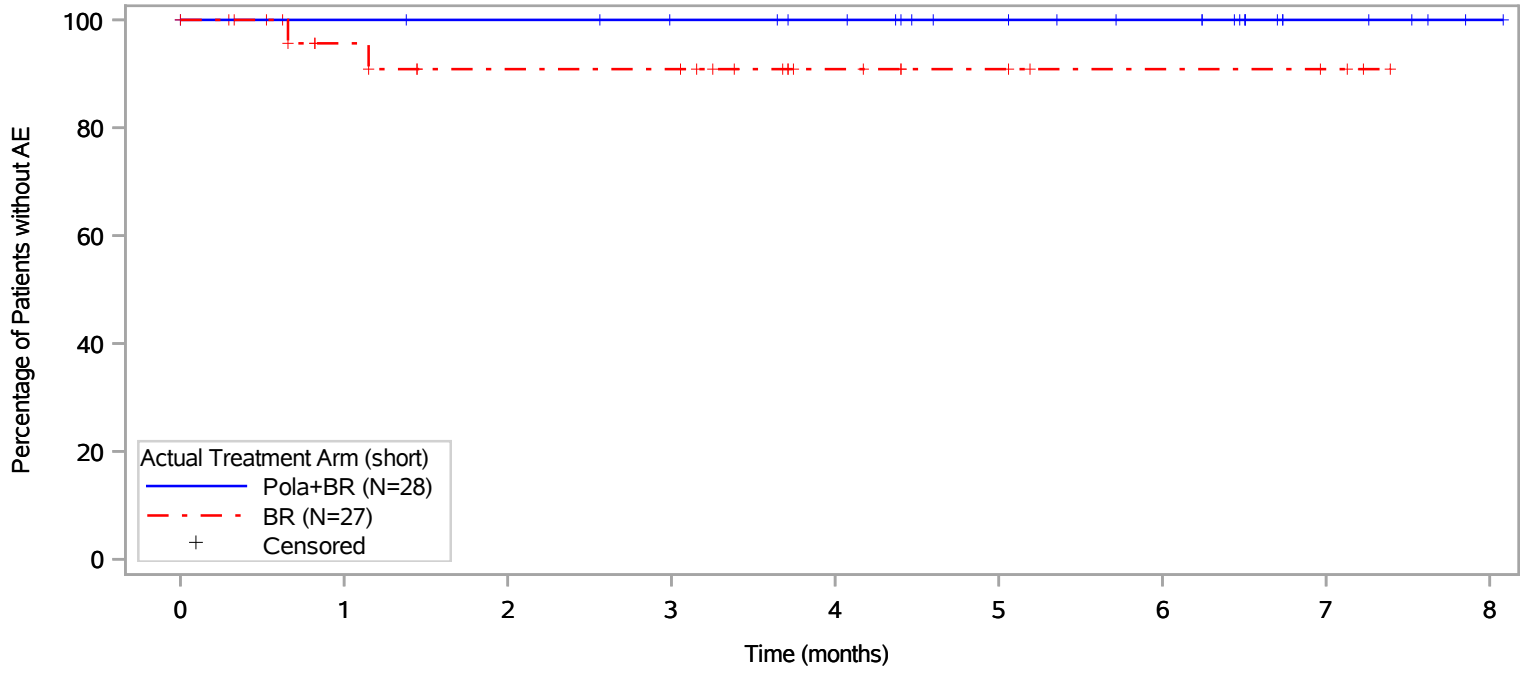
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, DEVICE RELATED INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	17	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	8	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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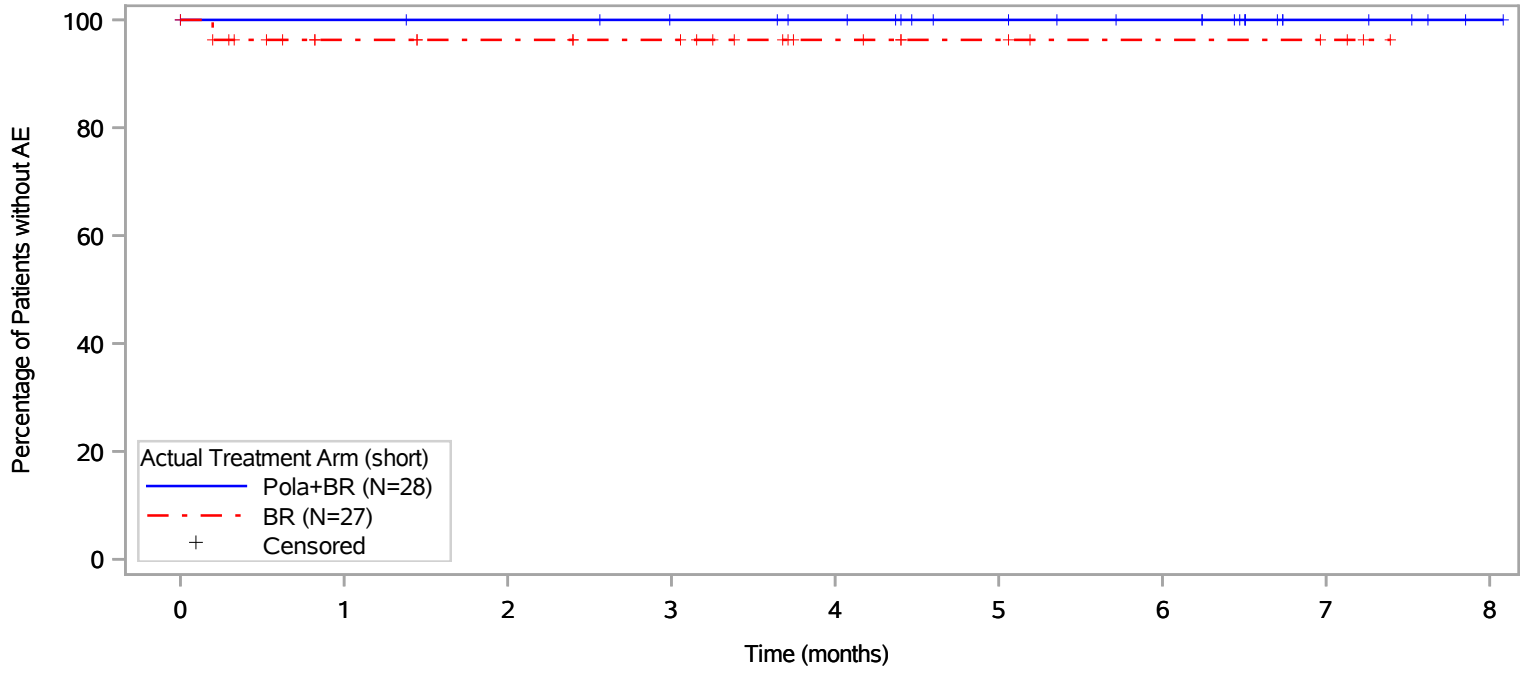
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ENTEROCOLITIS VIRAL



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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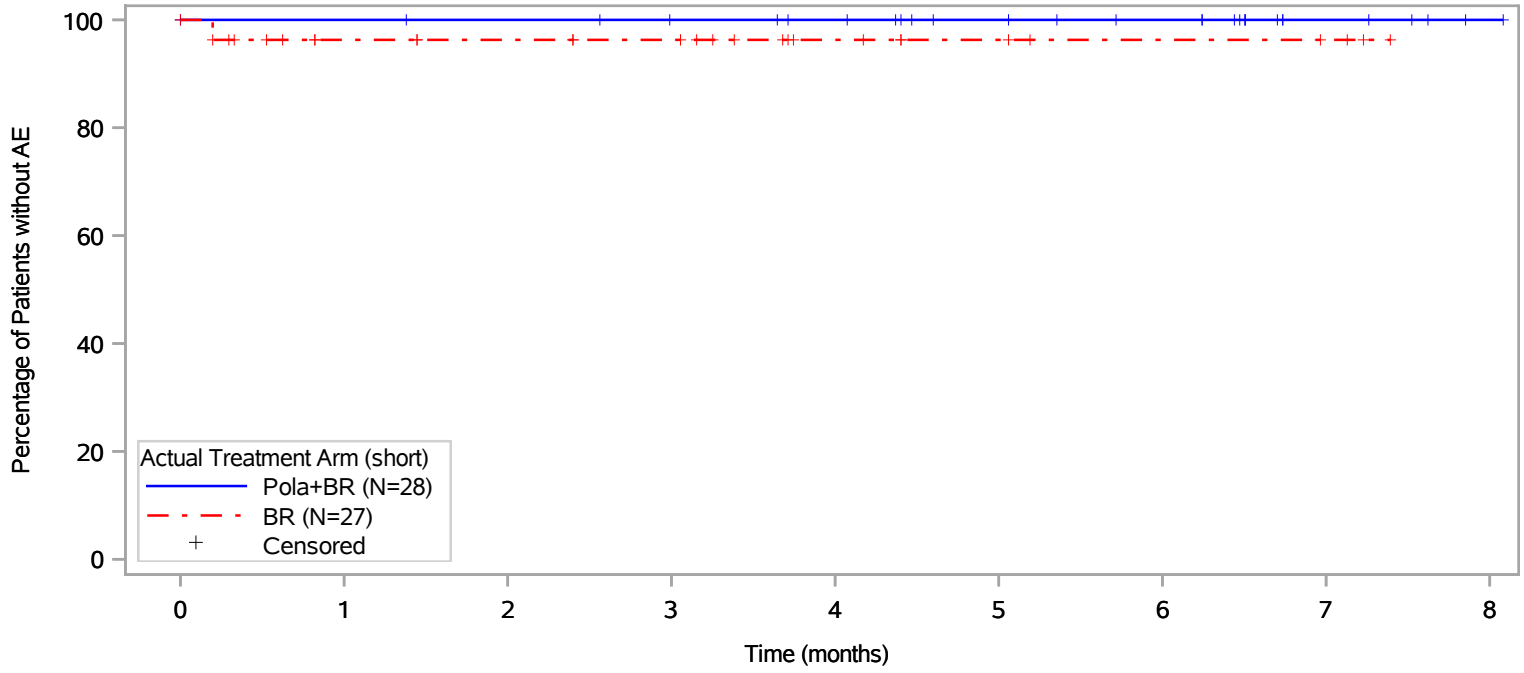
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ERYSIPELAS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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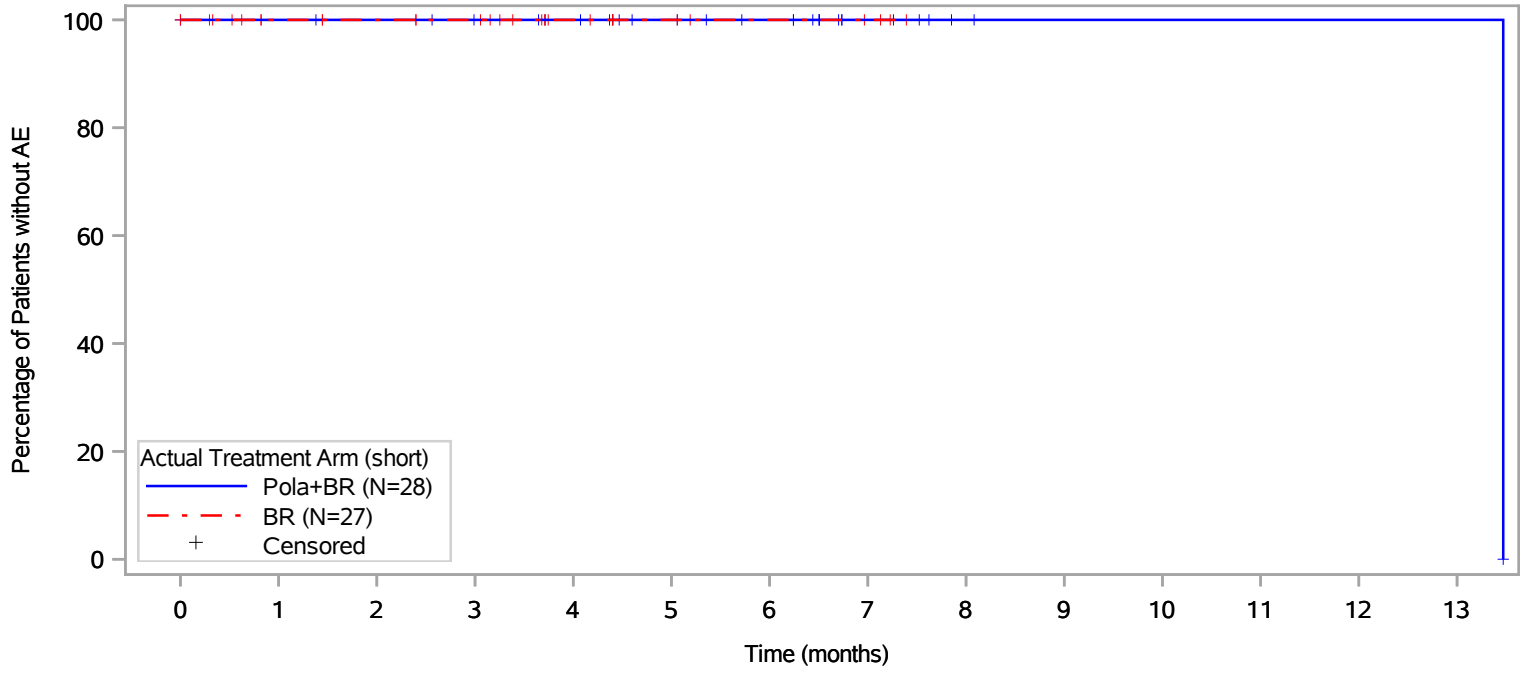
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, GASTROINTESTINAL BACTERIAL INFECTION



Patients at risk														
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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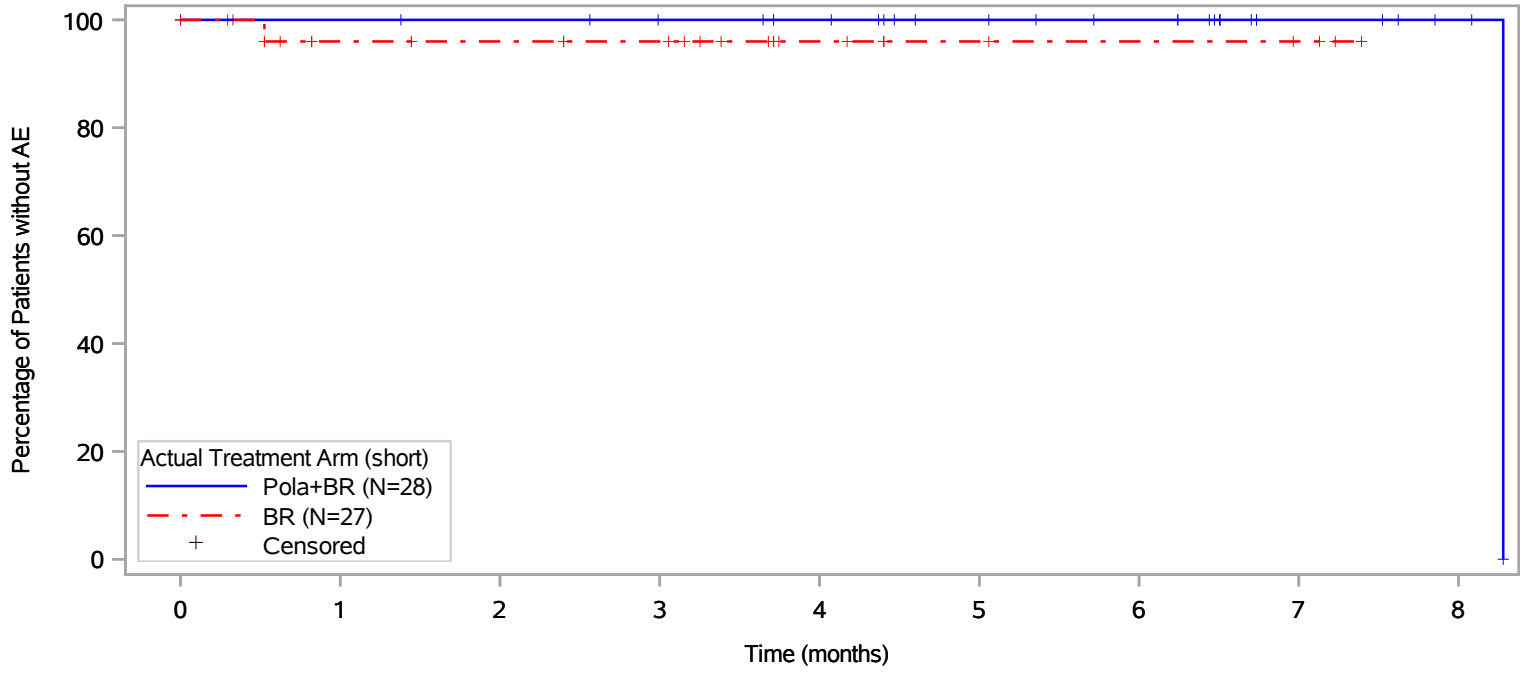
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	2
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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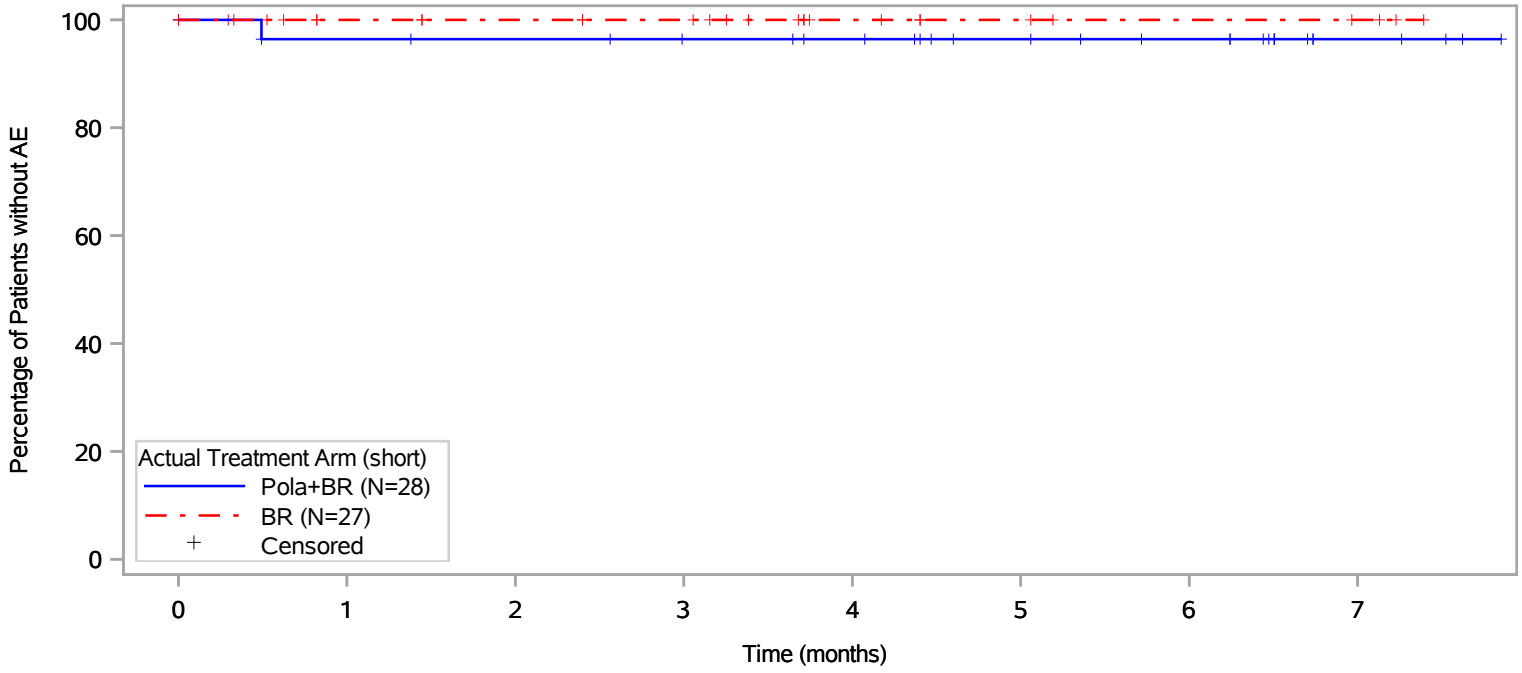
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HUMAN ANAPLASMOSIS



Patients at risk								
Pola+BR (N=28)	28	27	26	24	22	17	14	4
BR (N=27)	27	21	19	17	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	10	13	23
BR (N=27)	0	6	8	10	18	21	23	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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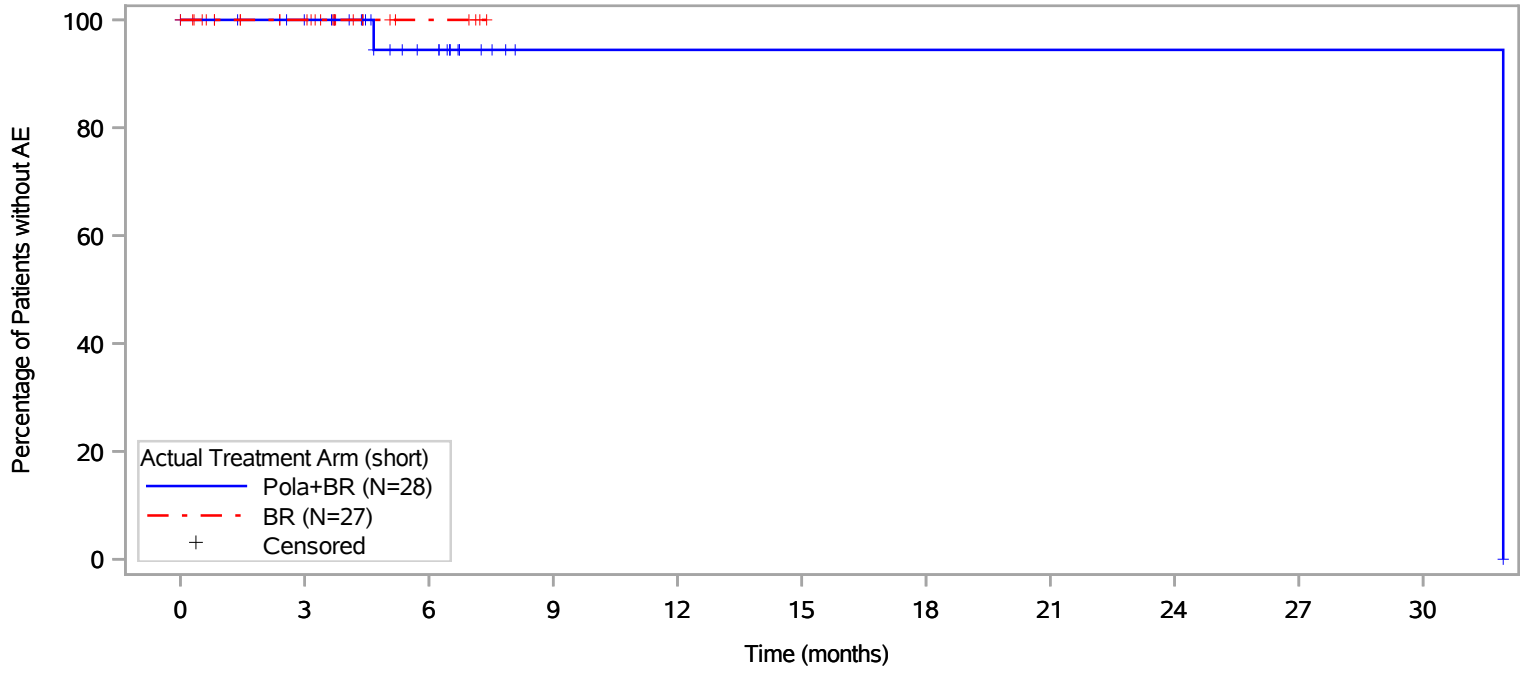
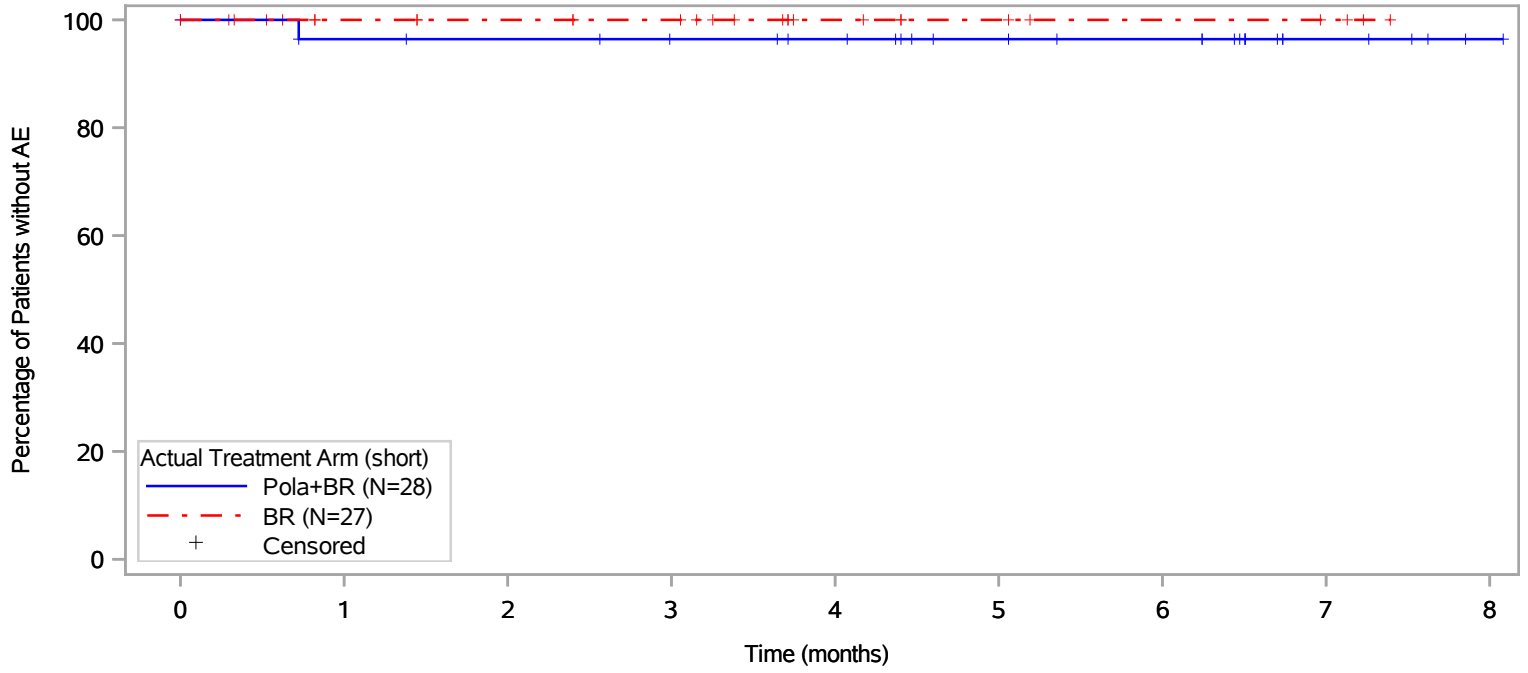
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk											
Pola+BR (N=28)	28	25	14	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	3	13	26	26	26	26	26	26	26	26
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

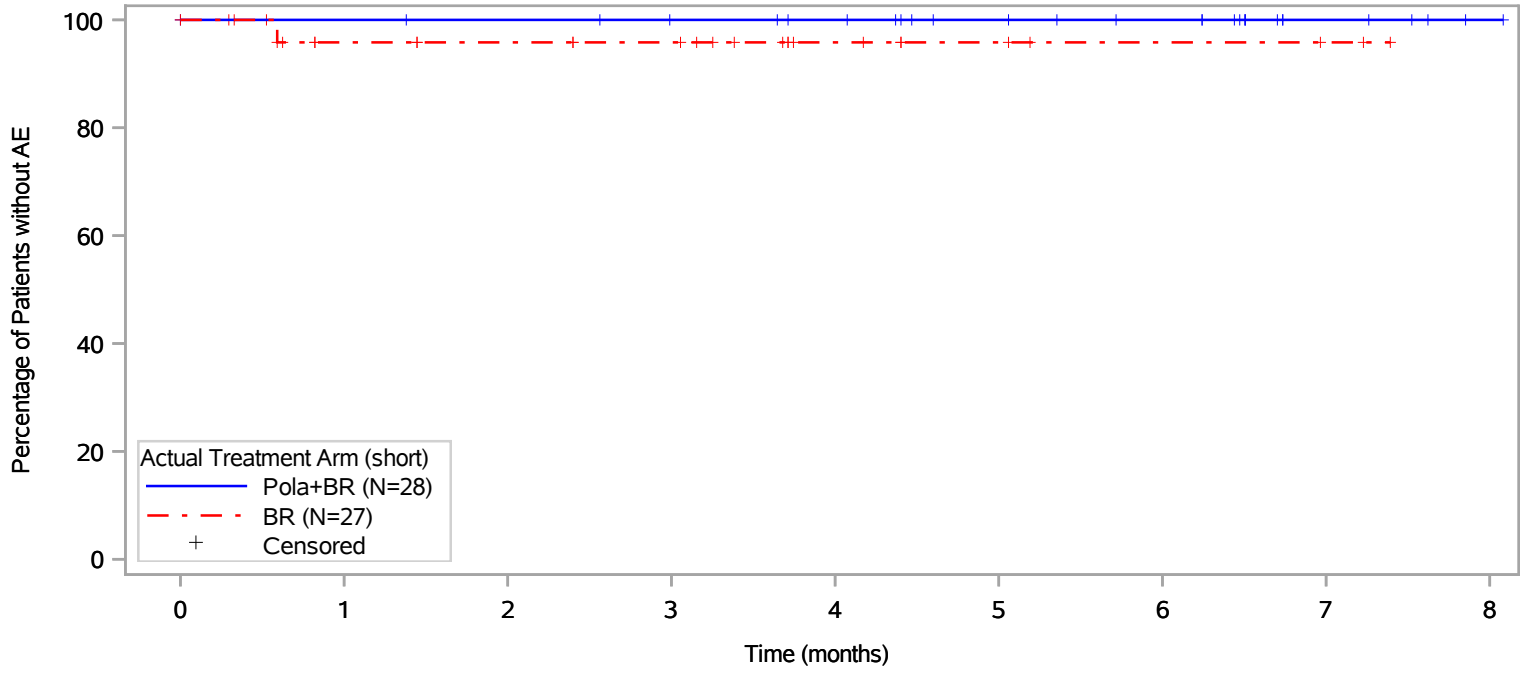
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFLUENZA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, LOWER RESPIRATORY TRACT INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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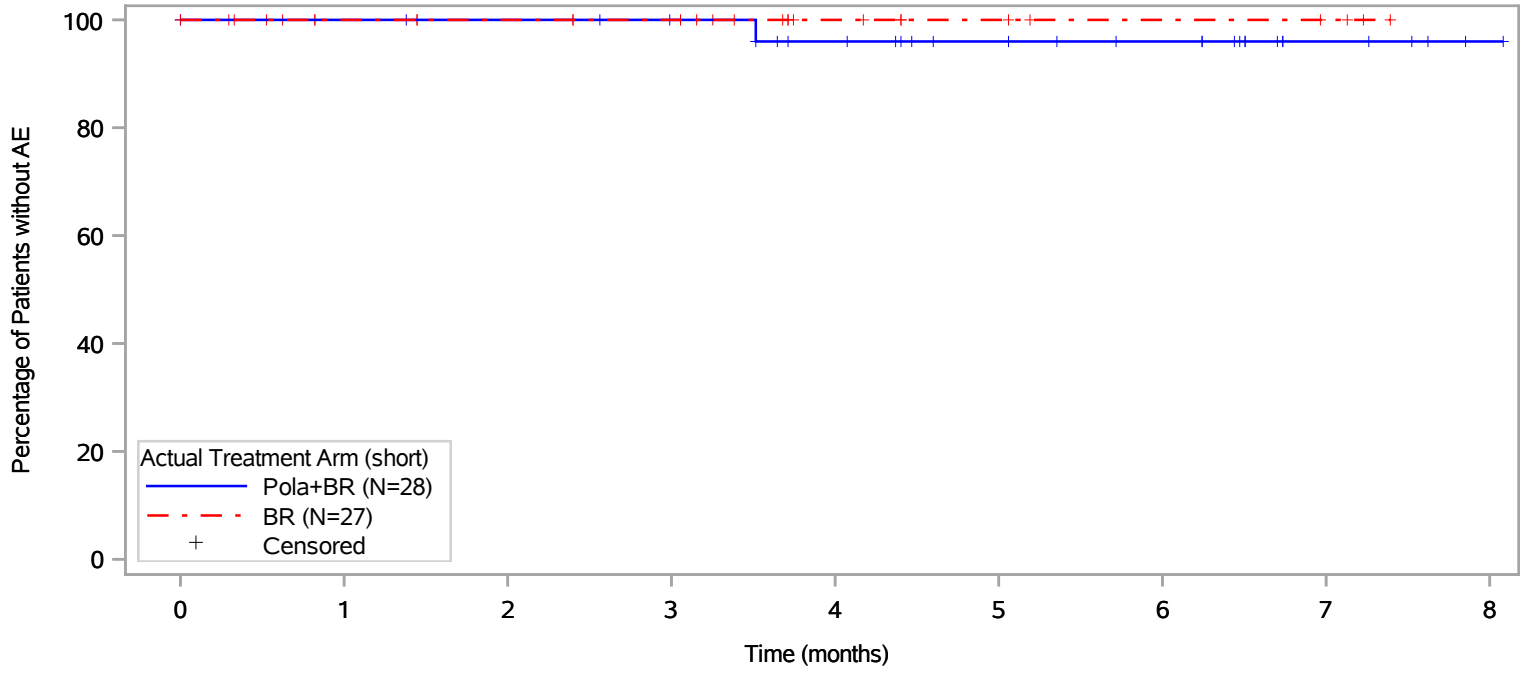
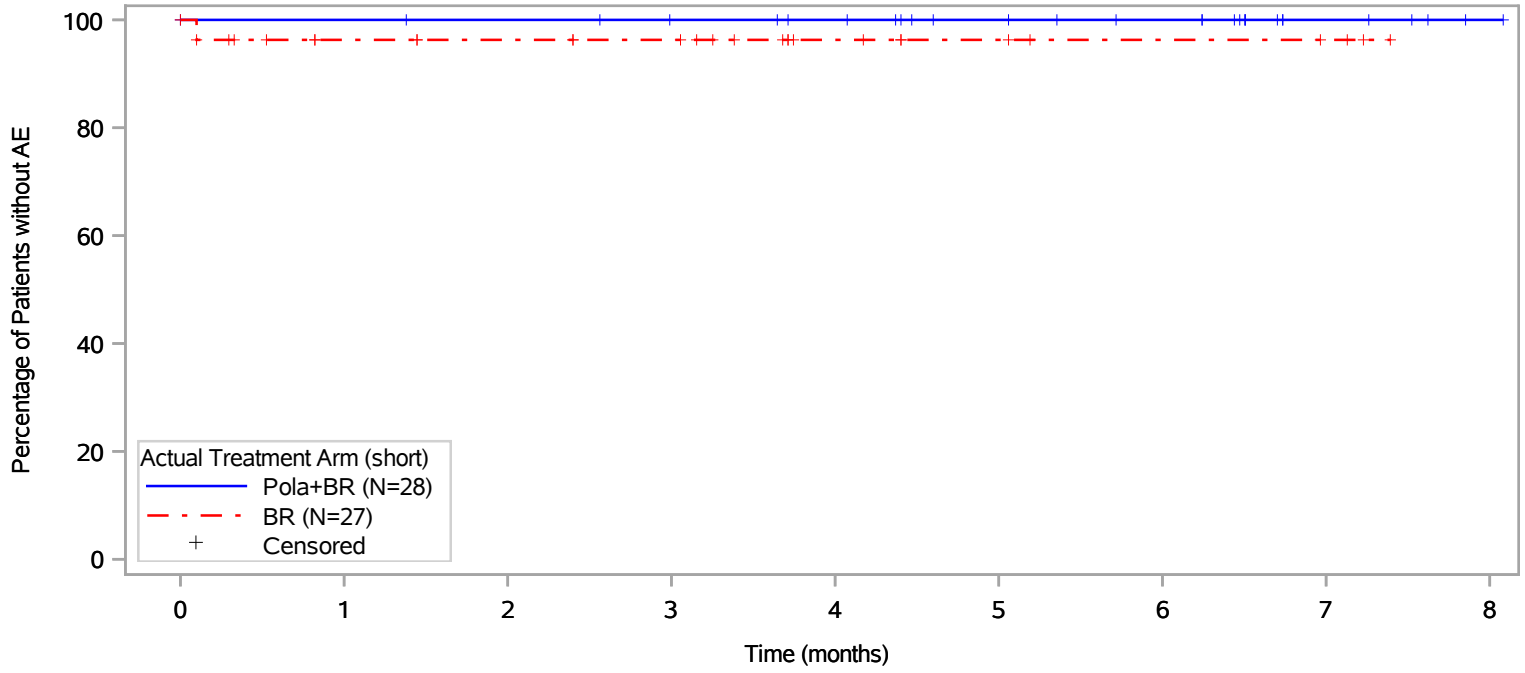
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NASOPHARYNGITIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NEUTROPENIC SEPSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	5	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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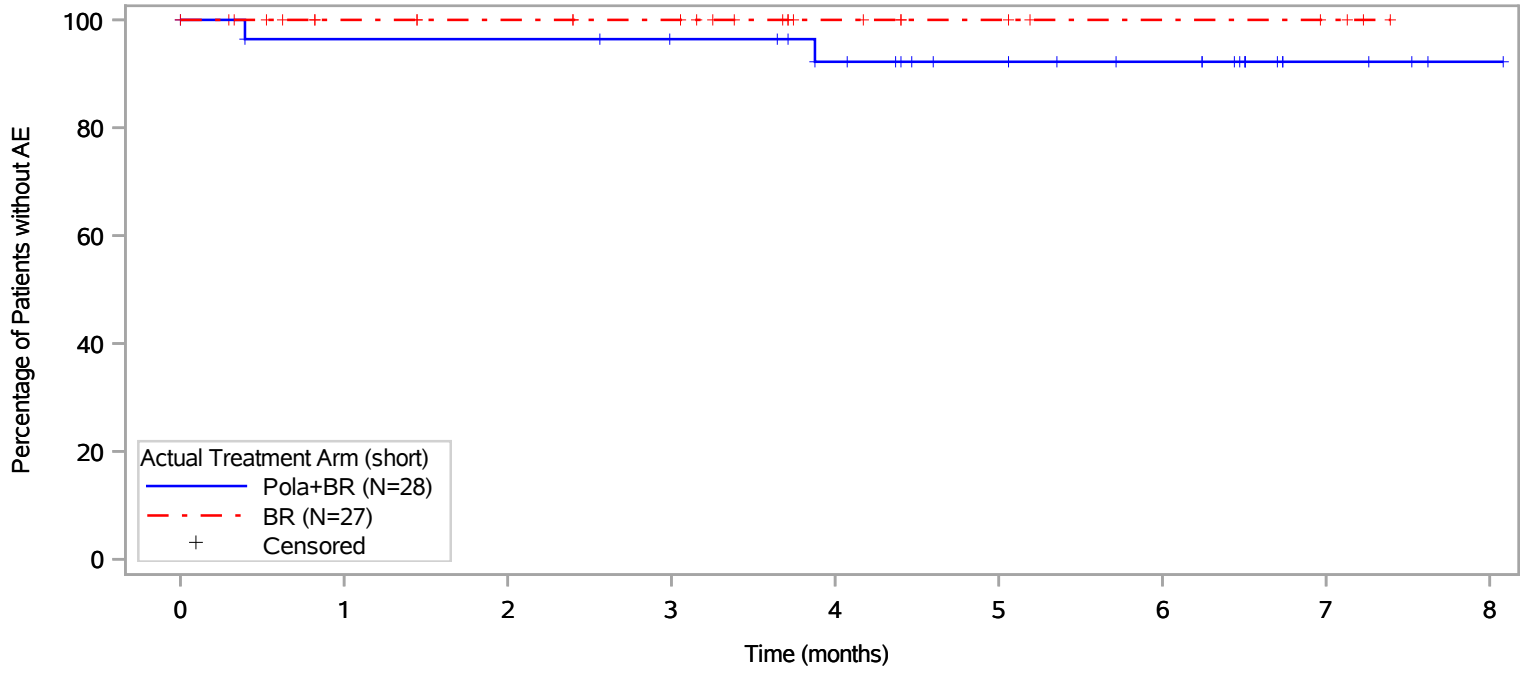
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ORAL CANDIDIASIS

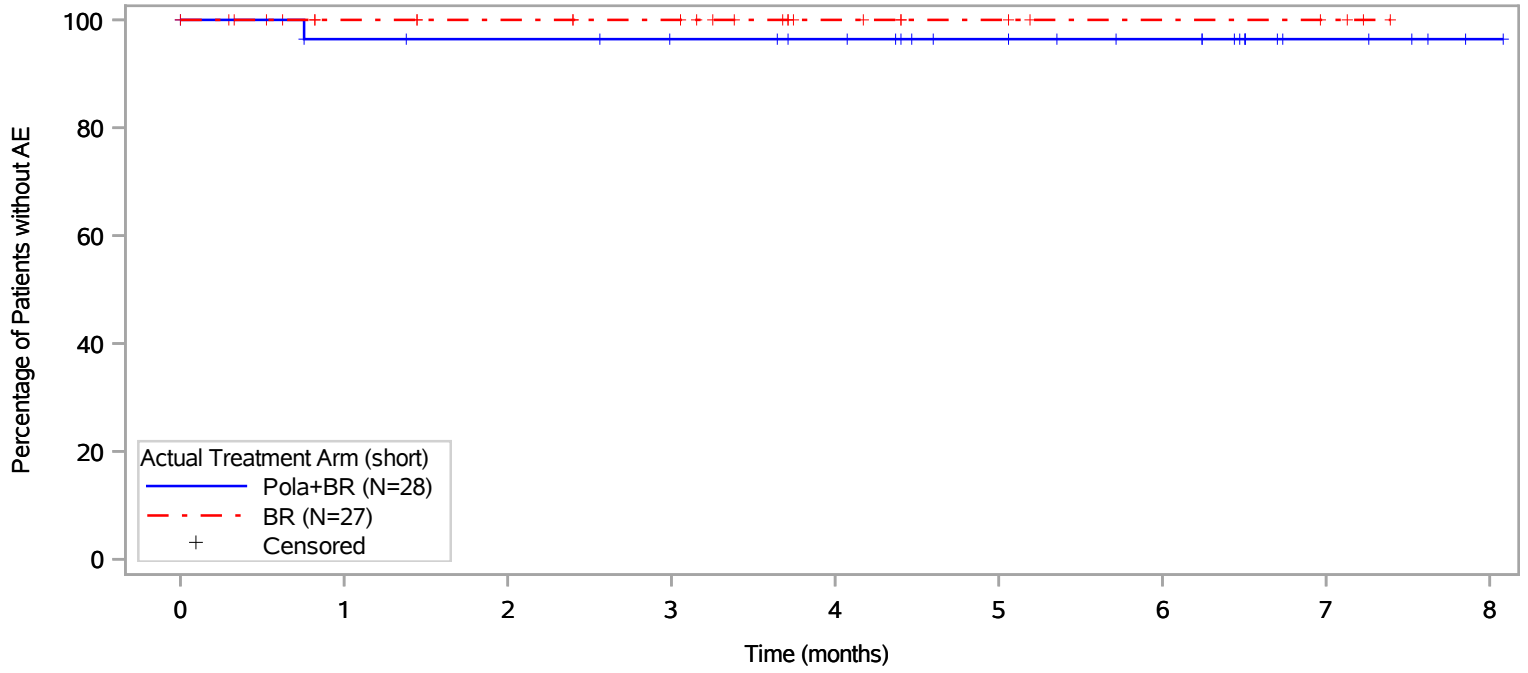


Patients at risk									
Pola+BR (N=28)	28	27	27	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMOCYSTIS JIROVECII PNEUMONIA

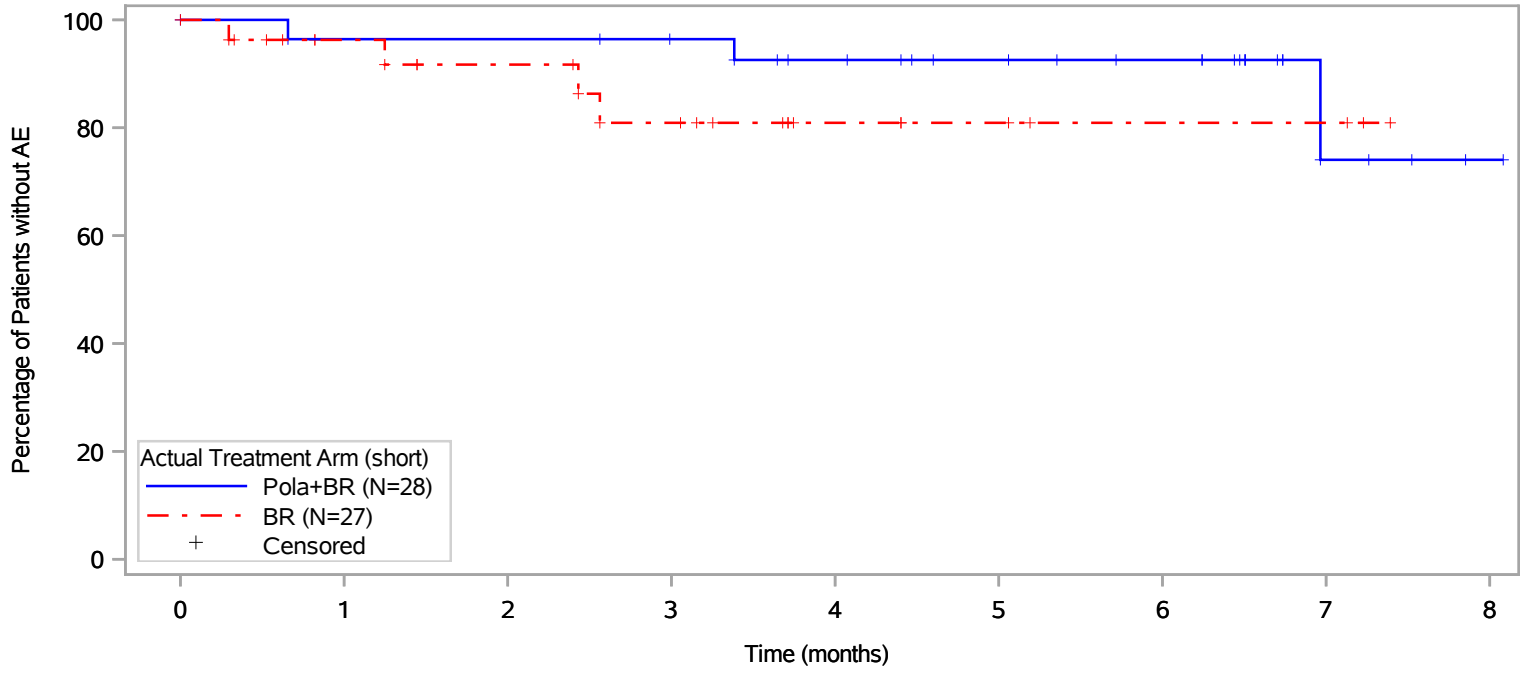


Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=28)	28	27	27	25	22	18	15	4	1
BR (N=27)	27	21	18	15	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	8	11	21	24
BR (N=27)	0	5	7	8	15	17	19	20	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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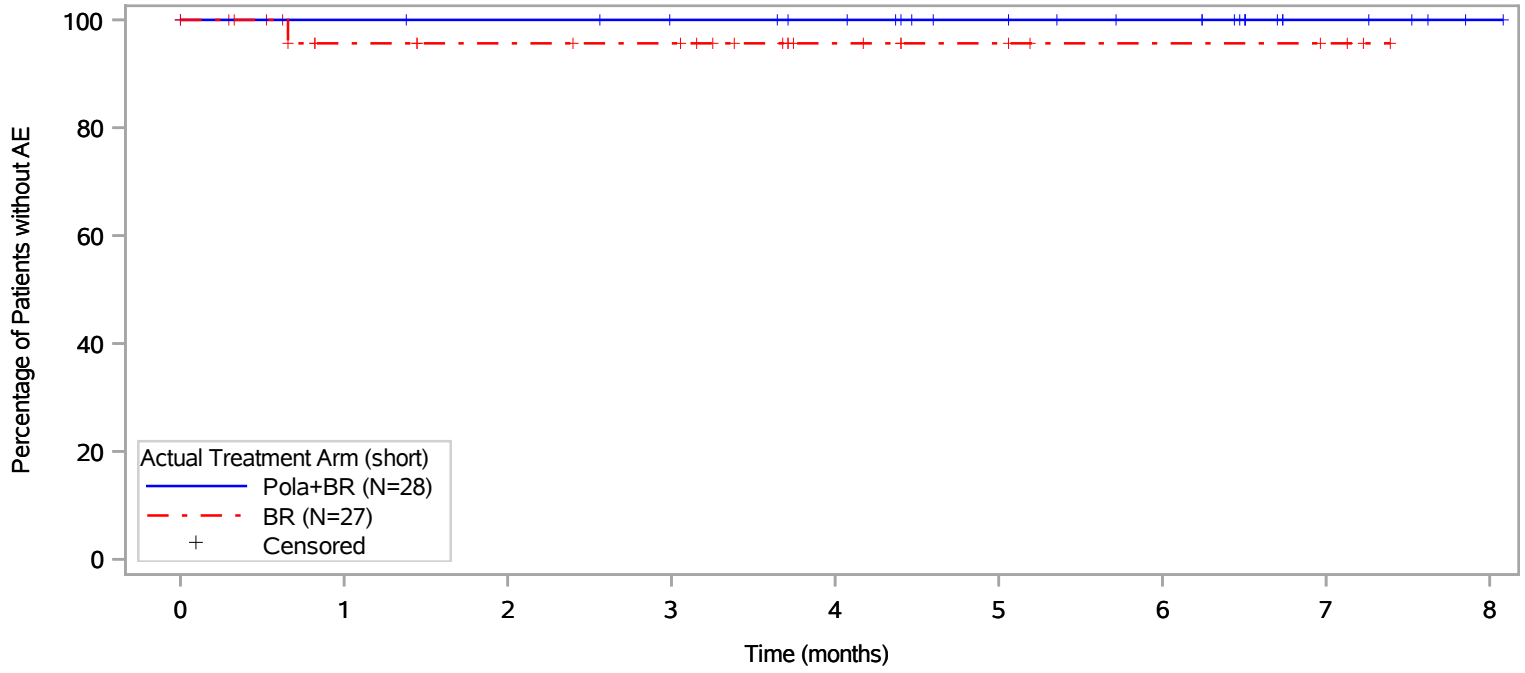
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA FUNGAL

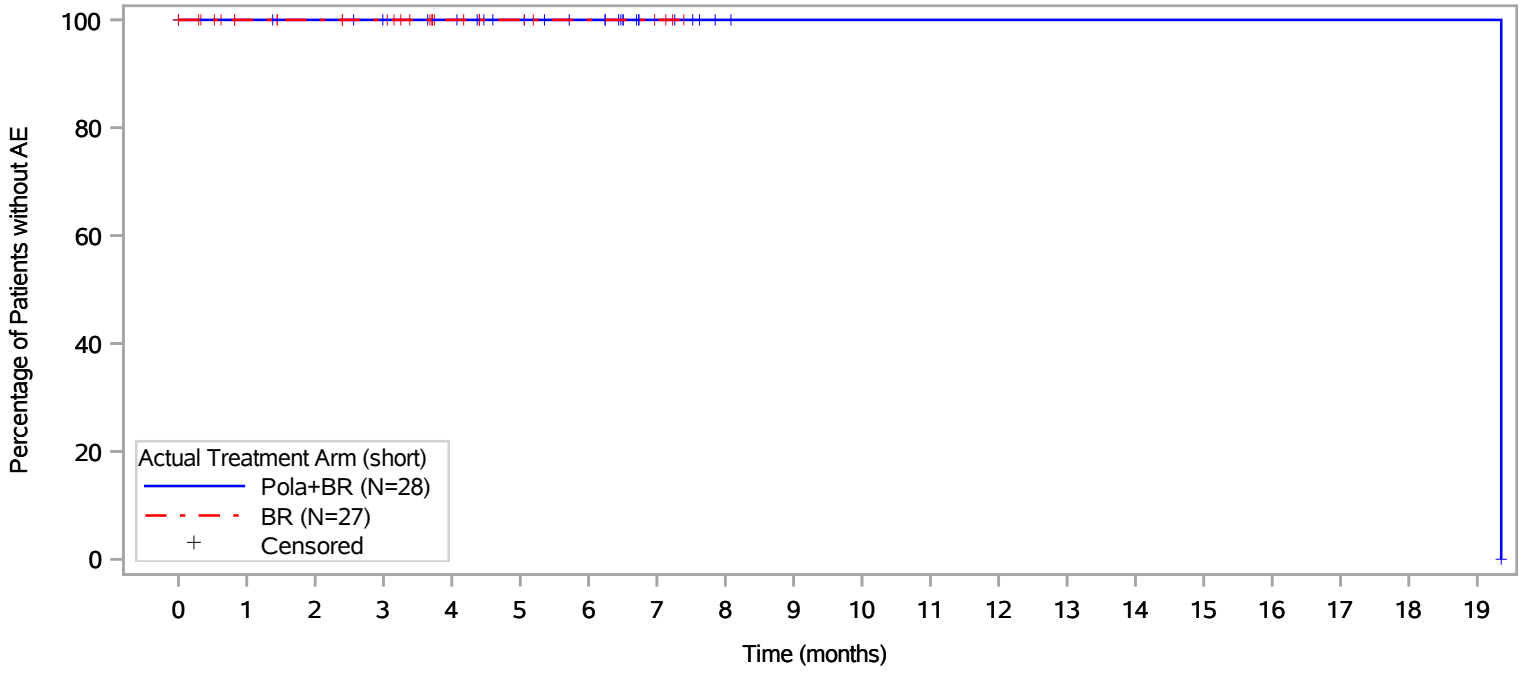


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA PNEUMOCOCCAL



Patients at risk																				
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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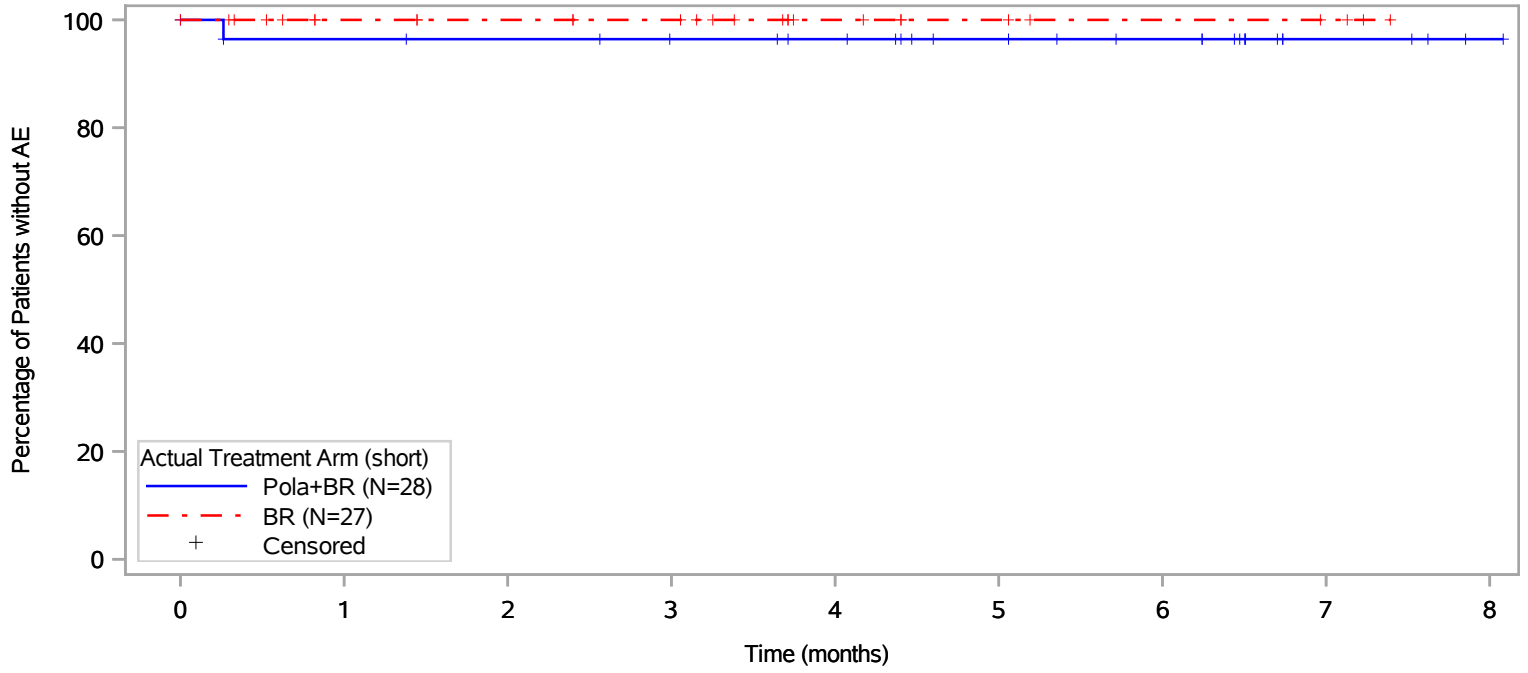
01DEC2022 21:22

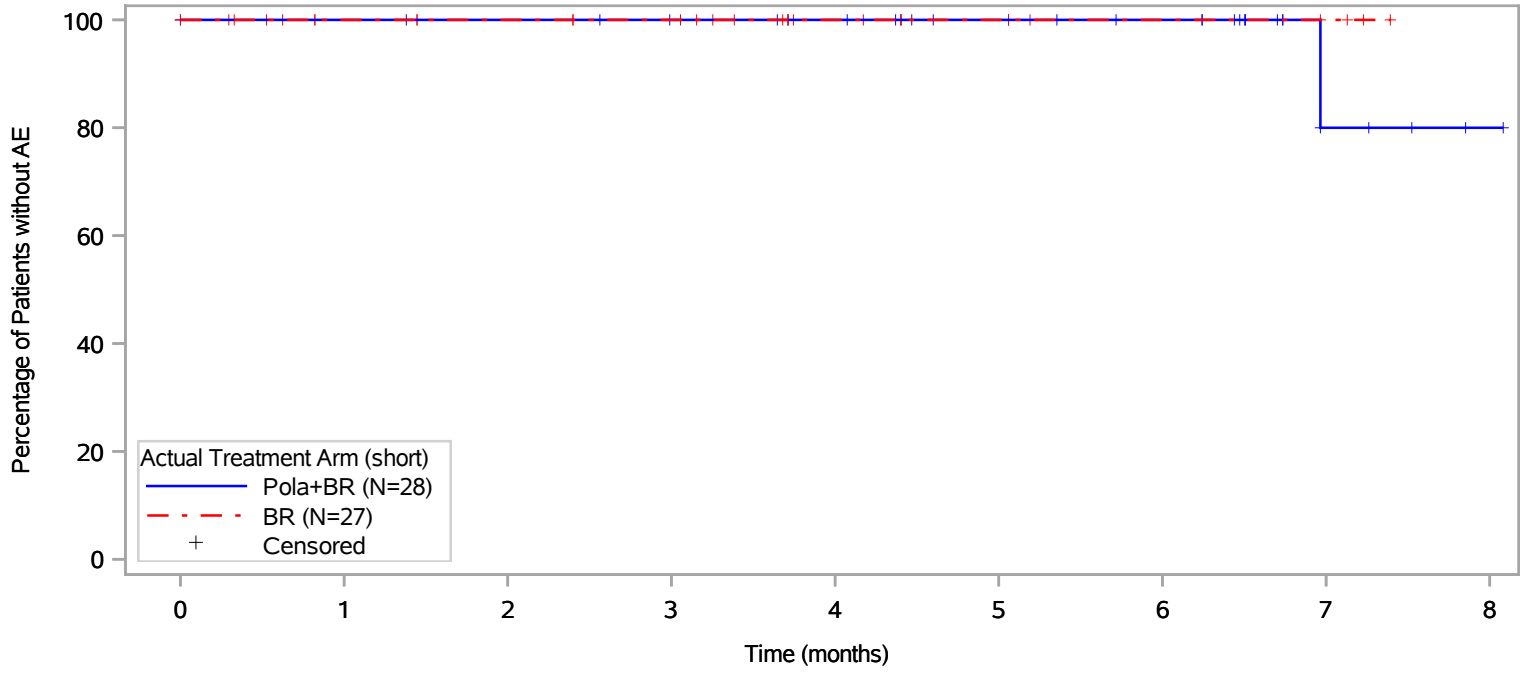
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PYURIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

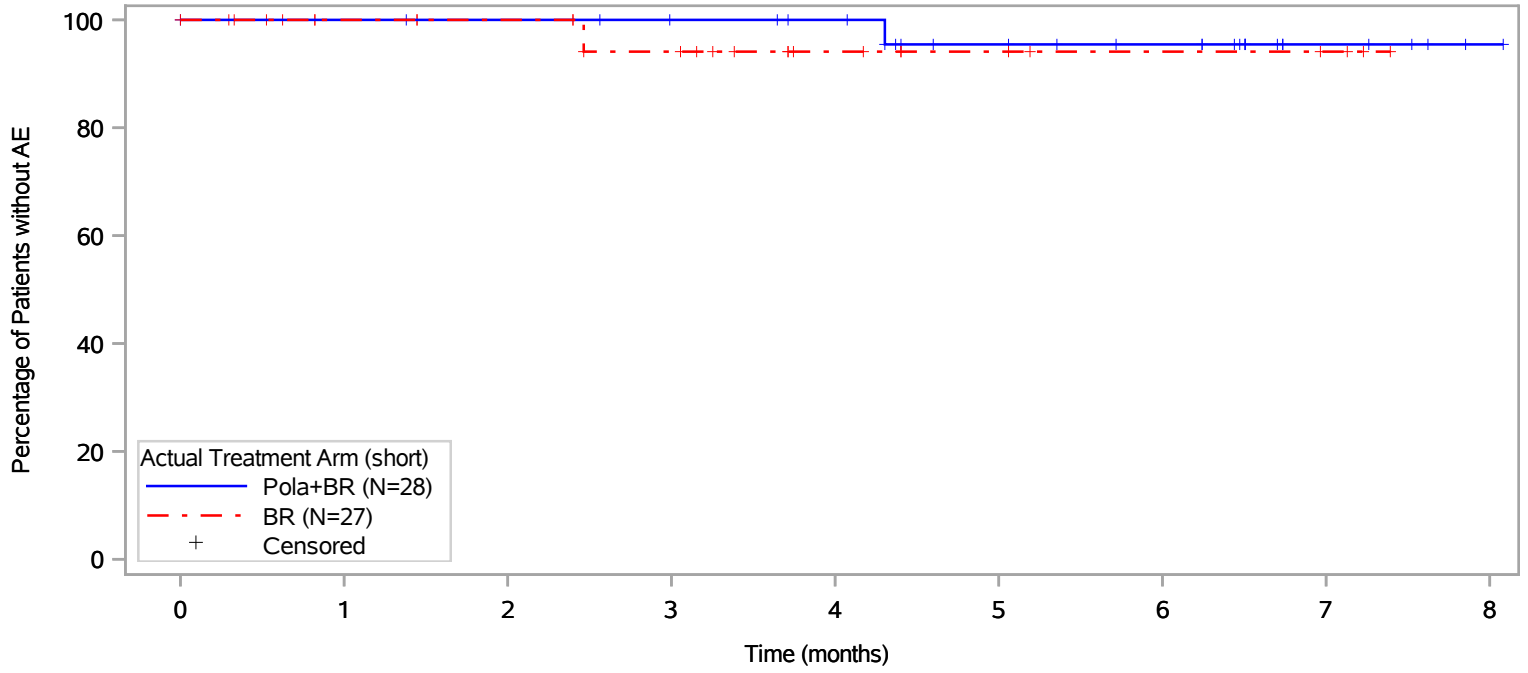
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, RHINOVIRUS INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS

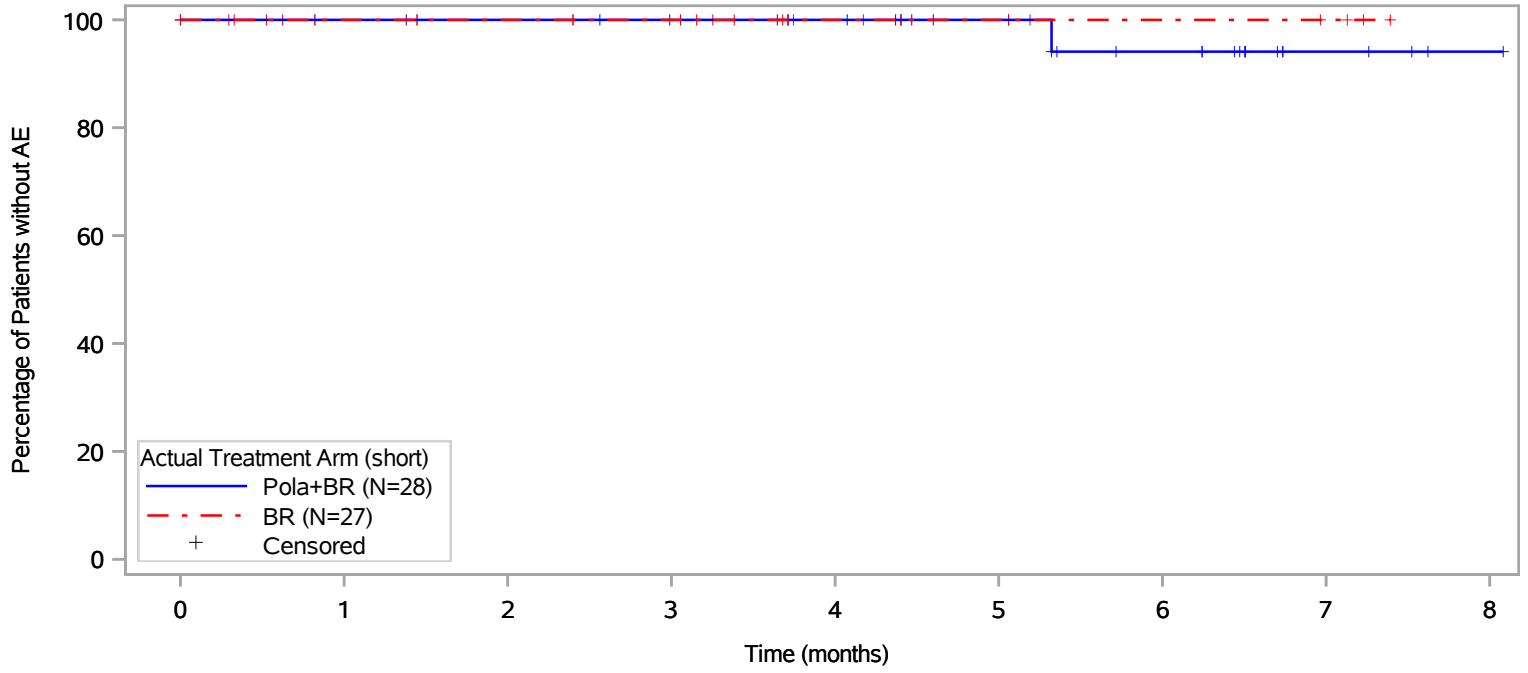


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

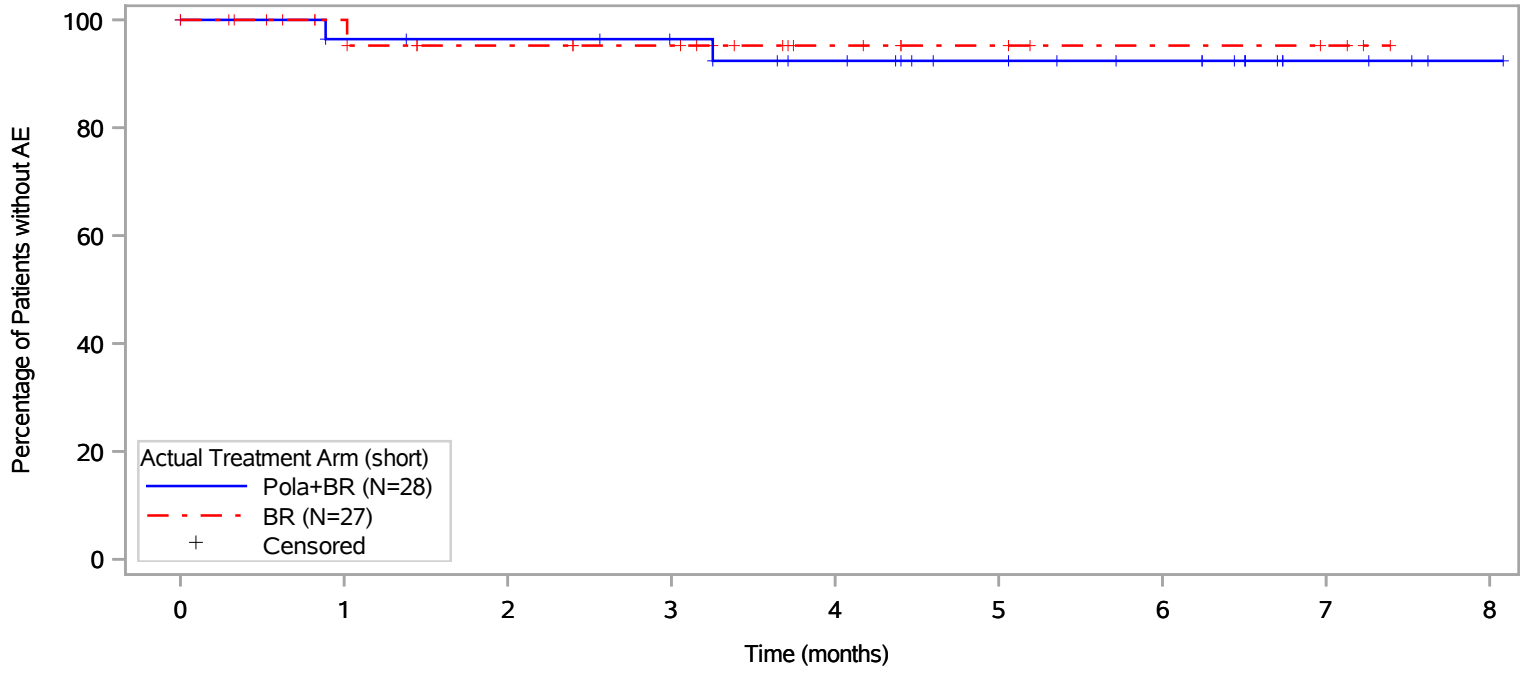
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SINUSITIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UPPER RESPIRATORY TRACT INFECTION



Patients at risk									
Pola+BR (N=28)	28	27	26	24	21	16	13	4	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	25
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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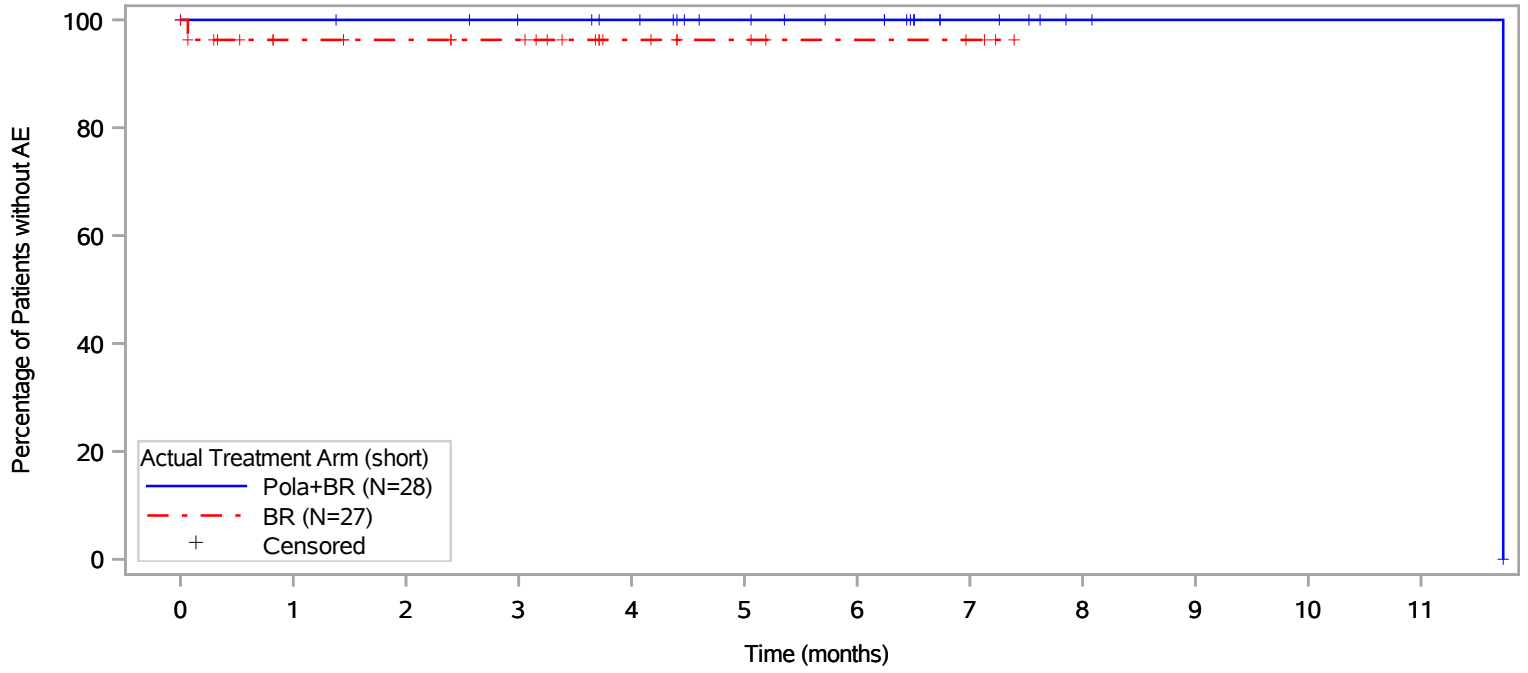
01DEC2022 21:22

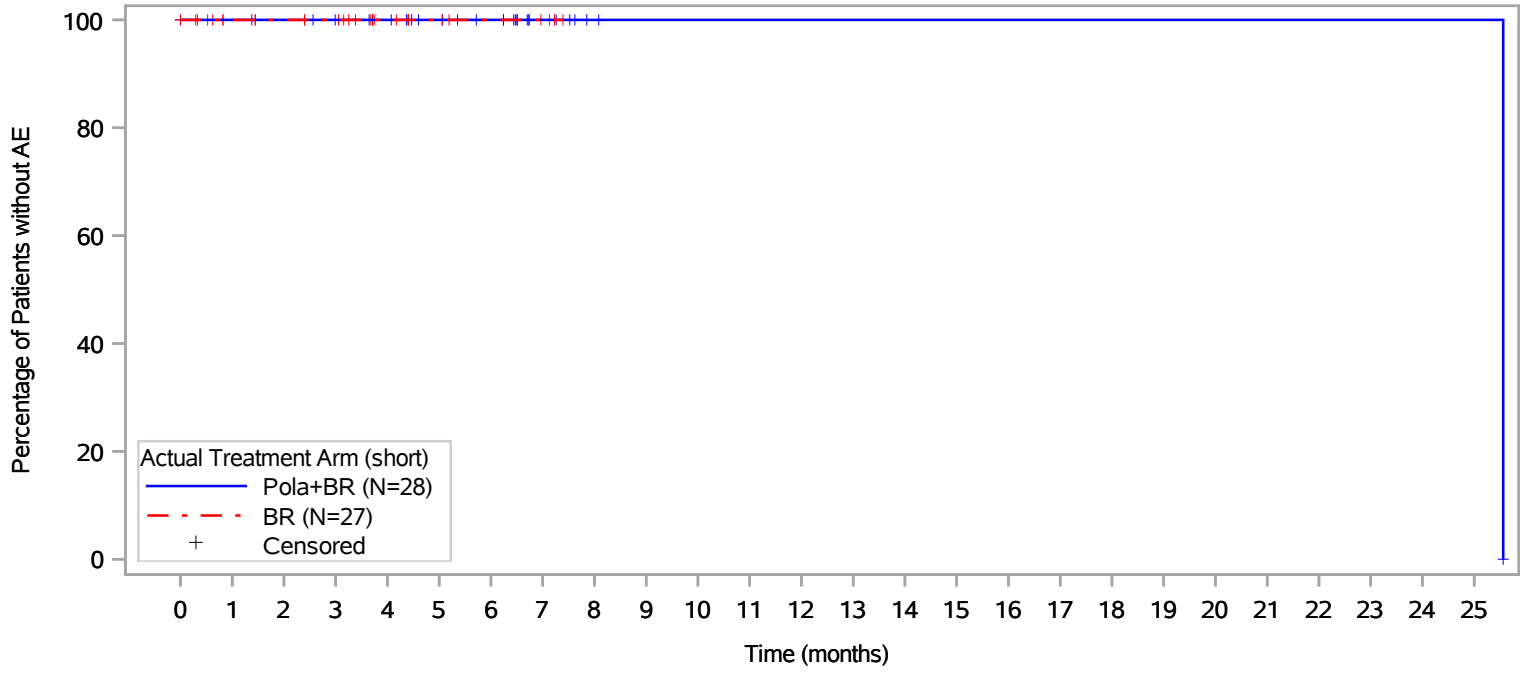
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk												
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27
BR (N=27)	0	5	7	9	17	20	22	23	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UROSEPSIS

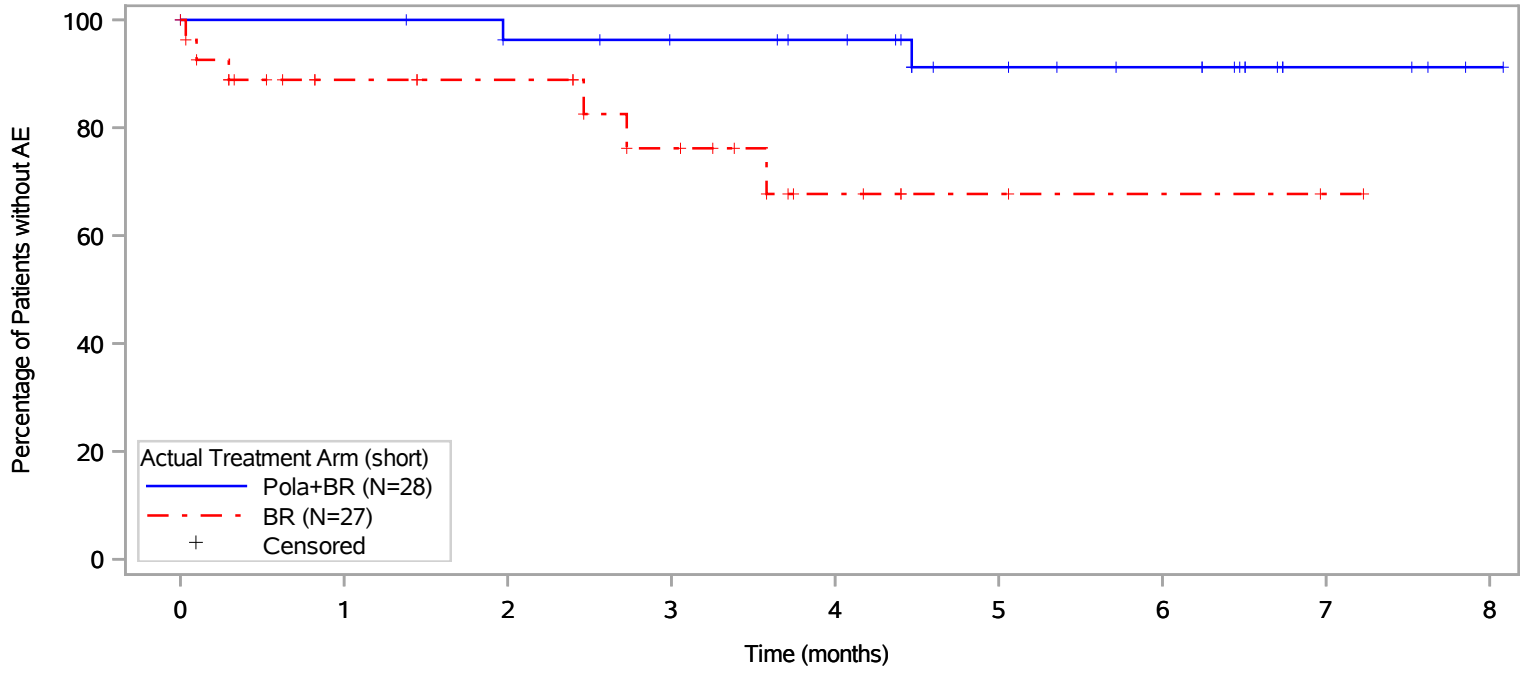


Patients at risk																										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	16	13	4	1
BR (N=27)	27	18	16	12	6	3	2	1	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	25
BR (N=27)	0	6	8	10	15	18	19	20	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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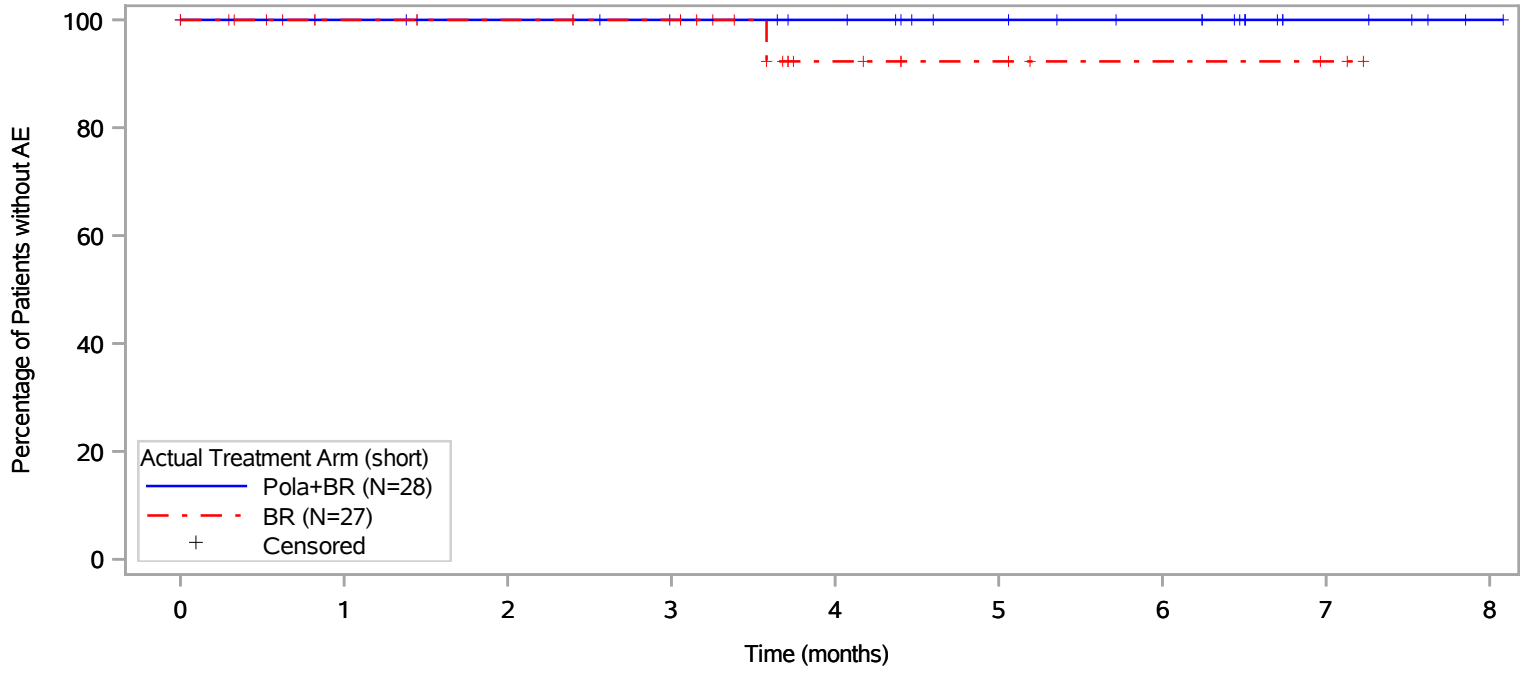
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FACIAL BONES FRACTURE

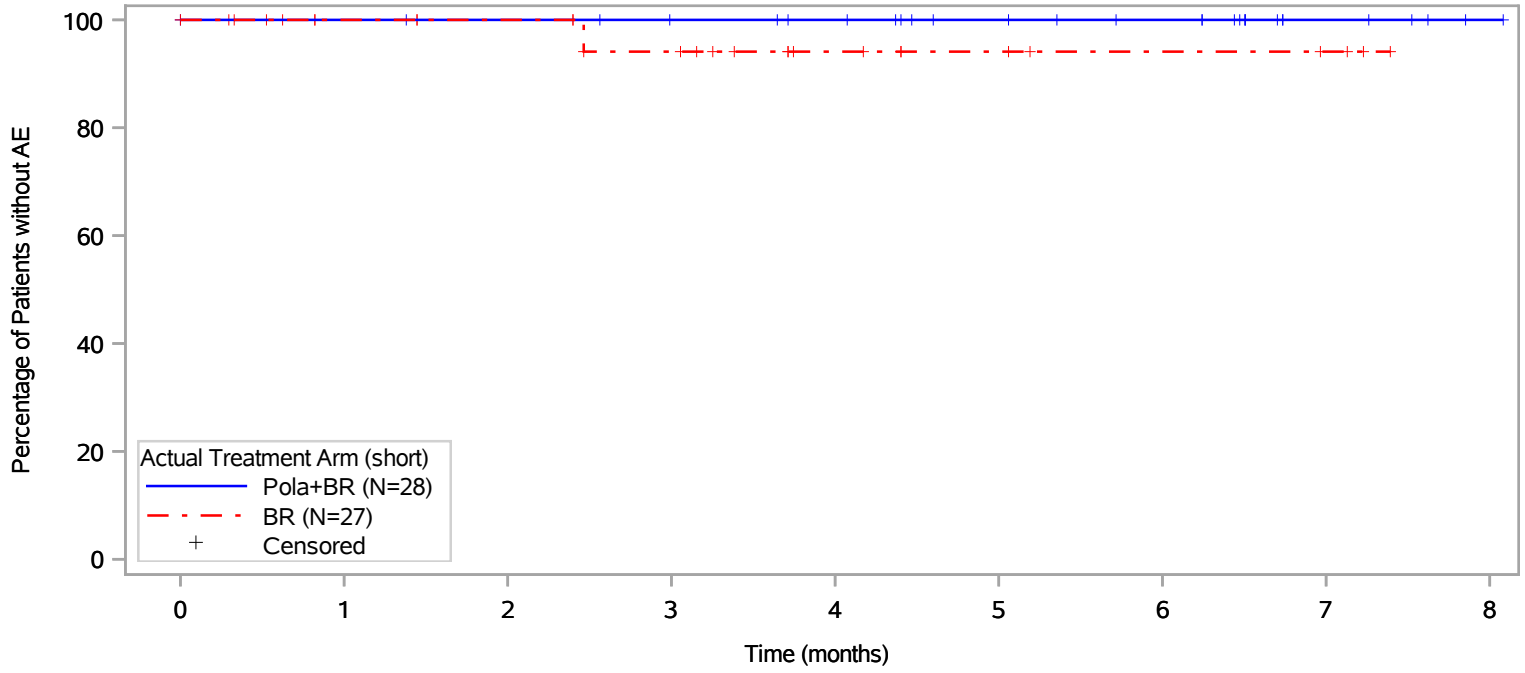


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL

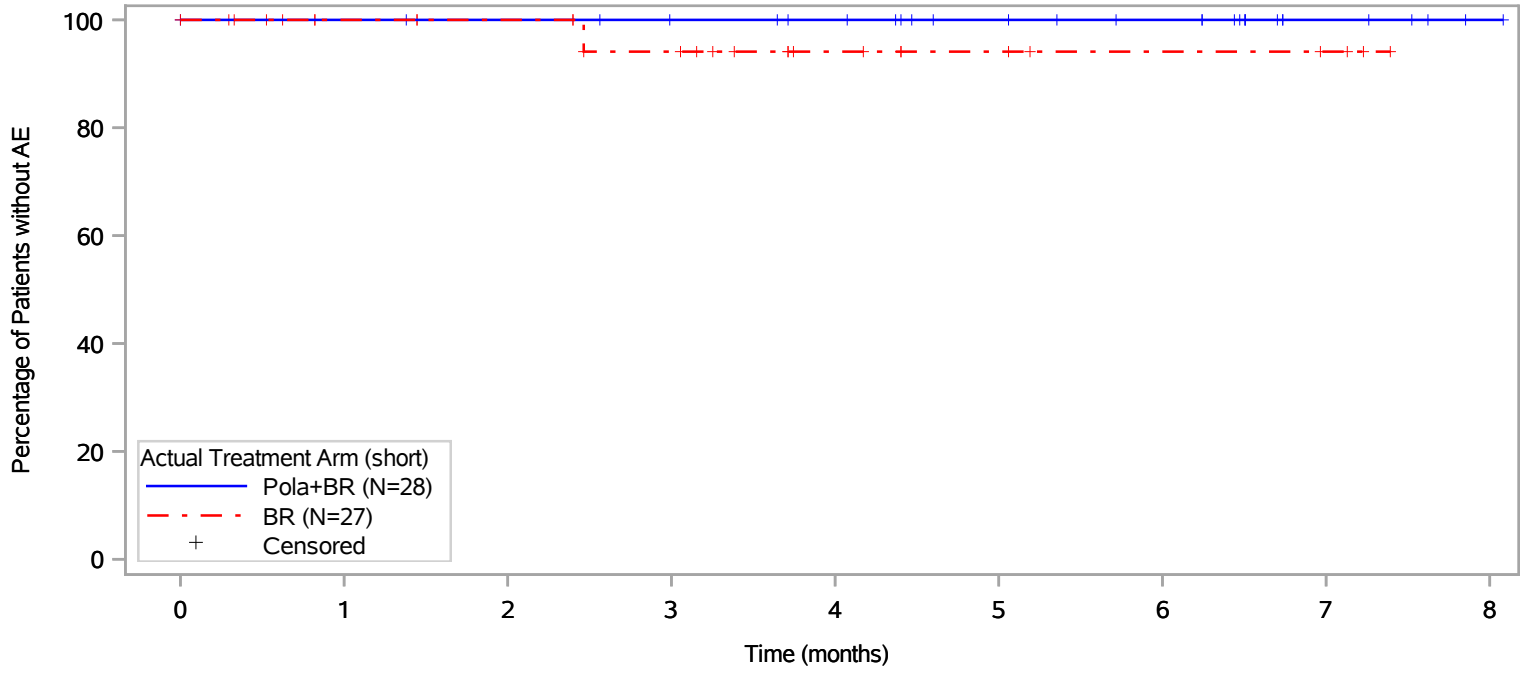


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, HEAD INJURY



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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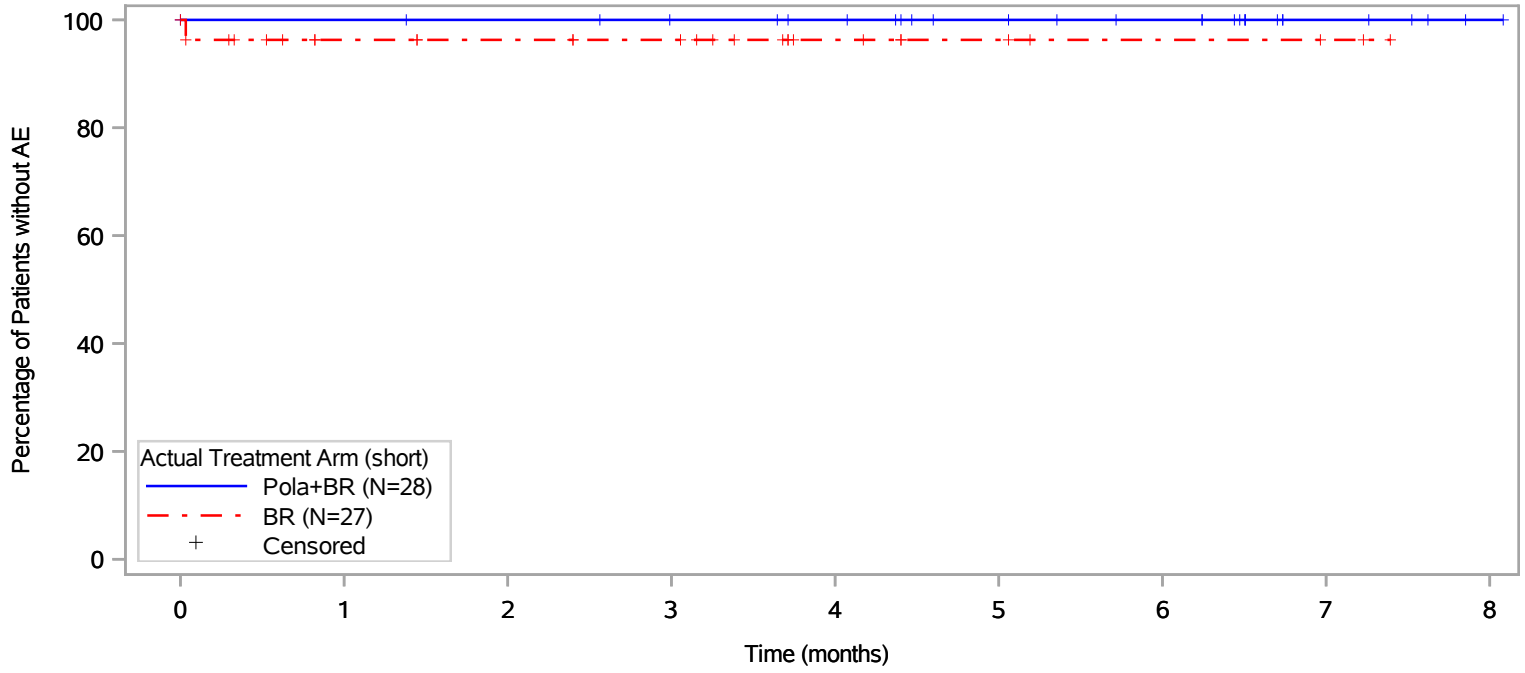
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, INFUSION RELATED REACTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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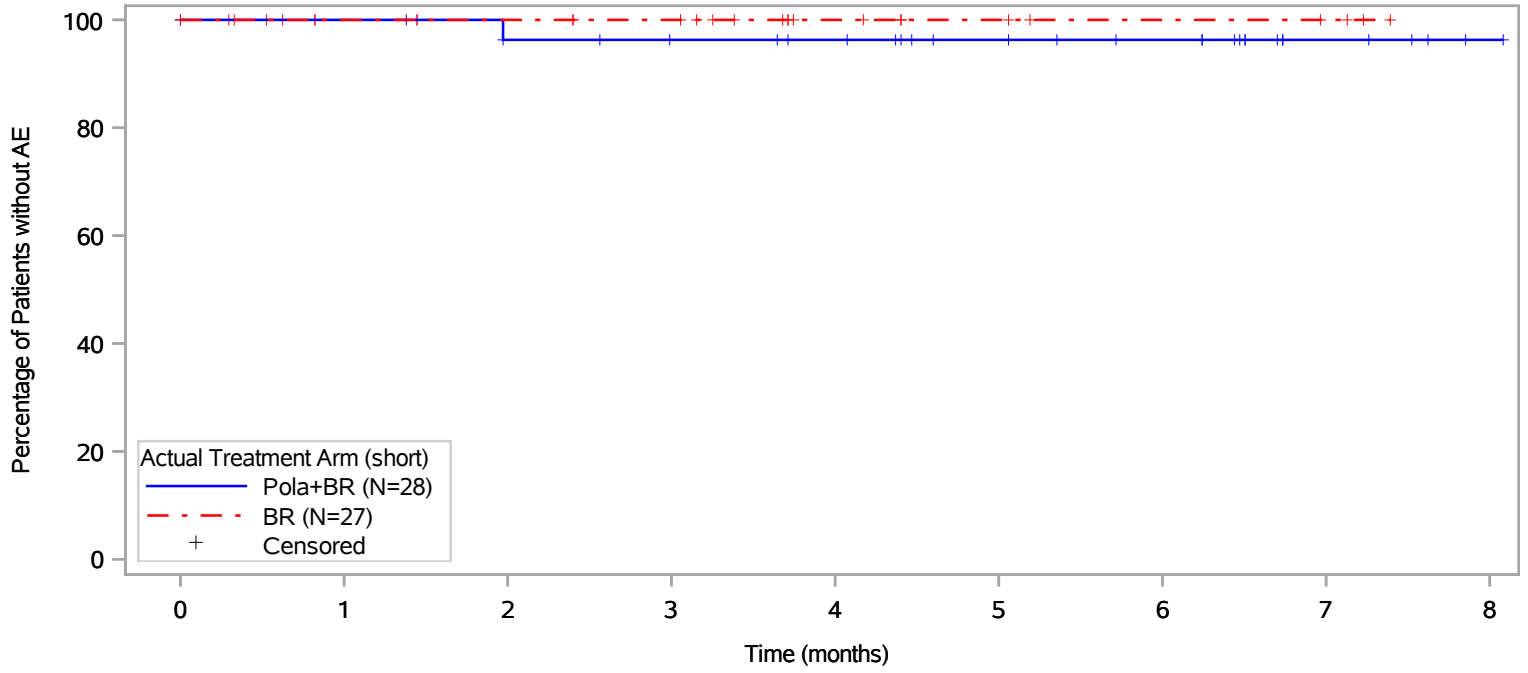
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, INJURY



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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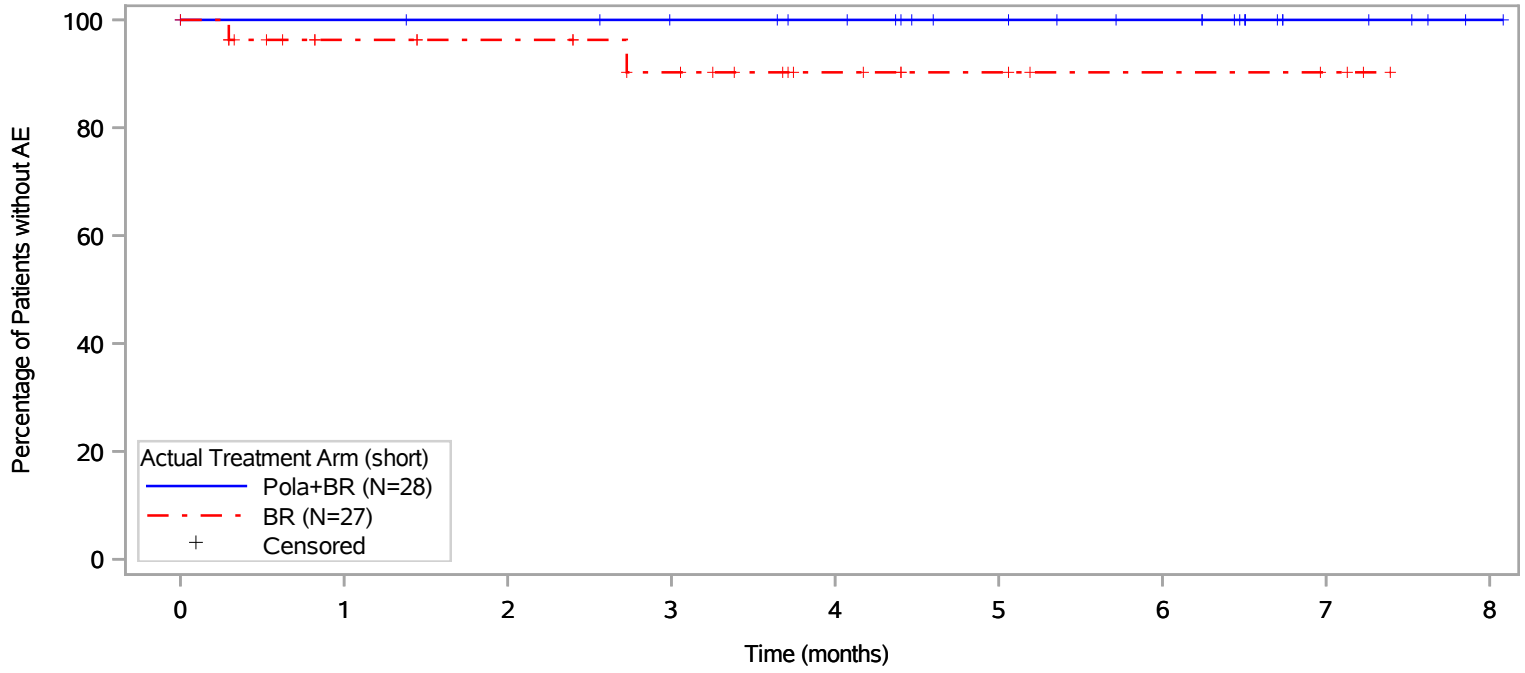
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, LIMB INJURY



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	15	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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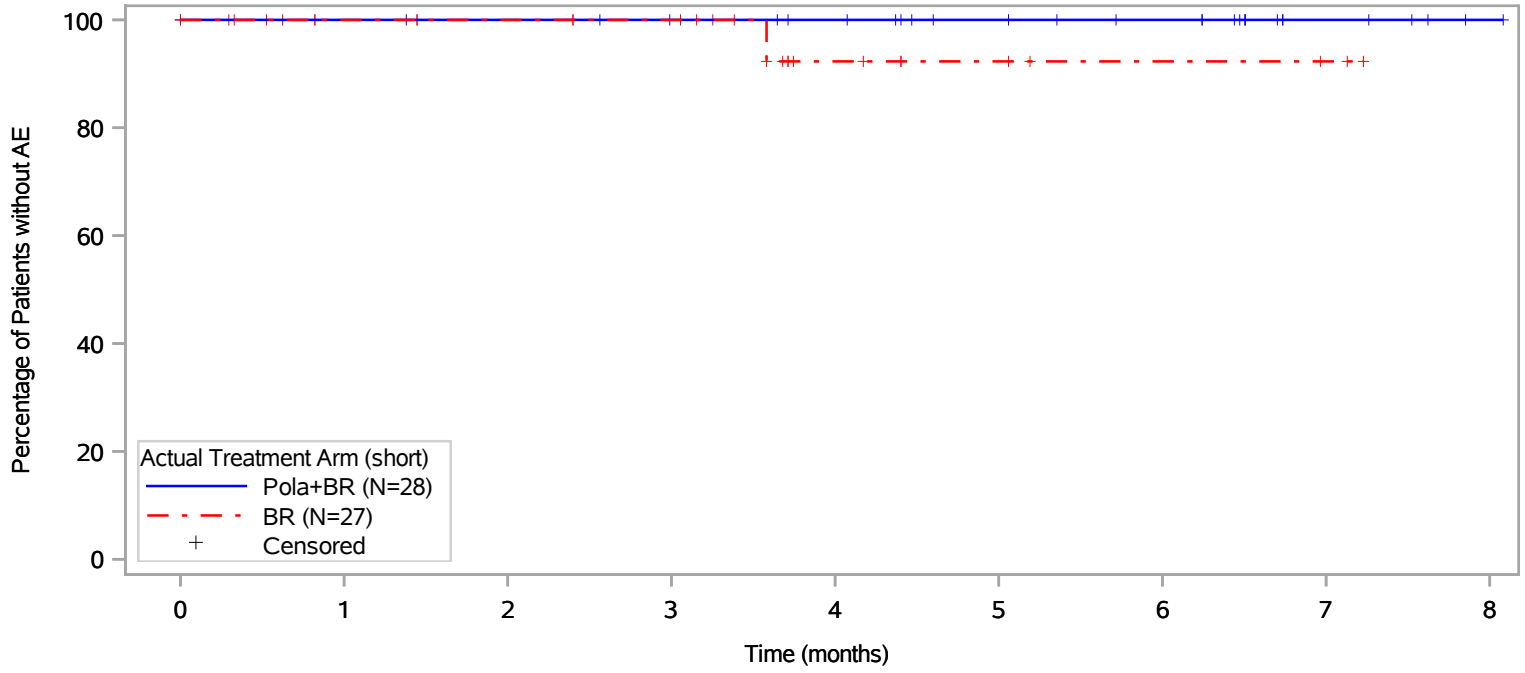
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, SKIN LACERATION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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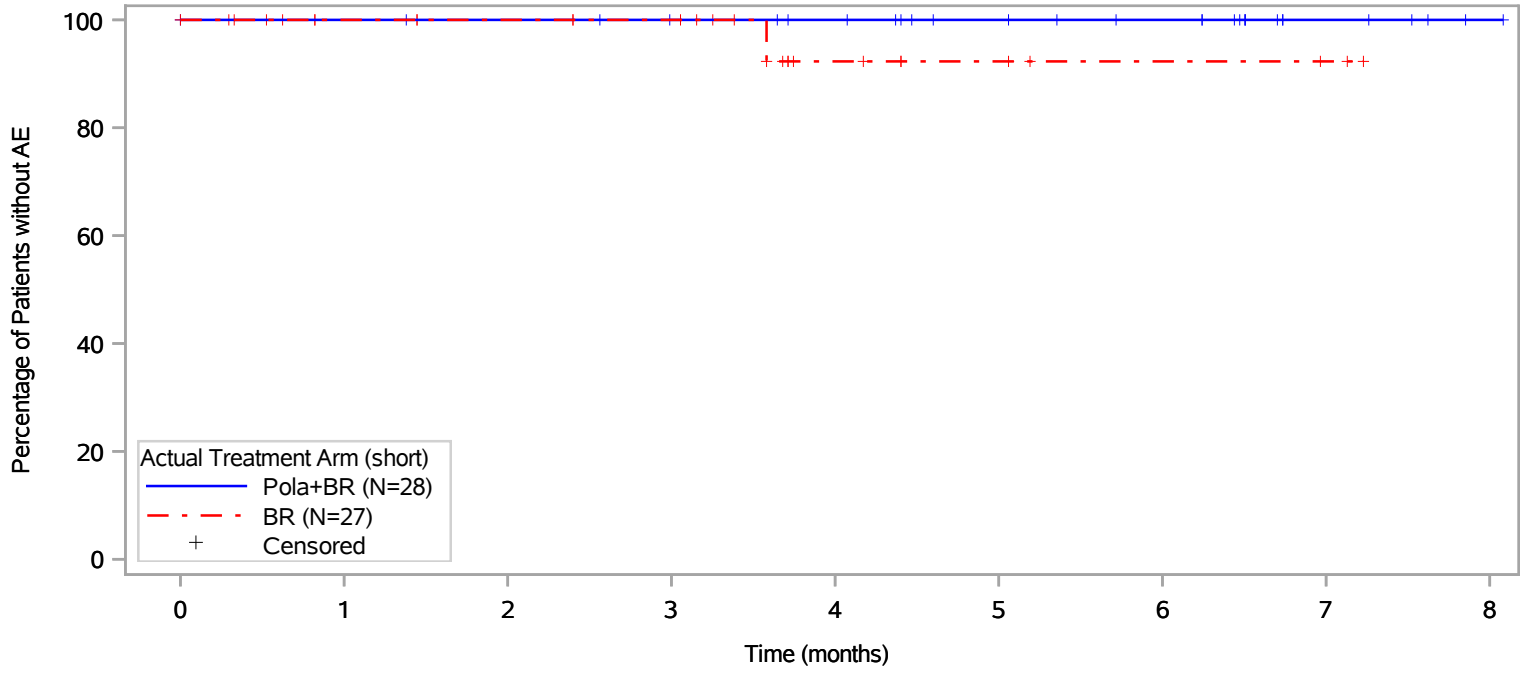
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, TOOTH FRACTURE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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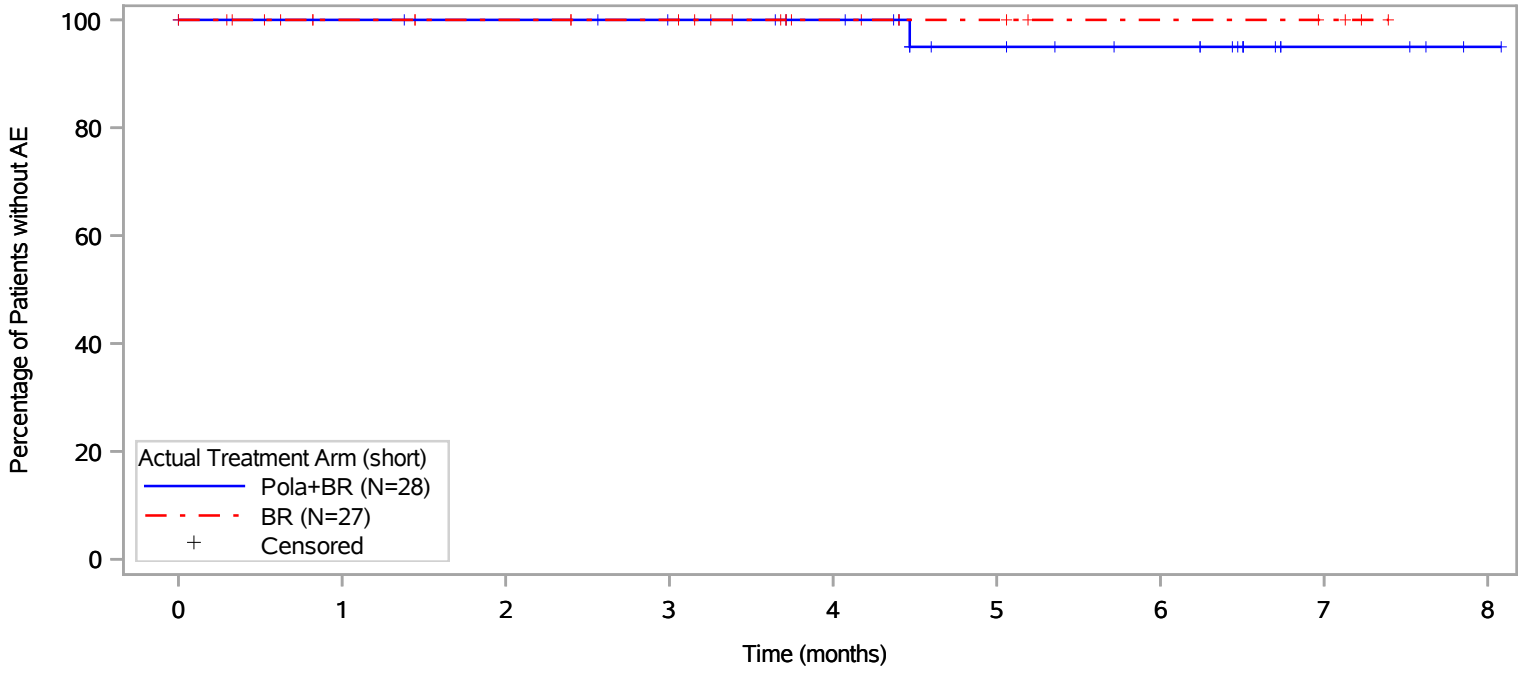
01DEC2022 21:22

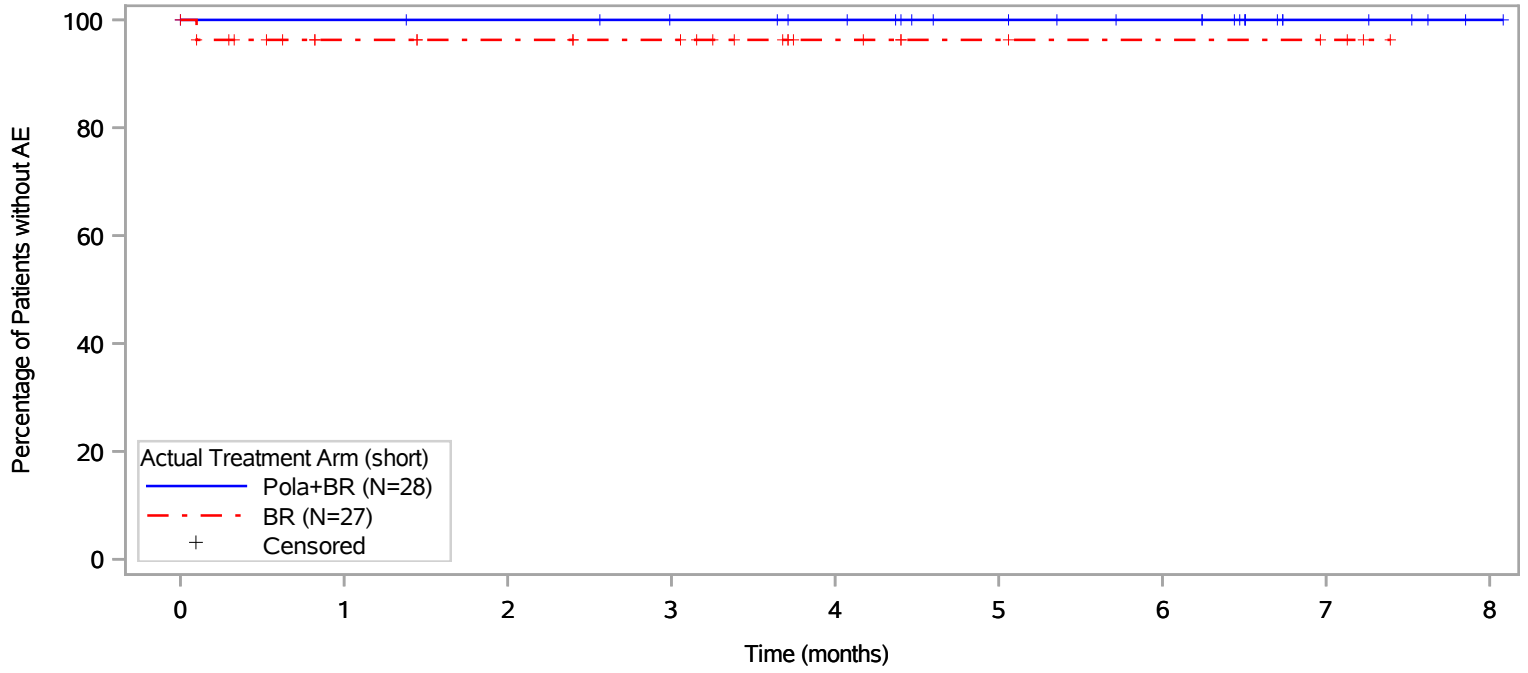
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, TRANSFUSION REACTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, VASCULAR ACCESS SITE PAIN



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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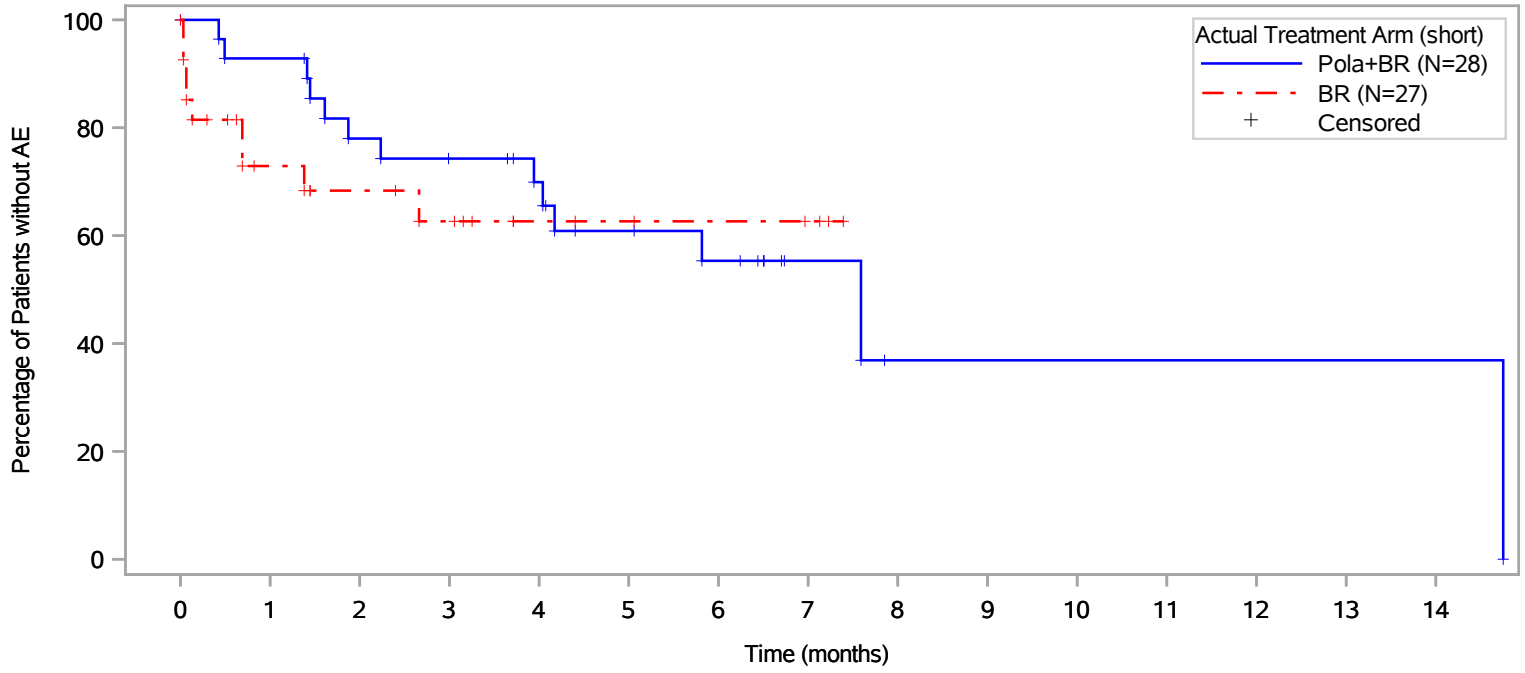
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk															
Pola+BR (N=28)	28	26	21	19	16	12	10	3	1	1	1	1	1	1	1
BR (N=27)	27	16	13	11	6	5	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	2	4	6	7	14	15	15	15	15	15	15	15
BR (N=27)	0	4	6	7	12	13	14	15	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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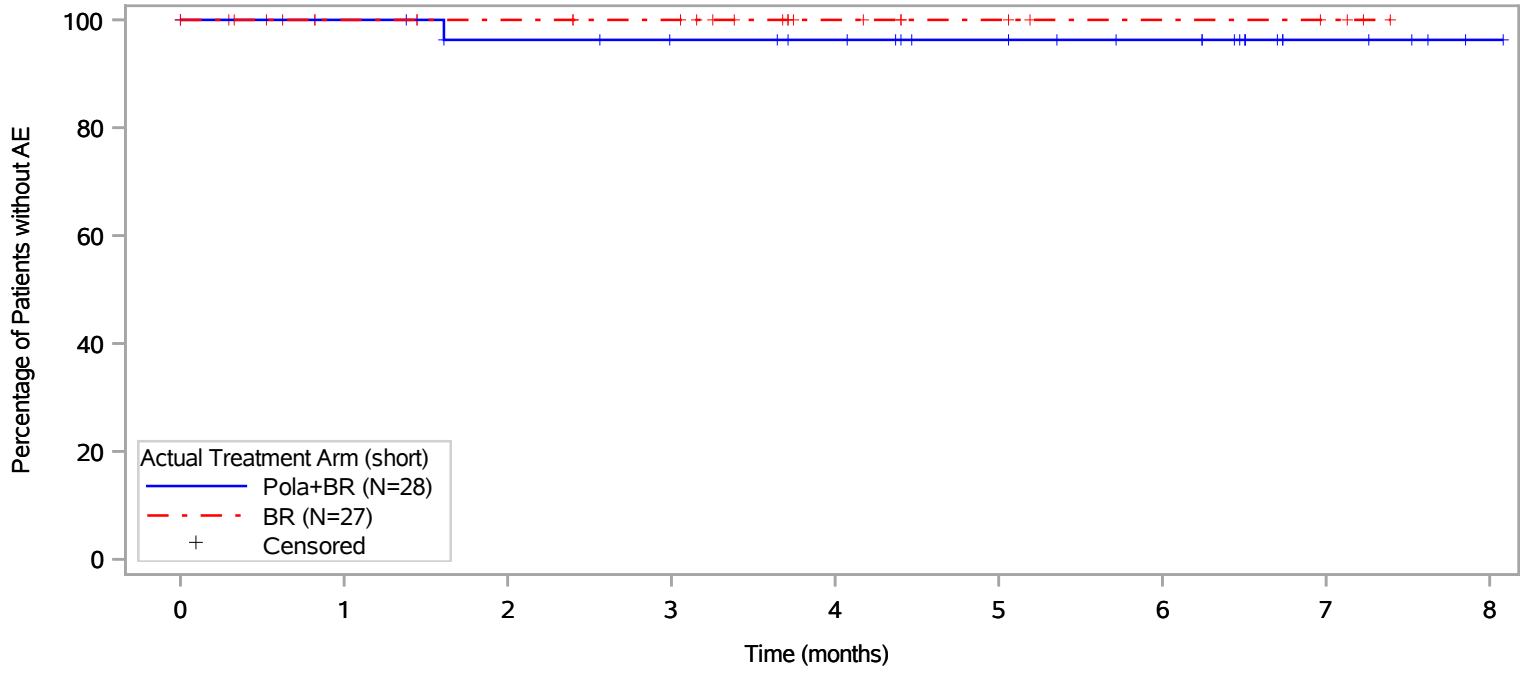
01DEC2022 21:22

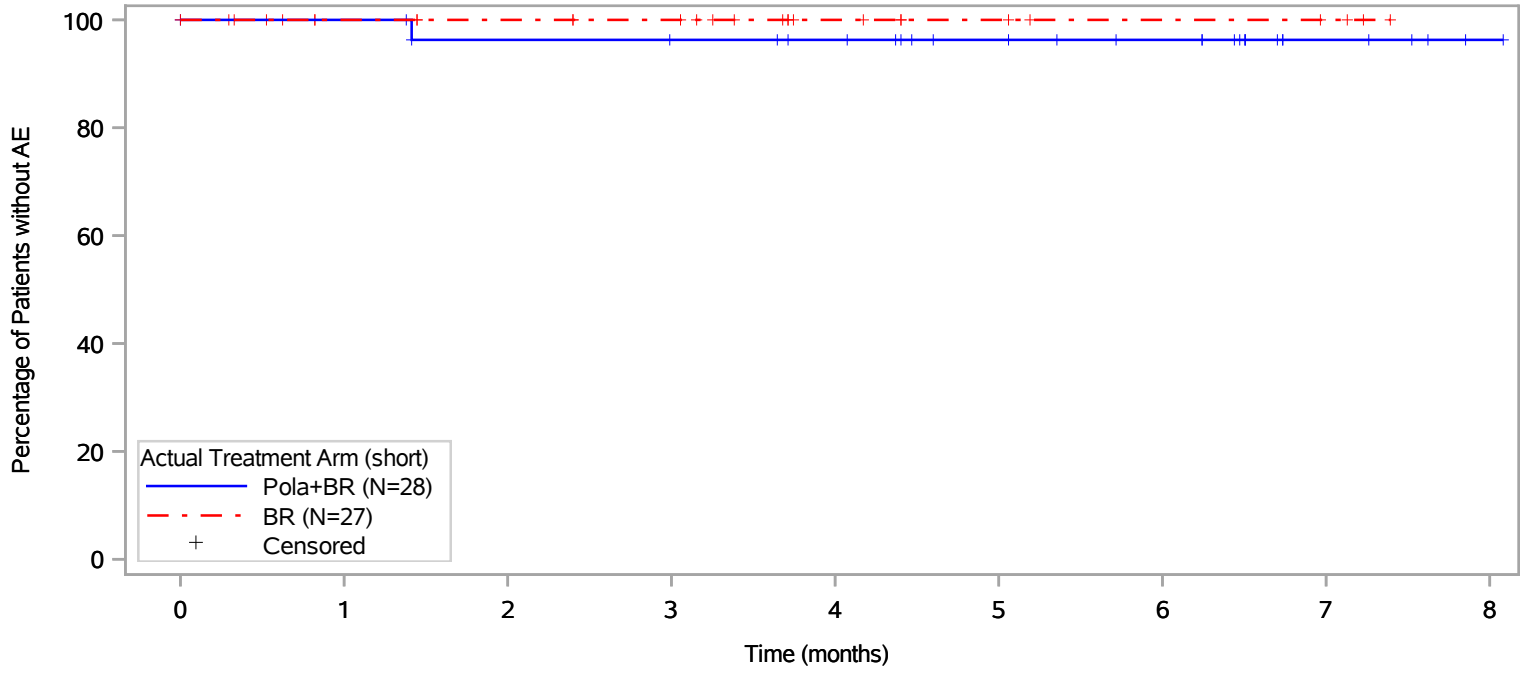
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ALANINE AMINOTRANSFERASE INCREASED



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, AMYLASE INCREASED



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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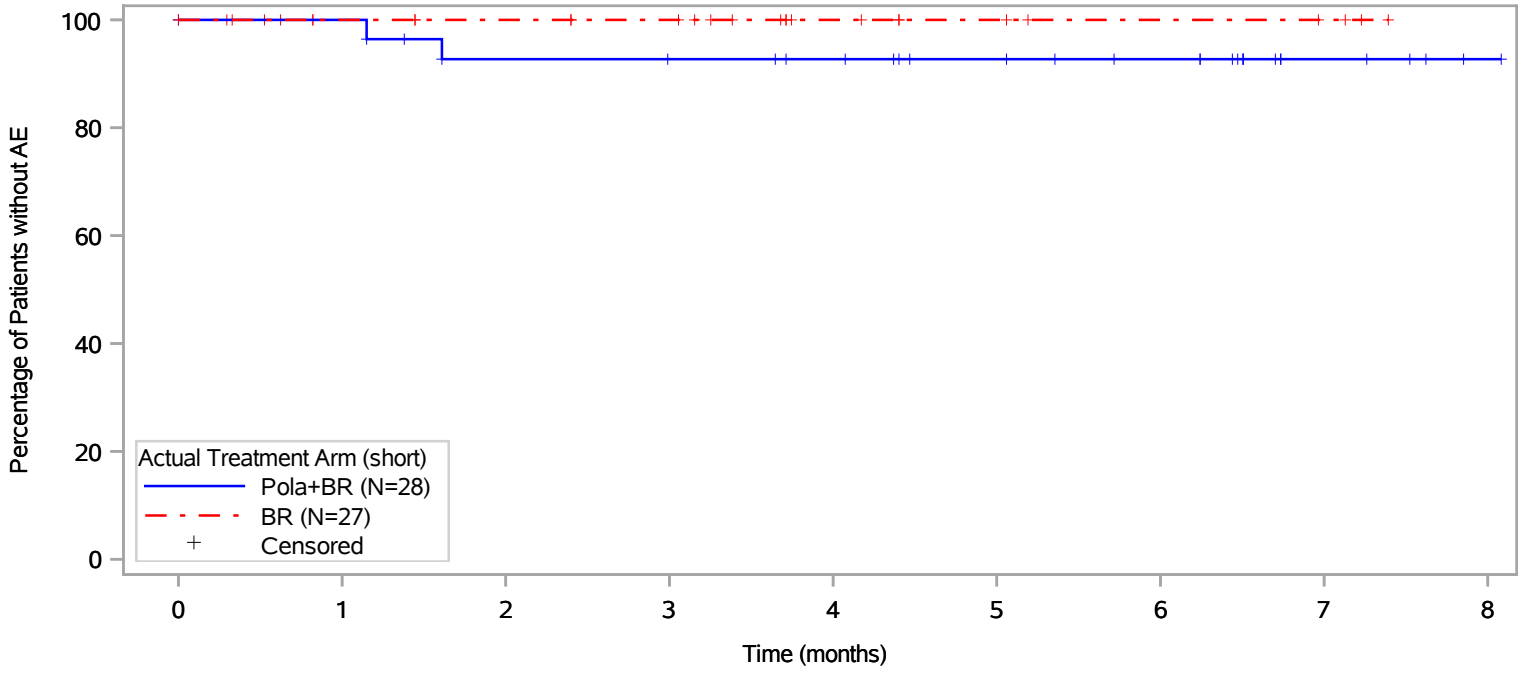
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ASPARTATE AMINOTRANSFERASE INCREASED



Patients at risk									
Pola+BR (N=28)	28	28	25	24	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	8	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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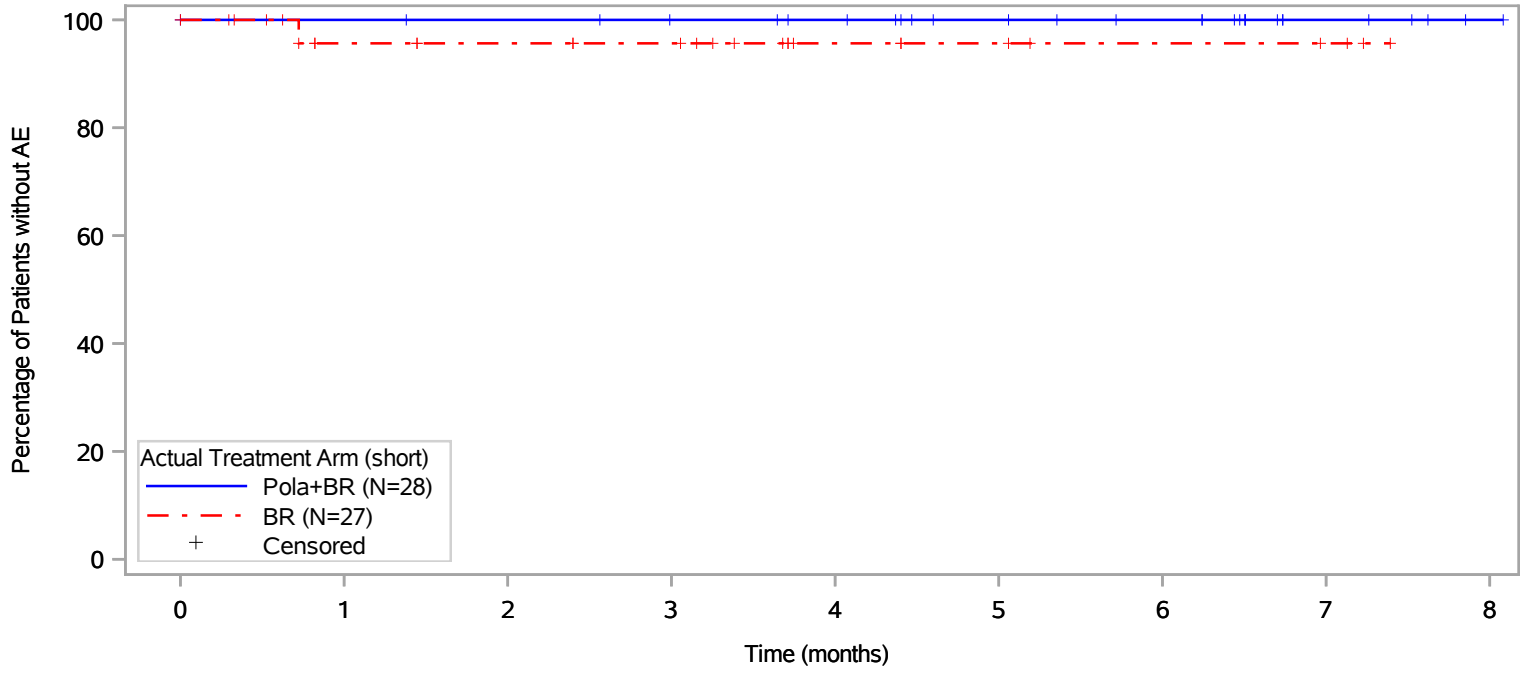
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALBUMIN DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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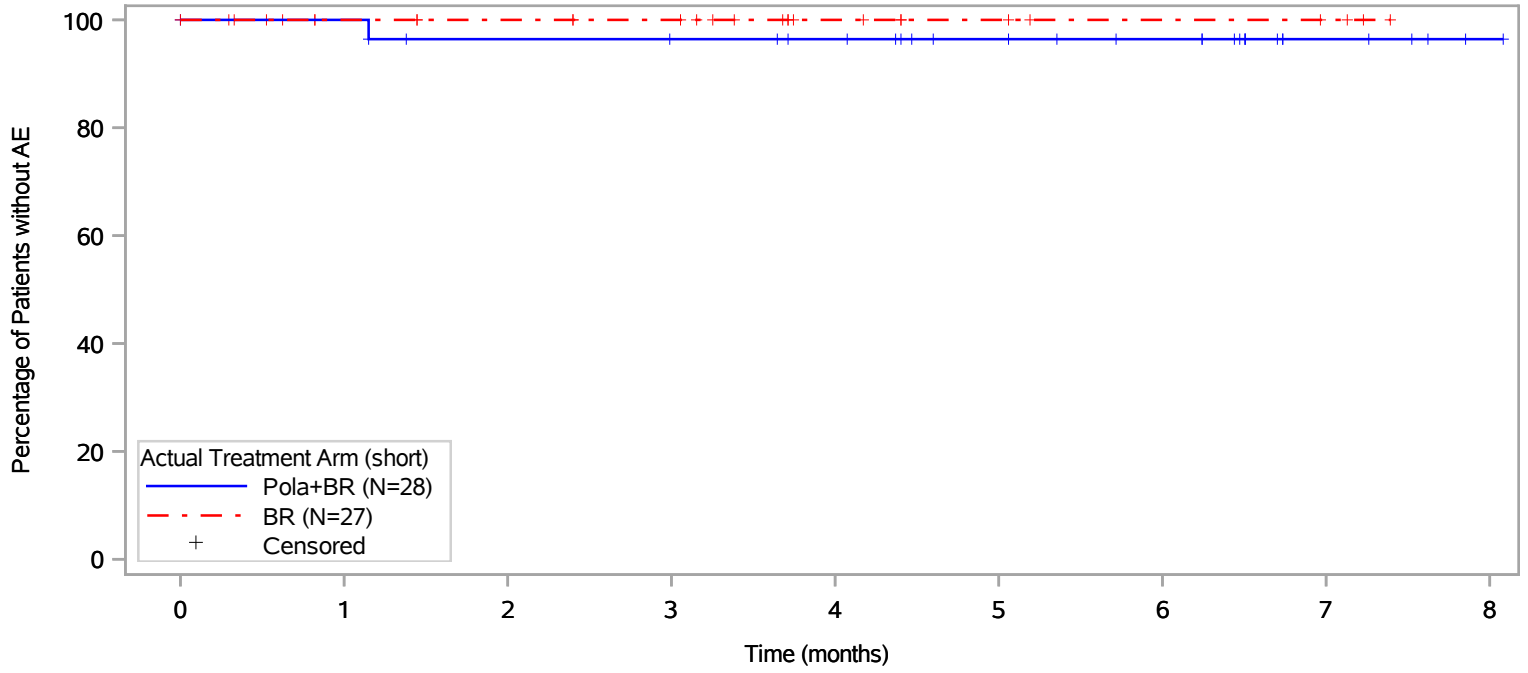
01DEC2022 21:22

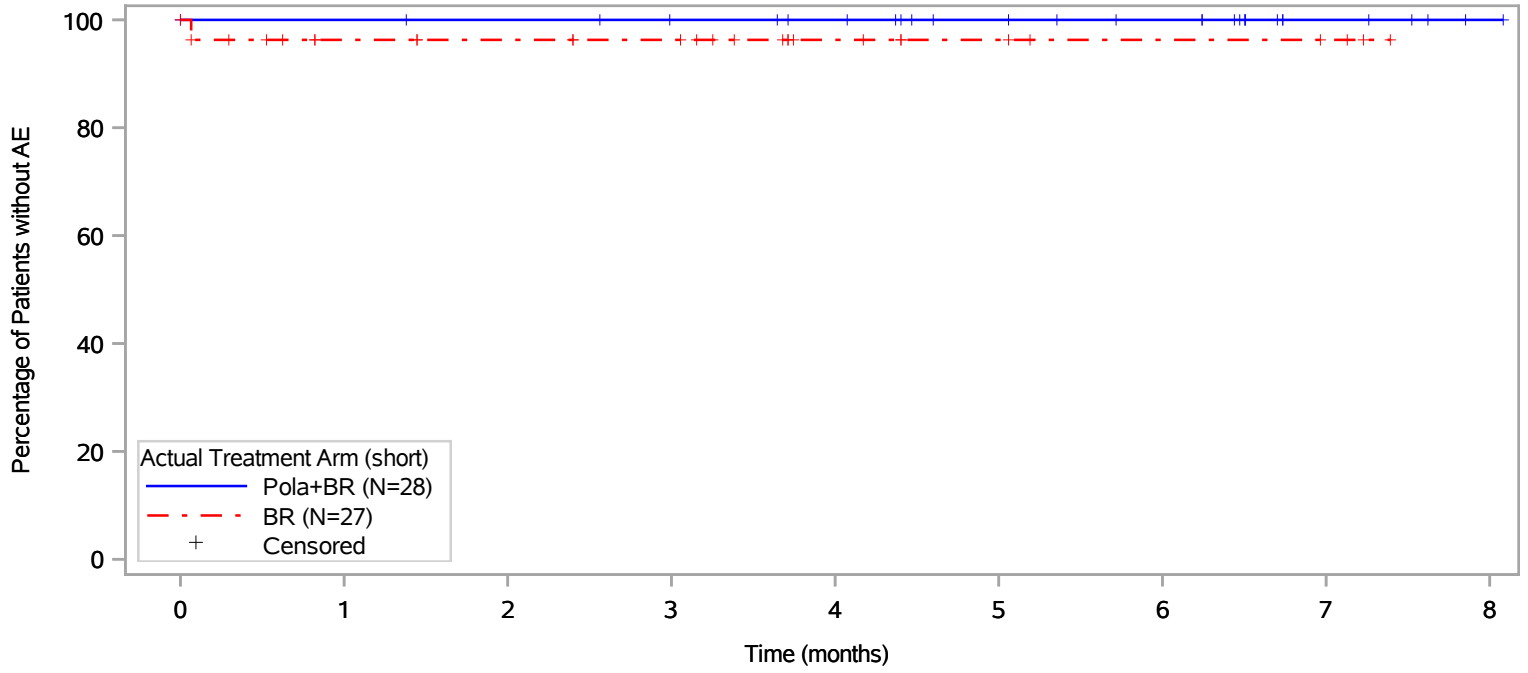
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALKALINE PHOSPHATASE INCREASED



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD CALCIUM DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	5	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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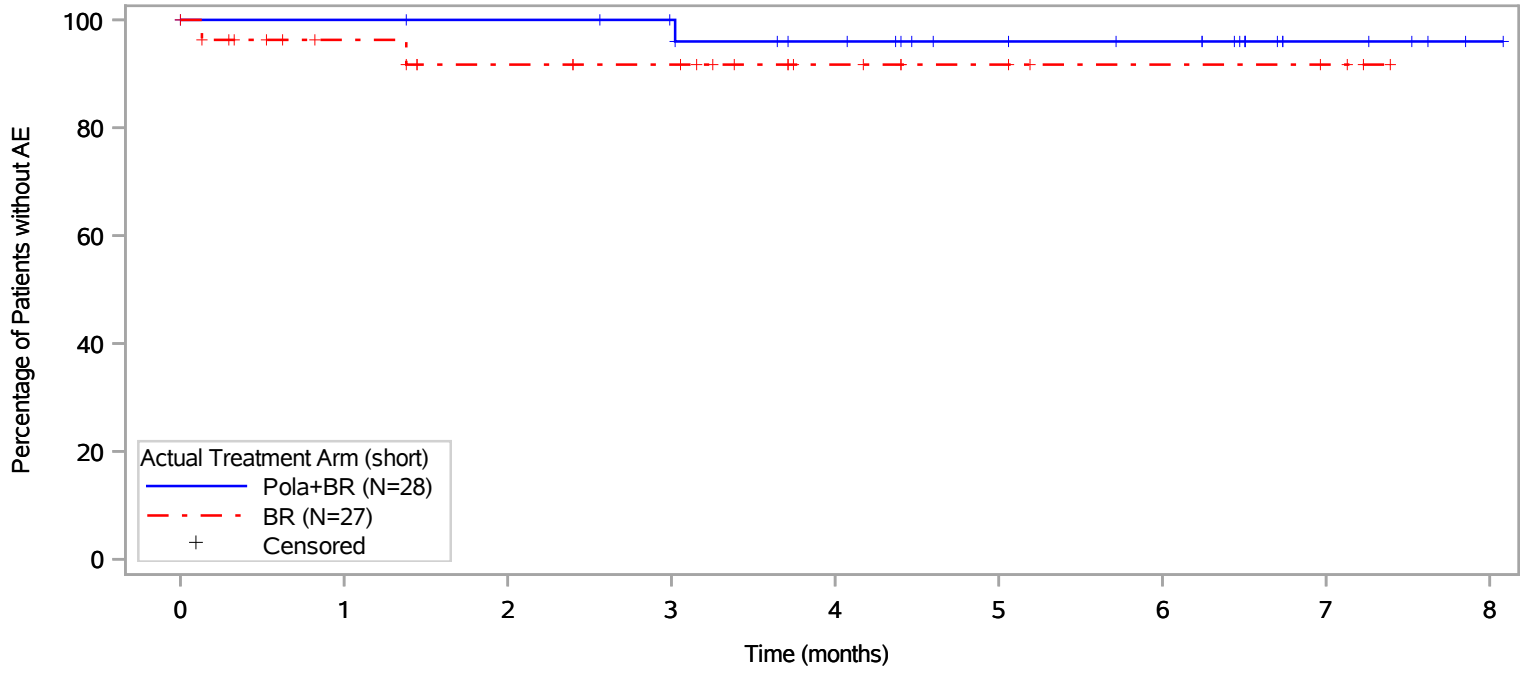
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD CREATININE INCREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	15	5	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	5	7	9	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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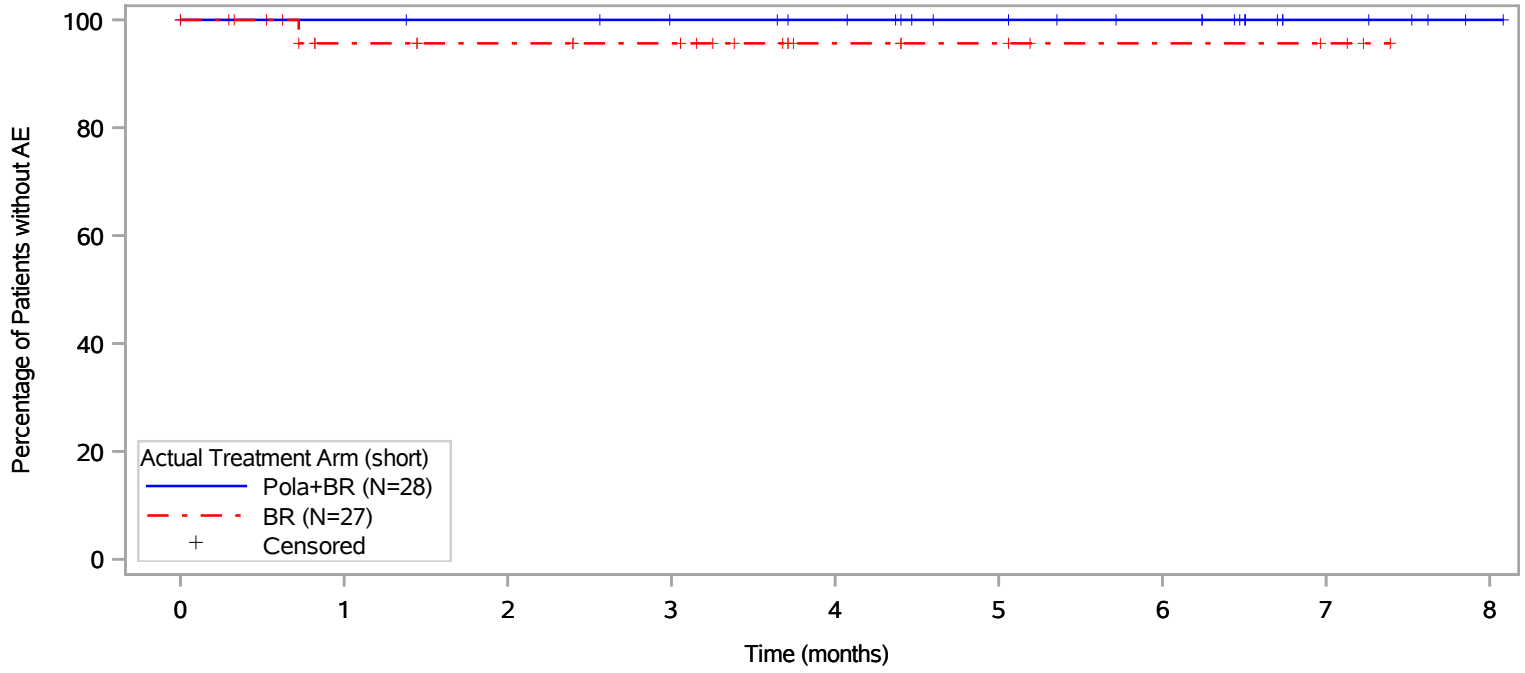
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD GLUCOSE DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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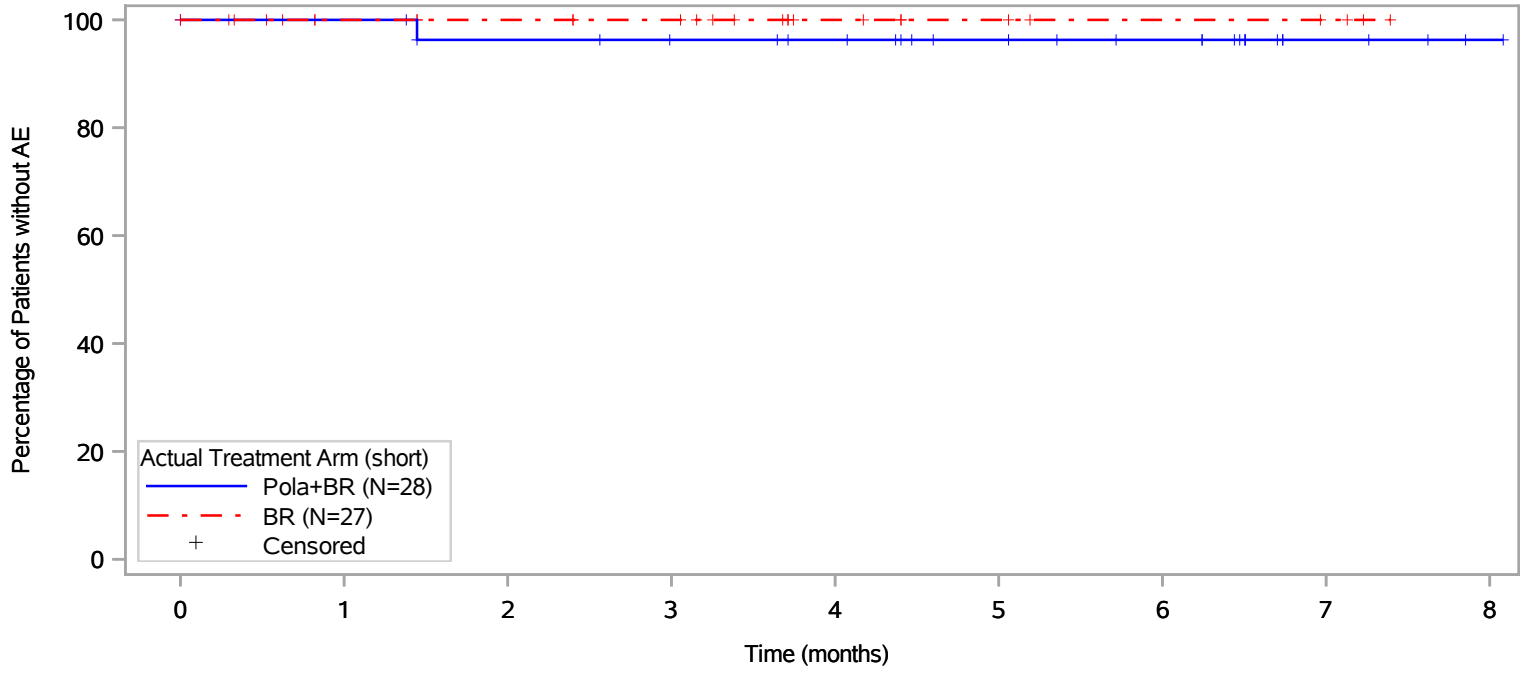
01DEC2022 21:22

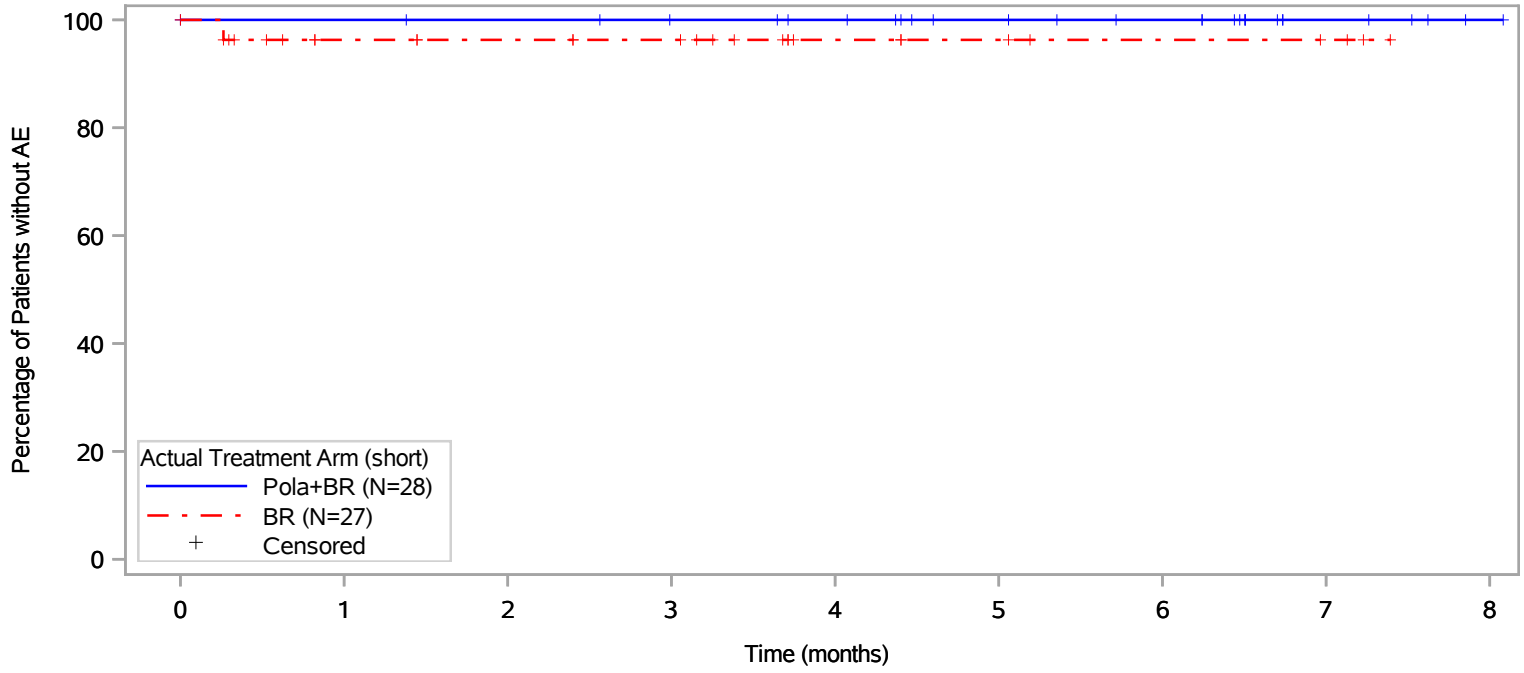
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD MAGNESIUM DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
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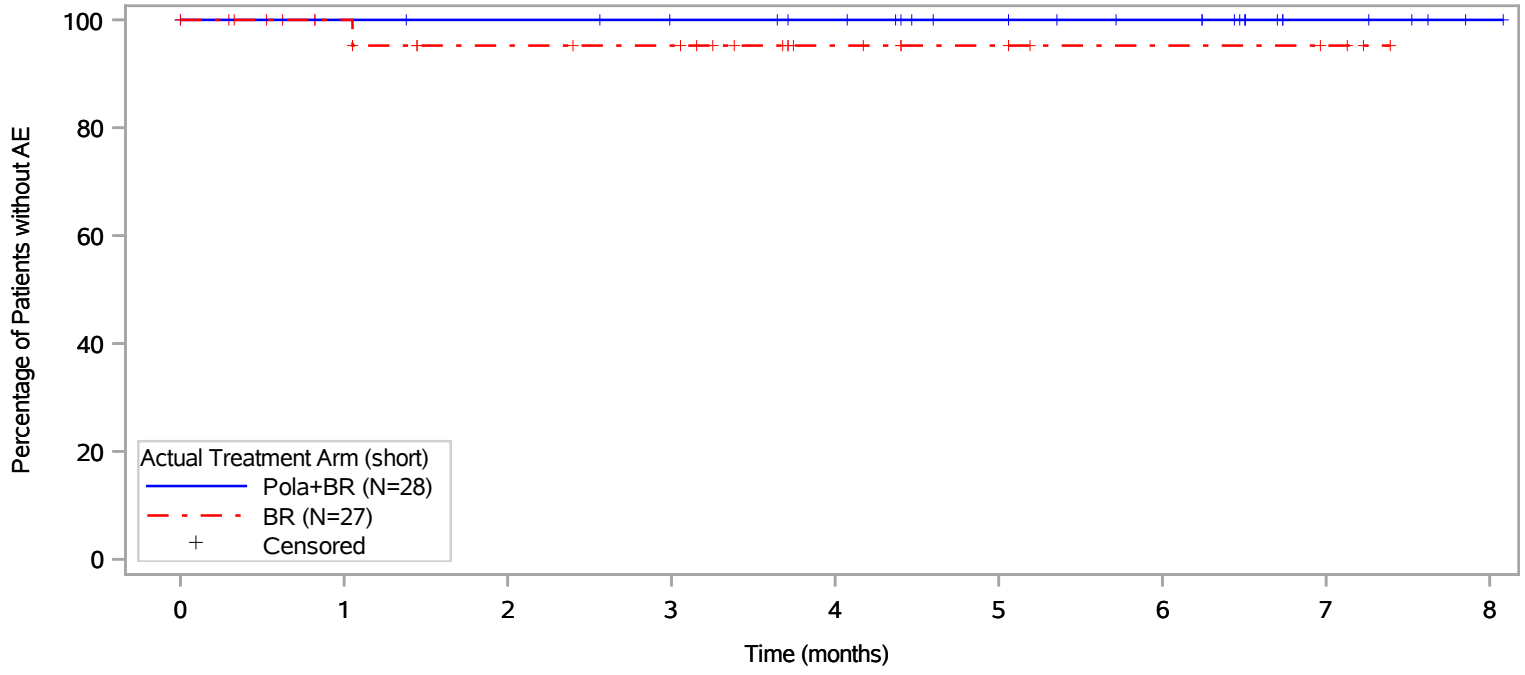
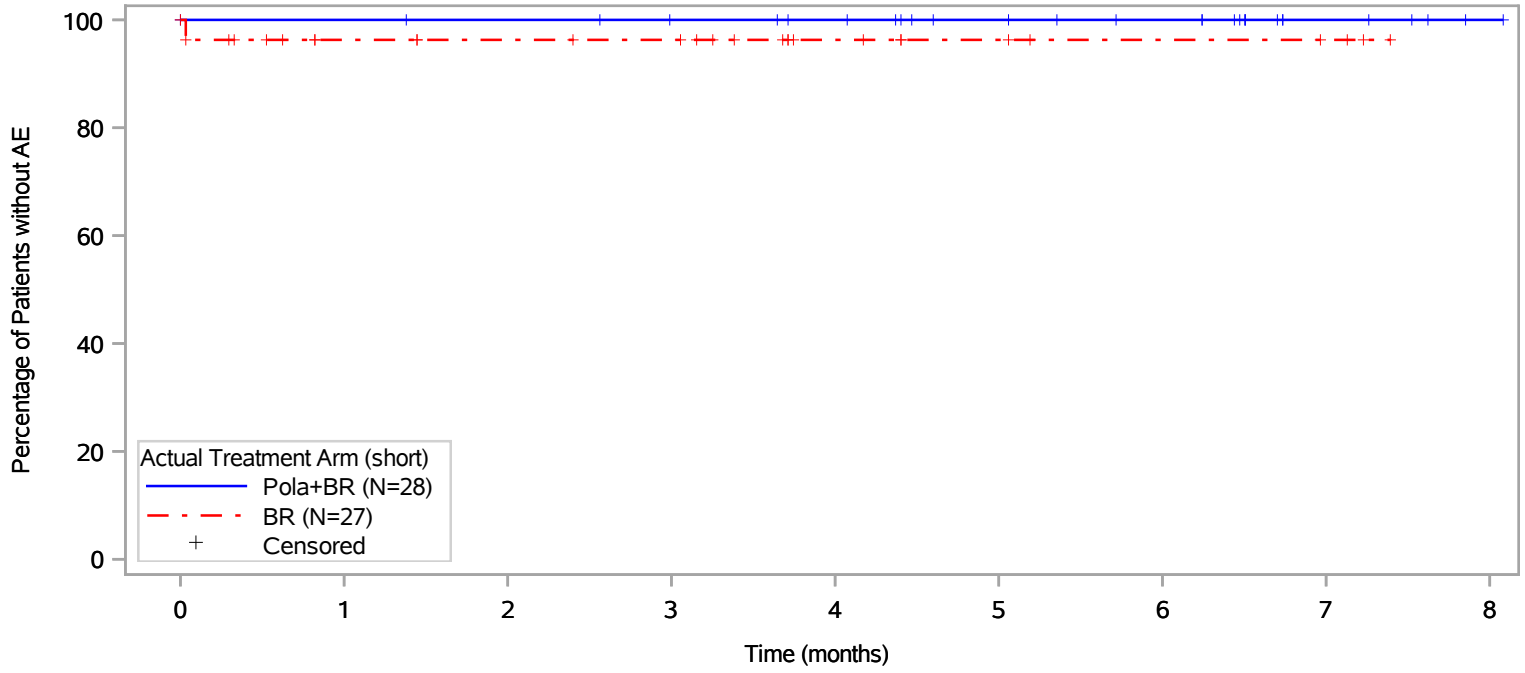
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD URINE PRESENT



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, C-REACTIVE PROTEIN INCREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
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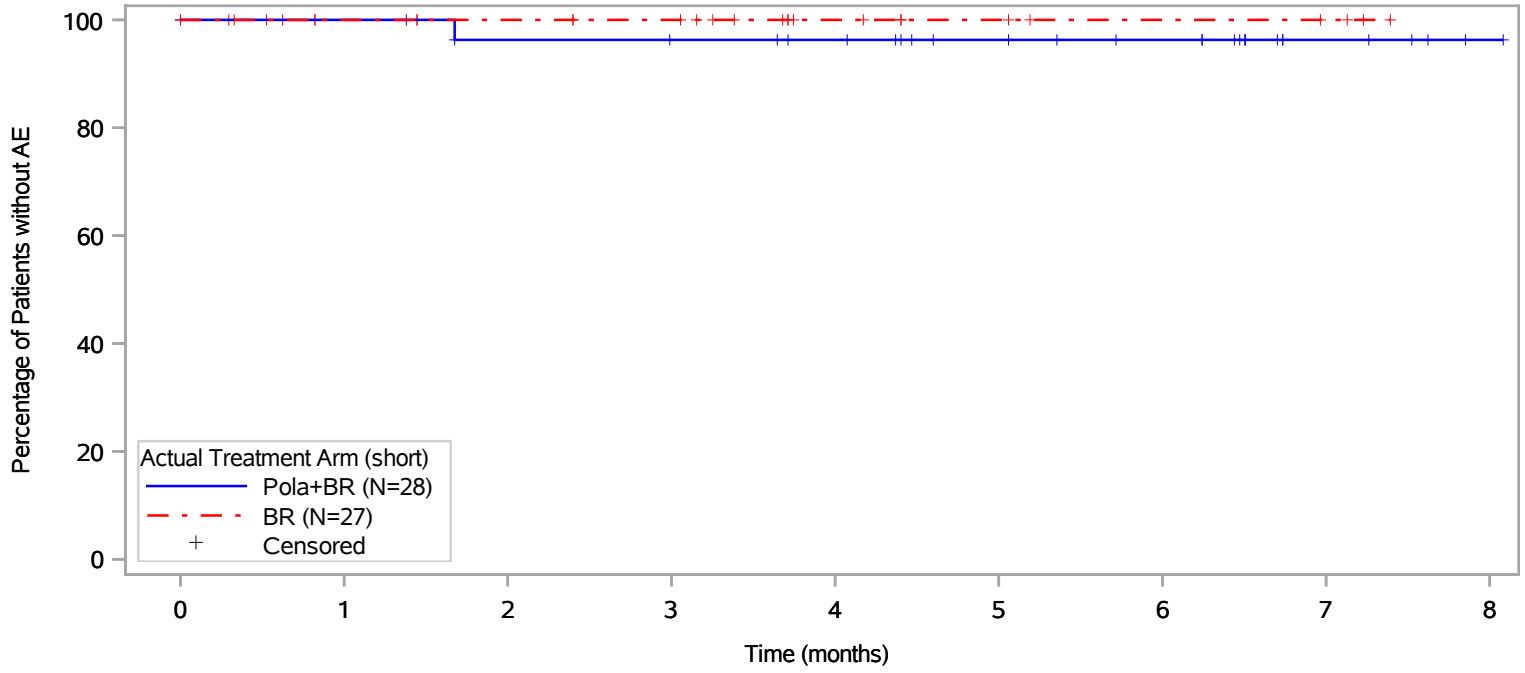
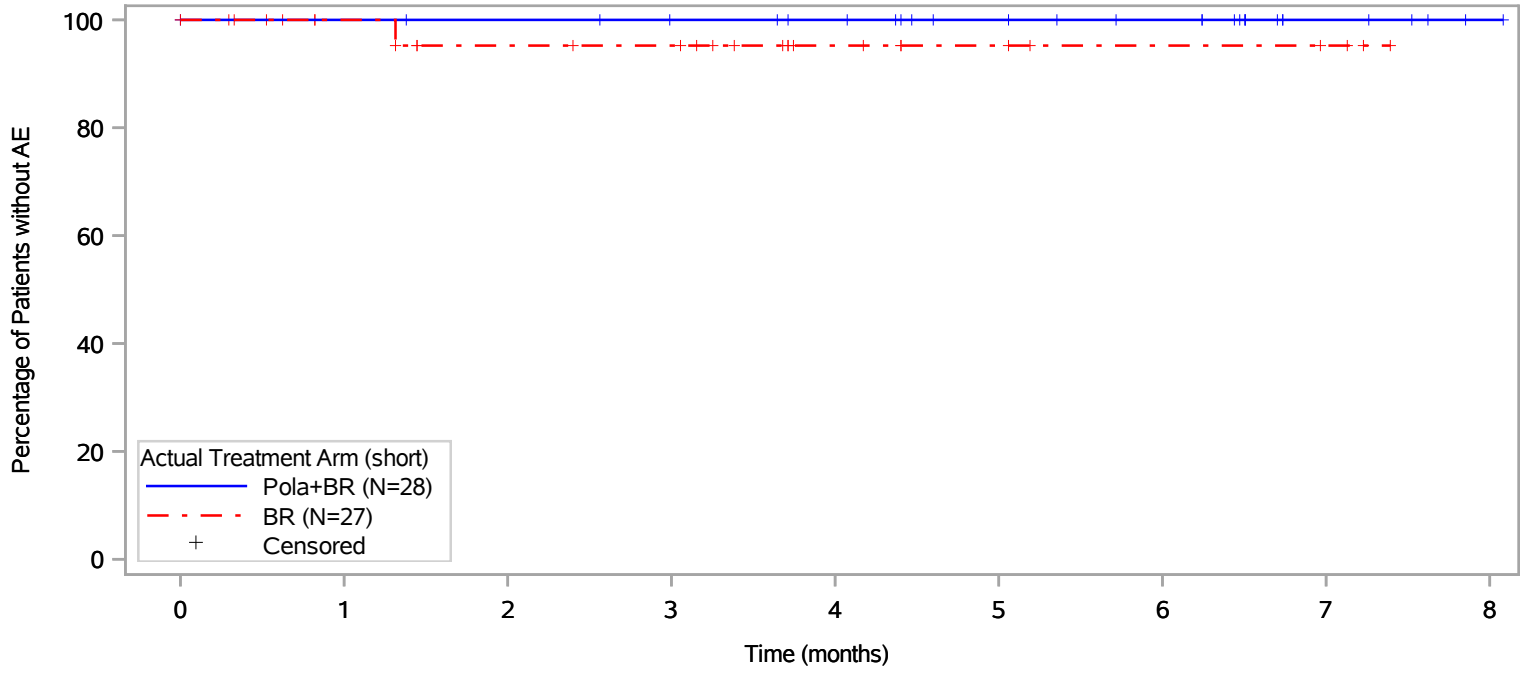
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CLOSTRIDIUM TEST POSITIVE



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

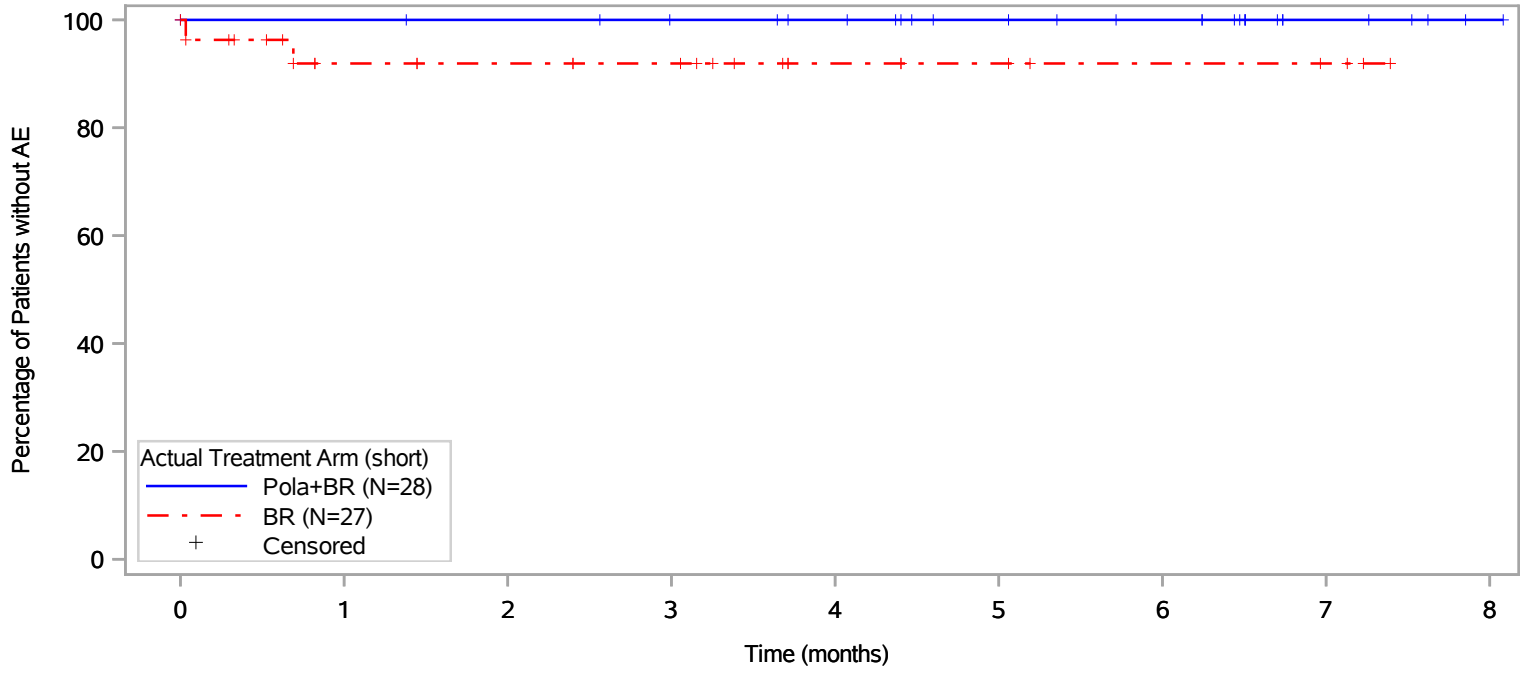
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYTOMEGALOVIRUS TEST POSITIVE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, HAEMOGLOBIN DECREASED

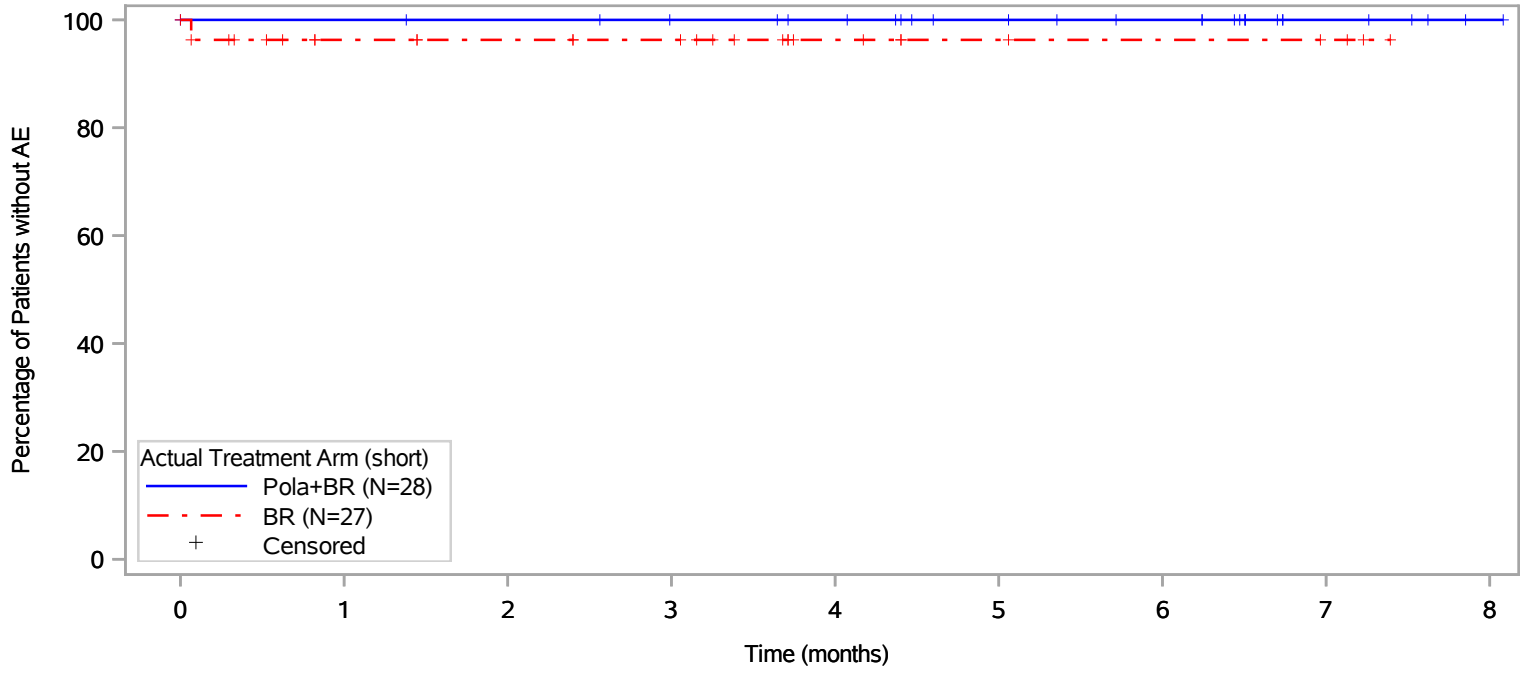


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	19	17	15	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, INTERNATIONAL NORMALISED RATIO INCREASED

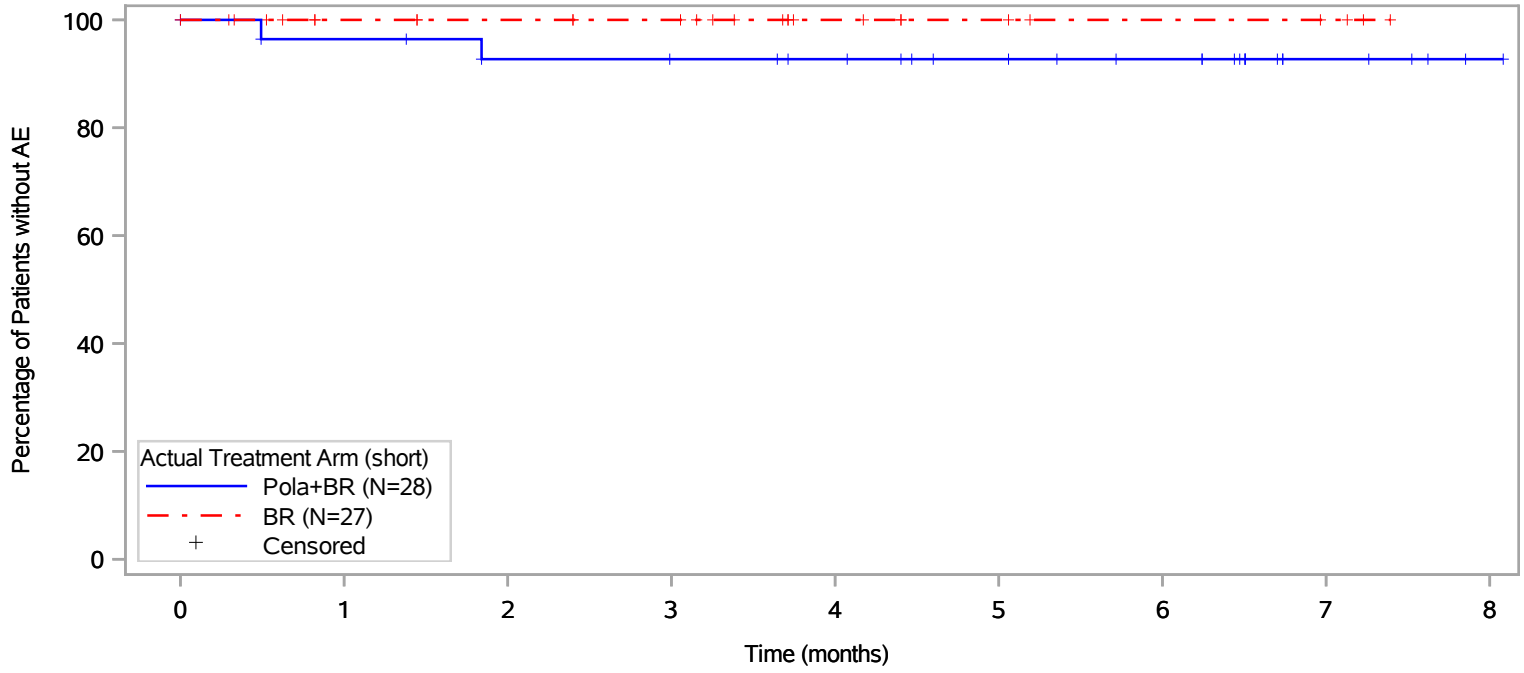


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

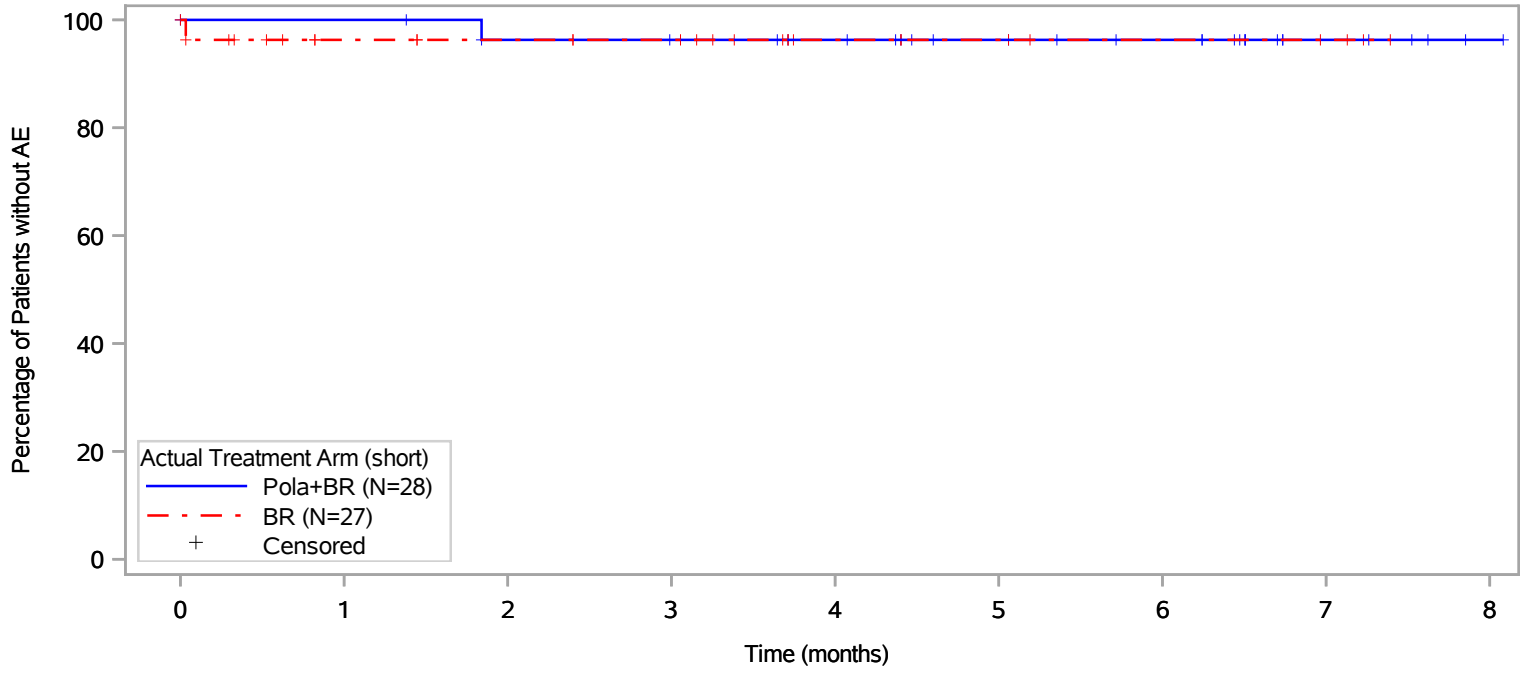
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LIPASE INCREASED



Patients at risk									
Pola+BR (N=28)	28	27	25	24	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	8	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED

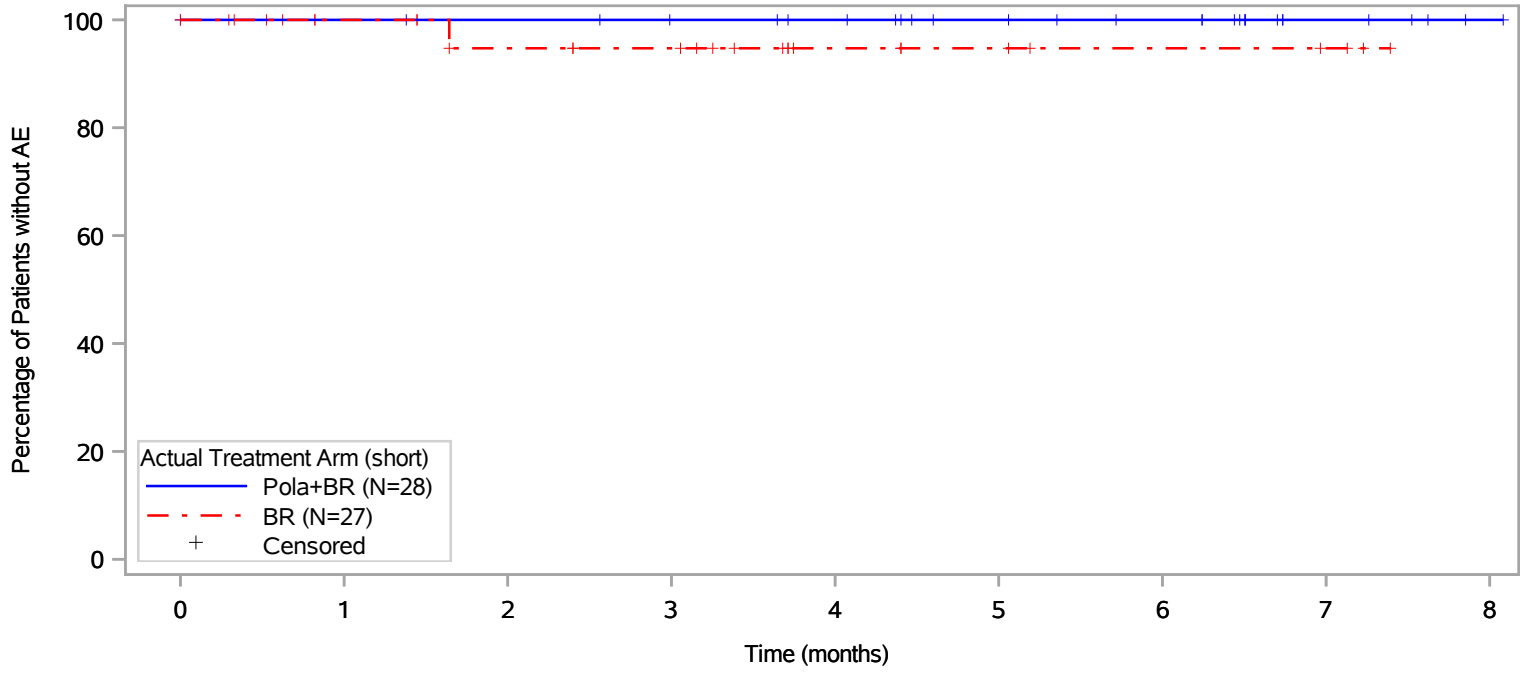


Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

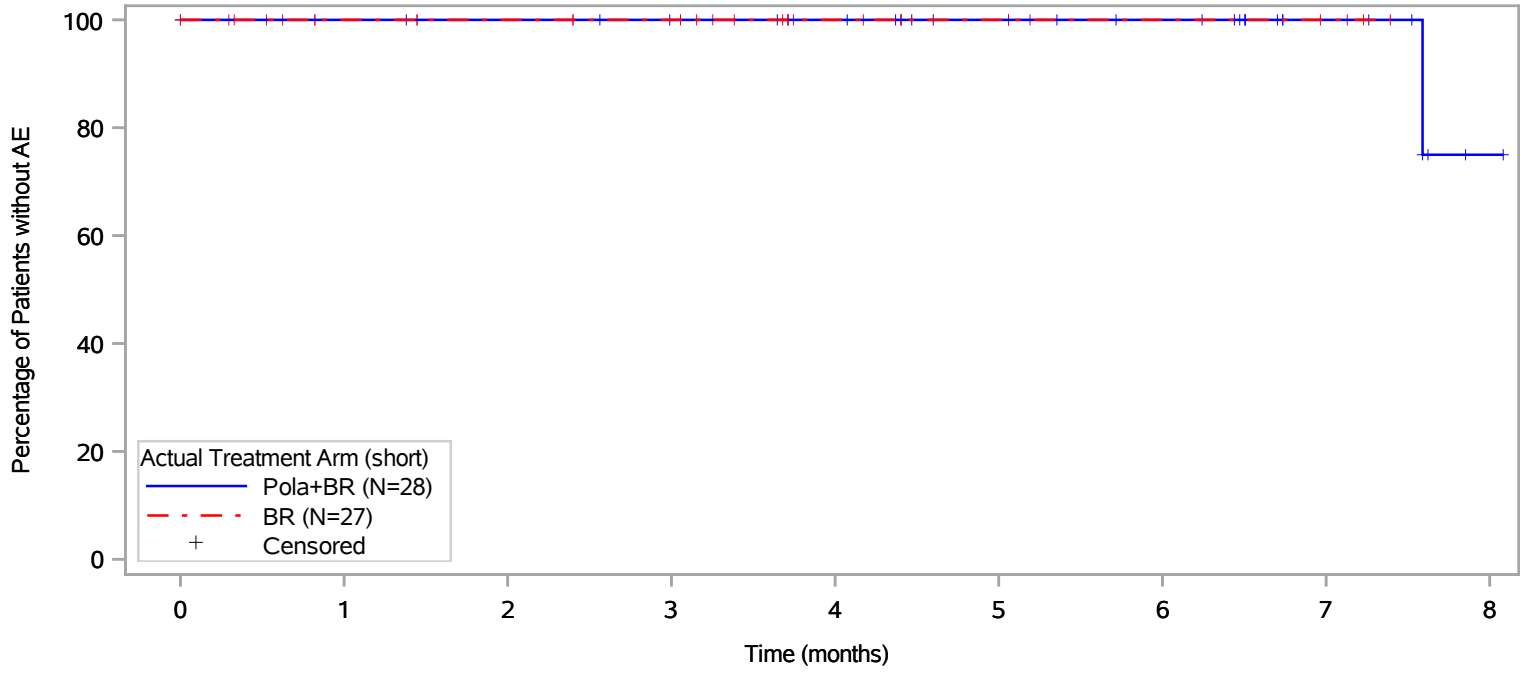
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MONOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

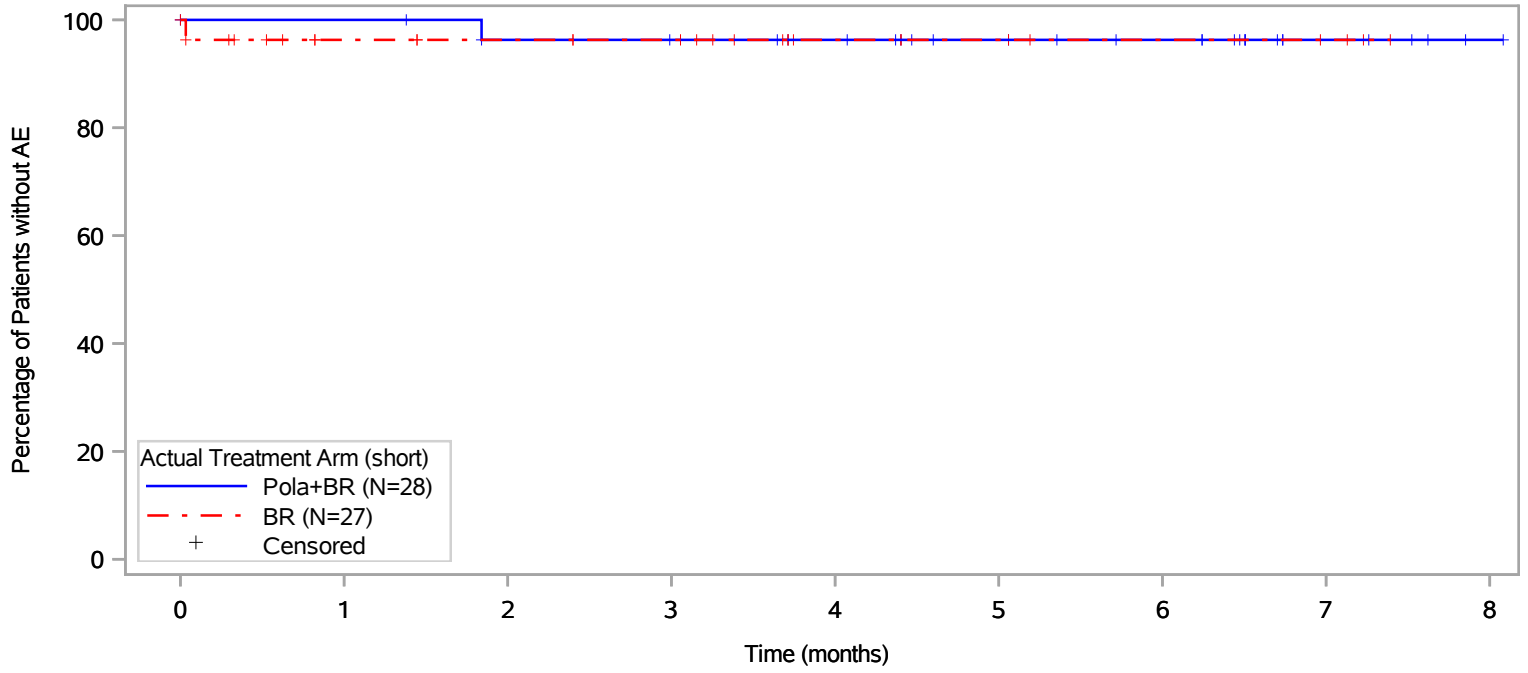
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MORAXELLA TEST POSITIVE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	6	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

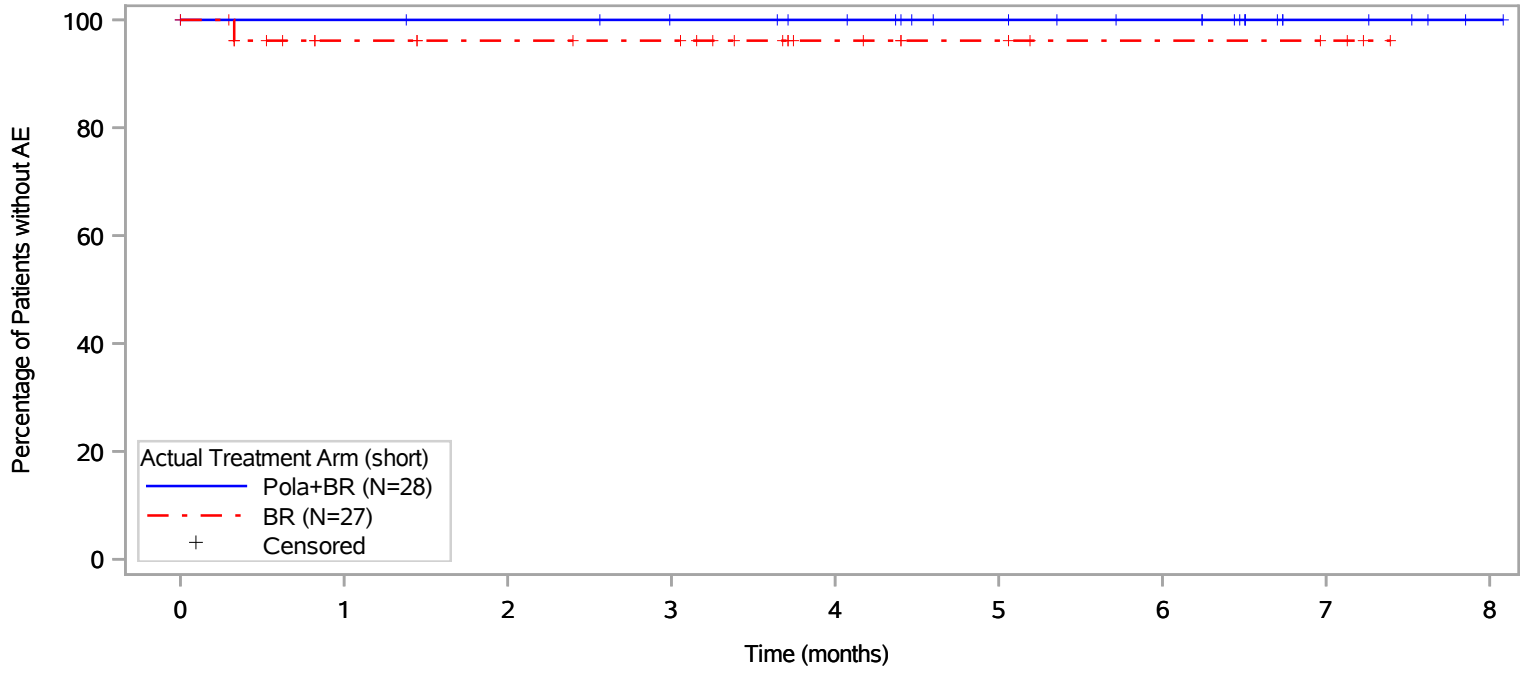


Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, OCCULT BLOOD POSITIVE

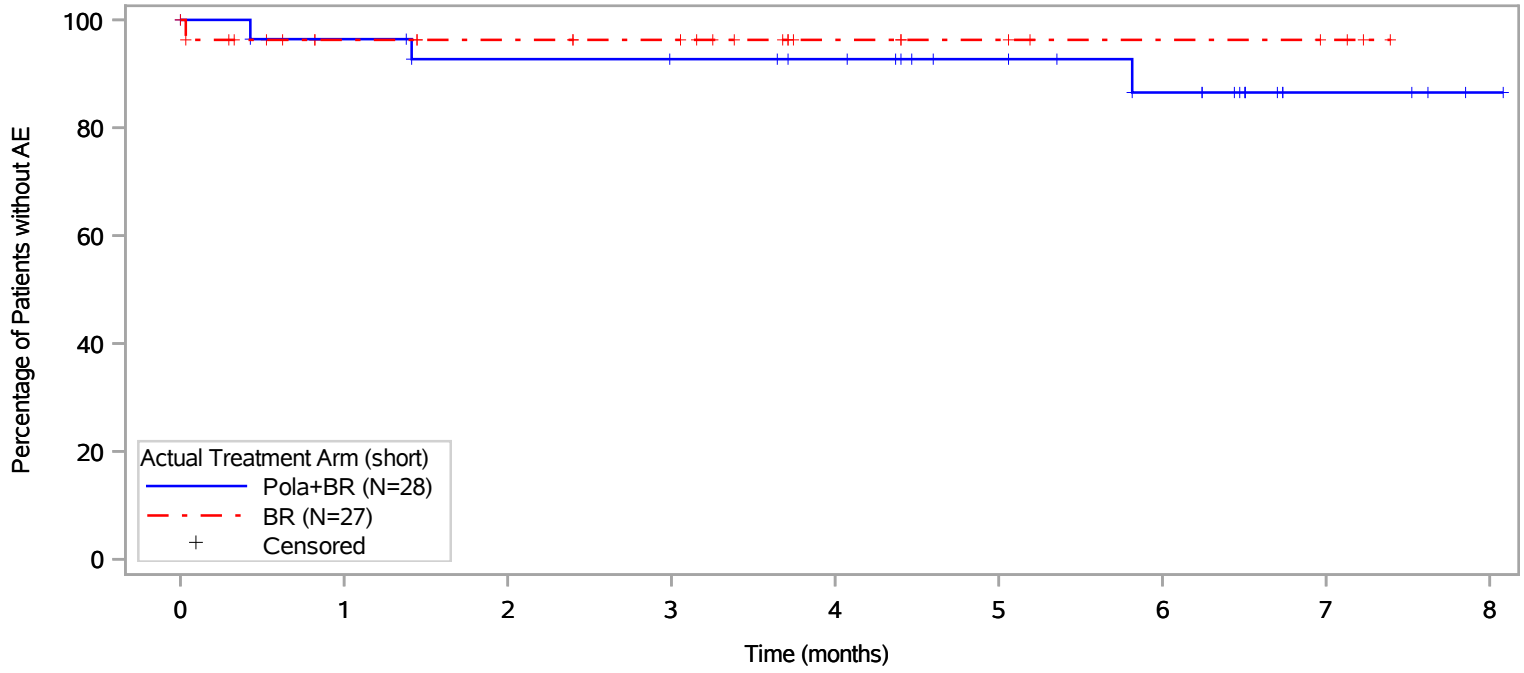


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

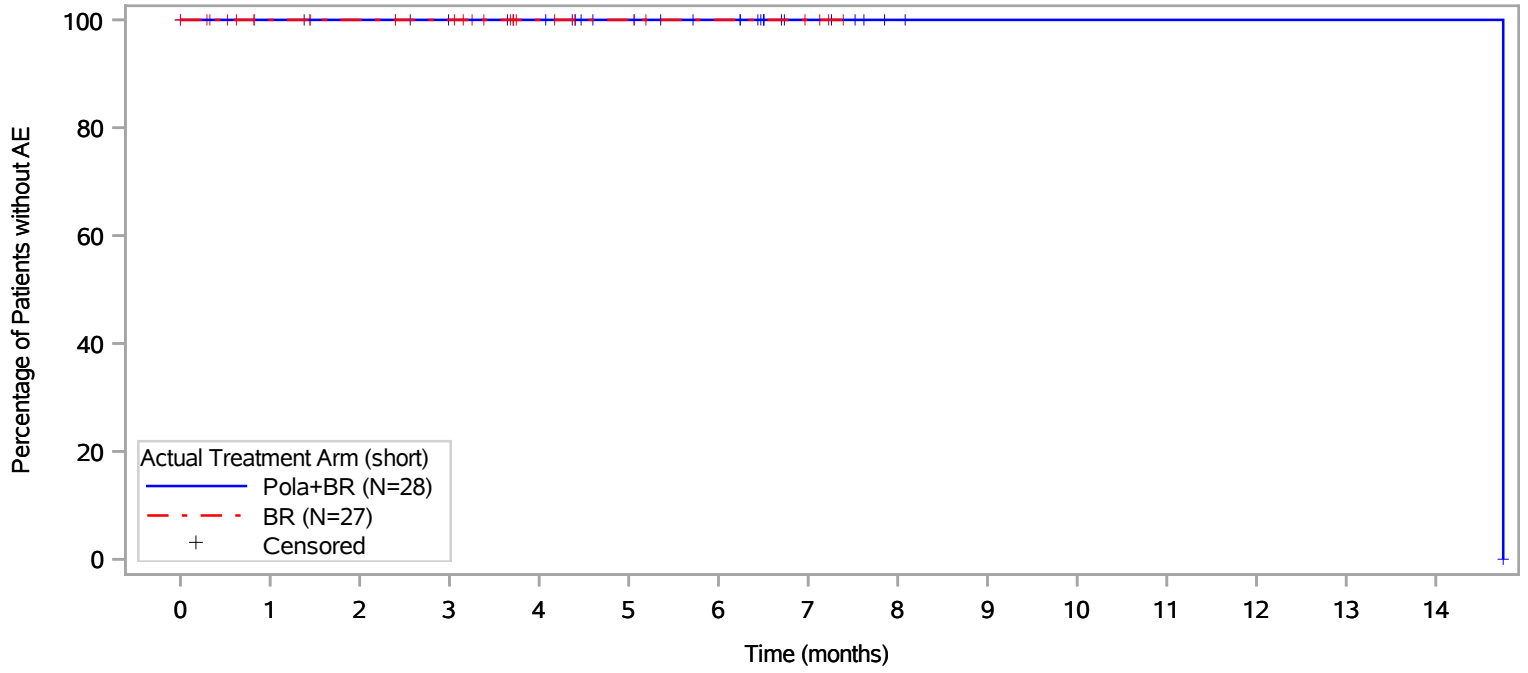


Patients at risk									
Pola+BR (N=28)	28	27	25	24	22	17	14	4	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	11	21	24
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, TRANSAMINASES INCREASED

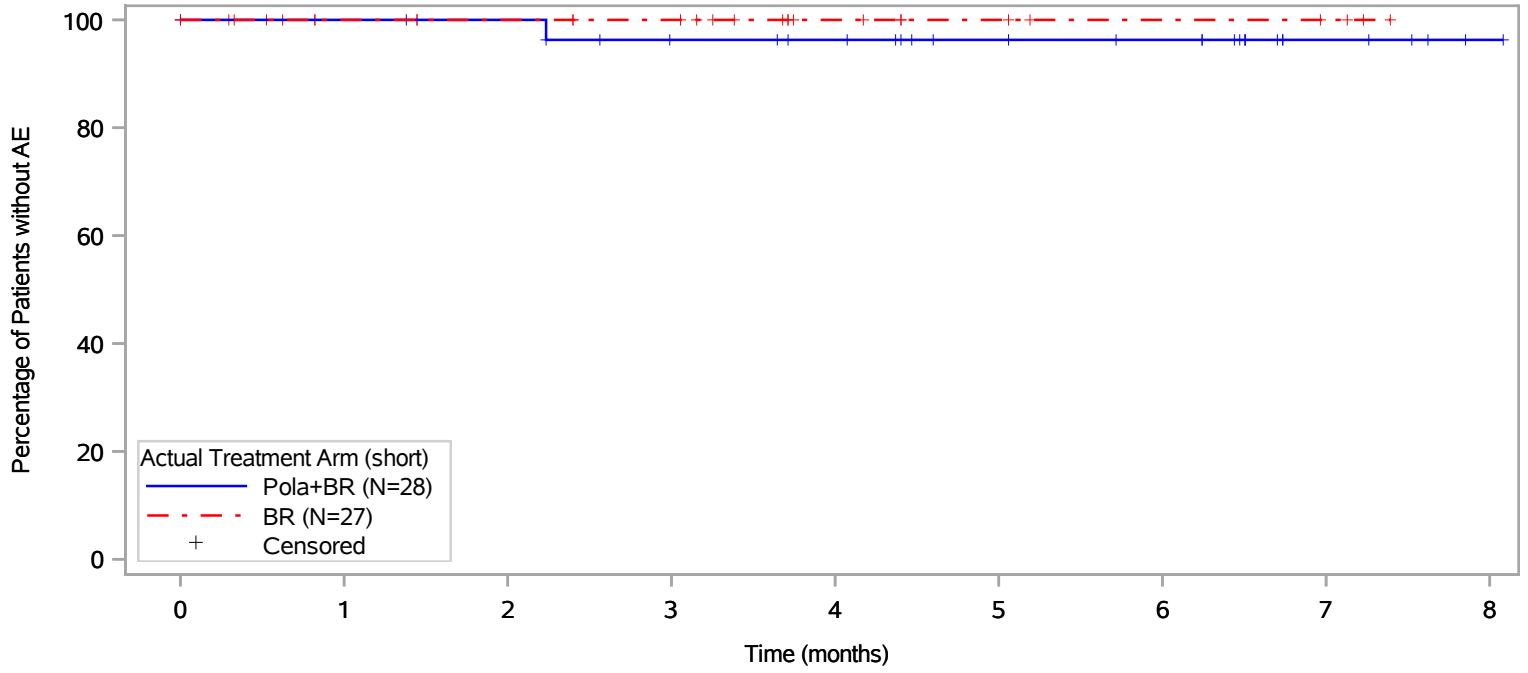


Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, VITAMIN D DECREASED

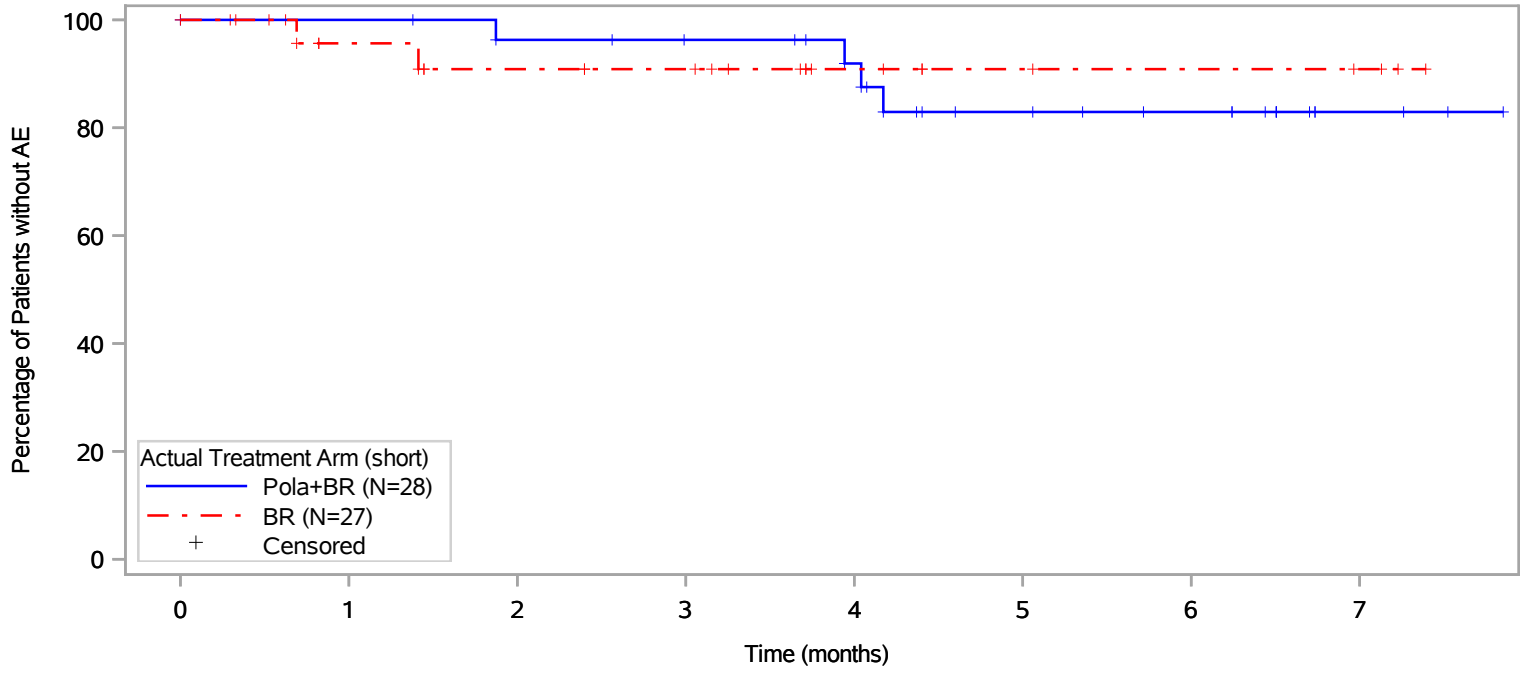


Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED

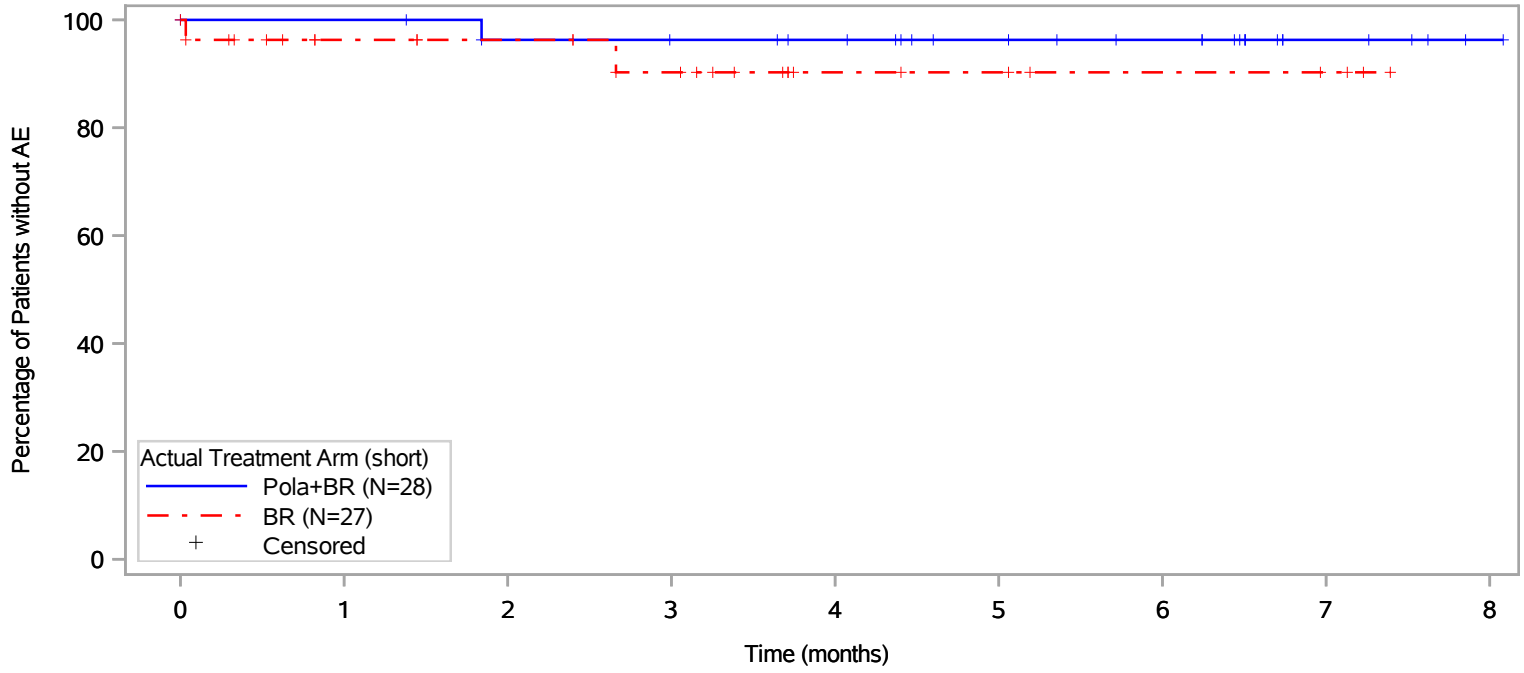


Patients at risk								
Pola+BR (N=28)	28	28	26	24	21	15	12	3
BR (N=27)	27	20	17	15	8	5	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	9	12	21
BR (N=27)	0	6	8	10	17	20	21	22

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

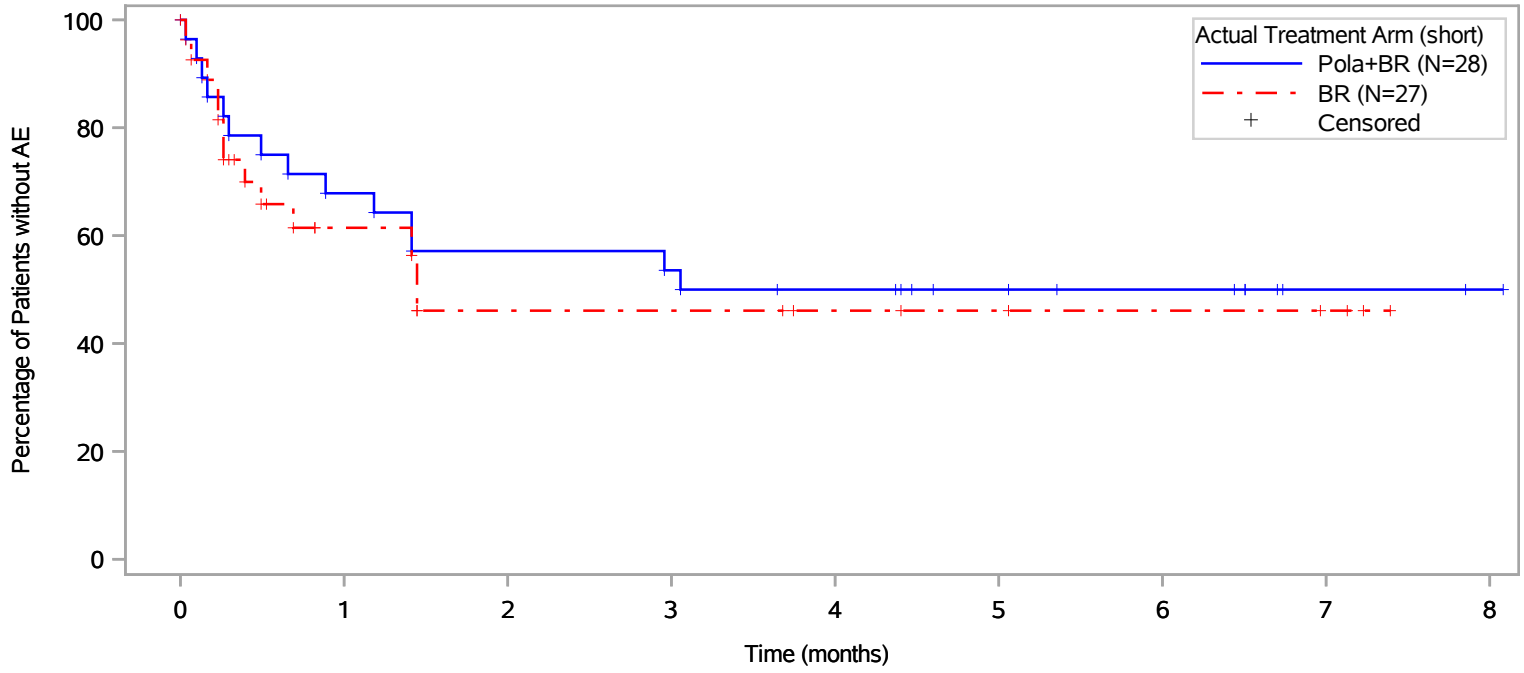
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	20	18	15	7	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	19	16	15	13	9	7	2	1
BR (N=27)	27	12	8	8	6	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	0	1	5	7	12	13
BR (N=27)	0	5	6	6	8	9	10	11	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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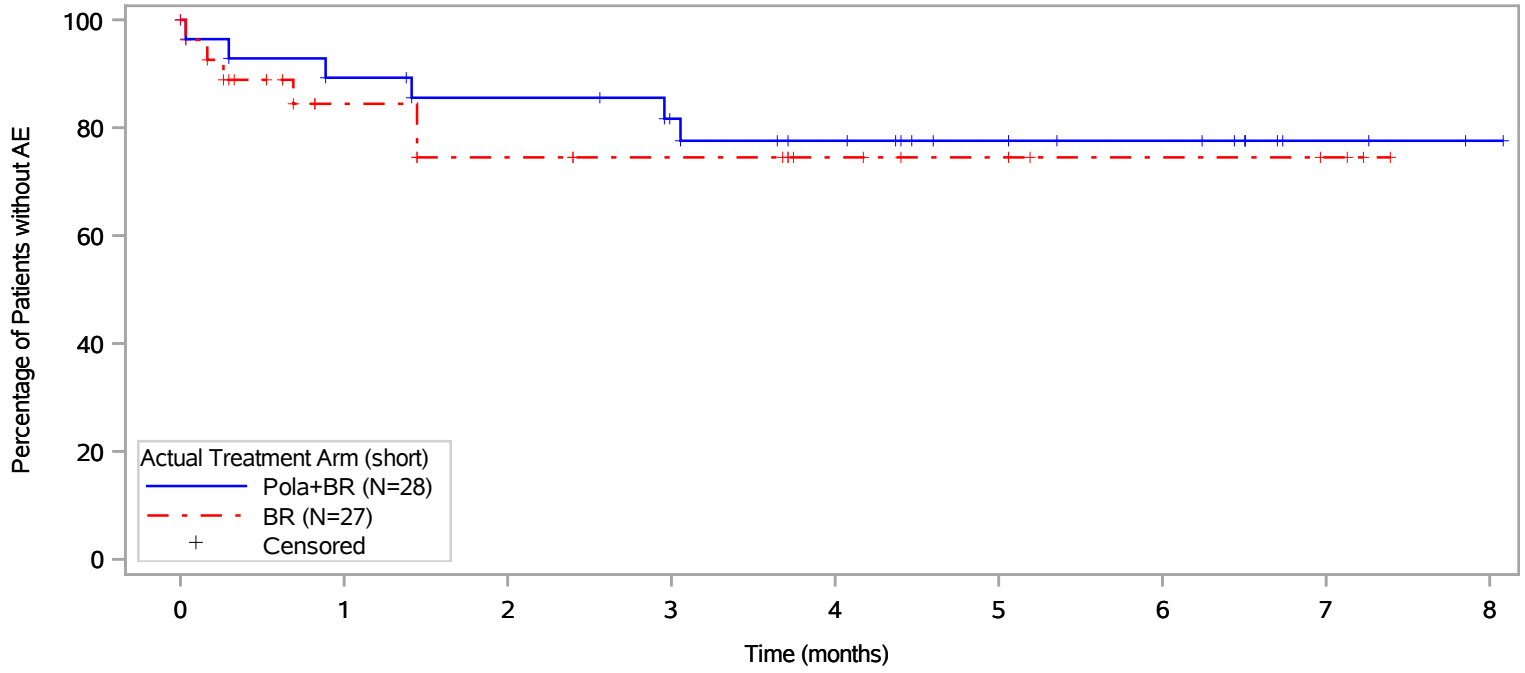
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE



Patients at risk									
Pola+BR (N=28)	28	25	23	20	17	12	10	3	1
BR (N=27)	27	17	14	12	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	19	21
BR (N=27)	0	6	7	9	13	15	17	18	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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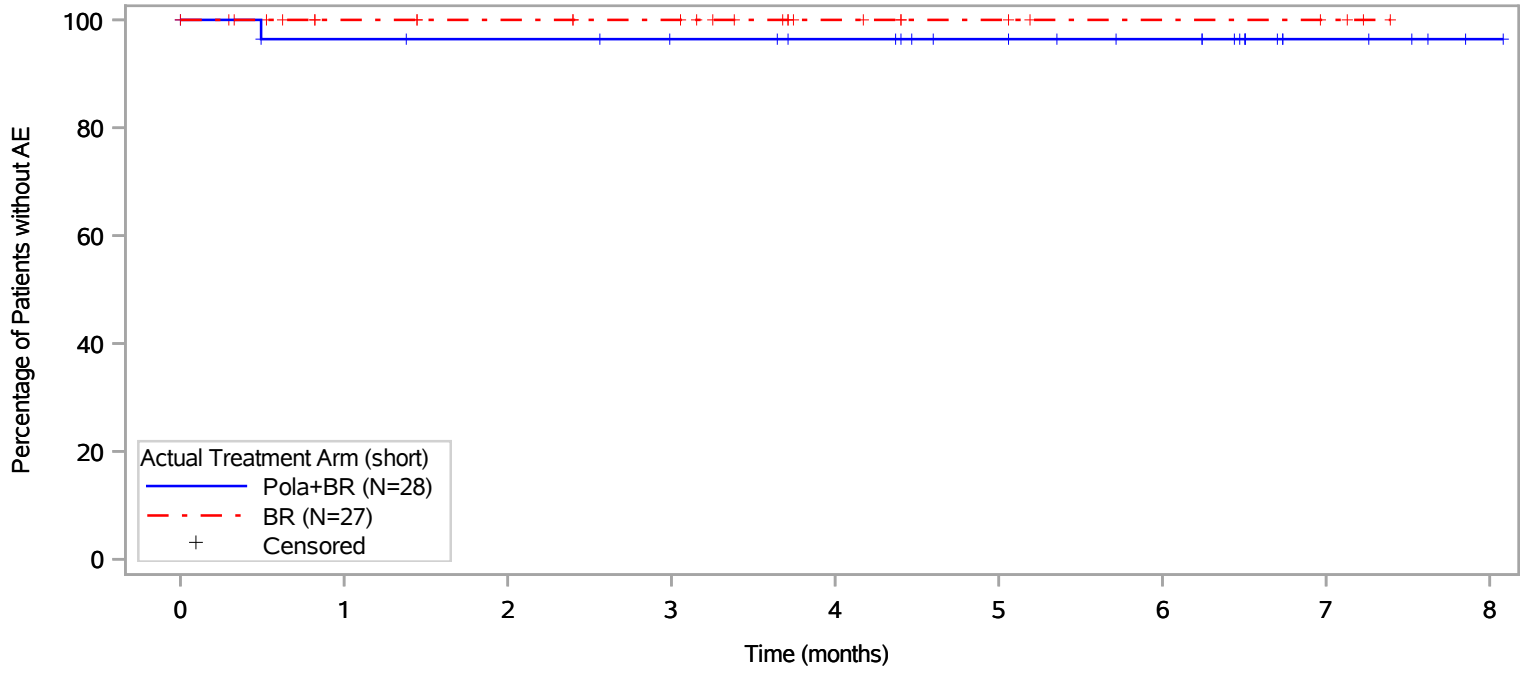
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, DEHYDRATION

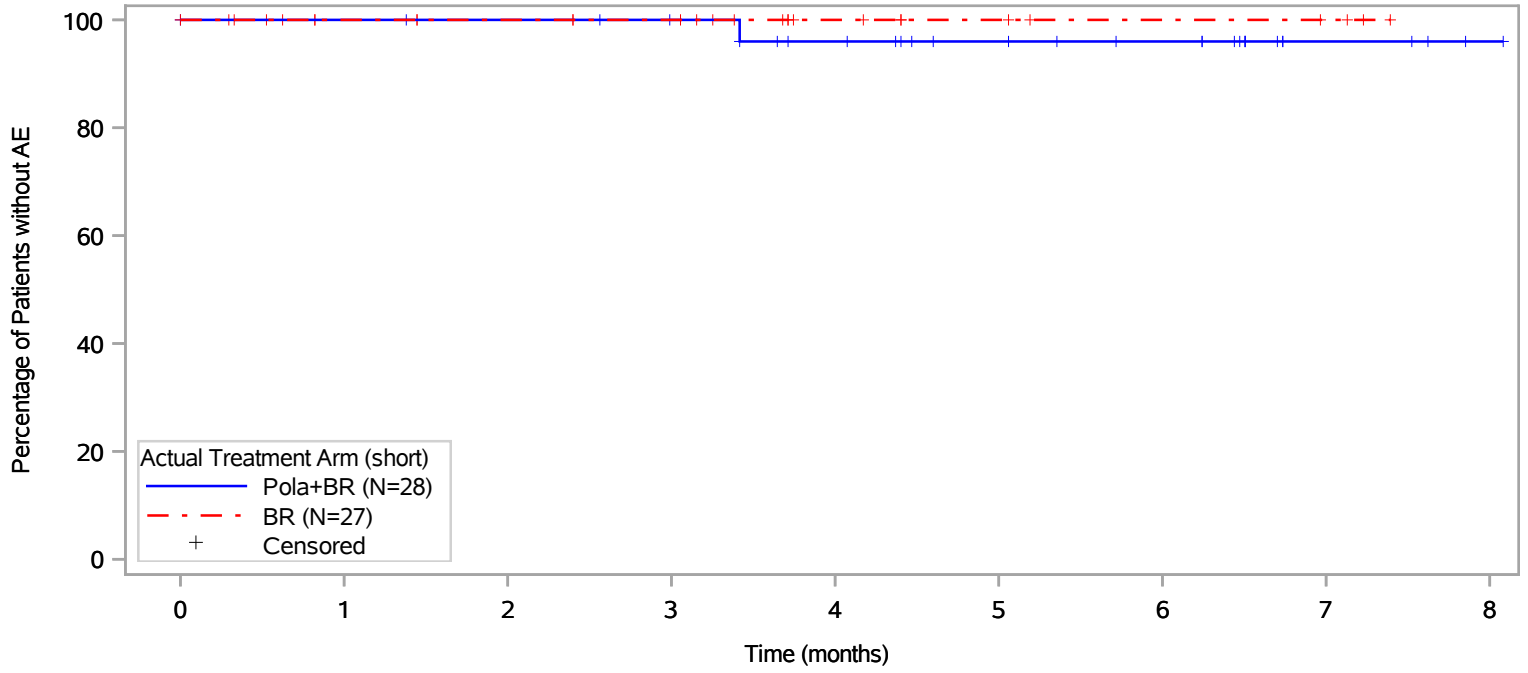


Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, ELECTROLYTE IMBALANCE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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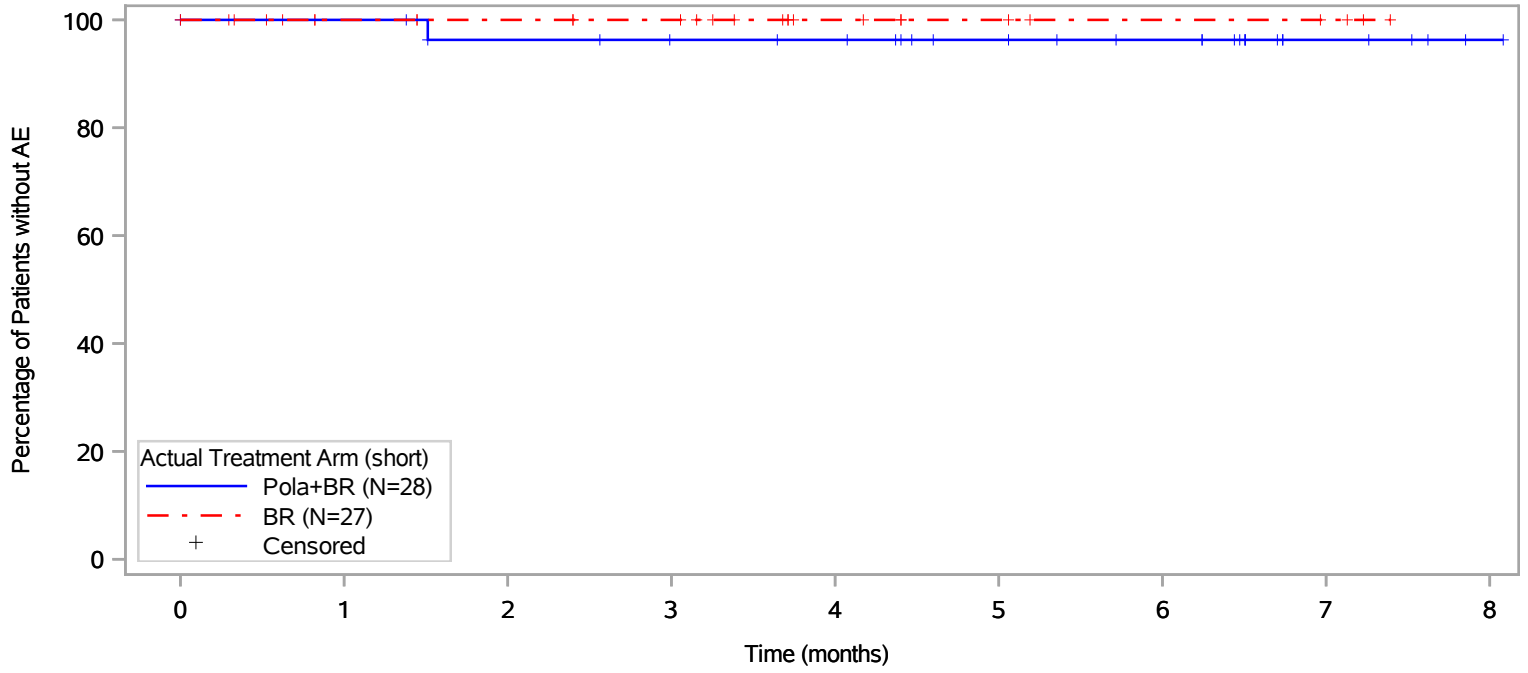
01DEC2022 21:22

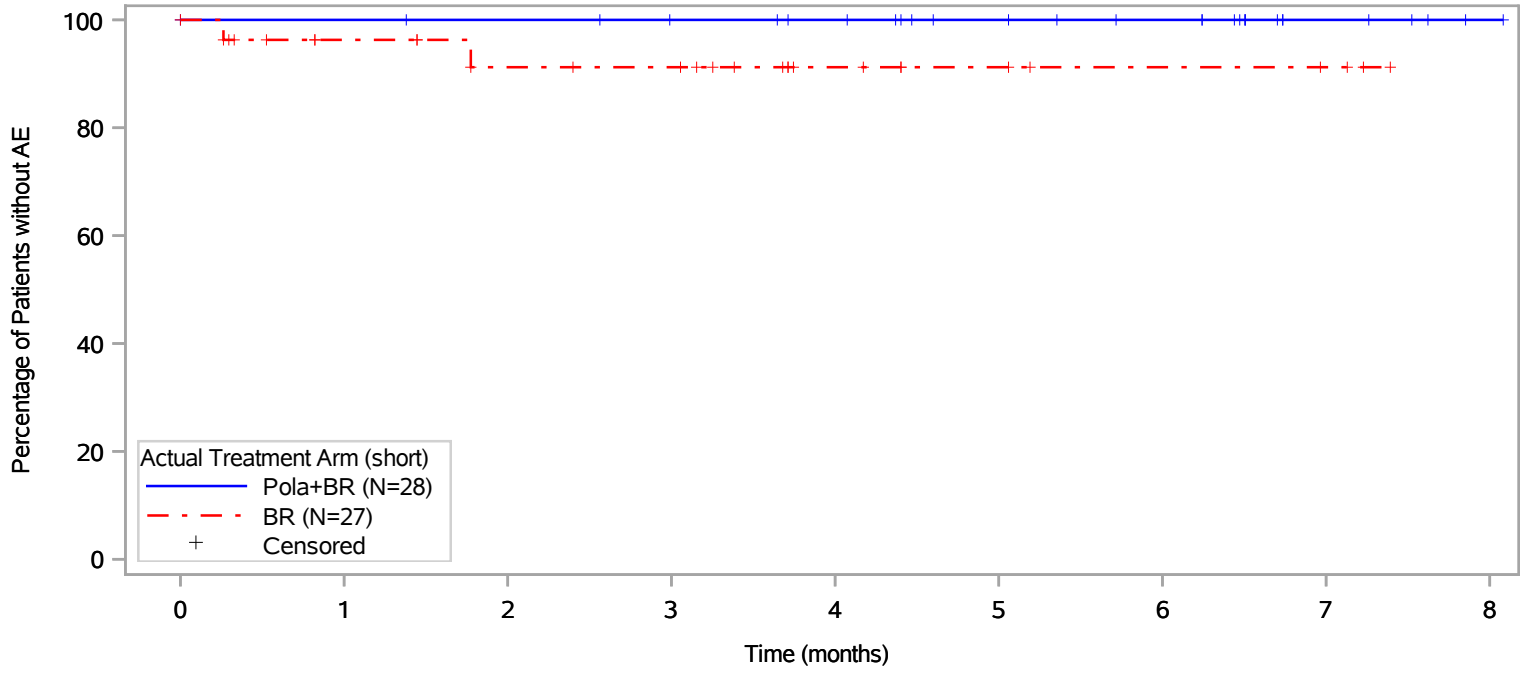
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, FOLATE DEFICIENCY



Patients at risk									
Pola+BR (N=28)	28	28	26	24	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERCALCAEMIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	5	7	8	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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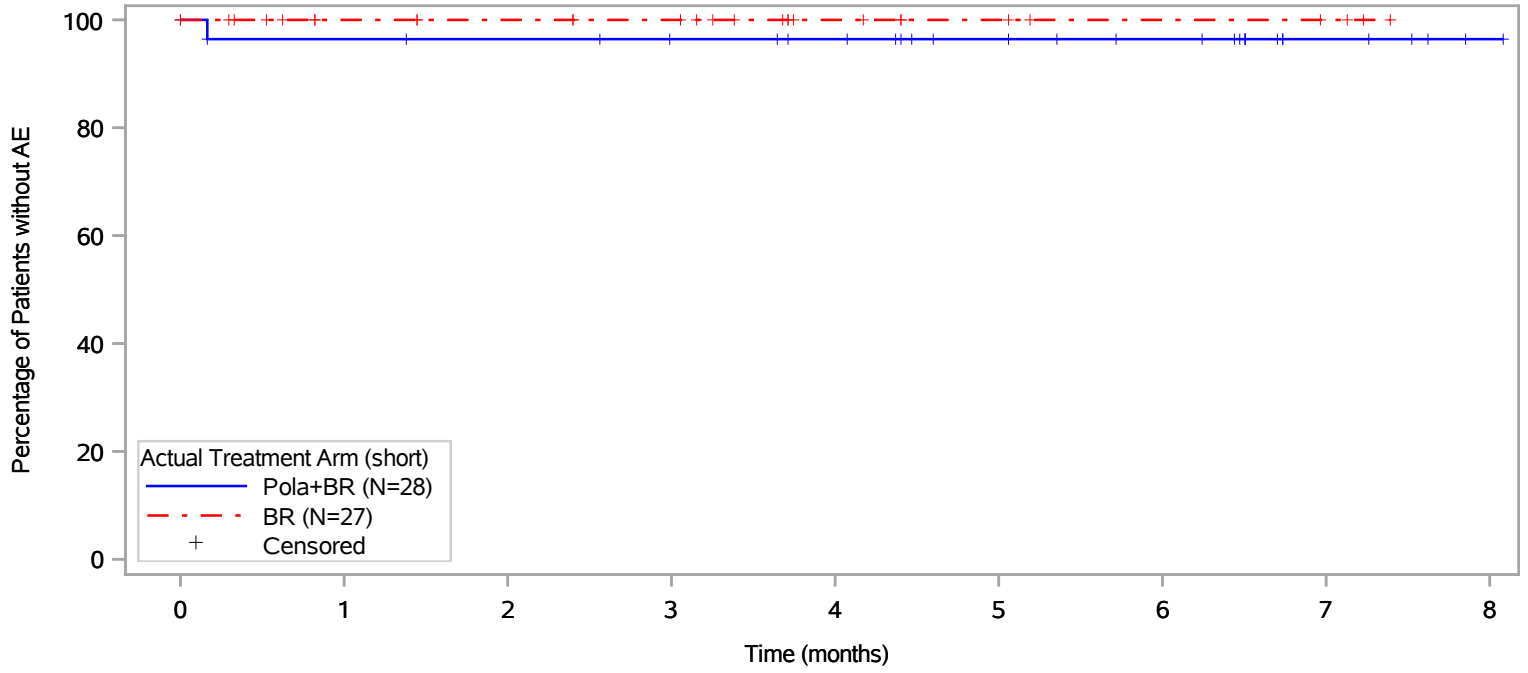
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERGLYCAEMIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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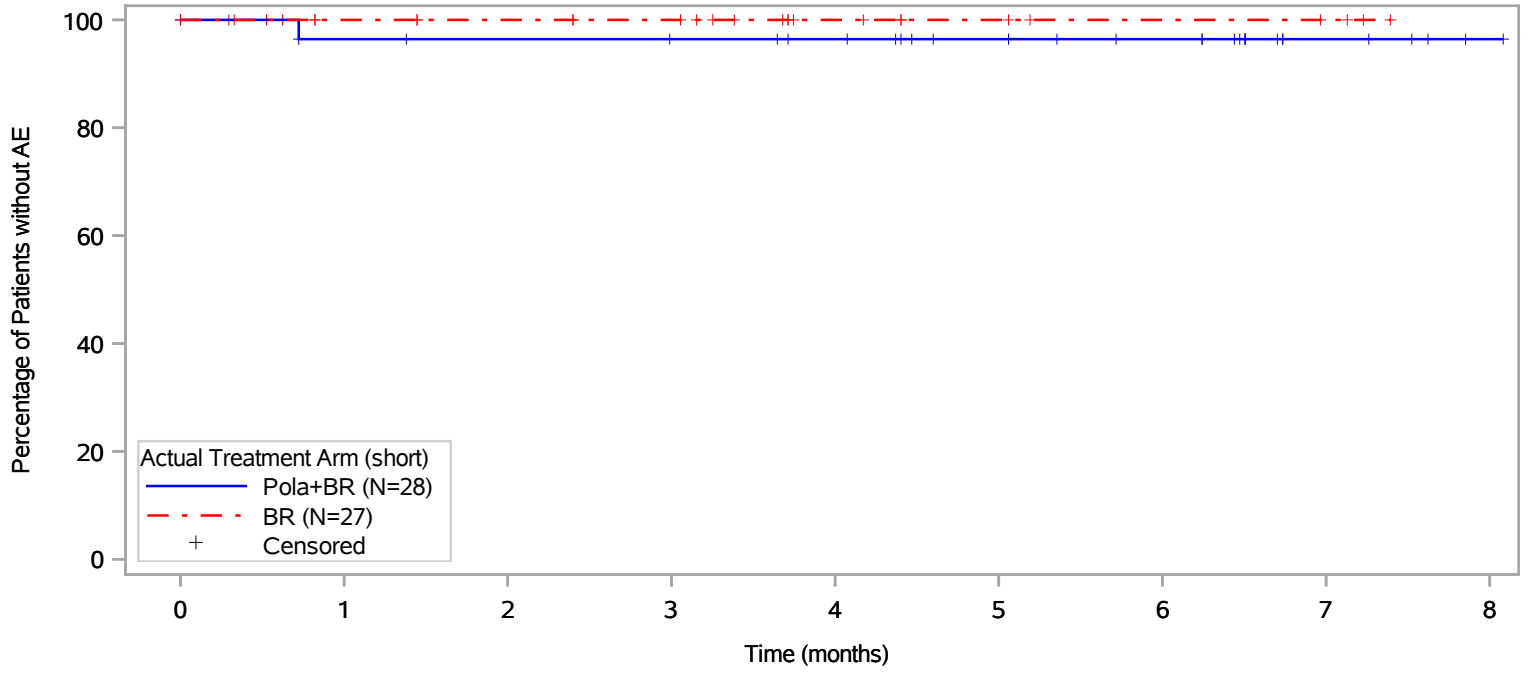
01DEC2022 21:22

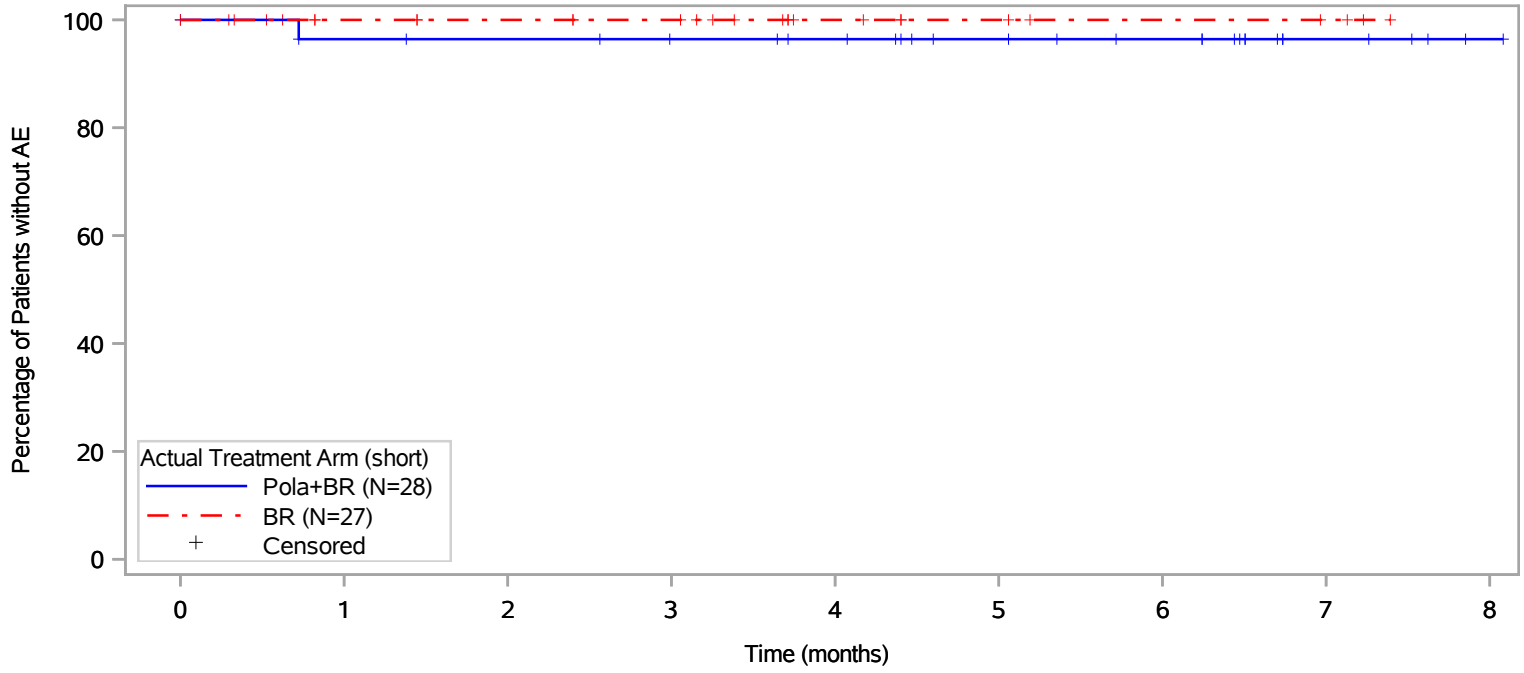
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERMAGNESAEMIA



Patients at risk									
Pola+BR (N=28)	28	27	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERURICAEMIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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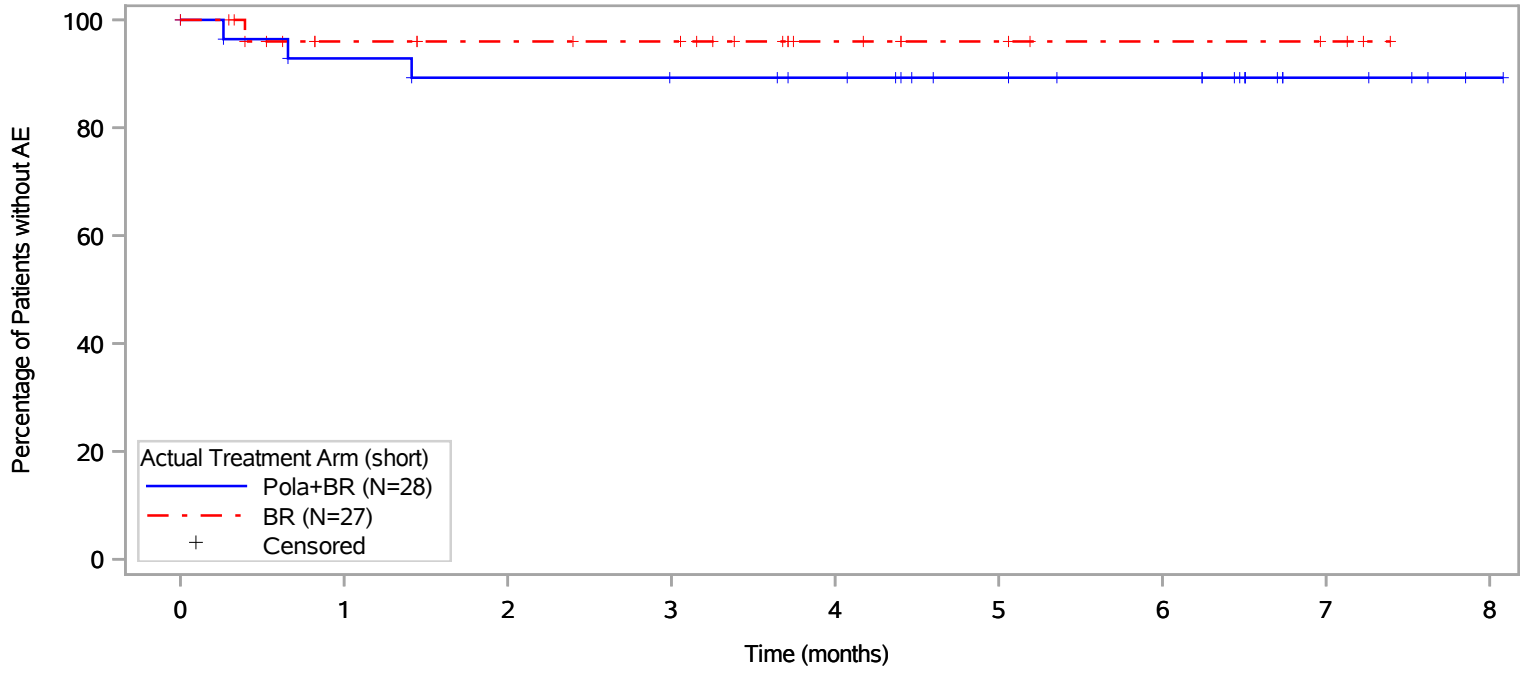
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA



Patients at risk									
Pola+BR (N=28)	28	26	25	24	22	17	15	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	3	8	10	20	24
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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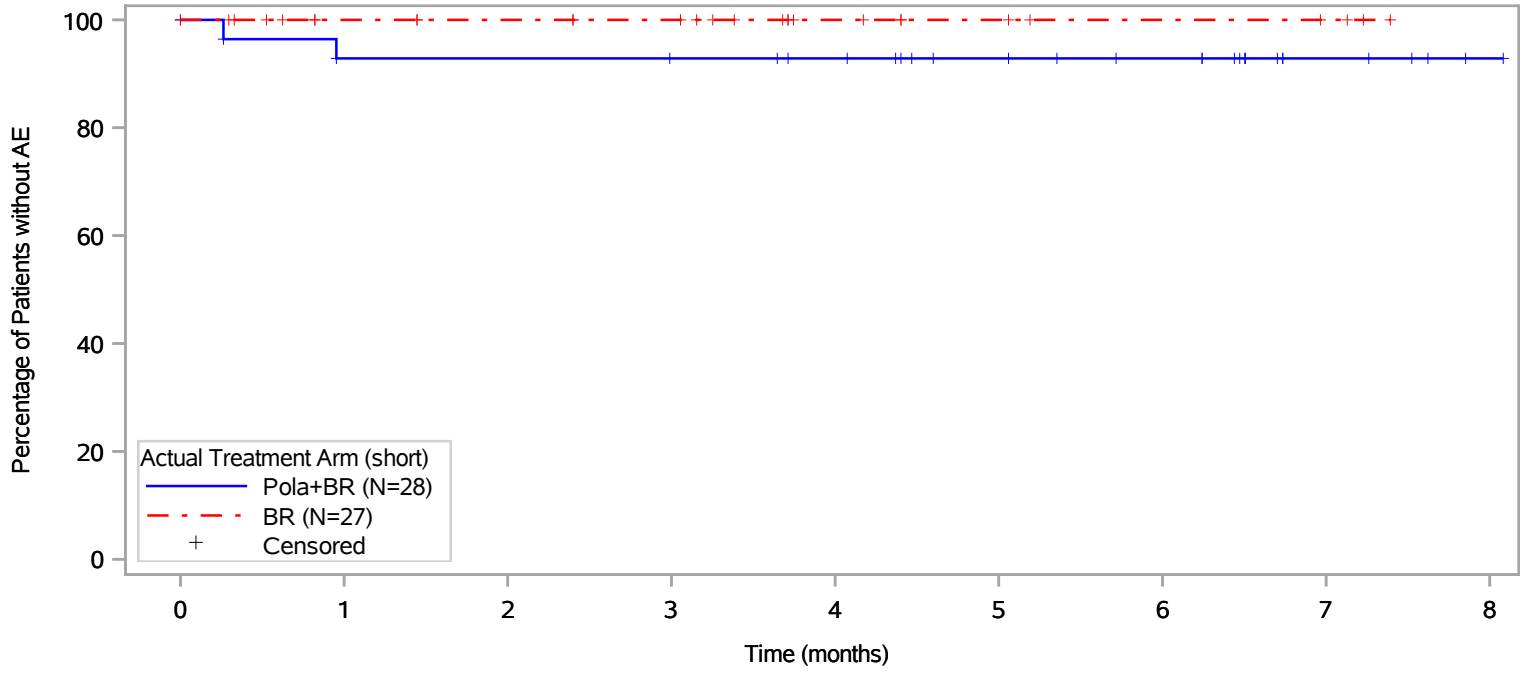
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOCALCAEMIA



Patients at risk									
Pola+BR (N=28)	28	26	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	3	8	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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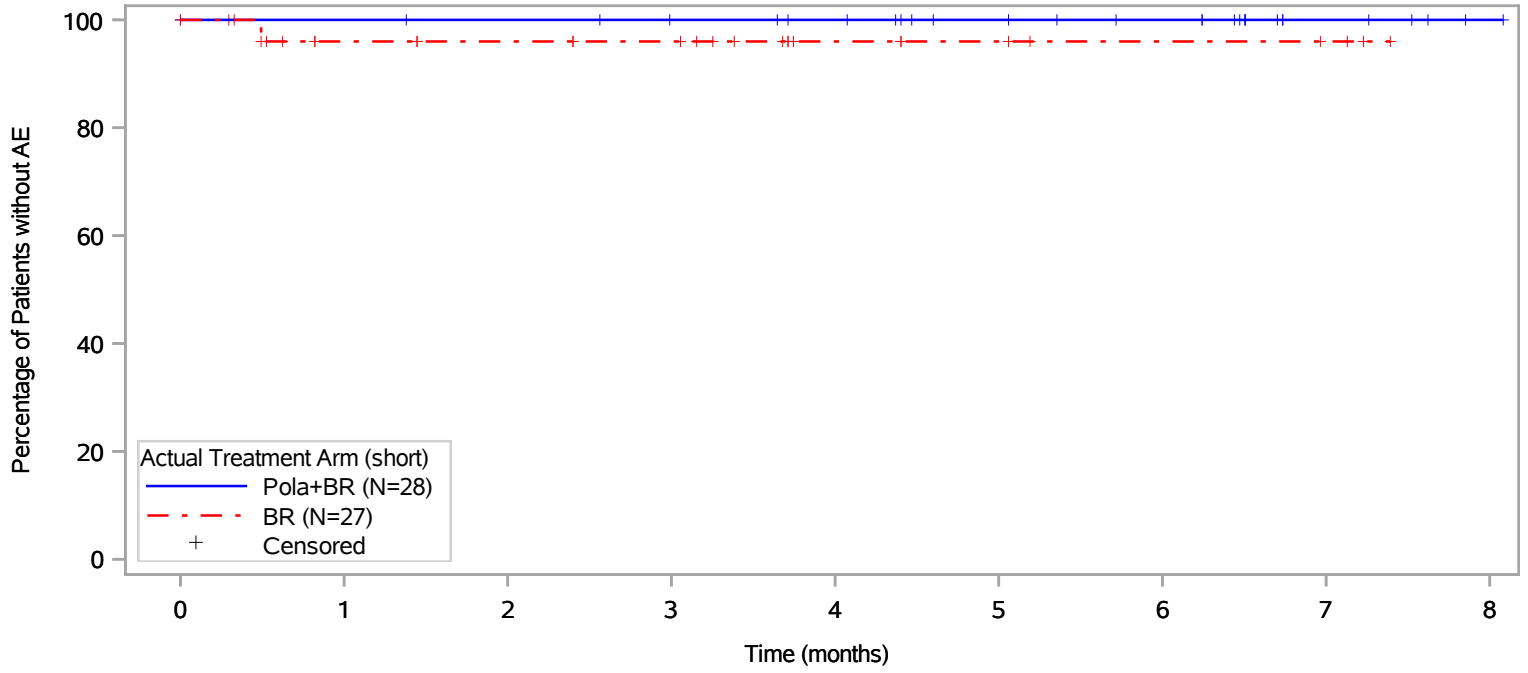
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOGLYCAEMIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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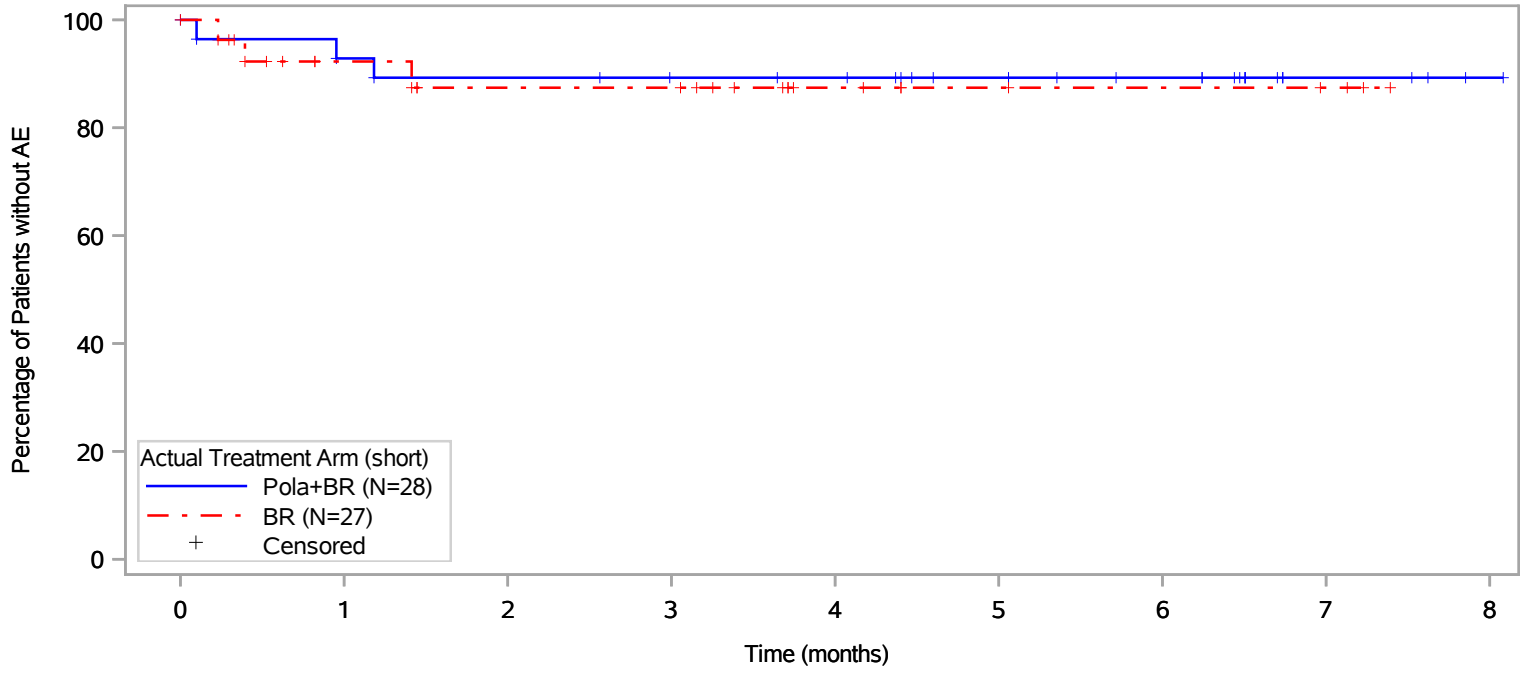
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk									
Pola+BR (N=28)	28	26	25	23	22	17	14	4	1
BR (N=27)	27	19	16	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	3	8	11	21	24
BR (N=27)	0	6	8	8	16	19	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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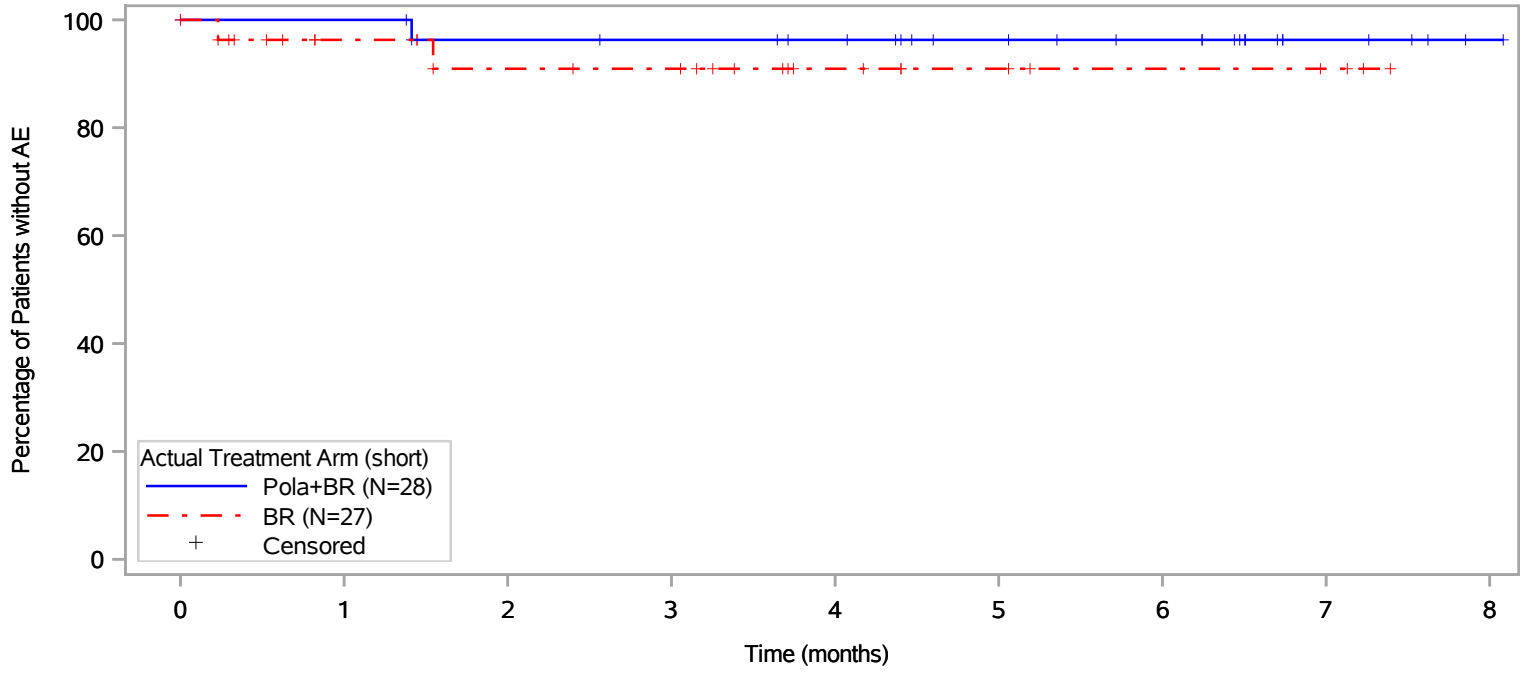
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOMAGNESAEMIA



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	20	17	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	9	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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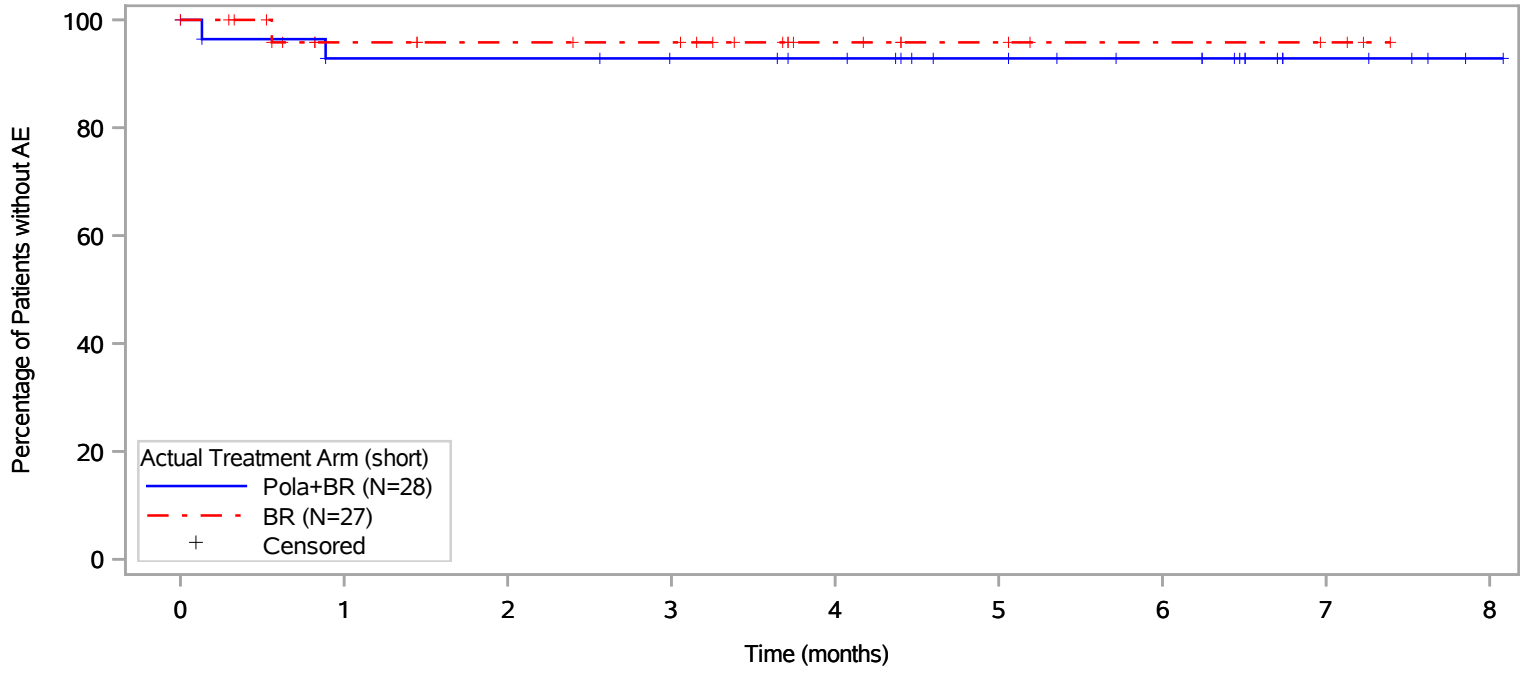
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOPHOSPHATAEMIA



Patients at risk									
Pola+BR (N=28)	28	26	26	24	22	17	14	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	21	25
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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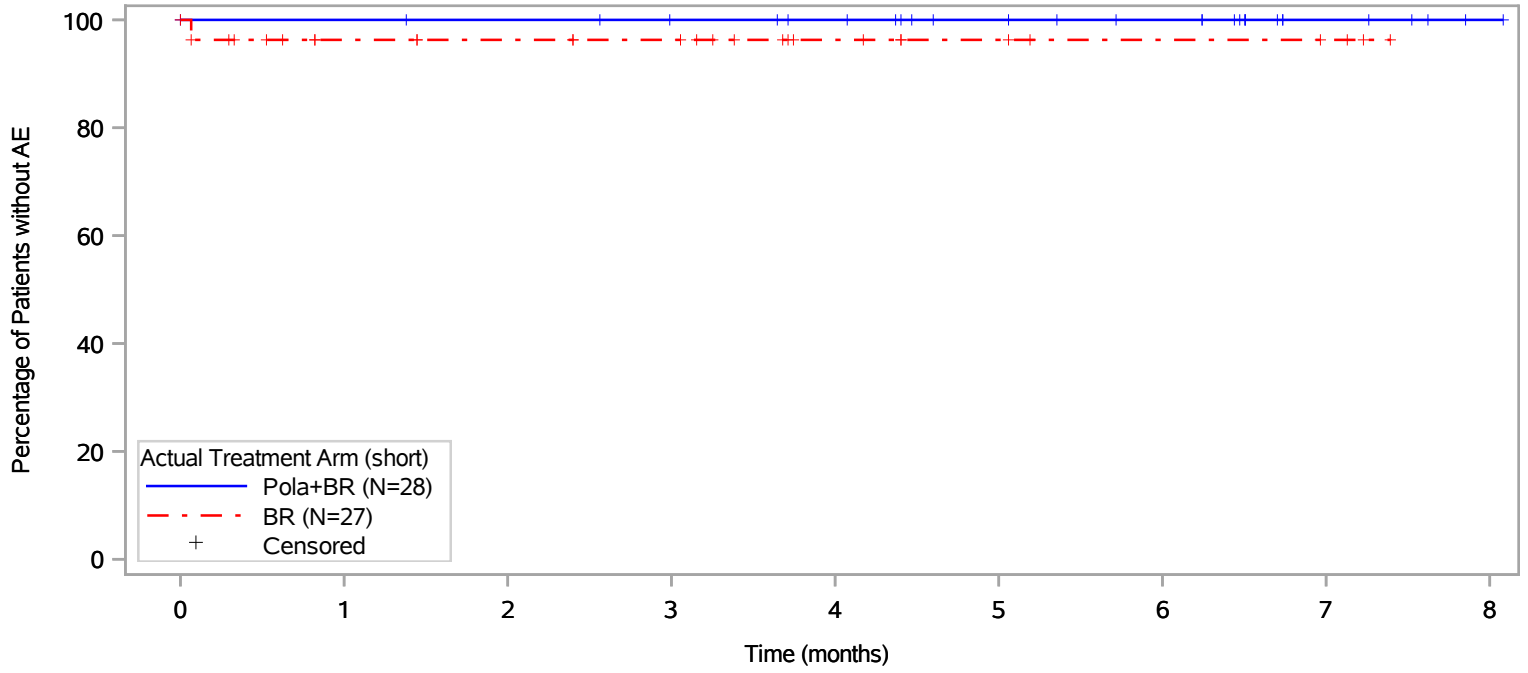
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, TYPE 2 DIABETES MELLITUS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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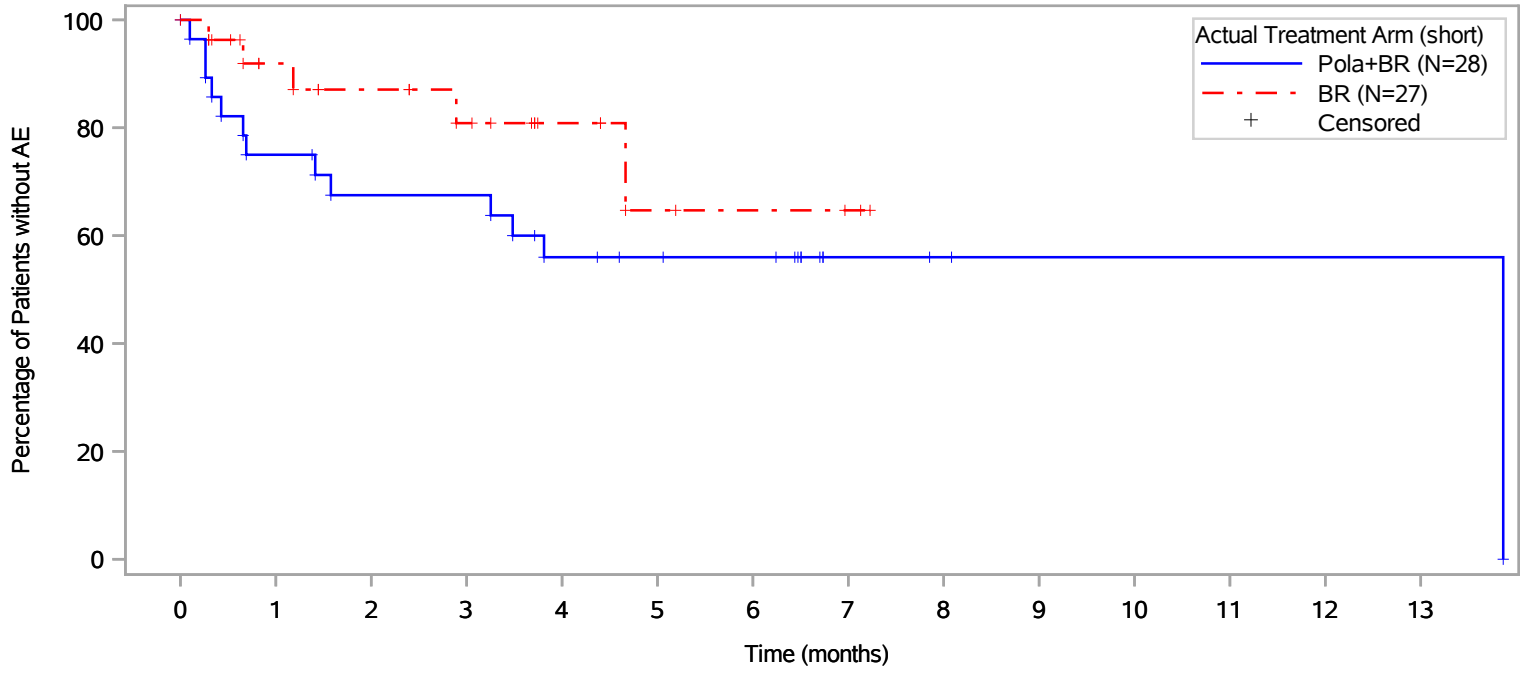
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk														
Pola+BR (N=28)	28	21	18	18	14	12	11	3	2	1	1	1	1	1
BR (N=27)	27	19	16	13	7	4	3	2	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	1	2	4	5	13	14	15	15	15	15	15
BR (N=27)	0	6	8	10	16	18	19	20	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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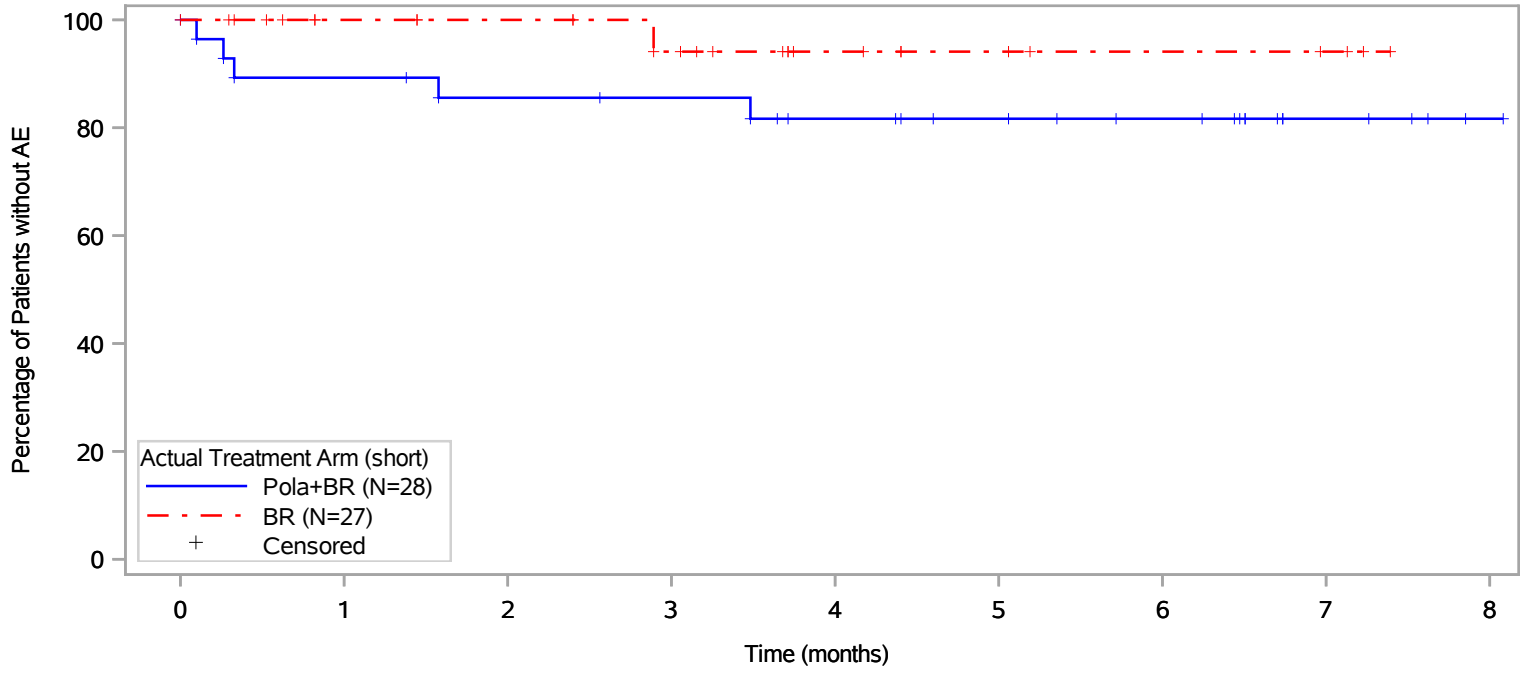
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, ARTHRALGIA



Patients at risk									
Pola+BR (N=28)	28	25	23	22	19	16	13	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	7	10	18	22
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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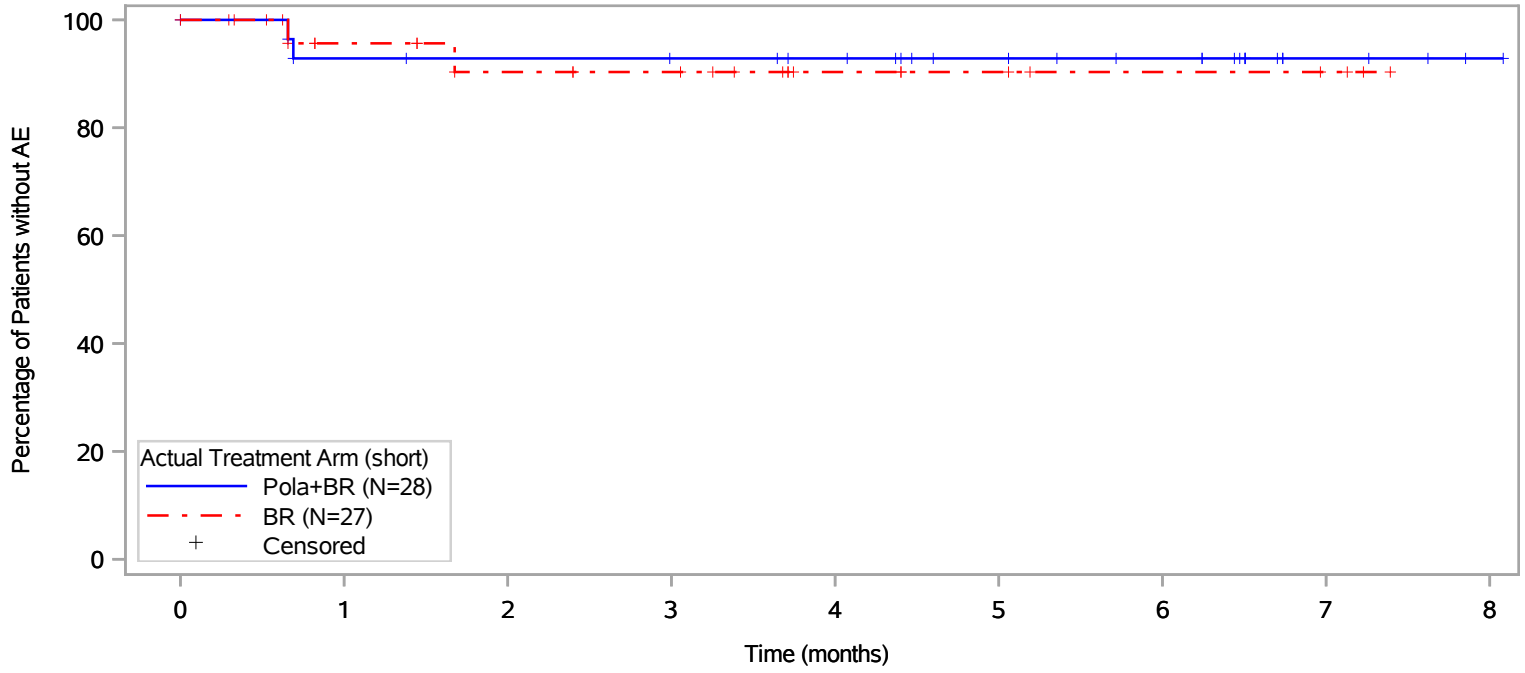
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN



Patients at risk									
Pola+BR (N=28)	28	26	25	24	22	17	14	4	1
BR (N=27)	27	20	17	15	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	25
BR (N=27)	0	6	8	10	17	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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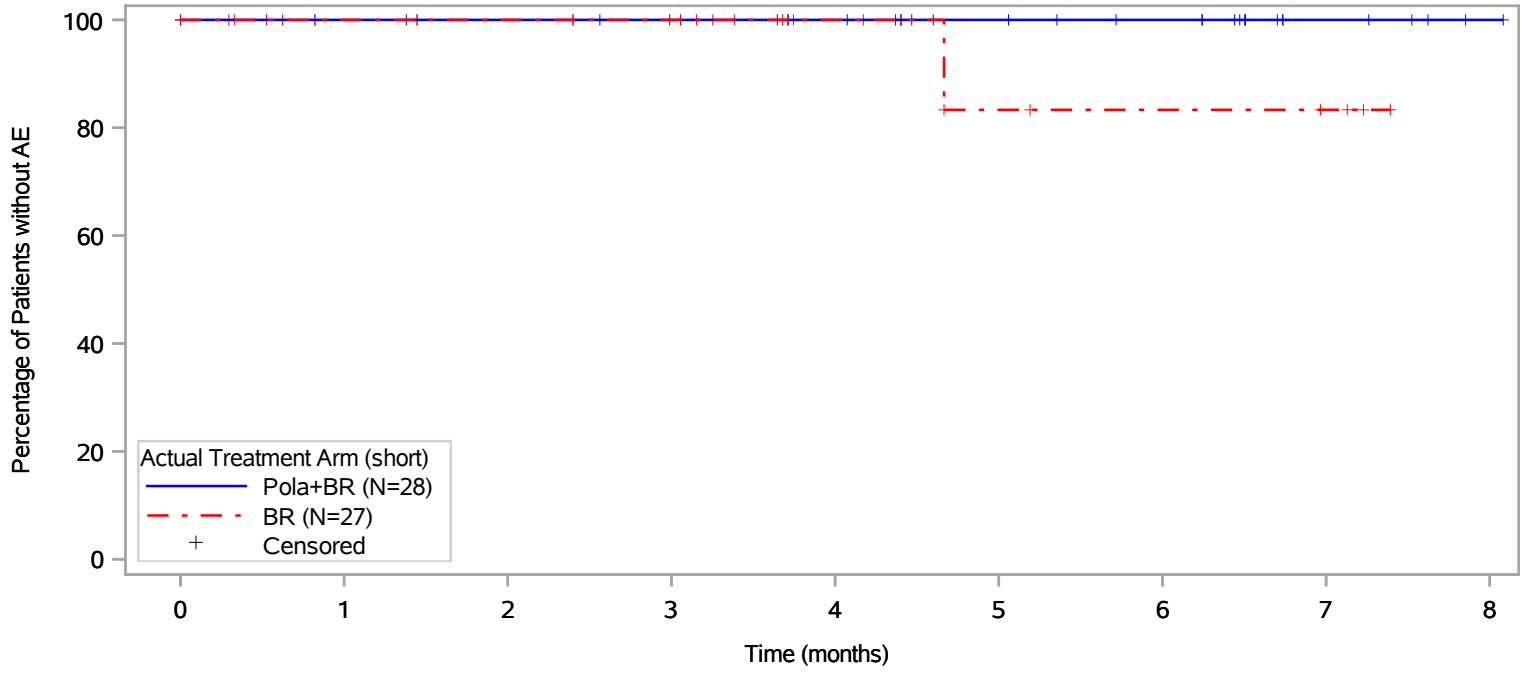
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, GROIN PAIN



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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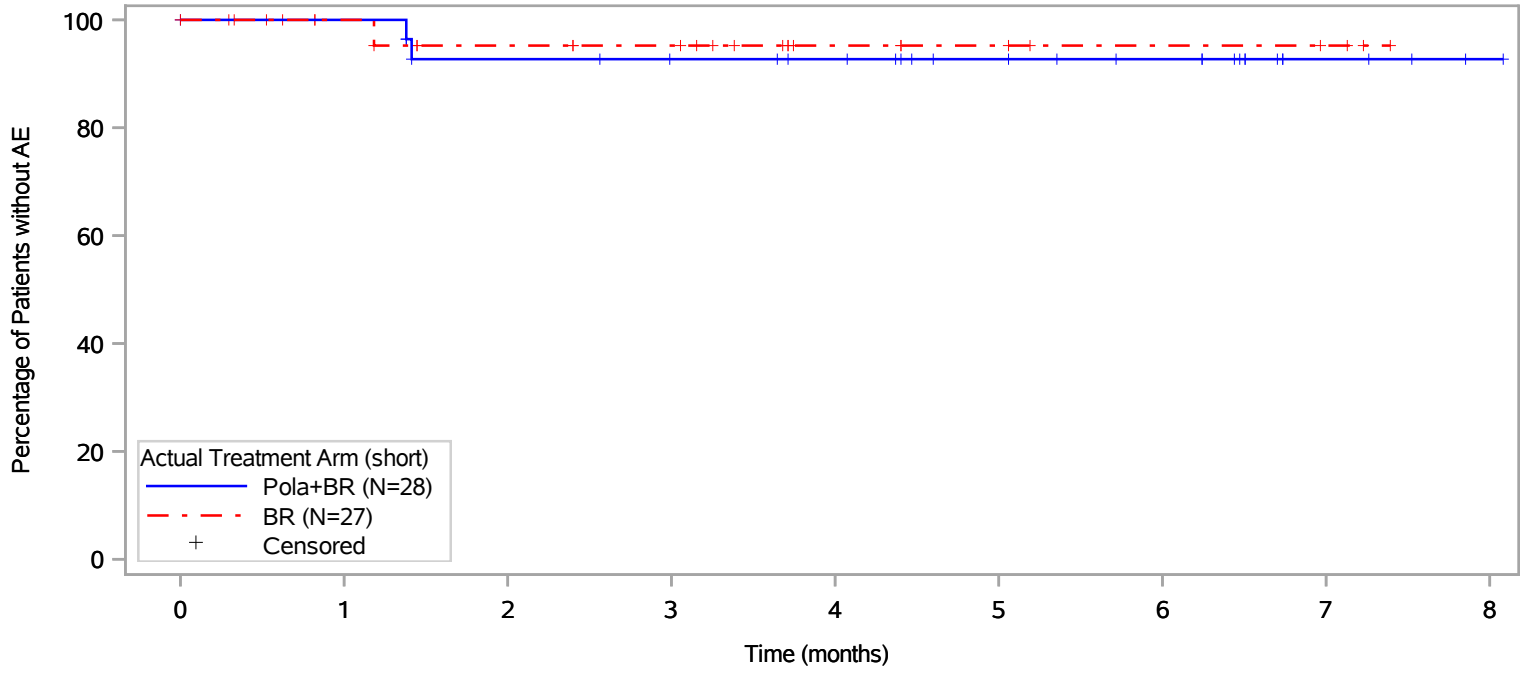
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCLE SPASMS



Patients at risk									
Pola+BR (N=28)	28	28	25	23	21	16	13	4	1
BR (N=27)	27	21	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	25
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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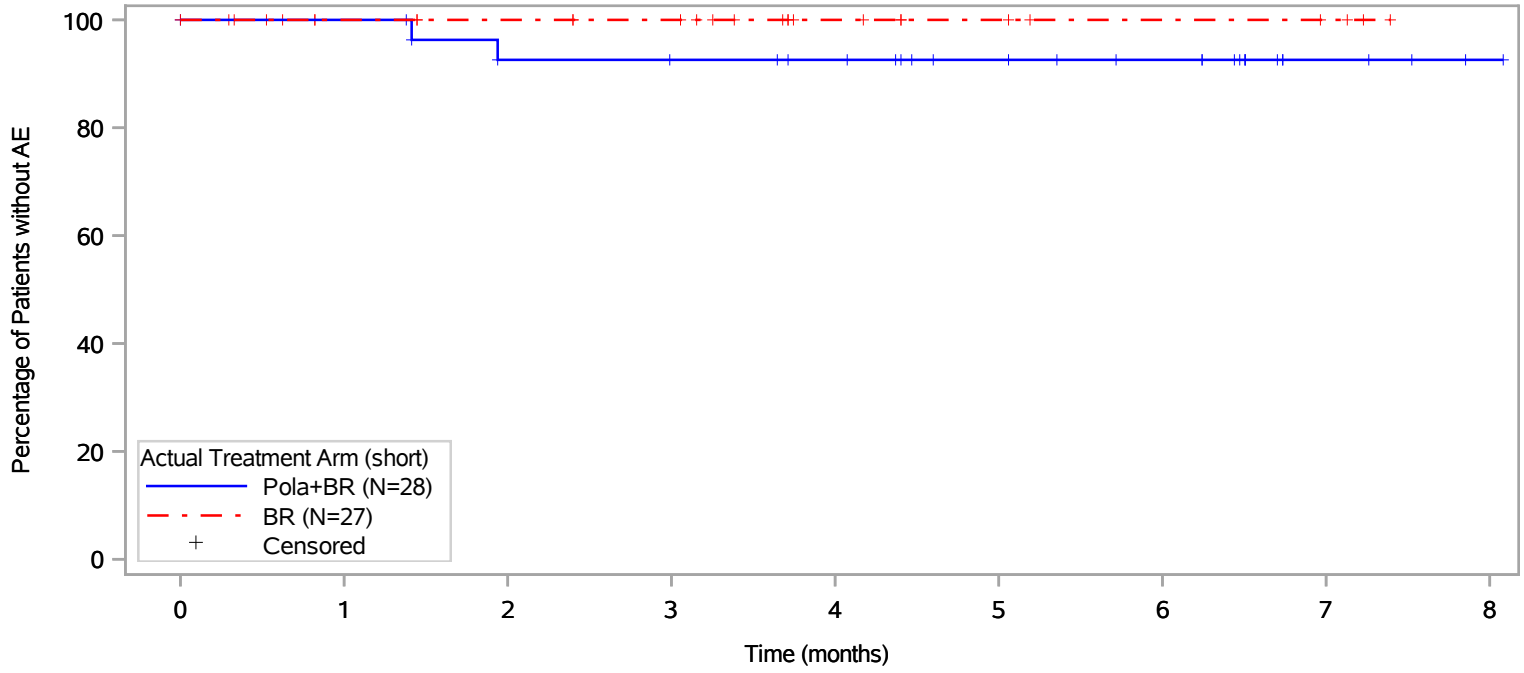
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

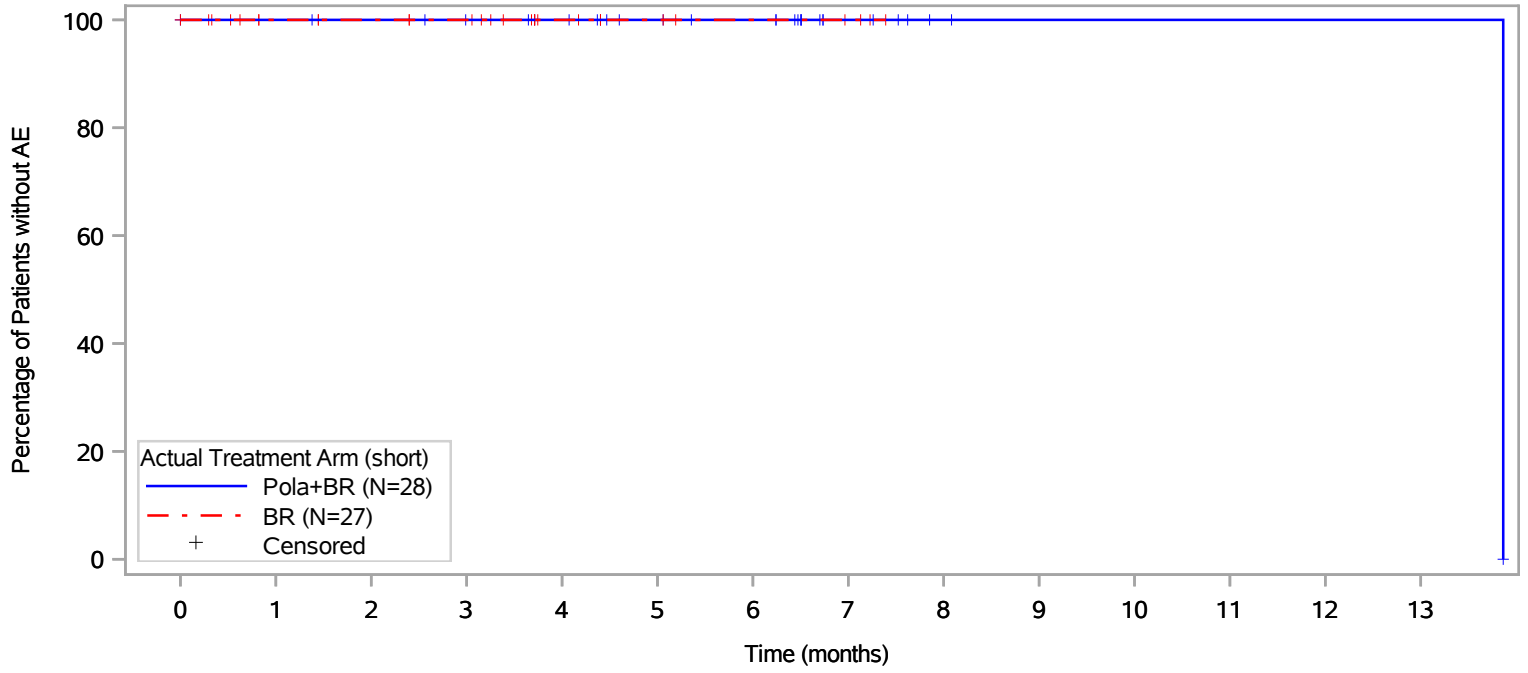
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULAR WEAKNESS



Patients at risk									
Pola+BR (N=28)	28	28	25	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULOSKELETAL CHEST PAIN



Patients at risk														
Pola+BR (N=28)	28	28	27	25	23	18	16	6	2	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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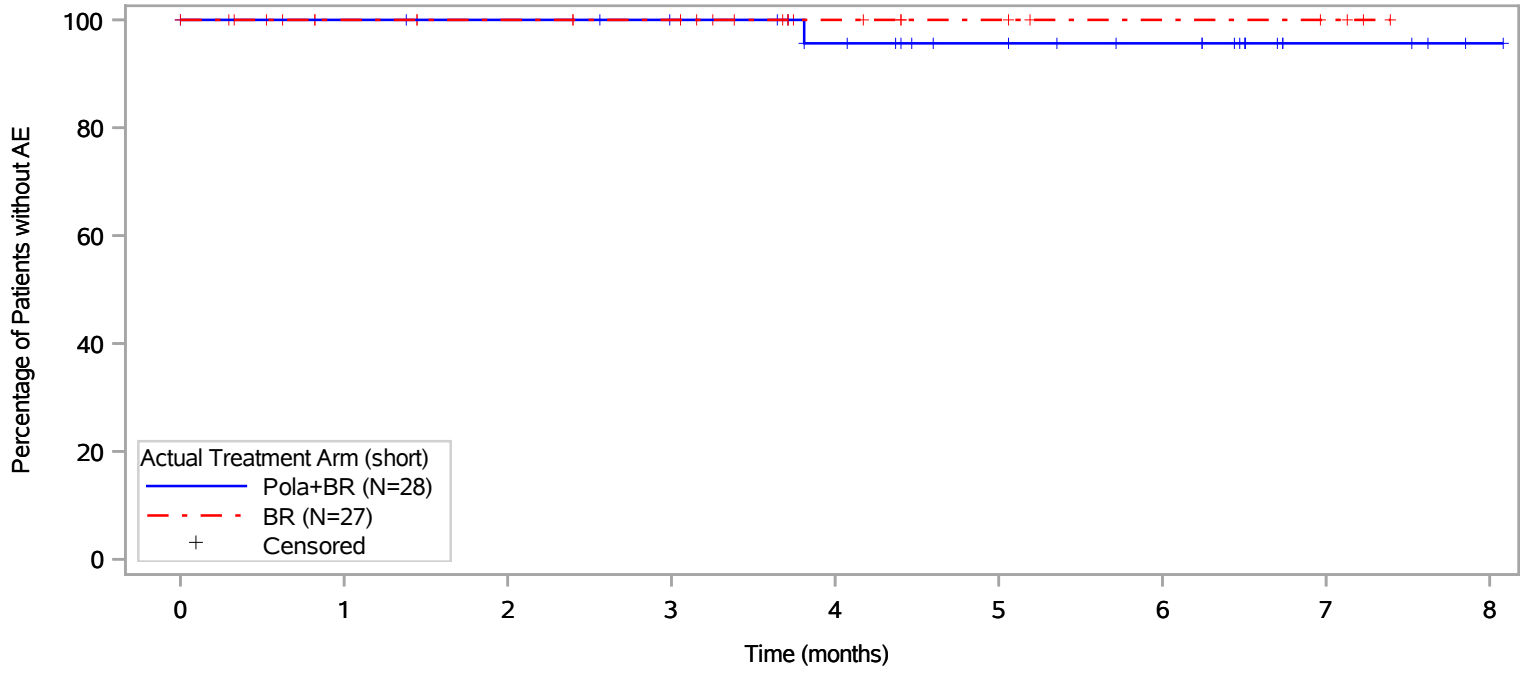
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MUSCULOSKELETAL PAIN

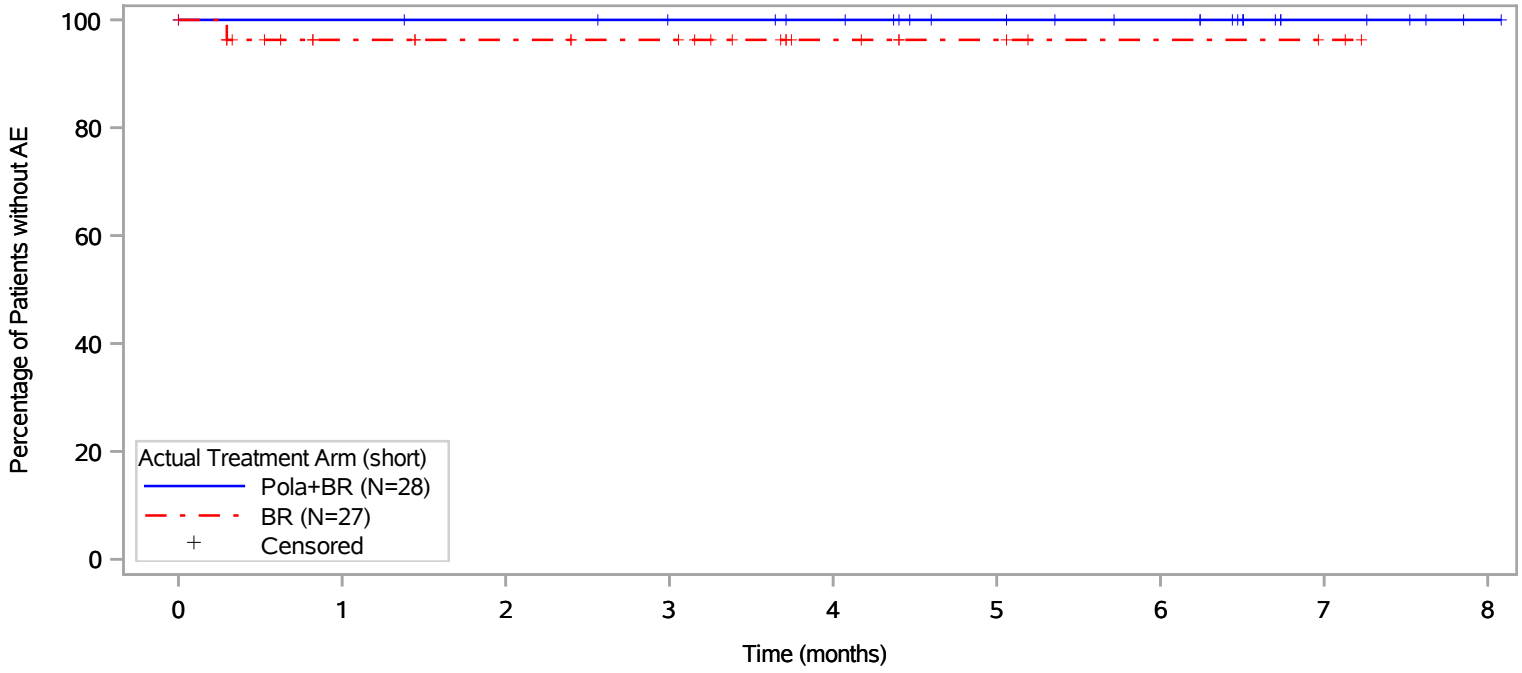


Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, MYALGIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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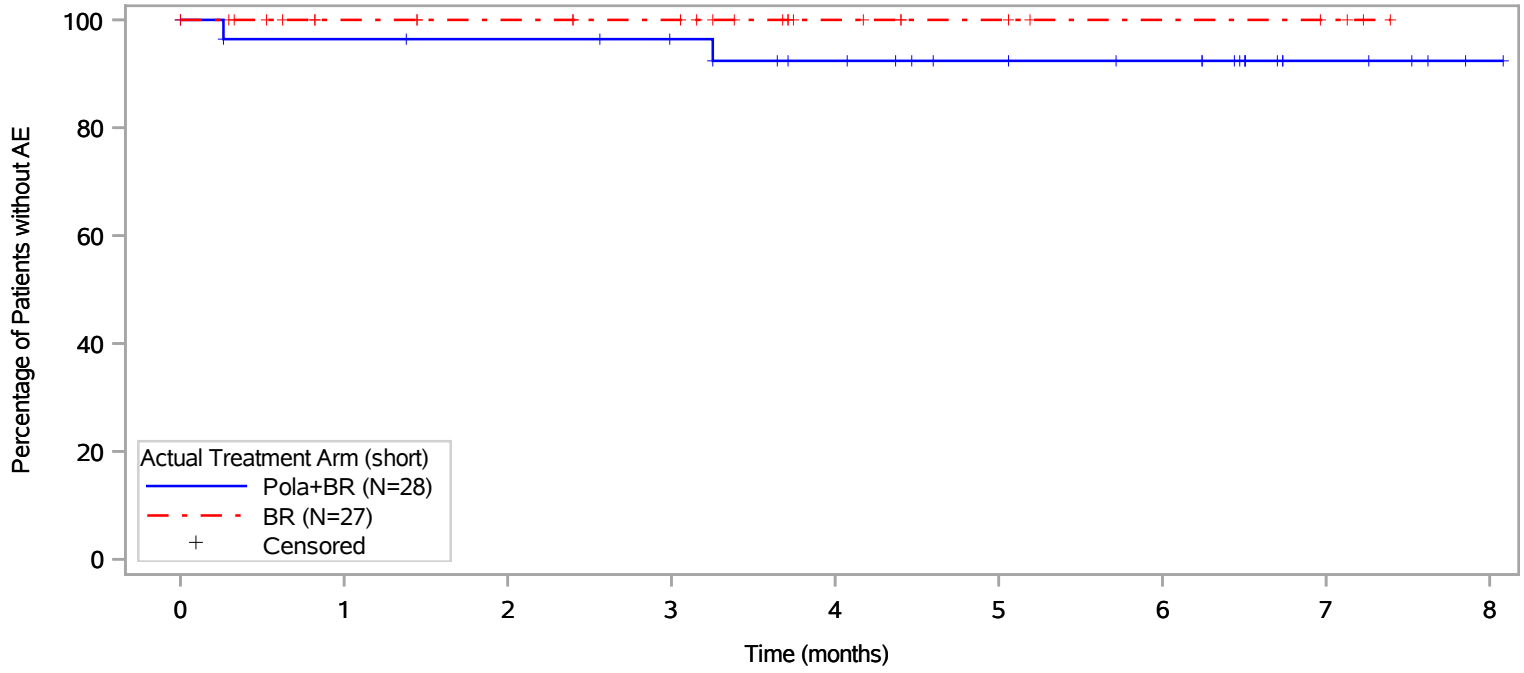
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

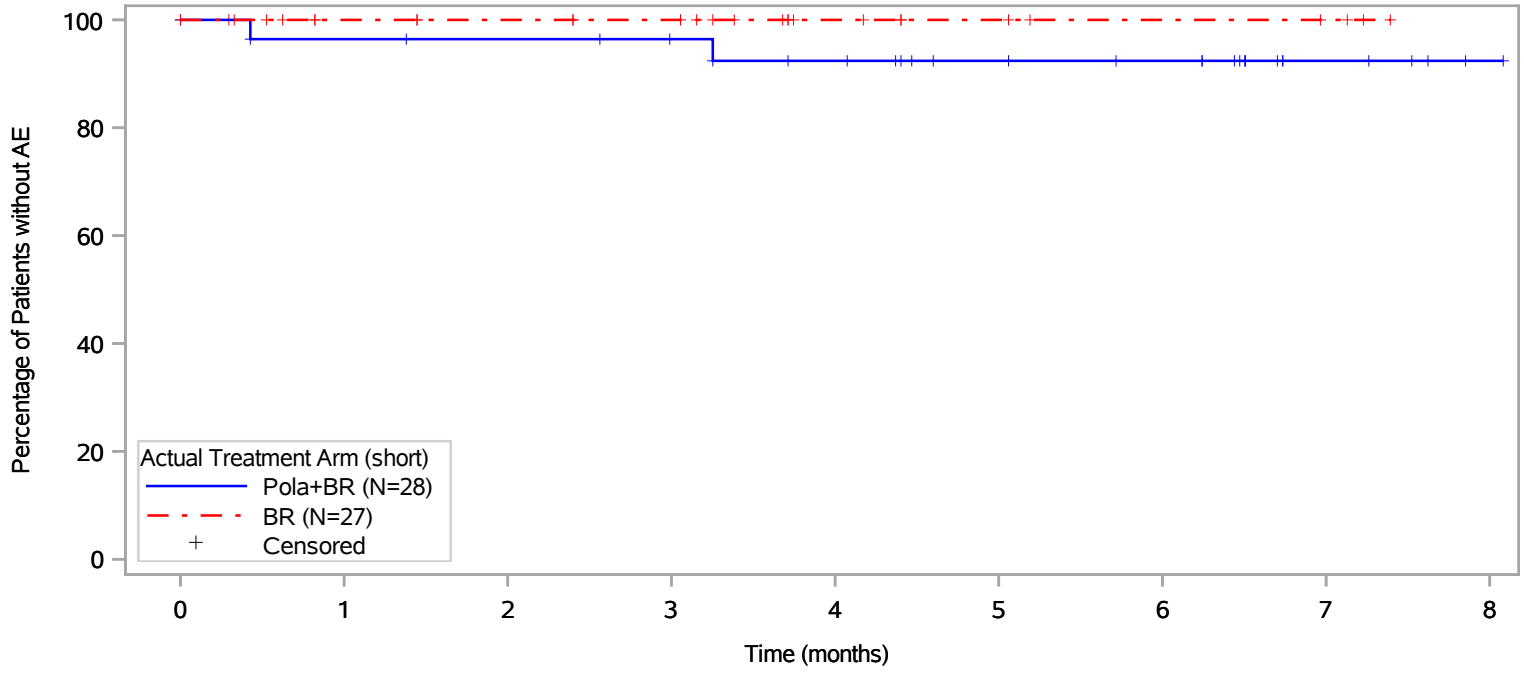
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, NECK PAIN



Patients at risk									
Pola+BR (N=28)	28	27	26	24	21	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, PAIN IN EXTREMITY



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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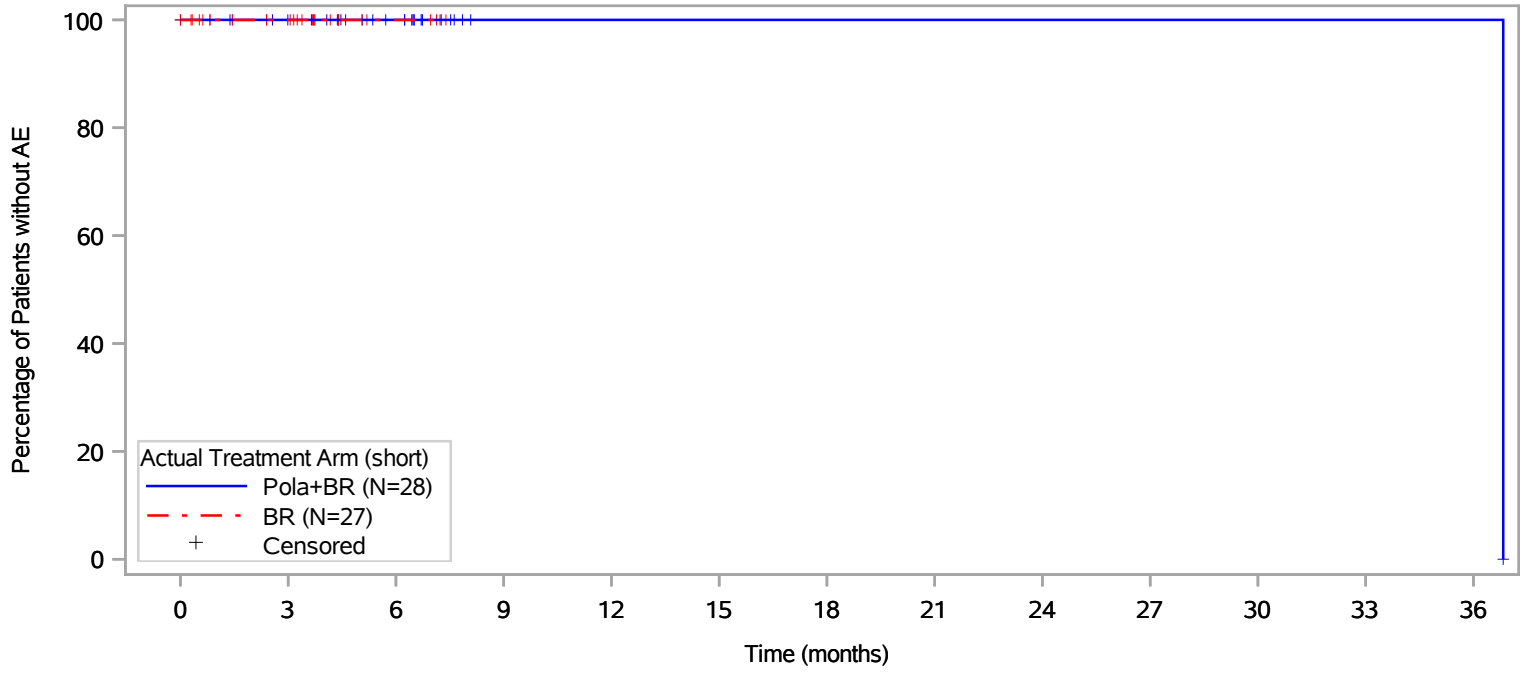
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All

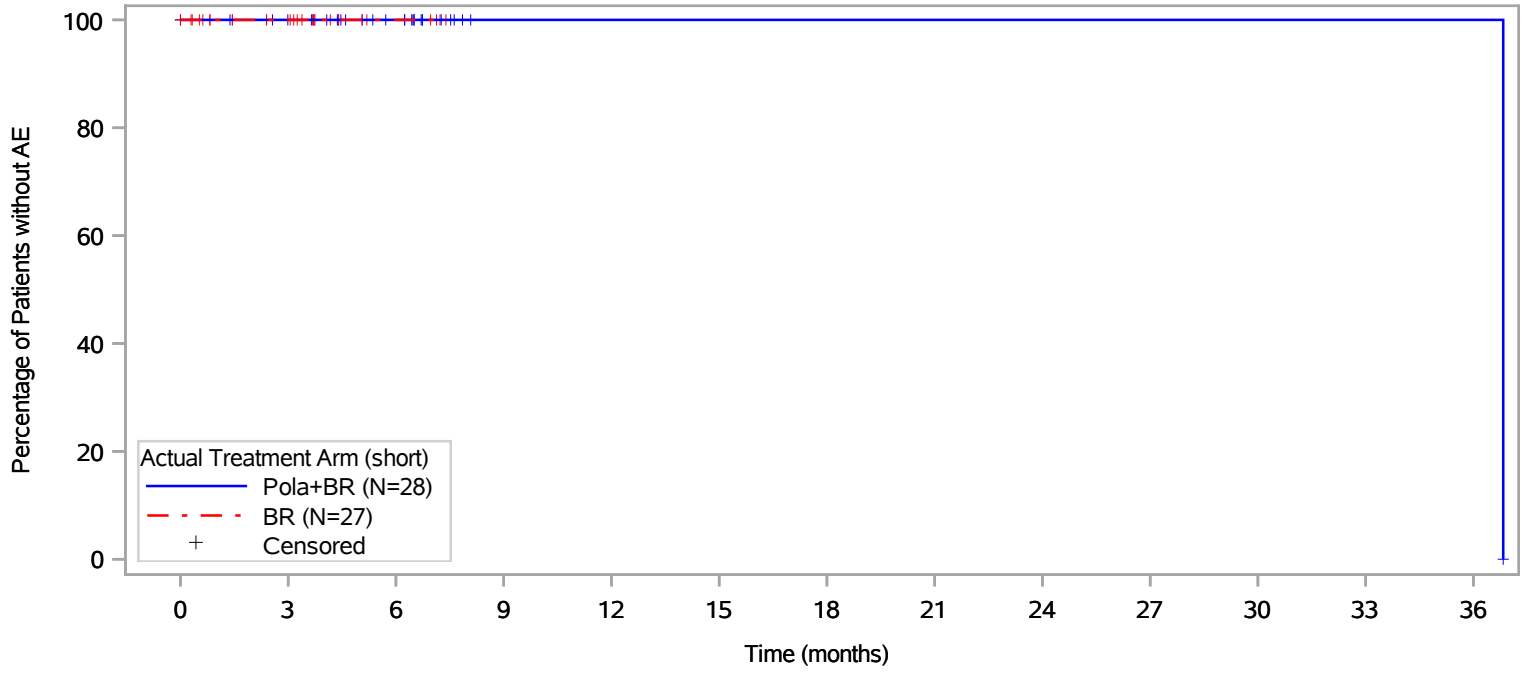


Patients at risk													
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

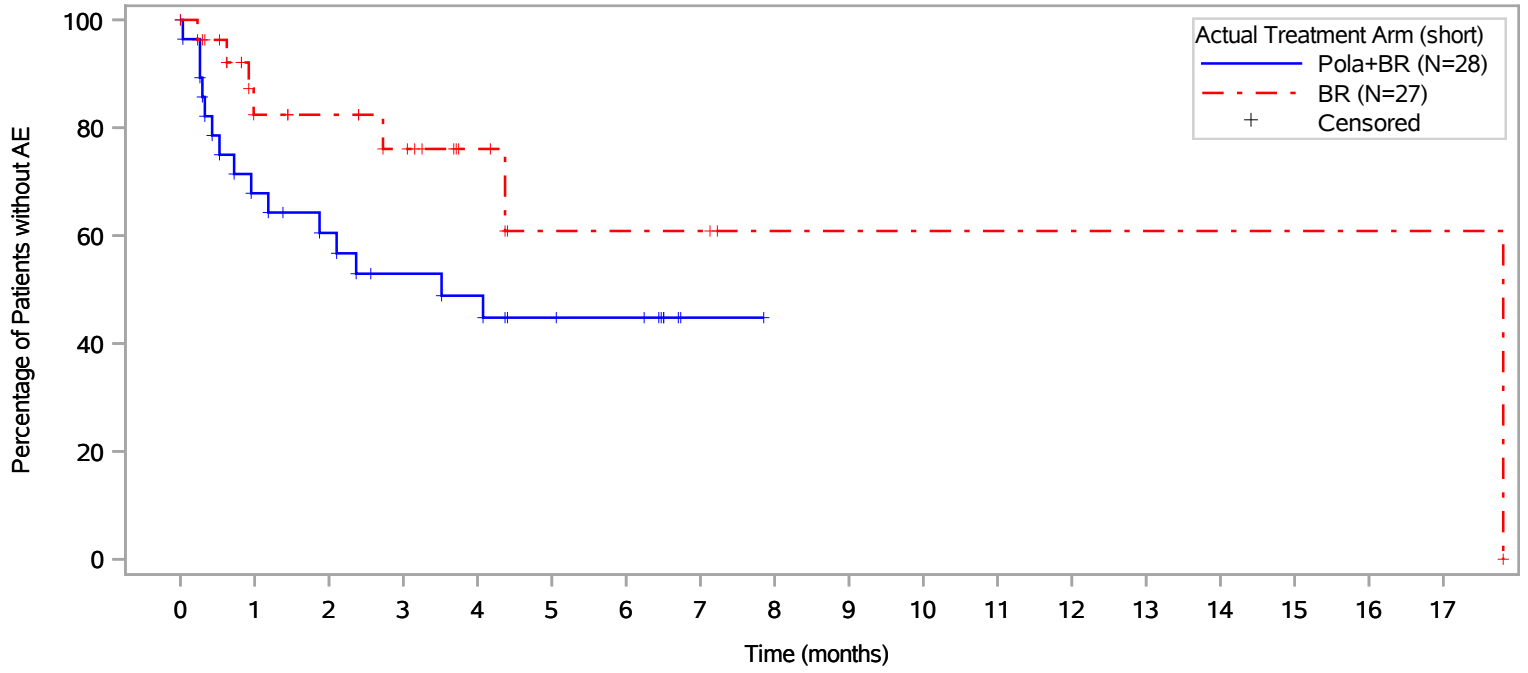
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MALIGNANT MELANOMA



Patients at risk													
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk																		
Pola+BR (N=28)	28	19	16	13	12	9	8	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	17	15	12	6	3	3	3	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=28)	0	0	1	2	2	4	5	12	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	16	18	18	18	20	20	20	20	20	20	20	20	20	20

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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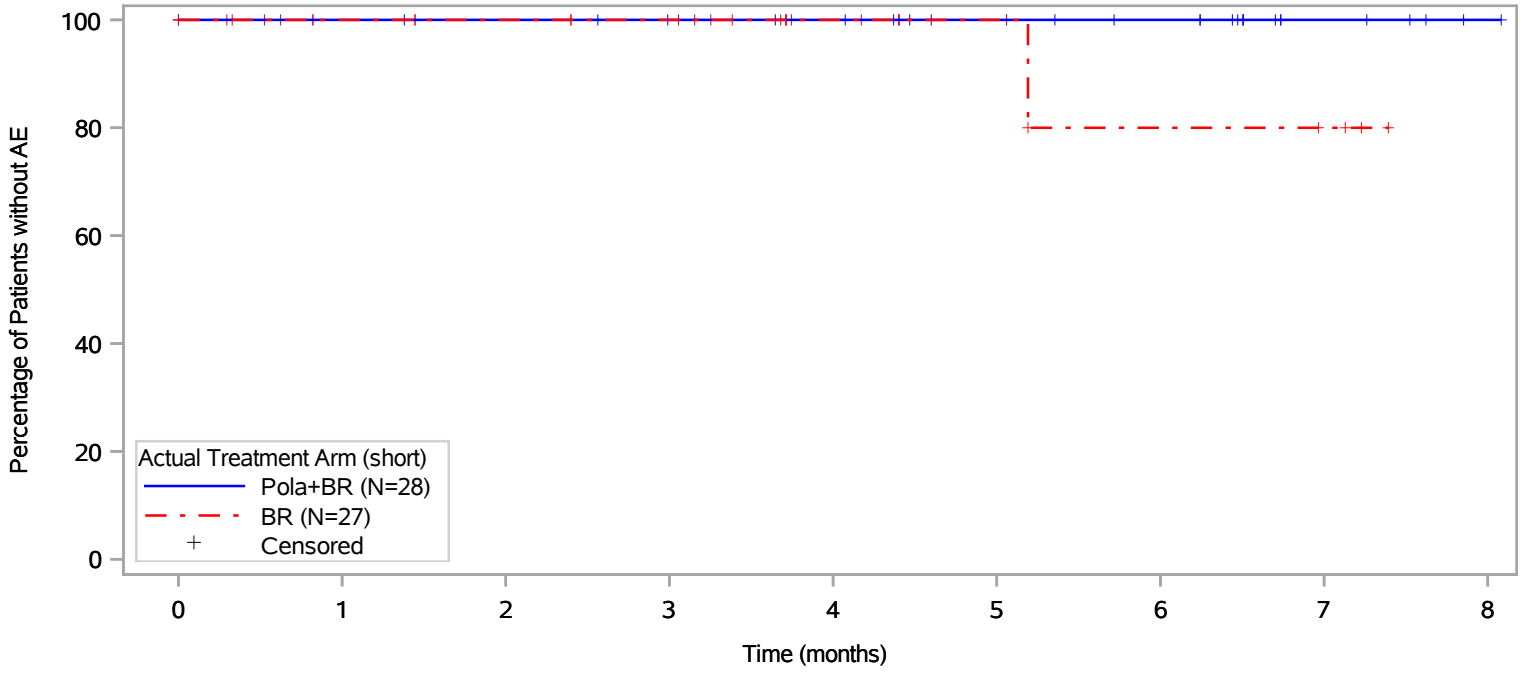
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

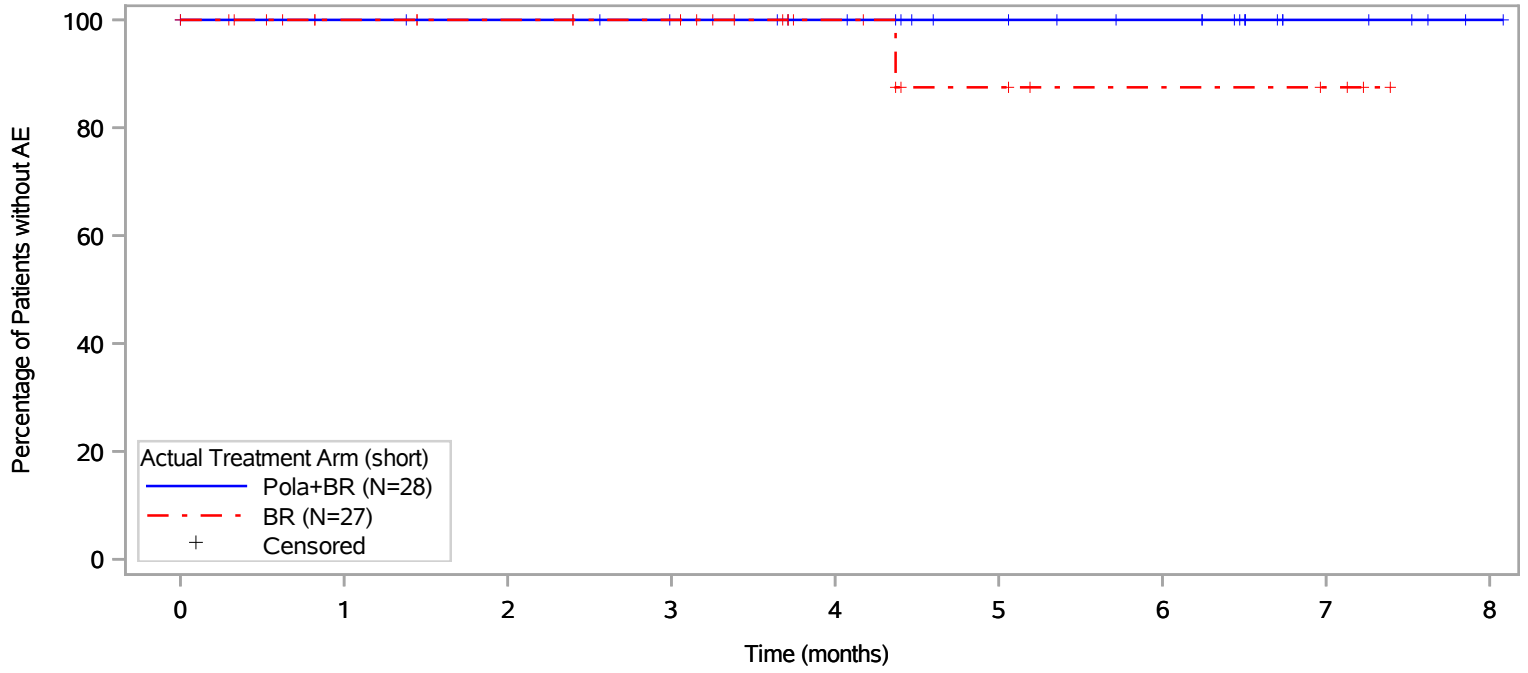
NERVOUS SYSTEM DISORDERS, CEREBRAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, CEREBROVASCULAR ACCIDENT



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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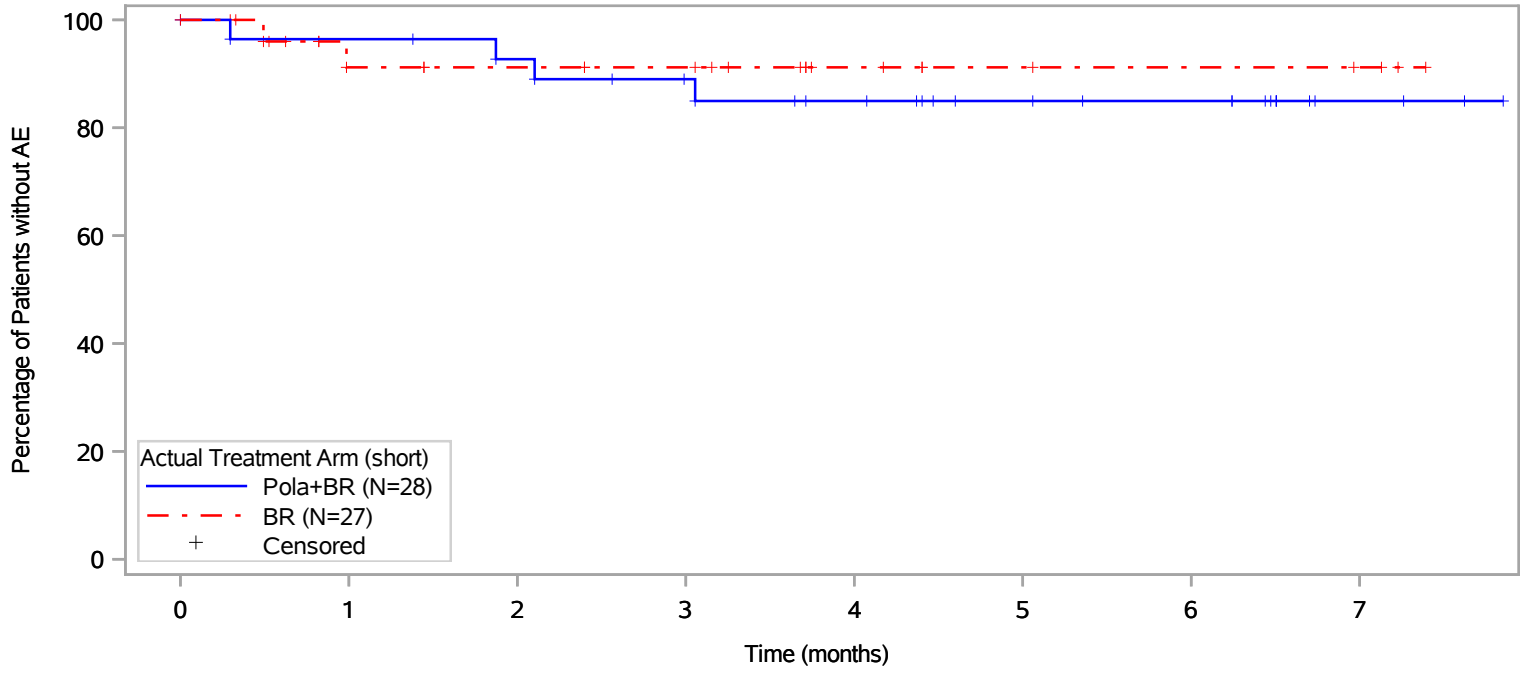
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, DIZZINESS



Patients at risk								
Pola+BR (N=28)	28	27	25	22	19	14	12	3
BR (N=27)	27	19	17	15	8	5	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	10	12	21
BR (N=27)	0	6	8	10	17	20	21	22

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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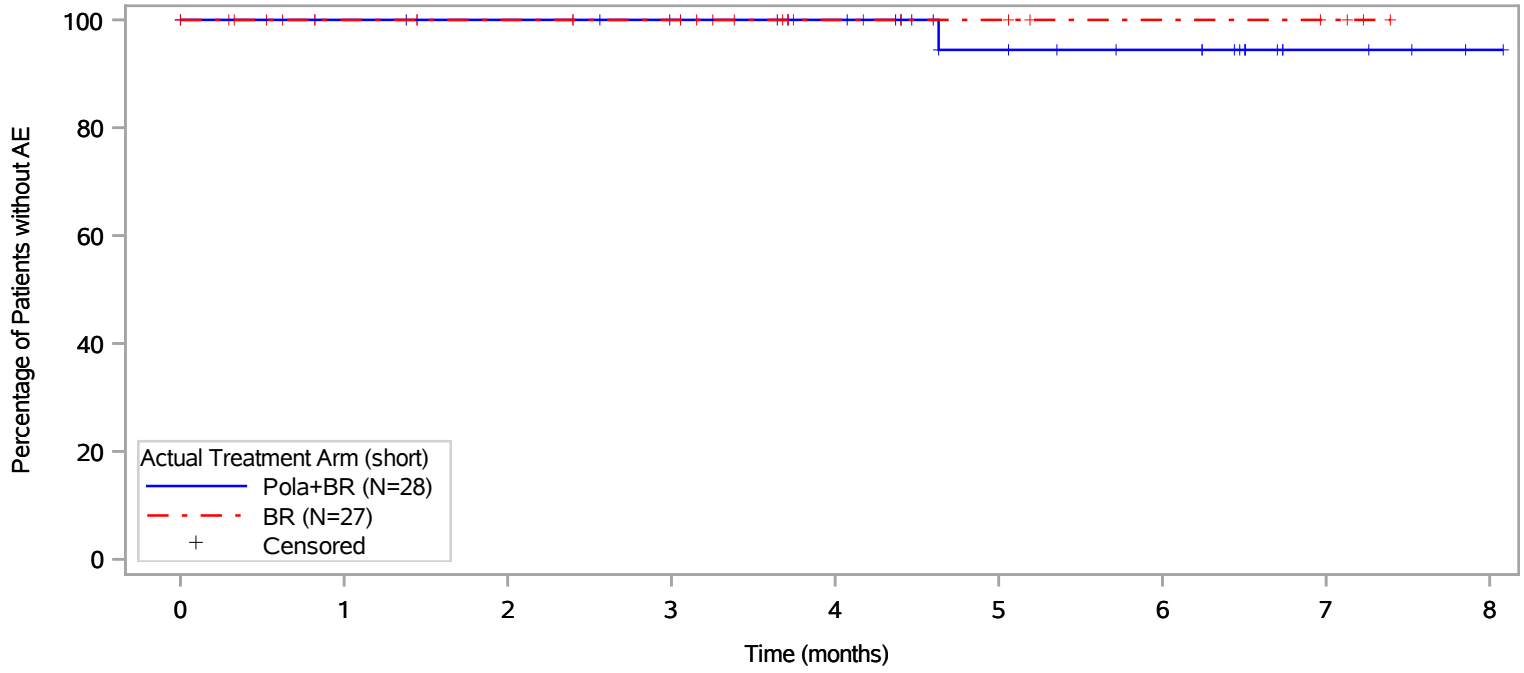
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, DYSGEUSIA

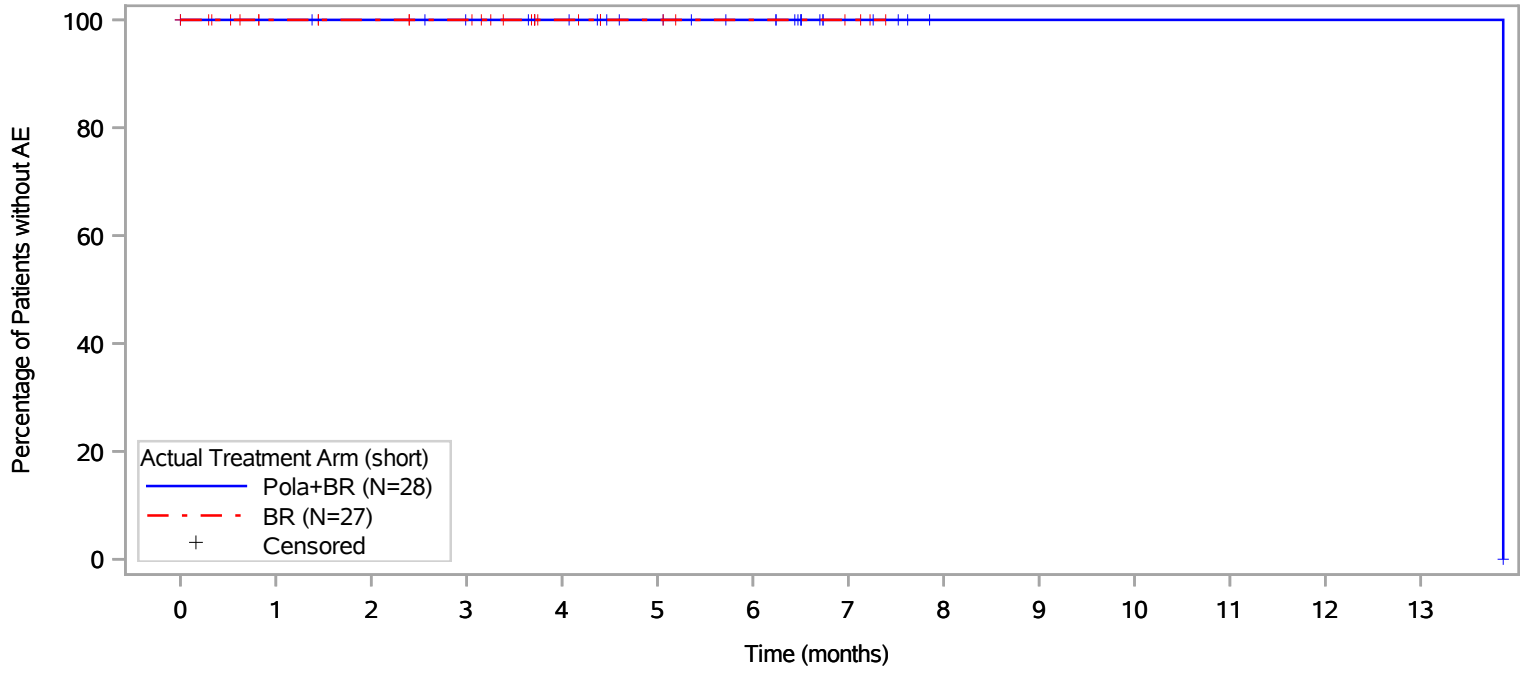


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HAEMORRHAGE INTRACRANIAL



Patients at risk														
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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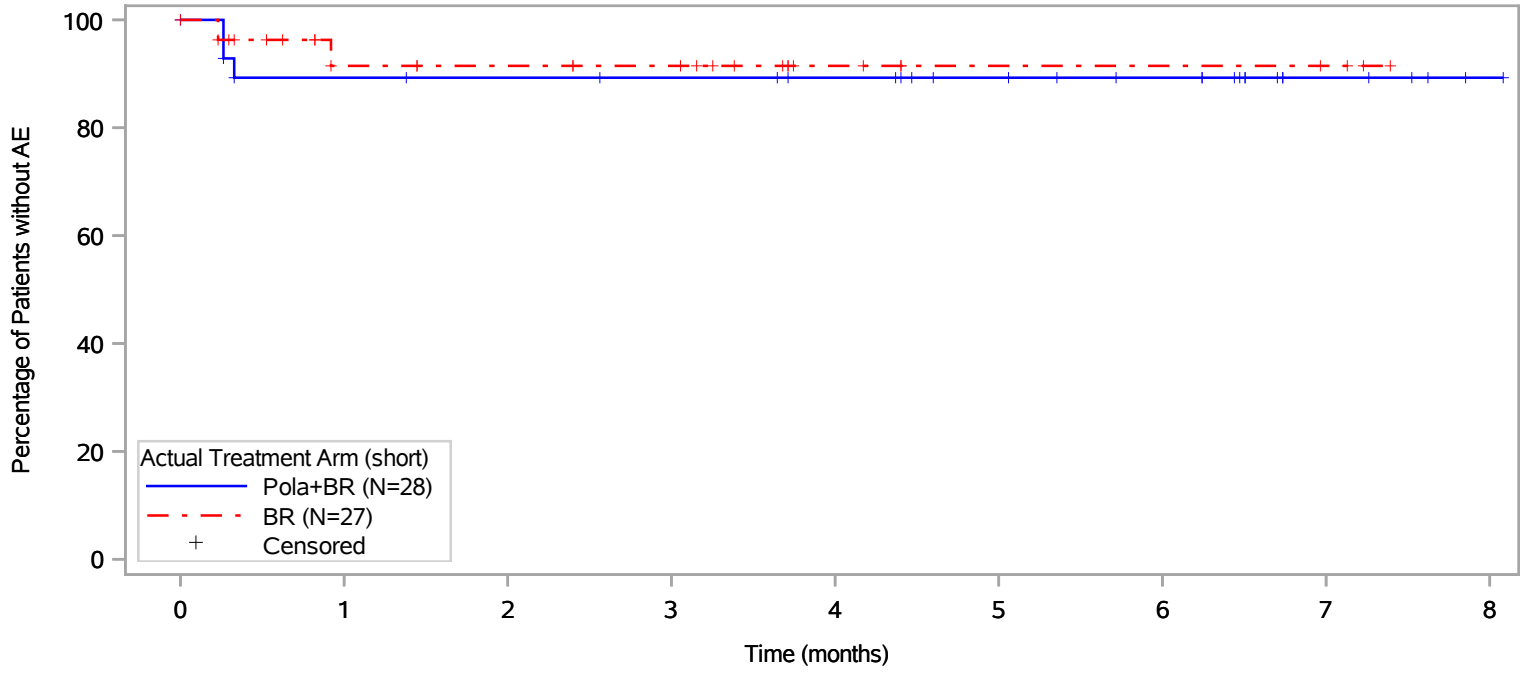
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, HEADACHE



Patients at risk									
Pola+BR (N=28)	28	25	24	23	21	17	14	5	1
BR (N=27)	27	19	17	15	7	4	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	8	11	20	24
BR (N=27)	0	6	8	10	18	21	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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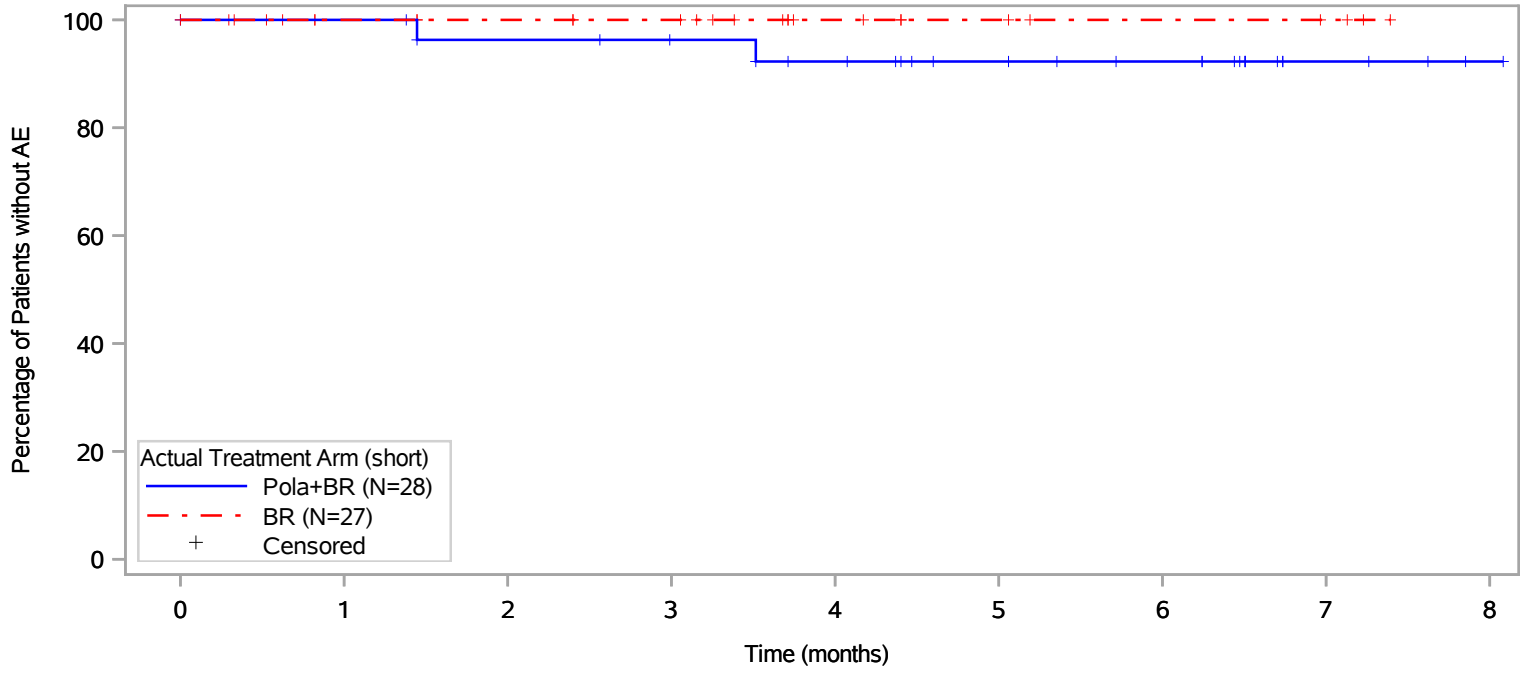
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HYPOAESTHESIA

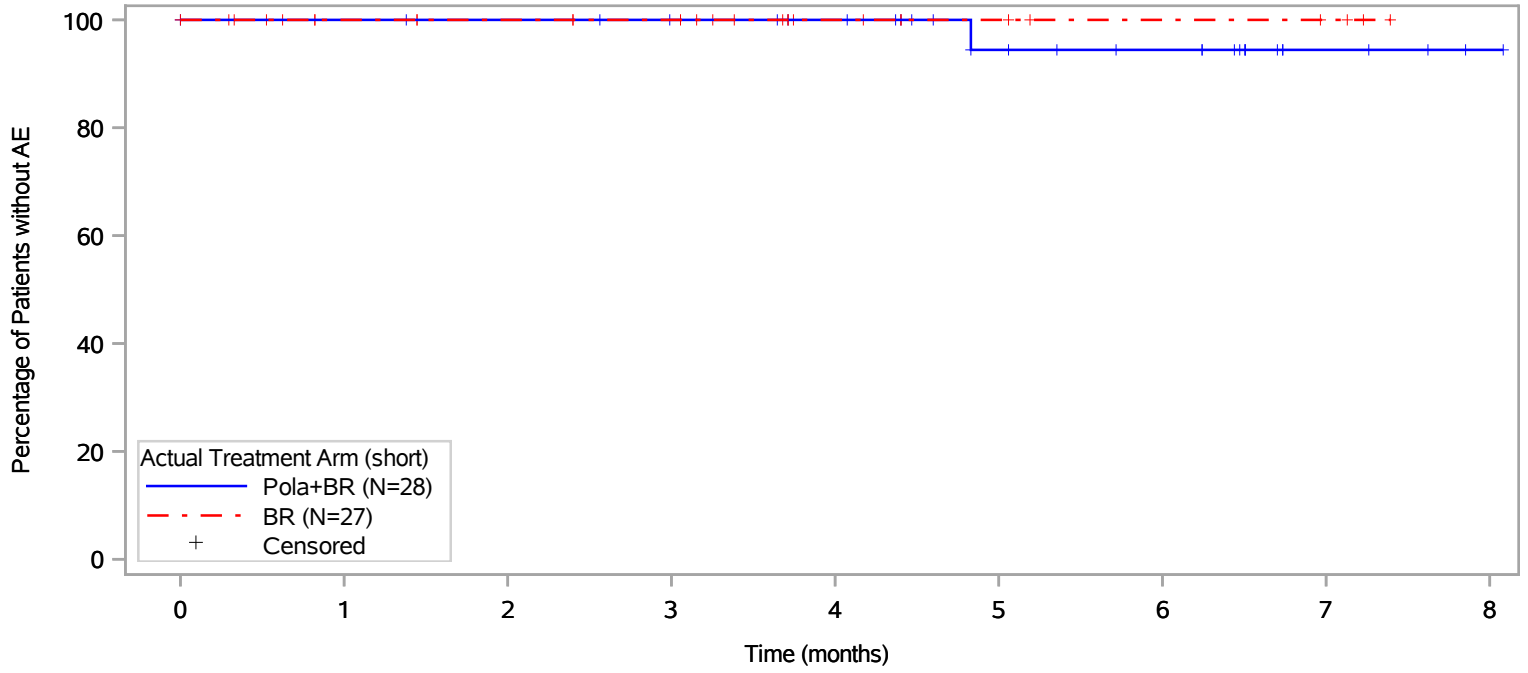


Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HYPOGEUSIA

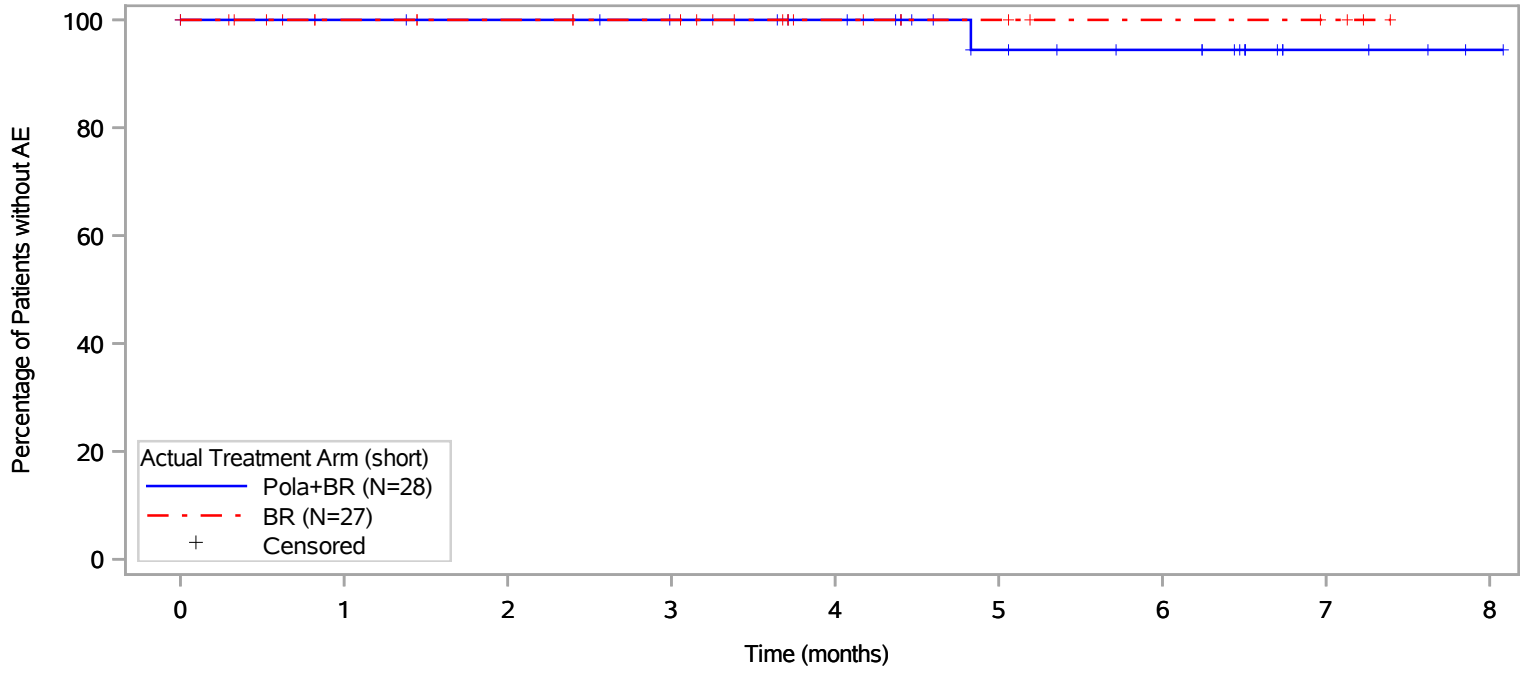


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

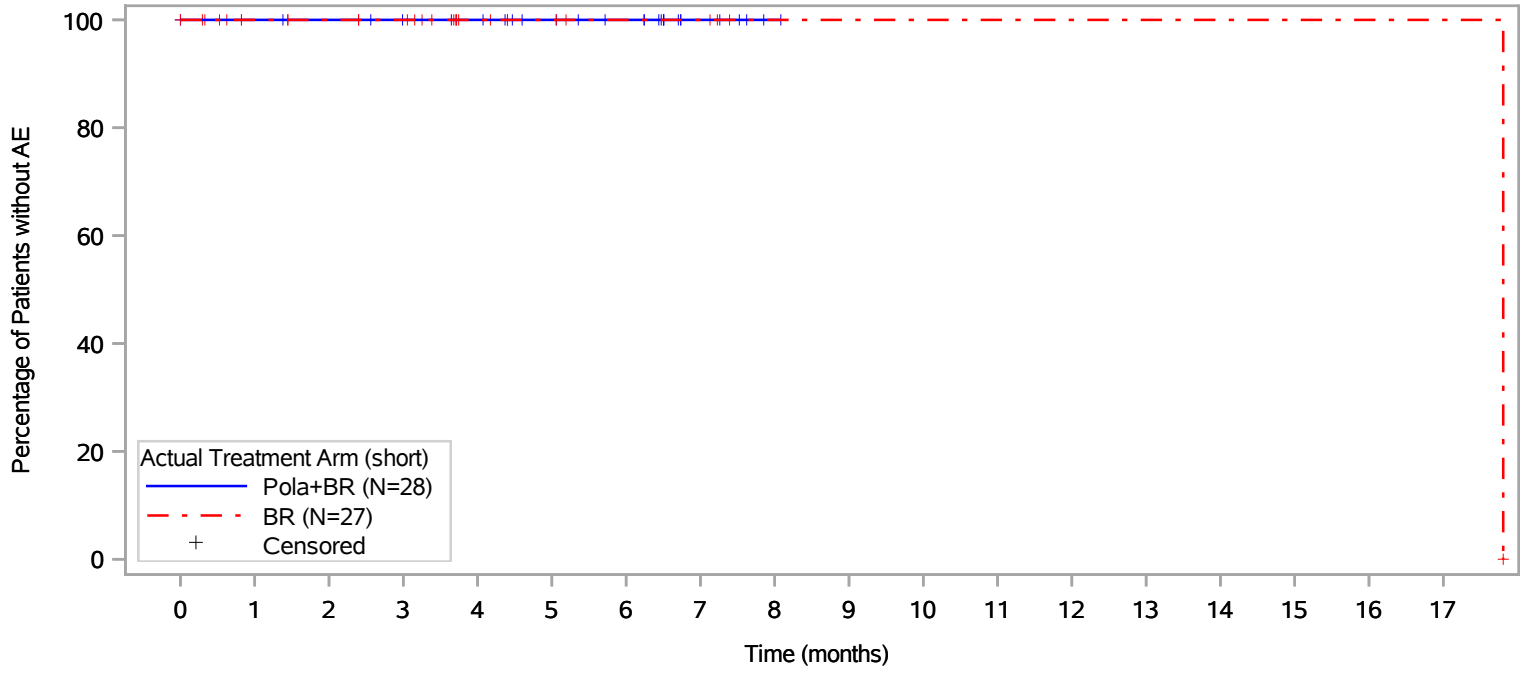
NERVOUS SYSTEM DISORDERS, HYPOSMIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, LEUKOENCEPHALOPATHY



Patients at risk																		
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	23	26	26	26	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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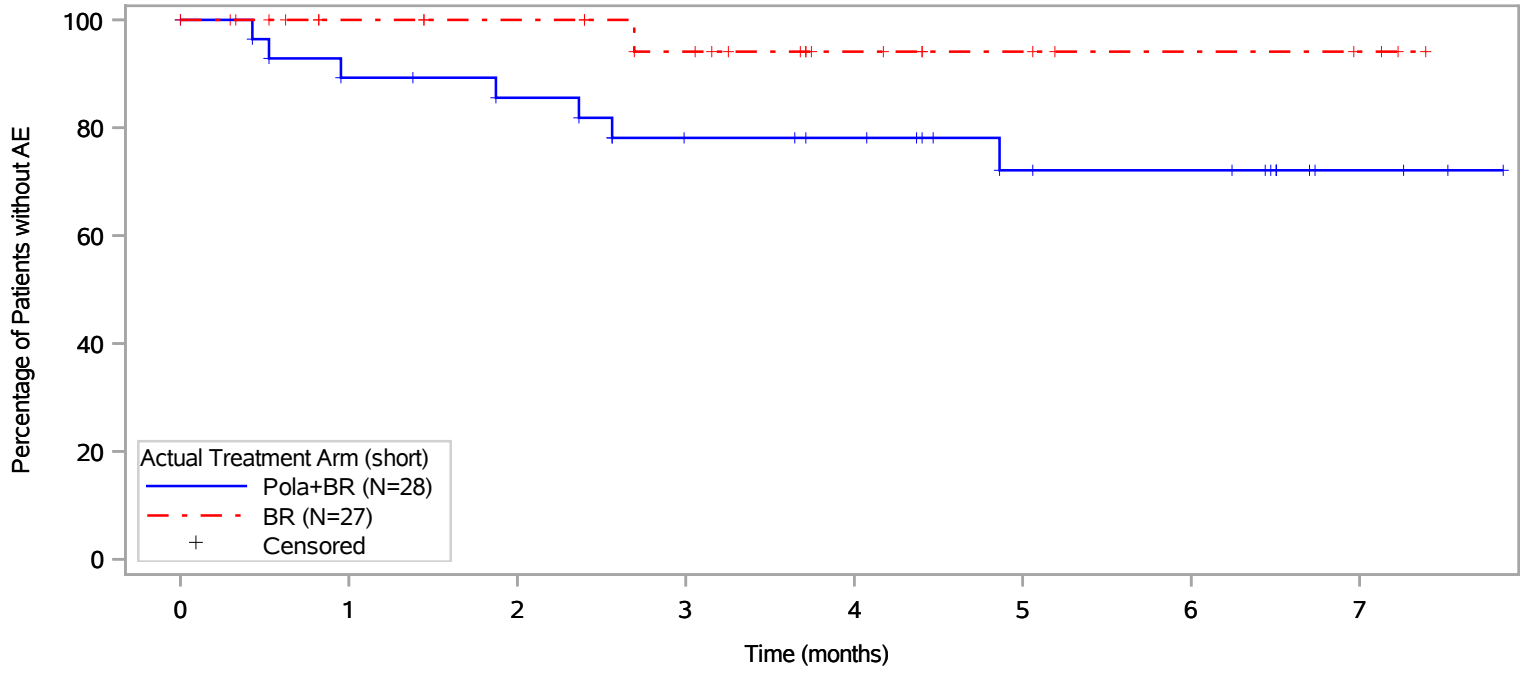
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, NEUROPATHY PERIPHERAL



Patients at risk								
Pola+BR (N=28)	28	25	23	19	17	12	11	3
BR (N=27)	27	21	19	16	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	9	10	18
BR (N=27)	0	6	8	10	17	20	22	23

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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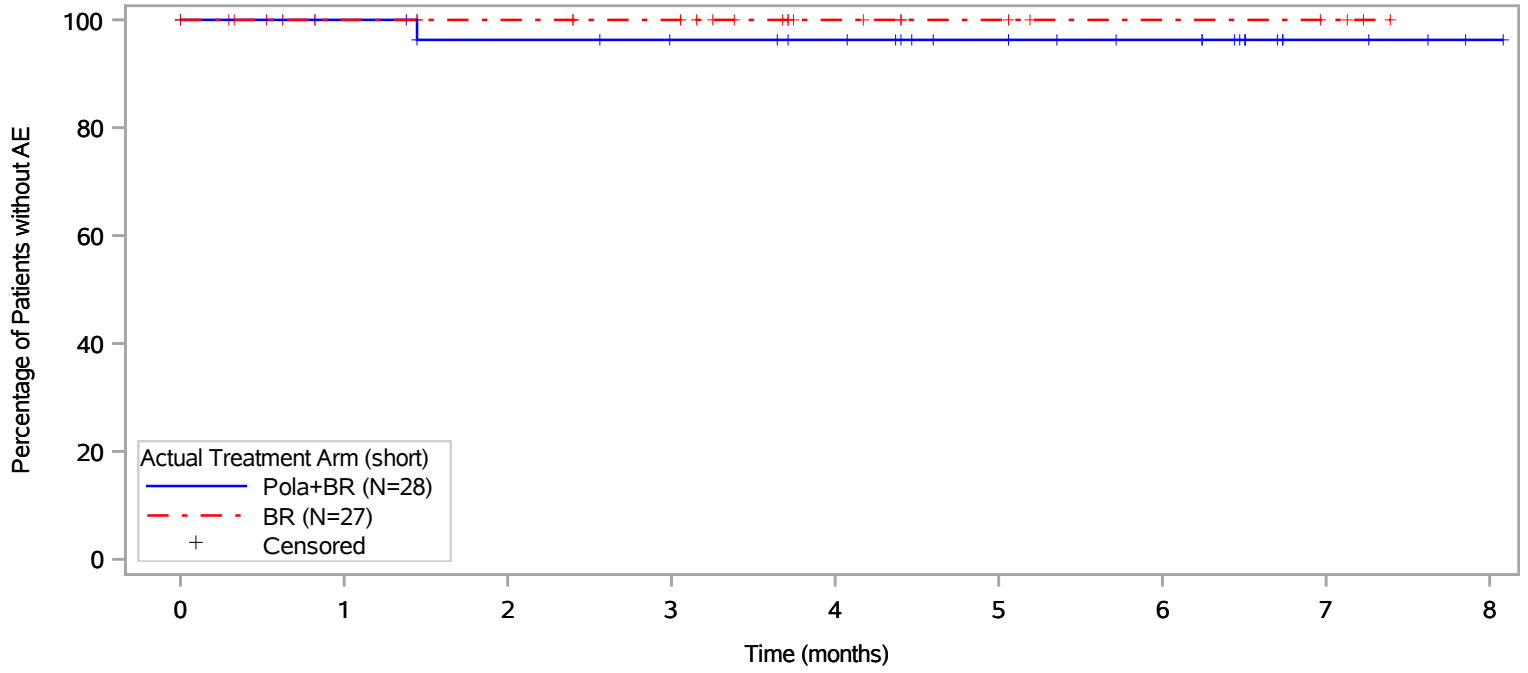
01DEC2022 21:22

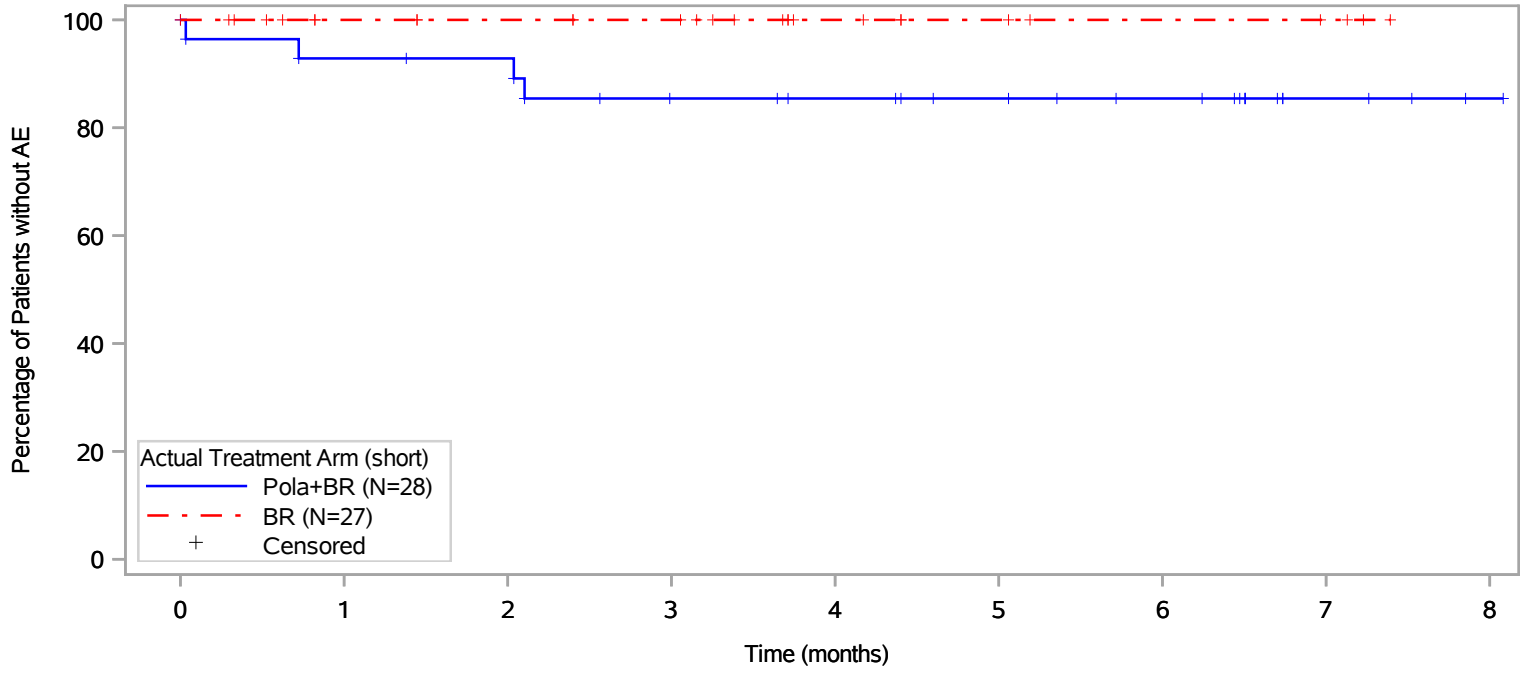
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, PARAESTHESIA



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, PERIPHERAL SENSORY NEUROPATHY

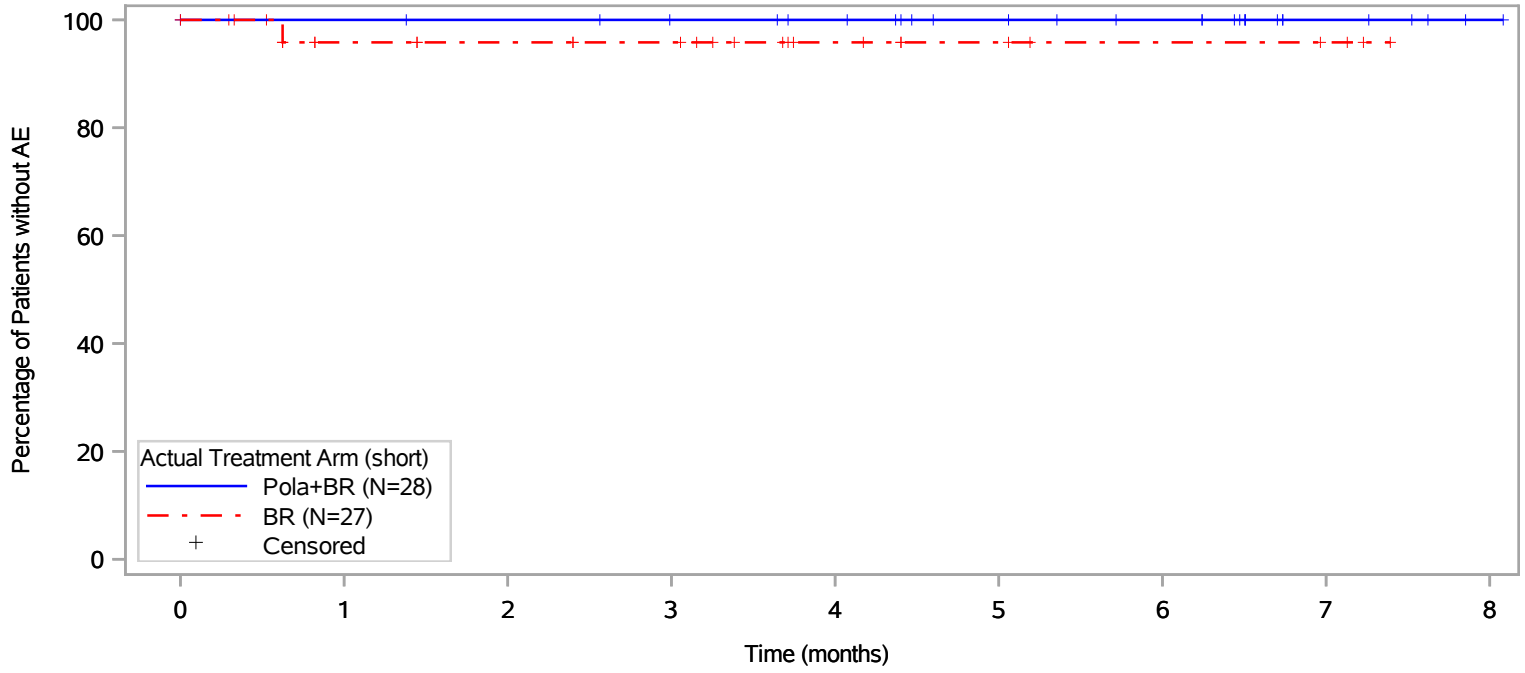


Patients at risk									
Pola+BR (N=28)	28	26	25	21	19	16	13	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	8	11	20	23
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

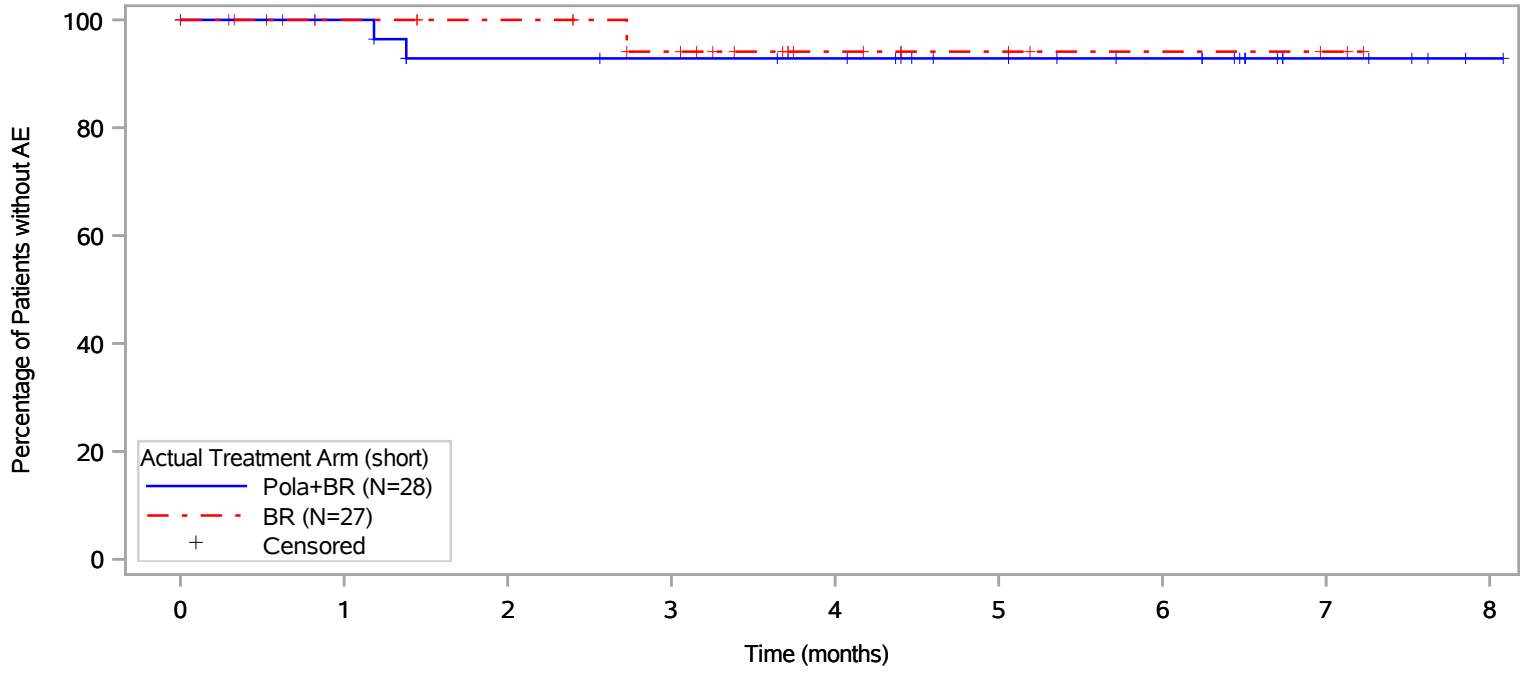
NERVOUS SYSTEM DISORDERS, SOMNOLENCE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, SYNCOPE

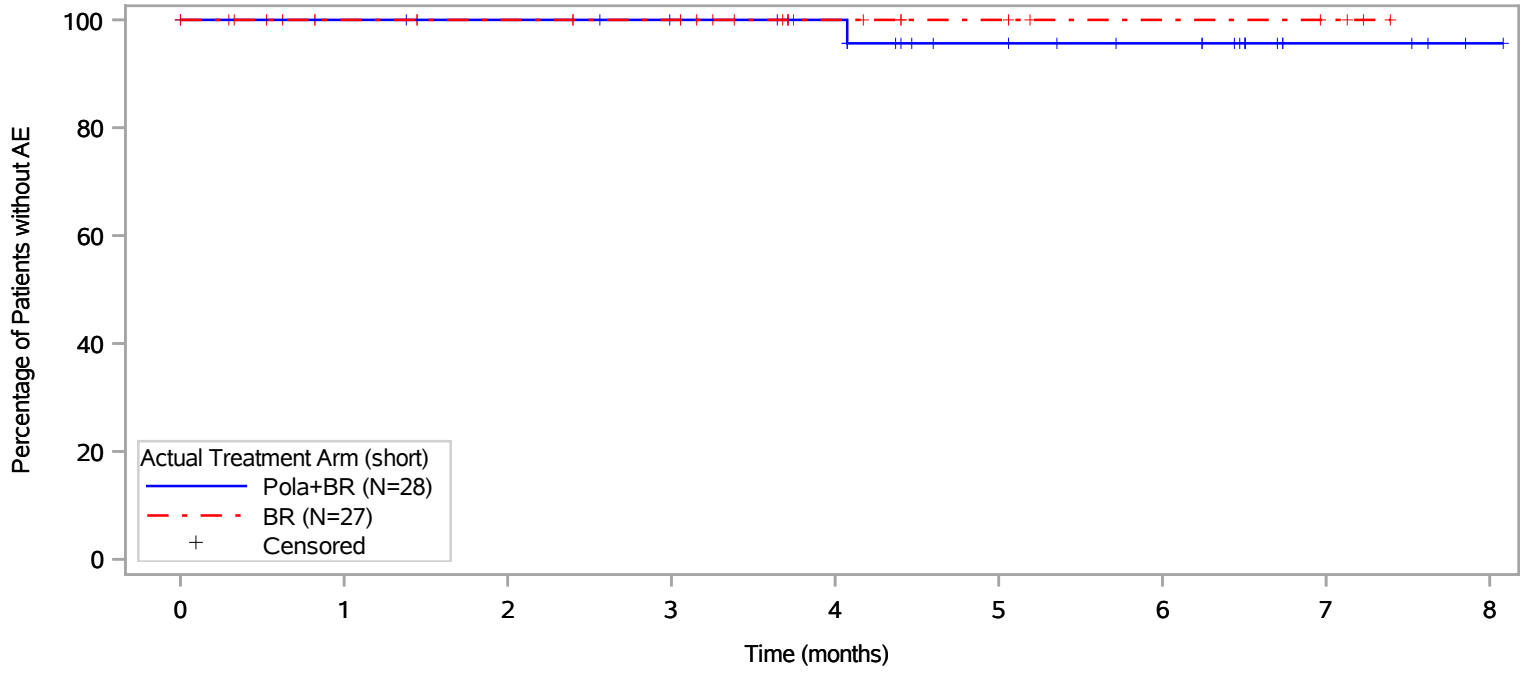


Patients at risk									
Pola+BR (N=28)	28	28	25	24	23	18	15	5	1
BR (N=27)	27	21	19	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	3	8	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, TREMOR

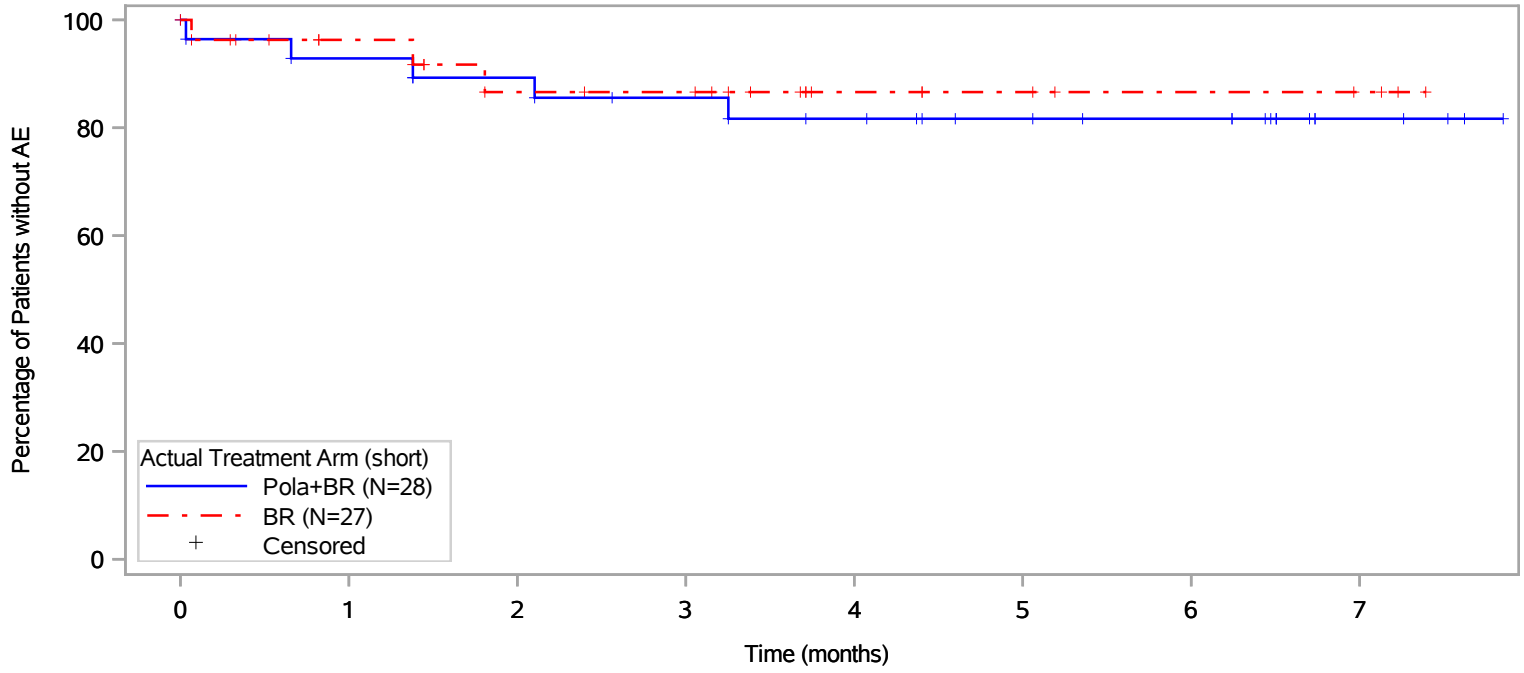


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, All



Patients at risk								
Pola+BR (N=28)	28	26	24	22	20	16	14	4
BR (N=27)	27	21	17	16	8	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	2	3	7	9	19
BR (N=27)	0	5	7	8	16	18	20	21

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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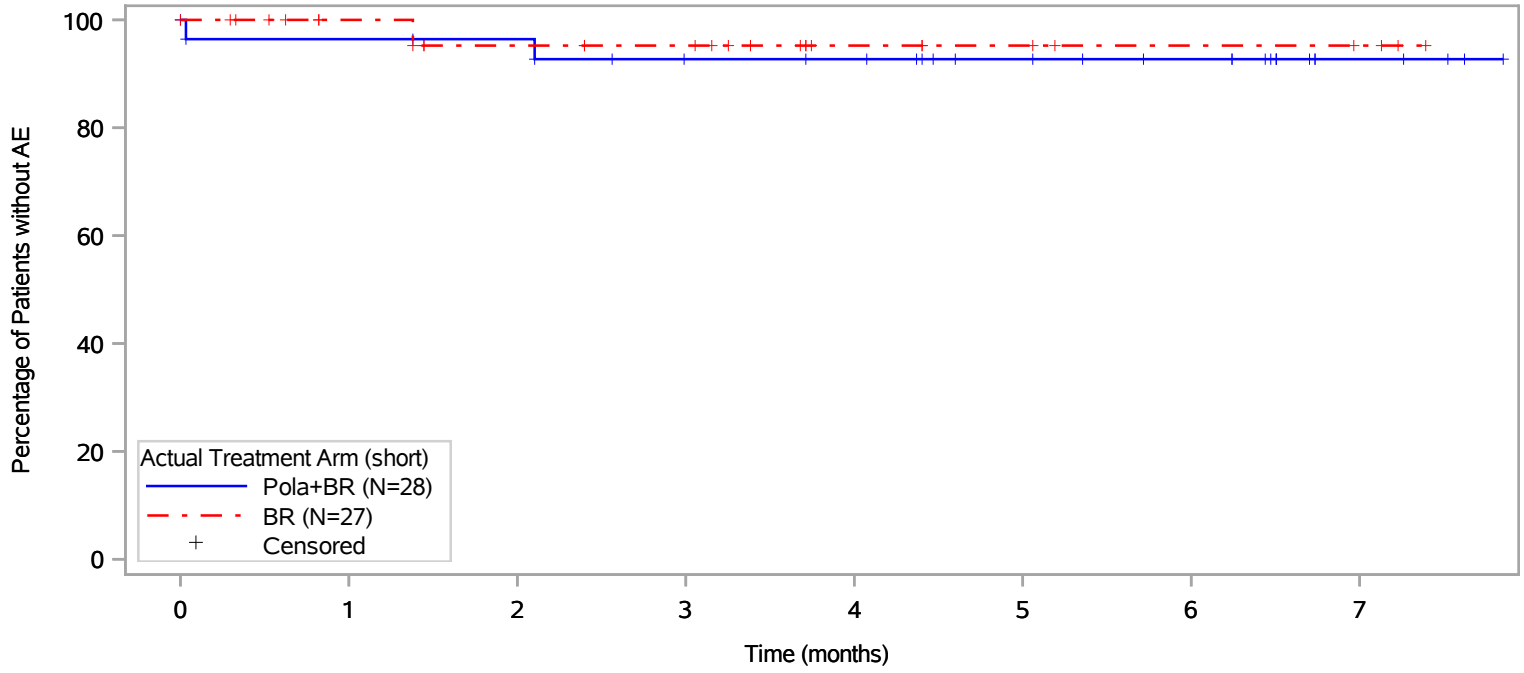
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, ANXIETY



Patients at risk								
Pola+BR (N=28)	28	27	26	23	22	17	14	4
BR (N=27)	27	21	18	16	8	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	4	9	12	22
BR (N=27)	0	6	8	10	18	20	22	23

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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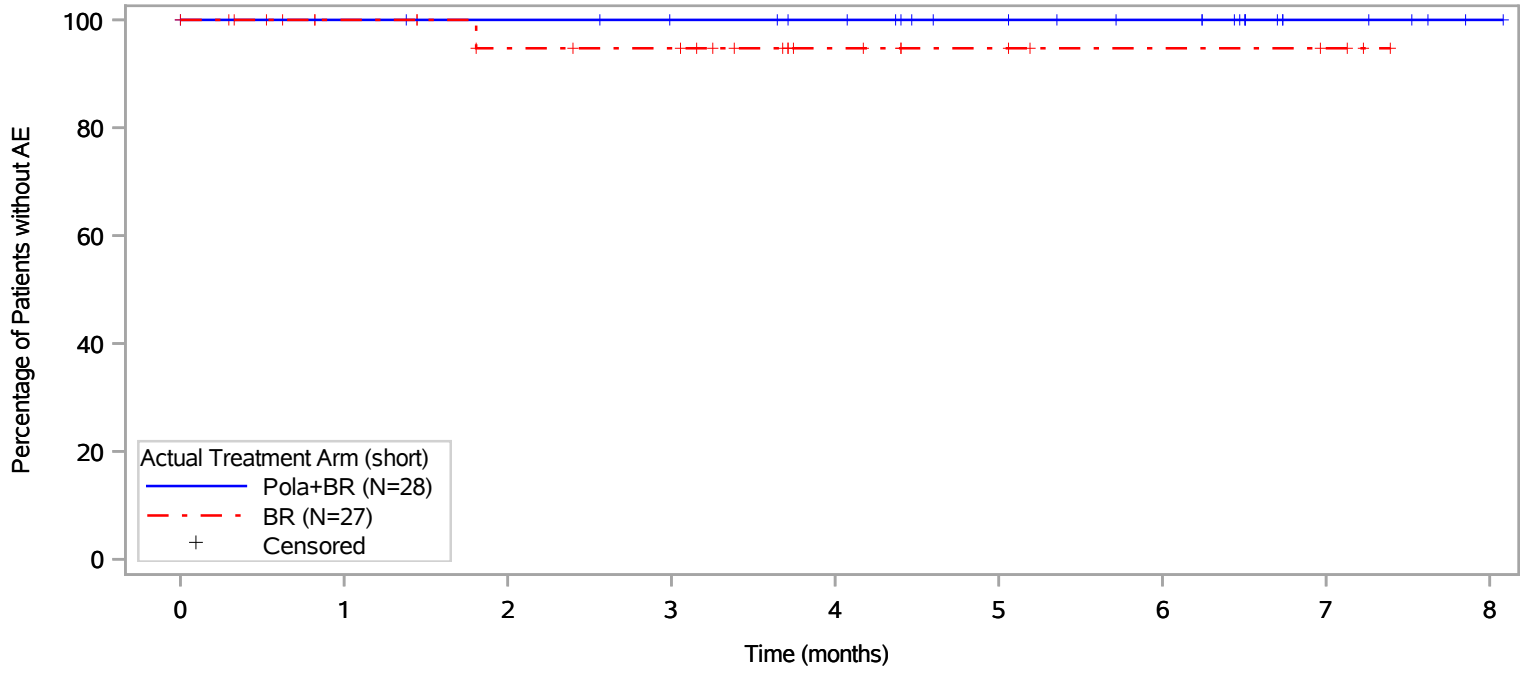
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, APATHY



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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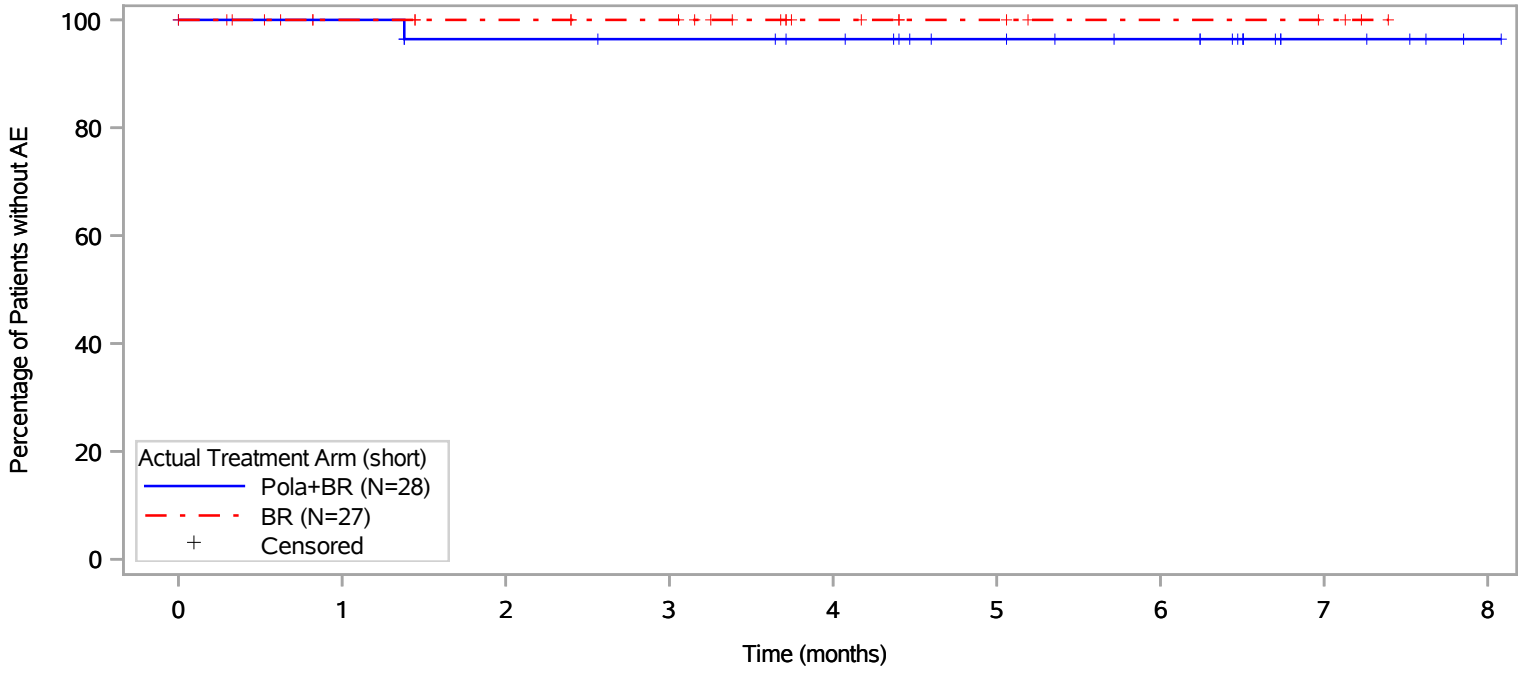
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, CONFUSIONAL STATE



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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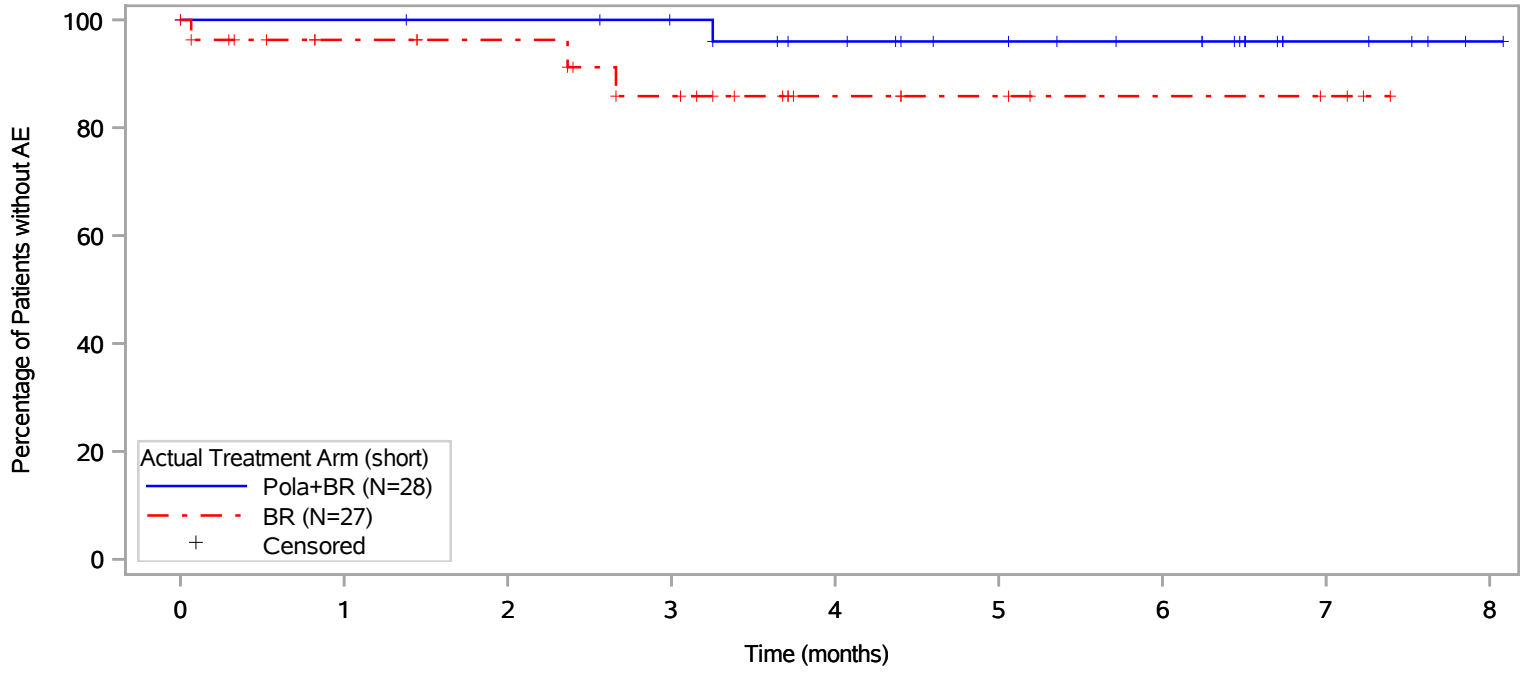
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, DEPRESSION

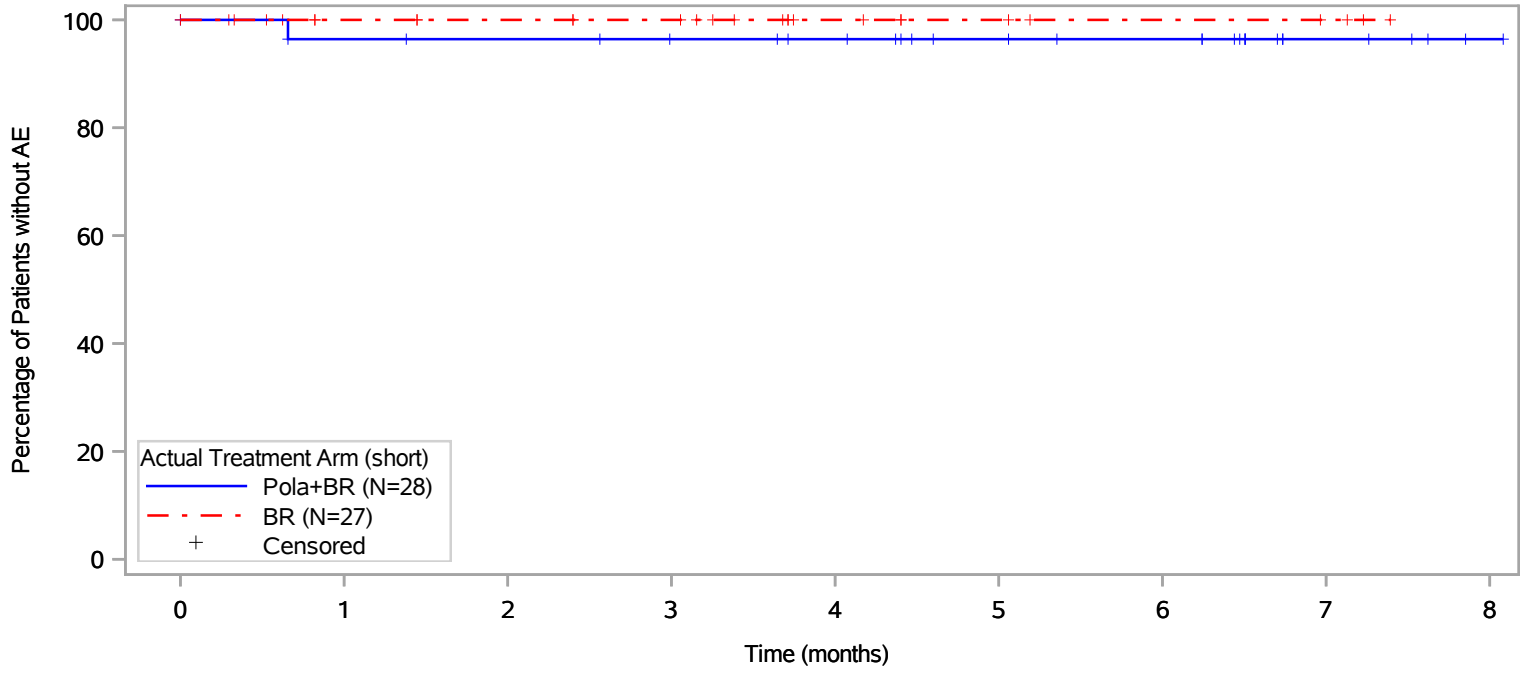


Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	5	1
BR (N=27)	27	21	19	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	5	7	8	16	18	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, INSOMNIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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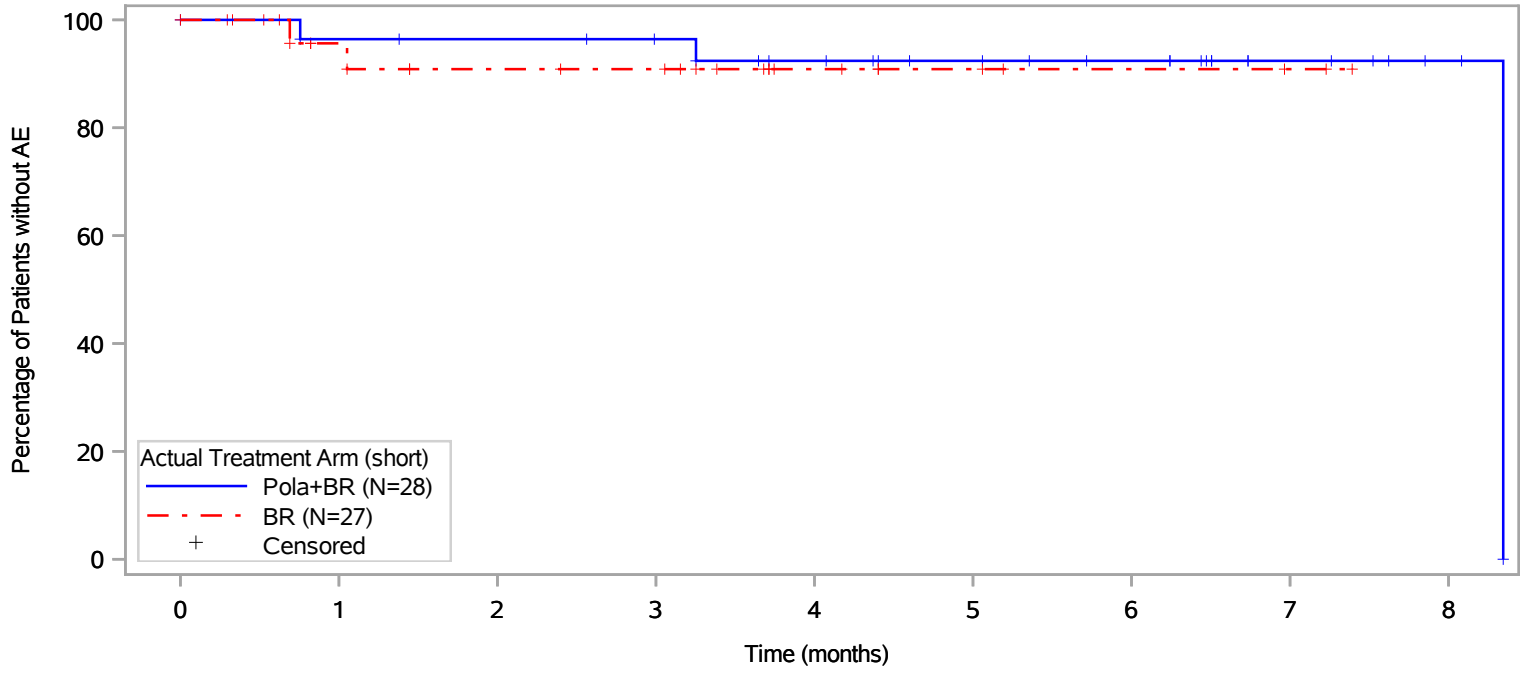
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	26	24	21	17	14	6	2
BR (N=27)	27	20	17	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	20	24
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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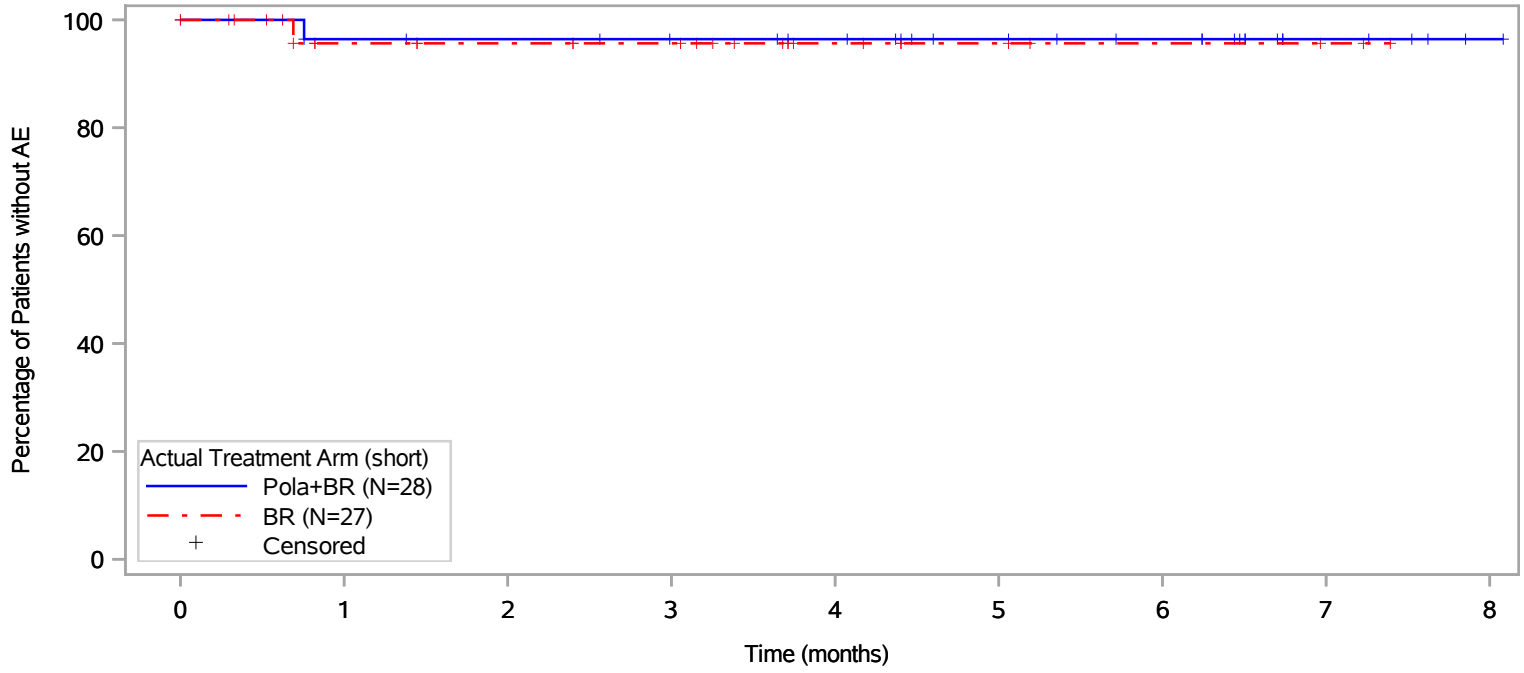
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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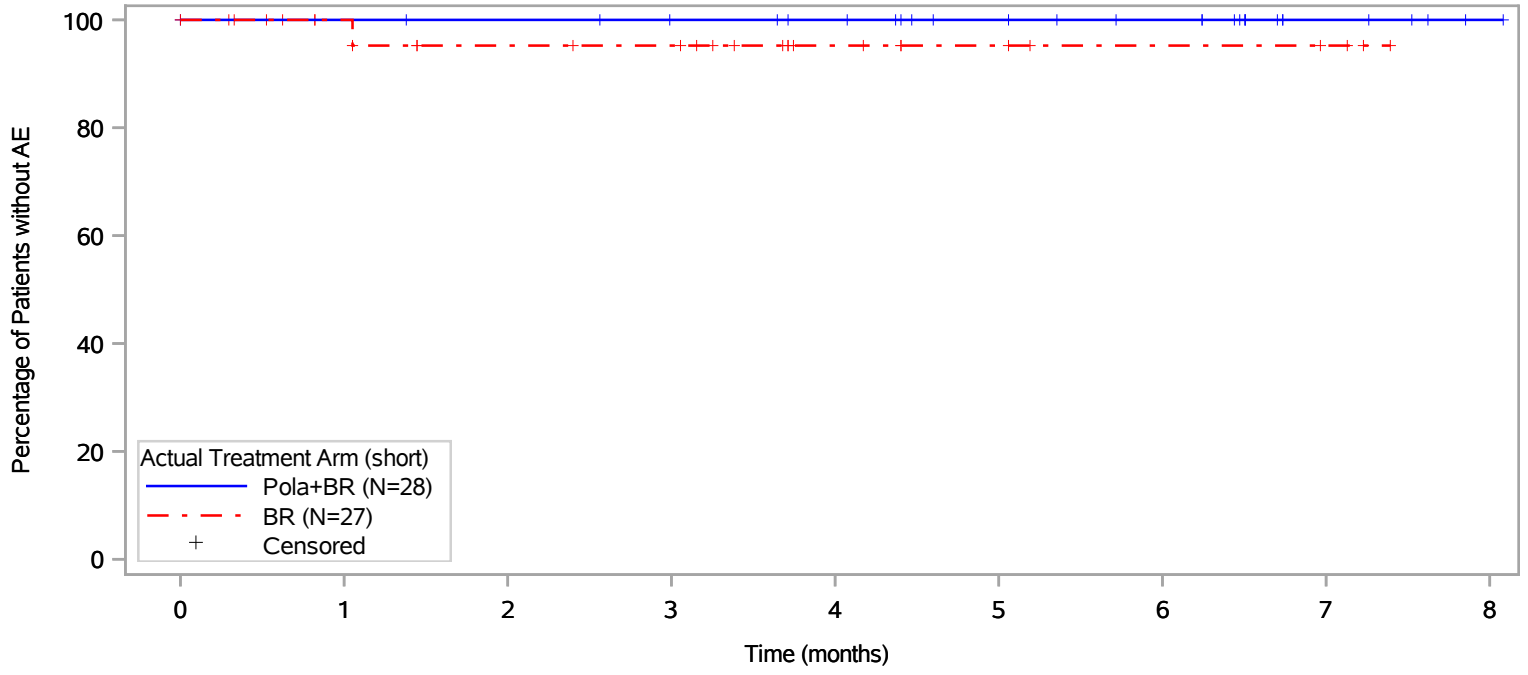
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HAEMATURIA

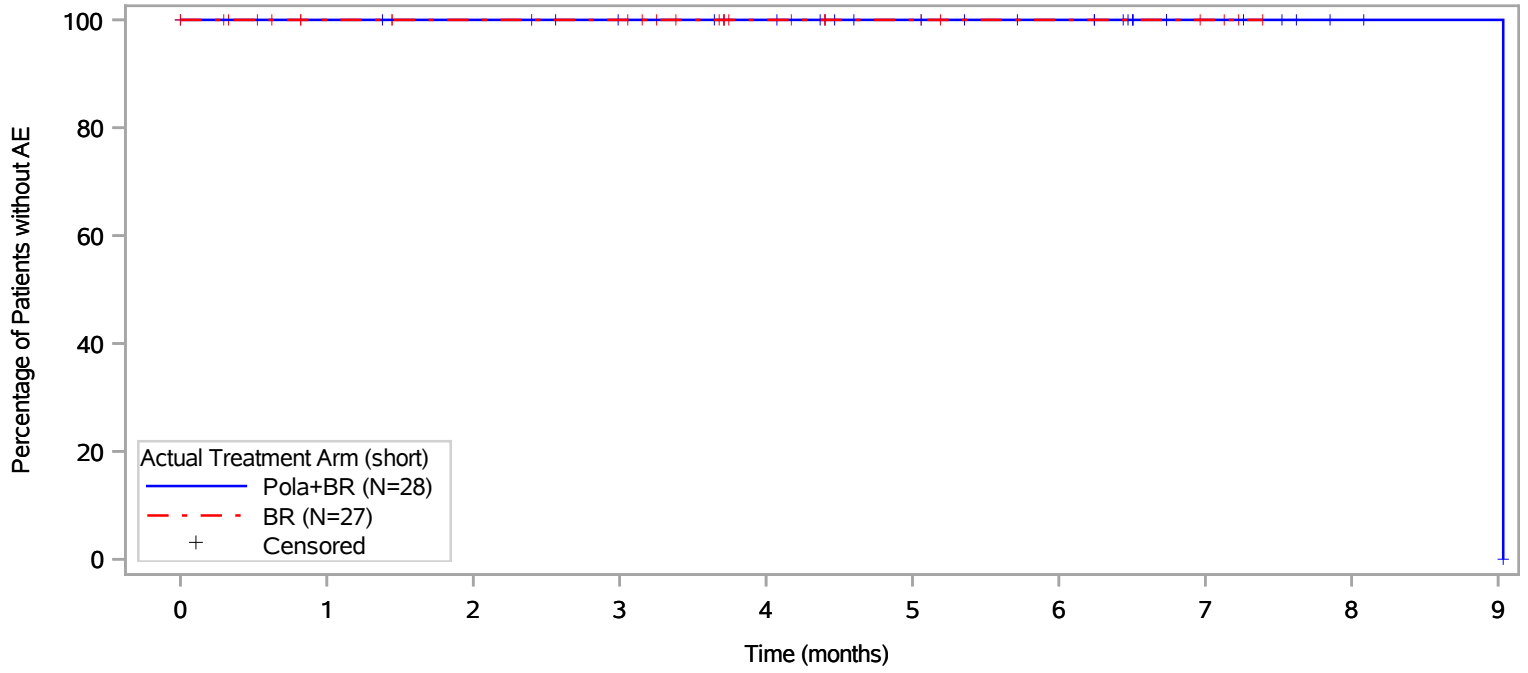


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS

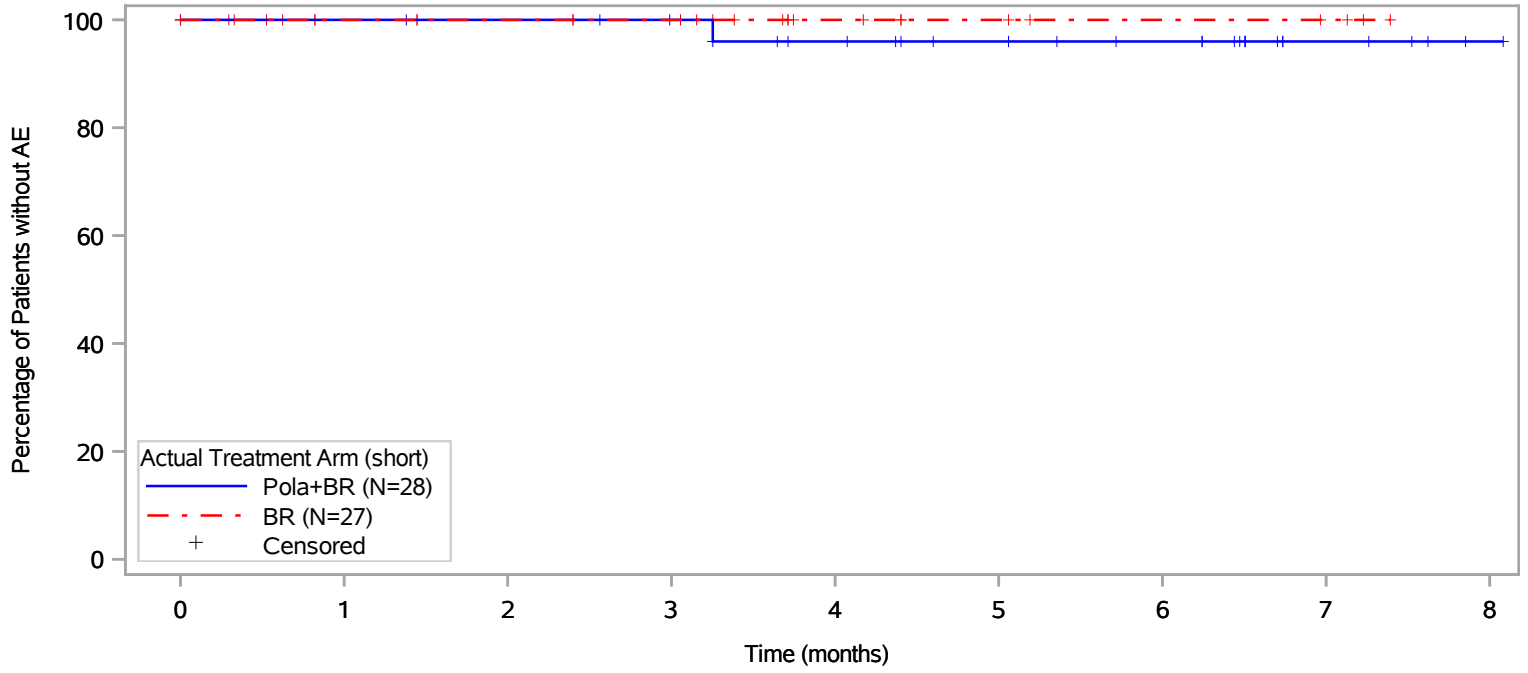


Patients at risk										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE
Patients censored										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, MICTURITION URGENCY



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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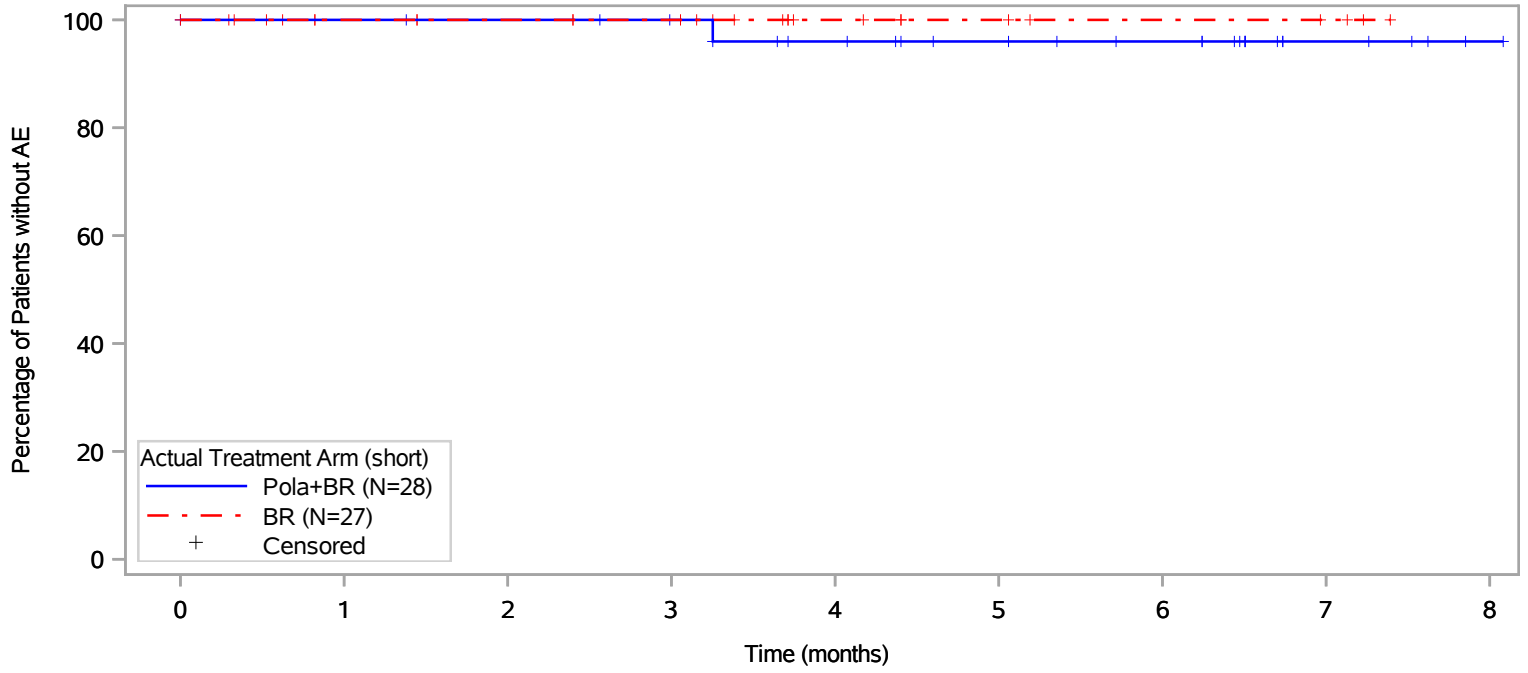
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, POLLAKIURIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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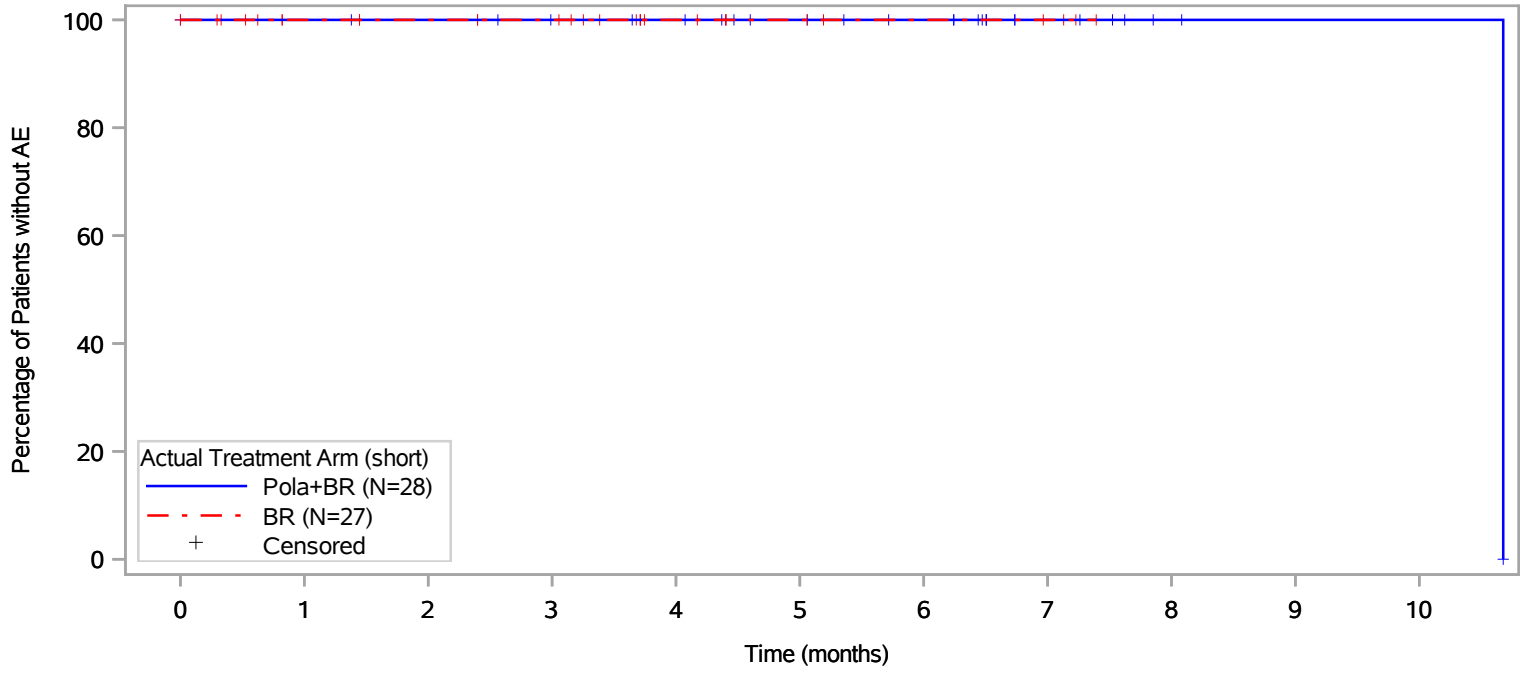
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE

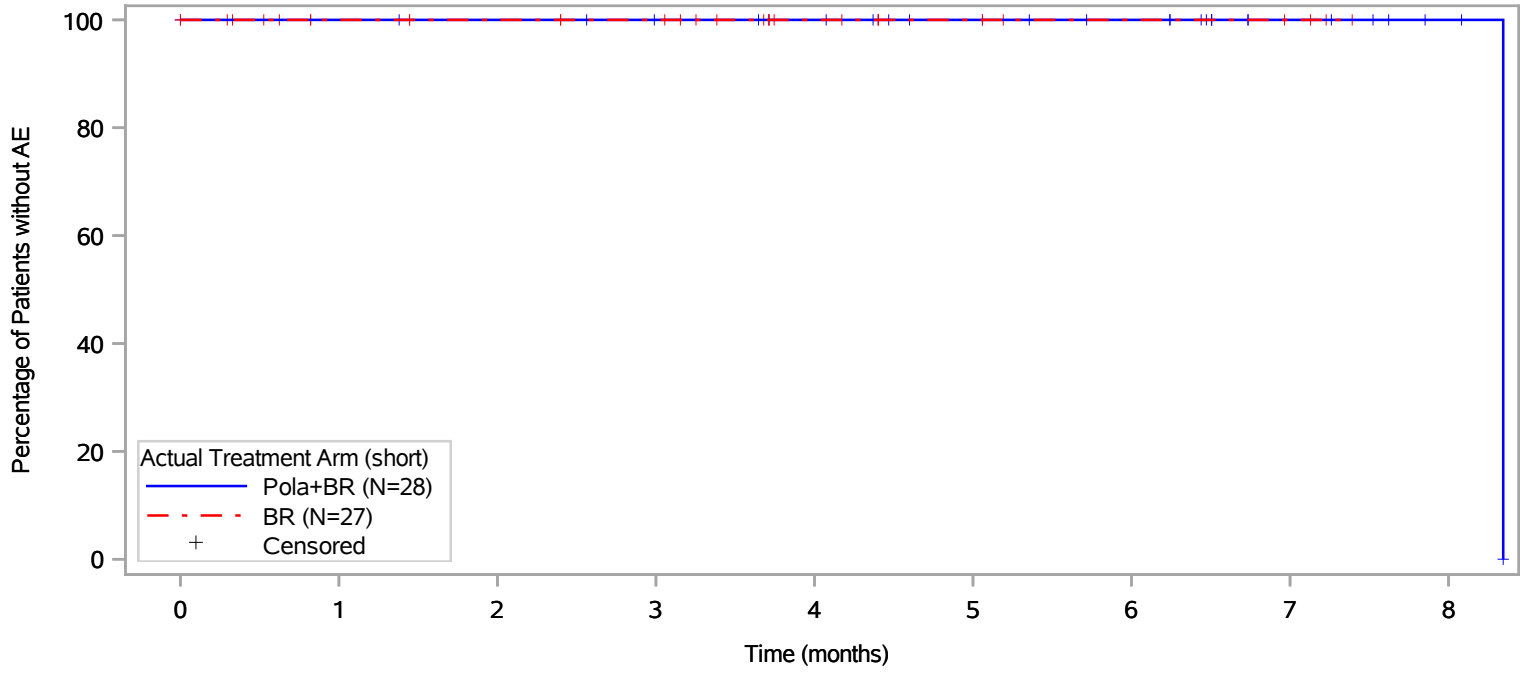


Patients at risk											
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL TUBULAR DISORDER

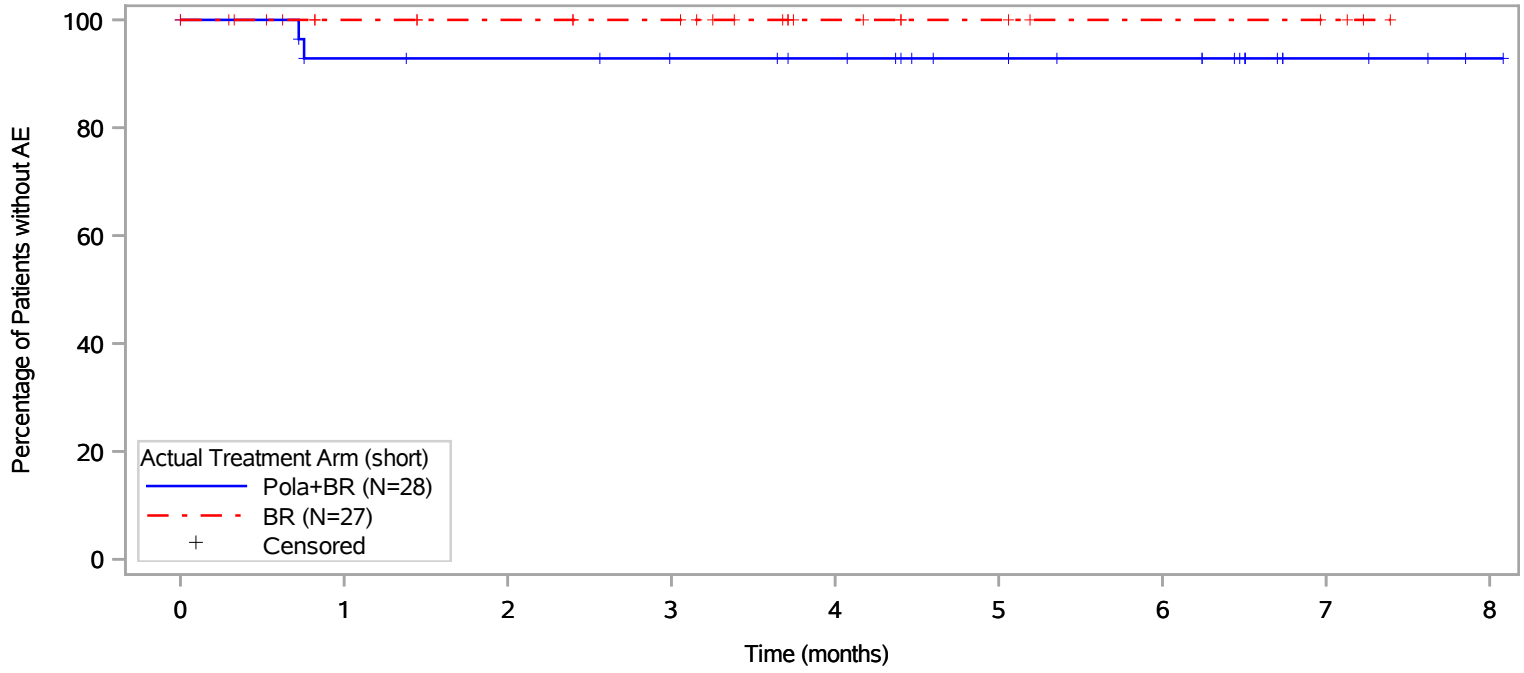


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

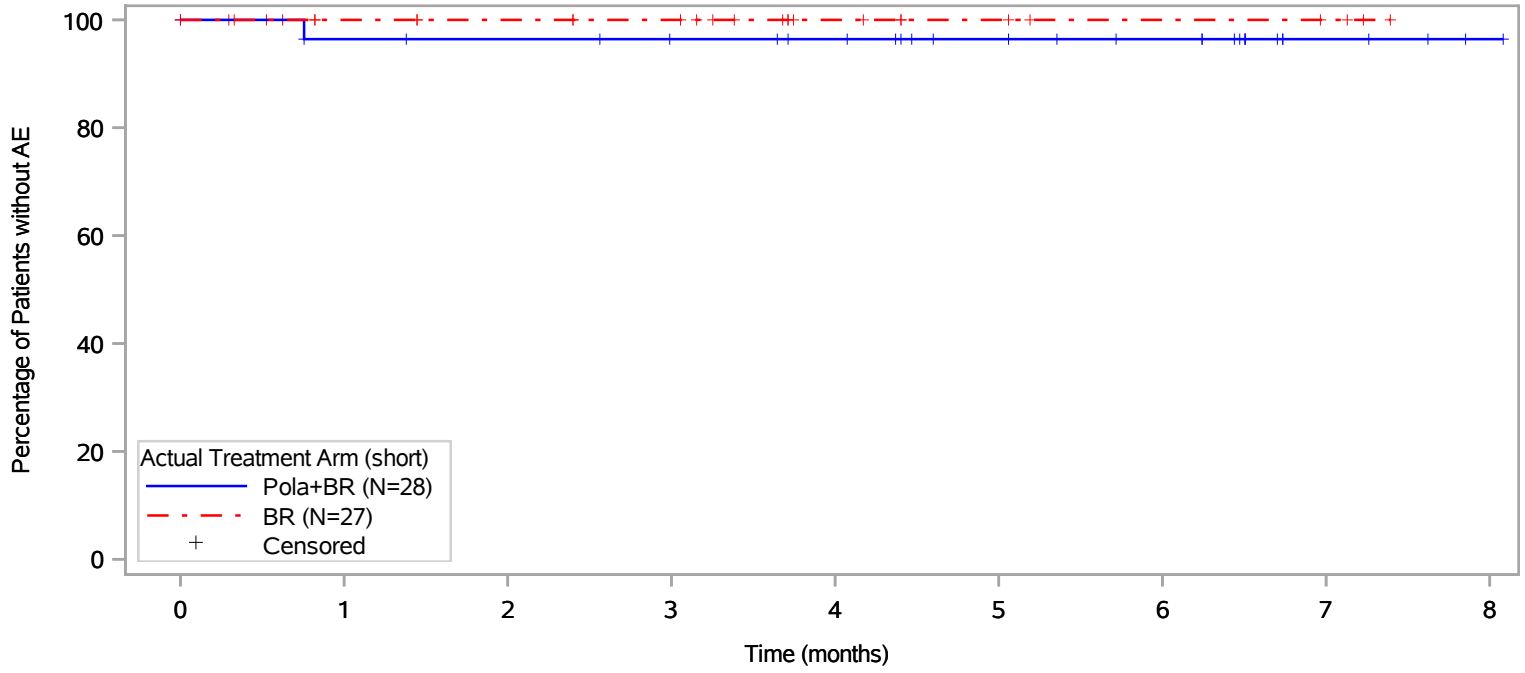
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
REPRODUCTIVE SYSTEM AND BREAST DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	26	25	23	21	16	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
REPRODUCTIVE SYSTEM AND BREAST DISORDERS, ERECTILE DYSFUNCTION



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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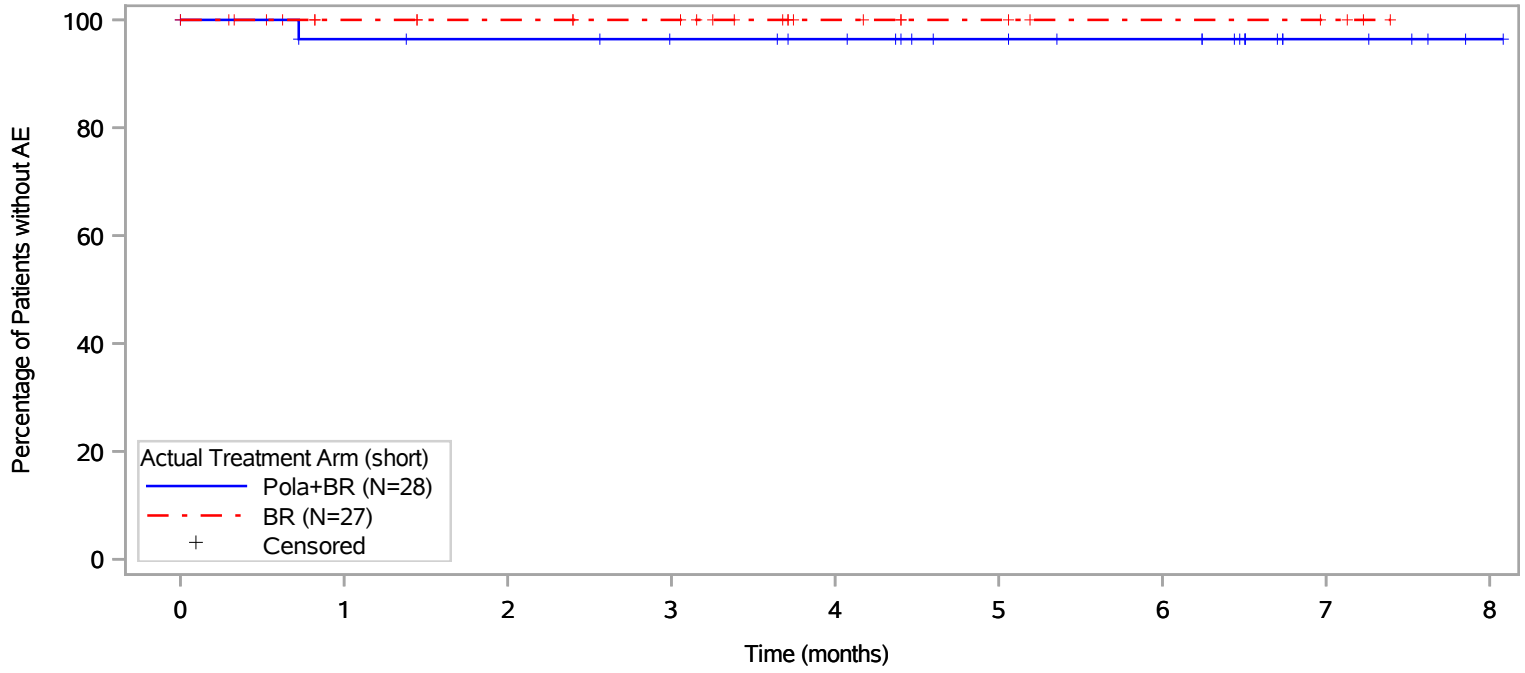
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

REPRODUCTIVE SYSTEM AND BREAST DISORDERS, GYNAECOMASTIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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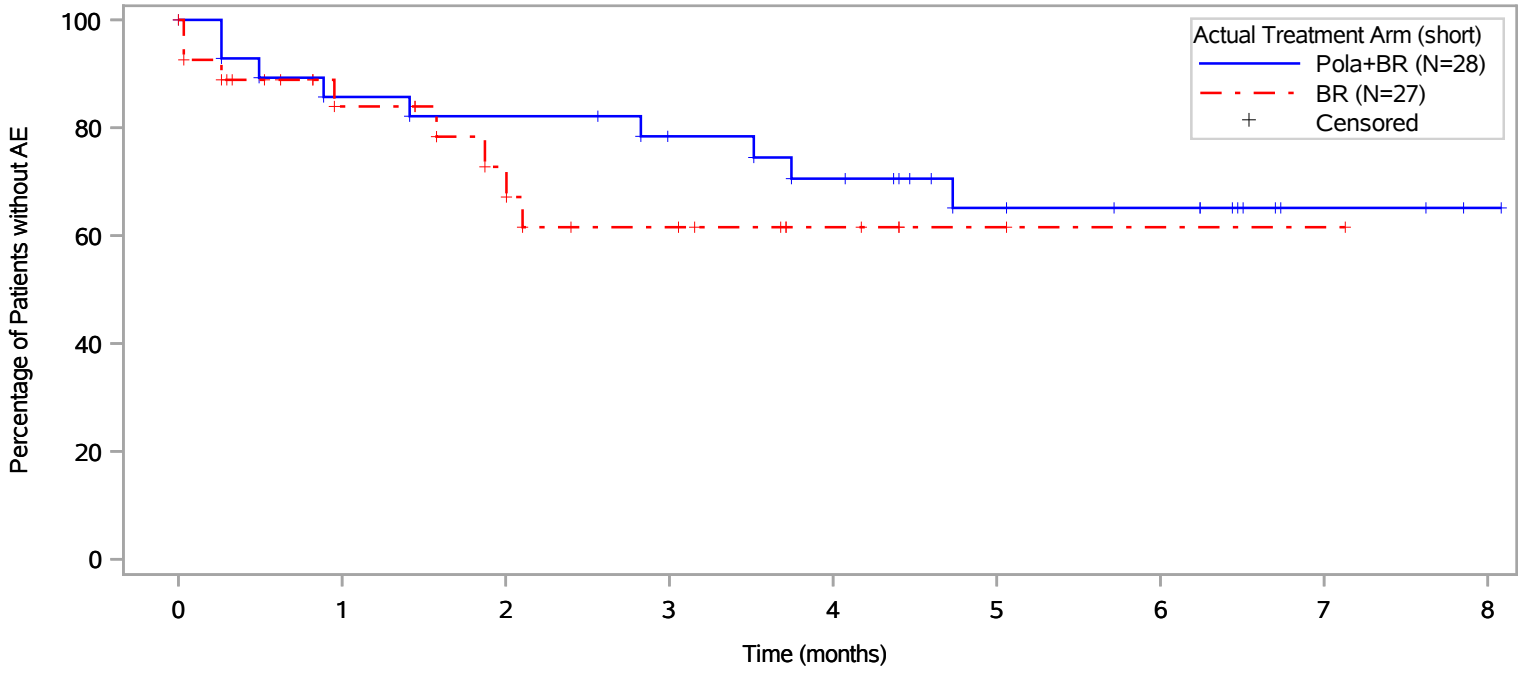
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	24	23	20	18	12	10	3	1
BR (N=27)	27	17	13	10	5	2	1	1	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	2	7	9	16	18
BR (N=27)	0	6	8	9	14	17	18	18	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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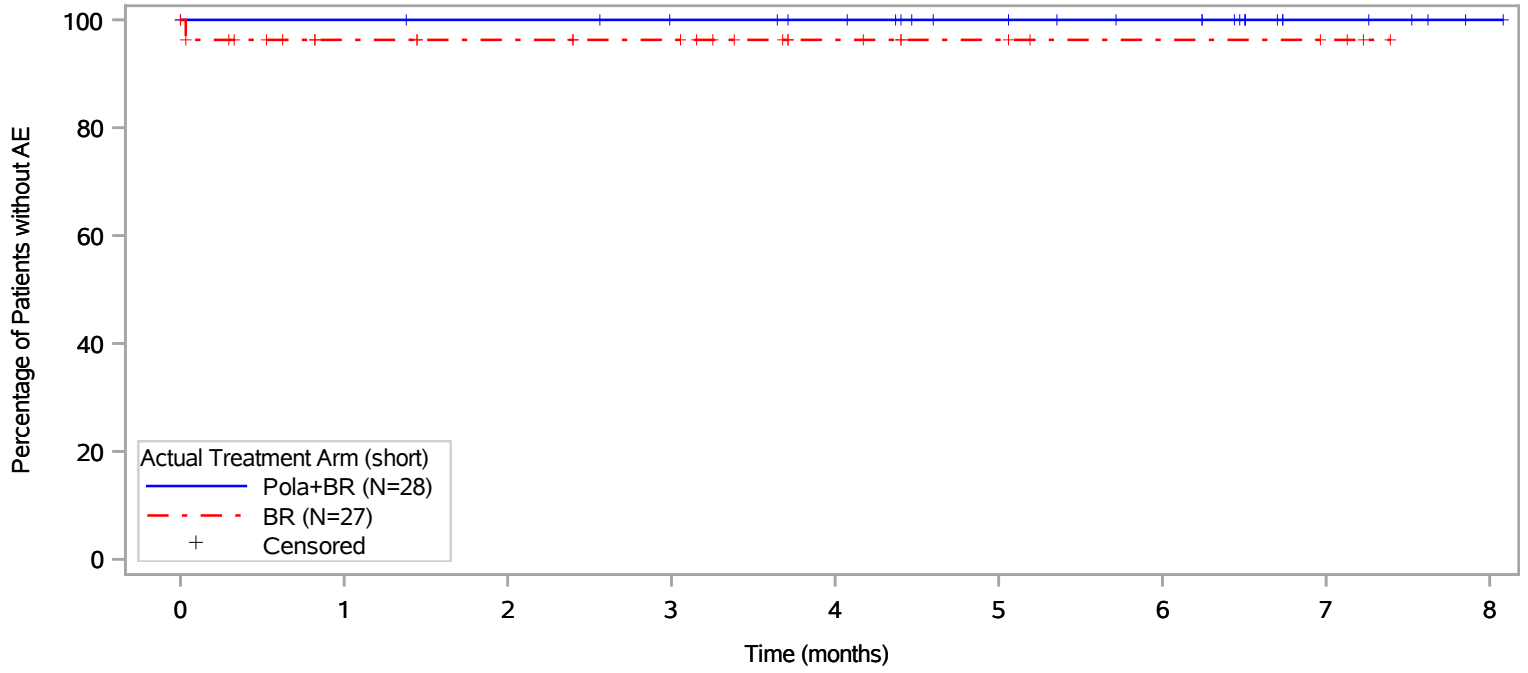
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, ASPHYXIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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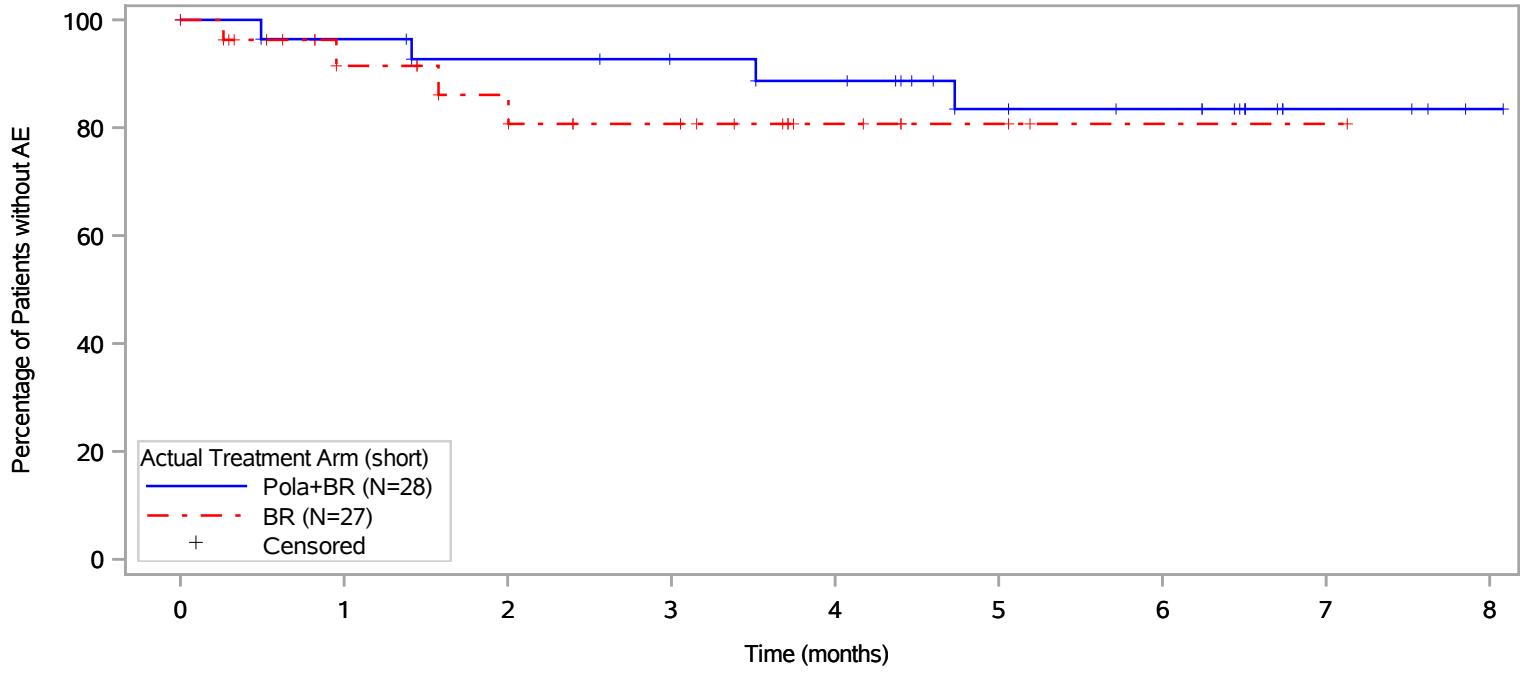
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, COUGH



Patients at risk									
Pola+BR (N=28)	28	27	25	23	22	16	14	4	1
BR (N=27)	27	19	16	13	6	3	1	1	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	3	8	10	20	23
BR (N=27)	0	6	8	10	17	20	22	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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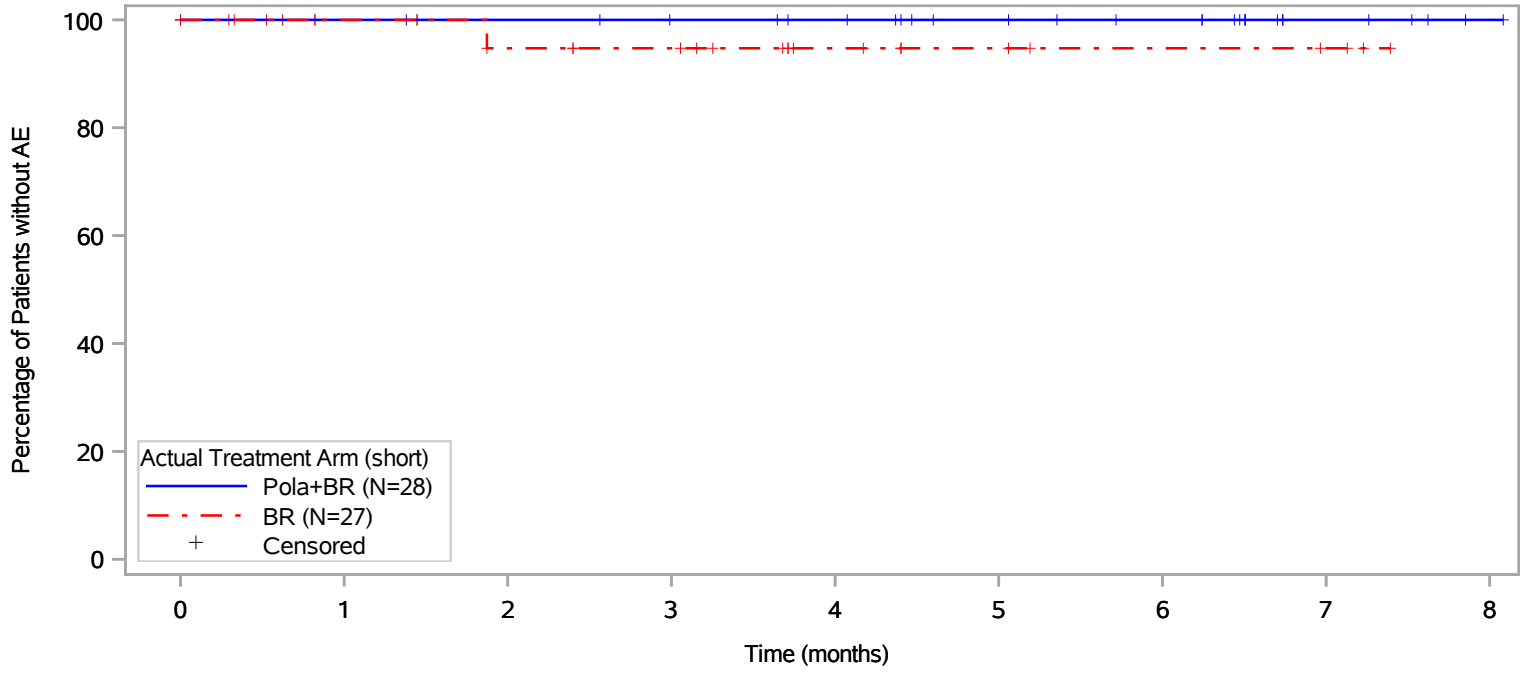
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPHONIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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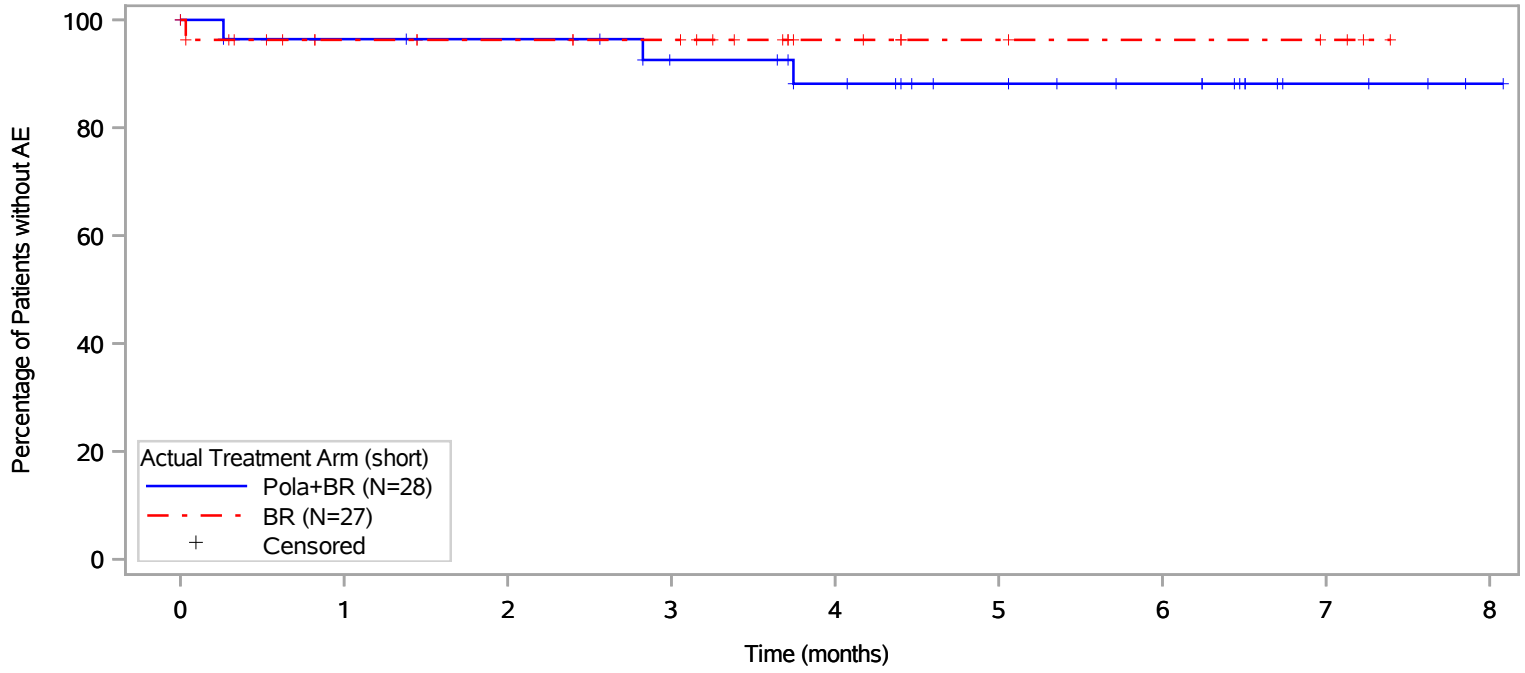
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPNOEA

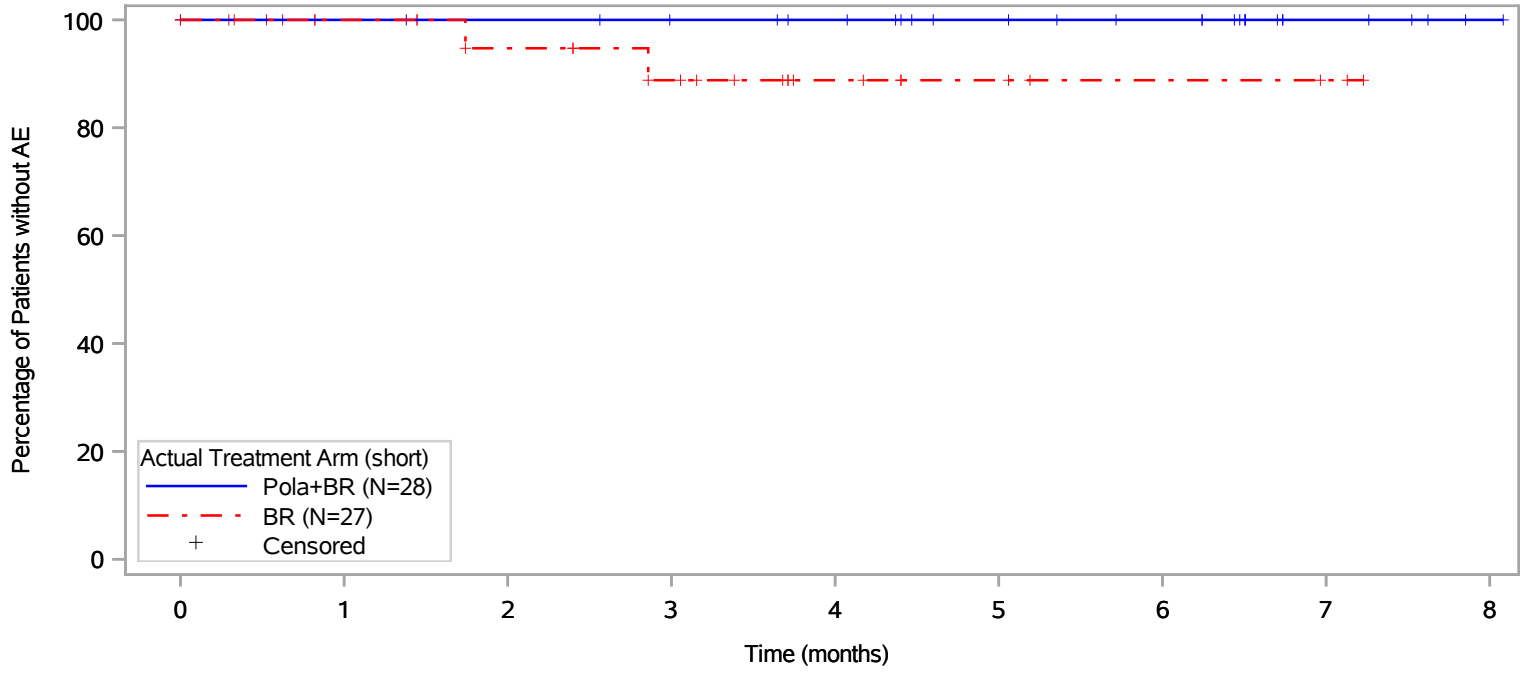


Patients at risk									
Pola+BR (N=28)	28	27	26	23	20	15	12	4	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	21	24
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPNOEA EXERTIONAL



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	15	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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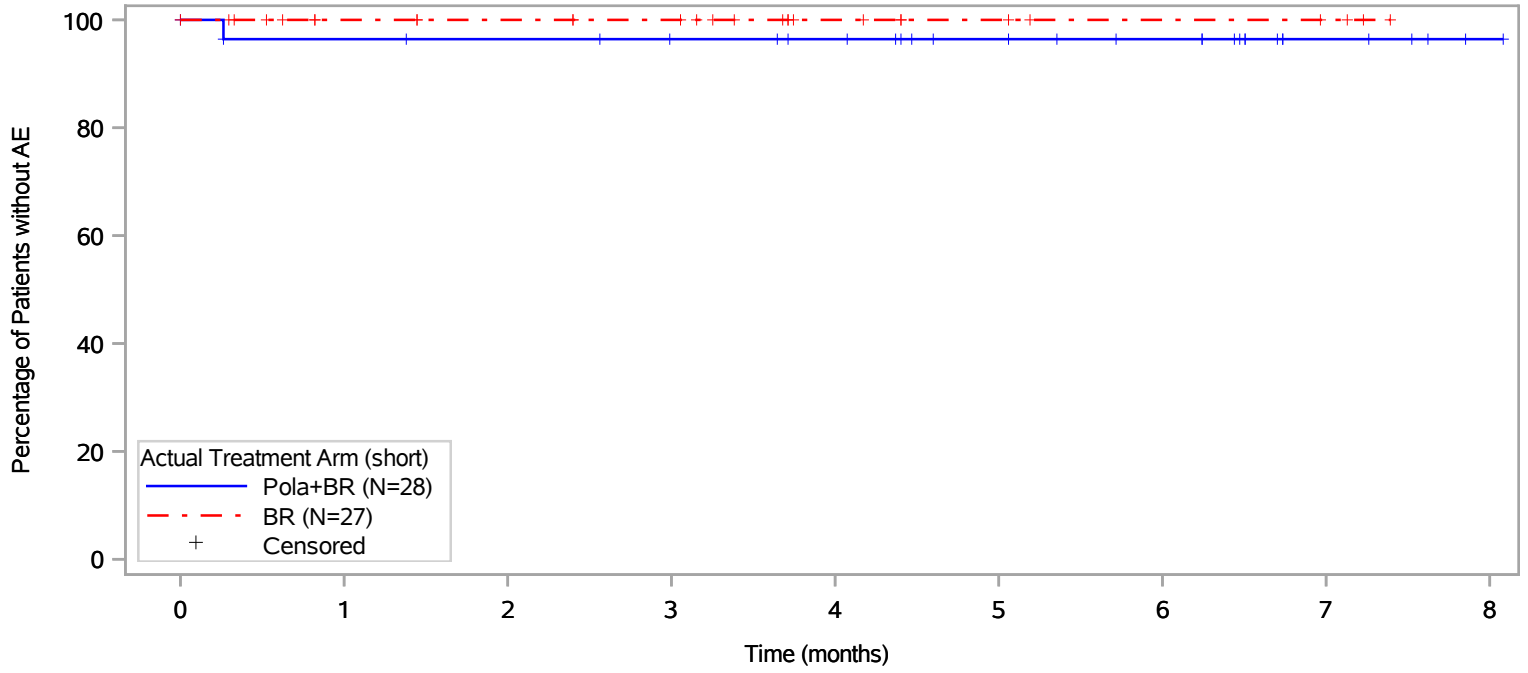
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, EPISTAXIS



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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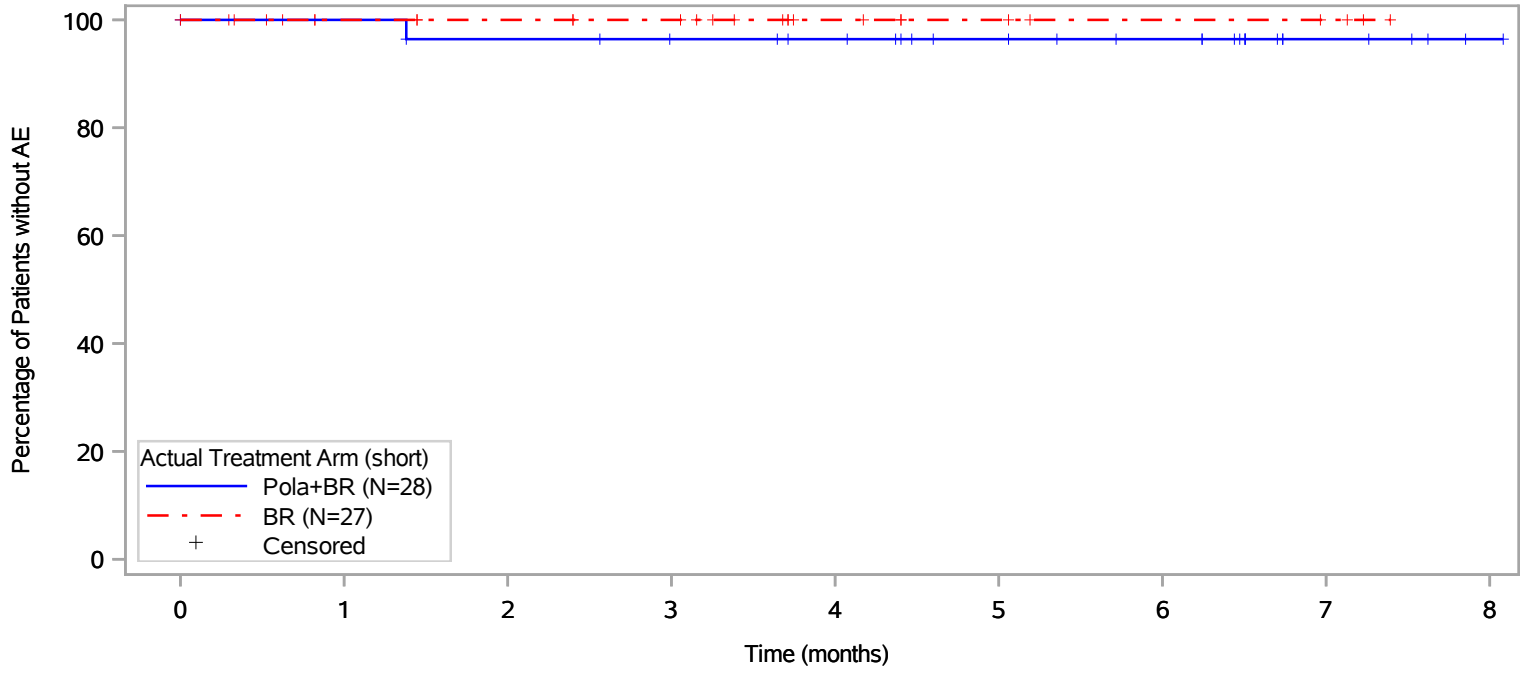
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HAEMOPTYSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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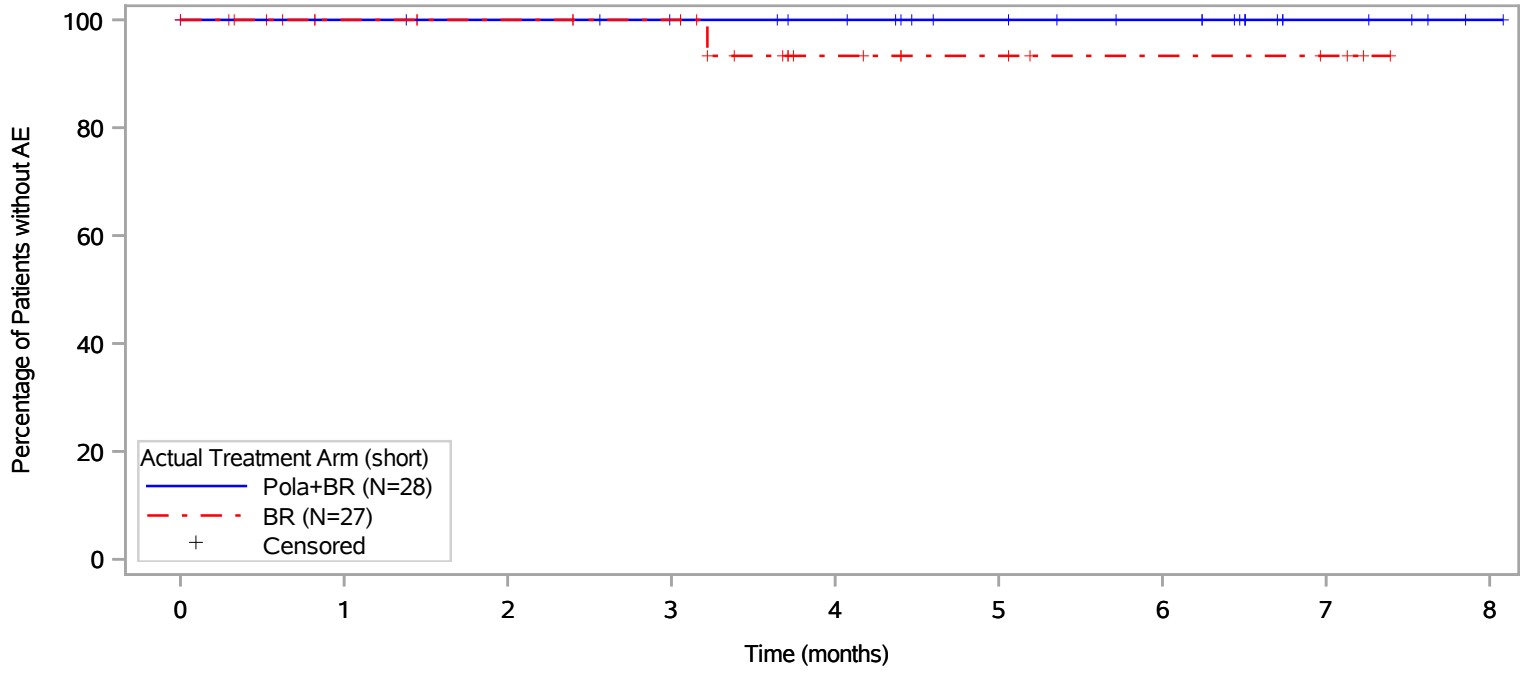
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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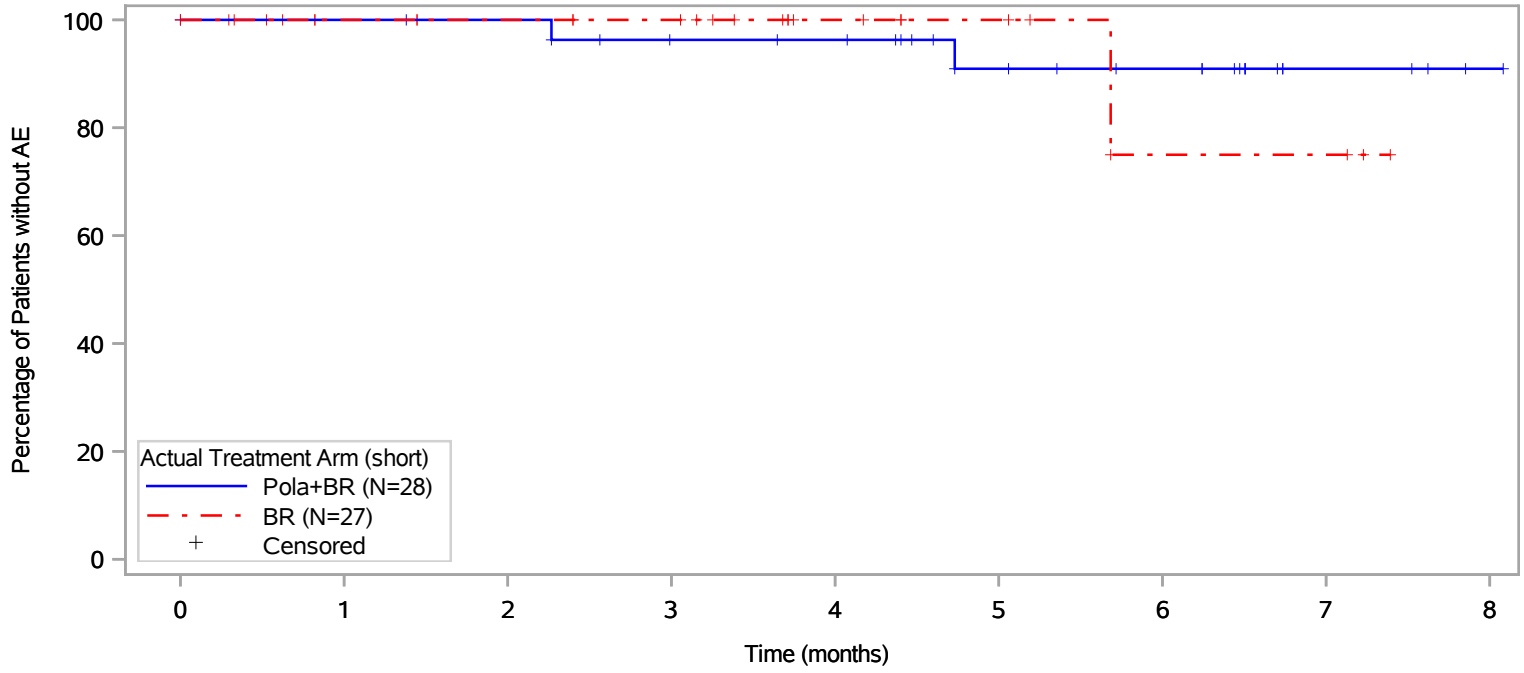
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, OROPHARYNGEAL PAIN



Patients at risk									
Pola+BR (N=28)	28	28	27	24	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	3	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	25
BR (N=27)	0	6	8	10	18	21	23	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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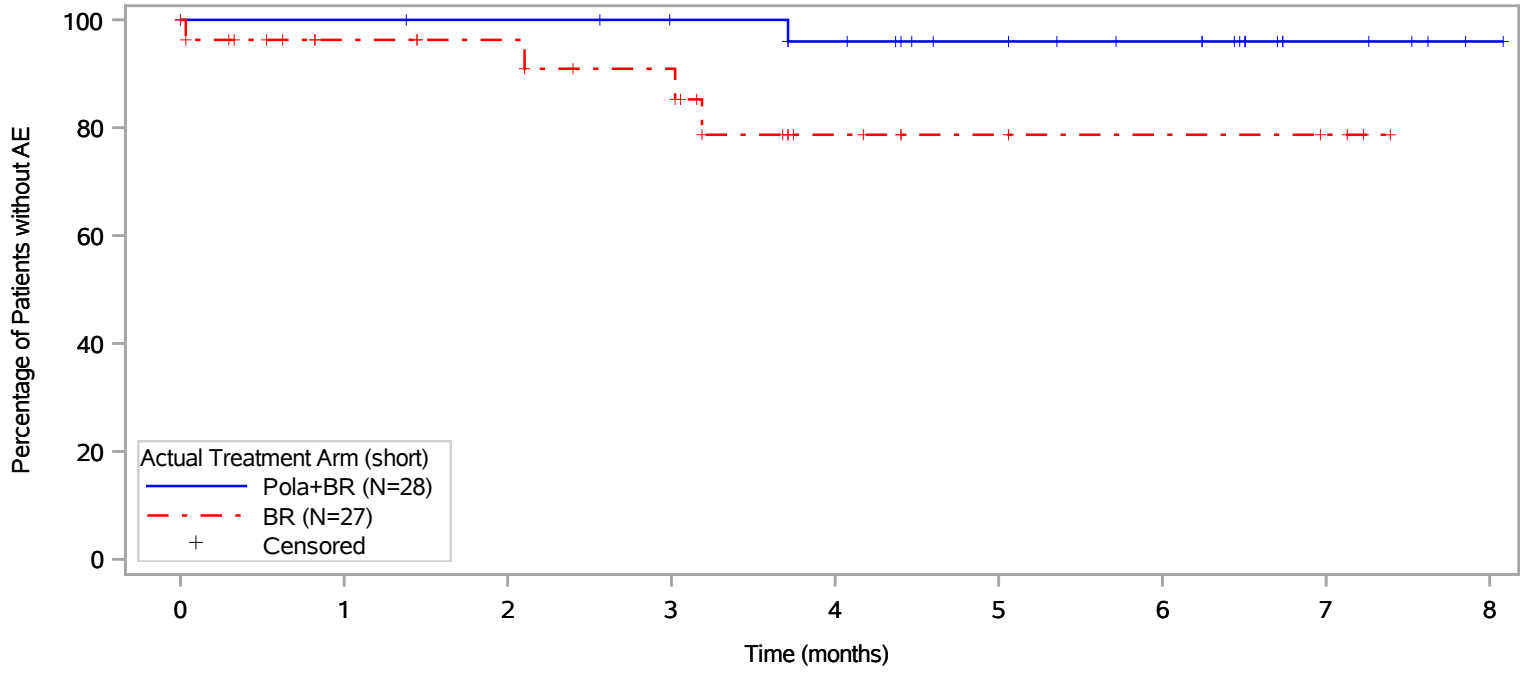
01DEC2022 21:22

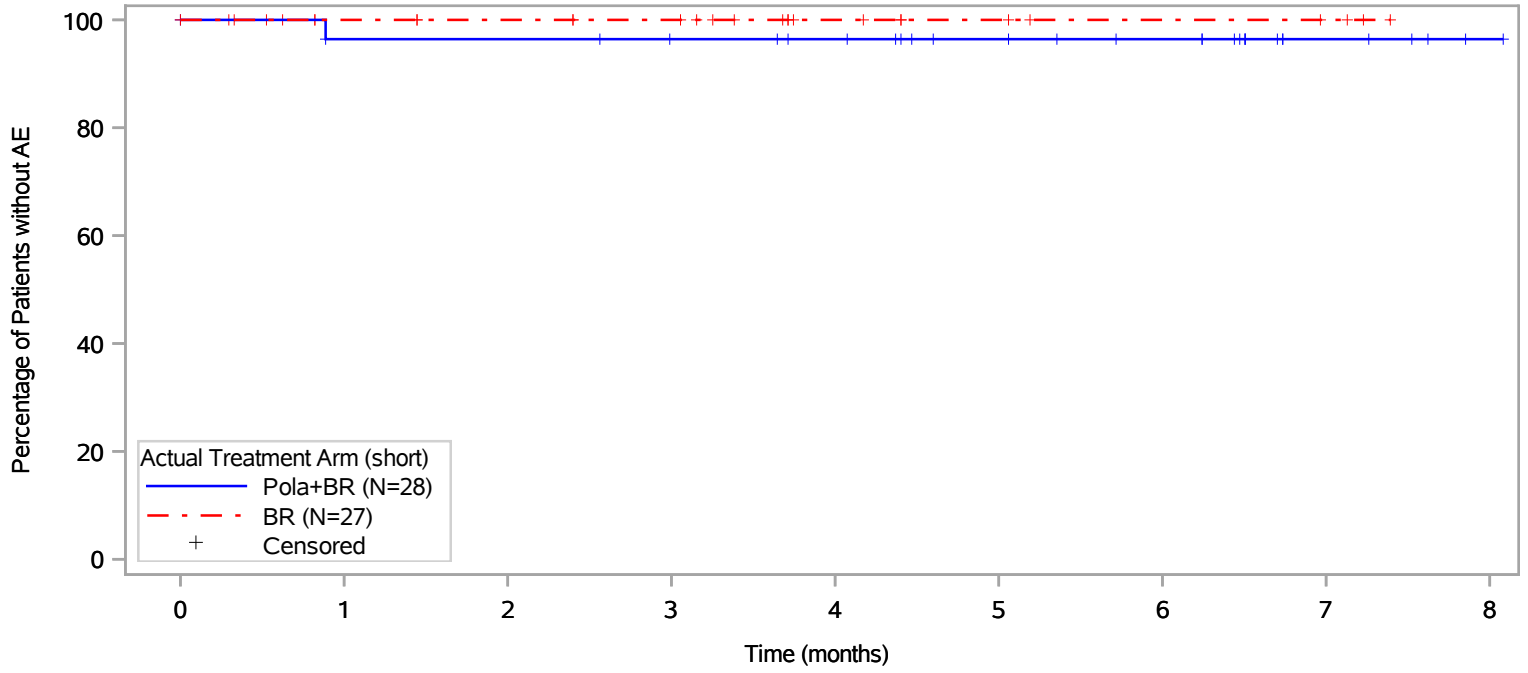
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	9	15	18	19	20	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY EMBOLISM



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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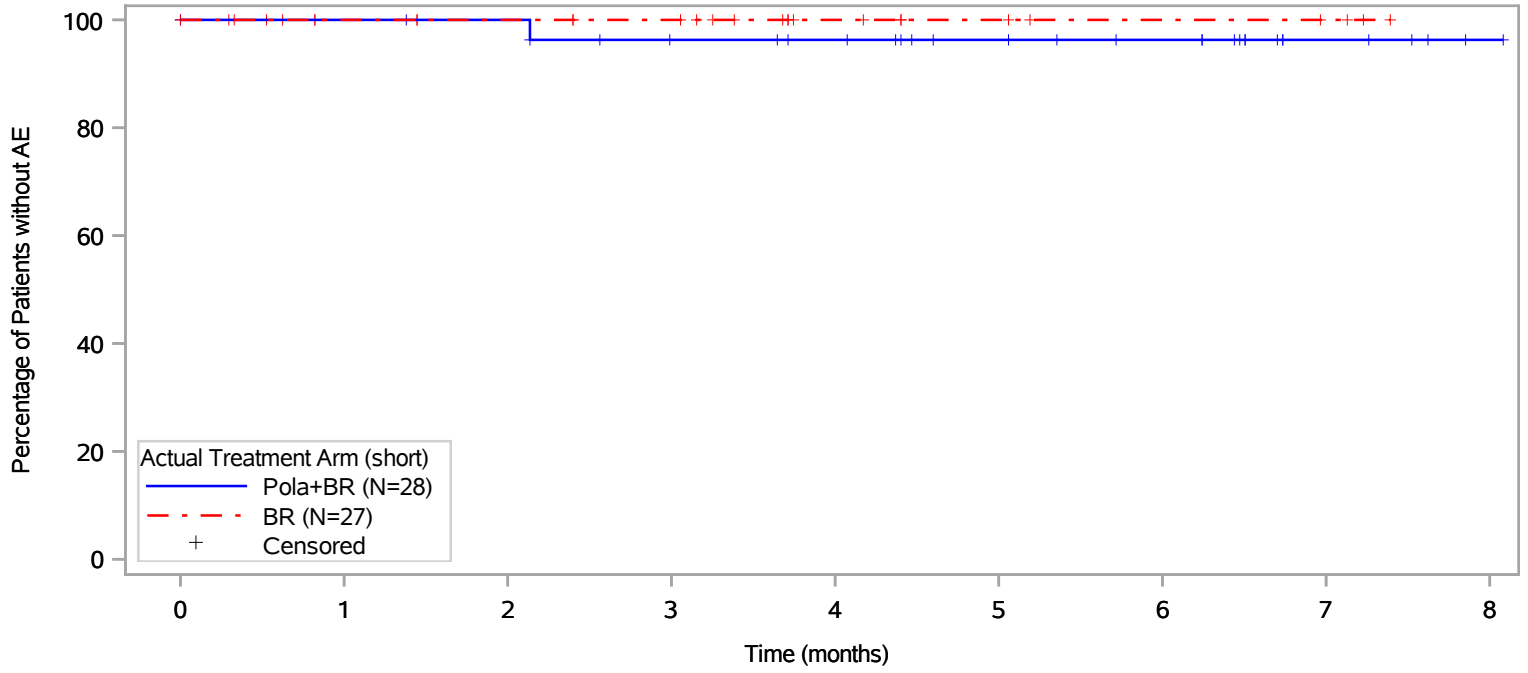
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, RHINORRHOEA

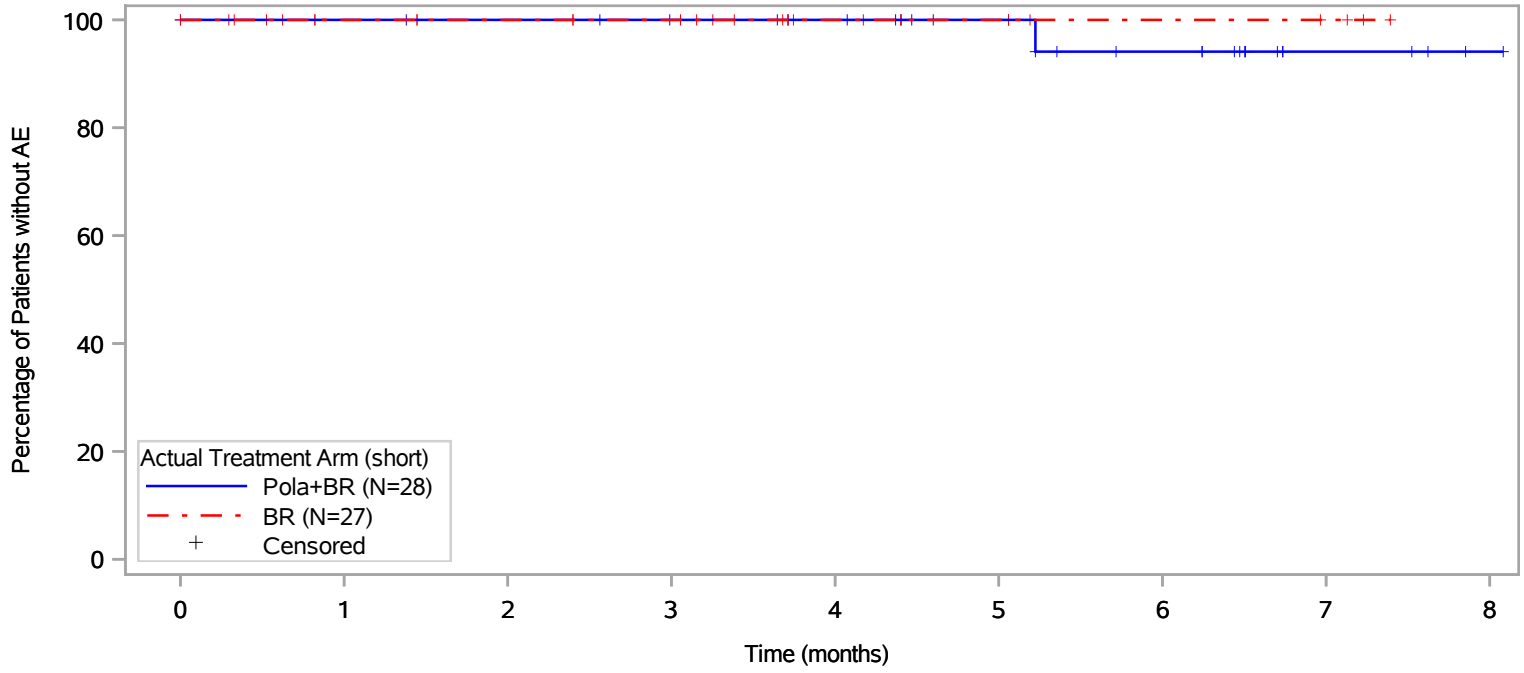


Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, UPPER-AIRWAY COUGH SYNDROME



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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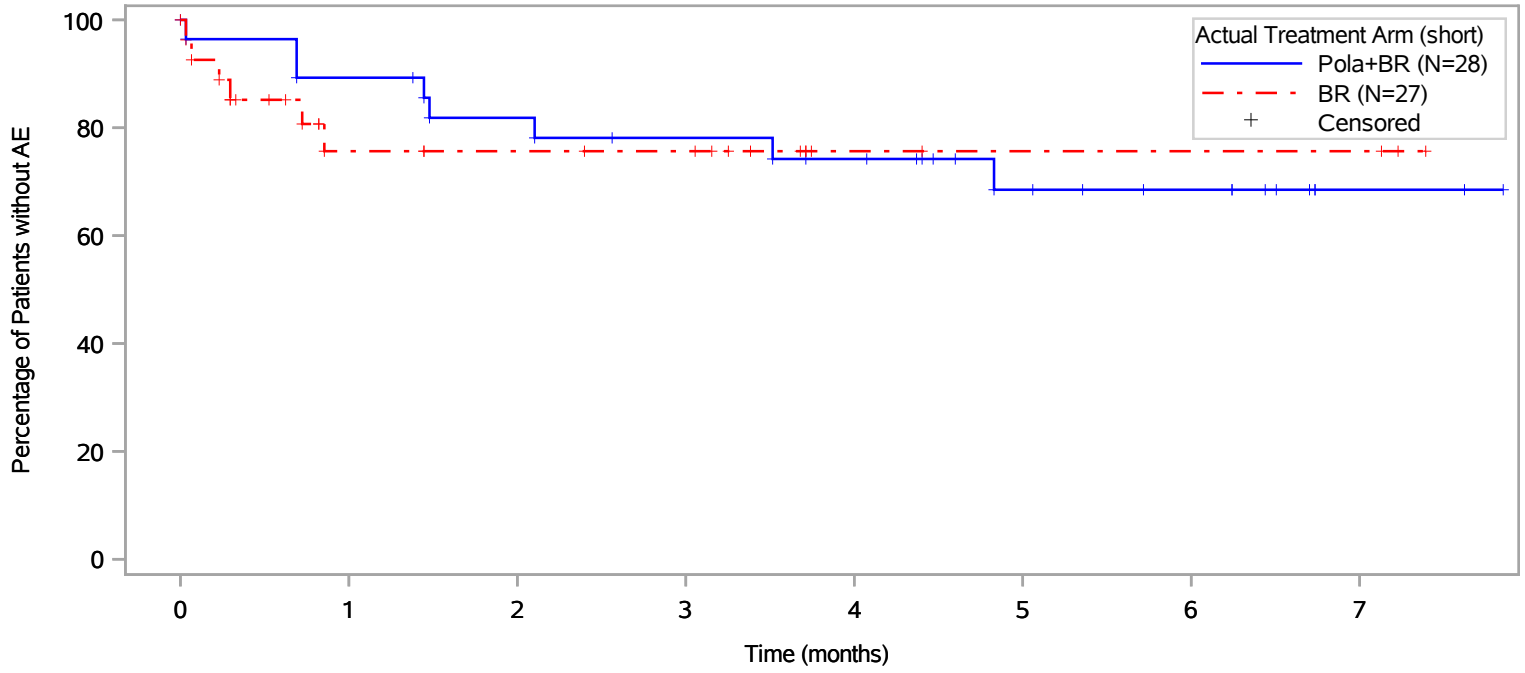
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk								
Pola+BR (N=28)	28	25	22	20	18	12	9	2
BR (N=27)	27	15	13	12	4	3	3	3
Patients censored								
Pola+BR (N=28)	0	0	1	2	3	8	11	18
BR (N=27)	0	6	8	9	17	18	18	18

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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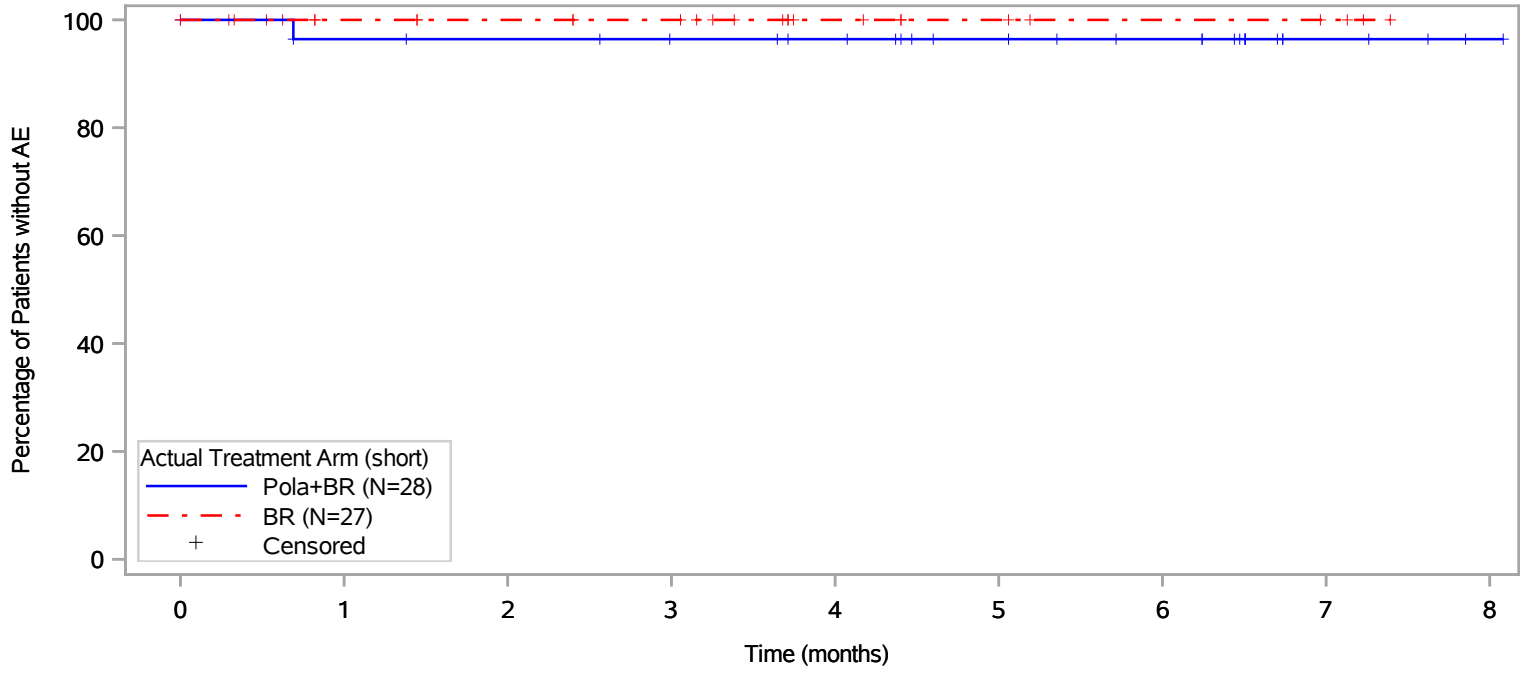
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, BUTTERFLY RASH

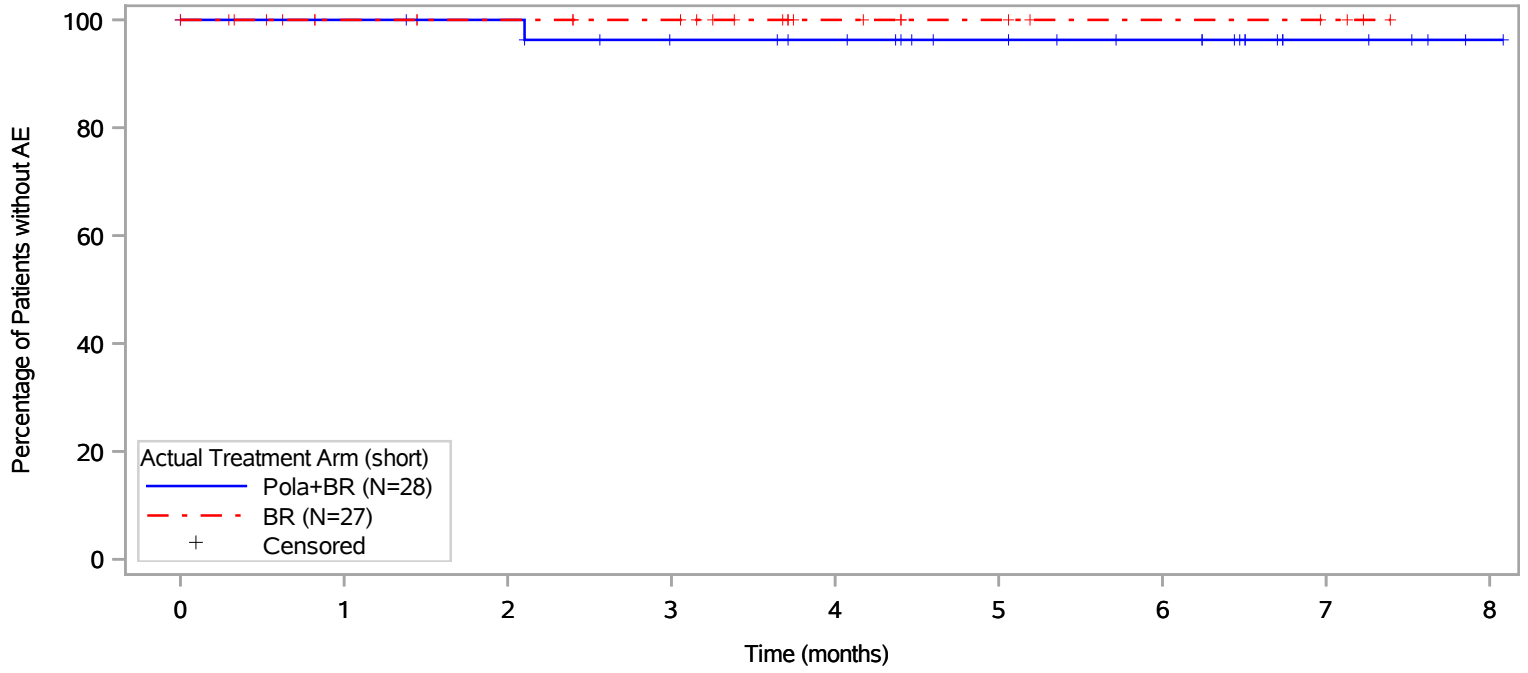


Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DERMATITIS EXFOLIATIVE GENERALISED



Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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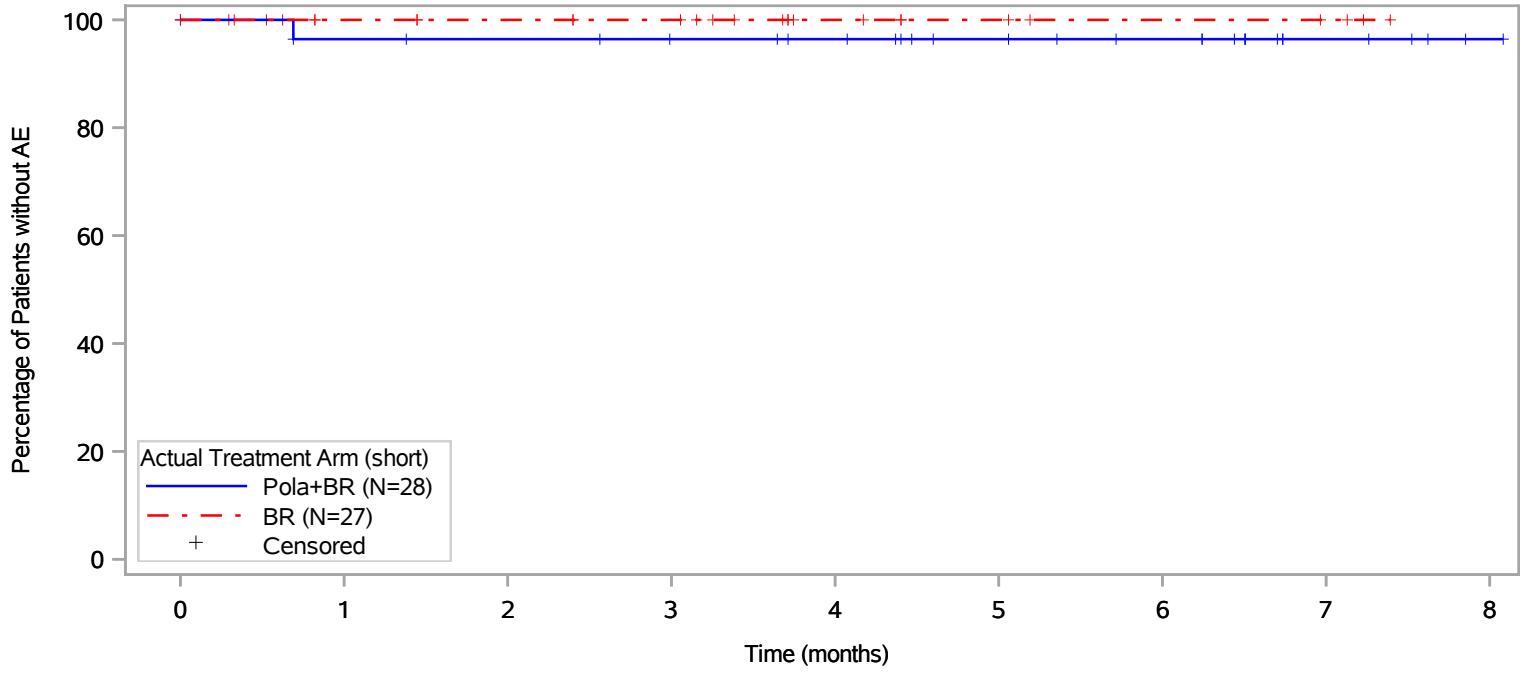
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DRUG ERUPTION



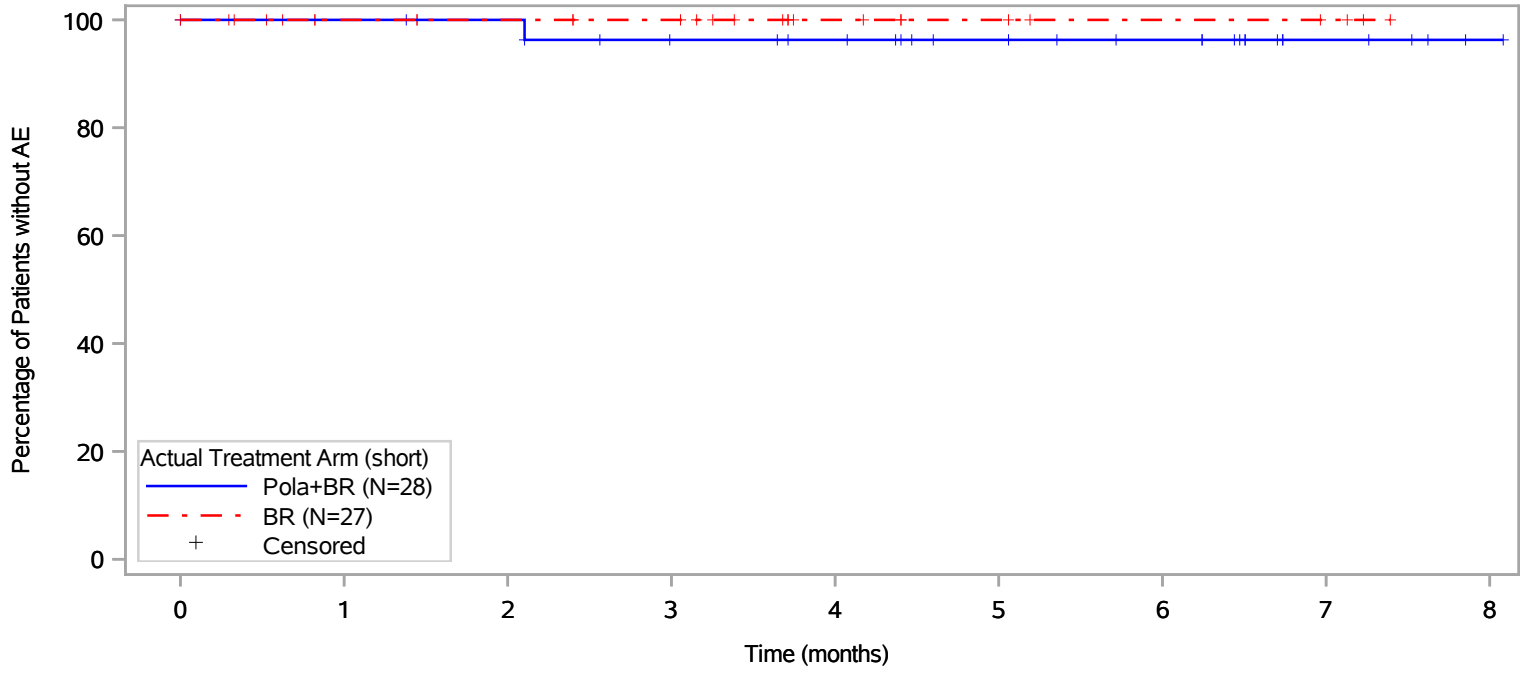
Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DRY SKIN



Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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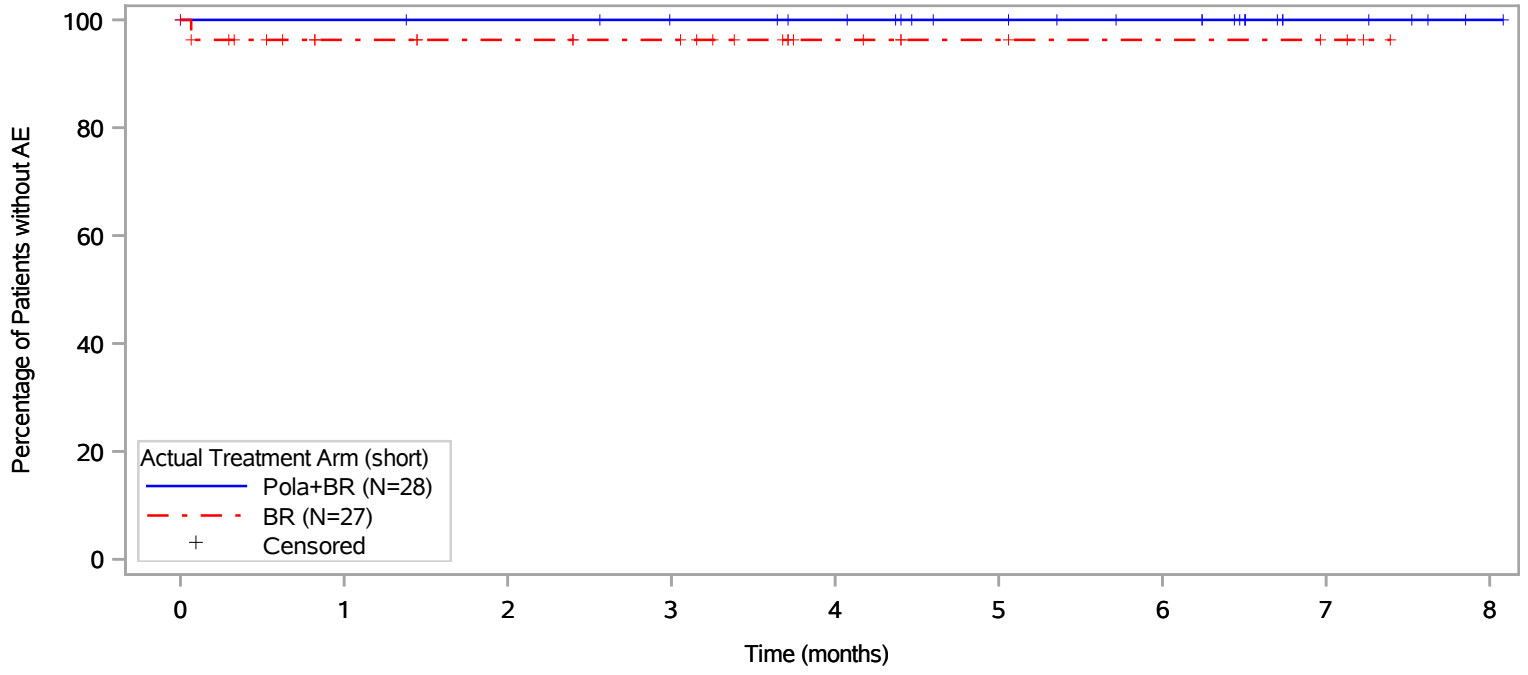
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, NIGHT SWEATS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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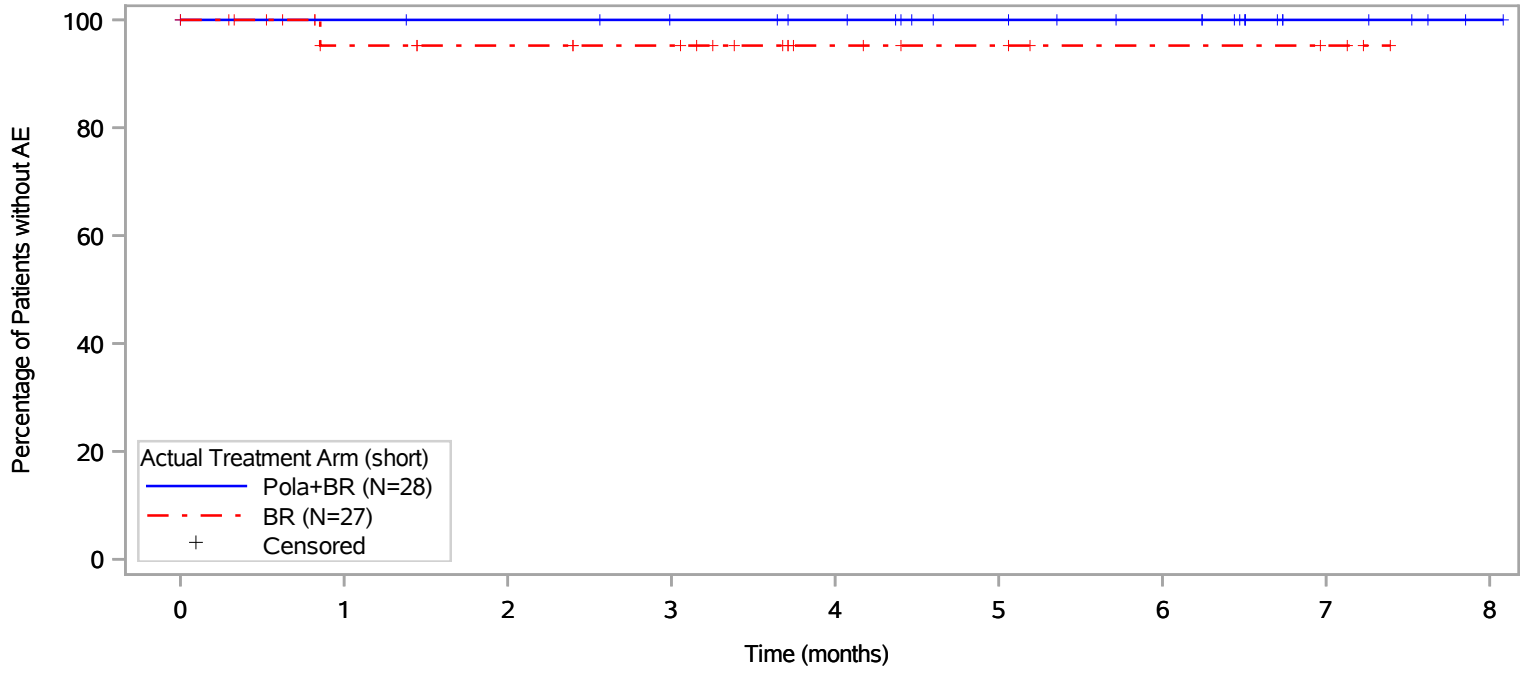
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PAPULE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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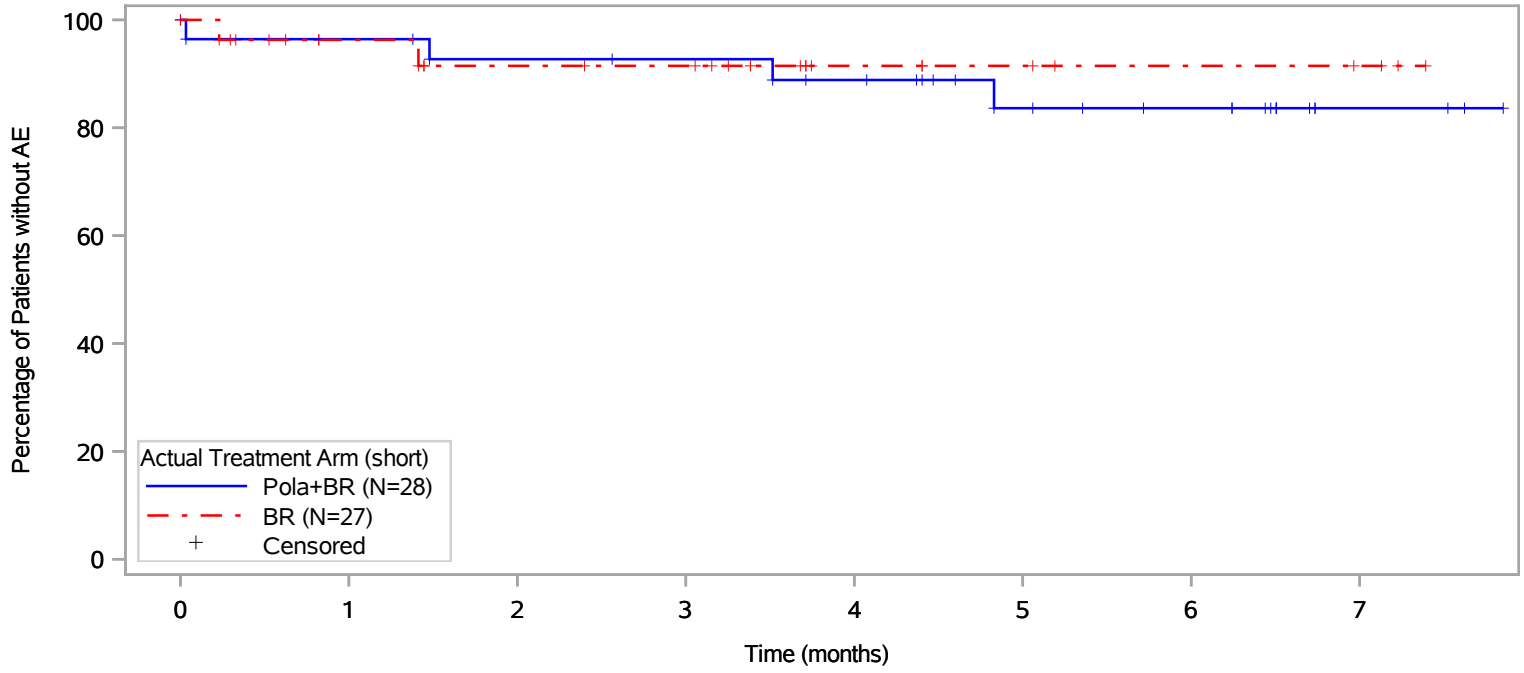
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS



Patients at risk								
Pola+BR (N=28)	28	27	25	24	22	16	13	3
BR (N=27)	27	20	17	16	8	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	2	3	8	11	21
BR (N=27)	0	6	8	9	17	19	21	22

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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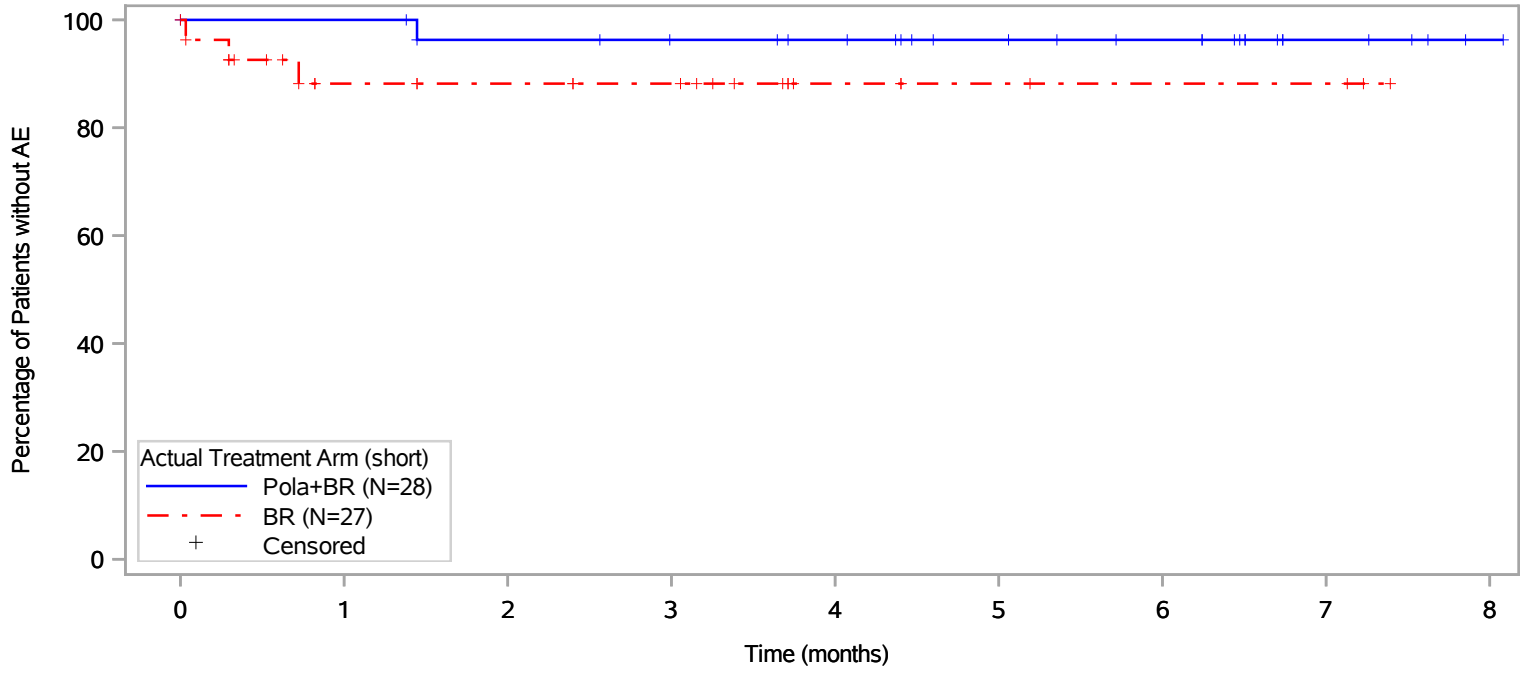
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	5	1
BR (N=27)	27	18	16	14	6	4	3	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	20	21	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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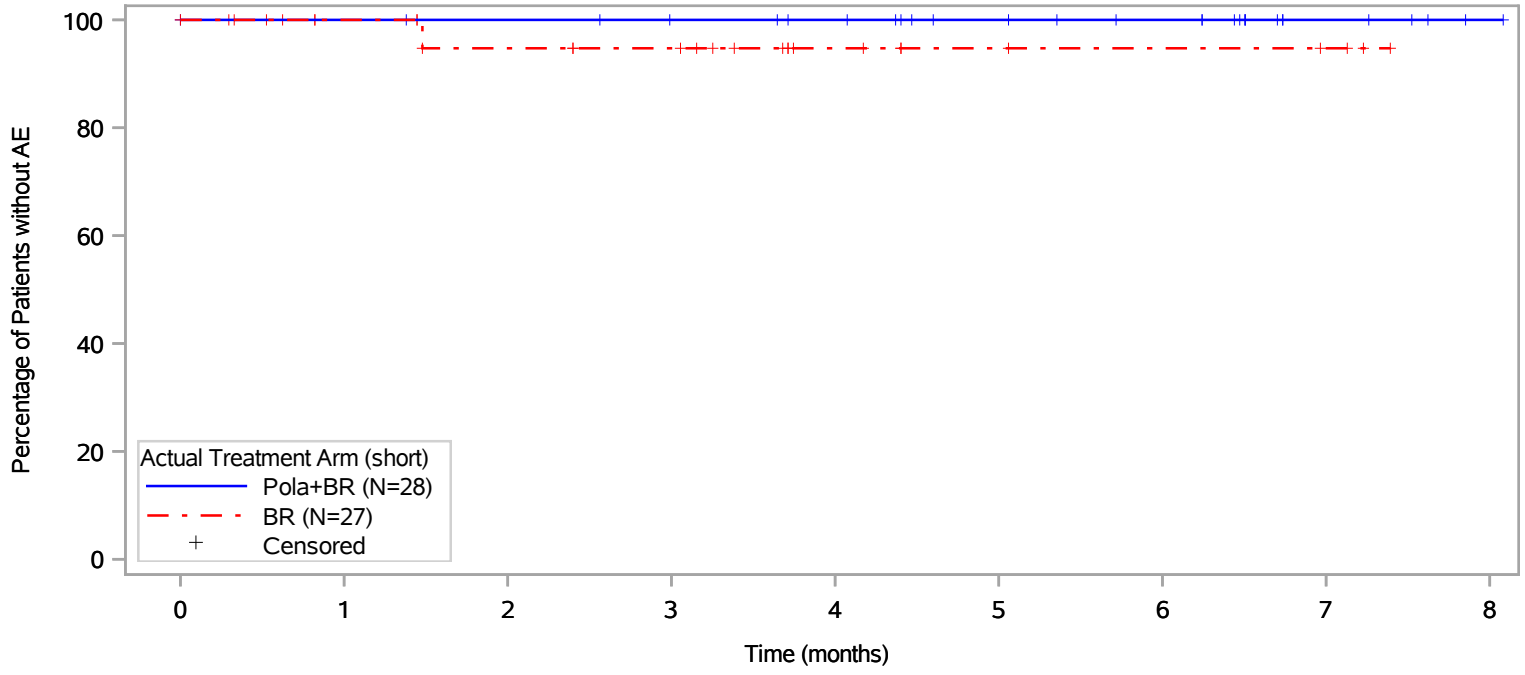
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH ERYTHEMATOUS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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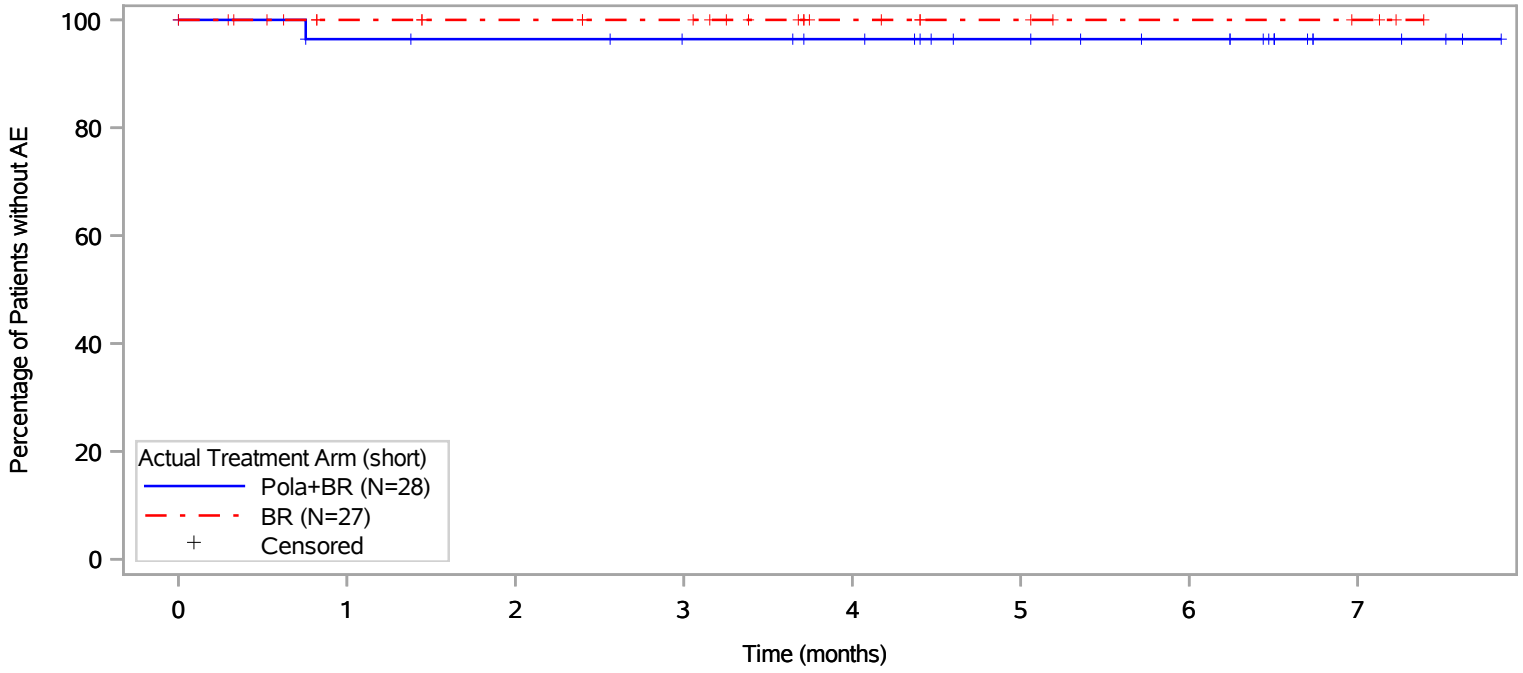
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH MACULO-PAPULAR

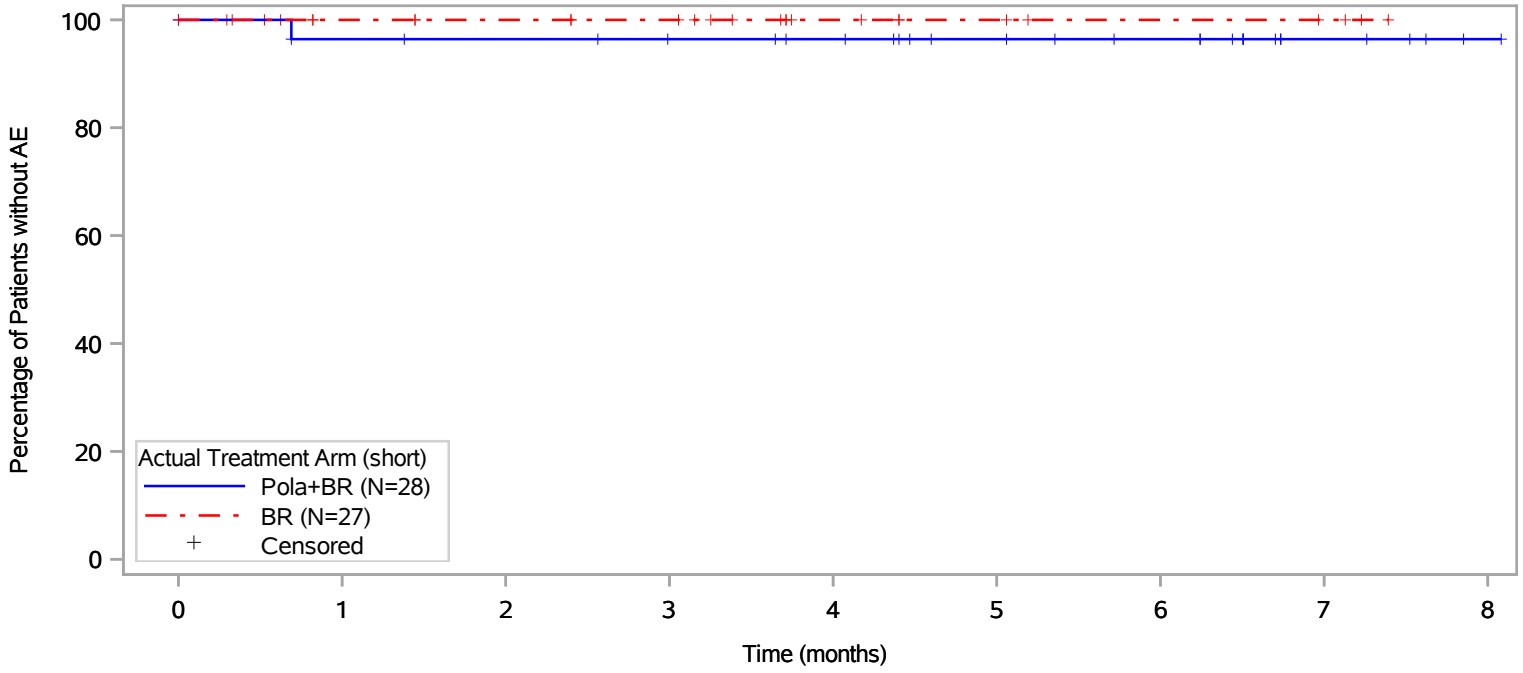


Patients at risk								
Pola+BR (N=28)	28	27	26	24	22	17	14	4
BR (N=27)	27	21	19	17	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	10	13	23
BR (N=27)	0	6	8	10	18	21	23	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, URTICARIA

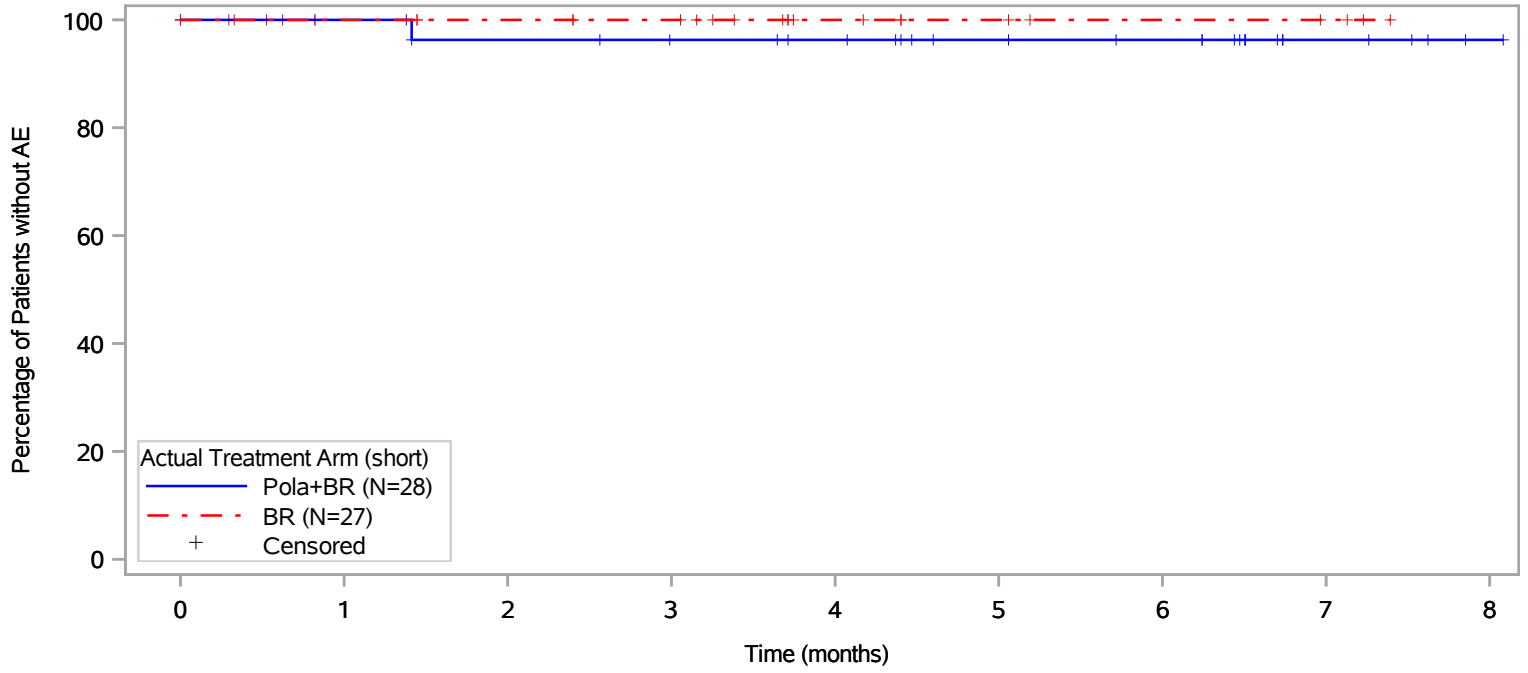


Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SURGICAL AND MEDICAL PROCEDURES, All



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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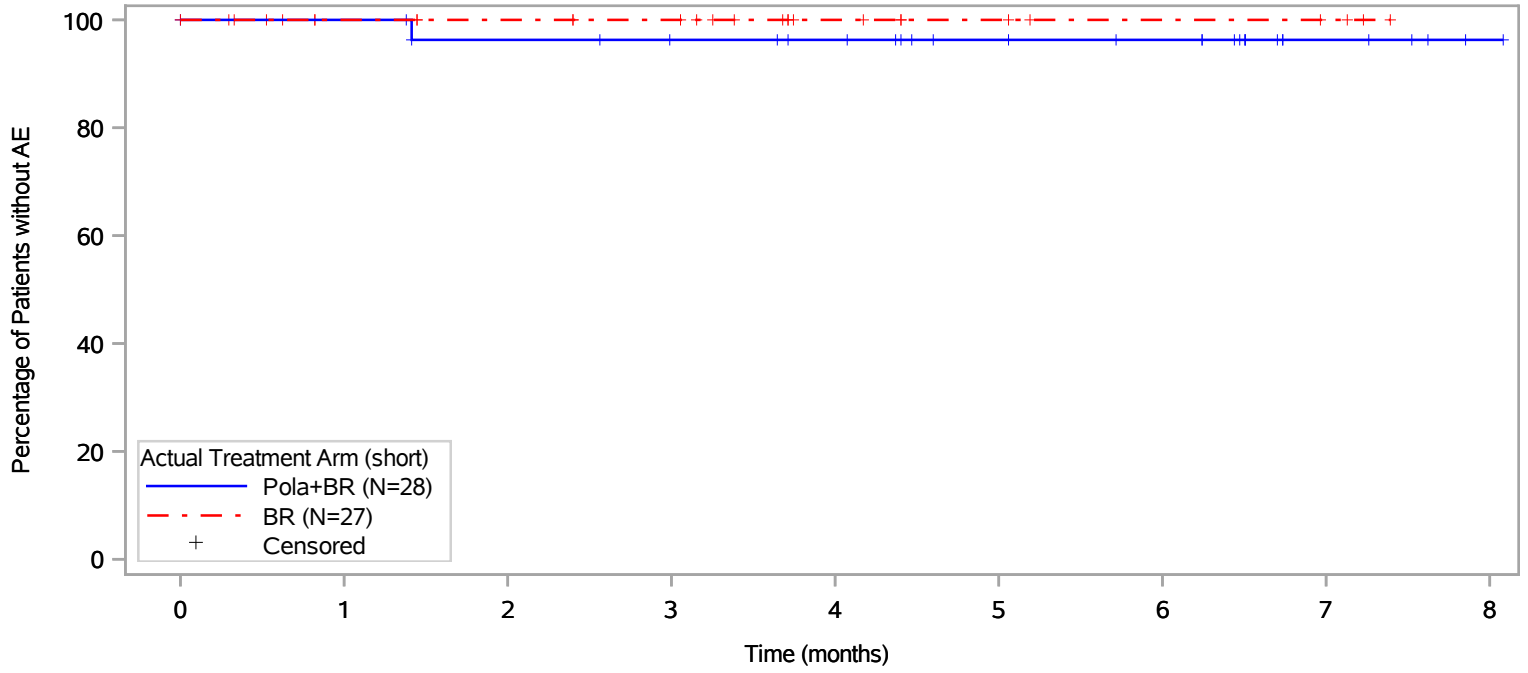
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SURGICAL AND MEDICAL PROCEDURES, SINUS OPERATION



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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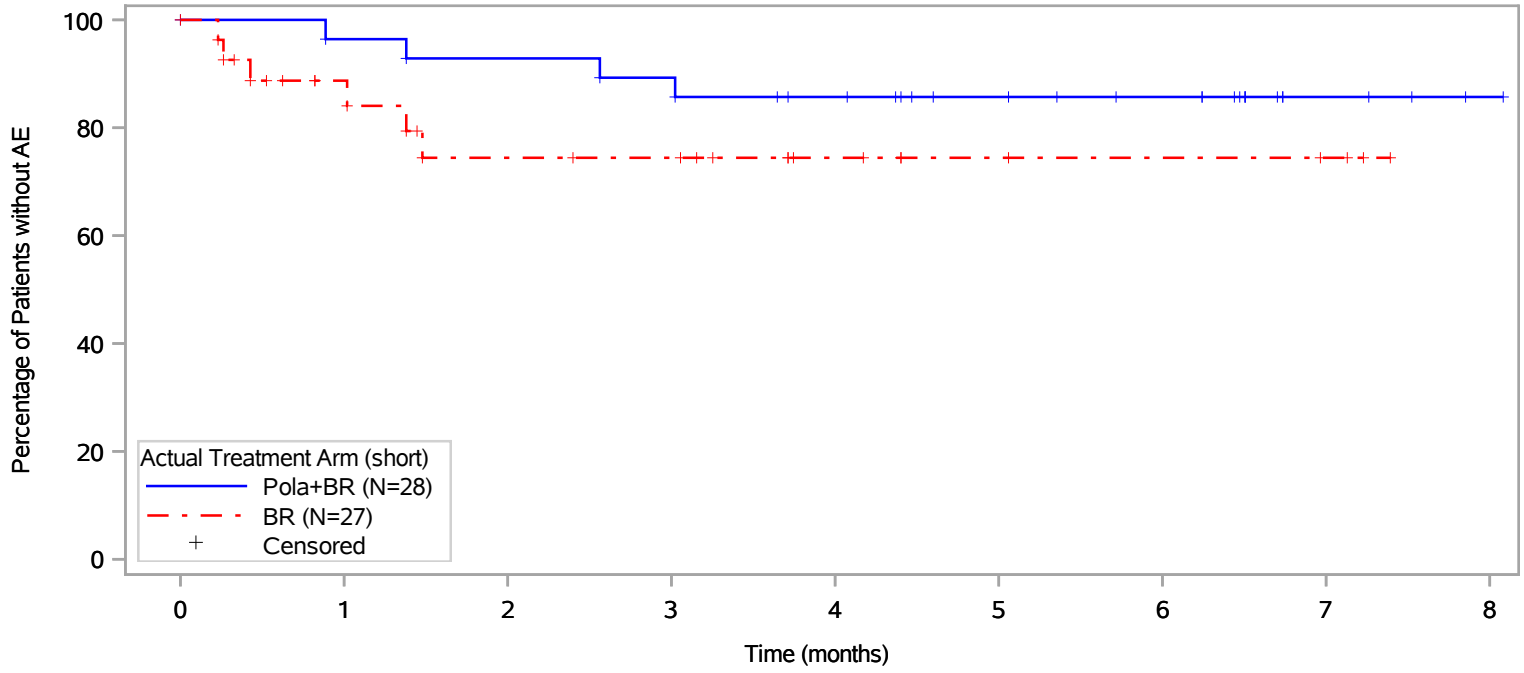
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	26	25	22	17	14	4	1
BR (N=27)	27	19	15	14	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	0	2	7	10	20	23
BR (N=27)	0	5	6	7	13	16	17	18	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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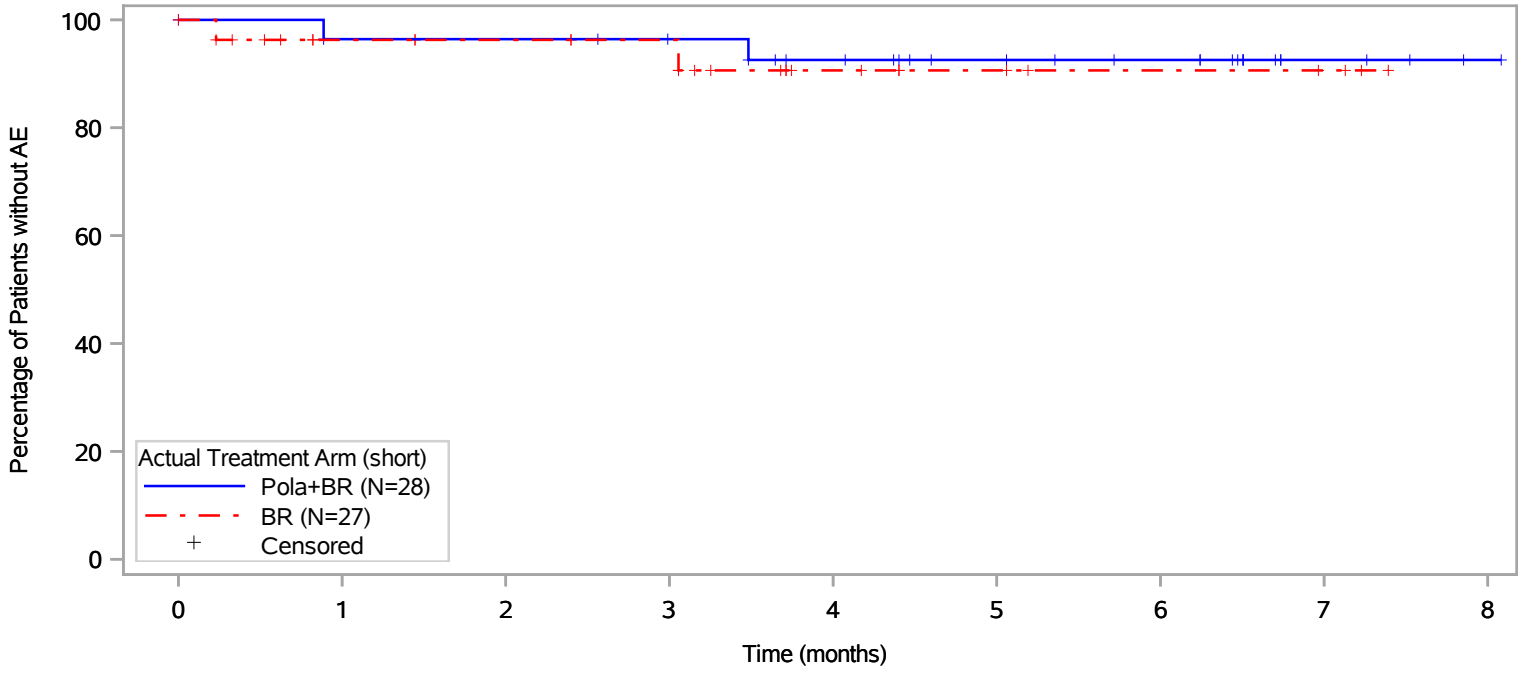
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DEEP VEIN THROMBOSIS



Patients at risk									
Pola+BR (N=28)	28	27	27	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	25
BR (N=27)	0	5	7	9	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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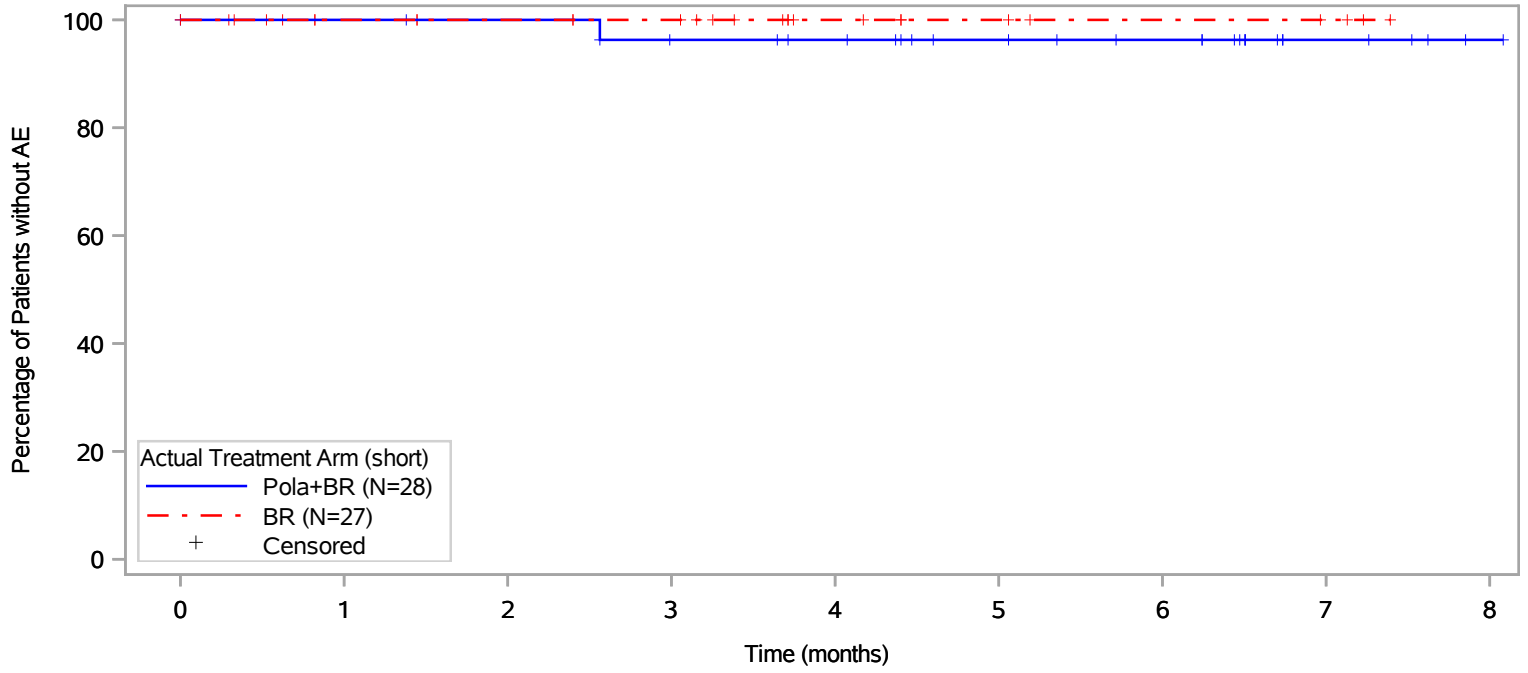
01DEC2022 21:22

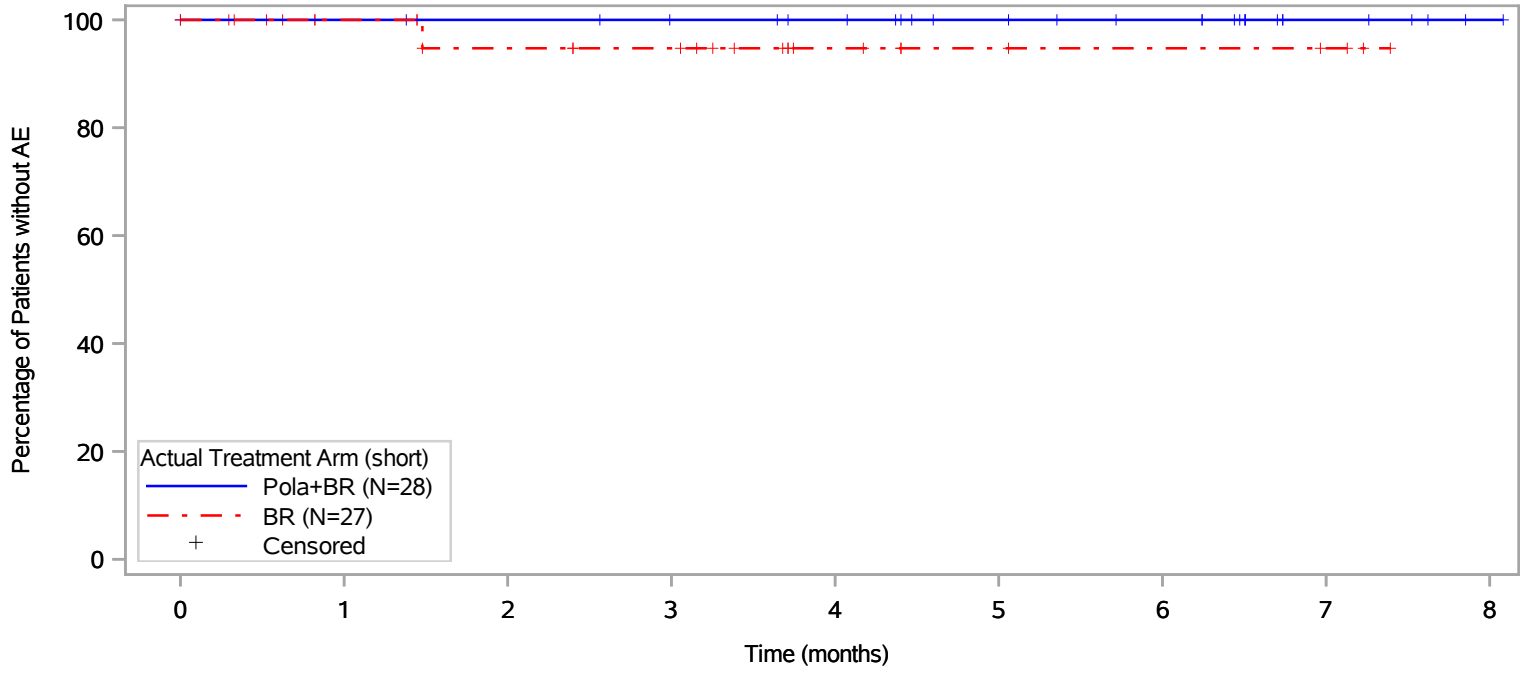
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DISTRIBUTIVE SHOCK



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, FLUSHING



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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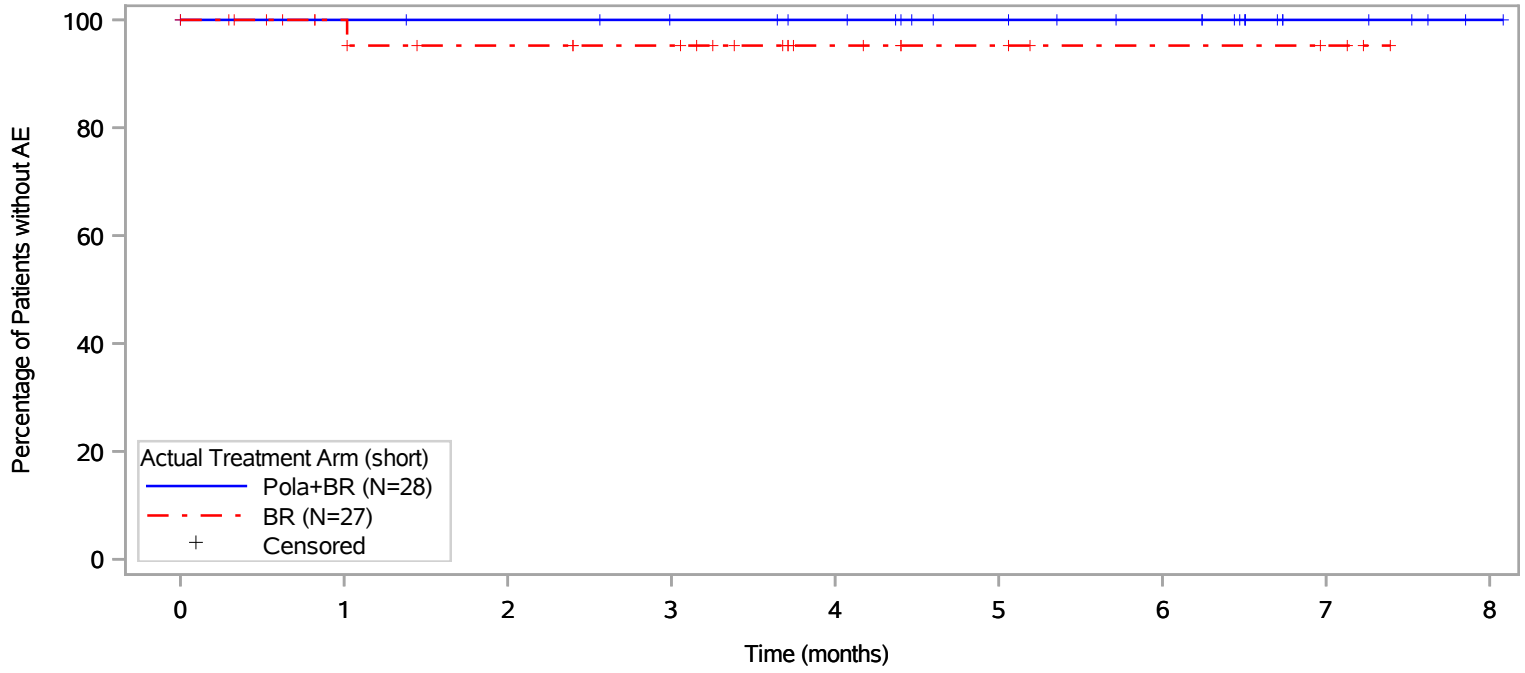
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HAEMATOMA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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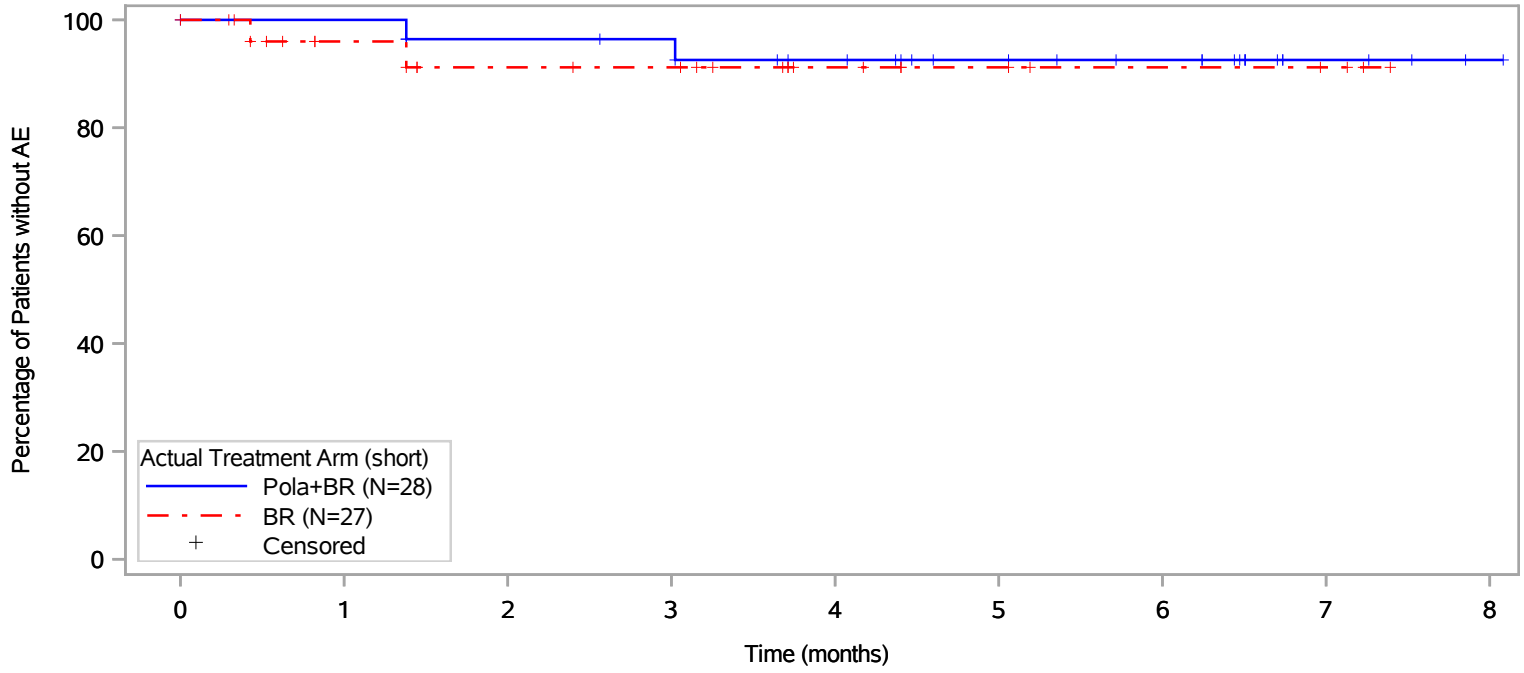
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION

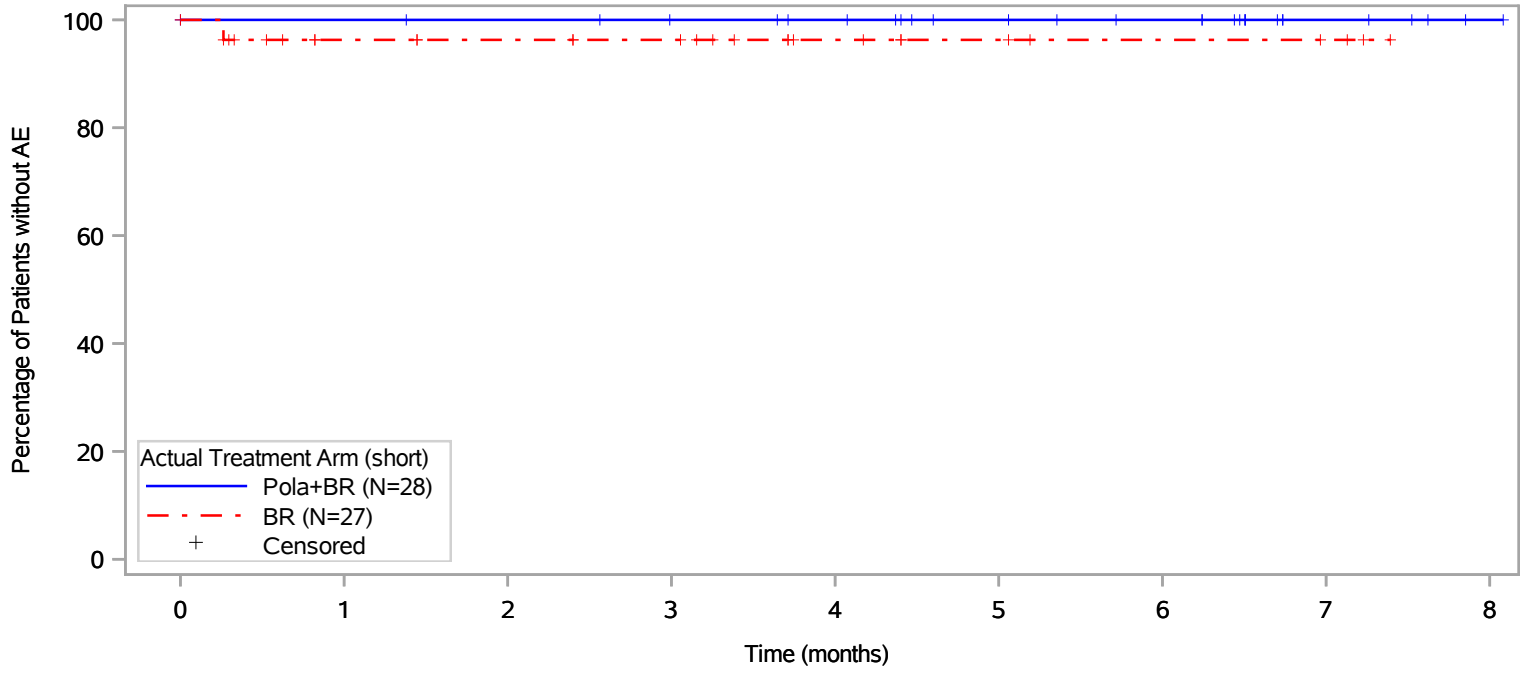


Patients at risk									
Pola+BR (N=28)	28	28	26	25	22	17	14	4	1
BR (N=27)	27	20	17	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	25
BR (N=27)	0	6	8	9	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, ORTHOSTATIC HYPOTENSION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			28	100.0	20	71.4	8	28.6	27	100.0	15	55.6	12	44.4	0.7353	1.12	0.57	2.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		28	100.0	7	25.0	21	75.0	27	100.0	5	18.5	22	81.5	0.9956	1.00	0.31	3.21		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		28	100.0	4	14.3	24	85.7	27	100.0	3	11.1	24	88.9	0.8199	1.22	0.22	6.74		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		28	100.0	3	10.7	25	89.3	27	100.0	2	7.4	25	92.6	0.8594	1.18	0.20	7.08		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		28	100.0	4	14.3	24	85.7	27	100.0	0	-	27	100.0	0.0548	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		28	100.0	13	46.4	15	53.6	27	100.0	8	29.6	19	70.4	0.4694	1.39	0.57	3.38		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		28	100.0	12	42.9	16	57.1	27	100.0	6	22.2	21	77.8	0.6455	1.26	0.47	3.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.9688	0.95	0.06	15.13		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FLUTTER		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	CARDIAC FAILURE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3261	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			28	100.0	9	32.1	19	67.9	27	100.0	4	14.8	23	85.2	0.6109	1.37	0.41	4.59		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.8010	1.36	0.12	15.25		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.4282	0.39	0.04	4.34		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.4708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4617	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ILEUS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.7714	0.75	0.10	5.39		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.7873	0.68	0.04	11.35		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3261	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			28	100.0	8	28.6	20	71.4	27	100.0	8	29.6	19	70.4	0.0964	0.39	0.13	1.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2162	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3447	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.7314	0.71	0.10	5.10		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INFECTIONS AND INFESTATIONS	SEPSIS		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.5978	0.48	0.03	7.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UROSEPSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			28	100.0	5	17.9	23	82.1	27	100.0	2	7.4	25	92.6	0.9450	0.94	0.15	5.81		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	HAEMOGLOBIN DECREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8761	0.80	0.05	12.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MORAXELLA TEST POSITIVE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.9364	1.11	0.09	12.86		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	TRANSAMINASES INCREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.3416	0.33	0.03	3.65		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			28	100.0	3	10.7	25	89.3	27	100.0	2	7.4	25	92.6	0.8107	1.24	0.21	7.46		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		28	100.0	3	10.7	25	89.3	27	100.0	1	3.7	26	96.3	0.4035	2.54	0.26	24.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8621	0.78	0.05	12.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8565	0.77	0.05	12.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8565	0.77	0.05	12.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			28	100.0	2	7.1	26	92.9	27	100.0	4	14.8	23	85.2	0.2333	0.34	0.05	2.16		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0652	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SYNCOPE		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8110	0.71	0.04	11.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.3884	0.36	0.03	4.03		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.0969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.4721	0.43	0.04	4.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.1291	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			28	100.0	4	14.3	24	85.7	27	100.0	0	-	27	100.0	0.0909	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4275	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

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

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 23:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	13	46.4	11	84.6	2	15.4	13	48.1	7	53.8	6	46.2	0.2649	1.72	0.66	4.48		Convergence criterion (GCONV=1E-8) satisfied.	0.2156
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	15	53.6	9	60.0	6	40.0	14	51.9	8	57.1	6	42.9	0.5788	0.76	0.29	2.02		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	13	46.4	4	30.8	9	69.2	13	48.1	3	23.1	10	76.9	0.8482	1.16	0.26	5.21		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	2	14.3	12	85.7	0.7536	0.73	0.10	5.22		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	2	15.4	11	84.6	0.5235	0.53	0.07	3.86		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.3124	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	2	15.4	11	84.6	0.9006	0.88	0.12	6.29		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	13	46.4	3	23.1	10	76.9	13	48.1	0	-	13	100.0	0.0833	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	13	46.4	7	53.8	6	46.2	13	48.1	5	38.5	8	61.5	0.5375	1.44	0.45	4.60		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	15	53.6	6	40.0	9	60.0	14	51.9	3	21.4	11	78.6	0.5768	1.48	0.37	5.99		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	13	46.4	6	46.2	7	53.8	13	48.1	4	30.8	9	69.2	0.8529	0.88	0.24	3.30		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	15	53.6	6	40.0	9	60.0	14	51.9	2	14.3	12	85.7	0.3837	2.01	0.40	9.98		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	13	46.4	5	38.5	8	61.5	13	48.1	1	7.7	12	92.3	0.1364	4.46	0.52	38.34		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	15	53.6	4	26.7	11	73.3	14	51.9	3	21.4	11	78.6	0.5184	0.59	0.12	2.97		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.6949	0.58	0.04	9.30		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	15	53.6	0	-	15	100.0	14	51.9	2	14.3	12	85.7	0.0963	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.4931	0.44	0.04	4.89		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.3879	0.36	0.03	4.07		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	15	53.6	7	46.7	8	53.3	14	51.9	6	42.9	8	57.1	0.1093	0.36	0.10	1.32		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.7833	0.67	0.04	11.38		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.8764	0.80	0.05	13.04		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.5636	0.44	0.03	7.45		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	13	46.4	3	23.1	10	76.9	13	48.1	0	-	13	100.0	0.3411	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	15	53.6	2	13.3	13	86.7	14	51.9	2	14.3	12	85.7	0.3812	0.36	0.03	3.97		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.7628	0.65	0.04	10.47		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	2	14.3	12	85.7	0.0692	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	13	46.4	2	15.4	11	84.6	13	48.1	2	15.4	11	84.6	0.9447	0.93	0.13	6.63		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	1	7.7	12	92.3	0.5807	1.94	0.18	21.44		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.2123	0.22	0.02	2.81		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	2	14.3	12	85.7	0.6864	0.55	0.03	10.01		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.8635	0.78	0.05	12.57		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	2	15.4	11	84.6	0.0816	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	13	46.4	0	-	13	100.0	13	48.1	2	15.4	11	84.6	0.0816	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	2	14.3	12	85.7	0.4131	0.38	0.03	4.22		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	15	53.6	0	-	15	100.0	14	51.9	2	14.3	12	85.7	0.1104	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.2193	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2525	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 23:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	15	53.6	11	73.3	4	26.7	18	66.7	10	55.6	8	44.4	0.9165	1.05	0.44	2.52		Convergence criterion (GCONV=1E-8) satisfied.	0.7915
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	13	46.4	9	69.2	4	30.8	9	33.3	5	55.6	4	44.4	0.6572	1.28	0.42	3.90		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	15	53.6	3	20.0	12	80.0	18	66.7	3	16.7	15	83.3	0.7254	0.75	0.14	3.86		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	13	46.4	4	30.8	9	69.2	9	33.3	2	22.2	7	77.8	0.7645	1.30	0.24	7.09		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	2	11.1	16	88.9	0.7742	1.42	0.13	16.03		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.9353	1.10	0.10	12.20		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.4958	0.44	0.04	4.91		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2491	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	15	53.6	3	20.0	12	80.0	18	66.7	0	-	18	100.0	0.0733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	15	53.6	5	33.3	10	66.7	18	66.7	6	33.3	12	66.7	0.4937	0.66	0.20	2.20		Convergence criterion (GCONV=1E-8) satisfied.	0.0773
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	13	46.4	8	61.5	5	38.5	9	33.3	2	22.2	7	77.8	0.0898	3.54	0.75	16.76		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	15	53.6	7	46.7	8	53.3	18	66.7	3	16.7	15	83.3	0.3305	1.94	0.50	7.56		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	13	46.4	5	38.5	8	61.5	9	33.3	3	33.3	6	66.7	0.5997	0.67	0.15	3.02		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9134	1.17	0.07	18.65		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	15	53.6	6	40.0	9	60.0	18	66.7	3	16.7	15	83.3	0.8144	1.19	0.28	5.11		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	13	46.4	3	23.1	10	76.9	9	33.3	1	11.1	8	88.9	0.6244	1.75	0.18	16.90		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.7406	1.50	0.13	17.02		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.7613	0.65	0.04	10.45		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.6287	1.81	0.16	20.74		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.8386	0.74	0.04	12.88		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	15	53.6	5	33.3	10	66.7	18	66.7	5	27.8	13	72.2	0.3381	0.50	0.12	2.13		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	13	46.4	3	23.1	10	76.9	9	33.3	3	33.3	6	66.7	0.1774	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3017	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2253	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.6666	0.55	0.03	8.94		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	15	53.6	3	20.0	12	80.0	18	66.7	1	5.6	17	94.4	0.6479	1.74	0.16	19.17		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.6028	0.48	0.03	8.05		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3352	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.5706	0.45	0.03	7.48		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.8583	0.78	0.05	12.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9372	0.89	0.06	14.36		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.7870	1.39	0.13	15.34		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.7870	1.39	0.13	15.34		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9372	0.89	0.06	14.36		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	4	22.2	14	77.8	0.0690	0.14	0.01	1.50		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9885	0.98	0.06	15.89		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.8160	0.72	0.05	11.53		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.2090	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2736	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2736	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 23:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	32.1	4	44.4	5	55.6	13	48.1	5	38.5	8	61.5	0.6731	0.75	0.20	2.84		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	67.9	16	84.2	3	15.8	14	51.9	10	71.4	4	28.6	0.7485	1.14	0.51	2.58		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	5	35.7	9	64.3	0.5651	0.71	0.21	2.33		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	2	14.3	12	85.7	0.8479	0.85	0.15	4.72		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	2	14.3	12	85.7	0.9205	0.91	0.15	5.50		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	0	-	14	100.0	0.0880	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	32.1	2	22.2	7	77.8	13	48.1	3	23.1	10	76.9	0.6746	0.68	0.11	4.18		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	19	67.9	11	57.9	8	42.1	14	51.9	5	35.7	9	64.3	0.4091	1.57	0.54	4.57		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	32.1	2	22.2	7	77.8	13	48.1	1	7.7	12	92.3	0.4861	2.29	0.21	25.40		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	67.9	10	52.6	9	47.4	14	51.9	5	35.7	9	64.3	0.8079	0.87	0.29	2.62		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	9	32.1	3	33.3	6	66.7	13	48.1	2	15.4	11	84.6	0.6289	1.55	0.26	9.40		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	2	14.3	12	85.7	0.8137	1.22	0.23	6.60		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.3339	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.8671	1.27	0.08	20.38		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1693	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	2	14.3	12	85.7	0.2007	0.23	0.02	2.65		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.5545	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	32.1	4	44.4	5	55.6	13	48.1	6	46.2	7	53.8	0.1287	0.30	0.06	1.54		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	2	14.3	12	85.7	0.6716	0.68	0.11	4.18		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4081	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.9301	1.13	0.07	18.50		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.4504	0.35	0.02	5.89		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	67.9	5	26.3	14	73.7	14	51.9	1	7.1	13	92.9	0.7779	1.40	0.14	14.38		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7508	0.64	0.04	10.30		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.8125	0.74	0.06	9.17		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.6991	0.58	0.04	9.32		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	2	14.3	12	85.7	0.6451	0.63	0.09	4.51		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.8167	1.33	0.12	14.66		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.6937	0.58	0.04	9.24		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7497	0.64	0.04	10.22		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7497	0.64	0.04	10.22		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	2	15.4	11	84.6	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	2	14.3	12	85.7	0.1050	0.14	0.01	1.94		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.0190	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.6878	0.57	0.04	9.12		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	2	14.3	12	85.7	0.2412	0.26	0.02	2.92		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	2	14.3	12	85.7	0.0502	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.8671	1.27	0.08	20.38		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	0	-	14	100.0	0.1310	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2854	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 23:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	20	71.4	13	65.0	7	35.0	18	66.7	11	61.1	7	38.9	0.5122	0.76	0.33	1.73		Convergence criterion (GCONV=1E-8) satisfied.	0.0686
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	8	28.6	7	87.5	1	12.5	9	33.3	4	44.4	5	55.6	0.0852	2.91	0.82	10.33		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	20	71.4	4	20.0	16	80.0	18	66.7	5	27.8	13	72.2	0.3160	0.51	0.13	1.95		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	8	28.6	3	37.5	5	62.5	9	33.3	0	-	9	100.0	0.1069	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	3	16.7	15	83.3	0.5647	0.56	0.08	4.05		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2079	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	20	71.4	3	15.0	17	85.0	18	66.7	2	11.1	16	88.9	0.8986	1.12	0.19	6.76		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	20	71.4	3	15.0	17	85.0	18	66.7	0	-	18	100.0	0.1050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	20	71.4	8	40.0	12	60.0	18	66.7	6	33.3	12	66.7	0.9469	0.96	0.33	2.83		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	8	28.6	5	62.5	3	37.5	9	33.3	2	22.2	7	77.8	0.1940	2.86	0.55	15.02		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	20	71.4	7	35.0	13	65.0	18	66.7	5	27.8	13	72.2	0.6025	0.73	0.22	2.41		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	8	28.6	5	62.5	3	37.5	9	33.3	1	11.1	8	88.9	0.1611	4.12	0.48	35.33		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	2	22.2	7	77.8	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	20	71.4	7	35.0	13	65.0	18	66.7	4	22.2	14	77.8	0.9573	0.97	0.27	3.48		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2263	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8877	0.82	0.05	13.10		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.4114	0.38	0.03	4.21		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8845	0.81	0.05	13.06		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8774	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8774	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	20	71.4	8	40.0	12	60.0	18	66.7	5	27.8	13	72.2	0.4338	0.61	0.17	2.14		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	8	28.6	0	-	8	100.0	9	33.3	3	33.3	6	66.7	0.0488	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2850	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	2	11.1	16	88.9	0.6467	0.63	0.09	4.56		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	20	71.4	3	15.0	17	85.0	18	66.7	2	11.1	16	88.9	0.7381	0.72	0.10	5.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8497	0.76	0.05	12.34		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8191	0.72	0.05	11.59		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.3271	0.32	0.03	3.54		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.4111	0.38	0.03	4.19		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.1601	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8526	0.77	0.05	12.30		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.1601	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8684	0.79	0.05	12.67		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8684	0.79	0.05	12.67		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	20	71.4	2	10.0	18	90.0	18	66.7	3	16.7	15	83.3	0.6182	0.60	0.08	4.54		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8055	0.71	0.04	11.32		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.9018	0.84	0.05	13.81		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.4690	0.42	0.04	4.67		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	20	71.4	0	-	20	100.0	18	66.7	2	11.1	16	88.9	0.1246	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	20	71.4	3	15.0	17	85.0	18	66.7	0	-	18	100.0	0.1526	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.2341	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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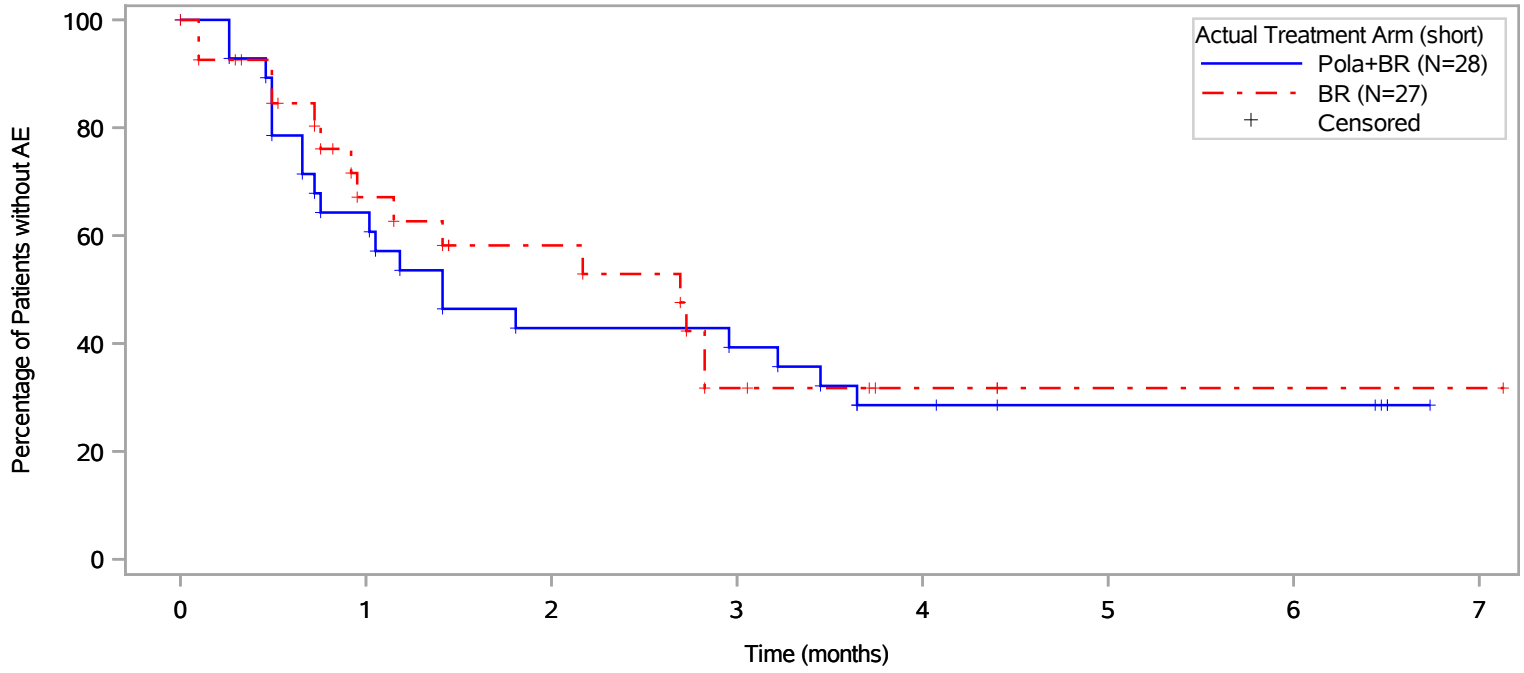
30NOV2022 23:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk								
Pola+BR (N=28)	28	18	12	11	7	5	5	NE
BR (N=27)	27	15	11	6	3	1	1	1
Patients censored								
Pola+BR (N=28)	0	0	0	0	1	3	3	NE
BR (N=27)	0	4	6	6	9	11	11	11

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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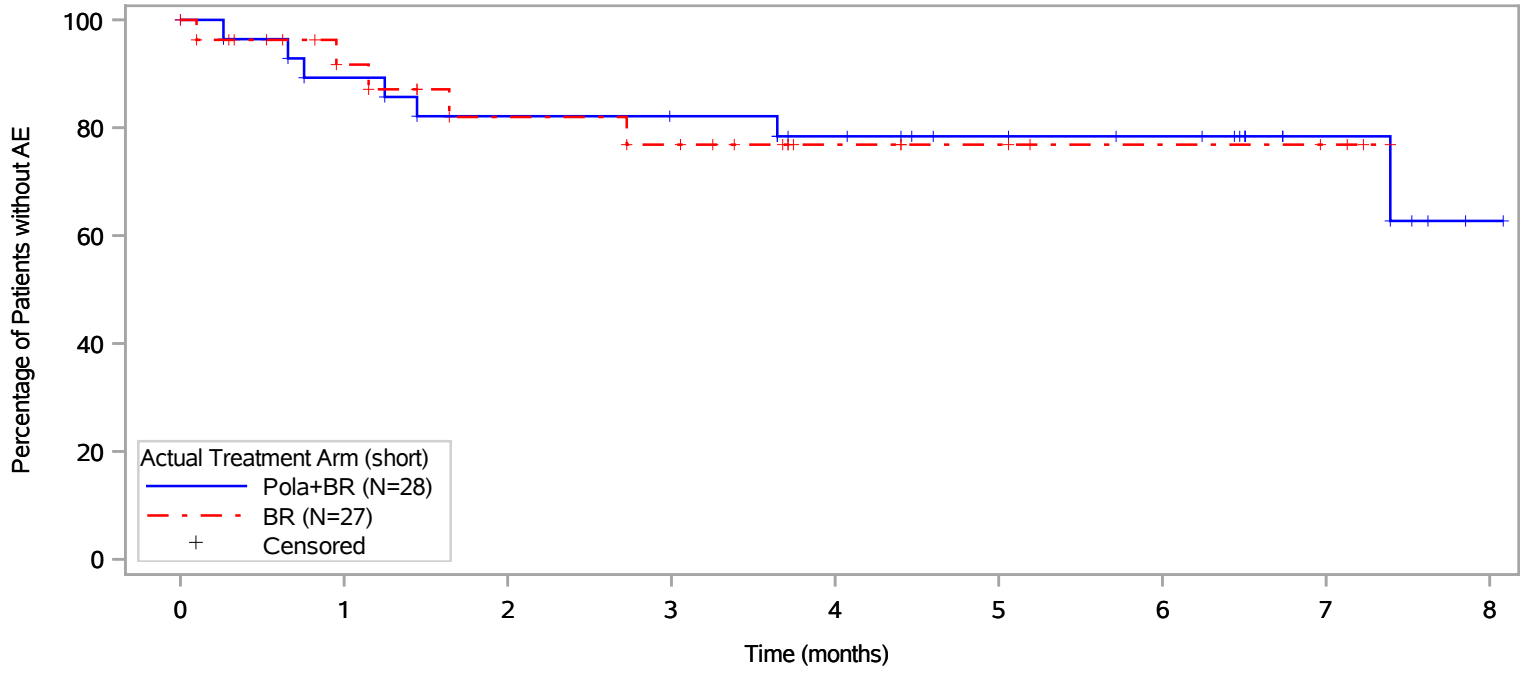
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk									
Pola+BR (N=28)	28	25	23	22	19	15	13	5	1
BR (N=27)	27	20	16	15	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	3	7	9	17	20
BR (N=27)	0	5	7	7	14	16	18	19	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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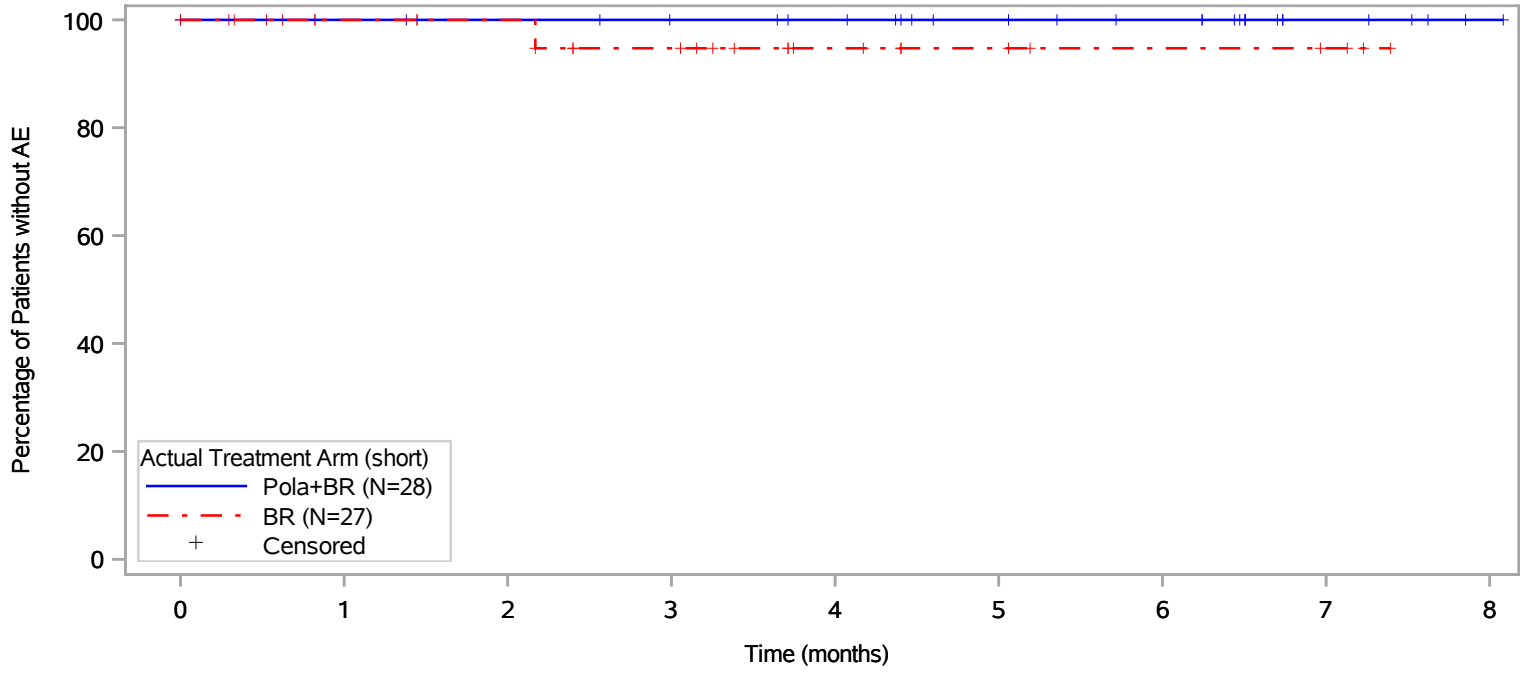
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE BONE MARROW APLASIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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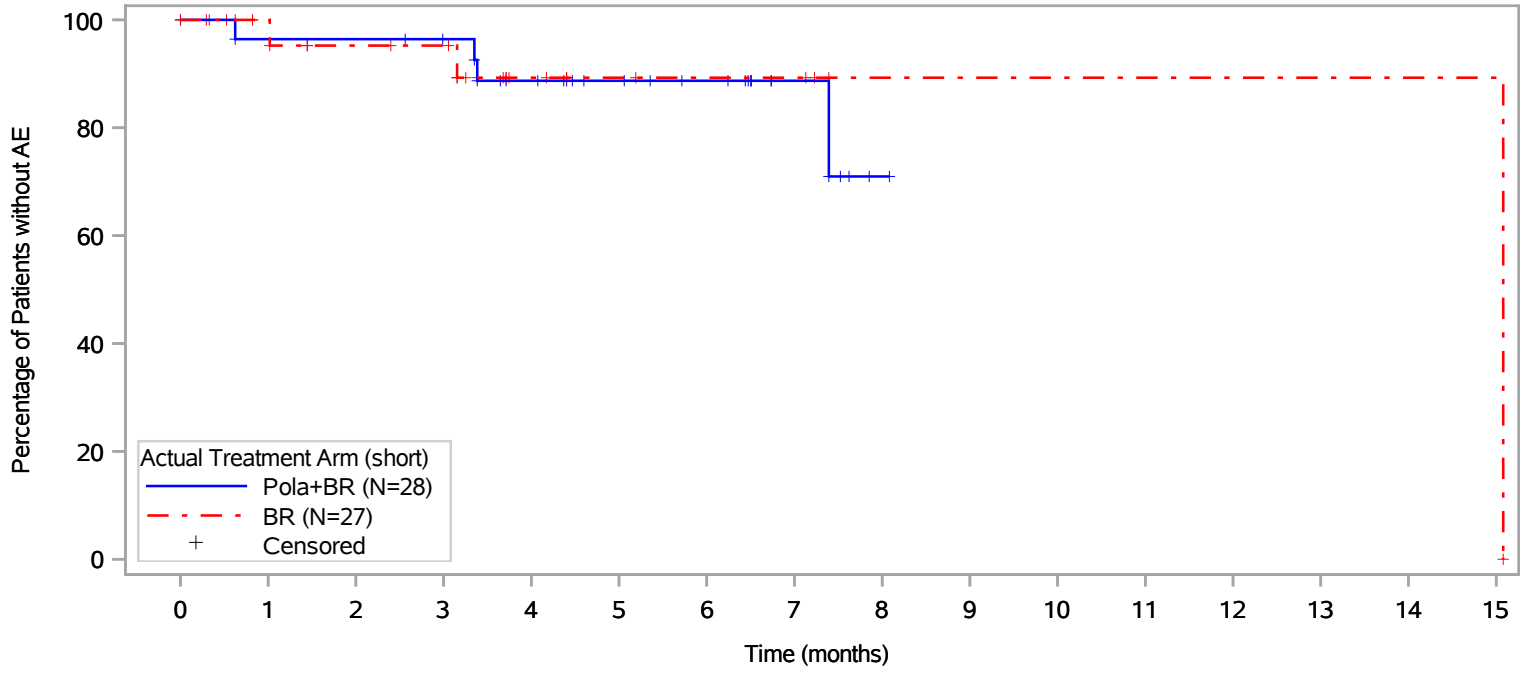
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk																
Pola+BR (N=28)	28	27	27	25	21	16	13	5	1	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	18	17	8	5	4	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=28)	0	0	0	2	4	9	12	20	23	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	9	17	20	21	21	24	24	24	24	24	24	24	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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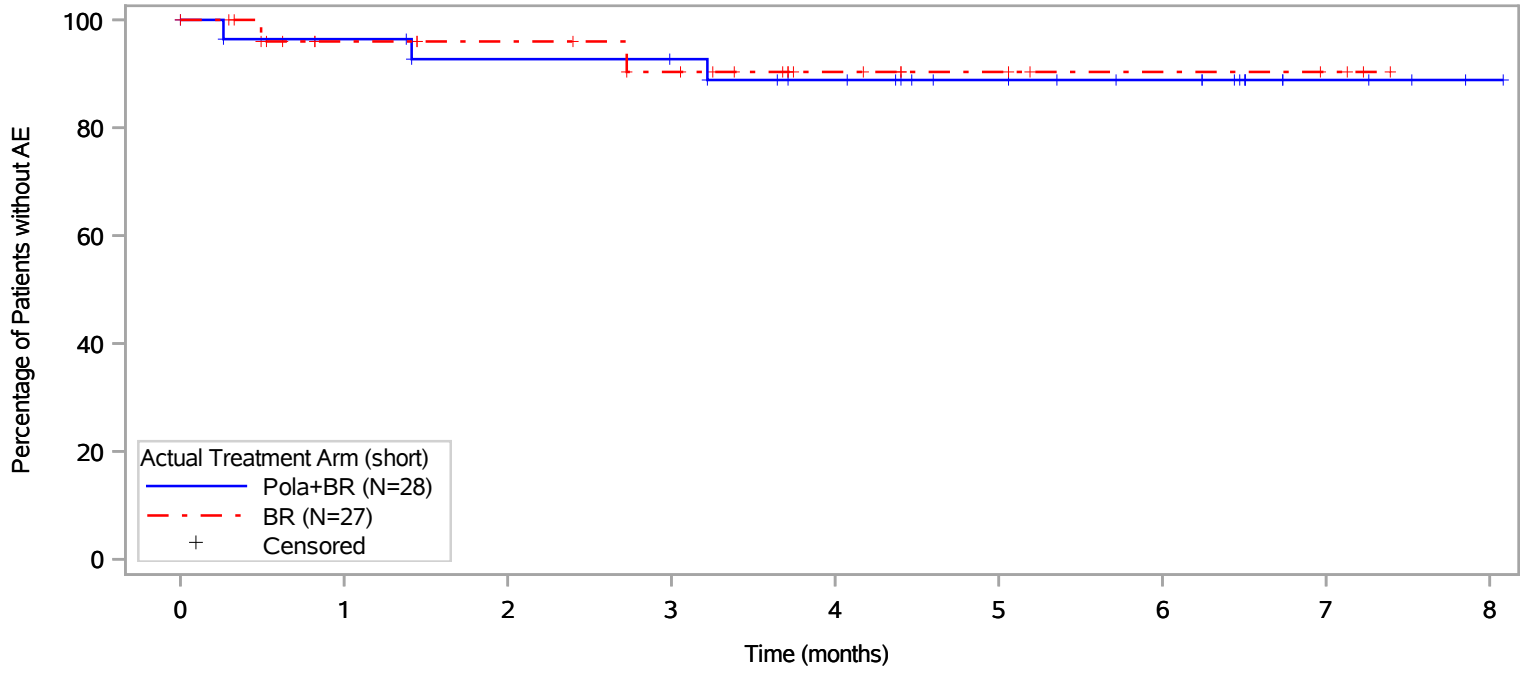
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA

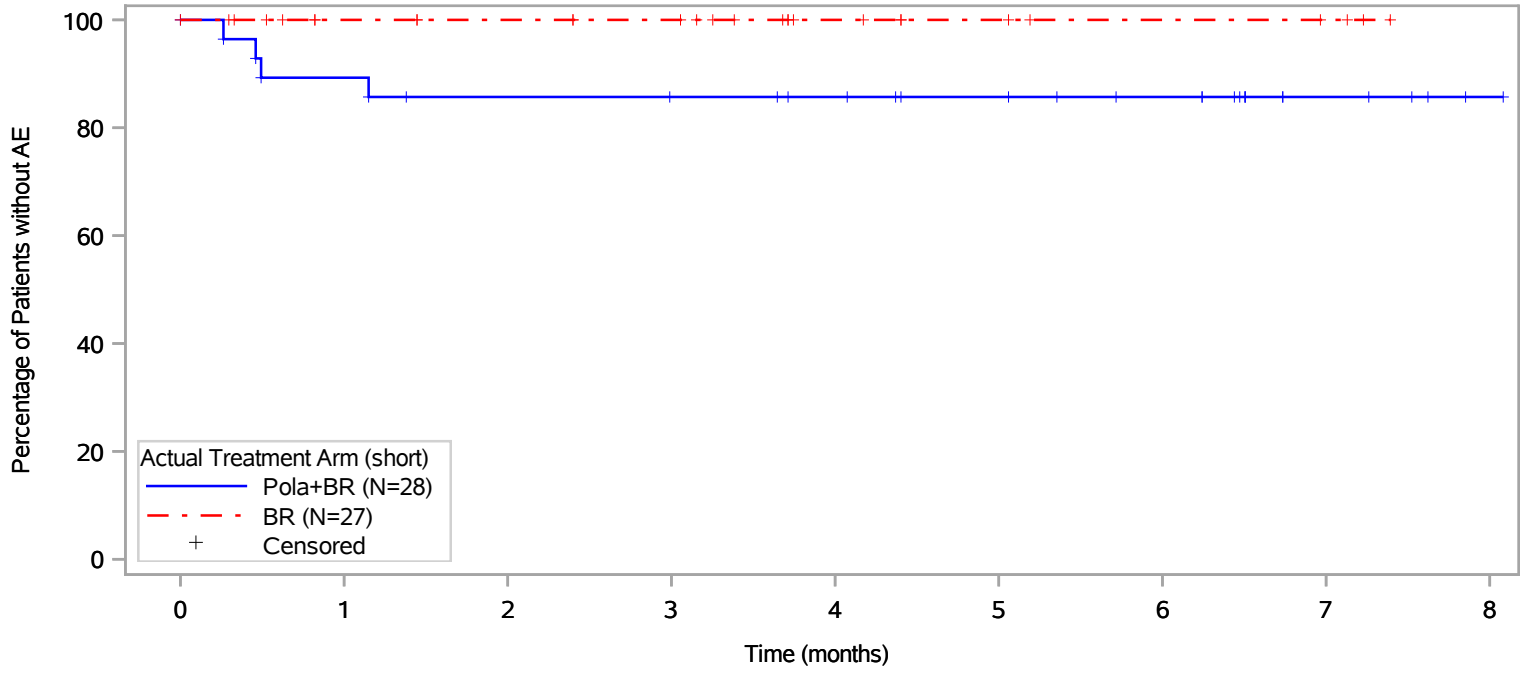


Patients at risk									
Pola+BR (N=28)	28	27	25	24	21	16	13	4	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	21	24
BR (N=27)	0	6	8	9	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA

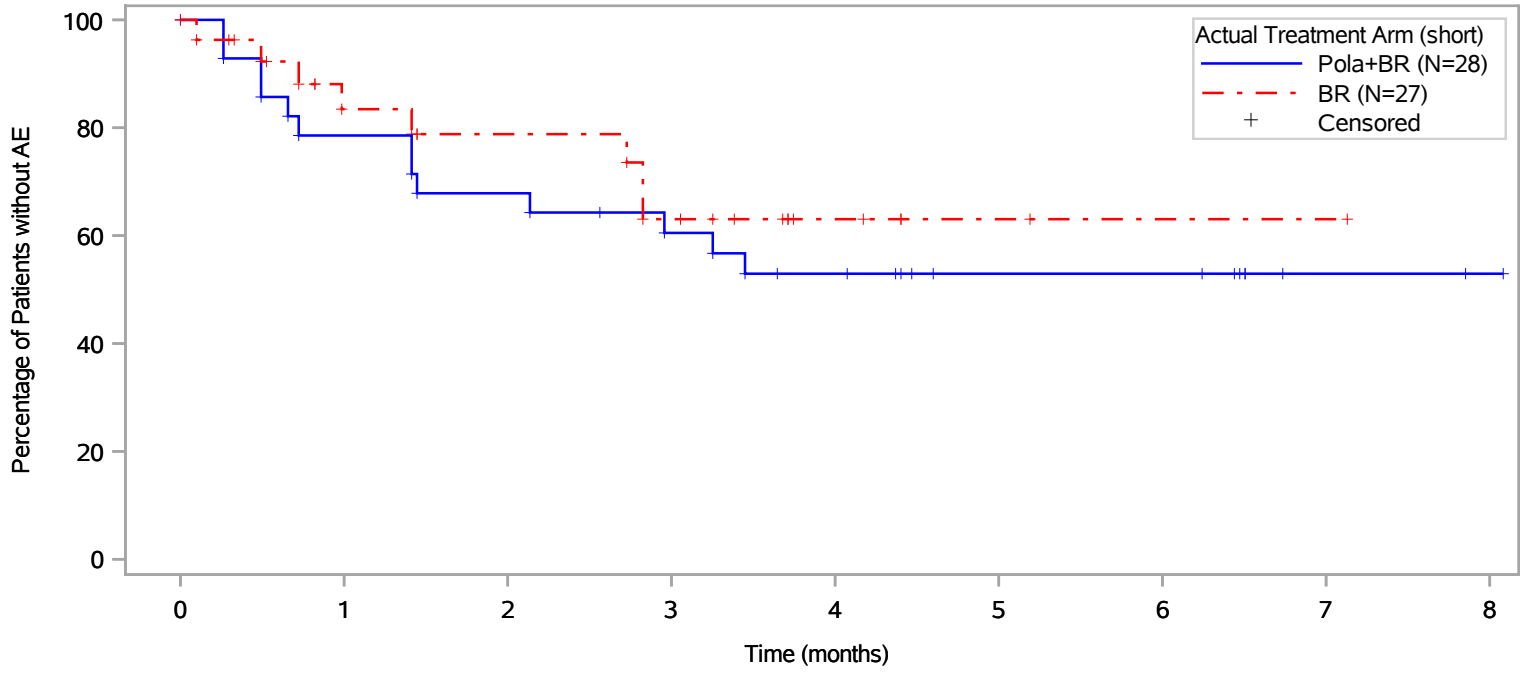


Patients at risk									
Pola+BR (N=28)	28	25	23	22	20	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	7	10	19	23
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk									
Pola+BR (N=28)	28	22	19	16	13	8	8	2	1
BR (N=27)	27	18	15	12	5	2	1	1	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	2	7	7	13	14
BR (N=27)	0	5	7	7	14	17	18	18	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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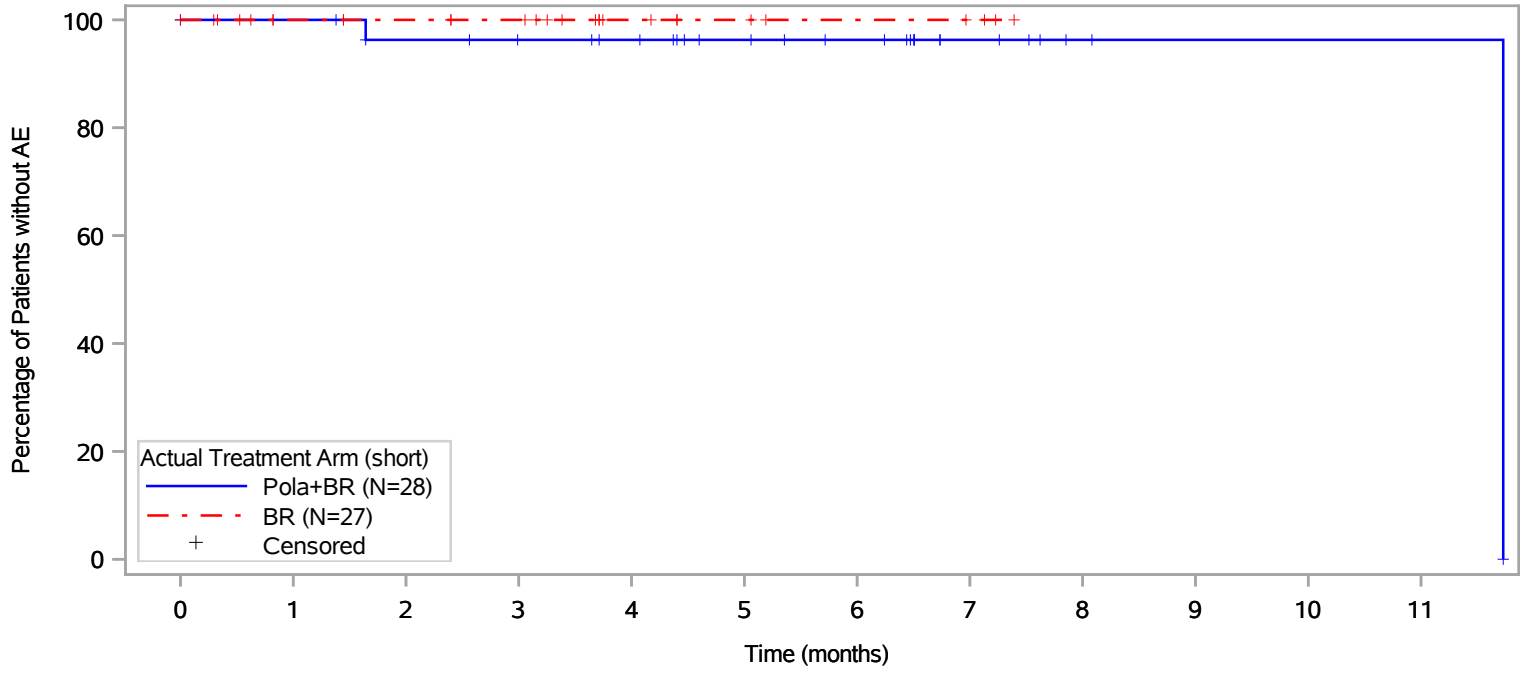
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA

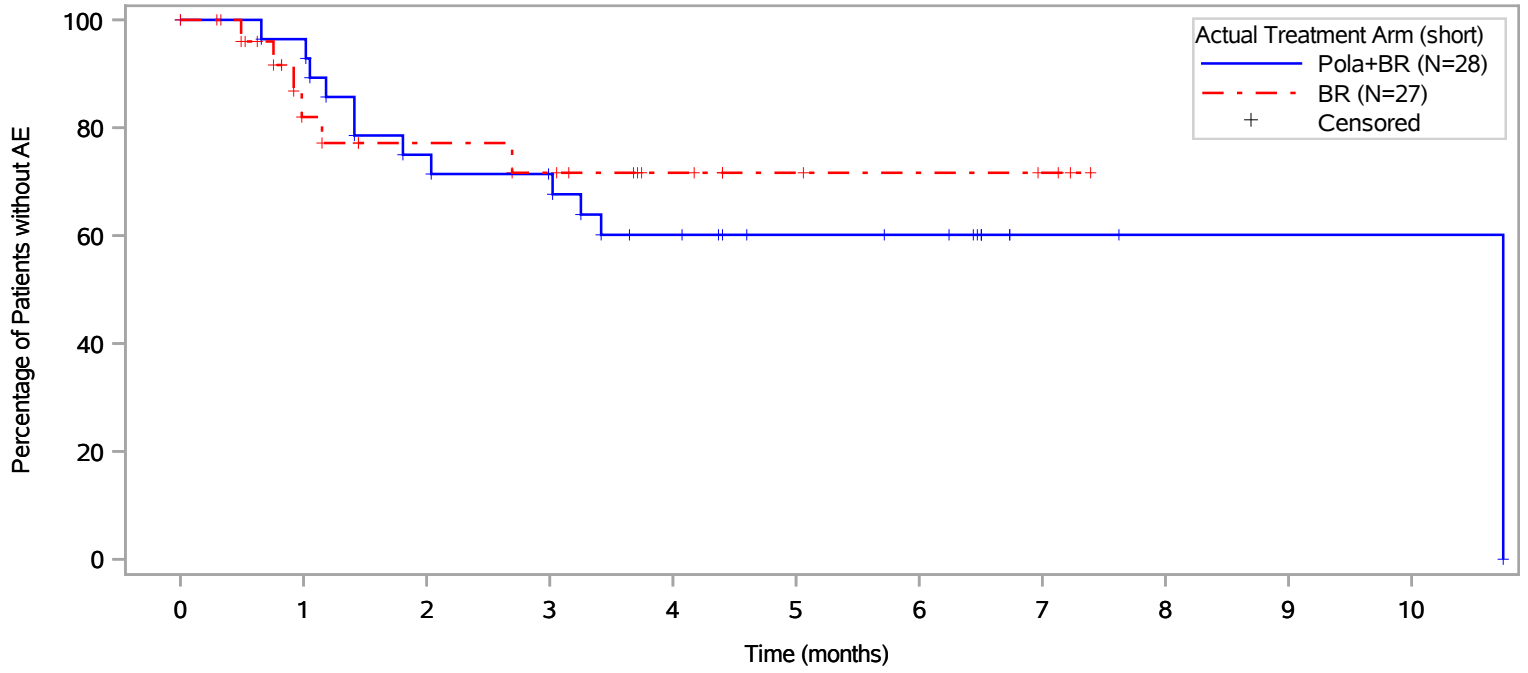


Patients at risk												
Pola+BR (N=28)	28	28	26	24	22	17	14	6	2	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=28)	0	0	1	3	5	10	13	21	25	26	26	26
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk											
Pola+BR (N=28)	28	27	21	19	15	11	10	2	1	1	1
BR (N=27)	27	17	14	13	8	5	4	3	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	0	0	1	2	6	7	15	16	16	16
BR (N=27)	0	6	8	8	13	16	17	18	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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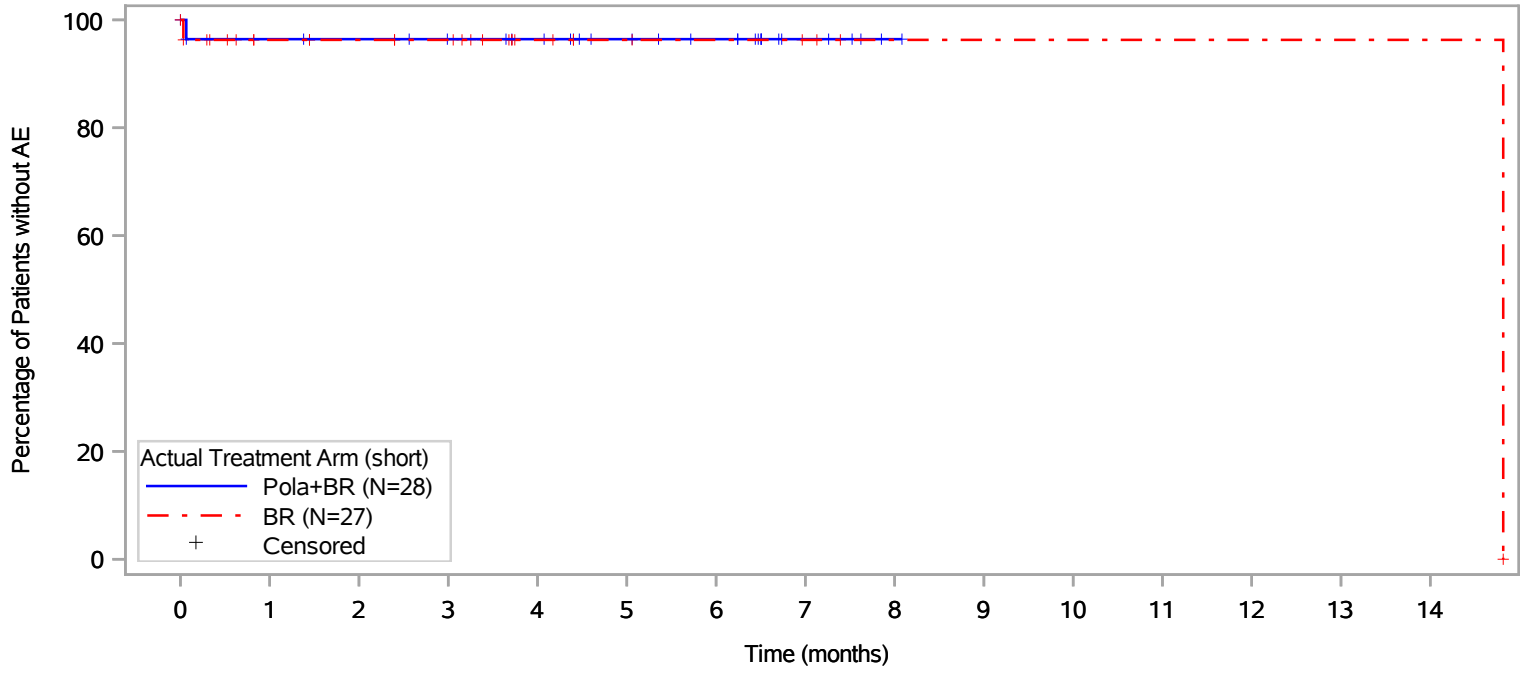
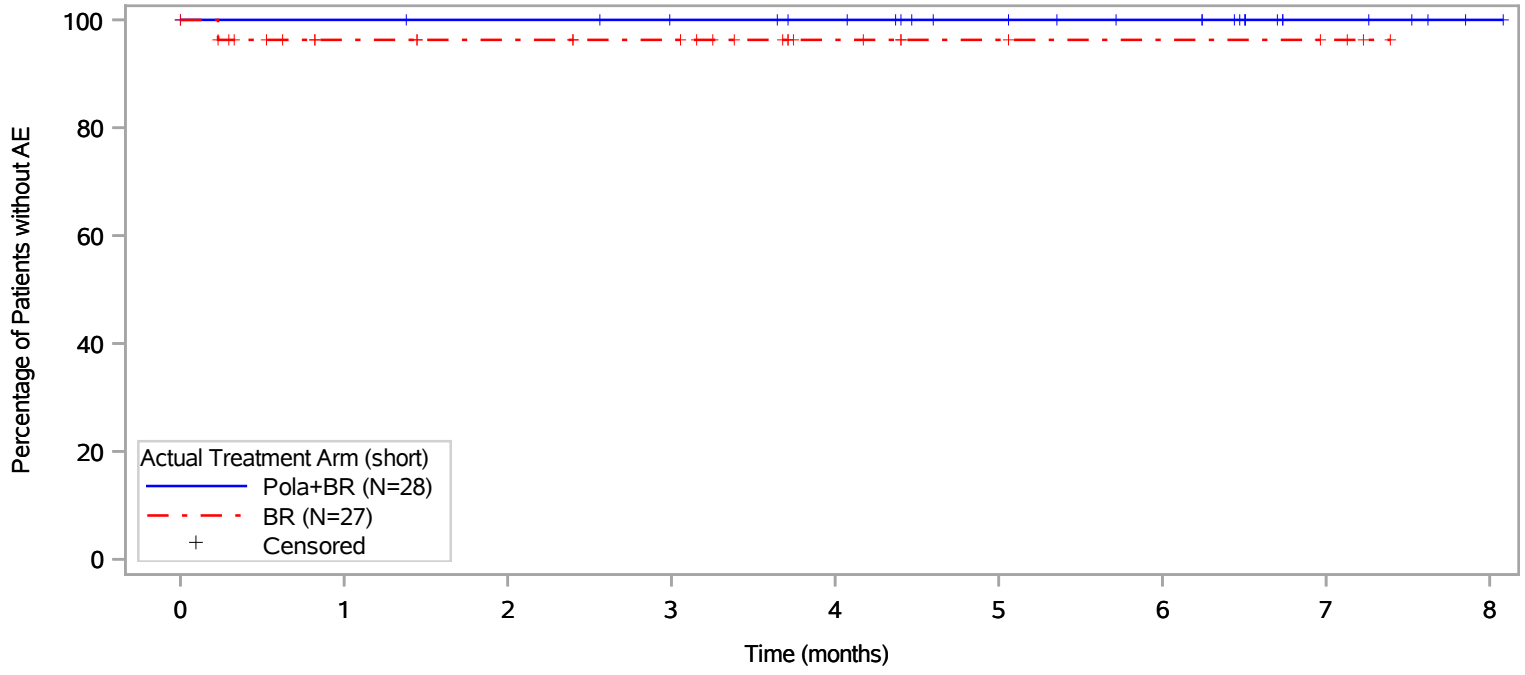
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk															
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1	NE	NE	NE	NE	NE	NE
BR (N=27)	27	20	18	16	8	5	4	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	22	23	25	25	25	25	25	25	25

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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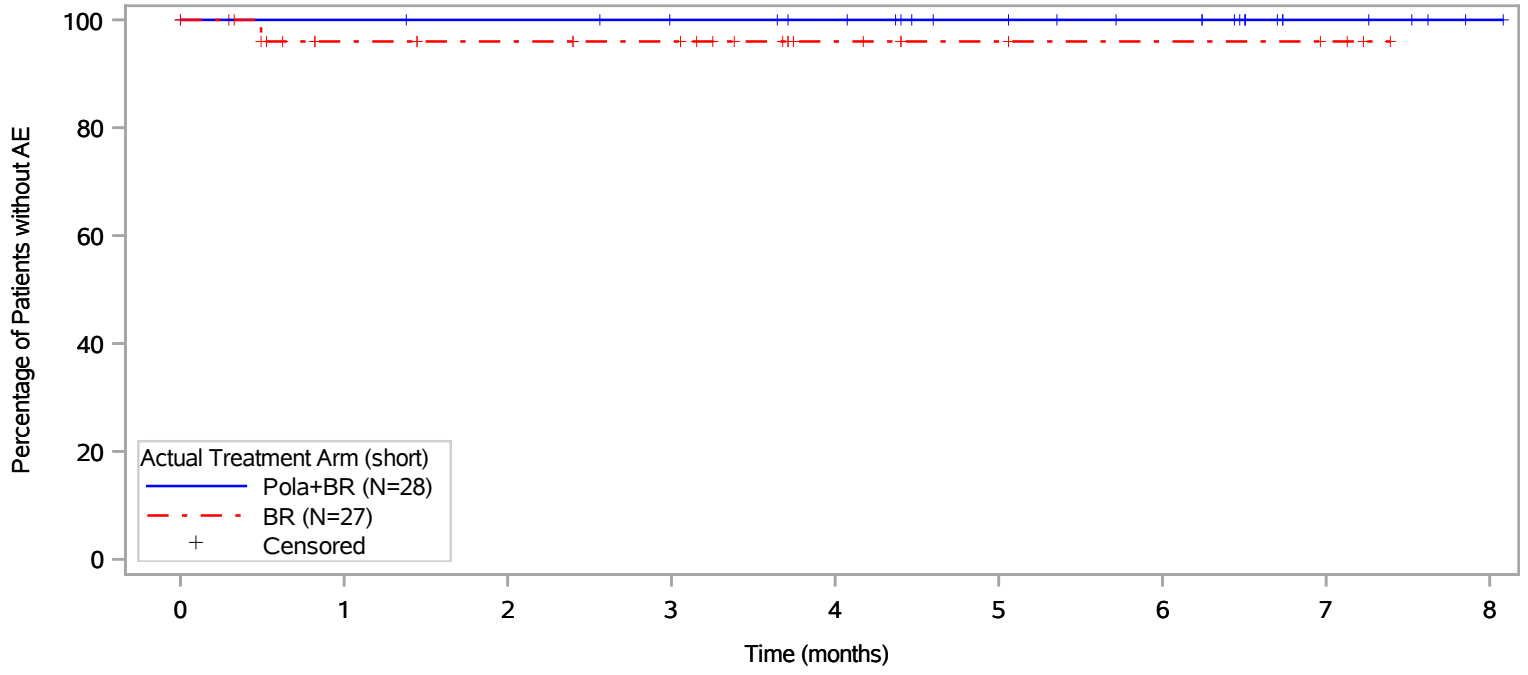
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FLUTTER



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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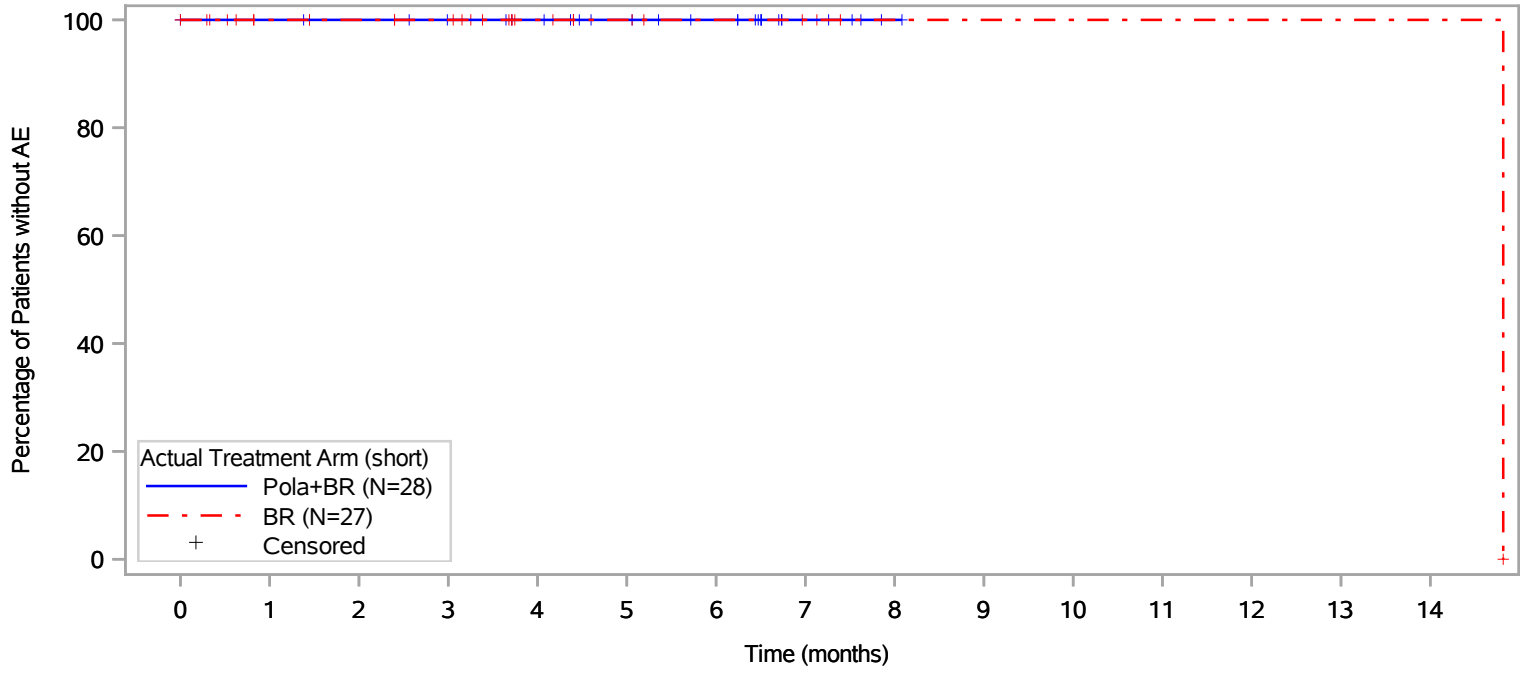
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, CARDIAC FAILURE



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	24	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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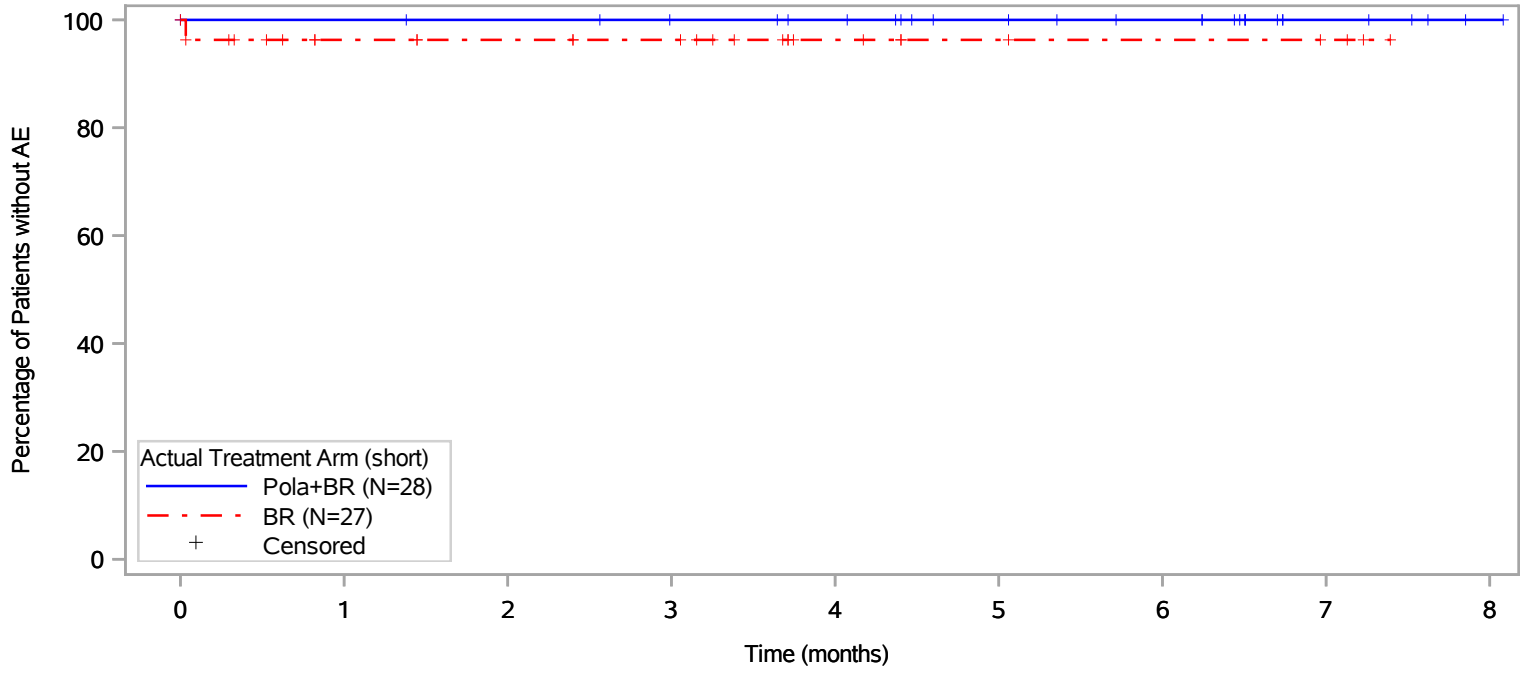
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SUPRAVENTRICULAR TACHYCARDIA

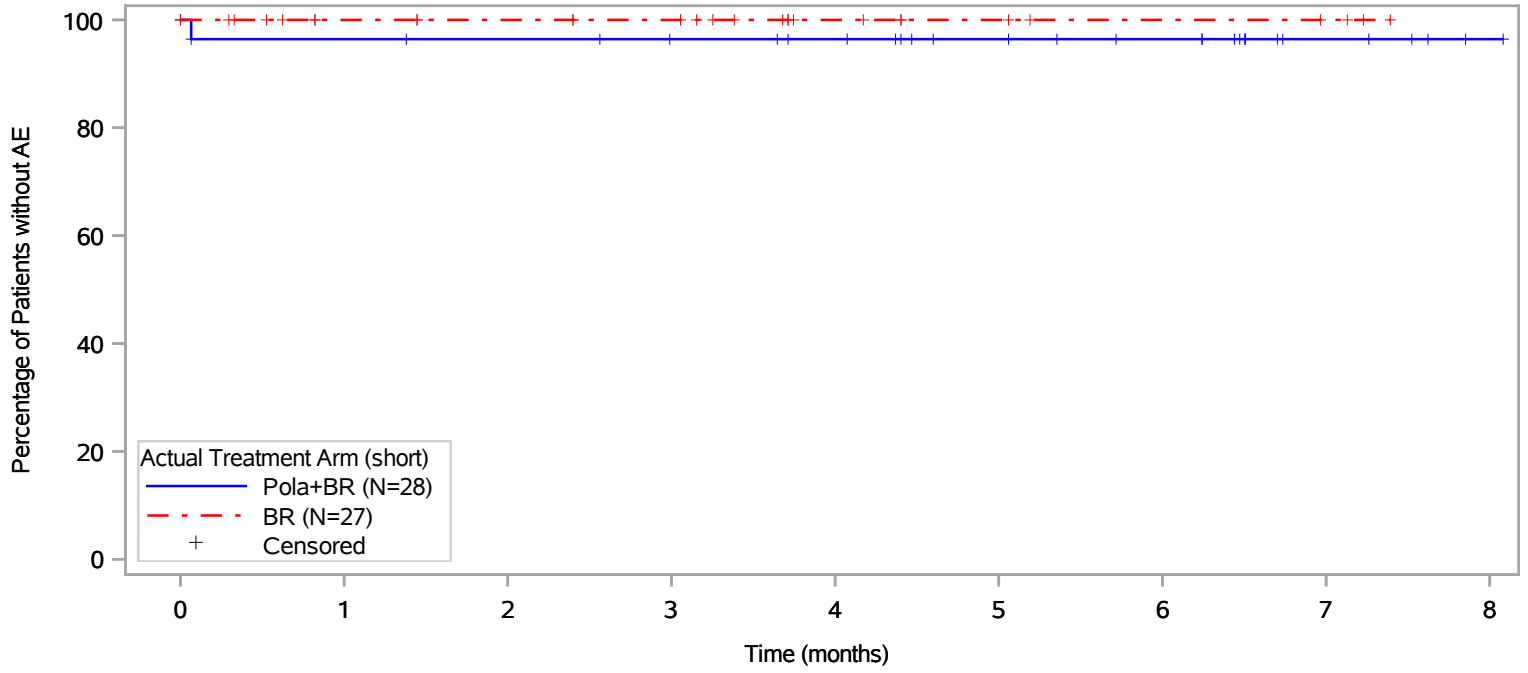


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

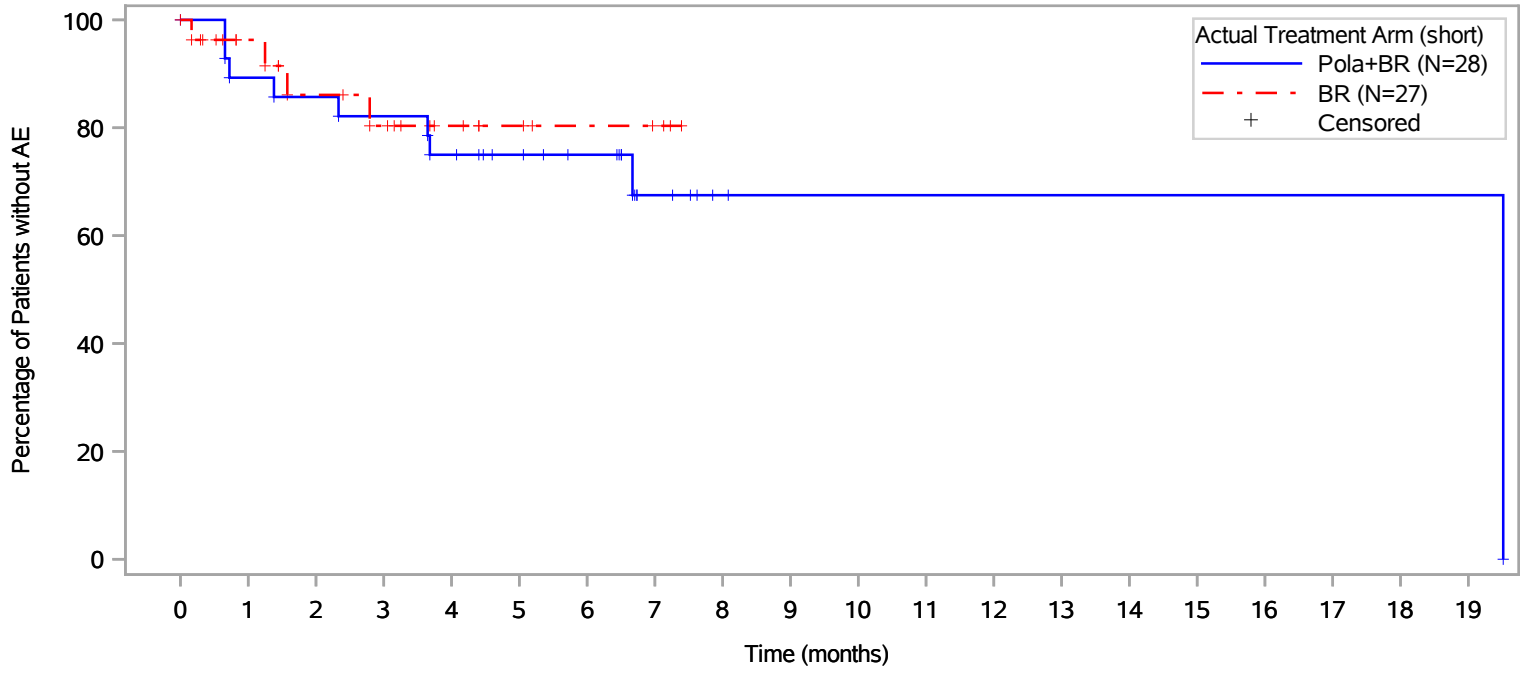
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

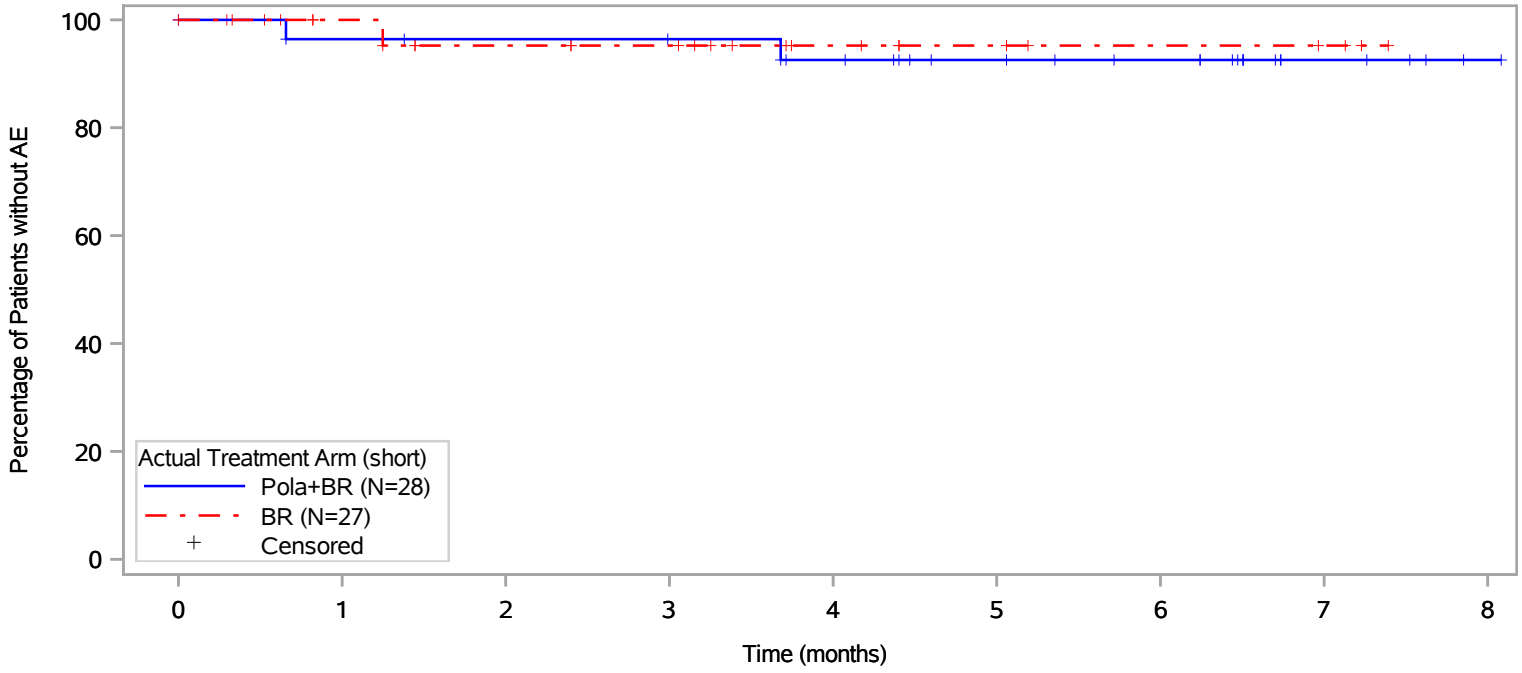
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk																				
Pola+BR (N=28)	28	25	24	23	21	17	14	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	20	16	14	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	0	0	0	4	7	14	18	19	19	19	19	19	19	19	19	19	19	19
BR (N=27)	0	6	8	9	14	17	19	20	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=28)	28	27	26	25	23	18	15	5	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	3	8	11	21	25
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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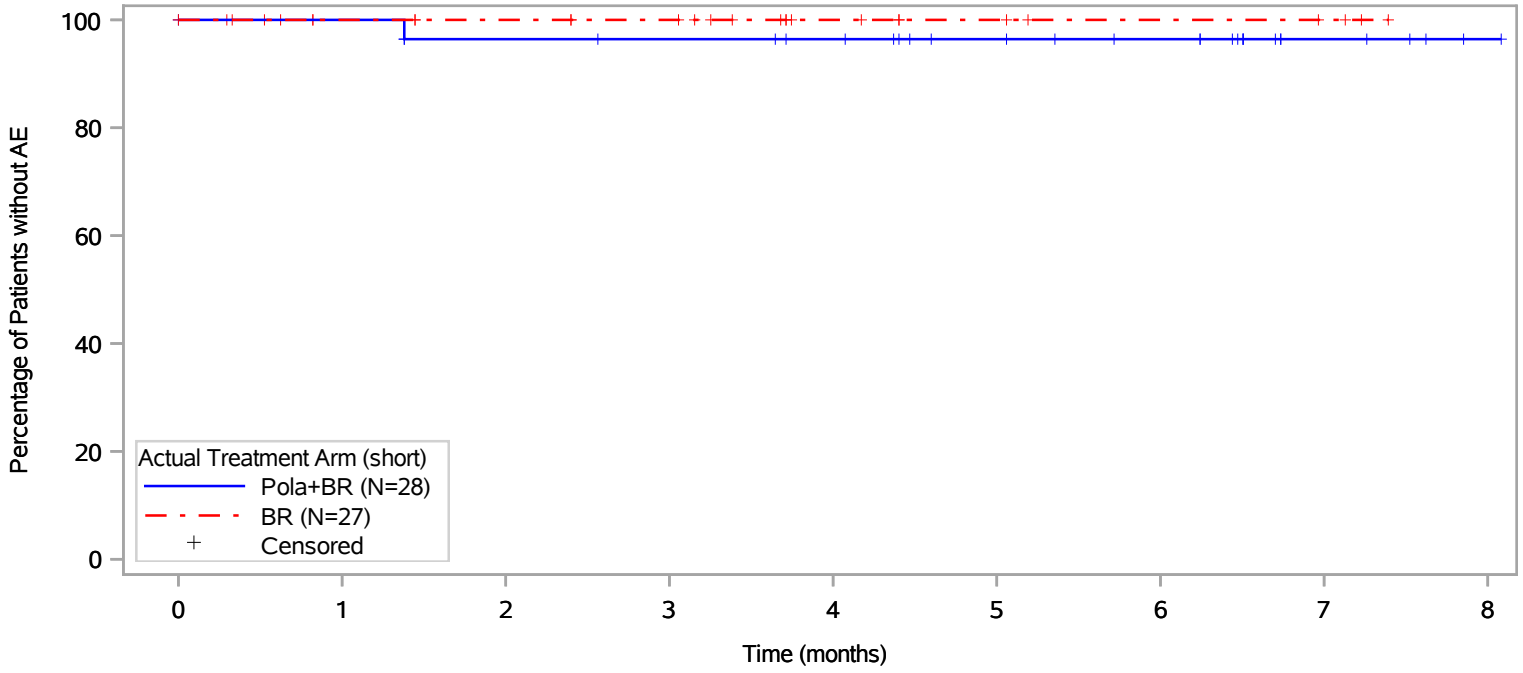
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN UPPER

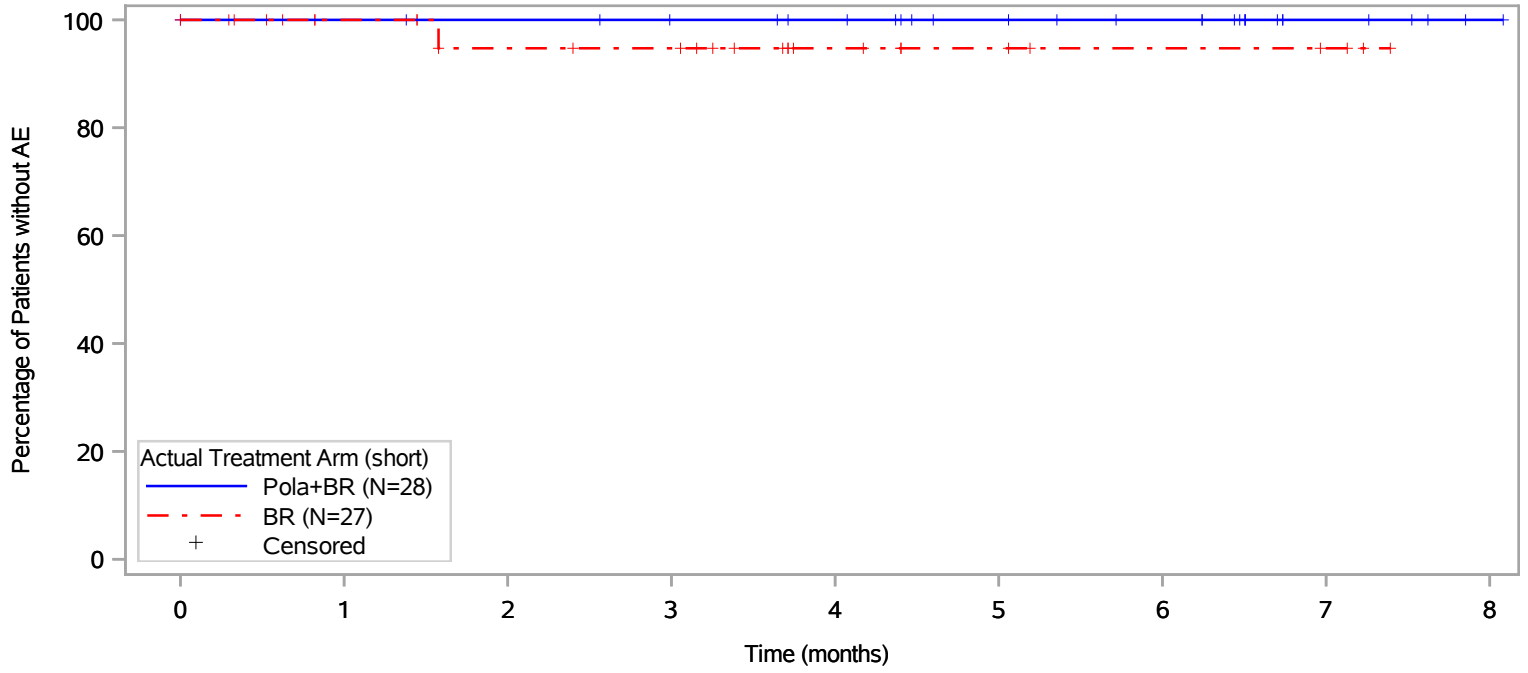


Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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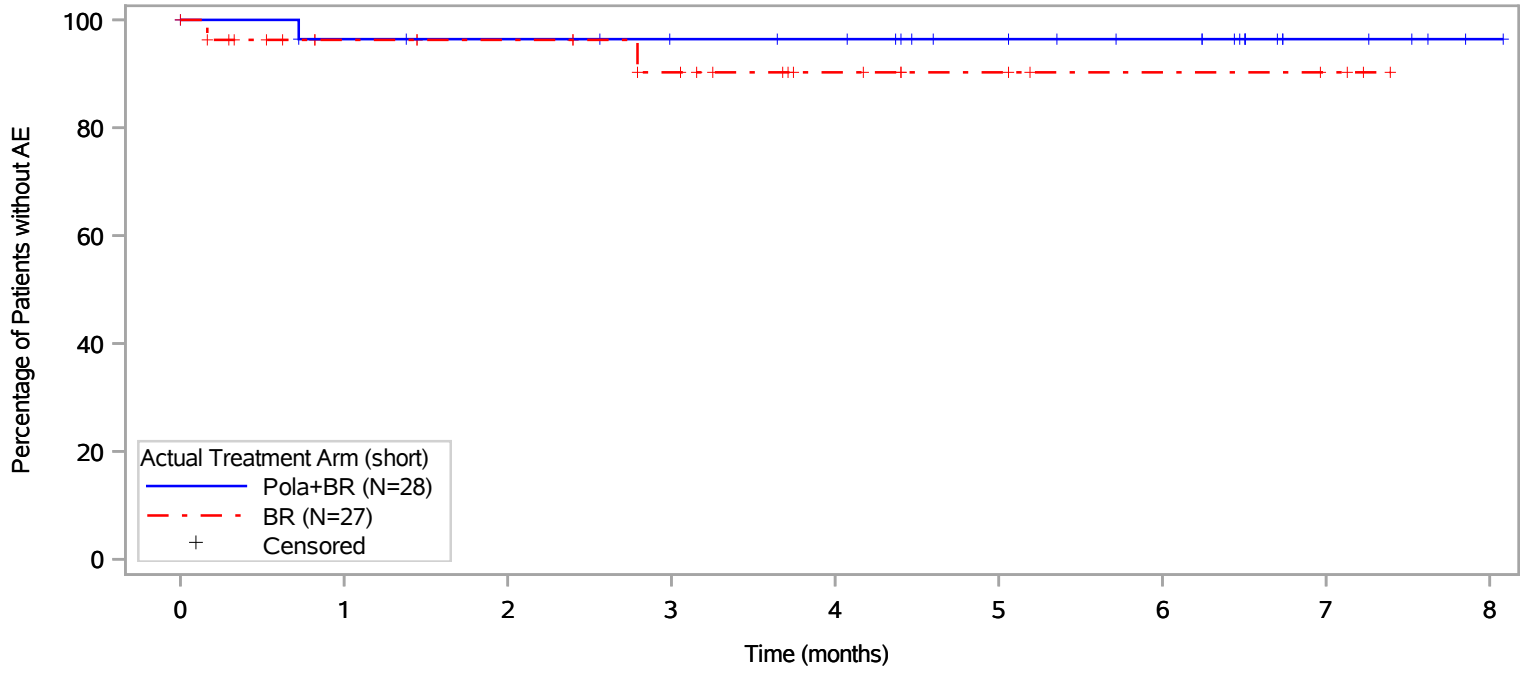
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



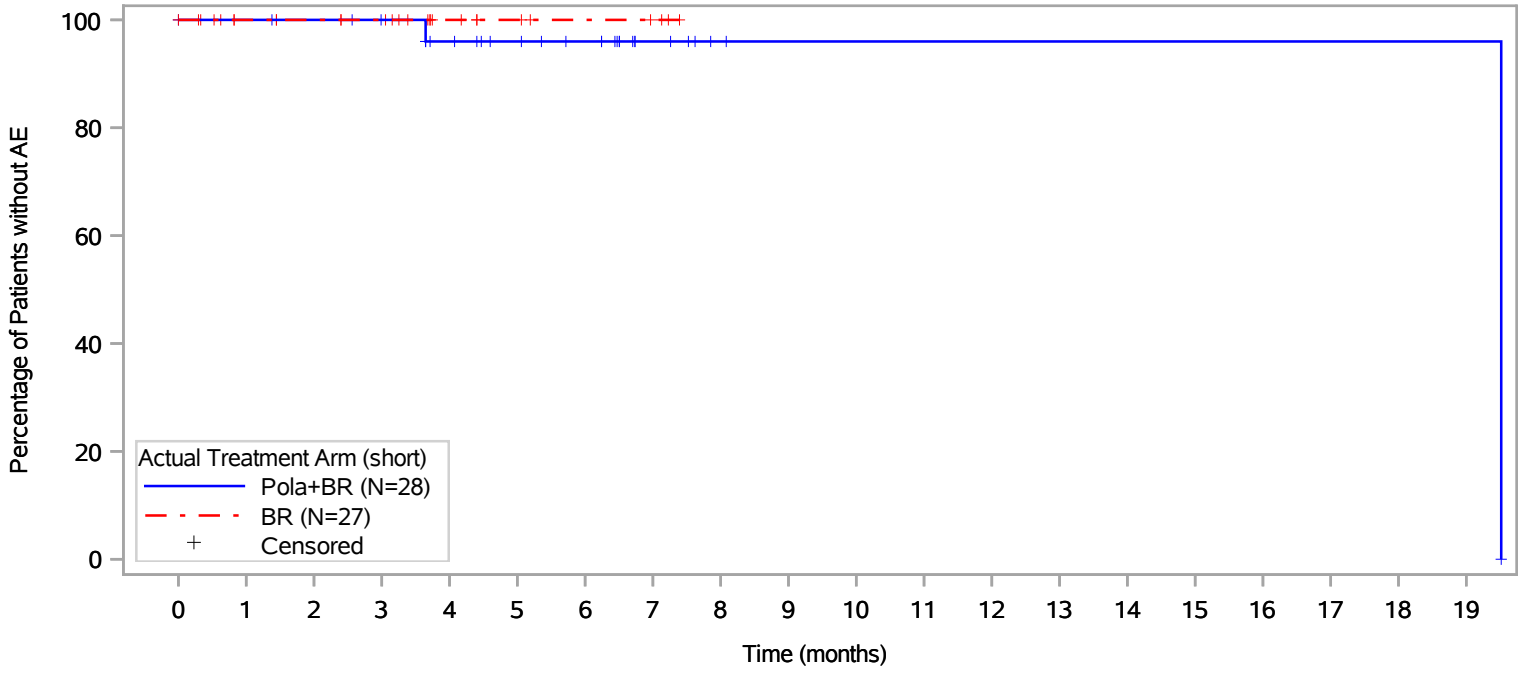
Patients at risk									
Pola+BR (N=28)	28	27	26	24	23	18	15	5	1
BR (N=27)	27	20	18	15	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	10	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

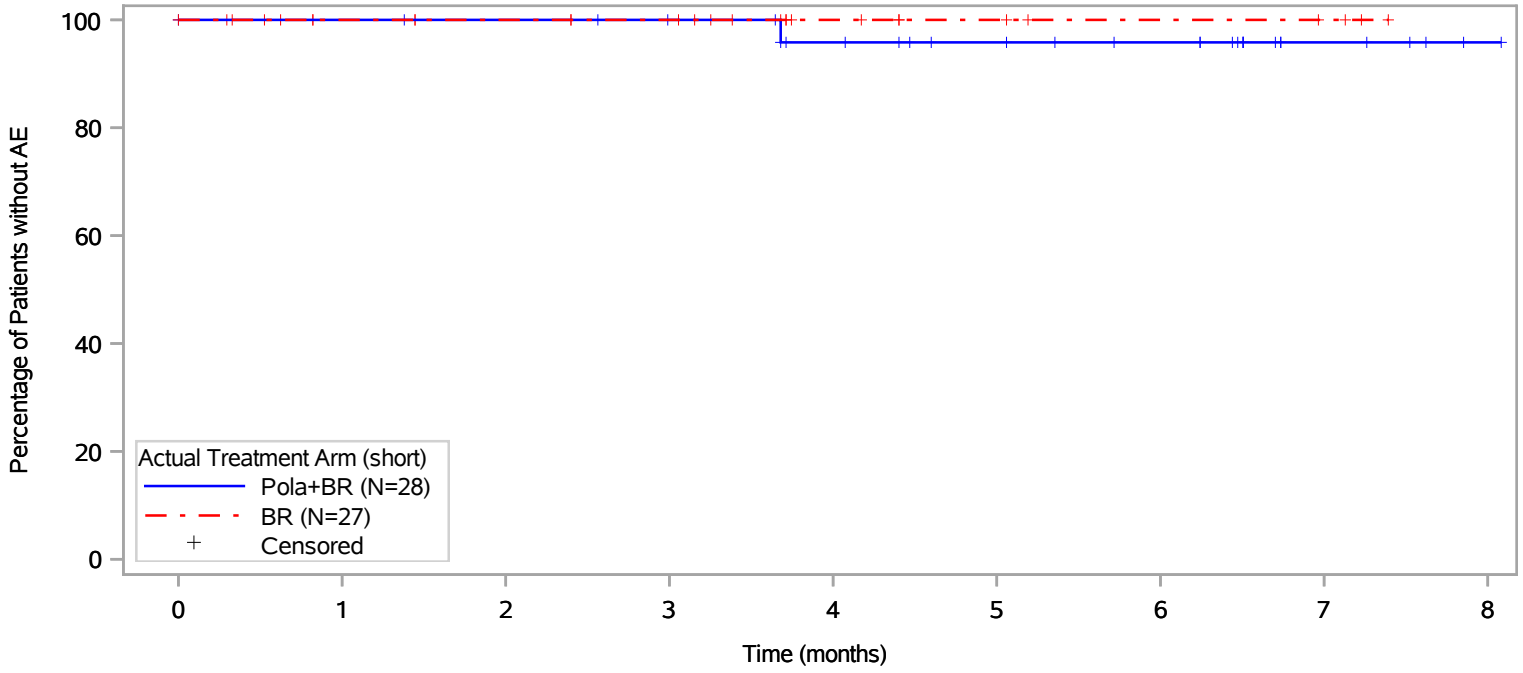
GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk																				
Pola+BR (N=28)	28	28	27	25	22	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	5	9	12	21	25	26	26	26	26	26	26	26	26	26	26	26
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

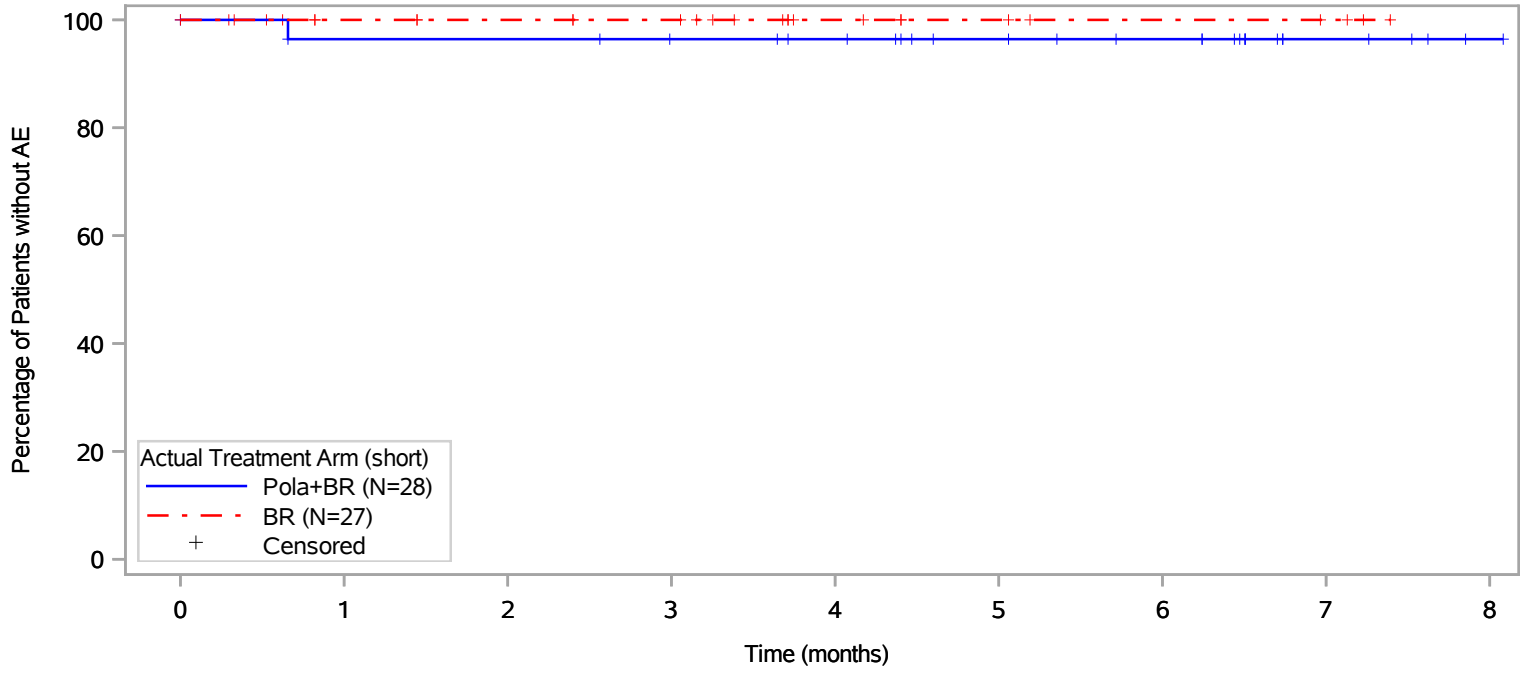
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTROINTESTINAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ILEUS



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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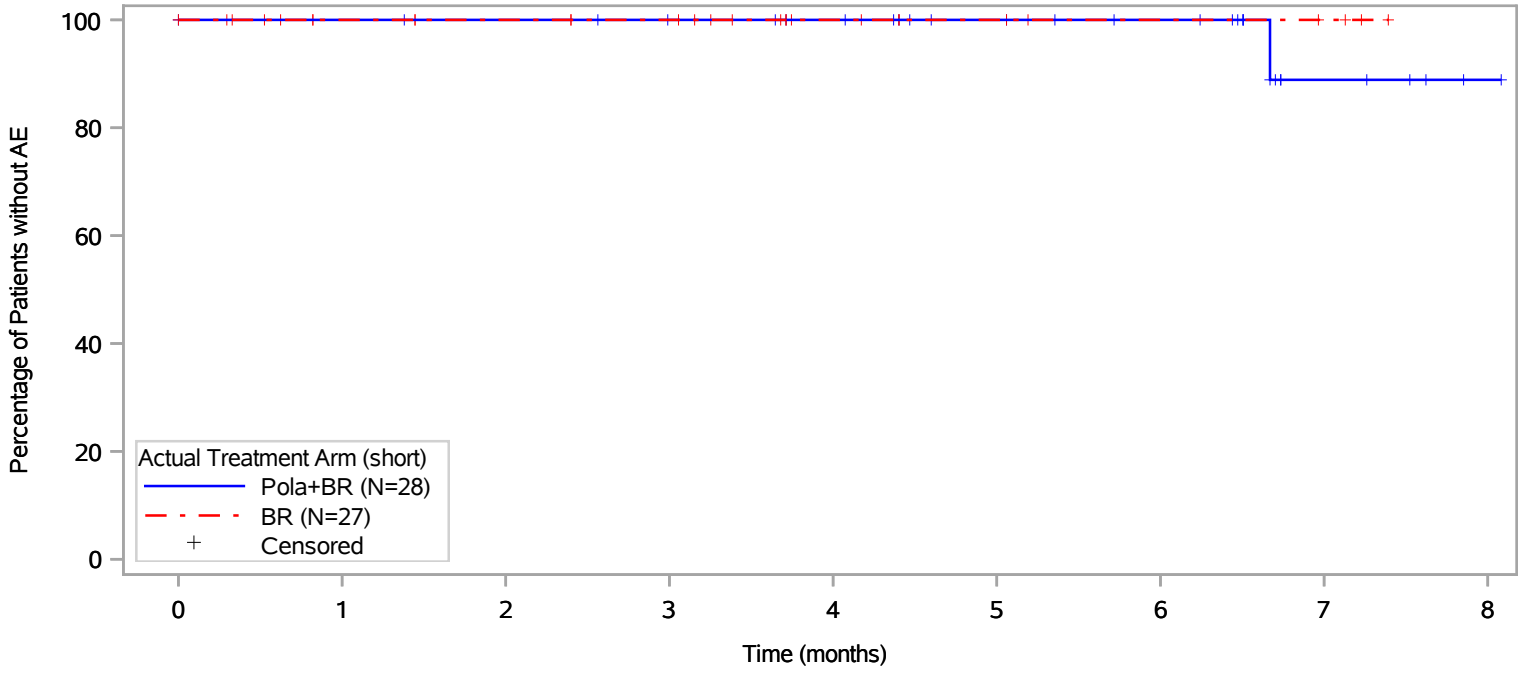
02DEC2022 2:10

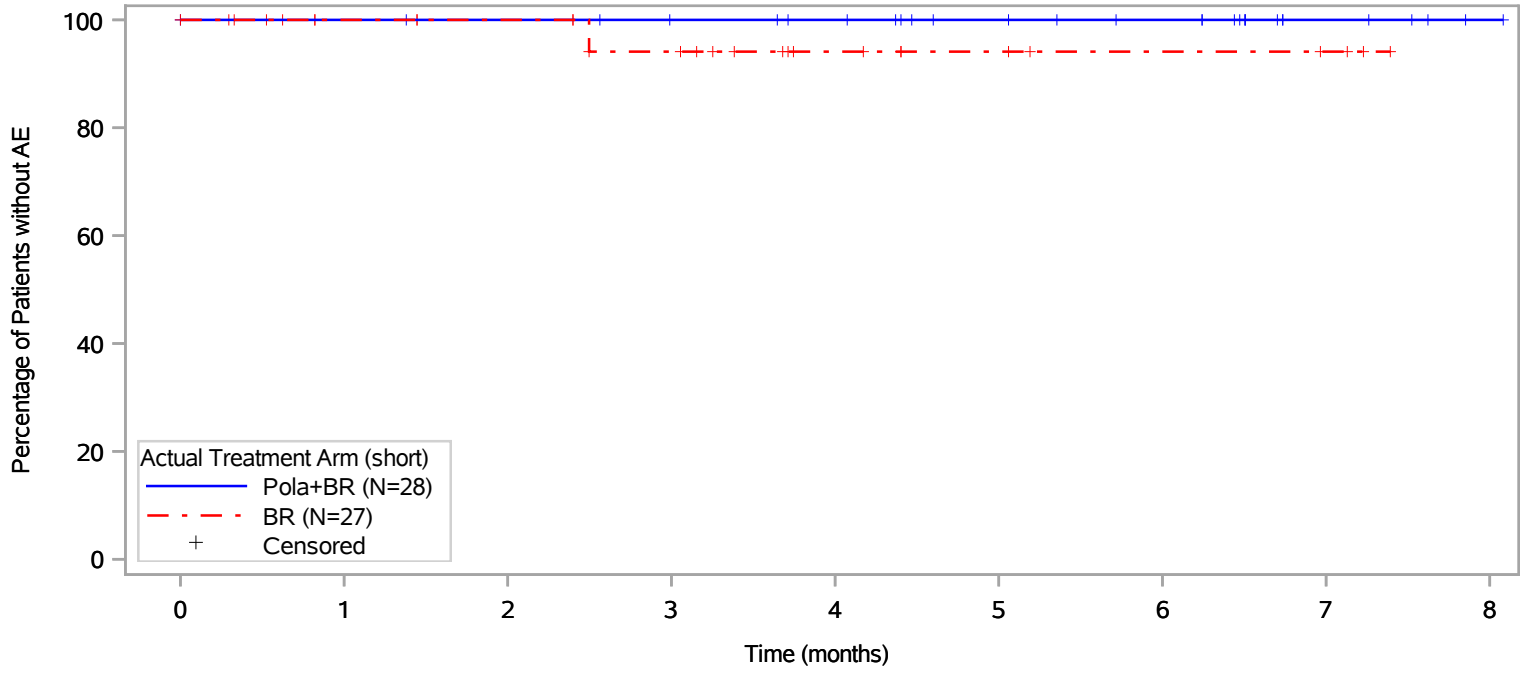
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, OBSTRUCTION GASTRIC



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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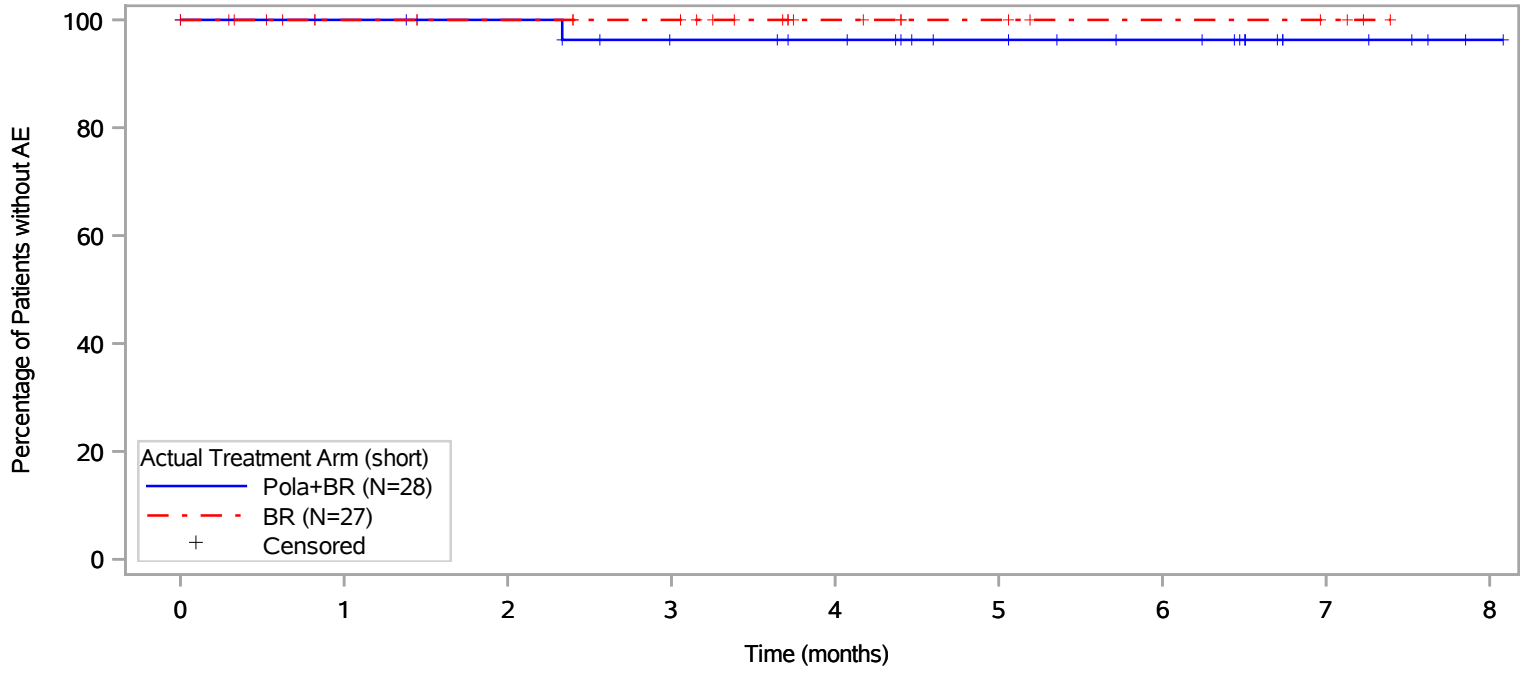
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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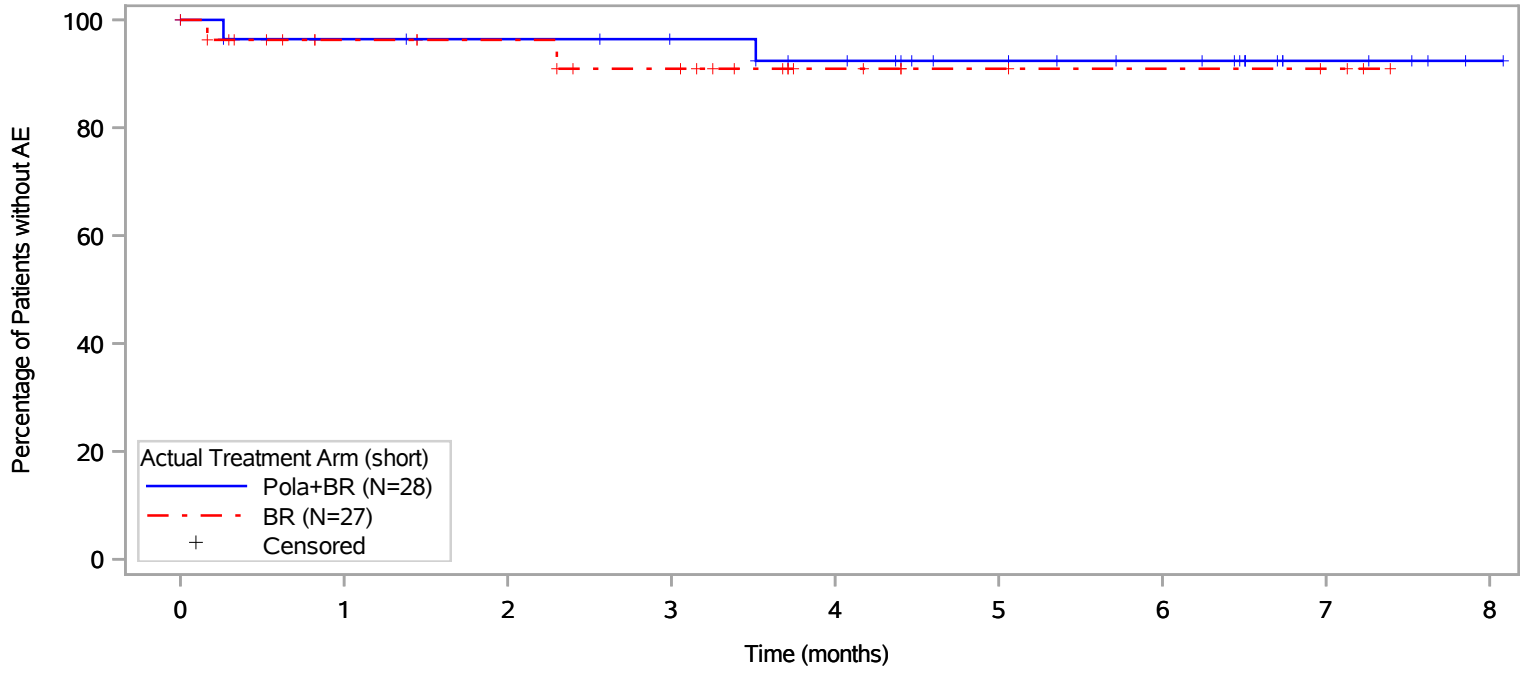
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	21	25
BR (N=27)	0	6	8	9	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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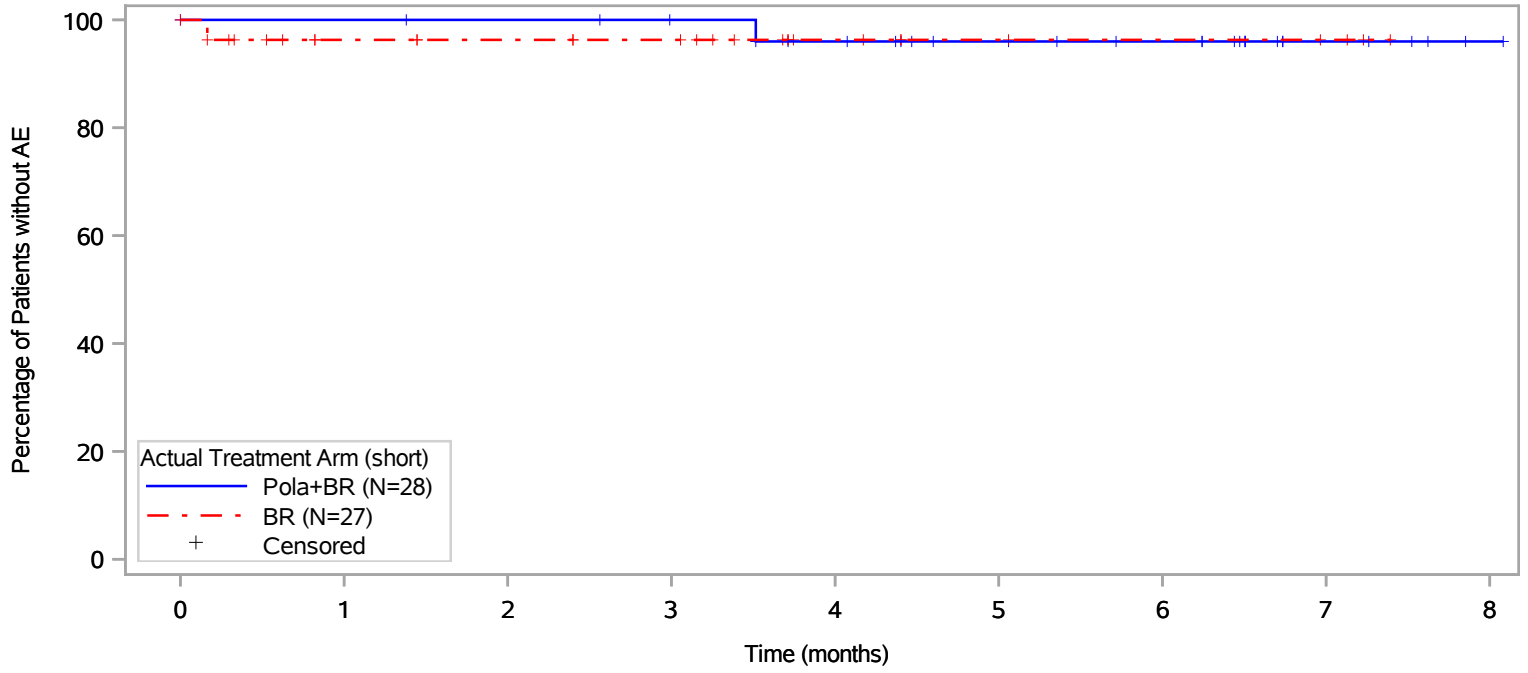
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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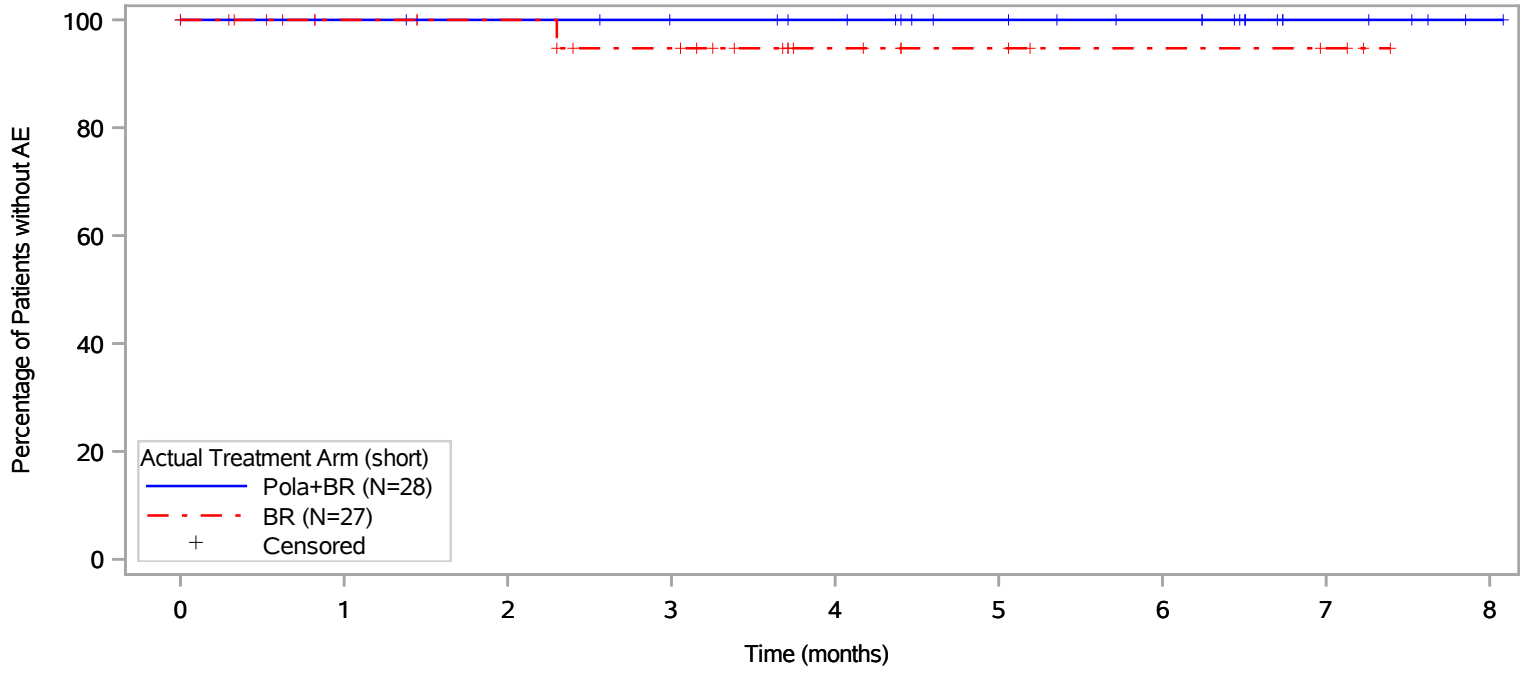
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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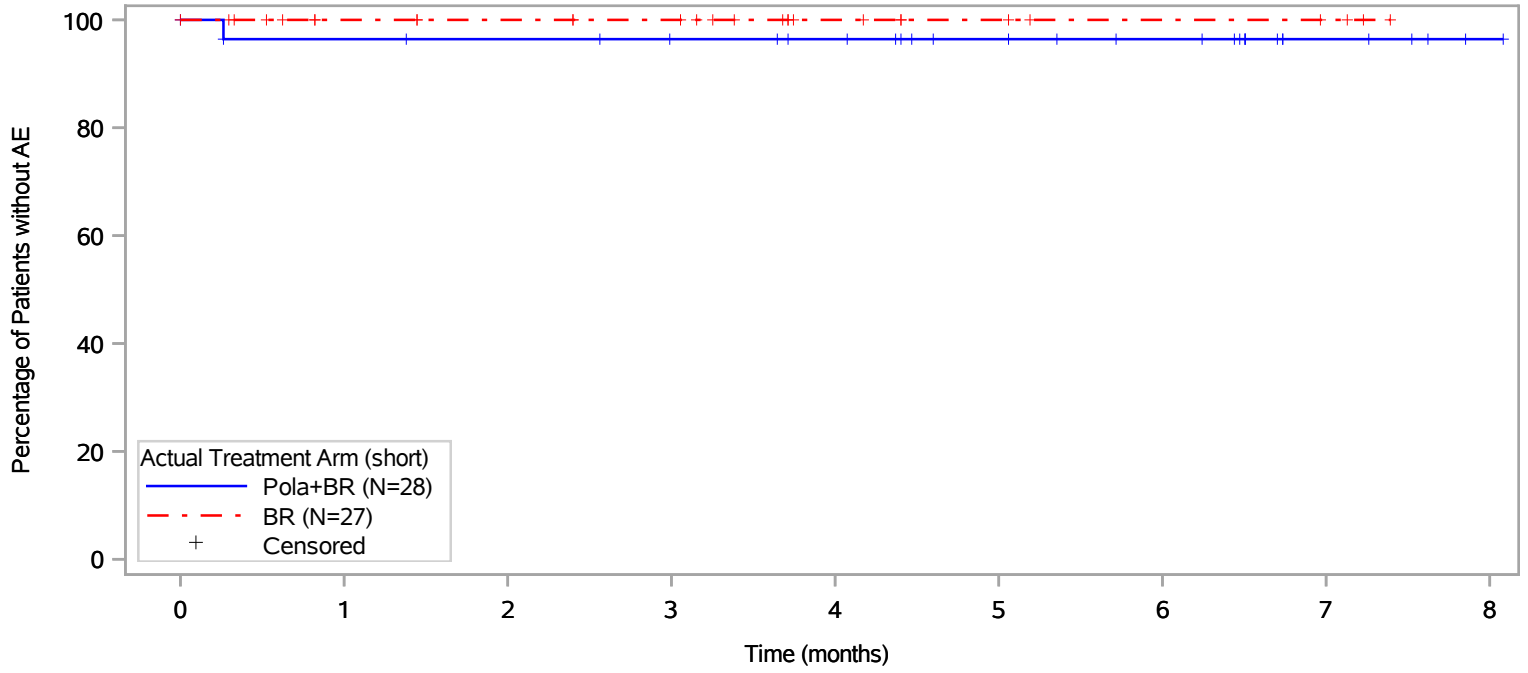
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

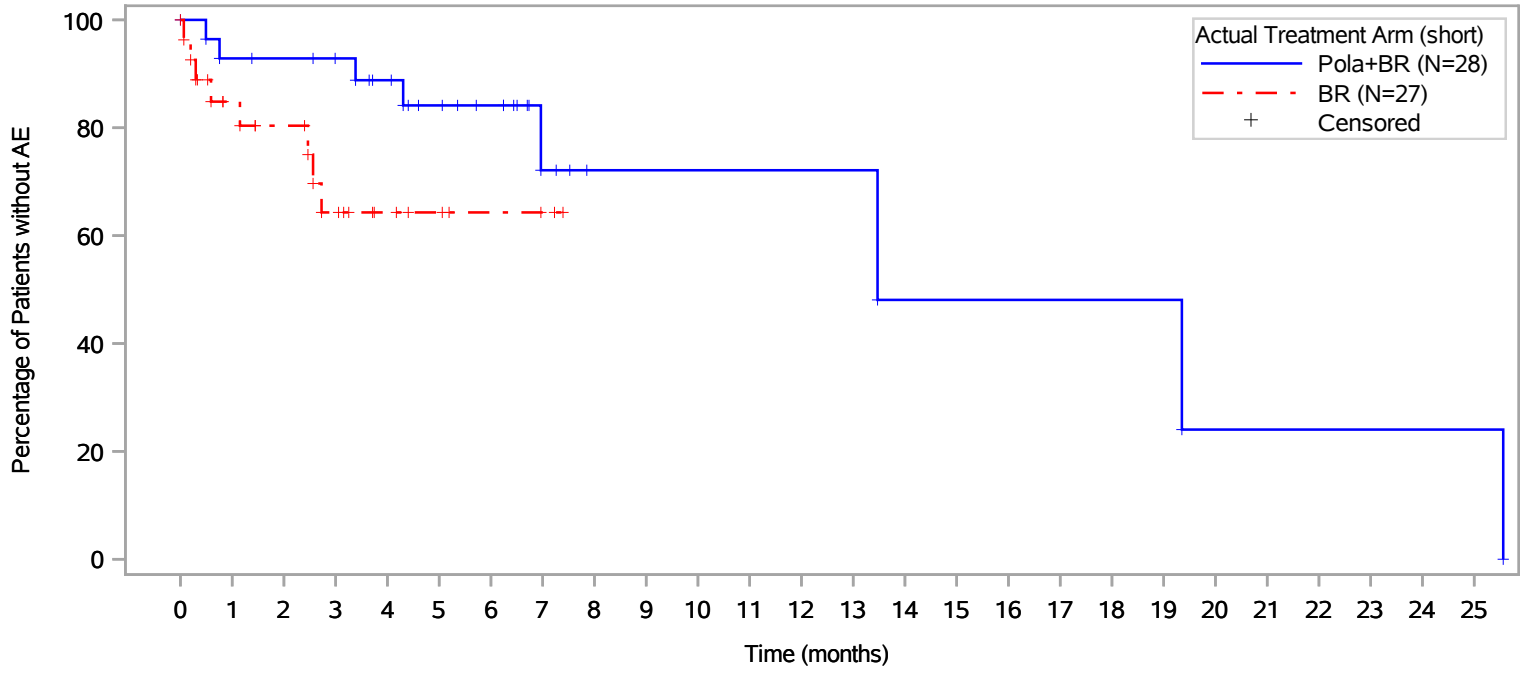
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All

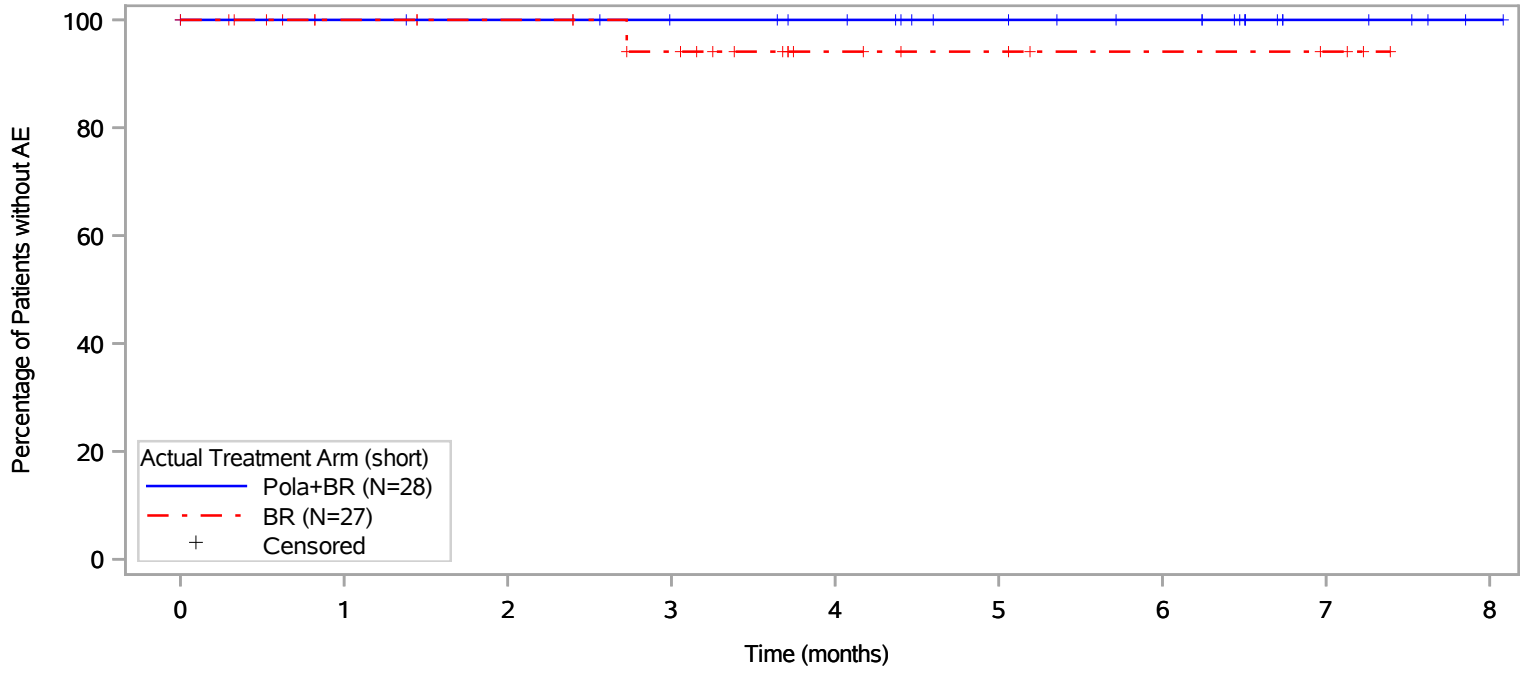


Patients at risk																										
Pola+BR (N=28)	28	26	25	23	20	16	13	6	3	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=27)	27	19	16	12	7	5	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	1	3	5	8	11	17	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
BR (N=27)	0	4	6	7	12	14	16	17	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, CYTOMEGALOVIRUS INFECTION

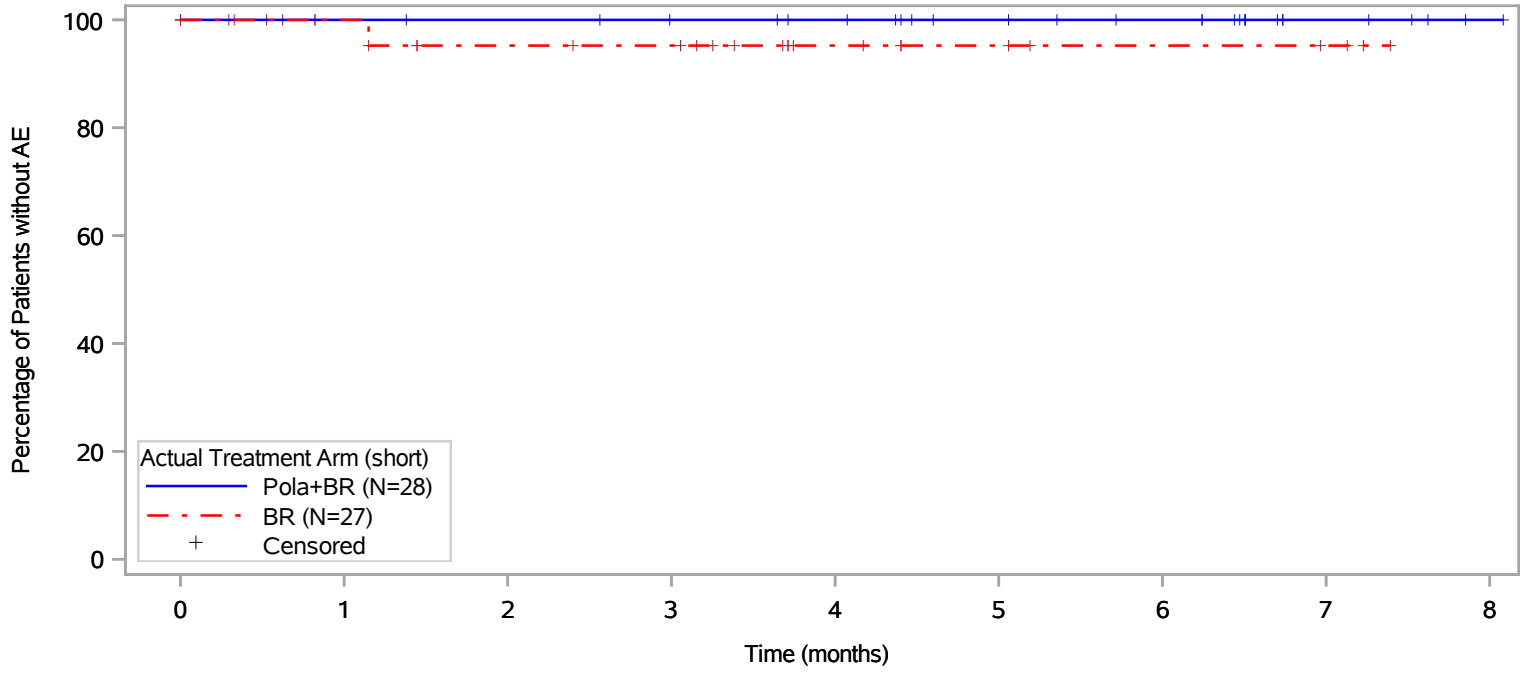


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, DEVICE RELATED INFECTION

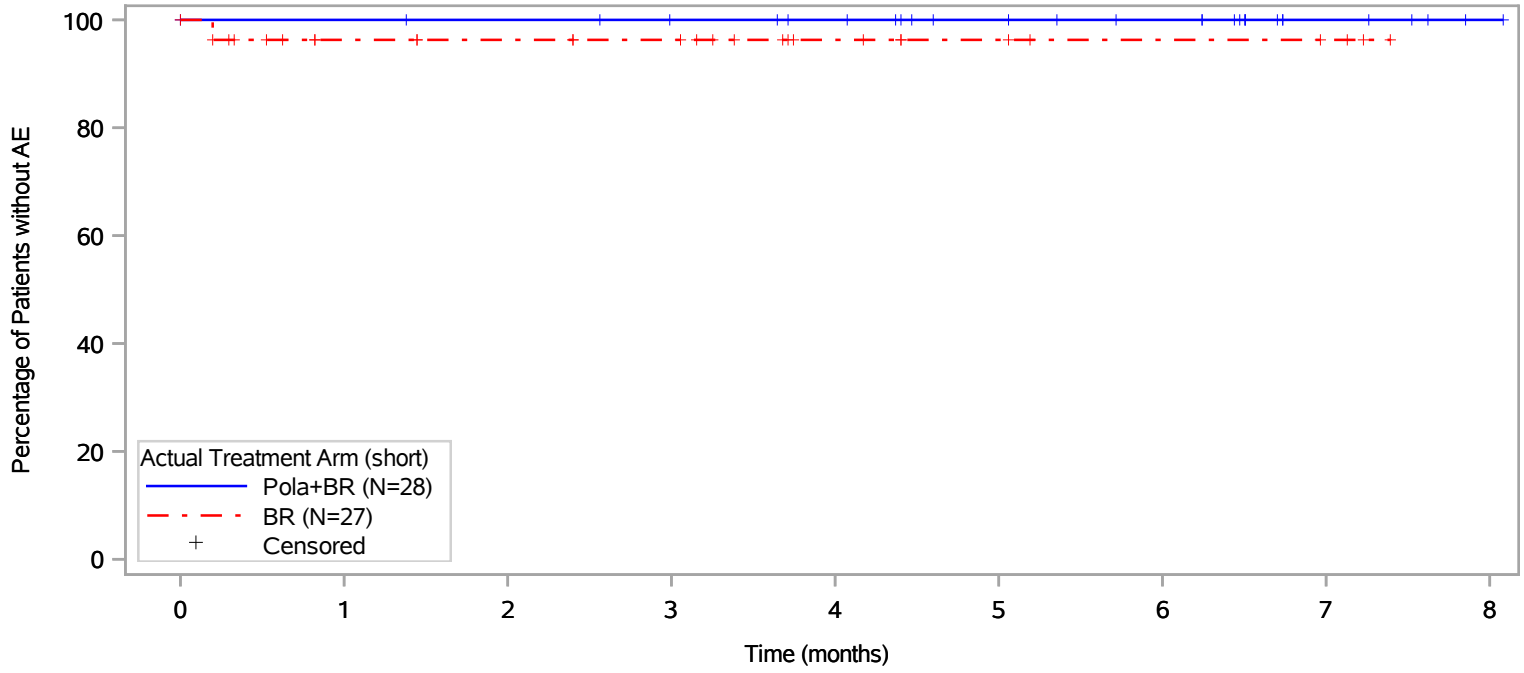


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ENTEROCOLITIS VIRAL

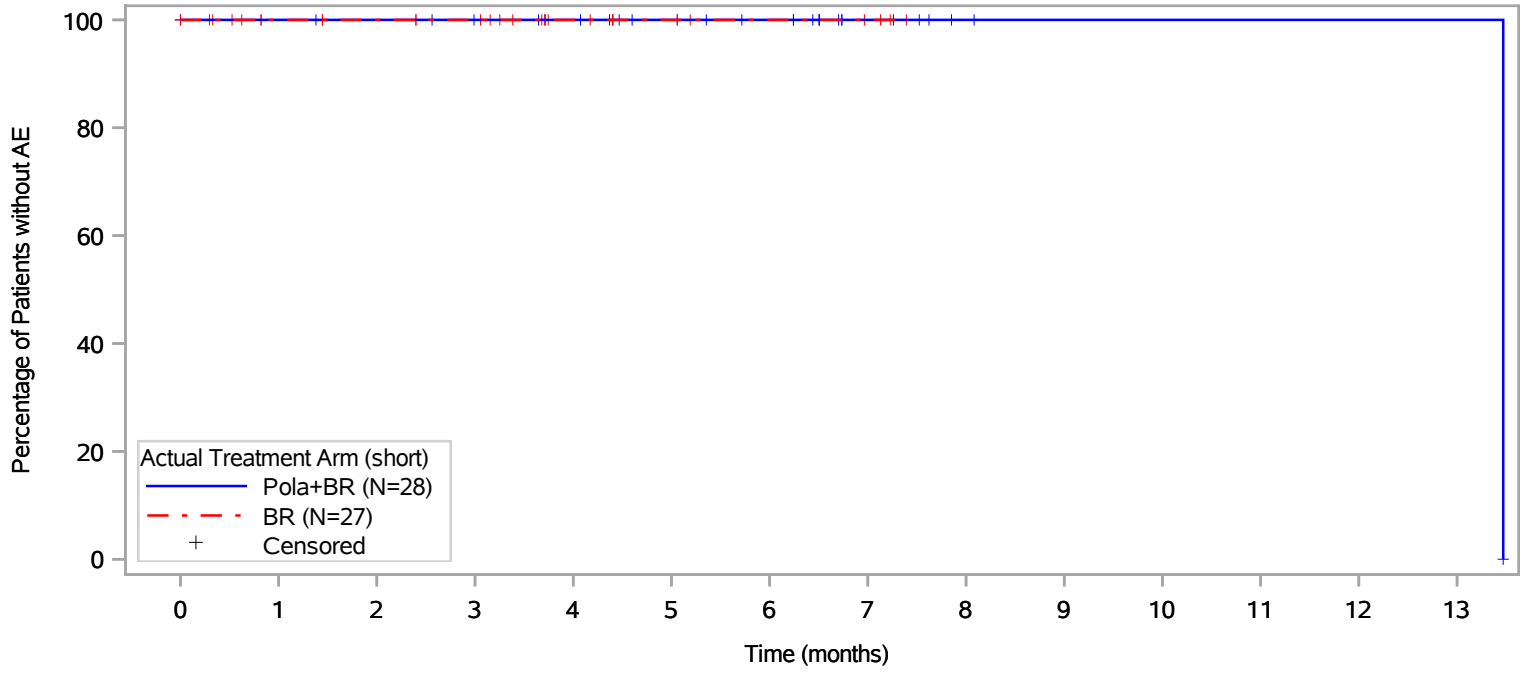


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, GASTROINTESTINAL BACTERIAL INFECTION



Patients at risk														
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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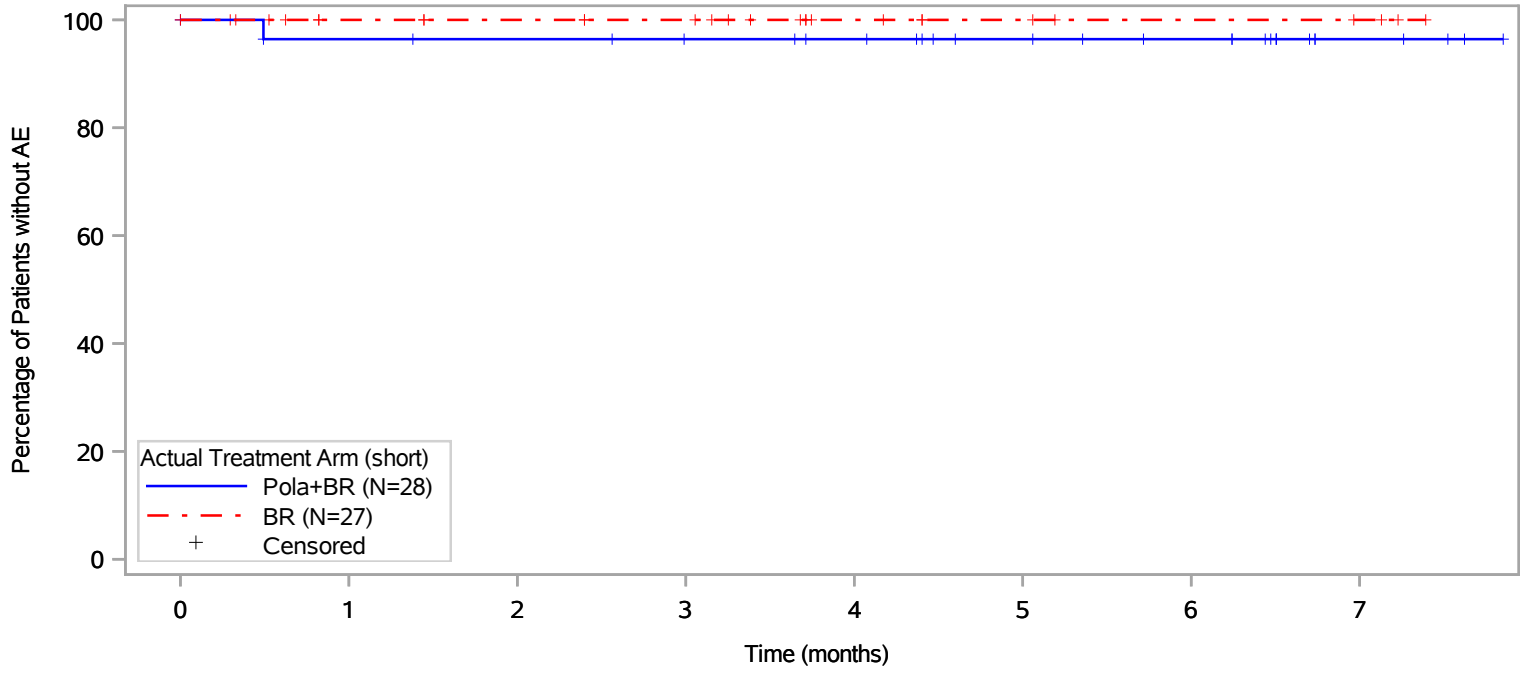
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HUMAN ANAPLASMOSIS

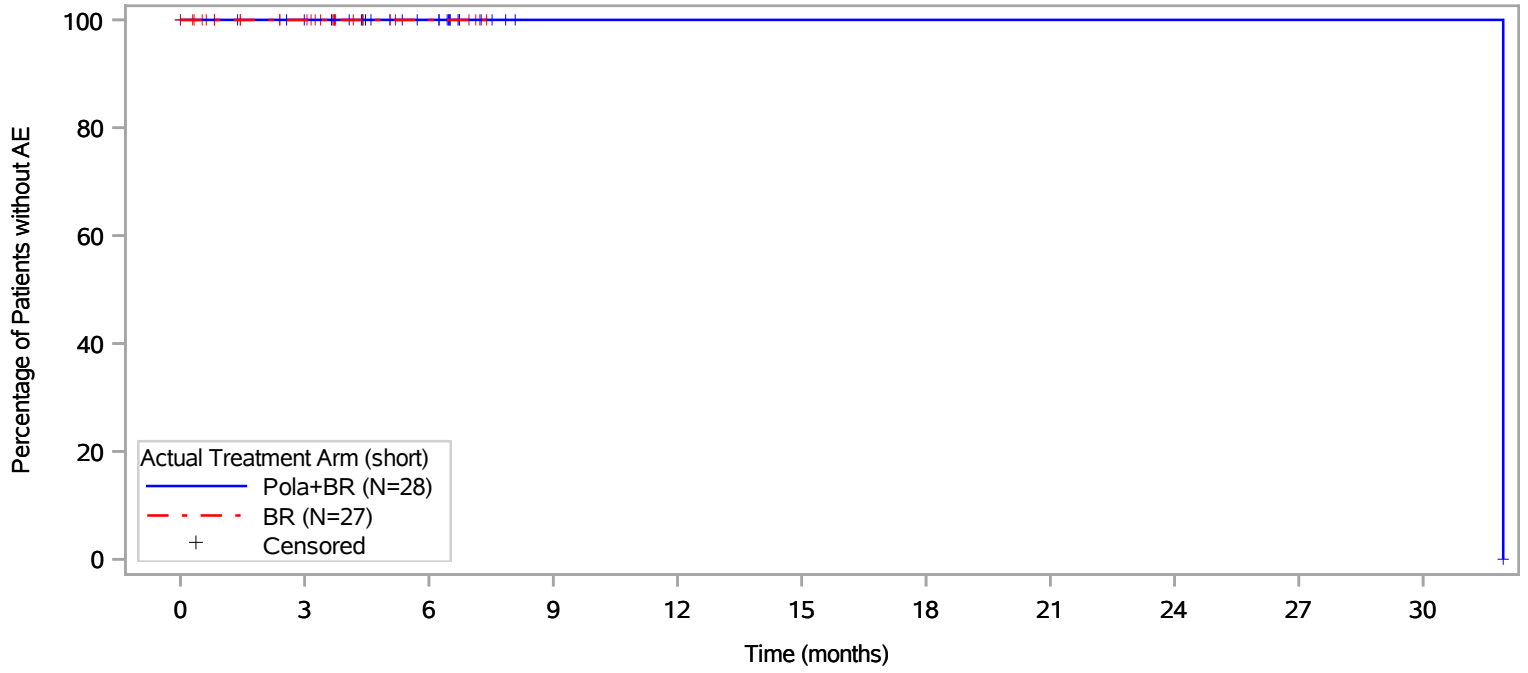


Patients at risk								
Pola+BR (N=28)	28	27	26	24	22	17	14	4
BR (N=27)	27	21	19	17	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	10	13	23
BR (N=27)	0	6	8	10	18	21	23	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION

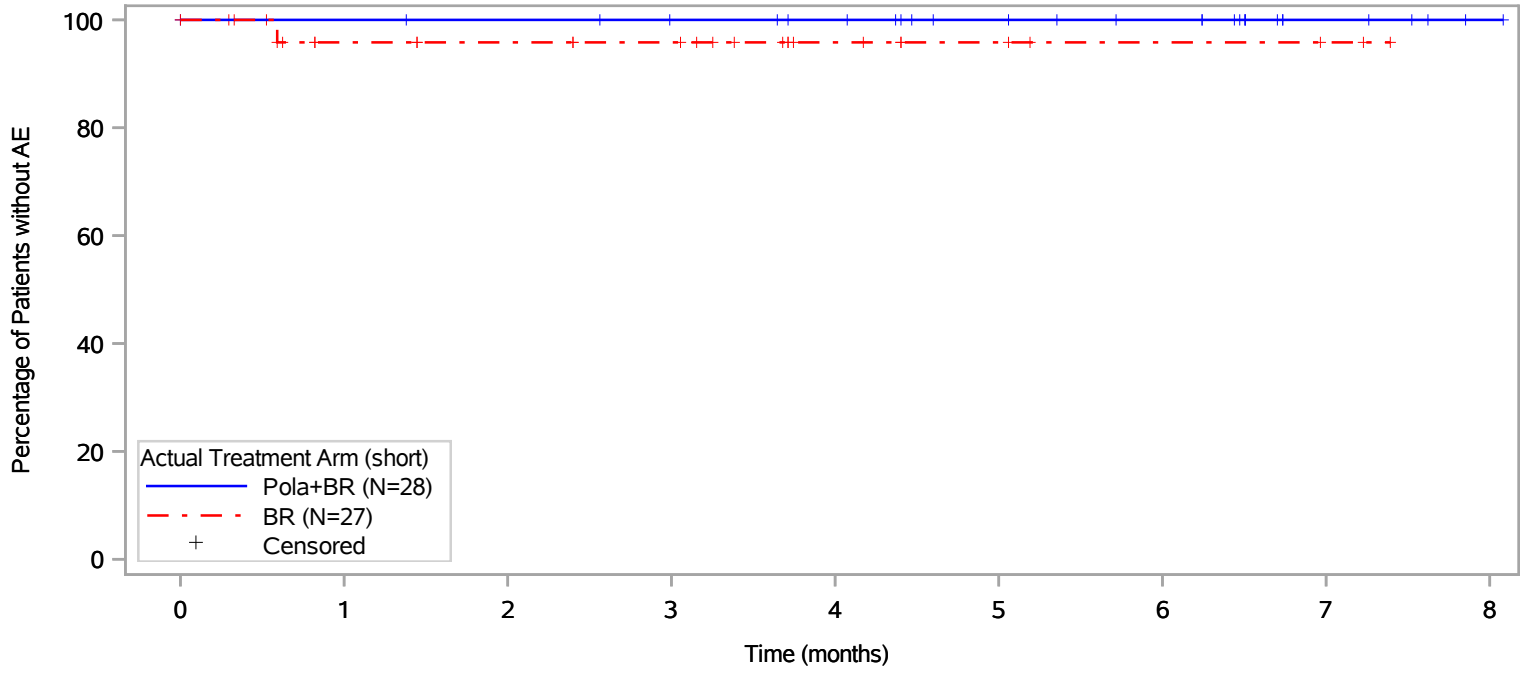


Patients at risk											
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, LOWER RESPIRATORY TRACT INFECTION

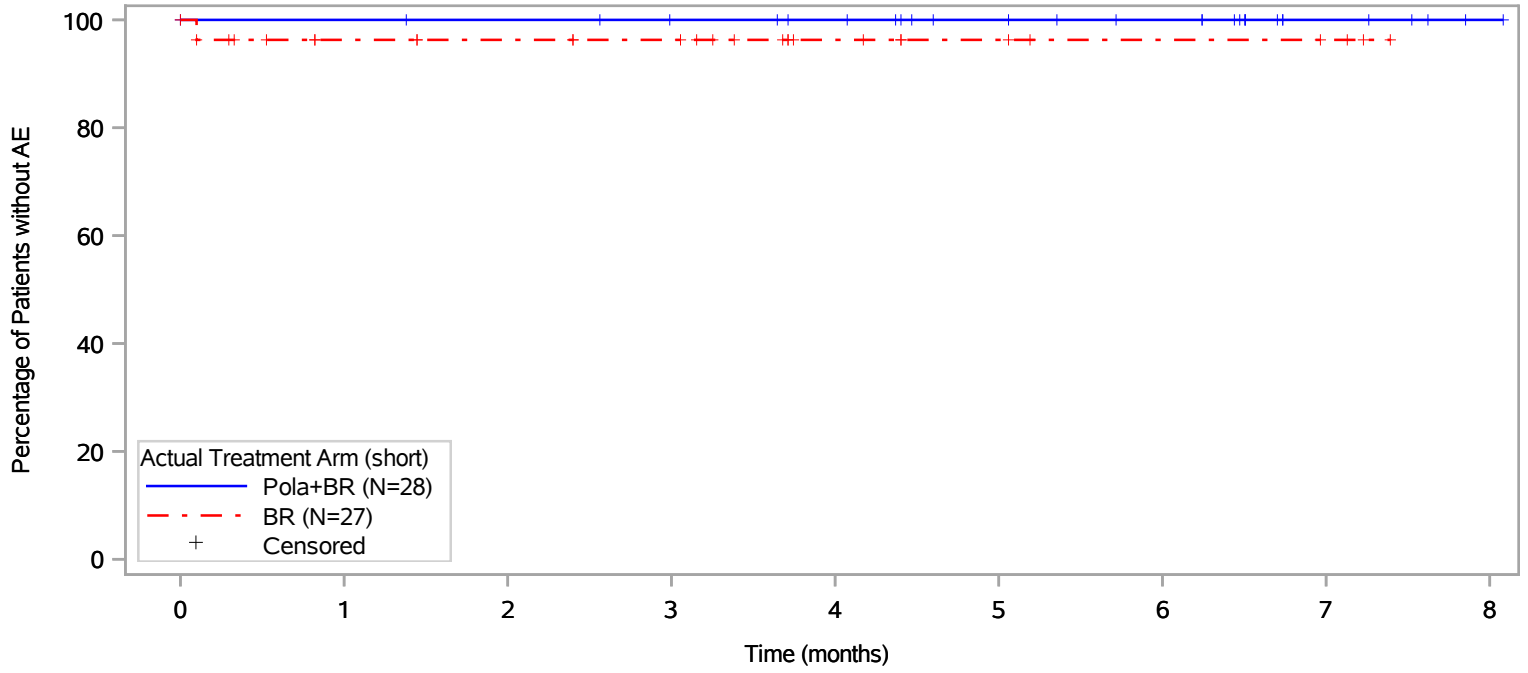


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NEUTROPENIC SEPSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	5	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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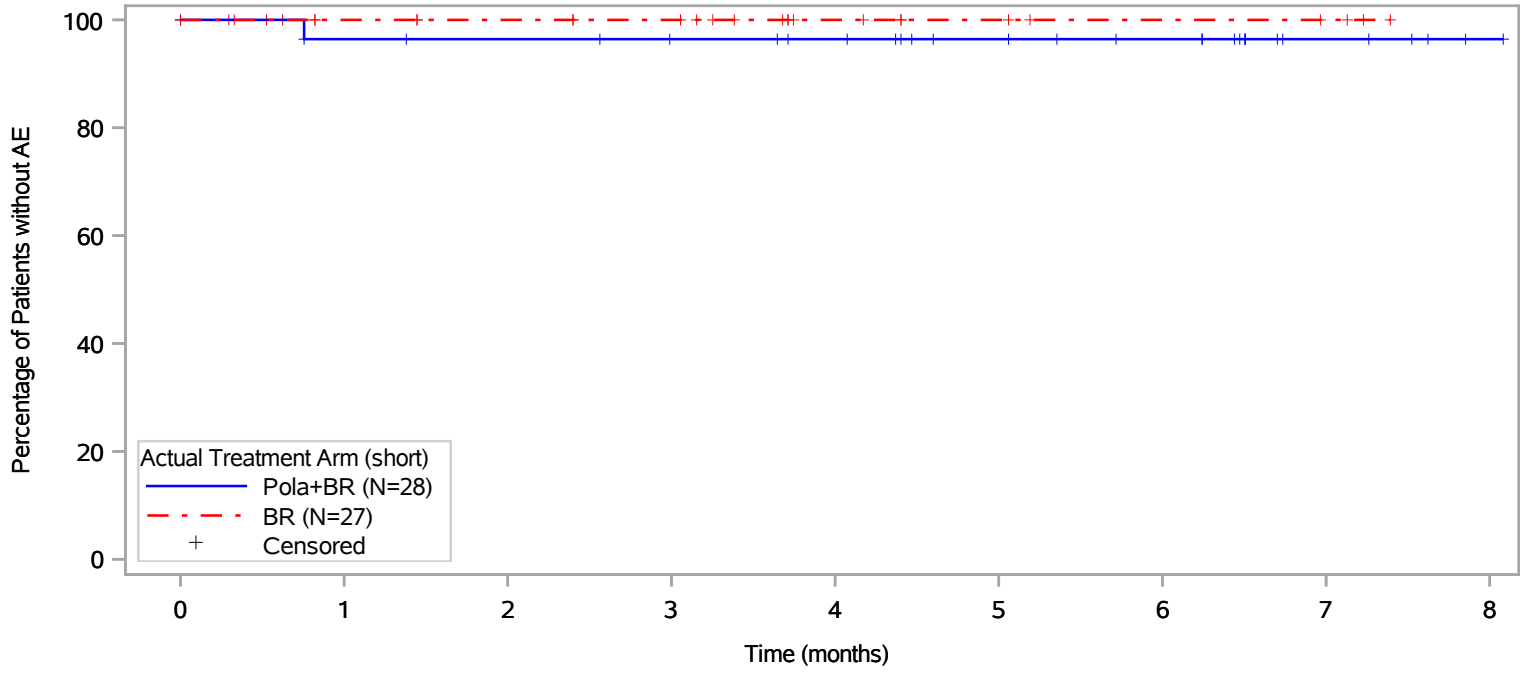
02DEC2022 2:10

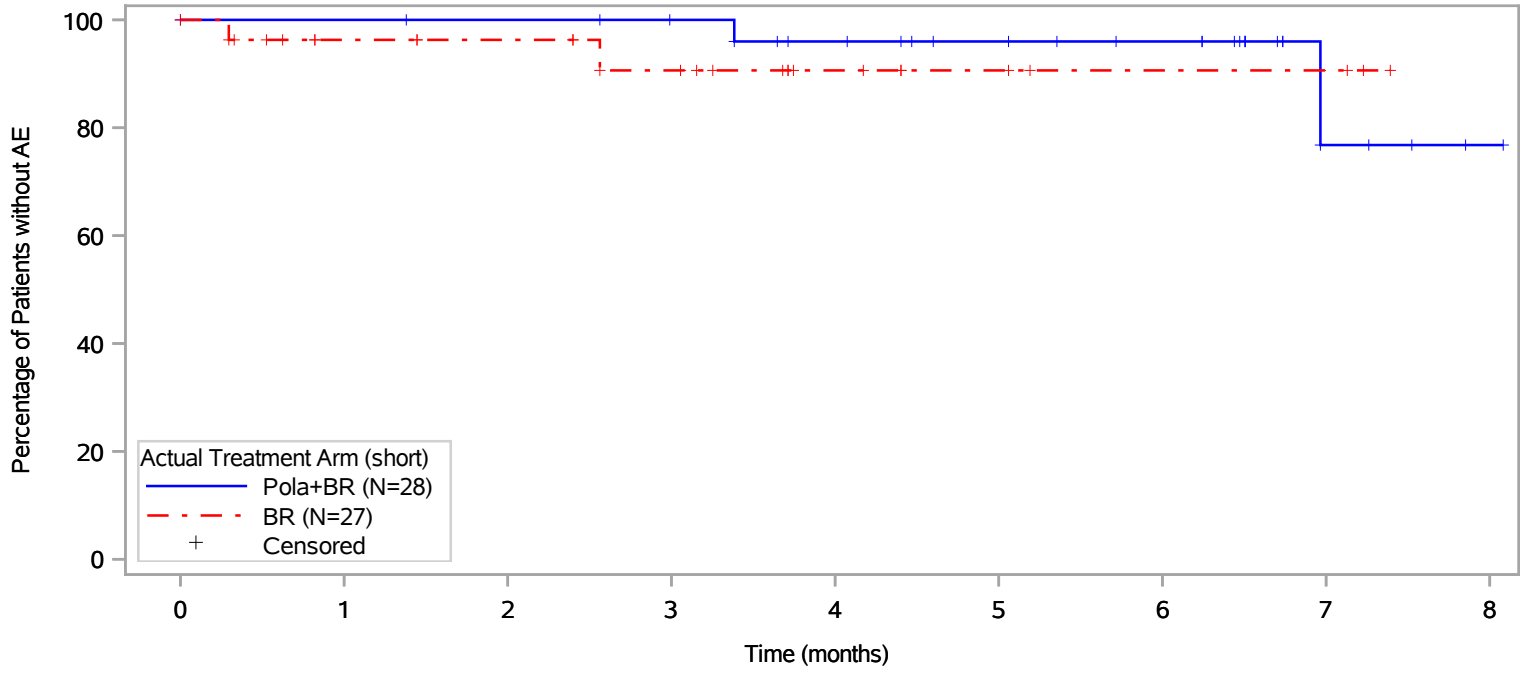
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMOCYSTIS JIROVECII PNEUMONIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA

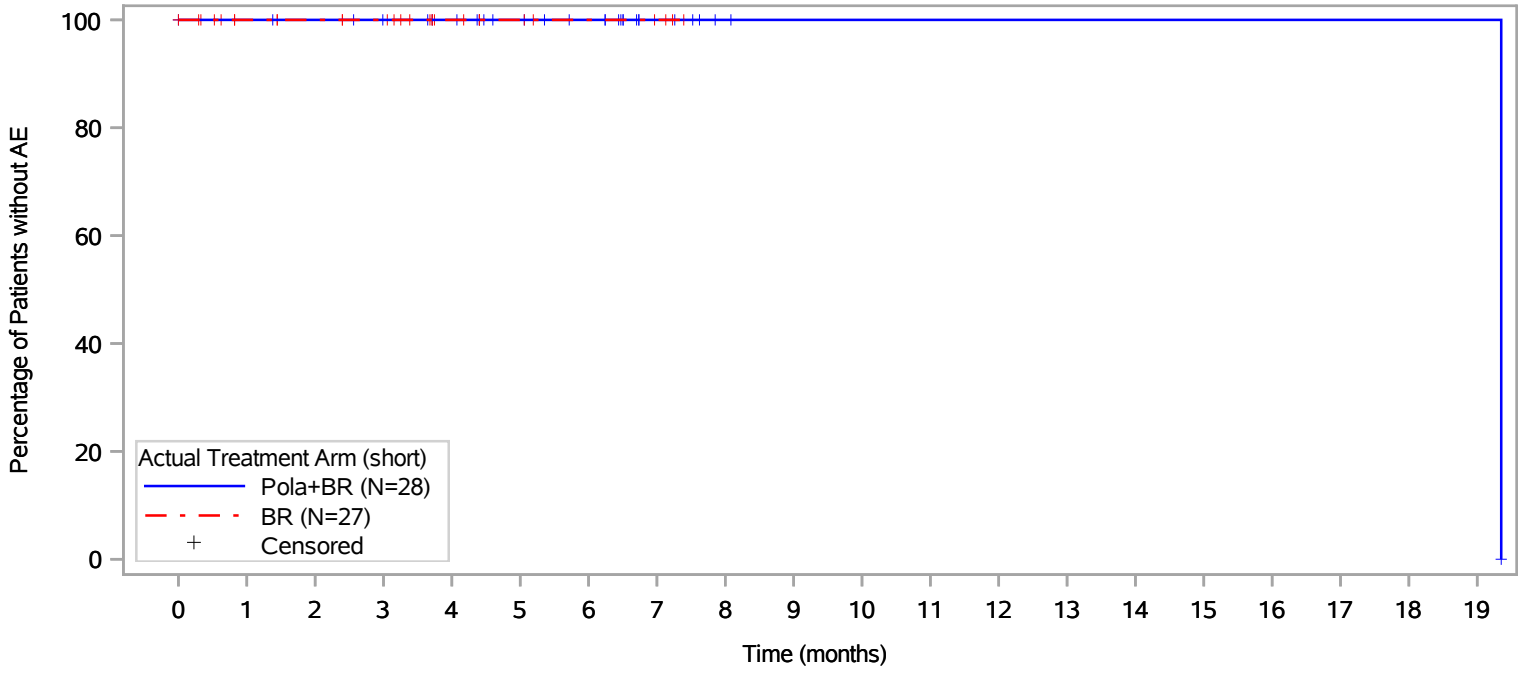


Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	4	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	25
BR (N=27)	0	5	7	9	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

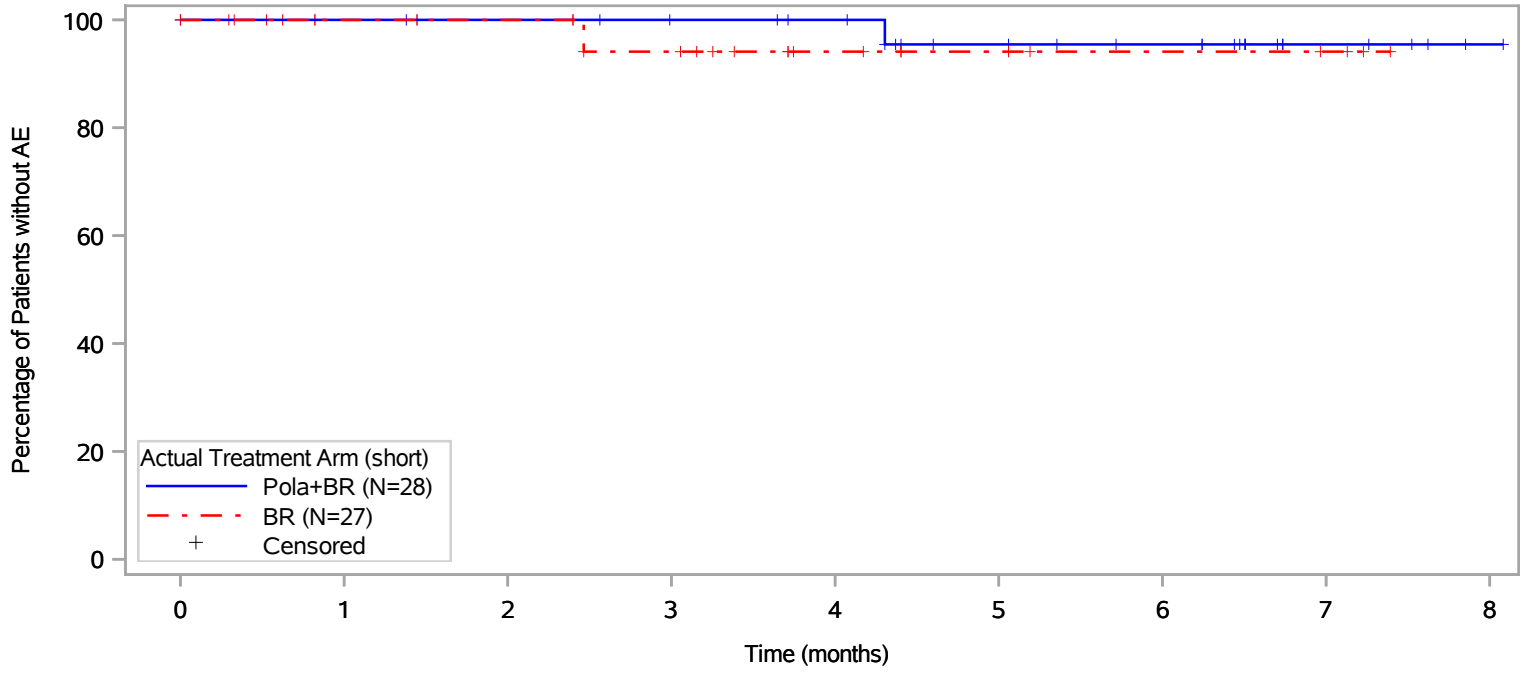
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA PNEUMOCOCCAL



Patients at risk																				
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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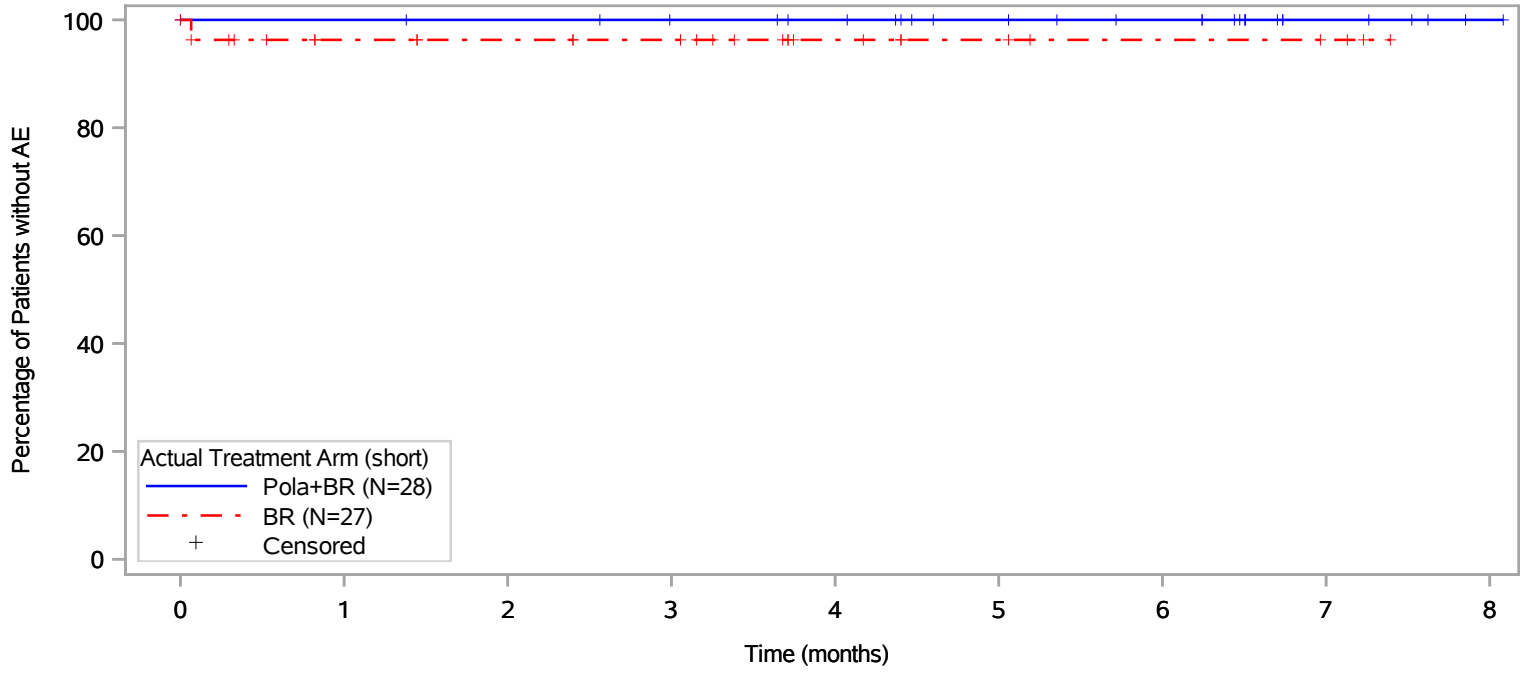
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	5	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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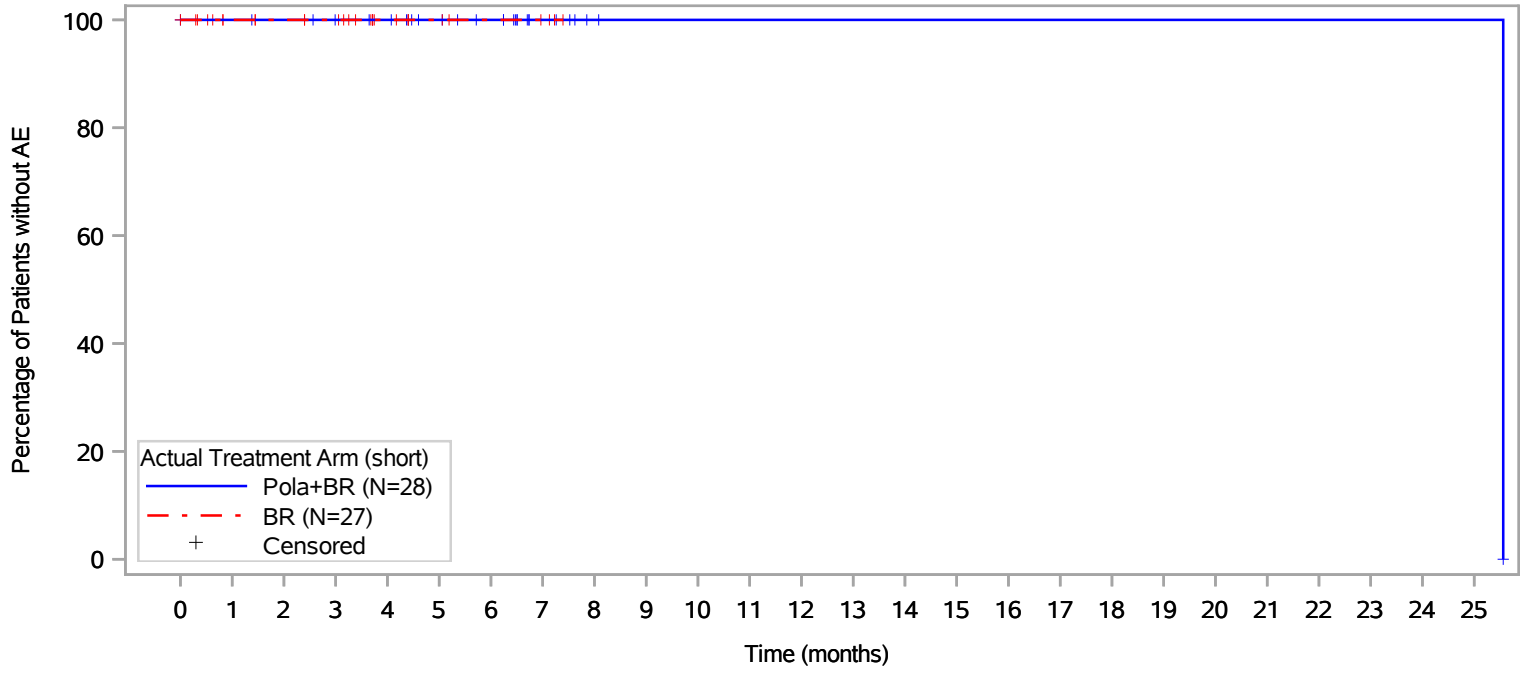
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UROSEPSIS

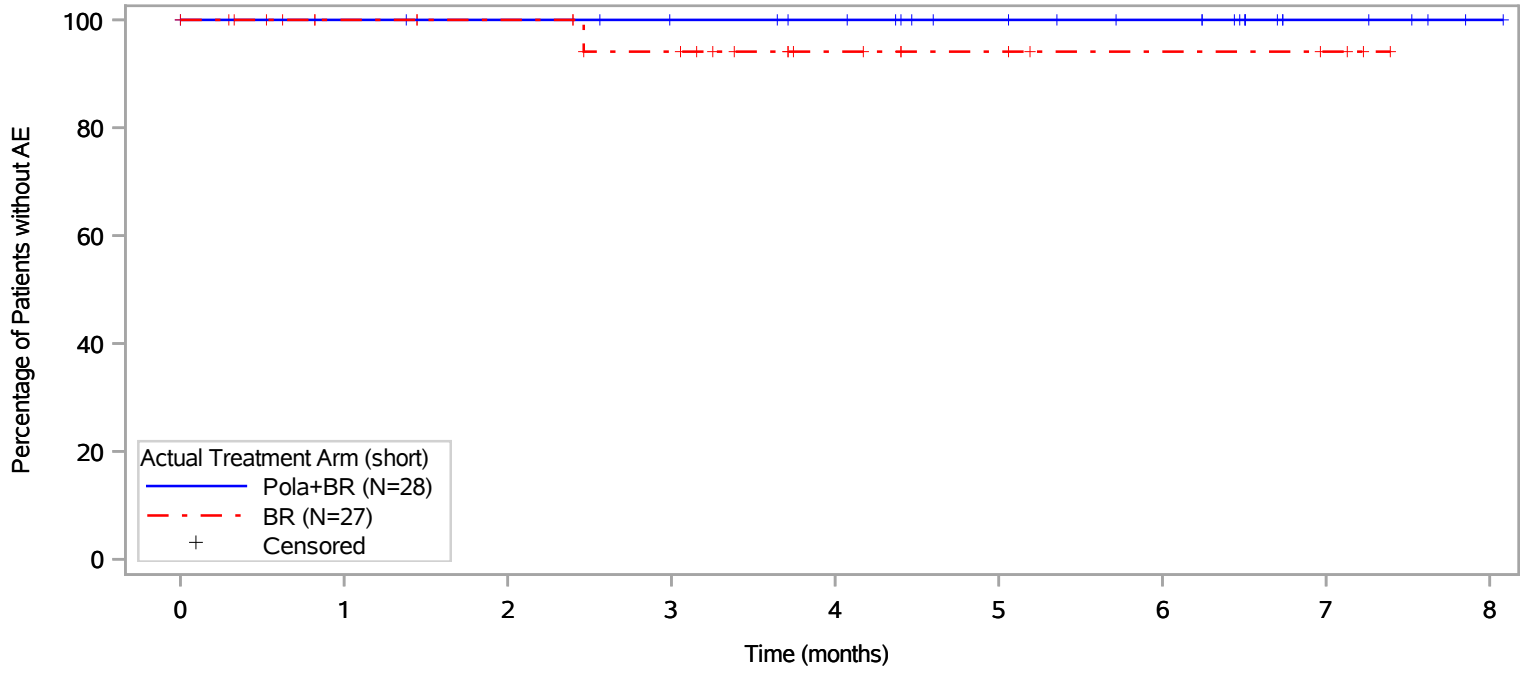


Patients at risk																										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All

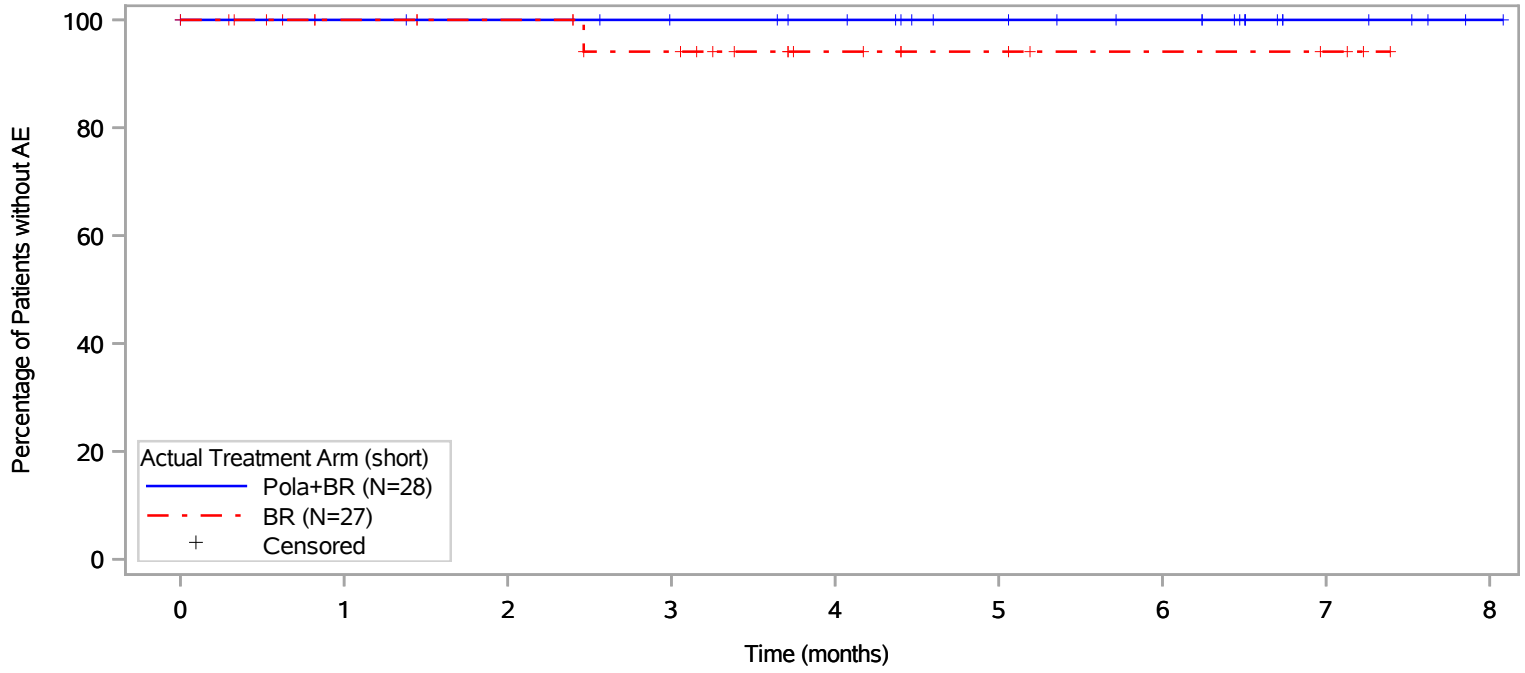


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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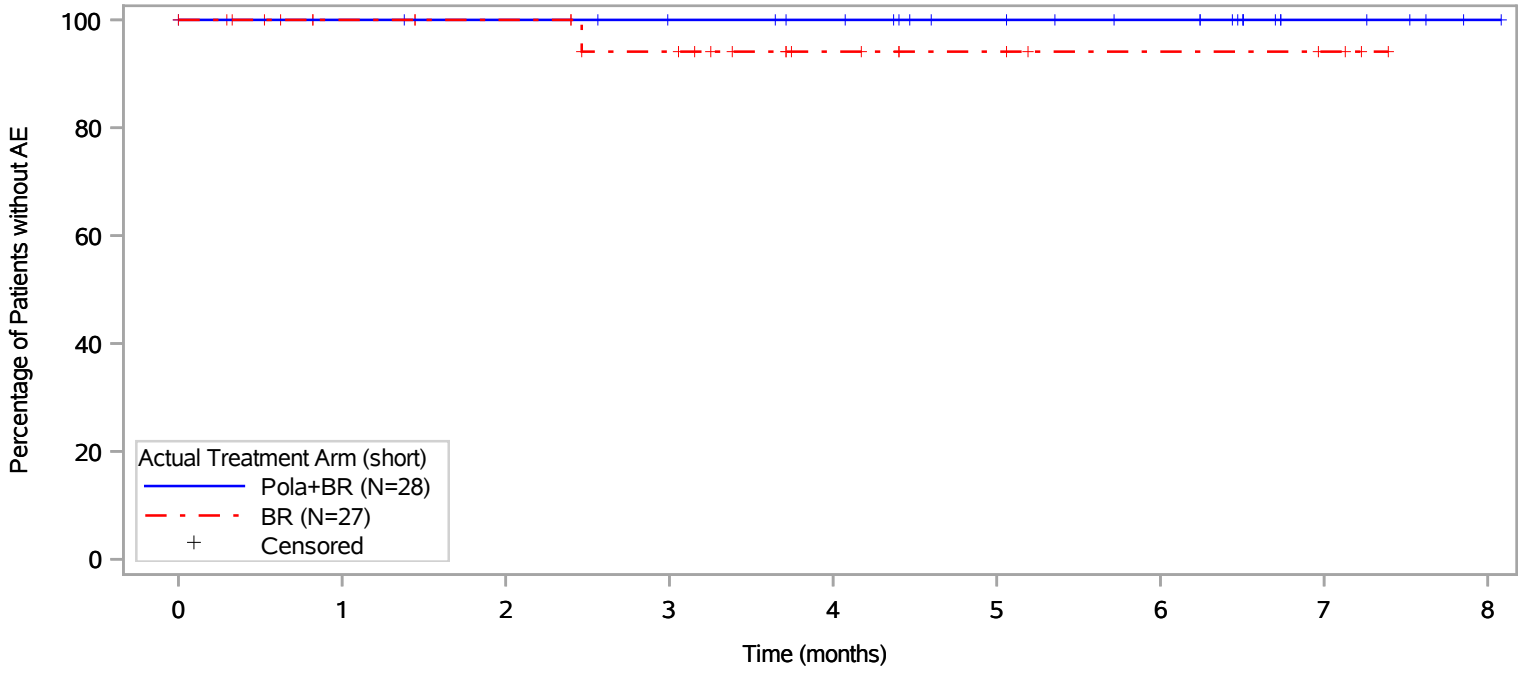
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, HEAD INJURY

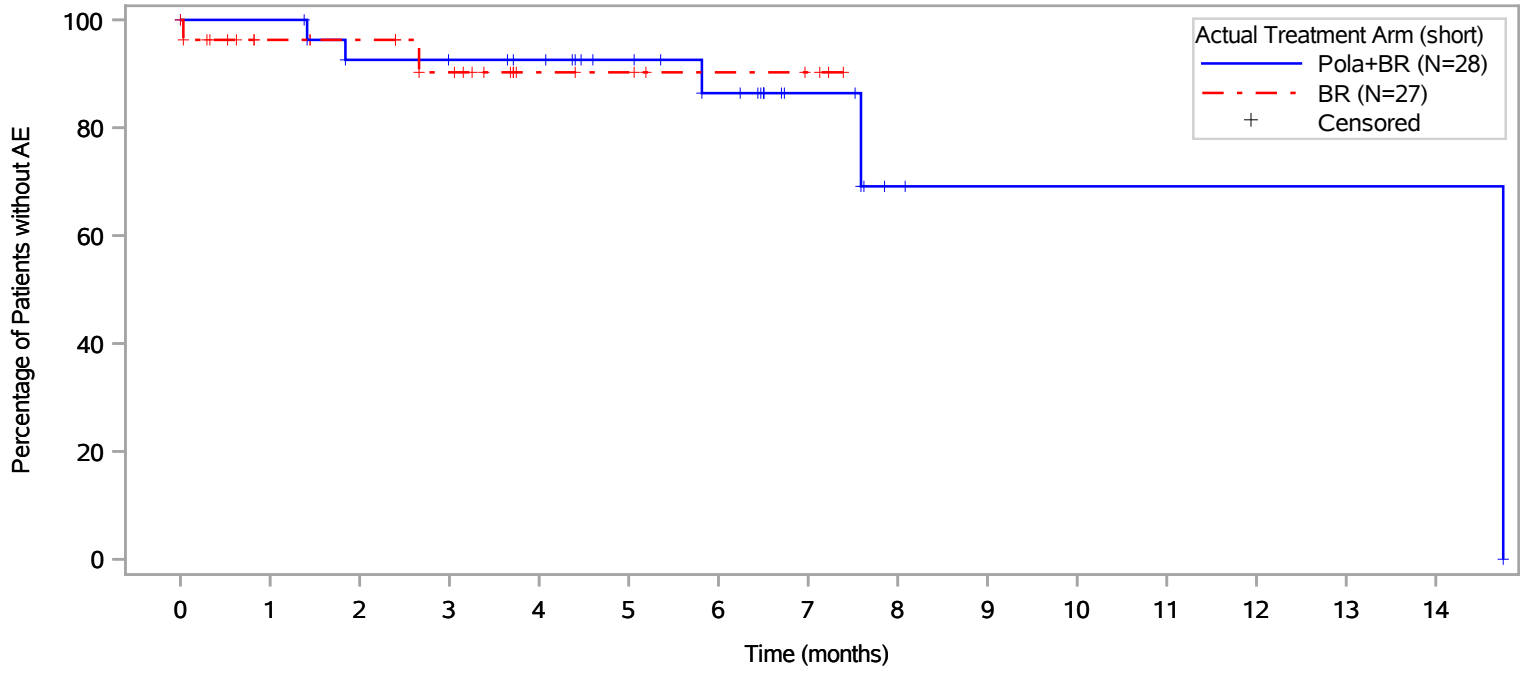


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

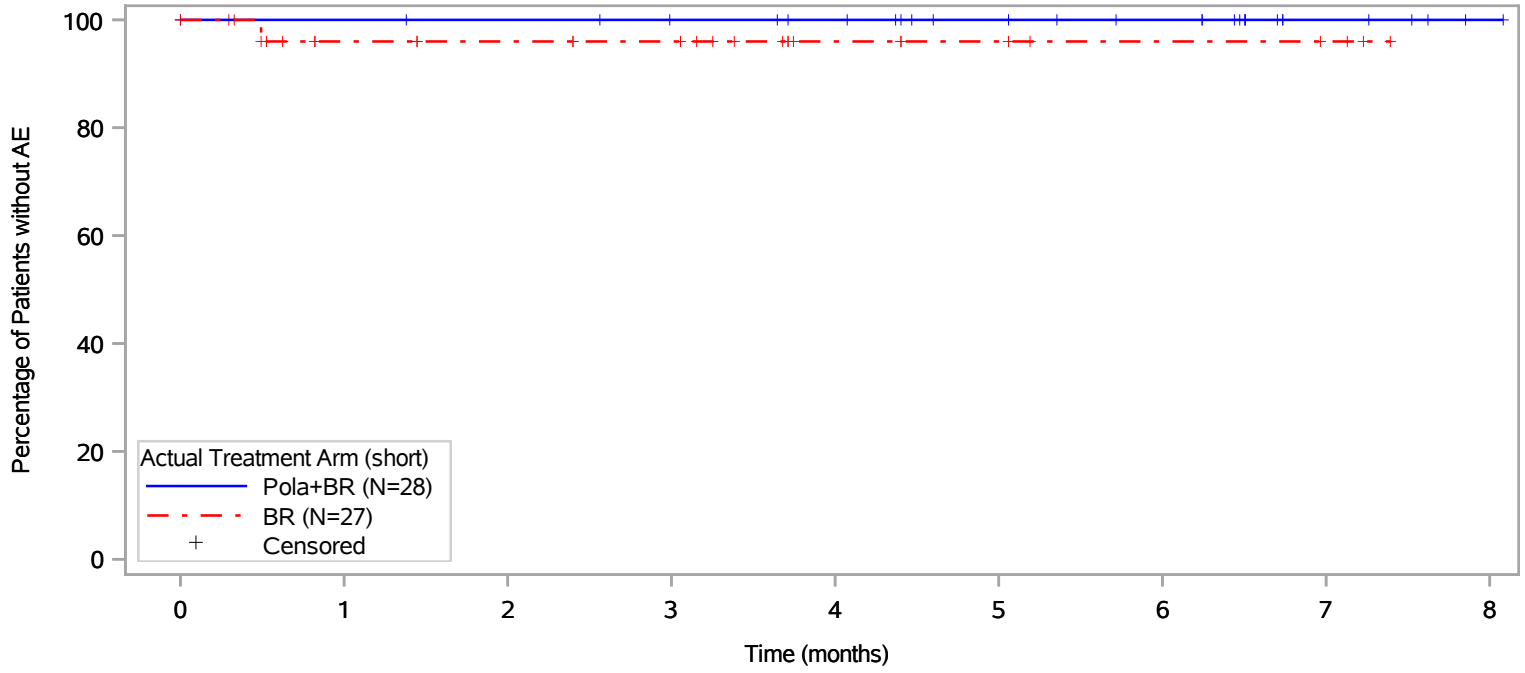


Patients at risk															
Pola+BR (N=28)	28	28	25	24	22	17	14	6	2	1	1	1	1	1	1
BR (N=27)	27	20	18	15	7	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	2	4	9	11	19	22	23	23	23	23	23	23
BR (N=27)	0	6	8	10	18	19	21	22	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, HAEMOGLOBIN DECREASED

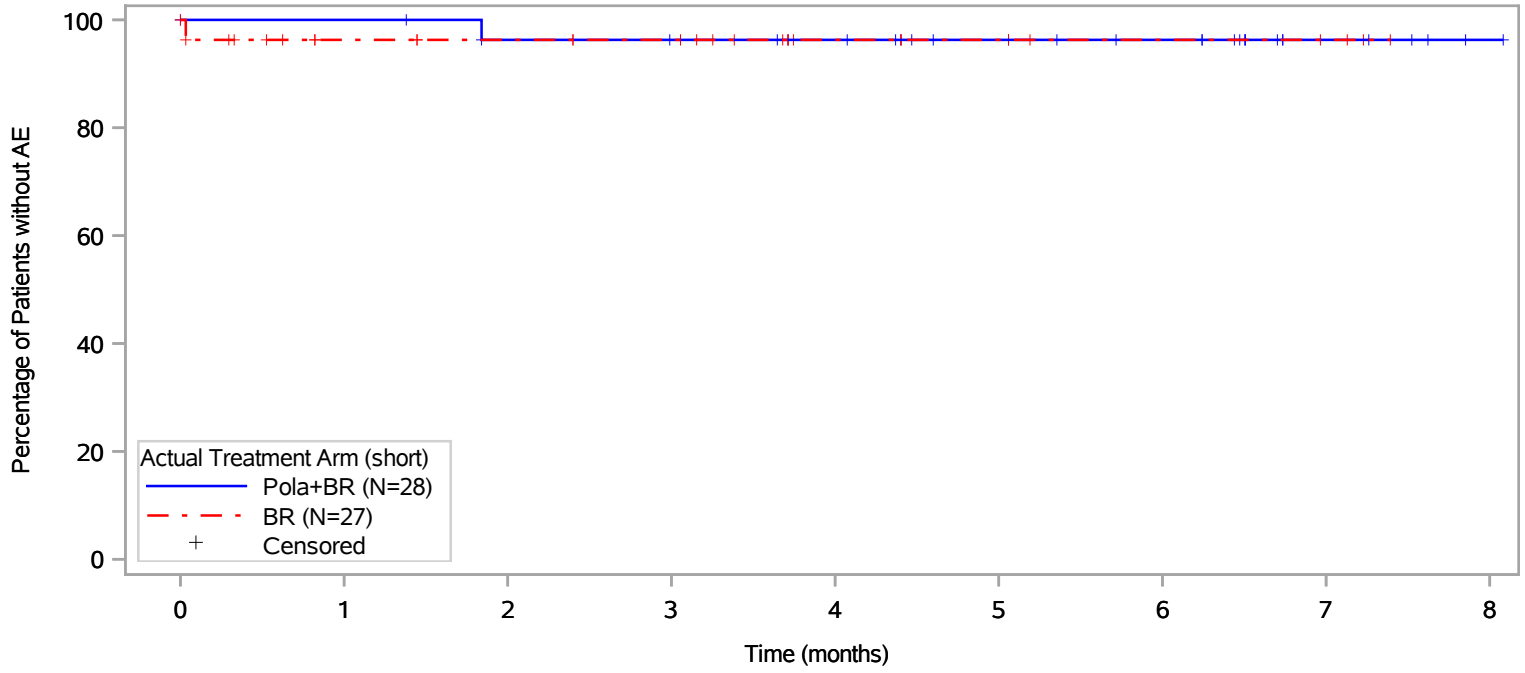


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED

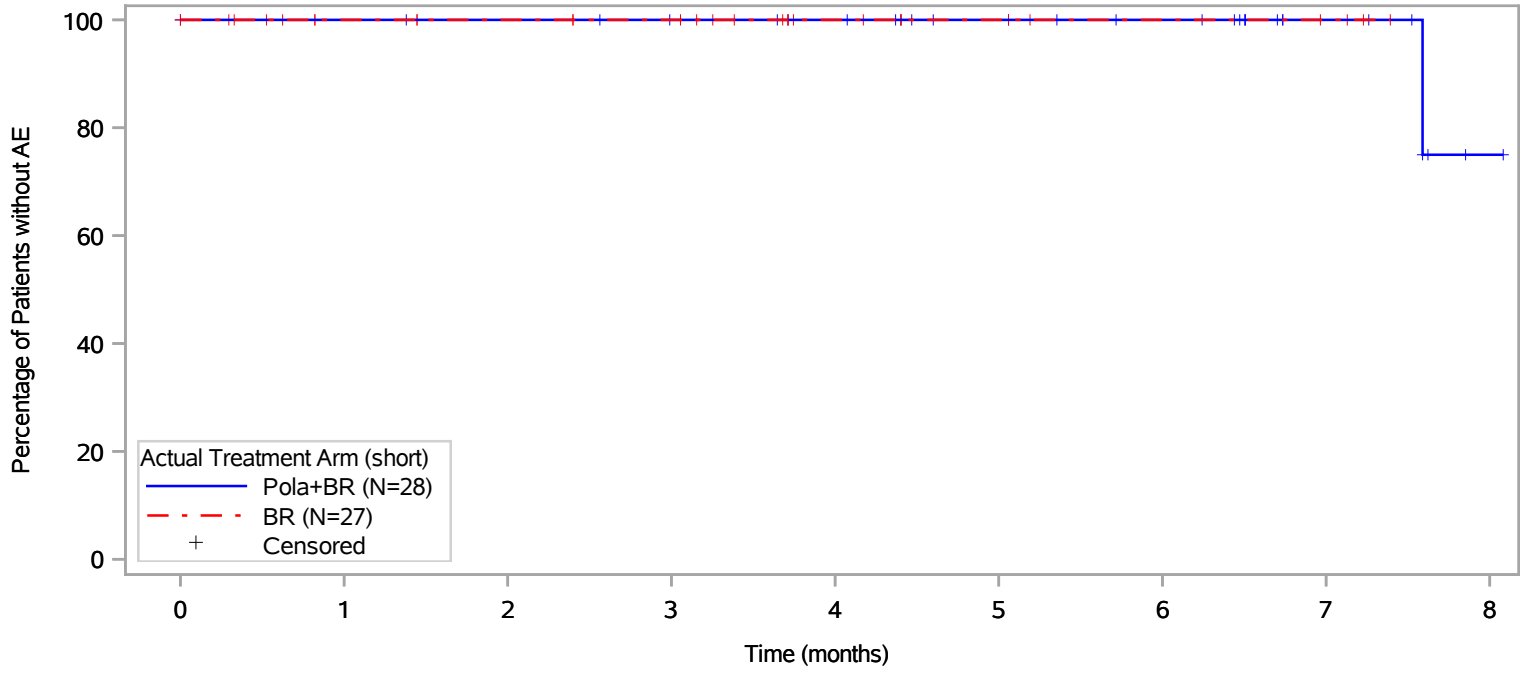


Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

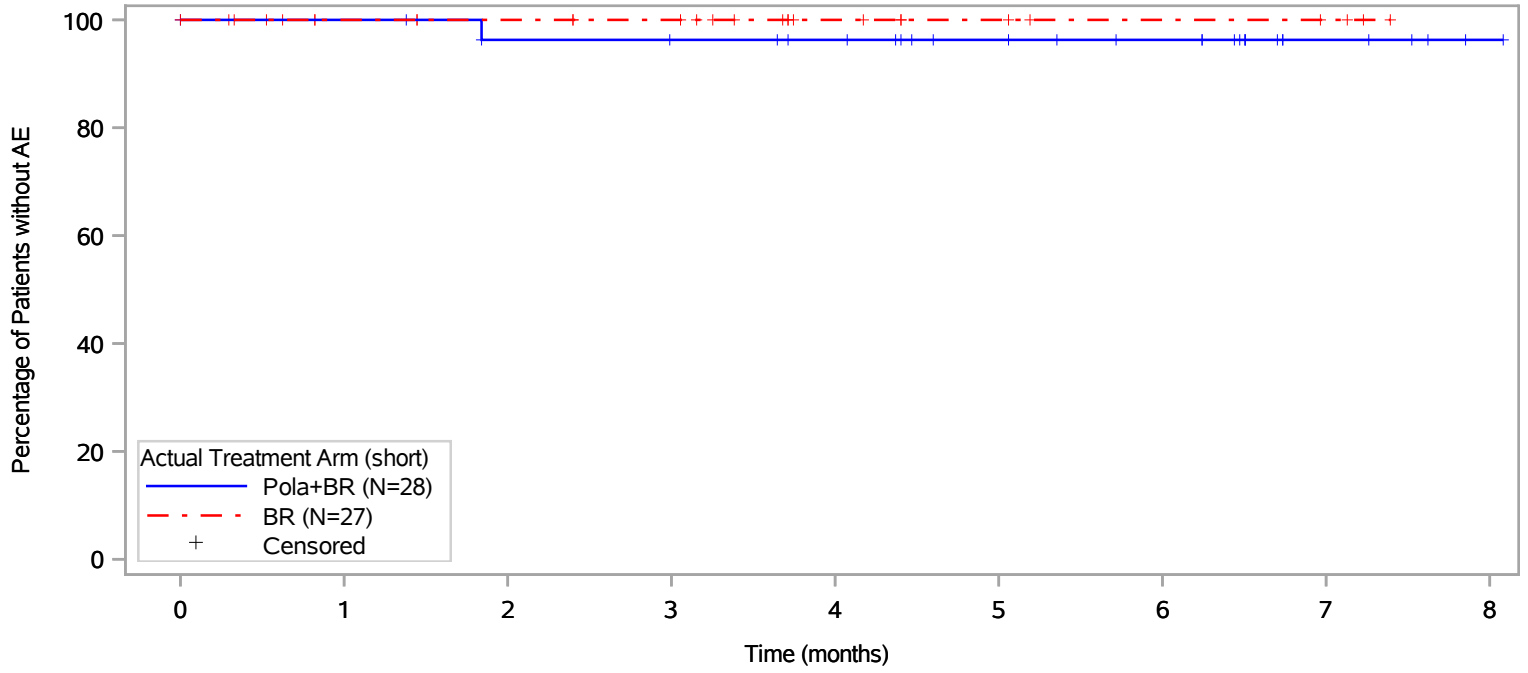
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MORAXELLA TEST POSITIVE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	6	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

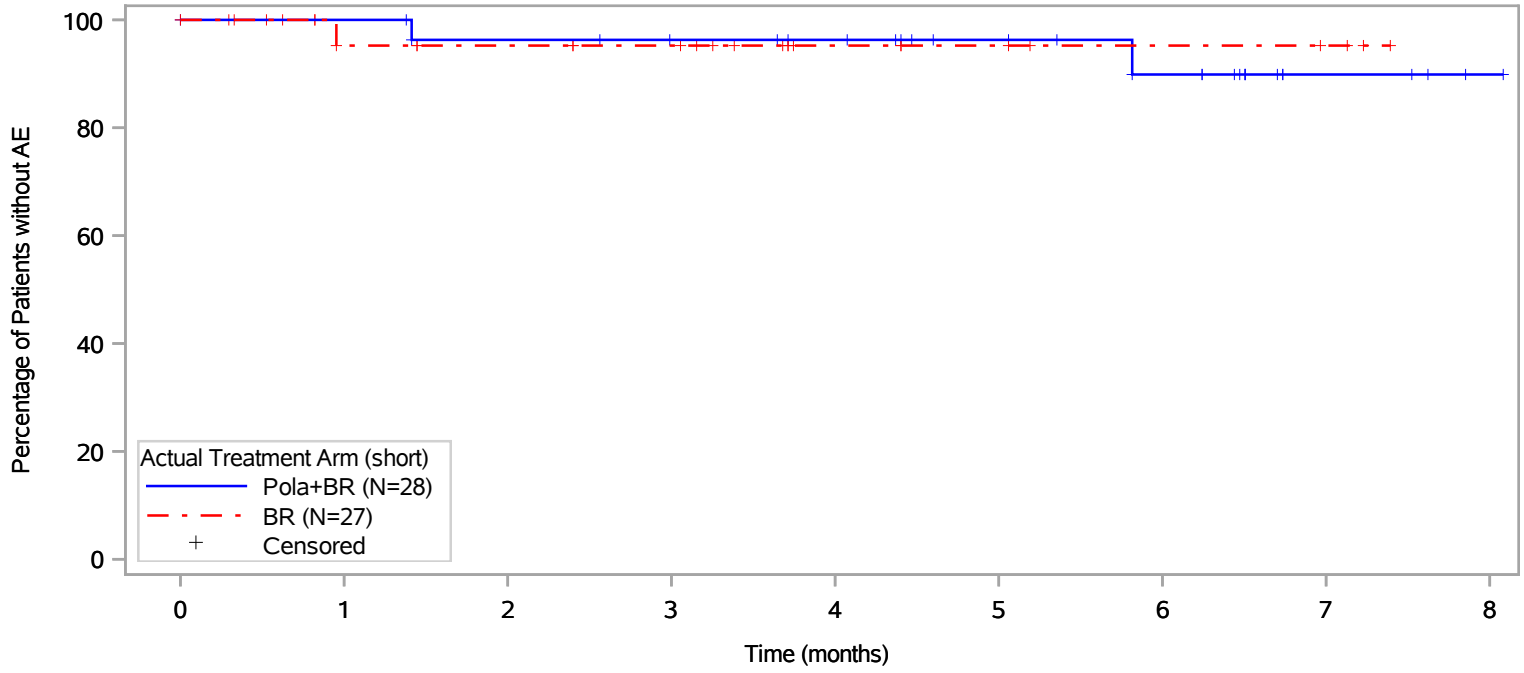


Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

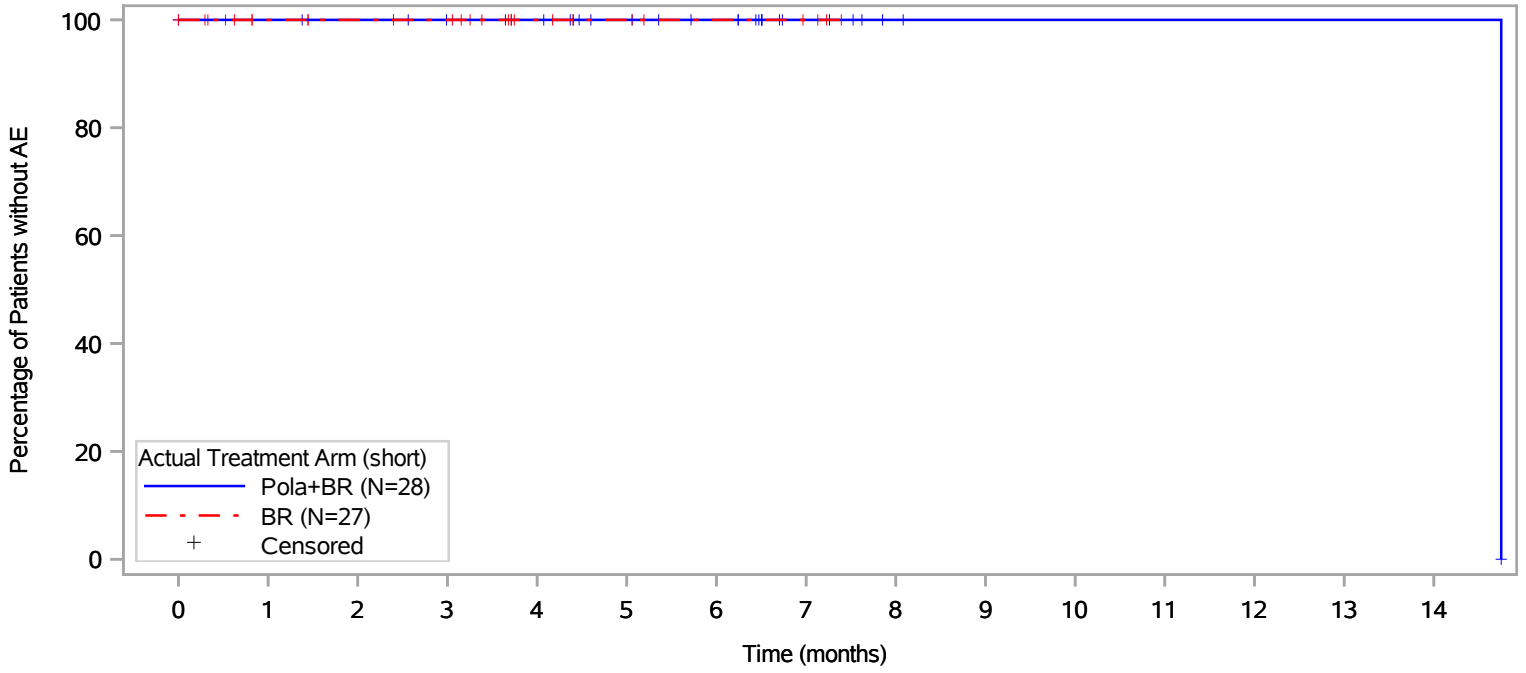


Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	4	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	25
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

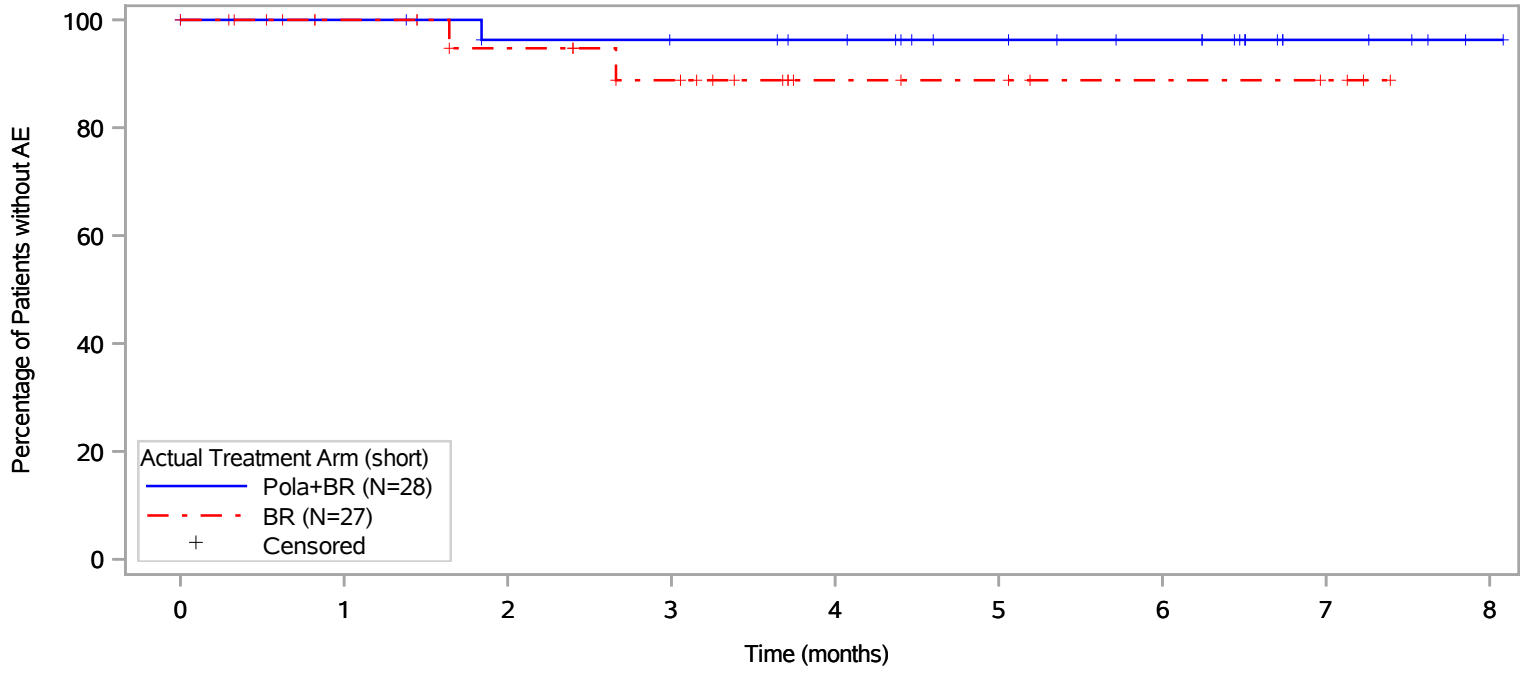
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, TRANSAMINASES INCREASED



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

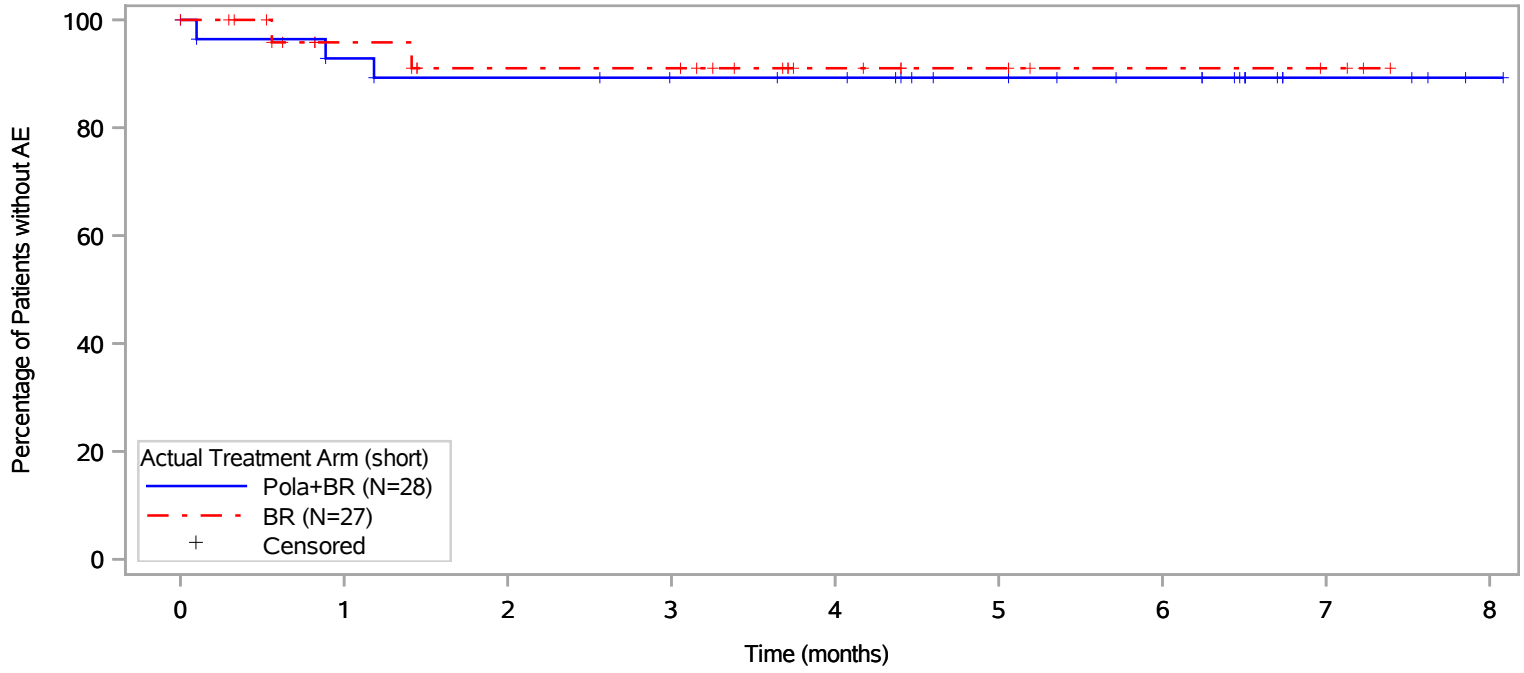
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	18	15	7	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	26	25	23	22	17	14	4	1
BR (N=27)	27	20	17	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	3	8	11	21	24
BR (N=27)	0	6	8	8	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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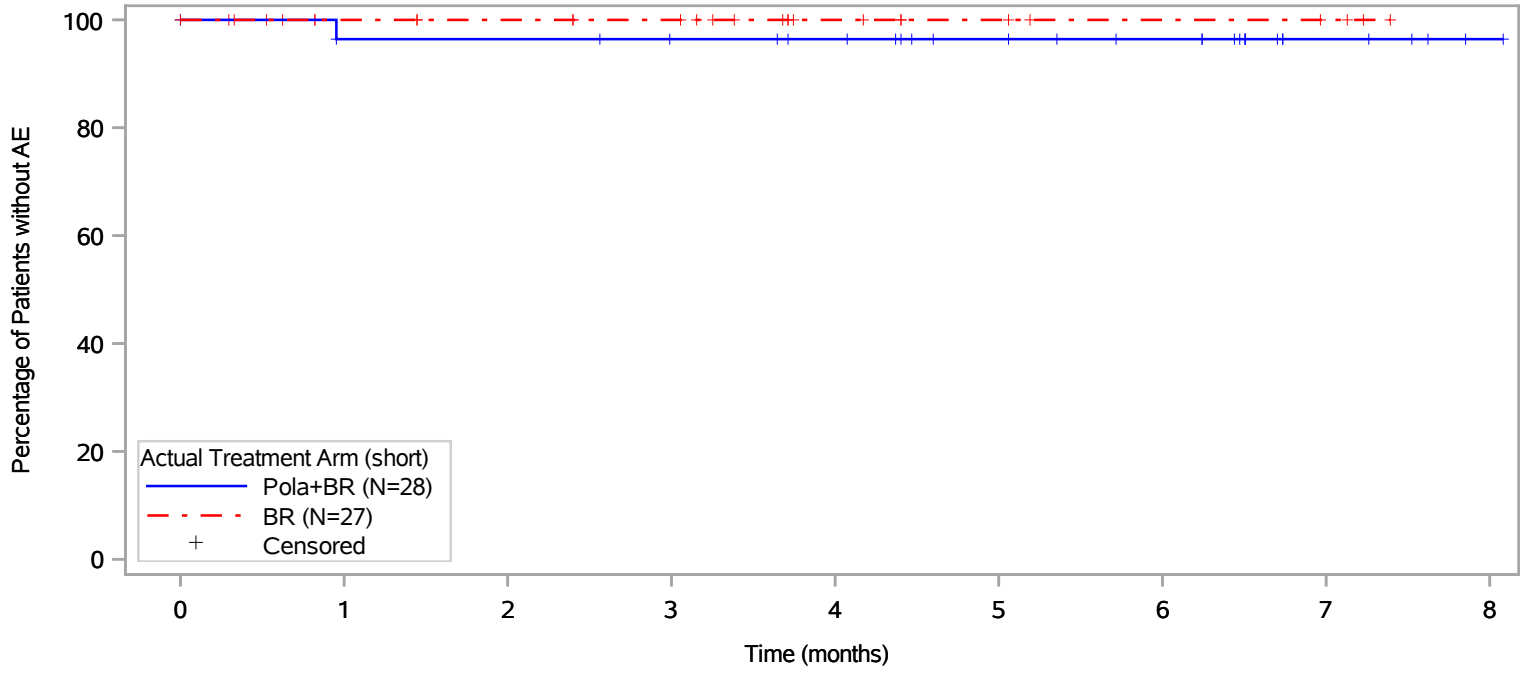
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOCALCAEMIA

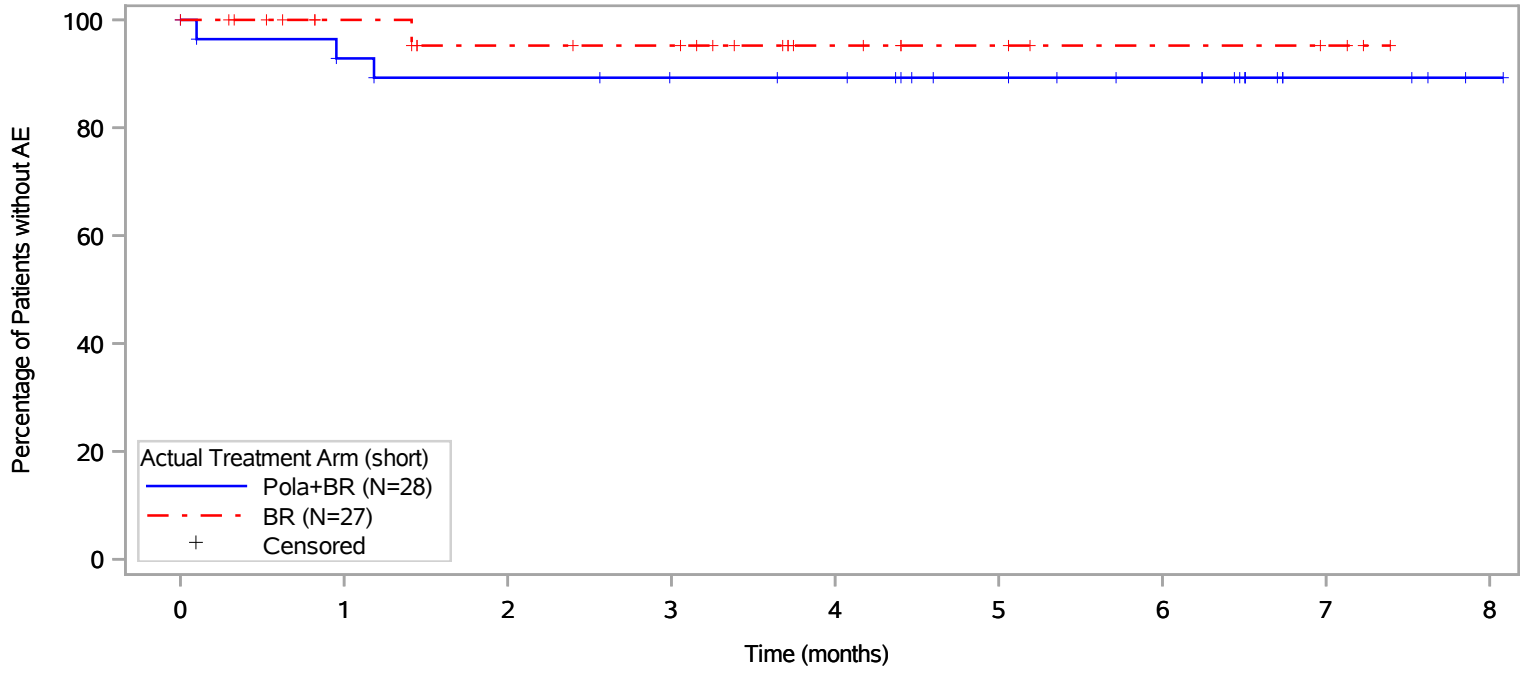


Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk									
Pola+BR (N=28)	28	26	25	23	22	17	14	4	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	3	8	11	21	24
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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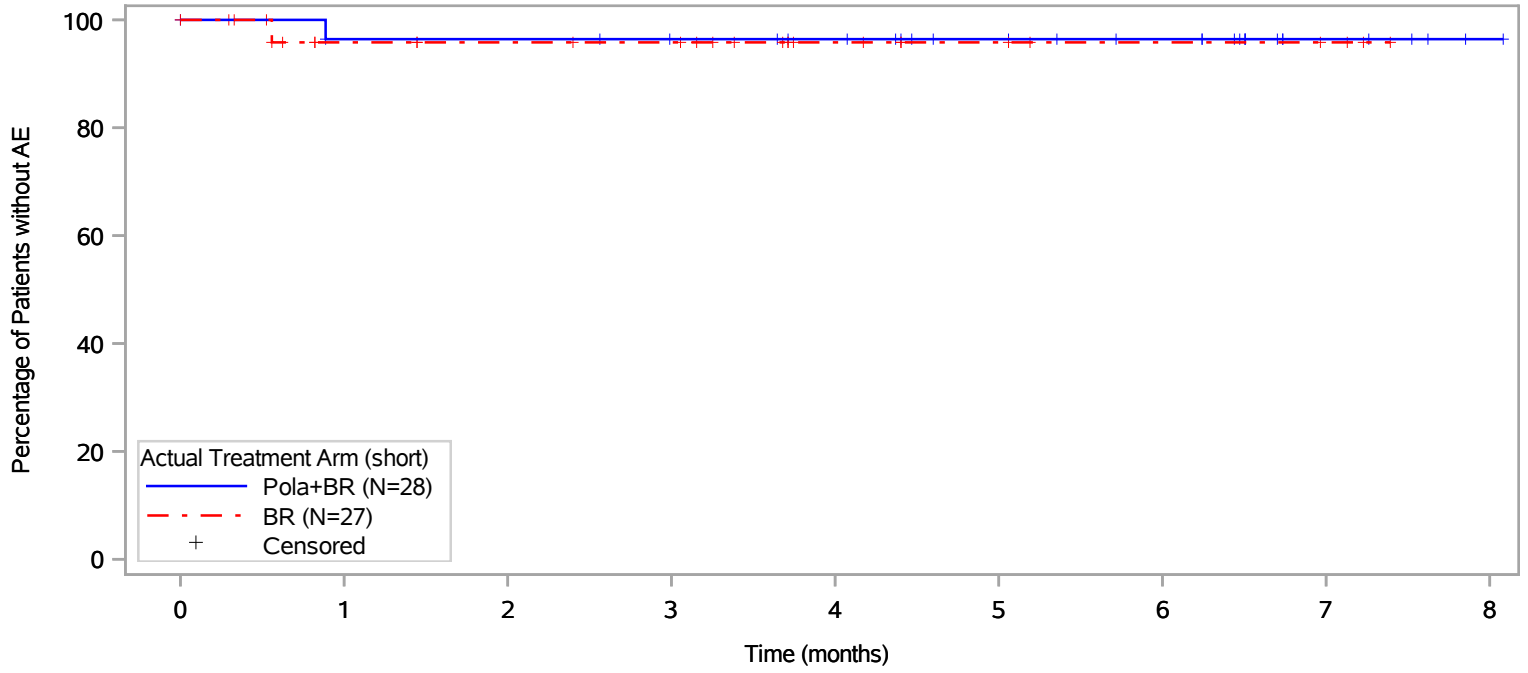
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOPHOSPHATAEMIA

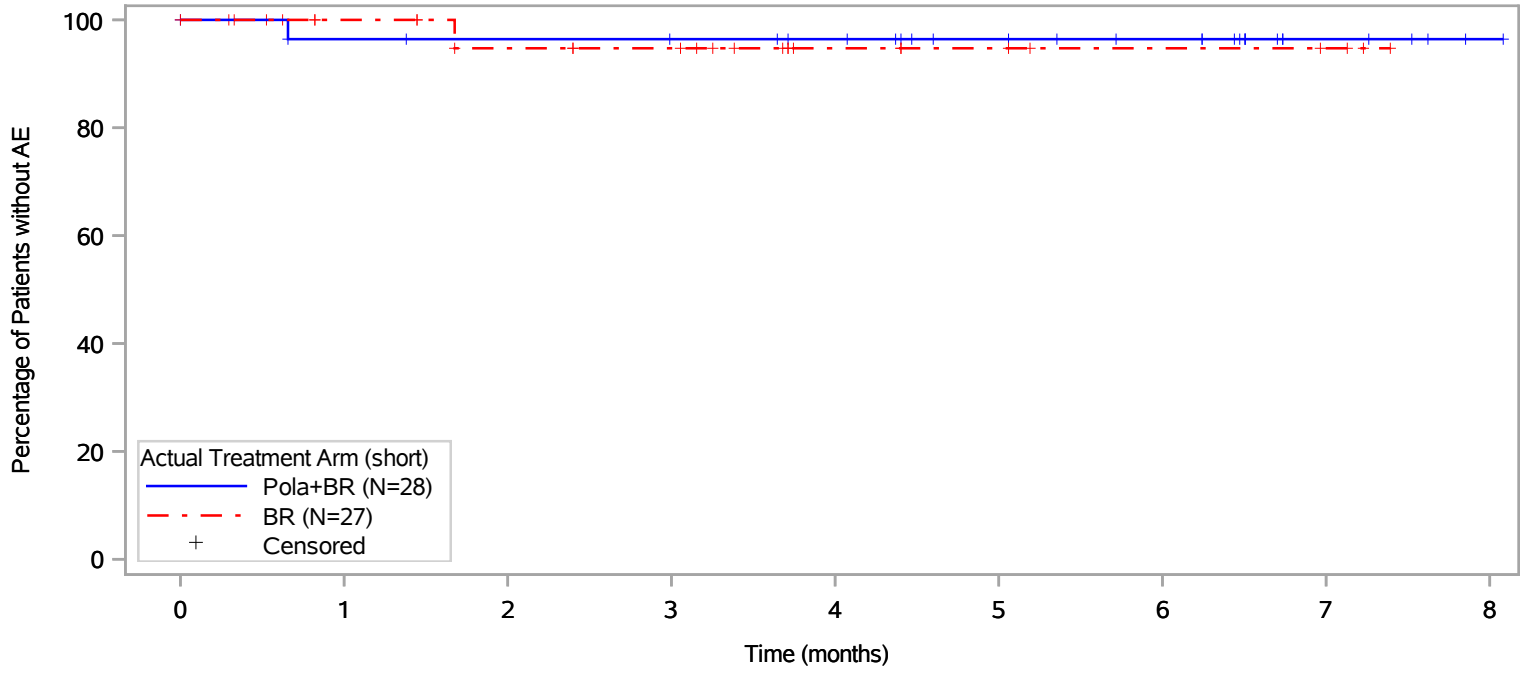


Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All

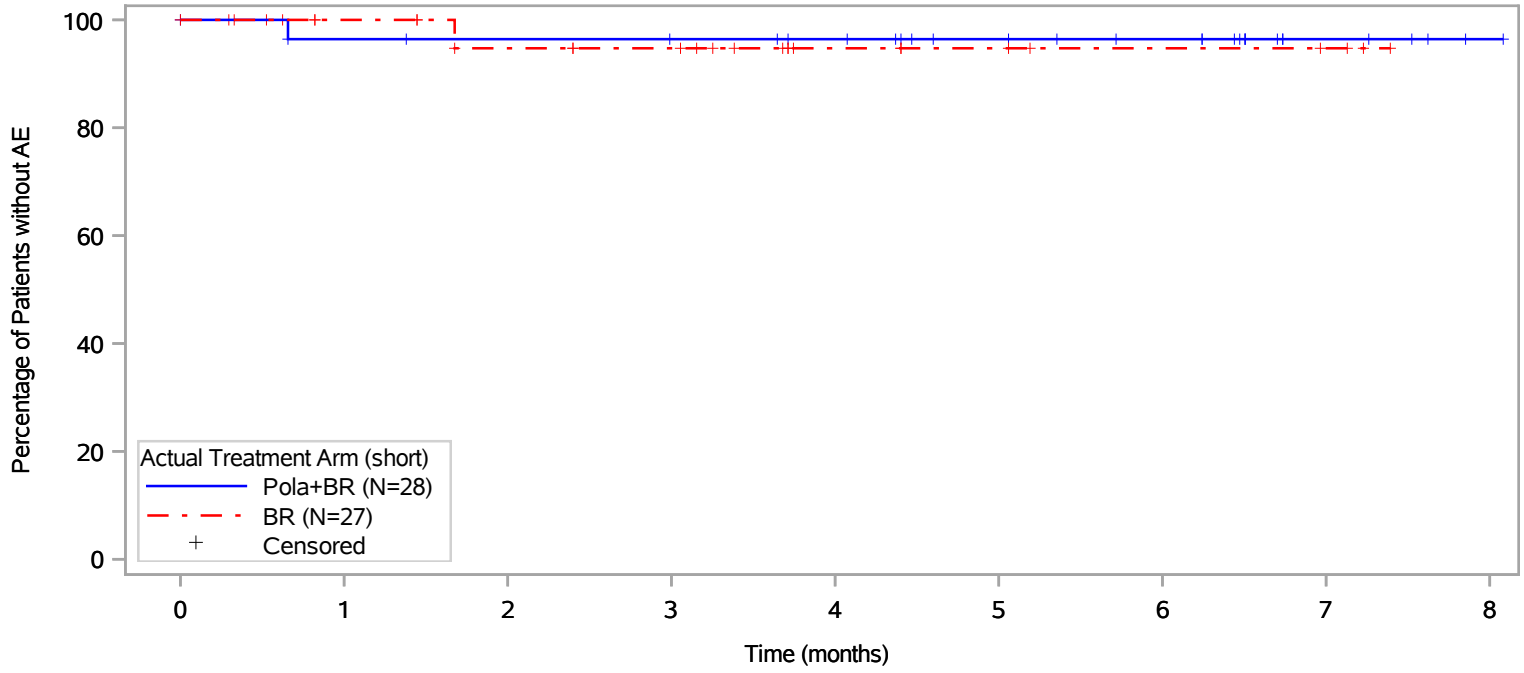


Patients at risk									
Pola+BR (N=28)	28	27	26	25	23	18	15	5	1
BR (N=27)	27	21	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN



Patients at risk									
Pola+BR (N=28)	28	27	26	25	23	18	15	5	1
BR (N=27)	27	21	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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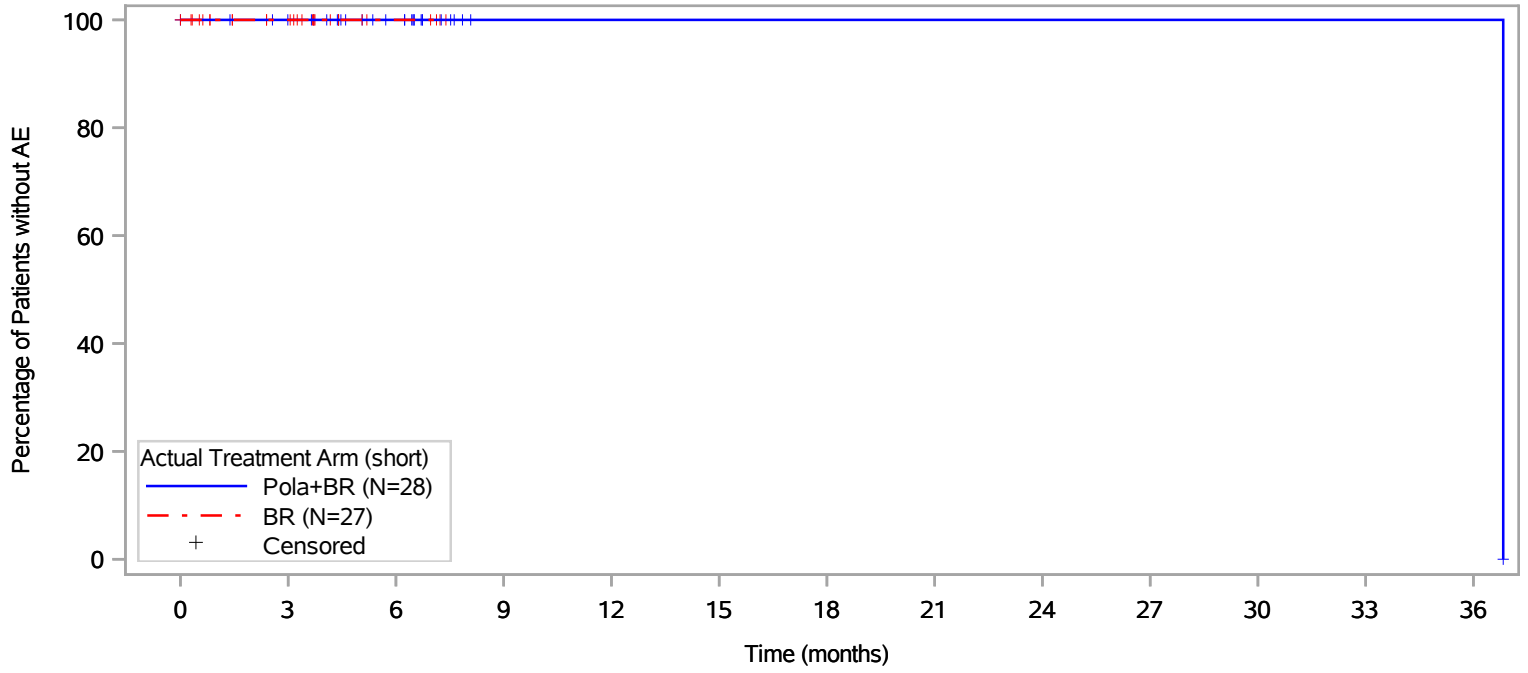
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All

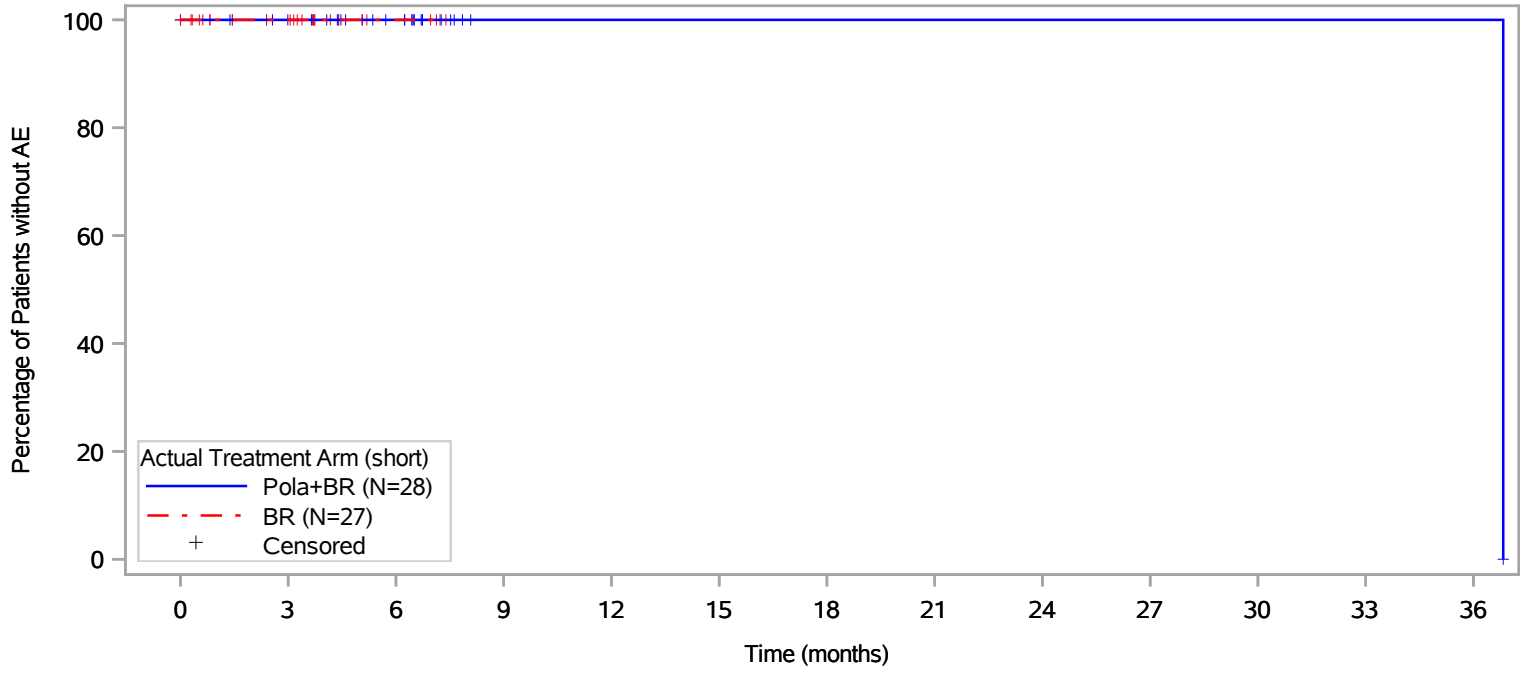


Patients at risk													
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

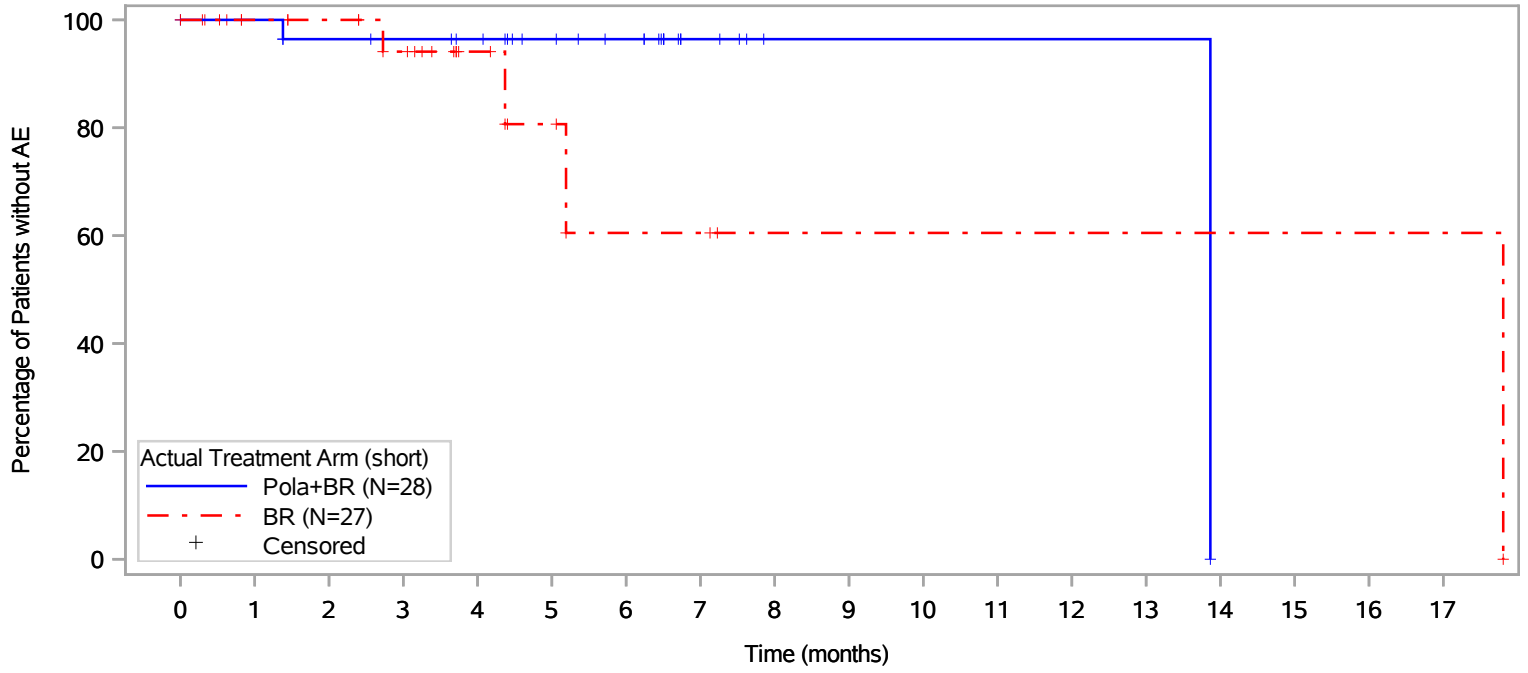
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MALIGNANT MELANOMA



Patients at risk													
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk																		
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1	1	1	1	1	1	NE	NE	NE	NE
BR (N=27)	27	21	19	16	8	5	3	3	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26	26	26	26	26	26	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	20	21	21	23	23	23	23	23	23	23	23	23	23

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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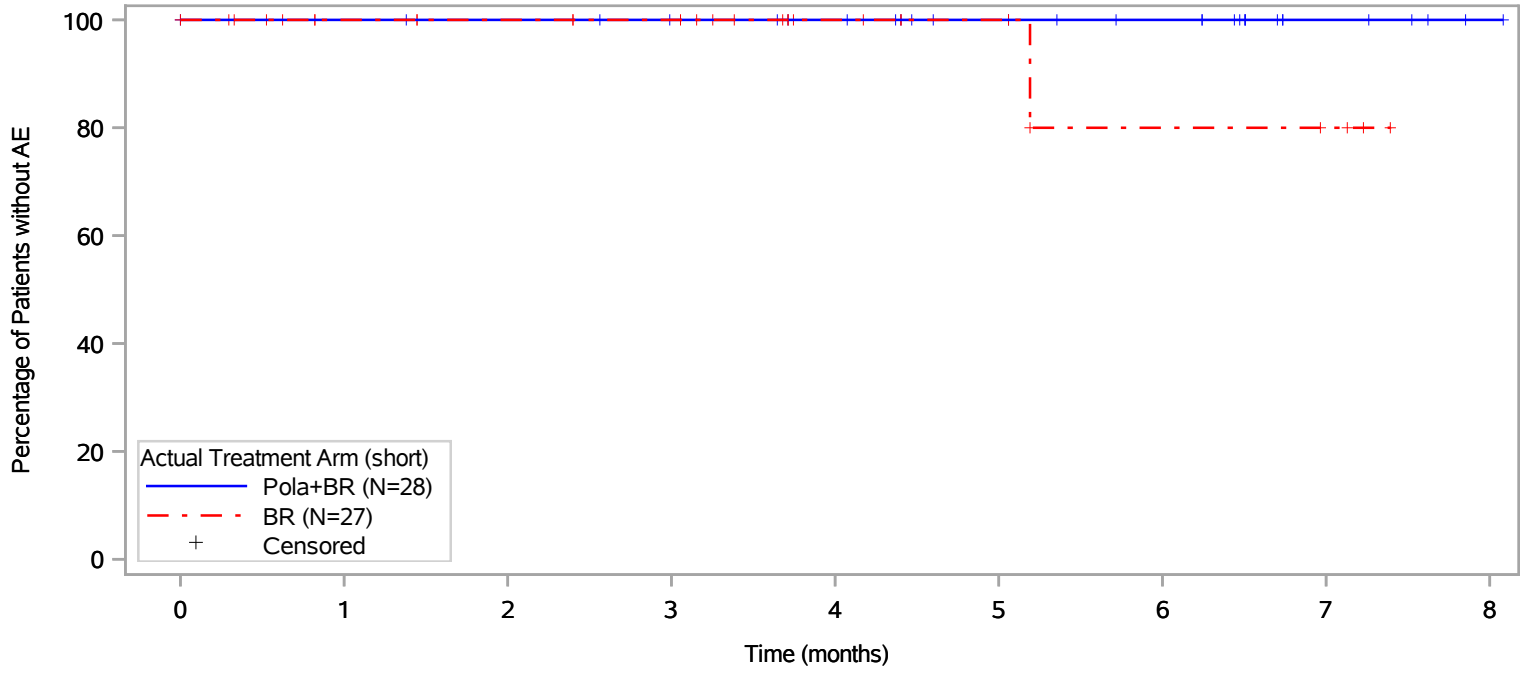
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, CEREBRAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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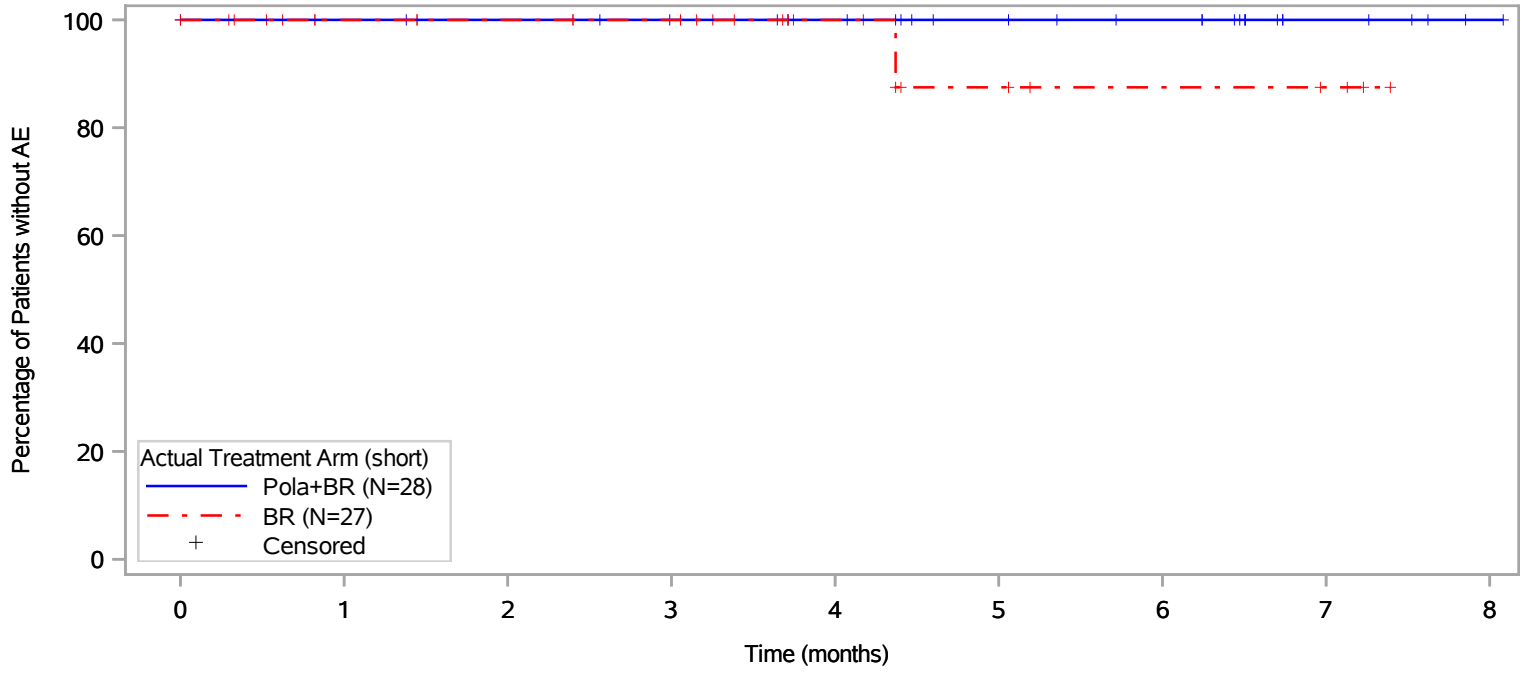
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, CEREBROVASCULAR ACCIDENT

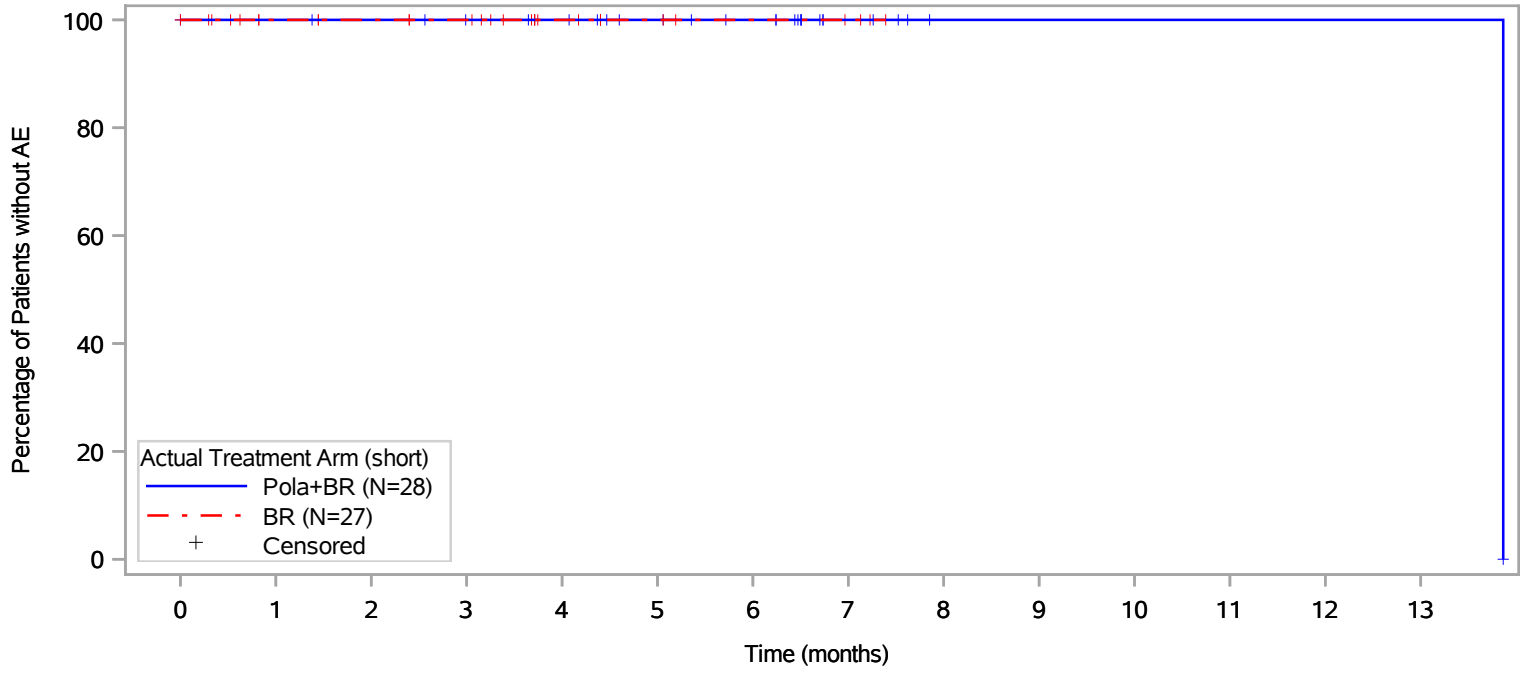


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HAEMORRHAGE INTRACRANIAL



Patients at risk														
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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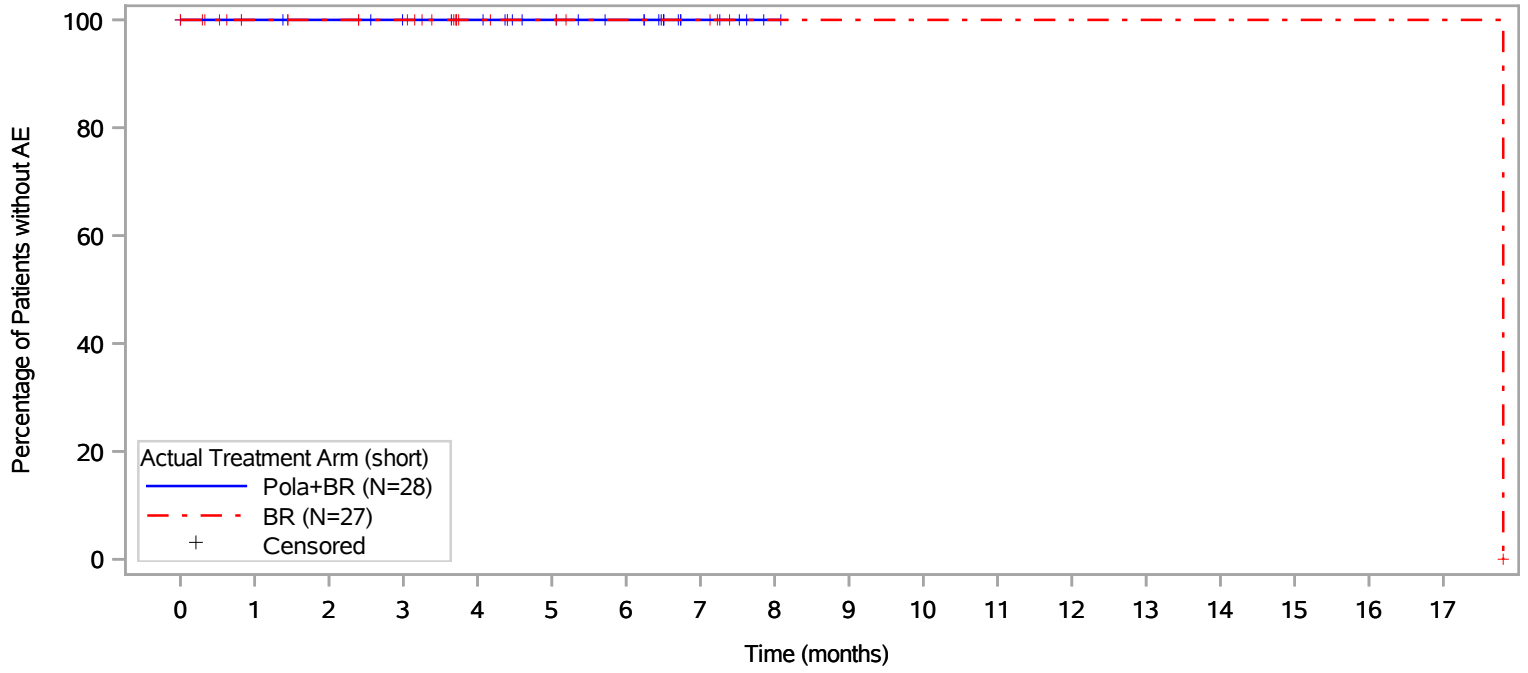
02DEC2022 2:10

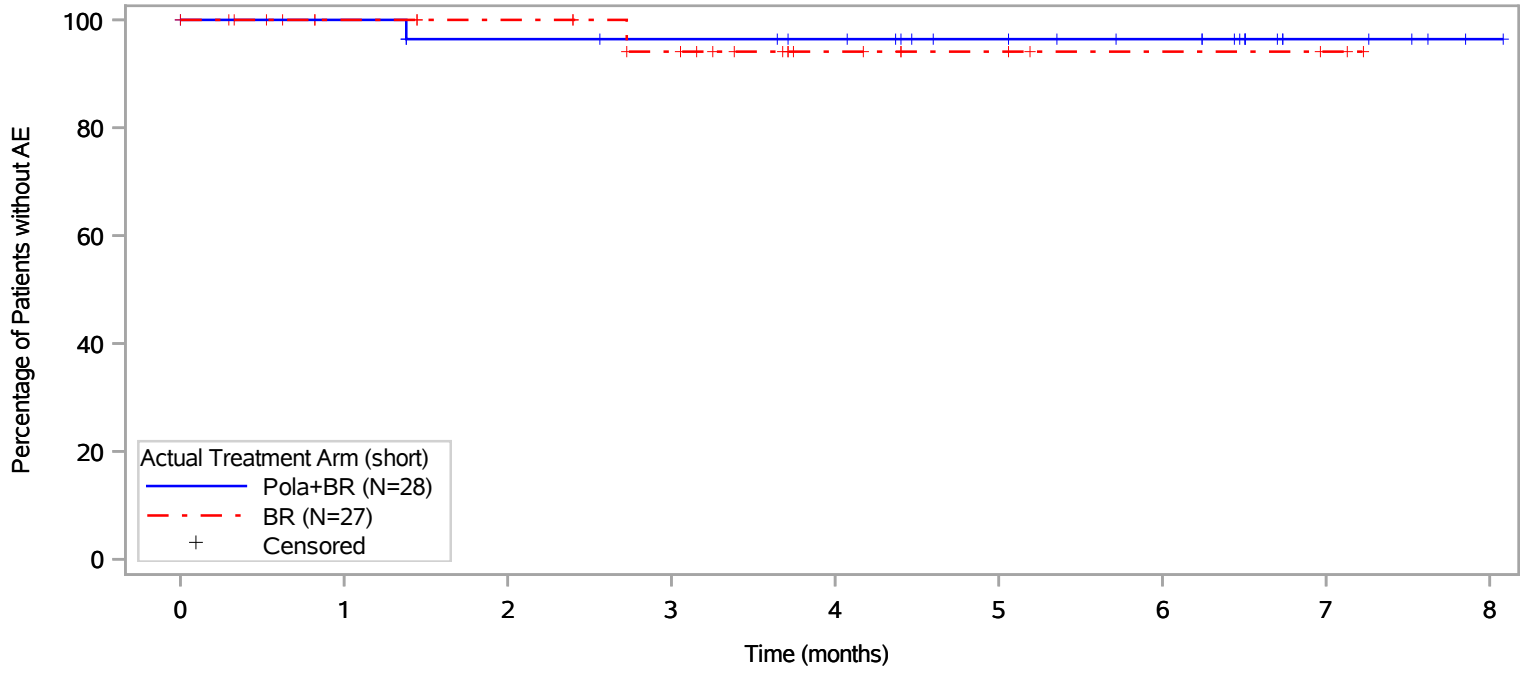
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, LEUKOENCEPHALOPATHY



Patients at risk																		
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	23	26	26	26	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, SYNCOPE



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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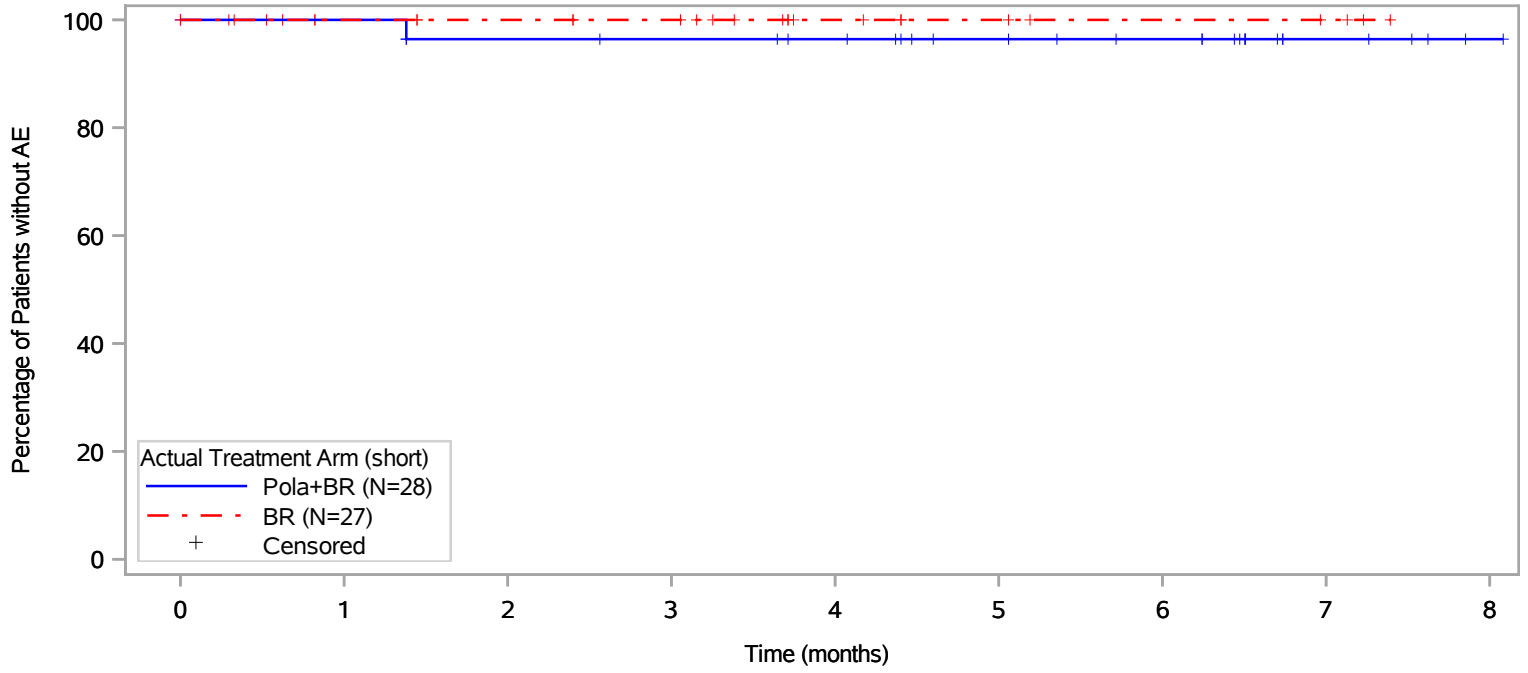
02DEC2022 2:10

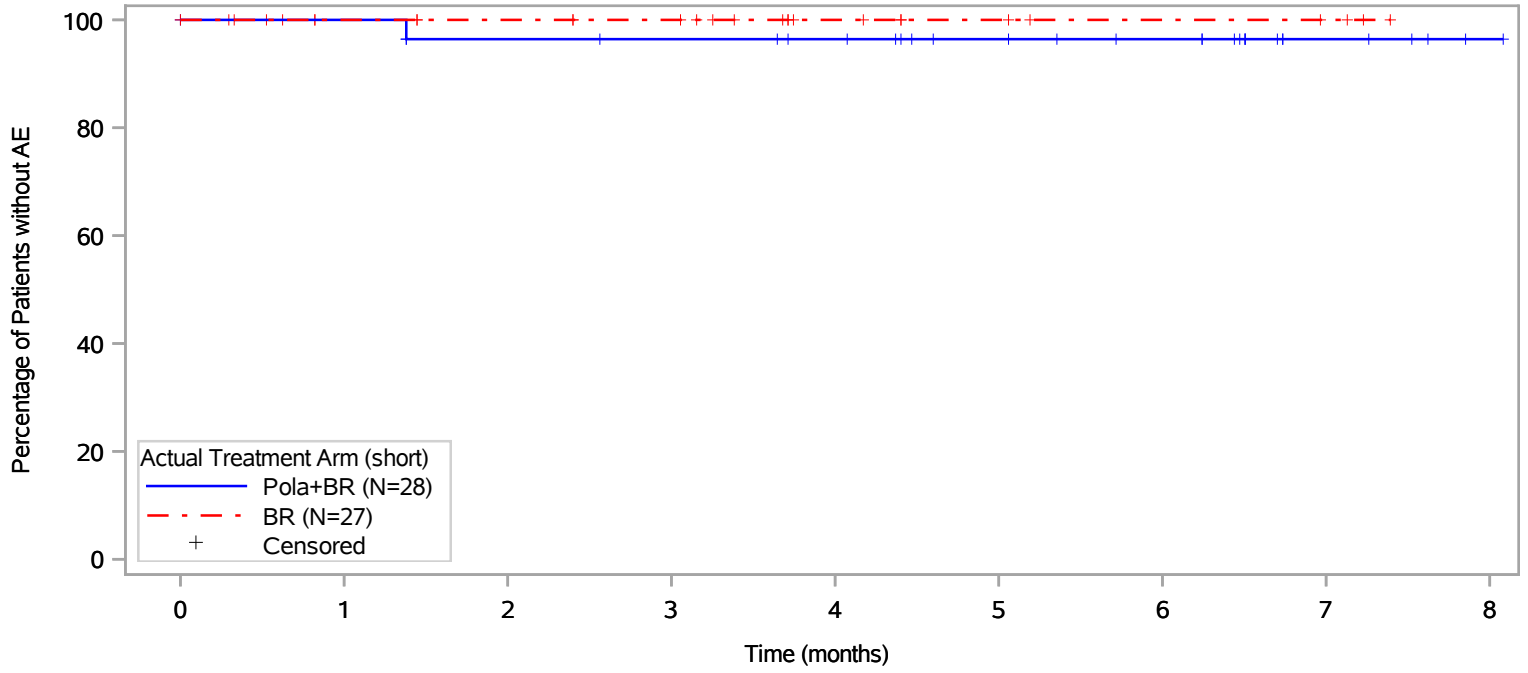
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

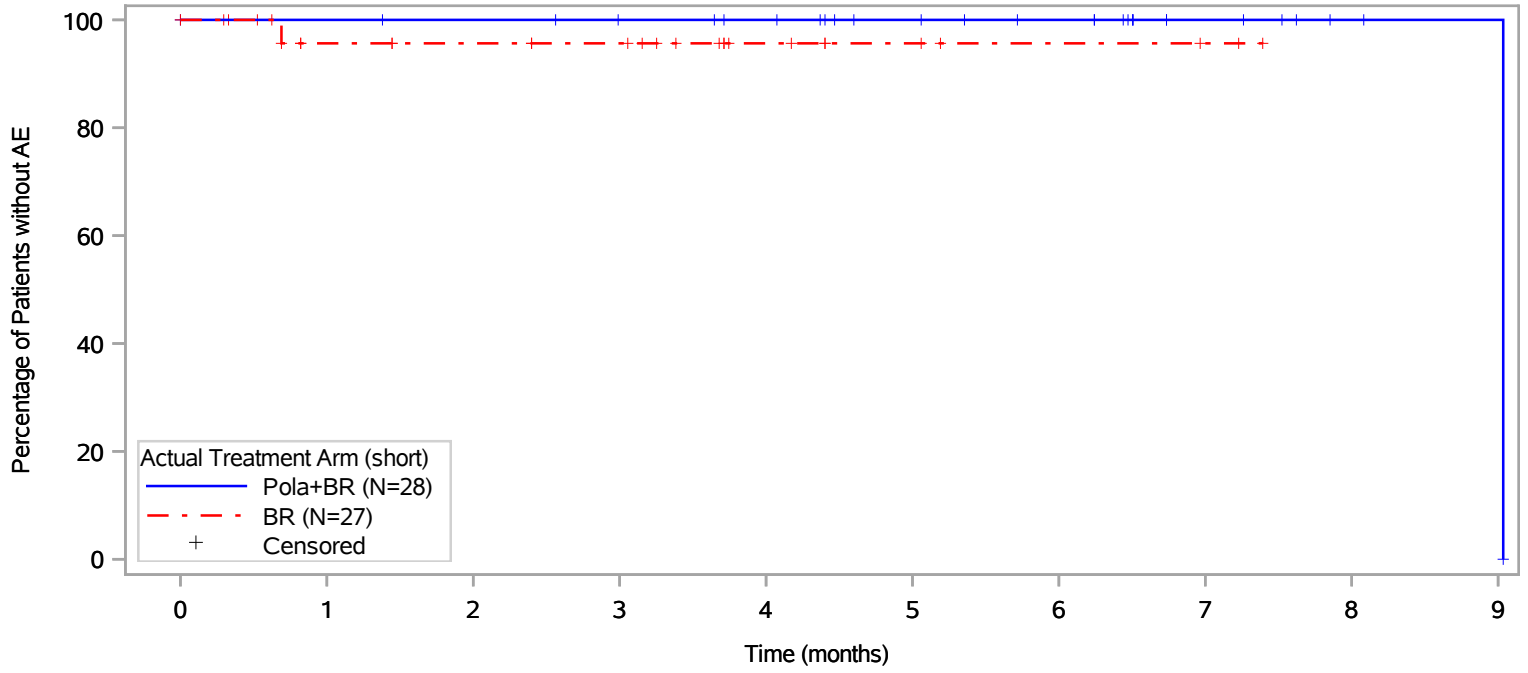
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, CONFUSIONAL STATE



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1
BR (N=27)	27	20	18	16	8	5	3	2	NE	NE
Patients censored										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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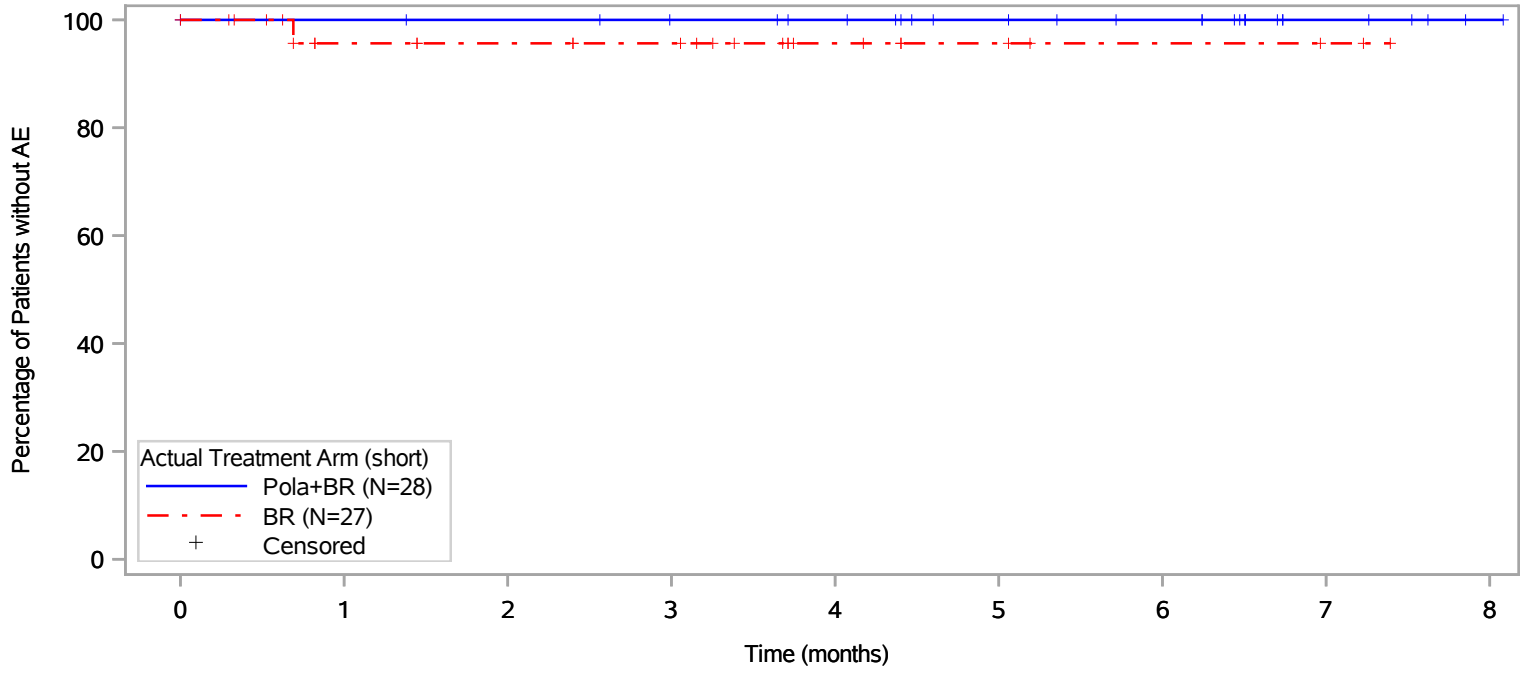
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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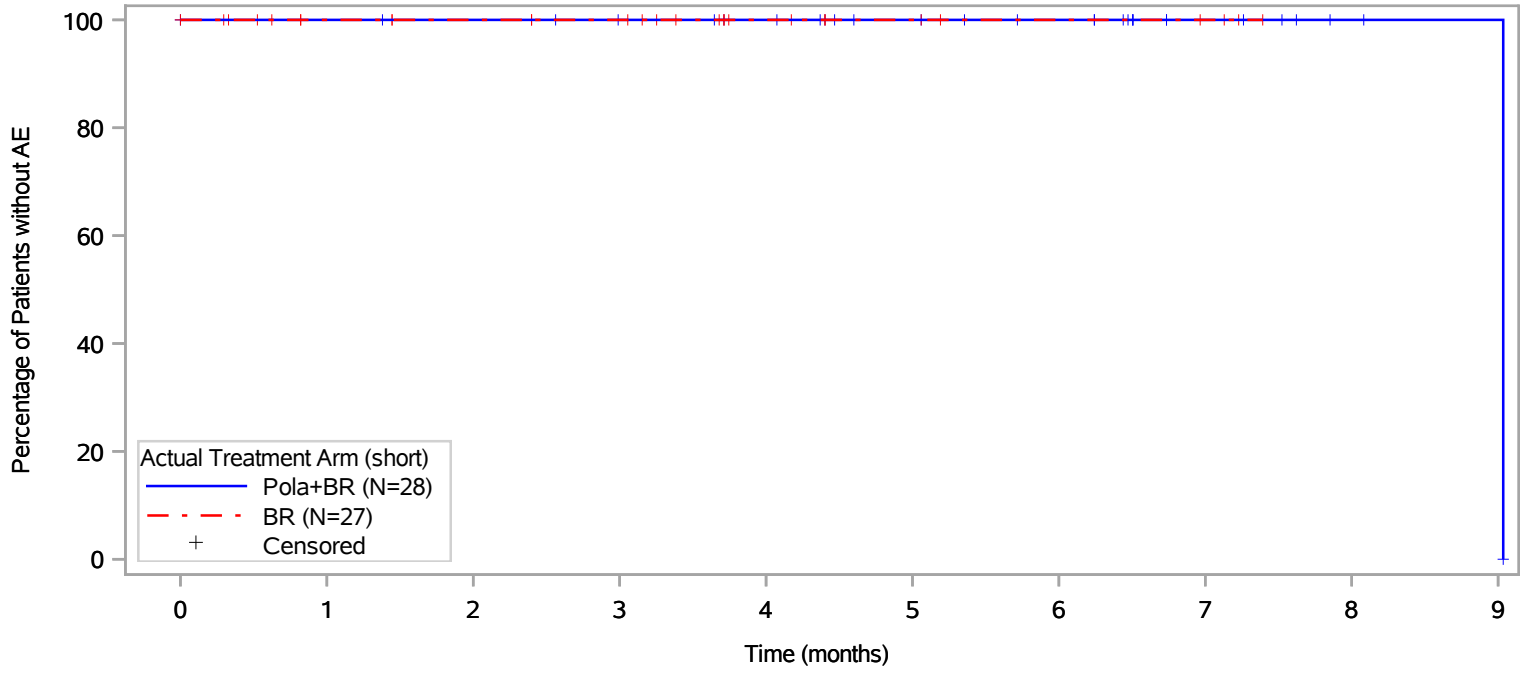
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE
Patients censored										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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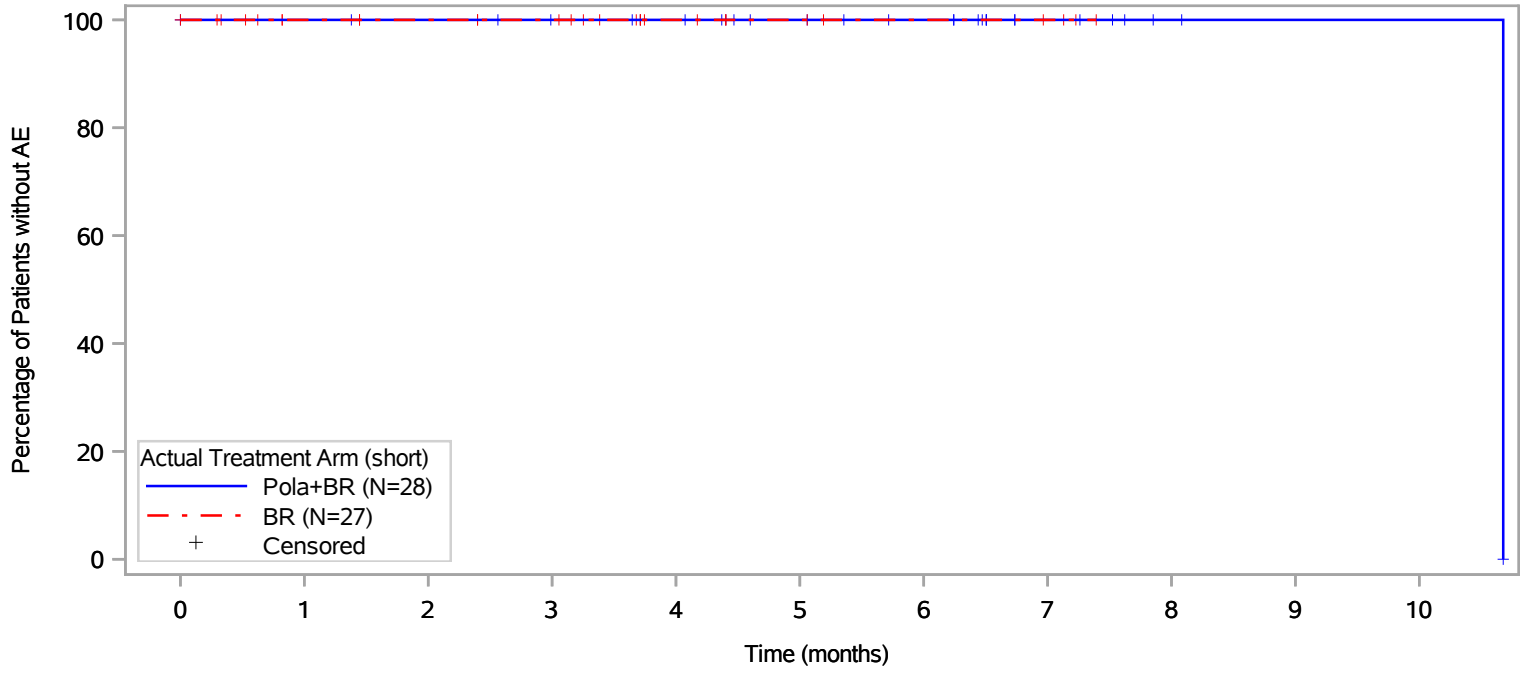
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE



Patients at risk											
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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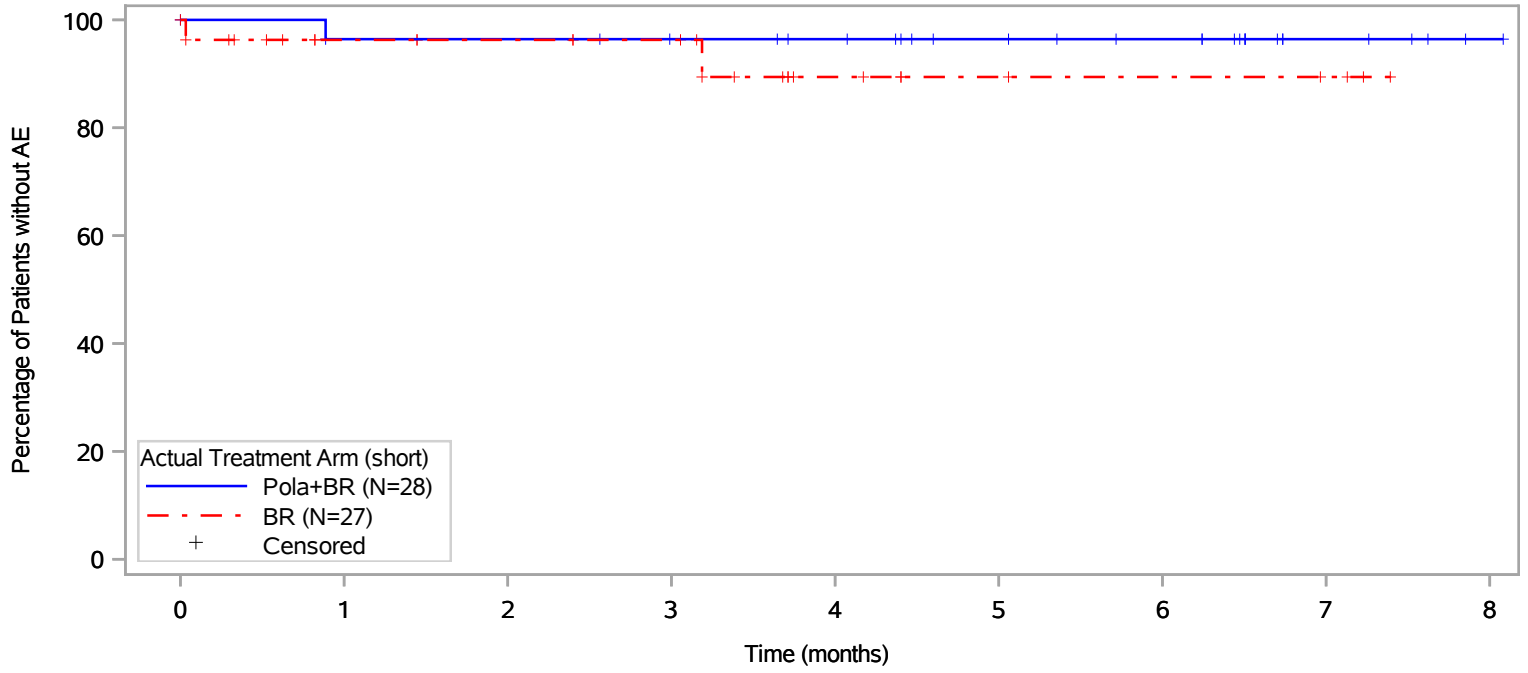
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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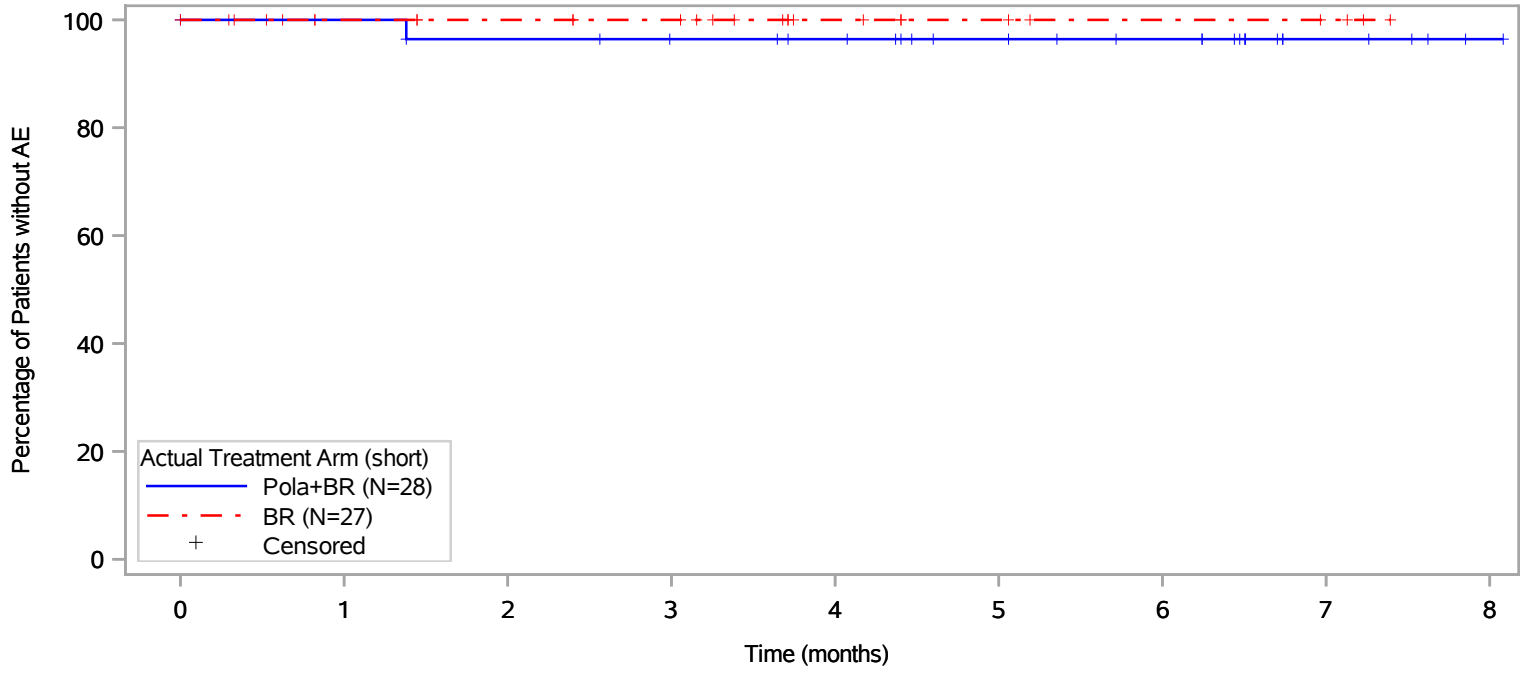
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

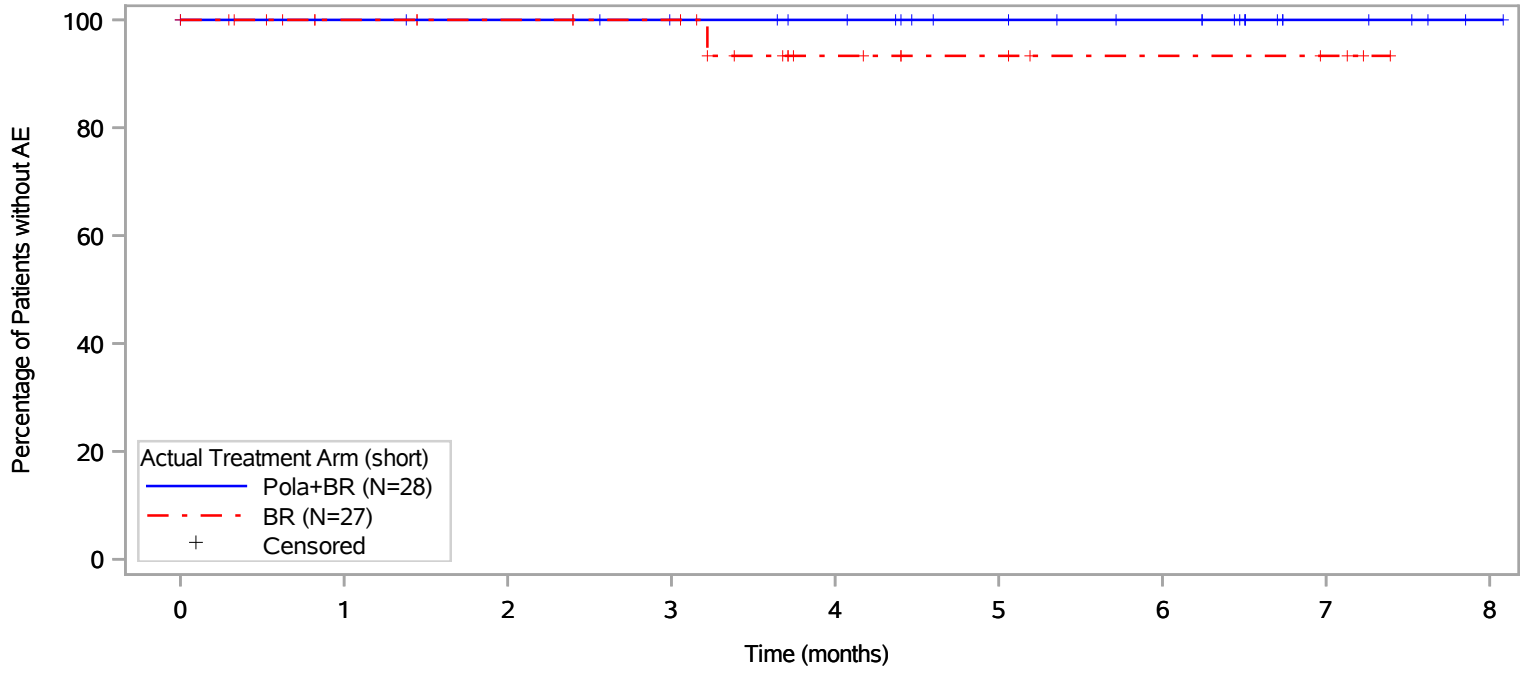
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HAEMOPTYSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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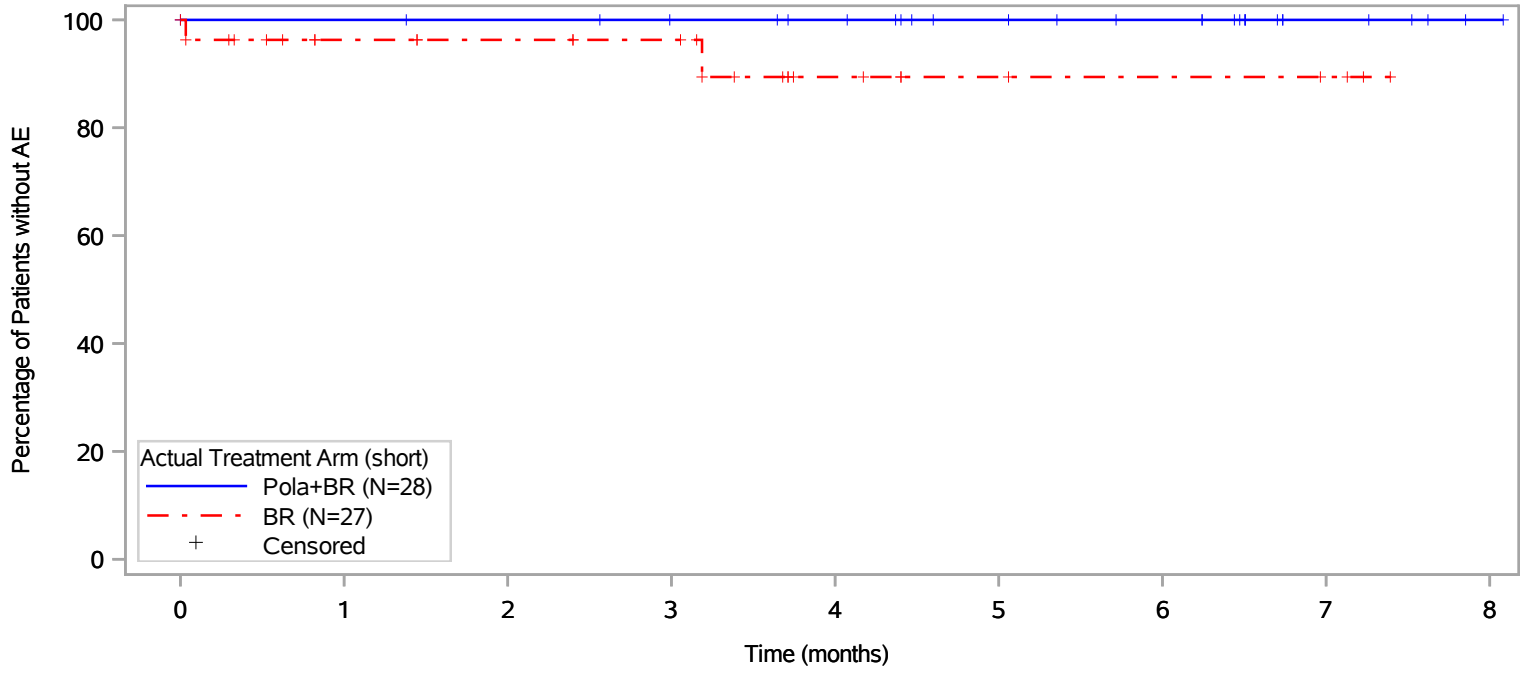
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION



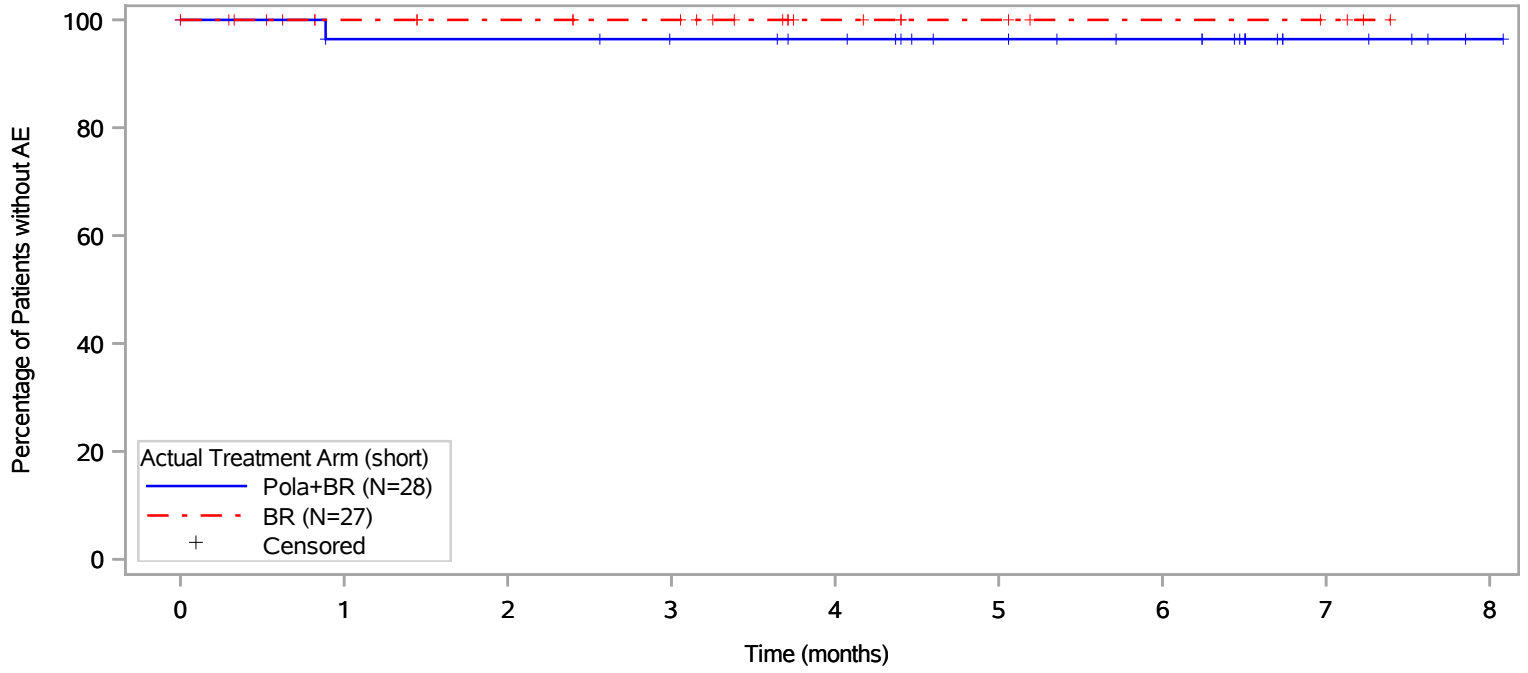
Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY EMBOLISM



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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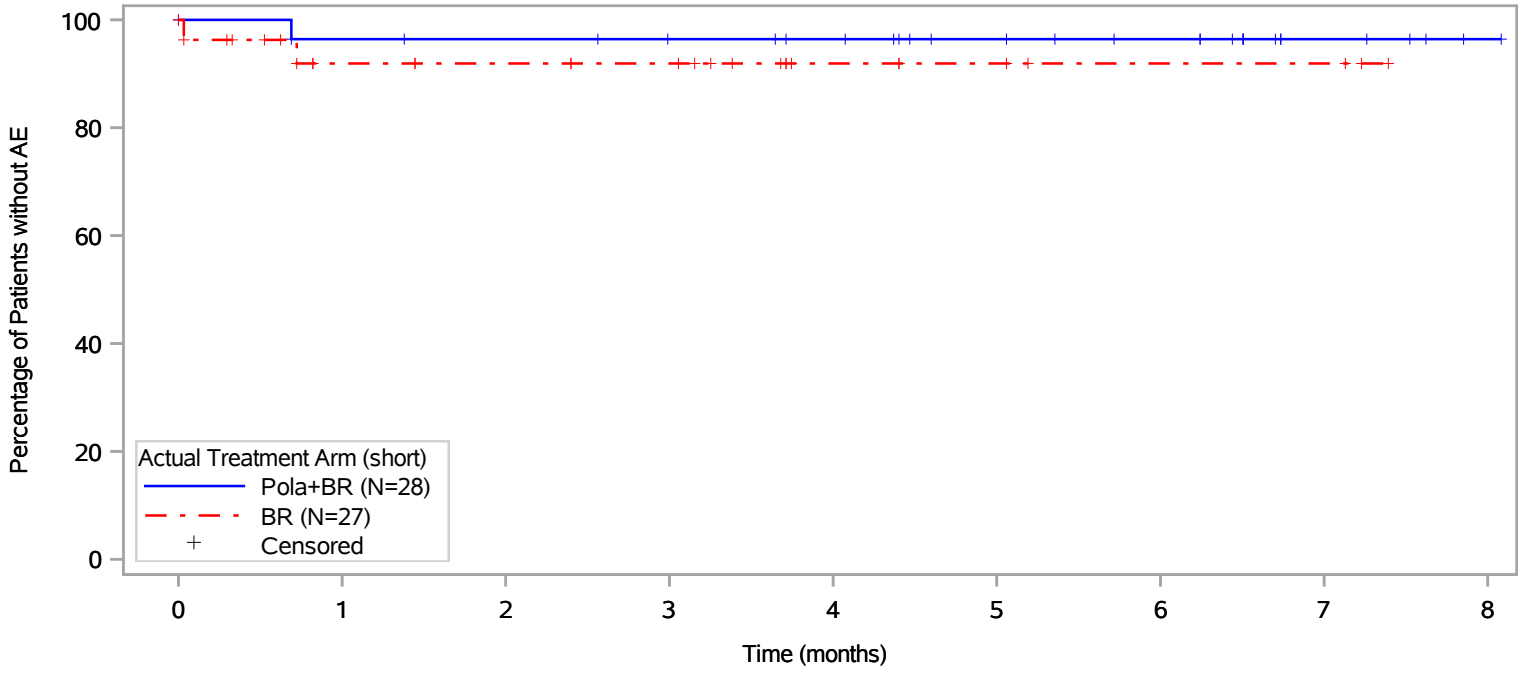
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	19	17	15	7	5	3	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	20	22	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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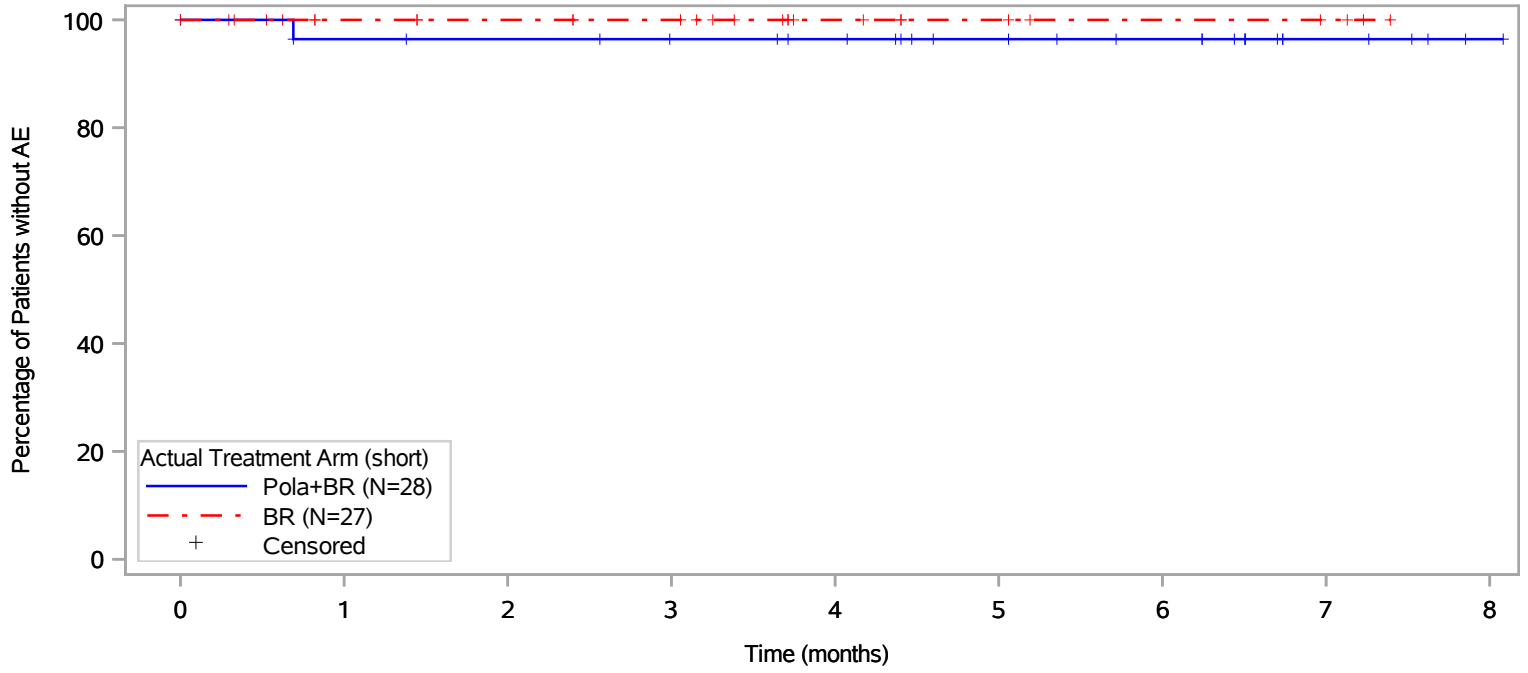
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DRUG ERUPTION



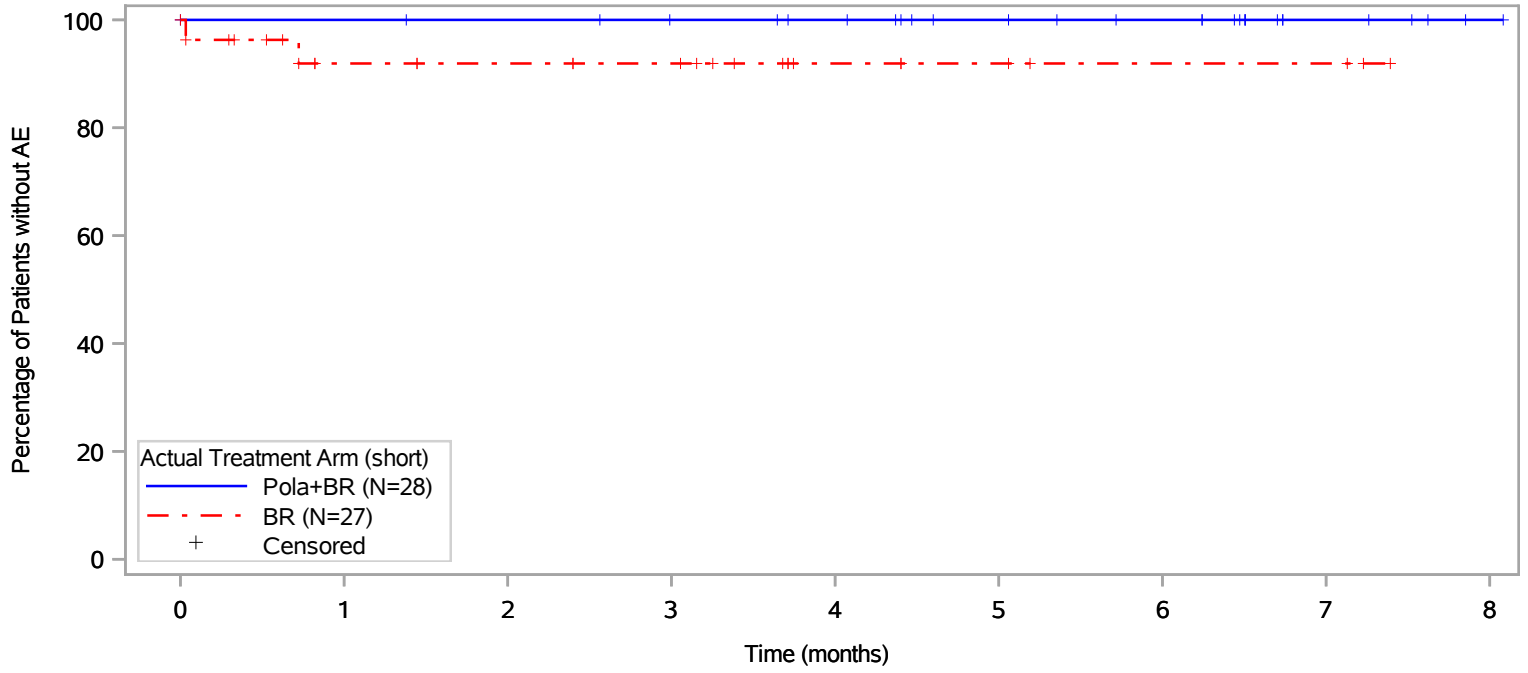
Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	19	17	15	7	5	3	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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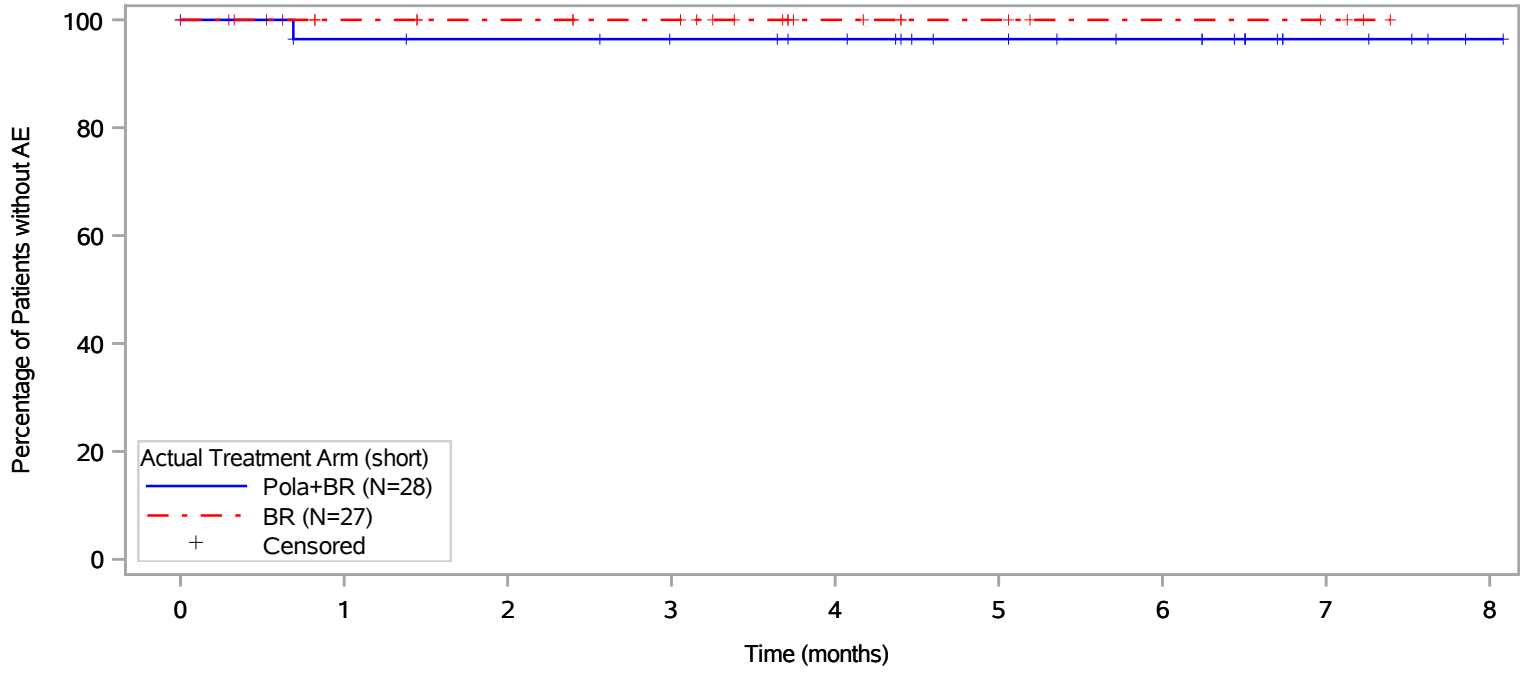
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

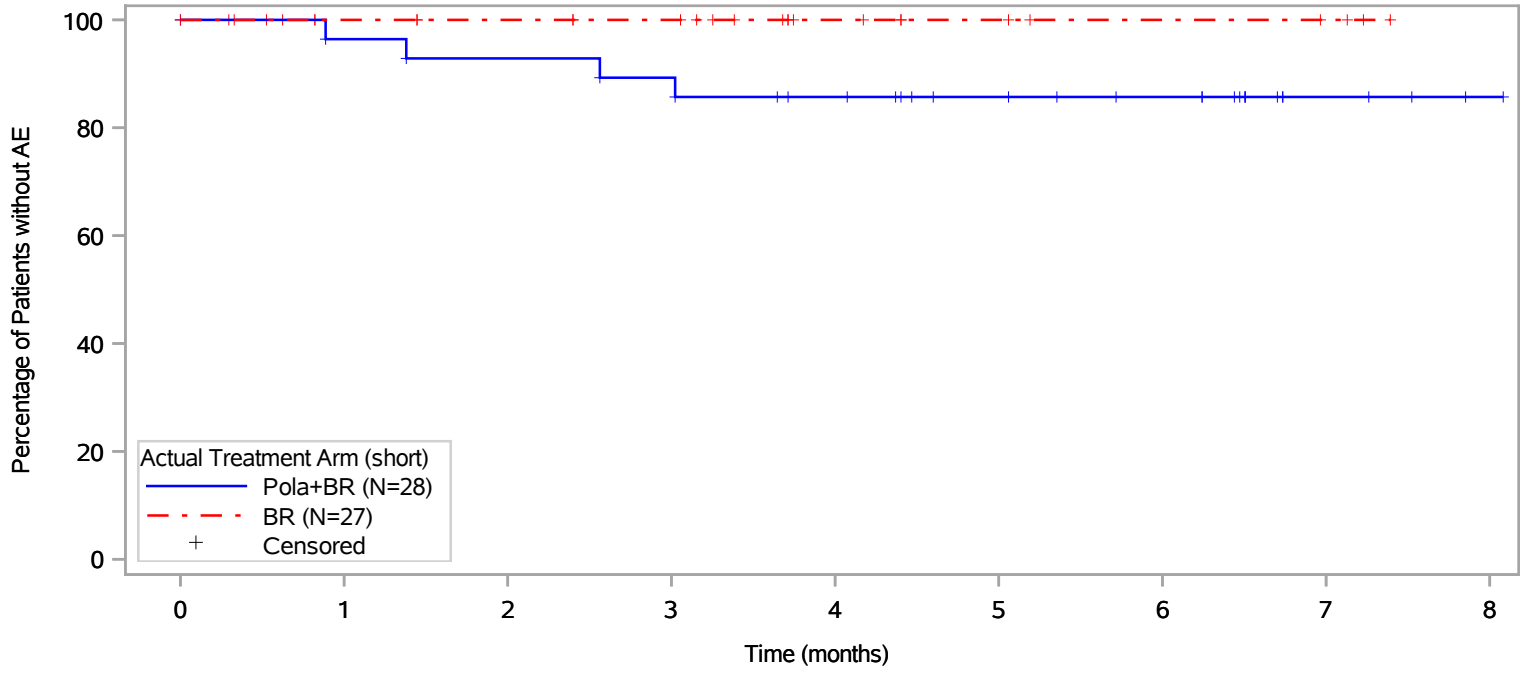
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, URTICARIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

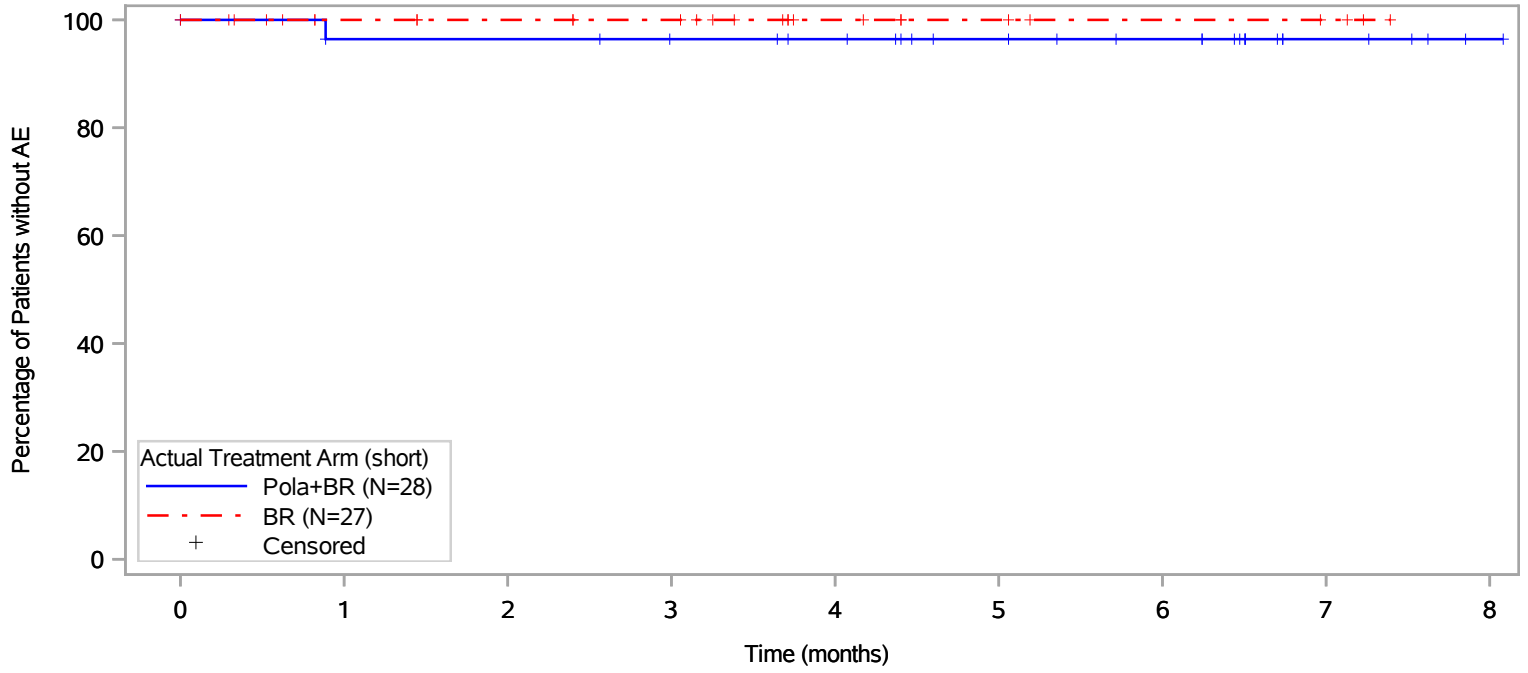
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	26	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	0	2	7	10	20	23
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DEEP VEIN THROMBOSIS



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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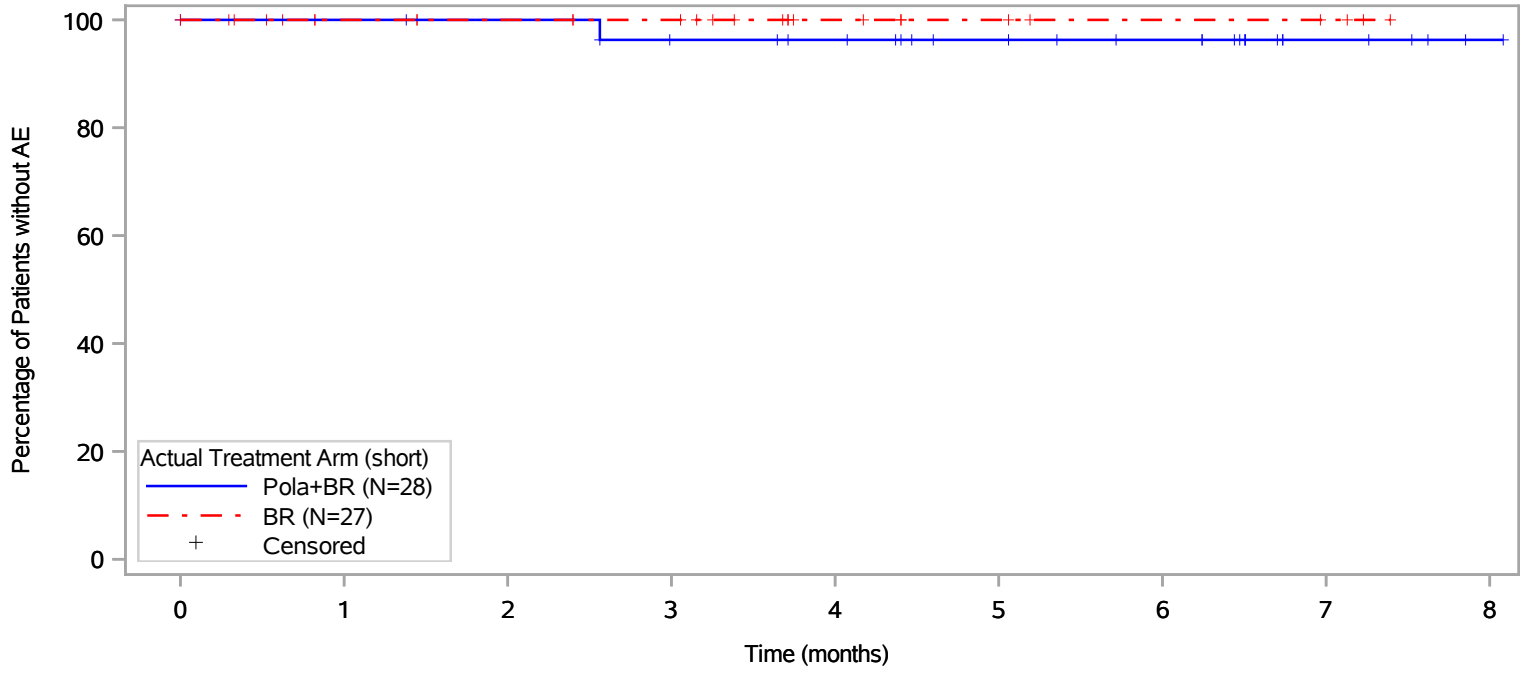
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DISTRIBUTIVE SHOCK



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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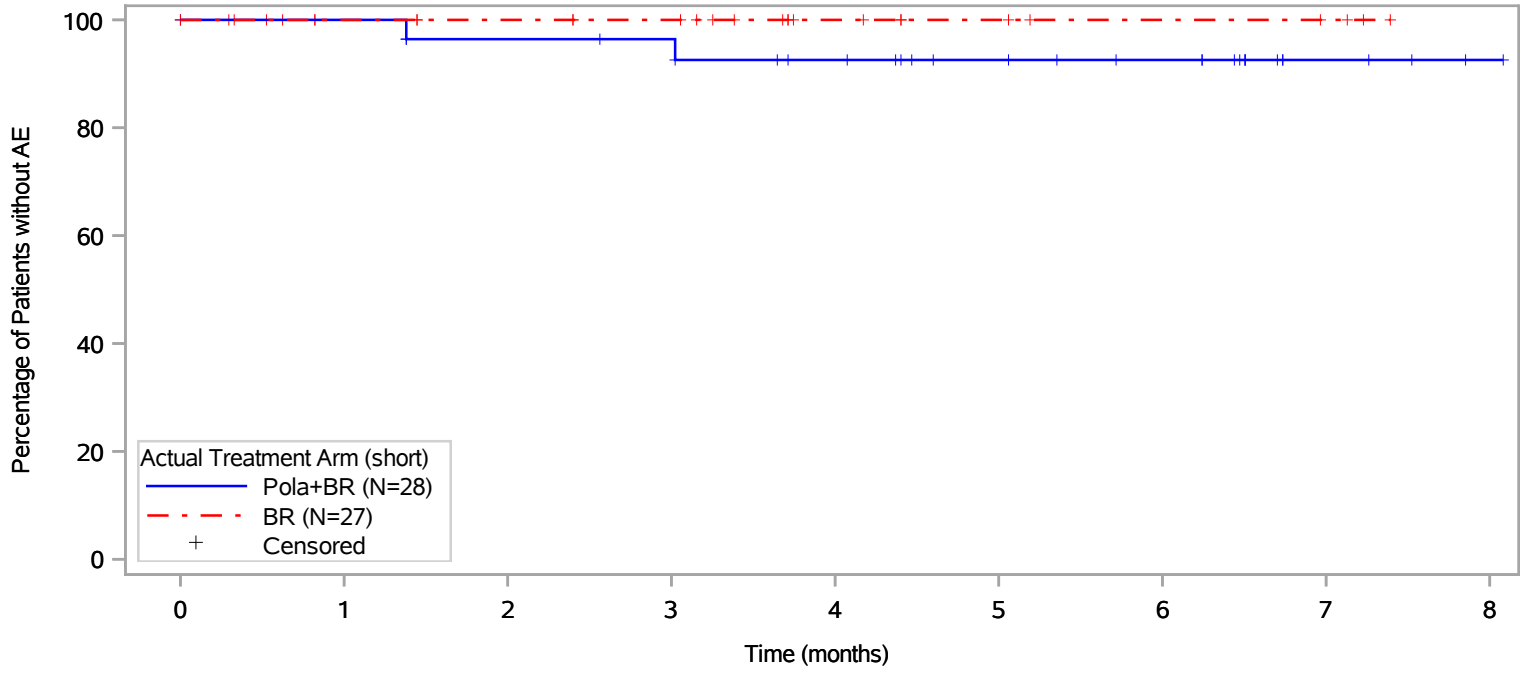
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION



Patients at risk									
Pola+BR (N=28)	28	28	26	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_365/g_km_soc_TTGR345AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 2:10

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			28	100.0	18	64.3	10	35.7	27	100.0	14	51.9	13	48.1	0.9546	1.02	0.50	2.08		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		28	100.0	7	25.0	21	75.0	27	100.0	5	18.5	22	81.5	0.9956	1.00	0.31	3.21		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.4650	0.48	0.06	3.61		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		28	100.0	3	10.7	25	89.3	27	100.0	1	3.7	26	96.3	0.4247	2.45	0.25	23.66		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.1964	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		28	100.0	11	39.3	17	60.7	27	100.0	6	22.2	21	77.8	0.3596	1.59	0.58	4.36		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		28	100.0	9	32.1	19	67.9	27	100.0	3	11.1	24	88.9	0.2232	2.21	0.60	8.19		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.9688	0.95	0.06	15.13		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FLUTTER		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3261	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			28	100.0	8	28.6	20	71.4	27	100.0	3	11.1	24	88.9	0.3597	1.85	0.49	7.04		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.8010	1.36	0.12	15.25		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.4282	0.39	0.04	4.34		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4617	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ILEUS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.7190	1.55	0.14	17.53		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.7873	0.68	0.04	11.35		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3261	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			28	100.0	5	17.9	23	82.1	27	100.0	6	22.2	21	77.8	0.0318	0.20	0.04	1.01		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2162	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.8373	1.29	0.12	14.30		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UROSEPSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.9054	0.85	0.05	13.59		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	HAEMOGLOBIN DECREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MORAXELLA TEST POSITIVE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8348	0.75	0.05	11.92		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

METABOLISM AND NUTRITION DISORDERS			28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.8578	0.84	0.12	5.95		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.6634	1.69	0.15	18.73		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8621	0.78	0.05	12.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8565	0.77	0.05	12.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8565	0.77	0.05	12.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8110	0.71	0.04	11.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	SYNCOPE		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.8110	0.71	0.04	11.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.3884	0.36	0.03	4.03		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.0969	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.4721	0.43	0.04	4.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		28	100.0	0	-	28	100.0	27	100.0	2	7.4	25	92.6	0.1291	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			28	100.0	3	10.7	25	89.3	27	100.0	0	-	27	100.0	0.1374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2319	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 23:49

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	13	46.4	10	76.9	3	23.1	13	48.1	7	53.8	6	46.2	0.5436	1.35	0.51	3.61		Convergence criterion (GCONV=1E-8) satisfied.	0.4102
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	15	53.6	8	53.3	7	46.7	14	51.9	7	50.0	7	50.0	0.6168	0.77	0.27	2.17		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	13	46.4	4	30.8	9	69.2	13	48.1	3	23.1	10	76.9	0.8482	1.16	0.26	5.21		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	2	14.3	12	85.7	0.7536	0.73	0.10	5.22		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.2831	0.28	0.02	3.25		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	1	7.7	12	92.3	0.5992	1.88	0.17	20.82		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	13	46.4	7	53.8	6	46.2	13	48.1	3	23.1	10	76.9	0.1718	2.52	0.64	9.90		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	3	21.4	11	78.6	0.9688	0.97	0.21	4.40		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	13	46.4	5	38.5	8	61.5	13	48.1	2	15.4	11	84.6	0.3830	2.04	0.40	10.56		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	1	7.1	13	92.9	0.3446	2.76	0.31	24.74		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	13	46.4	5	38.5	8	61.5	13	48.1	0	-	13	100.0	0.0350	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	15	53.6	3	20.0	12	80.0	14	51.9	3	21.4	11	78.6	0.5434	0.61	0.12	3.06		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.6949	0.58	0.04	9.30		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	15	53.6	0	-	15	100.0	14	51.9	2	14.3	12	85.7	0.0963	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.9774	0.96	0.06	15.37		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.7363	0.62	0.04	10.25		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	15	53.6	4	26.7	11	73.3	14	51.9	5	35.7	9	64.3	0.0175	0.11	0.01	0.97		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.8764	0.80	0.05	13.04		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.8569	0.77	0.05	12.53		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.7628	0.65	0.04	10.47		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.5282	0.47	0.04	5.19		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.9755	0.96	0.06	15.32		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.8635	0.78	0.05	12.57		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.8635	0.78	0.05	12.57		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	2	15.4	11	84.6	0.0816	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	13	46.4	0	-	13	100.0	13	48.1	2	15.4	11	84.6	0.0816	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	2	14.3	12	85.7	0.4131	0.38	0.03	4.22		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	15	53.6	0	-	15	100.0	14	51.9	2	14.3	12	85.7	0.1104	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2525	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4227	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 23:49

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	15	53.6	9	60.0	6	40.0	18	66.7	9	50.0	9	50.0	0.7231	0.84	0.32	2.19		Convergence criterion (GCONV=1E-8) satisfied.	0.5839
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	13	46.4	9	69.2	4	30.8	9	33.3	5	55.6	4	44.4	0.6572	1.28	0.42	3.90		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	15	53.6	3	20.0	12	80.0	18	66.7	3	16.7	15	83.3	0.7254	0.75	0.14	3.86		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	13	46.4	4	30.8	9	69.2	9	33.3	2	22.2	7	77.8	0.7645	1.30	0.24	7.09		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.5374	0.42	0.02	7.28		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.6729	0.55	0.03	8.90		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9748	0.96	0.06	15.35		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2491	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1580	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	15	53.6	4	26.7	11	73.3	18	66.7	5	27.8	13	72.2	0.4974	0.63	0.17	2.40		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	13	46.4	7	53.8	6	46.2	9	33.3	1	11.1	8	88.9	0.0464	6.44	0.79	52.73		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	15	53.6	5	33.3	10	66.7	18	66.7	1	5.6	17	94.4	0.1424	4.40	0.51	38.13		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	13	46.4	4	30.8	9	69.2	9	33.3	2	22.2	7	77.8	0.8987	1.12	0.20	6.12		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9134	1.17	0.07	18.65		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	15	53.6	5	33.3	10	66.7	18	66.7	2	11.1	16	88.9	0.4603	1.85	0.35	9.79		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	13	46.4	3	23.1	10	76.9	9	33.3	1	11.1	8	88.9	0.6244	1.75	0.18	16.90		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.7406	1.50	0.13	17.02		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.7613	0.65	0.04	10.45		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.6287	1.81	0.16	20.74		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.8386	0.74	0.04	12.88		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	3	16.7	15	83.3	0.0571	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	13	46.4	3	23.1	10	76.9	9	33.3	3	33.3	6	66.7	0.1774	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2253	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.3352	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3352	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9372	0.89	0.06	14.36		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.7833	0.68	0.04	10.86		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.7833	0.68	0.04	10.86		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9372	0.89	0.06	14.36		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9885	0.98	0.06	15.89		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.8160	0.72	0.05	11.53		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2736	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2736	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 23:49

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	32.1	4	44.4	5	55.6	13	48.1	5	38.5	8	61.5	0.6731	0.75	0.20	2.84		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	67.9	14	73.7	5	26.3	14	51.9	9	64.3	5	35.7	0.9923	1.00	0.42	2.36		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	5	35.7	9	64.3	0.5651	0.71	0.21	2.33		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	2	14.3	12	85.7	0.3340	0.39	0.05	2.83		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	1	7.1	13	92.9	0.5827	1.87	0.19	18.11		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2552	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	32.1	2	22.2	7	77.8	13	48.1	3	23.1	10	76.9	0.6746	0.68	0.11	4.18		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	19	67.9	9	47.4	10	52.6	14	51.9	3	21.4	11	78.6	0.2398	2.17	0.58	8.12		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	32.1	2	22.2	7	77.8	13	48.1	1	7.7	12	92.3	0.4861	2.29	0.21	25.40		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	67.9	7	36.8	12	63.2	14	51.9	2	14.3	12	85.7	0.4044	1.93	0.40	9.38		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	9	32.1	3	33.3	6	66.7	13	48.1	2	15.4	11	84.6	0.6289	1.55	0.26	9.40		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	19	67.9	5	26.3	14	73.7	14	51.9	1	7.1	13	92.9	0.4200	2.40	0.27	21.32		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3428	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.3339	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.8671	1.27	0.08	20.38		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1693	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.5545	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.5545	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	32.1	3	33.3	6	66.7	13	48.1	4	30.8	9	69.2	0.1569	0.23	0.02	2.10		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	2	14.3	12	85.7	0.1412	0.19	0.02	2.20		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.4504	0.35	0.02	5.89		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.7508	0.64	0.04	10.30		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.6844	0.57	0.04	9.07		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	2	14.3	12	85.7	0.6451	0.63	0.09	4.51		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.8167	1.33	0.12	14.66		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.6937	0.58	0.04	9.24		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7497	0.64	0.04	10.22		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.7497	0.64	0.04	10.22		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.6878	0.57	0.04	9.12		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.6878	0.57	0.04	9.12		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	2	14.3	12	85.7	0.2412	0.26	0.02	2.92		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	2	14.3	12	85.7	0.0502	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.8671	1.27	0.08	20.38		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	0	-	14	100.0	0.1856	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2854	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.xls
30NOV2022 23:49

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	20	71.4	12	60.0	8	40.0	18	66.7	10	55.6	8	44.4	0.5824	0.79	0.33	1.86		Convergence criterion (GCONV=1E-8) satisfied.	0.2837
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	8	28.6	6	75.0	2	25.0	9	33.3	4	44.4	5	55.6	0.3198	1.89	0.53	6.77		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	20	71.4	4	20.0	16	80.0	18	66.7	5	27.8	13	72.2	0.3160	0.51	0.13	1.95		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	8	28.6	3	37.5	5	62.5	9	33.3	0	-	9	100.0	0.1069	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE BONE MARROW APLASIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.2150	0.23	0.02	2.76		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	20	71.4	3	15.0	17	85.0	18	66.7	1	5.6	17	94.4	0.4535	2.32	0.24	22.47		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.2005	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	20	71.4	7	35.0	13	65.0	18	66.7	4	22.2	14	77.8	0.6312	1.36	0.39	4.74		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	8	28.6	4	50.0	4	50.0	9	33.3	2	22.2	7	77.8	0.3491	2.22	0.40	12.22		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	20	71.4	4	20.0	16	80.0	18	66.7	2	11.1	16	88.9	0.7100	1.38	0.25	7.65		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	8	28.6	5	62.5	3	37.5	9	33.3	1	11.1	8	88.9	0.1611	4.12	0.48	35.33		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	20	71.4	6	30.0	14	70.0	18	66.7	3	16.7	15	83.3	0.7026	1.31	0.32	5.33		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2263	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8877	0.82	0.05	13.10		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.4114	0.38	0.03	4.21		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTROINTESTINAL HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ILEUS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ILEUS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8774	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8774	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	20	71.4	5	25.0	15	75.0	18	66.7	4	22.2	14	77.8	0.0957	0.26	0.05	1.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	8	28.6	0	-	8	100.0	9	33.3	2	22.2	7	77.8	0.1382	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2850	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.9206	1.13	0.10	12.56		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.8702	0.79	0.05	12.76		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8191	0.72	0.05	11.59		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	20	71.4	0	-	20	100.0	18	66.7	2	11.1	16	88.9	0.1070	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.1601	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.1601	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2781	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8684	0.79	0.05	12.67		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8684	0.79	0.05	12.67		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8055	0.71	0.04	11.32		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	SYNCOPE	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.8055	0.71	0.04	11.32		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	SYNCOPE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	CONFUSIONAL STATE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.9018	0.84	0.05	13.81		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PULMONARY EMBOLISM	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.4690	0.42	0.04	4.67		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	DRUG ERUPTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	20	71.4	0	-	20	100.0	18	66.7	2	11.1	16	88.9	0.1246	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.2341	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.2341	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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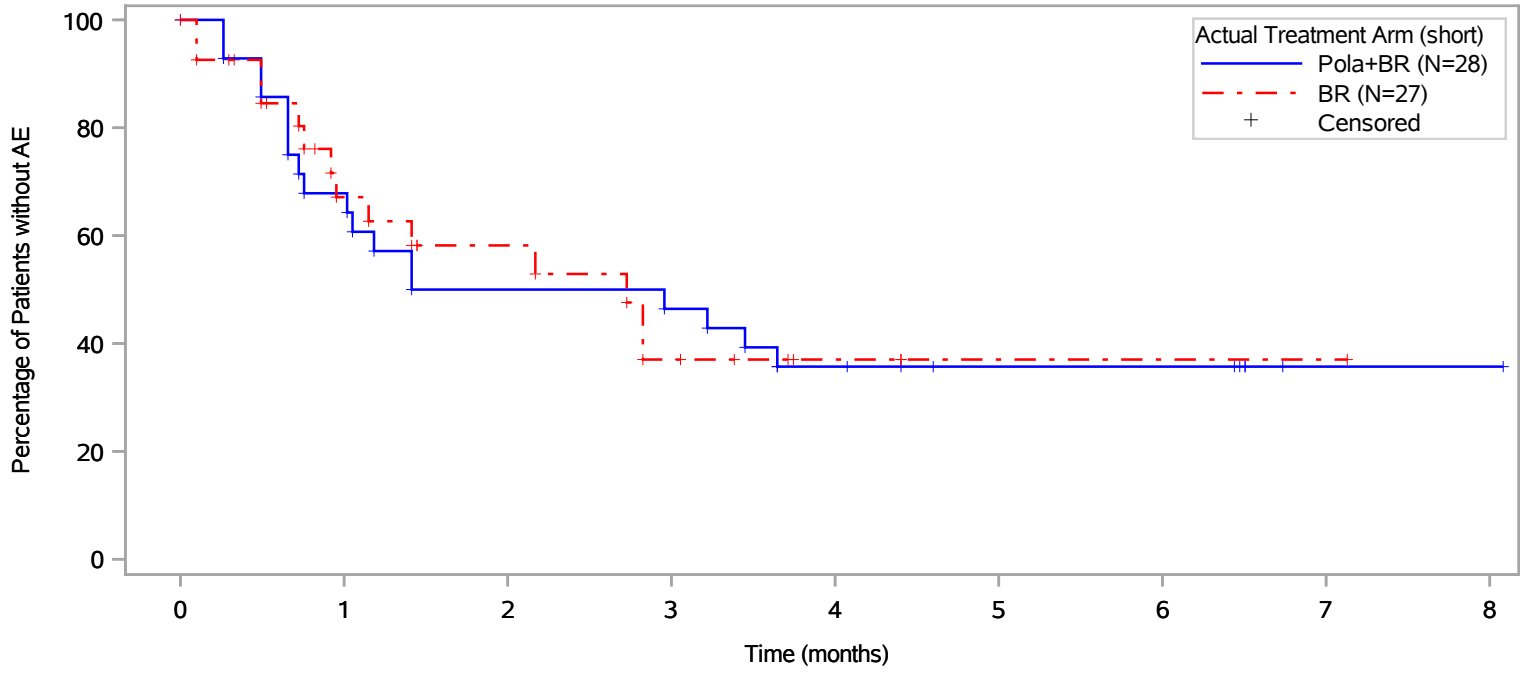
30NOV2022 23:49

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	19	14	13	9	6	6	1	1
BR (N=27)	27	15	11	7	3	1	1	1	NE
Patients censored									
Pola+BR (N=28)	0	0	0	0	1	4	4	9	9
BR (N=27)	0	4	6	6	10	12	12	12	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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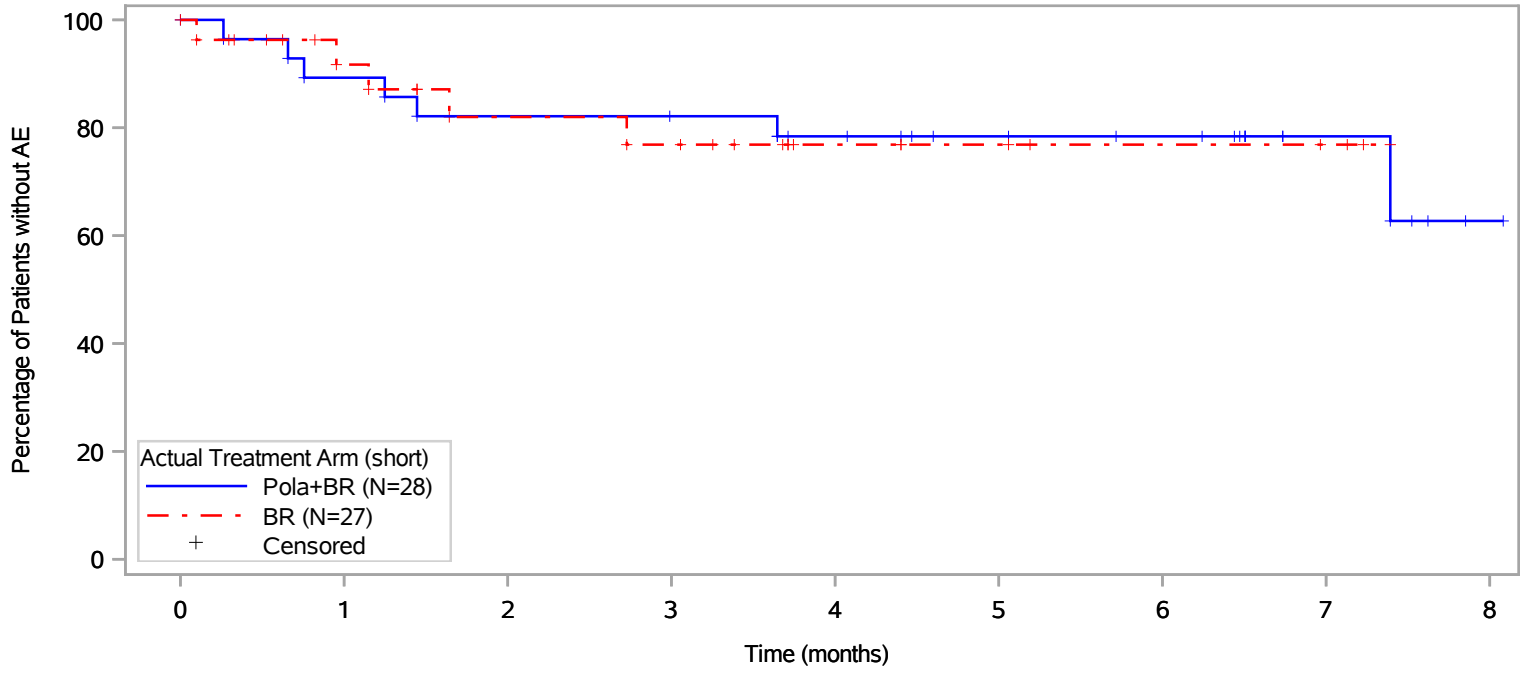
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA

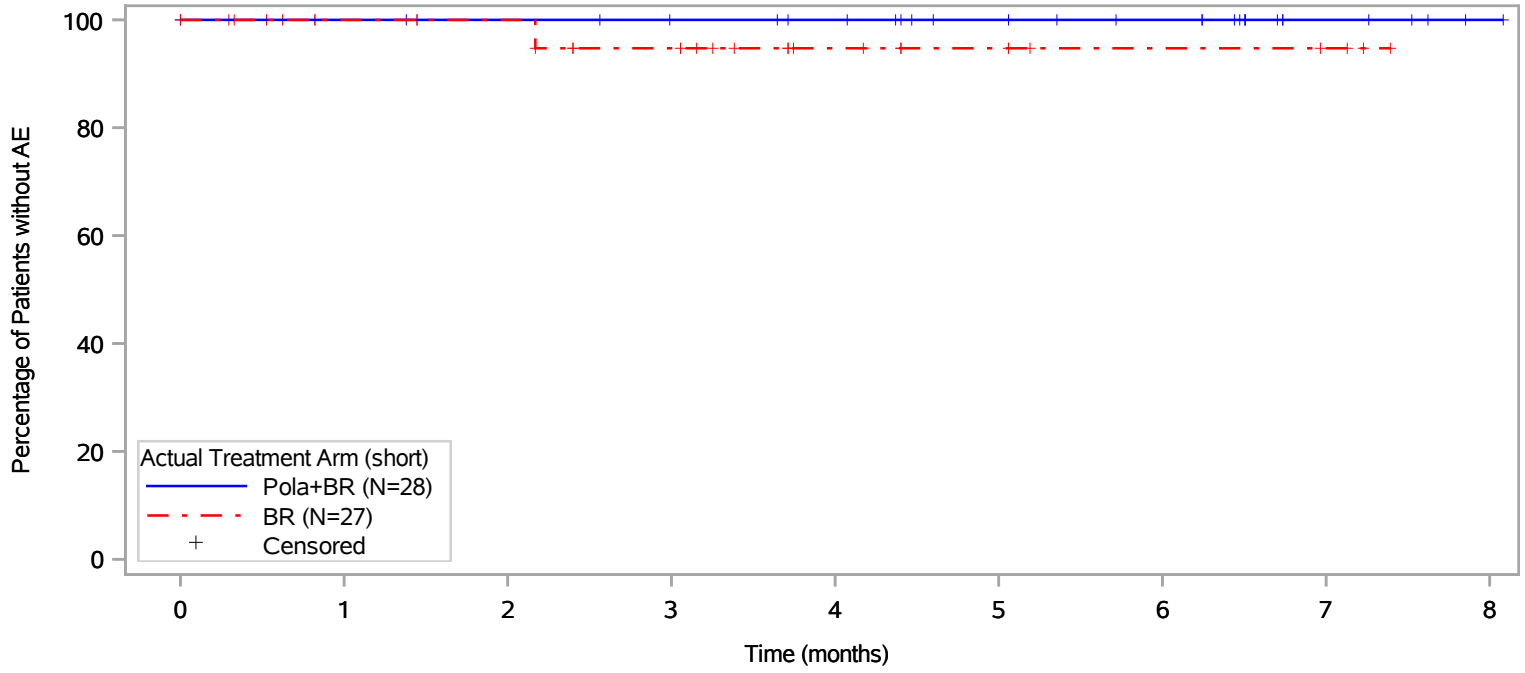


Patients at risk									
Pola+BR (N=28)	28	25	23	22	19	15	13	5	1
BR (N=27)	27	20	16	15	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	3	7	9	17	20
BR (N=27)	0	5	7	7	14	16	18	19	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE BONE MARROW APLASIA

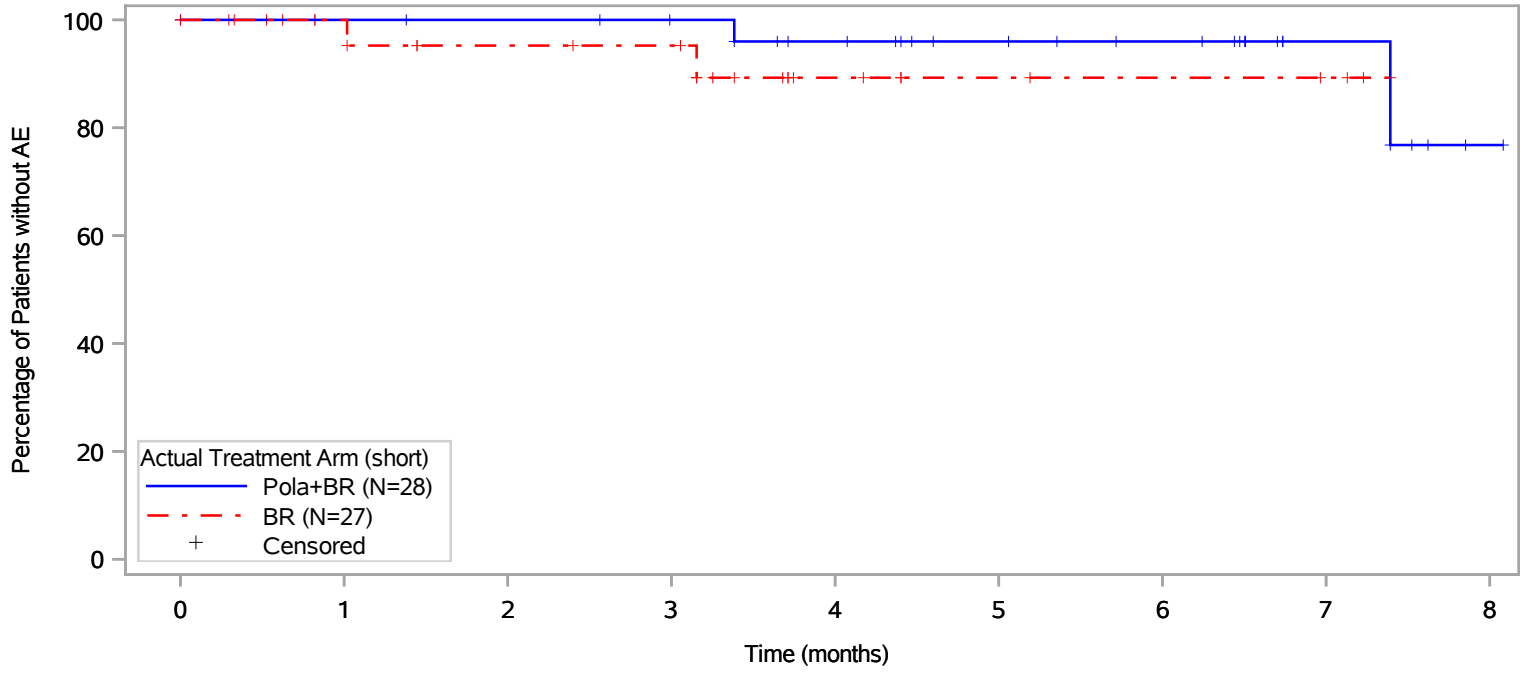


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

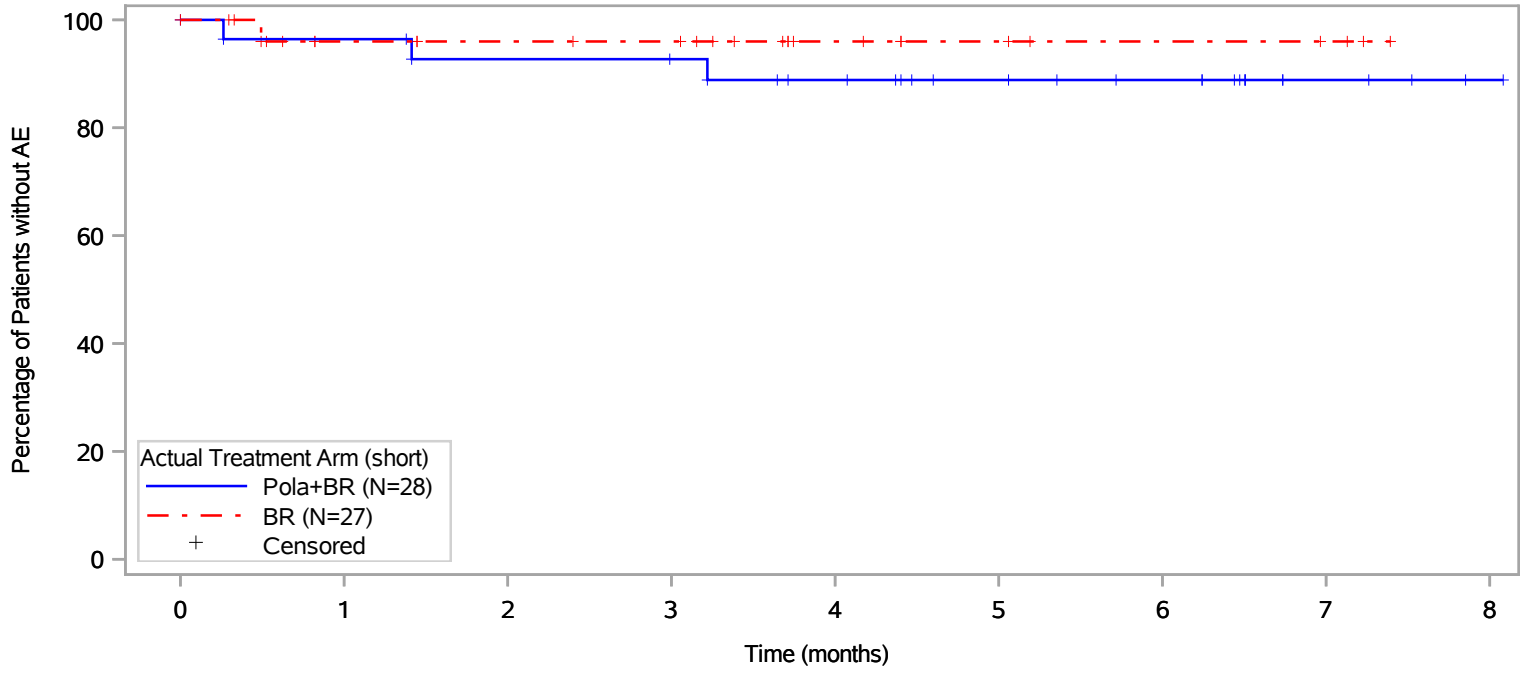
BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	14	5	1
BR (N=27)	27	21	18	17	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	25
BR (N=27)	0	6	8	9	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk									
Pola+BR (N=28)	28	27	25	24	21	16	13	4	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	21	24
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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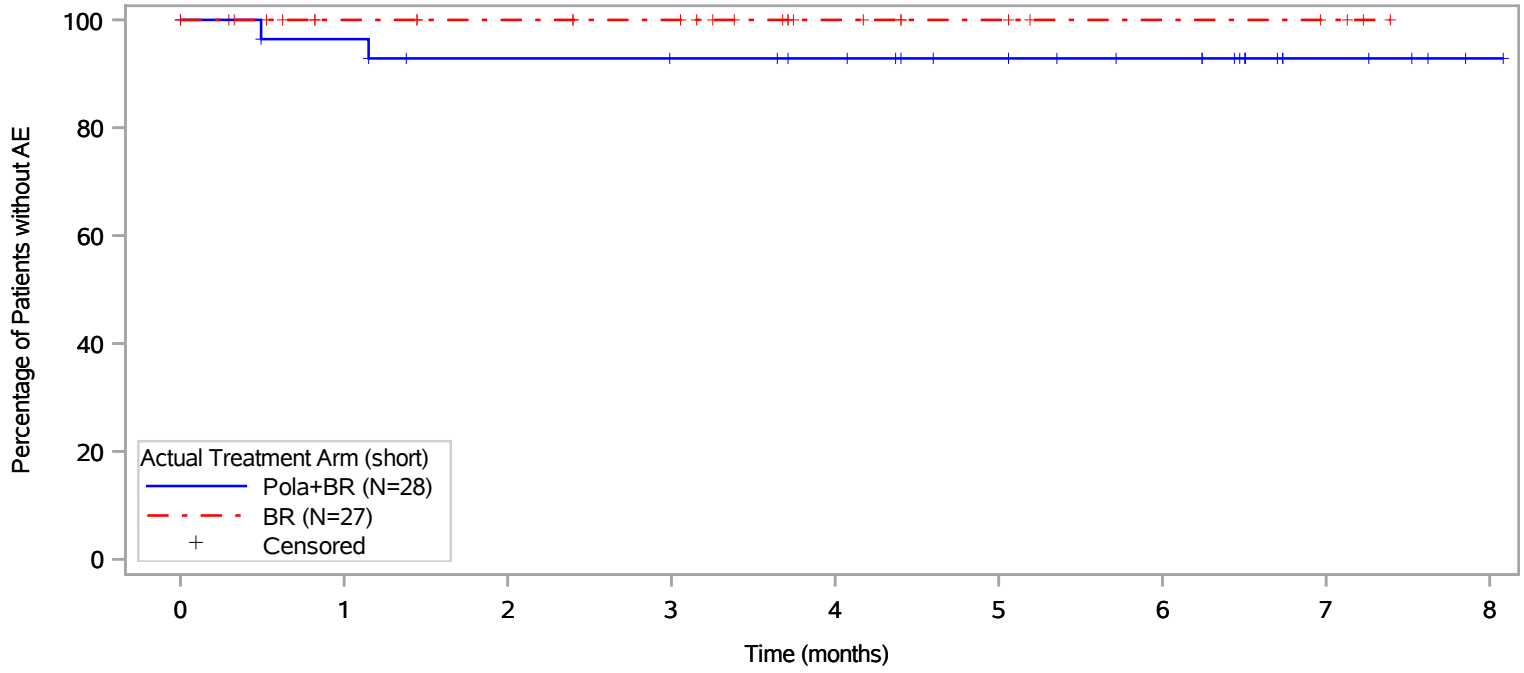
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA

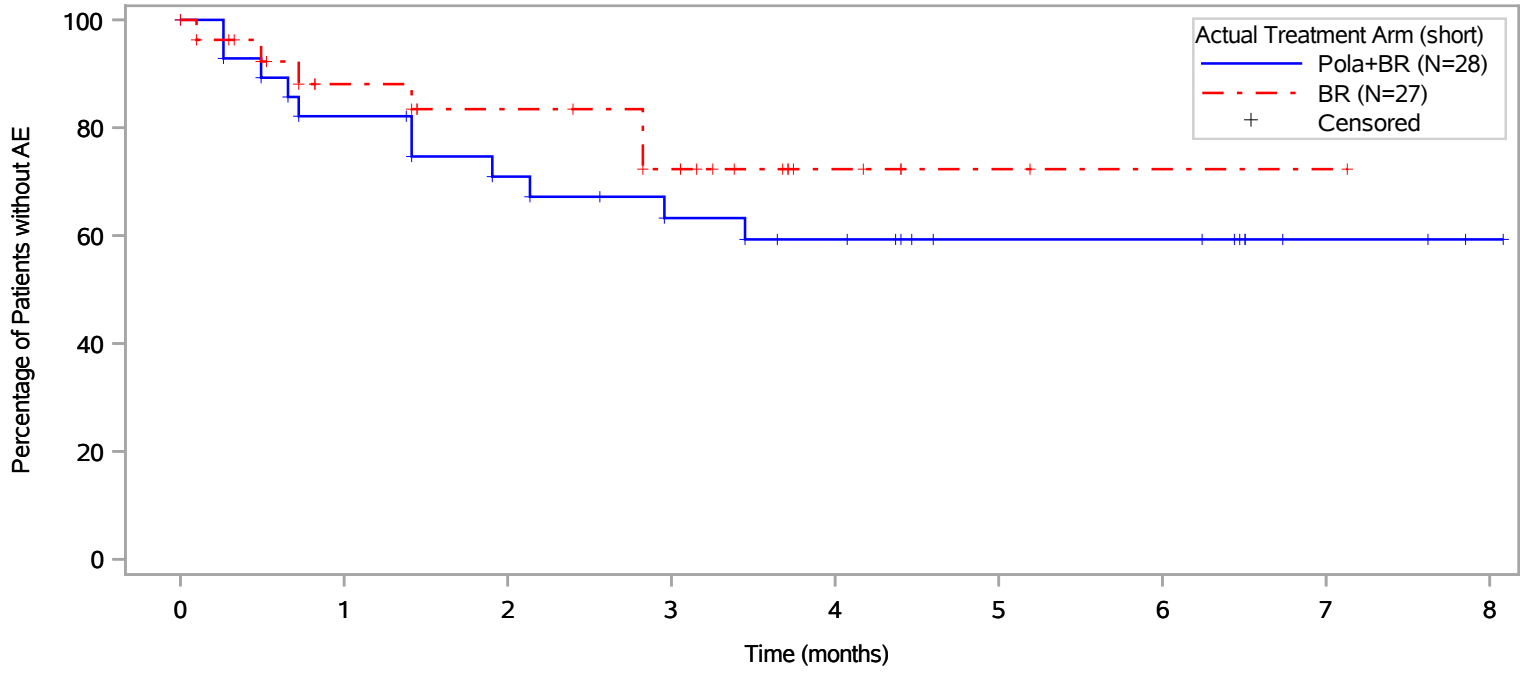


Patients at risk									
Pola+BR (N=28)	28	27	25	24	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	8	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk									
Pola+BR (N=28)	28	23	19	16	14	9	9	3	1
BR (N=27)	27	19	16	13	5	2	1	1	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	3	8	8	14	16
BR (N=27)	0	5	7	8	16	19	20	20	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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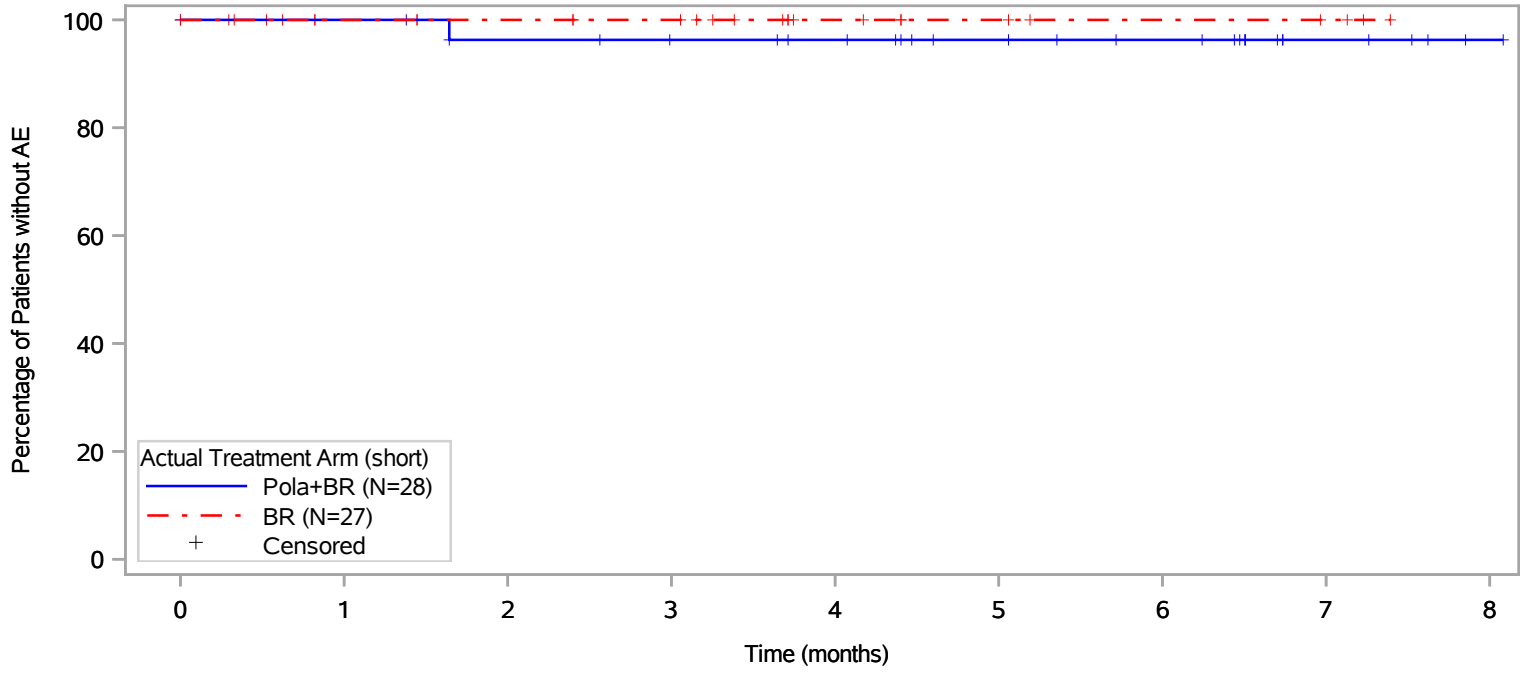
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA

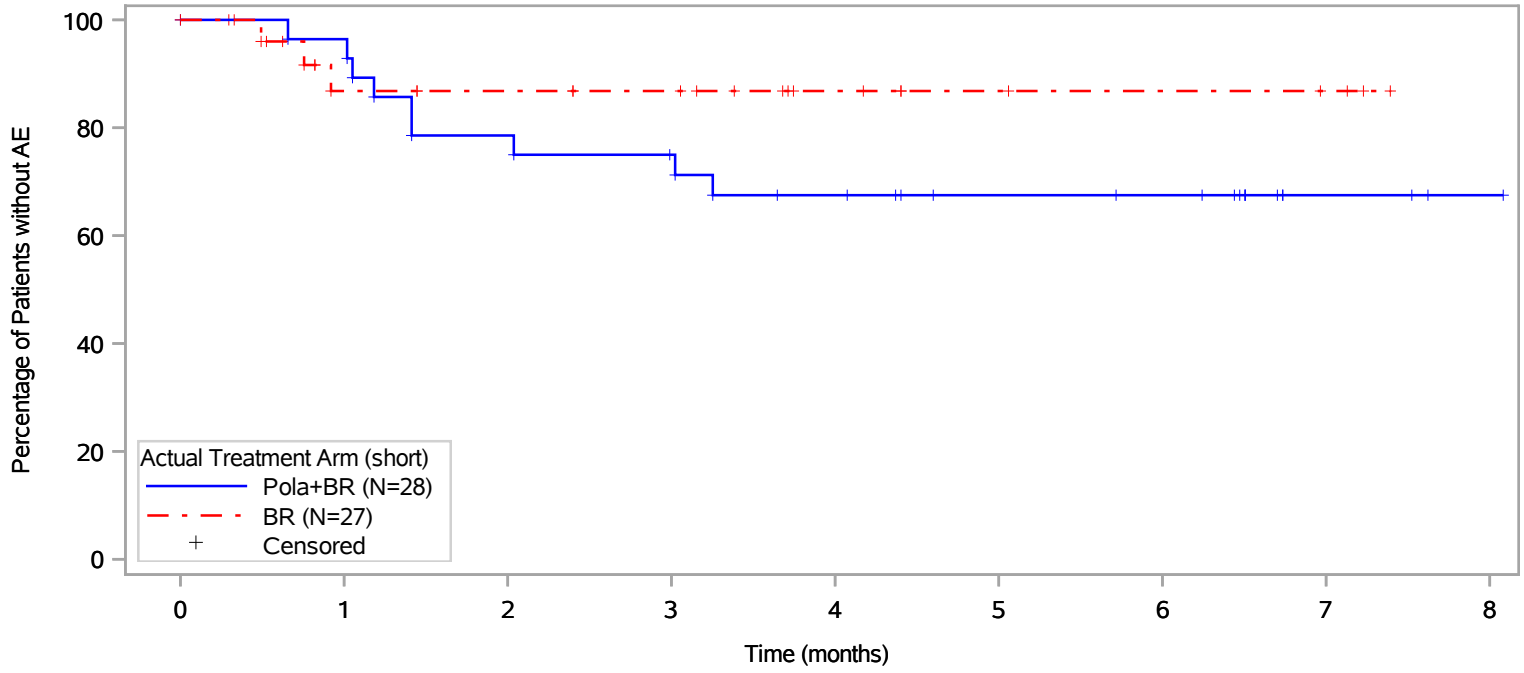


Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk									
Pola+BR (N=28)	28	27	22	20	17	13	12	3	1
BR (N=27)	27	18	16	14	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	2	6	7	16	18
BR (N=27)	0	6	8	10	16	19	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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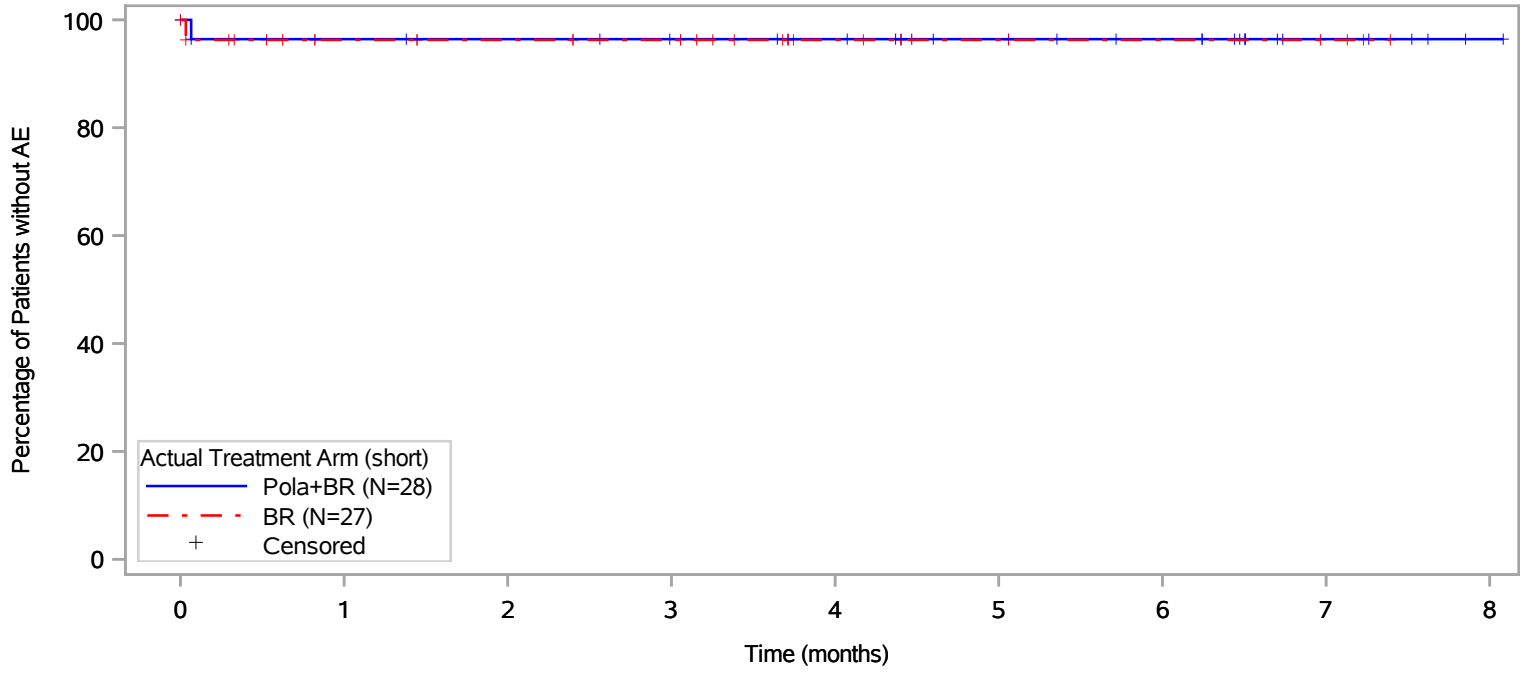
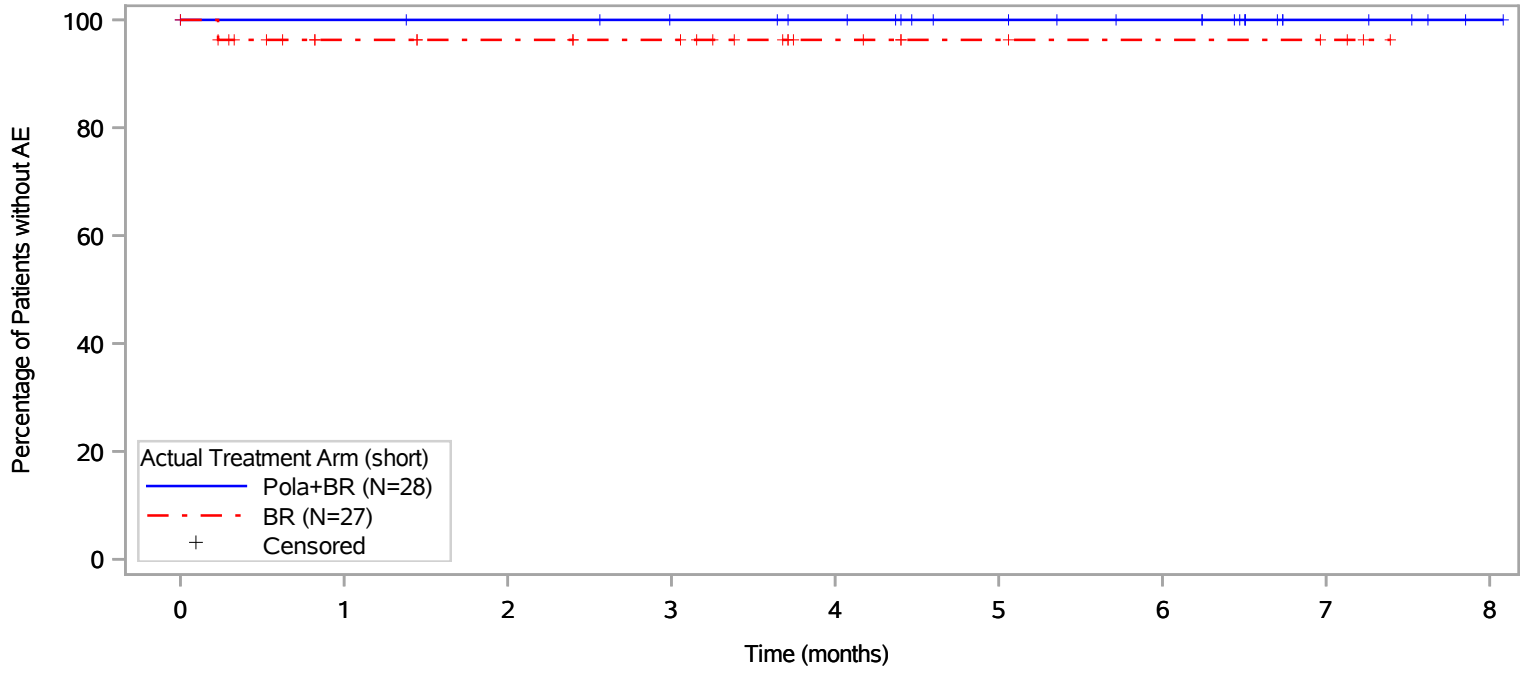
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

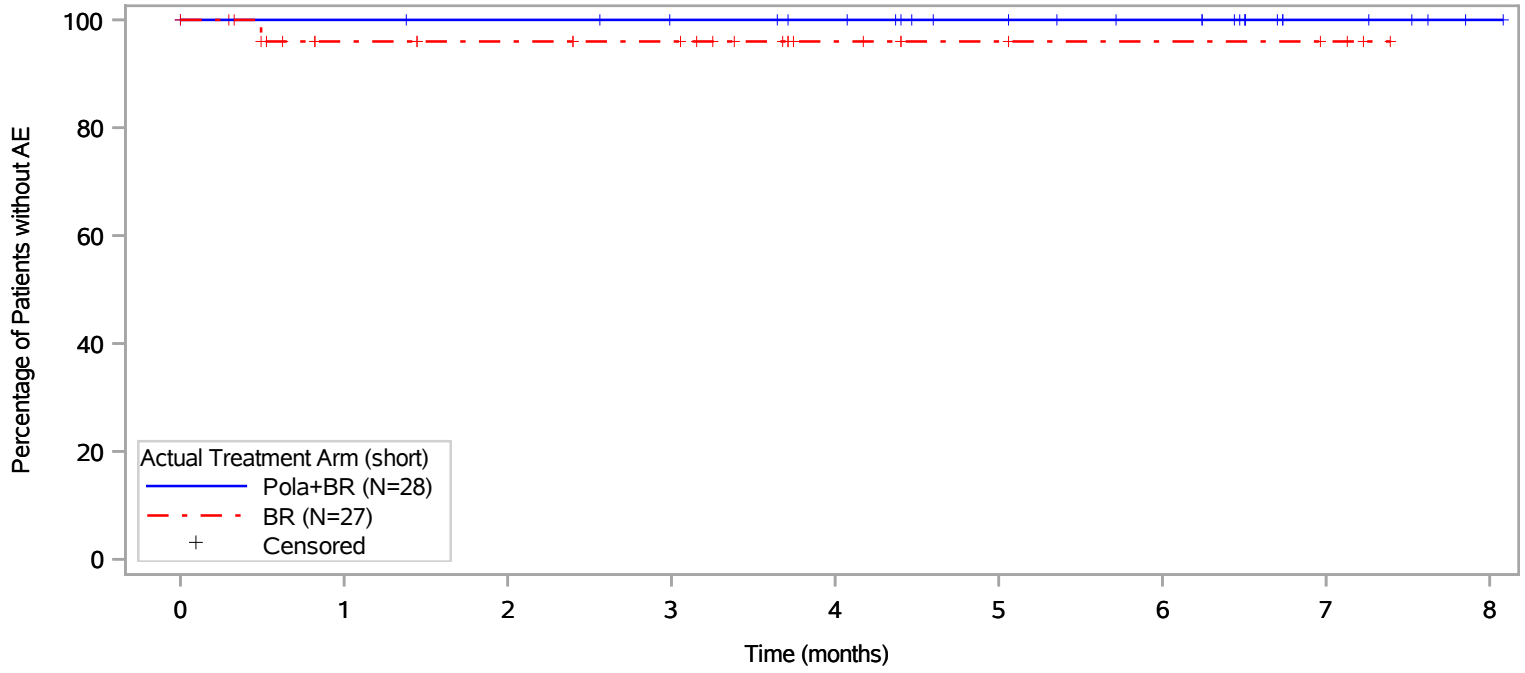
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

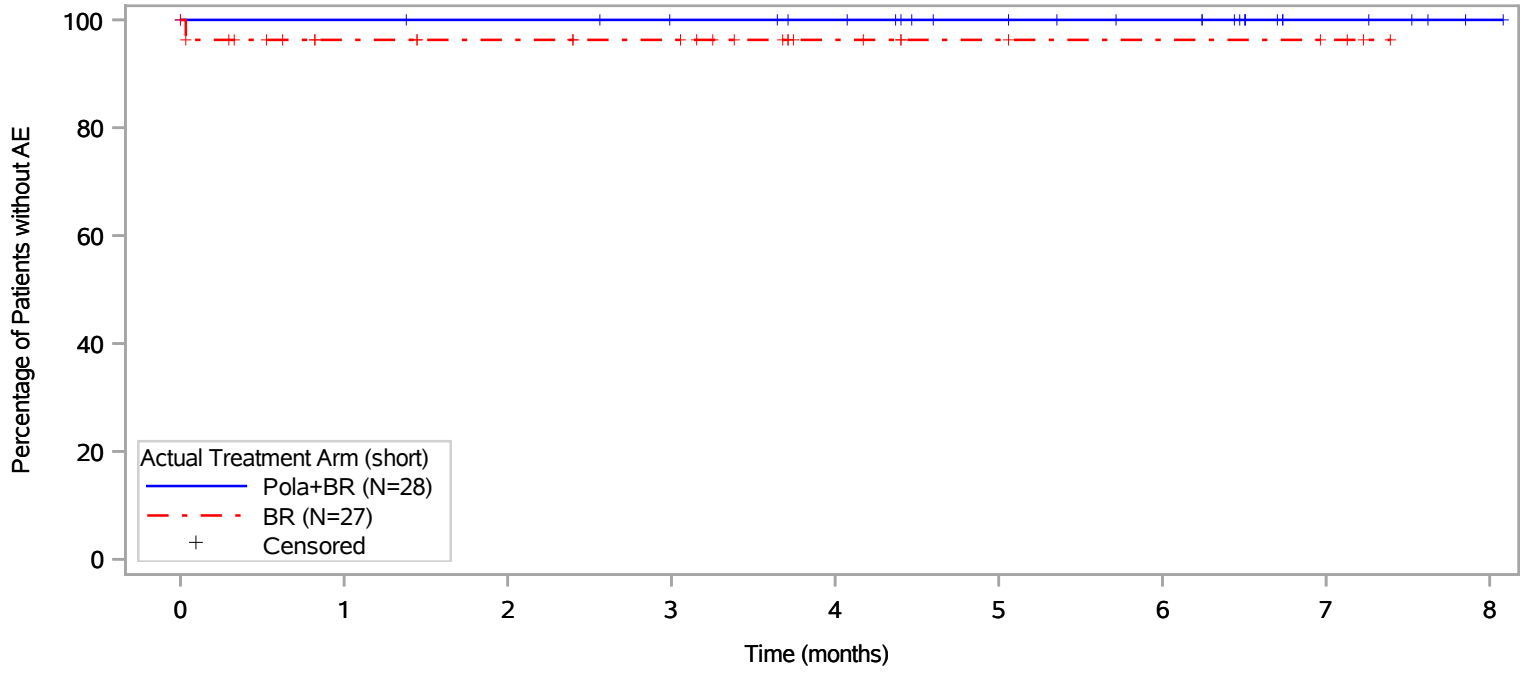
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FLUTTER



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

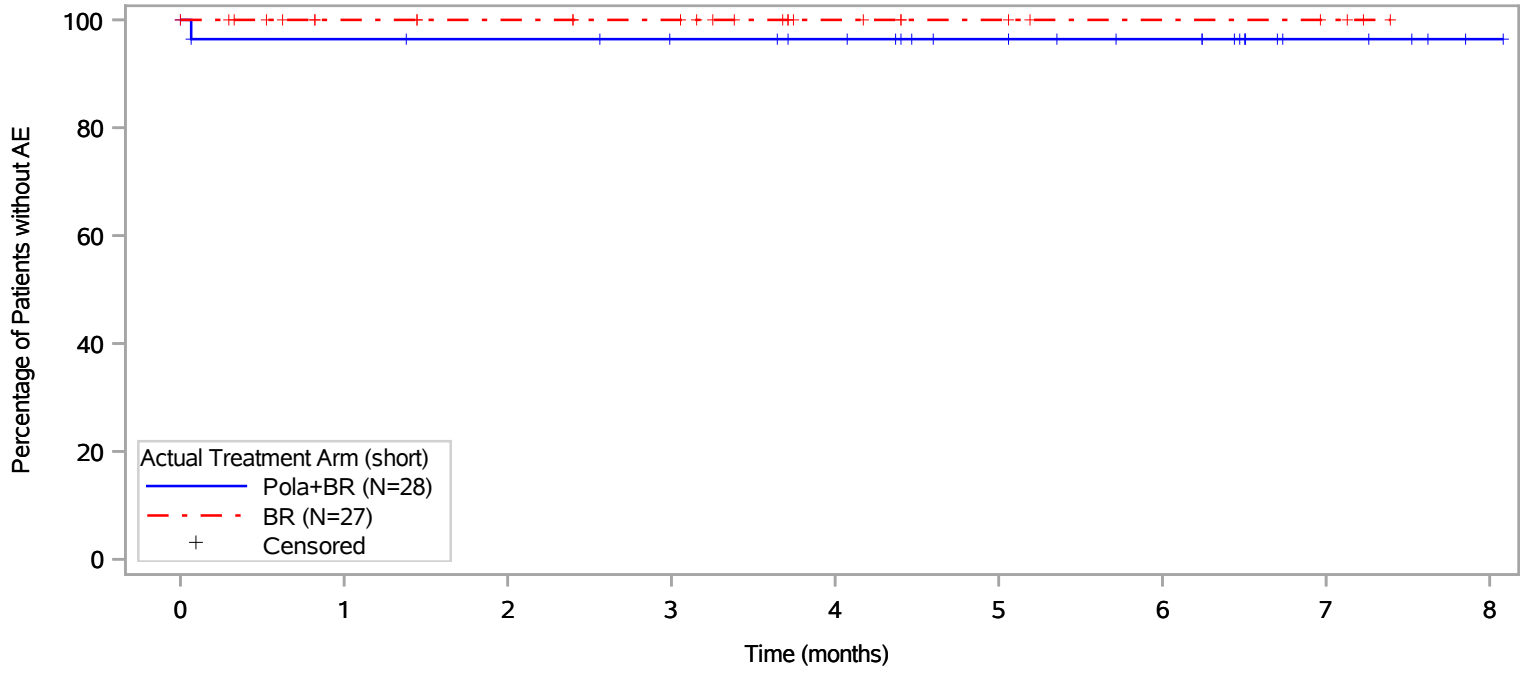
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SUPRAVENTRICULAR TACHYCARDIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

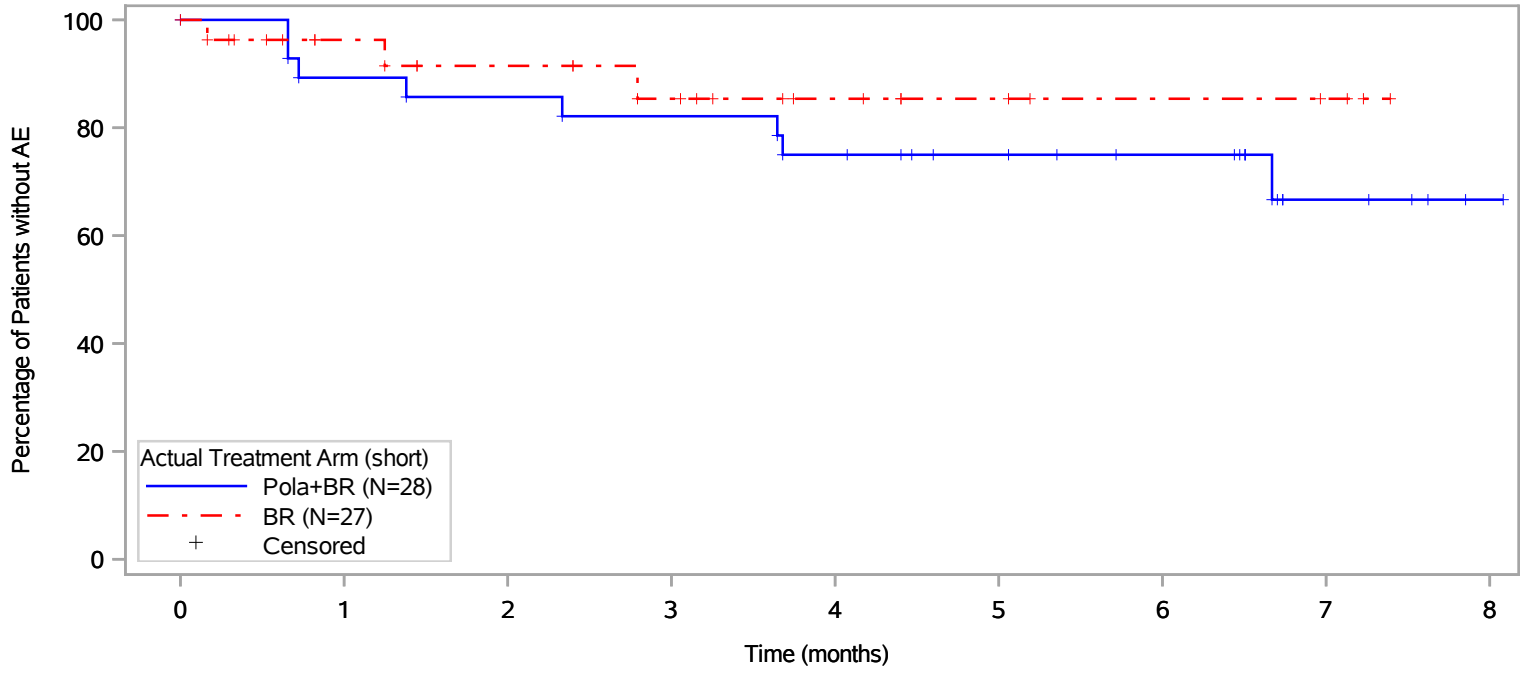
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	25	24	23	21	17	14	5	1
BR (N=27)	27	20	17	14	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	0	0	4	7	15	19
BR (N=27)	0	6	8	10	15	18	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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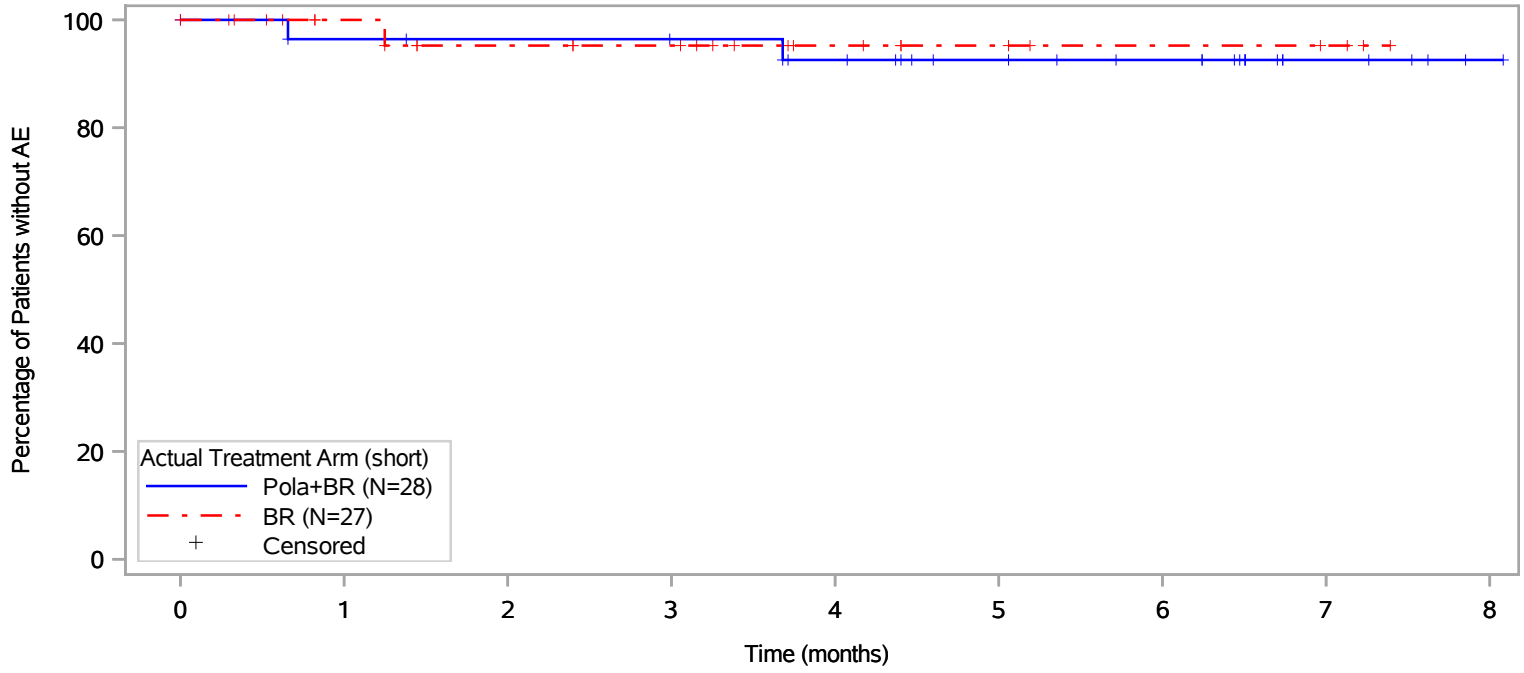
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=28)	28	27	26	25	23	18	15	5	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	3	8	11	21	25
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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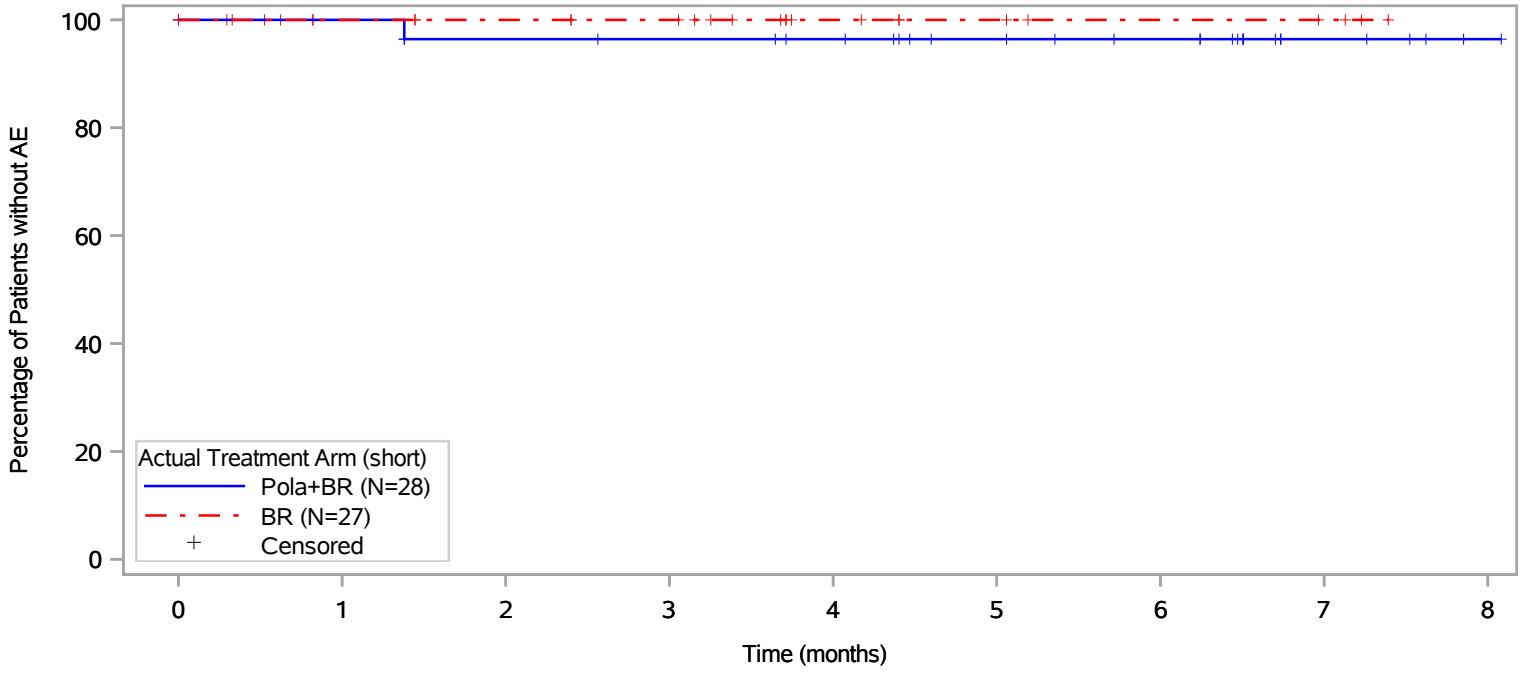
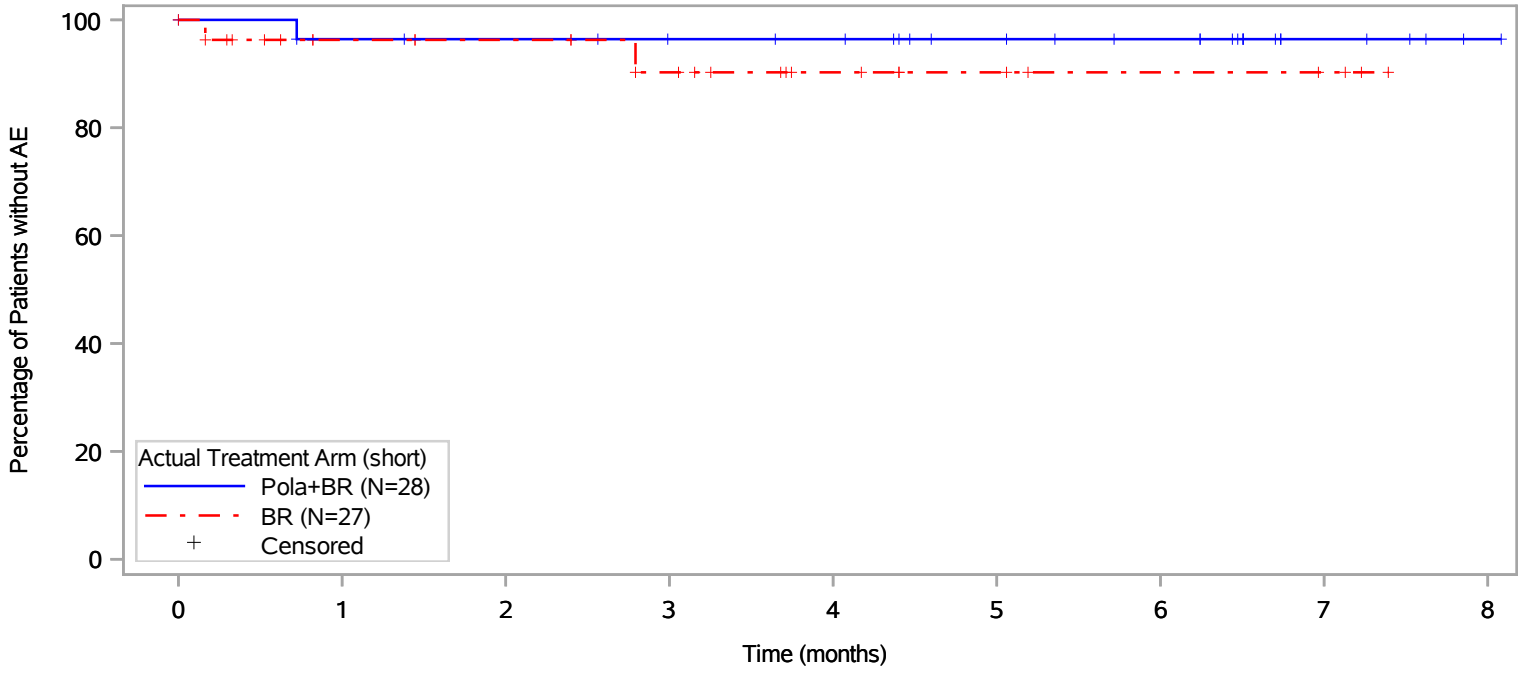
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN UPPER



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

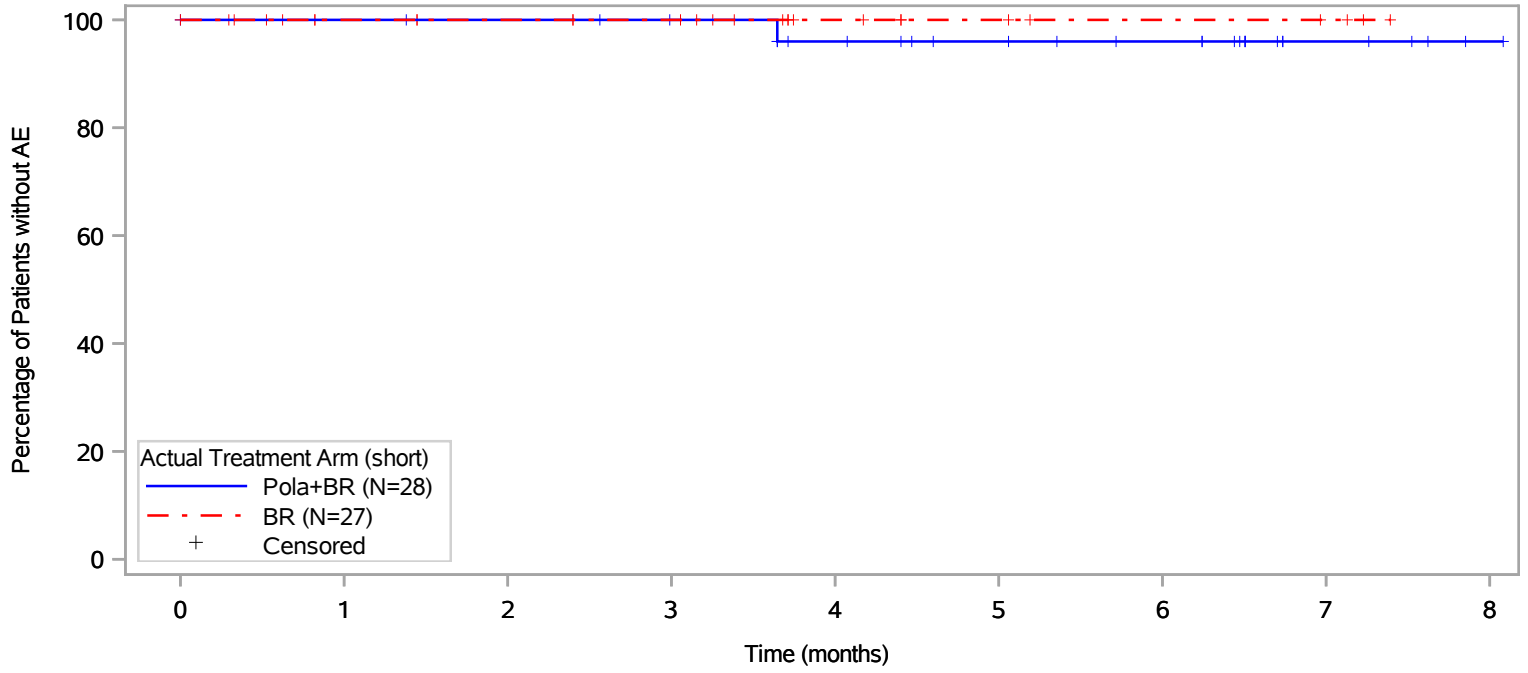
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	23	18	15	5	1
BR (N=27)	27	20	18	15	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	10	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

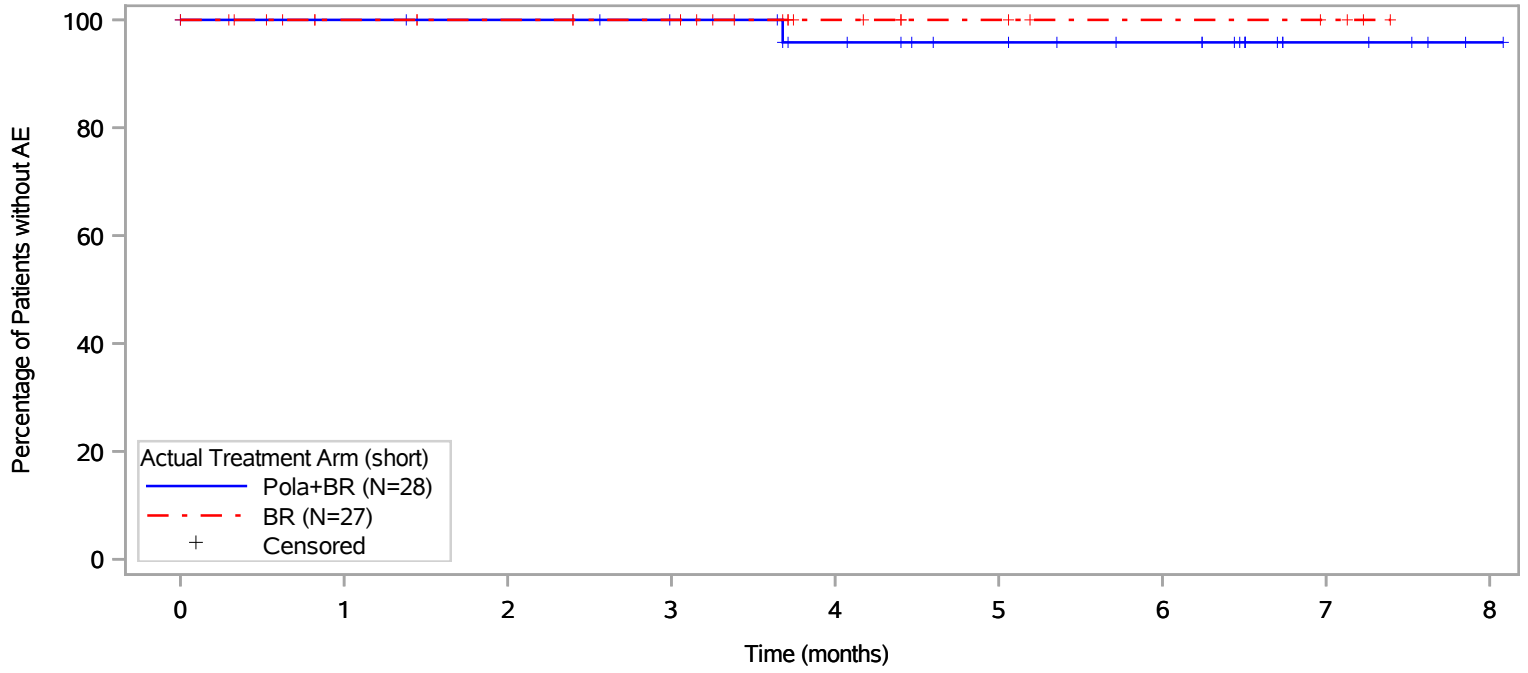
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

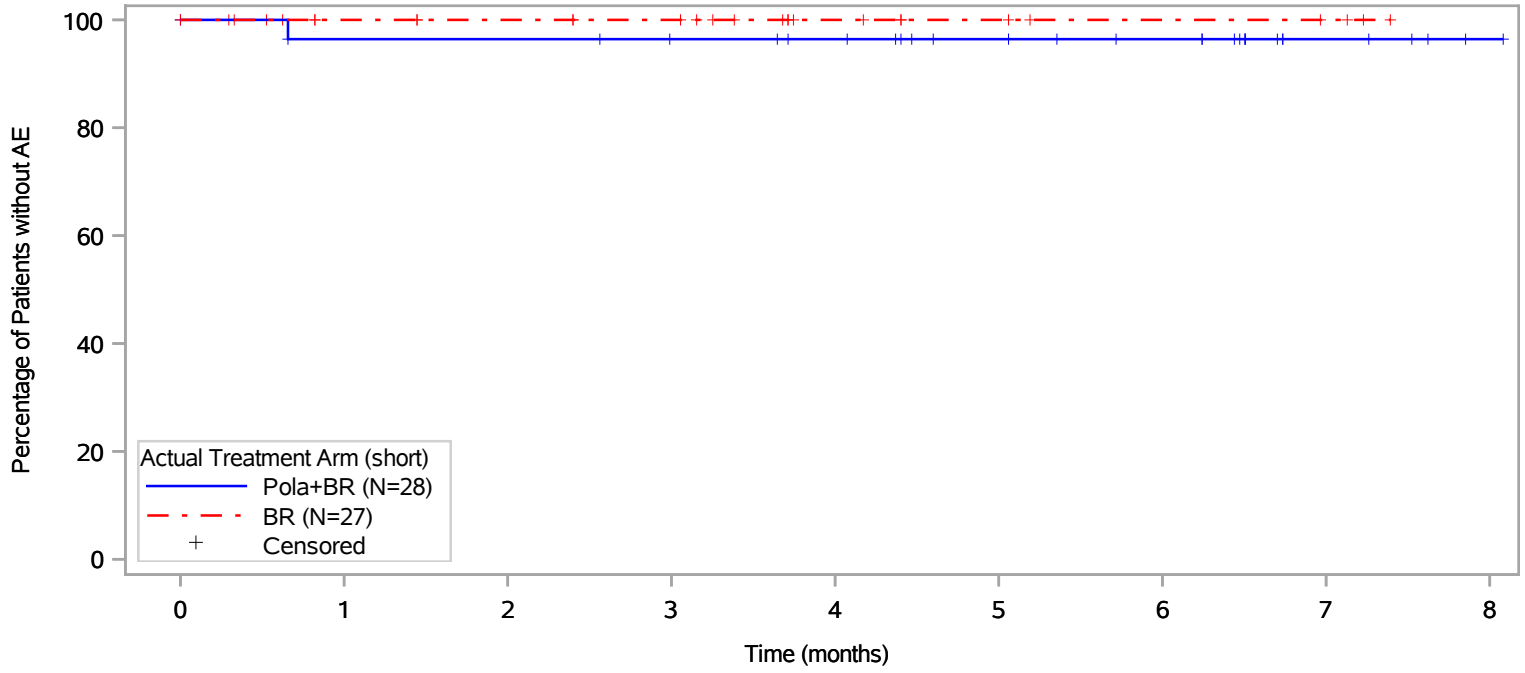
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTROINTESTINAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

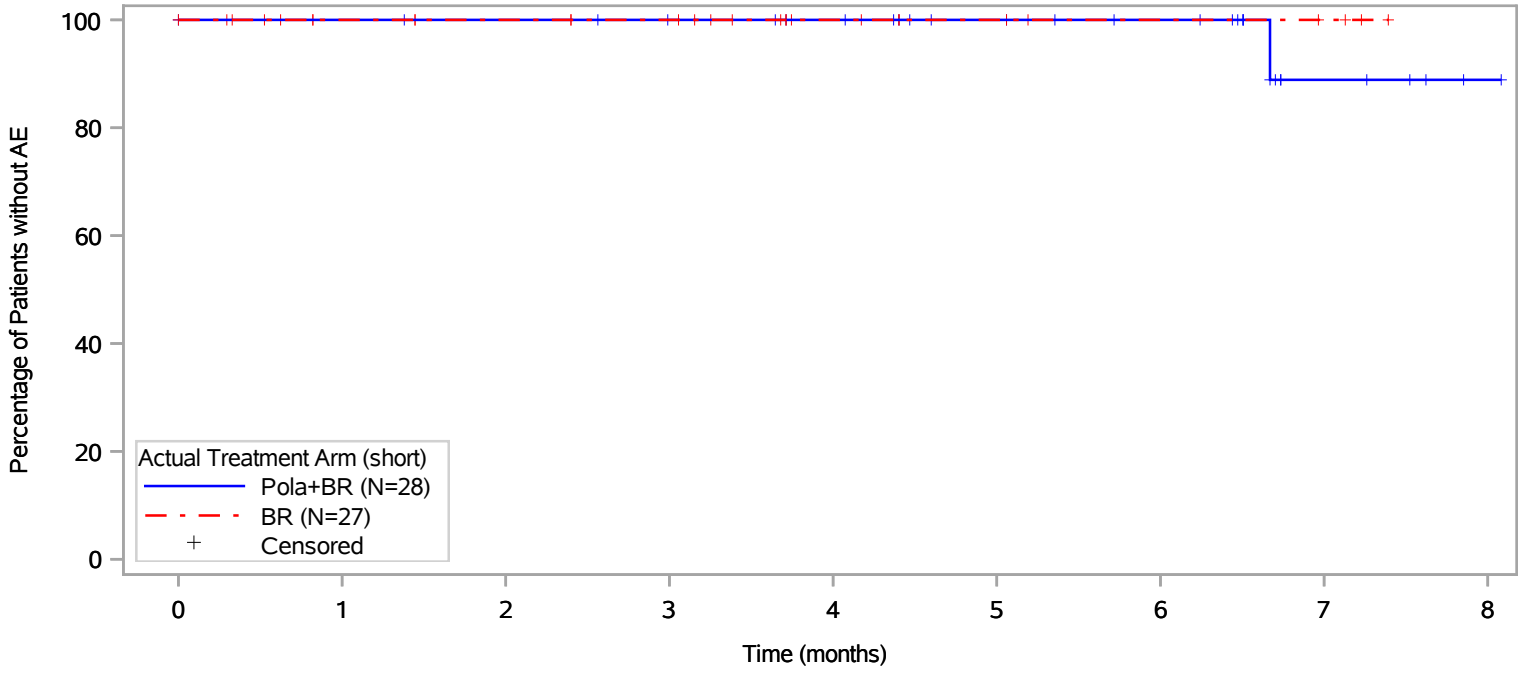
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ILEUS



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

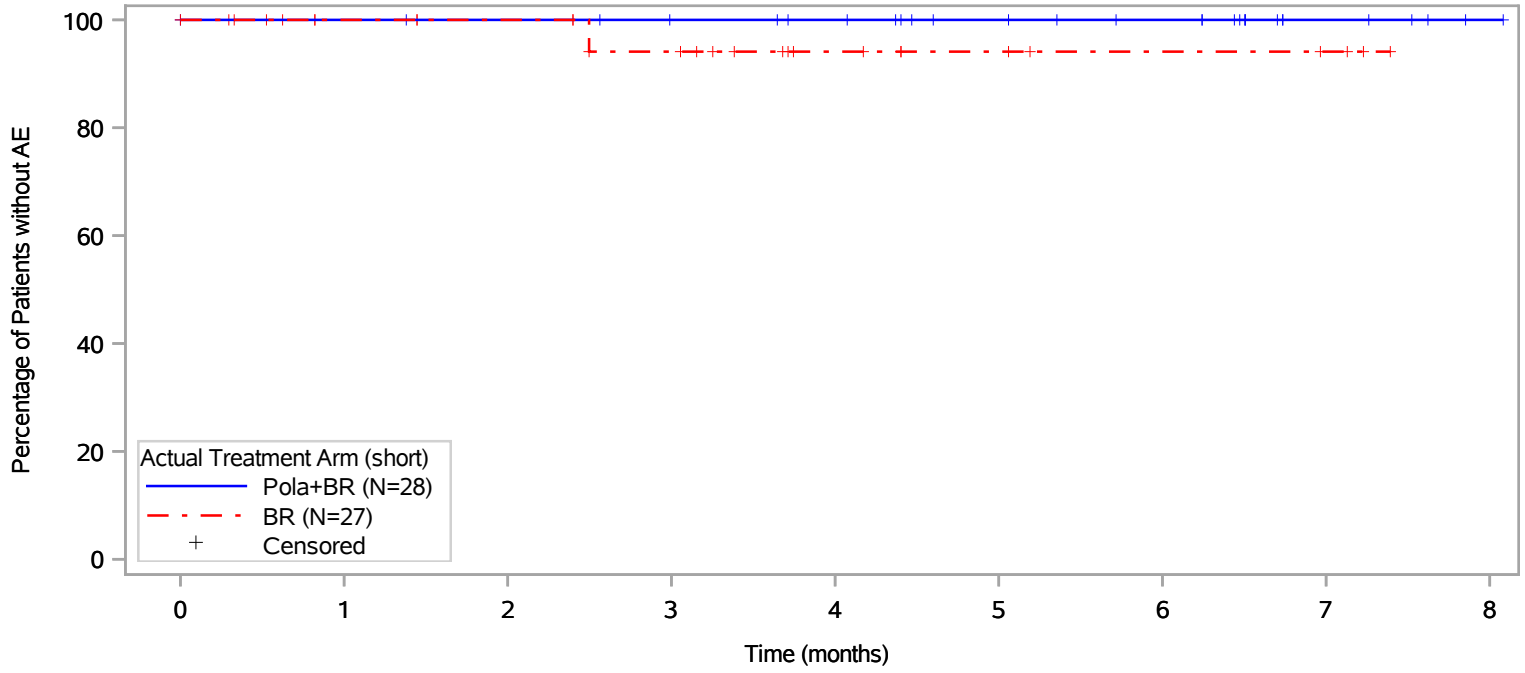
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, OBSTRUCTION GASTRIC



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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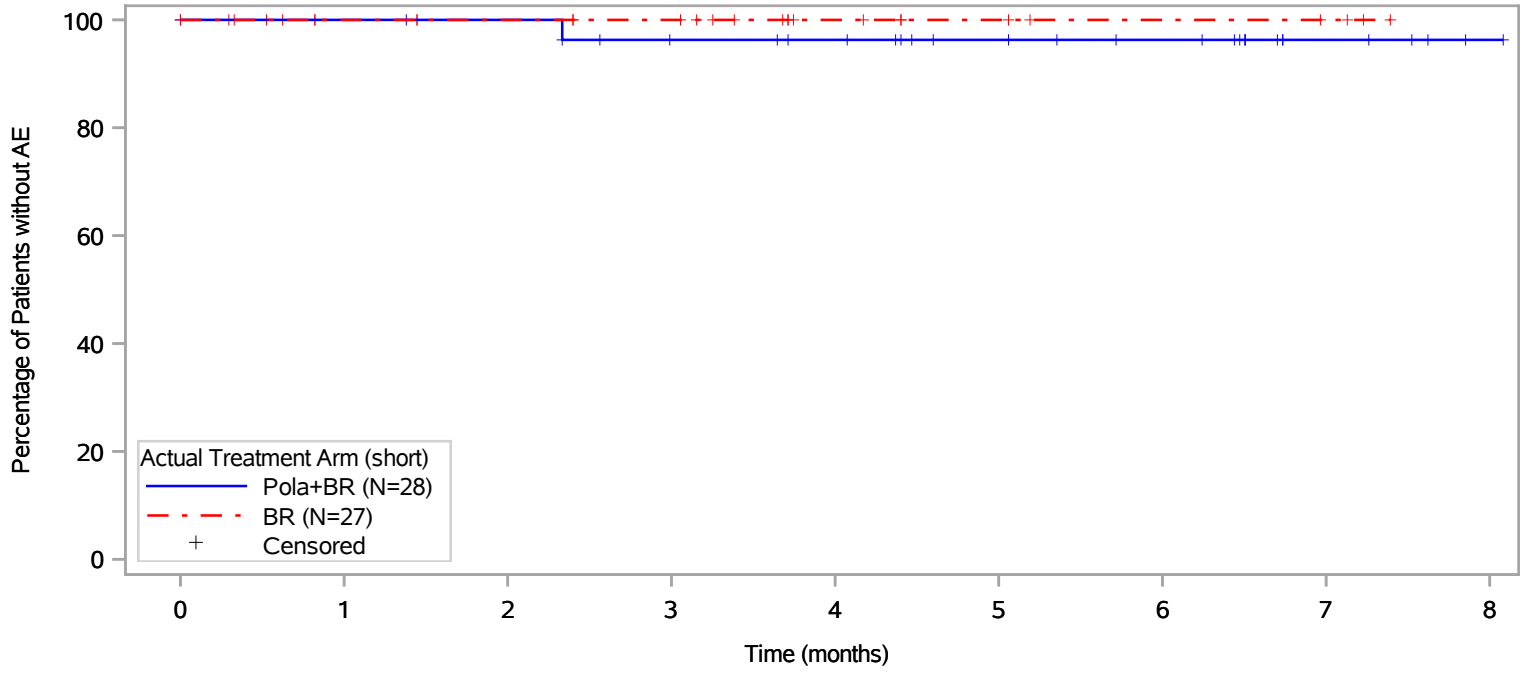
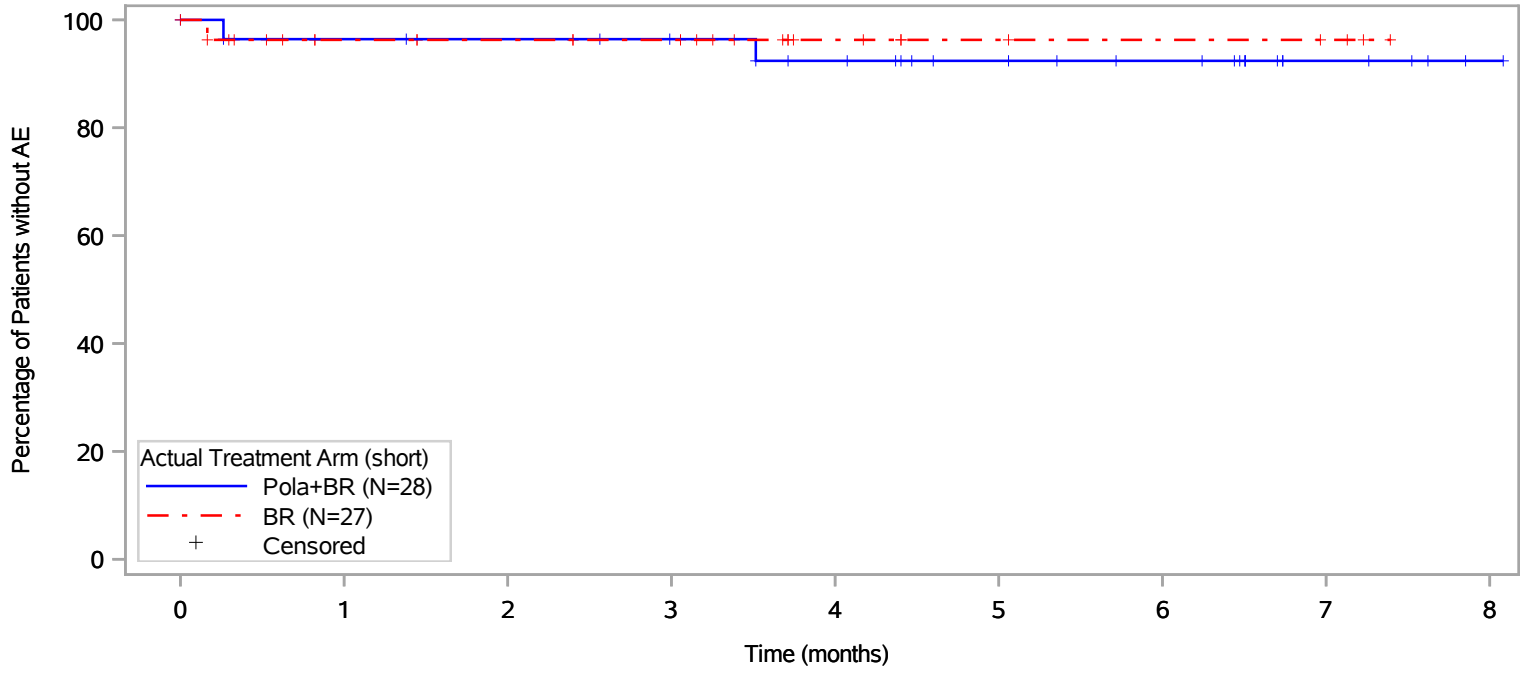
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All

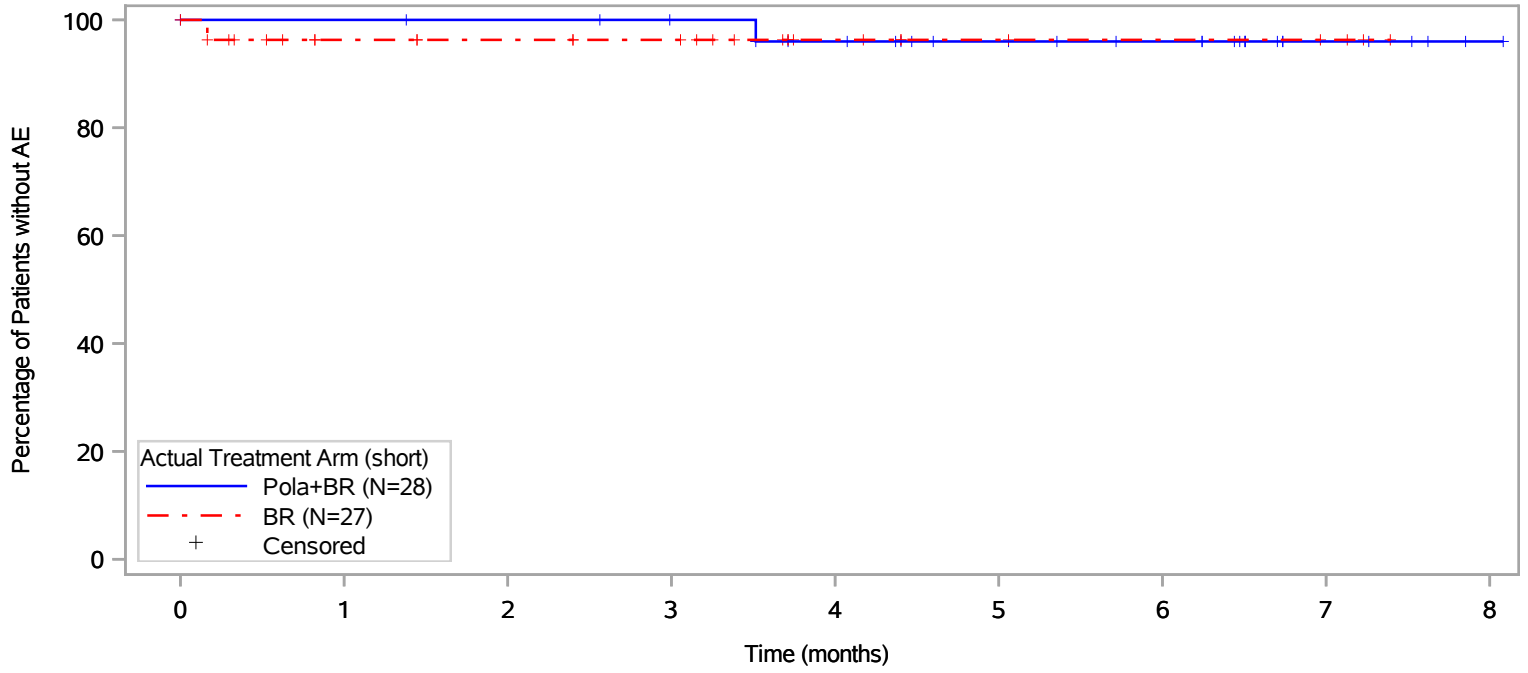


Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	21	25
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE

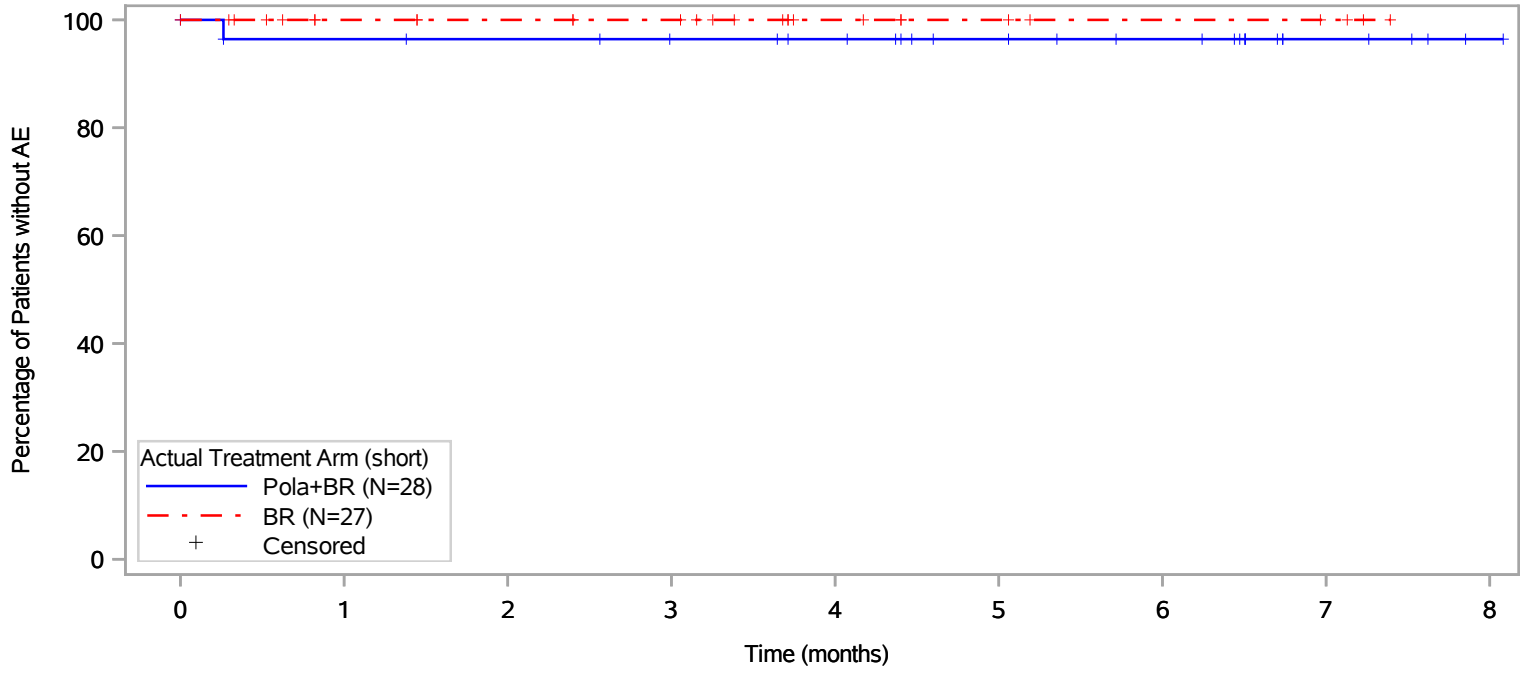


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

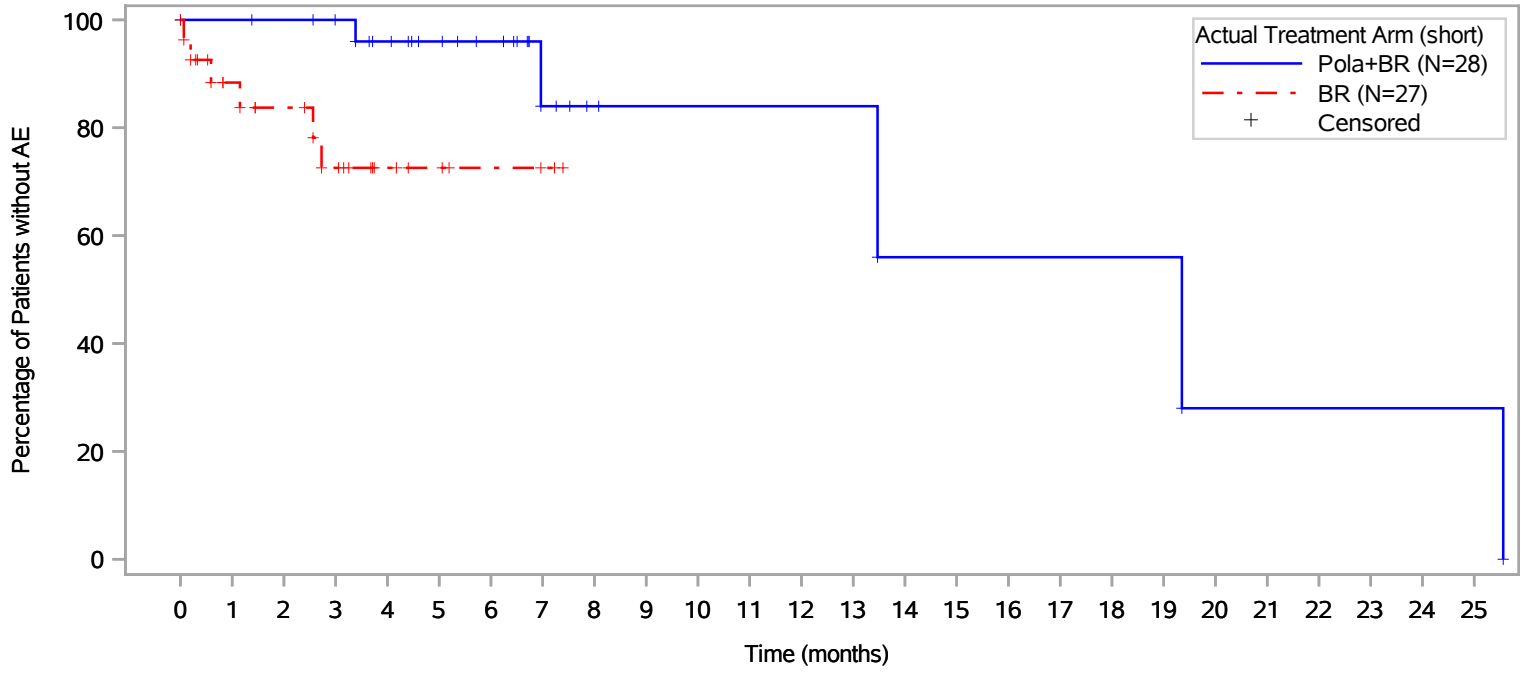
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk																										
Pola+BR (N=28)	28	28	27	25	22	18	15	7	4	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=27)	27	19	16	13	7	5	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	1	3	5	9	12	19	22	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23	23
BR (N=27)	0	5	7	8	14	16	18	19	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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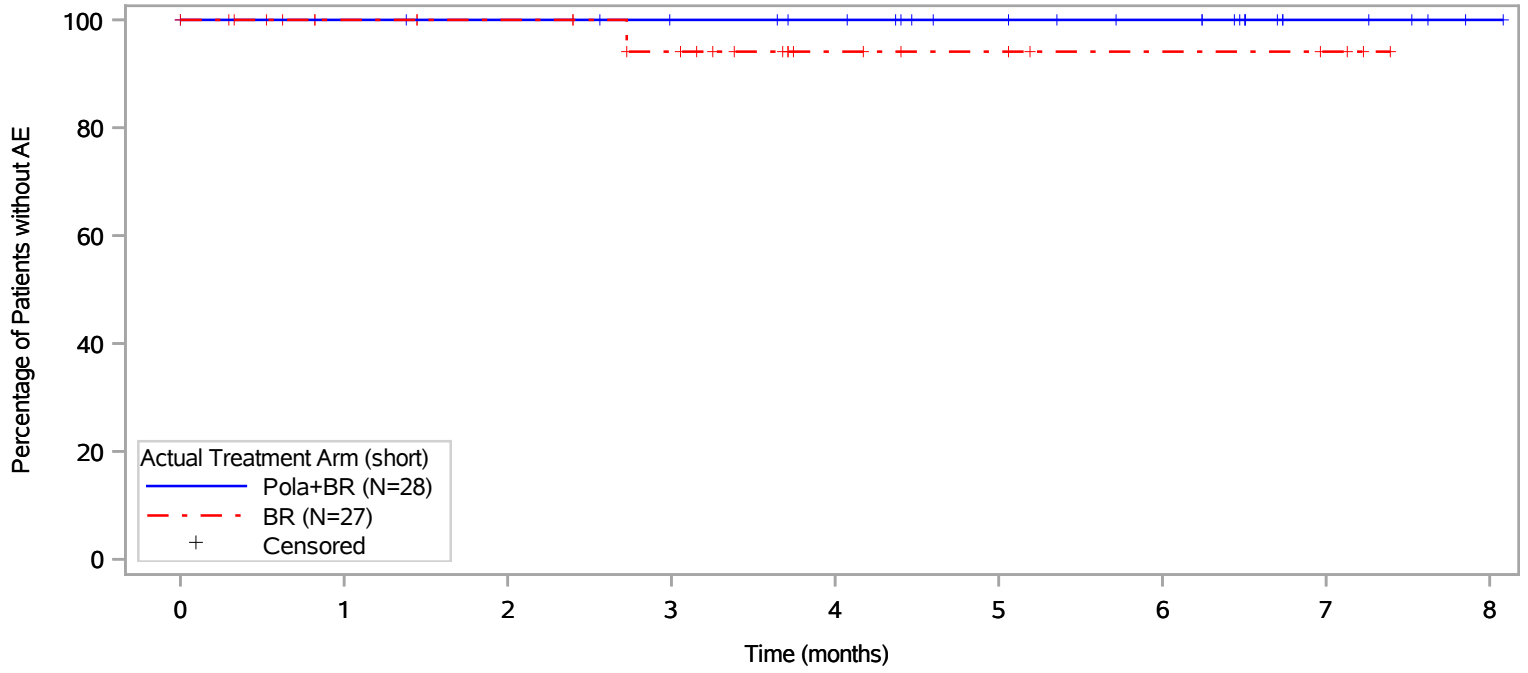
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, CYTOMEGALOVIRUS INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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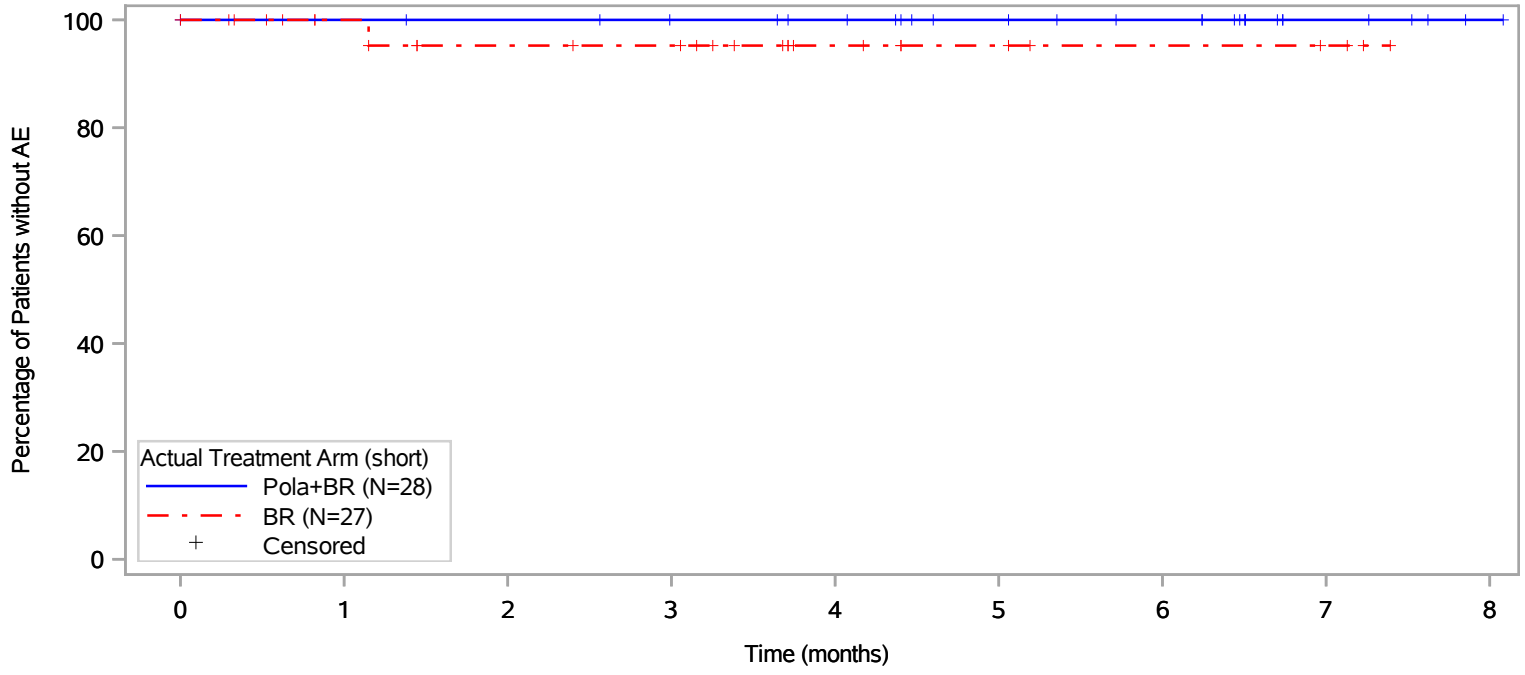
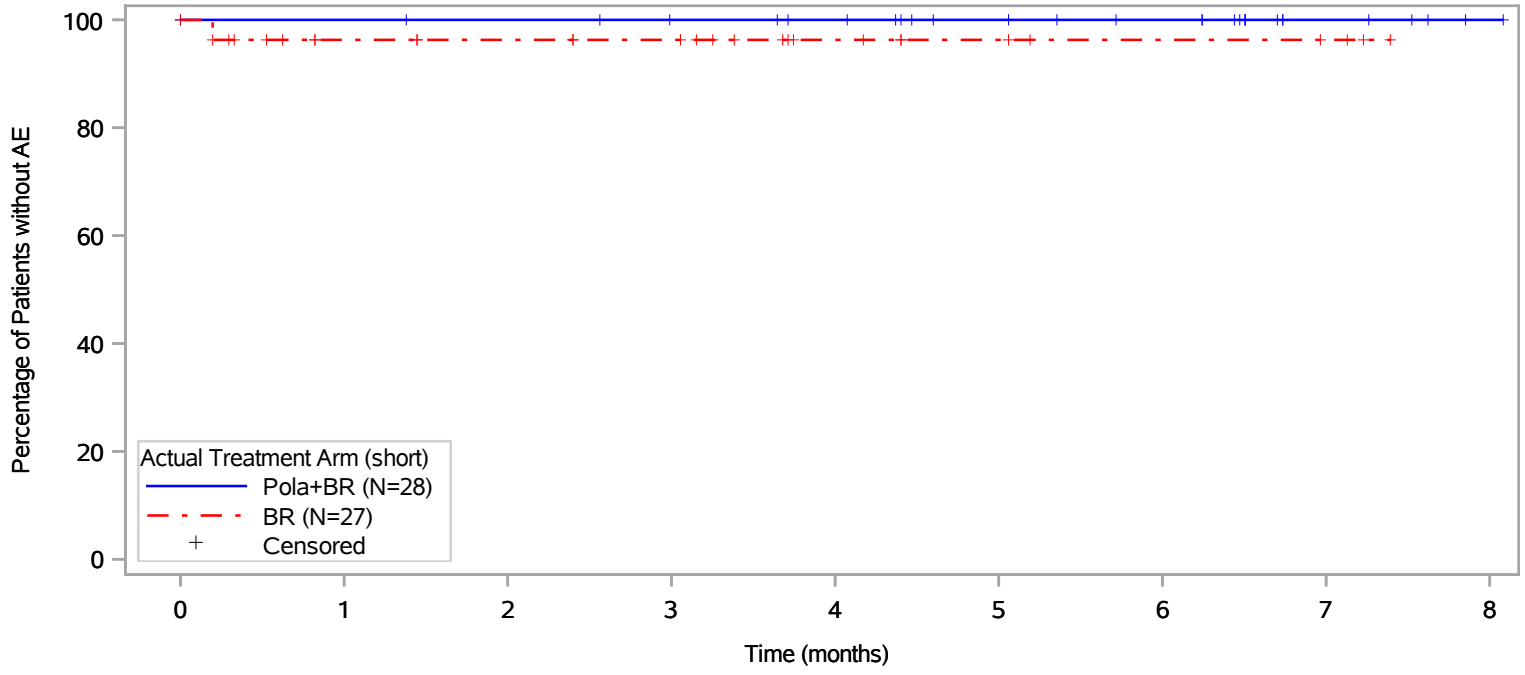
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, DEVICE RELATED INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ENTEROCOLITIS VIRAL



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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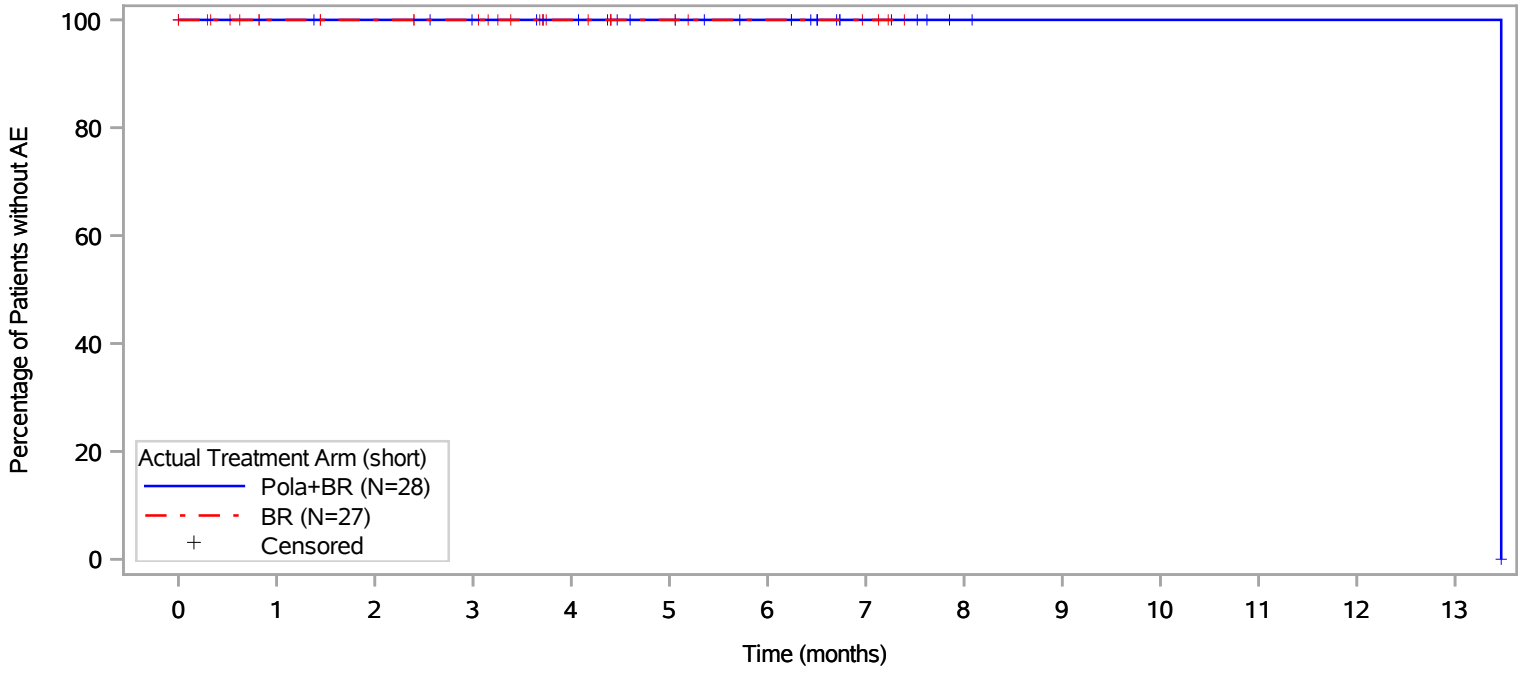
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

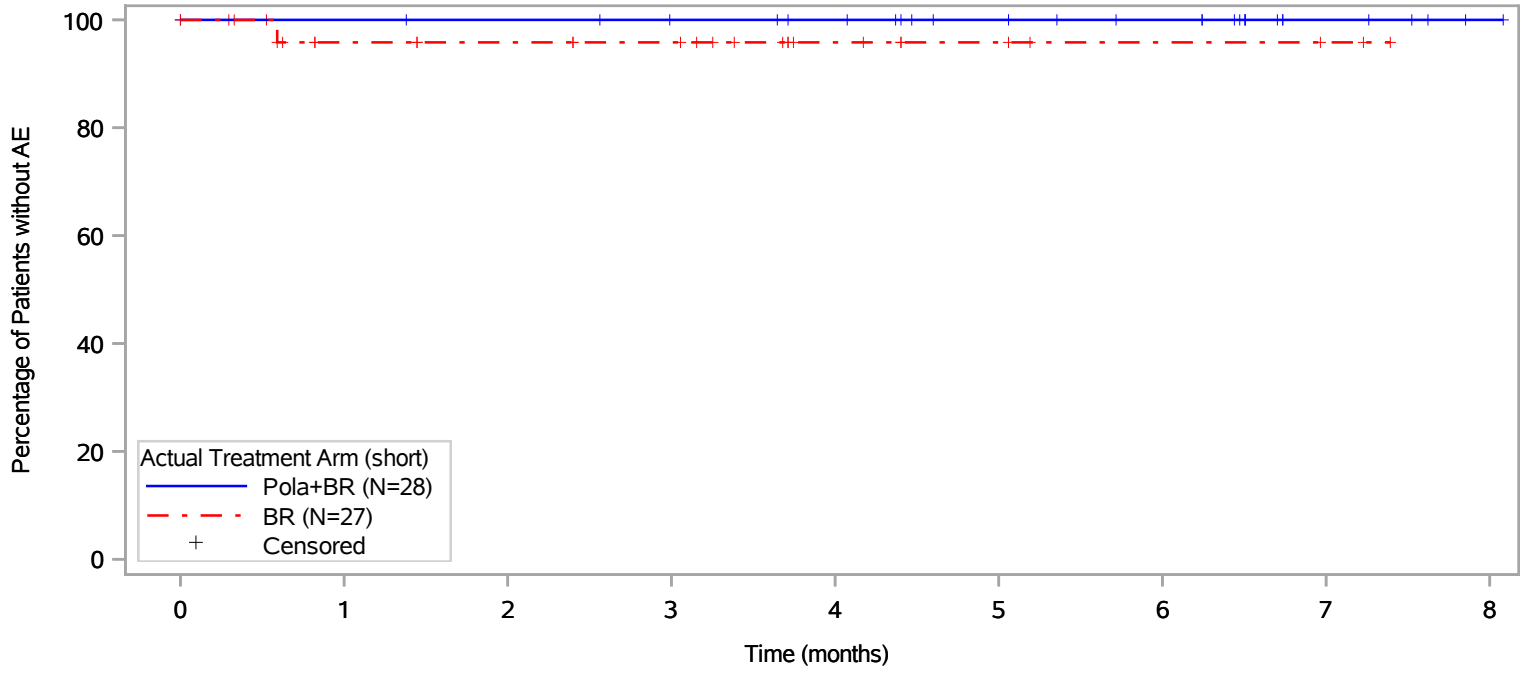
INFECTIONS AND INFESTATIONS, GASTROINTESTINAL BACTERIAL INFECTION



Patients at risk														
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

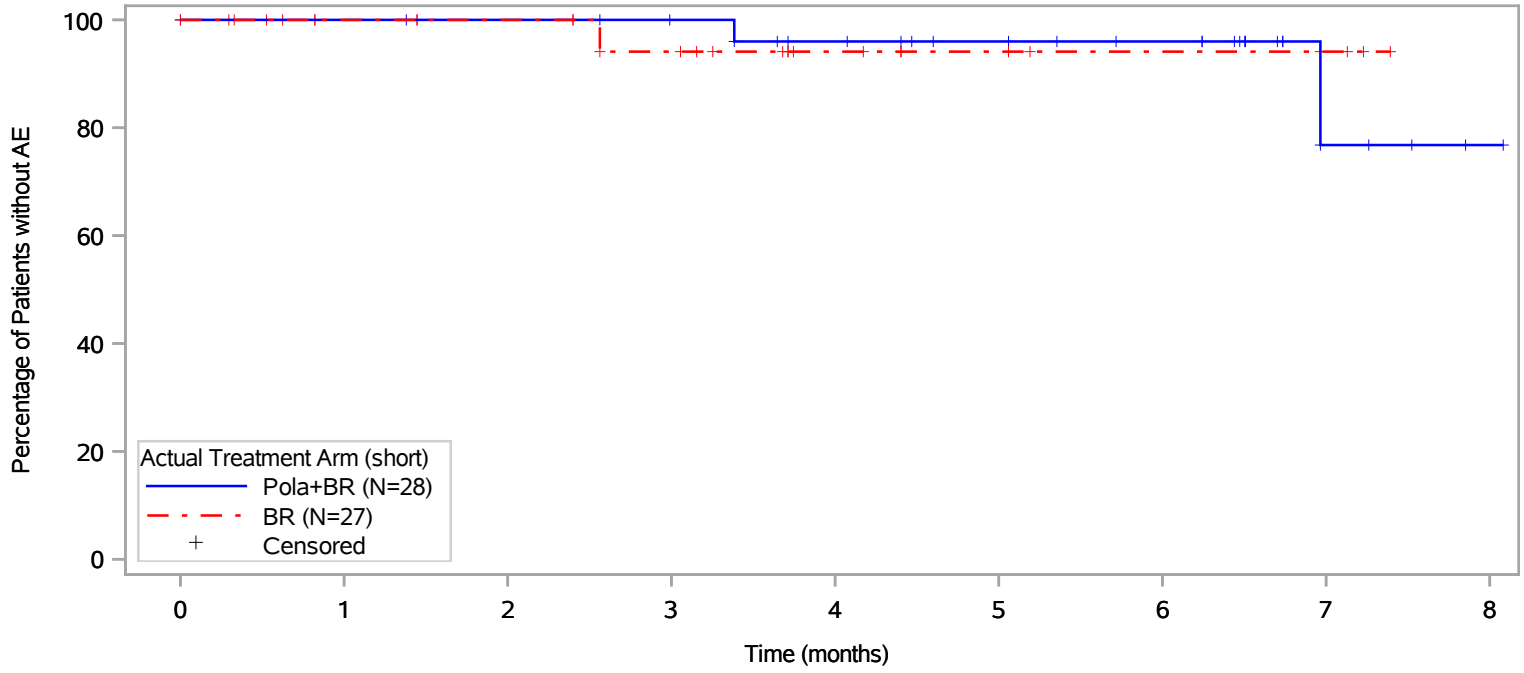
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, LOWER RESPIRATORY TRACT INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	4	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	25
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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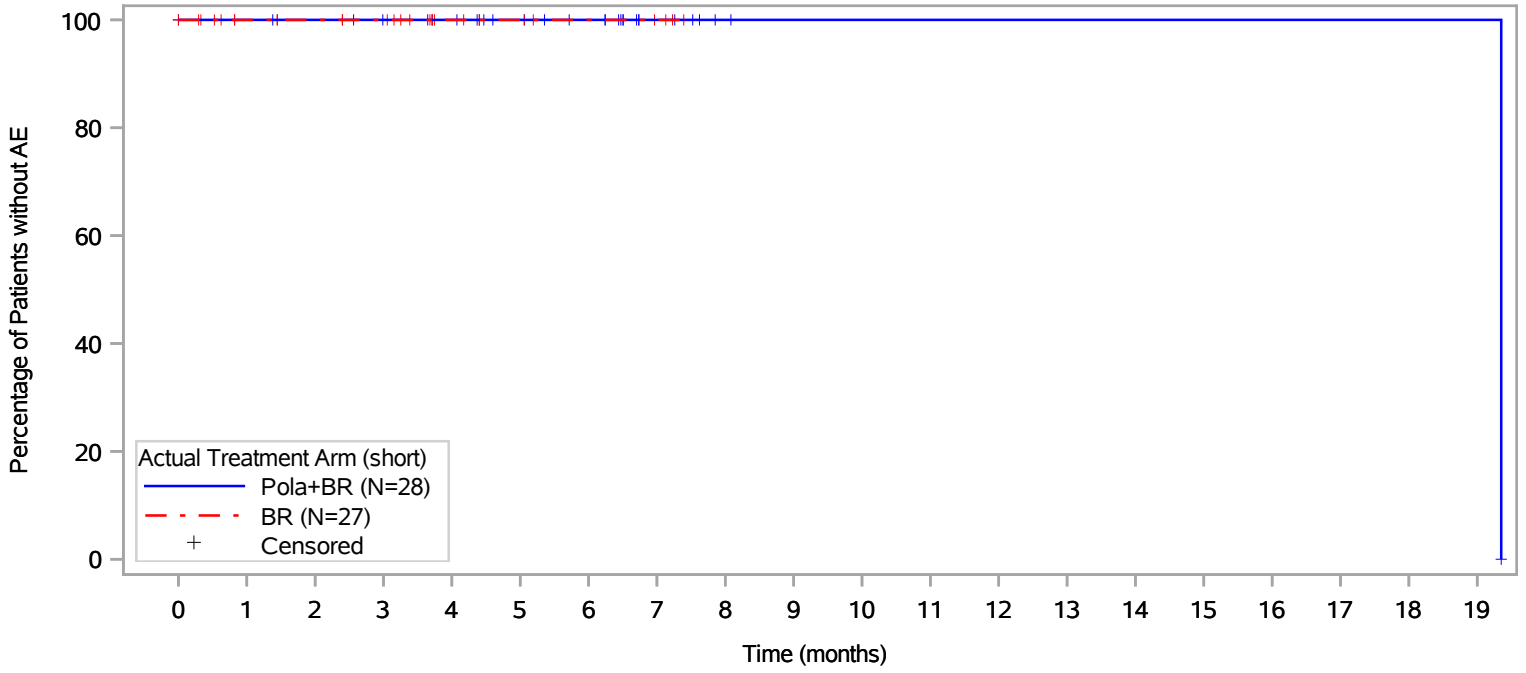
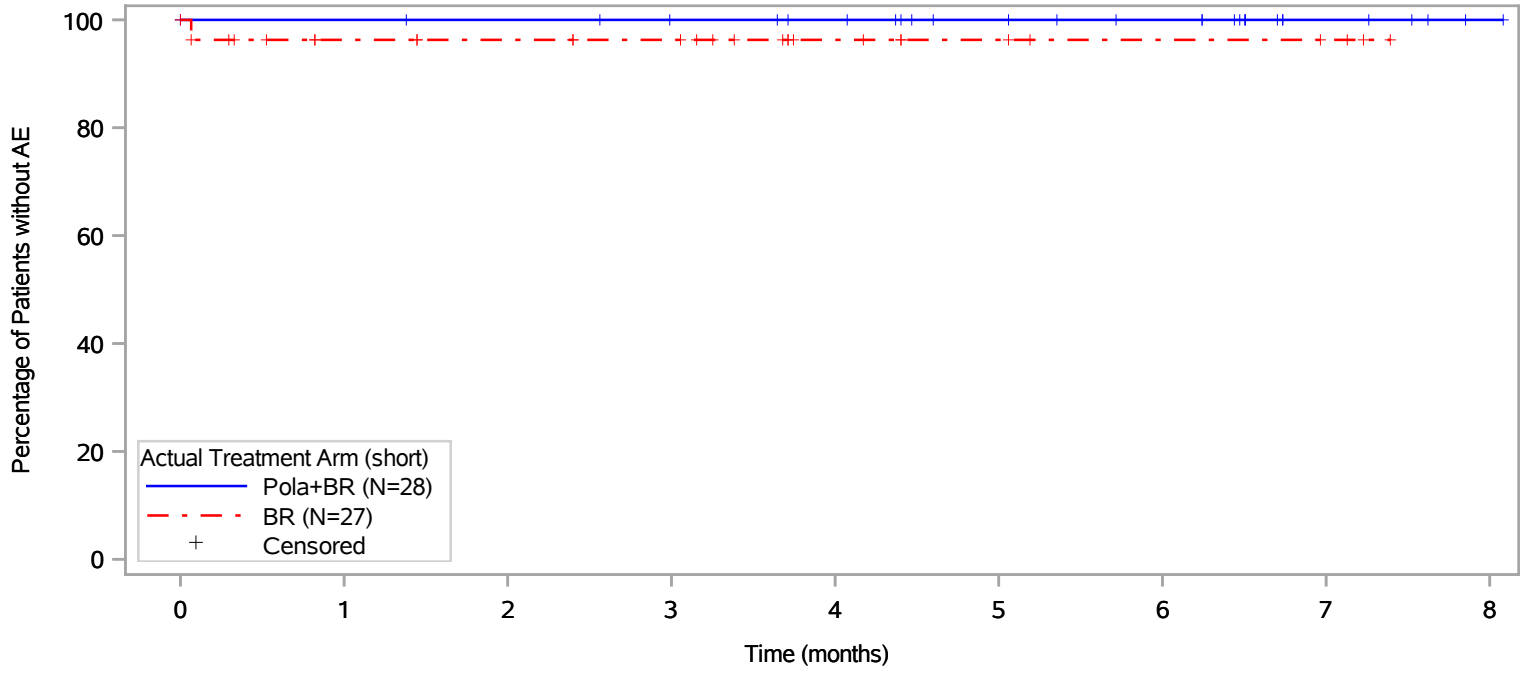
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA PNEUMOCOCCAL



Patients at risk																				
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION

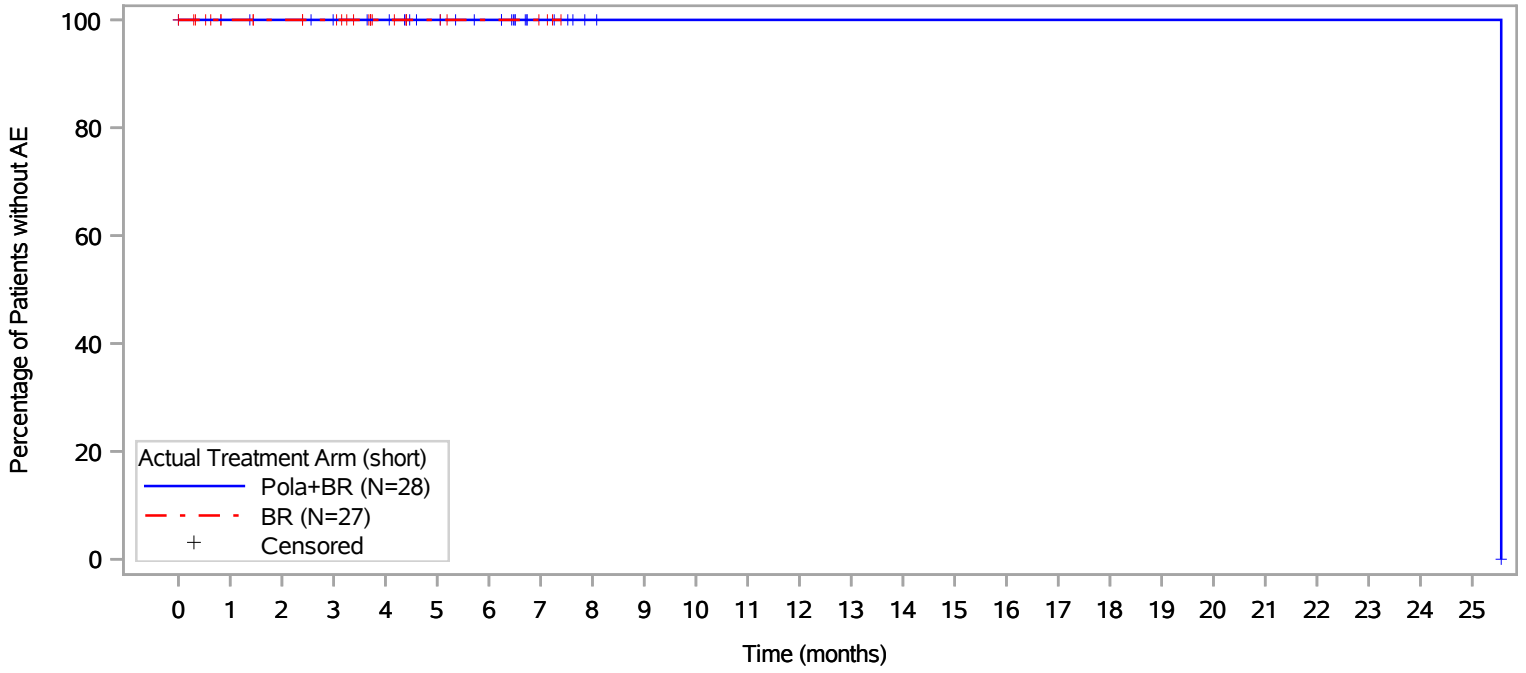


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	5	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 3:20

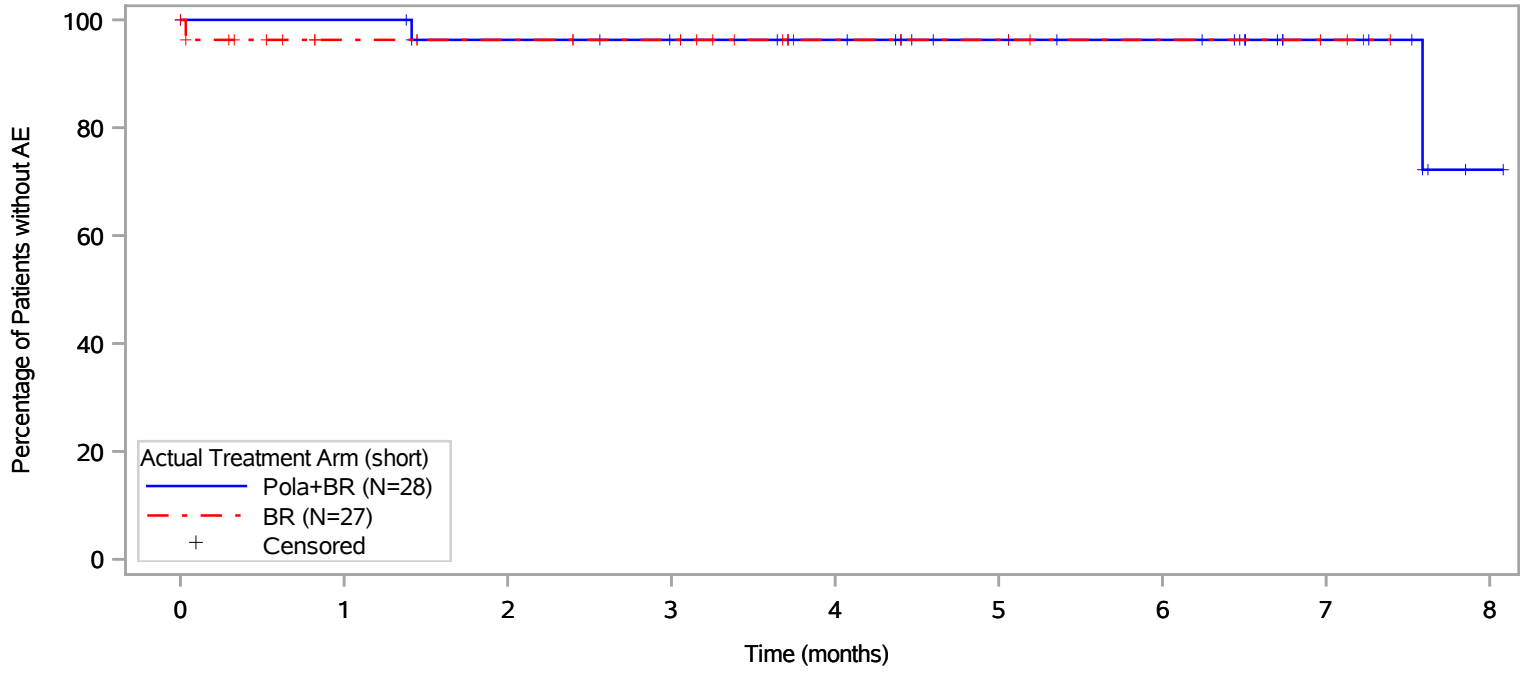
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UROSEPSIS



Patients at risk																										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	15	6	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	21	25
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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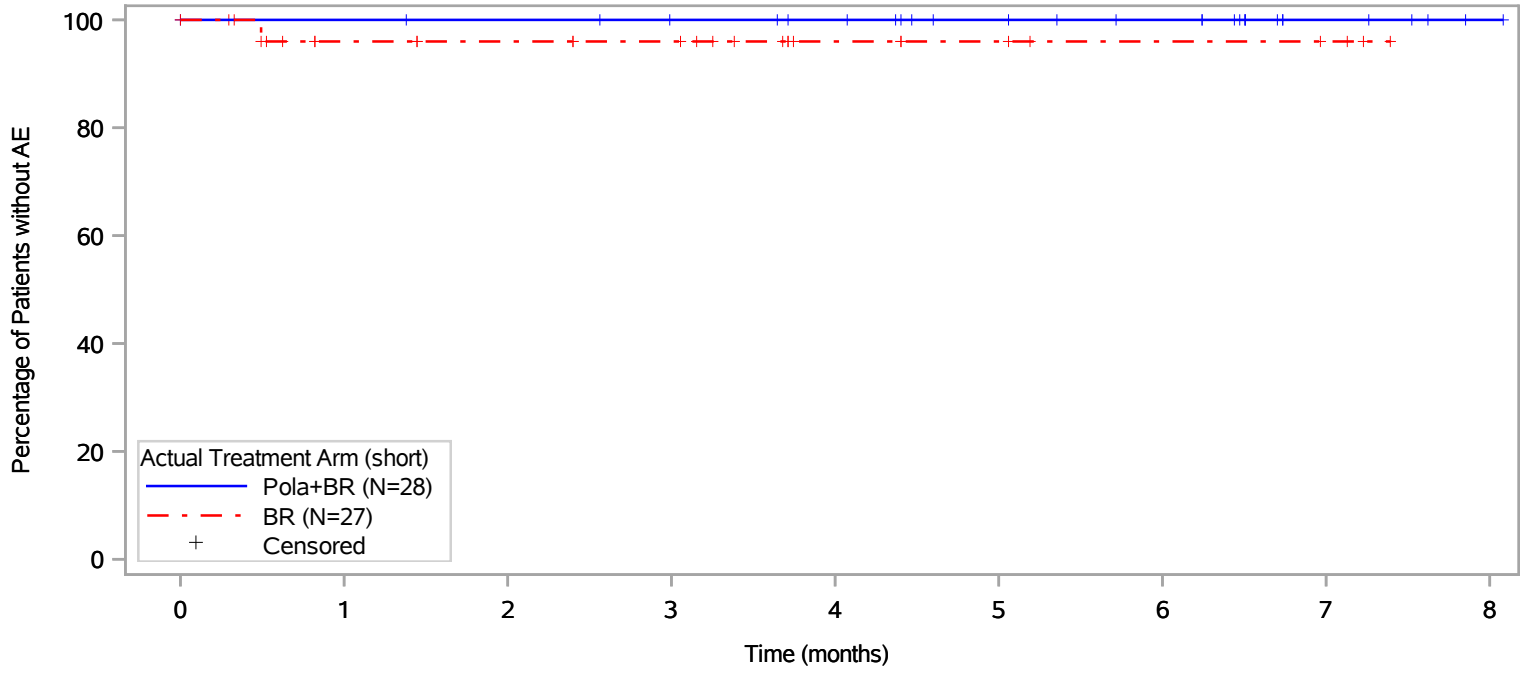
02DEC2022 3:20

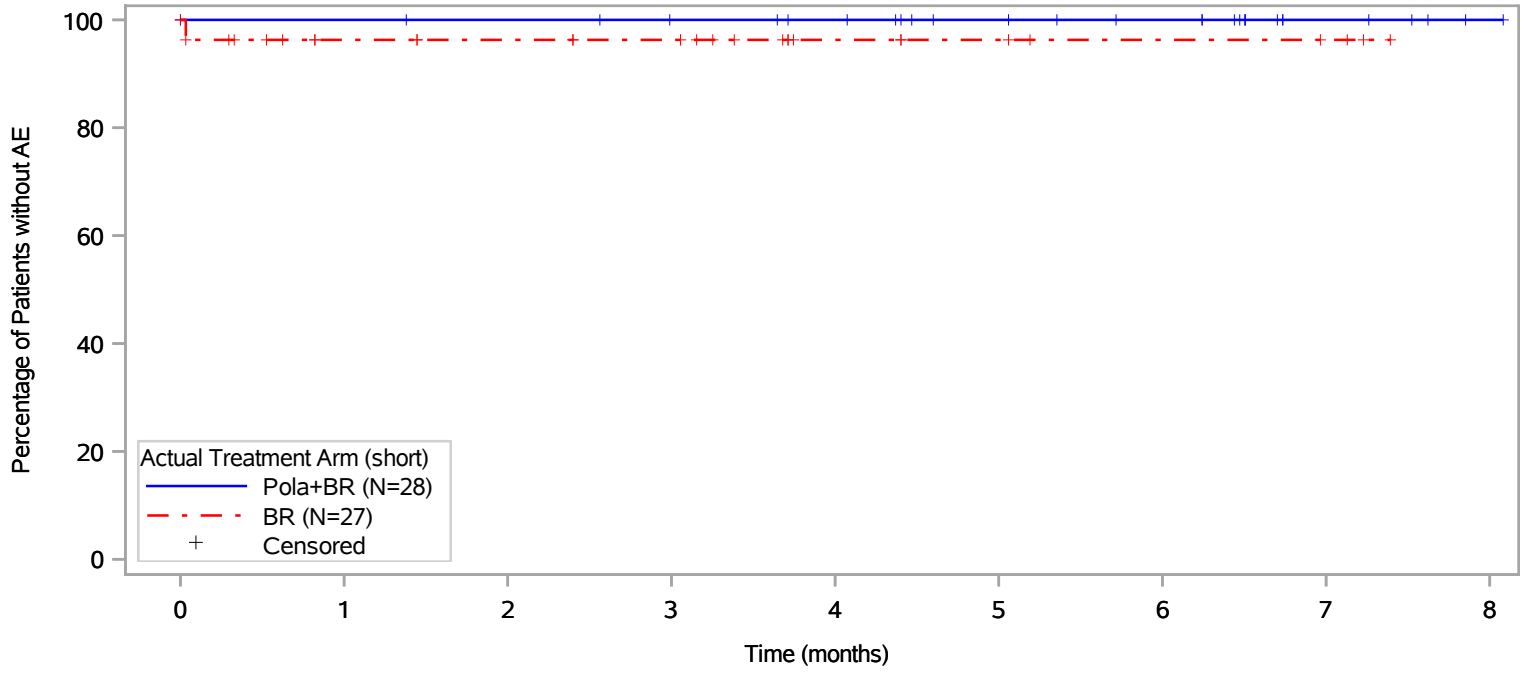
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, HAEMOGLOBIN DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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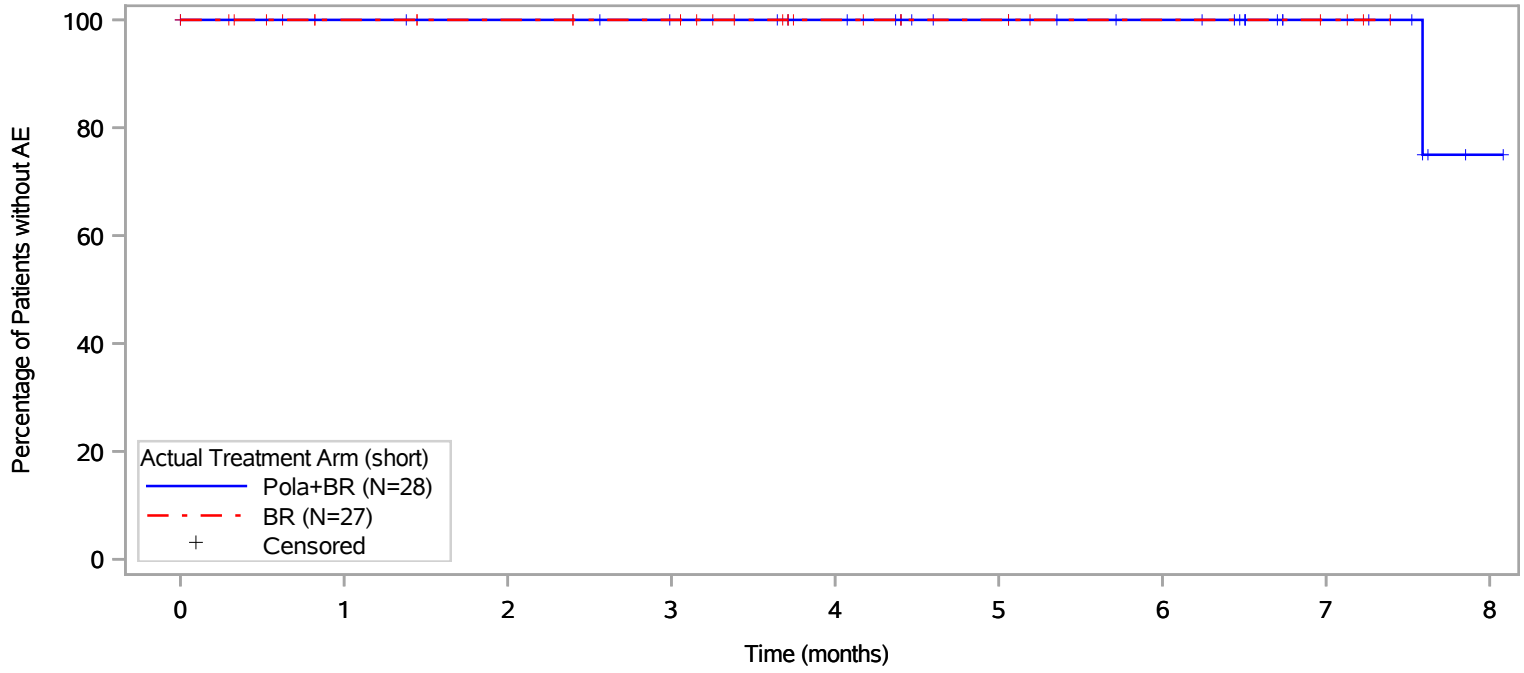
02DEC2022 3:20

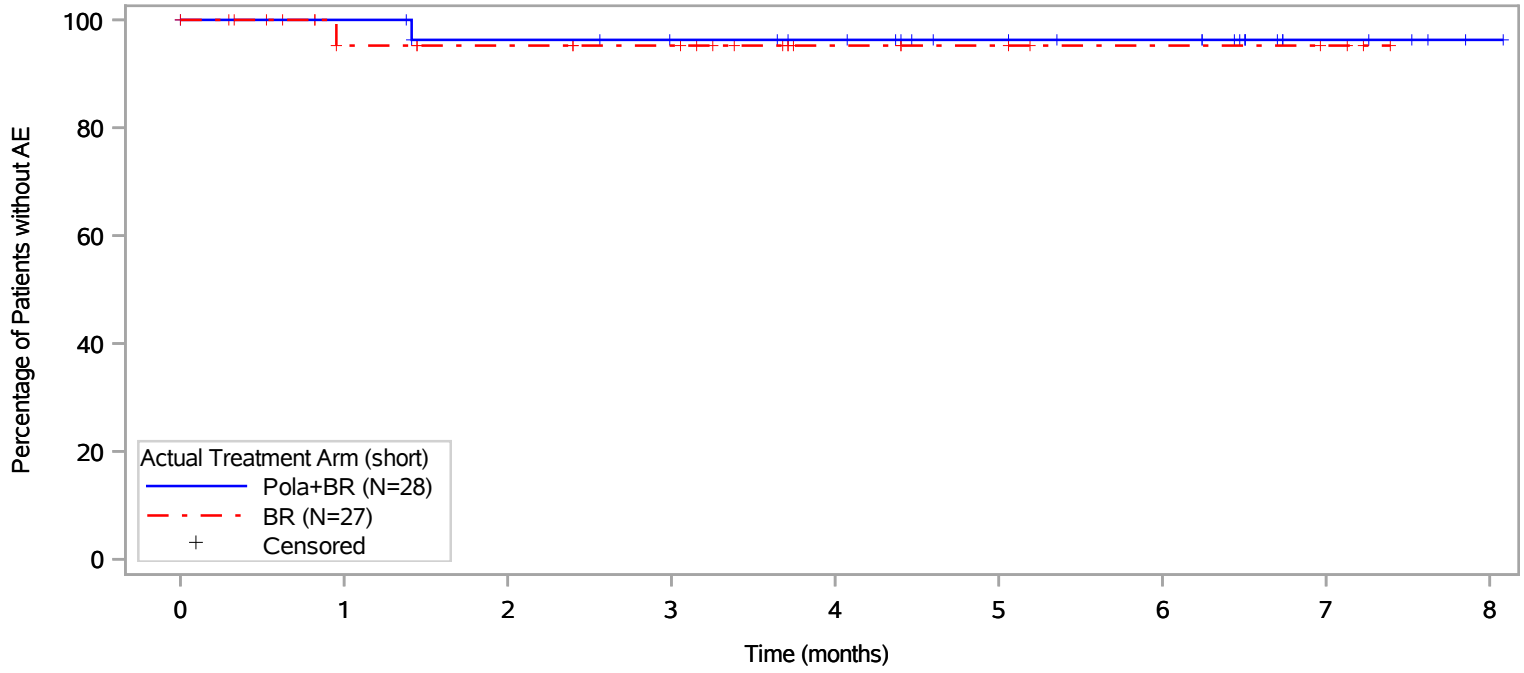
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MORAXELLA TEST POSITIVE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	6	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

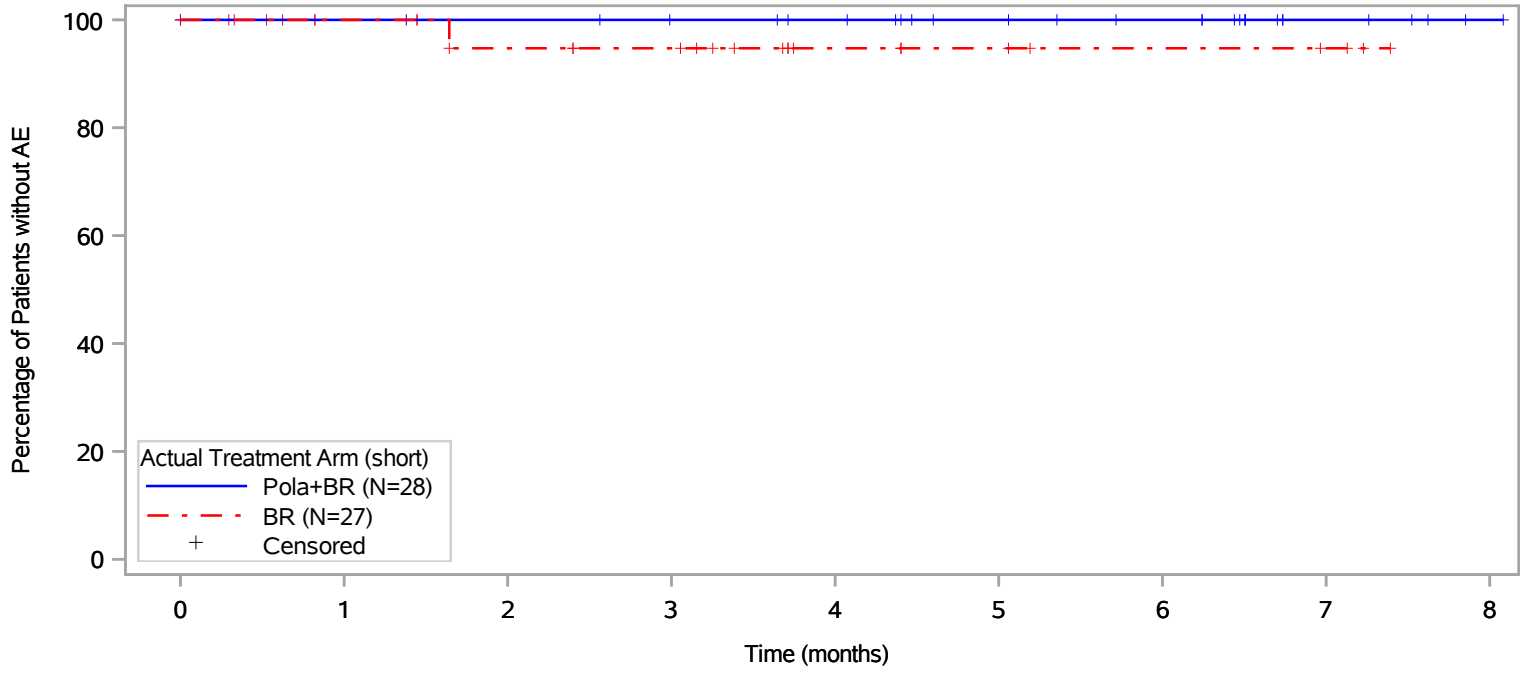


Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	15	5	1
BR (N=27)	27	20	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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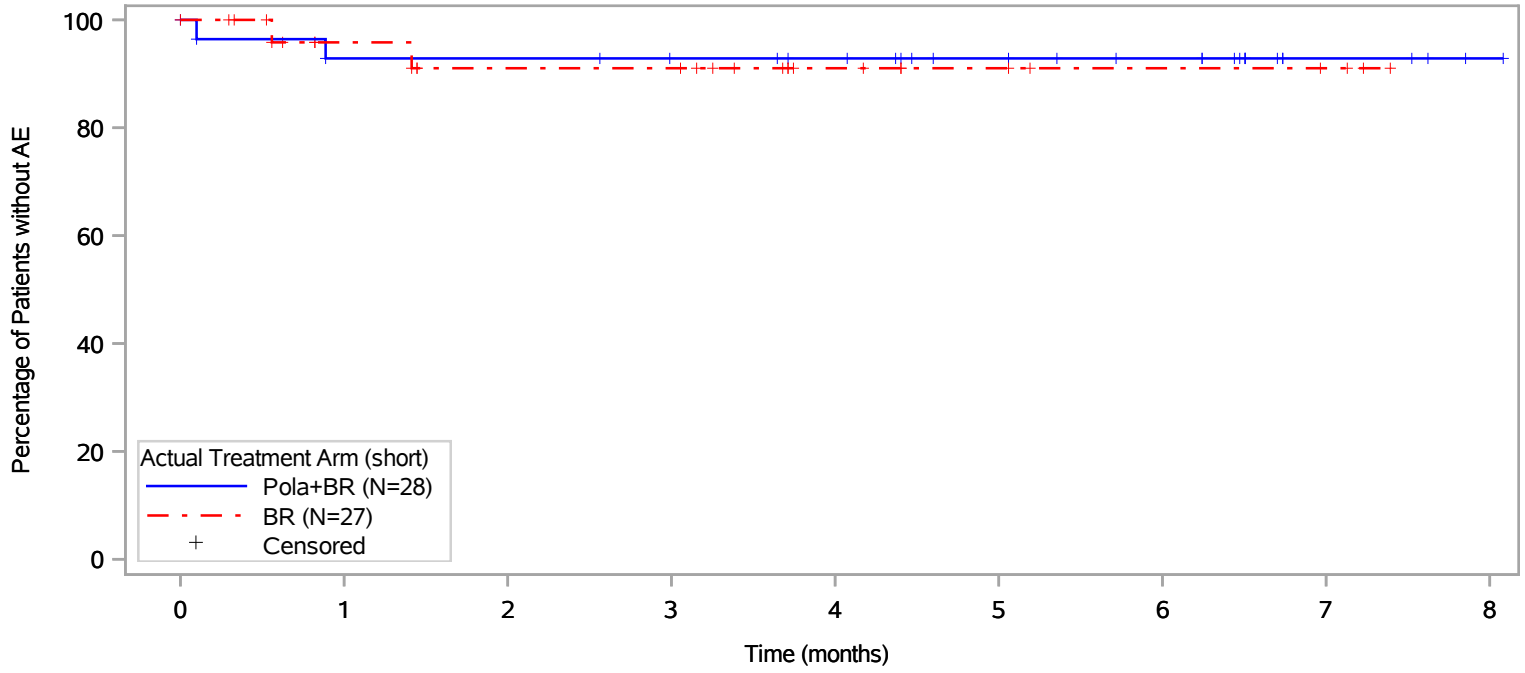
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	26	26	24	22	17	14	4	1
BR (N=27)	27	20	17	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	25
BR (N=27)	0	6	8	8	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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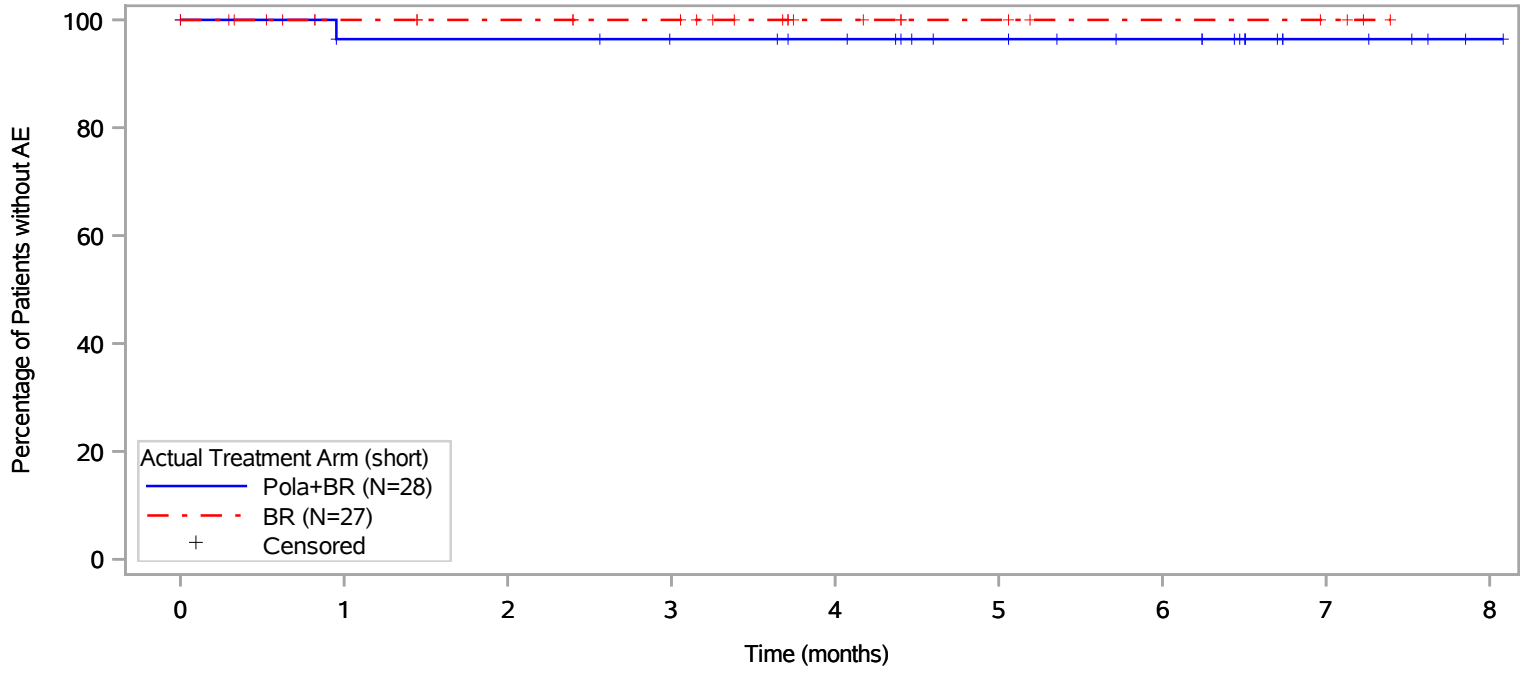
02DEC2022 3:20

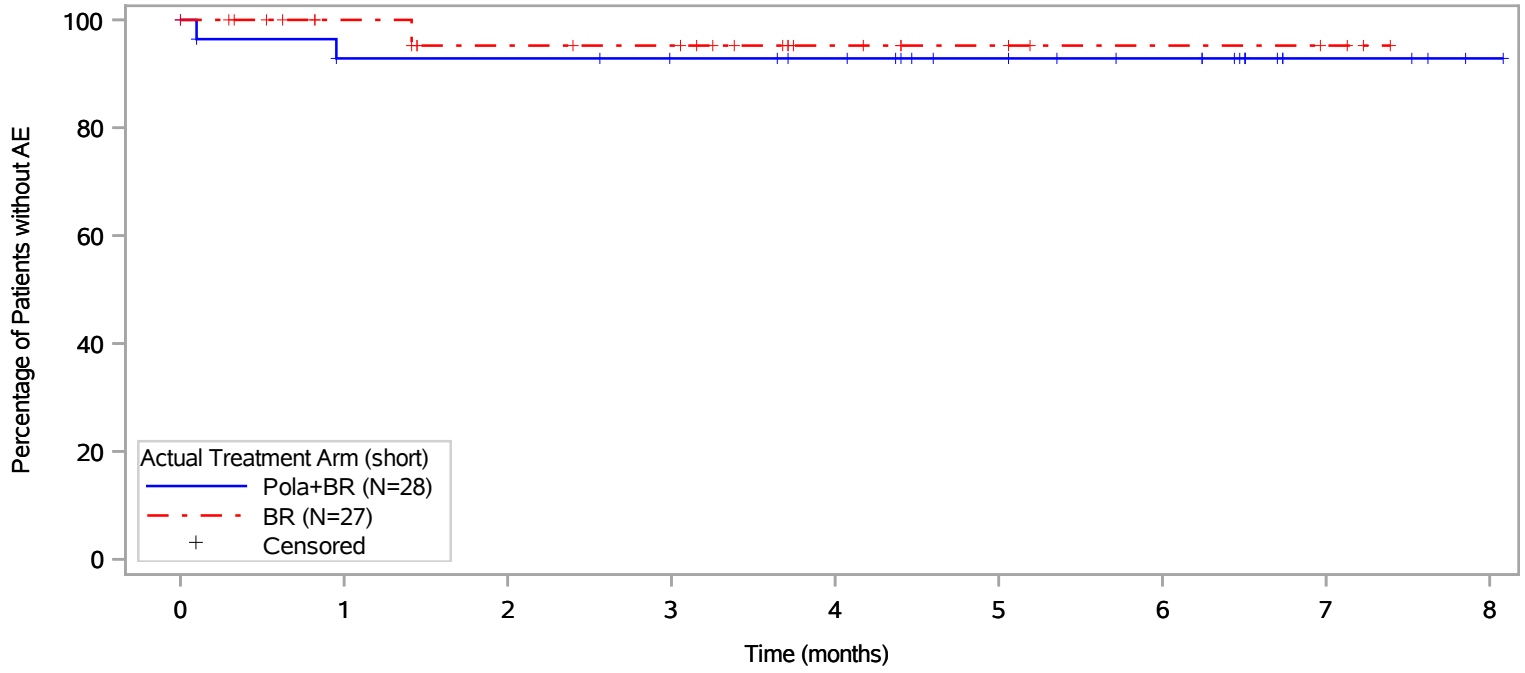
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOCALCAEMIA



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



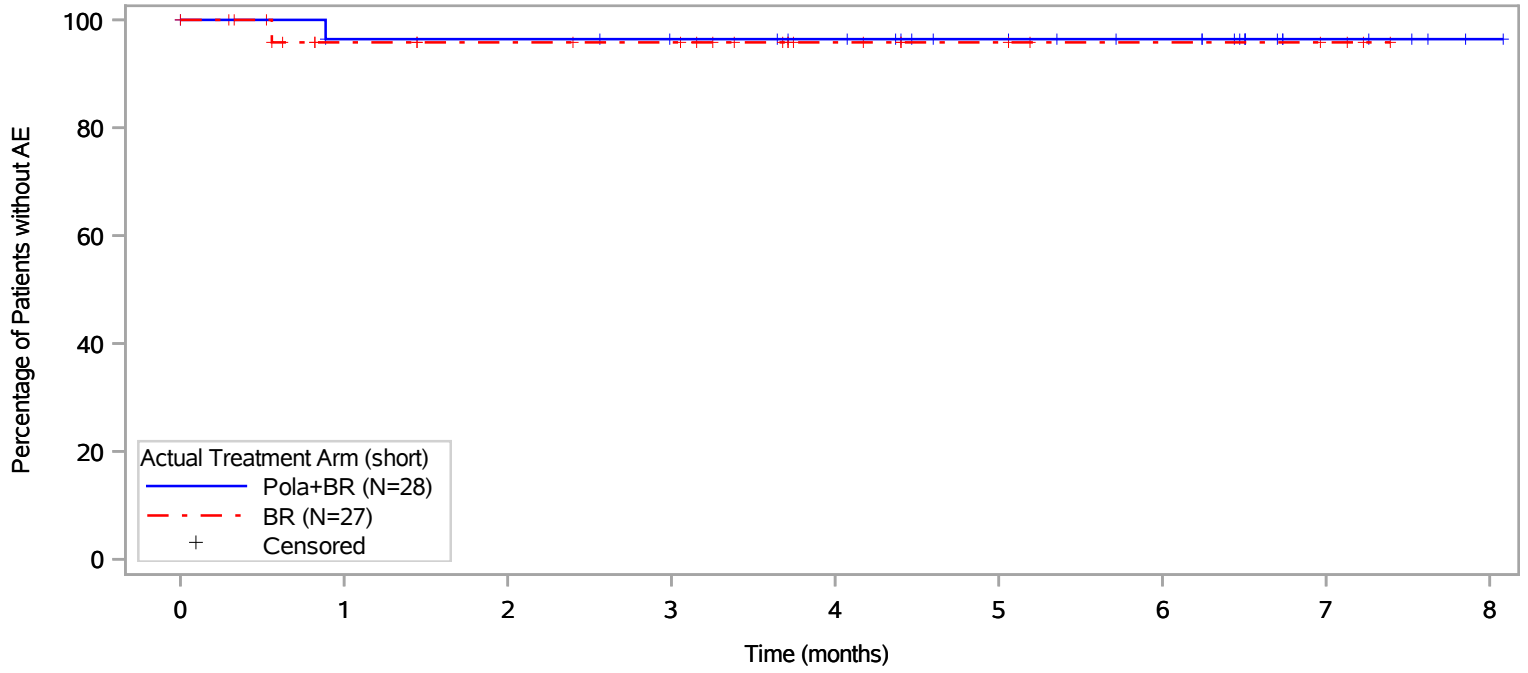
Patients at risk									
Pola+BR (N=28)	28	26	26	24	22	17	14	4	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	25
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

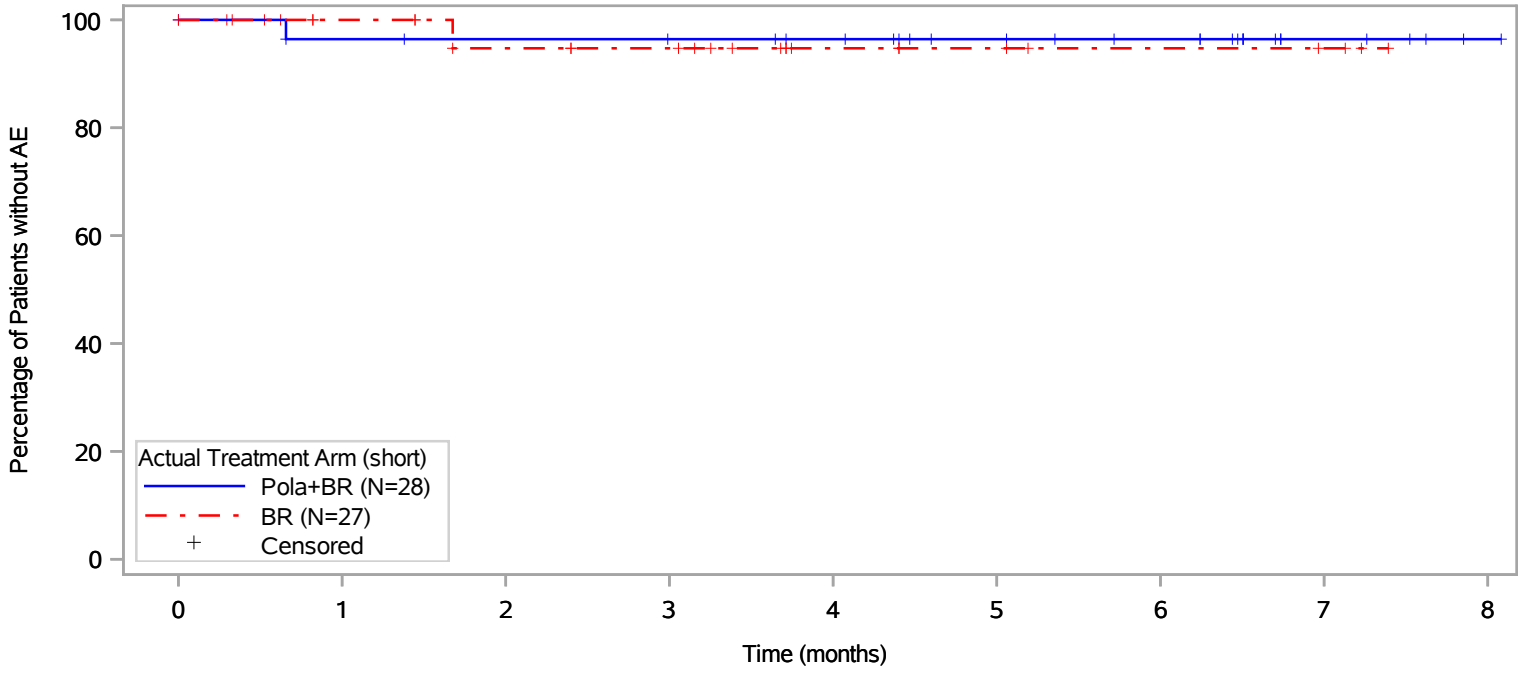
METABOLISM AND NUTRITION DISORDERS, HYPOPHOSPHATAEMIA



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

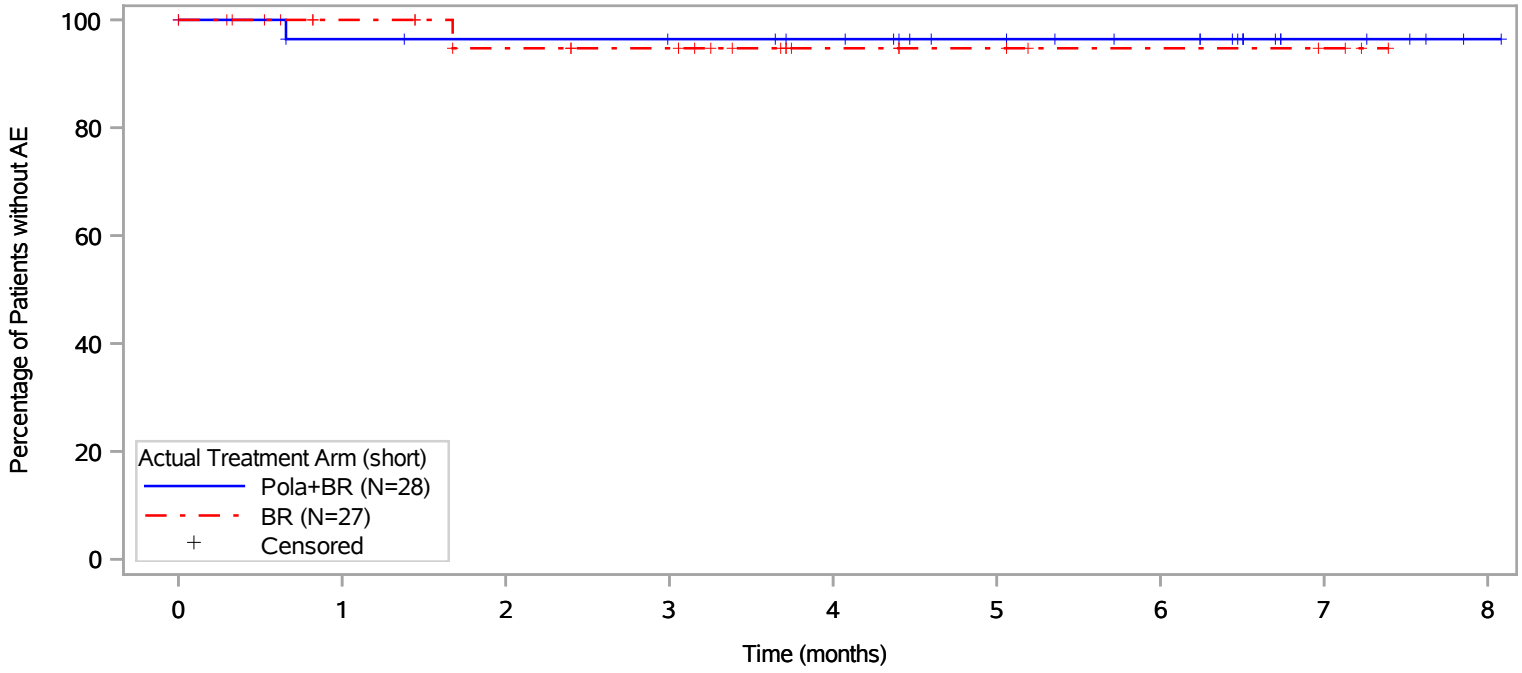
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	26	25	23	18	15	5	1
BR (N=27)	27	21	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN



Patients at risk									
Pola+BR (N=28)	28	27	26	25	23	18	15	5	1
BR (N=27)	27	21	18	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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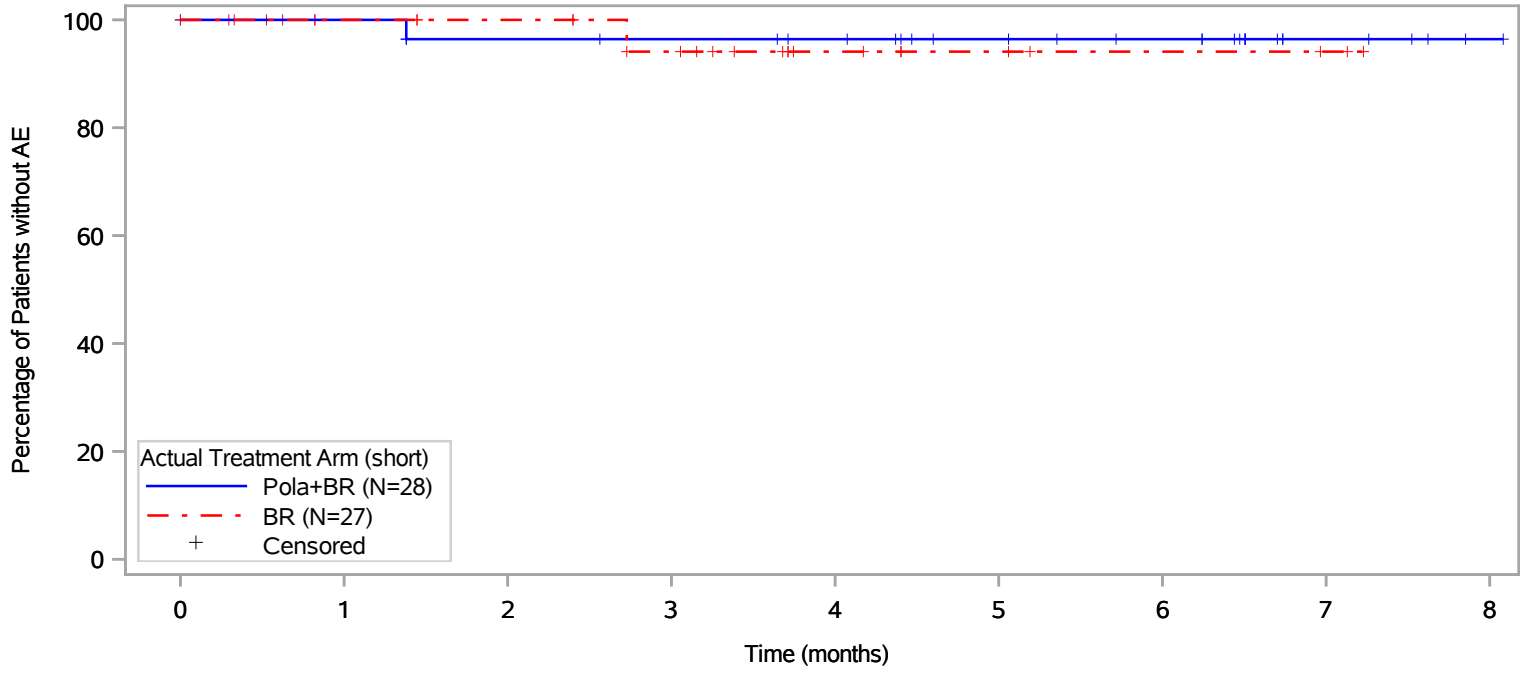
02DEC2022 3:20

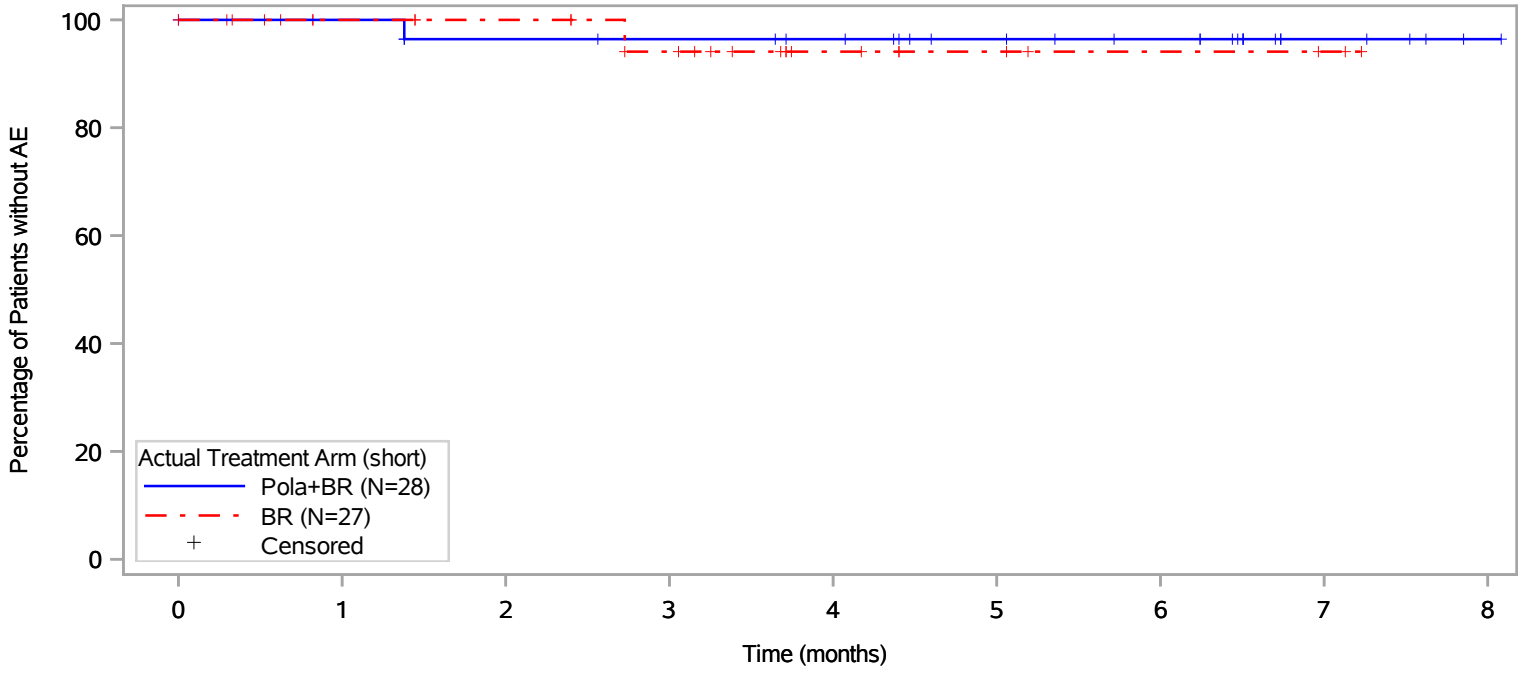
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, SYNCOPE

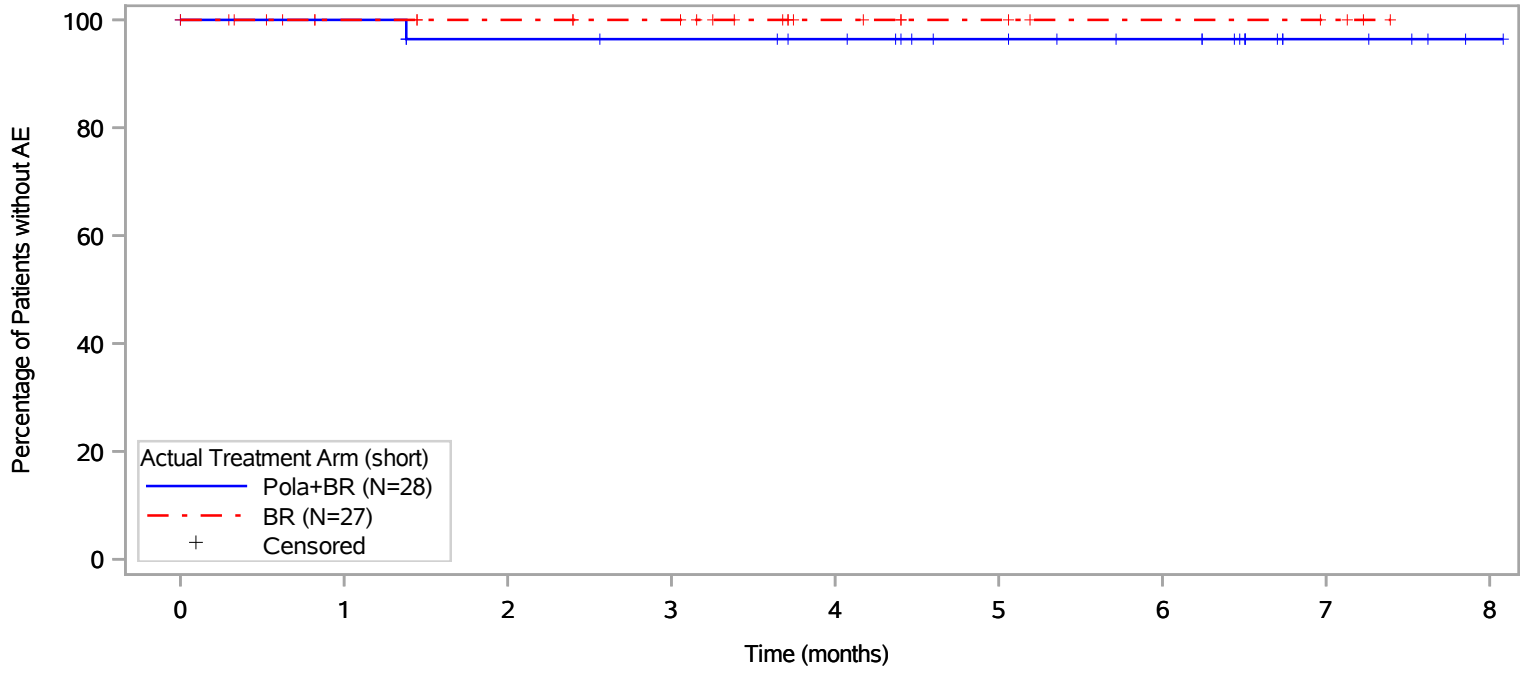


Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 3:20

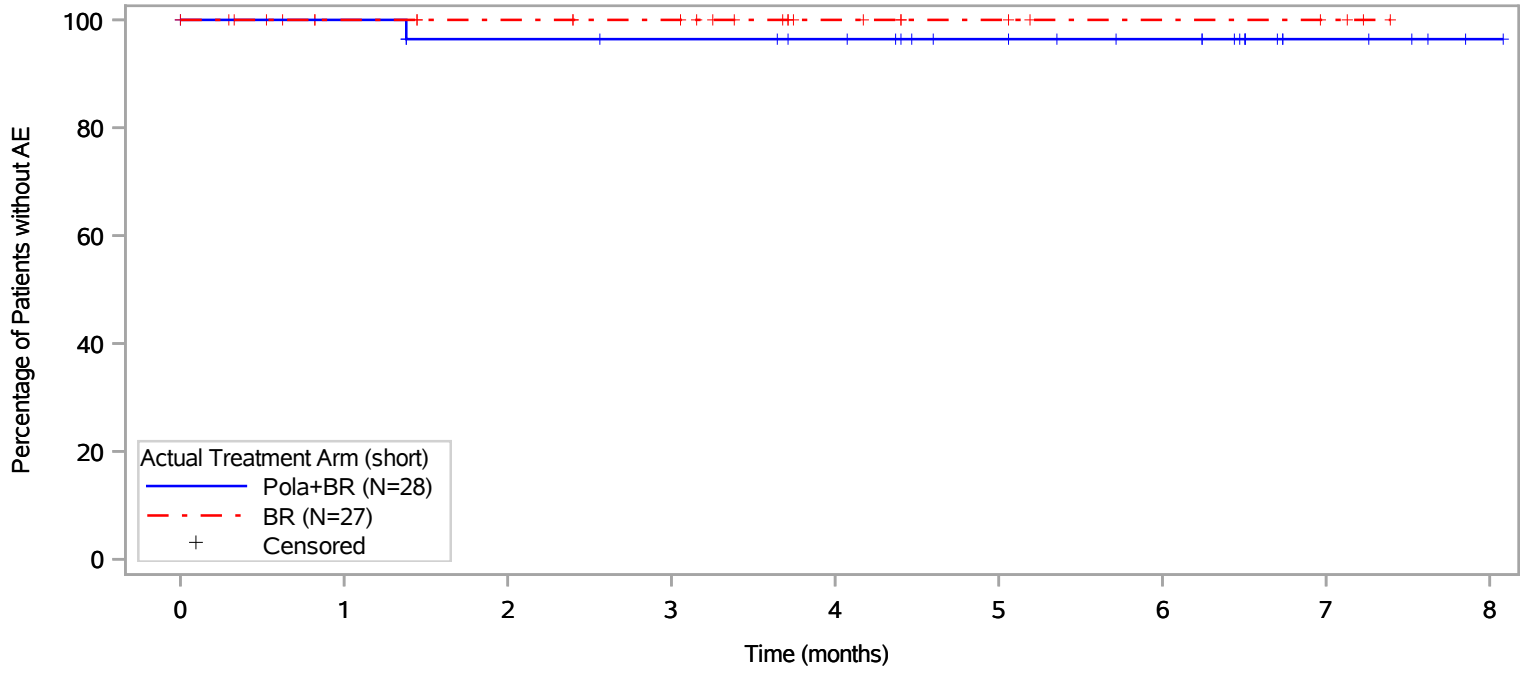
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

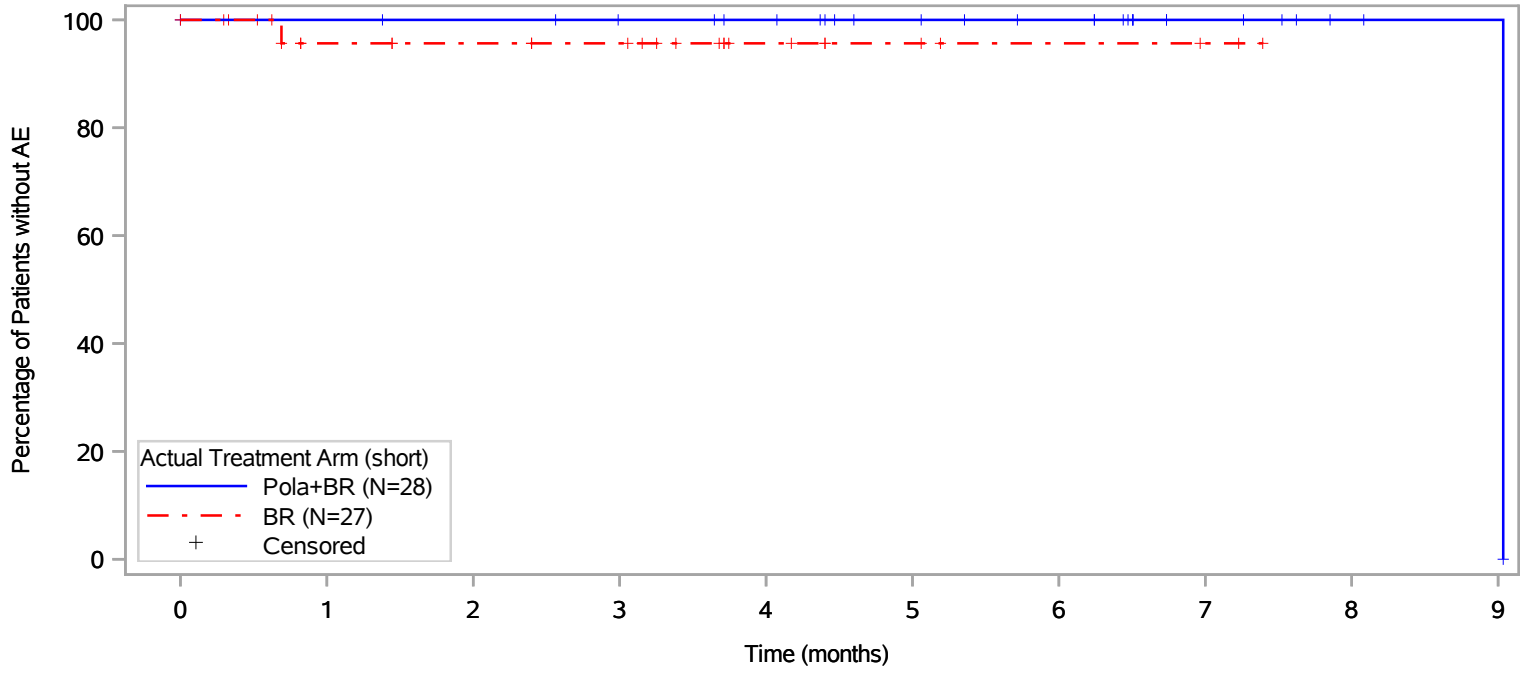
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, CONFUSIONAL STATE



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All

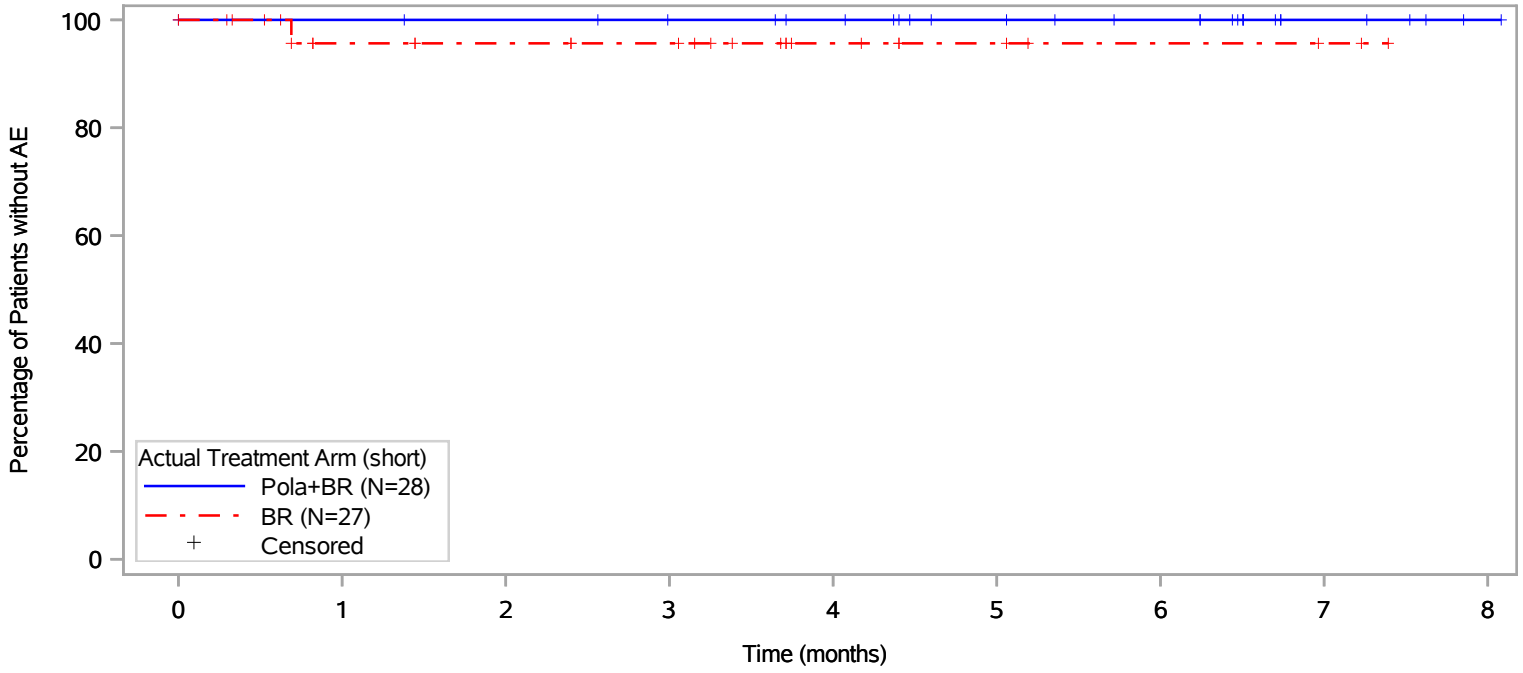


Patients at risk										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1
BR (N=27)	27	20	18	16	8	5	3	2	NE	NE
Patients censored										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY

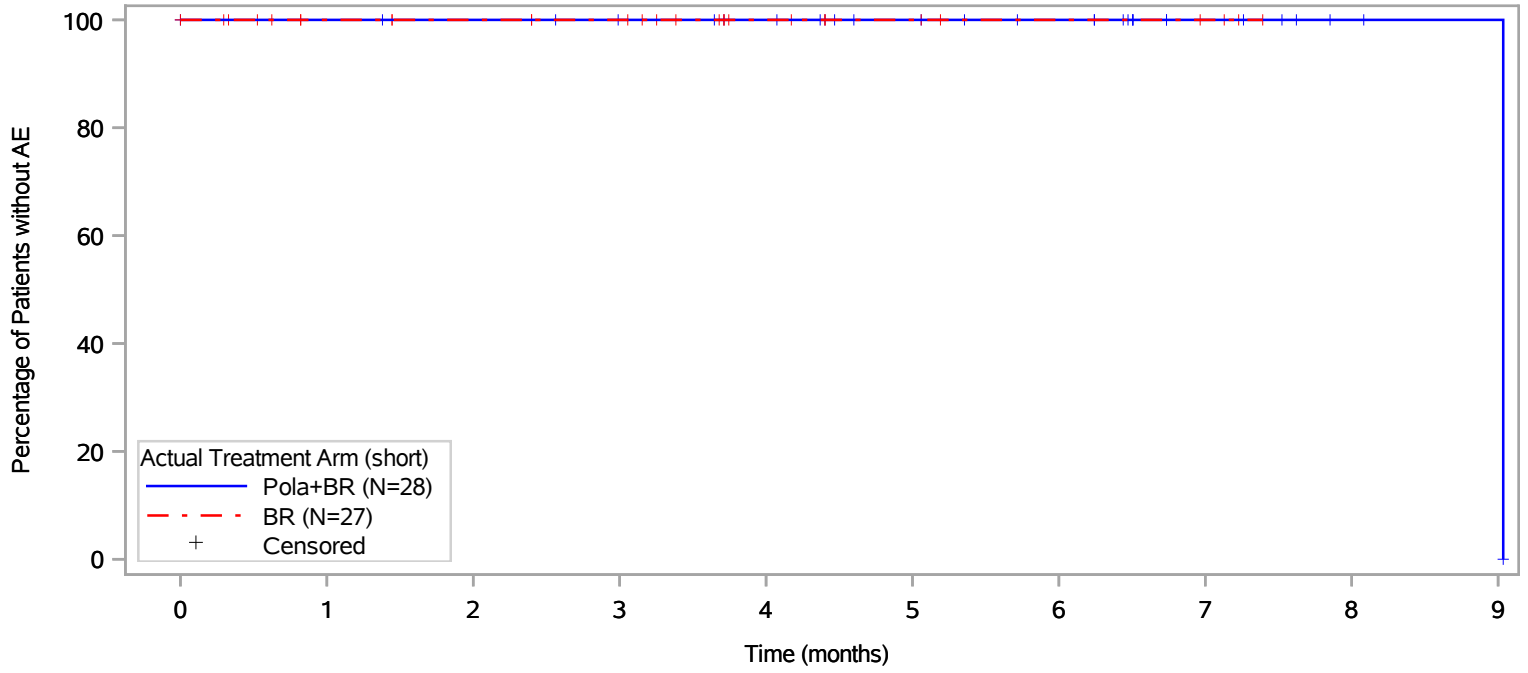


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS

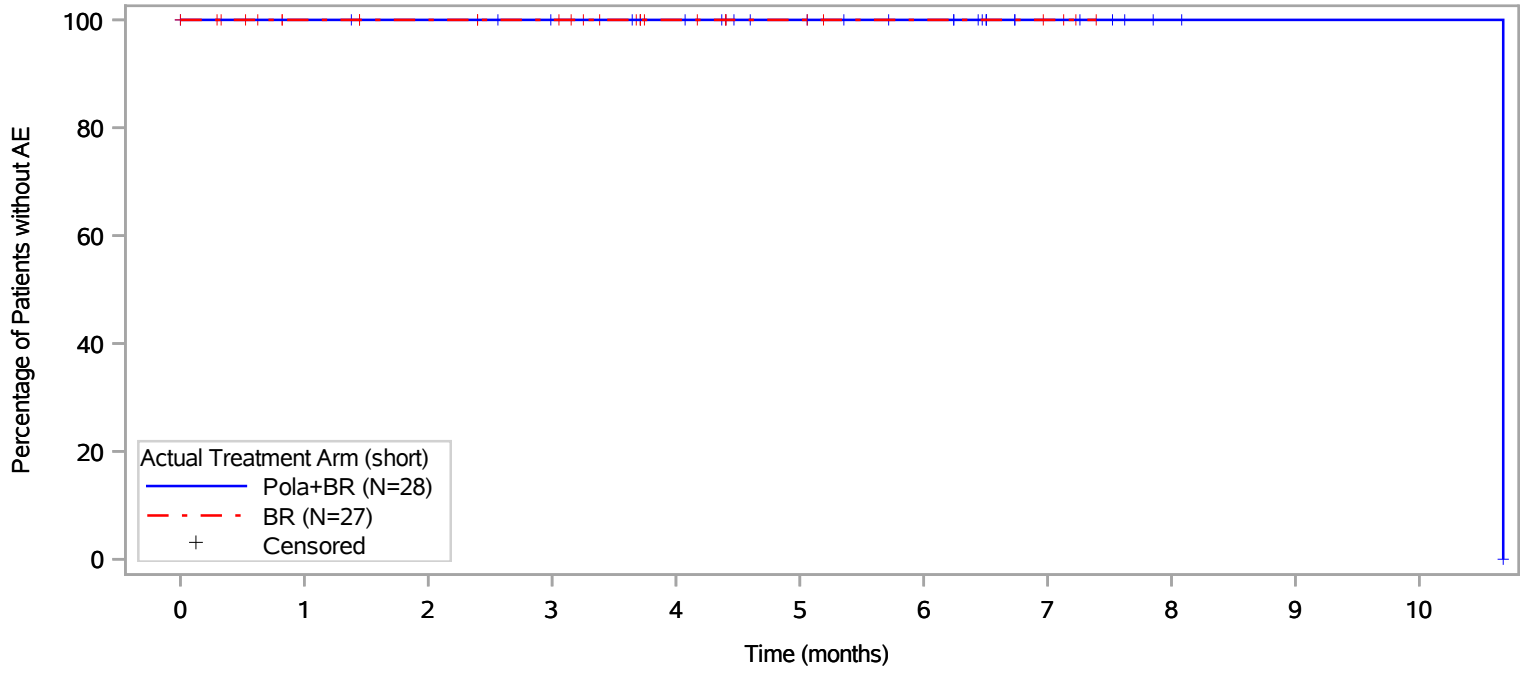


Patients at risk										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE
Patients censored										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE



Patients at risk											
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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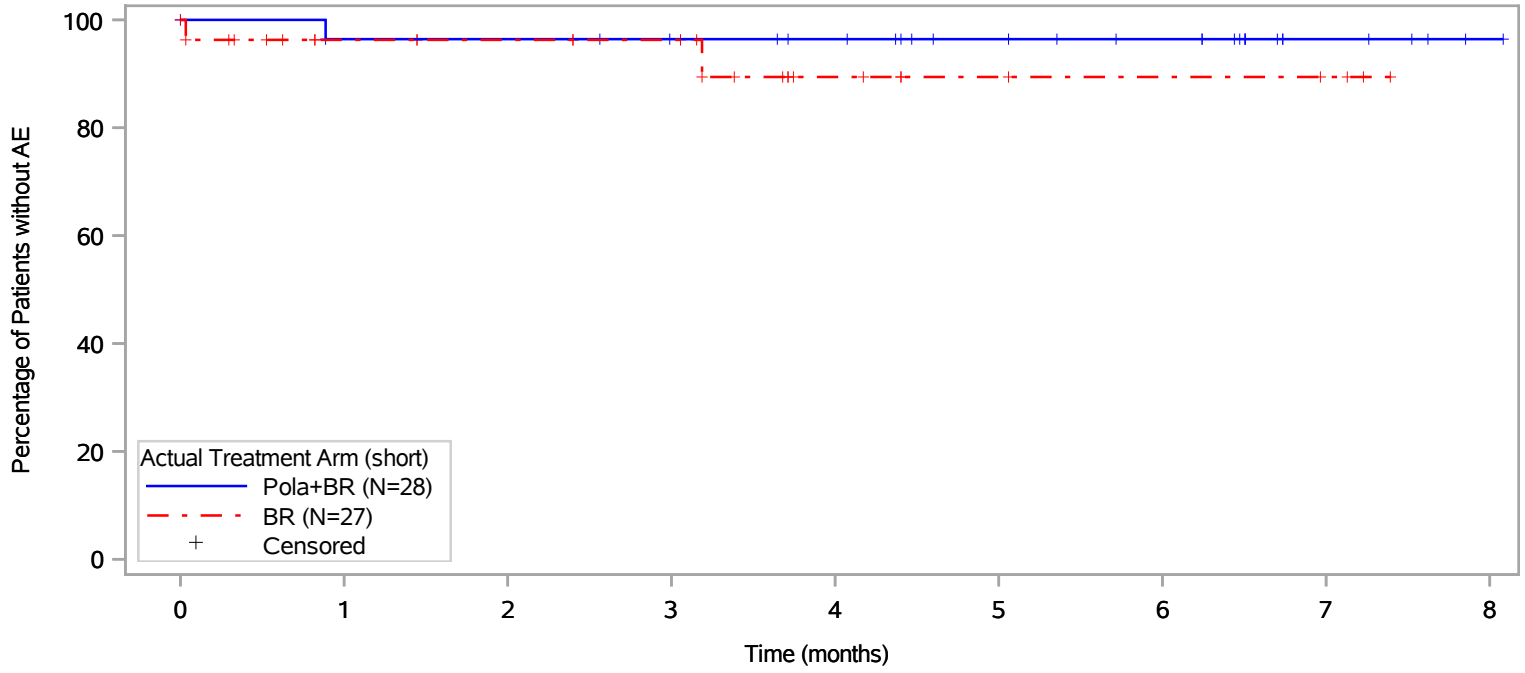
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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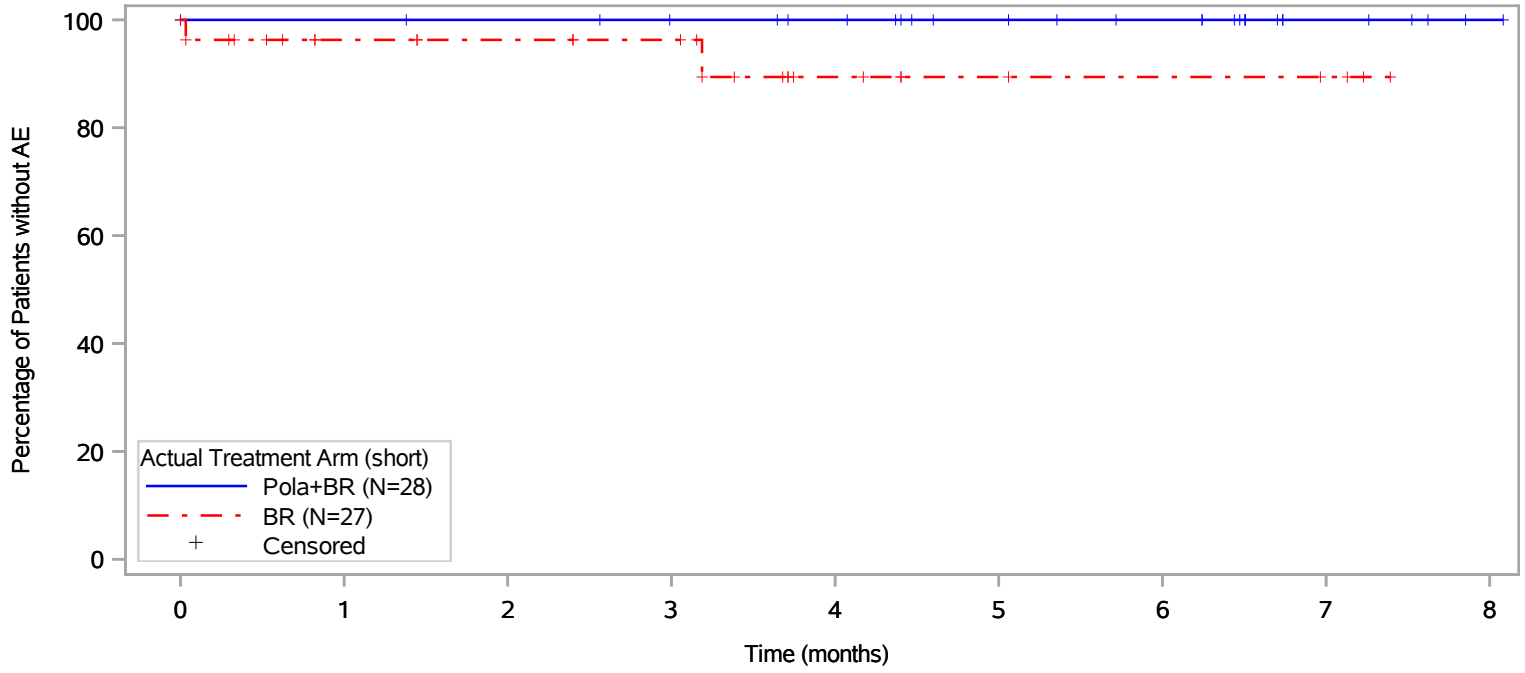
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

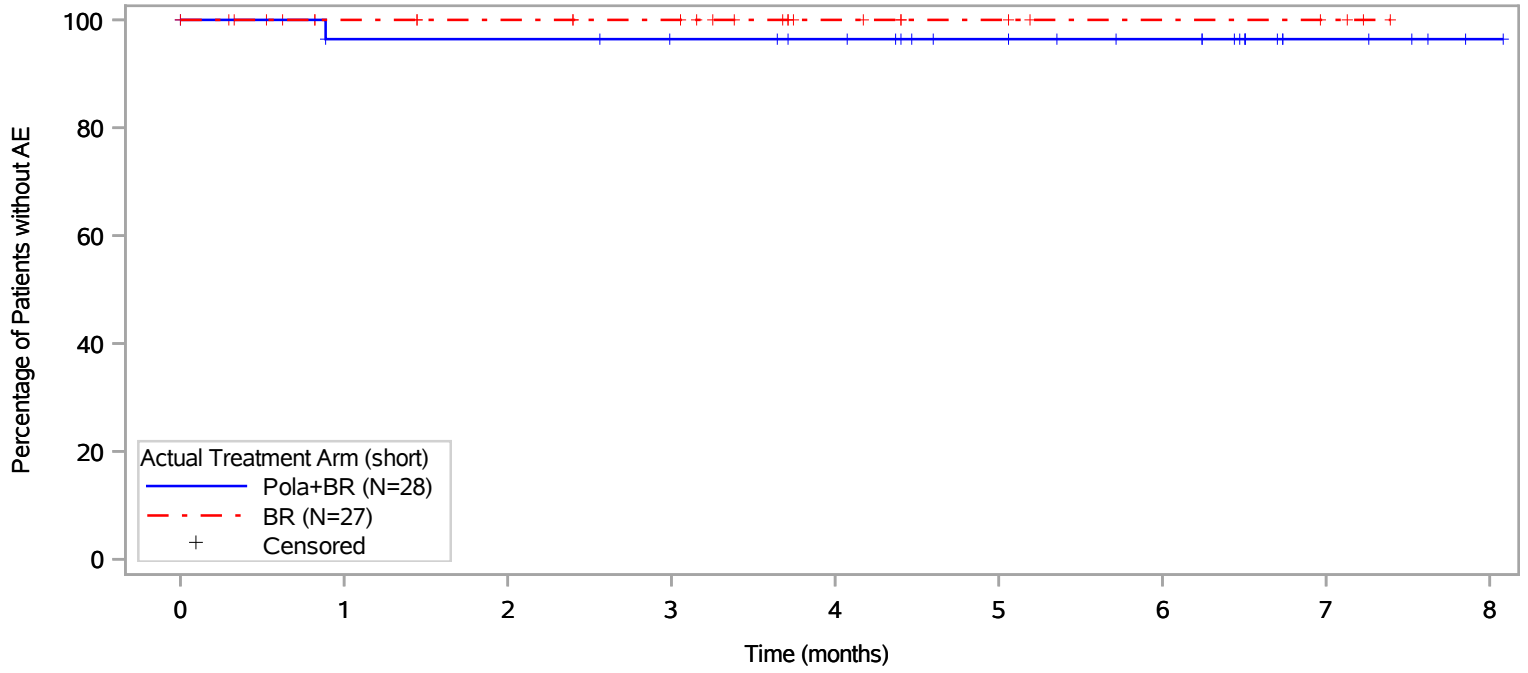
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

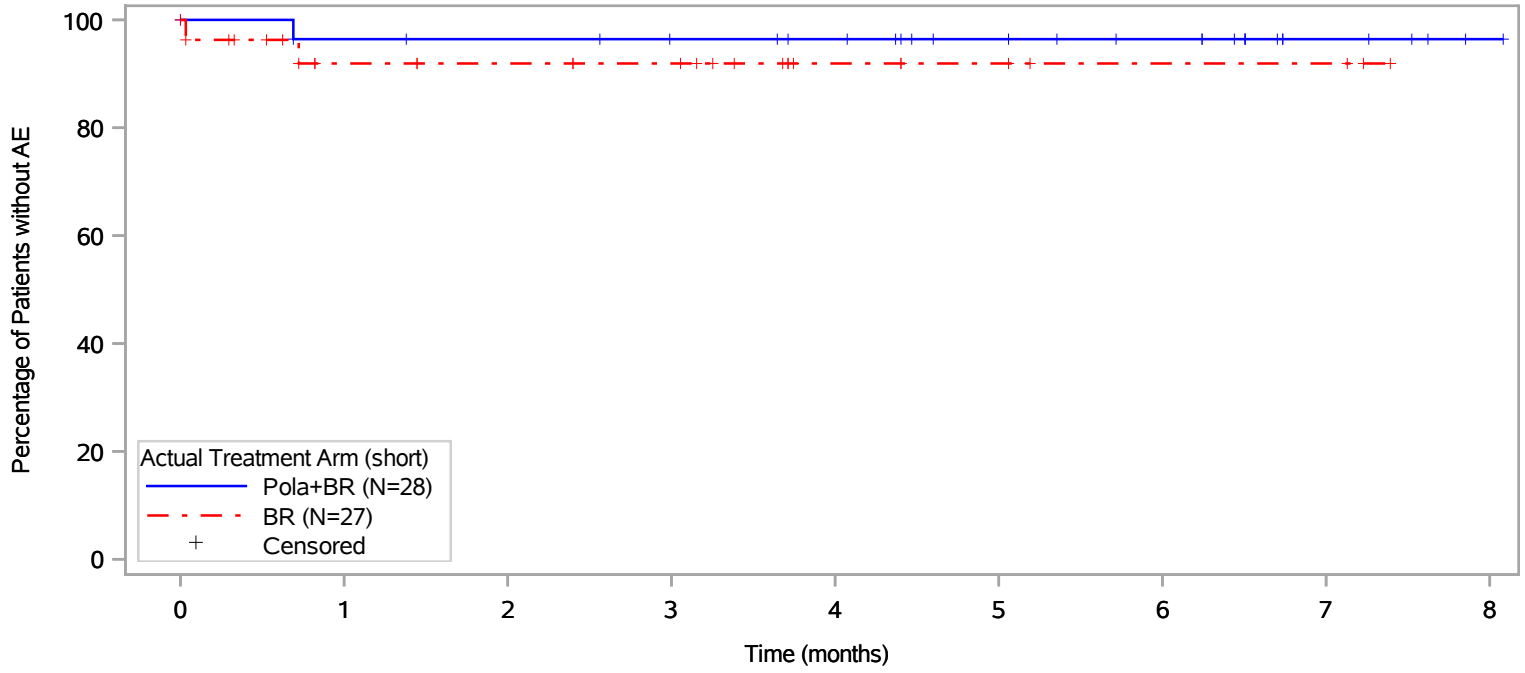
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PULMONARY EMBOLISM



Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All

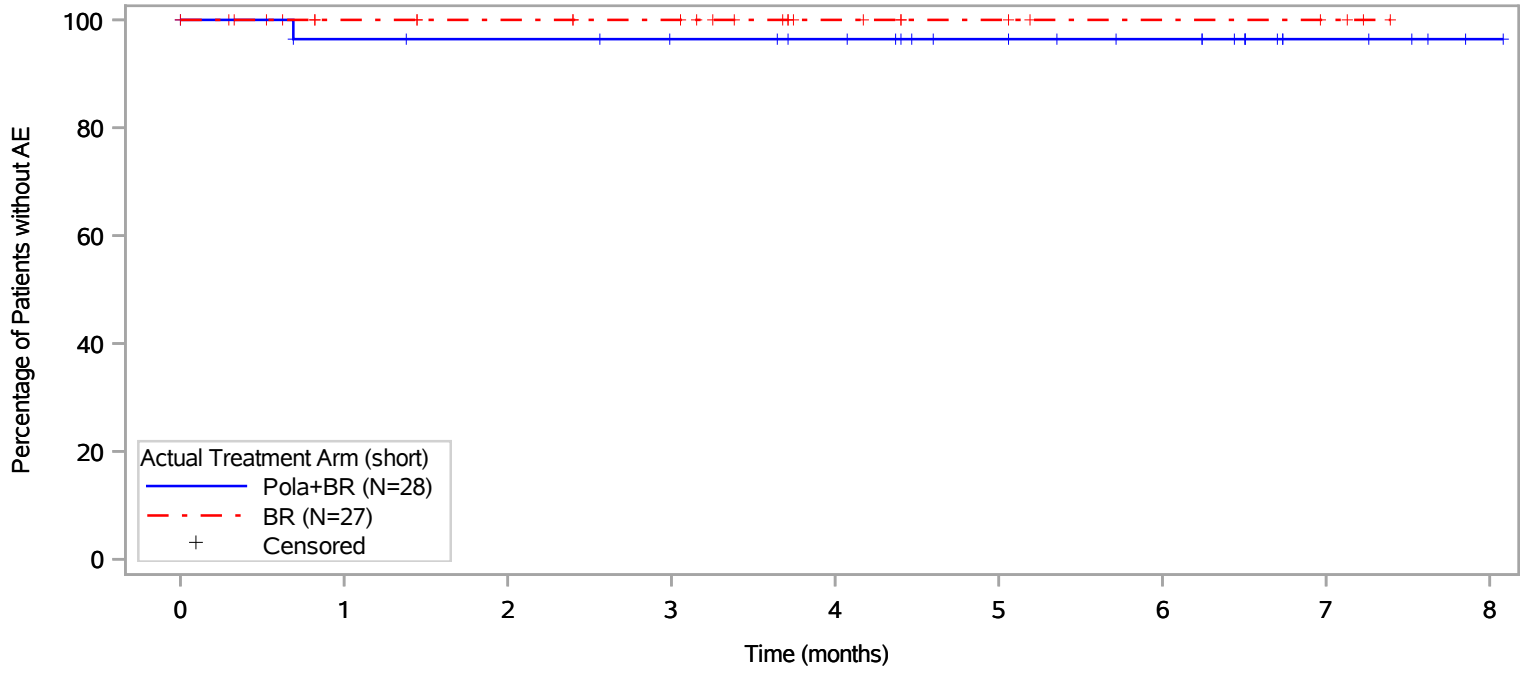


Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	19	17	15	7	5	3	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	20	22	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, DRUG ERUPTION

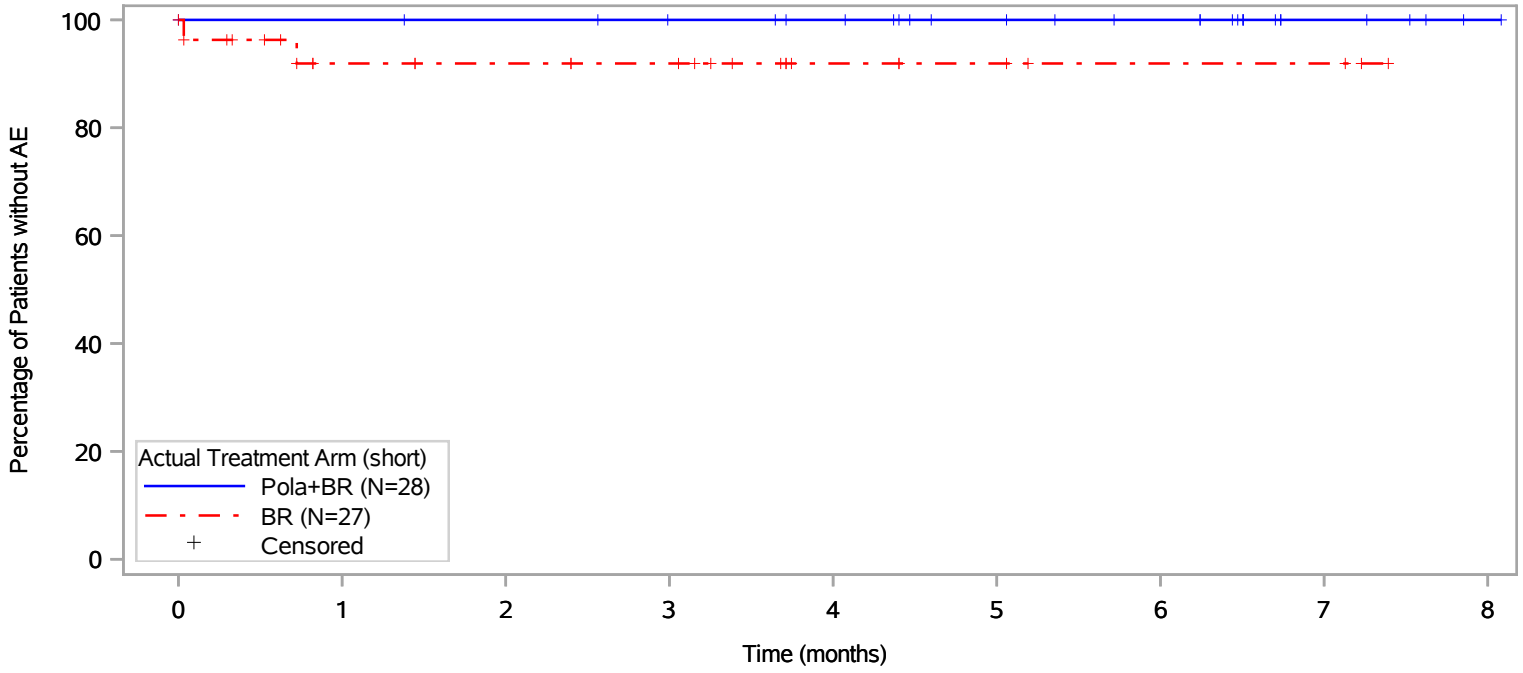


Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	19	17	15	7	5	3	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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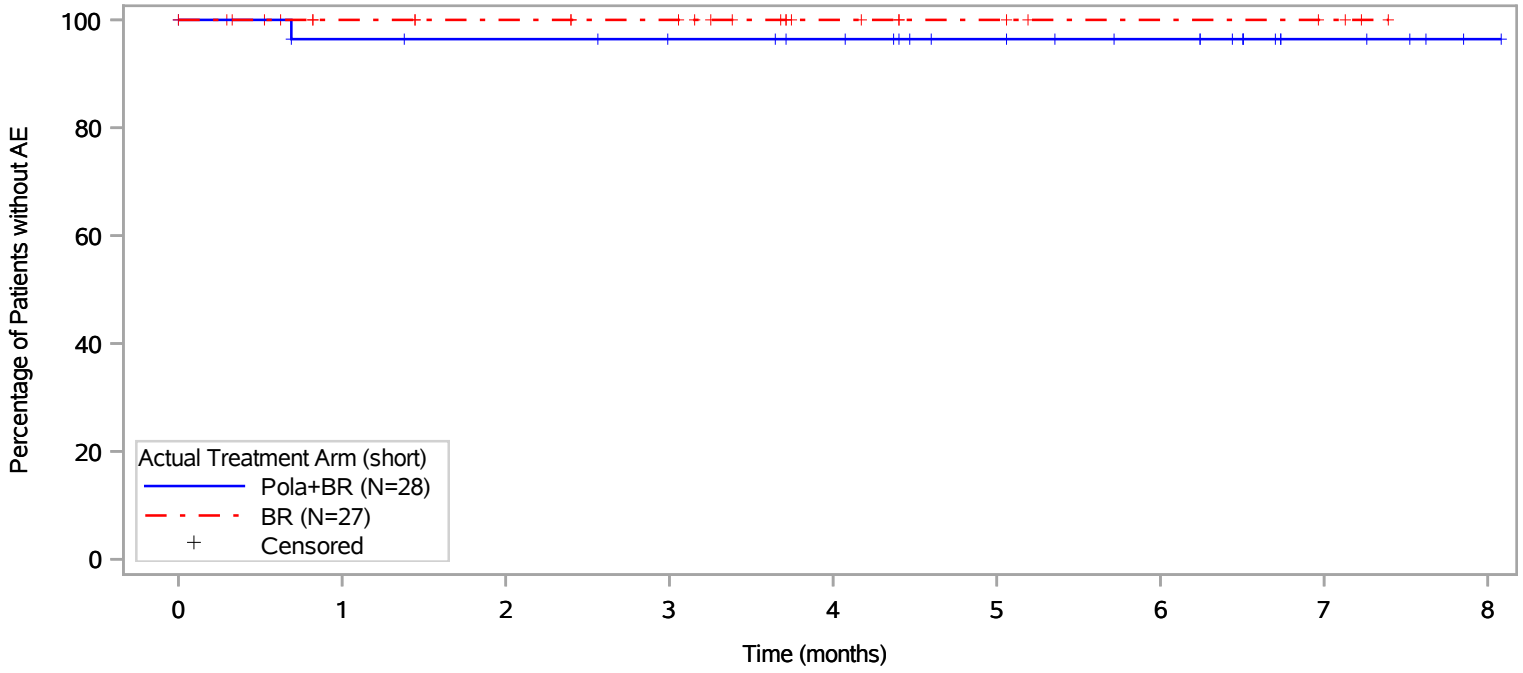
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

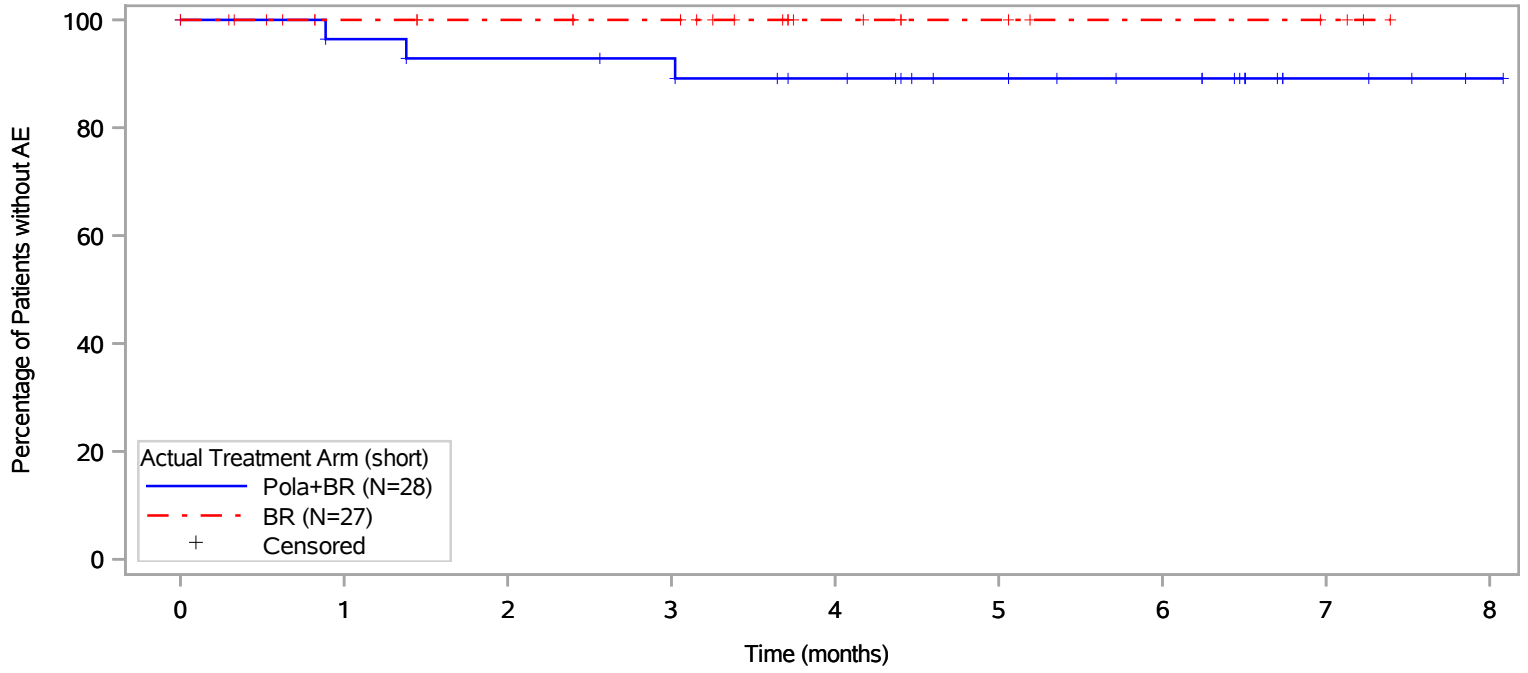
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, URTICARIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

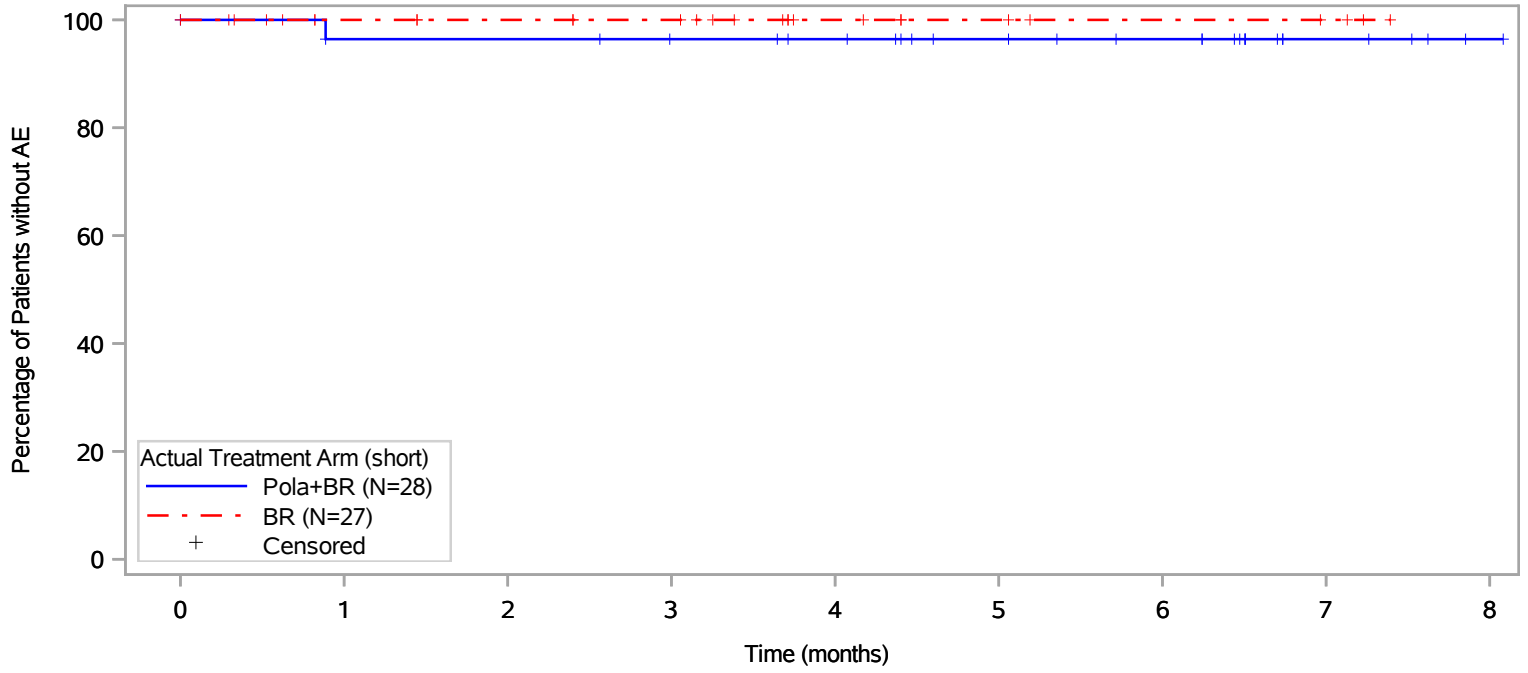
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	26	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	3	8	11	21	24
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DEEP VEIN THROMBOSIS

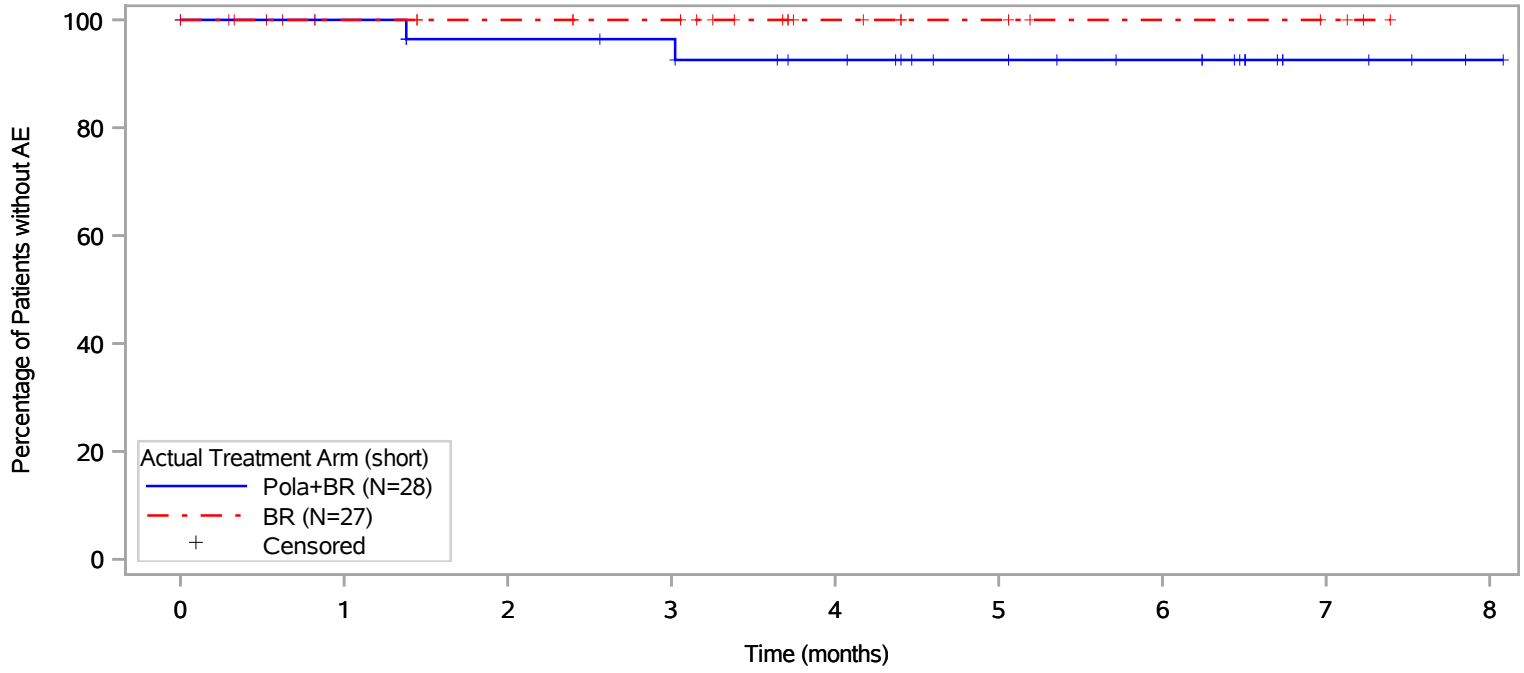


Patients at risk									
Pola+BR (N=28)	28	27	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR3AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 3:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION



Patients at risk									
Pola+BR (N=28)	28	28	26	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			28	100.0	10	35.7	18	64.3	27	100.0	7	25.9	20	74.1	0.5667	1.34	0.49	3.71		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.2356	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.3835	0.36	0.03	3.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.1692	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		28	100.0	7	25.0	21	75.0	27	100.0	4	14.8	23	85.2	0.6855	1.29	0.38	4.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		28	100.0	5	17.9	23	82.1	27	100.0	4	14.8	23	85.2	0.4517	0.59	0.14	2.39		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			28	100.0	3	10.7	25	89.3	27	100.0	1	3.7	26	96.3	0.4740	2.25	0.23	22.13		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3447	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			28	100.0	3	10.7	25	89.3	27	100.0	1	3.7	26	96.3	0.9812	1.03	0.09	11.88		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.6056	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	TRANSAMINASES INCREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.7824	0.68	0.04	10.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2158	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2158	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR4AE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 0:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	13	46.4	5	38.5	8	61.5	13	48.1	5	38.5	8	61.5	0.9143	0.93	0.27	3.23		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	15	53.6	5	33.3	10	66.7	14	51.9	2	14.3	12	85.7	0.2000	3.72	0.43	31.95		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.4387	0.40	0.04	4.42		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	13	46.4	4	30.8	9	69.2	13	48.1	4	30.8	9	69.2	0.7764	0.82	0.20	3.28		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	0	-	14	100.0	0.1385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	3	23.1	10	76.9	0.1689	0.23	0.02	2.24		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	1	7.1	13	92.9	0.8303	1.30	0.12	14.34		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	15	53.6	3	20.0	12	80.0	14	51.9	1	7.1	13	92.9	0.5129	2.11	0.21	20.75		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	13	46.4	3	23.1	10	76.9	13	48.1	0	-	13	100.0	0.3411	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	TRANSAMINASES INCREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3576	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR4AE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 0:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	15	53.6	5	33.3	10	66.7	18	66.7	5	27.8	13	72.2	0.8825	1.10	0.30	4.14		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	13	46.4	5	38.5	8	61.5	9	33.3	2	22.2	7	77.8	0.4788	1.81	0.34	9.51		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1087	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3017	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	3	16.7	15	83.3	0.4583	0.51	0.09	3.09		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	13	46.4	5	38.5	8	61.5	9	33.3	1	11.1	8	88.9	0.2522	3.28	0.38	28.14		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	15	53.6	3	20.0	12	80.0	18	66.7	2	11.1	16	88.9	0.9728	1.03	0.17	6.23		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	2	22.2	7	77.8	0.2931	0.30	0.03	3.28		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	15	53.6	3	20.0	12	80.0	18	66.7	1	5.6	17	94.4	0.3723	2.72	0.28	26.63		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3017	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5186	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.8583	0.78	0.05	12.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	TRANSAMINASES INCREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.8583	0.78	0.05	12.43		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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01DEC2022 0:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	67.9	9	47.4	10	52.6	14	51.9	6	42.9	8	57.1	0.9372	0.96	0.34	2.72		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.3174	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	2	14.3	12	85.7	0.2930	0.30	0.03	3.28		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.2271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	4	28.6	10	71.4	0.8362	0.88	0.25	3.10		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	67.9	5	26.3	14	73.7	14	51.9	4	28.6	10	71.4	0.2804	0.47	0.12	1.90		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.8403	1.33	0.08	21.29		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.3229	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4081	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	0	-	14	100.0	0.4008	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.7389	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	TRANSAMINASES INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4344	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR4AE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 0:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	20	71.4	6	30.0	14	70.0	18	66.7	7	38.9	11	61.1	0.6062	0.74	0.23	2.34	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	8	28.6	4	50.0	4	50.0	9	33.3	0	-	9	100.0	0.0419	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.4795	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3496	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.3816	0.36	0.03	3.95	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LYMPHOPENIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3173	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	20	71.4	4	20.0	16	80.0	18	66.7	4	22.2	14	77.8	0.5618	0.67	0.17	2.66	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	8	28.6	3	37.5	5	62.5	9	33.3	0	-	9	100.0	0.1012	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	20	71.4	4	20.0	16	80.0	18	66.7	4	22.2	14	77.8	0.2446	0.42	0.09	1.90	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	20	71.4	3	15.0	17	85.0	18	66.7	0	-	18	100.0	0.1508	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5762	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.7714	0.66	0.04	10.64	Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.4142	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4142	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	TRANSAMINASES INCREASED	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.7714	0.66	0.04	10.64		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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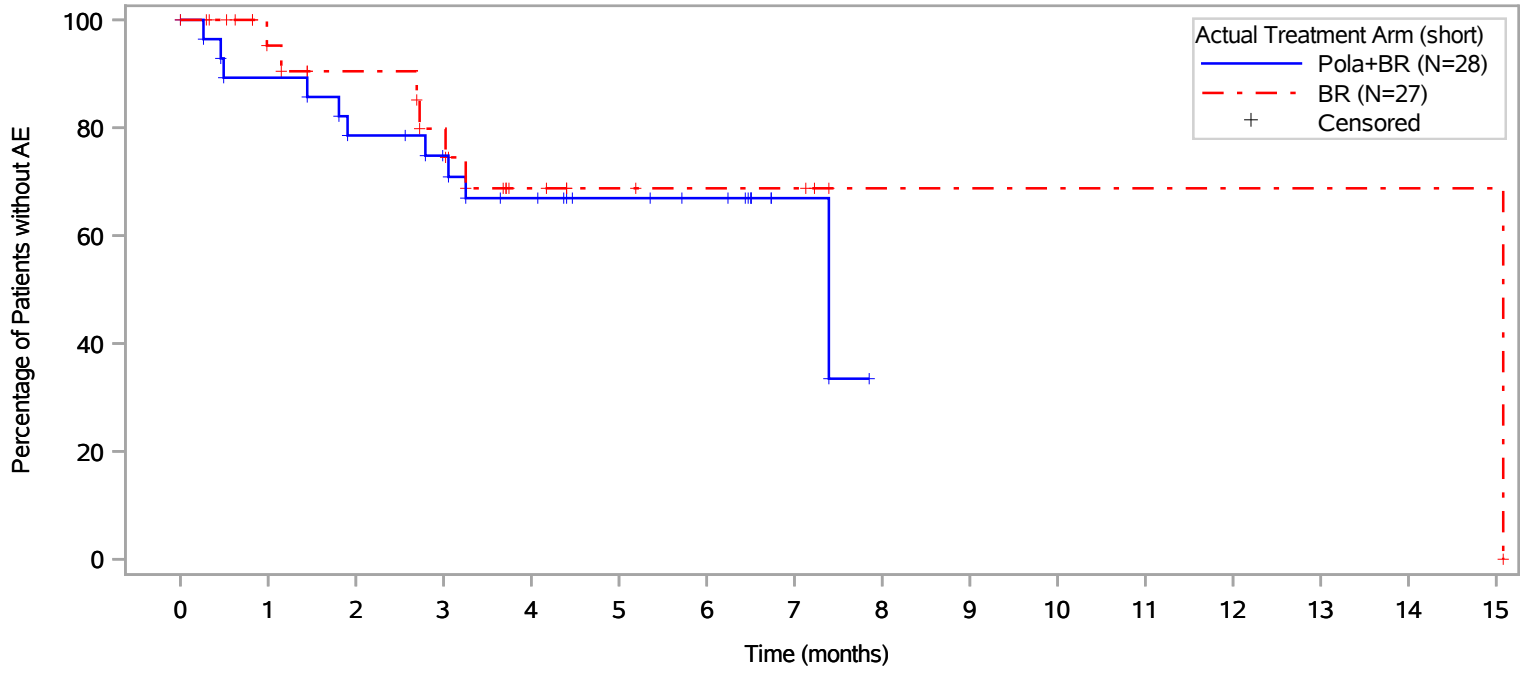
01DEC2022 0:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk																
Pola+BR (N=28)	28	25	22	19	16	12	10	2	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	20	17	15	8	5	4	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=28)	0	0	0	2	3	7	9	17	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	8	13	16	17	17	20	20	20	20	20	20	20	20

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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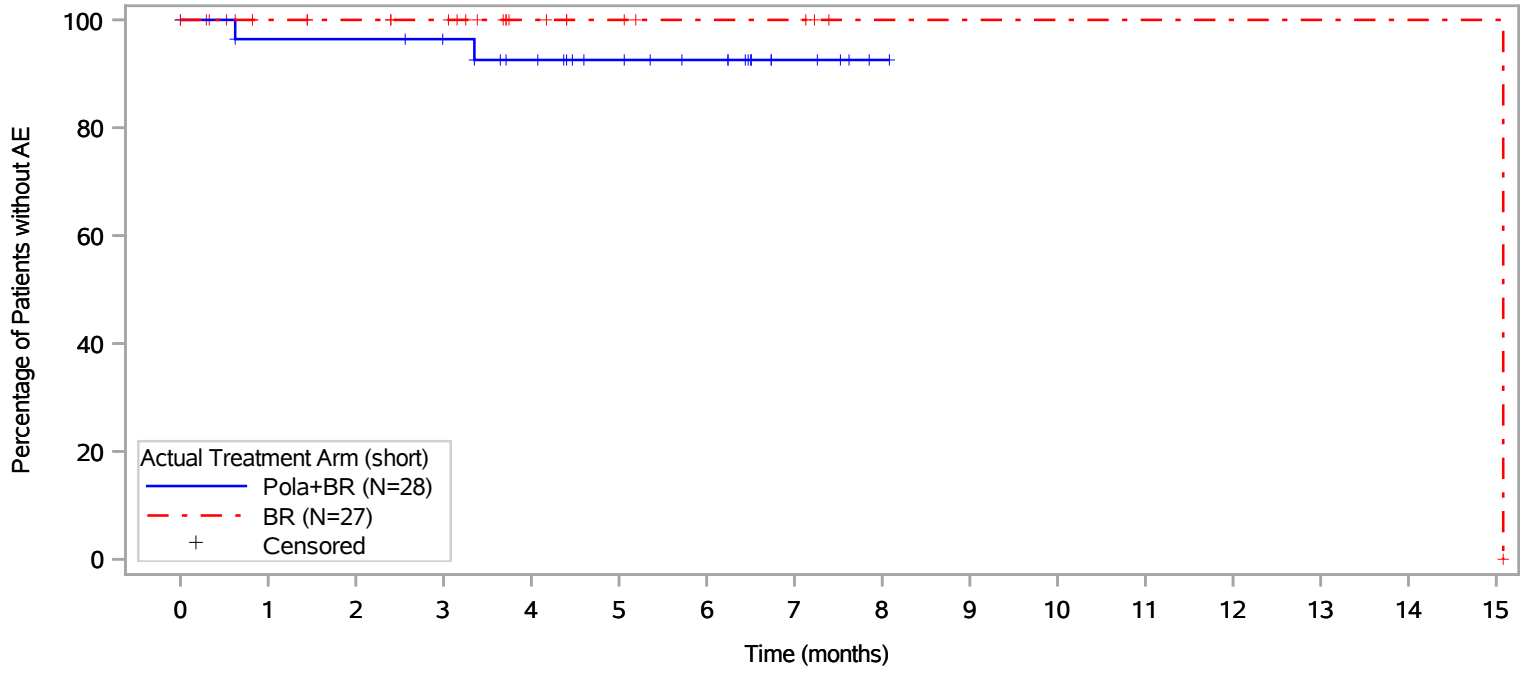
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA

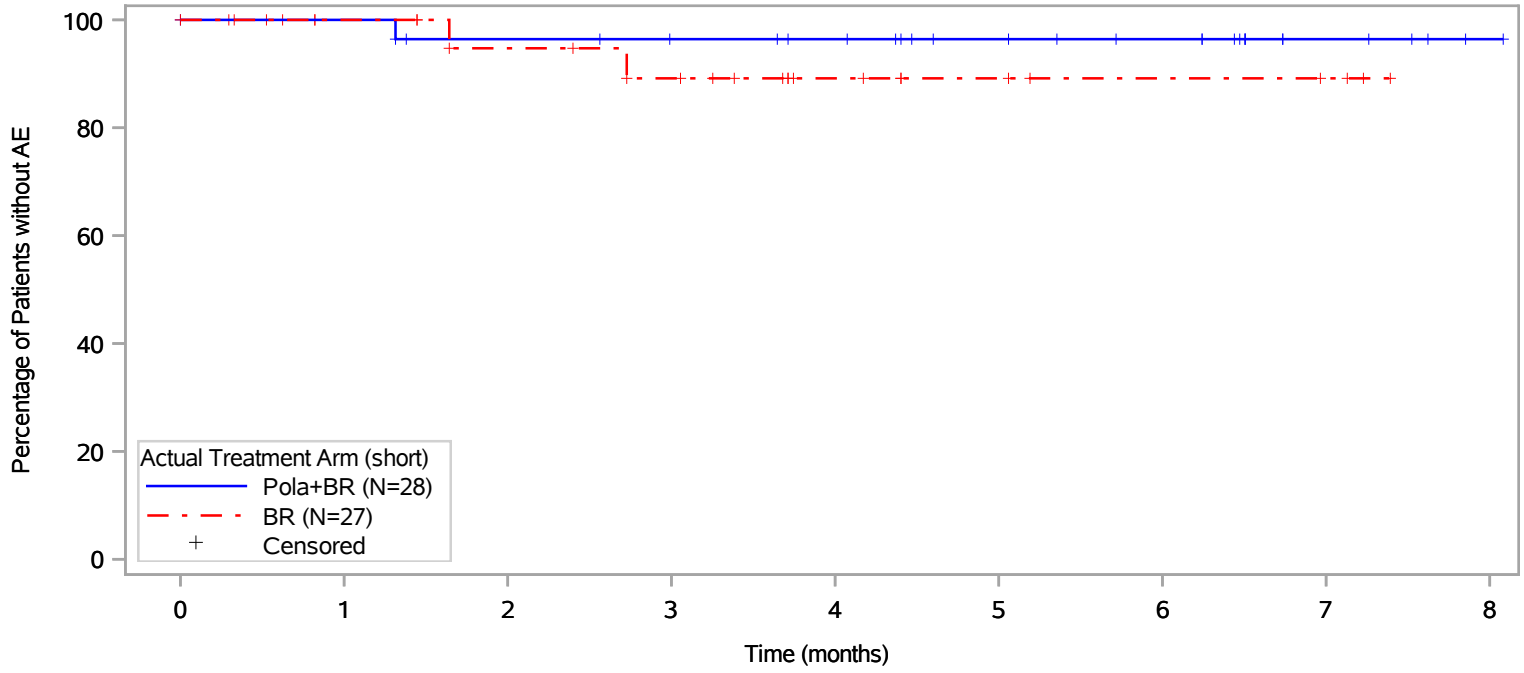


Patients at risk																
Pola+BR (N=28)	28	27	27	25	22	17	14	5	1	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=28)	0	0	0	2	4	9	12	21	25	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	23	26	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA

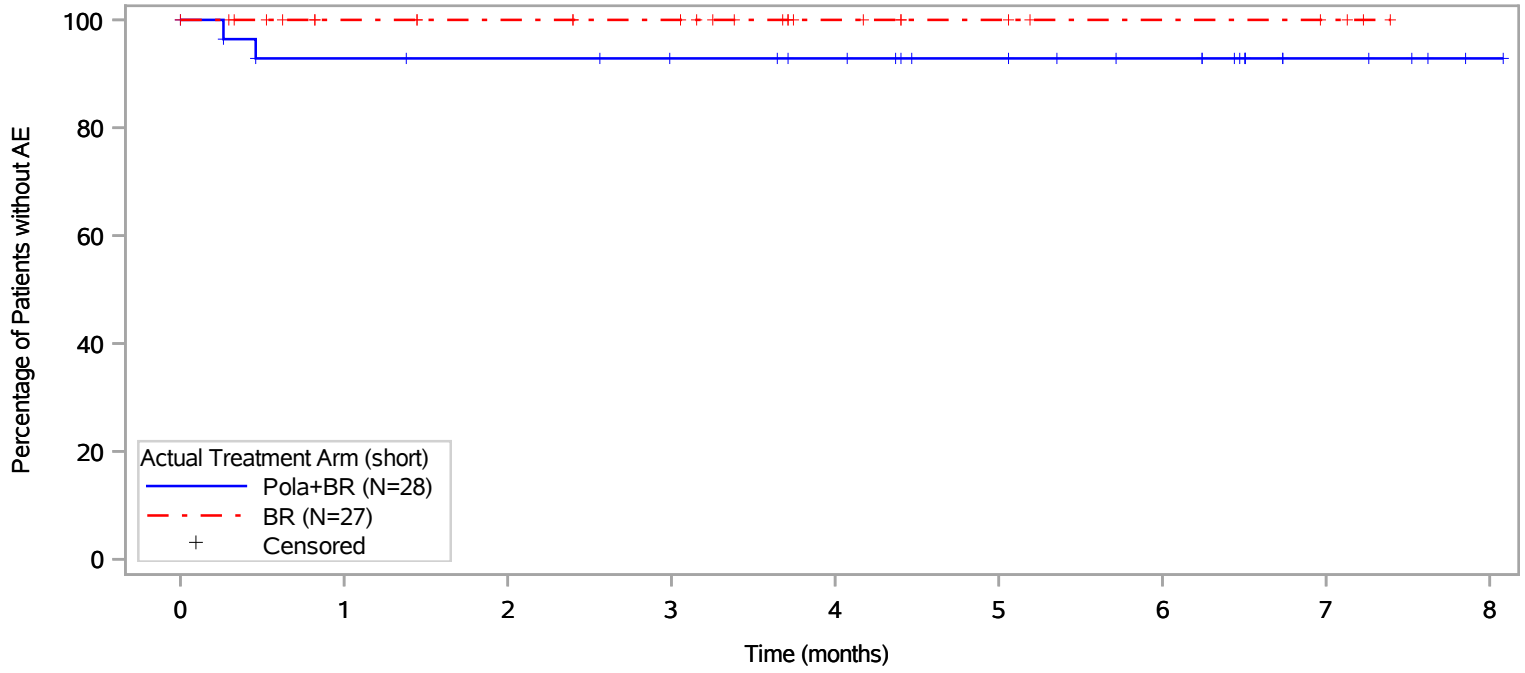


Patients at risk									
Pola+BR (N=28)	28	28	26	24	22	17	14	5	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	9	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LYMPHOPENIA

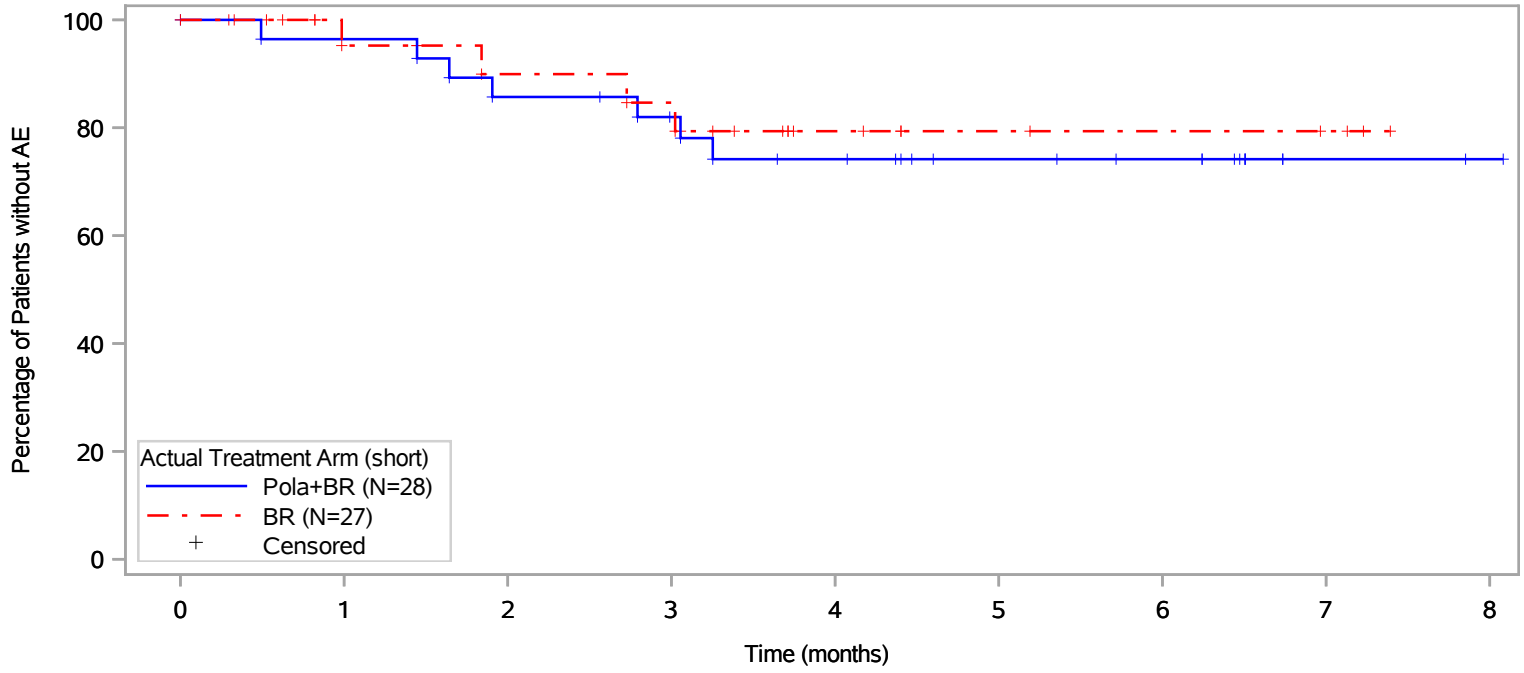


Patients at risk									
Pola+BR (N=28)	28	26	25	23	21	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA

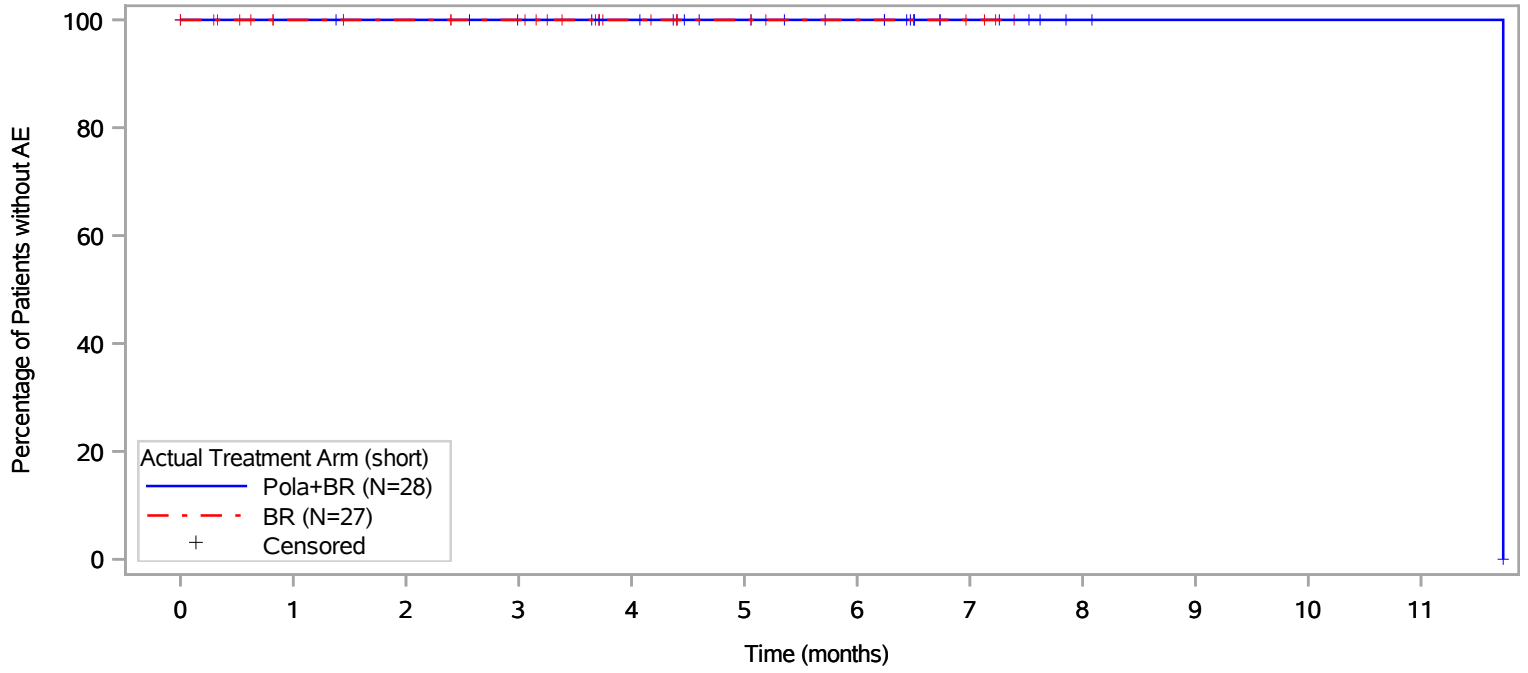


Patients at risk									
Pola+BR (N=28)	28	27	24	21	18	13	11	2	1
BR (N=27)	27	20	17	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	3	8	10	19	20
BR (N=27)	0	6	8	8	15	18	19	20	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA

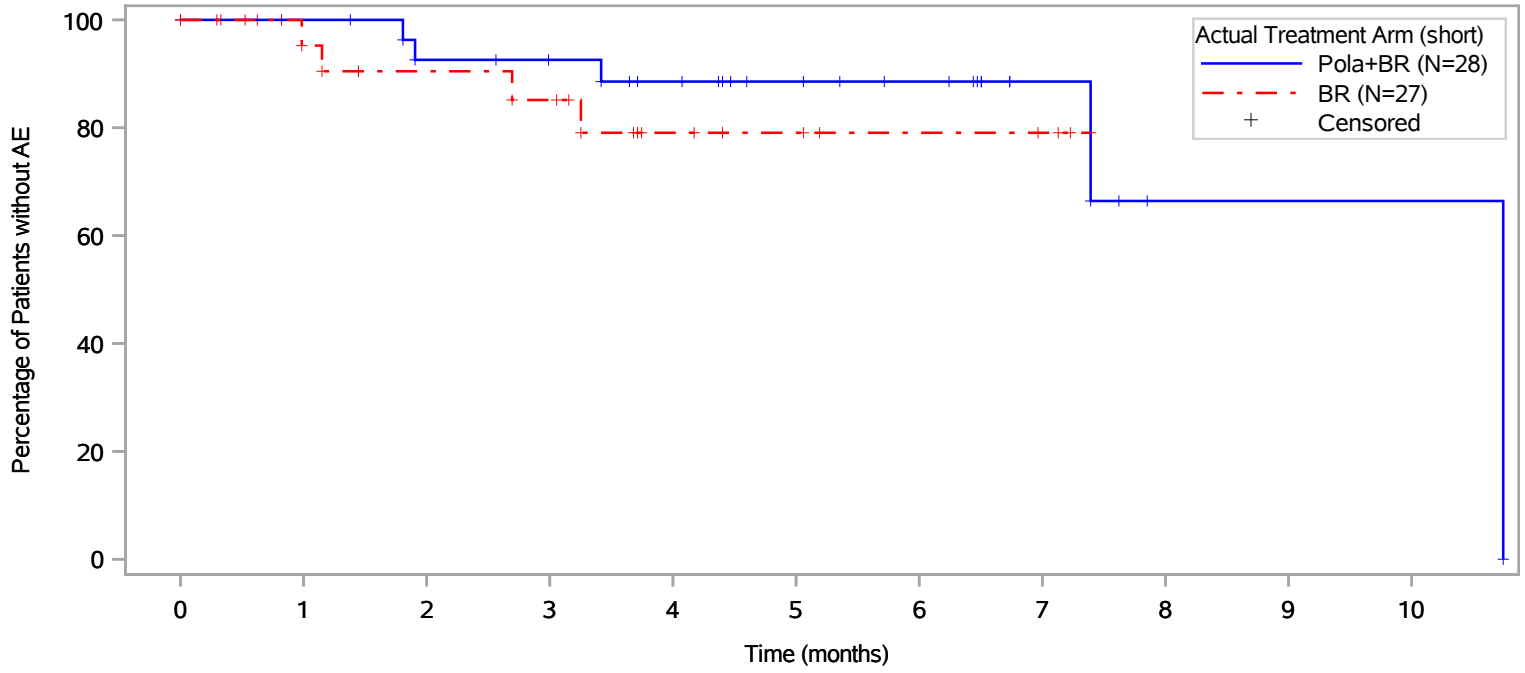


Patients at risk												
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

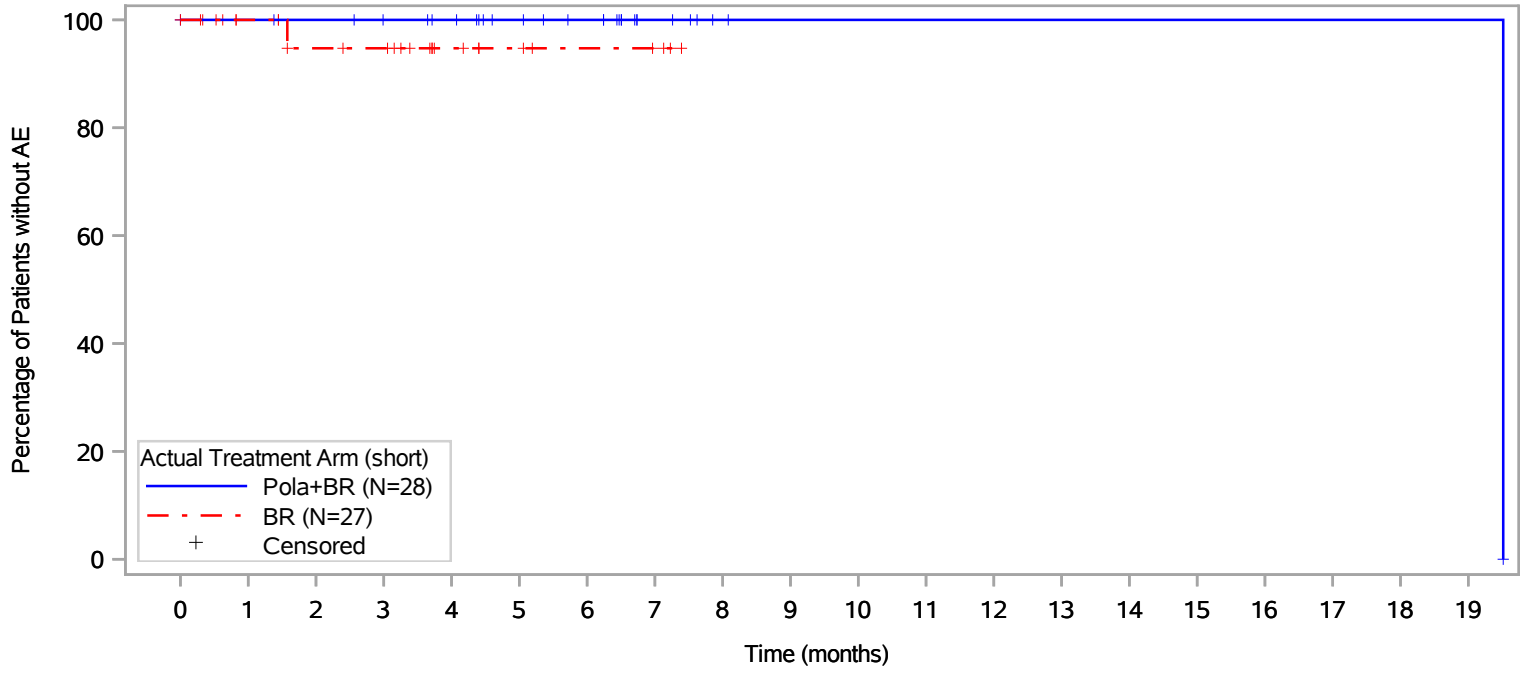
BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk											
Pola+BR (N=28)	28	28	25	23	20	15	12	4	1	1	1
BR (N=27)	27	20	17	16	9	6	4	3	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	0	1	3	5	10	13	21	23	23	23
BR (N=27)	0	6	8	8	14	17	19	20	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

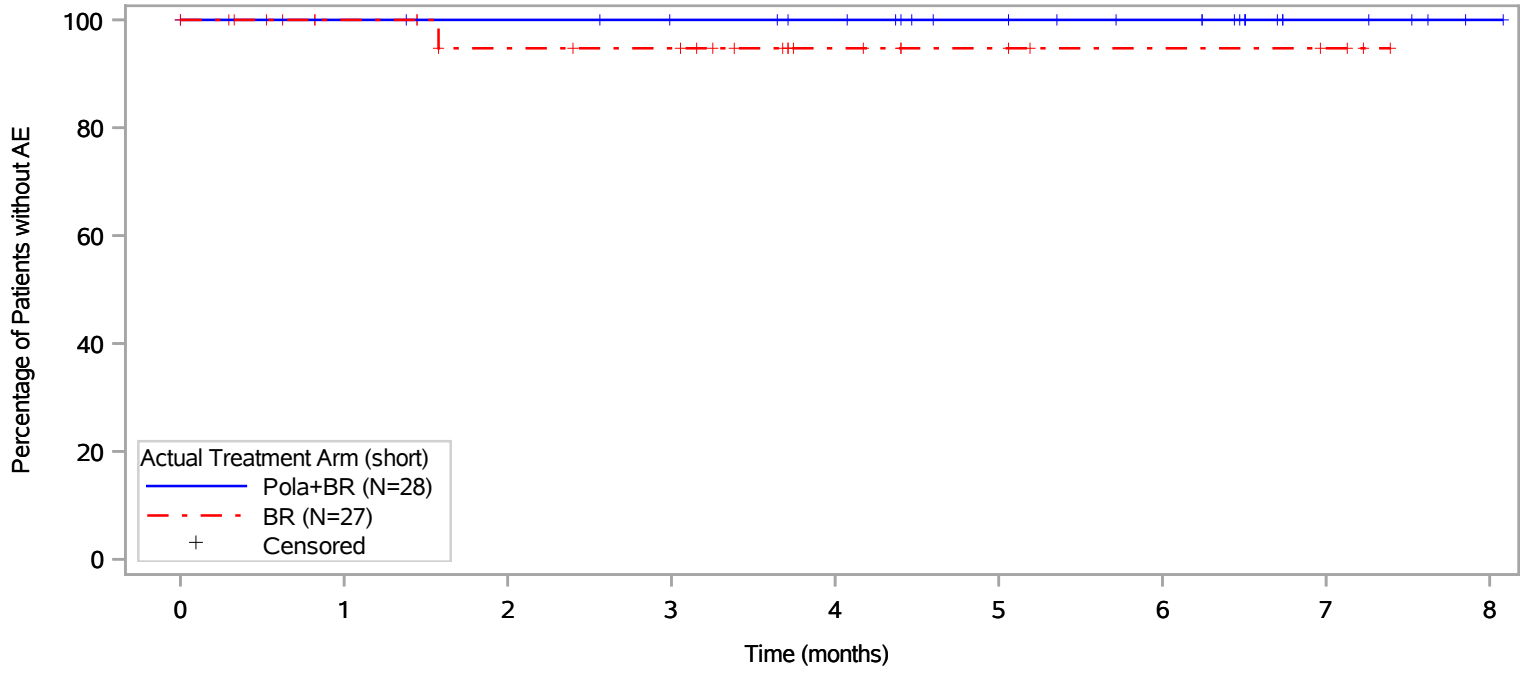
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk																				
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	18	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	9	17	20	22	23	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION

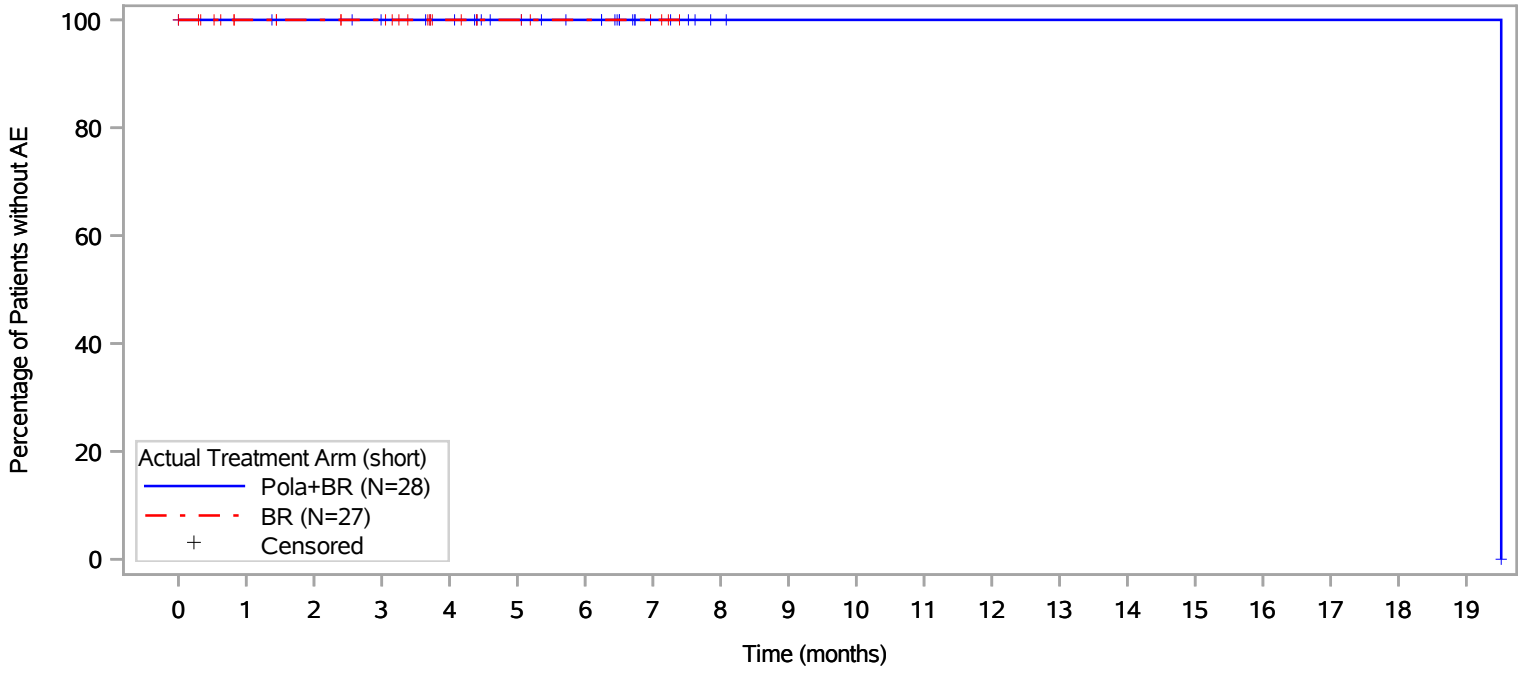


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

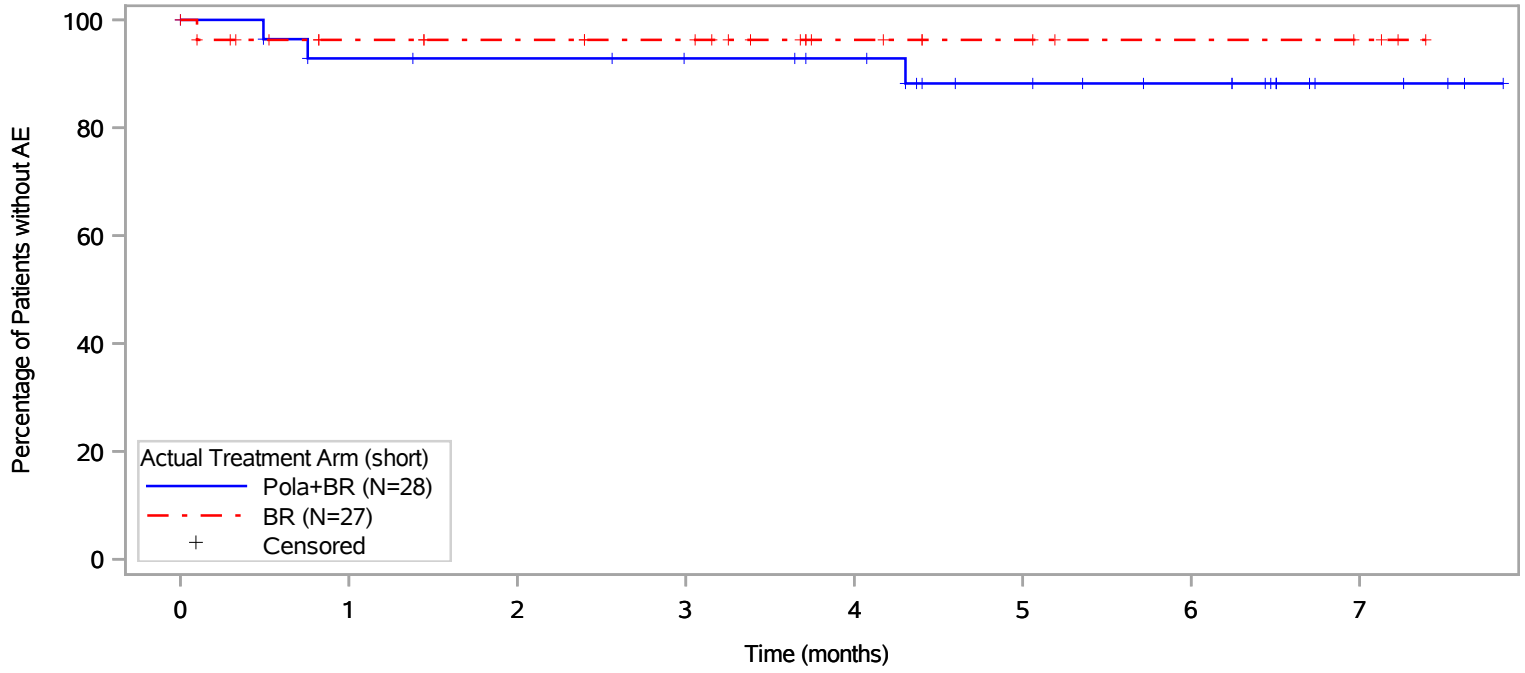
GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk																				
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

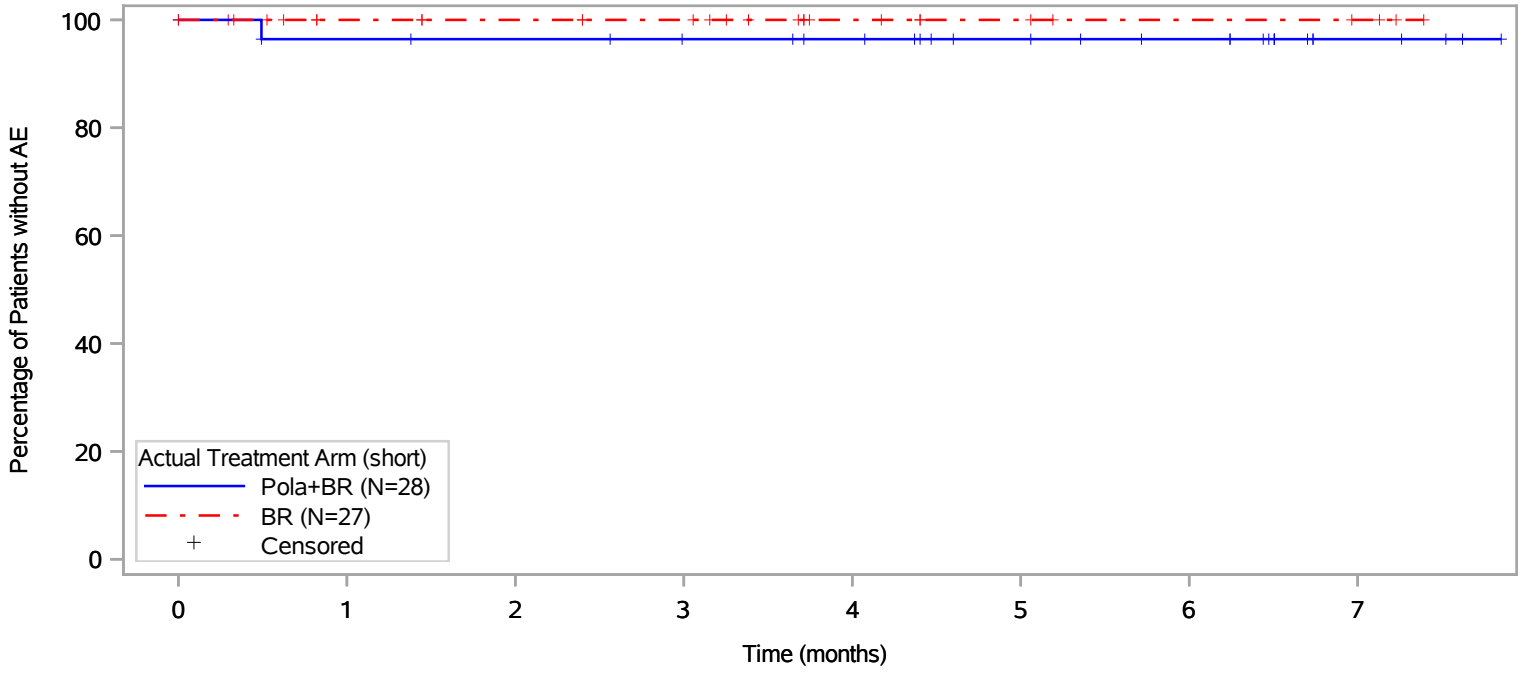
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk								
Pola+BR (N=28)	28	26	25	23	21	16	13	4
BR (N=27)	27	21	19	17	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	9	12	21
BR (N=27)	0	5	7	9	17	20	22	23

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

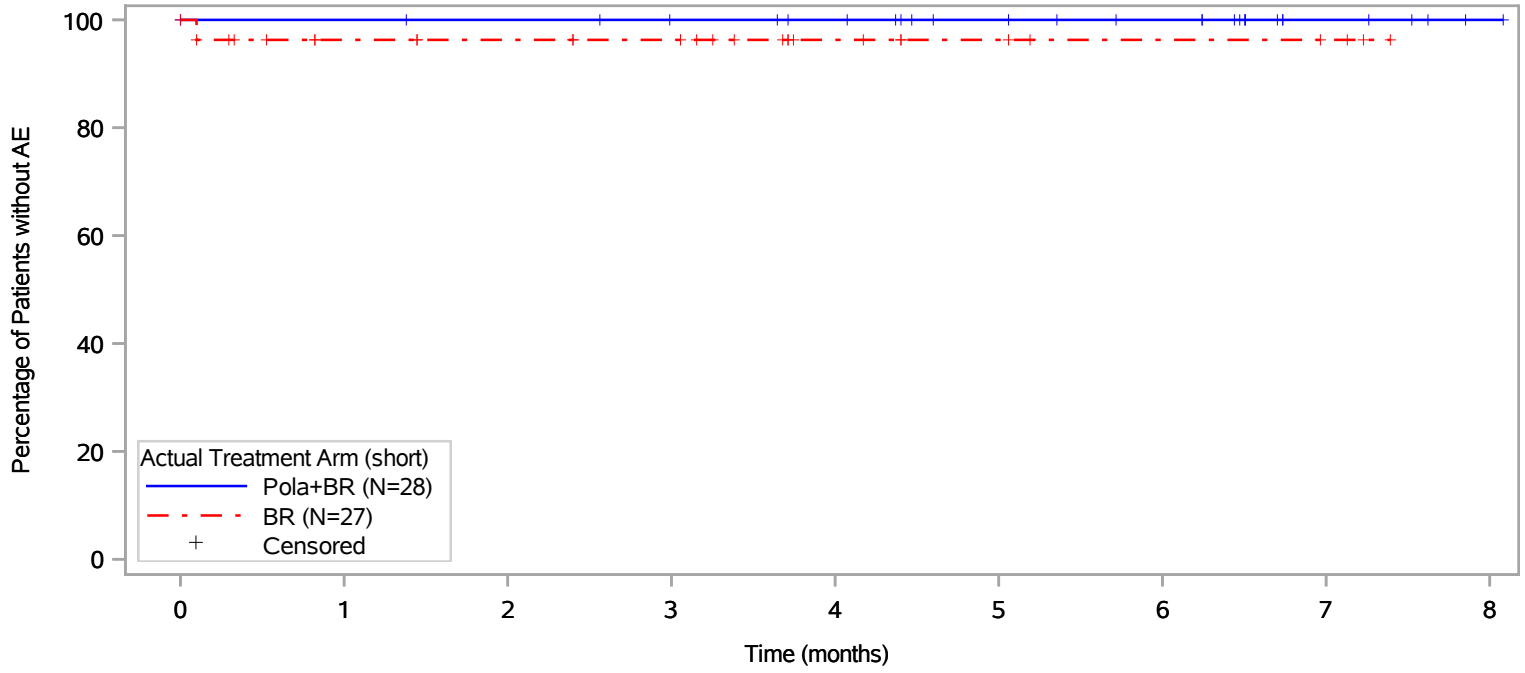
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HUMAN ANAPLASMOSIS



Patients at risk								
Pola+BR (N=28)	28	27	26	24	22	17	14	4
BR (N=27)	27	21	19	17	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	10	13	23
BR (N=27)	0	6	8	10	18	21	23	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NEUTROPENIC SEPSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	5	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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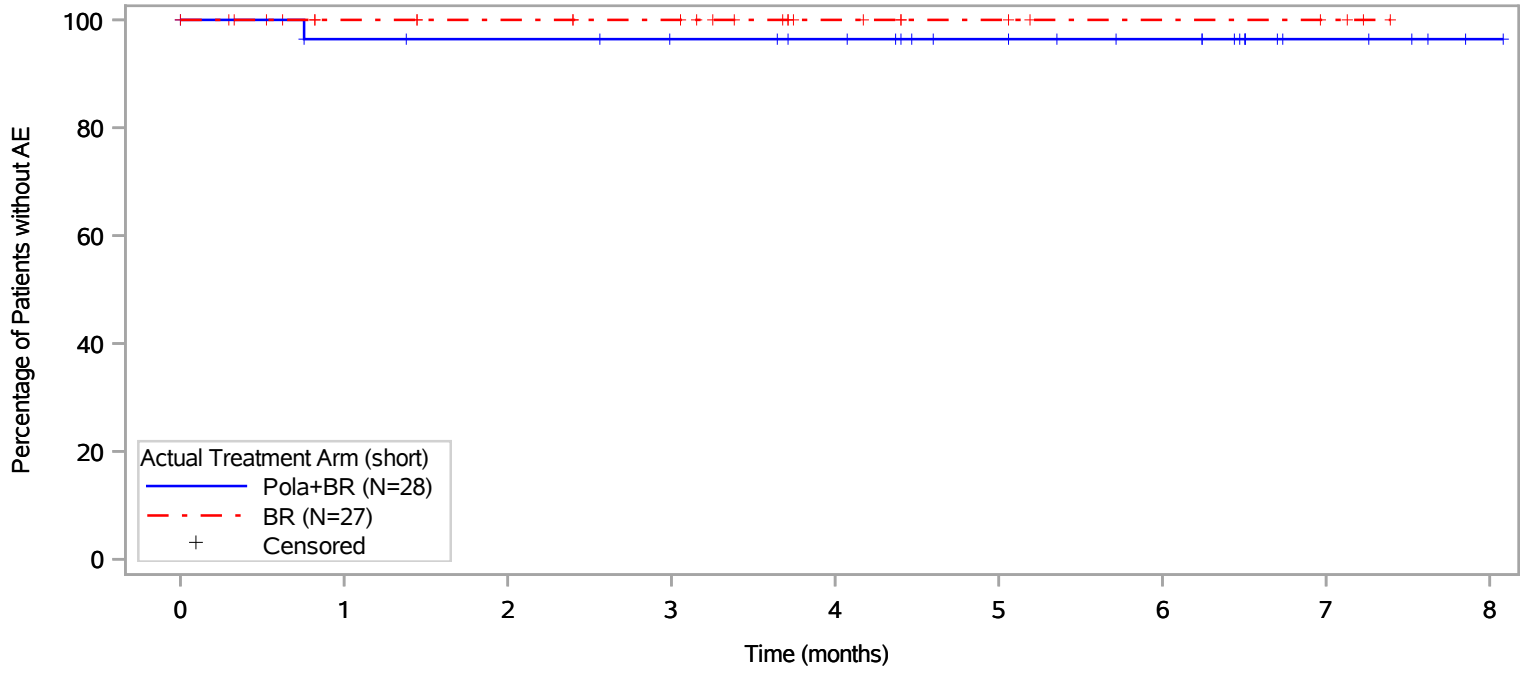
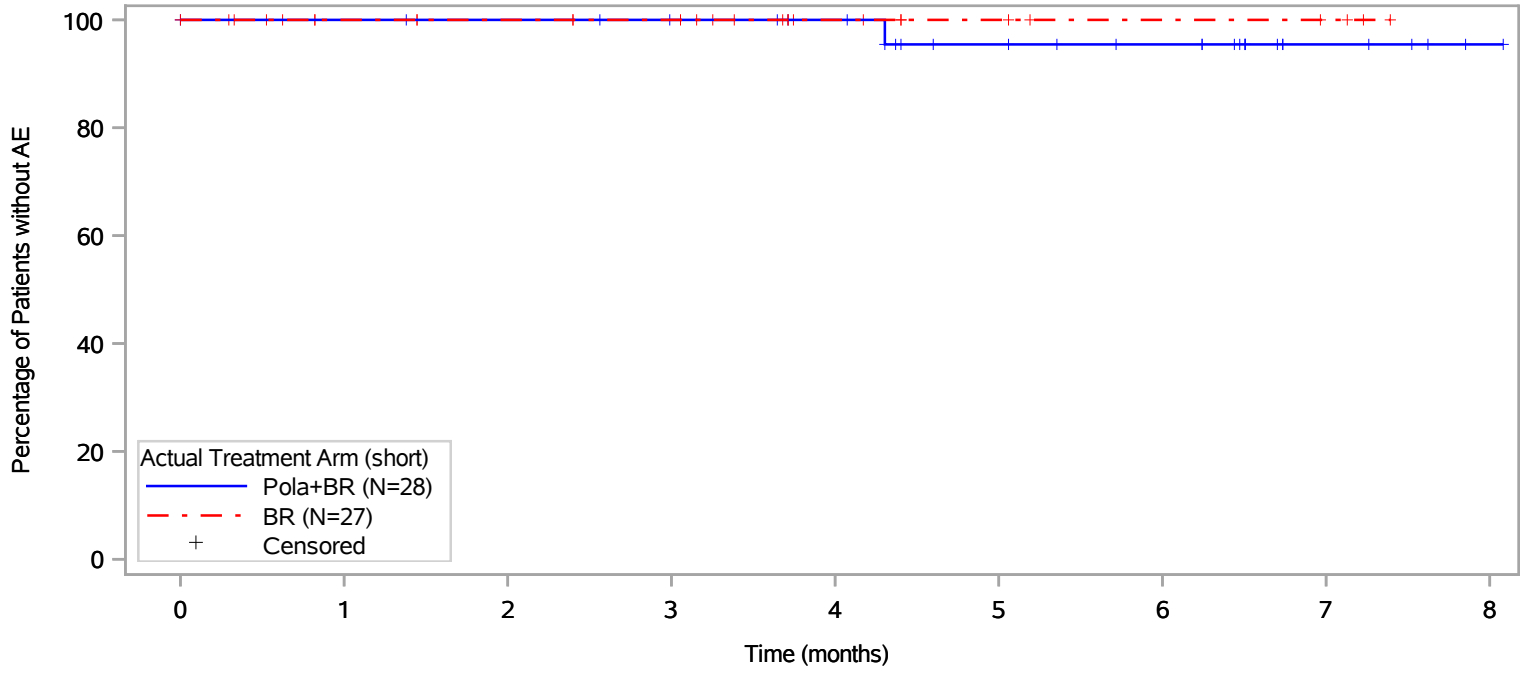
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMOCYSTIS JIROVECII PNEUMONIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

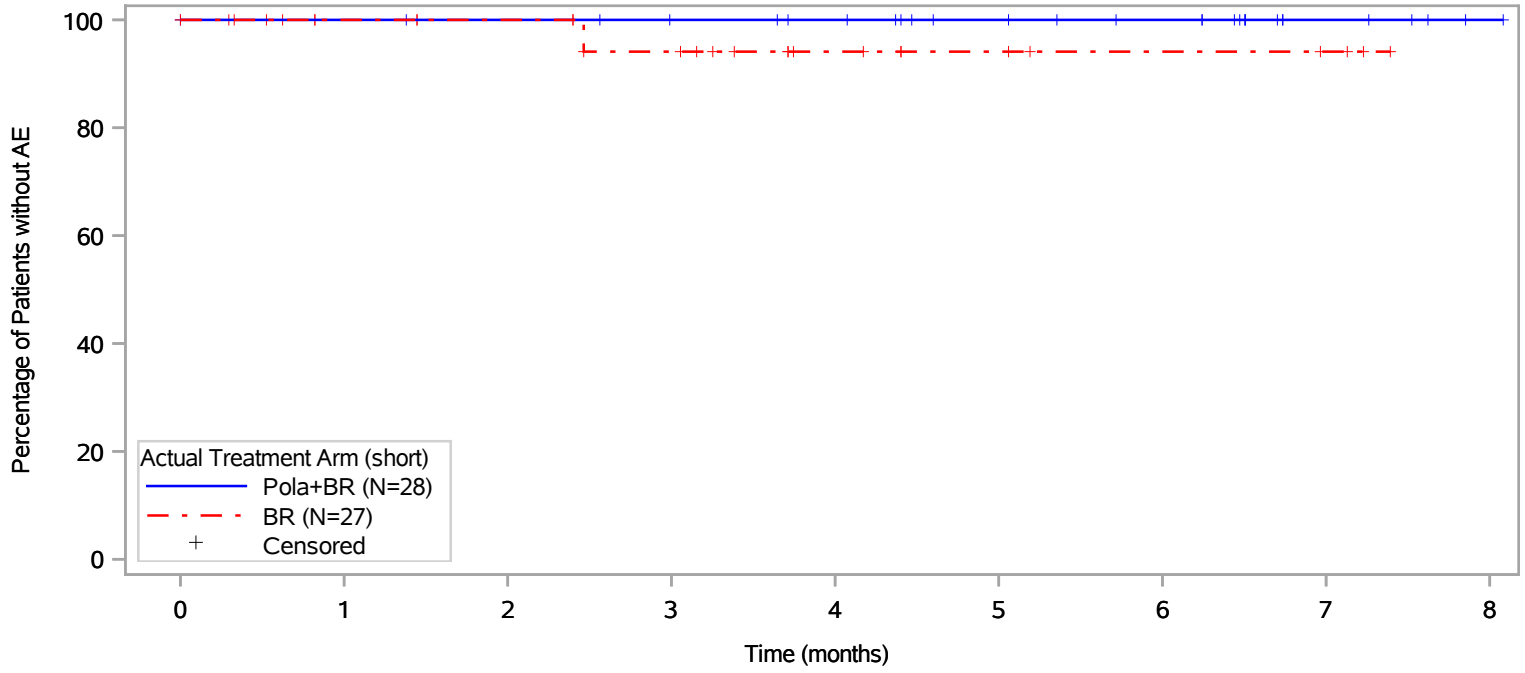
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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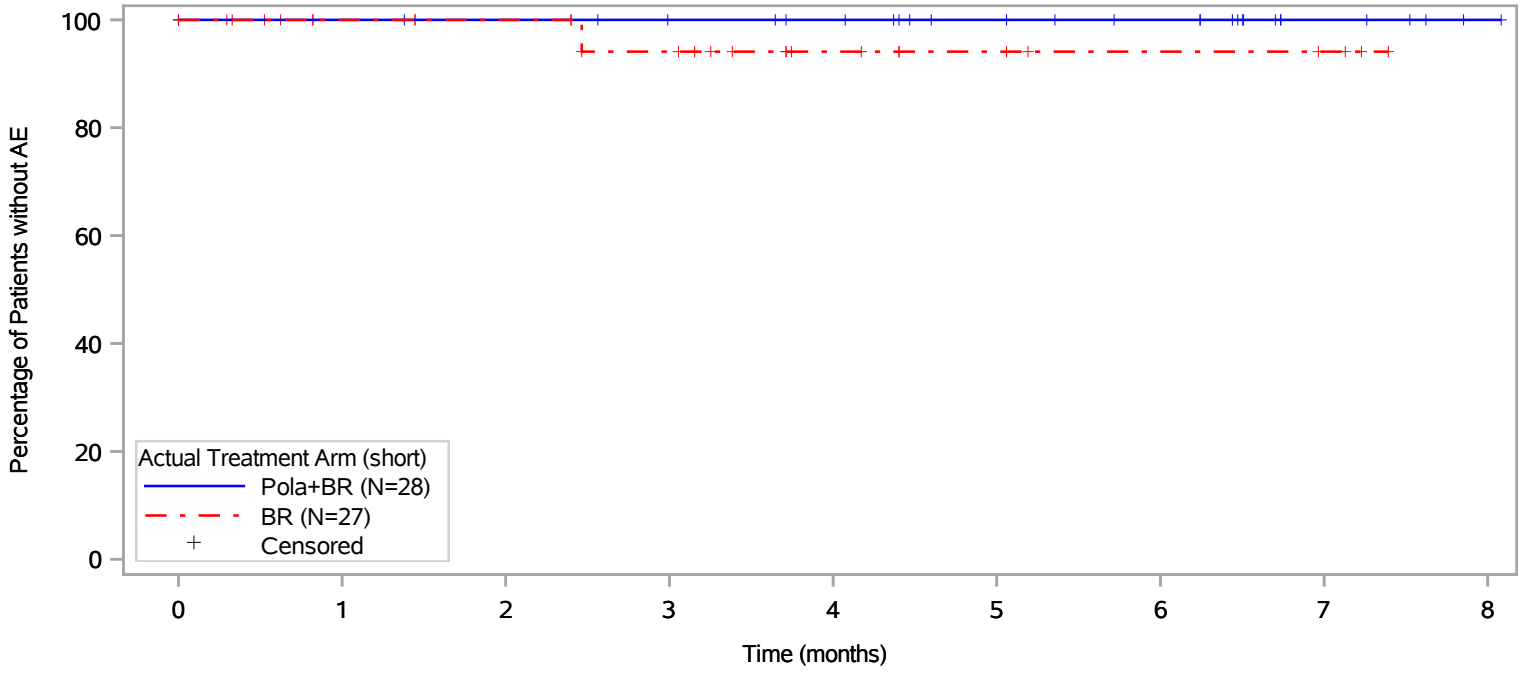
02DEC2022 4:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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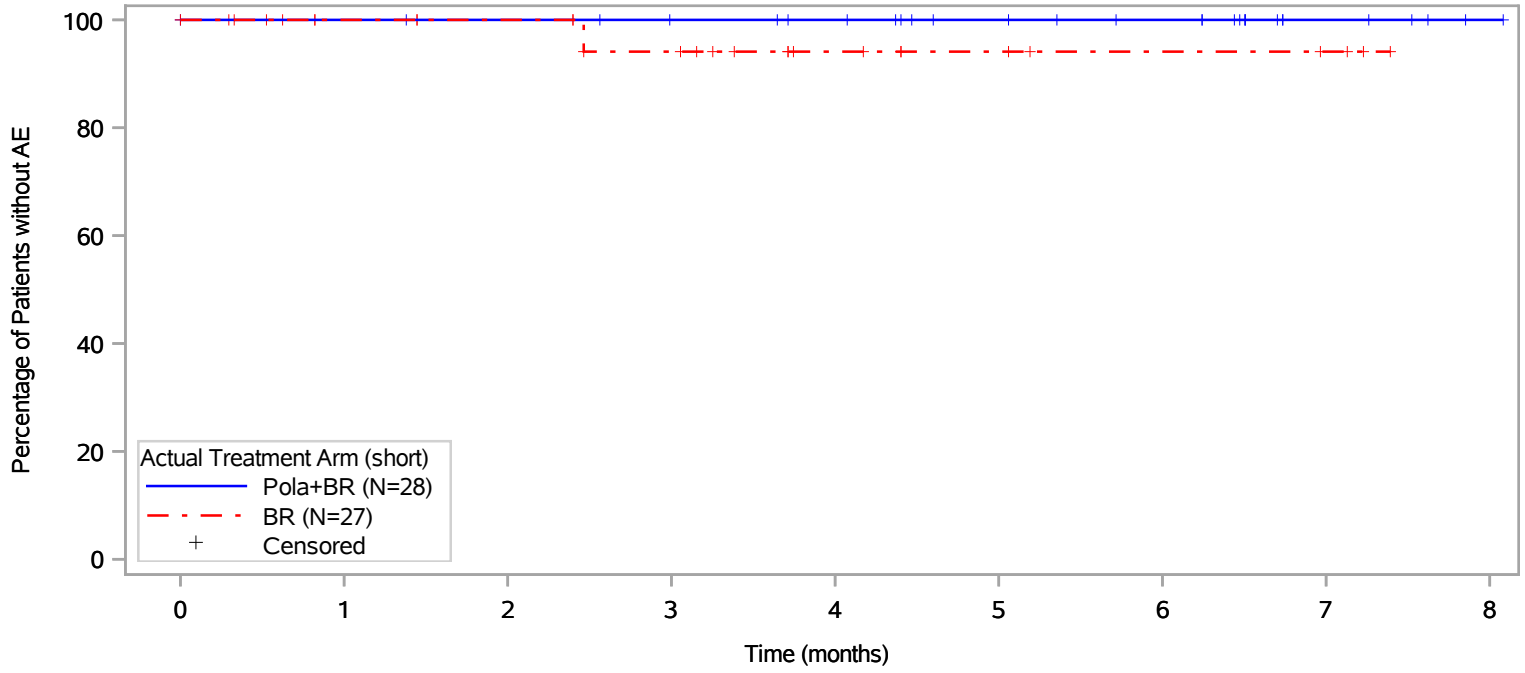
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, HEAD INJURY



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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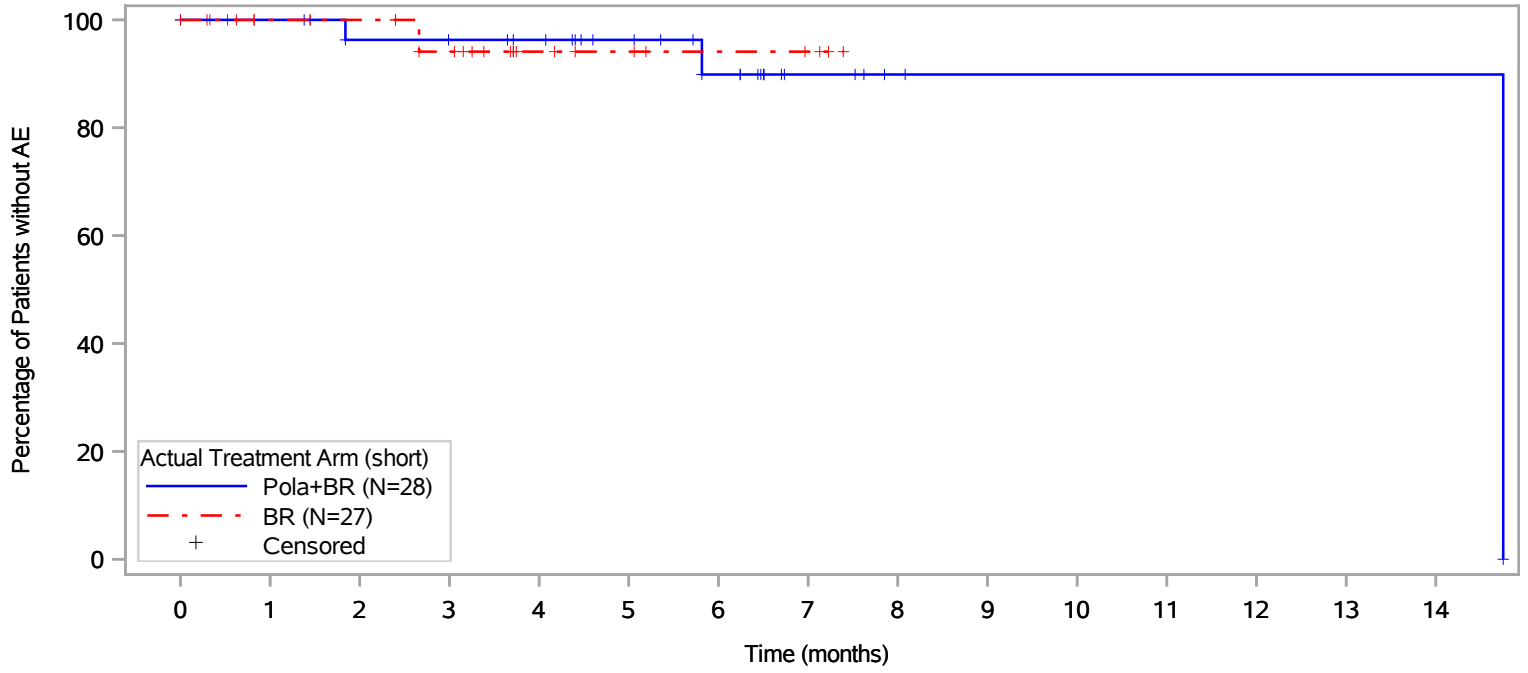
02DEC2022 4:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk															
Pola+BR (N=28)	28	28	26	25	23	18	14	5	2	1	1	1	1	1	1
BR (N=27)	27	21	19	16	8	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	2	4	9	12	21	24	25	25	25	25	25	25
BR (N=27)	0	6	8	10	18	20	22	23	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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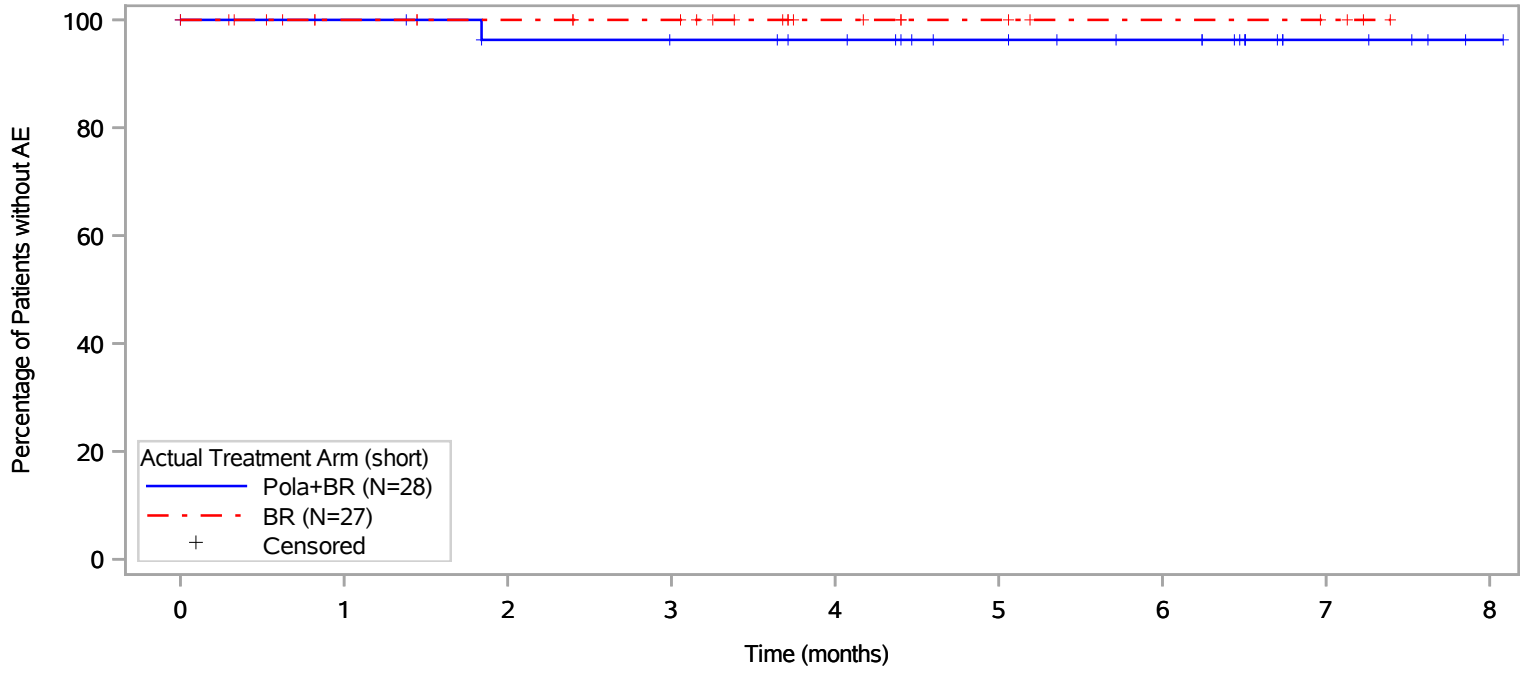
02DEC2022 4:41

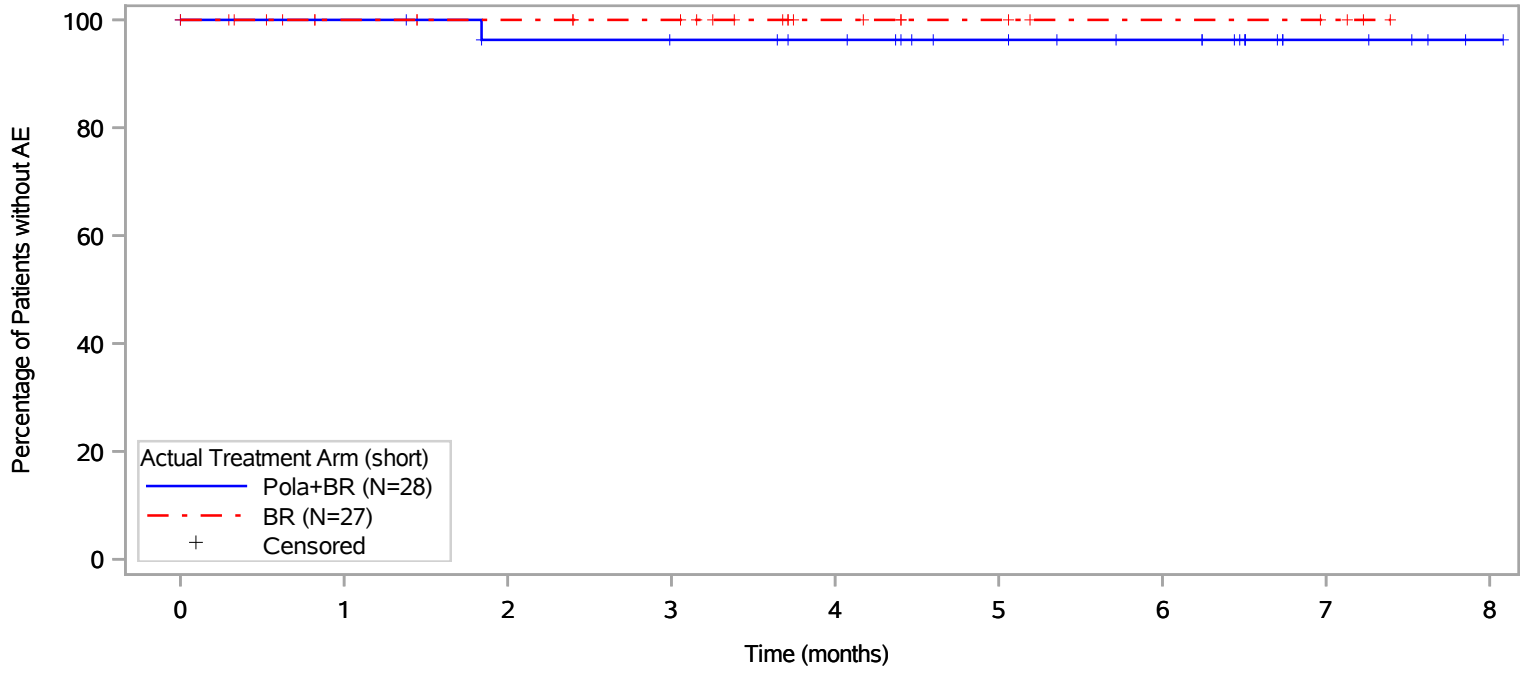
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

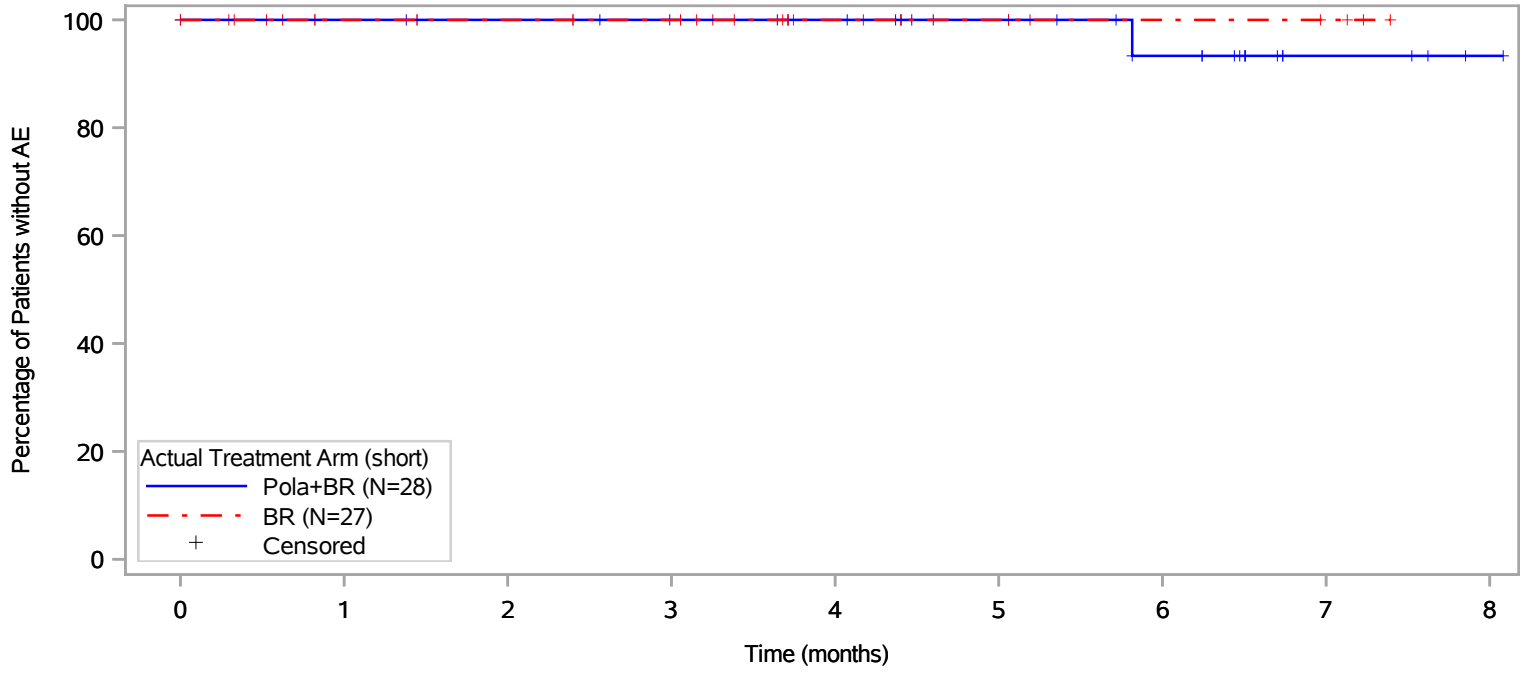
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

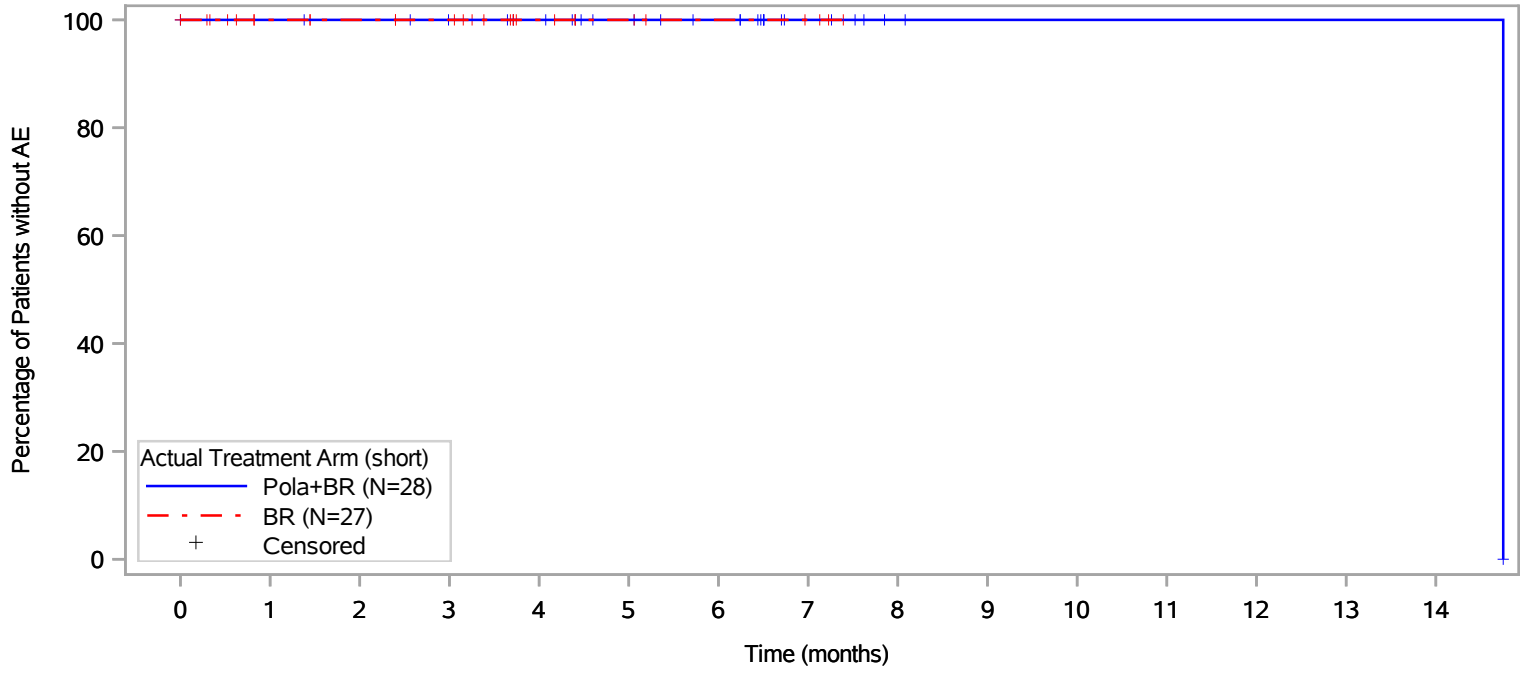
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

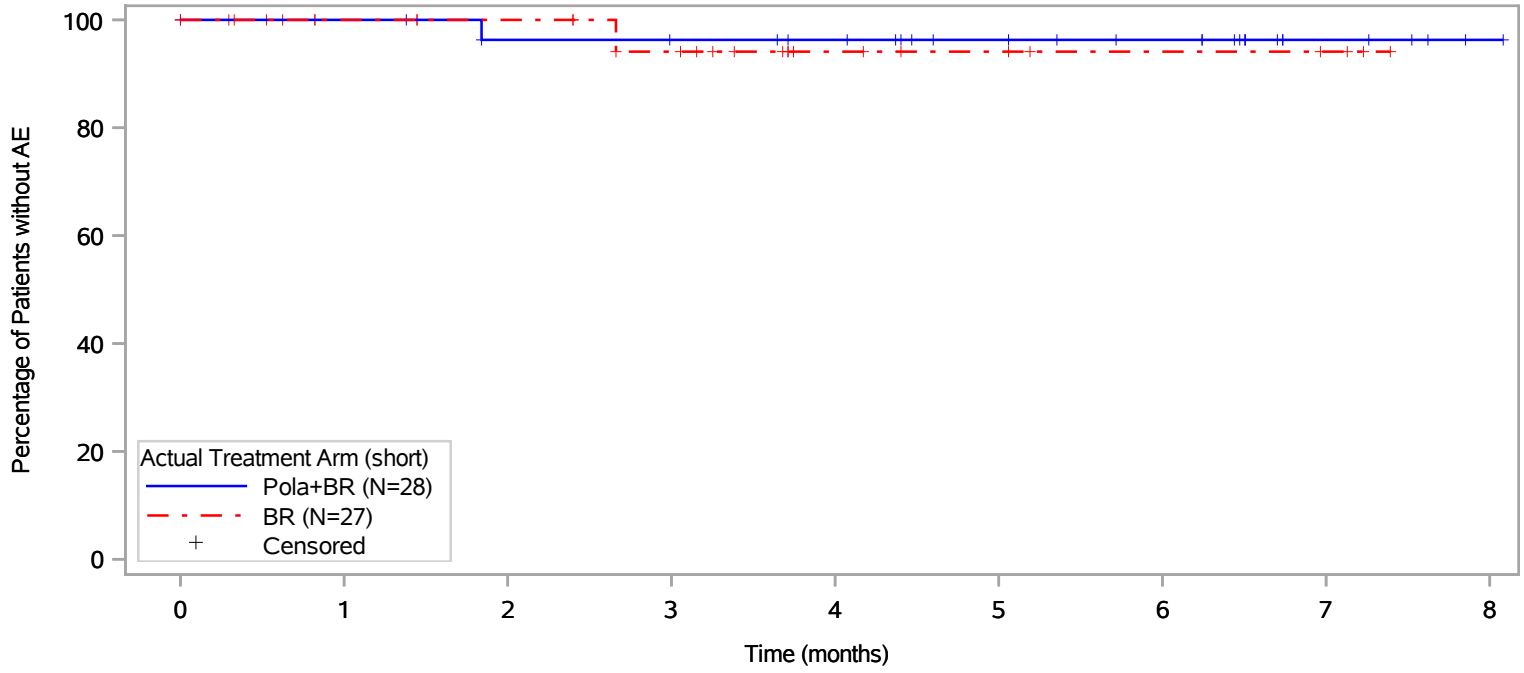
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, TRANSAMINASES INCREASED



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk									
Pola+BR (N=28)	28	28	26	25	23	18	15	5	1
BR (N=27)	27	21	19	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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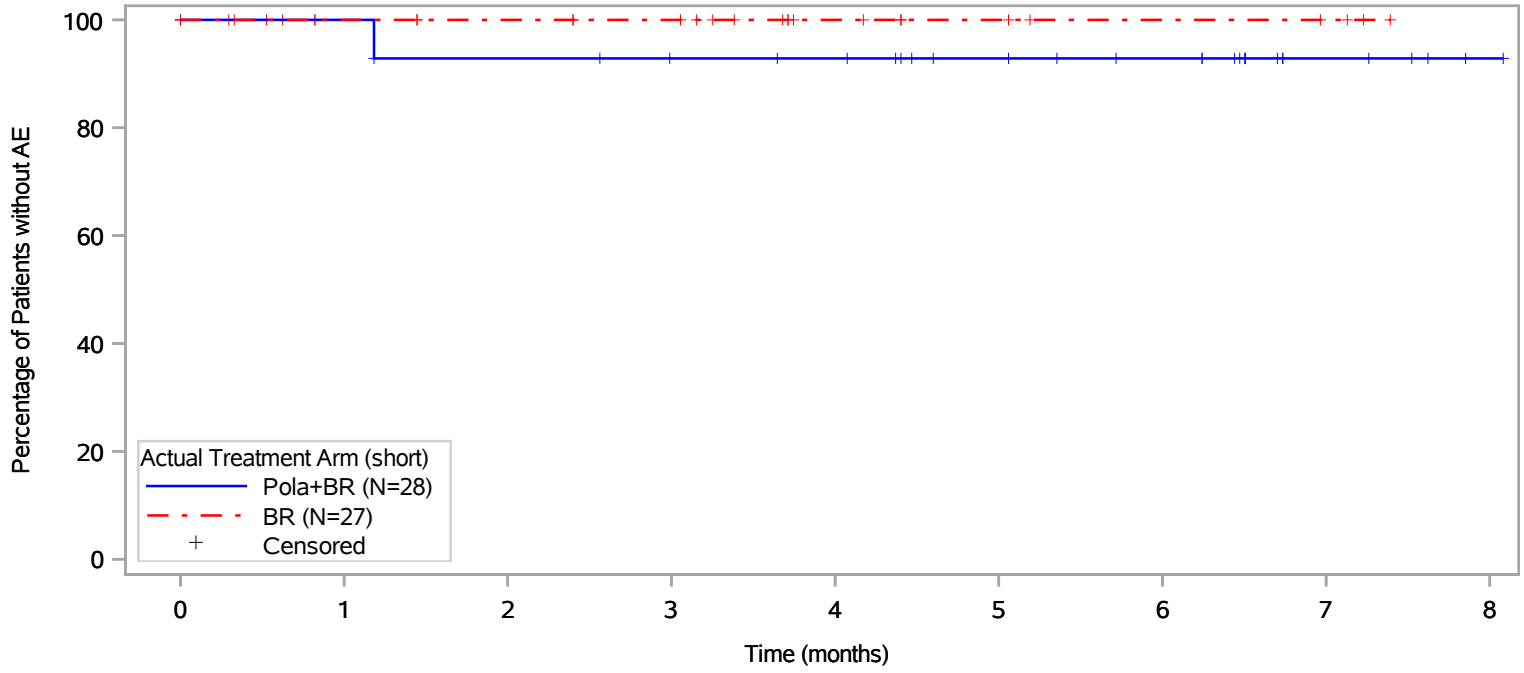
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	28	26	24	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	3	8	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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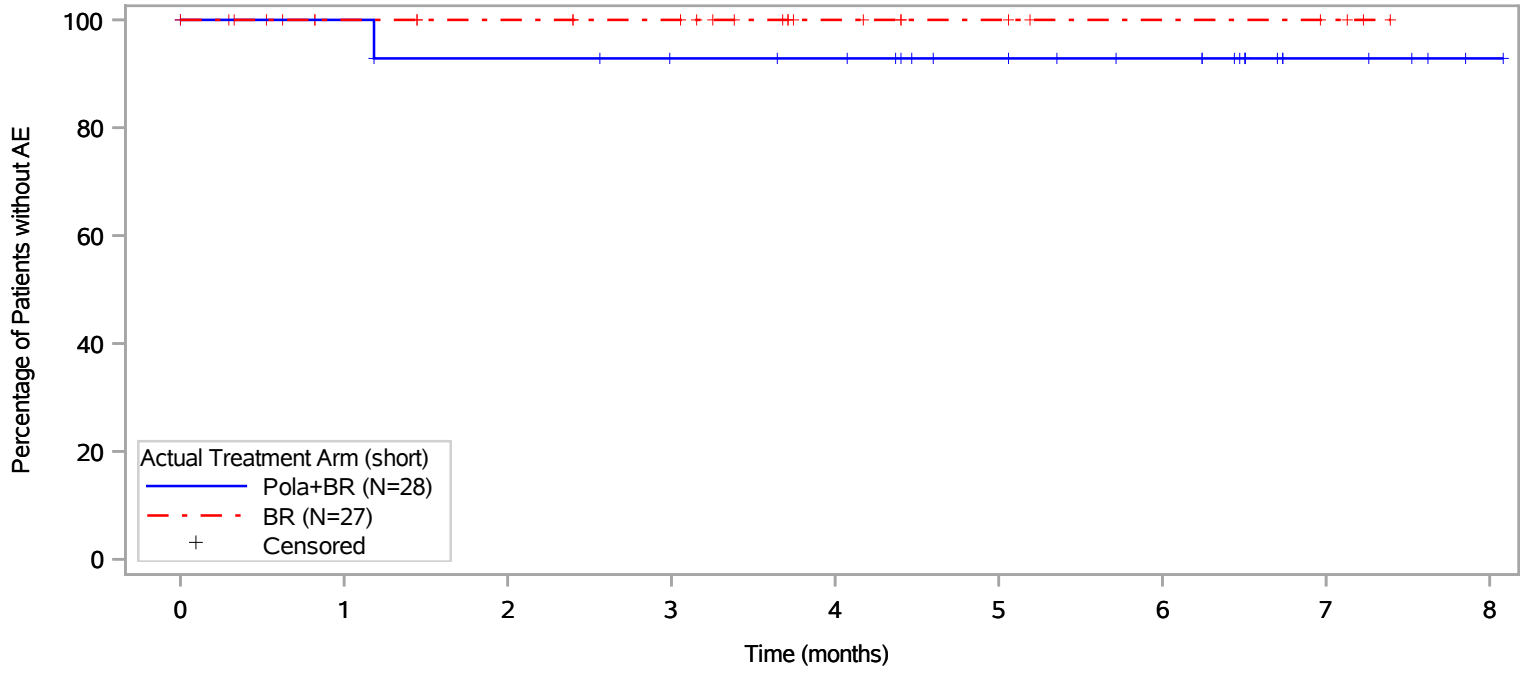
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

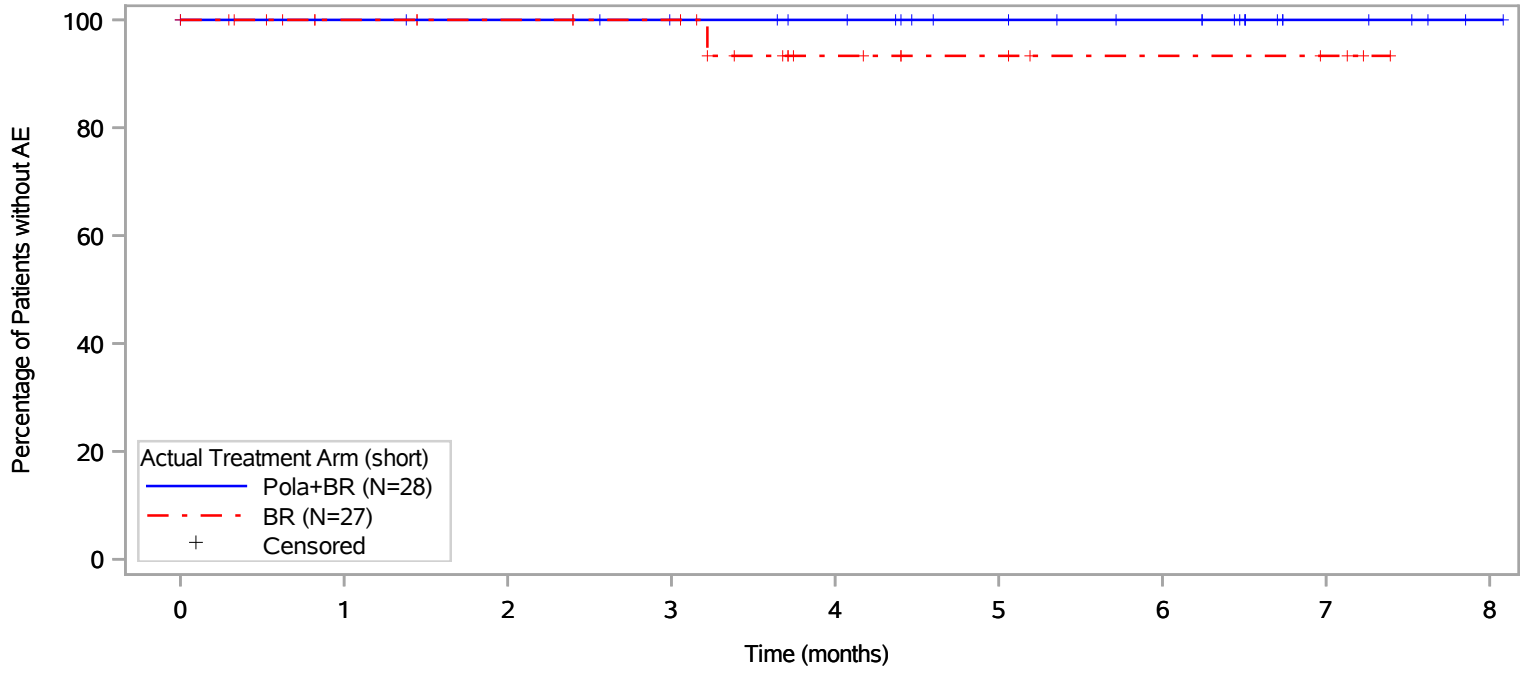
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk									
Pola+BR (N=28)	28	28	26	24	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	3	8	11	21	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All

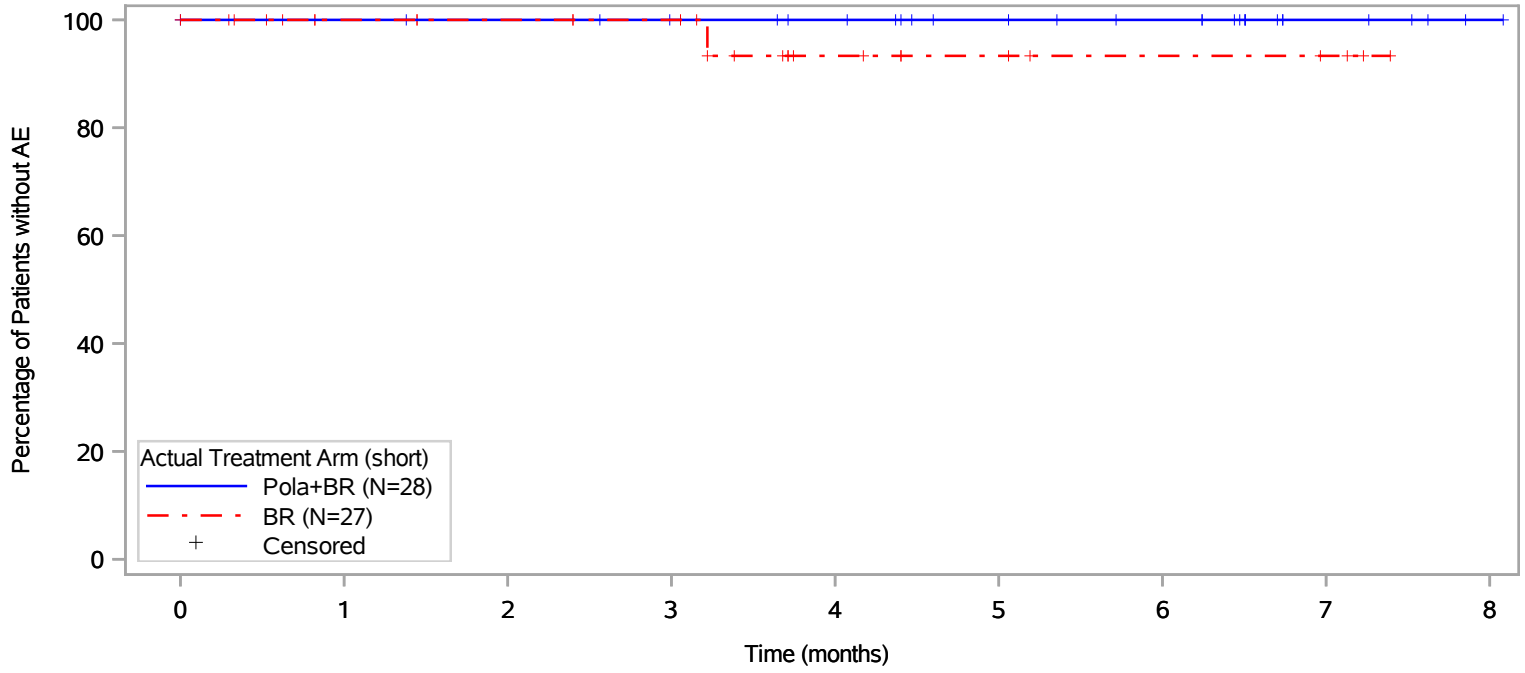


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR4AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 4:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR4AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 4:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
CARDIAC DISORDERS			28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	CARDIAC FAILURE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.3108	0.30	0.03	3.46		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.7347	0.61	0.04	10.54		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	3	11.1	24	88.9	0.2018	0.23	0.02	2.65		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0652	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4275	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4275	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR5AE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 1:17

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
CARDIAC DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.7505	0.63	0.04	10.88		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.7505	0.63	0.04	10.88		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	2	14.3	12	85.7	0.6864	0.55	0.03	10.01		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

VASCULAR DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR5AE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 1:17

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
CARDIAC DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1386	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.5465	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.5465	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	3	16.7	15	83.3	0.2211	0.24	0.02	2.80	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.0679	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.1213	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3980	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-

VASCULAR DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTGR5AE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 1:17

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
CARDIAC DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	2	15.4	11	84.6	0.4736	0.42	0.04	4.85		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.9114	0.85	0.05	14.99		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	2	15.4	11	84.6	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.0190	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.0190	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

VASCULAR DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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01DEC2022 1:17

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
CARDIAC DISORDERS		Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.6897	0.56	0.03	9.72		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.6897	0.56	0.03	9.72		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.6901	0.56	0.03	10.06		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

VASCULAR DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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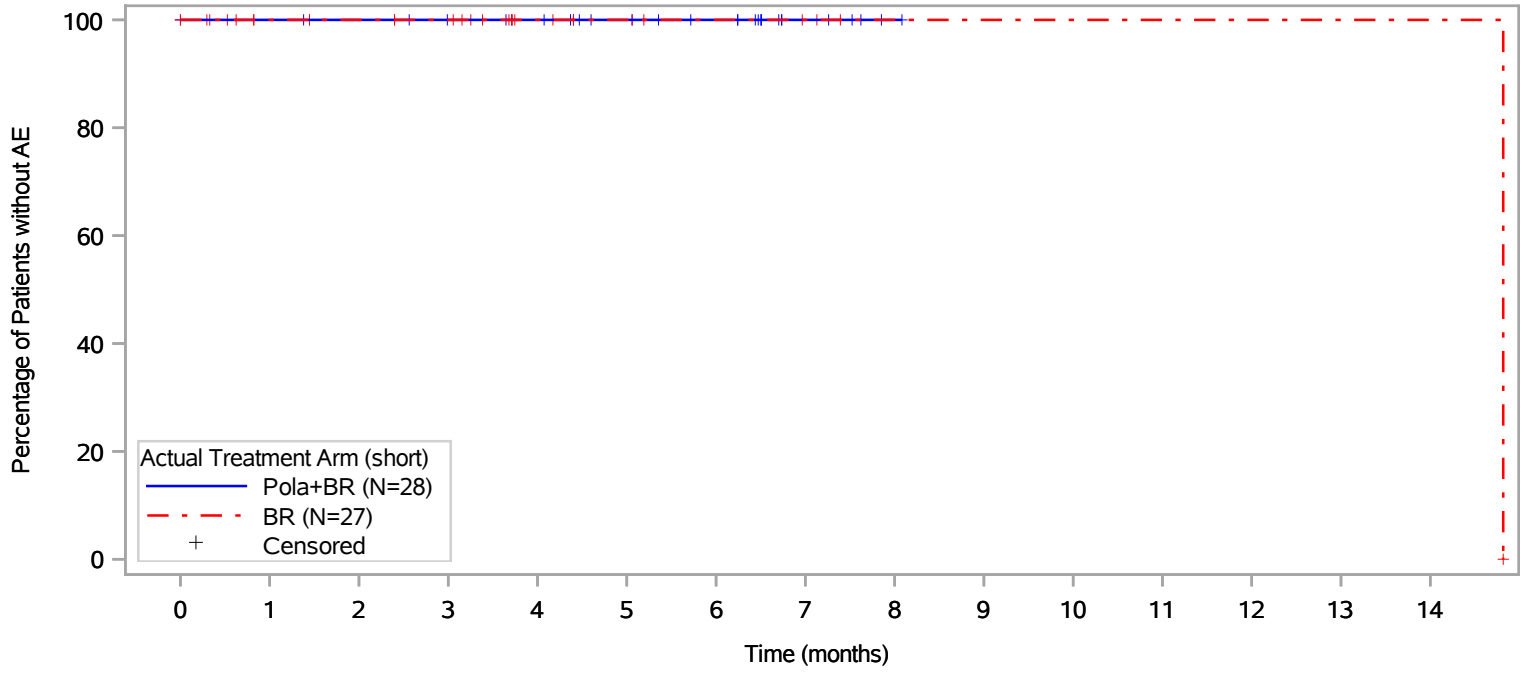
01DEC2022 1:17

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	24	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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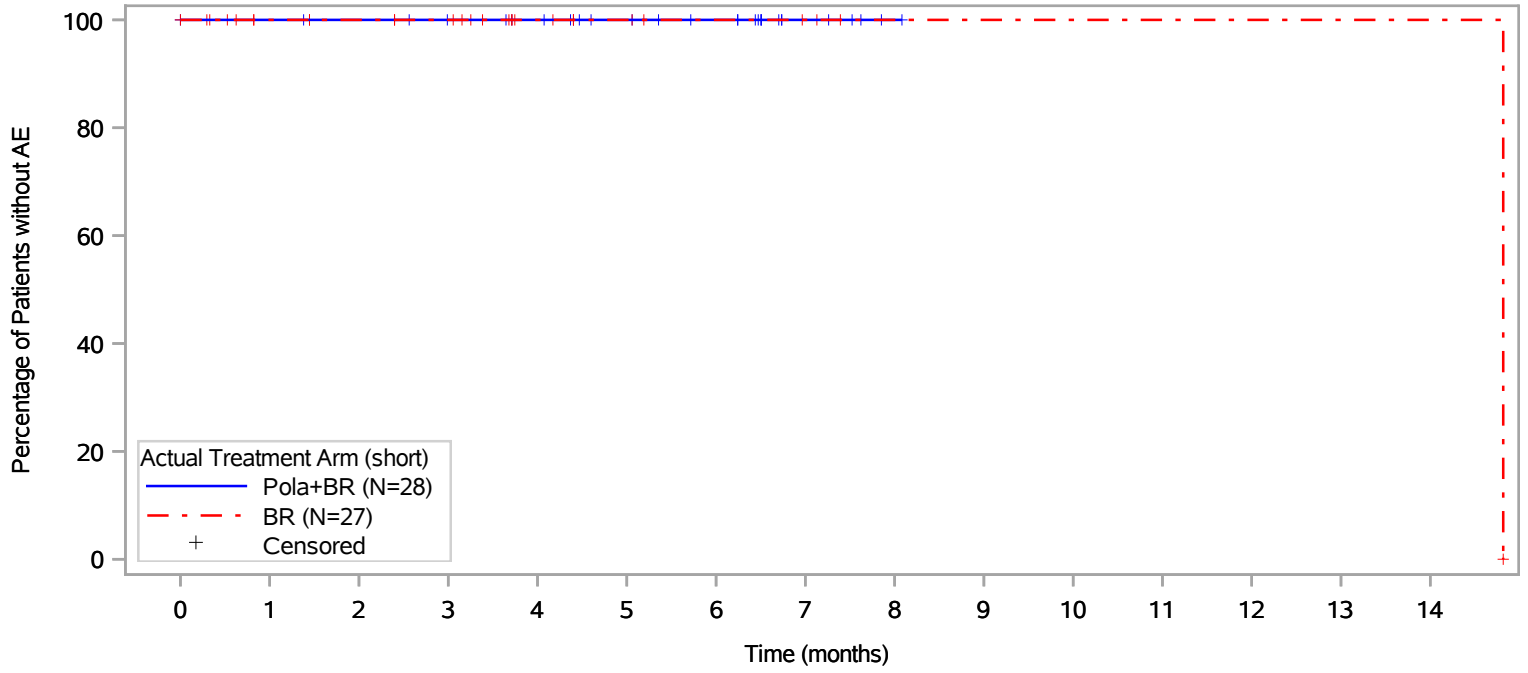
02DEC2022 5:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, CARDIAC FAILURE



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	24	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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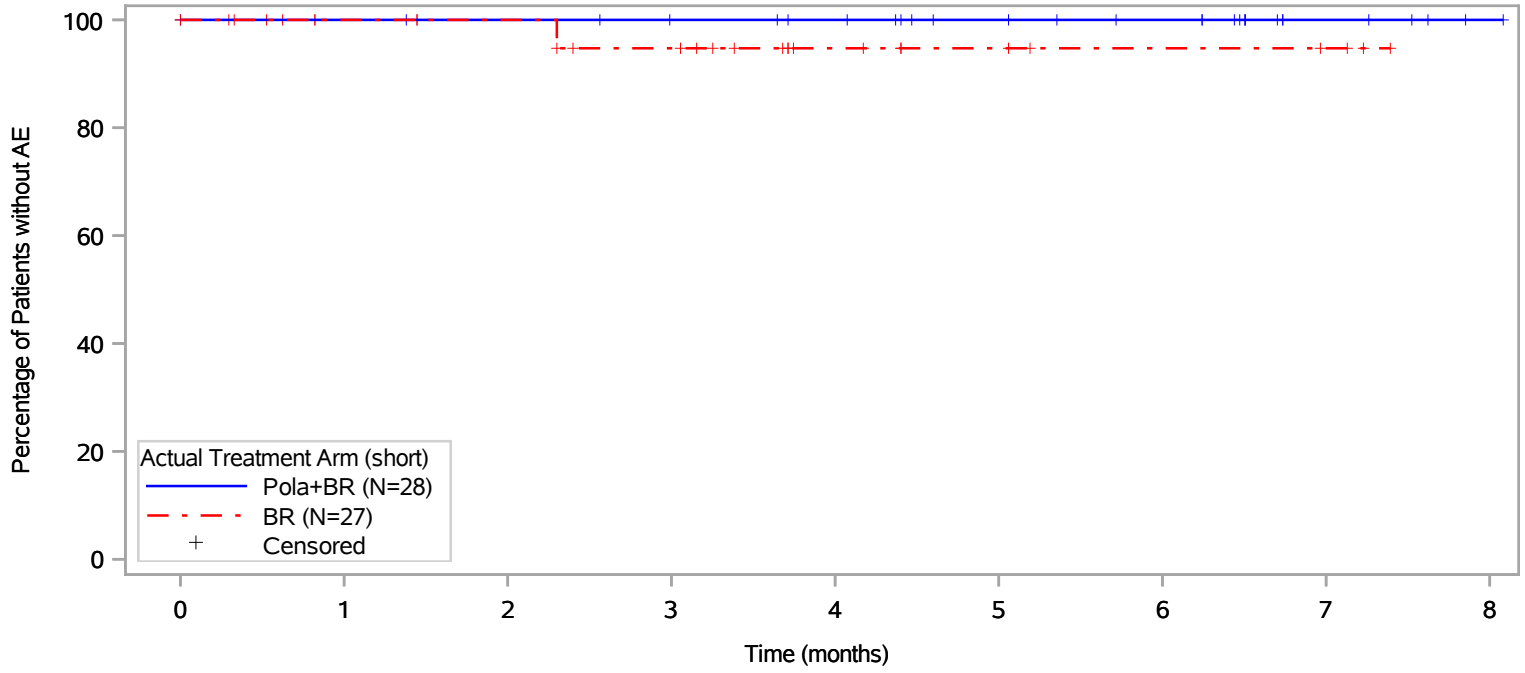
02DEC2022 5:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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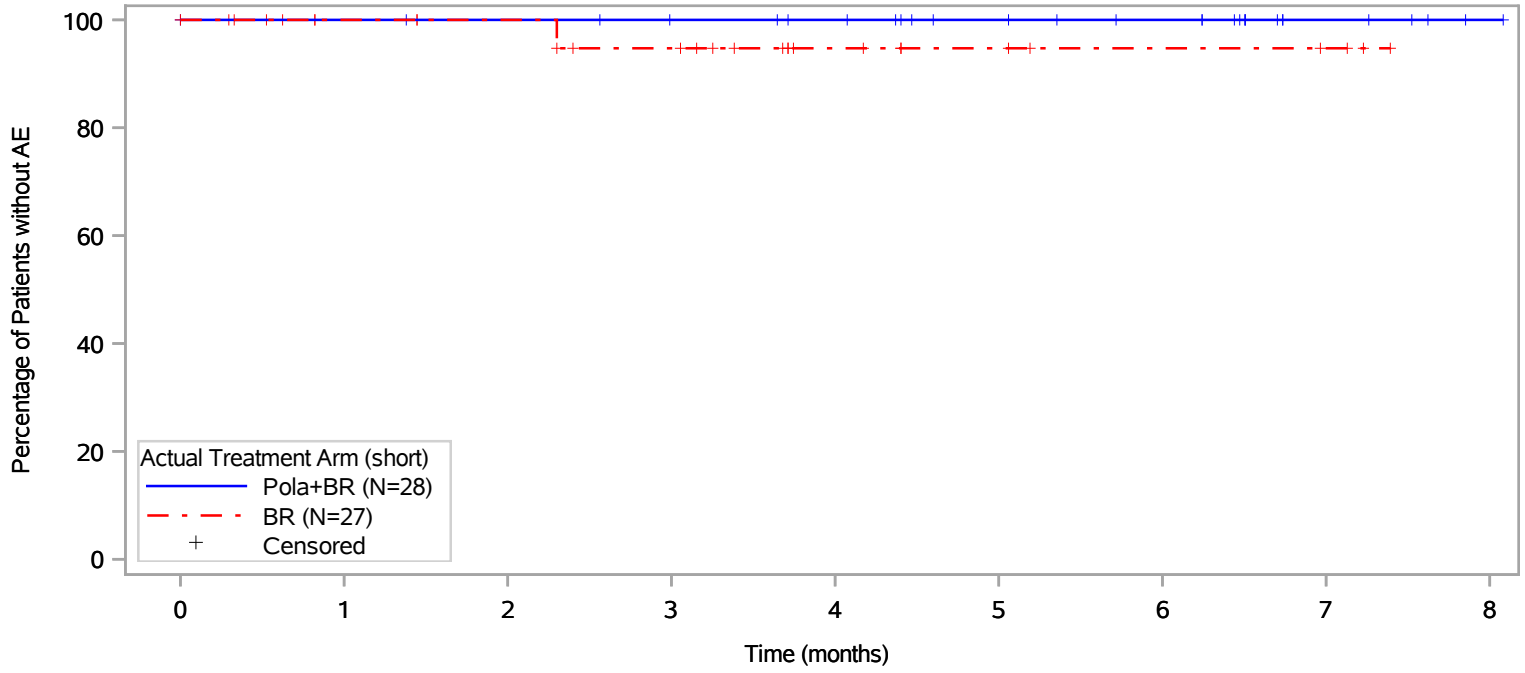
02DEC2022 5:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

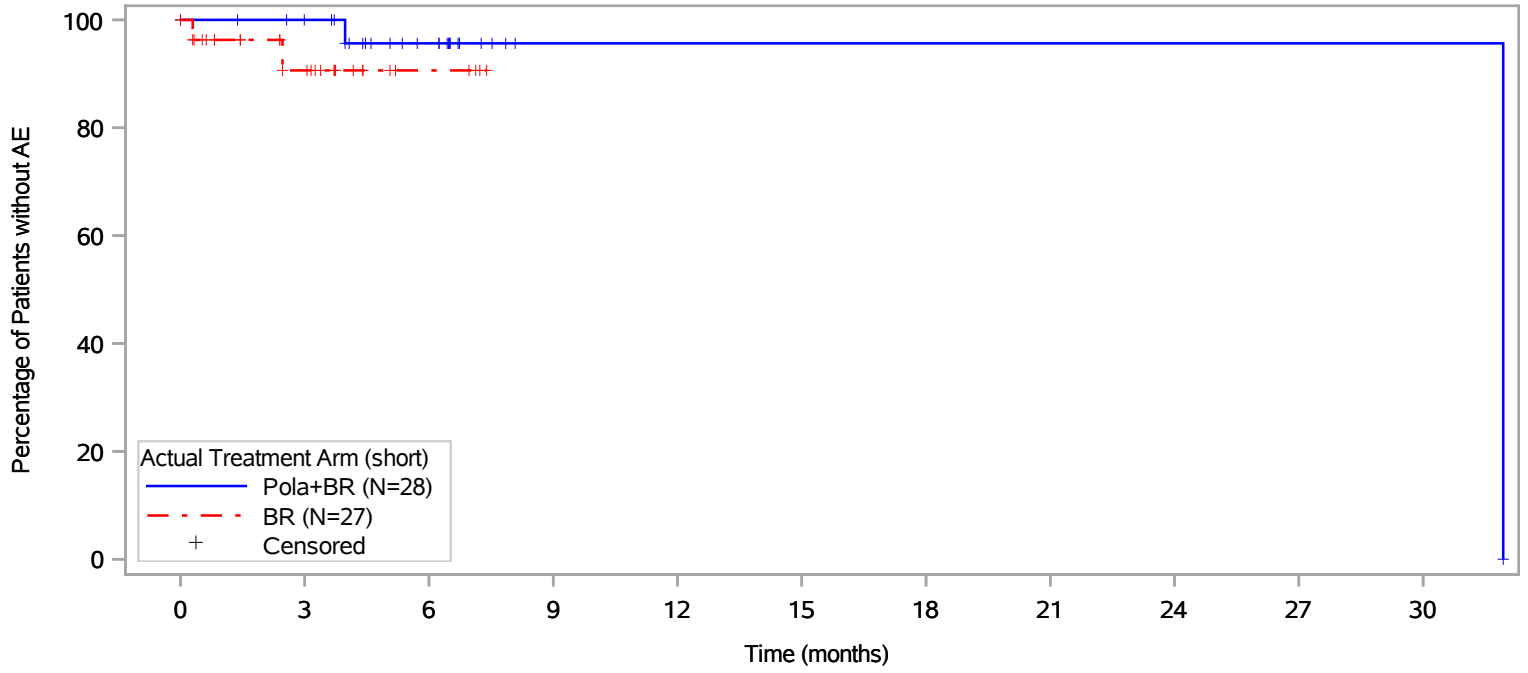
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk											
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1
BR (N=27)	27	16	4	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	3	12	26	26	26	26	26	26	26	26
BR (N=27)	0	9	21	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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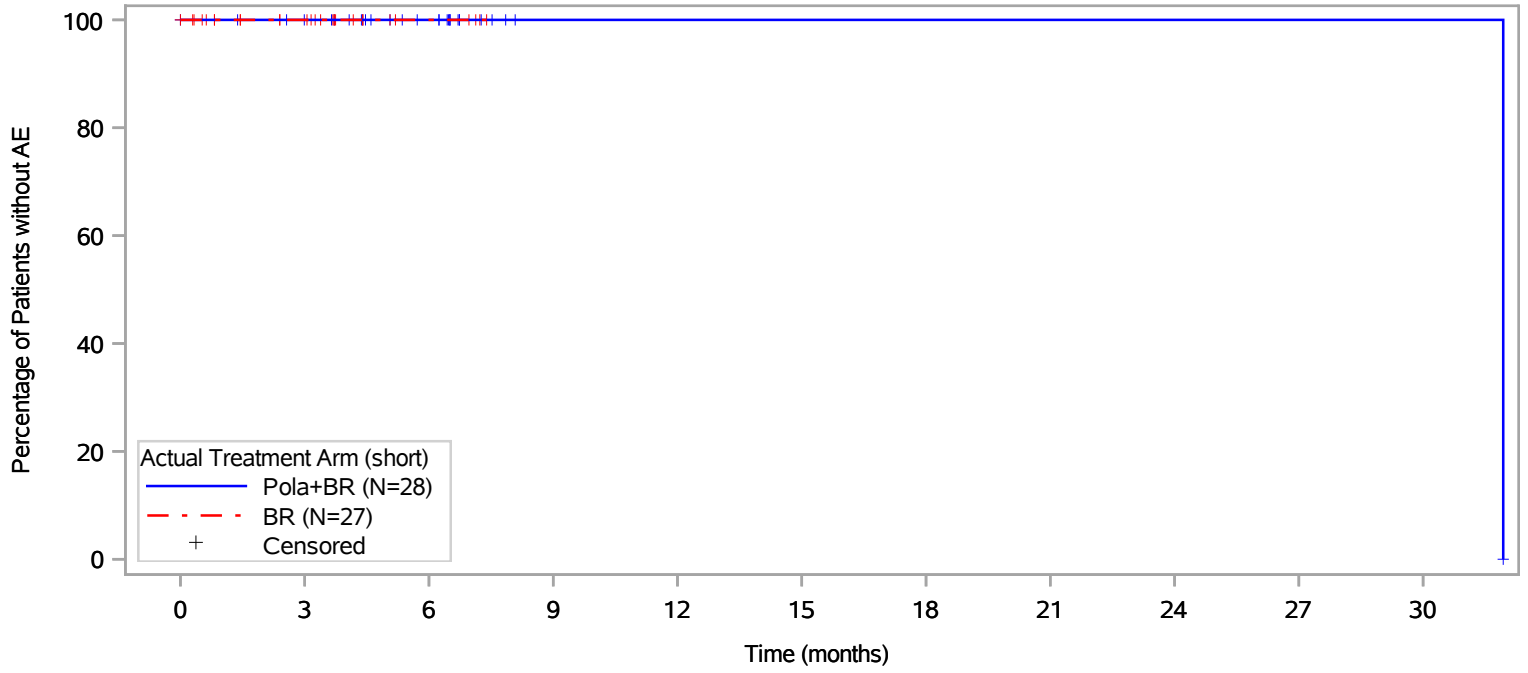
02DEC2022 5:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk											
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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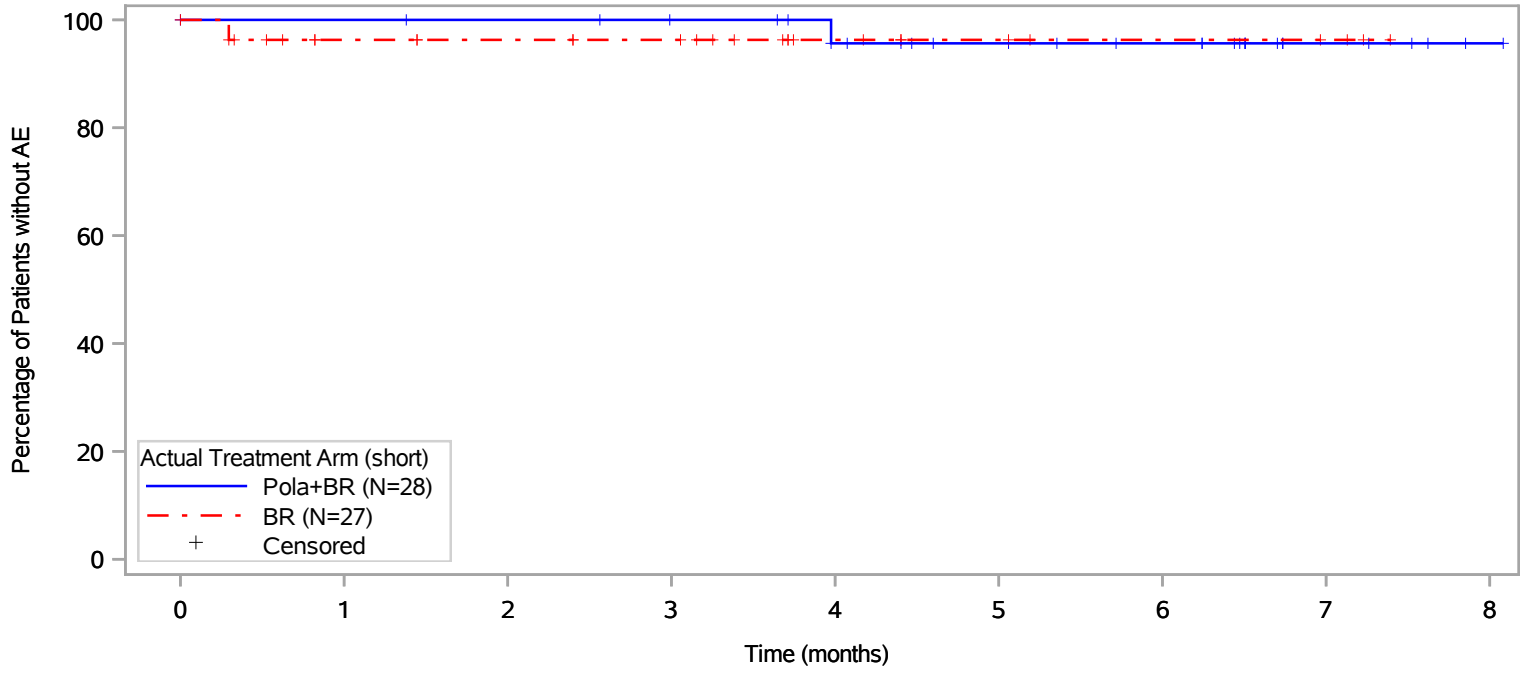
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	5	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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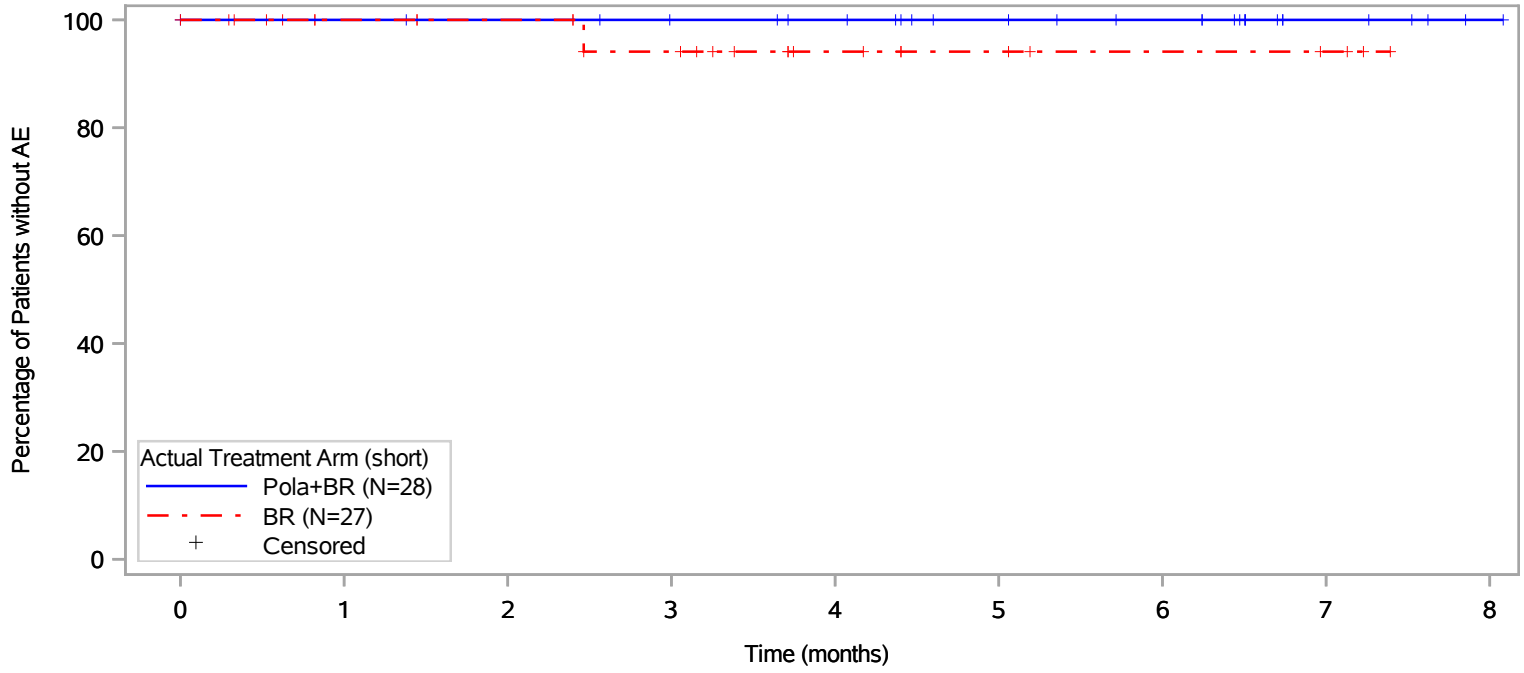
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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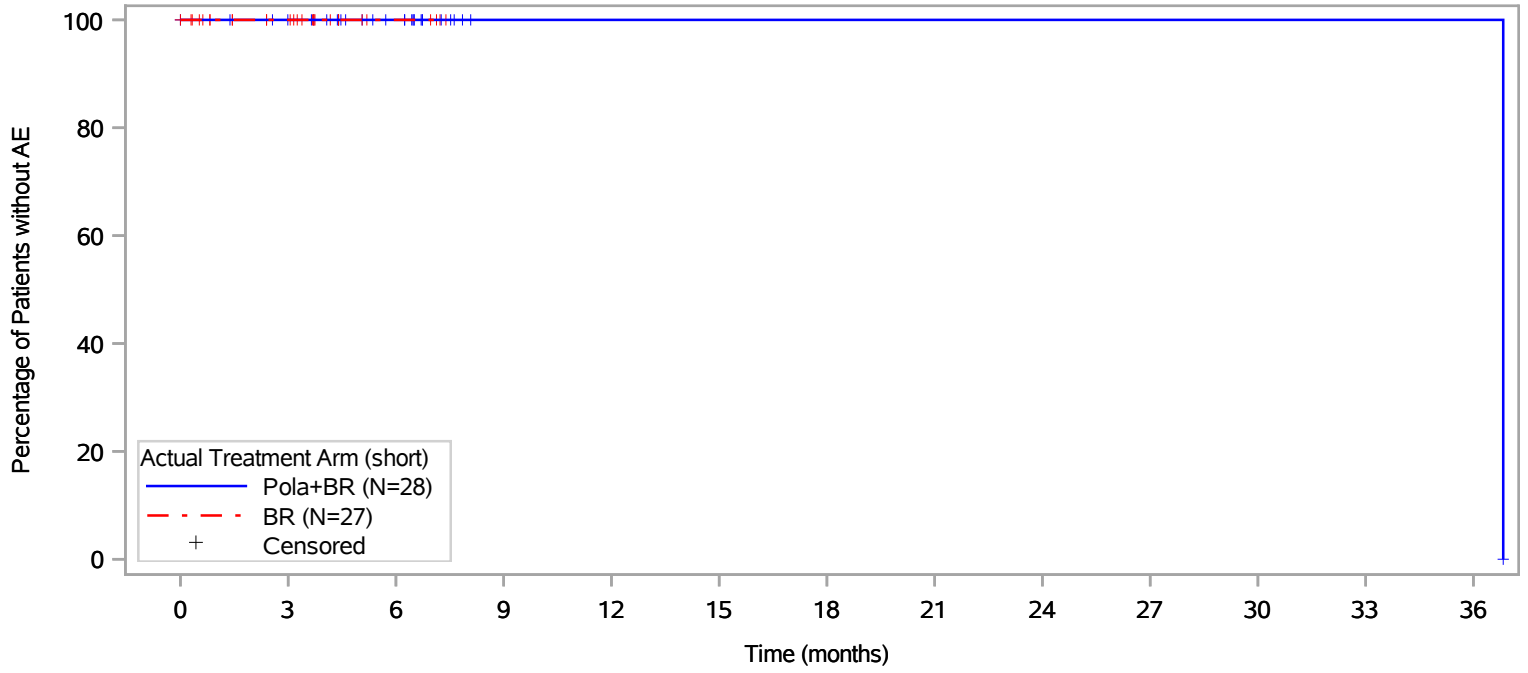
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All

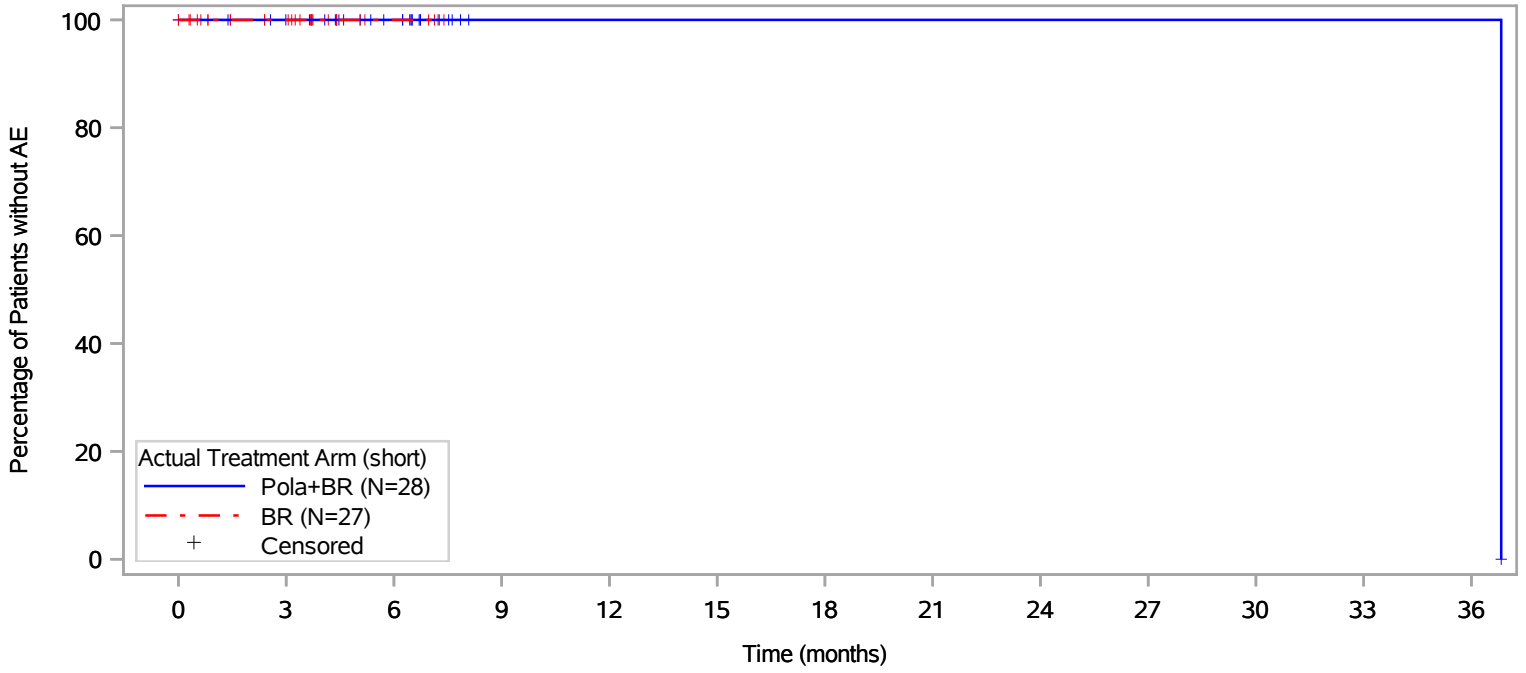


Patients at risk													
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

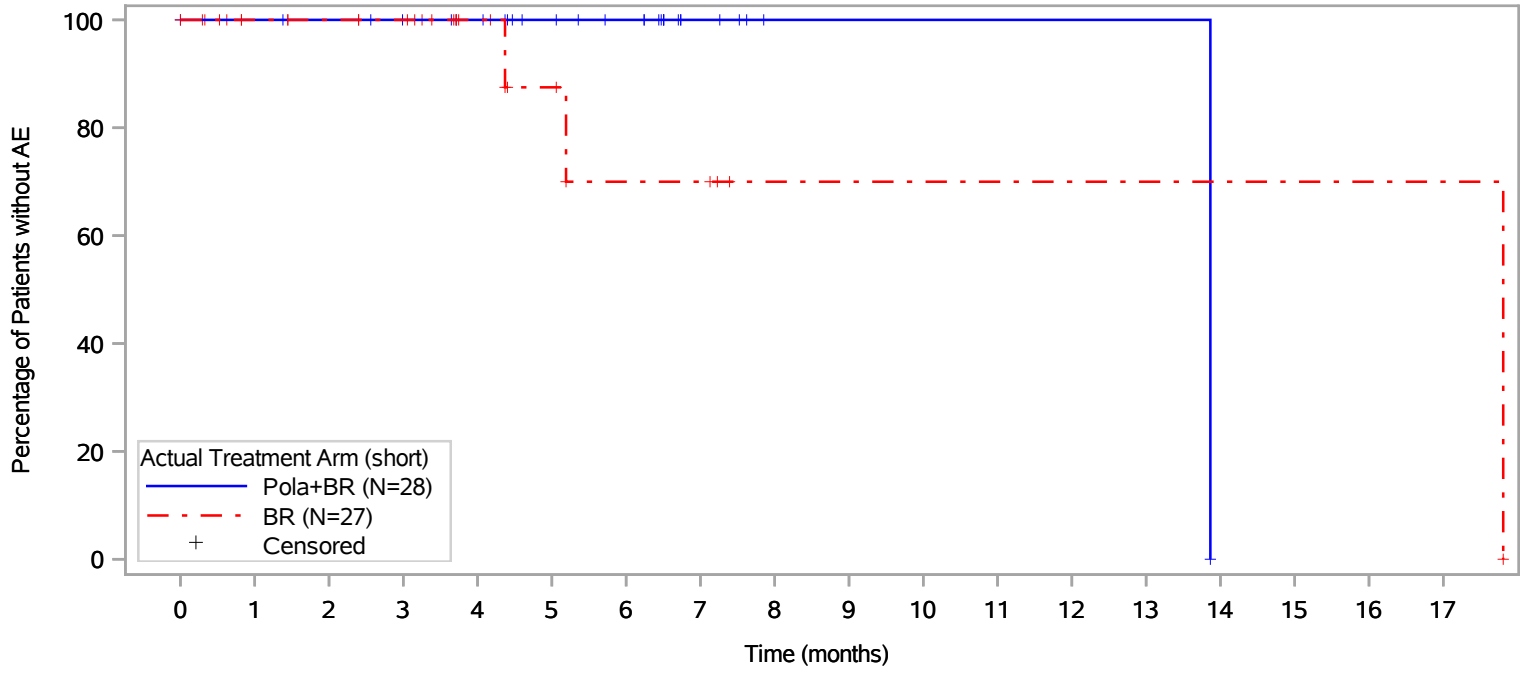
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MALIGNANT MELANOMA



Patients at risk													
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk																		
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	1	1	1	1	1	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	27	27	27	27	27	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	20	21	21	24	24	24	24	24	24	24	24	24	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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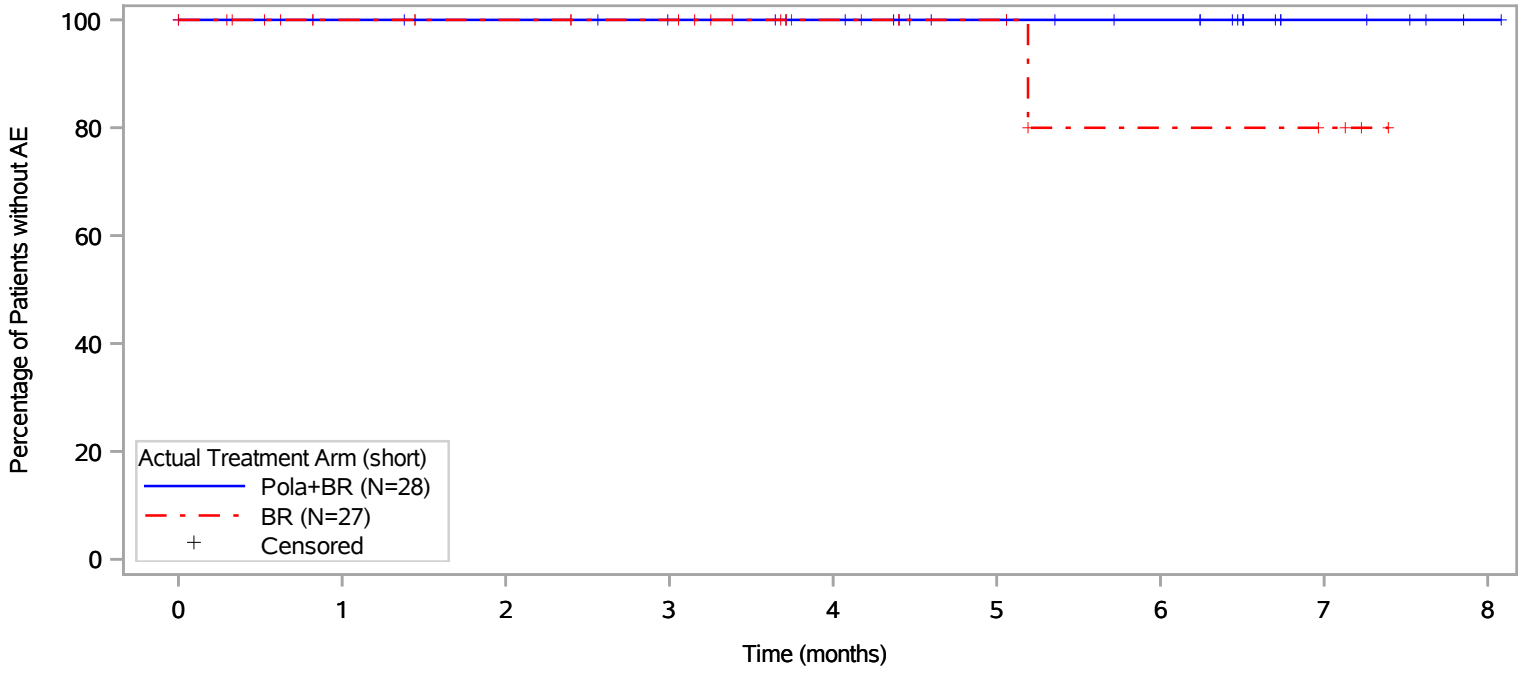
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, CEREBRAL HAEMORRHAGE

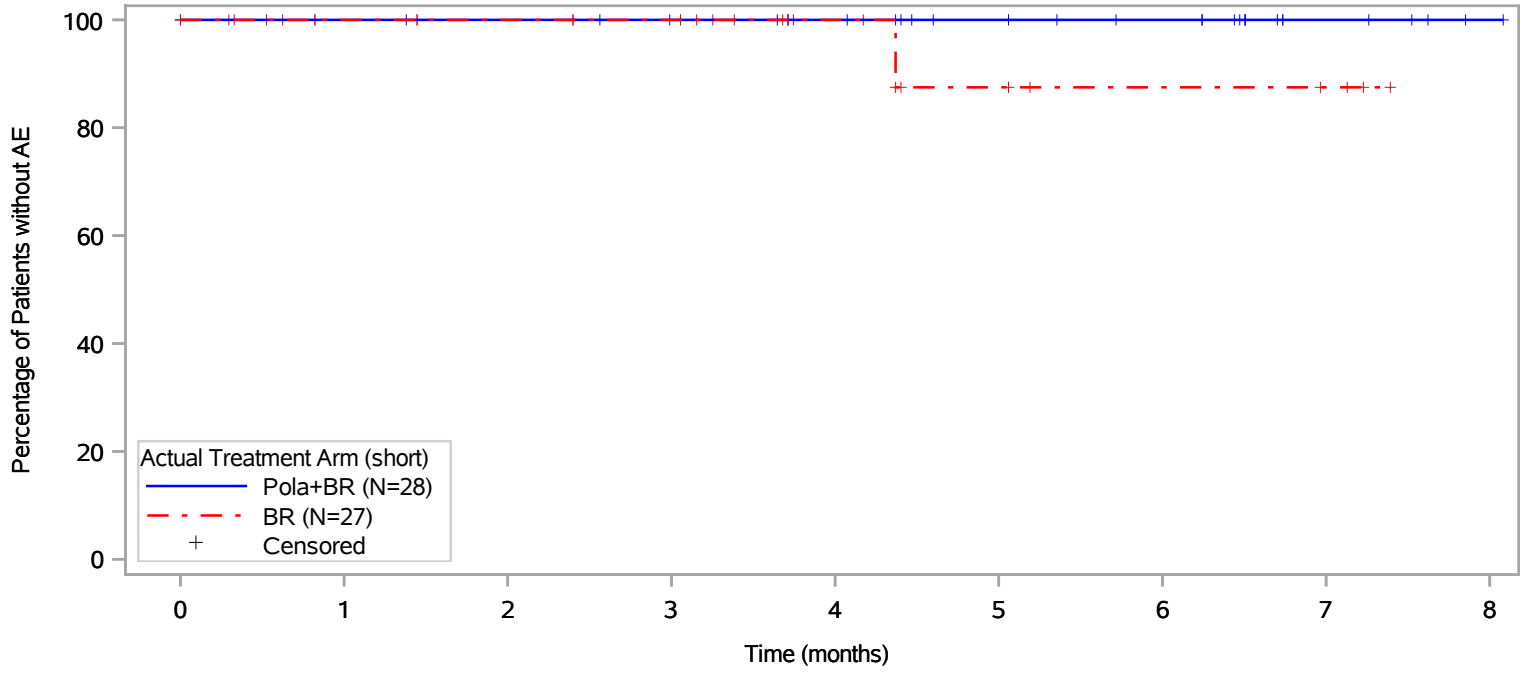


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR5AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, CEREBROVASCULAR ACCIDENT



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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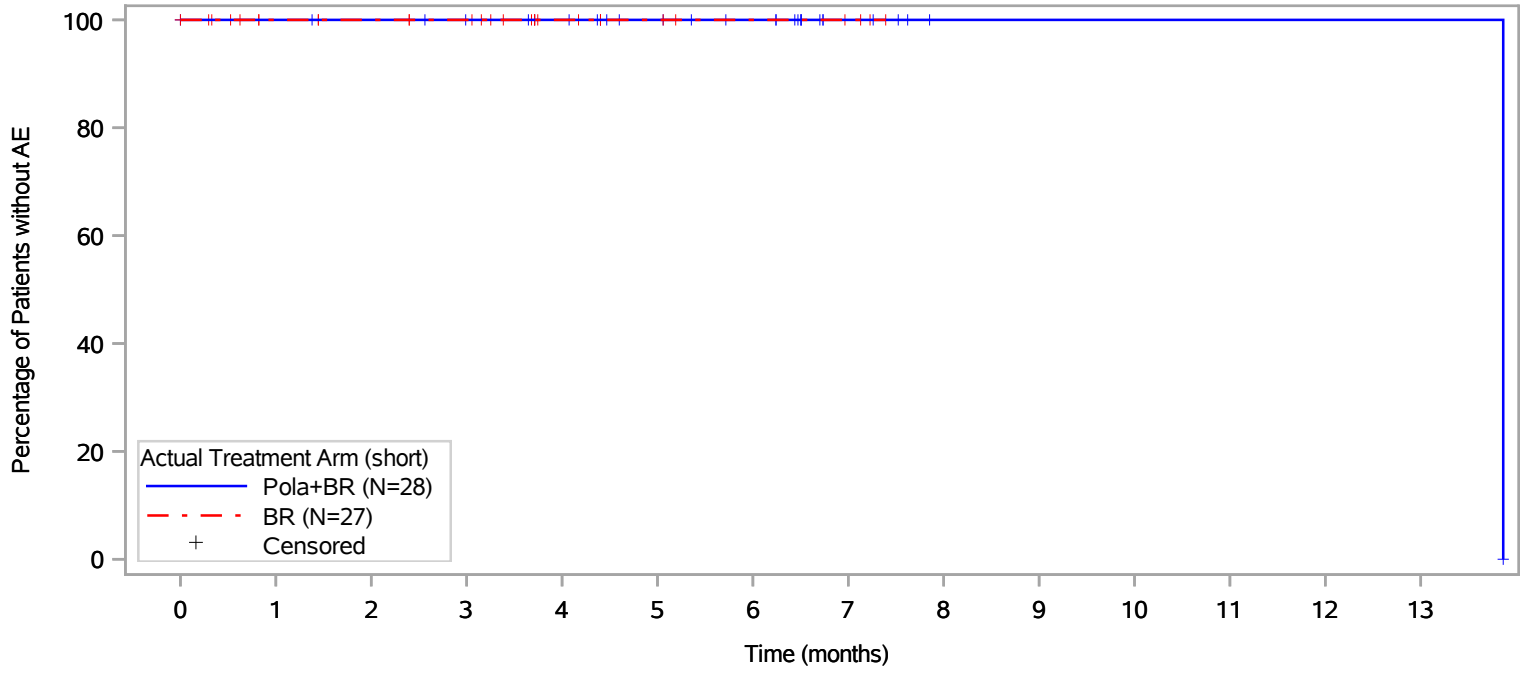
02DEC2022 5:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HAEMORRHAGE INTRACRANIAL

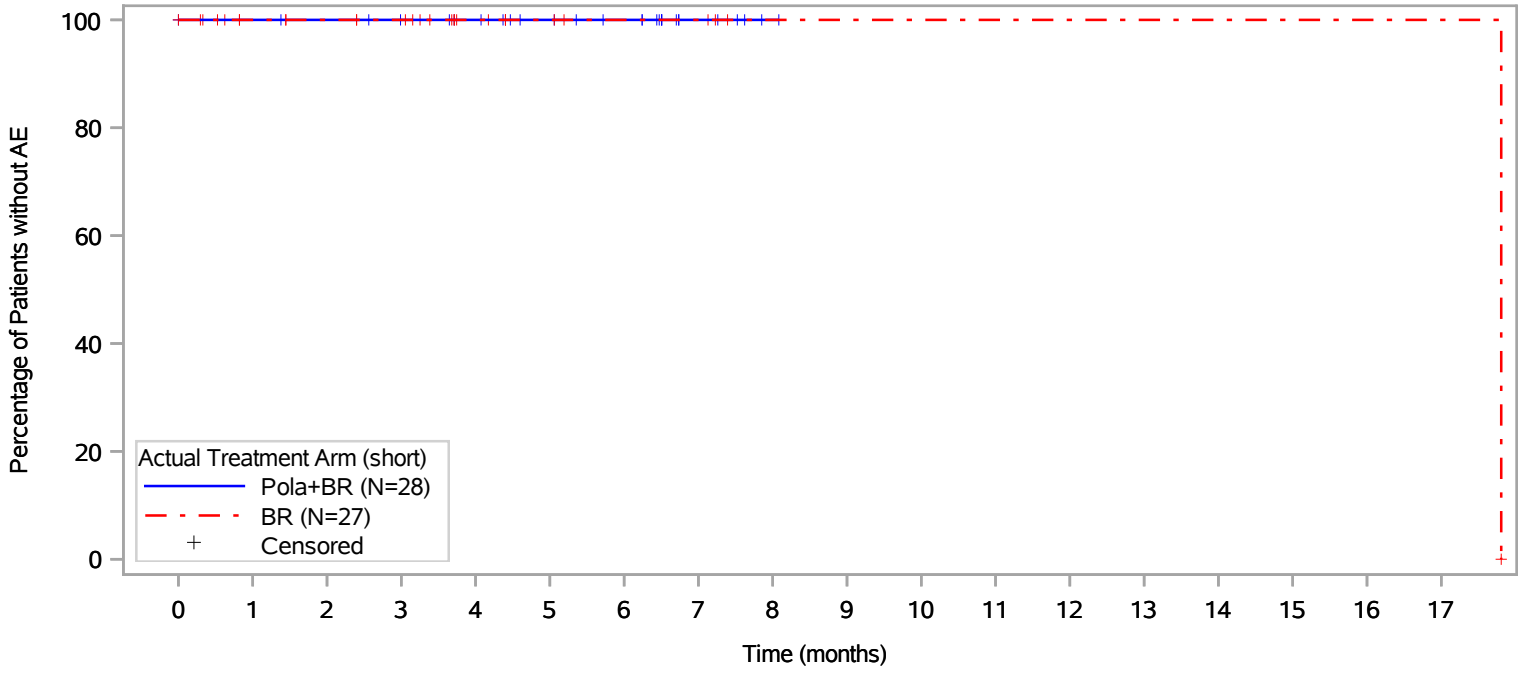


Patients at risk														
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR5AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:16

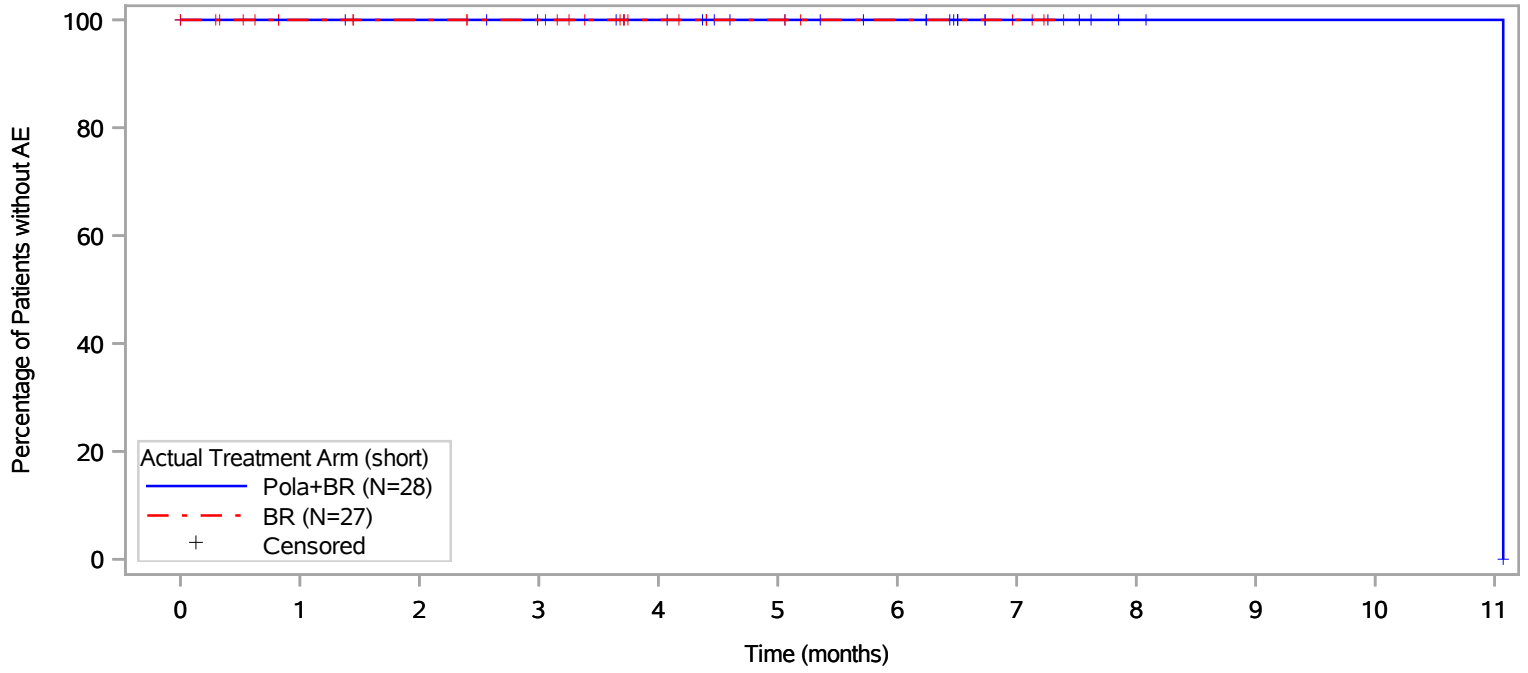
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, LEUKOENCEPHALOPATHY



Patients at risk																		
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	23	26	26	26	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

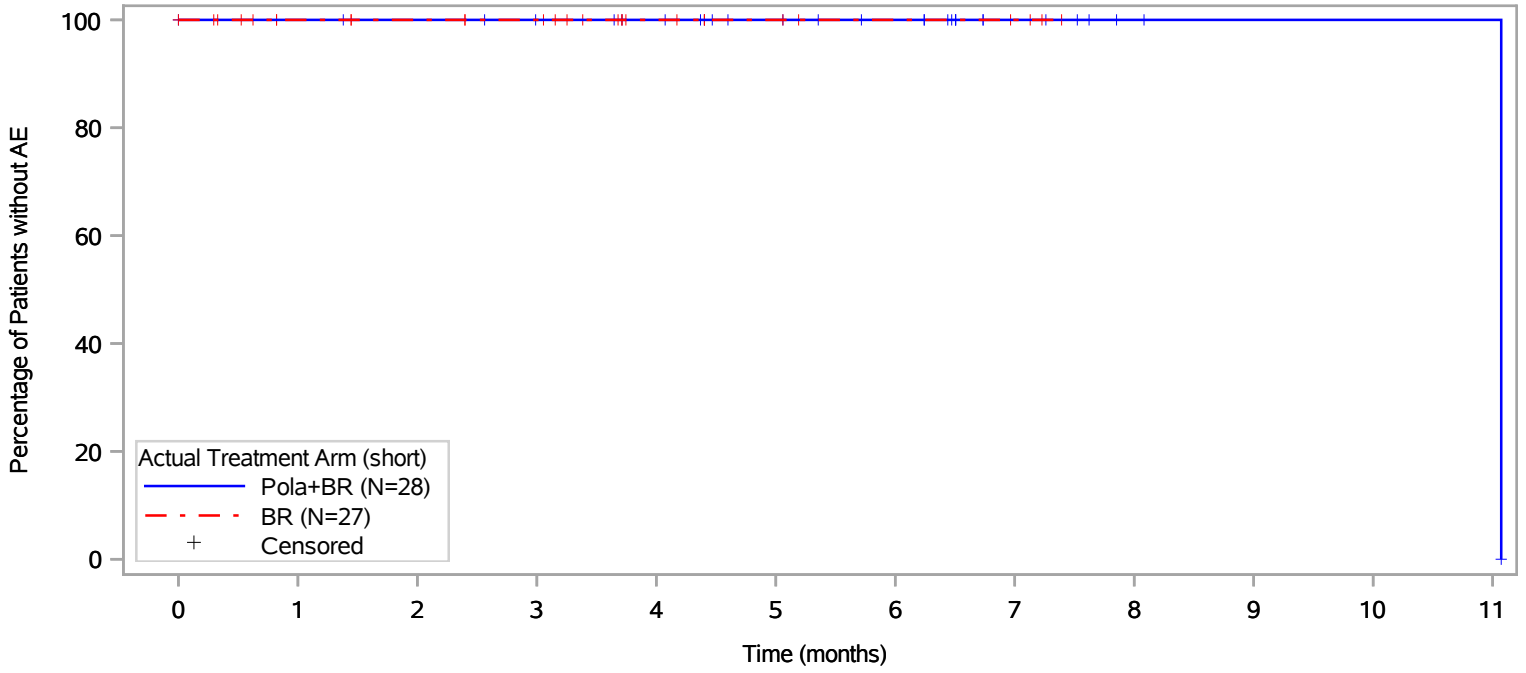
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk												
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

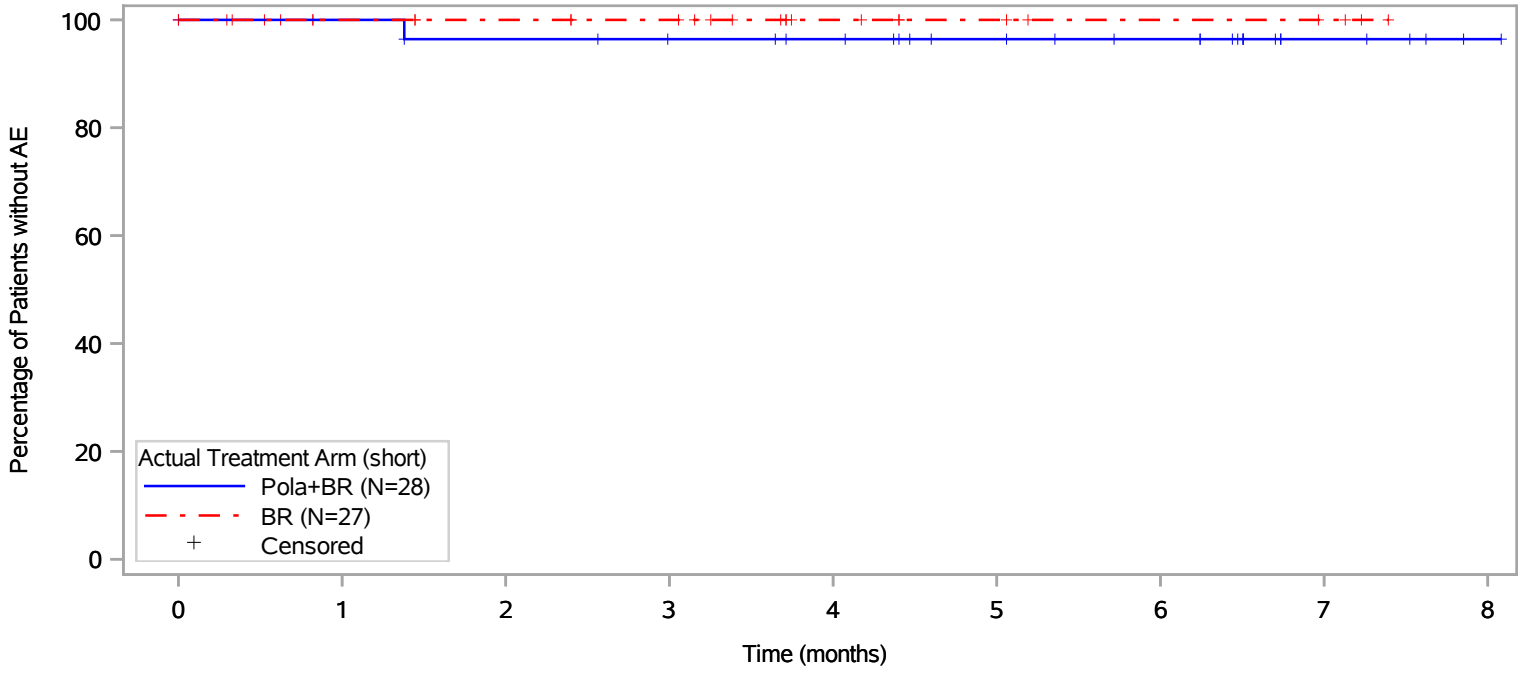
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE



Patients at risk												
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

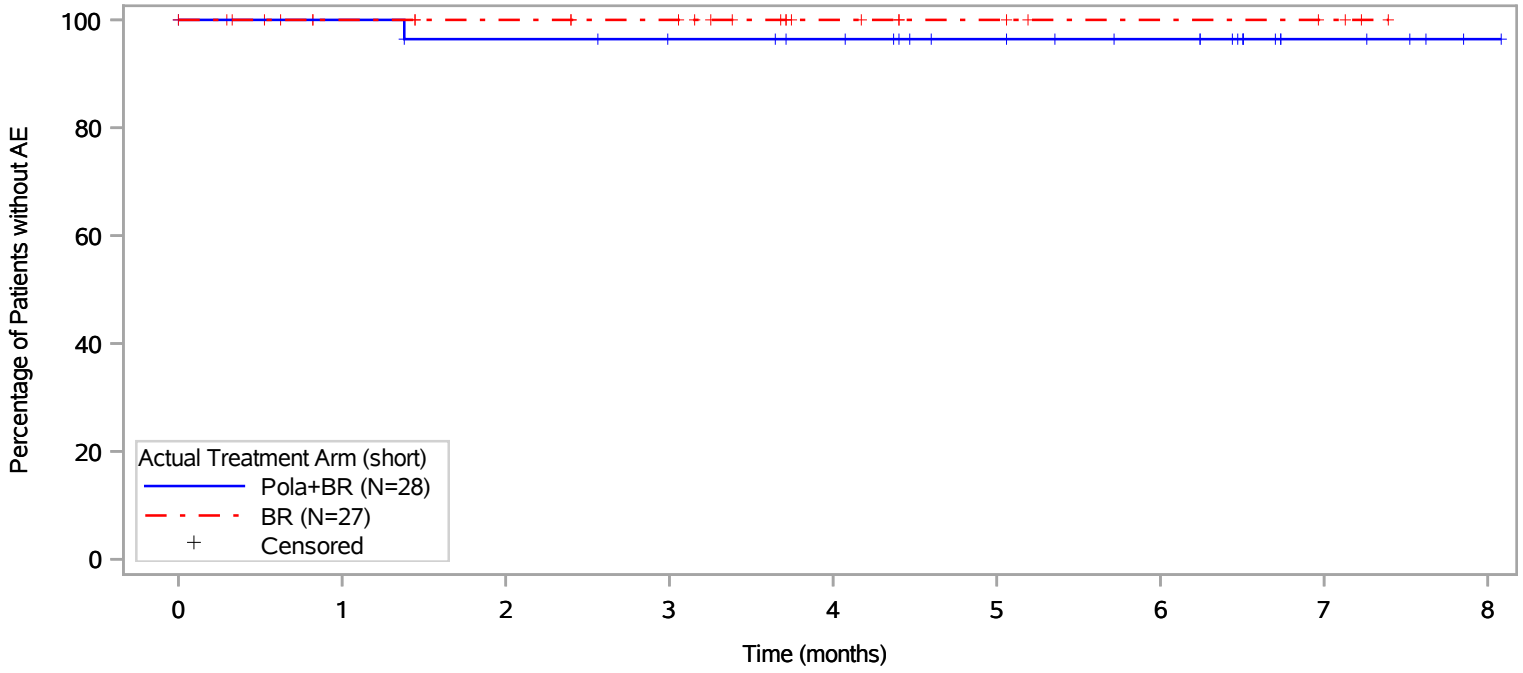
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

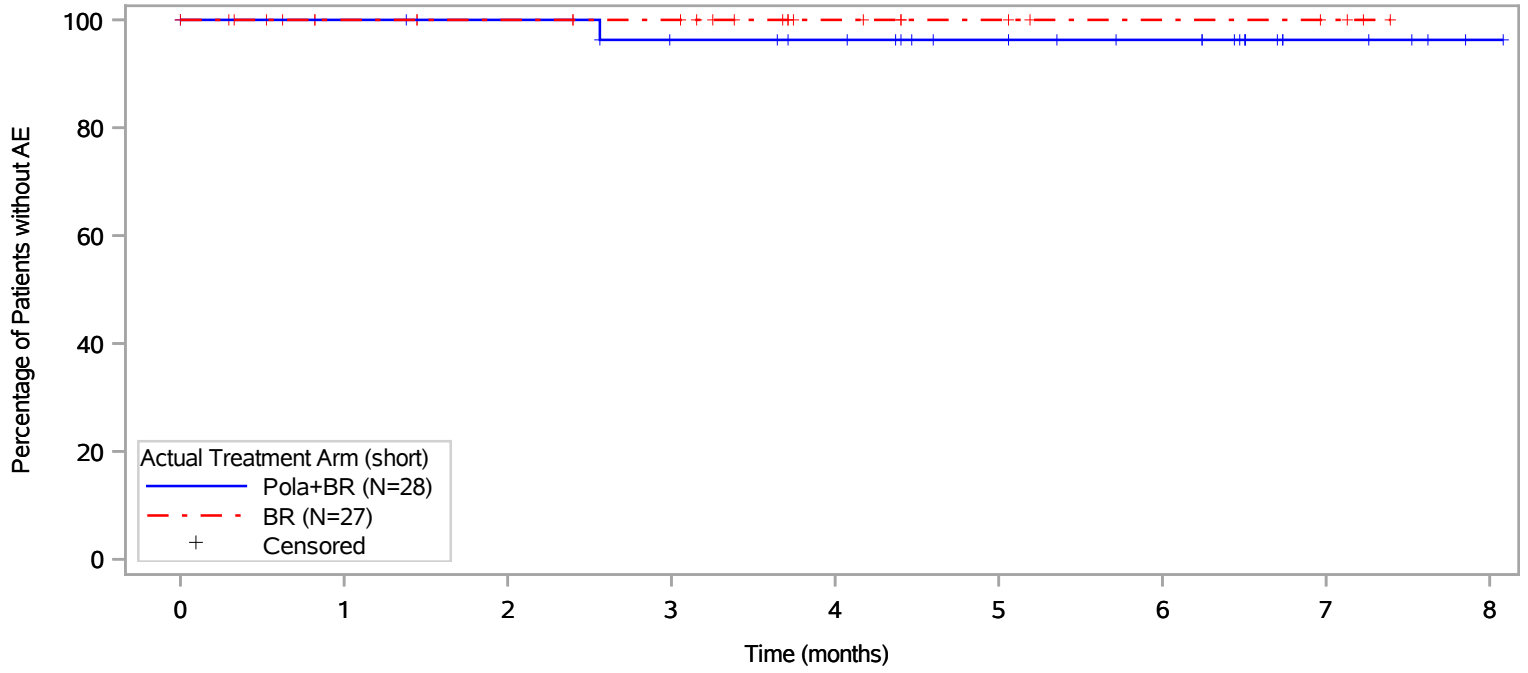
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HAEMOPTYSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All

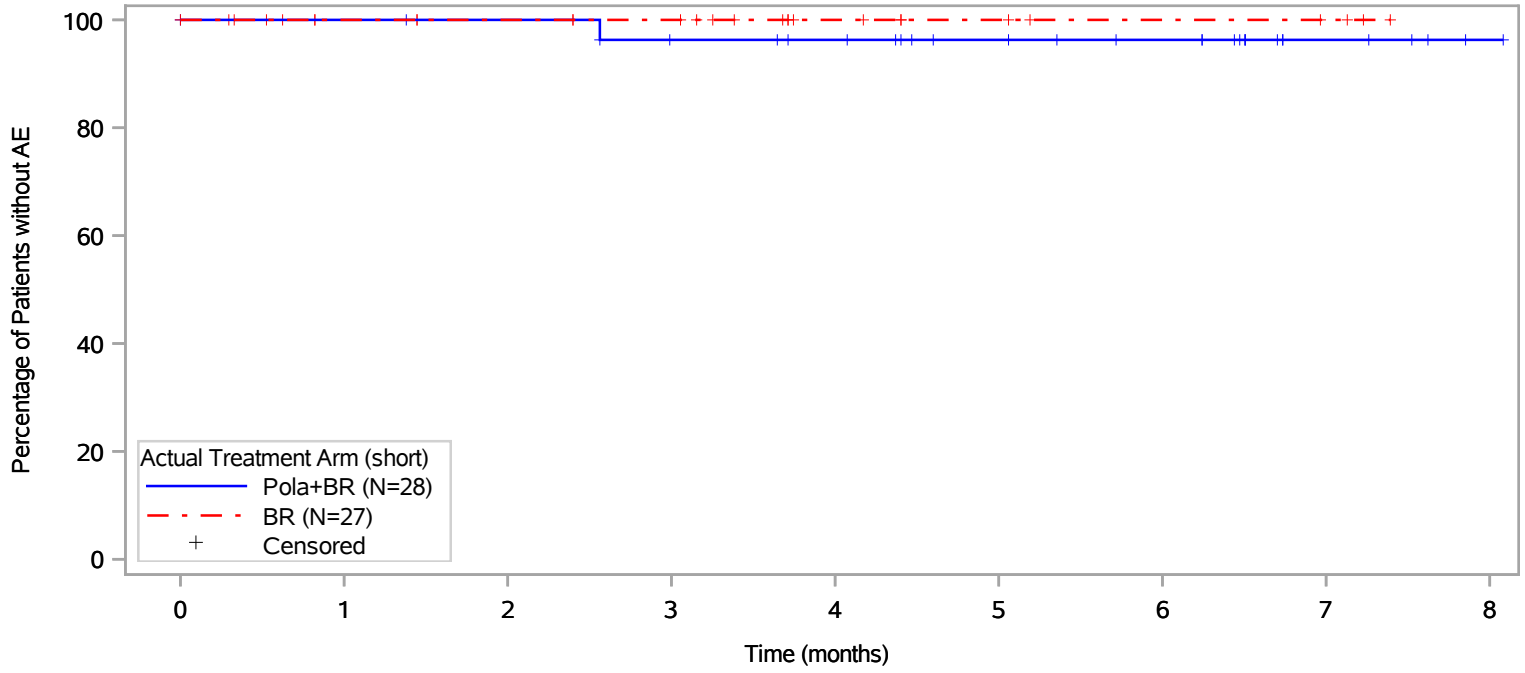


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR5AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DISTRIBUTIVE SHOCK



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..INAL_CSR_Pooled/prod/output_365/g_km_soc_TTGR5AE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 5:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			28	100.0	6	21.4	22	78.6	27	100.0	3	11.1	24	88.9	0.3942	1.99	0.40	9.96		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.9360	0.90	0.08	10.72		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA		28	100.0	4	14.3	24	85.7	27	100.0	2	7.4	25	92.6	0.3974	2.51	0.28	22.71		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2162	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.0909	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.8378	0.77	0.06	9.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	2	7.4	25	92.6	0.9688	0.95	0.06	15.13		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FIBRILLATION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	ATRIAL FLUTTER		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	CARDIAC FAILURE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3261	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			28	100.0	6	21.4	22	78.6	27	100.0	3	11.1	24	88.9	0.9022	1.09	0.26	4.63		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE		28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.4708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	PANCREATITIS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			28	100.0	4	14.3	24	85.7	27	100.0	1	3.7	26	96.3	0.2459	3.39	0.38	30.35		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2332	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		28	100.0	4	14.3	24	85.7	27	100.0	0	-	27	100.0	0.0648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			28	100.0	8	28.6	20	71.4	27	100.0	8	29.6	19	70.4	0.0964	0.39	0.13	1.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2162	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3447	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2801	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		28	100.0	2	7.1	26	92.9	27	100.0	3	11.1	24	88.9	0.4081	0.48	0.08	2.88		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3711	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPSIS		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.5978	0.48	0.03	7.85		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UROSEPSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2076	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MORAXELLA TEST POSITIVE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	TRANSAMINASES INCREASED		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)			28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	3	11.1	24	88.9	0.2018	0.23	0.02	2.65		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0652	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL FAILURE		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			28	100.0	2	7.1	26	92.9	27	100.0	2	7.4	25	92.6	0.6582	0.64	0.09	4.65		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.7646	0.65	0.04	10.99		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			28	100.0	2	7.1	26	92.9	27	100.0	0	-	27	100.0	0.2839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4708	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.4275	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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01DEC2022 2:07

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	13	46.4	3	23.1	10	76.9	13	48.1	2	15.4	11	84.6	0.8973	0.89	0.15	5.37		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	15	53.6	3	20.0	12	80.0	14	51.9	1	7.1	13	92.9	0.1579	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.7363	0.62	0.04	10.25		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	1	7.7	12	92.3	0.8999	1.17	0.10	13.15		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.3124	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	13	46.4	0	-	13	100.0	13	48.1	2	15.4	11	84.6	0.1023	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.7211	0.60	0.04	10.02		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2980	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	13	46.4	3	23.1	10	76.9	13	48.1	1	7.7	12	92.3	0.4651	2.28	0.24	22.05		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	15	53.6	3	20.0	12	80.0	14	51.9	2	14.3	12	85.7	0.6472	0.63	0.09	4.58		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.5002	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3805	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	13	46.4	2	15.4	11	84.6	13	48.1	1	7.7	12	92.3	0.5995	1.88	0.17	20.77		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2325	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.1663	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2325	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.3879	0.36	0.03	4.07		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	15	53.6	7	46.7	8	53.3	14	51.9	6	42.9	8	57.1	0.1093	0.36	0.10	1.32		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.2770	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2636	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.3006	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3918	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.3879	0.36	0.03	4.07		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.8764	0.80	0.05	13.04		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.5636	0.44	0.03	7.45		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2123	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	2	14.3	12	85.7	0.6864	0.55	0.03	10.01		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	13	46.4	0	-	13	100.0	13	48.1	2	15.4	11	84.6	0.0816	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2807	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.1757	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	0.4328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTSAE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 2:07

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	15	53.6	3	20.0	12	80.0	18	66.7	2	11.1	16	88.9	0.4350	2.41	0.25	23.53		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	13	46.4	3	23.1	10	76.9	9	33.3	1	11.1	8	88.9	0.6449	1.69	0.18	16.30		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.6729	0.55	0.03	8.90		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.2253	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.9353	1.10	0.10	12.20		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.5054	0.39	0.02	6.73		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.9134	1.17	0.07	18.65		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	15	53.6	4	26.7	11	73.3	18	66.7	1	5.6	17	94.4	0.6184	1.77	0.18	17.39		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	13	46.4	2	15.4	11	84.6	9	33.3	2	22.2	7	77.8	0.9137	1.14	0.10	12.70		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.4631	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2593	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.4054	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1730	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1542	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.7870	1.39	0.13	15.34		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	15	53.6	2	13.3	13	86.7	18	66.7	0	-	18	100.0	0.1542	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	0	-	9	100.0	0.2437	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS		>=3	15	53.6	5	33.3	10	66.7	18	66.7	5	27.8	13	72.2	0.3381	0.50	0.12	2.13		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS		<3	13	46.4	3	23.1	10	76.9	9	33.3	3	33.3	6	66.7	0.1774	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2542	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3017	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1386	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.7990	1.37	0.12	15.45		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	SEPSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.6666	0.55	0.03	8.94		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	SEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INFECTIONS AND INFESTATIONS	UROSEPSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INFECTIONS AND INFESTATIONS	UROSEPSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INVESTIGATIONS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INVESTIGATIONS		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INVESTIGATIONS	MORAXELLA TEST POSITIVE	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
INVESTIGATIONS	TRANSAMINASES INCREASED	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
INVESTIGATIONS	TRANSAMINASES INCREASED	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3340	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.		-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	3	16.7	15	83.3	0.2211	0.24	0.02	2.80		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.0679	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.1213	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	15	53.6	2	13.3	13	86.7	18	66.7	1	5.6	17	94.4	0.7482	1.49	0.13	17.37		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3519	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.1904	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.7918	0.68	0.04	12.16		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTSAE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 2:07

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	67.9	5	26.3	14	73.7	14	51.9	2	14.3	12	85.7	0.9086	0.90	0.16	5.03		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.4890	0.38	0.02	6.47		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	1	7.1	13	92.9	0.6059	1.78	0.19	16.19		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1693	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	2	14.3	12	85.7	0.0573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.7535	0.68	0.06	7.81		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2267	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Europe	9	32.1	3	33.3	6	66.7	13	48.1	2	15.4	11	84.6	0.2778	3.27	0.34	31.46		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	1	7.1	13	92.9	0.7054	0.62	0.05	7.57		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	1	7.1	13	92.9	0.5420	2.00	0.21	19.20		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2008	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2294	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	0	-	14	100.0	0.1648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Europe	9	32.1	4	44.4	5	55.6	13	48.1	6	46.2	7	53.8	0.1287	0.30	0.06	1.54		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	2	14.3	12	85.7	0.6716	0.68	0.11	4.18		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4081	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2689	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	1	7.7	12	92.3	0.9301	1.13	0.07	18.50		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	2	14.3	12	85.7	0.1605	0.20	0.02	2.34		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.2888	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4268	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	2	15.4	11	84.6	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.0190	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.0190	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	2	14.3	12	85.7	0.4049	0.44	0.06	3.22		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.5545	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	0	-	14	100.0	0.3684	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_soc_sgl_TTSAE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 2:07

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	20	71.4	4	20.0	16	80.0	18	66.7	3	16.7	15	83.3	0.7979	1.25	0.23	6.92		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2079	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.9354	0.90	0.08	10.50		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	2	11.1	16	88.9	0.9087	1.15	0.10	12.83		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	FEBRILE NEUTROPENIA	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2079	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.0881	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.5594	0.43	0.02	7.69		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	2	22.2	7	77.8	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FIBRILLATION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	ATRIAL FLUTTER	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	ATRIAL FLUTTER	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	CARDIAC FAILURE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	CARDIAC FAILURE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SUPRAVENTRICULAR TACHYCARDIA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3428	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	20	71.4	5	25.0	15	75.0	18	66.7	2	11.1	16	88.9	0.8526	1.18	0.21	6.57		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DUODENAL ULCER HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	OBSTRUCTION GASTRIC	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	PANCREATITIS	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	PANCREATITIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	20	71.4	3	15.0	17	85.0	18	66.7	1	5.6	17	94.4	0.4190	2.47	0.26	23.72		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2320	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MULTIPLE ORGAN DYSFUNCTION SYNDROME	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	20	71.4	3	15.0	17	85.0	18	66.7	0	-	18	100.0	0.1164	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	20	71.4	8	40.0	12	60.0	18	66.7	5	27.8	13	72.2	0.4338	0.61	0.17	2.14		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	8	28.6	0	-	8	100.0	9	33.3	3	33.3	6	66.7	0.0488	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2083	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	CYTOMEGALOVIRUS INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	DEVICE RELATED INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.2918	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	ENTEROCOLITIS VIRAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	GASTROINTESTINAL BACTERIAL INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HUMAN ANAPLASMOSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	LOWER RESPIRATORY TRACT INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2850	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	NEUTROPENIC SEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMOCYSTIS JIROVECII PNEUMONIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	20	71.4	2	10.0	18	90.0	18	66.7	3	16.7	15	83.3	0.3504	0.43	0.07	2.63		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA PNEUMOCOCCAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	RHINOVIRUS INFECTION	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UROSEPSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UROSEPSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FALL	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	HEAD INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MORAXELLA TEST POSITIVE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	TRANSAMINASES INCREASED	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	TRANSAMINASES INCREASED	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.3566	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	MALIGNANT MELANOMA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	2	11.1	16	88.9	0.6901	0.56	0.03	10.06		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBRAL HAEMORRHAGE	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	CEREBROVASCULAR ACCIDENT	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HAEMORRHAGE INTRACRANIAL	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	LEUKOENCEPHALOPATHY	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	ACUTE KIDNEY INJURY	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL FAILURE	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL FAILURE	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	8	28.6	2	25.0	6	75.0	9	33.3	1	11.1	8	88.9	0.7975	1.38	0.12	15.83		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Male	20	71.4	0	-	20	100.0	18	66.7	1	5.6	17	94.4	0.1797	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HYPOXIA	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8012	0.69	0.04	12.04		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	20	71.4	2	10.0	18	90.0	18	66.7	0	-	18	100.0	0.3074	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DEEP VEIN THROMBOSIS	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	DISTRIBUTIVE SHOCK	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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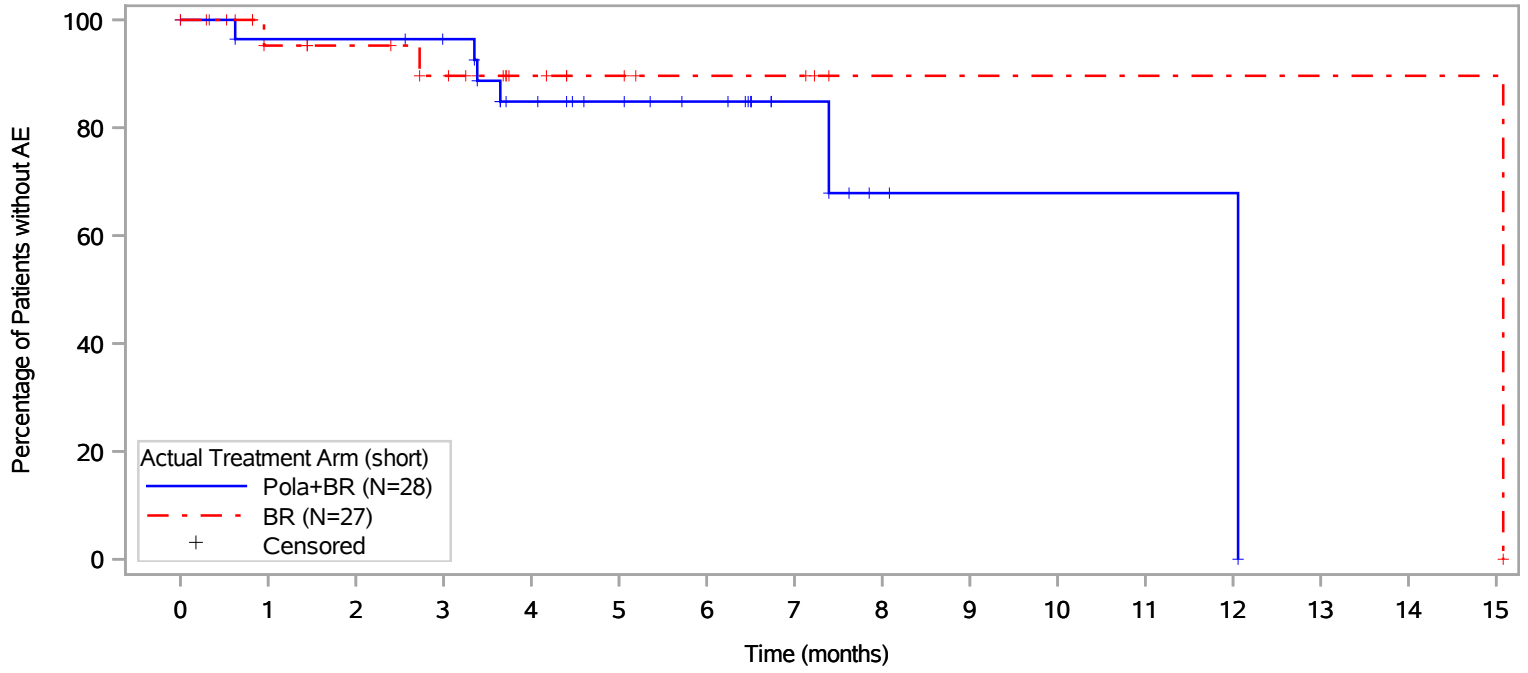
01DEC2022 2:07

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk																
Pola+BR (N=28)	28	27	27	25	20	16	13	5	2	1	1	1	1	NE	NE	NE
BR (N=27)	27	20	18	16	9	6	4	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=28)	0	0	0	2	4	8	11	19	21	22	22	22	22	NE	NE	NE
BR (N=27)	0	6	8	9	16	19	21	21	24	24	24	24	24	24	24	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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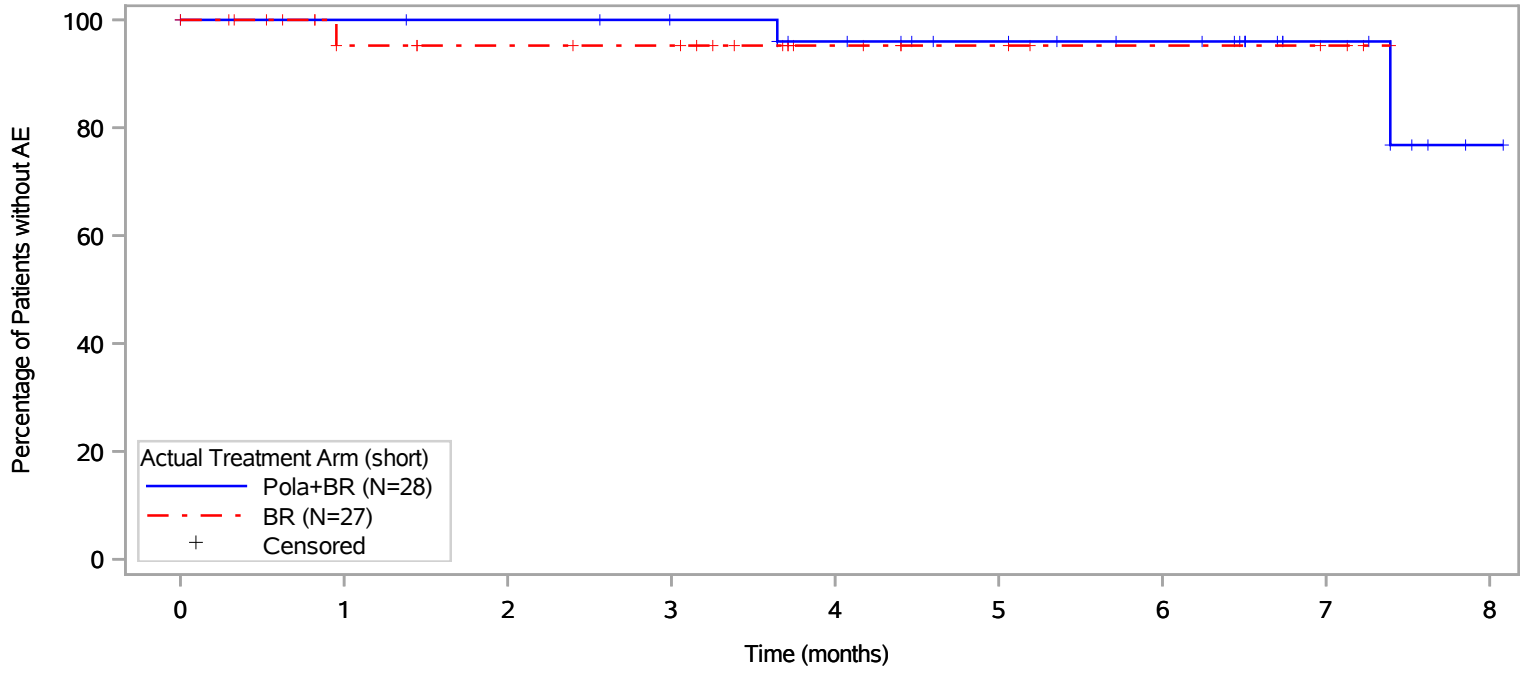
02DEC2022 6:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	6	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	21	25
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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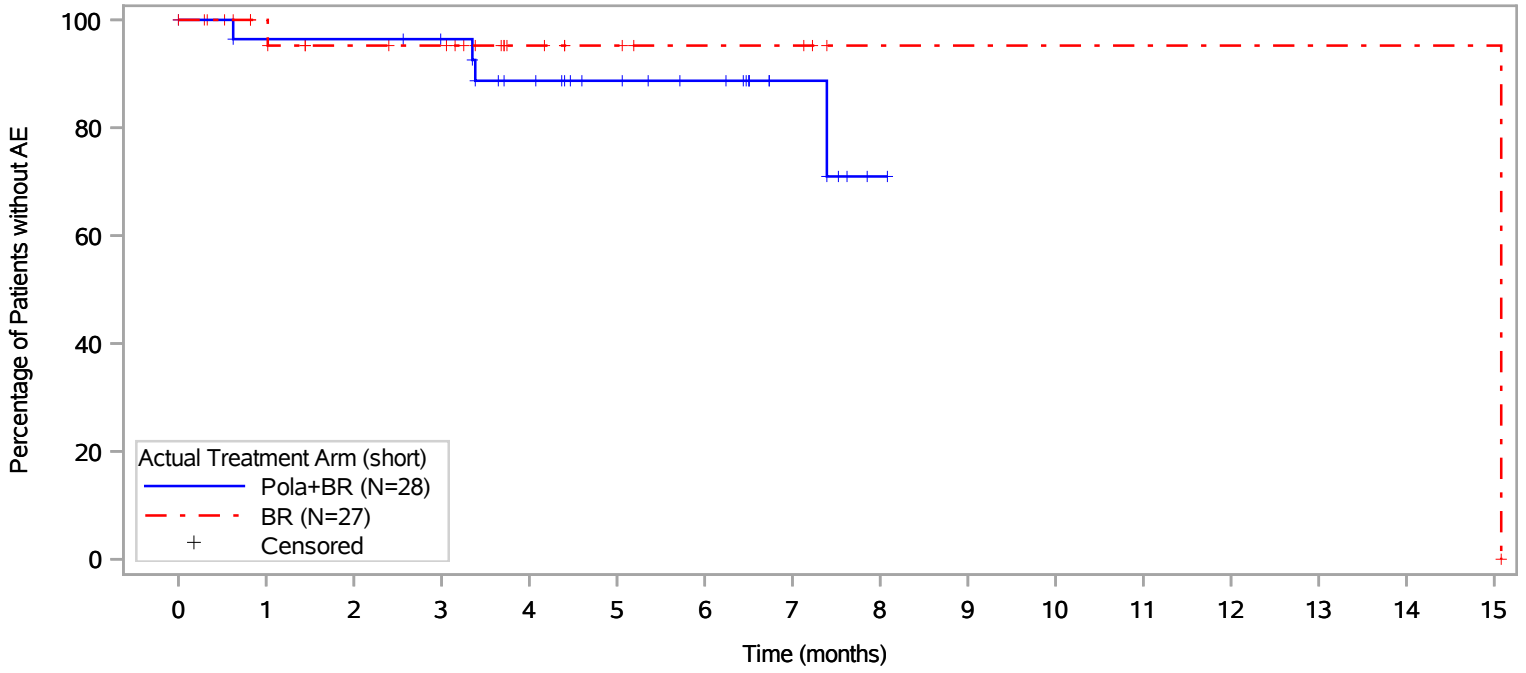
02DEC2022 6:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, FEBRILE NEUTROPENIA

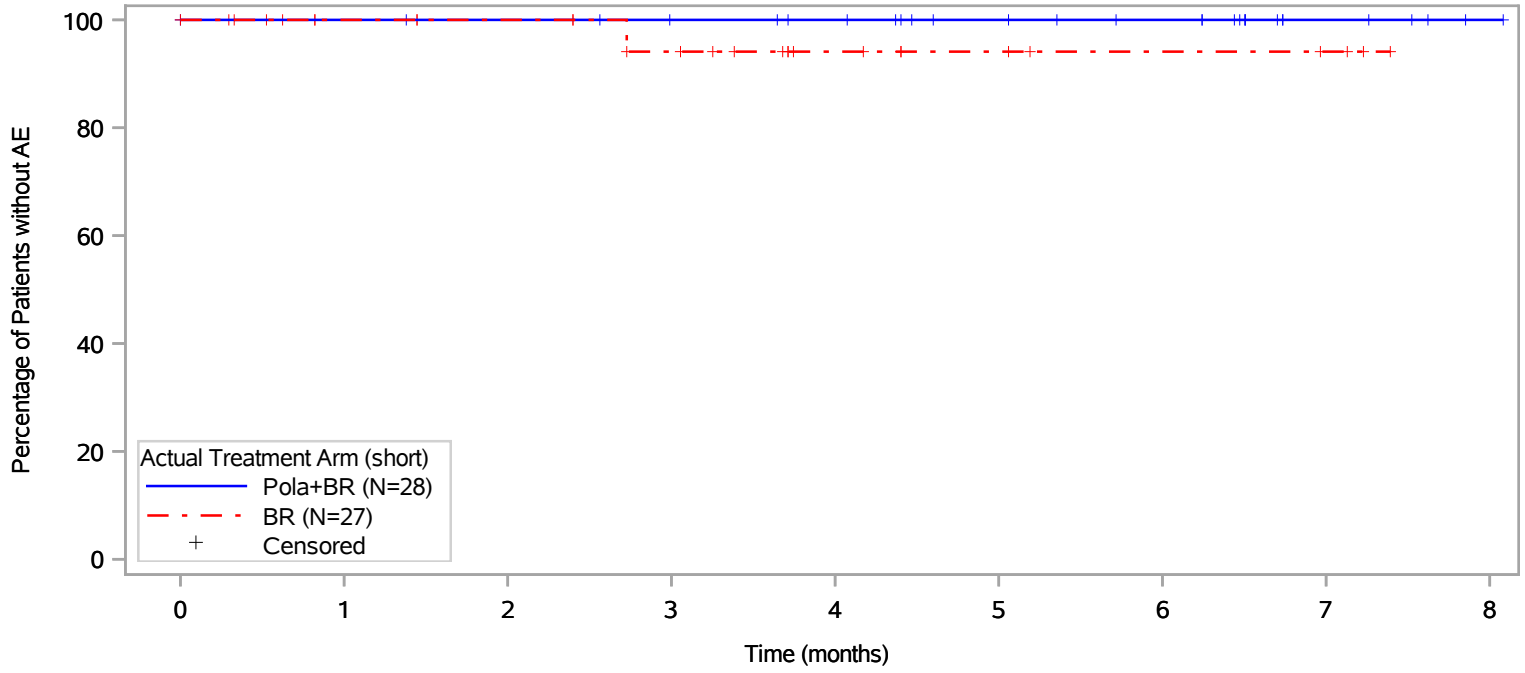


Patients at risk																
Pola+BR (N=28)	28	27	27	25	21	16	13	5	1	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	18	17	9	6	4	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=28)	0	0	0	2	4	9	12	20	23	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	9	17	20	22	22	25	25	25	25	25	25	25	25

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA

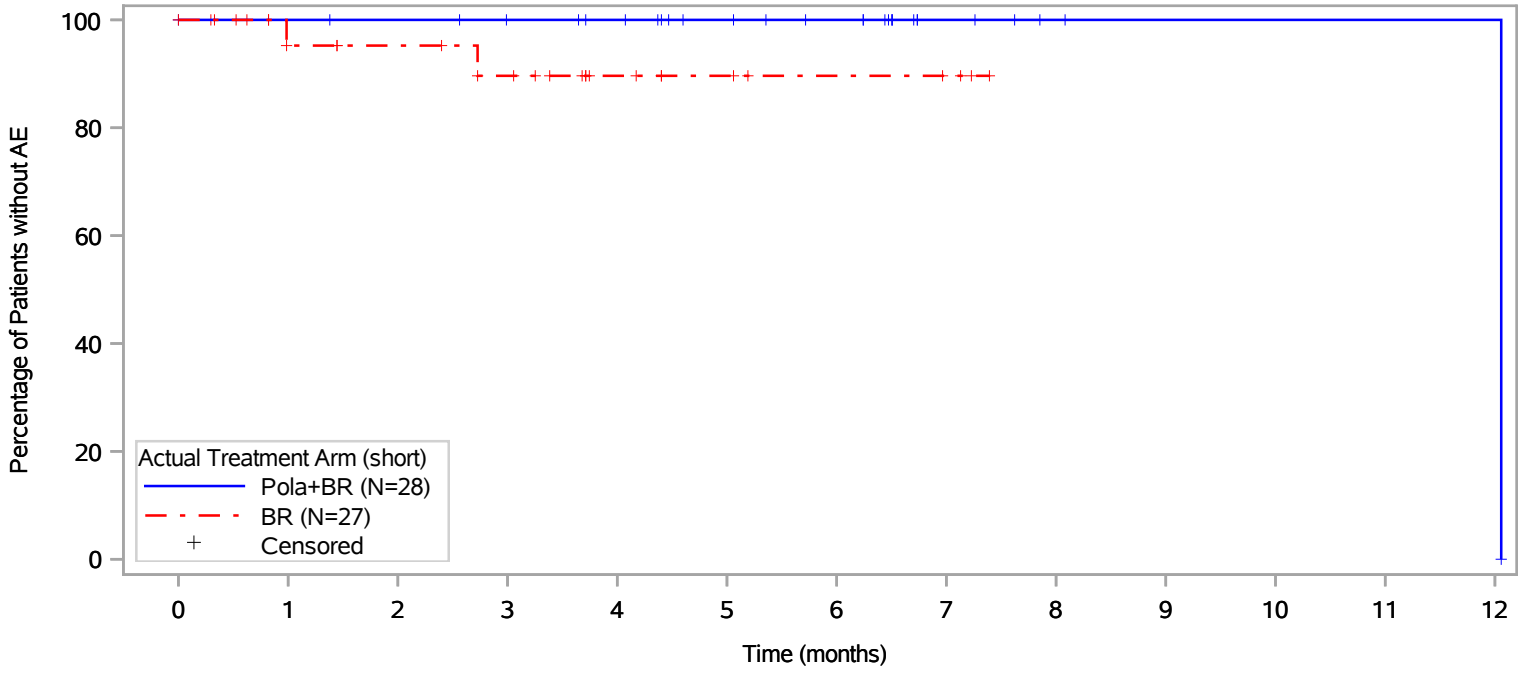


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA

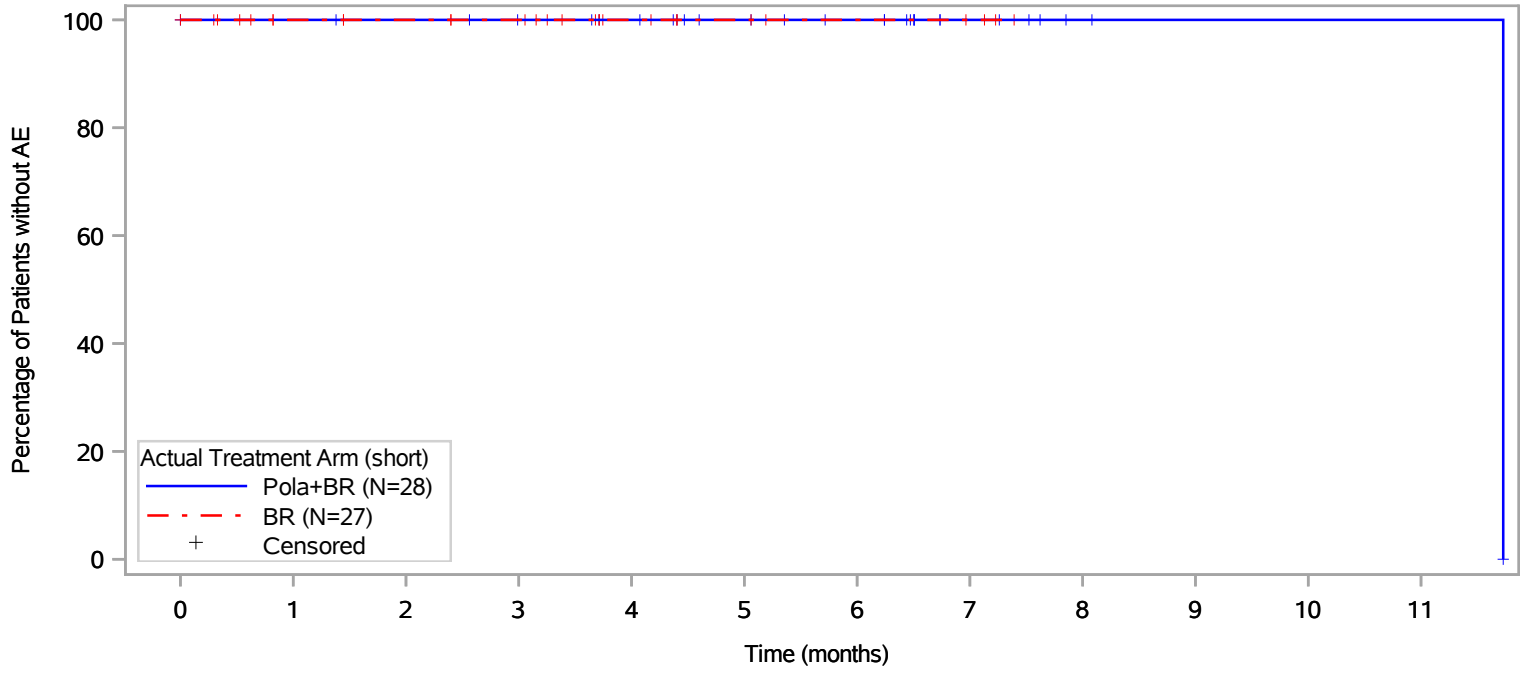


Patients at risk													
Pola+BR (N=28)	28	28	27	25	23	18	15	5	2	1	1	1	1
BR (N=27)	27	20	18	16	9	6	4	3	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26	27	27	27	27
BR (N=27)	0	6	8	9	16	19	21	22	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, PANCYTOPENIA

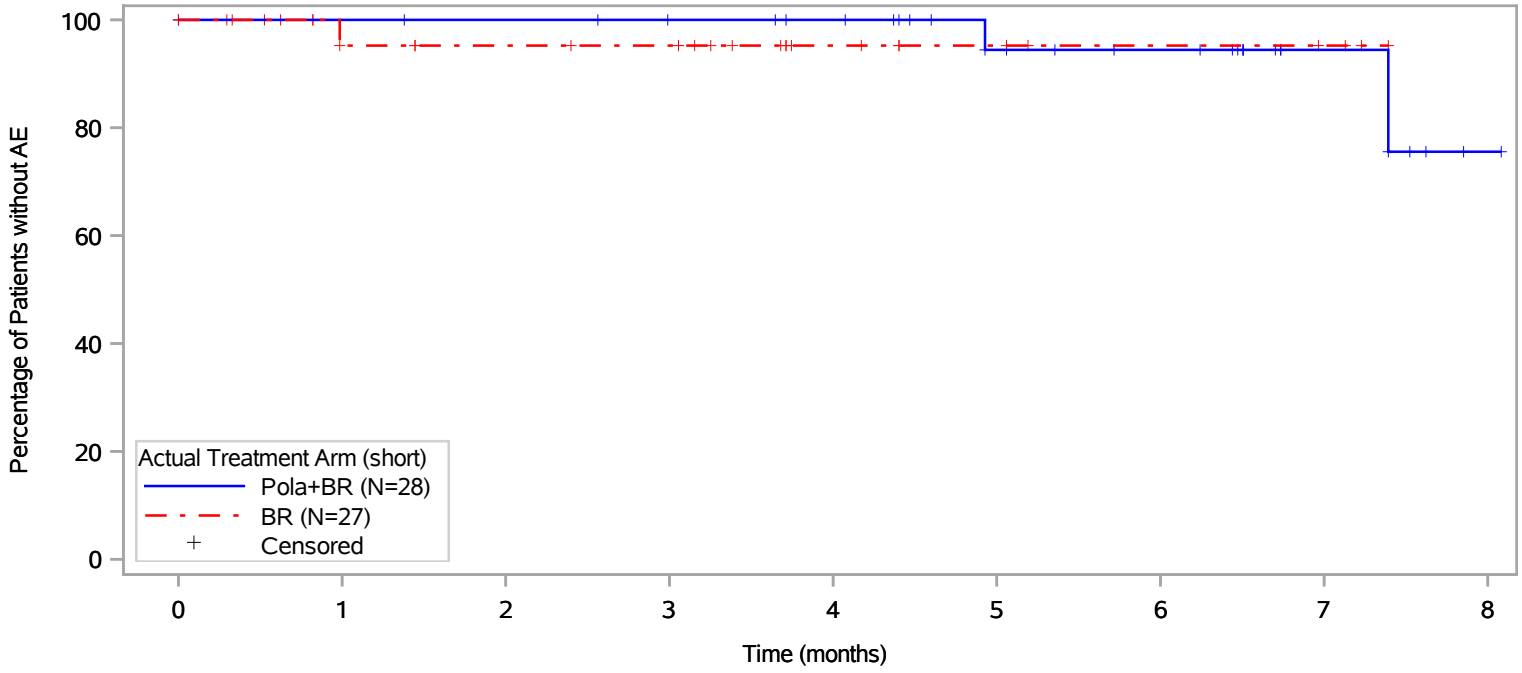


Patients at risk												
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE
Patients censored												
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

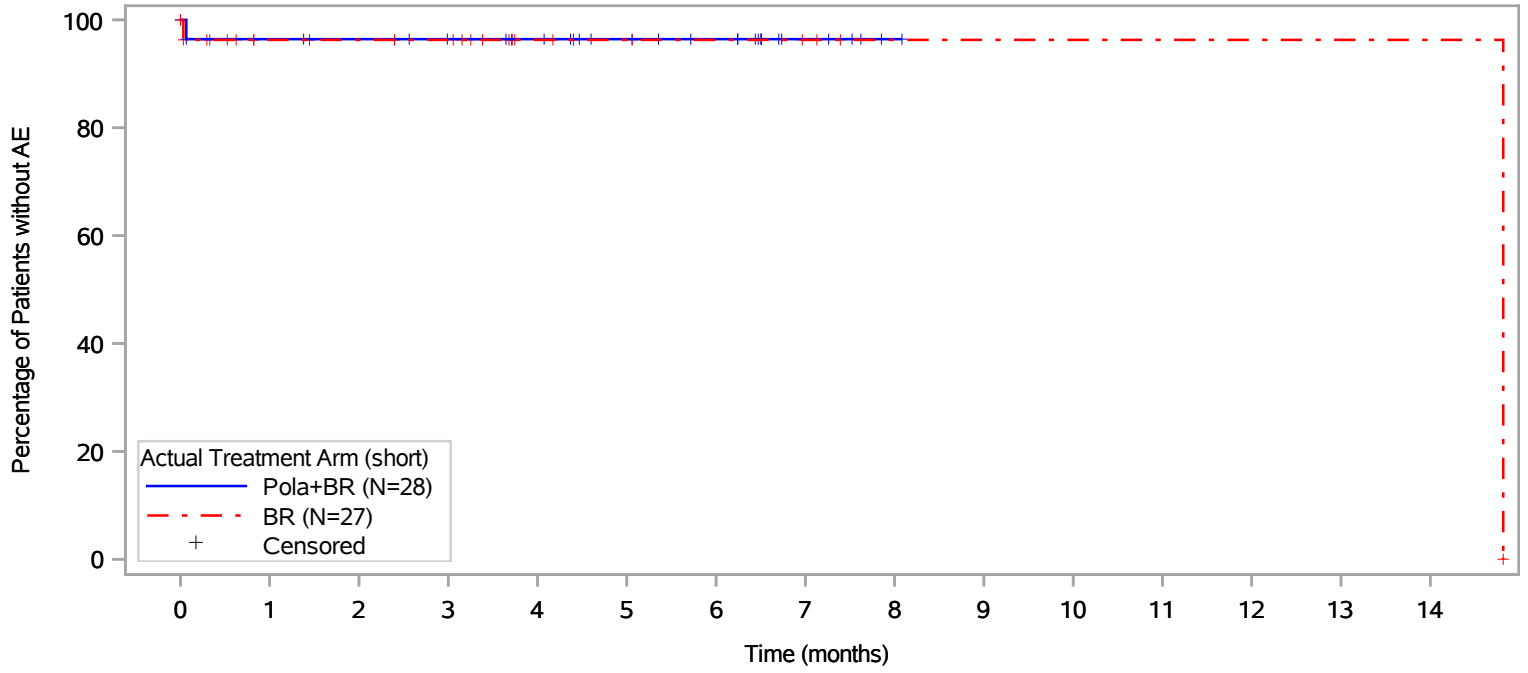
BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	25
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

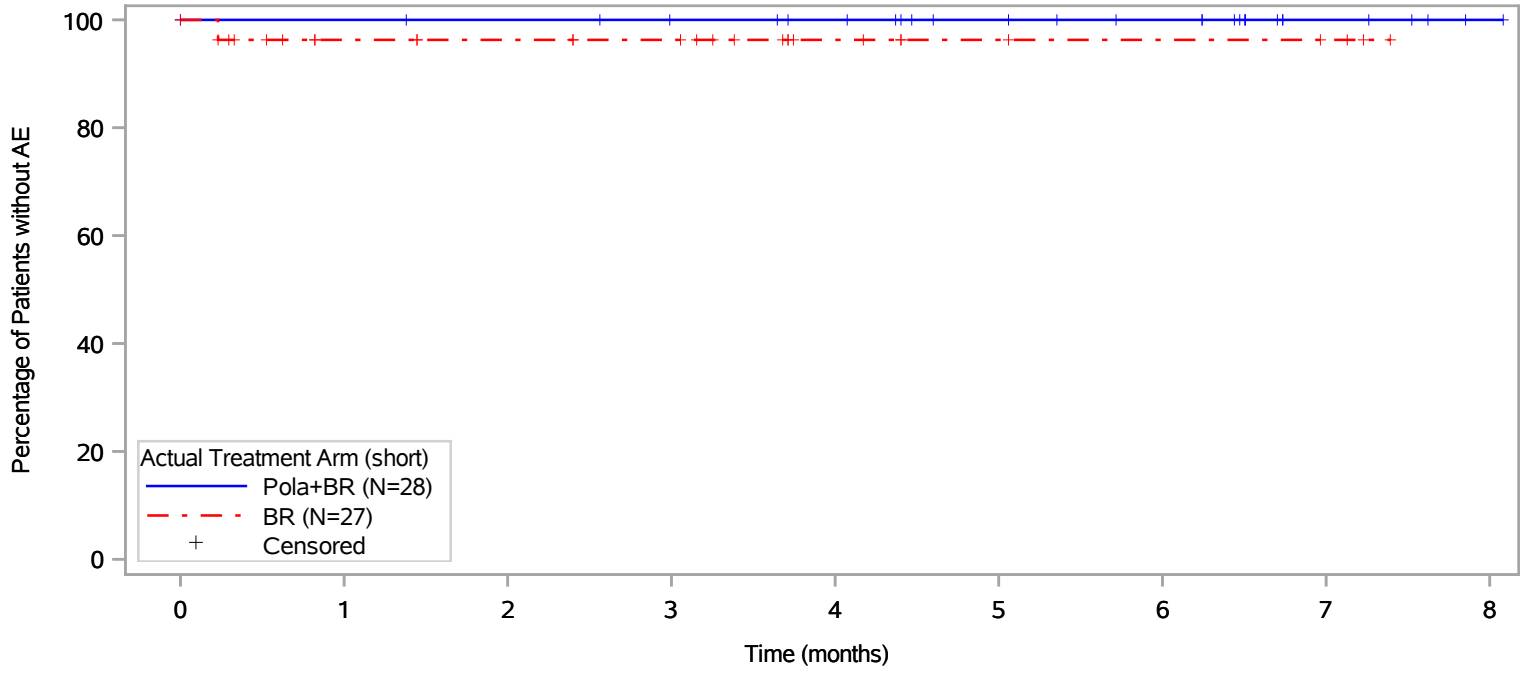
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk															
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1	NE	NE	NE	NE	NE	NE
BR (N=27)	27	20	18	16	8	5	4	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	22	23	25	25	25	25	25	25	25

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

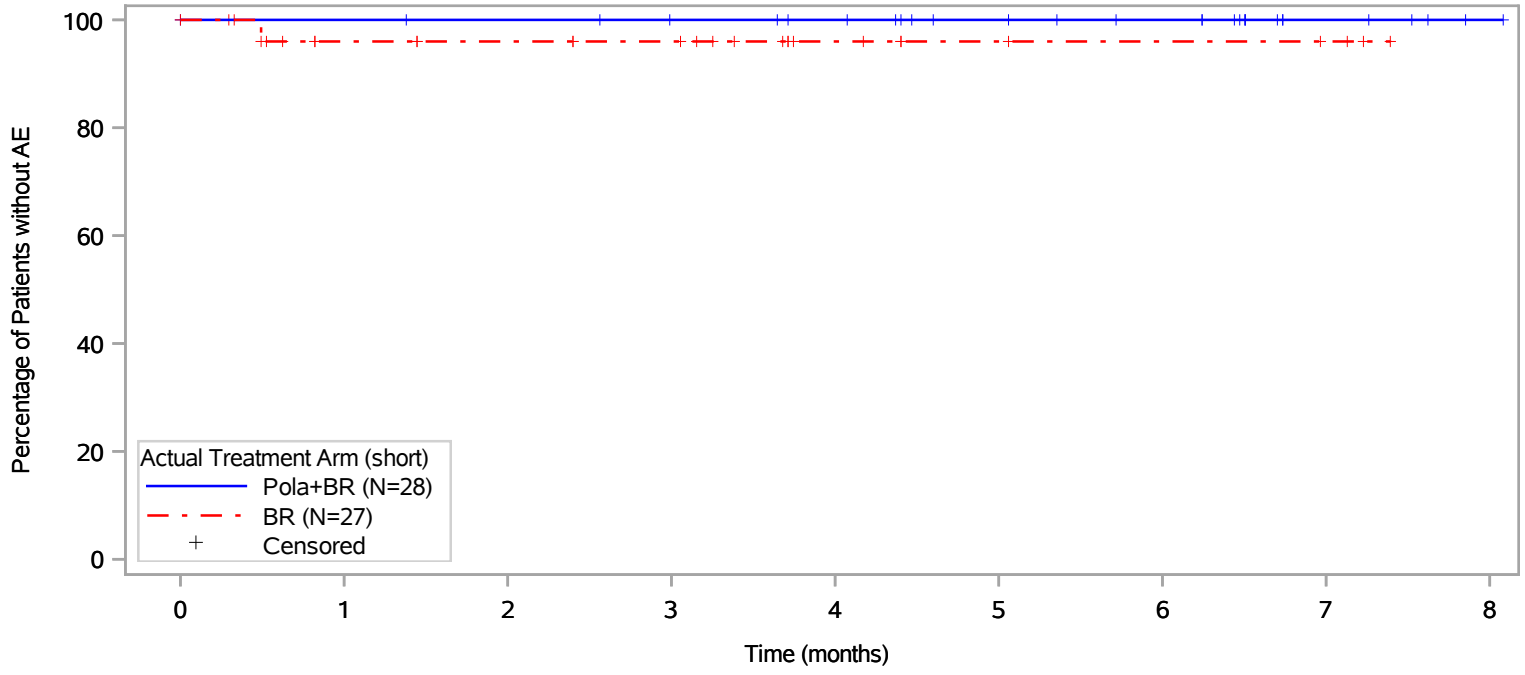
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FIBRILLATION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

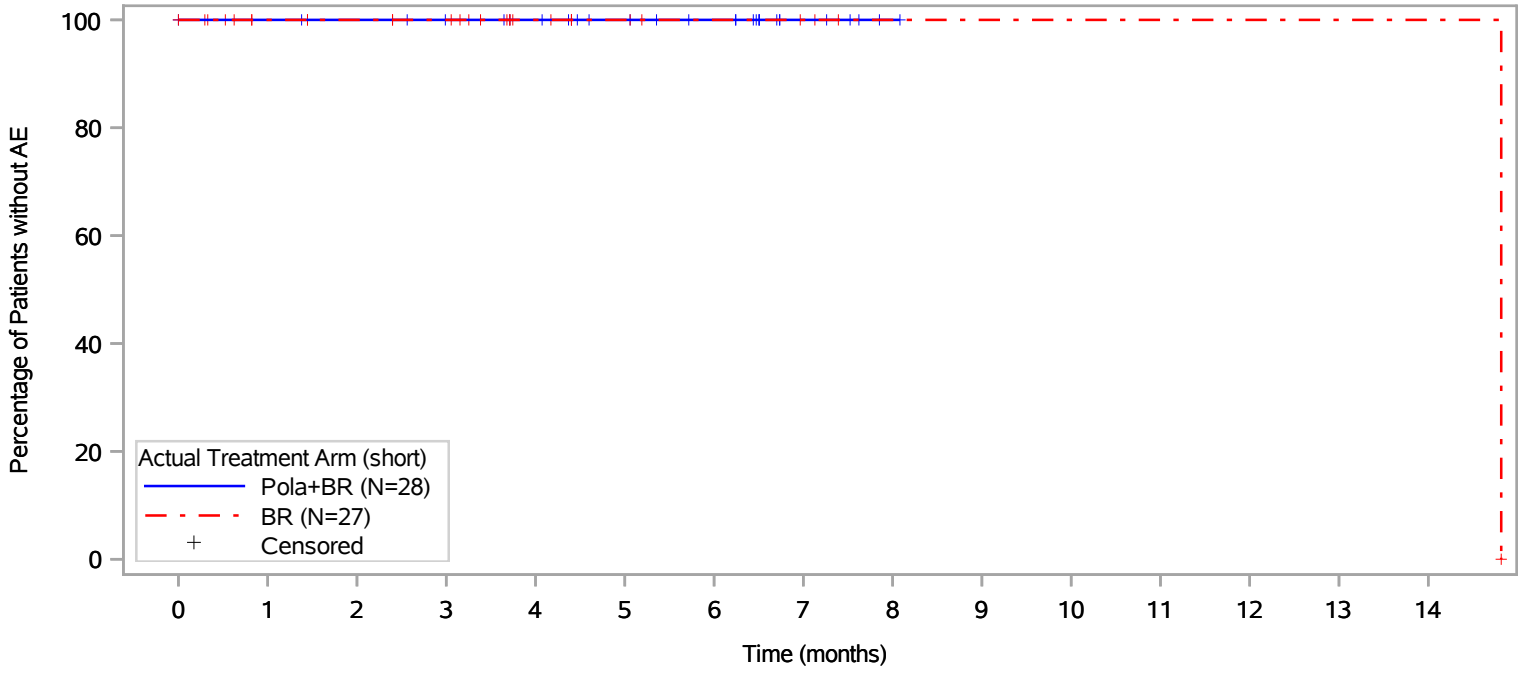
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, ATRIAL FLUTTER



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, CARDIAC FAILURE



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	3	1	1	1	1	1	1	1
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	24	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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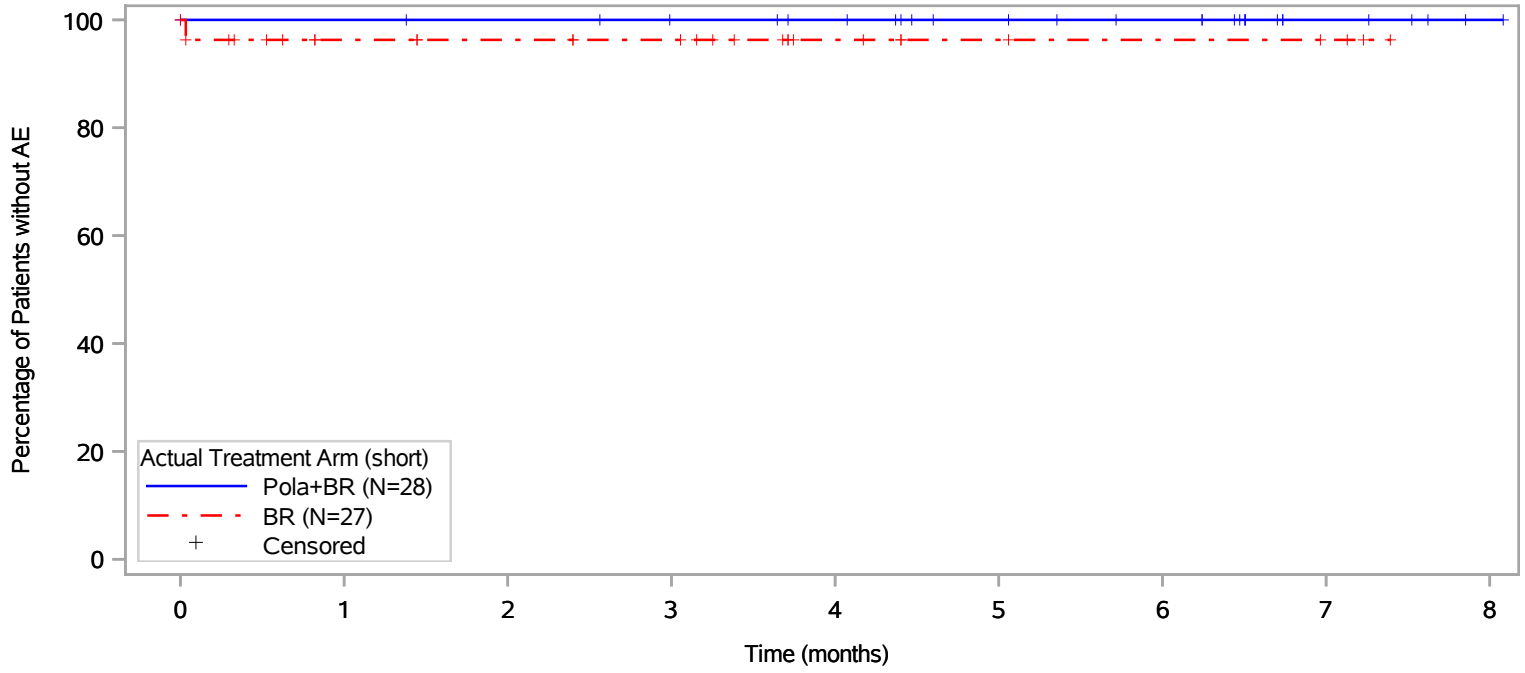
02DEC2022 6:11

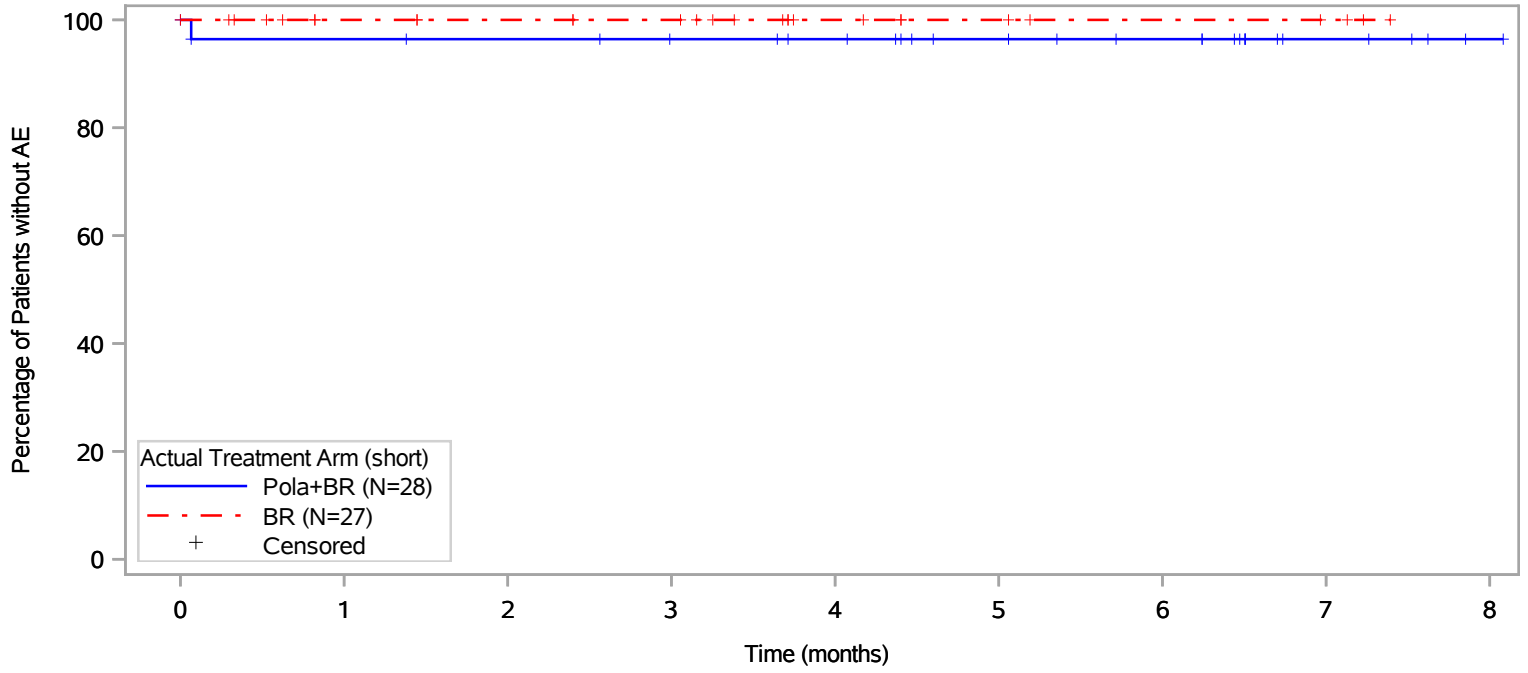
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SUPRAVENTRICULAR TACHYCARDIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

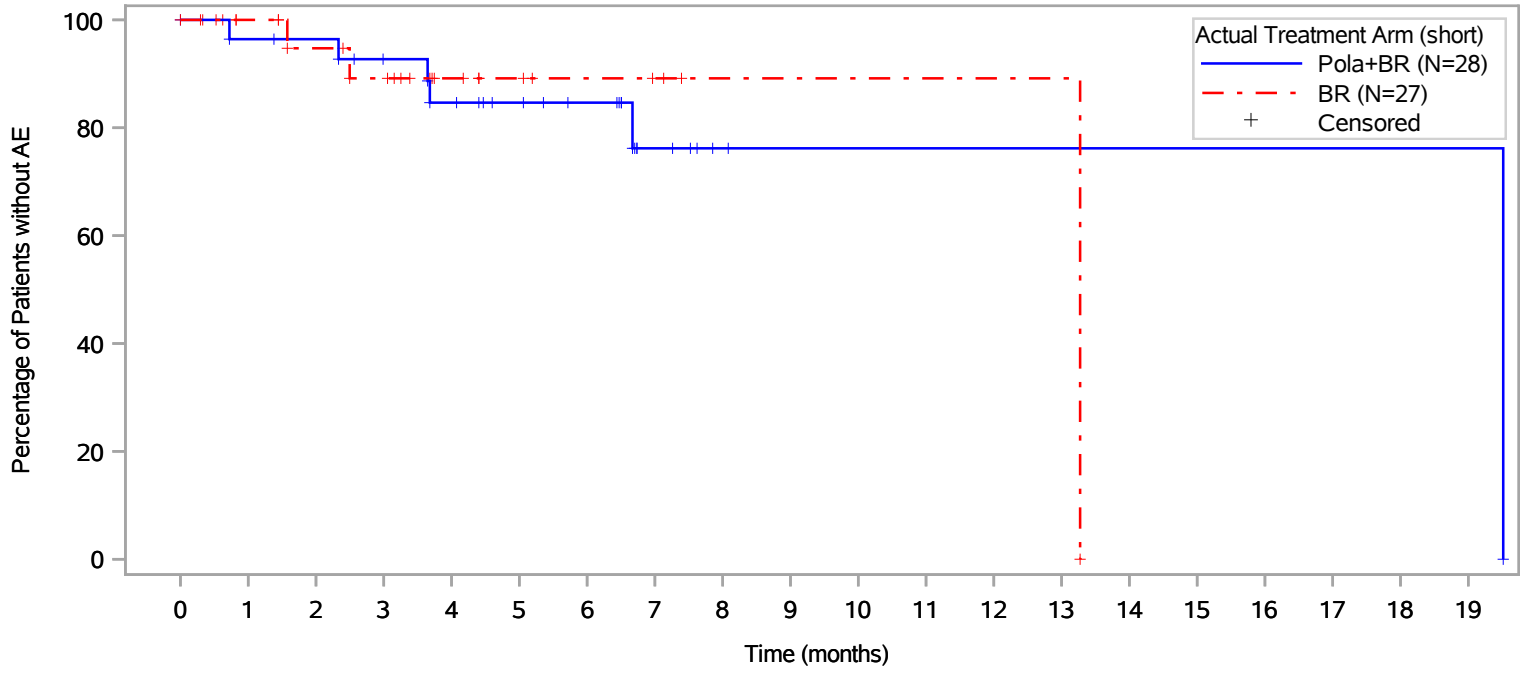
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk																				
Pola+BR (N=28)	28	27	26	23	21	17	14	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	18	16	9	6	4	3	1	1	1	1	1	1	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	3	7	10	17	21	22	22	22	22	22	22	22	22	22	22	22
BR (N=27)	0	6	8	9	16	19	21	22	24	24	24	24	24	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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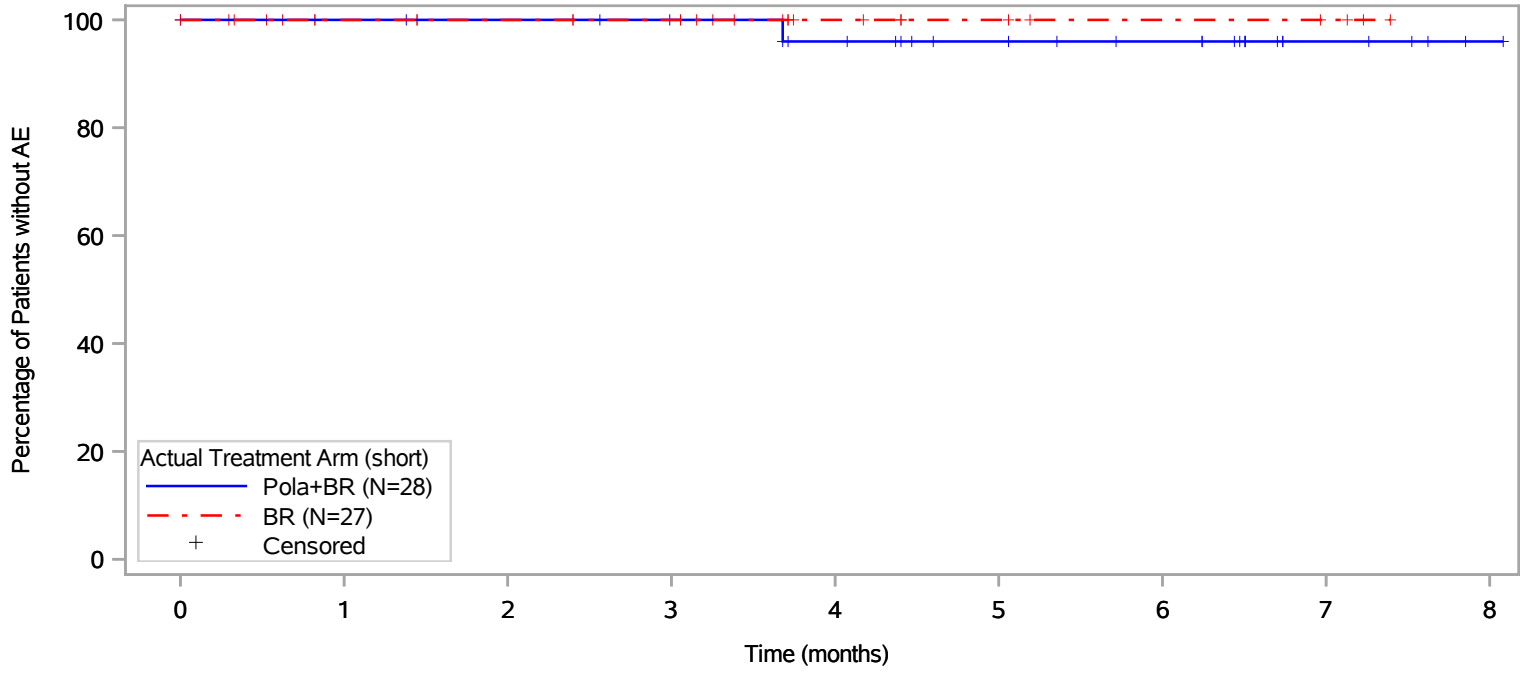
02DEC2022 6:11

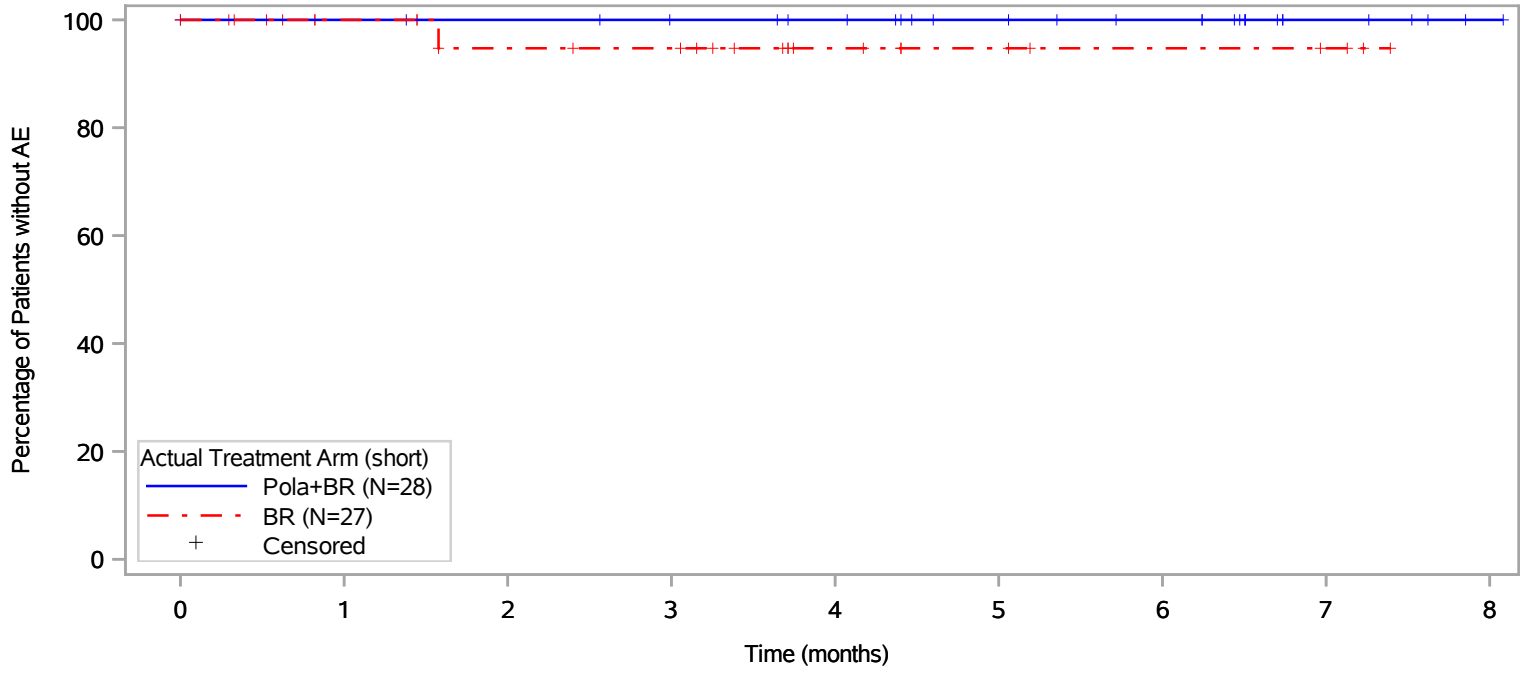
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

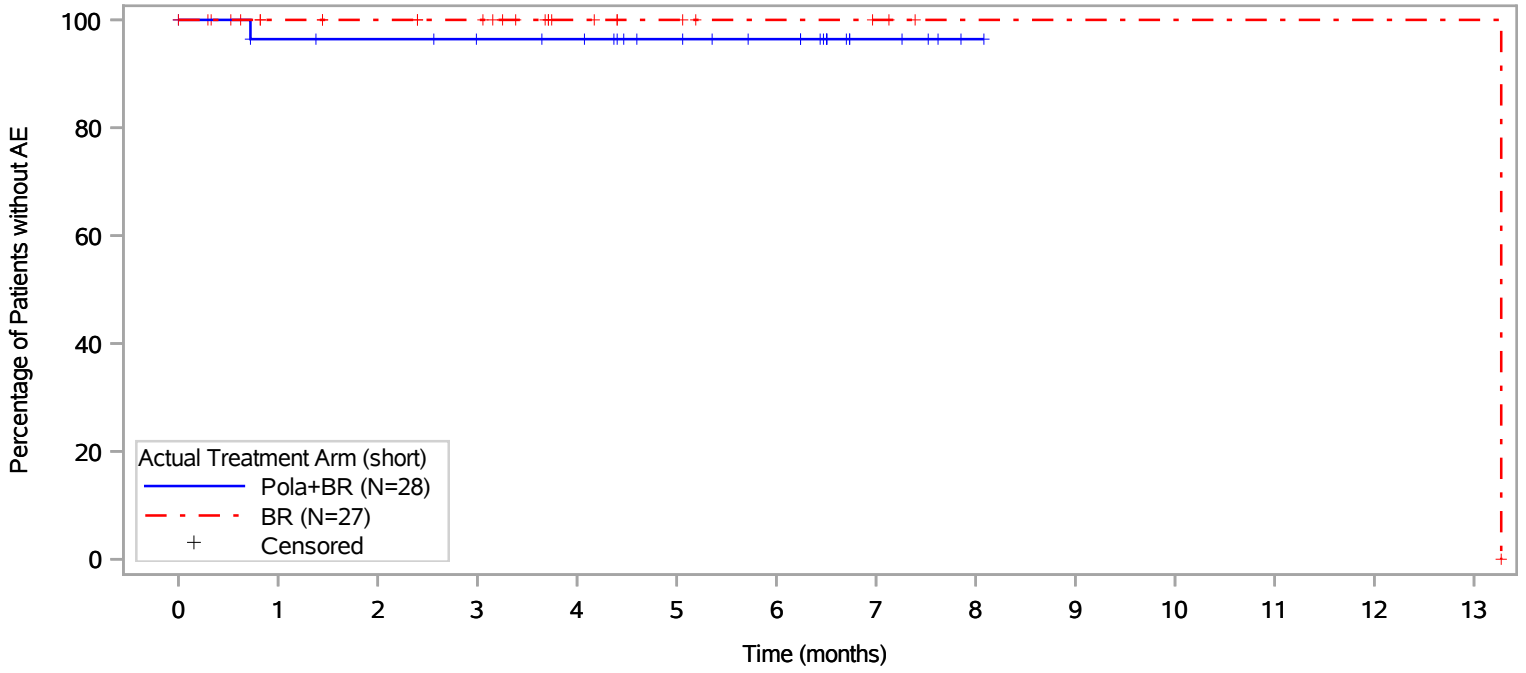
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



Patients at risk														
Pola+BR (N=28)	28	27	26	24	23	18	15	5	1	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	3	1	1	1	1	1	1
Patients censored														
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	24	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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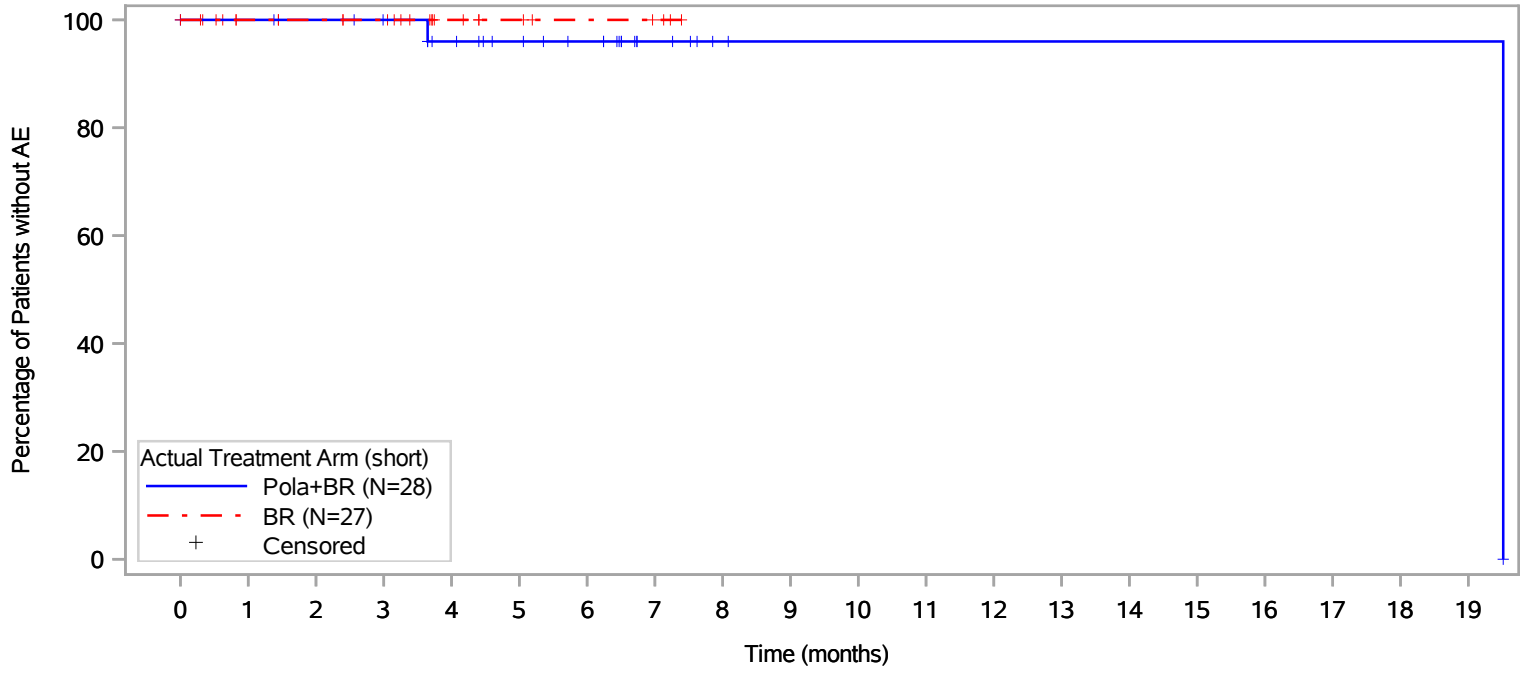
02DEC2022 6:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

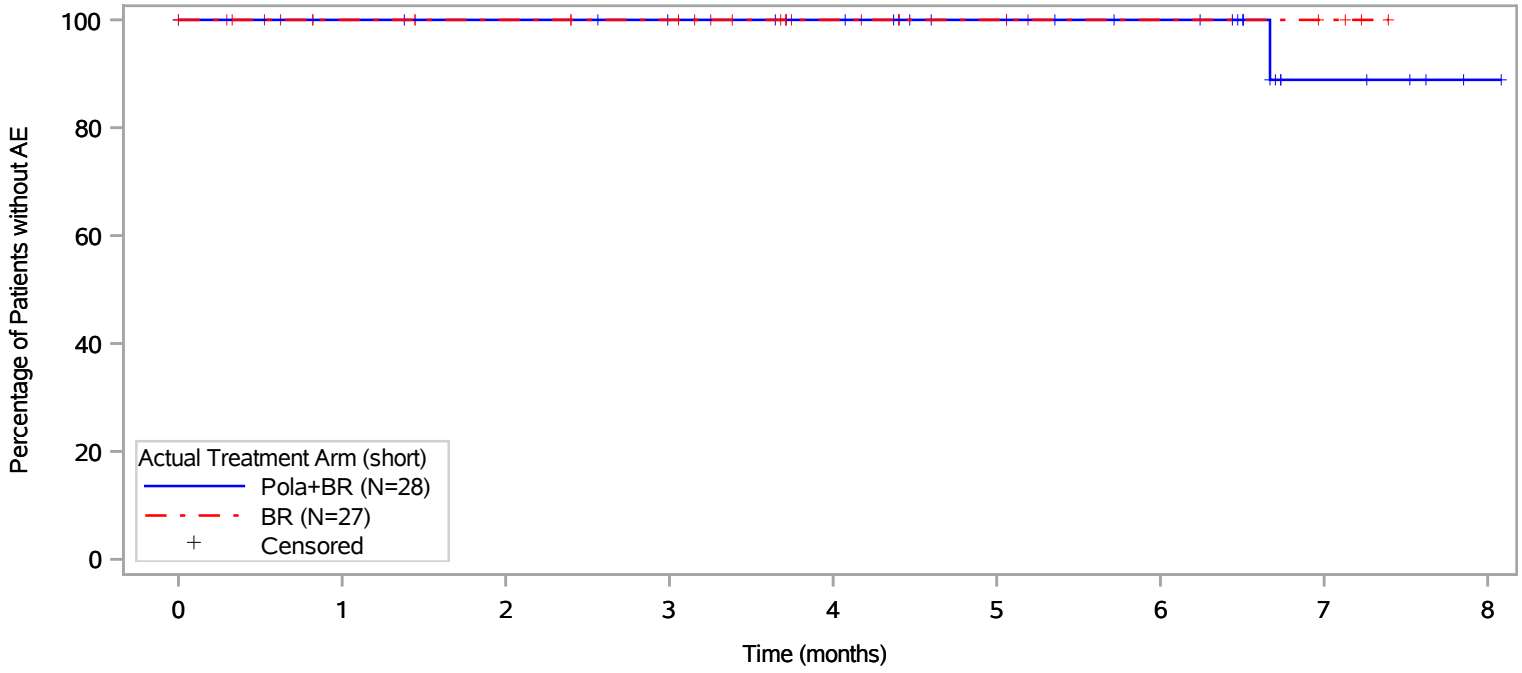
GASTROINTESTINAL DISORDERS, DUODENAL ULCER HAEMORRHAGE



Patients at risk																				
Pola+BR (N=28)	28	28	27	25	22	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	5	9	12	21	25	26	26	26	26	26	26	26	26	26	26	26
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

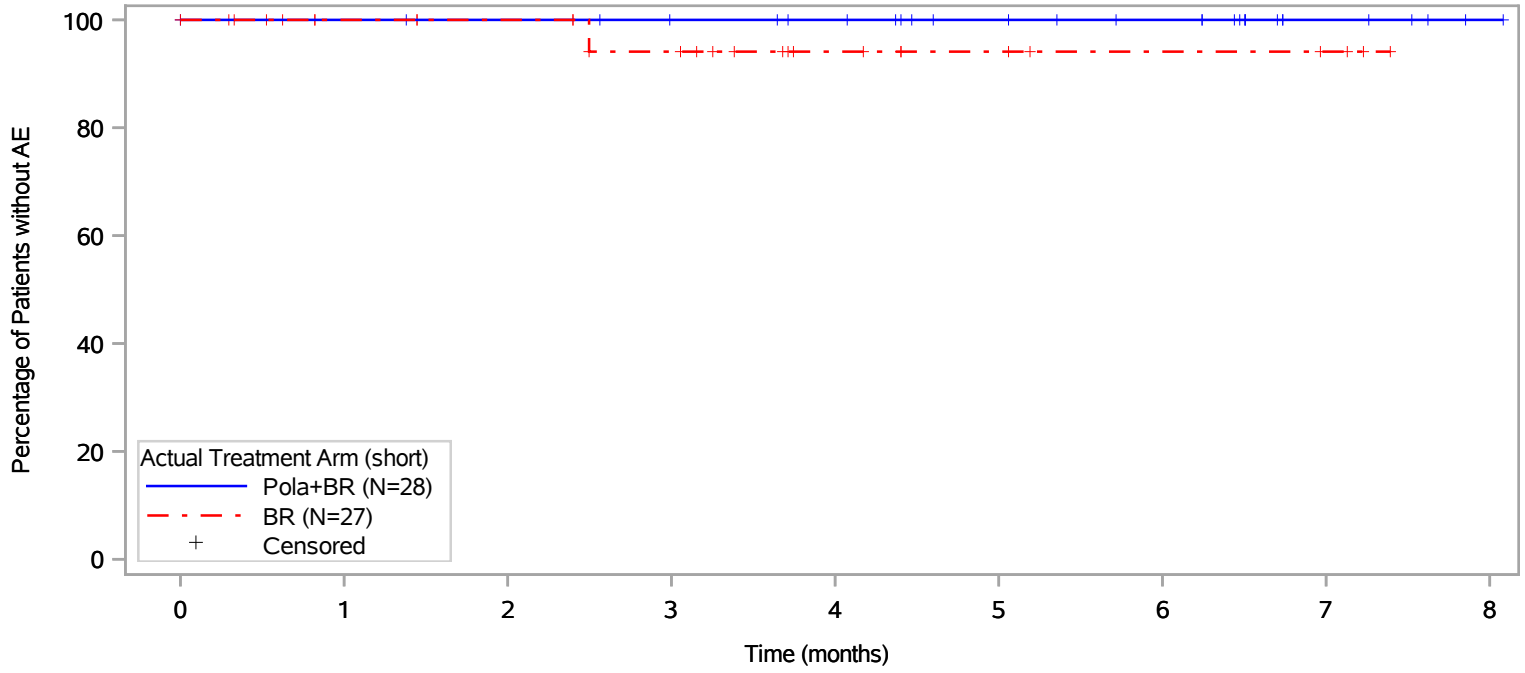
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, OBSTRUCTION GASTRIC



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, PANCREATITIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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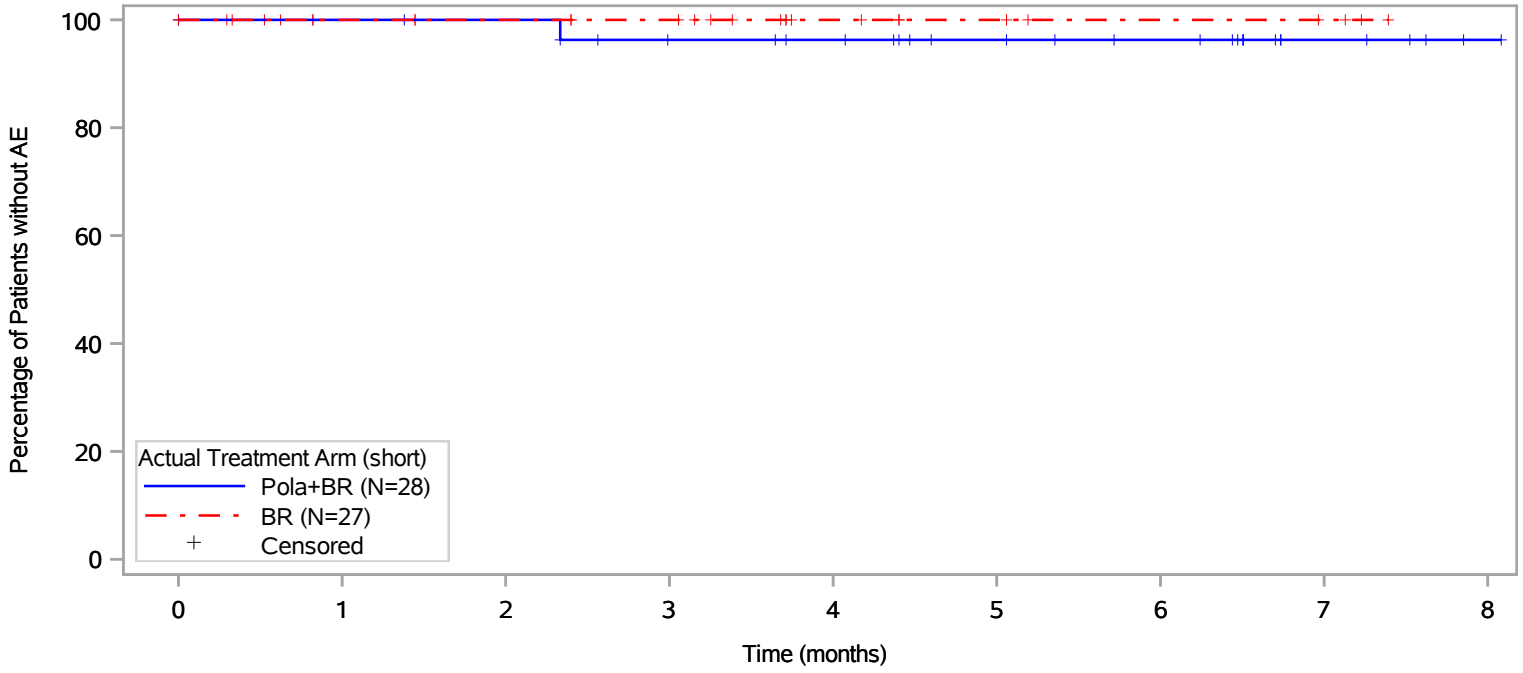
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING



Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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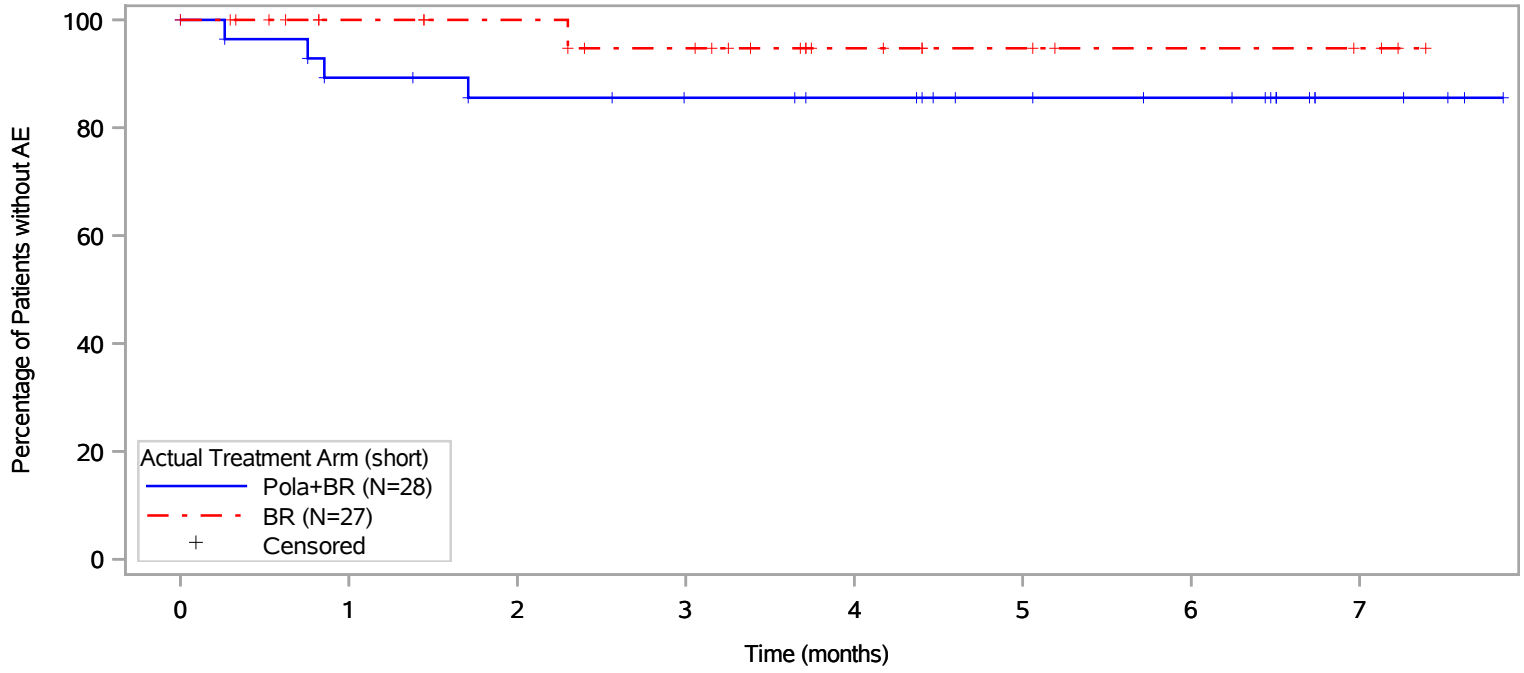
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk								
Pola+BR (N=28)	28	25	23	21	19	15	13	4
BR (N=27)	27	21	19	17	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	9	11	20
BR (N=27)	0	6	8	9	17	20	22	23

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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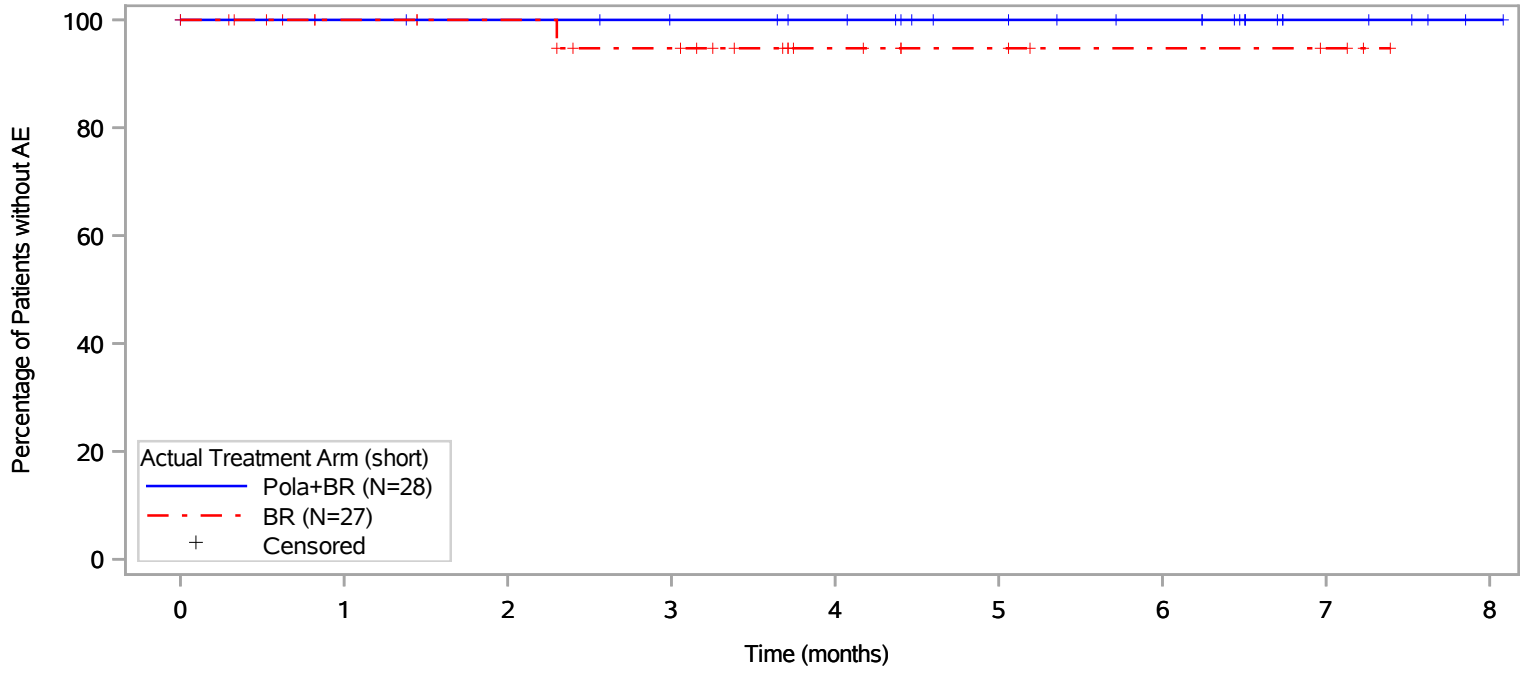
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MULTIPLE ORGAN DYSFUNCTION SYNDROME



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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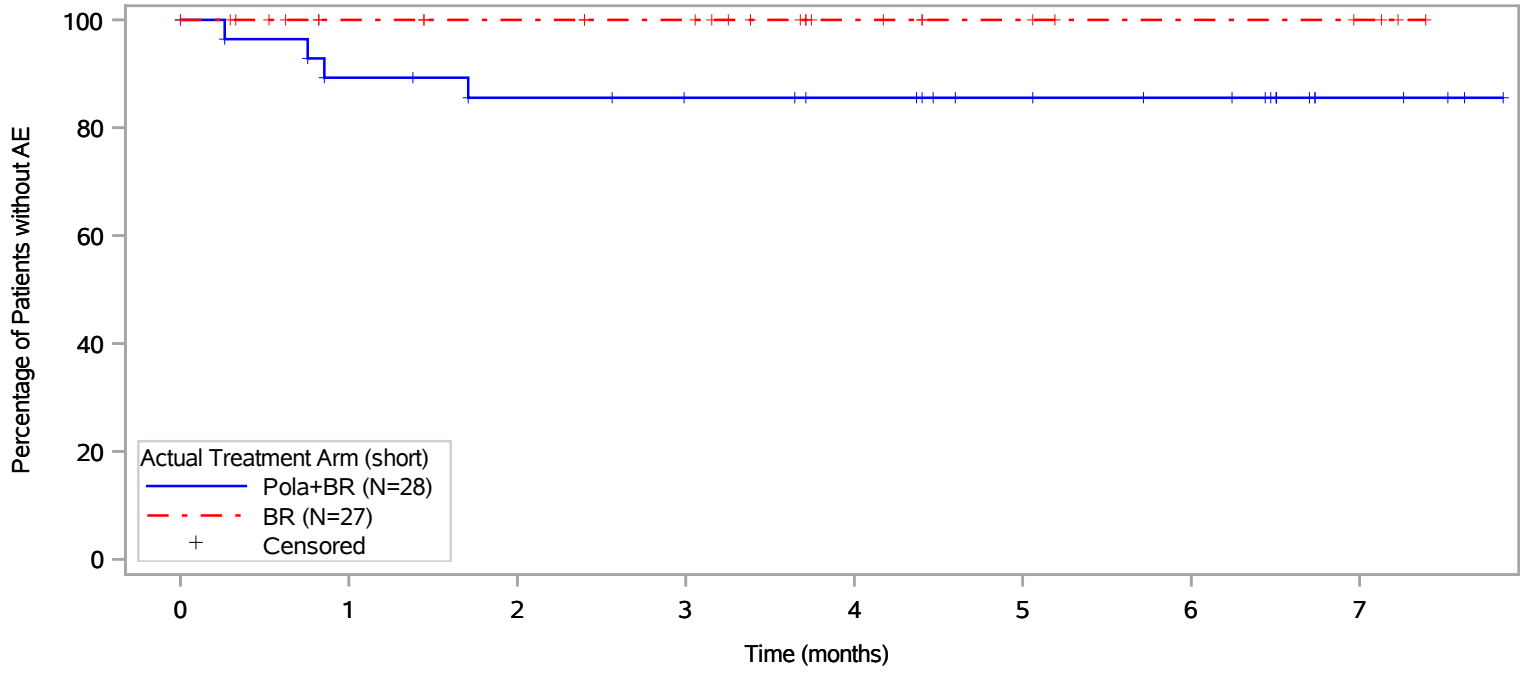
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk								
Pola+BR (N=28)	28	25	23	21	19	15	13	4
BR (N=27)	27	21	19	17	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	9	11	20
BR (N=27)	0	6	8	10	18	21	23	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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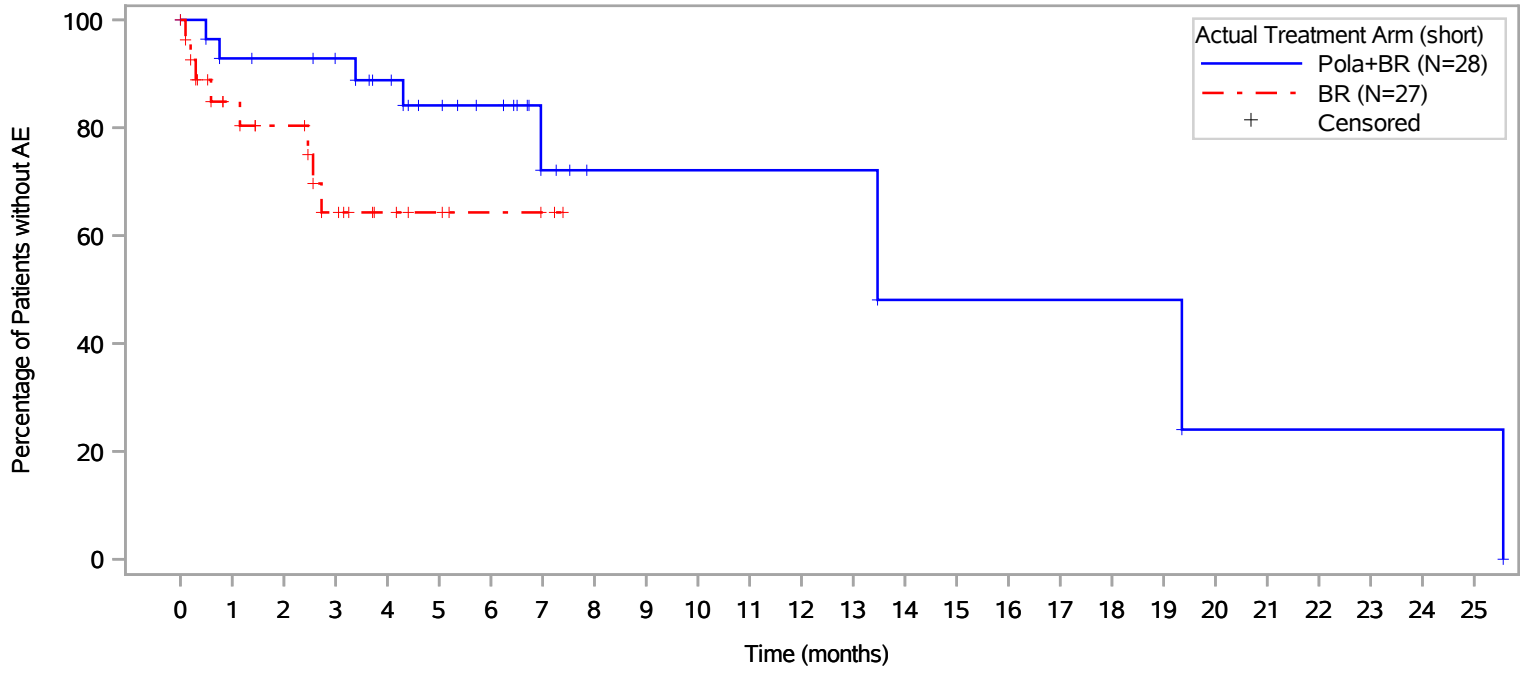
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk																										
Pola+BR (N=28)	28	26	25	23	20	16	13	6	3	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=27)	27	19	16	12	7	5	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	1	3	5	8	11	17	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
BR (N=27)	0	4	6	7	12	14	16	17	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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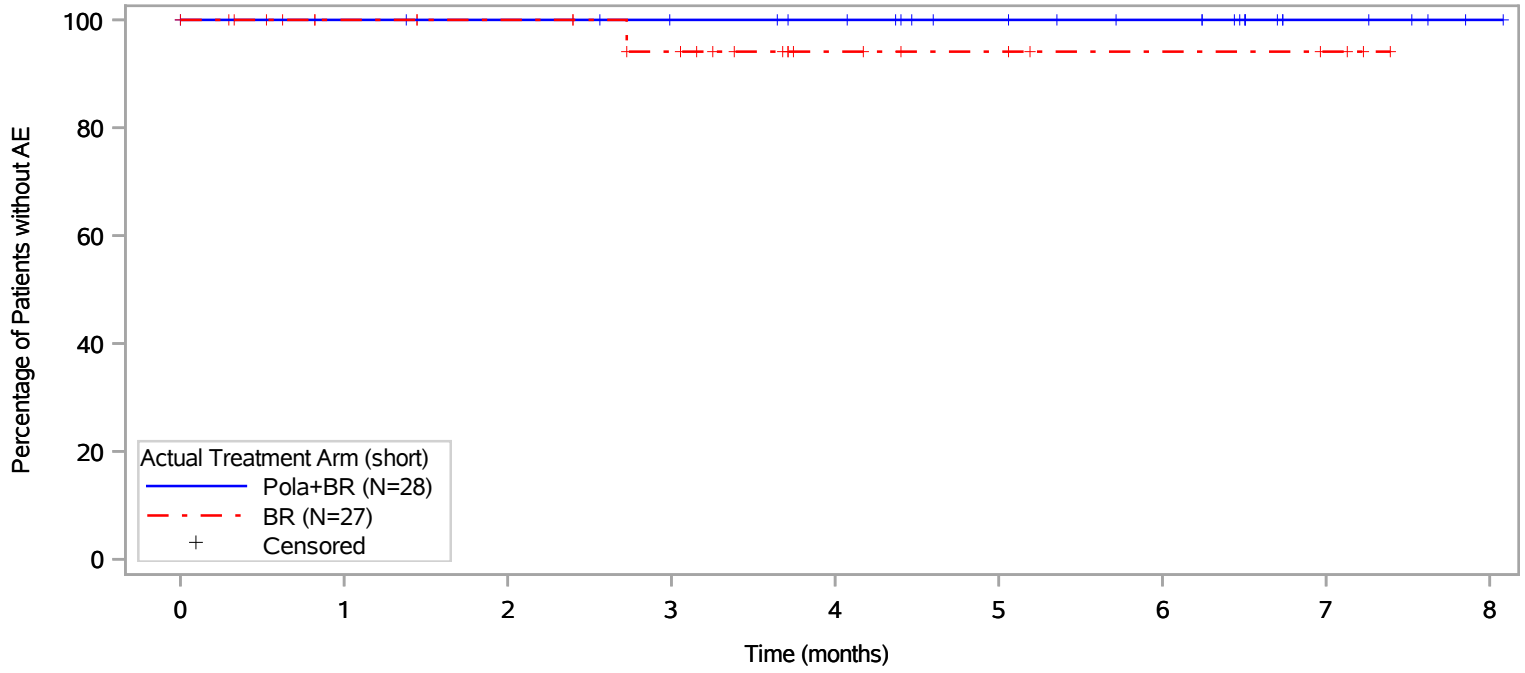
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

INFECTIONS AND INFESTATIONS, CYTOMEGALOVIRUS INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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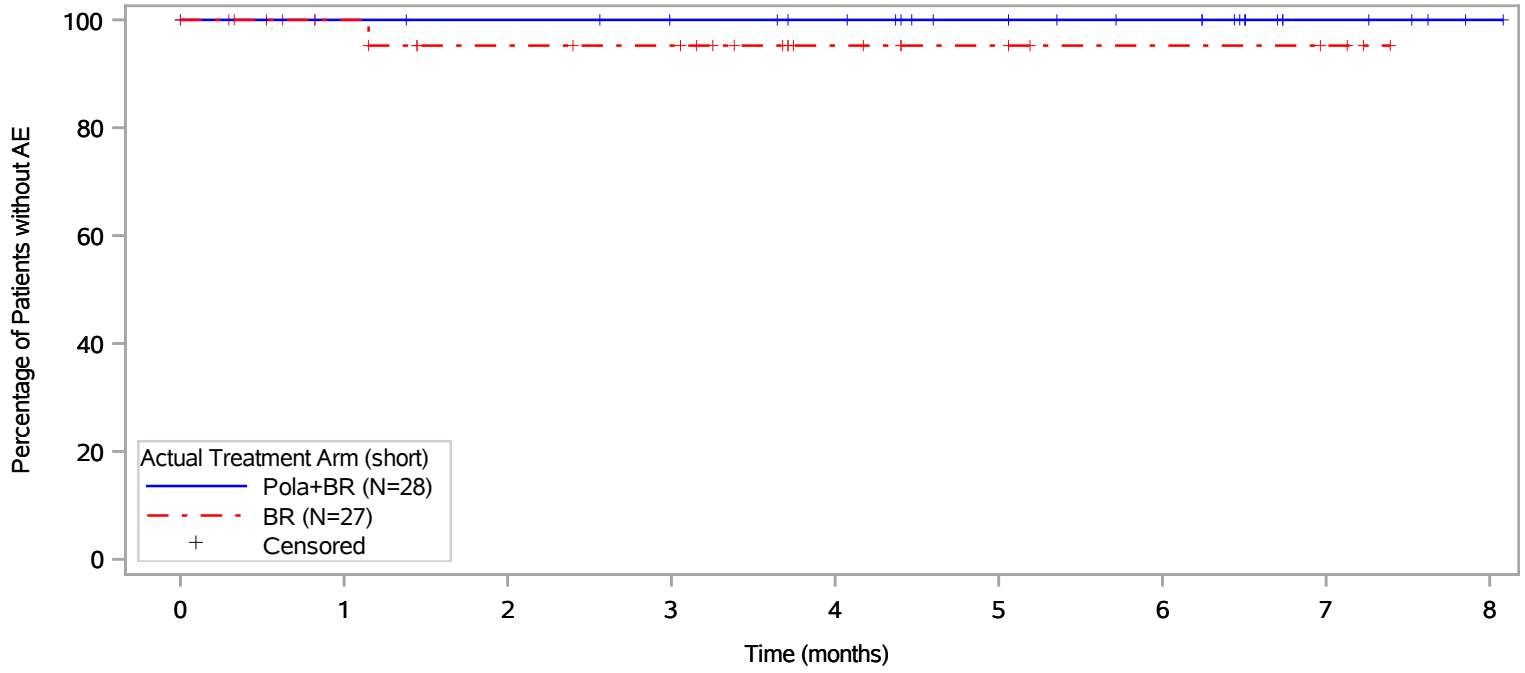
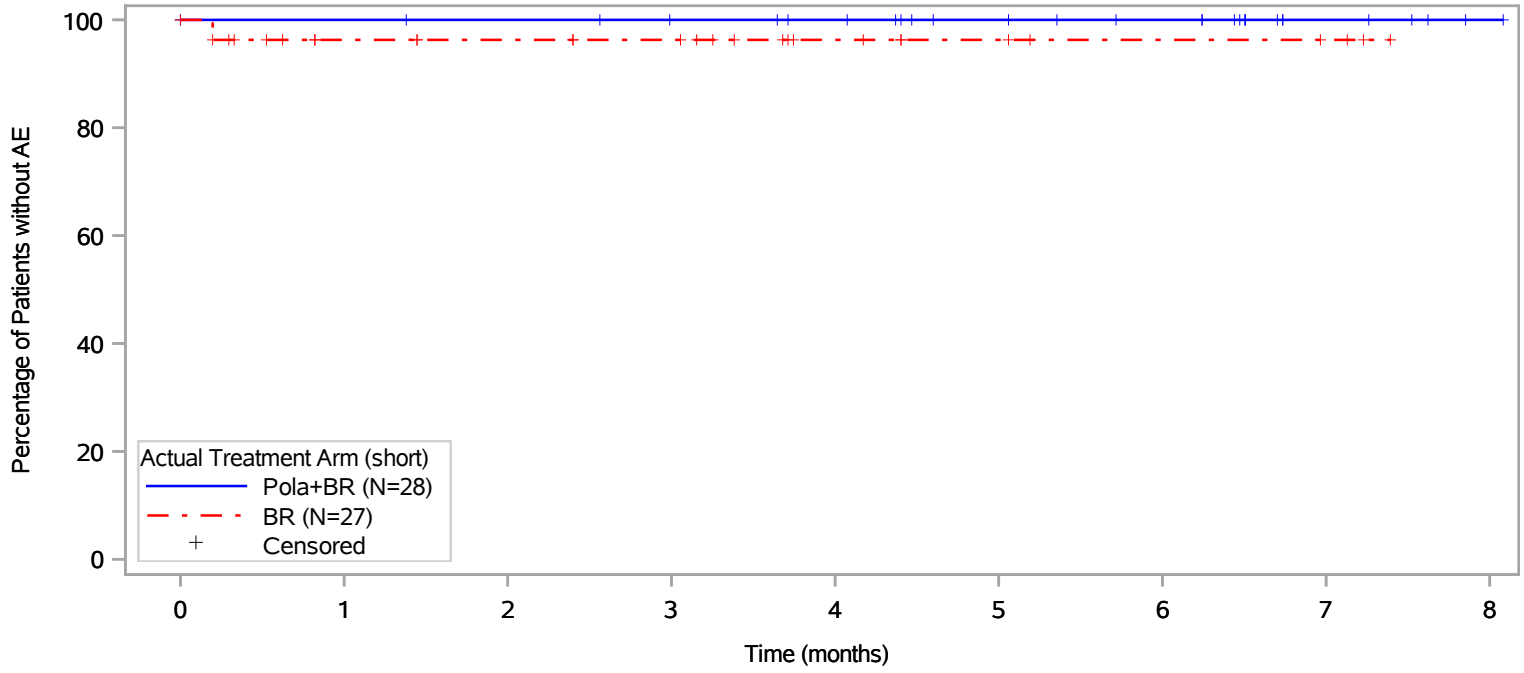
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, DEVICE RELATED INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, ENTEROCOLITIS VIRAL



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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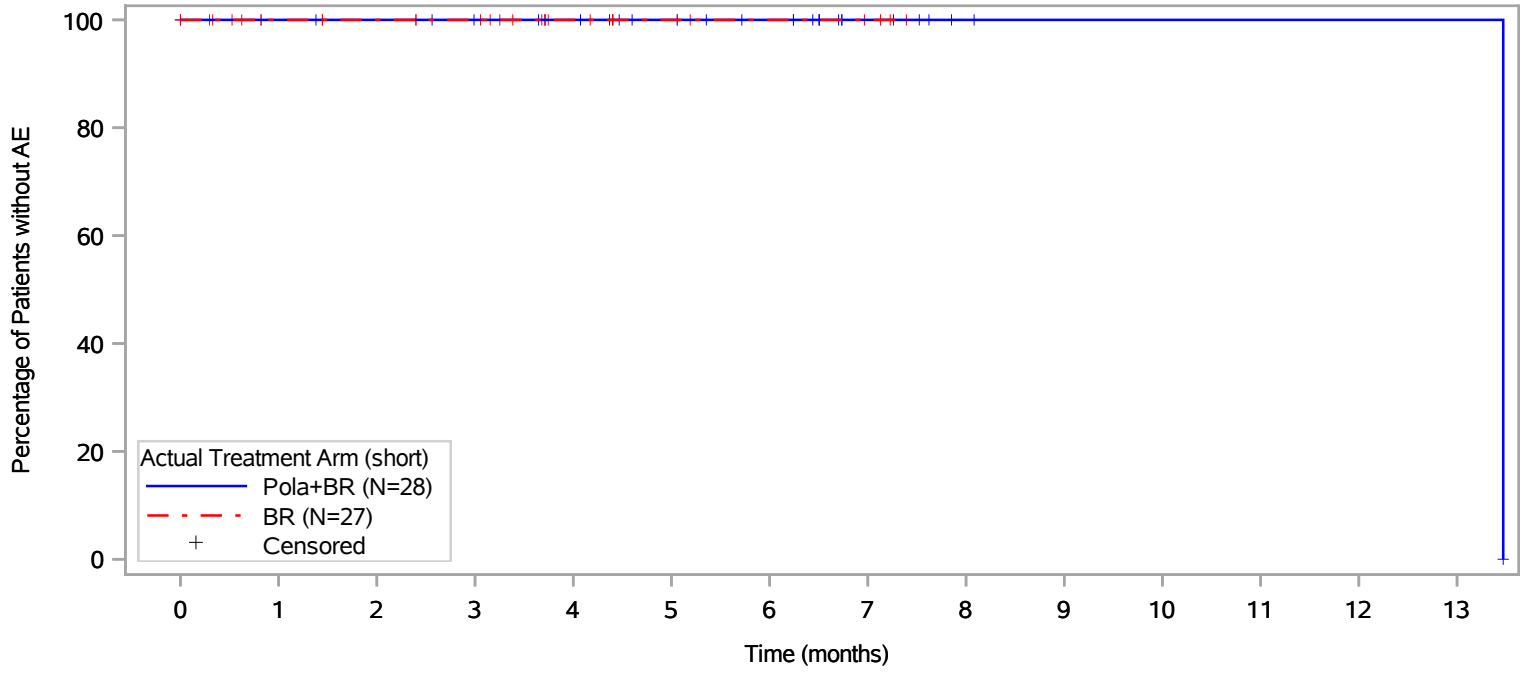
02DEC2022 6:11

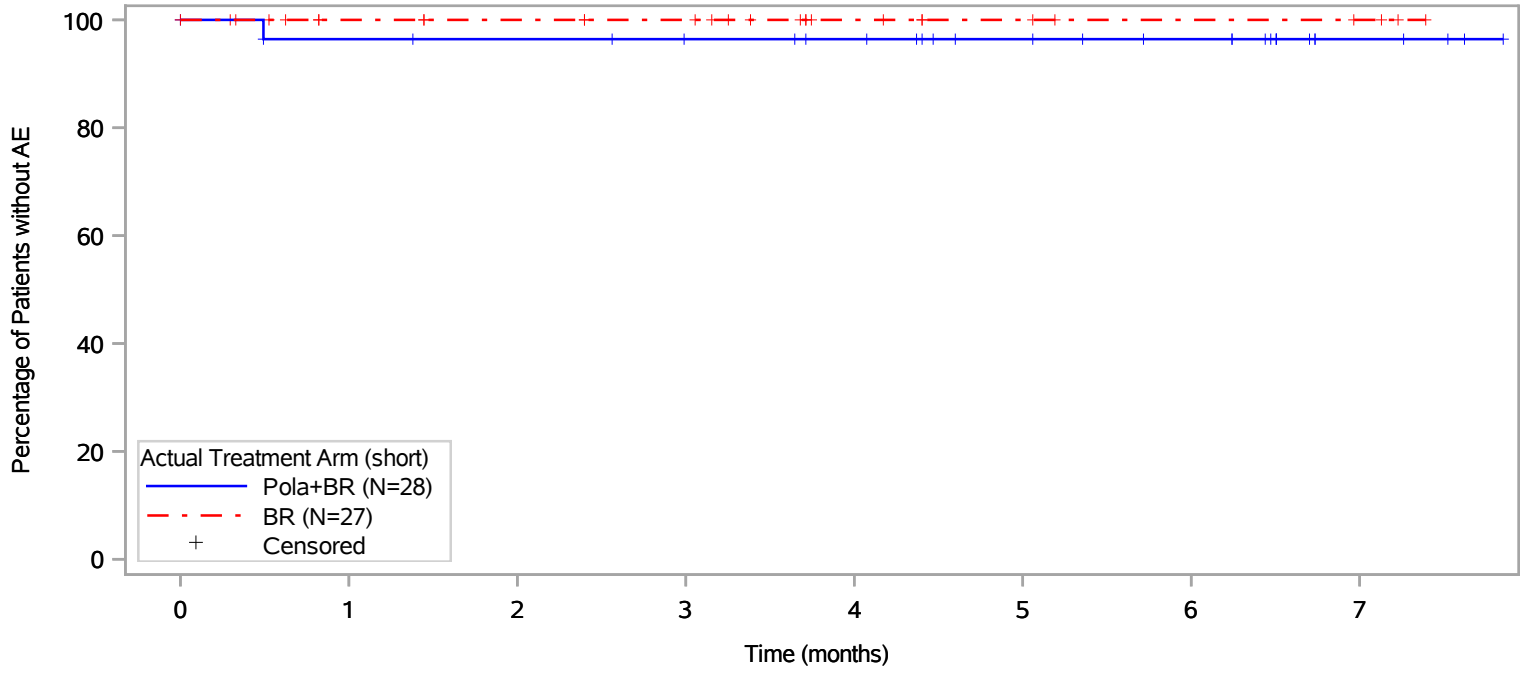
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, GASTROINTESTINAL BACTERIAL INFECTION



Patients at risk														
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

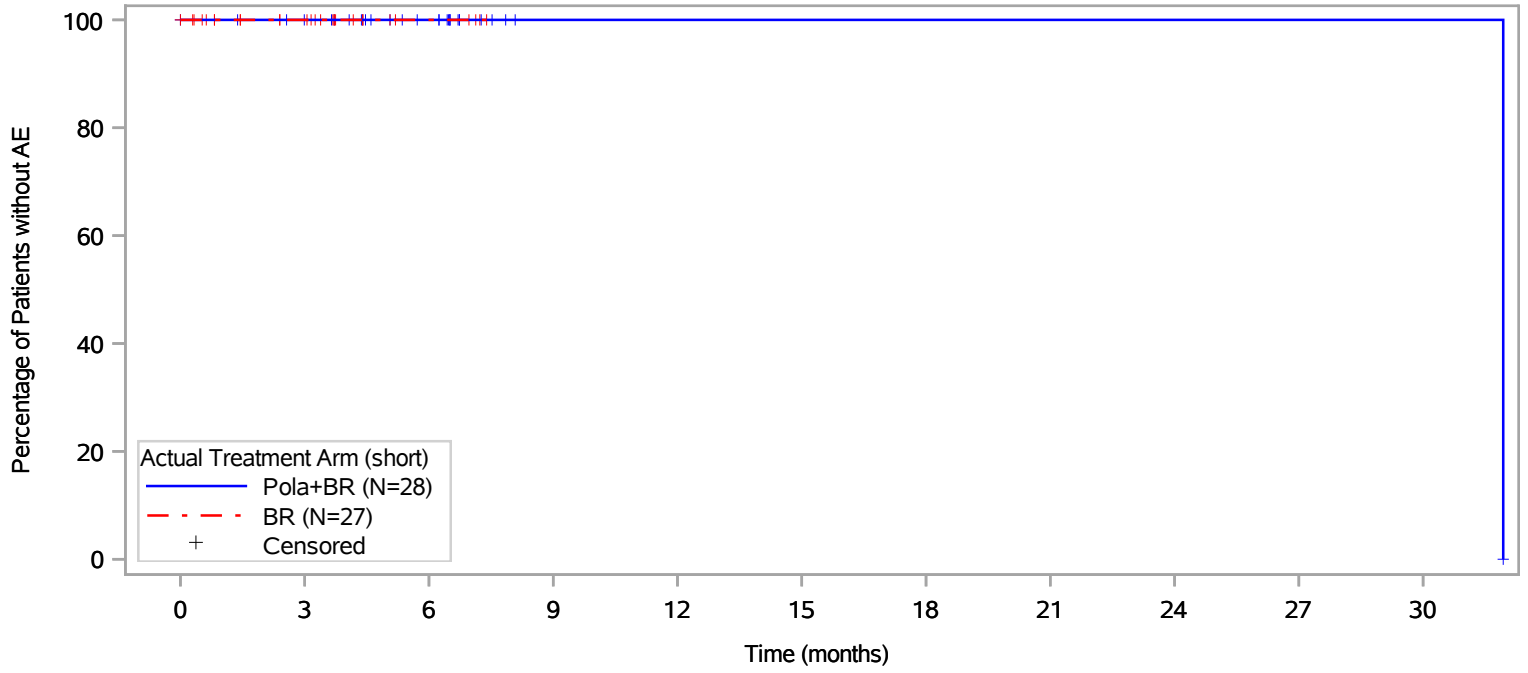
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HUMAN ANAPLASMOSIS



Patients at risk								
Pola+BR (N=28)	28	27	26	24	22	17	14	4
BR (N=27)	27	21	19	17	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	10	13	23
BR (N=27)	0	6	8	10	18	21	23	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk											
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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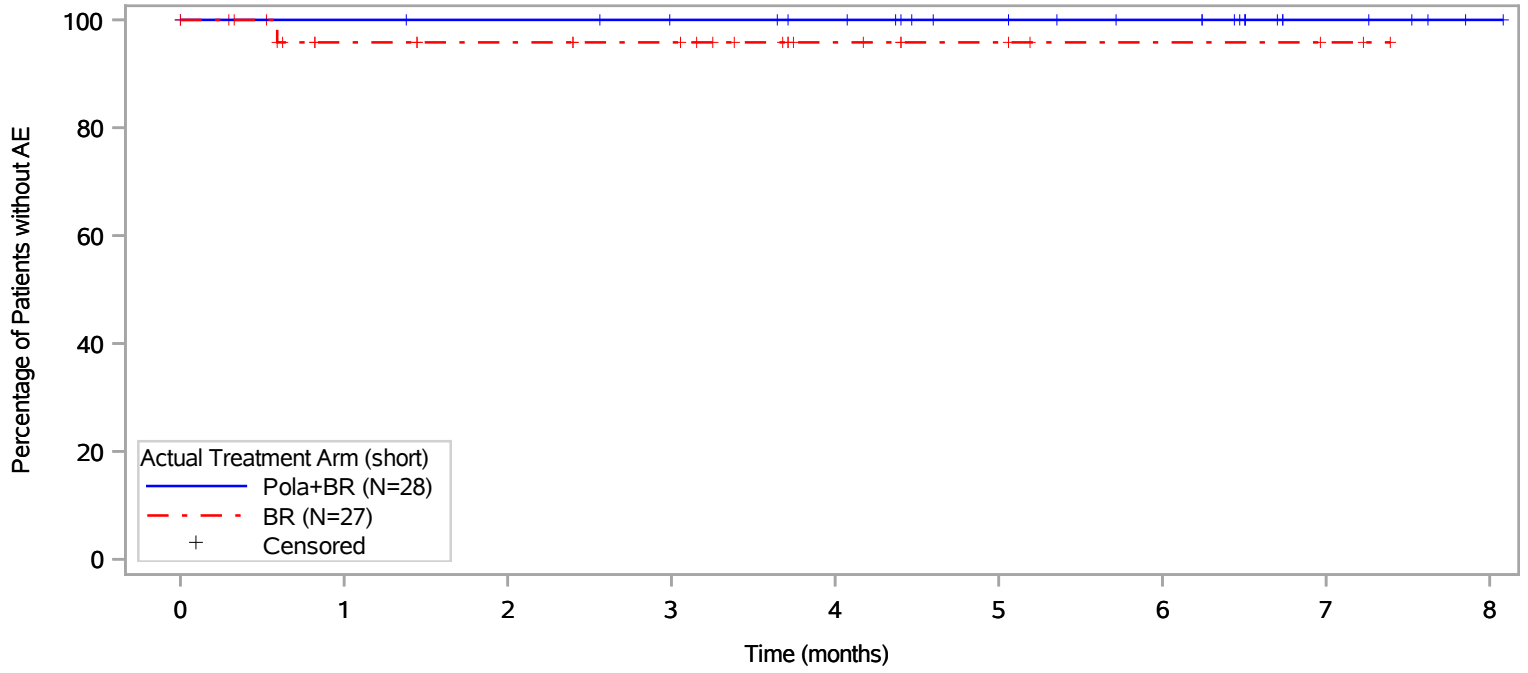
02DEC2022 6:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, LOWER RESPIRATORY TRACT INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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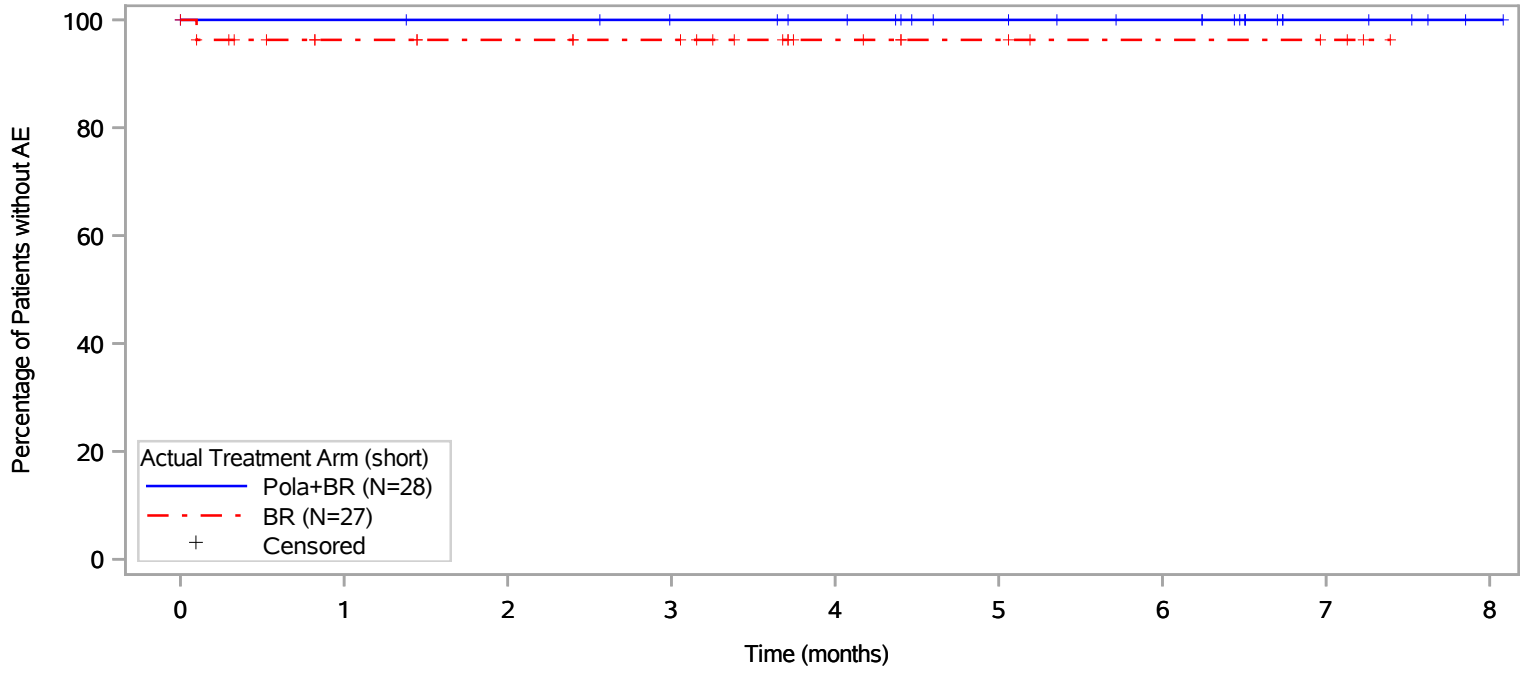
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, NEUTROPENIC SEPSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	5	7	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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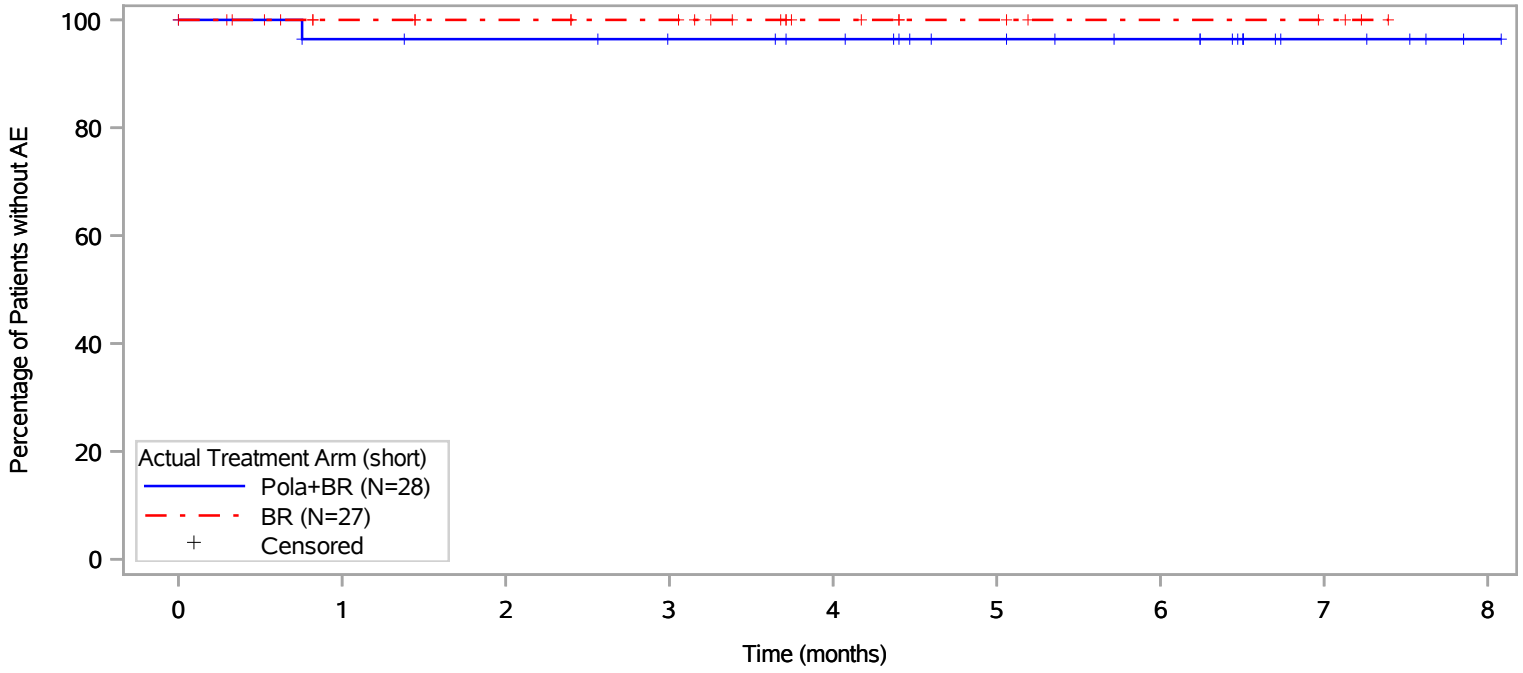
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

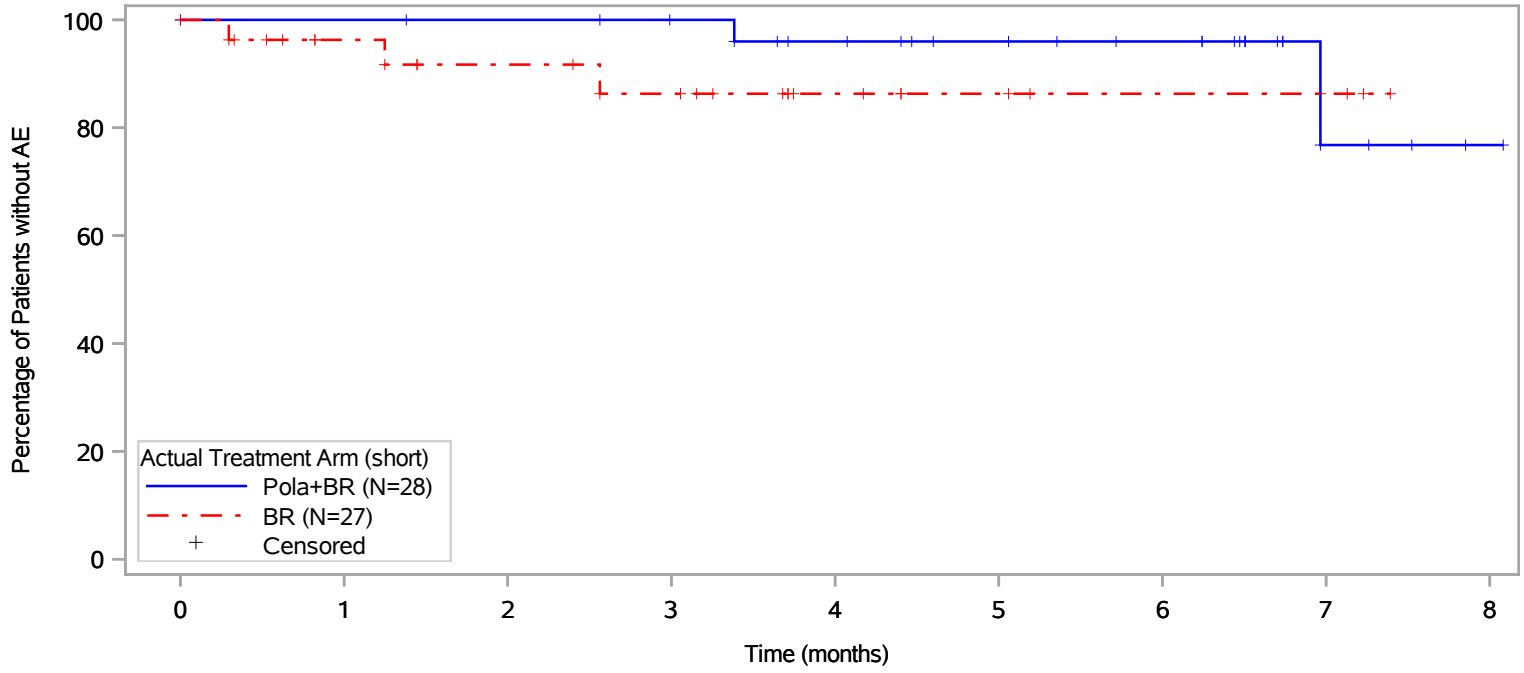
INFECTIONS AND INFESTATIONS, PNEUMOCYSTIS JIROVECII PNEUMONIA



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

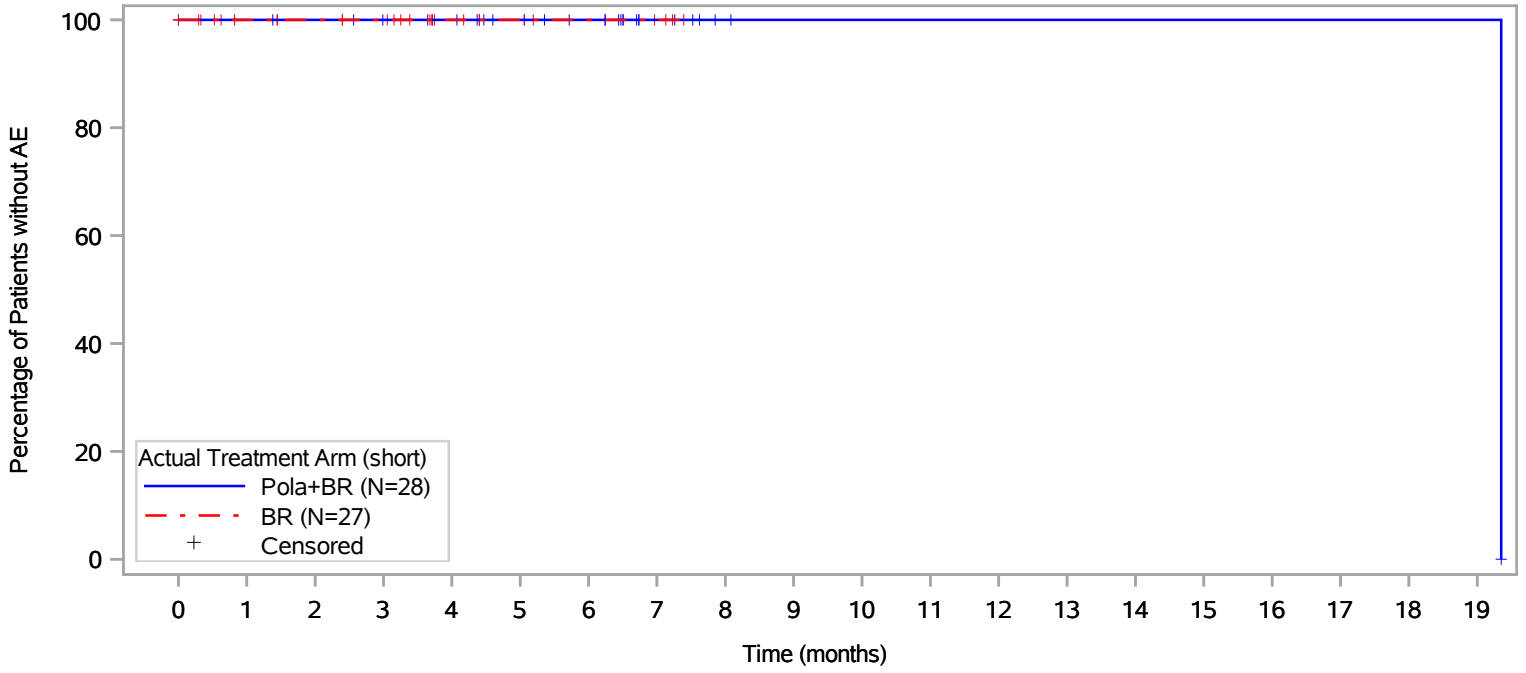
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	4	1
BR (N=27)	27	21	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	25
BR (N=27)	0	5	7	8	15	18	20	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

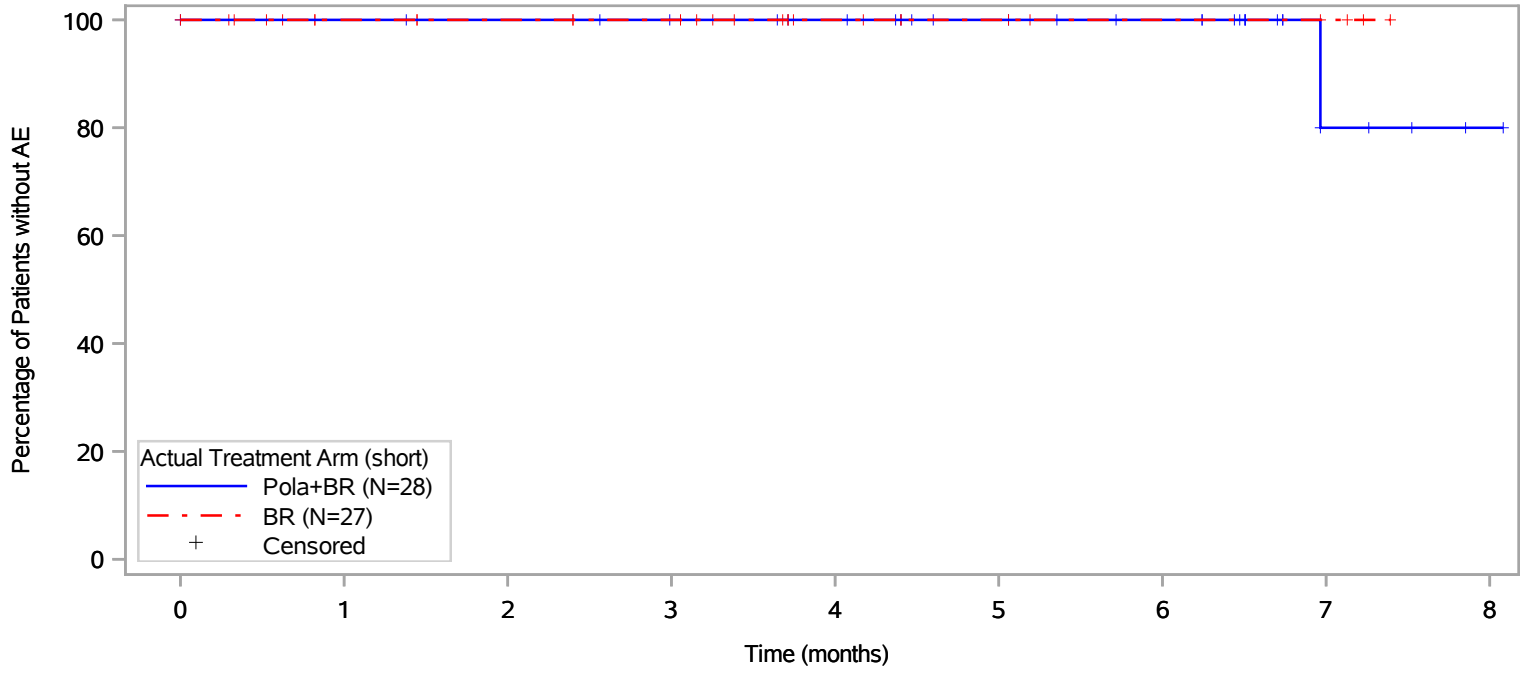
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA PNEUMOCOCCAL



Patients at risk																				
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

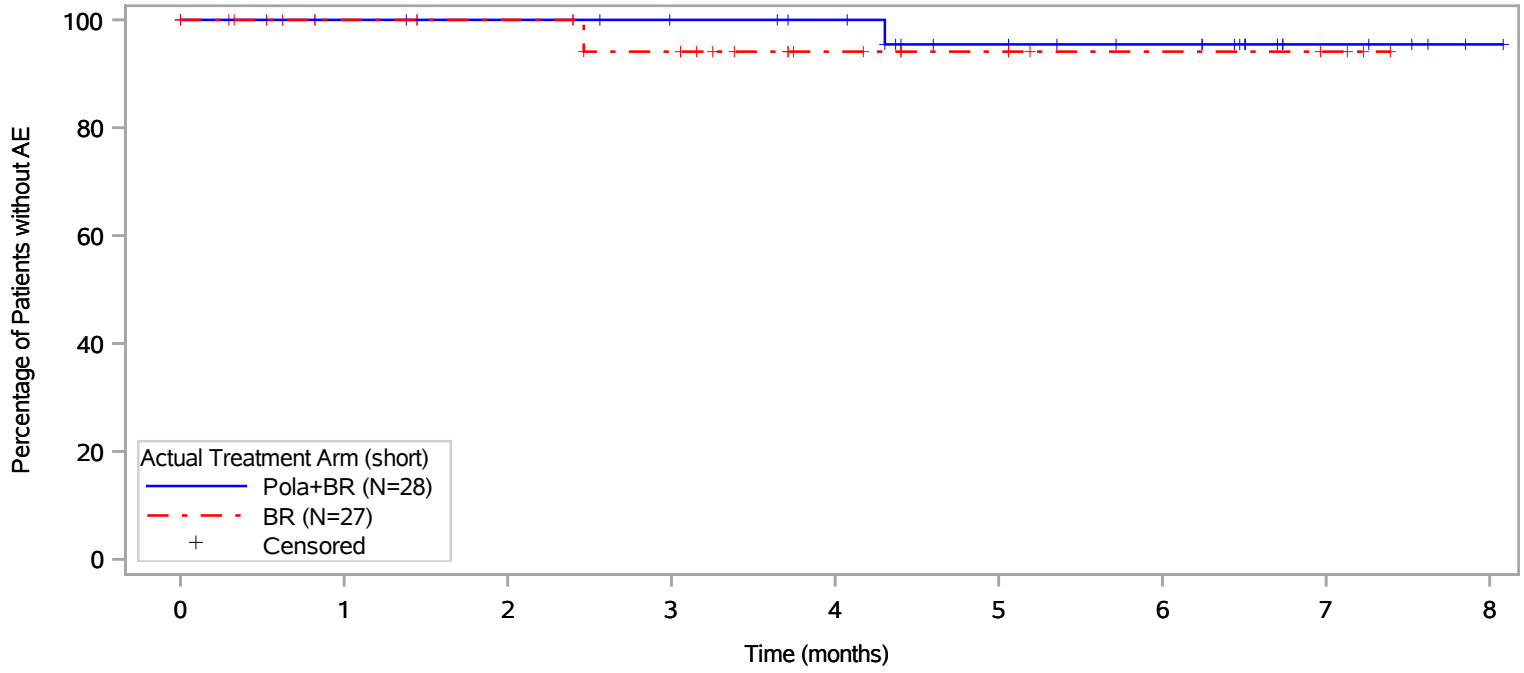
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, RHINOVIRUS INFECTION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	22	26
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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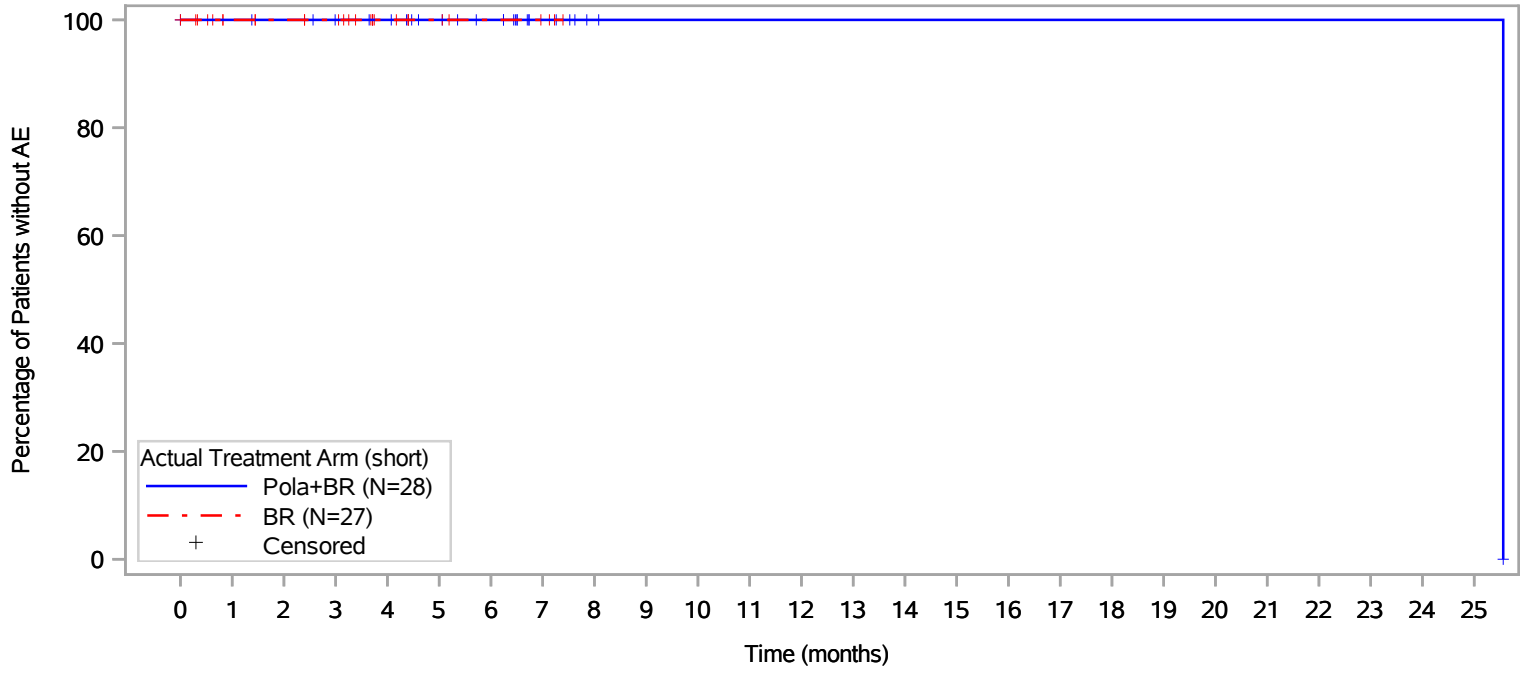
02DEC2022 6:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UROSEPSIS



Patients at risk																										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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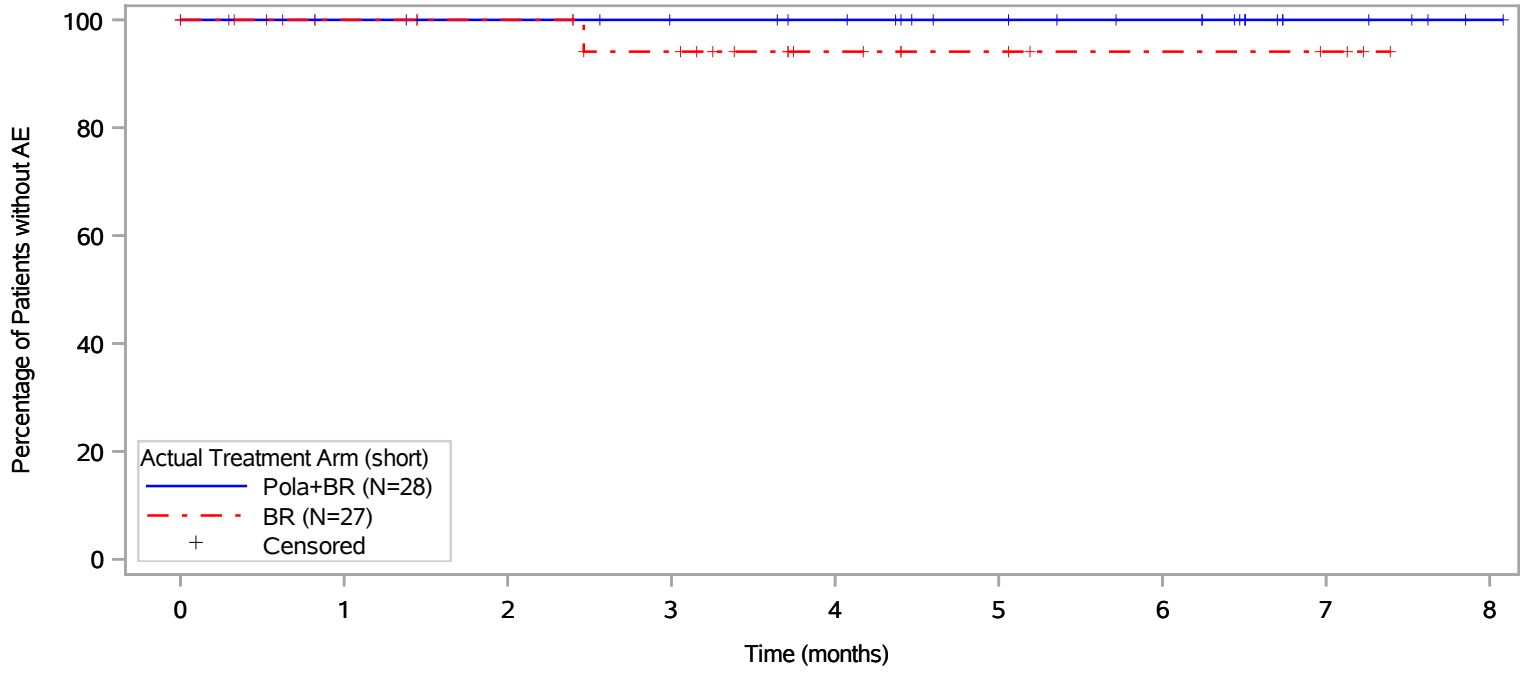
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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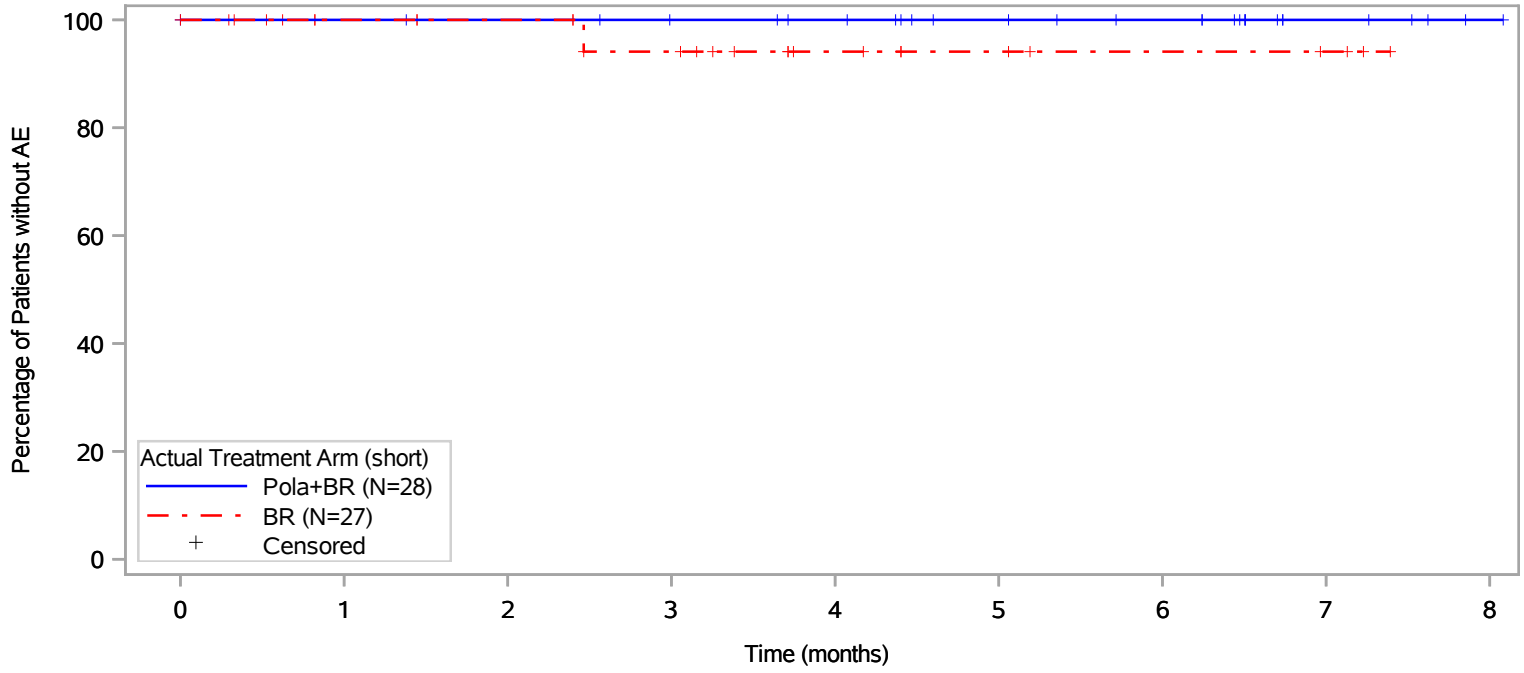
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FALL



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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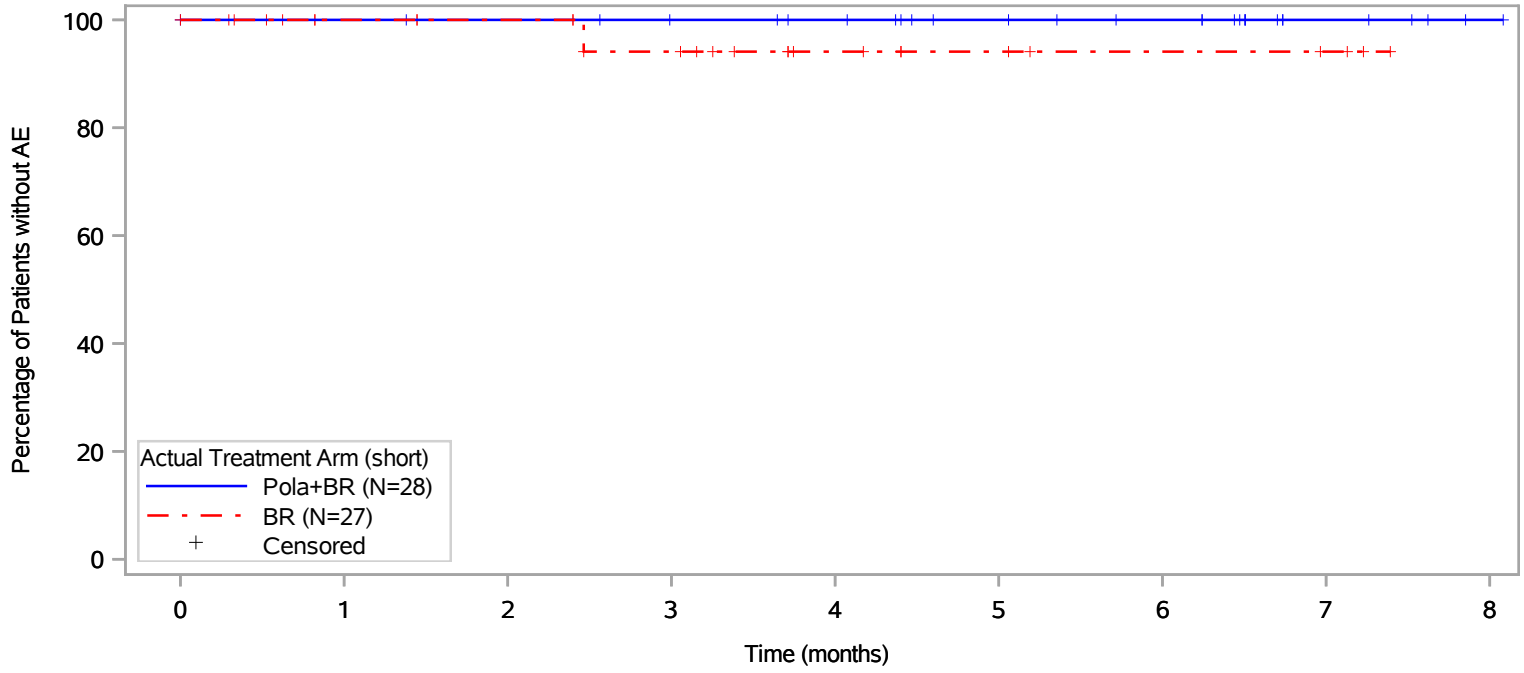
02DEC2022 6:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, HEAD INJURY



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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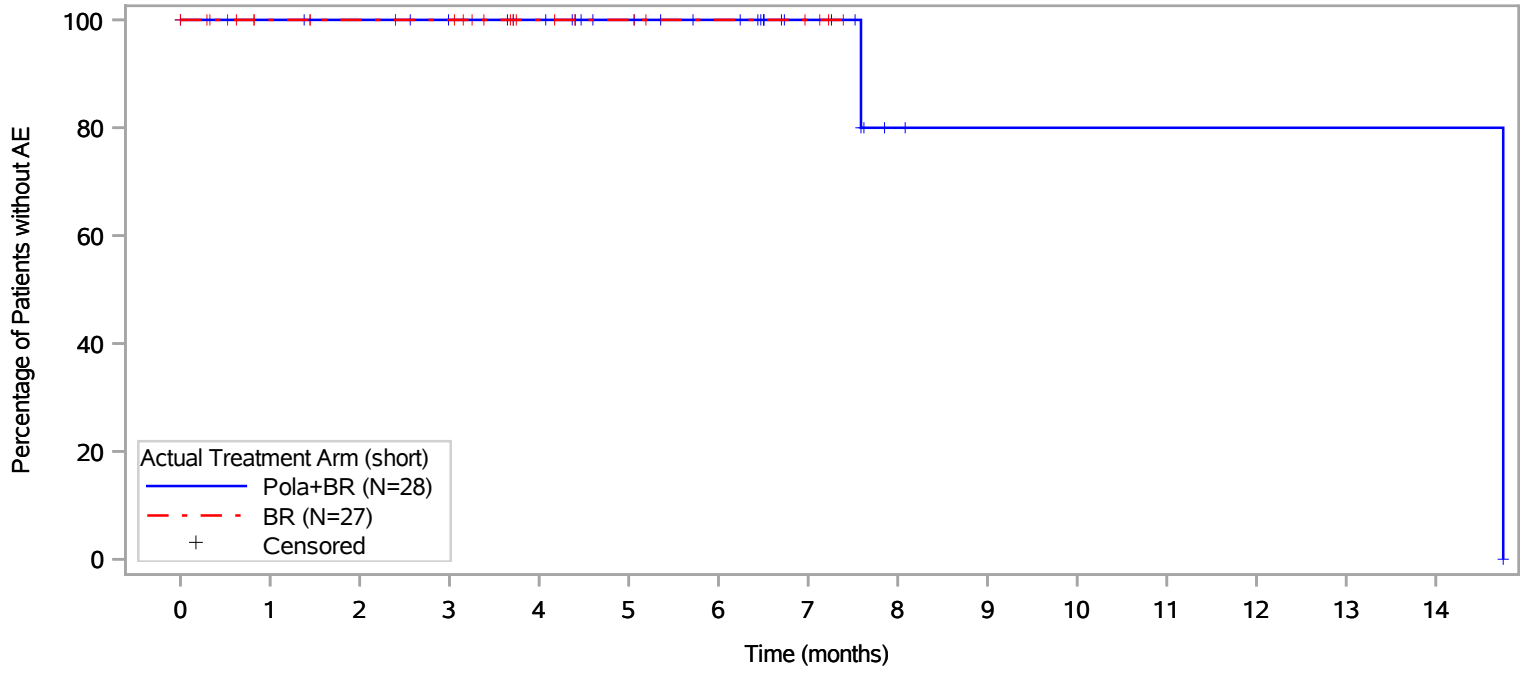
02DEC2022 6:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

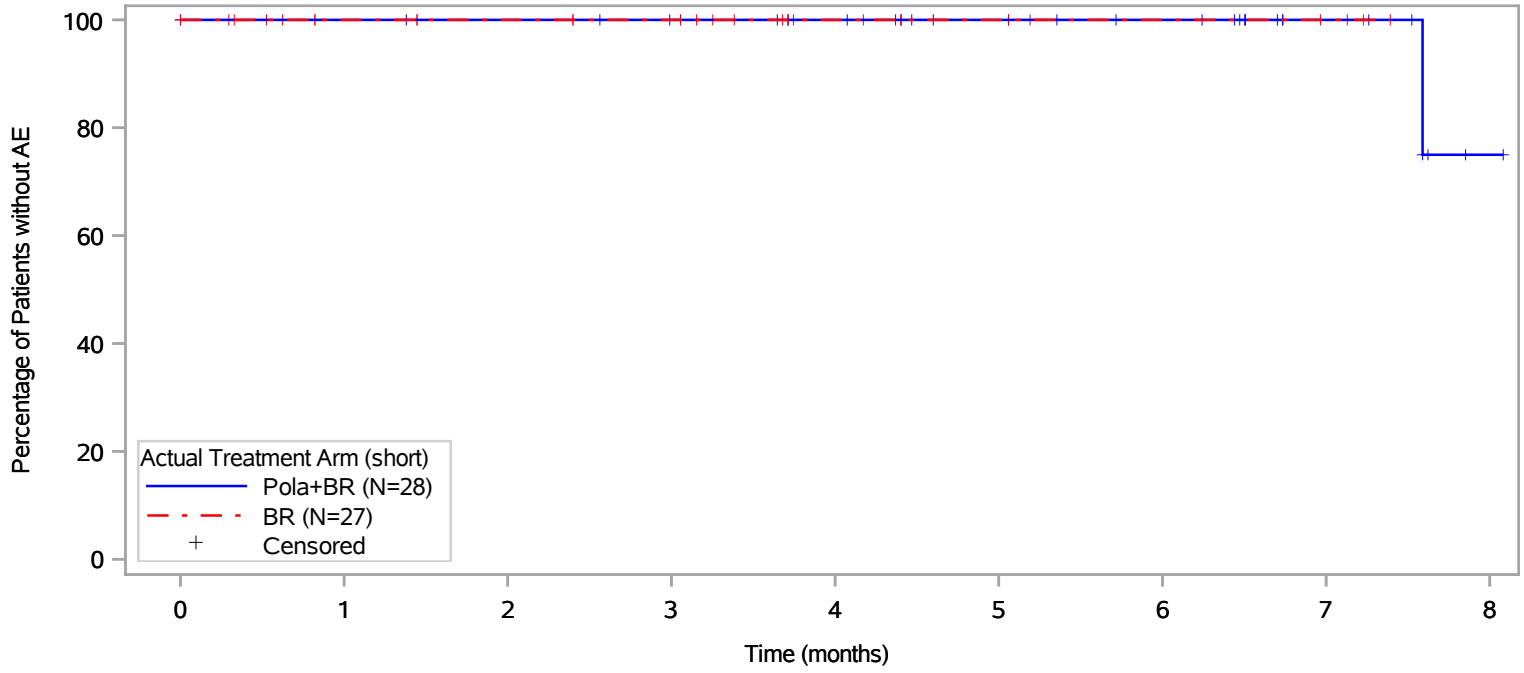


Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	7	2	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	21	25	26	26	26	26	26	26
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 6:11

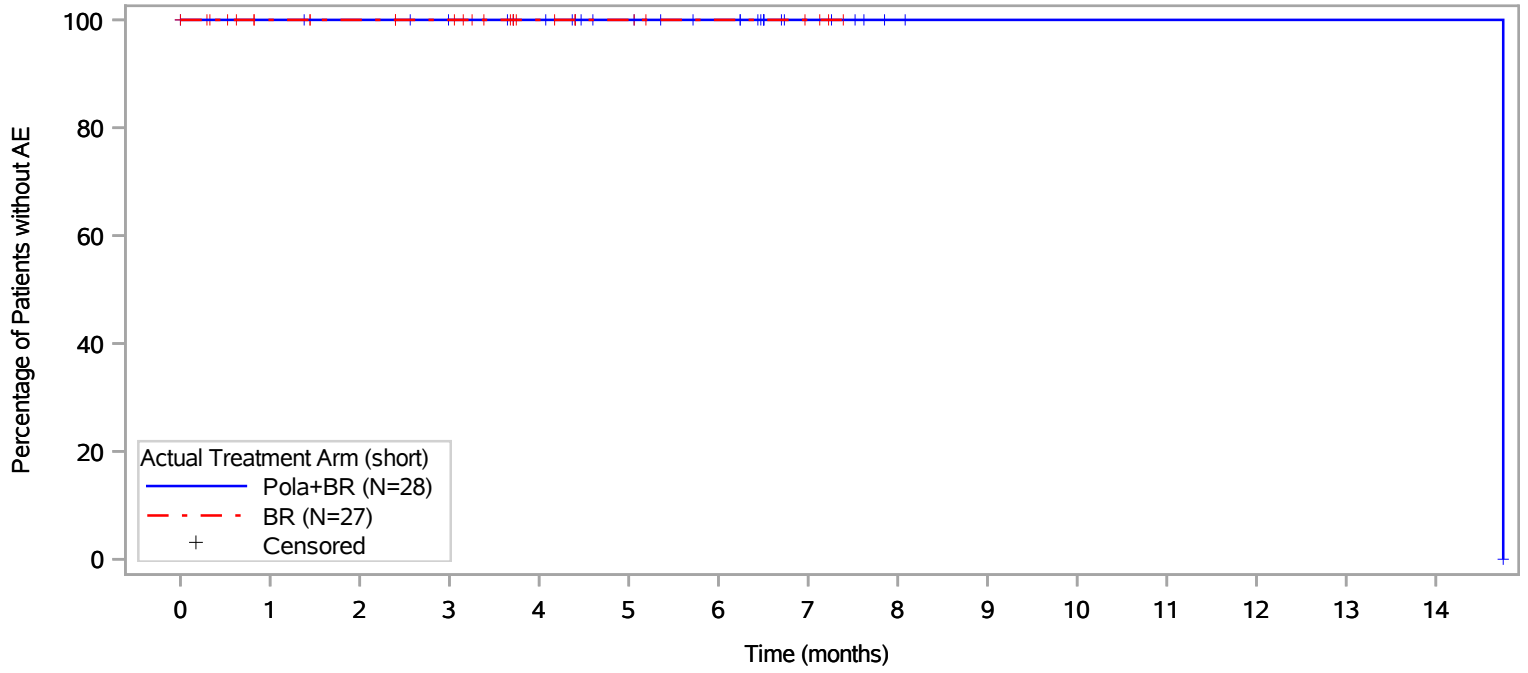
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MORAXELLA TEST POSITIVE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	6	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, TRANSAMINASES INCREASED



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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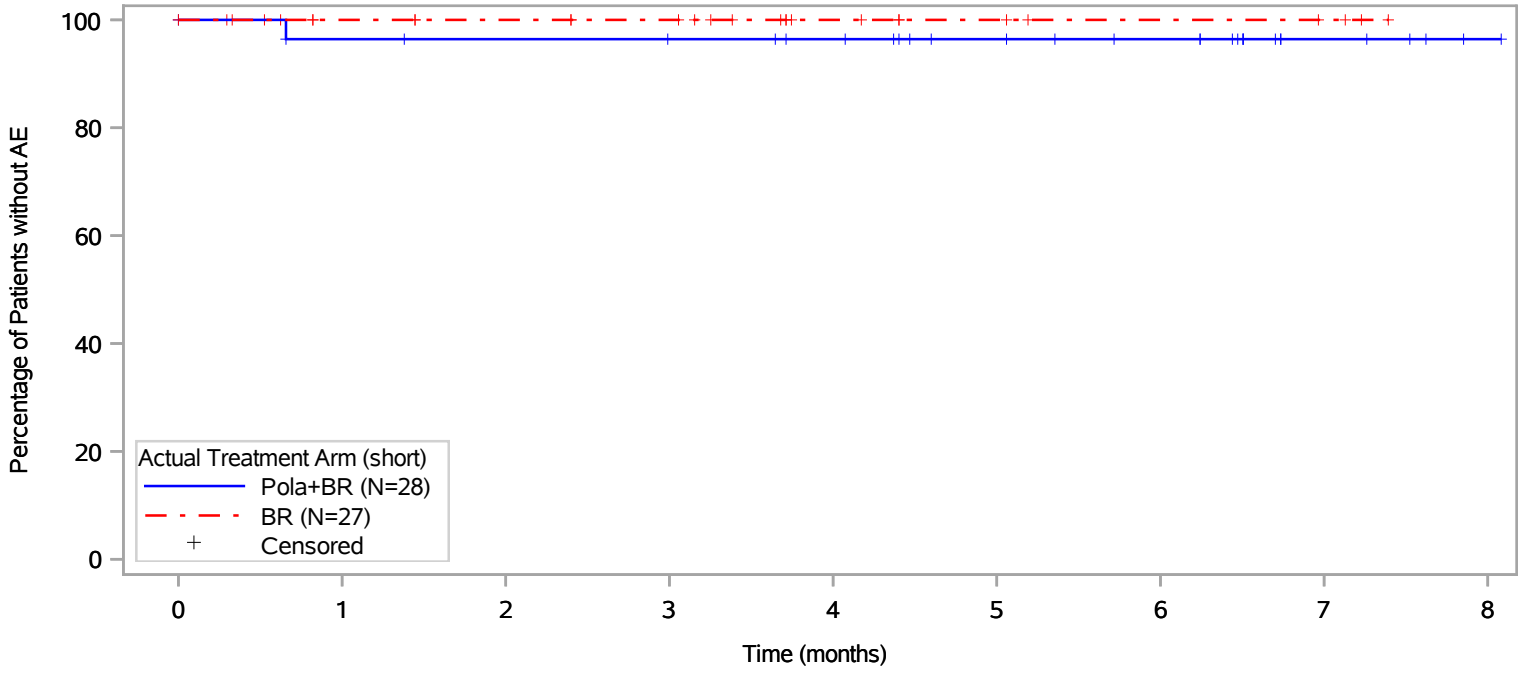
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

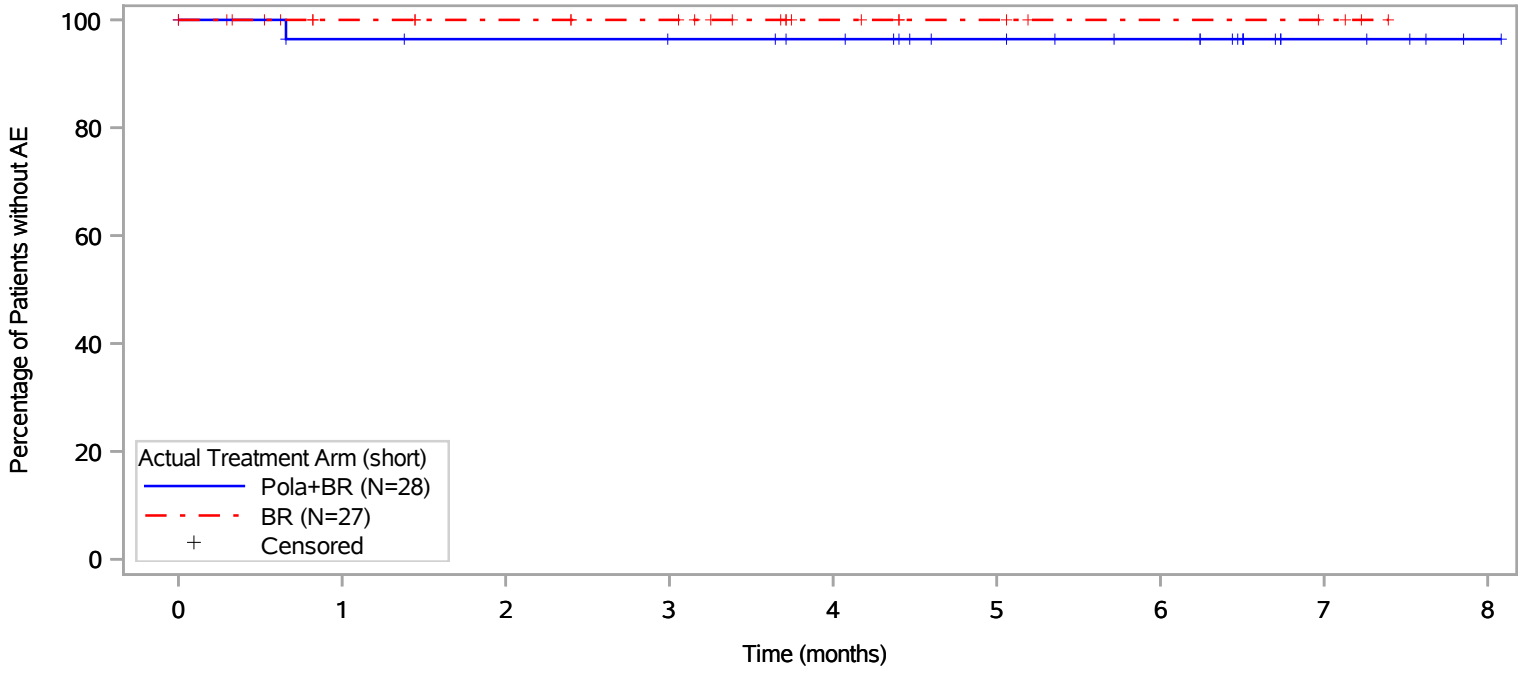
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	27	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN

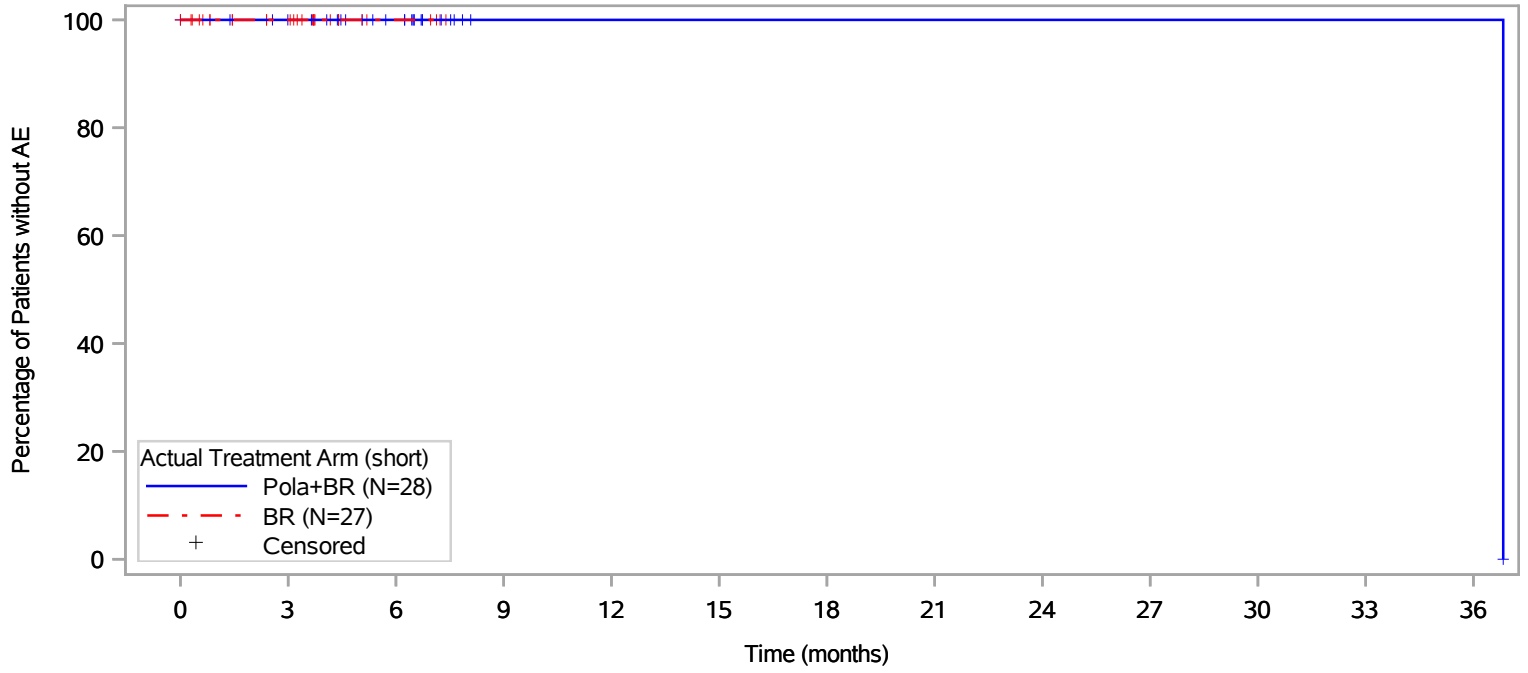


Patients at risk									
Pola+BR (N=28)	28	27	26	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), All

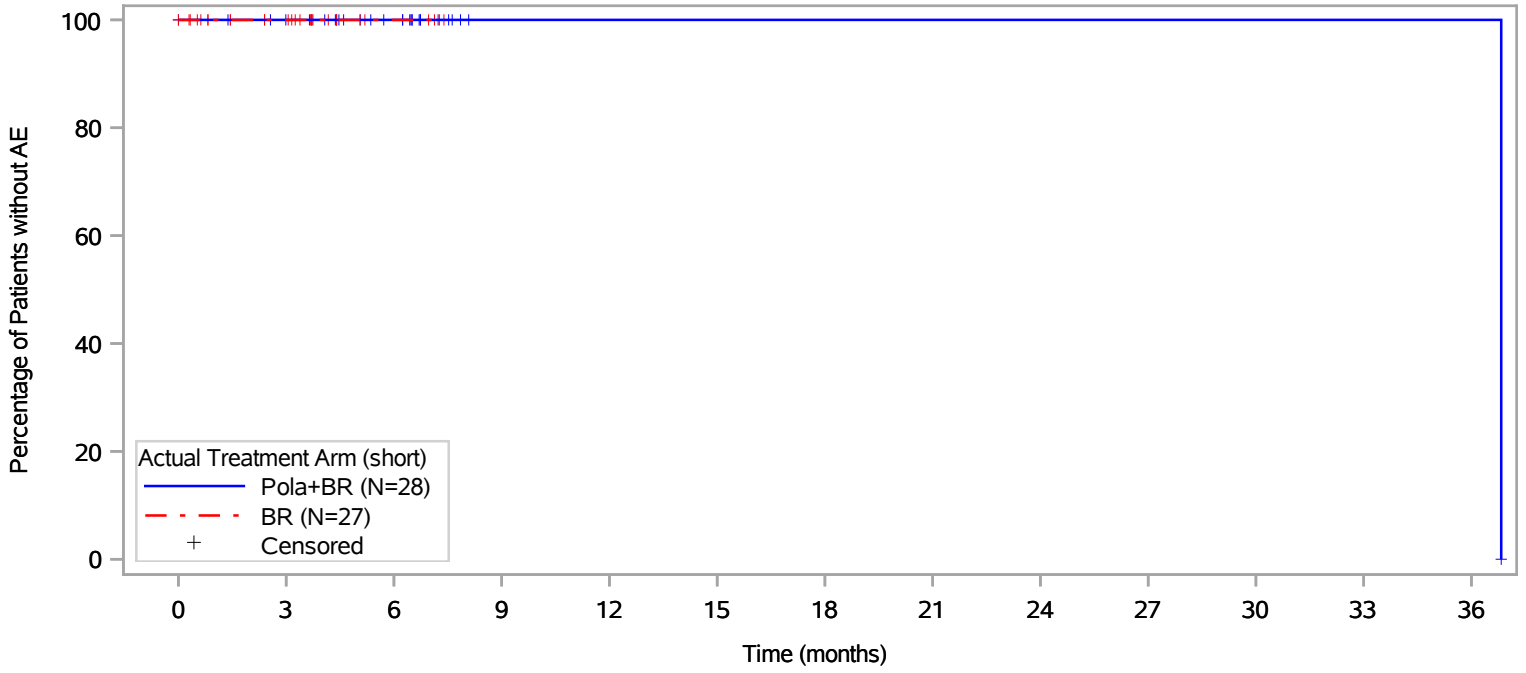


Patients at risk													
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

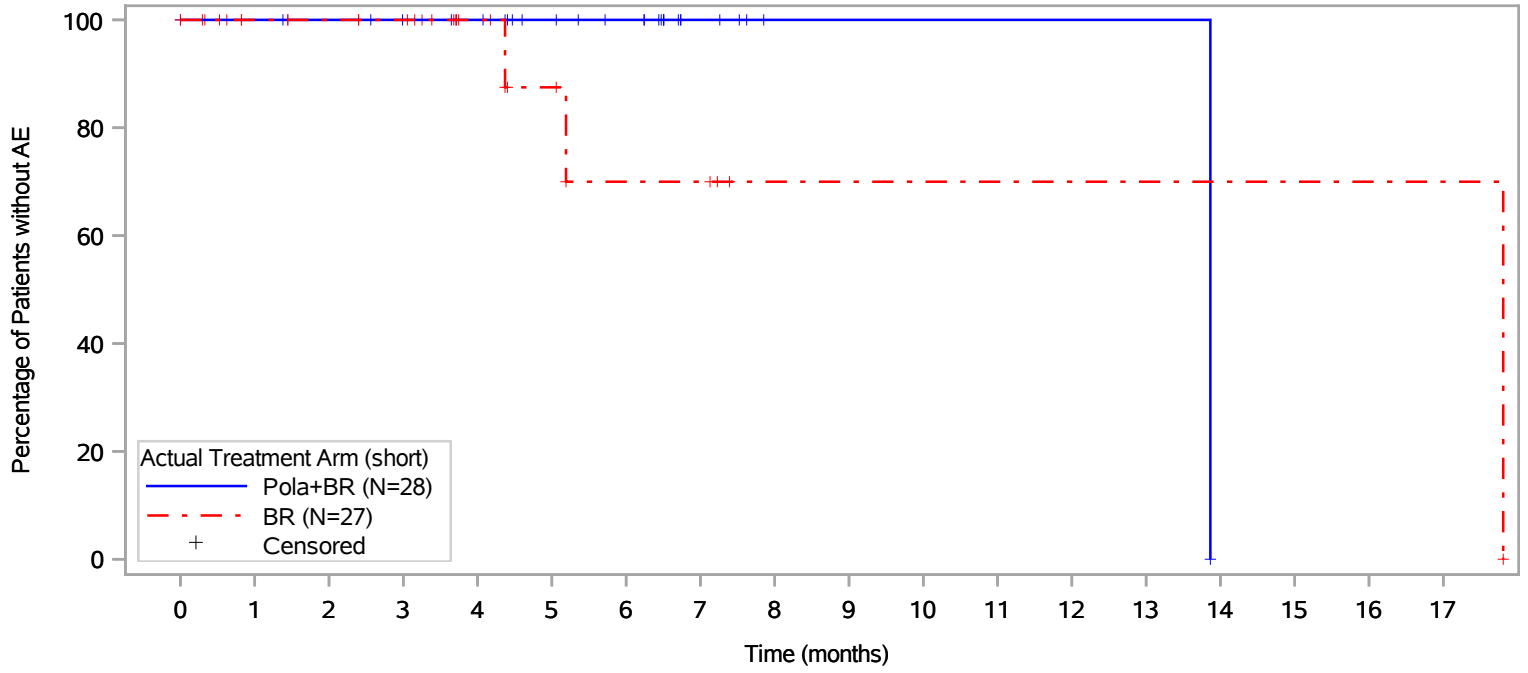
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS), MALIGNANT MELANOMA



Patients at risk													
Pola+BR (N=28)	28	25	15	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	17	4	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored													
Pola+BR (N=28)	0	3	13	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	10	23	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All

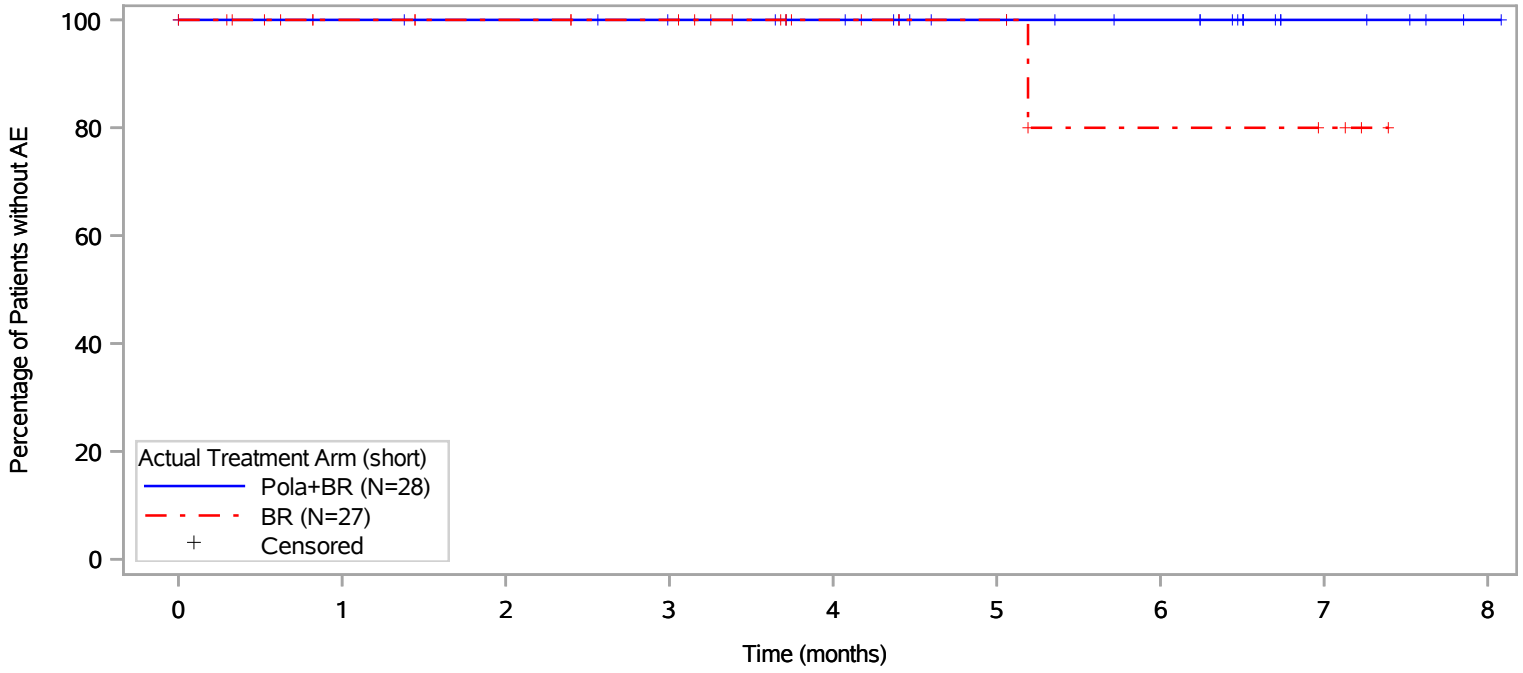


Patients at risk																		
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	1	1	1	1	1	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	27	27	27	27	27	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	20	21	21	24	24	24	24	24	24	24	24	24	24

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_soc_TTSAE_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 6:11

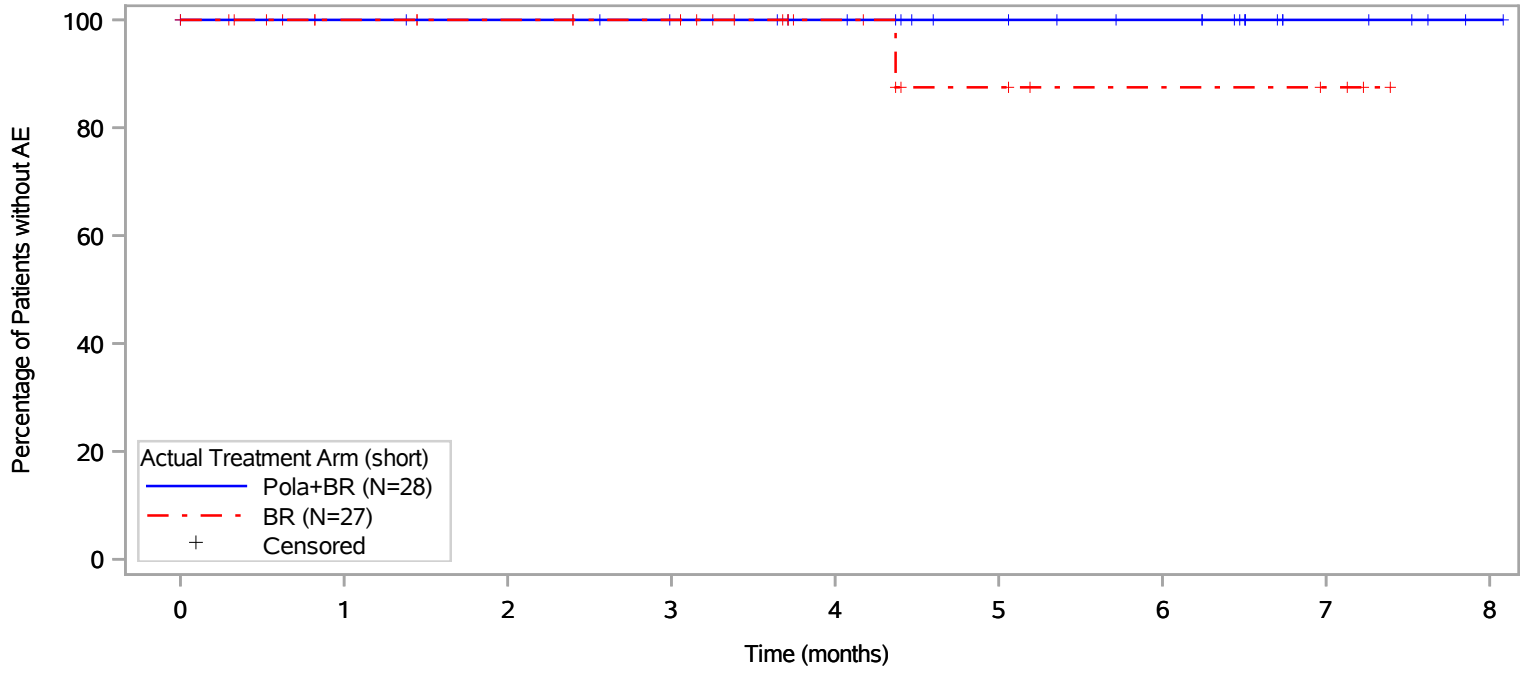
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, CEREBRAL HAEMORRHAGE



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, CEREBROVASCULAR ACCIDENT

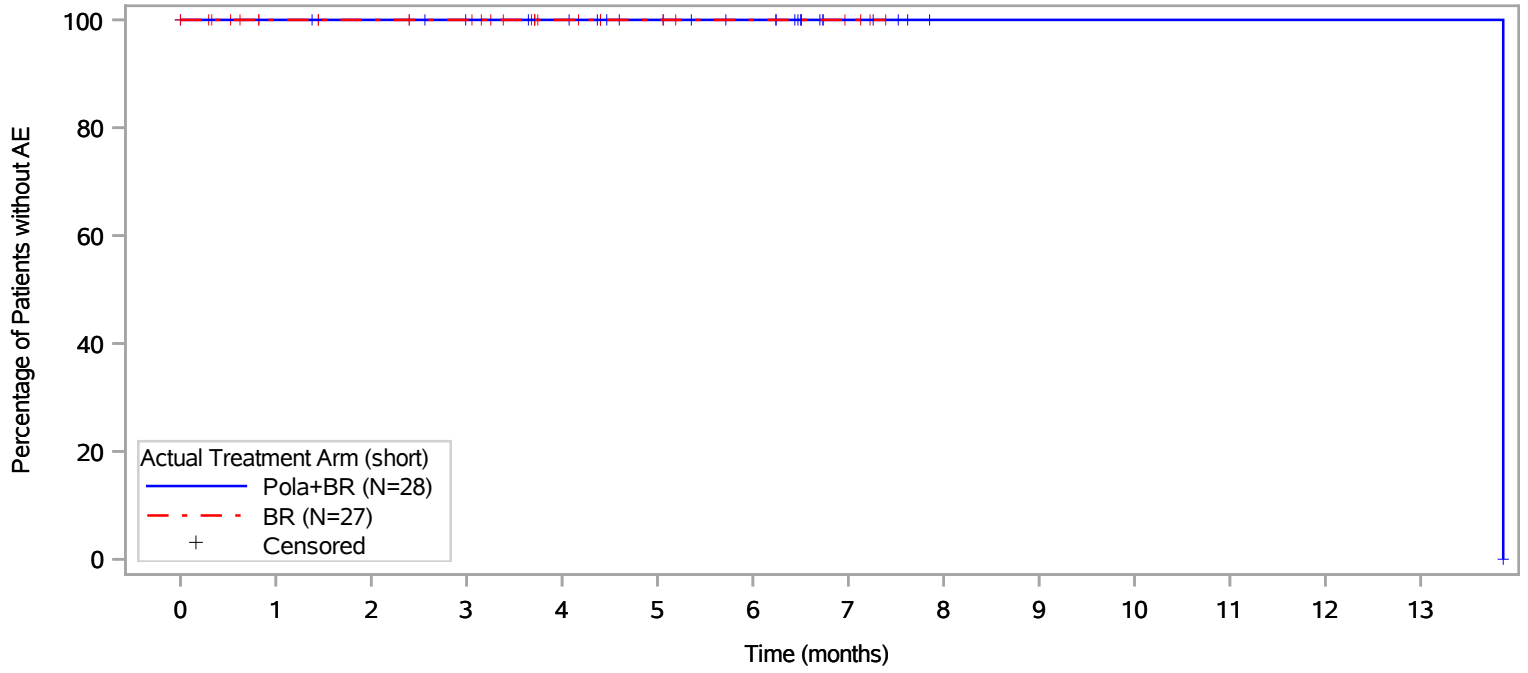


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

NERVOUS SYSTEM DISORDERS, HAEMORRHAGE INTRACRANIAL



Patients at risk														
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE
Patients censored														
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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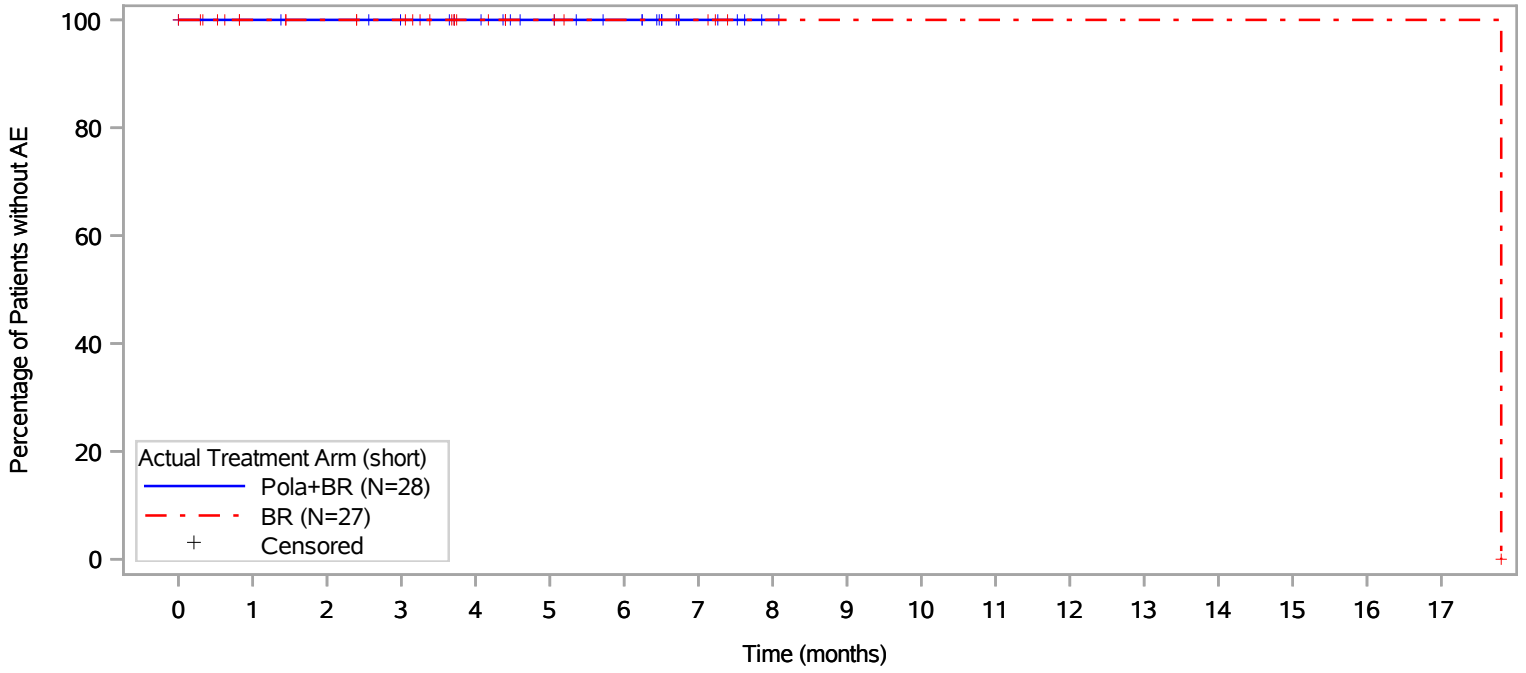
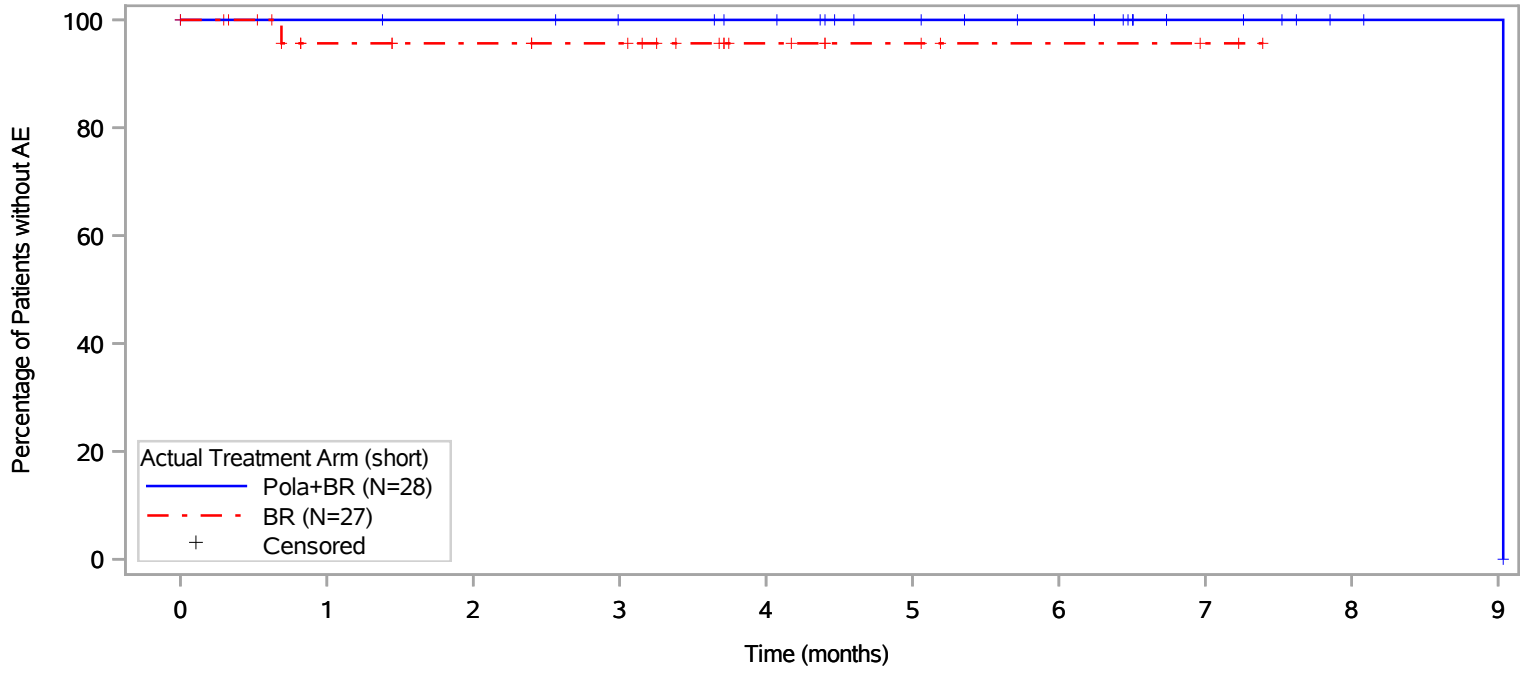
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, LEUKOENCEPHALOPATHY



Patients at risk																		
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	27	21	19	17	9	6	4	4	1	1	1	1	1	1	1	1	1	1
Patients censored																		
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27	NE	NE	NE	NE	NE	NE	NE	NE	NE
BR (N=27)	0	6	8	10	18	21	23	23	26	26	26	26	26	26	26	26	26	26

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1
BR (N=27)	27	20	18	16	8	5	3	2	NE	NE
Patients censored										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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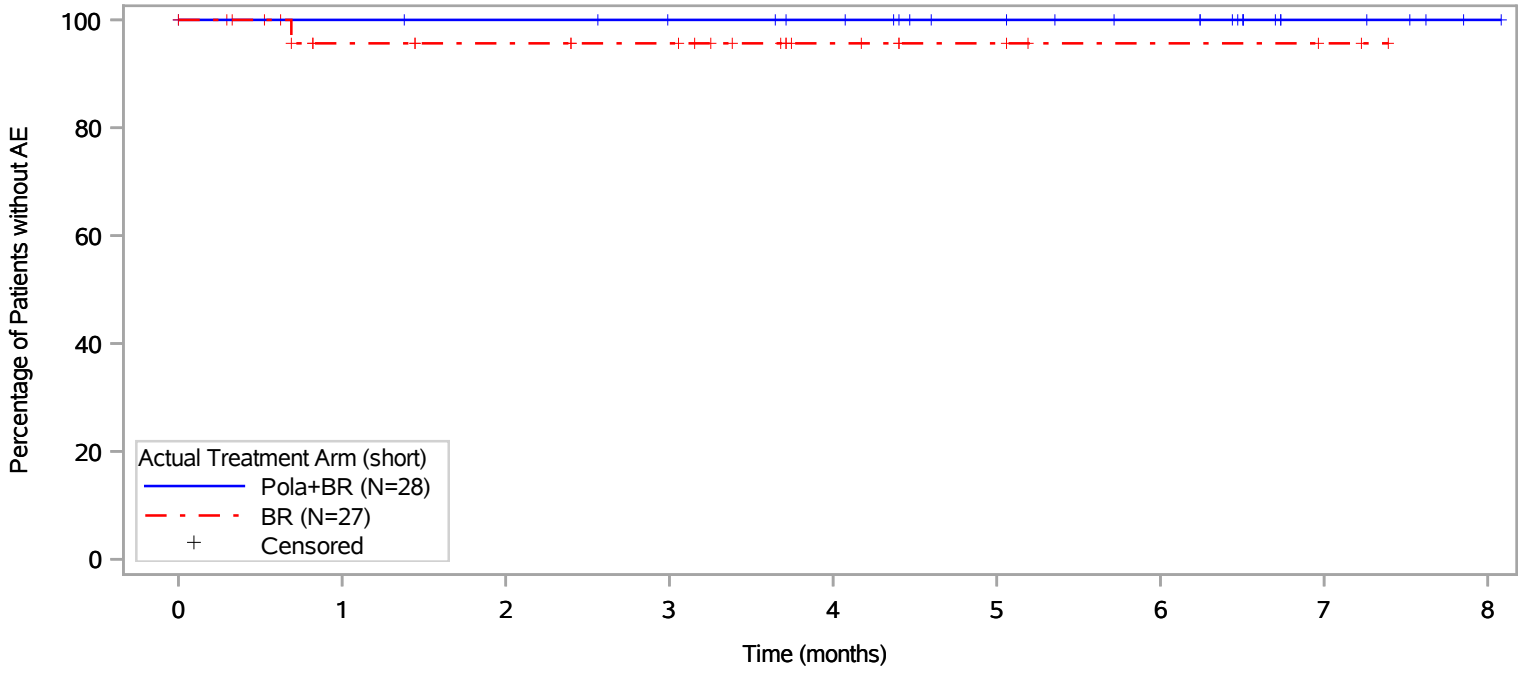
02DEC2022 6:11

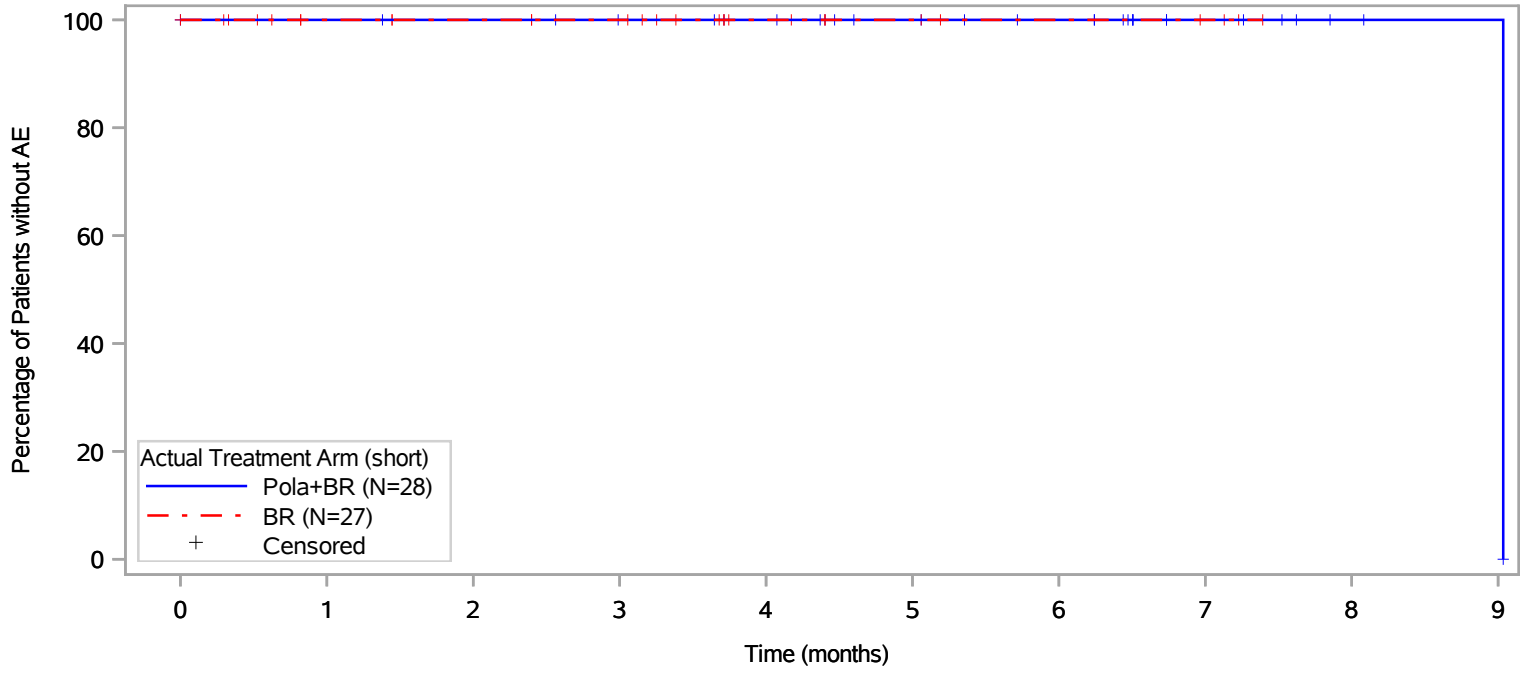
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, ACUTE KIDNEY INJURY



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk										
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE
Patients censored										
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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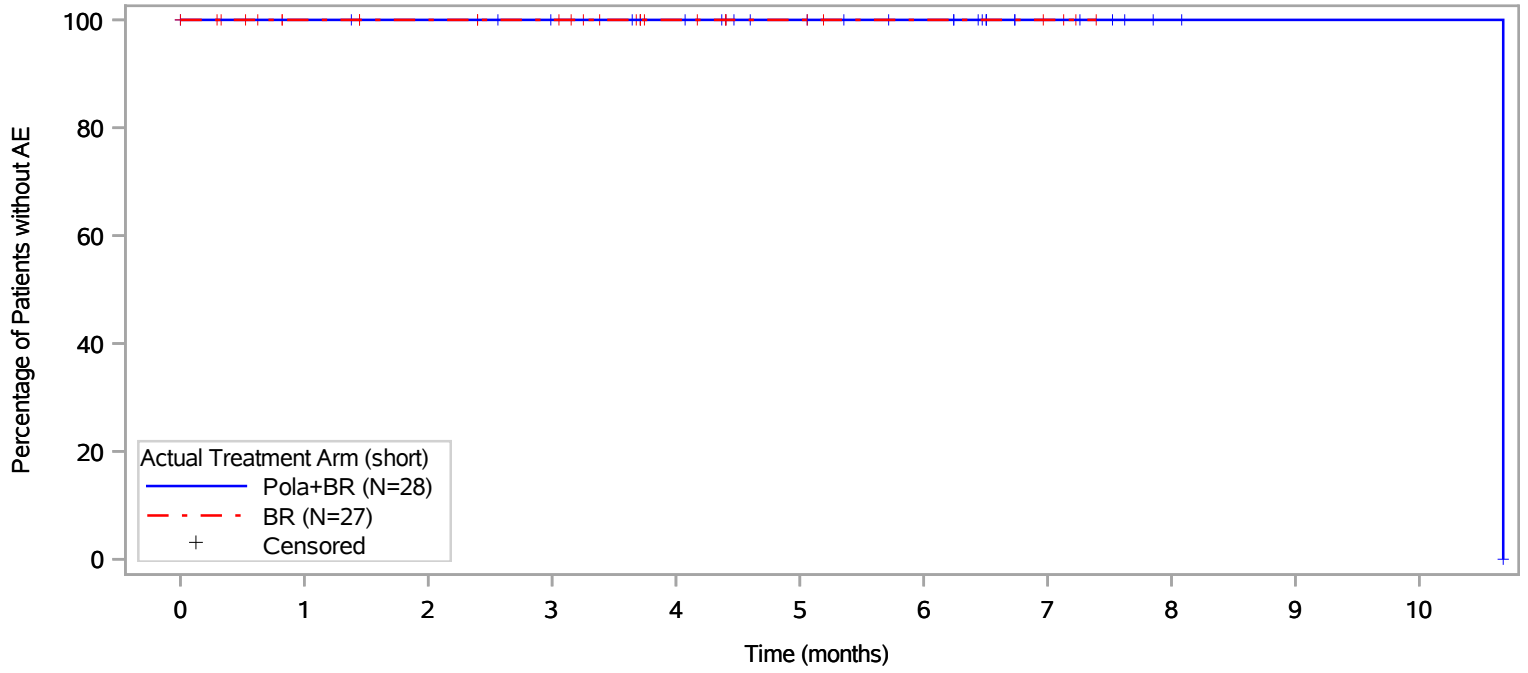
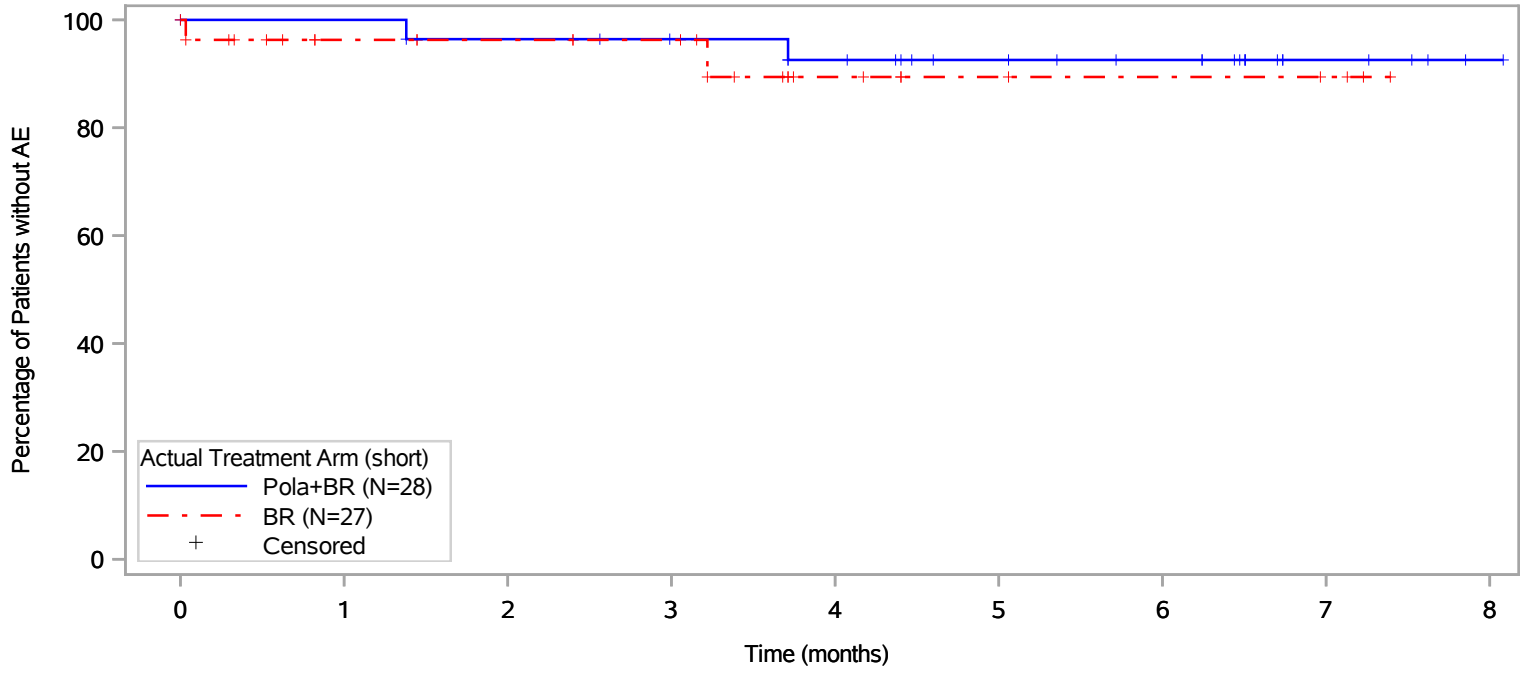
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL FAILURE



Patients at risk											
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All

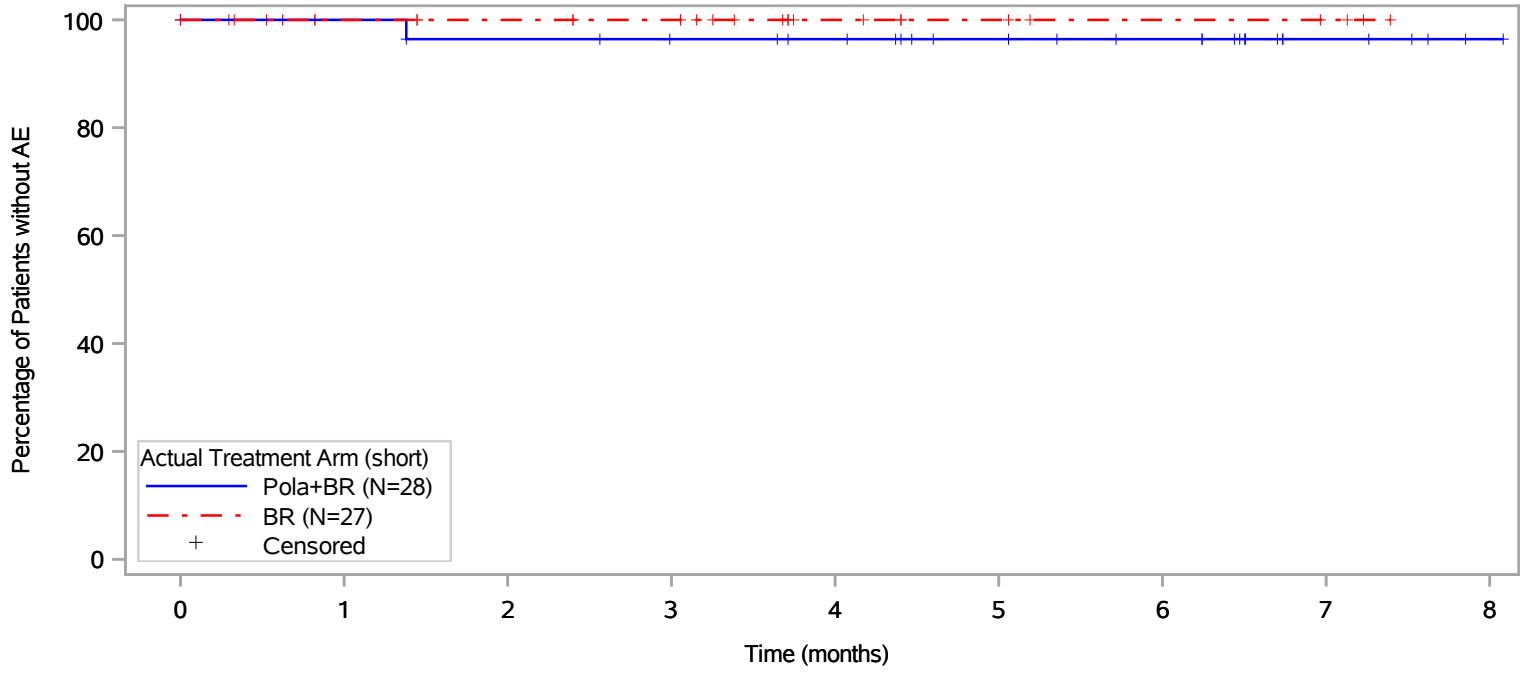


Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	3	8	11	21	25
BR (N=27)	0	6	8	10	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

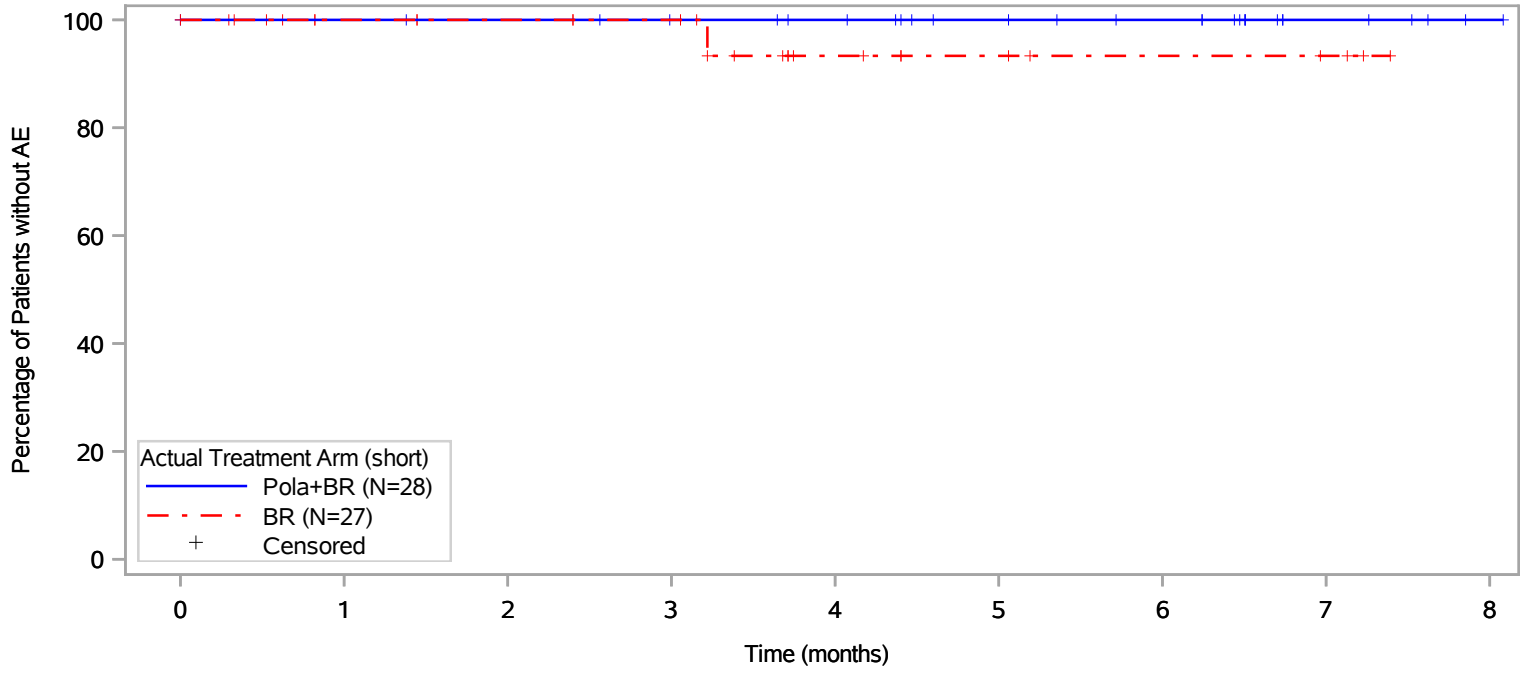
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HAEMOPTYSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HYPOXIA



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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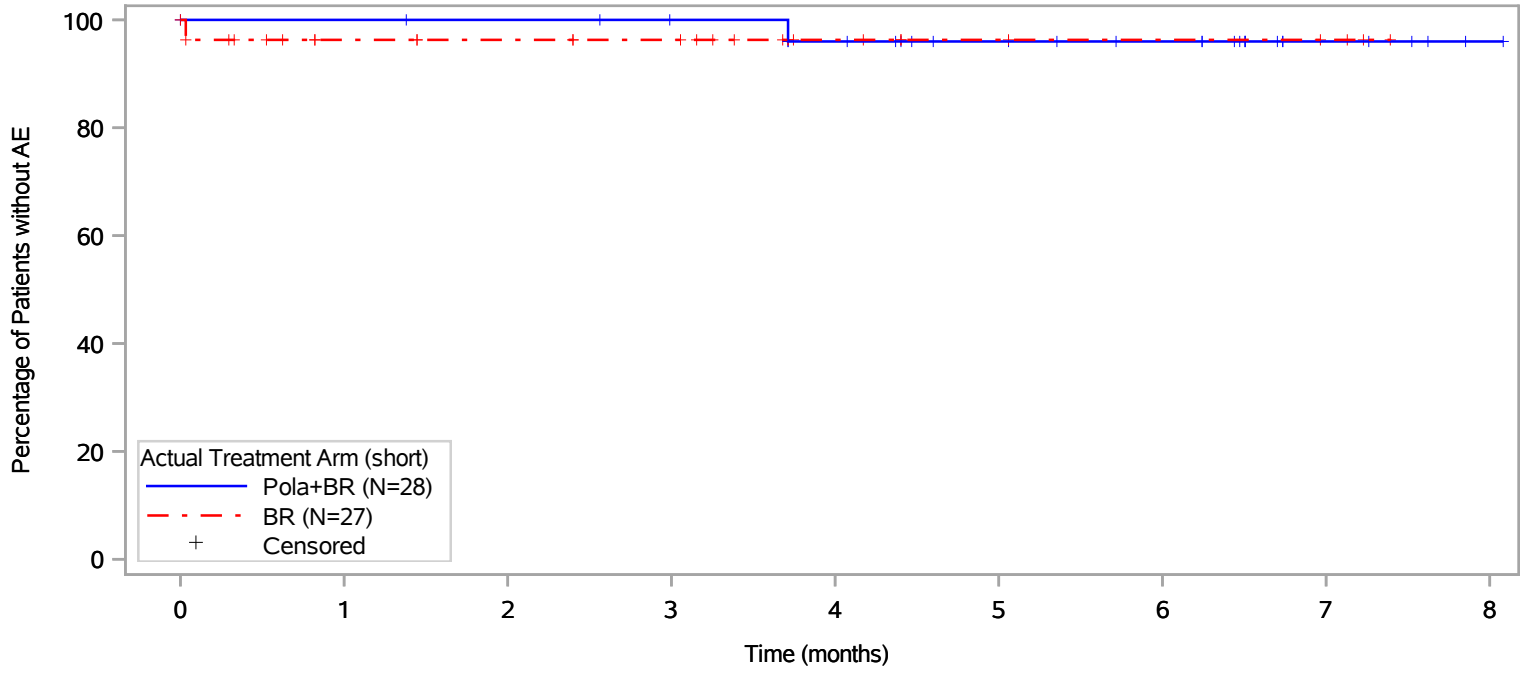
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

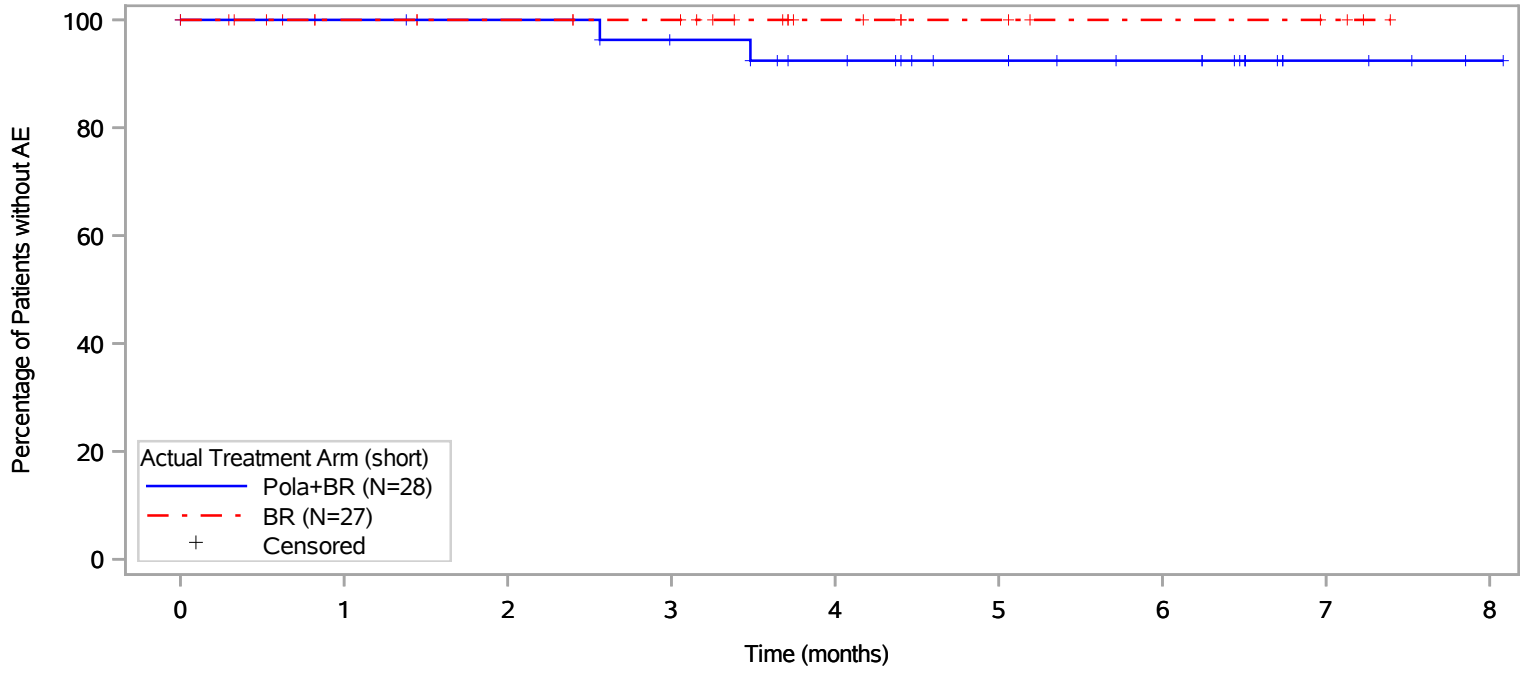
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

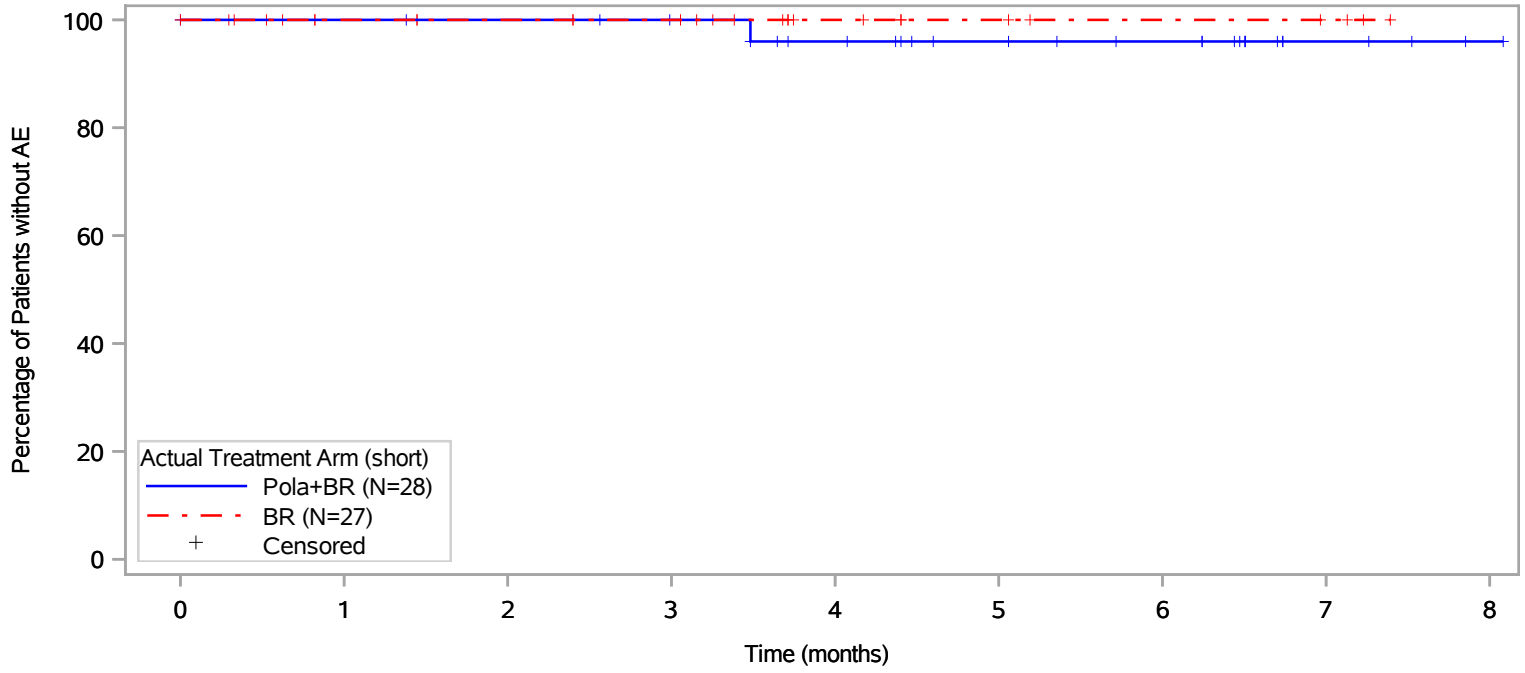
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	25
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

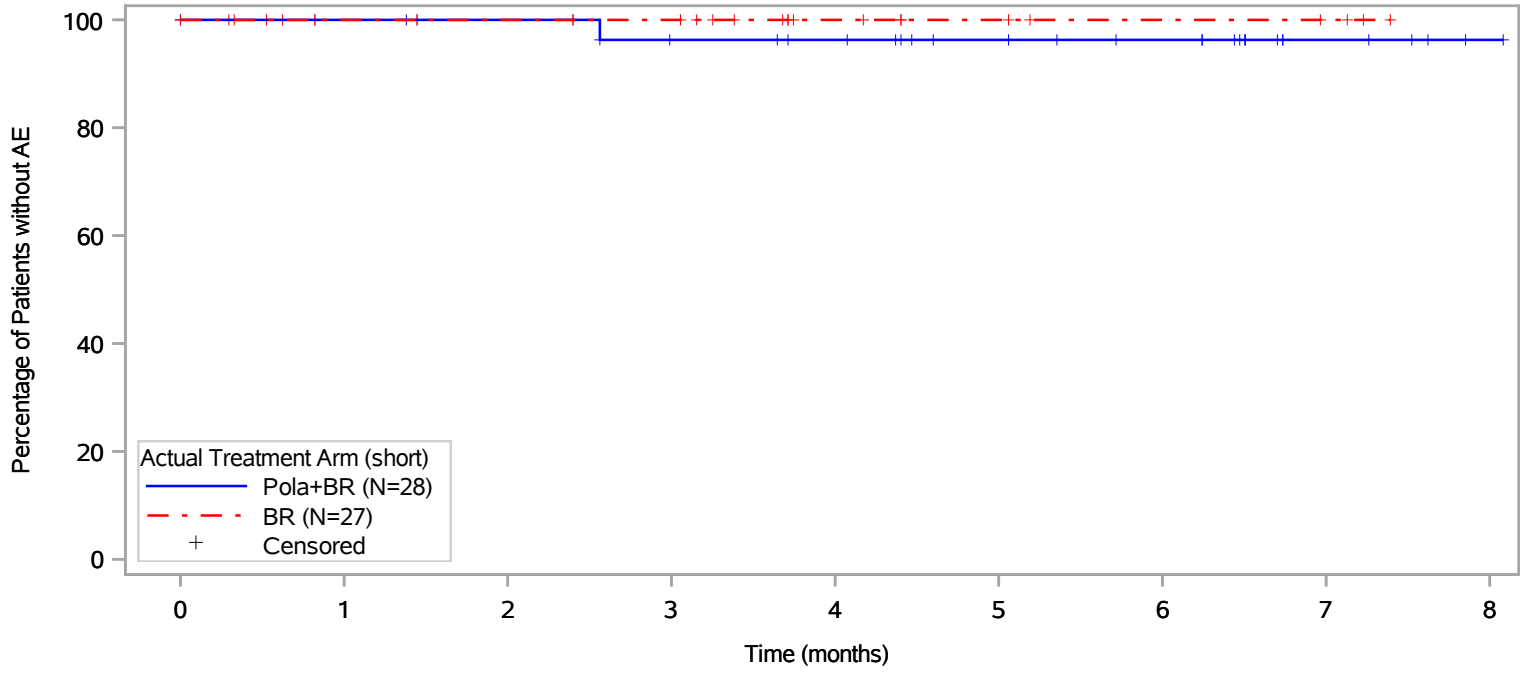
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DEEP VEIN THROMBOSIS



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, DISTRIBUTIVE SHOCK



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

All

			Pola+BR (N=28)				BR (N=27)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS			28	100.0	5	17.9	27	100.0	2	7.4
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		28	100.0	2	7.1	27	100.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA		28	100.0	1	3.6	27	100.0	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		28	100.0	4	14.3	27	100.0	2	7.4
INFECTIONS AND INFESTATIONS			28	100.0	0	-	27	100.0	1	3.7
INFECTIONS AND INFESTATIONS	PNEUMONIA		28	100.0	0	-	27	100.0	1	3.7
INVESTIGATIONS			28	100.0	2	7.1	27	100.0	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		28	100.0	1	3.6	27	100.0	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED		28	100.0	1	3.6	27	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			28	100.0	1	3.6	27	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		28	100.0	1	3.6	27	100.0	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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24JAN2023 17:51

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=28)				BR (N=27)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	13	46.4	2	15.4	13	48.1	1	7.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	15	53.6	3	20.0	14	51.9	1	7.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	13	46.4	1	7.7	13	48.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	15	53.6	1	6.7	14	51.9	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	< 65	13	46.4	0	-	13	48.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>= 65	15	53.6	1	6.7	14	51.9	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	13	46.4	2	15.4	13	48.1	1	7.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	15	53.6	2	13.3	14	51.9	1	7.1
INFECTIONS AND INFESTATIONS		< 65	13	46.4	0	-	13	48.1	1	7.7
INFECTIONS AND INFESTATIONS		>= 65	15	53.6	0	-	14	51.9	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	13	46.4	0	-	13	48.1	1	7.7
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	15	53.6	0	-	14	51.9	0	-
INVESTIGATIONS		< 65	13	46.4	1	7.7	13	48.1	0	-
INVESTIGATIONS		>= 65	15	53.6	1	6.7	14	51.9	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	13	46.4	1	7.7	13	48.1	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	15	53.6	0	-	14	51.9	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	13	46.4	0	-	13	48.1	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	15	53.6	1	6.7	14	51.9	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	13	46.4	0	-	13	48.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	15	53.6	1	6.7	14	51.9	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	13	46.4	0	-	13	48.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	15	53.6	1	6.7	14	51.9	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:51

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=28)				BR (N=27)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	15	53.6	3	20.0	18	66.7	1	5.6
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	13	46.4	2	15.4	9	33.3	1	11.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	15	53.6	1	6.7	18	66.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	13	46.4	1	7.7	9	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	>=3	15	53.6	1	6.7	18	66.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	<3	13	46.4	0	-	9	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	15	53.6	2	13.3	18	66.7	1	5.6
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	13	46.4	2	15.4	9	33.3	1	11.1
INFECTIONS AND INFESTATIONS		>=3	15	53.6	0	-	18	66.7	1	5.6
INFECTIONS AND INFESTATIONS		<3	13	46.4	0	-	9	33.3	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	15	53.6	0	-	18	66.7	1	5.6
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	13	46.4	0	-	9	33.3	0	-
INVESTIGATIONS		>=3	15	53.6	2	13.3	18	66.7	0	-
INVESTIGATIONS		<3	13	46.4	0	-	9	33.3	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	15	53.6	1	6.7	18	66.7	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	13	46.4	0	-	9	33.3	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	15	53.6	1	6.7	18	66.7	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	13	46.4	0	-	9	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	15	53.6	1	6.7	18	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	13	46.4	0	-	9	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	15	53.6	1	6.7	18	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	13	46.4	0	-	9	33.3	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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24JAN2023 17:51

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=28)				BR (N=27)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Europe	9	32.1	1	11.1	13	48.1	1	7.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	67.9	4	21.1	14	51.9	1	7.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Europe	9	32.1	0	-	13	48.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	19	67.9	2	10.5	14	51.9	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Europe	9	32.1	0	-	13	48.1	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Non-Europe	19	67.9	1	5.3	14	51.9	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Europe	9	32.1	1	11.1	13	48.1	1	7.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	67.9	3	15.8	14	51.9	1	7.1
INFECTIONS AND INFESTATIONS		Europe	9	32.1	0	-	13	48.1	1	7.7
INFECTIONS AND INFESTATIONS		Non-Europe	19	67.9	0	-	14	51.9	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Europe	9	32.1	0	-	13	48.1	1	7.7
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	67.9	0	-	14	51.9	0	-
INVESTIGATIONS		Europe	9	32.1	0	-	13	48.1	0	-
INVESTIGATIONS		Non-Europe	19	67.9	2	10.5	14	51.9	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Europe	9	32.1	0	-	13	48.1	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	19	67.9	1	5.3	14	51.9	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Europe	9	32.1	0	-	13	48.1	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	67.9	1	5.3	14	51.9	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Europe	9	32.1	0	-	13	48.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	67.9	1	5.3	14	51.9	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Europe	9	32.1	0	-	13	48.1	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	19	67.9	1	5.3	14	51.9	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_soc_descriptive_sg1_TTWDAE_L3PLUS_ARMCDSE_365_29365_41543.xls
24JAN2023 17:51

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=28)				BR (N=27)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	20	71.4	4	20.0	18	66.7	2	11.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	8	28.6	1	12.5	9	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	20	71.4	1	5.0	18	66.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	8	28.6	1	12.5	9	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Male	20	71.4	1	5.0	18	66.7	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	PANCYTOPENIA	Female	8	28.6	0	-	9	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	20	71.4	3	15.0	18	66.7	2	11.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	8	28.6	1	12.5	9	33.3	0	-
INFECTIONS AND INFESTATIONS		Male	20	71.4	0	-	18	66.7	1	5.6
INFECTIONS AND INFESTATIONS		Female	8	28.6	0	-	9	33.3	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	20	71.4	0	-	18	66.7	1	5.6
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	8	28.6	0	-	9	33.3	0	-
INVESTIGATIONS		Male	20	71.4	2	10.0	18	66.7	0	-
INVESTIGATIONS		Female	8	28.6	0	-	9	33.3	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	20	71.4	1	5.0	18	66.7	0	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	8	28.6	0	-	9	33.3	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	20	71.4	1	5.0	18	66.7	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	8	28.6	0	-	9	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	20	71.4	0	-	18	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	8	28.6	1	12.5	9	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	20	71.4	0	-	18	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	8	28.6	1	12.5	9	33.3	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_soc_descriptive_sg1_TTWDAE_L3PLUS_ARMCDSE_365_29365_41543.xls
24JAN2023 17:51

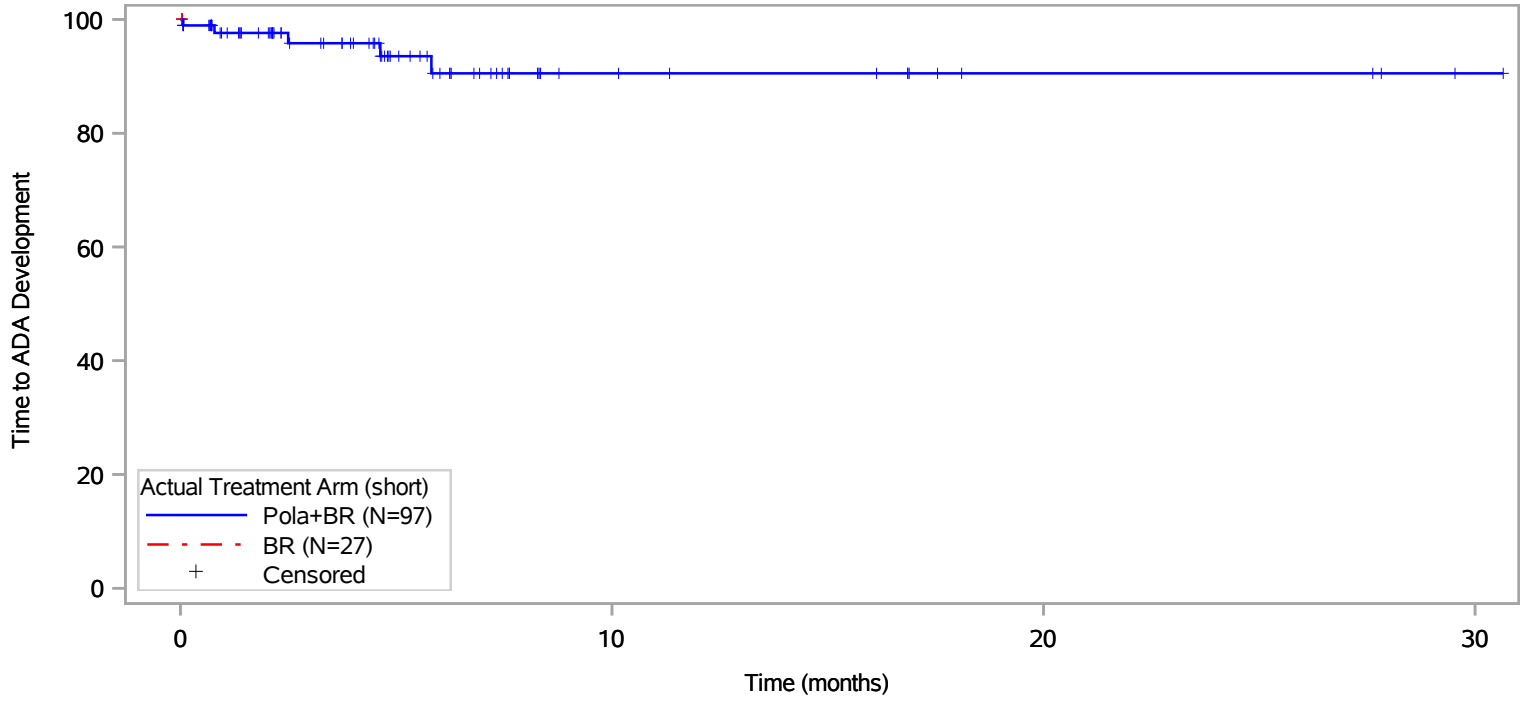
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTADAP_L3PLUS_ARMCDSE_365_29365_41543.xls
06APR2023 19:29

POPULATION: Safety-Evaluable Patients, Study GO29365, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=97)	97	52	29	12	10	10	5	4	4	4	1
BR (N=27)	27	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored											
Pola+BR (N=97)	0	42	63	80	82	82	87	88	88	88	91
BR (N=27)	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ysis/ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTADAP_L3PLUS_365_SE_29365_41543.pdf
06APR2023 19:51

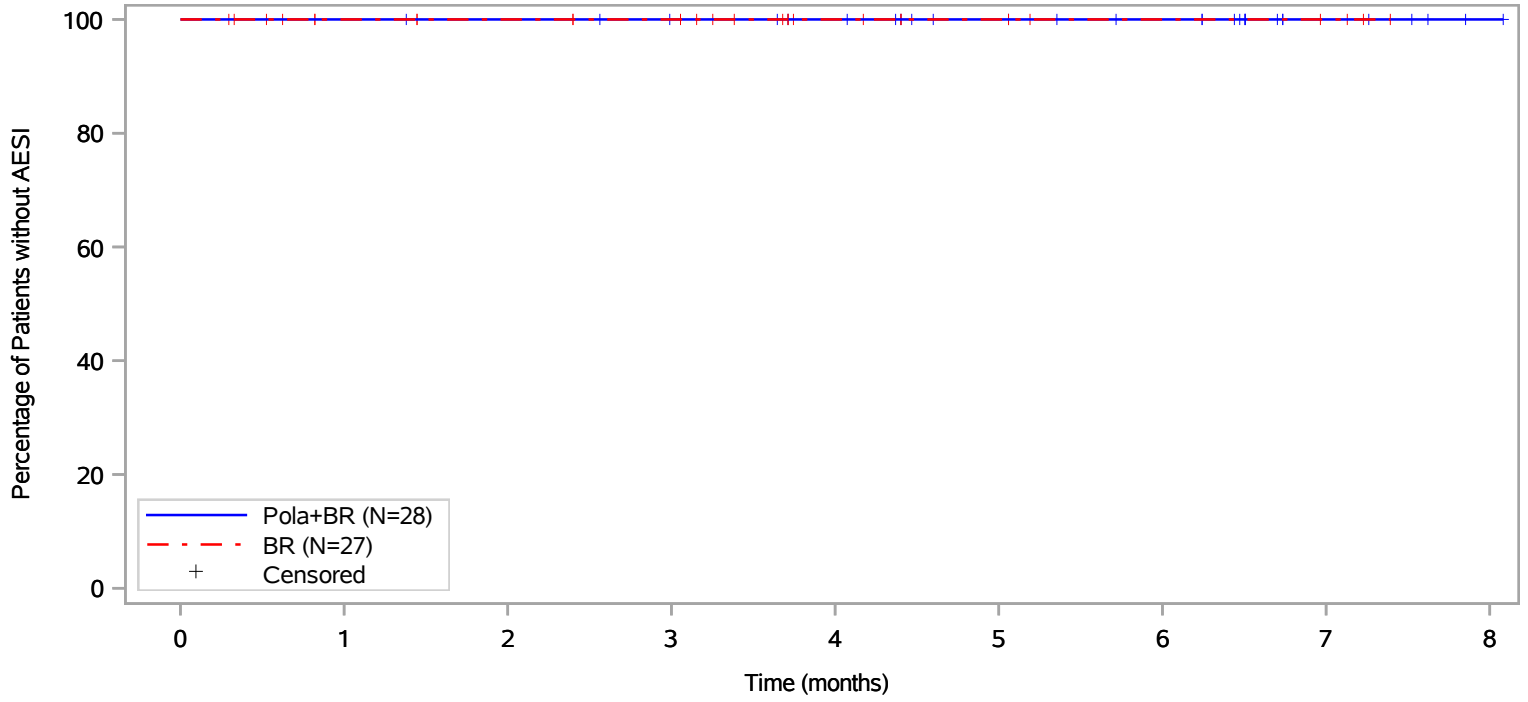
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTALOPE_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 19:49

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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01DEC2022 22:24

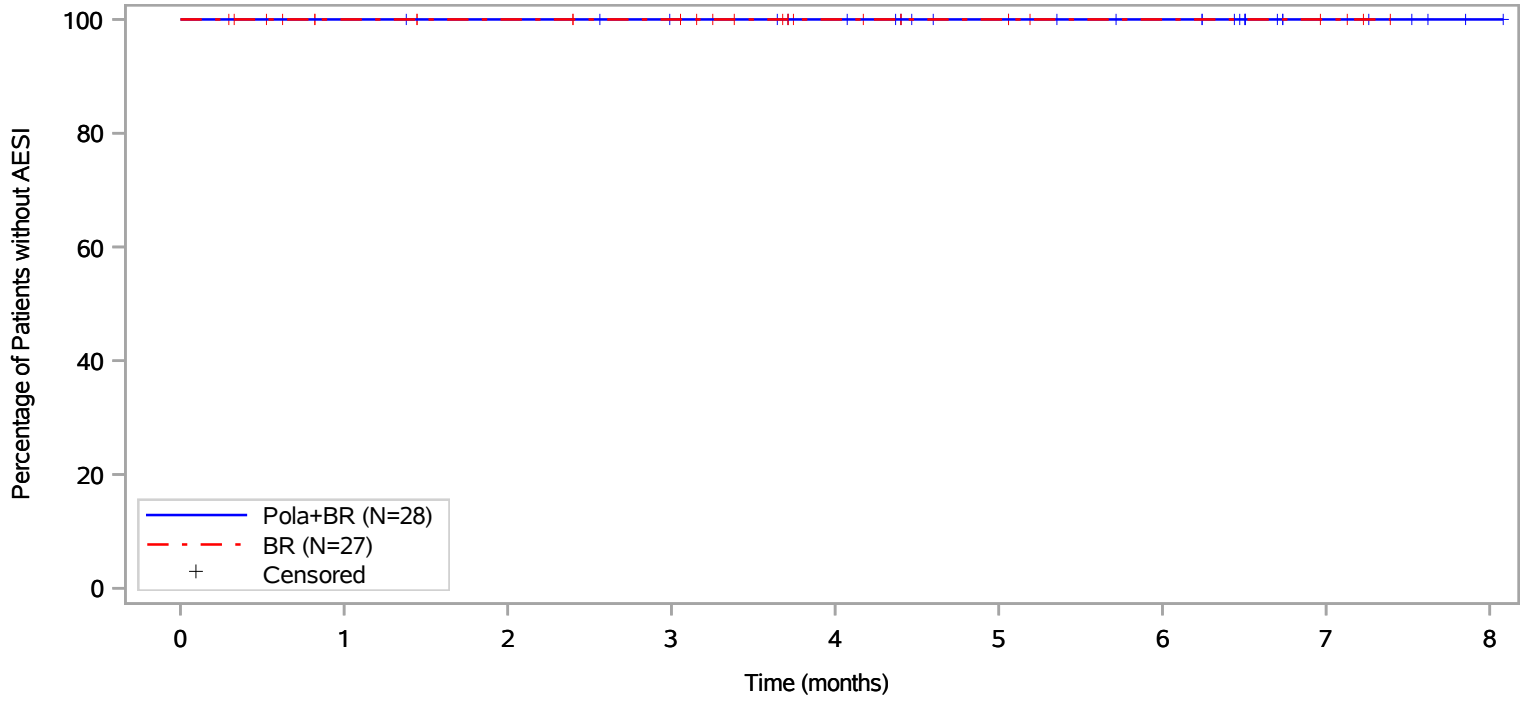
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTALOPE35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 22:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 17:02

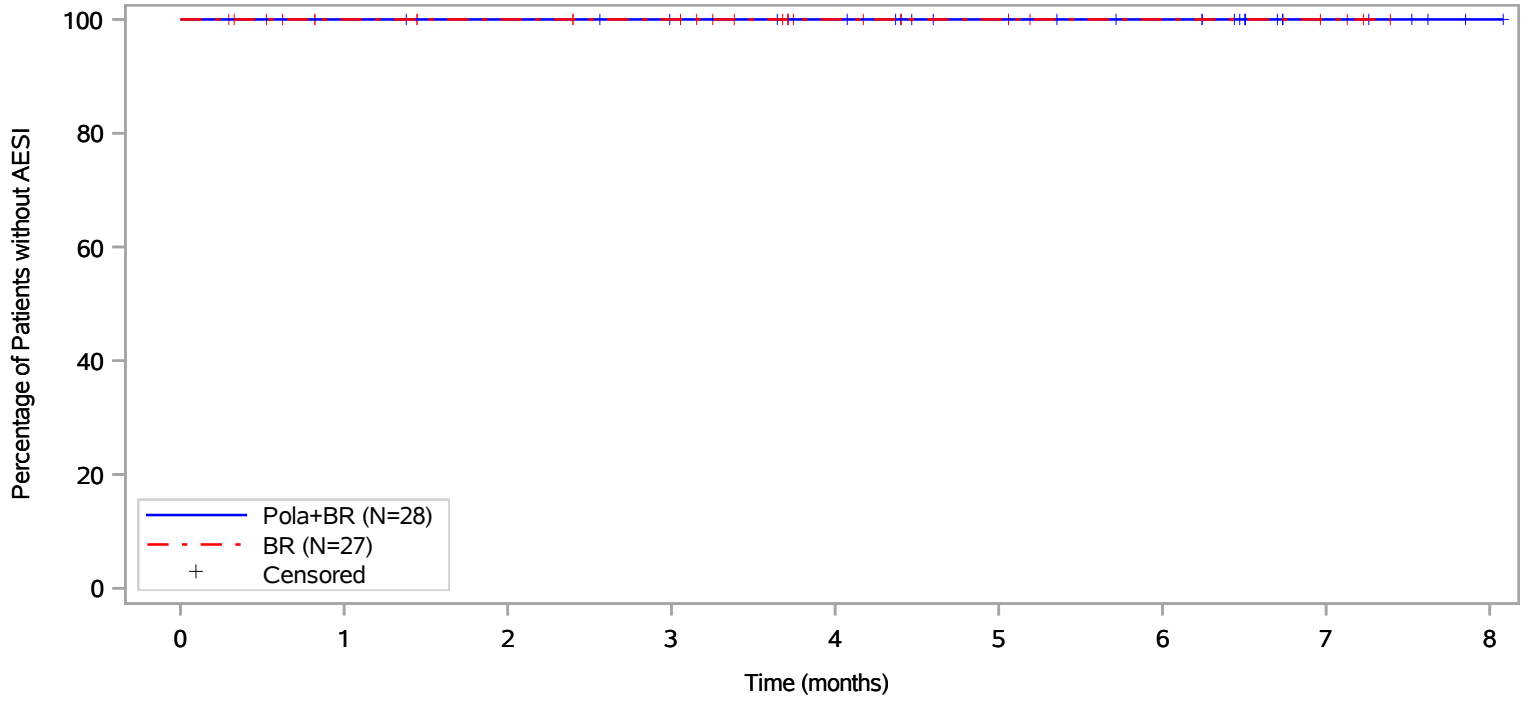
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTALOPES_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:59

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Alopecia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 17:01

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	16	57.1	12	42.9	27	100.0	5	18.5	22	81.5	0.0649	2.51	0.91	6.89		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	11	55.0	9	45.0	18	66.7	5	27.8	13	72.2	0.4525	1.50	0.52	4.35		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	5	62.5	3	37.5	9	33.3	0	-	9	100.0	0.0252	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	10	76.9	3	23.1	13	48.1	3	23.1	10	76.9	0.0485	3.42	0.93	12.53		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	6	40.0	9	60.0	14	51.9	2	14.3	12	85.7	0.5340	1.68	0.32	8.72		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	8	53.3	7	46.7	18	66.7	3	16.7	15	83.3	0.2601	2.13	0.56	8.14		Convergence criterion (GCONV=1E-8) satisfied.	0.8627
	<3	13	46.4	8	61.5	5	38.5	9	33.3	2	22.2	7	77.8	0.1985	2.68	0.56	12.77		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	4	44.4	5	55.6	13	48.1	0	-	13	100.0	0.0487	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	12	63.2	7	36.8	14	51.9	5	35.7	9	64.3	0.4643	1.48	0.52	4.22		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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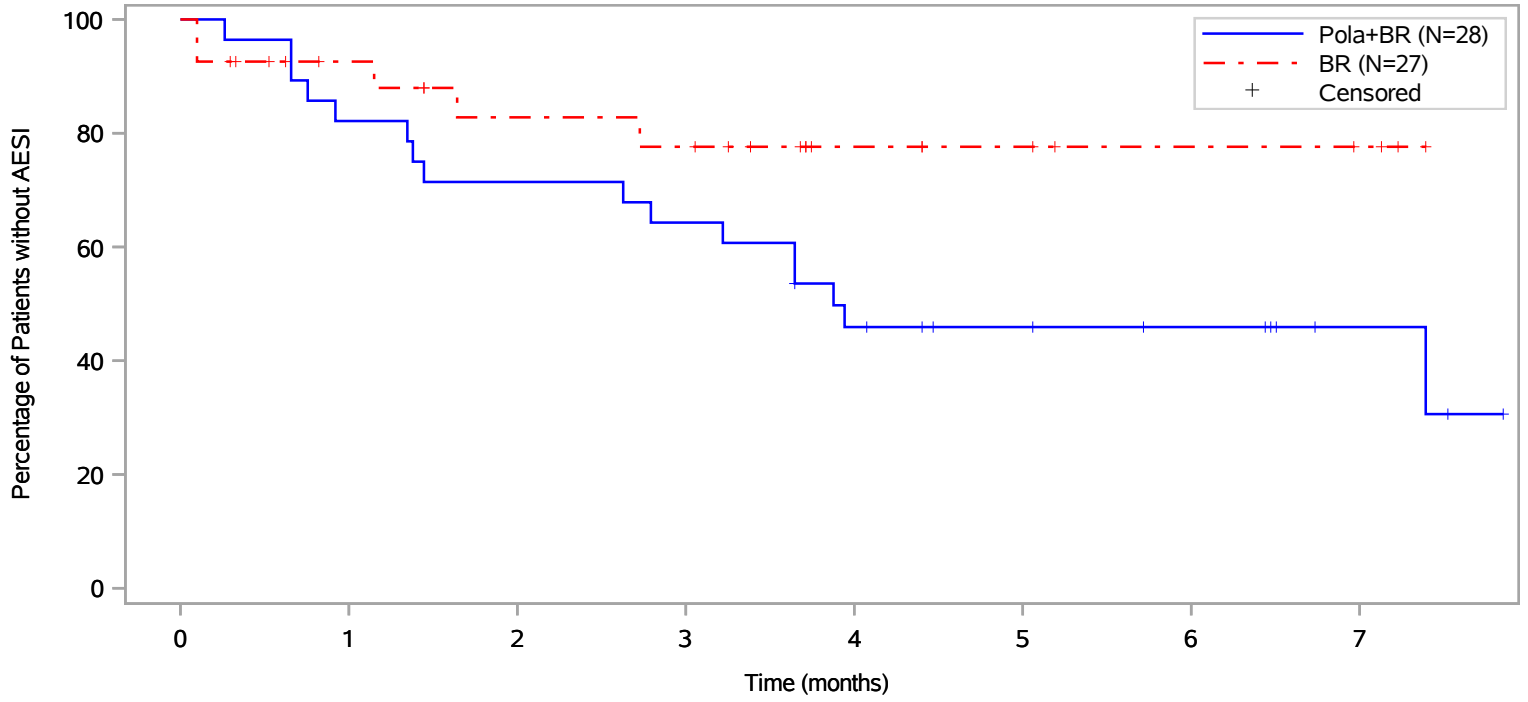
01DEC2022 1:20

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=28)	28	23	20	18	12	9	7	3
BR (N=27)	27	20	16	15	8	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	0	0	1	4	6	10
BR (N=27)	0	5	7	7	14	16	18	19

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 17:06

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	7	25.0	21	75.0	27	100.0	5	18.5	22	81.5	0.9956	1.00	0.31	3.21		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	4	20.0	16	80.0	18	66.7	5	27.8	13	72.2	0.3160	0.51	0.13	1.95		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	3	37.5	5	62.5	9	33.3	0	-	9	100.0	0.1069	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	4	30.8	9	69.2	13	48.1	3	23.1	10	76.9	0.8482	1.16	0.26	5.21		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	2	14.3	12	85.7	0.7536	0.73	0.10	5.22		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	3	20.0	12	80.0	18	66.7	3	16.7	15	83.3	0.7254	0.75	0.14	3.86		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	4	30.8	9	69.2	9	33.3	2	22.2	7	77.8	0.7645	1.30	0.24	7.09		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	5	35.7	9	64.3	0.5651	0.71	0.21	2.33		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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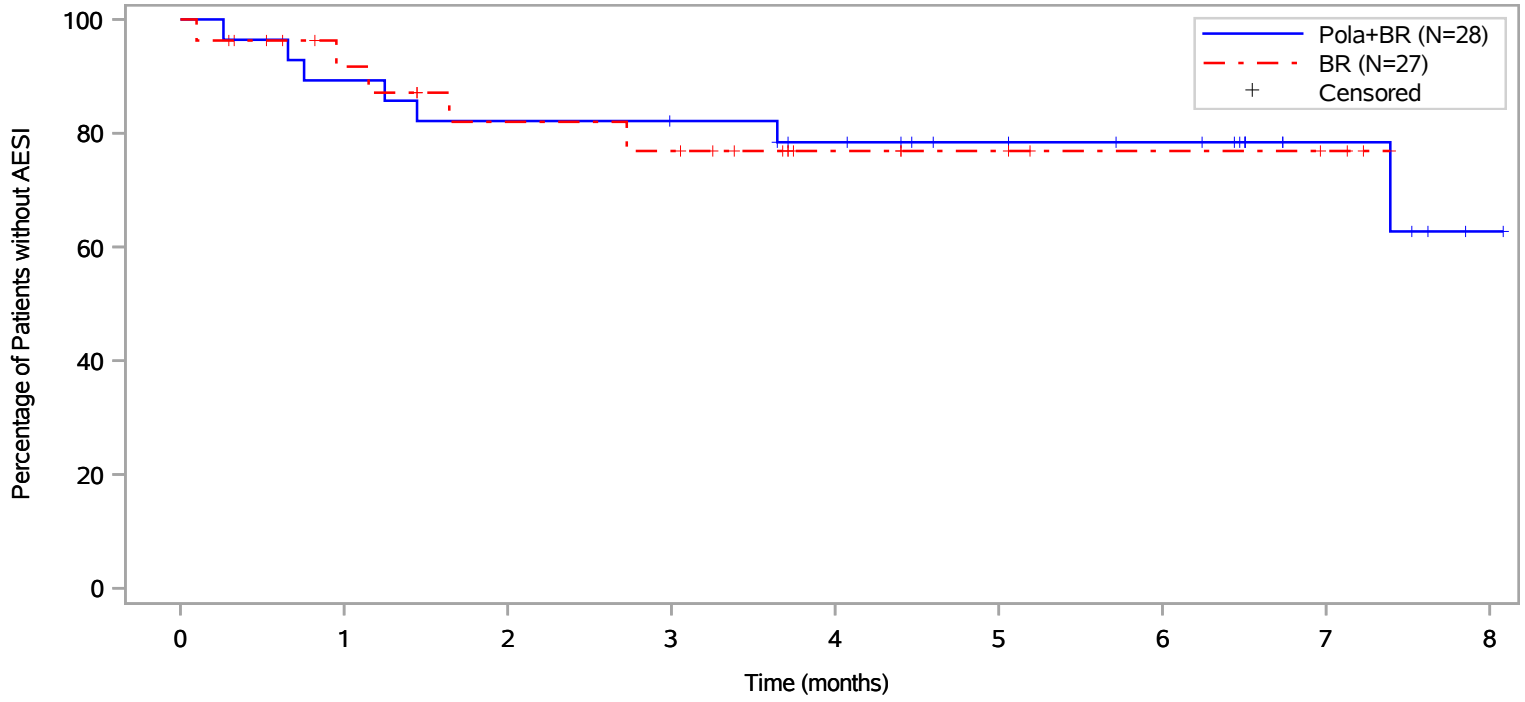
02DEC2022 20:32

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	25	23	22	19	15	13	5	1
BR (N=27)	27	20	16	15	8	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	0	1	3	7	9	17	20
BR (N=27)	0	5	7	7	14	16	18	19	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 17:11

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.9360	0.90	0.08	10.72		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.9354	0.90	0.08	10.50		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.7363	0.62	0.04	10.25		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.6729	0.55	0.03	8.90		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.3458	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.4890	0.38	0.02	6.47		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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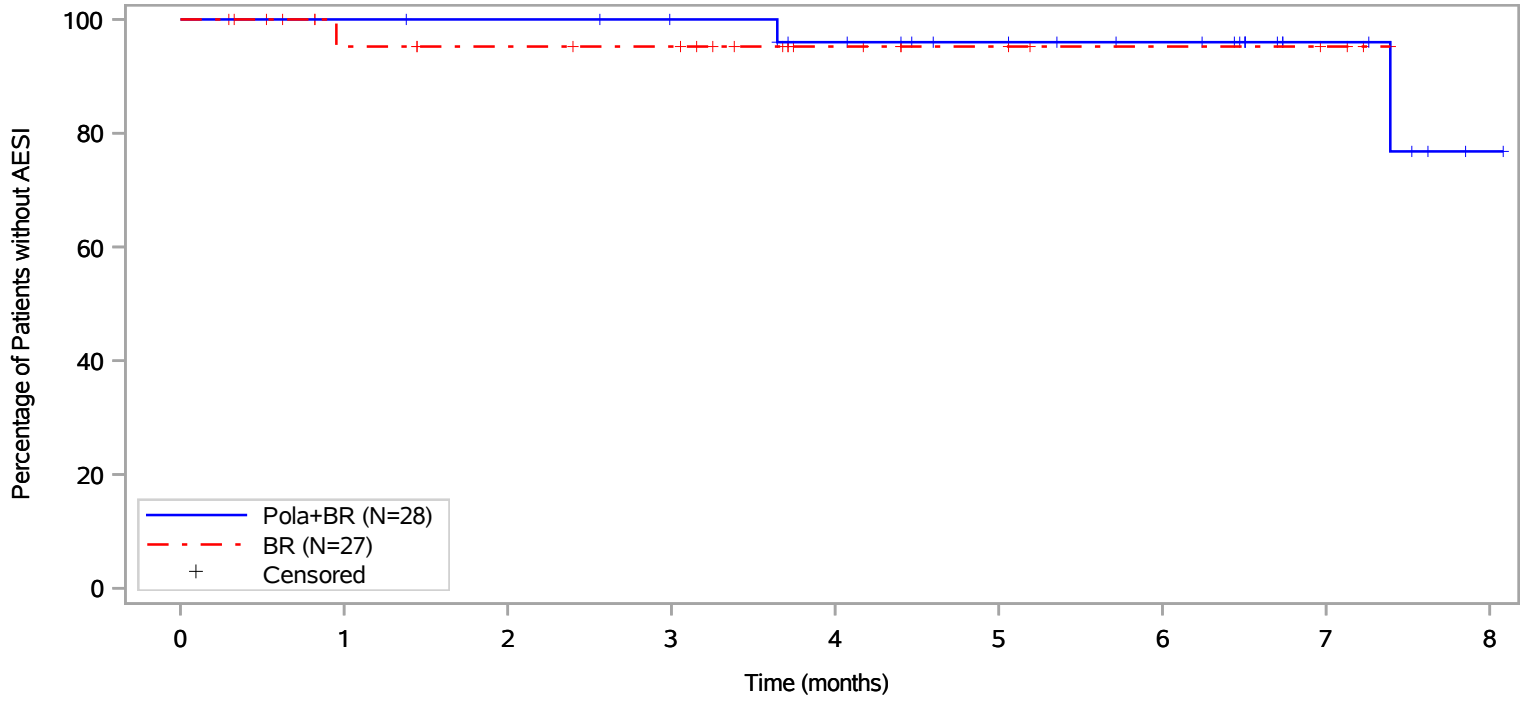
02DEC2022 20:28

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Anemia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	22	18	15	6	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	9	12	21	25
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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03DEC2022 17:14

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	4	14.8	23	85.2	0.0232	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	3	16.7	15	83.3	0.0412	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	3	21.4	11	78.6	0.0334	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	2	11.1	16	88.9	0.1587	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	2	22.2	7	77.8	0.0701	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	3	21.4	11	78.6	0.0238	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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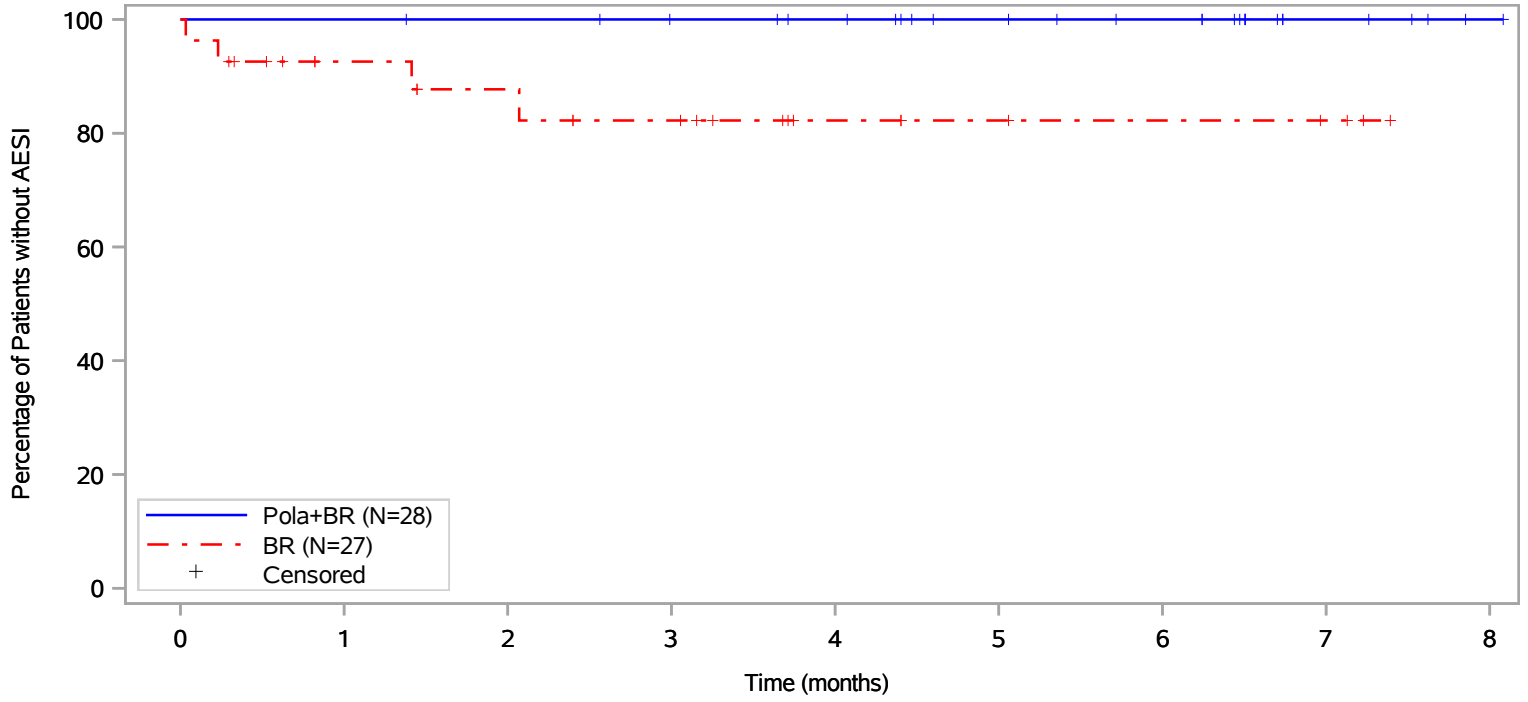
25JAN2023 17:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	19	16	13	7	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	16	18	19	20	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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01DEC2022 22:31

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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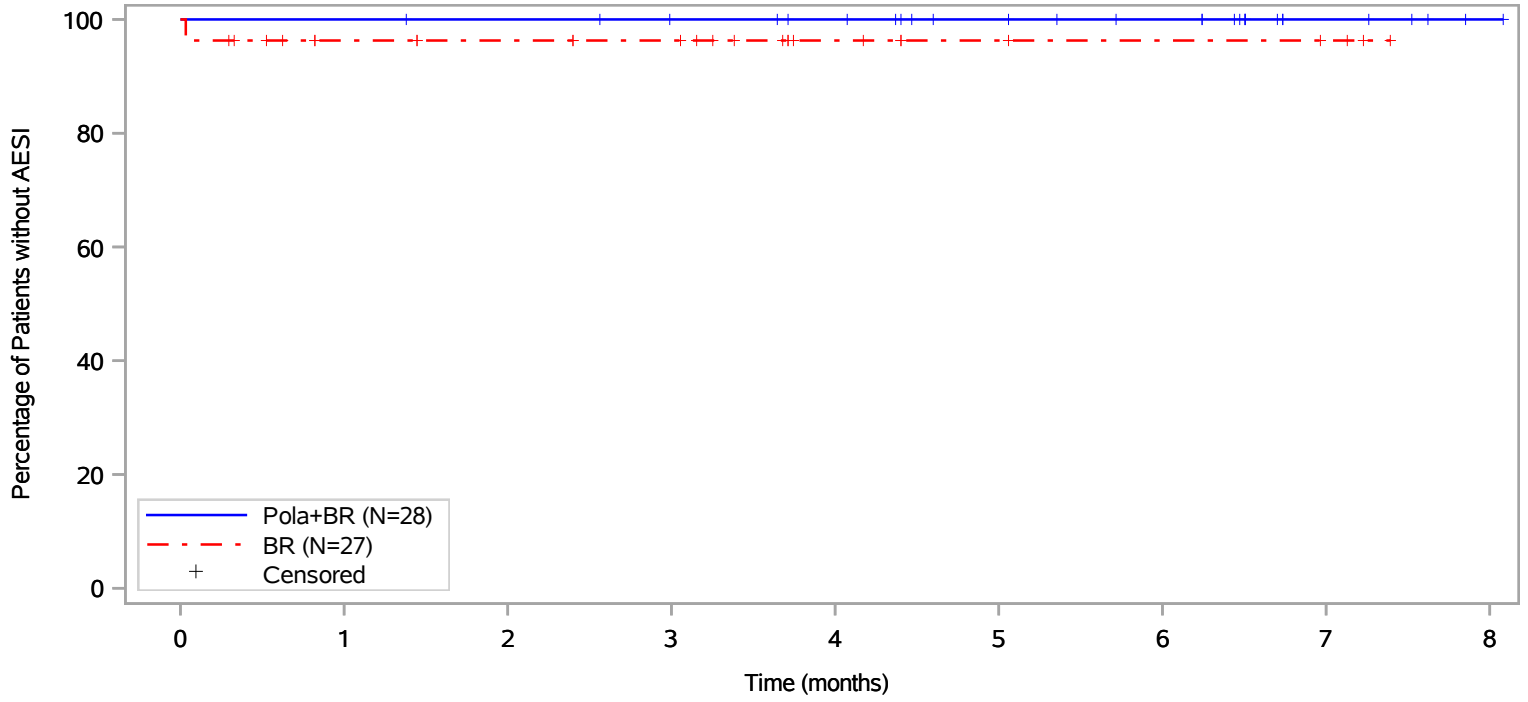
25JAN2023 17:23

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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02DEC2022 14:17

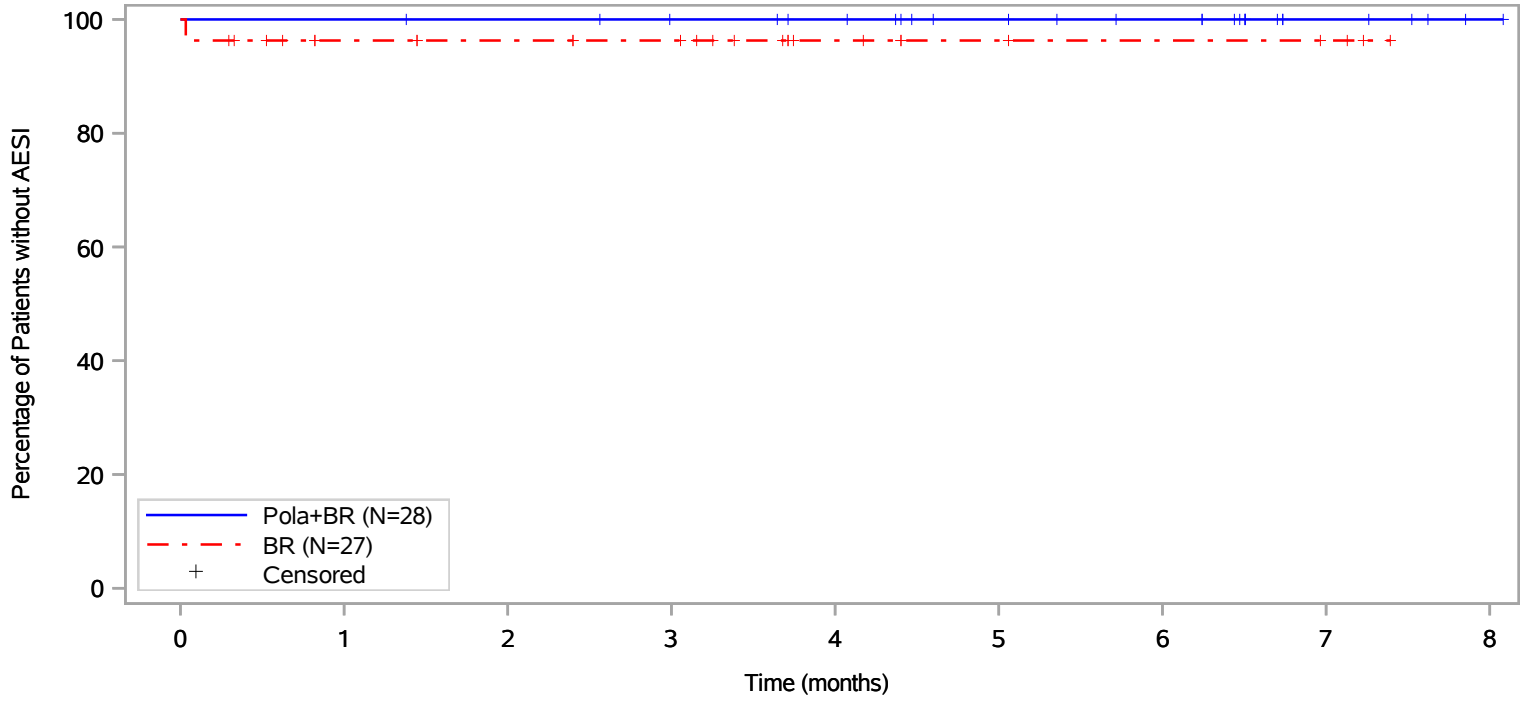
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.3085	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3458	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3613	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTCTAARS_L3PLUS_ARMCDSE_365_29365_41543.xls
25JAN2023 17:32

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTCTAARS_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:18

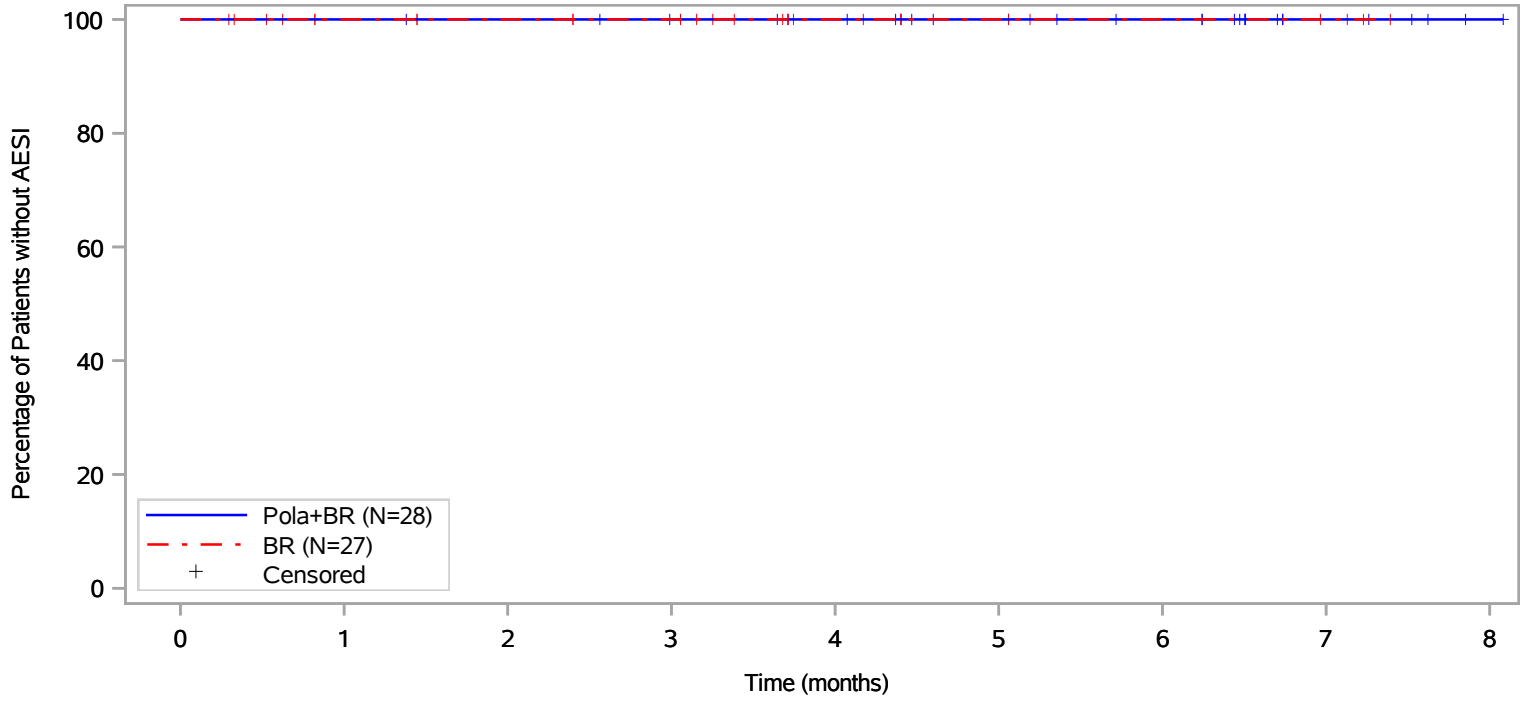
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTDDIN_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 22:12

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Drug Drug Interaction
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTDDIN_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 23:35

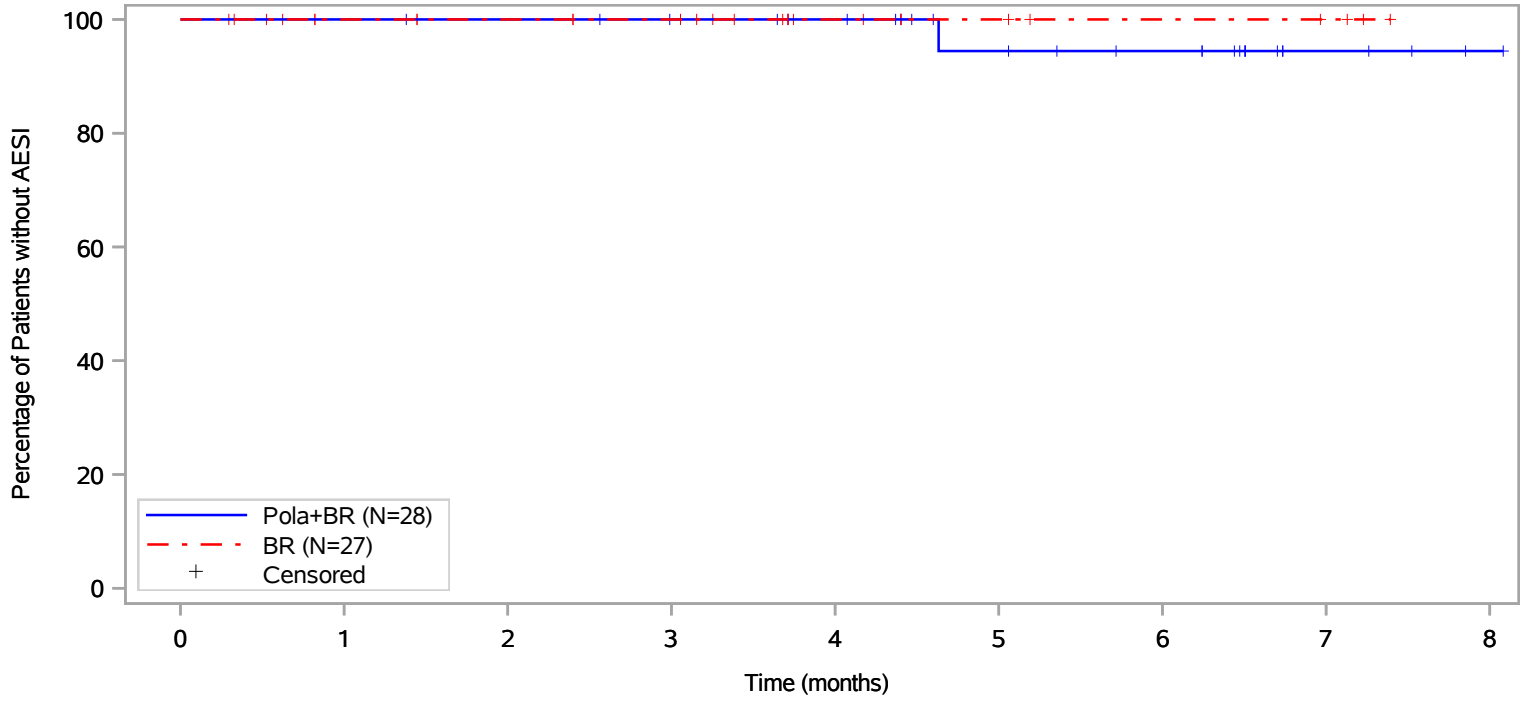
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.6310	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTDYSGUE_L3PLUS_ARMCDSE_365_29365_41543.xls
25JAN2023 17:40

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	4	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	26
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTDYSGUE_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 22:45

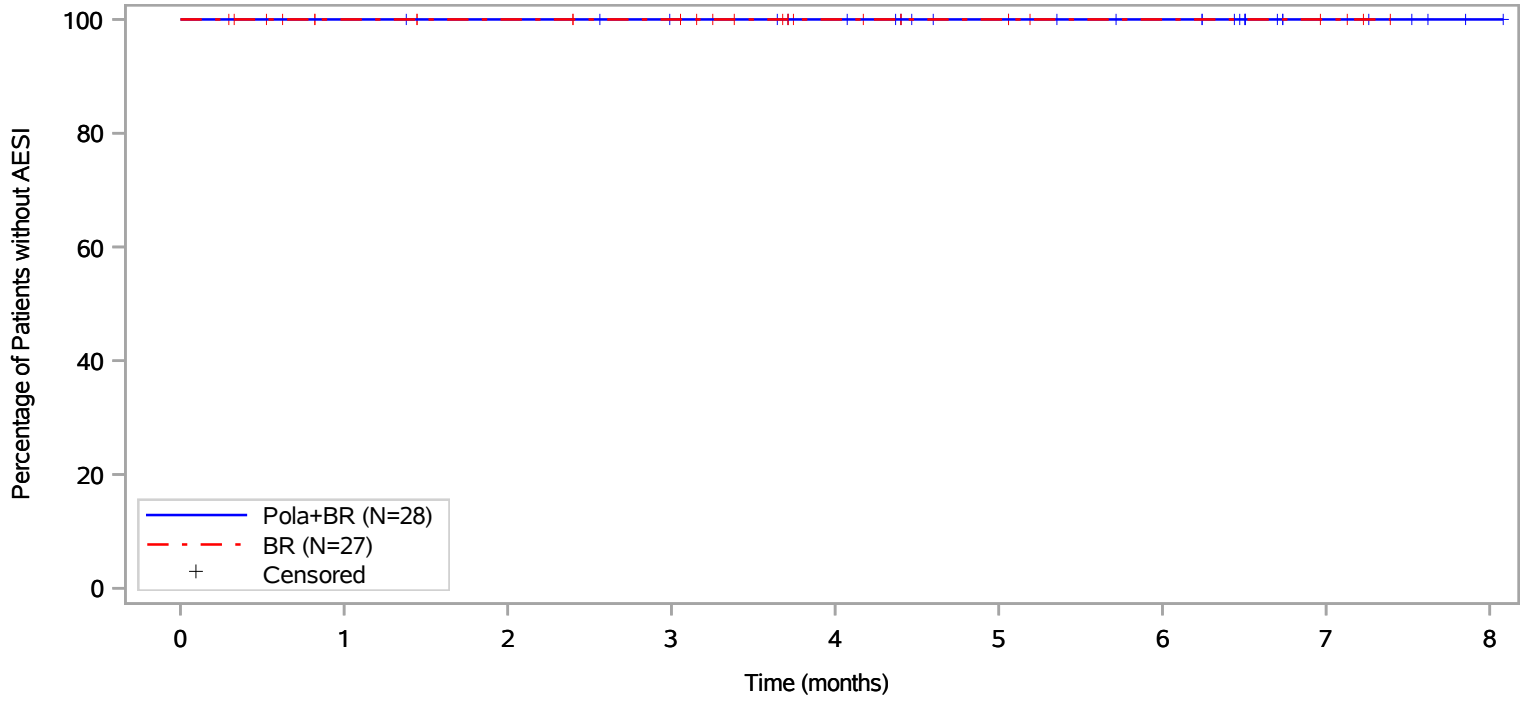
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTDYSGUE35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 22:25

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_365/g_km_TTDYSGUE35_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:29

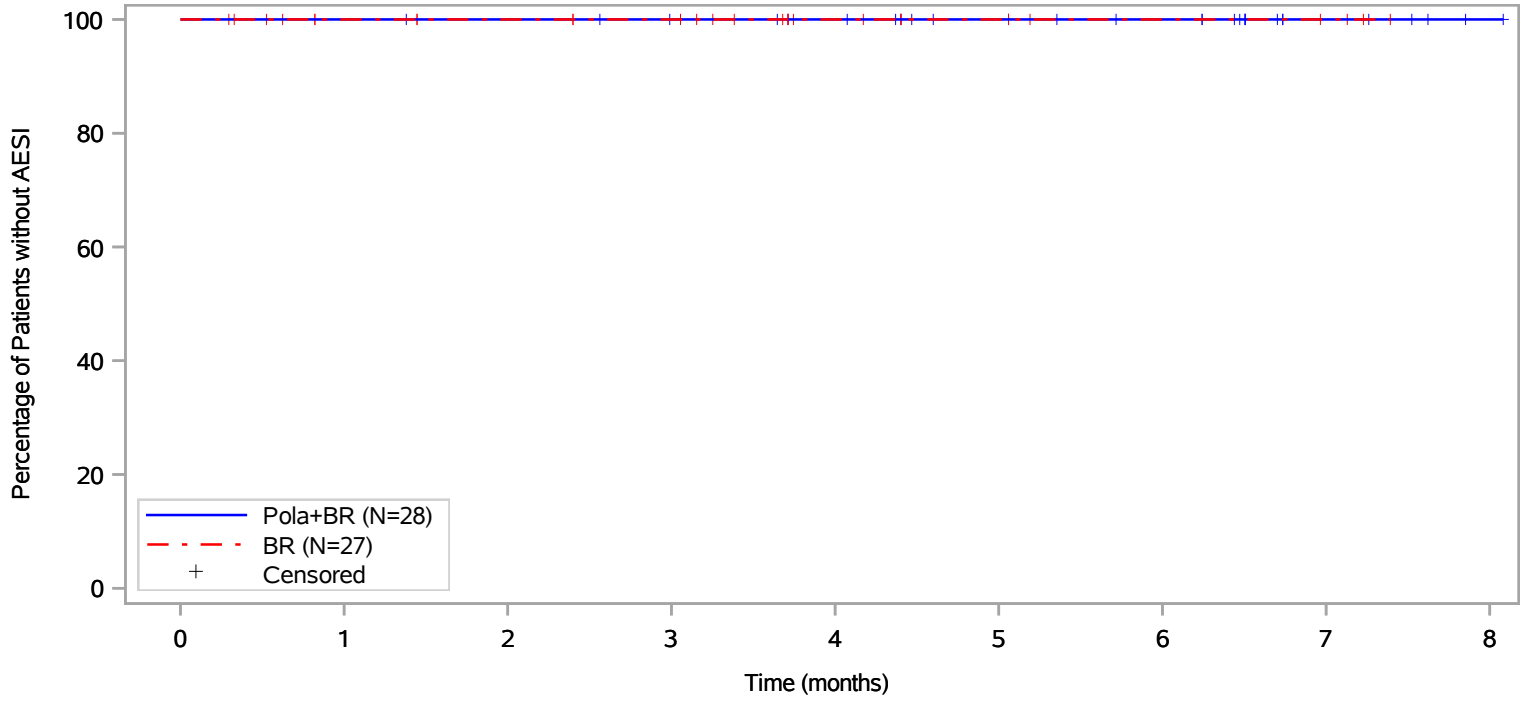
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTDYSGUES_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 22:21

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTDYSGUES_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 0:24

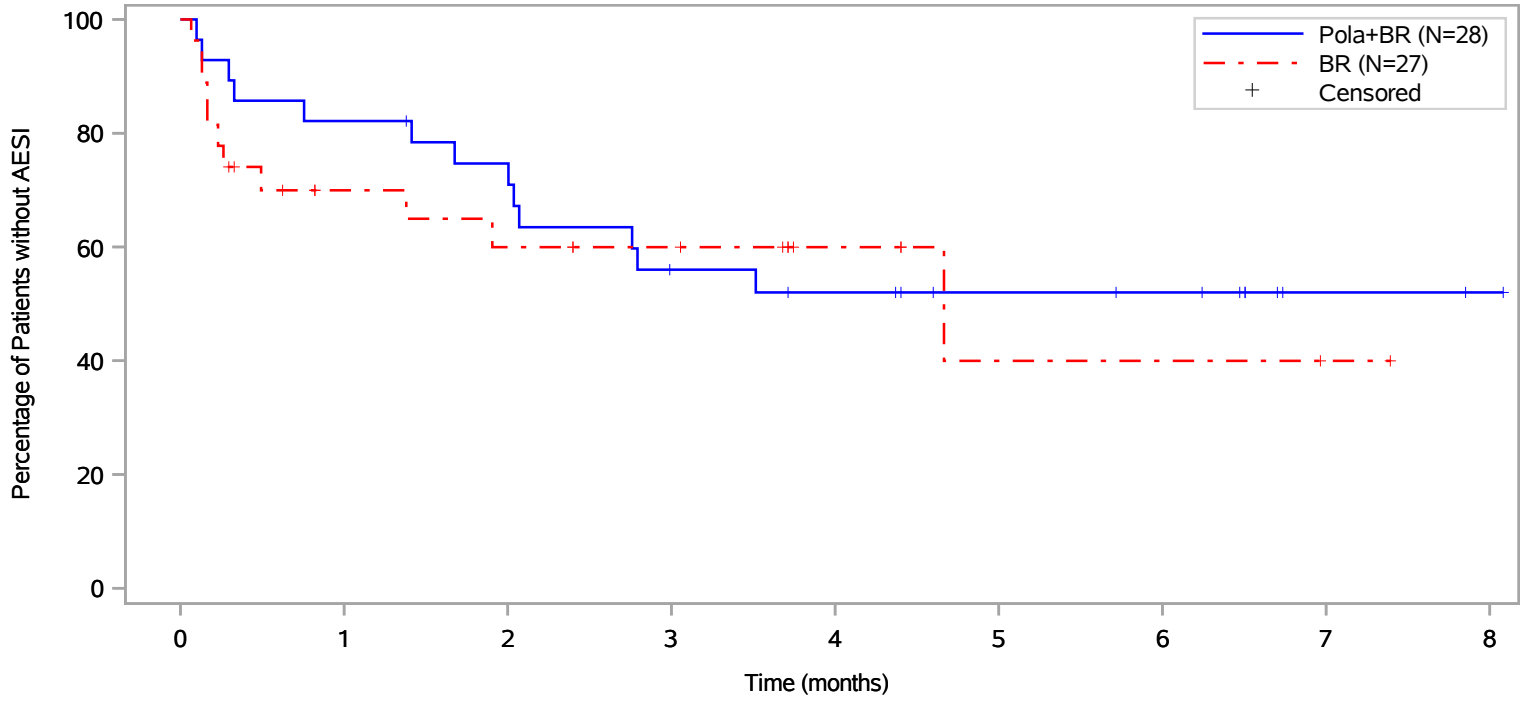
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	13	46.4	15	53.6	27	100.0	11	40.7	16	59.3	0.7035	0.85	0.38	1.92		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	8	40.0	12	60.0	18	66.7	6	33.3	12	66.7	0.9709	0.98	0.34	2.85		Convergence criterion (GCONV=1E-8) satisfied.	0.6717
	Female	8	28.6	5	62.5	3	37.5	9	33.3	5	55.6	4	44.4	0.5415	0.68	0.19	2.39		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	6	46.2	7	53.8	13	48.1	5	38.5	8	61.5	0.8386	0.88	0.27	2.91		Convergence criterion (GCONV=1E-8) satisfied.	0.8249
	>= 65	15	53.6	7	46.7	8	53.3	14	51.9	6	42.9	8	57.1	0.7862	0.86	0.28	2.59		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	6	40.0	9	60.0	18	66.7	7	38.9	11	61.1	0.5640	0.72	0.24	2.19		Convergence criterion (GCONV=1E-8) satisfied.	0.6369
	<3	13	46.4	7	53.8	6	46.2	9	33.3	4	44.4	5	55.6	0.9452	1.04	0.30	3.59		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	3	33.3	6	66.7	13	48.1	4	30.8	9	69.2	0.6773	0.72	0.16	3.32		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	10	52.6	9	47.4	14	51.9	7	50.0	7	50.0	0.6579	0.80	0.30	2.13		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTFAA_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 4:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	23	20	14	12	9	8	2	1
BR (N=27)	27	14	12	10	5	2	2	1	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	3	6	7	13	14
BR (N=27)	0	5	5	7	12	14	14	15	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTFAA_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:34

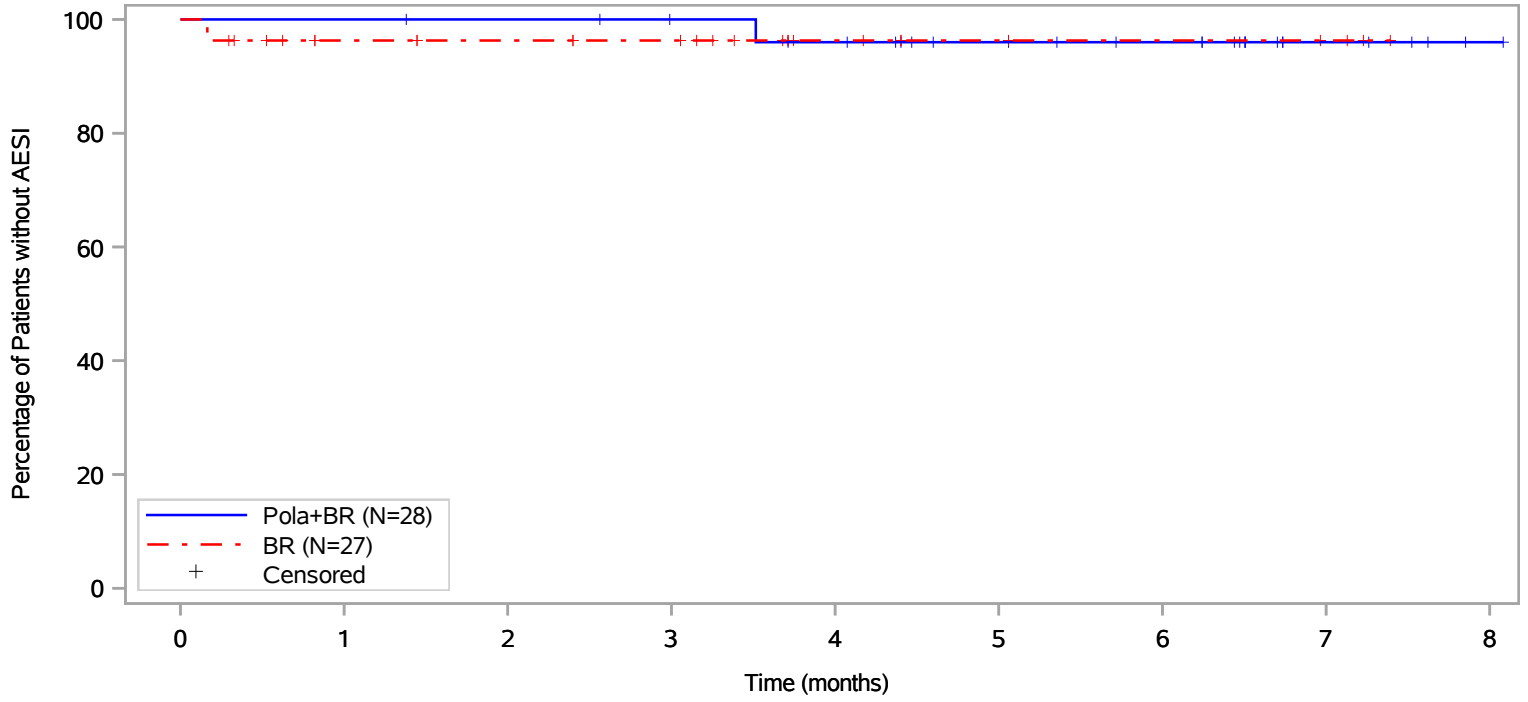
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.7873	0.68	0.04	11.35		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.8774	0.80	0.05	13.34		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	1	7.7	12	92.3	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	0.4497	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	1	5.6	17	94.4	0.8386	0.74	0.04	12.88		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	1	7.1	13	92.9	0.5545	0.43	0.02	7.60		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTFAA35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:13

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	8	5	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	4	9	12	22	26
BR (N=27)	0	6	8	10	18	21	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_TTFAA35_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 11:37

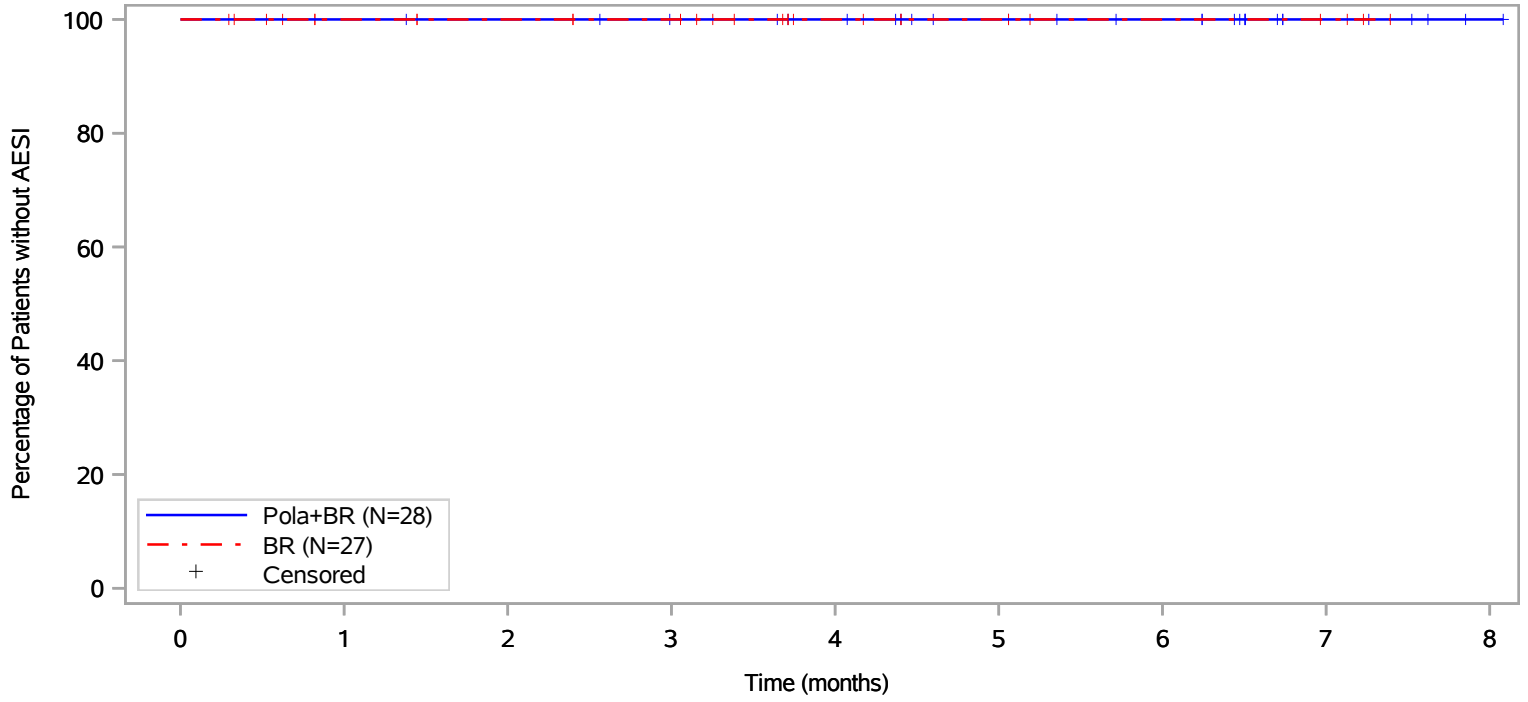
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTFAAS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:15

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTFAAS_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:38

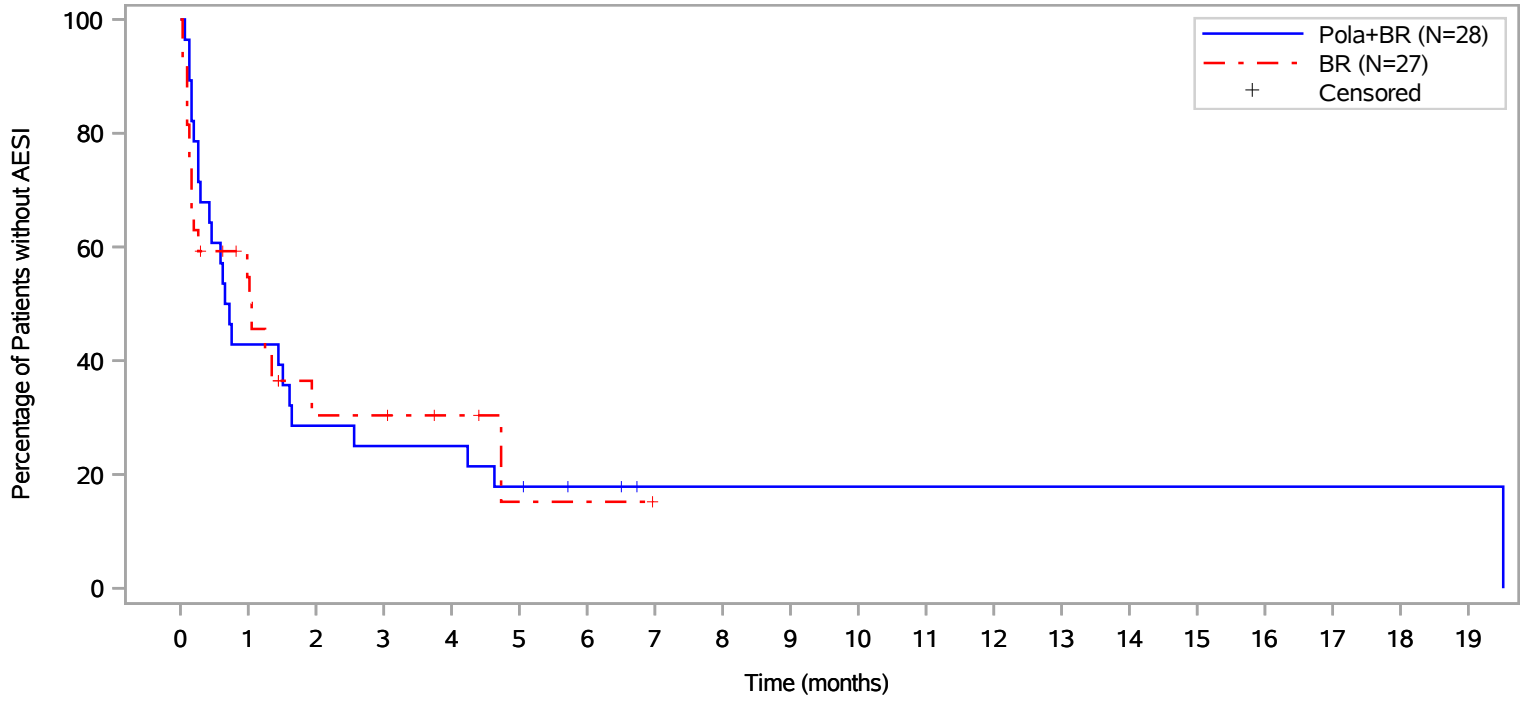
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	24	85.7	4	14.3	27	100.0	18	66.7	9	33.3	0.9981	1.00	0.53	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	17	85.0	3	15.0	18	66.7	12	66.7	6	33.3	0.9517	1.02	0.48	2.19		Convergence criterion (GCONV=1E-8) satisfied.	0.8587
	Female	8	28.6	7	87.5	1	12.5	9	33.3	6	66.7	3	33.3	0.6301	0.76	0.24	2.36		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	12	92.3	1	7.7	13	48.1	7	53.8	6	46.2	0.2304	1.77	0.69	4.53		Convergence criterion (GCONV=1E-8) satisfied.	0.1012
	>= 65	15	53.6	12	80.0	3	20.0	14	51.9	11	78.6	3	21.4	0.3271	0.65	0.28	1.54		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	12	80.0	3	20.0	18	66.7	12	66.7	6	33.3	0.8019	0.90	0.39	2.07		Convergence criterion (GCONV=1E-8) satisfied.	0.6444
	<3	13	46.4	12	92.3	1	7.7	9	33.3	6	66.7	3	33.3	0.7897	1.14	0.42	3.09		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	7	77.8	2	22.2	13	48.1	6	46.2	7	53.8	0.4130	1.58	0.53	4.72		Convergence criterion (GCONV=1E-8) satisfied.	0.2886
	Non-Europe	19	67.9	17	89.5	2	10.5	14	51.9	12	85.7	2	14.3	0.4036	0.72	0.34	1.55		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGASTOX_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 6:32

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=28)	28	12	8	7	7	5	3	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	12	5	5	3	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	0	0	0	0	2	4	4	4	4	4	4	4	4	4	4	4	4	4
BR (N=27)	0	3	5	5	7	8	8	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 17:43

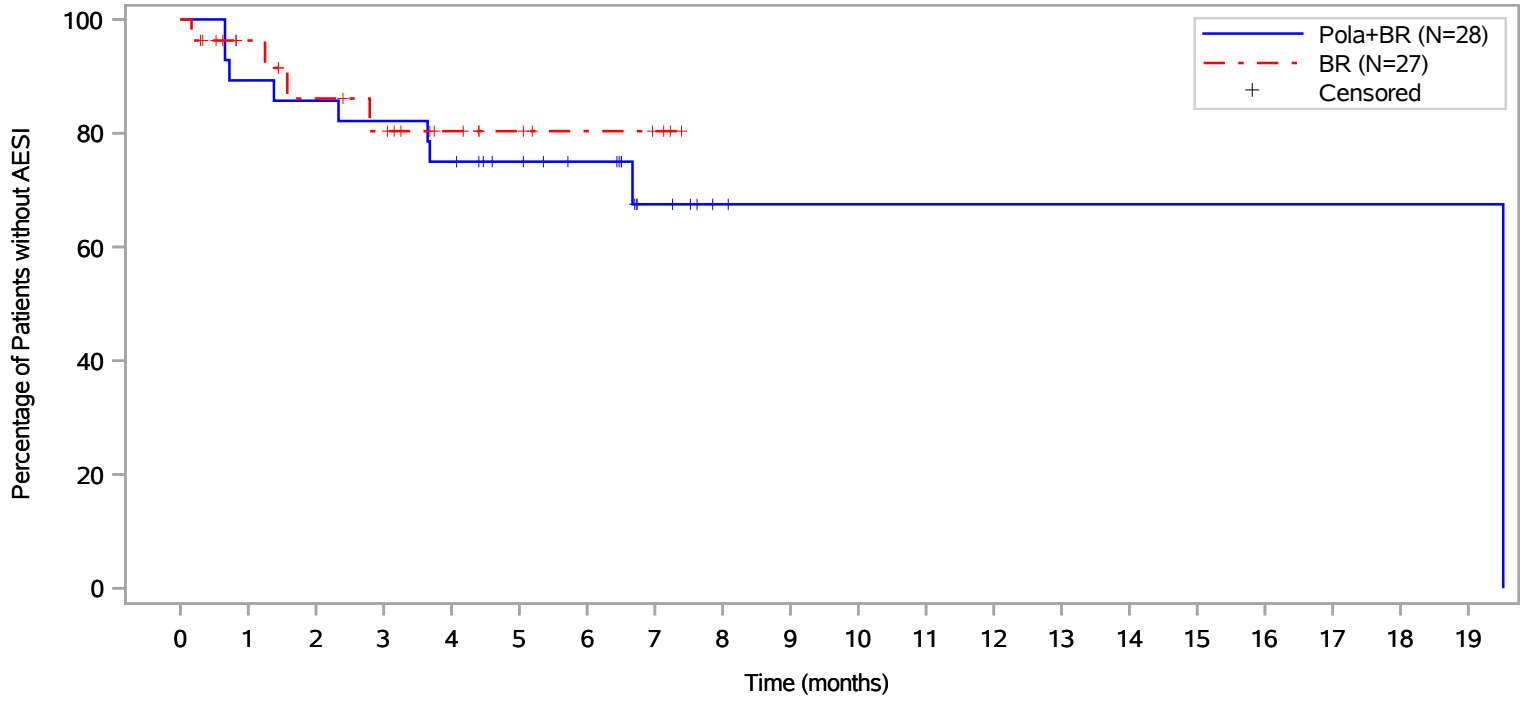
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	9	32.1	19	67.9	27	100.0	4	14.8	23	85.2	0.6109	1.37	0.41	4.59		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	7	35.0	13	65.0	18	66.7	4	22.2	14	77.8	0.9573	0.97	0.27	3.48		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	2	25.0	6	75.0	9	33.3	0	-	9	100.0	0.2263	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	5	38.5	8	61.5	13	48.1	1	7.7	12	92.3	0.1364	4.46	0.52	38.34		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	3	21.4	11	78.6	0.5184	0.59	0.12	2.97		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	6	40.0	9	60.0	18	66.7	3	16.7	15	83.3	0.8144	1.19	0.28	5.11		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	3	23.1	10	76.9	9	33.3	1	11.1	8	88.9	0.6244	1.75	0.18	16.90		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	3	33.3	6	66.7	13	48.1	2	15.4	11	84.6	0.6289	1.55	0.26	9.40		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	6	31.6	13	68.4	14	51.9	2	14.3	12	85.7	0.8137	1.22	0.23	6.60		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGASTOX35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:33

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=28)	28	25	24	23	21	17	14	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	20	16	14	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	0	0	0	4	7	14	18	19	19	19	19	19	19	19	19	19	19	19
BR (N=27)	0	6	8	9	14	17	19	20	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_365/g_km_TTGASTOX35_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 17:48

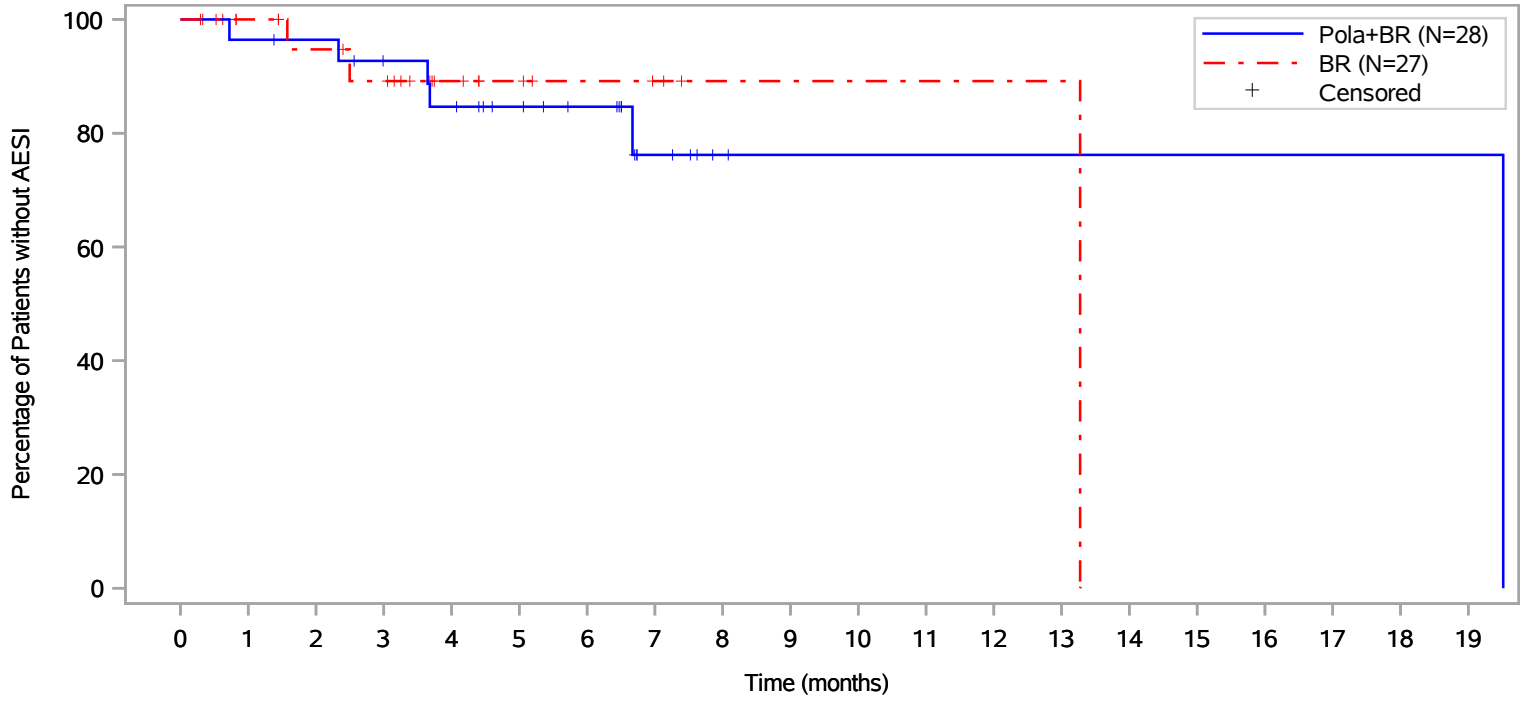
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	6	21.4	22	78.6	27	100.0	3	11.1	24	88.9	0.9022	1.09	0.26	4.63		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	5	25.0	15	75.0	18	66.7	2	11.1	16	88.9	0.8526	1.18	0.21	6.57		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	1	12.5	7	87.5	9	33.3	1	11.1	8	88.9	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	3	23.1	10	76.9	13	48.1	1	7.7	12	92.3	0.4651	2.28	0.24	22.05		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	2	14.3	12	85.7	0.6472	0.63	0.09	4.58		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	4	26.7	11	73.3	18	66.7	1	5.6	17	94.4	0.6184	1.77	0.18	17.39		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	2	15.4	11	84.6	9	33.3	2	22.2	7	77.8	0.9137	1.14	0.10	12.70		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	3	33.3	6	66.7	13	48.1	2	15.4	11	84.6	0.2778	3.27	0.34	31.46		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	1	7.1	13	92.9	0.7054	0.62	0.05	7.57		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGASTOXS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:36

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=28)	28	27	26	23	21	17	14	6	2	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	18	16	9	6	4	3	1	1	1	1	1	1	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	1	3	3	7	10	17	21	22	22	22	22	22	22	22	22	22	22	22
BR (N=27)	0	6	8	9	16	19	21	22	24	24	24	24	24	24	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTGASTOXS_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 8:34

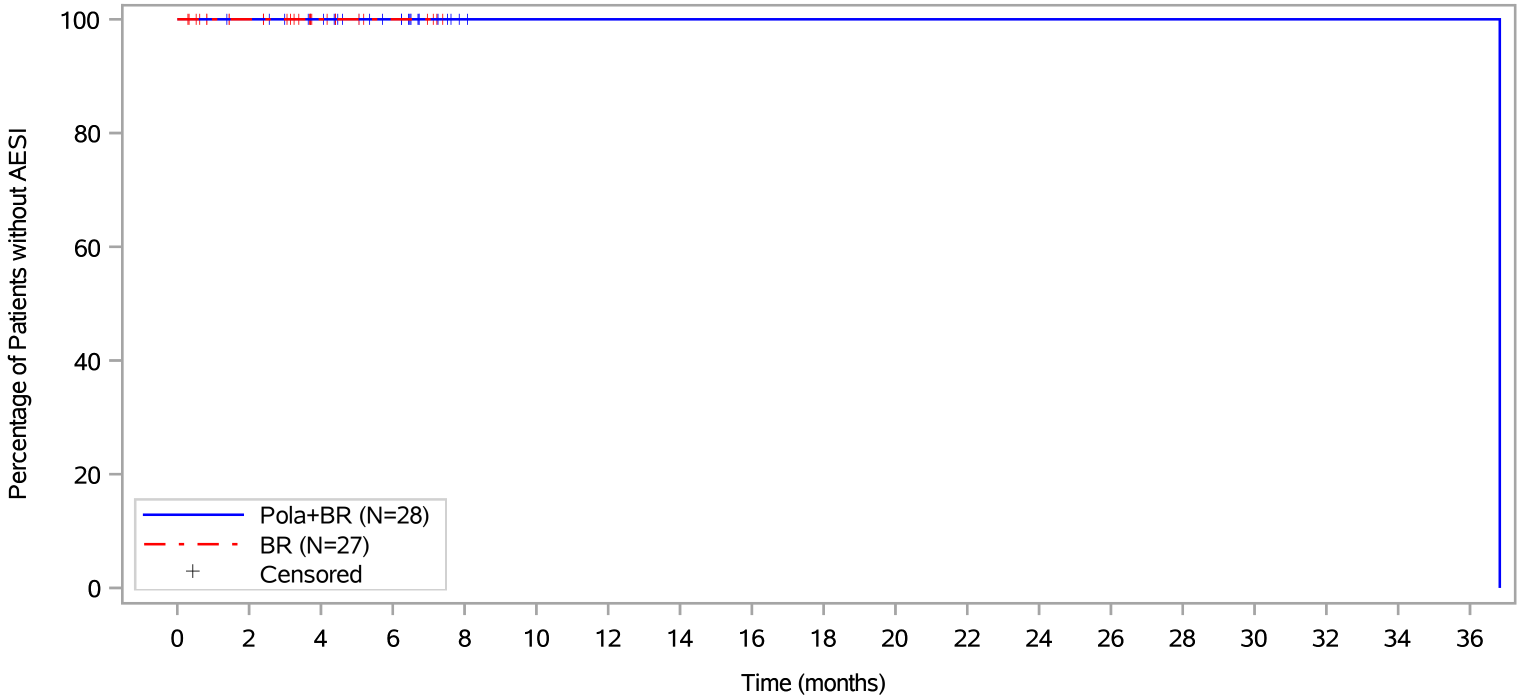
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGENCAR_L3PLUS_ARMCDSE_365_29365_41543.xls
25JAN2023 17:51

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk																																					
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																					
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTGENCAR_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 23:14

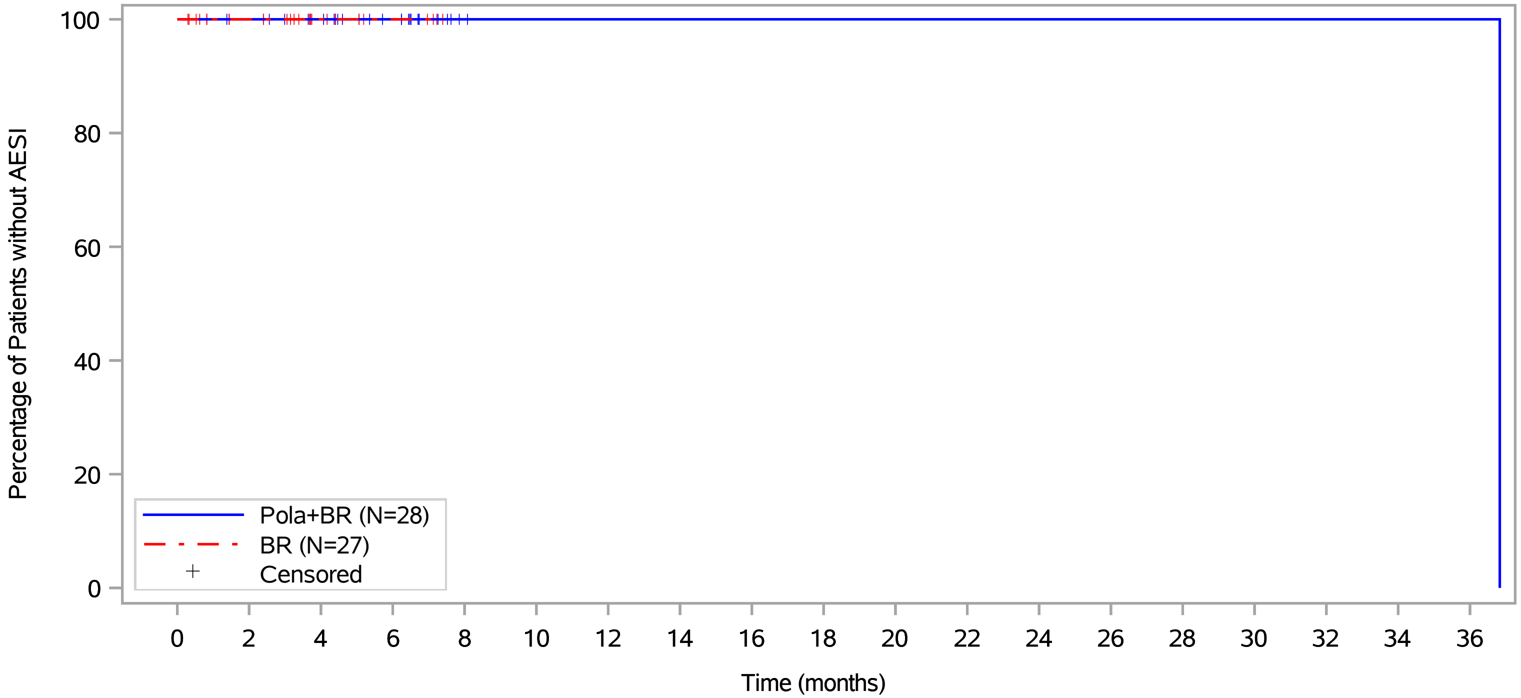
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGENCAR35_L3PLUS_ARMCDSE_365_29365_41543.xls
25JAN2023 17:54

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk																																					
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																					
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 17:55

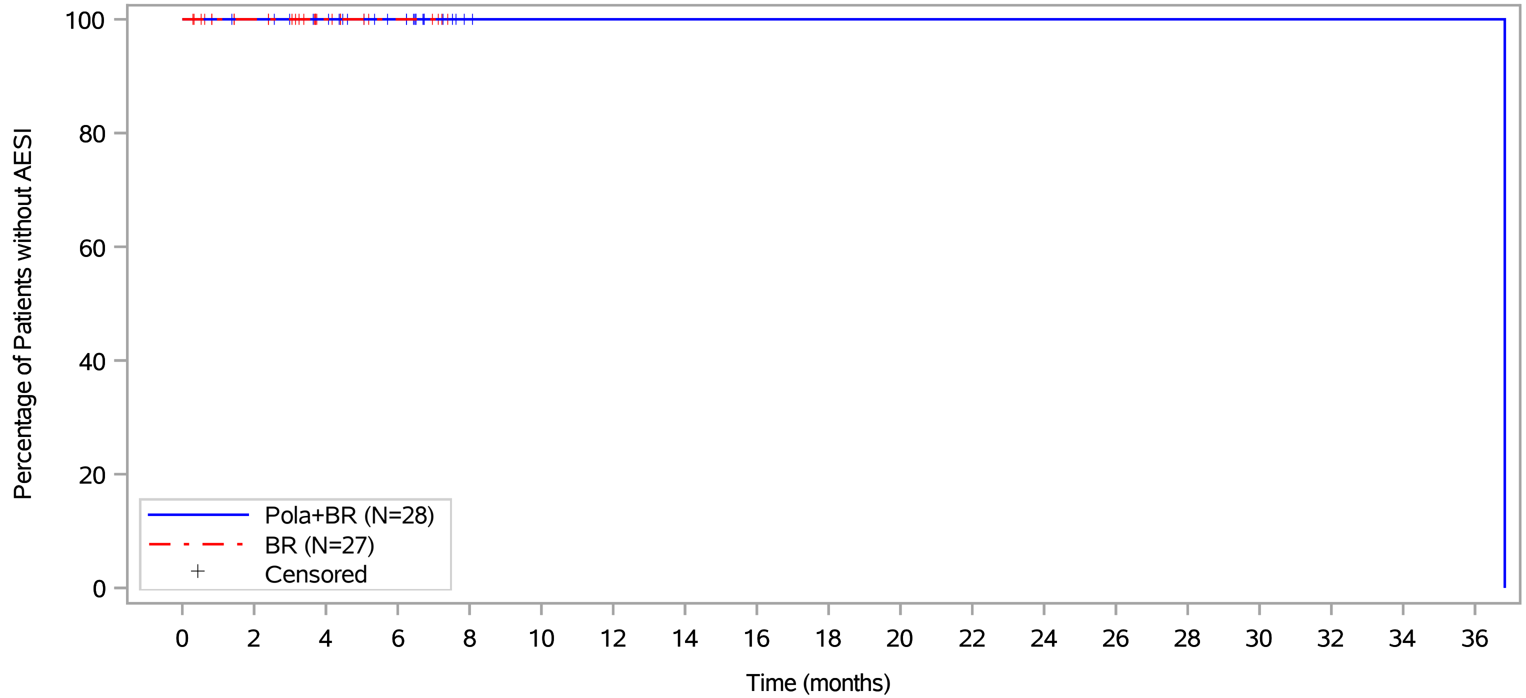
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTGENCARS_L3PLUS_ARMCDSE_365_29365_41543.xls
25JAN2023 17:57

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk																																					
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																																					
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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02DEC2022 9:36

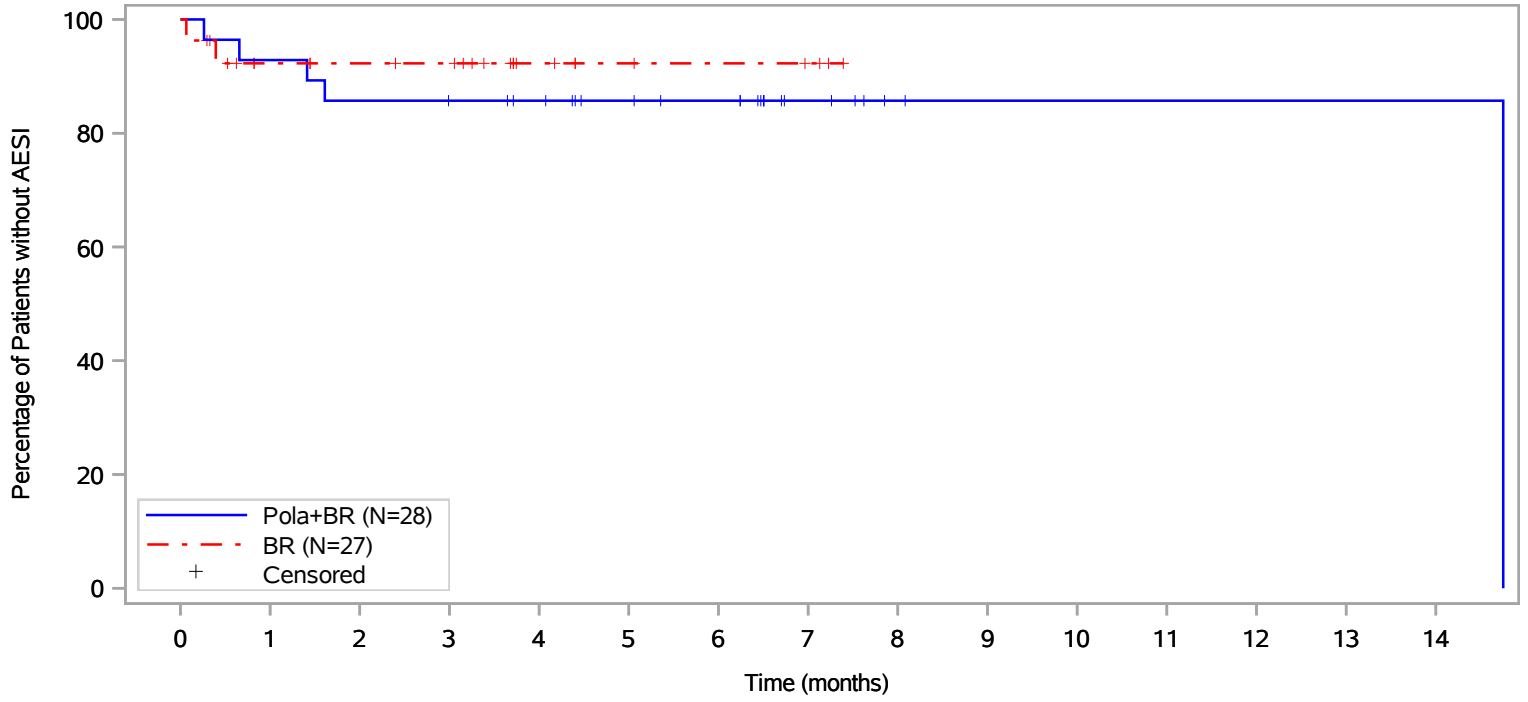
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	5	17.9	23	82.1	27	100.0	2	7.4	25	92.6	0.5608	1.65	0.30	9.02		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.6676	1.68	0.15	18.60		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	3	37.5	5	62.5	9	33.3	1	11.1	8	88.9	0.7430	1.50	0.13	16.93		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	3	23.1	10	76.9	13	48.1	2	15.4	11	84.6	0.8867	0.87	0.12	6.19		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	0	-	14	100.0	0.2289	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	4	26.7	11	73.3	18	66.7	2	11.1	16	88.9	0.4398	1.93	0.35	10.61		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	5	26.3	14	73.7	14	51.9	2	14.3	12	85.7	0.8047	1.24	0.23	6.78		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHEPAT_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 3:54

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk															
Pola+BR (N=28)	28	26	24	23	21	17	15	6	2	1	1	1	1	1	1
BR (N=27)	27	19	17	16	8	5	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	0	1	3	7	9	18	22	23	23	23	23	23	23
BR (N=27)	0	6	8	9	17	20	21	22	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:18

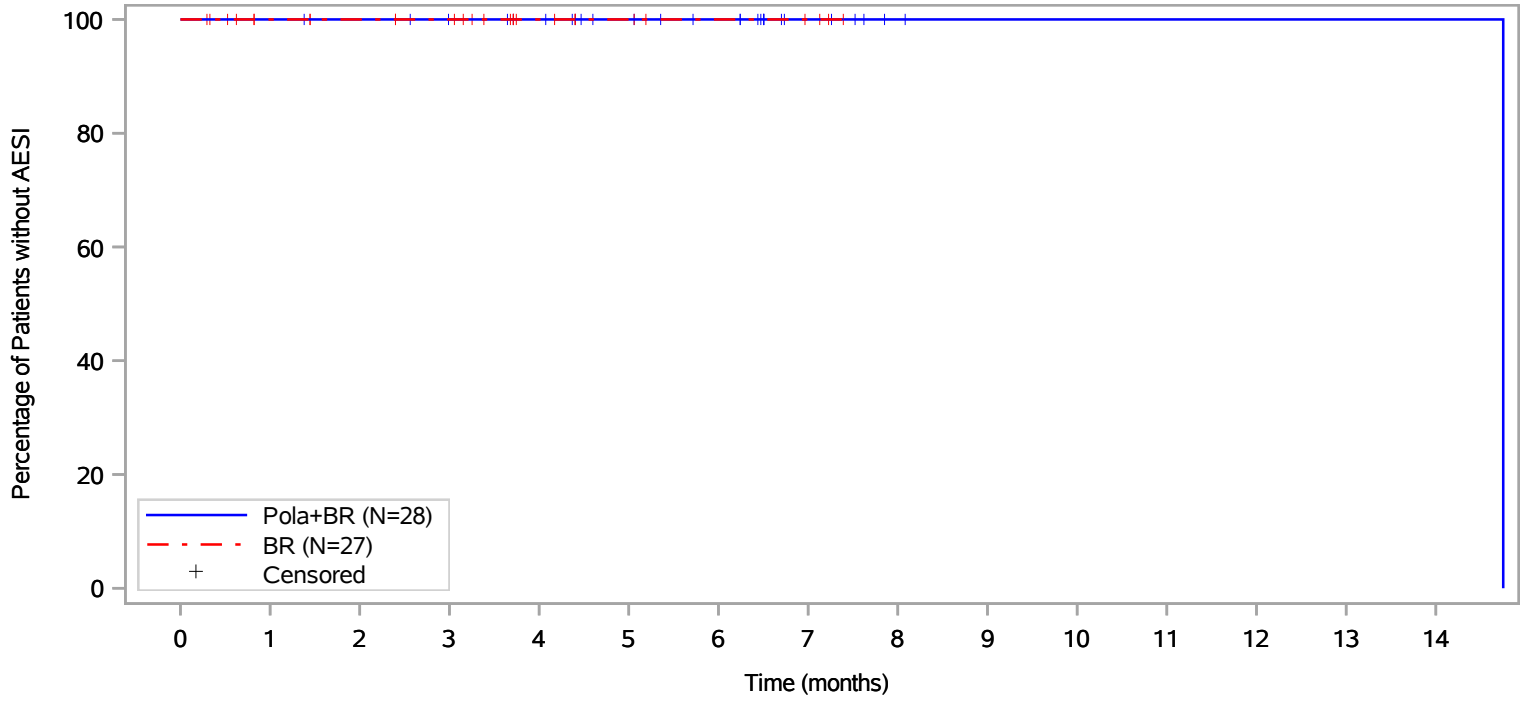
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHEPAT35_L3PLUS_ARMCDSE_365_29365_41543.xls
25JAN2023 18:00

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTHEPAT35_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:25

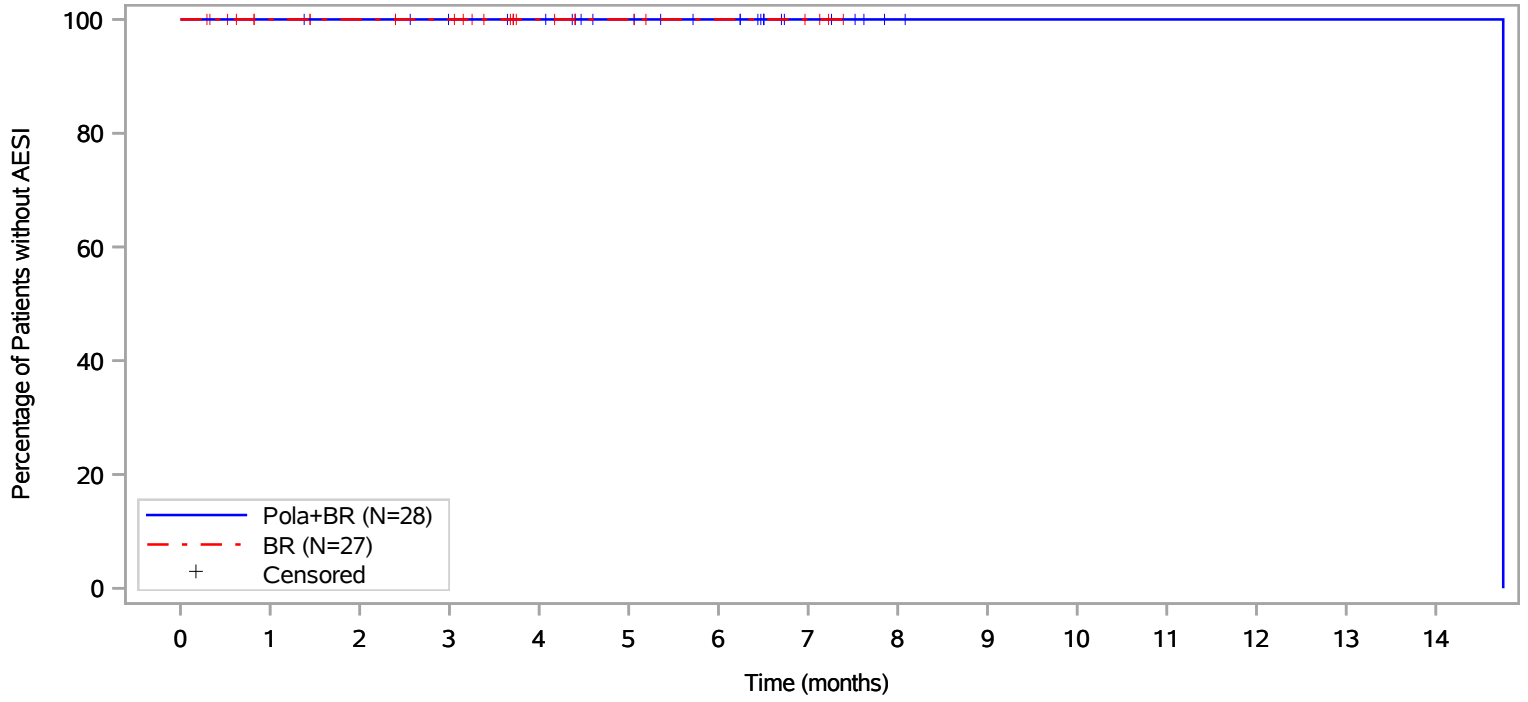
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	1	7.7	12	92.3	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHEPATS_L3PLUS_ARMCDSE_365_29365_41543.xls
25JAN2023 18:08

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk															
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1	1	1	1	1
BR (N=27)	27	21	19	17	9	6	4	3	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27	27	27	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTHEPATS_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:30

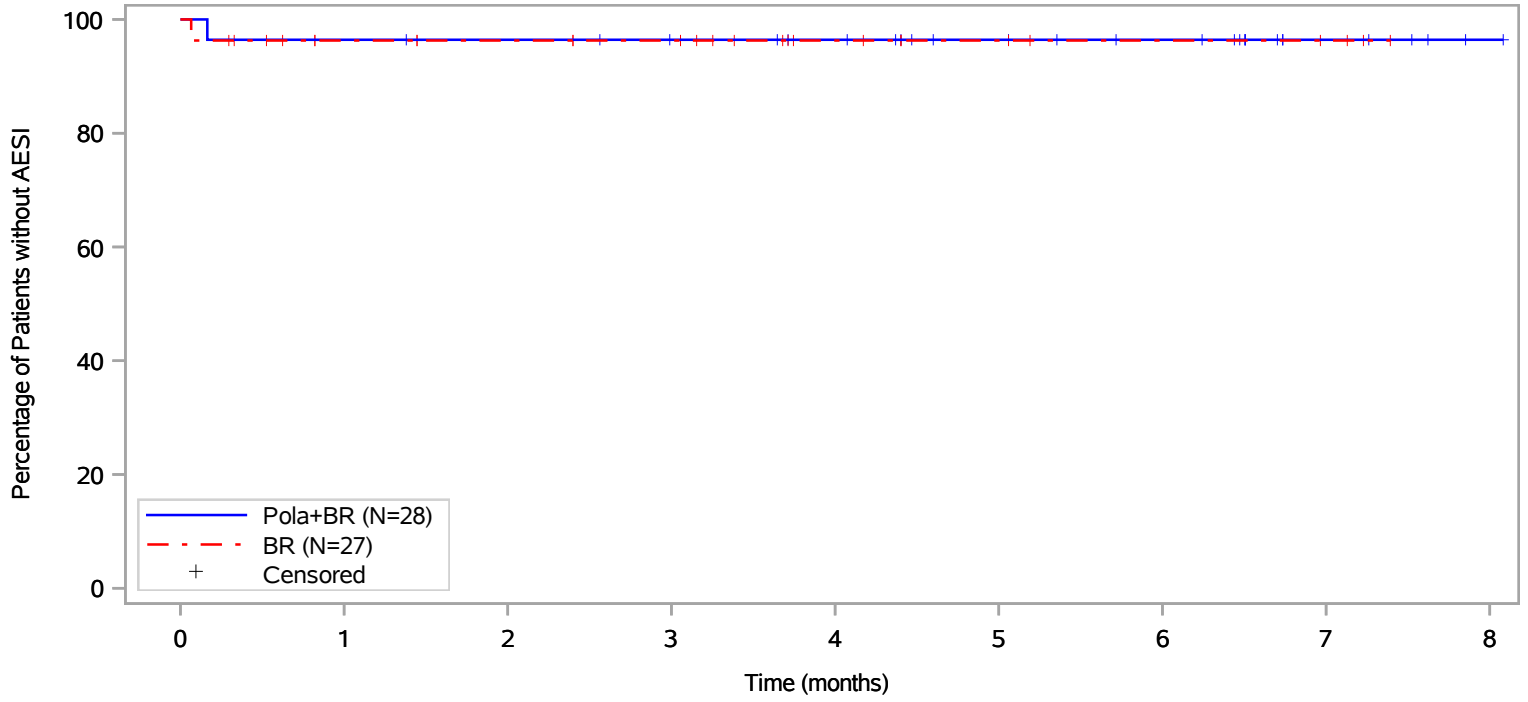
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.9688	0.95	0.06	15.13		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.9245	0.87	0.05	13.99		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	1	7.1	13	92.9	0.9402	0.90	0.06	14.38		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.2733	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	0.3907	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHYPGL_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 5:14

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	27	26	24	22	17	14	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_TTHYPGL_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:41

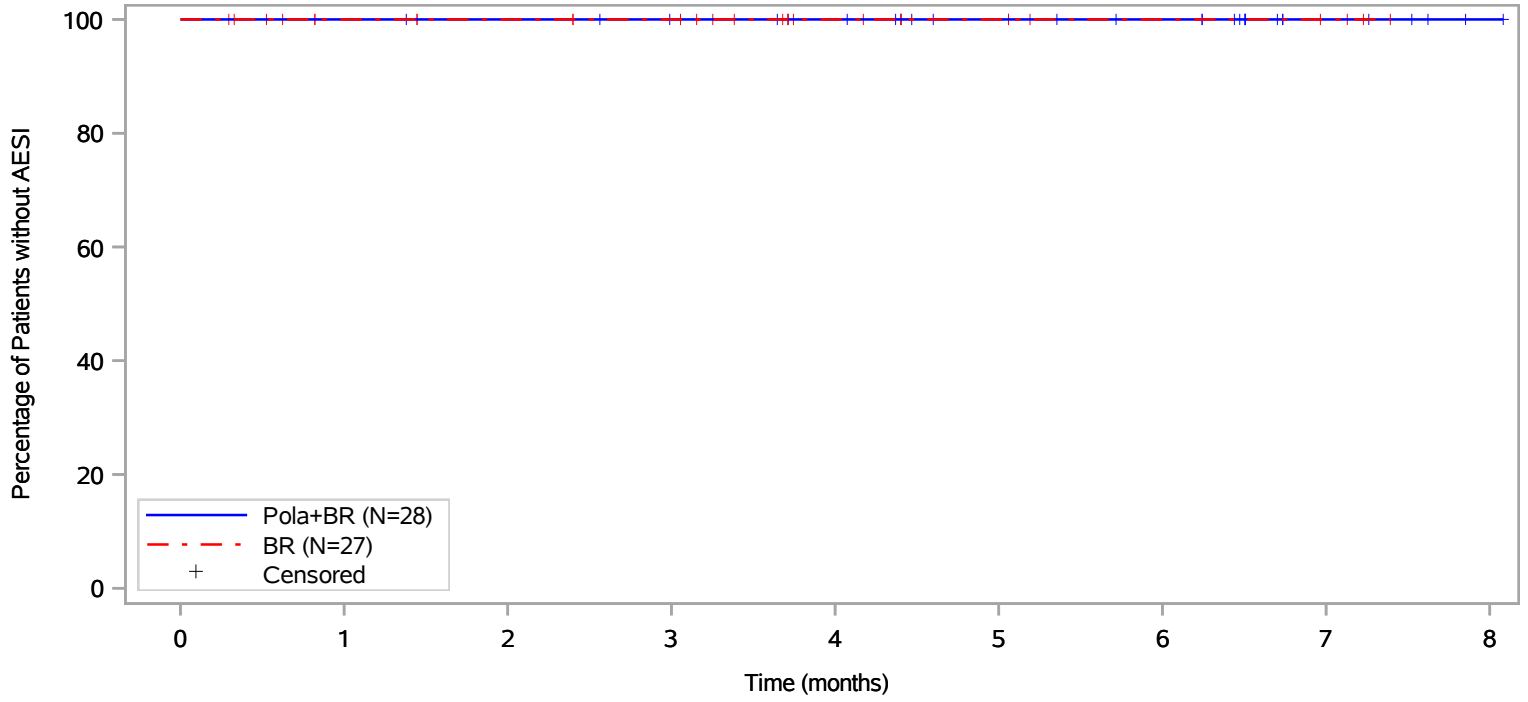
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHYPGL35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:19

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTHYPGL35_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:40

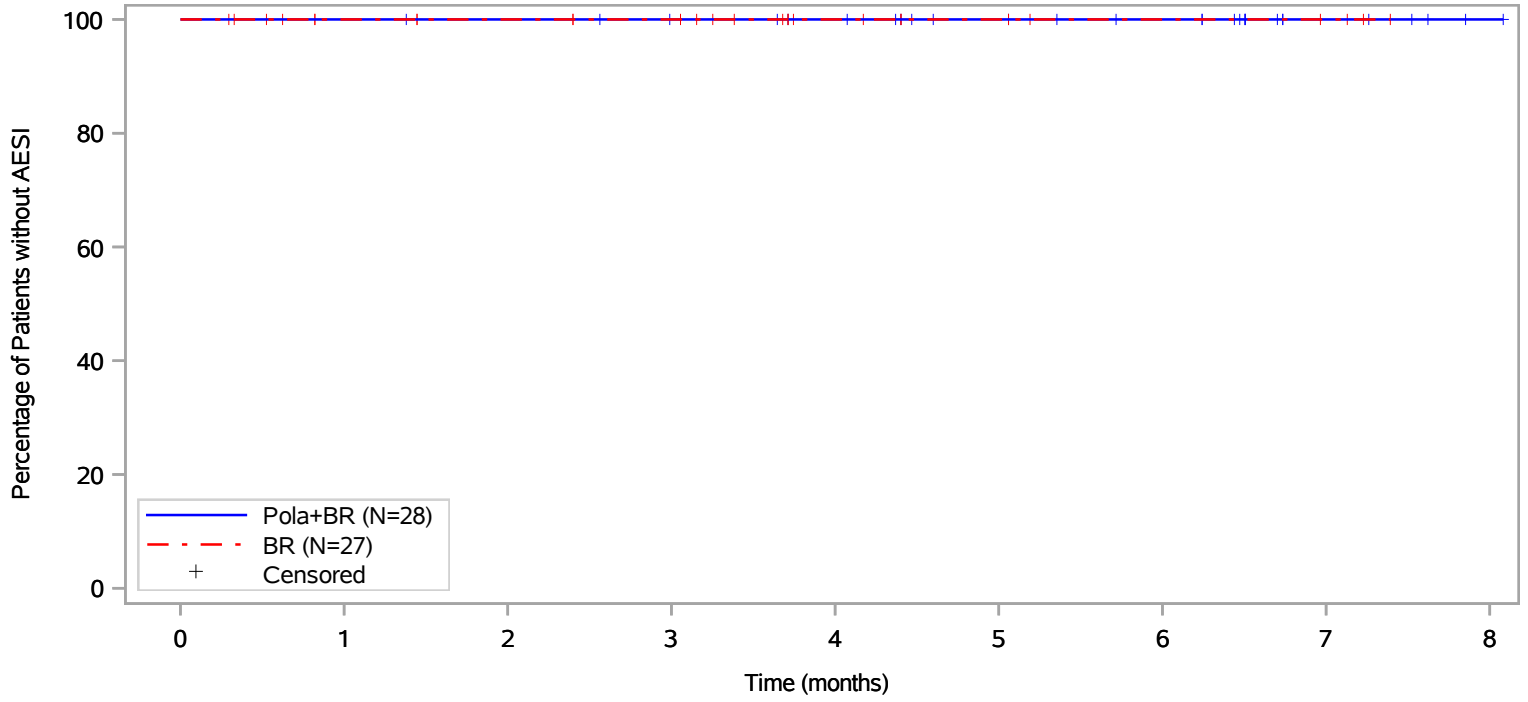
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTHYPGLS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:22

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTHYPGLS_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:45

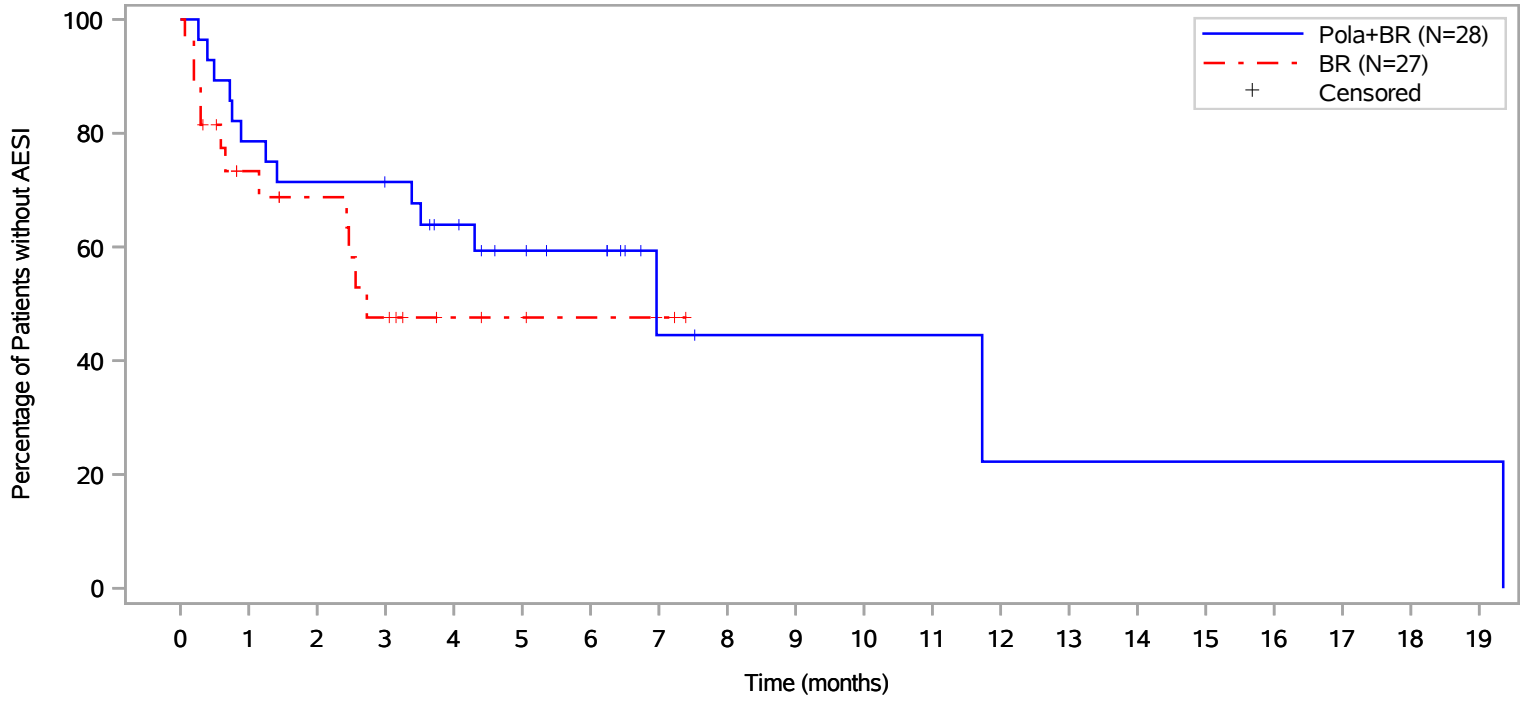
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	14	50.0	14	50.0	27	100.0	12	44.4	15	55.6	0.3454	0.68	0.30	1.53		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	11	55.0	9	45.0	18	66.7	8	44.4	10	55.6	0.4711	0.70	0.27	1.85		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	3	37.5	5	62.5	9	33.3	4	44.4	5	55.6	0.5693	0.65	0.14	2.92		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	5	38.5	8	61.5	13	48.1	4	30.8	9	69.2	0.7594	0.80	0.20	3.28		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	9	60.0	6	40.0	14	51.9	8	57.1	6	42.9	0.2422	0.55	0.20	1.51		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	9	60.0	6	40.0	18	66.7	8	44.4	10	55.6	0.7237	0.84	0.31	2.26		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	5	38.5	8	61.5	9	33.3	4	44.4	5	55.6	0.3503	0.52	0.13	2.10		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	5	55.6	4	44.4	13	48.1	7	53.8	6	46.2	0.4665	0.65	0.20	2.09		Convergence criterion (GCONV=1E-8) satisfied.	0.9413
	Non-Europe	19	67.9	9	47.4	10	52.6	14	51.9	5	35.7	9	64.3	0.6705	0.78	0.24	2.49		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTINECT_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 2:47

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk																				
Pola+BR (N=28)	28	22	20	19	15	11	9	3	2	2	2	2	1	1	1	1	1	1	1	1
BR (N=27)	27	16	13	9	5	4	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																				
Pola+BR (N=28)	0	0	0	1	3	6	8	13	14	14	14	14	14	14	14	14	14	14	14	14
BR (N=27)	0	4	6	6	10	11	12	13	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_TTINECT_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:50

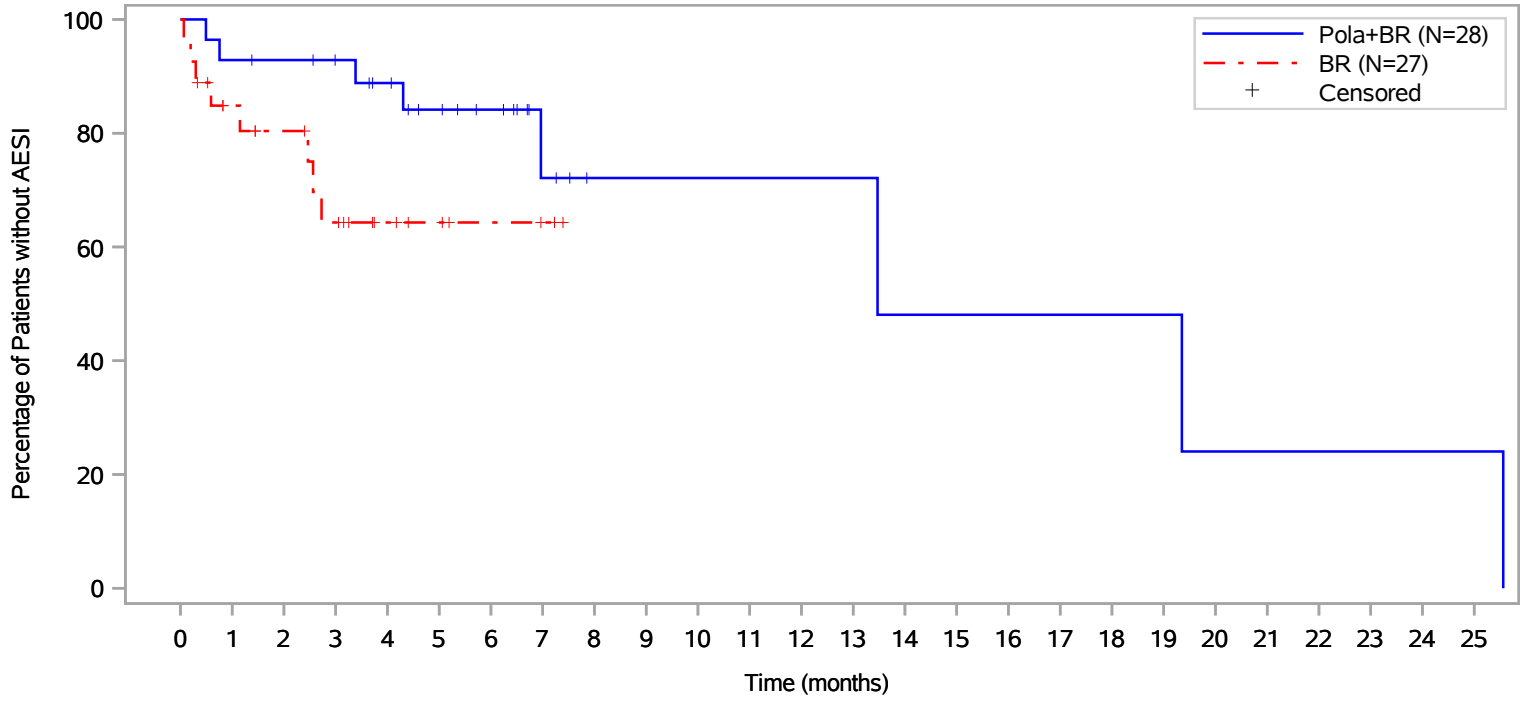
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	8	28.6	20	71.4	27	100.0	8	29.6	19	70.4	0.0964	0.39	0.13	1.23		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	8	40.0	12	60.0	18	66.7	5	27.8	13	72.2	0.4338	0.61	0.17	2.14		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	3	33.3	6	66.7	0.0488	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.3879	0.36	0.03	4.07		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	7	46.7	8	53.3	14	51.9	6	42.9	8	57.1	0.1093	0.36	0.10	1.32		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	5	33.3	10	66.7	18	66.7	5	27.8	13	72.2	0.3381	0.50	0.12	2.13		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	3	23.1	10	76.9	9	33.3	3	33.3	6	66.7	0.1774	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	4	44.4	5	55.6	13	48.1	6	46.2	7	53.8	0.1287	0.30	0.06	1.54		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	2	14.3	12	85.7	0.6716	0.68	0.11	4.18		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTINECT35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 20:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk																										
Pola+BR (N=28)	28	26	25	23	20	16	13	6	3	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=27)	27	19	16	12	7	5	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	1	3	5	8	11	17	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
BR (N=27)	0	4	6	7	12	14	16	17	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTINECT35_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 10:26

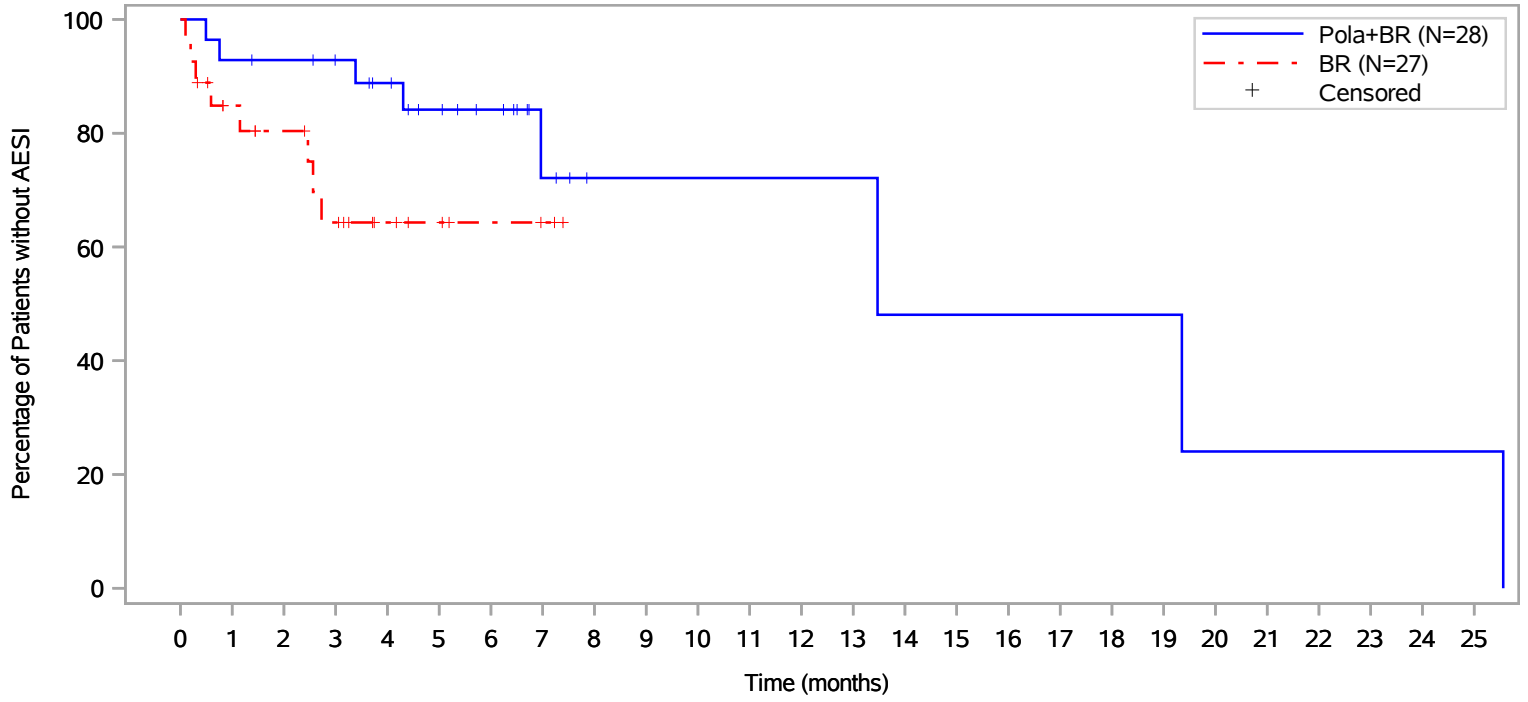
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	8	28.6	20	71.4	27	100.0	8	29.6	19	70.4	0.0964	0.39	0.13	1.23		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	8	40.0	12	60.0	18	66.7	5	27.8	13	72.2	0.4338	0.61	0.17	2.14		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	3	33.3	6	66.7	0.0488	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	2	15.4	11	84.6	0.3879	0.36	0.03	4.07		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	7	46.7	8	53.3	14	51.9	6	42.9	8	57.1	0.1093	0.36	0.10	1.32		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	5	33.3	10	66.7	18	66.7	5	27.8	13	72.2	0.3381	0.50	0.12	2.13		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	3	23.1	10	76.9	9	33.3	3	33.3	6	66.7	0.1774	0.31	0.05	1.88		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	4	44.4	5	55.6	13	48.1	6	46.2	7	53.8	0.1287	0.30	0.06	1.54		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	2	14.3	12	85.7	0.6716	0.68	0.11	4.18		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTINECTS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 20:49

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk																										
Pola+BR (N=28)	28	26	25	23	20	16	13	6	3	3	3	3	3	3	2	2	2	2	2	2	1	1	1	1	1	1
BR (N=27)	27	19	16	12	7	5	3	2	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored																										
Pola+BR (N=28)	0	0	1	3	5	8	11	17	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20	20
BR (N=27)	0	4	6	7	12	14	16	17	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTINECTS_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 7:22

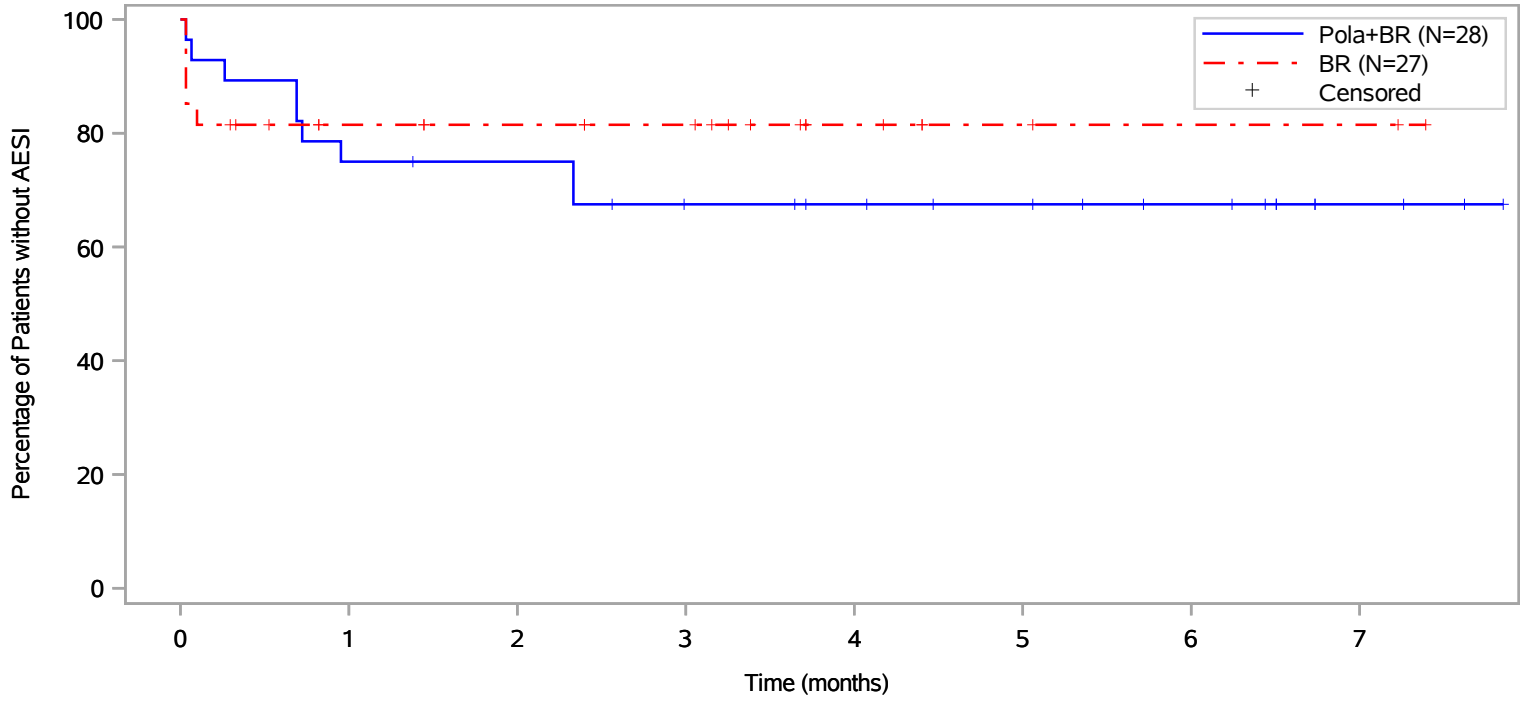
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	9	32.1	19	67.9	27	100.0	5	18.5	22	81.5	0.4279	1.56	0.51	4.76		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	8	40.0	12	60.0	18	66.7	1	5.6	17	94.4	0.0237	7.75	0.96	62.50		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	1	12.5	7	87.5	9	33.3	4	44.4	5	55.6	0.1025	0.18	0.02	1.73		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	5	38.5	8	61.5	13	48.1	2	15.4	11	84.6	0.3354	2.22	0.42	11.68		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	4	26.7	11	73.3	14	51.9	3	21.4	11	78.6	0.8960	1.11	0.24	5.14		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	5	33.3	10	66.7	18	66.7	3	16.7	15	83.3	0.4456	1.75	0.41	7.47		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	4	30.8	9	69.2	9	33.3	2	22.2	7	77.8	0.7990	1.25	0.23	6.92		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	4	44.4	5	55.6	13	48.1	4	30.8	9	69.2	0.7872	1.22	0.29	5.02		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	5	26.3	14	73.7	14	51.9	1	7.1	13	92.9	0.2339	3.43	0.40	29.58		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTIRR_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 3:16

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=28)	28	21	20	16	14	12	9	3
BR (N=27)	27	17	15	13	6	3	2	2
Patients censored								
Pola+BR (N=28)	0	0	1	3	5	7	10	16
BR (N=27)	0	5	7	9	16	19	20	20

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTIRR_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:58

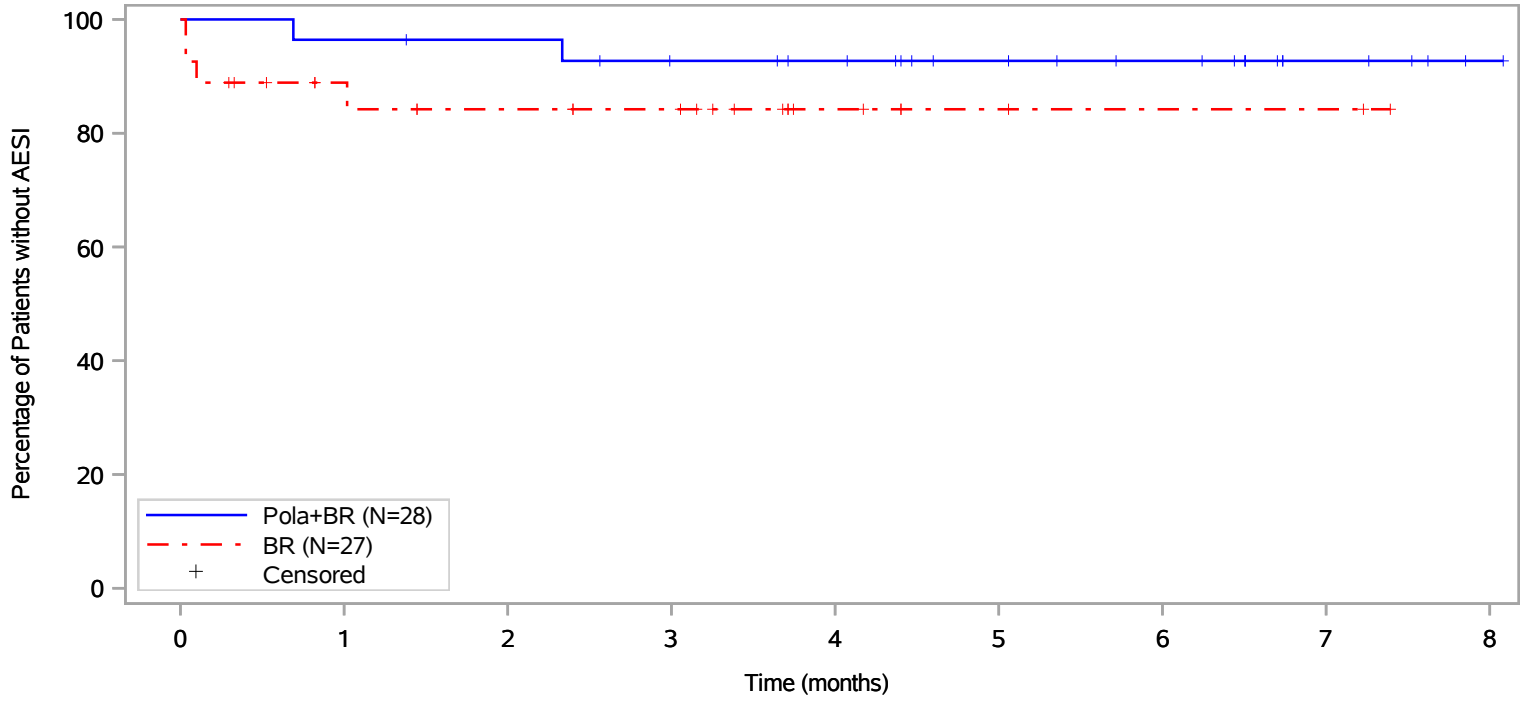
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	2	7.1	26	92.9	27	100.0	4	14.8	23	85.2	0.2737	0.40	0.07	2.19		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.7056	1.58	0.14	17.51		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	3	33.3	6	66.7	0.0645	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.8969	0.83	0.05	13.46		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	3	21.4	11	78.6	0.2017	0.25	0.03	2.46		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	3	16.7	15	83.3	0.3087	0.32	0.03	3.18		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.7833	0.68	0.04	10.86		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	2	22.2	7	77.8	13	48.1	3	23.1	10	76.9	0.7500	0.75	0.12	4.52		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTIRR35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 20:54

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	27	26	23	21	16	13	5	1
BR (N=27)	27	19	16	14	6	3	2	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	21	25
BR (N=27)	0	5	7	9	17	20	21	21	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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02DEC2022 10:46

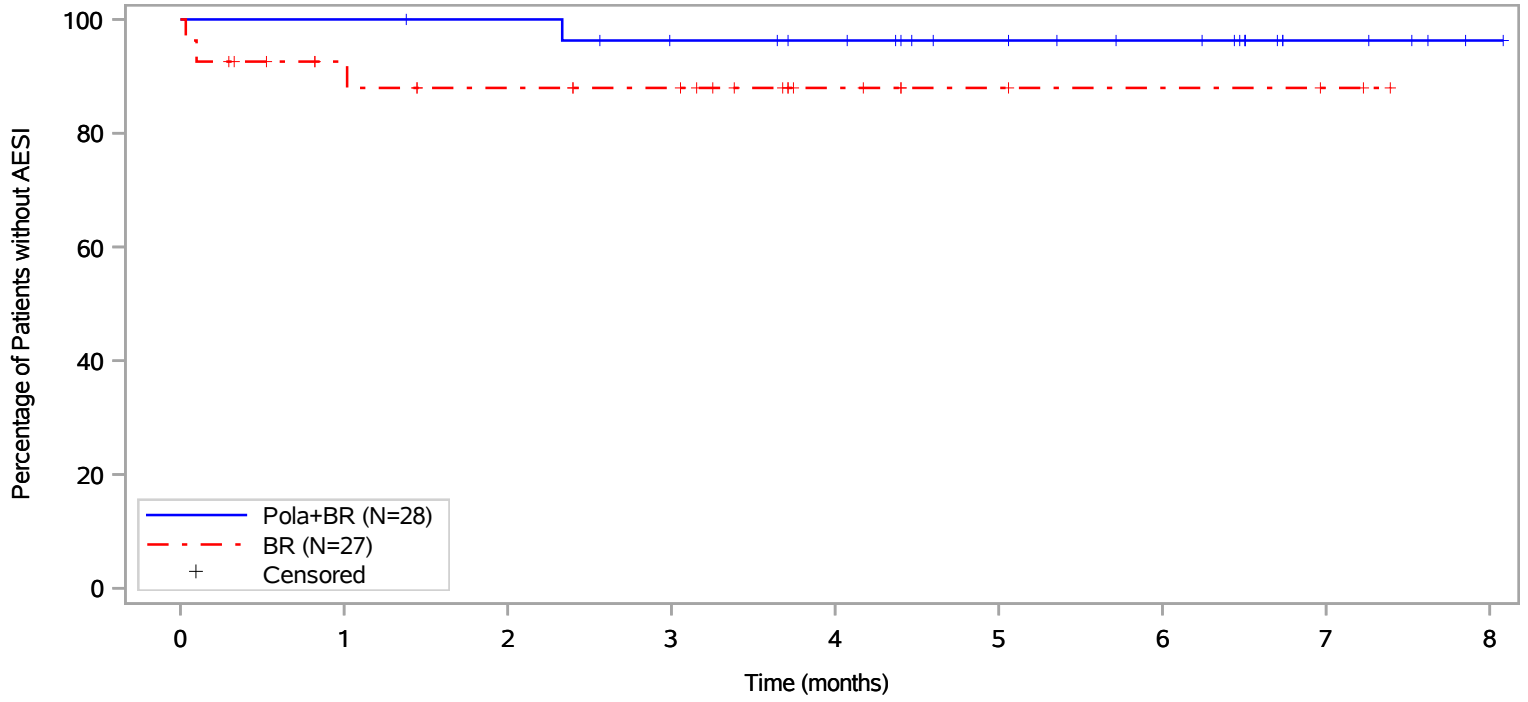
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	3	11.1	24	88.9	0.2160	0.26	0.03	2.55		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	0.4028	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	3	33.3	6	66.7	0.0645	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.8969	0.83	0.05	13.46		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	2	14.3	12	85.7	0.1104	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.5559	0.49	0.04	5.50		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	1	11.1	8	88.9	0.2024	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	1	11.1	8	88.9	13	48.1	2	15.4	11	84.6	0.6040	0.53	0.05	5.98		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	1	7.1	13	92.9	0.2440	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTIRRS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 20:54

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	24	22	17	14	5	1
BR (N=27)	27	20	17	15	7	4	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26
BR (N=27)	0	5	7	9	17	20	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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02DEC2022 7:28

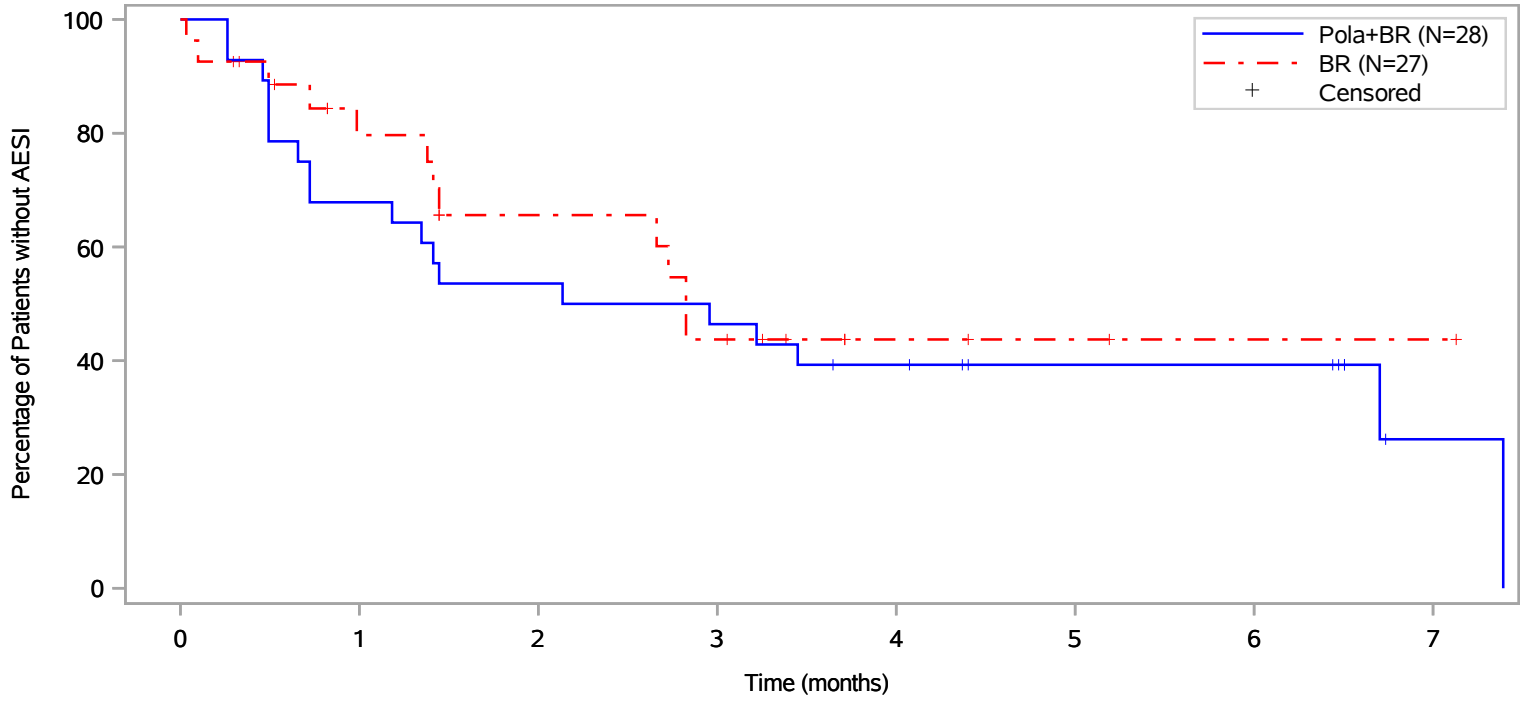
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	19	67.9	9	32.1	27	100.0	12	44.4	15	55.6	0.5476	1.26	0.60	2.64		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	12	60.0	8	40.0	18	66.7	8	44.4	10	55.6	0.8006	0.89	0.34	2.28		Convergence criterion (GCONV=1E-8) satisfied.	0.1705
	Female	8	28.6	7	87.5	1	12.5	9	33.3	4	44.4	5	55.6	0.1277	2.61	0.73	9.30		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	10	76.9	3	23.1	13	48.1	6	46.2	7	53.8	0.1473	2.12	0.75	5.97		Convergence criterion (GCONV=1E-8) satisfied.	0.2205
	>= 65	15	53.6	9	60.0	6	40.0	14	51.9	6	42.9	8	57.1	0.6960	0.81	0.27	2.37		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	11	73.3	4	26.7	18	66.7	8	44.4	10	55.6	0.9354	1.04	0.39	2.77		Convergence criterion (GCONV=1E-8) satisfied.	0.6724
	<3	13	46.4	8	61.5	5	38.5	9	33.3	4	44.4	5	55.6	0.5527	1.44	0.43	4.85		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	3	33.3	6	66.7	13	48.1	6	46.2	7	53.8	0.2876	0.47	0.11	1.94		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	16	84.2	3	15.8	14	51.9	6	42.9	8	57.1	0.2463	1.77	0.67	4.71		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTNIFNEU_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 0:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=28)	28	19	15	13	10	7	7	1
BR (N=27)	27	17	12	8	3	2	1	1
Patients censored								
Pola+BR (N=28)	0	0	0	0	1	4	4	9
BR (N=27)	0	5	7	7	12	13	14	14

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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01DEC2022 20:27

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	17	60.7	11	39.3	27	100.0	10	37.0	17	63.0	0.4094	1.40	0.63	3.11		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	11	55.0	9	45.0	18	66.7	8	44.4	10	55.6	0.7525	0.86	0.33	2.22		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	6	75.0	2	25.0	9	33.3	2	22.2	7	77.8	0.0708	4.03	0.79	20.48		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	9	69.2	4	30.8	13	48.1	5	38.5	8	61.5	0.1797	2.10	0.69	6.33		Convergence criterion (GCONV=1E-8) satisfied.	0.4317
	>= 65	15	53.6	8	53.3	7	46.7	14	51.9	5	35.7	9	64.3	0.9534	0.97	0.30	3.09		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	9	60.0	6	40.0	18	66.7	7	38.9	11	61.1	0.9391	1.04	0.37	2.94		Convergence criterion (GCONV=1E-8) satisfied.	0.4389
	<3	13	46.4	8	61.5	5	38.5	9	33.3	3	33.3	6	66.7	0.2918	2.02	0.53	7.66		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	2	22.2	7	77.8	13	48.1	4	30.8	9	69.2	0.3701	0.46	0.08	2.59		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	15	78.9	4	21.1	14	51.9	6	42.9	8	57.1	0.2652	1.73	0.65	4.57		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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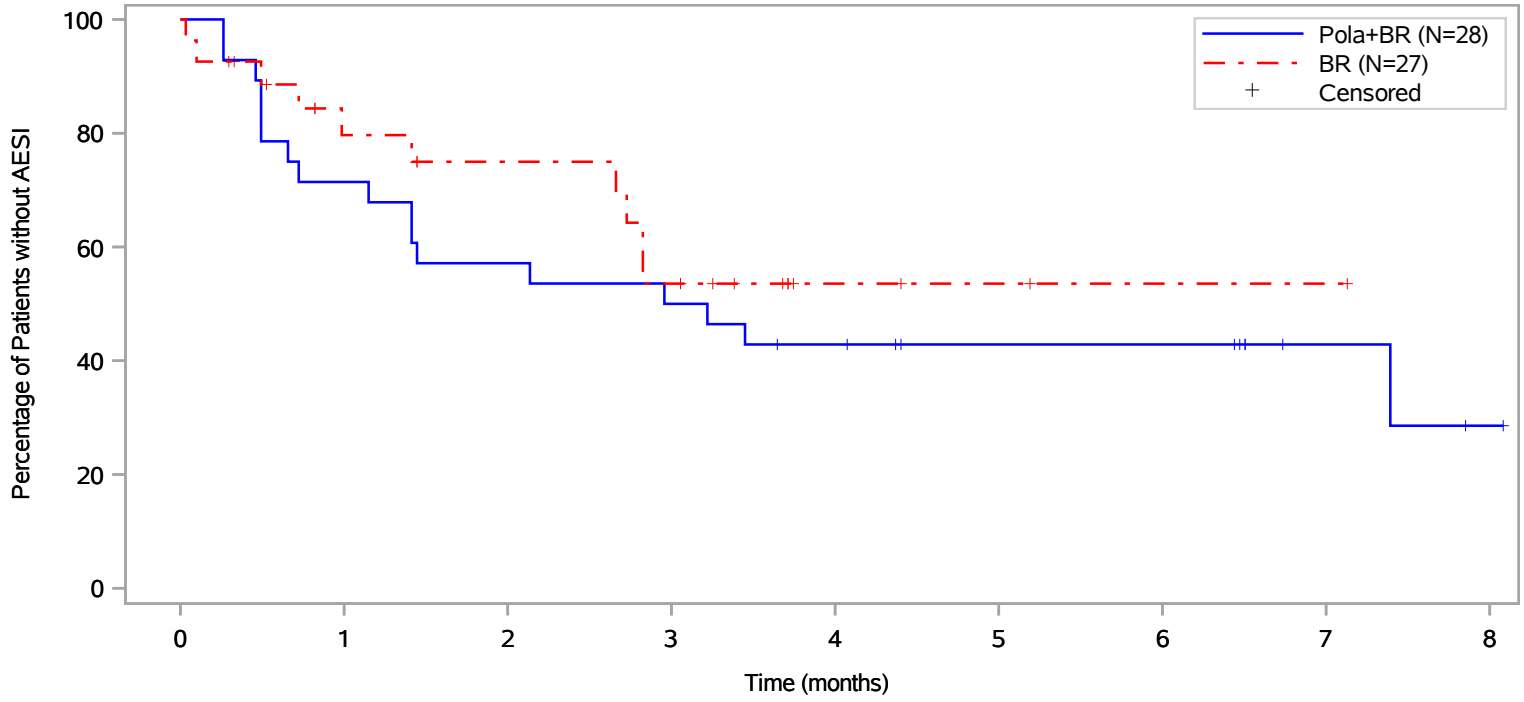
02DEC2022 20:02

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	20	16	14	11	8	8	3	1
BR (N=27)	27	17	14	10	3	2	1	1	NE
Patients censored									
Pola+BR (N=28)	0	0	0	0	1	4	4	9	10
BR (N=27)	0	5	7	7	14	15	16	16	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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02DEC2022 8:48

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	5	17.9	23	82.1	27	100.0	4	14.8	23	85.2	0.8346	1.17	0.28	4.95		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	3	15.0	17	85.0	18	66.7	3	16.7	15	83.3	0.9870	0.99	0.16	5.98		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	2	25.0	6	75.0	9	33.3	1	11.1	8	88.9	0.6626	1.70	0.15	18.97		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	2	15.4	11	84.6	13	48.1	2	15.4	11	84.6	0.6062	0.60	0.08	4.31		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	3	20.0	12	80.0	14	51.9	2	14.3	12	85.7	0.5240	2.09	0.21	21.00		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	3	20.0	12	80.0	18	66.7	3	16.7	15	83.3	0.7881	1.28	0.21	7.80		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.9353	1.10	0.10	12.20		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	2	15.4	11	84.6	0.4054	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	5	26.3	14	73.7	14	51.9	2	14.3	12	85.7	0.9086	0.90	0.16	5.03		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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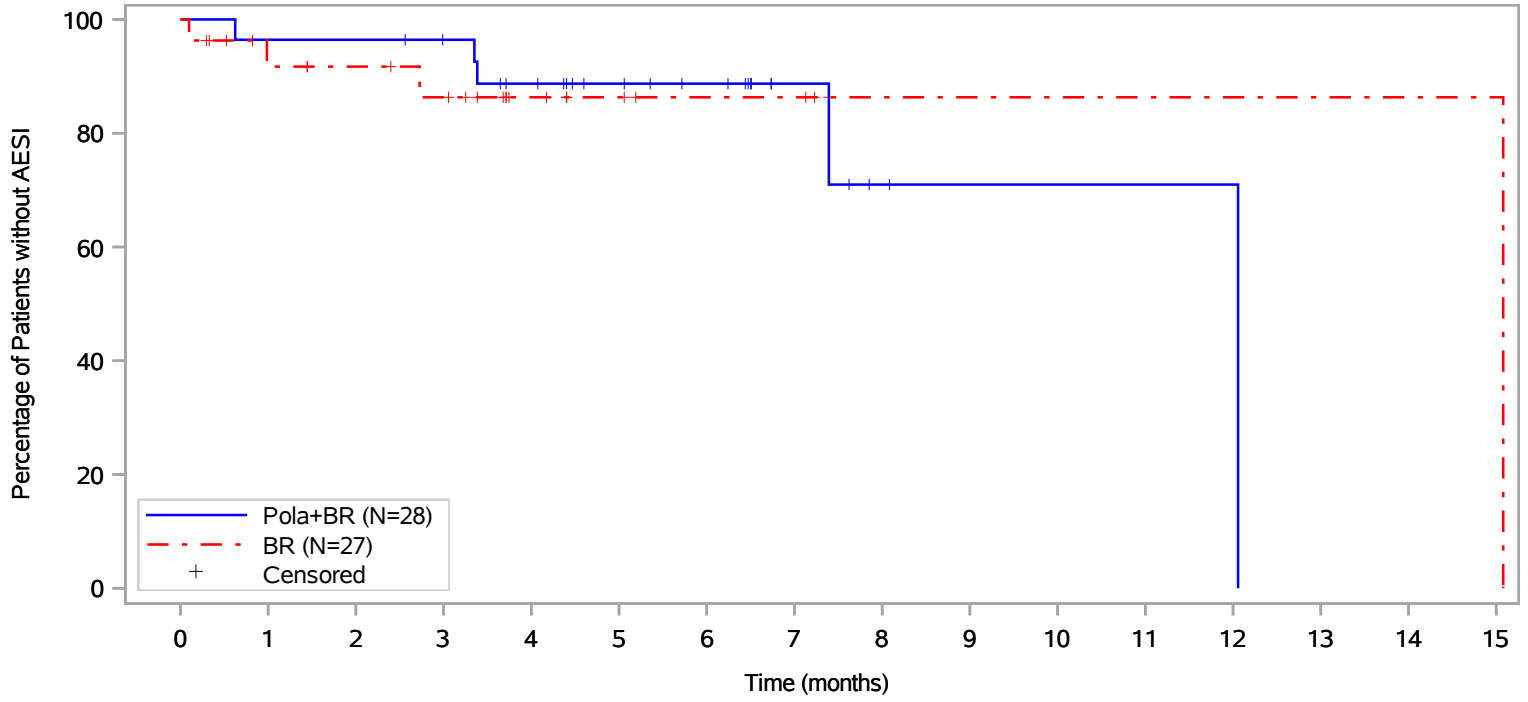
02DEC2022 19:50

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk																
Pola+BR (N=28)	28	27	27	25	21	16	13	5	2	1	1	1	1	NE	NE	NE
BR (N=27)	27	20	18	16	9	6	4	4	1	1	1	1	1	1	1	1
Patients censored																
Pola+BR (N=28)	0	0	0	2	4	9	12	20	22	23	23	23	23	NE	NE	NE
BR (N=27)	0	5	7	8	15	18	20	20	23	23	23	23	23	23	23	23

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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02DEC2022 6:50

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	1	3.7	26	96.3	0.2899	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2827	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	1	5.6	17	94.4	0.3329	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3865	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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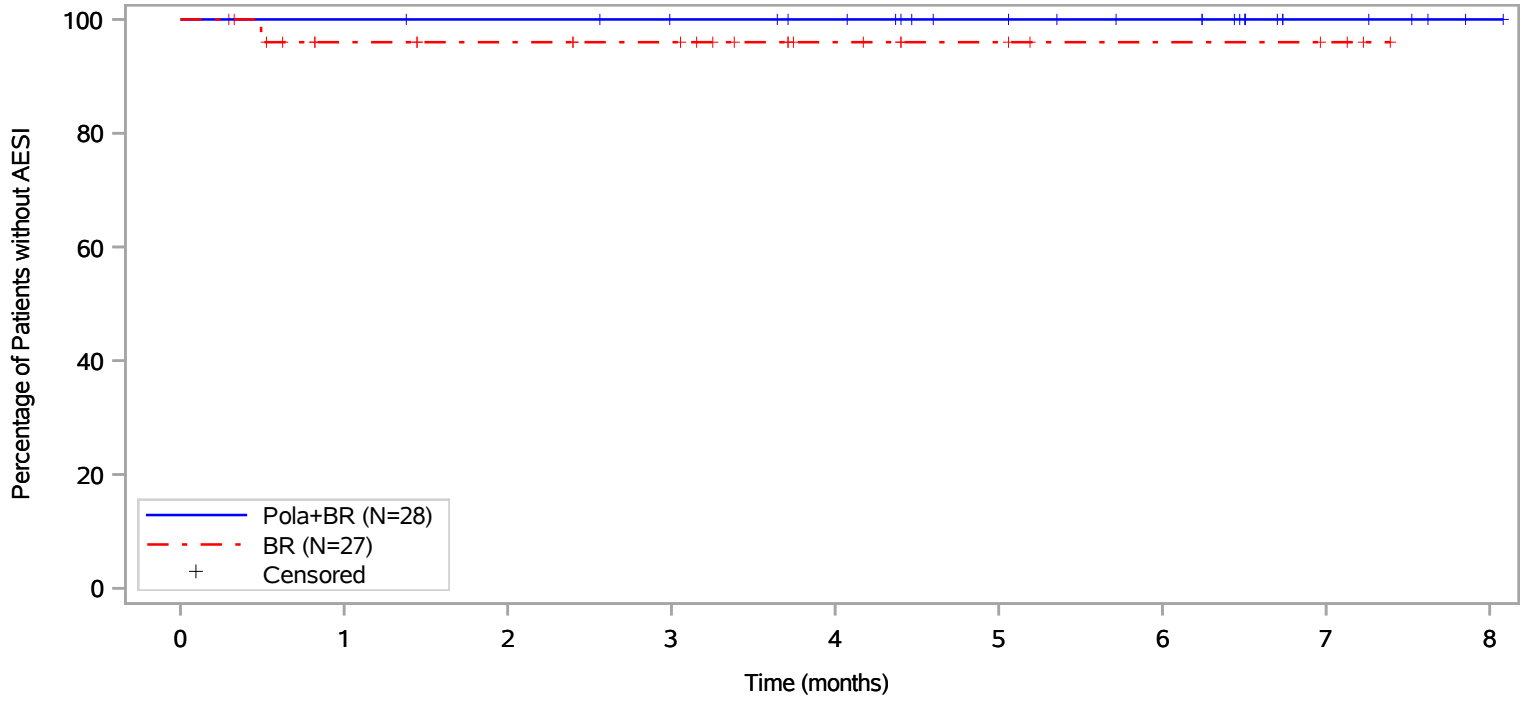
25JAN2023 18:21

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	20	18	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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01DEC2022 22:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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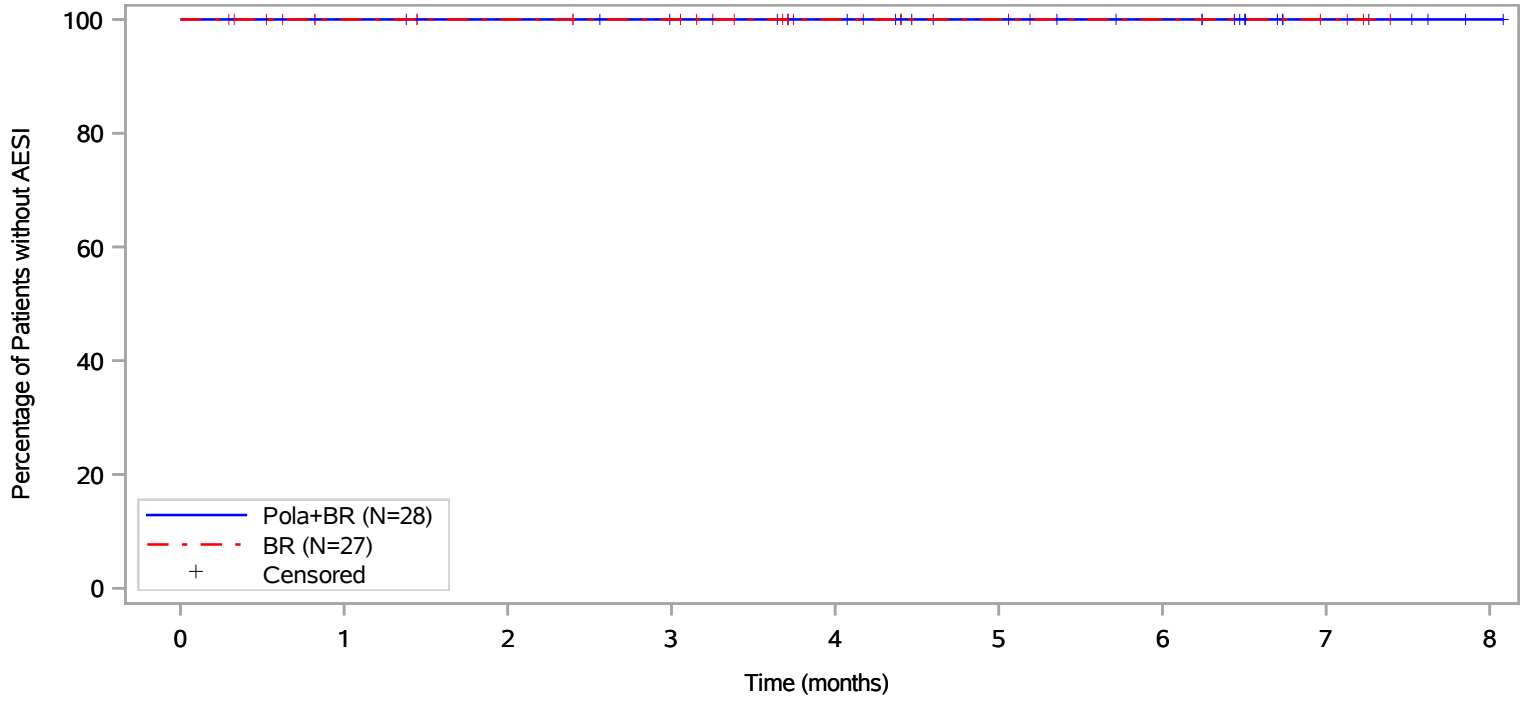
02DEC2022 22:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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02DEC2022 14:37

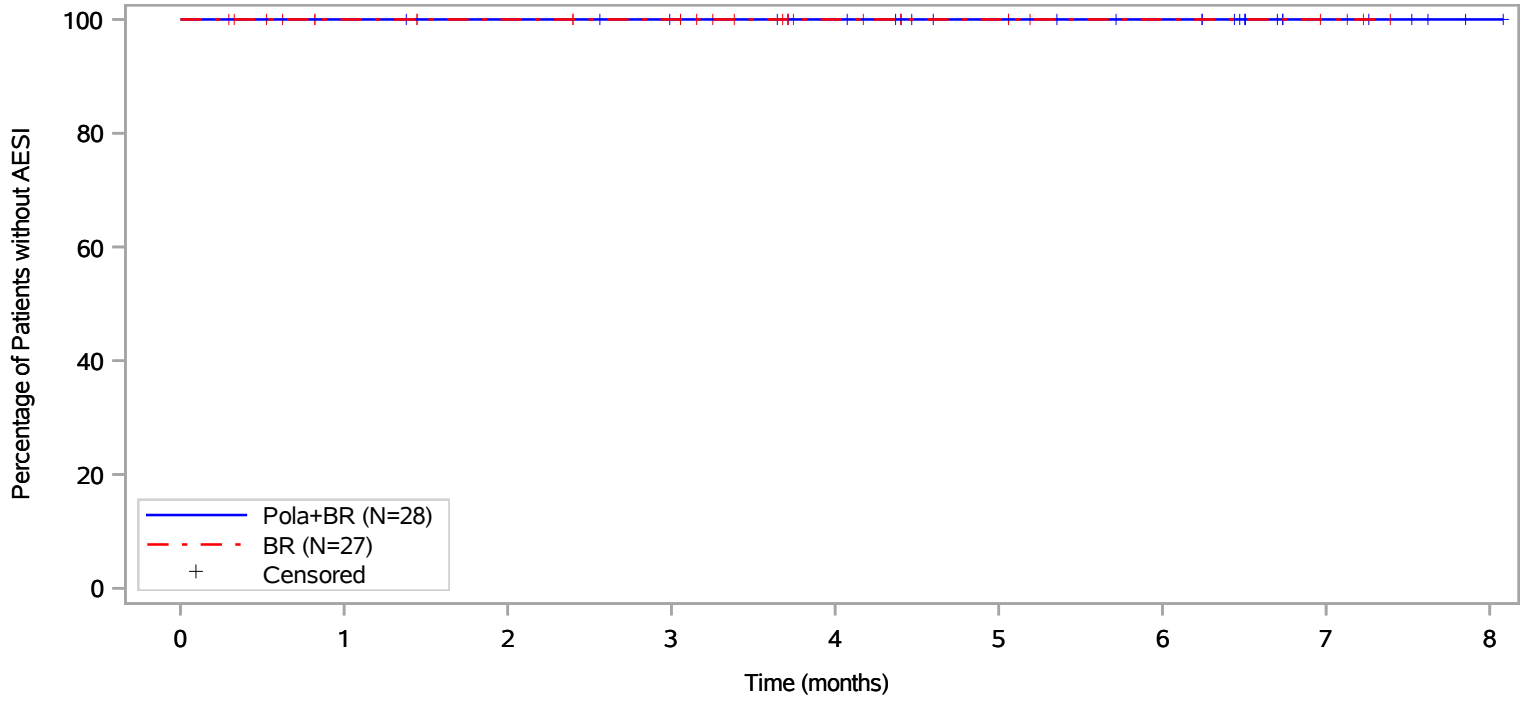
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Ocular Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTOCUTOXS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 22:14

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Ocular Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTOCUTOXS_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:31

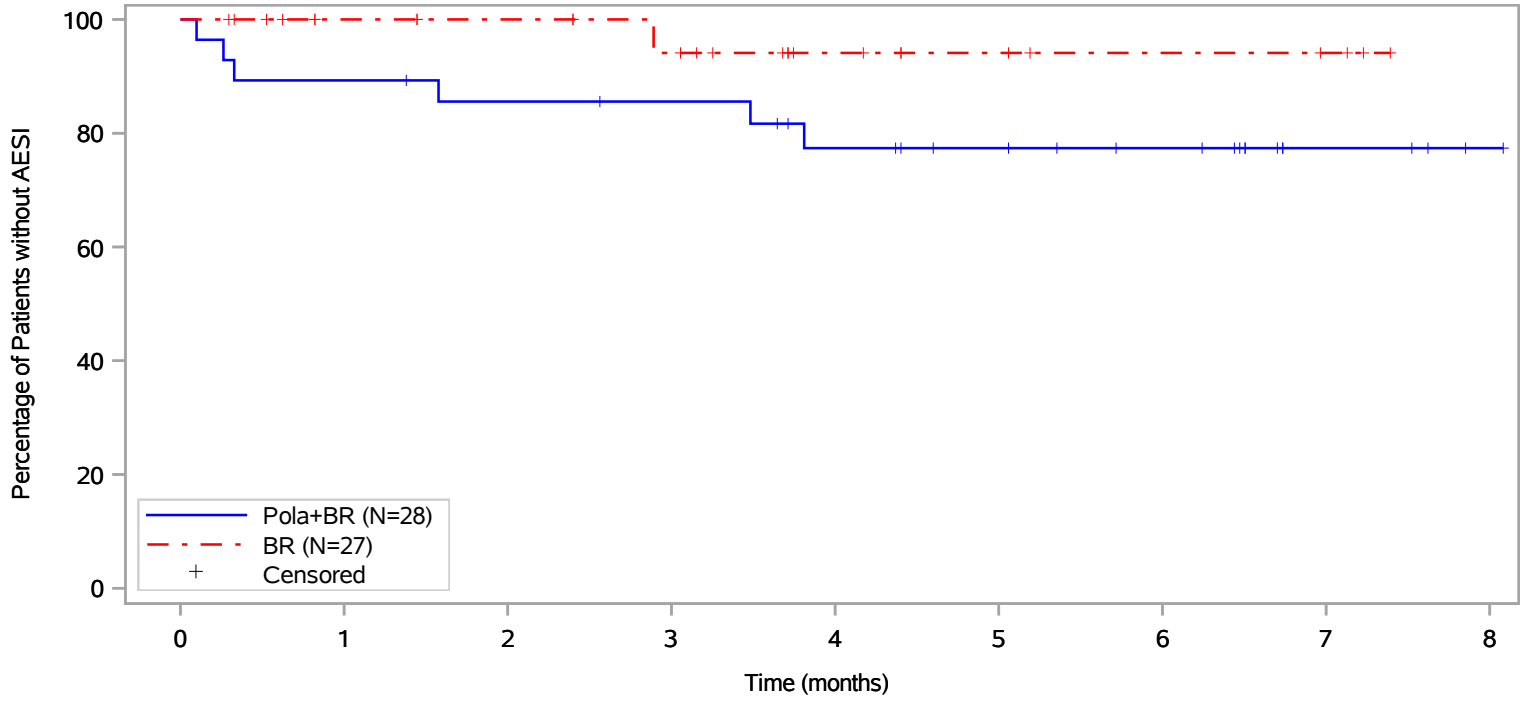
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	6	21.4	22	78.6	27	100.0	1	3.7	26	96.3	0.1132	4.75	0.57	39.77		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	5	25.0	15	75.0	18	66.7	1	5.6	17	94.4	0.1635	4.10	0.48	35.28		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	4	30.8	9	69.2	13	48.1	0	-	13	100.0	0.0664	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	2	13.3	13	86.7	14	51.9	1	7.1	13	92.9	0.7491	1.48	0.13	16.44		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	3	20.0	12	80.0	18	66.7	1	5.6	17	94.4	0.3809	2.66	0.27	25.85		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	3	23.1	10	76.9	9	33.3	0	-	9	100.0	0.1765	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	2	22.2	7	77.8	13	48.1	0	-	13	100.0	0.1198	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	4	21.1	15	78.9	14	51.9	1	7.1	13	92.9	0.4686	2.22	0.24	20.23		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPAIN_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 8:04

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	25	23	22	18	15	12	4	1
BR (N=27)	27	21	19	16	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	2	4	7	10	18	21
BR (N=27)	0	6	8	10	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPAIN_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:36

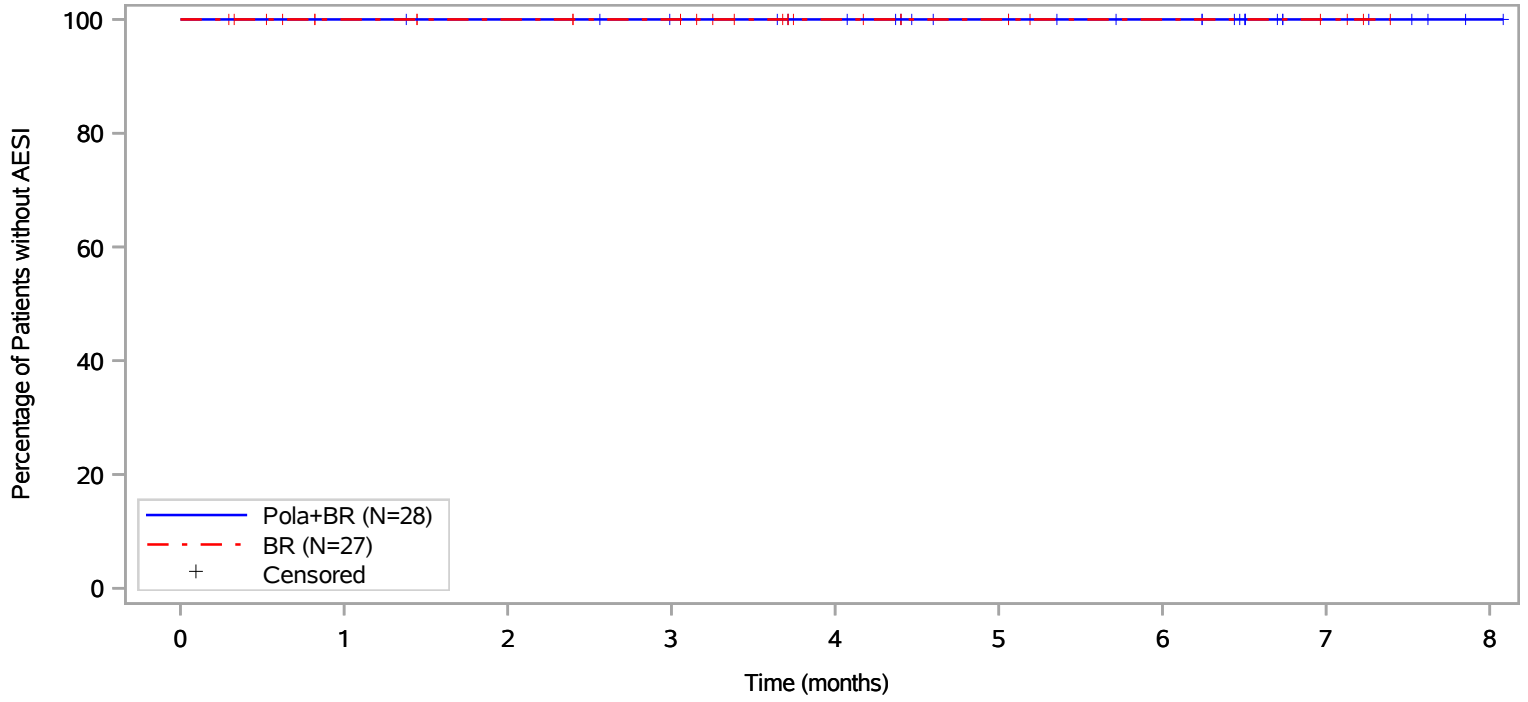
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPAIN35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:53

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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02DEC2022 13:23

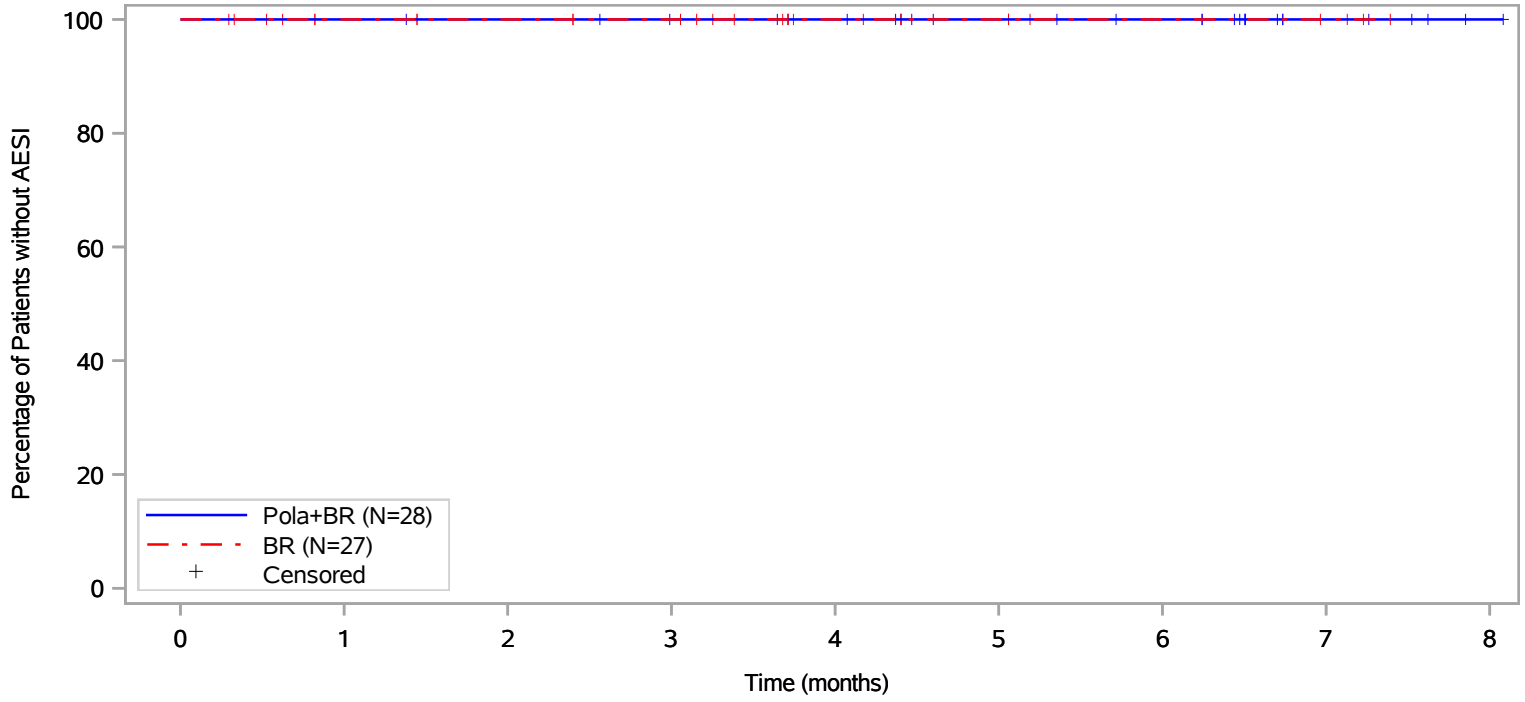
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPAINS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:53

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_TTPAINS_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 12:05

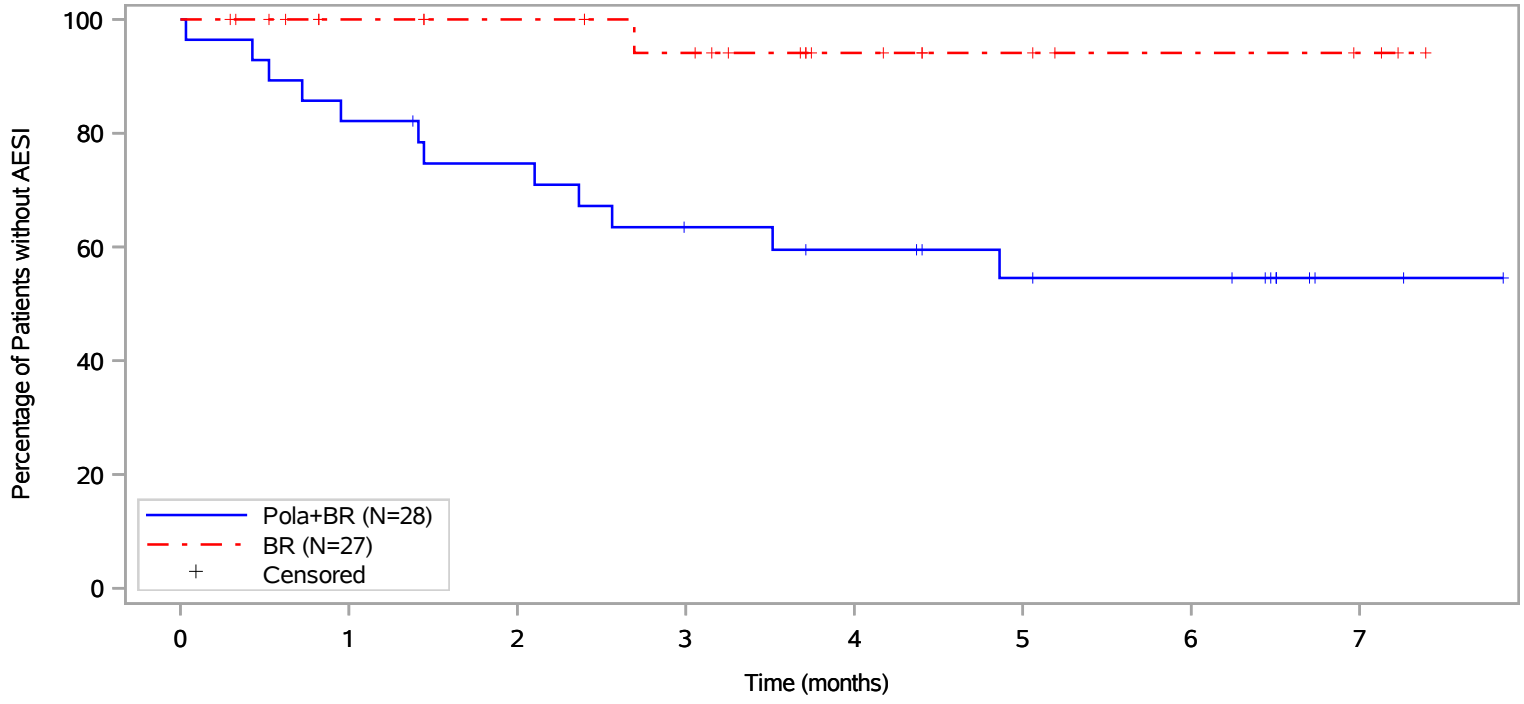
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	12	42.9	16	57.1	27	100.0	1	3.7	26	96.3	0.0041	10.88	1.41	83.81		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	8	40.0	12	60.0	18	66.7	1	5.6	17	94.4	0.0384	6.72	0.84	54.05		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	4	50.0	4	50.0	9	33.3	0	-	9	100.0	0.0432	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	5	38.5	8	61.5	13	48.1	0	-	13	100.0	0.0262	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	7	46.7	8	53.3	14	51.9	1	7.1	13	92.9	0.0588	5.95	0.73	48.60		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	8	53.3	7	46.7	18	66.7	1	5.6	17	94.4	0.0177	8.28	1.03	66.48		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	4	30.8	9	69.2	9	33.3	0	-	9	100.0	0.0849	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	1	11.1	8	88.9	13	48.1	0	-	13	100.0	0.2482	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	11	57.9	8	42.1	14	51.9	1	7.1	13	92.9	0.0139	8.54	1.10	66.40		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPHENEU_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 0:35

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=28)	28	23	20	16	14	11	10	2
BR (N=27)	27	21	19	16	9	6	4	3
Patients censored								
Pola+BR (N=28)	0	0	1	2	3	5	6	14
BR (N=27)	0	6	8	10	17	20	22	23

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTPHENEU_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:45

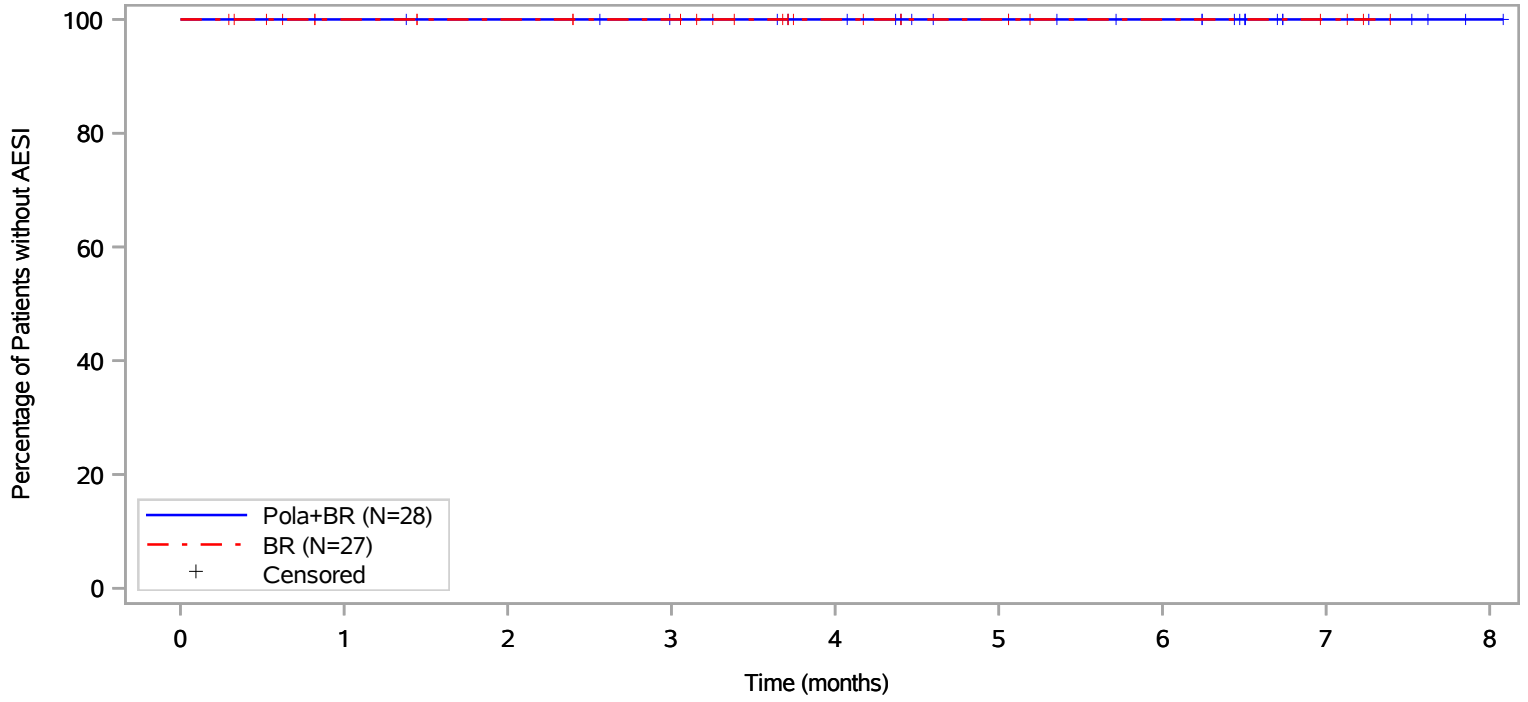
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPHENEU35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 20:26

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_365/g_km_TTPHENEU35_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:50

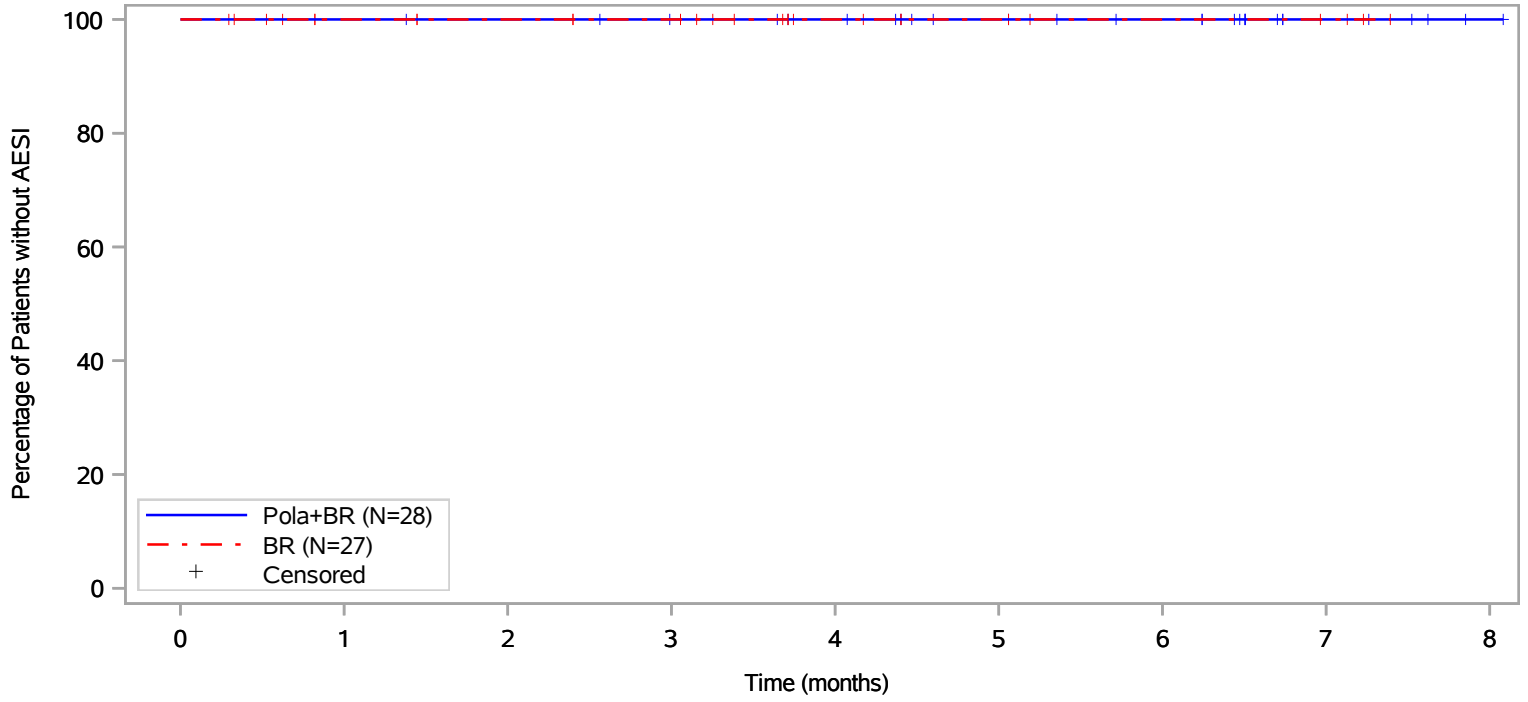
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPHENEUS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 20:18

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTPHENEUS_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 6:58

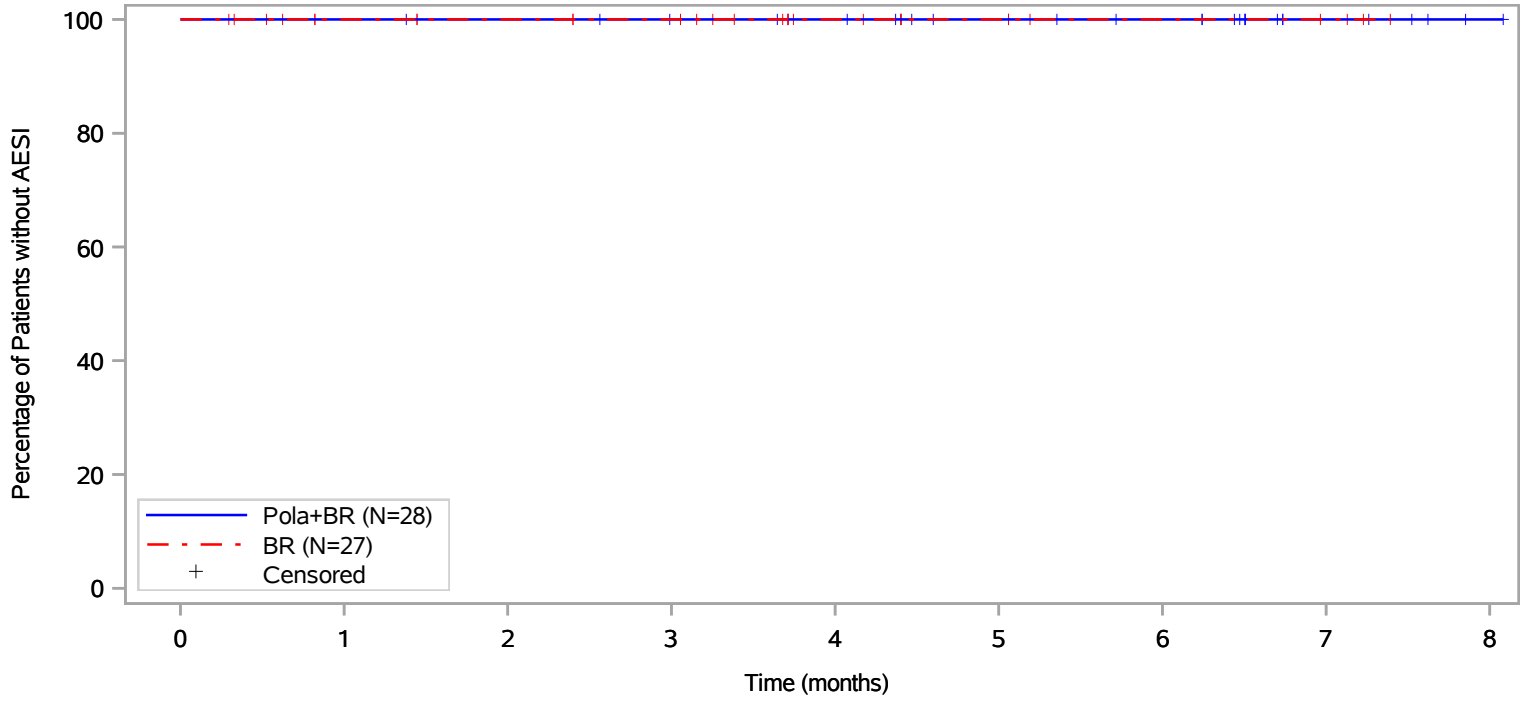
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPULTOX_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 7:21

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTPULTOX_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 20:54

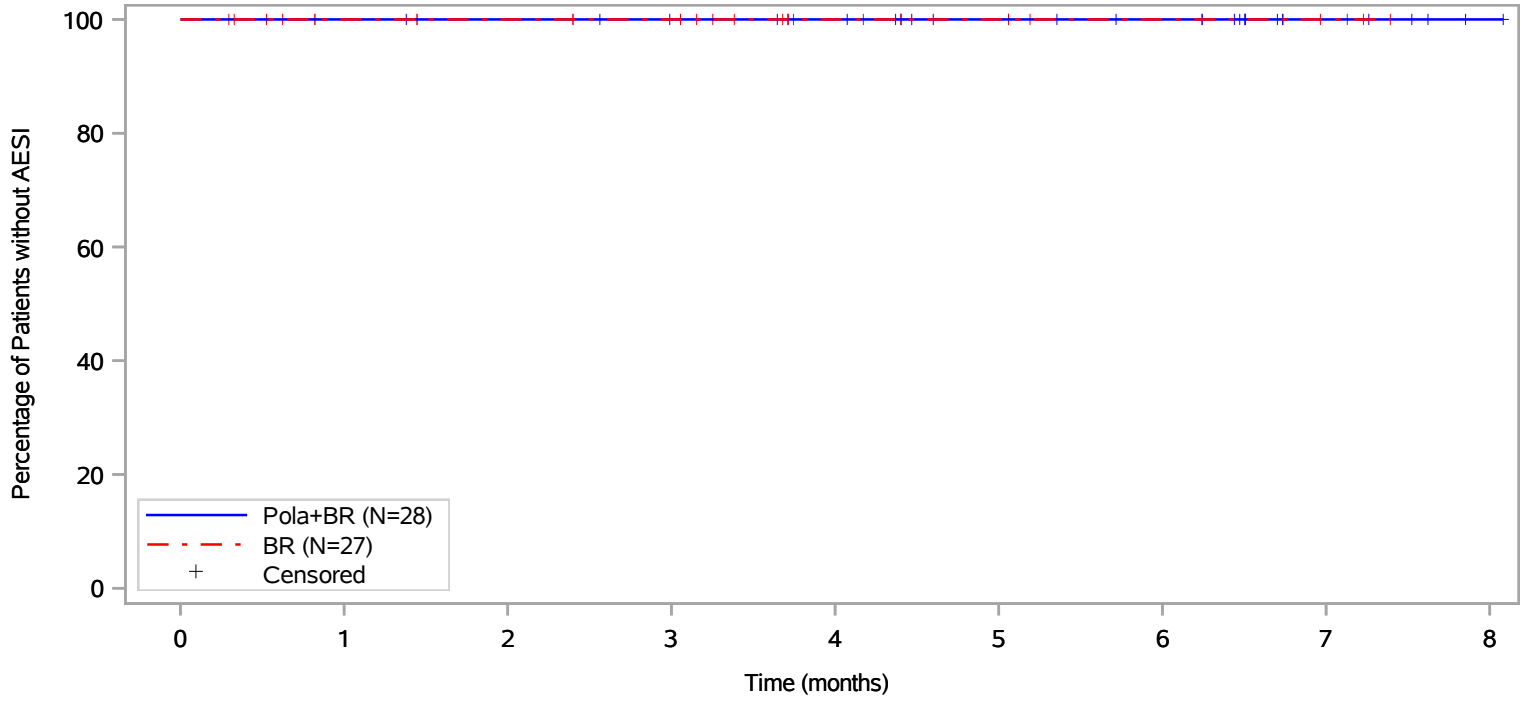
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPULTOX35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:43

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_365/g_km_TTPULTOX35_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 12:59

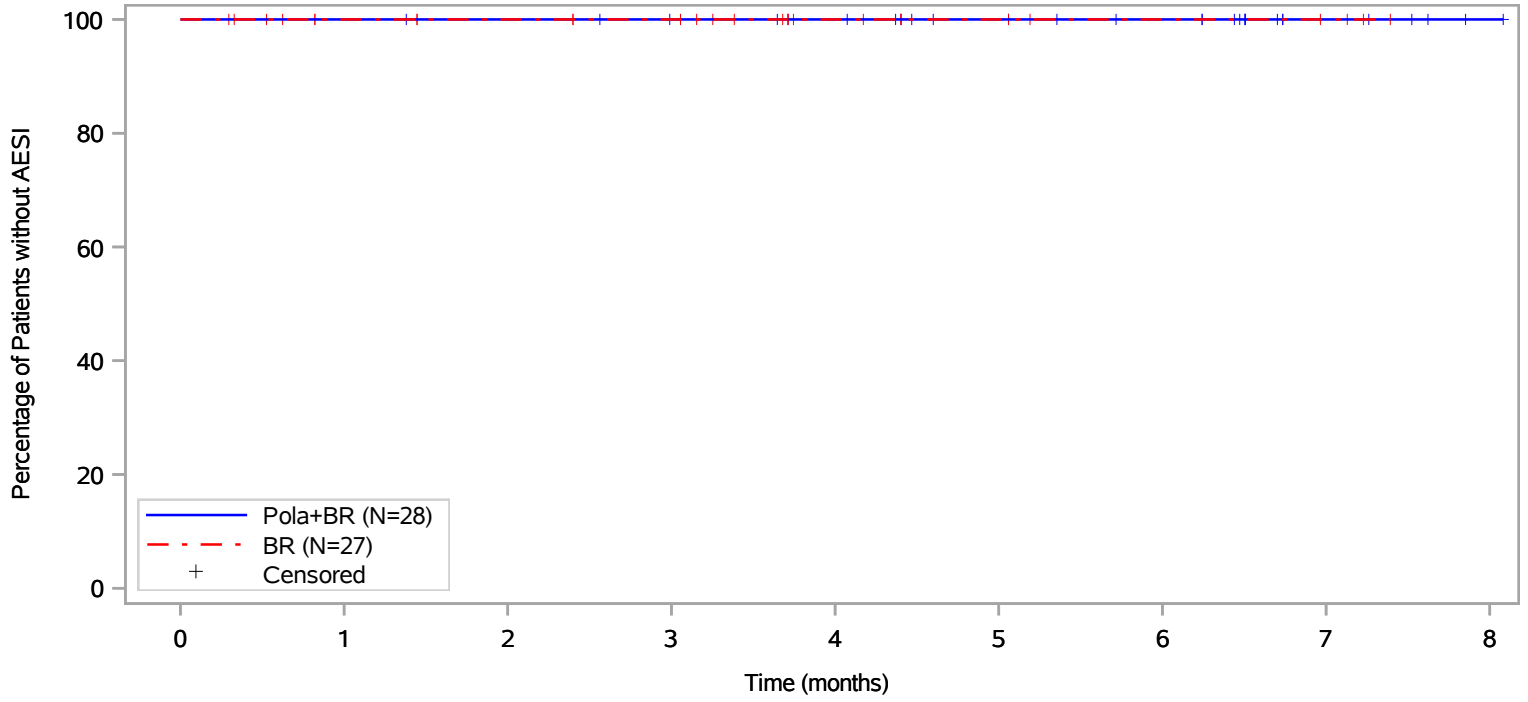
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTPULTOXS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:43

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTPULTOXS_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 16:14

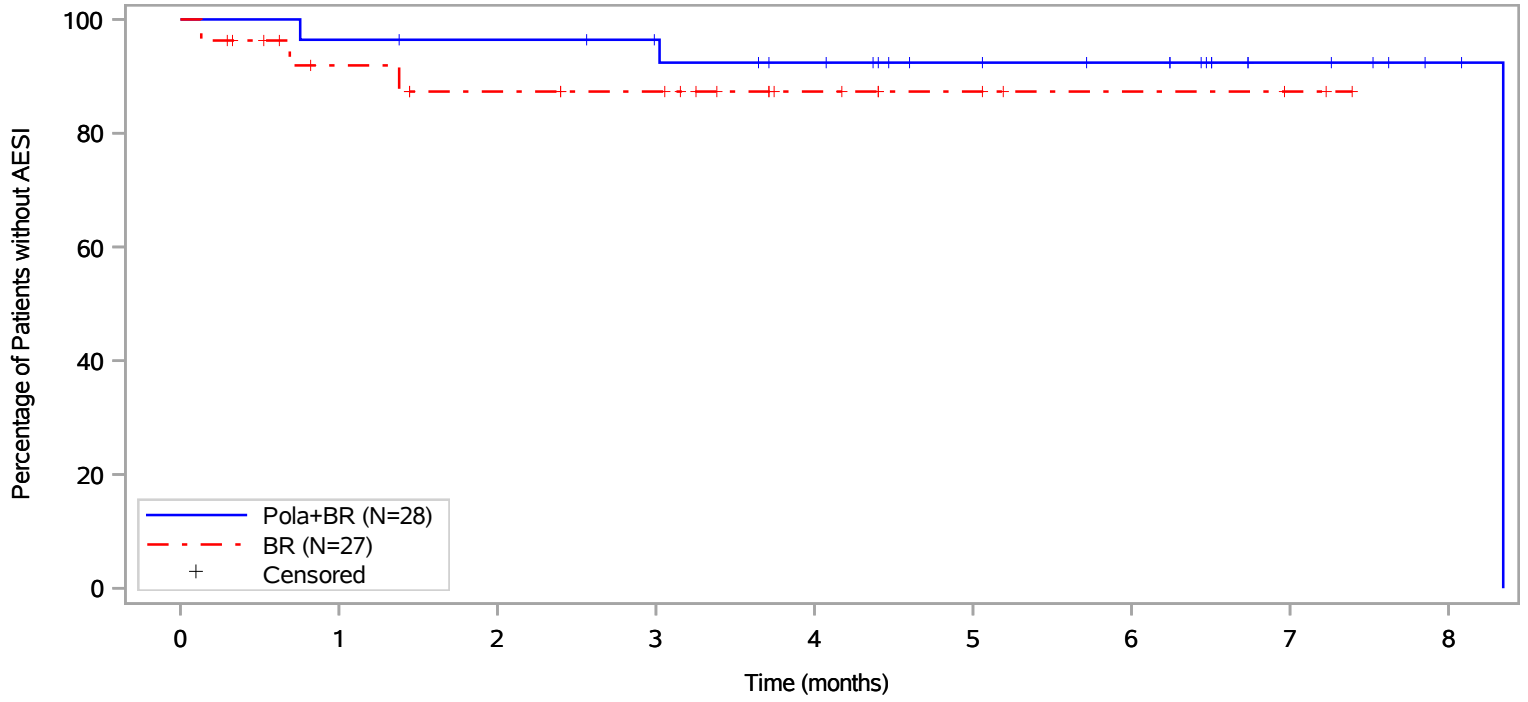
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	3	10.7	25	89.3	27	100.0	3	11.1	24	88.9	0.4526	0.51	0.08	3.06		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	2	10.0	18	90.0	18	66.7	1	5.6	17	94.4	0.9075	0.85	0.05	13.58		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	1	12.5	7	87.5	9	33.3	2	22.2	7	77.8	0.2863	0.29	0.03	3.25		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	2	15.4	11	84.6	13	48.1	0	-	13	100.0	0.3367	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	3	21.4	11	78.6	0.1475	0.22	0.02	2.10		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	2	11.1	16	88.9	0.5559	0.49	0.04	5.46		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	2	15.4	11	84.6	9	33.3	1	11.1	8	88.9	0.7053	0.59	0.04	9.49		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	2	15.4	11	84.6	0.1780	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	3	15.8	16	84.2	14	51.9	1	7.1	13	92.9	0.8440	1.27	0.12	14.07		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTRENTOX_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 5:56

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	27	26	24	21	16	14	6	2
BR (N=27)	27	20	17	15	8	5	3	2	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	12	20	24
BR (N=27)	0	5	7	9	16	19	21	22	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTRENTOX_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:48

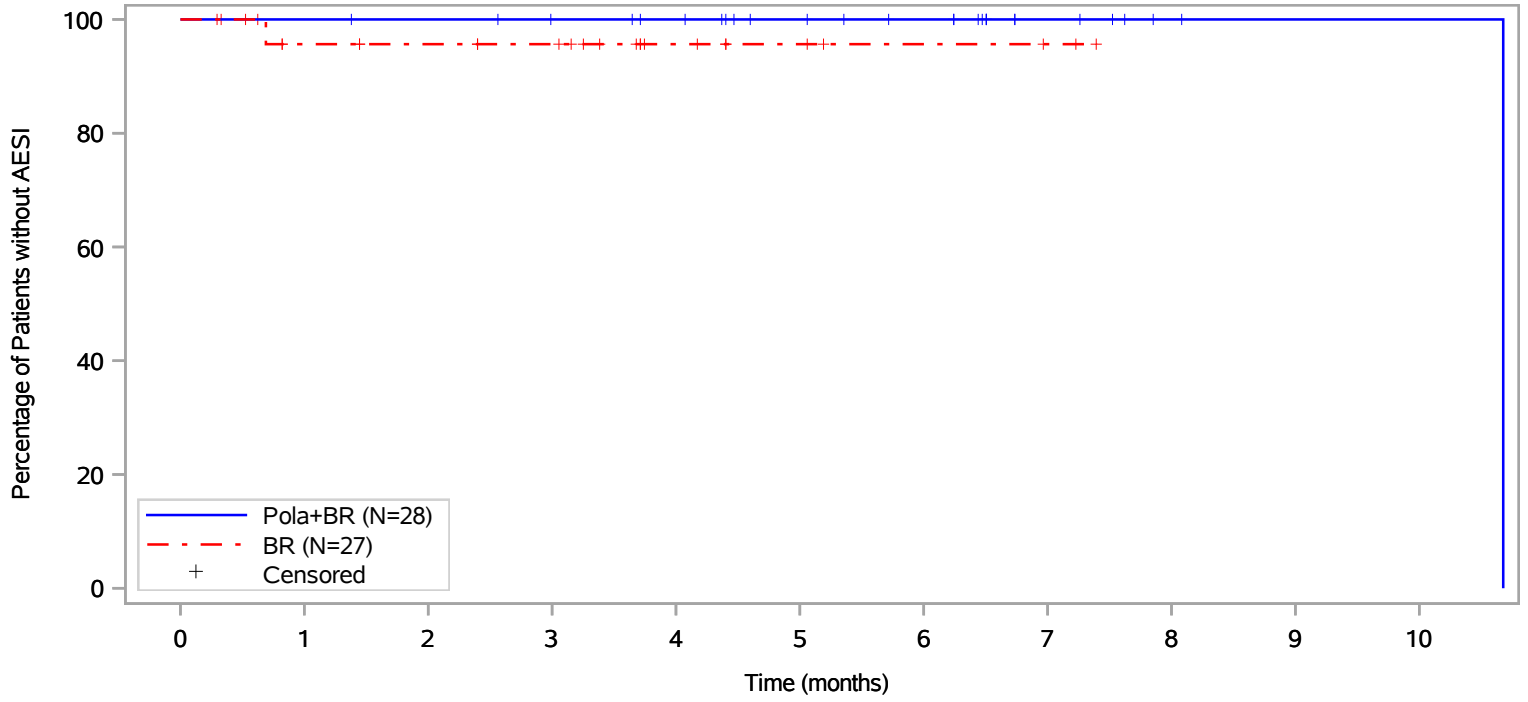
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTRENTOX35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:26

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1
BR (N=27)	27	20	18	16	8	5	3	2	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_365/g_km_TTRENTOX35_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 12:19

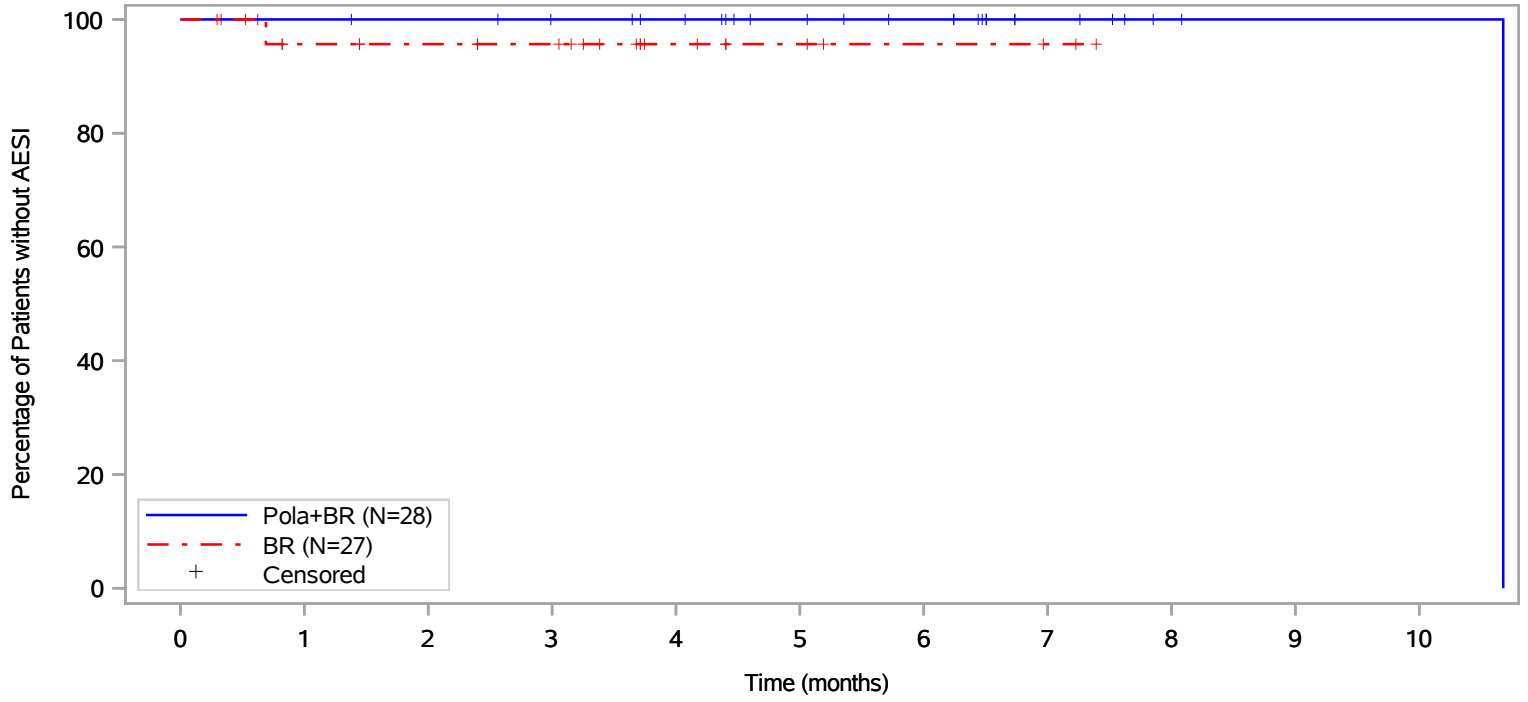
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	1	3.6	27	96.4	27	100.0	1	3.7	26	96.3	0.2699	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	1	5.0	19	95.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	1	11.1	8	88.9	0.2482	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	1	7.1	13	92.9	0.2429	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.2294	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	1	7.7	12	92.3	0.3657	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	1	5.3	18	94.7	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTRENTOXS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 21:29

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=28)	28	28	27	25	23	18	15	6	2	1	1
BR (N=27)	27	20	18	16	8	5	3	2	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	0	1	3	5	10	13	22	26	27	27
BR (N=27)	0	6	8	10	18	21	23	24	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTRENTOXS_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:20

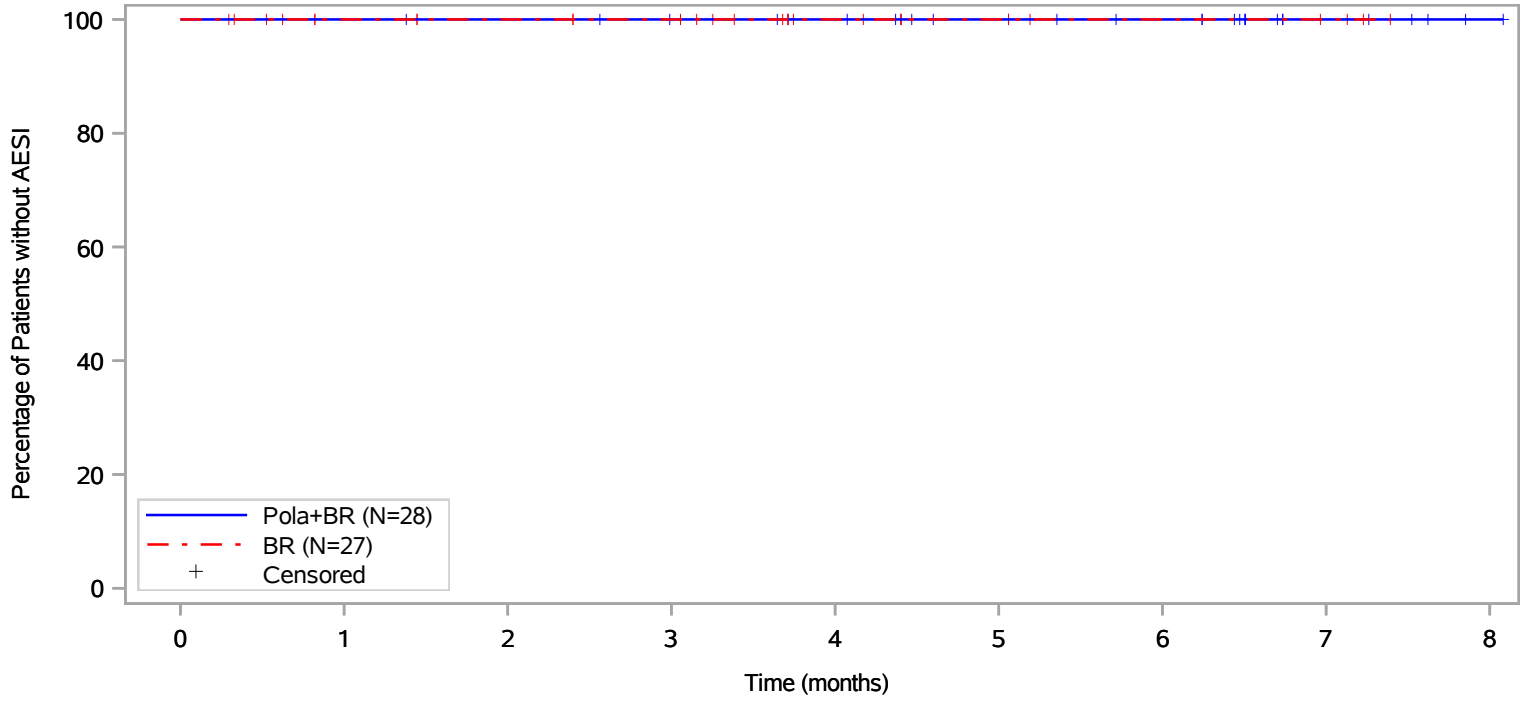
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTREPROD_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 4:27

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Reproductive Toxicity
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTREPROD_L3PLUS_ARMCDSE_365_29365_41543.pdf
01DEC2022 21:27

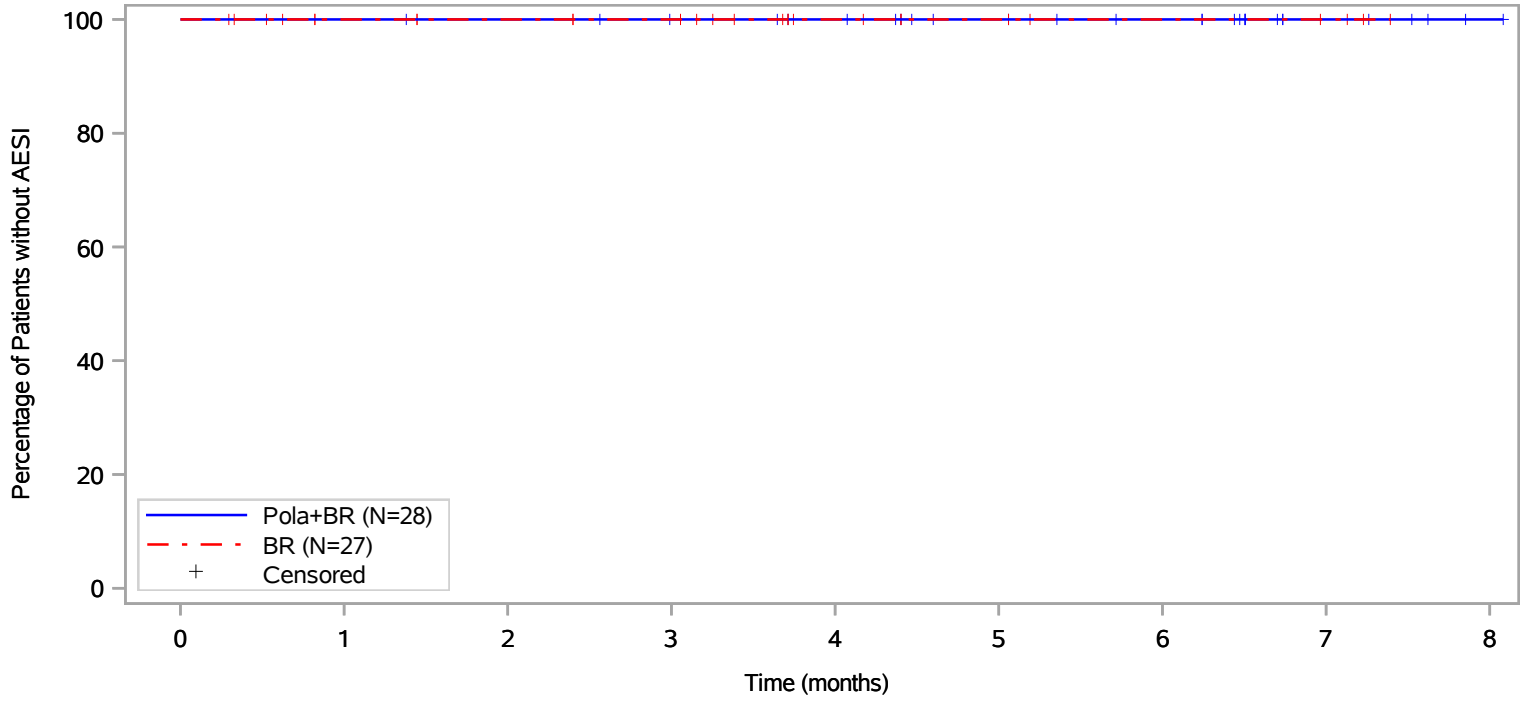
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTSTIAMP_L3PLUS_ARMCDSE_365_29365_41543.xls
04DEC2022 13:56

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTSTIAMP_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 14:20

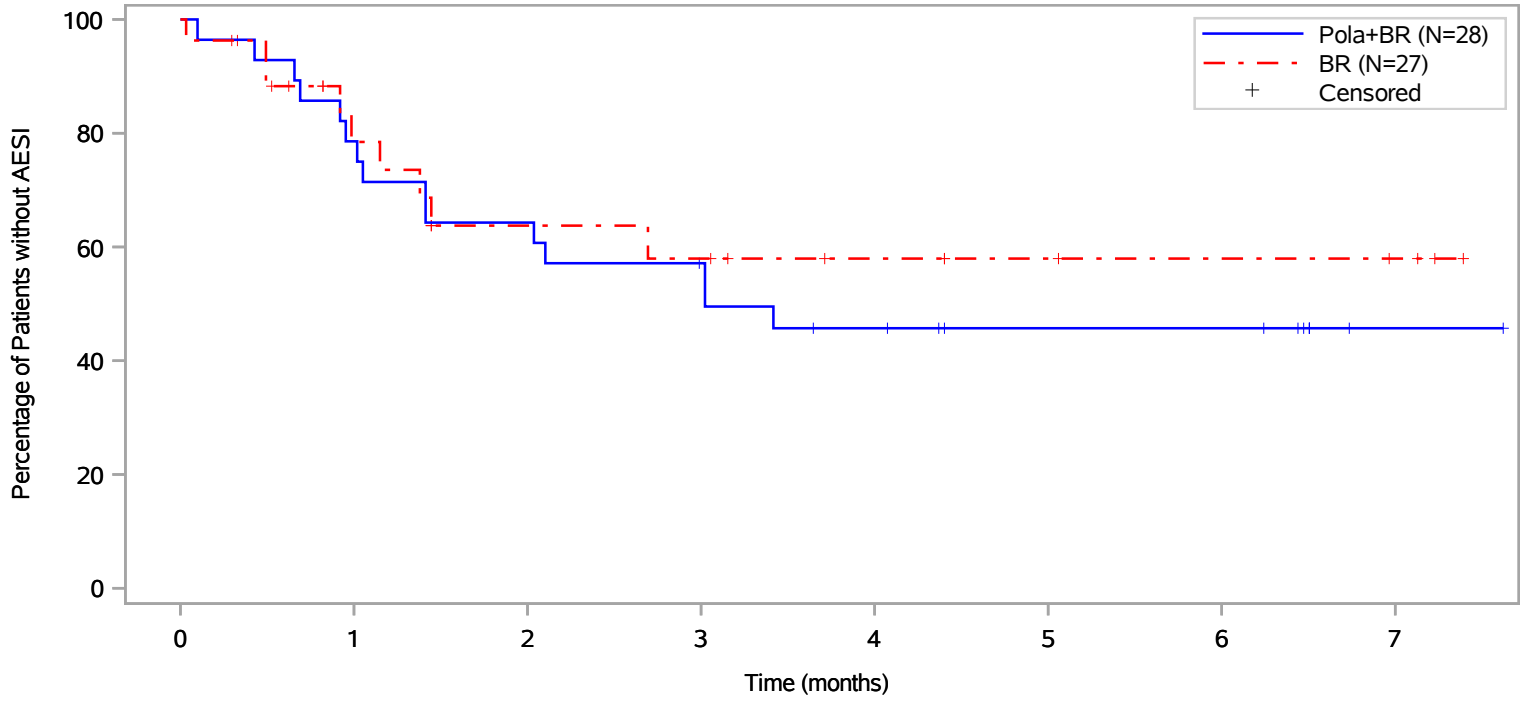
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	15	53.6	13	46.4	27	100.0	9	33.3	18	66.7	0.5758	1.27	0.55	2.91		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	8	40.0	12	60.0	18	66.7	6	33.3	12	66.7	0.9659	0.98	0.34	2.84		Convergence criterion (GCONV=1E-8) satisfied.	0.3366
	Female	8	28.6	7	87.5	1	12.5	9	33.3	3	33.3	6	66.7	0.3218	2.00	0.50	8.08		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	8	61.5	5	38.5	13	48.1	5	38.5	8	61.5	0.4453	1.54	0.50	4.74		Convergence criterion (GCONV=1E-8) satisfied.	0.6897
	>= 65	15	53.6	7	46.7	8	53.3	14	51.9	4	28.6	10	71.4	0.9039	1.08	0.31	3.73		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	9	60.0	6	40.0	18	66.7	4	22.2	14	77.8	0.1431	2.37	0.72	7.75		Convergence criterion (GCONV=1E-8) satisfied.	0.0755
	<3	13	46.4	6	46.2	7	53.8	9	33.3	5	55.6	4	44.4	0.3297	0.55	0.16	1.86		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	2	22.2	7	77.8	13	48.1	3	23.1	10	76.9	0.8681	0.86	0.14	5.16		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	13	68.4	6	31.6	14	51.9	6	42.9	8	57.1	0.6588	1.25	0.47	3.31		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTTHROM_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 2:09

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=28)	28	22	18	15	11	8	8	1
BR (N=27)	27	16	11	10	7	5	4	3
Patients censored								
Pola+BR (N=28)	0	0	0	1	2	5	5	12
BR (N=27)	0	6	8	8	11	13	14	15

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_365/g_km_TTTHROM_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:40

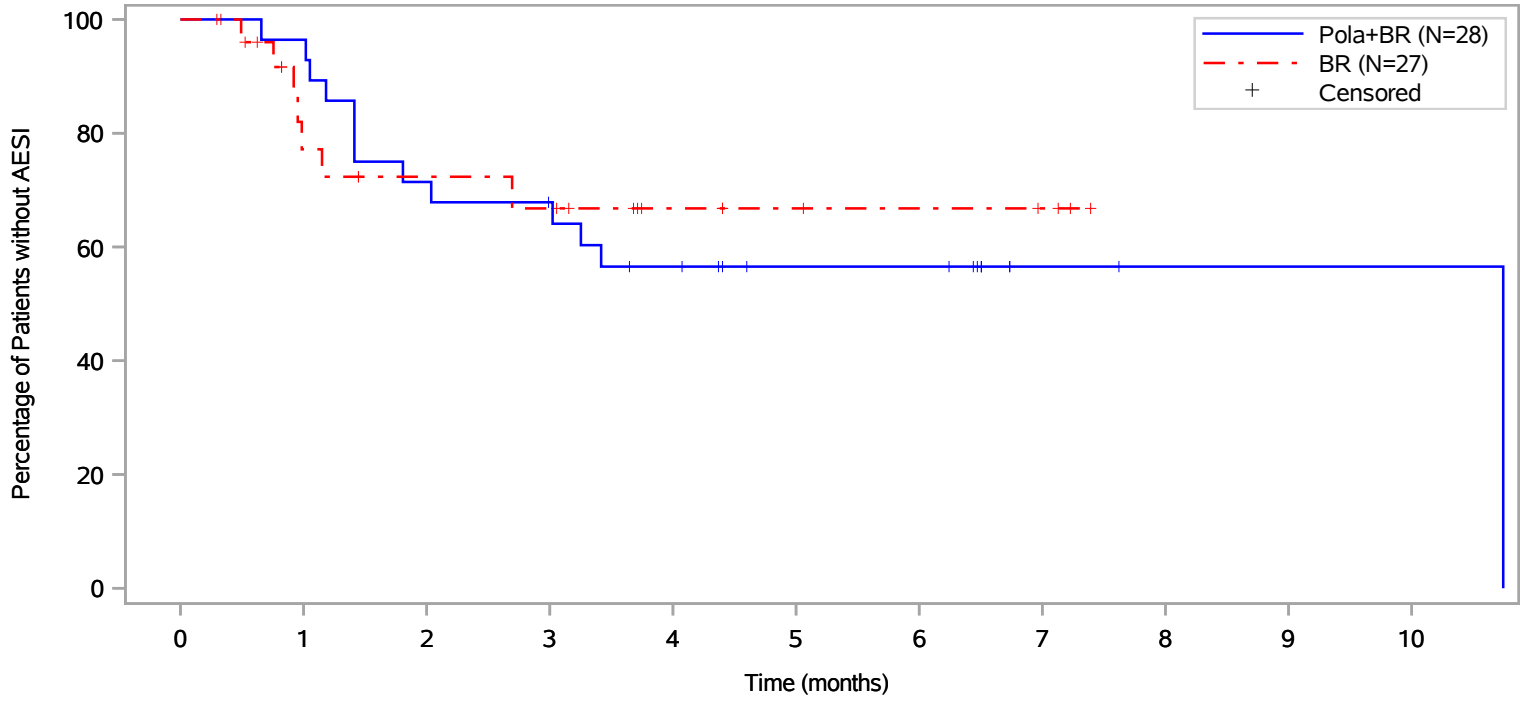
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		28	100.0	13	46.4	15	53.6	27	100.0	7	25.9	20	74.1	0.7883	1.14	0.45	2.90	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	8	40.0	12	60.0	18	66.7	6	33.3	12	66.7	0.4646	0.66	0.22	2.01	Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	5	62.5	3	37.5	9	33.3	1	11.1	8	88.9	0.1611	4.12	0.48	35.33	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	6	46.2	7	53.8	13	48.1	4	30.8	9	69.2	0.8529	0.88	0.24	3.30	Convergence criterion (GCONV=1E-8) satisfied.	0.6248
	>= 65	15	53.6	7	46.7	8	53.3	14	51.9	3	21.4	11	78.6	0.5704	1.48	0.38	5.76	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	8	53.3	7	46.7	18	66.7	3	16.7	15	83.3	0.2017	2.34	0.61	8.94	Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	5	38.5	8	61.5	9	33.3	4	44.4	5	55.6	0.2284	0.43	0.11	1.75	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	2	22.2	7	77.8	13	48.1	1	7.7	12	92.3	0.4861	2.29	0.21	25.40	Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	11	57.9	8	42.1	14	51.9	6	42.9	8	57.1	0.5385	0.73	0.26	2.03	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTTHROM35_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 20:41

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk											
Pola+BR (N=28)	28	27	20	18	14	10	10	2	1	1	1
BR (N=27)	27	16	13	12	7	5	4	3	NE	NE	NE
Patients censored											
Pola+BR (N=28)	0	0	0	1	2	6	6	14	15	15	15
BR (N=27)	0	6	8	8	13	15	16	17	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_365/g_km_TTTHROM35_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:47

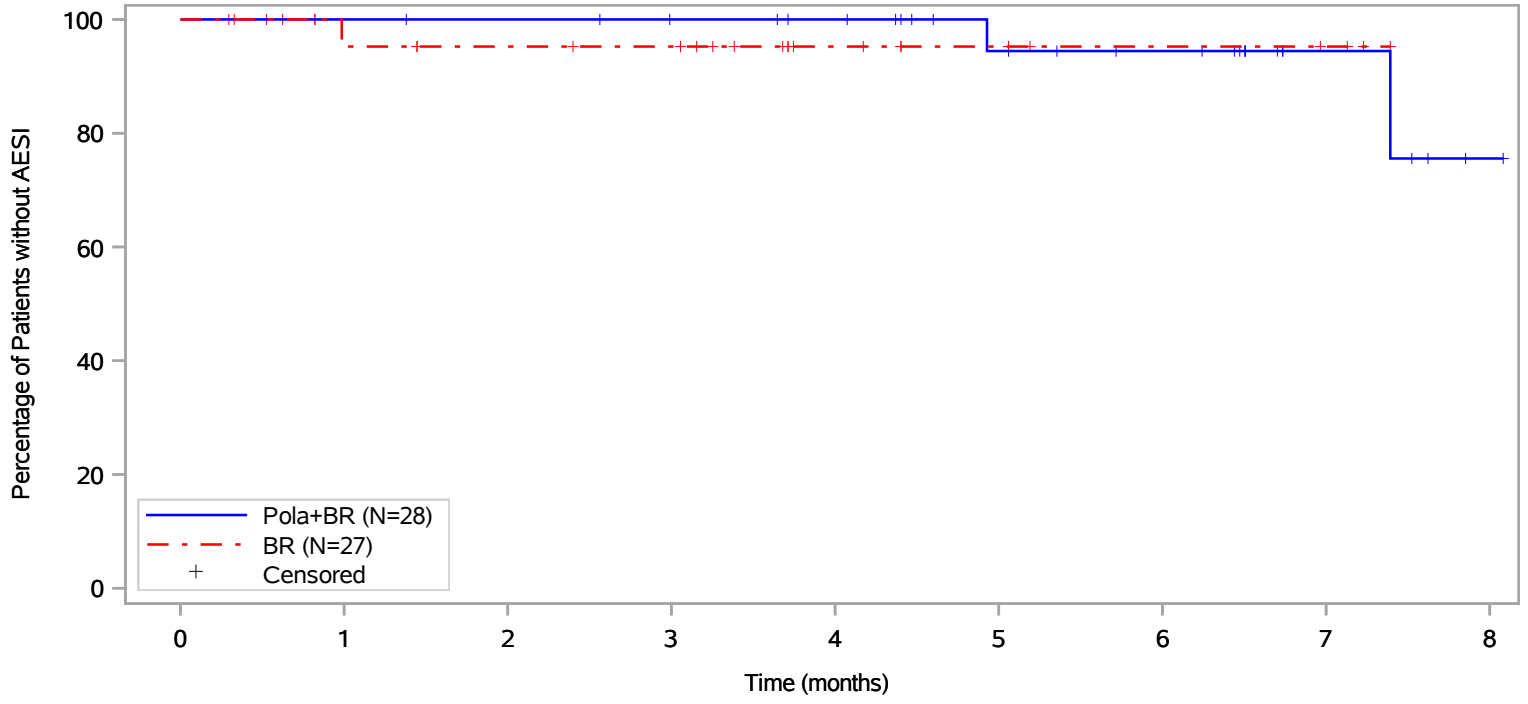
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	2	7.1	26	92.9	27	100.0	1	3.7	26	96.3	0.8378	0.77	0.06	9.23		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	1	5.0	19	95.0	18	66.7	1	5.6	17	94.4	0.5594	0.43	0.02	7.69		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	1	12.5	7	87.5	9	33.3	0	-	9	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	1	7.7	12	92.3	13	48.1	1	7.7	12	92.3	0.7211	0.60	0.04	10.02		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	1	6.7	14	93.3	14	51.9	0	-	14	100.0	NE	1.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	1	6.7	14	93.3	18	66.7	0	-	18	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	1	7.7	12	92.3	9	33.3	1	11.1	8	88.9	0.5054	0.39	0.02	6.73		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	2	10.5	17	89.5	14	51.9	1	7.1	13	92.9	0.7535	0.68	0.06	7.81		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTTHROMS_L3PLUS_ARMCDSE_365_29365_41543.xls
02DEC2022 20:38

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	17	14	5	1
BR (N=27)	27	20	18	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	22	25
BR (N=27)	0	6	8	9	17	20	22	23	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_365/g_km_TTTHROMS_L3PLUS_ARMCDSE_365_29365_41543.pdf
02DEC2022 7:16

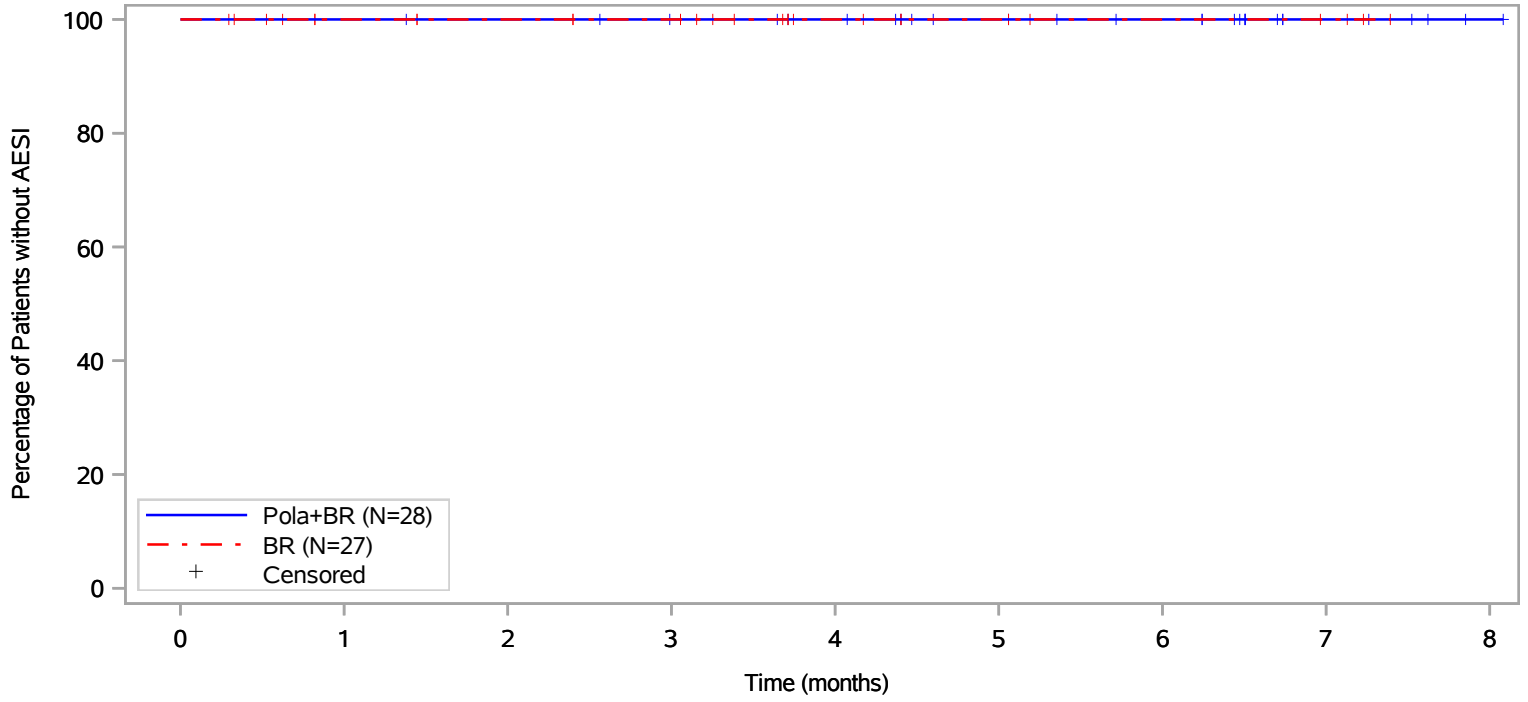
POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=28)						BR (N=27)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		28	100.0	0	-	28	100.0	27	100.0	0	-	27	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	20	71.4	0	-	20	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	8	28.6	0	-	8	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	13	46.4	0	-	13	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	15	53.6	0	-	15	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	15	53.6	0	-	15	100.0	18	66.7	0	-	18	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	13	46.4	0	-	13	100.0	9	33.3	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Europe	9	32.1	0	-	9	100.0	13	48.1	0	-	13	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Non-Europe	19	67.9	0	-	19	100.0	14	51.9	0	-	14	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ttae_sg1_TTTLS_L3PLUS_ARMCDSE_365_29365_41543.xls
01DEC2022 21:24

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
STUDIES: GO29365, YO41543



Patients at risk									
Pola+BR (N=28)	28	28	27	25	23	18	15	5	1
BR (N=27)	27	21	19	17	9	6	4	3	NE
Patients censored									
Pola+BR (N=28)	0	0	1	3	5	10	13	23	27
BR (N=27)	0	6	8	10	18	21	23	24	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_365/g_km_TTTLS_L3PLUS_ARMCDSE_365_29365_41543.pdf
03DEC2022 21:53

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=28)														BR (N=27)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																													
All	409	291	71.1	5	1.2	100	24.4	3	0.7	9	2.2	1	0.2	0	0.0	277	174	62.8	5	1.8	86	31.0	5	1.8	2	0.7	5	1.8	0	0.0
Grade 1	176	115	65.3	0	0.0	52	29.5	0	0.0	8	4.5	1	0.6	0	0.0	117	82	70.1	3	2.6	30	25.6	0	0.0	1	0.9	1	0.9	0	0.0
Grade 2	109	77	70.6	2	1.8	29	26.6	0	0.0	1	0.9	0	0.0	0	0.0	86	45	52.3	0	0.0	36	41.9	0	0.0	1	1.2	4	4.7	0	0.0
Grade 3	85	69	81.2	3	3.5	13	15.3	0	0.0	0	0.0	0	0.0	0	0.0	53	41	77.4	1	1.9	11	20.8	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	36	30	83.3	0	0.0	6	16.7	0	0.0	0	0.0	0	0.0	0	0.0	16	6	37.5	1	6.3	9	56.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	5	0	0.0	0	0.0	0	0.0	5	100.0	0	0.0	0	0.0	0	0.0
AEs Grade >=3																													
All	124	99	79.8	3	2.4	19	15.3	3	2.4	0	0.0	0	0.0	0	0.0	74	47	63.5	2	2.7	20	27.0	5	6.8	0	0.0	0	0.0	0	0.0
Grade 3	85	69	81.2	3	3.5	13	15.3	0	0.0	0	0.0	0	0.0	0	0.0	53	41	77.4	1	1.9	11	20.8	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	36	30	83.3	0	0.0	6	16.7	0	0.0	0	0.0	0	0.0	0	0.0	16	6	37.5	1	6.3	9	56.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	5	0	0.0	0	0.0	0	0.0	5	100.0	0	0.0	0	0.0	0	0.0
AEs Grade 3																													
All	85	69	81.2	3	3.5	13	15.3	0	0.0	0	0.0	0	0.0	0	0.0	53	41	77.4	1	1.9	11	20.8	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	85	69	81.2	3	3.5	13	15.3	0	0.0	0	0.0	0	0.0	0	0.0	53	41	77.4	1	1.9	11	20.8	0	0.0	0	0.0	0	0.0	0	0.0
AEs Grade 4																													
All	36	30	83.3	0	0.0	6	16.7	0	0.0	0	0.0	0	0.0	0	0.0	16	6	37.5	1	6.3	9	56.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	36	30	83.3	0	0.0	6	16.7	0	0.0	0	0.0	0	0.0	0	0.0	16	6	37.5	1	6.3	9	56.3	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																													
All	24	20	83.3	0	0.0	1	4.2	3	12.5	0	0.0	0	0.0	0	0.0	30	17	56.7	1	3.3	7	23.3	5	16.7	0	0.0	0	0.0	0	0.0
Grade 1	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	10	10	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	14	11	78.6	0	0.0	3	21.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	6	5	83.3	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0	9	4	44.4	1	11.1	4	44.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	3	0	0.0	0	0.0	0	0.0	3	100.0	0	0.0	0	0.0	0	0.0	5	0	0.0	0	0.0	0	0.0	5	100.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ae_resolved.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_365/t_s_ae_resolved_L3PLUS_ARMCDSE_365_29365_41543.xls
29NOV2022 8:50

POPULATION: Study GO29365, Safety Population, Arms C,D, Third-line or beyond (3L+) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=28)															BR (N=27)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Neutropenia Including Febrile Neutropenia																														
All	64	54	84.4	2	3.1	8	12.5	0	0.0	0	0.0	0	0.0	0	0.0	32	28	87.5	0	0.0	4	12.5	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	5	4	80.0	0	0.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	6	4	66.7	0	0.0	2	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	7	6	85.7	1	14.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	31	28	90.3	1	3.2	2	6.5	0	0.0	0	0.0	0	0.0	0	0.0	15	15	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	21	16	76.2	0	0.0	5	23.8	0	0.0	0	0.0	0	0.0	0	0.0	8	6	75.0	0	0.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Neutropenia Including Febrile Neutropenia																														
All	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral Neuropathy																														
All	19	13	68.4	0	0.0	5	26.3	0	0.0	1	5.3	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	15	11	73.3	0	0.0	3	20.0	0	0.0	1	6.7	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	4	2	50.0	0	0.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Peripheral Neuropathy																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Anemia																														
All	24	19	79.2	0	0.0	4	16.7	0	0.0	1	4.2	0	0.0	0	0.0	8	4	50.0	0	0.0	4	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	3	1	33.3	0	0.0	1	33.3	0	0.0	1	33.3	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	8	6	75.0	0	0.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	13	12	92.3	0	0.0	1	7.7	0	0.0	0	0.0	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Anemia																														
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Thrombocytopenia																														
All	45	35	77.8	3	6.7	7	15.6	0	0.0	0	0.0	0	0.0	0	0.0	18	9	50.0	3	16.7	6	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	10	9	90.0	0	0.0	1	10.0	0	0.0	0	0.0	0	0.0	0	0.0	5	1	20.0	2	40.0	2	40.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	11	7	63.6	1	9.1	3	27.3	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	14	9	64.3	2	14.3	3	21.4	0	0.0	0	0.0	0	0.0	0	0.0	6	5	83.3	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	10	10	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	0	0.0	0	0.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Thrombocytopenia																														
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Infections and Infestations																														
All	23	18	78.3	0	0.0	4	17.4	1	4.3	0	0.0	0	0.0	0	0.0	18	11	61.1	0	0.0	5	27.8	2	11.1	0	0.0	0	0.0	0	0.0
Grade 1	5	4	80.0	0	0.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	12	10	83.3	0	0.0	2	16.7	0	0.0	0	0.0	0	0.0	0	0.0	7	4	57.1	0	0.0	3	42.9	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
Serious Infections and Infestations																														
All	7	5	71.4	0	0.0	1	14.3	1	14.3	0	0.0	0	0.0	0	0.0	10	6	60.0	0	0.0	2	20.0	2	20.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	4	66.7	0	0.0	2	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
Infusion Related Reactions																														
All	18	16	88.9	0	0.0	1	5.6	0	0.0	1	5.6	0	0.0	0	0.0	17	15	88.2	0	0.0	2	11.8	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	8	7	87.5	0	0.0	1	12.5	0	0.0	0	0.0	0	0.0	0	0.0	9	8	88.9	0	0.0	1	11.1	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	7	6	85.7	0	0.0	0	0.0	0	0.0	1	14.3	0	0.0	0	0.0	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Infusion Related Reactions																														
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hepatic Toxicity																														
All	9	3	33.3	0	0.0	6	66.7	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	7	3	42.9	0	0.0	4	57.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hepatic Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Fatigue and Asthenia																														
All	17	7	41.2	0	0.0	10	58.8	0	0.0	0	0.0	0	0.0	0	0.0	15	8	53.3	1	6.7	6	40.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	13	6	46.2	0	0.0	7	53.8	0	0.0	0	0.0	0	0.0	0	0.0	11	6	54.5	1	9.1	4	36.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Fatigue and Asthenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Hyperglycemias																																
All	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Hyperglycemias																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Renal Toxicity																																
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	4	2	50.0	0	0.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Renal Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Gastrointestinal Toxicity																																
All	67	46	68.7	0	0.0	17	25.4	0	0.0	4	6.0	0	0.0	0	0.0	51	34	66.7	1	2.0	15	29.4	0	0.0	0	0.0	1	2.0	0	0.0		
Grade 1	36	26	72.2	0	0.0	7	19.4	0	0.0	3	8.3	0	0.0	0	0.0	24	18	75.0	0	0.0	6	25.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	24	16	66.7	0	0.0	7	29.2	0	0.0	1	4.2	0	0.0	0	0.0	22	14	63.6	0	0.0	7	31.8	0	0.0	0	0.0	1	4.5	0	0.0		
Grade 3	7	4	57.1	0	0.0	3	42.9	0	0.0	0	0.0	0	0.0	0	0.0	4	2	50.0	0	0.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Gastrointestinal Toxicity																																
All	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 3	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Pulmonary Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Pulmonary Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Joint Pains, Arthralgia, Skeletal Pain																																
All	6	4	66.7	0	0.0	2	33.3	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Joint Pains, Arthralgia, Skeletal Pain																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Alopecia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Alopecia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Cardiac Toxicity and Arrhythmias																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9	7	77.8	0	0.0	2	22.2	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Cardiac Toxicity and Arrhythmias																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Dysgeusia																																
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Dysgeusia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
Serious Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		

POPULATION: Intent-to-Treat Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Demographics and Baseline Characteristics

	Pola+BR (N=9)	BR (N=5)	All (N=14)
Age (Years)			
n	9	5	14
Mean (SD)	56.7 (13.6)	58.0 (17.8)	57.1 (14.5)
Median	57	65	61
Min - Max	27 - 70	31 - 76	27 - 76
Age Group (Years)			
n	9	5	14
18 - 40	1 (11.1%)	1 (20.0%)	2 (14.3%)
41 - 64	4 (44.4%)	1 (20.0%)	5 (35.7%)
>= 65	4 (44.4%)	3 (60.0%)	7 (50.0%)
Sex			
n	9	5	14
Male	7 (77.8%)	1 (20.0%)	8 (57.1%)
Female	2 (22.2%)	4 (80.0%)	6 (42.9%)
Race			
n	9	5	14
Asian	9 (100%)	5 (100%)	14 (100%)
Ethnicity			
n	9	5	14
Not Hispanic or Latino	9 (100%)	5 (100%)	14 (100%)
Weight (kg) at Baseline			
n	9	5	14
Mean (SD)	66.12 (10.86)	61.40 (7.51)	64.44 (9.77)
Median	66	57.5	64.5
Min - Max	44.0 - 80.0	54.0 - 70.0	44.0 - 80.0
Height (cm) at Baseline			

n	9	5	14
Mean (SD)	168.6 (9.91)	159.0 (9.06)	165.1 (10.41)
Median	170	160	169
Min - Max	148.0 - 177.0	150.0 - 173.0	148.0 - 177.0
ECOG score at Baseline			
n	9	5	14
0	5 (55.6%)	3 (60.0%)	8 (57.1%)
1	3 (33.3%)	2 (40.0%)	5 (35.7%)
2	1 (11.1%)	0	1 (7.1%)
Bulky disease at Baseline			
n	9	5	14
Yes	5 (55.6%)	0	5 (35.7%)
No	4 (44.4%)	5 (100%)	9 (64.3%)
Primary Reason for Stem Cell Transplant Ineligibility			
n	9	5	14
Age	3 (33.3%)	3 (60.0%)	6 (42.9%)
Patient Refused Transplant	3 (33.3%)	1 (20.0%)	4 (28.6%)
Other	3 (33.3%)	1 (20.0%)	4 (28.6%)
Duration of response to prior therapy (IxRS)			
n	9	5	14
<=12 Months	7 (77.8%)	4 (80.0%)	11 (78.6%)
>12 Months	2 (22.2%)	1 (20.0%)	3 (21.4%)
Duration of response to prior therapy (CRF)			
n	9	5	14
<=12 Months	8 (88.9%)	4 (80.0%)	12 (85.7%)
>12 Months	1 (11.1%)	1 (20.0%)	2 (14.3%)

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_dm.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_dm_L2_Polarose_IT_29365_41543.xls
08DEC2022 17:53

POPULATION: Intent-to-Treat Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of Patients who discontinued Study or Treatment

Status / Primary Reason for Discontinuation	Pola+BR (N=9)	BR (N=5)	All (N=14)
Number of Patients Randomized	9 (100.0%)	5 (100.0%)	14 (100.0%)
Number of Patients Treated	8 (88.9%)	5 (100.0%)	13 (92.9%)
Discontinued Study*			
Total	9 (100.0%)	5 (100.0%)	14 (100.0%)
Death	5 (55.6%)	4 (80.0%)	9 (64.3%)
Study Terminated By Sponsor	3 (33.3%)	1 (20.0%)	4 (28.6%)
Other	1 (11.1%)	0	1 (7.1%)
Discontinued Polatuzumab Vedotin Treatment or Placebo**			
Total	4 (50.0%)	5 (100.0%)	9 (69.2%)
Adverse Event	0	1 (20.0%)	1 (7.7%)
Progressive Disease	3 (37.5%)	4 (80.0%)	7 (53.8%)
Withdrawal by Subject	1 (12.5%)	0	1 (7.7%)
Discontinued Bendamustine Treatment**			
Total	4 (50.0%)	5 (100.0%)	9 (69.2%)
Adverse Event	0	1 (20.0%)	1 (7.7%)
Progressive Disease	3 (37.5%)	4 (80.0%)	7 (53.8%)
Withdrawal by Subject	1 (12.5%)	0	1 (7.7%)
Discontinued Rituximab or Obinutuzumab Treatment**			
Total	4 (50.0%)	5 (100.0%)	9 (69.2%)
Adverse Event	0	1 (20.0%)	1 (7.7%)
Progressive Disease	3 (37.5%)	4 (80.0%)	7 (53.8%)
Withdrawal by Subject	1 (12.5%)	0	1 (7.7%)

* Percentages are based on the number of patients randomized.
** Percentages are based on the number of patients treated.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ds.sas

Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_ds_L2_Polarose_IT_29365_41543.xls
08DEC2022 13:18

POPULATION: Intent-to-Treat Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Number of Centers/Countries/Geographical Regions with <10, >=10 Patients per Arm

	Center				Country				Geographical region			
	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients
Overall	5	100.0	14	100.0	1	100.0	14	100.0	1	100.0	14	100.0
with <10 patients per arm	5	100.0	14	100.0	1	100.0	14	100.0	1	100.0	14	100.0
with >=10 patients per arm	0	-	0	-	0	-	0	-	0	-	0	-

'<10 patients' category if at least one treatment arm has <10 patients; '>=10 patients' category if all treatment arms have >=10 patients.
Geographical regions: Asia/Pacific, Eastern Europe, North America, Western Europe.
'n': Number of centers/countries/regions; "%": Percent of centers/countries/regions compared to overall number of centers/countries/regions
'n of patients randomized': Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)
'% randomized patients': Percent of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_center.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_center_L2_Polarose_IT_29365_41543.xls
08DEC2022 0:43

POPULATION: Intent-to-Treat Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Concordance of Stratification Factors by eCRF and IxRS
MODEL: Descriptive
STUDIES: GO29365, YO41543
Stratification Factor: Duration of Response to prior therapy

	Pola+BR (N=9)			BR (N=5)		
	eCRF			eCRF		
	<=12 Months	>12 Months	Total	<=12 Months	>12 Months	Total
IxRS						
<=12 Months	7 (77.8%)	0	7 (77.8%)	4 (80.0%)	0	4 (80.0%)
>12 Months	1 (11.1%)	1 (11.1%)	2 (22.2%)	0	1 (20.0%)	1 (20.0%)
Total	8	1	9	4	1	5

Percentages are based on N in the column headings.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_strat.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_strat_L2_Polarose_IT_29365_41543.xls
08DEC2022 13:18

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: POLATUZUMAB VEDOTIN

	Pola+BR (N=8)
Treatment Duration (Months)	
n	8
Mean (SD)	2.57 (1.32)
Median	2.79
Interquartile Range	1.38 - 3.78
Min - Max	0.7 - 4.0
Number of Cycles	
n	8
Mean (SD)	4.5 (1.7)
Median	5
Interquartile Range	3.0 - 6.0
Min - Max	2 - 6
Total Cumulative Dose (mg)	
n	8
Mean (SD)	547.6 (221.8)
Median	535.8
Interquartile Range	349.7 - 754.2
Min - Max	270 - 832
Dose intensity (%) adjusted for dose reduction and delay	
n	8
Mean (SD)	96.0 (6.7)
Median	98.5
Interquartile Range	90.8 - 100.8
Min - Max	85 - 102

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas

Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_ex_L2_Polarose_SE_29365_41543.xls
20APR2023 11:15

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: BENDAMUSTINE

	Pola+BR (N=8)	BR (N=5)
Treatment Duration (Months)		
n	8	5
Mean (SD)	2.60 (1.32)	1.30 (0.81)
Median	2.83	1.38
Interquartile Range	1.41 - 3.81	1.31 - 1.41
Min - Max	0.7 - 4.0	0.1 - 2.3
Number of Cycles		
n	8	5
Mean (SD)	4.5 (1.7)	2.8 (1.1)
Median	5	3
Interquartile Range	3.0 - 6.0	3.0 - 3.0
Min - Max	2 - 6	1 - 4
Total Cumulative Dose (mg)		
n	8	5
Mean (SD)	1420.8 (540.1)	810.7 (288.7)
Median	1381.2	842.4
Interquartile Range	962.1 - 1927.2	842.4 - 950.4
Min - Max	705 - 2120	328 - 1091
Dose intensity (%) adjusted for dose reduction and delay		
n	8	5
Mean (SD)	93.8 (7.9)	98.9 (4.9)
Median	97.3	100
Interquartile Range	88.5 - 99.2	95.5 - 101.6
Min - Max	81 - 100	93 - 105

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_ex_L2_Polarose_SE_29365_41543.xls
20APR2023 11:15

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: RITUXIMAB

	Pola+BR (N=8)	BR (N=5)
Treatment Duration (Months)		
n	8	5
Mean (SD)	2.60 (1.32)	1.29 (0.82)
Median	2.83	1.38
Interquartile Range	1.41 - 3.81	1.31 - 1.41
Min - Max	0.7 - 4.0	0.0 - 2.3
Number of Cycles		
n	8	5
Mean (SD)	4.5 (1.7)	2.8 (1.1)
Median	5	3
Interquartile Range	3.0 - 6.0	3.0 - 3.0
Min - Max	2 - 6	1 - 4
Total Cumulative Dose (mg)		
n	8	5
Mean (SD)	3047.4 (1176.3)	1687.5 (599.6)
Median	3078.8	1755
Interquartile Range	2004.4 - 4162.5	1755.0 - 1980.0
Min - Max	1470 - 4418	683 - 2265
Dose intensity (%) adjusted for dose reduction and delay		
n	8	5
Mean (SD)	95.9 (4.2)	99.8 (4.7)
Median	97.3	100
Interquartile Range	92.7 - 99.2	100.0 - 101.6
Min - Max	89 - 100	92 - 105

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_ex_L2_Polarose_SE_29365_41543.xls
20APR2023 11:15

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=8)	BR (N=5)	All (N=13)
n	8	5	13
Median	116	72	73

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 30 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_fu_D30_L2_Polarose_SE_29365_41543.xls
08DEC2022 17:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=8)	BR (N=5)	All (N=13)
n	8	5	13
Median	176	132	133

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 90 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_fu_D90_L2_Polarose_SE_29365_41543.xls
08DEC2022 17:31

POPULATION: Intent-to-Treat Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of New Anti-Lymphoma Therapy

	Pola+BR (N=9)	BR (N=5)
Total number of patients with at least one NALT treatment	4 (44.4%)	4 (80.0%)
Total number of NALT treatments	4	4
Total number of patients with at least one NALT treatment before PFS event	1 (11.1%)	2 (40.0%)
Total number of patients with at least one NALT treatment at or after PFS event	2 (22.2%)	1 (20.0%)
Total number of patients with at least one NALT treatment and without PFS event	1 (11.1%)	1 (20.0%)
Radiotherapy		
Total number of patients with at least one treatment	0	0
Total number of treatments	0	0
Systemic therapy		
Total number of patients with at least one treatment	4 (44.4%)	4 (80.0%)
Total number of treatments	4	4
Total number of patients received stem cell transplants	0	0
Autologous transplant	0	0
Allogeneic transplant	0	0
Unknown	0	0
Total number of patients received CAR-T	1 (11.1%)	0
Total number of patients received unknown treatment	0	0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_nalt.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_nalt_L2_Polarose_IT_29365_41543.xls
01FEB2023 19:18

POPULATION: Intent-to-Treat Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median observation time(of follow up)

Overall Survival

	Pola+BR (N=9)	BR (N=5)	All (N=14)
Patients with event (%)	4 (44.4%)	1 (20.0%)	5 (35.7%)
Latest contributing event			
Alive	4	1	5
Patients without event (%)	5 (55.6%)	4 (80.0%)	9 (64.3%)
Time to event (months)			
Median	13.4	12.1	13.4
95% CI	(12.6, NE)	NE	(12.1, NE)
25% and 75%-ile	12.6 - 13.6	12.1 - 12.1	12.1 - 13.6
Range	0 - 17*	6* - 12	0 - 17*

Summaries of Duration of Follow-up (median, percentiles) are based on reverse Kaplan-Meier estimates.
* Censored observation.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_obs_time.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_obs_time_OSDFU_L2_Polarose_IT_29365_41543.xls
08DEC2022 3:14

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Deaths and Primary Reason for Death

	Pola+BR (N=8)		BR (N=5)		All (N=13)	
	n	%	n	%	n	%
All Deaths	5	62.5	4	80.0	9	69.2
Progressive Disease	5	62.5	4	80.0	9	69.2

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_death.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_death_L2_Polarose_SE_29365_41543.xls
08DEC2022 18:27

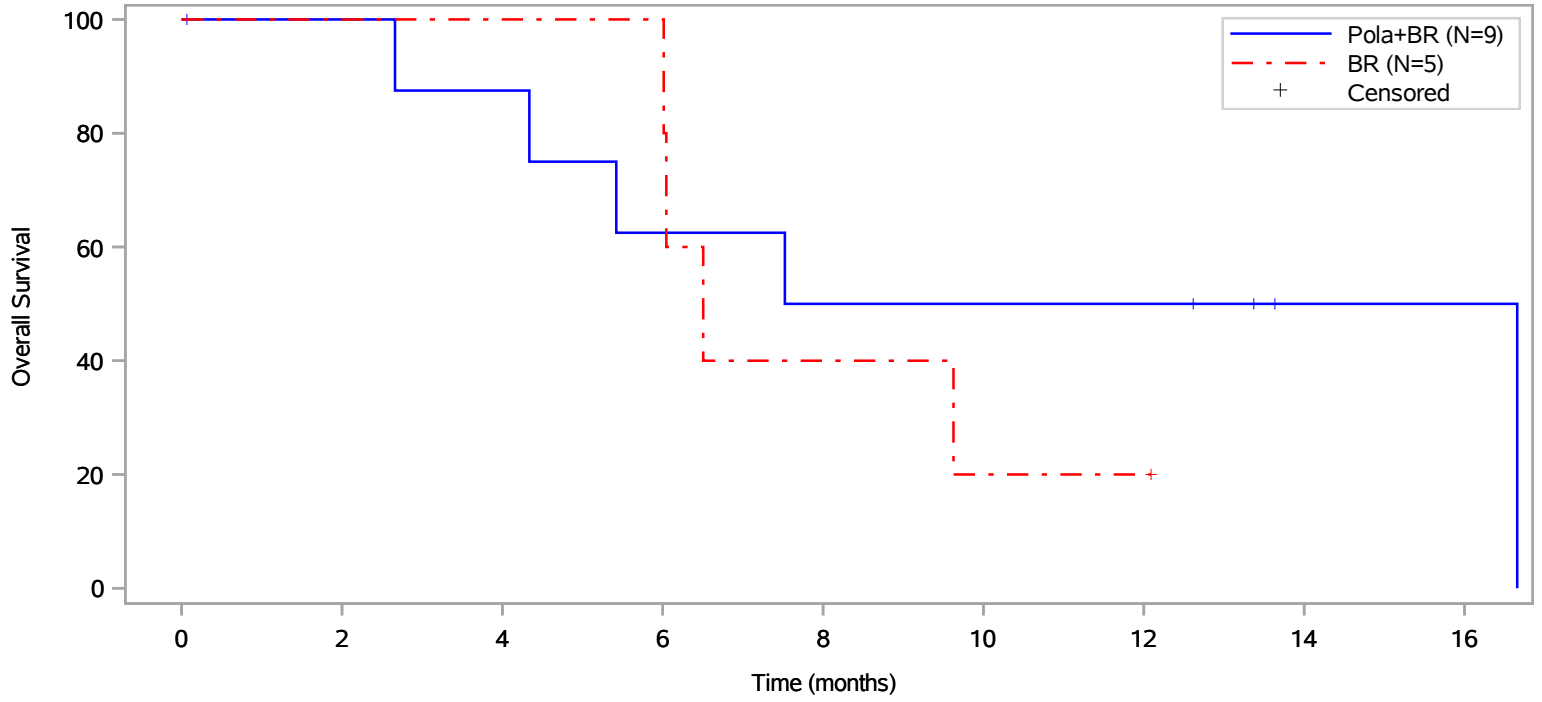
POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Study YO41543
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=9)											BR (N=5)											Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		9	100.0	5	55.6	4	44.4	4.9	2.7	NE	12.1	4.3	NE	5	100.0	4	80.0	1	20.0	6.0	6.0	9.6	6.5	6.0	NE	0.6614	0.73	0.18	3.00		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_eff_tte_gh_str_OS_Polarose_L2_IT_29365_41543.xls
20JAN2023 17:46

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Study YO41543
ENDPOINT: Overall Survival
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=9)	9	8	7	5	4	4	4	1	1
BR (N=5)	5	5	5	5	2	1	1	NE	NE
Patients censored								
Pola+BR (N=9)	0	1	1	1	1	1	1	4	4
BR (N=5)	0	0	0	0	0	0	0	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..is/ACE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_OS_Polarose_L2_IT_29365_41543.pdf
28NOV2022 14:48

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Study YO41543
ENDPOINT: Overall Survival
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=9)												BR (N=5)										Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		9	100.0	5	55.6	4	44.4	4.9	2.7	NE	12.1	4.3	NE	5	100.0	4	80.0	1	20.0	6.0	6.0	9.6	6.5	6.0	NE	0.5574	0.66	0.16	2.67		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	77.8	4	57.1	3	42.9	4.3	2.7	NE	7.5	4.3	NE	1	20.0	1	100.0	0	-	6.0	NE	NE	6.0	NE	NE	0.6159	0.56	0.06	5.47		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	2	22.2	1	50.0	1	50.0	16.7	NE	NE	16.7	NE	NE	4	80.0	3	75.0	1	25.0	6.3	6.0	9.6	8.1	6.0	NE	0.2994	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	55.6	3	60.0	2	40.0	4.3	2.7	NE	5.4	2.7	NE	2	40.0	1	50.0	1	50.0	9.6	9.6	NE	NE	9.6	NE	0.5877	1.87	0.13	18.41		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	4	44.4	2	50.0	2	50.0	7.5	7.5	NE	16.7	7.5	NE	3	60.0	3	100.0	0	-	6.0	6.0	NE	6.0	6.0	NE	0.0246	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	3	33.3	2	66.7	1	33.3	7.5	7.5	NE	12.1	7.5	NE	4	80.0	3	75.0	1	25.0	6.0	6.0	6.5	6.3	6.0	NE	0.3518	0.35	0.03	3.54		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	66.7	3	50.0	3	50.0	4.3	2.7	NE	NE	4.3	NE	1	20.0	1	100.0	0	-	9.6	NE	NE	9.6	NE	NE	0.7578	0.70	0.07	6.83		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	9	100.0	5	55.6	4	44.4	4.9	2.7	NE	12.1	4.3	NE	5	100.0	4	80.0	1	20.0	6.0	6.0	9.6	6.5	6.0	NE	0.5574	0.66	0.16	2.67		Convergence criterion (GCONV=1E-8) satisfied.	-
Duration of response to prior therapy	<=12 Months	7	77.8	5	71.4	2	28.6	4.3	2.7	7.3	6.3	4.3	NE	4	80.0	3	75.0	1	25.0	6.0	6.0	6.5	6.3	6.0	NE	0.9592	1.04	0.23	4.78		Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	2	22.2	0	-	2	100.0	NE	NE	NE	NE	NE	NE	1	20.0	1	100.0	0	-	9.6	NE	NE	9.6	NE	NE	0.1573	0.00	0.00	NE	*	WARNING: Iteration limit reached without convergence.	
Refractory to last prior anti-lymphoma therapy**	Yes	8	88.9	5	62.5	3	37.5	4.3	2.7	NE	7.5	4.3	NE	4	80.0	3	75.0	1	25.0	6.0	6.0	6.5	6.3	6.0	NE	0.7939	0.82	0.18	3.75		Convergence criterion (GCONV=1E-8) satisfied.	-
	No	1	11.1	0	-	1	100.0	NE	NE	NE	NE	NE	NE	1	20.0	1	100.0	0	-	9.6	NE	NE	9.6	NE	NE	0.3173	0.00	0.00	NE	*	WARNING: Iteration limit reached without convergence.	
Prior Bone Marrow Transplant	Yes	1	11.1	0	-	1	100.0	NE	NE	NE	NE	NE	NE	0	0.0	0	-	0	-	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	-
	No	8	88.9	5	62.5	3	37.5	4.3	2.7	NE	7.5	4.3	NE	5	100.0	4	80.0	1	20.0	6.0	6.0	9.6	6.5	6.0	NE	0.7680	0.81	0.20	3.28		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_eff_tte_gh_sg_OS_Polarose_L2_IT_29365_41543.xls
20JAN2023 17:53

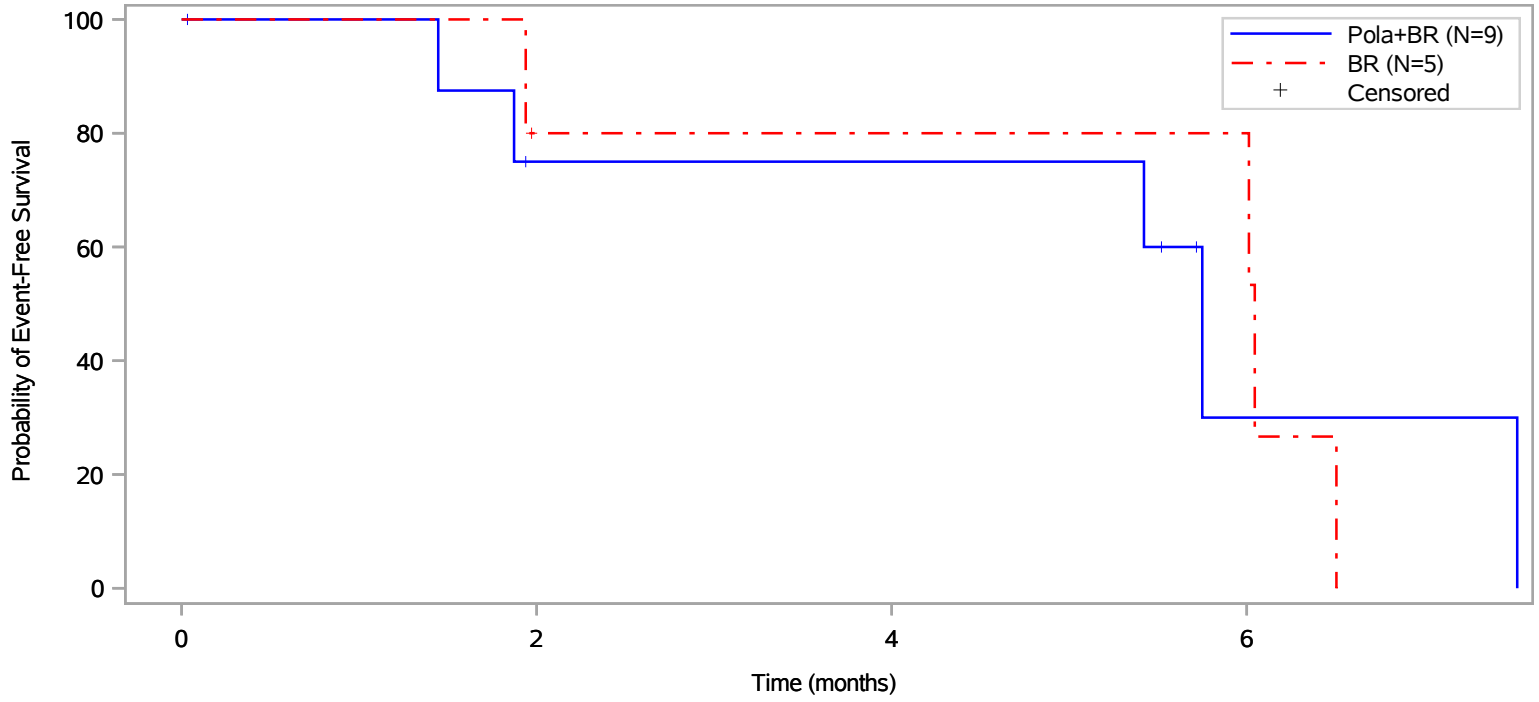
POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Study YO41543
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=9)											BR (N=5)											Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event					Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		9	100.0	5	55.6	4	44.4	3.6	1.4	NE	5.7	1.9	NE	5	100.0	4	80.0	1	20.0	6.0	1.9	6.0	6.0	1.9	NE	0.8866	1.11	0.26	4.67		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_eff_tte_gh_str_PFSIRC_Polarose_L2_IT_29365_41543.xls
20JAN2023 17:30

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Study YO41543
ENDPOINT: Progression-Free Survival (PFS) - IRC
STUDIES: GO29365, YO41543



Patients at risk				
Pola+BR (N=9)	9	5	5	1
BR (N=5)	5	3	3	3
Patients censored				
Pola+BR (N=9)	0	2	2	4
BR (N=5)	0	1	1	1

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_PFSIRC_Polarose_L2_IT_29365_41543.pdf
28NOV2022 14:24

POPULATION: Intent-to-Treat Patients, Second-line (2L) Patients, Study YO41543
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=9)												BR (N=5)										Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		9	100.0	5	55.6	4	44.4	3.6	1.4	NE	5.7	1.9	NE	5	100.0	4	80.0	1	20.0	6.0	1.9	6.0	6.0	1.9	NE	0.9139	1.08	0.26	4.55		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	77.8	4	57.1	3	42.9	1.9	1.4	NE	7.5	1.9	NE	1	20.0	1	100.0	0	-	6.0	NE	NE	6.0	NE	NE	0.9680	0.95	0.08	10.72		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	2	22.2	1	50.0	1	50.0	5.7	NE	NE	5.7	NE	NE	4	80.0	3	75.0	1	25.0	4.0	1.9	NE	6.0	1.9	NE	0.4504	2.83	0.17	47.15		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	55.6	3	60.0	2	40.0	1.9	1.4	NE	5.4	1.4	NE	2	40.0	1	50.0	1	50.0	1.9	1.9	NE	NE	1.9	NE	0.9814	1.03	0.09	11.48		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	4	44.4	2	50.0	2	50.0	5.7	5.7	NE	6.8	5.7	NE	3	60.0	3	100.0	0	-	6.0	6.0	NE	6.0	6.0	NE	0.6104	0.55	0.06	5.51		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	3	33.3	2	66.7	1	33.3	5.7	5.7	NE	6.6	5.7	NE	4	80.0	3	75.0	1	25.0	6.0	6.0	NE	6.0	6.0	NE	0.6104	0.55	0.06	5.51		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	66.7	3	50.0	3	50.0	1.9	1.4	NE	5.4	1.9	NE	1	20.0	1	100.0	0	-	1.9	NE	NE	1.9	NE	NE	0.4499	0.41	0.04	4.53		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	9	100.0	5	55.6	4	44.4	3.6	1.4	NE	5.7	1.9	NE	5	100.0	4	80.0	1	20.0	6.0	1.9	6.0	6.0	1.9	NE	0.9139	1.08	0.26	4.53		Convergence criterion (GCONV=1E-8) satisfied.	-
Duration of response to prior therapy	<=12 Months	7	77.8	5	71.4	2	28.6	1.9	1.4	5.7	5.4	1.9	NE	4	80.0	3	75.0	1	25.0	6.0	6.0	NE	6.0	6.0	NE	0.5009	1.69	0.36	7.90		Convergence criterion (GCONV=1E-8) satisfied.	-
	>12 Months	2	22.2	0	-	2	100.0	NE	NE	NE	NE	NE	NE	1	20.0	1	100.0	0	-	1.9	NE	NE	1.9	NE	NE	0.1573	0.00	0.00	NE	*	WARNING: Iteration limit reached without convergence.	
Refractory to last prior anti-lymphoma therapy**	Yes	8	88.9	5	62.5	3	37.5	1.9	1.4	5.7	5.7	1.9	NE	4	80.0	3	75.0	1	25.0	6.0	6.0	NE	6.0	6.0	NE	0.5771	1.55	0.33	7.36		Convergence criterion (GCONV=1E-8) satisfied.	-
	No	1	11.1	0	-	1	100.0	NE	NE	NE	NE	NE	NE	1	20.0	1	100.0	0	-	1.9	NE	NE	1.9	NE	NE	0.3173	0.00	0.00	NE	*	WARNING: Iteration limit reached without convergence.	
Prior Bone Marrow Transplant	Yes	1	11.1	0	-	1	100.0	NE	NE	NE	NE	NE	NE	0	0.0	0	-	0	-	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		NE	-
	No	8	88.9	5	62.5	3	37.5	1.9	1.4	5.7	5.7	1.9	NE	5	100.0	4	80.0	1	20.0	6.0	1.9	6.0	6.0	1.9	NE	0.8177	1.18	0.28	4.91		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_eff_tte_gh_sg_PFSIRC_Polarose_L2_IT_29365_41543.xls
20JAN2023 17:38

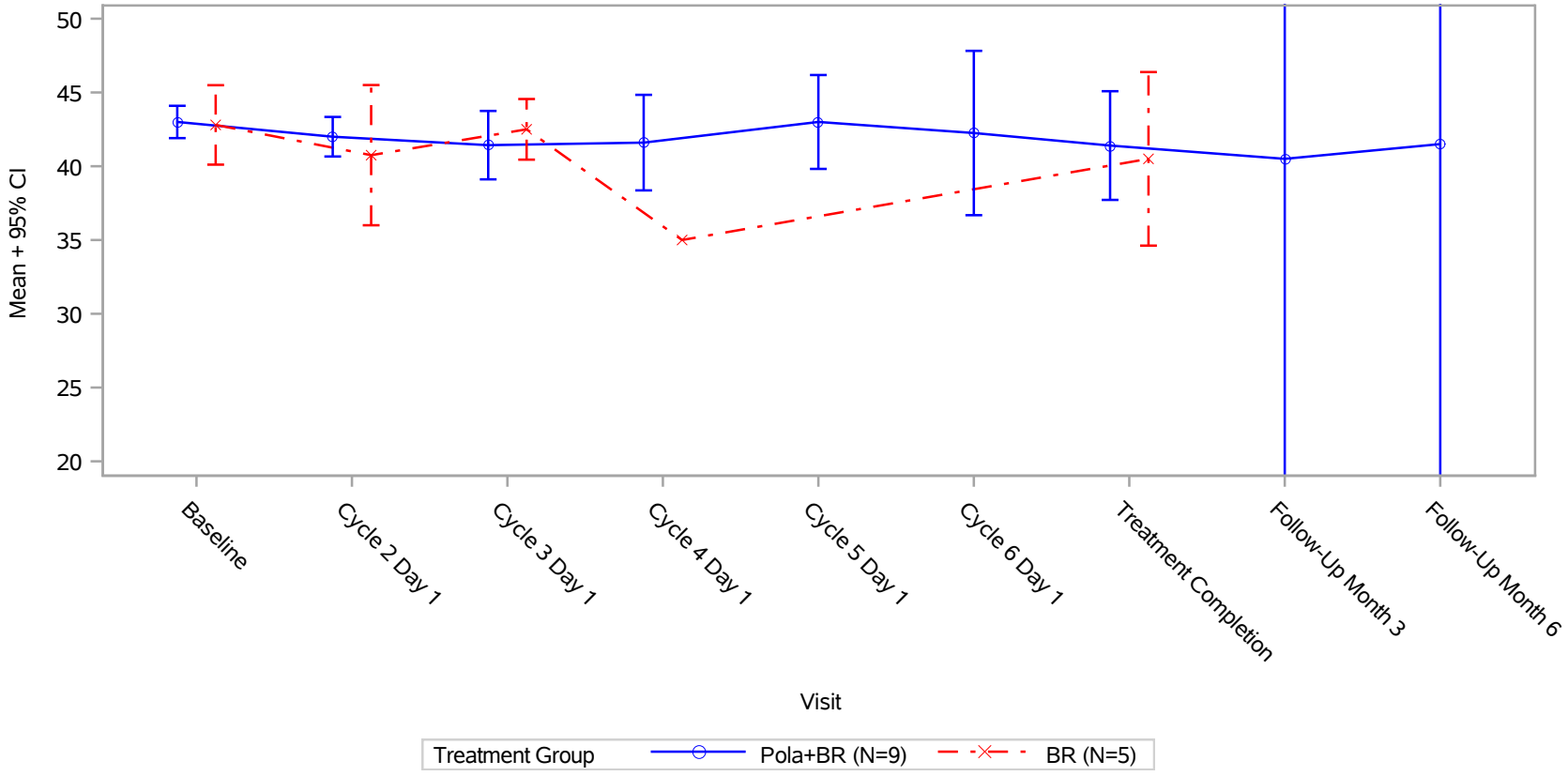
POPULATION: Intent-to-Treat Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: FACT-G NTX
MODEL: --
STUDIES: GO29365, YO41543
Compliance and Mean

		Pola+BR (N=9)						BR (N=5)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	Mean[2]	SD(Mean)	in study[1]	%	with value[1]	%	Mean[2]	SD(Mean)
All													
BASELINE		9	100.0	8	88.9	43.00	1.31	5	100.0	5	100.0	42.80	2.17
CYCLE 2 DAY 1		8	88.9	8	100.0	42.00	1.60	4	80.0	4	100.0	40.75	2.99
CYCLE 3 DAY 1		7	77.8	7	100.0	41.43	2.51	4	80.0	4	100.0	42.50	1.29
CYCLE 4 DAY 1		6	66.7	5	83.3	41.60	2.61	2	40.0	1	50.0	35.00	NE
CYCLE 5 DAY 1		4	44.4	4	100.0	43.00	2.00	0	-	0	-	NE	NE
CYCLE 6 DAY 1		4	44.4	4	100.0	42.25	3.50	0	-	0	-	NE	NE
TREATMENT COMPLETION		6	66.7	5	83.3	41.40	2.97	4	80.0	4	100.0	40.50	3.70
FOLLOW-UP MONTH 3		3	33.3	2	66.7	40.50	3.54	0	-	0	-	NE	NE
FOLLOW-UP MONTH 6		2	22.2	2	100.0	41.50	3.54	0	-	0	-	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD
[2] mean: descriptive statistics - absolute values
Early Discontinuation Visit is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_pro_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_pro_mean_PFGNTX_L2_Polarose_IT_29365_41543.xls
24FEB2023 17:27

POPULATION: Intent-to-Treat Patients, Study YO41543, Second-line (2L) Patients
STUDIES: GO29365, YO41543
Line Plot of Mean by Visit
FACT-GOG-NTX: Neurotoxicity subscale (NtxS)



Early Discontinuation Visit is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..7/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_mean_plot.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_mean_plot_PFGNTX_L2_Polarose_IT_29365_41543.pdf
24FEB2023 17:34

POPULATION: Intent-to-Treat Patients, Study YO41543, PRO-Evaluable for FACT-GOG-NTX, Second-line (2L) Patients
ENDPOINT: FACT-G NTX
MODEL: Unadjusted Analysis
STUDIES: GO29365, YO41543
Change from Baseline in FACT-G NTX (Analysis of MMRM)

FACT-GOG-NTX: Neurotoxicity subscale (NtxS)

			Pola+BR (N=8)					BR (N=5)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All		8	8	0	NE	NE	5	5	0	NE	NE	NE	NE	NE	NE	Intent-to-Treat Patients, Study YO41543, PRO-Evaluable for FACT-GOG-NTX, Second-line (2L) Patients	unadjusted
Cycle 2 Day 1	All		8	8	8	-0.99	0.52	4	4	4	-1.78	0.80	0.79	0.96	-1.37	2.94		
Cycle 3 Day 1	All		7	7	7	-1.74	0.73	4	4	4	-0.03	1.01	-1.71	1.25	-4.53	1.10		
Treatment Completion	All		6	6	5	-1.55	1.37	4	4	4	-1.83	1.44	0.29	2.00	-4.44	5.01		

[1] Patients with a value at baseline and at least one post-baseline value
[2] LSMeans of change from baseline from MMRM (including all available records from all visits)
[3] Contrasts from MMRM
Early Discontinuation Visit is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_pro_mmrm.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_pro_mmrm_PFGNTX_L2_FACTGpop_Polarose_IT_29365_41543.xls
03MAR2023 14:21

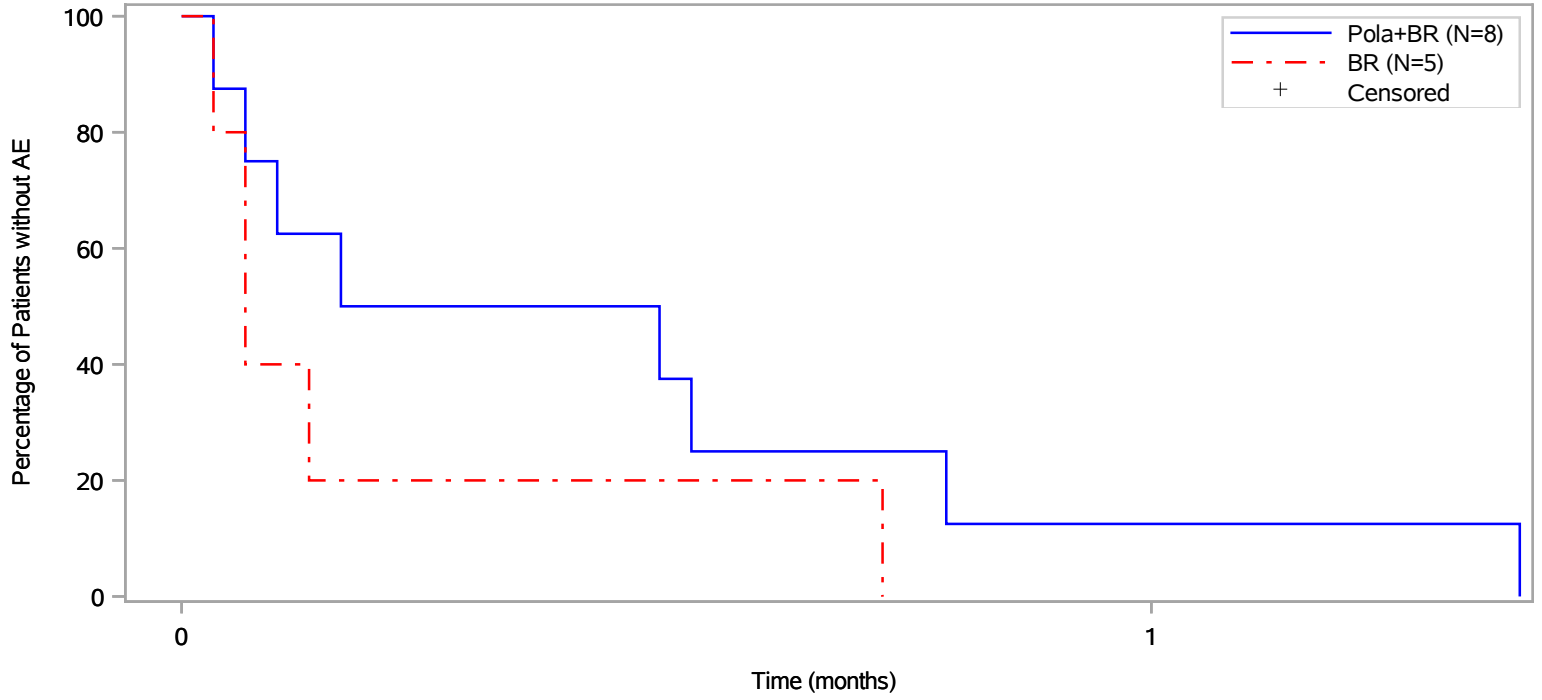
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	8	100.0	0	-	5	100.0	5	100.0	0	-	0.2525	0.49	0.14	1.70		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	7	100.0	0	-	1	20.0	1	100.0	0	-	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	1	100.0	0	-	4	80.0	4	100.0	0	-	0.7822	0.71	0.06	8.02		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	5	100.0	0	-	2	40.0	2	100.0	0	-	0.6372	0.64	0.10	4.19		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	3	100.0	0	-	3	60.0	3	100.0	0	-	0.3430	0.42	0.07	2.63		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	2	100.0	0	-	4	80.0	4	100.0	0	-	0.7702	0.75	0.11	5.16		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	6	100.0	0	-	1	20.0	1	100.0	0	-	0.7579	0.70	0.07	6.83		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	8	100.0	0	-	5	100.0	5	100.0	0	-	0.2525	0.49	0.14	1.70		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTAE_L2_Polarose_SE_29365_41543.xls
30NOV2022 18:28

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543



Patients at risk		
Pola+BR (N=8)	8	1
BR (N=5)	5	NE
Patients censored		
Pola+BR (N=8)	0	0
BR (N=5)	0	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ../ACE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTAE_L2_Polarose_SE_29365_41543.pdf
03DEC2022 19:53

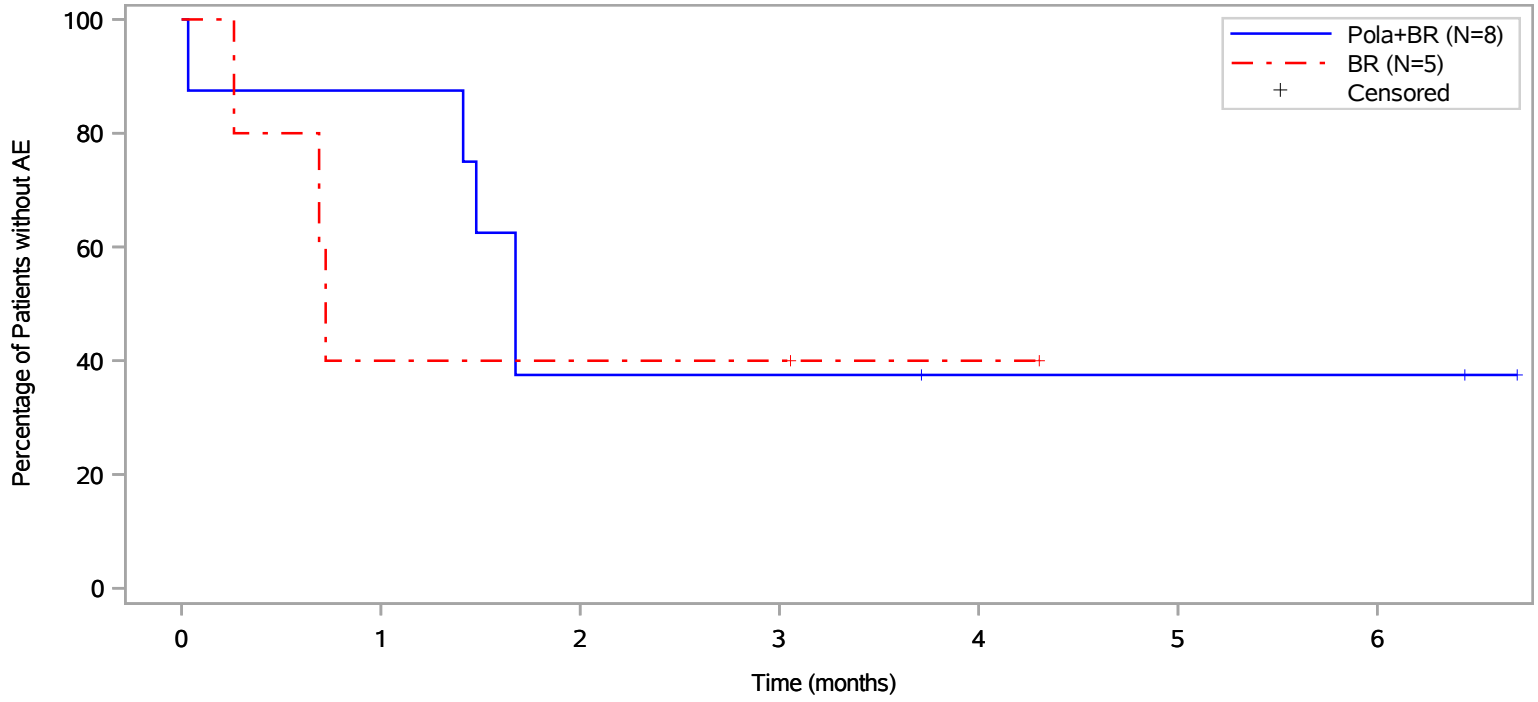
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	5	62.5	3	37.5	5	100.0	3	60.0	2	40.0	0.6996	0.75	0.17	3.29		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	4	57.1	3	42.9	1	20.0	0	-	1	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	1	100.0	0	-	4	80.0	3	75.0	1	25.0	0.7543	0.69	0.07	7.07		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	4	80.0	1	20.0	2	40.0	2	100.0	0	-	0.1230	0.18	0.02	2.05		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.8864	0.82	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	1	50.0	1	50.0	4	80.0	2	50.0	2	50.0	0.7822	0.71	0.06	8.02		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	4	66.7	2	33.3	1	20.0	1	100.0	0	-	0.1768	0.18	0.01	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	5	62.5	3	37.5	5	100.0	3	60.0	2	40.0	0.6996	0.75	0.17	3.29		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGR345AE_L2_Polarose_SE_29365_41543.xls
30NOV2022 19:14

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	7	3	3	2	2	2
BR (N=5)	5	2	2	2	1	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	1
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
03DEC2022 19:58

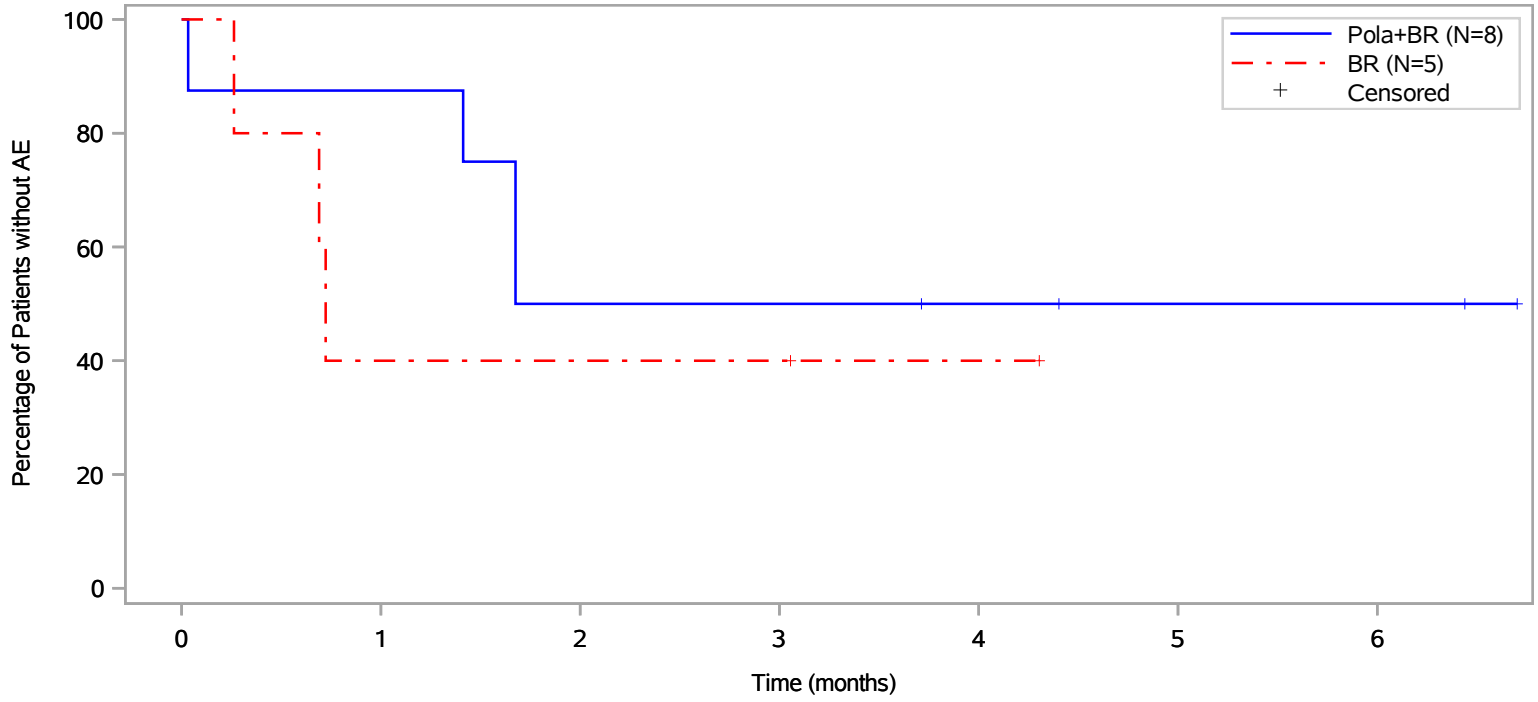
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	4	50.0	4	50.0	5	100.0	3	60.0	2	40.0	0.4945	0.58	0.12	2.78		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.4754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	1	100.0	0	-	4	80.0	3	75.0	1	25.0	0.7543	0.69	0.07	7.07		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	3	60.0	2	40.0	2	40.0	2	100.0	0	-	0.1230	0.18	0.02	2.05		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.8864	0.82	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	1	50.0	1	50.0	4	80.0	2	50.0	2	50.0	0.7822	0.71	0.06	8.02		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	3	50.0	3	50.0	1	20.0	1	100.0	0	-	0.1768	0.18	0.01	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	3	60.0	2	40.0	0.4945	0.58	0.12	2.78		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGR3AE_L2_Polarose_SE_29365_41543.xls
30NOV2022 19:54

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	7	4	4	3	2	2
BR (N=5)	5	2	2	2	1	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	2
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTGR3AE_L2_Polarose_SE_29365_41543.pdf
03DEC2022 20:05

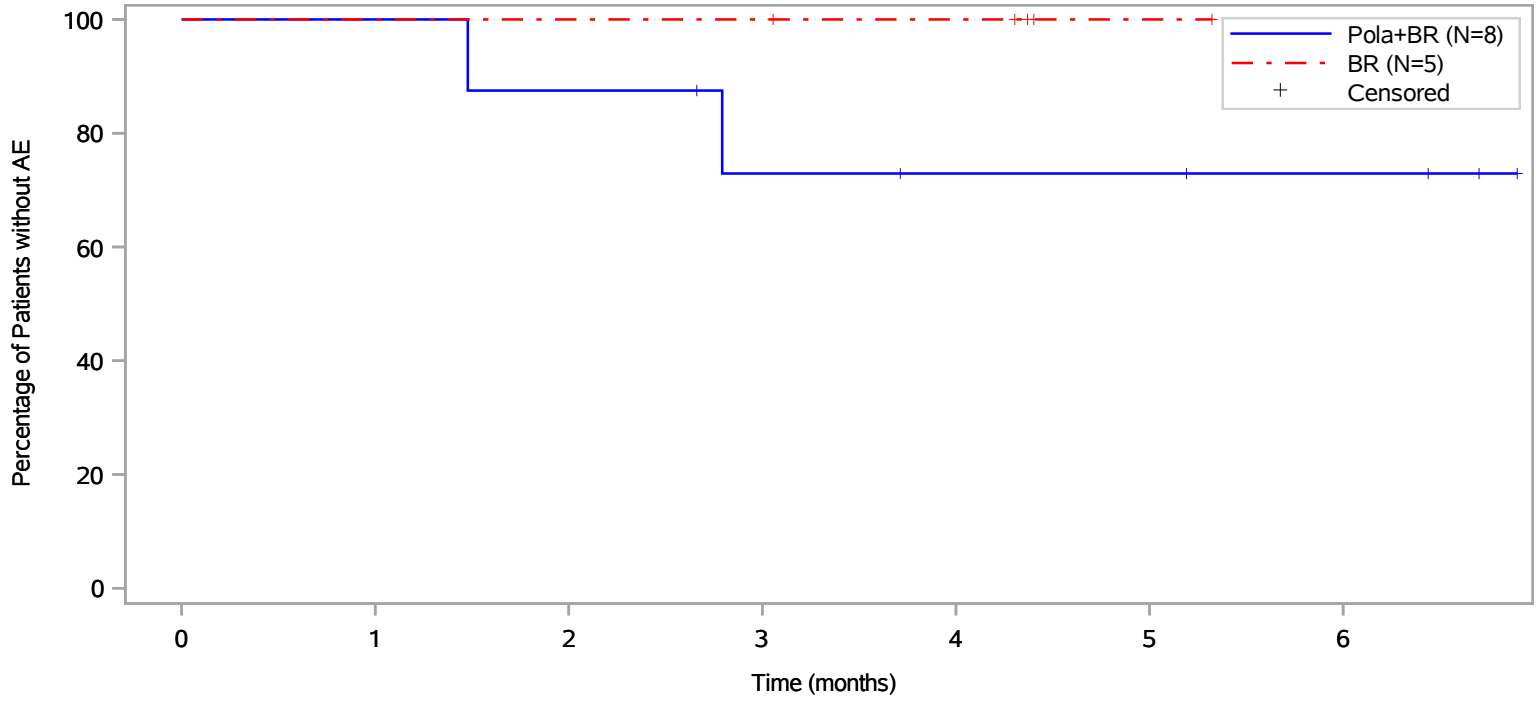
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)				Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	2	25.0	6	75.0	5	100.0	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	2	28.6	5	71.4	1	20.0	1	100.0	0.5583	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	2	40.0	3	60.0	2	40.0	2	100.0	0.3035	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0.5188	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGR4AE_L2_Polarose_SE_29365_41543.xls
30NOV2022 20:41

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	7	5	4	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTGR4AE_L2_Polarose_SE_29365_41543.pdf
03DEC2022 20:11

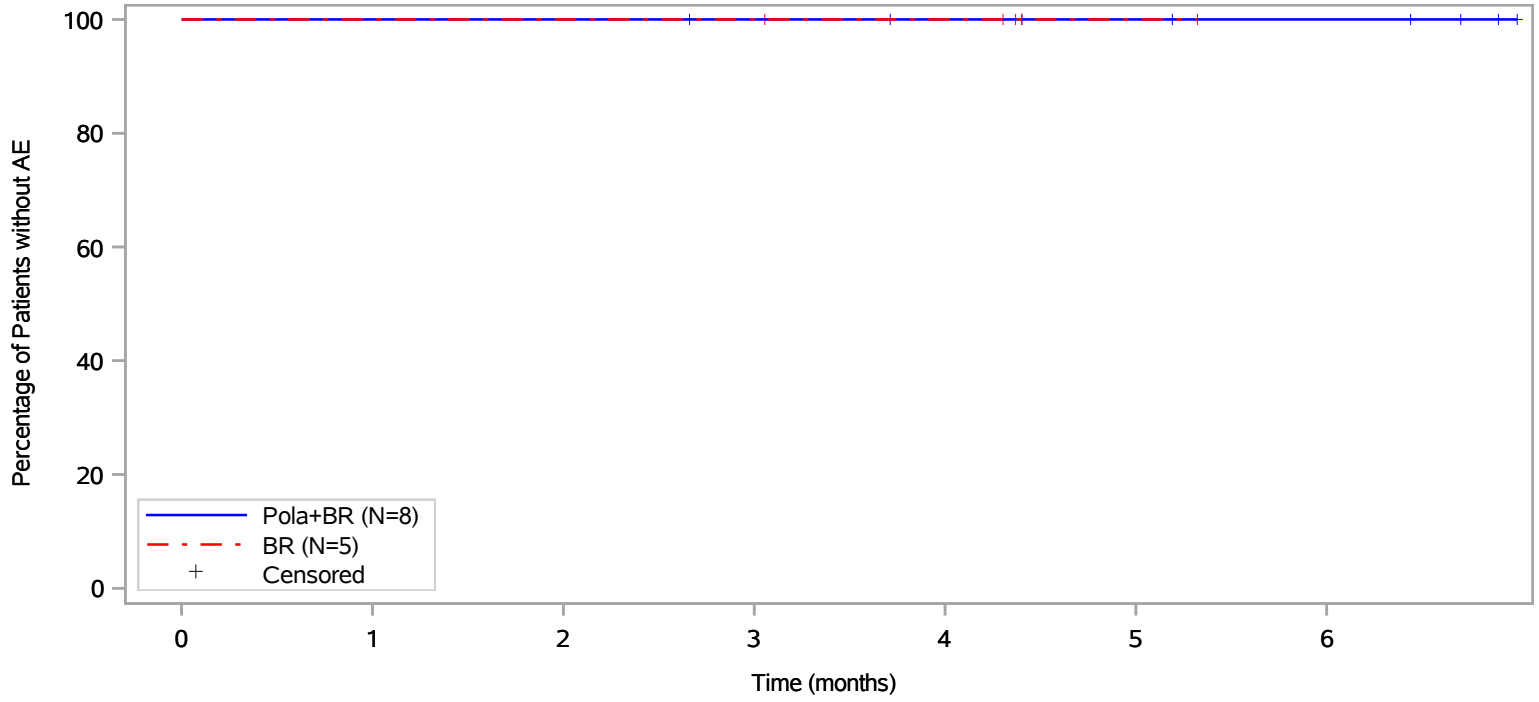
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGR5AE_L2_Polarose_SE_29365_41543.xls
30NOV2022 21:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTGR5AE_L2_Polarose_SE_29365_41543.pdf
03DEC2022 20:18

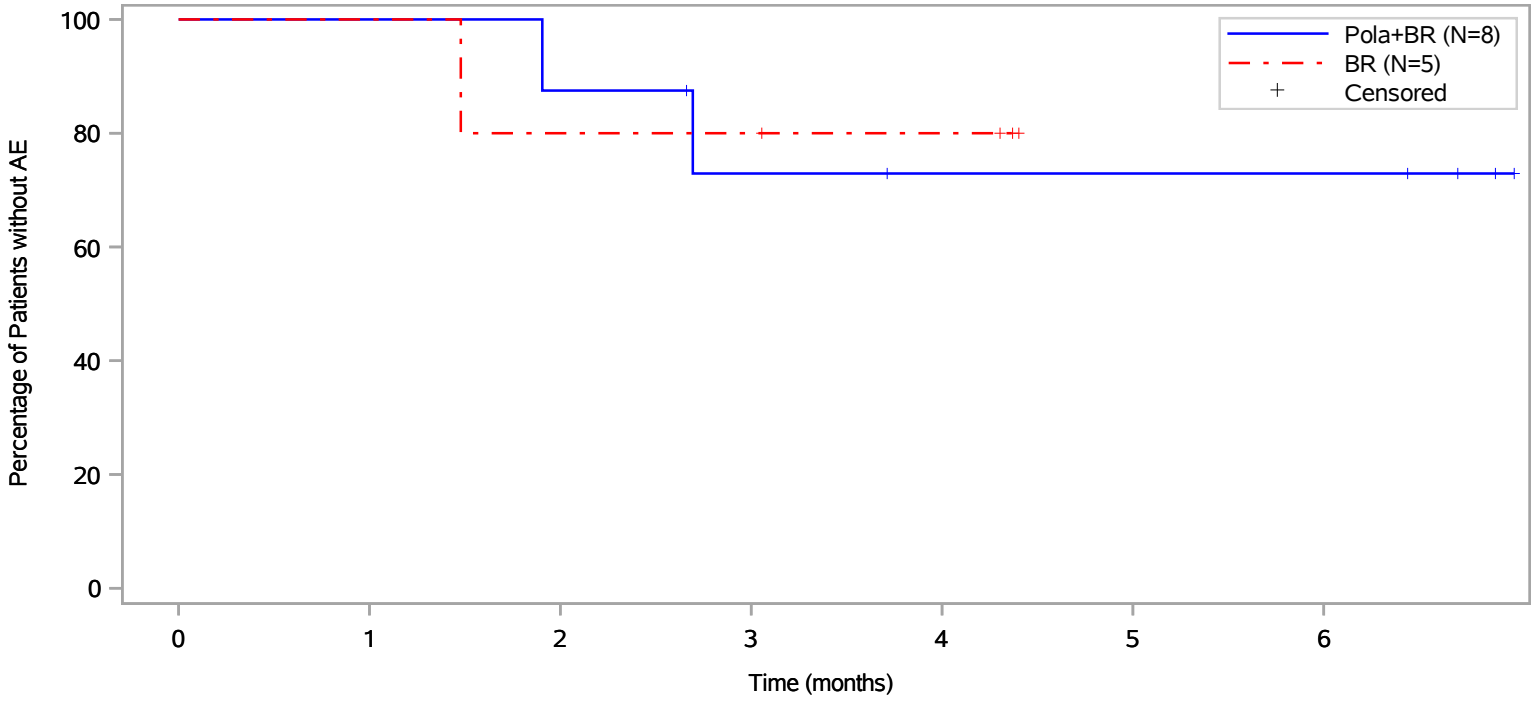
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.8878	1.19	0.11	13.16		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5583	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3035	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5188	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.8878	1.19	0.11	13.16		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTSAE_L2_Polarose_SE_29365_41543.xls
30NOV2022 22:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	7	5	4	4	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	2
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTSAE_L2_Polarose_SE_29365_41543.pdf
03DEC2022 20:23

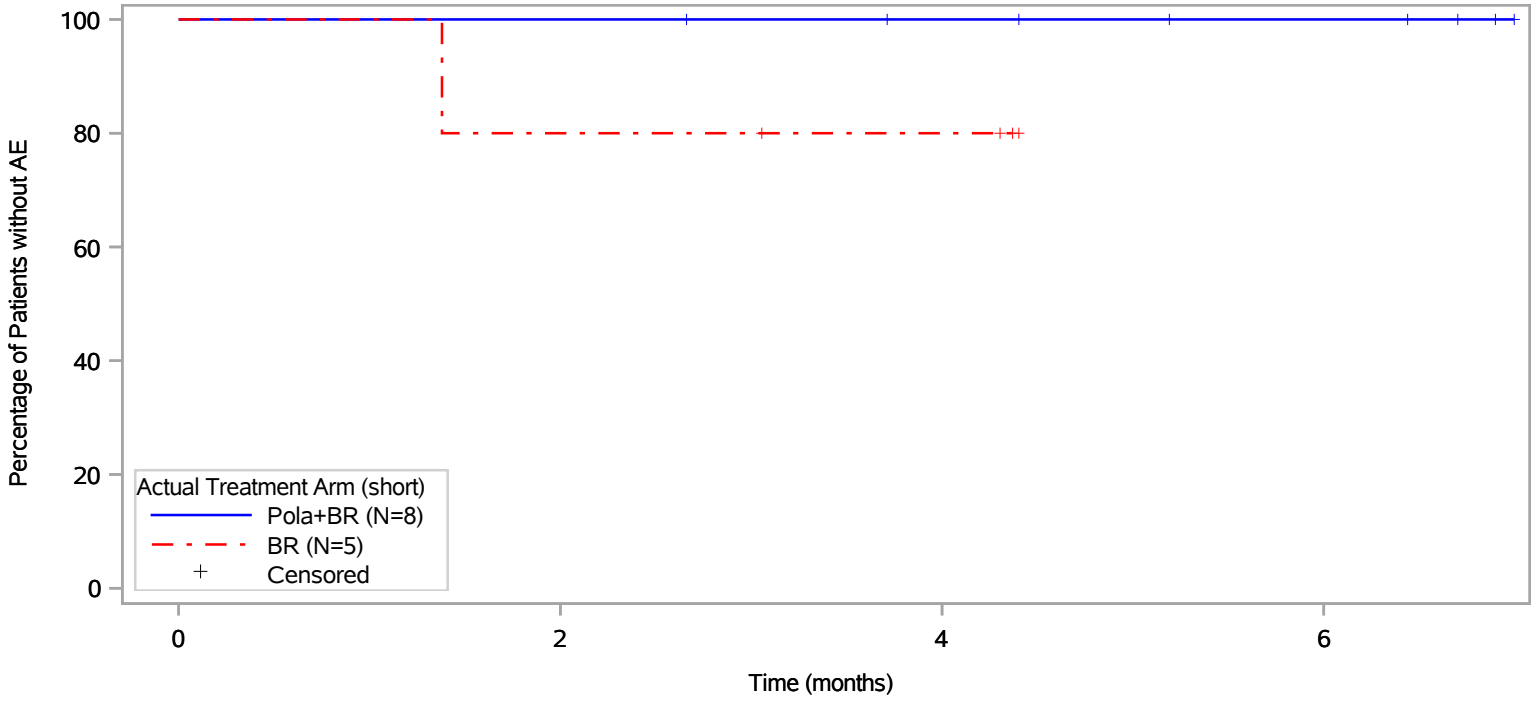
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTWDAE_L2_Polarose_SE_29365_41543.xls
24JAN2023 17:05

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTWDAE_L2_Polarose_SE_29365_41543.pdf
24JAN2023 18:53

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			8	100.0	5	62.5	3	37.5	5	100.0	1	20.0	4	80.0	0.2326	3.44	0.40	29.66		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.4478	2.28	0.25	20.49		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		8	100.0	3	37.5	5	62.5	5	100.0	1	20.0	4	80.0	0.5439	1.99	0.21	19.18		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.8878	1.19	0.11	13.16		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	BRADYCARDIA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SINUS TACHYCARDIA		8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS			8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	TINNITUS		8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			8	100.0	5	62.5	3	37.5	5	100.0	2	40.0	3	60.0	0.6065	1.56	0.29	8.50		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.7742	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DRY MOUTH		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DYSPEPSIA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	NAUSEA		8	100.0	3	37.5	5	62.5	5	100.0	2	40.0	3	60.0	0.9539	1.05	0.17	6.54		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		8	100.0	3	37.5	5	62.5	5	100.0	2	40.0	3	60.0	0.9751	0.97	0.14	6.50		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			8	100.0	4	50.0	4	50.0	5	100.0	3	60.0	2	40.0	0.6298	0.68	0.15	3.22		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA		8	100.0	0	-	8	100.0	5	100.0	2	40.0	3	60.0	0.0584	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.7643	1.44	0.13	15.96		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		8	100.0	3	37.5	5	62.5	5	100.0	0	-	5	100.0	0.1485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.2949	3.05	0.34	27.46		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HEPATITIS B		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION		8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.7742	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			8	100.0	7	87.5	1	12.5	5	100.0	5	100.0	0	-	0.0150	0.14	0.03	0.82		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED		8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.8450	1.27	0.11	14.04		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED		8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.7742	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	NE

INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD GLUCOSE INCREASED		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		8	100.0	0	-	8	100.0	5	100.0	2	40.0	3	60.0	0.0584	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		8	100.0	6	75.0	2	25.0	5	100.0	2	40.0	3	60.0	0.5947	1.56	0.30	8.18		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		8	100.0	3	37.5	5	62.5	5	100.0	3	60.0	2	40.0	0.1107	0.25	0.04	1.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		8	100.0	6	75.0	2	25.0	5	100.0	4	80.0	1	20.0	0.1366	0.35	0.09	1.47		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			8	100.0	4	50.0	4	50.0	5	100.0	3	60.0	2	40.0	0.8269	0.84	0.18	3.88		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA		8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.7261	0.60	0.03	10.90		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		8	100.0	4	50.0	4	50.0	5	100.0	2	40.0	3	60.0	0.7273	1.35	0.25	7.42		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			8	100.0	3	37.5	5	62.5	5	100.0	1	20.0	4	80.0	0.6349	1.72	0.18	16.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DYSGEUSIA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL		8	100.0	3	37.5	5	62.5	5	100.0	0	-	5	100.0	0.1439	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	2	40.0	3	60.0	0.2503	0.27	0.02	2.97		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH		8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.7551	0.65	0.04	10.32		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	2	40.0	3	60.0	0.2131	0.24	0.02	2.71		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.6771	0.56	0.03	8.98		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HAEMORRHAGE		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTAE_L2_Polarose_SE_29365_41543.xls
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POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	5	62.5	3	60.0	2	40.0	2	40.0	0	-	2	100.0	0.2119	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	37.5	2	66.7	1	33.3	3	60.0	1	33.3	2	66.7	0.6419	1.76	0.16	19.57		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	5	62.5	3	60.0	2	40.0	2	40.0	0	-	2	100.0	0.2119	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.7055	0.58	0.03	10.25		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.2436	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.8864	0.82	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	5	62.5	2	40.0	3	60.0	2	40.0	1	50.0	1	50.0	0.6828	0.61	0.05	6.84		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	BRADYCARDIA	< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	BRADYCARDIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3035	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	5	62.5	3	60.0	2	40.0	2	40.0	1	50.0	1	50.0	0.6598	1.75	0.14	21.82		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	3	37.5	2	66.7	1	33.3	3	60.0	1	33.3	2	66.7	0.6419	1.76	0.16	19.57		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	5	62.5	1	20.0	4	80.0	2	40.0	1	50.0	1	50.0	0.5596	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	< 65	5	62.5	2	40.0	3	60.0	2	40.0	1	50.0	1	50.0	0.9814	1.03	0.09	11.48		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.8864	0.82	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	5	62.5	2	40.0	3	60.0	2	40.0	1	50.0	1	50.0	0.9492	0.92	0.07	12.29		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.8864	0.82	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	5	62.5	3	60.0	2	40.0	2	40.0	0	-	2	100.0	0.1736	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	3	37.5	1	33.3	2	66.7	3	60.0	3	100.0	0	-	0.0246	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	2	66.7	1	33.3	0.1161	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.8864	1.22	0.08	19.86		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	5	62.5	3	60.0	2	40.0	2	40.0	0	-	2	100.0	0.1547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	5	62.5	2	40.0	3	60.0	2	40.0	1	50.0	1	50.0	0.9814	1.03	0.09	11.48		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	37.5	2	66.7	1	33.3	3	60.0	0	-	3	100.0	0.2253	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	< 65	5	62.5	1	20.0	4	80.0	2	40.0	1	50.0	1	50.0	0.5596	0.45	0.03	7.18		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	5	62.5	4	80.0	1	20.0	2	40.0	2	100.0	0	-	0.3561	0.38	0.05	3.10		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	3	37.5	3	100.0	0	-	3	60.0	3	100.0	0	-	0.0246	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.8864	0.82	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	5	62.5	4	80.0	1	20.0	2	40.0	1	50.0	1	50.0	0.8051	1.32	0.14	12.02		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	3	37.5	2	66.7	1	33.3	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	3	100.0	0	-	0.0246	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	5	62.5	4	80.0	1	20.0	2	40.0	2	100.0	0	-	0.2899	0.36	0.05	2.59		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	3	37.5	2	66.7	1	33.3	3	60.0	2	66.7	1	33.3	0.1161	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	5	62.5	2	40.0	3	60.0	2	40.0	1	50.0	1	50.0	0.8132	0.75	0.07	8.42		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	3	37.5	2	66.7	1	33.3	3	60.0	2	66.7	1	33.3	0.5860	1.73	0.23	12.78		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	3	37.5	2	66.7	1	33.3	3	60.0	2	66.7	1	33.3	0.9458	0.93	0.13	6.88		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.7055	0.58	0.03	10.25		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	2	66.7	1	33.3	0.1161	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	1	50.0	1	50.0	0.3497	0.28	0.02	4.71		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	5	62.5	1	20.0	4	80.0	2	40.0	1	50.0	1	50.0	0.3497	0.28	0.02	4.71		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMORRHAGE	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMORRHAGE	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTAE_L2_Polarose_SE_29365_41543.xls
30NOV2022 18:35

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	2	25.0	2	100.0	0	-	4	80.0	1	25.0	3	75.0	0.2072	4.22	0.37	47.51		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	6	75.0	3	50.0	3	50.0	1	20.0	0	-	1	100.0	0.4325	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	1	25.0	3	75.0	0.8084	1.41	0.08	23.57		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	6	75.0	3	50.0	3	50.0	1	20.0	0	-	1	100.0	0.4325	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	1	25.0	3	75.0	0.6949	1.73	0.11	27.89		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.4804	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5188	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	BRADYCARDIA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	BRADYCARDIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5188	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	2	25.0	2	100.0	0	-	4	80.0	1	25.0	3	75.0	0.2072	4.22	0.37	47.51		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	6	75.0	3	50.0	3	50.0	1	20.0	1	100.0	0	-	0.6250	0.50	0.03	8.46		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	6	75.0	1	16.7	5	83.3	1	20.0	1	100.0	0	-	0.1768	0.18	0.01	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	1	25.0	3	75.0	0.6949	1.73	0.11	27.89		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0	-	0.4499	0.41	0.04	4.53		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	2	25.0	1	50.0	1	50.0	4	80.0	1	25.0	3	75.0	0.6949	1.73	0.11	27.89		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0	-	0.3723	0.29	0.02	5.13		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	2	25.0	1	50.0	1	50.0	4	80.0	3	75.0	1	25.0	0.3518	0.35	0.03	3.54		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	6	75.0	3	50.0	3	50.0	1	20.0	0	-	1	100.0	0.4036	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>=3	2	25.0	0	-	2	100.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	2	25.0	1	50.0	1	50.0	4	80.0	1	25.0	3	75.0	0.4504	2.83	0.17	47.15		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	6	75.0	3	50.0	3	50.0	1	20.0	0	-	1	100.0	0.3871	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	2	25.0	2	100.0	0	-	4	80.0	0	-	4	100.0	0.0455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0	-	0.4499	0.41	0.04	4.53		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	<3	6	75.0	1	16.7	5	83.3	1	20.0	1	100.0	0	-	0.1768	0.18	0.01	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	2	25.0	2	100.0	0	-	4	80.0	4	100.0	0	-	0.0448	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	6	75.0	5	83.3	1	16.7	1	20.0	1	100.0	0	-	0.4499	0.41	0.04	4.53		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4142	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	2	25.0	2	100.0	0	-	4	80.0	1	25.0	3	75.0	1.0000	1.00	0.05	18.91		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	6	75.0	4	66.7	2	33.3	1	20.0	1	100.0	0	-	0.0143	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	2	25.0	1	50.0	1	50.0	4	80.0	3	75.0	1	25.0	0.1439	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	2	25.0	2	100.0	0	-	4	80.0	3	75.0	1	25.0	0.1439	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	6	75.0	4	66.7	2	33.3	1	20.0	1	100.0	0	-	0.1768	0.18	0.01	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	2	25.0	2	100.0	0	-	4	80.0	3	75.0	1	25.0	0.1415	6.00	0.46	79.06		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	1	25.0	3	75.0	0.5762	2.45	0.10	58.92		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	2	25.0	2	100.0	0	-	4	80.0	2	50.0	2	50.0	0.3209	2.63	0.36	19.07		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	2	25.0	1	50.0	1	50.0	4	80.0	1	25.0	3	75.0	0.8084	1.41	0.08	23.57		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HAEMORRHAGE	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMORRHAGE	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTAE_L2_Polarose_SE_29365_41543.xls
30NOV2022 18:35

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	8	100.0	5	62.5	3	37.5	5	100.0	1	20.0	4	80.0	0.2326	3.44	0.40	29.66		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.4478	2.28	0.25	20.49		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	1	20.0	4	80.0	0.5439	1.99	0.21	19.18		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.8878	1.19	0.11	13.16		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	BRADYCARDIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	8	100.0	5	62.5	3	37.5	5	100.0	2	40.0	3	60.0	0.6065	1.56	0.29	8.50		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.7742	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	2	40.0	3	60.0	0.9539	1.05	0.17	6.54		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	2	40.0	3	60.0	0.9751	0.97	0.14	6.50		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	3	60.0	2	40.0	0.6298	0.68	0.15	3.22		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	2	40.0	3	60.0	0.0584	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.7643	1.44	0.13	15.96		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	0	-	5	100.0	0.1485	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.2949	3.05	0.34	27.46		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.7742	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	8	100.0	7	87.5	1	12.5	5	100.0	5	100.0	0	-	0.0150	0.14	0.03	0.82		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.8450	1.27	0.11	14.04		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.7742	0.67	0.04	10.70		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.1859	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	2	40.0	3	60.0	0.0584	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	8	100.0	6	75.0	2	25.0	5	100.0	2	40.0	3	60.0	0.5947	1.56	0.30	8.18		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	3	60.0	2	40.0	0.1107	0.25	0.04	1.55		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	8	100.0	6	75.0	2	25.0	5	100.0	4	80.0	1	20.0	0.1366	0.35	0.09	1.47		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	3	60.0	2	40.0	0.8269	0.84	0.18	3.88		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.7261	0.60	0.03	10.90		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	2	40.0	3	60.0	0.7273	1.35	0.25	7.42		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	1	20.0	4	80.0	0.6349	1.72	0.18	16.55		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	0	-	5	100.0	0.1439	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	2	40.0	3	60.0	0.2503	0.27	0.02	2.97		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.7551	0.65	0.04	10.32		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	2	40.0	3	60.0	0.2131	0.24	0.02	2.71		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.6771	0.56	0.03	8.98		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMORRHAGE	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTAE_L2_Polarose_SE_29365_41543.xls
30NOV2022 18:35

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	87.5	4	57.1	3	42.9	1	20.0	0	-	1	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	1	12.5	1	100.0	0	-	4	80.0	1	25.0	3	75.0	0.3508	3.46	0.22	55.78		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	7	87.5	4	57.1	3	42.9	1	20.0	0	-	1	100.0	0.4754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	1	12.5	1	100.0	0	-	4	80.0	1	25.0	3	75.0	0.3508	3.46	0.22	55.78		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5583	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5583	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	BRADYCARDIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	BRADYCARDIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5583	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	TINNITUS	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	TINNITUS	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	7	87.5	4	57.1	3	42.9	1	20.0	0	-	1	100.0	0.3599	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	1	12.5	1	100.0	0	-	4	80.0	2	50.0	2	50.0	0.7741	1.42	0.13	16.04		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL DISTENSION	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DRY MOUTH	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DRY MOUTH	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DYSPEPSIA	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
GASTROINTESTINAL DISORDERS	NAUSEA	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Female	1	12.5	1	100.0	0	-	4	80.0	2	50.0	2	50.0	0.3508	3.46	0.22	55.78		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	1	12.5	1	100.0	0	-	4	80.0	2	50.0	2	50.0	0.6949	1.73	0.11	27.89		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	7	87.5	4	57.1	3	42.9	1	20.0	1	100.0	0	-	0.2926	0.24	0.01	4.19		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	1	12.5	0	-	1	100.0	4	80.0	2	50.0	2	50.0	0.4452	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Male	7	87.5	0	-	7	100.0	1	20.0	1	100.0	0	-	0.0082				*	WARNING: Iteration limit reached without convergence.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PAIN	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
IMMUNE SYSTEM DISORDERS	ANAPHYLACTIC REACTION	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	1	12.5	1	100.0	0	-	4	80.0	1	25.0	3	75.0	0.0455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	1.0000	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HEPATITIS B REACTIVATION	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.3173				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	7	87.5	6	85.7	1	14.3	1	20.0	1	100.0	0	-	0.2926	0.24	0.01	4.19		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	1	12.5	1	100.0	0	-	4	80.0	4	100.0	0	-	0.1564	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD GLUCOSE INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	1	12.5	0	-	1	100.0	4	80.0	2	50.0	2	50.0	0.4452	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	7	87.5	5	71.4	2	28.6	1	20.0	0	-	1	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	1	12.5	1	100.0	0	-	4	80.0	2	50.0	2	50.0	0.4452	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	7	87.5	2	28.6	5	71.4	1	20.0	1	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	1	12.5	1	100.0	0	-	4	80.0	2	50.0	2	50.0	0.4452	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	7	87.5	5	71.4	2	28.6	1	20.0	0	-	1	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	1	12.5	1	100.0	0	-	4	80.0	4	100.0	0	-	0.1564	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	7	87.5	3	42.9	4	57.1	1	20.0	1	100.0	0	-	0.3530	0.34	0.03	3.74		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	1	12.5	1	100.0	0	-	4	80.0	2	50.0	2	50.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	7	87.5	3	42.9	4	57.1	1	20.0	1	100.0	0	-	0.1284	0.15	0.01	2.47		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	1	12.5	1	100.0	0	-	4	80.0	1	25.0	3	75.0	0.0455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	LIMB DISCOMFORT	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DYSGEUSIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	1	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Male	7	87.5	1	14.3	6	85.7	1	20.0	1	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	DYSPNOEA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	OROPHARYNGEAL PAIN	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	2	50.0	2	50.0	0.4452	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
VASCULAR DISORDERS	HAEMORRHAGE	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HAEMORRHAGE	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
VASCULAR DISORDERS	HYPERTENSION	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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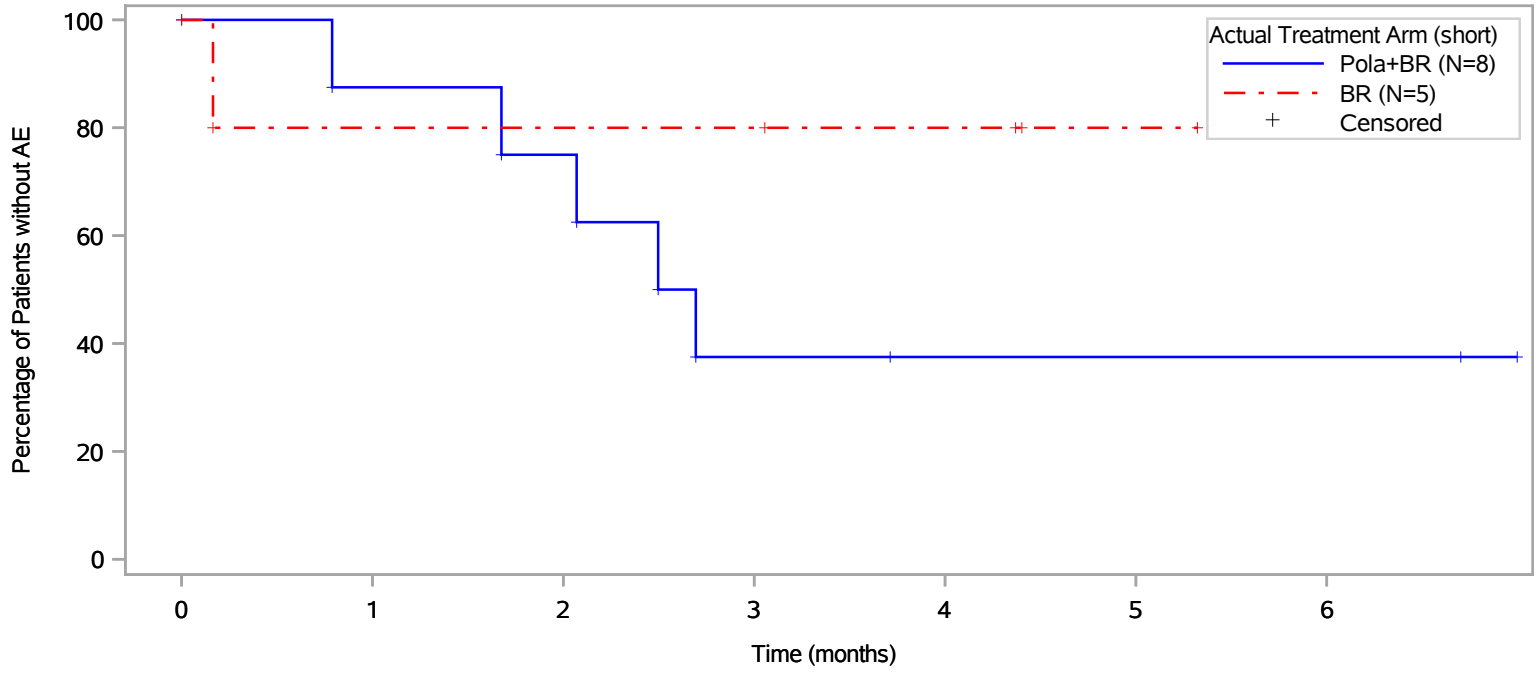
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	7	6	3	2	2	2
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	1
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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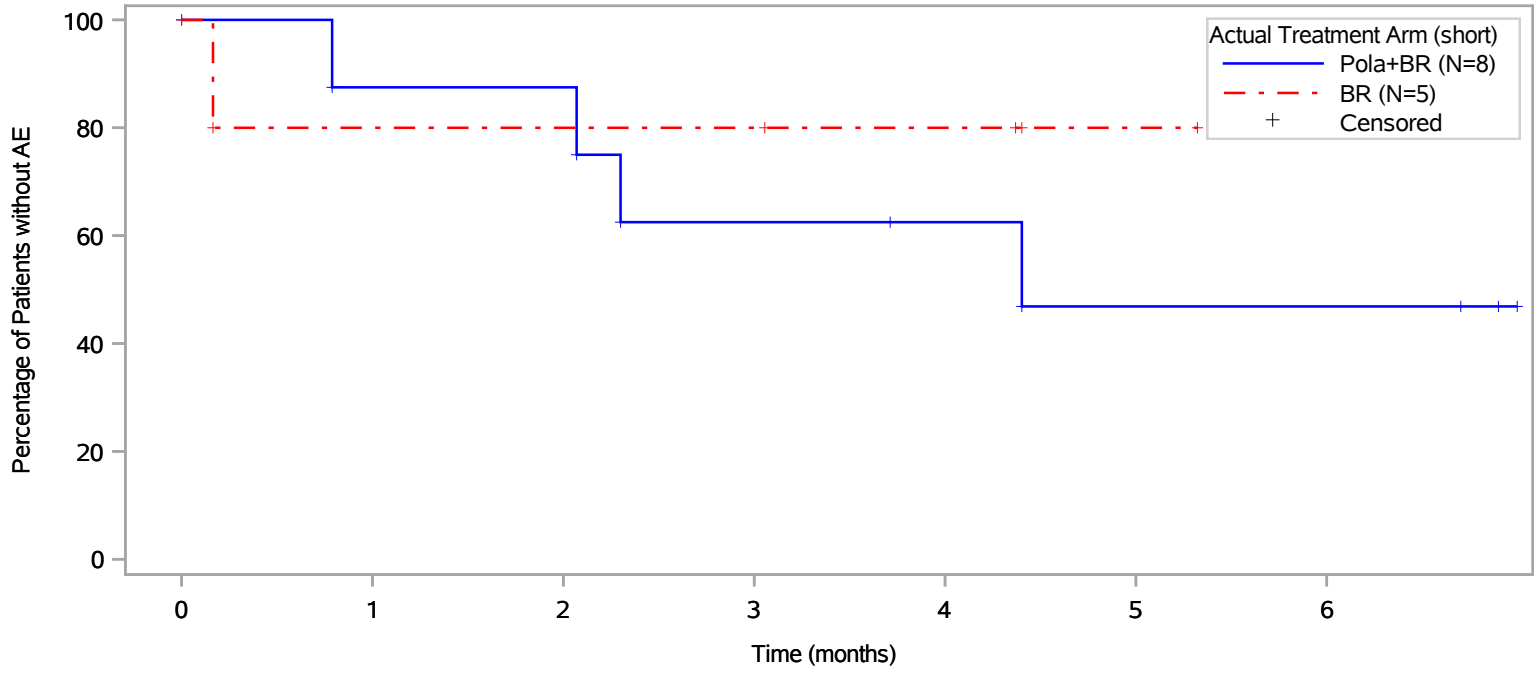
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk							
Pola+BR (N=8)	8	7	7	5	4	3	3
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	1
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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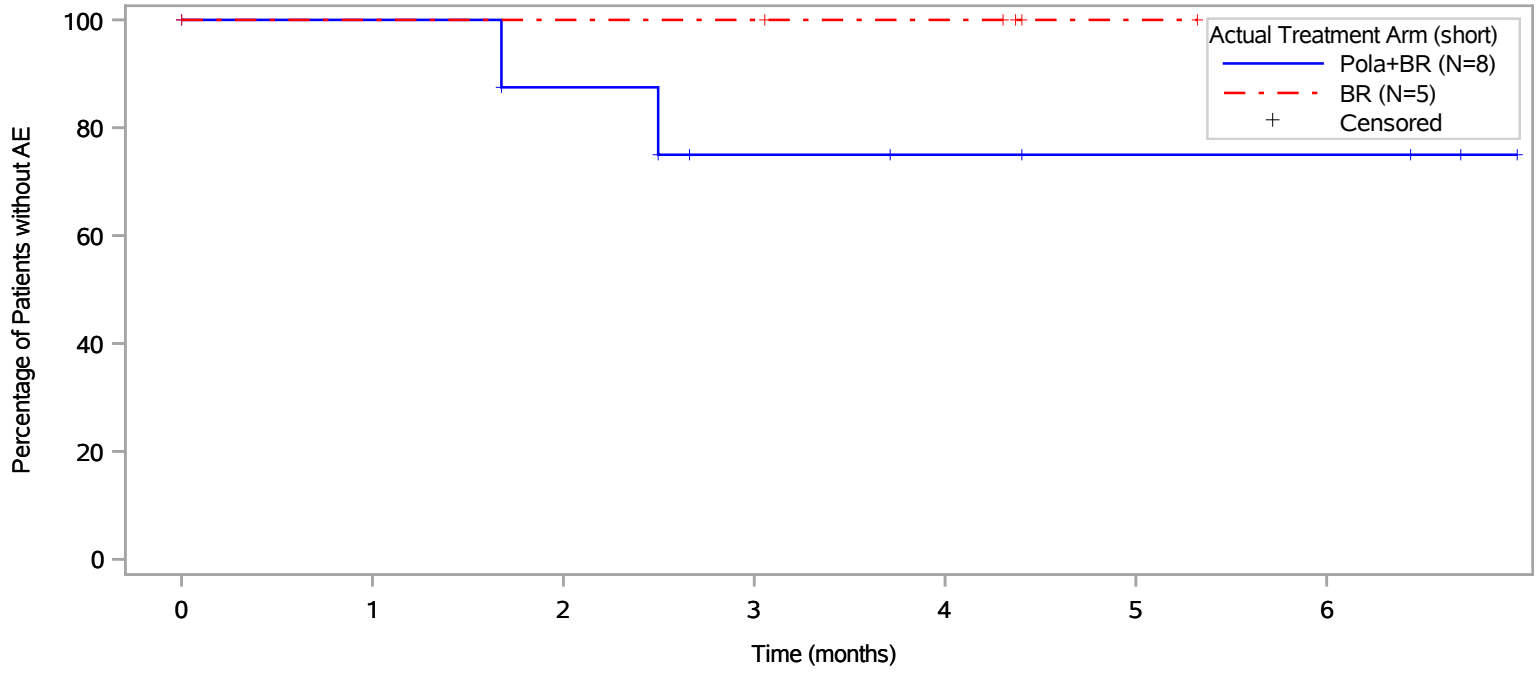
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



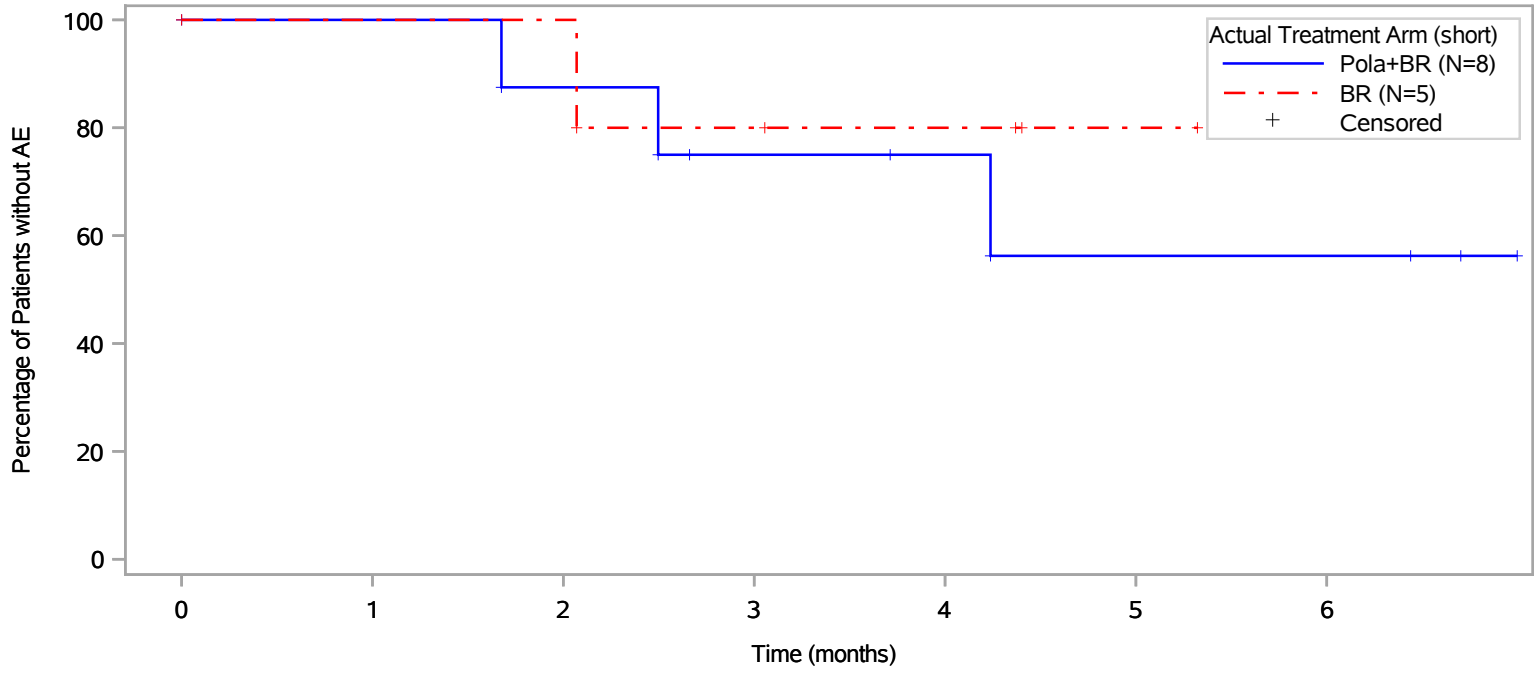
Patients at risk							
Pola+BR (N=8)	8	8	7	5	4	3	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



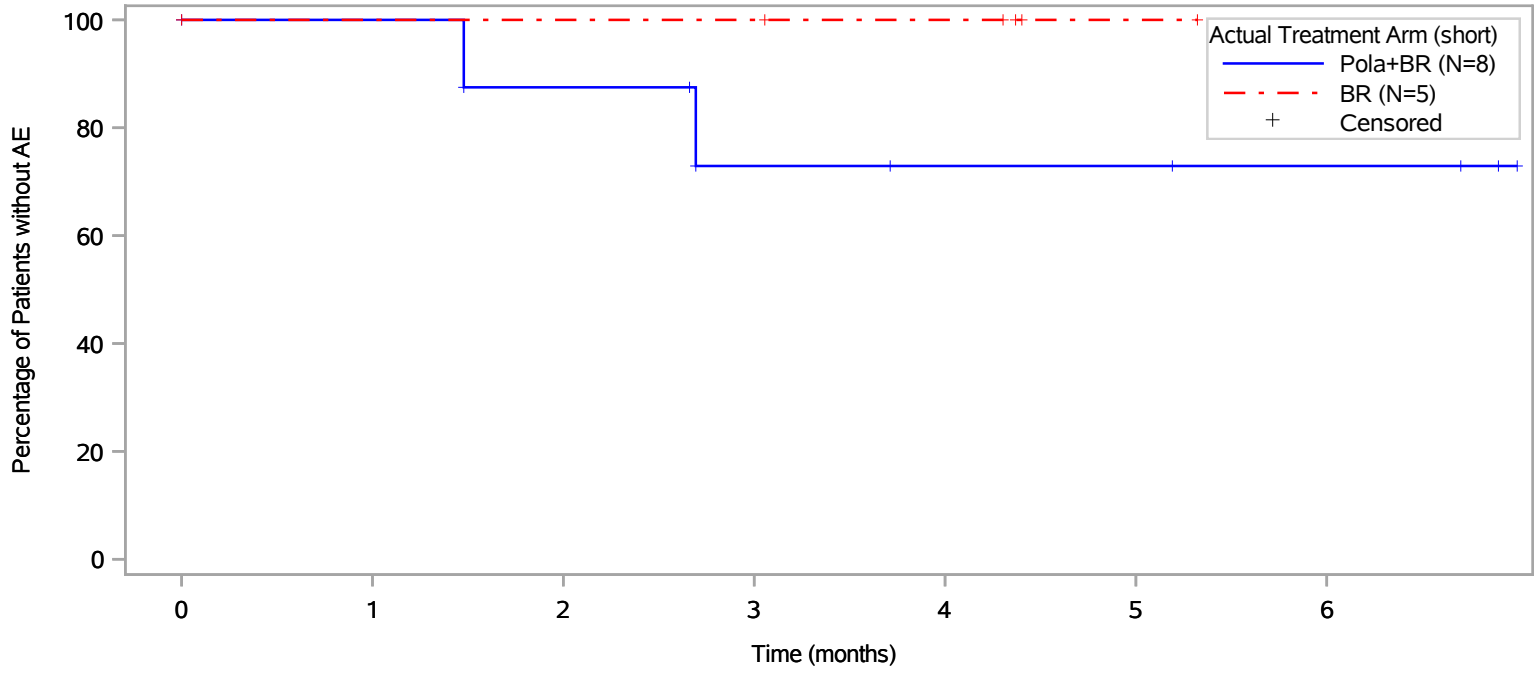
Patients at risk							
Pola+BR (N=8)	8	8	7	5	4	3	3
BR (N=5)	5	5	5	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	2
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA

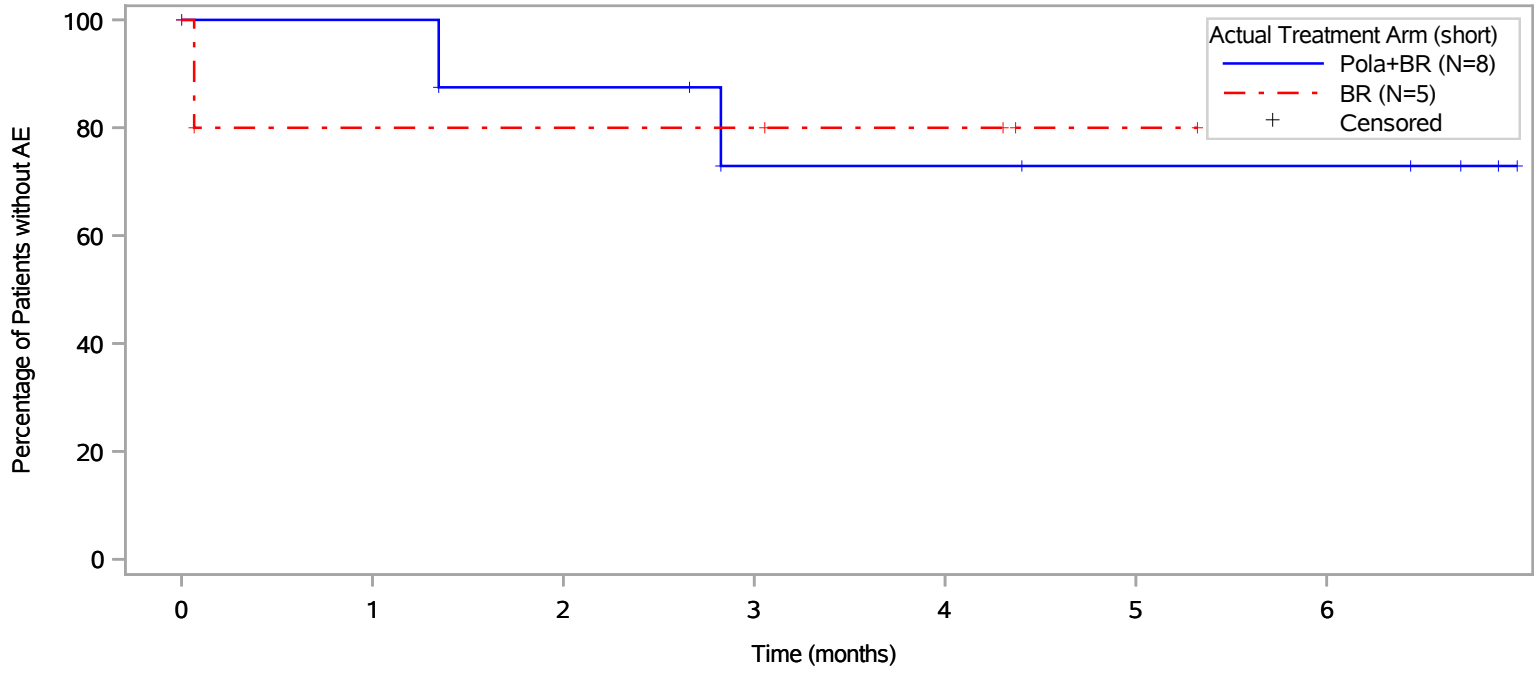


Patients at risk							
Pola+BR (N=8)	8	8	7	5	4	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All

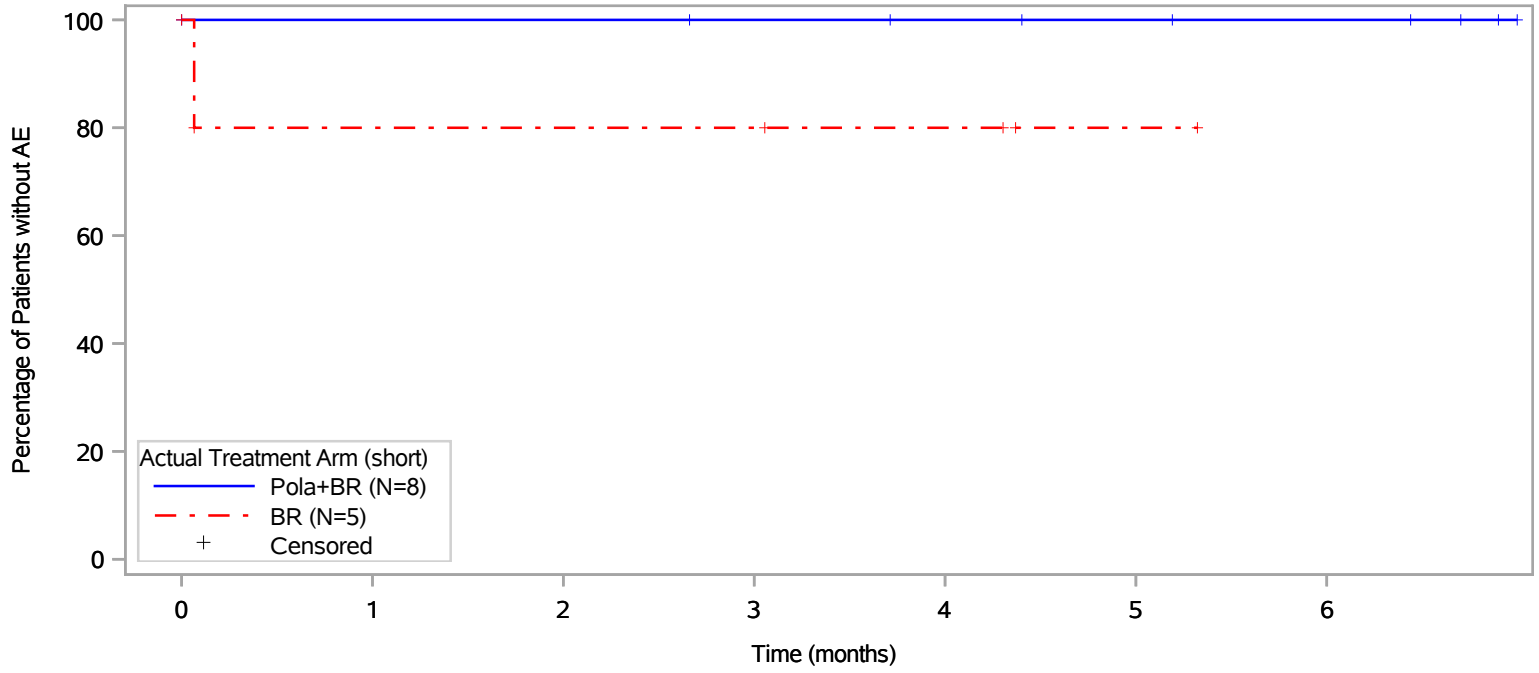


Patients at risk							
Pola+BR (N=8)	8	8	7	5	5	4	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	1	2	2
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, BRADYCARDIA

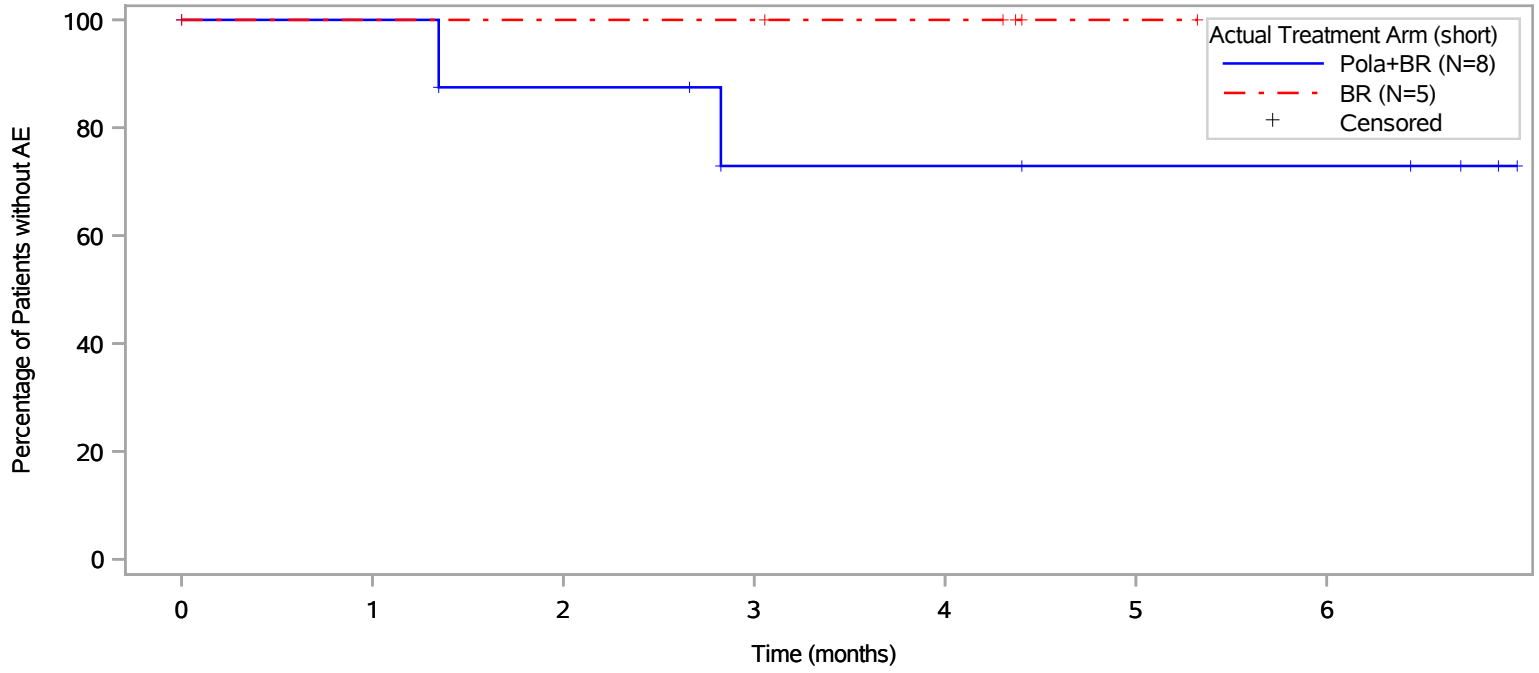


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SINUS TACHYCARDIA

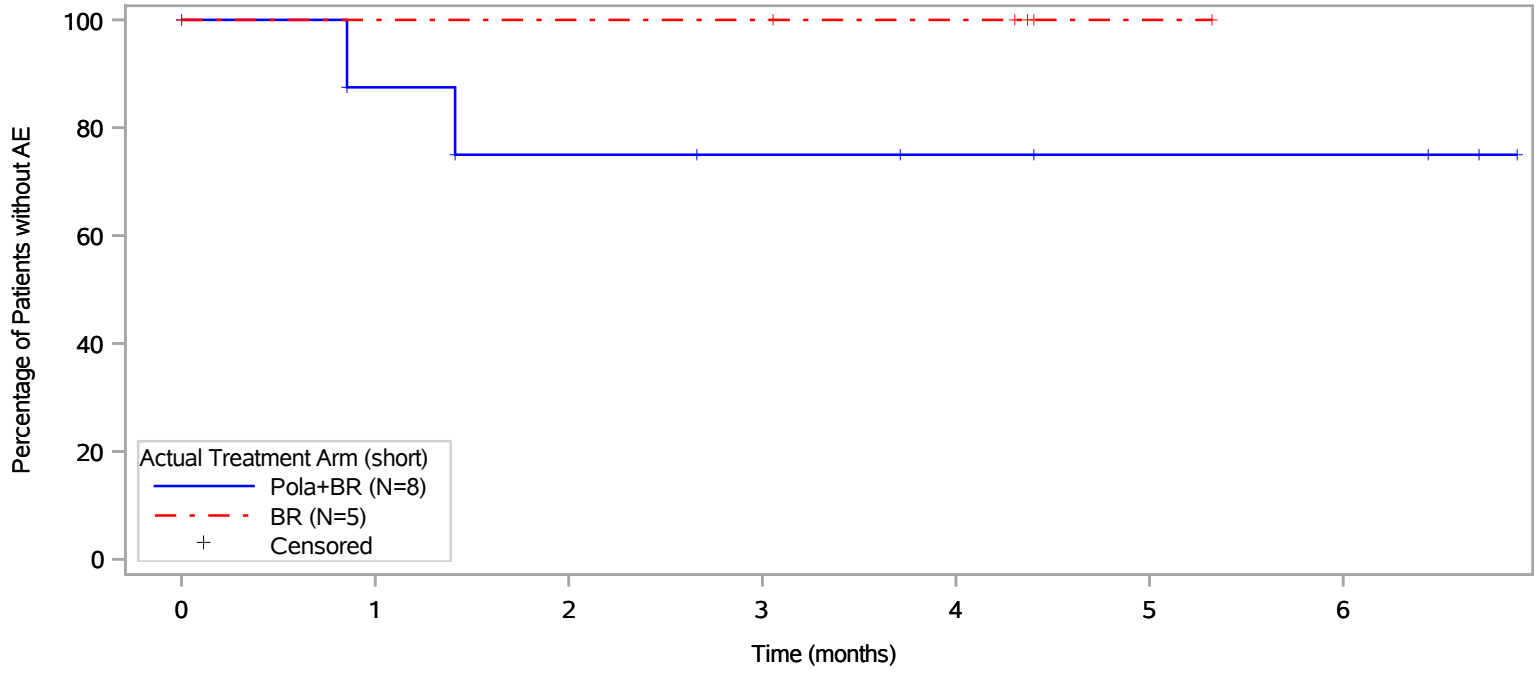


Patients at risk							
Pola+BR (N=8)	8	8	7	5	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	1	2	2
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, All

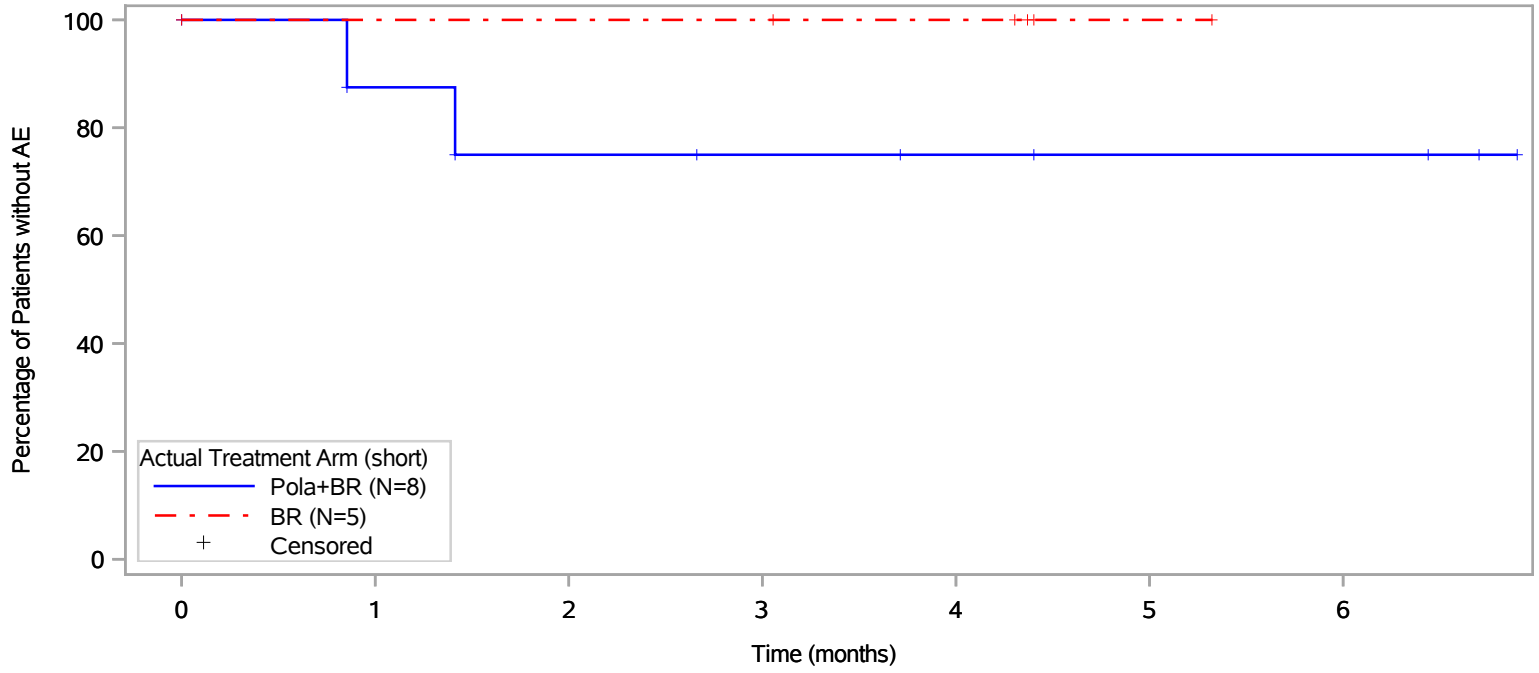


Patients at risk							
Pola+BR (N=8)	8	7	6	5	4	3	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, TINNITUS

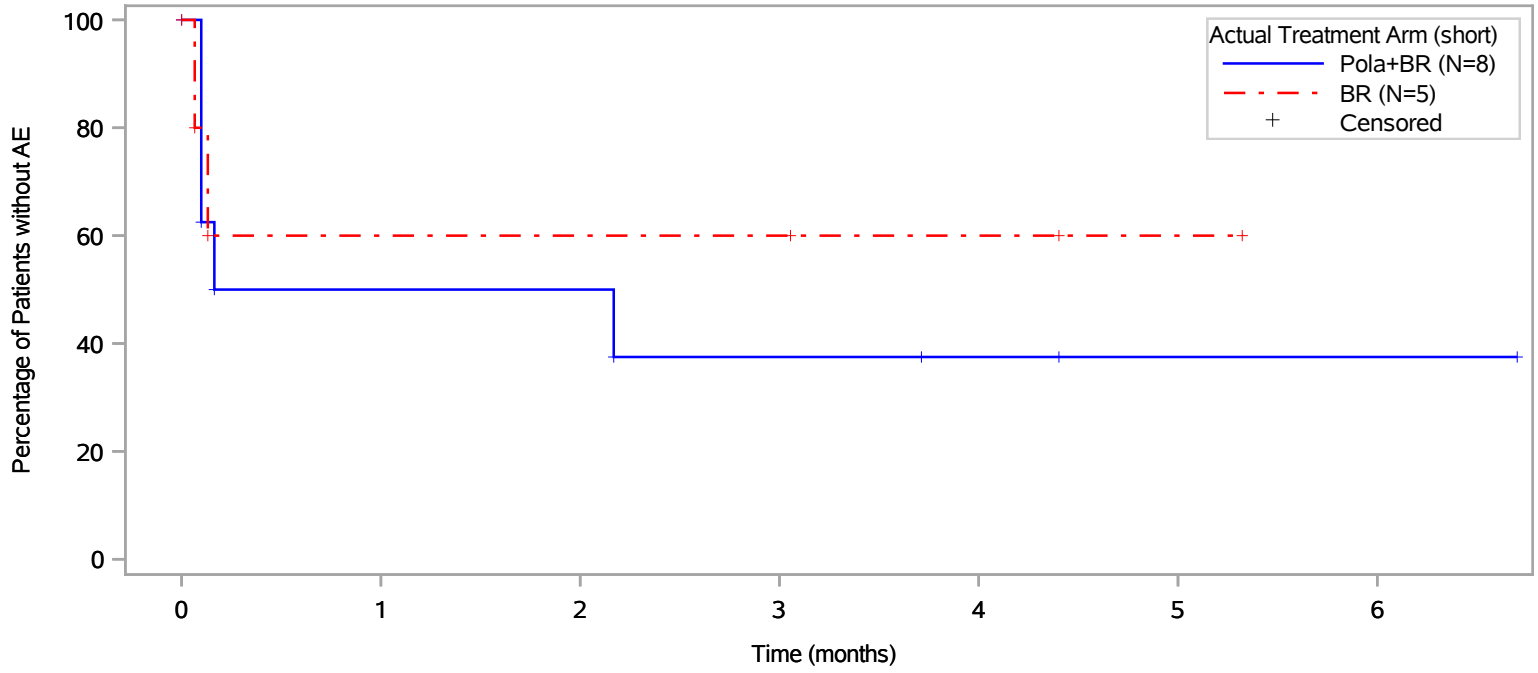


Patients at risk							
Pola+BR (N=8)	8	7	6	5	4	3	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All

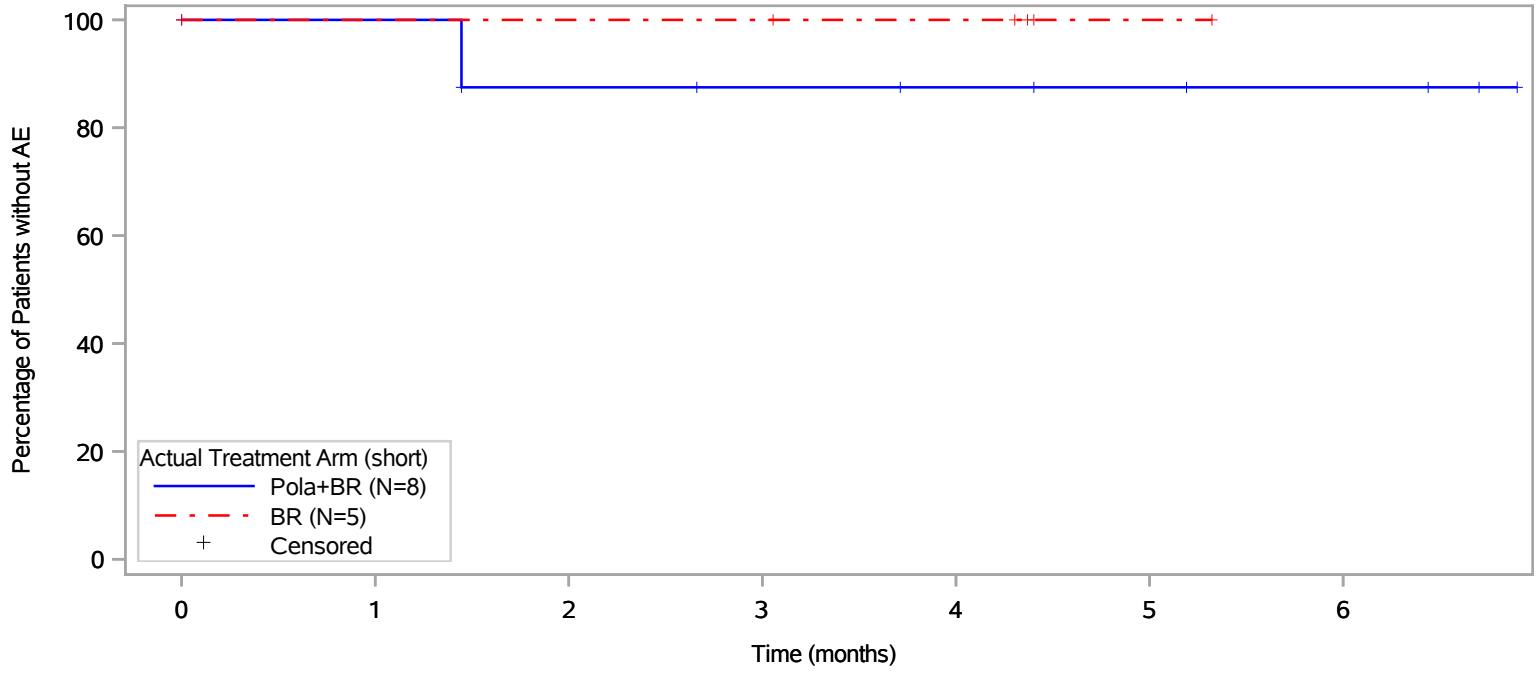


Patients at risk							
Pola+BR (N=8)	8	4	4	3	2	1	1
BR (N=5)	5	3	3	3	2	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	2
BR (N=5)	0	0	0	0	1	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL DISTENSION

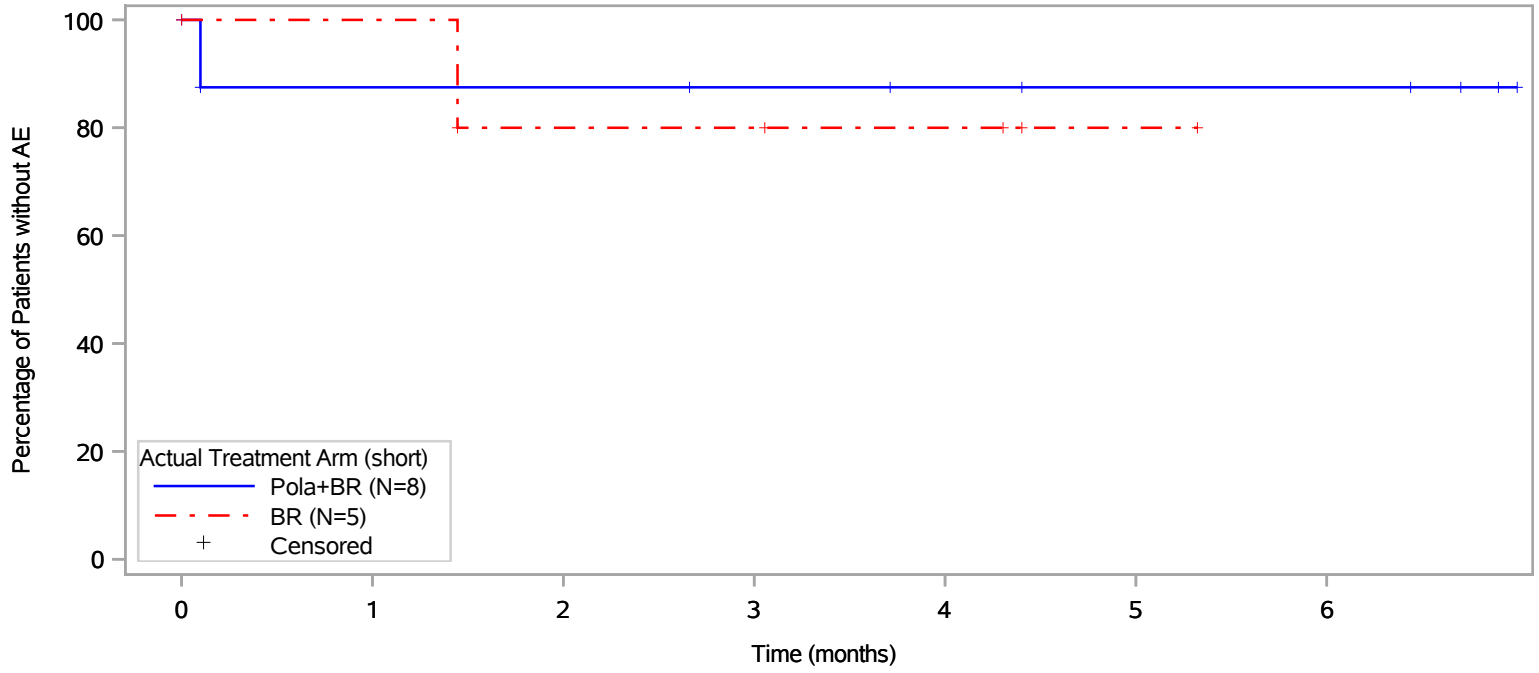


Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION

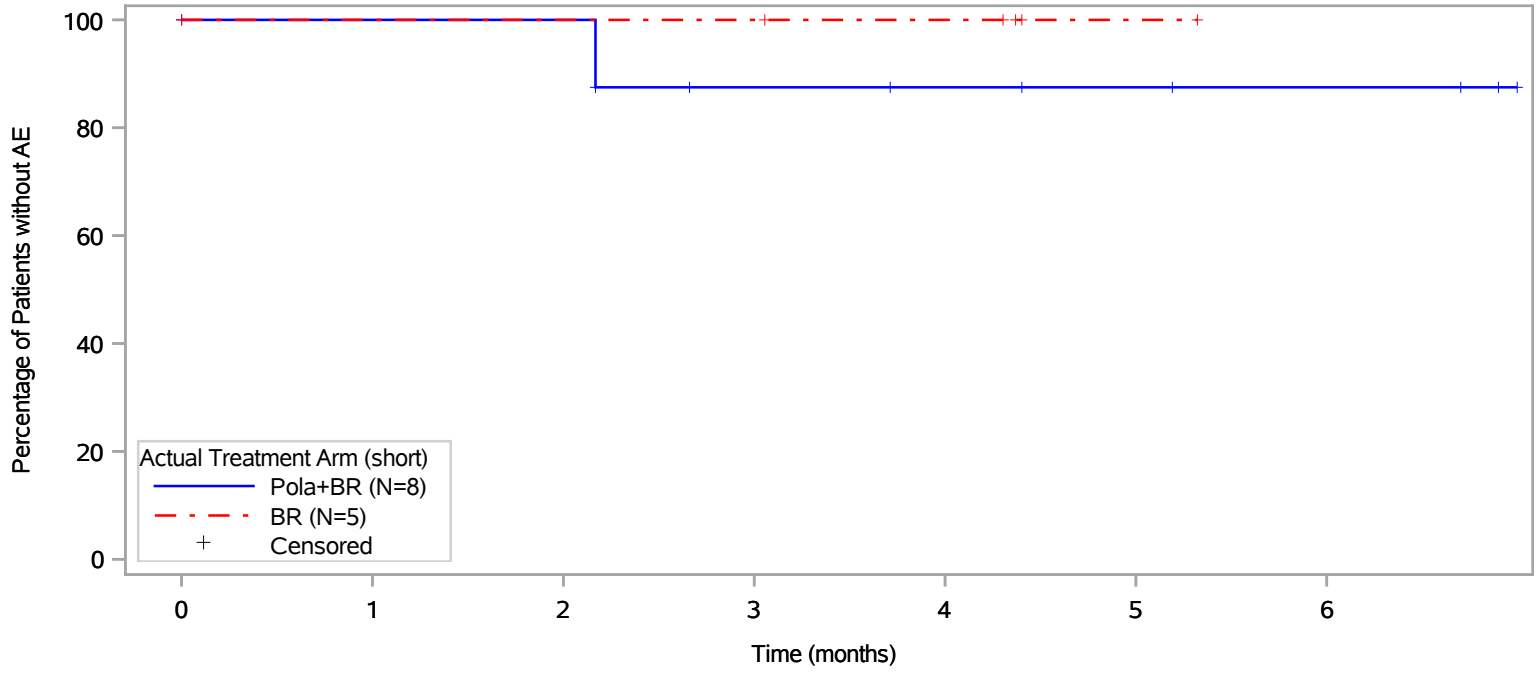


Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	4
BR (N=5)	5	5	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA

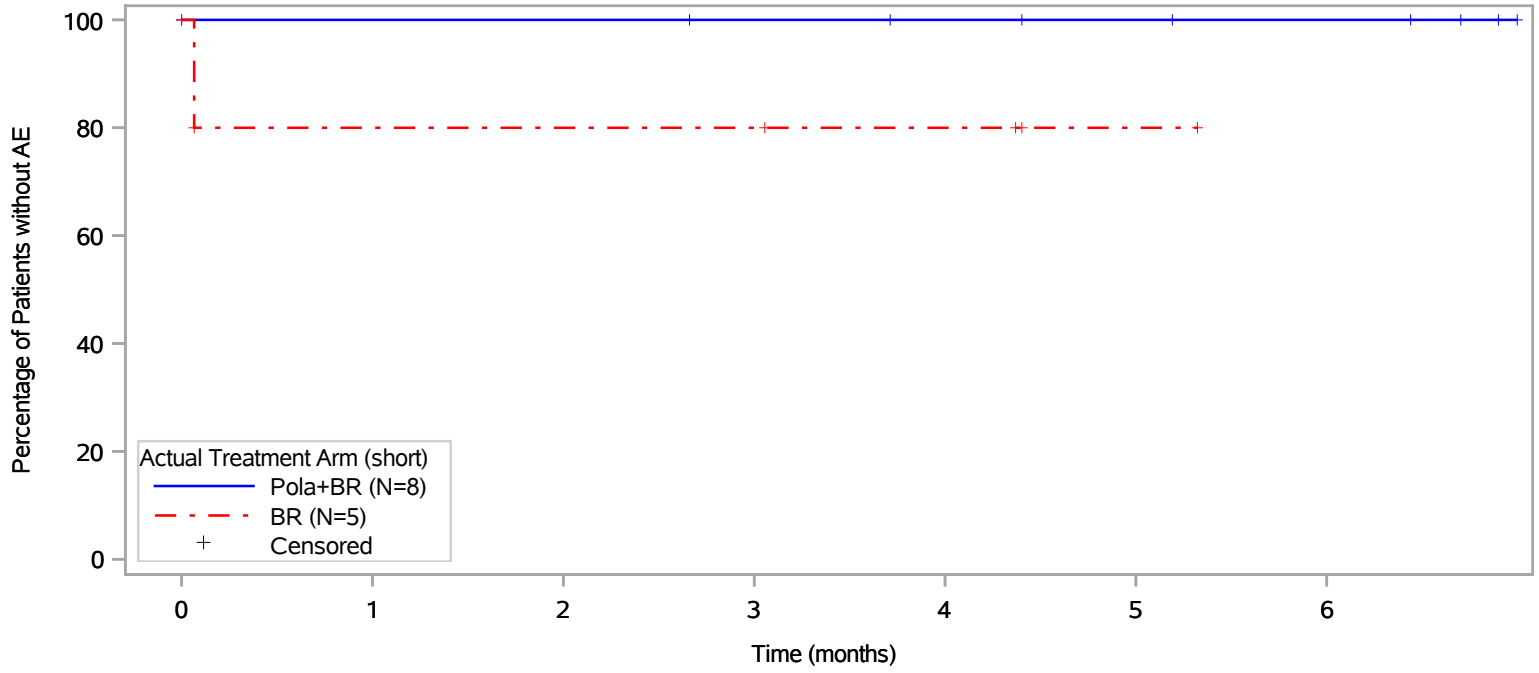


Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

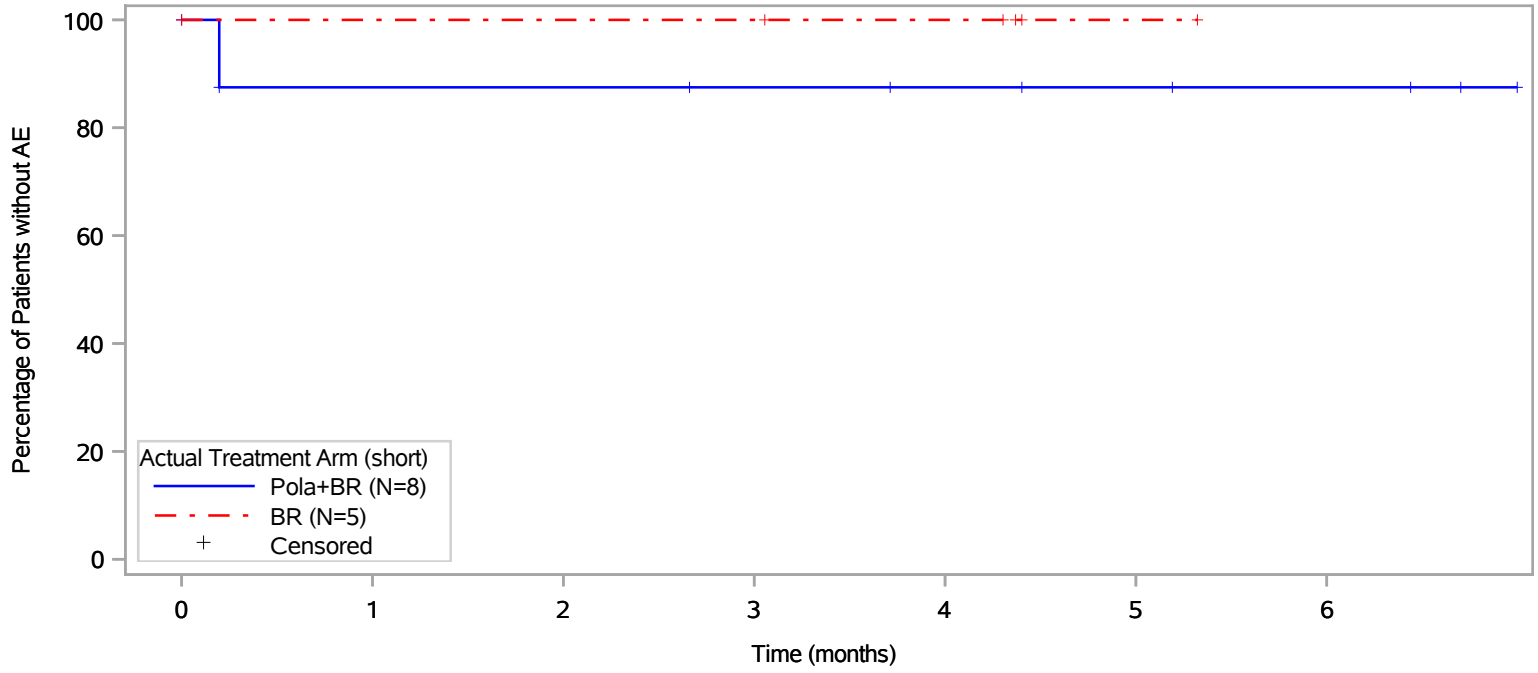
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DRY MOUTH



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DYSPEPSIA

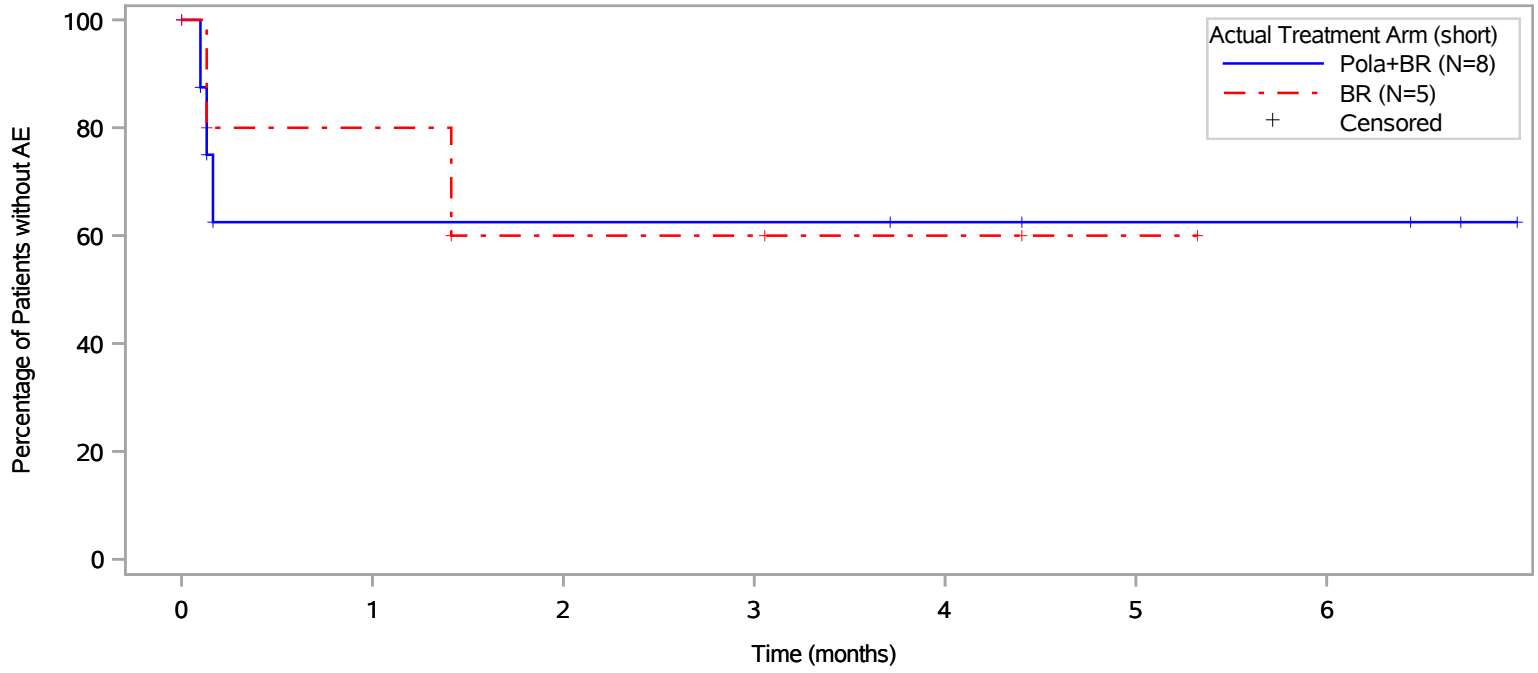


Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, NAUSEA

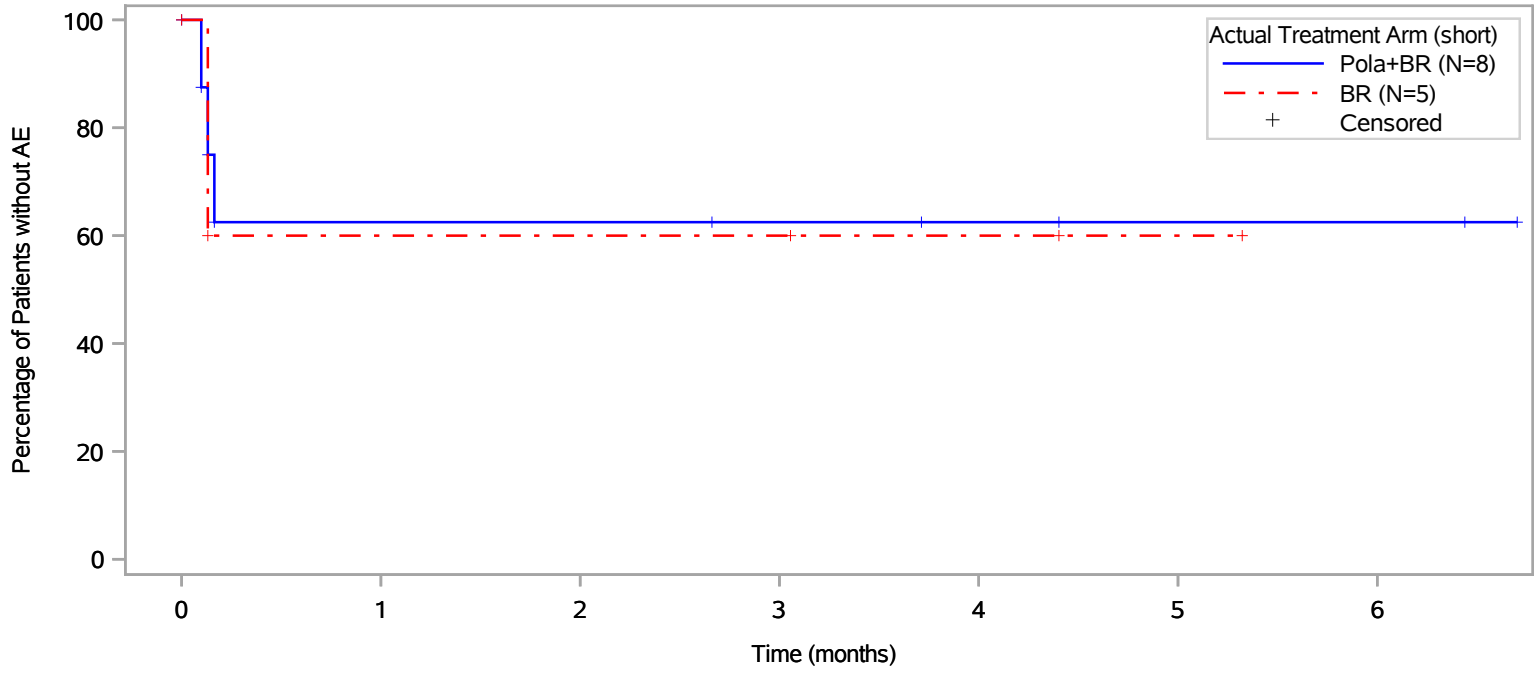


Patients at risk							
Pola+BR (N=8)	8	5	5	5	4	3	3
BR (N=5)	5	4	3	3	2	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	2
BR (N=5)	0	0	0	0	1	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING

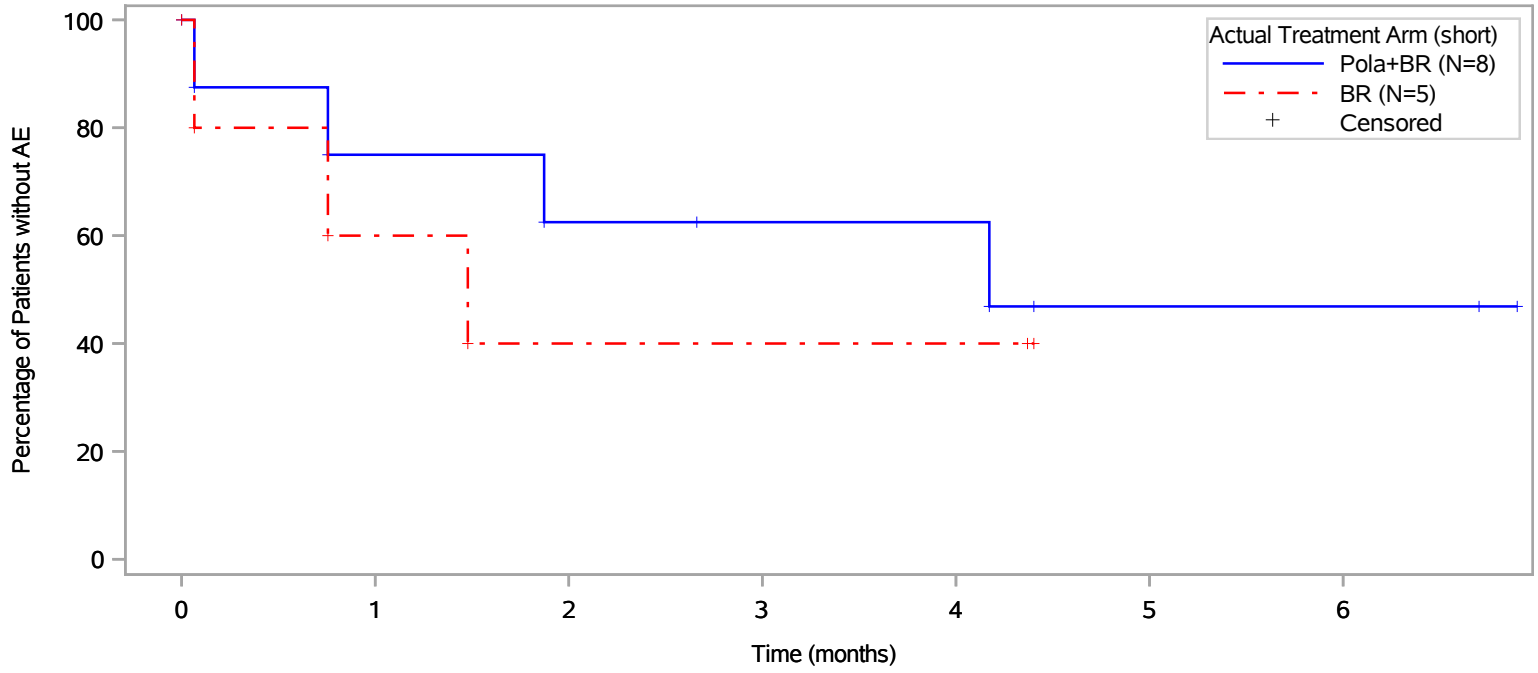


Patients at risk							
Pola+BR (N=8)	8	5	5	4	3	2	2
BR (N=5)	5	3	3	3	2	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



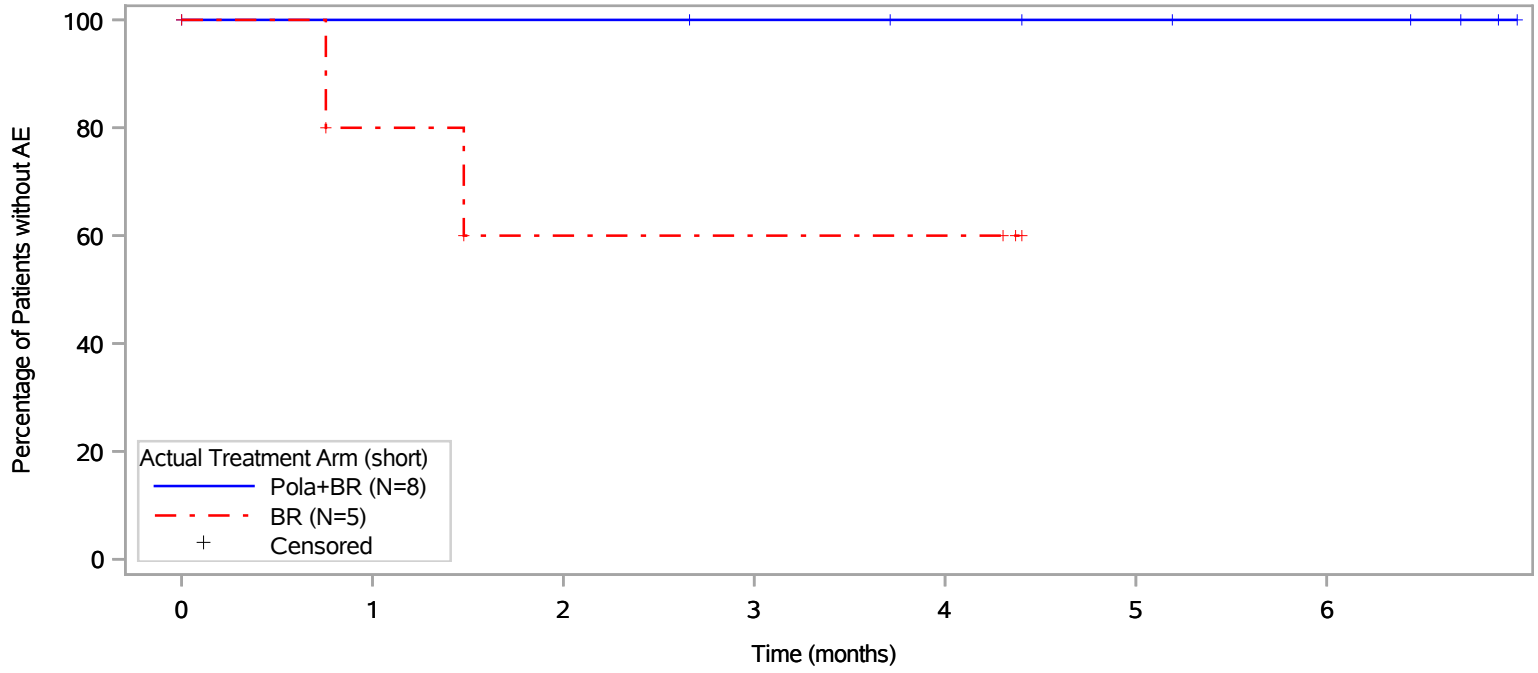
Patients at risk							
Pola+BR (N=8)	8	6	5	4	4	2	2
BR (N=5)	5	3	2	2	2	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	1	2	2
BR (N=5)	0	0	0	0	0	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, ASTHENIA

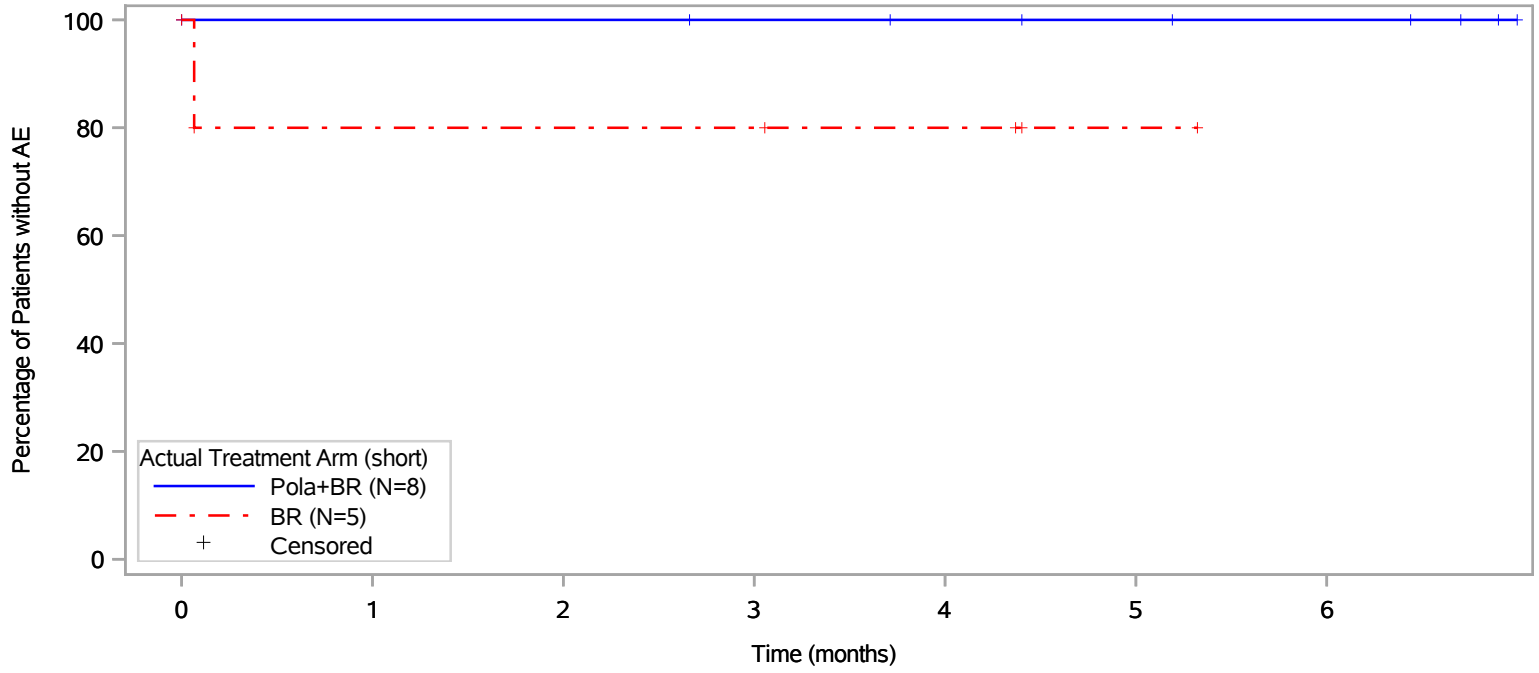


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	3	3	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	0	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHEST DISCOMFORT

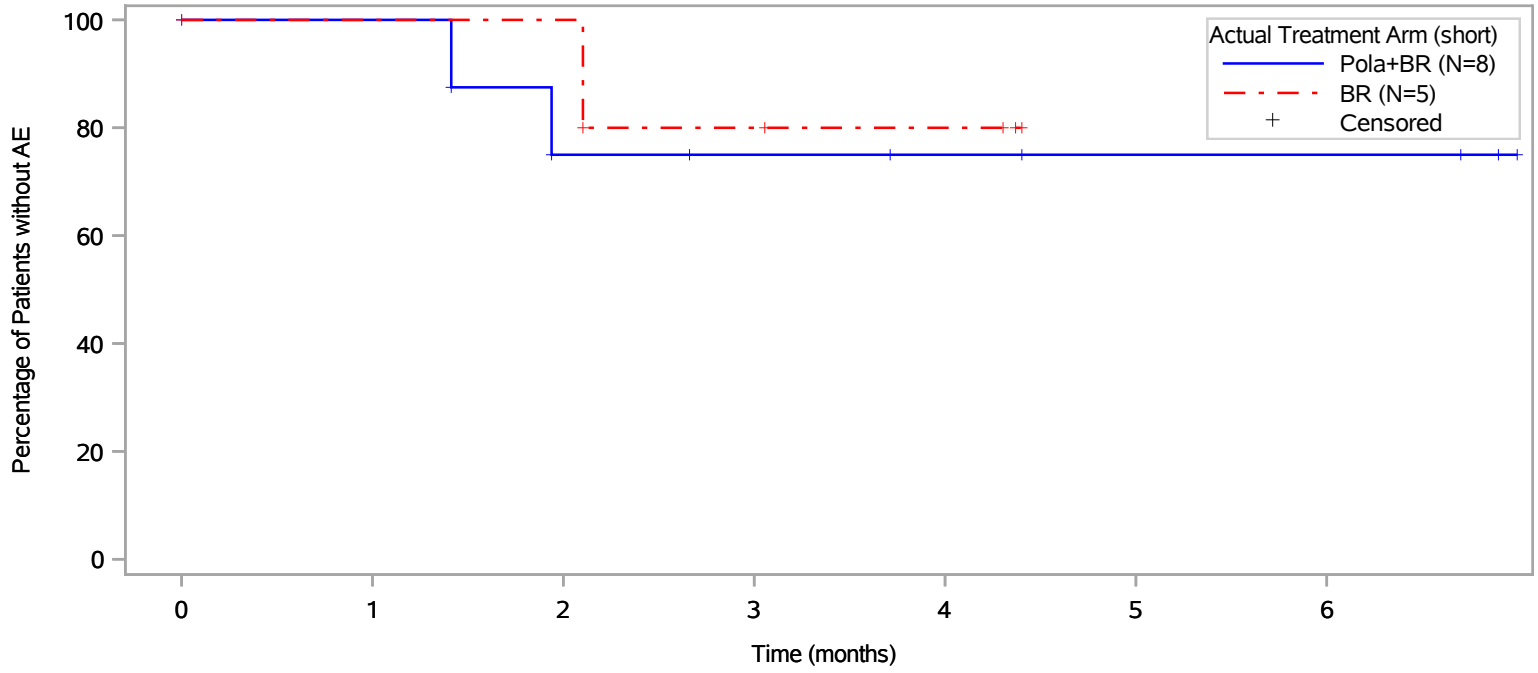


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE



Patients at risk							
Pola+BR (N=8)	8	8	6	5	4	3	3
BR (N=5)	5	5	5	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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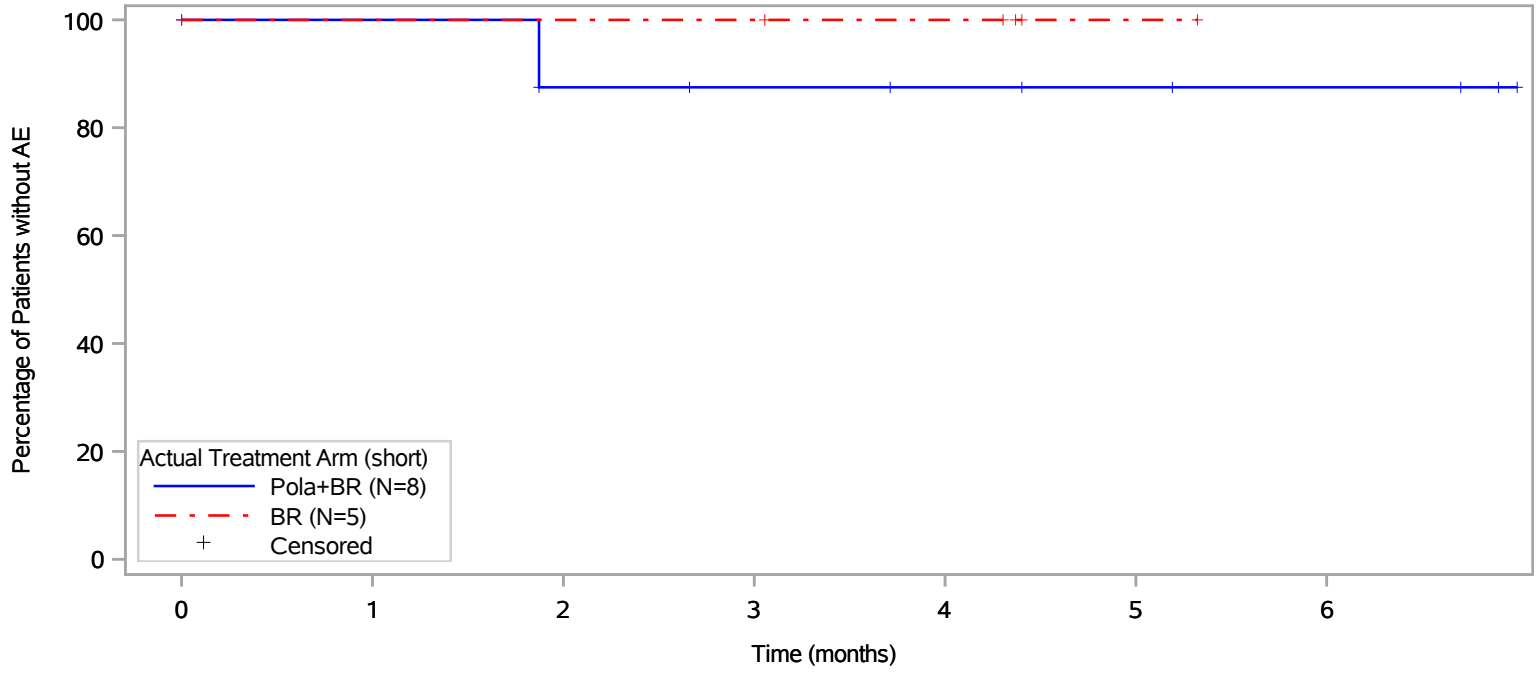
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MALAISE



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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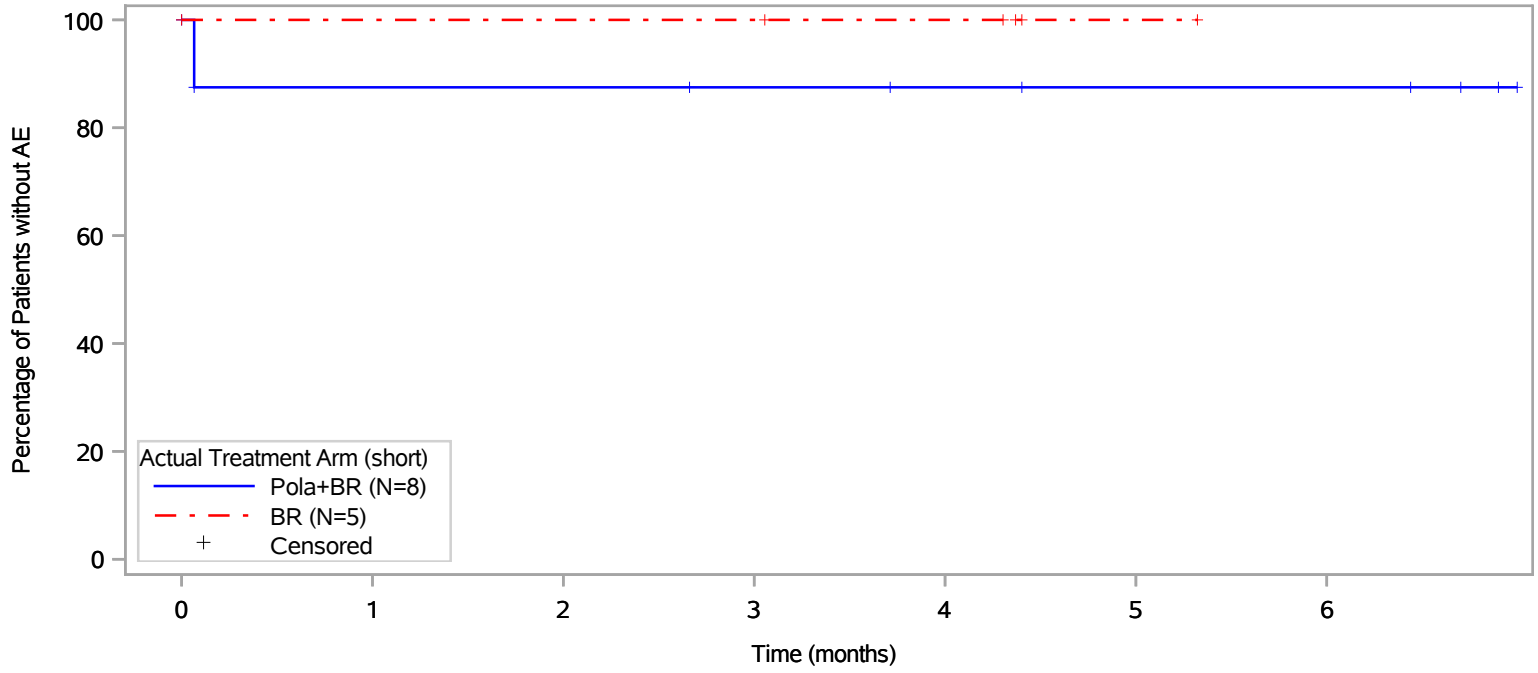
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

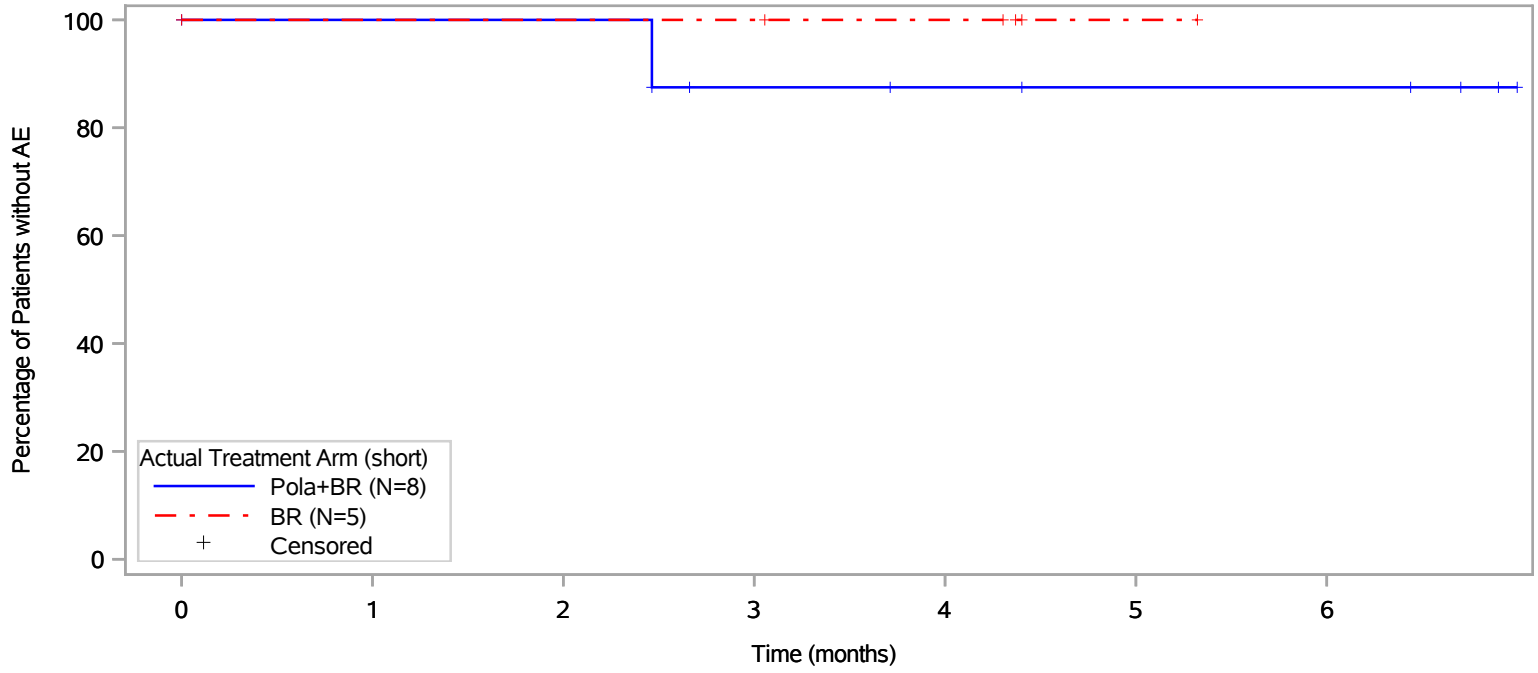
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA



Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PAIN



Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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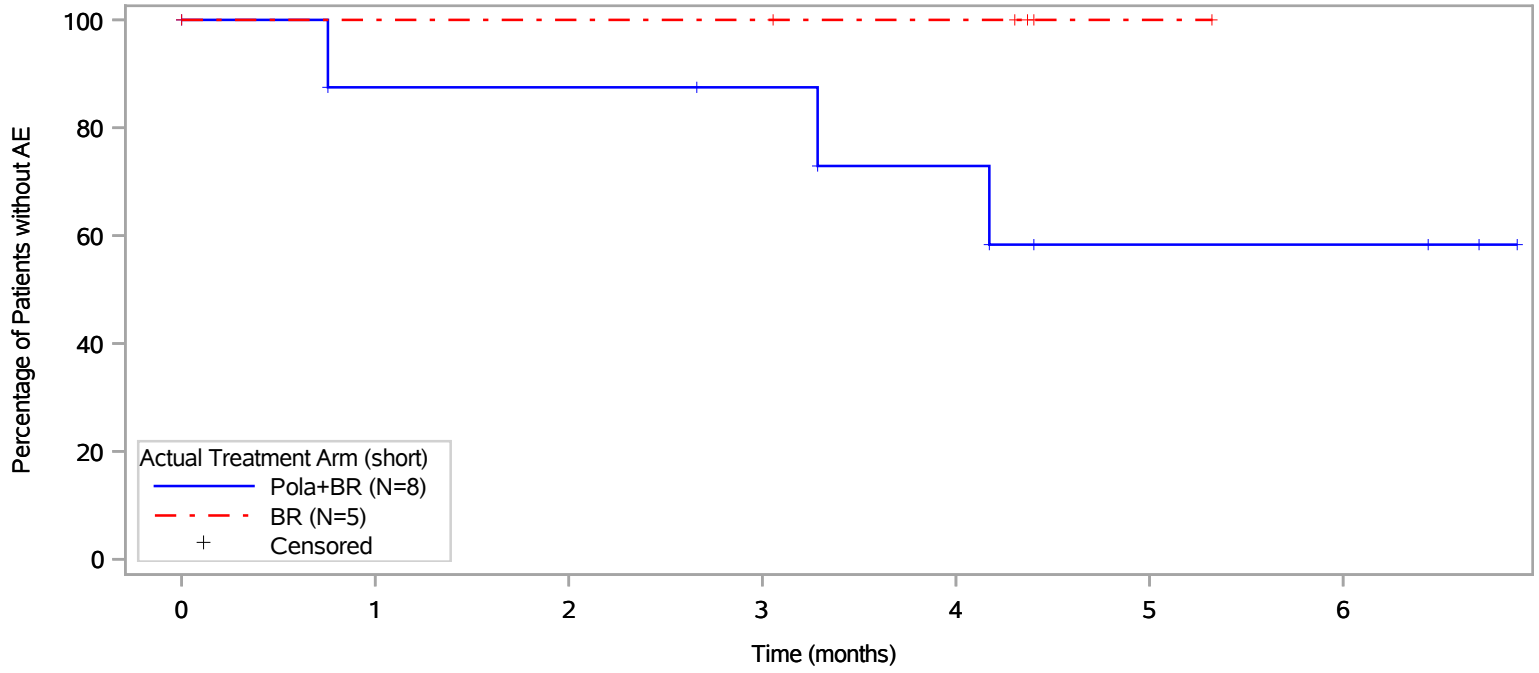
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA

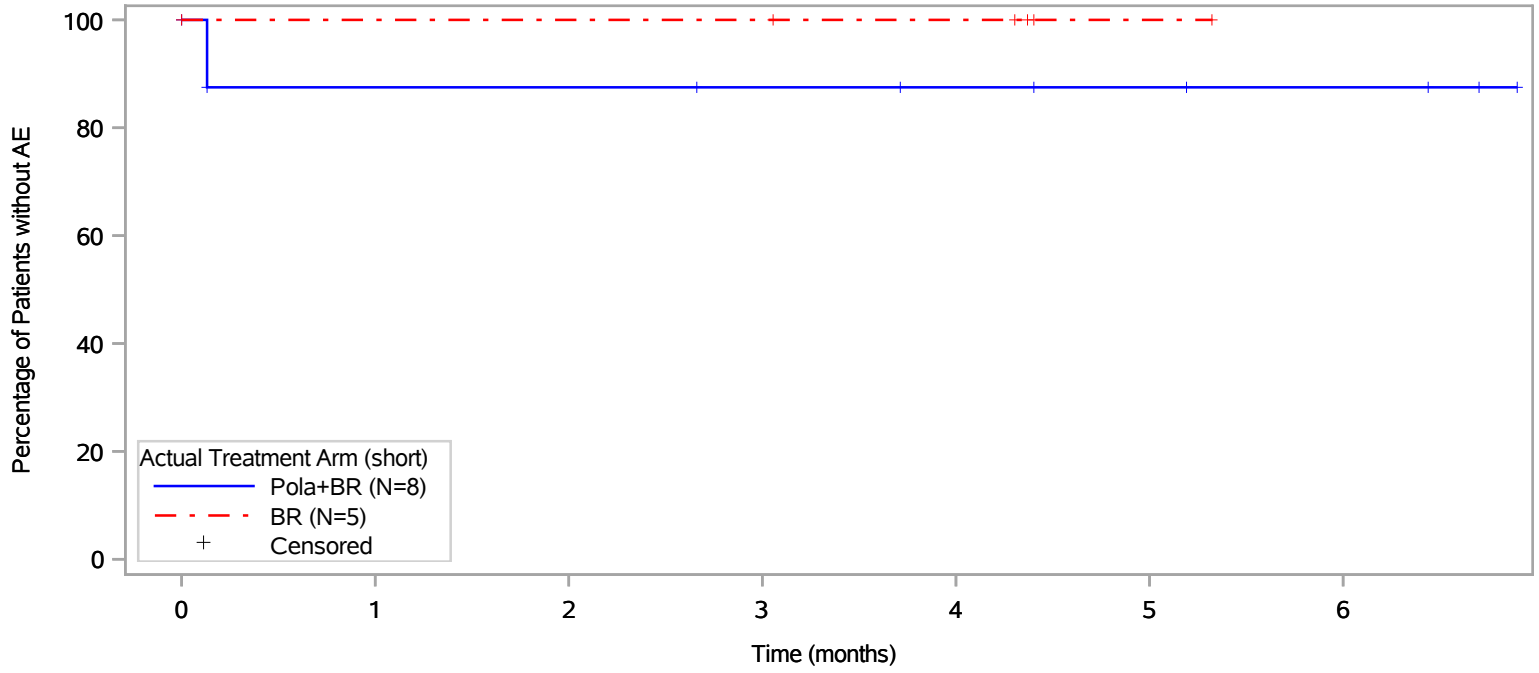


Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	3	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	1	2	2
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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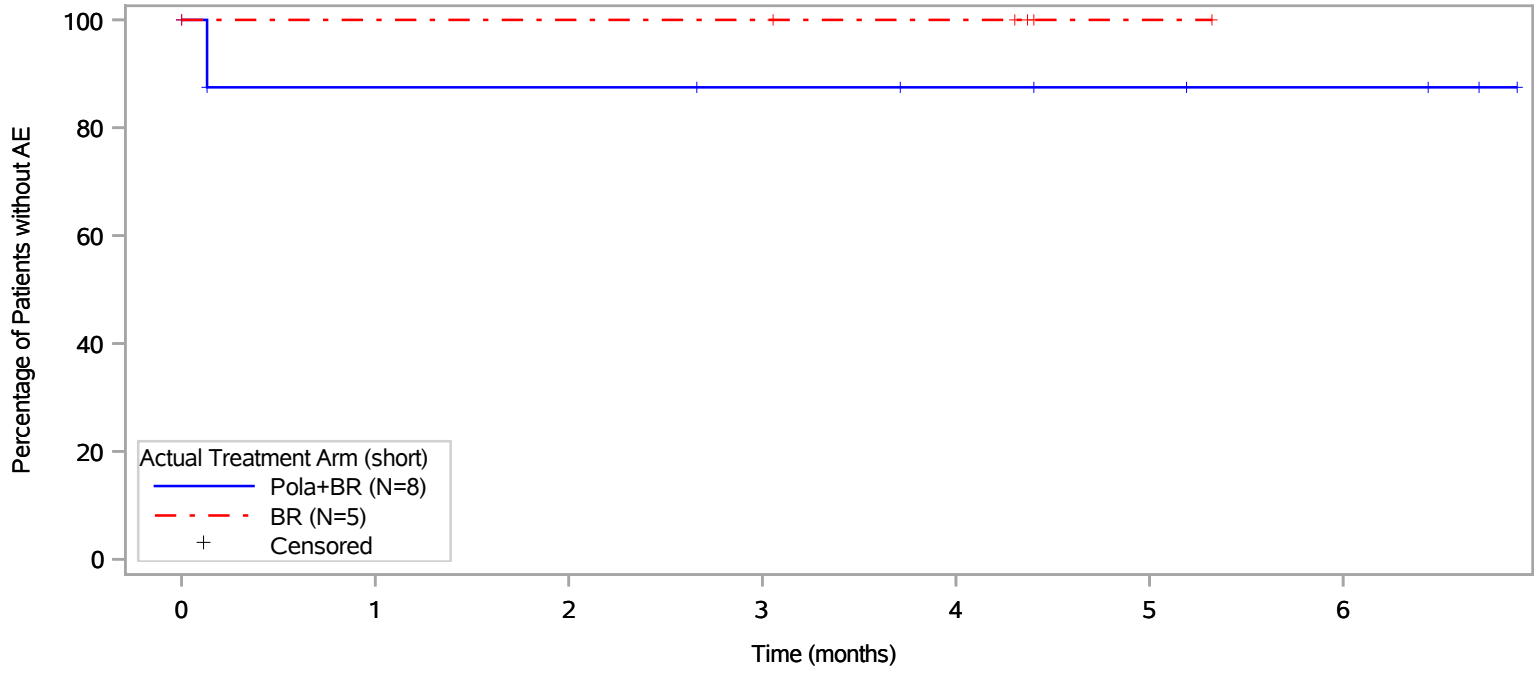
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
IMMUNE SYSTEM DISORDERS, ANAPHYLACTIC REACTION



Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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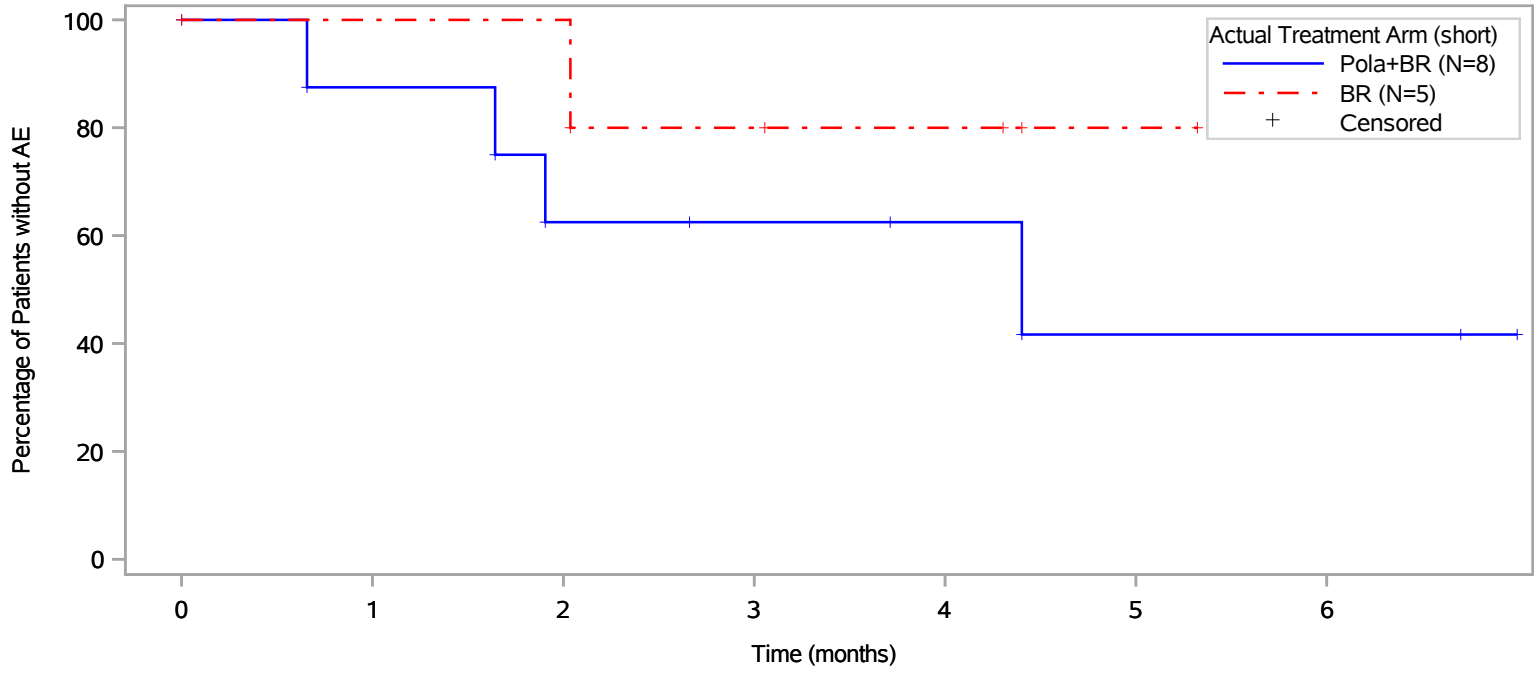
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk							
Pola+BR (N=8)	8	7	5	4	3	2	2
BR (N=5)	5	5	5	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	2
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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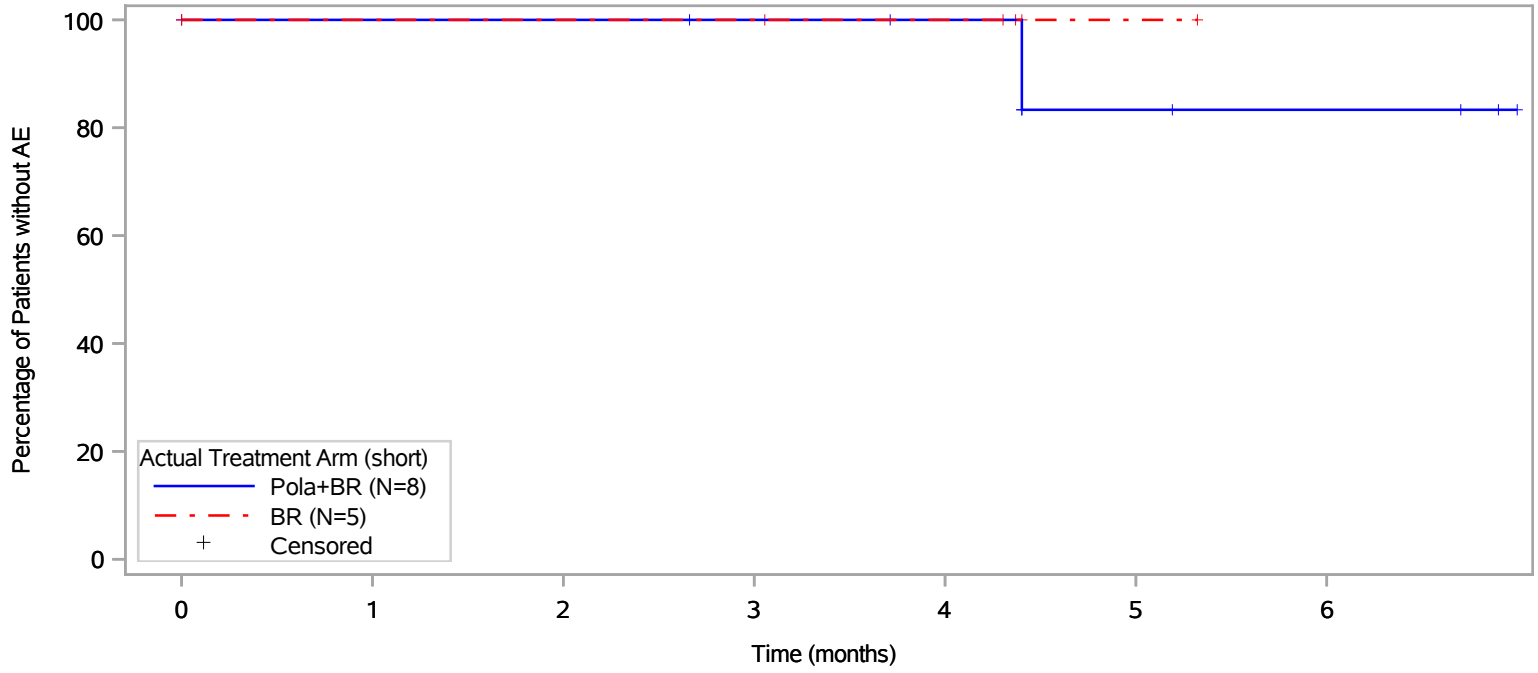
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HEPATITIS B



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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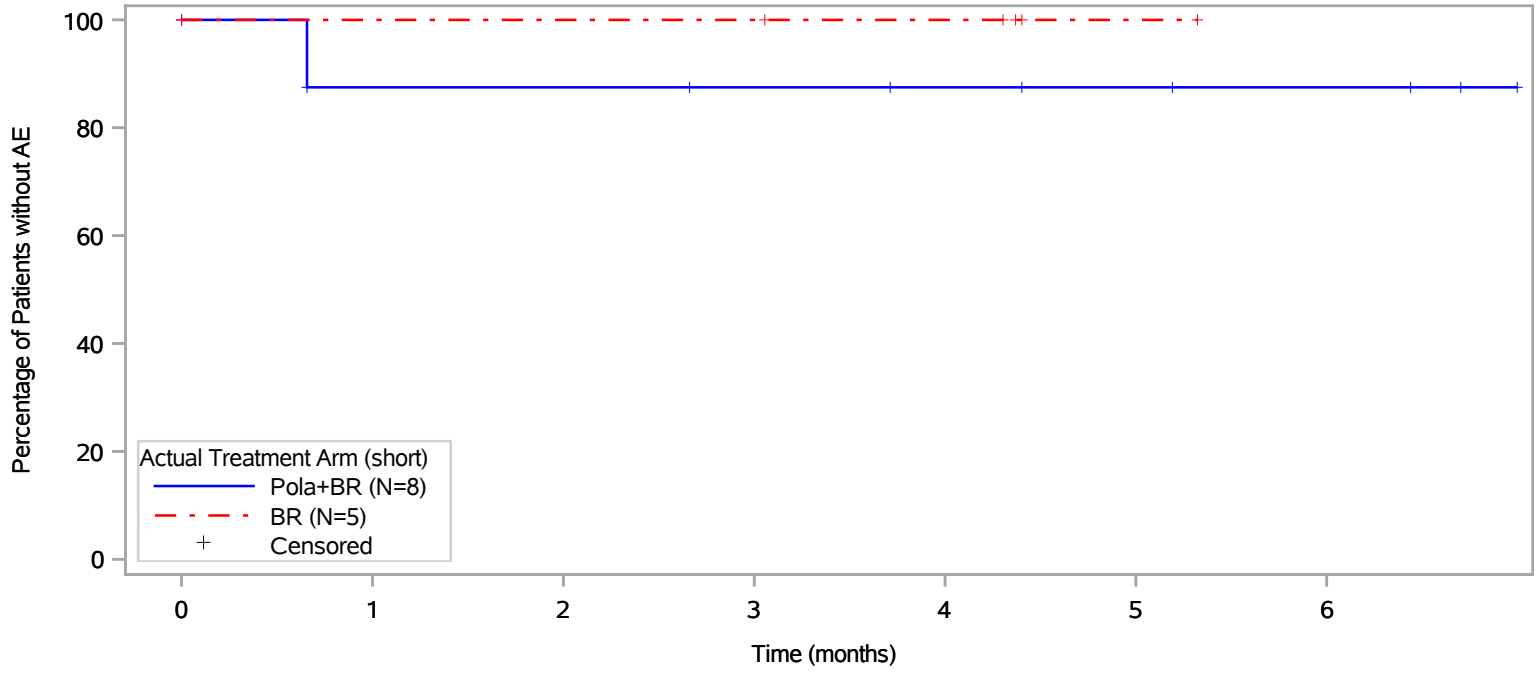
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HEPATITIS B REACTIVATION



Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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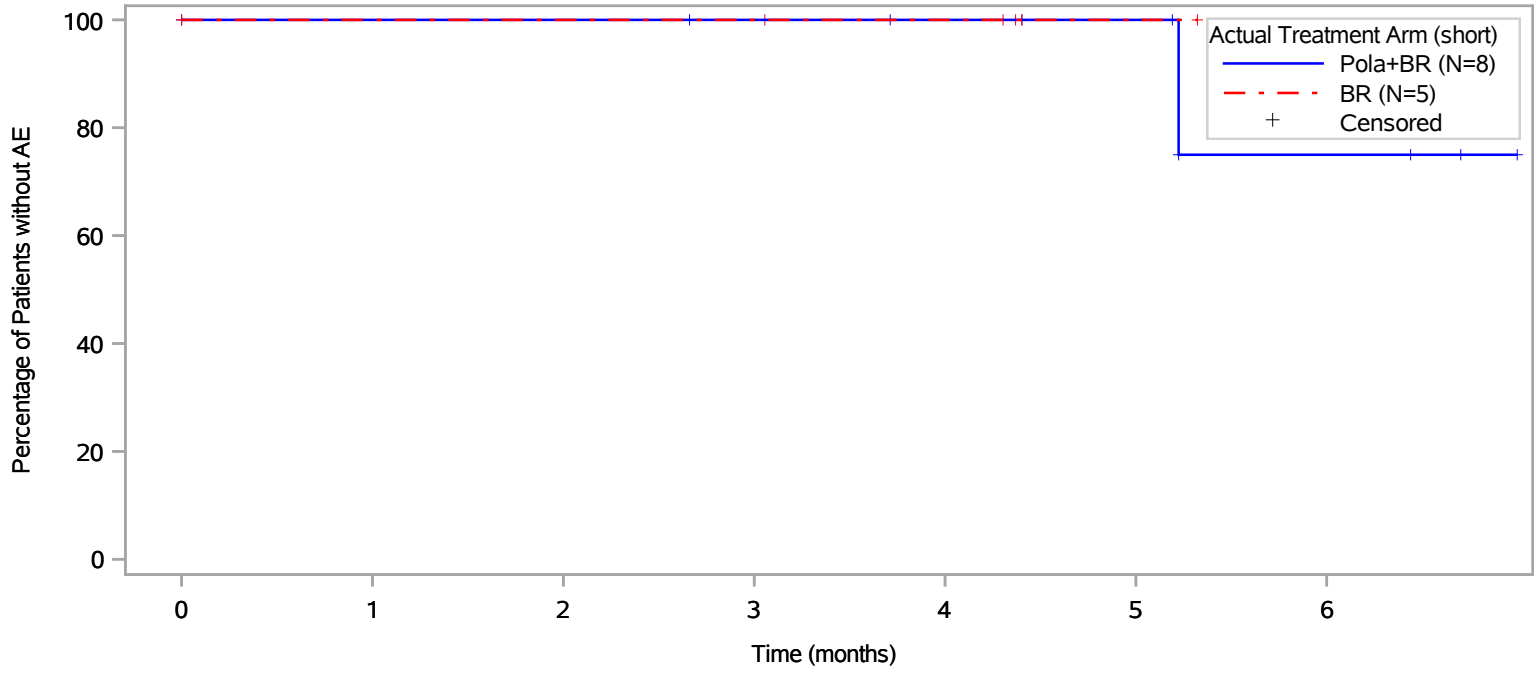
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER

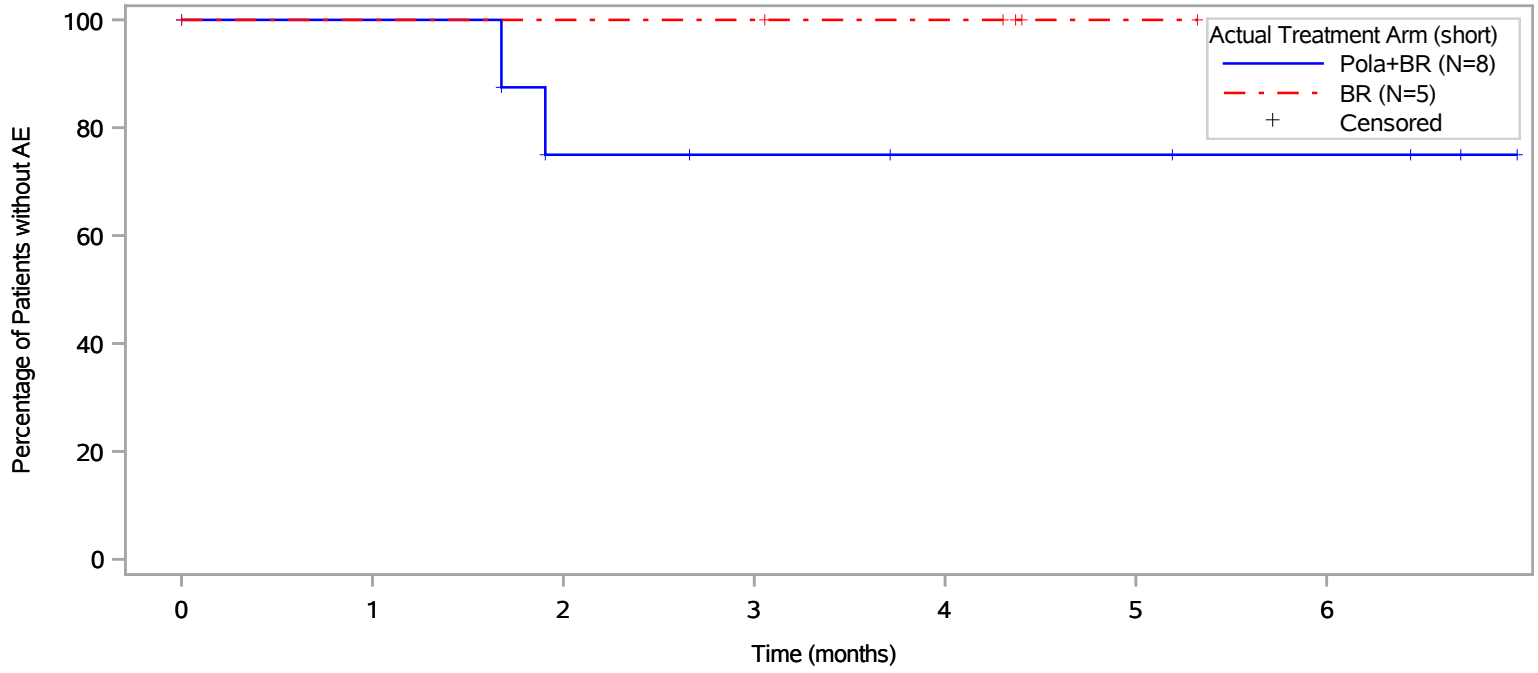


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA

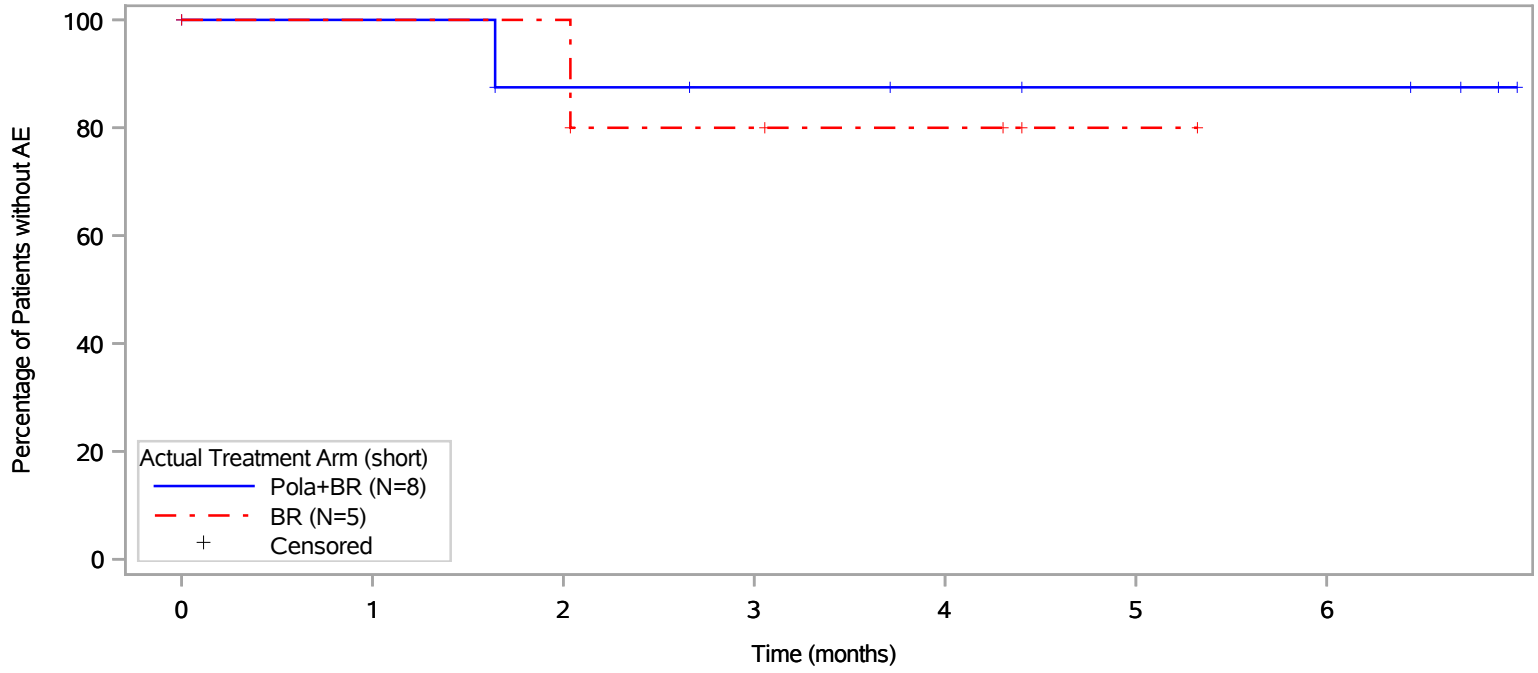


Patients at risk							
Pola+BR (N=8)	8	8	6	5	4	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UPPER RESPIRATORY TRACT INFECTION



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	4
BR (N=5)	5	5	5	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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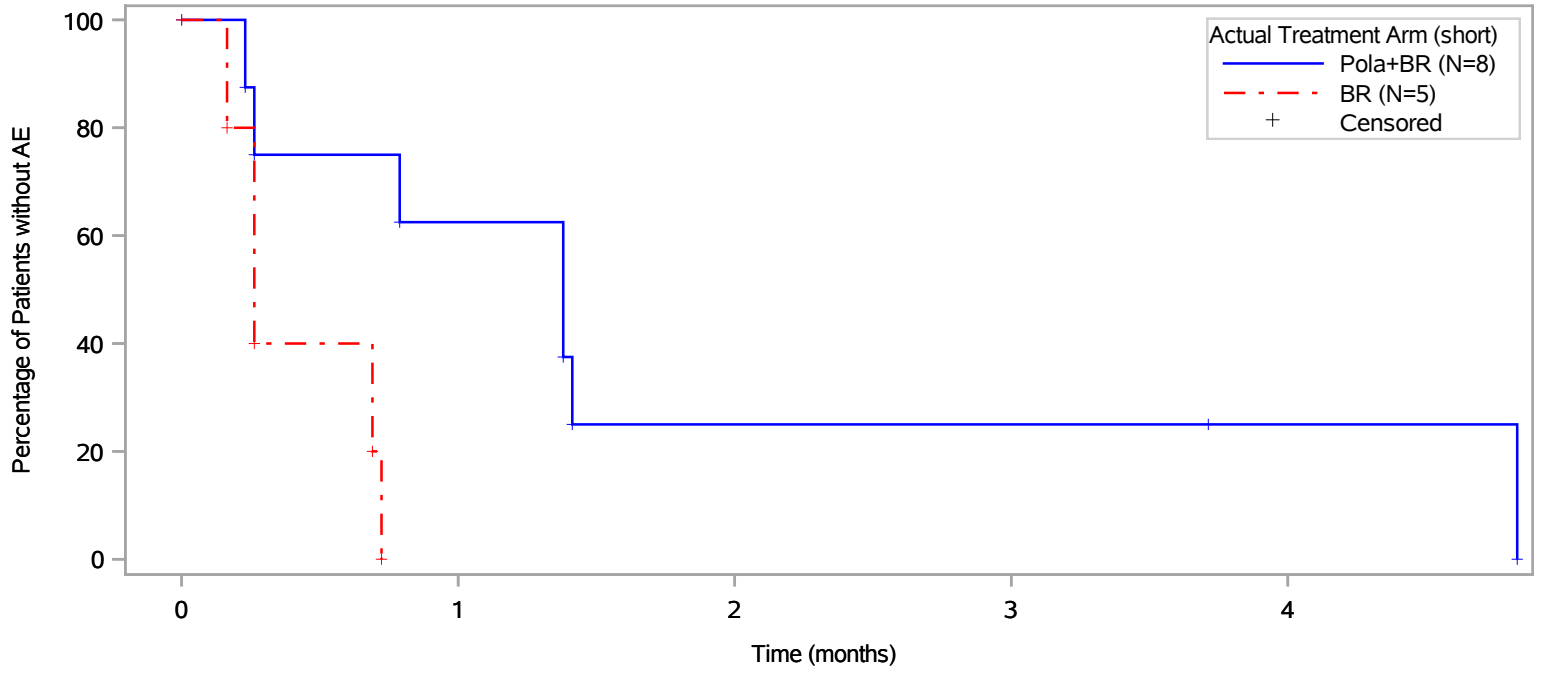
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk					
Pola+BR (N=8)	8	5	2	2	1
BR (N=5)	5	NE	NE	NE	NE
Patients censored					
Pola+BR (N=8)	0	0	0	0	1
BR (N=5)	0	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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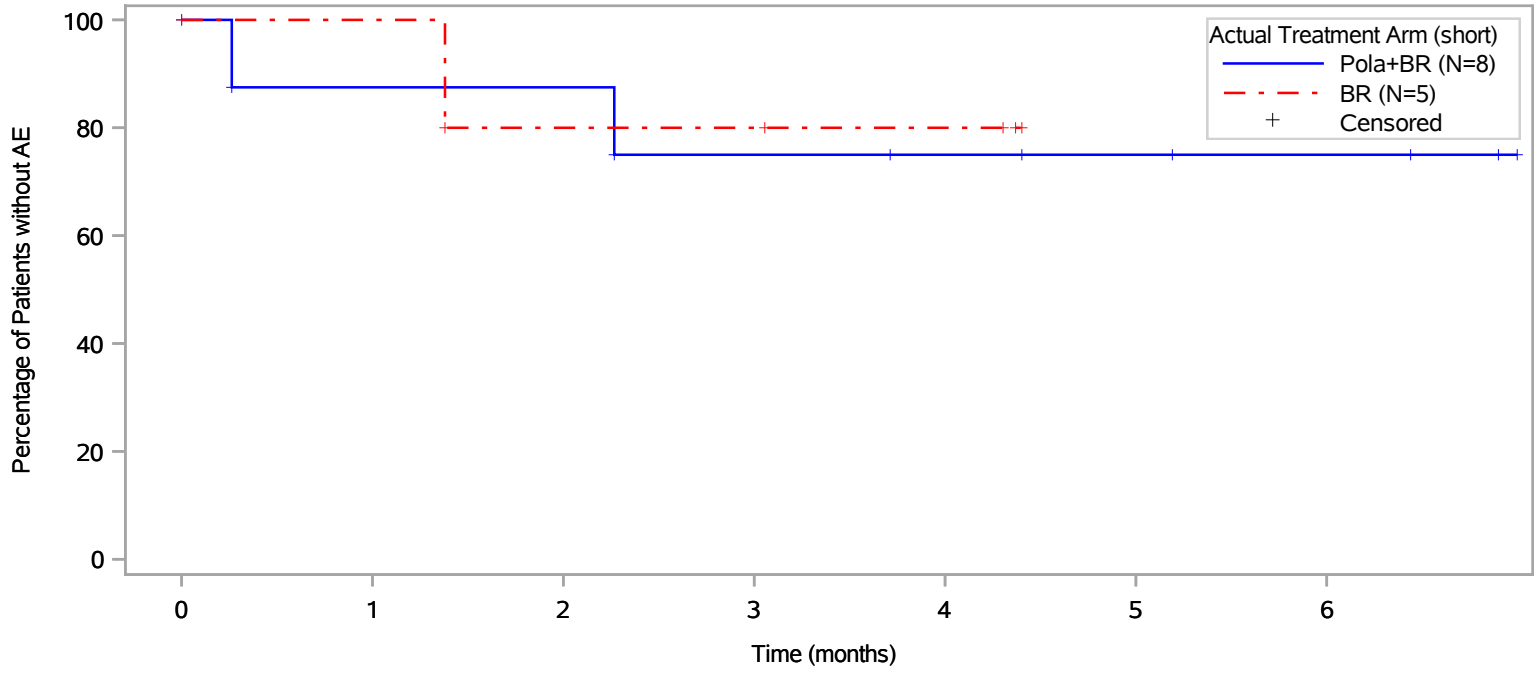
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ALANINE AMINOTRANSFERASE INCREASED



Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	3
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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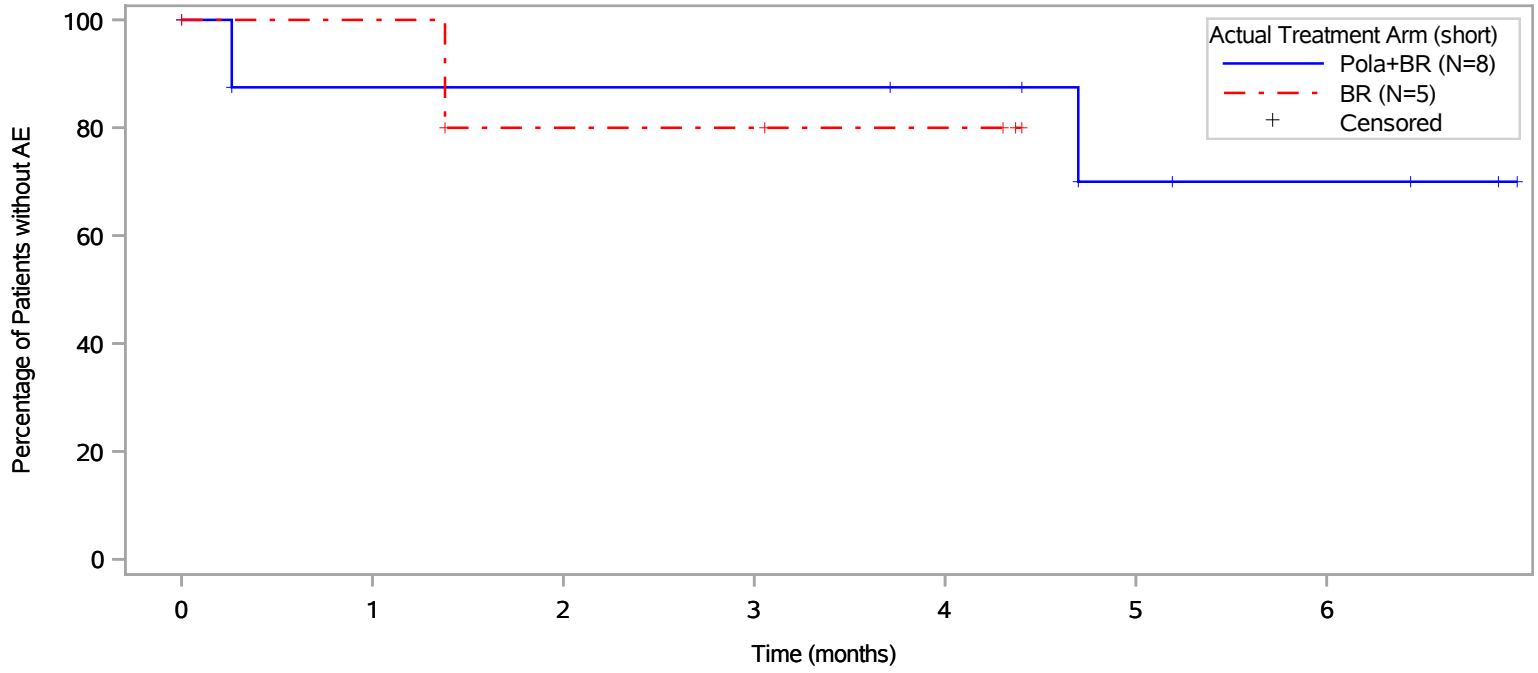
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ASPARTATE AMINOTRANSFERASE INCREASED



Patients at risk							
Pola+BR (N=8)	8	7	7	7	6	4	3
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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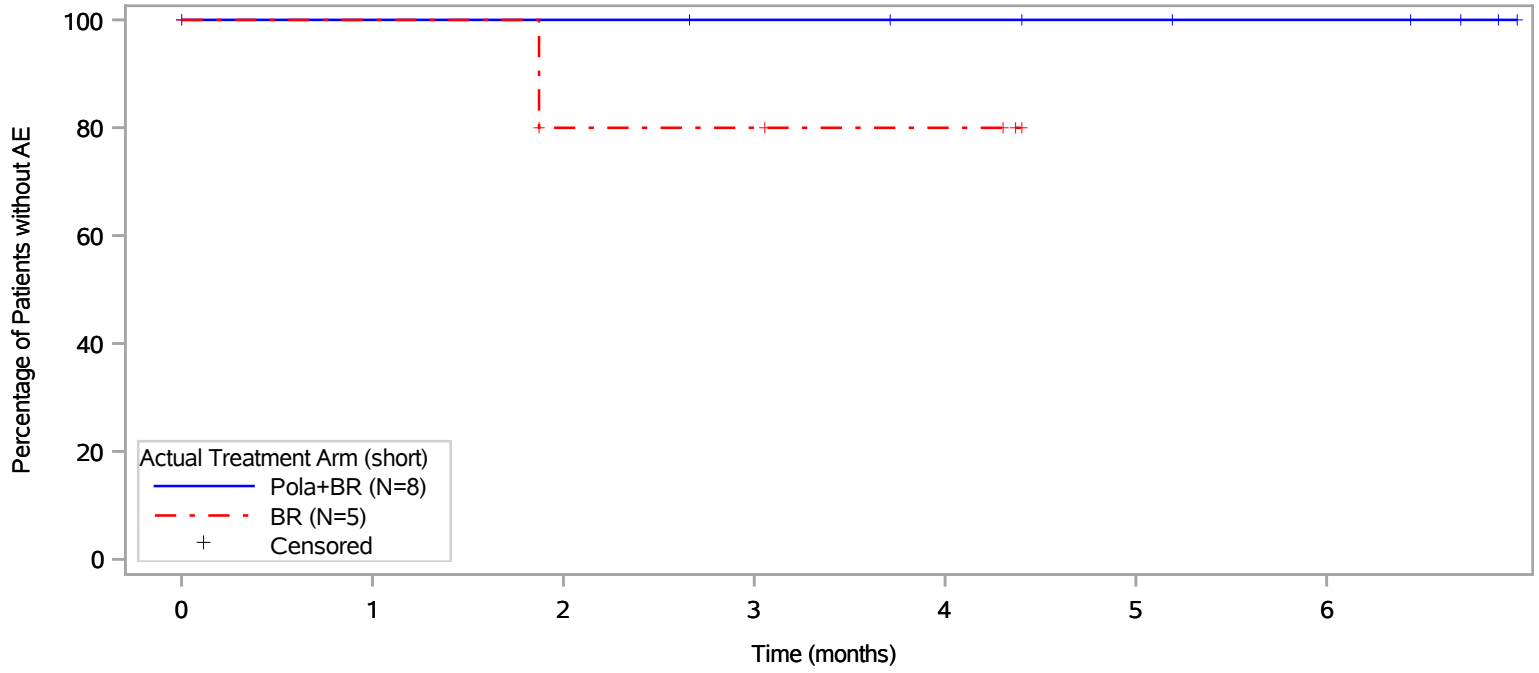
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BILIRUBIN CONJUGATED INCREASED

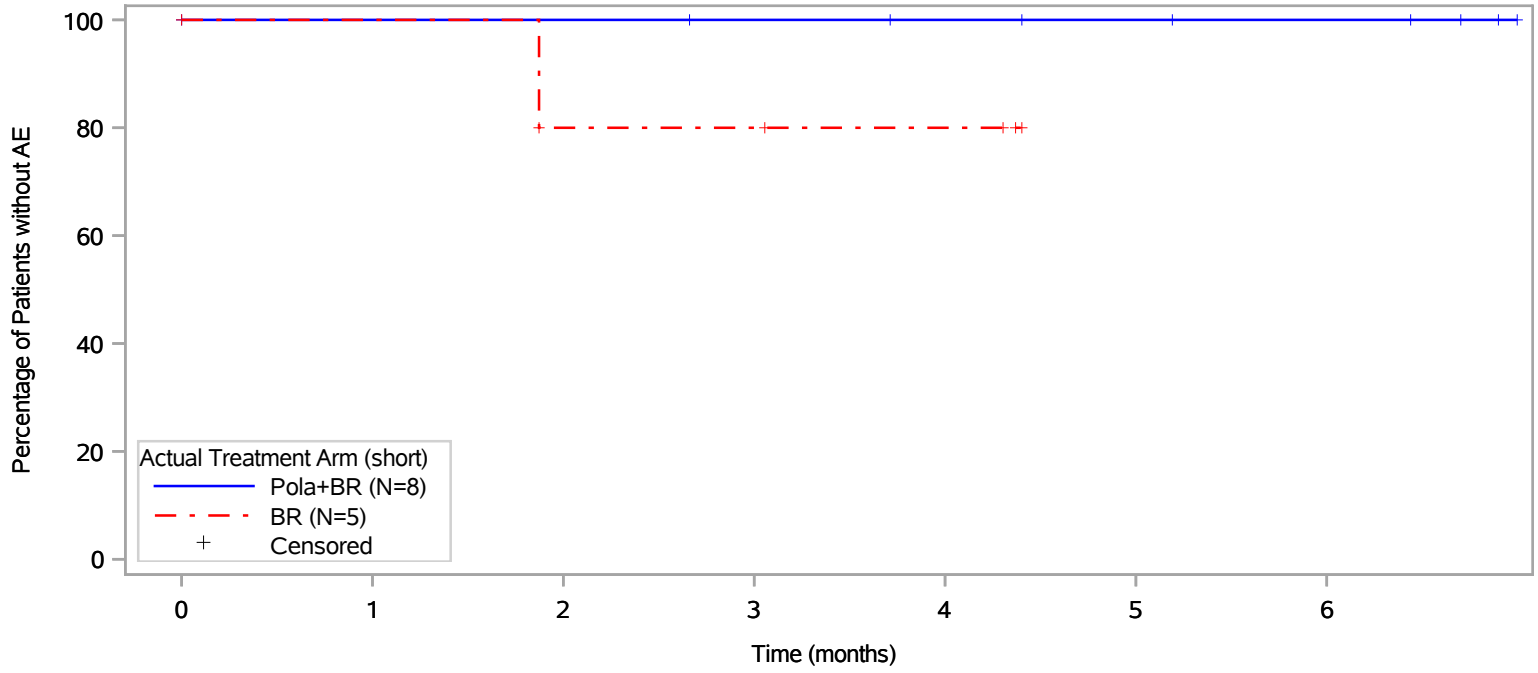


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD BILIRUBIN INCREASED



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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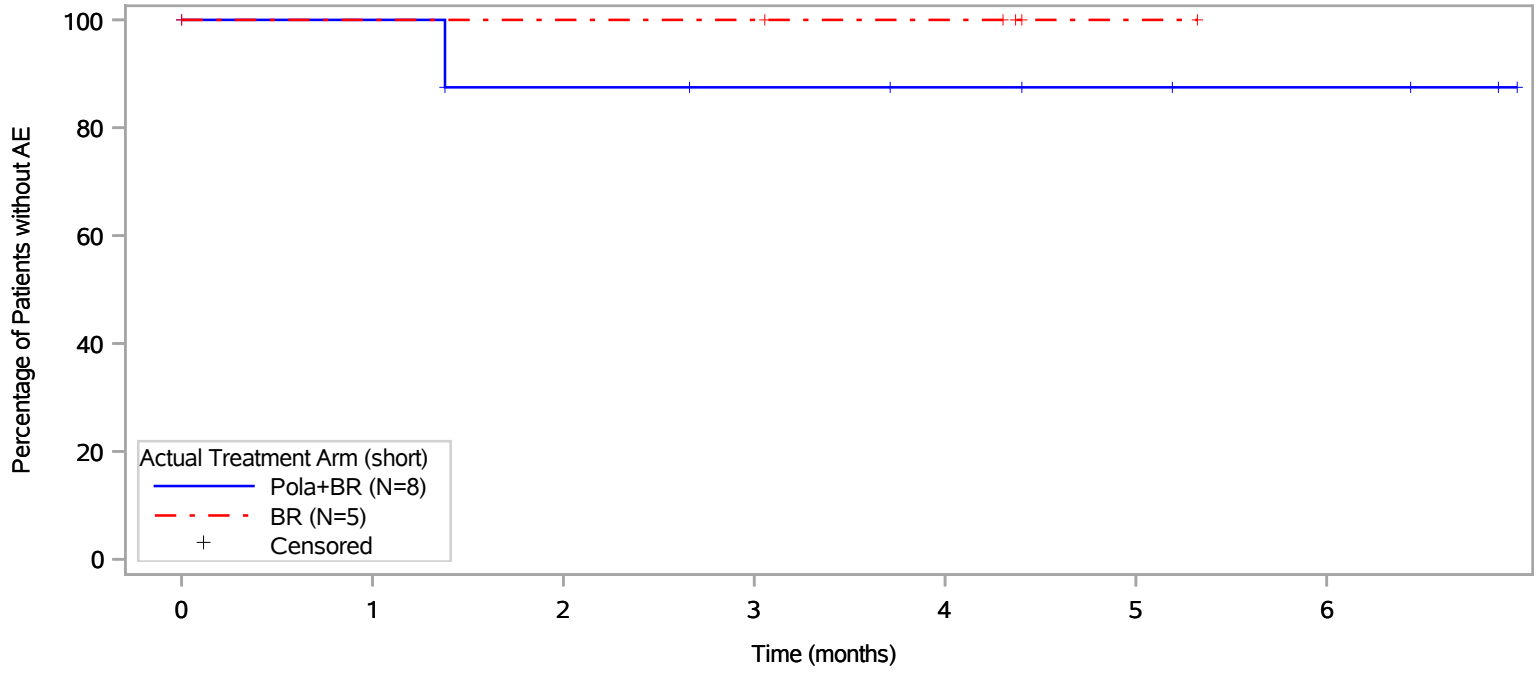
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD GLUCOSE INCREASED

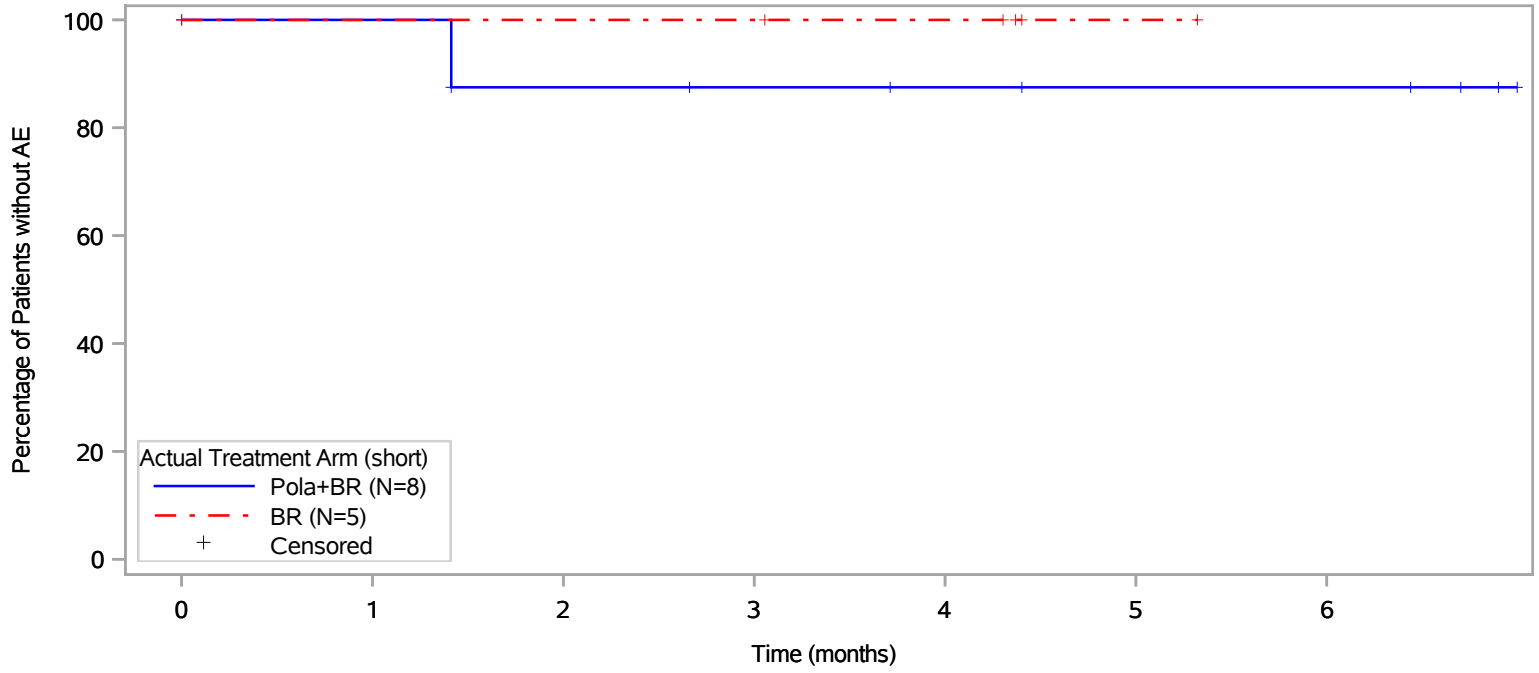


Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD LACTATE DEHYDROGENASE INCREASED

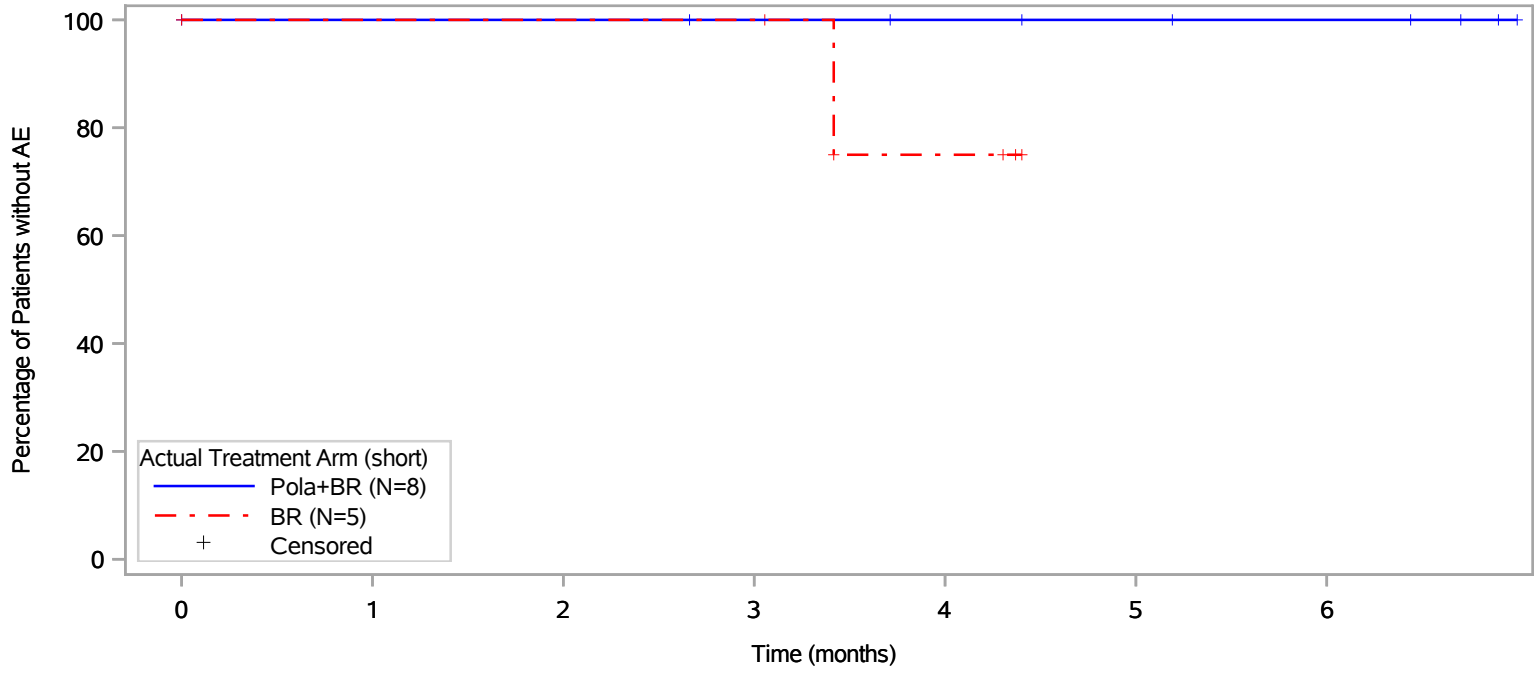


Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

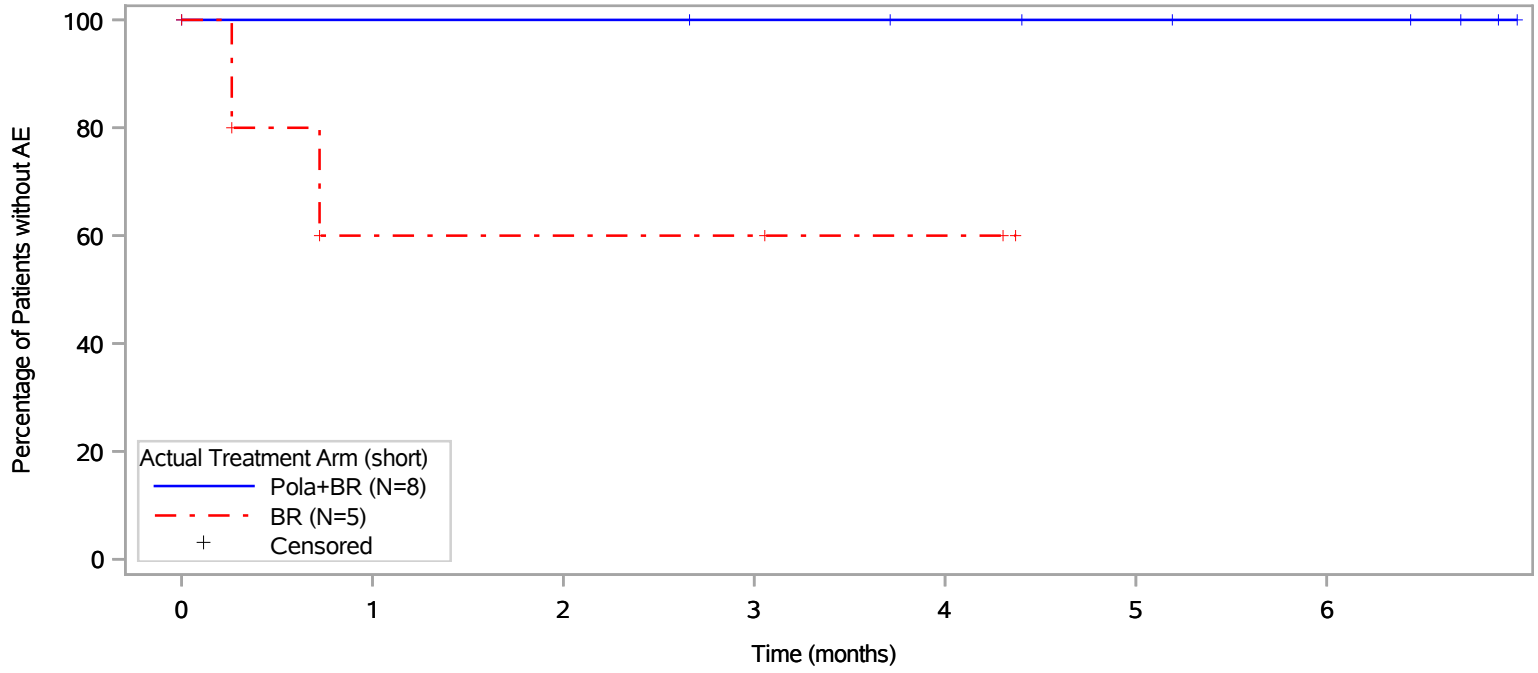
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GAMMA-GLUTAMYLTRANSFERASE INCREASED



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	3	3	3	2	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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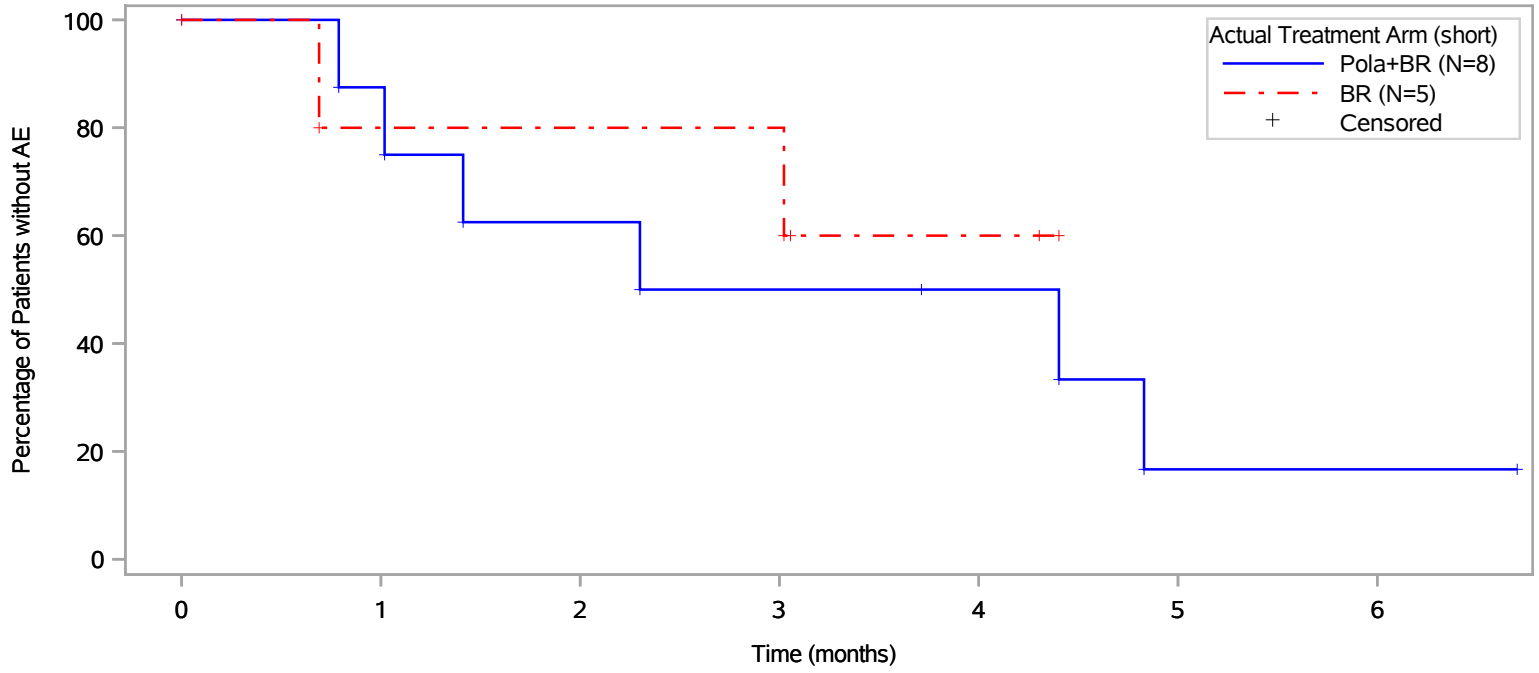
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk							
Pola+BR (N=8)	8	7	5	4	3	1	1
BR (N=5)	5	4	4	4	2	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	1
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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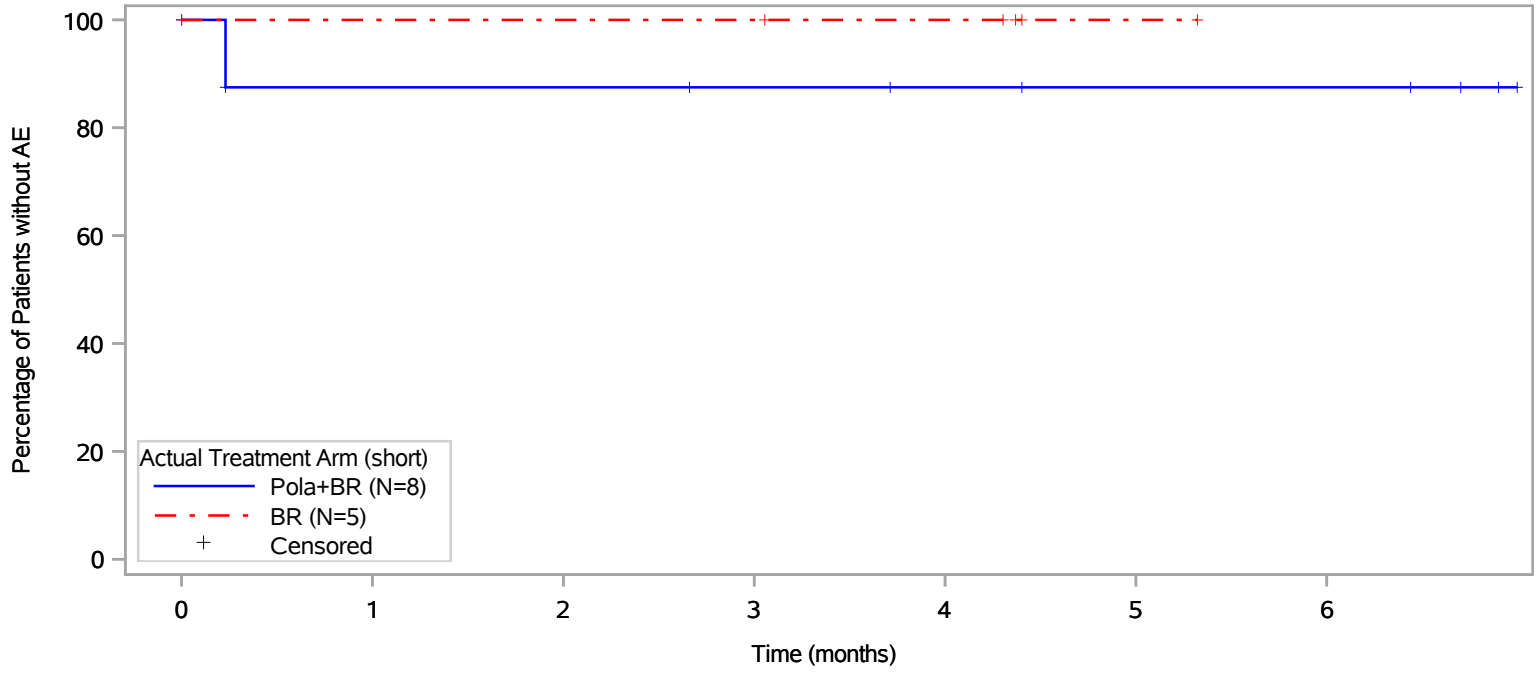
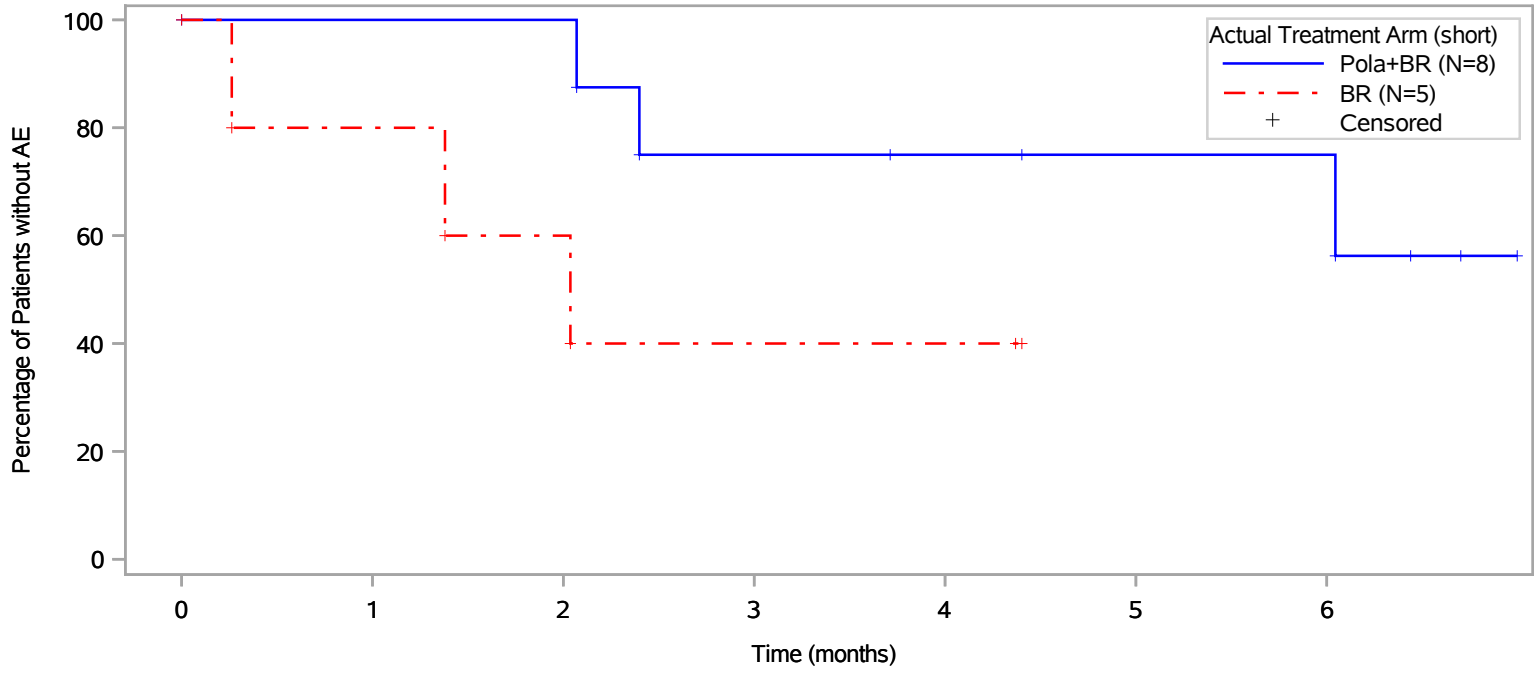
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT INCREASED



Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

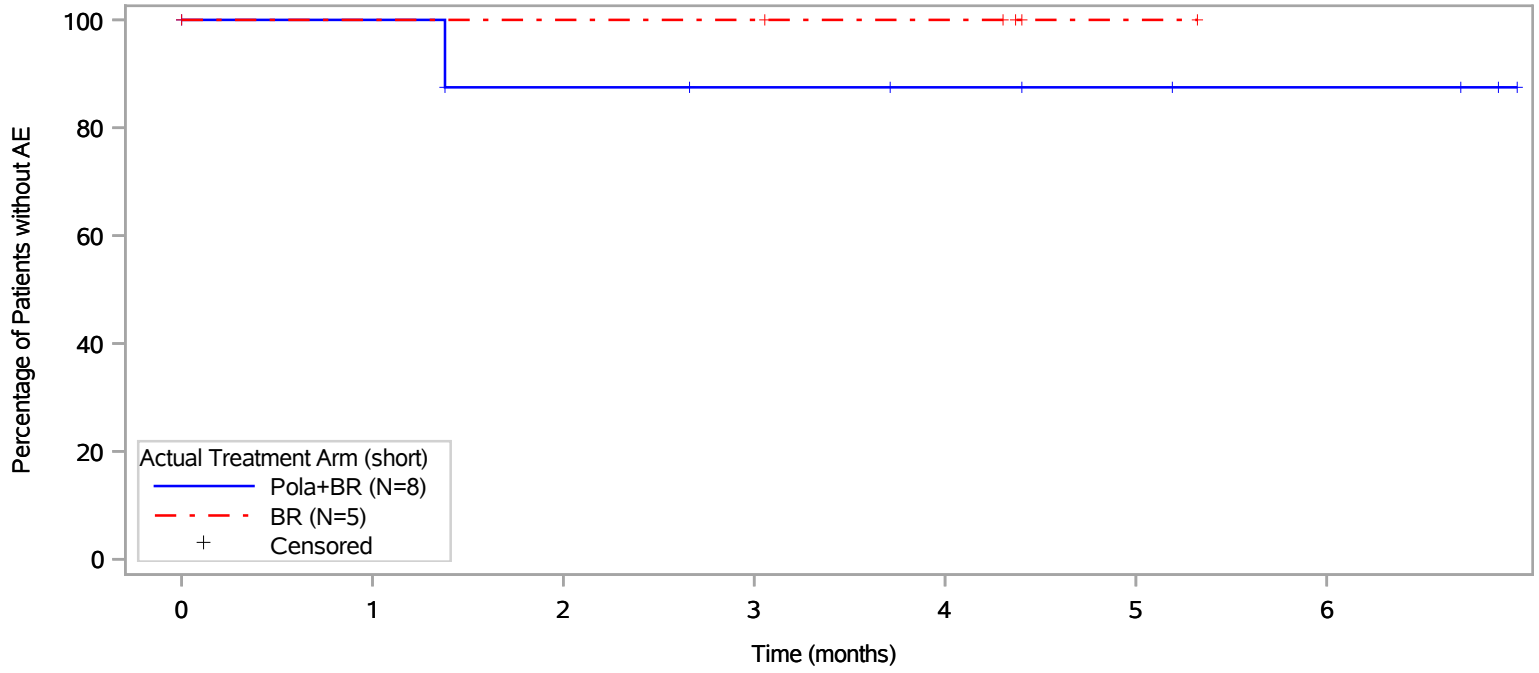


Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	4	3	2	2	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	2
BR (N=5)	0	0	0	0	0	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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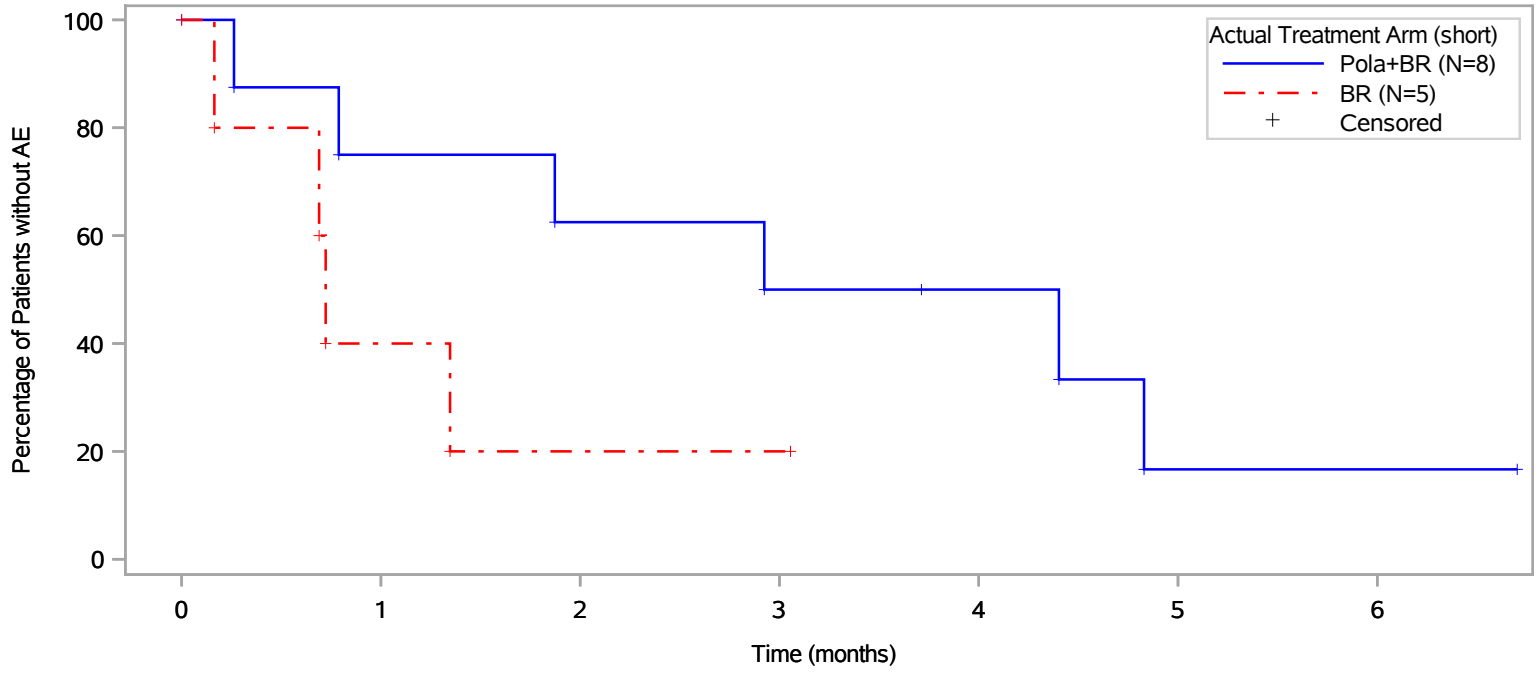
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED

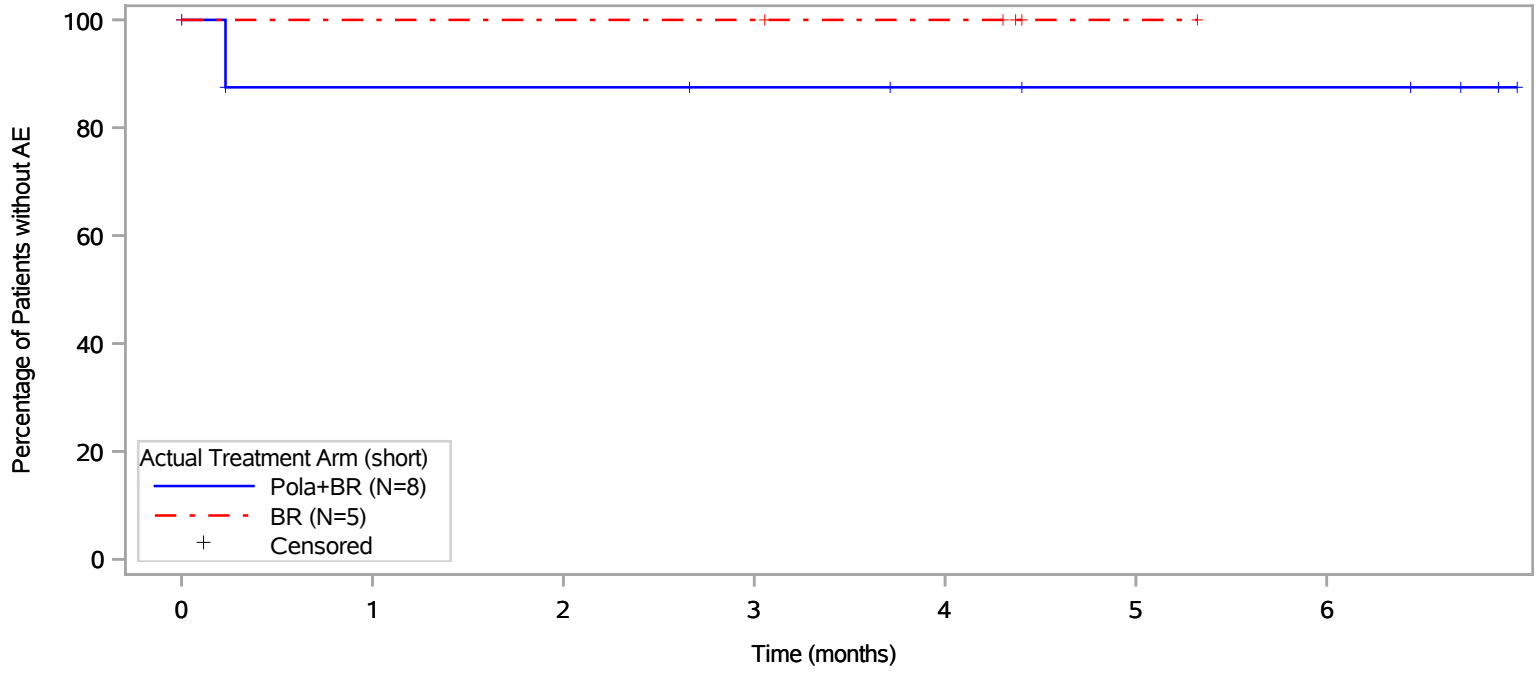


Patients at risk							
Pola+BR (N=8)	8	6	5	4	3	1	1
BR (N=5)	5	2	1	1	NE	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	1
BR (N=5)	0	0	0	0	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT INCREASED

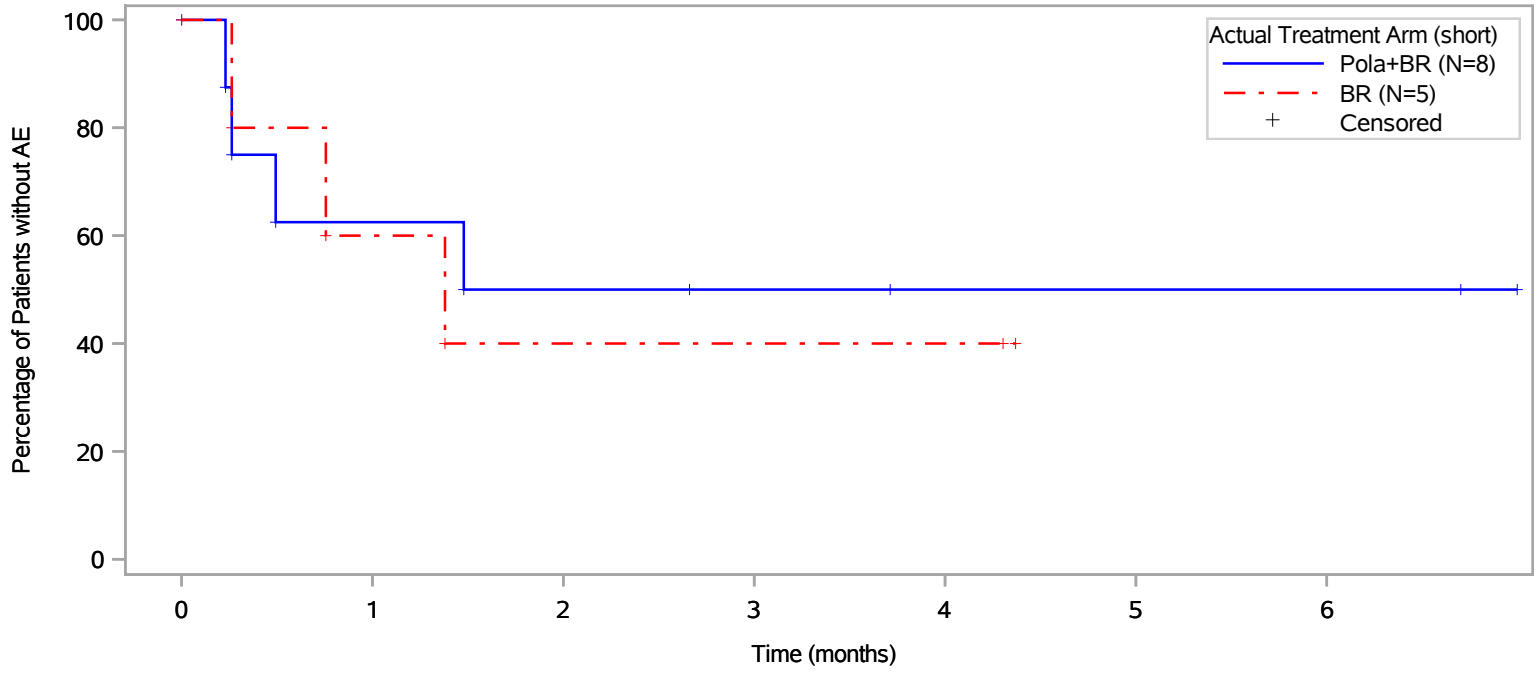


Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
01DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	5	4	3	2	2	2
BR (N=5)	5	3	2	2	2	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	2
BR (N=5)	0	0	0	0	0	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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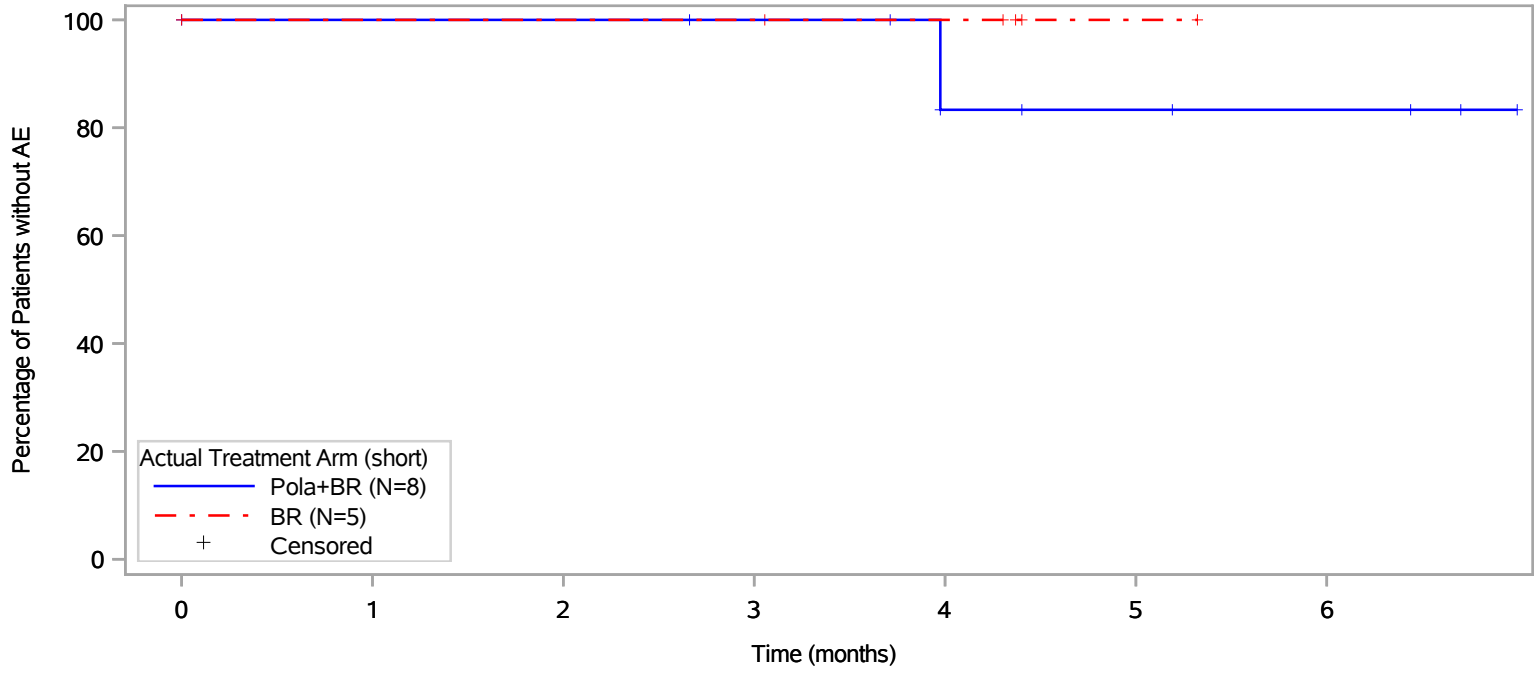
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE



Patients at risk							
Pola+BR (N=8)	8	8	8	7	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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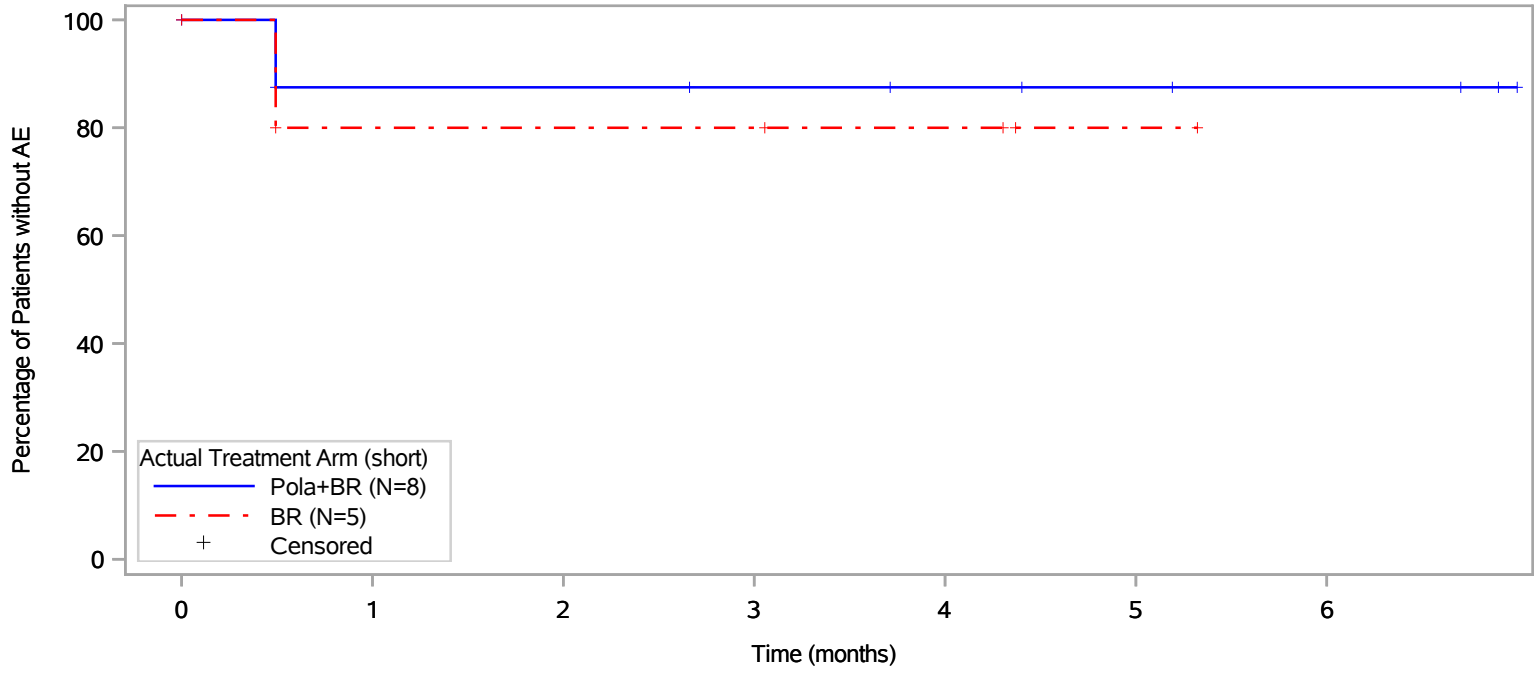
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPERLIPIDAEMIA



Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	3
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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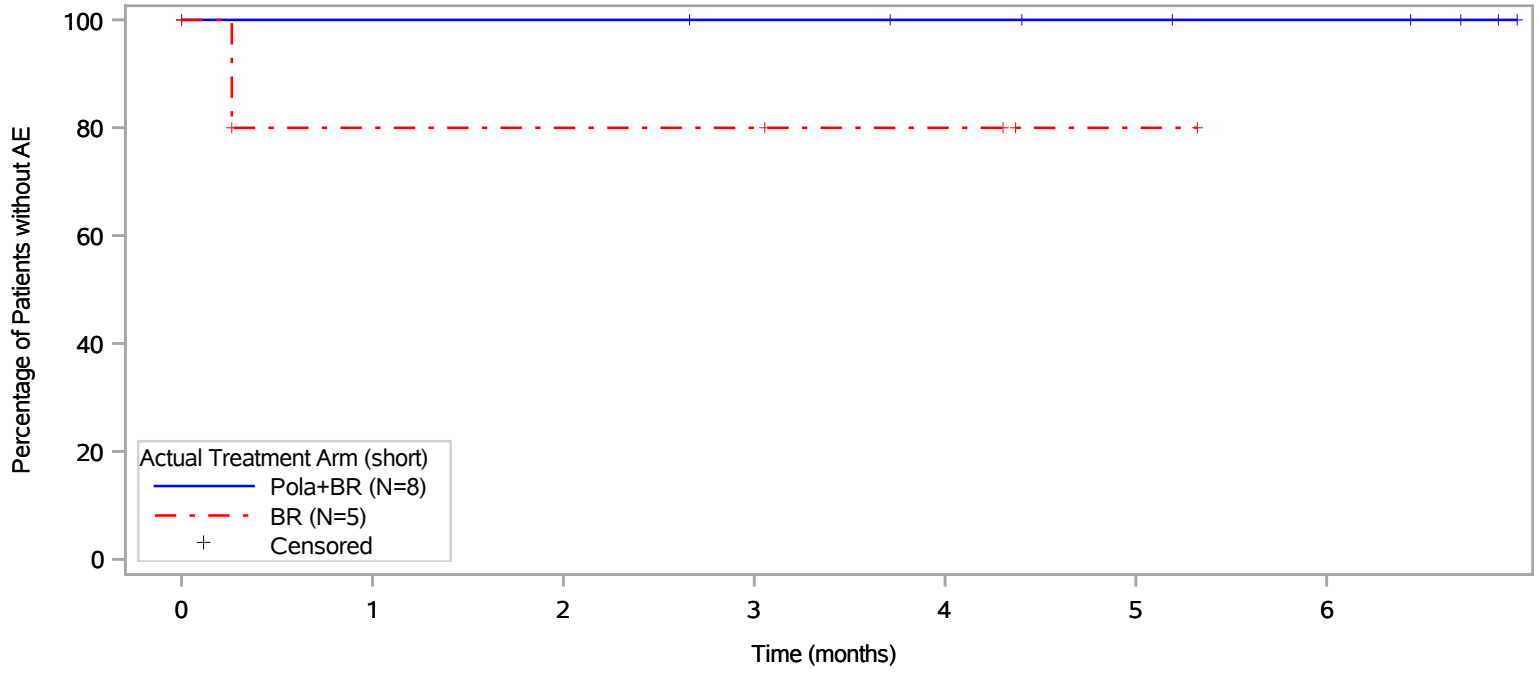
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERURICAEMIA



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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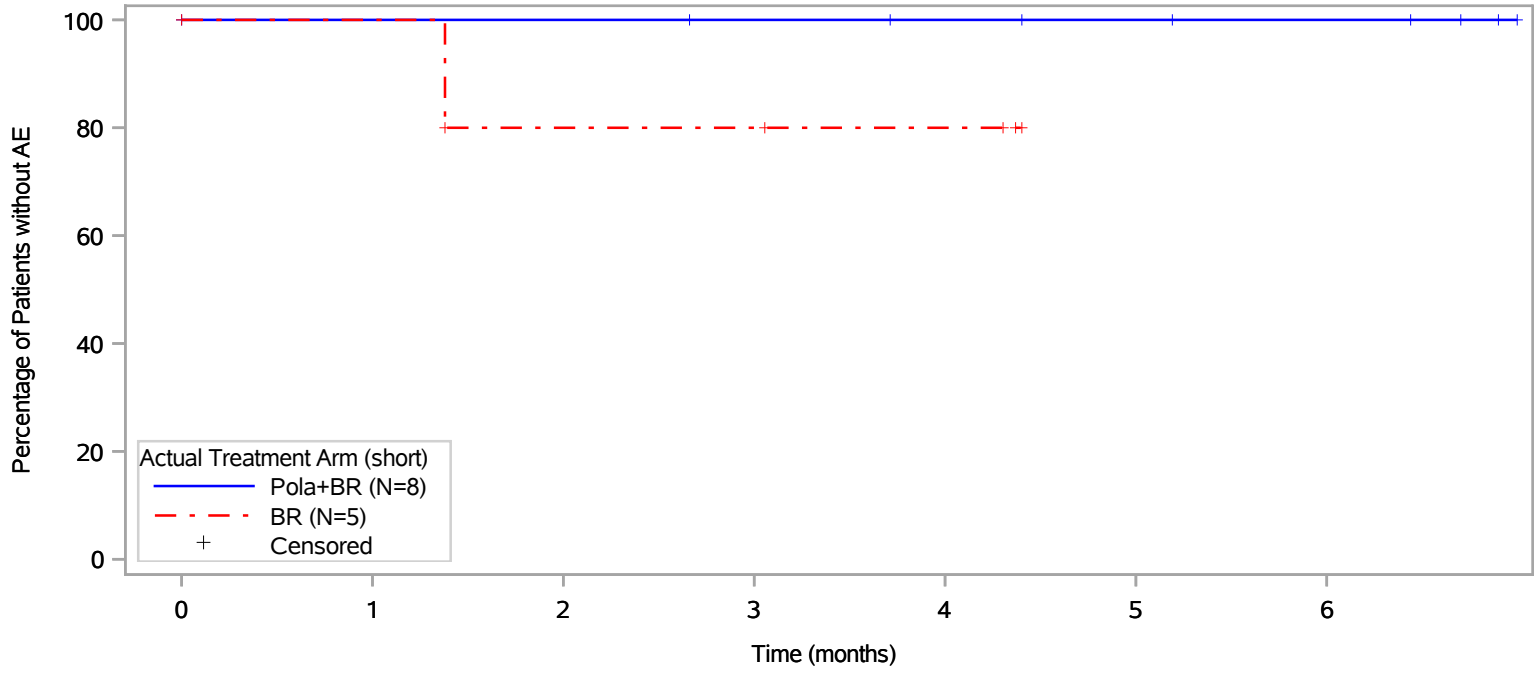
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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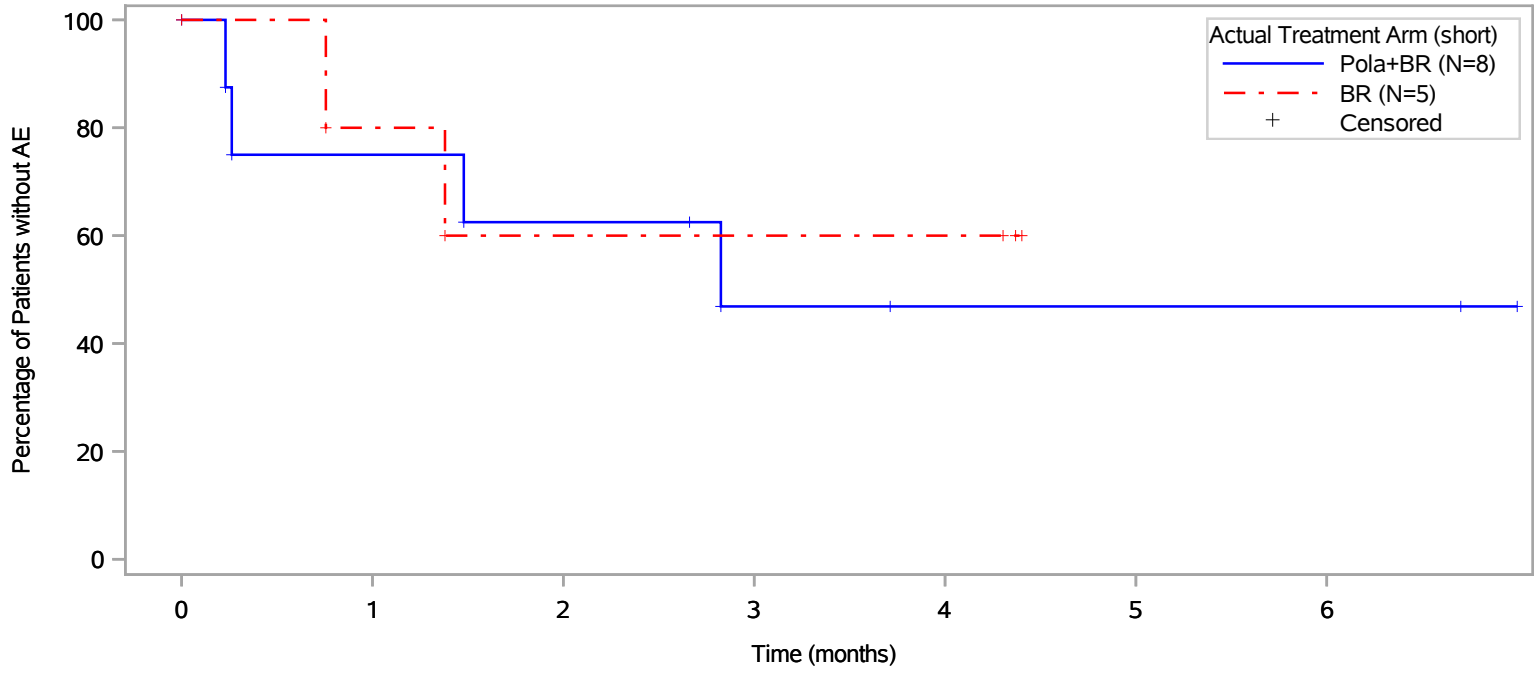
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk							
Pola+BR (N=8)	8	6	5	3	2	2	2
BR (N=5)	5	4	3	3	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	2
BR (N=5)	0	0	0	0	0	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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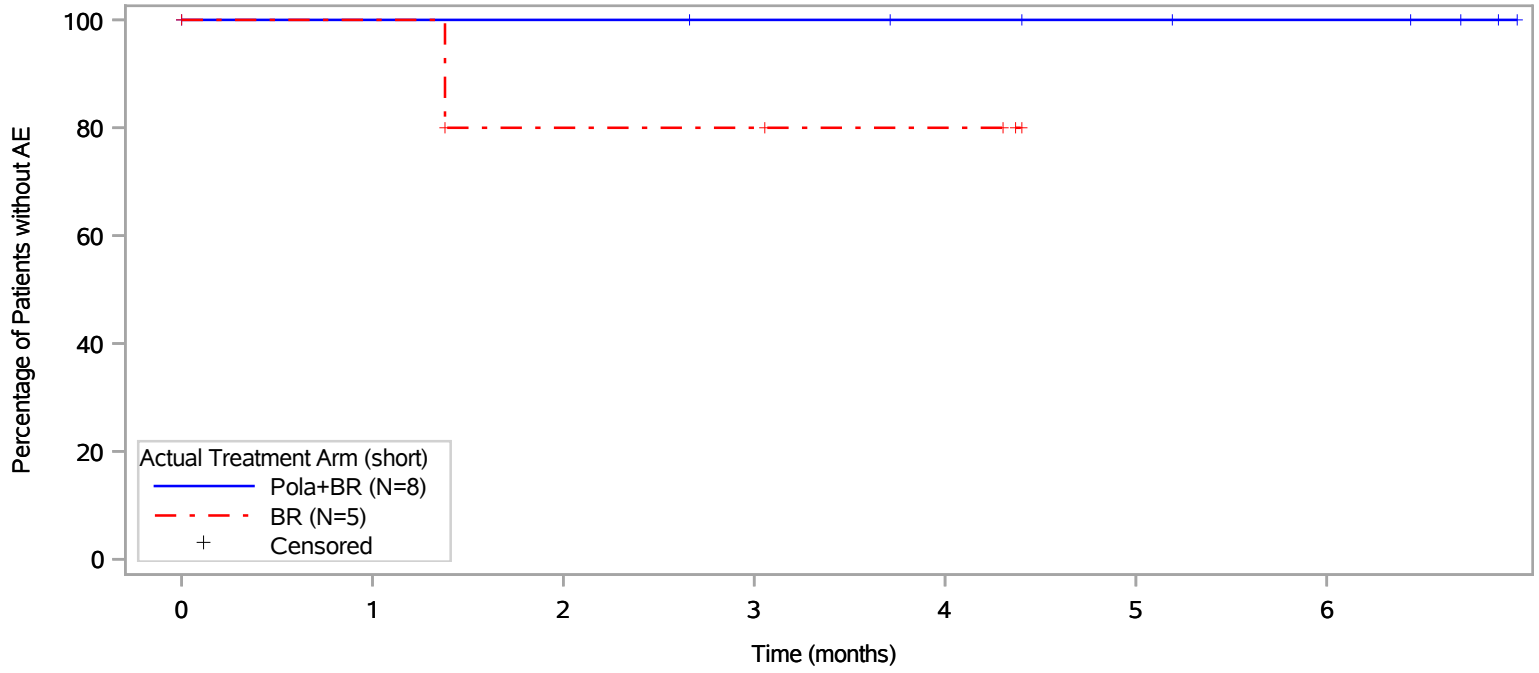
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPONATRAEMIA



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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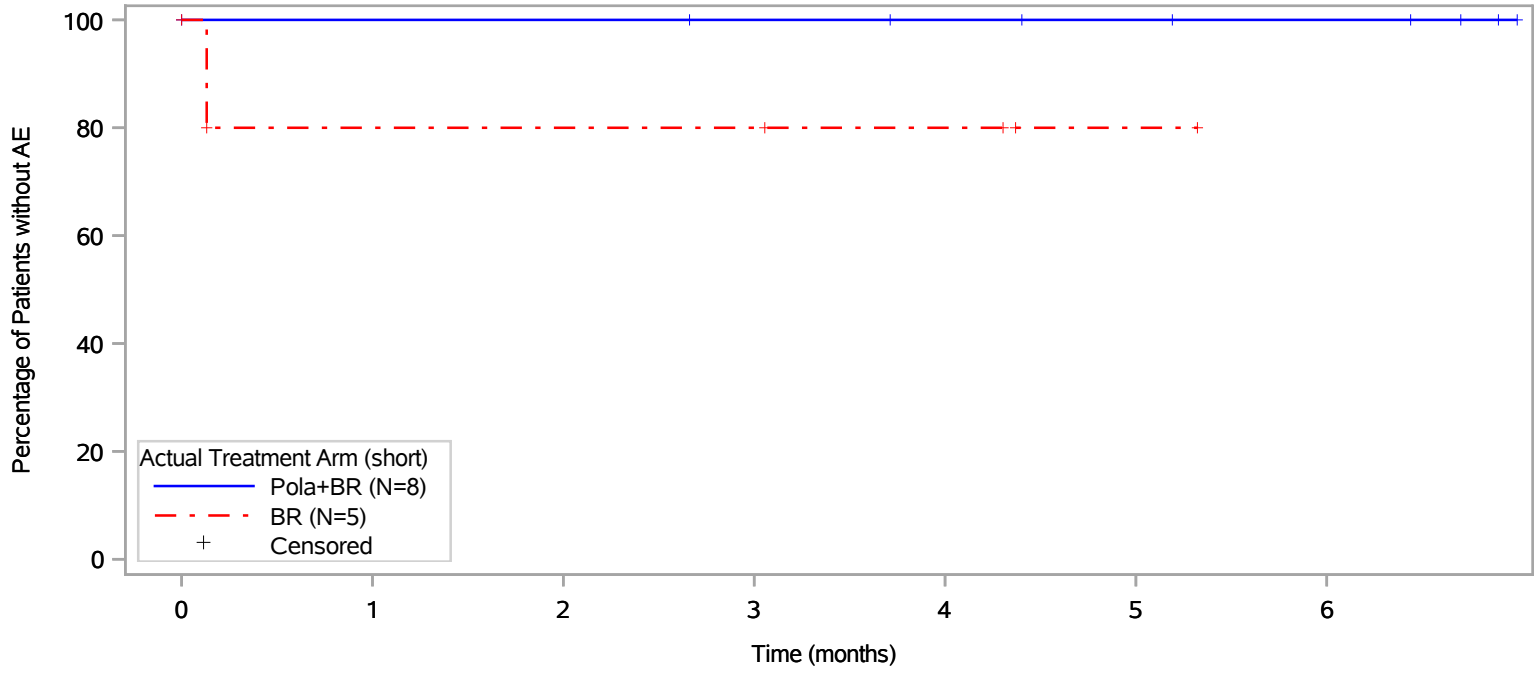
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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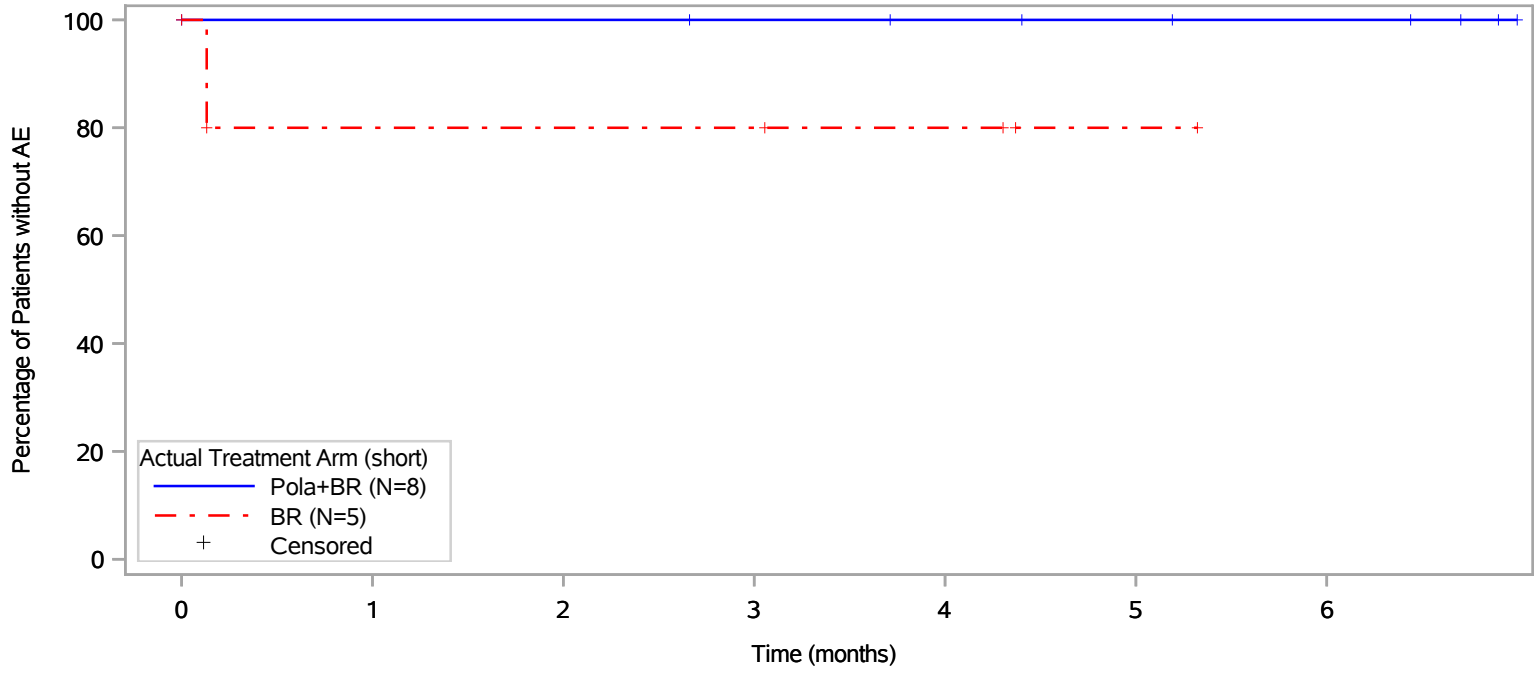
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, ARTHRALGIA



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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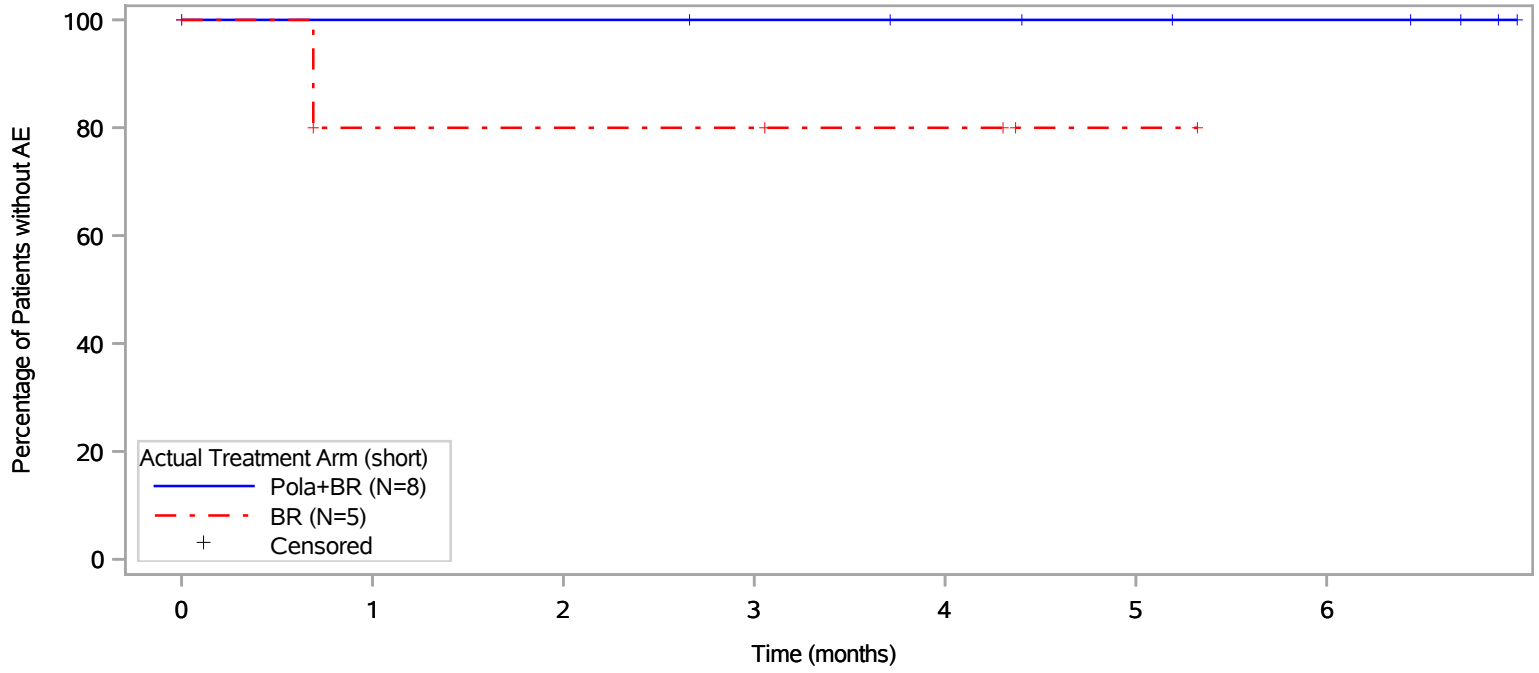
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, LIMB DISCOMFORT



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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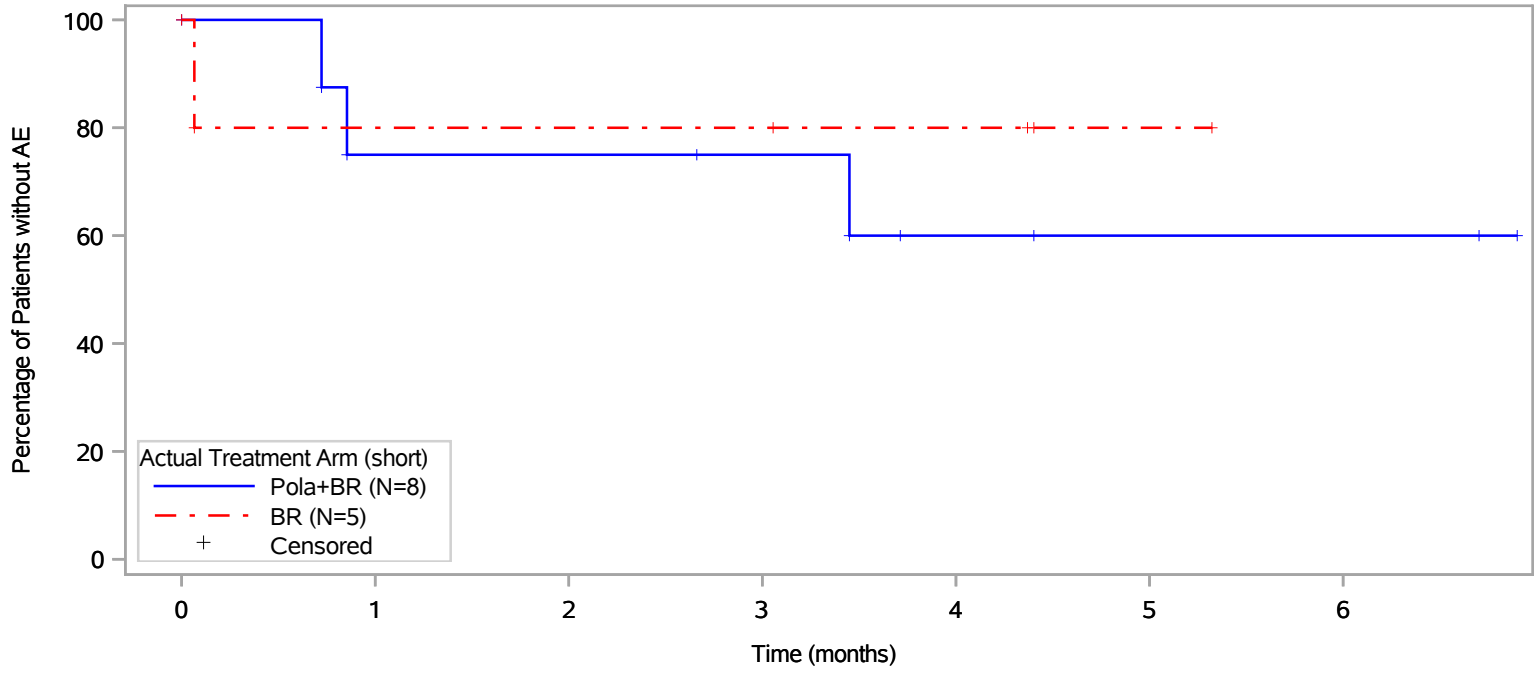
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	6	6	5	3	2	2
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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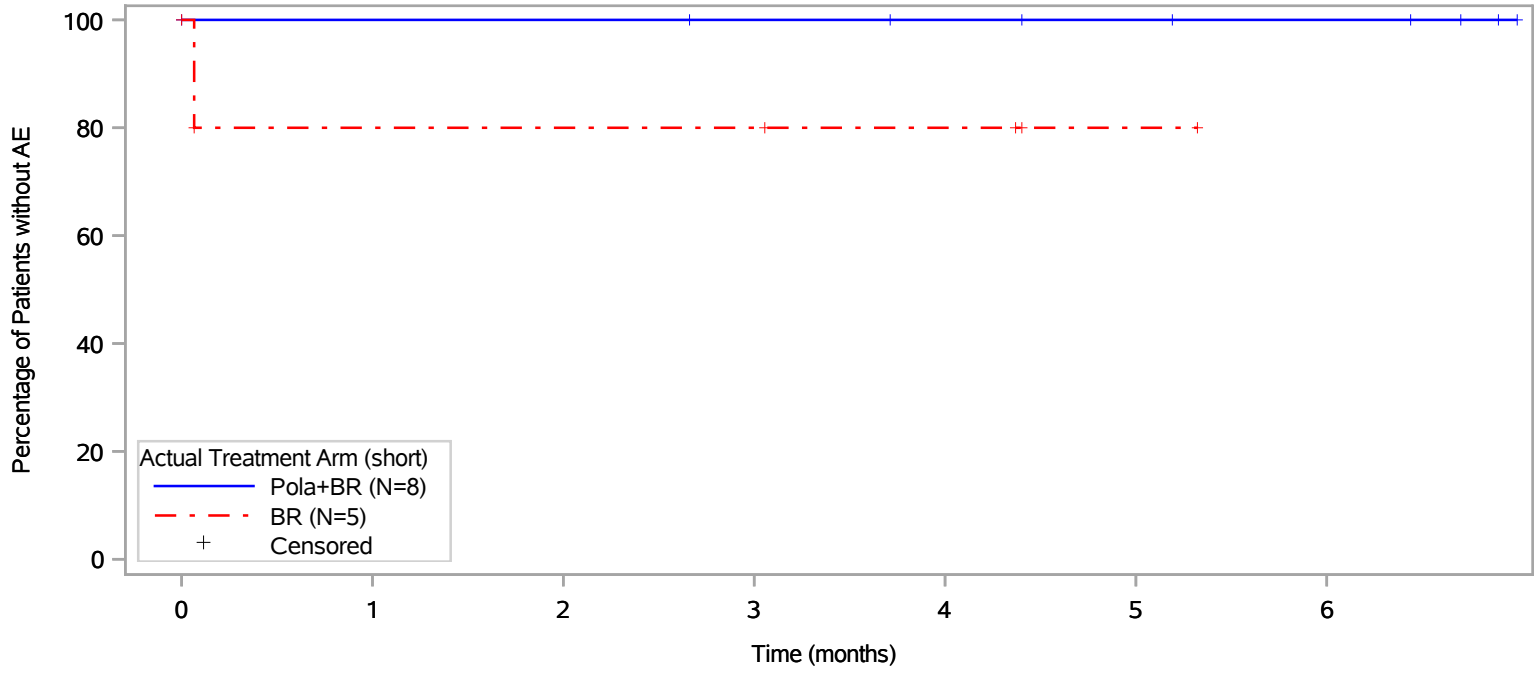
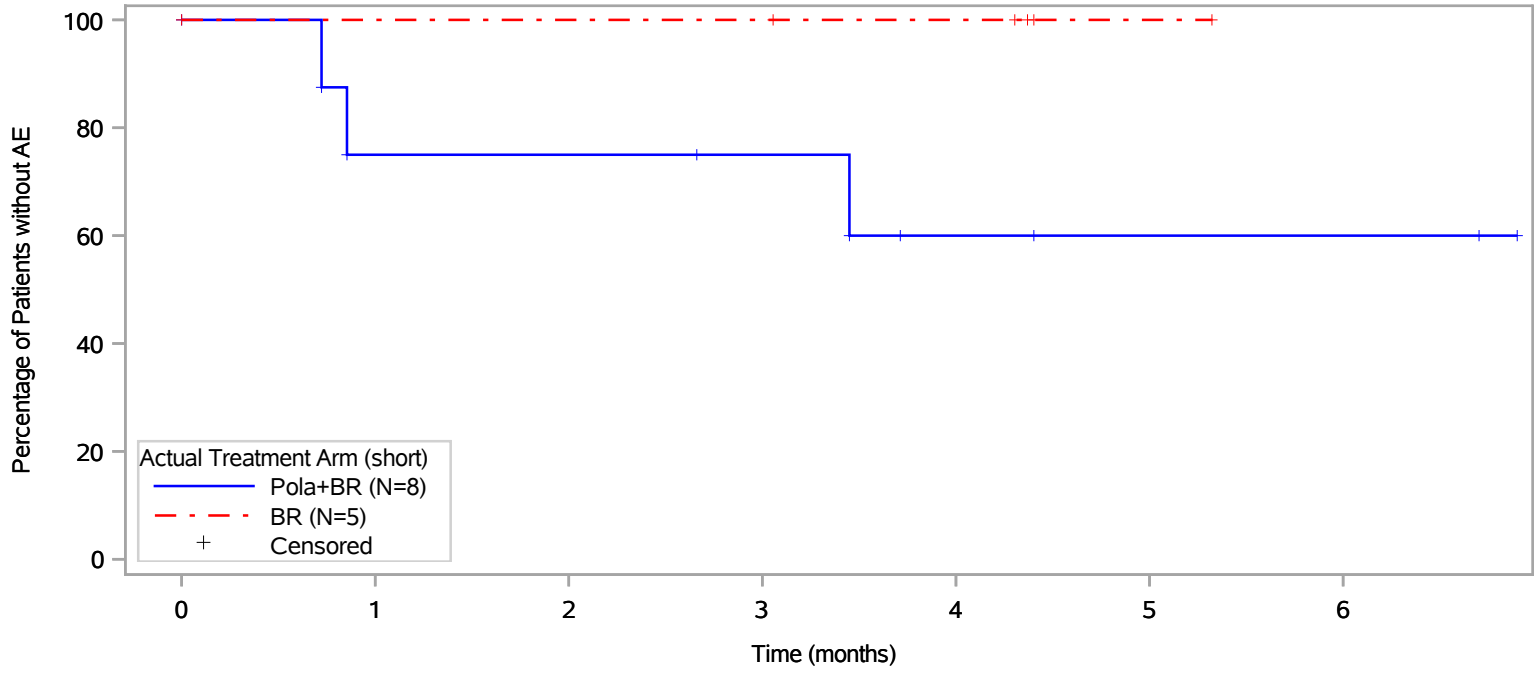
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, DYSGEUSIA



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, NEUROPATHY PERIPHERAL



Patients at risk							
Pola+BR (N=8)	8	6	6	5	3	2	2
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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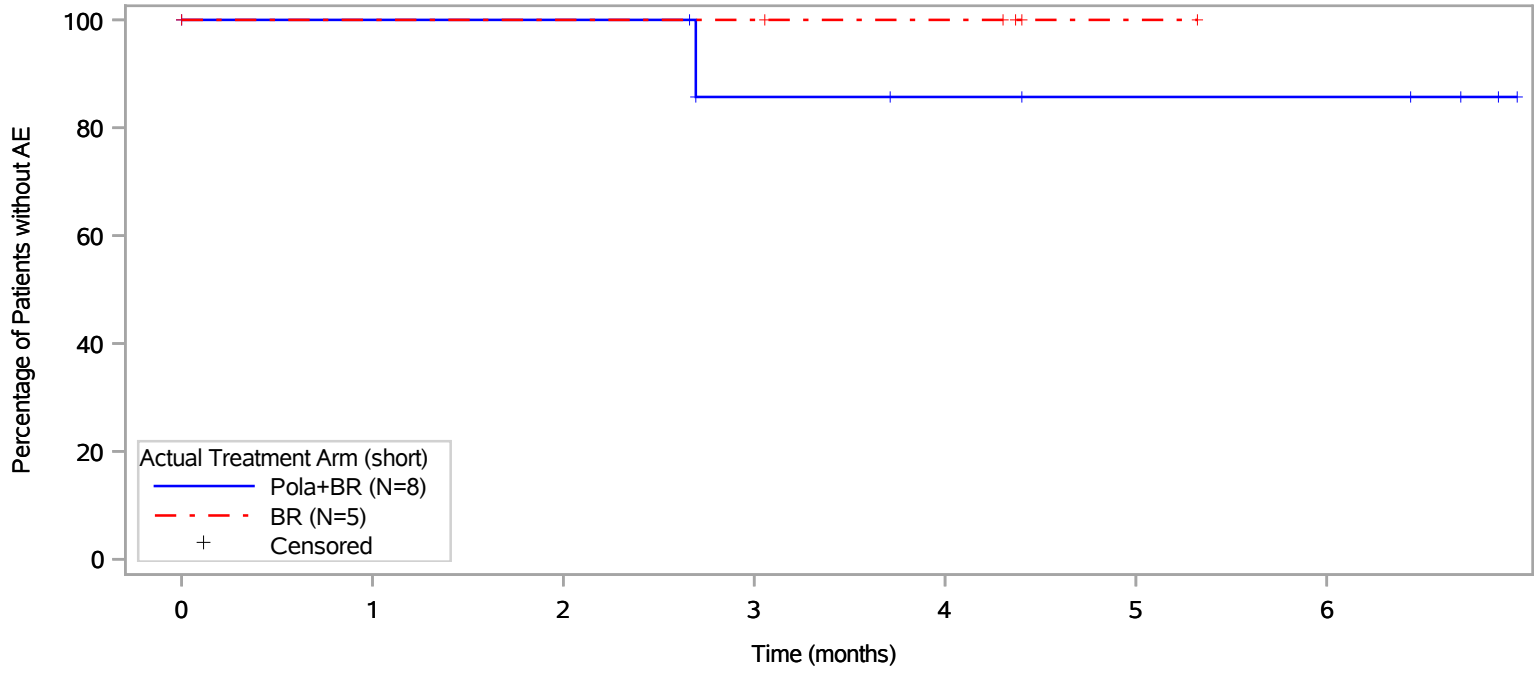
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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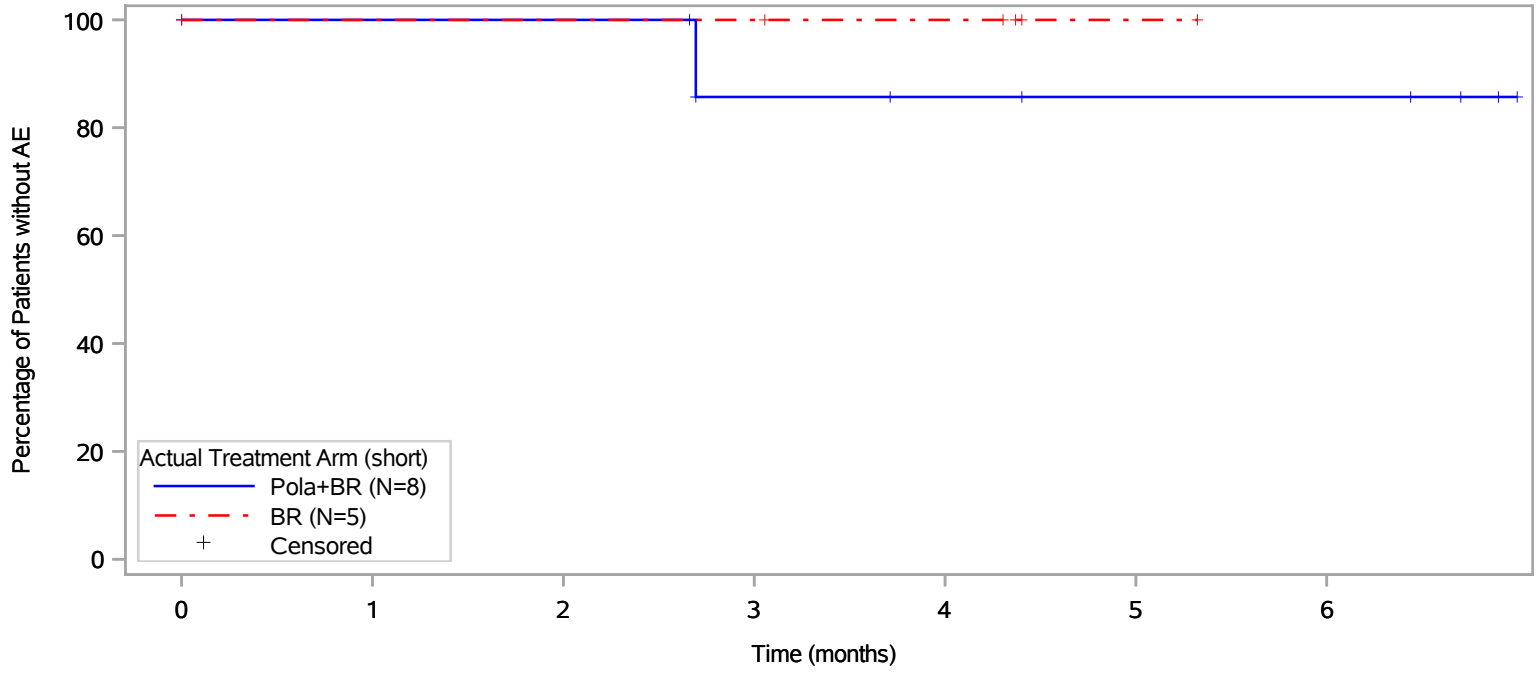
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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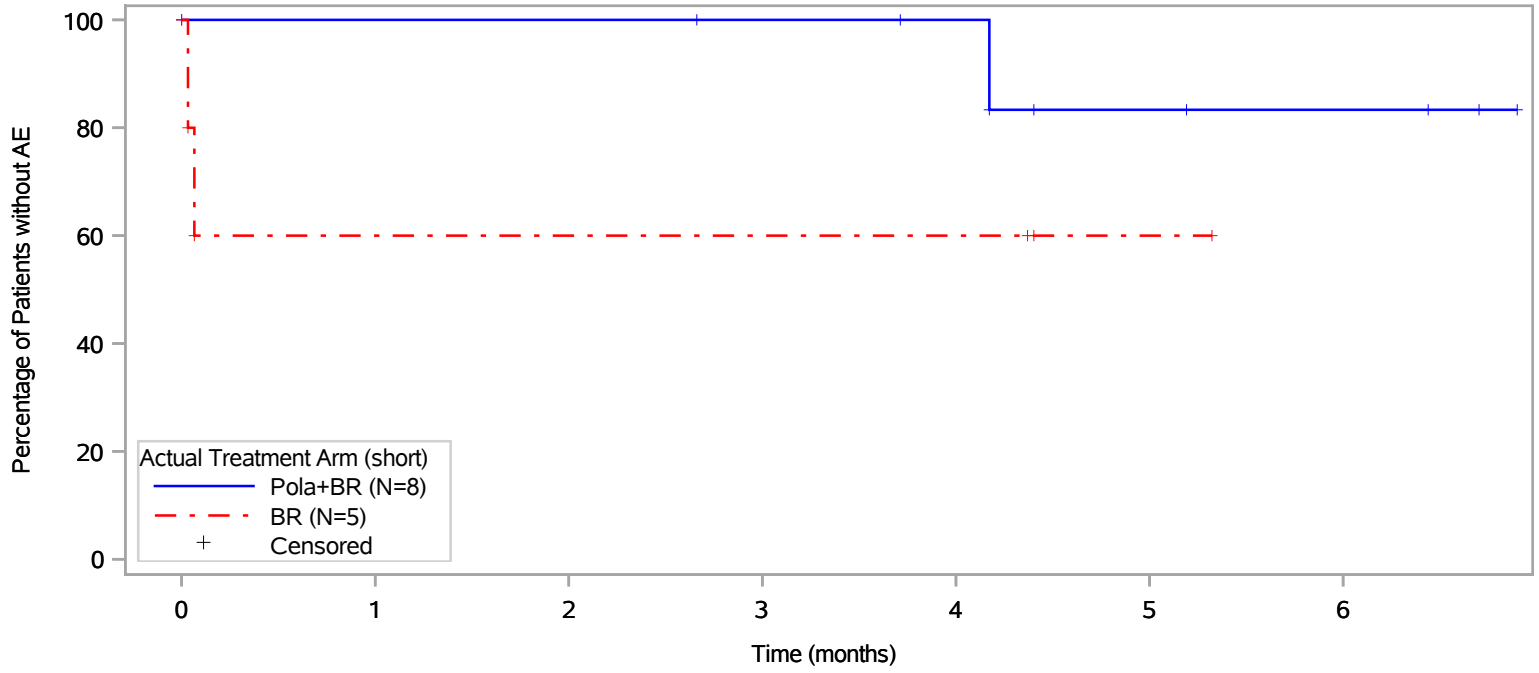
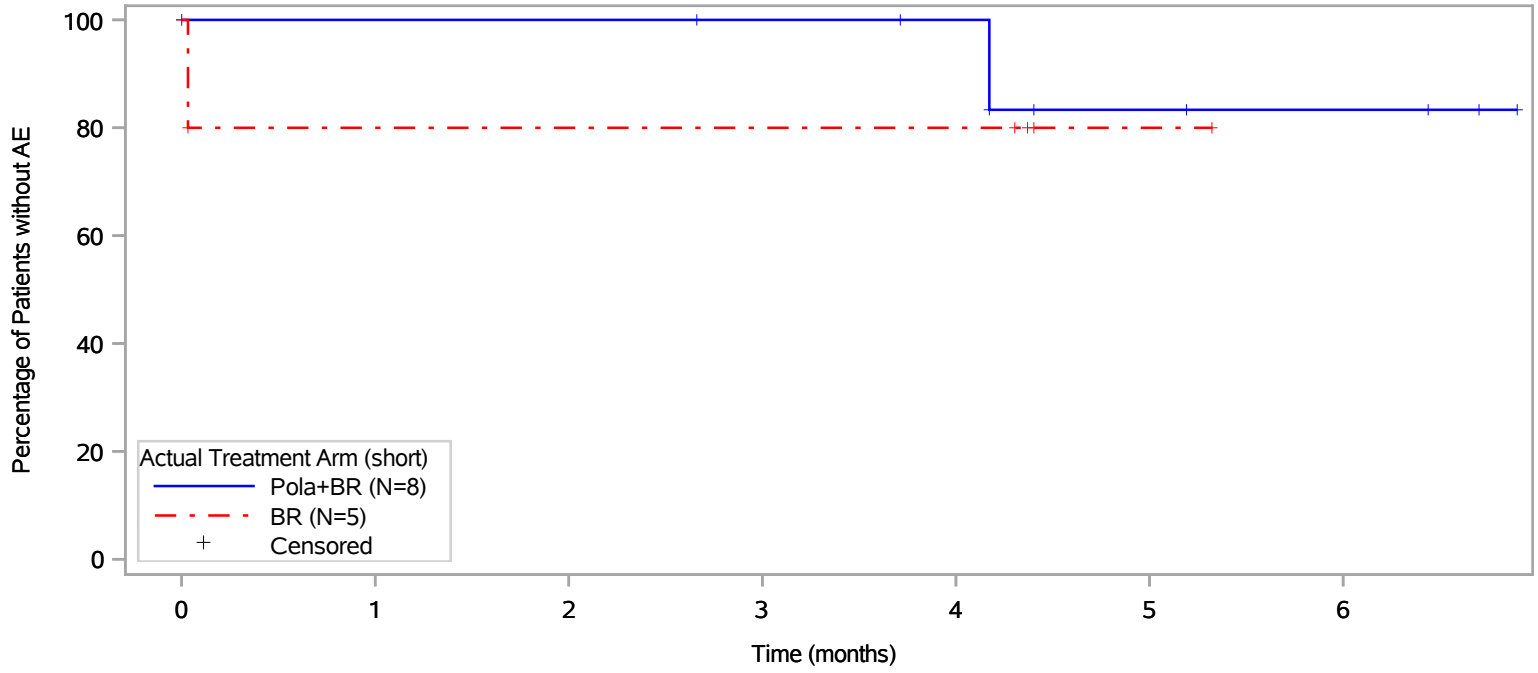
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	4	3
BR (N=5)	5	3	3	3	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	0	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, COUGH



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	4	3
BR (N=5)	5	4	4	4	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	0	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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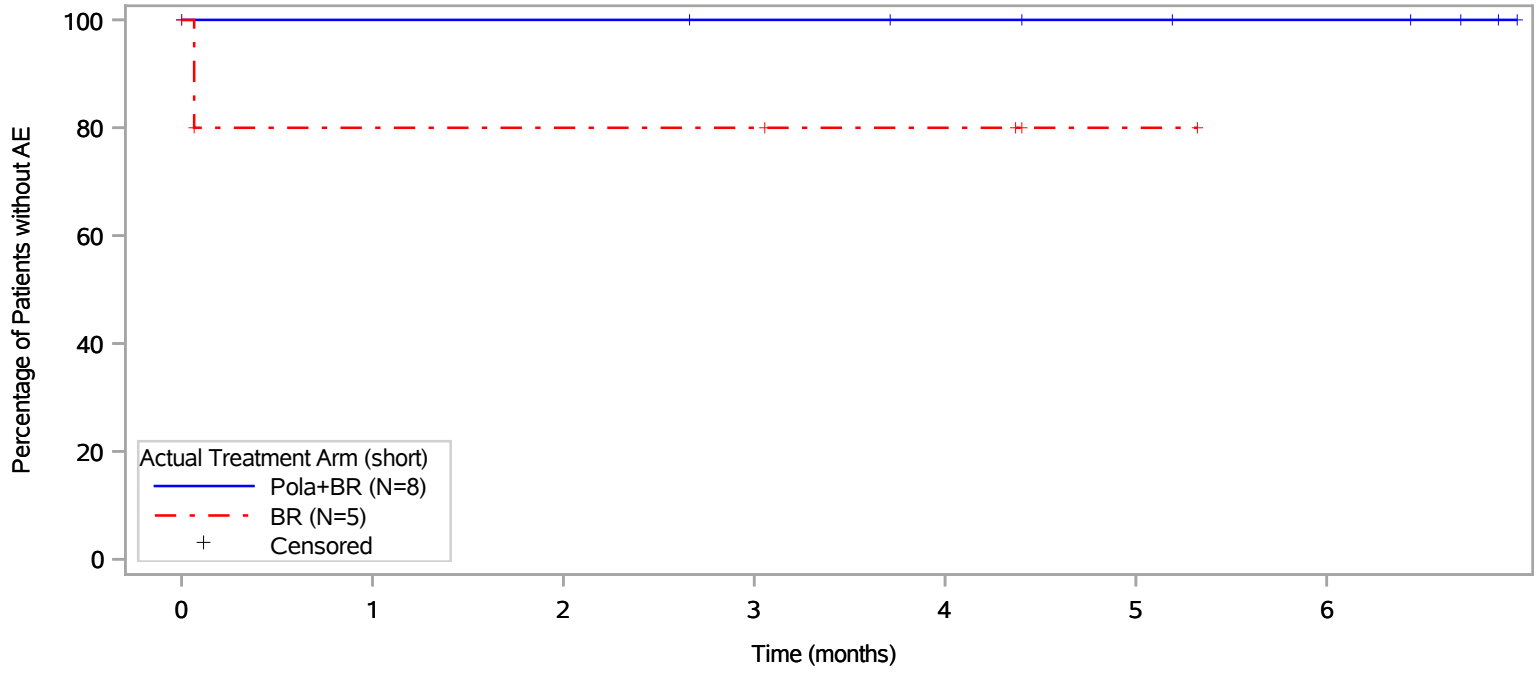
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, DYSPNOEA

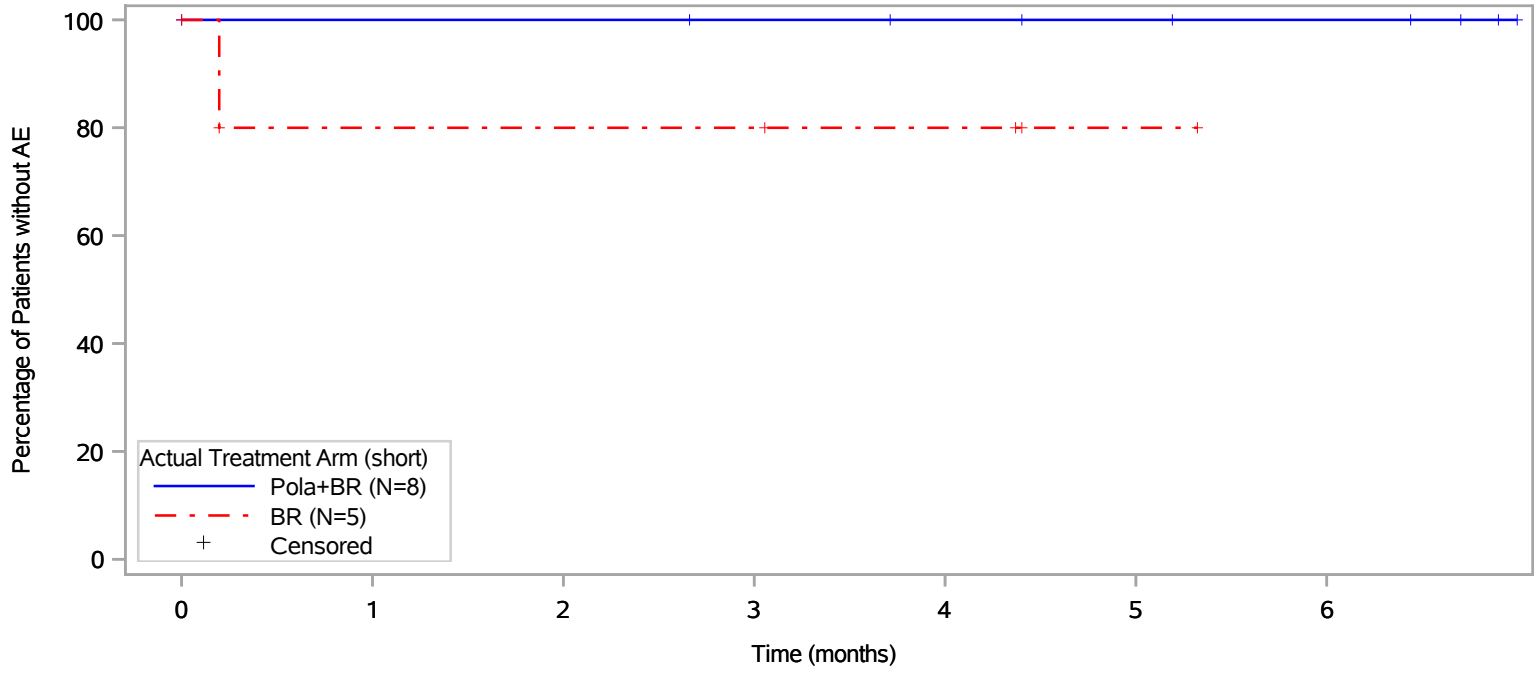


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, OROPHARYNGEAL PAIN



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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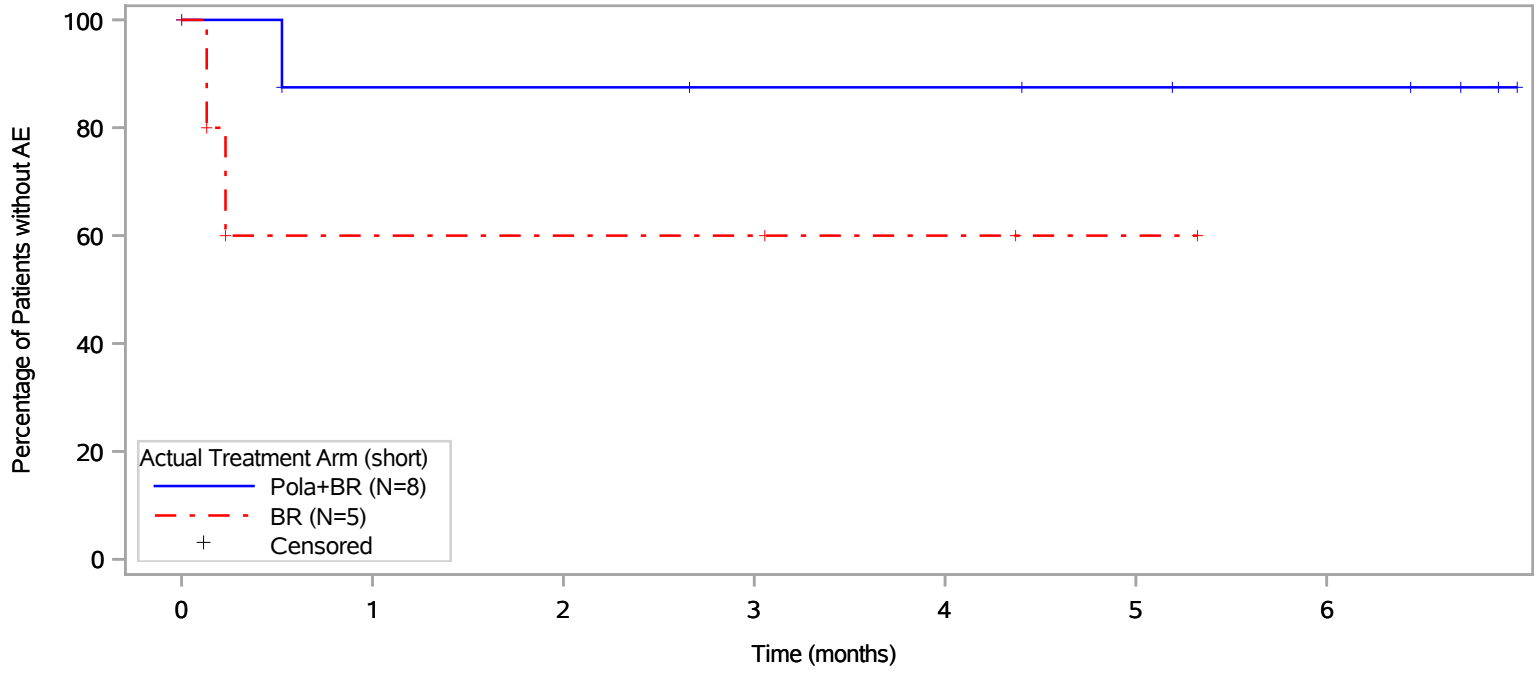
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	7	7	6	6	5	4
BR (N=5)	5	3	3	3	2	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	1	2	3
BR (N=5)	0	0	0	0	1	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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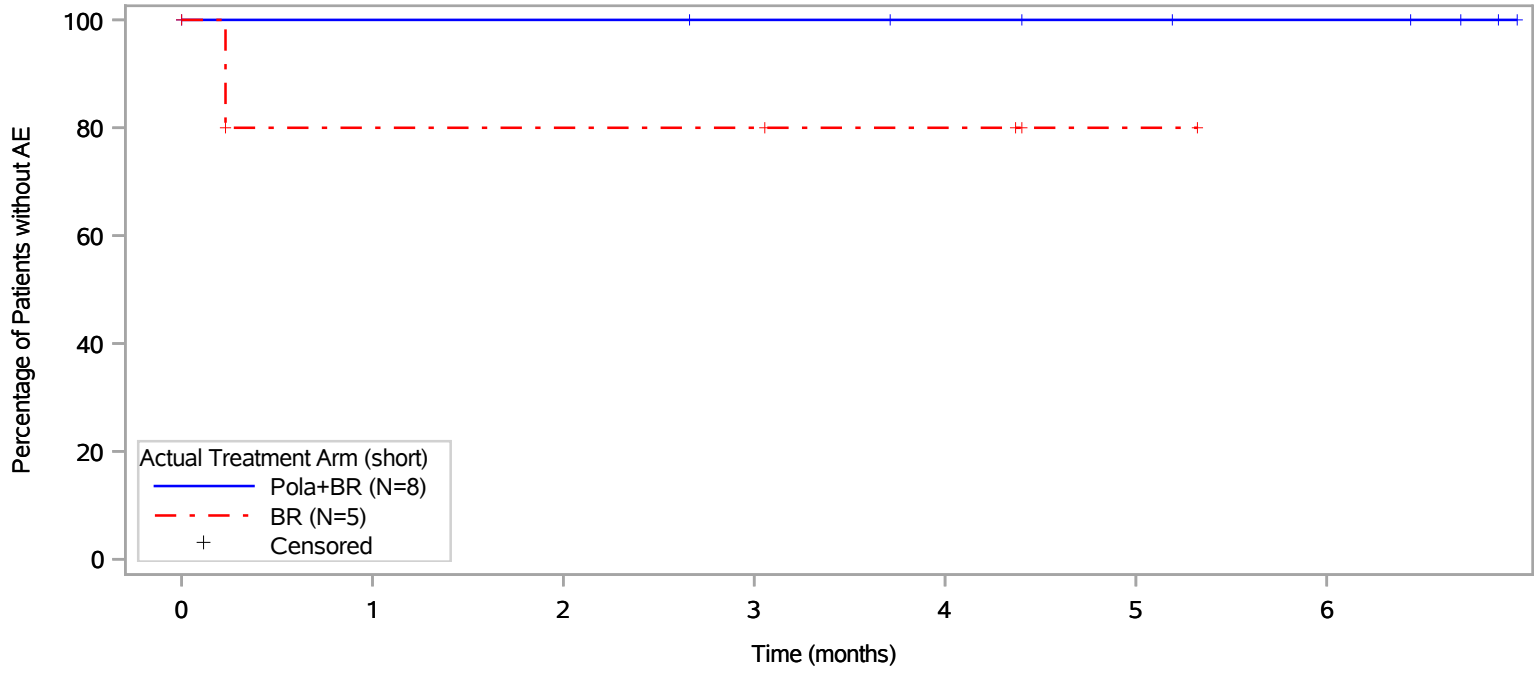
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS

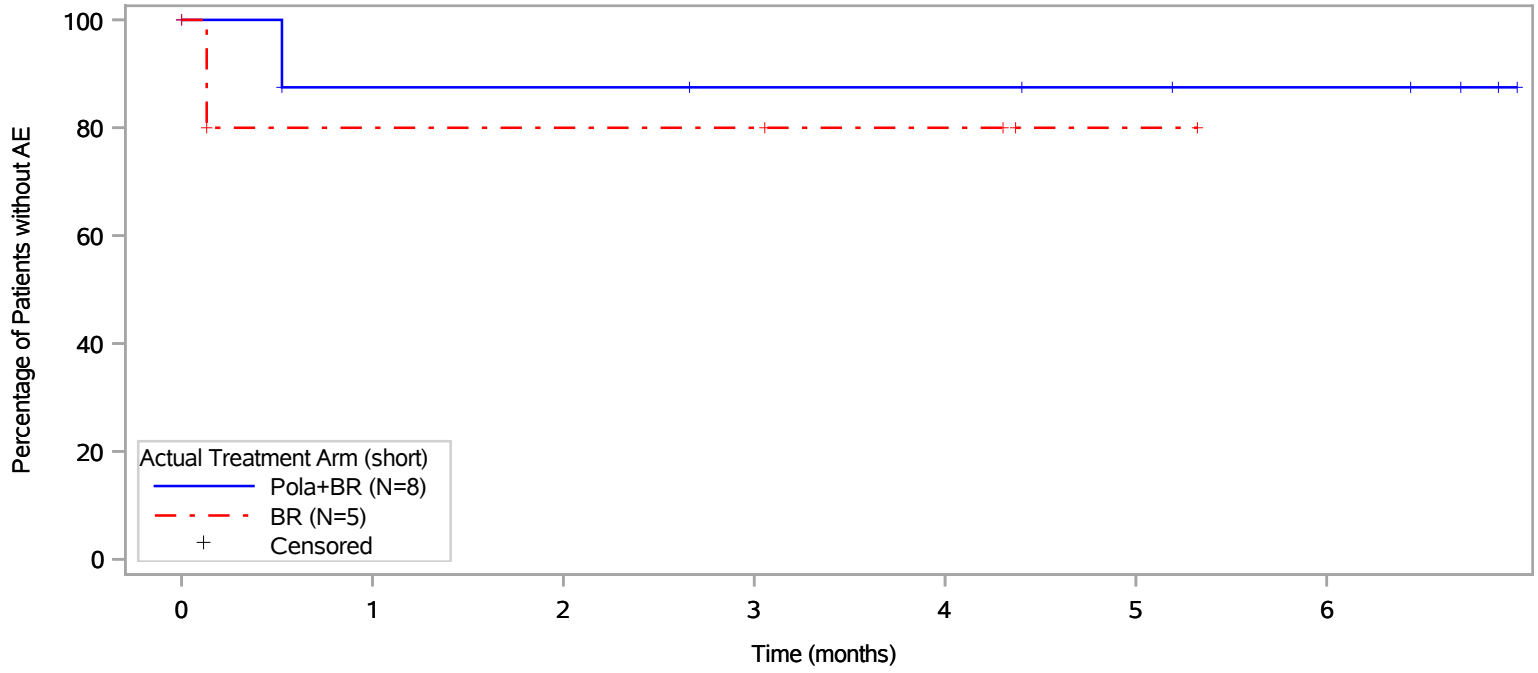


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH



Patients at risk							
Pola+BR (N=8)	8	7	7	6	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	1	2	3
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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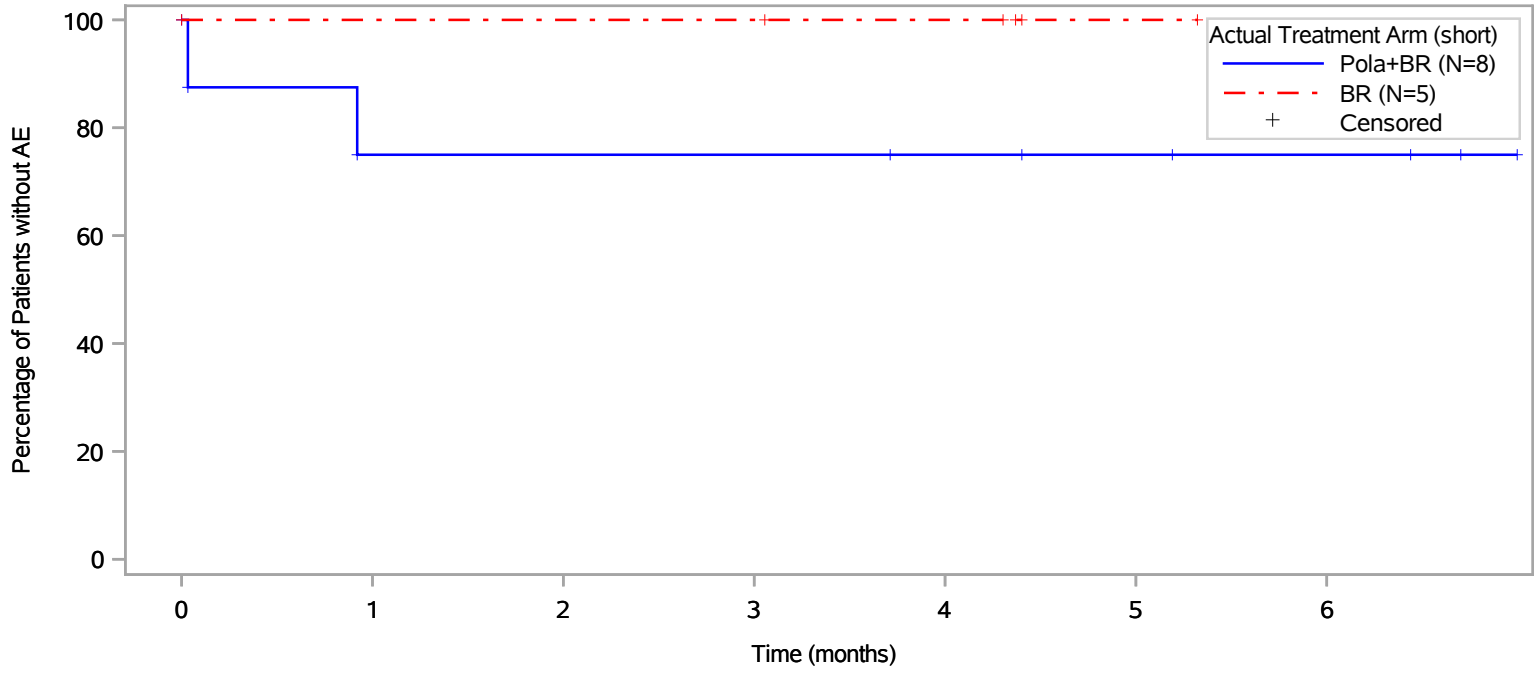
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	6	6	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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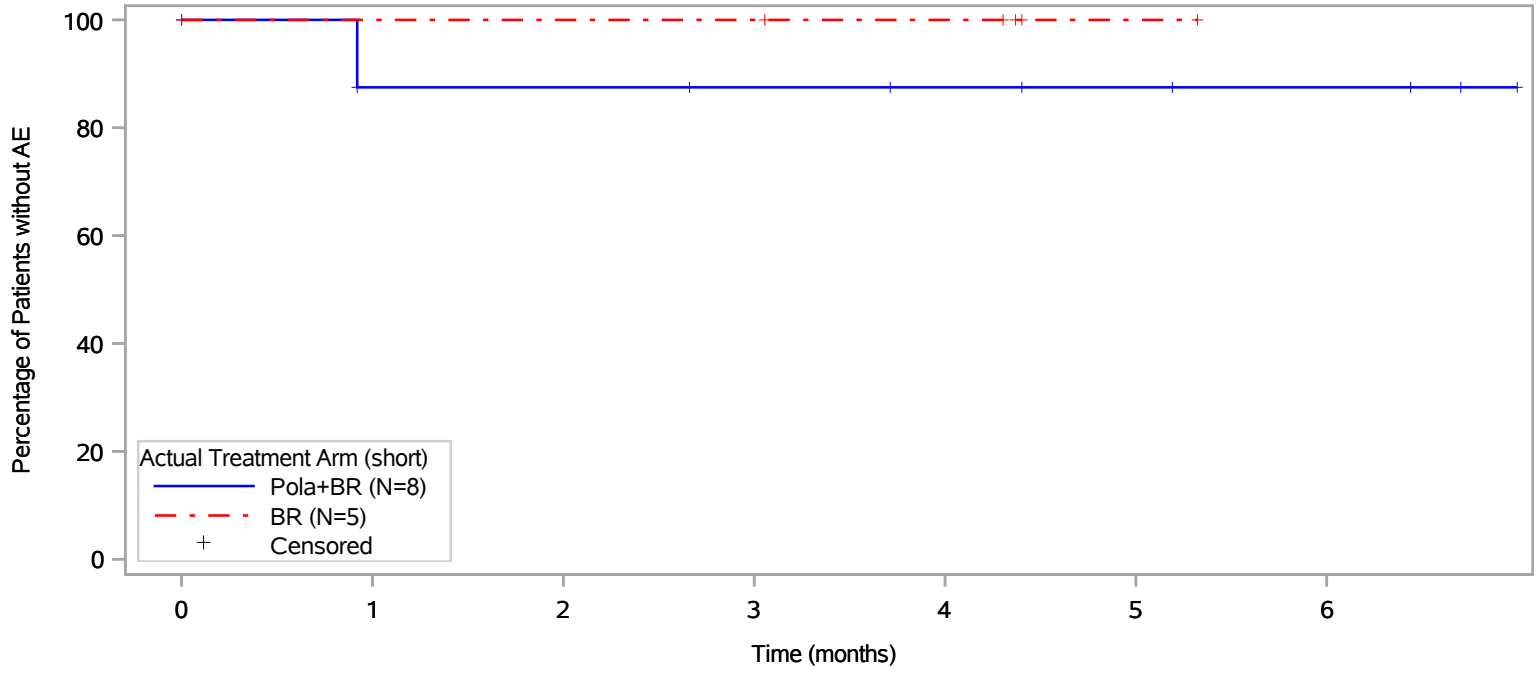
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HAEMORRHAGE



Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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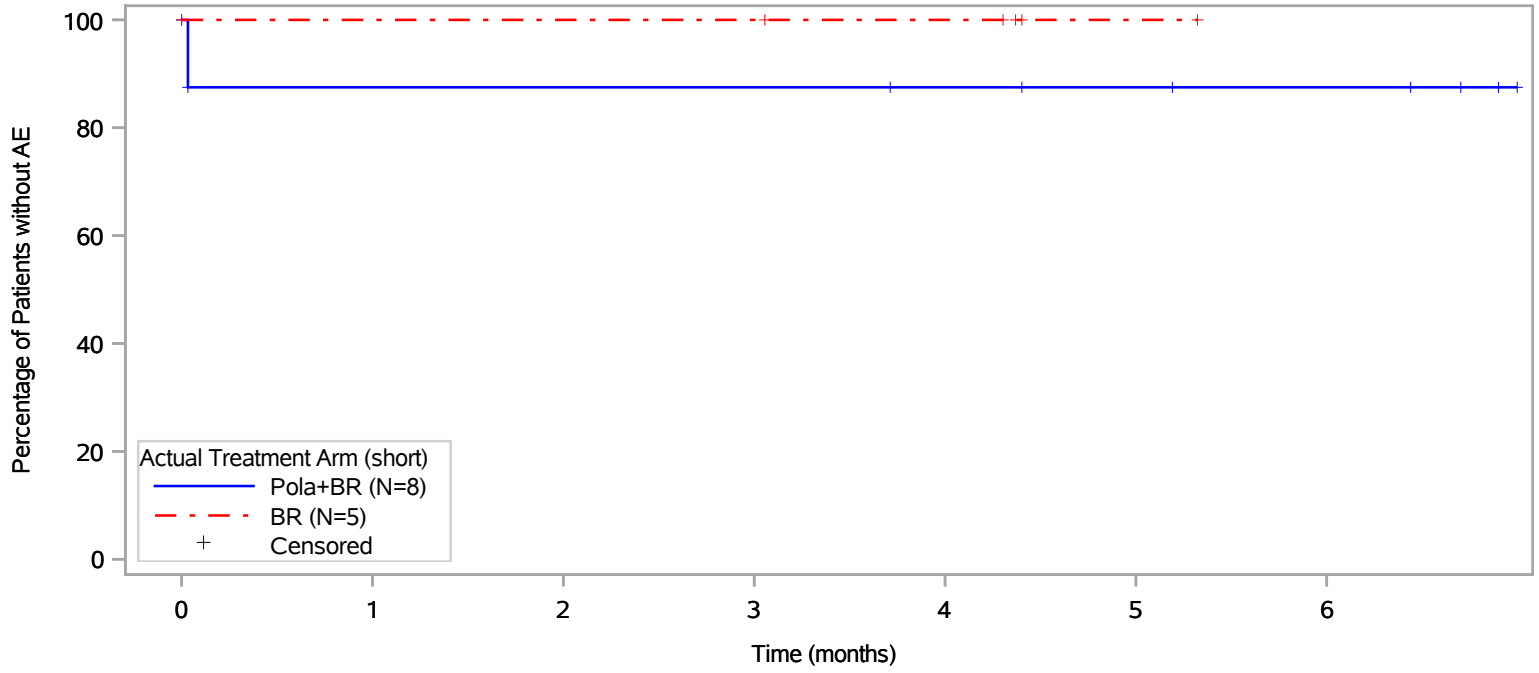
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION



Patients at risk							
Pola+BR (N=8)	8	7	7	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L2_Polarose_SE_29365_41543.pdf
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POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			8	100.0	4	50.0	4	50.0	5	100.0	3	60.0	2	40.0	0.2179	0.37	0.07	1.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		8	100.0	0	-	8	100.0	5	100.0	2	40.0	3	60.0	0.0584	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.4681	2.22	0.24	20.22		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.5139	2.05	0.23	18.69		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR345AE_L2_Polarose_SE_29365_41543.xls
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POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	5	62.5	3	60.0	2	40.0	2	40.0	2	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	5	62.5	3	60.0	2	40.0	2	40.0	1	50.0	1	50.0	0.9374	1.10	0.11	10.67		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	5	62.5	3	60.0	2	40.0	2	40.0	1	50.0	1	50.0	0.9065	0.87	0.09	8.51		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR345AE_L2_Polarose_SE_29365_41543.xls

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POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	2	25.0	1	50.0	1	50.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	6	75.0	3	50.0	3	50.0	1	20.0	1	100.0	0	-	0.0143	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	6	75.0	3	50.0	3	50.0	1	20.0	1	100.0	0	-	0.1768	0.18	0.01	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	6	75.0	3	50.0	3	50.0	1	20.0	1	100.0	0	-	0.0143	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR345AE_L2_Polarose_SE_29365_41543.xls

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POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2473	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	3	60.0	2	40.0	0.2179	0.37	0.07	1.89		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	2	40.0	3	60.0	0.0584	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.4681	2.22	0.24	20.22		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.5139	2.05	0.23	18.69		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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30NOV2022 19:35

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
INVESTIGATIONS		Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.4754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	1	12.5	1	100.0	0	-	4	80.0	3	75.0	1	25.0	0.2994	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	1	12.5	0	-	1	100.0	4	80.0	2	50.0	2	50.0	0.4452	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.4754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	1	12.5	1	100.0	0	-	4	80.0	1	25.0	3	75.0	0.6394	2.00	0.11	37.83		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.4754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	1	12.5	1	100.0	0	-	4	80.0	1	25.0	3	75.0	0.6394	2.00	0.11	37.83		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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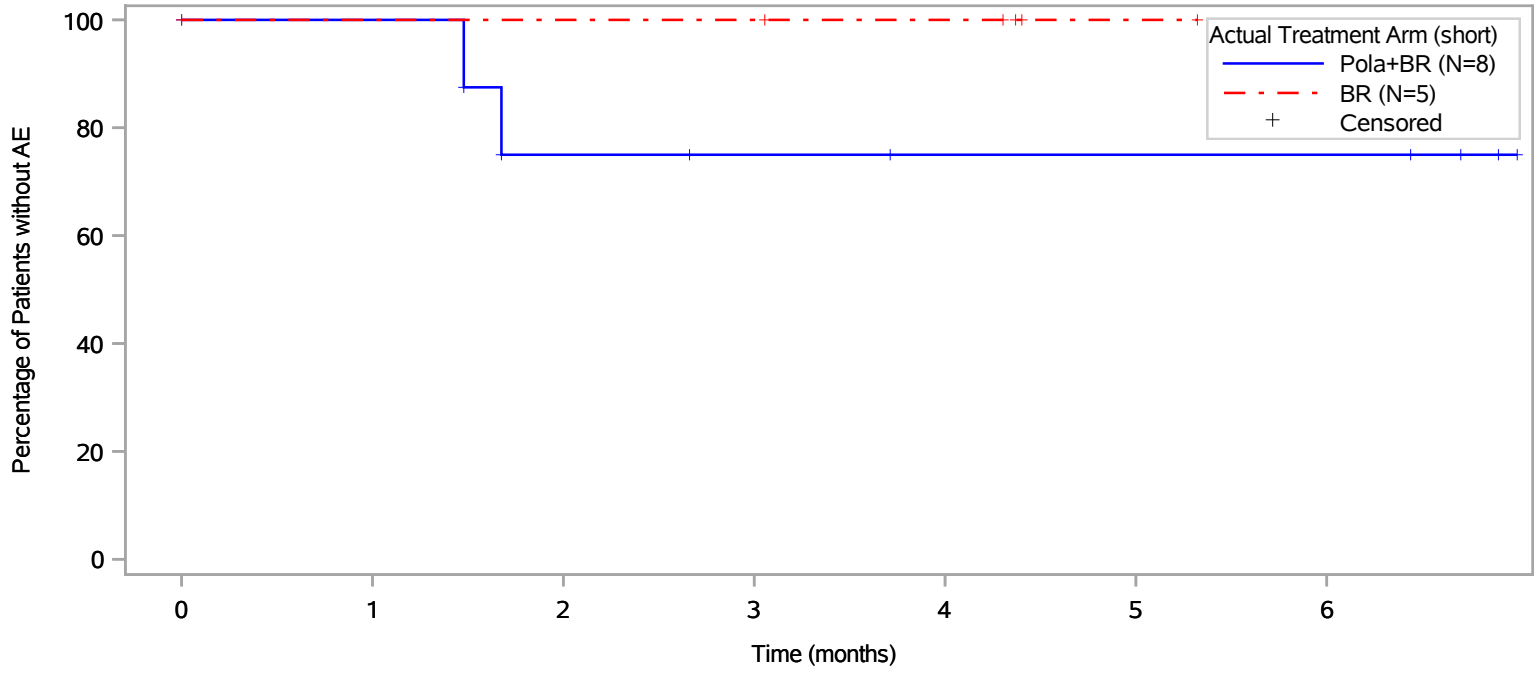
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	8	6	5	4	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	2
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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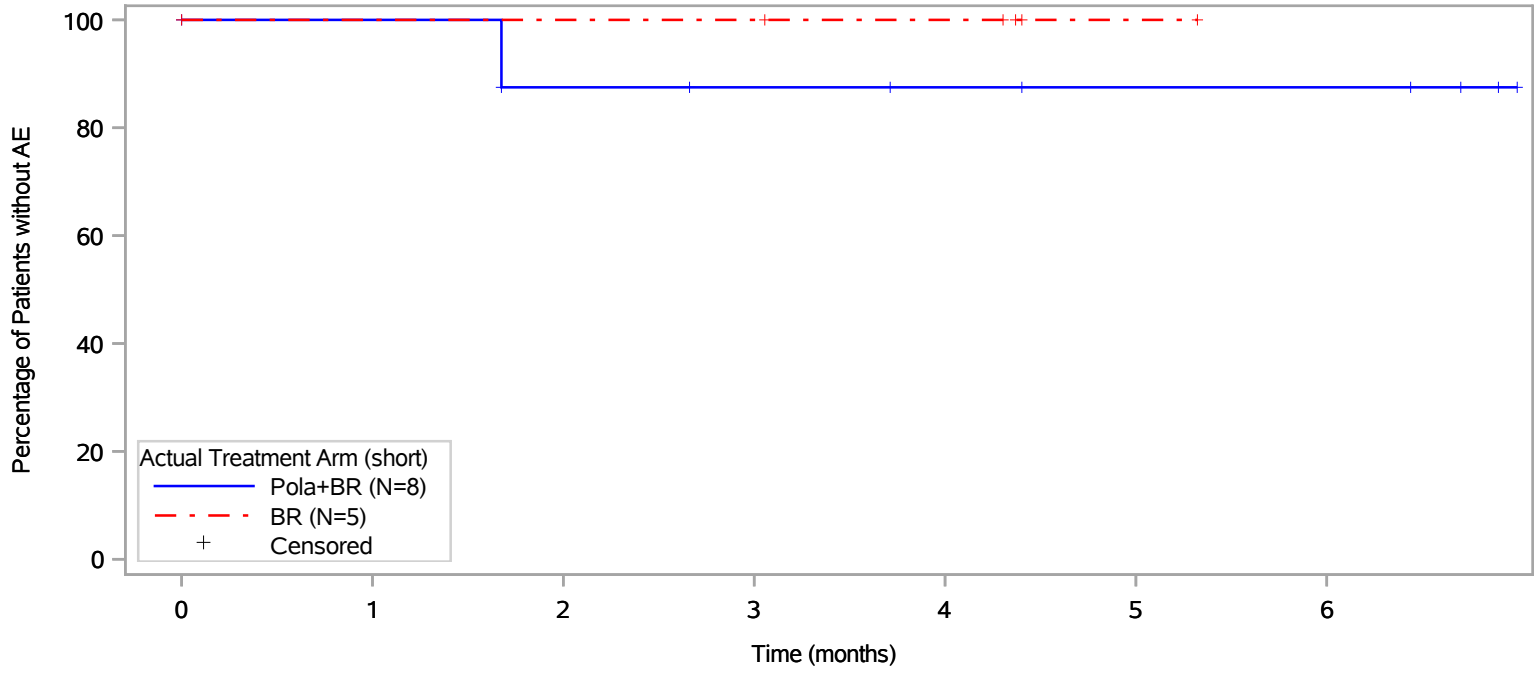
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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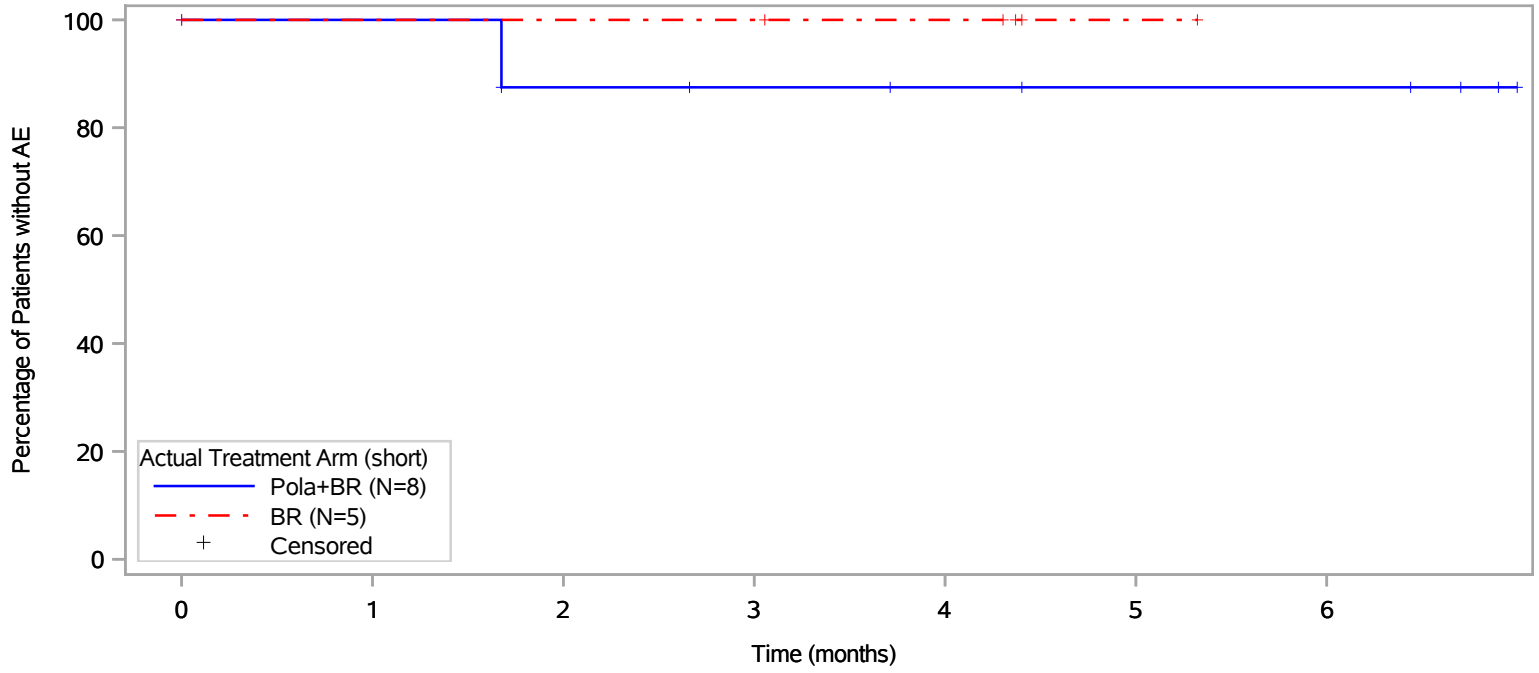
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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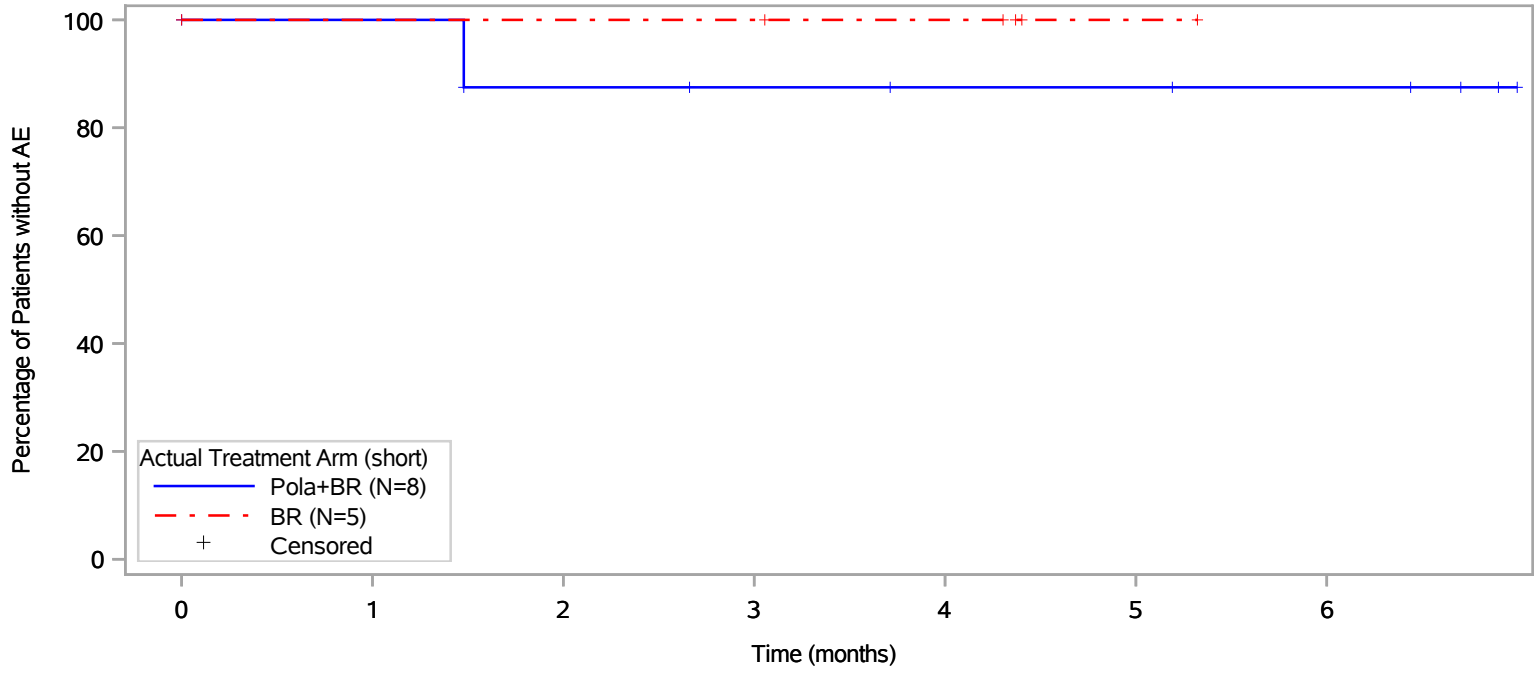
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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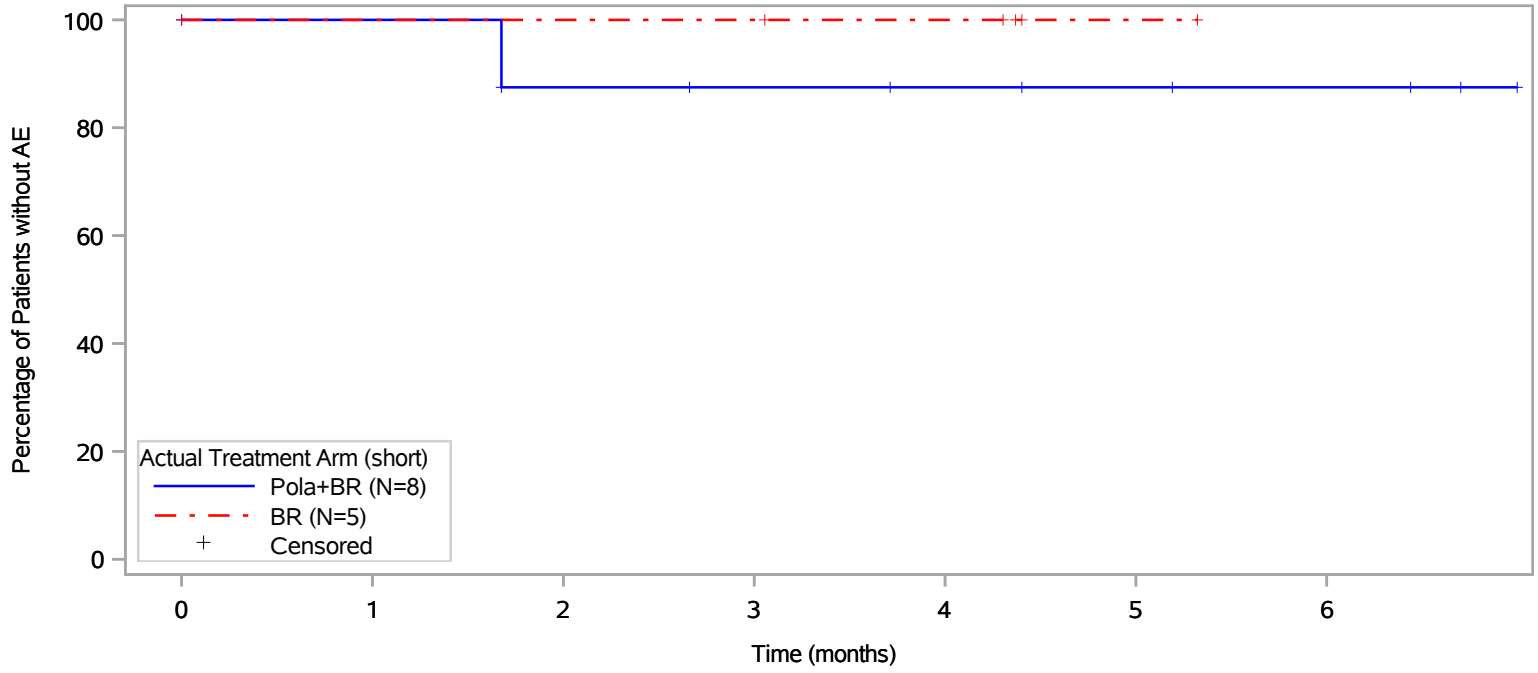
02DEC2022 1:57

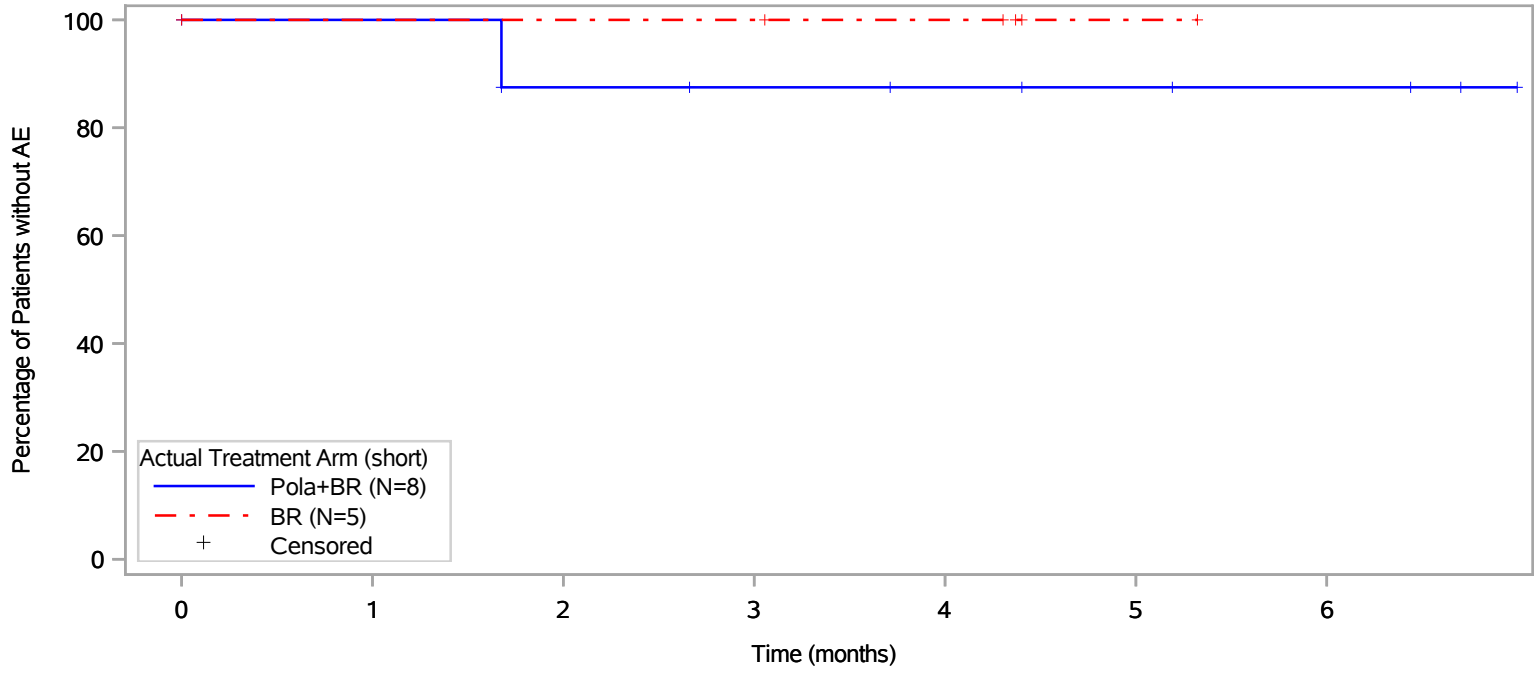
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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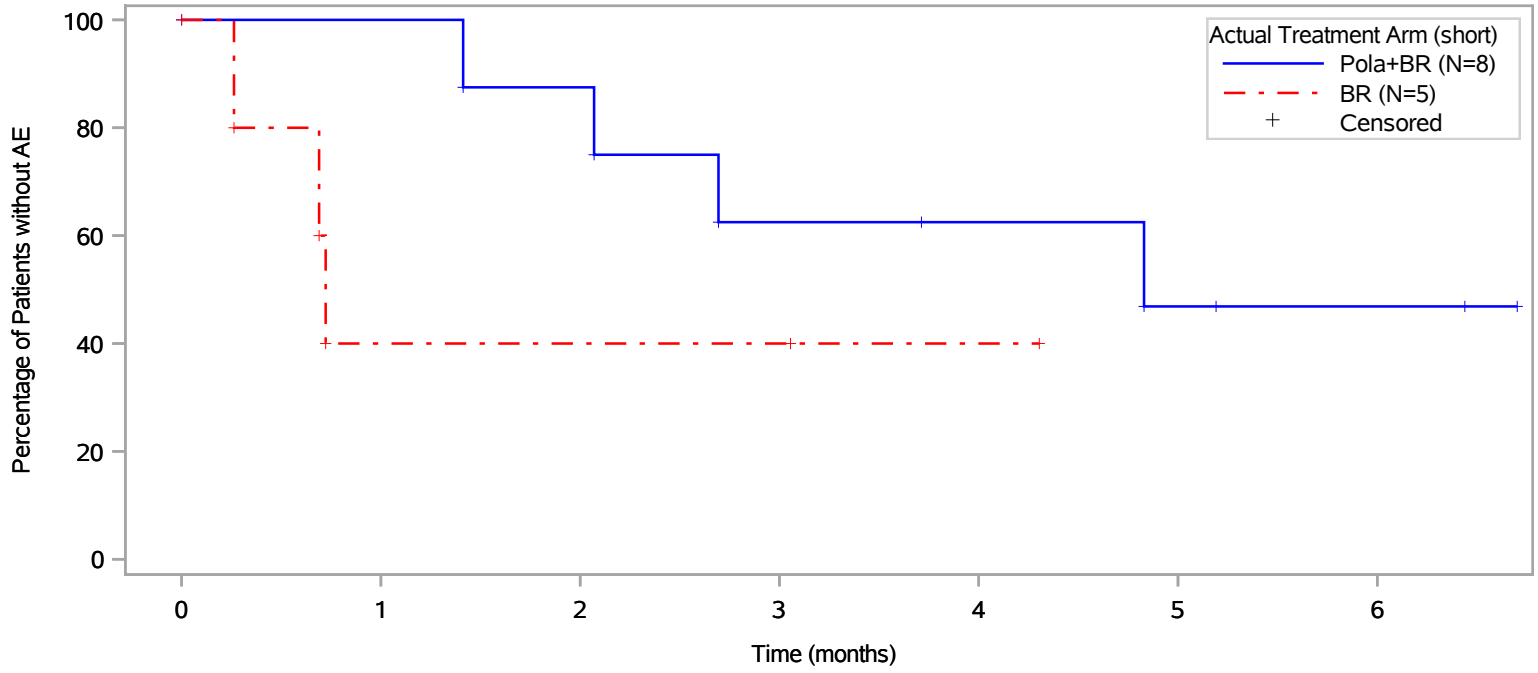
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

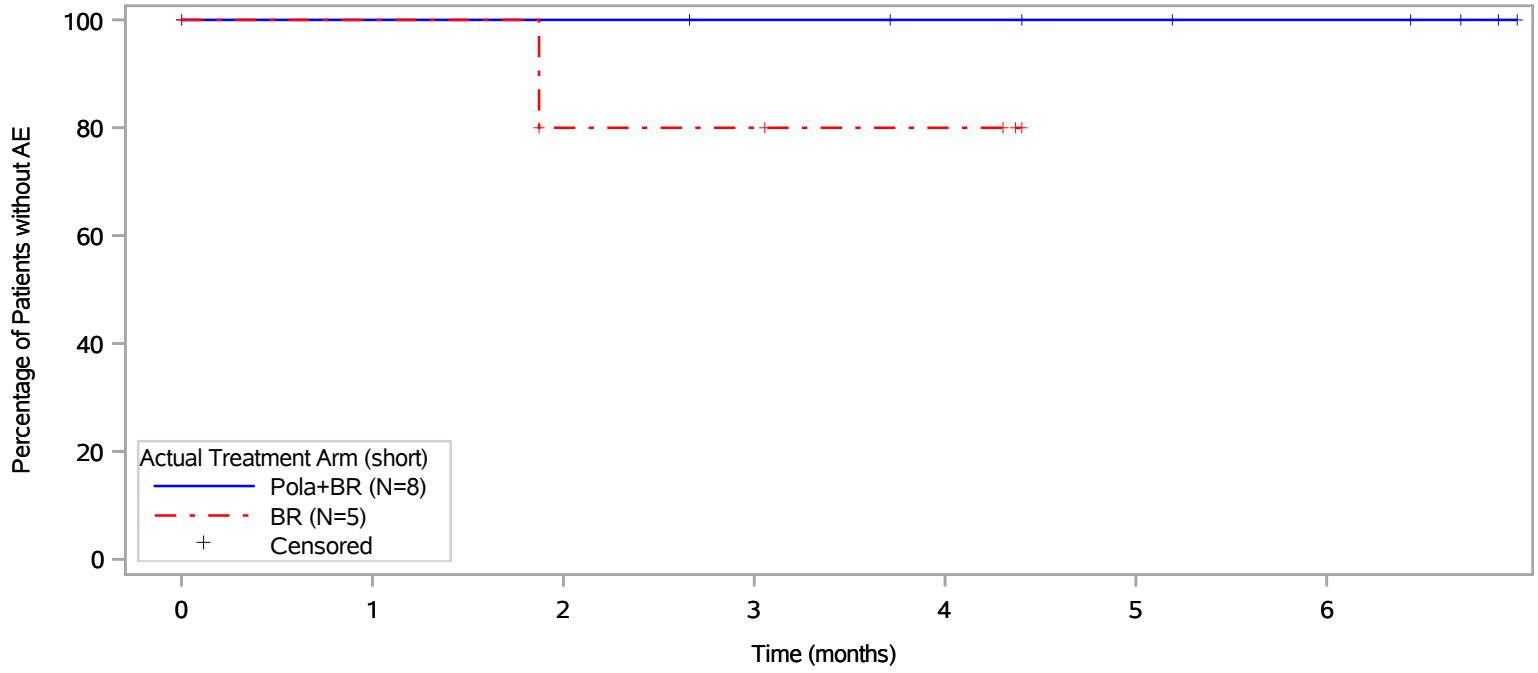


Patients at risk							
Pola+BR (N=8)	8	8	7	5	4	3	2
BR (N=5)	5	2	2	2	1	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	2
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BILIRUBIN CONJUGATED INCREASED

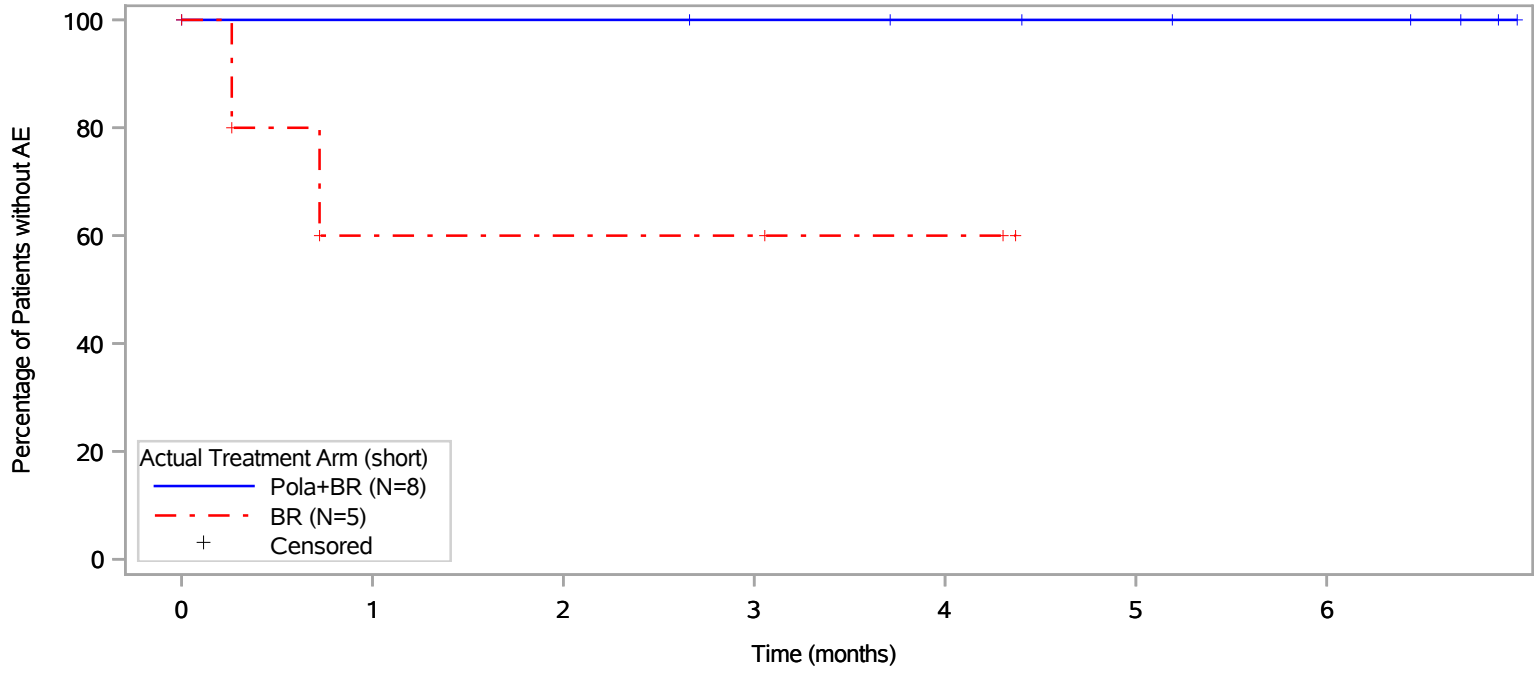


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED

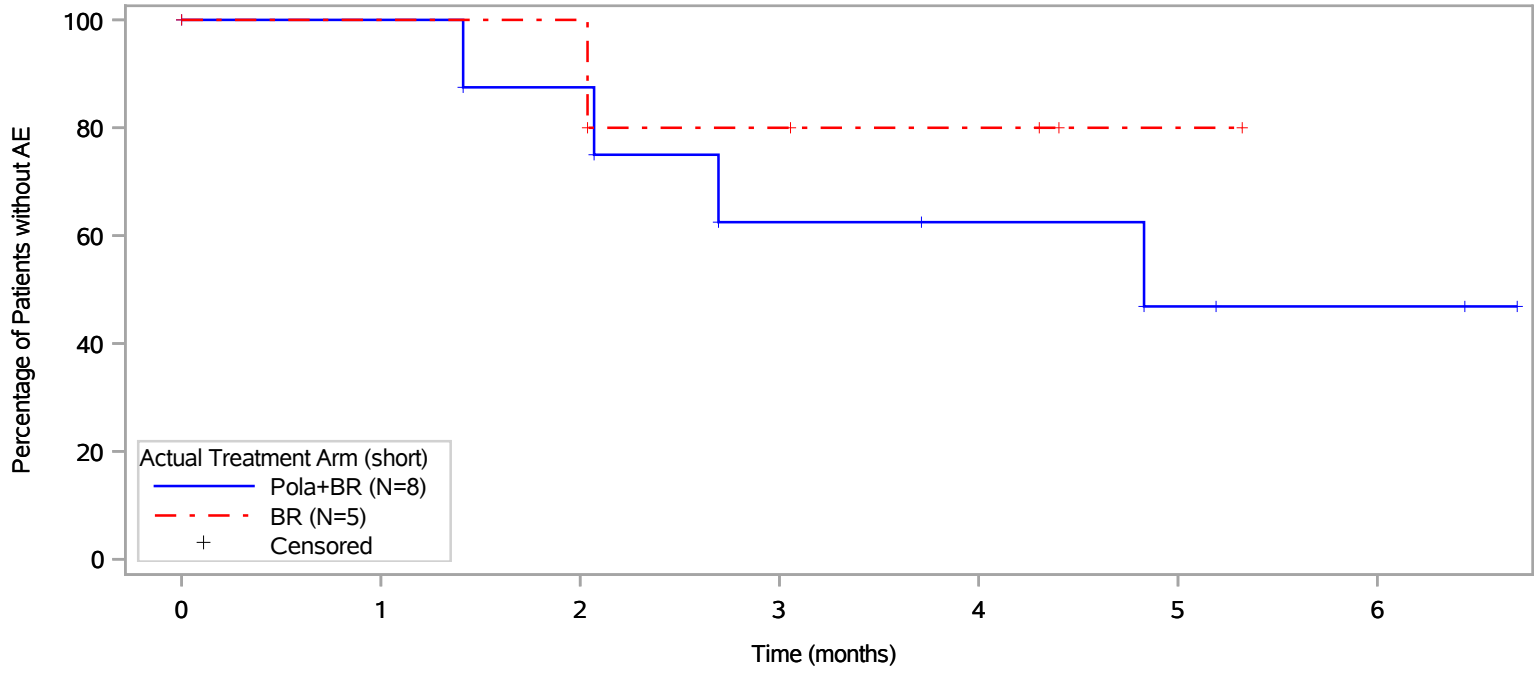


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	3	3	3	2	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

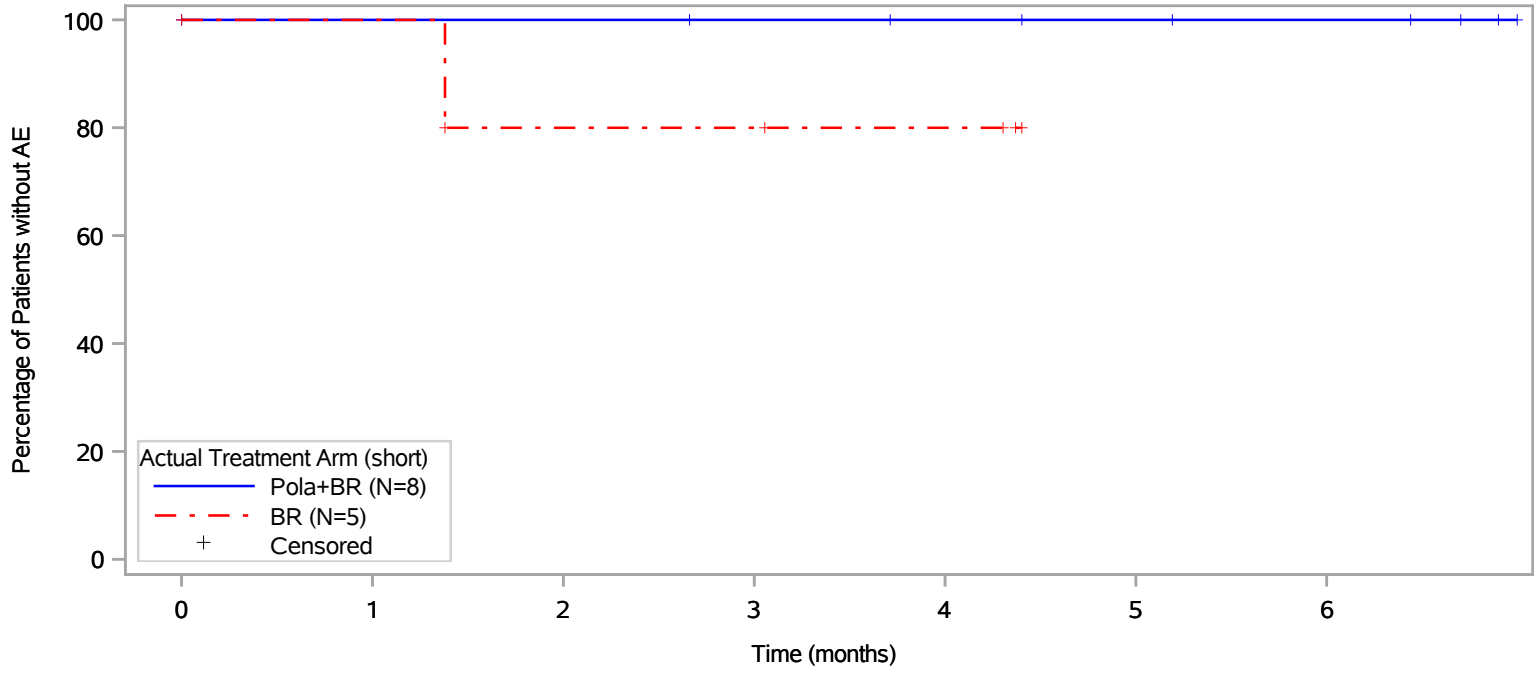


Patients at risk							
Pola+BR (N=8)	8	8	7	5	4	3	2
BR (N=5)	5	5	5	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	2
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

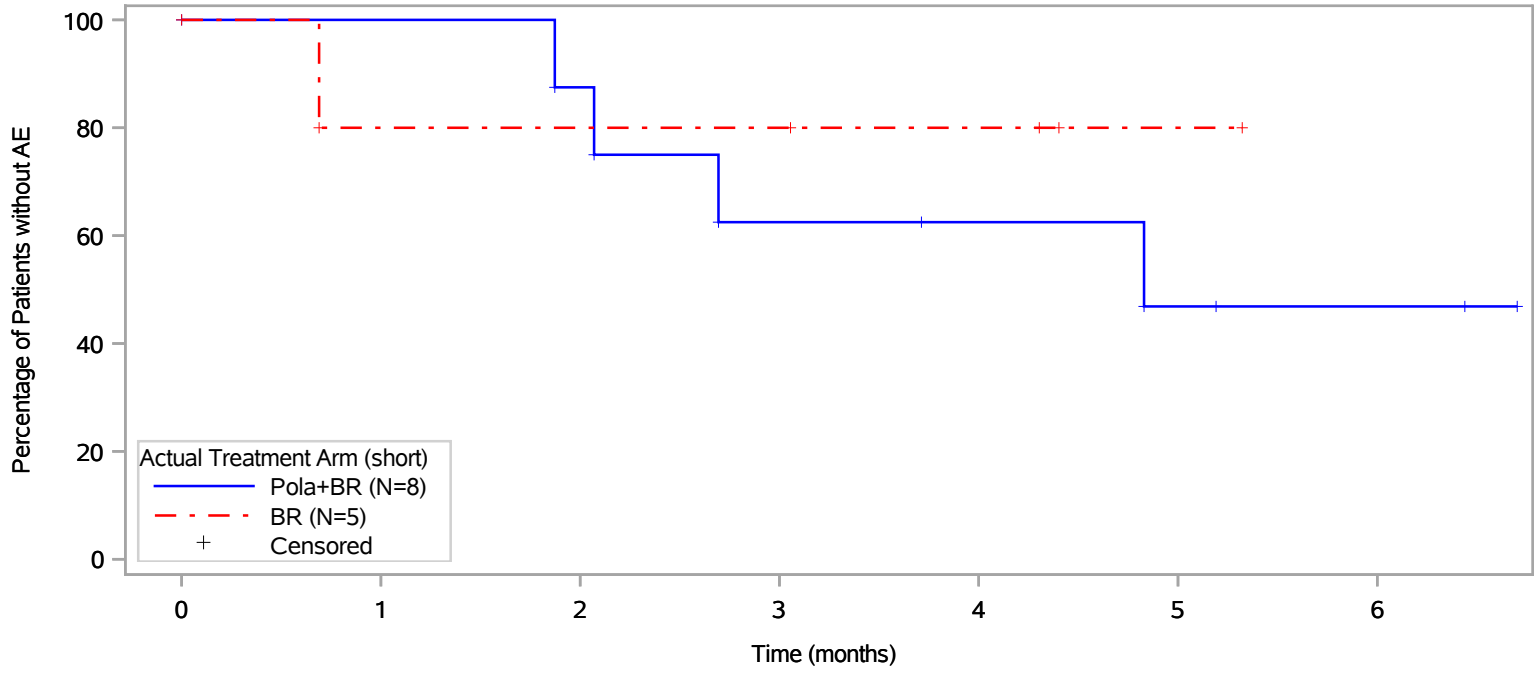


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED

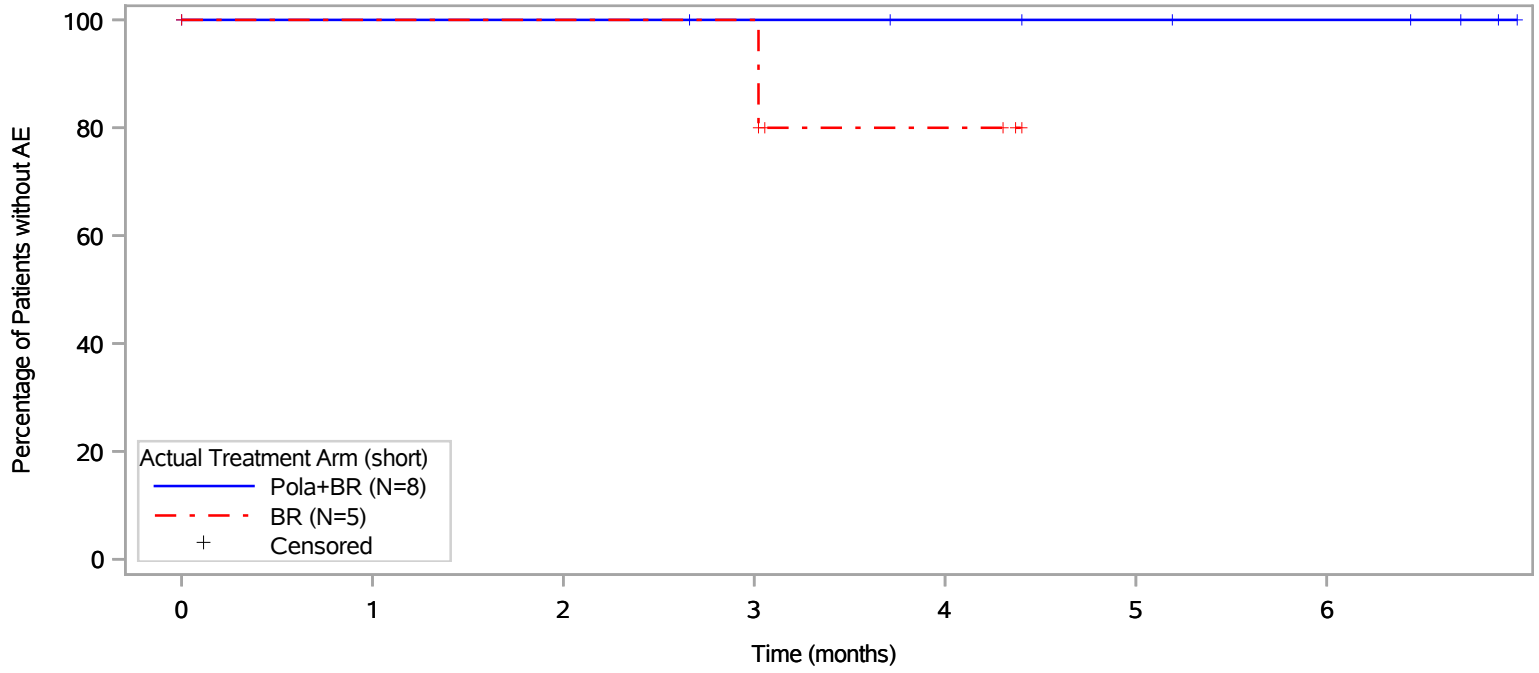


Patients at risk							
Pola+BR (N=8)	8	8	7	5	4	3	2
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	2
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



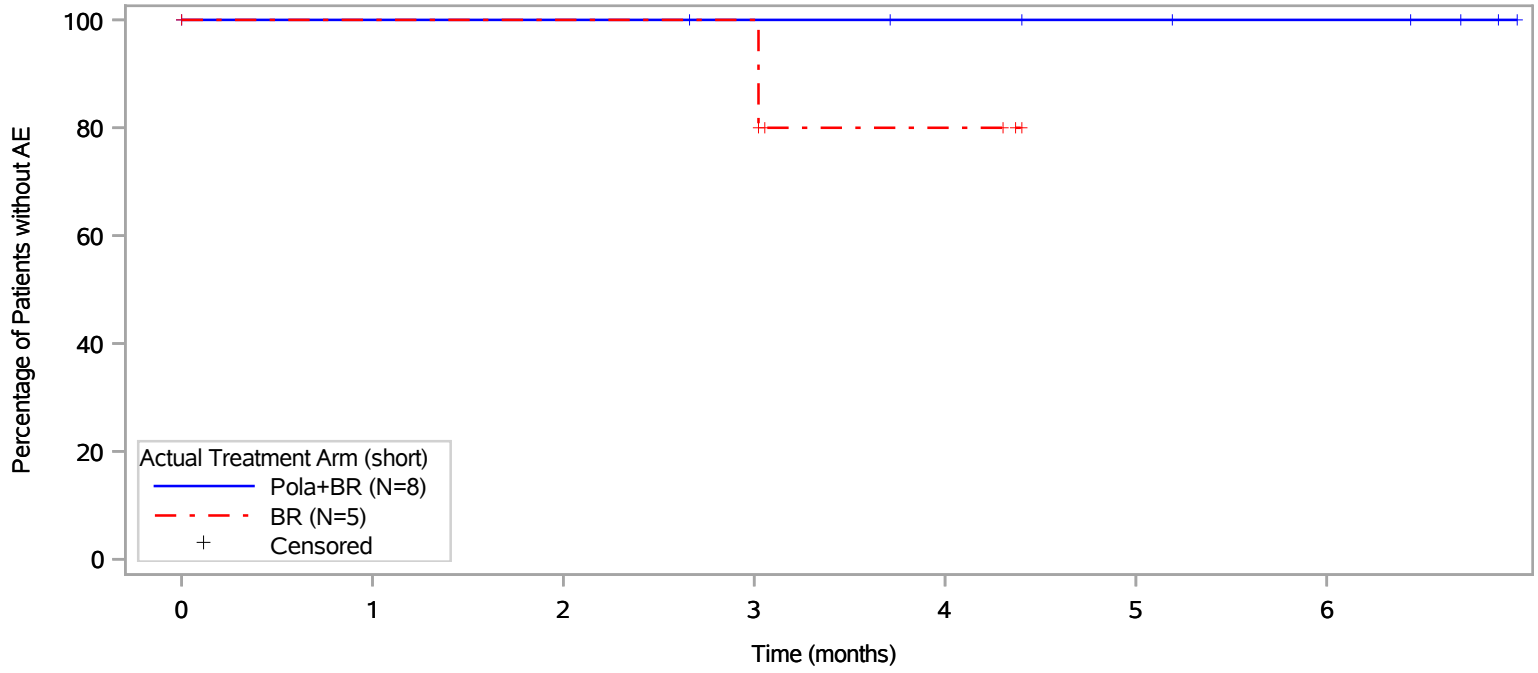
Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA

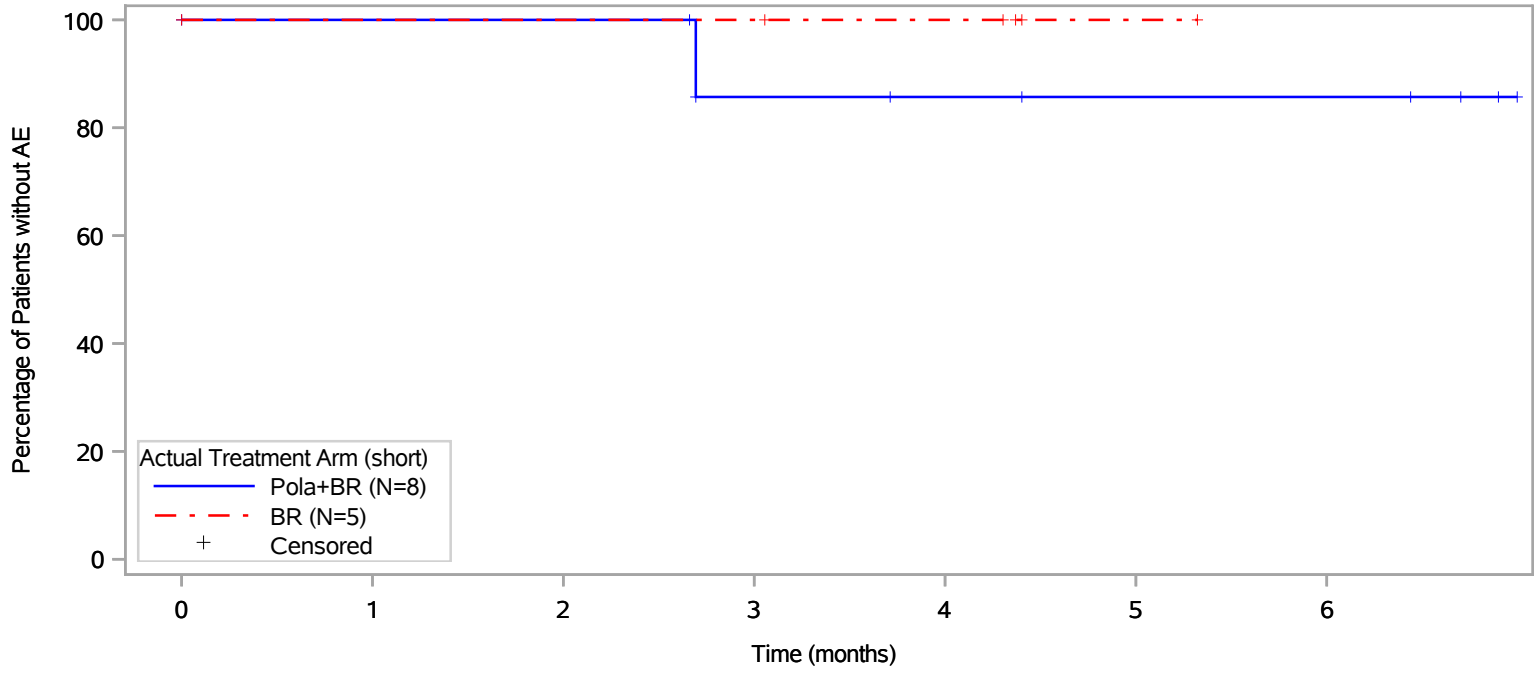


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All

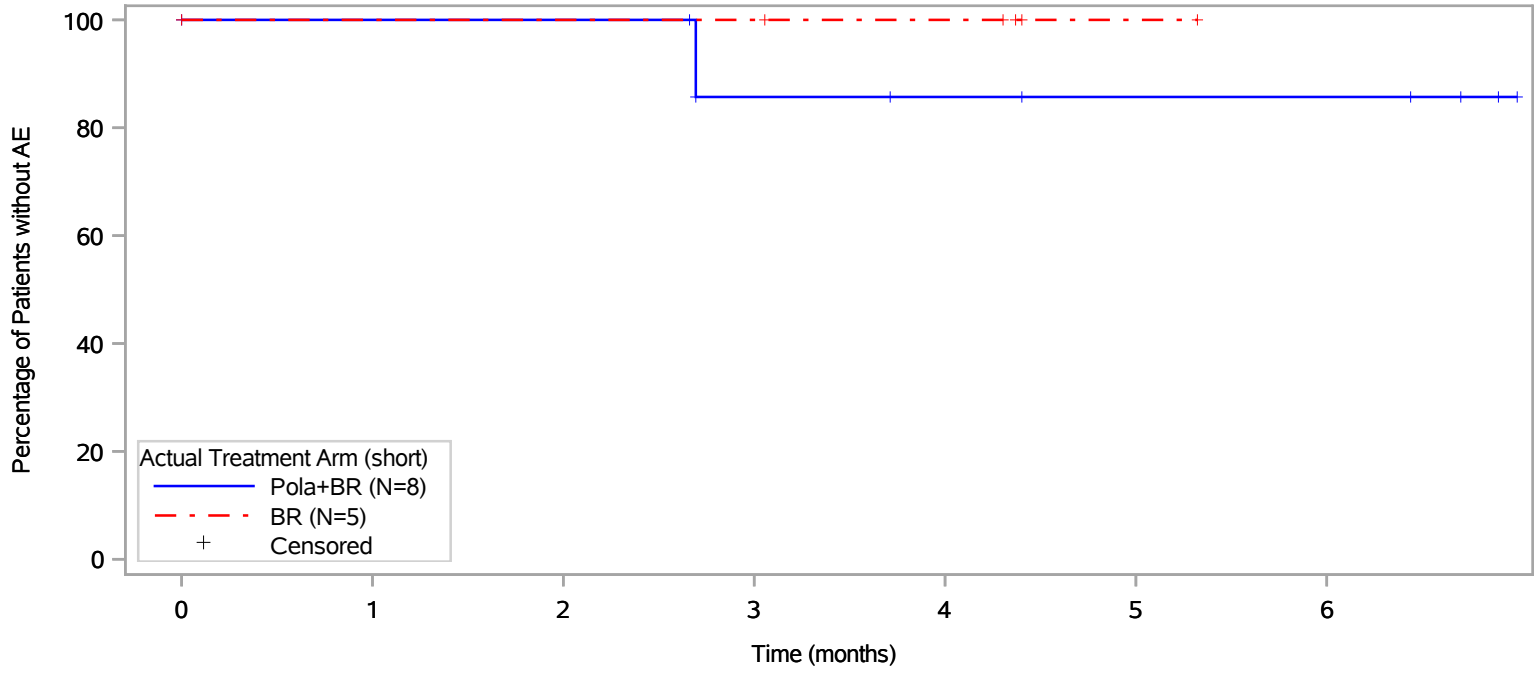


Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS

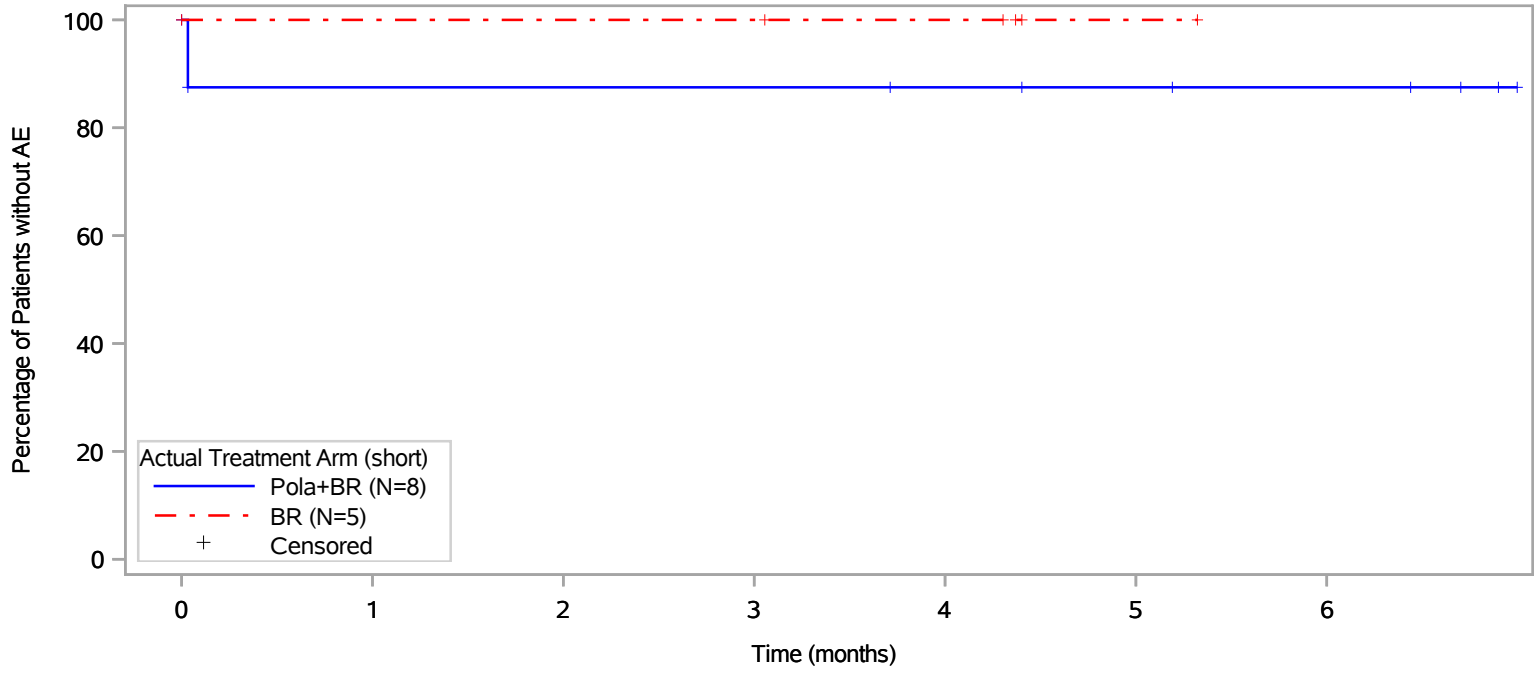


Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All

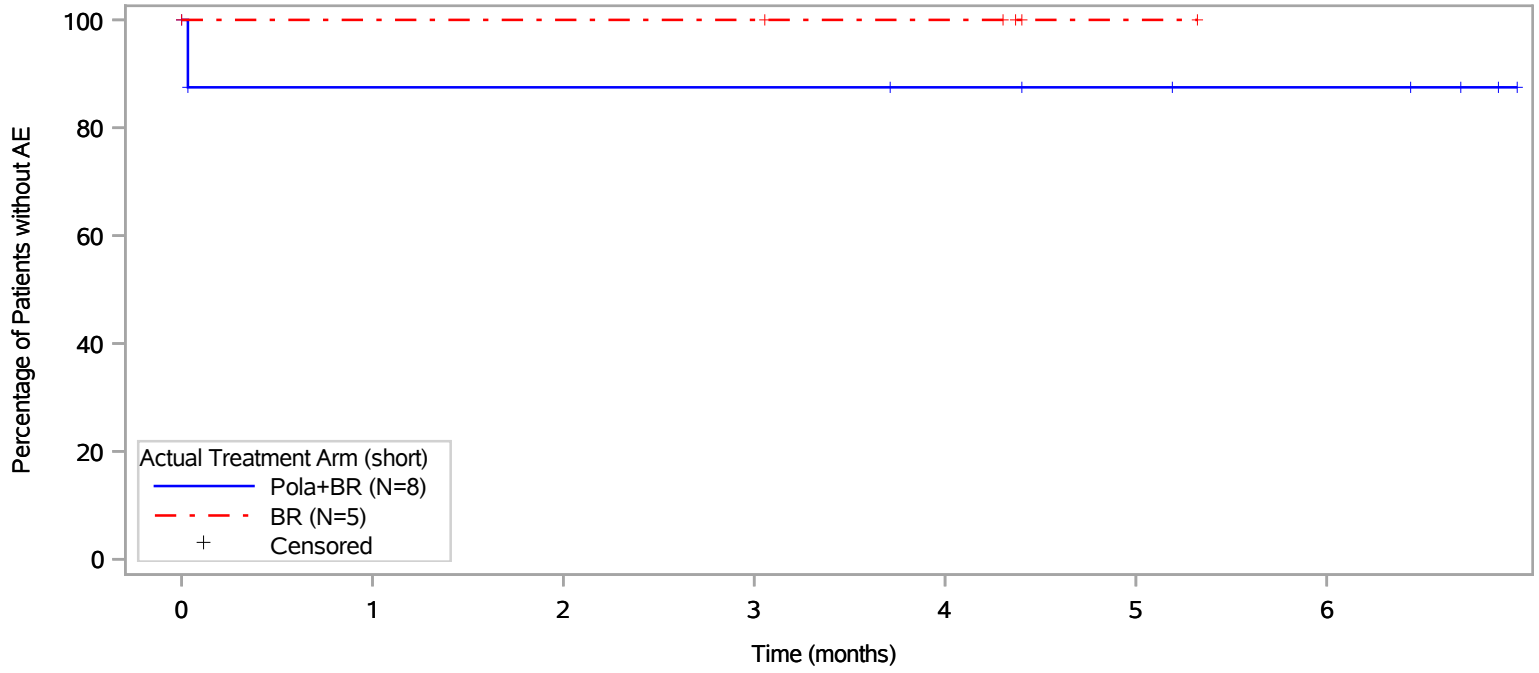


Patients at risk							
Pola+BR (N=8)	8	7	7	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION



Patients at risk							
Pola+BR (N=8)	8	7	7	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 1:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			8	100.0	3	37.5	5	62.5	5	100.0	3	60.0	2	40.0	0.1107	0.25	0.04	1.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		8	100.0	0	-	8	100.0	5	100.0	2	40.0	3	60.0	0.0584	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		8	100.0	3	37.5	5	62.5	5	100.0	1	20.0	4	80.0	0.6958	1.57	0.16	15.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		8	100.0	3	37.5	5	62.5	5	100.0	1	20.0	4	80.0	0.7601	1.43	0.14	14.01		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR3AE_L2_Polarose_SE_29365_41543.xls
30NOV2022 20:24

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	5	62.5	2	40.0	3	60.0	2	40.0	2	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	5	62.5	2	40.0	3	60.0	2	40.0	1	50.0	1	50.0	0.8132	0.75	0.07	8.42		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	5	62.5	2	40.0	3	60.0	2	40.0	1	50.0	1	50.0	0.6240	0.55	0.05	6.21		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR3AE_L2_Polarose_SE_29365_41543.xls
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POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	2	25.0	1	50.0	1	50.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0	-	0.0143	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0	-	0.1768	0.18	0.01	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0	-	0.0143	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR3AE_L2_Polarose_SE_29365_41543.xls
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POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	3	60.0	2	40.0	0.1107	0.25	0.04	1.55		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	2	40.0	3	60.0	0.0584	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	1	20.0	4	80.0	0.6958	1.57	0.16	15.55		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	1	20.0	4	80.0	0.7601	1.43	0.14	14.01		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2367	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR3AE_L2_Polarose_SE_29365_41543.xls
30NOV2022 20:24

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
INVESTIGATIONS		Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	1	12.5	1	100.0	0	-	4	80.0	3	75.0	1	25.0	0.2994	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	1	12.5	0	-	1	100.0	4	80.0	2	50.0	2	50.0	0.4452	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	1	12.5	1	100.0	0	-	4	80.0	1	25.0	3	75.0	0.6394	2.00	0.11	37.83		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	1	12.5	1	100.0	0	-	4	80.0	1	25.0	3	75.0	0.6394	2.00	0.11	37.83		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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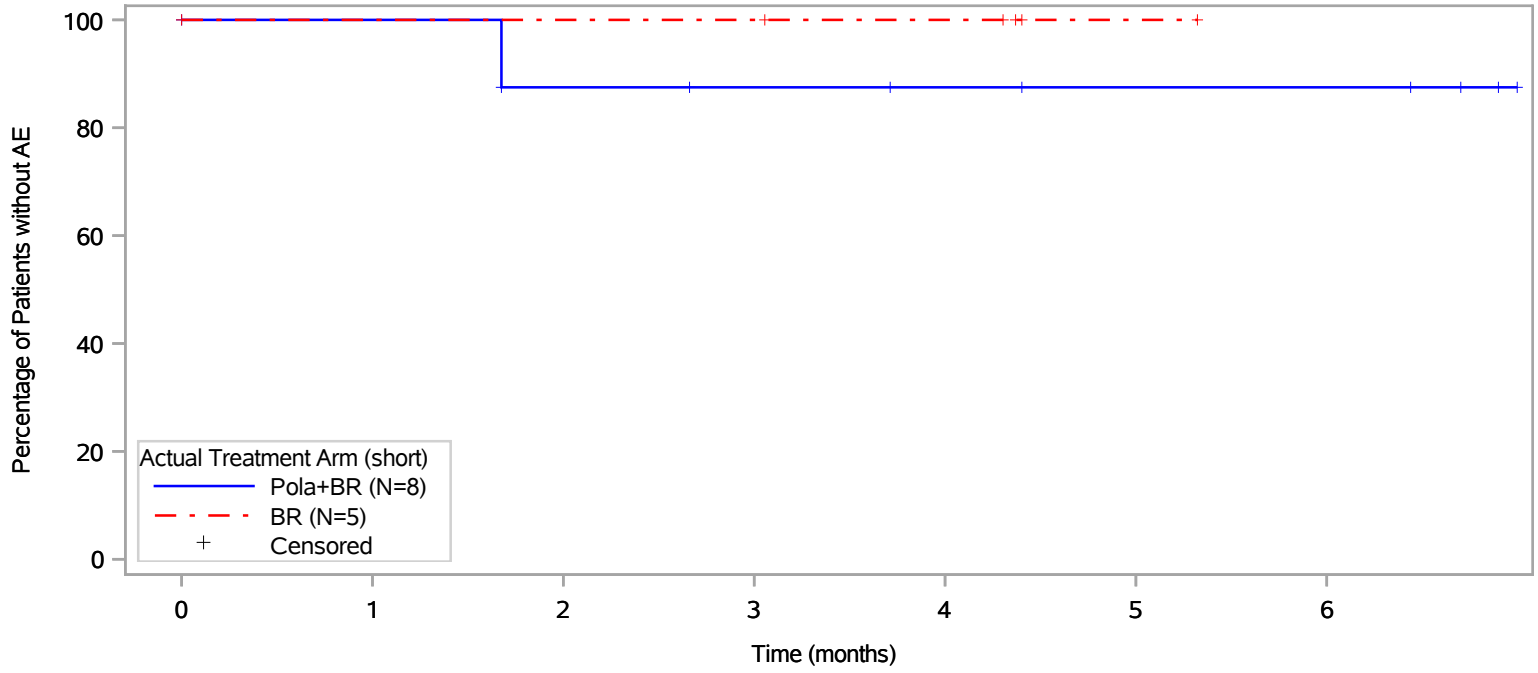
30NOV2022 20:24

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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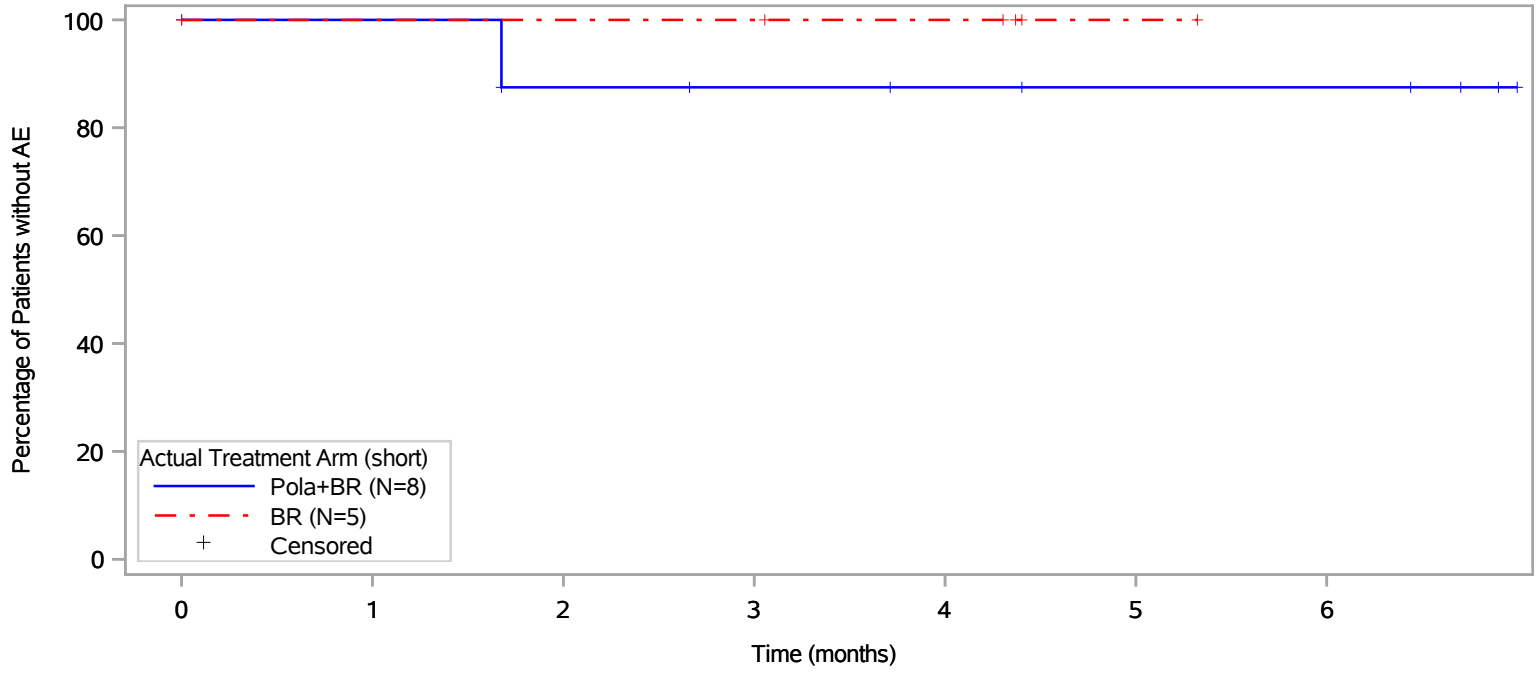
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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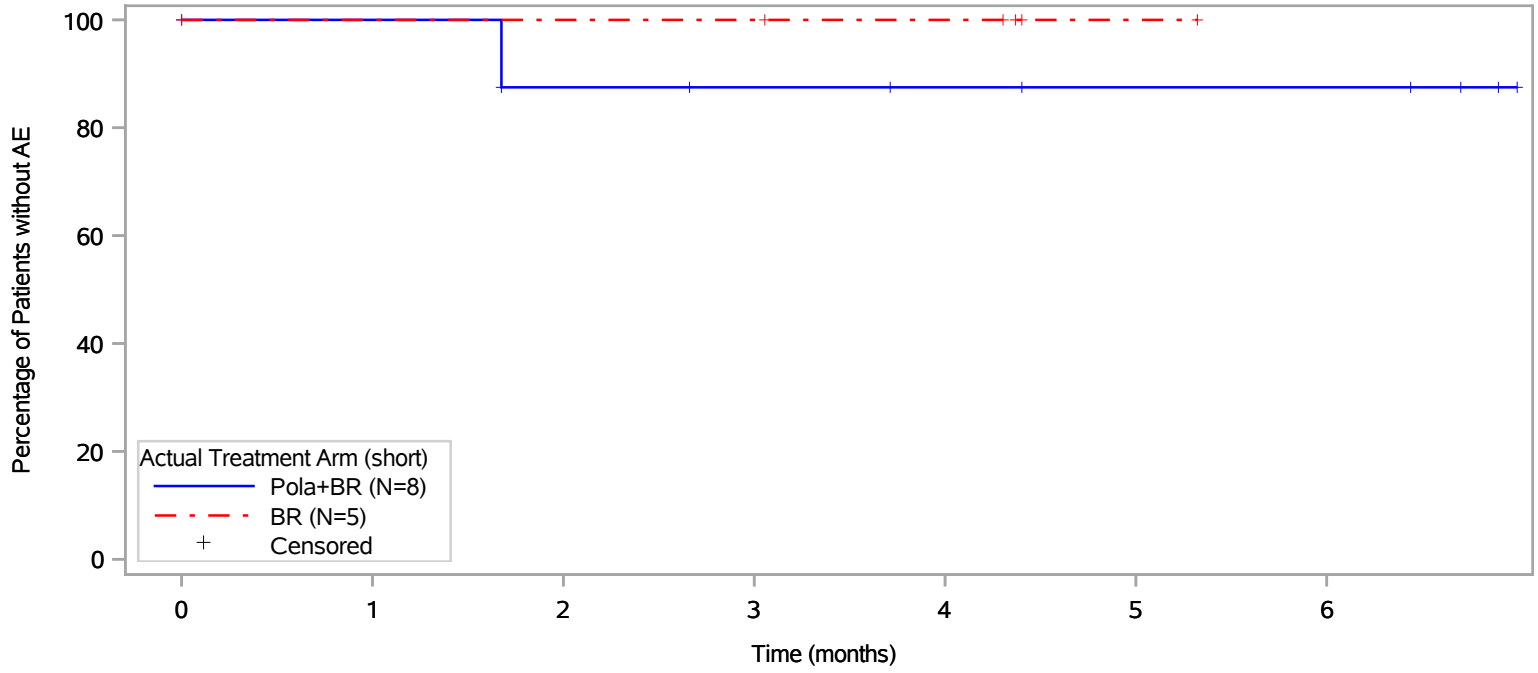
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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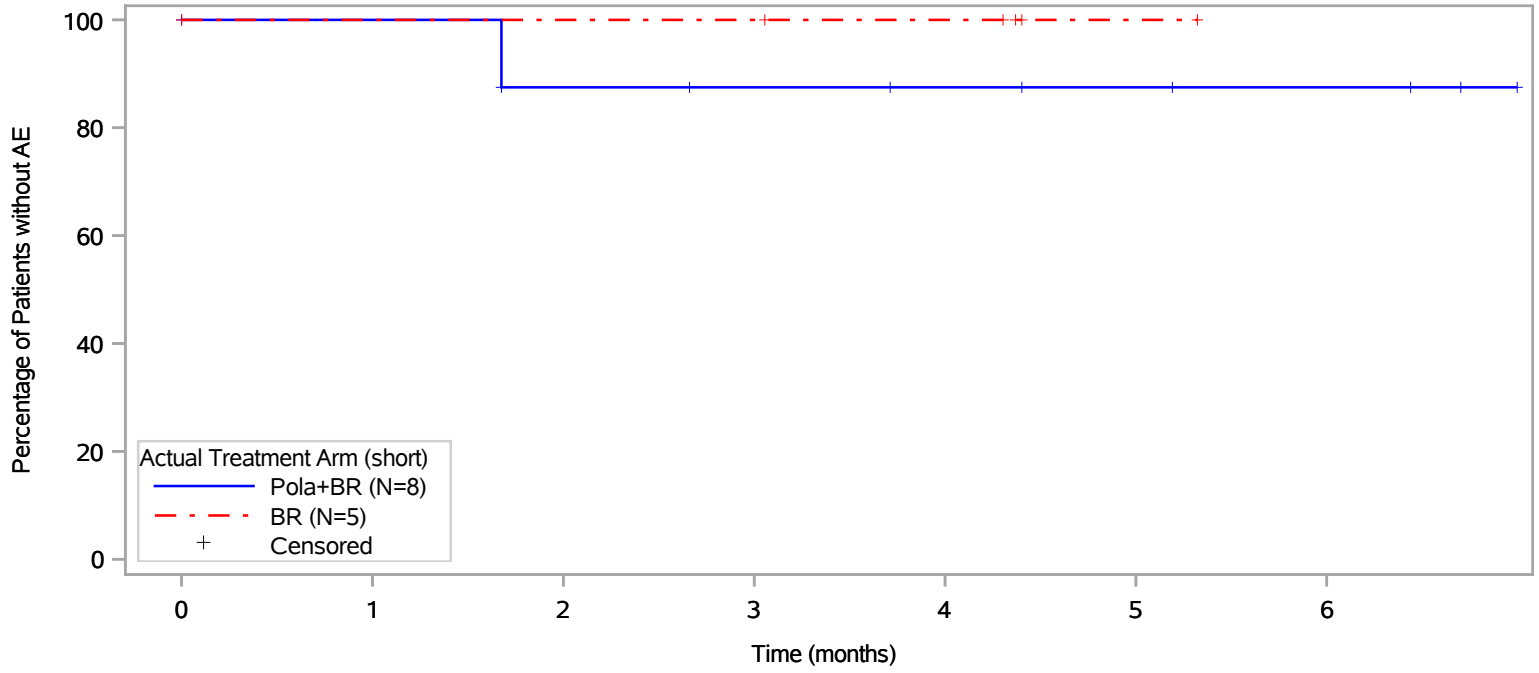
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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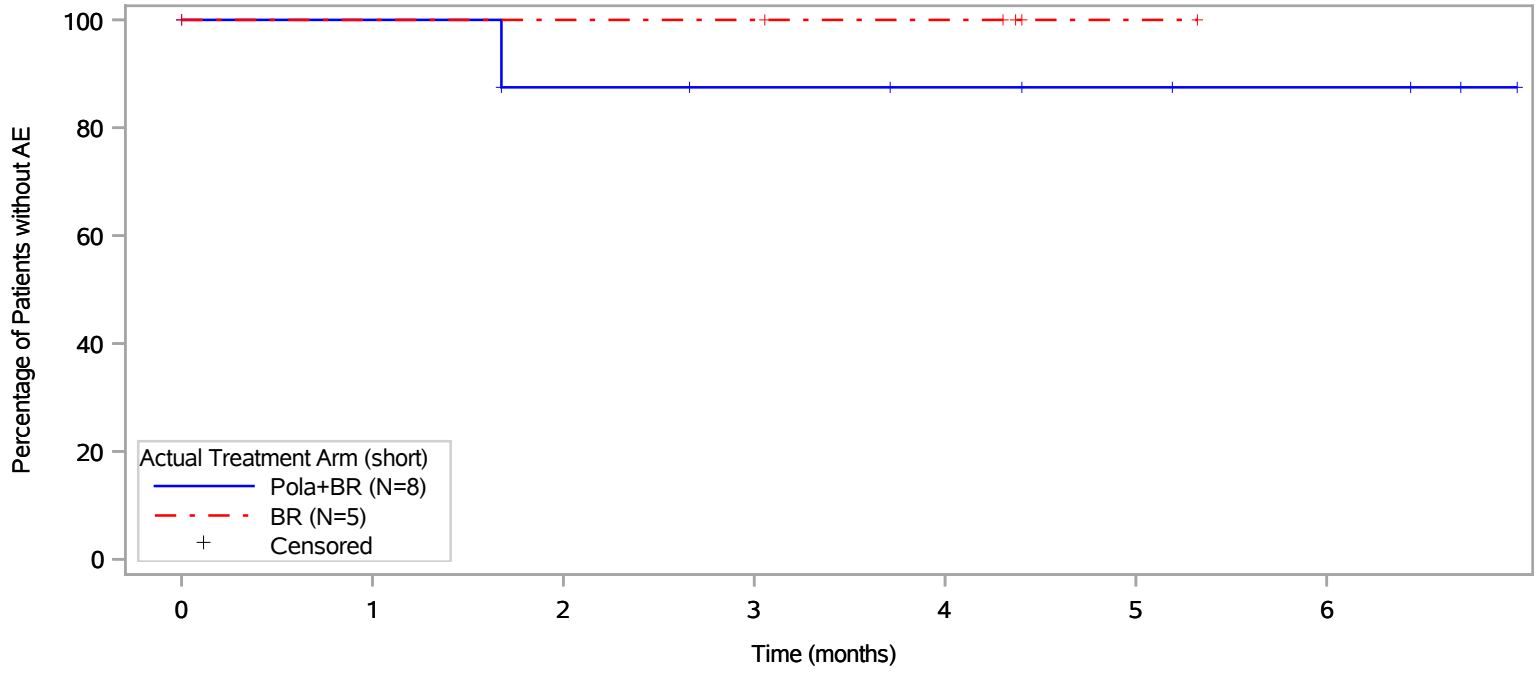
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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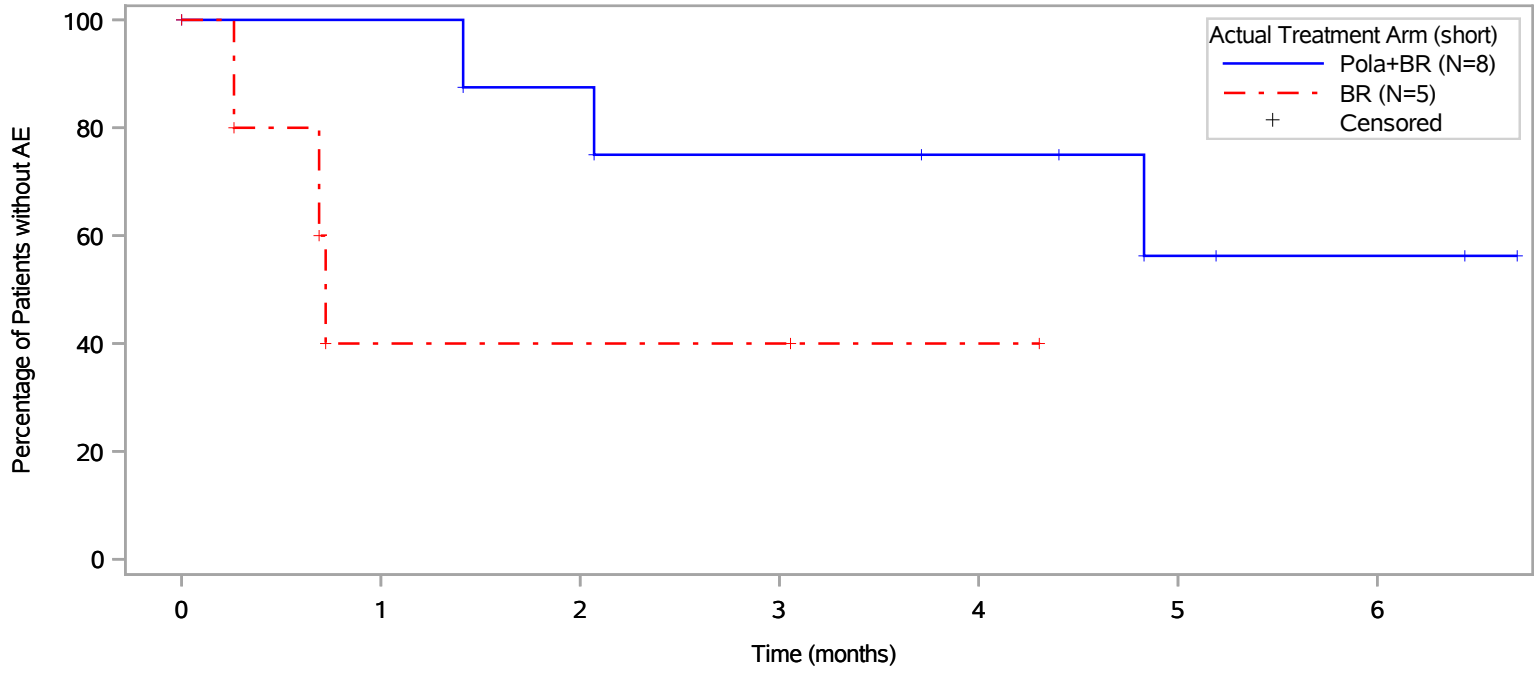
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	3	2
BR (N=5)	5	2	2	2	1	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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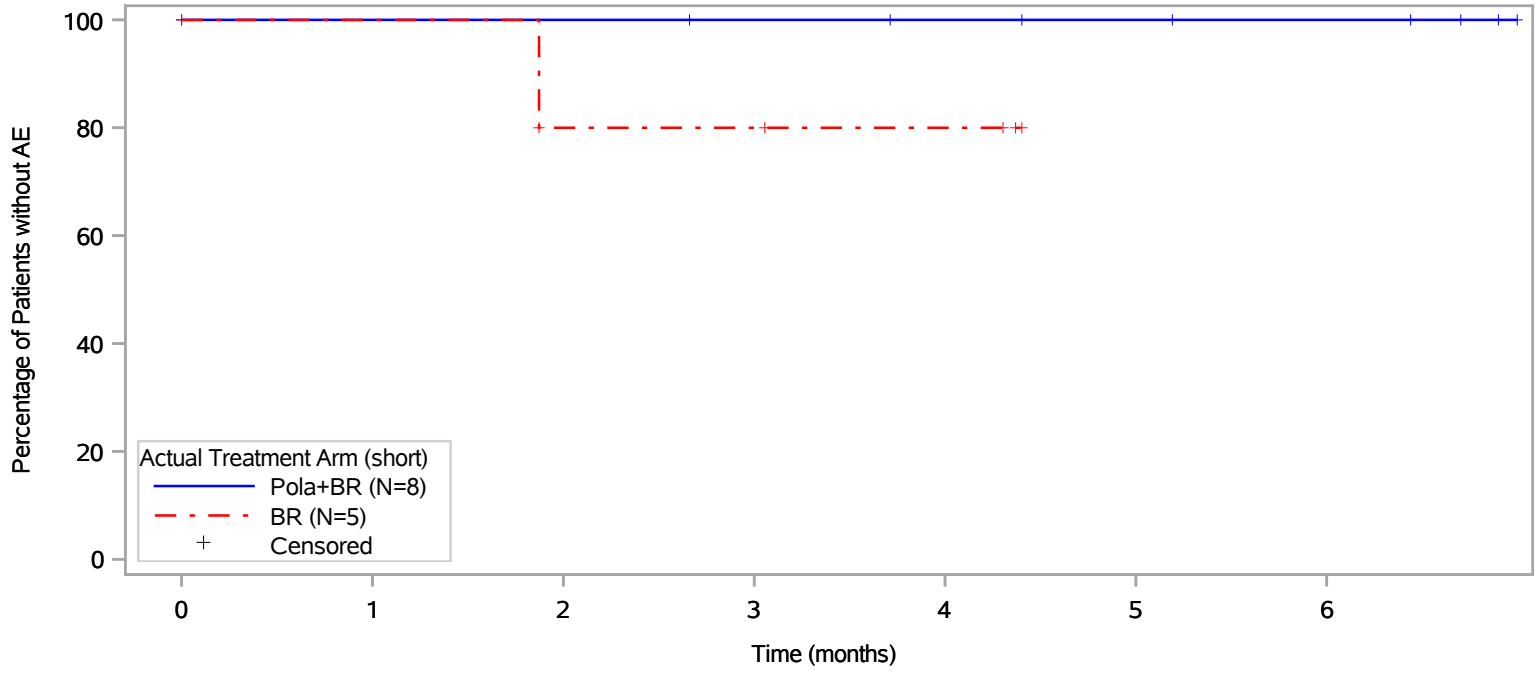
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BILIRUBIN CONJUGATED INCREASED



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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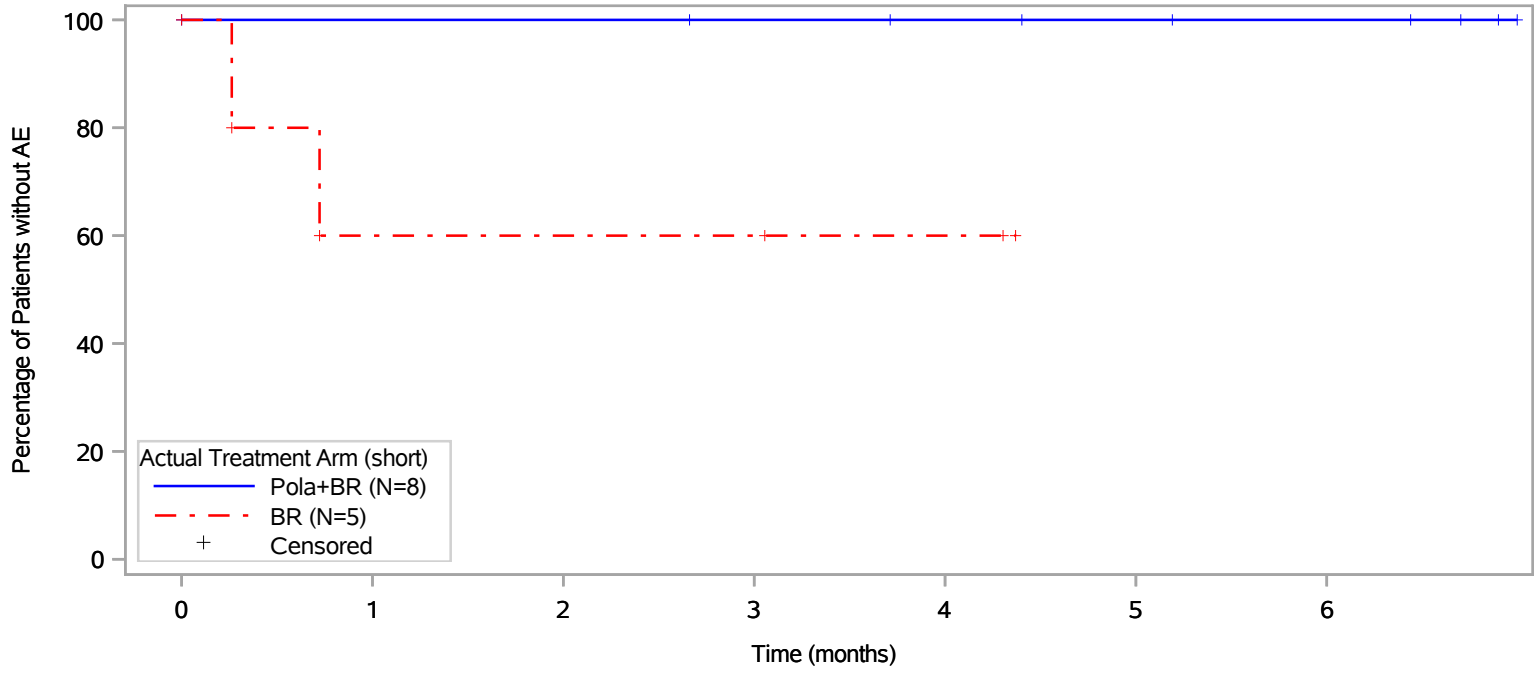
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	3	3	3	2	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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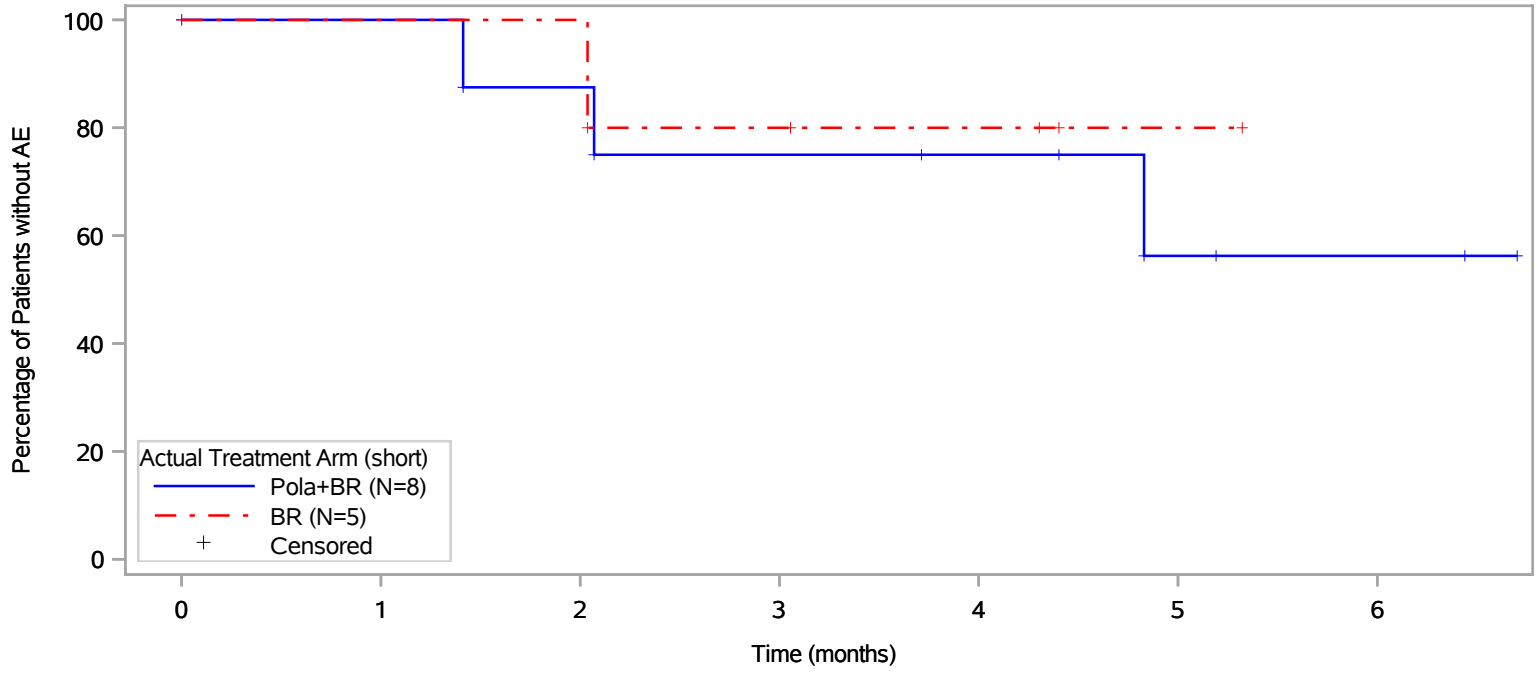
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	3	2
BR (N=5)	5	5	5	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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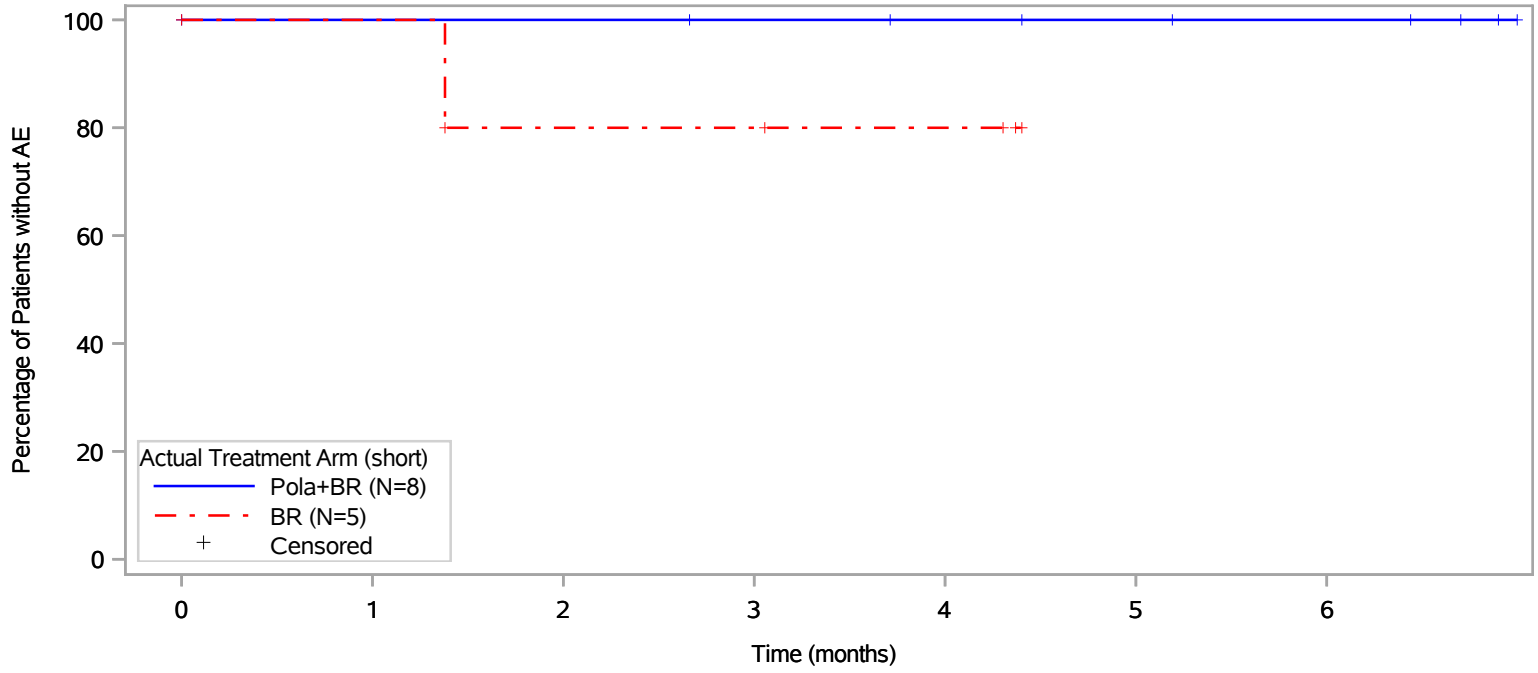
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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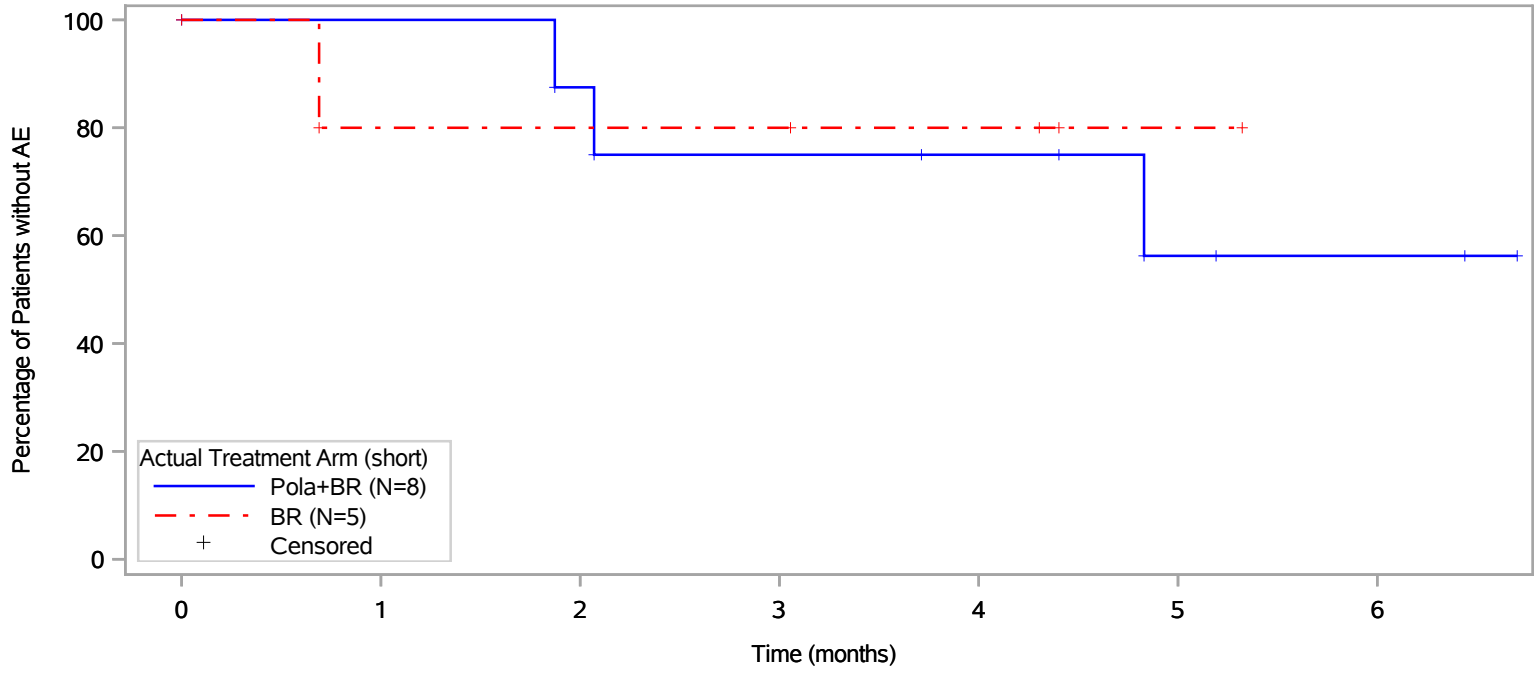
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	3	2
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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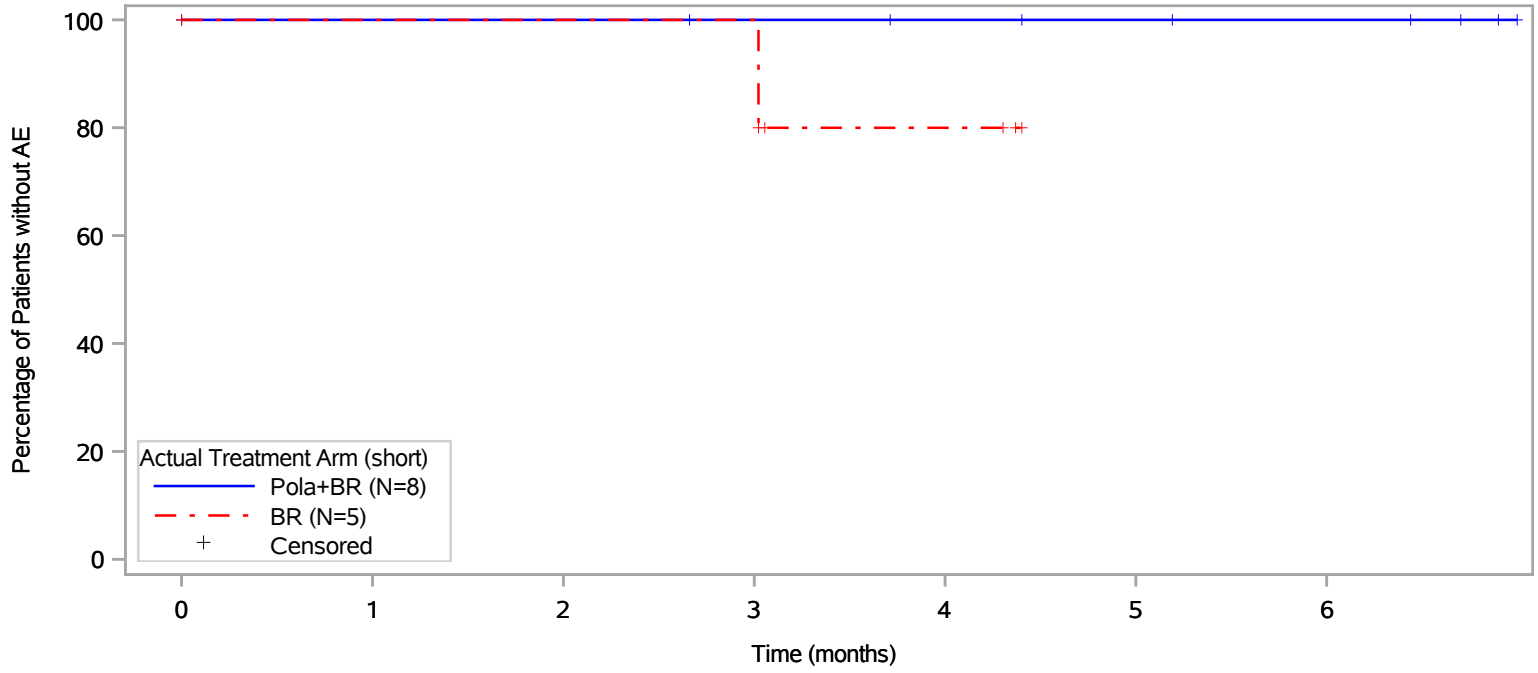
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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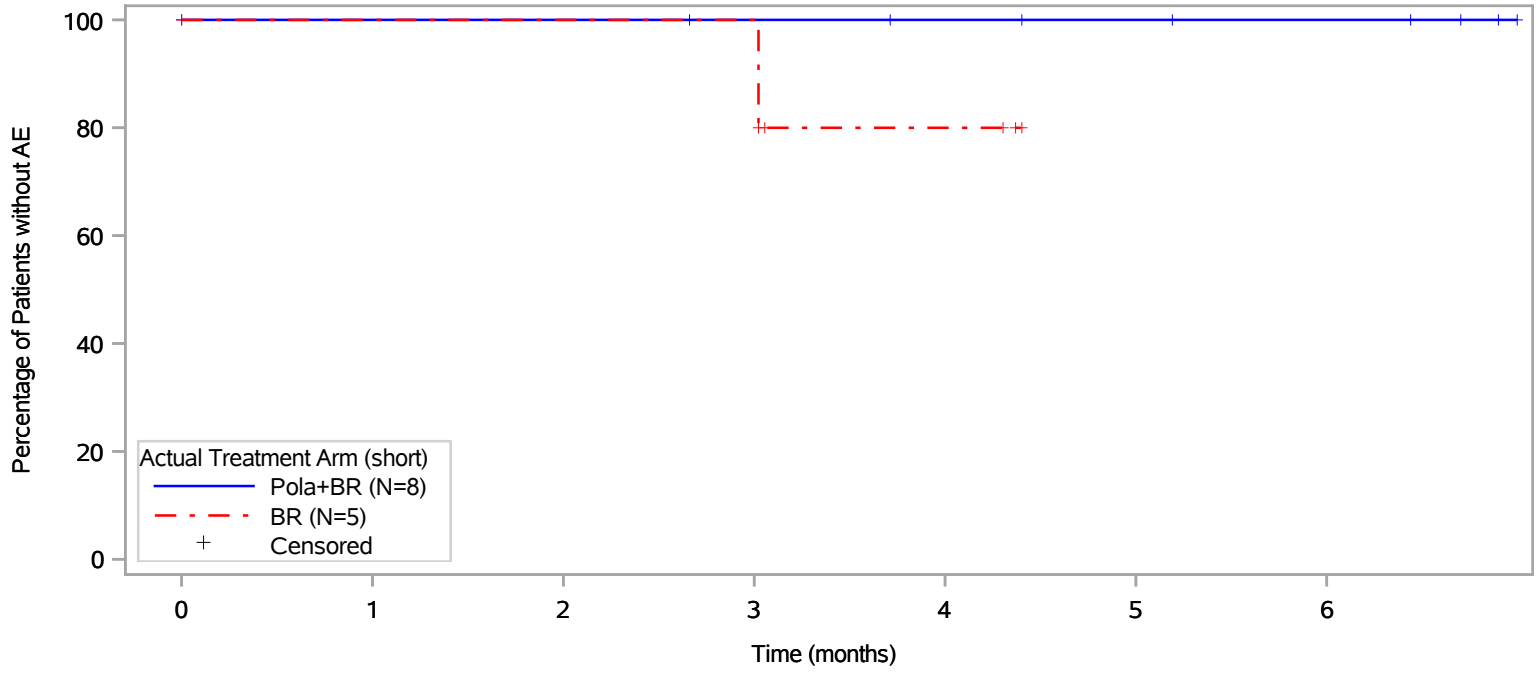
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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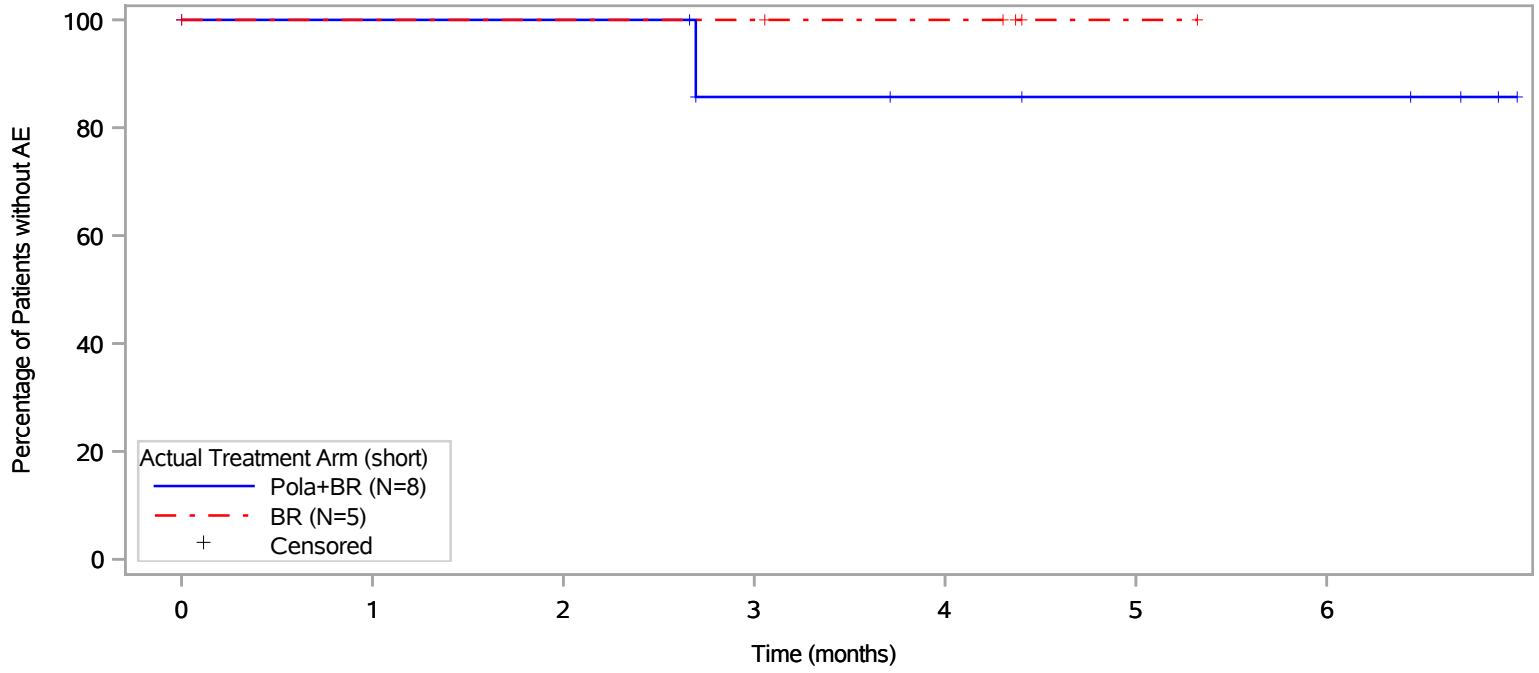
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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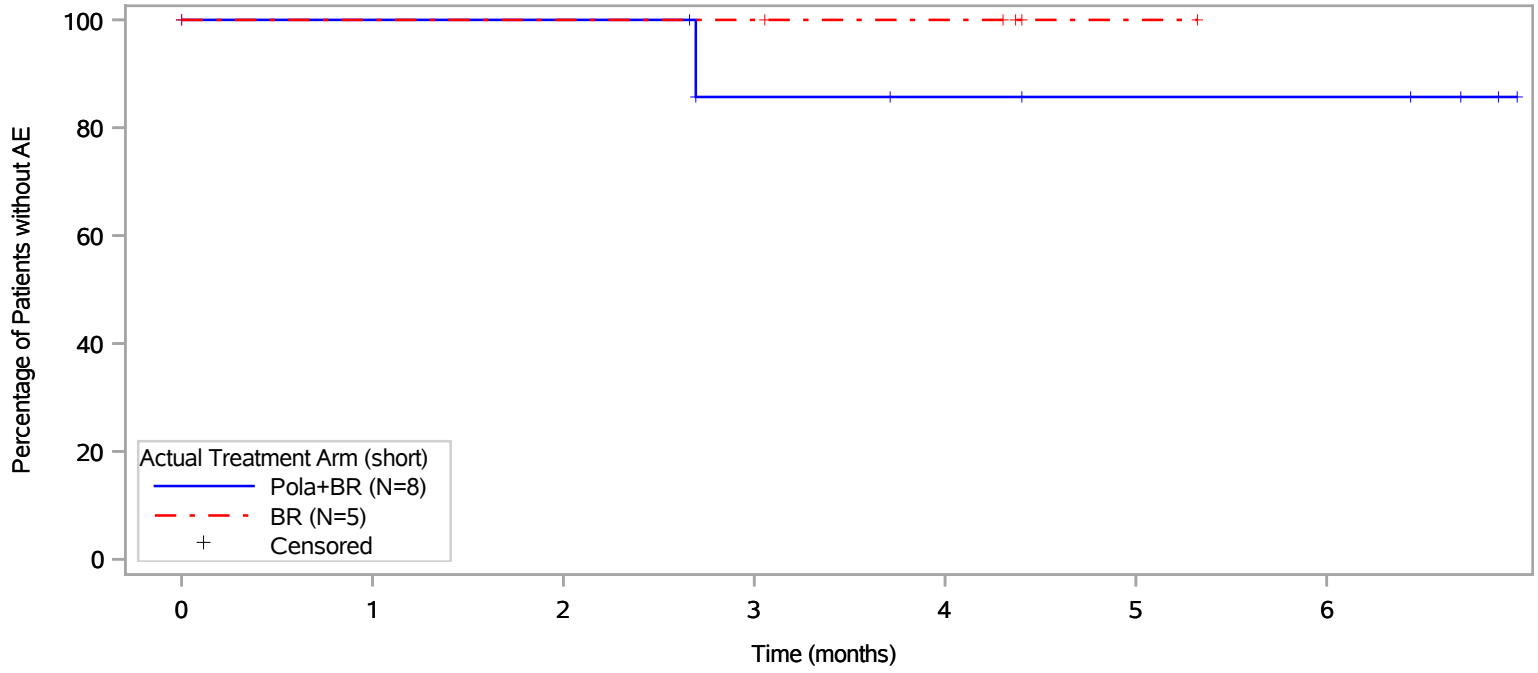
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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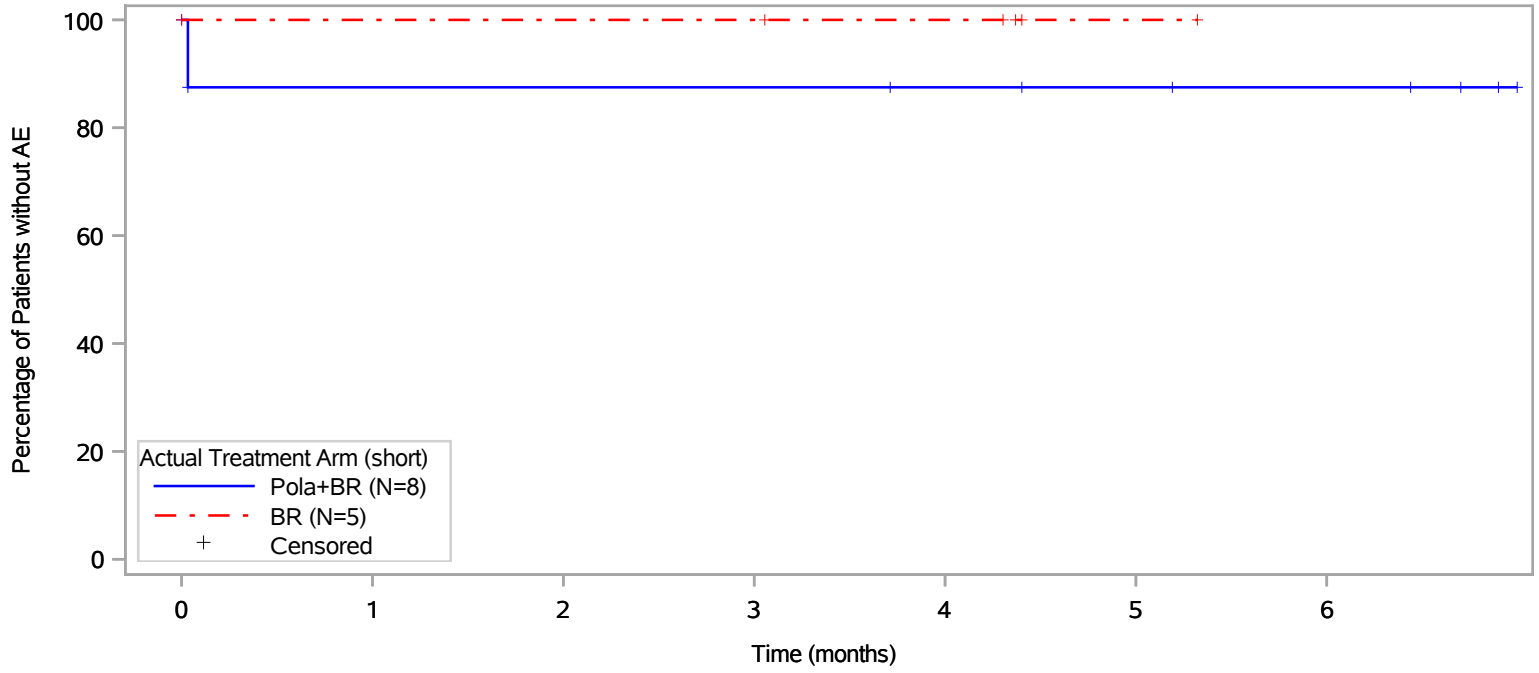
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	7	7	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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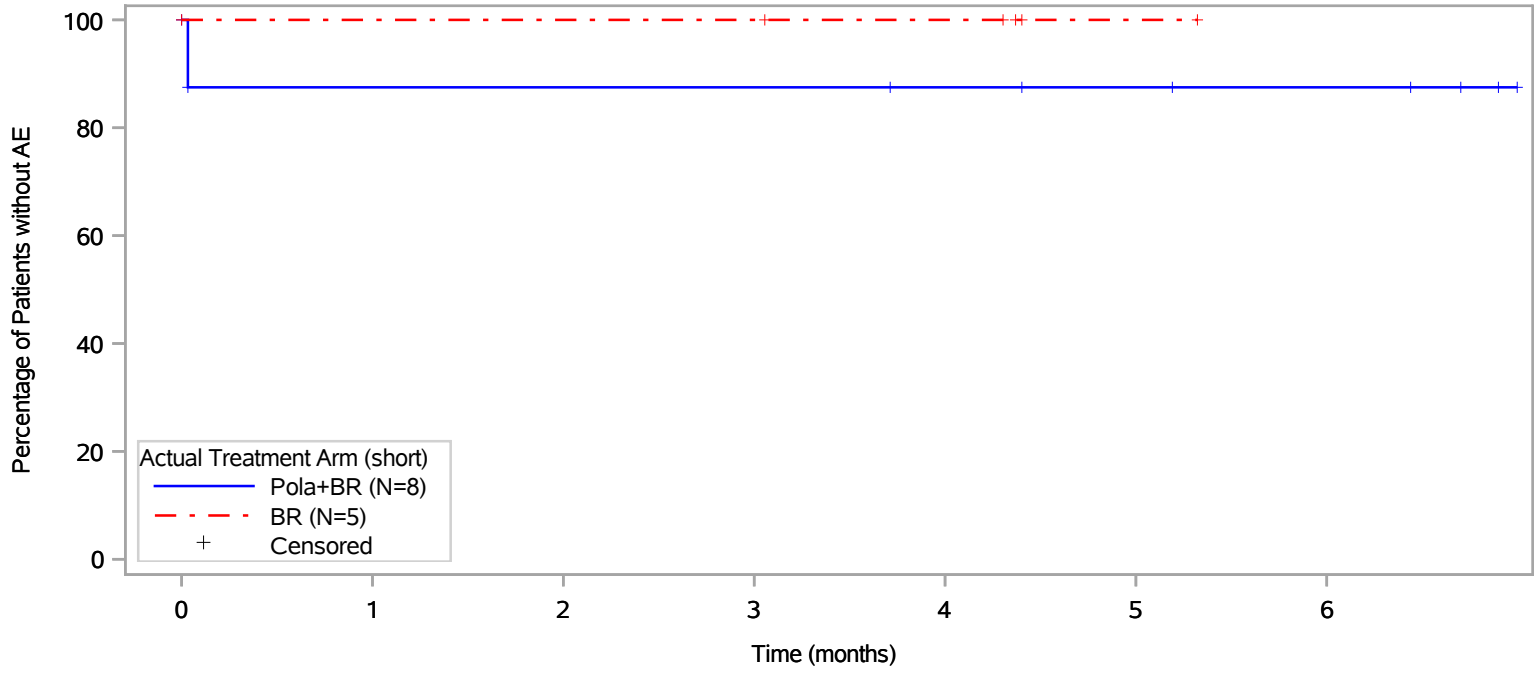
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION



Patients at risk							
Pola+BR (N=8)	8	7	7	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 3:11

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=8)						BR (N=5)				Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		8	100.0	1	12.5	7	87.5	5	100.0	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			8	100.0	2	25.0	6	75.0	5	100.0	5	100.0	0.2137	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		8	100.0	2	25.0	6	75.0	5	100.0	5	100.0	0.2137	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		8	100.0	2	25.0	6	75.0	5	100.0	5	100.0	0.2400	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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30NOV2022 21:14

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=8)						BR (N=5)				Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	5	62.5	2	40.0	3	60.0	2	40.0	2	100.0	0.2807	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	3	37.5	0	-	3	100.0	3	60.0	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	5	62.5	2	40.0	3	60.0	2	40.0	2	100.0	0.2807	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	5	62.5	2	40.0	3	60.0	2	40.0	2	100.0	0.2807	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	3	37.5	0	-	3	100.0	3	60.0	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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30NOV2022 21:14

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=8)						BR (N=5)				Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	2	25.0	0	-	2	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	2	25.0	0	-	2	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0.5024	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0.5024	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	2	25.0	0	-	2	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0.5024	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=8)						BR (N=5)				Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	5	100.0	0.2137	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	5	100.0	0.2137	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	5	100.0	0.2400	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=8)						BR (N=5)				Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	1	12.5	0	-	1	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	7	87.5	2	28.6	5	71.4	1	20.0	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	1	12.5	0	-	1	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	7	87.5	2	28.6	5	71.4	1	20.0	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	1	12.5	0	-	1	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	7	87.5	2	28.6	5	71.4	1	20.0	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	1	12.5	0	-	1	100.0	4	80.0	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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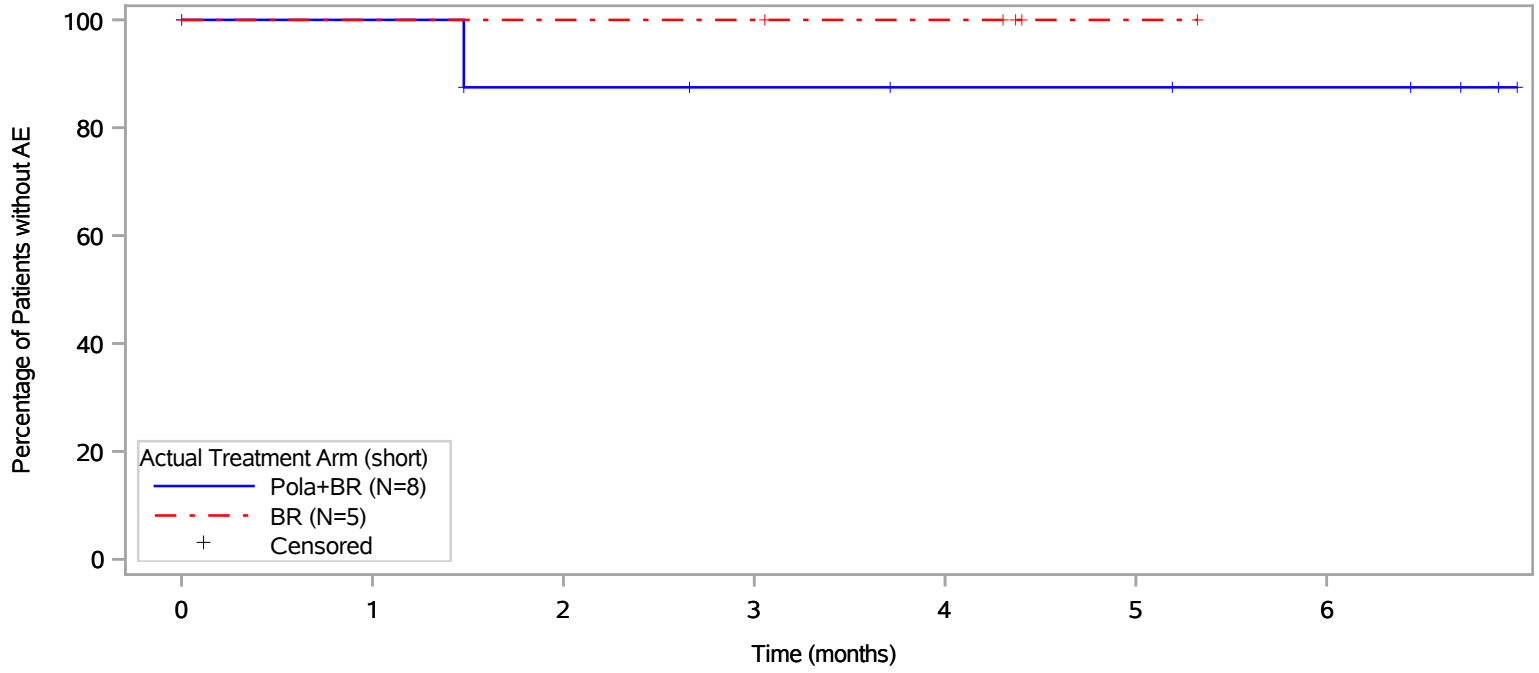
30NOV2022 21:14

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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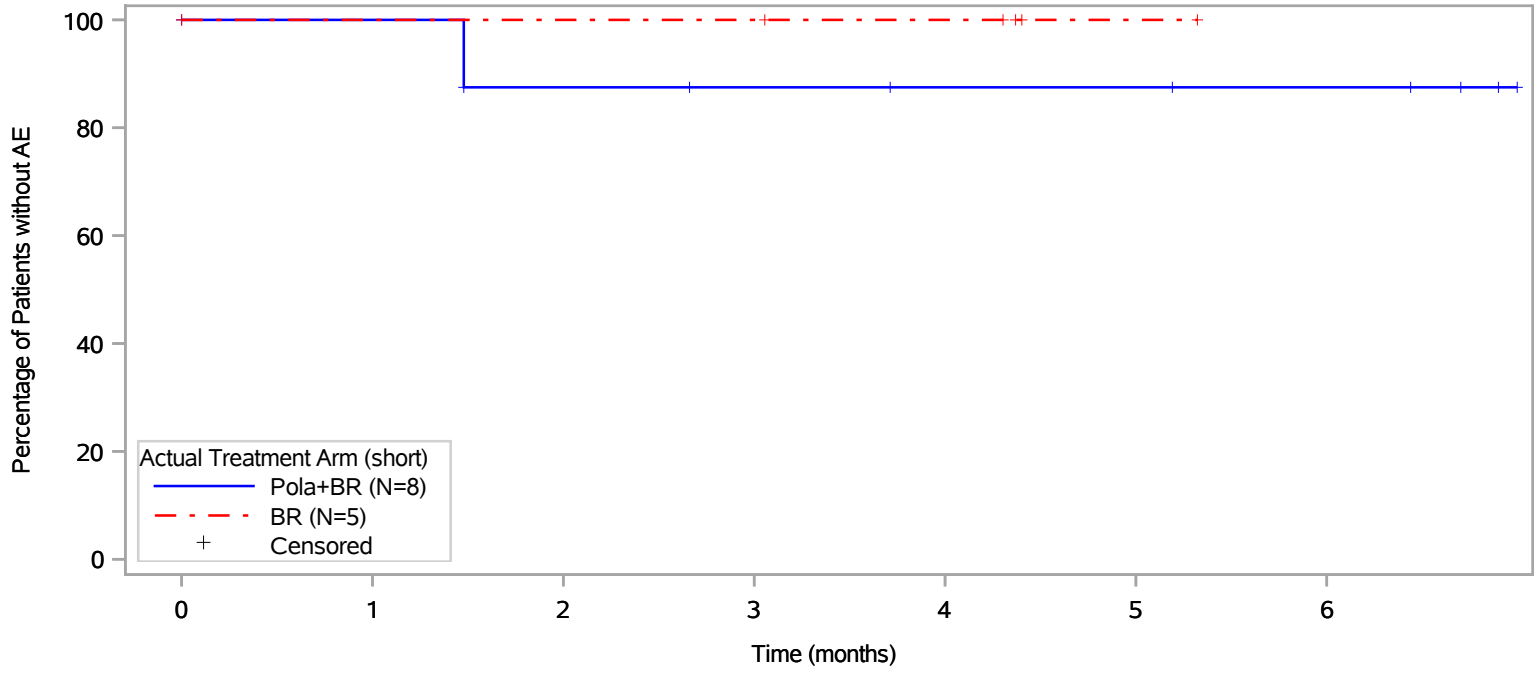
02DEC2022 4:33

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA

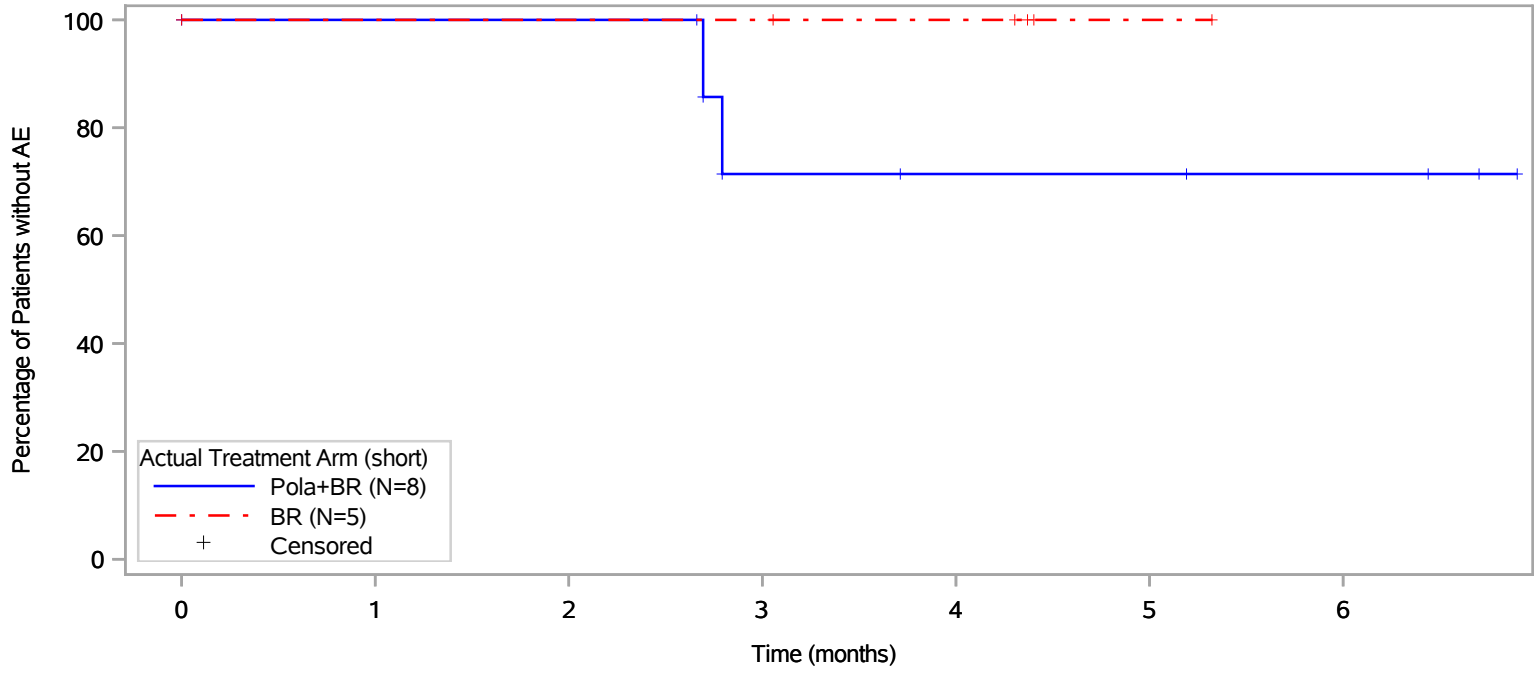


Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR4AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 4:33

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

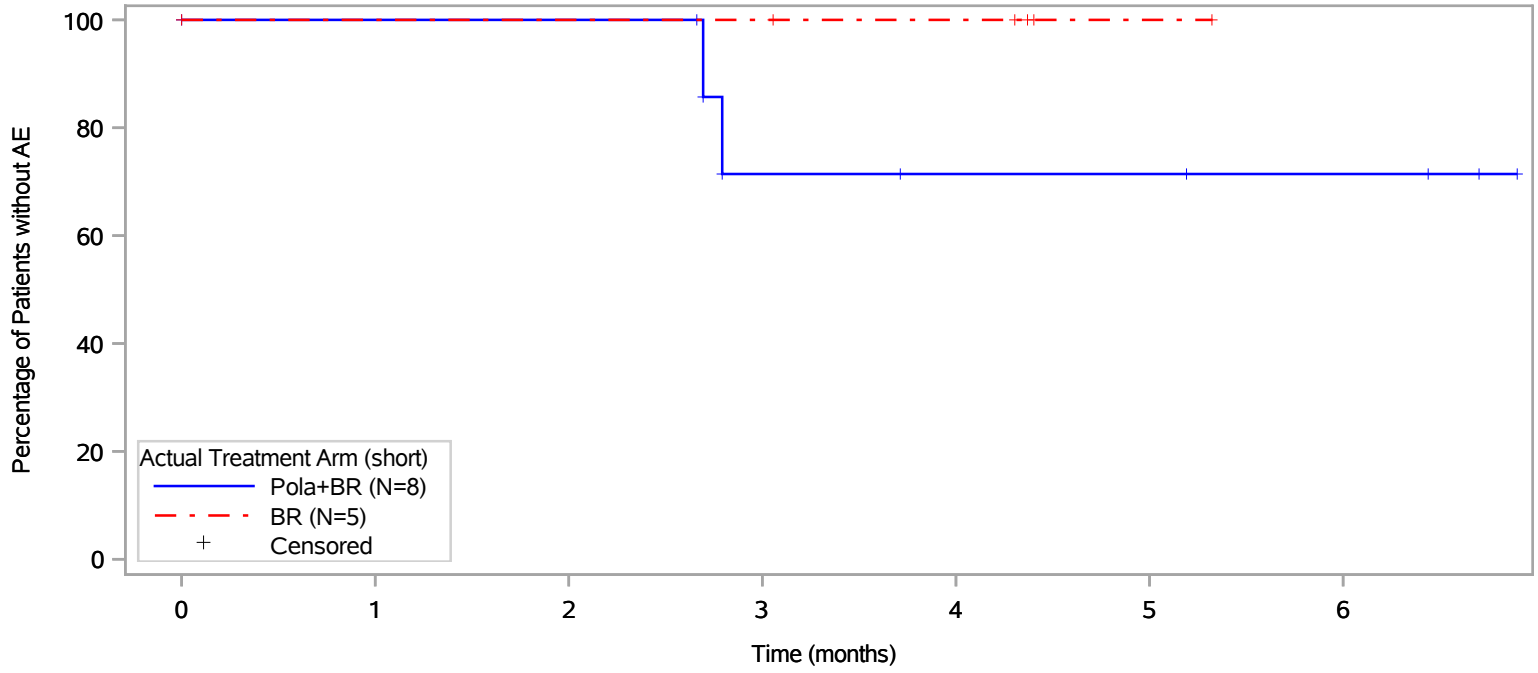


Patients at risk							
Pola+BR (N=8)	8	8	8	5	4	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR4AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 4:33

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

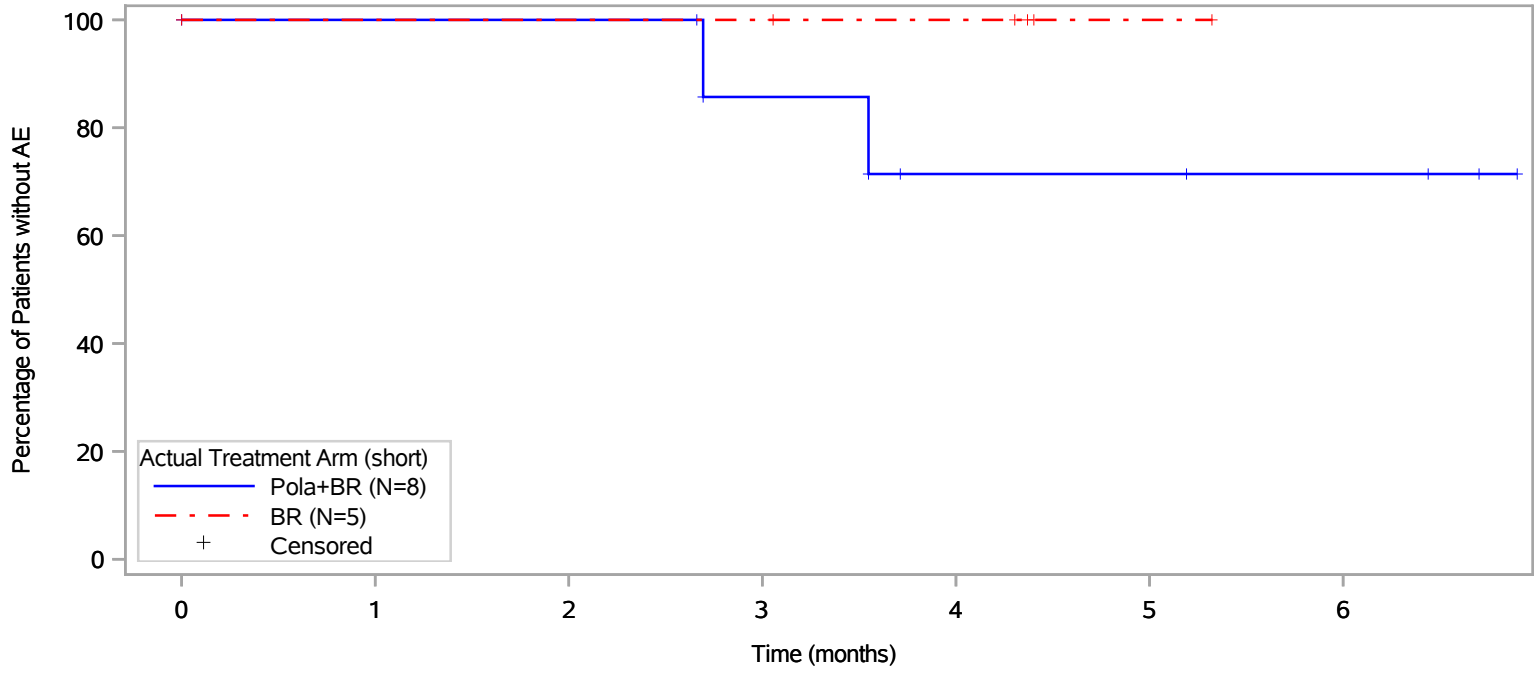


Patients at risk							
Pola+BR (N=8)	8	8	8	5	4	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR4AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 4:33

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk							
Pola+BR (N=8)	8	8	8	6	4	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR4AE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 4:33

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

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

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sg1_TTGR5AE_L2_Polarose_SE_29365_41543.xls
30NOV2022 22:16

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543

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

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR5AE_L2_Polarose_SE_29365_41543.xls
02DEC2022 5:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTSAE_L2_Polarose_SE_29365_41543.xls
30NOV2022 23:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTSAE_L2_Polarose_SE_29365_41543.xls
30NOV2022 23:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTSAE_L2_Polarose_SE_29365_41543.xls
30NOV2022 23:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.3980	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTSAE_L2_Polarose_SE_29365_41543.xls
30NOV2022 23:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	ASTHENIA	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HYDRONEPHROSIS	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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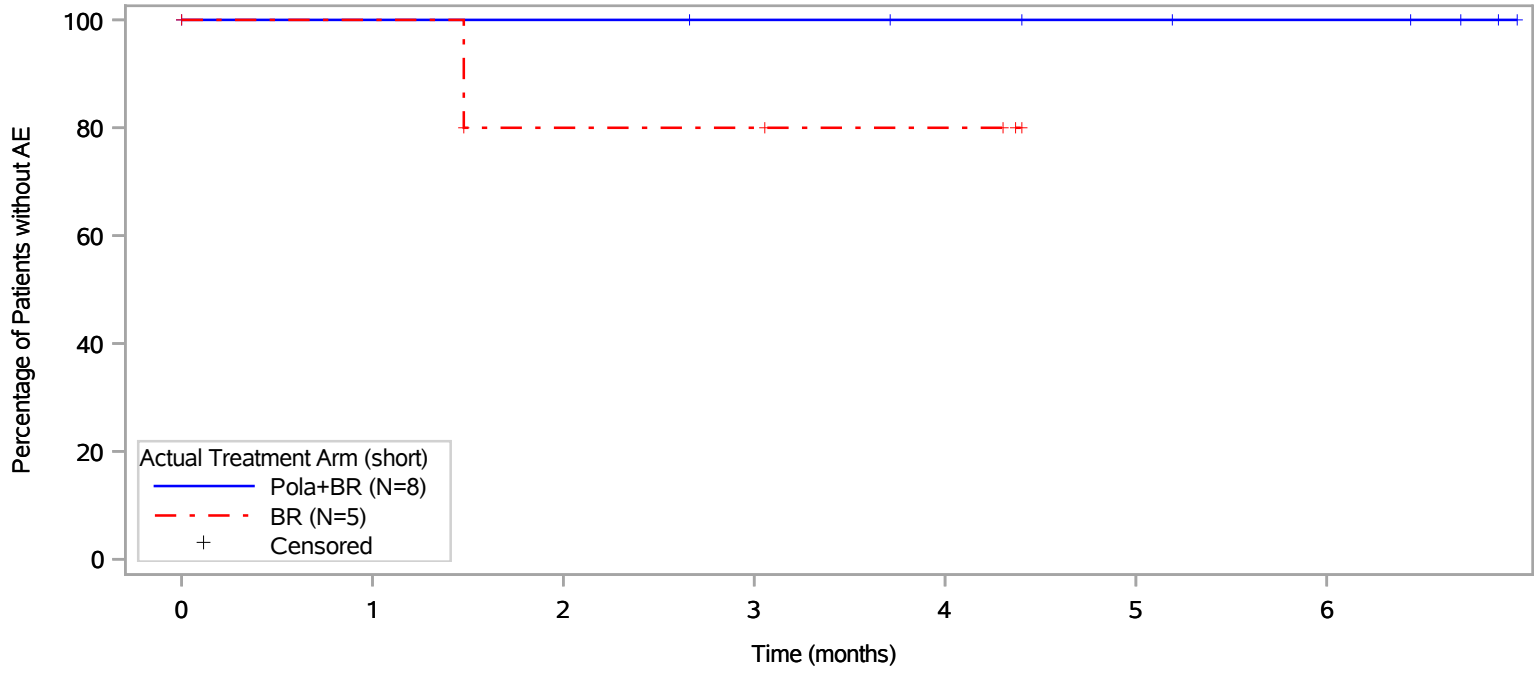
30NOV2022 23:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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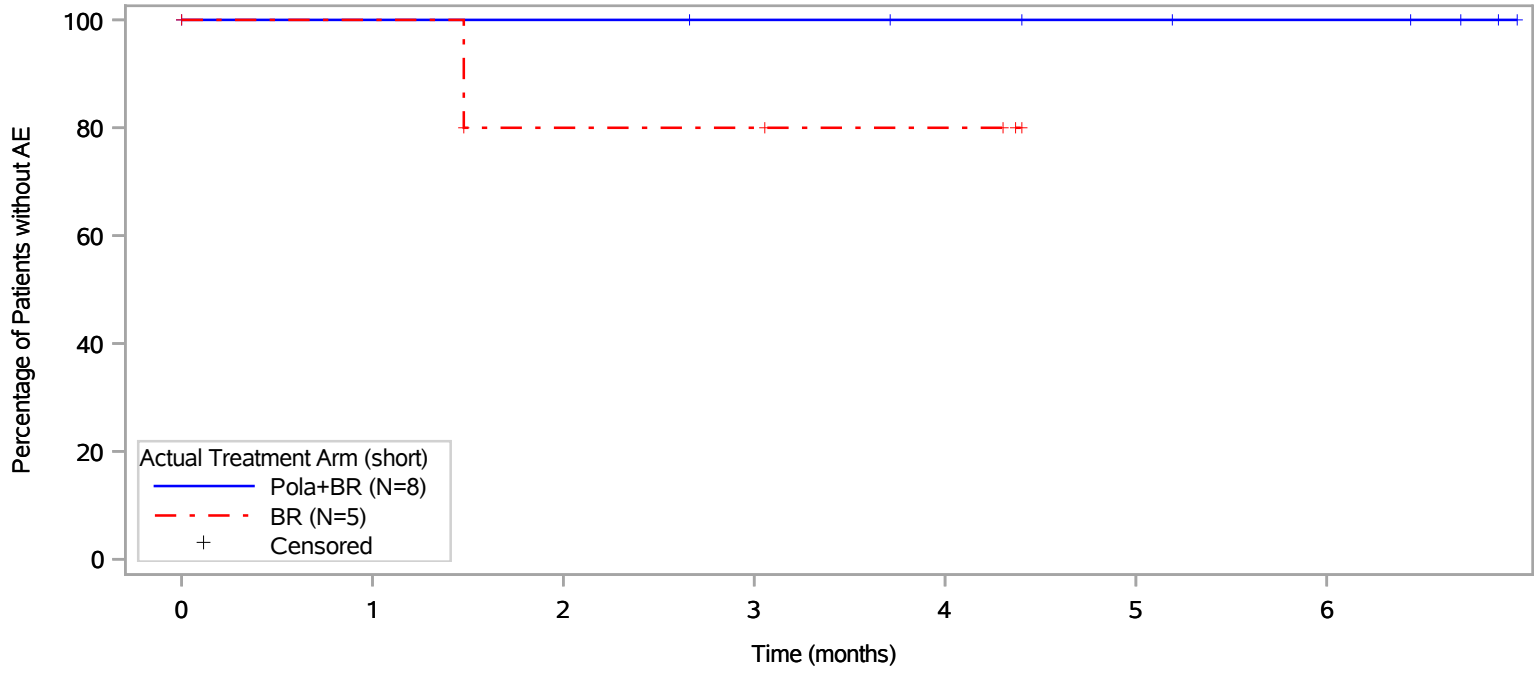
02DEC2022 5:58

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, ASTHENIA

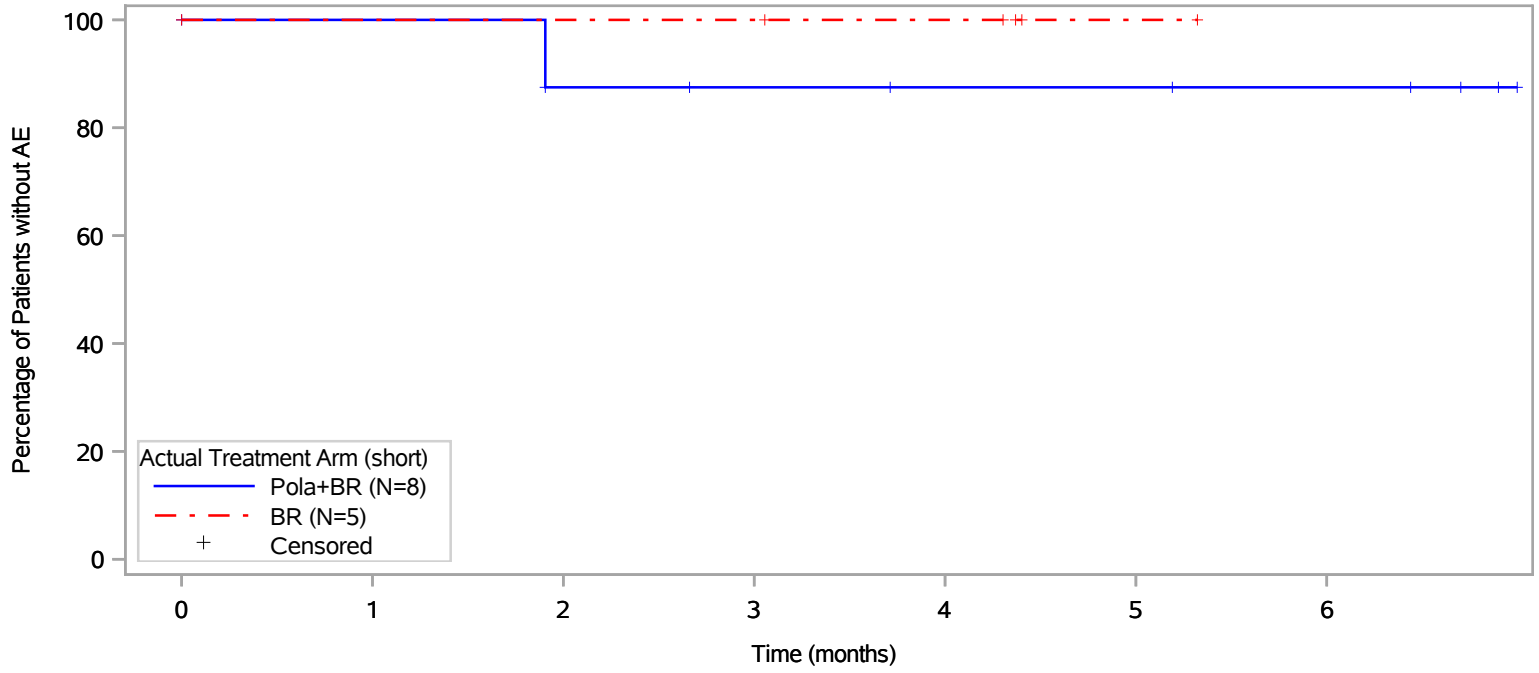


Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTSAE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 5:58

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All

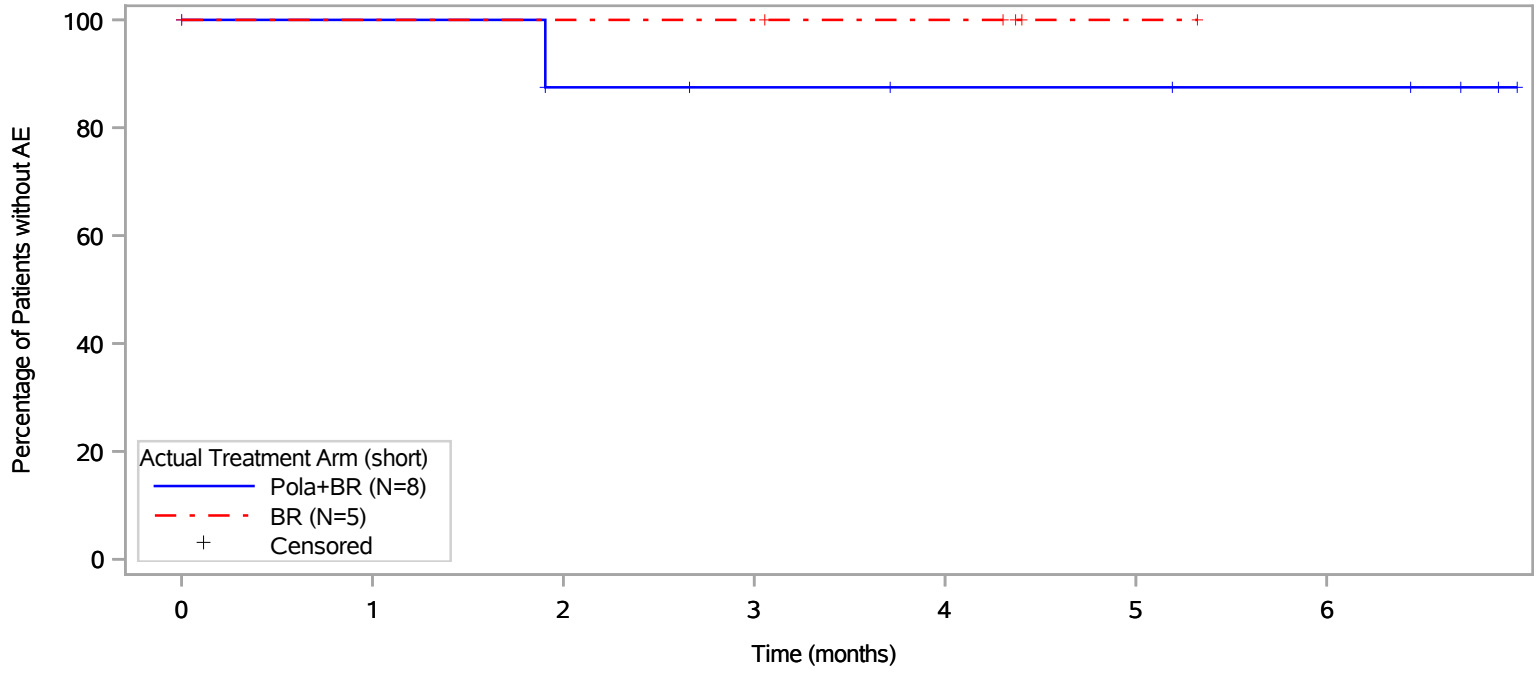


Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTSAE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 5:58

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA

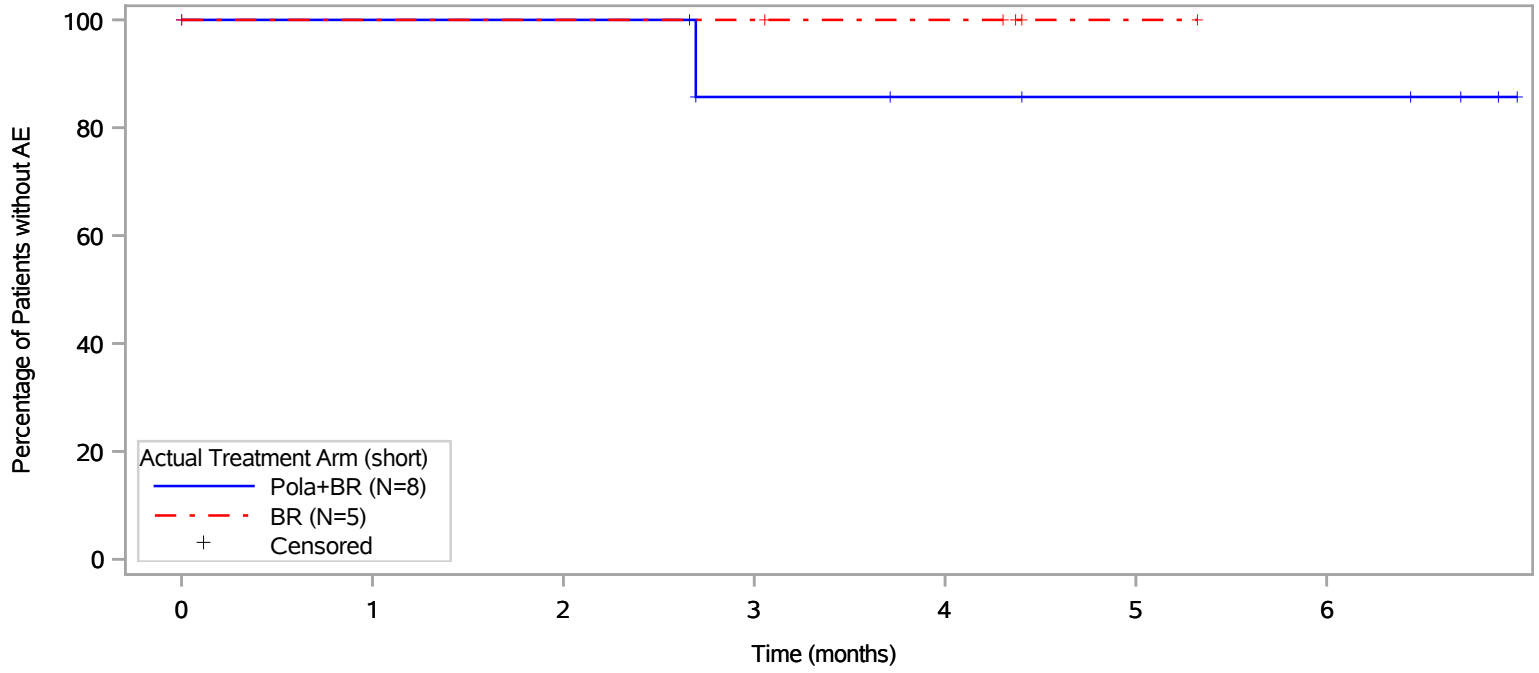


Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTSAE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 5:58

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All

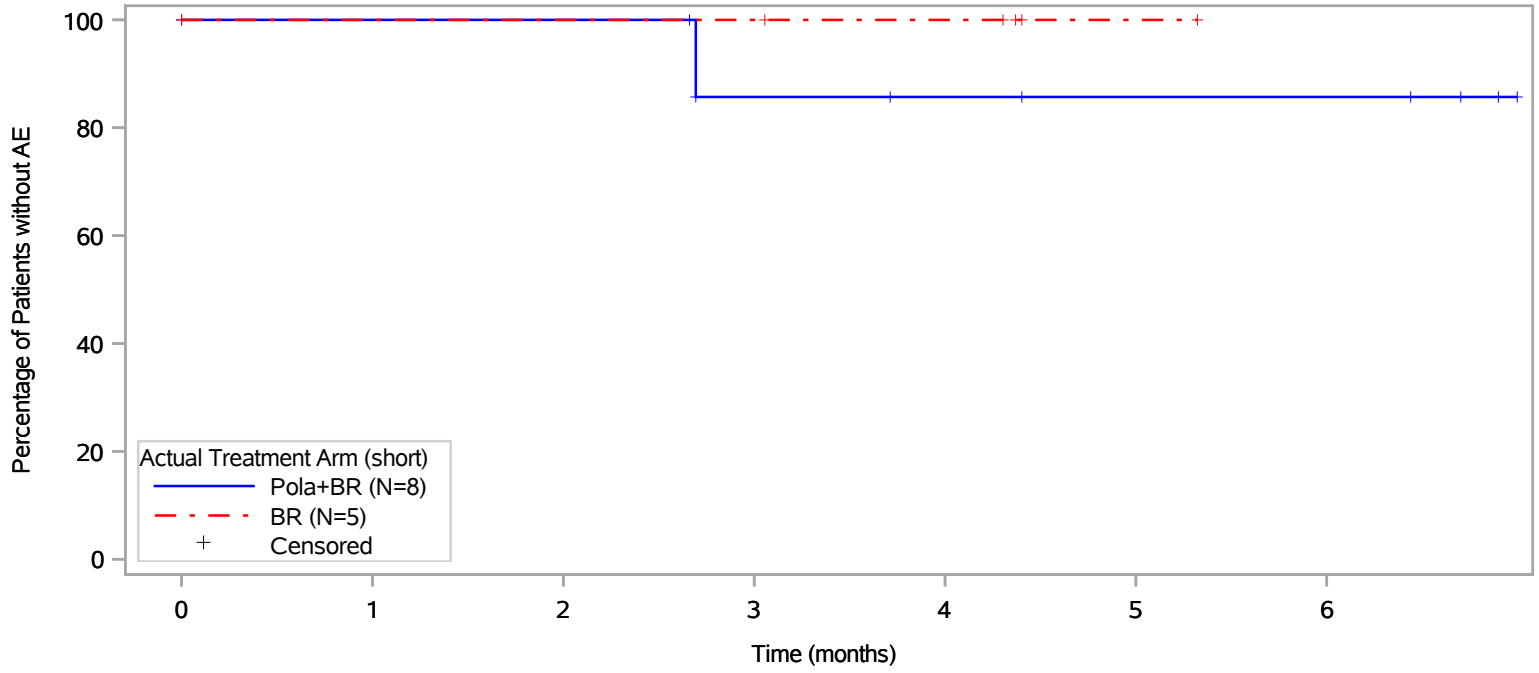


Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTSAE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 5:58

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HYDRONEPHROSIS



Patients at risk							
Pola+BR (N=8)	8	8	8	6	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTSAE_L2_Polarose_SE_29365_41543.pdf
02DEC2022 5:58

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

All

			Pola+BR (N=8)				BR (N=5)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
INVESTIGATIONS			8	100.0	0	-	5	100.0	1	20.0
INVESTIGATIONS	PLATELET COUNT DECREASED		8	100.0	0	-	5	100.0	1	20.0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_soc_descriptive_sg1_TTWDAE_L2_Polarose_SE_29365_41543.xls
24JAN2023 17:44

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=8)				BR (N=5)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
INVESTIGATIONS		< 65	5	62.5	0	-	2	40.0	0	-
INVESTIGATIONS		>= 65	3	37.5	0	-	3	60.0	1	33.3
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	5	62.5	0	-	2	40.0	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	3	37.5	0	-	3	60.0	1	33.3

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:44

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=8)				BR (N=5)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
INVESTIGATIONS		>=3	2	25.0	0	-	4	80.0	1	25.0
INVESTIGATIONS		<3	6	75.0	0	-	1	20.0	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	2	25.0	0	-	4	80.0	1	25.0
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	6	75.0	0	-	1	20.0	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:44

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=8)				BR (N=5)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
INVESTIGATIONS		Non-Europe	8	100.0	0	-	5	100.0	1	20.0
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	8	100.0	0	-	5	100.0	1	20.0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_soc_descriptive_sg1_TTWDAE_L2_Polarose_SE_29365_41543.xls
24JAN2023 17:44

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=8)				BR (N=5)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
INVESTIGATIONS		Male	7	87.5	0	-	1	20.0	0	-
INVESTIGATIONS		Female	1	12.5	0	-	4	80.0	1	25.0
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	7	87.5	0	-	1	20.0	0	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	1	12.5	0	-	4	80.0	1	25.0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:44

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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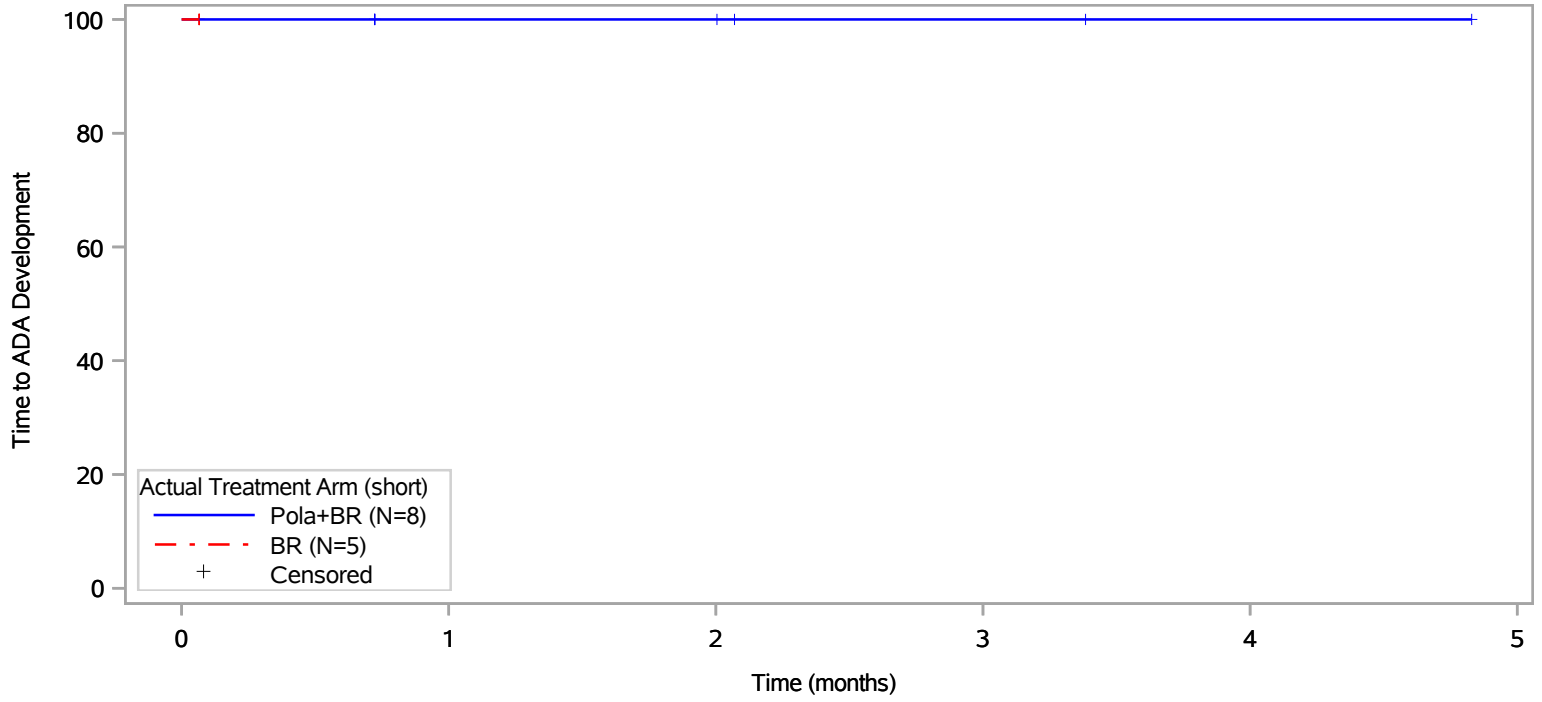
06APR2023 19:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
STUDIES: GO29365, YO41543



Patients at risk					
Pola+BR (N=8)	8	4	4	2	1
BR (N=5)	5	NE	NE	NE	NE
Patients censored					
Pola+BR (N=8)	0	4	4	6	7
BR (N=5)	0	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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06APR2023 19:47

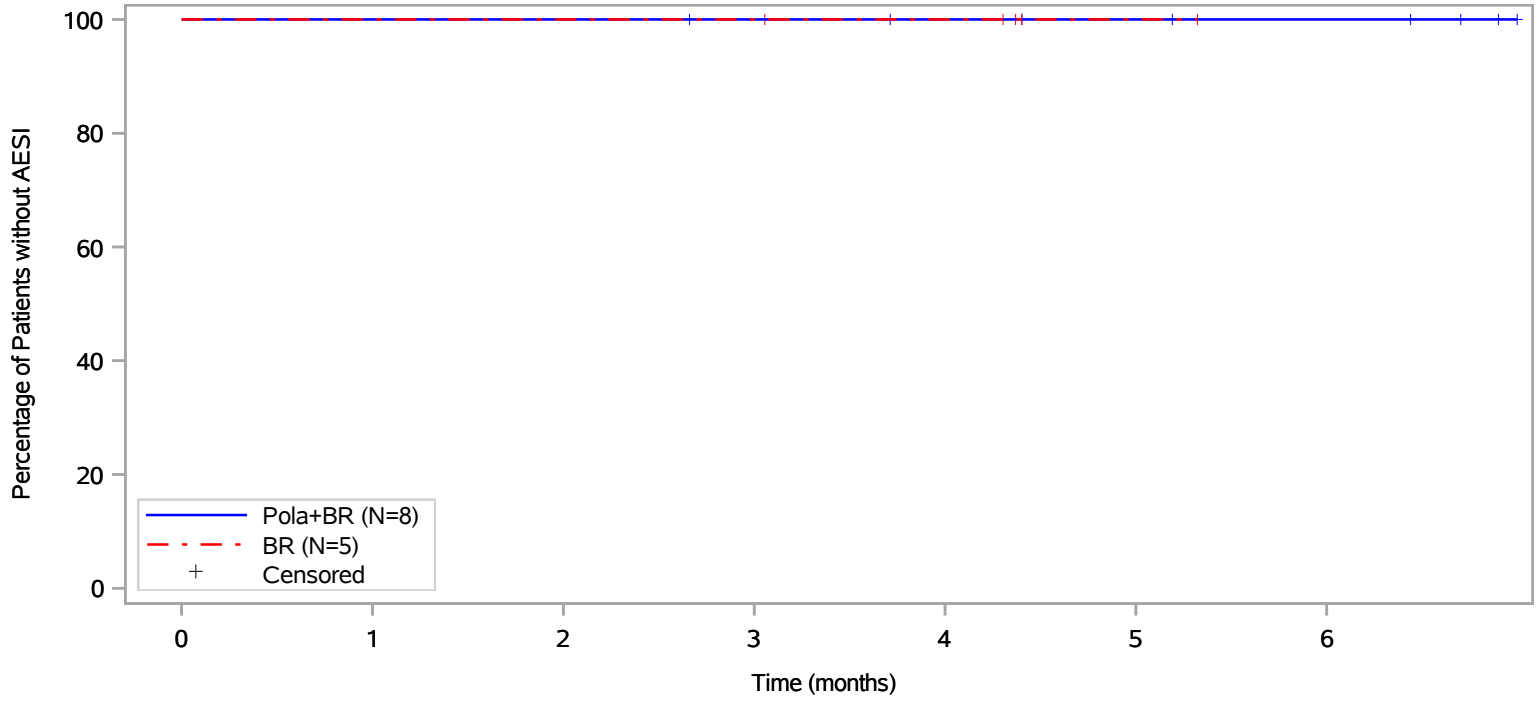
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTALOPE_L2_Polarose_SE_29365_41543.xls
01DEC2022 19:45

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Alopecia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTALOPE_L2_Polarose_SE_29365_41543.pdf
03DEC2022 21:49

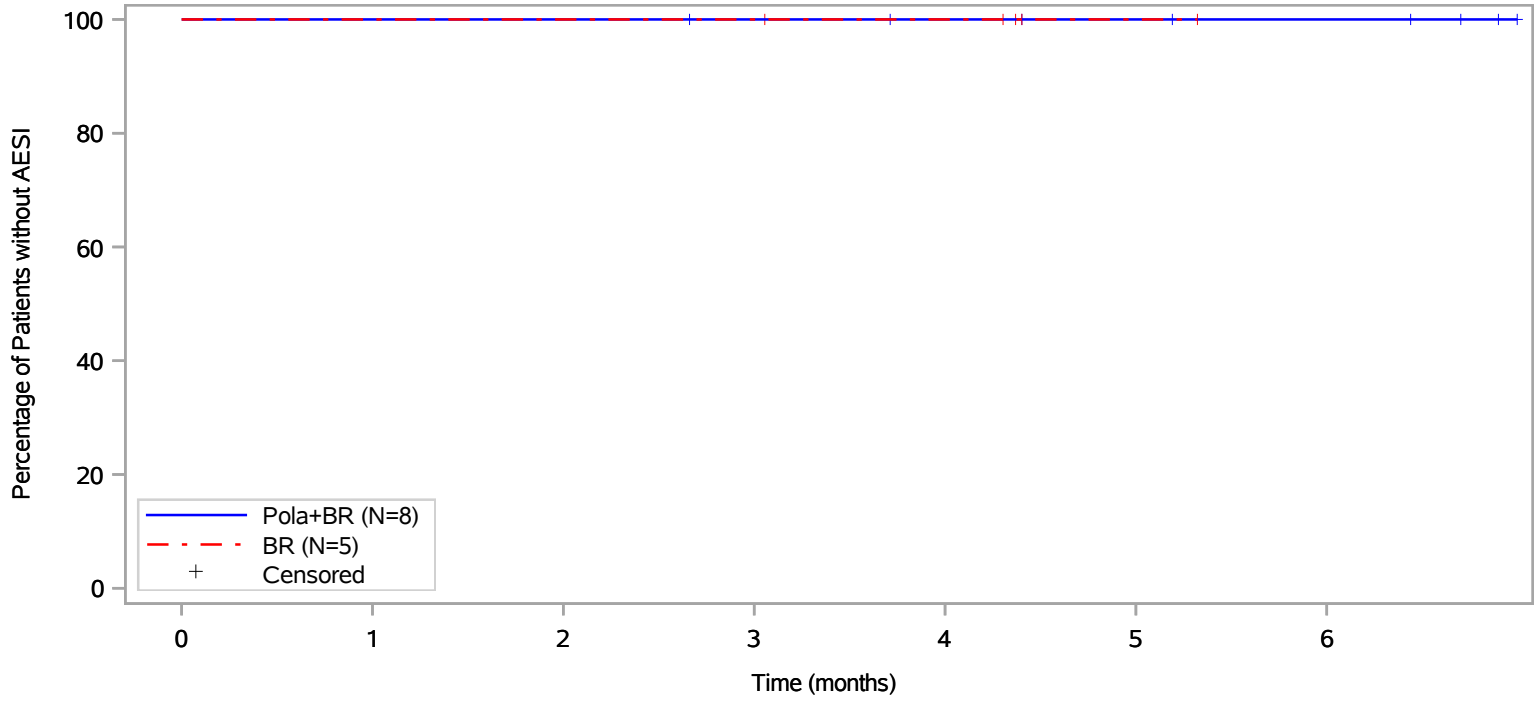
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTALOPE35_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:51

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTALOPE35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 23:57

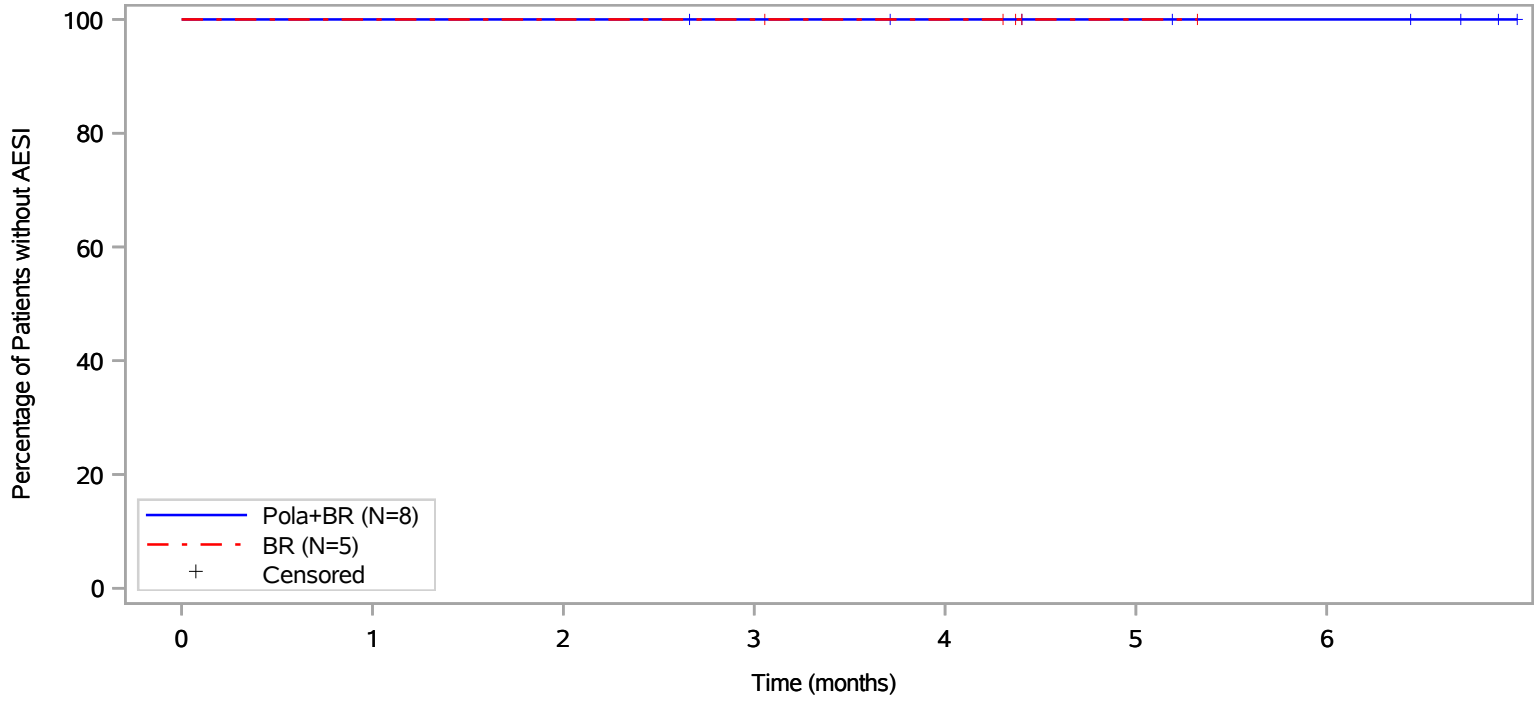
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTALOPES_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:54

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Alopecia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTALOPES_L2_Polarose_SE_29365_41543.pdf
04DEC2022 2:15

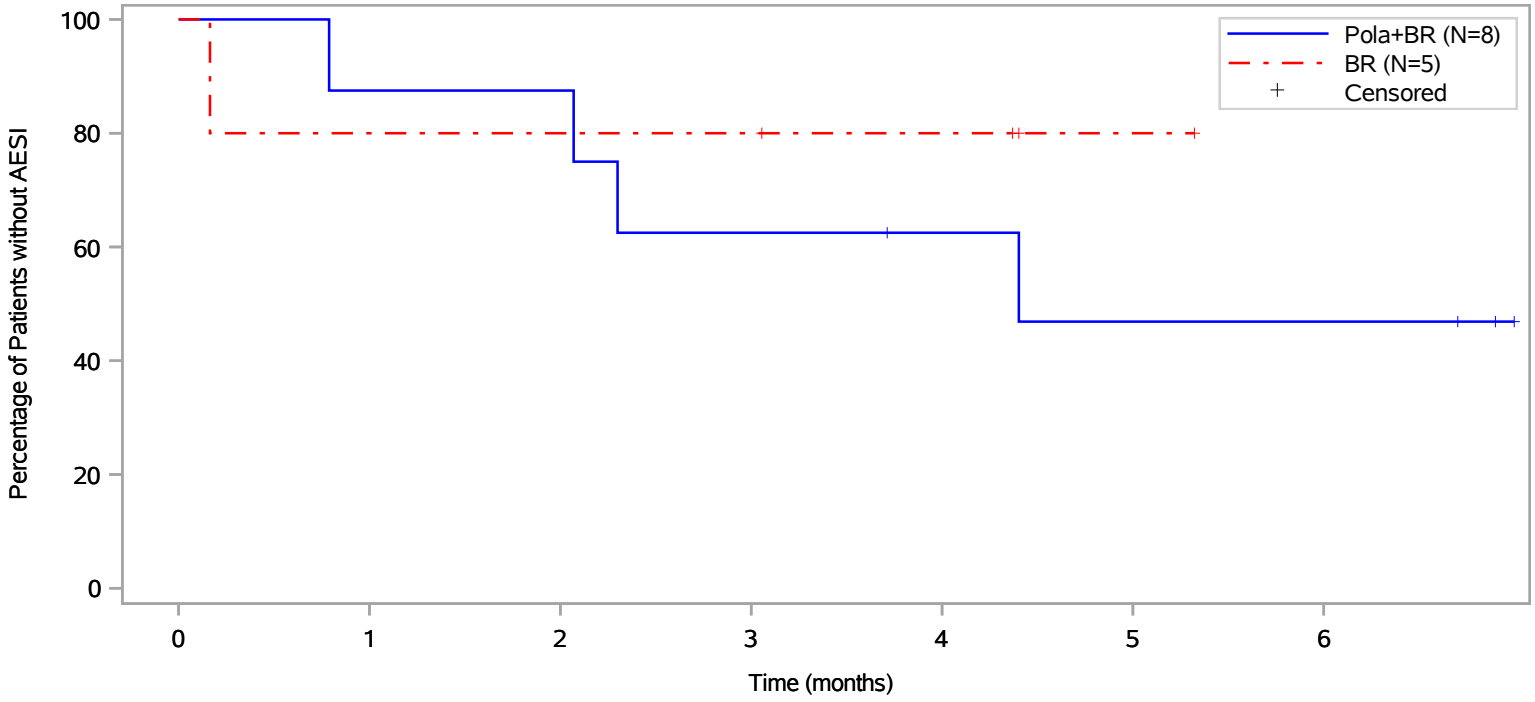
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.4478	2.28	0.25	20.49		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	4	57.1	3	42.9	1	20.0	0	-	1	100.0	0.4754	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	3	60.0	2	40.0	2	40.0	0	-	2	100.0	0.2119	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.7055	0.58	0.03	10.25		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	1	50.0	1	50.0	4	80.0	1	25.0	3	75.0	0.8084	1.41	0.08	23.57		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	3	50.0	3	50.0	1	20.0	0	-	1	100.0	0.4325	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.4478	2.28	0.25	20.49		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTANEIM_L2_Polarose_SE_29365_41543.xls
01DEC2022 1:08

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Anemia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	7	7	5	4	3	3
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	1
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTANEIM_L2_Polarose_SE_29365_41543.pdf
03DEC2022 20:40

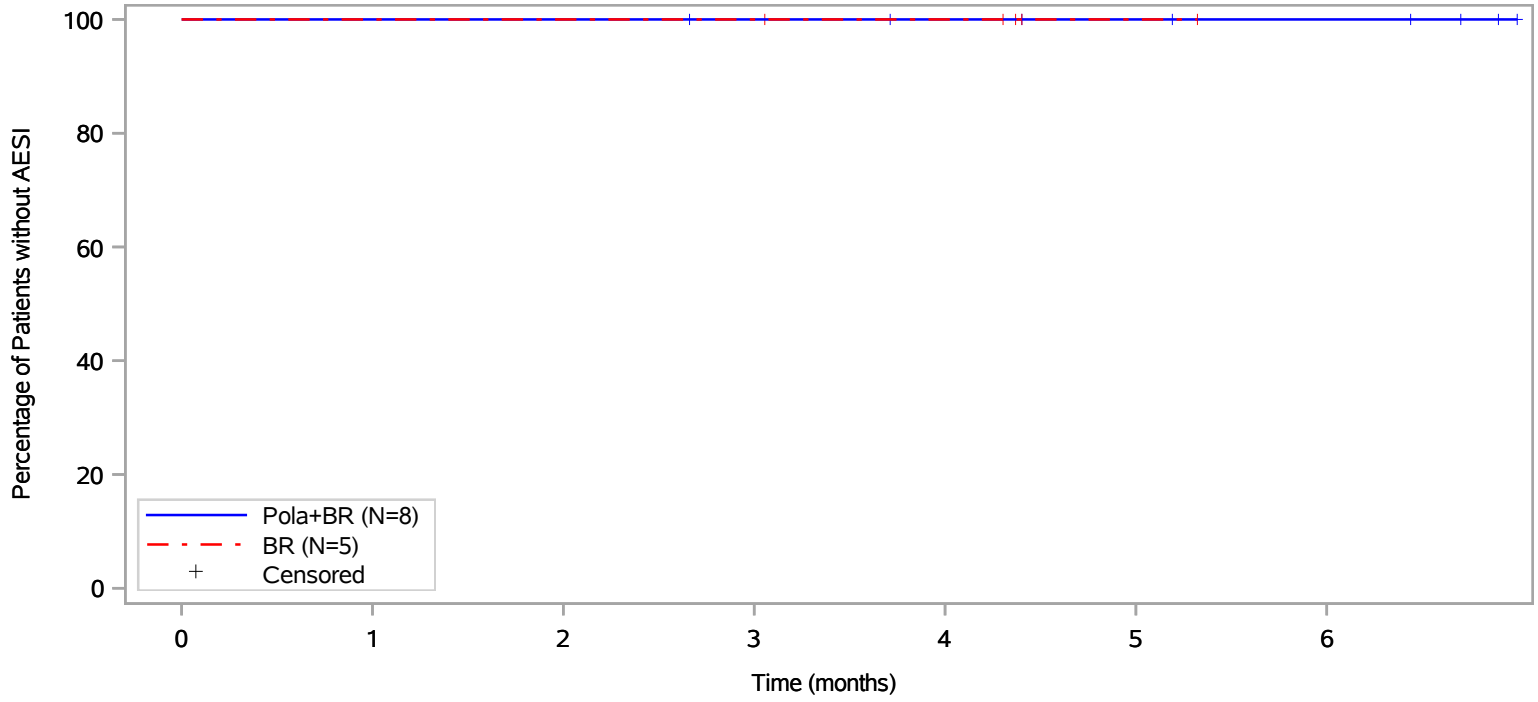
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTANEIM35_L2_Polarose_SE_29365_41543.xls
02DEC2022 20:26

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTANEIM35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 22:45

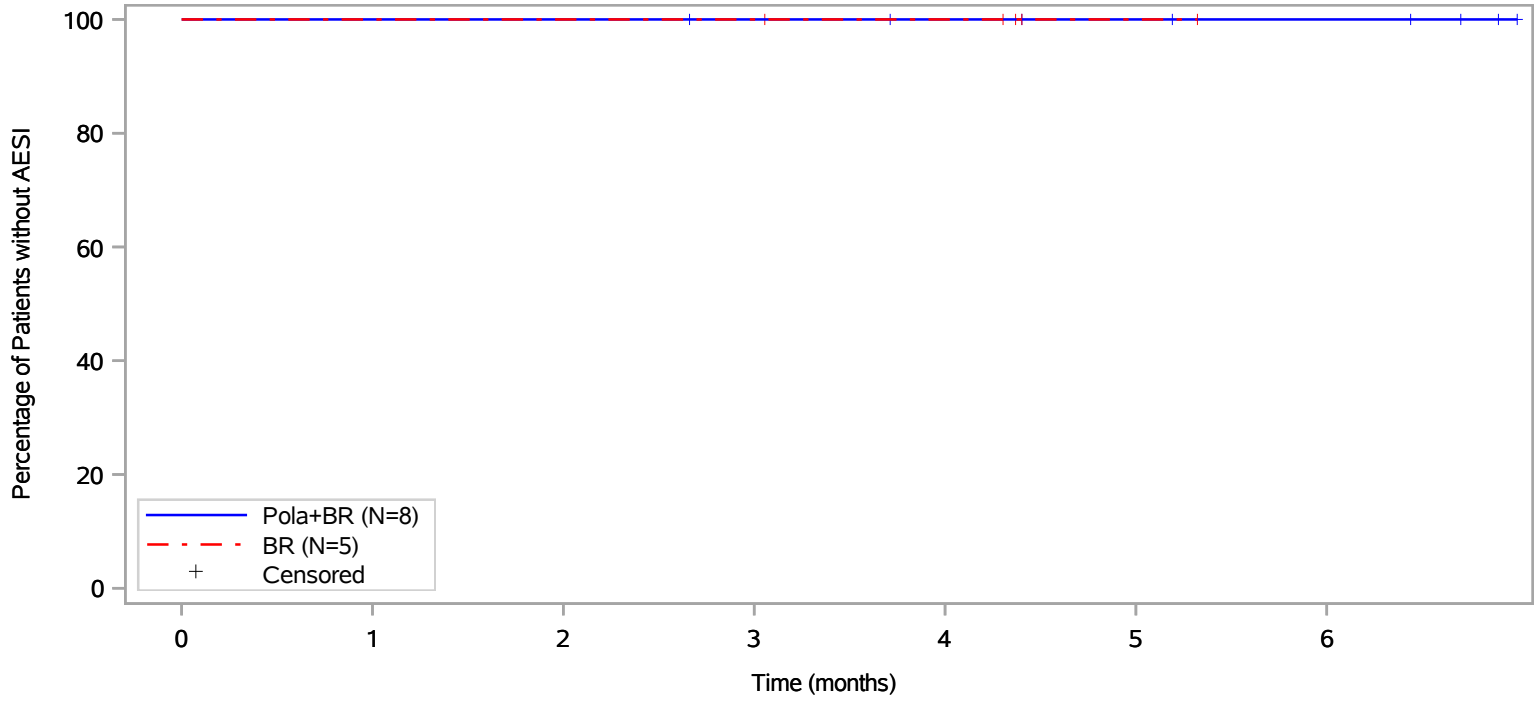
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTANEIMS_L2_Polarose_SE_29365_41543.xls
02DEC2022 20:26

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Anemia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTANEIMS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 0:53

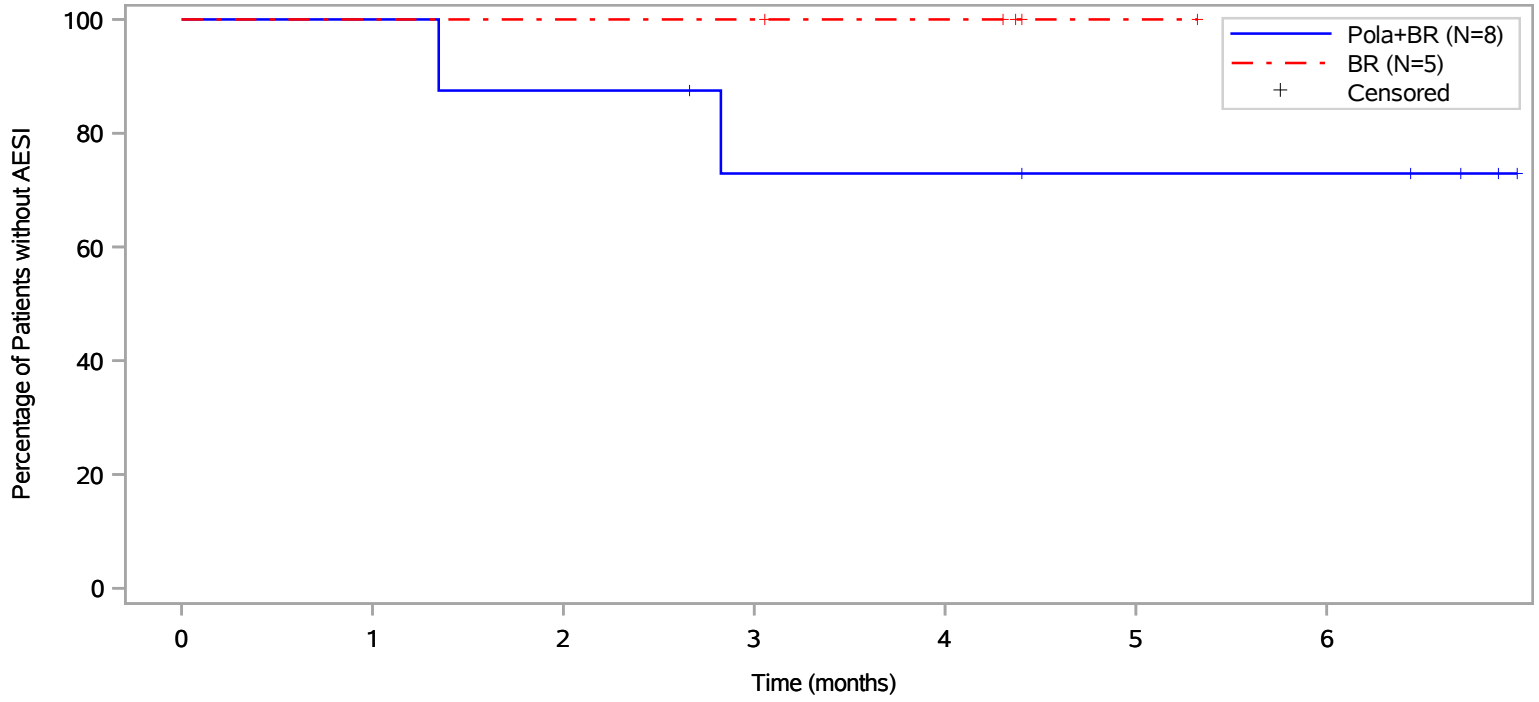
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5583	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3035	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5188	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	0	-	5	100.0	0.2280	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTCTAAR_L2_Polarose_SE_29365_41543.xls
24JAN2023 17:18

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	7	5	5	4	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	1	2	2
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTCTAAR_L2_Polarose_SE_29365_41543.pdf
03DEC2022 21:54

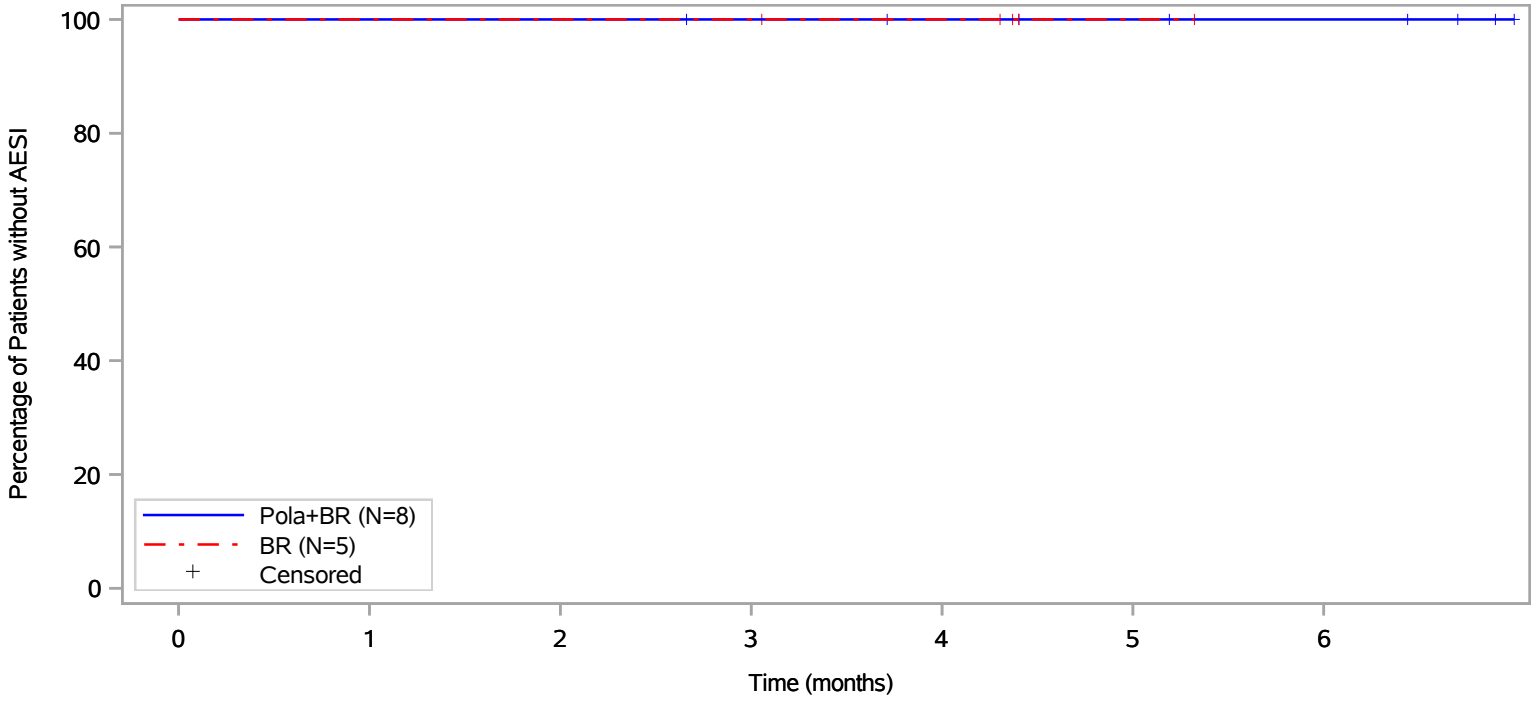
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTCTAAR35_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:58

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTCTAAR35_L2_Polarose_SE_29365_41543.pdf
04DEC2022 0:03

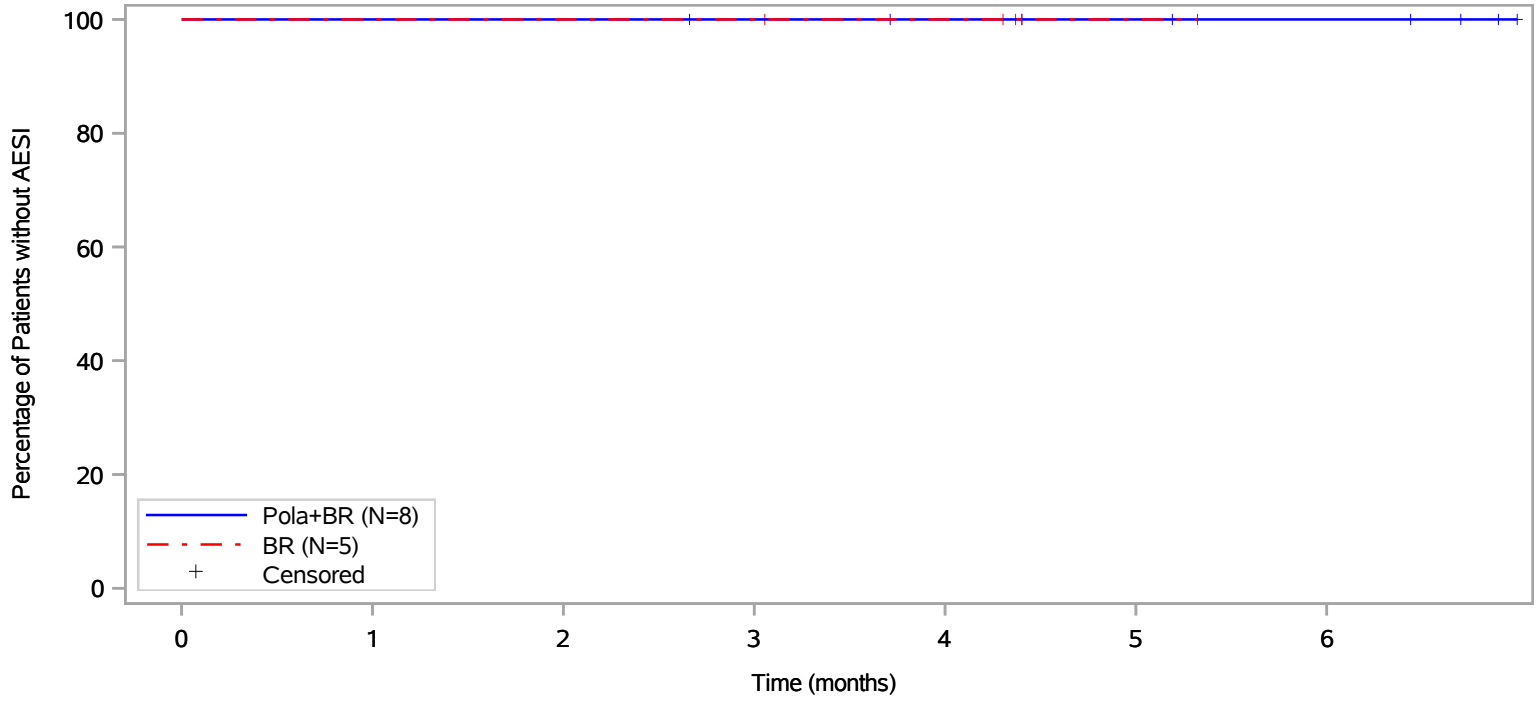
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTCTAARS_L2_Polarose_SE_29365_41543.xls
02DEC2022 22:04

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTCTAARS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 2:21

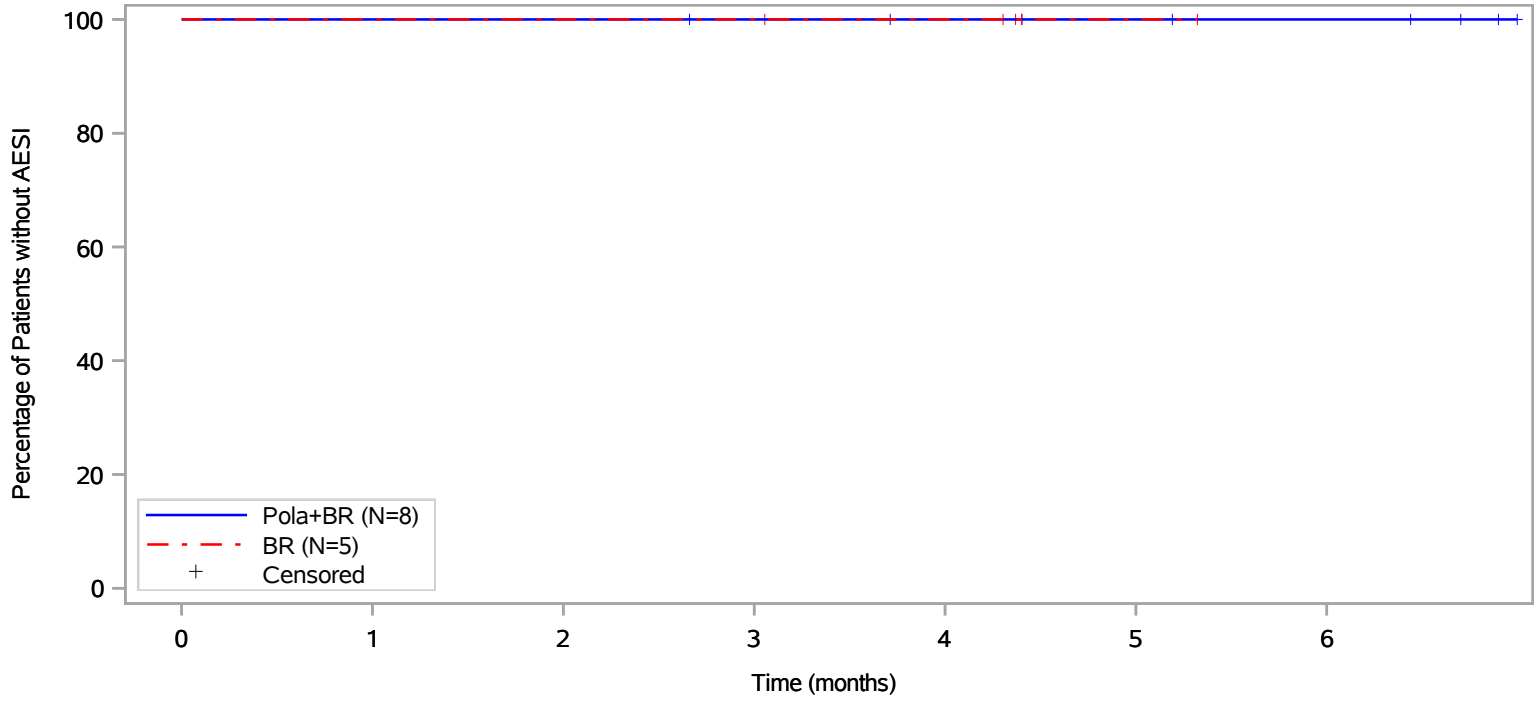
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTDDIN_L2_Polarose_SE_29365_41543.xls
01DEC2022 22:06

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Drug Drug Interaction
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTDDIN_L2_Polarose_SE_29365_41543.pdf
03DEC2022 22:26

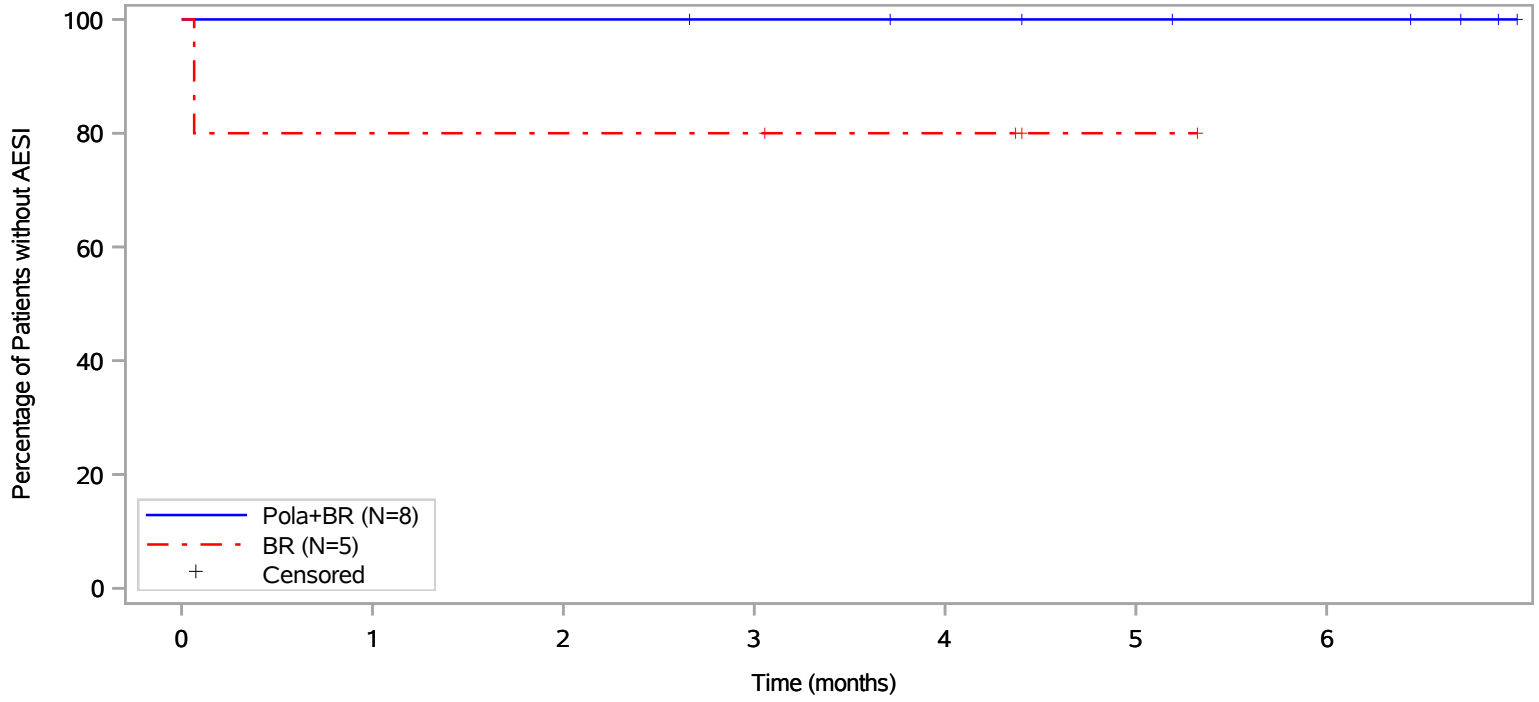
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTDYSGUE_L2_Polarose_SE_29365_41543.xls
24JAN2023 17:25

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTDYSGUE_L2_Polarose_SE_29365_41543.pdf
03DEC2022 22:07

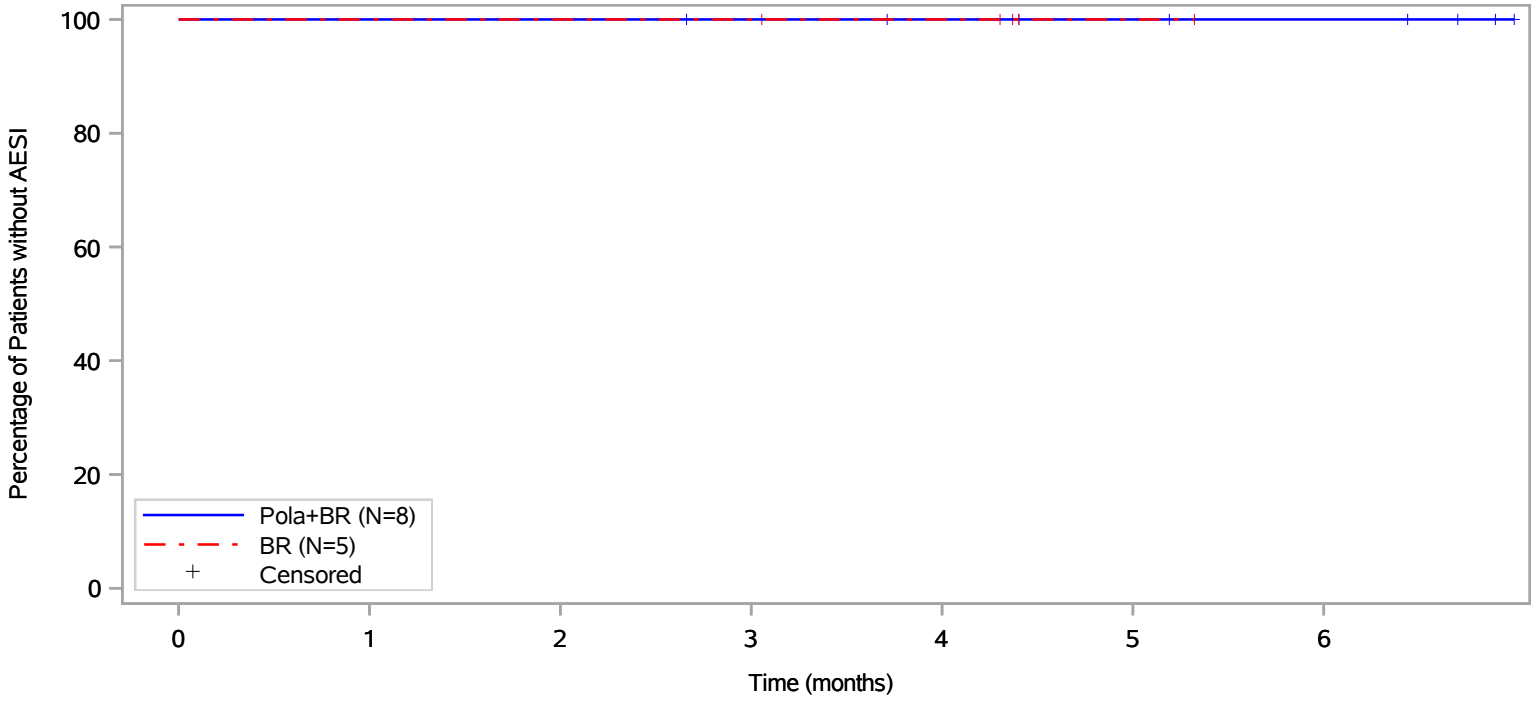
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTDYSGUE35_L2_Polarose_SE_29365_41543.xls
02DEC2022 22:16

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTDYSGUE35_L2_Polarose_SE_29365_41543.pdf
04DEC2022 0:17

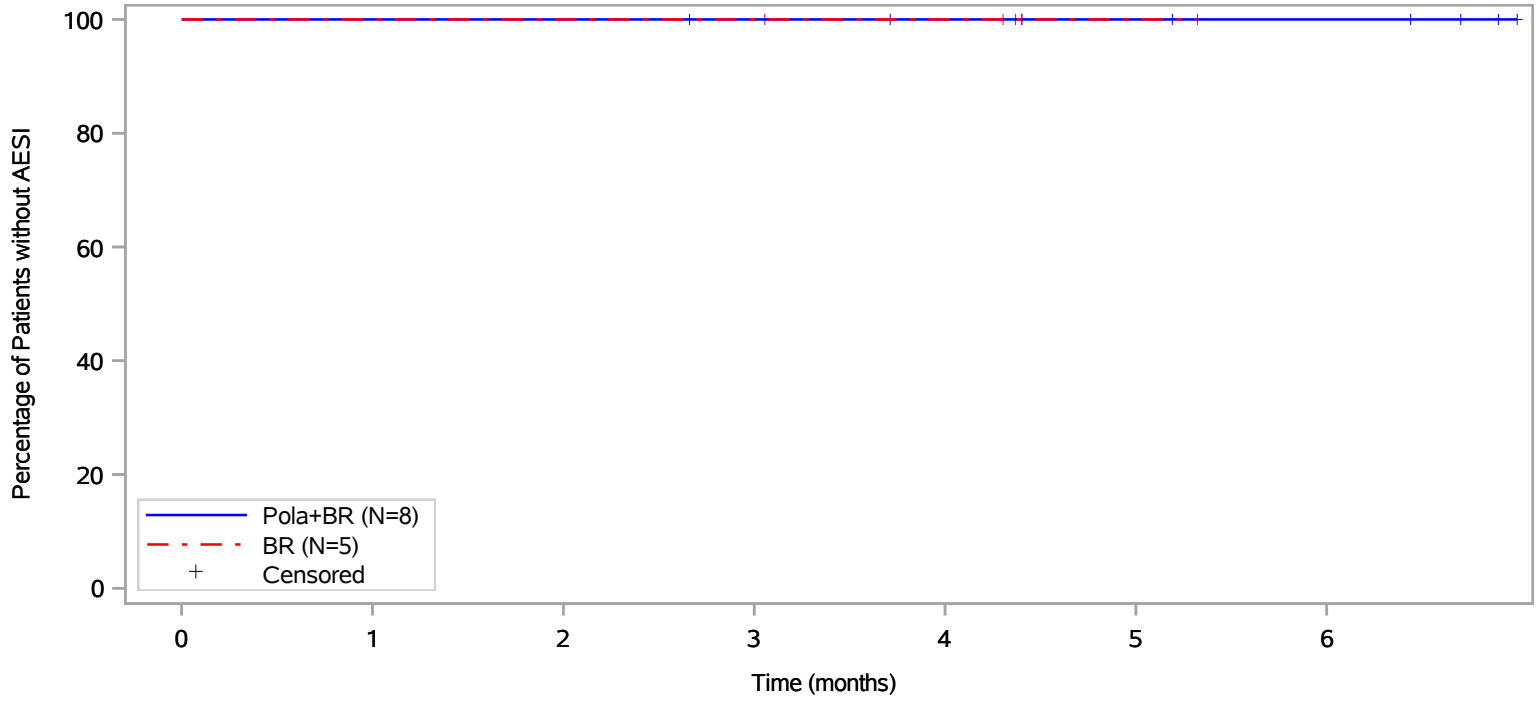
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTDYSGUES_L2_Polarose_SE_29365_41543.xls
02DEC2022 22:18

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTDYSGUES_L2_Polarose_SE_29365_41543.pdf
04DEC2022 2:37

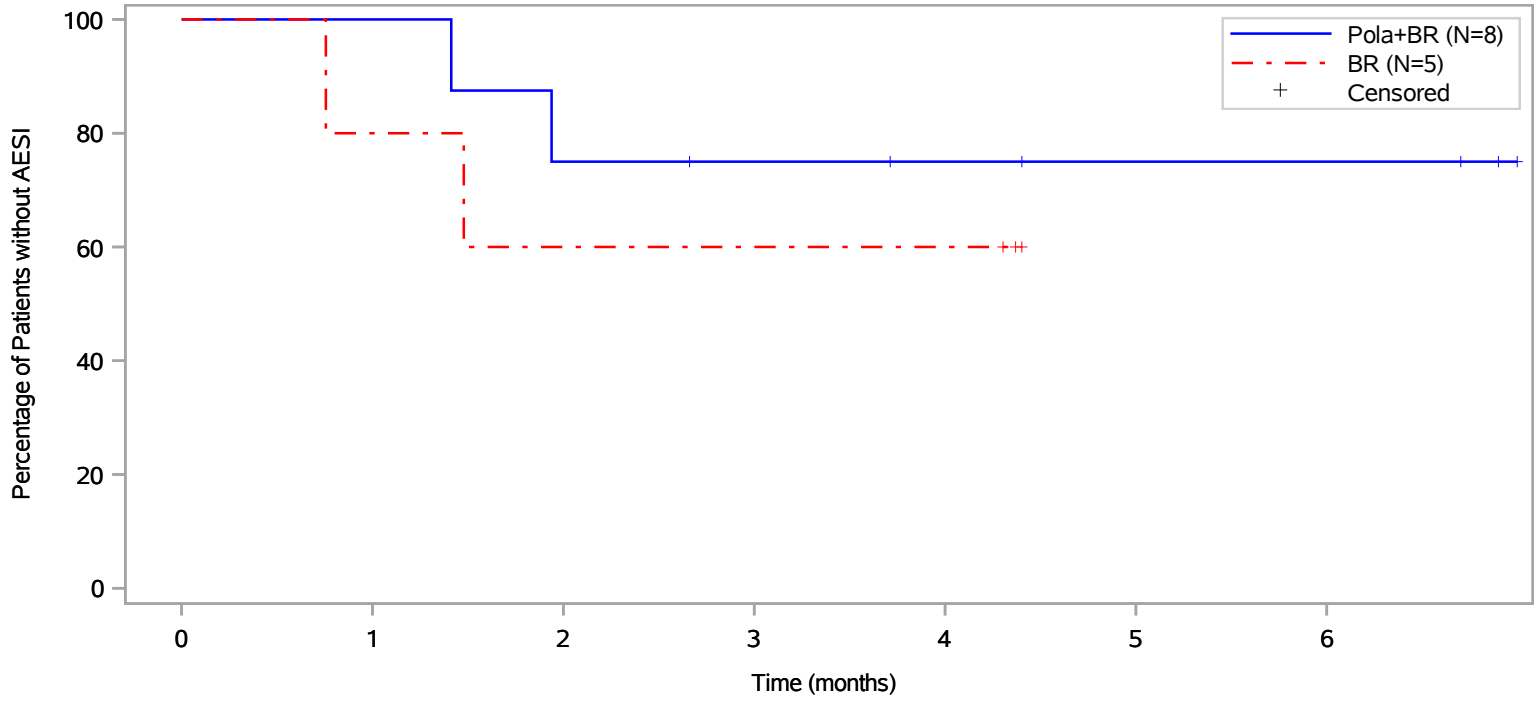
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	2	25.0	6	75.0	5	100.0	2	40.0	3	60.0	0.5146	0.53	0.07	3.75		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	2	28.6	5	71.4	1	20.0	1	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	2	66.7	1	33.3	0.3018	0.29	0.03	3.42		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	1	50.0	1	50.0	4	80.0	2	50.0	2	50.0	0.7822	0.71	0.06	8.02		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	2	40.0	3	60.0	0.5146	0.53	0.07	3.75		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTFAA_L2_Polarose_SE_29365_41543.xls
01DEC2022 4:43

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	6	5	4	3	3
BR (N=5)	5	4	3	3	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	0	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTFAA_L2_Polarose_SE_29365_41543.pdf
03DEC2022 21:14

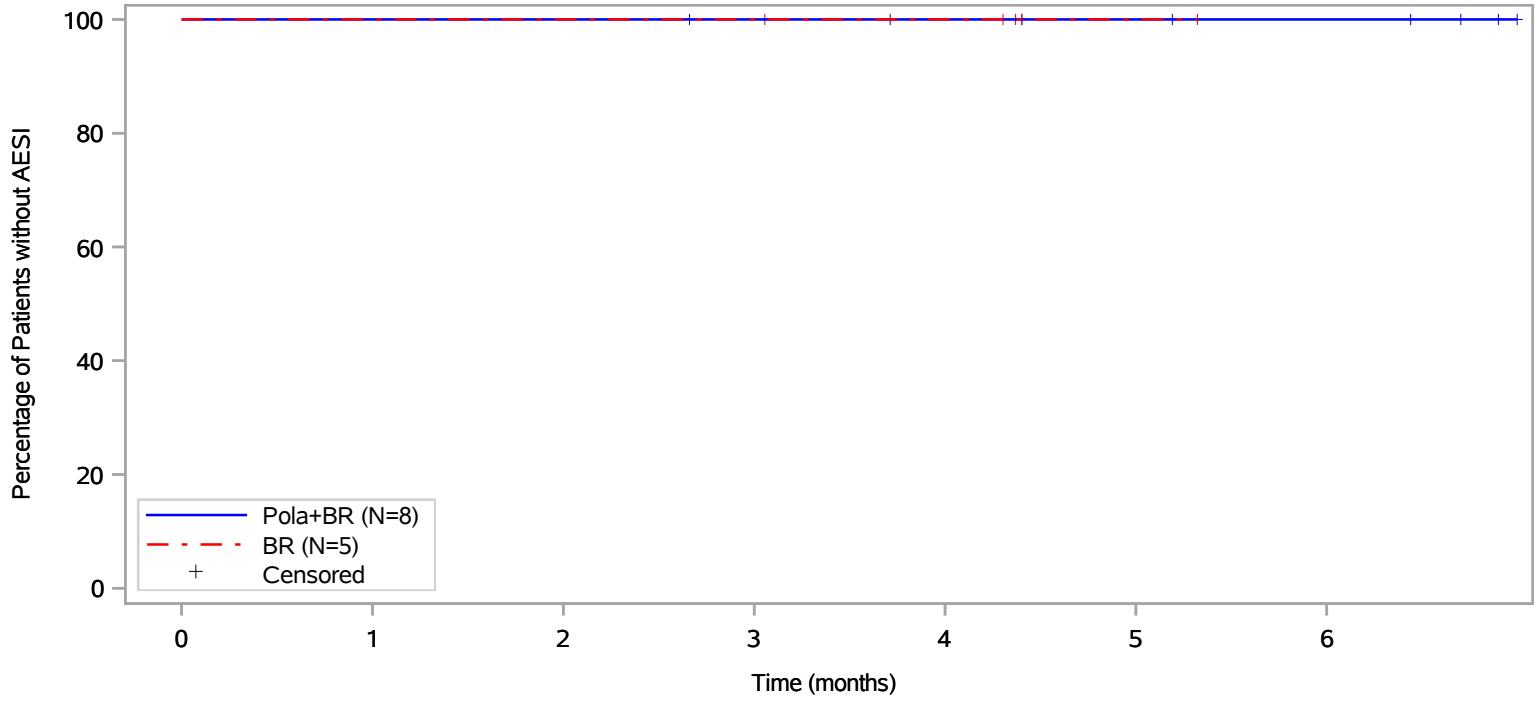
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTFAA35_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:07

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTFAA35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 23:24

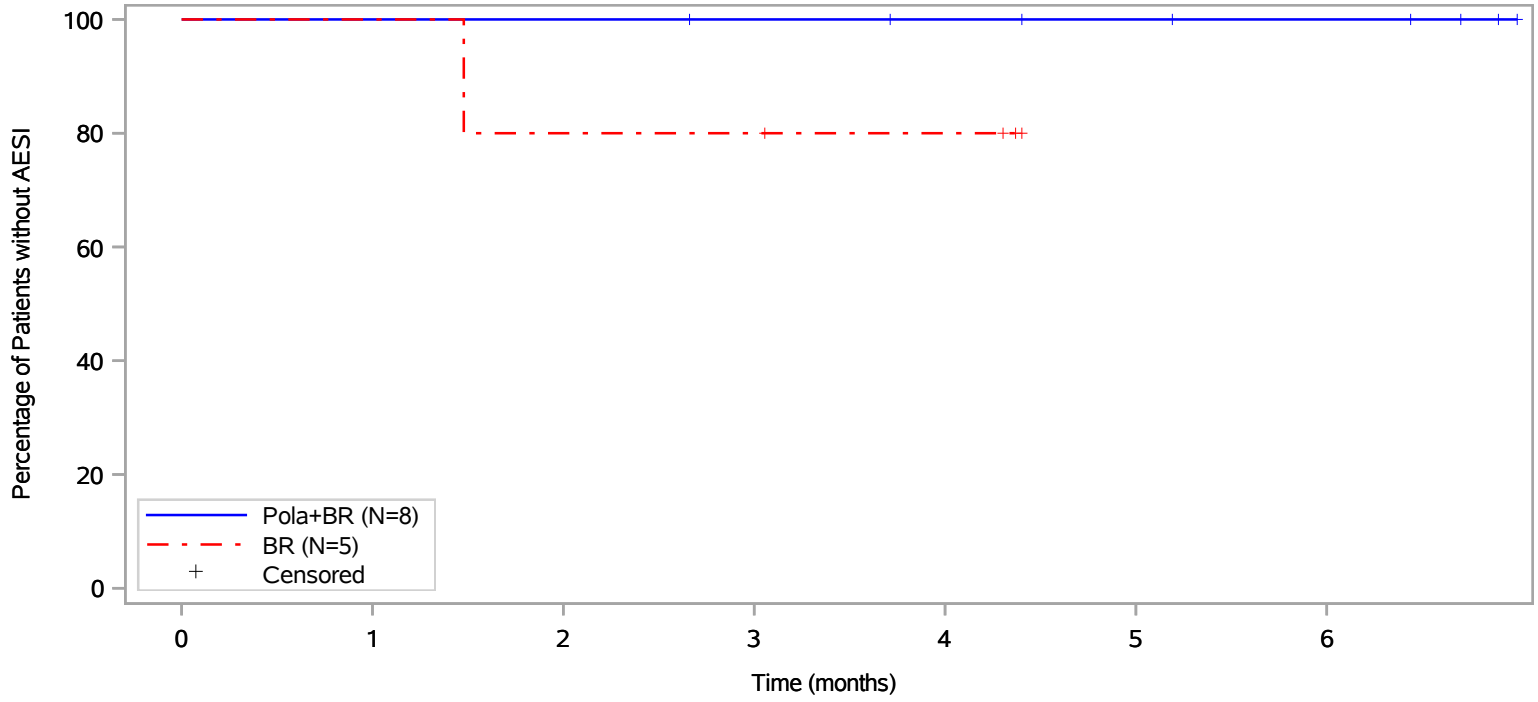
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTFAAS_L2_Polarose_SE_29365_41543.xls
24JAN2023 17:31

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTFAAS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 1:28

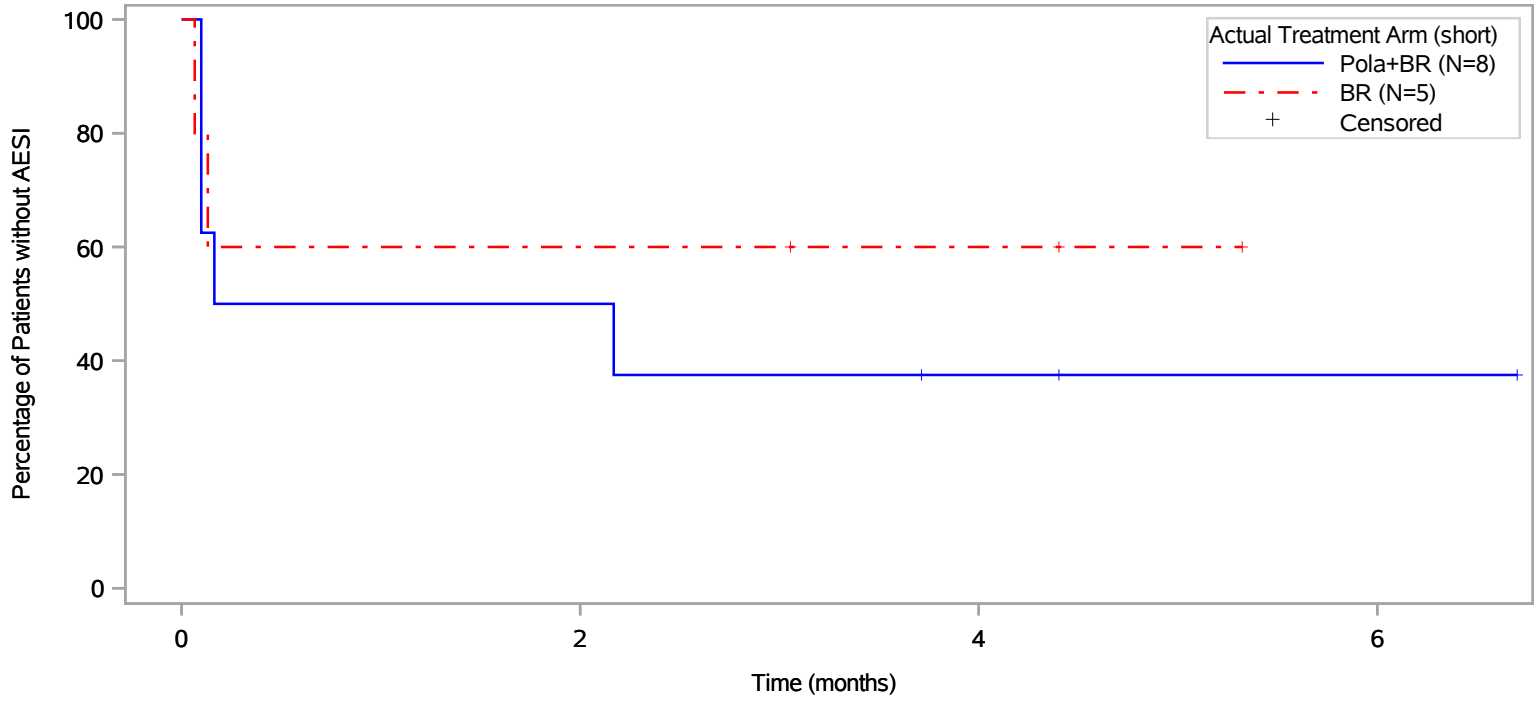
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	5	62.5	3	37.5	5	100.0	2	40.0	3	60.0	0.6065	1.56	0.29	8.50		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	4	57.1	3	42.9	1	20.0	0	-	1	100.0	0.3599	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	1	100.0	0	-	4	80.0	2	50.0	2	50.0	0.7741	1.42	0.13	16.04		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	3	60.0	2	40.0	2	40.0	1	50.0	1	50.0	0.6598	1.75	0.14	21.82		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	2	66.7	1	33.3	3	60.0	1	33.3	2	66.7	0.6419	1.76	0.16	19.57		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	2	100.0	0	-	4	80.0	1	25.0	3	75.0	0.2072	4.22	0.37	47.51		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	3	50.0	3	50.0	1	20.0	1	100.0	0	-	0.6250	0.50	0.03	8.46		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	5	62.5	3	37.5	5	100.0	2	40.0	3	60.0	0.6065	1.56	0.29	8.50		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGASTOX_L2_Polarose_SE_29365_41543.xls
30MAR2023 9:34

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	4	4	3	2	1	1
BR (N=5)	5	3	3	3	2	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	2
BR (N=5)	0	0	0	0	1	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTGASTOX_L2_Polarose_SE_29365_41543.pdf
30MAR2023 11:42

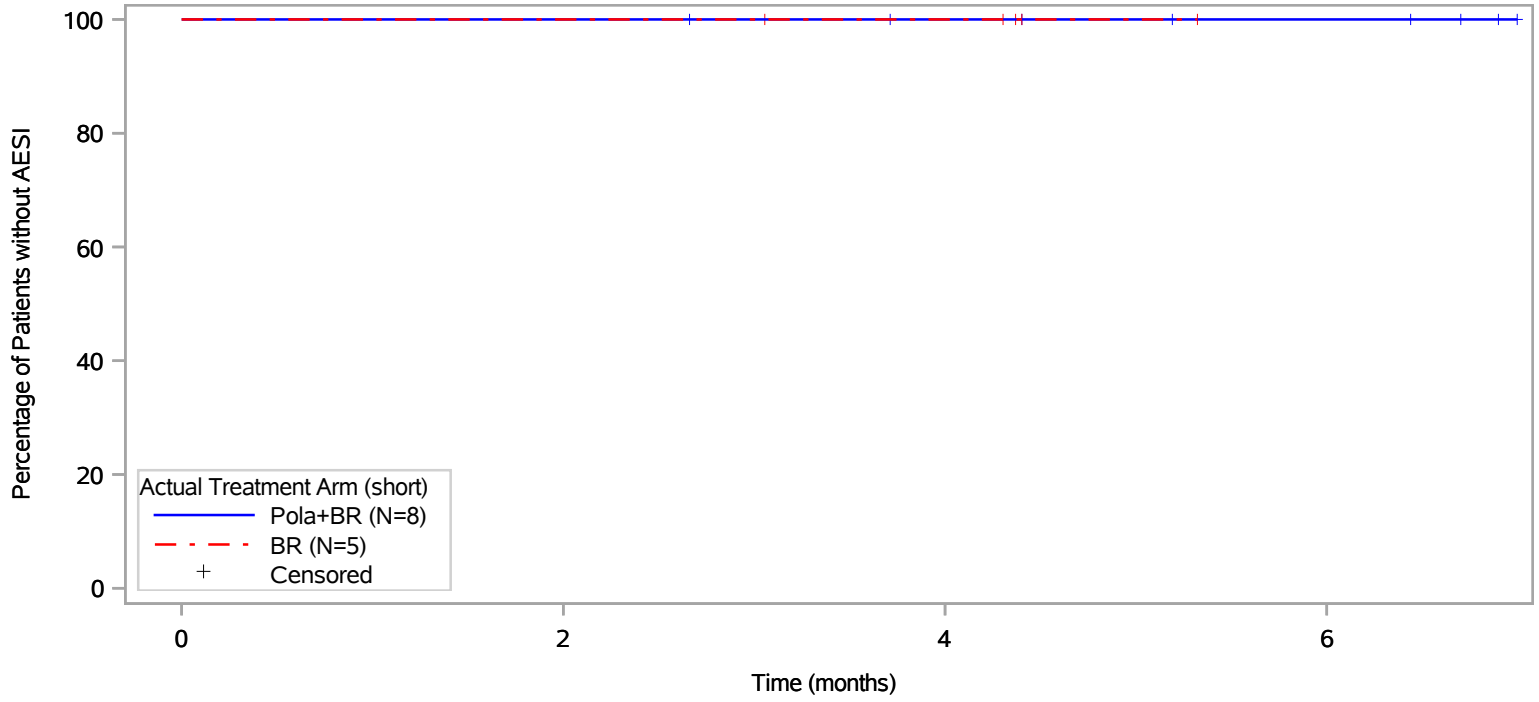
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGASTOX35_L2_Polarose_SE_29365_41543.xls
30MAR2023 11:12

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTGASTOX35_L2_Polarose_SE_29365_41543.pdf
30MAR2023 13:40

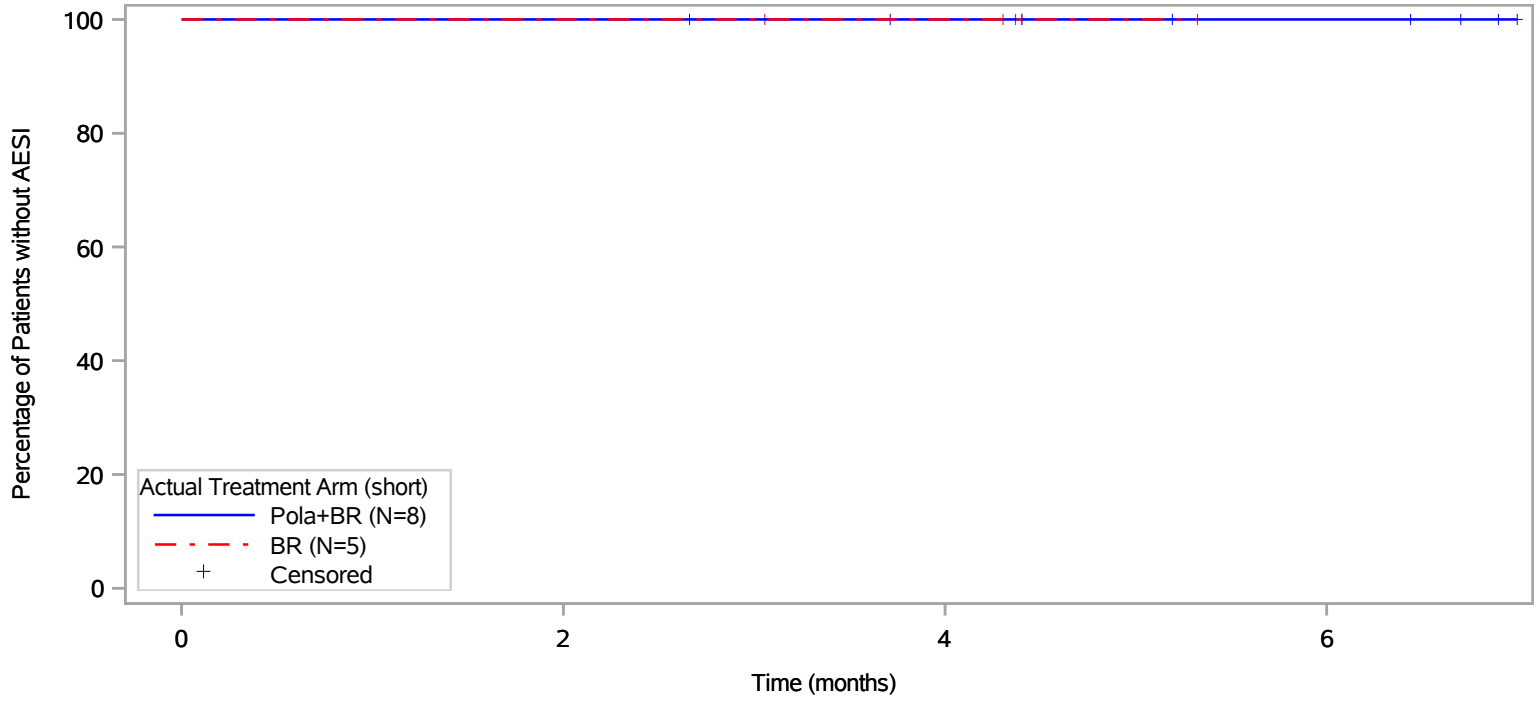
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGASTOXS_L2_Polarose_SE_29365_41543.xls
30MAR2023 10:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTGASTOXS_L2_Polarose_SE_29365_41543.pdf
30MAR2023 12:52

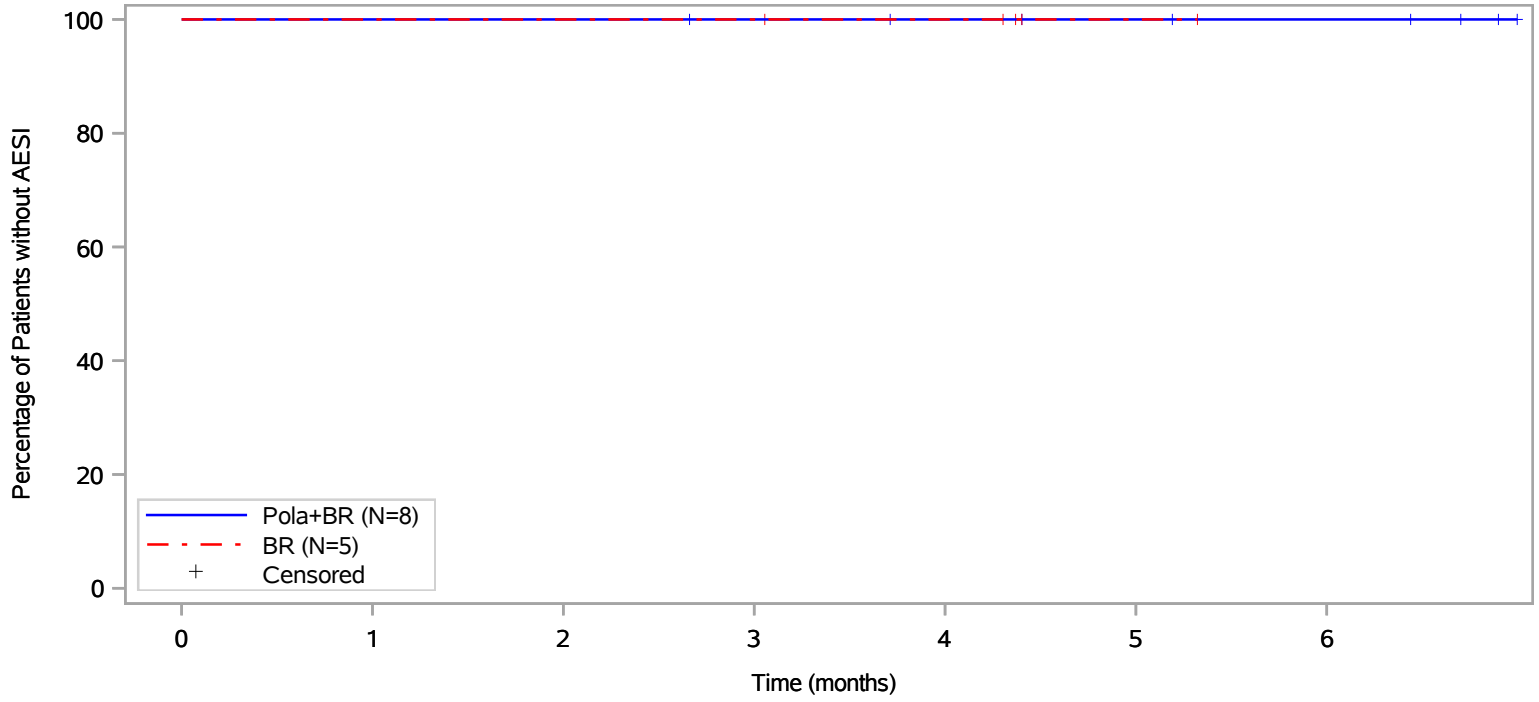
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGENCAR_L2_Polarose_SE_29365_41543.xls
01DEC2022 21:44

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTGENCAR_L2_Polarose_SE_29365_41543.pdf
03DEC2022 22:20

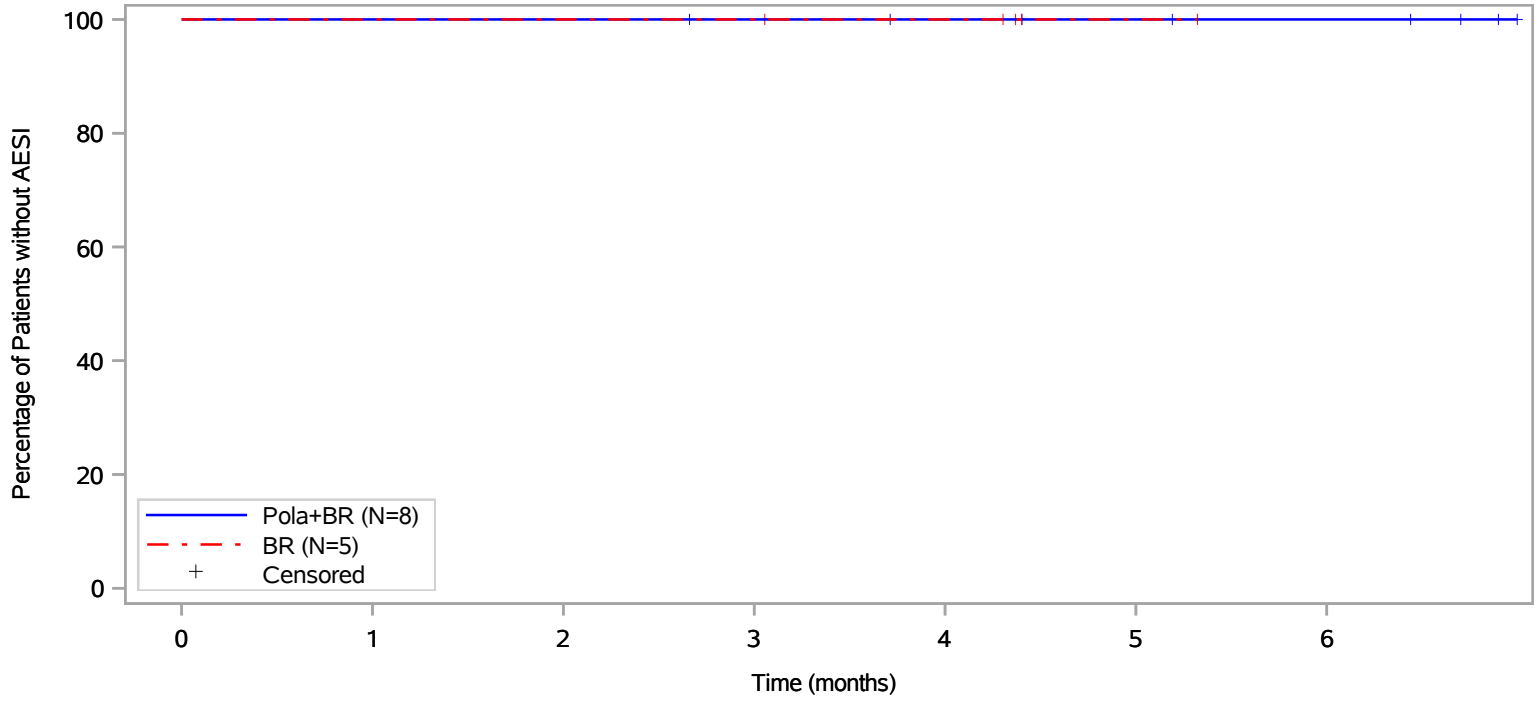
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGENCAR35_L2_Polarose_SE_29365_41543.xls
02DEC2022 22:27

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTGENCAR35_L2_Polarose_SE_29365_41543.pdf
04DEC2022 0:29

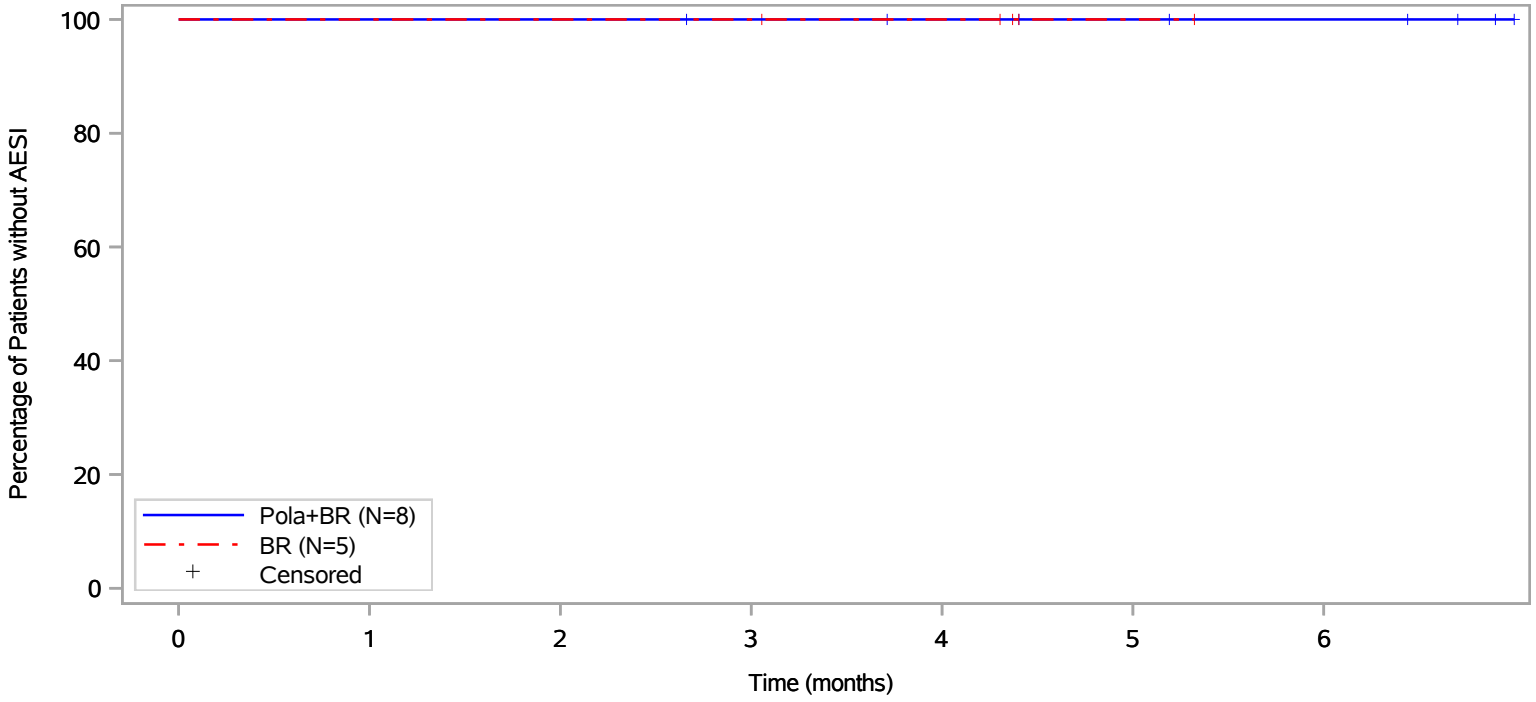
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGENCARS_L2_Polarose_SE_29365_41543.xls
02DEC2022 22:31

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTGENCARS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 2:50

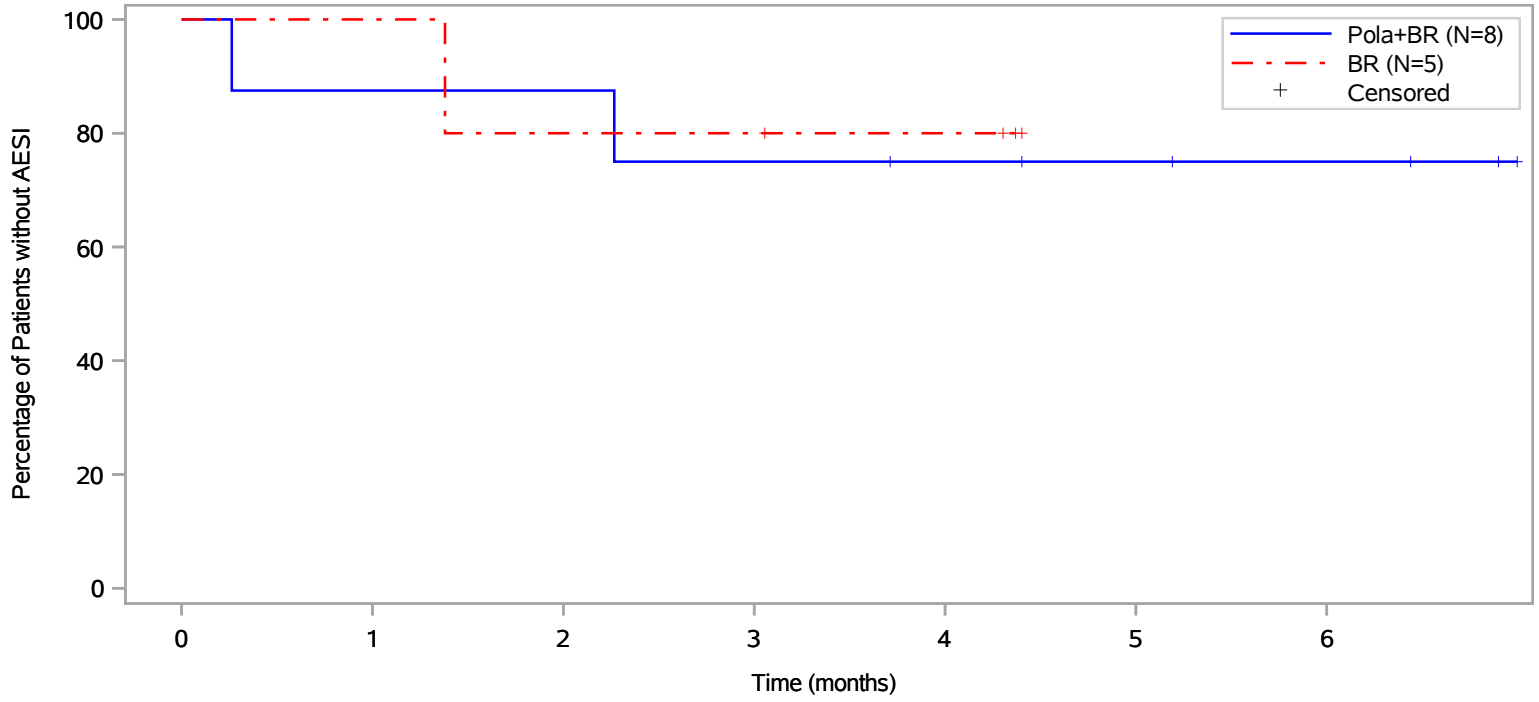
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.8450	1.27	0.11	14.04		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.8864	0.82	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	1	20.0	4	80.0	0.8450	1.27	0.11	14.04		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHEPAT_L2_Polarose_SE_29365_41543.xls
01DEC2022 3:43

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	7	7	6	5	4	3
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTHEPAT_L2_Polarose_SE_29365_41543.pdf
03DEC2022 21:03

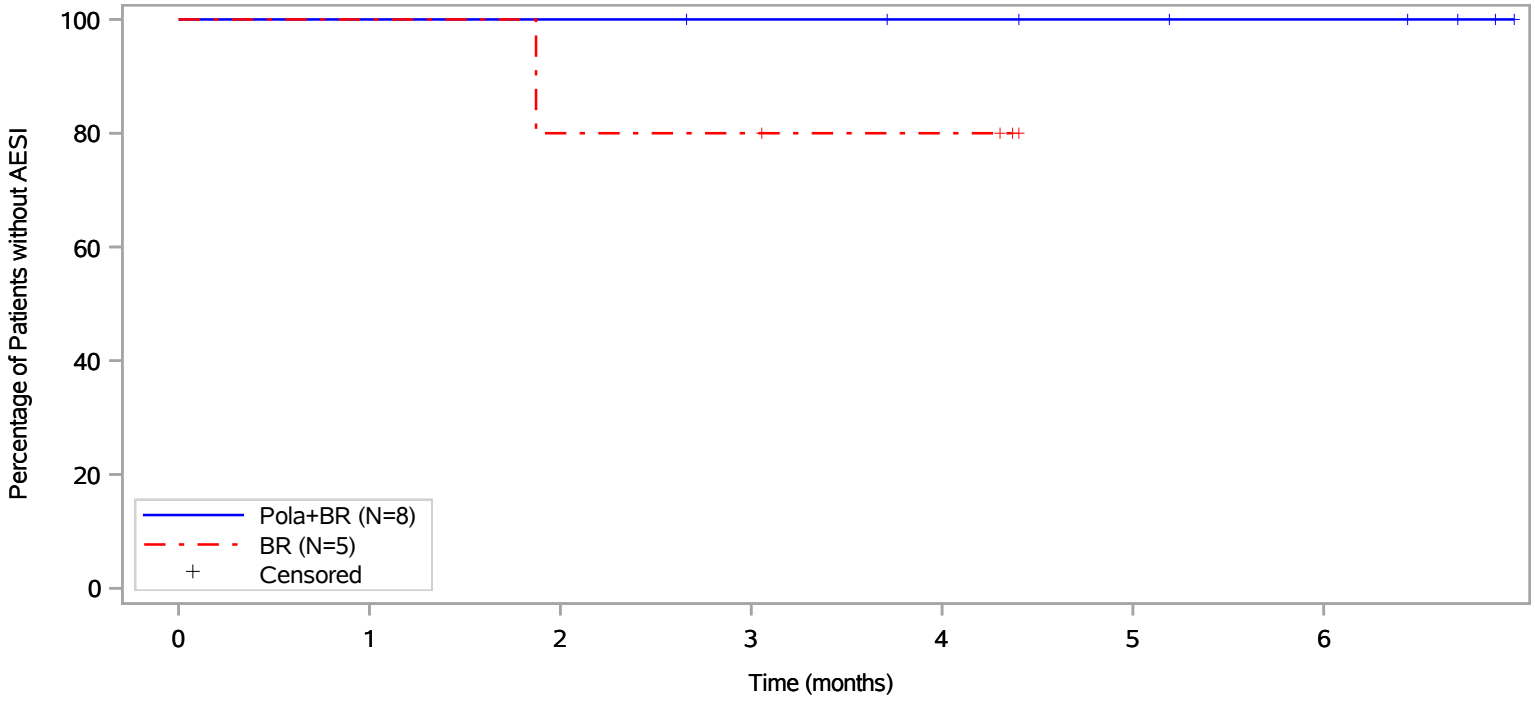
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHEPAT35_L2_Polarose_SE_29365_41543.xls
24JAN2023 17:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTHEPAT35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 23:13

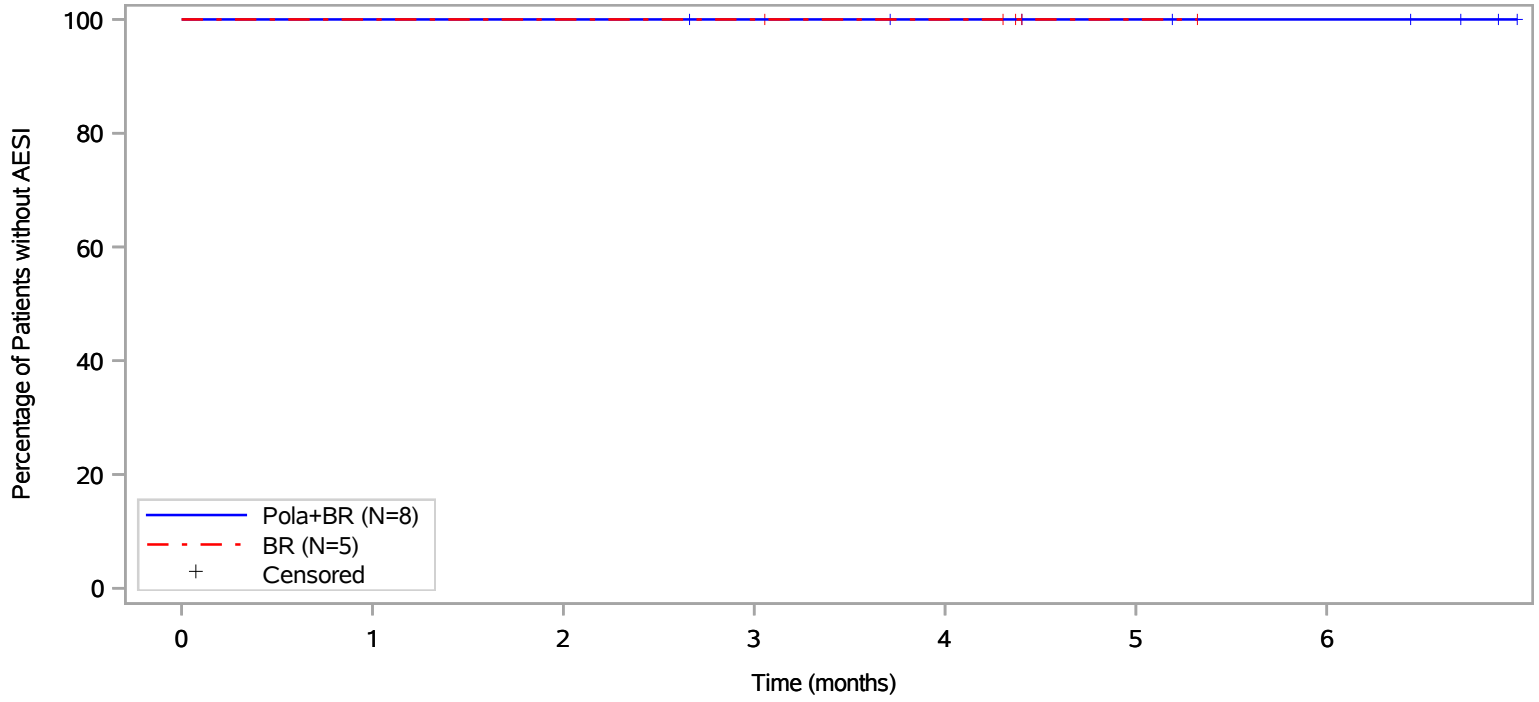
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHEPATS_L2_Polarose_SE_29365_41543.xls
02DEC2022 20:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTHEPATS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 1:18

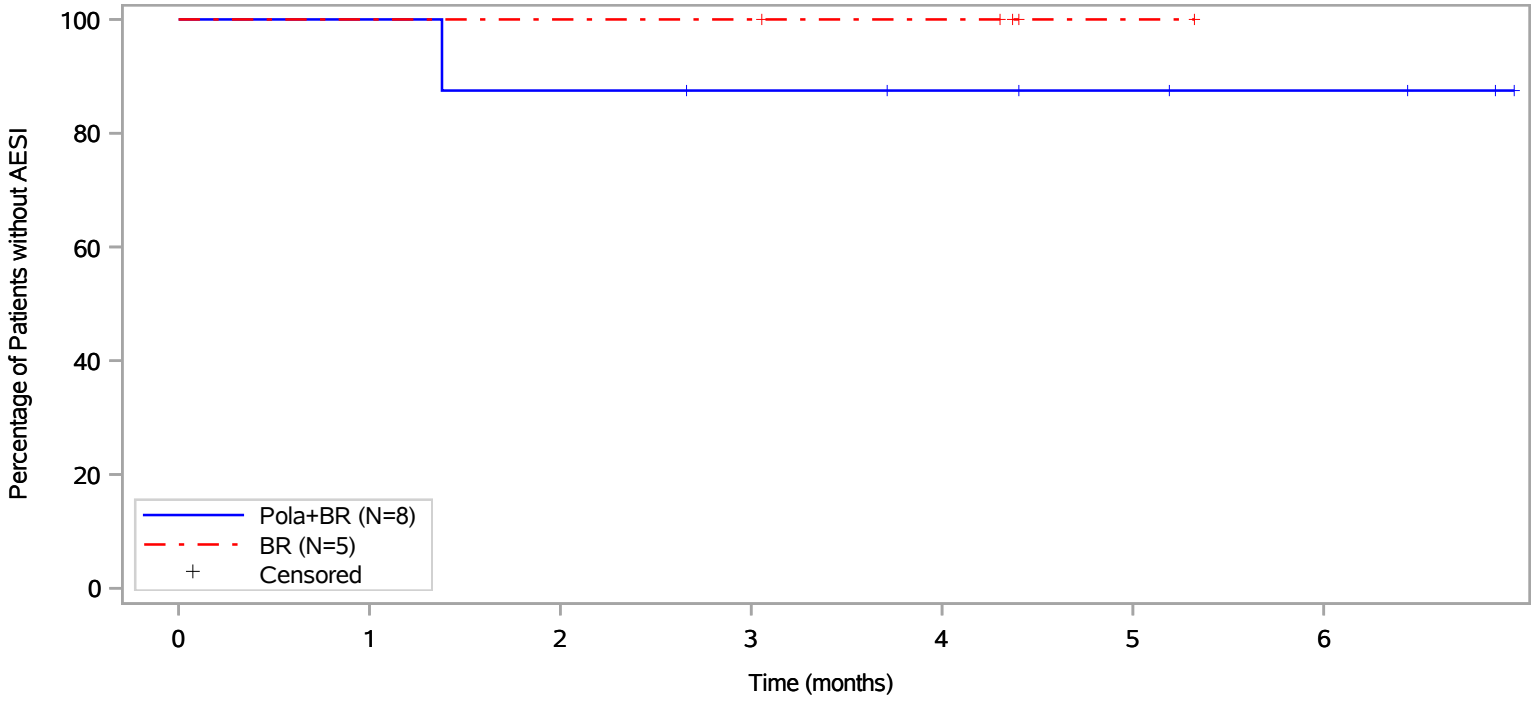
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHYPGL_L2_Polarose_SE_29365_41543.xls
24JAN2023 17:44

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTHYPGL_L2_Polarose_SE_29365_41543.pdf
03DEC2022 21:19

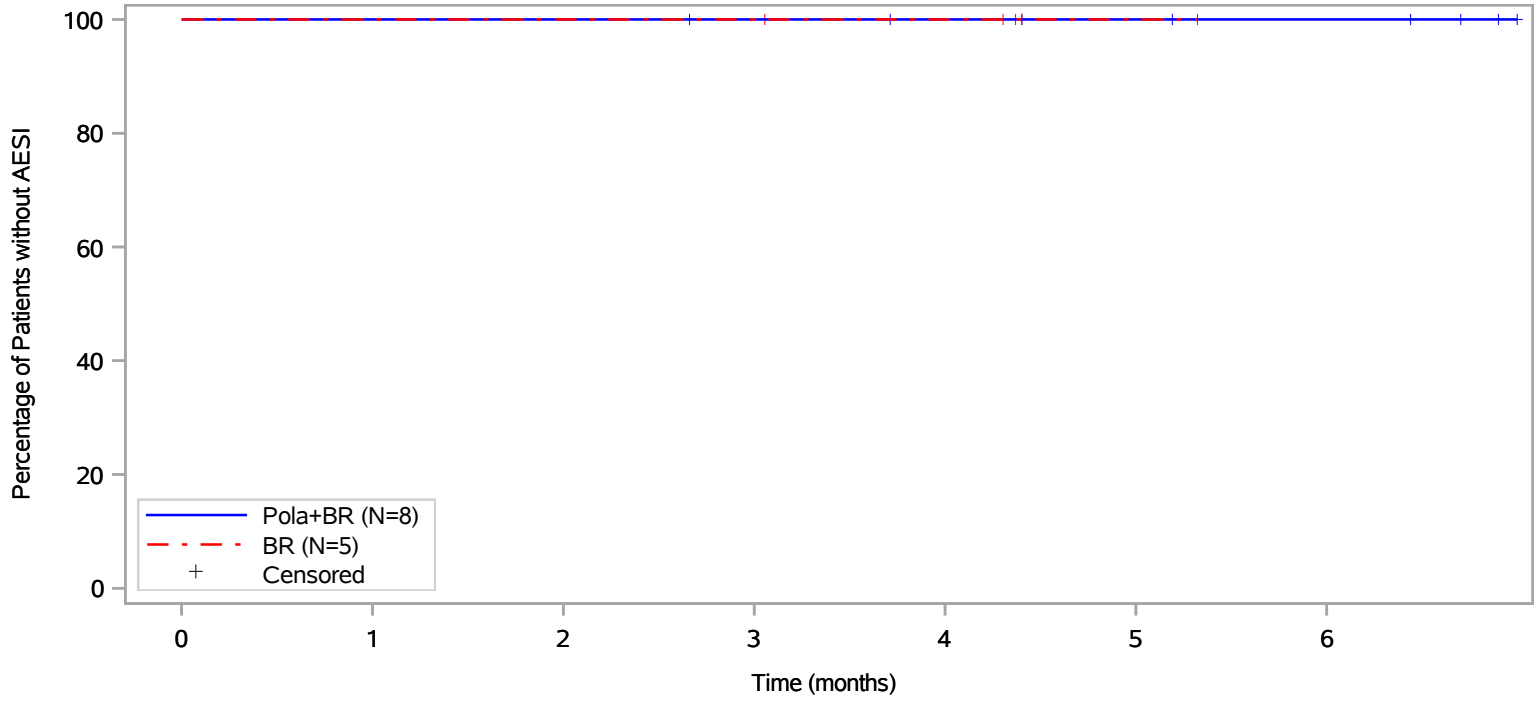
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHYPGL35_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:13

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTHYPGL35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 23:30

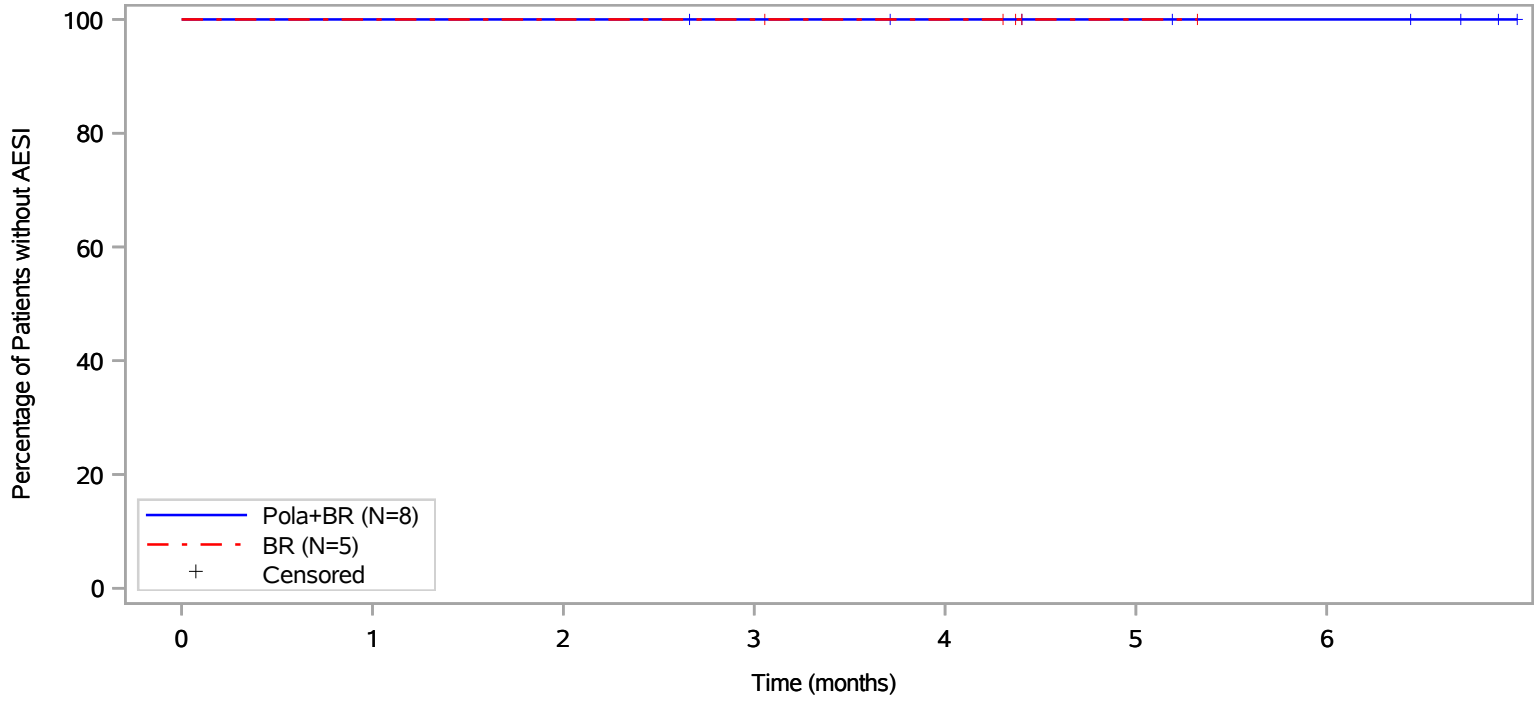
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHYPGLS_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTHYPGLS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 1:36

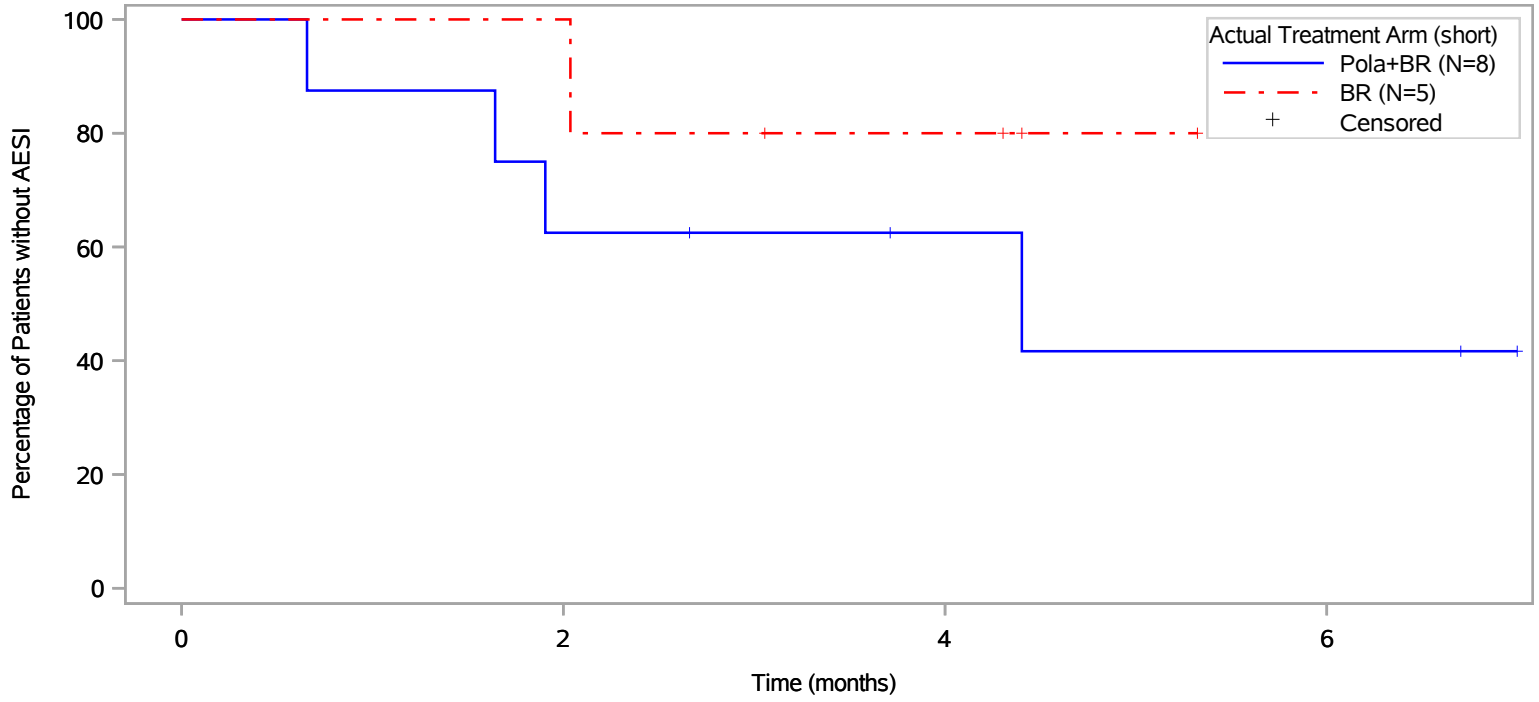
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.2949	3.05	0.34	27.46		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	1	100.0	0	-	4	80.0	1	25.0	3	75.0	0.0455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	2	40.0	3	60.0	2	40.0	1	50.0	1	50.0	0.9814	1.03	0.09	11.48		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	2	66.7	1	33.3	3	60.0	0	-	3	100.0	0.2253	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	2	100.0	0	-	4	80.0	0	-	4	100.0	0.0455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	2	33.3	4	66.7	1	20.0	1	100.0	0	-	0.4499	0.41	0.04	4.53		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	4	50.0	4	50.0	5	100.0	1	20.0	4	80.0	0.2949	3.05	0.34	27.46		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTINECT_L2_Polarose_SE_29365_41543.xls
30MAR2023 8:58

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	7	5	4	3	2	2
BR (N=5)	5	5	5	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	2
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTINECT_L2_Polarose_SE_29365_41543.pdf
30MAR2023 11:04

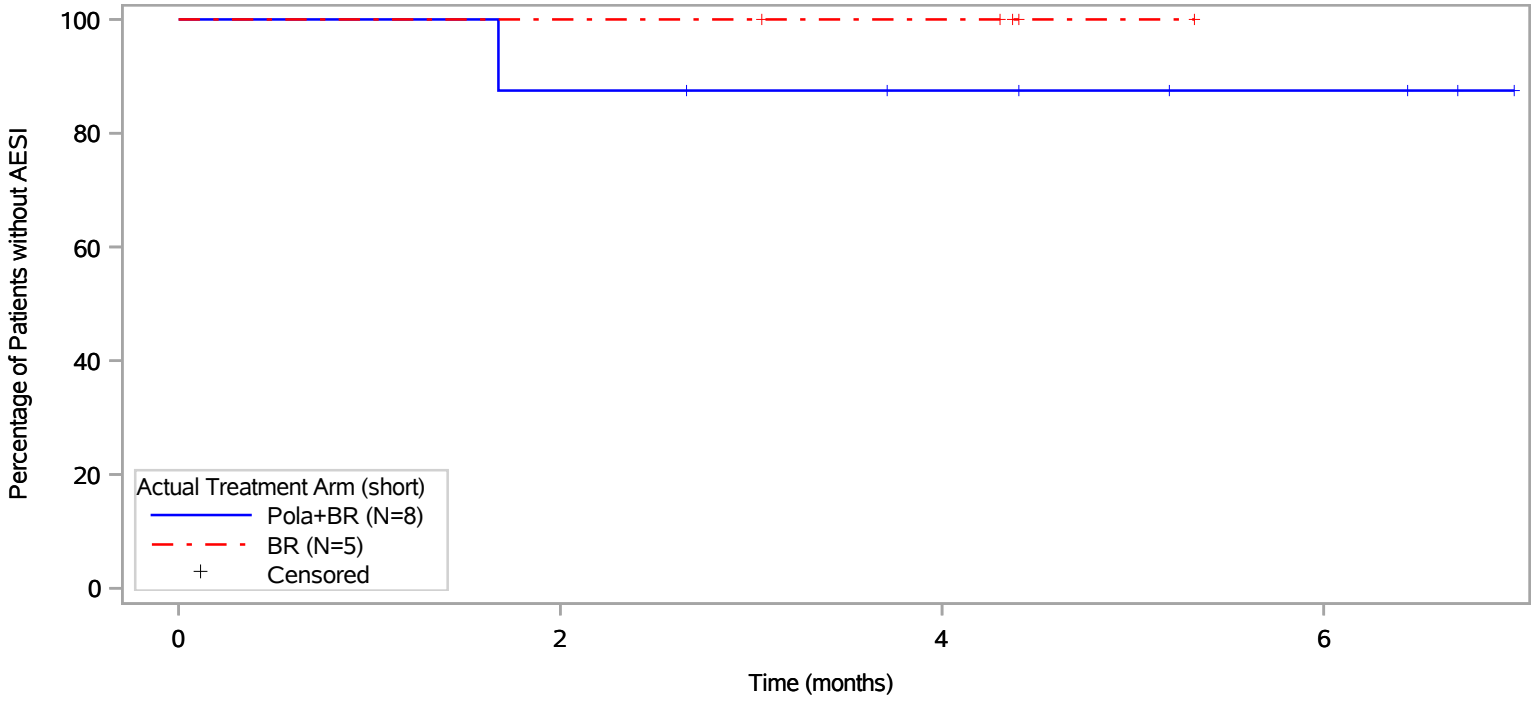
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	1	100.0	0	-	4	80.0	0	-	4	100.0	0.0455				*	WARNING: Iteration limit reached without convergence.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.1573	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTINECT35_L2_Polarose_SE_29365_41543.xls
30MAR2023 10:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	4	3
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTINECT35_L2_Polarose_SE_29365_41543.pdf
30MAR2023 13:15

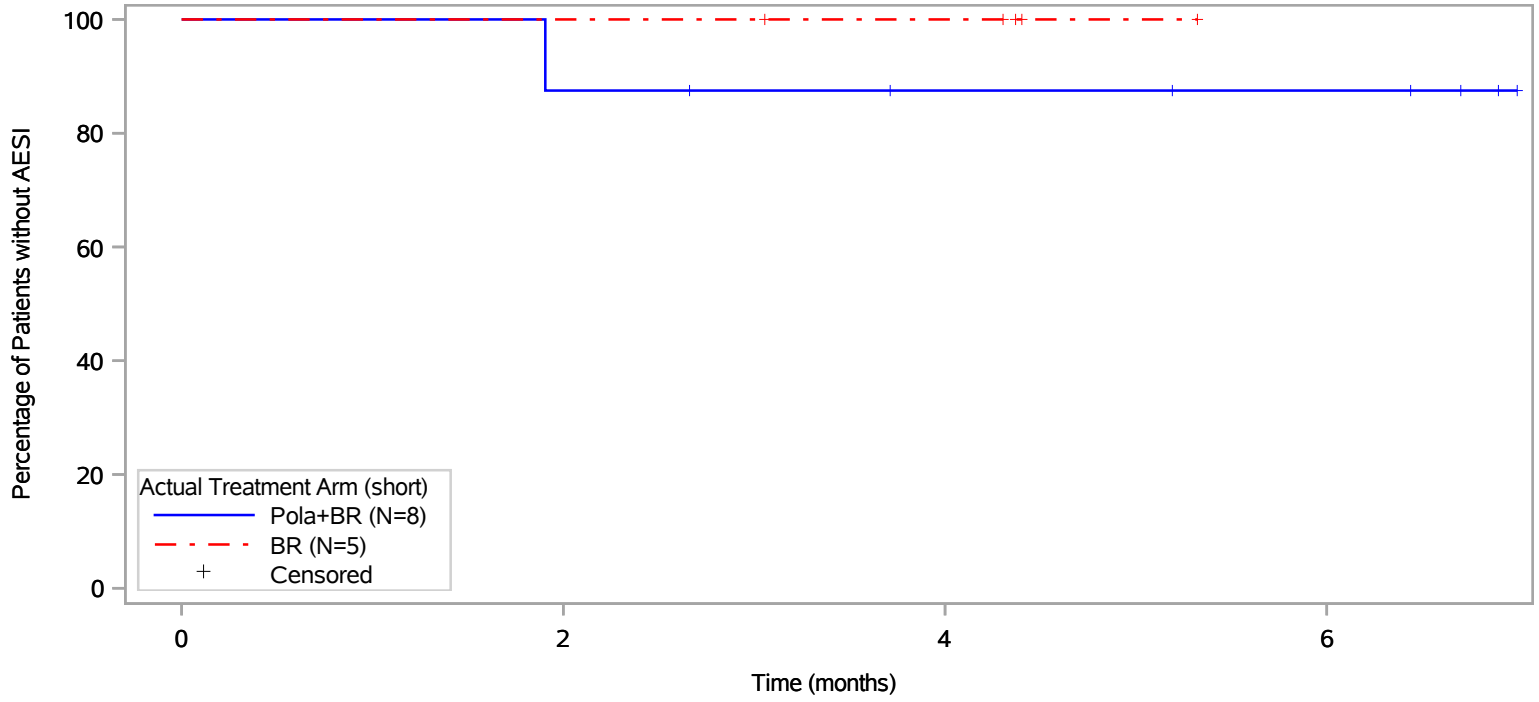
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTINECTS_L2_Polarose_SE_29365_41543.xls
30MAR2023 9:56

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTINECTS_L2_Polarose_SE_29365_41543.pdf
30MAR2023 12:20

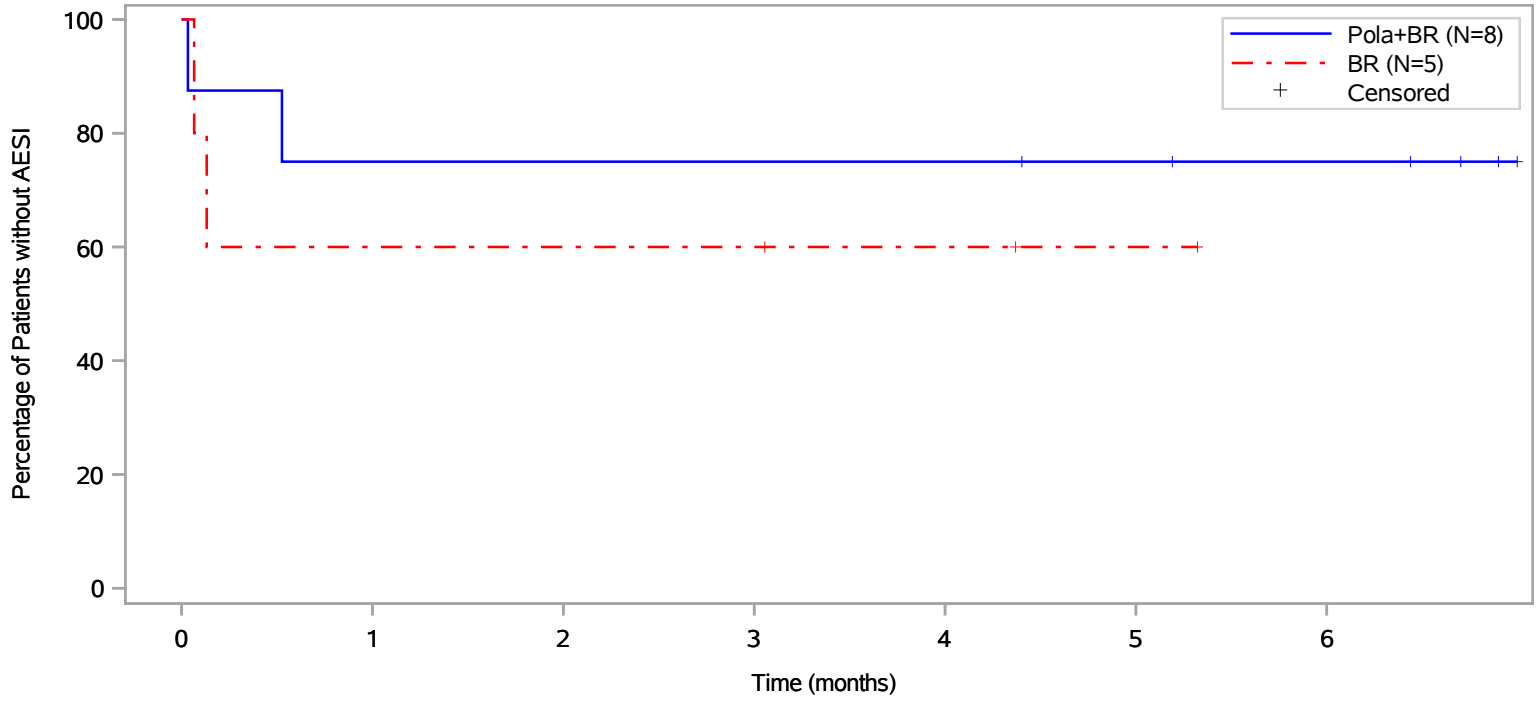
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	2	25.0	6	75.0	5	100.0	2	40.0	3	60.0	0.5772	0.58	0.08	4.12		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	2	28.6	5	71.4	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	2	50.0	2	50.0	0.4452	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	2	40.0	3	60.0	2	40.0	1	50.0	1	50.0	0.8132	0.75	0.07	8.42		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	2	25.0	6	75.0	5	100.0	2	40.0	3	60.0	0.5772	0.58	0.08	4.12		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTIRR_L2_Polarose_SE_29365_41543.xls
01DEC2022 3:06

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	6	6	6	6	5	4
BR (N=5)	5	3	3	3	2	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	0	1	2
BR (N=5)	0	0	0	0	1	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTIRR_L2_Polarose_SE_29365_41543.pdf
03DEC2022 20:57

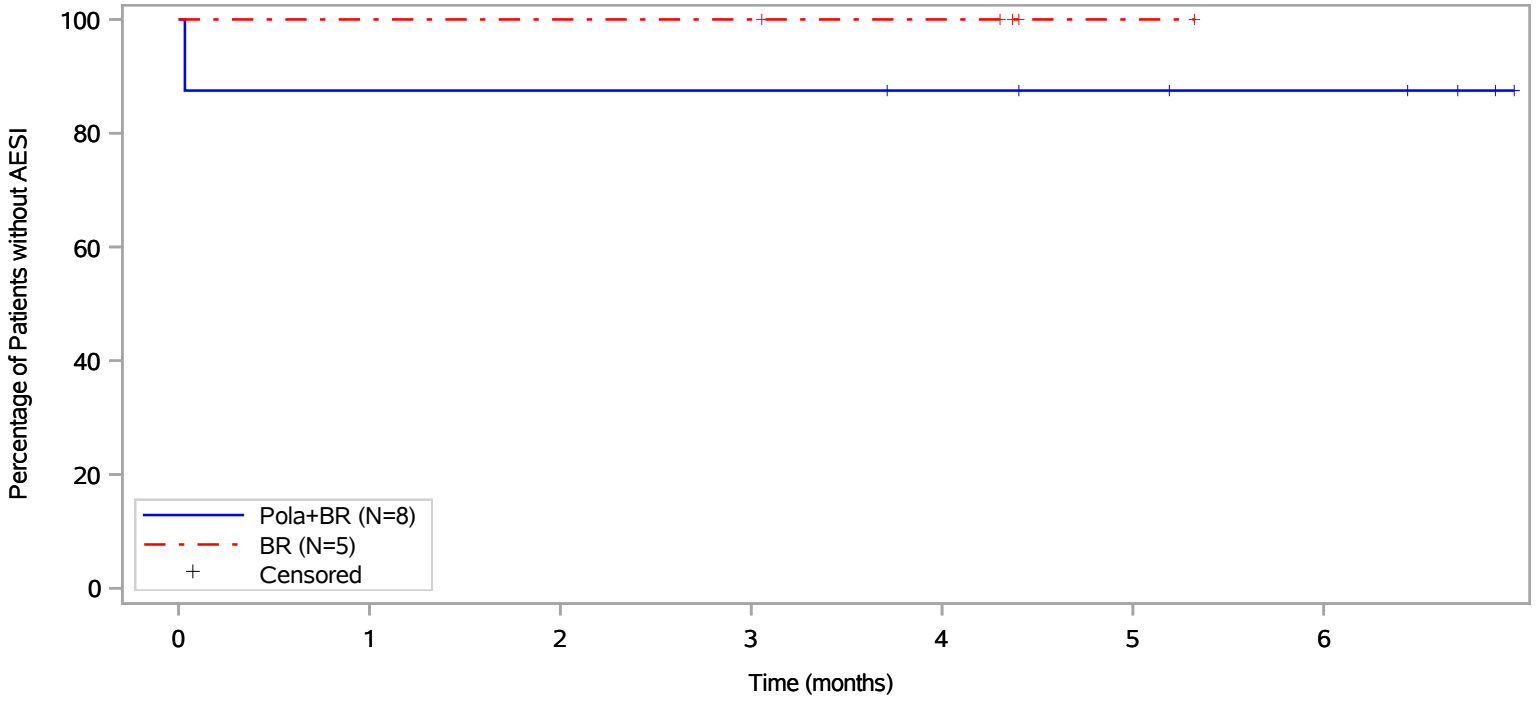
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	0	-	5	100.0	0.4292	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTIRR35_L2_Polarose_SE_29365_41543.xls
24JAN2023 17:55

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	7	7	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	2	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTIRR35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 23:06

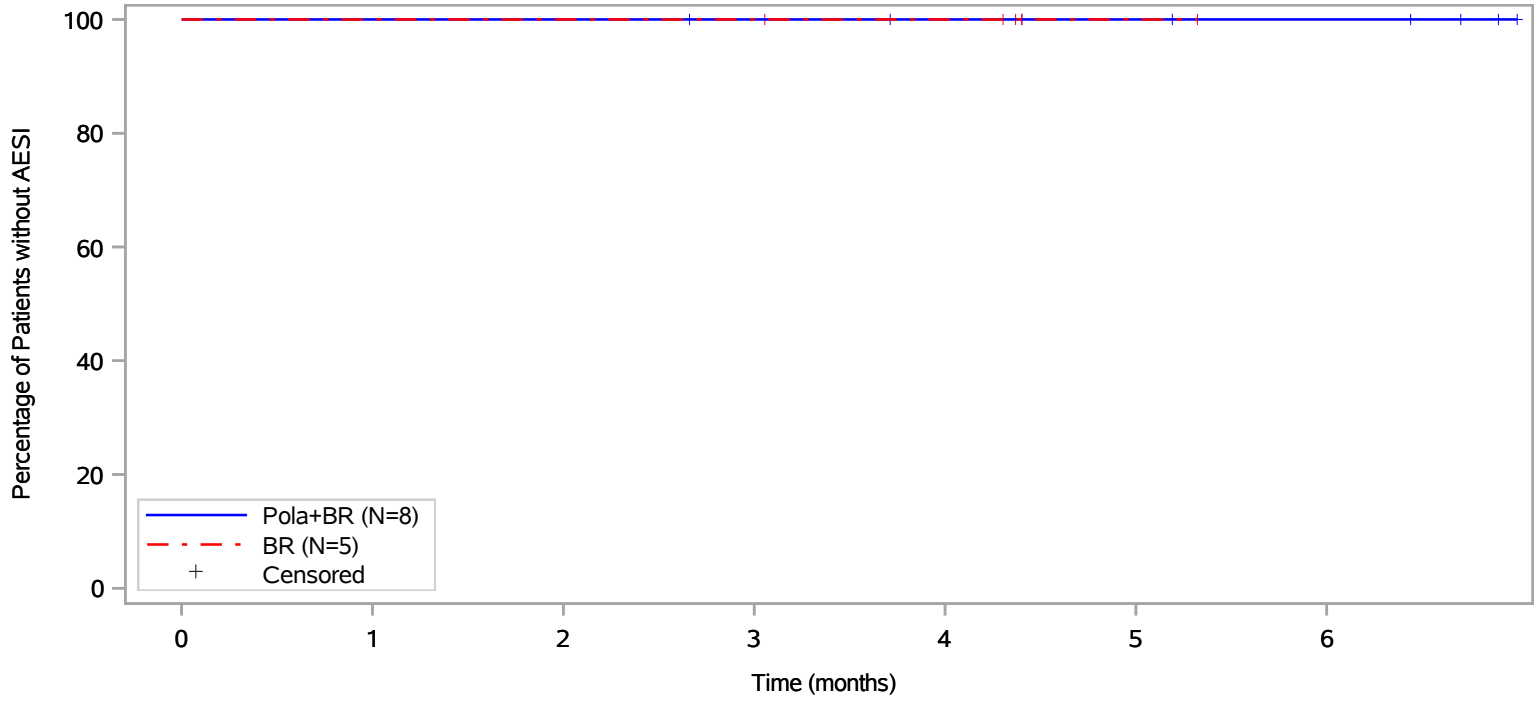
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTIRRS_L2_Polarose_SE_29365_41543.xls
02DEC2022 20:49

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTIRRS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 1:12

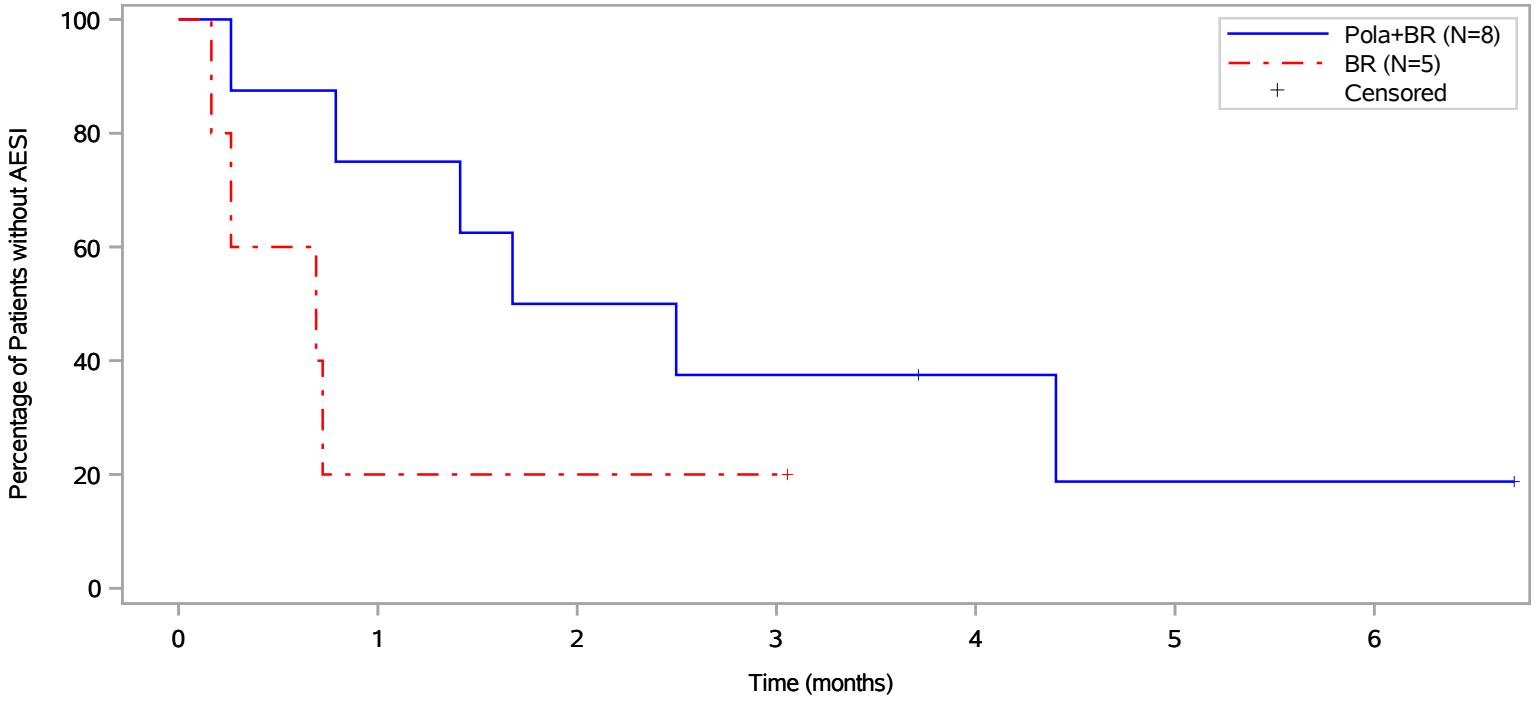
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	6	75.0	2	25.0	5	100.0	4	80.0	1	20.0	0.1506	0.38	0.10	1.49		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	5	71.4	2	28.6	1	20.0	0	-	1	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	1	100.0	0	-	4	80.0	4	100.0	0	-	0.1564	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	4	80.0	1	20.0	2	40.0	2	100.0	0	-	0.0823	0.13	0.01	1.67		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	2	66.7	1	33.3	3	60.0	2	66.7	1	33.3	0.3018	0.29	0.03	3.42		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	2	100.0	0	-	4	80.0	3	75.0	1	25.0	0.3518	0.35	0.03	3.54		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	4	66.7	2	33.3	1	20.0	1	100.0	0	-	0.1768	0.18	0.01	2.93		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	6	75.0	2	25.0	5	100.0	4	80.0	1	20.0	0.1506	0.38	0.10	1.49		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTNIFNEU_L2_Polarose_SE_29365_41543.xls
30NOV2022 23:55

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	6	4	3	2	1	1
BR (N=5)	5	1	1	1	NE	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	1
BR (N=5)	0	0	0	0	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:29

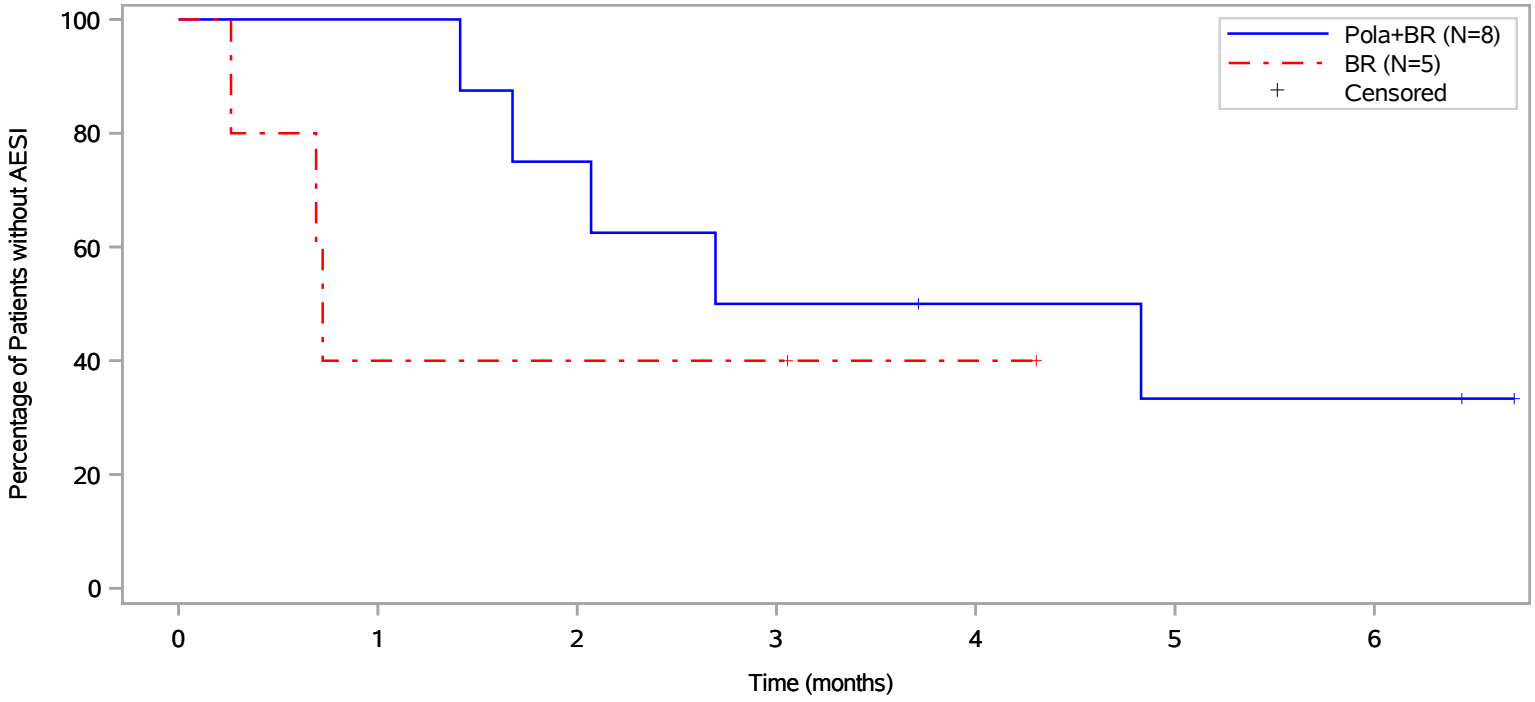
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	5	62.5	3	37.5	5	100.0	3	60.0	2	40.0	0.3711	0.51	0.11	2.30		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	4	57.1	3	42.9	1	20.0	0	-	1	100.0	0.3838	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	1	100.0	0	-	4	80.0	3	75.0	1	25.0	0.2994	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	4	80.0	1	20.0	2	40.0	2	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	1	50.0	1	50.0	4	80.0	2	50.0	2	50.0	0.2807	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	4	66.7	2	33.3	1	20.0	1	100.0	0	-	0.0143	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	5	62.5	3	37.5	5	100.0	3	60.0	2	40.0	0.3711	0.51	0.11	2.30		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTNIFNEU35_L2_Polarose_SE_29365_41543.xls
02DEC2022 19:51

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	6	4	3	2	2
BR (N=5)	5	2	2	2	1	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	1
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTNIFNEU35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 22:32

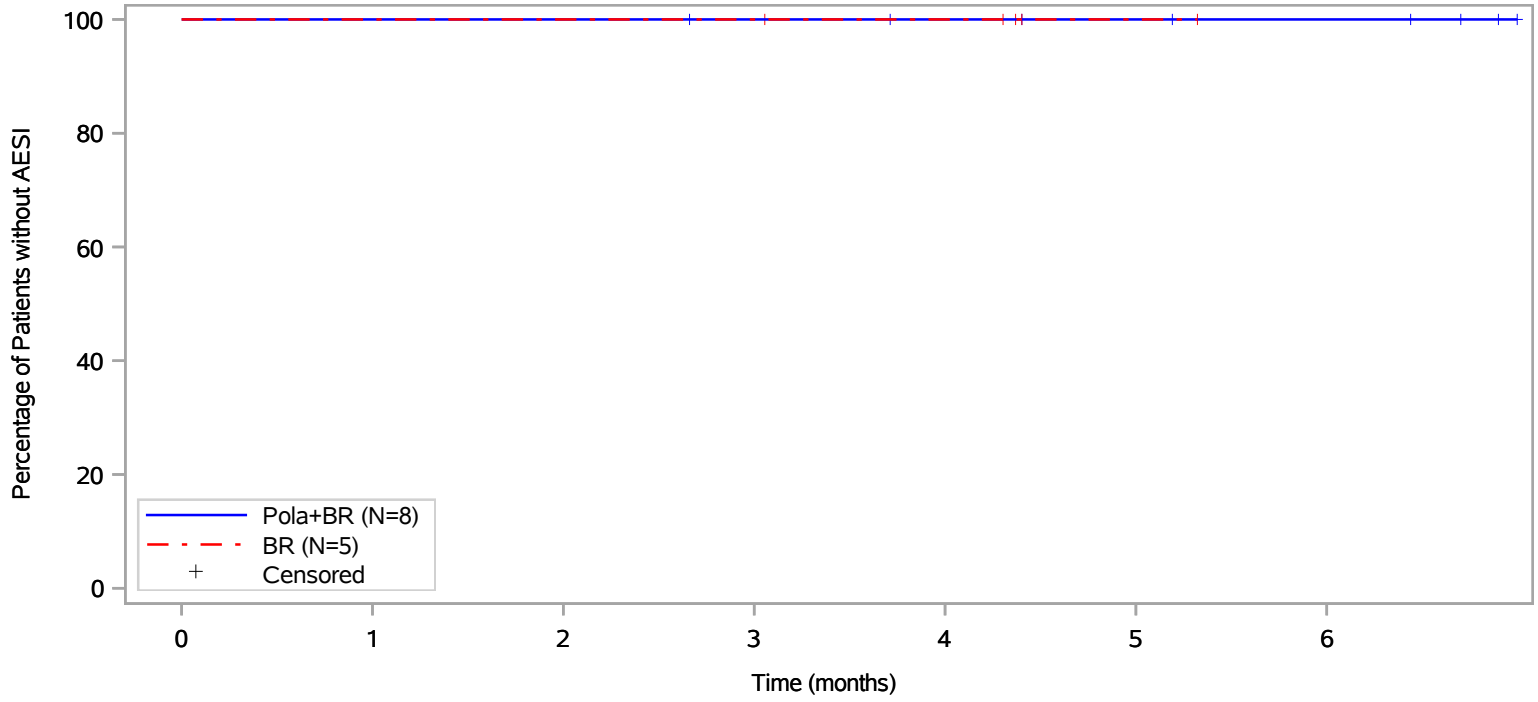
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTNIFNEUS_L2_Polarose_SE_29365_41543.xls
02DEC2022 19:48

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTNIFNEUS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 0:42

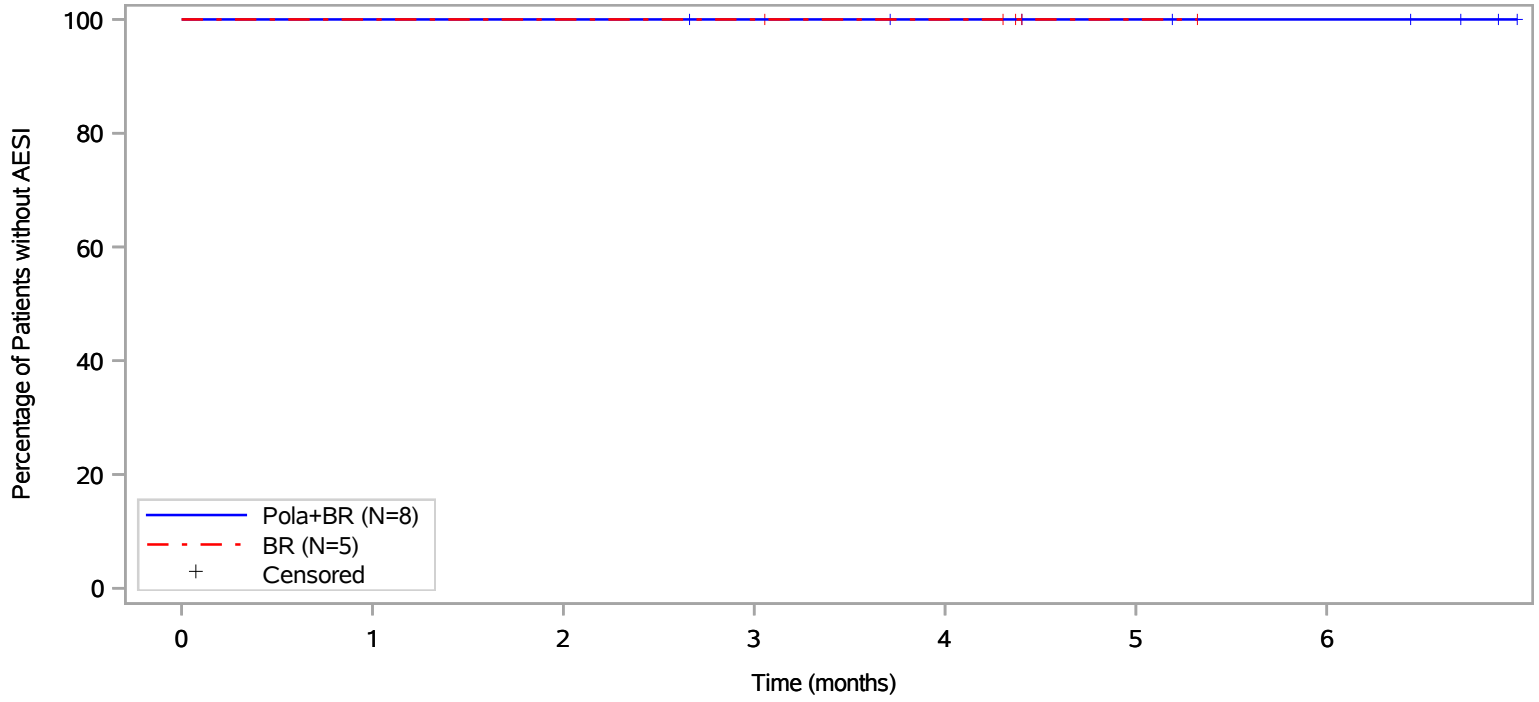
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTOCUTOX_L2_Polarose_SE_29365_41543.xls
01DEC2022 20:28

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Ocular Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTOCUTOX_L2_Polarose_SE_29365_41543.pdf
03DEC2022 22:00

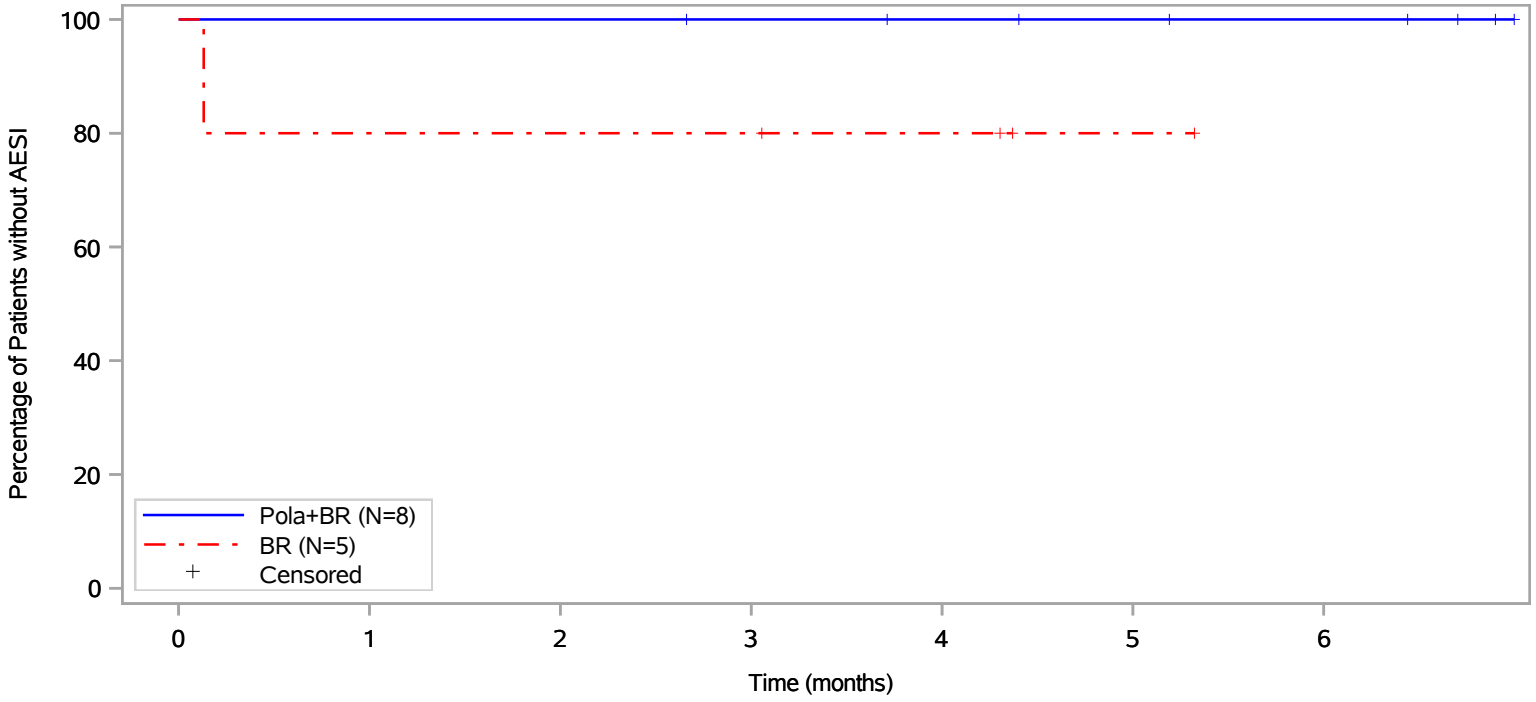
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	1	50.0	1	50.0	0.1138	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	1	20.0	4	80.0	0.2059	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPAIN_L2_Polarose_SE_29365_41543.xls
24JAN2023 18:04

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	4	4	4	3	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTPAIN_L2_Polarose_SE_29365_41543.pdf
03DEC2022 21:43

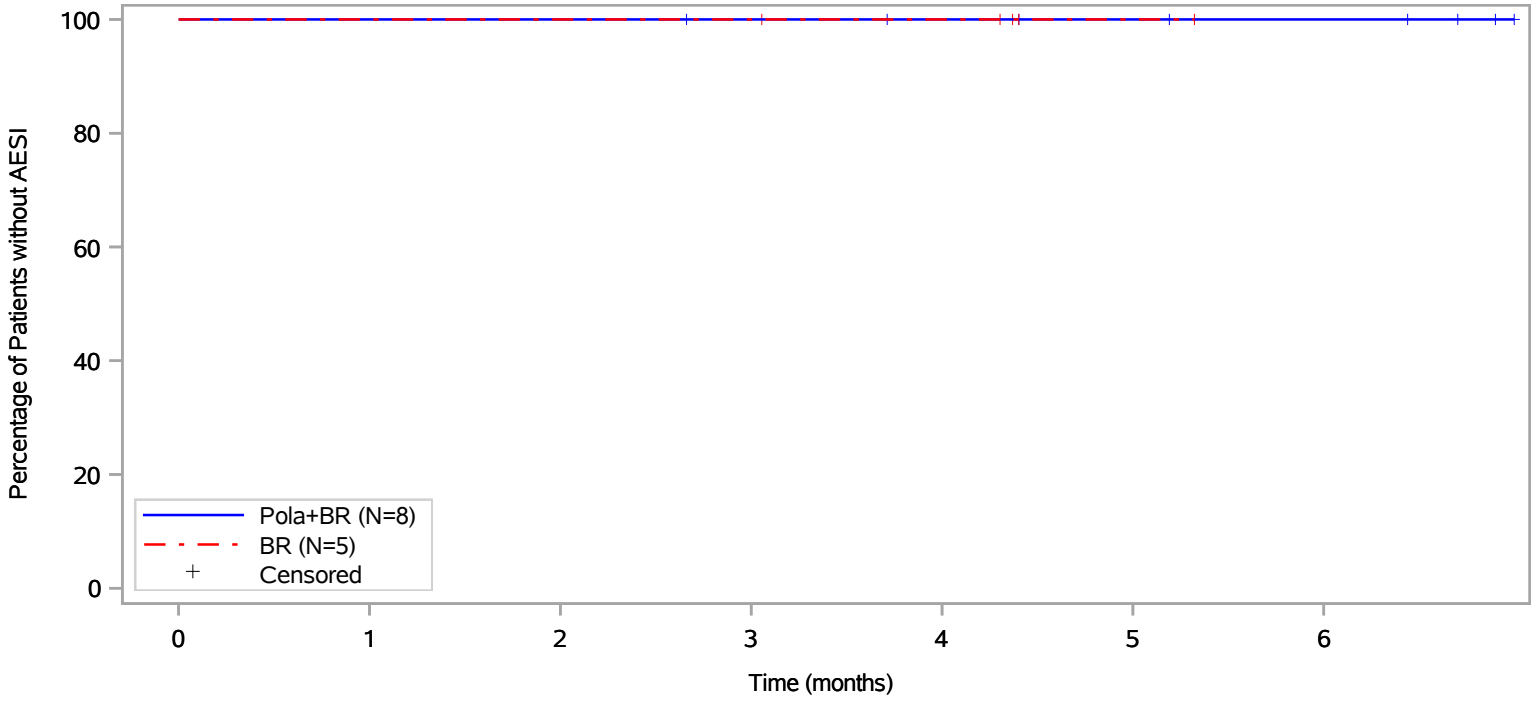
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPAIN35_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:43

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTPAIN35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 23:52

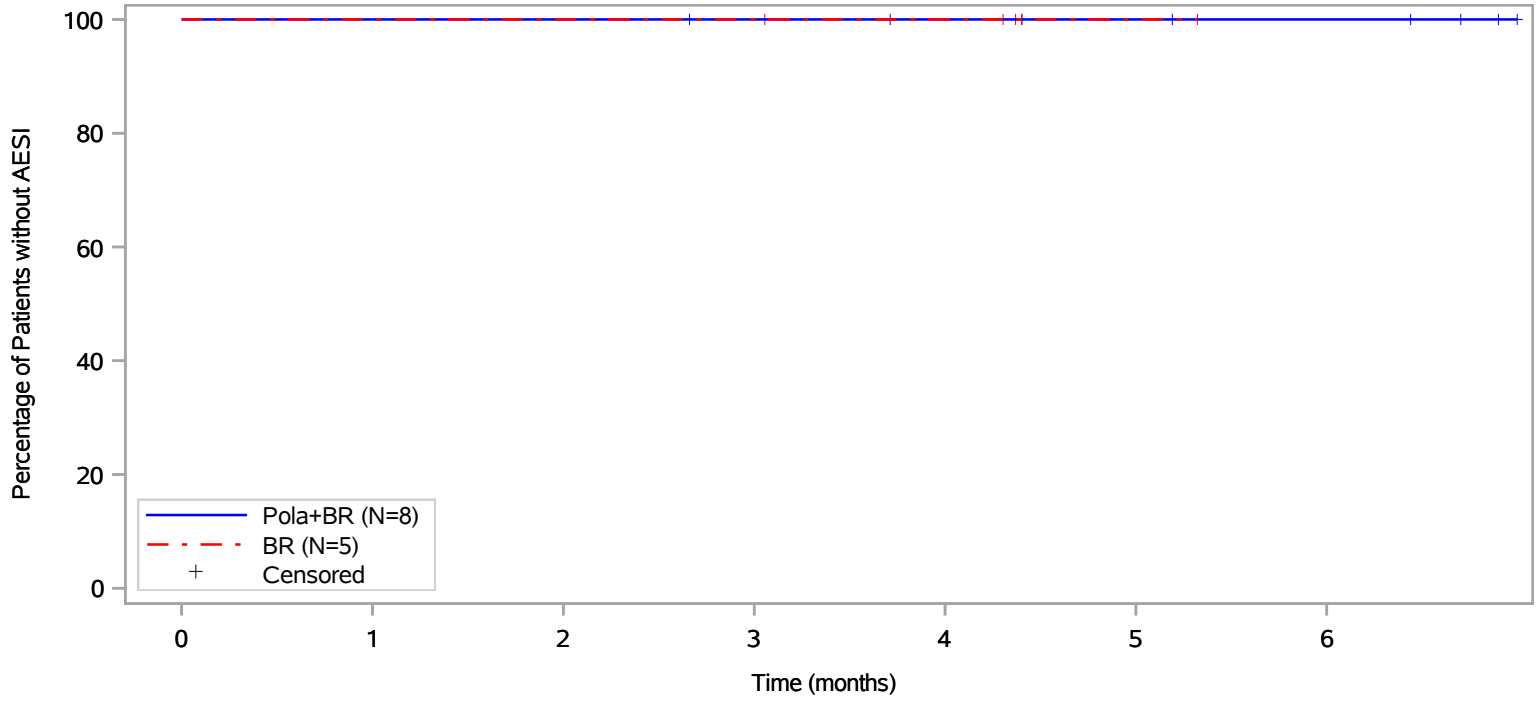
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPAINS_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:46

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTPAINS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 2:07

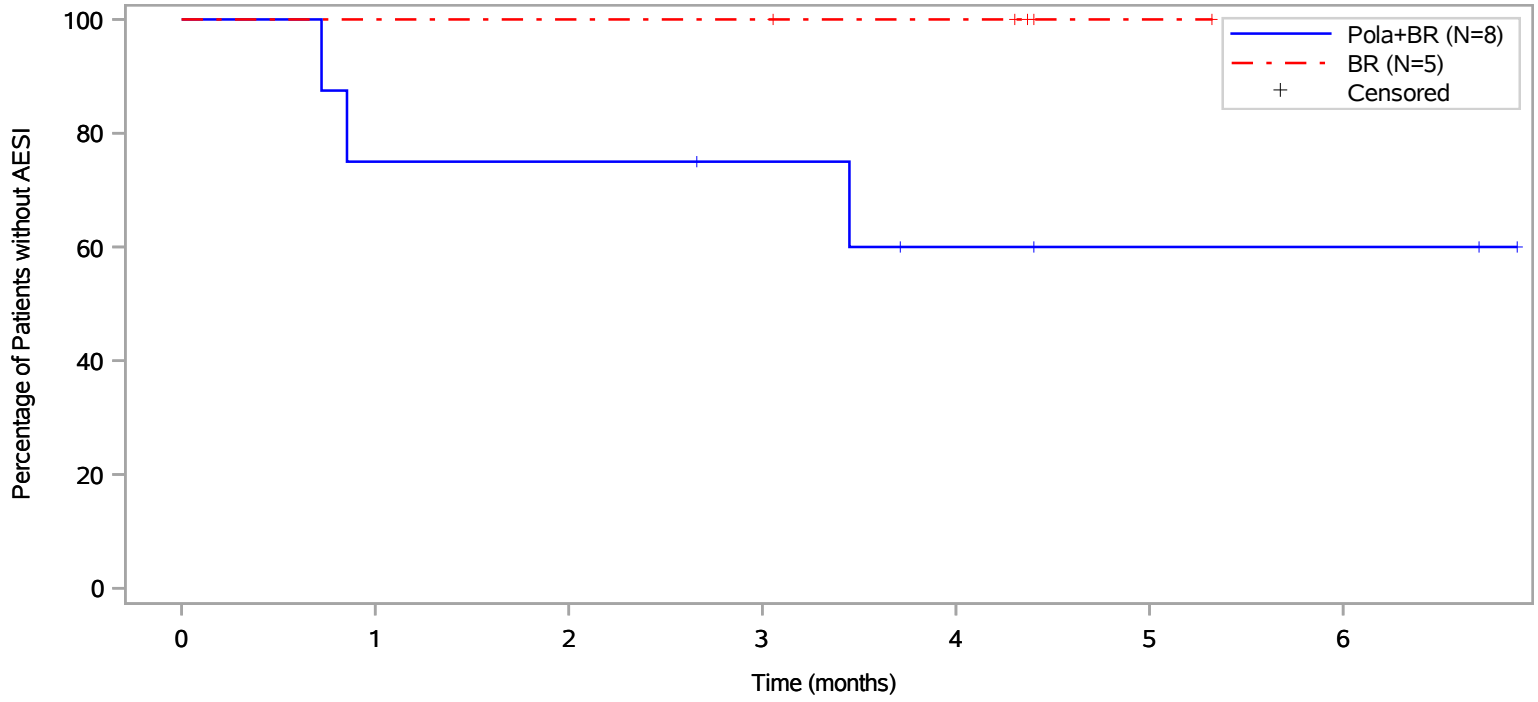
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	3	37.5	5	62.5	5	100.0	0	-	5	100.0	0.1439	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	3	42.9	4	57.1	1	20.0	0	-	1	100.0	0.5780	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	2	40.0	3	60.0	2	40.0	0	-	2	100.0	0.3431	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	1	33.3	2	66.7	3	60.0	0	-	3	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	1	50.0	1	50.0	4	80.0	0	-	4	100.0	0.2207	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	2	33.3	4	66.7	1	20.0	0	-	1	100.0	0.5449	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	3	37.5	5	62.5	5	100.0	0	-	5	100.0	0.1439	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPHENEU_L2_Polarose_SE_29365_41543.xls
24JAN2023 18:12

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	6	6	5	3	2	2
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	3
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTPHENEU_L2_Polarose_SE_29365_41543.pdf
03DEC2022 20:35

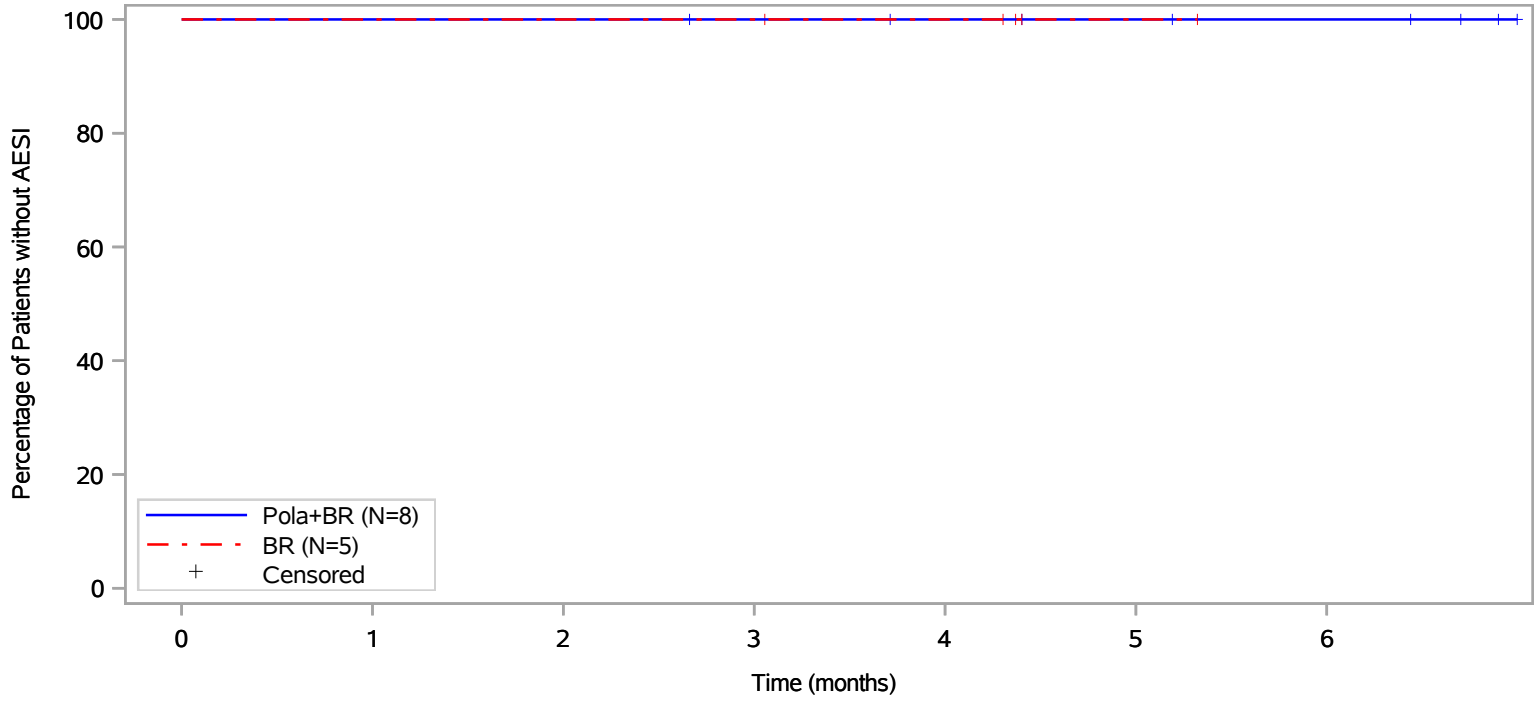
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPHENEU35_L2_Polarose_SE_29365_41543.xls
02DEC2022 20:04

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTPHENEU35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 22:39

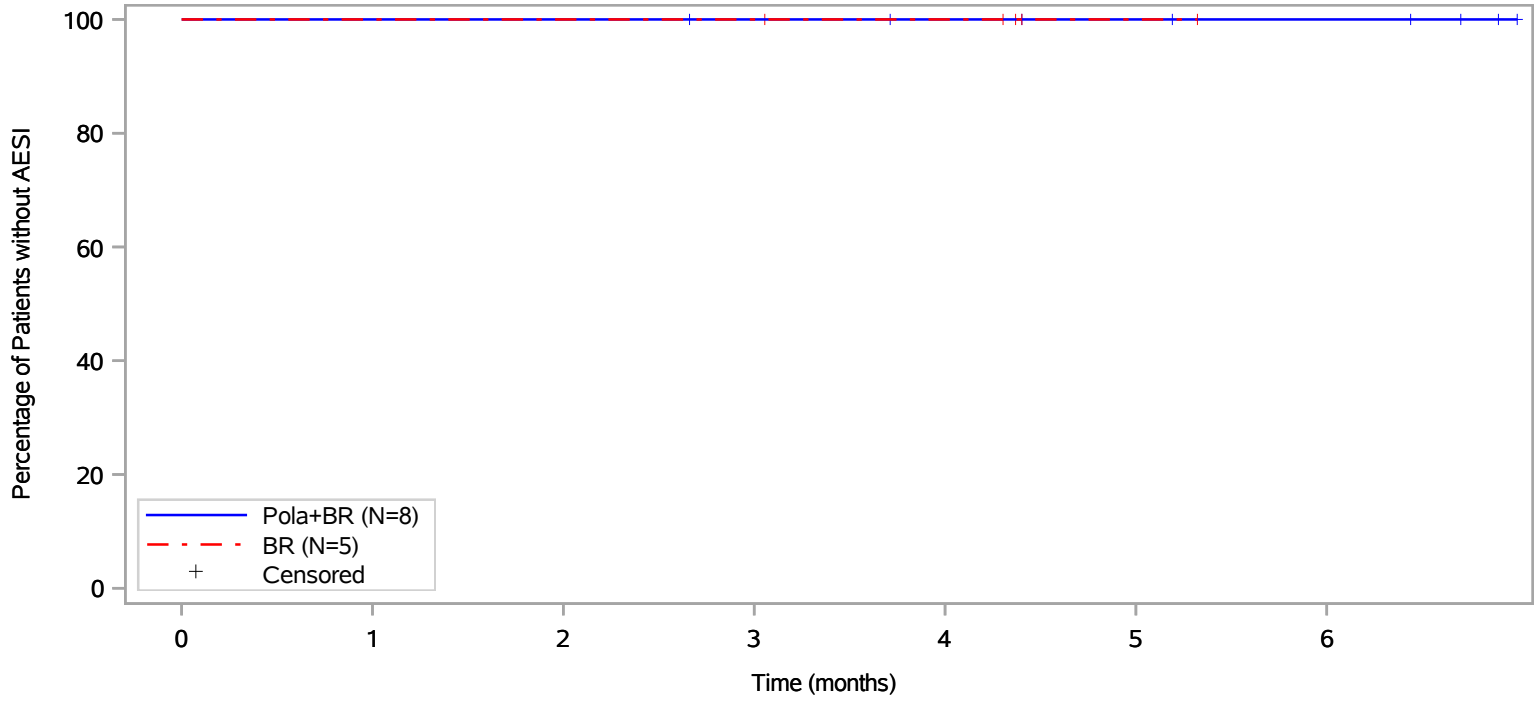
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPHENEUS_L2_Polarose_SE_29365_41543.xls
02DEC2022 20:07

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTPHENEUS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 0:47

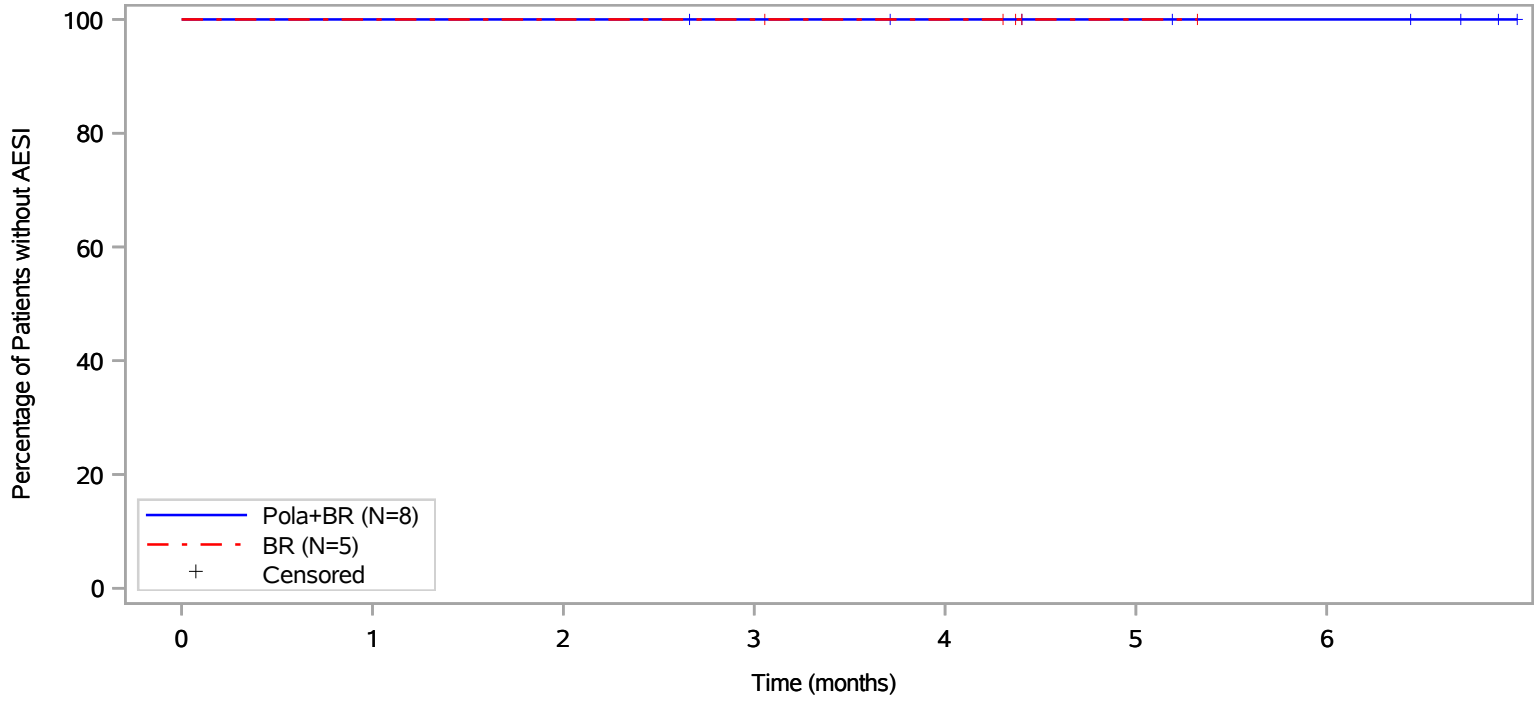
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPULTOX_L2_Polarose_SE_29365_41543.xls
01DEC2022 7:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTPULTOX_L2_Polarose_SE_29365_41543.pdf
03DEC2022 21:36

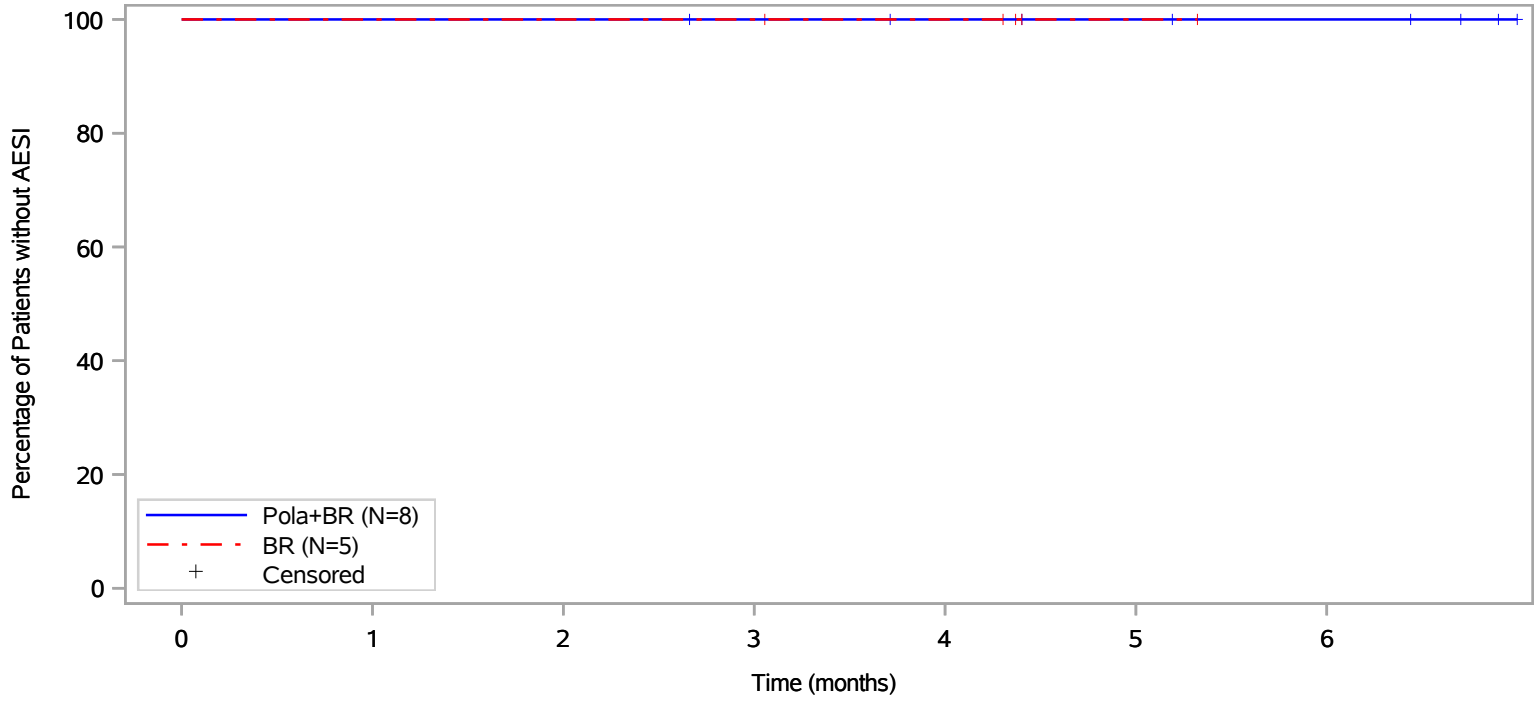
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPULTOX35_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:33

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTPULTOX35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 23:47

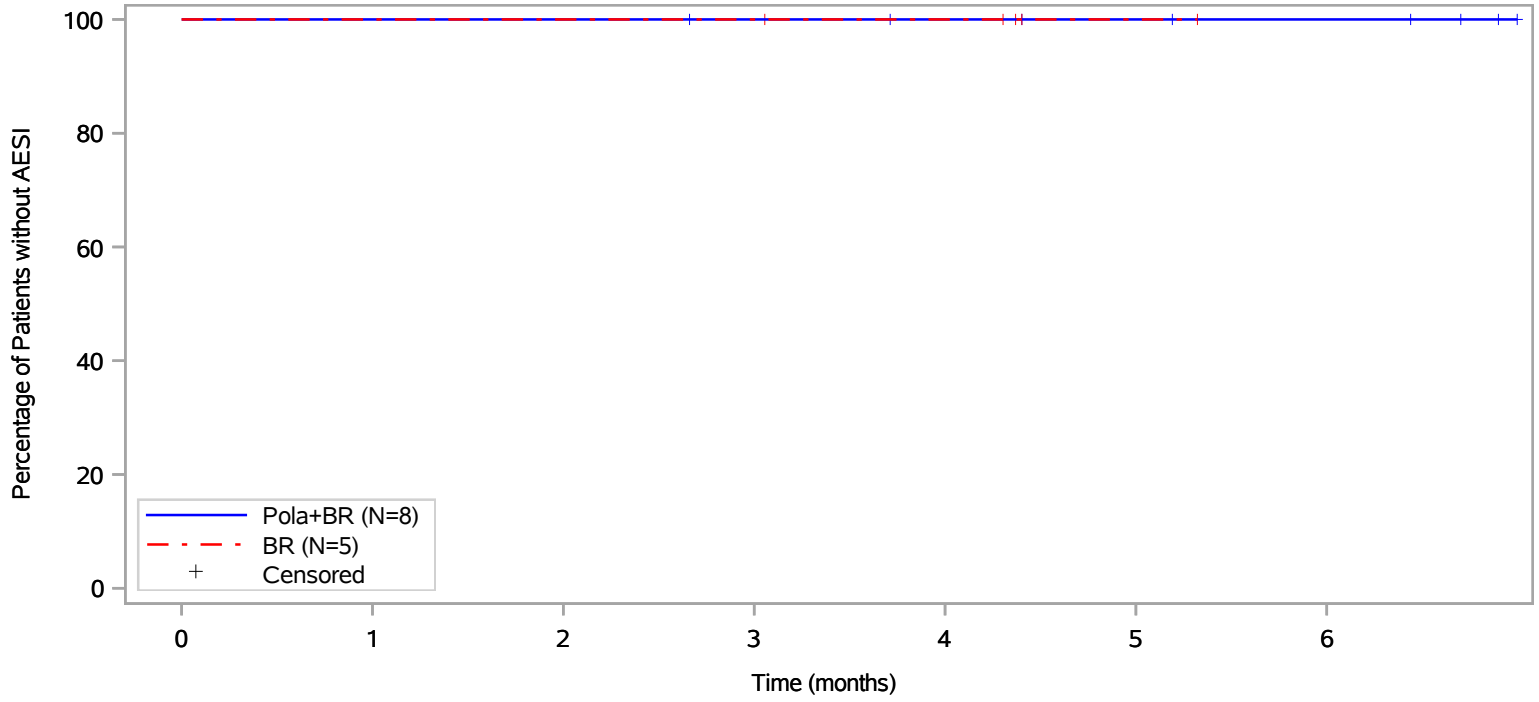
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPULTOXS_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTPULTOXS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 1:59

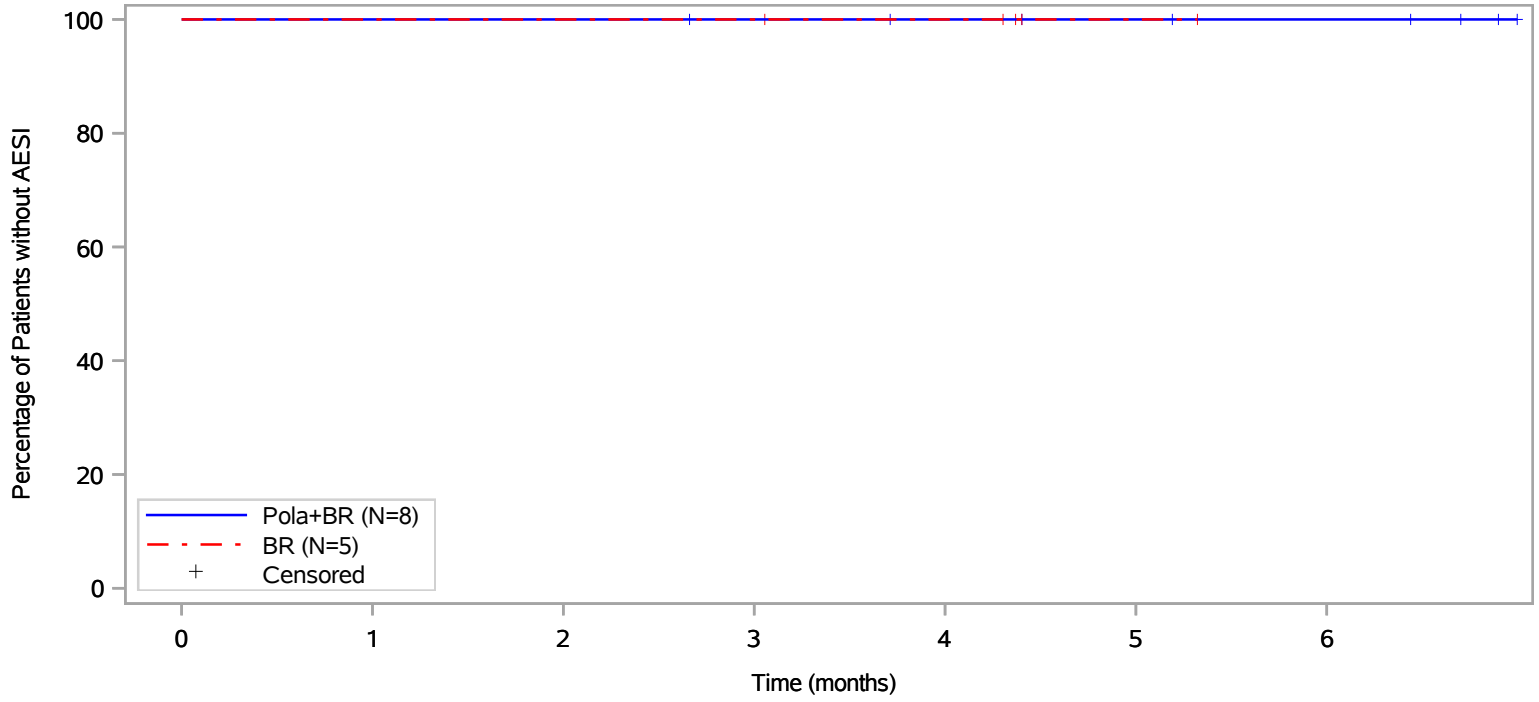
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTRENTOX_L2_Polarose_SE_29365_41543.xls
01DEC2022 5:48

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTRENTOX_L2_Polarose_SE_29365_41543.pdf
03DEC2022 21:25

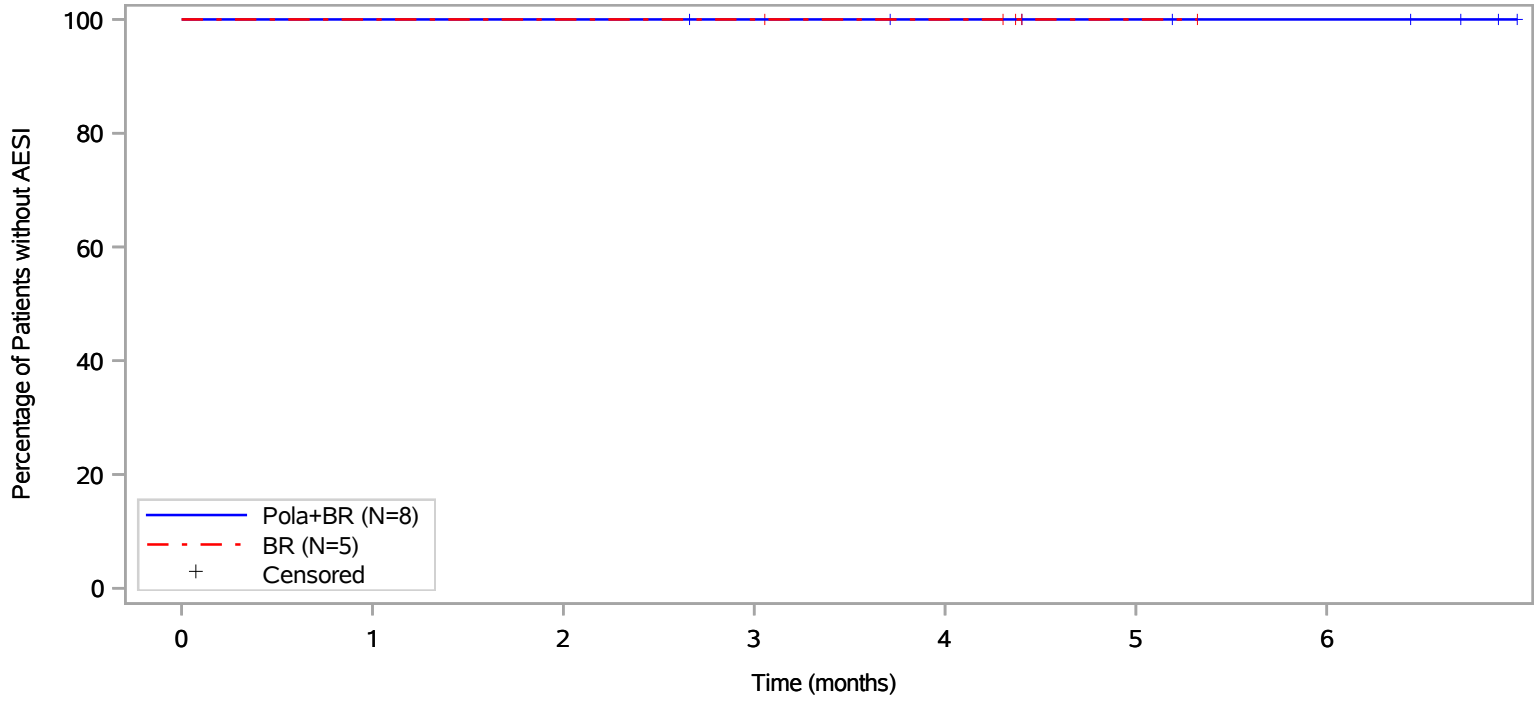
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTRENTOX35_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTRENTOX35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 23:37

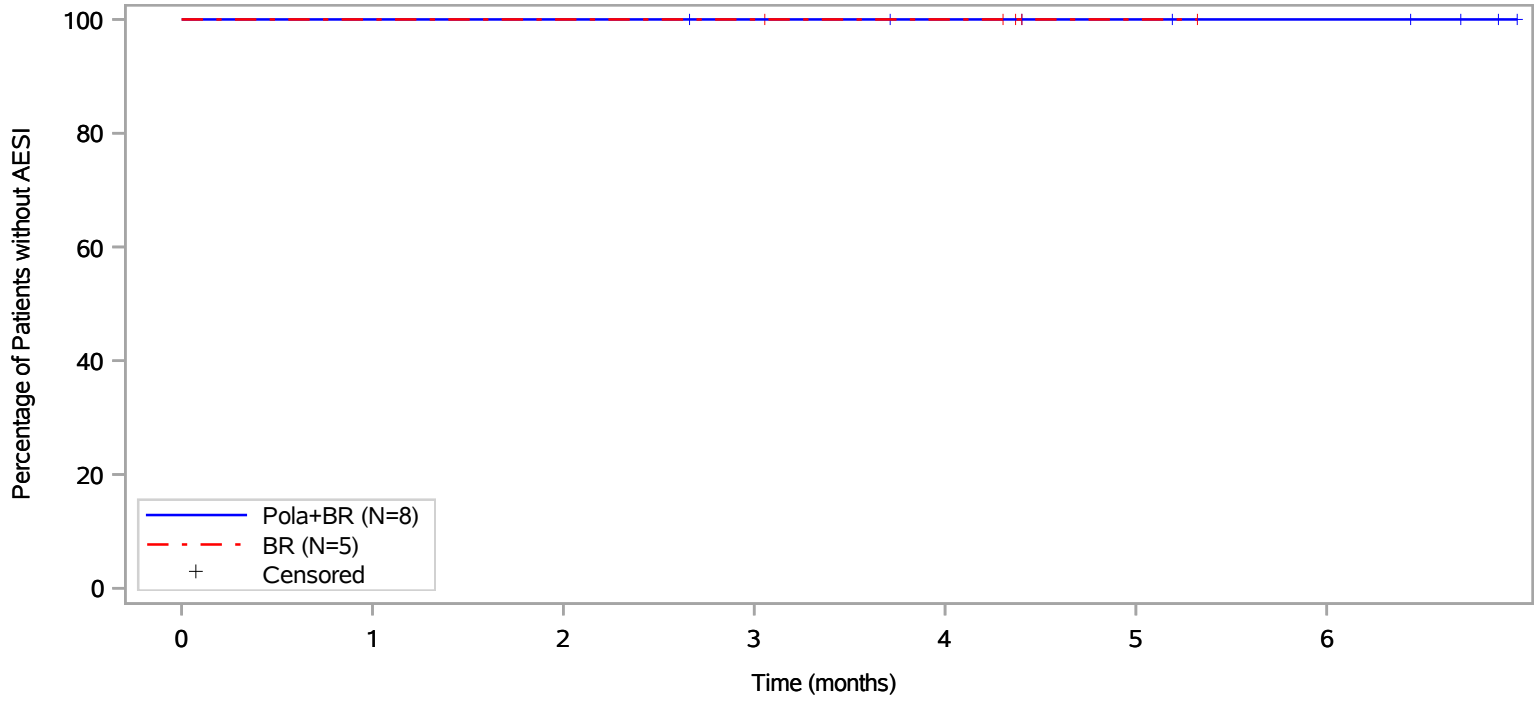
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTRENTOXS_L2_Polarose_SE_29365_41543.xls
02DEC2022 21:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTRENTOXS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 1:44

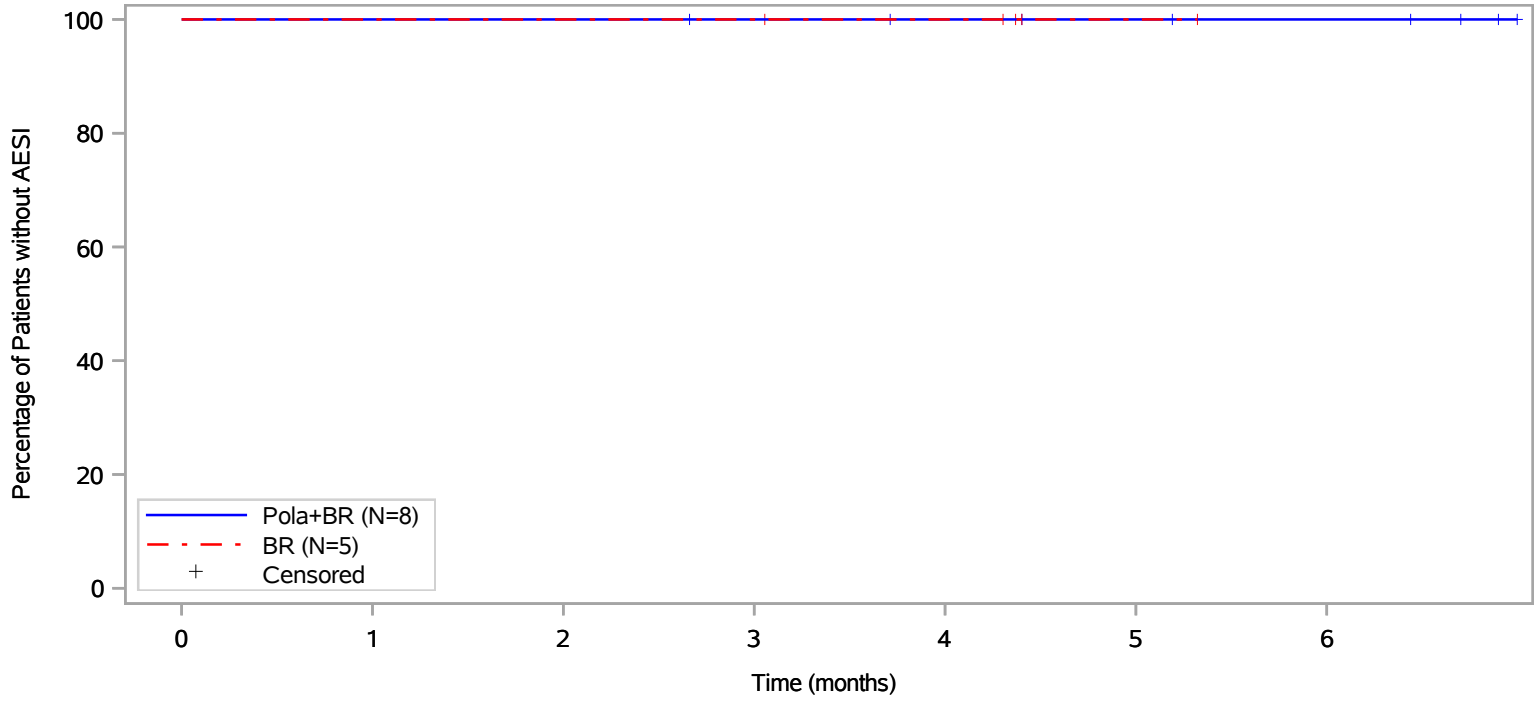
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTREPROD_L2_Polarose_SE_29365_41543.xls
01DEC2022 4:21

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Reproductive Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 21:08

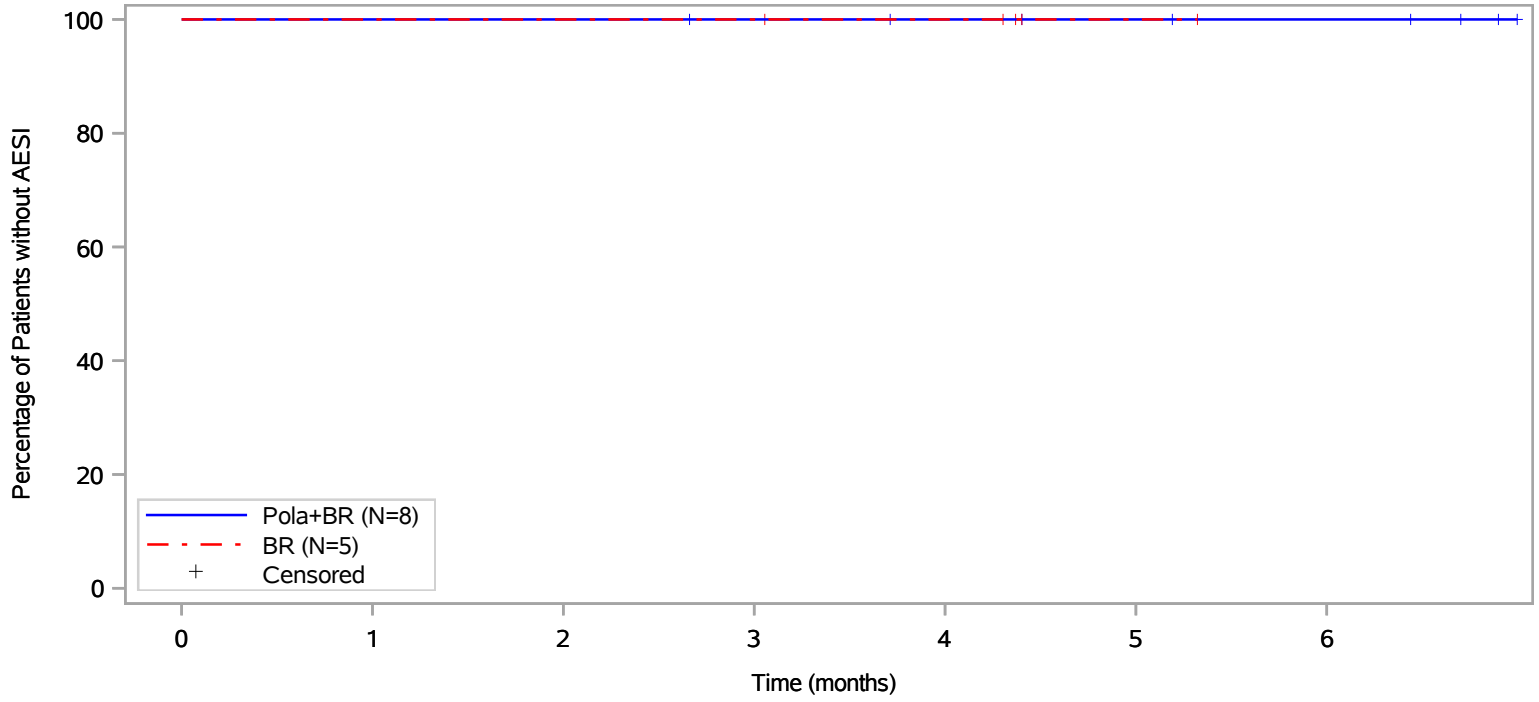
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTSTIAMP_L2_Polarose_SE_29365_41543.xls
04DEC2022 13:37

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTSTIAMP_L2_Polarose_SE_29365_41543.pdf
03DEC2022 14:18

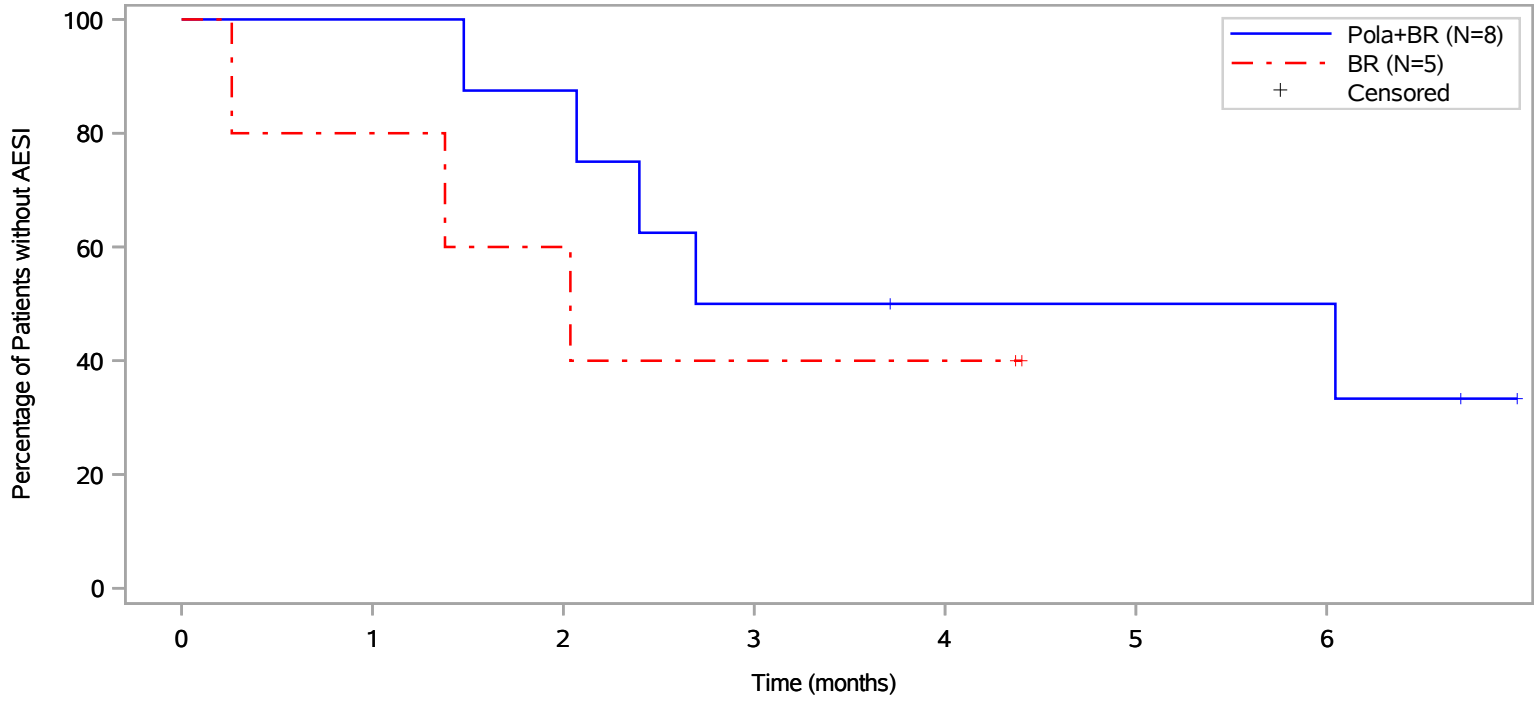
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	5	62.5	3	37.5	5	100.0	3	60.0	2	40.0	0.4265	0.55	0.12	2.47		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	4	57.1	3	42.9	1	20.0	1	100.0	0	-	0.0082	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	1	100.0	0	-	4	80.0	2	50.0	2	50.0	0.4452	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	3	60.0	2	40.0	2	40.0	0	-	2	100.0	0.2119	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	2	66.7	1	33.3	3	60.0	3	100.0	0	-	0.0246	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	2	100.0	0	-	4	80.0	3	75.0	1	25.0	0.3518	0.35	0.03	3.54		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	3	50.0	3	50.0	1	20.0	0	-	1	100.0	0.4325	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	5	62.5	3	37.5	5	100.0	3	60.0	2	40.0	0.4265	0.55	0.12	2.47		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTTHROM_L2_Polarose_SE_29365_41543.xls
01DEC2022 2:02

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	7	4	3	3	3
BR (N=5)	5	4	3	2	2	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	0	1	1	1
BR (N=5)	0	0	0	0	0	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..E_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTTHROM_L2_Polarose_SE_29365_41543.pdf
03DEC2022 20:46

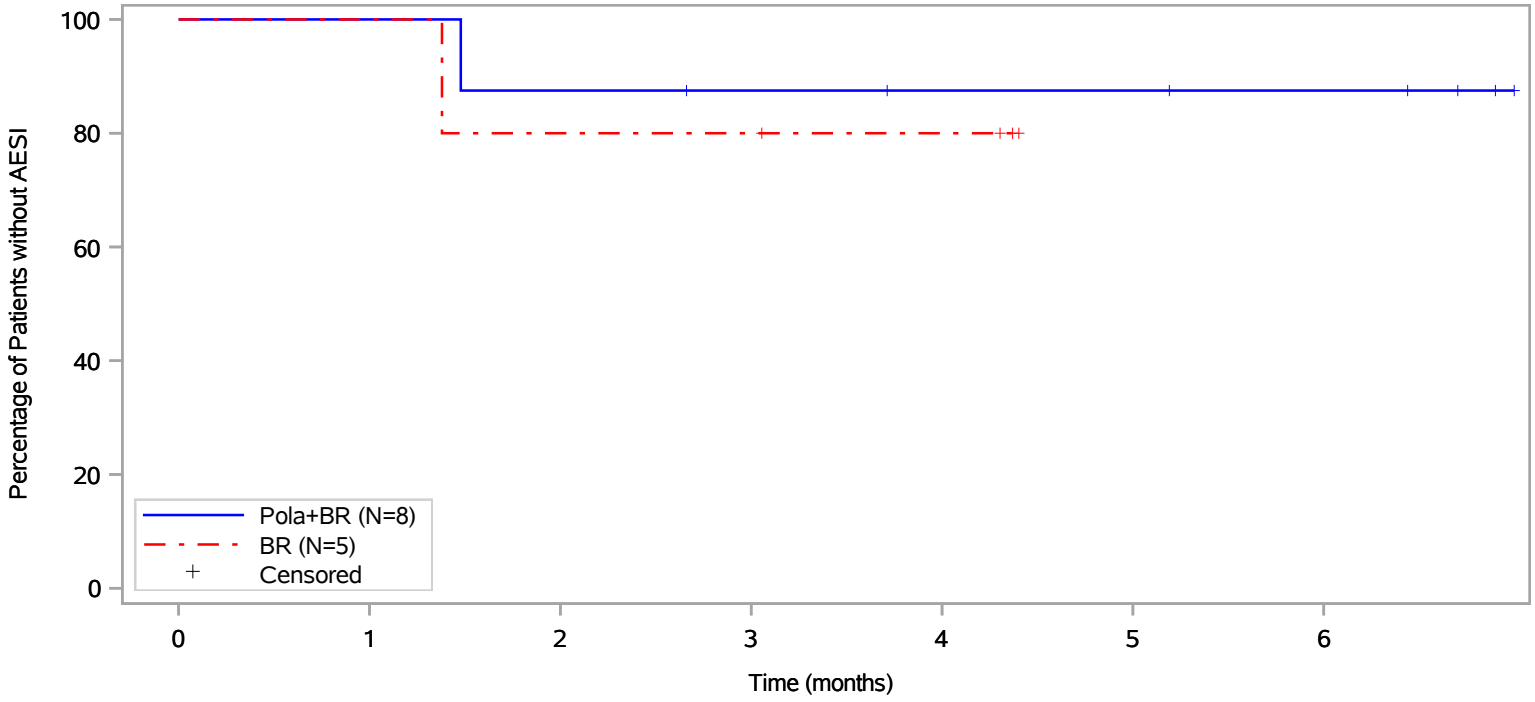
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.6771	0.56	0.03	8.98		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	1	14.3	6	85.7	1	20.0	0	-	1	100.0	0.7055	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	1	25.0	3	75.0	0.6171	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	1	20.0	4	80.0	2	40.0	0	-	2	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	1	33.3	2	66.7	0.3173	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	1	25.0	3	75.0	0.4795	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	1	16.7	5	83.3	1	20.0	0	-	1	100.0	0.6831	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	1	12.5	7	87.5	5	100.0	1	20.0	4	80.0	0.6771	0.56	0.03	8.98		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTTHROM35_L2_Polarose_SE_29365_41543.xls
02DEC2022 20:34

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	7	6	5	5	4
BR (N=5)	5	5	4	4	3	NE	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	2	3
BR (N=5)	0	0	0	0	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTTHROM35_L2_Polarose_SE_29365_41543.pdf
03DEC2022 22:51

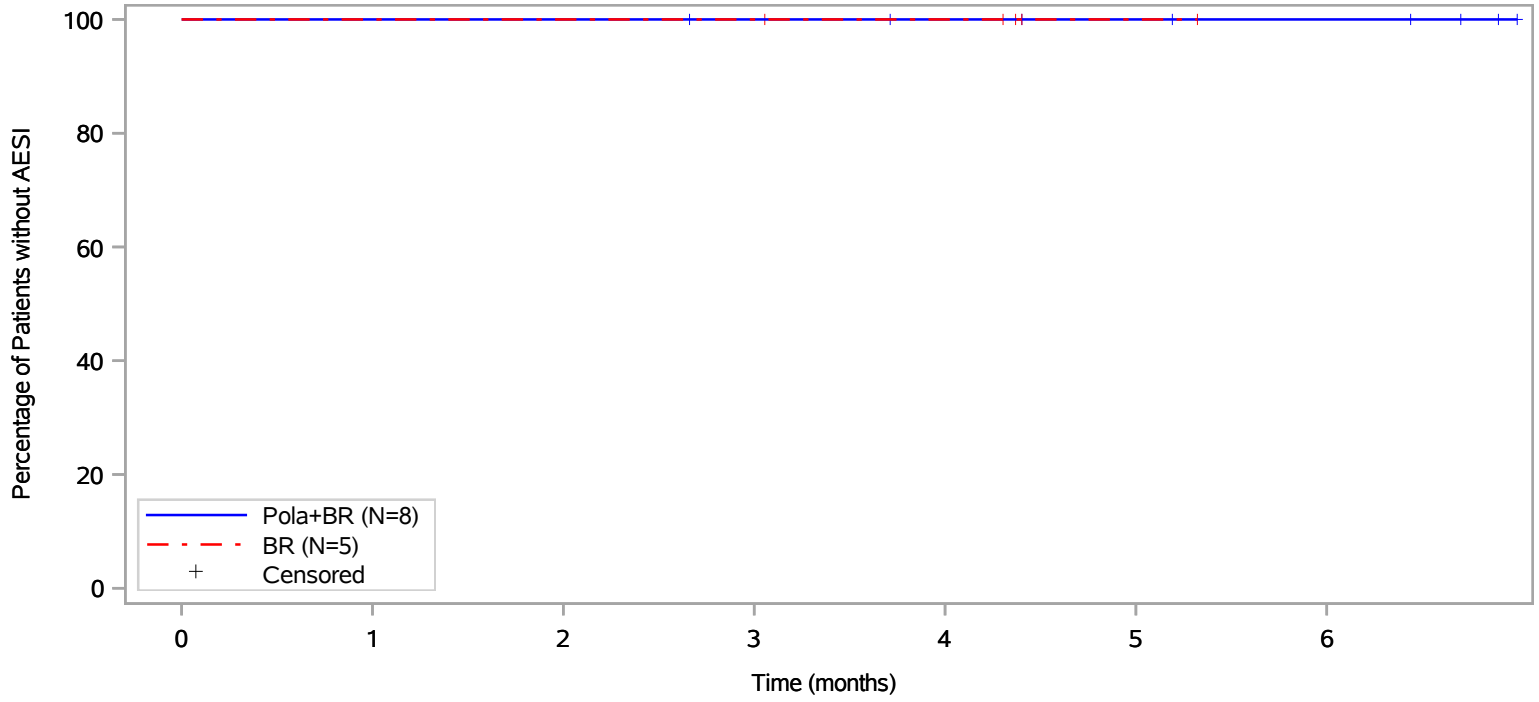
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTTHROMS_L2_Polarose_SE_29365_41543.xls
02DEC2022 20:34

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Serious Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTTHROMS_L2_Polarose_SE_29365_41543.pdf
04DEC2022 0:59

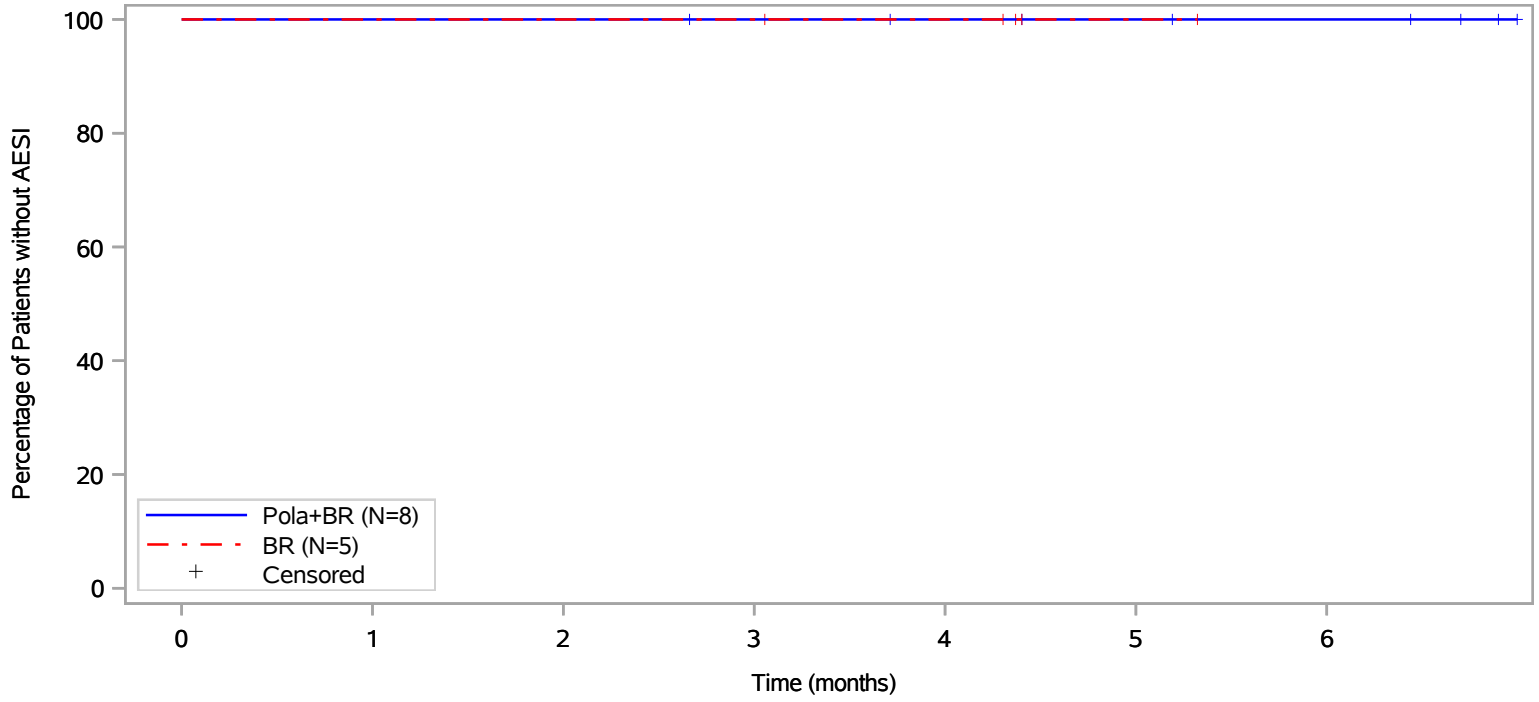
POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=8)						BR (N=5)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	7	87.5	0	-	7	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	1	12.5	0	-	1	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	5	62.5	0	-	5	100.0	2	40.0	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	37.5	0	-	3	100.0	3	60.0	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	2	25.0	0	-	2	100.0	4	80.0	0	-	4	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	6	75.0	0	-	6	100.0	1	20.0	0	-	1	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	8	100.0	0	-	8	100.0	5	100.0	0	-	5	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTTLS_L2_Polarose_SE_29365_41543.xls
01DEC2022 21:18

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=8)	8	8	8	7	6	5	4
BR (N=5)	5	5	5	5	4	1	NE
Patients censored							
Pola+BR (N=8)	0	0	0	1	2	3	4
BR (N=5)	0	0	0	0	1	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..ACE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTTLS_L2_Polarose_SE_29365_41543.pdf
03DEC2022 22:13

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=8)															BR (N=5)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																													
All	129	110	85.3	0	0.0	17	13.2	0	0.0	1	0.8	1	0.8	0	0.0	62	46	74.2	0	0.0	16	25.8	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	66	56	84.8	0	0.0	10	15.2	0	0.0	0	0.0	0	0.0	0	0.0	31	25	80.6	0	0.0	6	19.4	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	41	34	82.9	0	0.0	5	12.2	0	0.0	1	2.4	1	2.4	0	0.0	24	16	66.7	0	0.0	8	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	16	14	87.5	0	0.0	2	12.5	0	0.0	0	0.0	0	0.0	0	0.0	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	6	6	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AEs Grade >=3																													
All	22	20	90.9	0	0.0	2	9.1	0	0.0	0	0.0	0	0.0	0	0.0	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	16	14	87.5	0	0.0	2	12.5	0	0.0	0	0.0	0	0.0	0	0.0	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	6	6	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AEs Grade 3																													
All	16	14	87.5	0	0.0	2	12.5	0	0.0	0	0.0	0	0.0	0	0.0	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	16	14	87.5	0	0.0	2	12.5	0	0.0	0	0.0	0	0.0	0	0.0	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0
AEs Grade 4																													
All	6	6	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	6	6	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																													
All	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ae_resolved.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ae_resolved_L2_Polarose_SE_29365_41543.xls
29NOV2022 8:44

POPULATION: Safety-Evaluable Patients, Study YO41543, Second-line (2L) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=8)															BR (N=5)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Neutropenia Including Febrile Neutropenia																														
All	43	39	90.7	0	0.0	3	7.0	0	0.0	1	2.3	0	0.0	0	0.0	20	16	80.0	0	0.0	4	20.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	6	5	83.3	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0	7	5	71.4	0	0.0	2	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	19	18	94.7	0	0.0	0	0.0	0	0.0	1	5.3	0	0.0	0	0.0	9	7	77.8	0	0.0	2	22.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	13	11	84.6	0	0.0	2	15.4	0	0.0	0	0.0	0	0.0	0	0.0	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	5	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Neutropenia Including Febrile Neutropenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral Neuropathy																														
All	3	1	33.3	0	0.0	1	33.3	0	0.0	0	0.0	1	33.3	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Peripheral Neuropathy																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Anemia																														
All	4	1	25.0	0	0.0	3	75.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Anemia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Thrombocytopenia																														
All	7	4	57.1	0	0.0	3	42.9	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Thrombocytopenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infections and Infestations																														
All	6	4	66.7	0	0.0	2	33.3	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Infections and Infestations																														
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infusion Related Reactions																														
All	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Infusion Related Reactions																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hepatic Toxicity																														
All	7	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	4	50.0	0	0.0	4	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	7	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hepatic Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Fatigue and Asthenia																														
All	5	4	80.0	0	0.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Fatigue and Asthenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hyperglycemias																														
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hyperglycemias																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Renal Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Serious Renal Toxicity																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Gastrointestinal Toxicity																																			
All	21	21	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9	7	77.8	0	0.0	2	22.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	14	14	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	5	83.3	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	7	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Gastrointestinal Toxicity																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pulmonary Toxicity																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Pulmonary Toxicity																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Joint Pains, Arthralgia, Skeletal Pain																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Joint Pains, Arthralgia, Skeletal Pain																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Alopecia																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Alopecia																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Cardiac Toxicity and Arrhythmias																																			
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Cardiac Toxicity and Arrhythmias																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ocular Toxicity																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Ocular Toxicity																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dysgeusia																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Dysgeusia																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Tumor Lysis Syndrome																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Tumor Lysis Syndrome																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Genotoxicity Carcinogenecity																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Genotoxicity Carcinogenecity																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Drug Drug Interaction																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Drug Drug Interaction																																			
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

POPULATION: Intent-to-Treat Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Demographics and Baseline Characteristics

	Pola+BR (N=19)	BR (N=9)	All (N=28)
Age (Years)			
n	19	9	28
Mean (SD)	53.7 (11.9)	58.9 (10.2)	55.4 (11.5)
Median	57	58	58
Min - Max	30 - 69	36 - 72	30 - 72
Age Group (Years)			
n	19	9	28
18 - 40	3 (15.8%)	1 (11.1%)	4 (14.3%)
41 - 64	13 (68.4%)	6 (66.7%)	19 (67.9%)
>= 65	3 (15.8%)	2 (22.2%)	5 (17.9%)
Sex			
n	19	9	28
Male	14 (73.7%)	6 (66.7%)	20 (71.4%)
Female	5 (26.3%)	3 (33.3%)	8 (28.6%)
Race			
n	19	9	28
Asian	19 (100%)	9 (100%)	28 (100%)
Ethnicity			
n	19	9	28
Not Hispanic or Latino	19 (100%)	9 (100%)	28 (100%)
Weight (kg) at Baseline			
n	19	9	28
Mean (SD)	67.77 (12.76)	66.67 (9.50)	67.42 (11.65)
Median	68	70	68.5
Min - Max	41.0 - 90.0	53.0 - 78.0	41.0 - 90.0
Height (cm) at Baseline			
n	19	9	28

Mean (SD)	166.8 (5.88)	167.4 (8.16)	167.0 (6.55)
Median	169	172	169.5
Min - Max	158.0 - 176.0	152.0 - 175.0	152.0 - 176.0
ECOG score at Baseline			
n	19	9	28
0	5 (26.3%)	2 (22.2%)	7 (25.0%)
1	12 (63.2%)	6 (66.7%)	18 (64.3%)
2	2 (10.5%)	1 (11.1%)	3 (10.7%)
Bulky disease at Baseline			
n	19	9	28
Yes	5 (26.3%)	2 (22.2%)	7 (25.0%)
No	14 (73.7%)	7 (77.8%)	21 (75.0%)
Primary Reason for Stem Cell Transplant Ineligibility			
n	19	9	28
Age	2 (10.5%)	2 (22.2%)	4 (14.3%)
Failed Prior Transplant	1 (5.3%)	1 (11.1%)	2 (7.1%)
Insufficient Response to Salvage Therapy	4 (21.1%)	2 (22.2%)	6 (21.4%)
Patient Refused Transplant	7 (36.8%)	2 (22.2%)	9 (32.1%)
Other	5 (26.3%)	2 (22.2%)	7 (25.0%)
Duration of response to prior therapy (IxRS)			
n	19	9	28
<=12 Months	19 (100%)	9 (100%)	28 (100%)
Duration of response to prior therapy (CRF)			
n	19	9	28
<=12 Months	19 (100%)	9 (100%)	28 (100%)

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_dm.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_dm_L3PLUS_Polarose_IT_29365_41543.xls
08DEC2022 17:56

POPULATION: Intent-to-Treat Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of Patients who discontinued Study or Treatment

Status / Primary Reason for Discontinuation	Pola+BR (N=19)	BR (N=9)	All (N=28)
Number of Patients Randomized	19 (100.0%)	9 (100.0%)	28 (100.0%)
Number of Patients Treated	19 (100.0%)	9 (100.0%)	28 (100.0%)
Discontinued Study*			
Total	19 (100.0%)	9 (100.0%)	28 (100.0%)
Death	13 (68.4%)	6 (66.7%)	19 (67.9%)
Withdrawal by Subject	1 (5.3%)	0	1 (3.6%)
Study Terminated By Sponsor	5 (26.3%)	3 (33.3%)	8 (28.6%)
Discontinued Polatuzumab Vedotin Treatment or Placebo**			
Total	9 (47.4%)	5 (55.6%)	14 (50.0%)
Adverse Event	3 (15.8%)	1 (11.1%)	4 (14.3%)
Progressive Disease	5 (26.3%)	4 (44.4%)	9 (32.1%)
Withdrawal by Subject	1 (5.3%)	0	1 (3.6%)
Discontinued Bendamustine Treatment**			
Total	9 (47.4%)	5 (55.6%)	14 (50.0%)
Adverse Event	3 (15.8%)	1 (11.1%)	4 (14.3%)
Progressive Disease	5 (26.3%)	4 (44.4%)	9 (32.1%)
Withdrawal by Subject	1 (5.3%)	0	1 (3.6%)
Discontinued Rituximab or Obinutuzumab Treatment**			
Total	9 (47.4%)	5 (55.6%)	14 (50.0%)
Adverse Event	3 (15.8%)	1 (11.1%)	4 (14.3%)
Progressive Disease	5 (26.3%)	4 (44.4%)	9 (32.1%)
Withdrawal by Subject	1 (5.3%)	0	1 (3.6%)

* Percentages are based on the number of patients randomized.
** Percentages are based on the number of patients treated.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ds.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_ds_L3PLUS_Polarose_IT_29365_41543.xls
08DEC2022 13:22

POPULATION: Intent-to-Treat Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Number of Centers/Countries/Geographical Regions with <10, >=10 Patients per Arm

	Center				Country				Geographical region			
	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients	n	%	n of patients randomized	% randomized patients
Overall	8	100.0	28	100.0	1	100.0	28	100.0	1	100.0	28	100.0
with <10 patients per arm	8	100.0	28	100.0	1	100.0	28	100.0	1	100.0	28	100.0
with >=10 patients per arm	0	-	0	-	0	-	0	-	0	-	0	-

'<10 patients' category if at least one treatment arm has <10 patients; '>=10 patients' category if all treatment arms have >=10 patients.
Geographical regions: Asia/Pacific, Eastern Europe, North America, Western Europe.
'n': Number of centers/countries/regions; "%": Percent of centers/countries/regions compared to overall number of centers/countries/regions
'n of patients randomized': Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm)
'% randomized patients': Percent of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_center.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_center_L3PLUS_Polarose_IT_29365_41543.xls
08DEC2022 0:47

POPULATION: Intent-to-Treat Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Concordance of Stratification Factors by eCRF and IxRS
MODEL: Descriptive
STUDIES: GO29365, YO41543
Stratification Factor: Duration of Response to prior therapy

	Pola+BR (N=19)		BR (N=9)	
	eCRF		eCRF	
	<=12 Months	Total	<=12 Months	Total
IxRS				
<=12 Months	19 (100%)	19 (100%)	9 (100%)	9 (100%)
Total	19	19	9	9

Percentages are based on N in the column headings.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_strat.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_strat_L3PLUS_Polarose_IT_29365_41543.xls
08DEC2022 13:22

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: POLATUZUMAB VEDOTIN

	Pola+BR (N=19)
Treatment Duration (Months)	
n	19
Mean (SD)	2.66 (1.47)
Median	3.42
Interquartile Range	1.31 - 3.58
Min - Max	0.0 - 4.8
Number of Cycles	
n	19
Mean (SD)	4.6 (1.9)
Median	6
Interquartile Range	3.0 - 6.0
Min - Max	1 - 6
Total Cumulative Dose (mg)	
n	19
Mean (SD)	552.8 (261.7)
Median	594.9
Interquartile Range	358.2 - 764.1
Min - Max	99 - 898
Dose intensity (%) adjusted for dose reduction and delay	
n	19
Mean (SD)	95.4 (9.0)
Median	98.4
Interquartile Range	91.6 - 100.0
Min - Max	66 - 106

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_ex_L3PLUS_Polarose_SE_29365_41543.xls
20APR2023 11:32

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: BENDAMUSTINE

	Pola+BR (N=19)	BR (N=9)
Treatment Duration (Months)		
n	19	9
Mean (SD)	2.69 (1.47)	2.22 (1.40)
Median	3.45	2.04
Interquartile Range	1.35 - 3.61	1.41 - 3.52
Min - Max	0.1 - 4.8	0.1 - 3.7
Number of Cycles		
n	19	9
Mean (SD)	4.6 (1.9)	4.1 (2.0)
Median	6	4
Interquartile Range	3.0 - 6.0	3.0 - 6.0
Min - Max	1 - 6	1 - 6
Total Cumulative Dose (mg)		
n	19	9
Mean (SD)	1464.0 (635.2)	1316.0 (679.4)
Median	1684.8	1202.4
Interquartile Range	961.2 - 2019.6	793.8 - 1900.4
Min - Max	284 - 2146	328 - 2095
Dose intensity (%) adjusted for dose reduction and delay		
n	19	9
Mean (SD)	94.9 (7.8)	98.4 (2.7)
Median	95.5	99.2
Interquartile Range	93.3 - 99.2	96.2 - 100.0
Min - Max	67 - 103	95 - 102

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_ex_L3PLUS_Polarose_SE_29365_41543.xls
20APR2023 11:32

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Summary of Extent of Exposure

Treatment: RITUXIMAB

	Pola+BR (N=19)	BR (N=9)
Treatment Duration (Months)		
n	19	9
Mean (SD)	2.68 (1.48)	2.22 (1.40)
Median	3.45	2.04
Interquartile Range	1.35 - 3.61	1.41 - 3.52
Min - Max	0.0 - 4.8	0.0 - 3.7
Number of Cycles		
n	19	9
Mean (SD)	4.6 (1.9)	4.1 (2.0)
Median	6	4
Interquartile Range	3.0 - 6.0	3.0 - 6.0
Min - Max	1 - 6	1 - 6
Total Cumulative Dose (mg)		
n	19	9
Mean (SD)	3067.5 (1341.5)	2741.7 (1415.5)
Median	3510	2505
Interquartile Range	2002.5 - 4207.5	1653.8 - 3960.0
Min - Max	593 - 4545	683 - 4365
Dose intensity (%) adjusted for dose reduction and delay		
n	19	9
Mean (SD)	95.9 (7.1)	98.9 (2.5)
Median	98.4	100
Interquartile Range	93.3 - 100.0	96.5 - 100.0
Min - Max	73 - 103	95 - 102

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_ex.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_ex_L3PLUS_Polarose_SE_29365_41543.xls
20APR2023 11:32

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=19)	BR (N=9)	All (N=28)
n	19	9	28
Median	135	92	133.5

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 30 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_fu_D30_L3PLUS_Polarose_SE_29365_41543.xls
08DEC2022 17:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median Follow-up time [Days] per Arm

	Pola+BR (N=19)	BR (N=9)	All (N=28)
n	19	9	28
Median	195	134	191.5

Median follow-up time is calculated as:
median(min(datacut date, death date, lost to follow up date, withdrawal of consent date, date of last dose of study treatment + 90 days) - treatment start date)
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_fu.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_fu_D90_L3PLUS_Polarose_SE_29365_41543.xls
08DEC2022 17:33

POPULATION: Intent-to-Treat Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Summary of New Anti-Lymphoma Therapy

	Pola+BR (N=19)	BR (N=9)
Total number of patients with at least one NALT treatment	11 (57.9%)	7 (77.8%)
Total number of NALT treatments	15	8
Total number of patients with at least one NALT treatment before PFS event	2 (10.5%)	2 (22.2%)
Total number of patients with at least one NALT treatment at or after PFS event	9 (47.4%)	2 (22.2%)
Total number of patients with at least one NALT treatment and without PFS event	0	3 (33.3%)
Radiotherapy		
Total number of patients with at least one treatment	0	1 (11.1%)
Total number of treatments	0	1
Systemic therapy		
Total number of patients with at least one treatment	11 (57.9%)	4 (44.4%)
Total number of treatments	15	5
Total number of patients received stem cell transplants	0	0
Autologous transplant	0	0
Allogeneic transplant	0	0
Unknown	0	0
Total number of patients received CAR-T	3 (15.8%)	0
Total number of patients received unknown treatment	0	2 (22.2%)

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_nalt.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_nalt_L3PLUS_Polarose_IT_29365_41543.xls
01FEB2023 19:21

POPULATION: Intent-to-Treat Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Median observation time(of follow up)

Overall Survival

	Pola+BR (N=19)	BR (N=9)	All (N=28)
Patients with event (%)	6 (31.6%)	3 (33.3%)	9 (32.1%)
Latest contributing event			
Alive	6	3	9
Patients without event (%)	13 (68.4%)	6 (66.7%)	19 (67.9%)
Time to event (months)			
Median	17.1	13.5	17.1
95% CI	(13.3, NE)	(12.4, NE)	(13.5, 17.4)
25% and 75%-ile	16.0 - 17.2	12.4 - 17.4	13.5 - 17.4
Range	2 - 19	2* - 17	2 - 19

Summaries of Duration of Follow-up (median, percentiles) are based on reverse Kaplan-Meier estimates.
* Censored observation.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_obs_time.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_obs_time_OSDFU_L3PLUS_Polarose_IT_29365_41543.xls
08DEC2022 3:16

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: --
MODEL: Descriptive
STUDIES: GO29365, YO41543
Deaths and Primary Reason for Death

	Pola+BR (N=19)		BR (N=9)		All (N=28)	
	n	%	n	%	n	%
All Deaths	13	68.4	6	66.7	19	67.9
Adverse Event	0	-	1	11.1	1	3.6
Progressive Disease	12	63.2	5	55.6	17	60.7
Other	1	5.3	0	-	1	3.6

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_death.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_death_L3PLUS_Polarose_SE_29365_41543.xls
08DEC2022 18:29

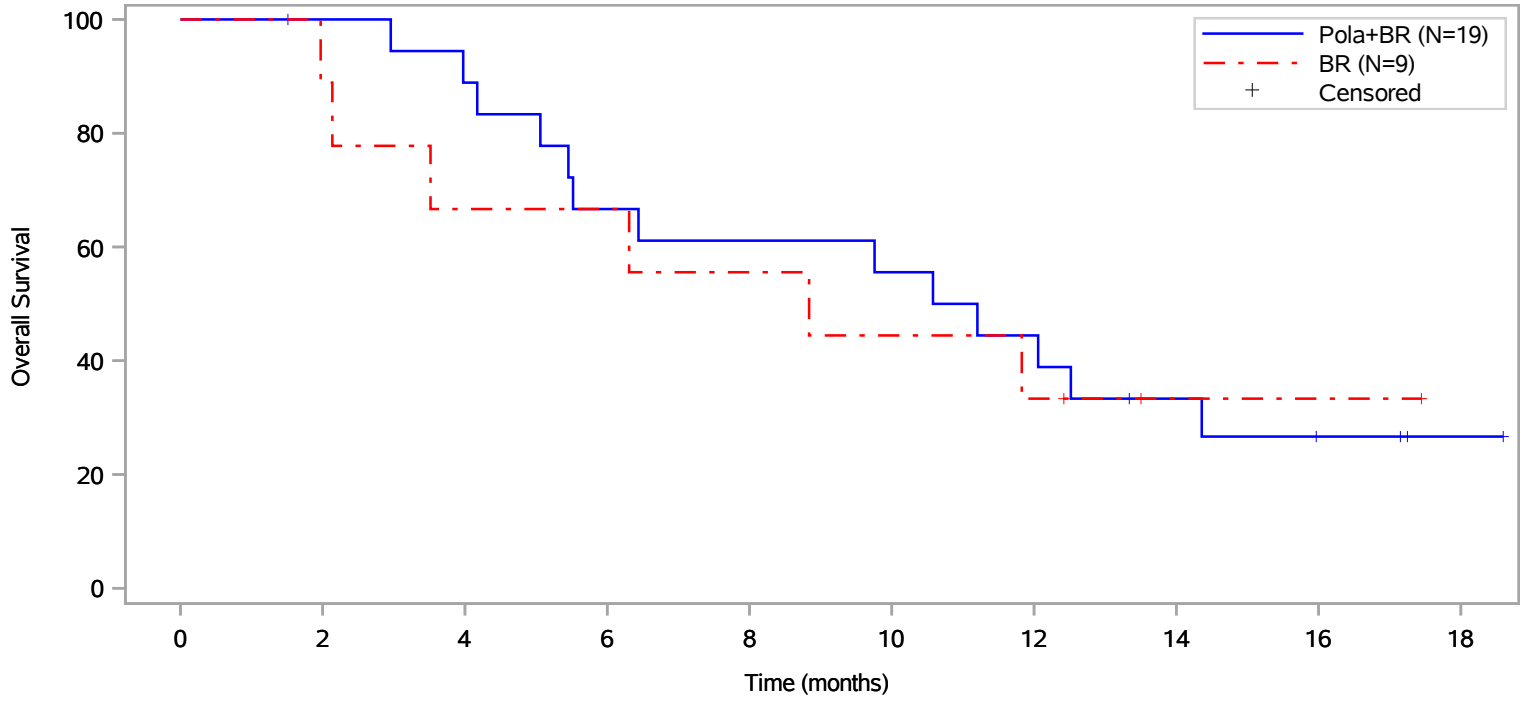
POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Study YO41543
ENDPOINT: Overall Survival
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=19)												BR (N=9)												Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		19	100.0	13	68.4	6	31.6	5.5	4.0	10.6	10.9	5.5	14.4	9	100.0	6	66.7	3	33.3	3.5	2.0	11.8	8.8	3.5	NE	0.7765	0.87	0.33	2.30		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_eff_tte_gh_str_OS_Polarose_L3PLUS_IT_29365_41543.xls
20JAN2023 17:51

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Study YO41543
ENDPOINT: Overall Survival
STUDIES: GO29365, YO41543



Patients at risk										
Pola+BR (N=19)	19	18	16	12	11	10	8	5	3	1
BR (N=9)	9	8	6	6	5	4	3	1	1	NE
Patients censored										
Pola+BR (N=19)	0	1	1	1	1	1	1	2	3	5
BR (N=9)	0	0	0	0	0	0	0	2	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..CE_FINAL_CSR_Pooled/prod/output_Polarose/g_km_OS_Polarose_L3PLUS_IT_29365_41543.pdf
28NOV2022 14:50

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Study YO41543
ENDPOINT: Overall Survival
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=19)												BR (N=9)										Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All		19	100.0	13	68.4	6	31.6	5.5	4.0	10.6	10.9	5.5	14.4	9	100.0	6	66.7	3	33.3	3.5	2.0	11.8	8.8	3.5	NE	0.7765	0.87	0.33	2.30	Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	9	64.3	5	35.7	5.5	4.2	10.6	10.6	5.5	NE	6	66.7	4	66.7	2	33.3	2.1	2.0	6.3	4.9	2.1	NE	0.5659	0.71	0.22	2.31	Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	4	80.0	1	20.0	9.8	4.0	12.5	11.2	4.0	NE	3	33.3	2	66.7	1	33.3	8.8	8.8	NE	11.8	8.8	NE	0.7555	1.31	0.24	7.24	Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	12	75.0	4	25.0	5.3	4.0	10.6	10.9	5.5	14.4	7	77.8	5	71.4	2	28.6	2.1	2.0	8.8	6.3	2.1	NE	0.4031	0.64	0.22	1.85	Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	5.5	5.5	NE	NE	5.5	NE	2	22.2	1	50.0	1	50.0	11.8	11.8	NE	NE	11.8	NE	0.8084	1.41	0.08	23.57	Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	10	71.4	4	28.6	5.1	4.0	6.4	6.4	5.1	12.1	6	66.7	5	83.3	1	16.7	2.1	2.0	8.8	6.2	2.1	11.8	0.5359	0.71	0.24	2.10	Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	3	60.0	2	40.0	12.5	11.2	NE	14.4	11.2	NE	3	33.3	1	33.3	2	66.7	6.3	6.3	NE	NE	6.3	NE	0.8304	1.28	0.13	12.58	Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	13	68.4	6	31.6	5.5	4.0	10.6	10.9	5.5	14.4	9	100.0	6	66.7	3	33.3	3.5	2.0	11.8	8.8	3.5	NE	0.7765	0.87	0.33	2.30	Convergence criterion (GCONV=1E-8) satisfied.	NE
Duration of response to prior therapy	<=12 Months	19	100.0	13	68.4	6	31.6	5.5	4.0	10.6	10.9	5.5	14.4	9	100.0	6	66.7	3	33.3	3.5	2.0	11.8	8.8	3.5	NE	0.7765	0.87	0.33	2.30	Convergence criterion (GCONV=1E-8) satisfied.	NE
Refractory to last prior anti-lymphoma therapy**	Yes	19	100.0	13	68.4	6	31.6	5.5	4.0	10.6	10.9	5.5	14.4	9	100.0	6	66.7	3	33.3	3.5	2.0	11.8	8.8	3.5	NE	0.7765	0.87	0.33	2.30	Convergence criterion (GCONV=1E-8) satisfied.	NE
Prior Bone Marrow Transplant	Yes	0	0.0	0	-	0	-	NE	NE	NE	NE	NE	NE	1	11.1	0	-	1	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
	No	19	100.0	13	68.4	6	31.6	5.5	4.0	10.6	10.9	5.5	14.4	8	88.9	6	75.0	2	25.0	2.8	2.0	8.8	7.6	2.1	NE	0.3979	0.66	0.24	1.76	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_eff_tte_gh_sg_OS_Polarose_L3PLUS_IT_29365_41543.xls
20JAN2023 17:59

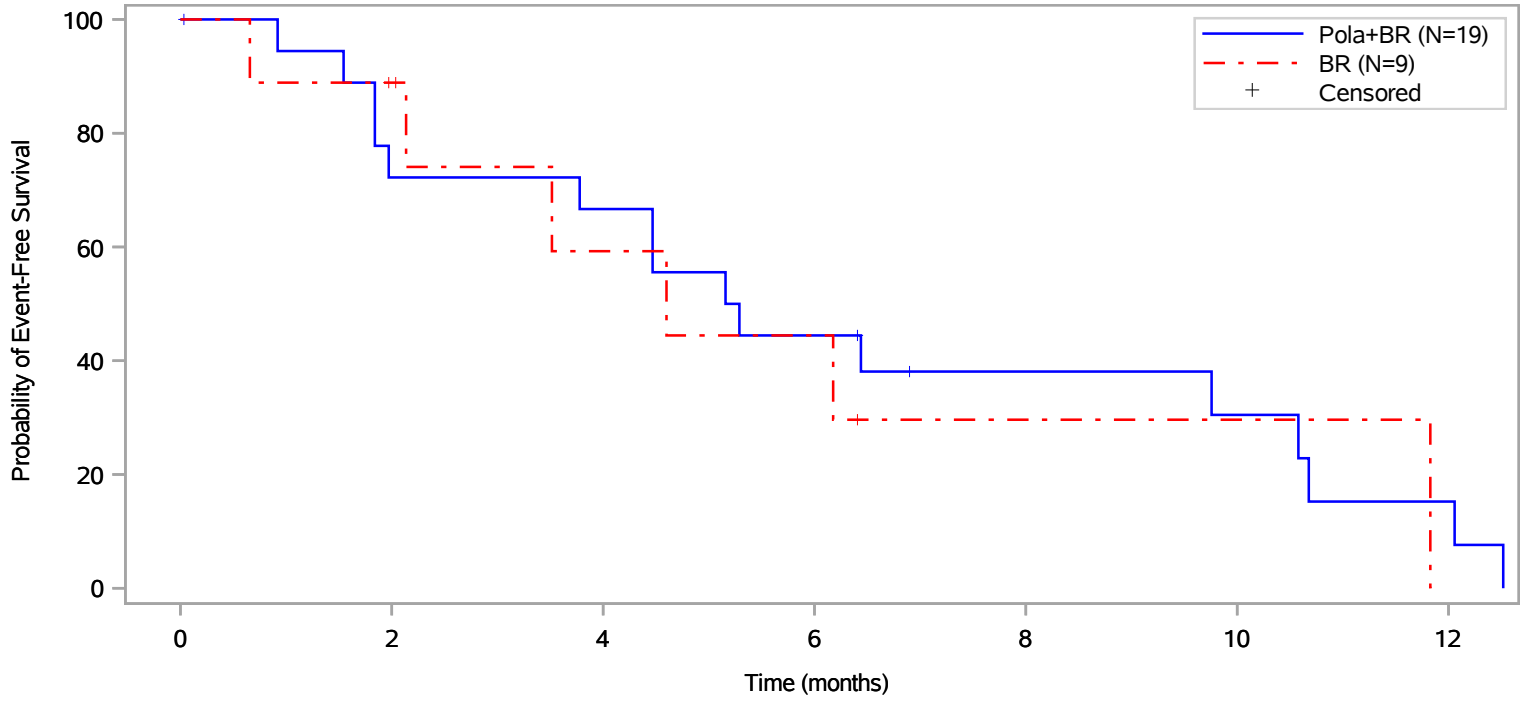
POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Study YO41543
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Stratified Analysis by DOR to prior therapy from IxRS (<=12/>12 months)
STUDIES: GO29365, YO41543
Time to Event Analysis (Efficacy)

		Pola+BR (N=19)												BR (N=9)												Pola + BR vs. BR					
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All		19	100.0	16	84.2	3	15.8	2.0	1.5	5.2	5.2	3.8	10.6	9	100.0	6	66.7	3	33.3	2.1	0.7	6.2	4.6	2.1	NE	0.7729	0.87	0.33	2.29		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_eff_tte_gh_str_PFSIRC_Polarose_L3PLUS_IT_29365_41543.xls
20JAN2023 17:35

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Study YO41543
ENDPOINT: Progression-Free Survival (PFS) - IRC
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	13	12	8	5	4	2
BR (N=9)	9	7	4	3	1	1	NE
Patients censored							
Pola+BR (N=19)	0	1	1	1	3	3	3
BR (N=9)	0	1	2	2	3	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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28NOV2022 17:43

POPULATION: Intent-to-Treat Patients, Third-line or beyond (3L+) Patients, Study YO41543
ENDPOINT: Progression-Free Survival (PFS) - IRC
MODEL: Unstratified Analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Efficacy)

		Pola+BR (N=19)												BR (N=9)										Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Time to event						Patients		Patients with Event		Censored		Time to event						log-rank	Hazard Ratio				Interaction Test
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	16	84.2	3	15.8	2.0	1.5	5.2	5.2	3.8	10.6	9	100.0	6	66.7	3	33.3	2.1	0.7	6.2	4.6	2.1	NE	0.7729	0.87	0.33	2.29		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	11	78.6	3	21.4	2.0	1.8	5.2	5.2	2.0	10.6	6	66.7	4	66.7	2	33.3	2.1	0.7	4.6	3.5	2.1	NE	0.4703	0.64	0.19	2.18		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	5	100.0	0	-	4.5	1.5	10.7	9.8	1.5	NE	3	33.3	2	66.7	1	33.3	6.2	6.2	NE	9.0	6.2	NE	0.8693	1.16	0.21	6.44		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	14	87.5	2	12.5	1.9	1.3	5.3	5.9	2.0	10.6	7	77.8	5	71.4	2	28.6	2.1	0.7	4.6	3.5	2.1	NE	0.1509	0.44	0.14	1.39		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	2	66.7	1	33.3	3.8	3.8	NE	4.1	3.8	NE	2	22.2	1	50.0	1	50.0	11.8	NE	NE	11.8	NE	NE	0.0896	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	12	85.7	2	14.3	1.8	1.5	4.5	4.5	1.8	9.8	6	66.7	5	83.3	1	16.7	2.1	0.7	6.2	3.5	2.1	NE	0.8461	0.90	0.30	2.66		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	4	80.0	1	20.0	5.3	5.2	NE	10.7	5.2	NE	3	33.3	1	33.3	2	66.7	4.6	4.6	NE	NE	4.8	NE	0.6240	0.55	0.05	6.21		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	16	84.2	3	15.8	2.0	1.5	5.2	5.2	3.8	10.6	9	100.0	6	66.7	3	33.3	2.1	0.7	6.2	4.6	2.1	NE	0.7729	0.87	0.33	2.29		Convergence criterion (GCONV=1E-8) satisfied.	NE
Duration of response to prior therapy	<=12 Months	19	100.0	16	84.2	3	15.8	2.0	1.3	5.2	5.2	3.8	10.6	9	100.0	6	66.7	3	33.3	2.1	0.7	6.2	4.6	2.1	NE	0.7729	0.87	0.33	2.29		Convergence criterion (GCONV=1E-8) satisfied.	NE
Refractory to last prior anti-lymphoma therapy**	Yes	19	100.0	16	84.2	3	15.8	2.0	1.5	5.2	5.2	3.8	10.6	9	100.0	6	66.7	3	33.3	2.1	0.7	6.2	4.6	2.1	NE	0.7729	0.87	0.33	2.29		Convergence criterion (GCONV=1E-8) satisfied.	NE
Prior Bone Marrow Transplant	Yes	0	0.0	0	-	0	-	NE	NE	NE	NE	NE	NE	1	11.1	0	-	1	100.0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	No	19	100.0	16	84.2	3	15.8	2.0	1.5	5.2	5.2	3.8	10.6	8	88.9	6	75.0	2	25.0	2.1	0.7	4.6	4.6	2.1	6.2	0.5143	0.72	0.27	1.92		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
** Defined as no response or progression or relapse within 6 months of last anti-lymphoma therapy end date.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_eff_tte_gh.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_eff_tte_gh_sg_PFSIRC_Polarose_L3PLUS_IT_29365_41543.xls
20JAN2023 17:43

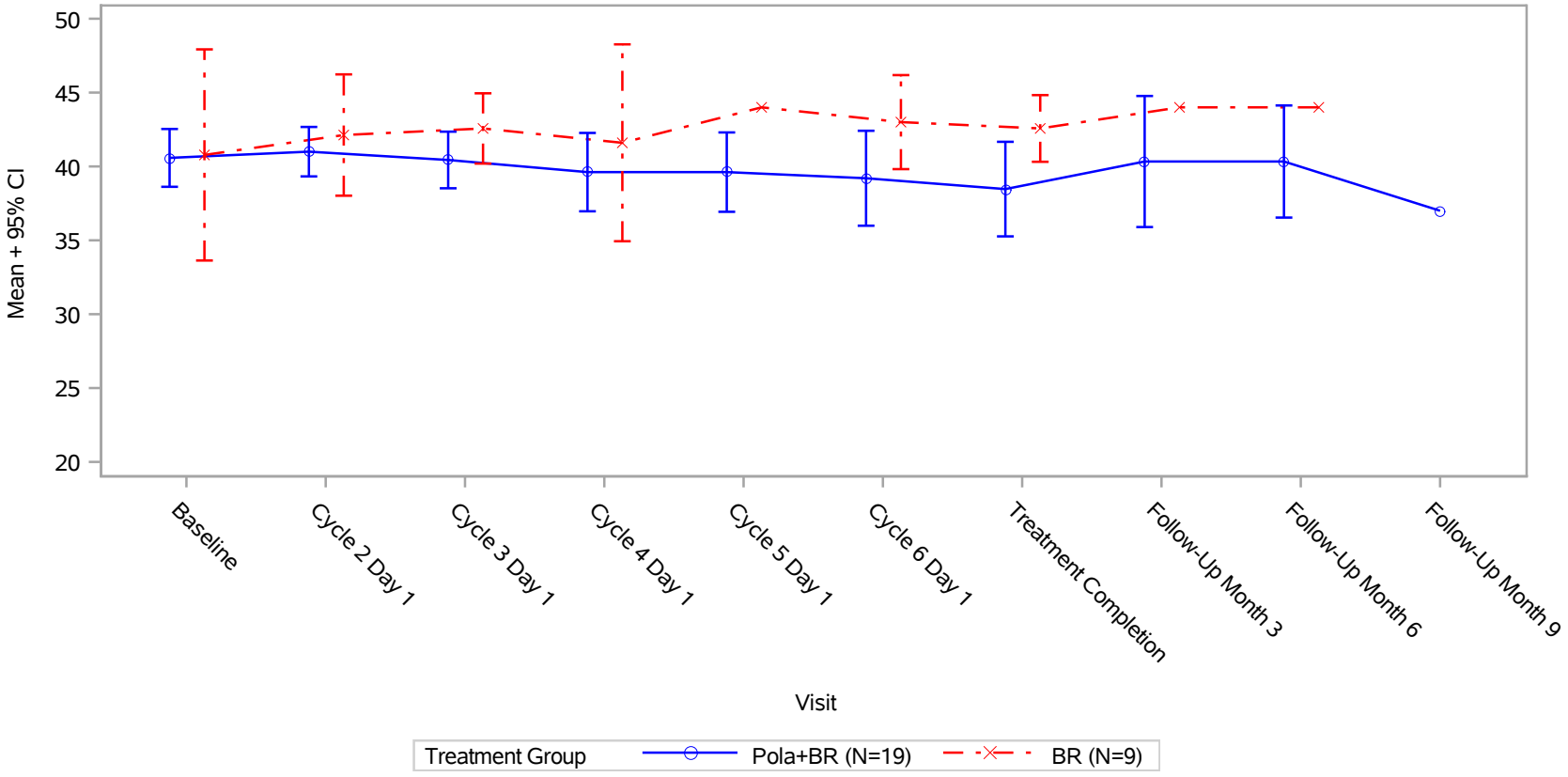
POPULATION: Intent-to-Treat Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: FACT-G NTX
MODEL: --
STUDIES: GO29365, YO41543
Compliance and Mean

		Pola+BR (N=19)						BR (N=9)					
		Patients				Statistics		Patients				Statistics	
Name Visit	Level	in study[1]	%	with value[1]	%	Mean[2]	SD(Mean)	in study[1]	%	with value[1]	%	Mean[2]	SD(Mean)
All													
BASELINE		19	100.0	19	100.0	40.58	4.06	9	100.0	9	100.0	40.78	9.30
CYCLE 2 DAY 1		16	84.2	16	100.0	41.00	3.14	8	88.9	8	100.0	42.13	4.91
CYCLE 3 DAY 1		16	84.2	16	100.0	40.44	3.60	8	88.9	7	87.5	42.57	2.57
CYCLE 4 DAY 1		14	73.7	13	92.9	39.62	4.39	5	55.6	5	100.0	41.60	5.37
CYCLE 5 DAY 1		13	68.4	13	100.0	39.62	4.44	4	44.4	4	100.0	44.00	0.00
CYCLE 6 DAY 1		10	52.6	10	100.0	39.20	4.49	4	44.4	4	100.0	43.00	2.00
TREATMENT COMPLETION		15	78.9	15	100.0	38.47	5.78	7	77.8	7	100.0	42.57	2.44
FOLLOW-UP MONTH 3		8	42.1	6	75.0	40.33	4.23	1	11.1	1	100.0	44.00	NE
FOLLOW-UP MONTH 6		5	26.3	3	60.0	40.33	1.53	1	11.1	1	100.0	44.00	NE
FOLLOW-UP MONTH 9		2	10.5	1	50.0	37.00	NE	0	-	0	-	NE	NE
FOLLOW-UP MONTH 12		1	5.3	0	-	NE	NE	0	-	0	-	NE	NE

[1] in study: number of subjects in study at respective visit; % based on baseline
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD
[2] mean: descriptive statistics - absolute values
Early Discontinuation Visit is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_pro_mean.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_pro_mean_PFGNTX_L3PLUS_Polarose_IT_29365_41543.xls
24FEB2023 17:30

POPULATION: Intent-to-Treat Patients, Study YO41543, Third-line or beyond (3L+) Patients
STUDIES: GO29365, YO41543
Line Plot of Mean by Visit
FACT-GOG-NTX: Neurotoxicity subscale (NtxS)



Early Discontinuation Visit is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..7/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_mean_plot.sas
Output: ..R_Pooled/prod/output_Polarose/g_mean_plot_PFGNTX_L3PLUS_Polarose_IT_29365_41543.pdf
24FEB2023 17:35

POPULATION: Intent-to-Treat Patients, Study YO41543, PRO-Evaluable for FACT-GOG-NTX, Third-line or beyond (3L+) Patients
ENDPOINT: FACT-G NTX
MODEL: Unadjusted Analysis
STUDIES: GO29365, YO41543
Change from Baseline in FACT-G NTX (Analysis of MMRM)

FACT-GOG-NTX: Neurotoxicity subscale (NtxS)

			Pola+BR (N=16)					BR (N=9)					Difference between Treatments (Polatuzumab Vedotin + R-CHP - R-CHOP)					
			N			Statistics		N			Statistics		Statistics					
Visit	Name	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% CI (LL)	95% CI (UL)	Population	Method
Baseline	All		16	16	0	NE	NE	9	9	0	NE	NE	NE	NE	NE	NE	Intent-to-Treat Patients, Study YO41543, PRO-Evaluable for FACT-GOG-NTX, Third-line or beyond (3L+) Patients	unadjusted
Cycle 2 Day 1	All		16	16	16	0.33	0.40	8	8	8	1.39	0.56	-1.06	0.68	-2.48	0.37		
Cycle 3 Day 1	All		16	16	16	-0.23	0.54	8	8	7	0.03	0.81	-0.26	0.98	-2.29	1.77		
Cycle 4 Day 1	All		14	14	13	-0.74	0.97	5	5	5	-0.70	1.47	-0.04	1.76	-3.71	3.62		
Cycle 5 Day 1	All		13	13	13	-0.69	0.86	4	4	4	-0.19	1.40	-0.50	1.64	-4.22	3.22		
Cycle 6 Day 1	All		10	10	10	-2.86	1.20	4	4	4	-2.14	1.80	-0.72	2.16	-5.41	3.97		
Treatment Completion	All		15	15	15	-2.44	1.07	7	7	7	-0.43	1.59	-2.01	1.92	-6.02	1.99		

[1] Patients with a value at baseline and at least one post-baseline value
[2] LSMeans of change from baseline from MMRM (including all available records from all visits)
[3] Contrasts from MMRM
Early Discontinuation Visit is mapped to the scheduled assessment that fits best after the last dose assessment (but will not be mapped to Follow-up assessments).
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_pro_mmrm.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_pro_mmrm_PFGNTX_L3PLUS_FACTGpop_Polarose_IT_29365_41543.xls
24FEB2023 17:40

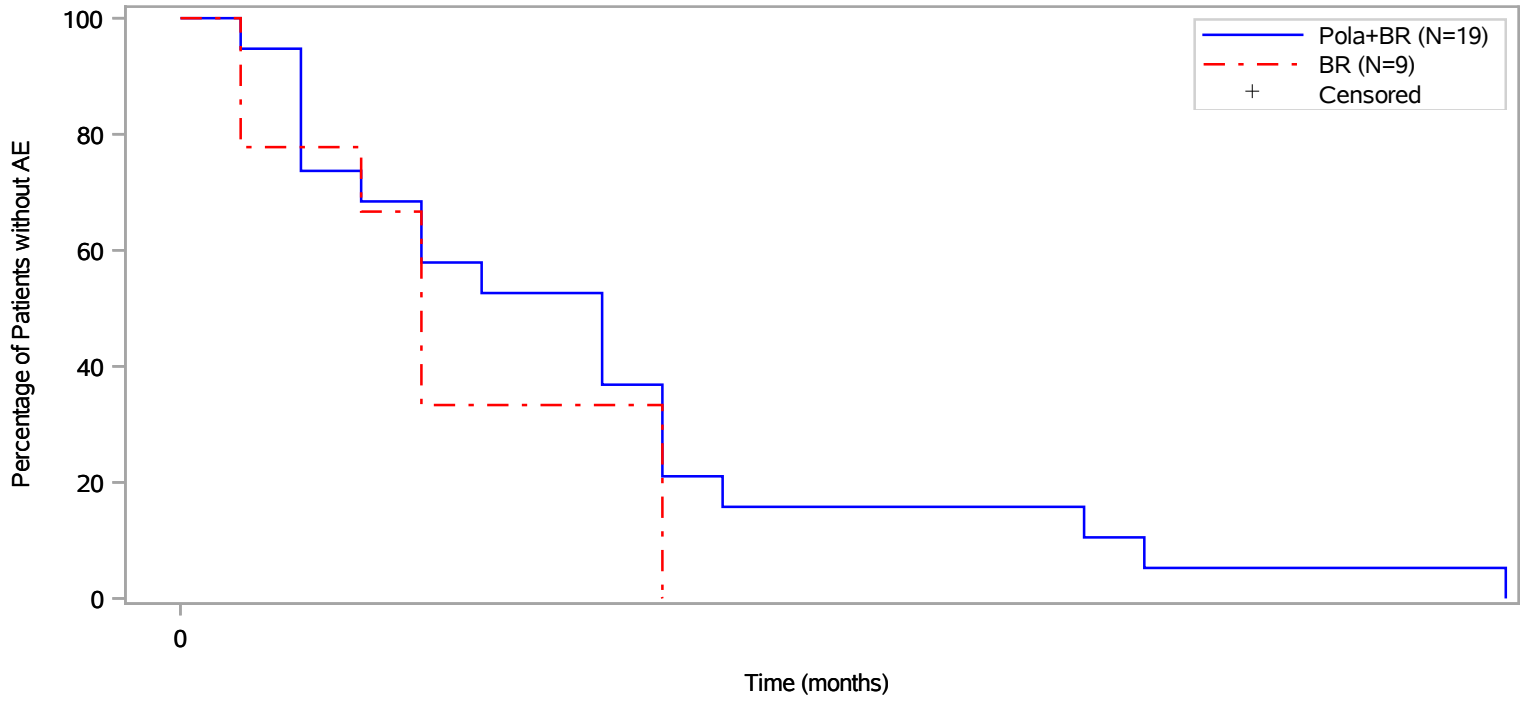
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	19	100.0	0	-	9	100.0	9	100.0	0	-	0.3104	0.61	0.23	1.60		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	14	100.0	0	-	6	66.7	6	100.0	0	-	0.7362	1.24	0.36	4.31		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	5	100.0	0	-	3	33.3	3	100.0	0	-	0.1609	0.27	0.04	1.84		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	16	100.0	0	-	7	77.8	7	100.0	0	-	0.3183	0.58	0.20	1.70		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	3	100.0	0	-	2	22.2	2	100.0	0	-	0.7389	0.58	0.02	14.74		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	14	100.0	0	-	6	66.7	6	100.0	0	-	0.1165	0.38	0.11	1.31		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	5	100.0	0	-	3	33.3	3	100.0	0	-	0.8537	1.18	0.20	7.15		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	19	100.0	0	-	9	100.0	9	100.0	0	-	0.3104	0.61	0.23	1.60		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTAE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 18:45

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543



Patients at risk	
Pola+BR (N=19)	19
BR (N=9)	9
Patients censored	
Pola+BR (N=19)	0
BR (N=9)	0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 19:55

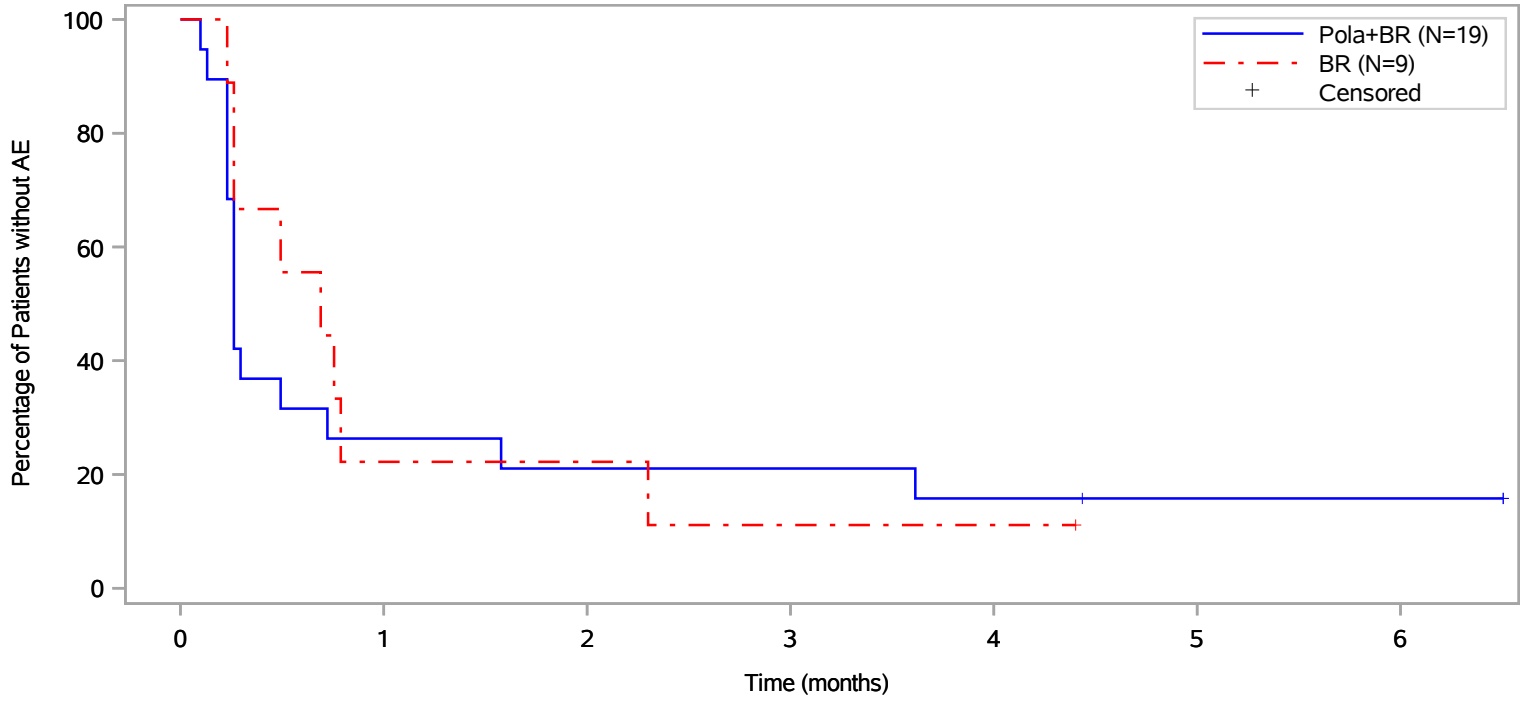
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	16	84.2	3	15.8	9	100.0	8	88.9	1	11.1	0.6823	1.21	0.49	3.02		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	13	92.9	1	7.1	6	66.7	5	83.3	1	16.7	0.2604	1.86	0.62	5.52		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	3	60.0	2	40.0	3	33.3	3	100.0	0	-	0.4778	0.53	0.09	3.12		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	13	81.3	3	18.8	7	77.8	6	85.7	1	14.3	0.9261	1.05	0.38	2.93		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	3	100.0	0	-	2	22.2	2	100.0	0	-	0.0645	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	12	85.7	2	14.3	6	66.7	6	100.0	0	-	0.9120	0.94	0.32	2.78		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	4	80.0	1	20.0	3	33.3	2	66.7	1	33.3	0.5675	1.67	0.29	9.73		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	16	84.2	3	15.8	9	100.0	8	88.9	1	11.1	0.6823	1.21	0.49	3.02		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 19:28

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	5	4	4	3	2	2
BR (N=9)	9	2	2	1	1	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	0	0	0	1	1
BR (N=9)	0	0	0	0	0	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:00

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	16	84.2	3	15.8	9	100.0	7	77.8	2	22.2	0.4774	1.40	0.55	3.58		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	13	92.9	1	7.1	6	66.7	4	66.7	2	33.3	0.1874	2.16	0.67	6.96		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	3	60.0	2	40.0	3	33.3	3	100.0	0	-	0.6461	0.68	0.13	3.56		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	13	81.3	3	18.8	7	77.8	5	71.4	2	28.6	0.3809	1.61	0.55	4.67		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	3	100.0	0	-	2	22.2	2	100.0	0	-	0.9122	0.89	0.10	7.64		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	12	85.7	2	14.3	6	66.7	5	83.3	1	16.7	0.6520	1.29	0.43	3.87		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	4	80.0	1	20.0	3	33.3	2	66.7	1	33.3	0.5675	1.67	0.29	9.73		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	16	84.2	3	15.8	9	100.0	7	77.8	2	22.2	0.4774	1.40	0.55	3.58		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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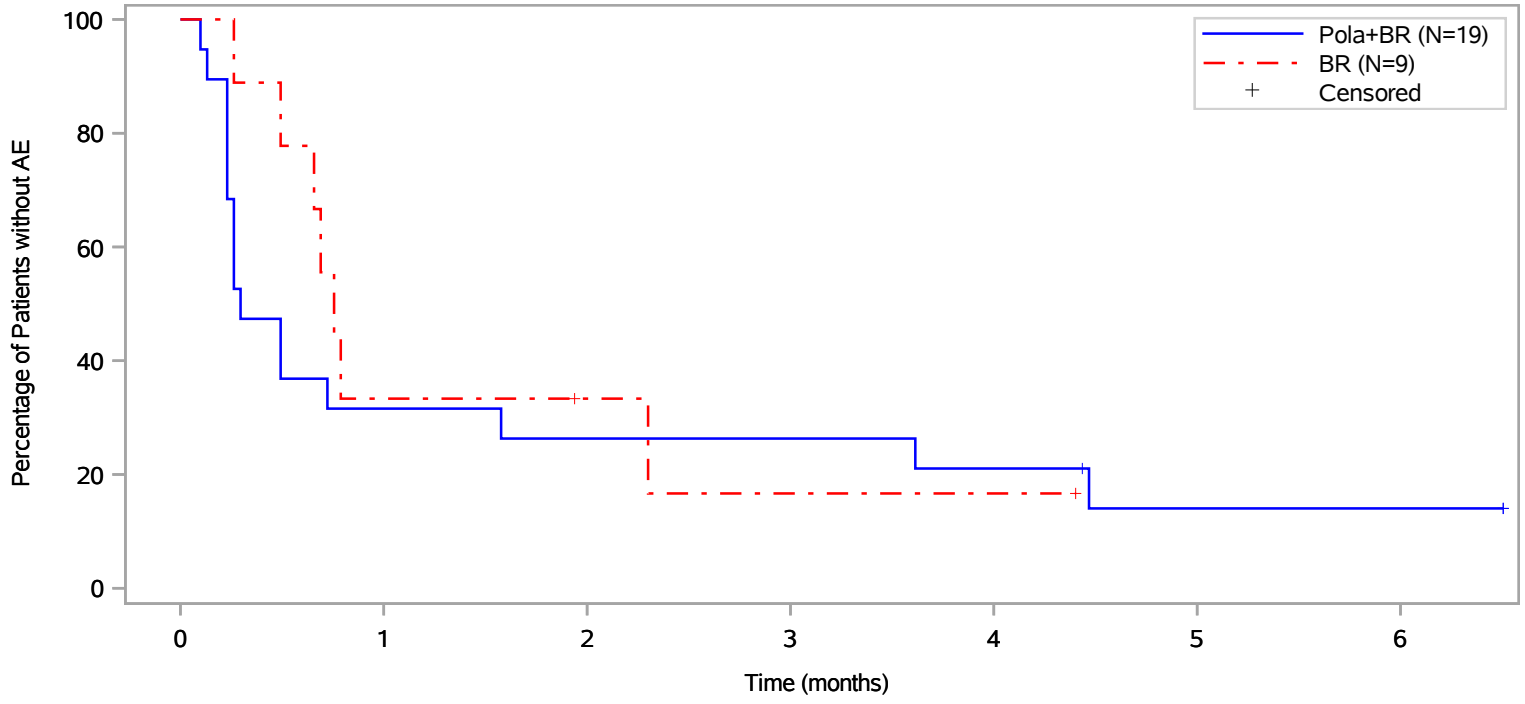
30NOV2022 20:09

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	6	5	5	4	2	2
BR (N=9)	9	3	2	1	1	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	0	0	0	1	1
BR (N=9)	0	0	1	1	1	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 20:07

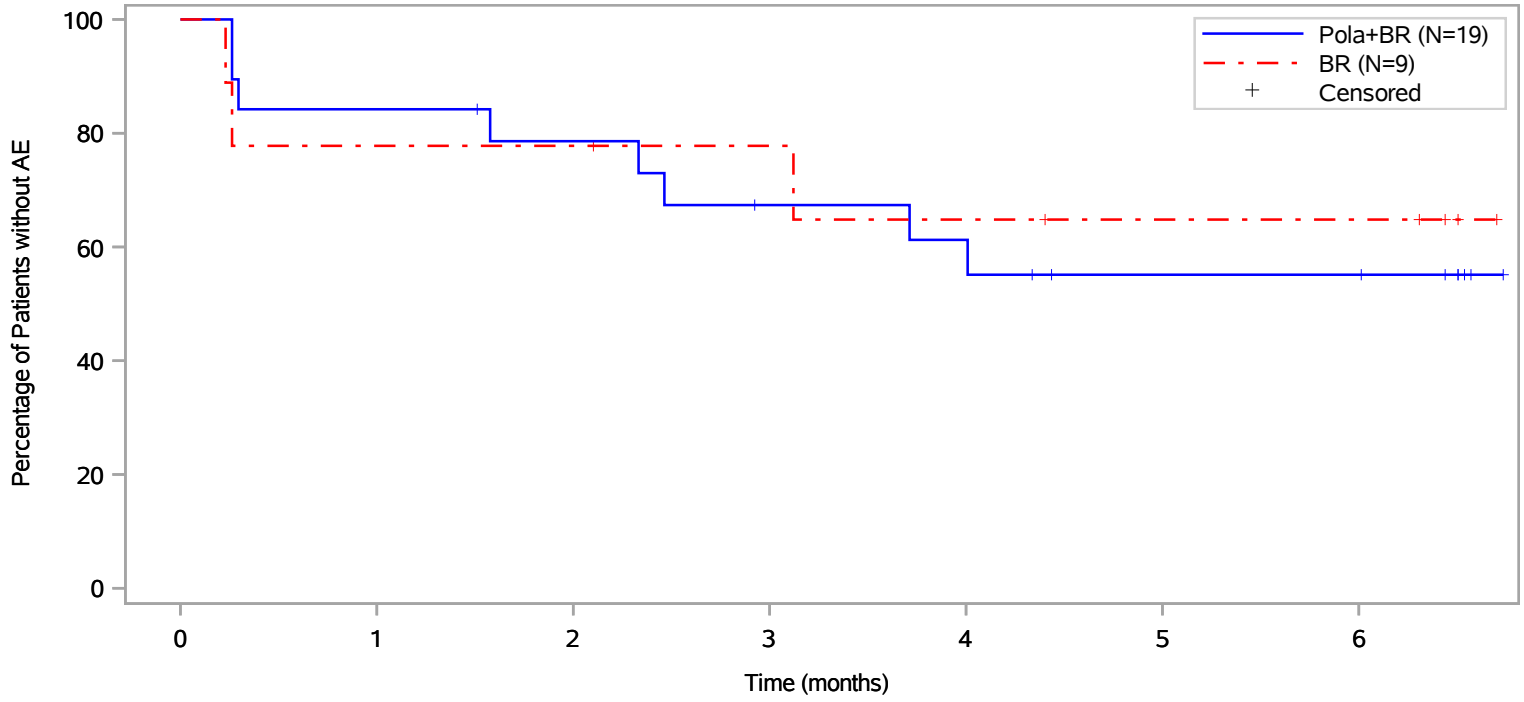
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	8	42.1	11	57.9	9	100.0	3	33.3	6	66.7	0.7749	1.22	0.32	4.64		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	7	50.0	7	50.0	6	66.7	2	33.3	4	66.7	0.5940	1.53	0.32	7.44		Convergence criterion (GCONV=1E-8) satisfied.	
	Female	5	26.3	1	20.0	4	80.0	3	33.3	1	33.3	2	66.7	0.6084	0.49	0.03	7.94		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	6	37.5	10	62.5	7	77.8	3	42.9	4	57.1	0.5539	0.66	0.16	2.64		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	0	-	2	100.0	0.1824	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	6	42.9	8	57.1	6	66.7	3	50.0	3	50.0	0.5966	0.68	0.16	2.83		Convergence criterion (GCONV=1E-8) satisfied.	
	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	8	42.1	11	57.9	9	100.0	3	33.3	6	66.7	0.7749	1.22	0.32	4.64		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGR4AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 20:52

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	16	14	11	10	7	7
BR (N=9)	9	7	7	6	5	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	2	4	4
BR (N=9)	0	0	0	1	1	2	2

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:13

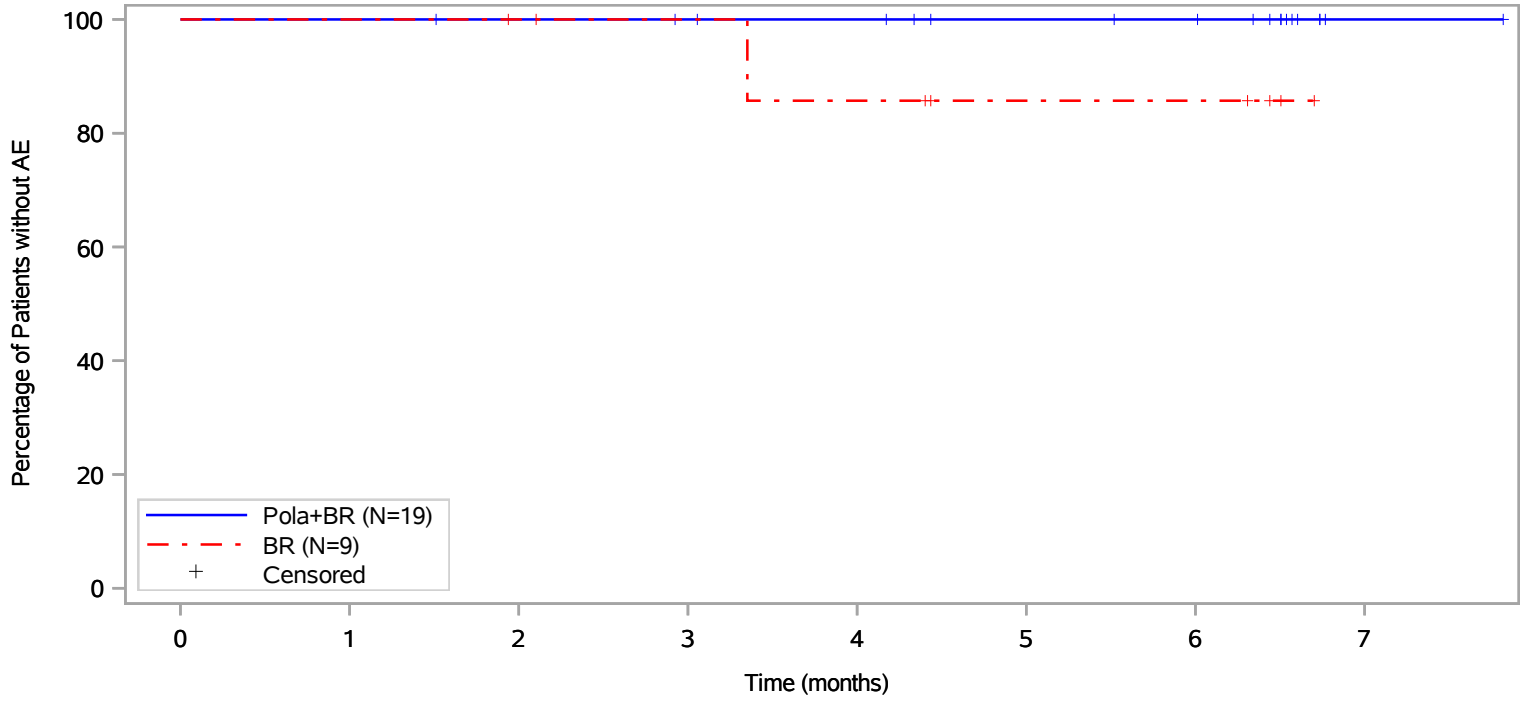
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)				BR (N=9)						Pola + BR vs. BR						
		Patients		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	14	100.0	6	66.7	1	16.7	5	83.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	16	100.0	7	77.8	1	14.3	6	85.7	0.0943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	14	100.0	6	66.7	1	16.7	5	83.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGR5AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 21:36

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:20

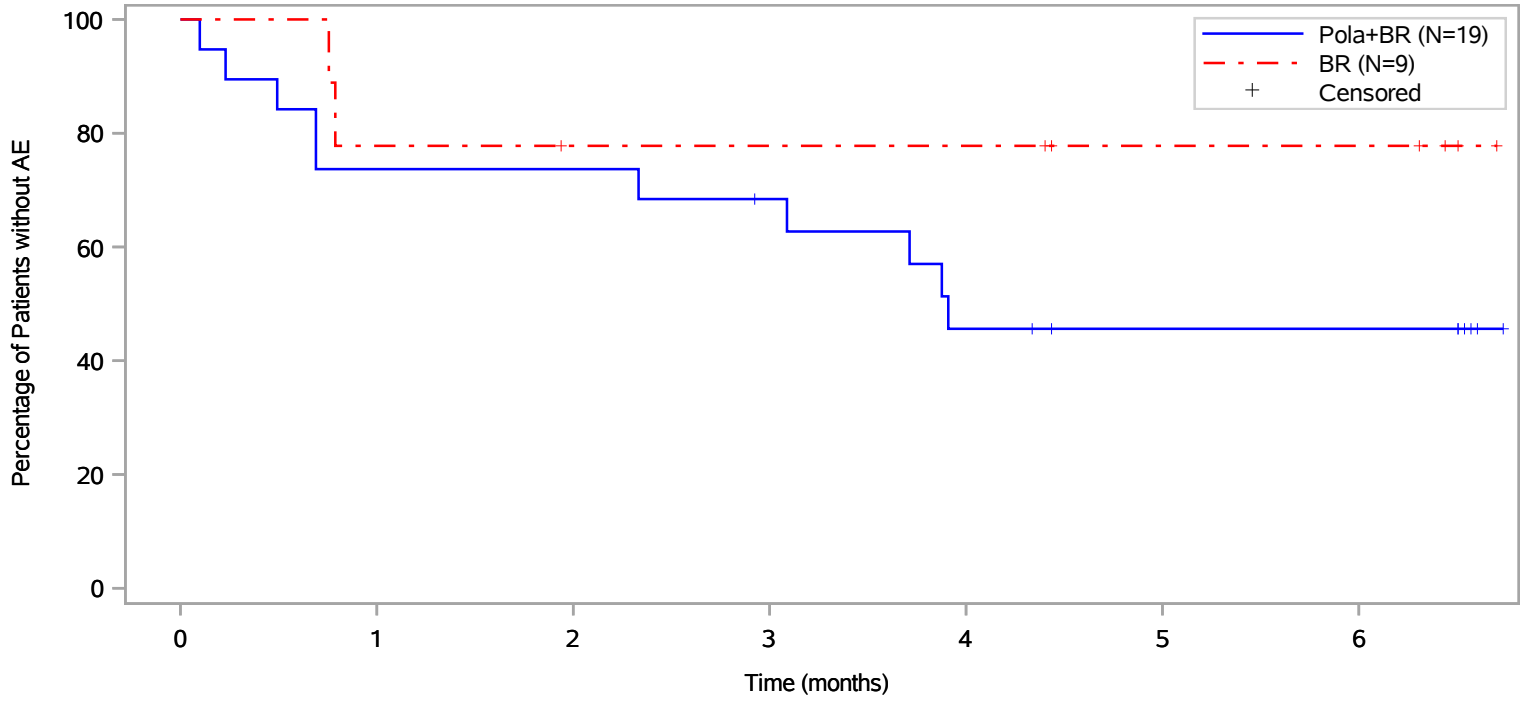
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	10	52.6	9	47.4	9	100.0	2	22.2	7	77.8	0.1744	2.75	0.60	12.62		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	8	57.1	6	42.9	6	66.7	2	33.3	4	66.7	0.4944	1.71	0.36	8.08		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	8	50.0	8	50.0	7	77.8	2	28.6	5	71.4	0.4732	1.76	0.37	8.34		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	0	-	2	100.0	0.1985	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	8	57.1	6	42.9	6	66.7	2	33.3	4	66.7	0.3716	2.01	0.42	9.56		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	10	52.6	9	47.4	9	100.0	2	22.2	7	77.8	0.1744	2.75	0.60	12.62		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTSAE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 22:26

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	14	14	12	8	6	6
BR (N=9)	9	7	6	6	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	0	1	1	3	3
BR (N=9)	0	0	1	1	1	3	3

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTSAE_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 20:25

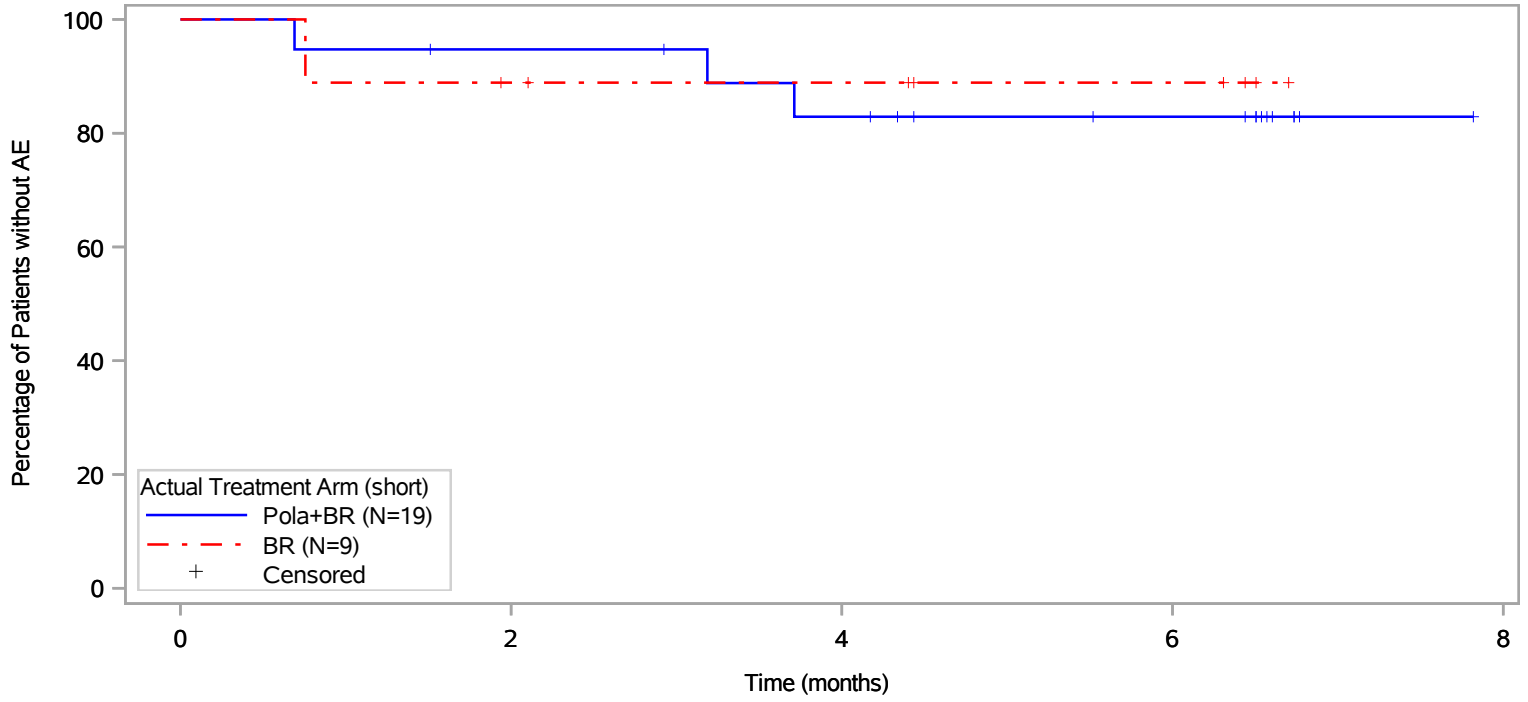
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	3	15.8	16	84.2	9	100.0	1	11.1	8	88.9	0.8163	1.31	0.14	12.60		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4111	0.33	0.02	5.37		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	3	18.8	13	81.3	7	77.8	1	14.3	6	85.7	0.9278	1.11	0.11	10.78		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.9448	1.08	0.11	10.53		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	1	11.1	8	88.9	0.8163	1.31	0.14	12.60		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTWDAE_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 17:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event leading to treatment discontinuation
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	18	17	16	14	11	10	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	15
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTWDAE_L3PLUS_Polarose_SE_29365_41543.pdf
24JAN2023 19:03

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	13	68.4	6	31.6	9	100.0	5	55.6	4	44.4	0.4936	1.44	0.51	4.10		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.3472	1.72	0.55	5.41		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5219	0.42	0.03	6.68		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		19	100.0	1	5.3	18	94.7	9	100.0	2	22.2	7	77.8	0.1791	0.22	0.02	2.46		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		19	100.0	2	10.5	17	89.5	9	100.0	2	22.2	7	77.8	0.3947	0.44	0.06	3.11		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			19	100.0	3	15.8	16	84.2	9	100.0	2	22.2	7	77.8	0.5976	0.62	0.10	3.74		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	PALPITATIONS		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5527	0.44	0.03	7.07		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	PNEUMOPERICARDIUM		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	SINUS TACHYCARDIA		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5384	0.43	0.03	6.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS			19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
EAR AND LABYRINTH DISORDERS	DEAFNESS		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.4838	1.50	0.48	4.75		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3468	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	CONSTIPATION		19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.9257	0.89	0.08	9.84		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	DIARRHOEA		19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0764	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	NAUSEA		19	100.0	8	42.1	11	57.9	9	100.0	2	22.2	7	77.8	0.3482	2.08	0.44	9.86		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	STOMATITIS		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	SUBILEUS		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5384	0.43	0.03	6.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	VOMITING		19	100.0	7	36.8	12	63.2	9	100.0	2	22.2	7	77.8	0.4439	1.83	0.38	8.88		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			19	100.0	13	68.4	6	31.6	9	100.0	5	55.6	4	44.4	0.5258	1.40	0.49	3.95		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE		19	100.0	7	36.8	12	63.2	9	100.0	4	44.4	5	55.6	0.6051	0.72	0.21	2.49		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		19	100.0	7	36.8	12	63.2	9	100.0	1	11.1	8	88.9	0.1753	3.85	0.47	31.50		Convergence criterion (GCONV=1E-8) satisfied.	NE
HEPATOBILIARY DISORDERS			19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	7	36.8	12	63.2	9	100.0	2	22.2	7	77.8	0.5803	1.55	0.32	7.49		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	HERPES ZOSTER		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1647	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			19	100.0	17	89.5	2	10.5	9	100.0	8	88.9	1	11.1	0.7713	1.16	0.42	3.19		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED		19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0783	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ANION GAP DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5211	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED		19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALBUMIN DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3696	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD CREATININE INCREASED		19	100.0	5	26.3	14	73.7	9	100.0	1	11.1	8	88.9	0.3637	2.62	0.30	22.69		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED		19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1617	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PRESSURE INCREASED		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD SODIUM DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD UREA INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD URIC ACID INCREASED		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED		19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2732	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	CYSTATIN C INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5384	0.43	0.03	6.89		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	FIBRIN D DIMER INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED		19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2202	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	HAEMOGLOBIN DECREASED		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3166	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	HEART RATE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LIPASE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		19	100.0	8	42.1	11	57.9	9	100.0	8	88.9	1	11.1	0.0347	0.29	0.09	0.95		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		19	100.0	13	68.4	6	31.6	9	100.0	5	55.6	4	44.4	0.4247	1.53	0.54	4.33		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NITRITE URINE PRESENT		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		19	100.0	13	68.4	6	31.6	9	100.0	4	44.4	5	55.6	0.2845	1.84	0.59	5.74		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PROCALCITONIN INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PROTEIN TOTAL DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5211	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PROTEIN URINE PRESENT		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	URINE OUTPUT DECREASED		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WEIGHT DECREASED		19	100.0	4	21.1	15	78.9	9	100.0	1	11.1	8	88.9	0.6082	1.76	0.20	15.77		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		19	100.0	14	73.7	5	26.3	9	100.0	5	55.6	4	44.4	0.5537	1.37	0.48	3.87		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.5562	1.41	0.44	4.51		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE		19	100.0	5	26.3	14	73.7	9	100.0	2	22.2	7	77.8	0.9298	1.08	0.21	5.61		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA		19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1536	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA		19	100.0	3	15.8	16	84.2	9	100.0	1	11.1	8	88.9	0.7541	1.45	0.14	14.70		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA		19	100.0	3	15.8	16	84.2	9	100.0	1	11.1	8	88.9	0.8329	1.28	0.13	12.27		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA		19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.9093	0.87	0.08	9.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		19	100.0	8	42.1	11	57.9	9	100.0	2	22.2	7	77.8	0.3365	2.11	0.45	9.98		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA		19	100.0	4	21.1	15	78.9	9	100.0	1	11.1	8	88.9	0.5768	1.85	0.21	16.56		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	2	22.2	7	77.8	0.1485	0.20	0.02	2.24		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS			19	100.0	4	21.1	15	78.9	9	100.0	2	22.2	7	77.8	0.9189	0.92	0.17	5.01		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	DIZZINESS		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	HEADACHE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL		19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.9409	0.91	0.08	10.09		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
NERVOUS SYSTEM DISORDERS	PARAESTHESIA		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS			19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
PSYCHIATRIC DISORDERS	INSOMNIA		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HAEMATURIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	RENAL INJURY		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1235	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			19	100.0	4	21.1	15	78.9	9	100.0	2	22.2	7	77.8	0.8803	0.88	0.16	4.80		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS		19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2588	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5870	0.47	0.03	7.55		Convergence criterion (GCONV=1E-8) satisfied.	NE
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			19	100.0	7	36.8	12	63.2	9	100.0	0	-	9	100.0	0.0494	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPERTENSION		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2317	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	VENOUS THROMBOSIS		19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2248	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTAE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 18:52

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	16	84.2	12	75.0	4	25.0	7	77.8	3	42.9	4	57.1	0.2516	2.07	0.58	7.39	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	2	100.0	0	-	0.7389	0.58	0.02	14.74	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	16	84.2	11	68.8	5	31.3	7	77.8	2	28.6	5	71.4	0.1943	2.63	0.58	11.95	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	2	100.0	0	-	0.4142	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.3717	0.30	0.02	4.99	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.4649	0.37	0.02	5.93	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5643	0.45	0.03	7.23	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	1	50.0	1	50.0	0.2207	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	16	84.2	2	12.5	14	87.5	7	77.8	1	14.3	6	85.7	0.9082	0.87	0.08	9.59	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	1	50.0	1	50.0	0.2207	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	16	84.2	2	12.5	14	87.5	7	77.8	2	28.6	5	71.4	0.2150	0.29	0.04	2.27	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PALPITATIONS	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.4806	0.38	0.02	6.14	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PALPITATIONS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PNEUMOPERICARDIUM	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PNEUMOPERICARDIUM	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	DEAFNESS	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	DEAFNESS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	16	84.2	11	68.8	5	31.3	7	77.8	4	57.1	3	42.9	0.8259	1.14	0.35	3.69	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3417	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5090	0.41	0.03	6.49	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	< 65	16	84.2	6	37.5	10	62.5	7	77.8	0	-	7	100.0	0.0946	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	< 65	16	84.2	7	43.8	9	56.3	7	77.8	2	28.6	5	71.4	0.5316	1.65	0.34	8.06	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SUBILEUS	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SUBILEUS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.4655	0.37	0.02	5.97		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	< 65	16	84.2	6	37.5	10	62.5	7	77.8	2	28.6	5	71.4	0.6711	1.41	0.28	7.07		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	16	84.2	11	68.8	5	31.3	7	77.8	5	71.4	2	28.6	0.9688	0.98	0.34	2.85		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	3	15.8	2	66.7	1	33.3	2	22.2	0	-	2	100.0	0.1167	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	< 65	16	84.2	5	31.3	11	68.8	7	77.8	4	57.1	3	42.9	0.1815	0.41	0.11	1.57		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	0	-	2	100.0	0.1167	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3417	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	16	84.2	7	43.8	9	56.3	7	77.8	1	14.3	6	85.7	0.2093	3.54	0.43	29.00		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS		< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1025	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	16	84.2	6	37.5	10	62.5	7	77.8	2	28.6	5	71.4	0.9691	0.97	0.19	4.85		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.2715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.0943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	3	15.8	2	66.7	1	33.3	2	22.2	0	-	2	100.0	0.1985	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	16	84.2	15	93.8	1	6.3	7	77.8	6	85.7	1	14.3	0.5716	1.38	0.45	4.19		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	3	15.8	2	66.7	1	33.3	2	22.2	2	100.0	0	-	0.7009	0.60	0.05	8.03		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	< 65	16	84.2	5	31.3	11	68.8	7	77.8	0	-	7	100.0	0.1503	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ANION GAP DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ANION GAP DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	< 65	16	84.2	5	31.3	11	68.8	7	77.8	0	-	7	100.0	0.1247	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	1	50.0	1	50.0	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	1	50.0	1	50.0	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.4263	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	< 65	16	84.2	4	25.0	12	75.0	7	77.8	0	-	7	100.0	0.1622	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	1	50.0	1	50.0	0.8084	1.41	0.08	23.57		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	< 65	16	84.2	4	25.0	12	75.0	7	77.8	0	-	7	100.0	0.1890	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3417	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD SODIUM DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD SODIUM DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD UREA INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD UREA INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URIC ACID INCREASED	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3417	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URIC ACID INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.3467	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYSTATIN C INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYSTATIN C INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.2361	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3417	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HEART RATE INCREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HEART RATE INCREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	16	84.2	6	37.5	10	62.5	7	77.8	6	85.7	1	14.3	0.0528	0.28	0.08	1.06		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	2	100.0	0	-	0.7009	0.60	0.05	8.03		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	16	84.2	12	75.0	4	25.0	7	77.8	3	42.9	4	57.1	0.1746	2.37	0.66	8.57		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	2	100.0	0	-	0.0896	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6547	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	16	84.2	11	68.8	5	31.3	7	77.8	2	28.6	5	71.4	0.1449	2.96	0.64	13.62		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	2	100.0	0	-	0.7822	1.41	0.12	15.84		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROCALCITONIN INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROCALCITONIN INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN TOTAL DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN TOTAL DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN URINE PRESENT	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.4315	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN URINE PRESENT	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	< 65	16	84.2	3	18.8	13	81.3	7	77.8	1	14.3	6	85.7	0.9552	1.07	0.11	10.31		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	16	84.2	13	81.3	3	18.8	7	77.8	3	42.9	4	57.1	0.2090	2.22	0.62	7.96		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	2	100.0	0	-	0.3018	0.29	0.03	3.42		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	16	84.2	11	68.8	5	31.3	7	77.8	4	57.1	3	42.9	0.9183	1.06	0.32	3.49		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	< 65	16	84.2	4	25.0	12	75.0	7	77.8	2	28.6	5	71.4	0.7374	0.75	0.13	4.15		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	< 65	16	84.2	4	25.0	12	75.0	7	77.8	0	-	7	100.0	0.1804	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	< 65	16	84.2	3	18.8	13	81.3	7	77.8	1	14.3	6	85.7	0.8103	1.33	0.13	13.74		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	< 65	16	84.2	3	18.8	13	81.3	7	77.8	1	14.3	6	85.7	0.9813	1.03	0.11	9.93		Convergence criterion (GCONV=1E-8) satisfied.	-

METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.4655	0.37	0.02	5.97		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	16	84.2	7	43.8	9	56.3	7	77.8	2	28.6	5	71.4	0.5913	1.54	0.32	7.45		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	< 65	16	84.2	4	25.0	12	75.0	7	77.8	1	14.3	6	85.7	0.6842	1.57	0.17	14.10		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5501	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.4620	0.37	0.02	5.93		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	1	50.0	1	50.0	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	1	50.0	1	50.0	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	>= 65	3	15.8	0	-	3	100.0	2	22.2	1	50.0	1	50.0	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		< 65	16	84.2	3	18.8	13	81.3	7	77.8	2	28.6	5	71.4	0.5306	0.57	0.09	3.44		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HEADACHE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	< 65	16	84.2	2	12.5	14	87.5	7	77.8	1	14.3	6	85.7	0.8554	0.80	0.07	8.89		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL INJURY	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL INJURY	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	16	84.2	4	25.0	12	75.0	7	77.8	0	-	7	100.0	0.2259	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		< 65	16	84.2	4	25.0	12	75.0	7	77.8	2	28.6	5	71.4	0.7274	0.74	0.13	4.07		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.3096	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5250	0.42	0.03	6.69		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	16	84.2	5	31.3	11	68.8	7	77.8	0	-	7	100.0	0.1251	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	3	15.8	2	66.7	1	33.3	2	22.2	0	-	2	100.0	0.1985	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3885	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	VENOUS THROMBOSIS	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.2505	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	VENOUS THROMBOSIS	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTAE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 18:52

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	14	73.7	10	71.4	4	28.6	6	66.7	4	66.7	2	33.3	0.6793	1.28	0.39	4.16		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	26.3	3	60.0	2	40.0	3	33.3	1	33.3	2	66.7	0.6031	1.84	0.18	19.00		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	14	73.7	9	64.3	5	35.7	6	66.7	3	50.0	3	50.0	0.5958	1.43	0.38	5.41		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	5	26.3	3	60.0	2	40.0	3	33.3	1	33.3	2	66.7	0.5138	2.10	0.22	20.49		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4754	0.38	0.02	6.08		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.4969	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5561	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	14	73.7	2	14.3	12	85.7	6	66.7	1	16.7	5	83.3	0.9099	0.87	0.08	9.61		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.8971	1.16	0.12	11.22		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PALPITATIONS	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PALPITATIONS	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PNEUMOPERICARDIUM	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PNEUMOPERICARDIUM	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4568	0.36	0.02	5.86		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	DEAFNESS	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	DEAFNESS	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	14	73.7	8	57.1	6	42.9	6	66.7	3	50.0	3	50.0	0.9263	1.07	0.28	4.05		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	5	26.3	4	80.0	1	20.0	3	33.3	1	33.3	2	66.7	0.2874	3.20	0.34	30.28		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3830	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	>=3	14	73.7	5	35.7	9	64.3	6	66.7	0	-	6	100.0	0.1246	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	>=3	14	73.7	6	42.9	8	57.1	6	66.7	2	33.3	4	66.7	0.7602	1.28	0.26	6.43		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SUBILEUS	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SUBILEUS	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	>=3	14	73.7	5	35.7	9	64.3	6	66.7	2	33.3	4	66.7	0.8956	1.12	0.21	5.83		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	14	73.7	9	64.3	5	35.7	6	66.7	3	50.0	3	50.0	0.6456	1.36	0.36	5.08		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	5	26.3	4	80.0	1	20.0	3	33.3	2	66.7	1	33.3	0.4686	1.88	0.33	10.59		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	>=3	14	73.7	6	42.9	8	57.1	6	66.7	2	33.3	4	66.7	0.8046	1.23	0.24	6.14		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	<3	5	26.3	1	20.0	4	80.0	3	33.3	2	66.7	1	33.3	0.2159	0.25	0.02	2.73		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.8095	1.32	0.14	12.72		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	5	26.3	4	80.0	1	20.0	3	33.3	0	-	3	100.0	0.0532	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS		>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	14	73.7	7	50.0	7	50.0	6	66.7	2	33.3	4	66.7	0.6797	1.39	0.29	6.80		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.1896	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	14	73.7	12	85.7	2	14.3	6	66.7	5	83.3	1	16.7	0.7406	1.22	0.37	4.03		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	26.3	5	100.0	0	-	3	33.3	3	100.0	0	-	0.8341	0.80	0.10	6.38		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2311	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	<3	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1559	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ANION GAP DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ANION GAP DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	1	33.3	2	66.7	0.7766	0.67	0.04	10.77		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	>=3	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.8116	1.32	0.14	12.74		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	>=3	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.1840	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD SODIUM DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD SODIUM DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD UREA INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD UREA INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URIC ACID INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URIC ACID INCREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.3181	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYSTATIN C INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYSTATIN C INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4568	0.36	0.02	5.86		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3354	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HEART RATE INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HEART RATE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	14	73.7	6	42.9	8	57.1	6	66.7	5	83.3	1	16.7	0.1109	0.33	0.08	1.34		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	5	26.3	2	40.0	3	60.0	3	33.3	3	100.0	0	-	0.2539	0.32	0.04	2.40		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5561	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5561	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	14	73.7	8	57.1	6	42.9	6	66.7	2	33.3	4	66.7	0.4744	1.76	0.37	8.39		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	5	26.3	5	100.0	0	-	3	33.3	3	100.0	0	-	0.0469	7.08	0.78	63.96		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5561	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	14	73.7	8	57.1	6	42.9	6	66.7	2	33.3	4	66.7	0.2755	2.33	0.49	11.12		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	5	26.3	5	100.0	0	-	3	33.3	2	66.7	1	33.3	0.8639	1.16	0.21	6.51		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROCALCITONIN INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROCALCITONIN INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN TOTAL DECREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN TOTAL DECREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN URINE PRESENT	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4364	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN URINE PRESENT	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	>=3	14	73.7	2	14.3	12	85.7	6	66.7	1	16.7	5	83.3	0.7525	0.68	0.06	7.59		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	14	73.7	9	64.3	5	35.7	6	66.7	3	50.0	3	50.0	0.9682	1.03	0.27	3.99		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	5	26.3	5	100.0	0	-	3	33.3	2	66.7	1	33.3	0.0847	5.55	0.63	48.68		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	14	73.7	9	64.3	5	35.7	6	66.7	4	66.7	2	33.3	0.6168	0.73	0.21	2.54		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1269	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	>=3	14	73.7	4	28.6	10	71.4	6	66.7	2	33.3	4	66.7	0.6892	0.71	0.13	3.94		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	>=3	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.1701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	>=3	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.8251	1.30	0.12	13.62		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	>=3	14	73.7	2	14.3	12	85.7	6	66.7	1	16.7	5	83.3	0.7791	0.71	0.06	7.90		Convergence criterion (GCONV=1E-8) satisfied.	-

METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4919	0.39	0.02	6.27		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	14	73.7	5	35.7	9	64.3	6	66.7	2	33.3	4	66.7	0.8665	1.15	0.22	6.02		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1269	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	>=3	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.8940	1.17	0.12	11.28		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	14	73.7	0	-	14	100.0	6	66.7	2	33.3	4	66.7	0.0238	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS		>=3	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.7926	1.35	0.14	13.02		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		<3	5	26.3	1	20.0	4	80.0	3	33.3	1	33.3	2	66.7	0.6084	0.49	0.03	7.94		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	DIZZINESS	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	HEADACHE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HEADACHE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5561	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS		>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
PSYCHIATRIC DISORDERS	INSOMNIA	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	RENAL INJURY	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5839	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL INJURY	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	14	73.7	5	35.7	9	64.3	6	66.7	0	-	6	100.0	0.1516	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		>=3	14	73.7	4	28.6	10	71.4	6	66.7	2	33.3	4	66.7	0.7641	0.77	0.14	4.22		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2881	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5300	0.42	0.03	6.76		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	14	73.7	5	35.7	9	64.3	6	66.7	0	-	6	100.0	0.1276	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2618	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	VENOUS THROMBOSIS	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3627	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	VENOUS THROMBOSIS	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTAE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 18:52

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	100.0	13	68.4	6	31.6	9	100.0	5	55.6	4	44.4	0.4936	1.44	0.51	4.10		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.3472	1.72	0.55	5.41		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5219	0.42	0.03	6.68		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	2	22.2	7	77.8	0.1791	0.22	0.02	2.46		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	2	22.2	7	77.8	0.3947	0.44	0.06	3.11		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	2	22.2	7	77.8	0.5976	0.62	0.10	3.74		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PALPITATIONS	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5527	0.44	0.03	7.07		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PNEUMOPERICARDIUM	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5384	0.43	0.03	6.89		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	DEAFNESS	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.4838	1.50	0.48	4.75		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3468	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.9257	0.89	0.08	9.84		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0764	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Non-Europe	19	100.0	8	42.1	11	57.9	9	100.0	2	22.2	7	77.8	0.3482	2.08	0.44	9.86		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	STOMATITIS	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SUBILEUS	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5384	0.43	0.03	6.89		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	2	22.2	7	77.8	0.4439	1.83	0.38	8.88		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	19	100.0	13	68.4	6	31.6	9	100.0	5	55.6	4	44.4	0.5258	1.40	0.49	3.95		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	4	44.4	5	55.6	0.6051	0.72	0.21	2.49		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	1	11.1	8	88.9	0.1753	3.85	0.47	31.50		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS		Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1336	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	2	22.2	7	77.8	0.5803	1.55	0.32	7.49		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1647	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	100.0	17	89.5	2	10.5	9	100.0	8	88.9	1	11.1	0.7713	1.16	0.42	3.19		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0783	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ANION GAP DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5211	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1093	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3696	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	1	11.1	8	88.9	0.3637	2.62	0.30	22.69		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1617	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD SODIUM DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD UREA INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URIC ACID INCREASED	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2732	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYSTATIN C INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5384	0.43	0.03	6.89		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5050	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2202	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3166	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HEART RATE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	19	100.0	8	42.1	11	57.9	9	100.0	8	88.9	1	11.1	0.0347	0.29	0.09	0.95		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	19	100.0	13	68.4	6	31.6	9	100.0	5	55.6	4	44.4	0.4247	1.53	0.54	4.33		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5465	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	100.0	13	68.4	6	31.6	9	100.0	4	44.4	5	55.6	0.2845	1.84	0.59	5.74		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROCALCITONIN INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN TOTAL DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5211	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN URINE PRESENT	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3701	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	1	11.1	8	88.9	0.6082	1.76	0.20	15.77		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	19	100.0	14	73.7	5	26.3	9	100.0	5	55.6	4	44.4	0.5537	1.37	0.48	3.87		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.5562	1.41	0.44	4.51		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	2	22.2	7	77.8	0.9298	1.08	0.21	5.61		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1536	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	1	11.1	8	88.9	0.7541	1.45	0.14	14.70		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	1	11.1	8	88.9	0.8329	1.28	0.13	12.27		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.9093	0.87	0.08	9.60		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	19	100.0	8	42.1	11	57.9	9	100.0	2	22.2	7	77.8	0.3365	2.11	0.45	9.98		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	1	11.1	8	88.9	0.5768	1.85	0.21	16.56		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	2	22.2	7	77.8	0.1485	0.20	0.02	2.24		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS		Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	2	22.2	7	77.8	0.9189	0.92	0.17	5.01		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	DIZZINESS	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	HEADACHE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.9409	0.91	0.08	10.09		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS		Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
PSYCHIATRIC DISORDERS	INSOMNIA	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	RENAL INJURY	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5271	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1235	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	2	22.2	7	77.8	0.8803	0.88	0.16	4.80		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2588	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5870	0.47	0.03	7.55		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	0	-	9	100.0	0.0494	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2317	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	VENOUS THROMBOSIS	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2248	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTAE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 18:52

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	10	71.4	4	28.6	6	66.7	2	33.3	4	66.7	0.1823	2.71	0.59	12.47	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	3	60.0	2	40.0	3	33.3	3	100.0	0	-	0.6461	0.68	0.13	3.56	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	14	73.7	9	64.3	5	35.7	6	66.7	1	16.7	5	83.3	0.0690	5.53	0.70	43.90	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	5	26.3	3	60.0	2	40.0	3	33.3	3	100.0	0	-	0.4901	0.56	0.11	2.95	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	COAGULOPATHY	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	HYPOGLOBULINAEMIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOCYTOSIS	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.4969	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	LEUKOPENIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4348	0.35	0.02	5.57	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	1	33.3	2	66.7	0.7766	0.67	0.04	10.77	Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5100	0.41	0.03	6.50	Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	1	33.3	2	66.7	0.7766	0.67	0.04	10.77	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	14	73.7	2	14.3	12	85.7	6	66.7	2	33.3	4	66.7	0.1796	0.27	0.04	2.05	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PALPITATIONS	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0714	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PALPITATIONS	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	PNEUMOPERICARDIUM	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	PNEUMOPERICARDIUM	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	SINUS TACHYCARDIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4568	0.36	0.02	5.86	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	SINUS TACHYCARDIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
EAR AND LABYRINTH DISORDERS	DEAFNESS	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
EAR AND LABYRINTH DISORDERS	DEAFNESS	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	14	73.7	9	64.3	5	35.7	6	66.7	2	33.3	4	66.7	0.3006	2.23	0.47	10.61	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	5	26.3	3	60.0	2	40.0	3	33.3	2	66.7	1	33.3	0.8410	0.83	0.14	5.06	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3830	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN UPPER	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CHRONIC GASTRITIS	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	CONSTIPATION	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4919	0.39	0.02	6.27	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	CONSTIPATION	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	DIARRHOEA	Male	14	73.7	6	42.9	8	57.1	6	66.7	0	-	6	100.0	0.0941	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	DIARRHOEA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	GASTRIC POLYPS	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	MOUTH ULCERATION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	NAUSEA	Male	14	73.7	7	50.0	7	50.0	6	66.7	1	16.7	5	83.3	0.2122	3.53	0.43	29.08	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	NAUSEA	Female	5	26.3	1	20.0	4	80.0	3	33.3	1	33.3	2	66.7	0.7766	0.67	0.04	10.77	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	STOMATITIS	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	STOMATITIS	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	SUBILEUS	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE	Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	SUBILEUS	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE	Convergence criterion (GCONV=1E-8) satisfied.	

GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	VOMITING	Male	14	73.7	7	50.0	7	50.0	6	66.7	0	-	6	100.0	0.0468	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	VOMITING	Female	5	26.3	0	-	5	100.0	3	33.3	2	66.7	1	33.3	0.0431	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	14	73.7	10	71.4	4	28.6	6	66.7	5	83.3	1	16.7	0.5260	0.70	0.24	2.09		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1215	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHEST DISCOMFORT	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	CHILLS	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Male	14	73.7	7	50.0	7	50.0	6	66.7	4	66.7	2	33.3	0.3223	0.54	0.15	1.88		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	FATIGUE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	MALAISE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	OEDEMA PERIPHERAL	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	14	73.7	4	28.6	10	71.4	6	66.7	1	16.7	5	83.3	0.6855	1.58	0.17	14.51		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1269	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
HEPATOBILIARY DISORDERS	HEPATIC FUNCTION ABNORMAL	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	4	28.6	10	71.4	6	66.7	1	16.7	5	83.3	0.7871	1.35	0.15	12.14		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	3	60.0	2	40.0	3	33.3	1	33.3	2	66.7	0.5800	1.88	0.19	18.13		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	HERPES ZOSTER	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	MYCOPLASMA INFECTION	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4031	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	UPPER RESPIRATORY TRACT INFECTION	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	SKIN INJURY	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	14	73.7	12	85.7	2	14.3	6	66.7	5	83.3	1	16.7	0.4827	1.63	0.41	6.47		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	5	100.0	0	-	3	33.3	3	100.0	0	-	0.2979	0.38	0.06	2.50		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ADENOSINE DEAMINASE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2560	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ALANINE AMINOTRANSFERASE INCREASED	Female	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1269	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ANION GAP DECREASED	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ANION GAP DECREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2630	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ASPARTATE AMINOTRANSFERASE INCREASED	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5561	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BILIRUBIN CONJUGATED INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALBUMIN DECREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD ALKALINE PHOSPHATASE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4111	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD BILIRUBIN INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD CREATININE INCREASED	Male	14	73.7	5	35.7	9	64.3	6	66.7	0	-	6	100.0	0.1062	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD CREATININE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD FIBRINOGEN DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2606	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD LACTATE DEHYDROGENASE INCREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD MAGNESIUM DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD SODIUM DECREASED	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD SODIUM DECREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD UREA INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD UREA INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD URIC ACID INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD URIC ACID INCREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BRAIN NATRIURETIC PEPTIDE INCREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	C-REACTIVE PROTEIN INCREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	CYSTATIN C INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	CYSTATIN C INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4568	0.36	0.02	5.86		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM HIGH VOLTAGE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM QT PROLONGED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	ELECTROCARDIOGRAM ST SEGMENT ELEVATION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL COUNT INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5351	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EOSINOPHIL PERCENTAGE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	EPSTEIN-BARR VIRUS ANTIBODY POSITIVE	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GLOMERULAR FILTRATION RATE DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GRANULOCYTE COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3354	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HAEMOGLOBIN DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	HEART RATE INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	HEART RATE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LIPASE INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LIPASE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	14	73.7	8	57.1	6	42.9	6	66.7	5	83.3	1	16.7	0.3576	0.53	0.14	2.07		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	3	100.0	0	-	0.0046	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	MONONUCLEAR CELL COUNT INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	14	73.7	10	71.4	4	28.6	6	66.7	3	50.0	3	50.0	0.4095	1.74	0.46	6.54		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	5	26.3	3	60.0	2	40.0	3	33.3	2	66.7	1	33.3	0.8537	1.18	0.20	7.15		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	14	73.7	10	71.4	4	28.6	6	66.7	2	33.3	4	66.7	0.6276	1.46	0.31	6.89		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	5	26.3	3	60.0	2	40.0	3	33.3	2	66.7	1	33.3	0.6083	1.62	0.25	10.38		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROCALCITONIN INCREASED	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROCALCITONIN INCREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN TOTAL DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN TOTAL DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PROTEIN URINE PRESENT	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4584	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PROTEIN URINE PRESENT	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	RED BLOOD CELLS URINE POSITIVE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WEIGHT DECREASED	Male	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.1819	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WEIGHT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	14	73.7	10	71.4	4	28.6	6	66.7	2	33.3	4	66.7	0.2633	2.35	0.50	10.94		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	5	26.3	4	80.0	1	20.0	3	33.3	3	100.0	0	-	0.8674	0.88	0.19	4.02		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT INCREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	14	73.7	10	71.4	4	28.6	6	66.7	3	50.0	3	50.0	0.6261	1.39	0.37	5.25		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	5	26.3	2	40.0	3	60.0	3	33.3	1	33.3	2	66.7	0.8702	1.22	0.11	13.58		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Male	14	73.7	5	35.7	9	64.3	6	66.7	1	16.7	5	83.3	0.4848	2.11	0.25	18.12		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	DECREASED APPETITE	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERCHOLESTEROLAEMIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERGLYCAEMIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERKALAEMIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2397	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERLIPIDAEMIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERNATRAEMIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERTRIGLYCERIDAEMIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Male	14	73.7	2	14.3	12	85.7	6	66.7	1	16.7	5	83.3	0.8940	0.84	0.07	10.75		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPERURICAEMIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Male	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.9666	0.95	0.10	9.24		Convergence criterion (GCONV=1E-8) satisfied.	-

METABOLISM AND NUTRITION DISORDERS	HYPOALBUMINAEMIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Male	14	73.7	2	14.3	12	85.7	6	66.7	1	16.7	5	83.3	0.8080	0.74	0.07	8.22		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOCALCAEMIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	14	73.7	6	42.9	8	57.1	6	66.7	1	16.7	5	83.3	0.3510	2.65	0.32	22.21		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	5	26.3	2	40.0	3	60.0	3	33.3	1	33.3	2	66.7	0.8702	1.22	0.11	13.58		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Male	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.9996	1.00	0.10	9.67		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPONATRAEMIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOPHOSPHATAEMIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
METABOLISM AND NUTRITION DISORDERS	HYPOPROTEINAEMIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4297	0.34	0.02	5.56		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	ARTHRALGIA	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	BACK PAIN	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	SPINAL PAIN	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS		Male	14	73.7	3	21.4	11	78.6	6	66.7	2	33.3	4	66.7	0.4528	0.51	0.08	3.09		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	DIZZINESS	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	DIZZINESS	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	HEADACHE	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	HEADACHE	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4111	0.33	0.02	5.37		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	NEUROPATHY PERIPHERAL	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	NEUROTOXICITY	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
NERVOUS SYSTEM DISORDERS	PARAESTHESIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
PSYCHIATRIC DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
PSYCHIATRIC DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
PSYCHIATRIC DISORDERS	INSOMNIA	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
PSYCHIATRIC DISORDERS	INSOMNIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RENAL AND URINARY DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RENAL AND URINARY DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RENAL AND URINARY DISORDERS	HAEMATURIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RENAL AND URINARY DISORDERS	HAEMATURIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RENAL AND URINARY DISORDERS	RENAL INJURY	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RENAL AND URINARY DISORDERS	RENAL INJURY	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.2176	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	COUGH	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	HAEMOPTYSIS	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PLEURAL EFFUSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PNEUMOMEDIASTINUM	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	PRODUCTIVE COUGH	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Male	14	73.7	3	21.4	11	78.6	6	66.7	2	33.3	4	66.7	0.4798	0.53	0.09	3.19		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ALOPECIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	ECZEMA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4212	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	PRURITUS	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1069	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	RASH	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	URTICARIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	14	73.7	6	42.9	8	57.1	6	66.7	0	-	6	100.0	0.0884	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPERTENSION	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPERTENSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3926	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	VENOUS THROMBOSIS	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	VENOUS THROMBOSIS	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.3865	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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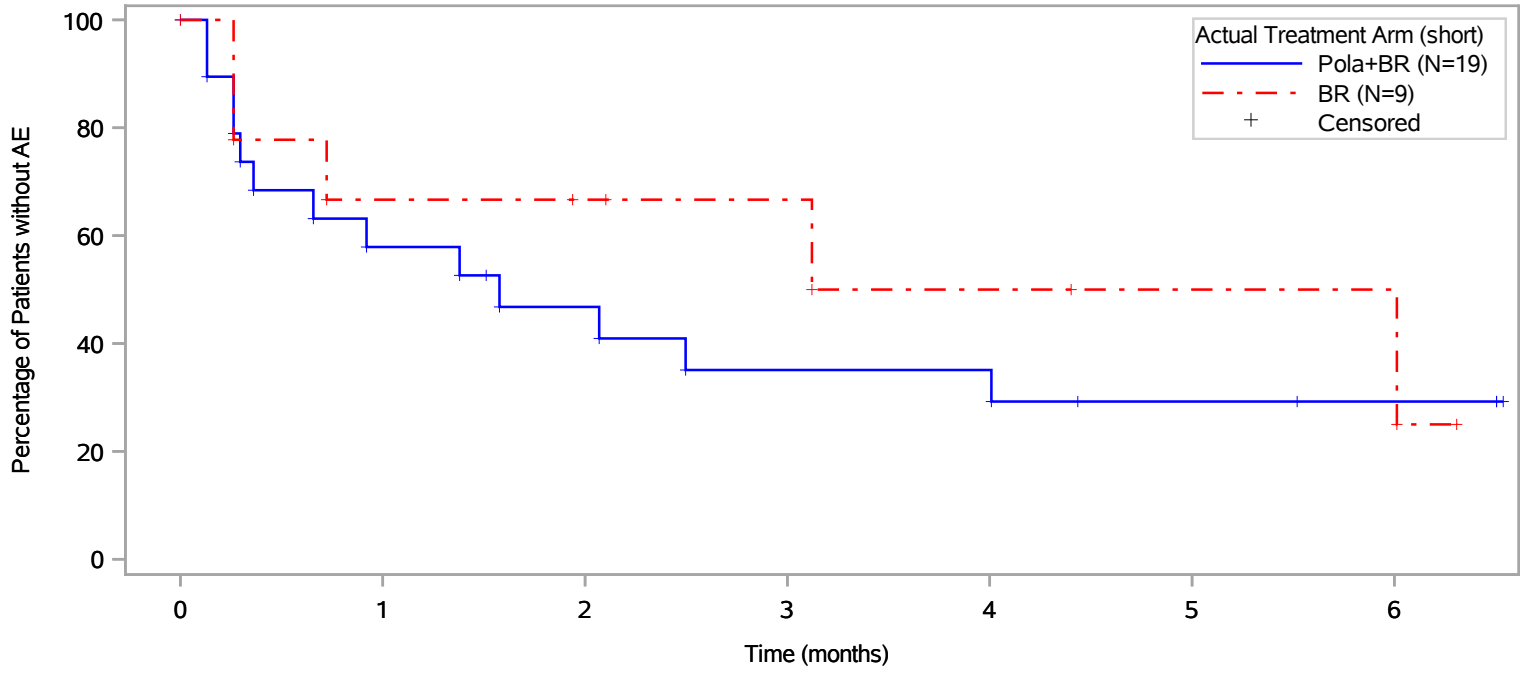
30NOV2022 18:52

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	11	8	6	6	4	3
BR (N=9)	9	6	5	4	3	2	2
Patients censored							
Pola+BR (N=19)	0	0	1	1	1	2	3
BR (N=9)	0	0	1	2	2	3	3

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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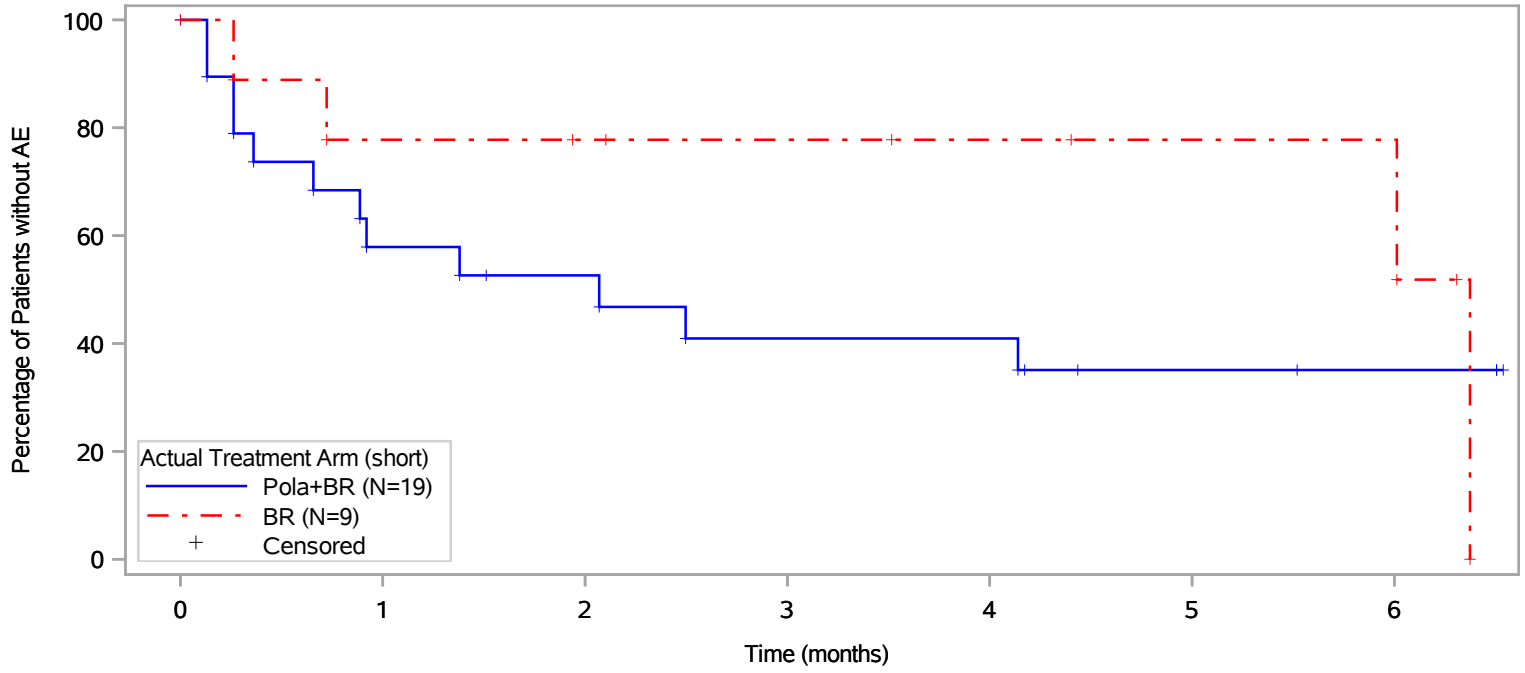
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk							
Pola+BR (N=19)	19	11	9	7	7	4	3
BR (N=9)	9	7	6	5	4	3	3
Patients censored							
Pola+BR (N=19)	0	0	1	1	1	3	4
BR (N=9)	0	0	1	2	3	4	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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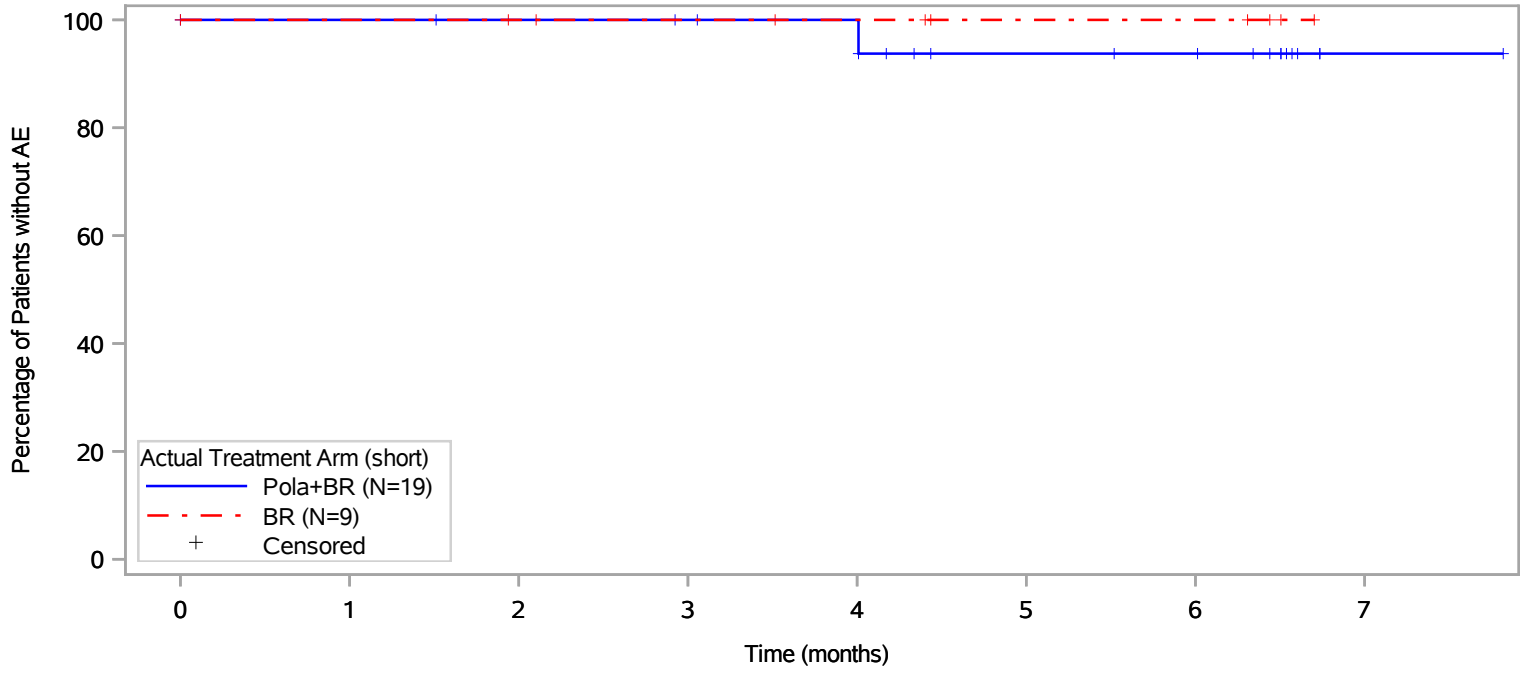
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, COAGULOPATHY



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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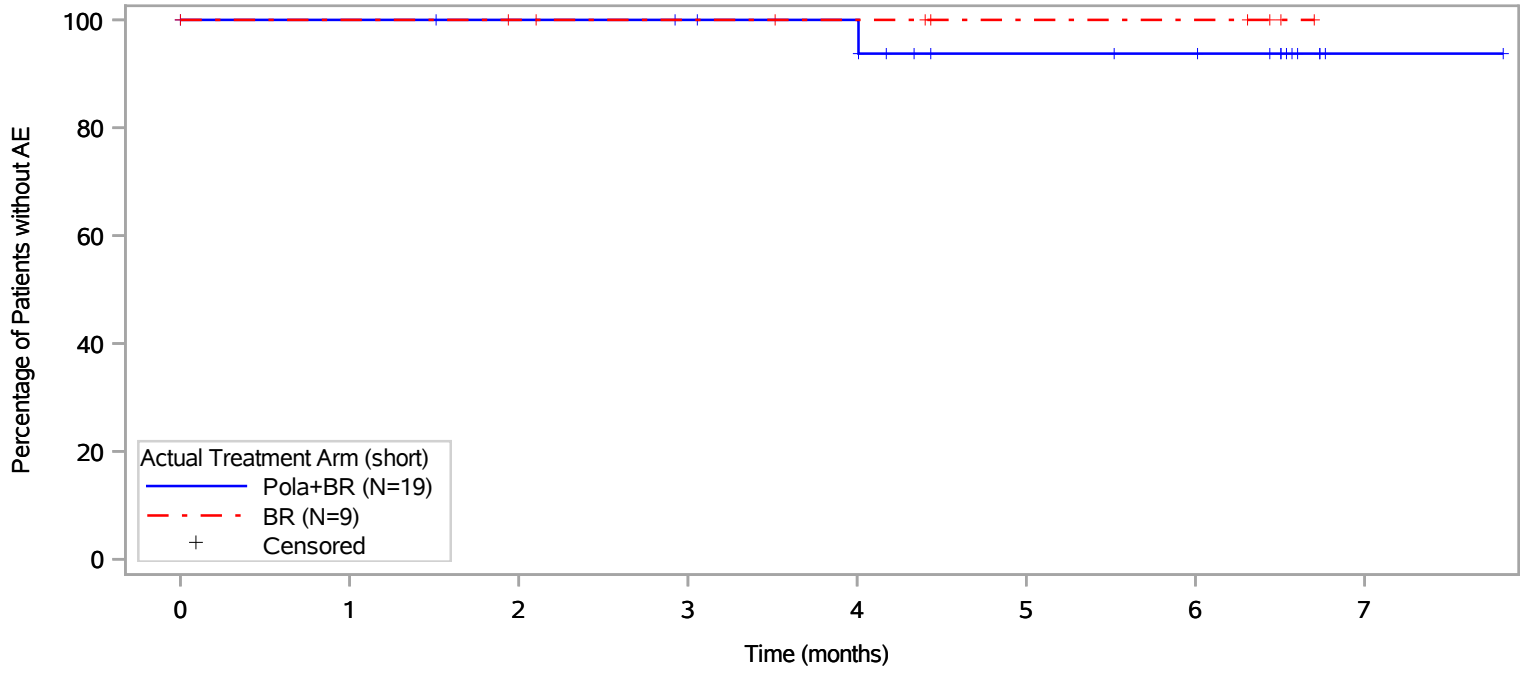
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, HYPOGLOBULINAEMIA



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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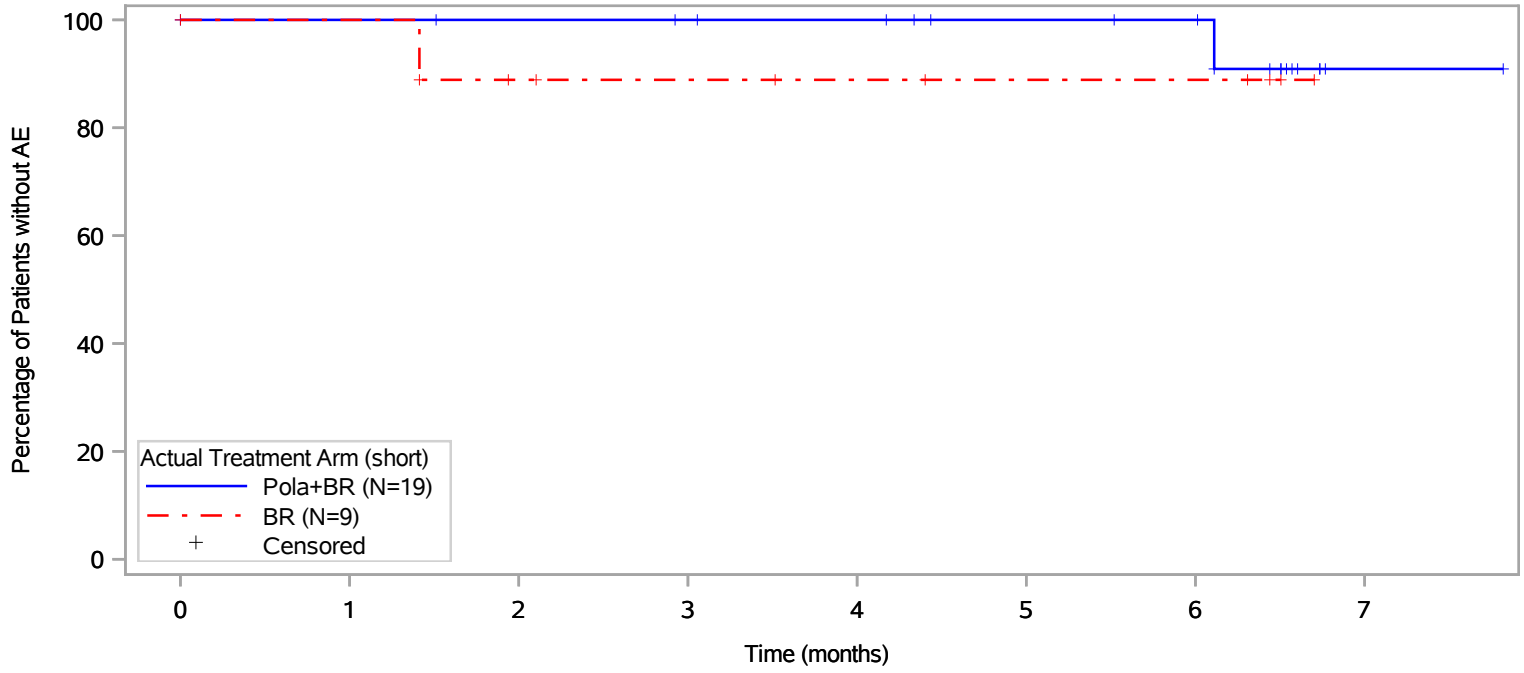
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOCYTOSIS



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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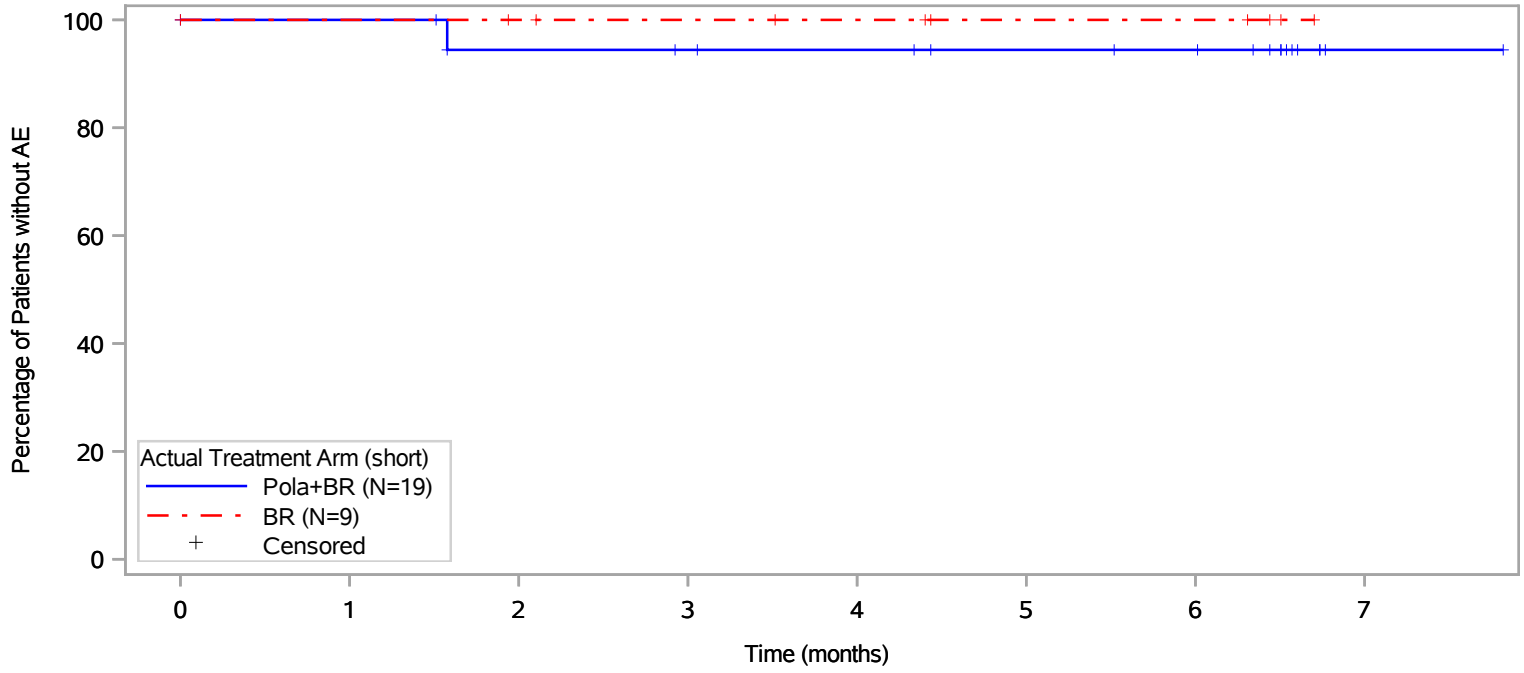
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, LEUKOPENIA



Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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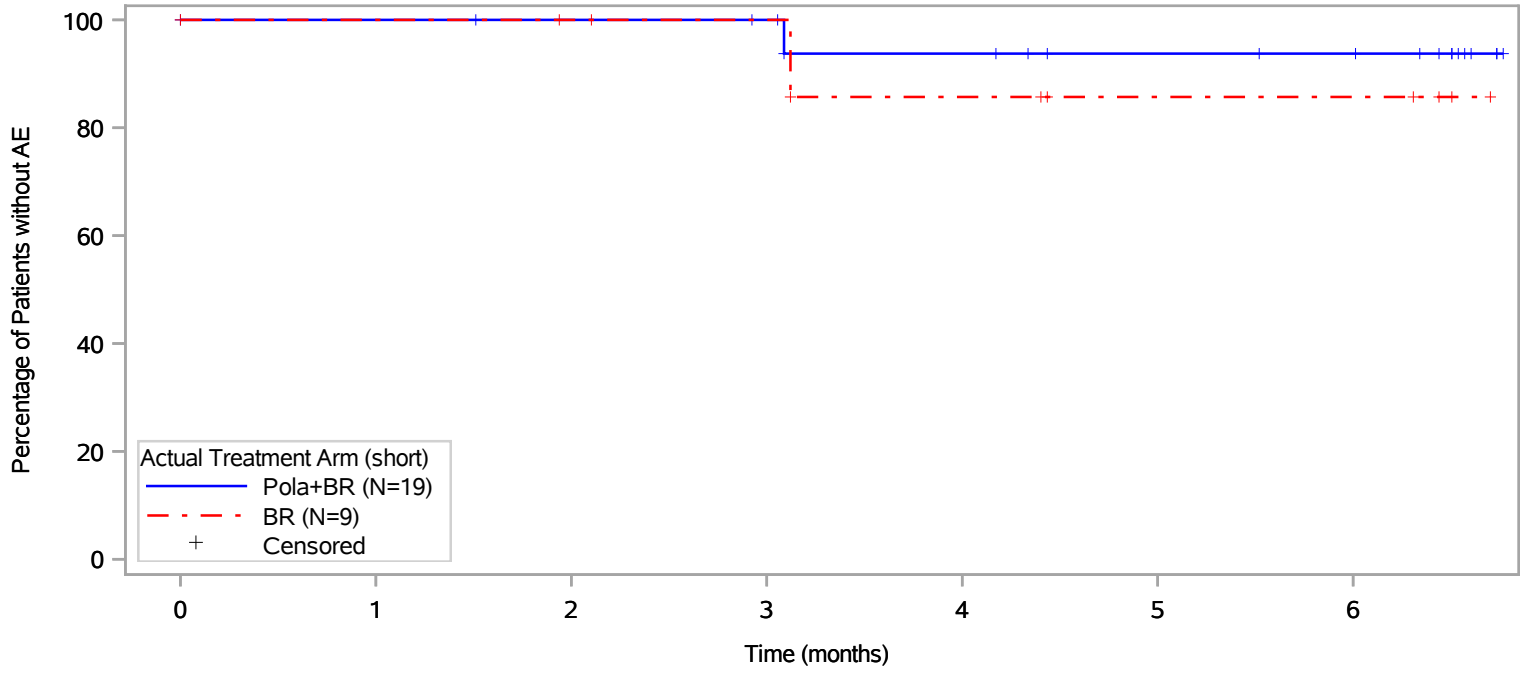
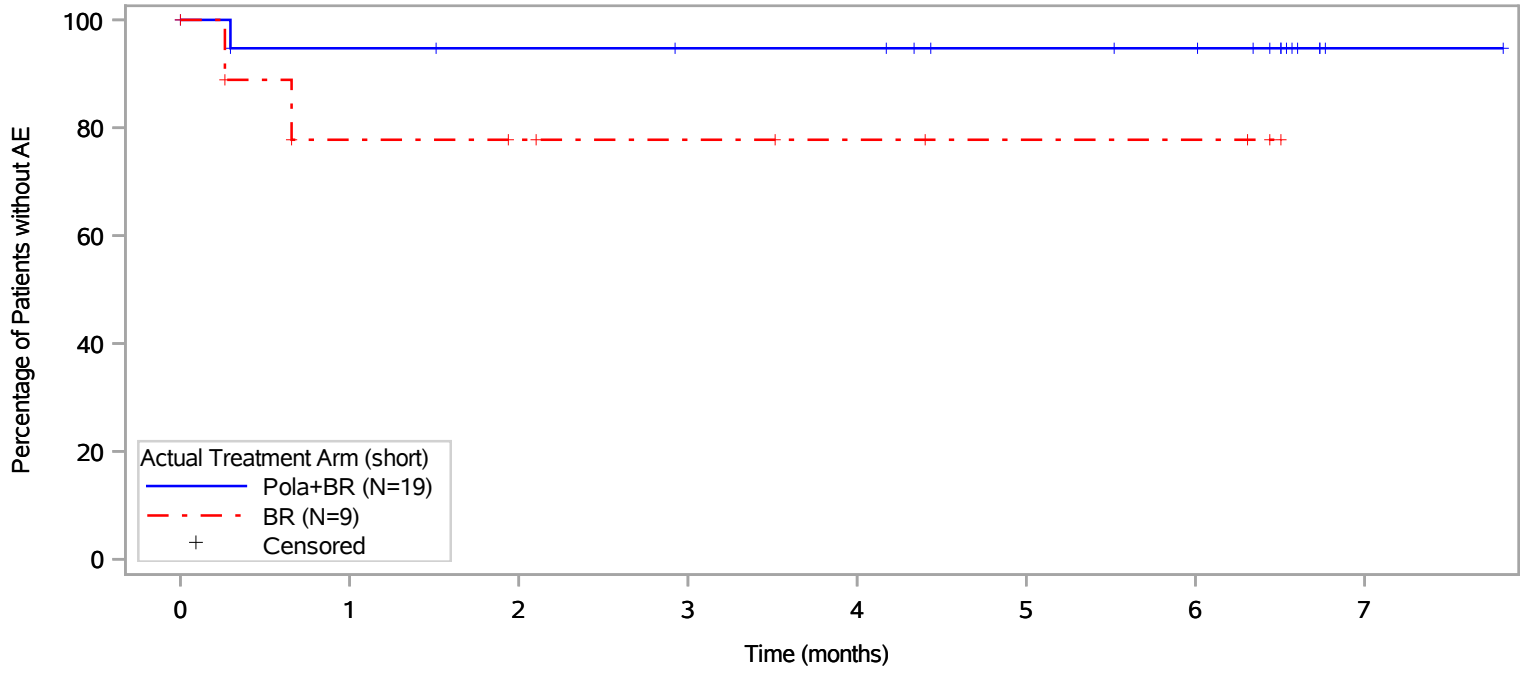
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, MYELOSUPPRESSION



Patients at risk							
Pola+BR (N=19)	19	19	18	17	15	12	11
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	2	4	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	16	13	12	1
BR (N=9)	9	7	6	5	4	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	17
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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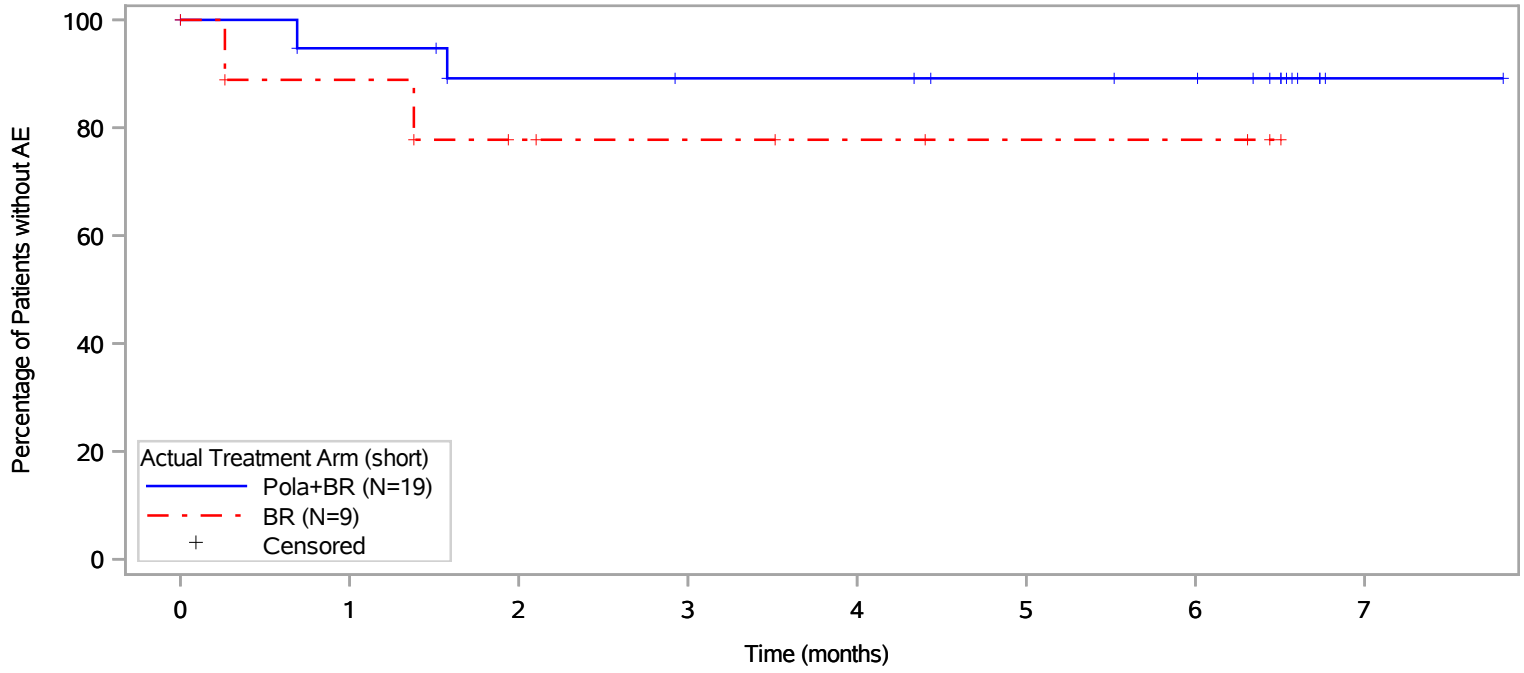
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk								
Pola+BR (N=19)	19	18	16	15	15	13	12	1
BR (N=9)	9	8	6	5	4	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	4	5	16
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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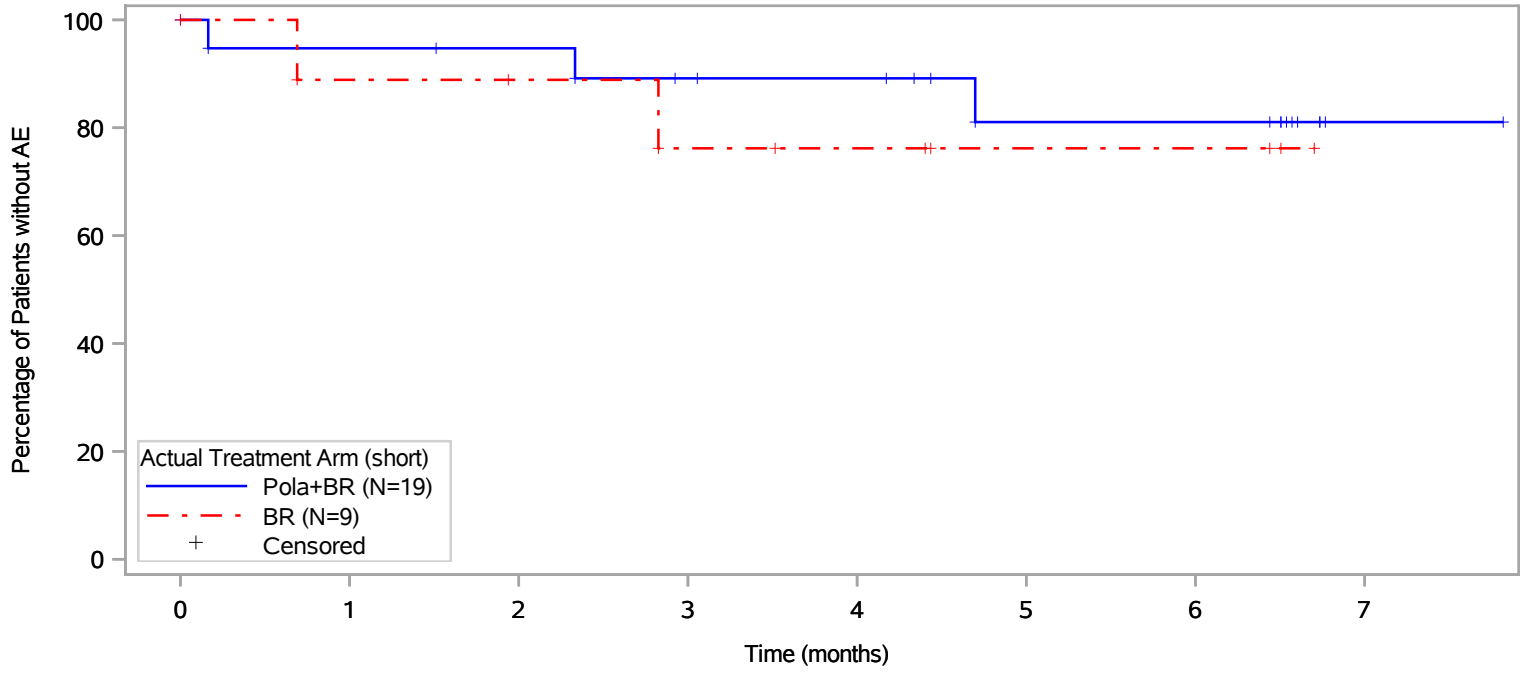
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	18	17	15	14	10	10	1
BR (N=9)	9	8	7	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	15
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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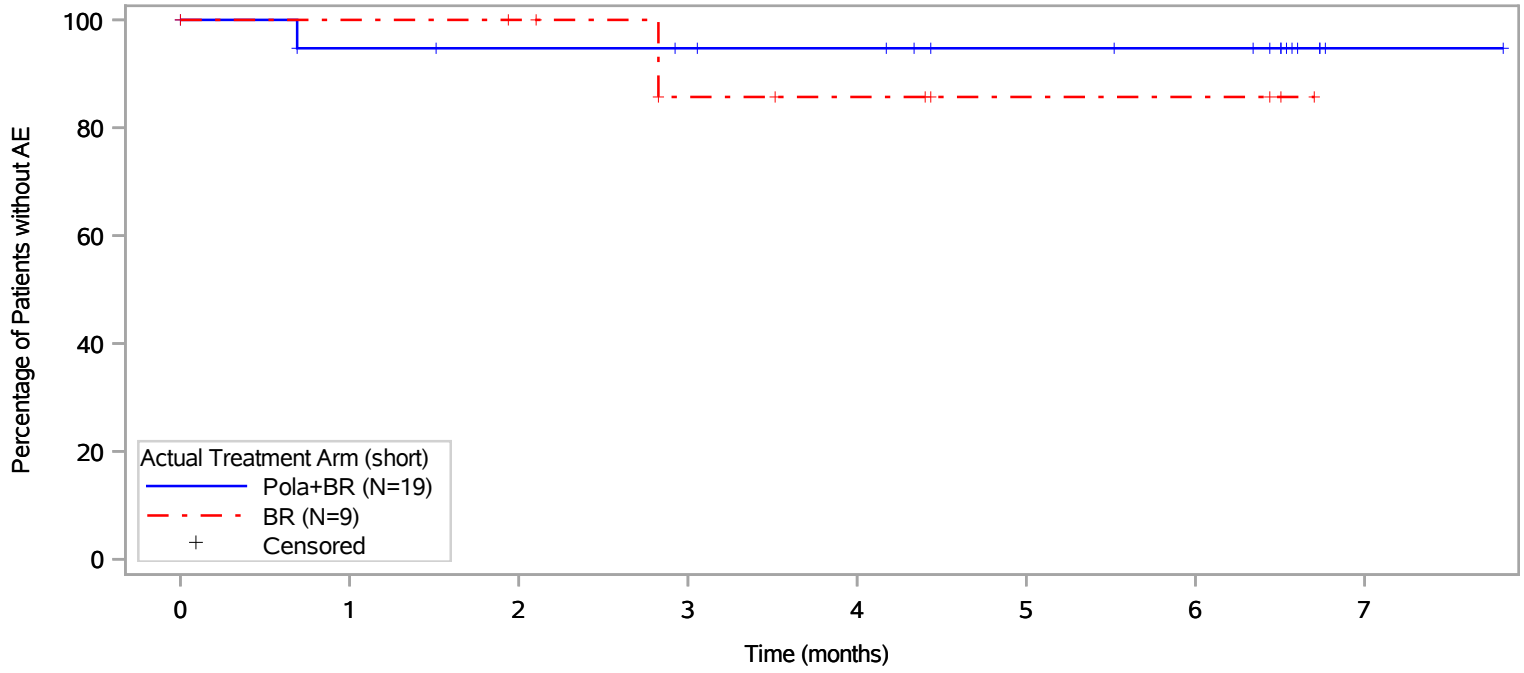
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, PALPITATIONS



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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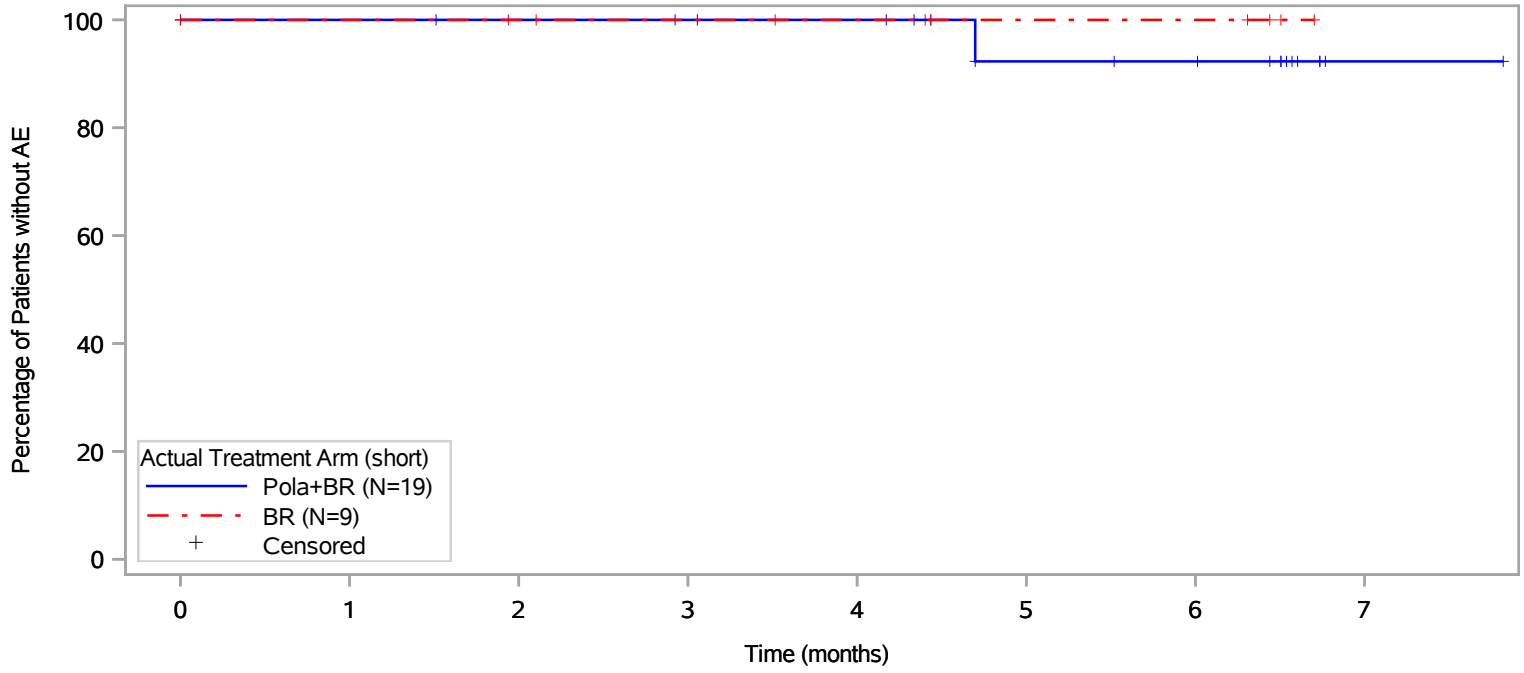
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, PNEUMOPERICARDIUM



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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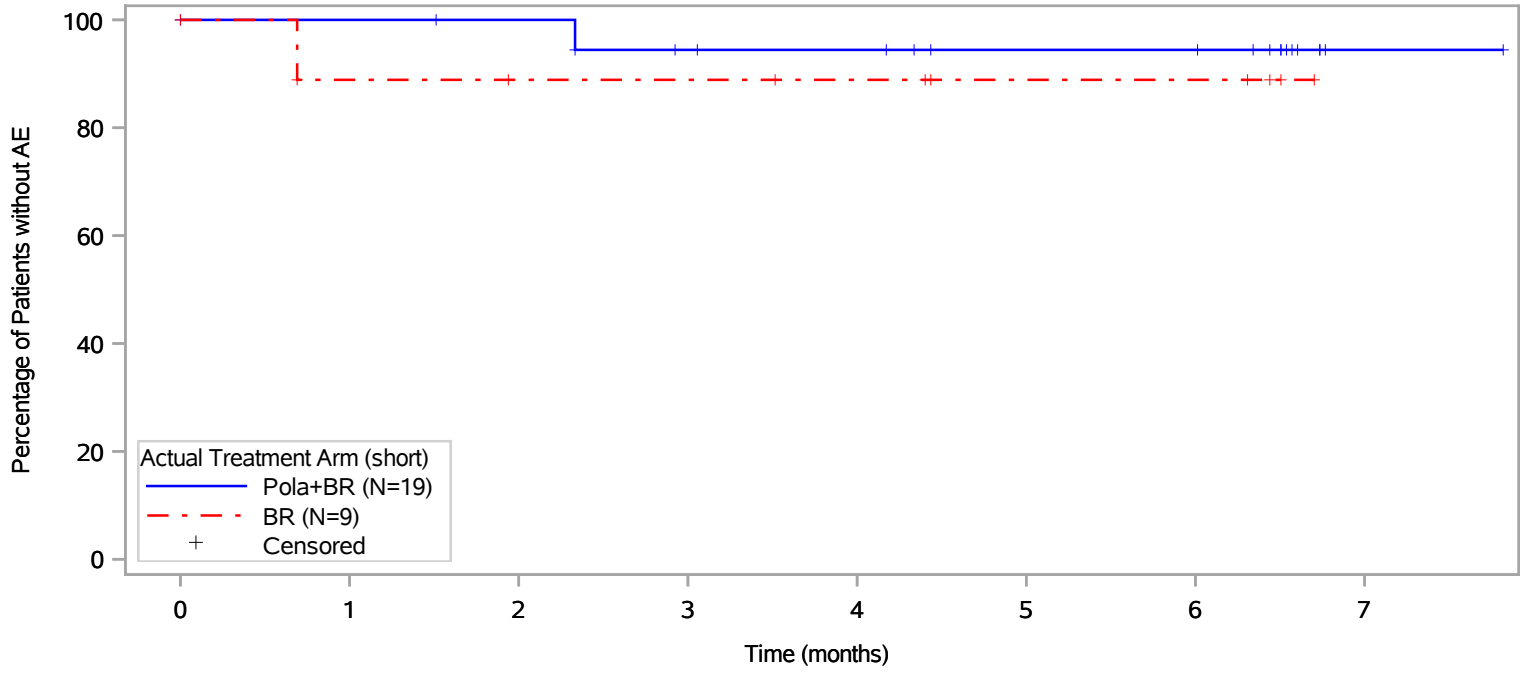
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, SINUS TACHYCARDIA



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	17
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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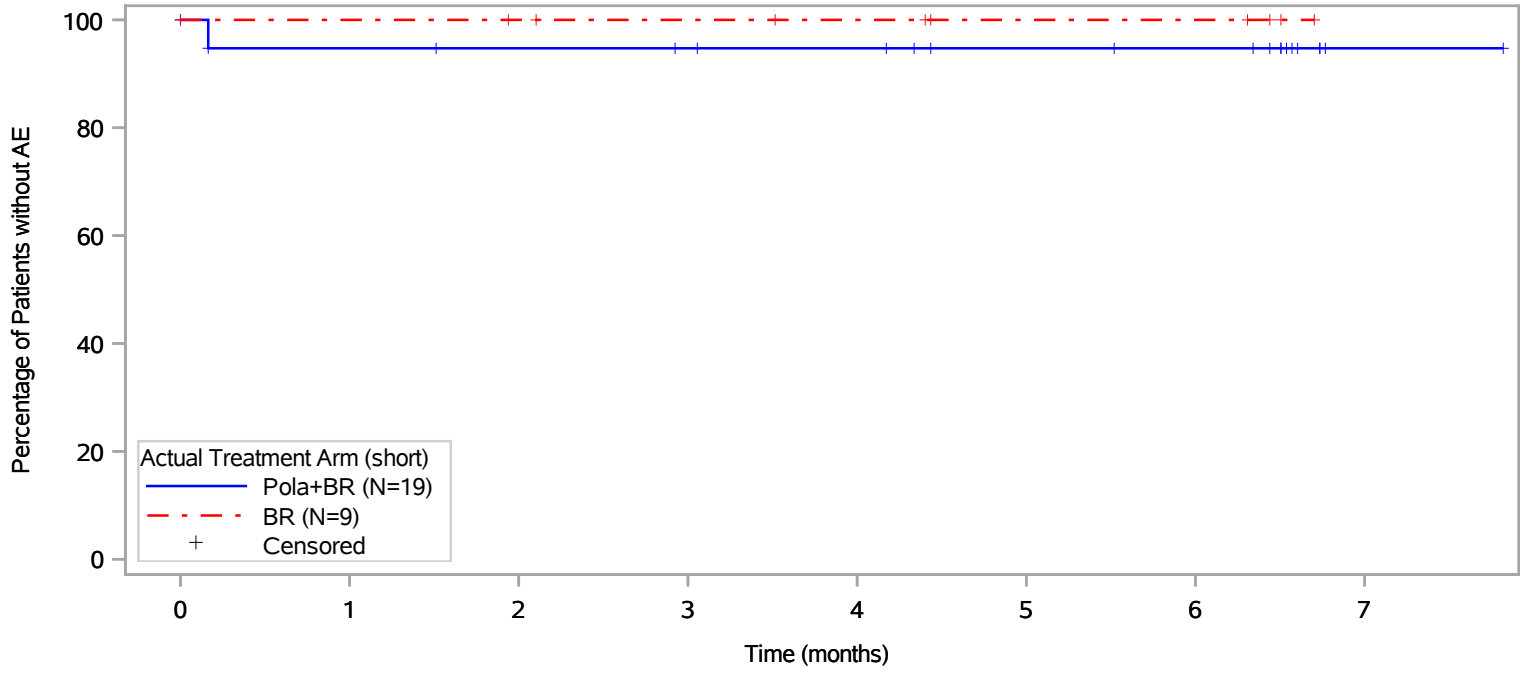
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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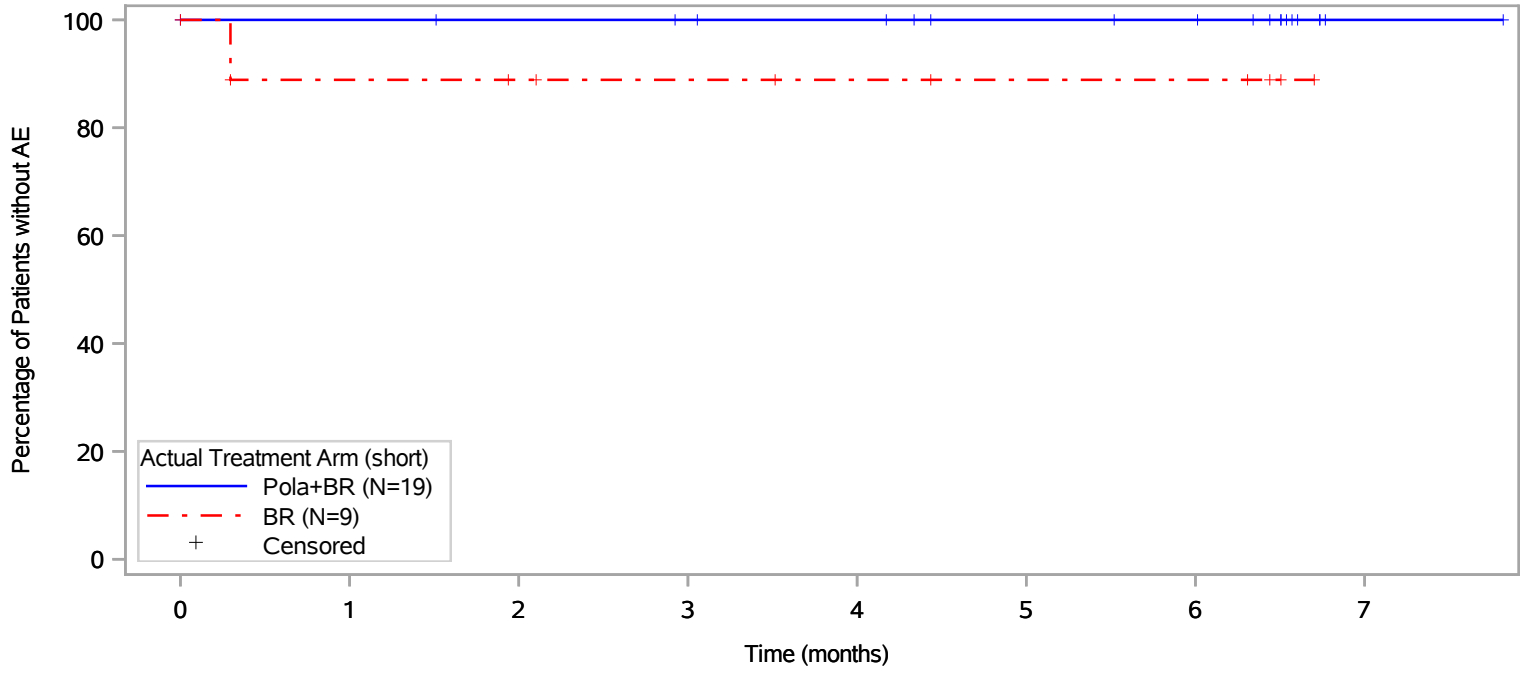
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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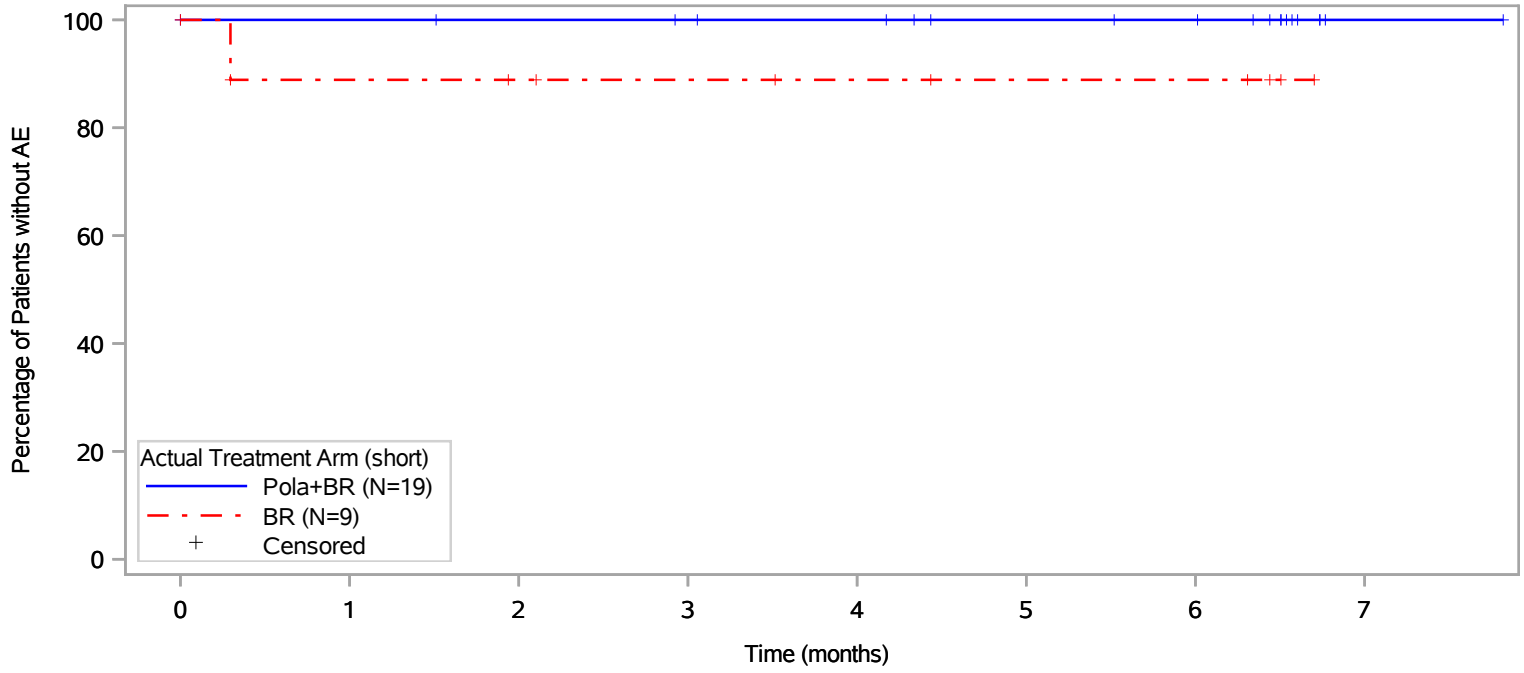
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
EAR AND LABYRINTH DISORDERS, DEAFNESS



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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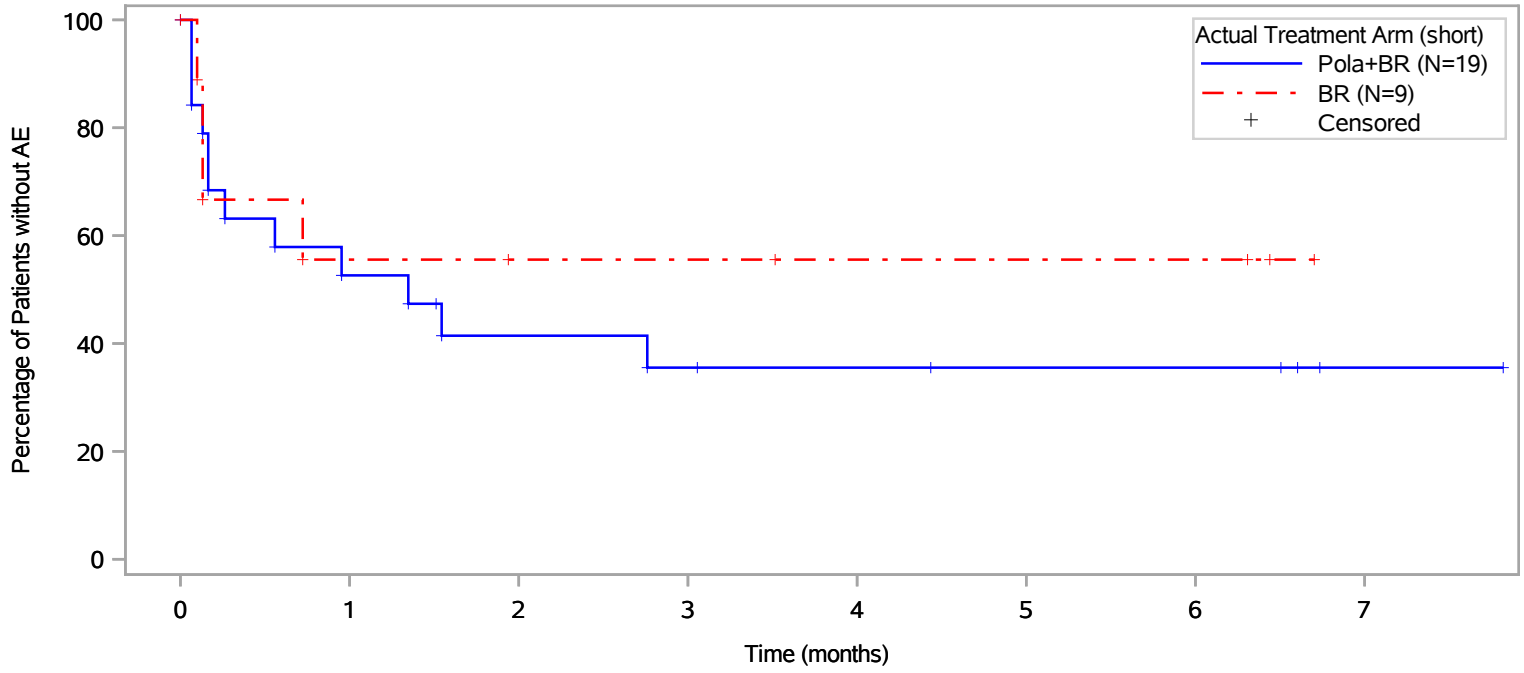
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	10	7	6	5	4	4	1
BR (N=9)	9	5	4	4	3	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	1	2	3	3	6
BR (N=9)	0	0	1	1	2	2	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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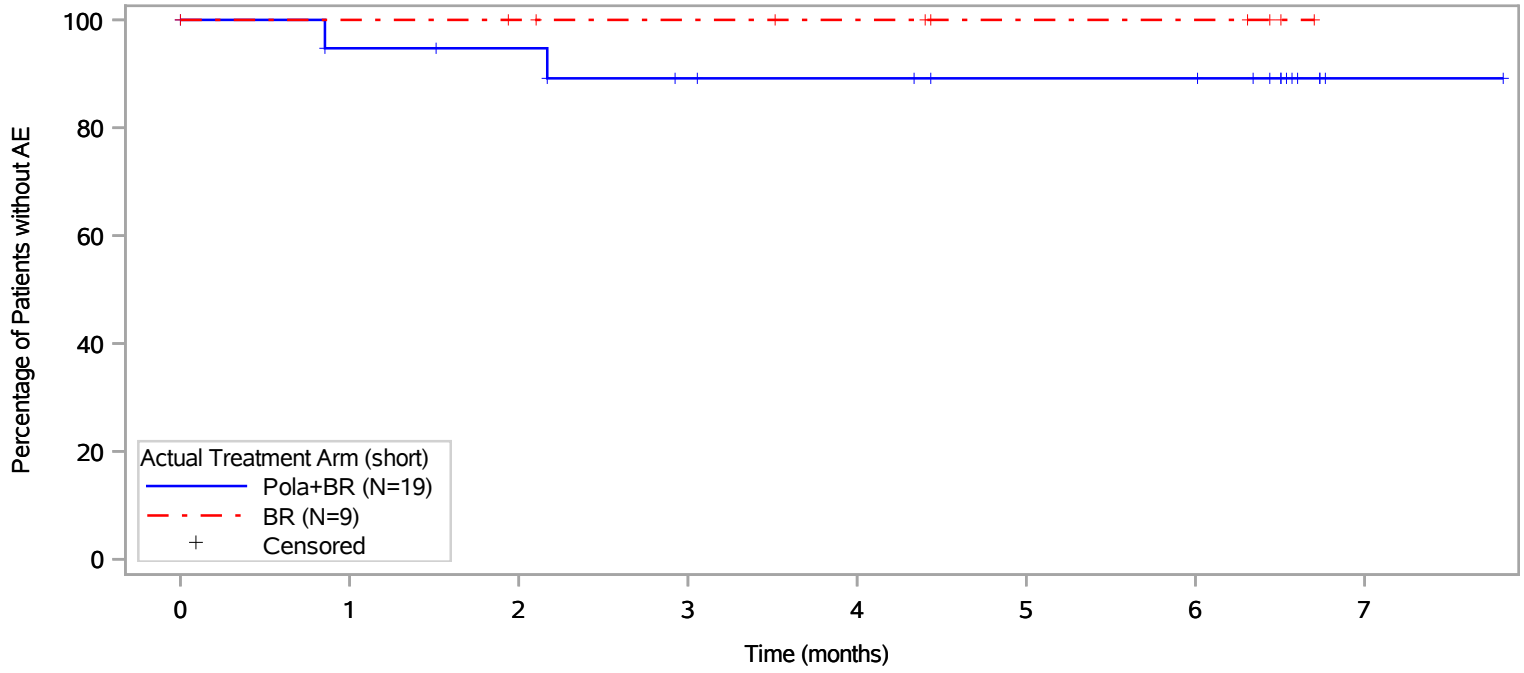
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk								
Pola+BR (N=19)	19	18	17	15	14	12	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	5	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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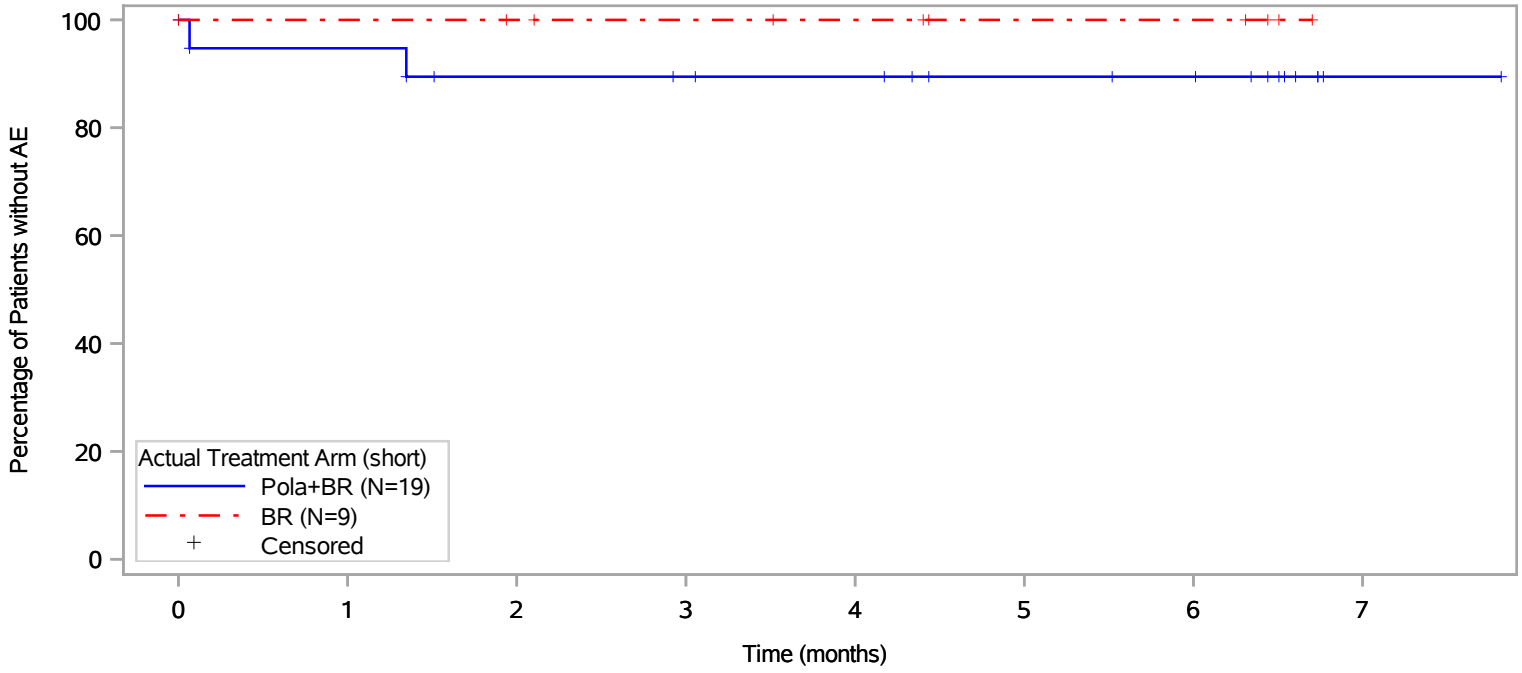
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN UPPER



Patients at risk								
Pola+BR (N=19)	19	18	16	15	14	11	10	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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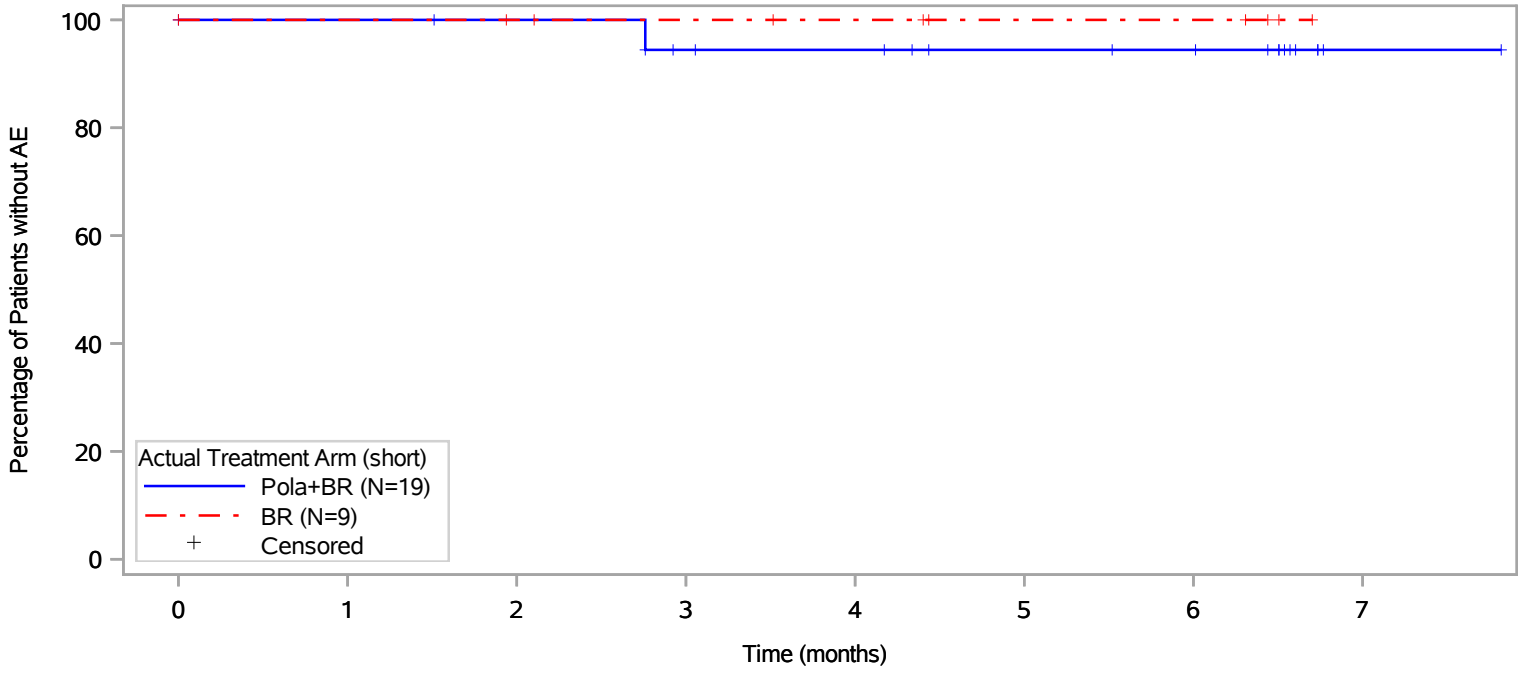
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CHRONIC GASTRITIS



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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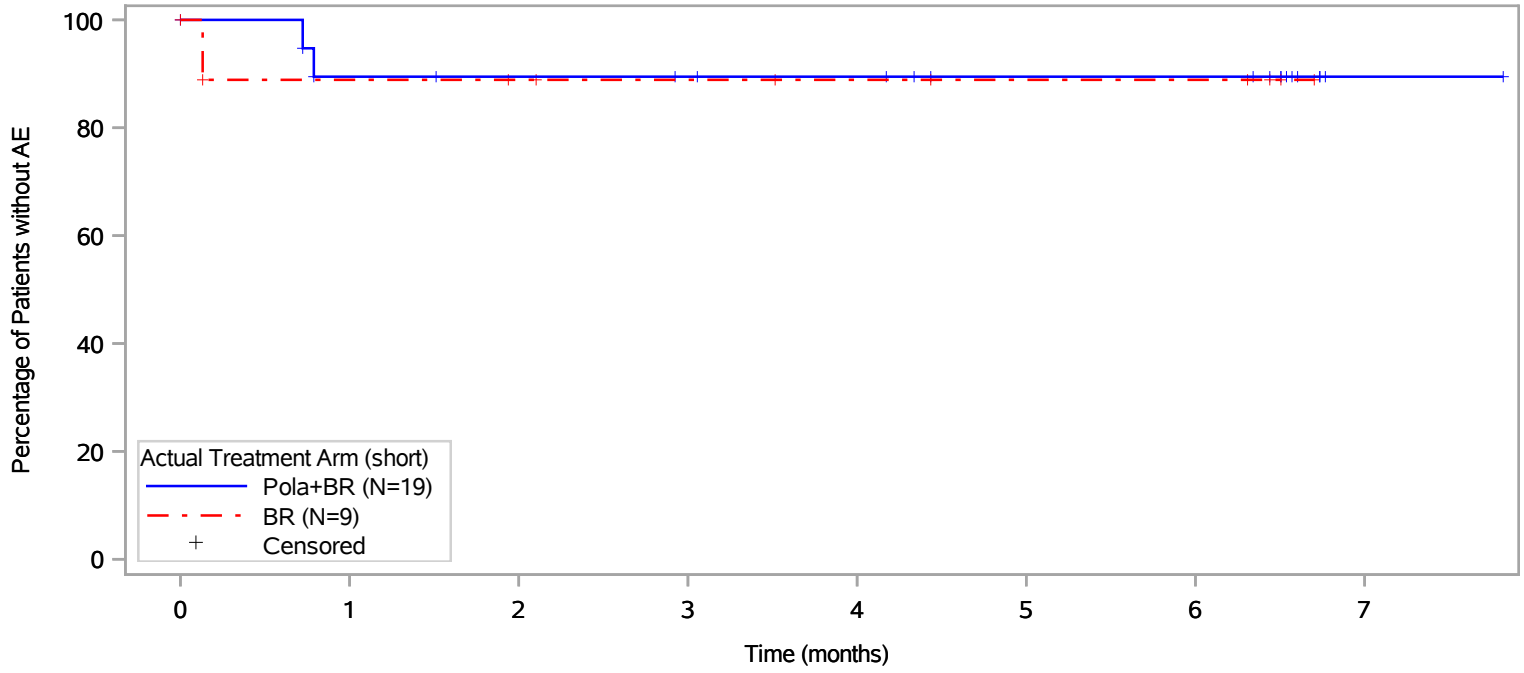
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, CONSTIPATION



Patients at risk								
Pola+BR (N=19)	19	17	16	15	14	11	11	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	16
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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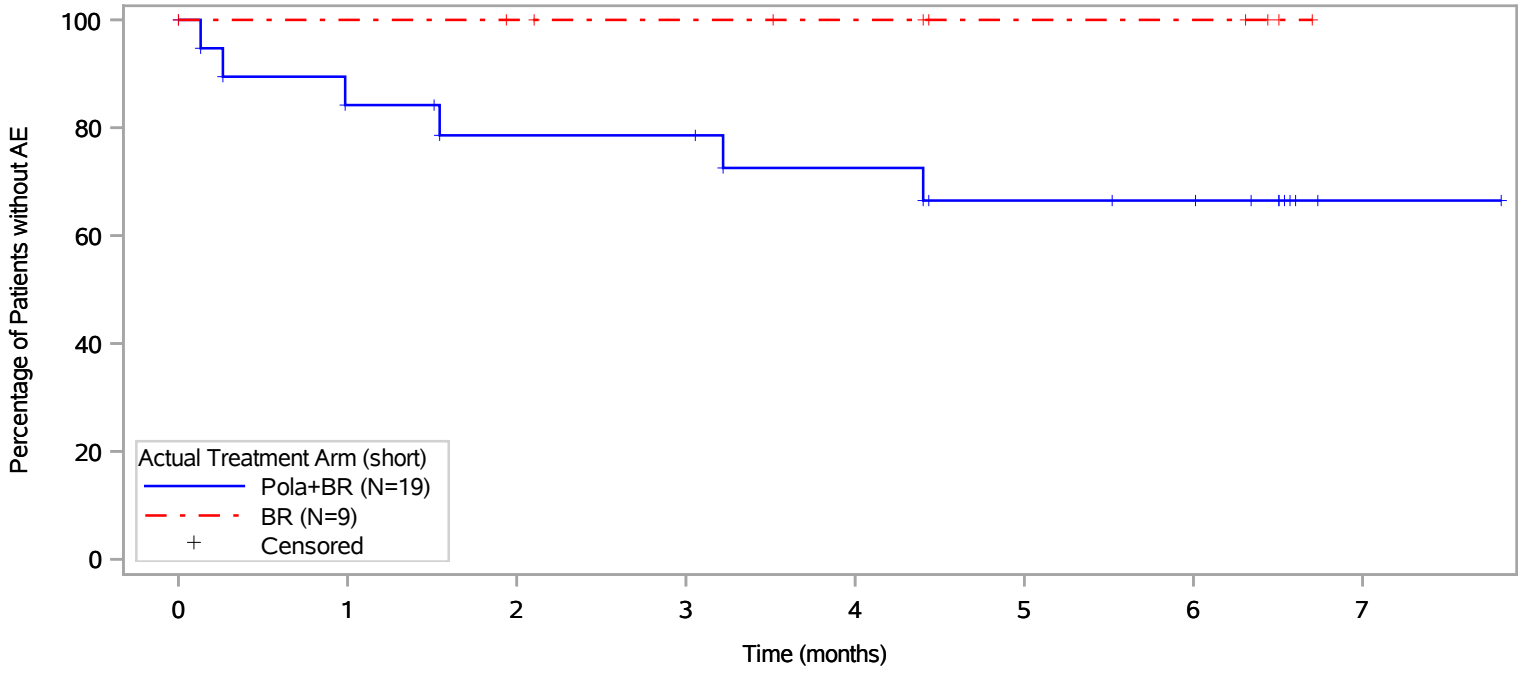
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, DIARRHOEA



Patients at risk								
Pola+BR (N=19)	19	16	14	14	12	10	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	1	2	3	4	12
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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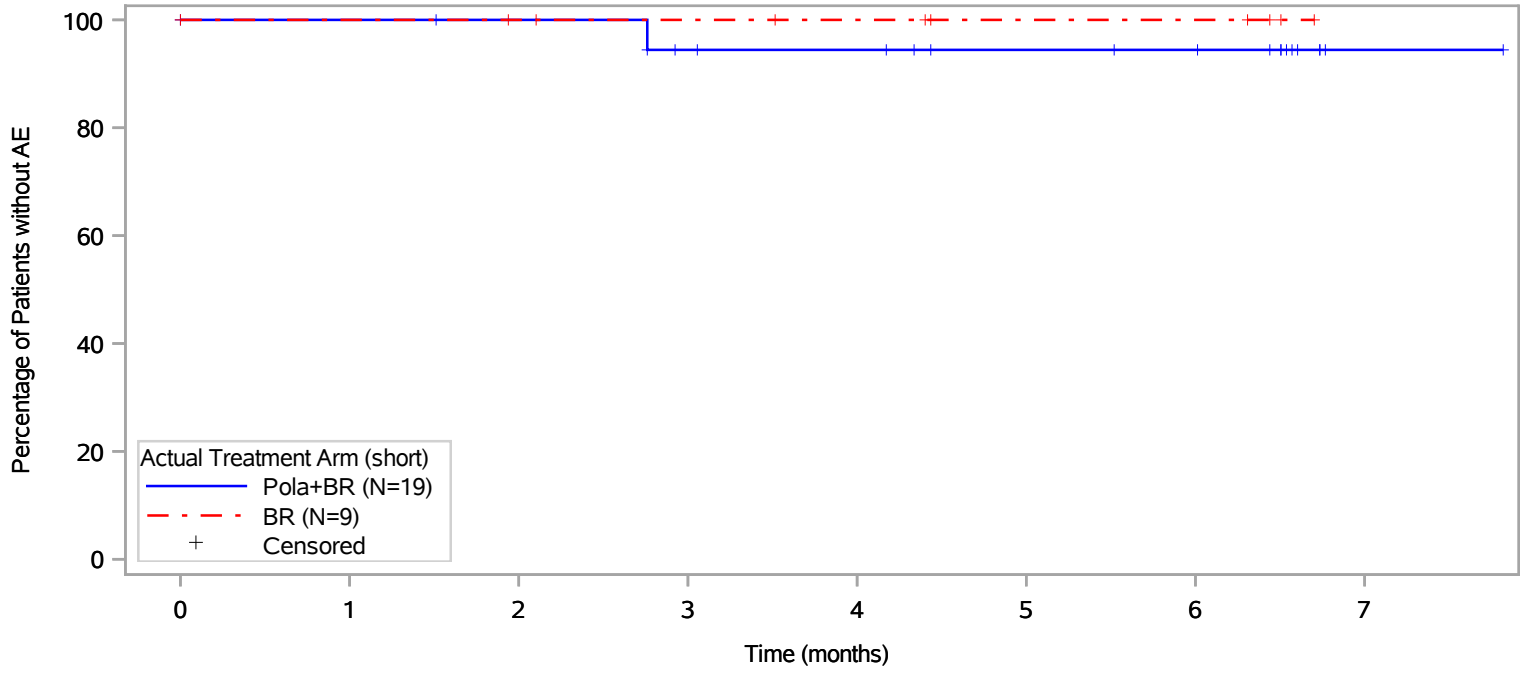
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, GASTRIC POLYPS



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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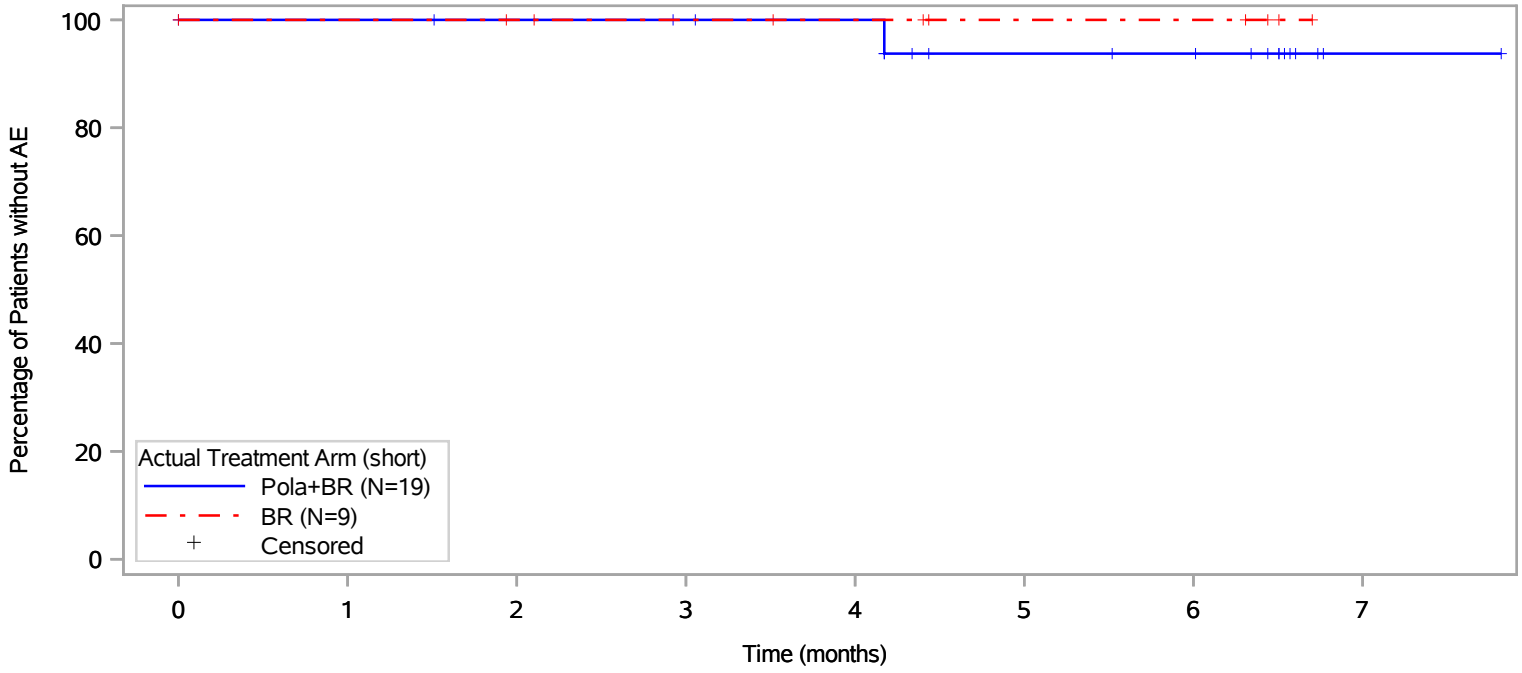
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, MOUTH ULCERATION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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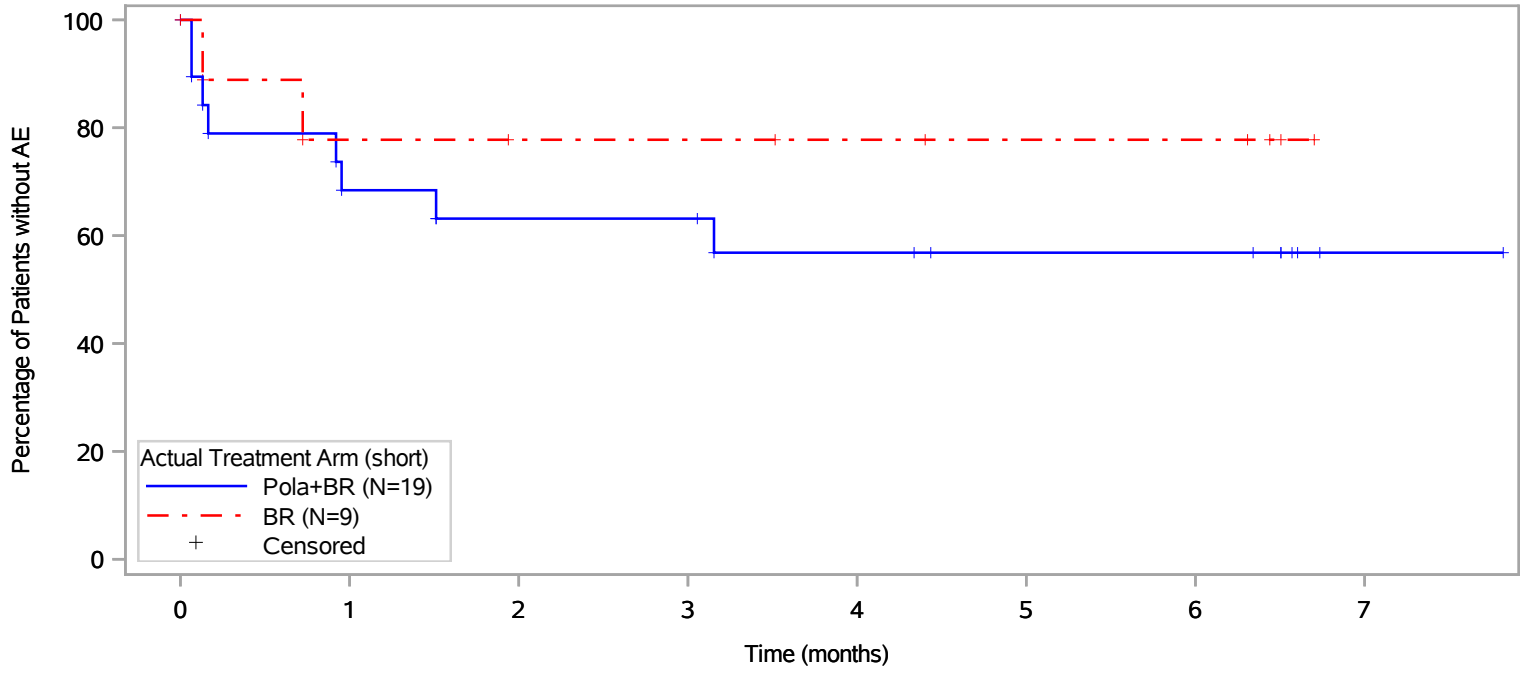
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, NAUSEA



Patients at risk								
Pola+BR (N=19)	19	13	11	11	9	7	7	1
BR (N=9)	9	7	6	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	1	2	4	4	10
BR (N=9)	0	0	1	1	2	3	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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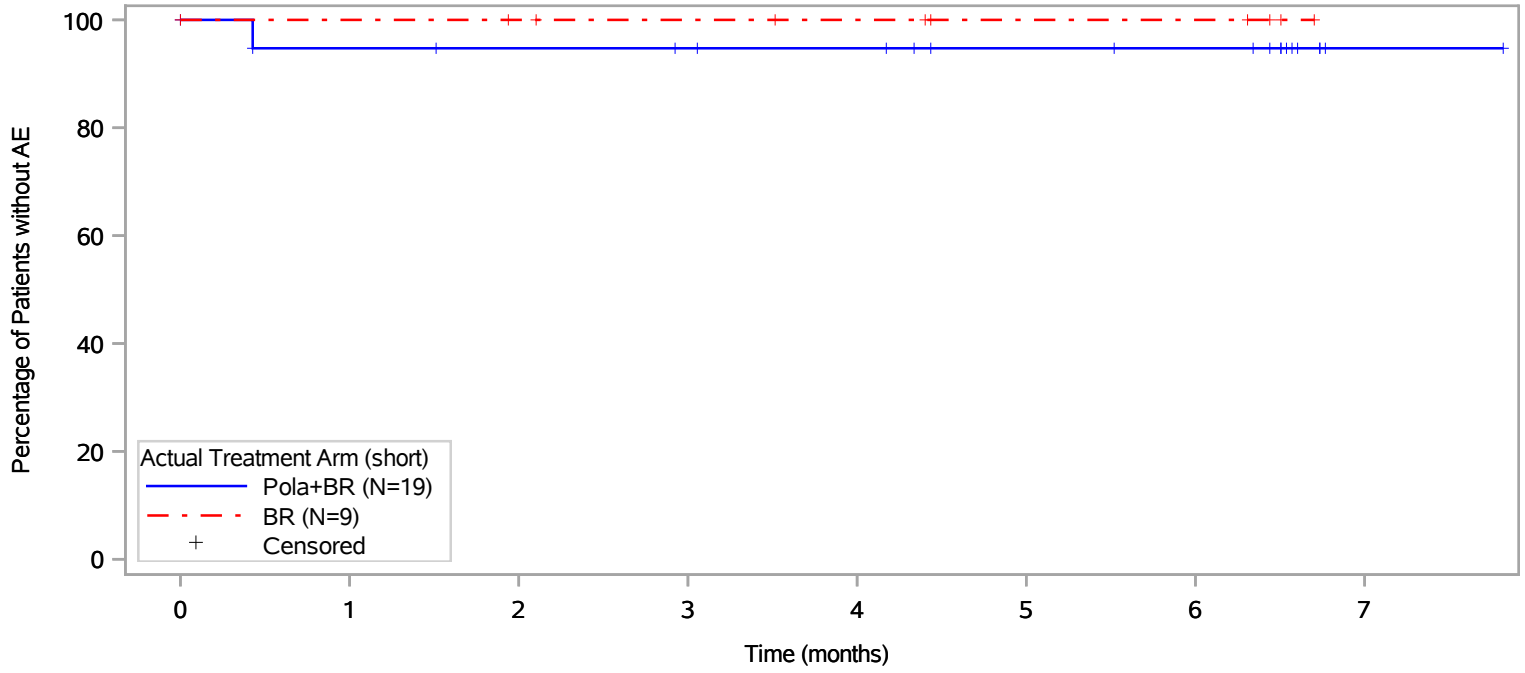
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, STOMATITIS



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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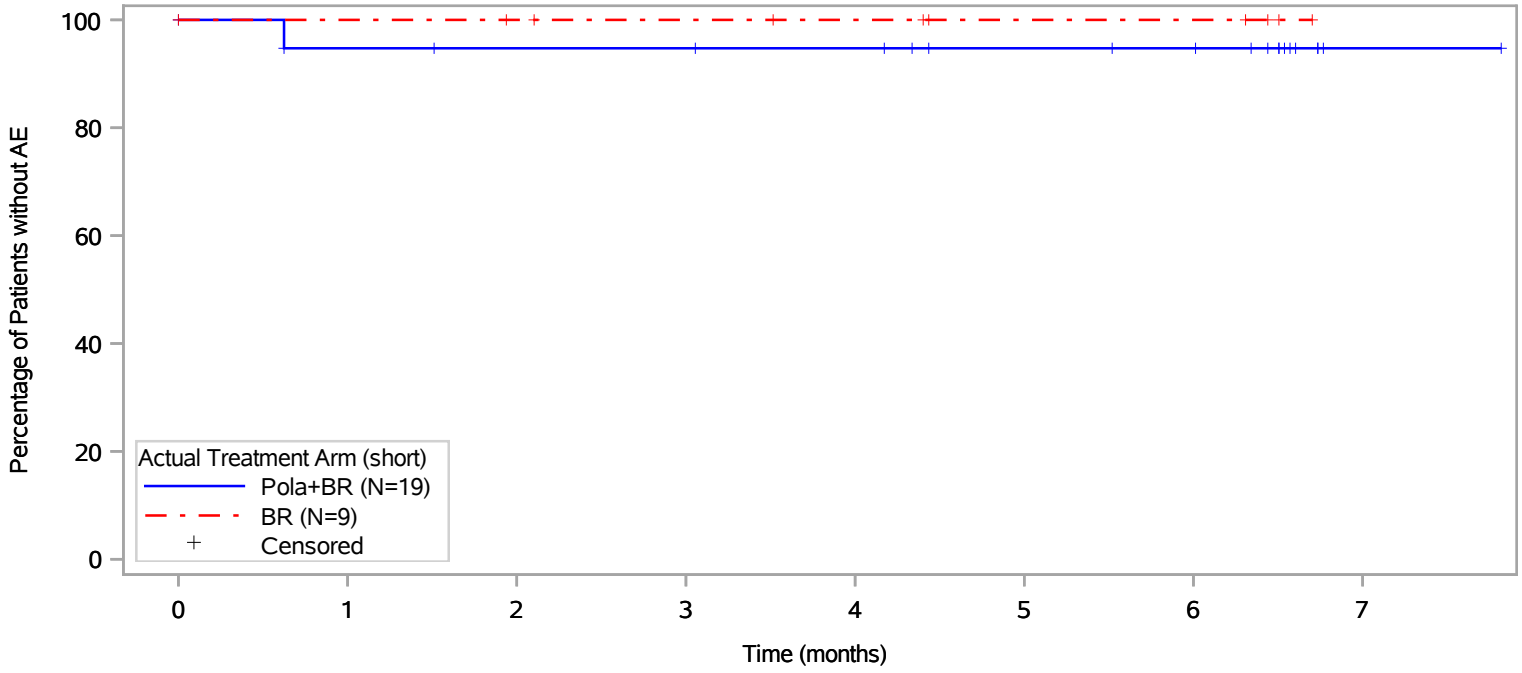
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, SUBILEUS



Patients at risk								
Pola+BR (N=19)	19	18	17	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	1	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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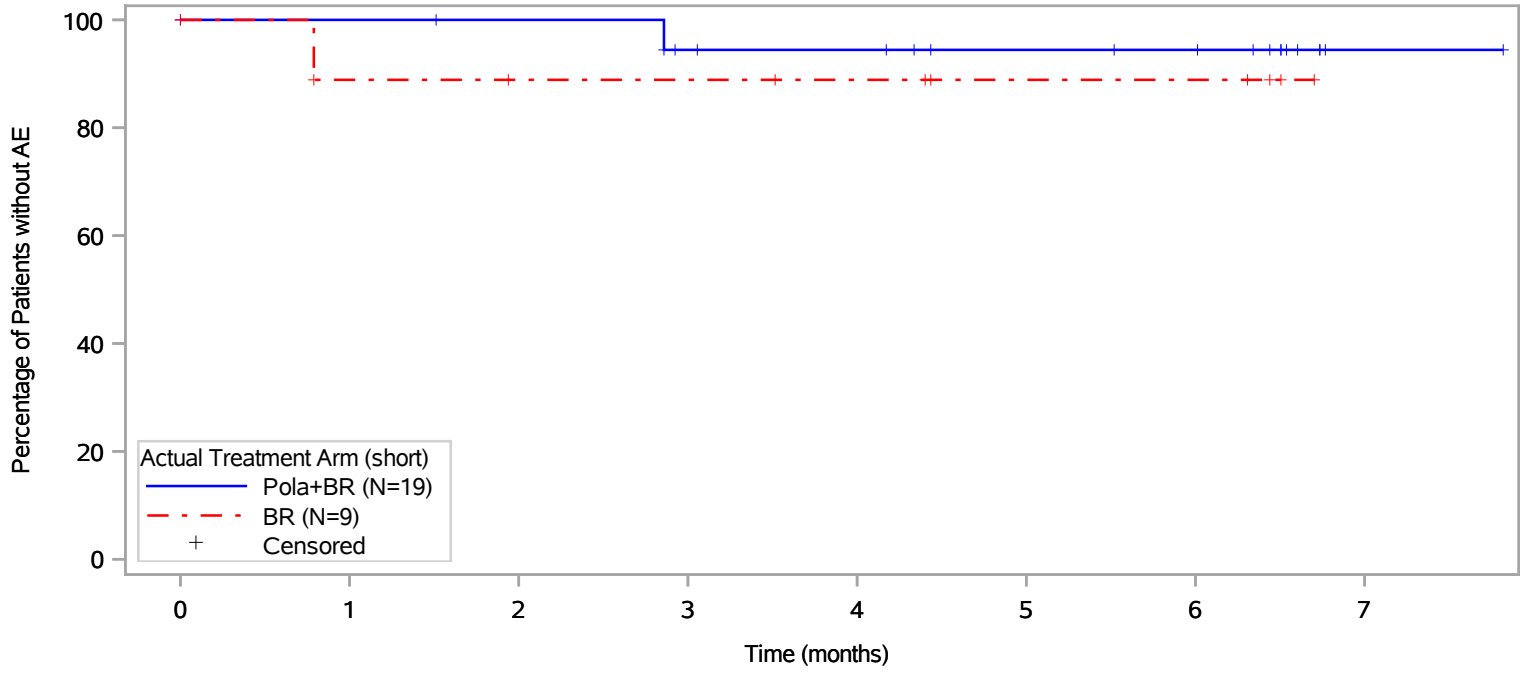
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, UPPER GASTROINTESTINAL HAEMORRHAGE



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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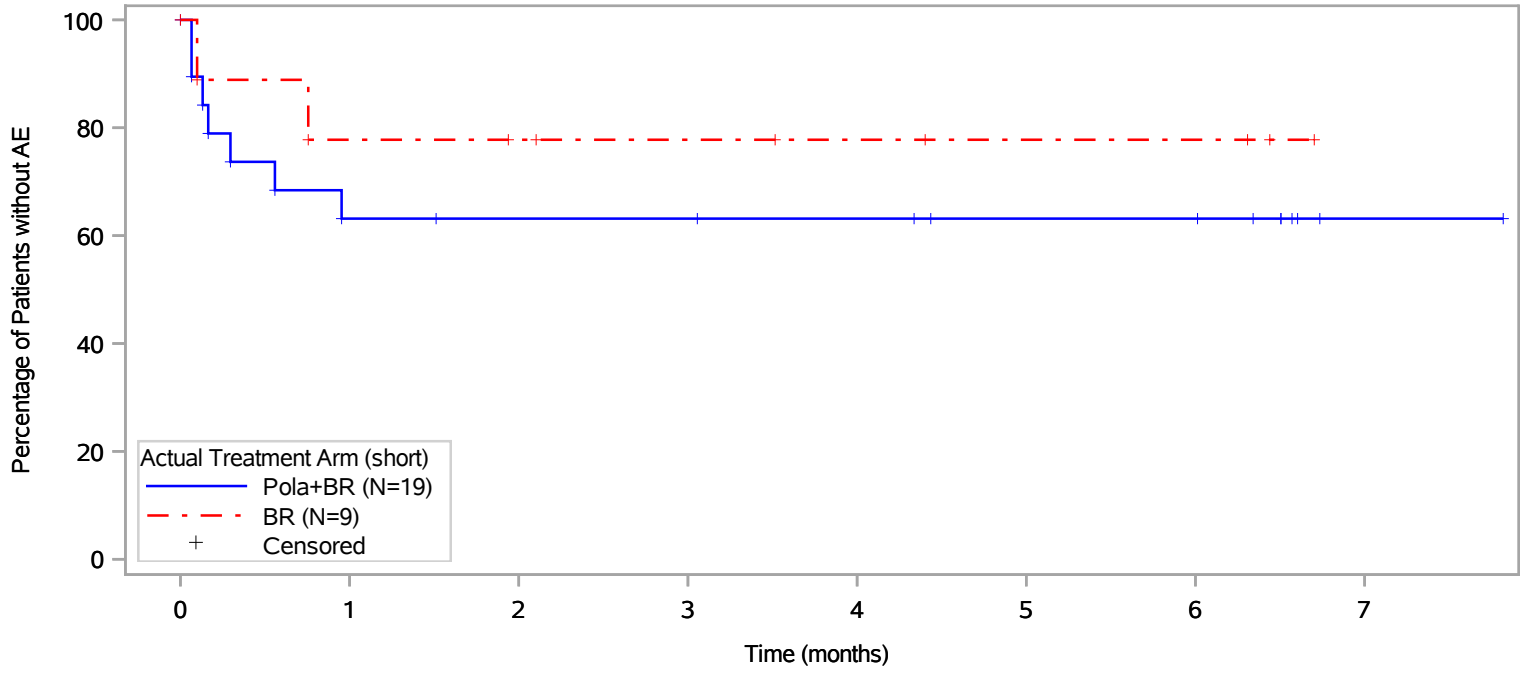
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, VOMITING

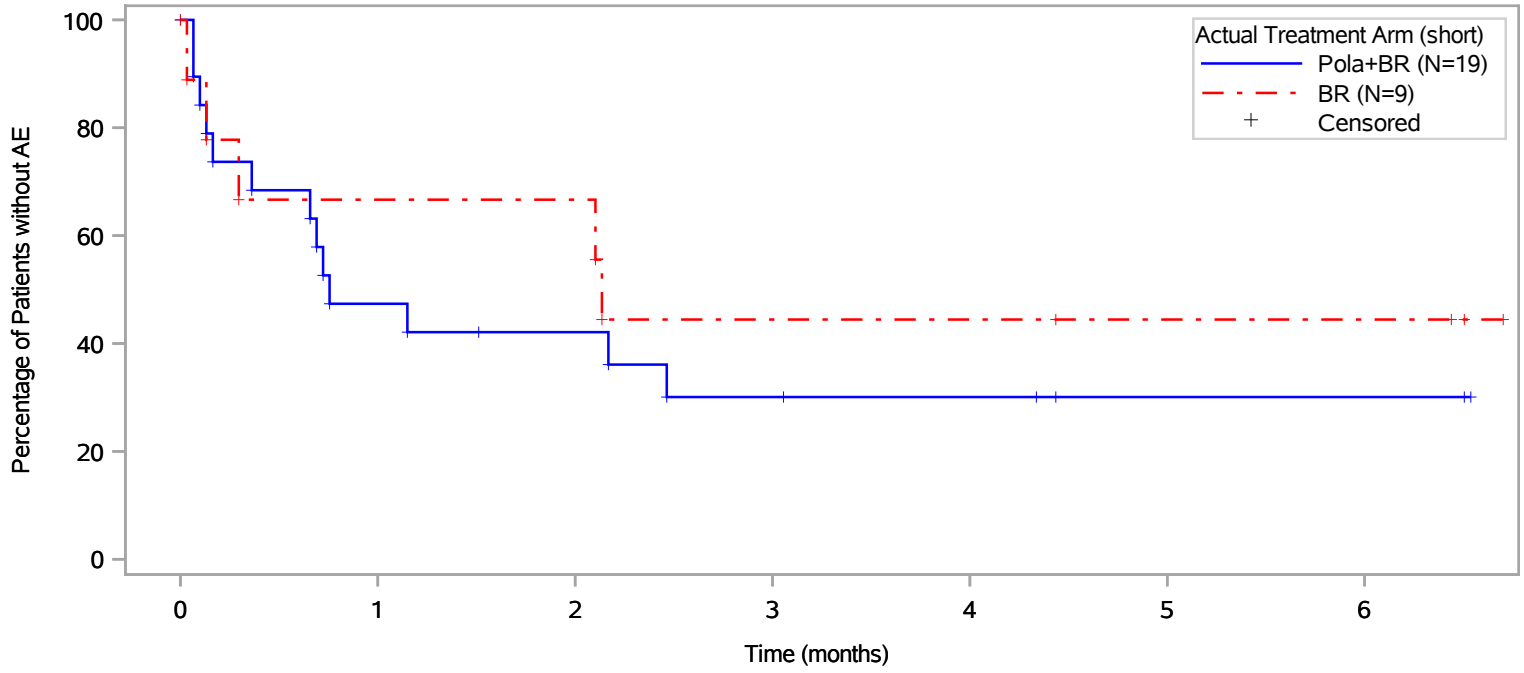


Patients at risk								
Pola+BR (N=19)	19	12	11	11	10	8	8	1
BR (N=9)	9	7	6	5	4	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	1	2	4	4	11
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk							
Pola+BR (N=19)	19	9	7	5	4	2	2
BR (N=9)	9	6	6	4	4	3	3
Patients censored							
Pola+BR (N=19)	0	0	1	1	2	4	4
BR (N=9)	0	0	0	0	0	1	1

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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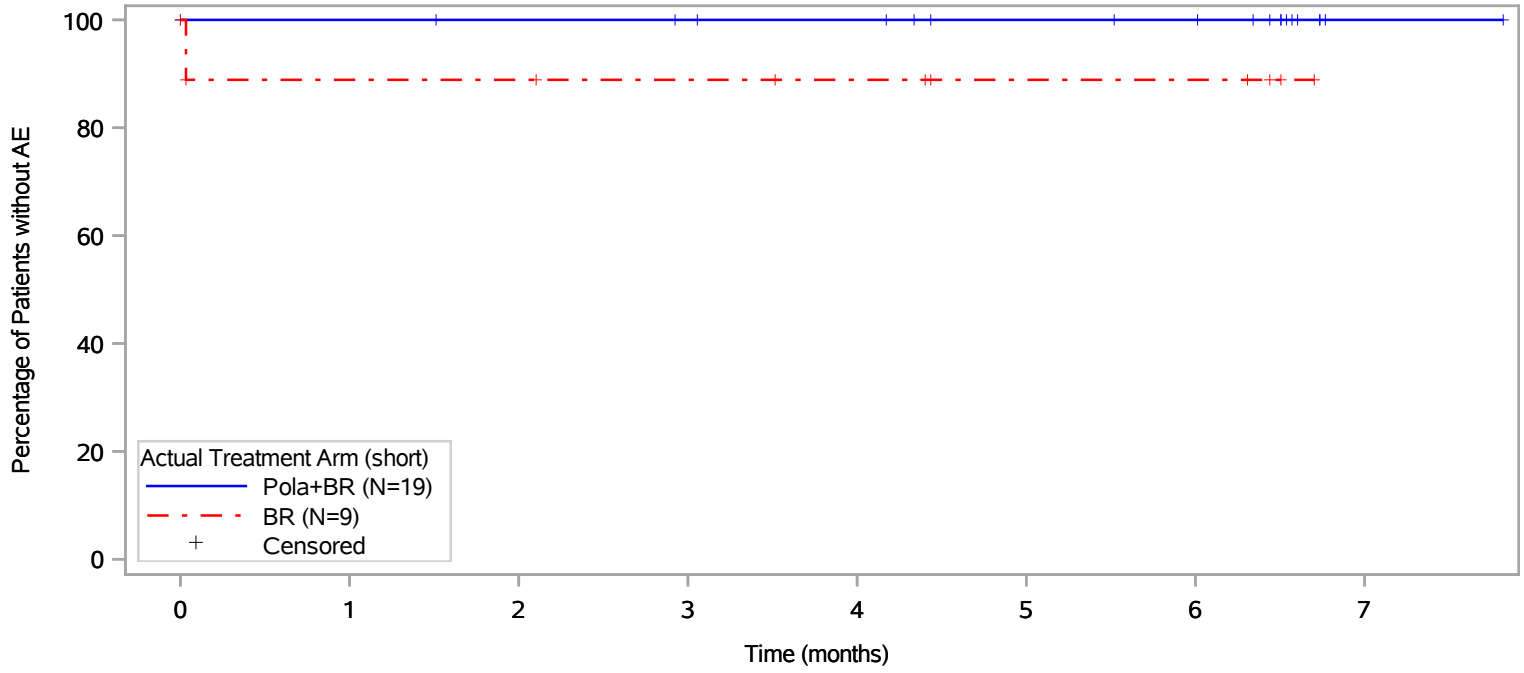
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHEST DISCOMFORT



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	0	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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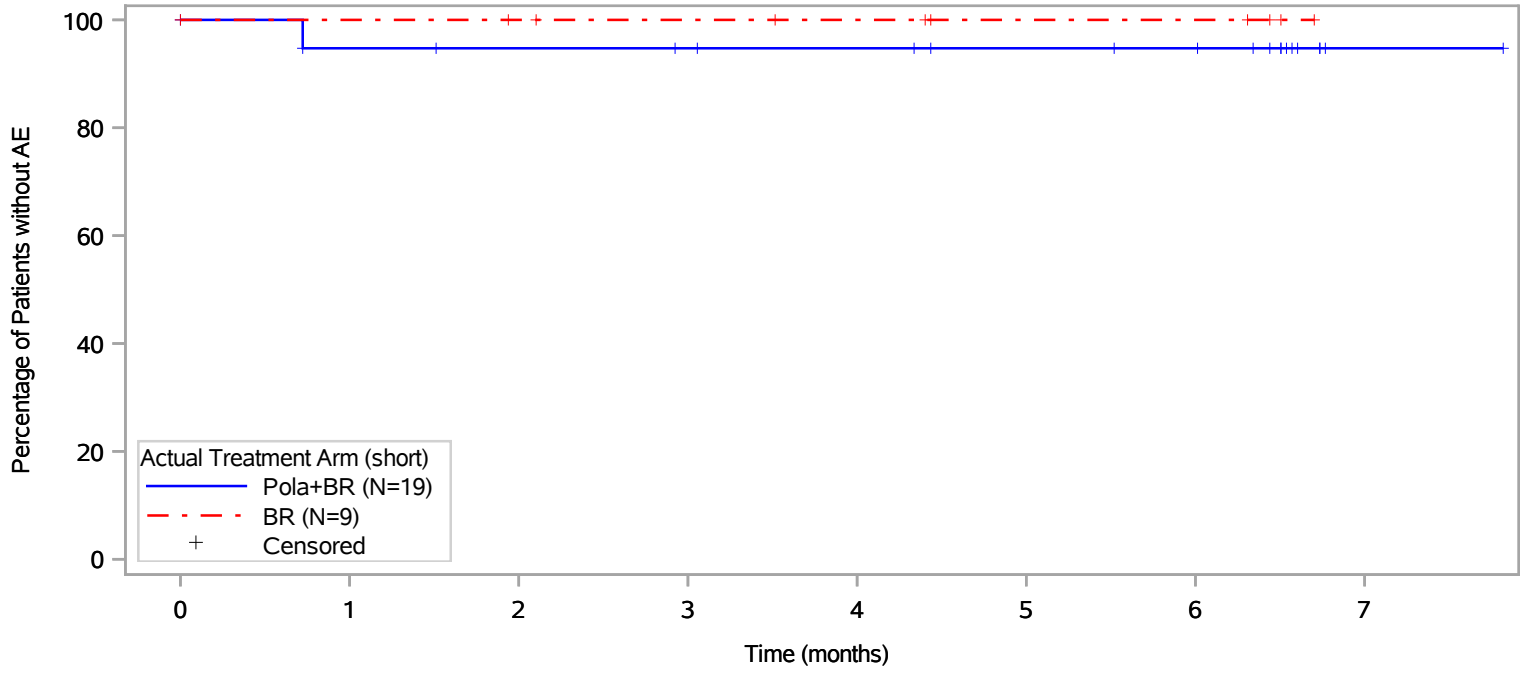
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, CHILLS

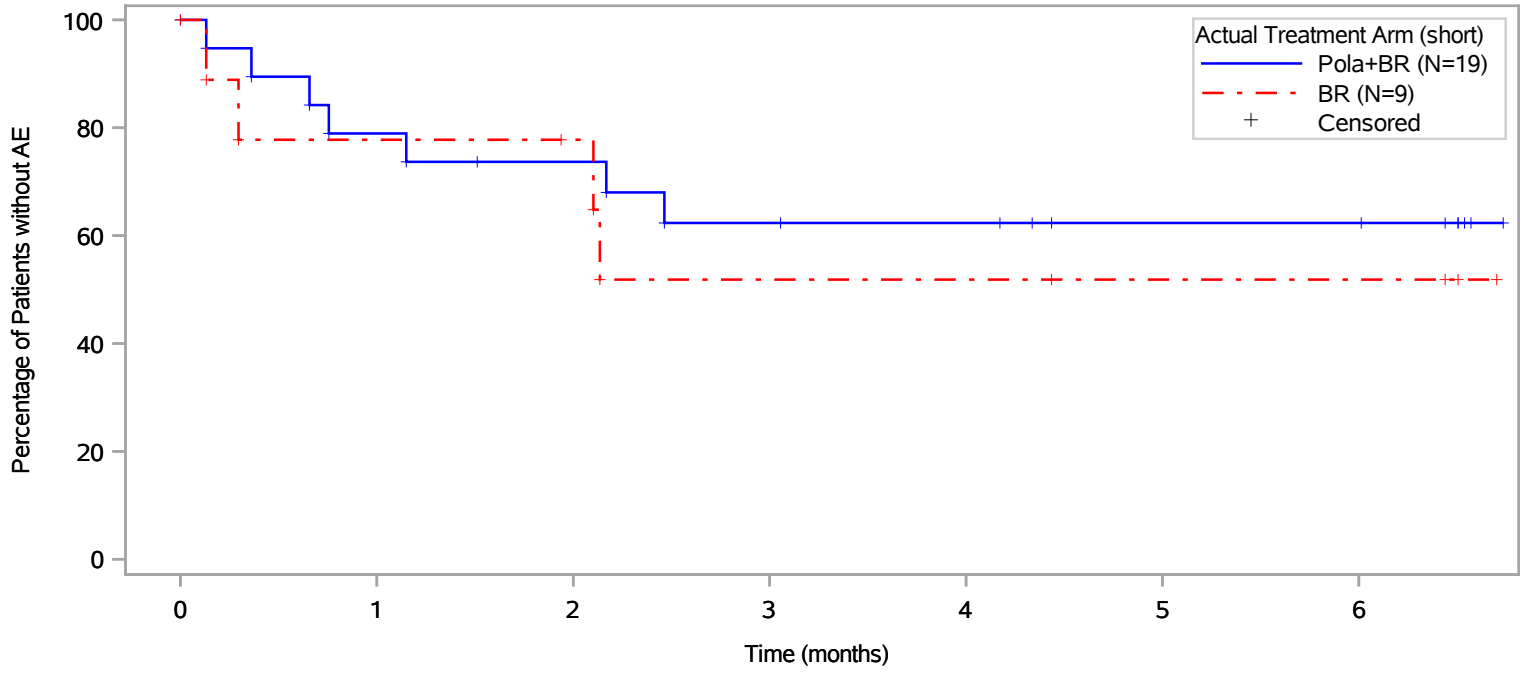


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, FATIGUE



Patients at risk							
Pola+BR (N=19)	19	15	13	11	10	7	7
BR (N=9)	9	7	6	4	4	3	3
Patients censored							
Pola+BR (N=19)	0	0	1	1	2	5	5
BR (N=9)	0	0	1	1	1	2	2

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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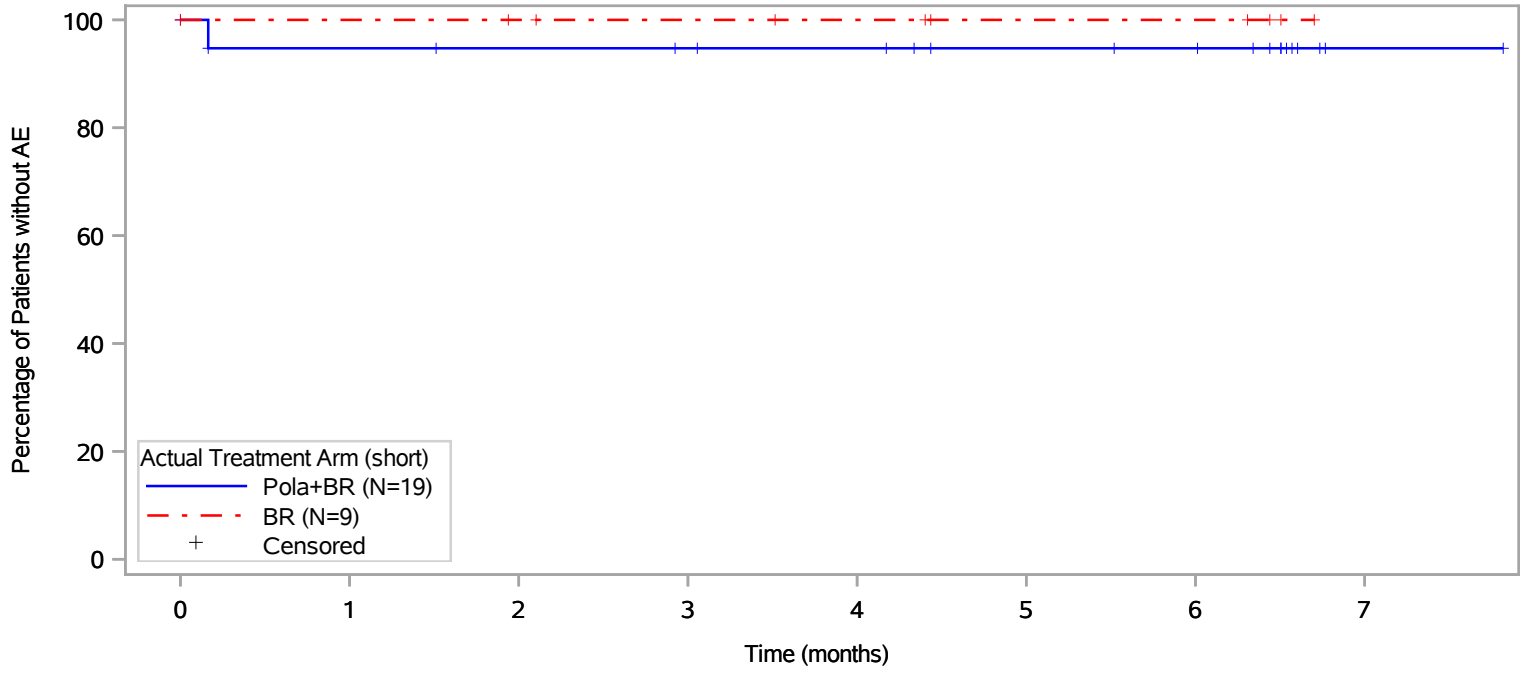
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, MALAISE



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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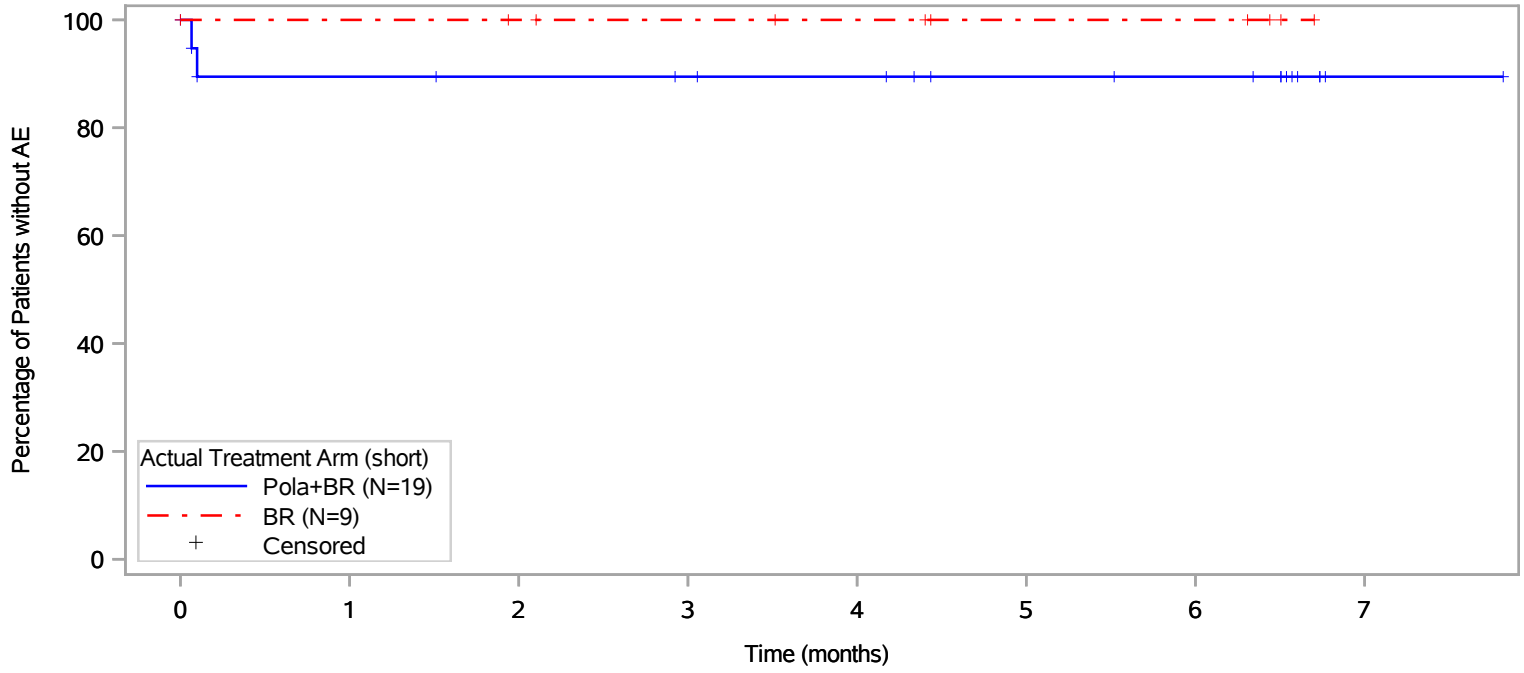
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, OEDEMA PERIPHERAL



Patients at risk								
Pola+BR (N=19)	19	17	16	15	14	11	10	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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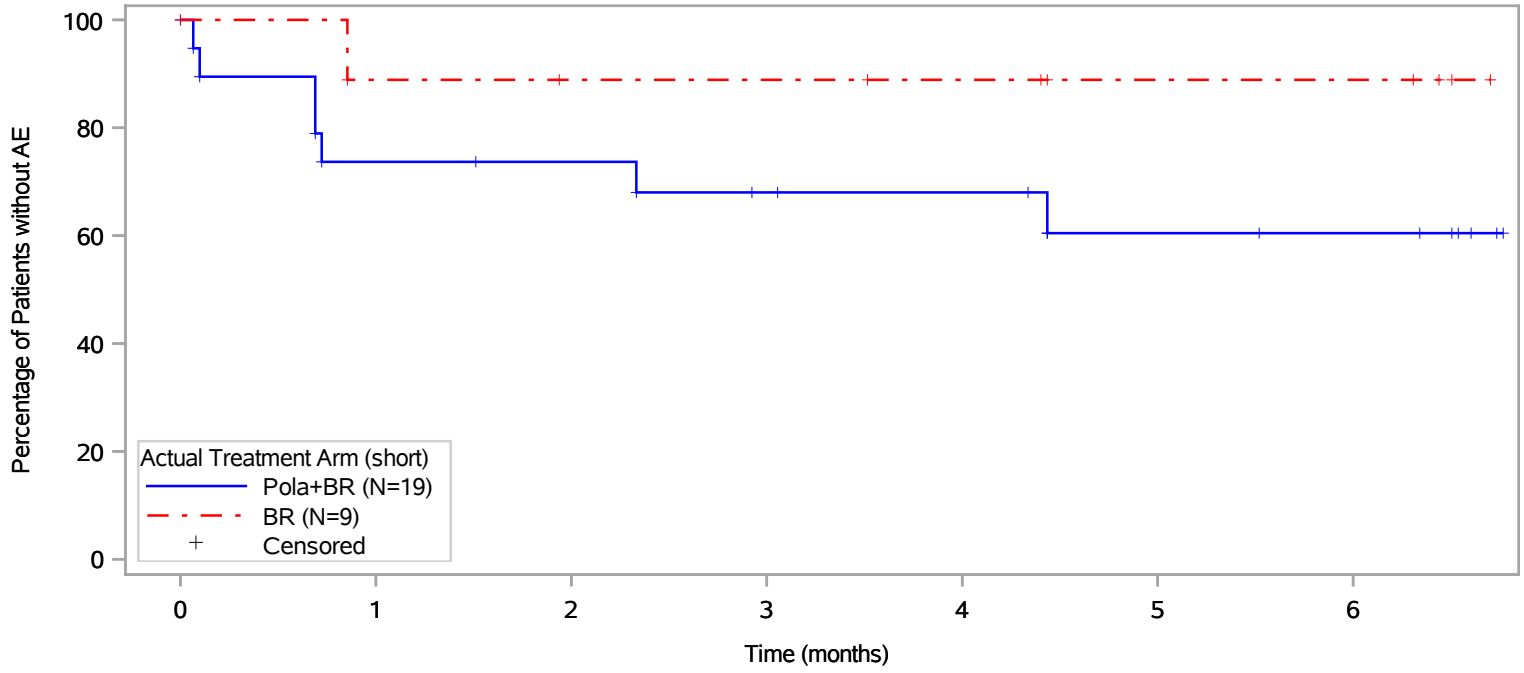
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

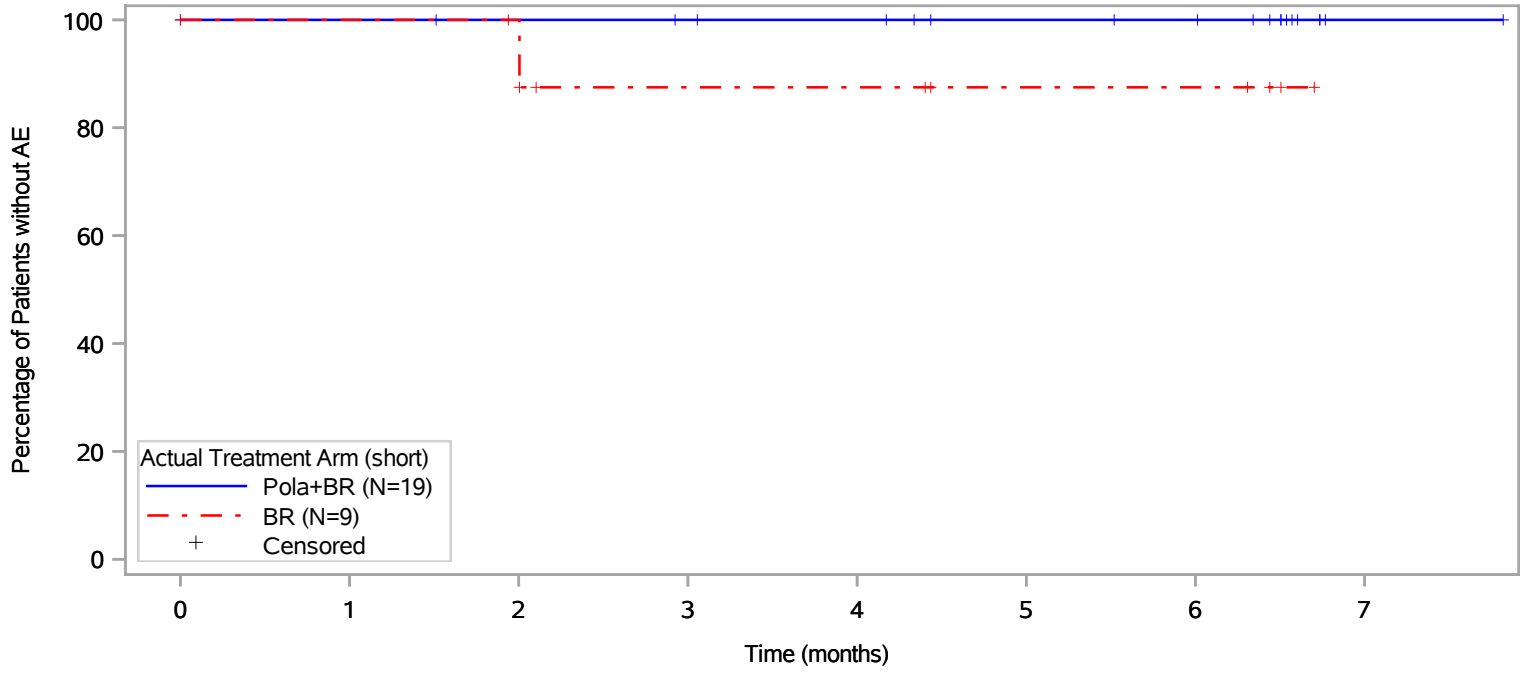
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk							
Pola+BR (N=19)	19	14	13	11	10	7	6
BR (N=9)	9	8	7	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	5	6
BR (N=9)	0	0	1	1	2	4	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
HEPATOBILIARY DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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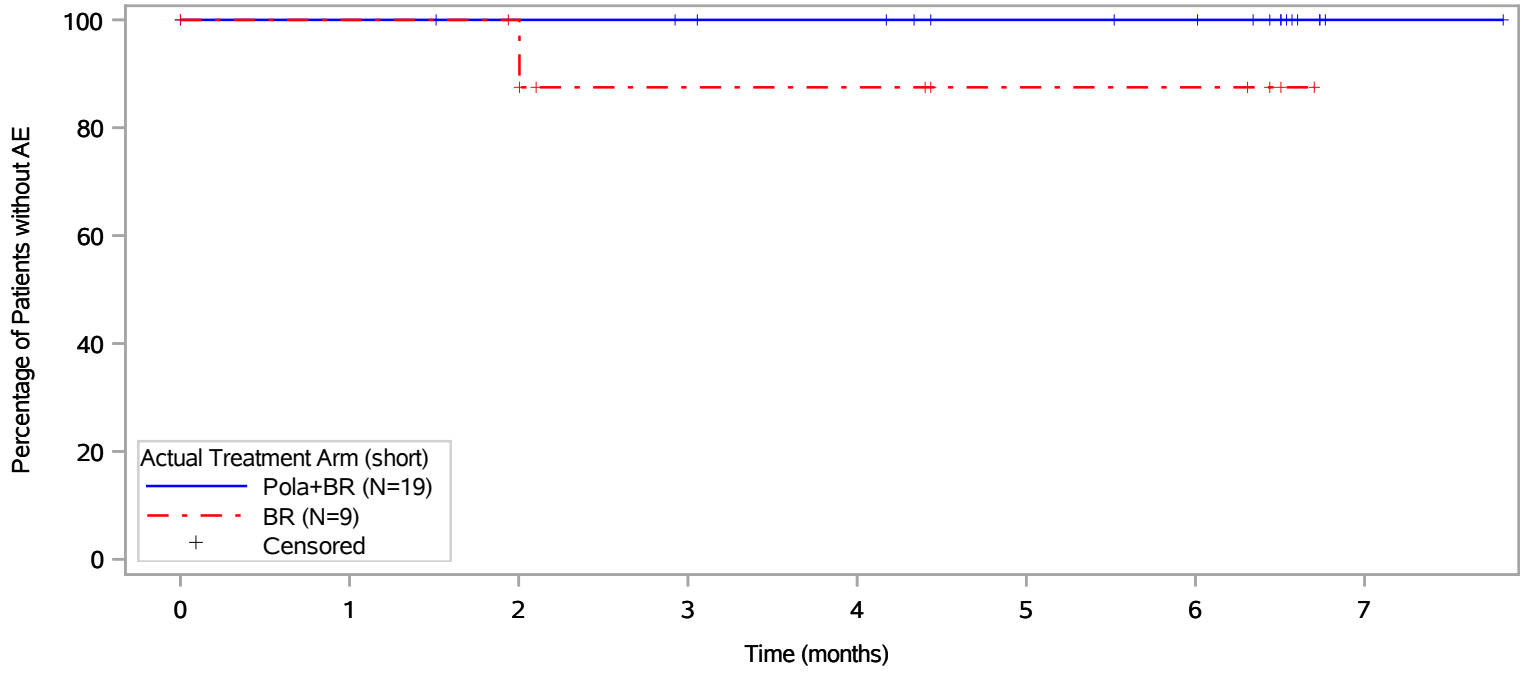
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
HEPATOBILIARY DISORDERS, HEPATIC FUNCTION ABNORMAL



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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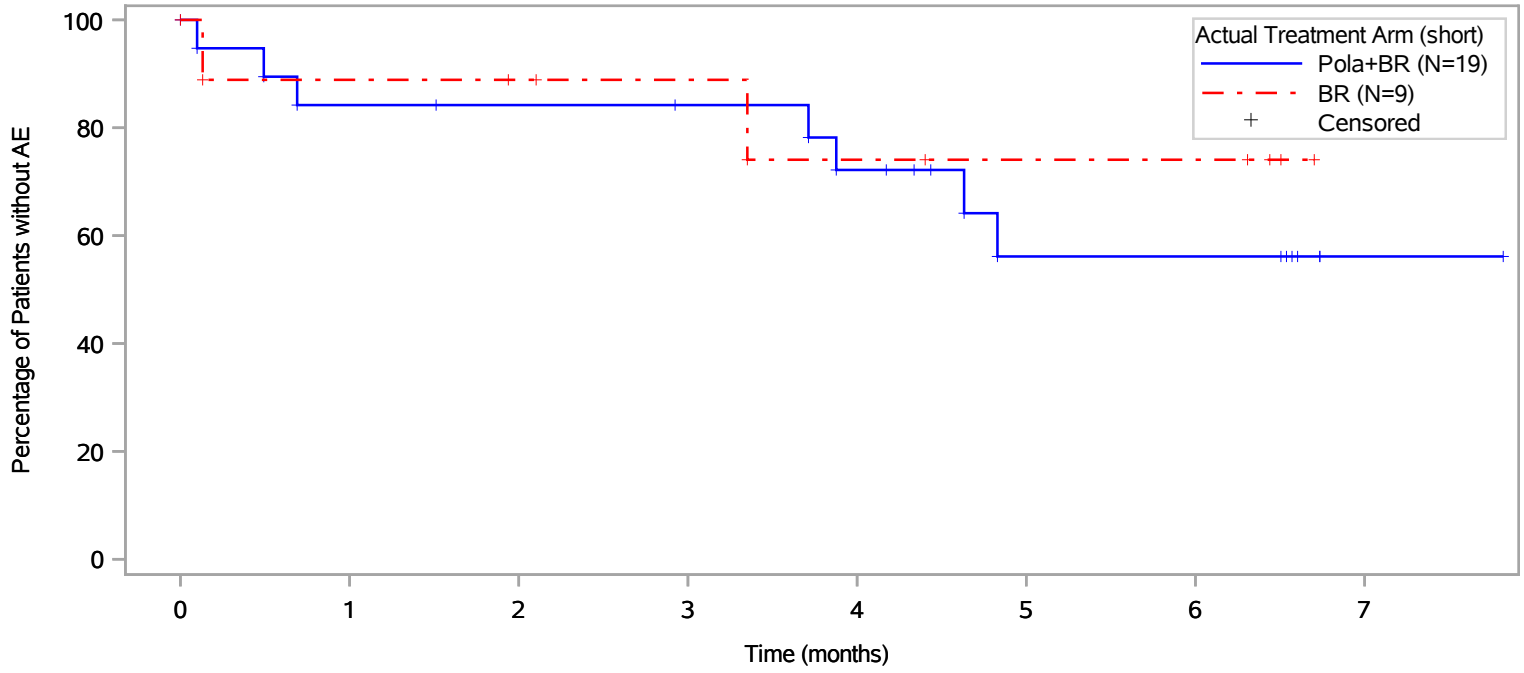
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk								
Pola+BR (N=19)	19	16	15	14	12	7	7	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	11
BR (N=9)	0	0	1	2	2	3	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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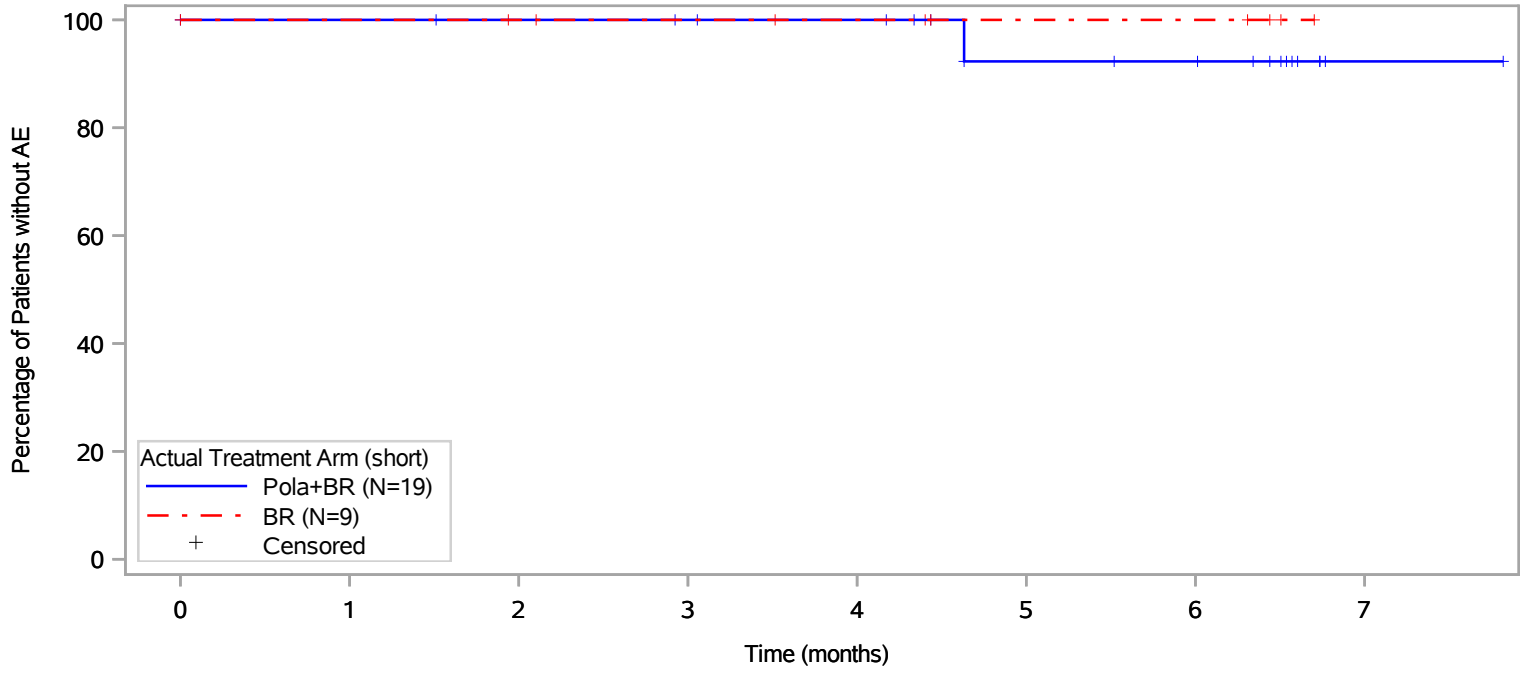
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, HERPES ZOSTER



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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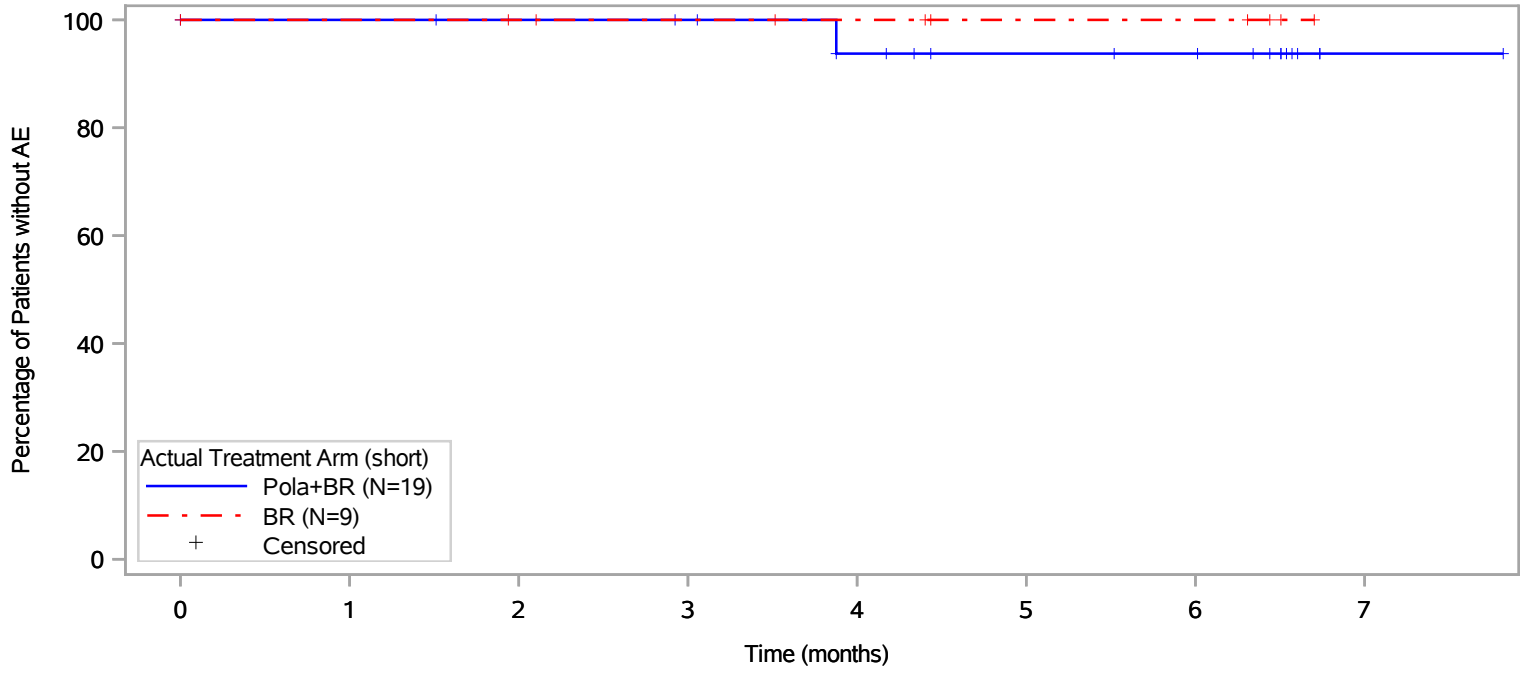
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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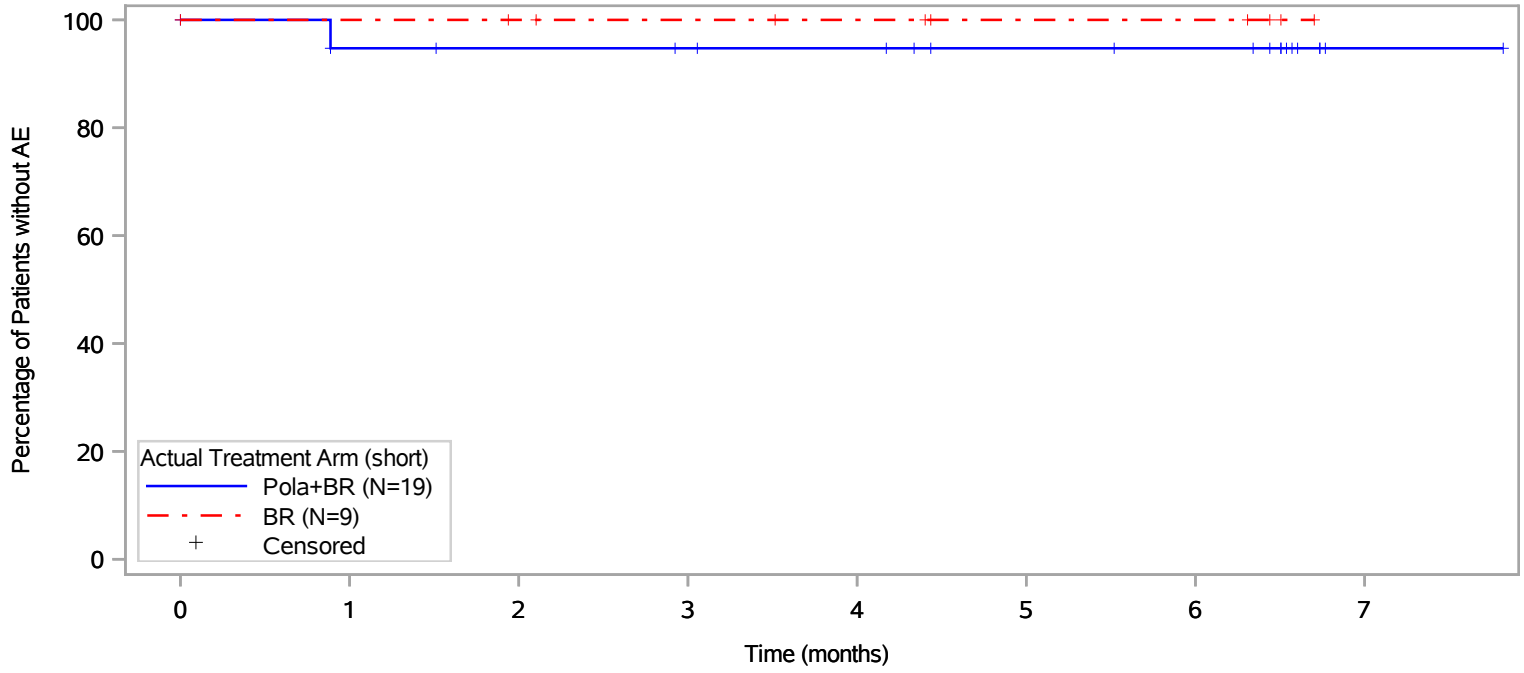
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, MYCOPLASMA INFECTION



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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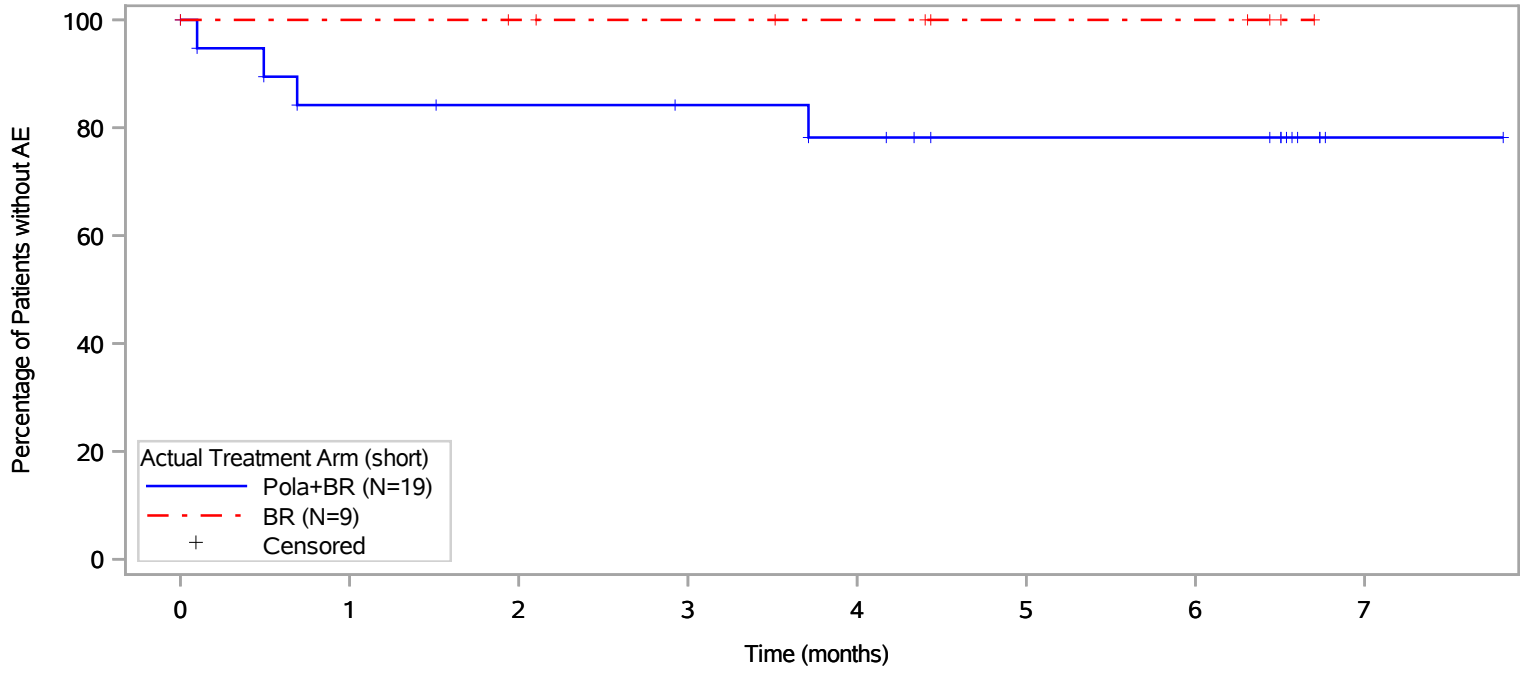
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk								
Pola+BR (N=19)	19	16	15	14	13	10	10	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	14
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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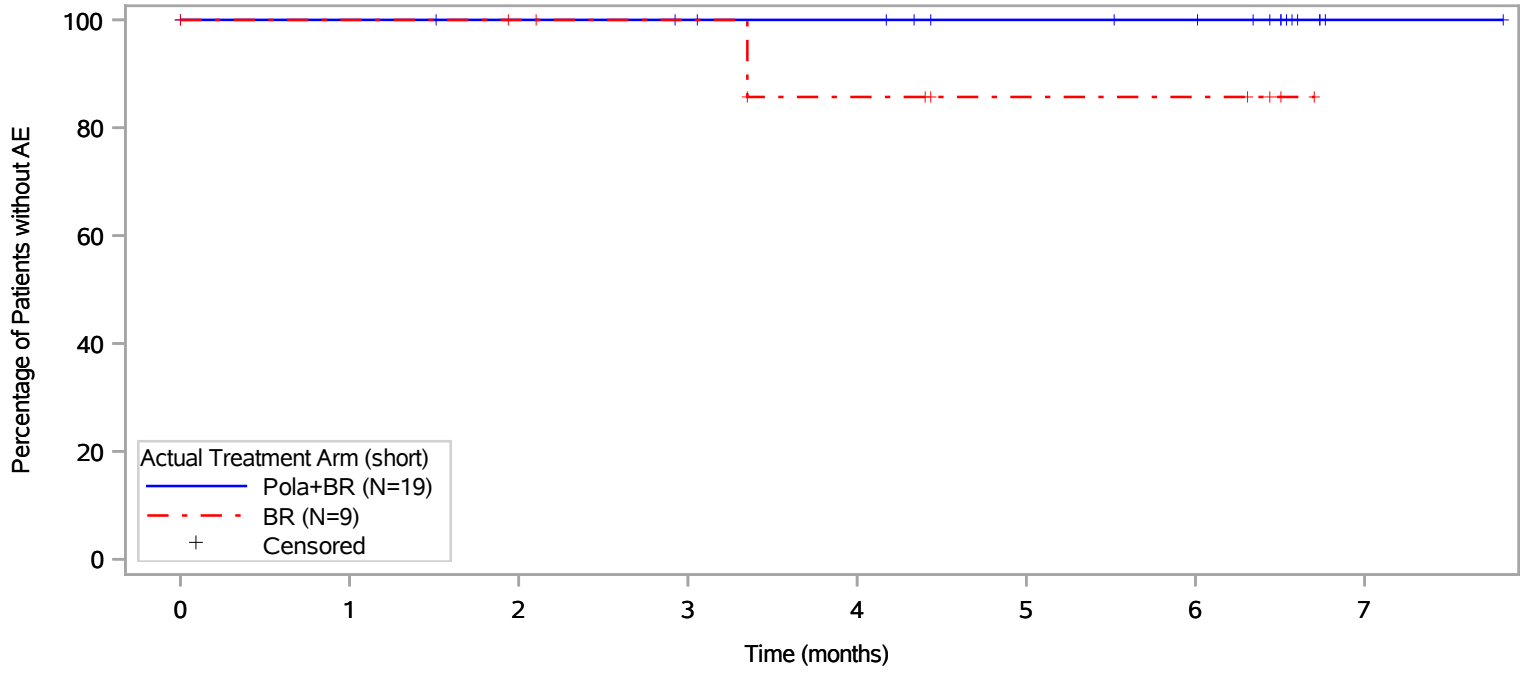
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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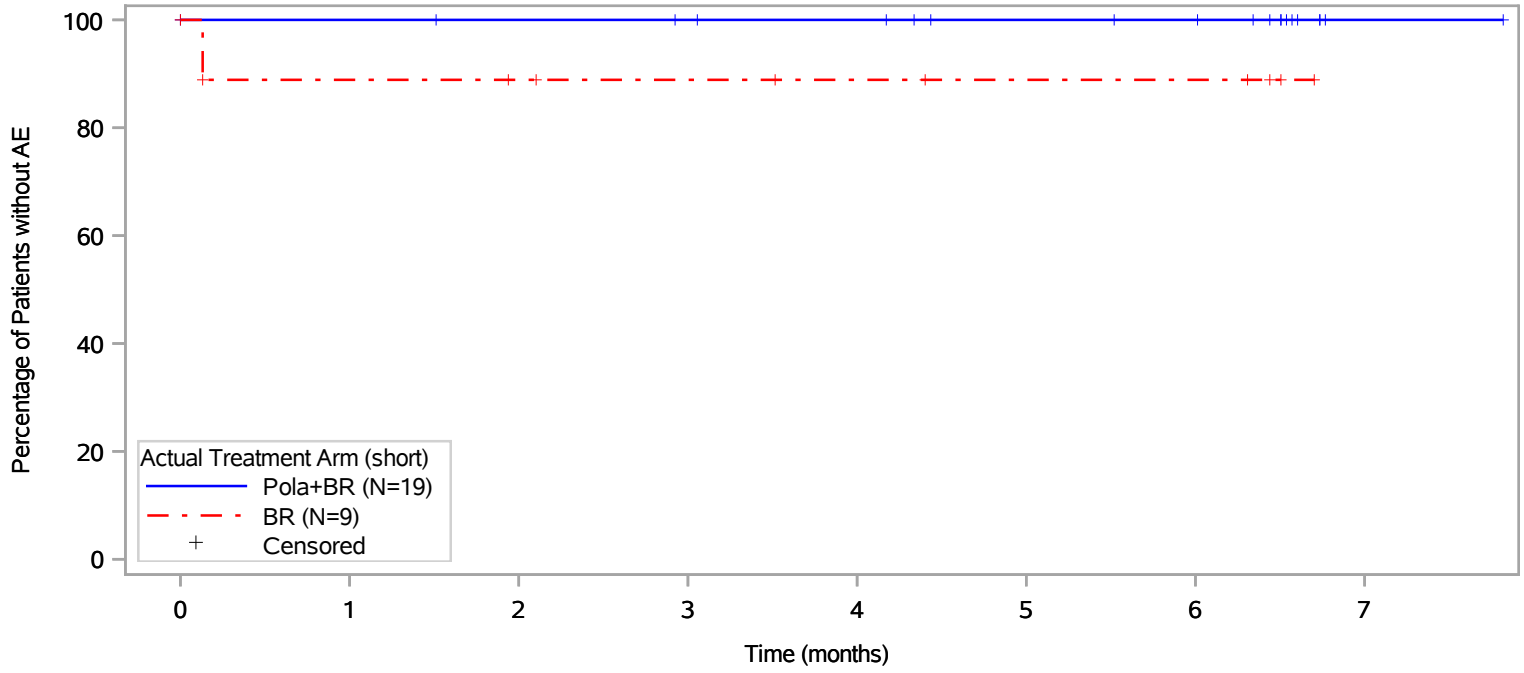
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, UPPER RESPIRATORY TRACT INFECTION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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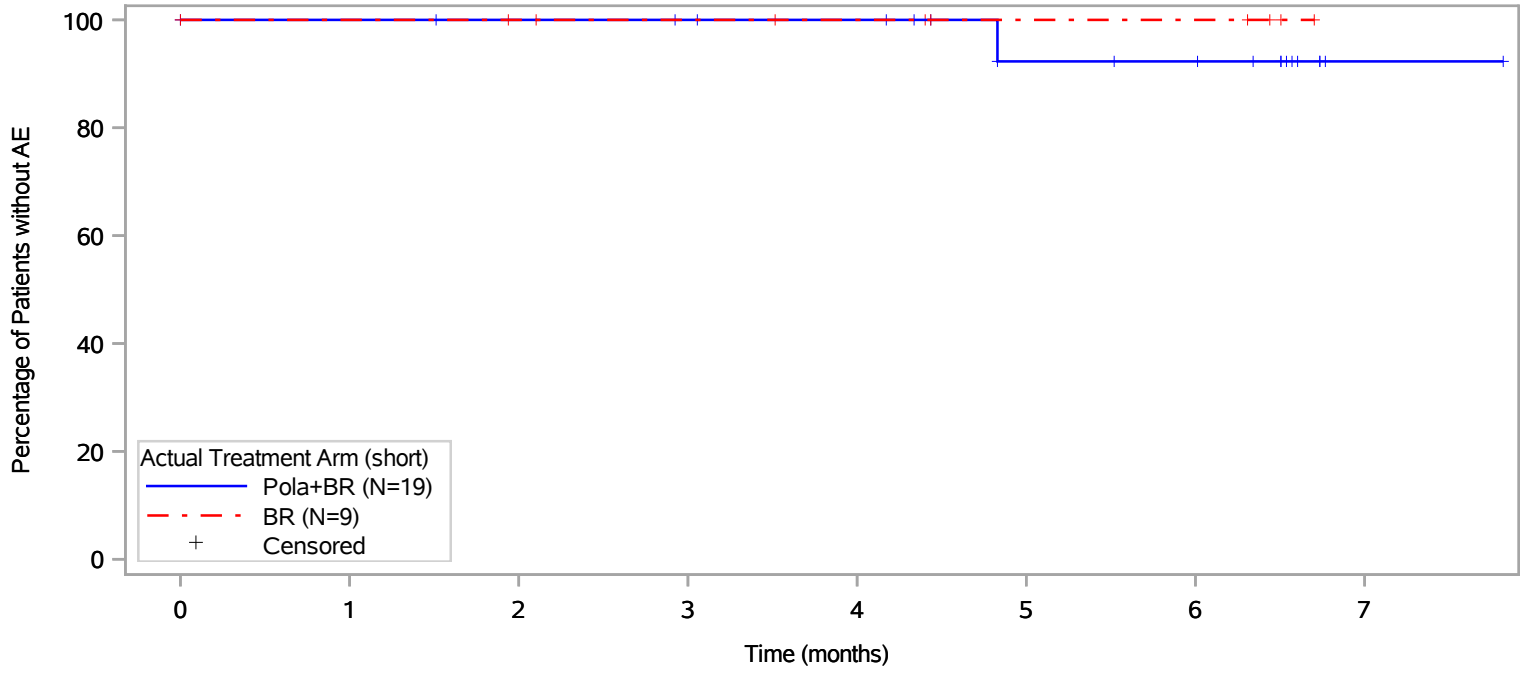
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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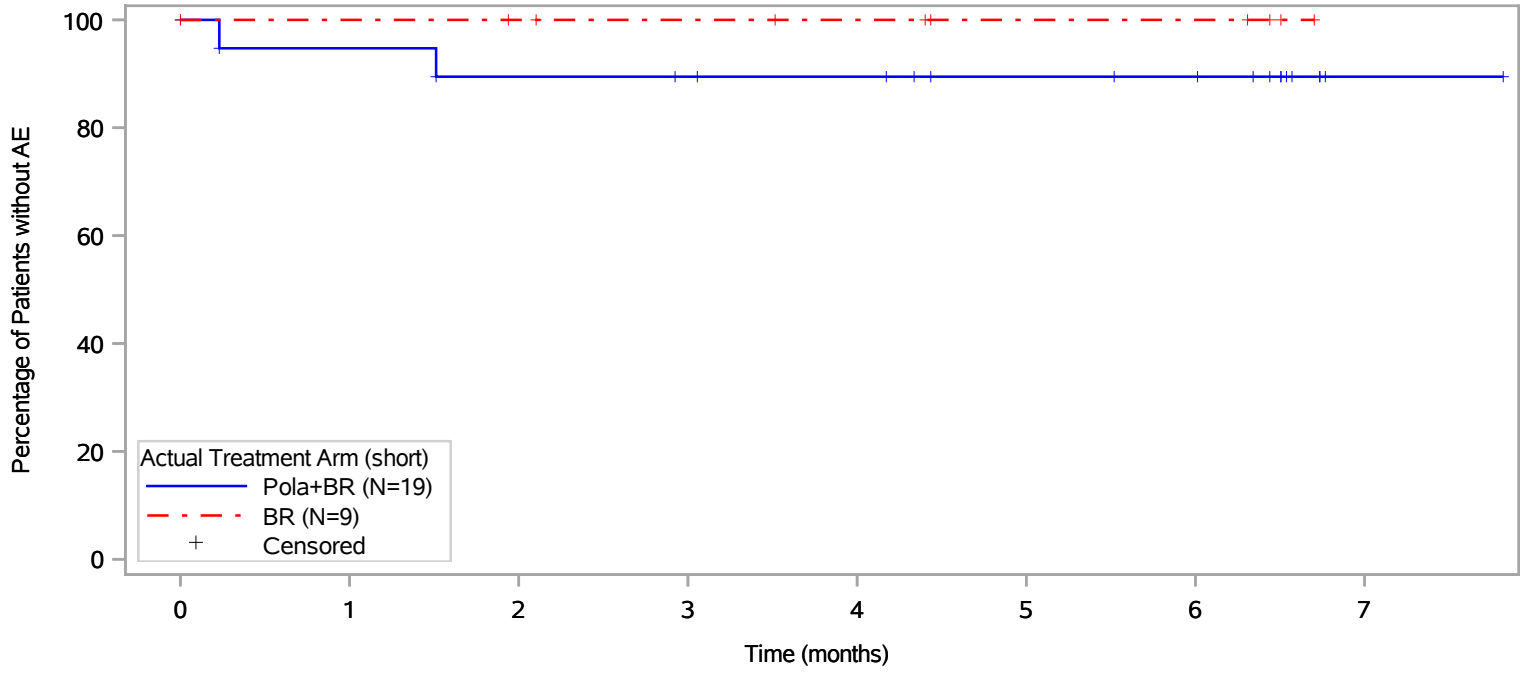
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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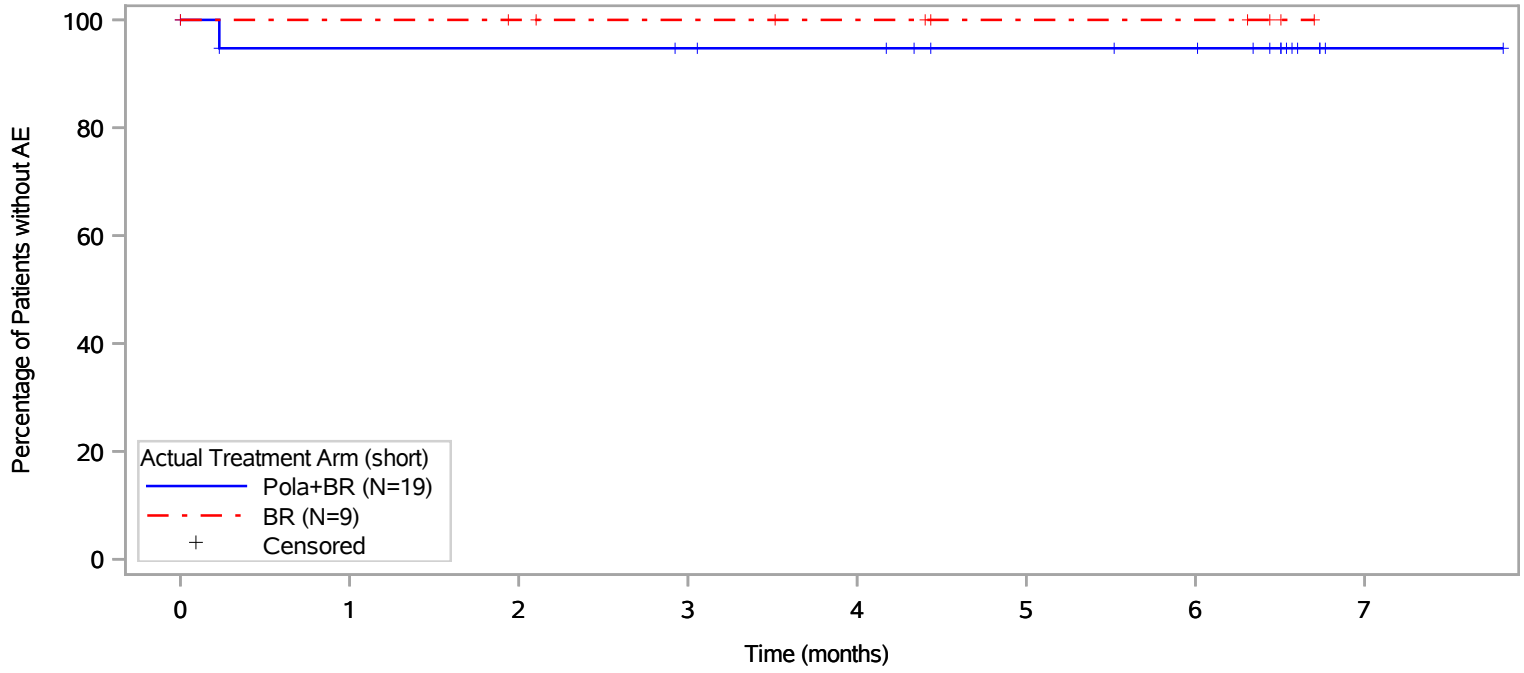
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FEMUR FRACTURE



Patients at risk								
Pola+BR (N=19)	19	18	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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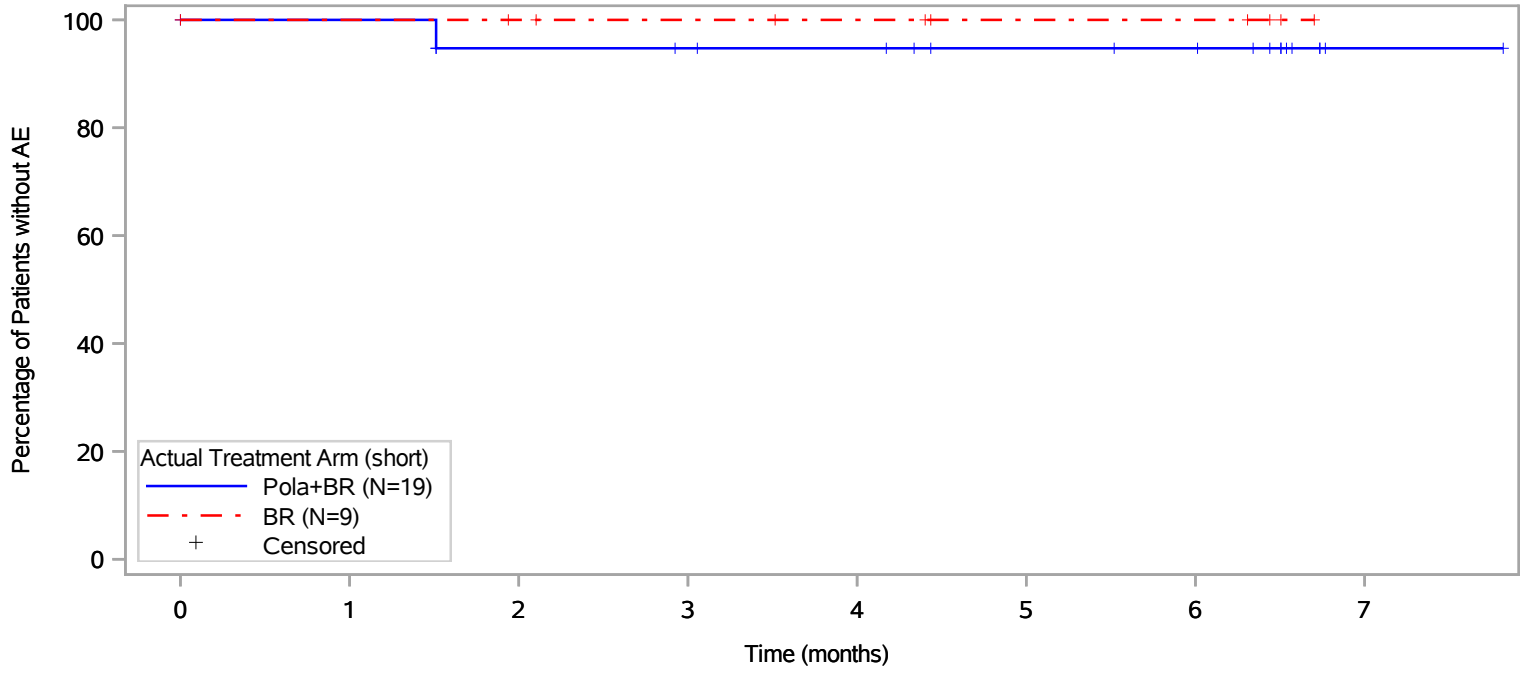
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, SKIN INJURY



Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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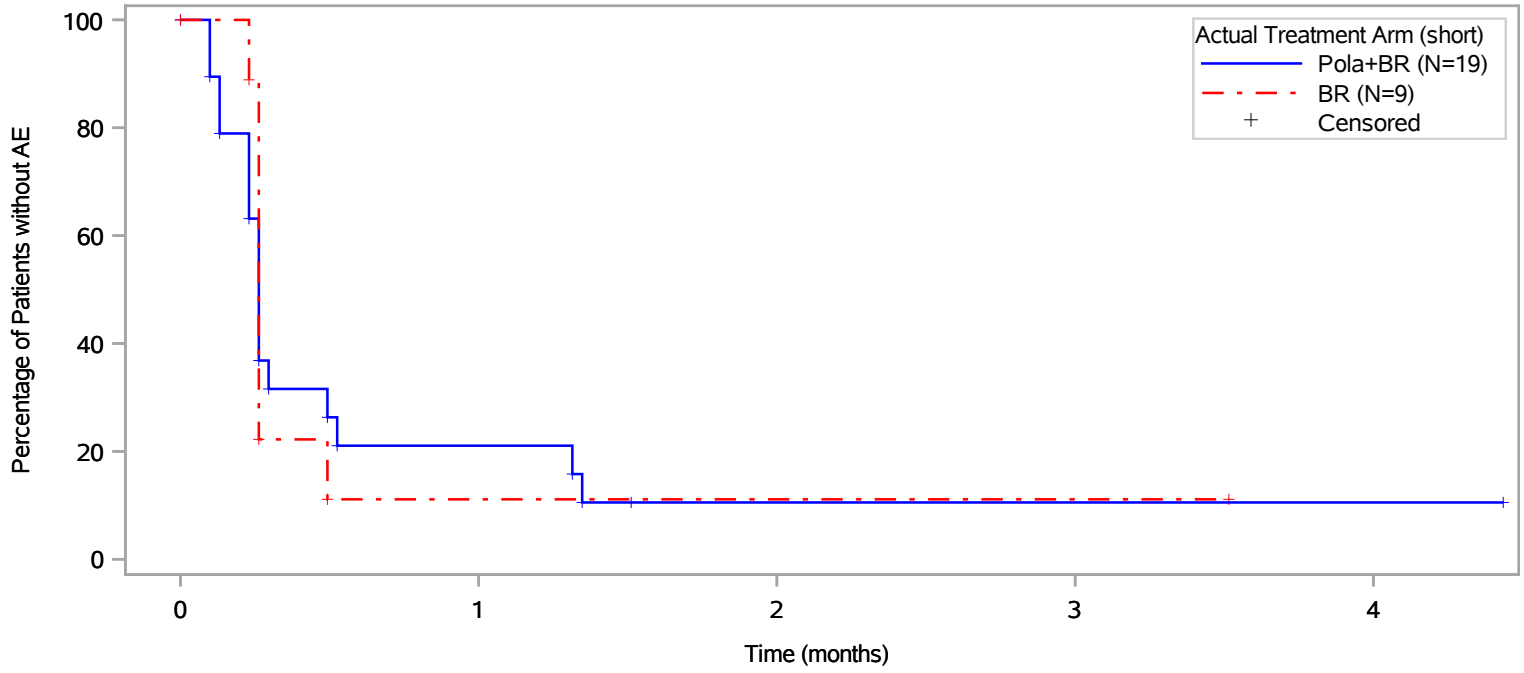
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk					
Pola+BR (N=19)	19	4	1	1	1
BR (N=9)	9	1	1	1	NE
Patients censored					
Pola+BR (N=19)	0	0	1	1	1
BR (N=9)	0	0	0	0	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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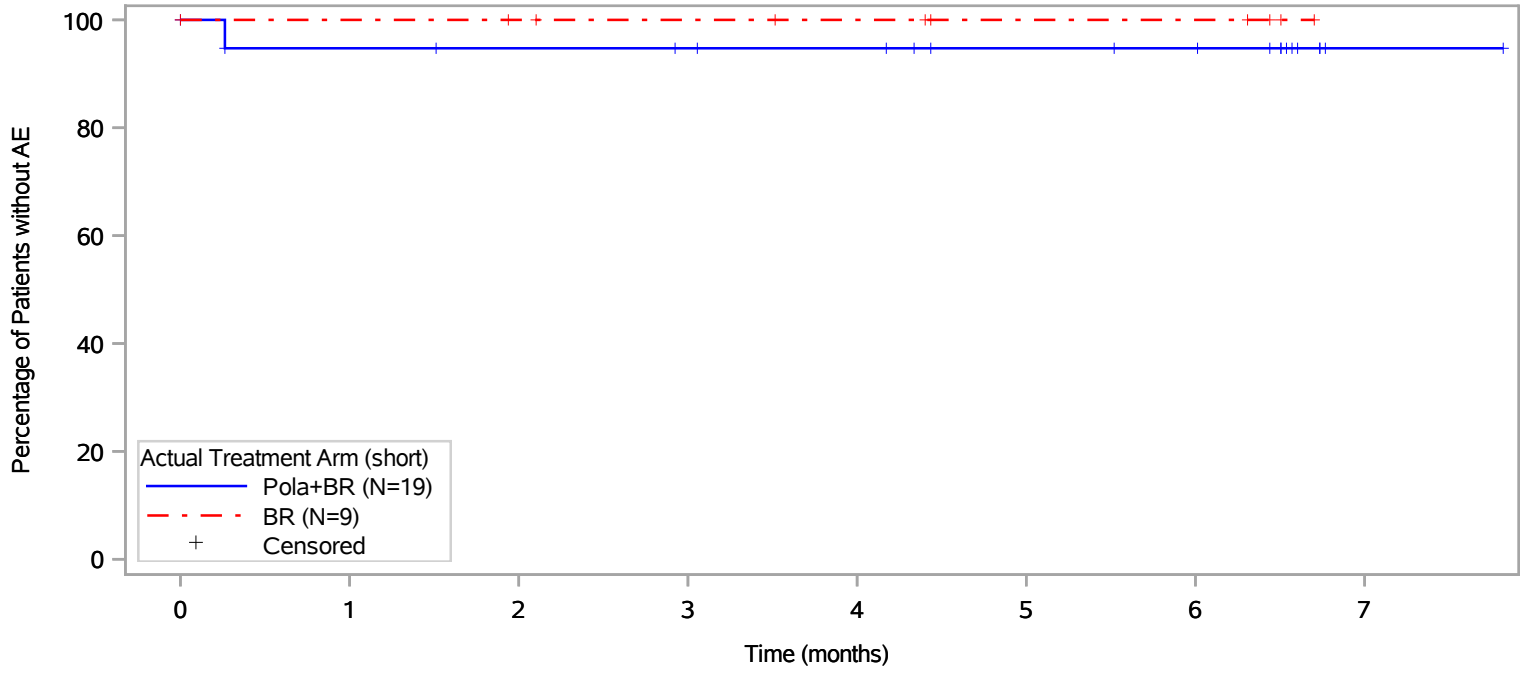
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ADENOSINE DEAMINASE INCREASED



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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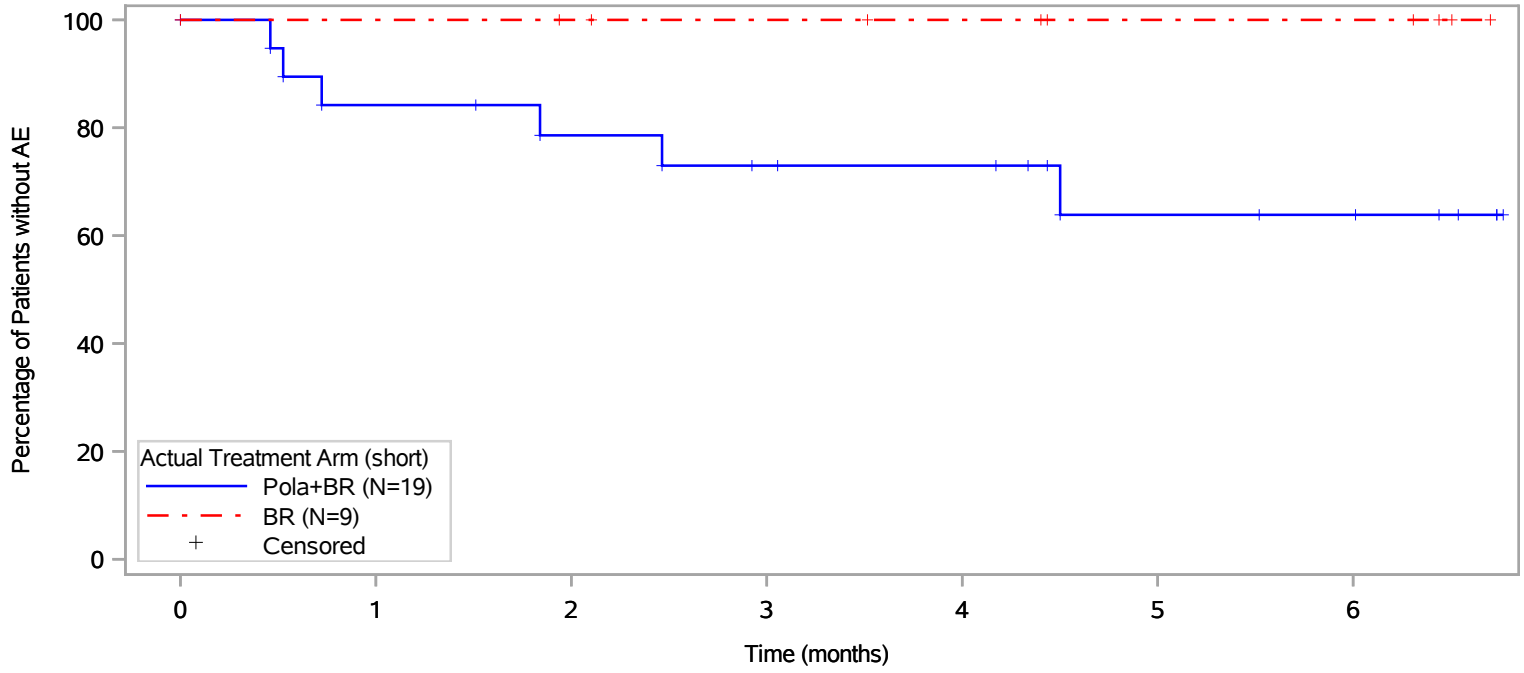
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ALANINE AMINOTRANSFERASE INCREASED



Patients at risk							
Pola+BR (N=19)	19	16	14	12	11	7	6
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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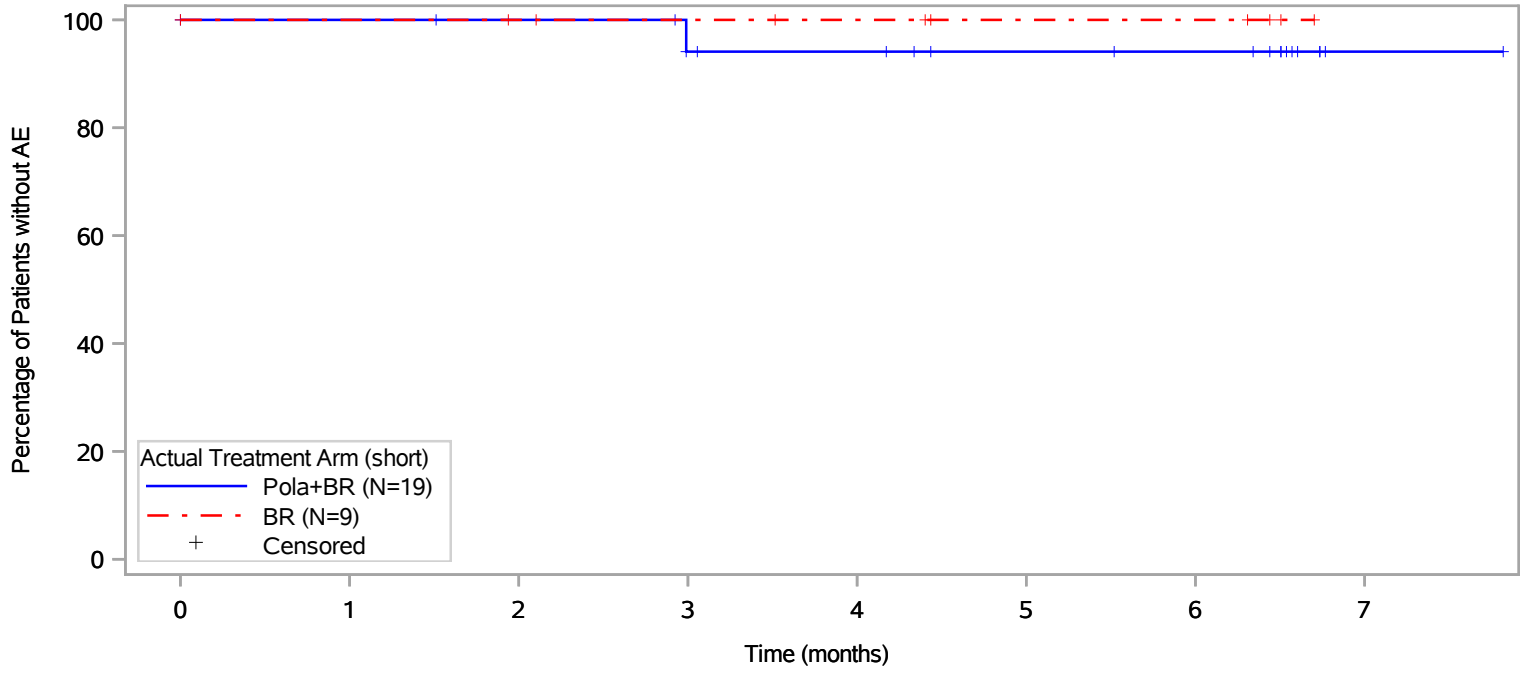
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ANION GAP DECREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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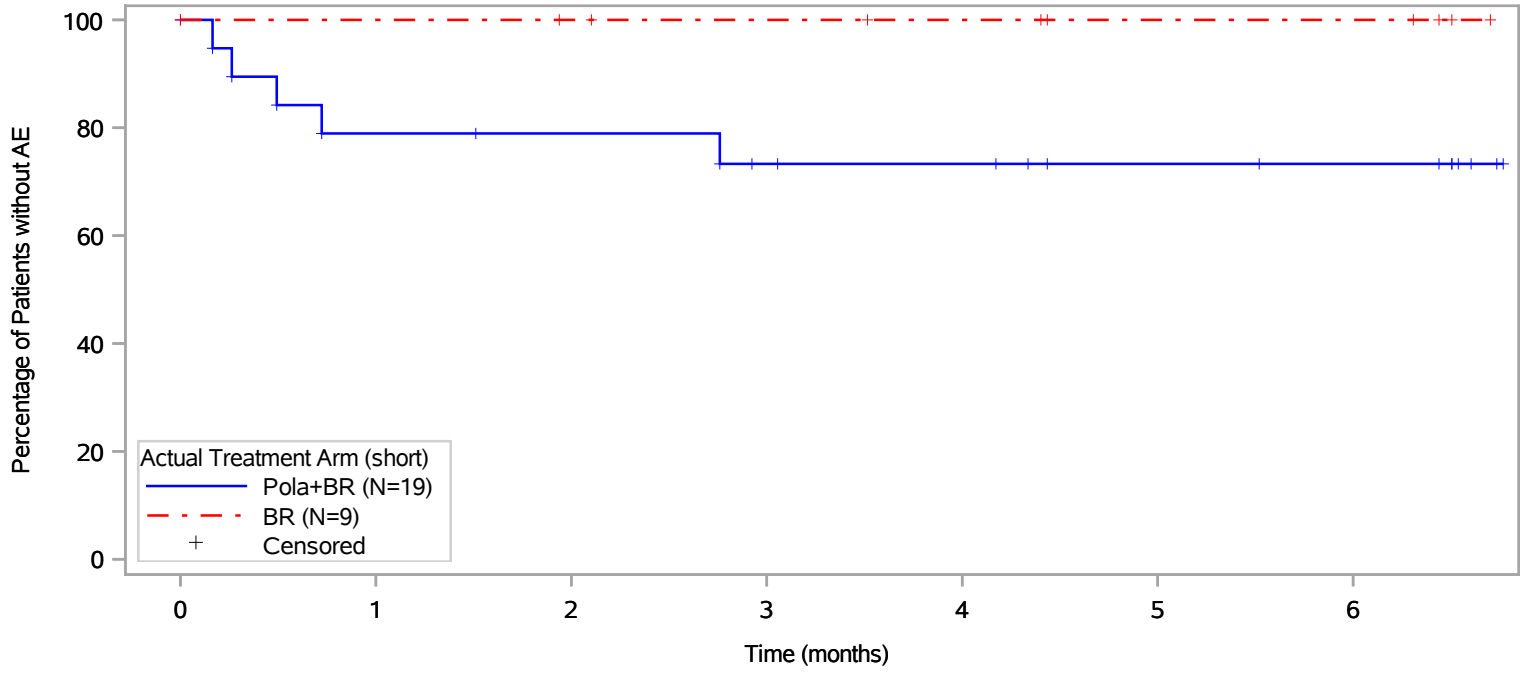
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ASPARTATE AMINOTRANSFERASE INCREASED



Patients at risk							
Pola+BR (N=19)	19	15	14	12	11	8	7
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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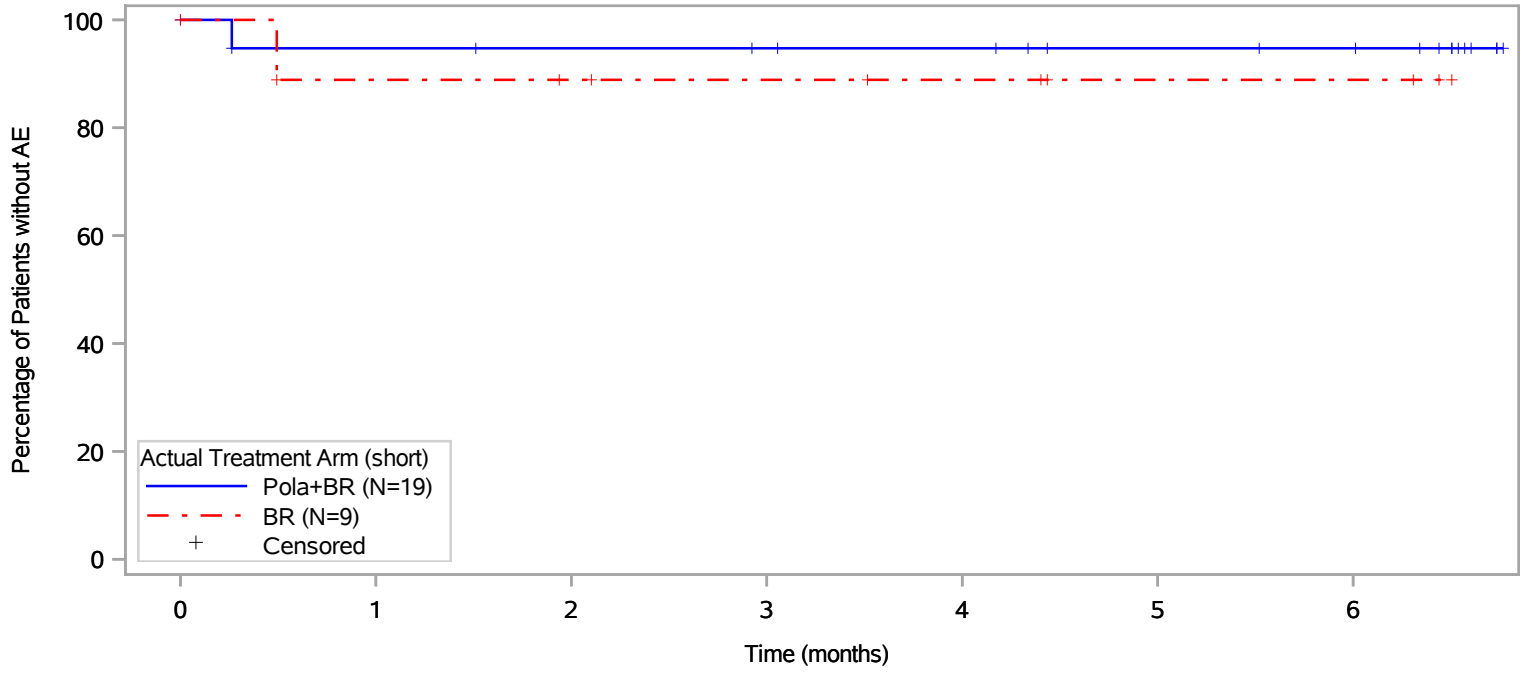
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BILIRUBIN CONJUGATED INCREASED



Patients at risk							
Pola+BR (N=19)	19	18	17	16	15	12	11
BR (N=9)	9	8	7	6	5	3	3
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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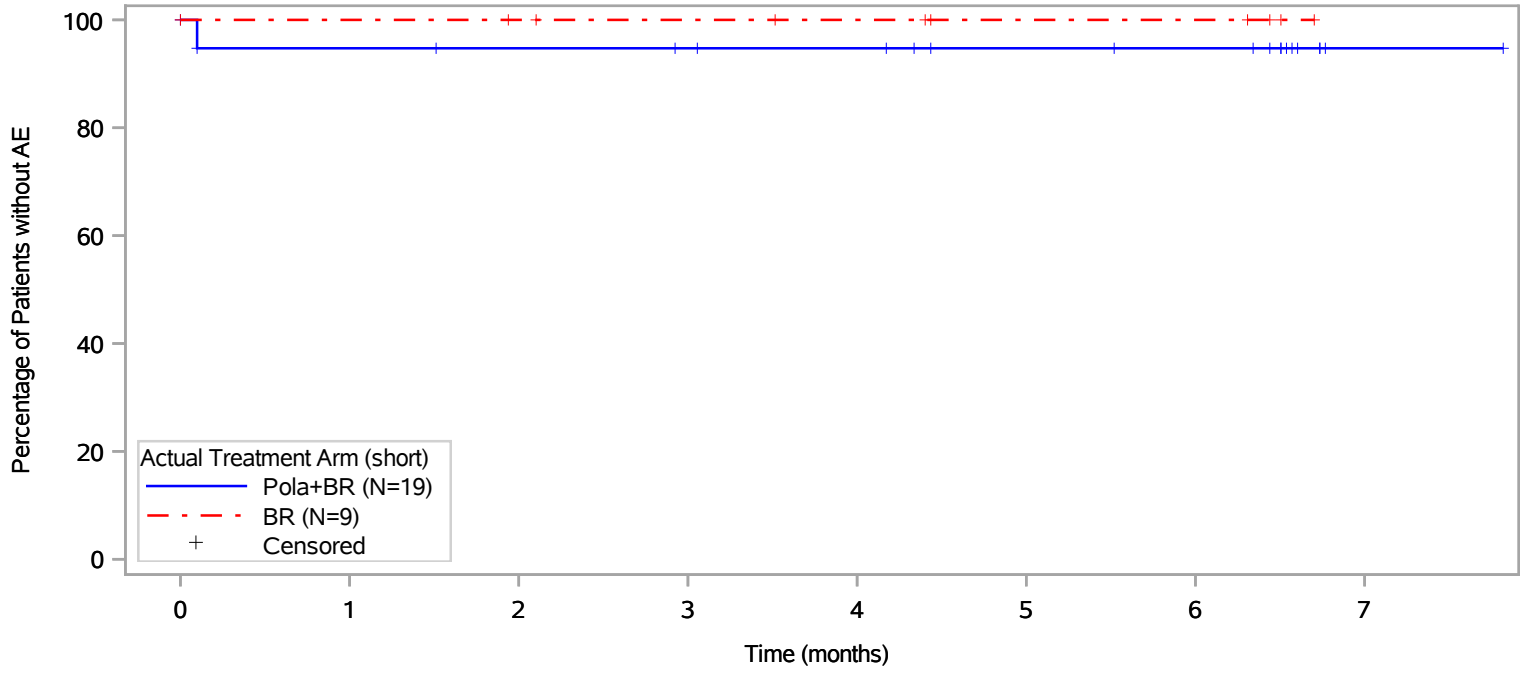
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALBUMIN DECREASED



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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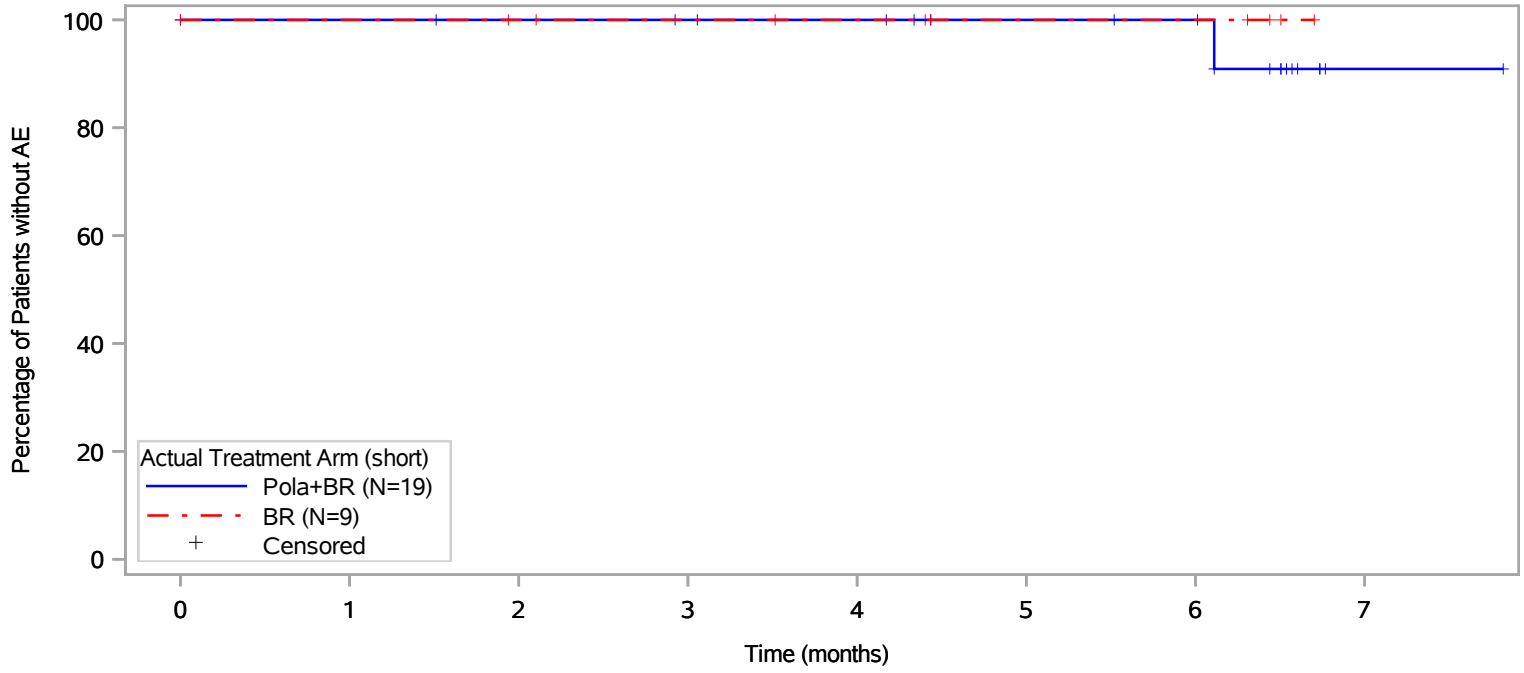
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD ALKALINE PHOSPHATASE INCREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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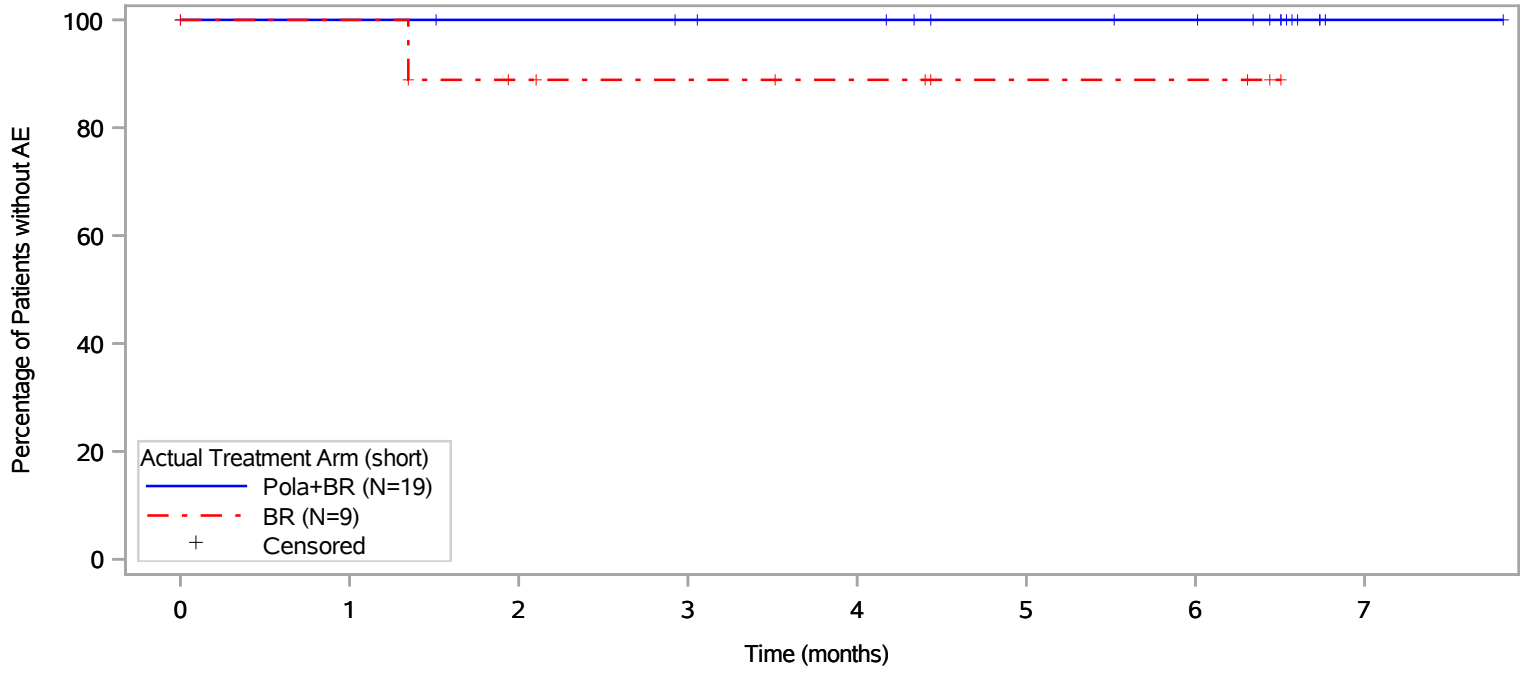
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD BILIRUBIN DECREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	7	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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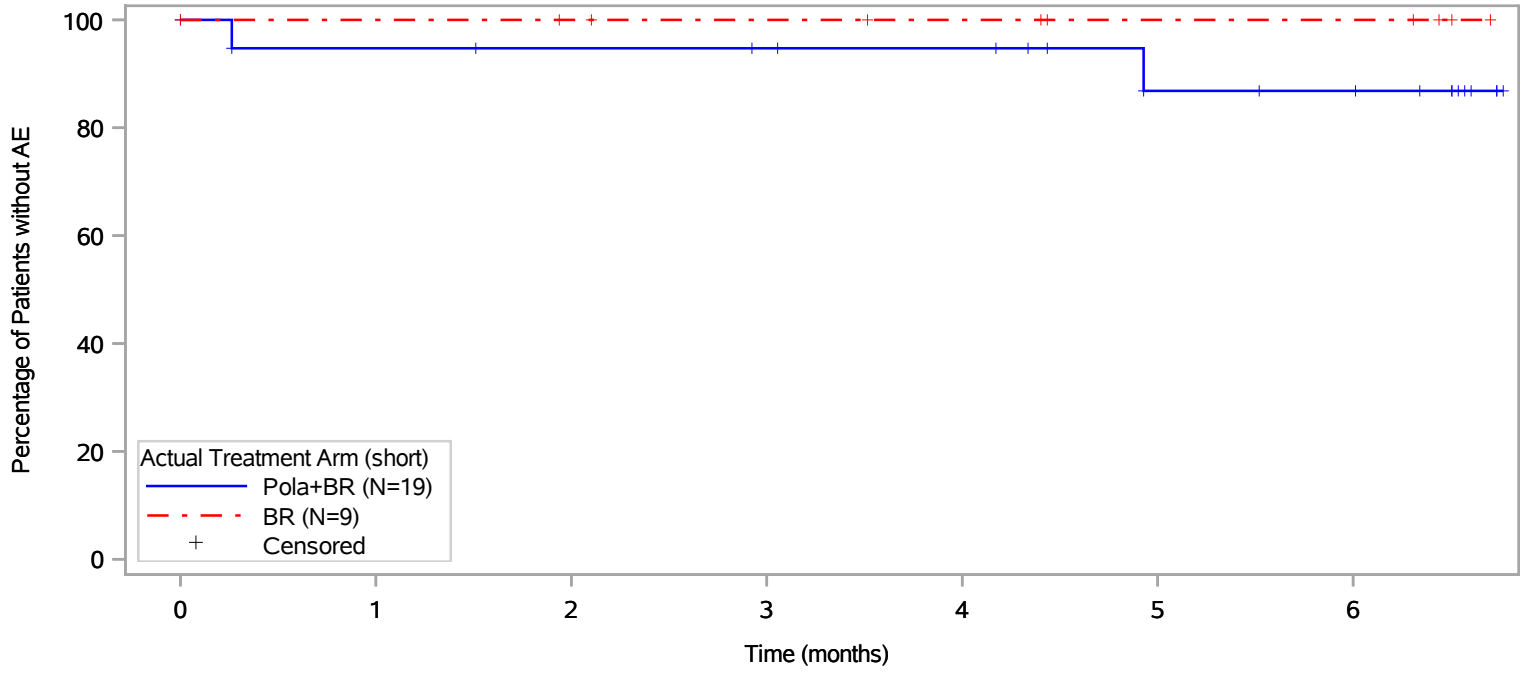
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD BILIRUBIN INCREASED



Patients at risk							
Pola+BR (N=19)	19	18	17	16	15	11	10
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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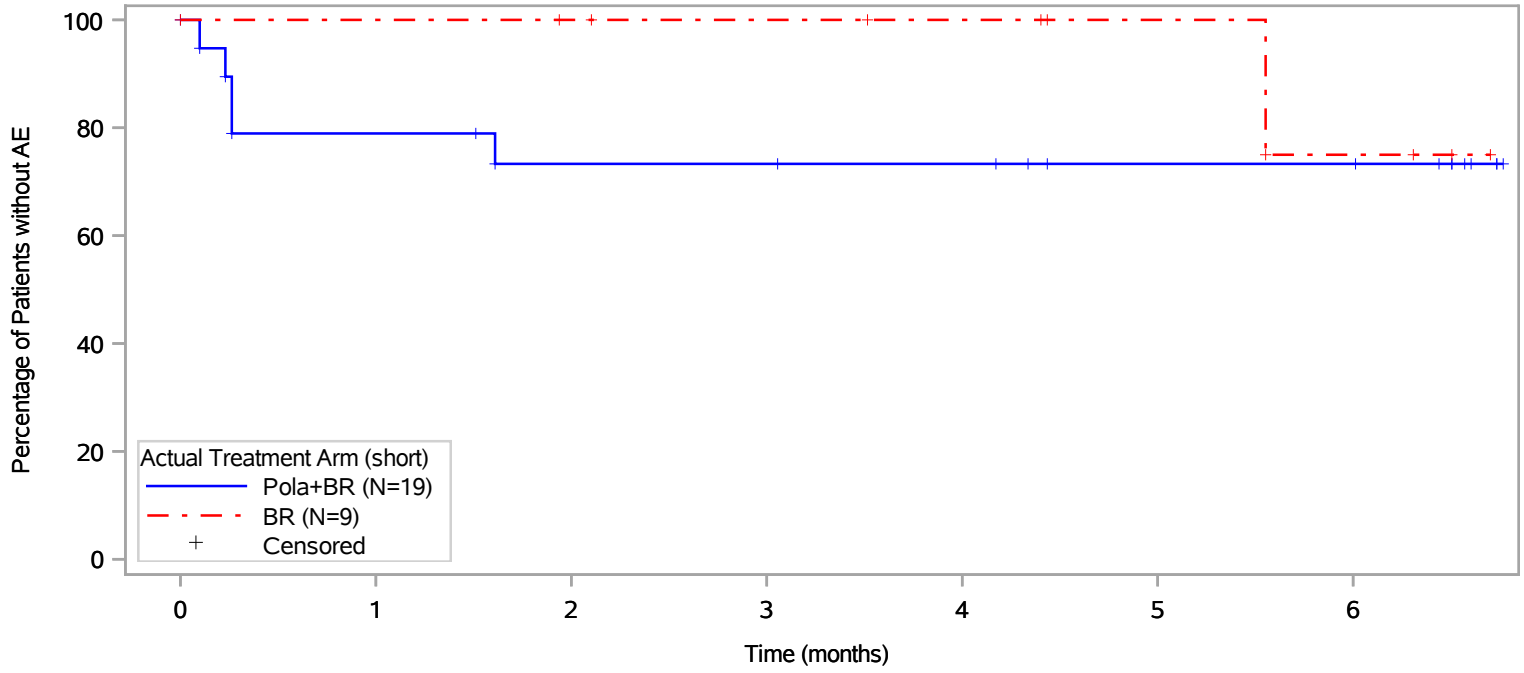
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD CREATININE INCREASED



Patients at risk							
Pola+BR (N=19)	19	15	13	13	12	9	9
BR (N=9)	9	9	8	7	6	4	3
Patients censored							
Pola+BR (N=19)	0	0	1	1	2	5	5
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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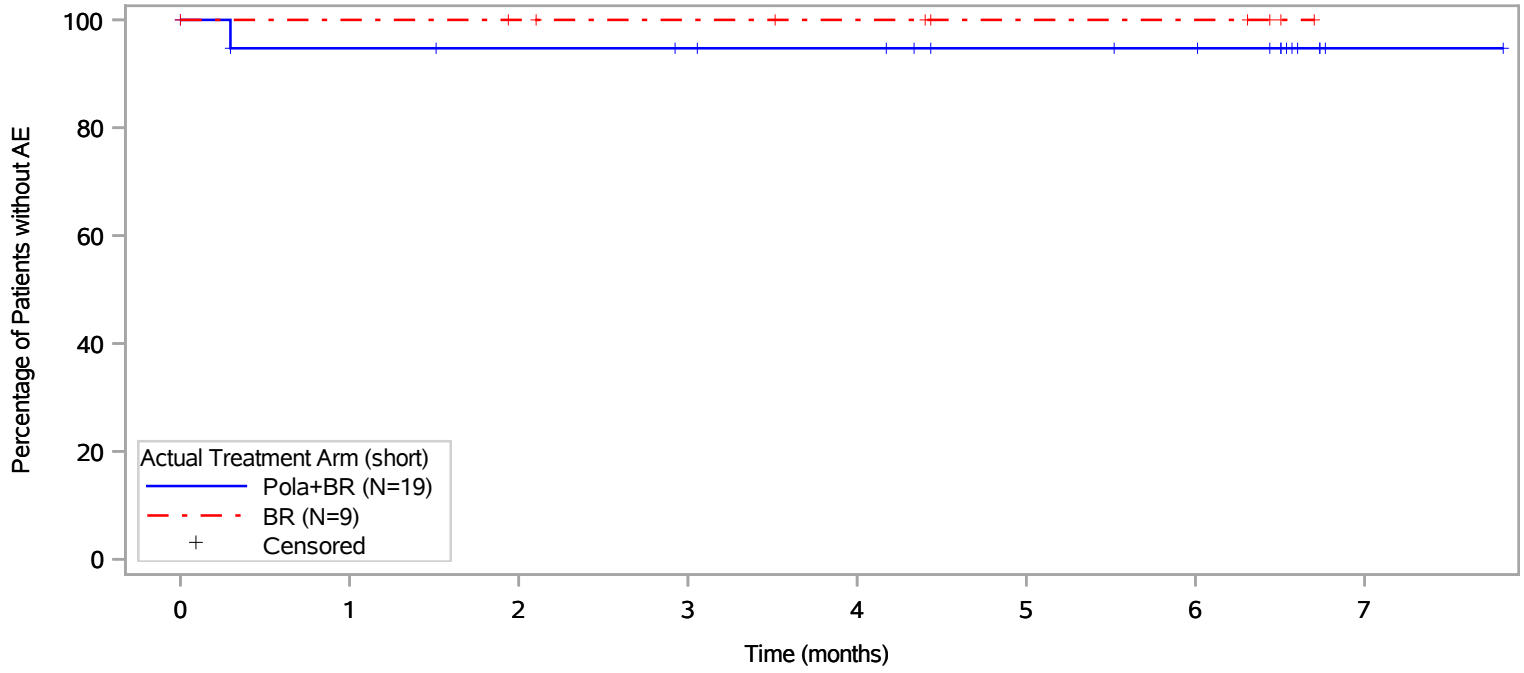
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD FIBRINOGEN DECREASED



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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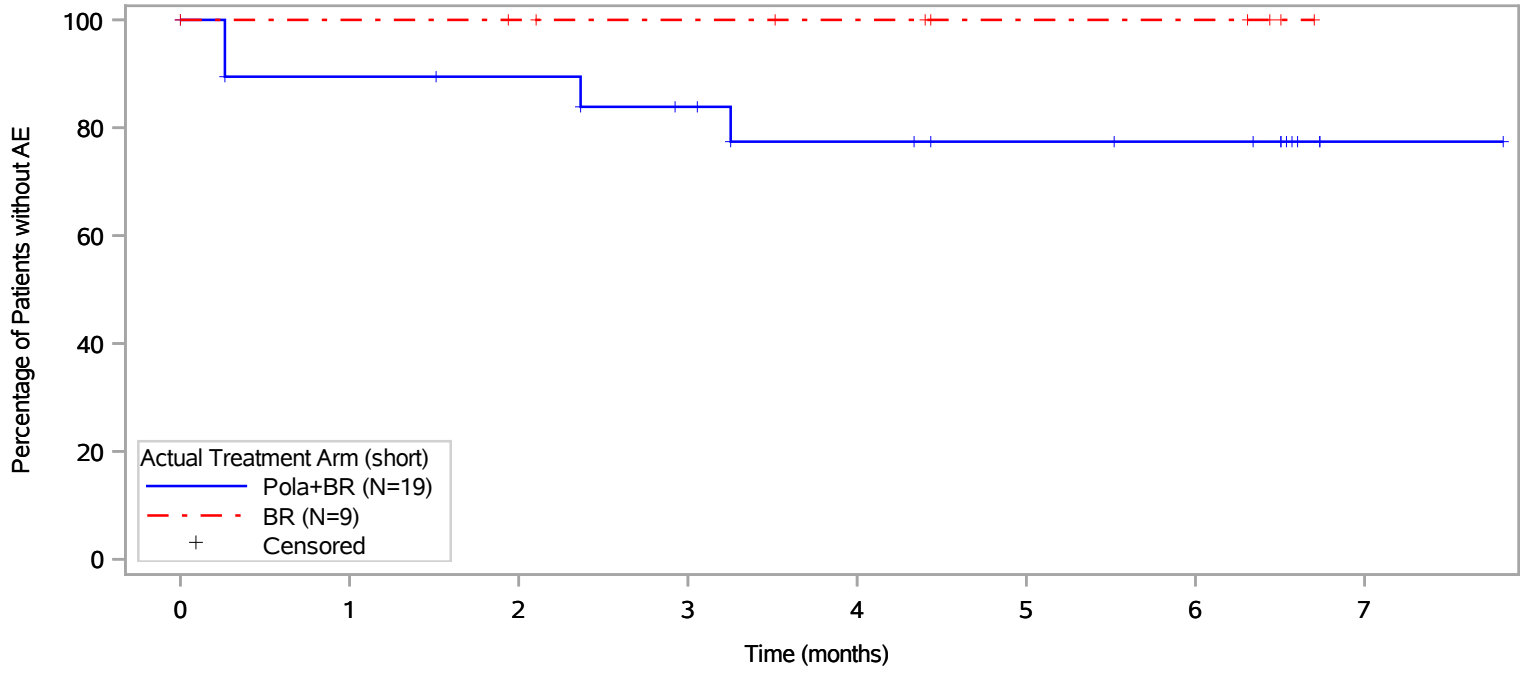
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD LACTATE DEHYDROGENASE INCREASED



Patients at risk								
Pola+BR (N=19)	19	17	16	14	12	10	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	14
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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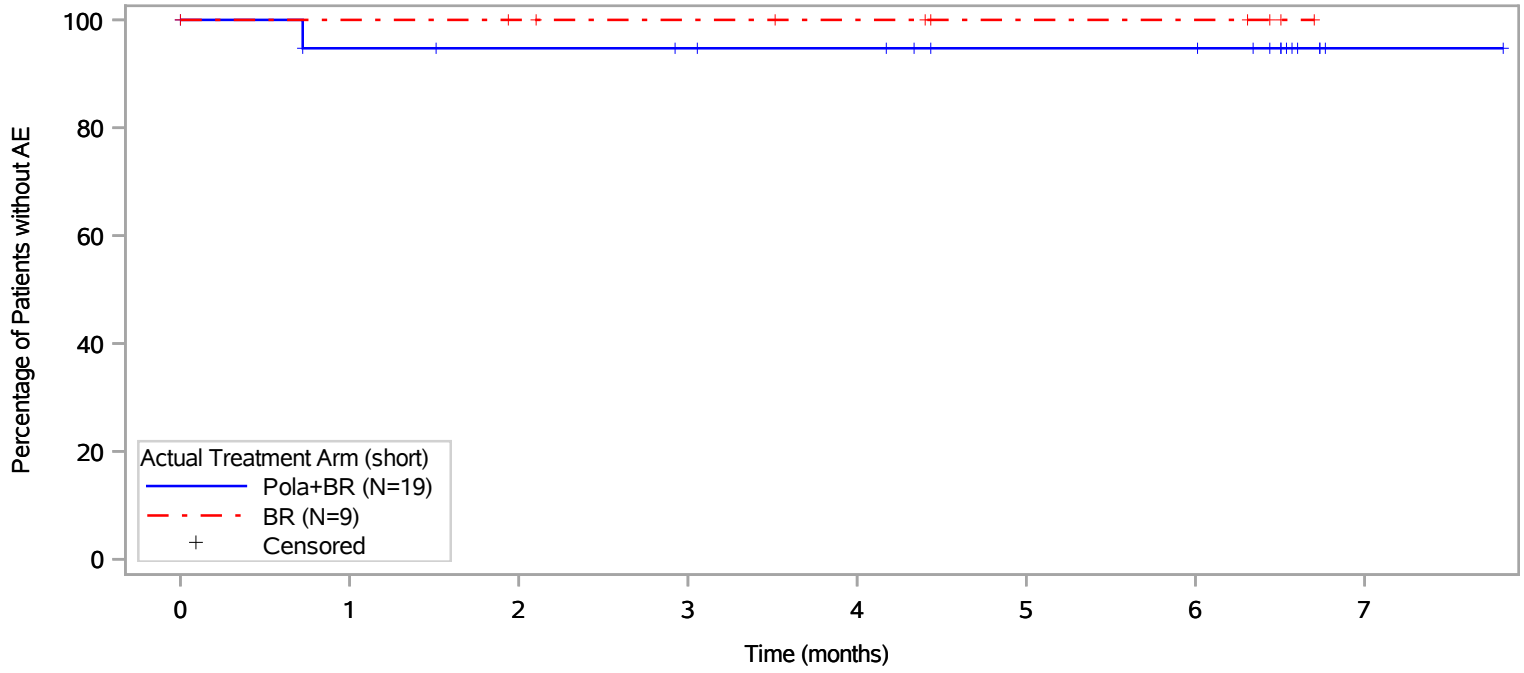
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD MAGNESIUM DECREASED

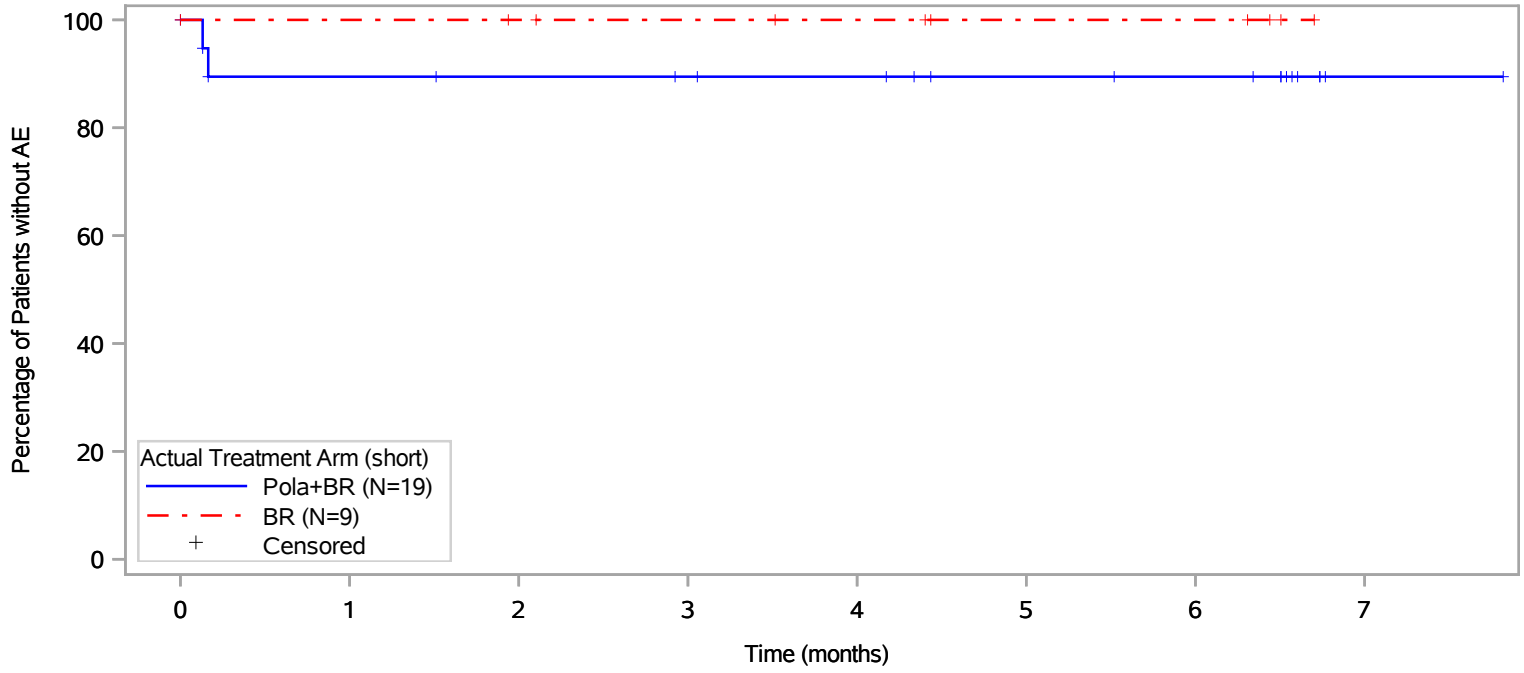


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED



Patients at risk								
Pola+BR (N=19)	19	17	16	15	14	11	10	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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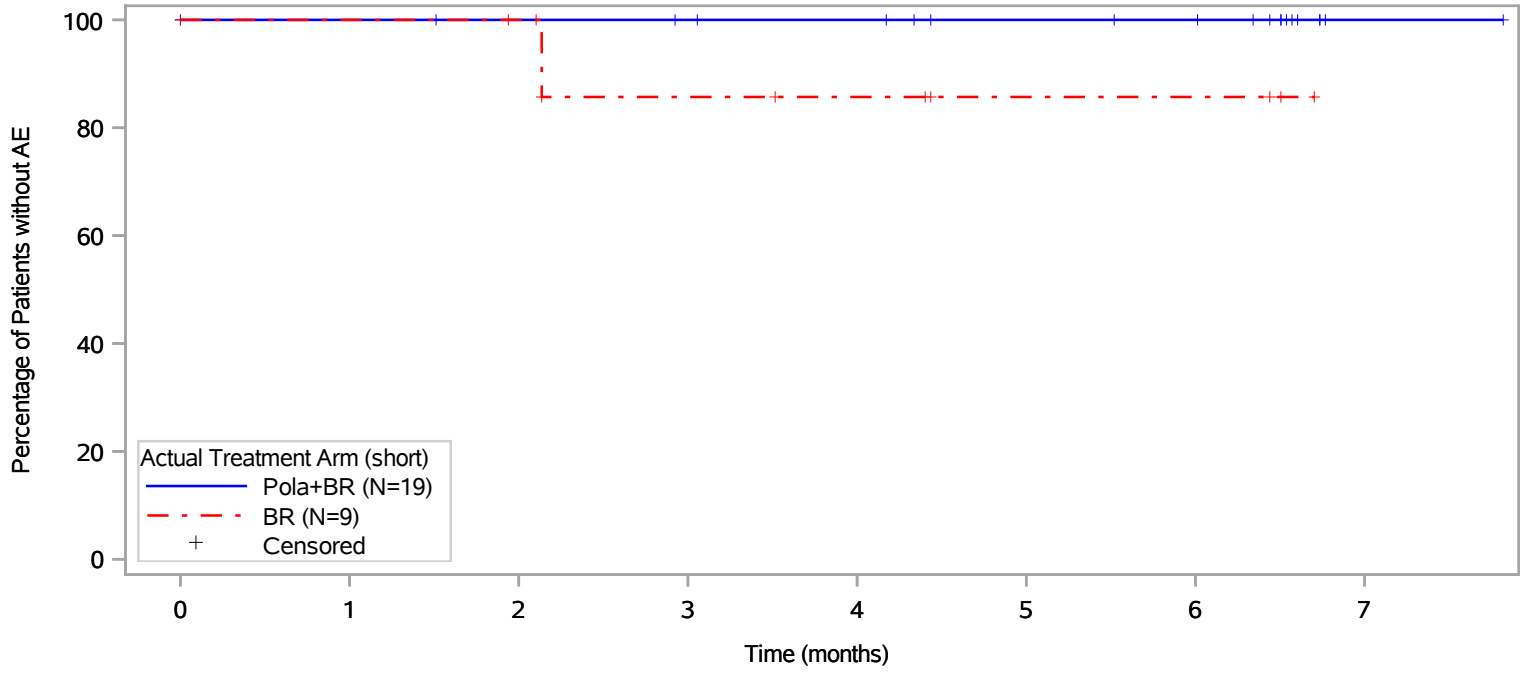
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PRESSURE INCREASED

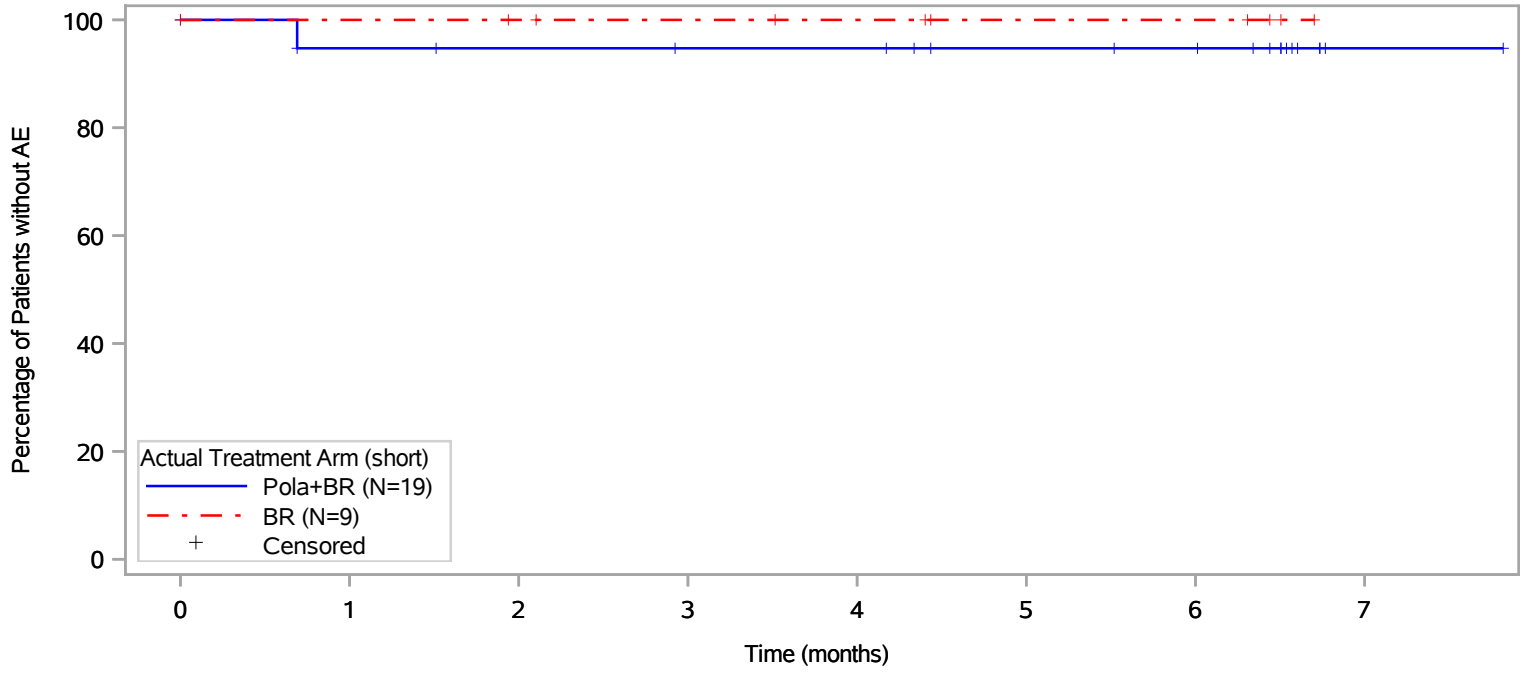


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD SODIUM DECREASED

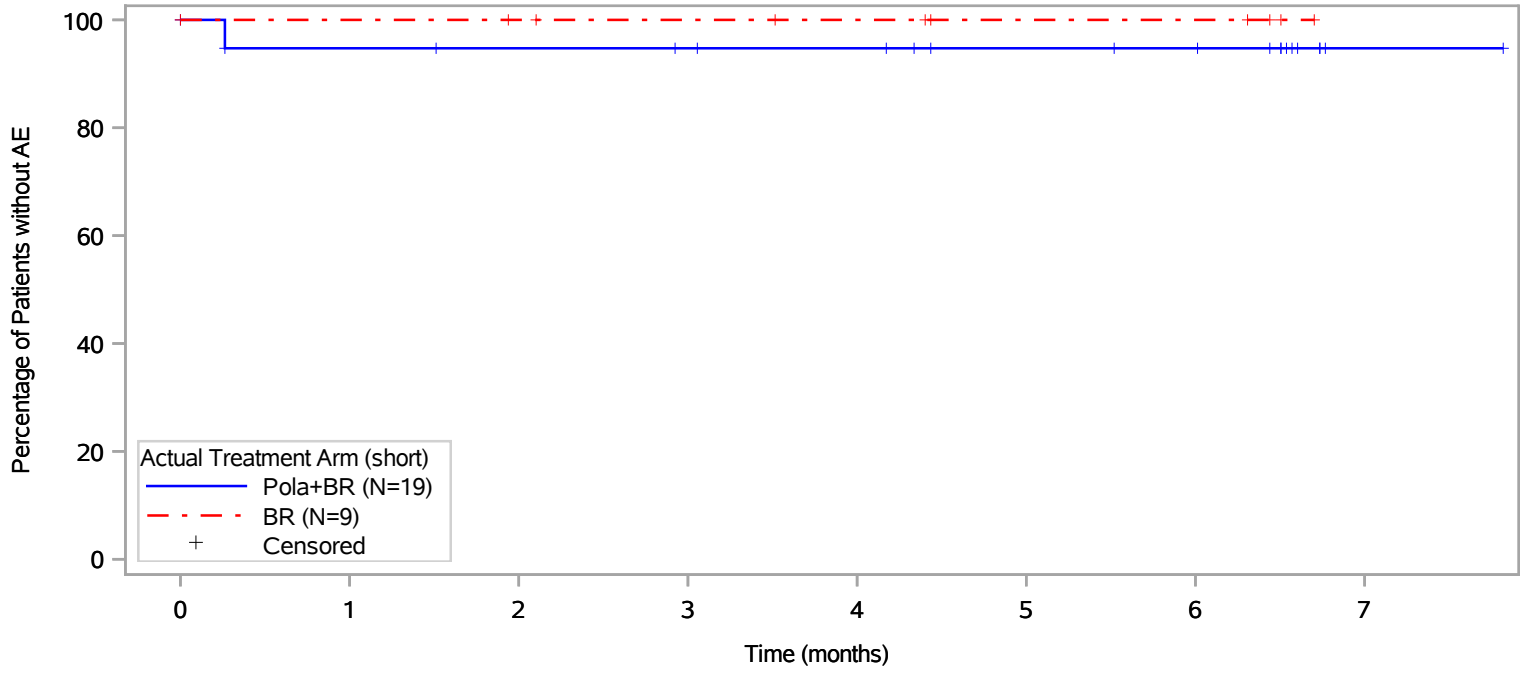


Patients at risk								
Pola+BR (N=19)	19	18	17	16	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD UREA INCREASED



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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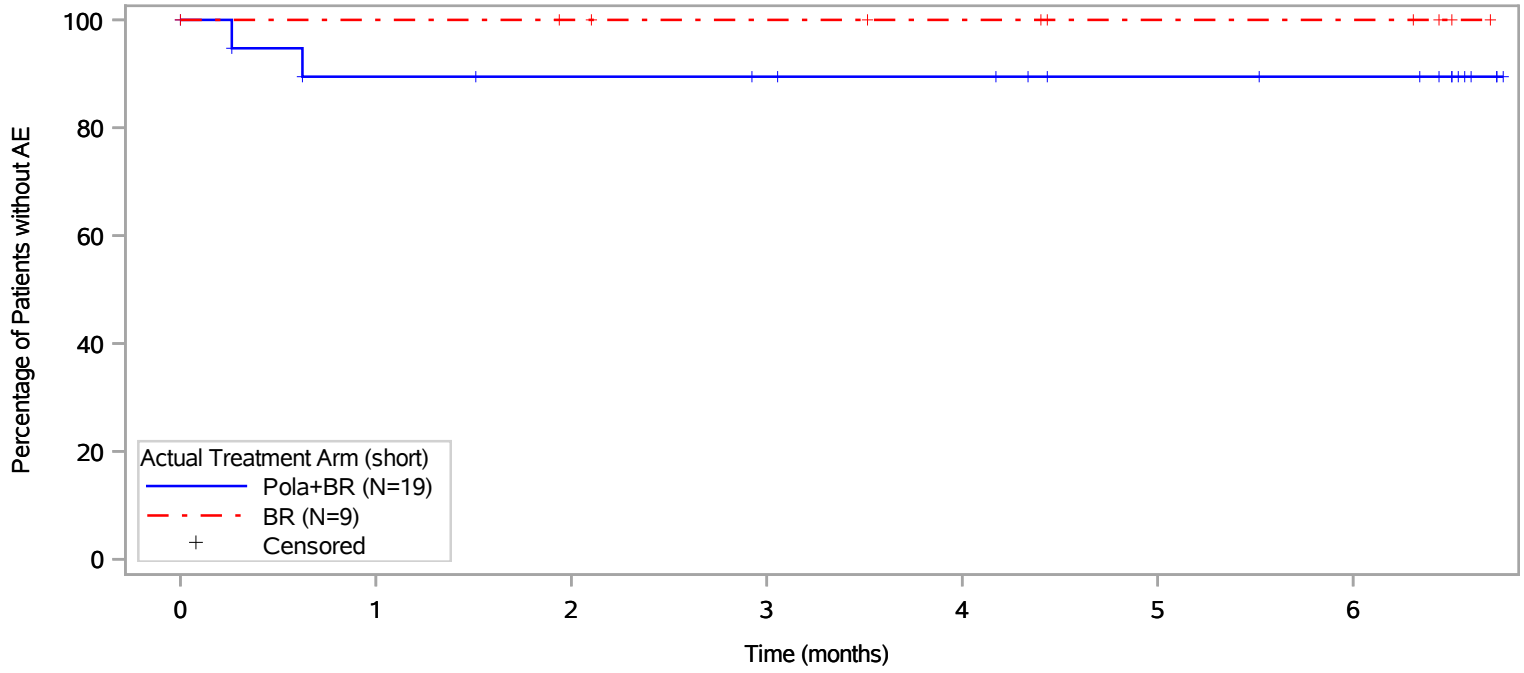
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD URIC ACID INCREASED

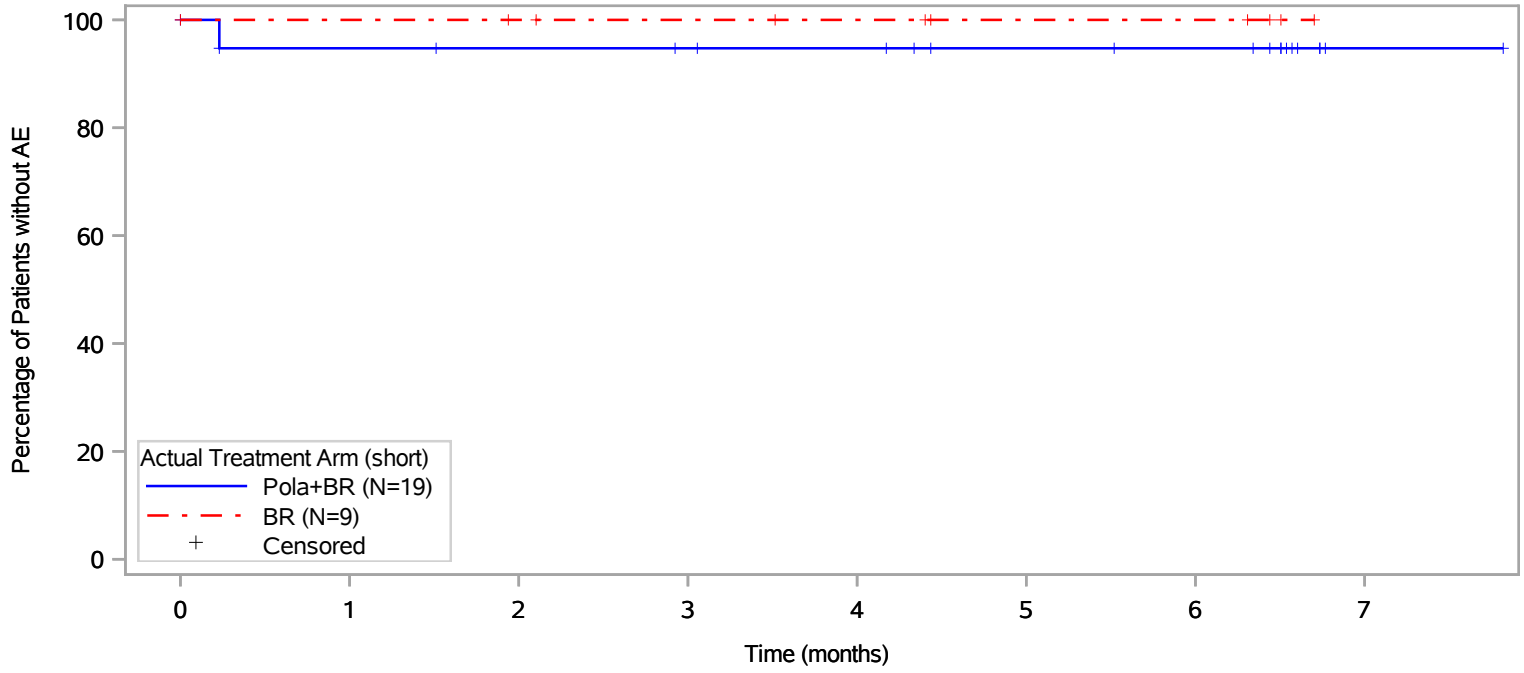


Patients at risk							
Pola+BR (N=19)	19	17	16	15	14	11	10
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BRAIN NATRIURETIC PEPTIDE INCREASED

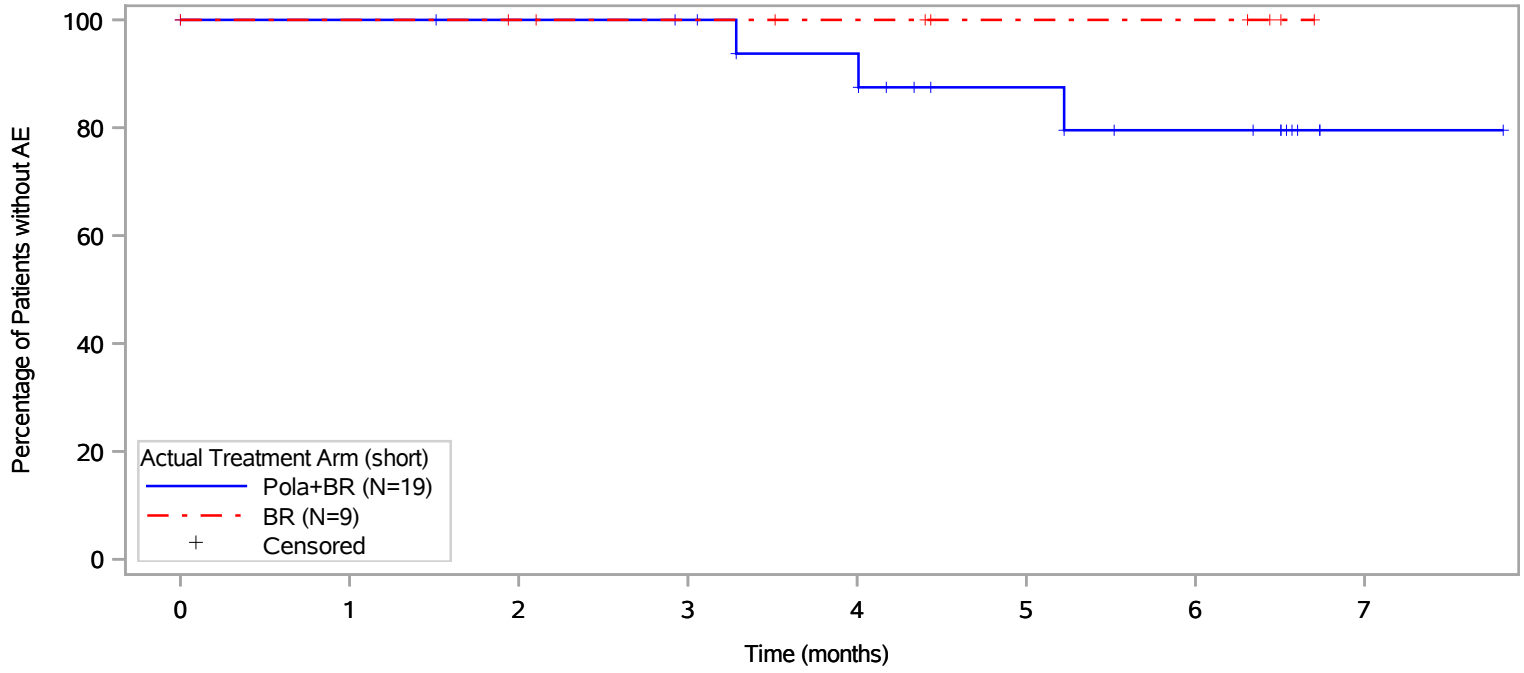


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, C-REACTIVE PROTEIN INCREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	11	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	15
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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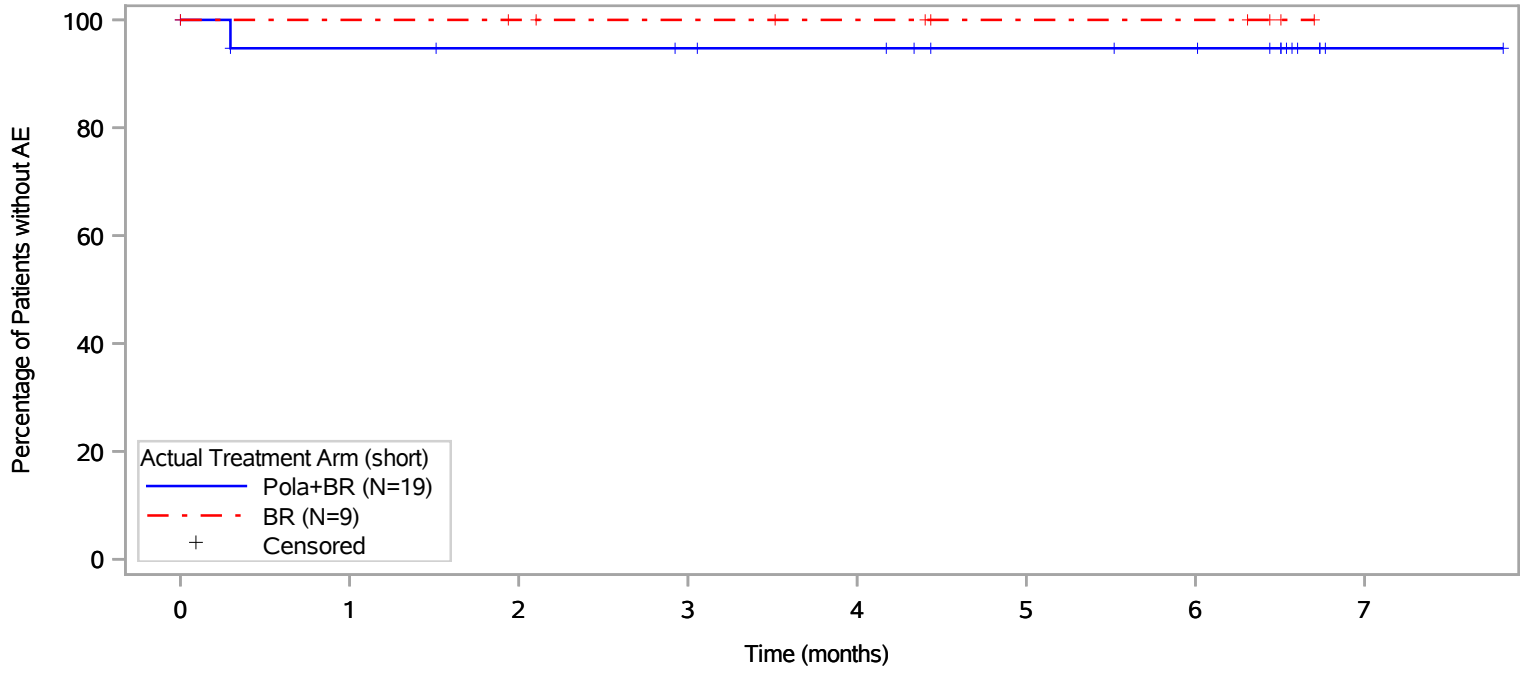
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, CYSTATIN C INCREASED



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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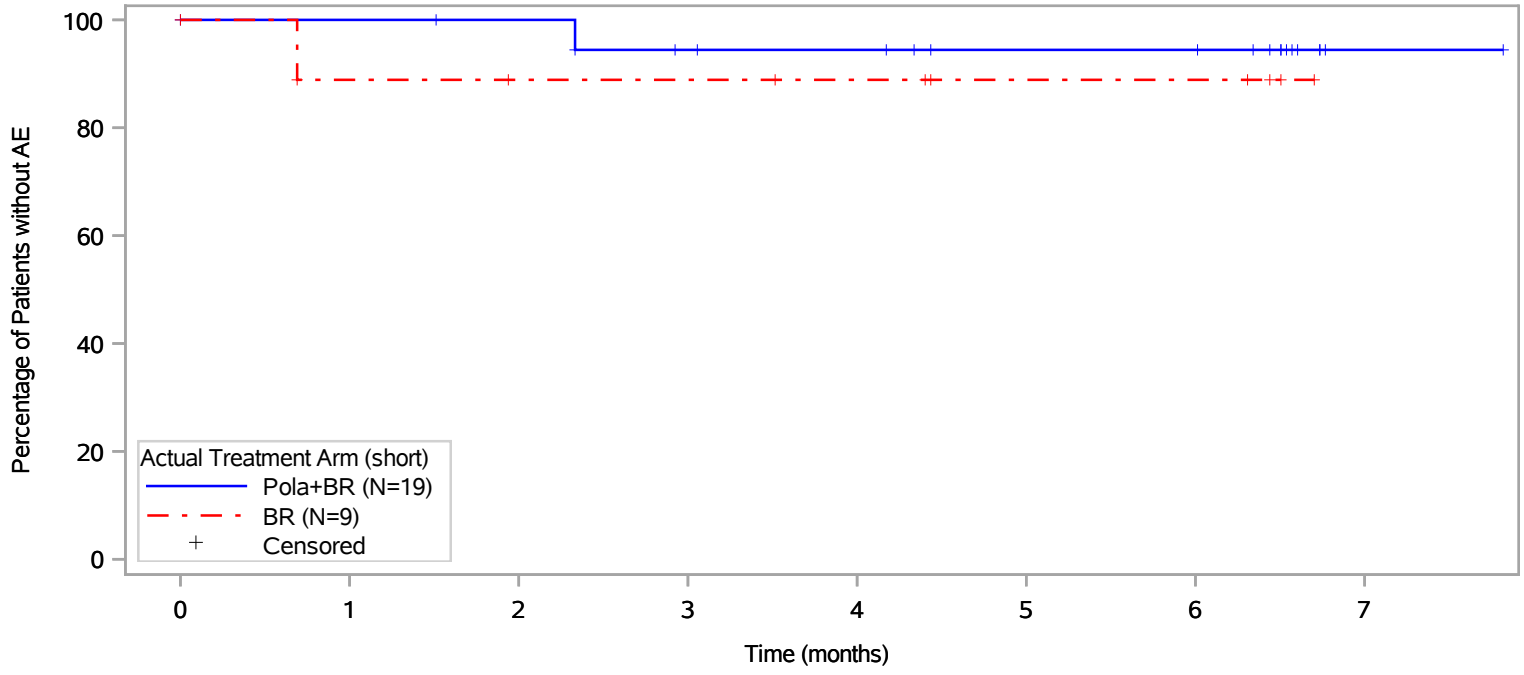
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ELECTROCARDIOGRAM HIGH VOLTAGE

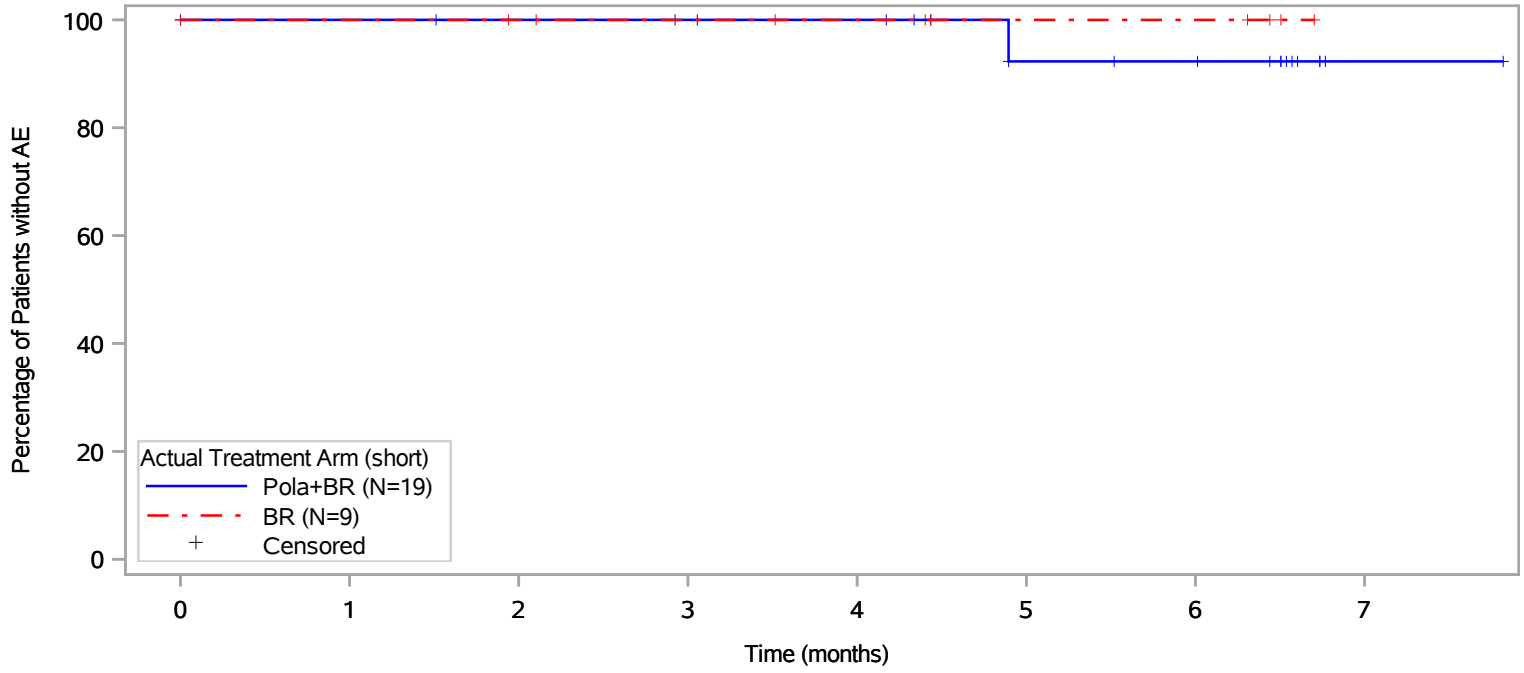


Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	17
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ELECTROCARDIOGRAM QT PROLONGED

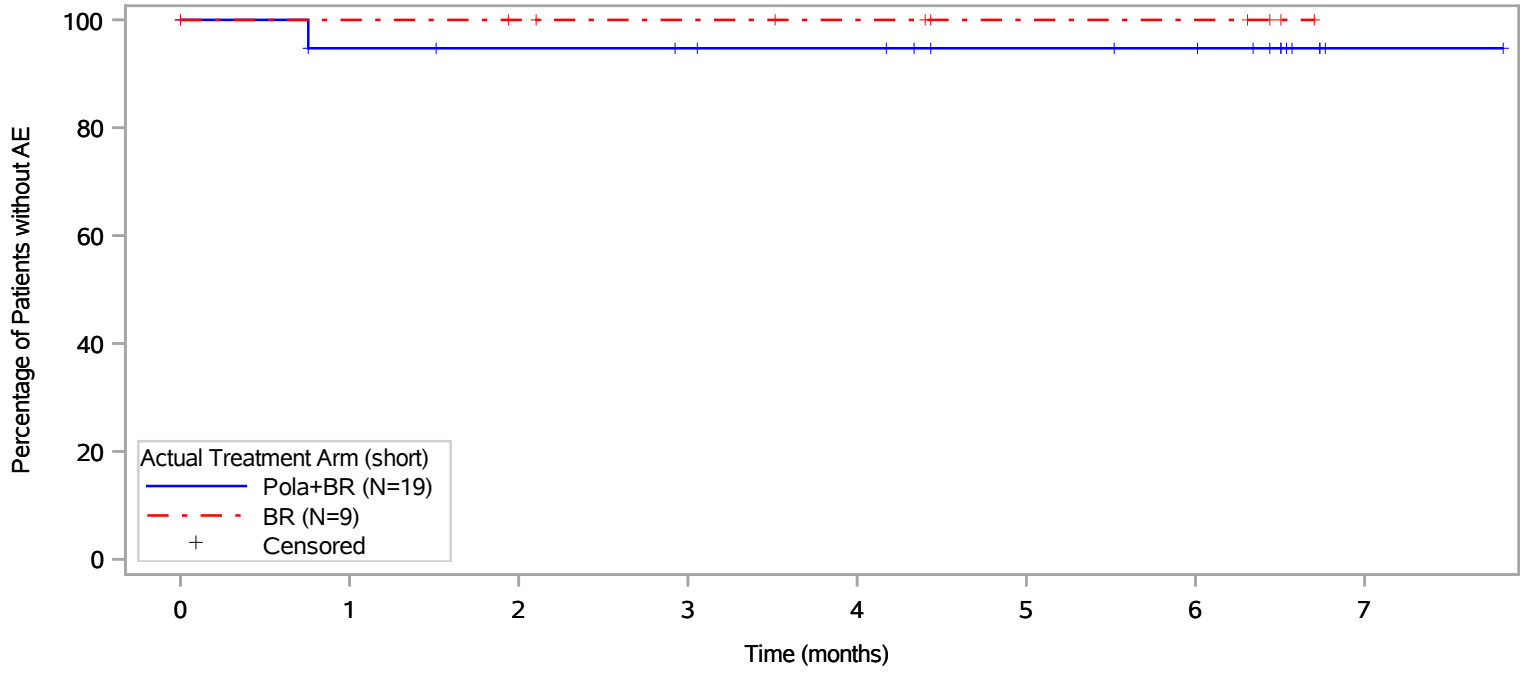


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, ELECTROCARDIOGRAM ST SEGMENT ELEVATION

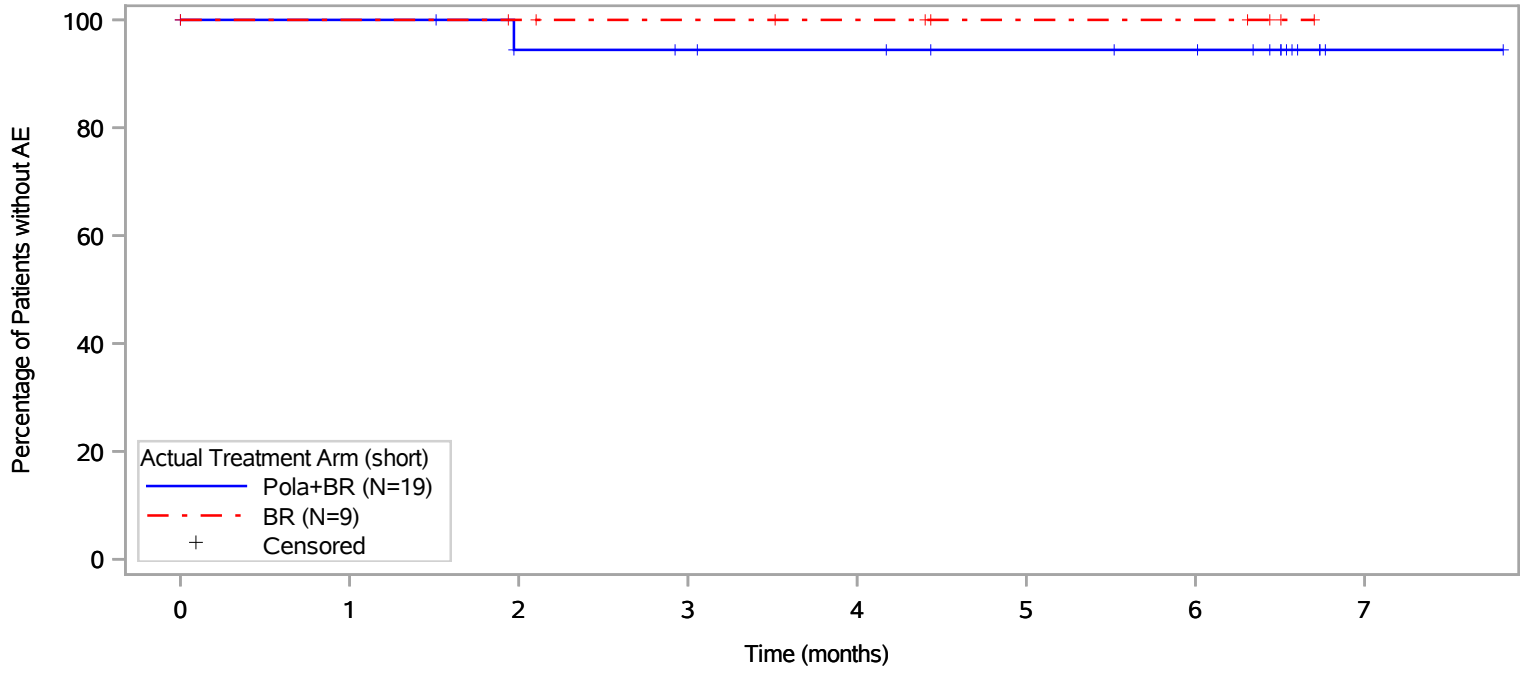


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, EOSINOPHIL COUNT INCREASED

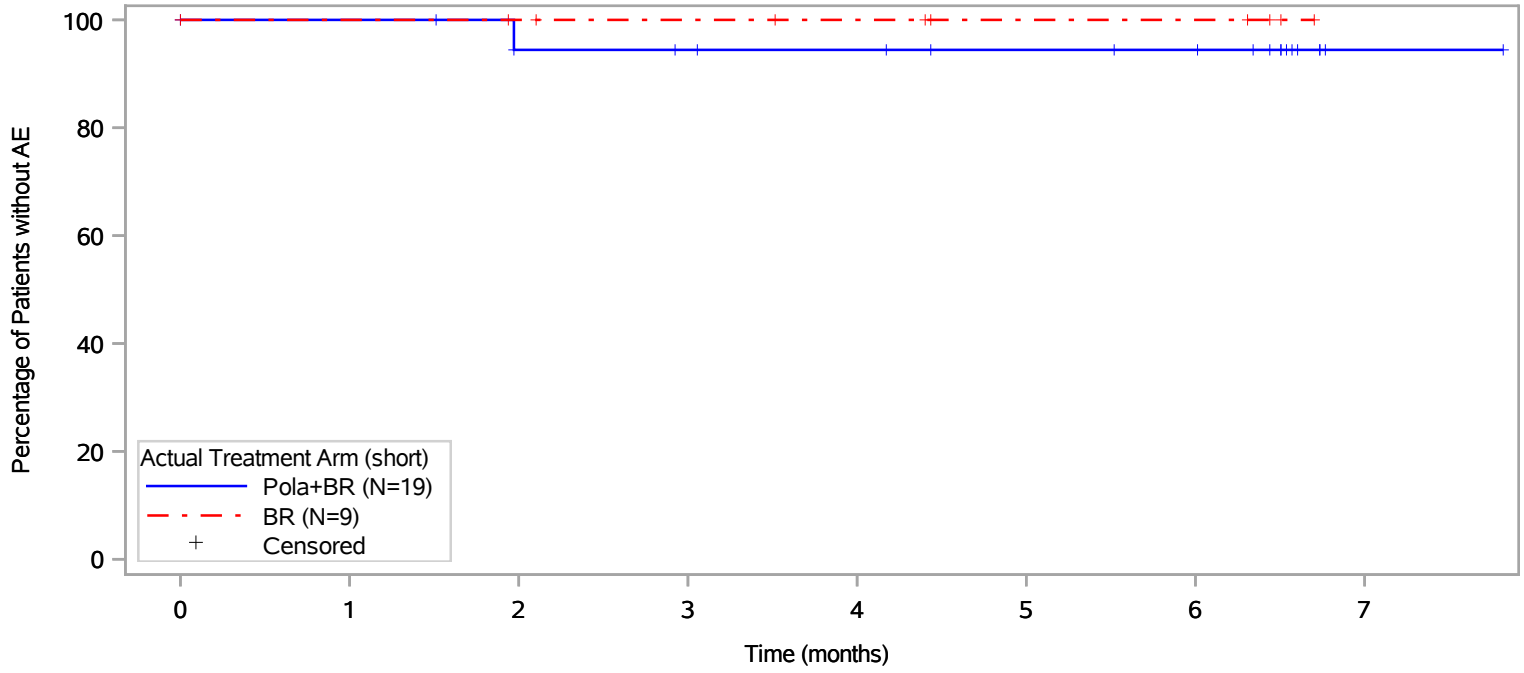


Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, EOSINOPHIL PERCENTAGE INCREASED



Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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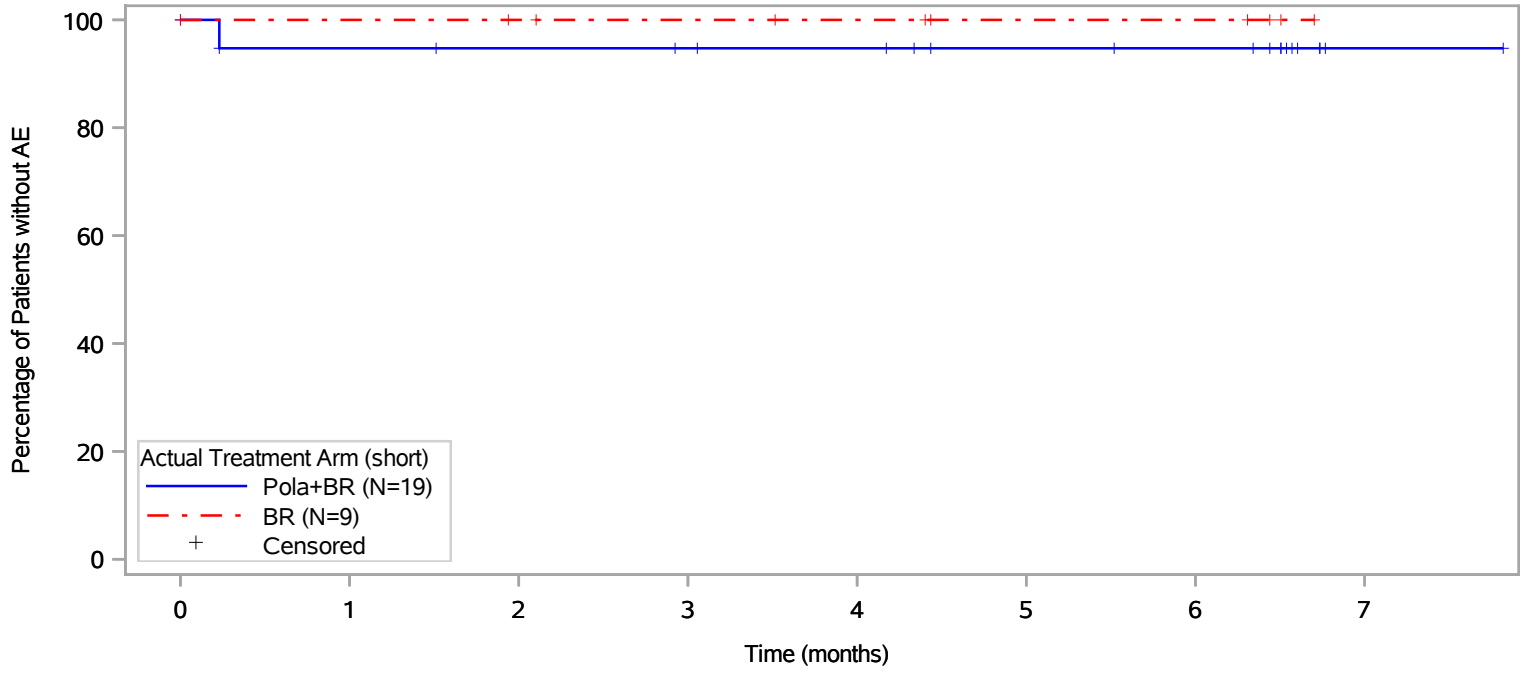
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, EPSTEIN-BARR VIRUS ANTIBODY POSITIVE



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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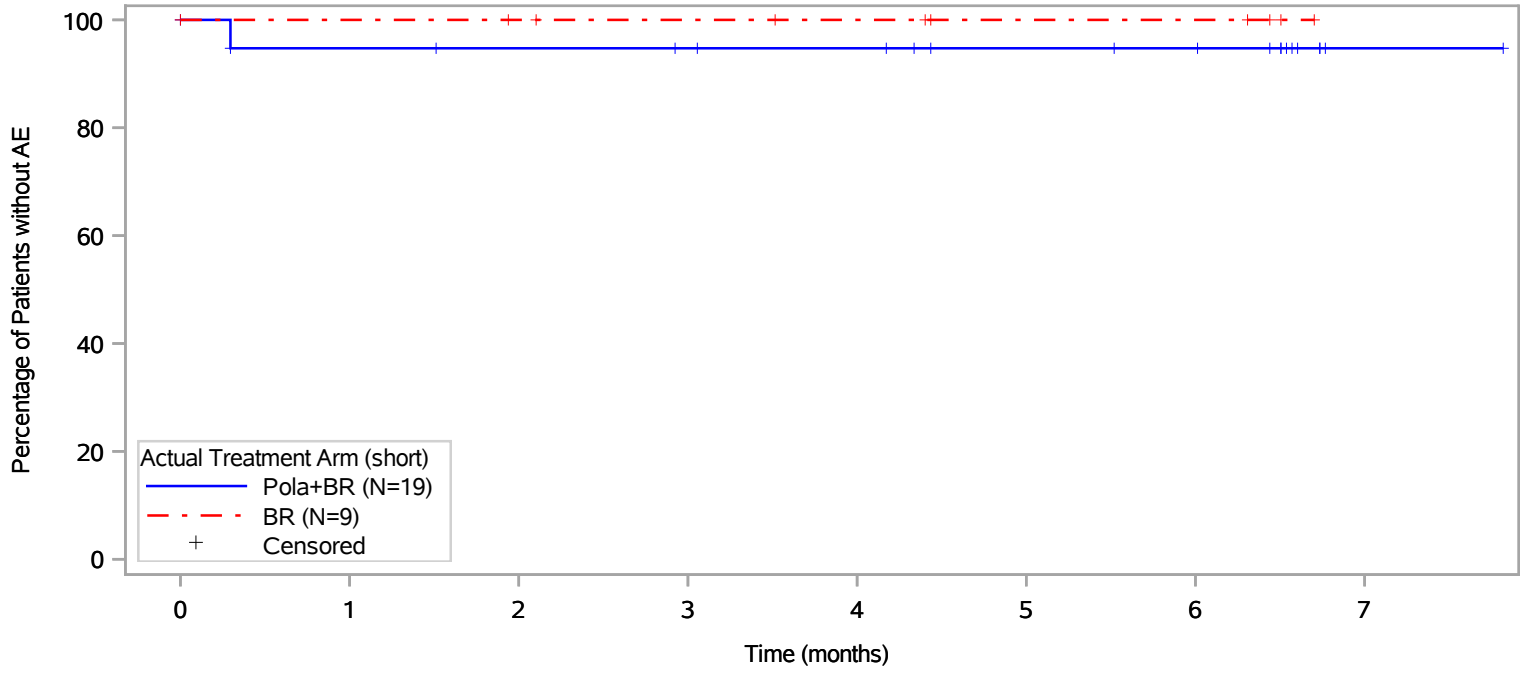
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, FIBRIN D DIMER INCREASED



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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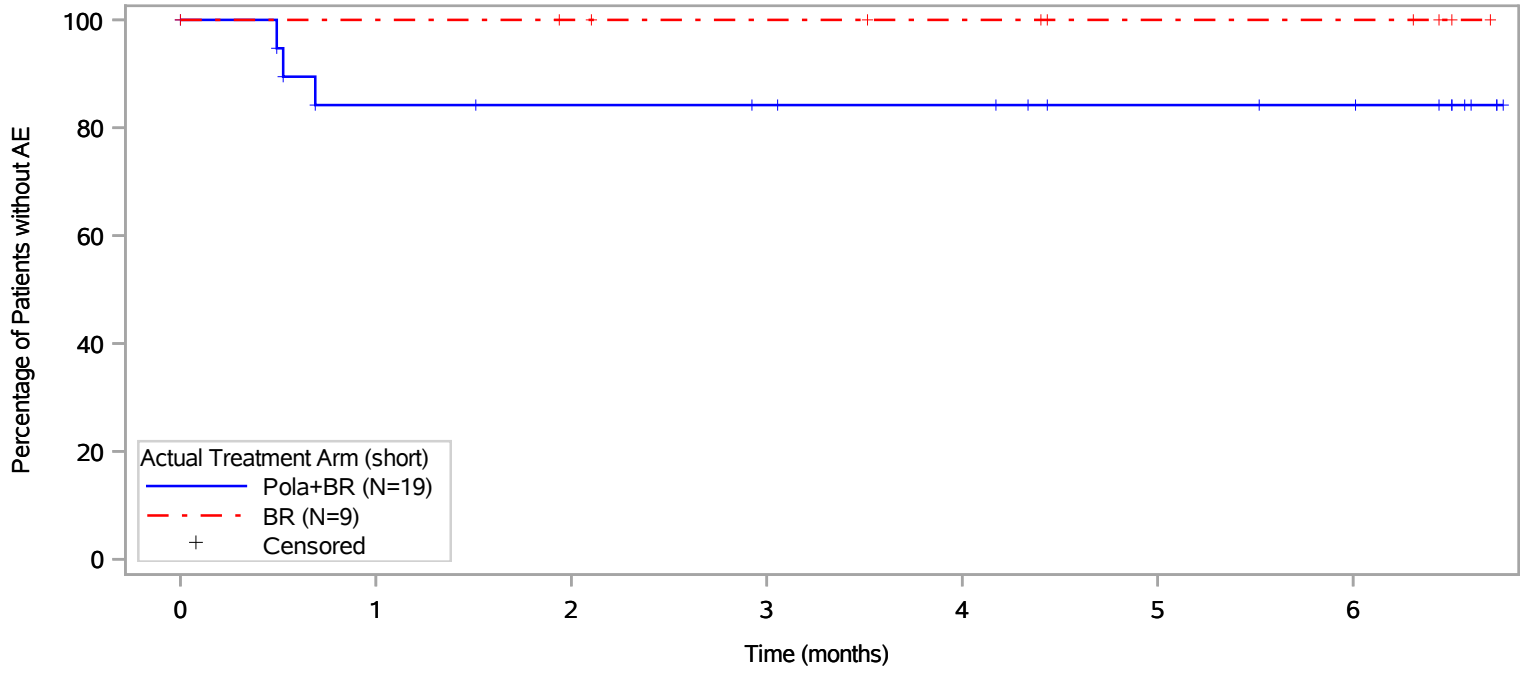
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GAMMA-GLUTAMYLTRANSFERASE INCREASED



Patients at risk							
Pola+BR (N=19)	19	16	15	14	13	10	9
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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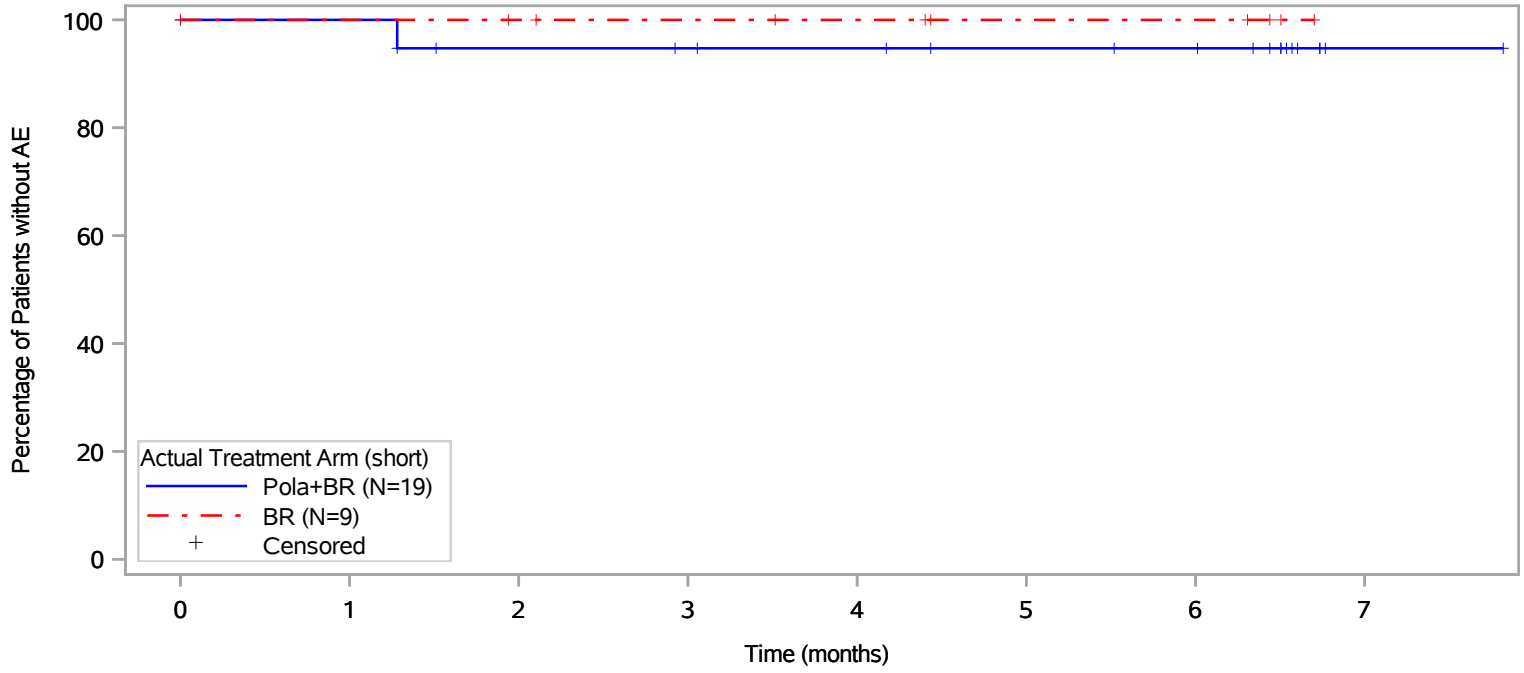
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GLOMERULAR FILTRATION RATE DECREASED

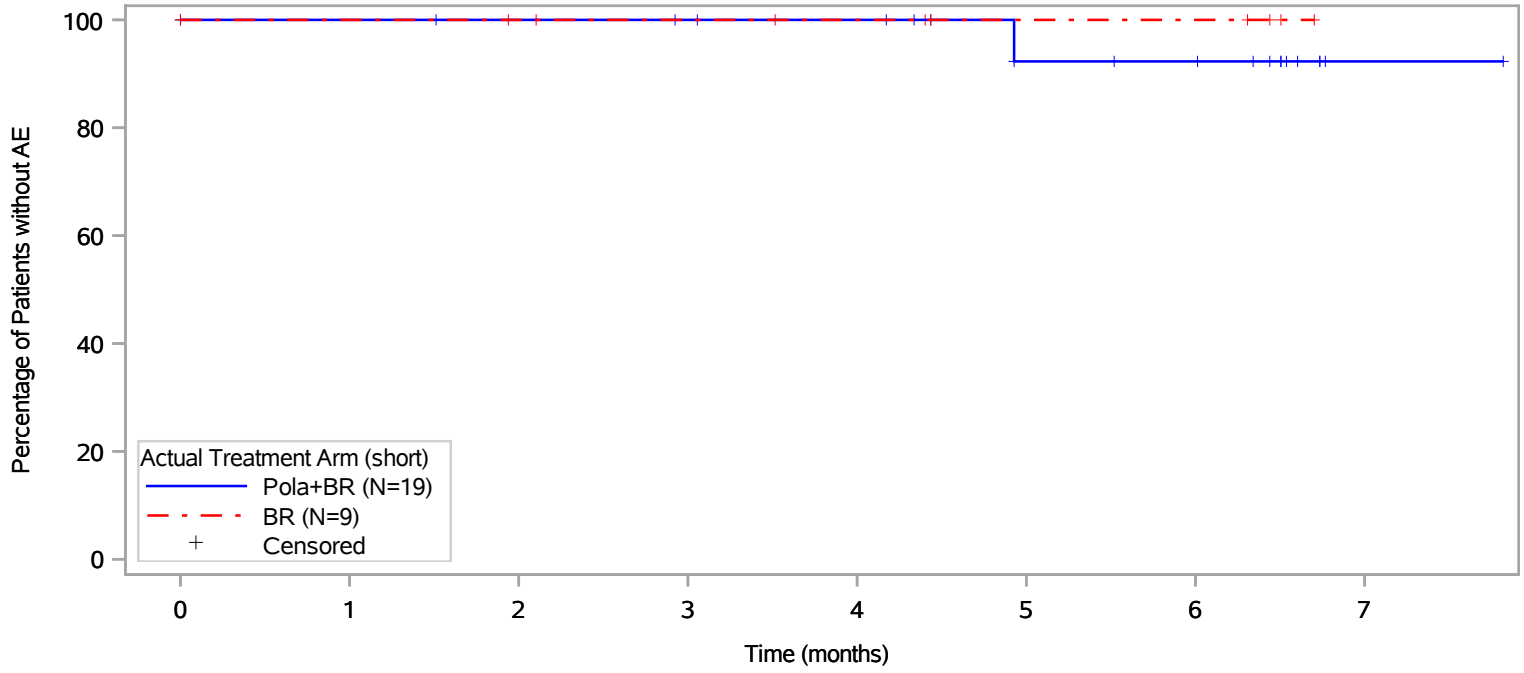


Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GRANULOCYTE COUNT DECREASED

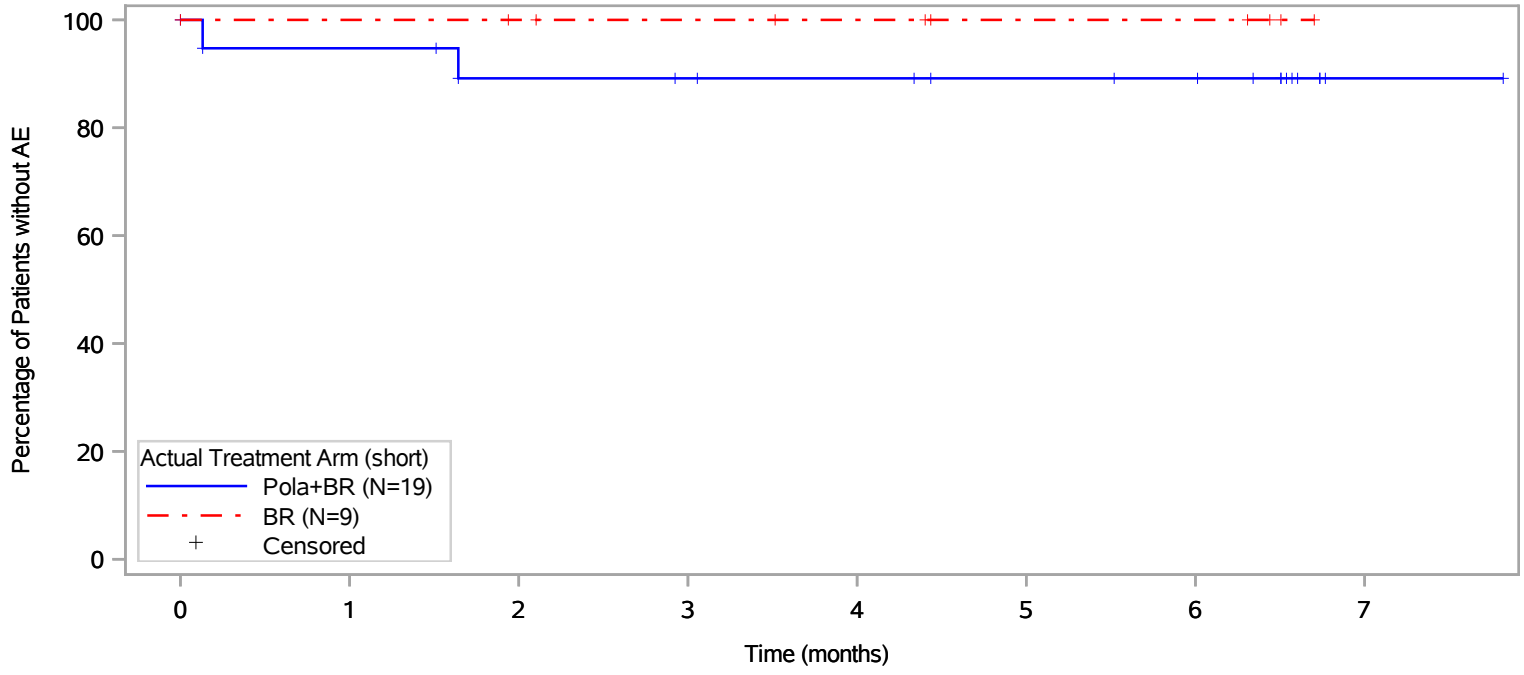


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, HAEMOGLOBIN DECREASED

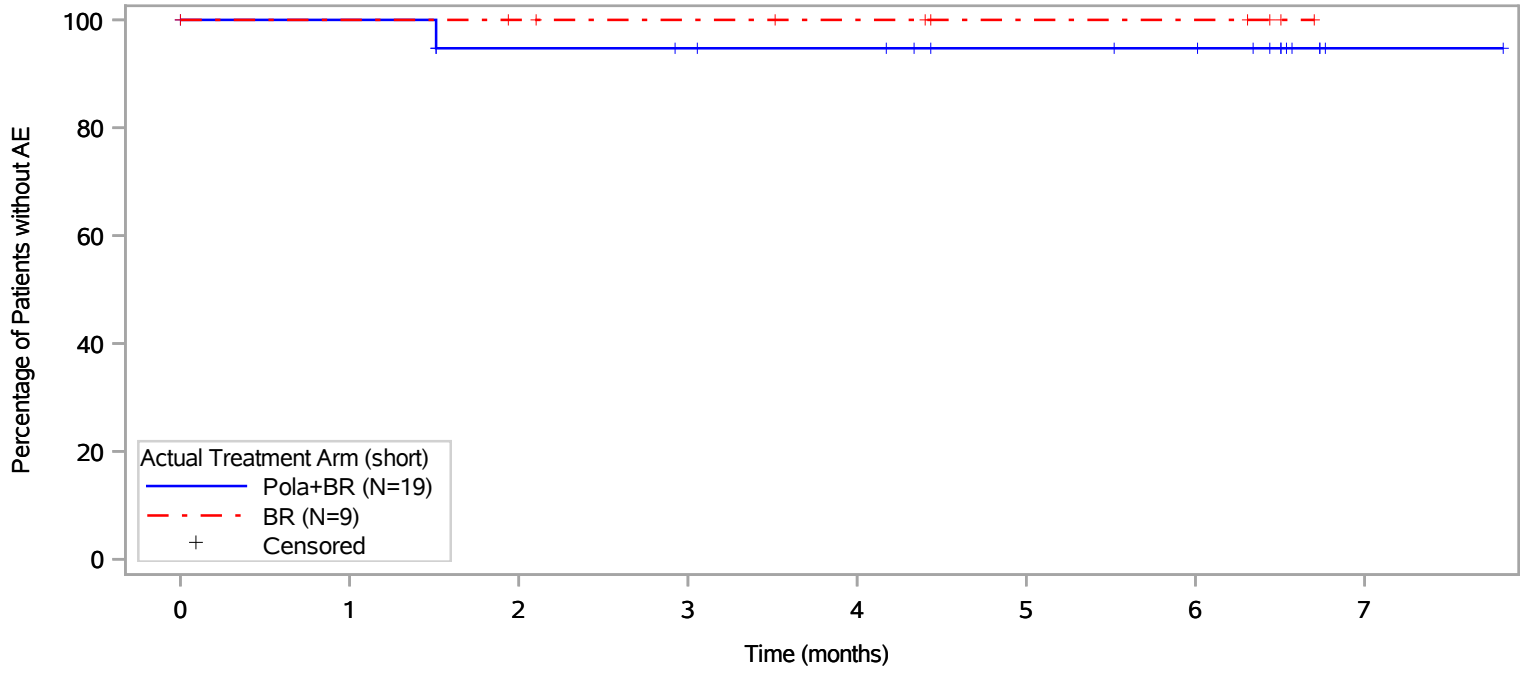


Patients at risk								
Pola+BR (N=19)	19	18	16	15	14	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, HEART RATE INCREASED

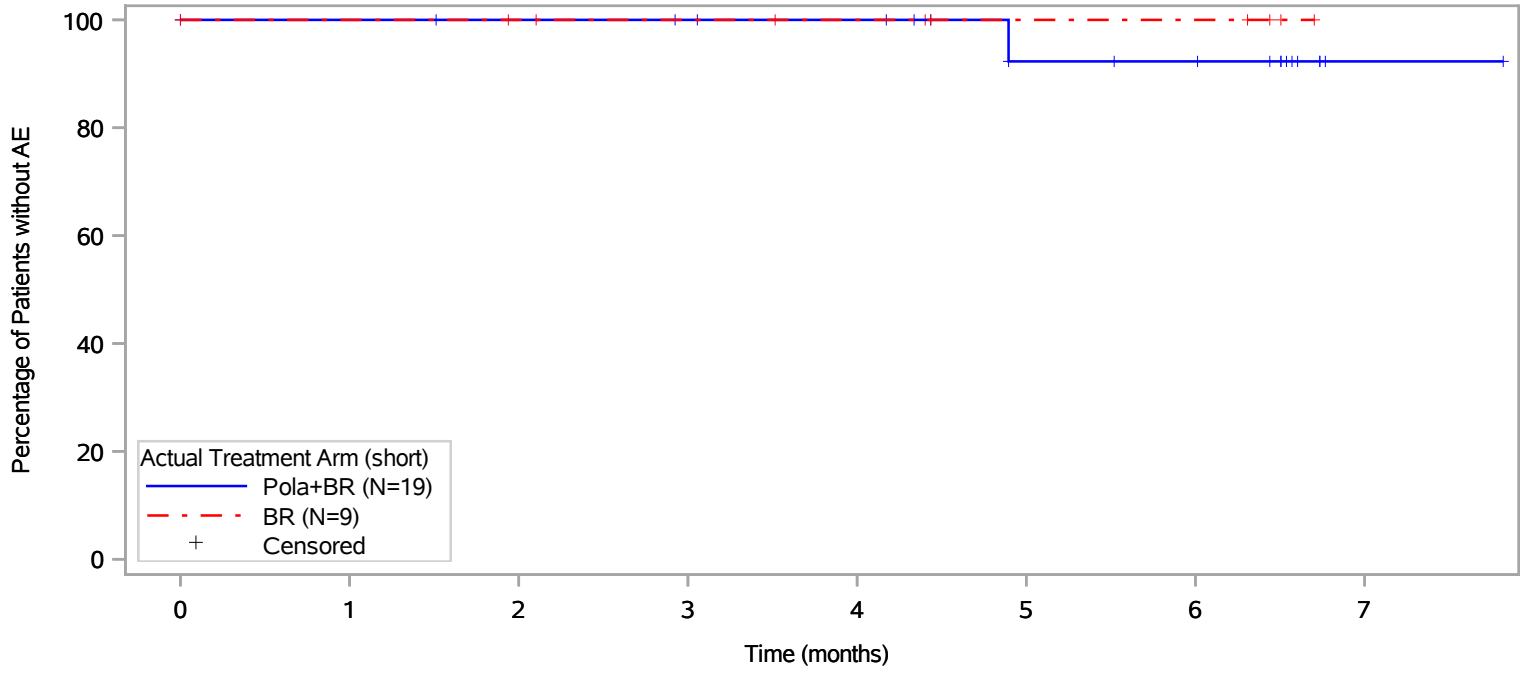


Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LIPASE INCREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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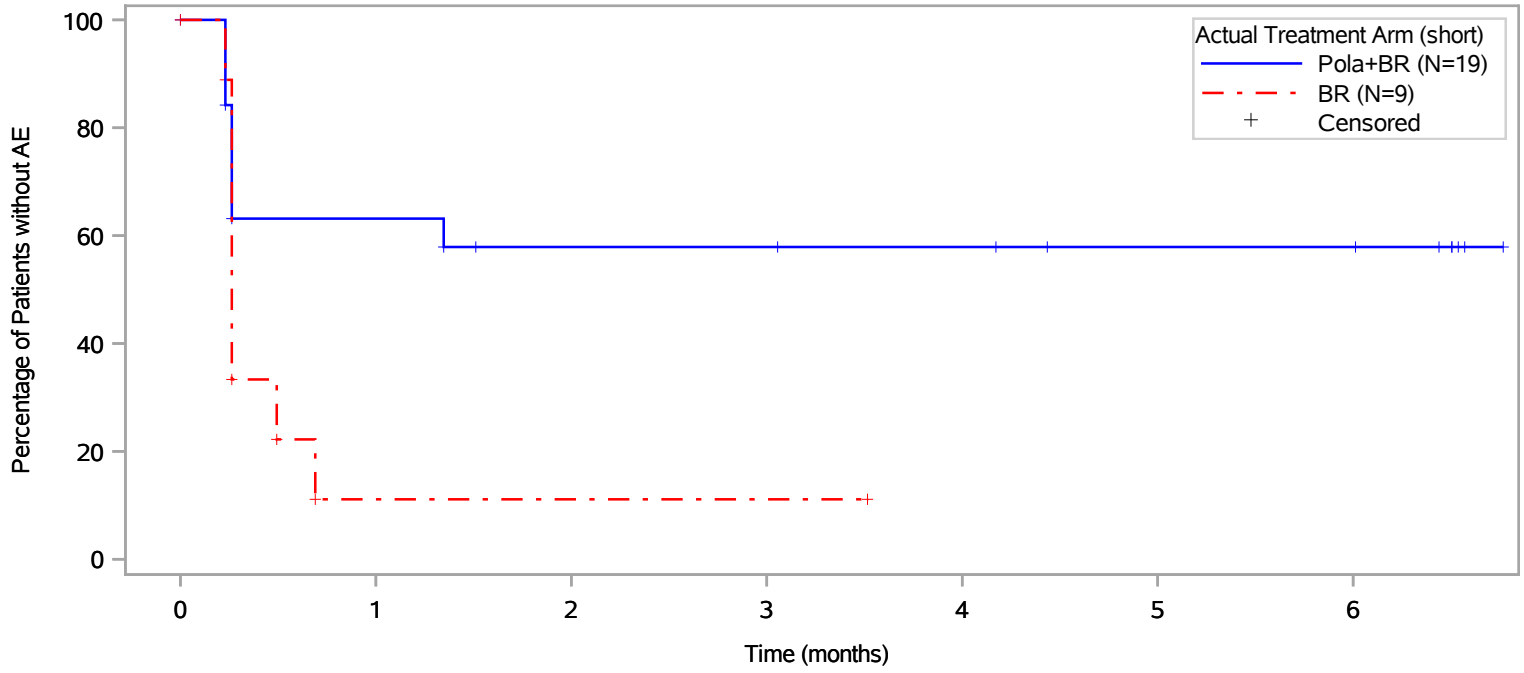
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk							
Pola+BR (N=19)	19	12	10	10	9	7	7
BR (N=9)	9	1	1	1	NE	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	1	1	2	4	4
BR (N=9)	0	0	0	0	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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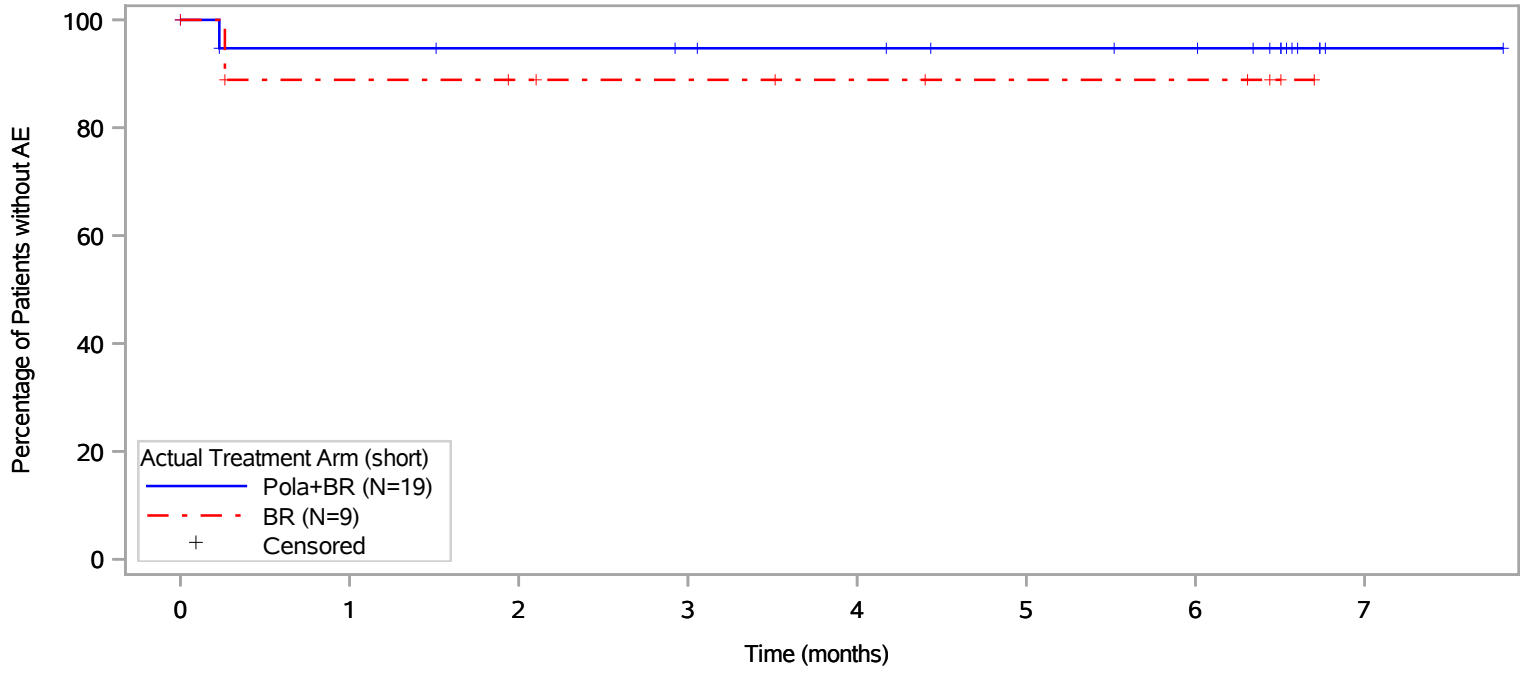
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE PERCENTAGE DECREASED

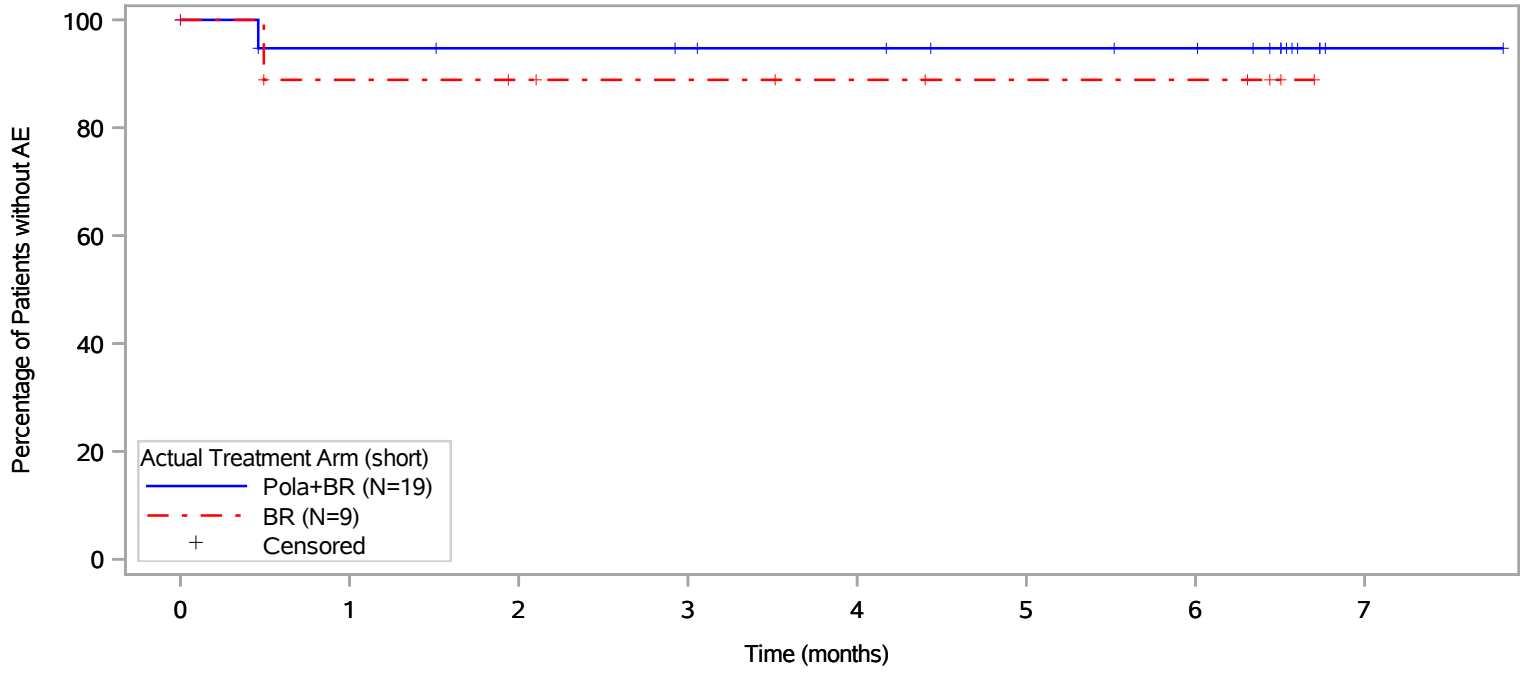


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, MONONUCLEAR CELL COUNT INCREASED

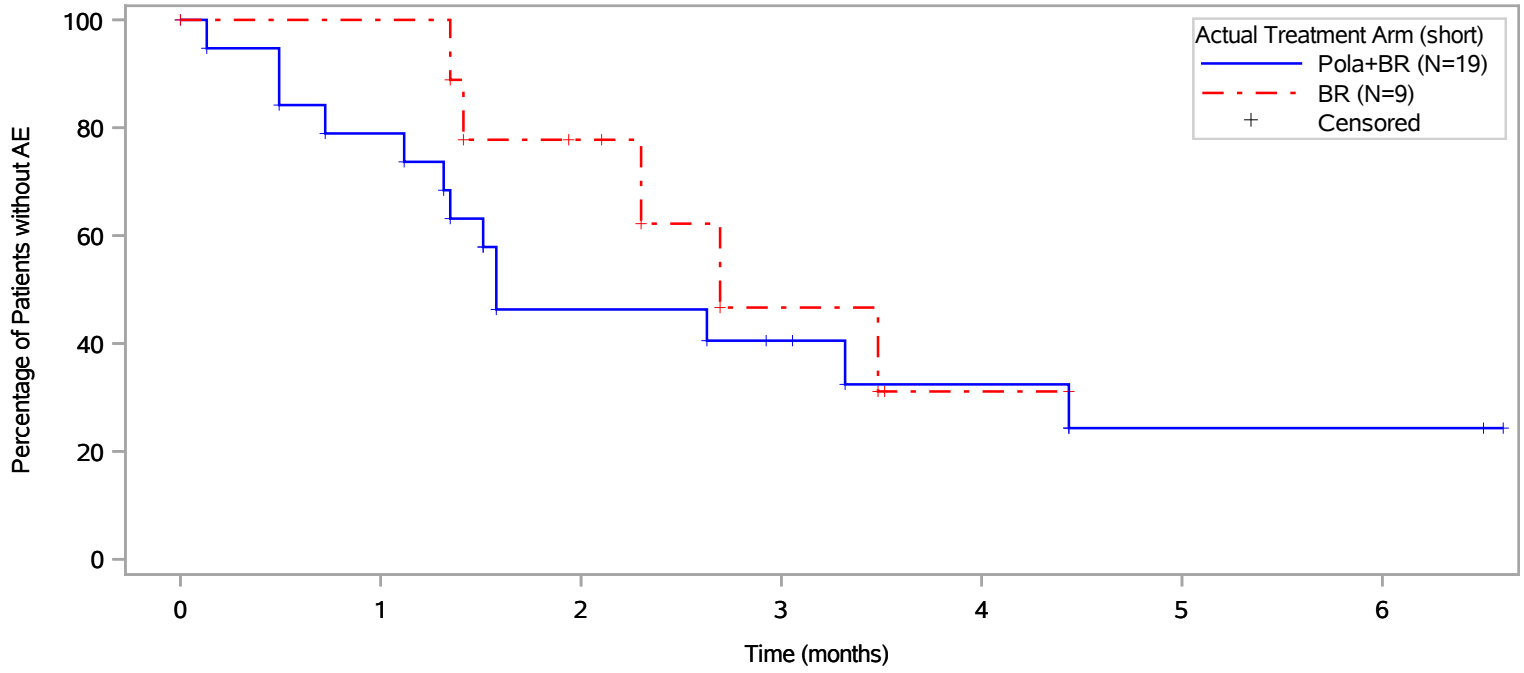


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

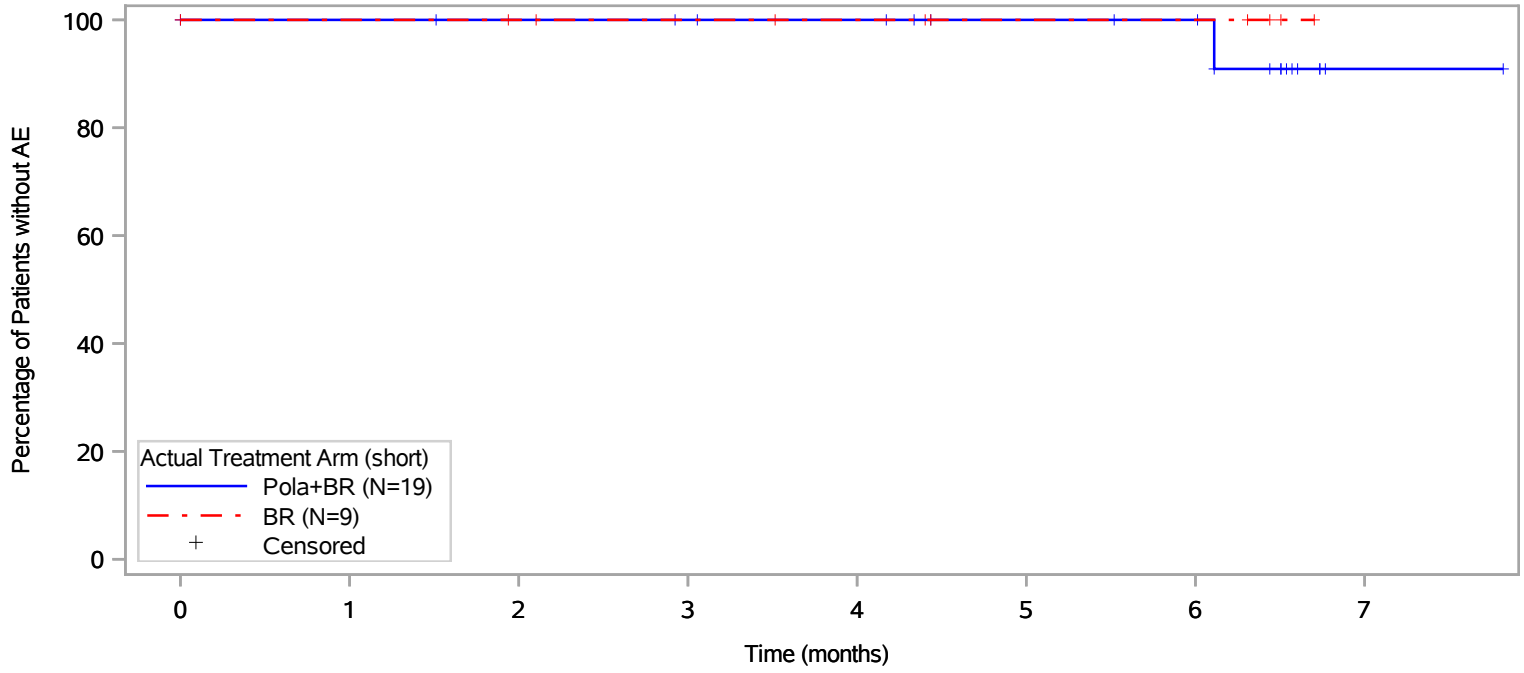


Patients at risk							
Pola+BR (N=19)	19	15	8	6	4	2	2
BR (N=9)	9	9	6	3	1	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	4	4
BR (N=9)	0	0	1	2	3	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT INCREASED

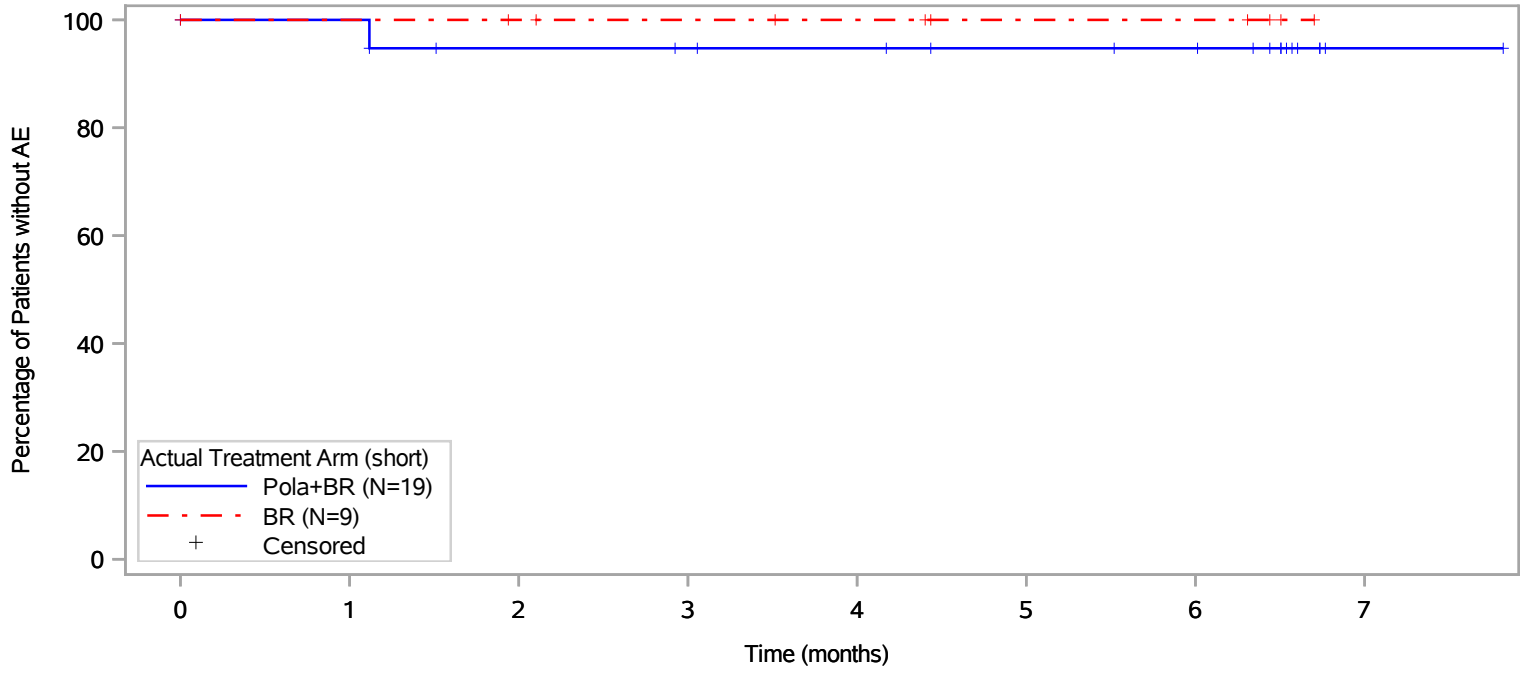


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL PERCENTAGE DECREASED

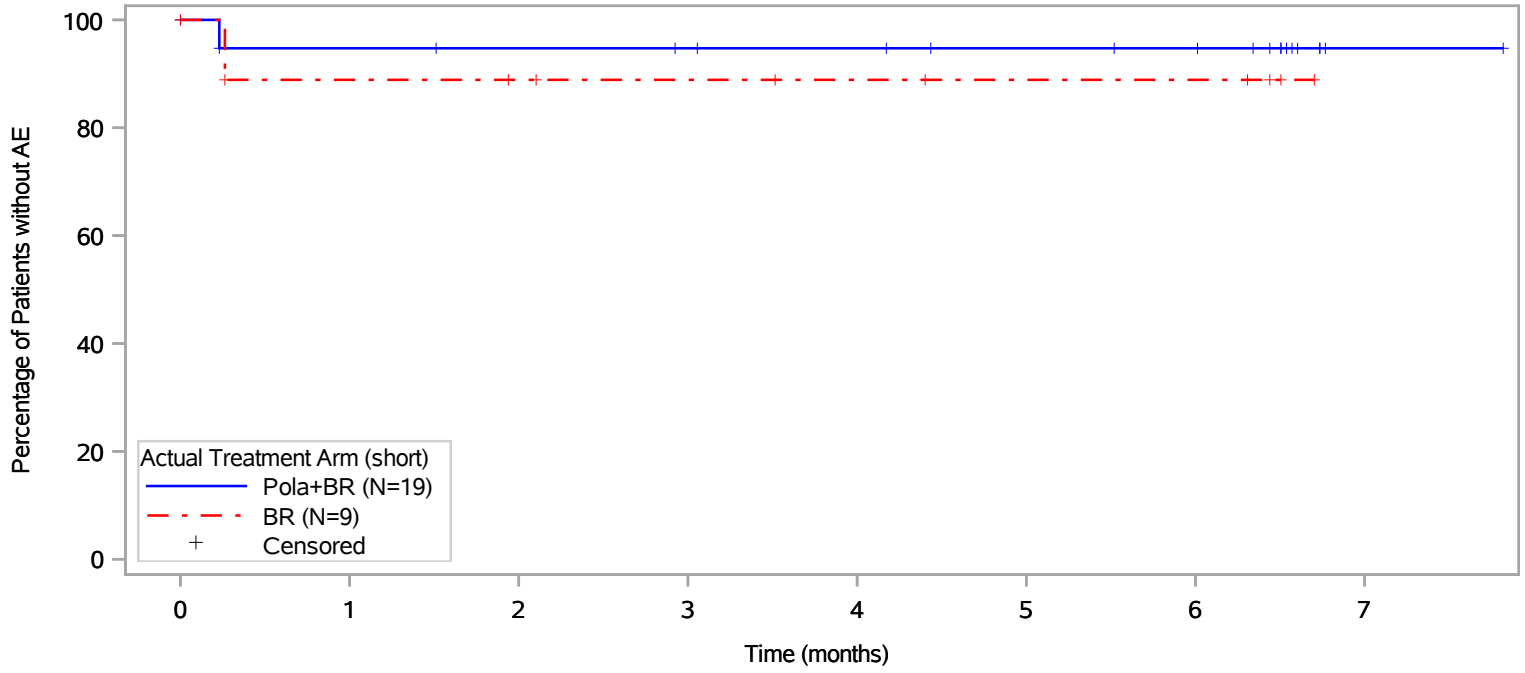


Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL PERCENTAGE INCREASED

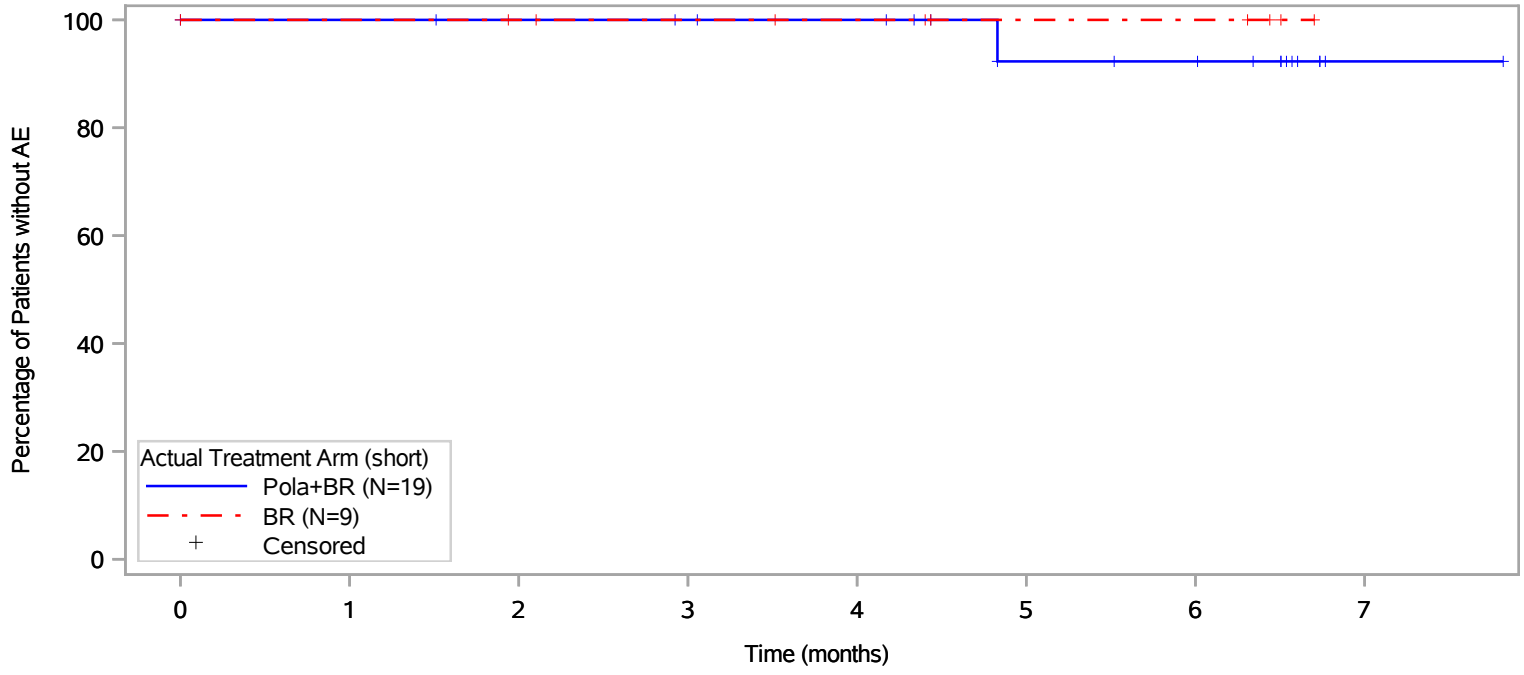


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NITRITE URINE PRESENT

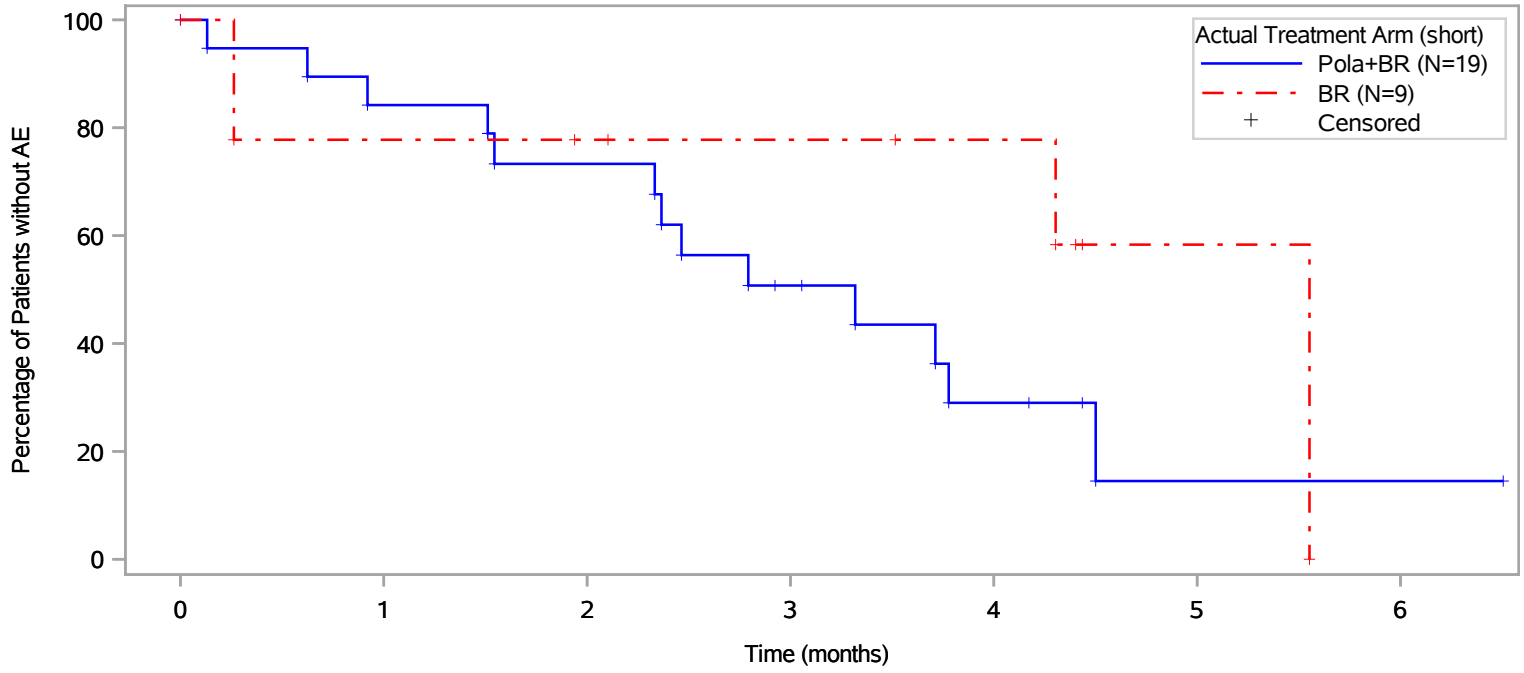


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

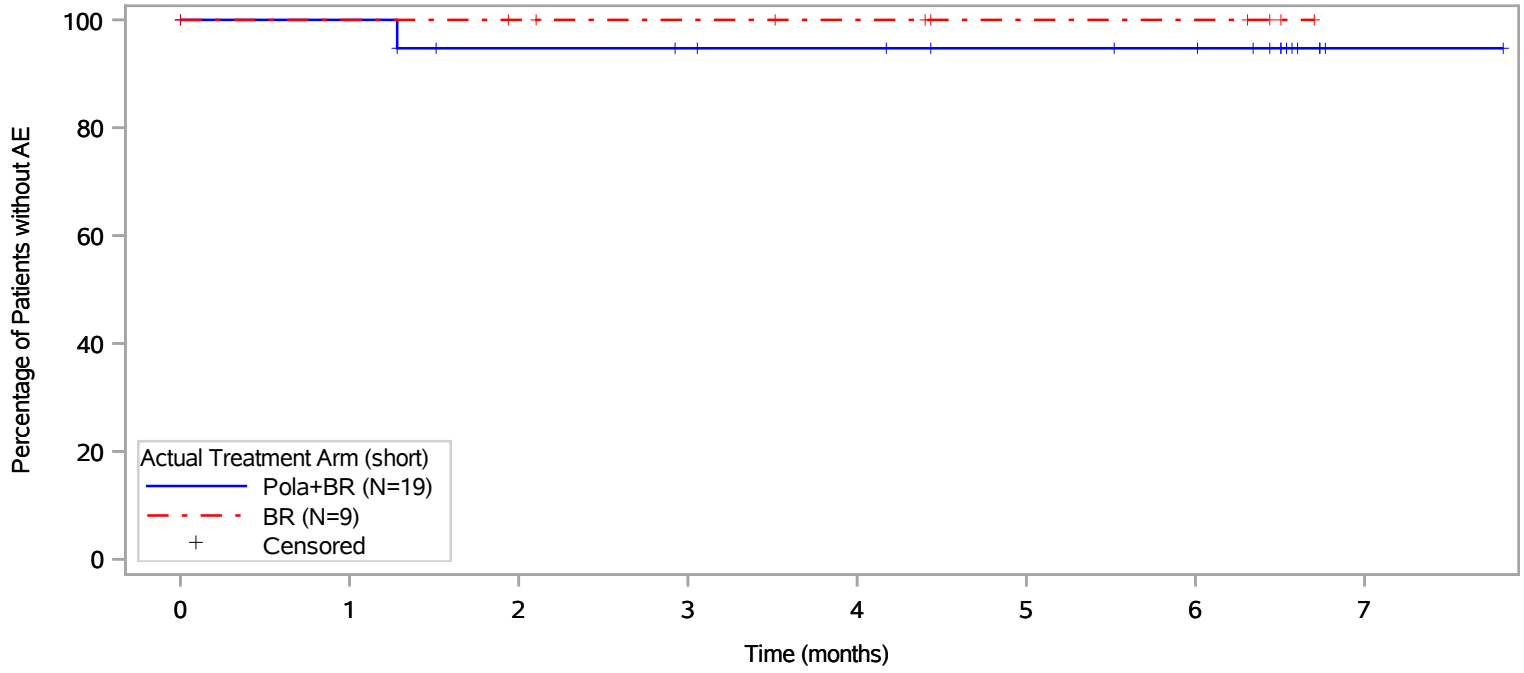


Patients at risk							
Pola+BR (N=19)	19	16	13	8	4	1	1
BR (N=9)	9	7	6	5	4	1	NE
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	5	5
BR (N=9)	0	0	1	2	3	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT INCREASED

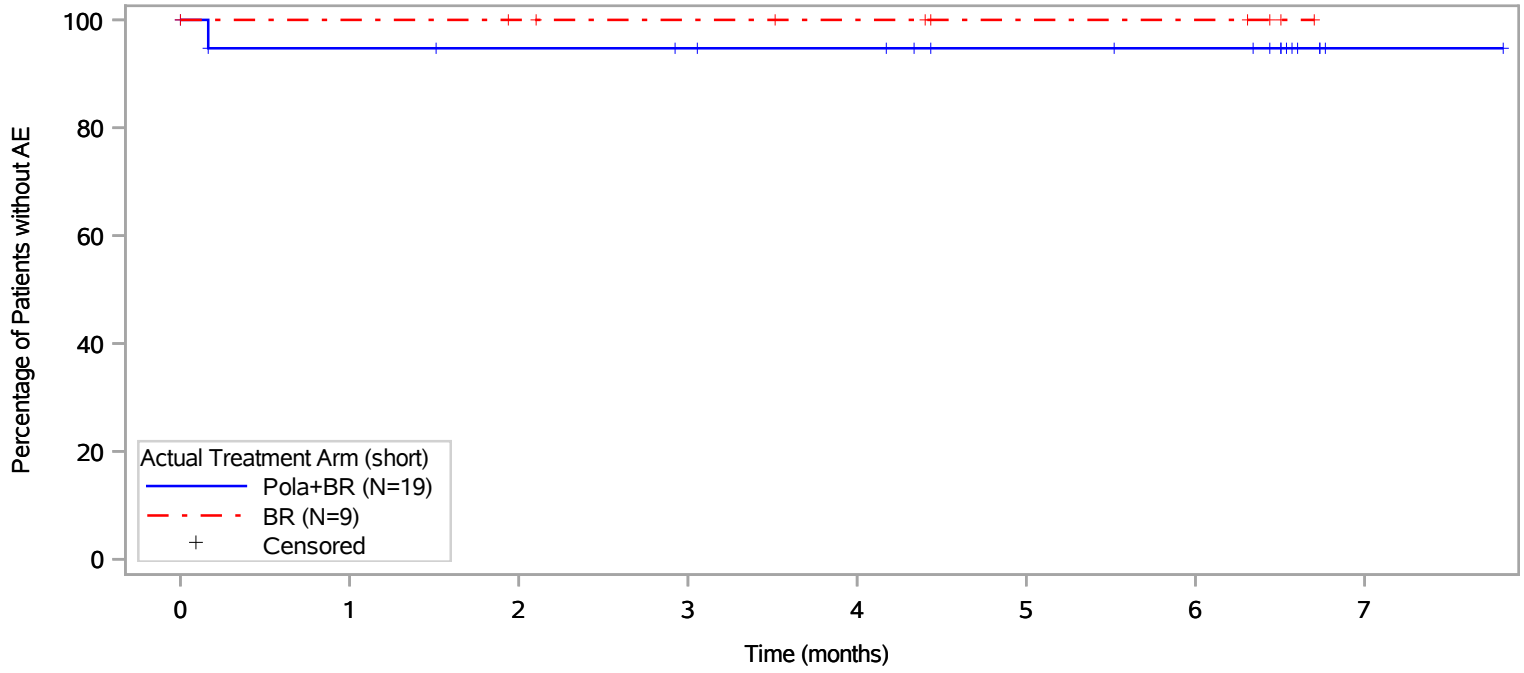


Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PROCALCITONIN INCREASED



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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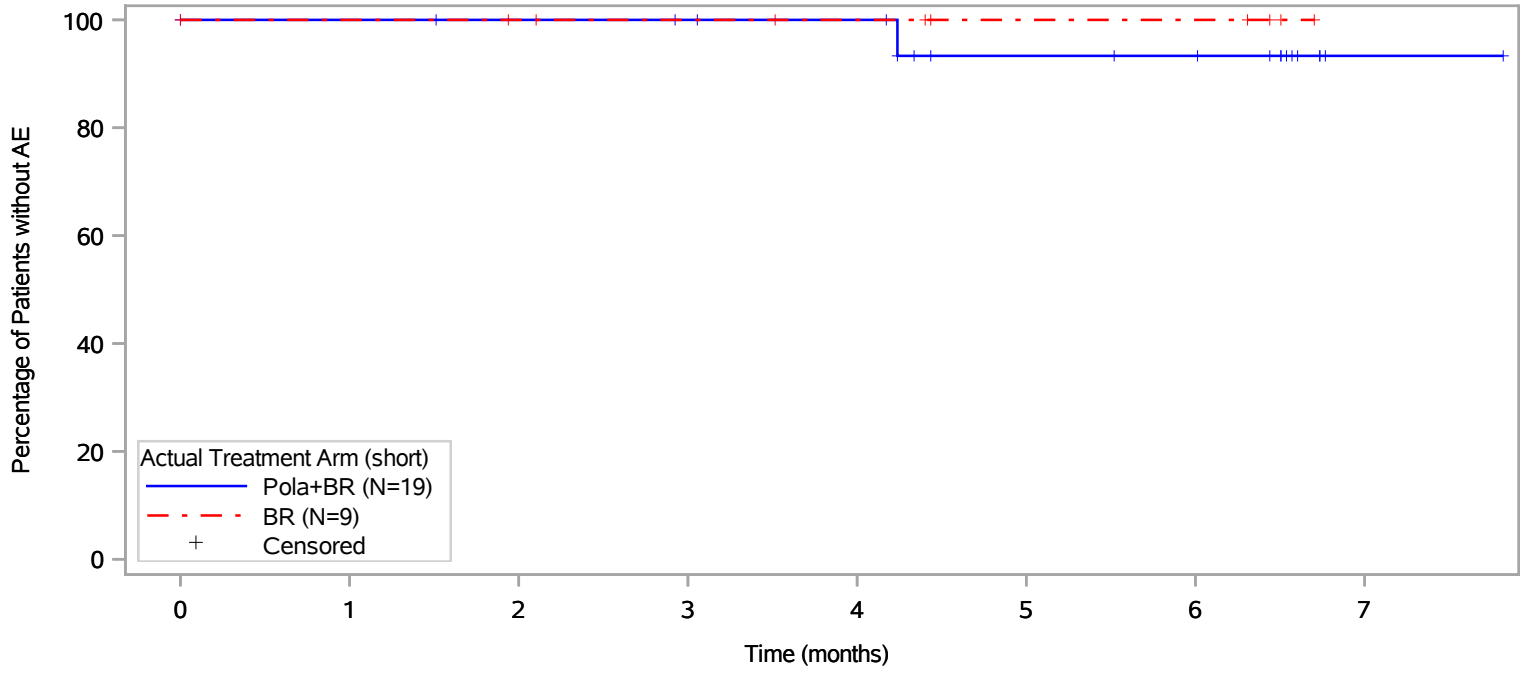
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PROHORMONE BRAIN NATRIURETIC PEPTIDE INCREASED

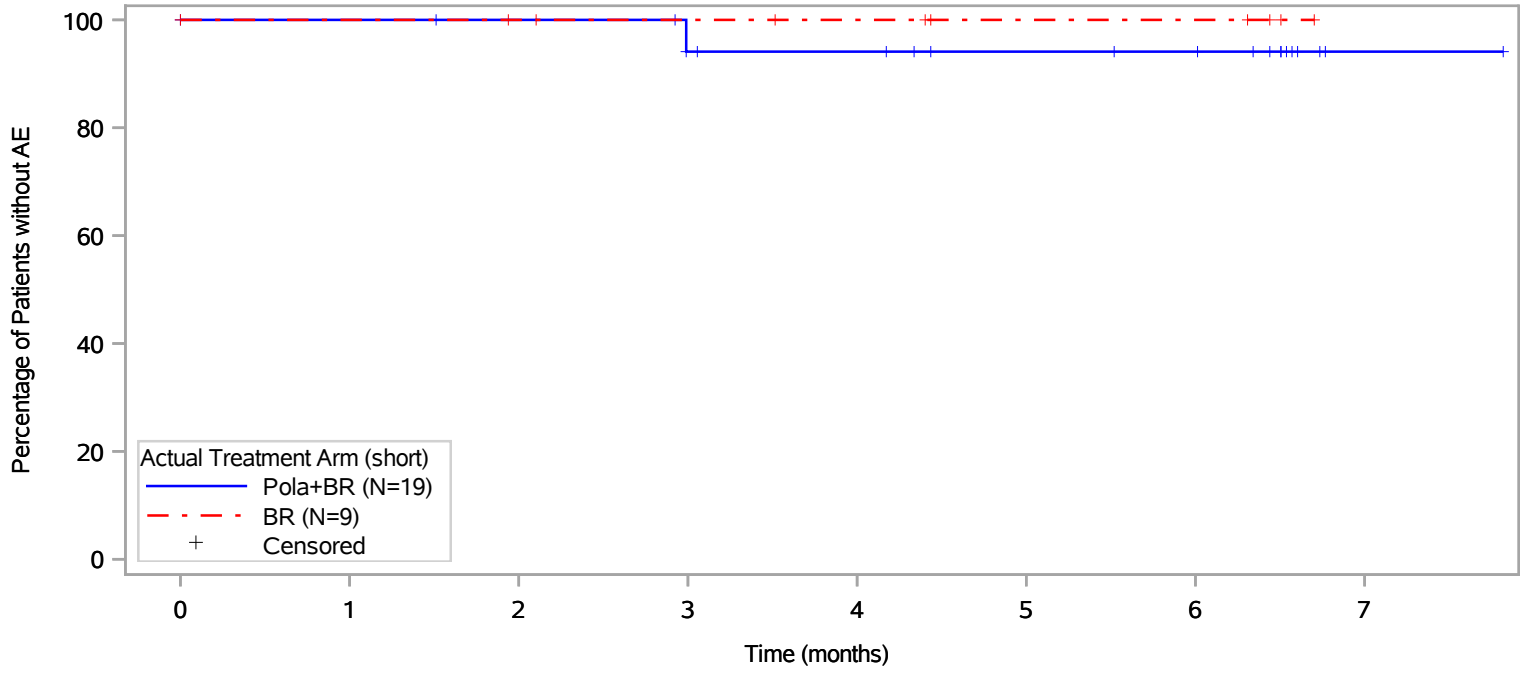


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PROTEIN TOTAL DECREASED

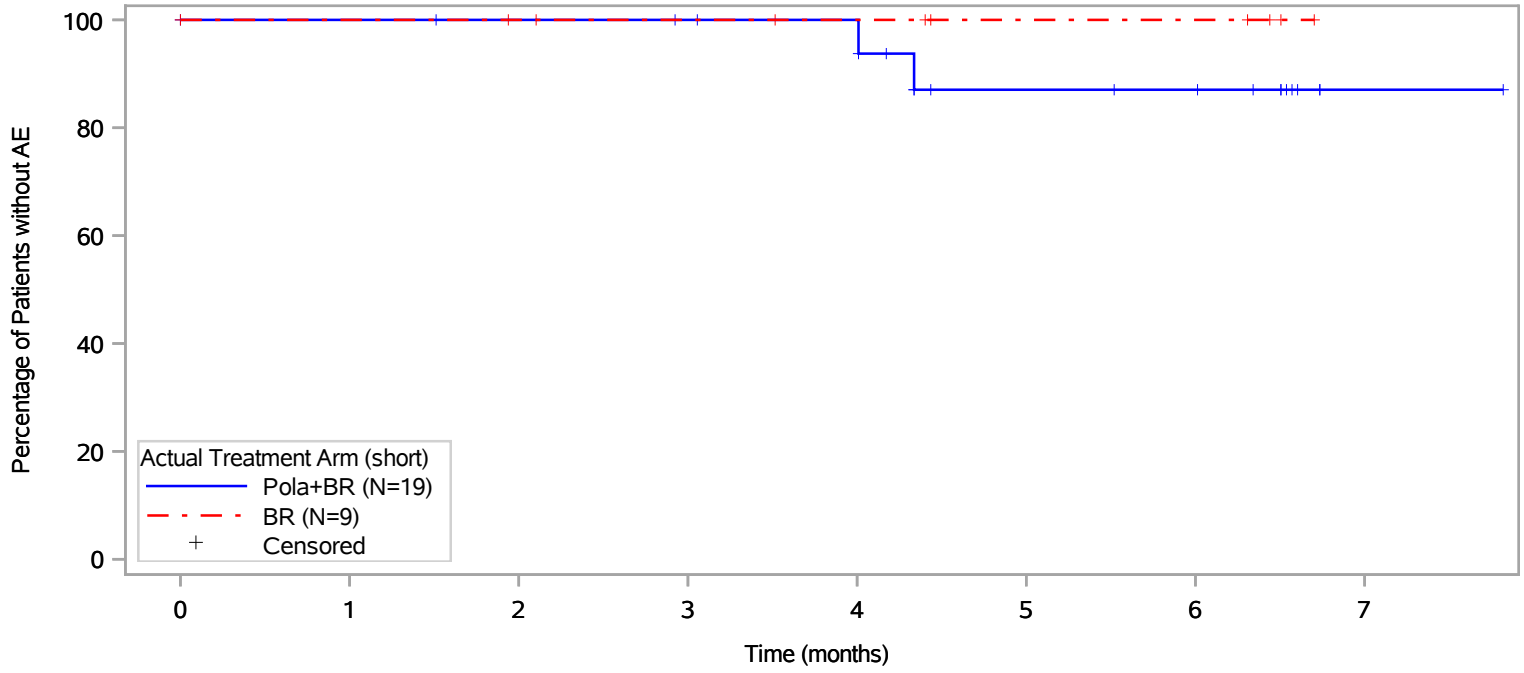


Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PROTEIN URINE PRESENT

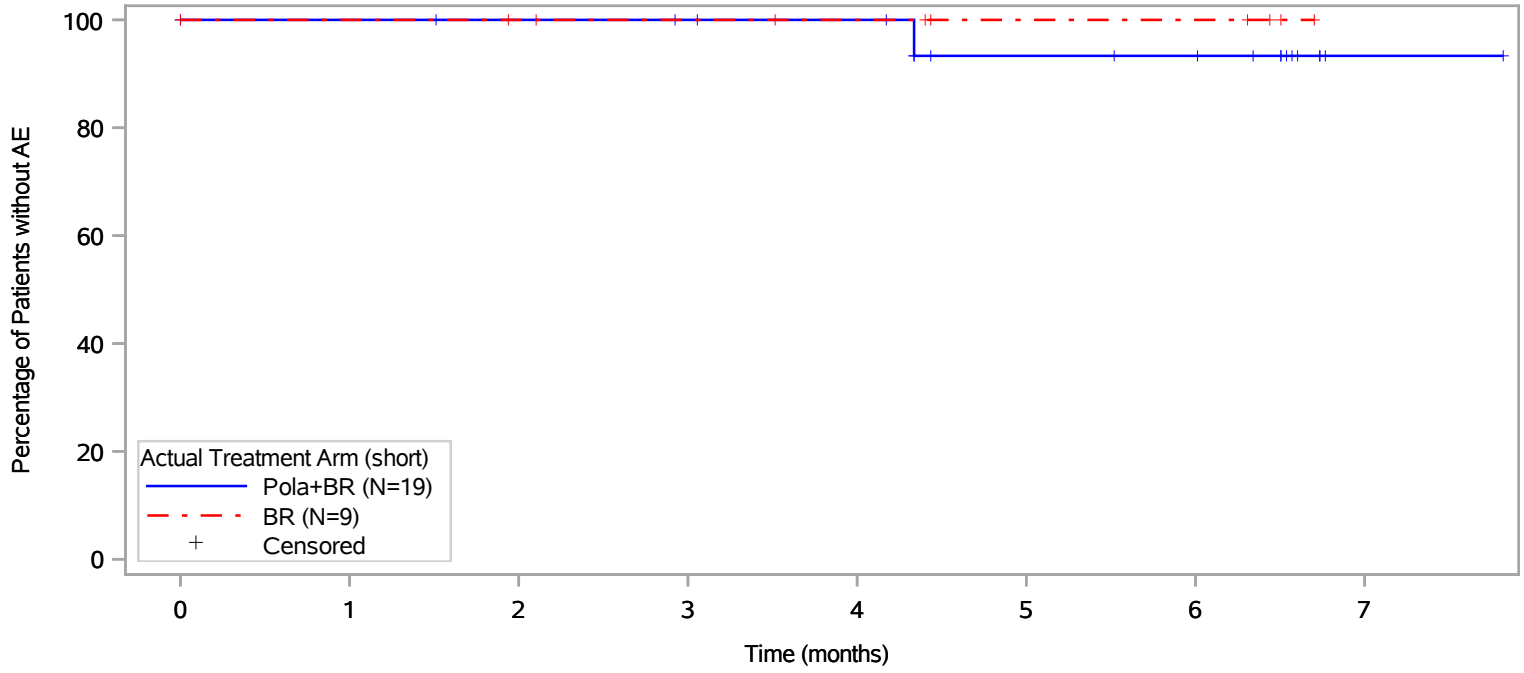


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	11	10	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, RED BLOOD CELLS URINE POSITIVE

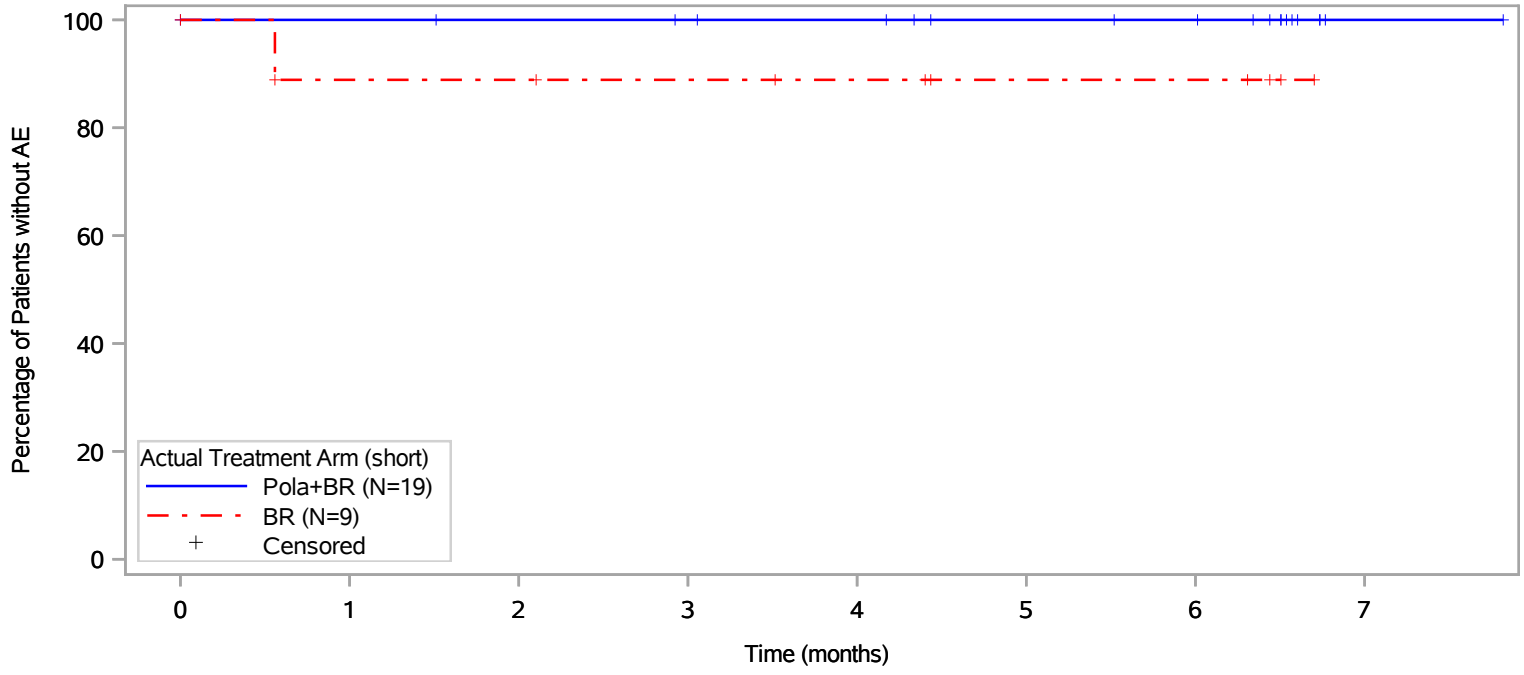


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, URINE OUTPUT DECREASED

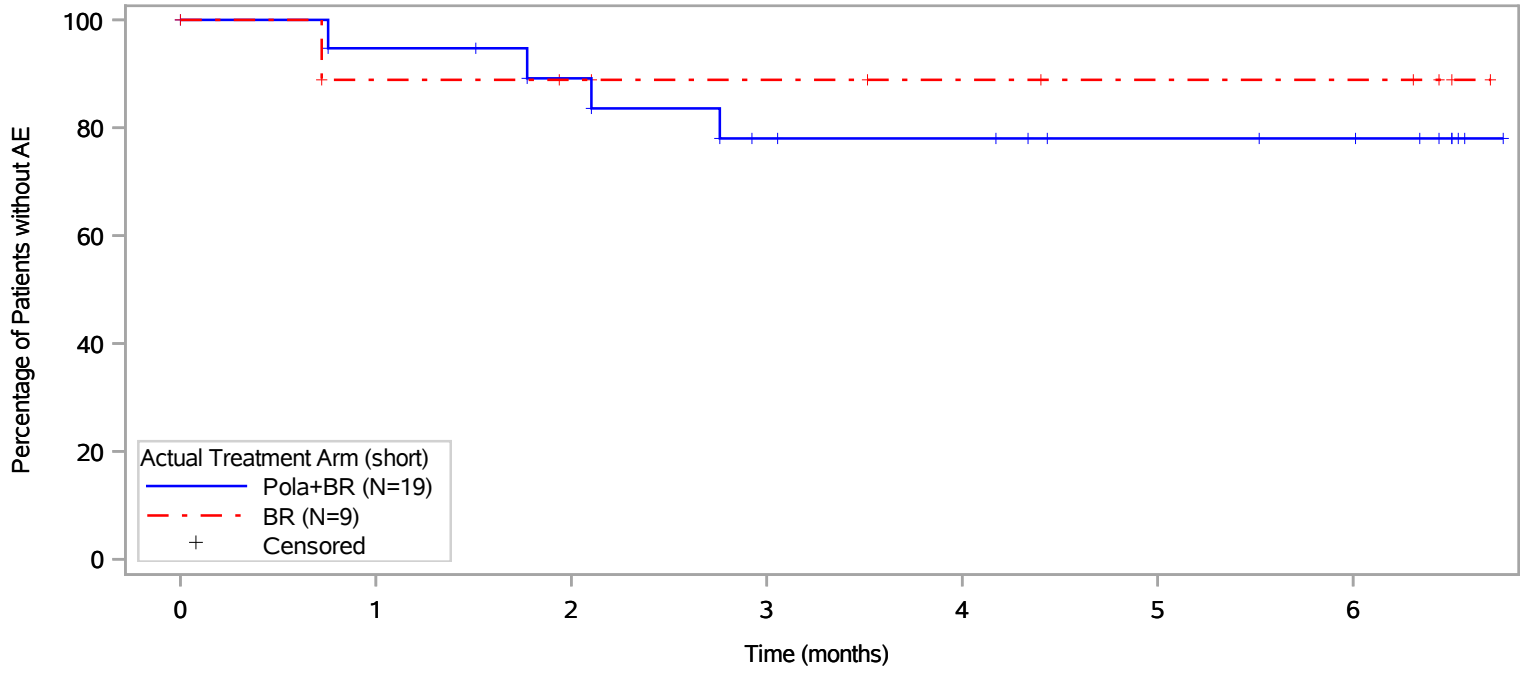


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	0	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WEIGHT DECREASED

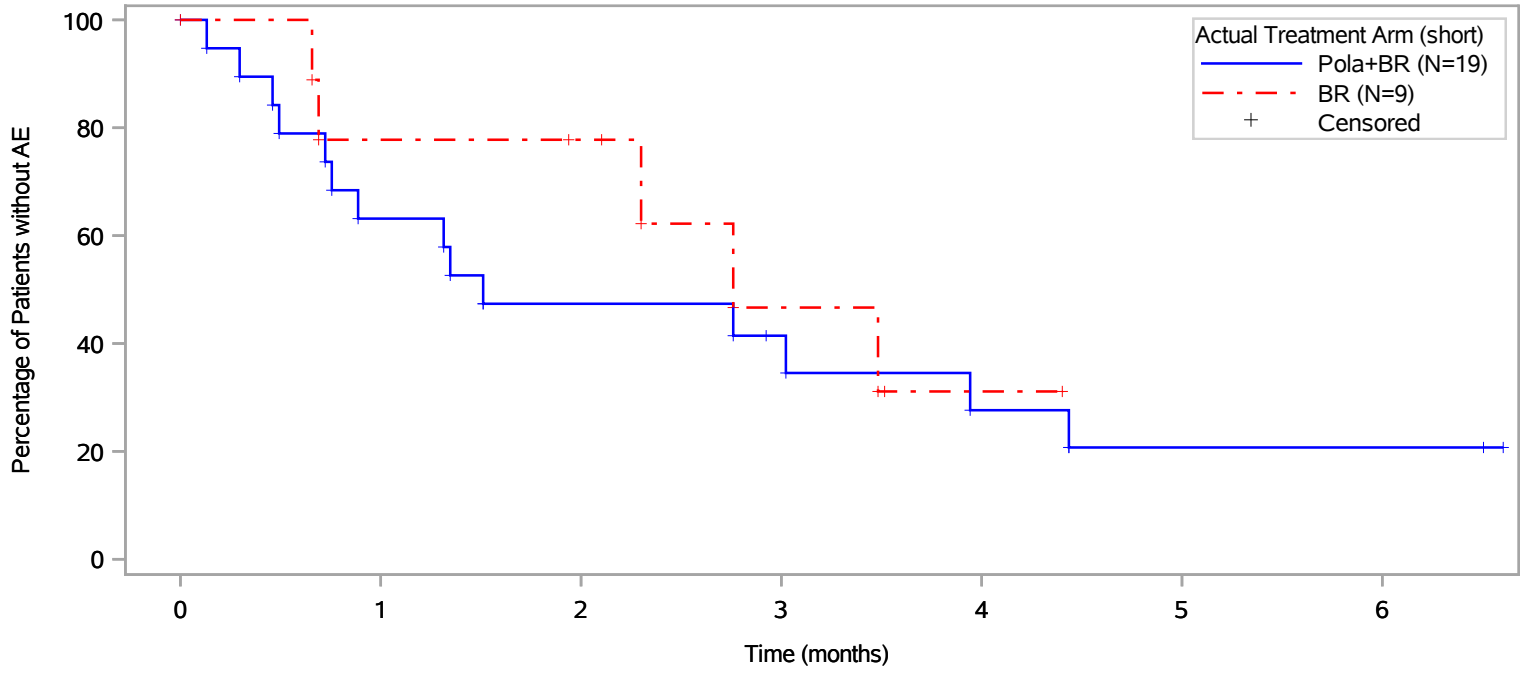


Patients at risk							
Pola+BR (N=19)	19	18	16	13	12	9	8
BR (N=9)	9	8	7	6	5	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	4	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED

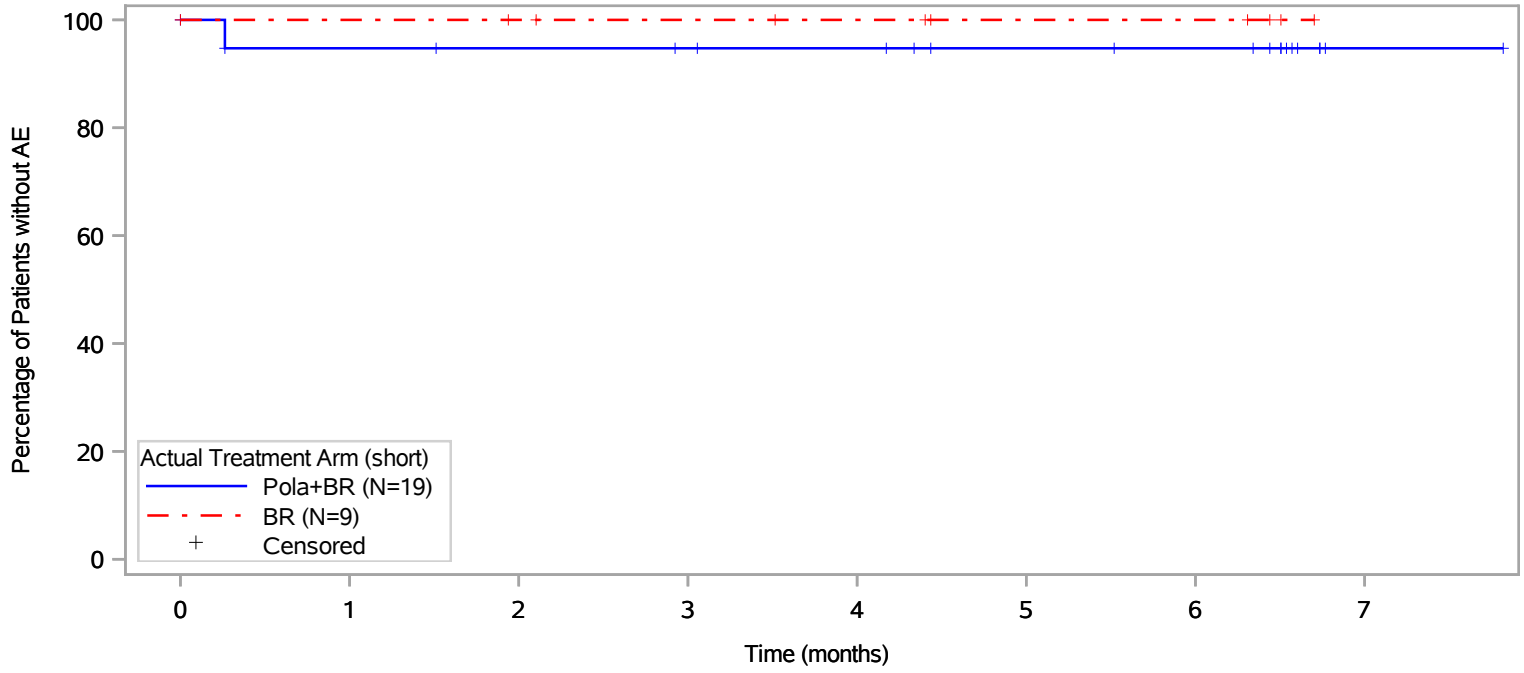


Patients at risk							
Pola+BR (N=19)	19	12	8	6	4	2	2
BR (N=9)	9	7	6	3	1	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	1	2	2	3	3
BR (N=9)	0	0	1	2	3	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT INCREASED

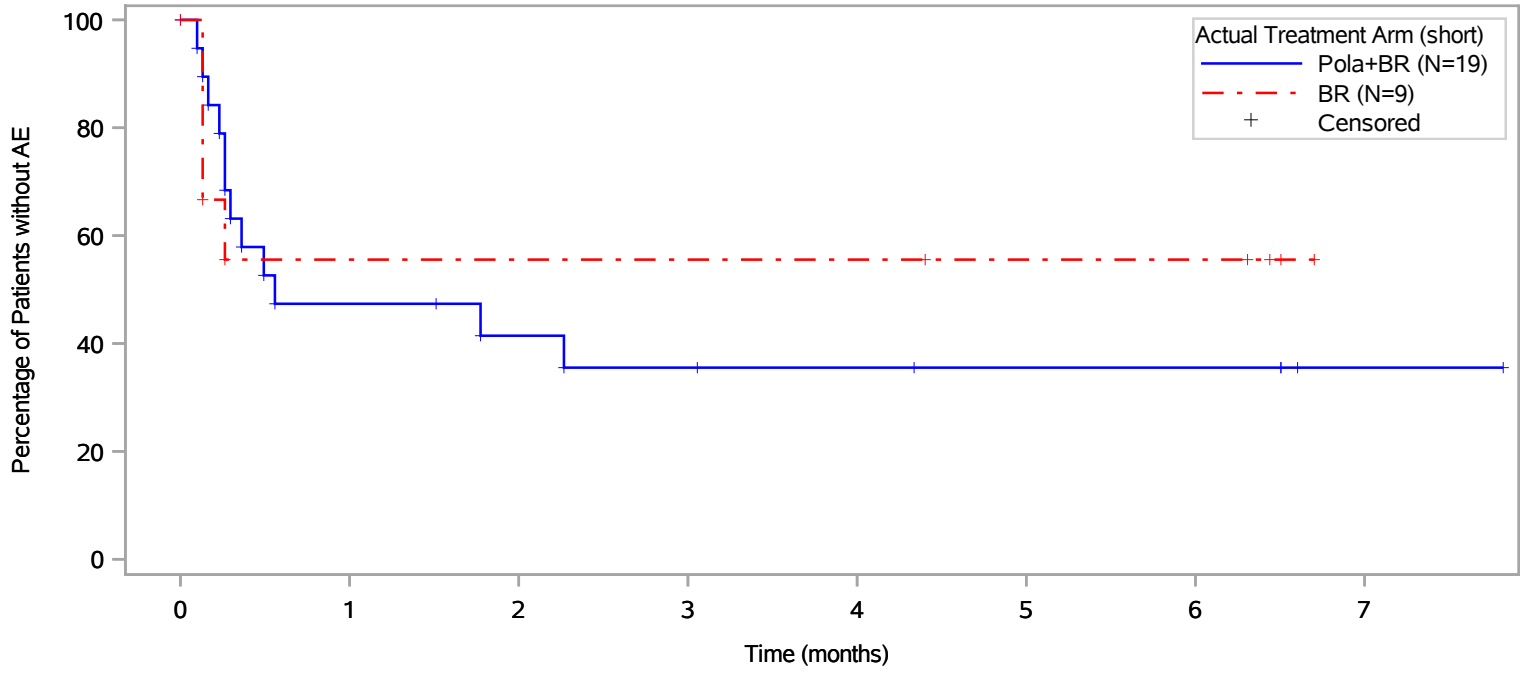


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All

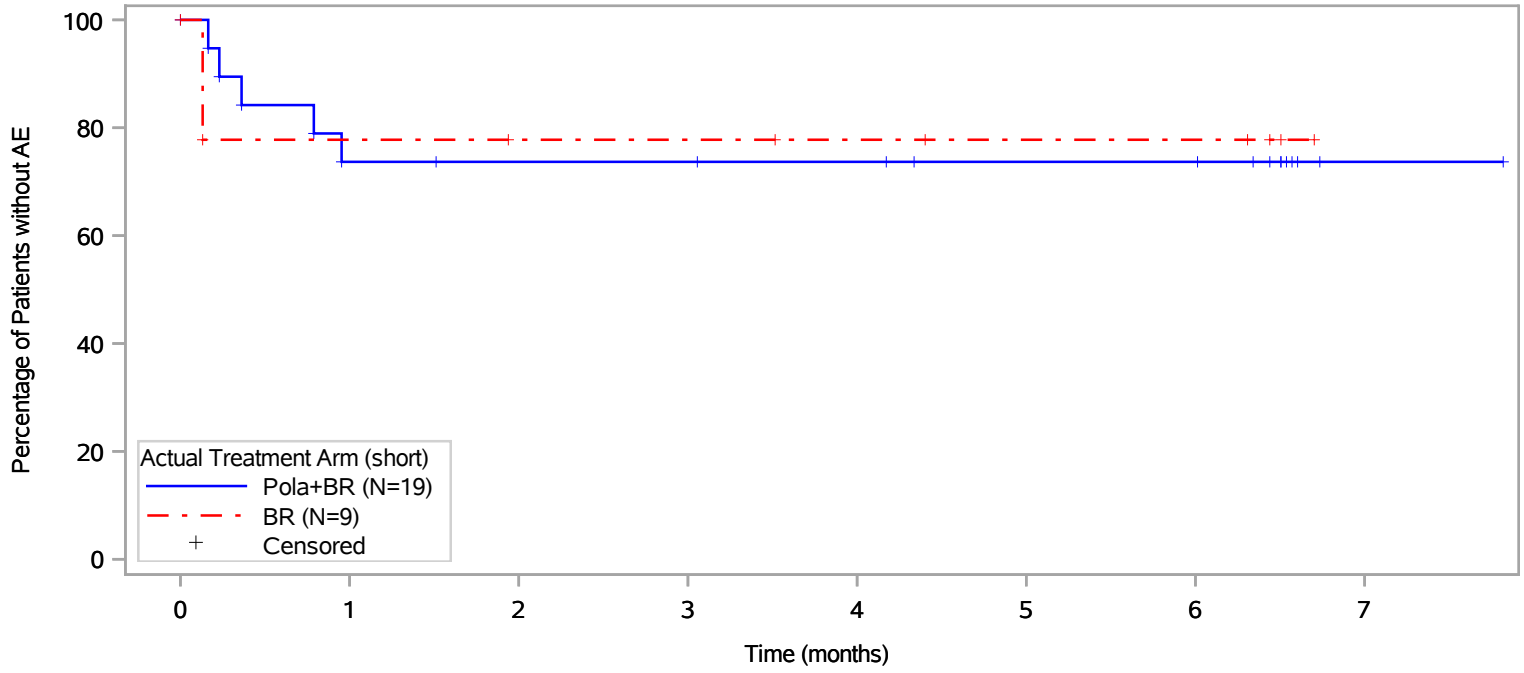


Patients at risk								
Pola+BR (N=19)	19	9	7	6	5	4	4	1
BR (N=9)	9	5	5	5	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	1	2	3	3	6
BR (N=9)	0	0	0	0	0	1	1	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, DECREASED APPETITE

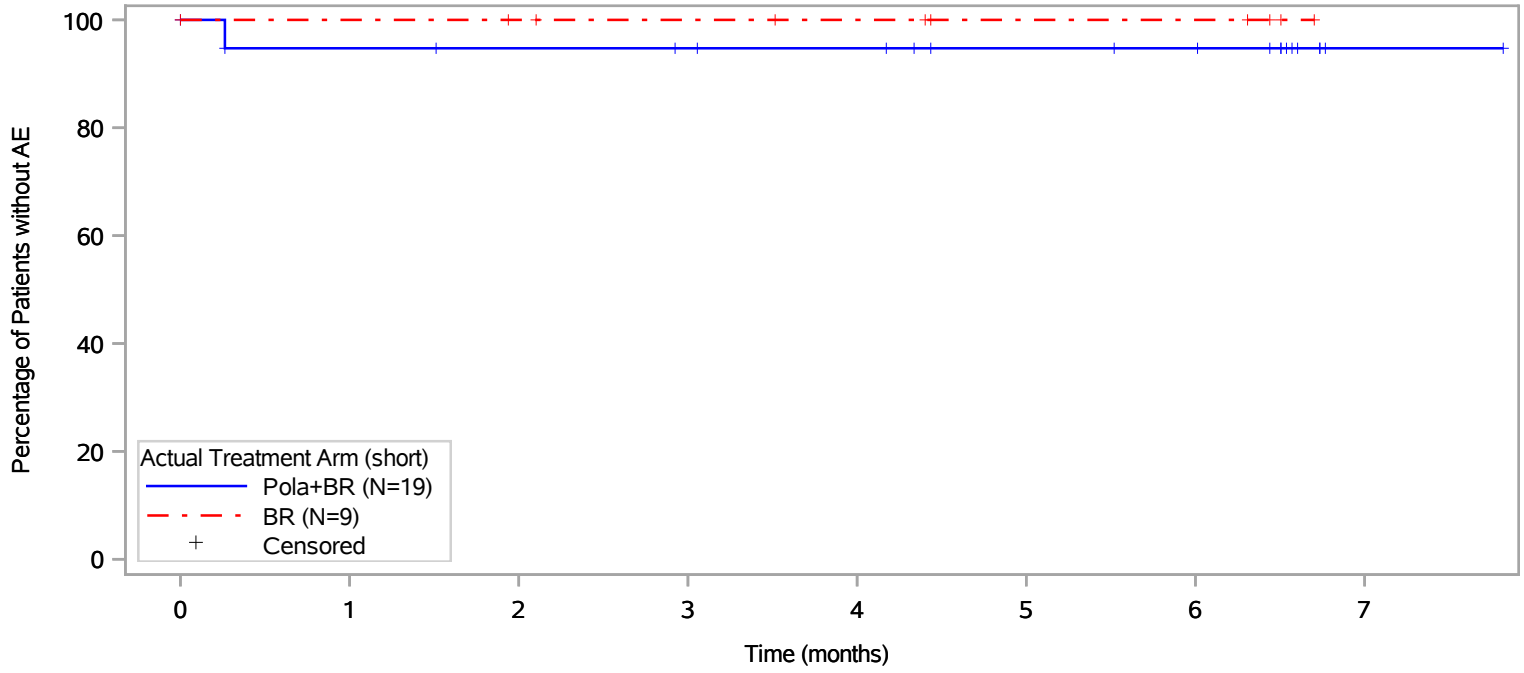


Patients at risk								
Pola+BR (N=19)	19	14	13	13	12	10	10	1
BR (N=9)	9	7	6	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	1	2	4	4	13
BR (N=9)	0	0	1	1	2	3	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERCHOLESTEROLAEMIA

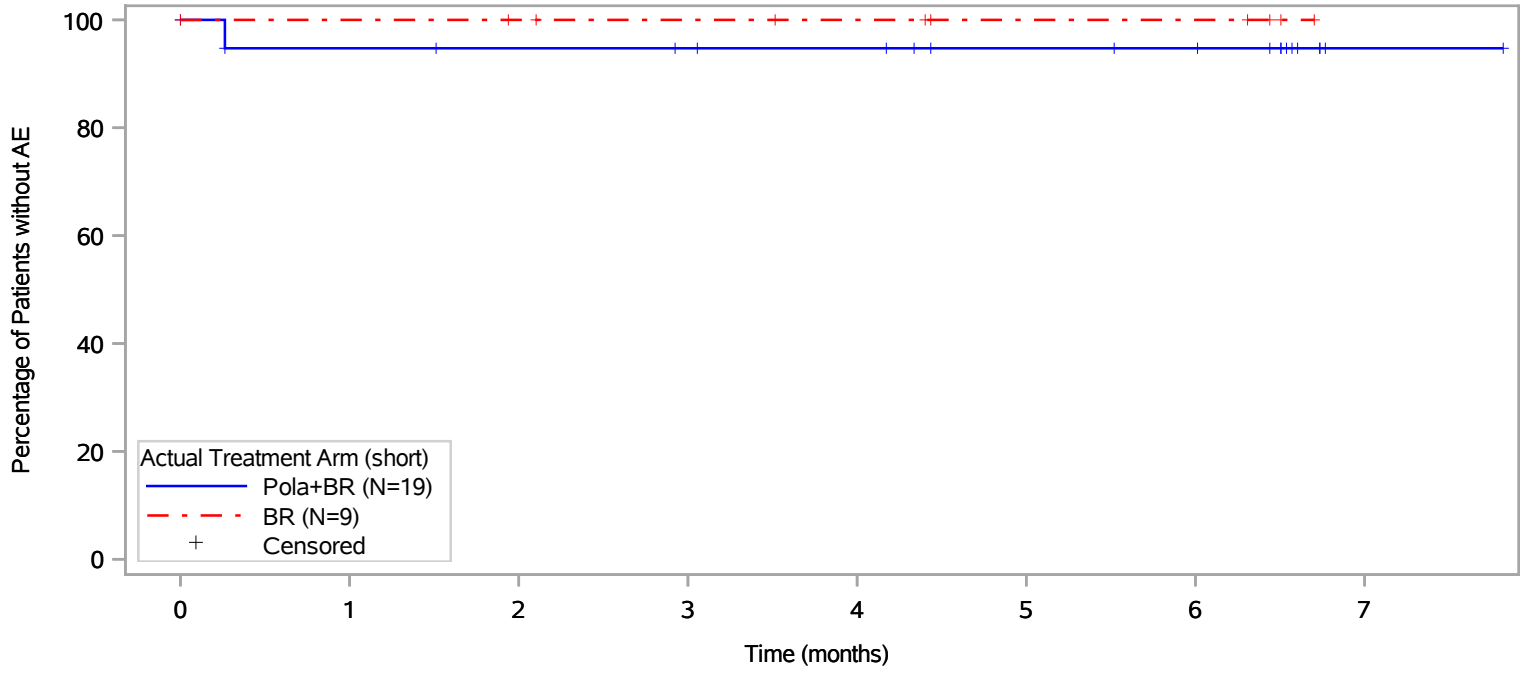


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERGLYCAEMIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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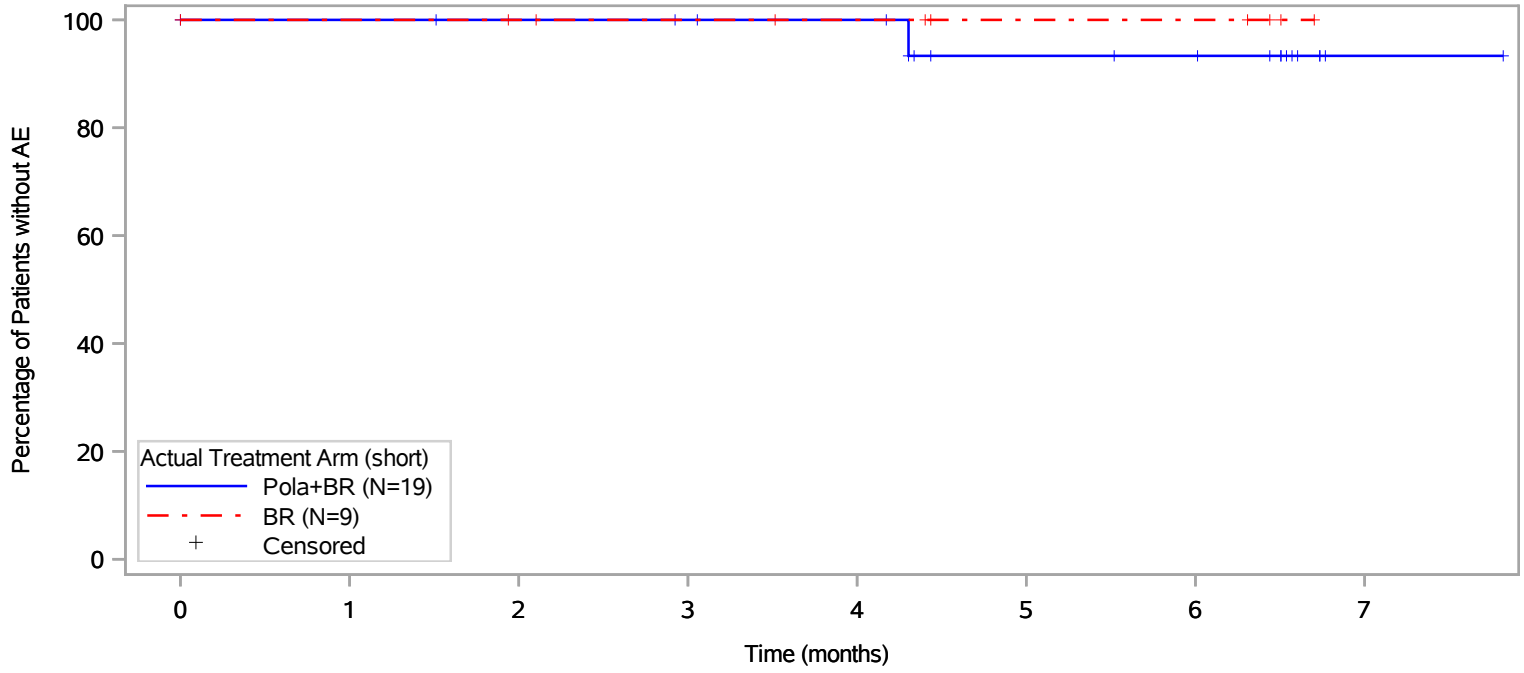
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERKALAEMIA



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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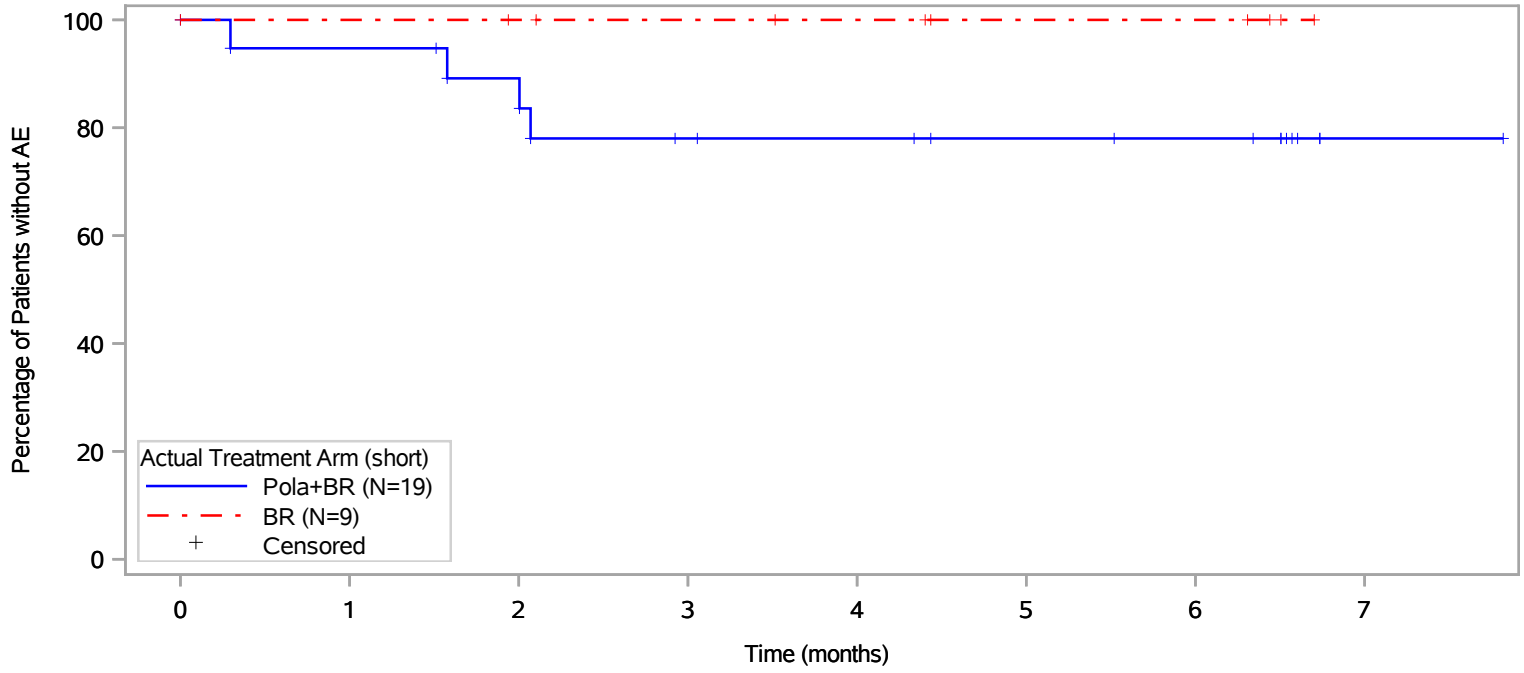
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERLIPIDAEMIA



Patients at risk								
Pola+BR (N=19)	19	18	16	13	12	10	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	14
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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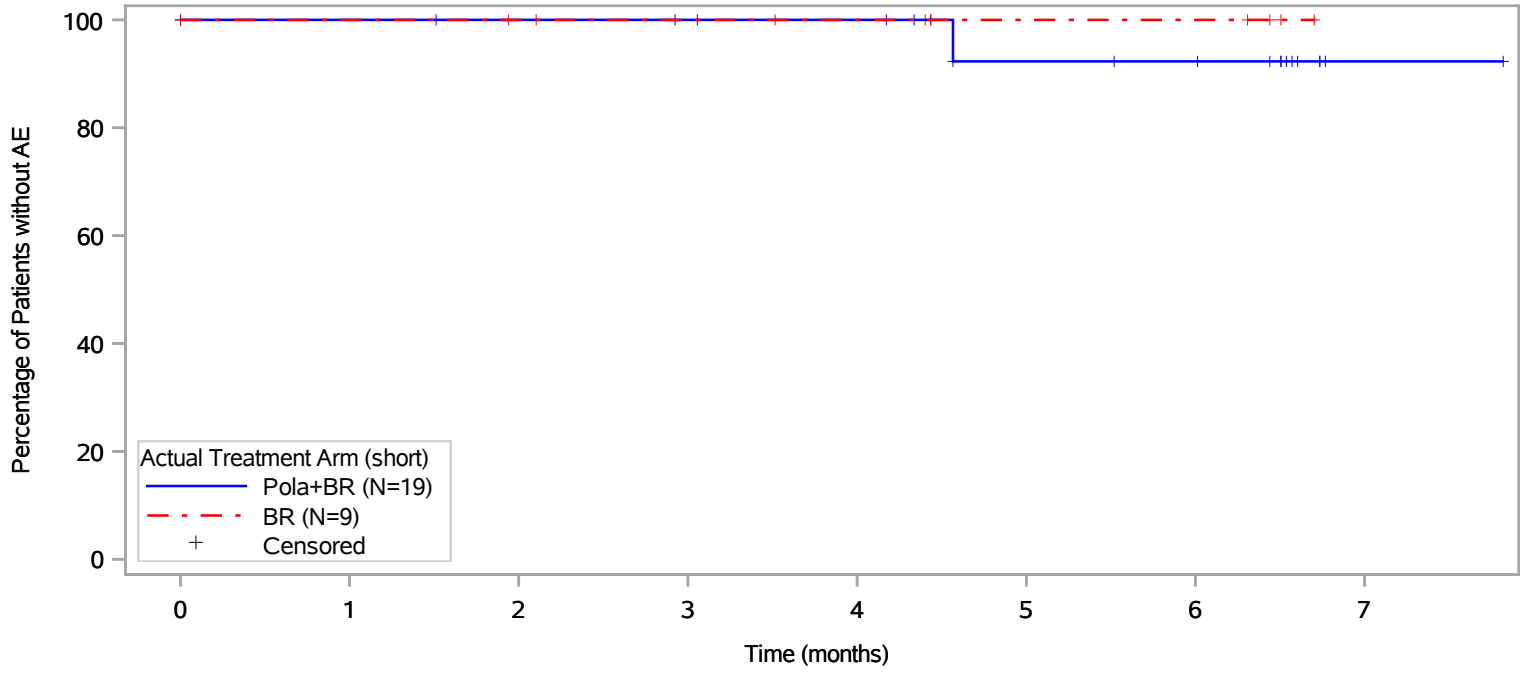
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERNATRAEMIA



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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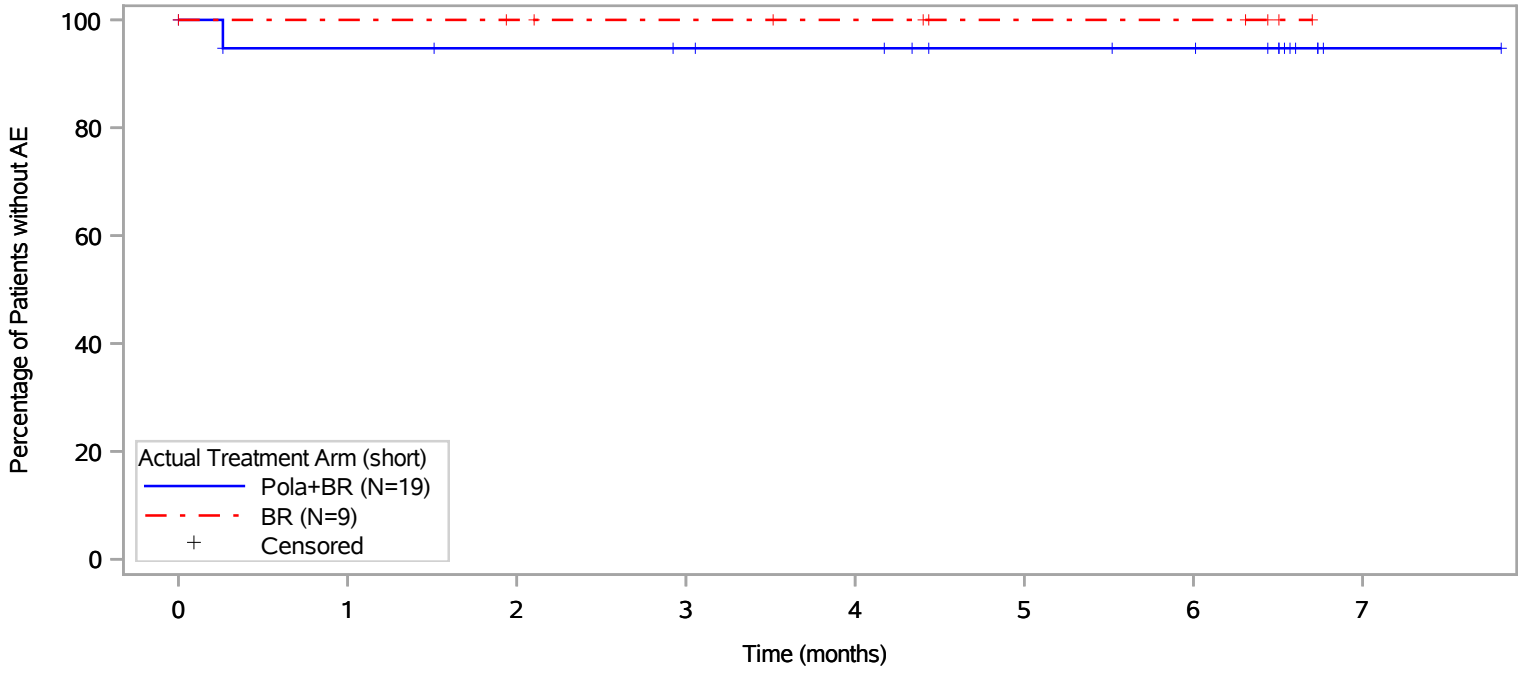
01DEC2022 22:10

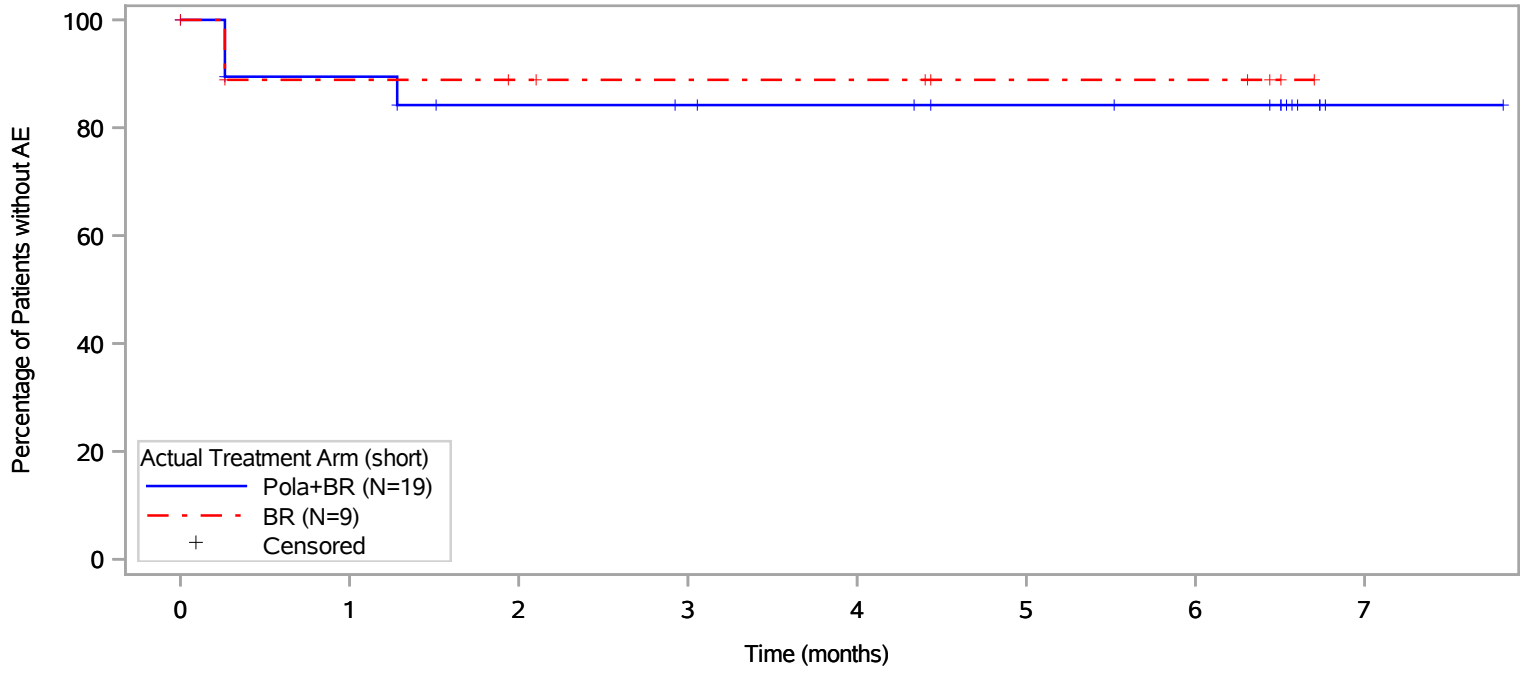
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERTRIGLYCERIDAEMIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPERURICAEMIA



Patients at risk								
Pola+BR (N=19)	19	17	15	14	13	11	10	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	15
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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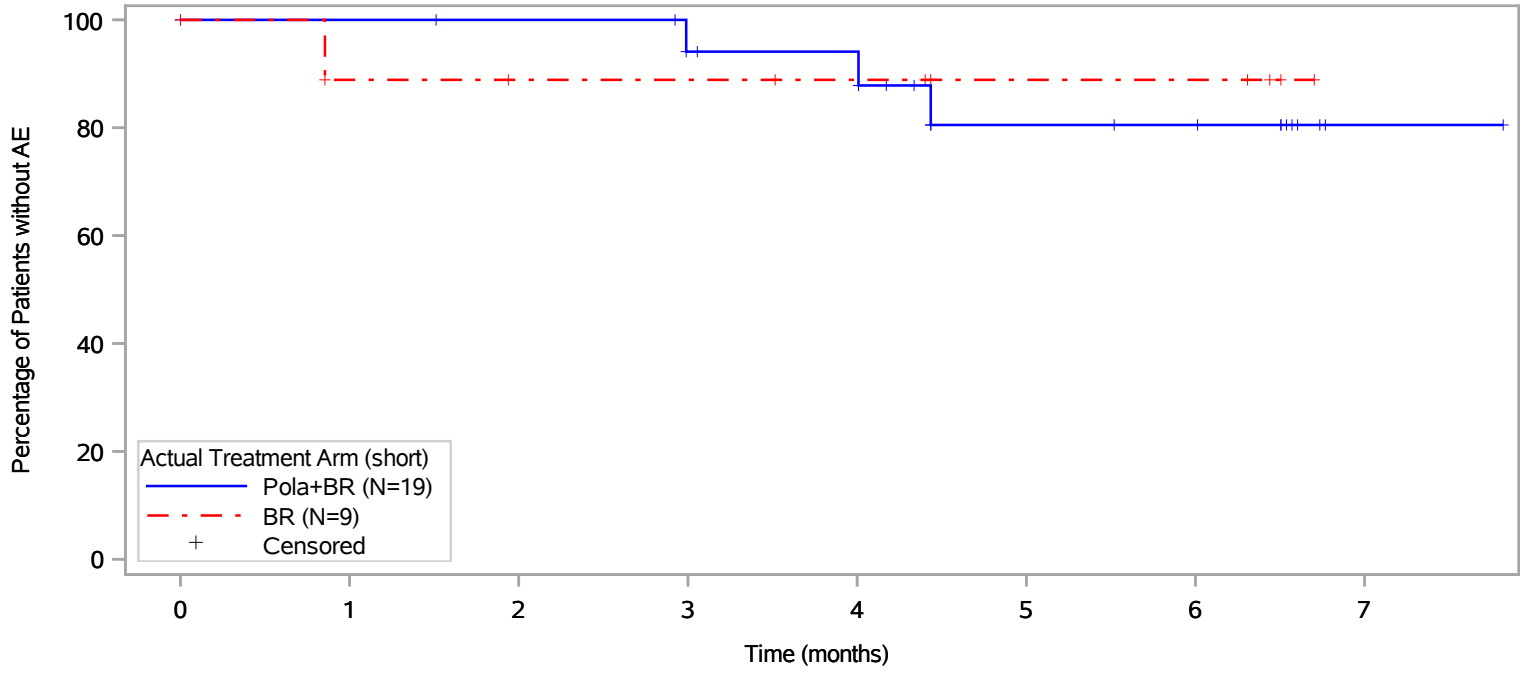
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOALBUMINAEMIA



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	10	9	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	15
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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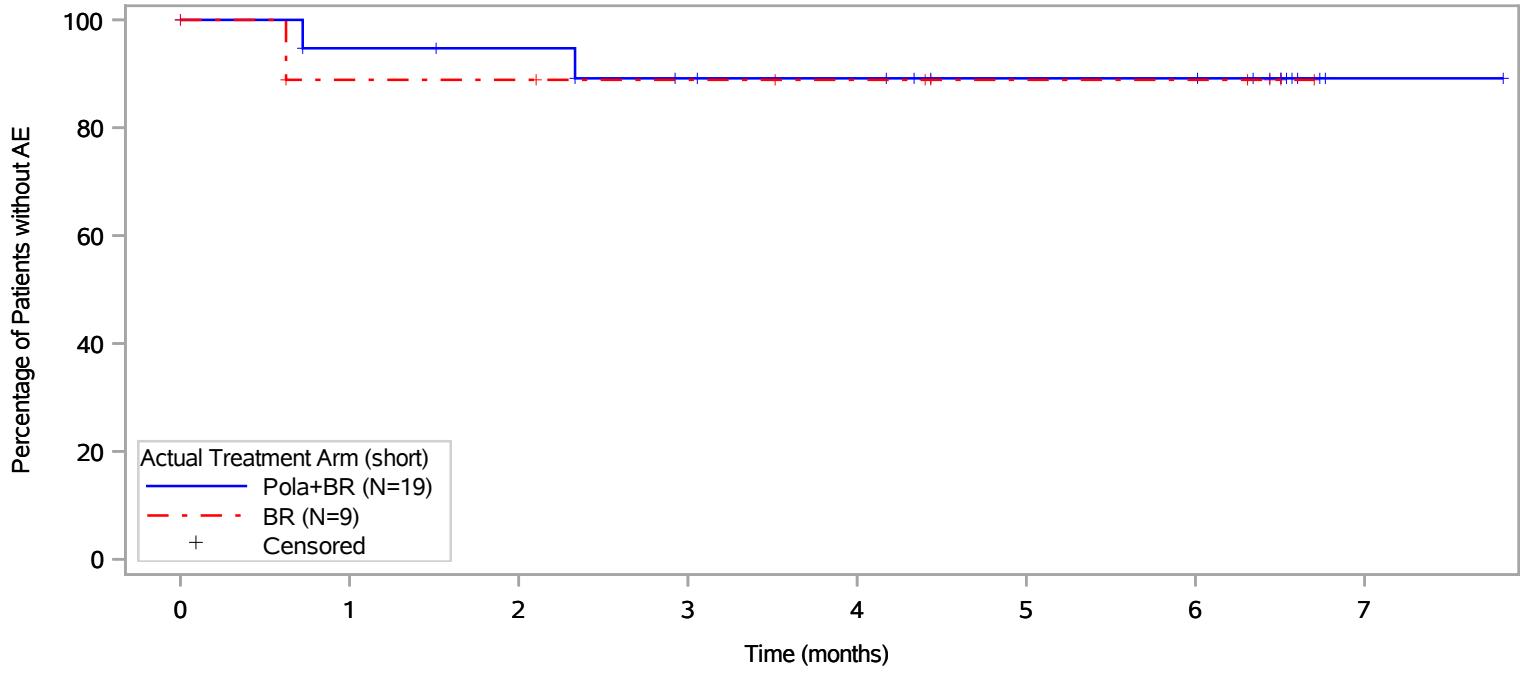
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOCALCAEMIA



Patients at risk								
Pola+BR (N=19)	19	18	17	15	14	11	11	1
BR (N=9)	9	8	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	16
BR (N=9)	0	0	0	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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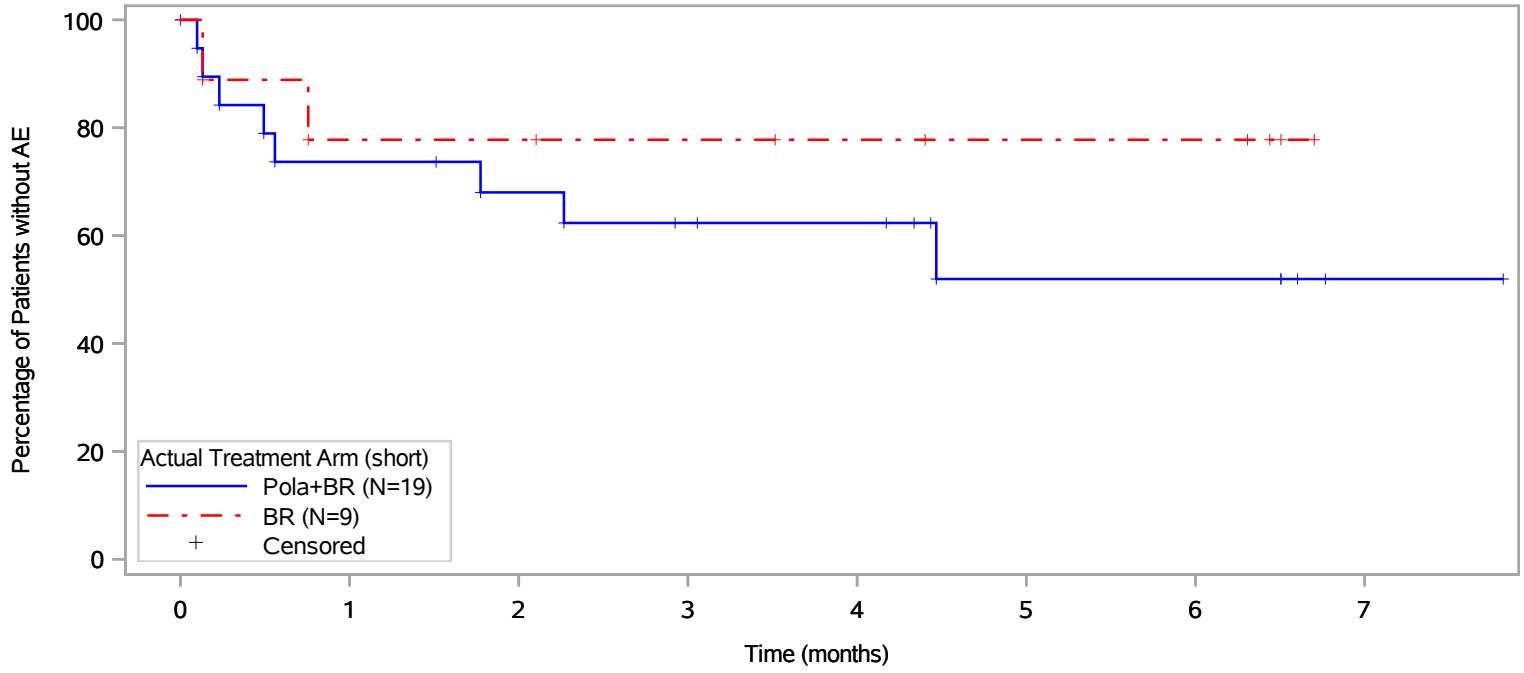
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk								
Pola+BR (N=19)	19	14	12	10	9	5	5	1
BR (N=9)	9	7	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	10
BR (N=9)	0	0	0	1	2	3	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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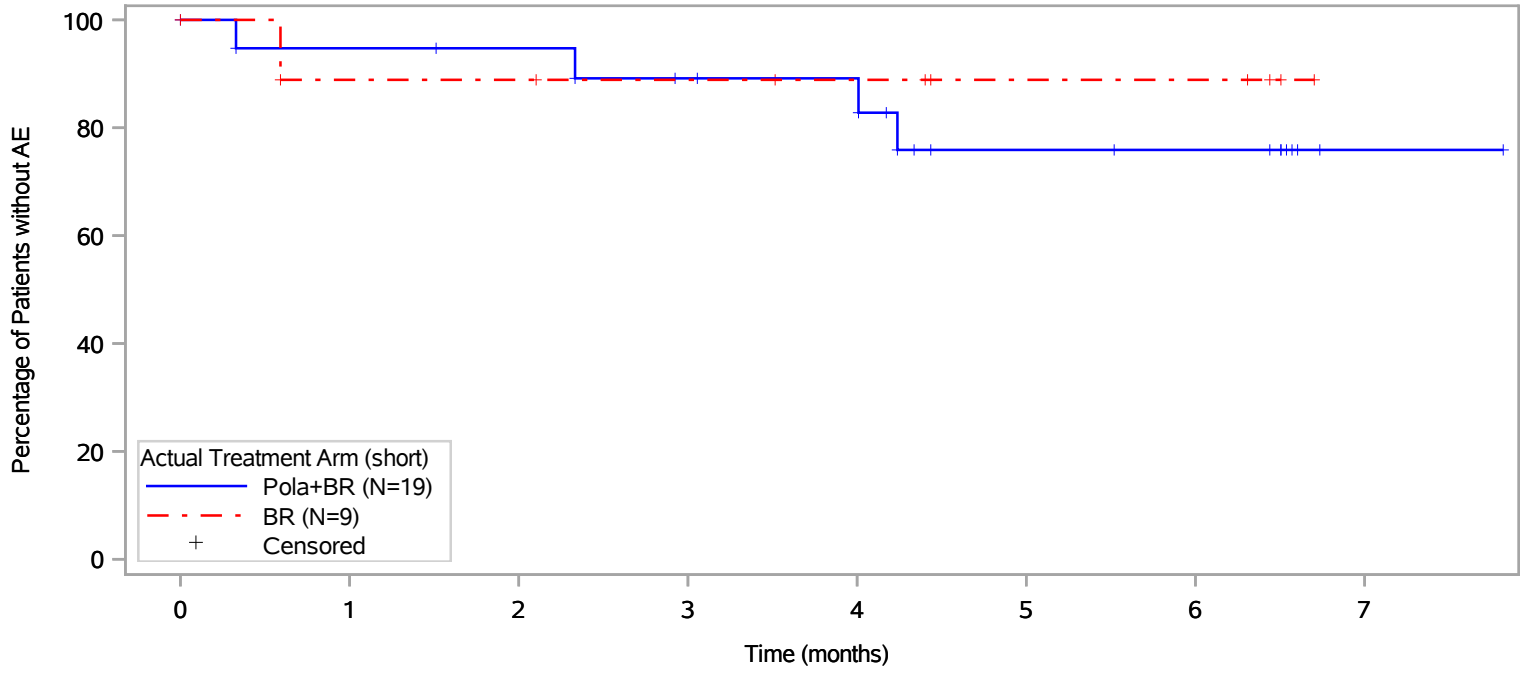
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPONATRAEMIA

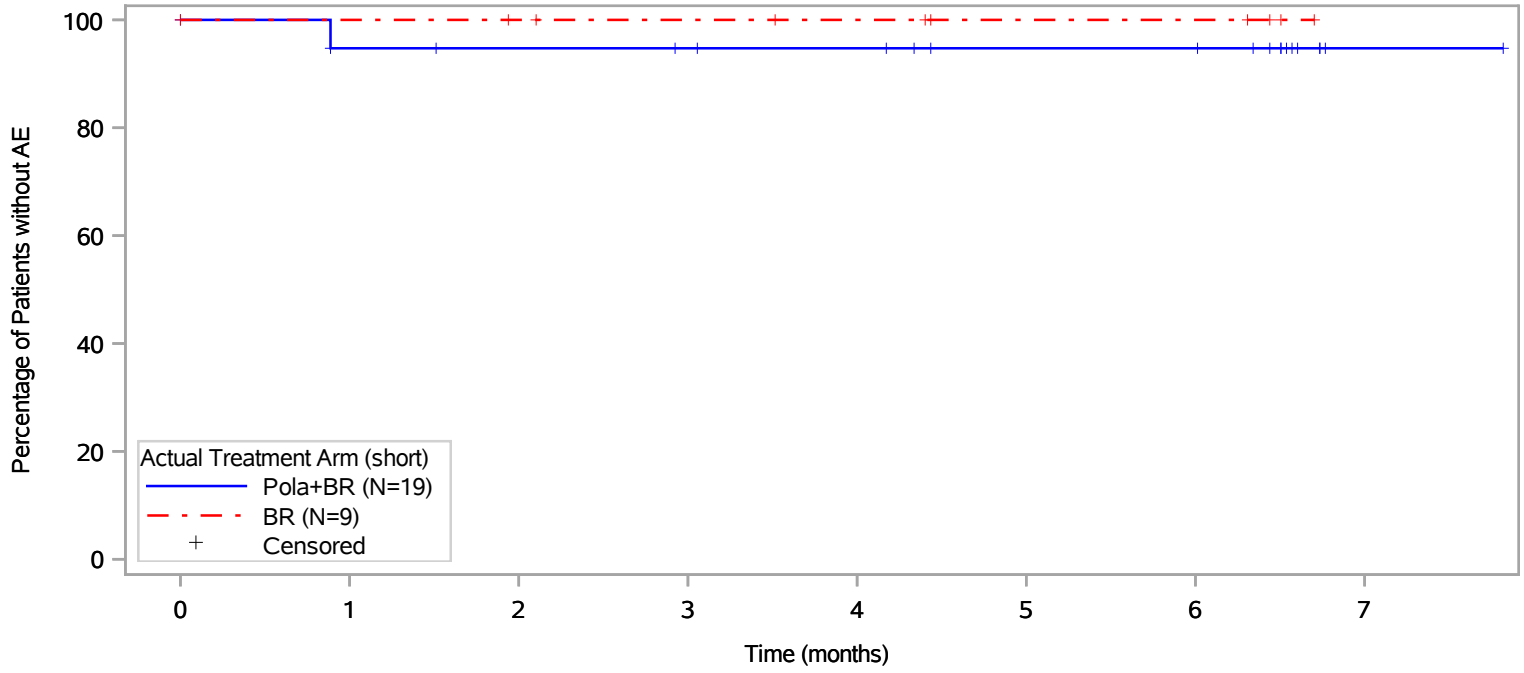


Patients at risk								
Pola+BR (N=19)	19	18	17	15	14	9	8	1
BR (N=9)	9	8	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	14
BR (N=9)	0	0	0	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOPHOSPHATAEMIA

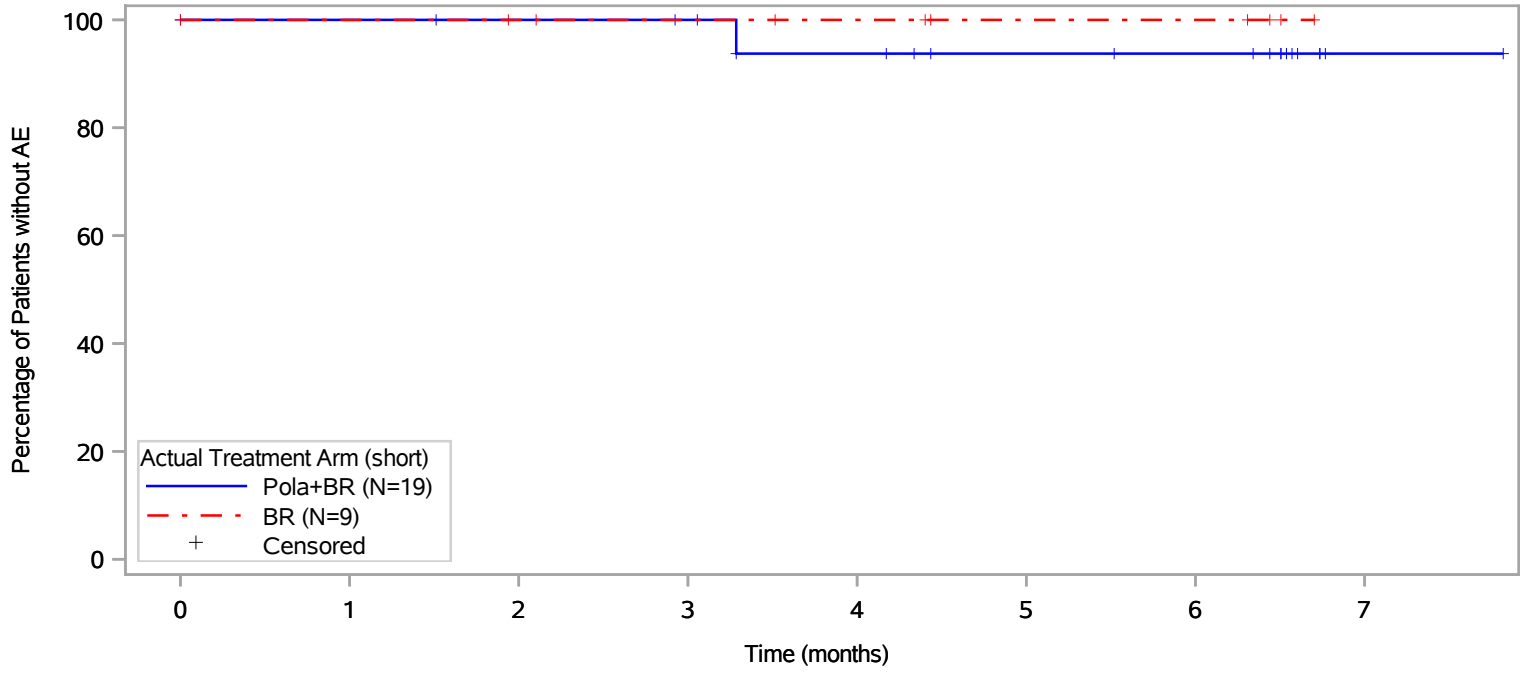


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOPROTEINAEMIA

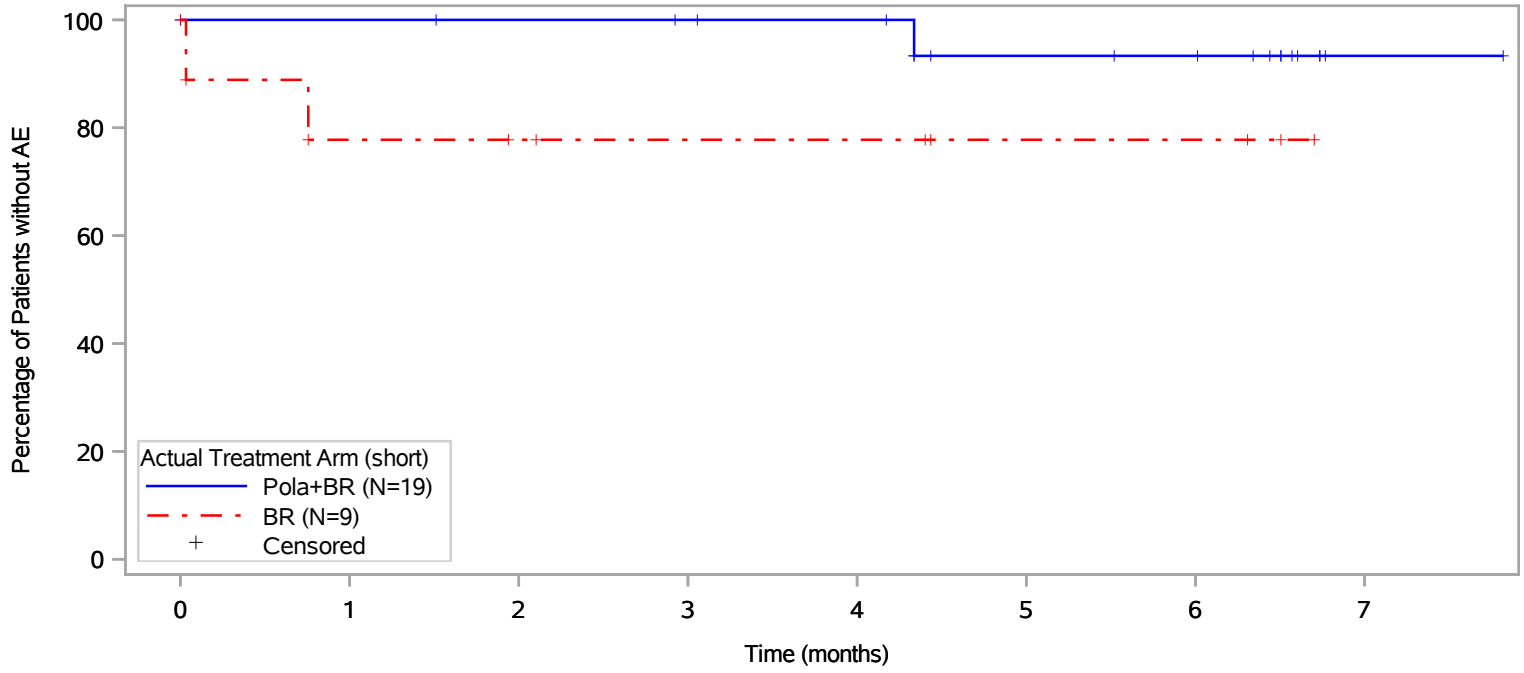


Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

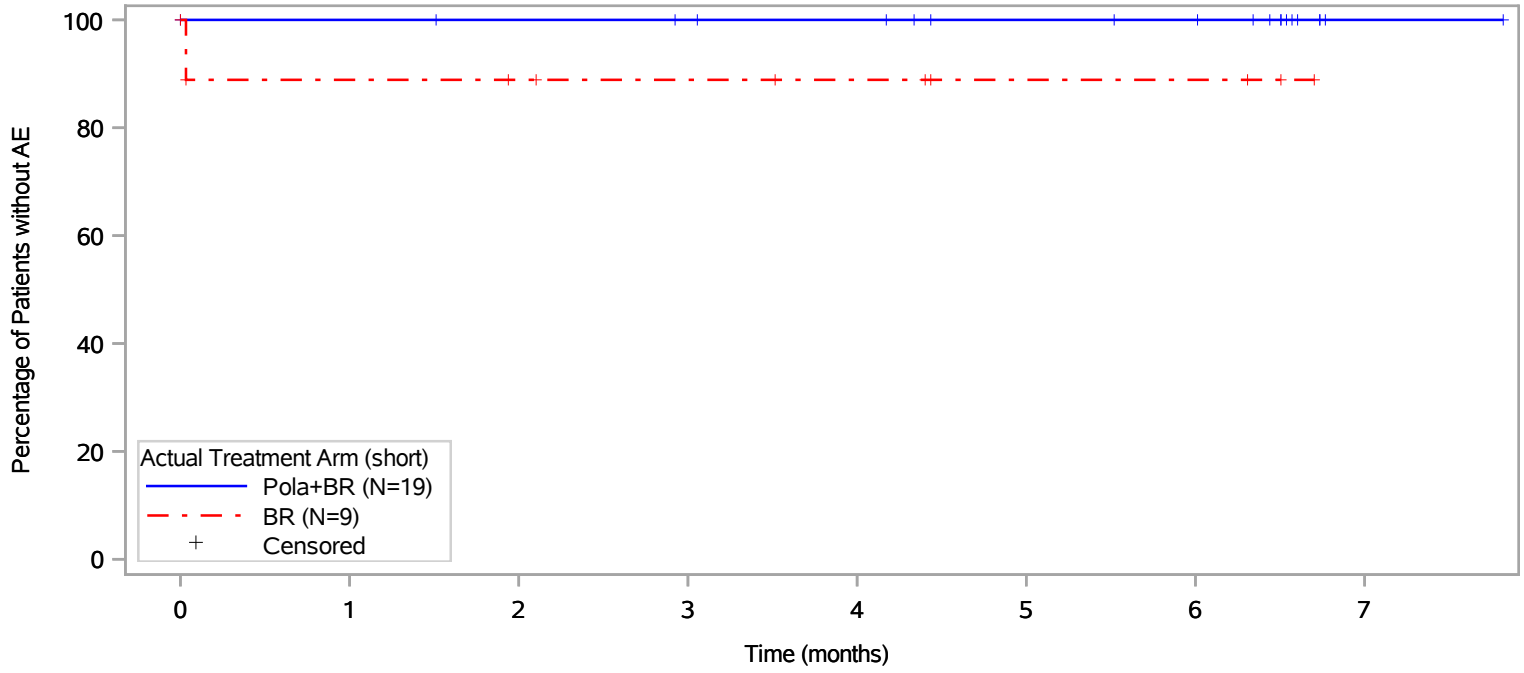
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	7	6	5	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, ARTHRALGIA



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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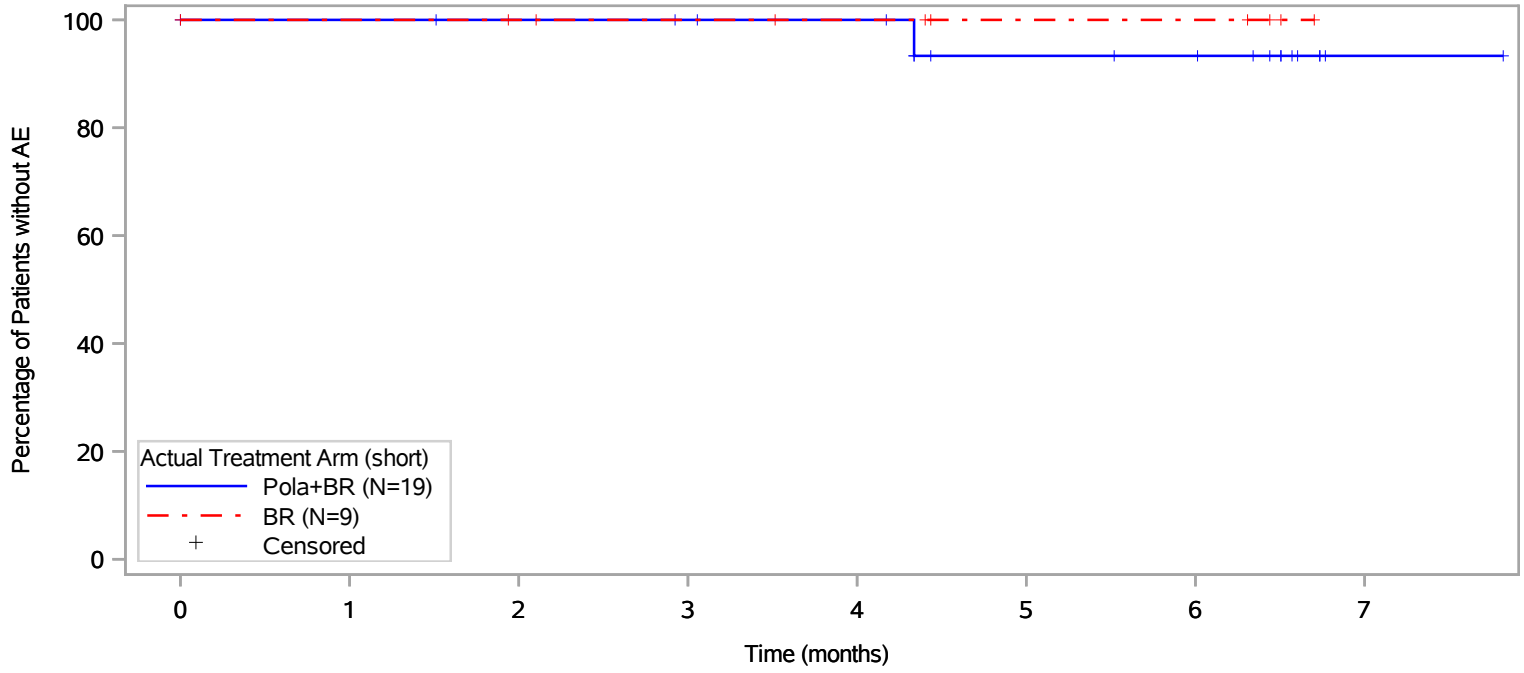
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, BACK PAIN



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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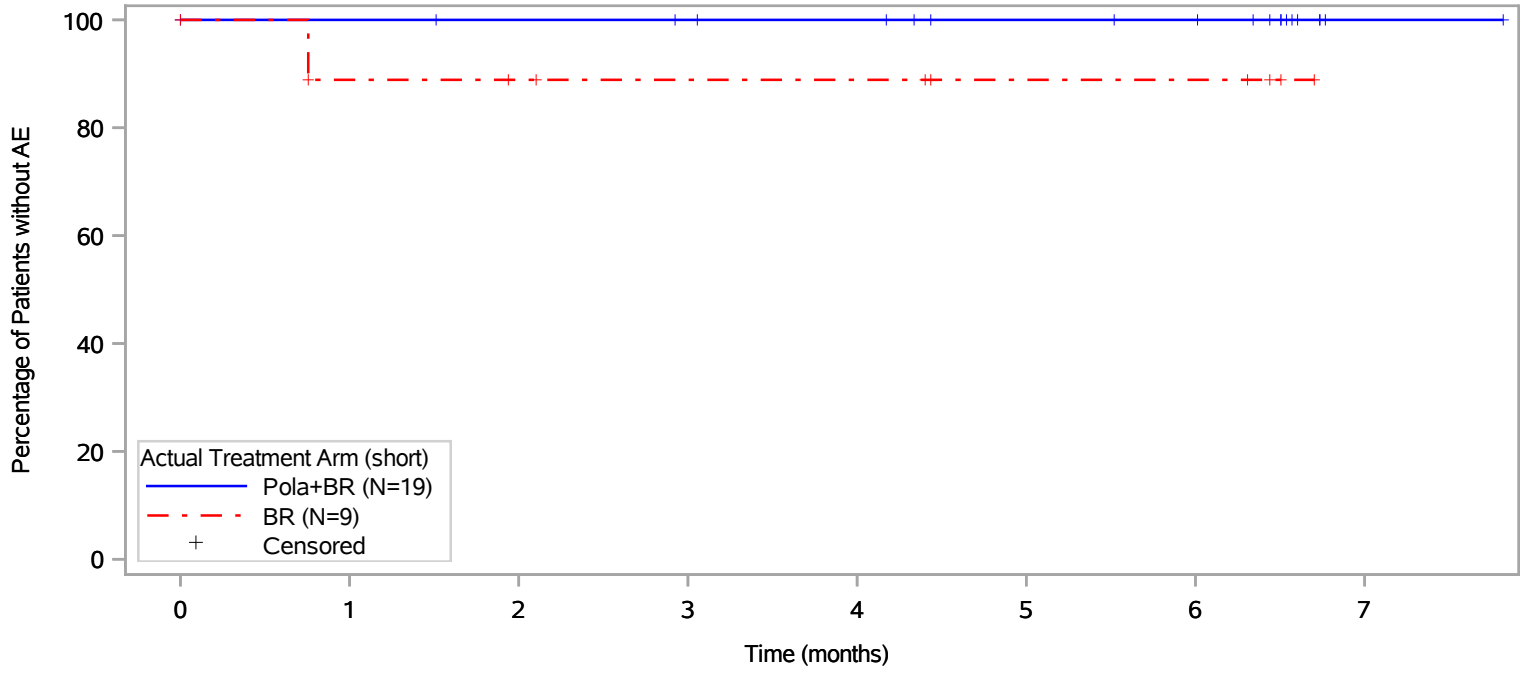
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, INTERVERTEBRAL DISC PROTRUSION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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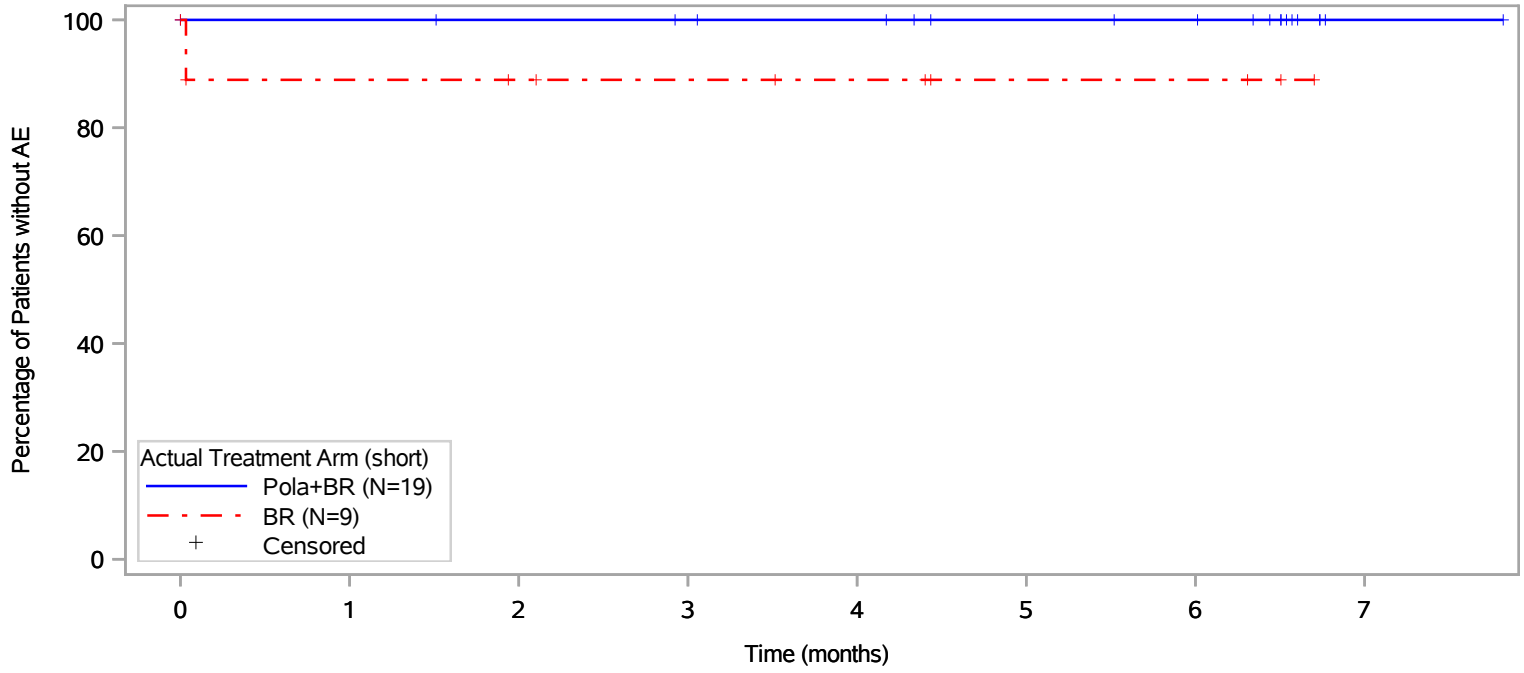
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, SPINAL PAIN



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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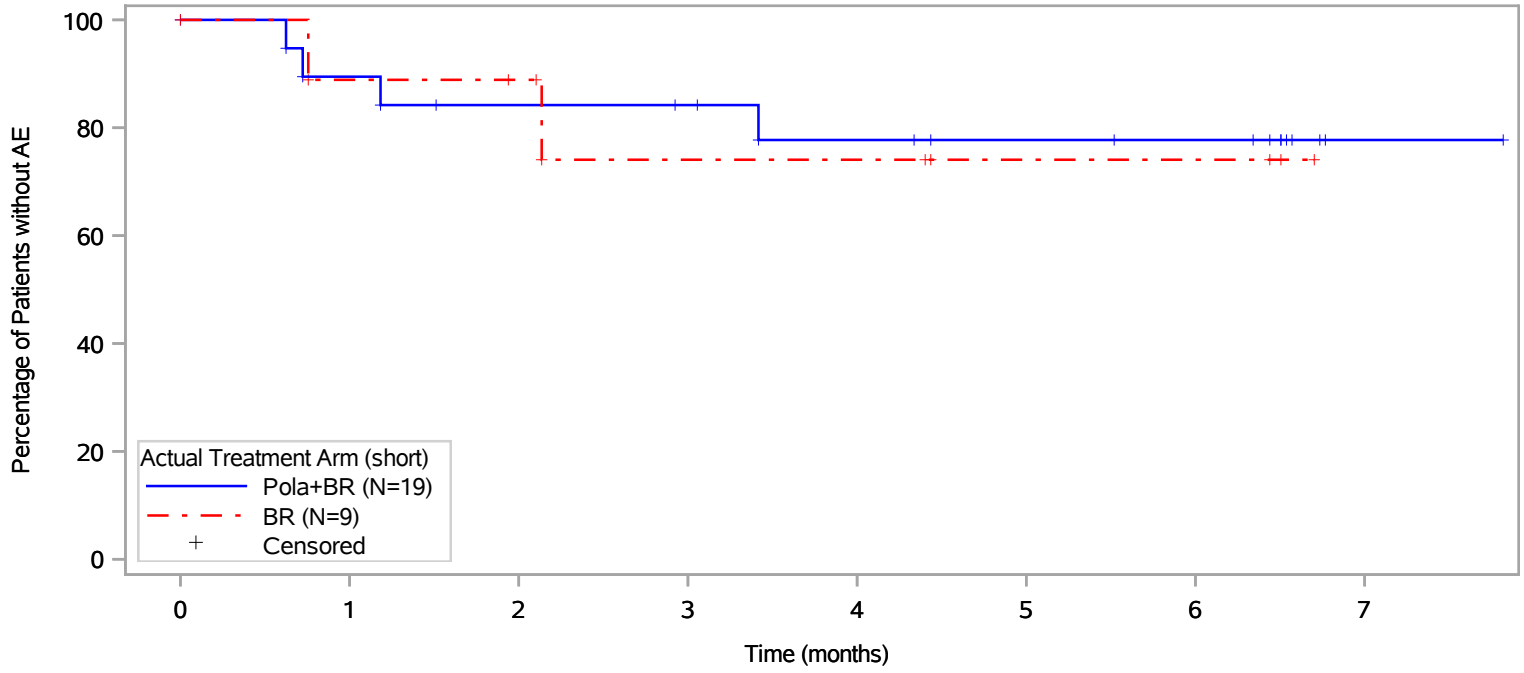
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	17	15	14	12	10	9	1
BR (N=9)	9	8	7	5	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	14
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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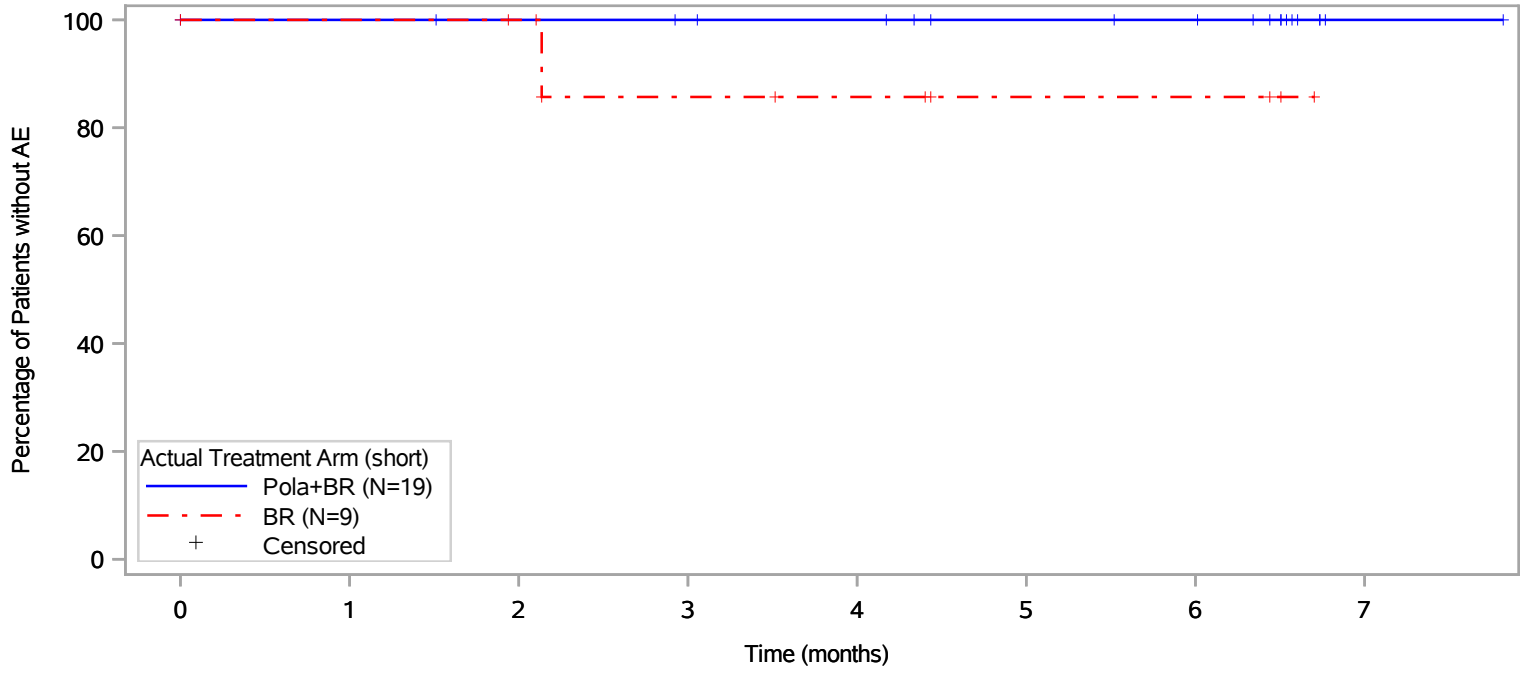
01DEC2022 22:10

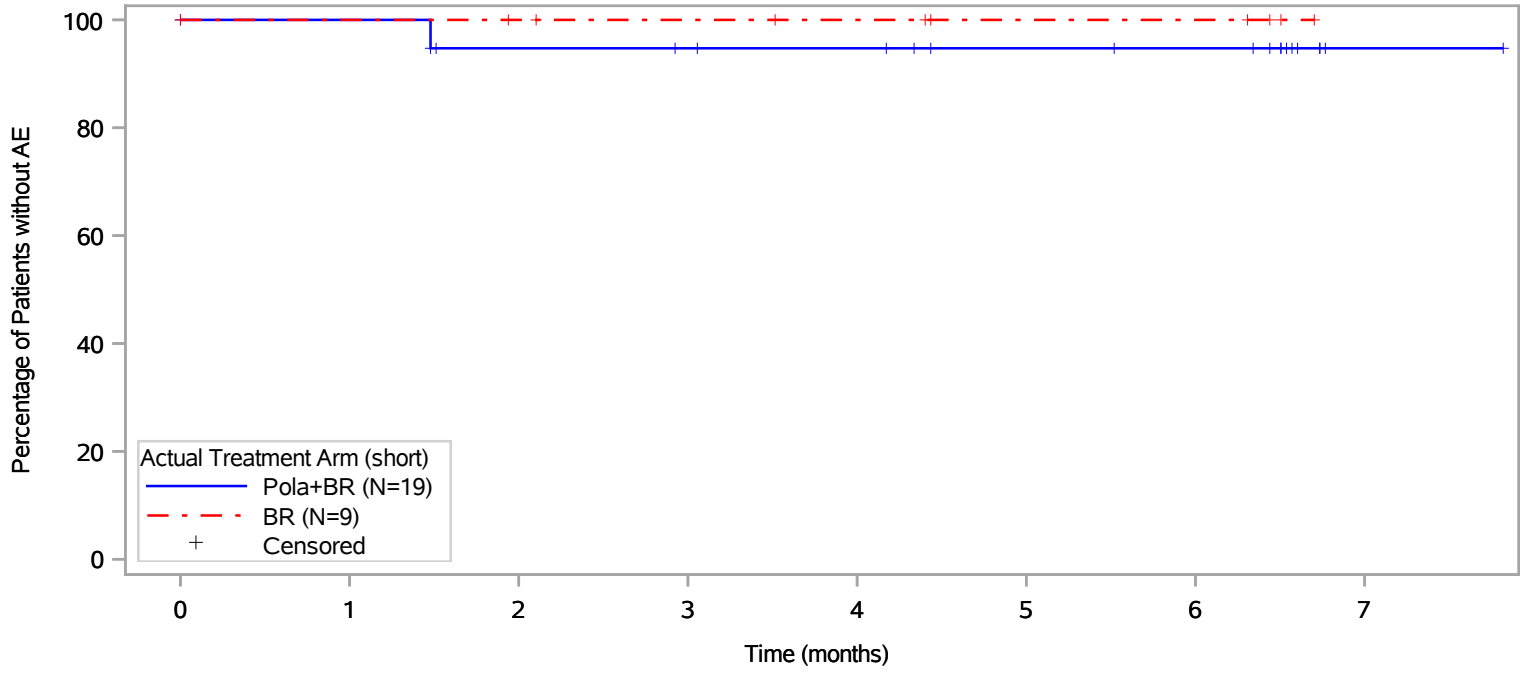
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, DIZZINESS



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, HEADACHE



Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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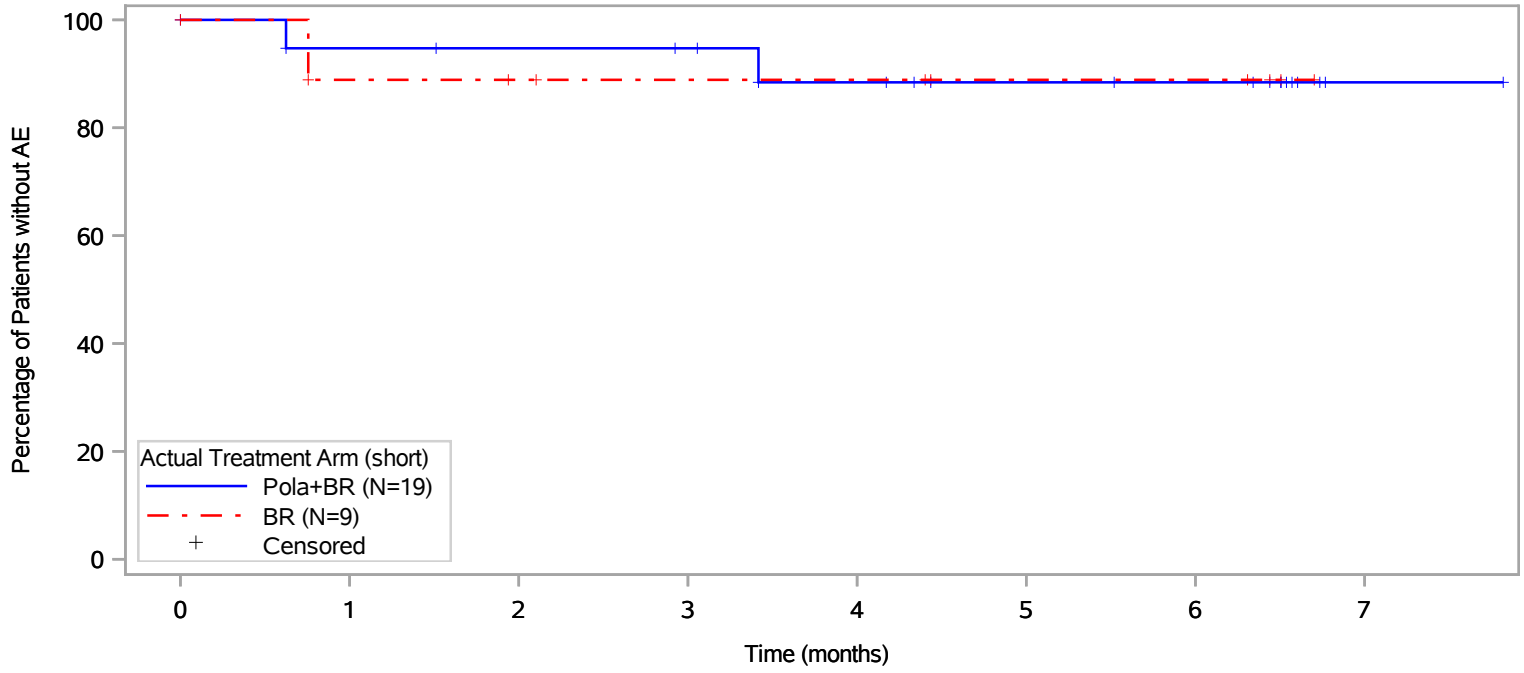
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, NEUROPATHY PERIPHERAL



Patients at risk								
Pola+BR (N=19)	19	18	17	16	14	11	10	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	16
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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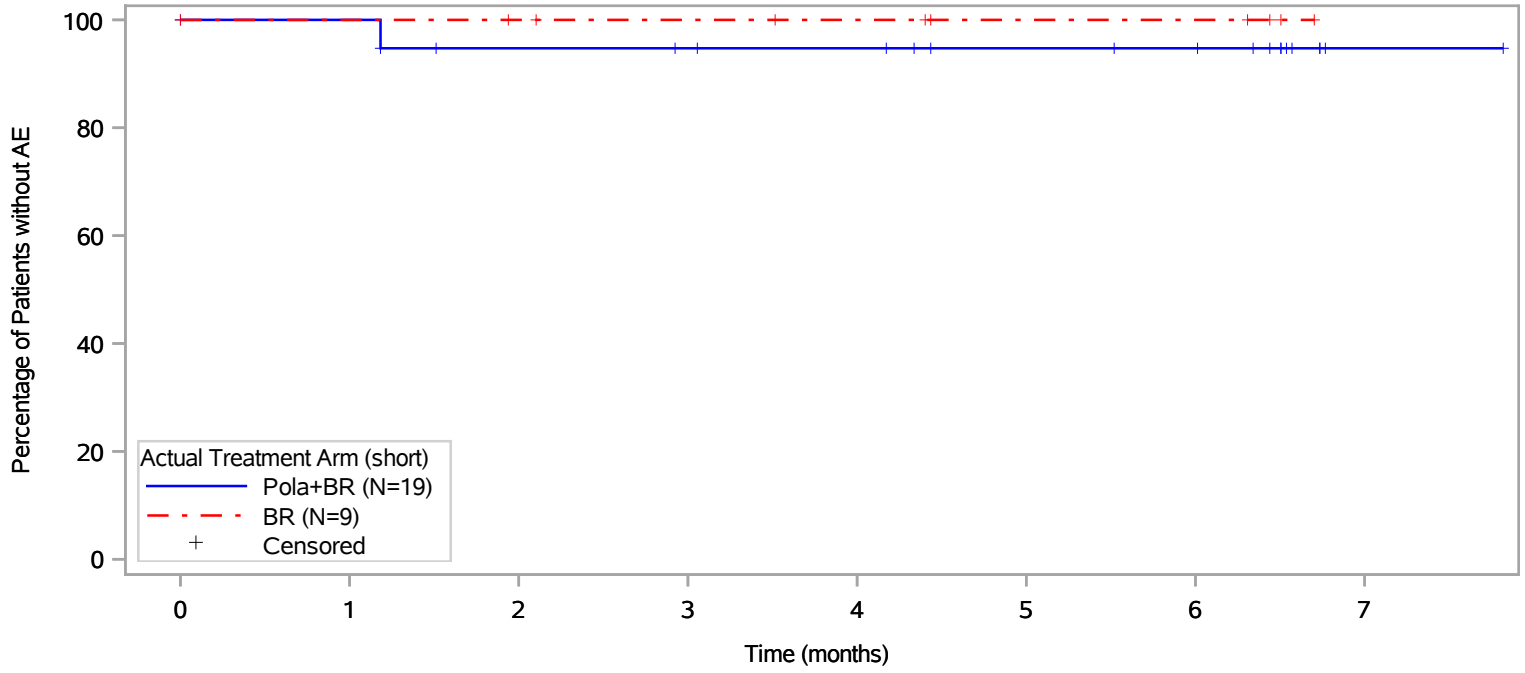
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, NEUROTOXICITY



Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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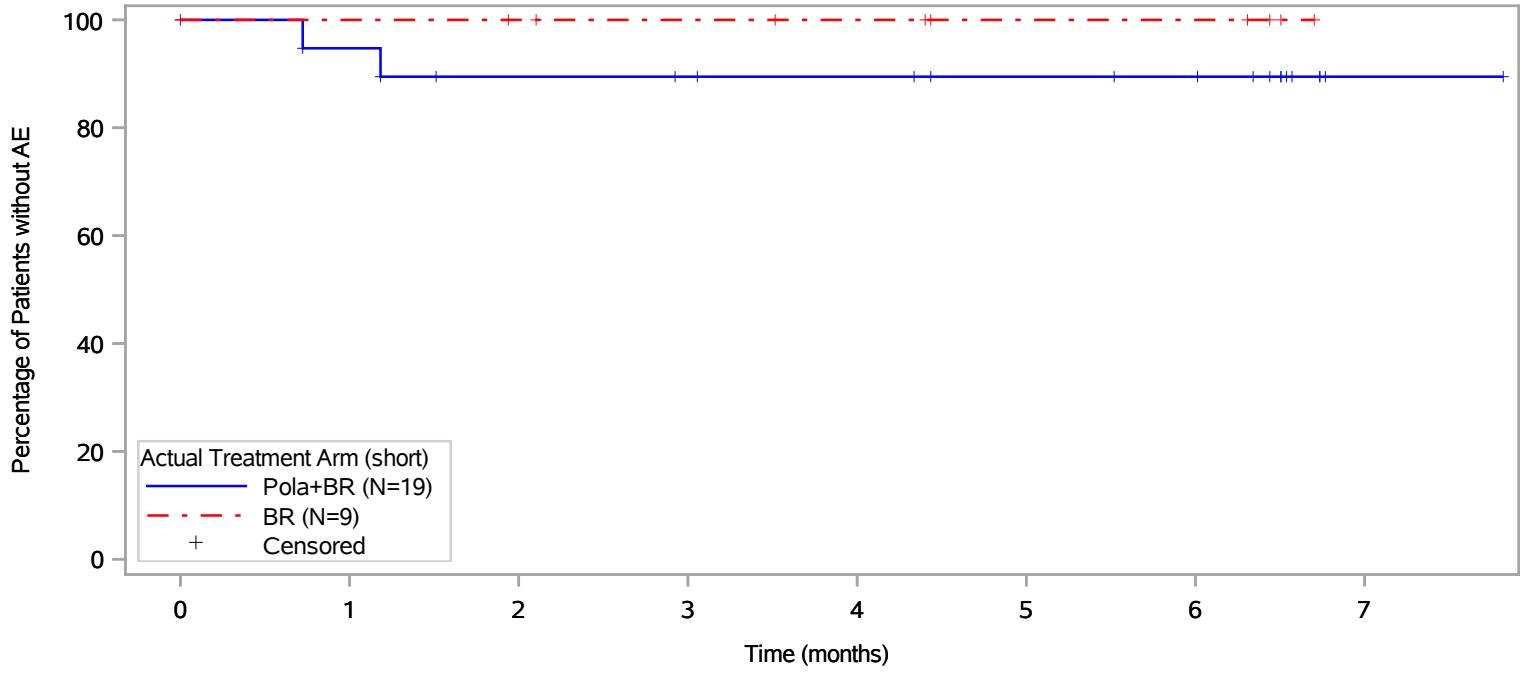
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
NERVOUS SYSTEM DISORDERS, PARAESTHESIA



Patients at risk								
Pola+BR (N=19)	19	18	16	15	14	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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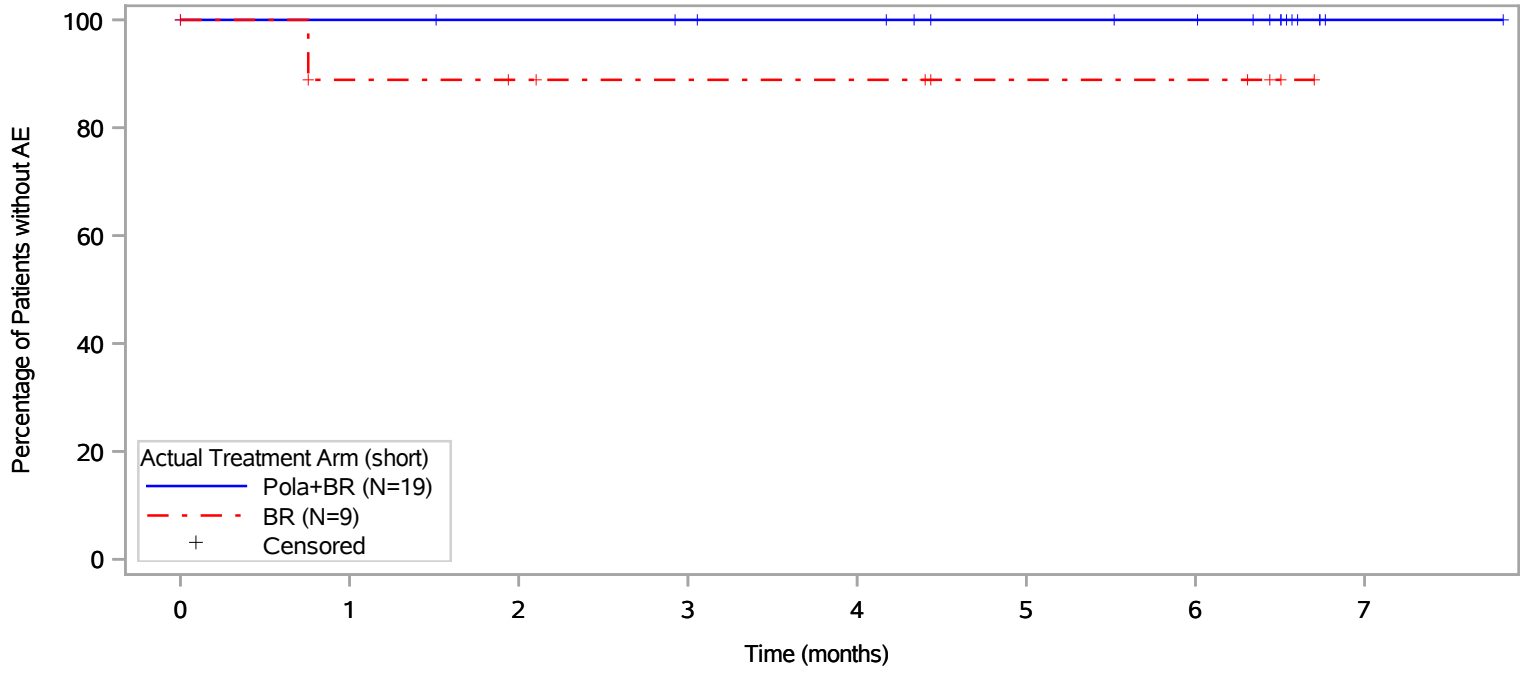
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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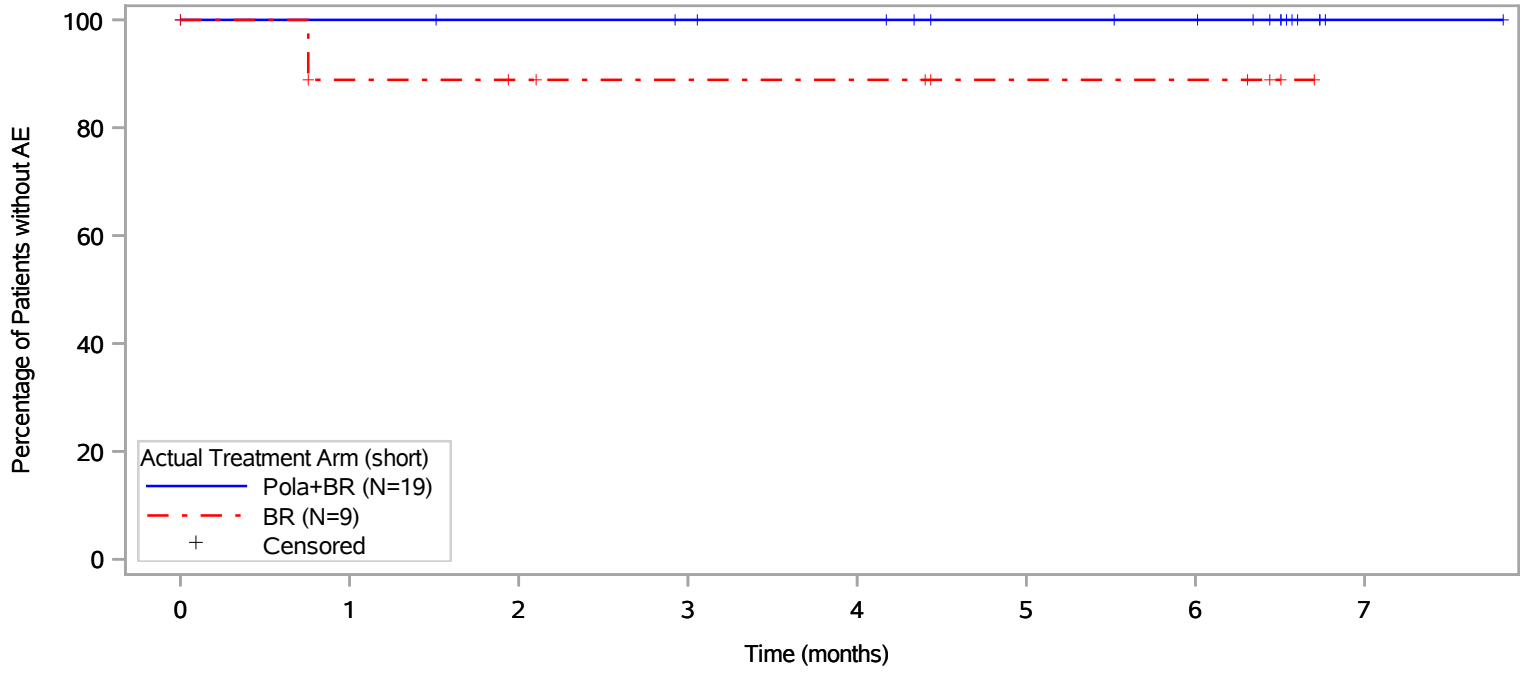
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
PSYCHIATRIC DISORDERS, INSOMNIA



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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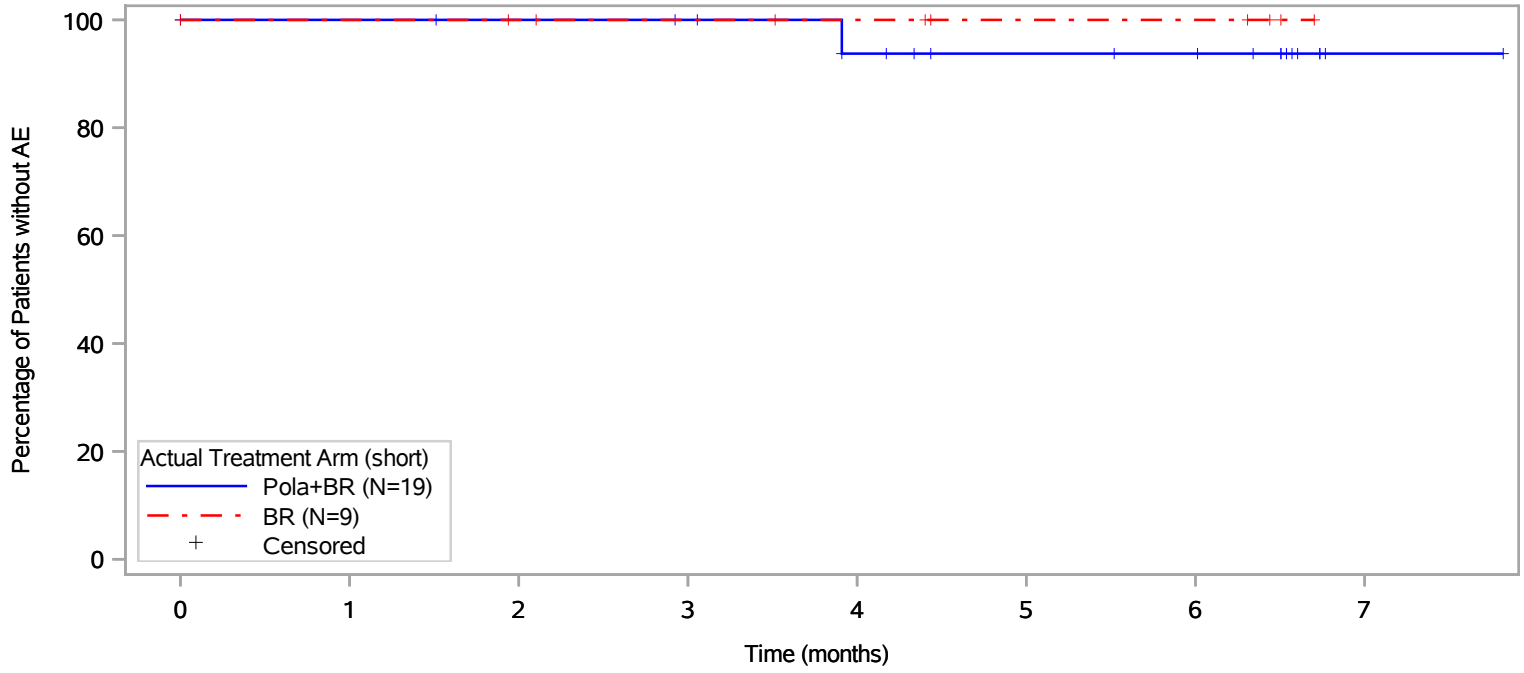
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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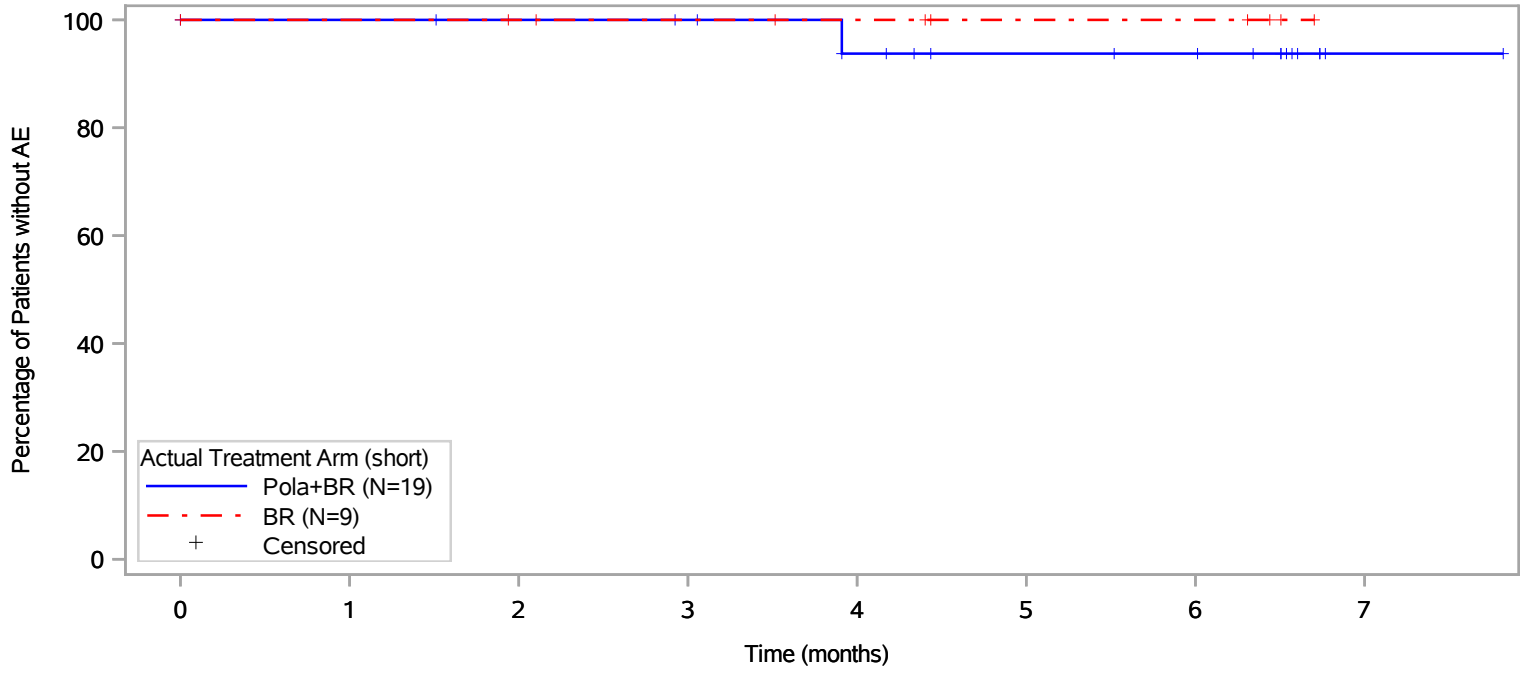
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HAEMATURIA



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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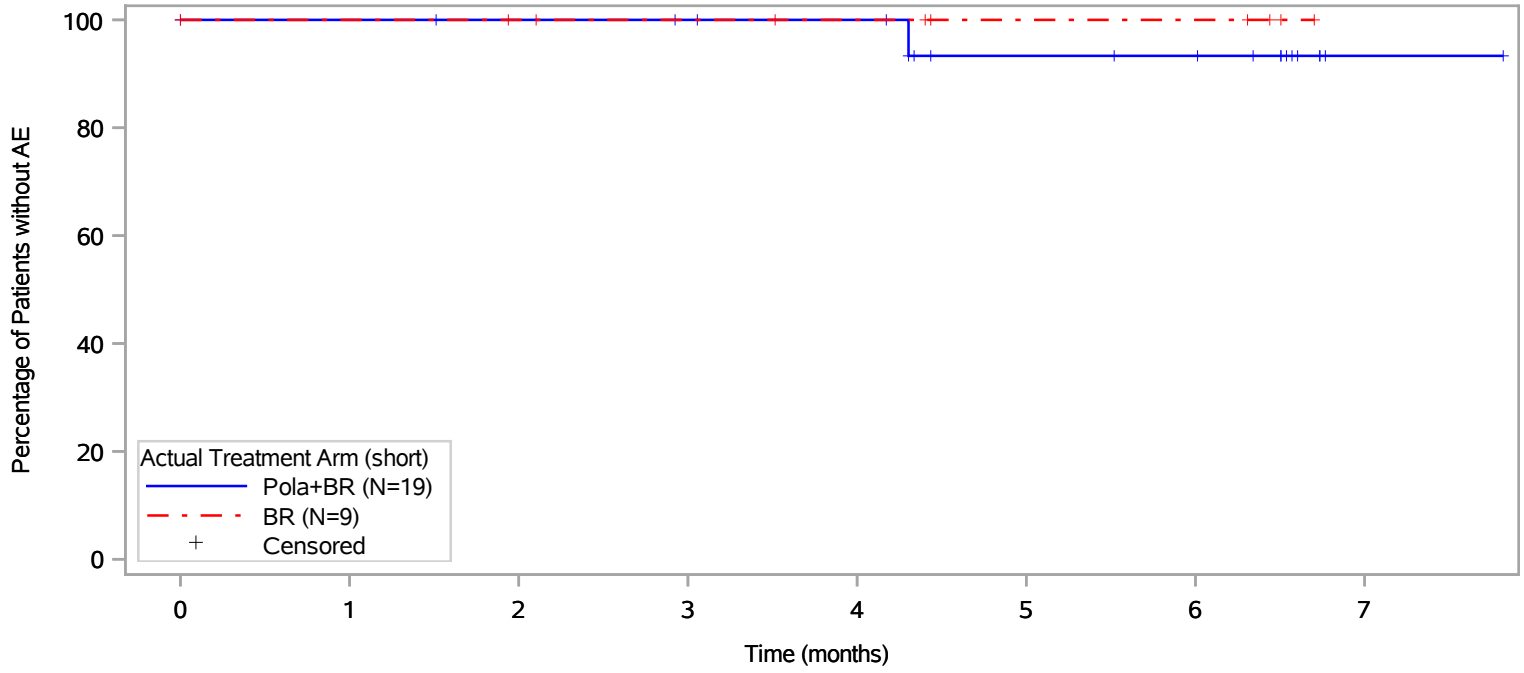
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, RENAL INJURY



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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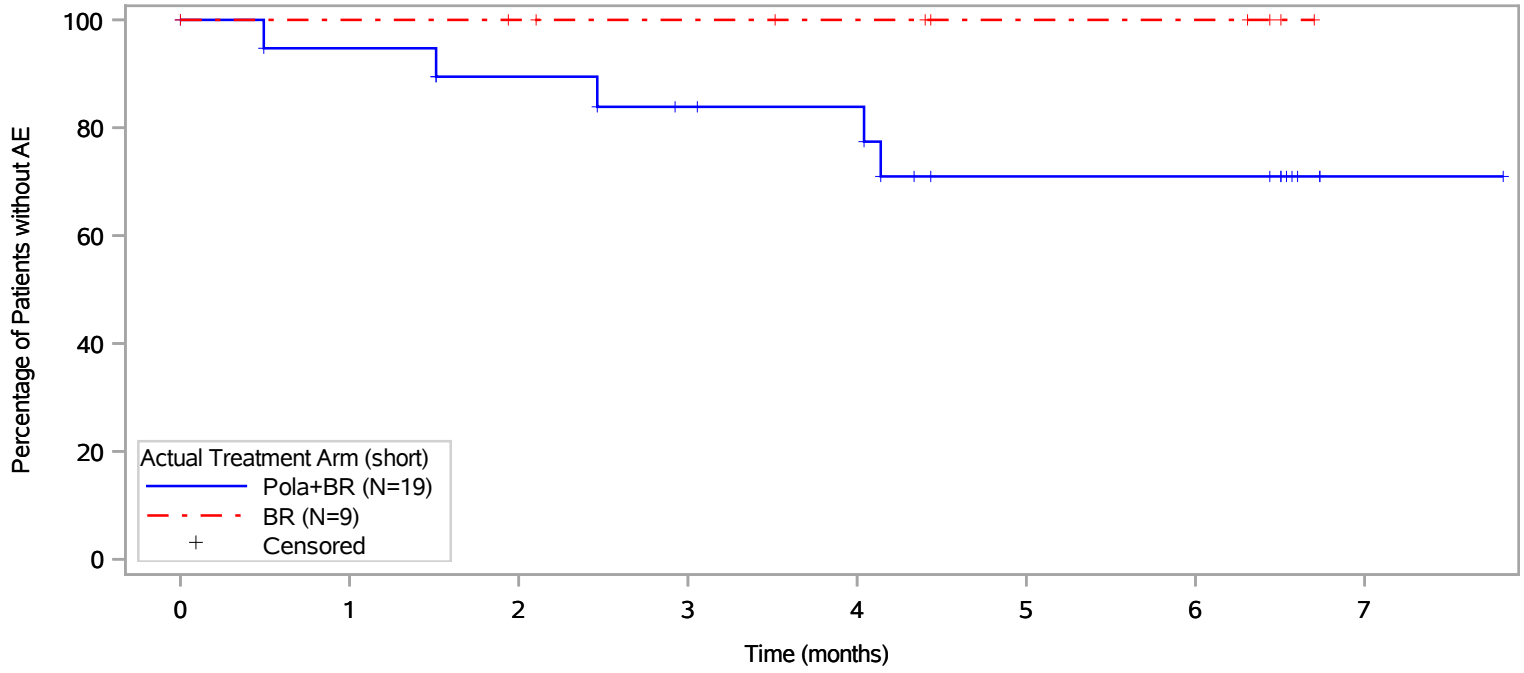
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	18	16	14	13	9	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	5	13
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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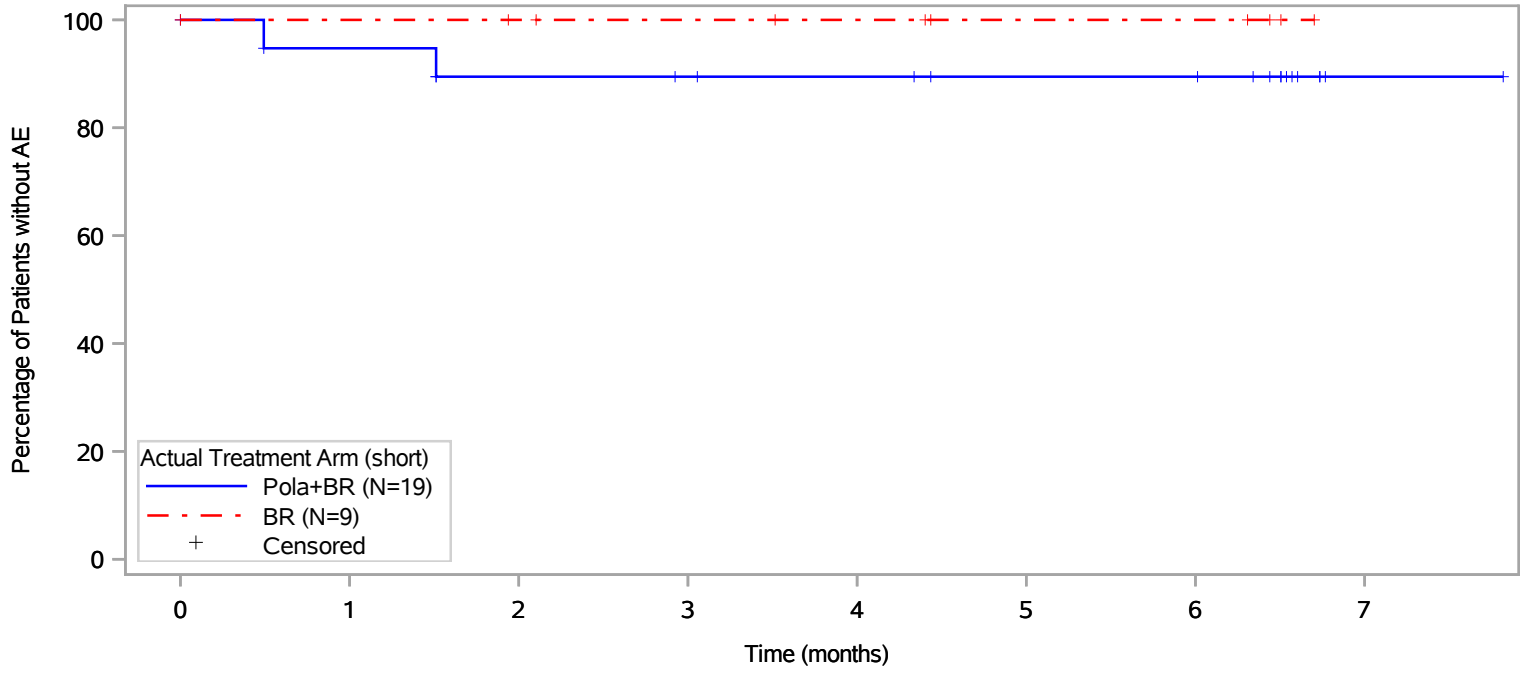
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, COUGH



Patients at risk								
Pola+BR (N=19)	19	18	16	15	14	12	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	5	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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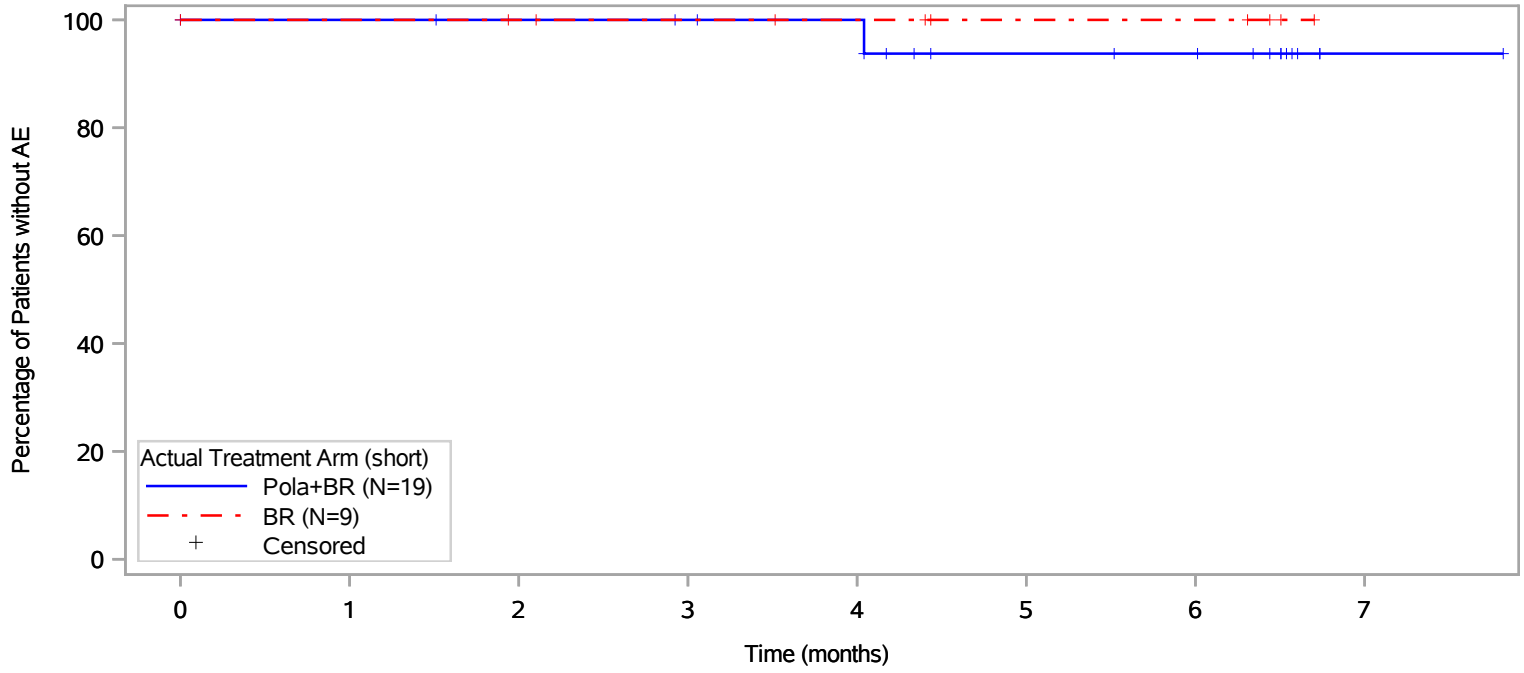
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, HAEMOPTYSIS

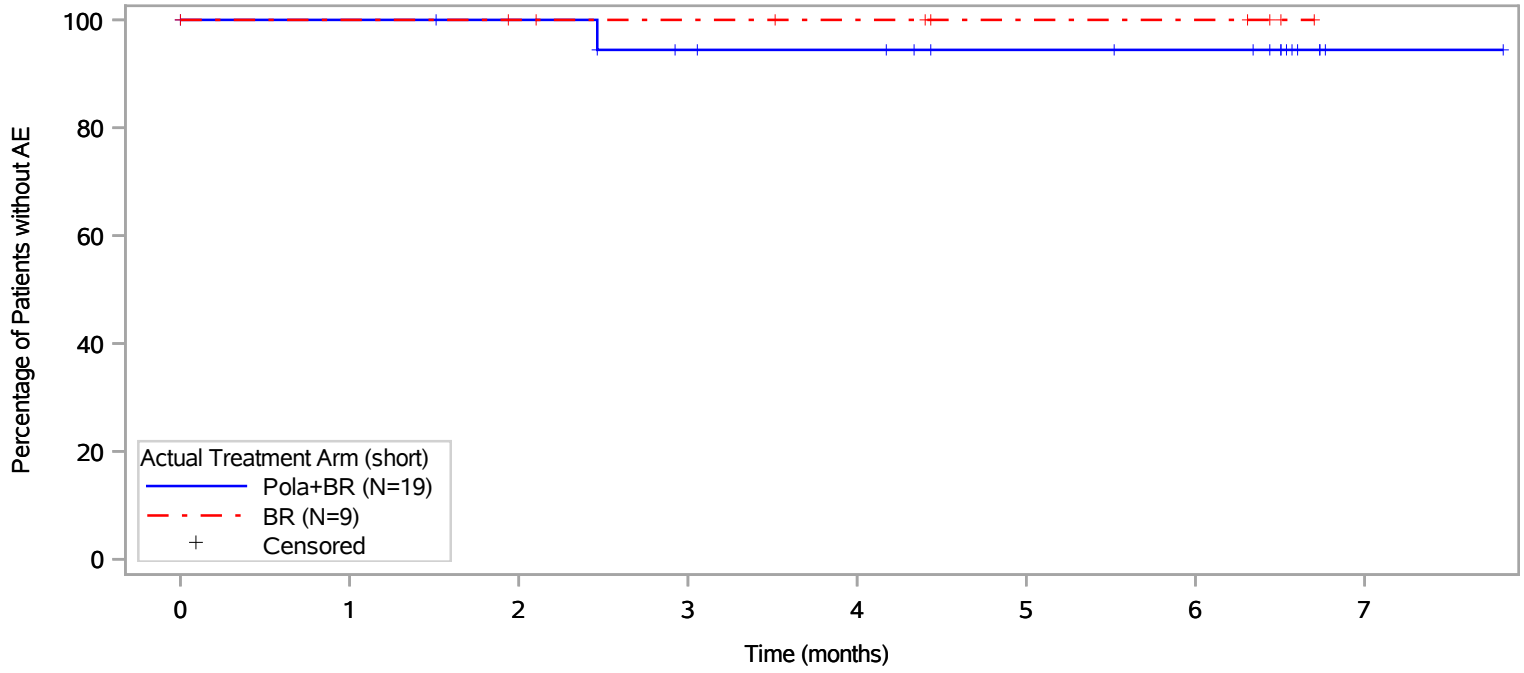


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, INTERSTITIAL LUNG DISEASE

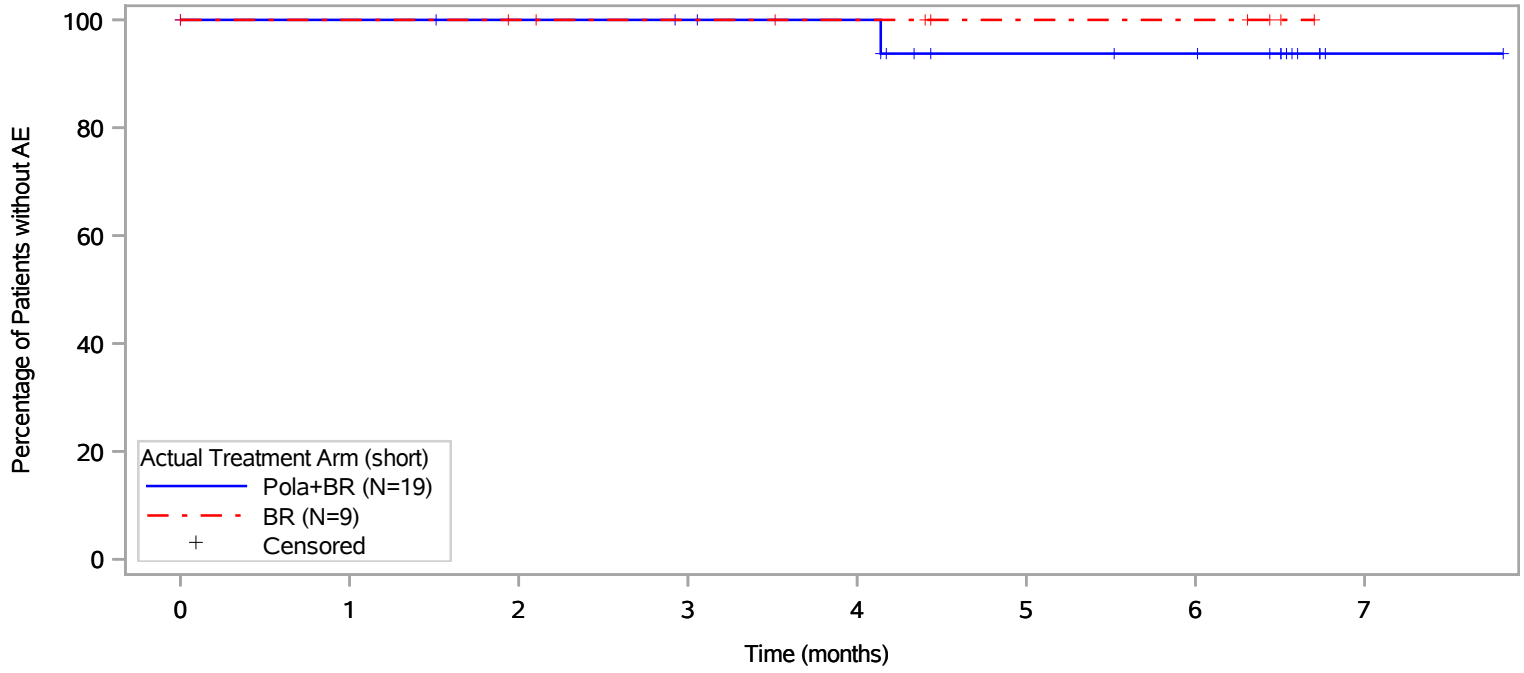


Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PLEURAL EFFUSION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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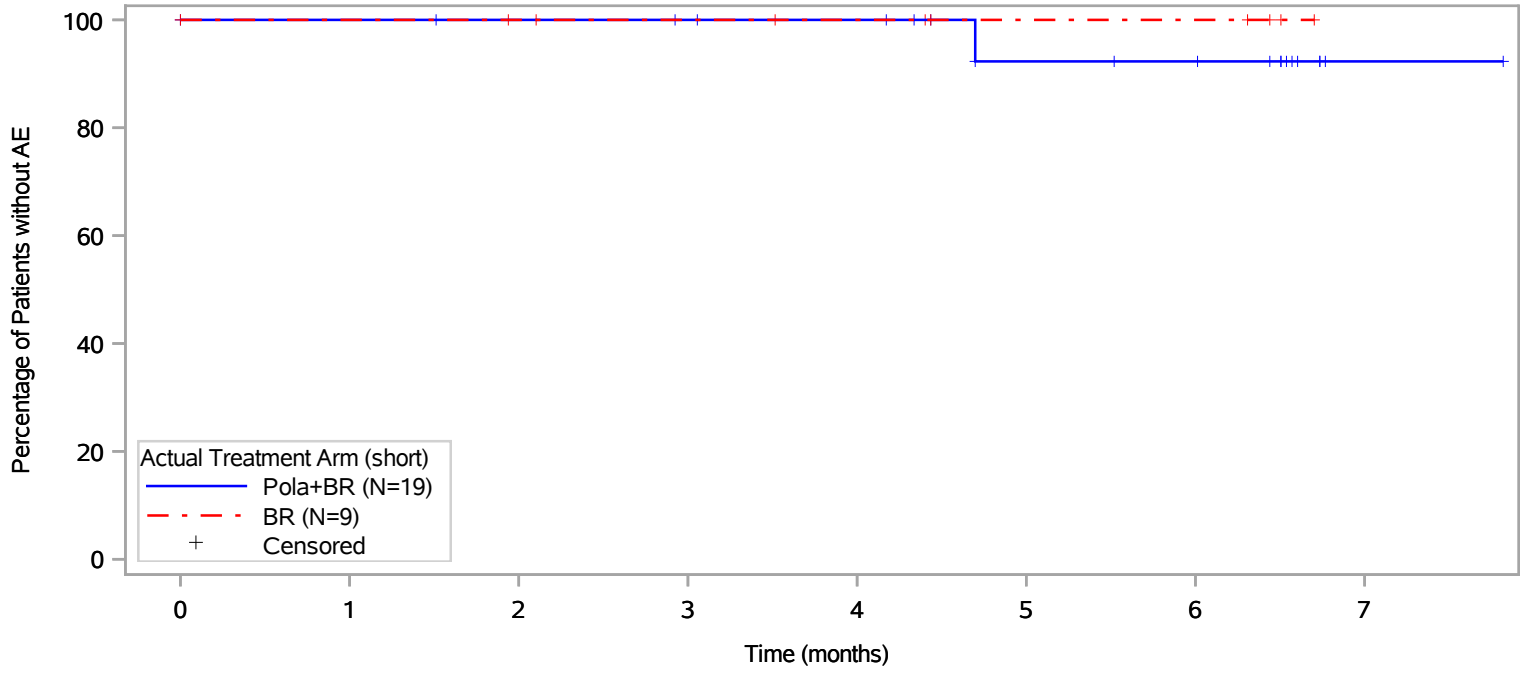
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PNEUMOMEDIASTINUM



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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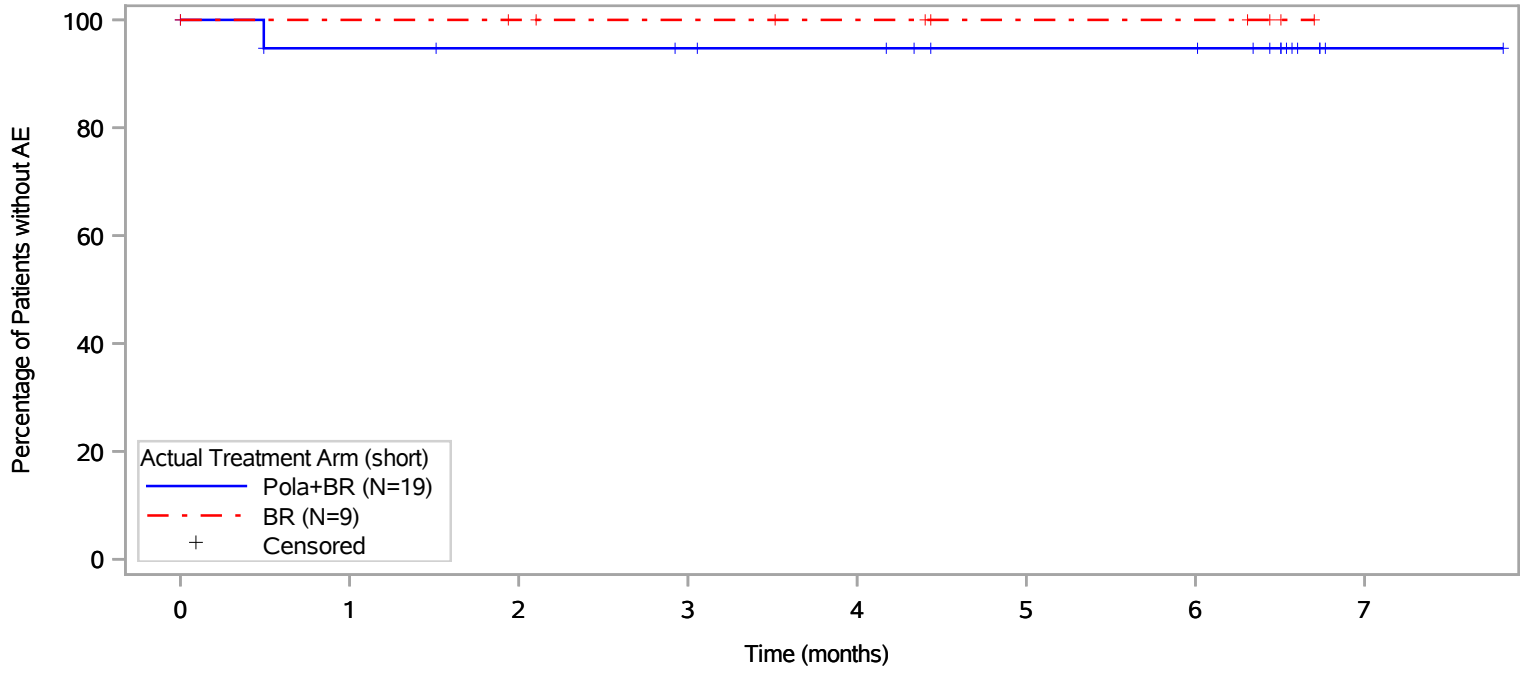
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, PRODUCTIVE COUGH

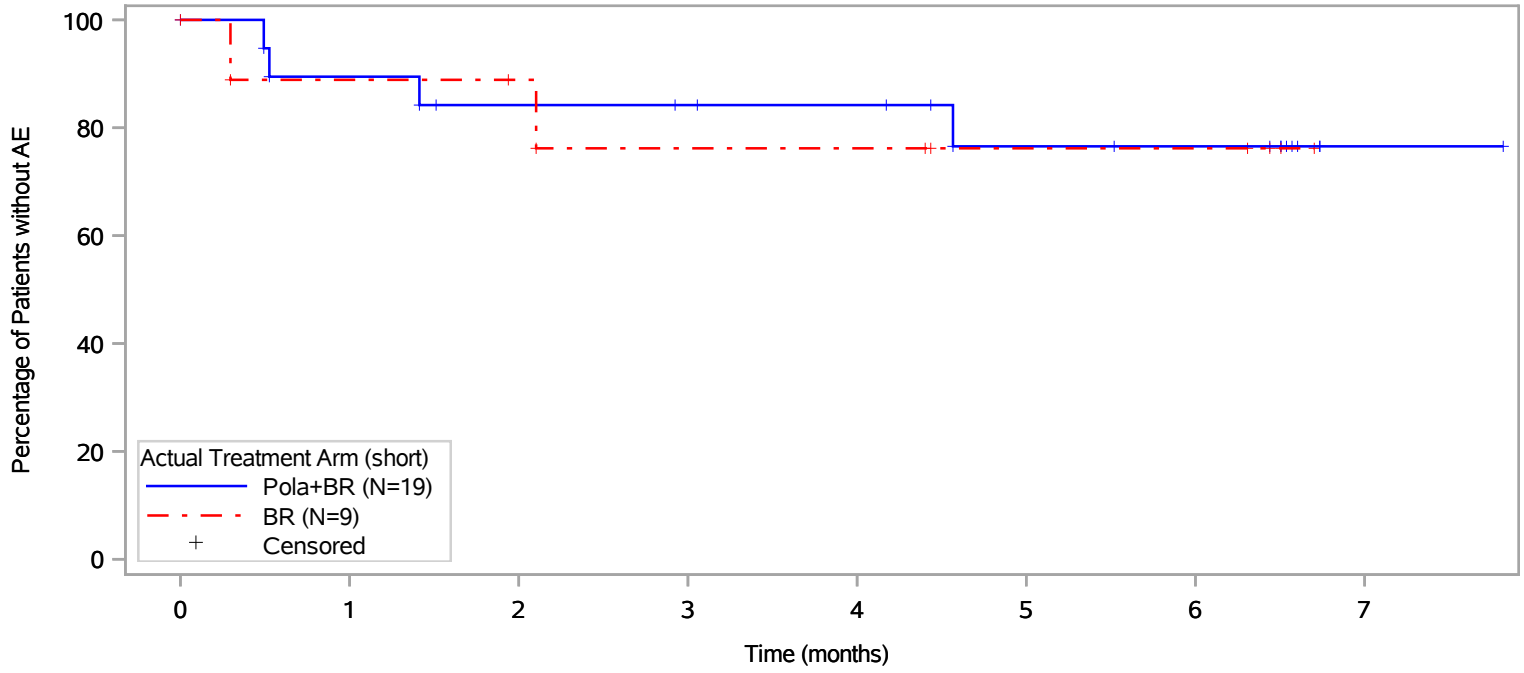


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	17	15	14	13	10	9	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	14
BR (N=9)	0	0	1	1	1	3	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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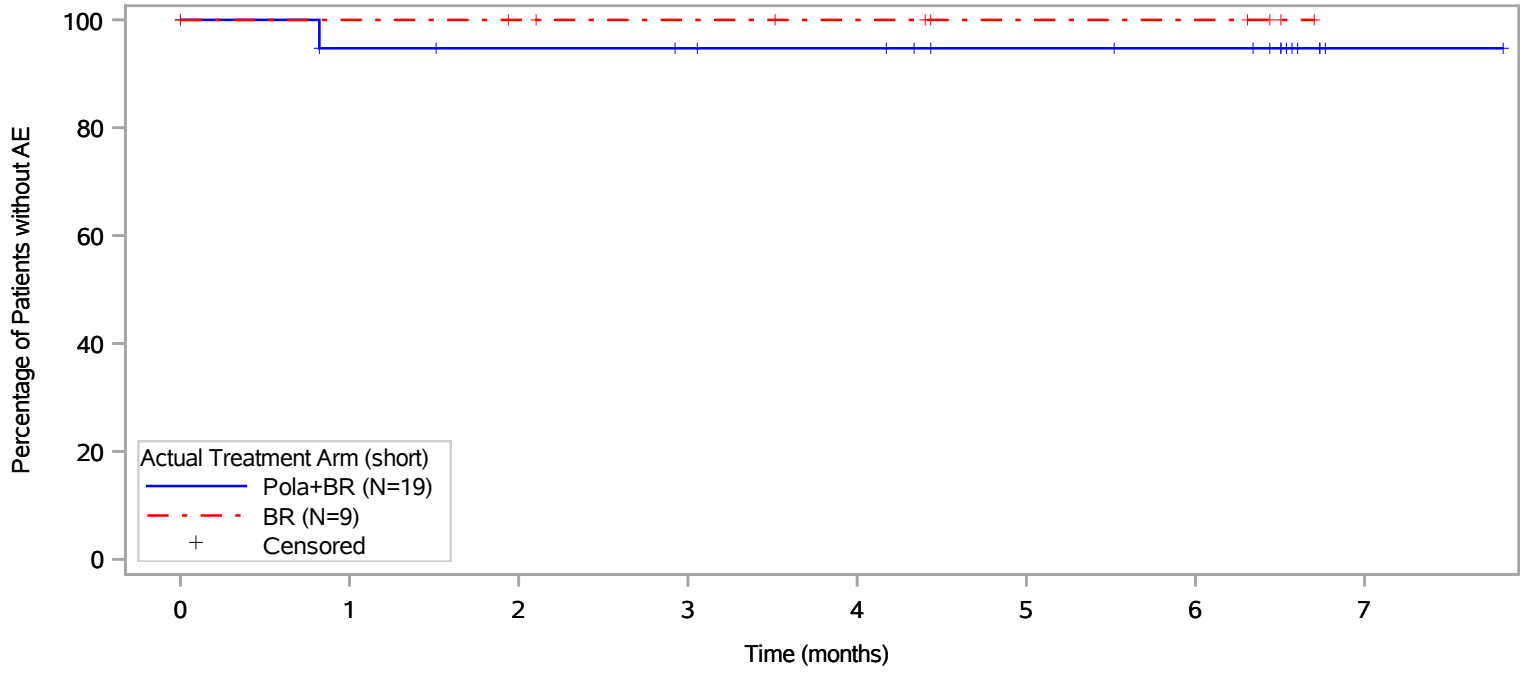
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, ALOPECIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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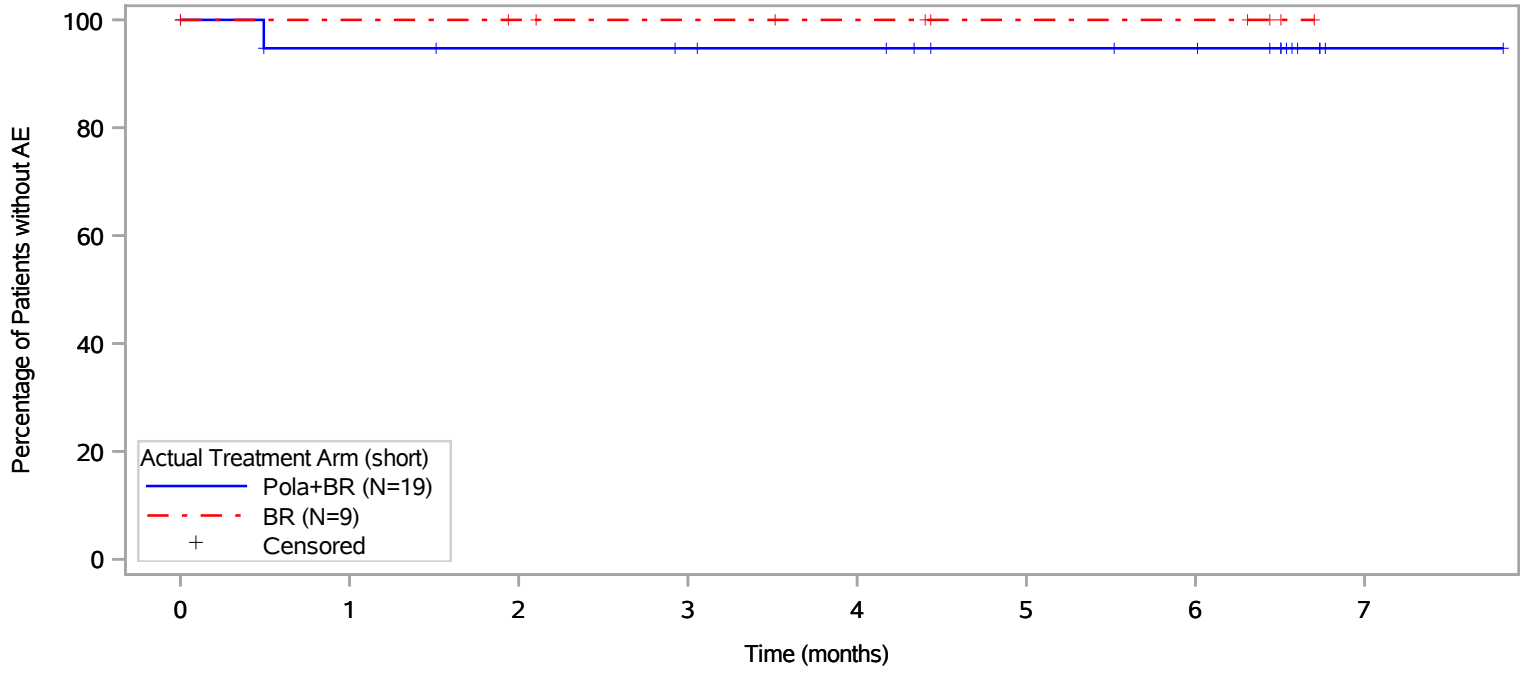
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, ECZEMA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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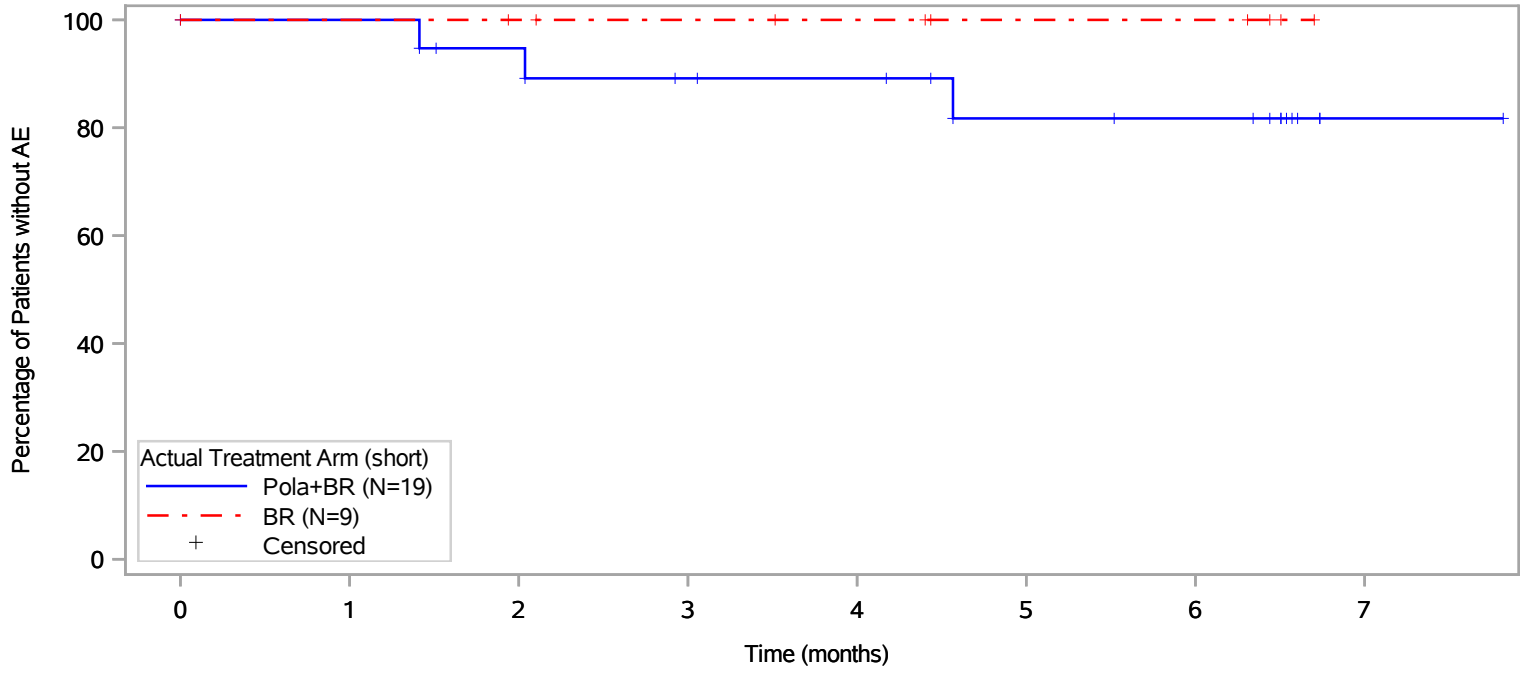
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, PRURITUS

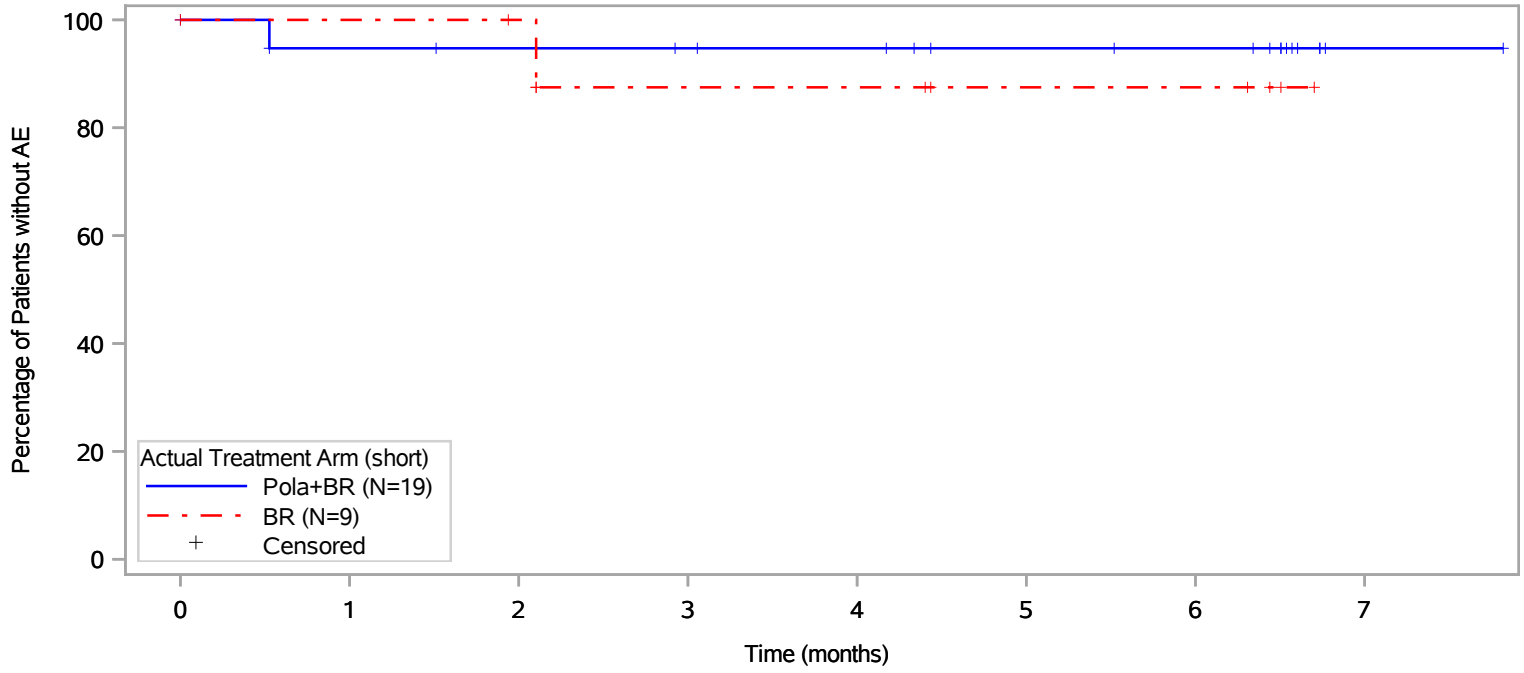


Patients at risk								
Pola+BR (N=19)	19	19	17	15	14	11	10	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	15
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543

SKIN AND SUBCUTANEOUS TISSUE DISORDERS, RASH

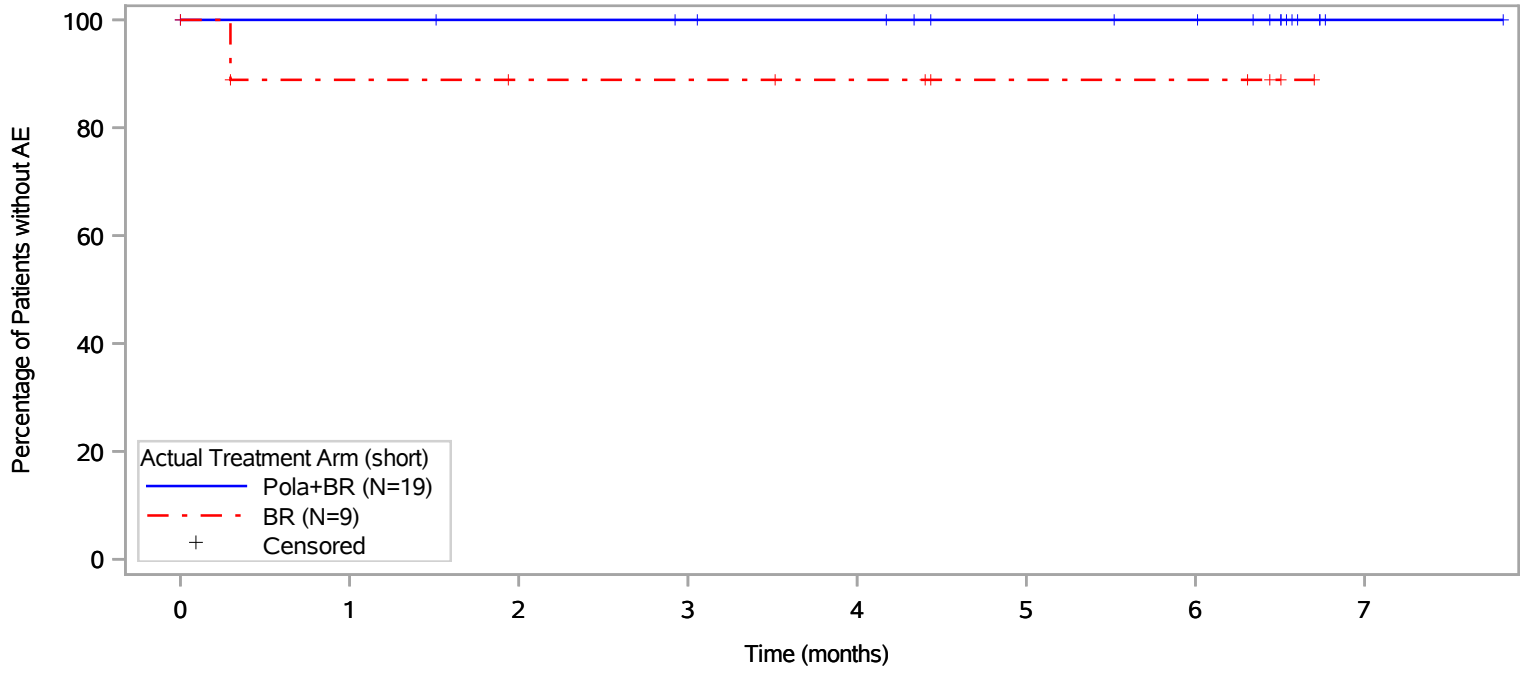


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
SKIN AND SUBCUTANEOUS TISSUE DISORDERS, URTICARIA



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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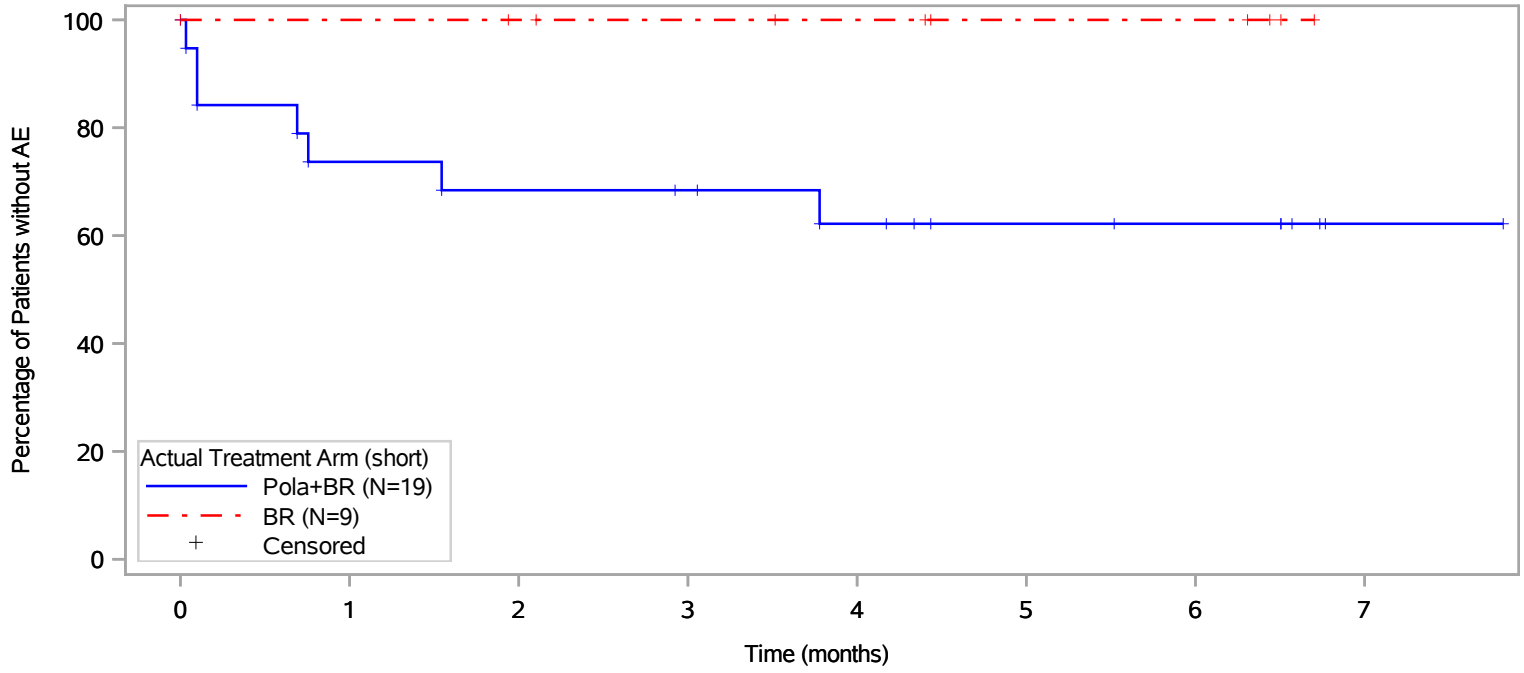
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All

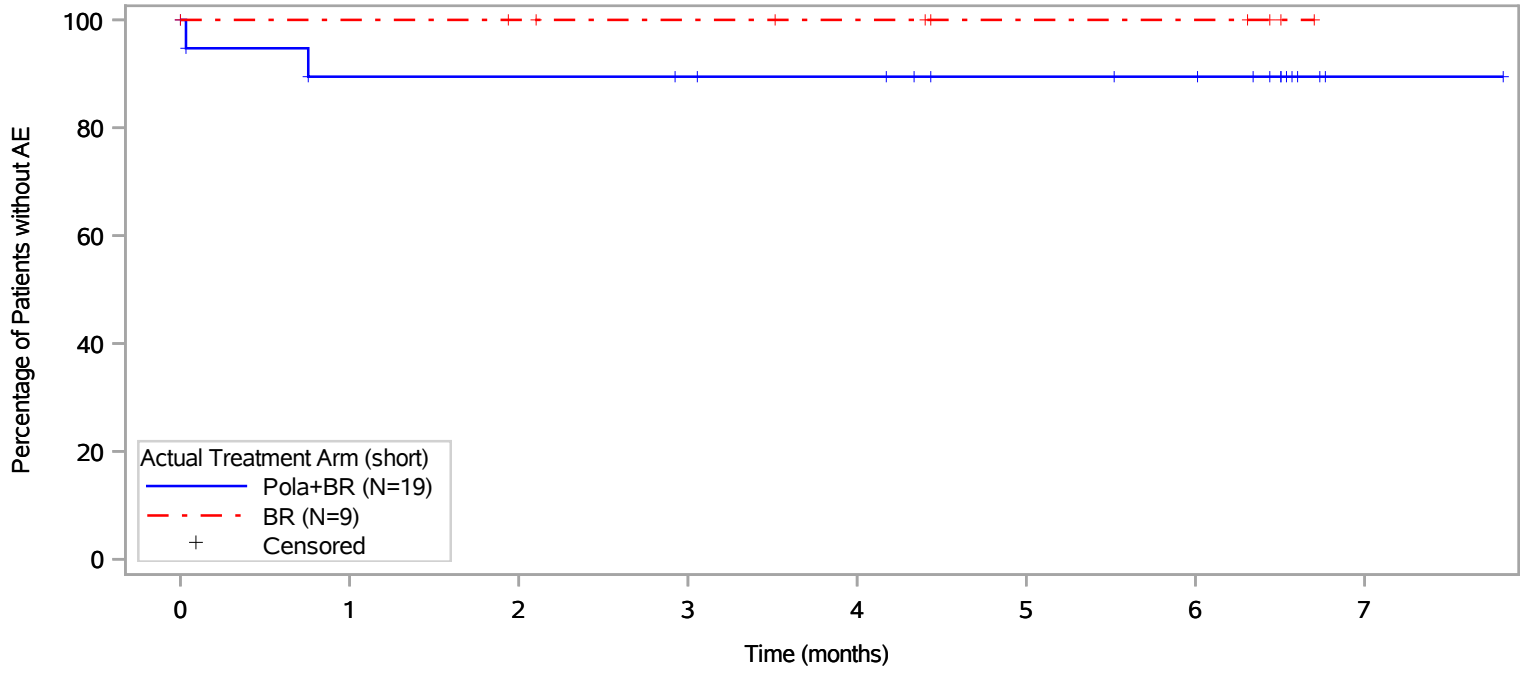


Patients at risk								
Pola+BR (N=19)	19	14	13	12	10	7	6	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	11
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPERTENSION

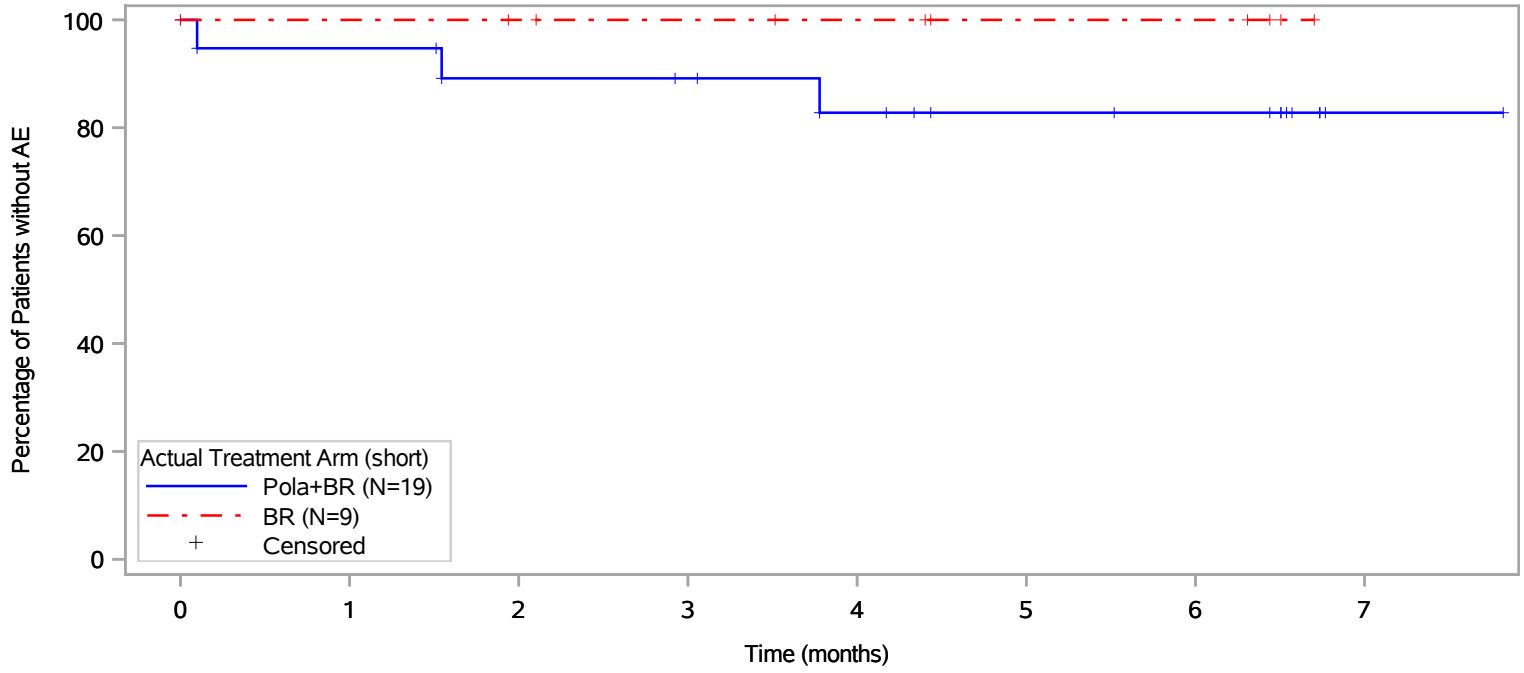


Patients at risk								
Pola+BR (N=19)	19	17	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION

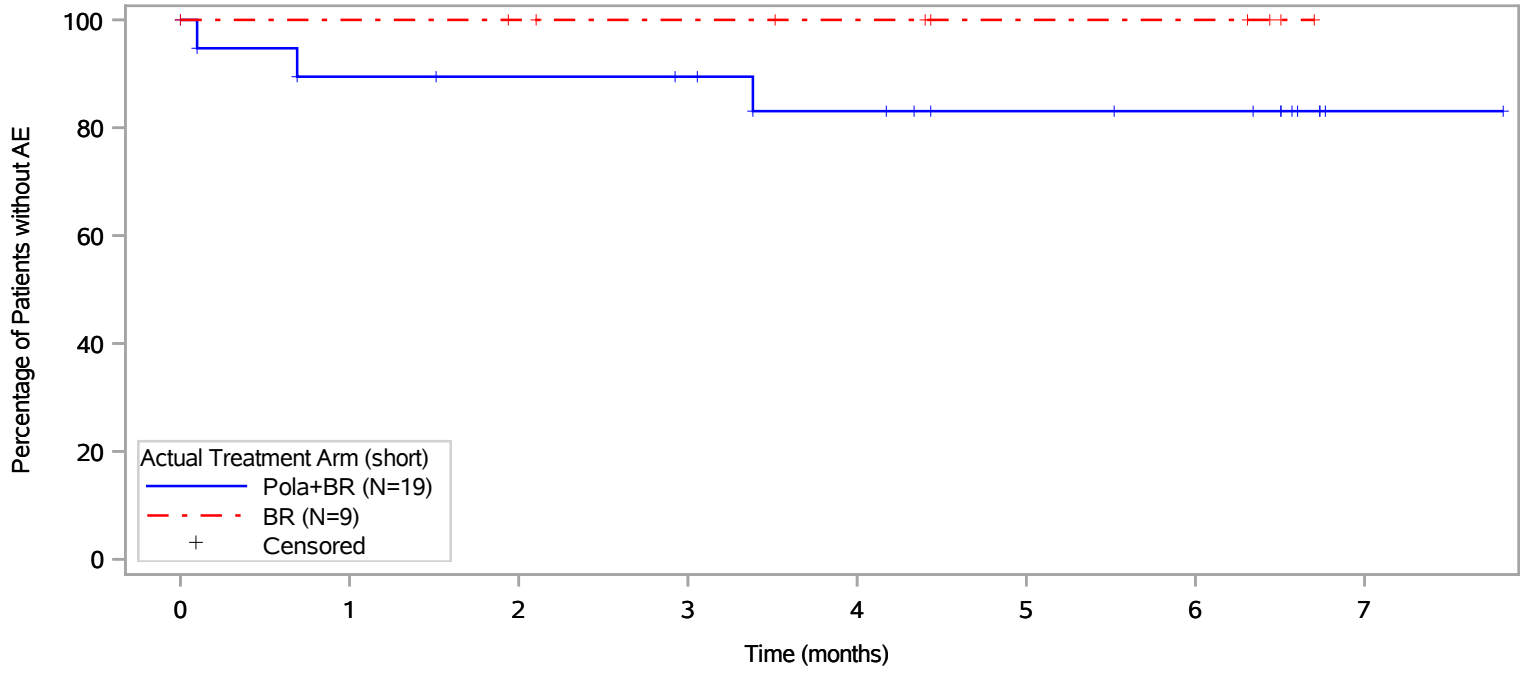


Patients at risk								
Pola+BR (N=19)	19	18	16	15	13	10	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	15
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, VENOUS THROMBOSIS



Patients at risk								
Pola+BR (N=19)	19	17	16	15	13	10	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	15
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_soc_TTAE_L3PLUS_Polarose_SE_29365_41543.pdf
01DEC2022 22:10

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	7	36.8	12	63.2	9	100.0	2	22.2	7	77.8	0.5030	1.70	0.35	8.20		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0825	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5722	0.46	0.03	7.34		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	6	31.6	13	68.4	9	100.0	1	11.1	8	88.9	0.3089	2.86	0.34	23.76		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1647	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			19	100.0	14	73.7	5	26.3	9	100.0	6	66.7	3	33.3	0.7933	1.15	0.41	3.16		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PRESSURE INCREASED		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	FIBRIN D DIMER INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		19	100.0	7	36.8	12	63.2	9	100.0	6	66.7	3	33.3	0.2284	0.49	0.15	1.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		19	100.0	11	57.9	8	42.1	9	100.0	2	22.2	7	77.8	0.1714	2.75	0.61	12.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NITRITE URINE PRESENT		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1303	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	URINE OUTPUT DECREASED		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		19	100.0	9	47.4	10	52.6	9	100.0	0	-	9	100.0	0.0308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1109	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1109	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HAEMATURIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sg1_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.xls

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POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	16	84.2	7	43.8	9	56.3	7	77.8	2	28.6	5	71.4	0.6499	1.44	0.30	6.95		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	16	84.2	6	37.5	10	62.5	7	77.8	0	-	7	100.0	0.1048	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.4649	0.37	0.02	5.93		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5090	0.41	0.03	6.49		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	16	84.2	5	31.3	11	68.8	7	77.8	1	14.3	6	85.7	0.5861	1.80	0.21	15.54		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.2715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.0943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	16	84.2	12	75.0	4	25.0	7	77.8	4	57.1	3	42.9	0.6777	1.29	0.39	4.22		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	3	15.8	2	66.7	1	33.3	2	22.2	2	100.0	0	-	0.5408	2.22	0.16	29.97		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	16	84.2	5	31.3	11	68.8	7	77.8	4	57.1	3	42.9	0.3290	0.49	0.12	2.07		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	2	100.0	0	-	0.5408	2.22	0.16	29.97		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	16	84.2	10	62.5	6	37.5	7	77.8	1	14.3	6	85.7	0.1291	4.33	0.55	34.03		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	1	50.0	1	50.0	0.8084	0.71	0.04	11.79		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	16	84.2	5	31.3	11	68.8	7	77.8	0	-	7	100.0	0.1668	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	16	84.2	8	50.0	8	50.0	7	77.8	0	-	7	100.0	0.0729	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	16	84.2	5	31.3	11	68.8	7	77.8	0	-	7	100.0	0.1330	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	16	84.2	5	31.3	11	68.8	7	77.8	0	-	7	100.0	0.1330	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 19:50

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	14	73.7	5	35.7	9	64.3	6	66.7	2	33.3	4	66.7	0.8870	0.89	0.17	4.62		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	14	73.7	5	35.7	9	64.3	6	66.7	0	-	6	100.0	0.1516	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5561	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5100	0.41	0.03	6.50		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.4969	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	14	73.7	6	42.9	8	57.1	6	66.7	1	16.7	5	83.3	0.3586	2.60	0.31	21.66		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.1896	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	14	73.7	10	71.4	4	28.6	6	66.7	4	66.7	2	33.3	0.9432	0.95	0.27	3.39		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	26.3	4	80.0	1	20.0	3	33.3	2	66.7	1	33.3	0.5394	1.70	0.30	9.54		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	14	73.7	5	35.7	9	64.3	6	66.7	4	66.7	2	33.3	0.2647	0.44	0.10	1.92		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	5	26.3	2	40.0	3	60.0	3	33.3	2	66.7	1	33.3	0.7633	0.74	0.10	5.30		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5561	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	14	73.7	7	50.0	7	50.0	6	66.7	0	-	6	100.0	0.0667	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	5	26.3	4	80.0	1	20.0	3	33.3	2	66.7	1	33.3	0.9730	1.03	0.17	6.25		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2956	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	14	73.7	6	42.9	8	57.1	6	66.7	0	-	6	100.0	0.1216	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1269	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2690	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2690	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 19:50

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	2	22.2	7	77.8	0.5030	1.70	0.35	8.20		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0825	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5722	0.46	0.03	7.34		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	1	11.1	8	88.9	0.3089	2.86	0.34	23.76		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1647	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	100.0	14	73.7	5	26.3	9	100.0	6	66.7	3	33.3	0.7933	1.15	0.41	3.16		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	6	66.7	3	33.3	0.2284	0.49	0.15	1.60		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	19	100.0	11	57.9	8	42.1	9	100.0	2	22.2	7	77.8	0.1714	2.75	0.61	12.43		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1303	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	19	100.0	9	47.4	10	52.6	9	100.0	0	-	9	100.0	0.0308	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1109	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1109	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.xls

30NOV2022 19:50

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	4	28.6	10	71.4	6	66.7	1	16.7	5	83.3	0.7521	1.42	0.16	12.73		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	3	60.0	2	40.0	3	33.3	1	33.3	2	66.7	0.3587	2.80	0.28	27.61		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1269	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4348	0.35	0.02	5.57		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	1	33.3	2	66.7	0.7766	0.67	0.04	10.77		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5100	0.41	0.03	6.50		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.4969	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	4	28.6	10	71.4	6	66.7	1	16.7	5	83.3	0.7871	1.35	0.15	12.14		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4031	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	14	73.7	12	85.7	2	14.3	6	66.7	3	50.0	3	50.0	0.1796	2.41	0.64	9.00		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	2	40.0	3	60.0	3	33.3	3	100.0	0	-	0.0568	0.13	0.01	1.38		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	14	73.7	7	50.0	7	50.0	6	66.7	3	50.0	3	50.0	0.8834	1.12	0.26	4.79		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	3	100.0	0	-	0.0046	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	14	73.7	10	71.4	4	28.6	6	66.7	2	33.3	4	66.7	0.6138	1.49	0.31	7.12		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	14	73.7	5	35.7	9	64.3	6	66.7	0	-	6	100.0	0.1681	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	14	73.7	8	57.1	6	42.9	6	66.7	0	-	6	100.0	0.0592	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.1869	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.1869	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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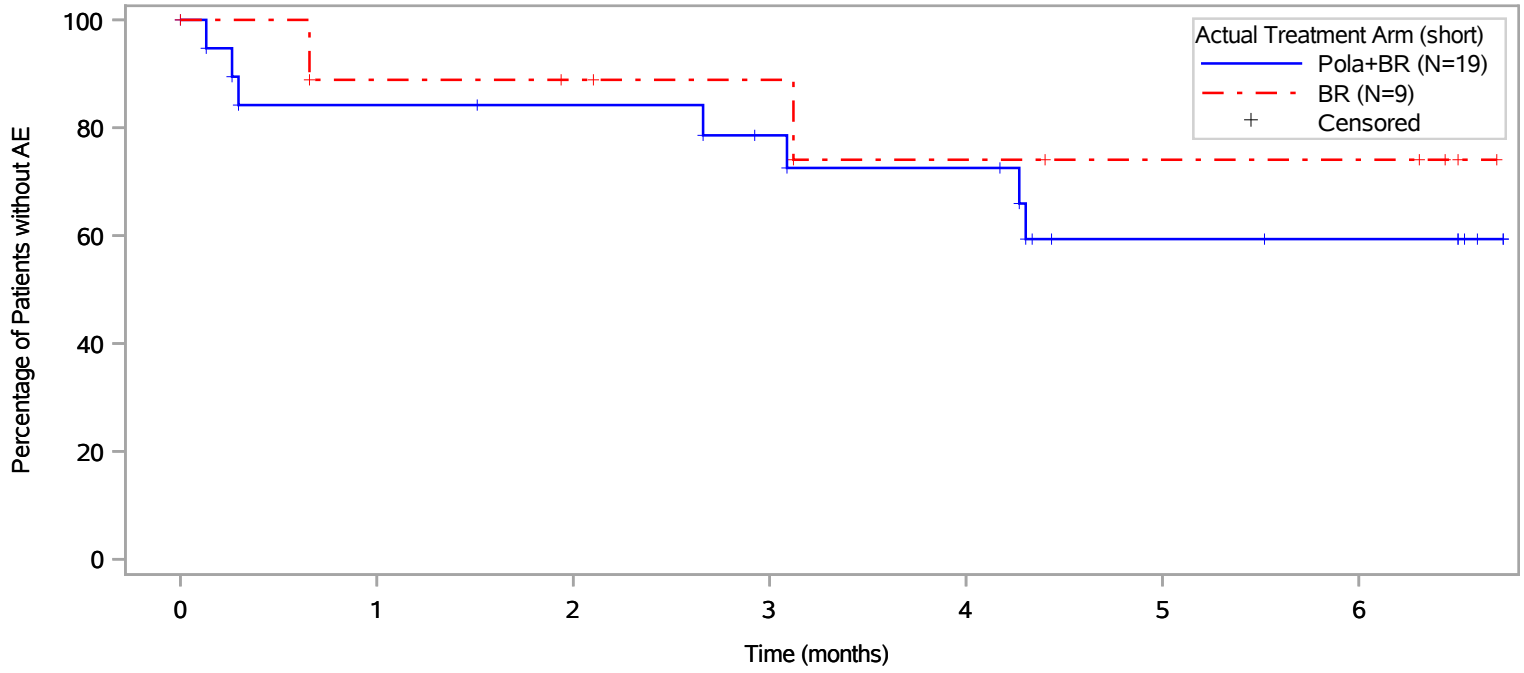
30NOV2022 19:50

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	16	15	13	12	7	6
BR (N=9)	9	8	7	6	5	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	2	5	6
BR (N=9)	0	0	1	2	2	3	3

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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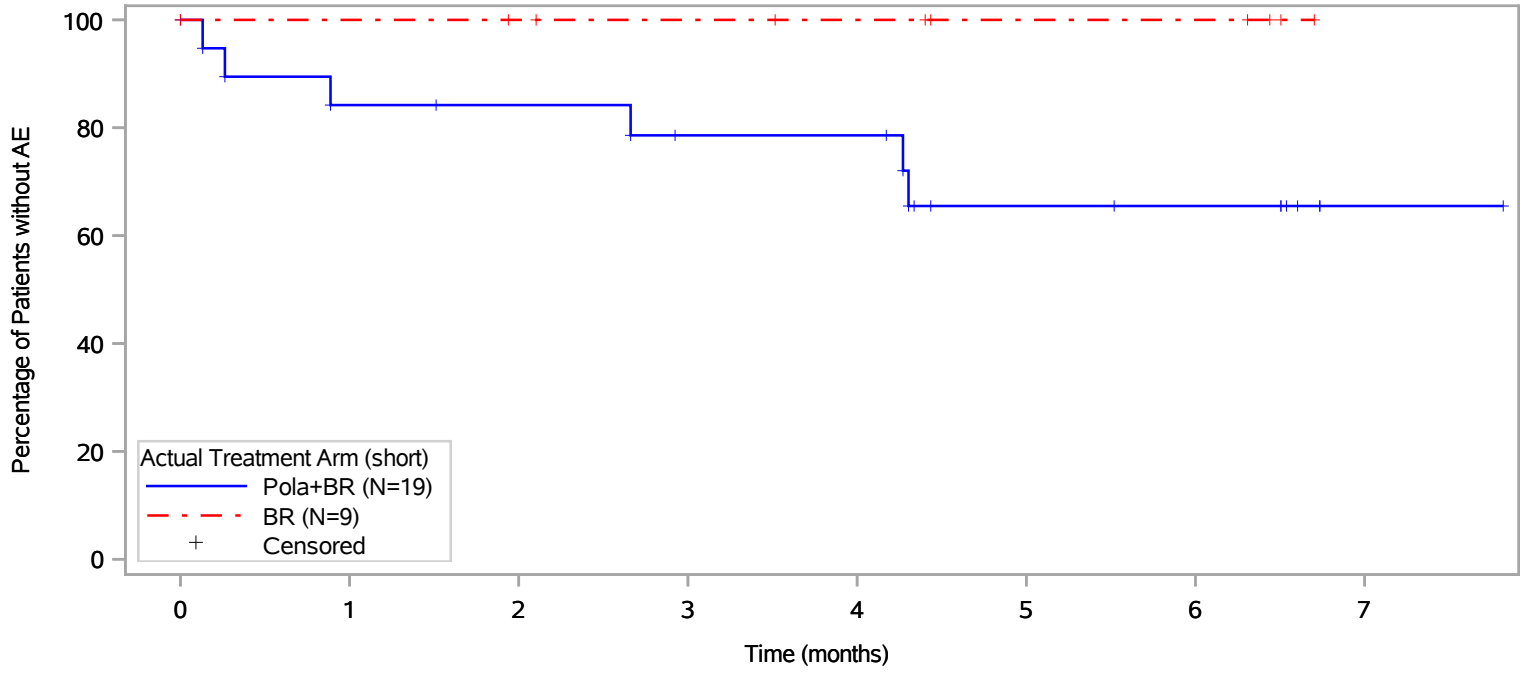
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk								
Pola+BR (N=19)	19	16	15	13	13	8	7	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	12
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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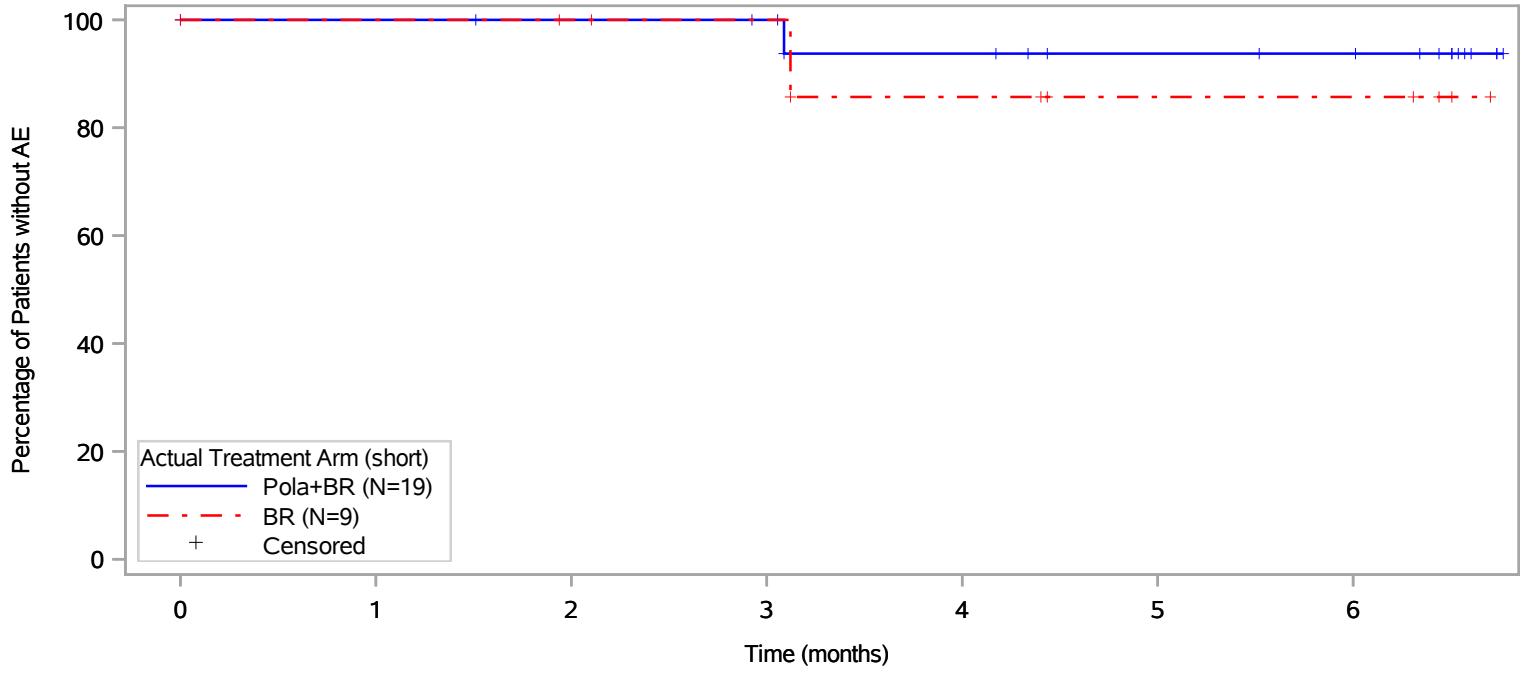
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, MYELOSUPPRESSION



Patients at risk							
Pola+BR (N=19)	19	19	18	17	15	12	11
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	2	4	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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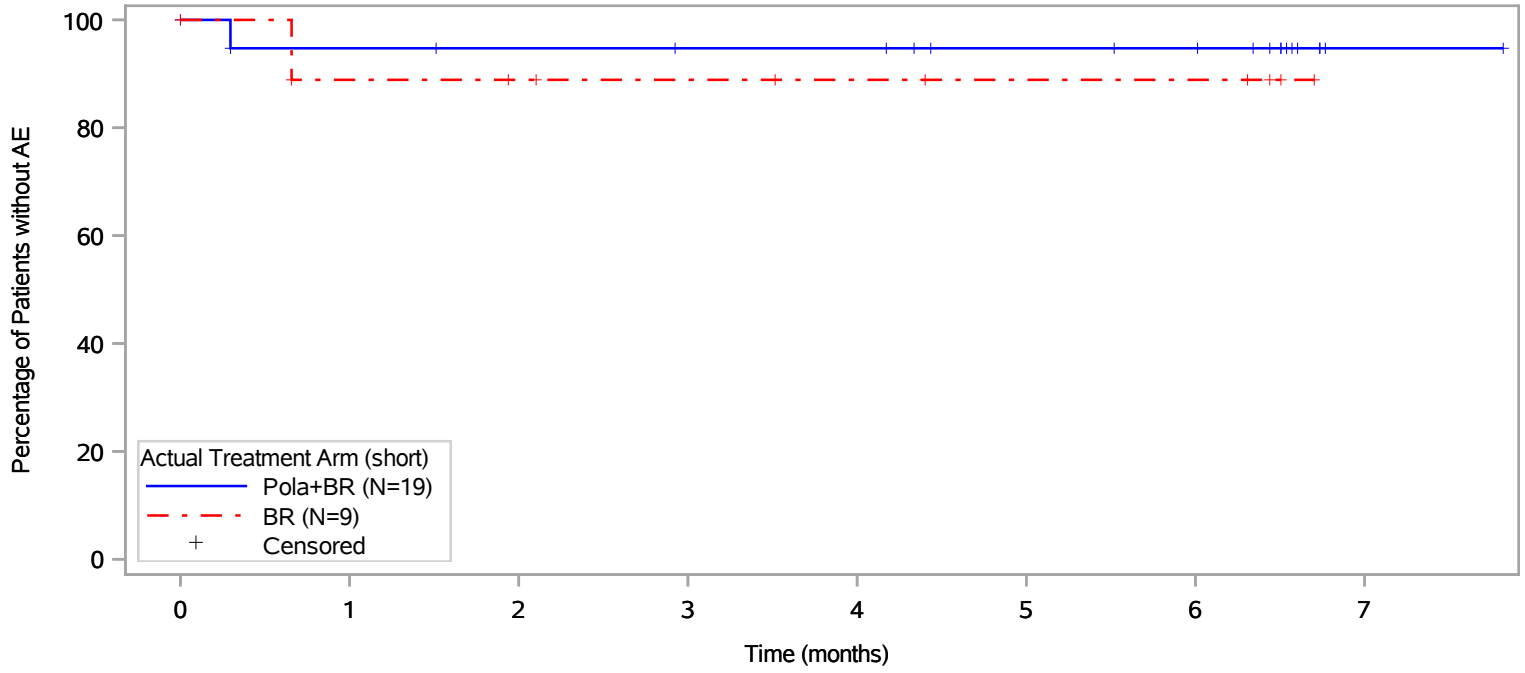
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	16	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	17
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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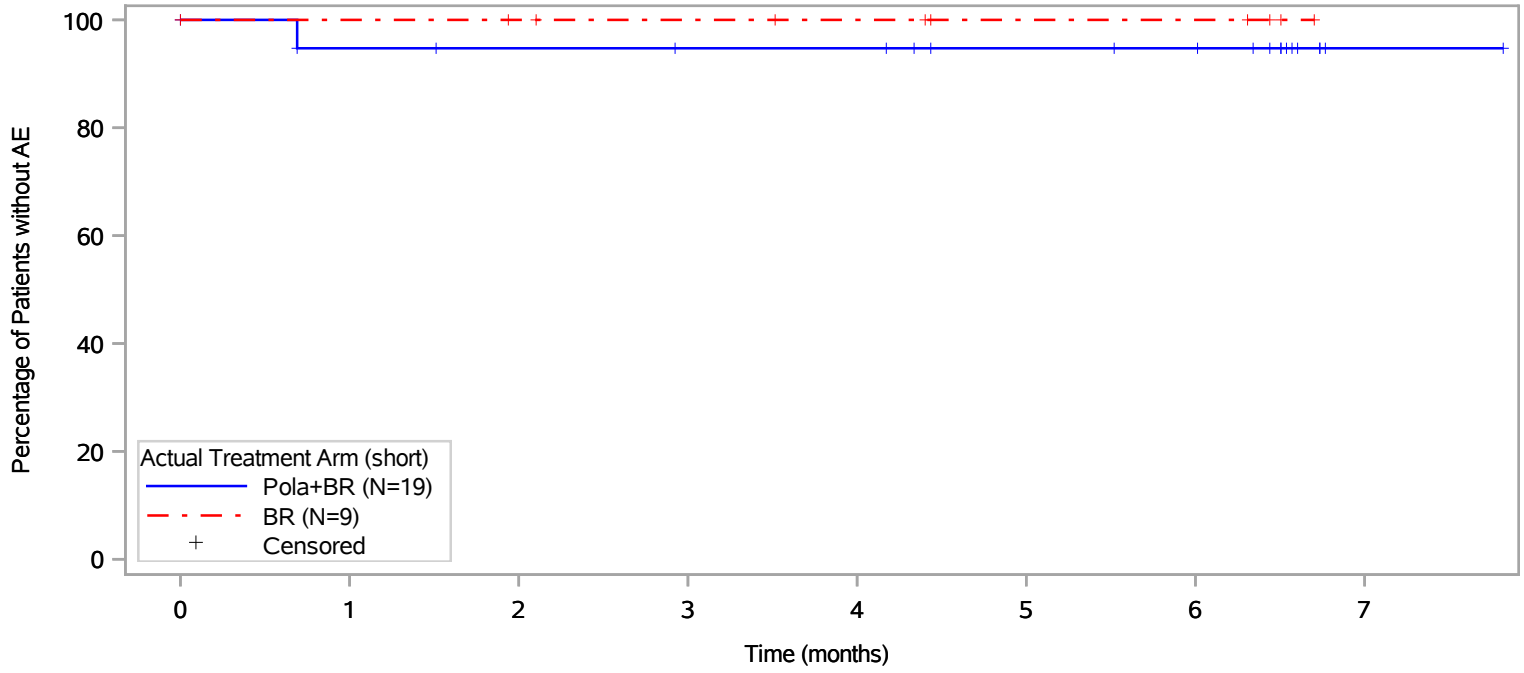
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

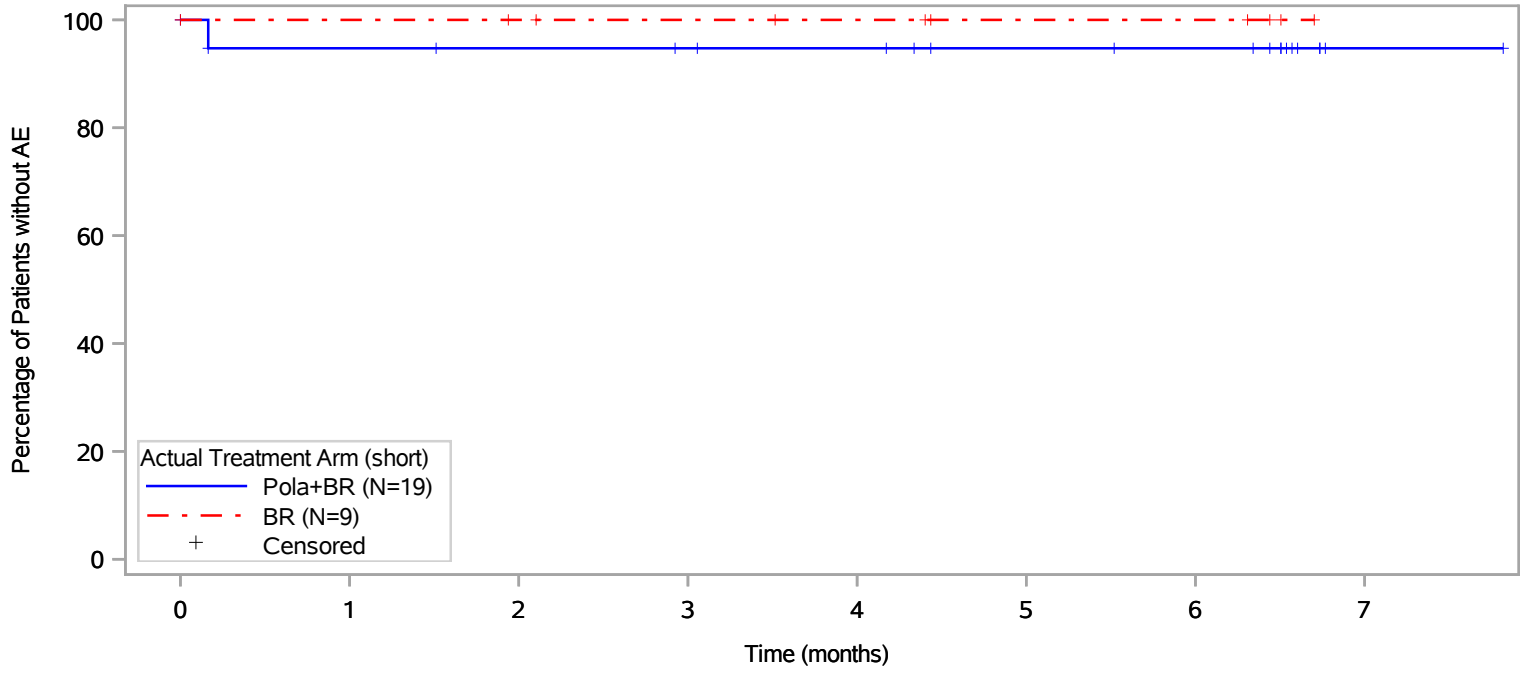
BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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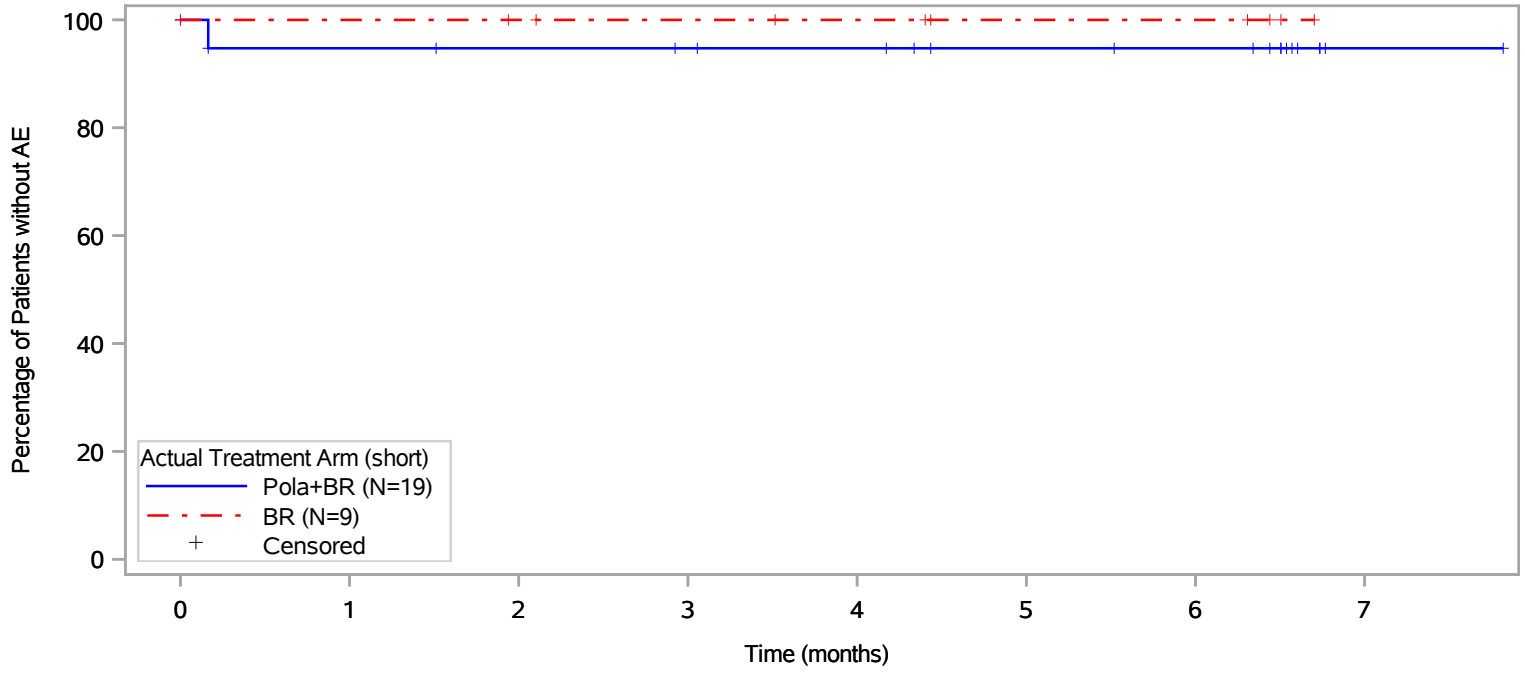
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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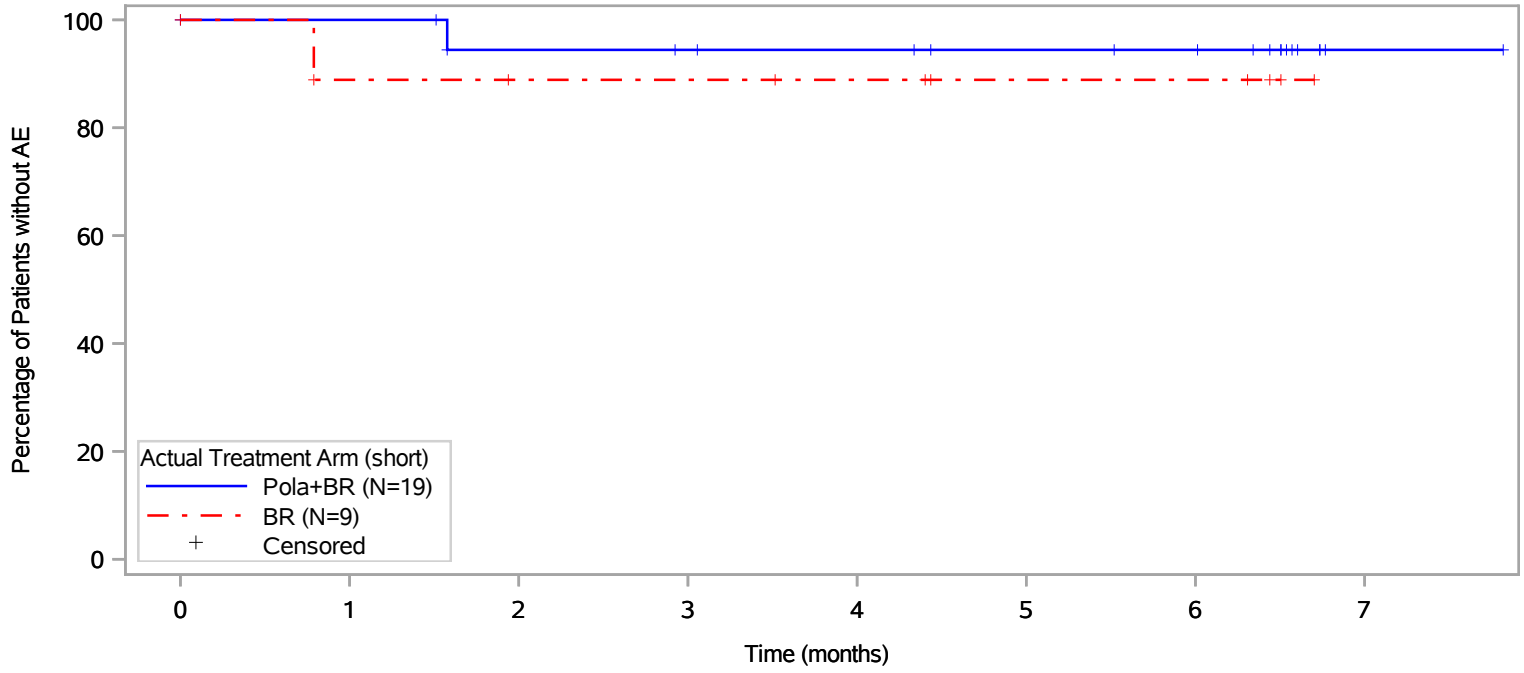
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All

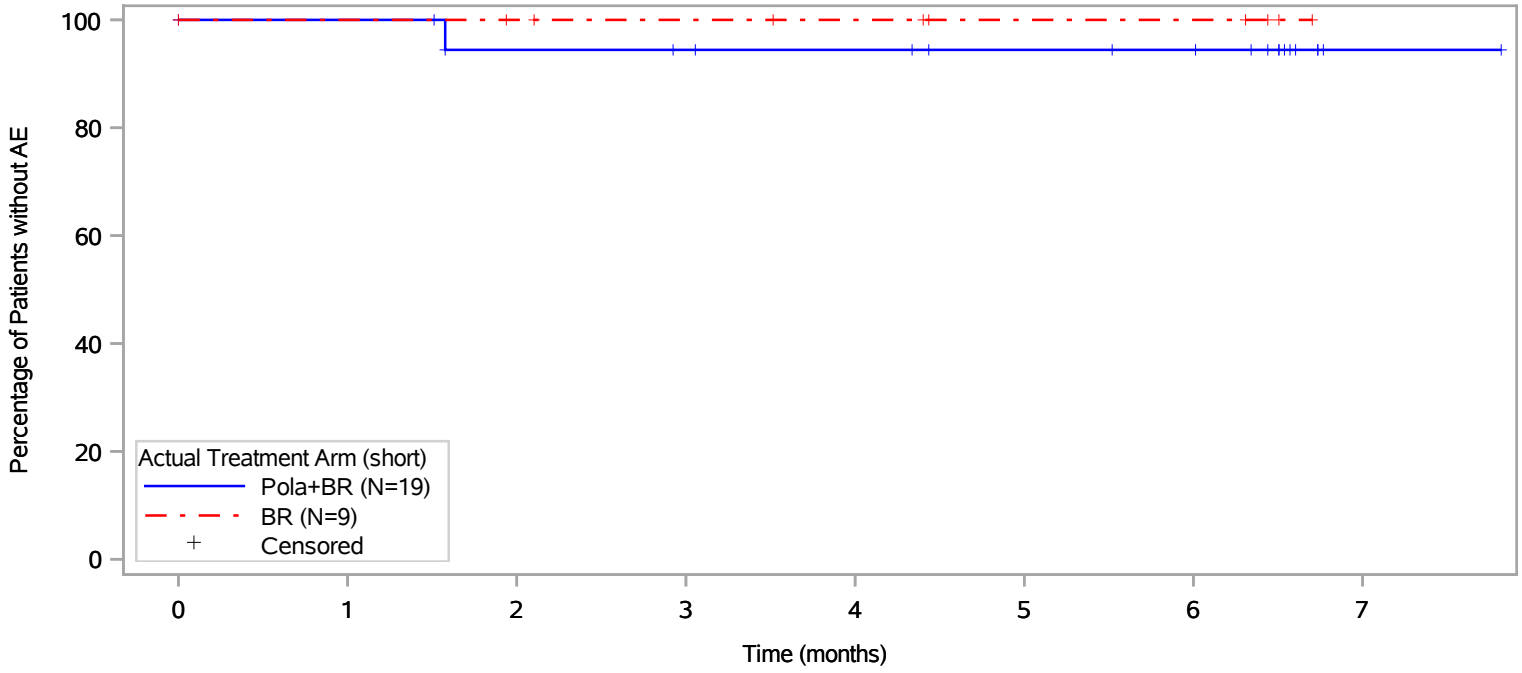


Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN

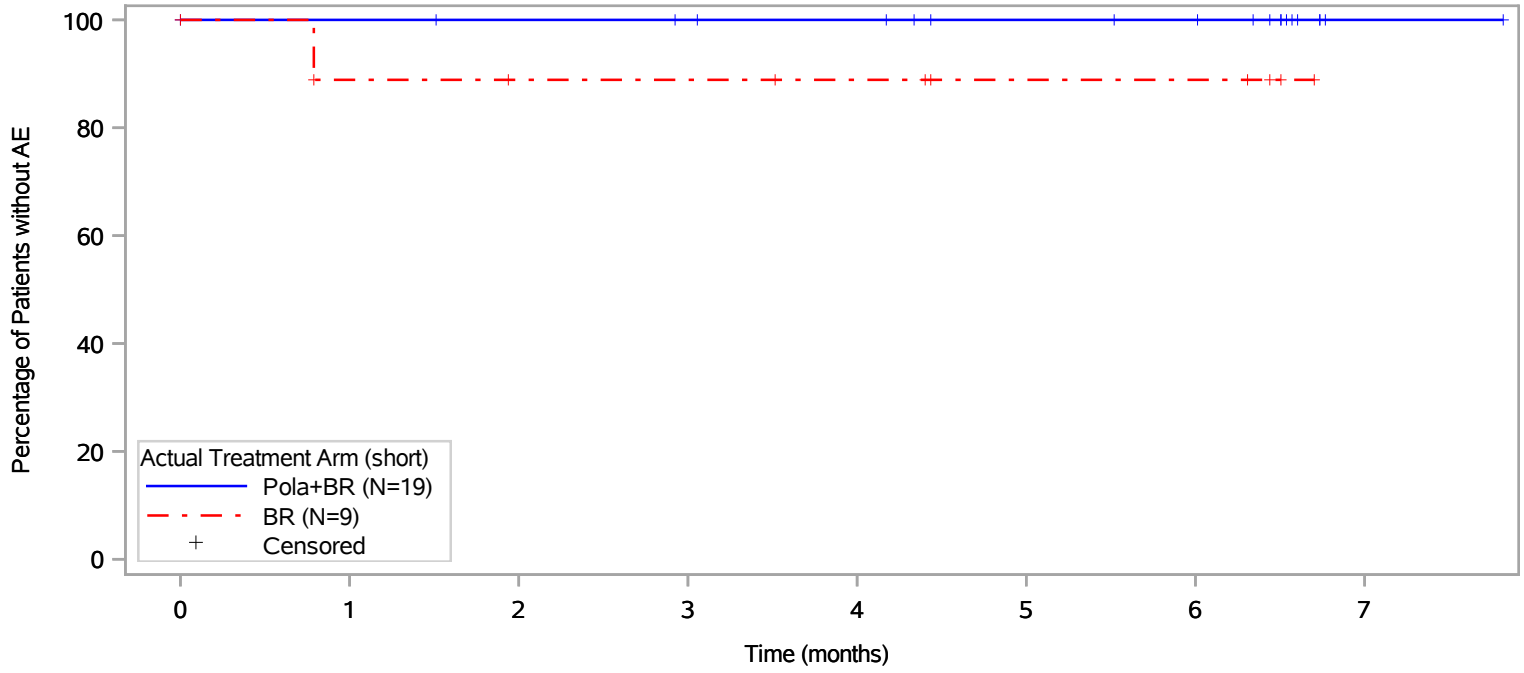


Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, UPPER GASTROINTESTINAL HAEMORRHAGE

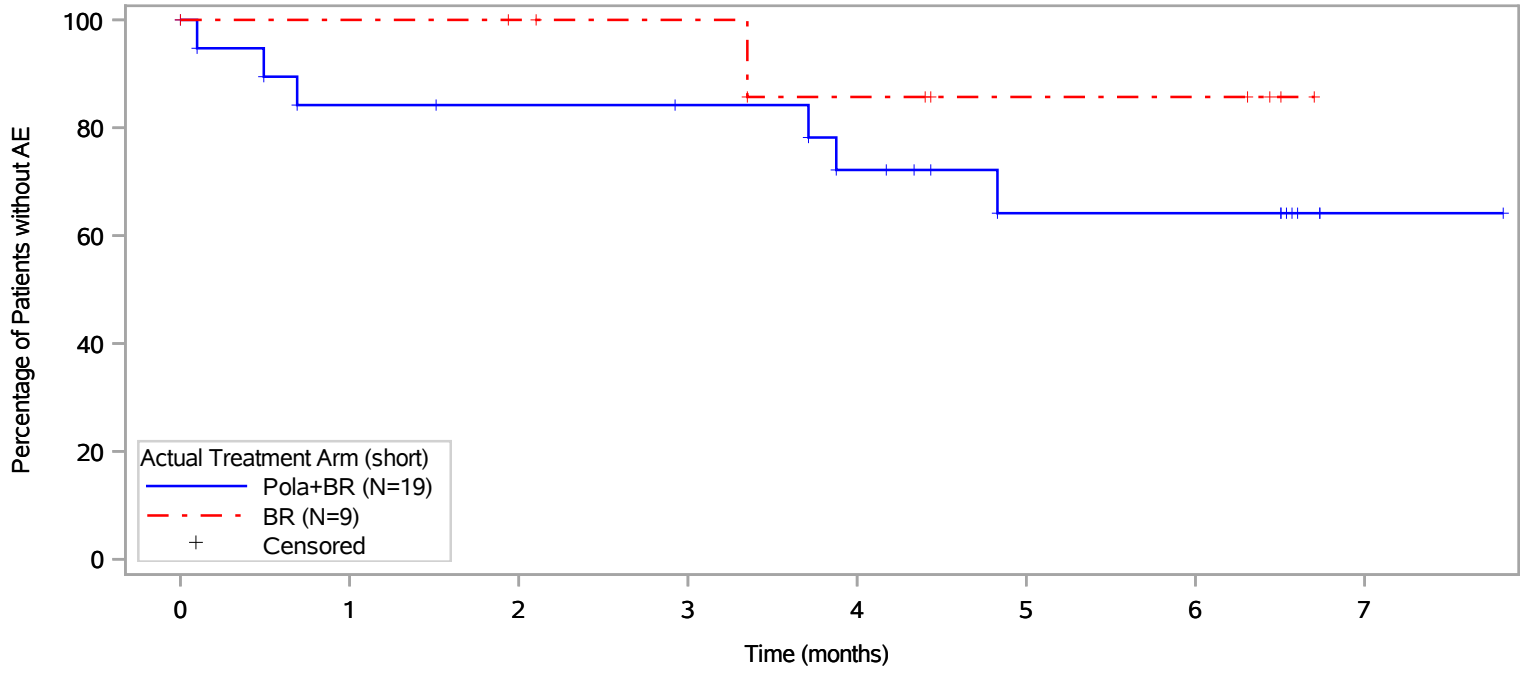


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk								
Pola+BR (N=19)	19	16	15	14	12	8	8	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	12
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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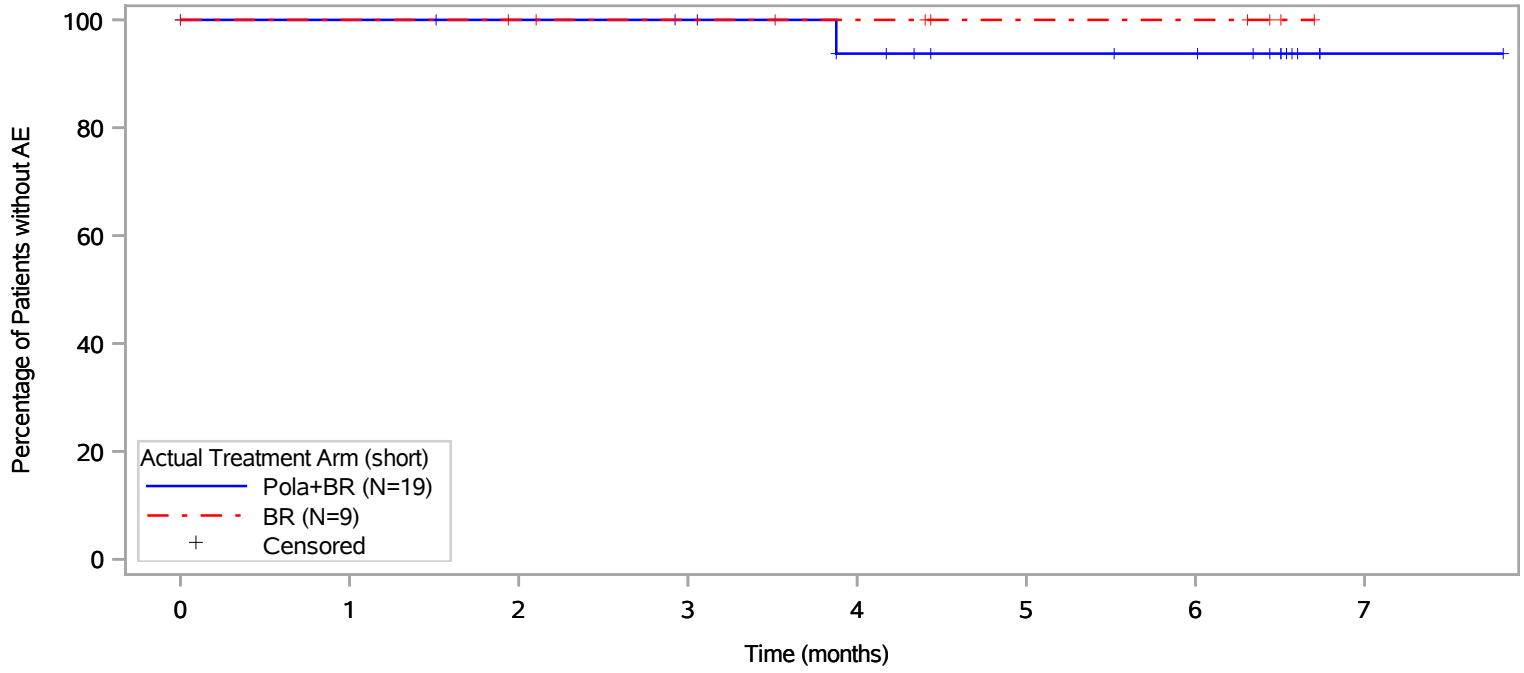
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION

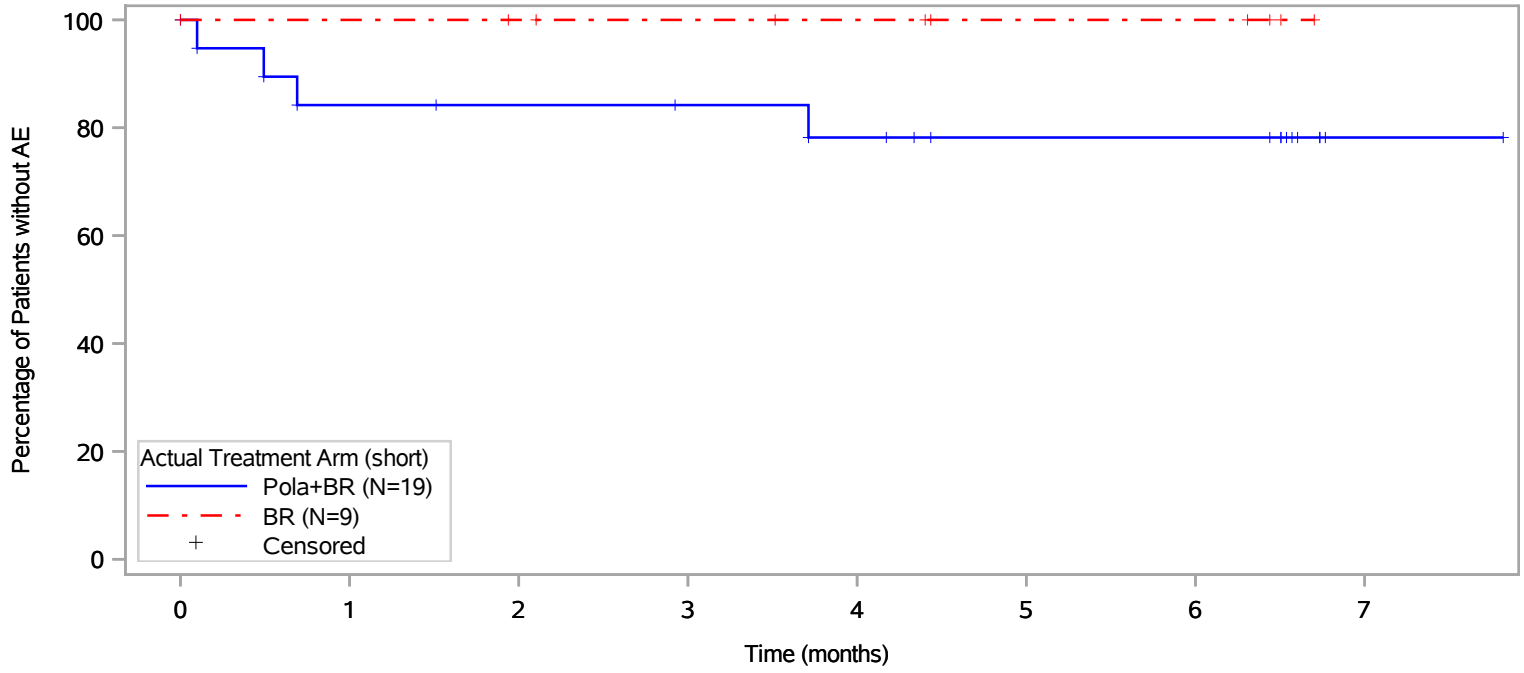


Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA

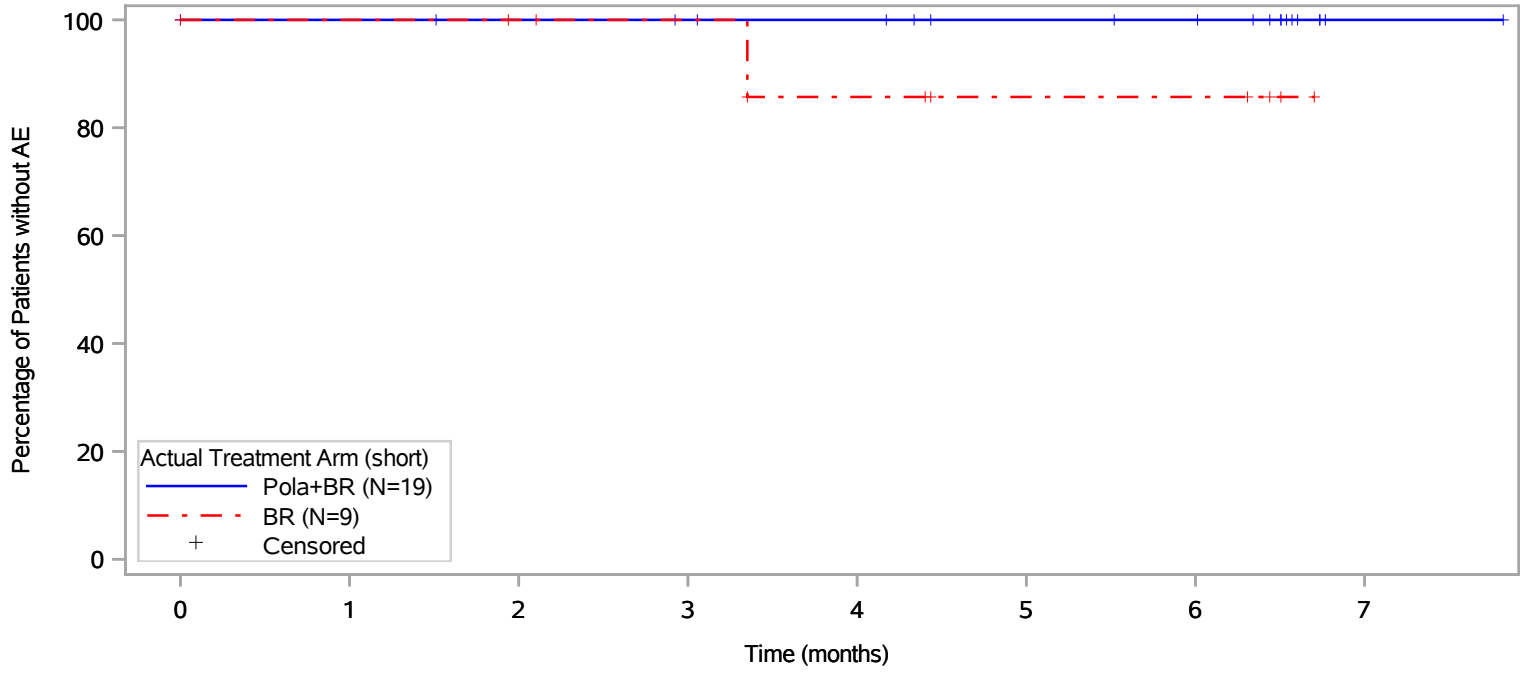


Patients at risk								
Pola+BR (N=19)	19	16	15	14	13	10	10	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	14
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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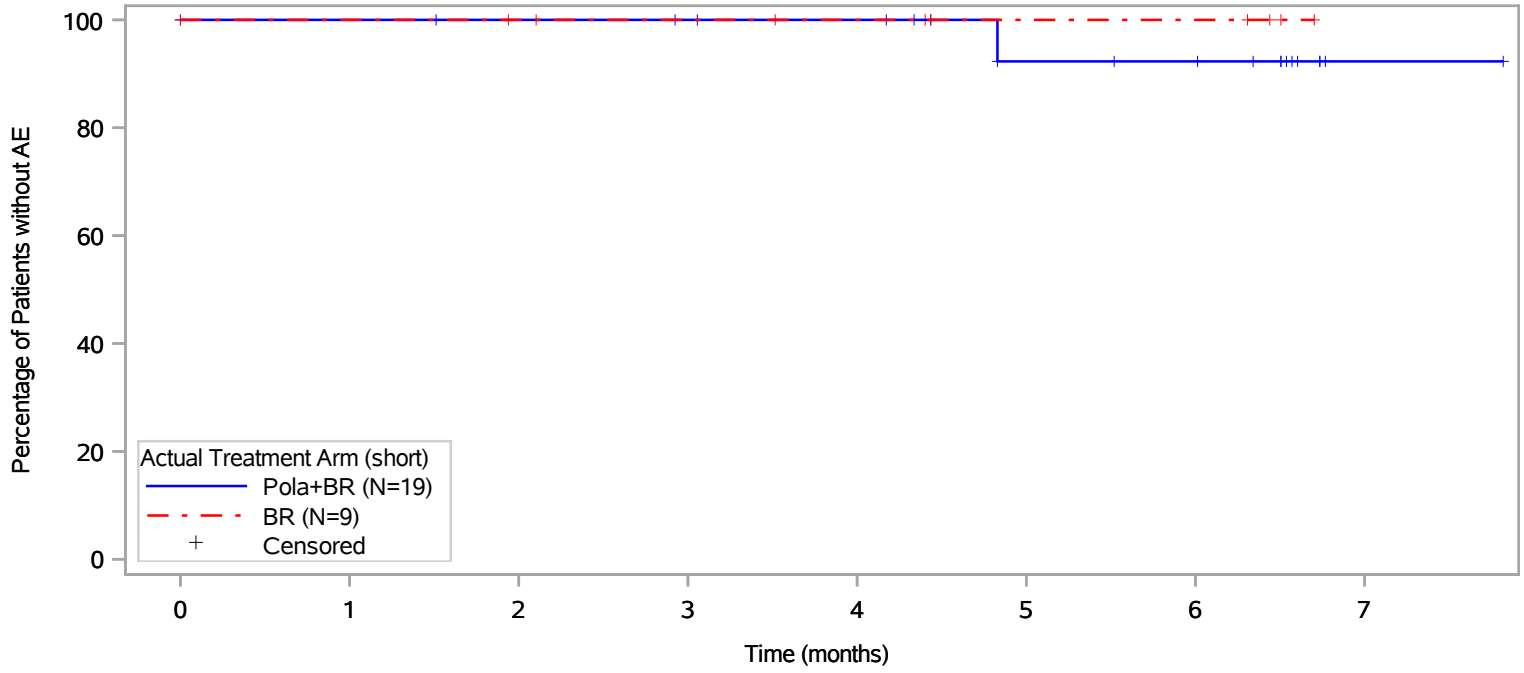
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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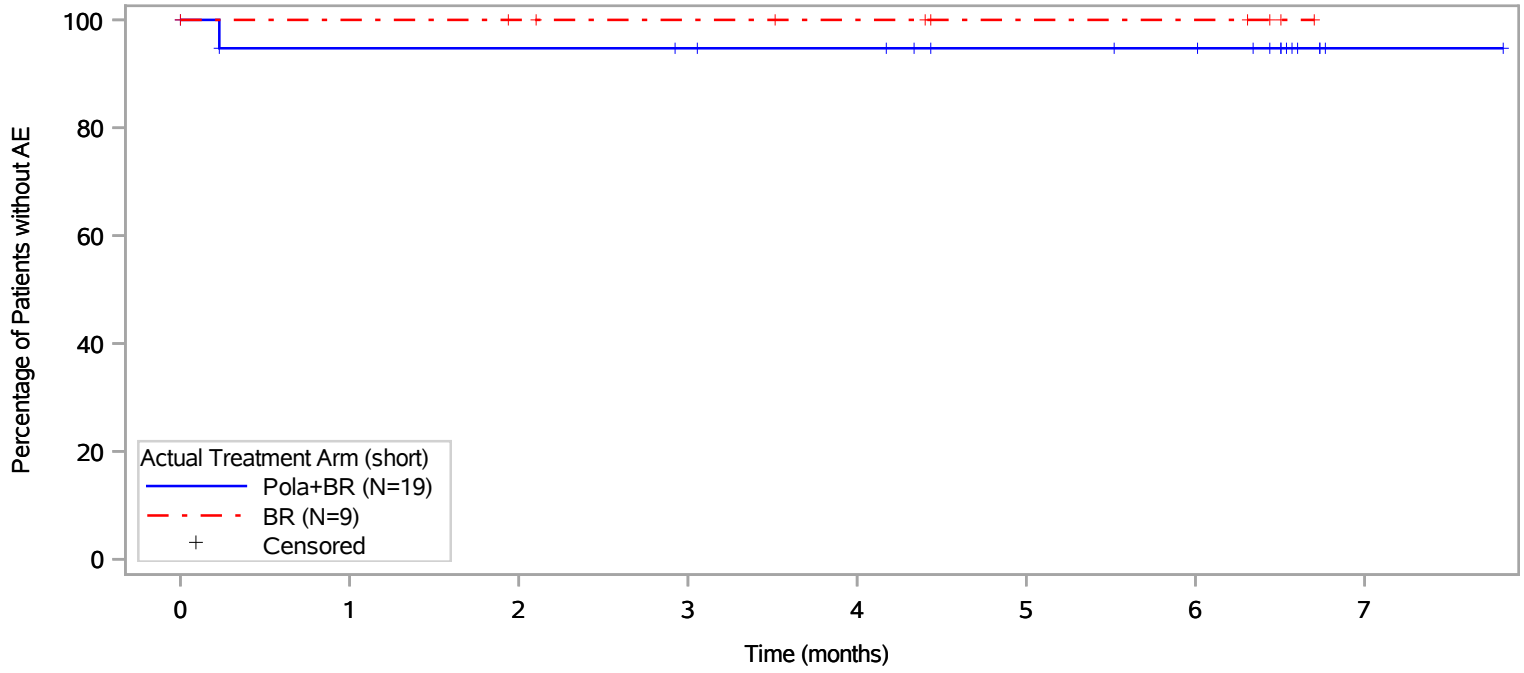
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk								
Pola+BR (N=19)	19	18	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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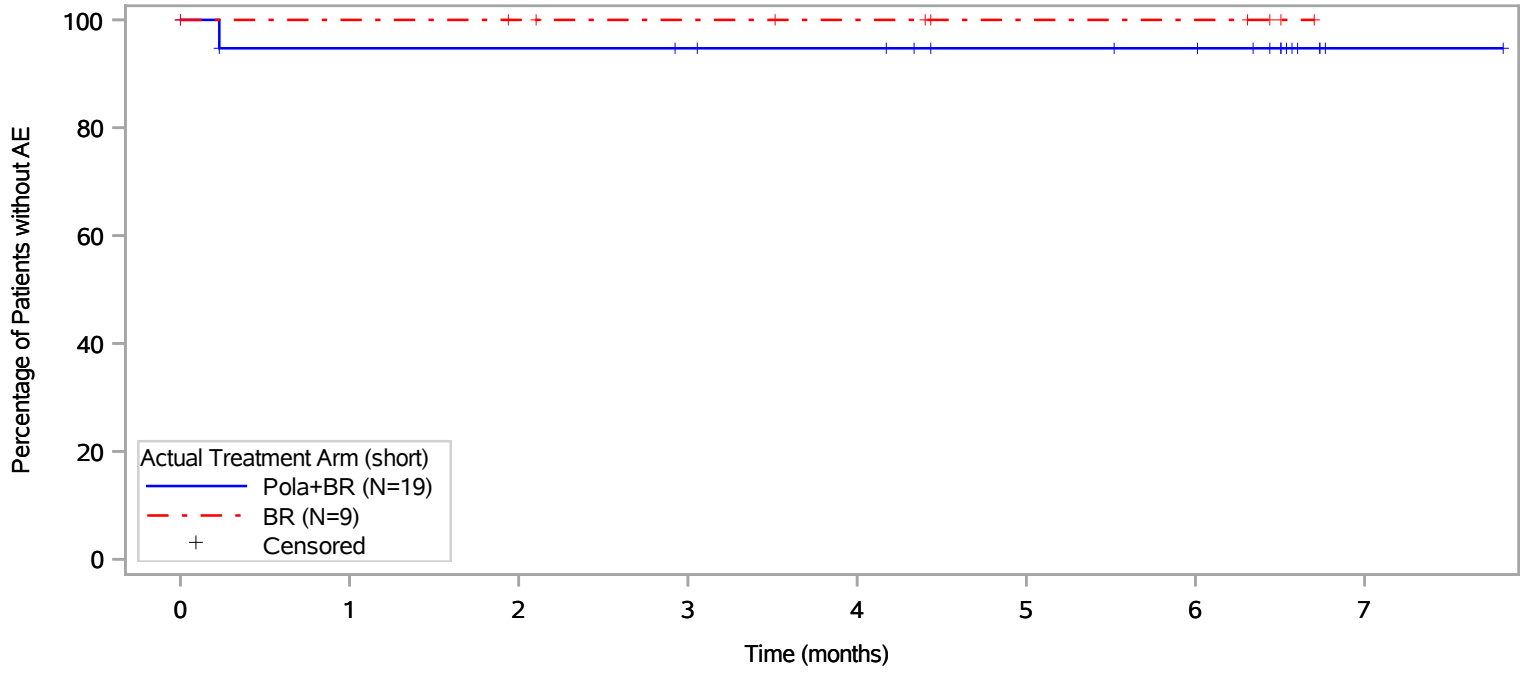
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FEMUR FRACTURE

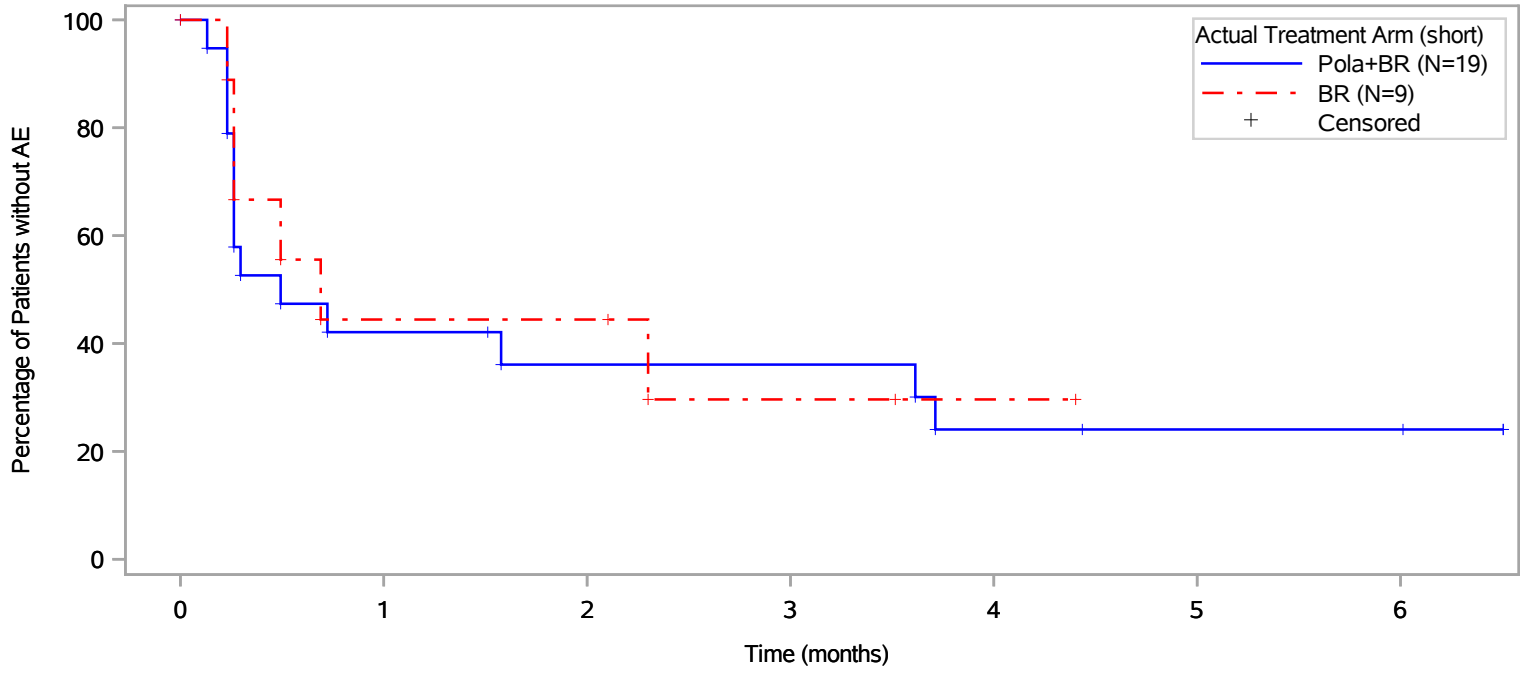


Patients at risk								
Pola+BR (N=19)	19	18	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

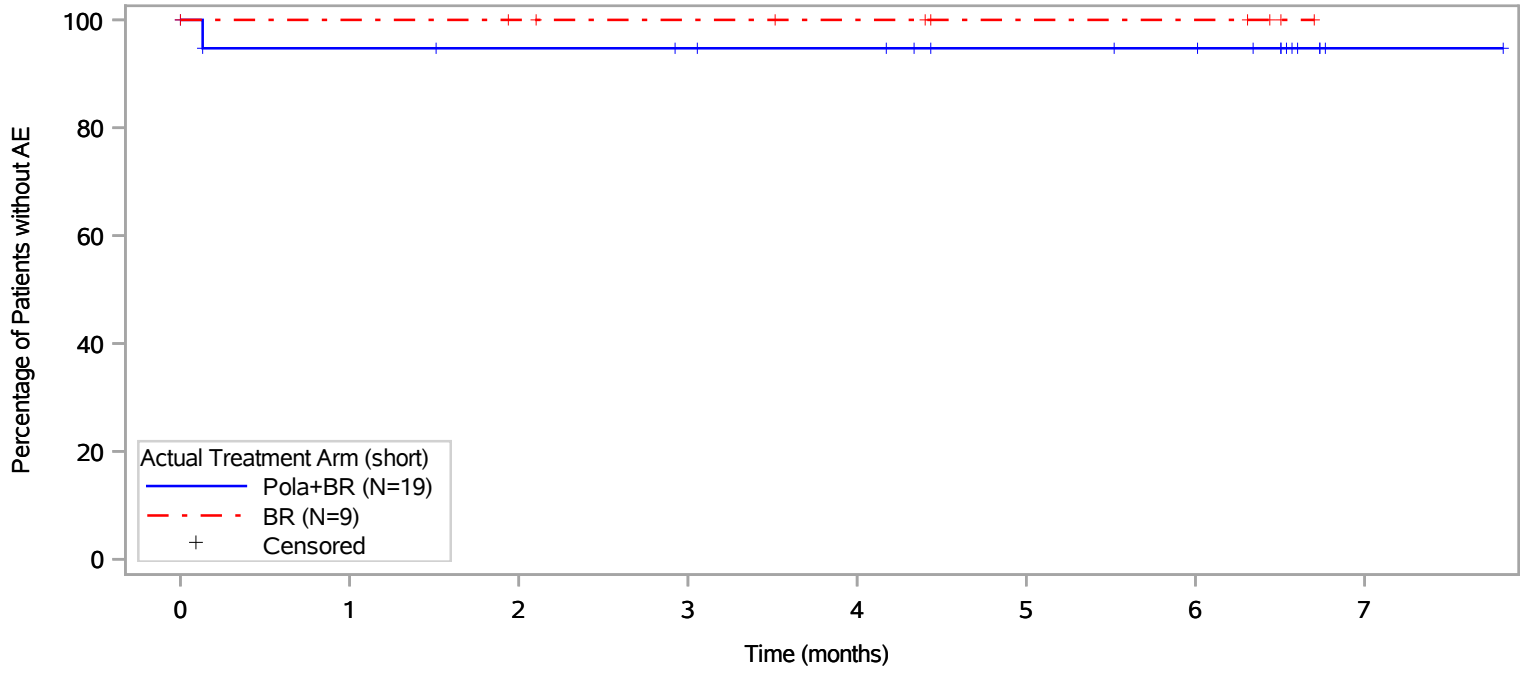


Patients at risk							
Pola+BR (N=19)	19	8	6	6	4	3	3
BR (N=9)	9	4	4	2	1	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	1	1	1	2	2
BR (N=9)	0	0	0	1	2	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED

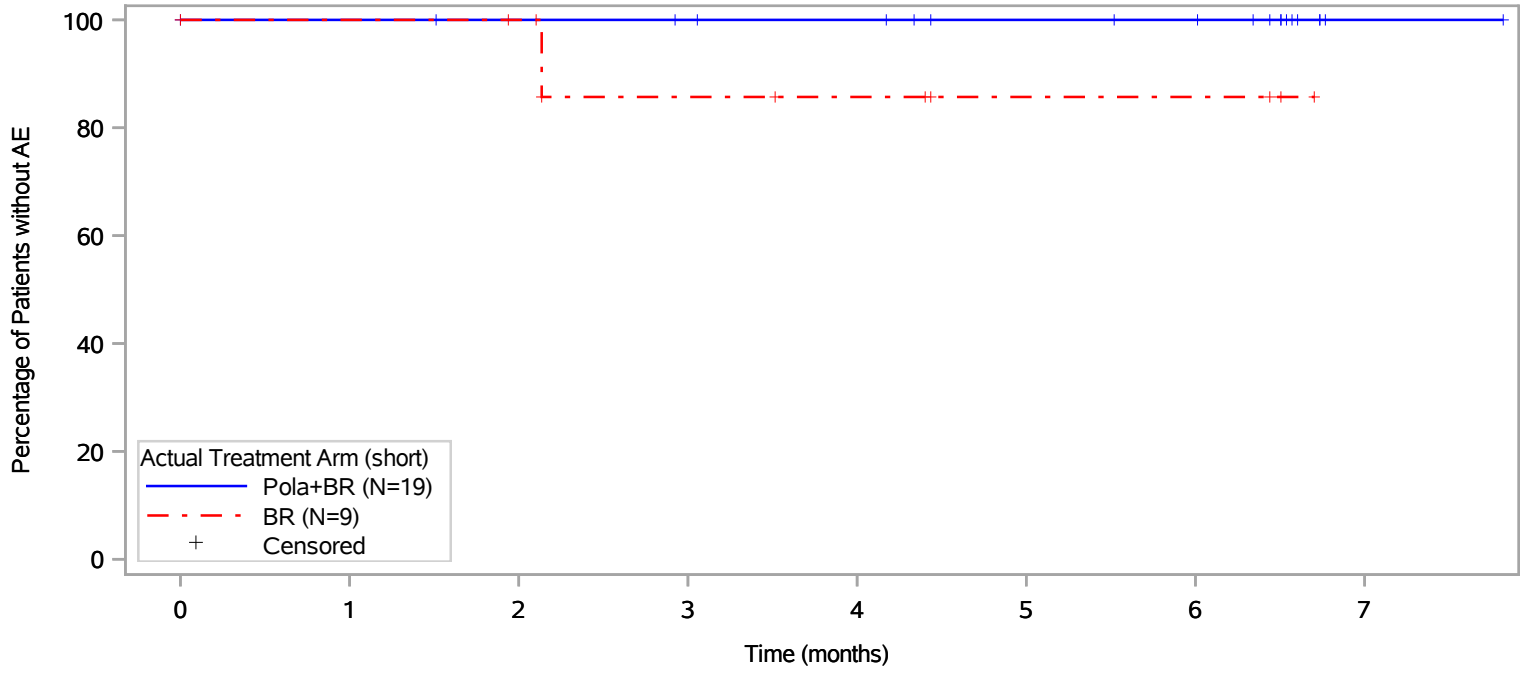


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

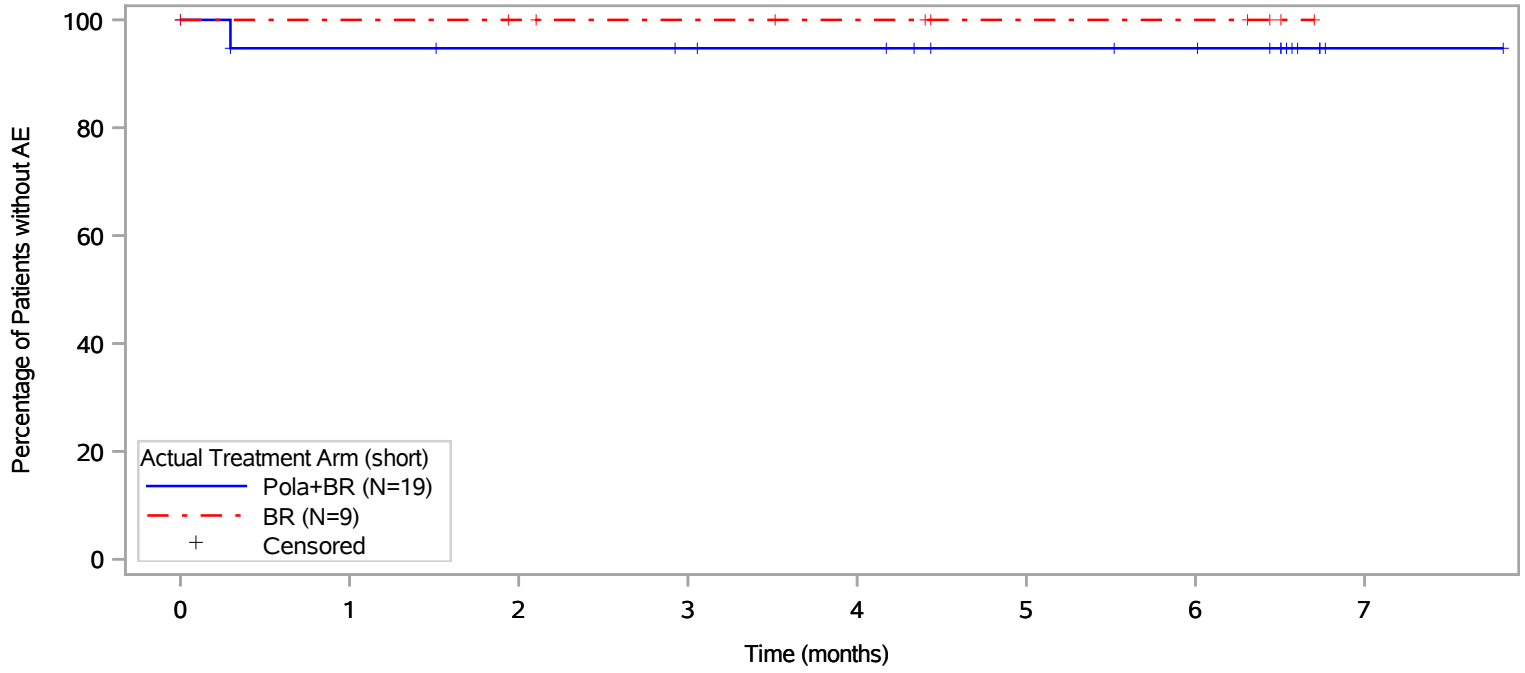
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PRESSURE INCREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, FIBRIN D DIMER INCREASED

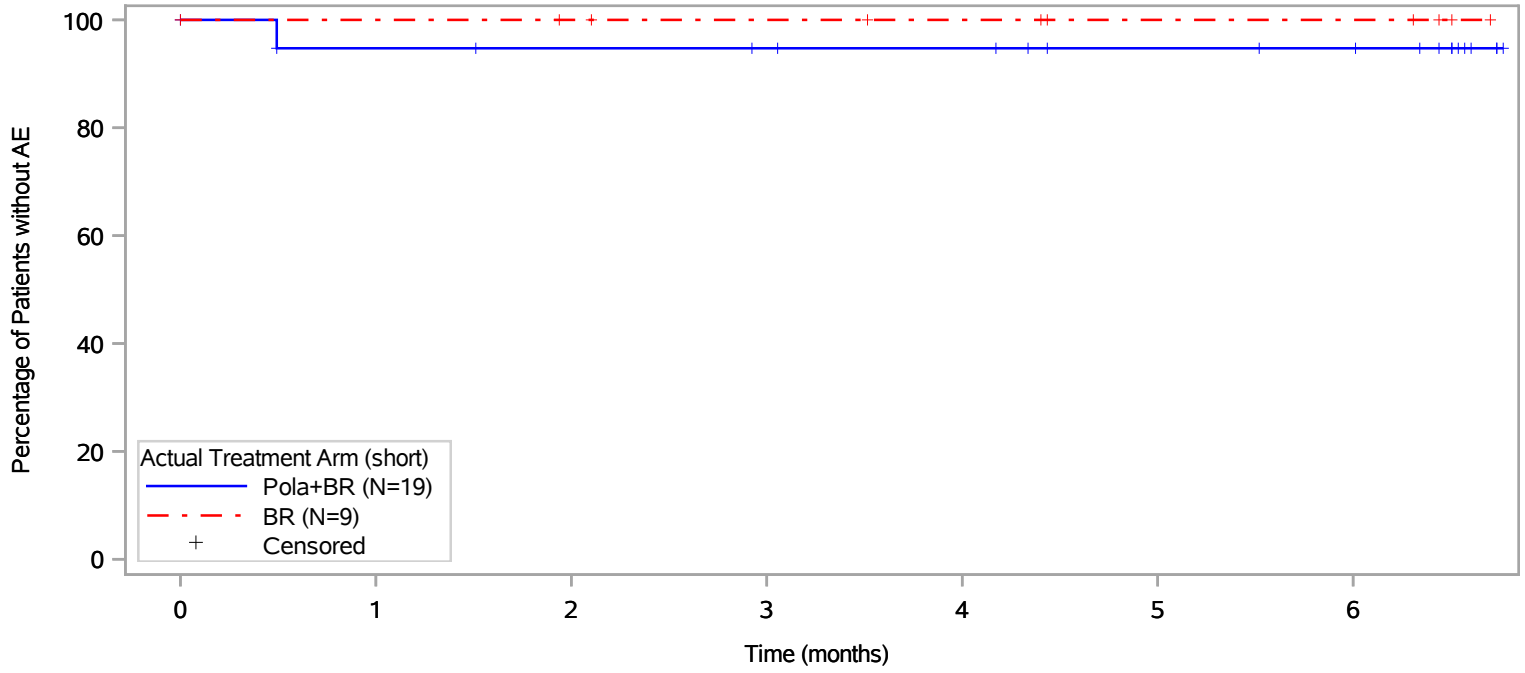


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GAMMA-GLUTAMYLTRANSFERASE INCREASED

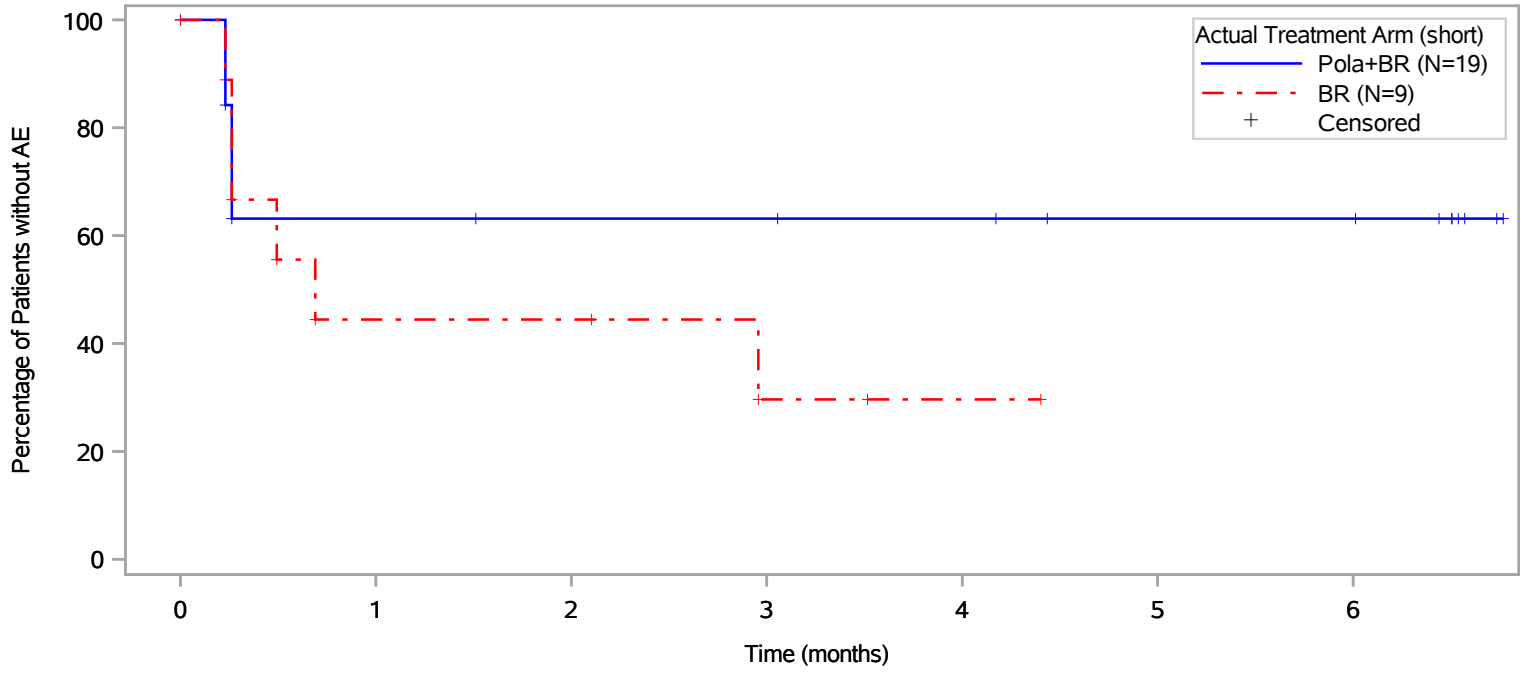


Patients at risk							
Pola+BR (N=19)	19	18	17	16	15	12	11
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED

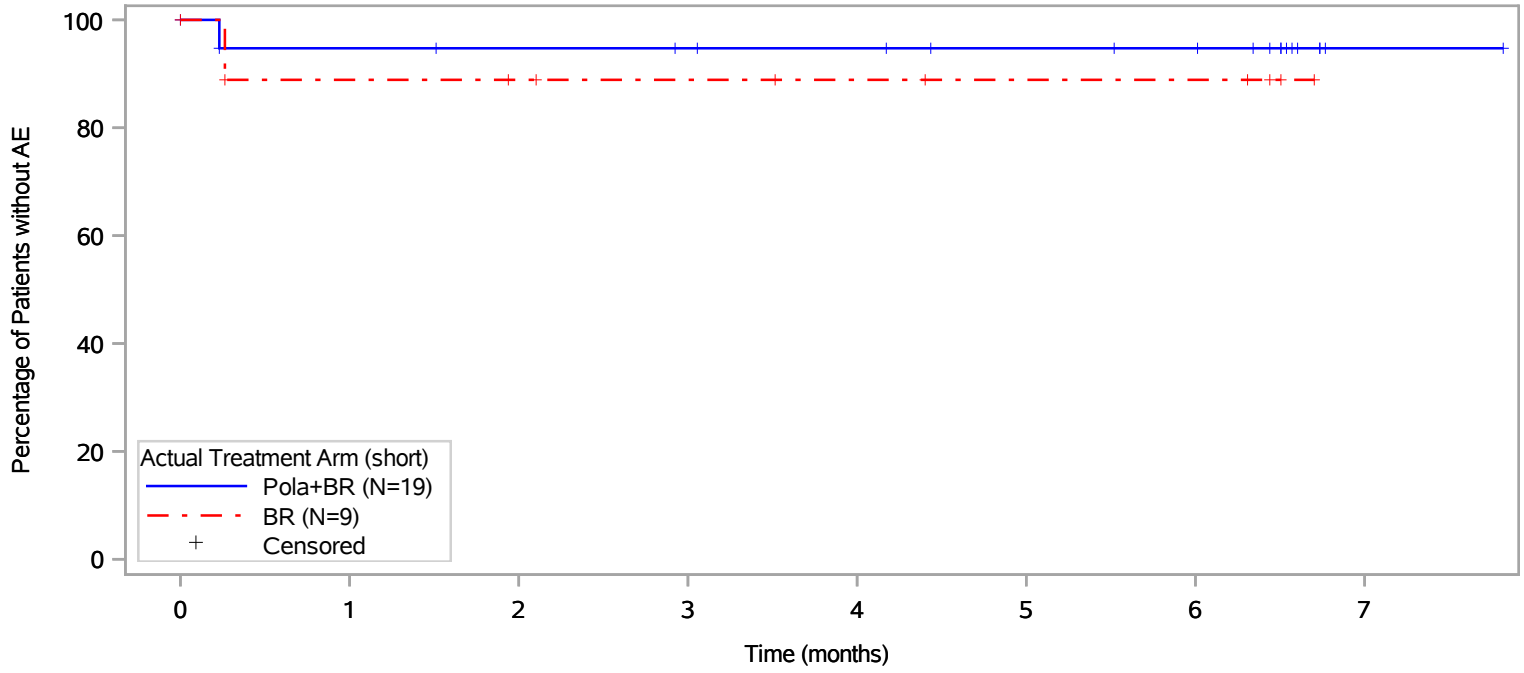


Patients at risk							
Pola+BR (N=19)	19	12	11	11	10	8	8
BR (N=9)	9	4	4	2	1	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	1	1	2	4	4
BR (N=9)	0	0	0	1	2	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE PERCENTAGE DECREASED

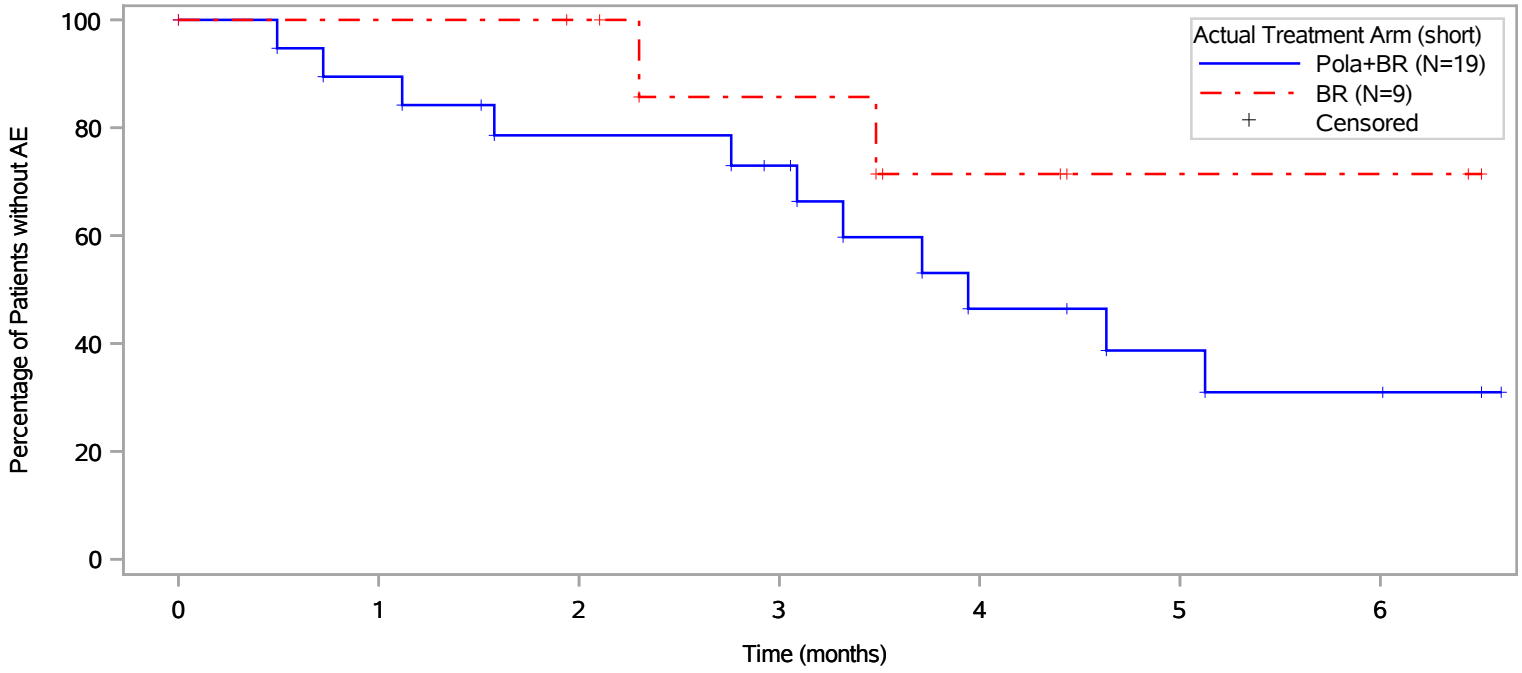


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED

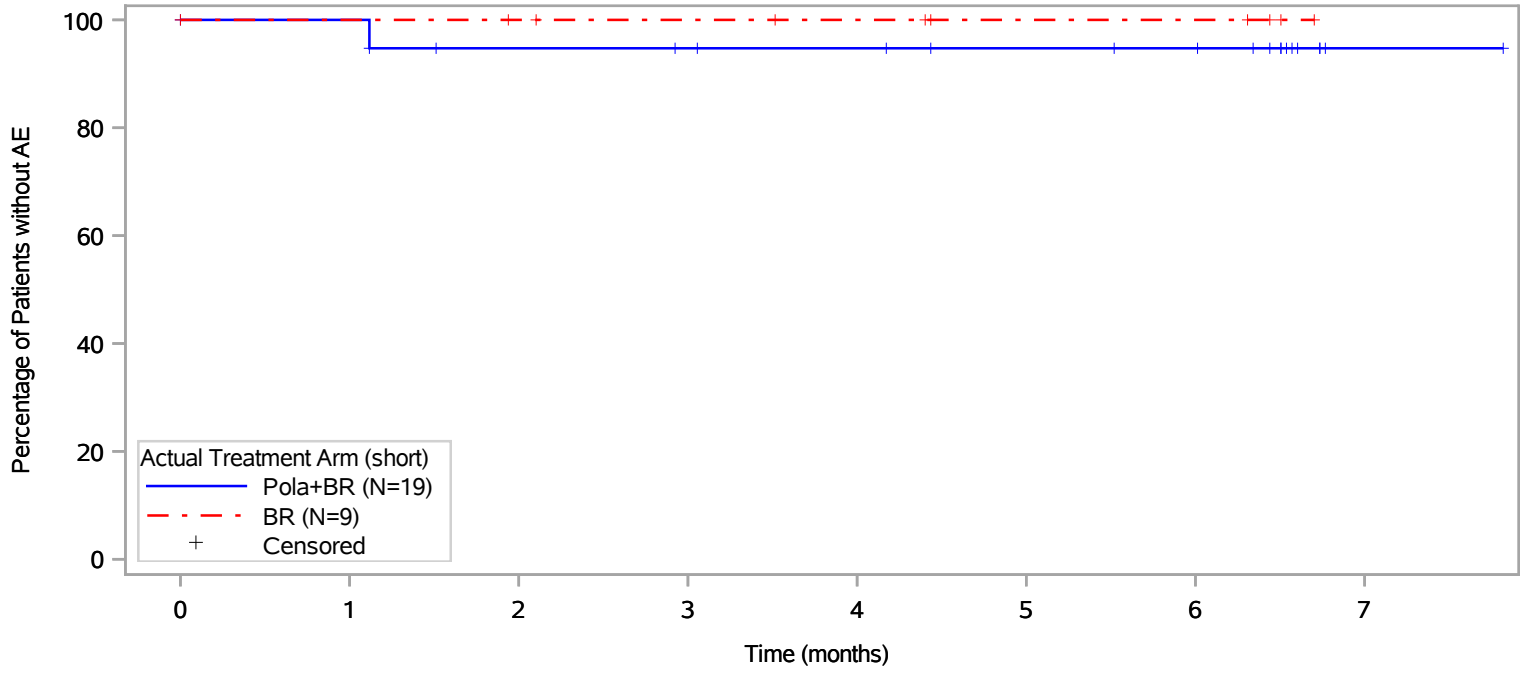


Patients at risk							
Pola+BR (N=19)	19	17	14	12	7	5	4
BR (N=9)	9	9	8	6	4	2	2
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	4	4
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

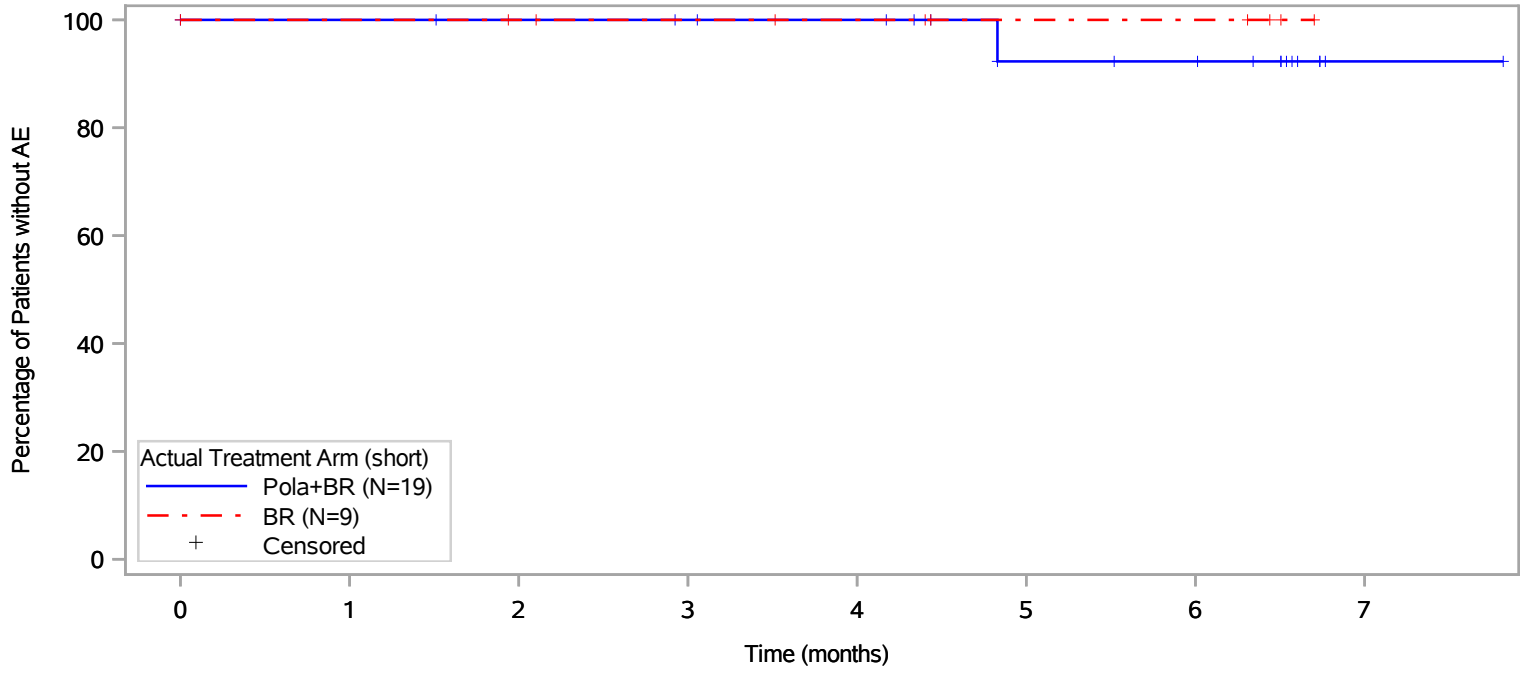
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL PERCENTAGE DECREASED



Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

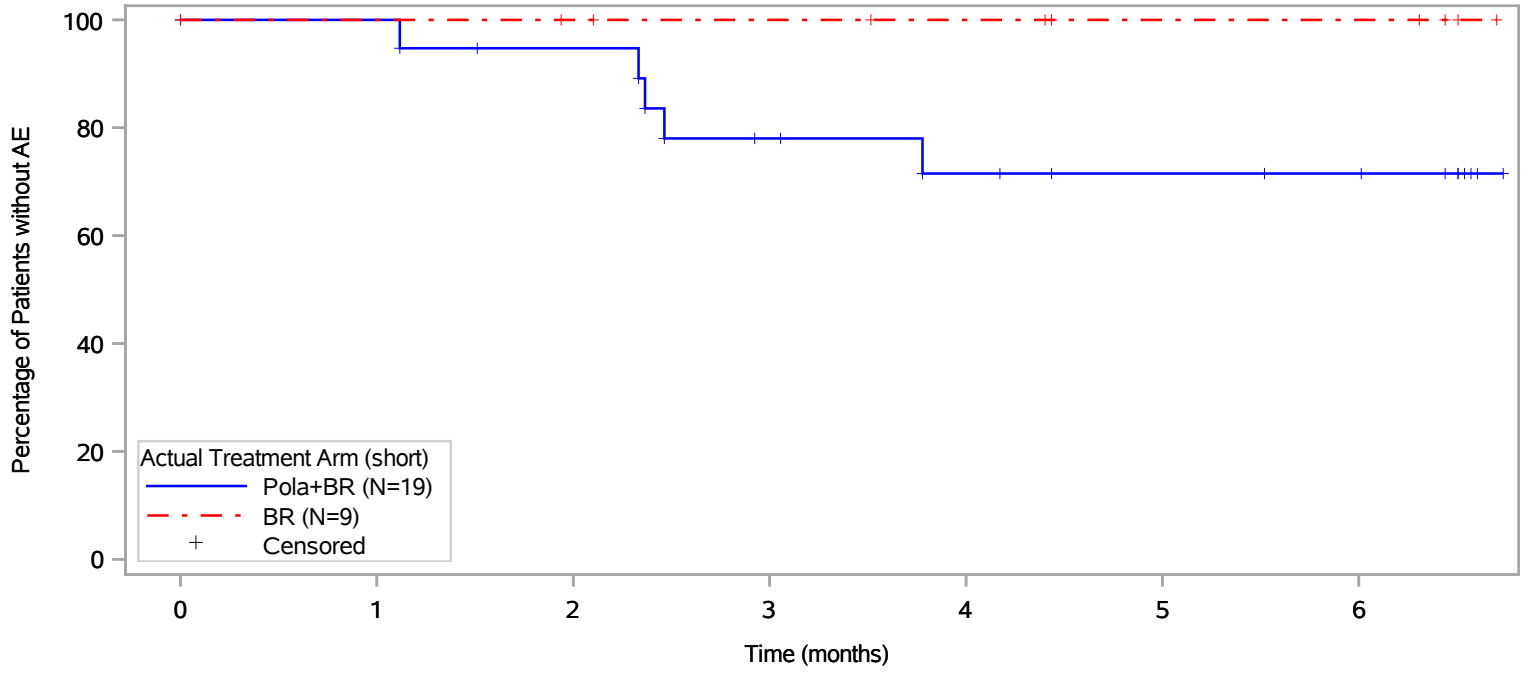
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NITRITE URINE PRESENT



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk							
Pola+BR (N=19)	19	19	17	13	11	9	8
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	5	6
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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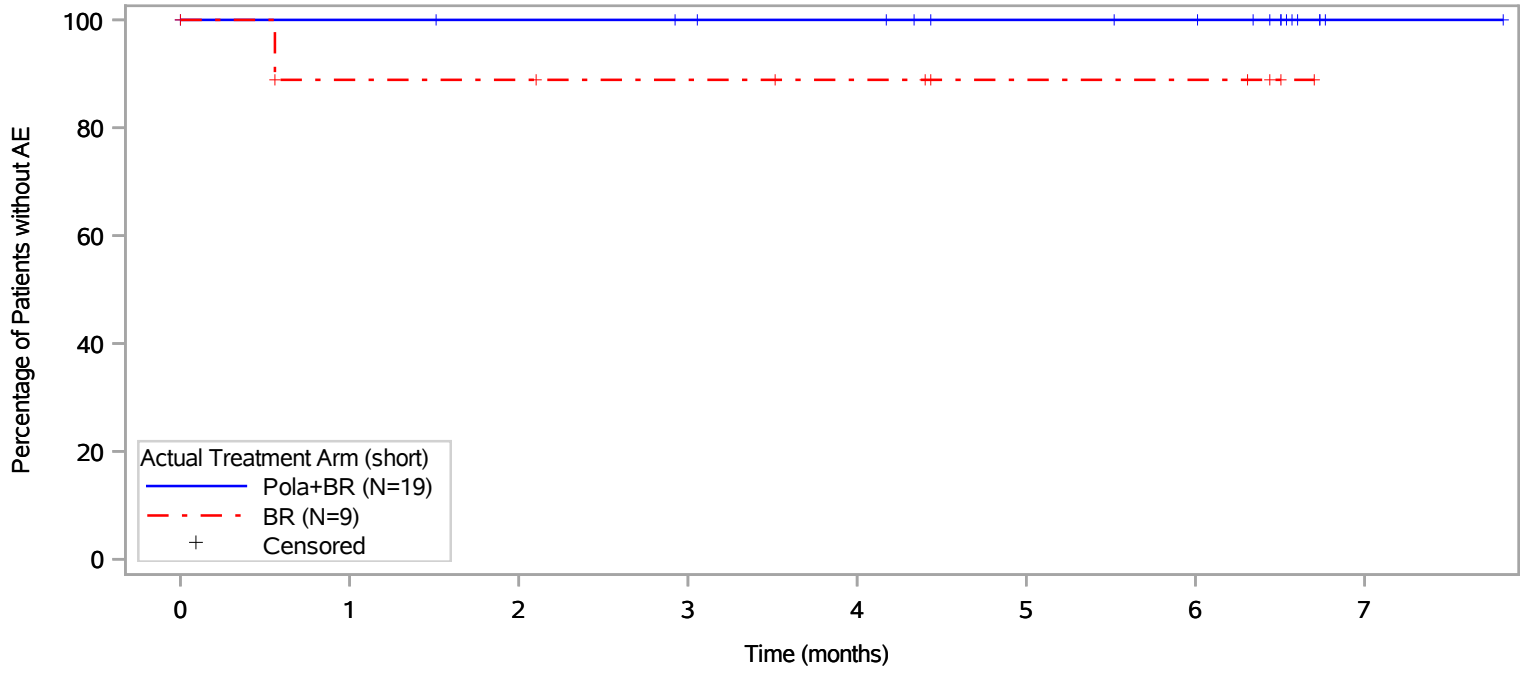
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, URINE OUTPUT DECREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	0	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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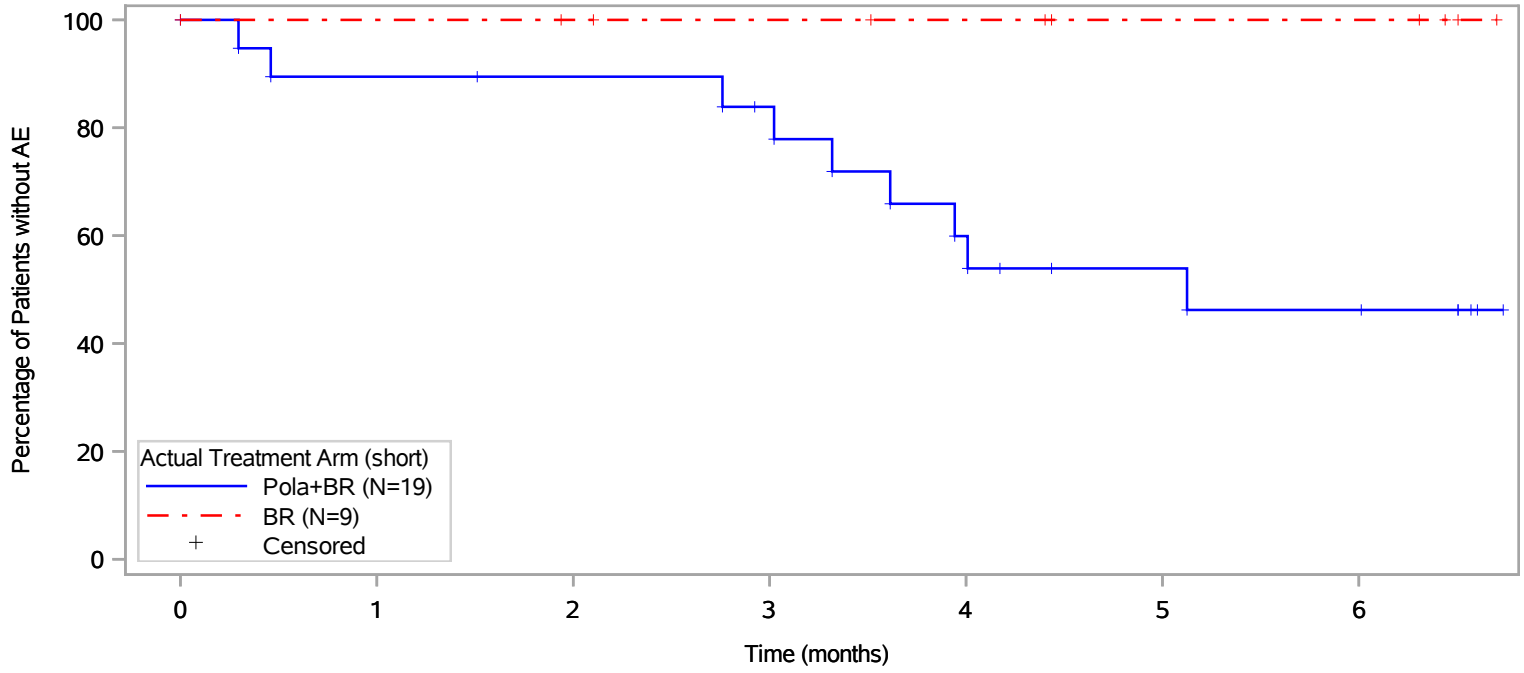
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED

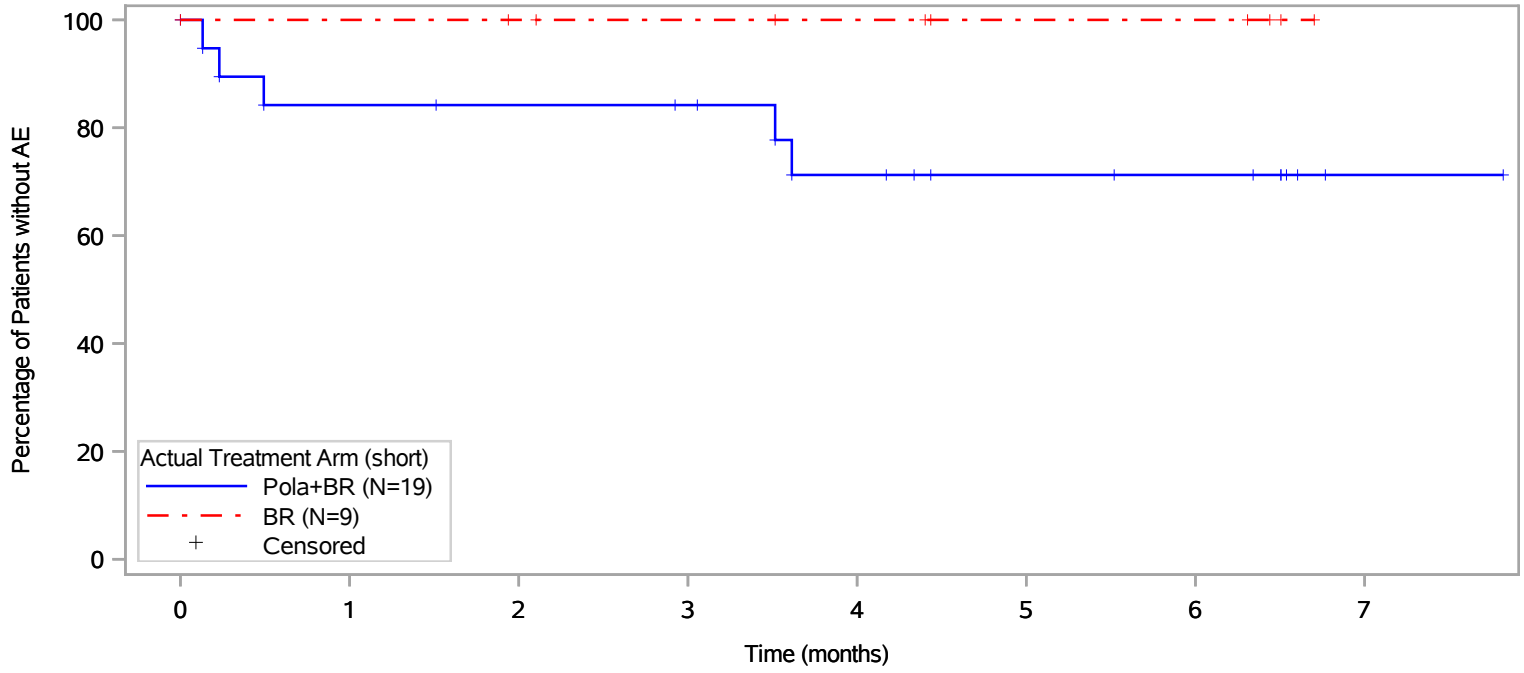


Patients at risk							
Pola+BR (N=19)	19	17	16	14	10	7	6
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	2	4	4
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	16	15	14	11	8	7	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	13
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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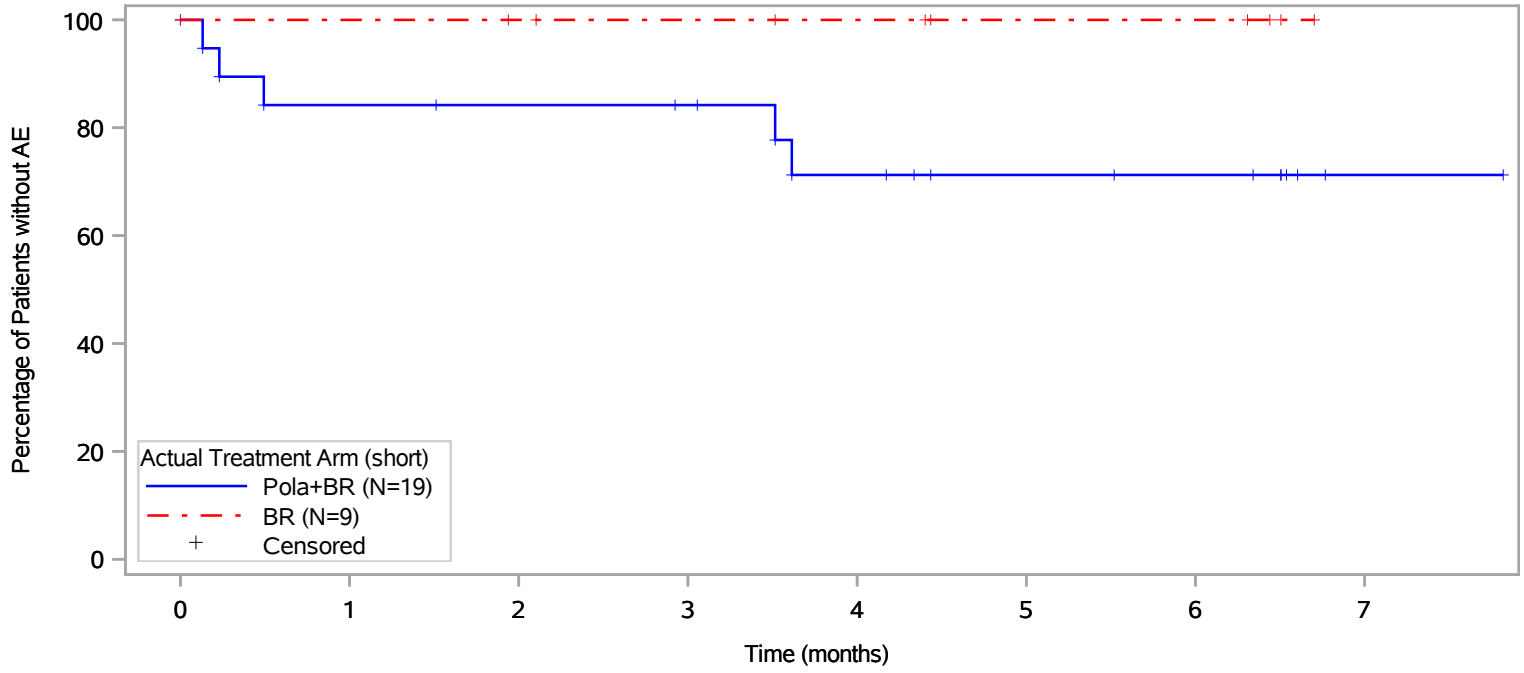
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk								
Pola+BR (N=19)	19	16	15	14	11	8	7	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	13
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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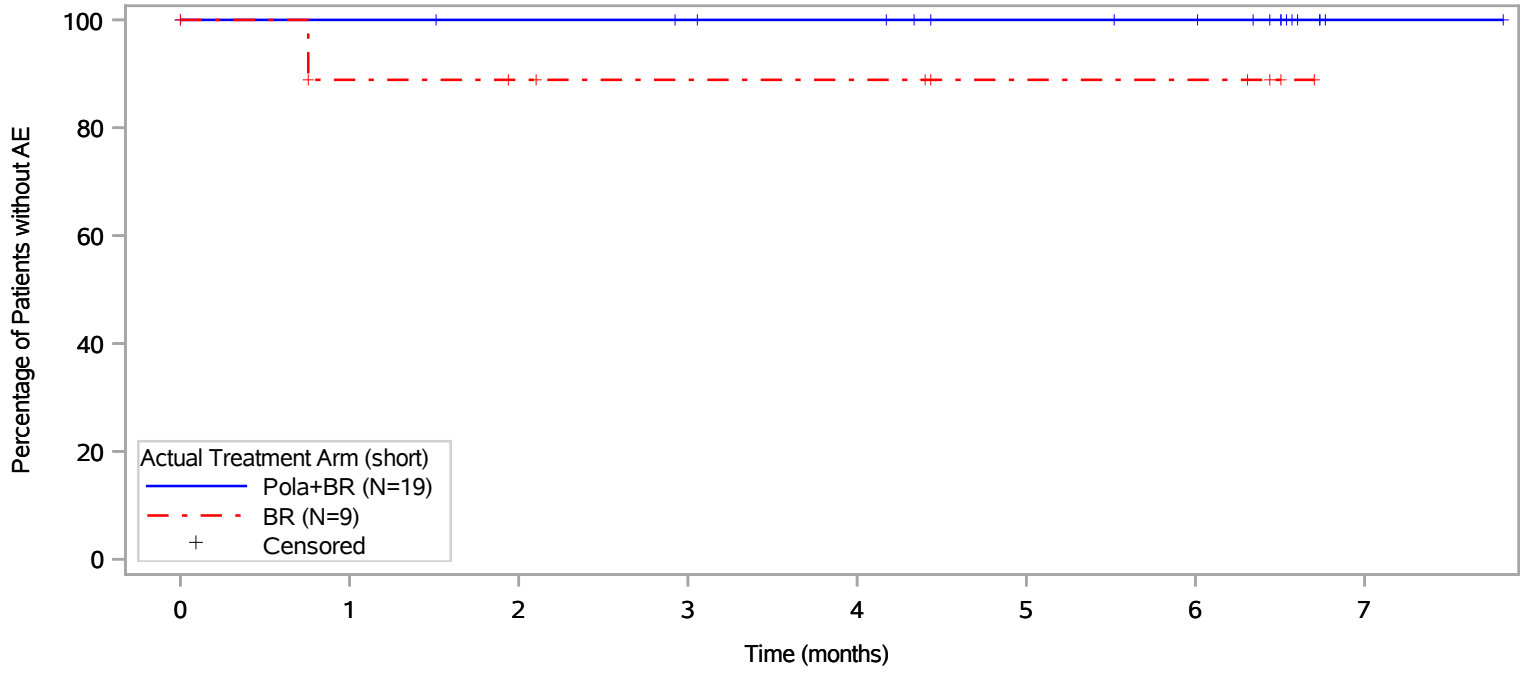
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



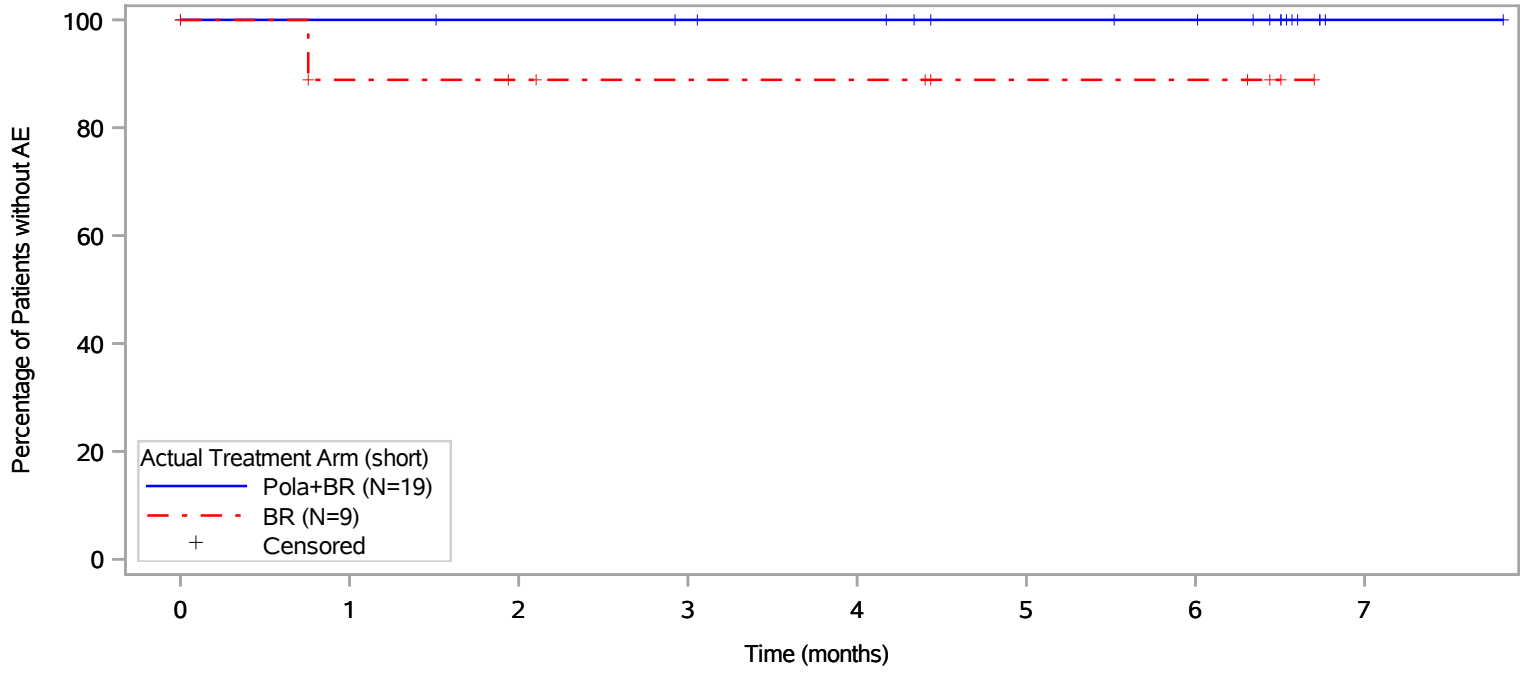
Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543

MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, INTERVERTEBRAL DISC PROTRUSION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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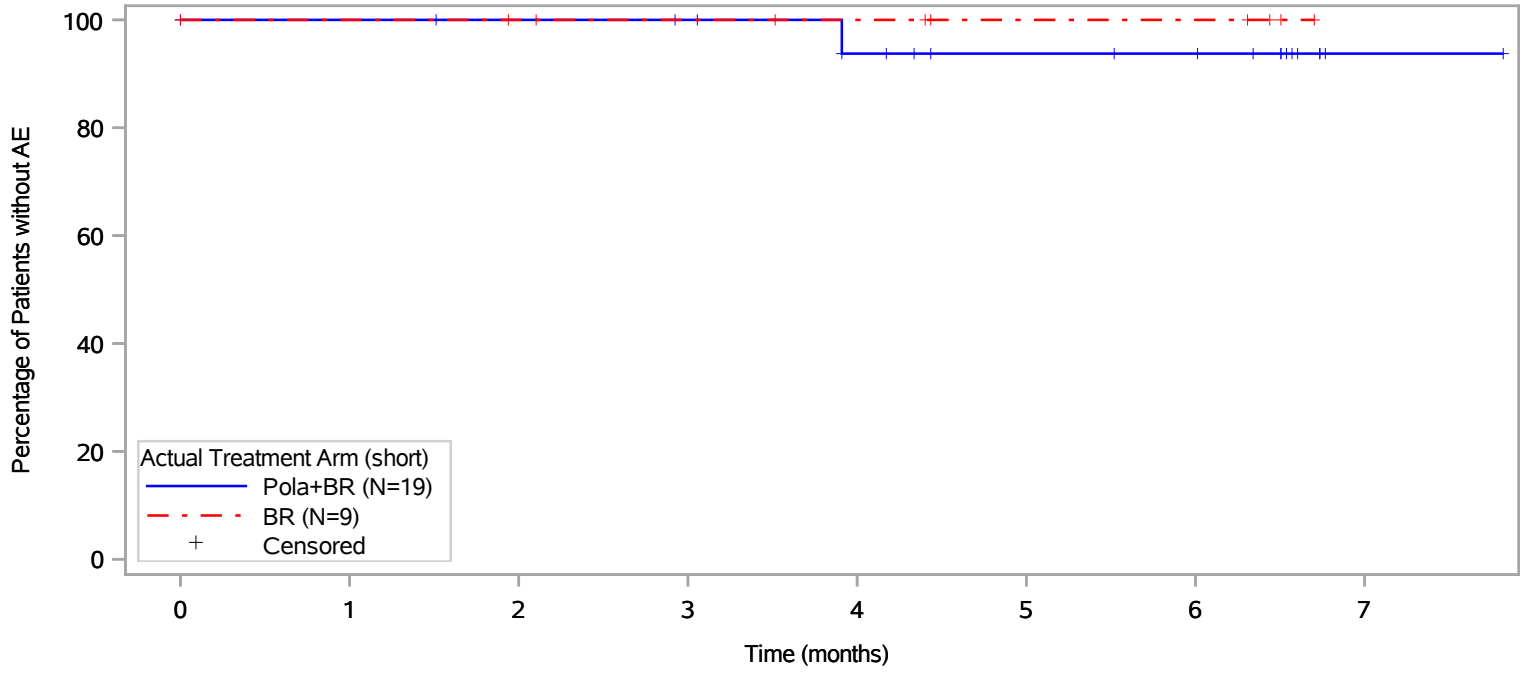
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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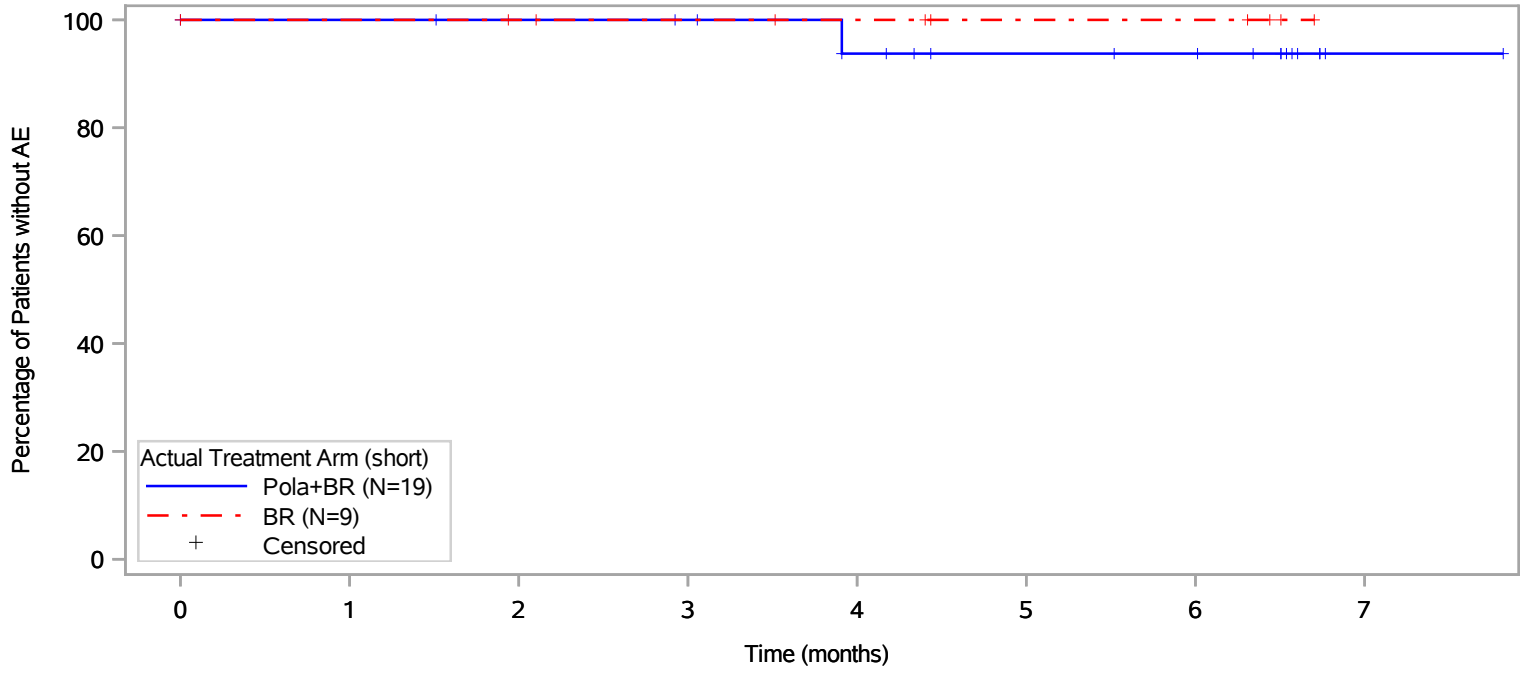
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HAEMATURIA



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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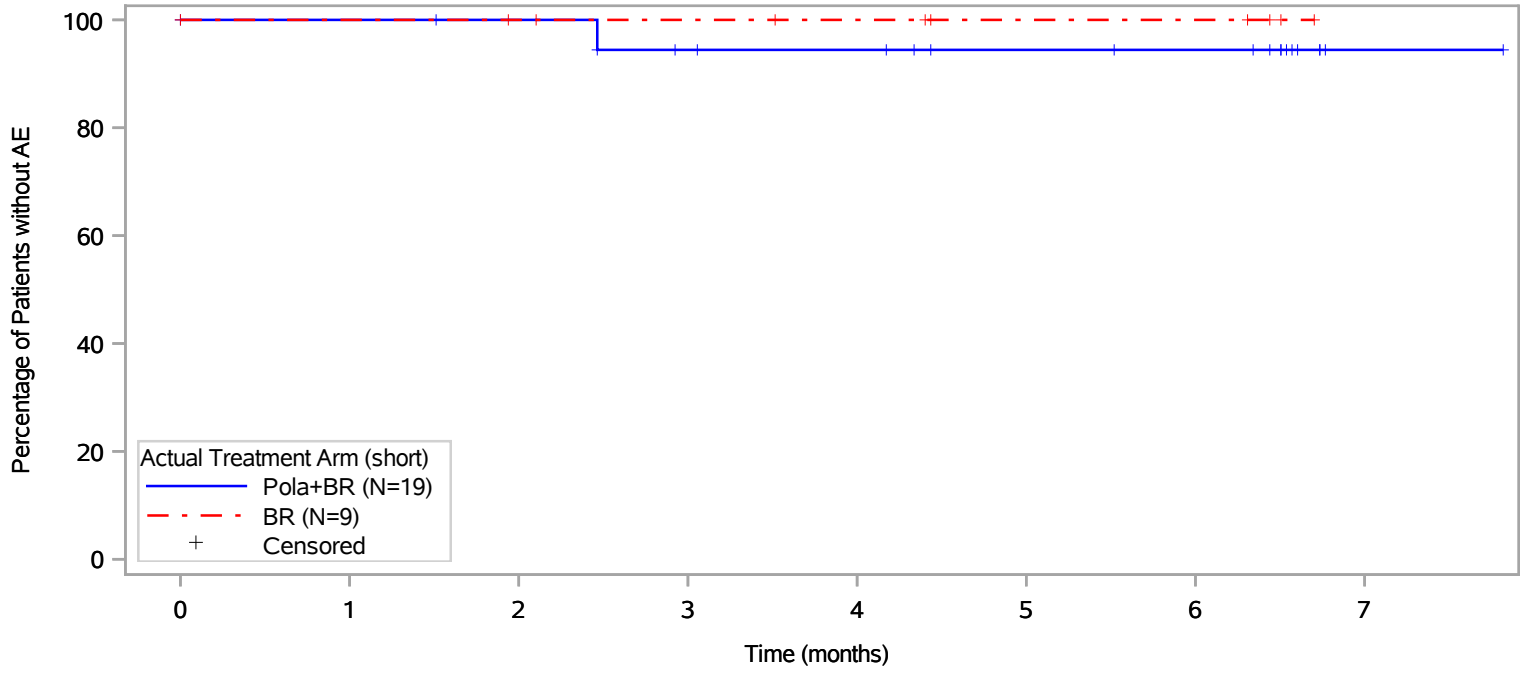
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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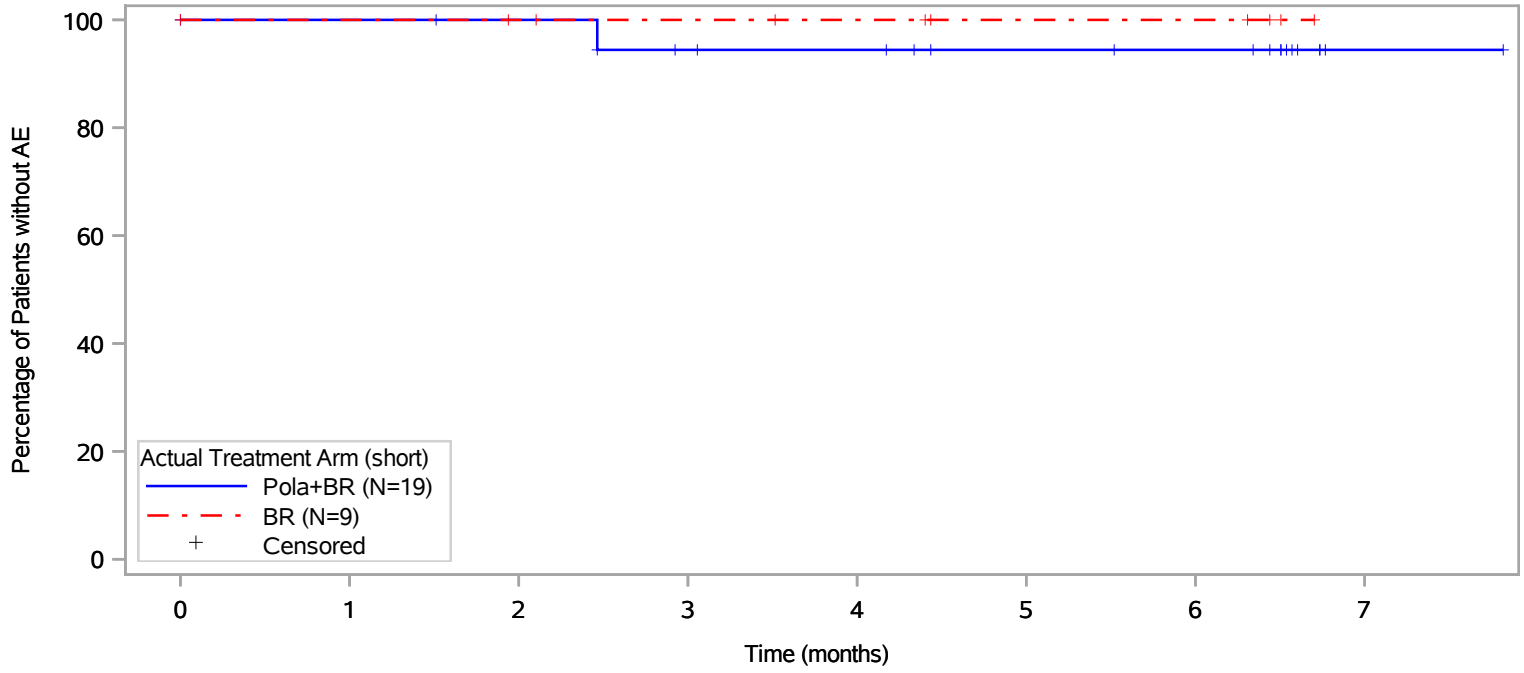
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, INTERSTITIAL LUNG DISEASE



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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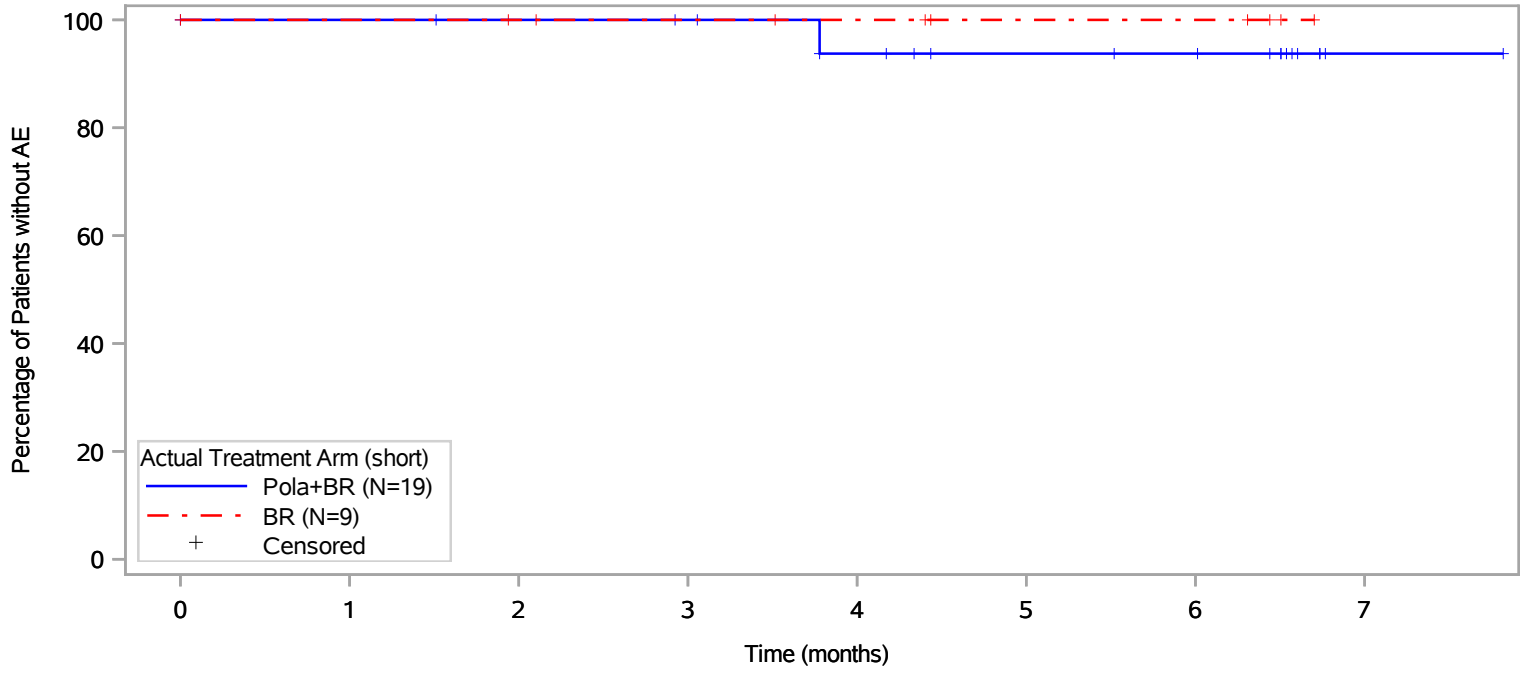
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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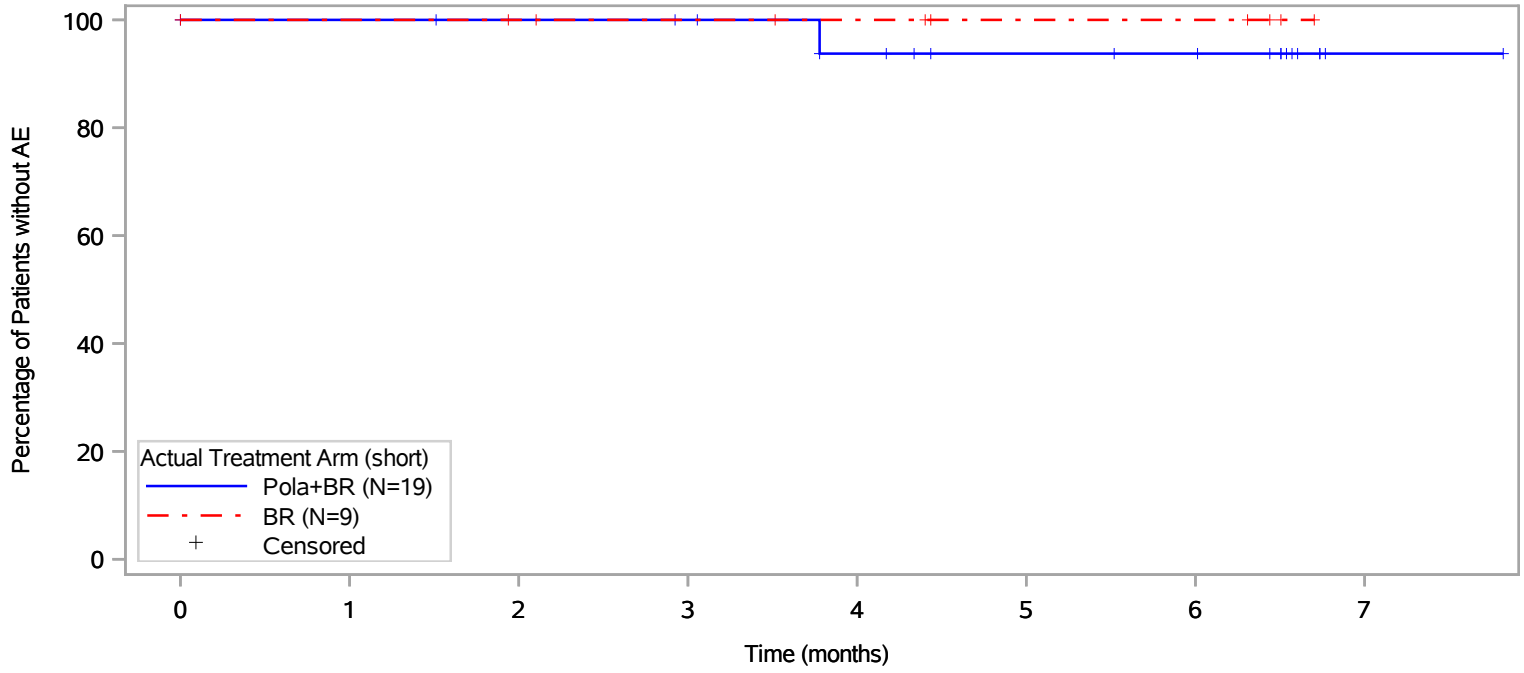
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3/4/5 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..R_Pooled/prod/output_Polarose/g_km_soc_TTGR345AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 2:23

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	6	31.6	13	68.4	9	100.0	1	11.1	8	88.9	0.3100	2.85	0.34	23.75		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA		19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0825	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
CARDIAC DISORDERS	TACHYCARDIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5722	0.46	0.03	7.34		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1796	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.6372	1.33	0.41	4.30		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD PRESSURE INCREASED		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	FIBRIN D DIMER INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		19	100.0	6	31.6	13	68.4	9	100.0	4	44.4	5	55.6	0.4546	0.60	0.15	2.33		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		19	100.0	10	52.6	9	47.4	9	100.0	2	22.2	7	77.8	0.2764	2.27	0.50	10.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NITRITE URINE PRESENT		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3468	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		19	100.0	7	36.8	12	63.2	9	100.0	0	-	9	100.0	0.0648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS			19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1109	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA		19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1109	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HAEMATURIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
VASCULAR DISORDERS	HYPOTENSION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 20:39

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	16	84.2	6	37.5	10	62.5	7	77.8	1	14.3	6	85.7	0.3917	2.45	0.29	20.52		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	< 65	16	84.2	6	37.5	10	62.5	7	77.8	0	-	7	100.0	0.1048	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5090	0.41	0.03	6.49		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.3264	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	16	84.2	10	62.5	6	37.5	7	77.8	2	28.6	5	71.4	0.2118	2.60	0.55	12.28		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	3	15.8	2	66.7	1	33.3	2	22.2	2	100.0	0	-	0.0624	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.0736	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	16	84.2	5	31.3	11	68.8	7	77.8	2	28.6	5	71.4	0.7906	1.26	0.23	6.96		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	2	100.0	0	-	0.0624	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	16	84.2	9	56.3	7	43.8	7	77.8	1	14.3	6	85.7	0.1915	3.64	0.46	28.92		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	1	50.0	1	50.0	0.8084	0.71	0.04	11.79		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.6698	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3803	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	16	84.2	6	37.5	10	62.5	7	77.8	0	-	7	100.0	0.1378	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		< 65	16	84.2	5	31.3	11	68.8	7	77.8	0	-	7	100.0	0.1330	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	< 65	16	84.2	5	31.3	11	68.8	7	77.8	0	-	7	100.0	0.1330	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 20:39

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	14	73.7	5	35.7	9	64.3	6	66.7	1	16.7	5	83.3	0.5849	1.81	0.21	15.66		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	>=3	14	73.7	5	35.7	9	64.3	6	66.7	0	-	6	100.0	0.1516	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5561	0.44	0.03	7.11		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5100	0.41	0.03	6.50		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.4969	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.2029	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3455	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	14	73.7	8	57.1	6	42.9	6	66.7	2	33.3	4	66.7	0.6760	1.41	0.28	7.06		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	26.3	4	80.0	1	20.0	3	33.3	2	66.7	1	33.3	0.5394	1.70	0.30	9.54		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	14	73.7	4	28.6	10	71.4	6	66.7	2	33.3	4	66.7	0.6785	0.68	0.11	4.26		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	5	26.3	2	40.0	3	60.0	3	33.3	2	66.7	1	33.3	0.7633	0.74	0.10	5.30		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	14	73.7	6	42.9	8	57.1	6	66.7	0	-	6	100.0	0.1073	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	5	26.3	4	80.0	1	20.0	3	33.3	2	66.7	1	33.3	0.9730	1.03	0.17	6.25		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3830	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.2309	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1269	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2690	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2690	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 20:39

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	1	11.1	8	88.9	0.3100	2.85	0.34	23.75		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0825	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.6029	0.49	0.03	7.78		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5722	0.46	0.03	7.34		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4795	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1796	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3238	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.6372	1.33	0.41	4.30		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1088	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	4	44.4	5	55.6	0.4546	0.60	0.15	2.33		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	19	100.0	10	52.6	9	47.4	9	100.0	2	22.2	7	77.8	0.2764	2.27	0.50	10.40		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3468	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	0	-	9	100.0	0.0648	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1109	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	0	-	9	100.0	0.1109	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 20:39

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	3	60.0	2	40.0	3	33.3	1	33.3	2	66.7	0.3587	2.80	0.28	27.61		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	ANAEMIA	Female	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1269	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	NEUTROPENIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	1	33.3	2	66.7	0.7766	0.67	0.04	10.77		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
CARDIAC DISORDERS	TACHYCARDIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
CARDIAC DISORDERS	TACHYCARDIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5100	0.41	0.03	6.50		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.4969	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	ABDOMINAL PAIN	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.3212	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	URINARY TRACT INFECTION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	14	73.7	11	78.6	3	21.4	6	66.7	2	33.3	4	66.7	0.2692	2.35	0.50	11.12		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	1	20.0	4	80.0	3	33.3	2	66.7	1	33.3	0.1645	0.18	0.01	2.46		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD POTASSIUM DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0714	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	BLOOD PRESSURE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	FIBRIN D DIMER INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	GAMMA-GLUTAMYLTRANSFERASE INCREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	14	73.7	6	42.9	8	57.1	6	66.7	2	33.3	4	66.7	0.8158	1.22	0.22	6.66		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	2	66.7	1	33.3	0.0431	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	14	73.7	9	64.3	5	35.7	6	66.7	2	33.3	4	66.7	0.9750	1.03	0.21	5.05		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL PERCENTAGE DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NITRITE URINE PRESENT	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6374	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NITRITE URINE PRESENT	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.3830	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	14	73.7	7	50.0	7	50.0	6	66.7	0	-	6	100.0	0.0906	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS		Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS		Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.1869	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2385	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
METABOLISM AND NUTRITION DISORDERS	HYPOKALAEMIA	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.1869	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
VASCULAR DISORDERS	HYPOTENSION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
VASCULAR DISORDERS	HYPOTENSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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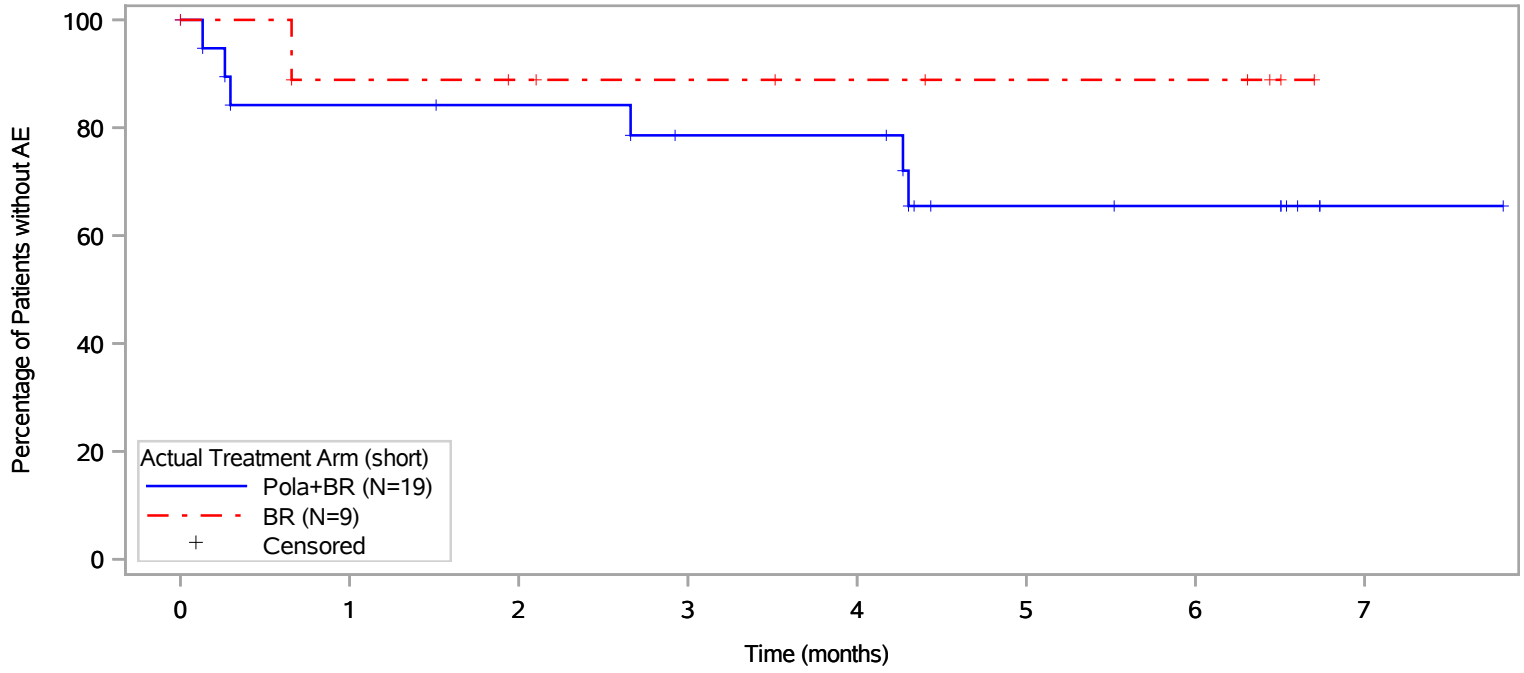
30NOV2022 20:39

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	16	15	13	13	8	7	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	12
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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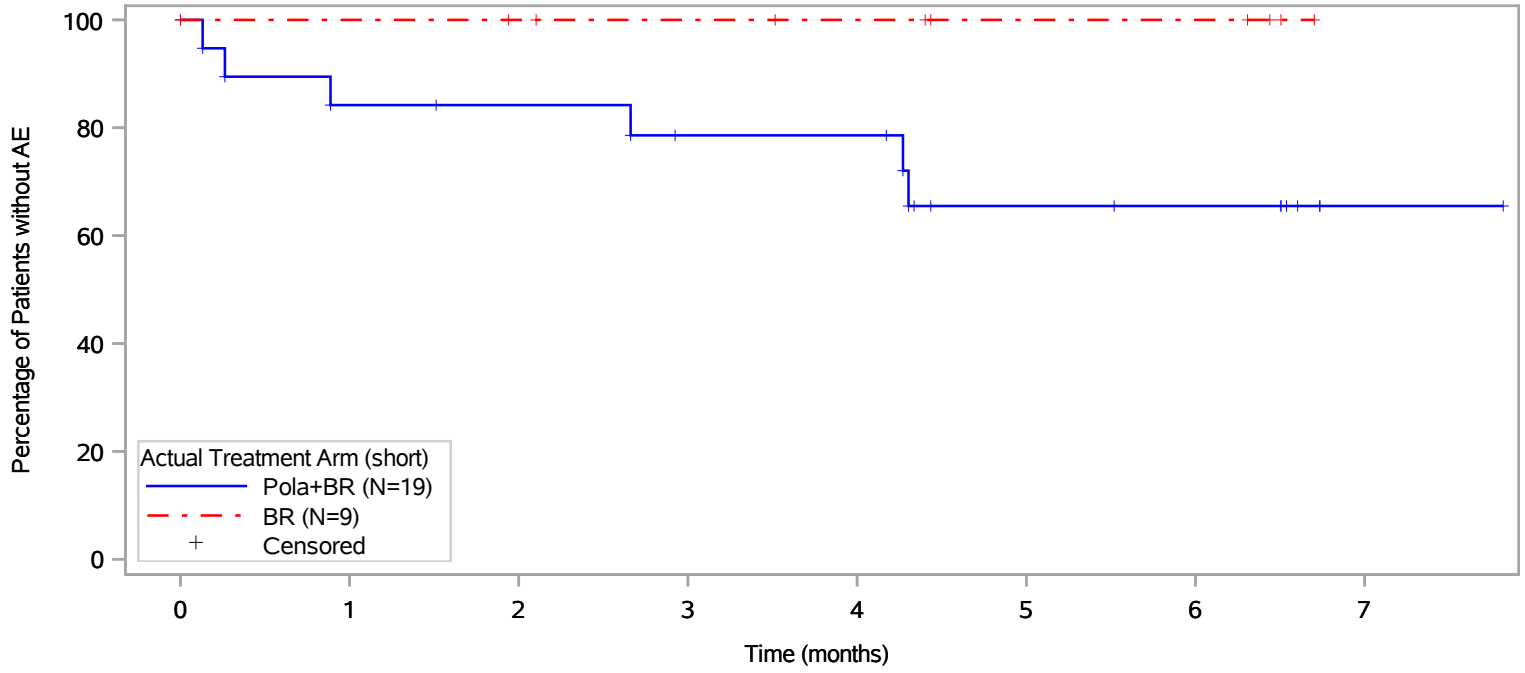
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, ANAEMIA



Patients at risk								
Pola+BR (N=19)	19	16	15	13	13	8	7	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	12
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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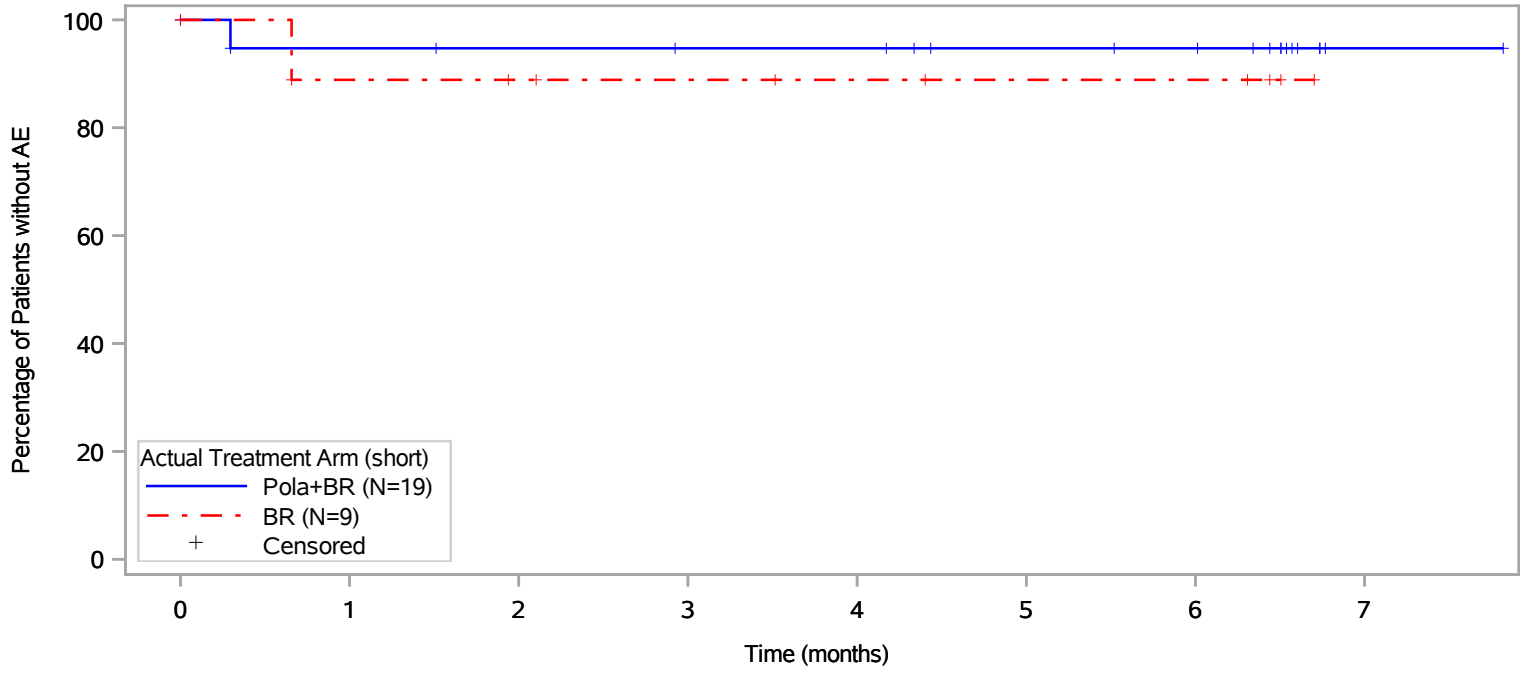
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, NEUTROPENIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	16	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	17
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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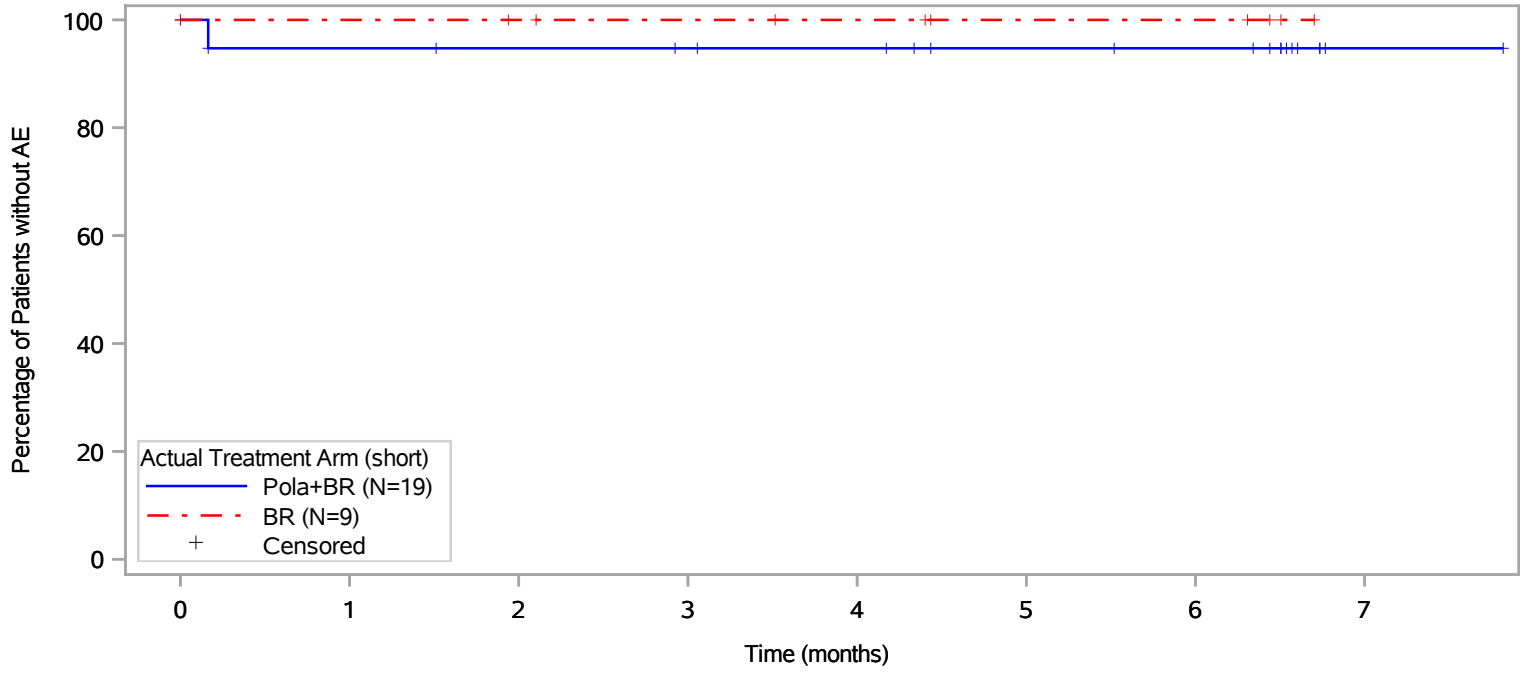
02DEC2022 3:38

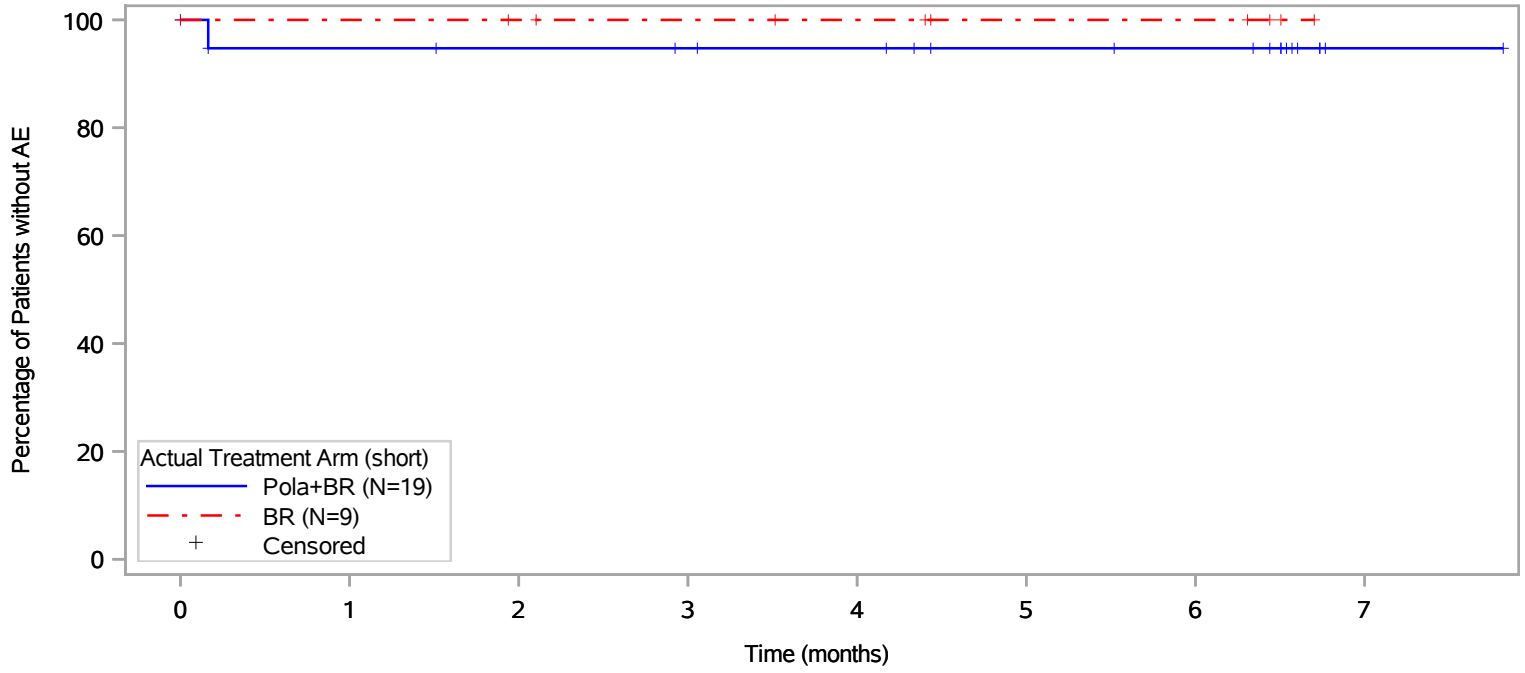
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

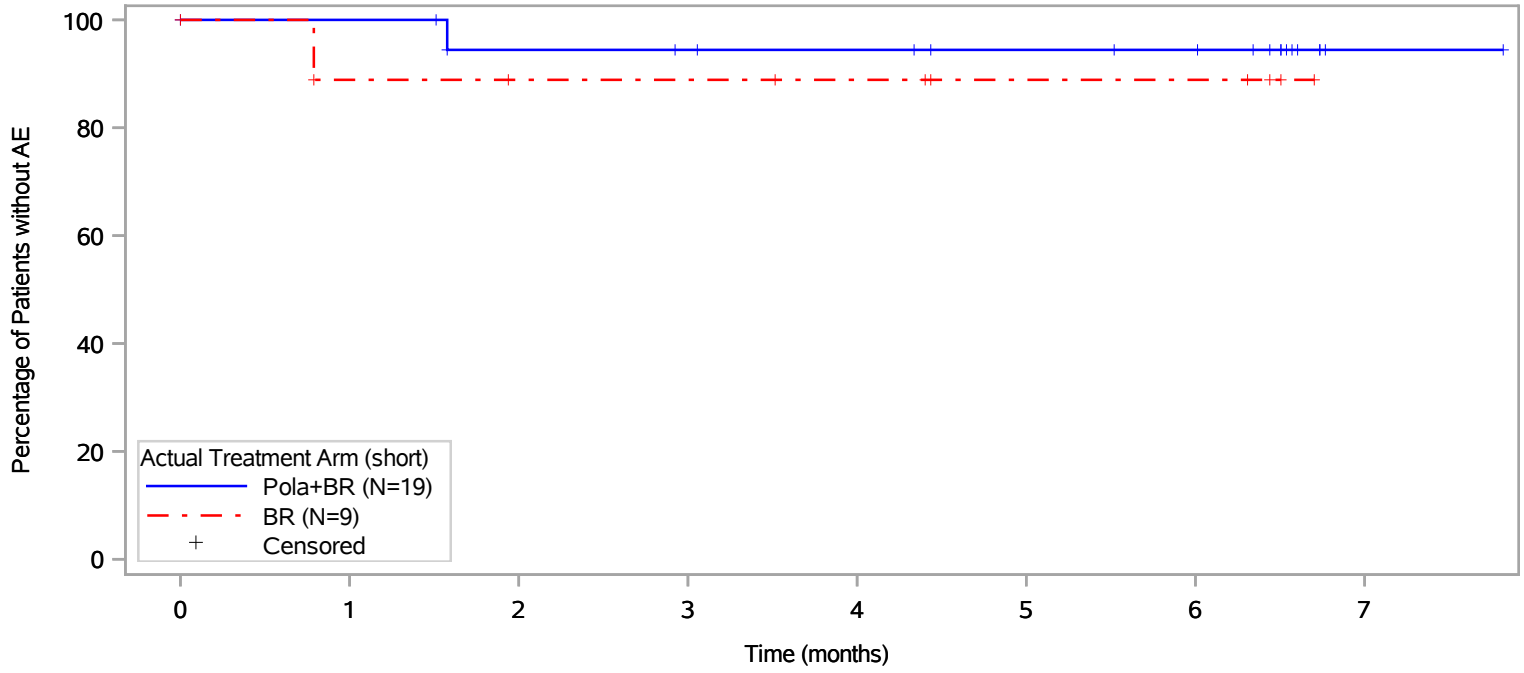
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
CARDIAC DISORDERS, TACHYCARDIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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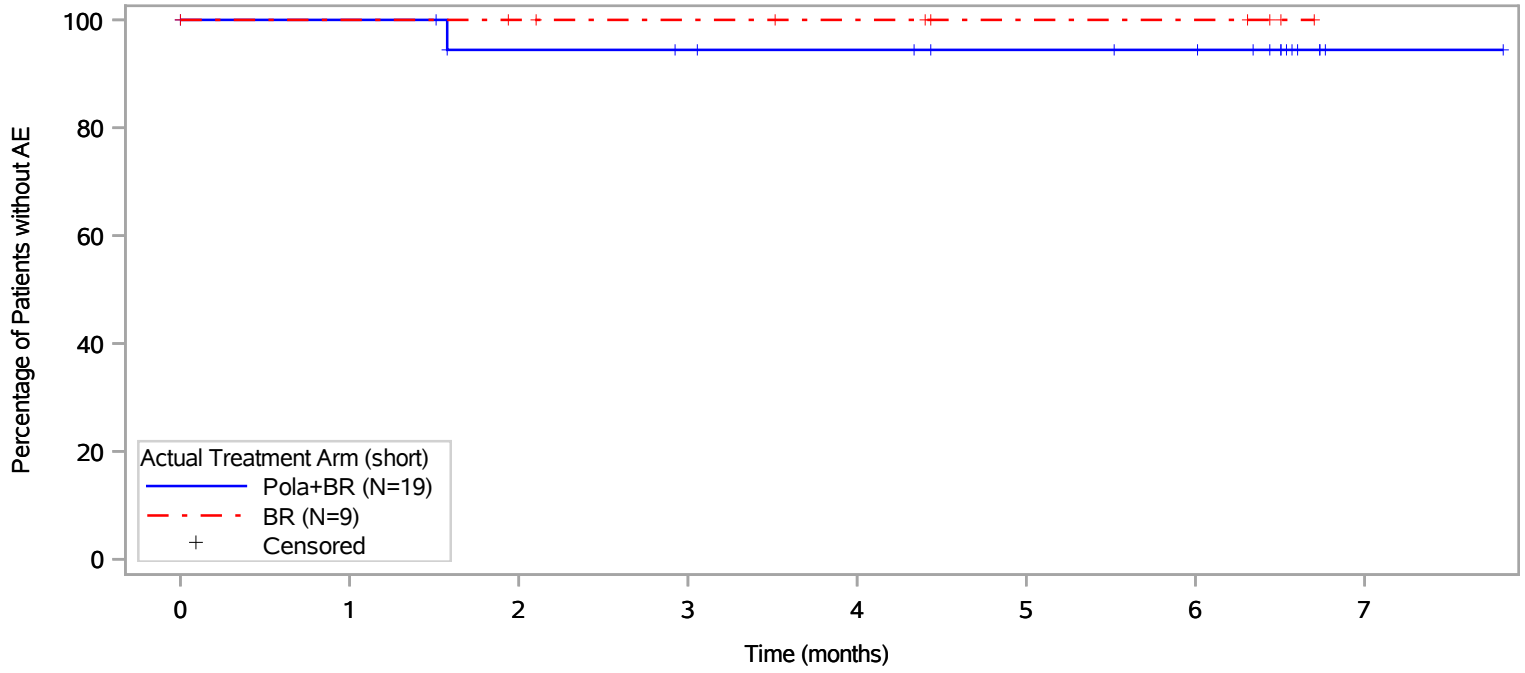
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, ABDOMINAL PAIN



Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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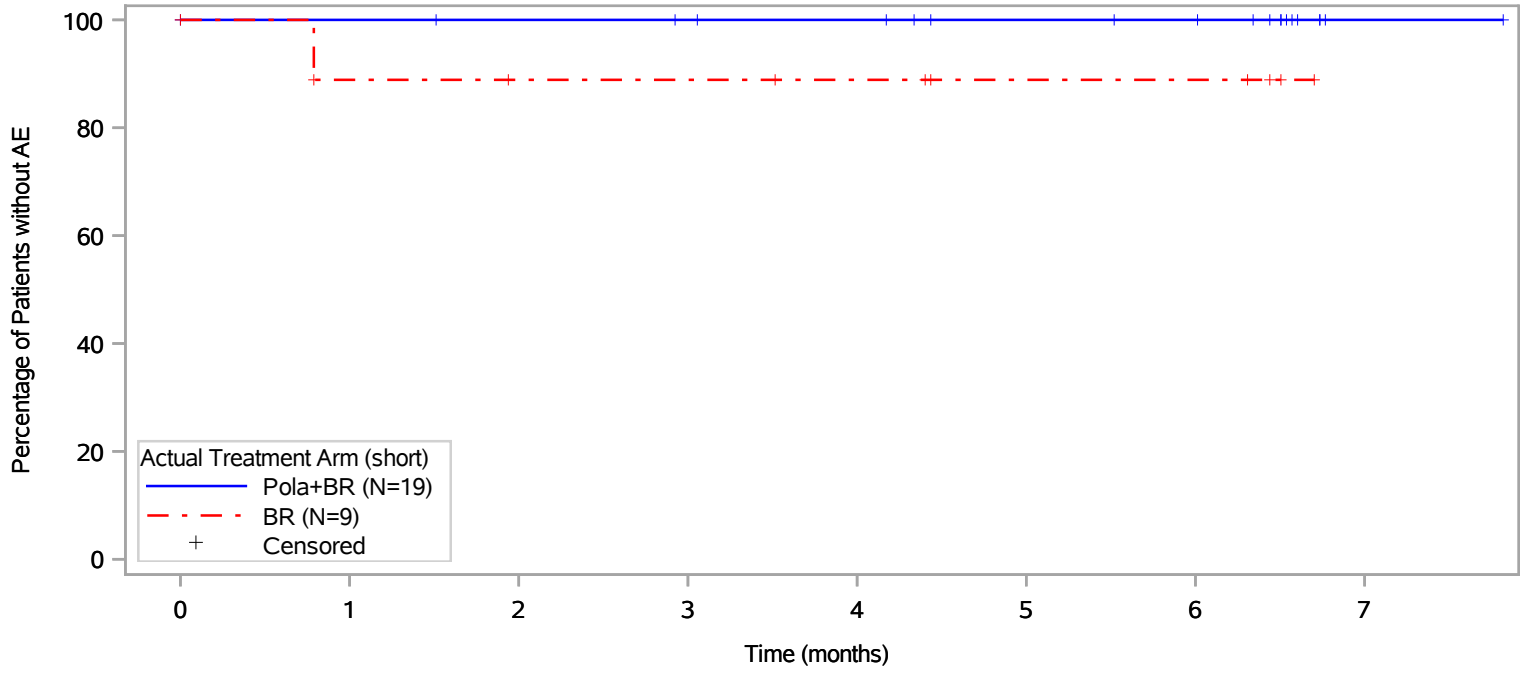
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543

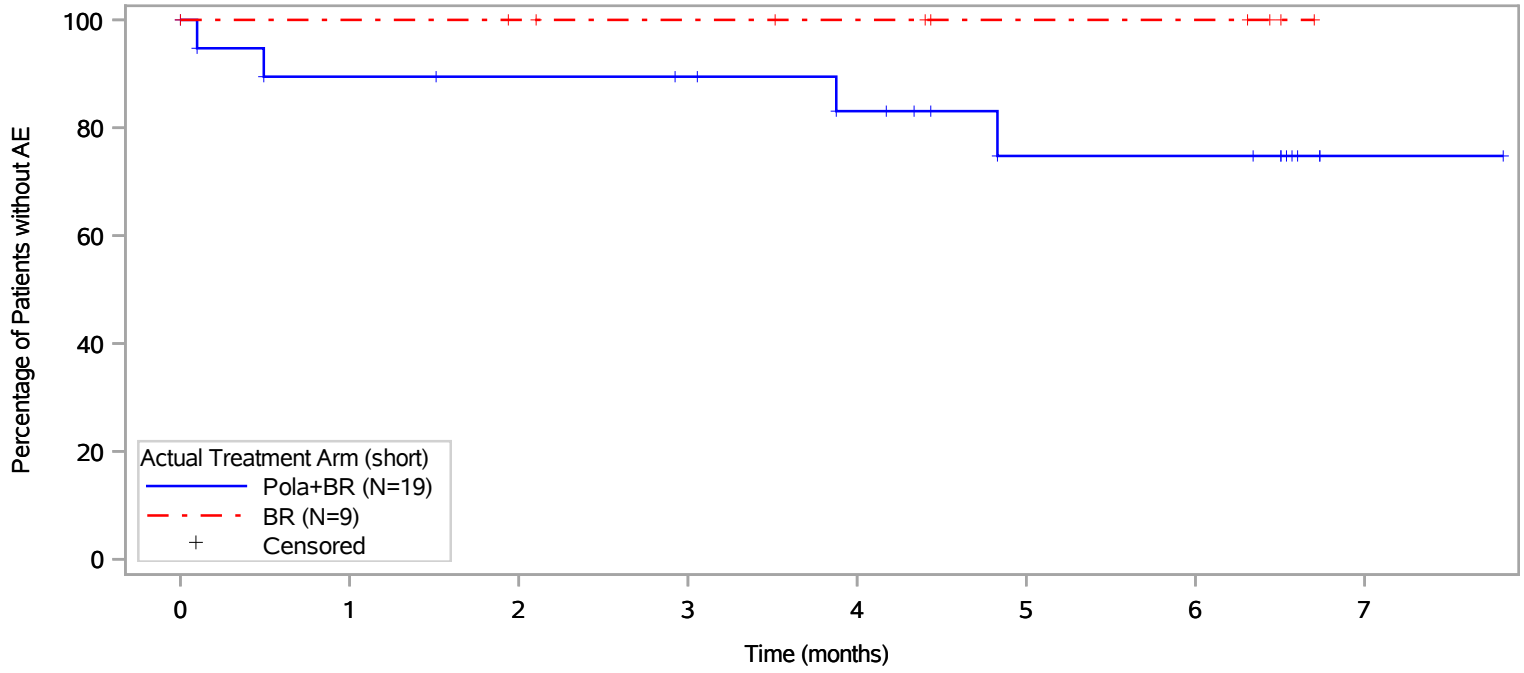
GASTROINTESTINAL DISORDERS, UPPER GASTROINTESTINAL HAEMORRHAGE



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk								
Pola+BR (N=19)	19	17	16	15	13	9	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	14
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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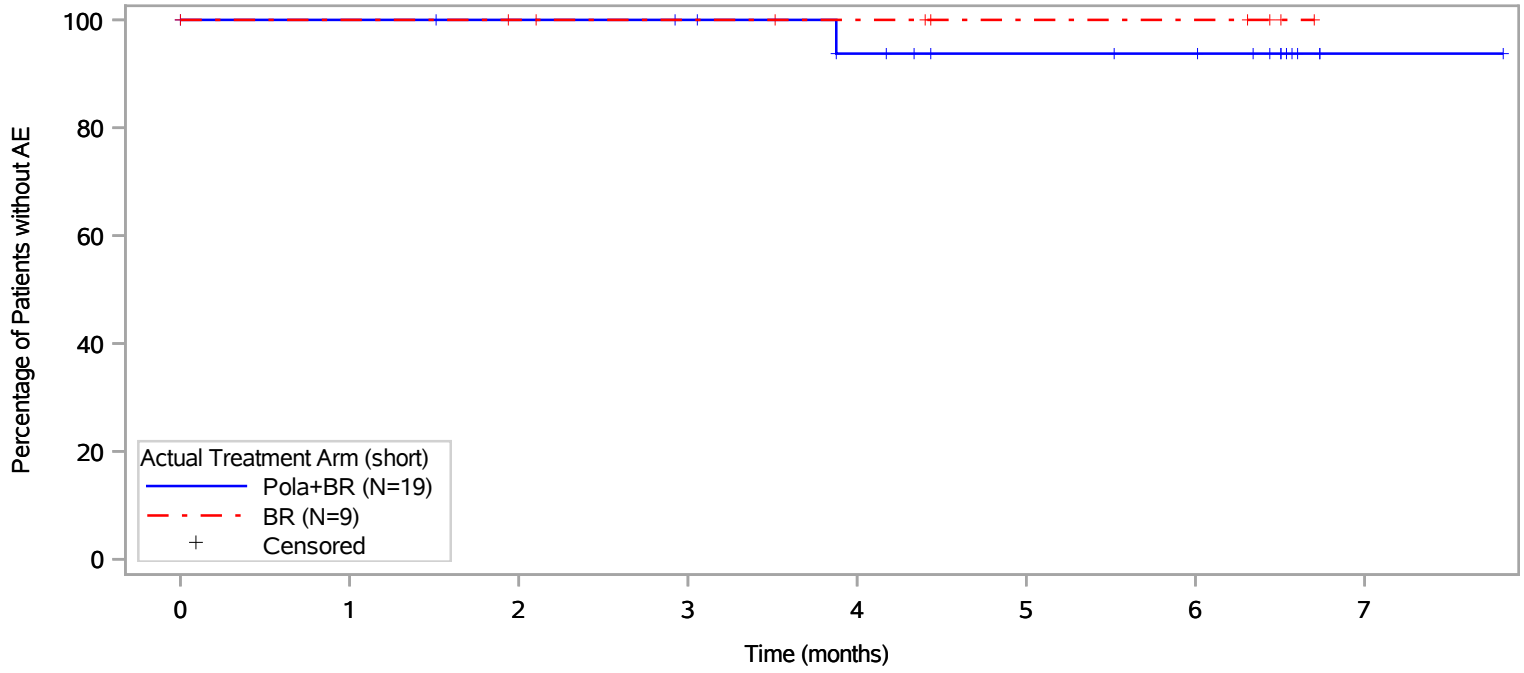
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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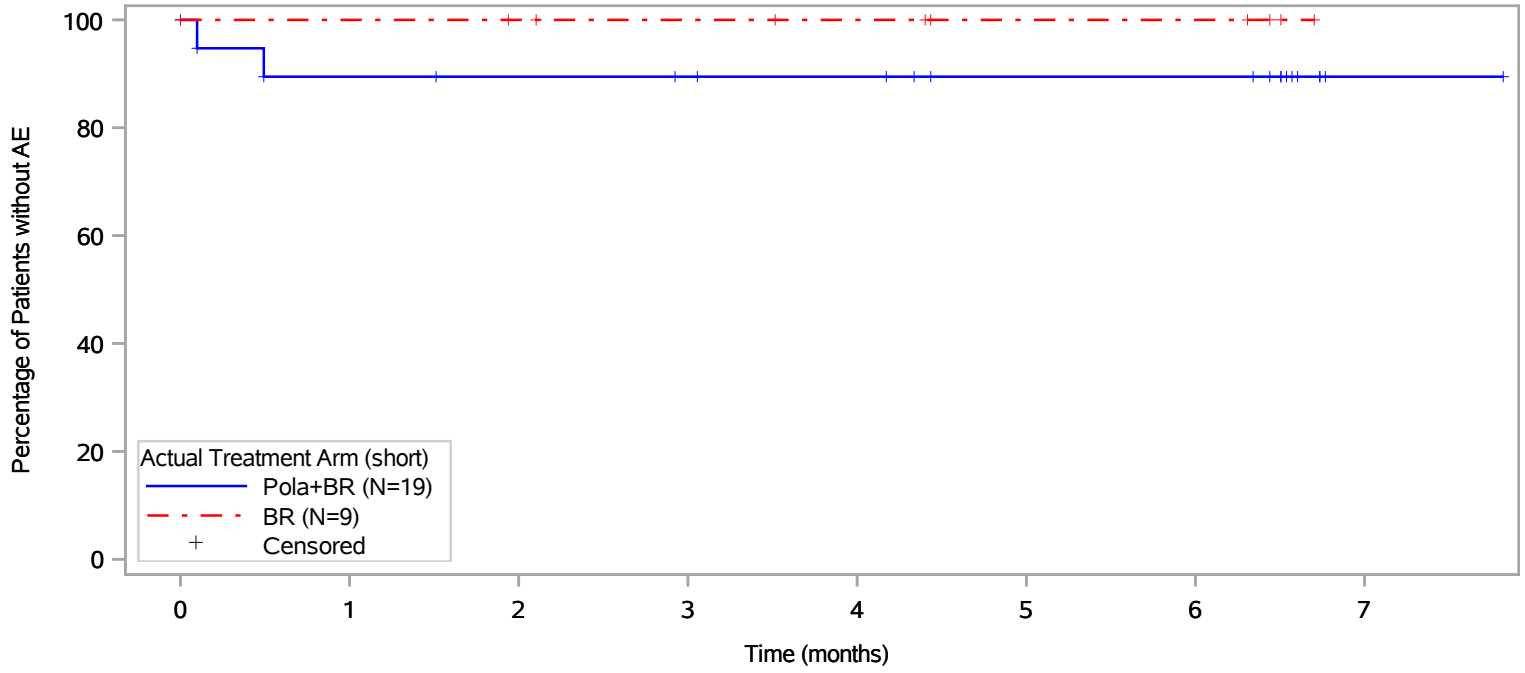
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk								
Pola+BR (N=19)	19	17	16	15	14	11	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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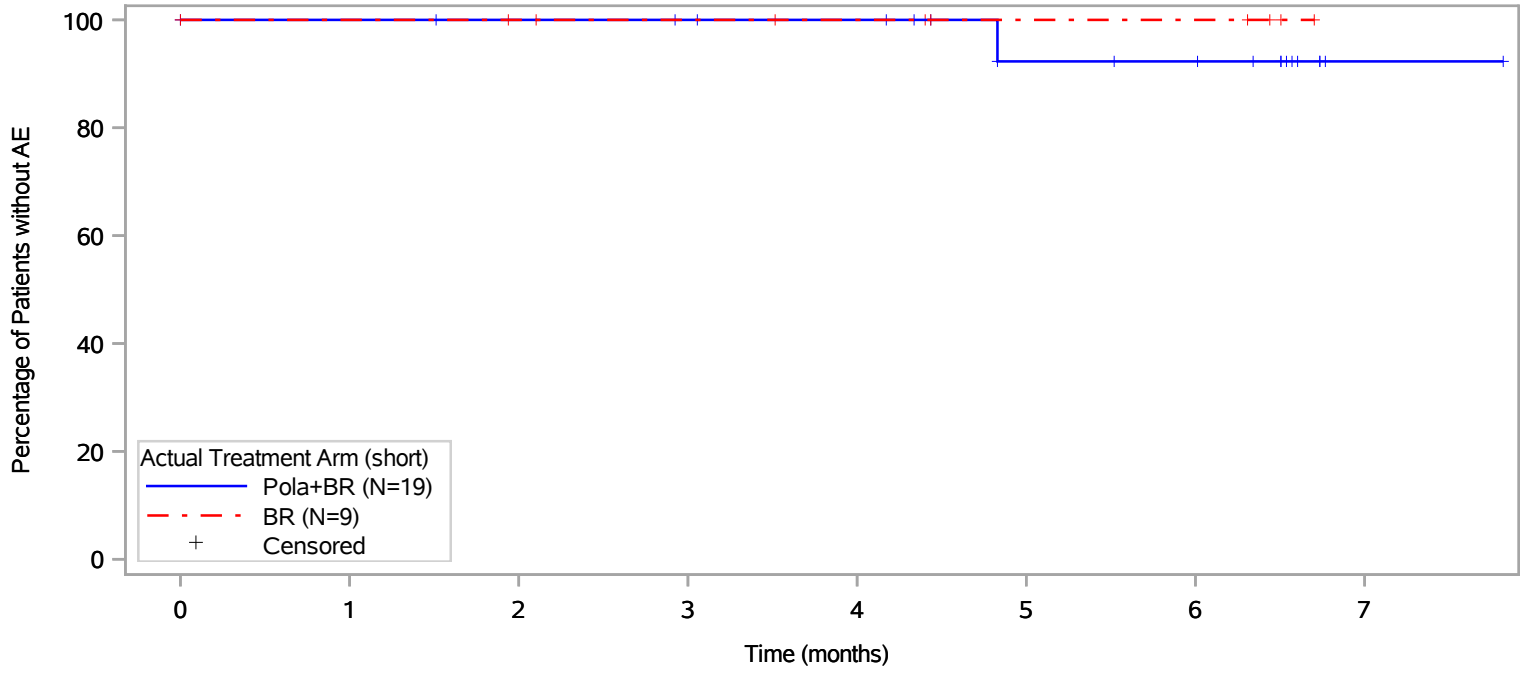
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, URINARY TRACT INFECTION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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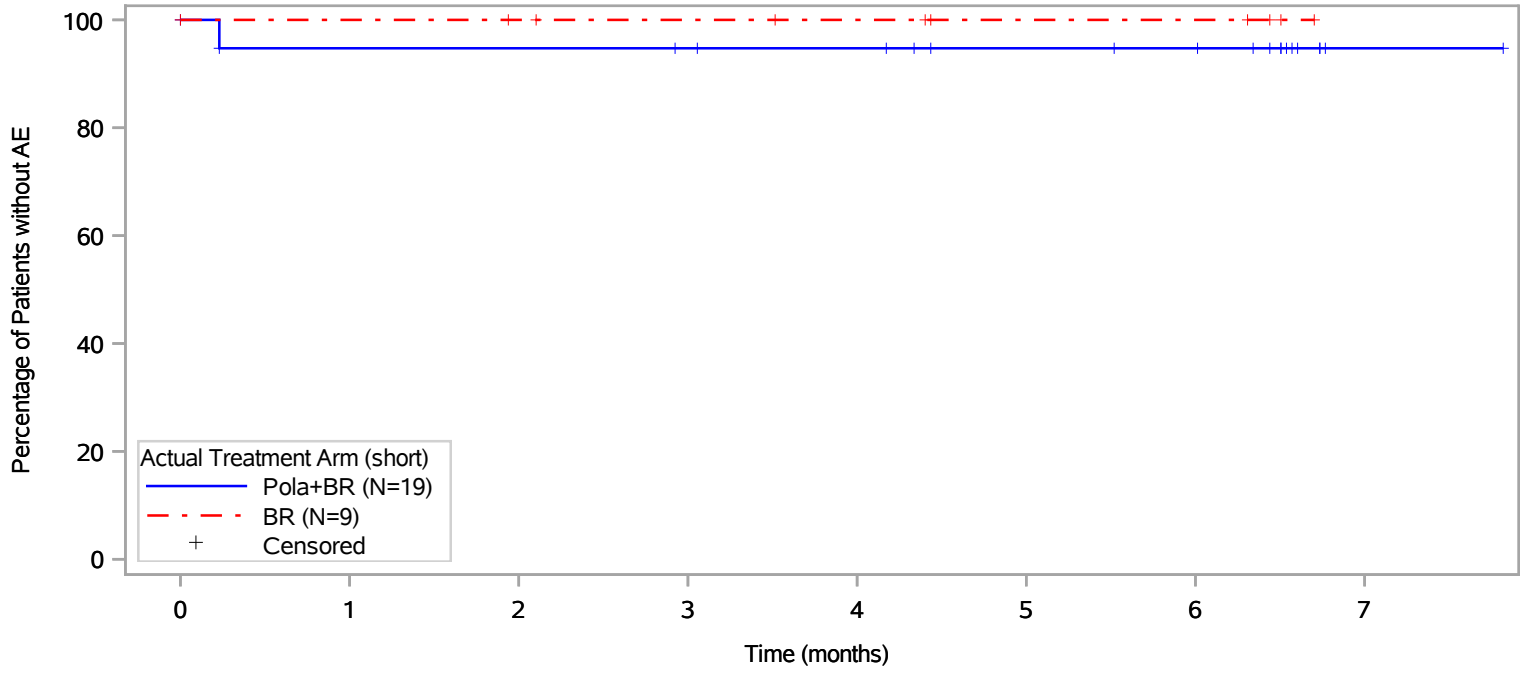
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk								
Pola+BR (N=19)	19	18	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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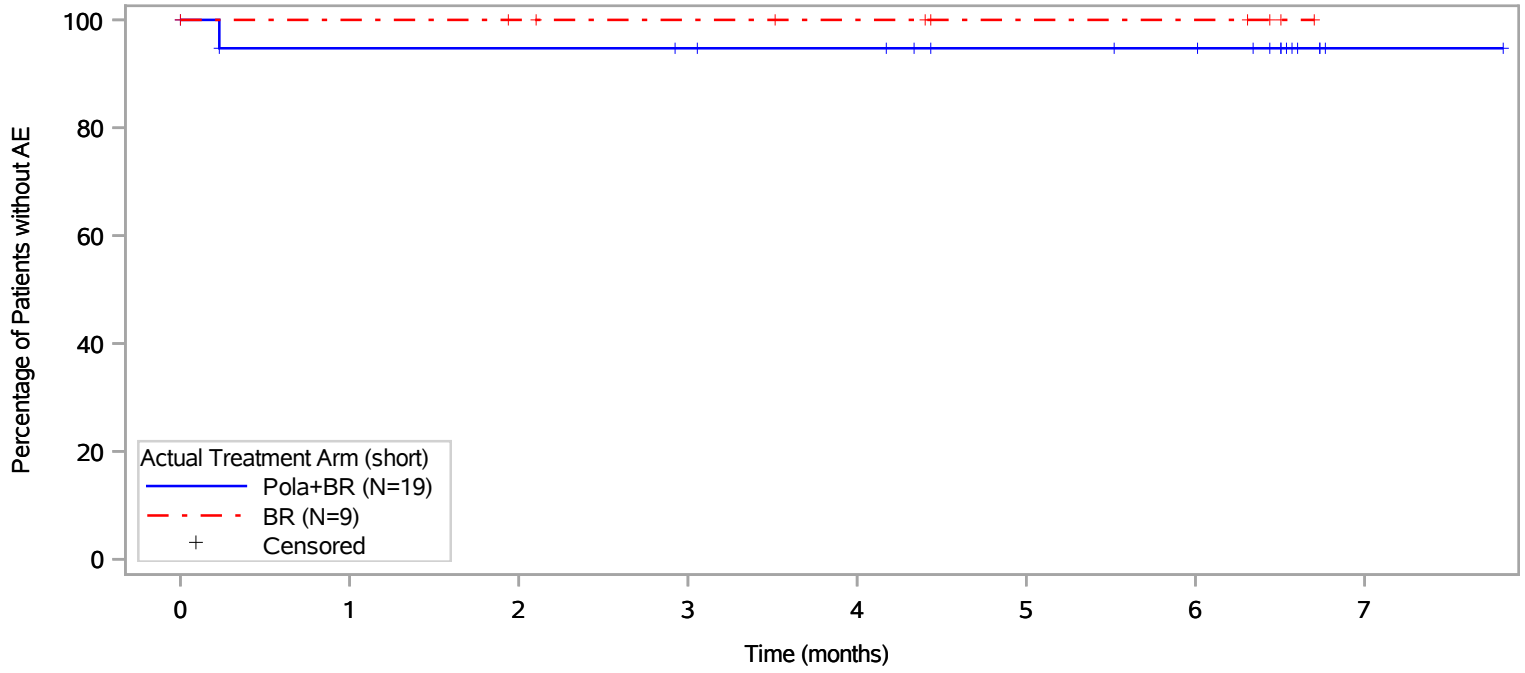
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FEMUR FRACTURE



Patients at risk								
Pola+BR (N=19)	19	18	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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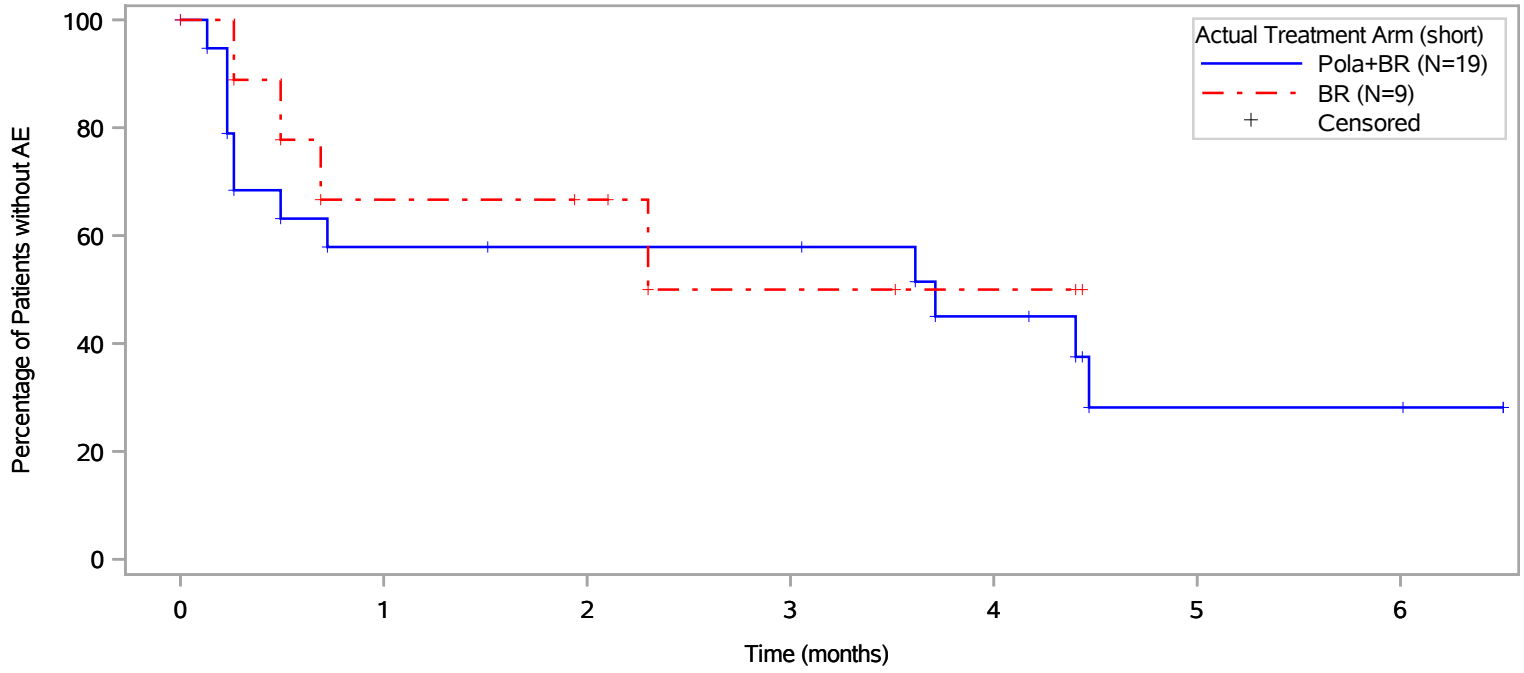
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All

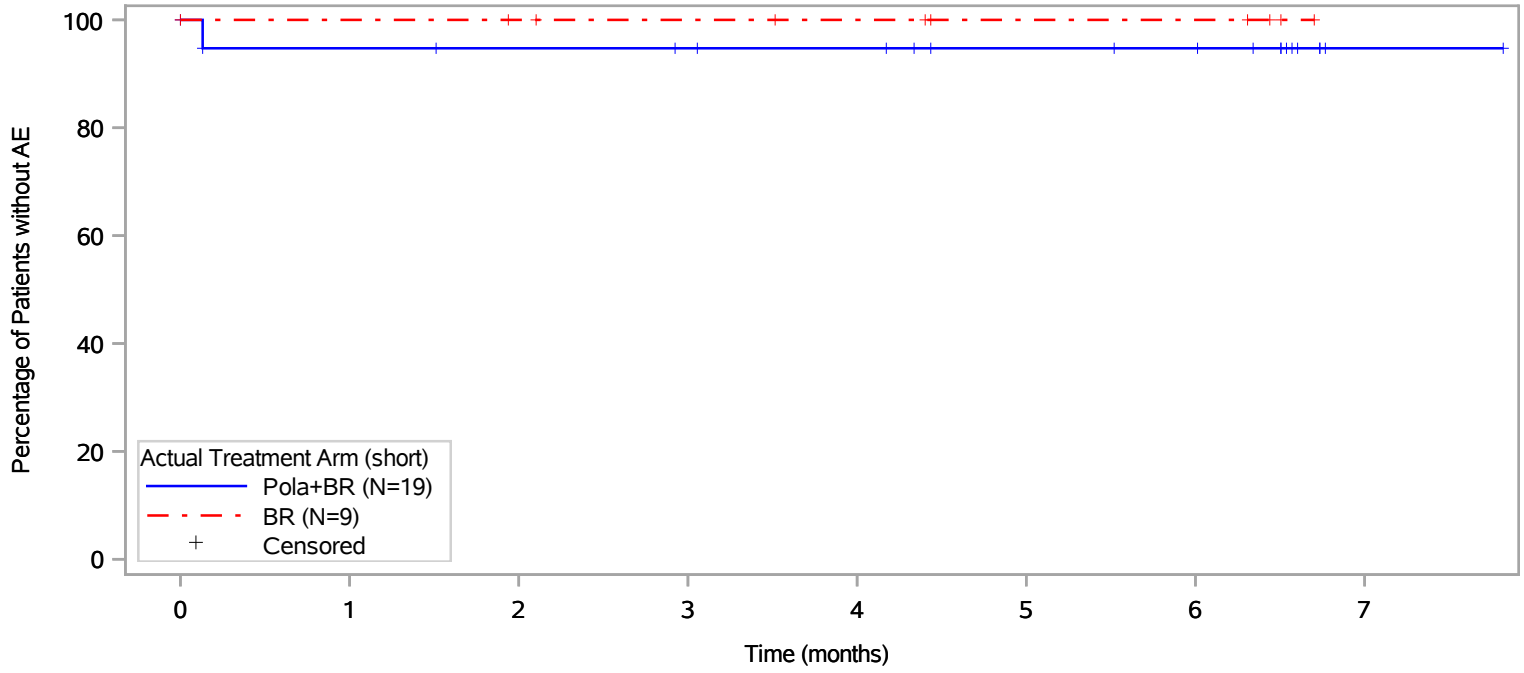


Patients at risk							
Pola+BR (N=19)	19	11	10	10	7	3	3
BR (N=9)	9	6	5	3	2	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	1	1	2	4	4
BR (N=9)	0	0	1	2	3	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD POTASSIUM DECREASED

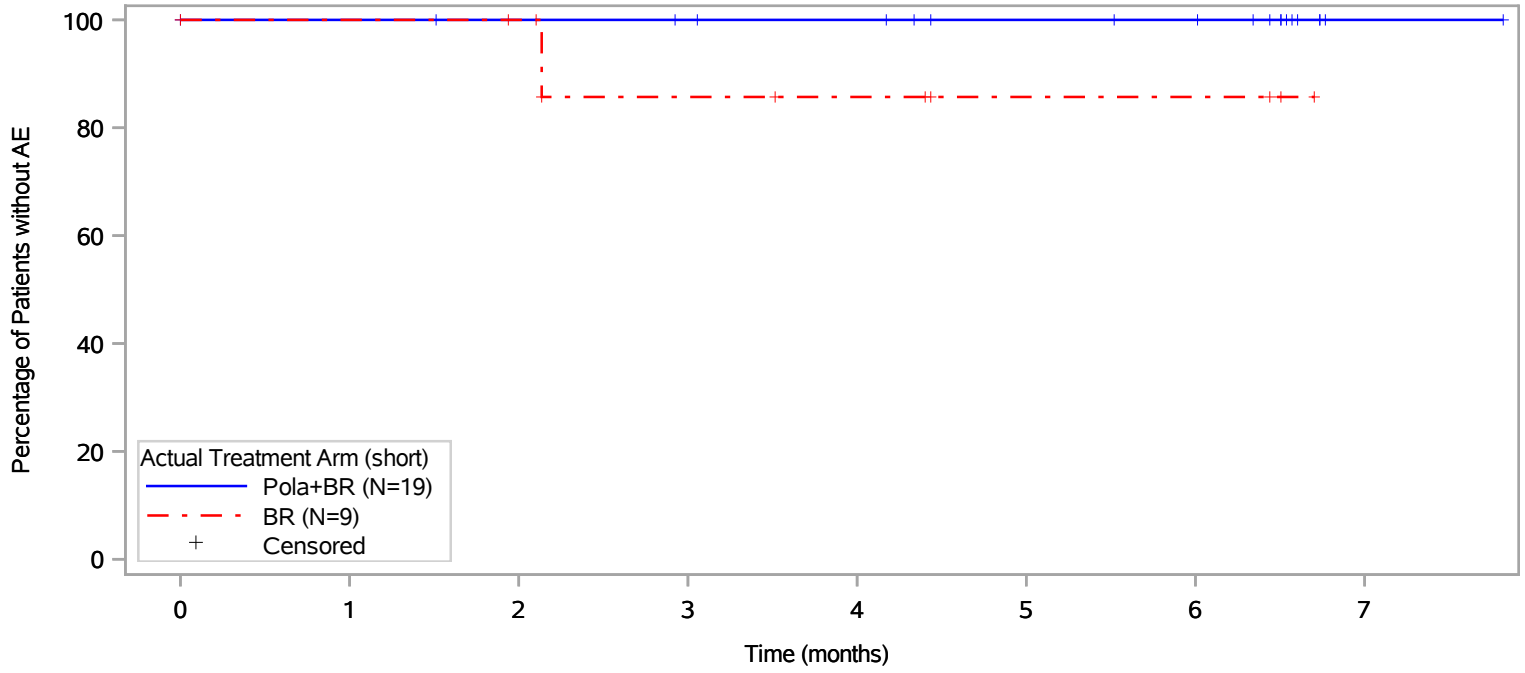


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

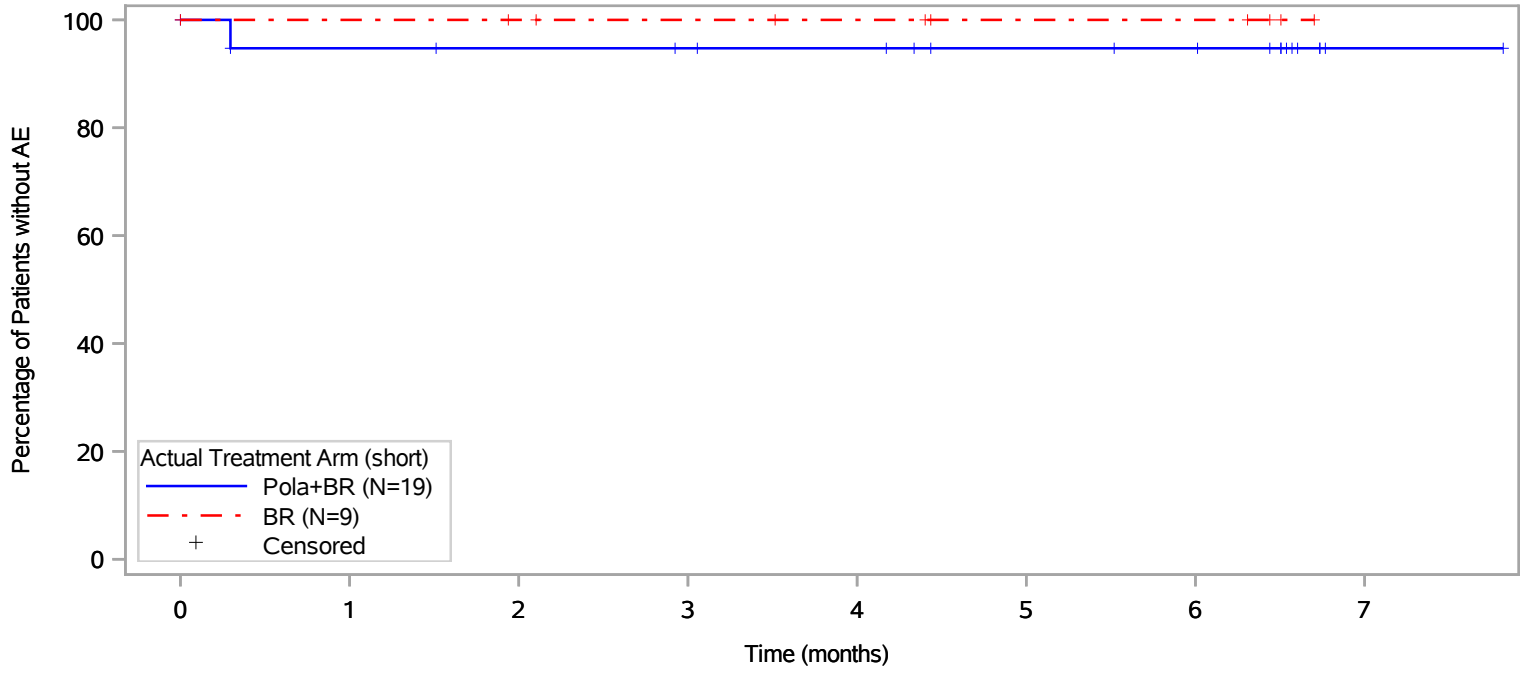
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, BLOOD PRESSURE INCREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, FIBRIN D DIMER INCREASED



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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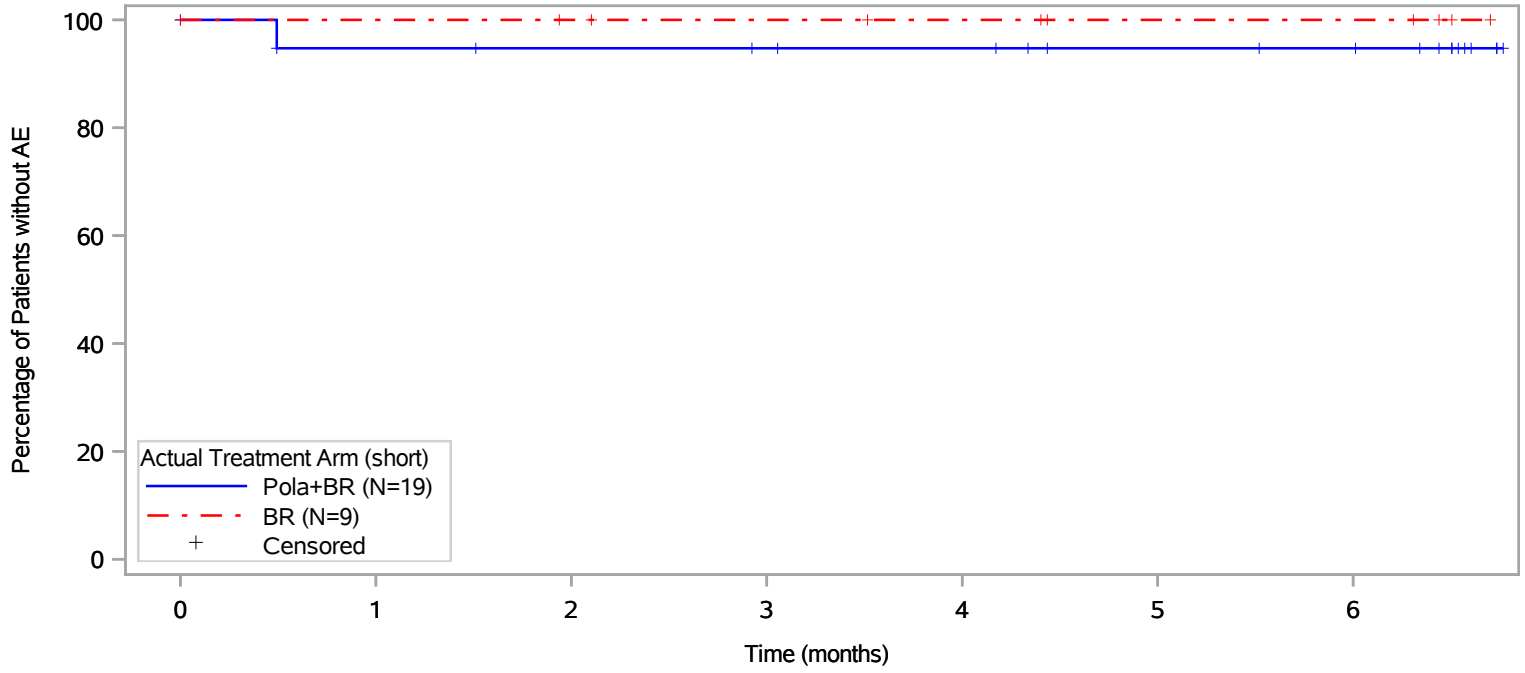
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, GAMMA-GLUTAMYLTRANSFERASE INCREASED

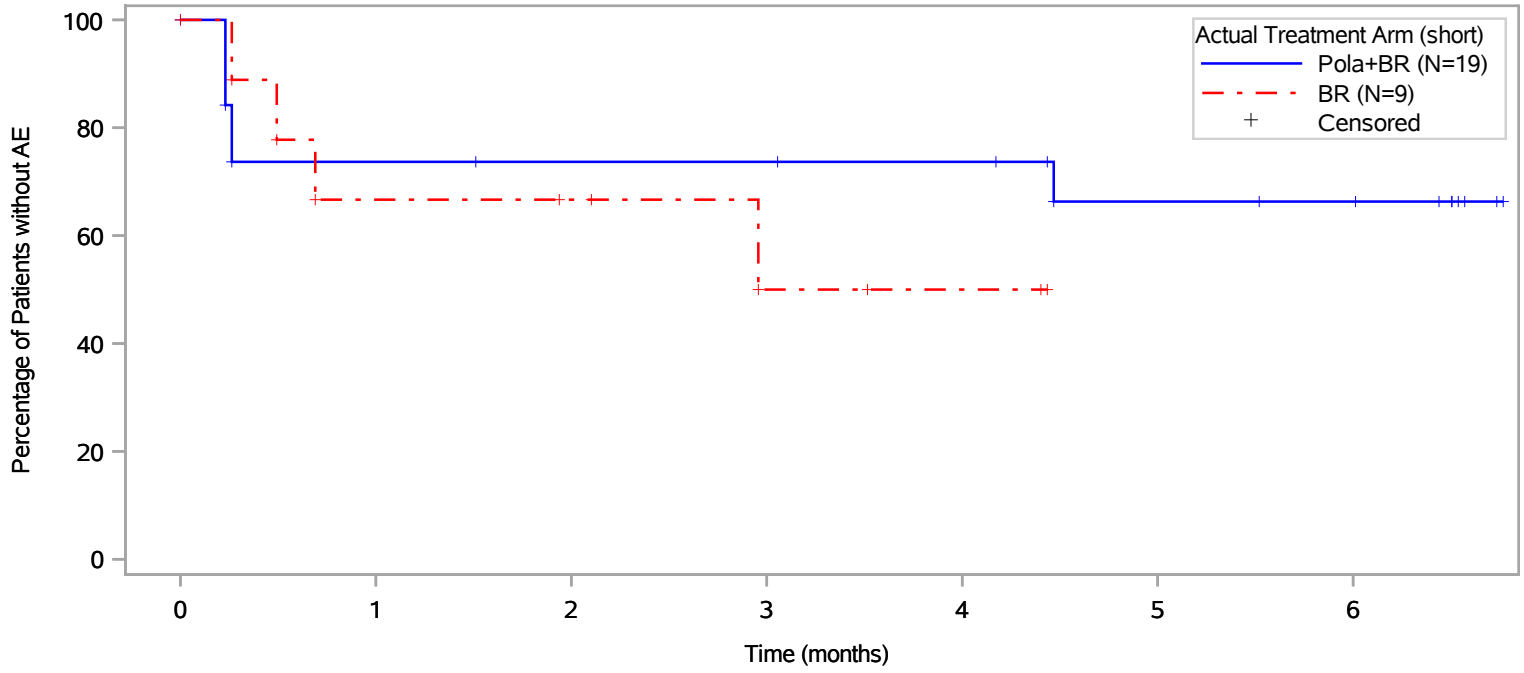


Patients at risk							
Pola+BR (N=19)	19	18	17	16	15	12	11
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk							
Pola+BR (N=19)	19	14	13	13	12	9	8
BR (N=9)	9	6	5	3	2	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	1	1	2	4	5
BR (N=9)	0	0	1	2	3	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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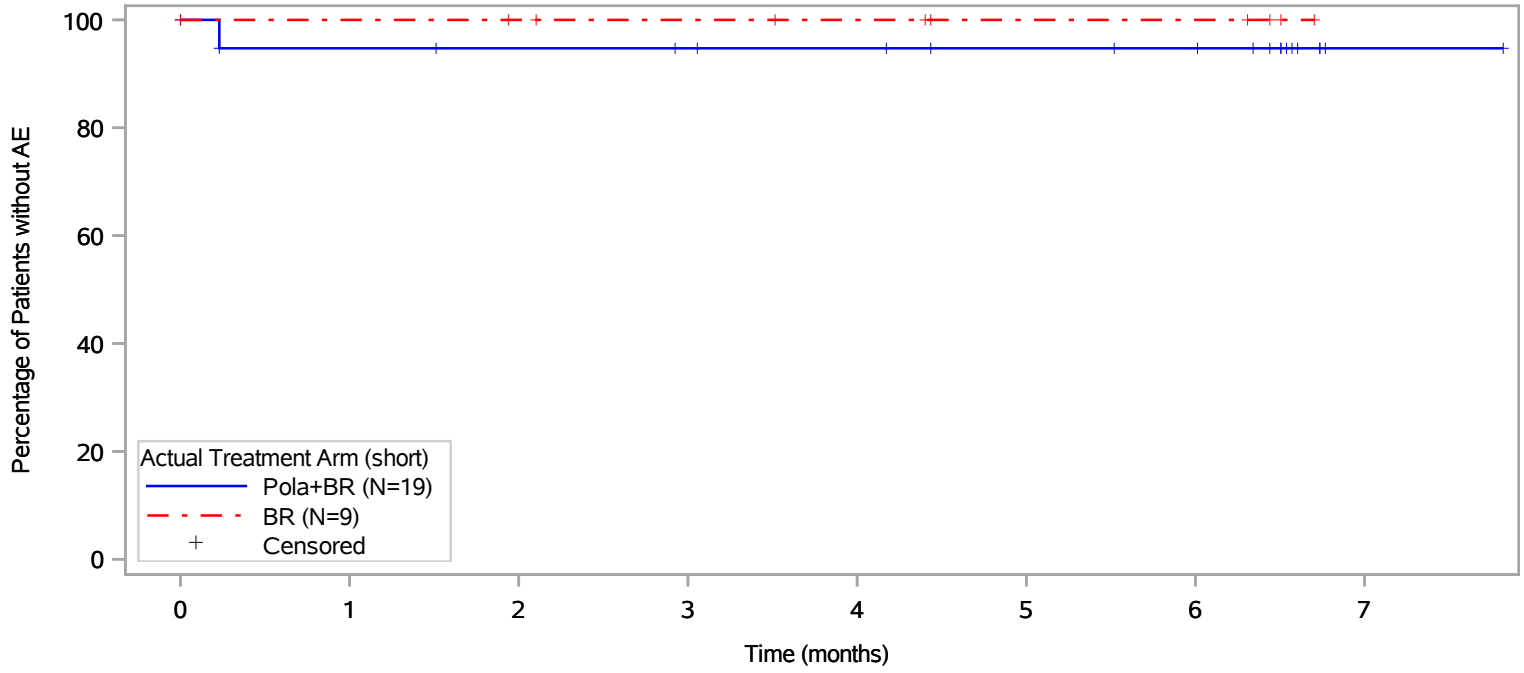
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE PERCENTAGE DECREASED

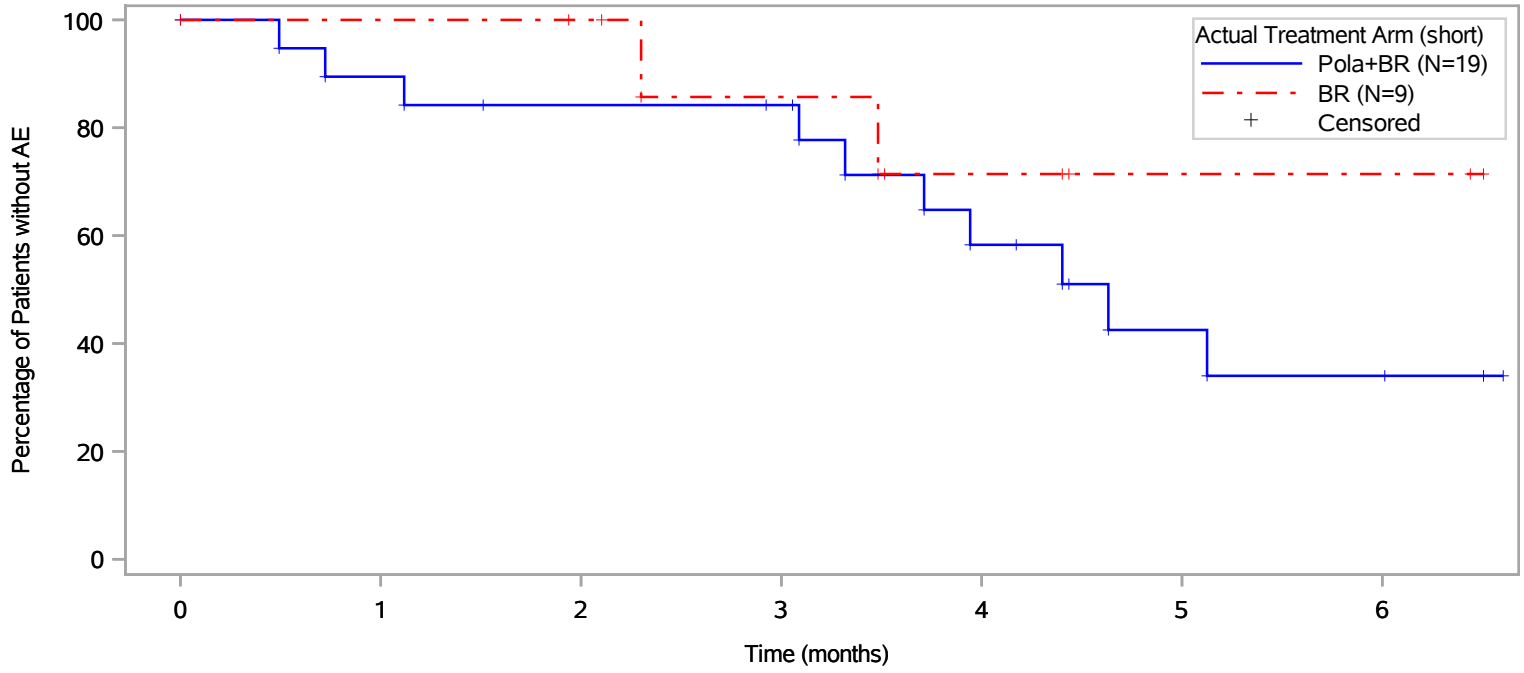


Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk							
Pola+BR (N=19)	19	17	15	14	9	5	4
BR (N=9)	9	9	8	6	4	2	2
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	5	5
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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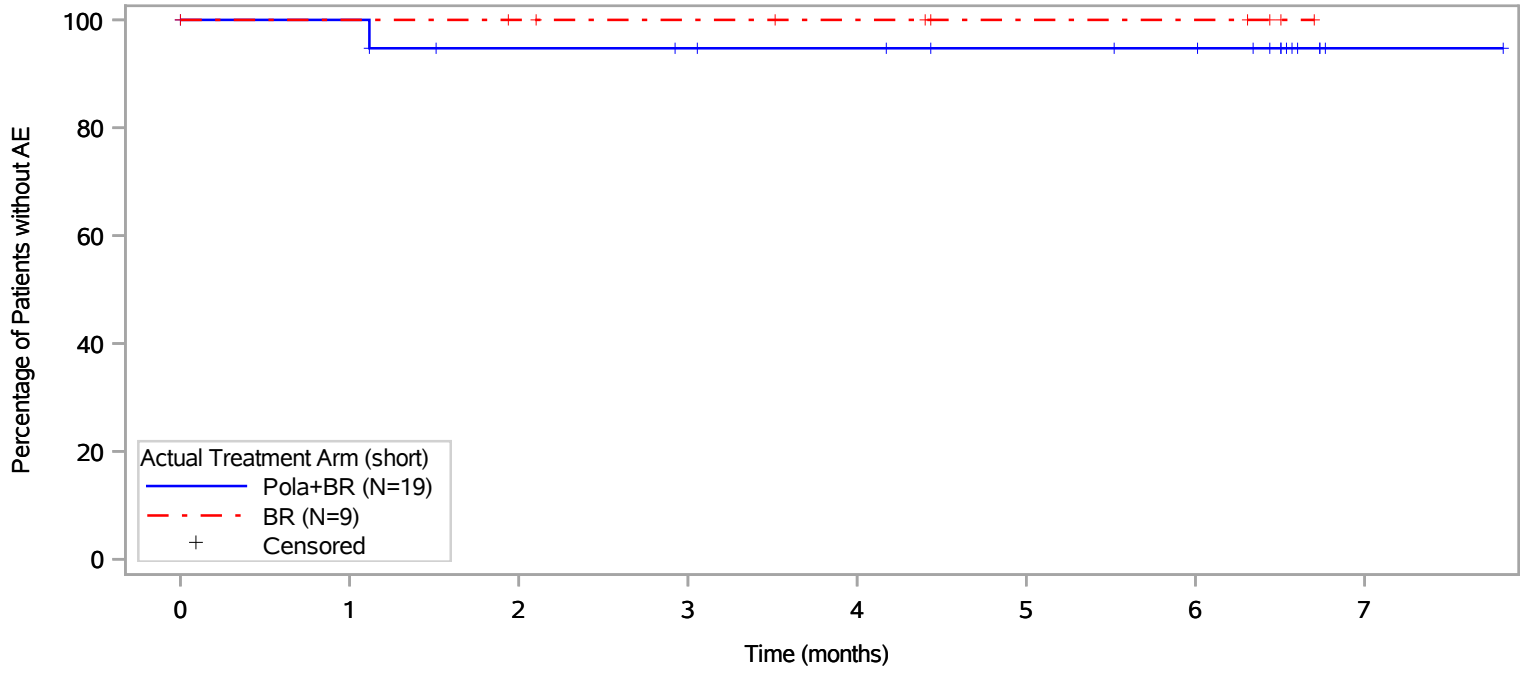
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL PERCENTAGE DECREASED

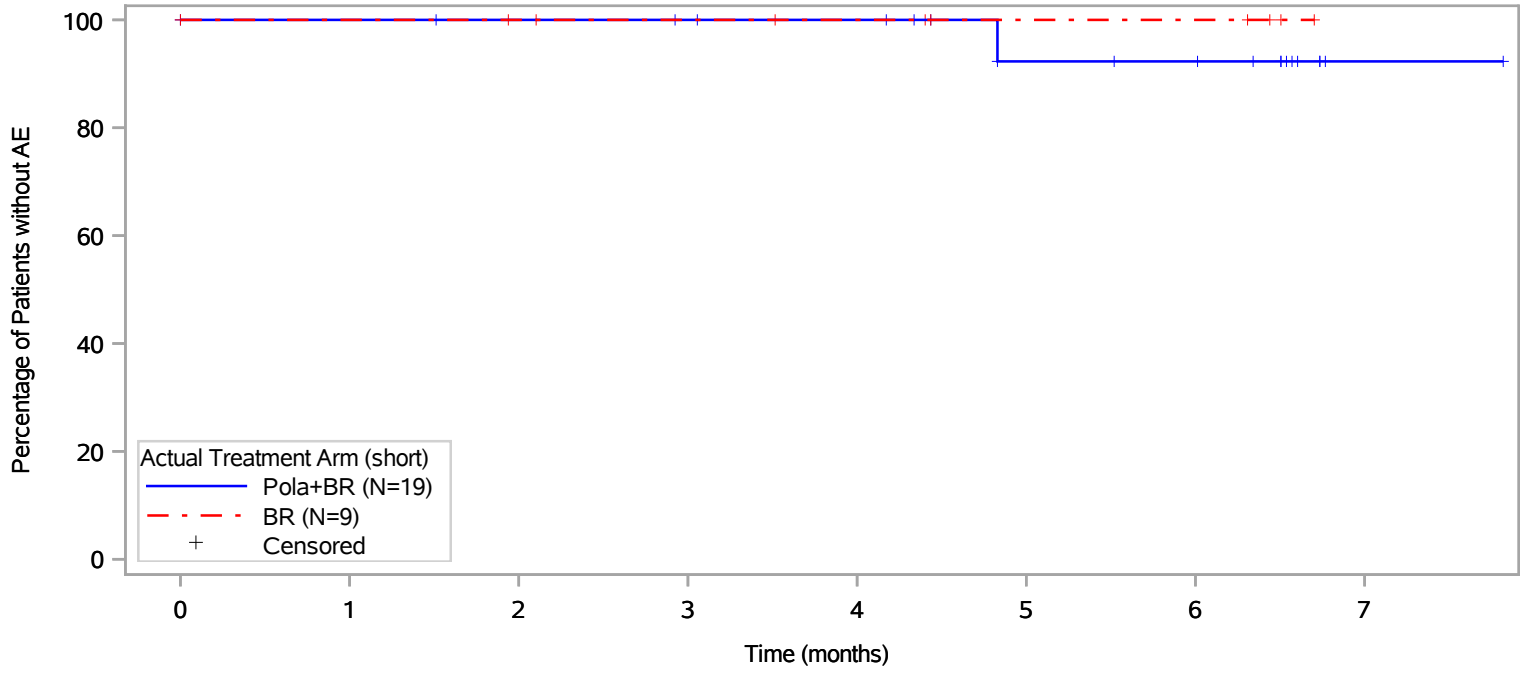


Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NITRITE URINE PRESENT



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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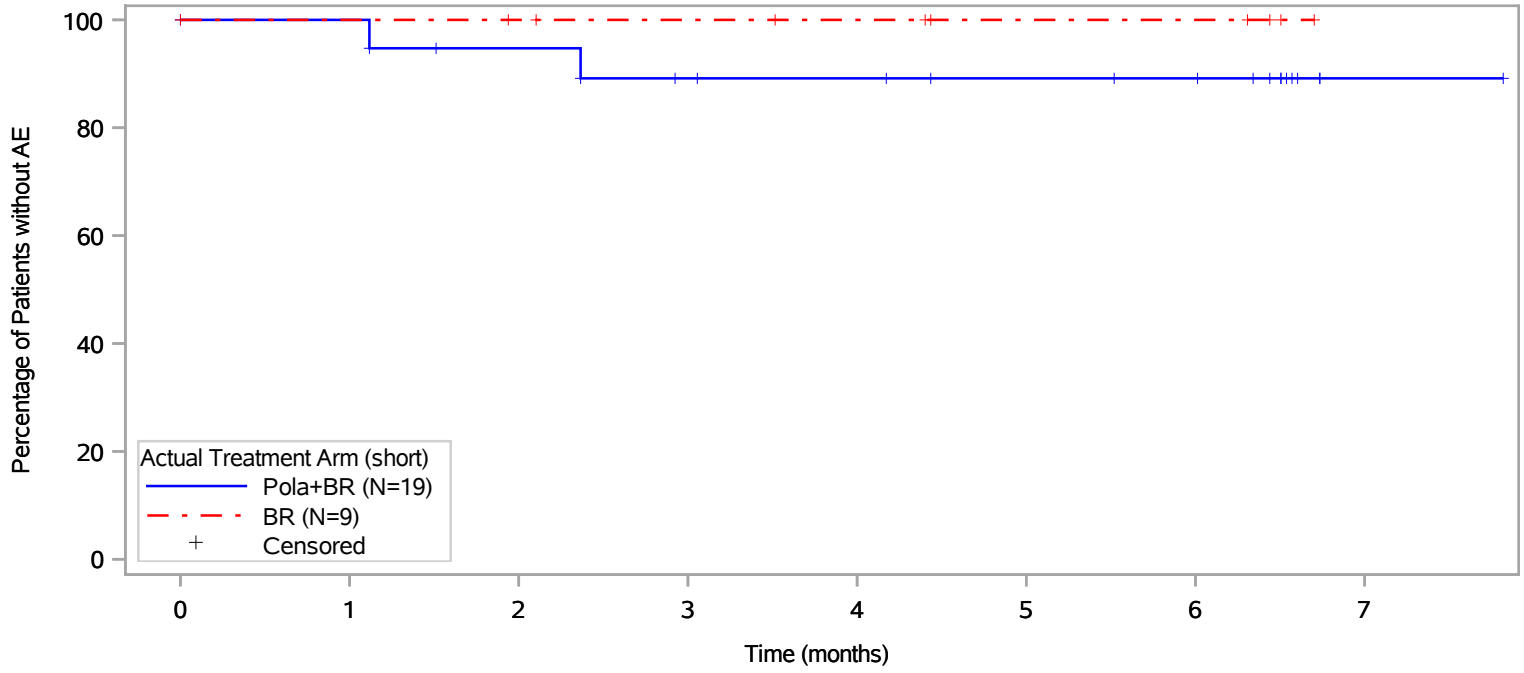
02DEC2022 3:38

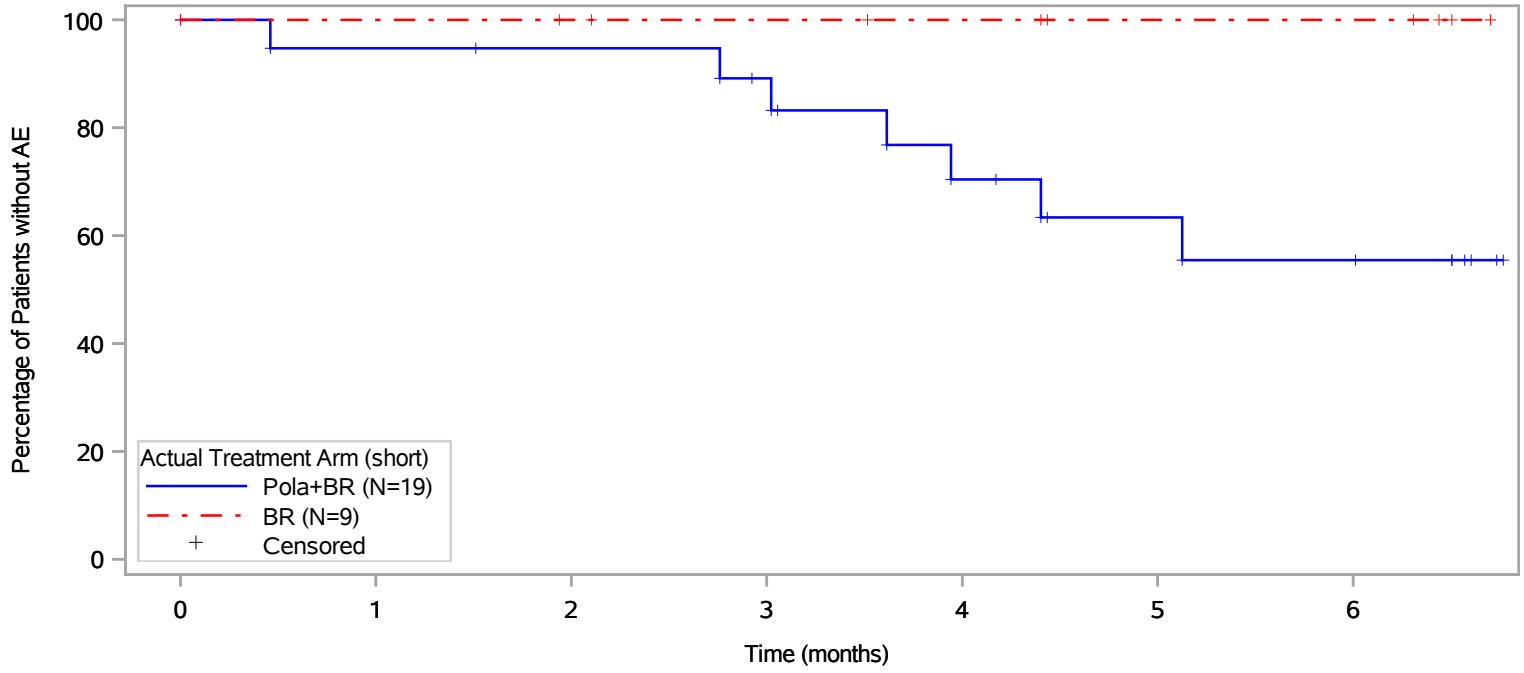
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk								
Pola+BR (N=19)	19	19	17	15	14	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED

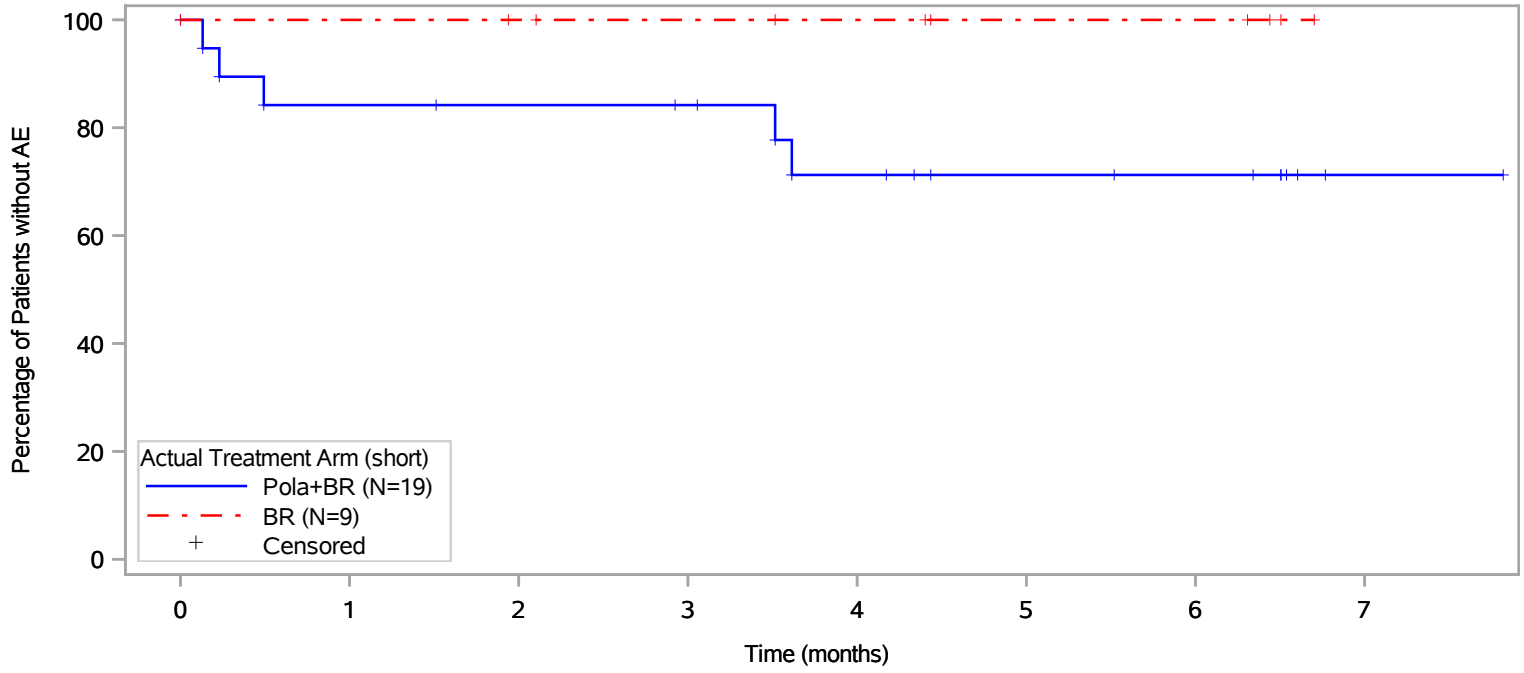


Patients at risk							
Pola+BR (N=19)	19	18	17	15	11	8	7
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	5	5
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	16	15	14	11	8	7	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	13
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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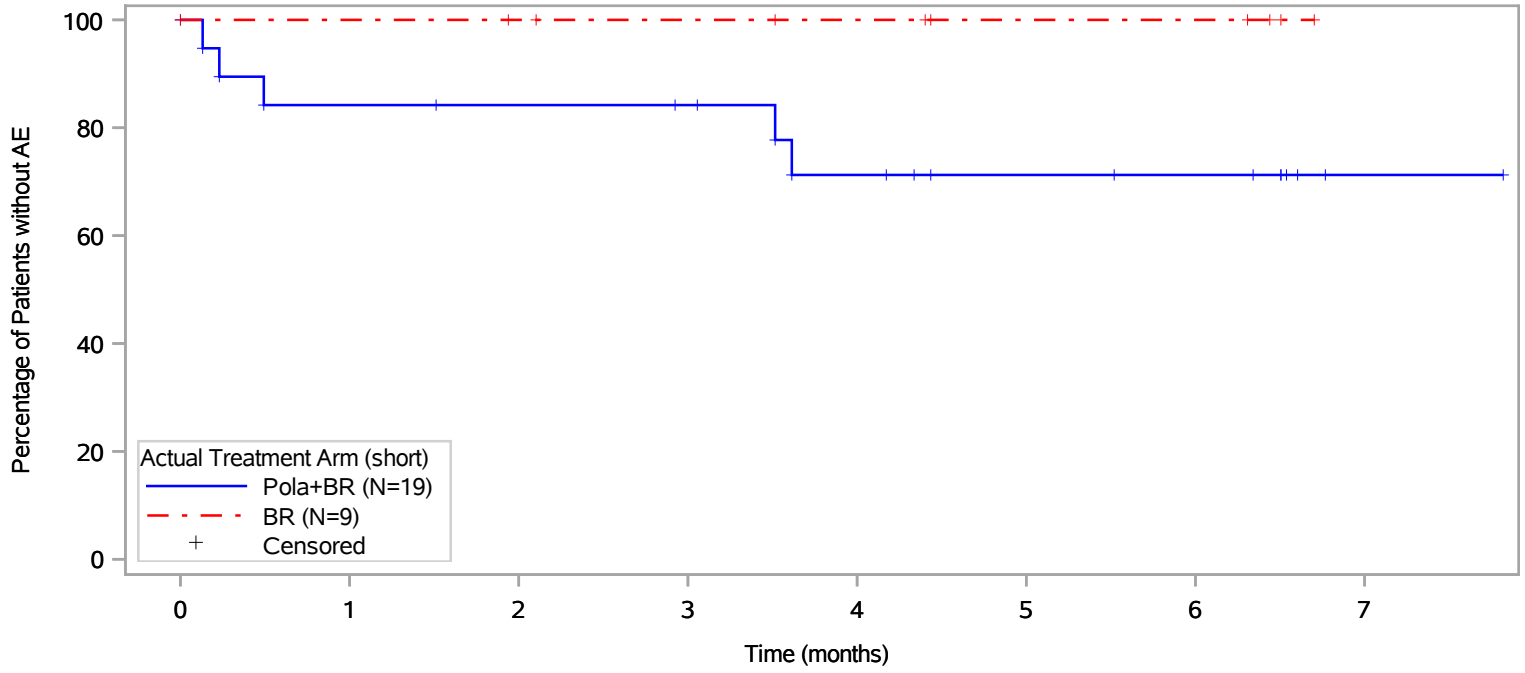
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
METABOLISM AND NUTRITION DISORDERS, HYPOKALAEMIA



Patients at risk								
Pola+BR (N=19)	19	16	15	14	11	8	7	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	13
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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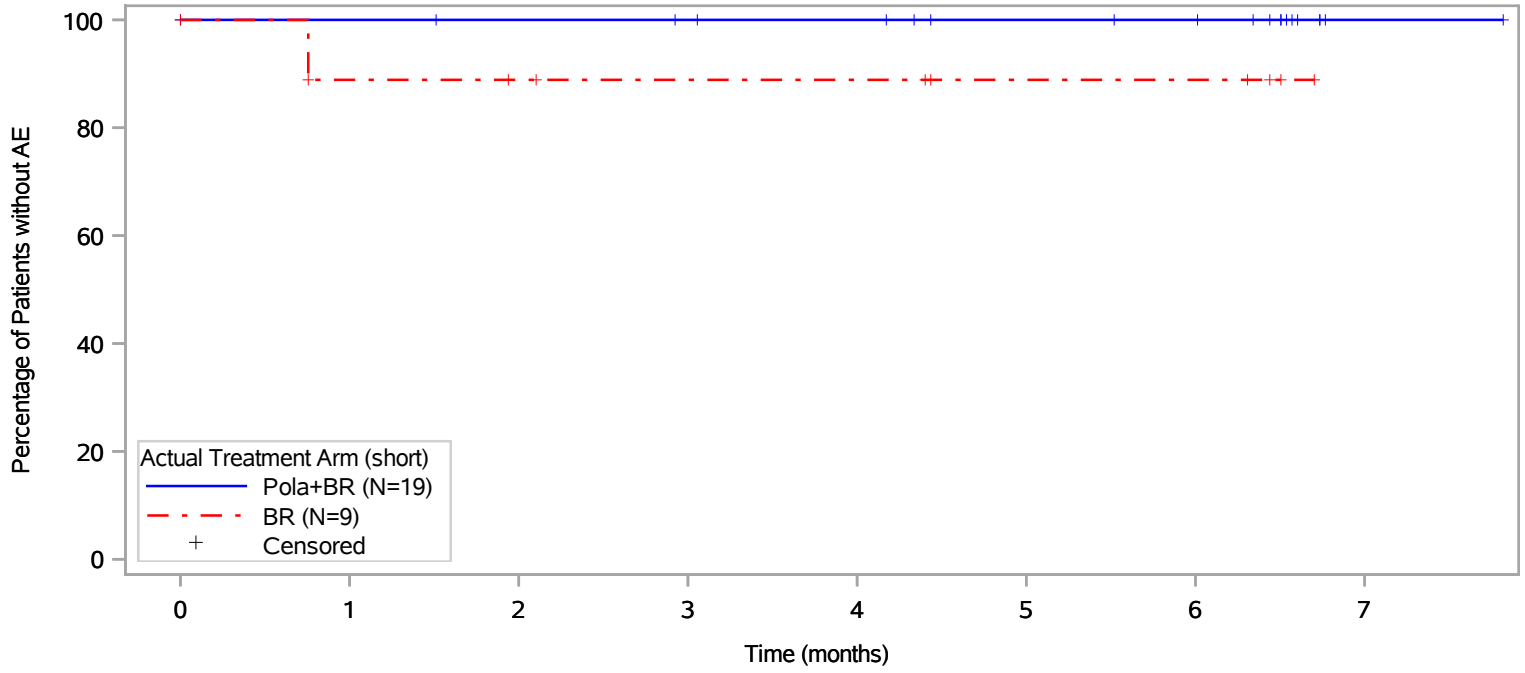
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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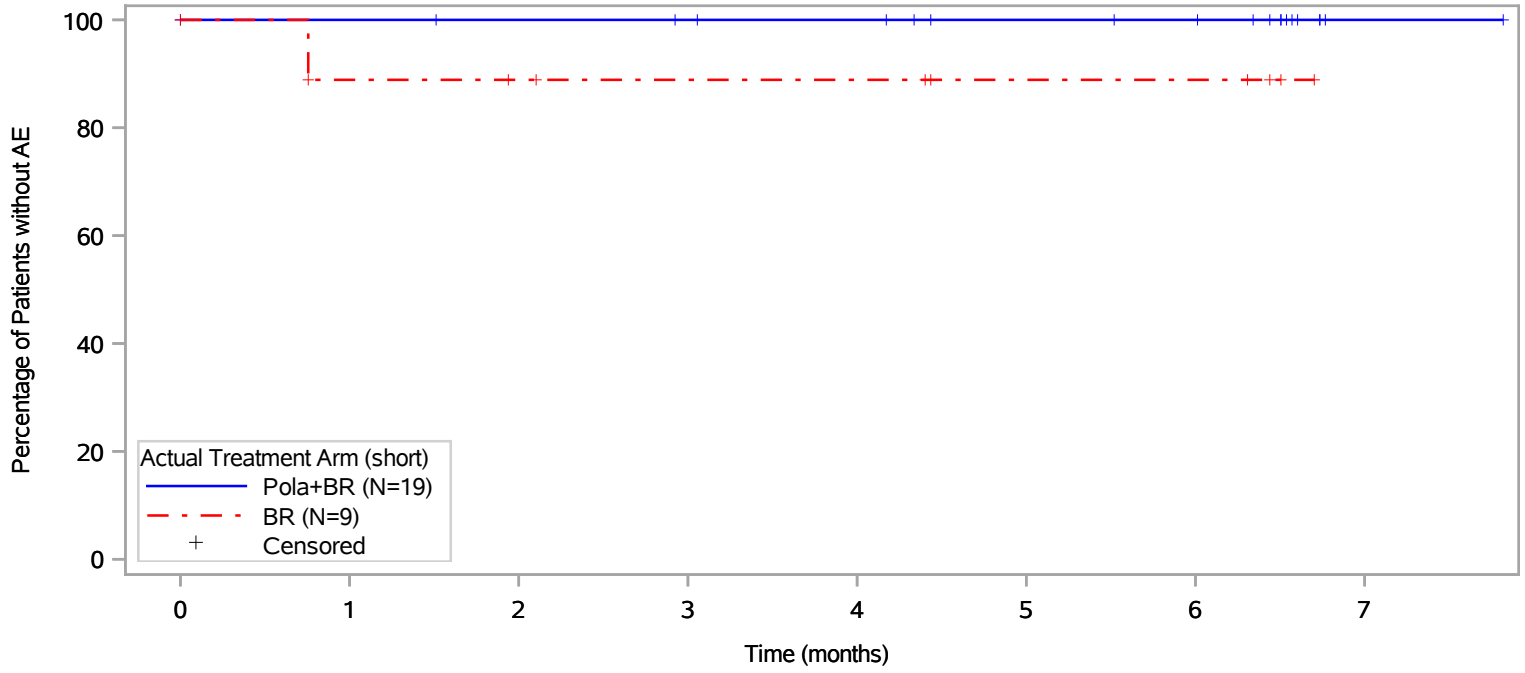
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, INTERVERTEBRAL DISC PROTRUSION

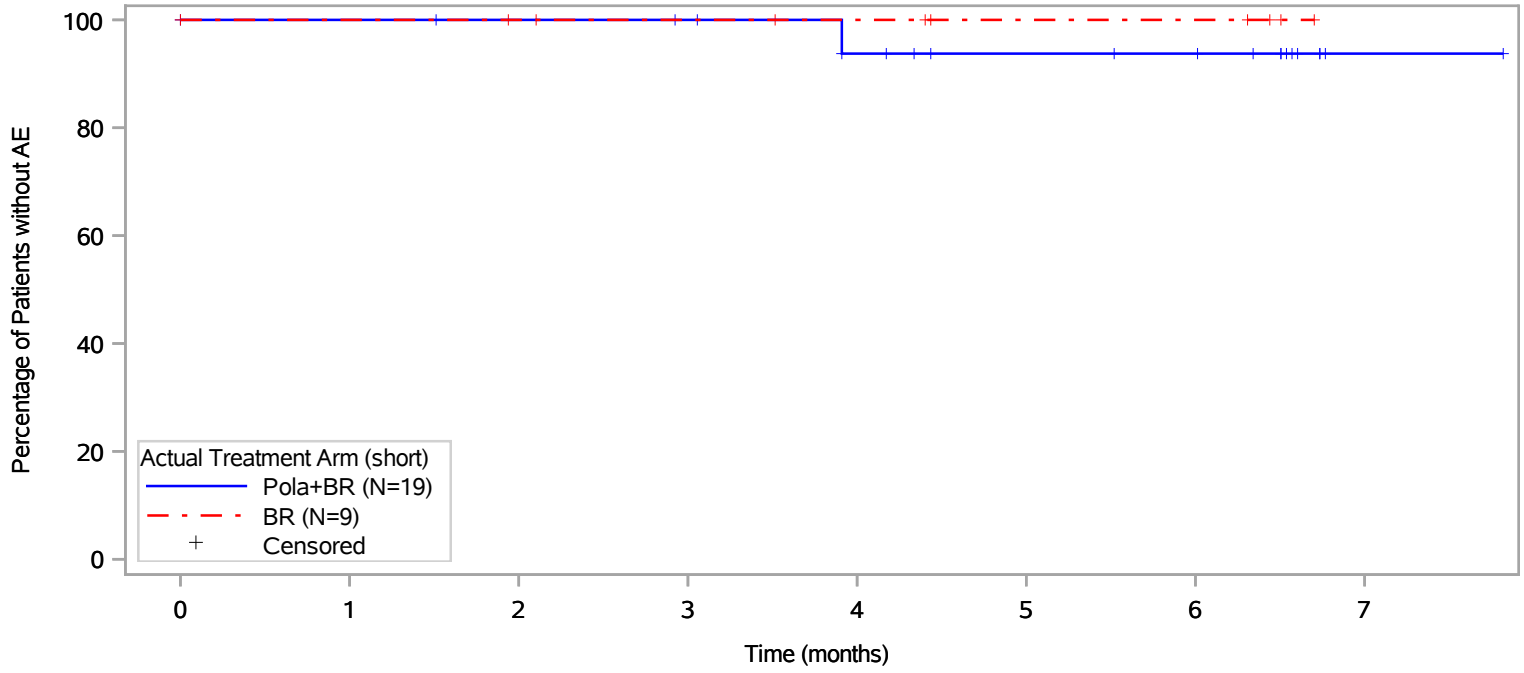


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All

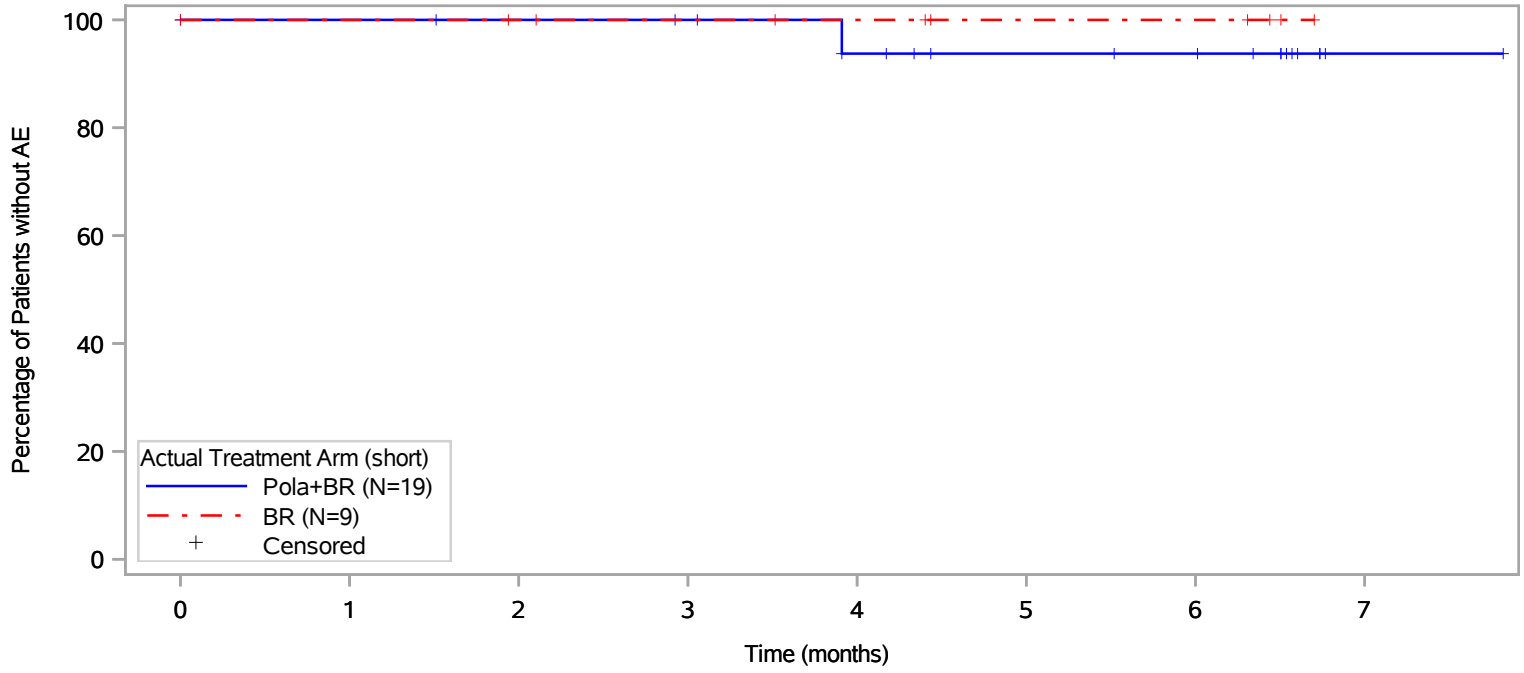


Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HAEMATURIA

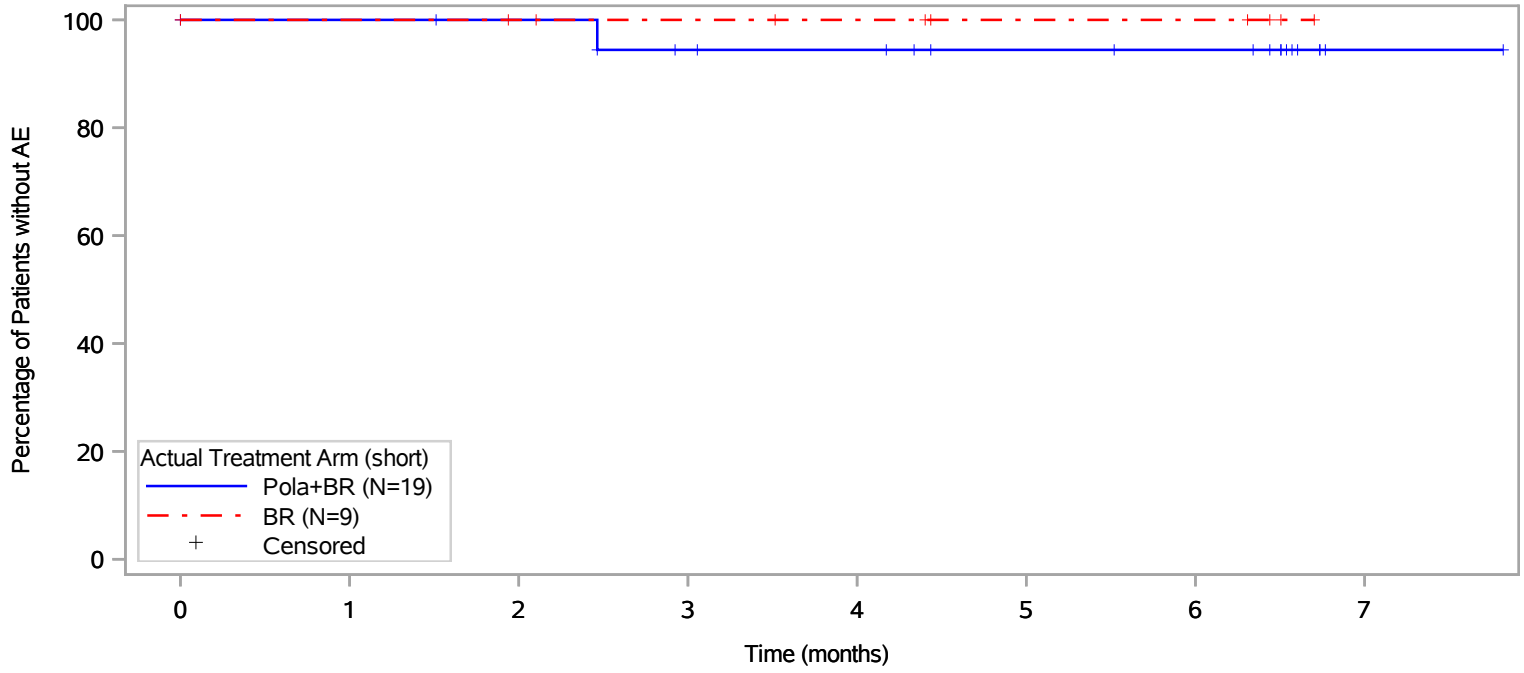


Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All

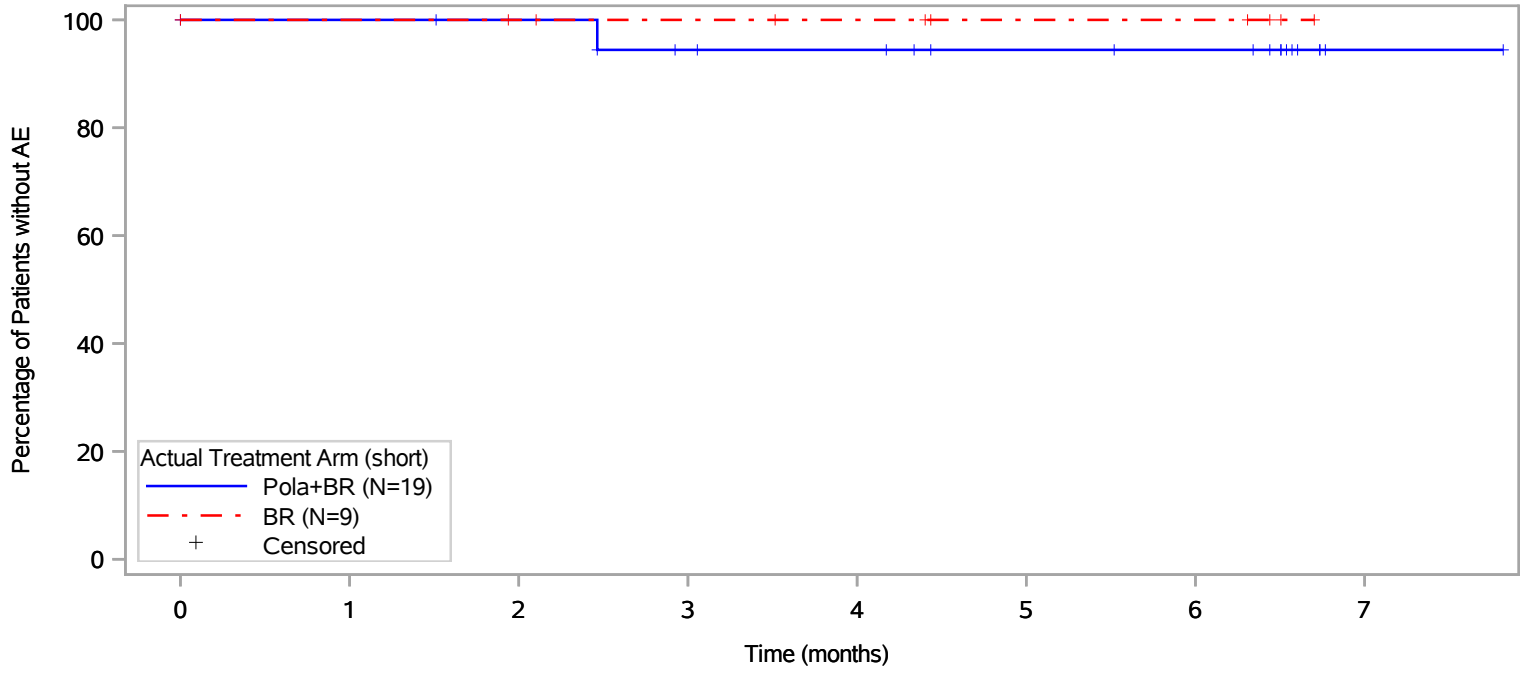


Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, INTERSTITIAL LUNG DISEASE

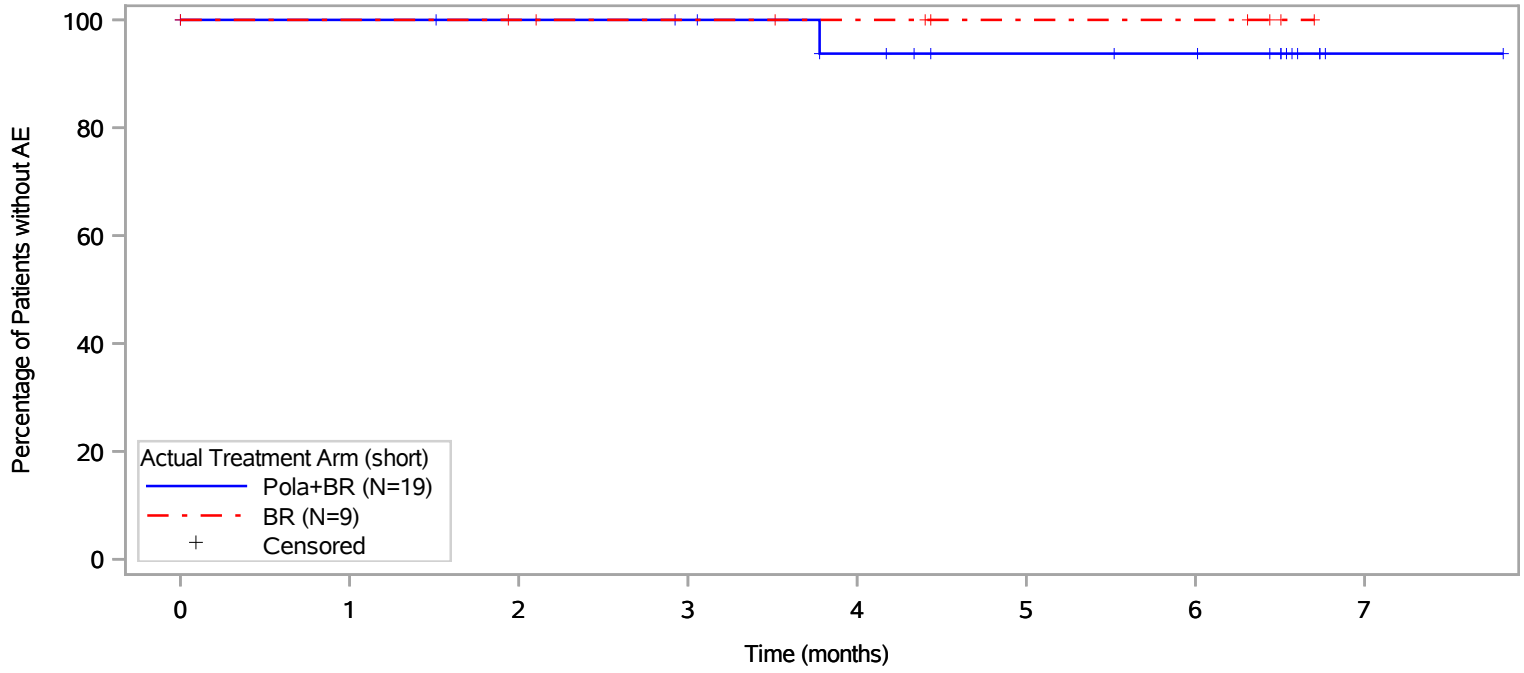


Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, All

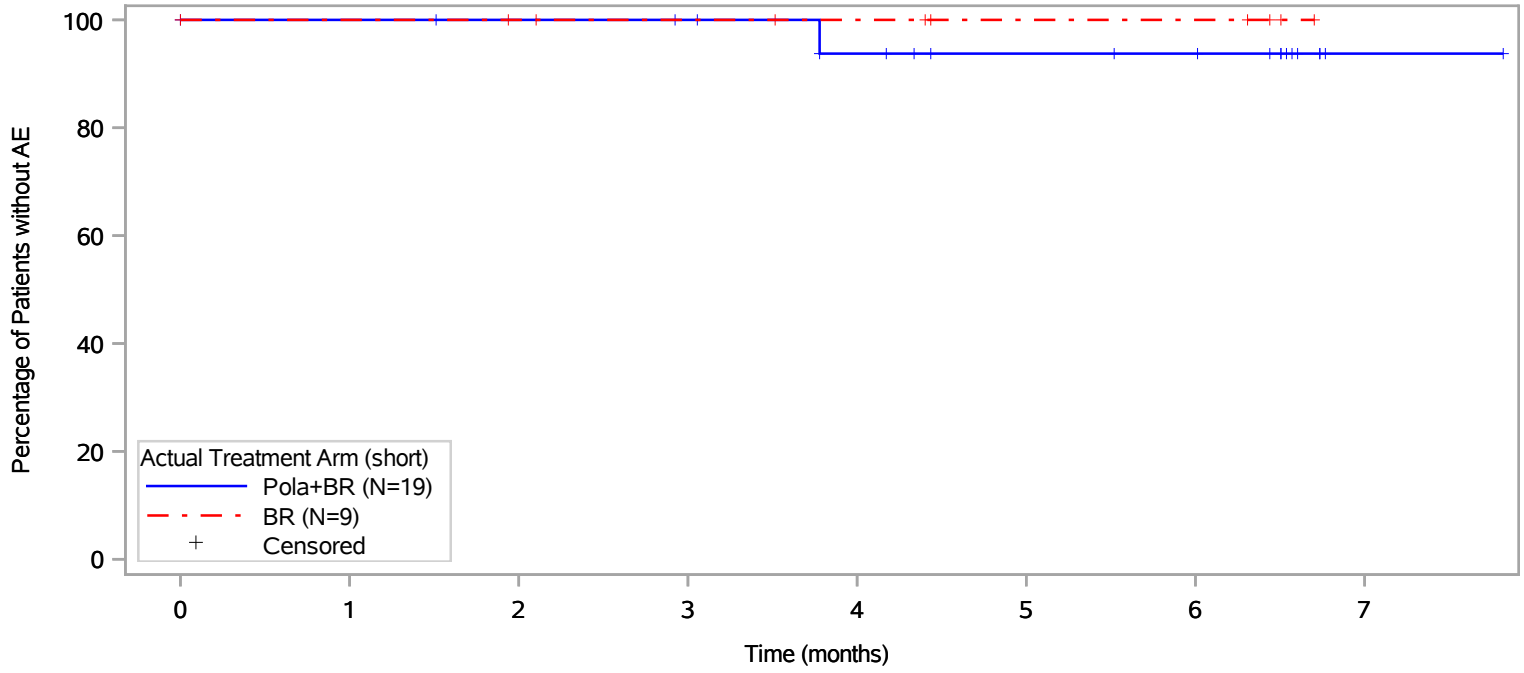


Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 3 adverse event
STUDIES: GO29365, YO41543
VASCULAR DISORDERS, HYPOTENSION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR3AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 3:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.9444	0.92	0.08	10.13		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			19	100.0	8	42.1	11	57.9	9	100.0	2	22.2	7	77.8	0.4534	1.80	0.38	8.61		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED		19	100.0	3	15.8	16	84.2	9	100.0	2	22.2	7	77.8	0.6142	0.63	0.10	3.94		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED		19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1712	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2676	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	URINE OUTPUT DECREASED		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED		19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1872	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR4AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 21:30

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	16	84.2	2	12.5	14	87.5	7	77.8	1	14.3	6	85.7	0.8425	0.78	0.07	8.67		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.4649	0.37	0.02	5.93		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3958	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3958	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	16	84.2	6	37.5	10	62.5	7	77.8	2	28.6	5	71.4	0.9788	0.98	0.20	4.86		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	3	15.8	2	66.7	1	33.3	2	22.2	0	-	2	100.0	0.1824	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	2	28.6	5	71.4	0.1102	0.17	0.02	1.95		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	0	-	2	100.0	0.1824	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.2937	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.3224	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.3106	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR4AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 21:30

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4962	0.39	0.02	6.33		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4031	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4031	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	14	73.7	6	42.9	8	57.1	6	66.7	2	33.3	4	66.7	0.9686	1.03	0.20	5.32		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	>=3	14	73.7	2	14.3	12	85.7	6	66.7	2	33.3	4	66.7	0.2856	0.33	0.04	2.70		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	>=3	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.2747	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	>=3	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.2328	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTGR4AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 21:30

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.9444	0.92	0.08	10.13		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5643	0.45	0.03	7.23		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3572	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	100.0	8	42.1	11	57.9	9	100.0	2	22.2	7	77.8	0.4534	1.80	0.38	8.61		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	2	22.2	7	77.8	0.6142	0.63	0.10	3.94		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1712	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	100.0	3	15.8	16	84.2	9	100.0	0	-	9	100.0	0.2676	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1872	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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30NOV2022 21:30

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4348	0.35	0.02	5.57		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.4348	0.35	0.02	5.57		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	14	73.7	7	50.0	7	50.0	6	66.7	1	16.7	5	83.3	0.2863	2.97	0.36	24.35		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	1	20.0	4	80.0	3	33.3	1	33.3	2	66.7	0.6084	0.49	0.03	7.94		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Male	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.8991	1.16	0.12	11.49		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	LYMPHOCYTE PERCENTAGE DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Male	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.2167	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	NEUTROPHIL COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	URINE OUTPUT DECREASED	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	URINE OUTPUT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.3412	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	WHITE BLOOD CELL COUNT DECREASED	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
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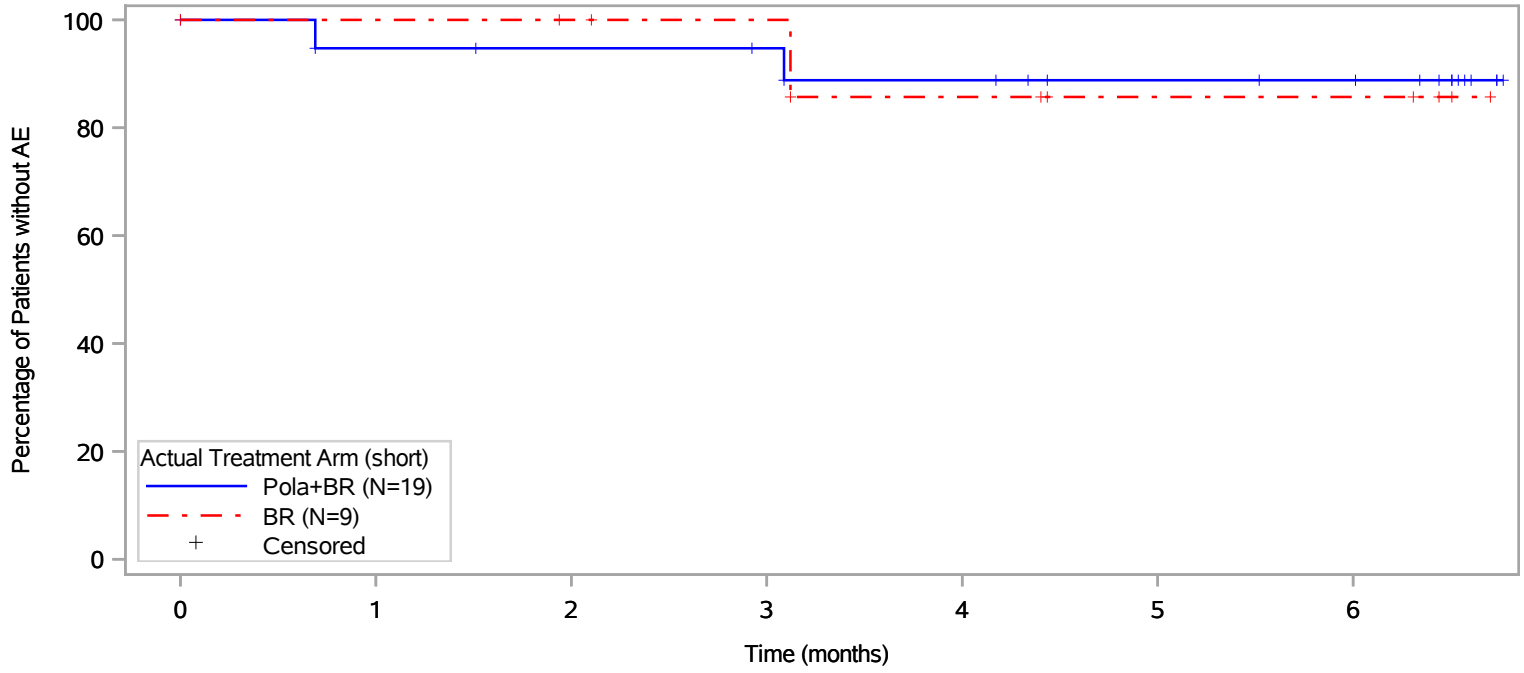
30NOV2022 21:30

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	18	17	16	15	12	11
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	2	5	6
BR (N=9)	0	0	1	2	2	4	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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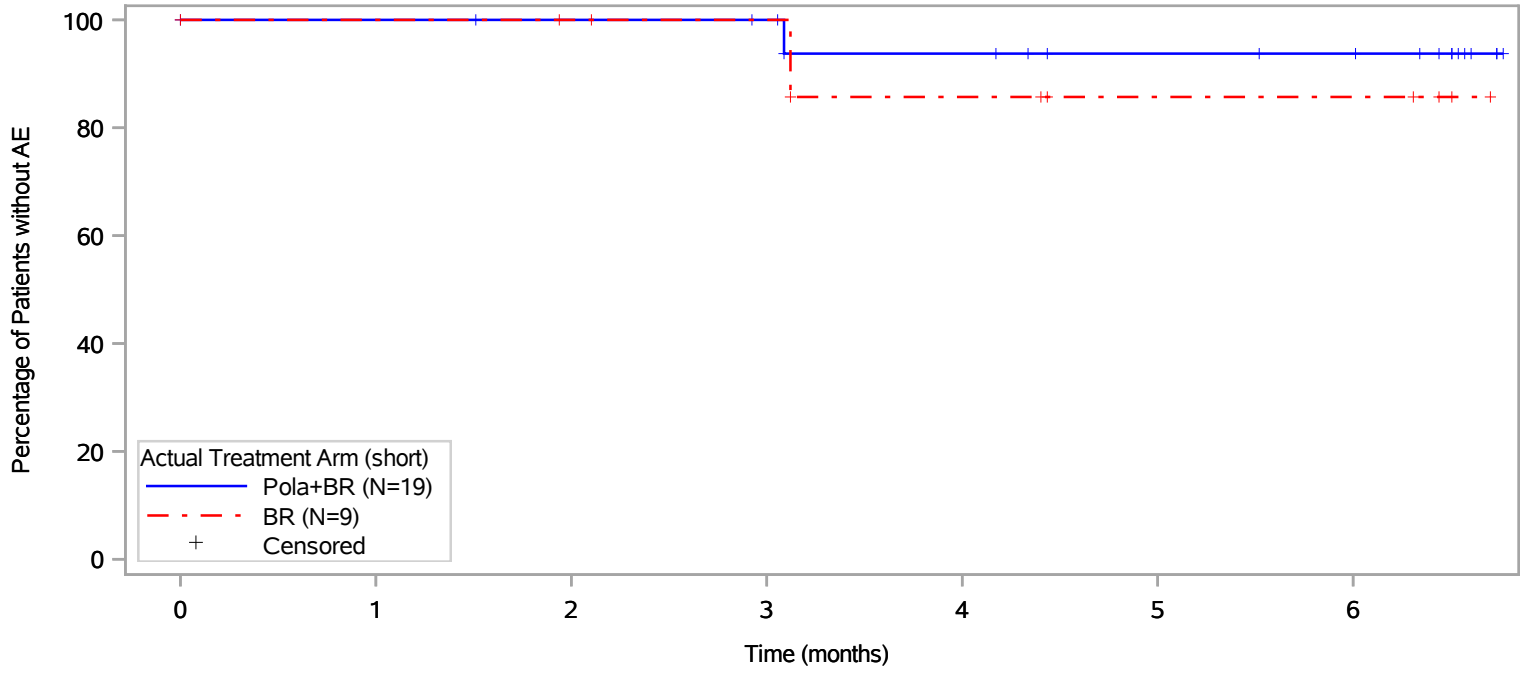
02DEC2022 4:46

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, MYELOSUPPRESSION



Patients at risk							
Pola+BR (N=19)	19	19	18	17	15	12	11
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	2	4	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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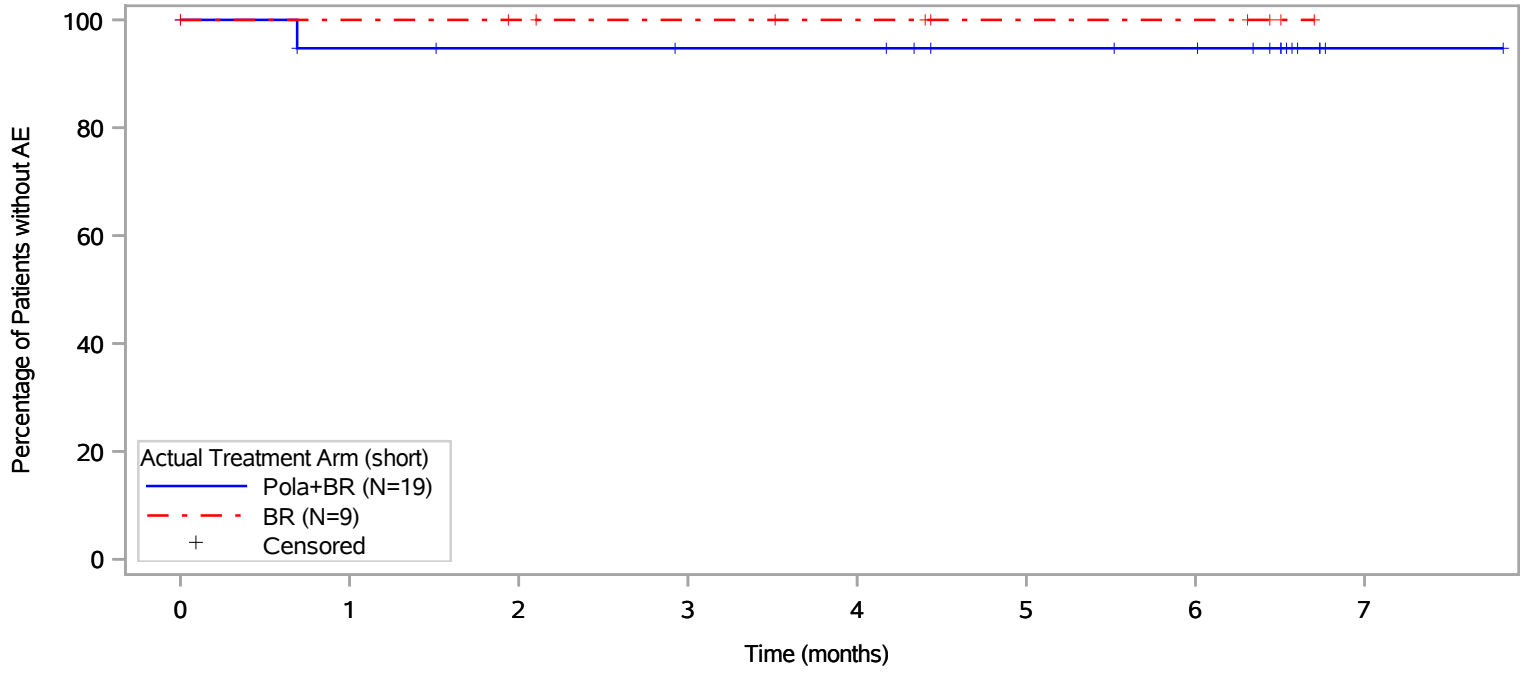
02DEC2022 4:46

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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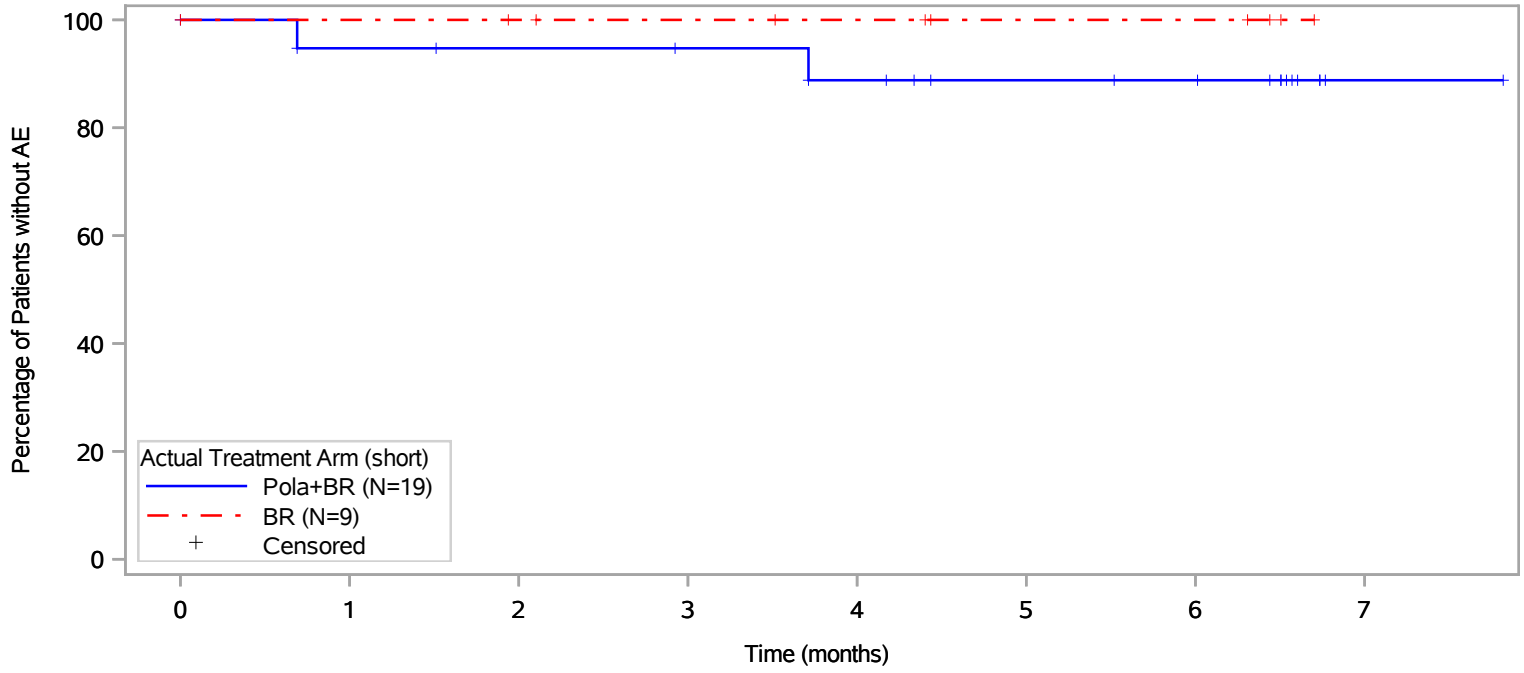
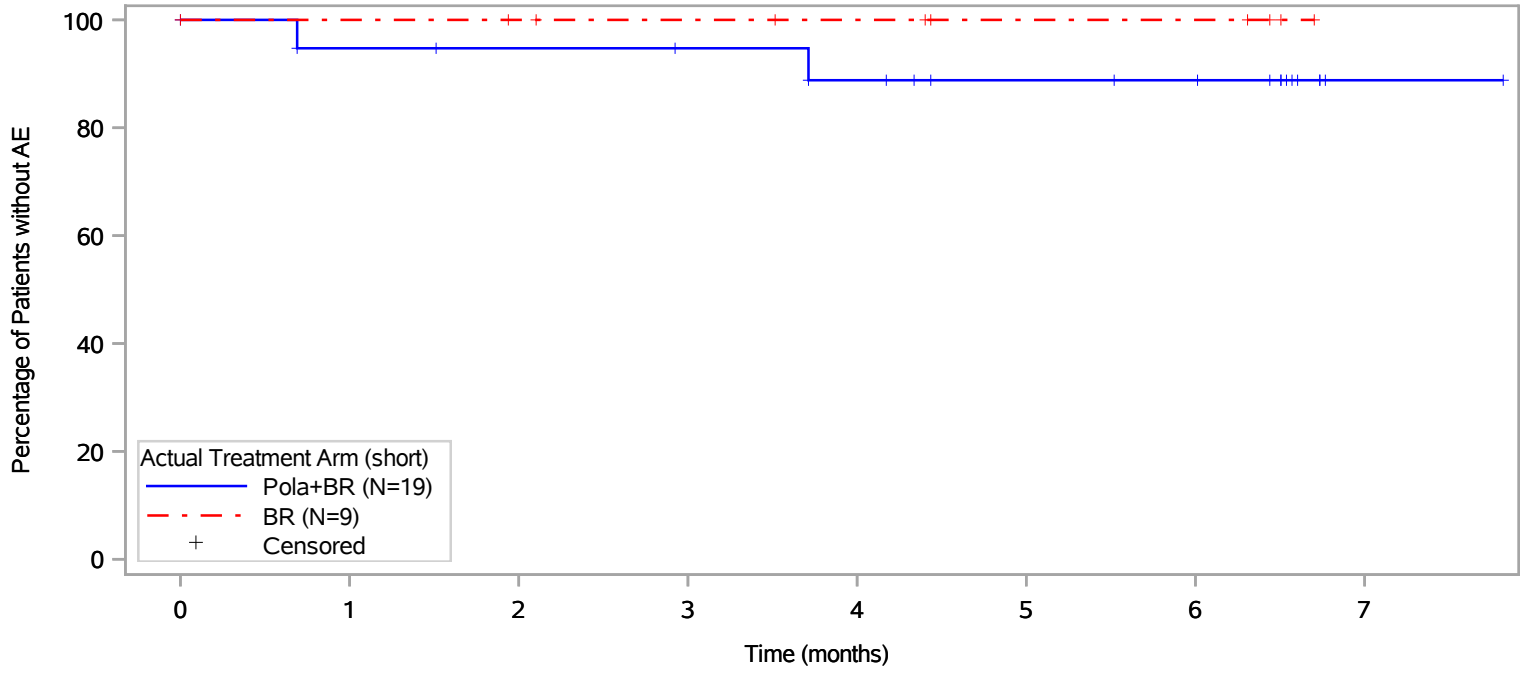
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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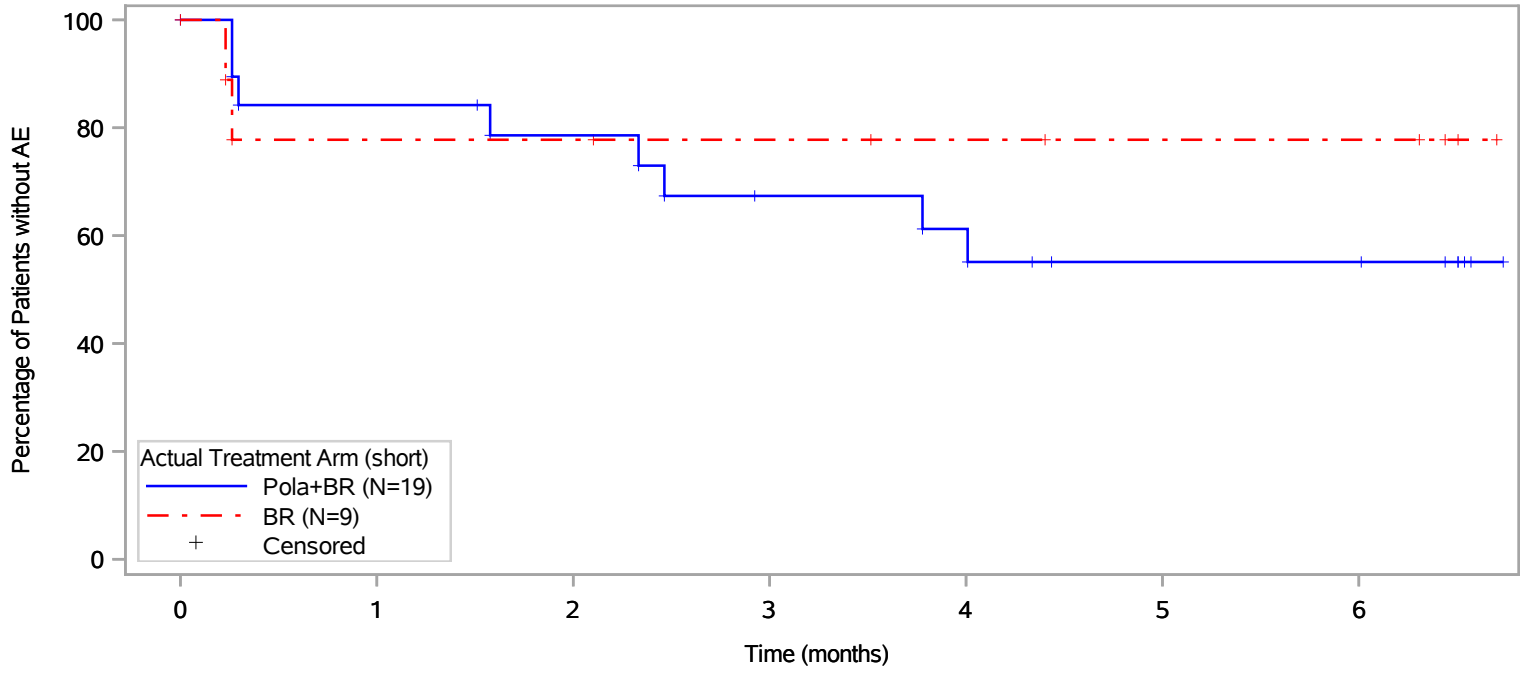
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk							
Pola+BR (N=19)	19	16	14	11	10	7	7
BR (N=9)	9	7	7	6	5	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	2	4	4
BR (N=9)	0	0	0	1	2	3	3

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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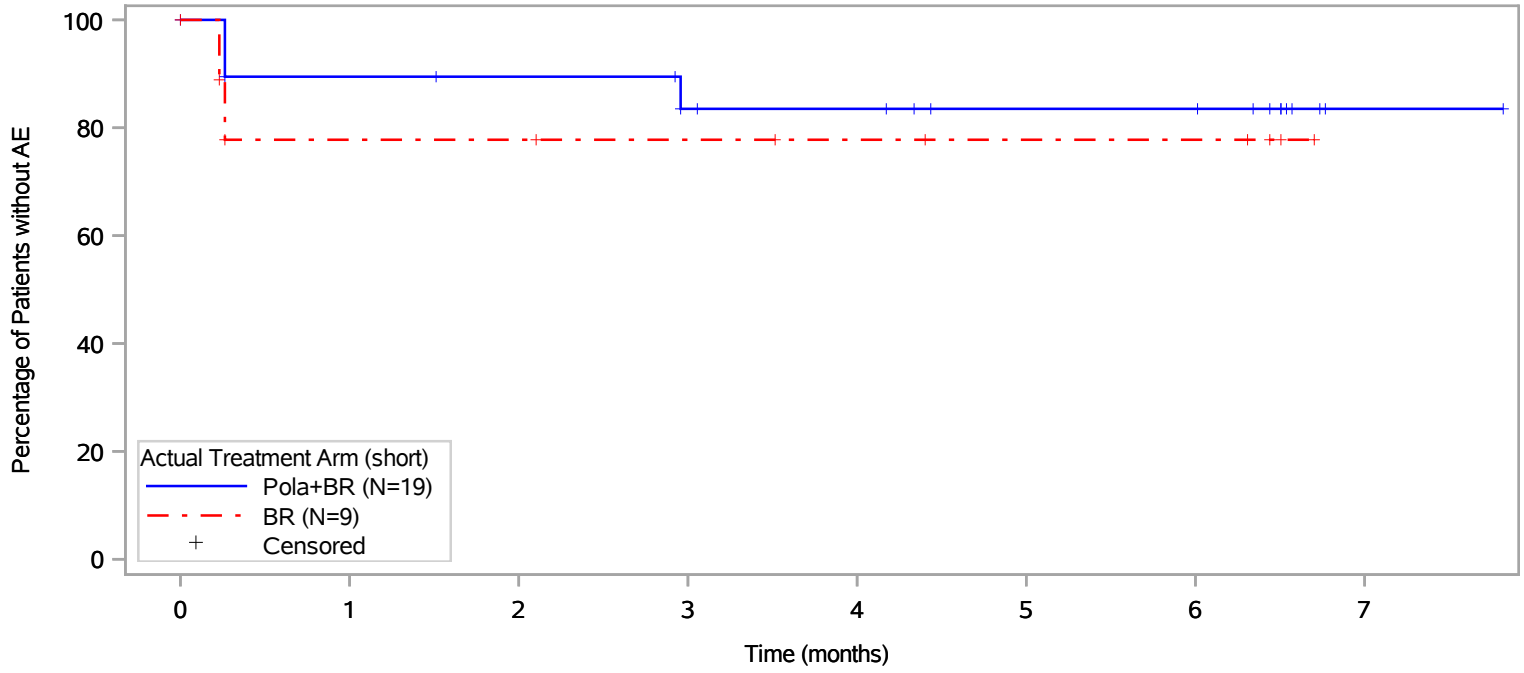
02DEC2022 4:46

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE COUNT DECREASED



Patients at risk								
Pola+BR (N=19)	19	17	16	14	13	10	10	1
BR (N=9)	9	7	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	15
BR (N=9)	0	0	0	1	2	3	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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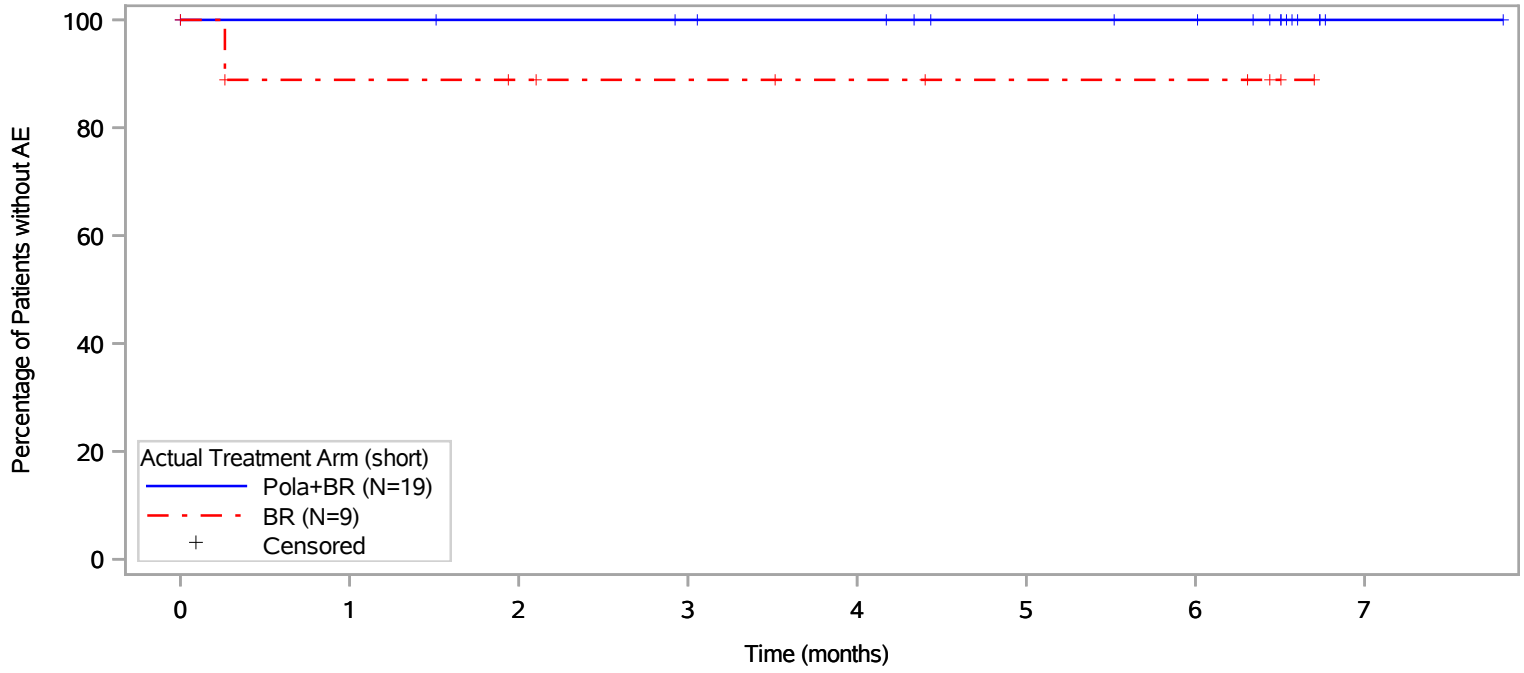
02DEC2022 4:46

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, LYMPHOCYTE PERCENTAGE DECREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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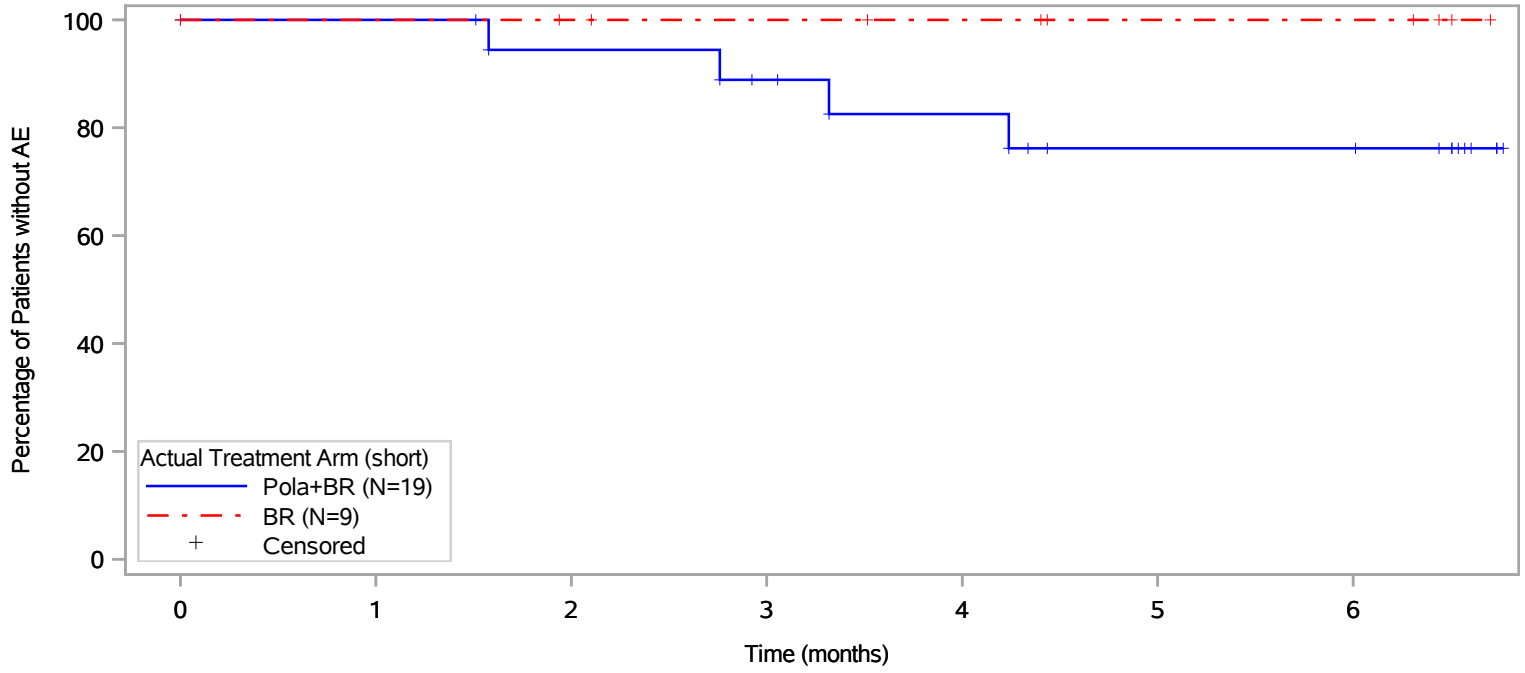
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, NEUTROPHIL COUNT DECREASED



Patients at risk							
Pola+BR (N=19)	19	19	17	15	13	10	10
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	5	5
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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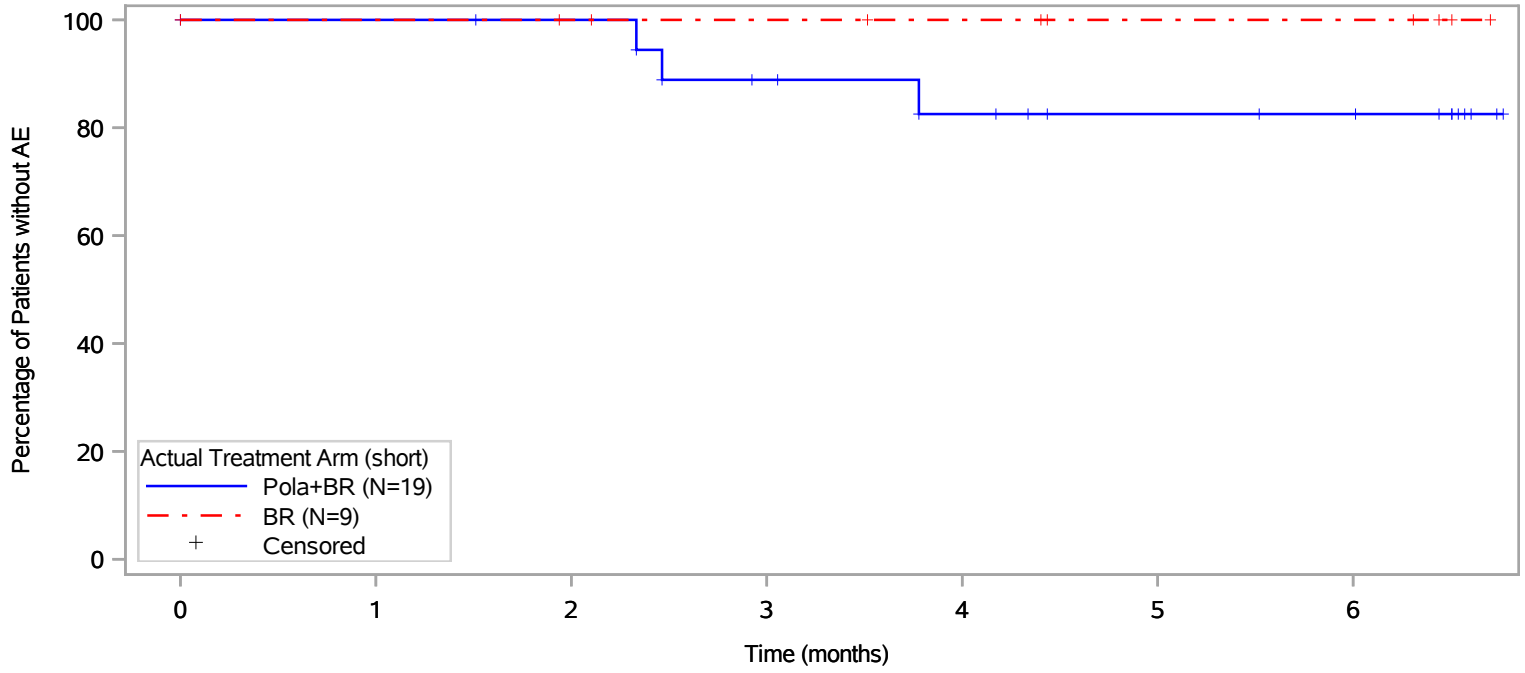
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED

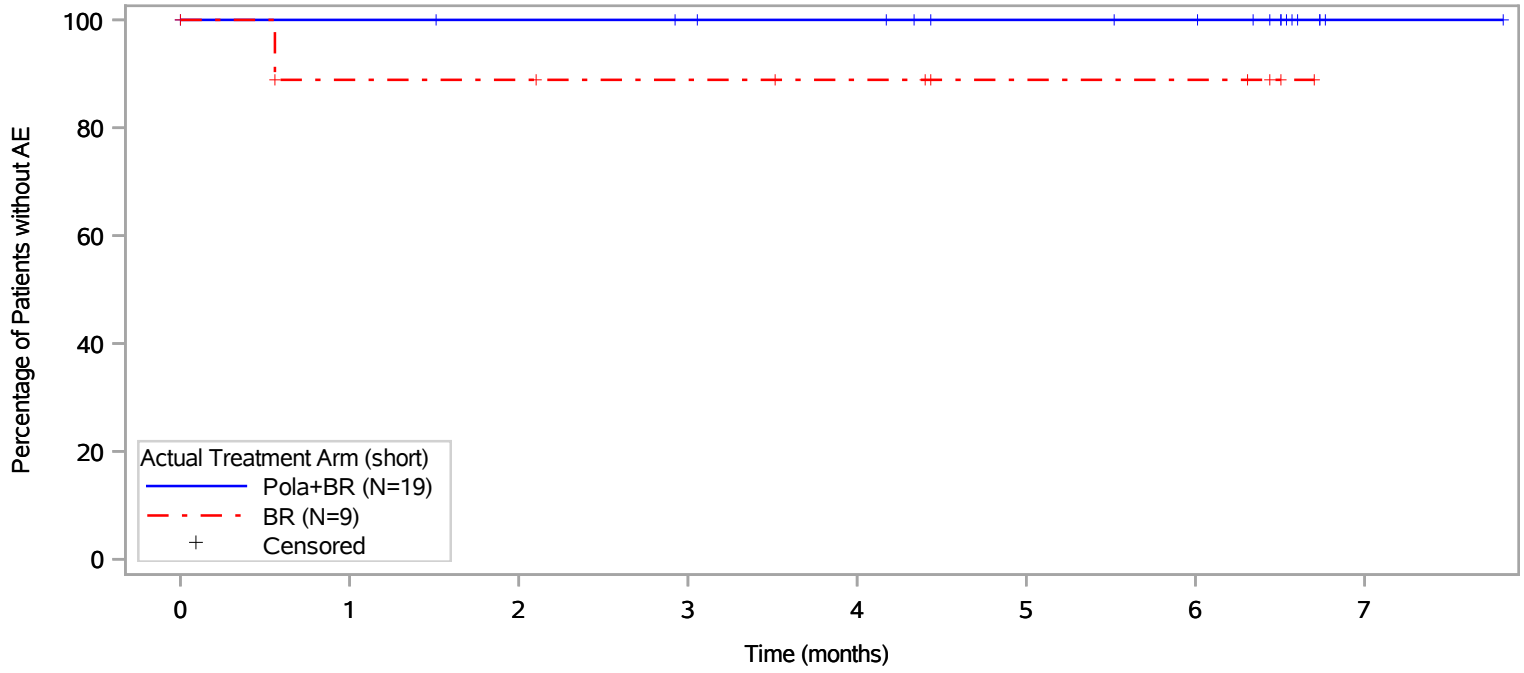


Patients at risk							
Pola+BR (N=19)	19	19	18	15	13	10	9
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR4AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 4:46

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, URINE OUTPUT DECREASED

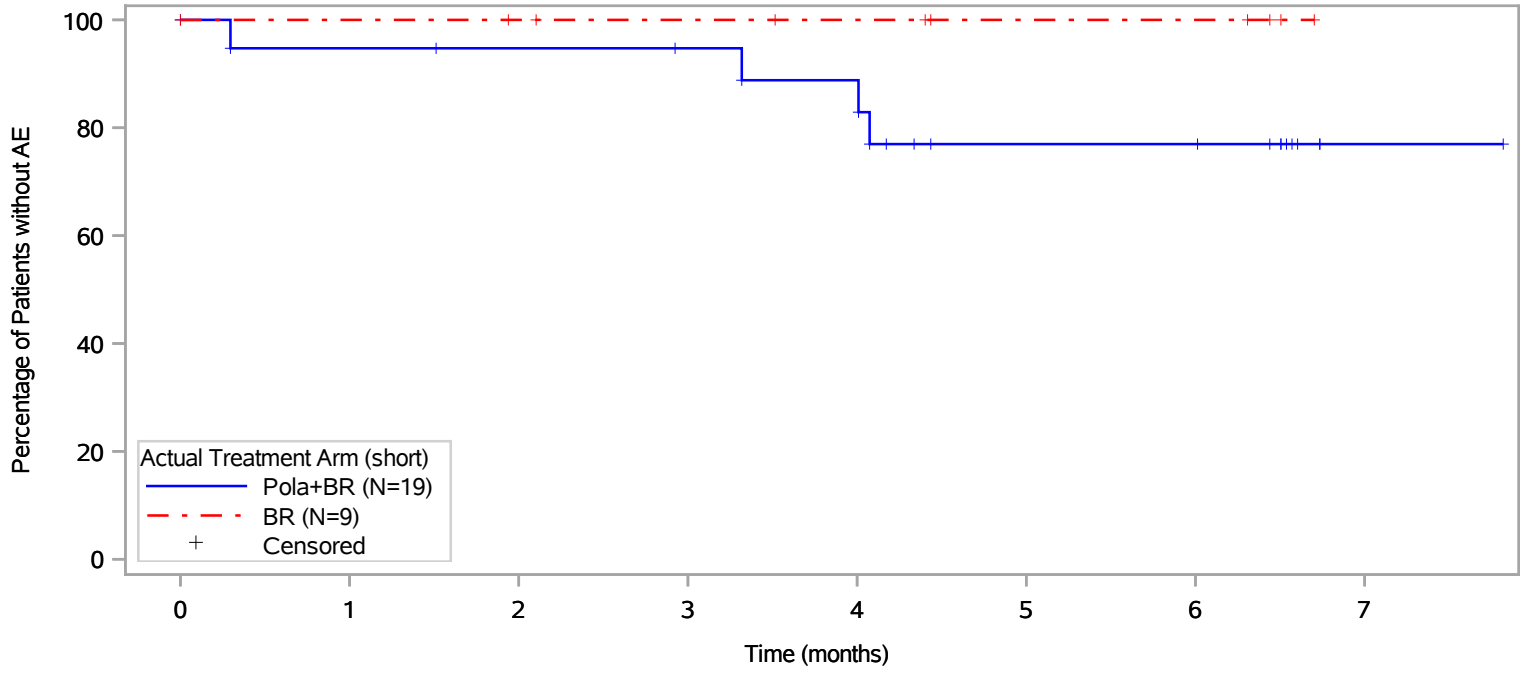


Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	0	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..CSR_Pooled/prod/output_Polarose/g_km_soc_TTGR4AE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 4:46

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 4 adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, WHITE BLOOD CELL COUNT DECREASED



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	10	10	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	14
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)				BR (N=9)						Pola + BR vs. BR						
			Patients		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
INFECTIONS AND INFESTATIONS			19	100.0	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		19	100.0	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sg1_TTGR5AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 22:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)				BR (N=9)						Pola + BR vs. BR						
			Patients		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
INFECTIONS AND INFESTATIONS		< 65	16	84.2	16	100.0	7	77.8	1	14.3	6	85.7	0.0943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	15.8	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	16	84.2	16	100.0	7	77.8	1	14.3	6	85.7	0.0943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	3	15.8	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sg1_TTGR5AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 22:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)				BR (N=9)						Pola + BR vs. BR						
			Patients		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
INFECTIONS AND INFESTATIONS		>=3	14	73.7	14	100.0	6	66.7	1	16.7	5	83.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	26.3	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	14	73.7	14	100.0	6	66.7	1	16.7	5	83.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	5	26.3	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sg1_TTGR5AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 22:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)				BR (N=9)						Pola + BR vs. BR						
			Patients		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
INFECTIONS AND INFESTATIONS		Non-Europe	19	100.0	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	19	100.0	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sg1_TTGR5AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 22:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

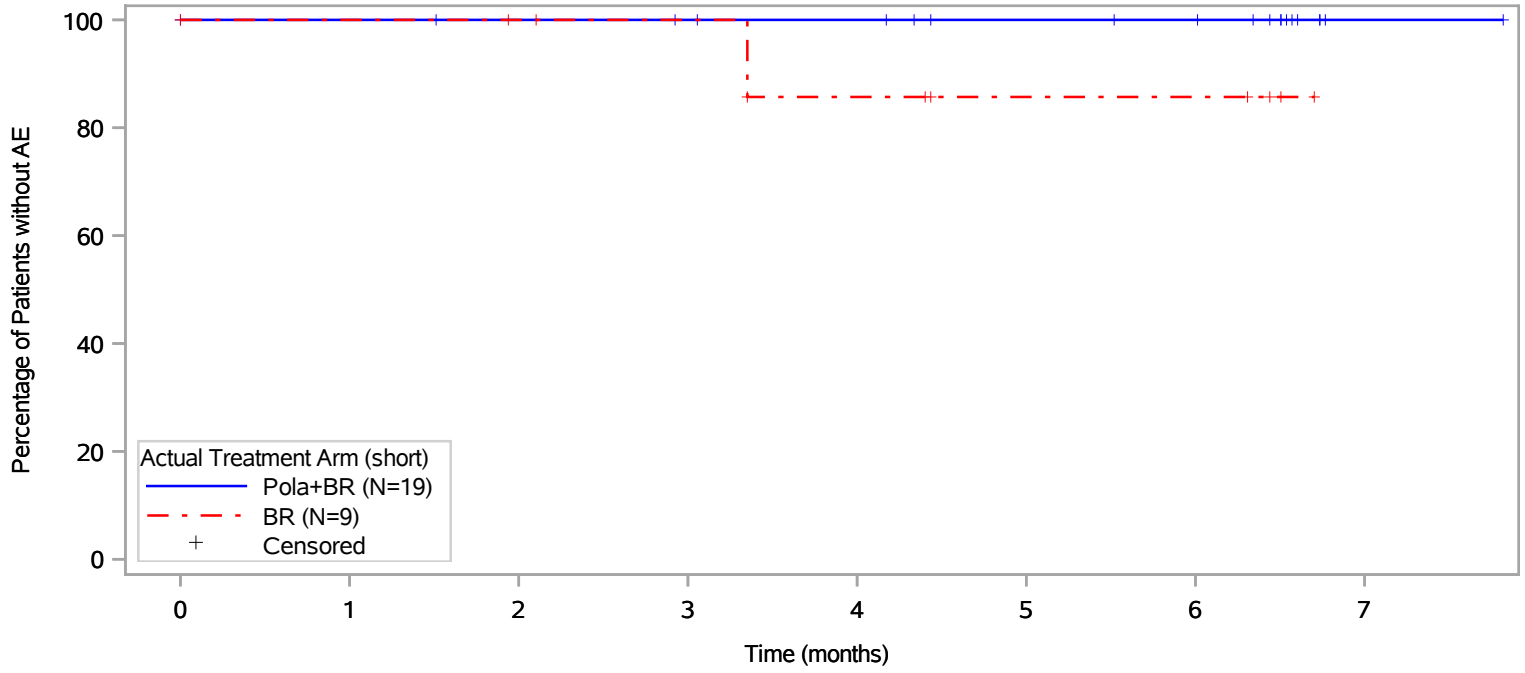
Sex

			Pola+BR (N=19)				BR (N=9)						Pola + BR vs. BR						
			Patients		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
INFECTIONS AND INFESTATIONS		Male	14	73.7	14	100.0	6	66.7	1	16.7	5	83.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	14	73.7	14	100.0	6	66.7	1	16.7	5	83.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	5	26.3	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sg1_TTGR5AE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 22:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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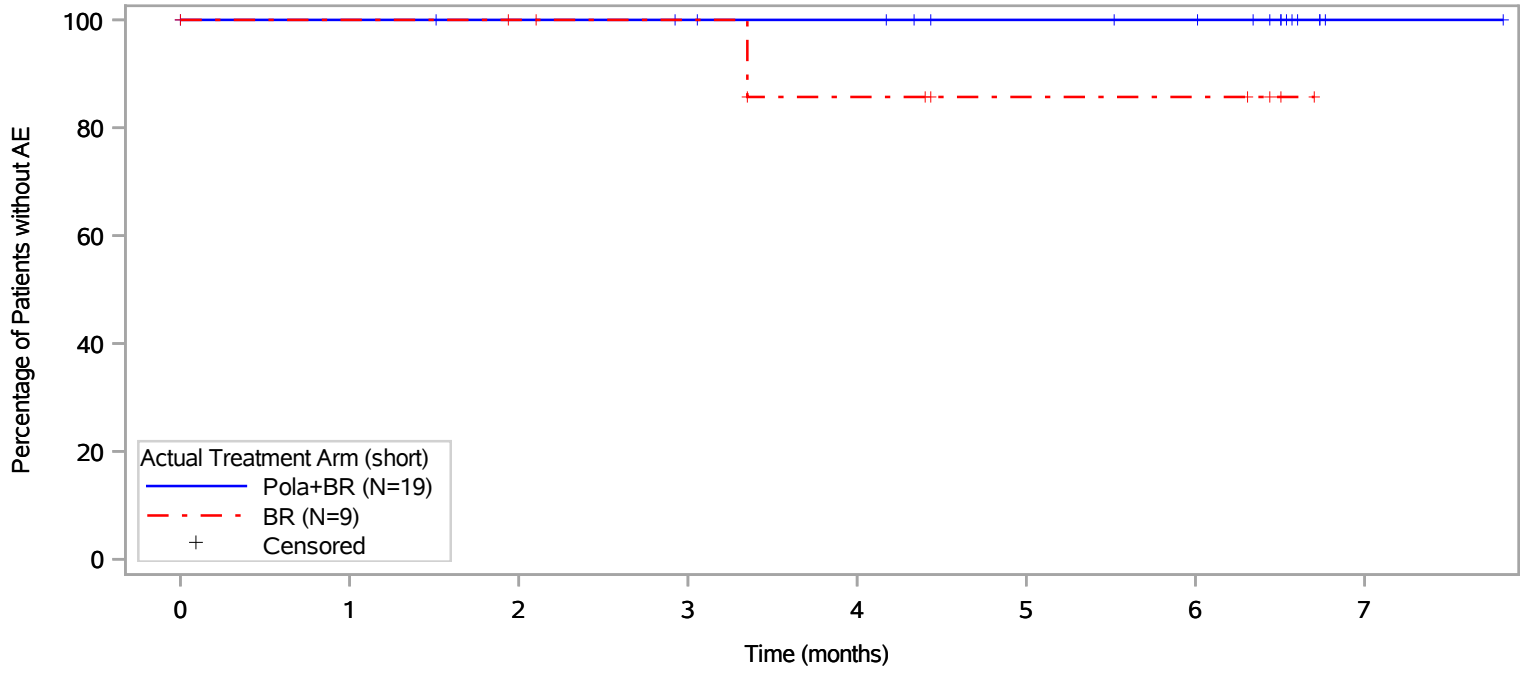
02DEC2022 5:21

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first grade 5 adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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02DEC2022 5:21

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3398	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS			19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS			19	100.0	5	26.3	14	73.7	9	100.0	1	11.1	8	88.9	0.4074	2.41	0.28	20.63		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	INFECTION		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1647	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
INVESTIGATIONS	PLATELET COUNT DECREASED		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RENAL AND URINARY DISORDERS	HAEMATURIA		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTSAE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 23:37

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3729	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5501	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		< 65	16	84.2	4	25.0	12	75.0	7	77.8	1	14.3	6	85.7	0.6993	1.54	0.17	13.80		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	16	84.2	3	18.8	13	81.3	7	77.8	0	-	7	100.0	0.2715	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.0943	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5930	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTSAE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 23:37

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		>=3	14	73.7	5	35.7	9	64.3	6	66.7	1	16.7	5	83.3	0.4852	2.11	0.25	18.13		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.1896	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0973	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6015	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae_soc.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_soc_sgl_TTSAE_L3PLUS_Polarose_SE_29365_41543.xls
30NOV2022 23:37

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3398	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	1	11.1	8	88.9	0.4074	2.41	0.28	20.63		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	0	-	9	100.0	0.1647	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5403	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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30NOV2022 23:37

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR					
			Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio				Interaction Test
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5637	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	THROMBOCYTOPENIA	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GASTROINTESTINAL DISORDERS	UPPER GASTROINTESTINAL HAEMORRHAGE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	PYREXIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS		Male	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.9892	1.02	0.10	9.83		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS		Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	INFECTION	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	INFECTION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	2	14.3	12	85.7	6	66.7	0	-	6	100.0	0.4031	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.0833	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	FEMUR FRACTURE	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
INVESTIGATIONS	PLATELET COUNT DECREASED	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
INVESTIGATIONS	PLATELET COUNT DECREASED	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS		Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS		Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RENAL AND URINARY DISORDERS	HAEMATURIA	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.6171	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RENAL AND URINARY DISORDERS	HAEMATURIA	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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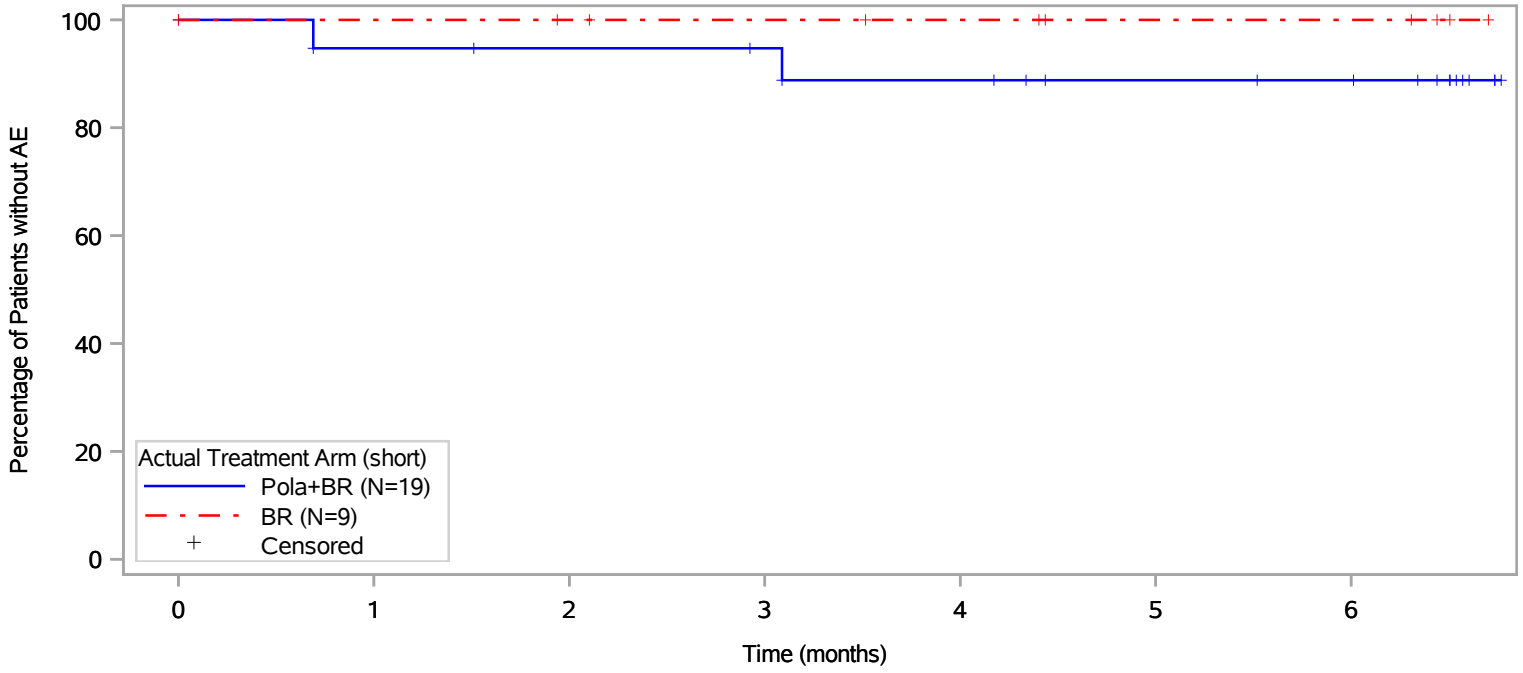
30NOV2022 23:37

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

BLOOD AND LYMPHATIC SYSTEM DISORDERS, All



Patients at risk							
Pola+BR (N=19)	19	18	17	16	15	12	11
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	2	5	6
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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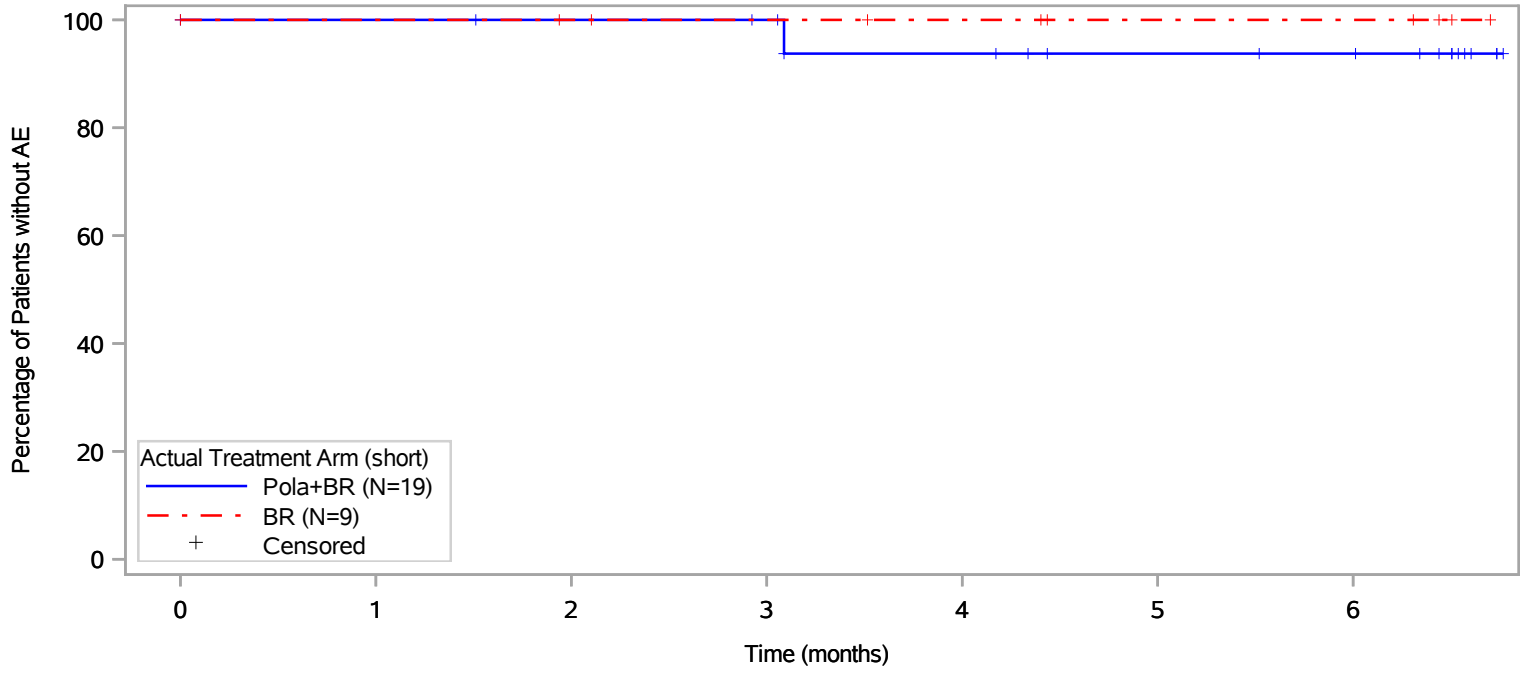
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
BLOOD AND LYMPHATIC SYSTEM DISORDERS, MYELOSUPPRESSION



Patients at risk							
Pola+BR (N=19)	19	19	18	17	15	12	11
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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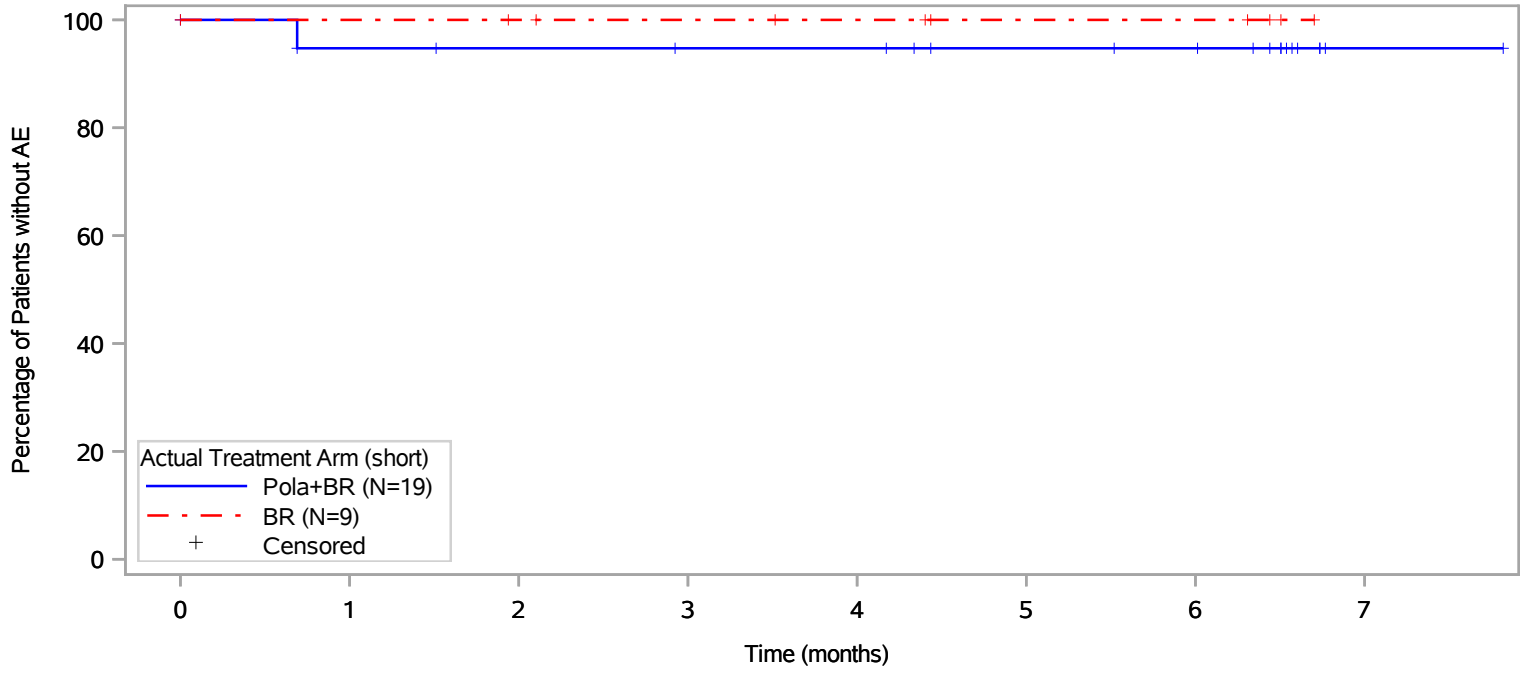
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

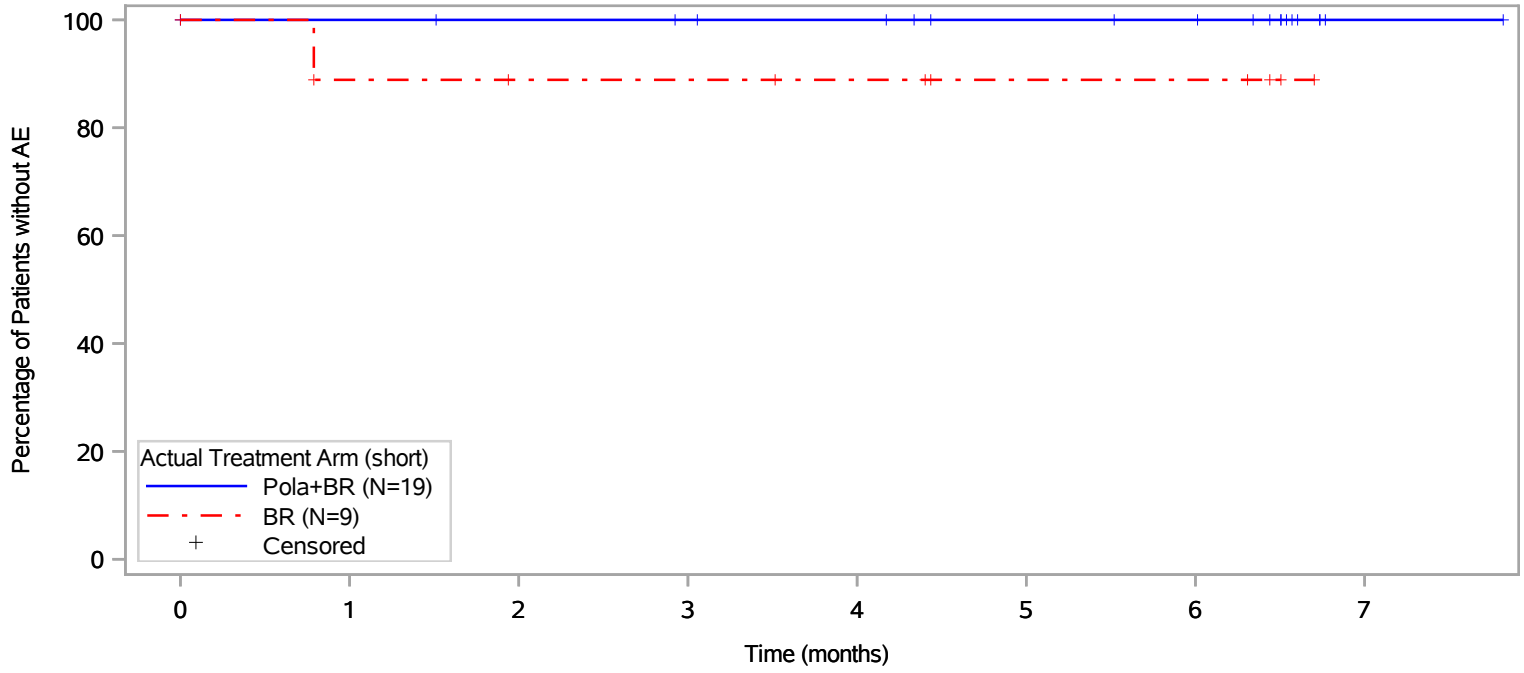
BLOOD AND LYMPHATIC SYSTEM DISORDERS, THROMBOCYTOPENIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GASTROINTESTINAL DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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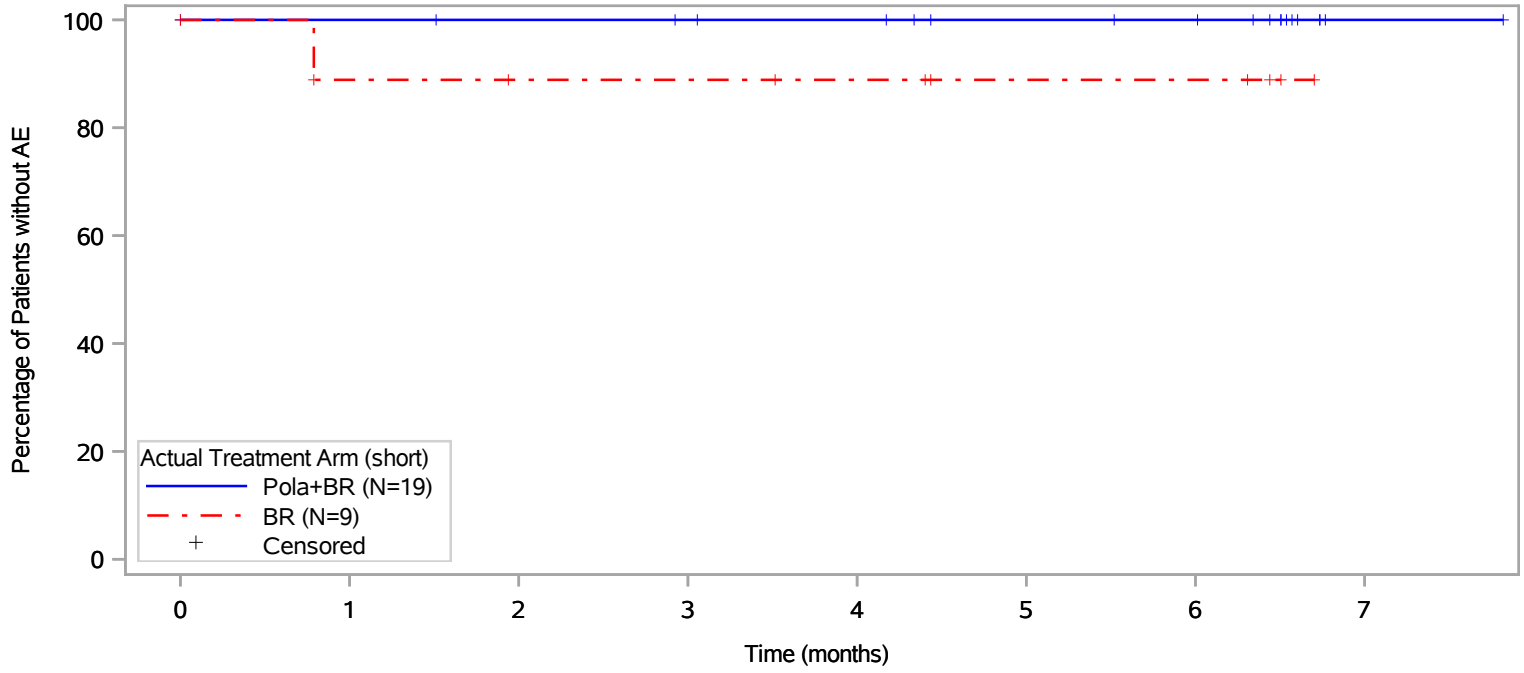
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

GASTROINTESTINAL DISORDERS, UPPER GASTROINTESTINAL HAEMORRHAGE



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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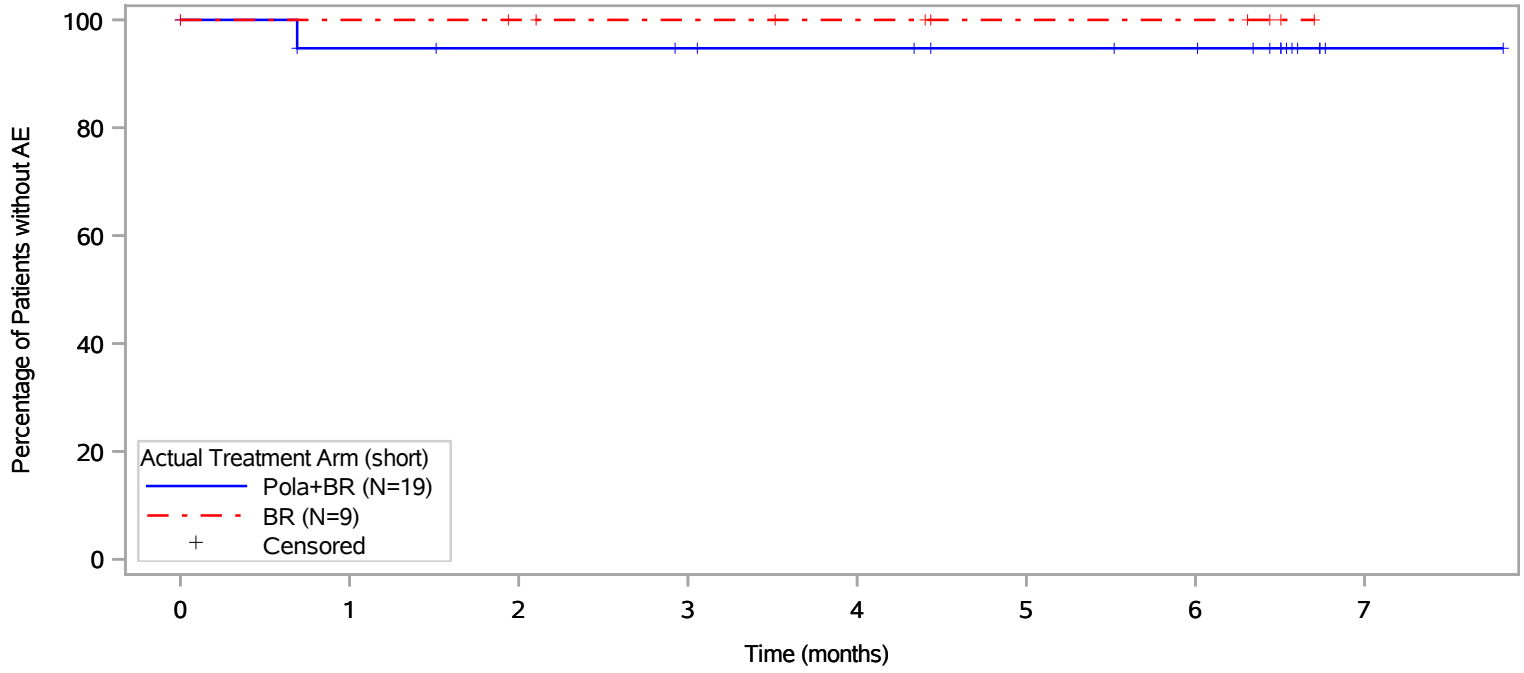
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, All



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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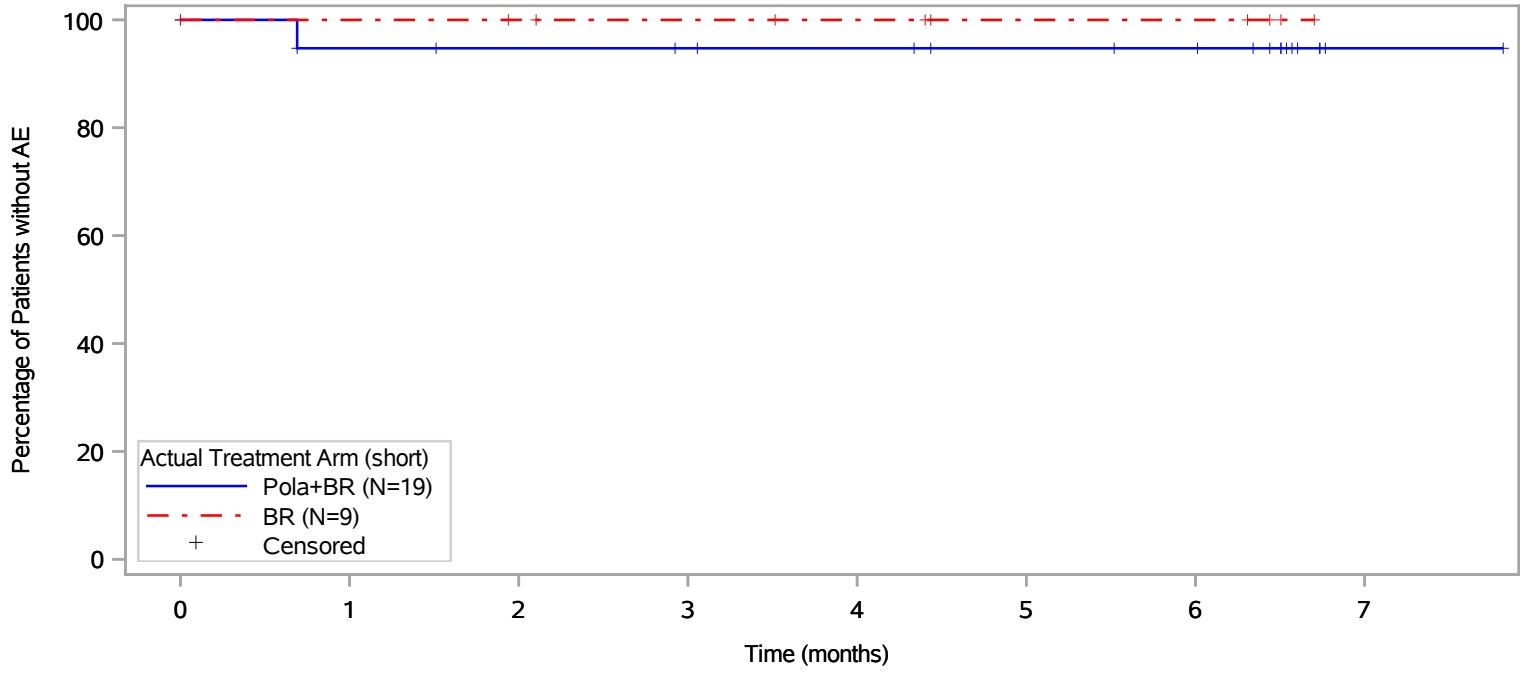
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS, PYREXIA



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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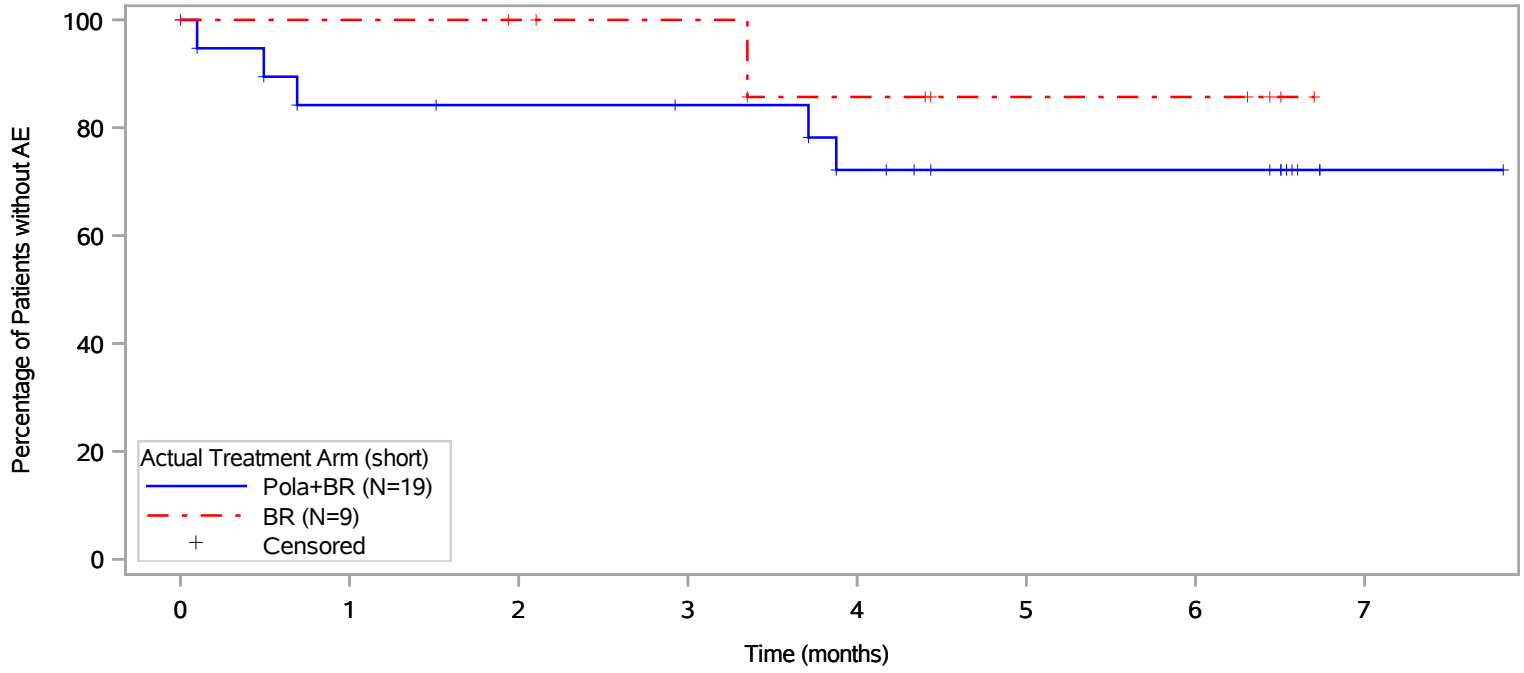
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, All



Patients at risk								
Pola+BR (N=19)	19	16	15	14	12	9	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	13
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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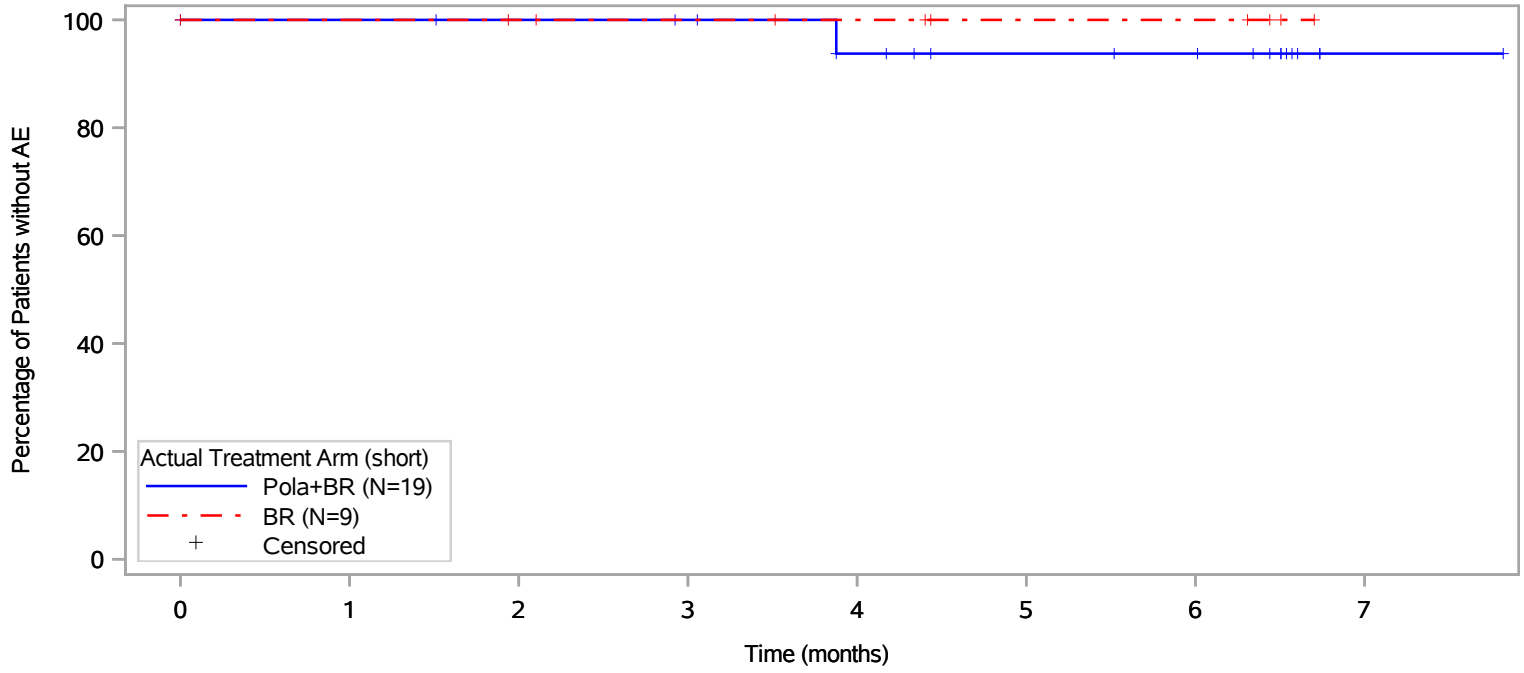
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, INFECTION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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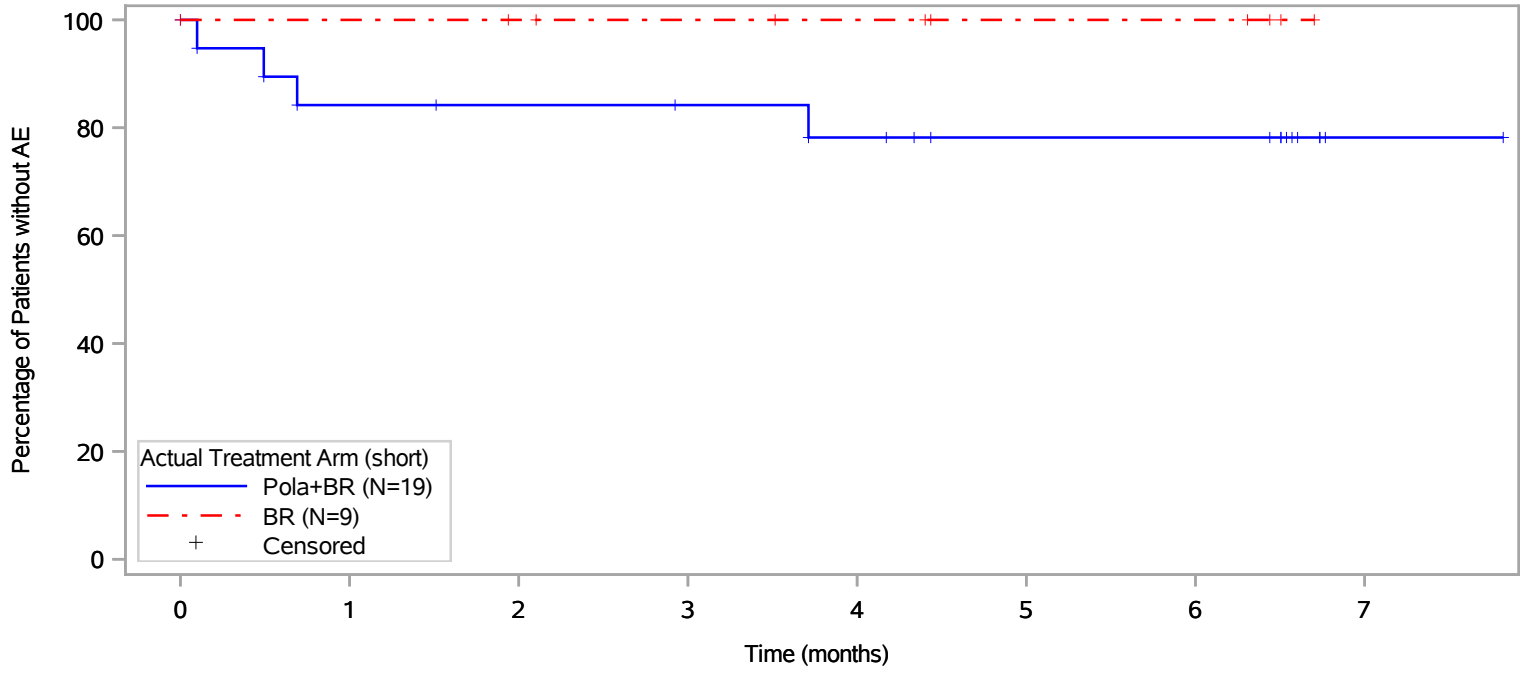
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, PNEUMONIA

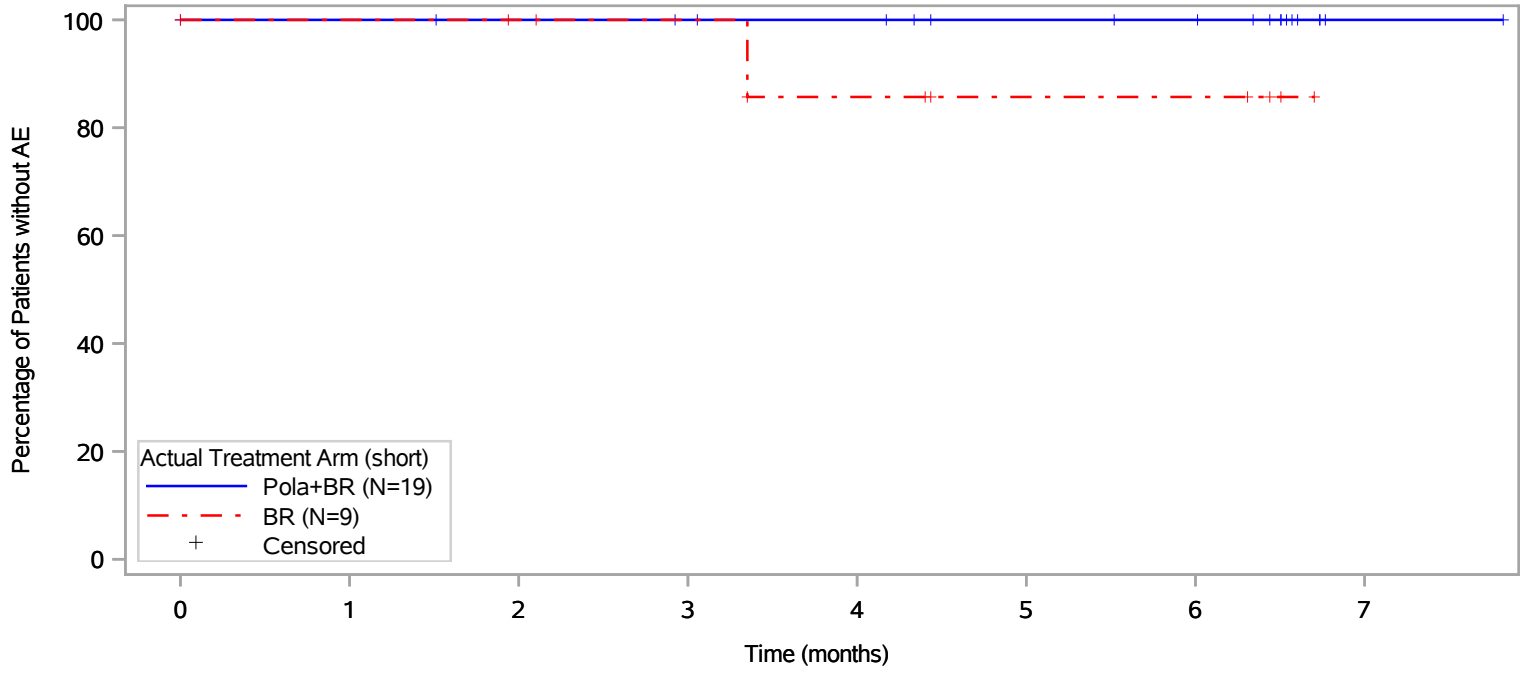


Patients at risk								
Pola+BR (N=19)	19	16	15	14	13	10	10	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	14
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_soc_TTSAE_L3PLUS_Polarose_SE_29365_41543.pdf
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INFECTIONS AND INFESTATIONS, SEPTIC SHOCK



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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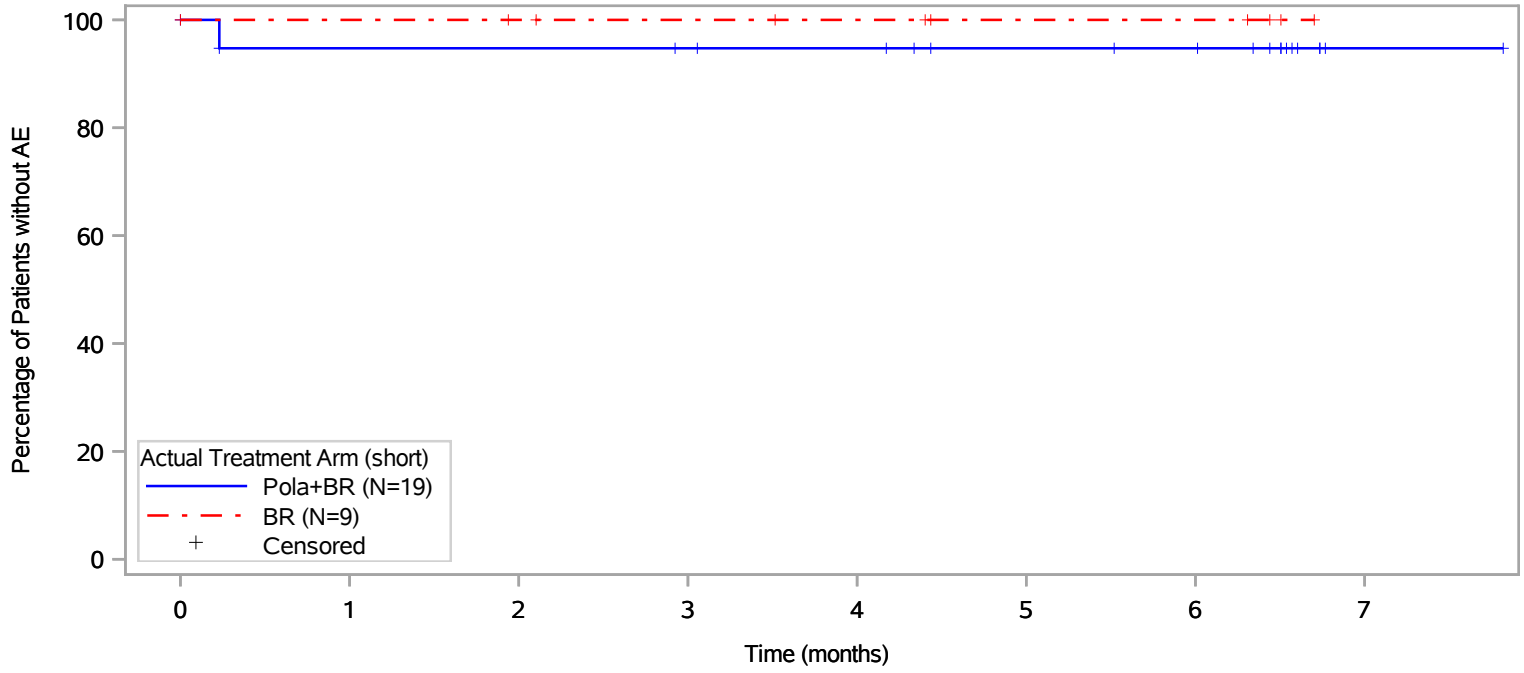
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, All



Patients at risk								
Pola+BR (N=19)	19	18	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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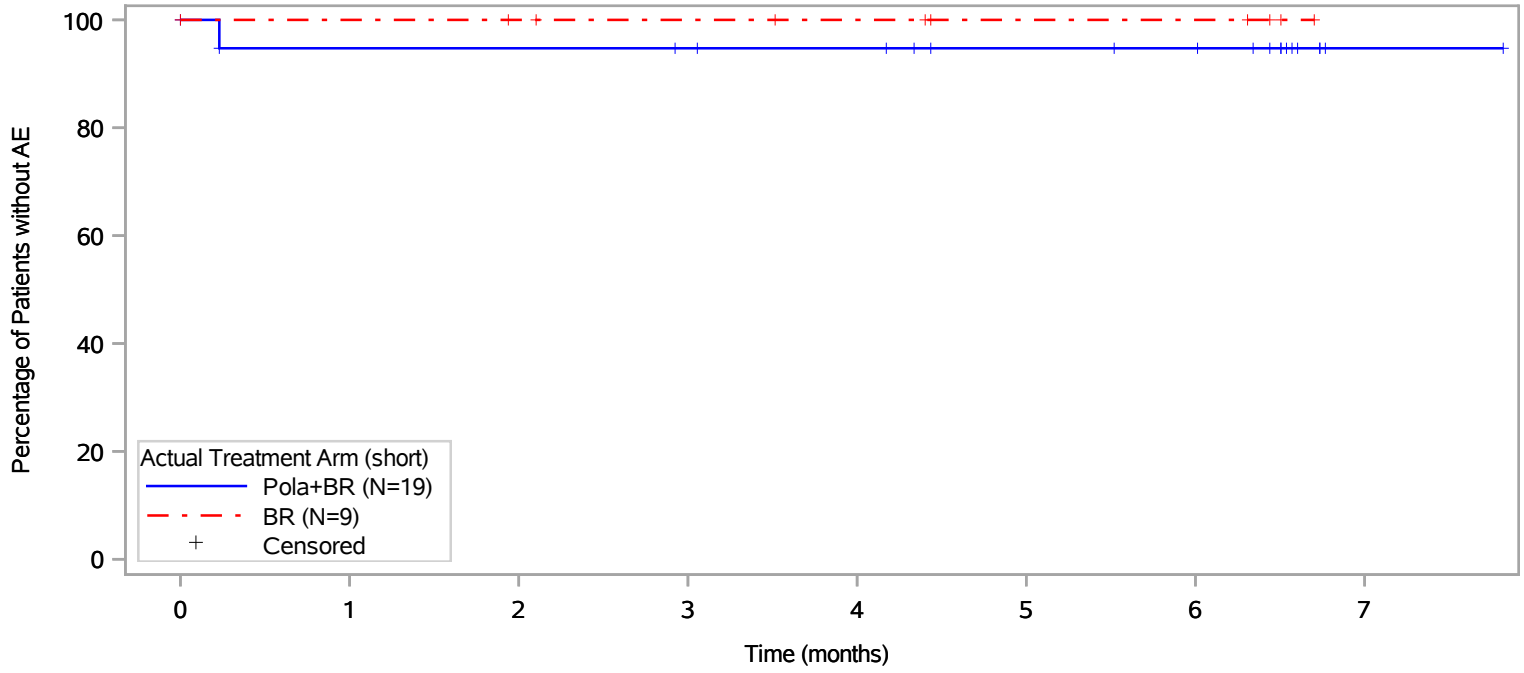
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INJURY, POISONING AND PROCEDURAL COMPLICATIONS, FEMUR FRACTURE



Patients at risk								
Pola+BR (N=19)	19	18	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	5	6	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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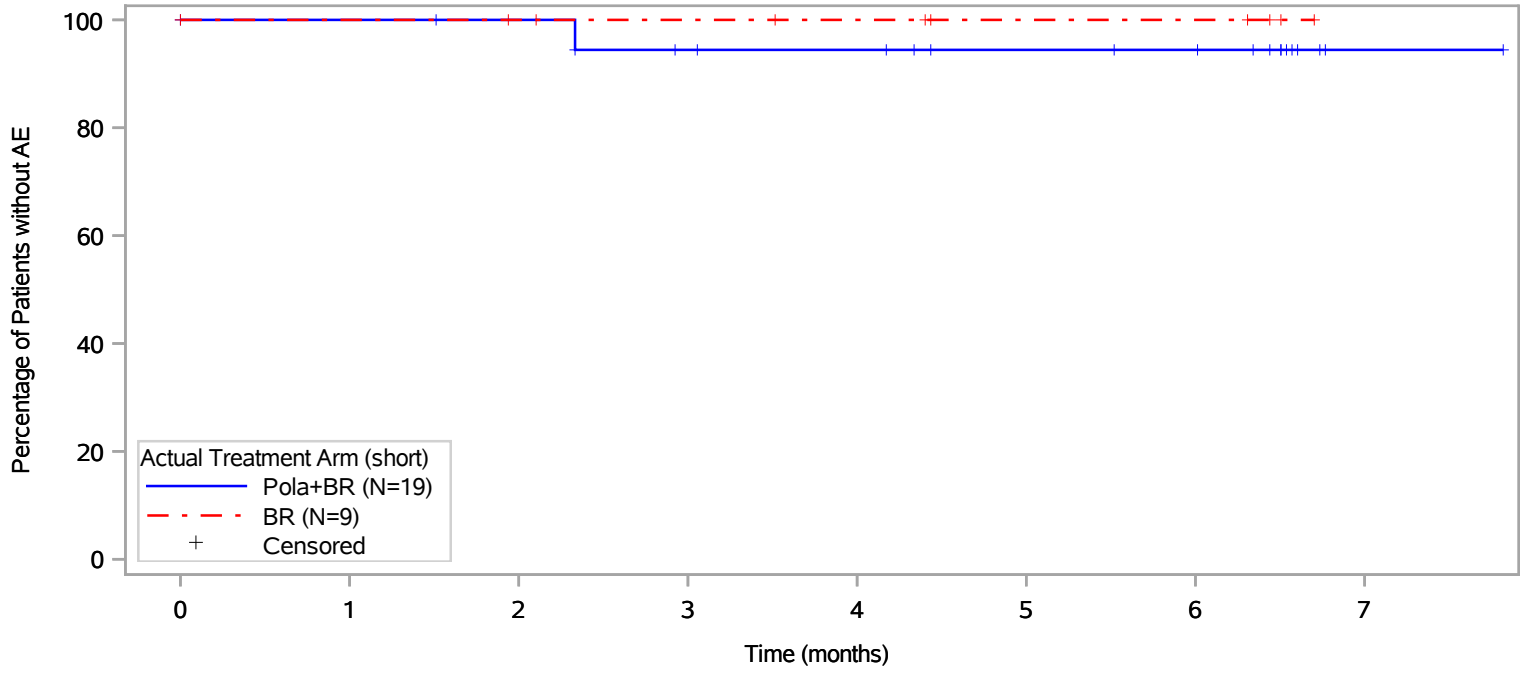
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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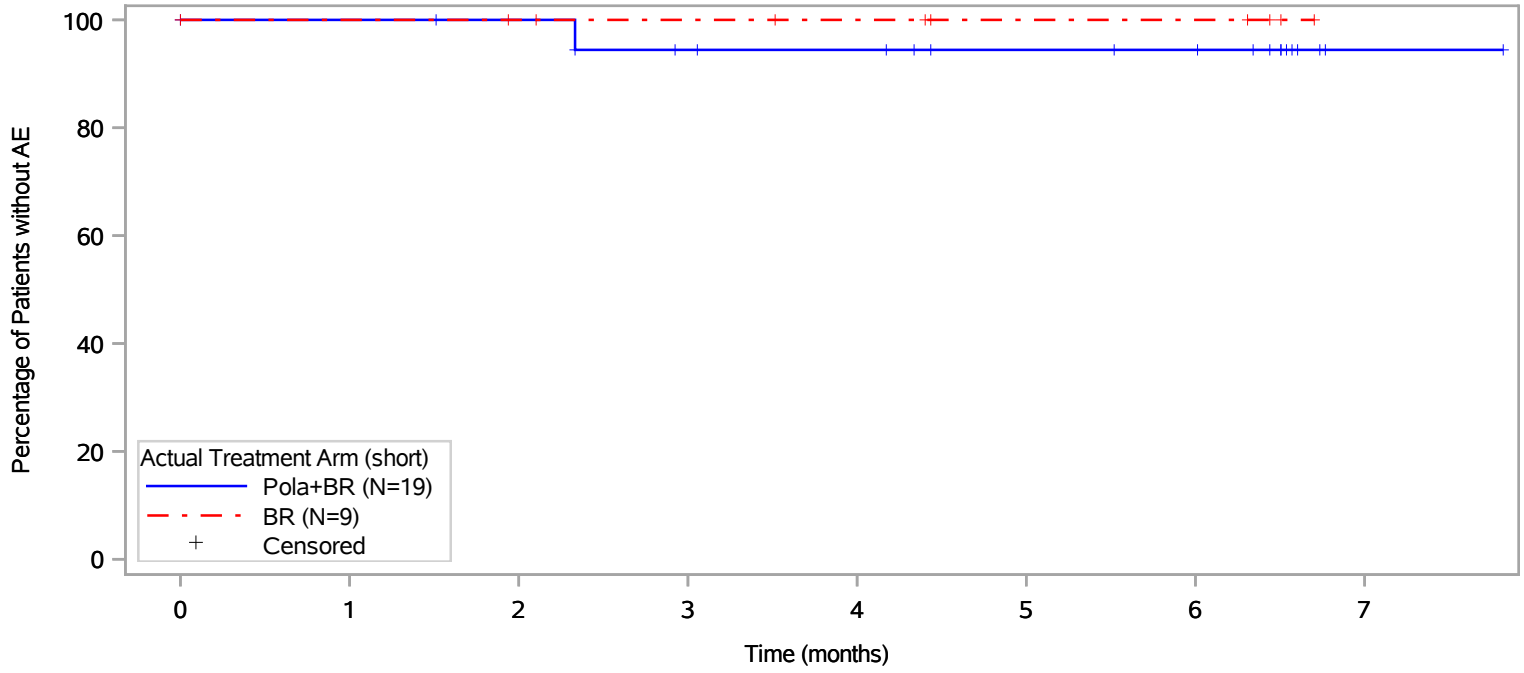
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
INVESTIGATIONS, PLATELET COUNT DECREASED



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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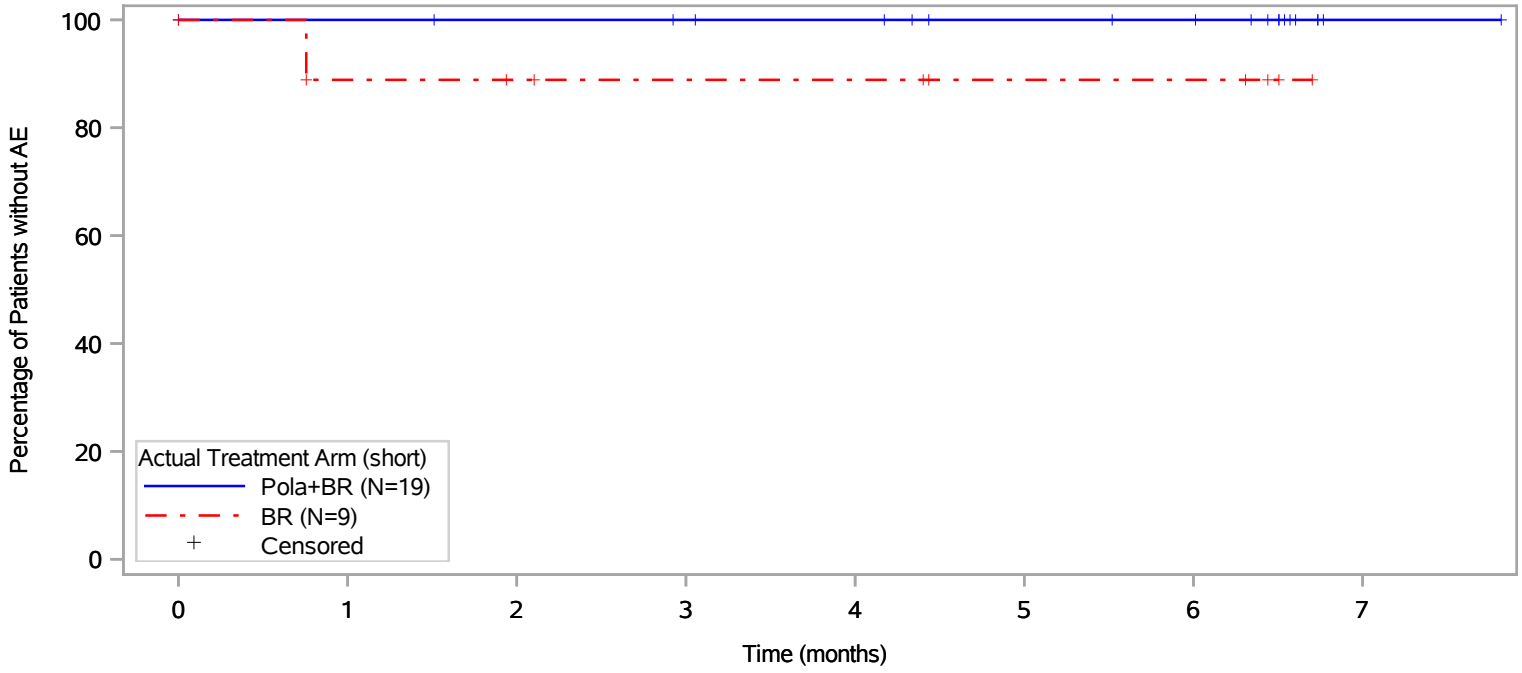
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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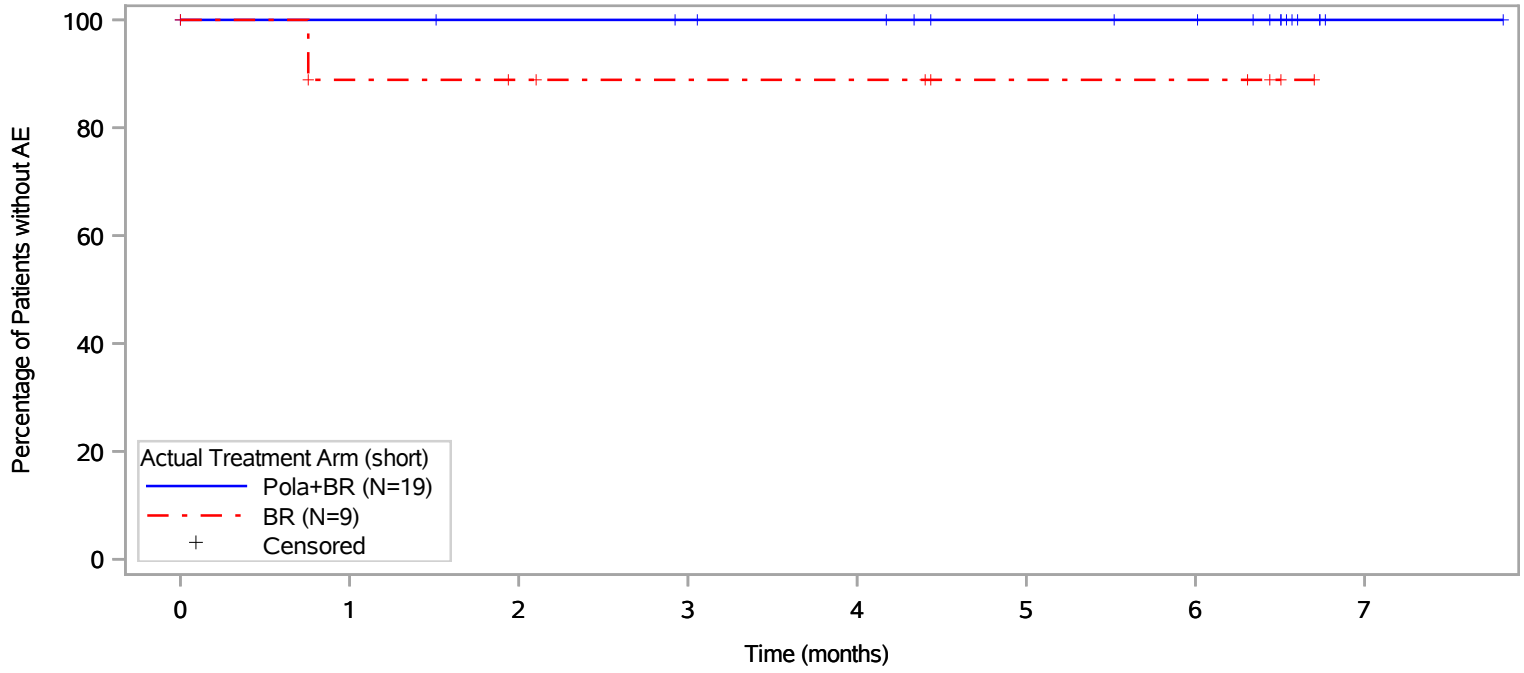
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS, INTERVERTEBRAL DISC PROTRUSION



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

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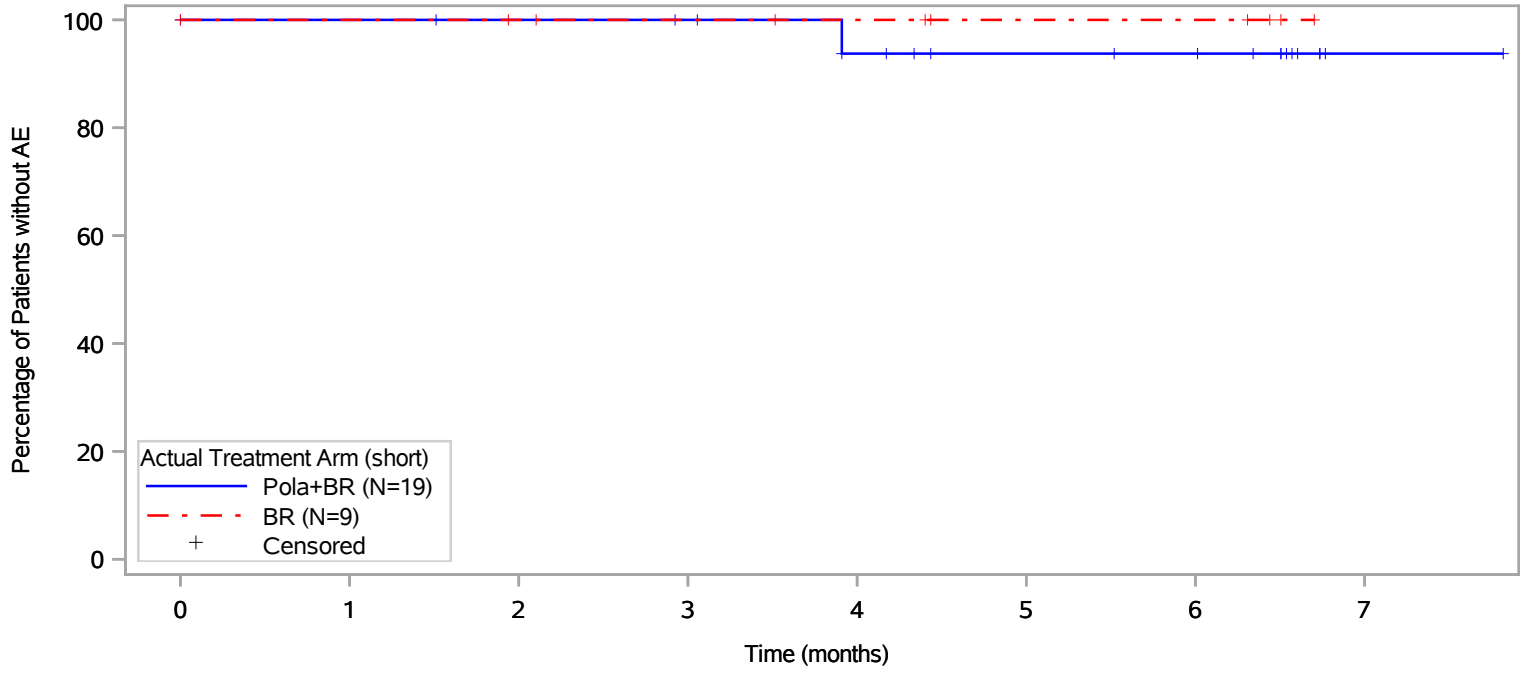
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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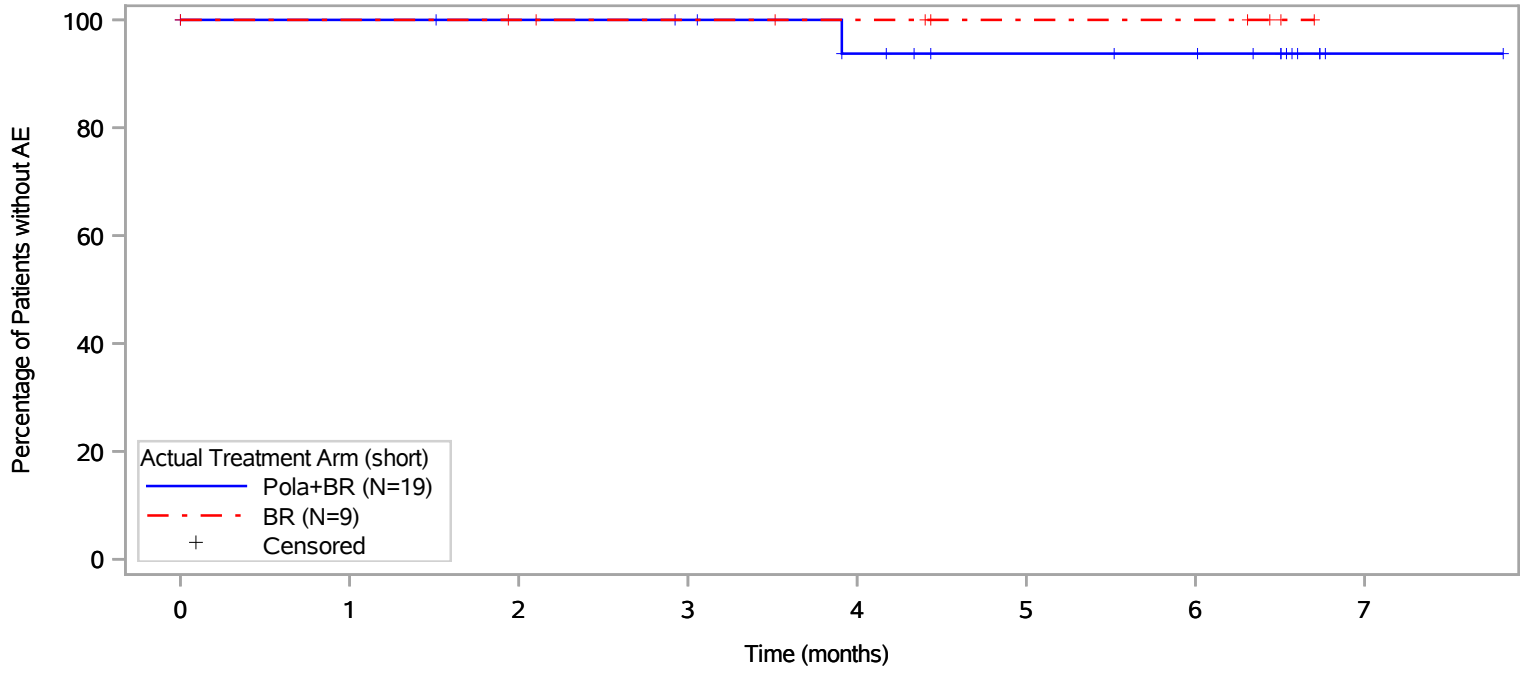
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RENAL AND URINARY DISORDERS, HAEMATURIA



Patients at risk								
Pola+BR (N=19)	19	19	18	17	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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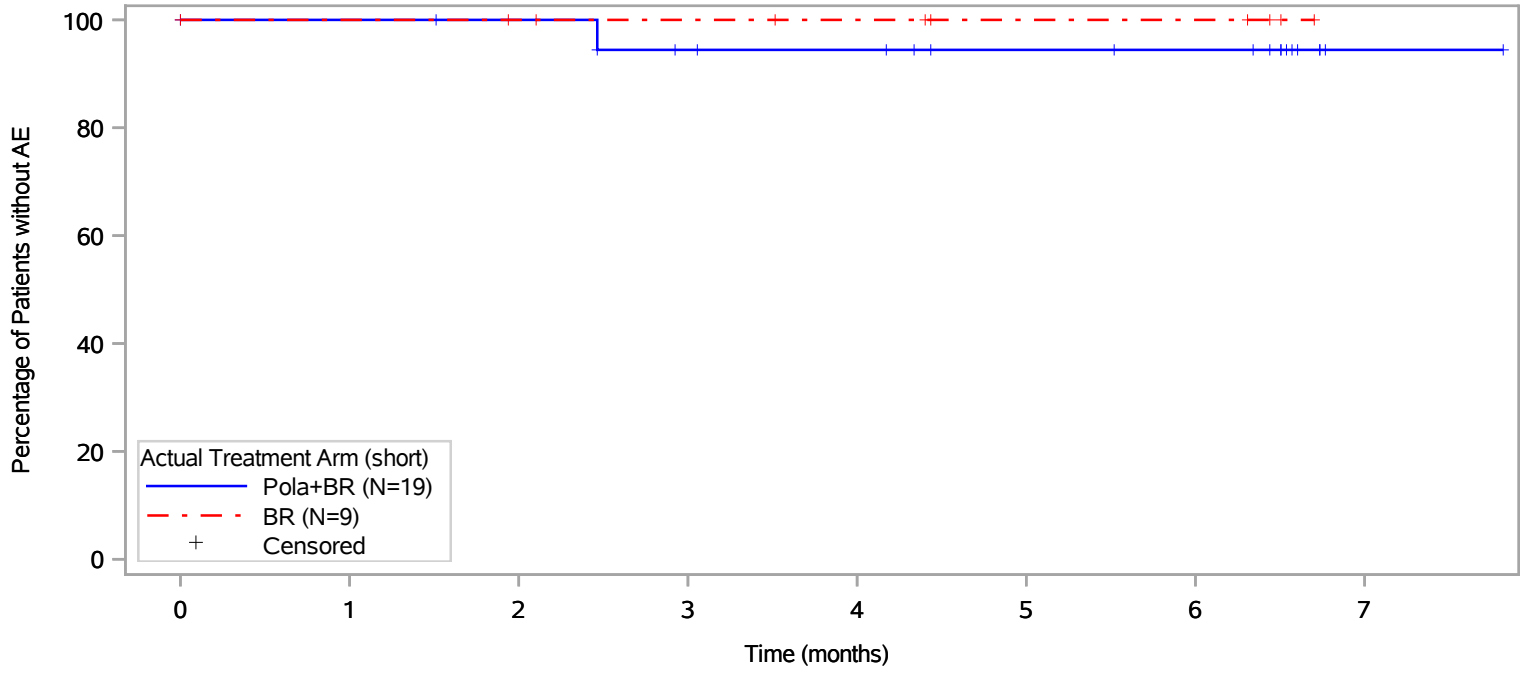
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, All



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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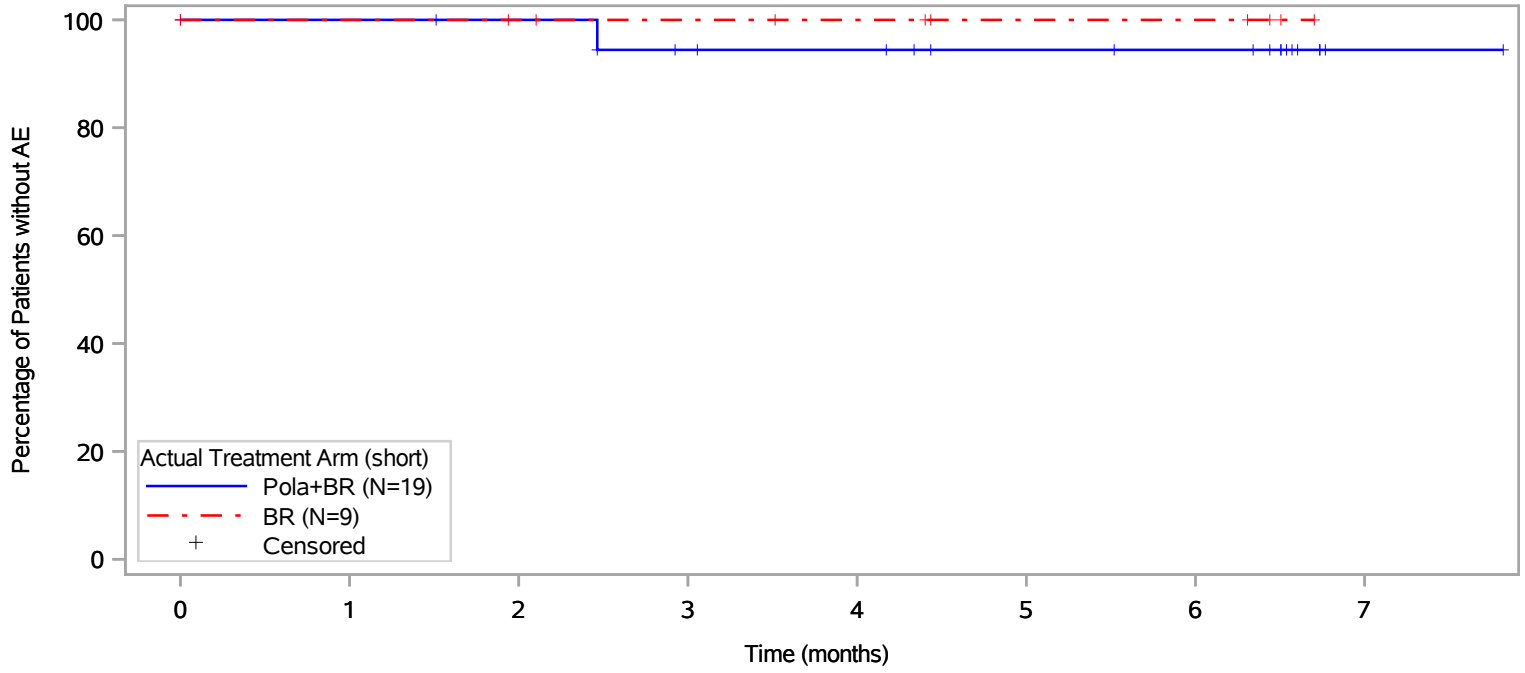
02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first serious adverse event
STUDIES: GO29365, YO41543
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS, INTERSTITIAL LUNG DISEASE



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..1077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km_soc.sas
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02DEC2022 6:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

All

			Pola+BR (N=19)				BR (N=9)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS			19	100.0	0	-	9	100.0	1	11.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION		19	100.0	0	-	9	100.0	1	11.1
INFECTIONS AND INFESTATIONS			19	100.0	2	10.5	9	100.0	1	11.1
INFECTIONS AND INFESTATIONS	PNEUMONIA		19	100.0	2	10.5	9	100.0	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK		19	100.0	0	-	9	100.0	1	11.1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			19	100.0	0	-	9	100.0	1	11.1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION		19	100.0	0	-	9	100.0	1	11.1
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS			19	100.0	1	5.3	9	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE		19	100.0	1	5.3	9	100.0	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_soc_descriptive_sg1_TTWDAE_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 17:55

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Age (years)

			Pola+BR (N=19)				BR (N=9)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		< 65	16	84.2	0	-	7	77.8	1	14.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>= 65	3	15.8	0	-	2	22.2	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	< 65	16	84.2	0	-	7	77.8	1	14.3
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>= 65	3	15.8	0	-	2	22.2	0	-
INFECTIONS AND INFESTATIONS		< 65	16	84.2	2	12.5	7	77.8	1	14.3
INFECTIONS AND INFESTATIONS		>= 65	3	15.8	0	-	2	22.2	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	< 65	16	84.2	2	12.5	7	77.8	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>= 65	3	15.8	0	-	2	22.2	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	< 65	16	84.2	0	-	7	77.8	1	14.3
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>= 65	3	15.8	0	-	2	22.2	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		< 65	16	84.2	0	-	7	77.8	1	14.3
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>= 65	3	15.8	0	-	2	22.2	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	< 65	16	84.2	0	-	7	77.8	1	14.3
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>= 65	3	15.8	0	-	2	22.2	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		< 65	16	84.2	1	6.3	7	77.8	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>= 65	3	15.8	0	-	2	22.2	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	< 65	16	84.2	1	6.3	7	77.8	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>= 65	3	15.8	0	-	2	22.2	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:55

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

IPI at study entry

			Pola+BR (N=19)				BR (N=9)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		>=3	14	73.7	0	-	6	66.7	1	16.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS		<3	5	26.3	0	-	3	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	>=3	14	73.7	0	-	6	66.7	1	16.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	<3	5	26.3	0	-	3	33.3	0	-
INFECTIONS AND INFESTATIONS		>=3	14	73.7	2	14.3	6	66.7	1	16.7
INFECTIONS AND INFESTATIONS		<3	5	26.3	0	-	3	33.3	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	>=3	14	73.7	2	14.3	6	66.7	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	<3	5	26.3	0	-	3	33.3	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	>=3	14	73.7	0	-	6	66.7	1	16.7
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	<3	5	26.3	0	-	3	33.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		>=3	14	73.7	0	-	6	66.7	1	16.7
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		<3	5	26.3	0	-	3	33.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	>=3	14	73.7	0	-	6	66.7	1	16.7
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	<3	5	26.3	0	-	3	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		>=3	14	73.7	1	7.1	6	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		<3	5	26.3	0	-	3	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	>=3	14	73.7	1	7.1	6	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	<3	5	26.3	0	-	3	33.3	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:55

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Geographic region

			Pola+BR (N=19)				BR (N=9)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Non-Europe	19	100.0	0	-	9	100.0	1	11.1
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Non-Europe	19	100.0	0	-	9	100.0	1	11.1
INFECTIONS AND INFESTATIONS		Non-Europe	19	100.0	2	10.5	9	100.0	1	11.1
INFECTIONS AND INFESTATIONS	PNEUMONIA	Non-Europe	19	100.0	2	10.5	9	100.0	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Non-Europe	19	100.0	0	-	9	100.0	1	11.1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Non-Europe	19	100.0	0	-	9	100.0	1	11.1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Non-Europe	19	100.0	0	-	9	100.0	1	11.1
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Non-Europe	19	100.0	1	5.3	9	100.0	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Non-Europe	19	100.0	1	5.3	9	100.0	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:55

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Descriptive
STUDIES: GO29365, YO41543
Dichotomous Analysis by Subgroups (Safety)

Sex

			Pola+BR (N=19)				BR (N=9)			
			Patients		Patients with Event		Patients		Patients with Event	
MedDRA System Organ Class	MedDRA Preferred Term	Level	n	%	n	%	n	%	n	%
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Male	14	73.7	0	-	6	66.7	1	16.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS		Female	5	26.3	0	-	3	33.3	0	-
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Male	14	73.7	0	-	6	66.7	1	16.7
BLOOD AND LYMPHATIC SYSTEM DISORDERS	MYELOSUPPRESSION	Female	5	26.3	0	-	3	33.3	0	-
INFECTIONS AND INFESTATIONS		Male	14	73.7	1	7.1	6	66.7	1	16.7
INFECTIONS AND INFESTATIONS		Female	5	26.3	1	20.0	3	33.3	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Male	14	73.7	1	7.1	6	66.7	0	-
INFECTIONS AND INFESTATIONS	PNEUMONIA	Female	5	26.3	1	20.0	3	33.3	0	-
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Male	14	73.7	0	-	6	66.7	1	16.7
INFECTIONS AND INFESTATIONS	SEPTIC SHOCK	Female	5	26.3	0	-	3	33.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Male	14	73.7	0	-	6	66.7	1	16.7
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		Female	5	26.3	0	-	3	33.3	0	-
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Male	14	73.7	0	-	6	66.7	1	16.7
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	INTERVERTEBRAL DISC PROTRUSION	Female	5	26.3	0	-	3	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Male	14	73.7	0	-	6	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS		Female	5	26.3	1	20.0	3	33.3	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Male	14	73.7	0	-	6	66.7	0	-
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	INTERSTITIAL LUNG DISEASE	Female	5	26.3	1	20.0	3	33.3	0	-

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_soc_descriptive.sas
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24JAN2023 17:55

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
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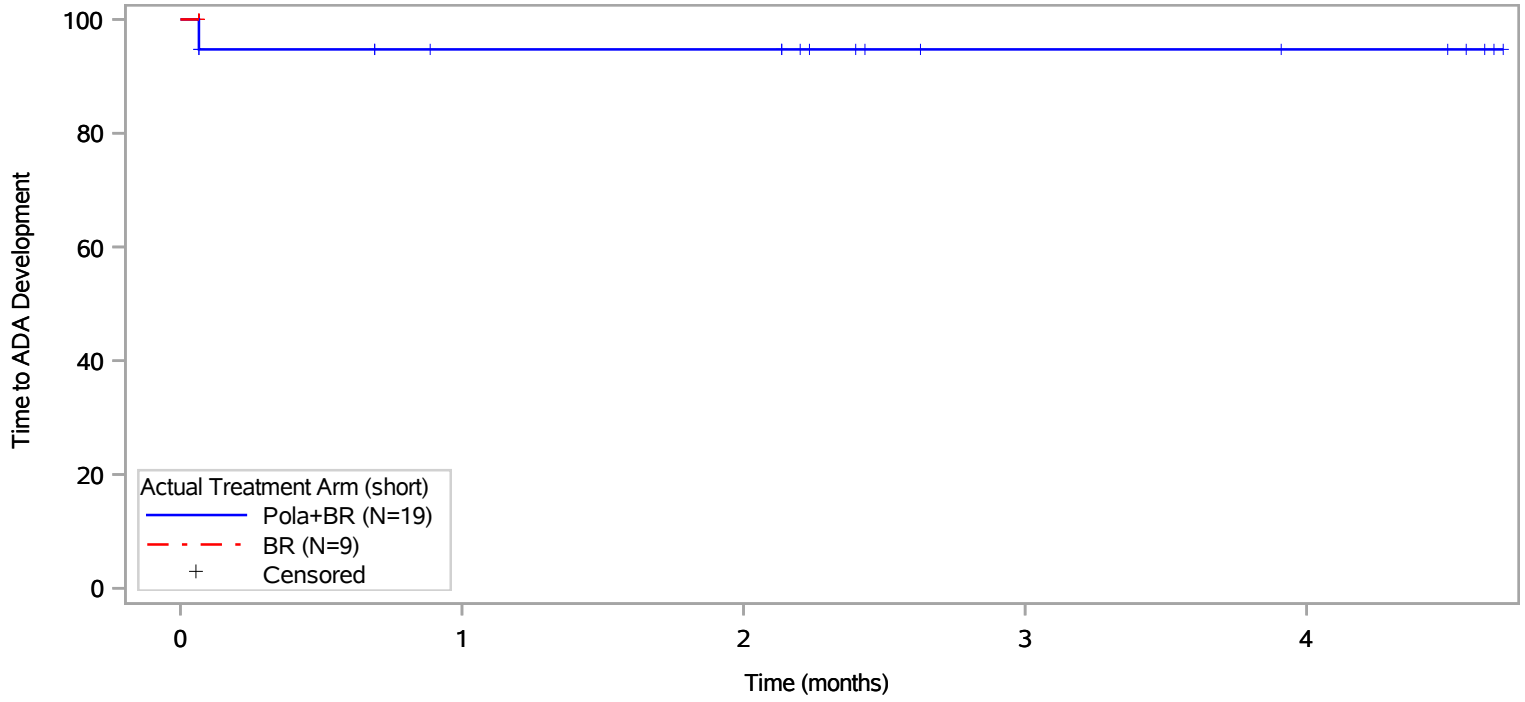
06APR2023 19:32

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to first Immunogenicity against Polatuzumab
STUDIES: GO29365, YO41543



Patients at risk					
Pola+BR (N=19)	19	13	13	6	5
BR (N=9)	9	NE	NE	NE	NE
Patients censored					
Pola+BR (N=19)	0	5	5	12	13
BR (N=9)	0	NE	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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06APR2023 19:53

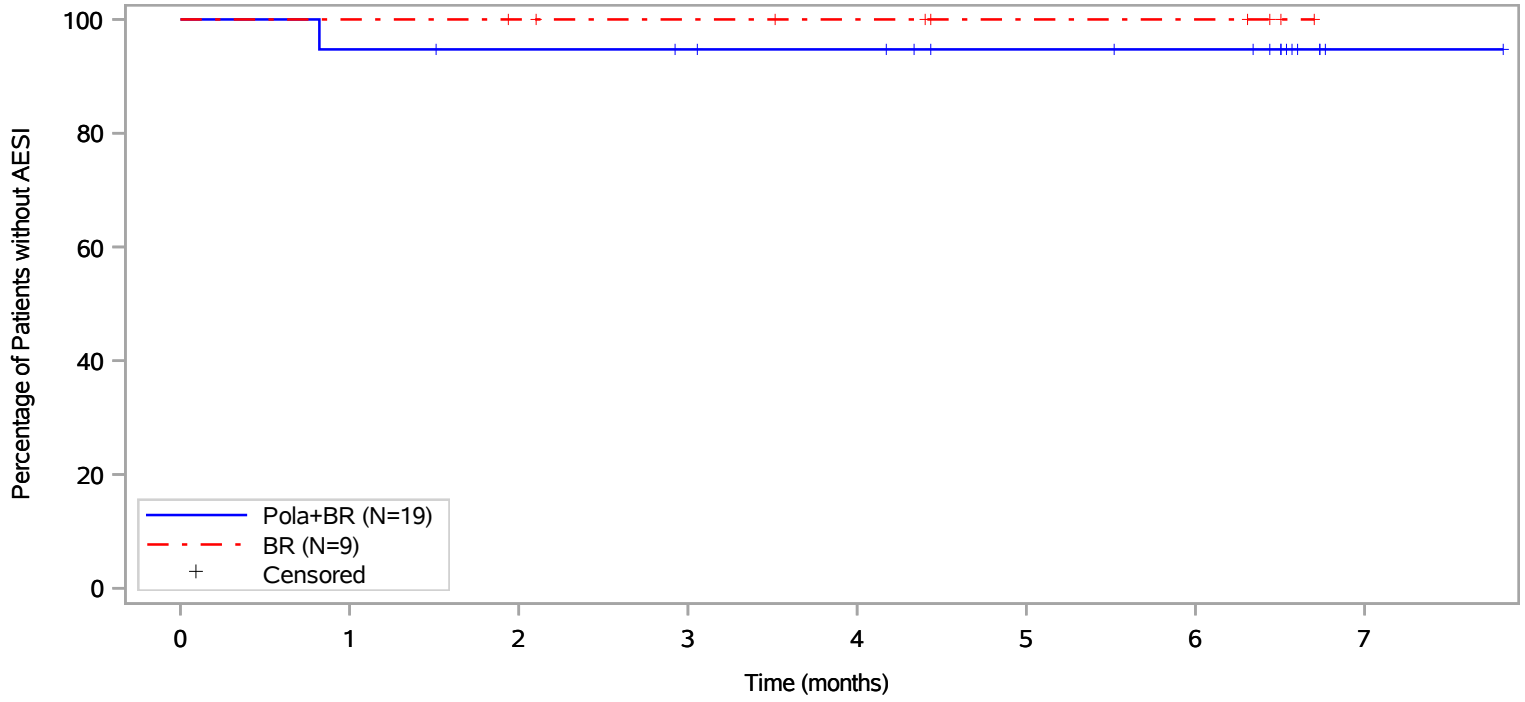
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTALOPE_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 17:07

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 21:51

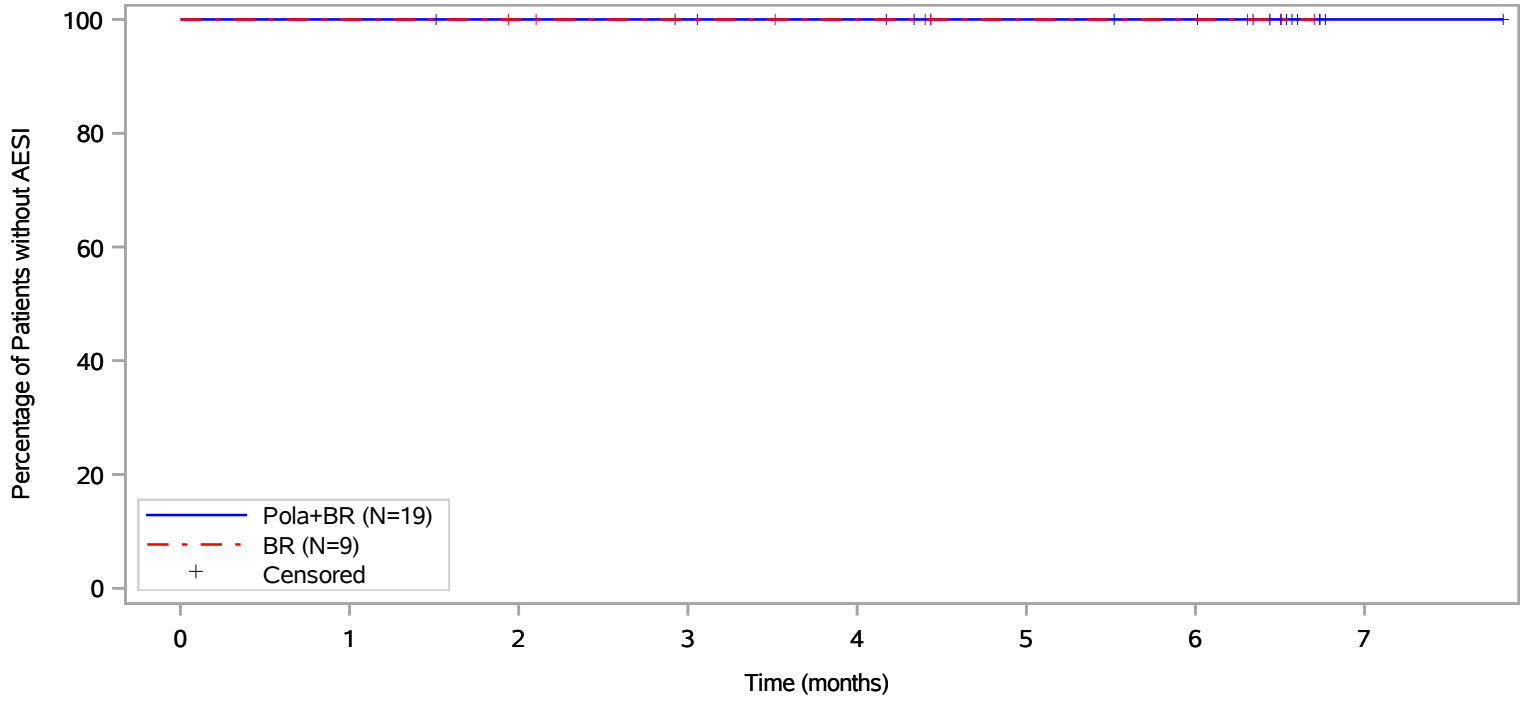
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTALOPE35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:55

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Alopecia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTALOPE35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 23:59

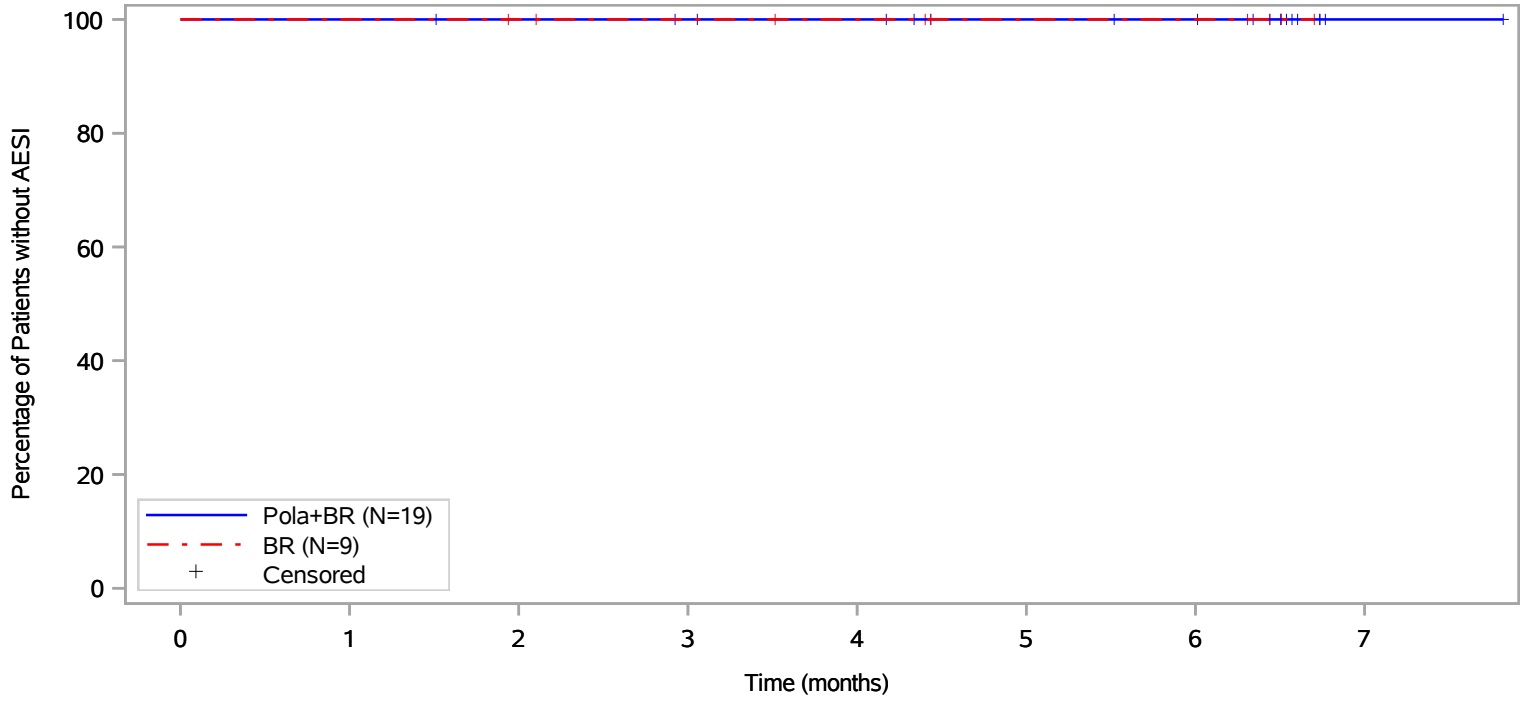
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Alopecia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTALOPES_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Alopecia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTALOPES_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 2:17

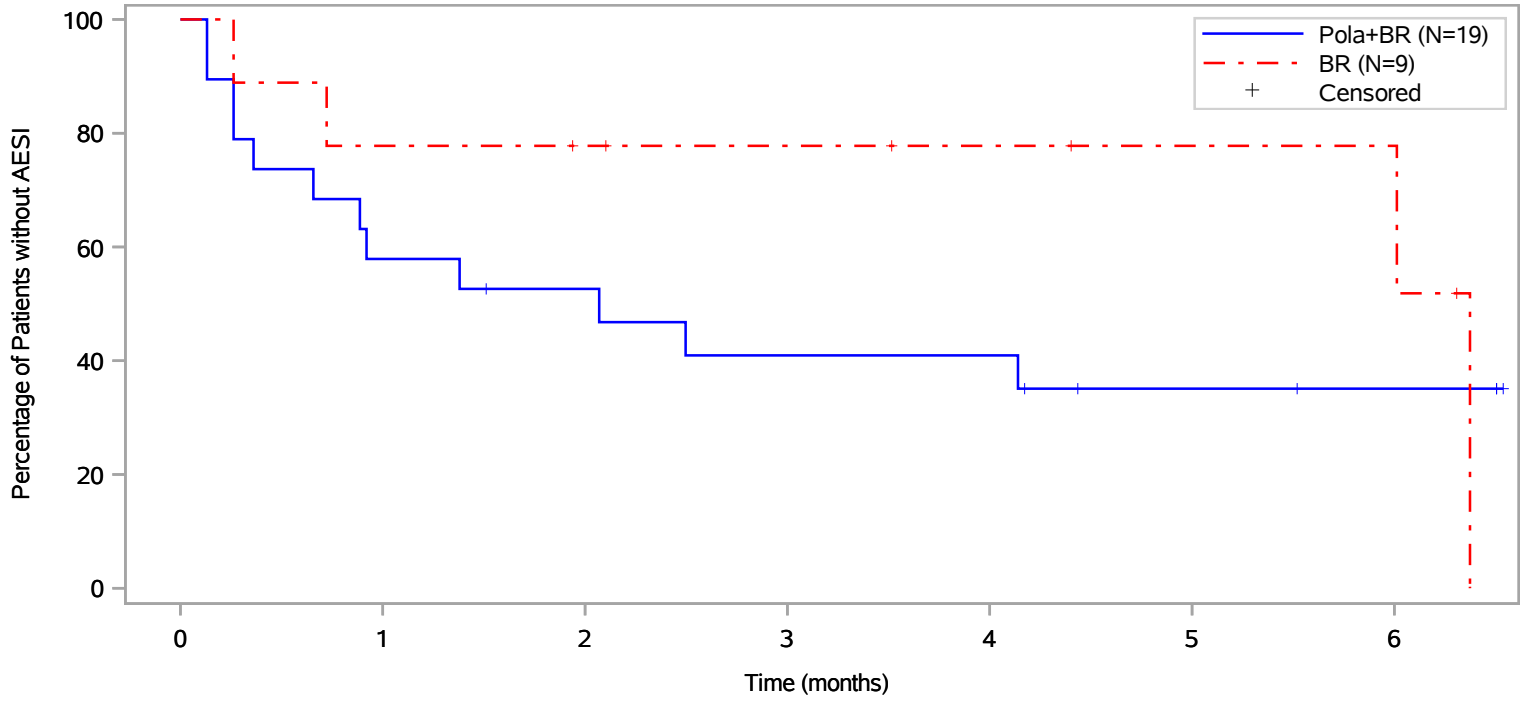
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.3472	1.72	0.55	5.41		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	9	64.3	5	35.7	6	66.7	1	16.7	5	83.3	0.0690	5.53	0.70	43.90		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	3	60.0	2	40.0	3	33.3	3	100.0	0	-	0.4901	0.56	0.11	2.95		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	11	68.8	5	31.3	7	77.8	2	28.6	5	71.4	0.1943	2.63	0.58	11.95		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	2	100.0	0	-	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	9	64.3	5	35.7	6	66.7	3	50.0	3	50.0	0.5958	1.43	0.38	5.41		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	3	60.0	2	40.0	3	33.3	1	33.3	2	66.7	0.5138	2.10	0.22	20.49		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.3472	1.72	0.55	5.41		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTANEIM_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 1:22

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	11	9	7	7	4	3
BR (N=9)	9	7	6	5	4	3	3
Patients censored							
Pola+BR (N=19)	0	0	1	1	1	3	4
BR (N=9)	0	0	1	2	3	4	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_TTANEIM_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 20:42

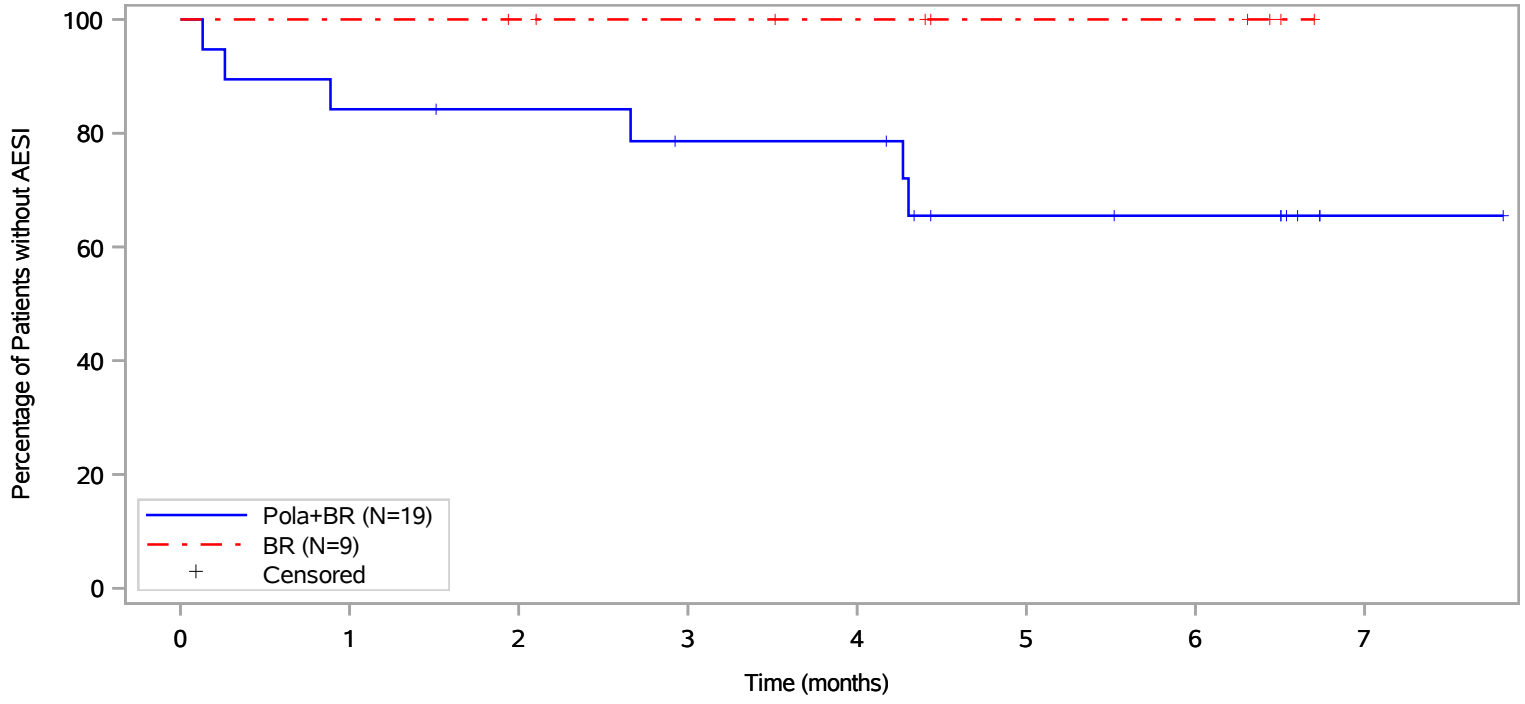
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0825	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	3	21.4	11	78.6	6	66.7	0	-	6	100.0	0.3320	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	3	60.0	2	40.0	3	33.3	0	-	3	100.0	0.1269	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	6	37.5	10	62.5	7	77.8	0	-	7	100.0	0.1048	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	5	35.7	9	64.3	6	66.7	0	-	6	100.0	0.1516	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0825	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTANEIM35_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 17:15

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Anemia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	16	15	13	13	8	7	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	12
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTANEIM35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 22:47

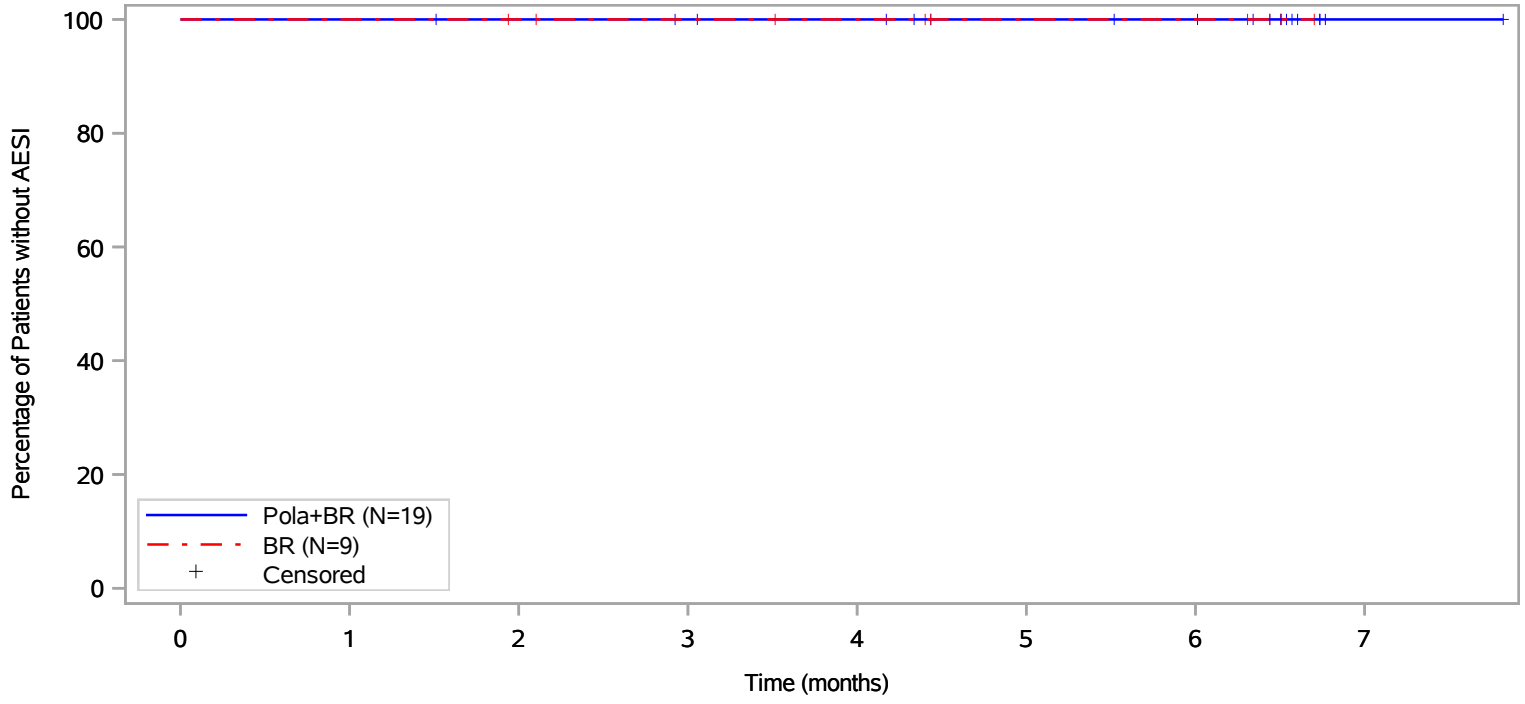
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Anemia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTANEIMS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 20:29

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Anemia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 0:55

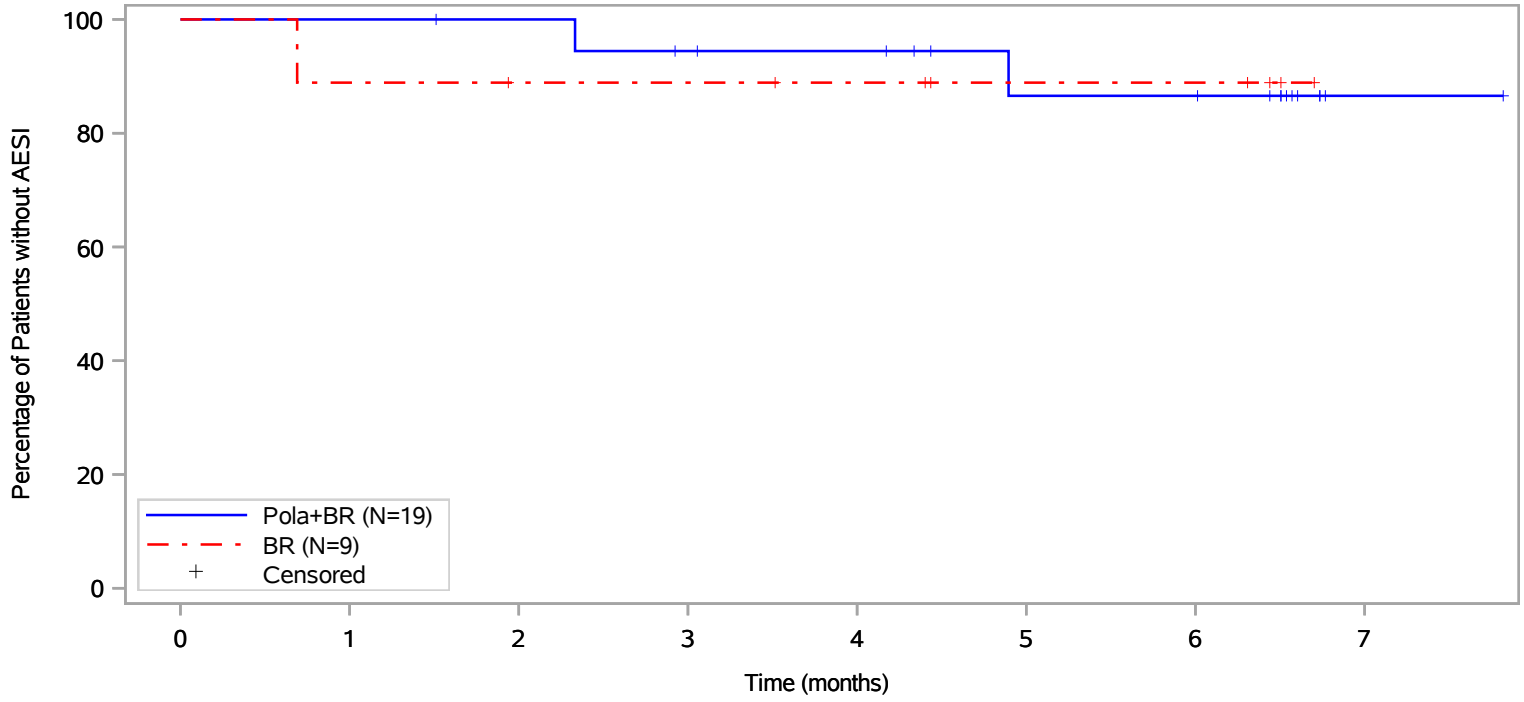
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.8488	0.79	0.07	8.78		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	2	14.3	12	85.7	6	66.7	1	16.7	5	83.3	0.7211	0.65	0.06	7.22		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.3541	0.28	0.02	4.82		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.3173	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	2	14.3	12	85.7	6	66.7	1	16.7	5	83.3	0.7465	0.67	0.06	7.49		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	1	11.1	8	88.9	0.8488	0.79	0.07	8.78		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTCTAAR_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 20:13

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	11	11	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	6	16
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_TTCTAAR_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 21:56

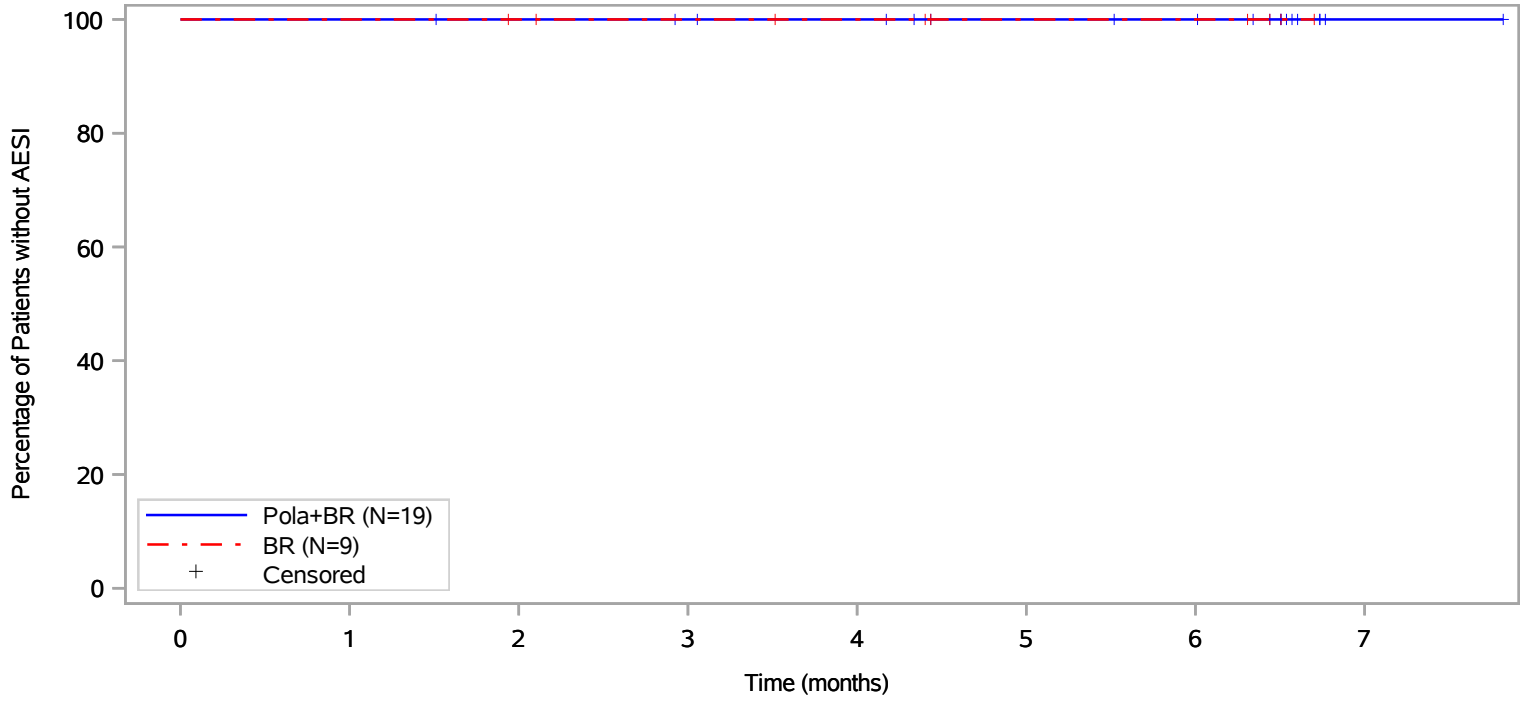
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTCTAAR35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 22:04

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Cardiac Toxicity and Arrhythmias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTCTAAR35_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 0:05

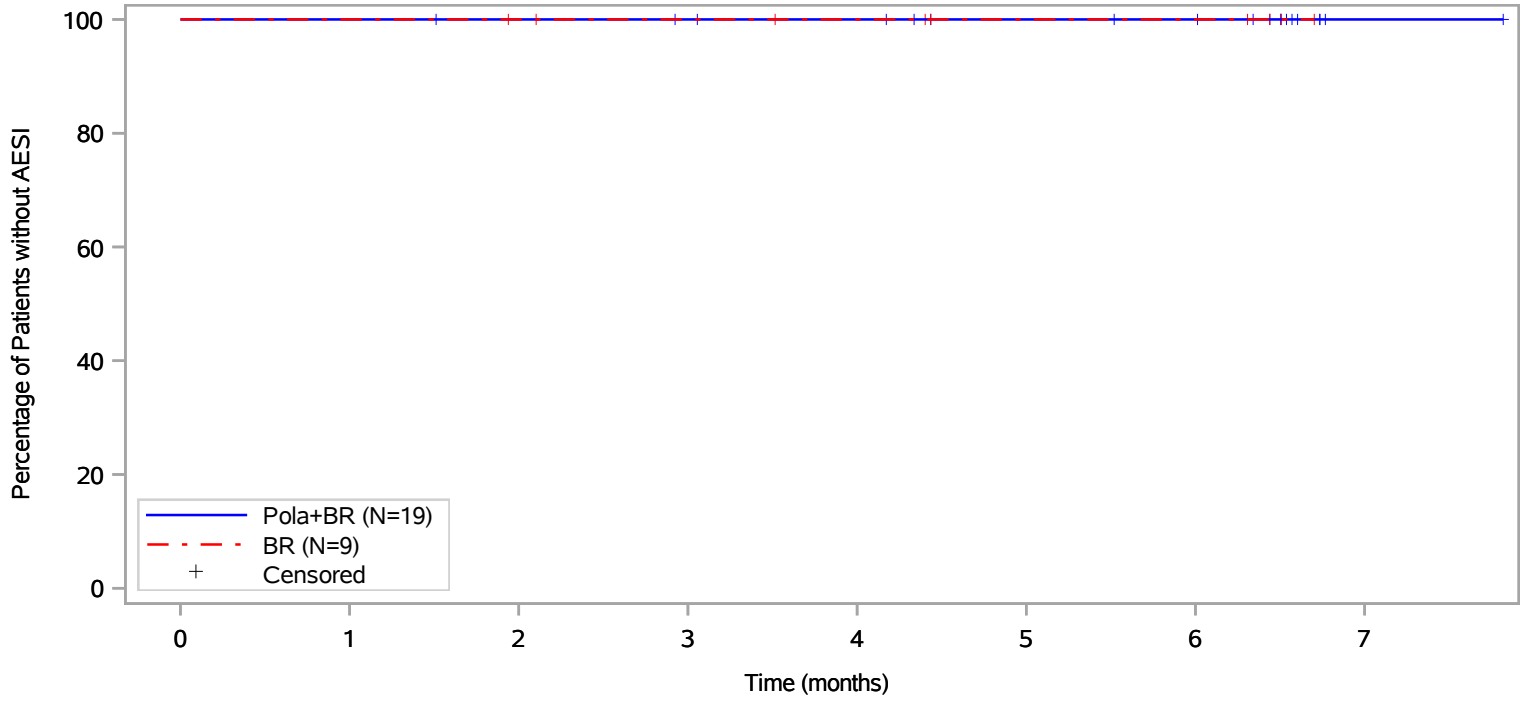
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTCTAARS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 22:08

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Cardiac Toxicity and Arrhythmias
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 2:23

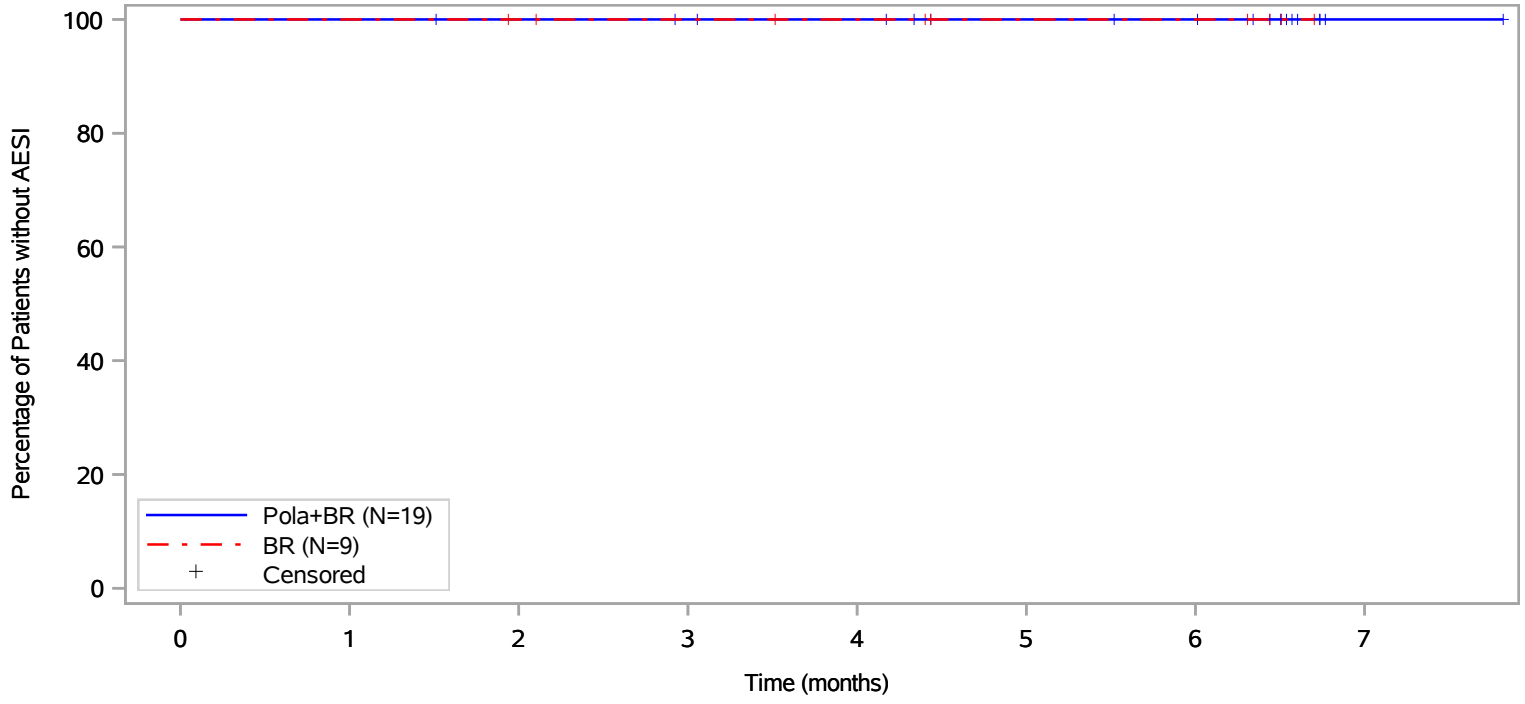
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Drug Drug Interaction
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTDDIN_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 22:14

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Drug Drug Interaction
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 22:28

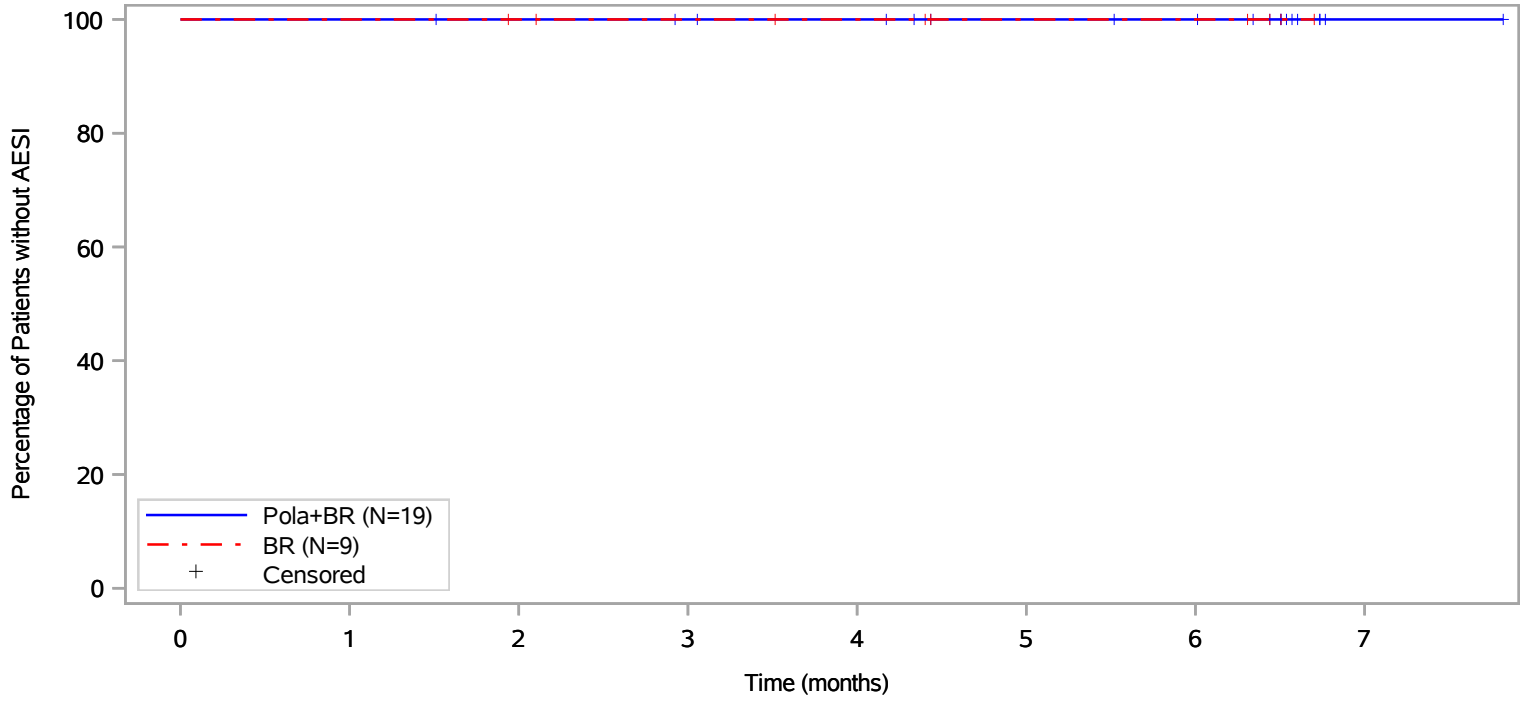
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTDYSGUE_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 21:01

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 22:09

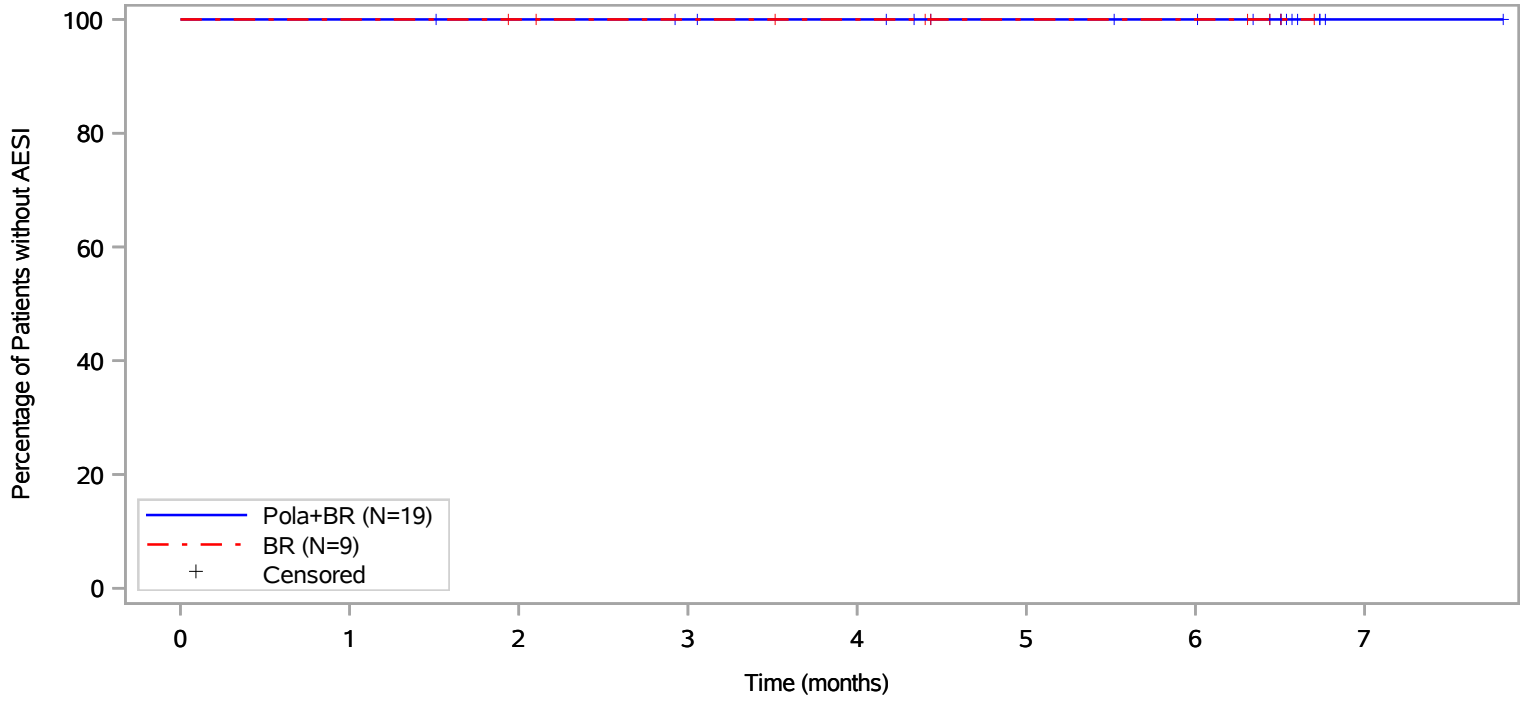
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTDYSGUE35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 22:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Dysgeusia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 0:19

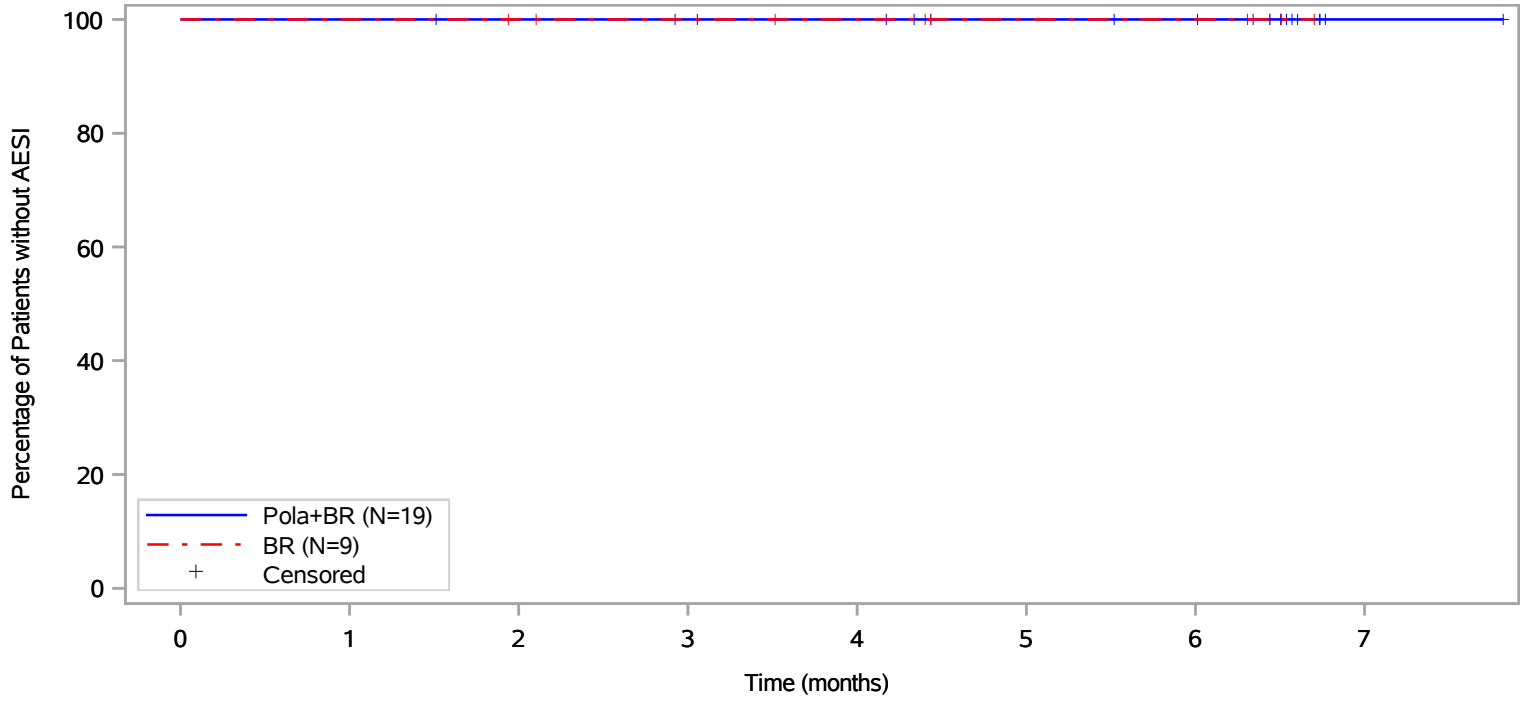
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Dysgeusia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTDYSGUES_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 22:22

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Dysgeusia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 2:40

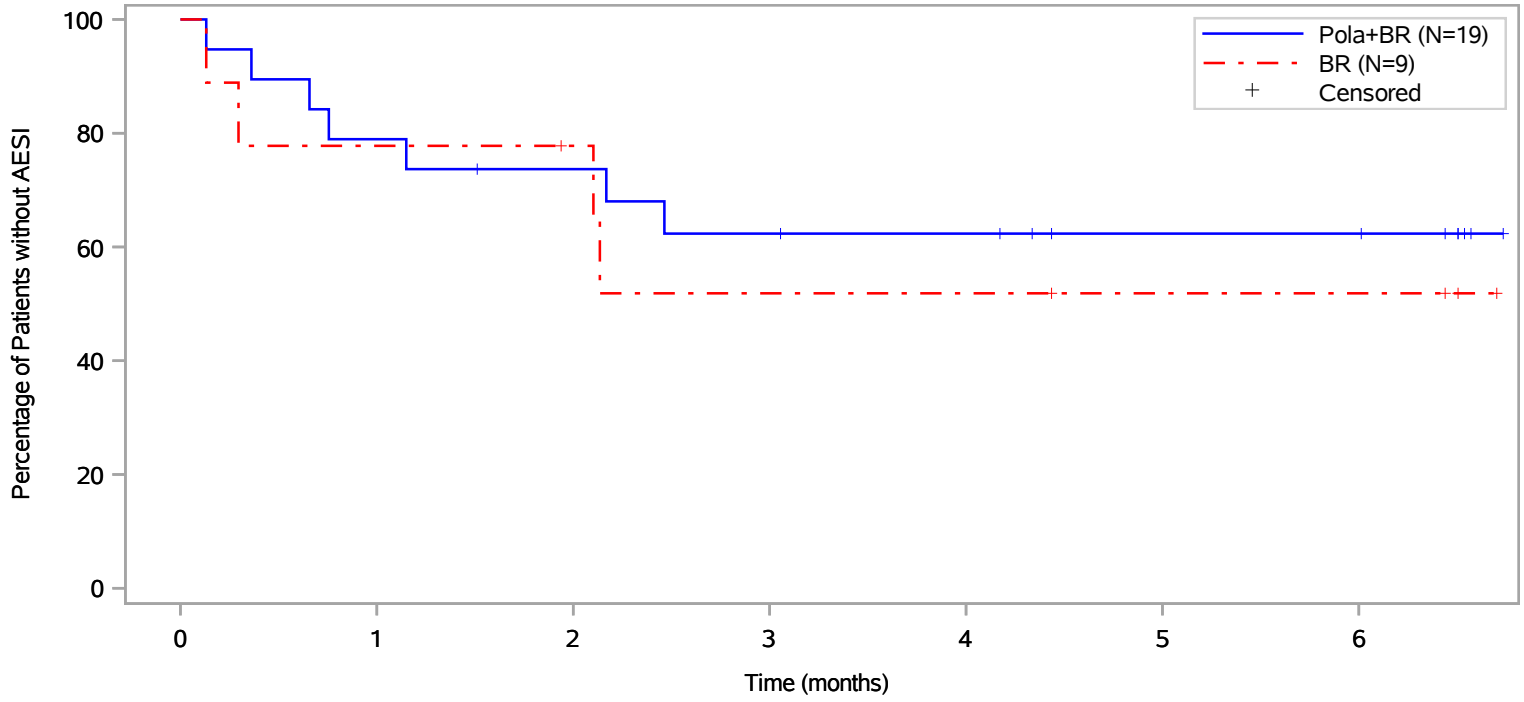
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	7	36.8	12	63.2	9	100.0	4	44.4	5	55.6	0.6051	0.72	0.21	2.49		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	7	50.0	7	50.0	6	66.7	4	66.7	2	33.3	0.3223	0.54	0.15	1.88		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	5	31.3	11	68.8	7	77.8	4	57.1	3	42.9	0.1815	0.41	0.11	1.57		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	0	-	2	100.0	0.1167	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	6	42.9	8	57.1	6	66.7	2	33.3	4	66.7	0.8046	1.23	0.24	6.14		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	1	20.0	4	80.0	3	33.3	2	66.7	1	33.3	0.2159	0.25	0.02	2.73		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	4	44.4	5	55.6	0.6051	0.72	0.21	2.49		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTFAA_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 4:51

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	15	13	11	10	7	7
BR (N=9)	9	7	6	4	4	3	3
Patients censored							
Pola+BR (N=19)	0	0	1	1	2	5	5
BR (N=9)	0	0	1	1	1	2	2

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTFAA_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 21:16

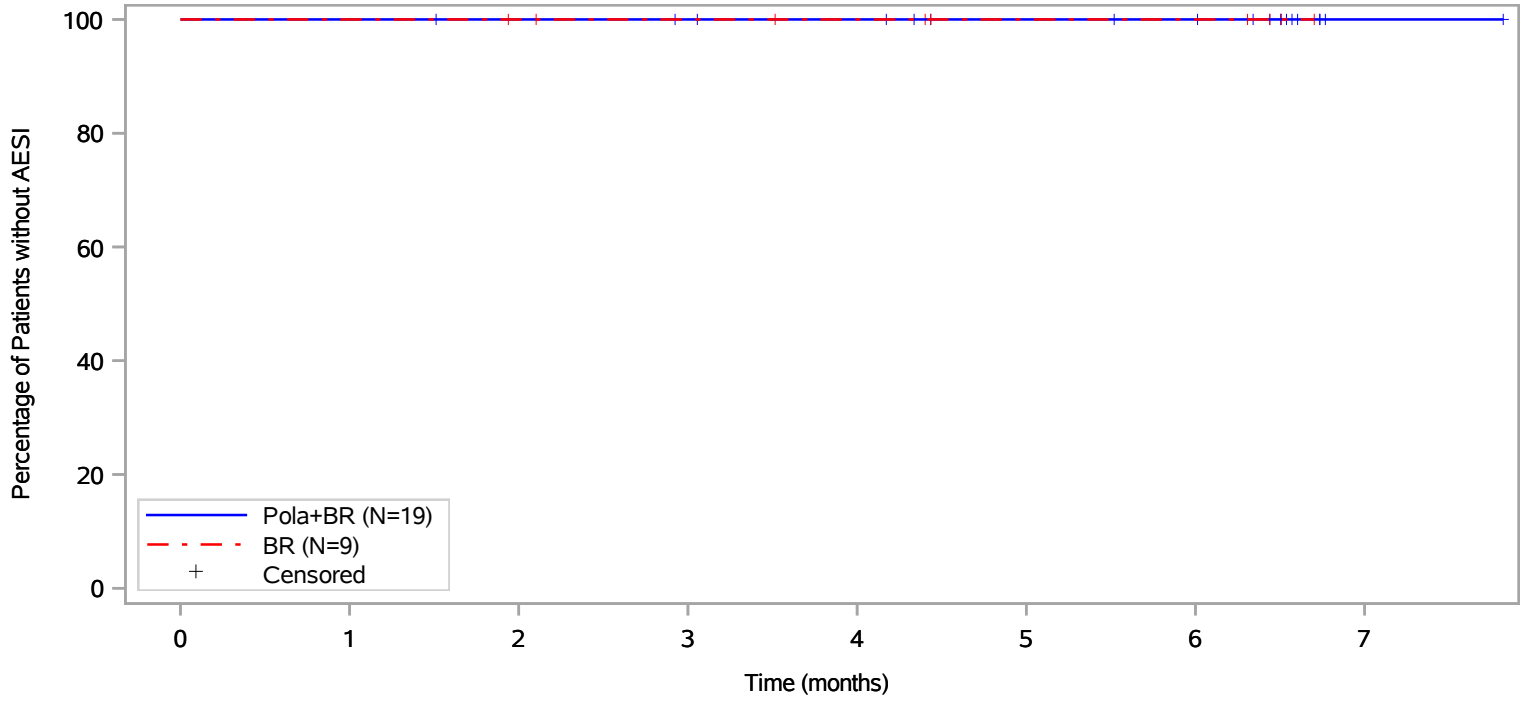
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTFAA35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:09

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Fatigue and Asthenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 23:26

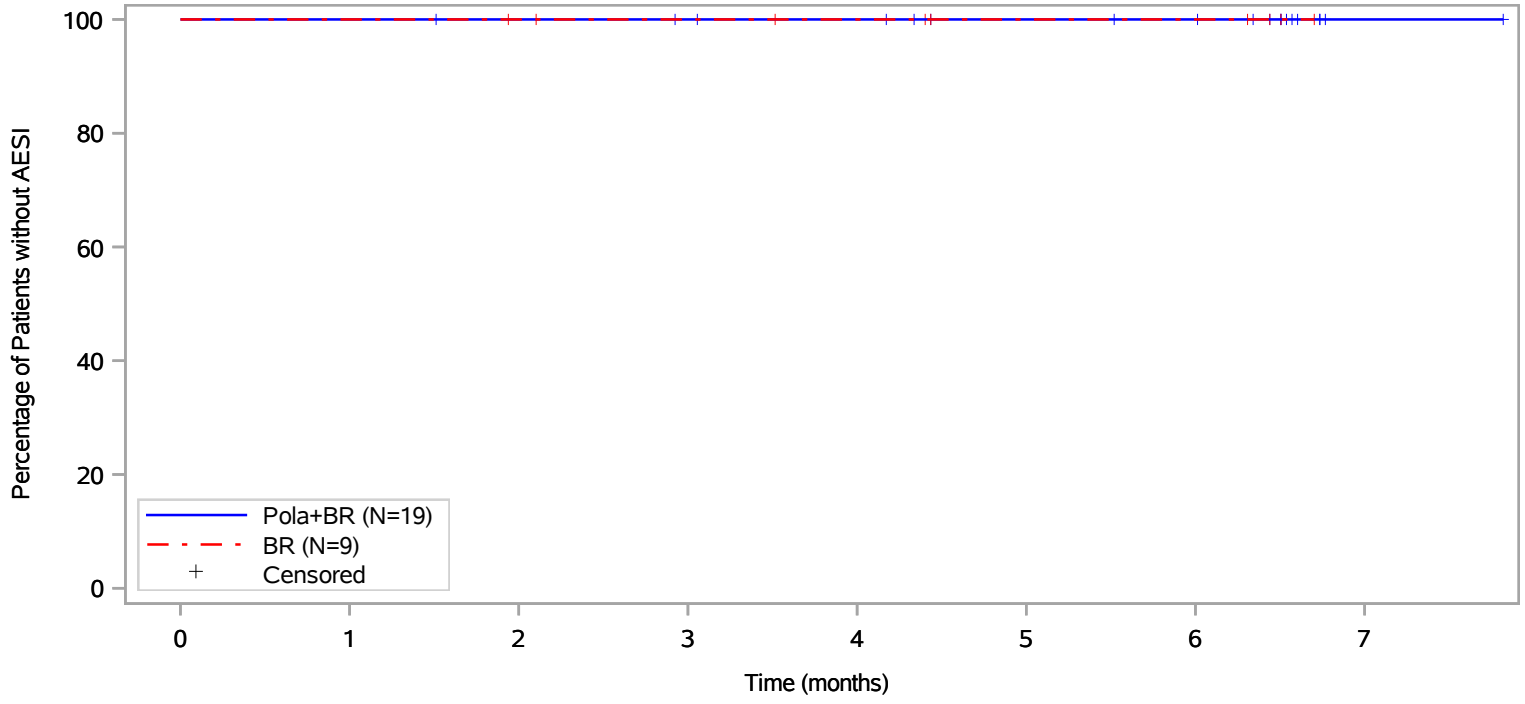
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTFAAS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:13

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Fatigue and Asthenia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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04DEC2022 1:30

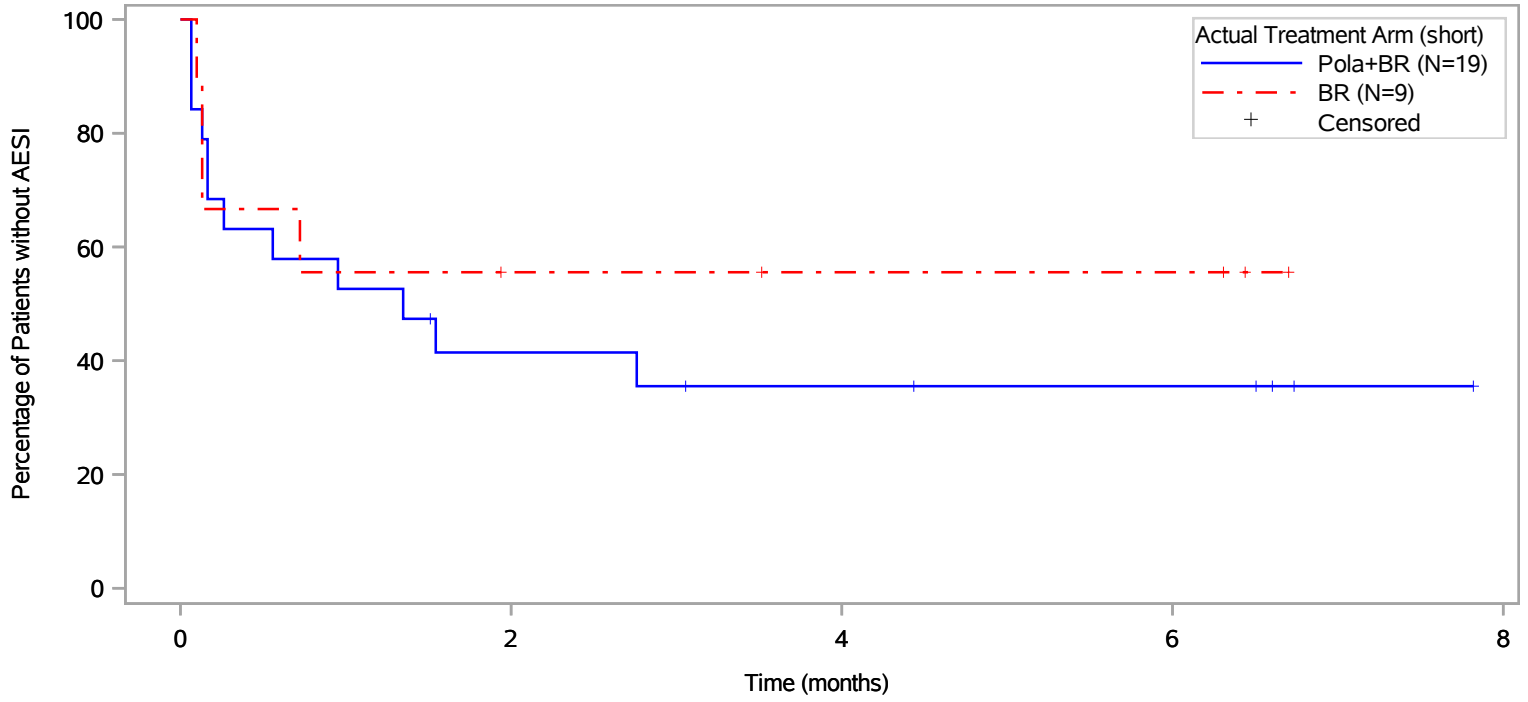
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.4838	1.50	0.48	4.75		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	9	64.3	5	35.7	6	66.7	2	33.3	4	66.7	0.3006	2.23	0.47	10.61		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	3	60.0	2	40.0	3	33.3	2	66.7	1	33.3	0.8410	0.83	0.14	5.06		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	11	68.8	5	31.3	7	77.8	4	57.1	3	42.9	0.8259	1.14	0.35	3.69		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	8	57.1	6	42.9	6	66.7	3	50.0	3	50.0	0.9263	1.07	0.28	4.05		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	4	80.0	1	20.0	3	33.3	1	33.3	2	66.7	0.2874	3.20	0.34	30.28		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	12	63.2	7	36.8	9	100.0	4	44.4	5	55.6	0.4838	1.50	0.48	4.75		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGASTOX_L3PLUS_Polarose_SE_29365_41543.xls
30MAR2023 9:41

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	10	7	6	5	4	4	1
BR (N=9)	9	5	4	4	3	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	1	2	3	3	6
BR (N=9)	0	0	1	1	2	2	2	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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30MAR2023 11:54

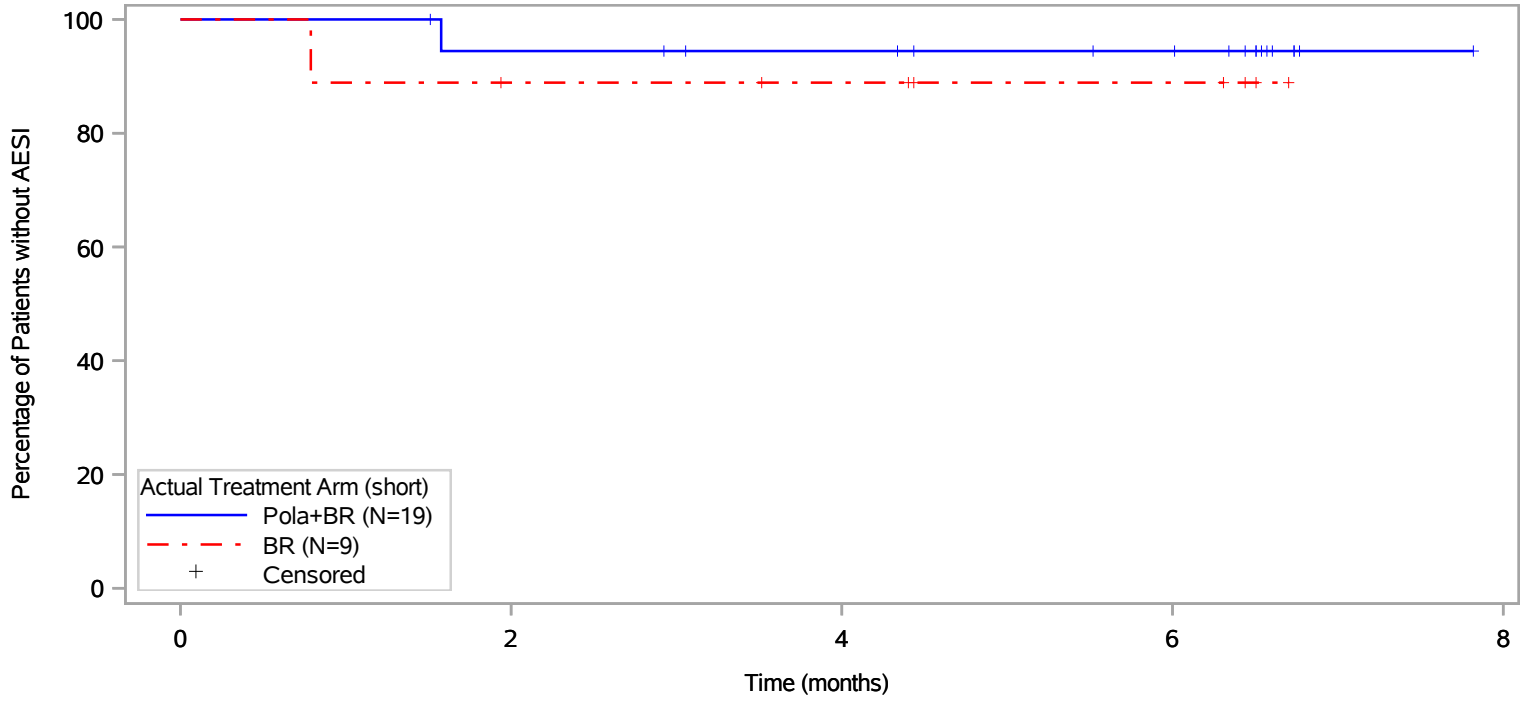
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5722	0.46	0.03	7.34		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5100	0.41	0.03	6.50		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	1	6.3	15	93.8	7	77.8	1	14.3	6	85.7	0.5090	0.41	0.03	6.49		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	1	7.1	13	92.9	6	66.7	1	16.7	5	83.3	0.5100	0.41	0.03	6.50		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	1	11.1	8	88.9	0.5722	0.46	0.03	7.34		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGASTOX35_L3PLUS_Polarose_SE_29365_41543.xls
30MAR2023 11:21

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Gastrointestinal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	17	16	15	13	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	17
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._CSR_Pooled/prod/output_Polarose/g_km_TTGASTOX35_L3PLUS_Polarose_SE_29365_41543.pdf
30MAR2023 13:51

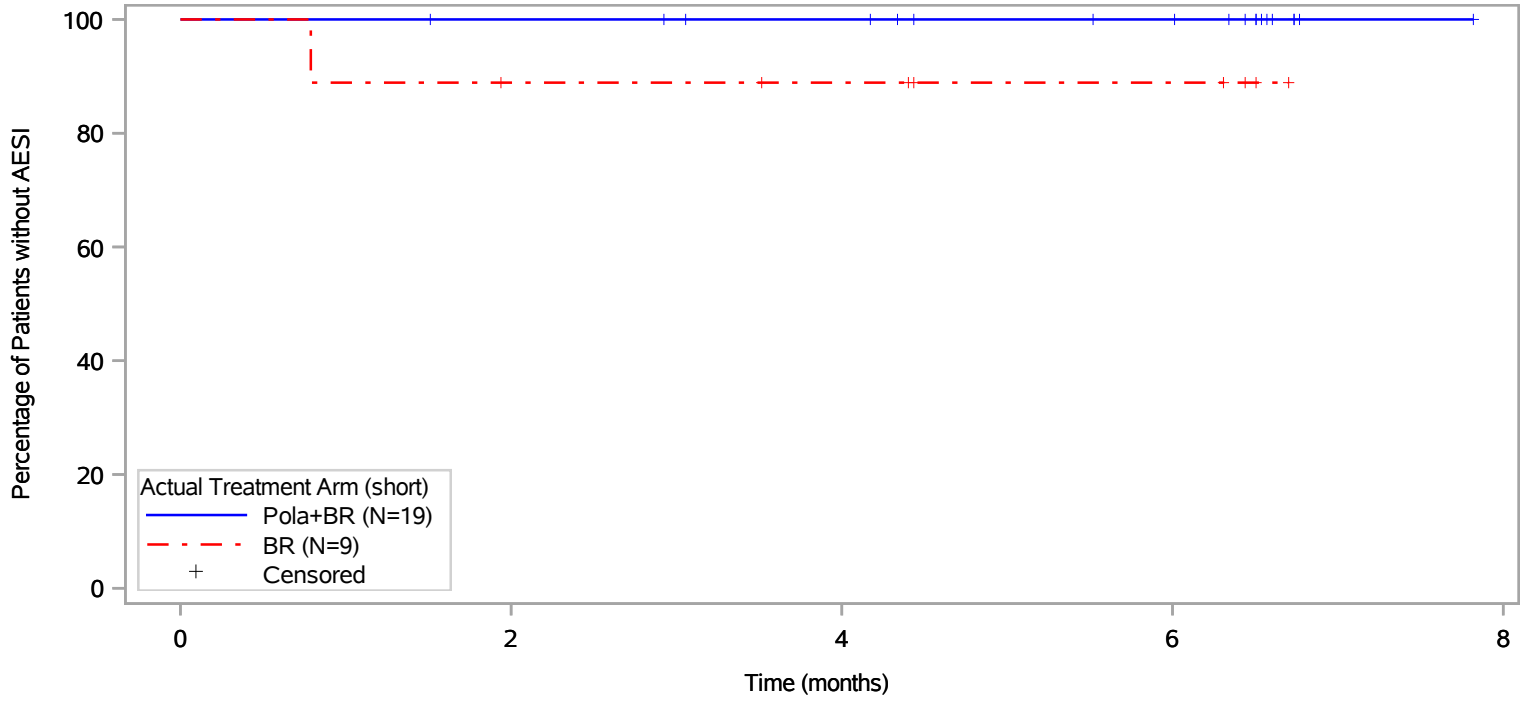
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGASTOXS_L3PLUS_Polarose_SE_29365_41543.xls
30MAR2023 10:33

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Gastrointestinal Toxicity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTGASTOXS_L3PLUS_Polarose_SE_29365_41543.pdf
30MAR2023 13:00

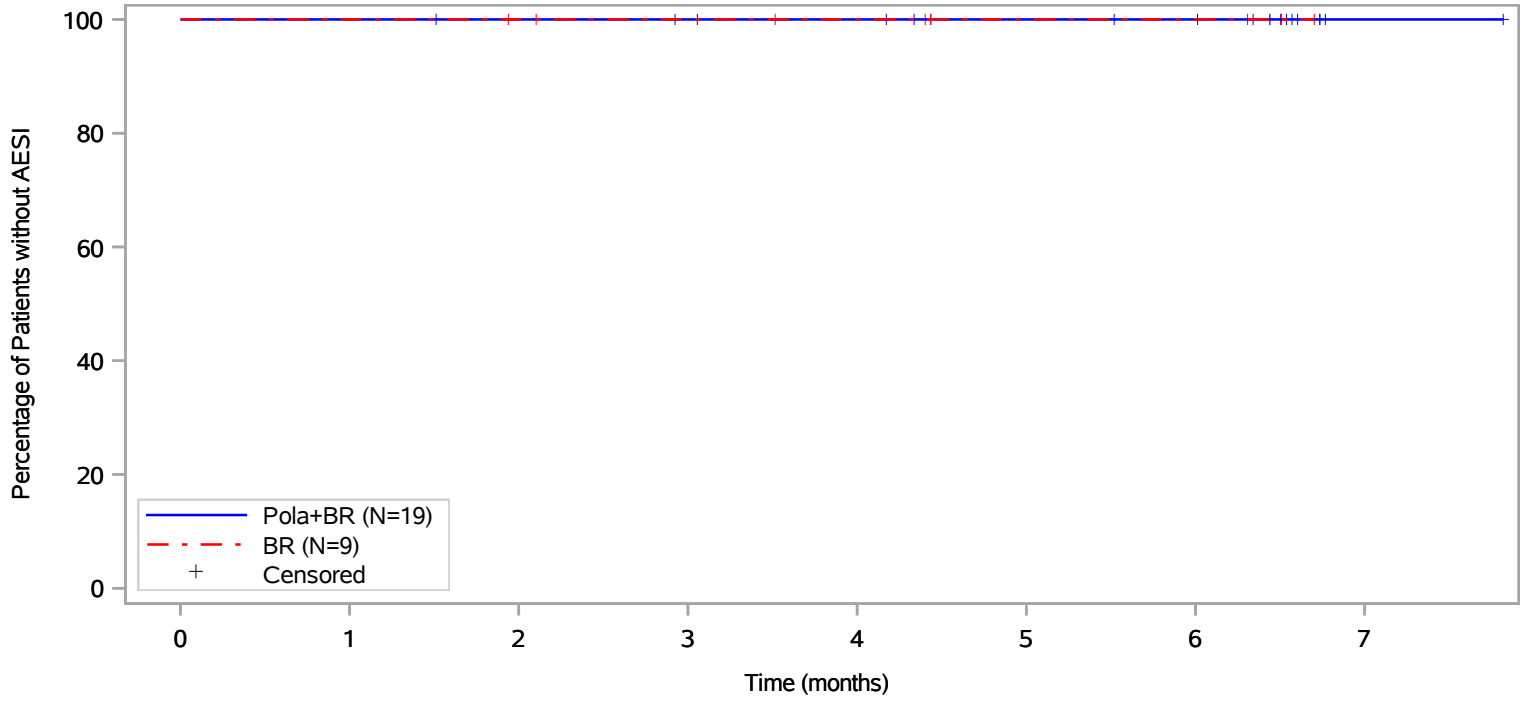
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGENCAR_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 21:51

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTGENCAR_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 22:22

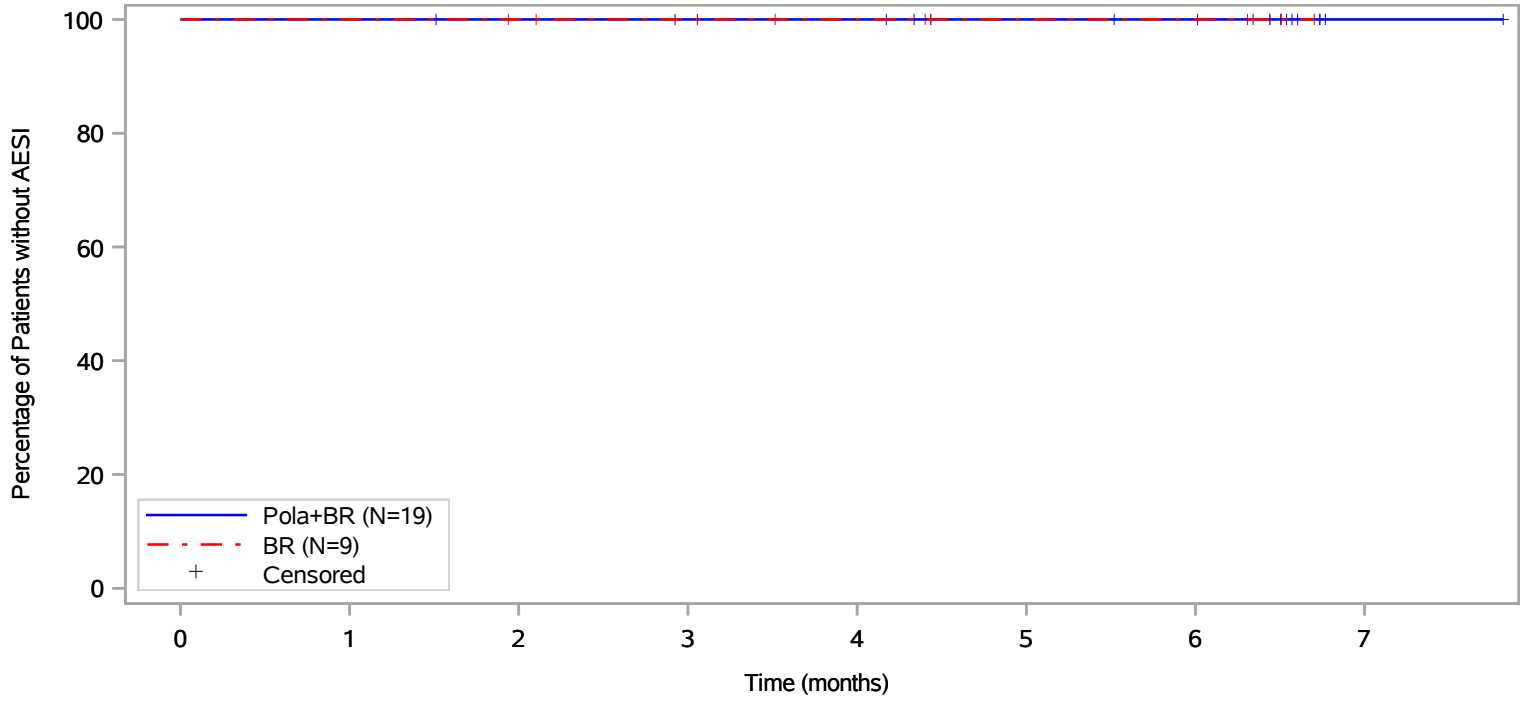
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGENCAR35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 22:32

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Genotoxicity Carcinogenecity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._CSR_Pooled/prod/output_Polarose/g_km_TTGENCAR35_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 0:31

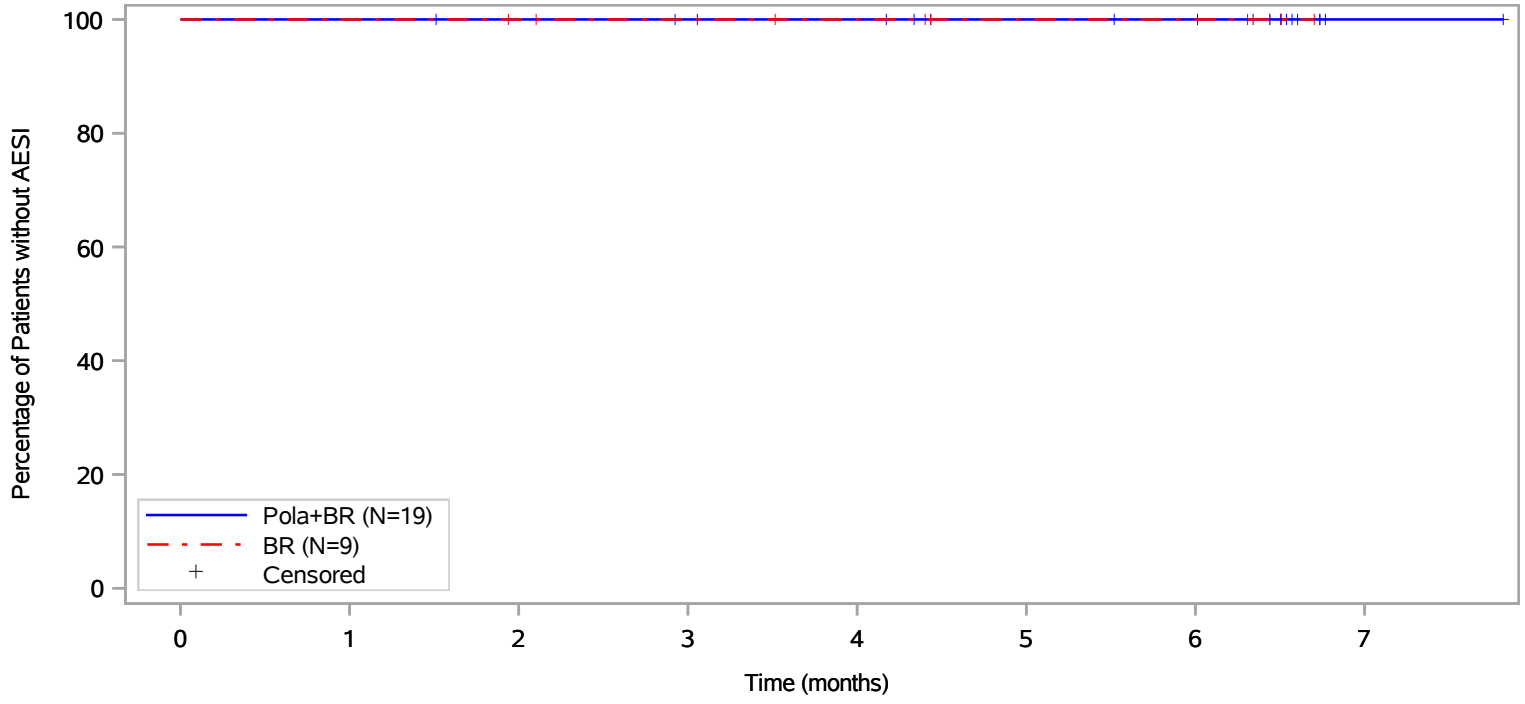
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTGENCARS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 22:36

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Genotoxicity Carcinogenecity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTGENCARS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 2:53

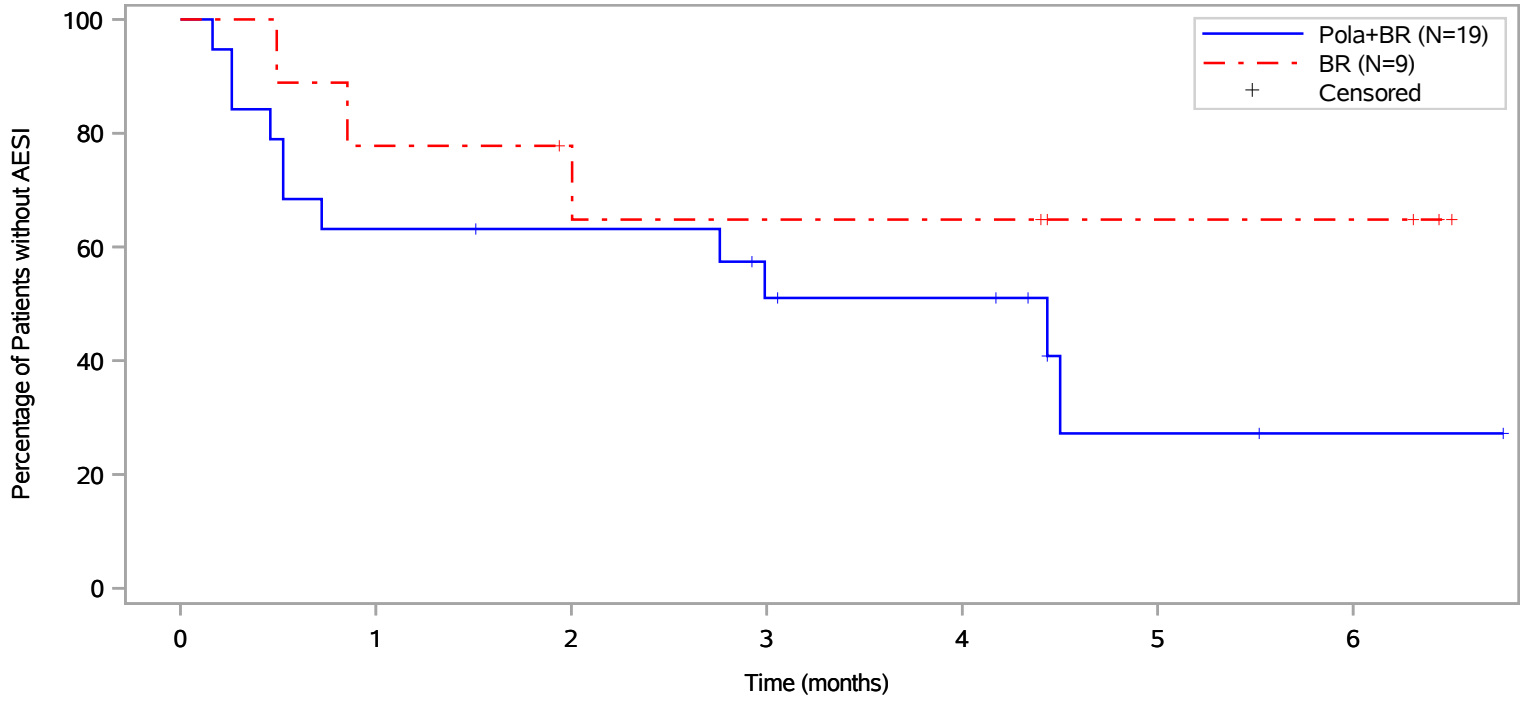
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	11	57.9	8	42.1	9	100.0	3	33.3	6	66.7	0.2250	2.18	0.60	7.88		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	7	50.0	7	50.0	6	66.7	3	50.0	3	50.0	0.8784	0.90	0.23	3.54		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	4	80.0	1	20.0	3	33.3	0	-	3	100.0	0.0434	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	10	62.5	6	37.5	7	77.8	2	28.6	5	71.4	0.1560	2.89	0.62	13.38		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	1	50.0	1	50.0	0.8864	0.82	0.05	13.24		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	6	42.9	8	57.1	6	66.7	2	33.3	4	66.7	0.6167	1.50	0.30	7.51		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	5	100.0	0	-	3	33.3	1	33.3	2	66.7	0.2005	3.72	0.43	32.18		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	11	57.9	8	42.1	9	100.0	3	33.3	6	66.7	0.2250	2.18	0.60	7.88		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHEPAT_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 3:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	12	11	8	7	2	1
BR (N=9)	9	7	6	5	5	3	3
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	1	1	3	3

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_TTHEPAT_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 21:05

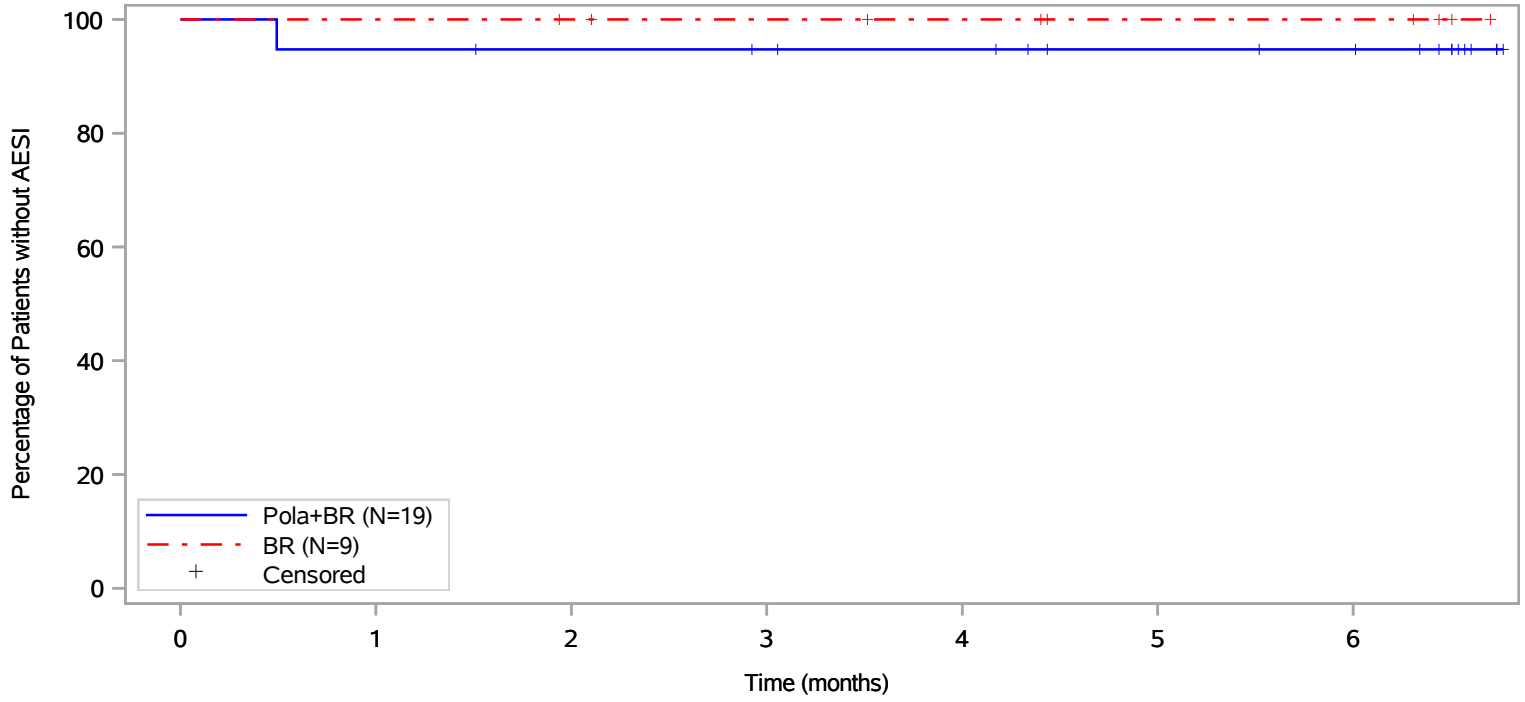
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHEPAT35_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 17:35

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hepatic Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	18	17	16	15	12	11
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	3	6	7
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTHEPAT35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 23:15

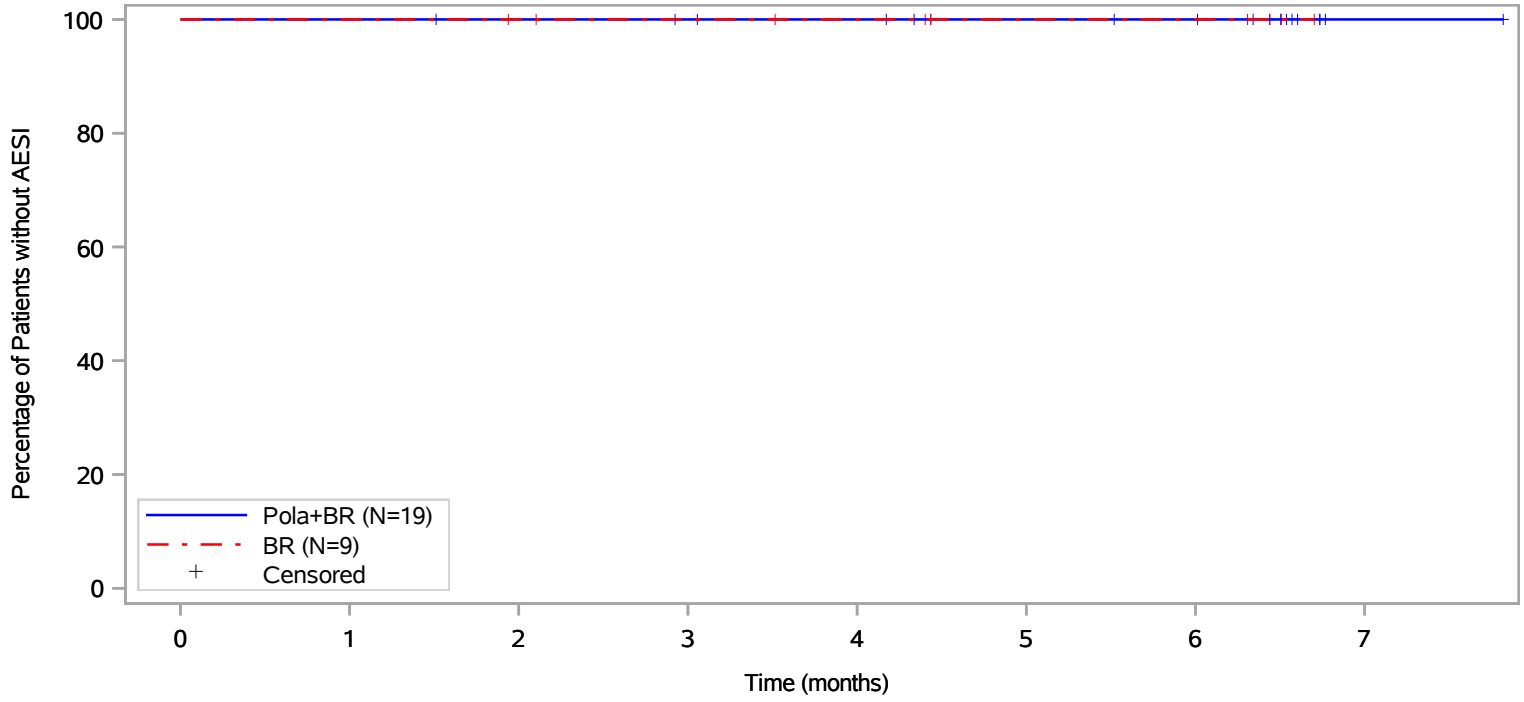
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHEPATS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:00

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hepatic Toxicity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTHEPATS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 1:19

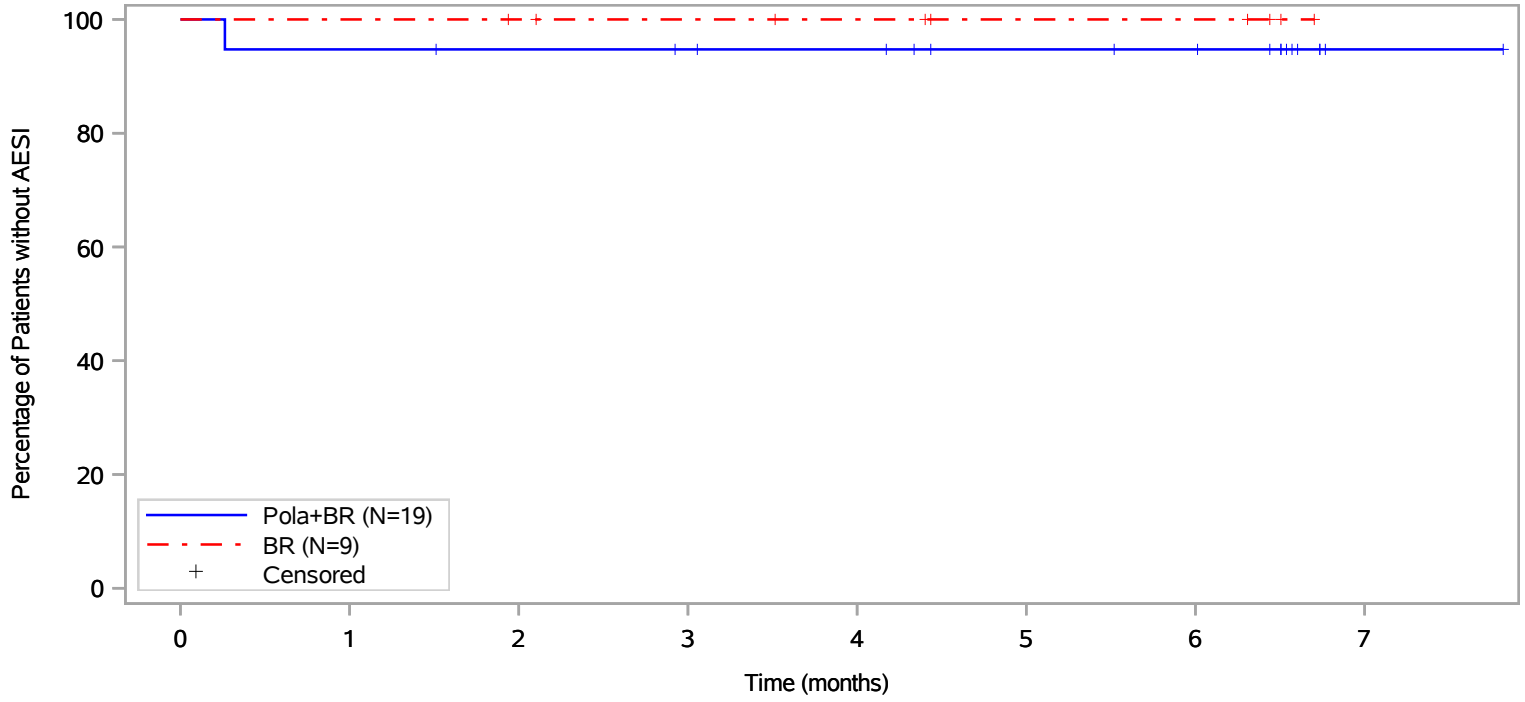
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5083	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.4913	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHYPGL_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 17:47

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	18	17	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_TTHYPGL_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 21:21

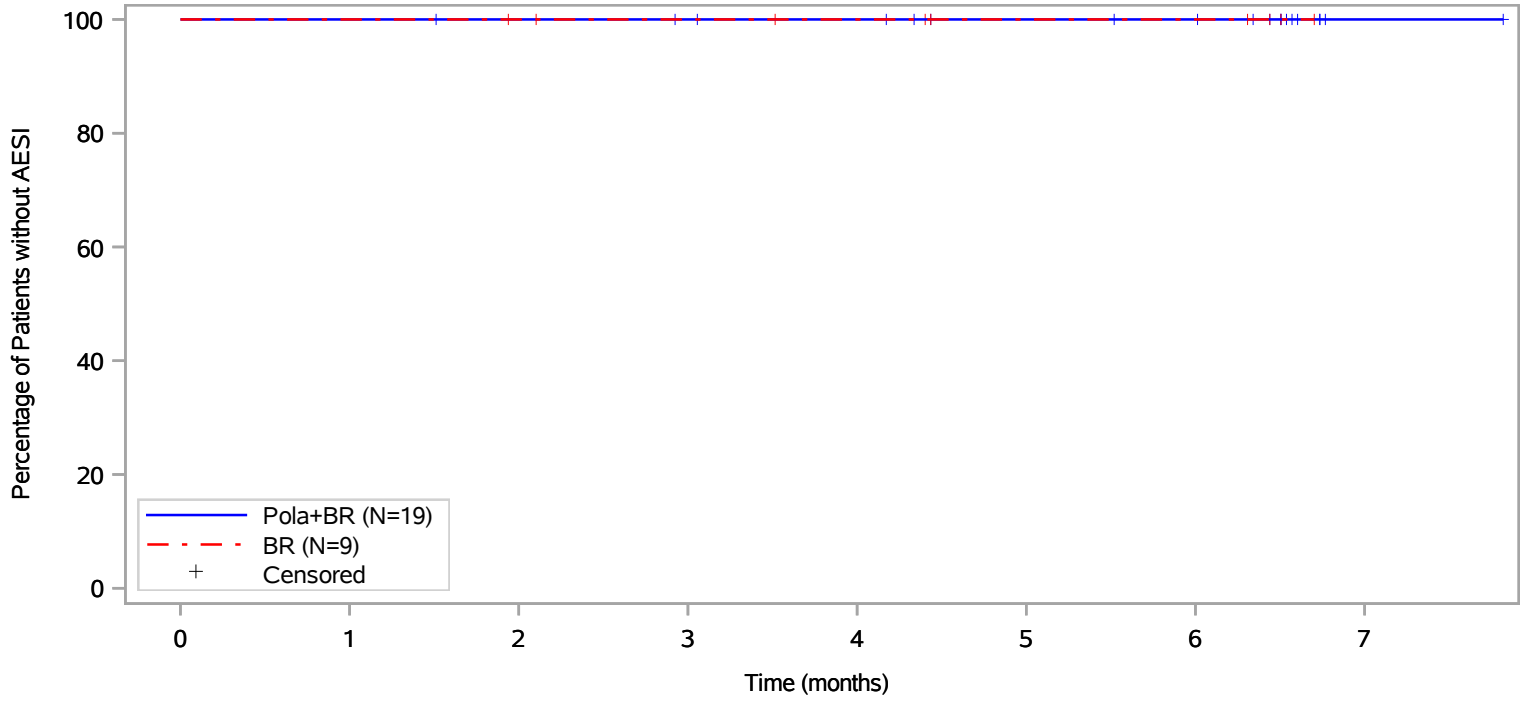
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHYPGL35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:16

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Hyperglycemias of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTHYPGL35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 23:32

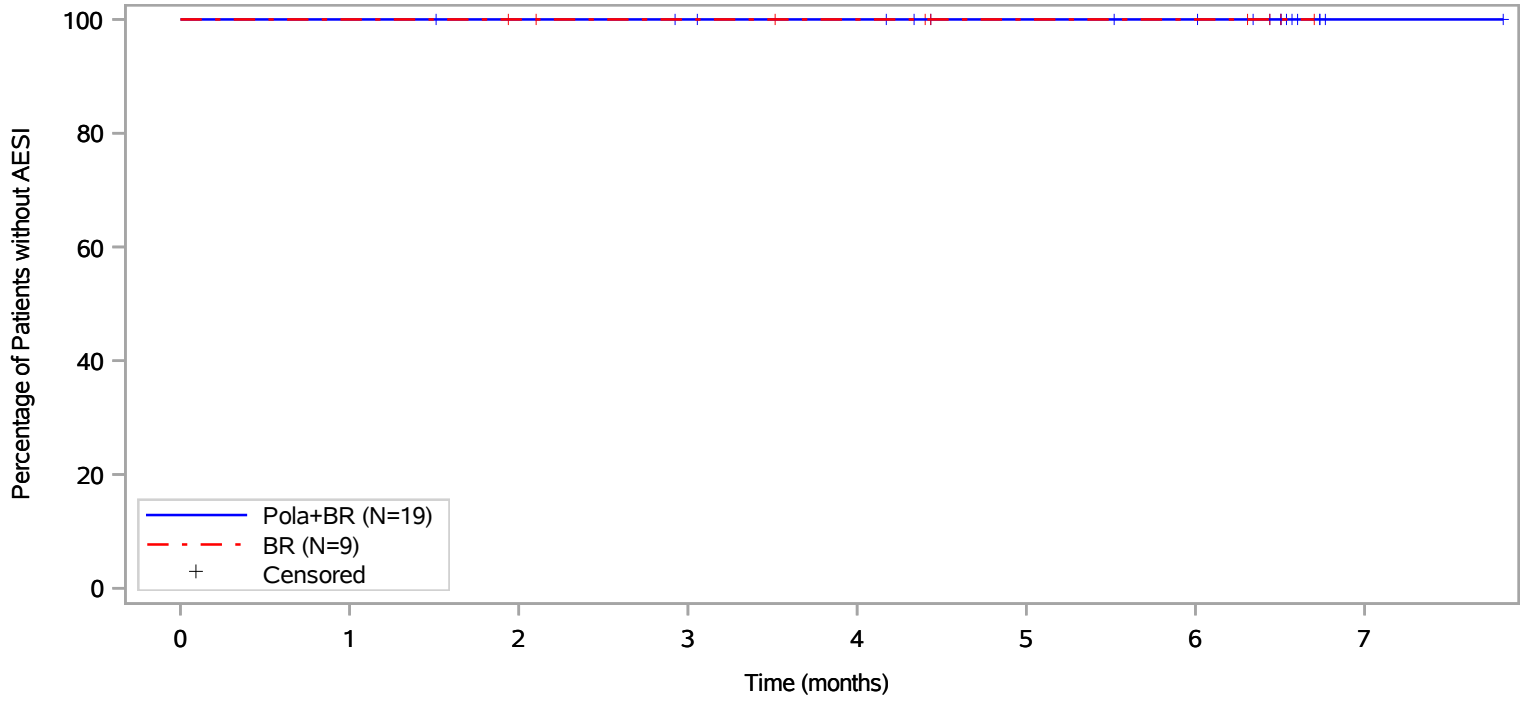
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hyperglycemias
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTHYPGLS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:20

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Hyperglycemias
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTHYPGLS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 1:39

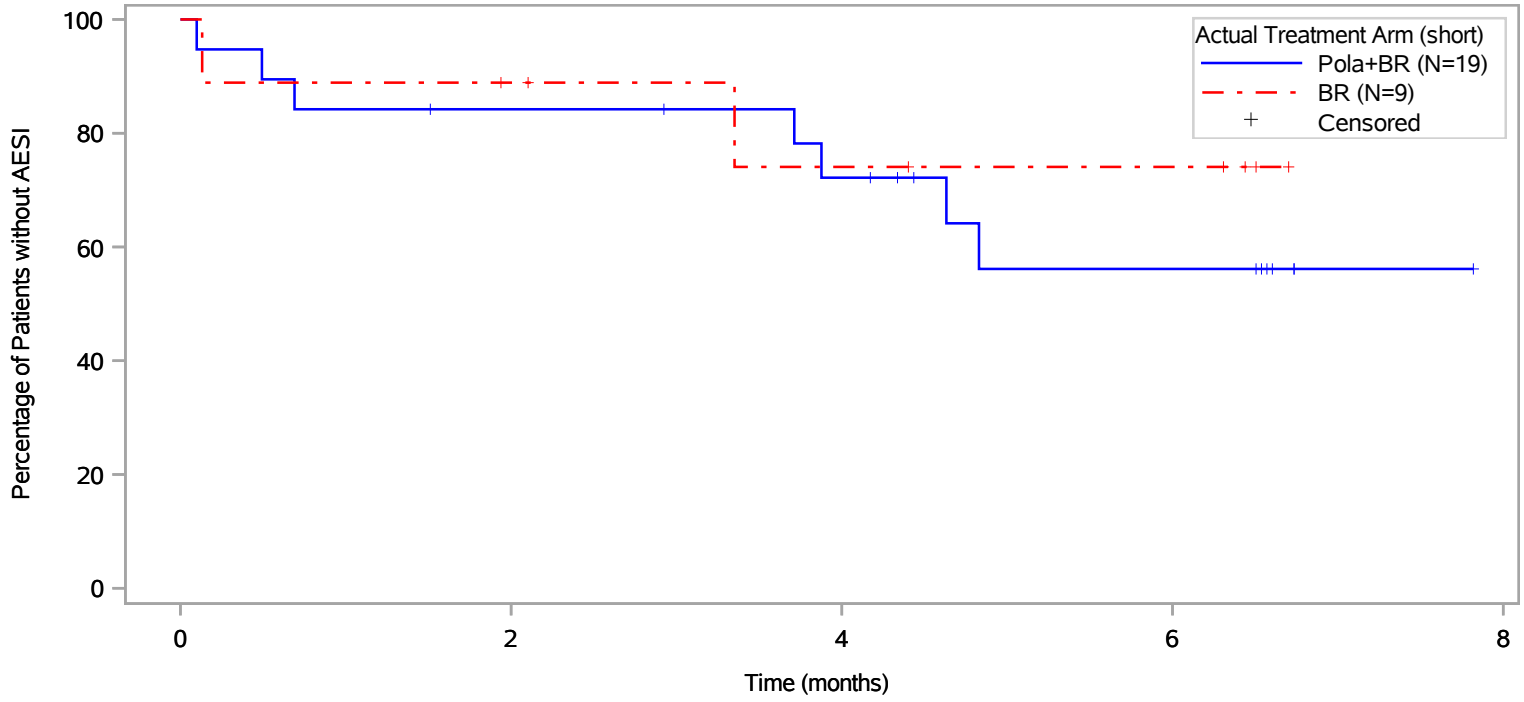
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	7	36.8	12	63.2	9	100.0	2	22.2	7	77.8	0.5803	1.55	0.32	7.49		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	4	28.6	10	71.4	6	66.7	1	16.7	5	83.3	0.7871	1.35	0.15	12.14		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	3	60.0	2	40.0	3	33.3	1	33.3	2	66.7	0.5800	1.88	0.19	18.13		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	6	37.5	10	62.5	7	77.8	2	28.6	5	71.4	0.9691	0.97	0.19	4.85		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	7	50.0	7	50.0	6	66.7	2	33.3	4	66.7	0.6797	1.39	0.29	6.80		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	7	36.8	12	63.2	9	100.0	2	22.2	7	77.8	0.5803	1.55	0.32	7.49		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTINECT_L3PLUS_Polarose_SE_29365_41543.xls
30MAR2023 9:17

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	16	15	14	12	7	7	1
BR (N=9)	9	8	7	6	5	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	11
BR (N=9)	0	0	1	2	2	3	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_TTINECT_L3PLUS_Polarose_SE_29365_41543.pdf
30MAR2023 11:21

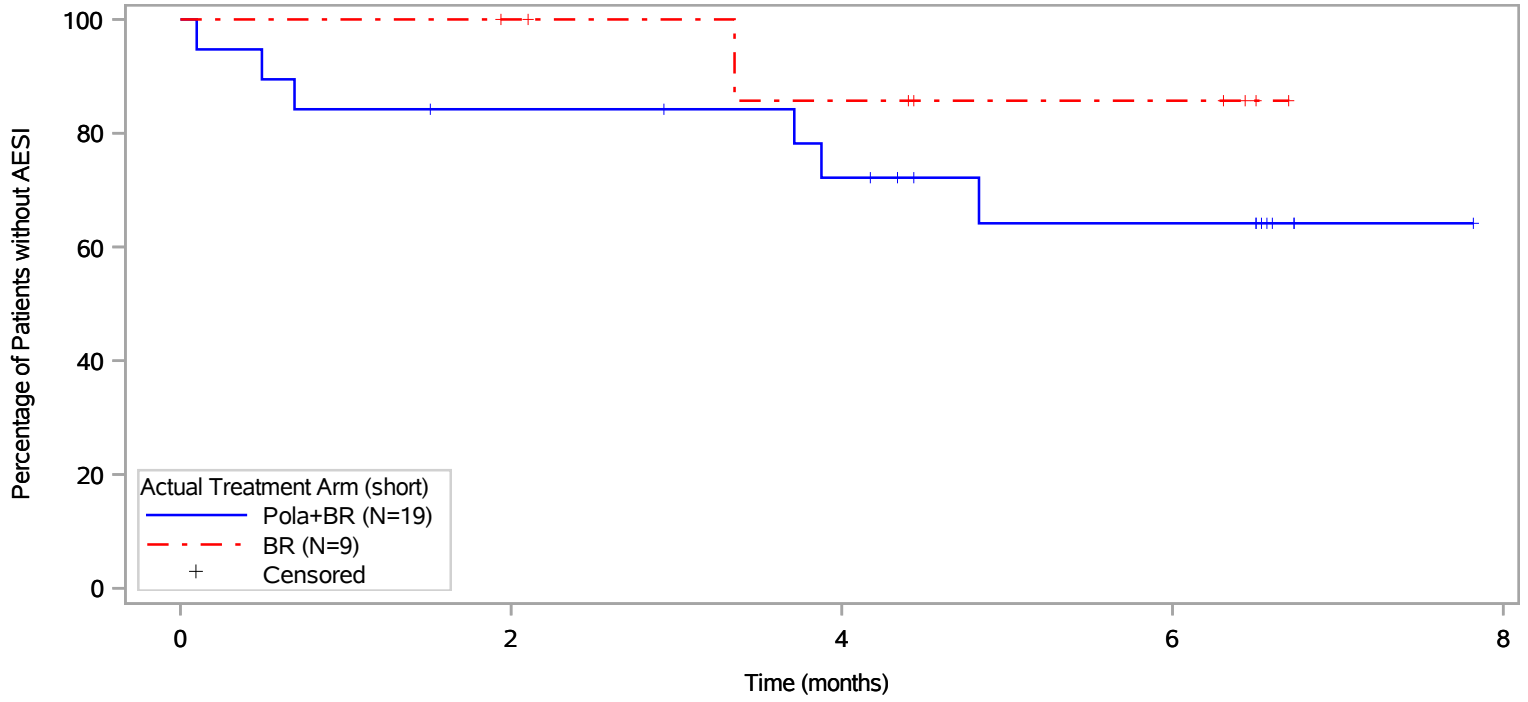
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	6	31.6	13	68.4	9	100.0	1	11.1	8	88.9	0.3089	2.86	0.34	23.76		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	4	28.6	10	71.4	6	66.7	1	16.7	5	83.3	0.7871	1.35	0.15	12.14		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	5	31.3	11	68.8	7	77.8	1	14.3	6	85.7	0.5861	1.80	0.21	15.54		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	6	42.9	8	57.1	6	66.7	1	16.7	5	83.3	0.3586	2.60	0.31	21.66		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	1	11.1	8	88.9	0.3089	2.86	0.34	23.76		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTINECT35_L3PLUS_Polarose_SE_29365_41543.xls
30MAR2023 10:57

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infections and Infestations of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	16	15	14	12	8	8	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	12
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTINECT35_L3PLUS_Polarose_SE_29365_41543.pdf
30MAR2023 13:21

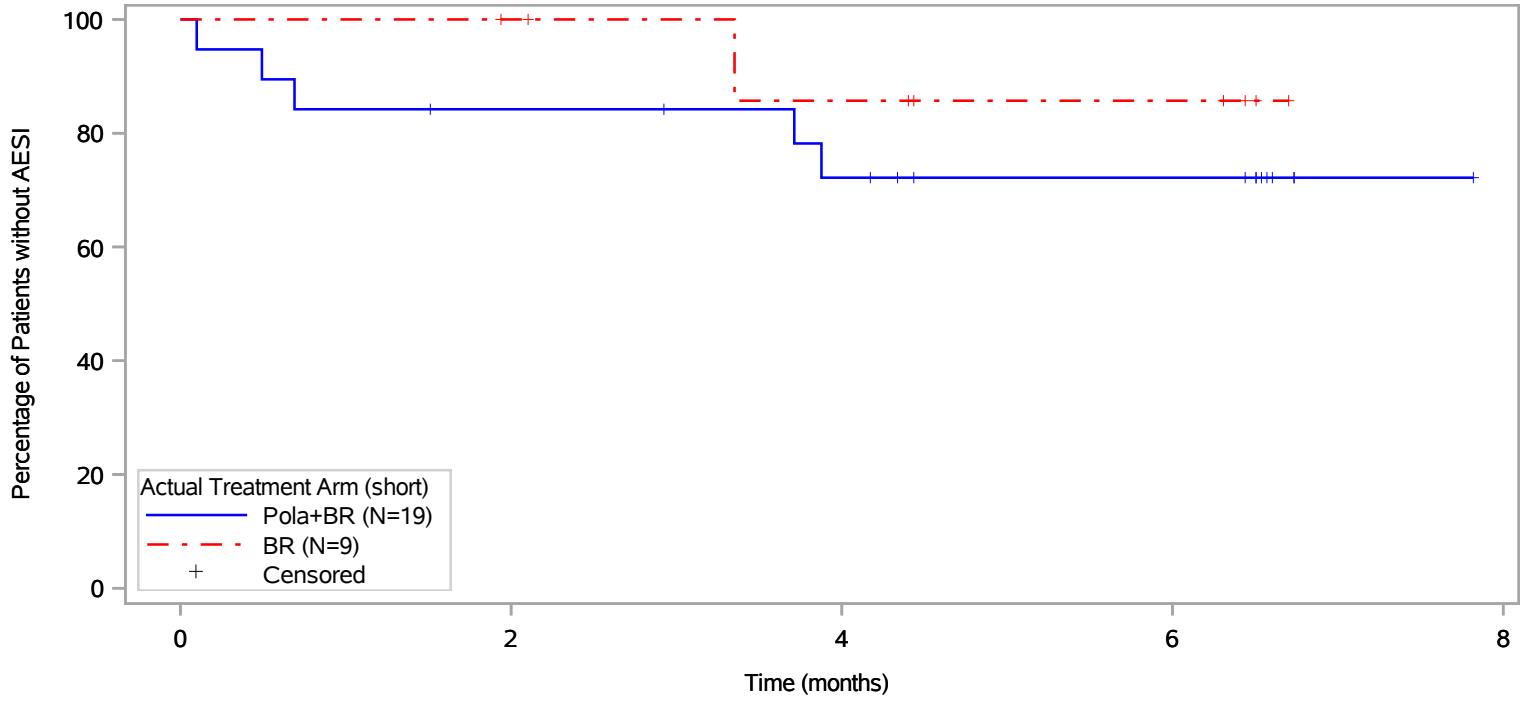
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infections and Infestations
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	5	26.3	14	73.7	9	100.0	1	11.1	8	88.9	0.4074	2.41	0.28	20.63		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.9892	1.02	0.10	9.83		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	4	25.0	12	75.0	7	77.8	1	14.3	6	85.7	0.6993	1.54	0.17	13.80		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	5	35.7	9	64.3	6	66.7	1	16.7	5	83.3	0.4852	2.11	0.25	18.13		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	1	11.1	8	88.9	0.4074	2.41	0.28	20.63		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTINECTS_L3PLUS_Polarose_SE_29365_41543.xls
30MAR2023 10:05

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infections and Infestations
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	16	15	14	12	9	9	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	5	13
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTINECTS_L3PLUS_Polarose_SE_29365_41543.pdf
30MAR2023 12:29

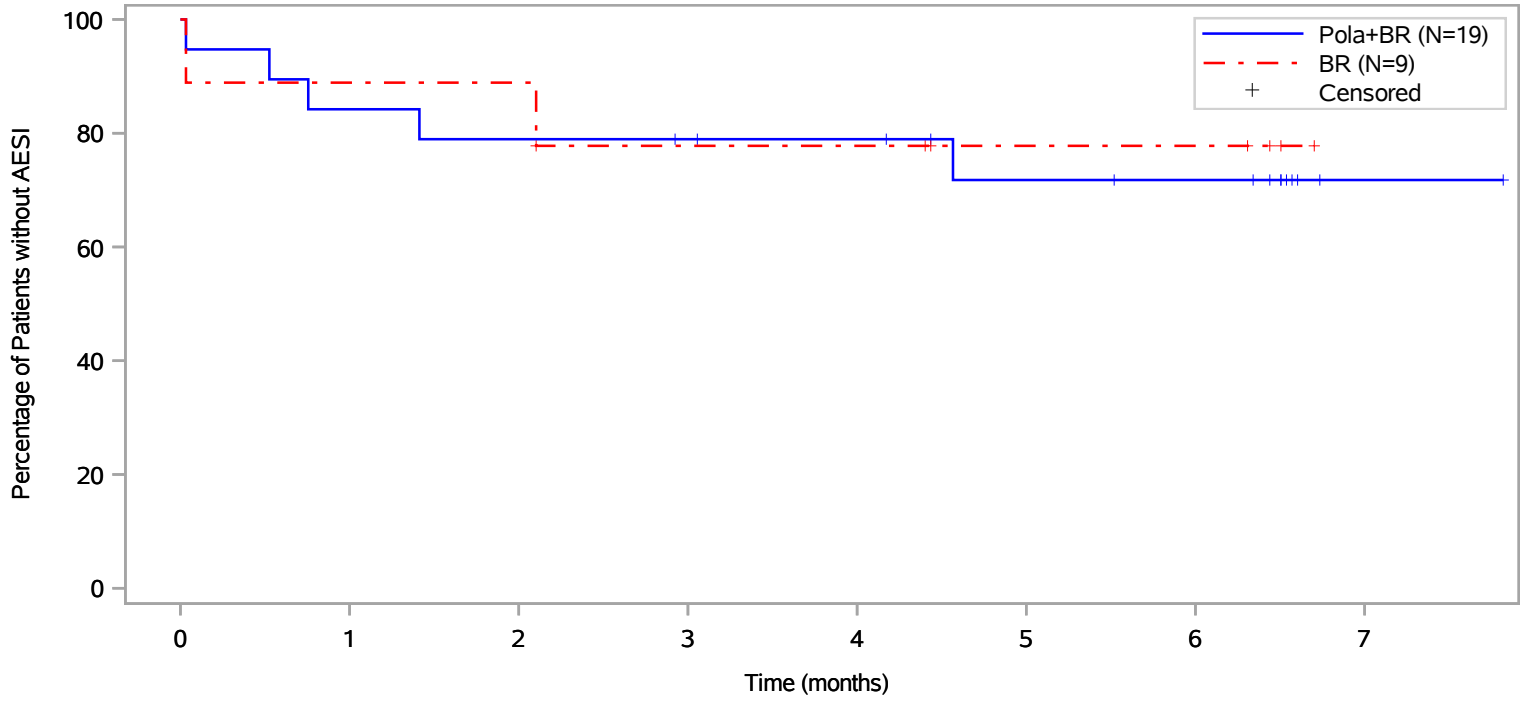
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	5	26.3	14	73.7	9	100.0	2	22.2	7	77.8	0.8583	1.16	0.22	6.05		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	4	28.6	10	71.4	6	66.7	2	33.3	4	66.7	0.7715	0.78	0.14	4.34		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	4	25.0	12	75.0	7	77.8	2	28.6	5	71.4	0.7555	0.76	0.14	4.21		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	4	28.6	10	71.4	6	66.7	2	33.3	4	66.7	0.7883	0.79	0.14	4.41		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	5	26.3	14	73.7	9	100.0	2	22.2	7	77.8	0.8583	1.16	0.22	6.05		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTIRR_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 3:22

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	16	15	14	13	10	9	1
BR (N=9)	9	8	8	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	0	1	2	4	5	13
BR (N=9)	0	0	0	1	1	3	3	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTIRR_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 20:59

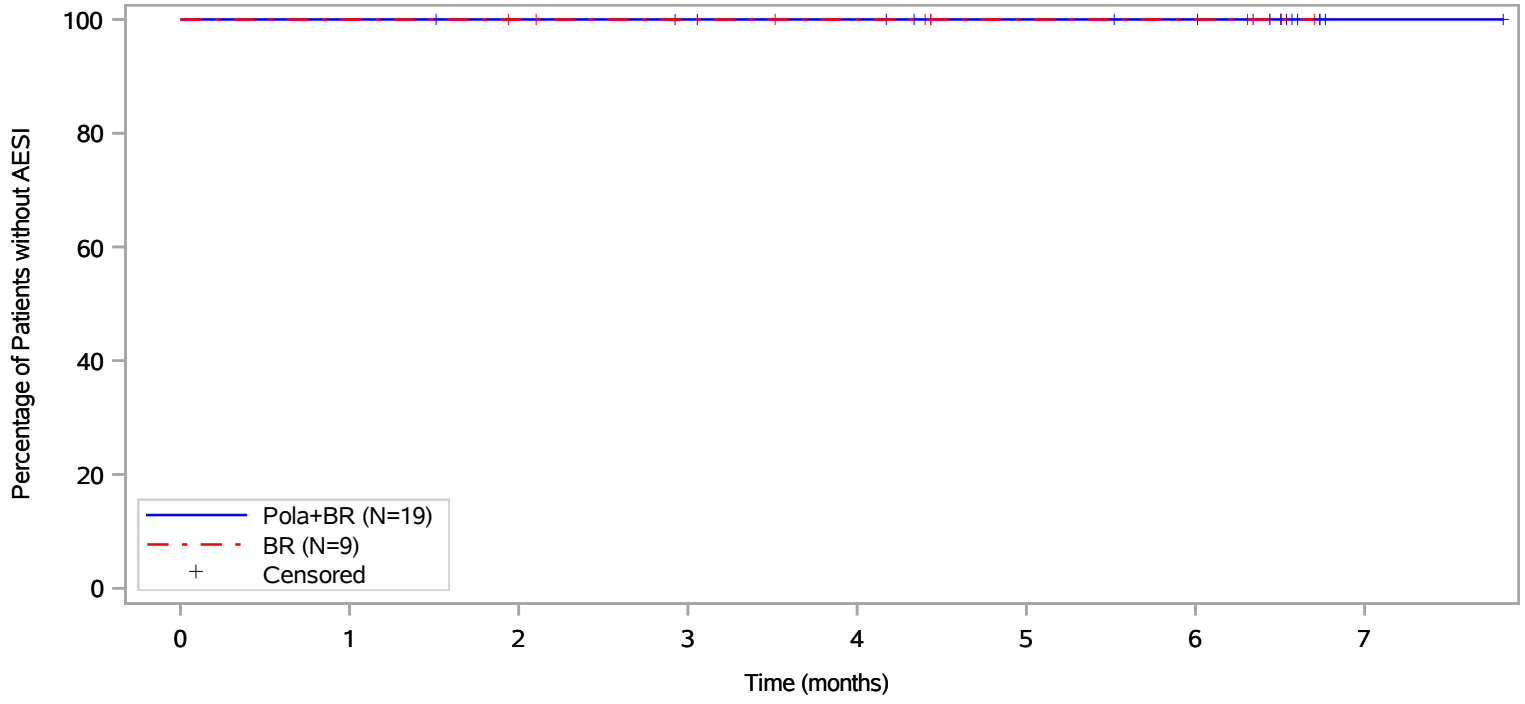
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTIRR35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 20:51

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Infusion Related Reactions of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_TTIRR35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 23:09

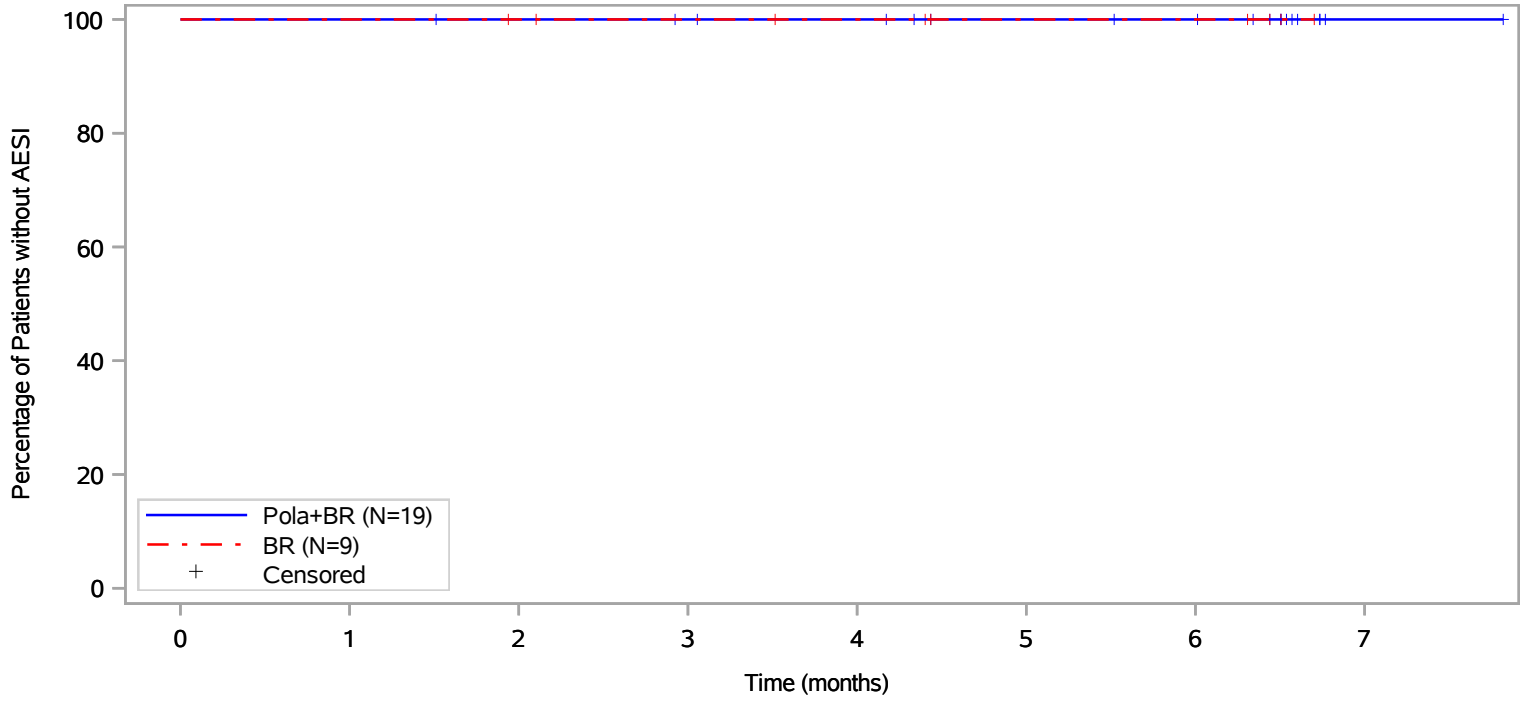
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTIRRS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 20:52

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Infusion Related Reactions
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTIRRS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 1:14

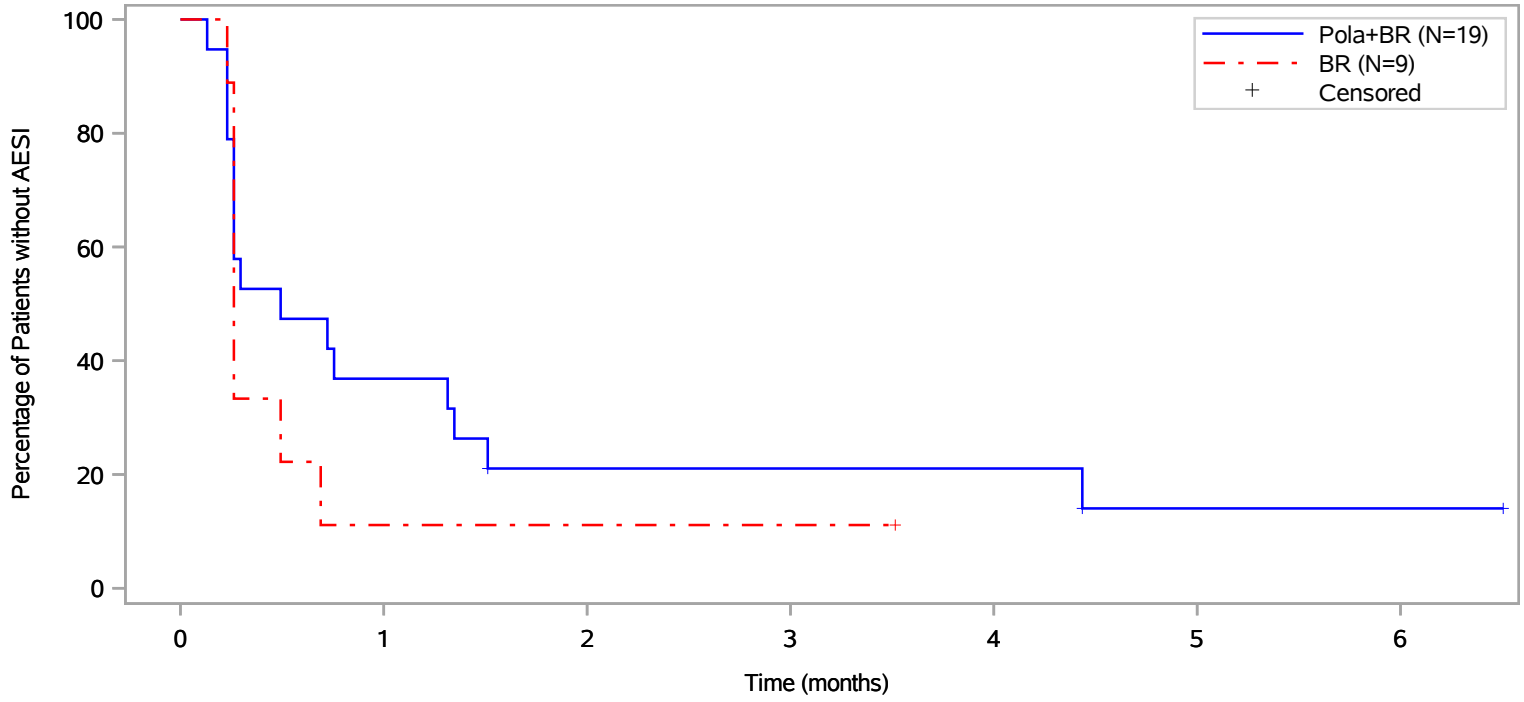
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	16	84.2	3	15.8	9	100.0	8	88.9	1	11.1	0.3607	0.63	0.24	1.69		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	12	85.7	2	14.3	6	66.7	5	83.3	1	16.7	0.8253	0.87	0.25	2.99		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	4	80.0	1	20.0	3	33.3	3	100.0	0	-	0.0568	0.13	0.01	1.38		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	14	87.5	2	12.5	7	77.8	6	85.7	1	14.3	0.5127	0.70	0.24	2.04		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	2	100.0	0	-	0.7009	0.60	0.05	8.03		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	11	78.6	3	21.4	6	66.7	5	83.3	1	16.7	0.5054	0.66	0.20	2.22		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	5	100.0	0	-	3	33.3	3	100.0	0	-	0.4778	0.53	0.09	3.12		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	16	84.2	3	15.8	9	100.0	8	88.9	1	11.1	0.3607	0.63	0.24	1.69		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTNIFNEU_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 0:08

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	7	3	3	3	1	1
BR (N=9)	9	1	1	1	NE	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	1	1	1	2	2
BR (N=9)	0	0	0	0	NE	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTNIFNEU_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 20:31

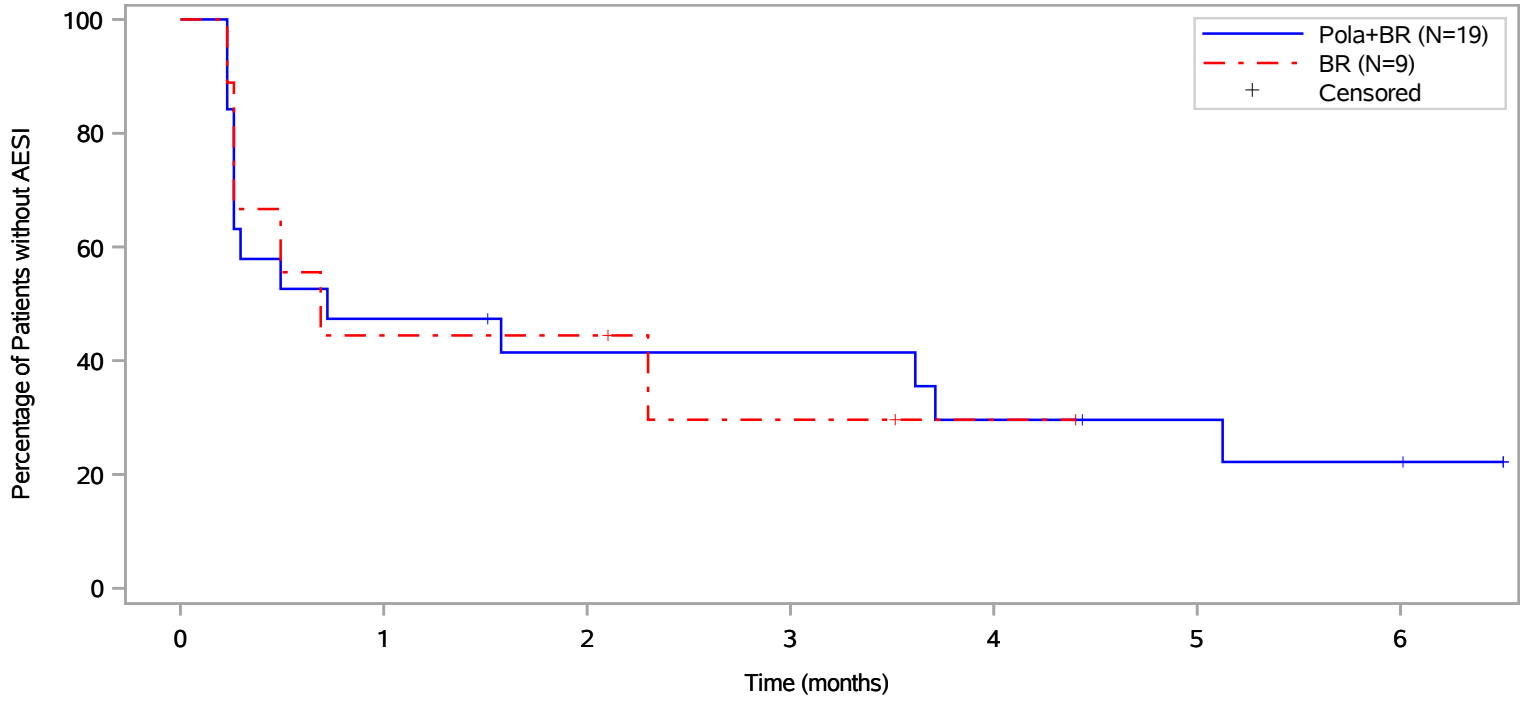
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	14	73.7	5	26.3	9	100.0	6	66.7	3	33.3	0.9346	0.96	0.34	2.69		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	12	85.7	2	14.3	6	66.7	3	50.0	3	50.0	0.3453	1.89	0.50	7.18		Convergence criterion (GCONV=1E-8) satisfied.	
	Female	5	26.3	2	40.0	3	60.0	3	33.3	3	100.0	0	-	0.0568	0.13	0.01	1.38		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	12	75.0	4	25.0	7	77.8	4	57.1	3	42.9	0.9361	1.05	0.31	3.52		Convergence criterion (GCONV=1E-8) satisfied.	
	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	2	100.0	0	-	0.5408	2.22	0.16	29.97		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	10	71.4	4	28.6	6	66.7	4	66.7	2	33.3	0.6485	0.74	0.20	2.72		Convergence criterion (GCONV=1E-8) satisfied.	
	<3	5	26.3	4	80.0	1	20.0	3	33.3	2	66.7	1	33.3	0.5394	1.70	0.30	9.54		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	14	73.7	5	26.3	9	100.0	6	66.7	3	33.3	0.9346	0.96	0.34	2.69		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTNIFNEU35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 19:58

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Neutropenia Including Febrile Neutropenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	9	7	7	5	4	3
BR (N=9)	9	4	4	2	1	NE	NE
Patients censored							
Pola+BR (N=19)	0	0	1	1	1	2	2
BR (N=9)	0	0	0	1	2	NE	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._CSR_Pooled/prod/output_Polarose/g_km_TTNIFNEU35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 22:34

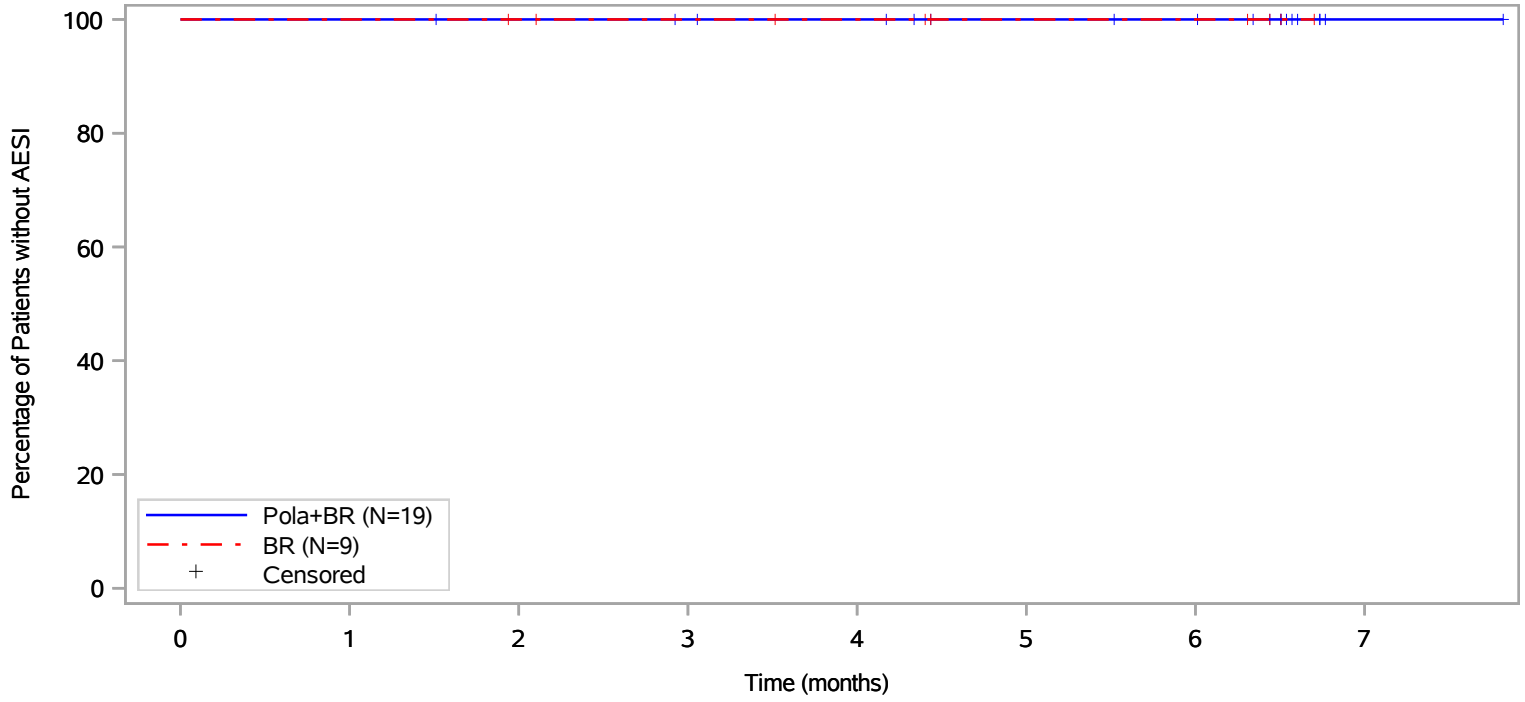
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTNIFNEUS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 19:54

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Neutropenia Including Febrile Neutropenia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTNIFNEUS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 0:44

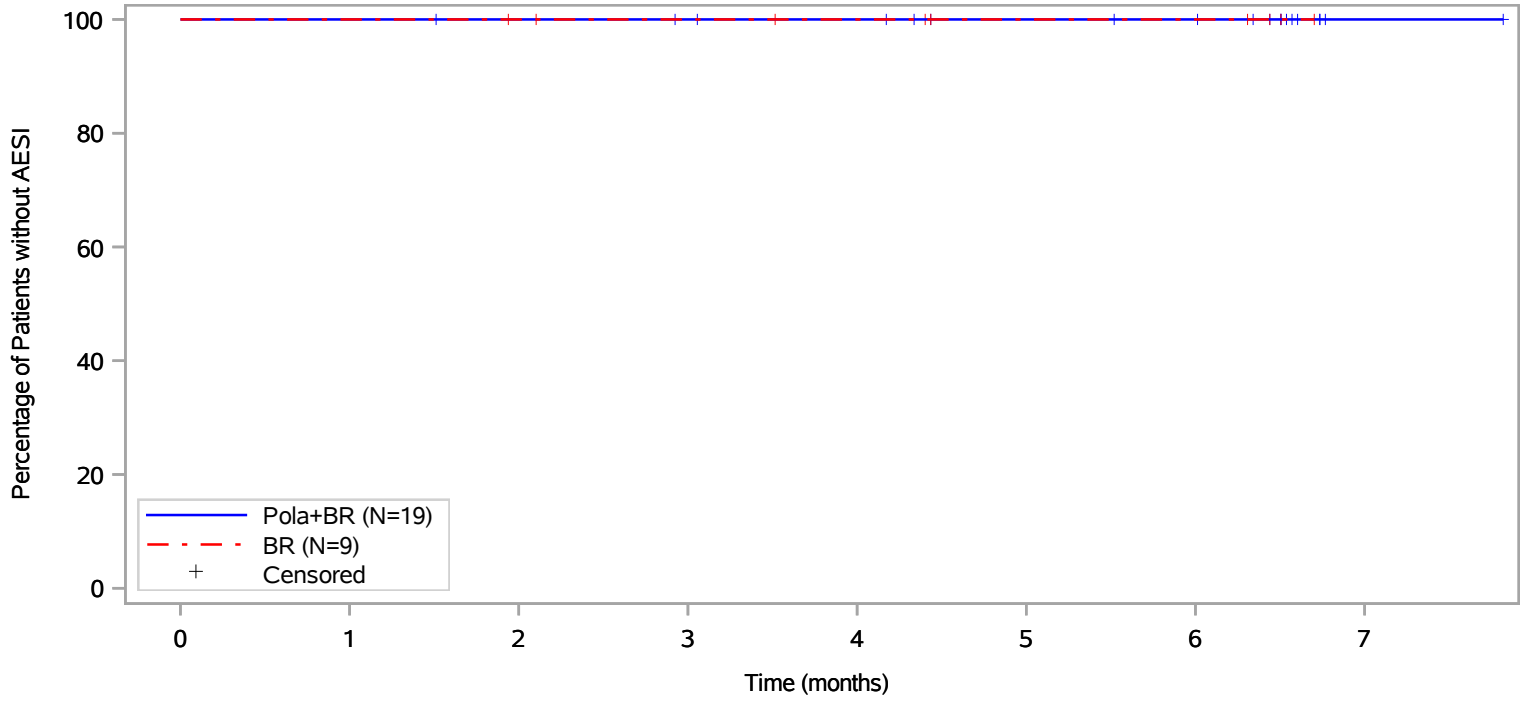
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTOCUTOX_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 20:39

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTOCUTOX_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 22:03

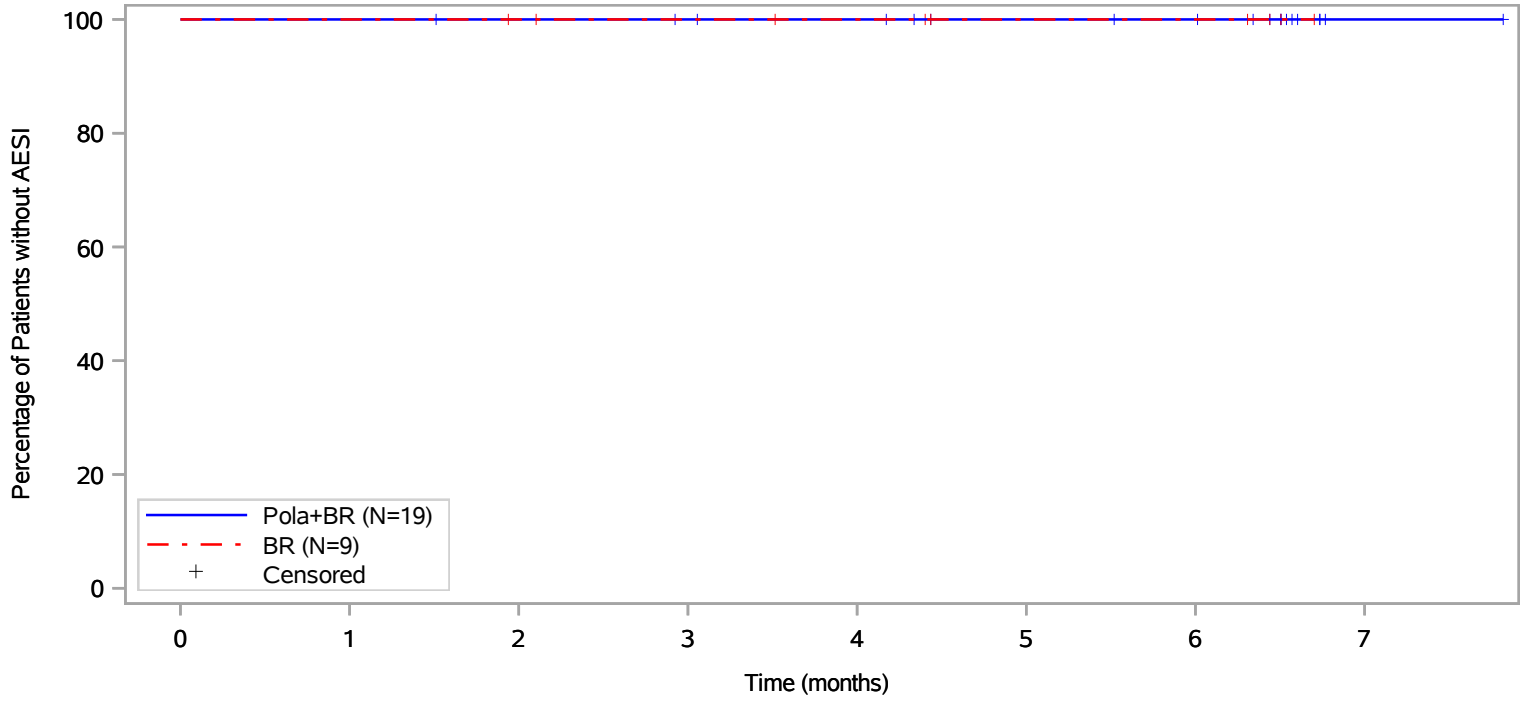
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTOCUTOX35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 22:12

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Ocular Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._CSR_Pooled/prod/output_Polarose/g_km_TTOCUTOX35_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 0:12

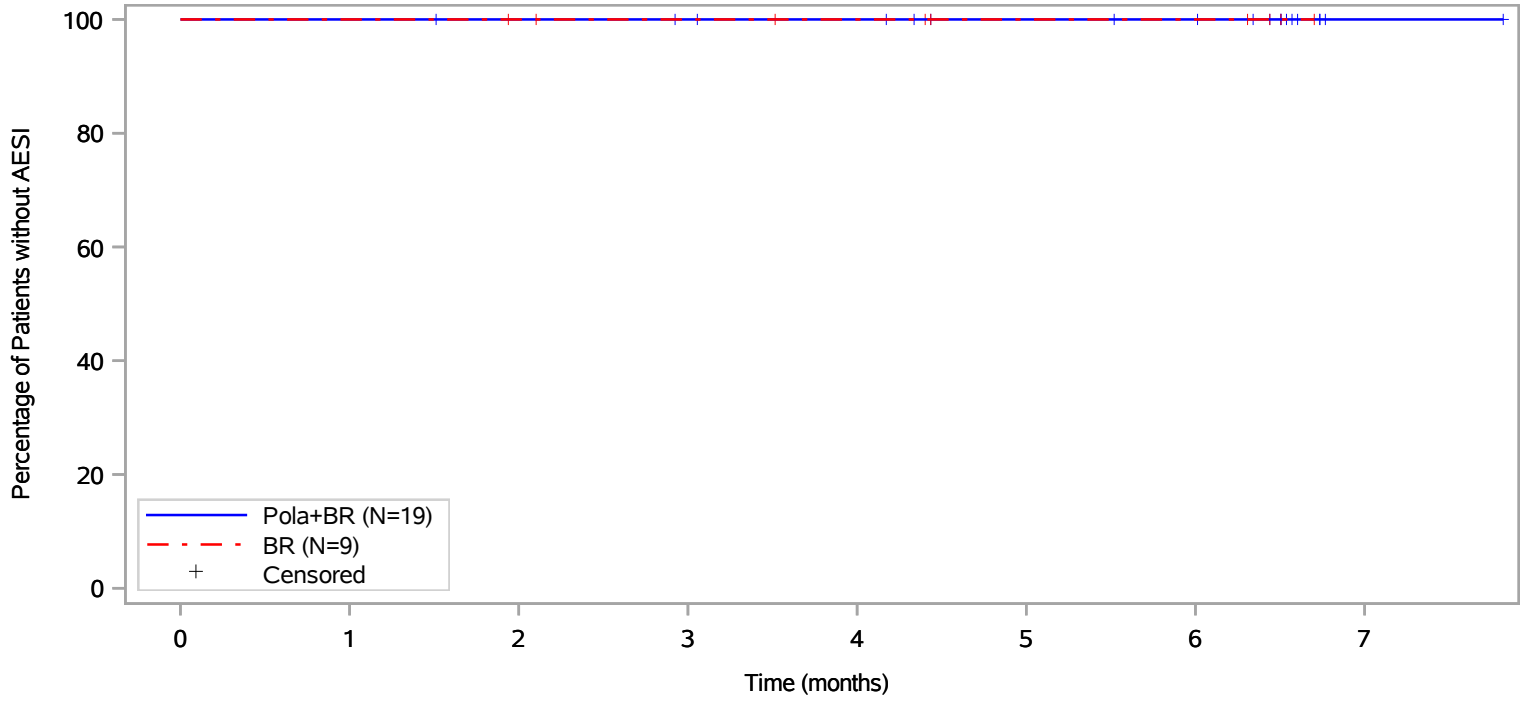
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Ocular Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTOCUTOXS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 22:14

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Ocular Toxicity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTOCUTOXS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 2:29

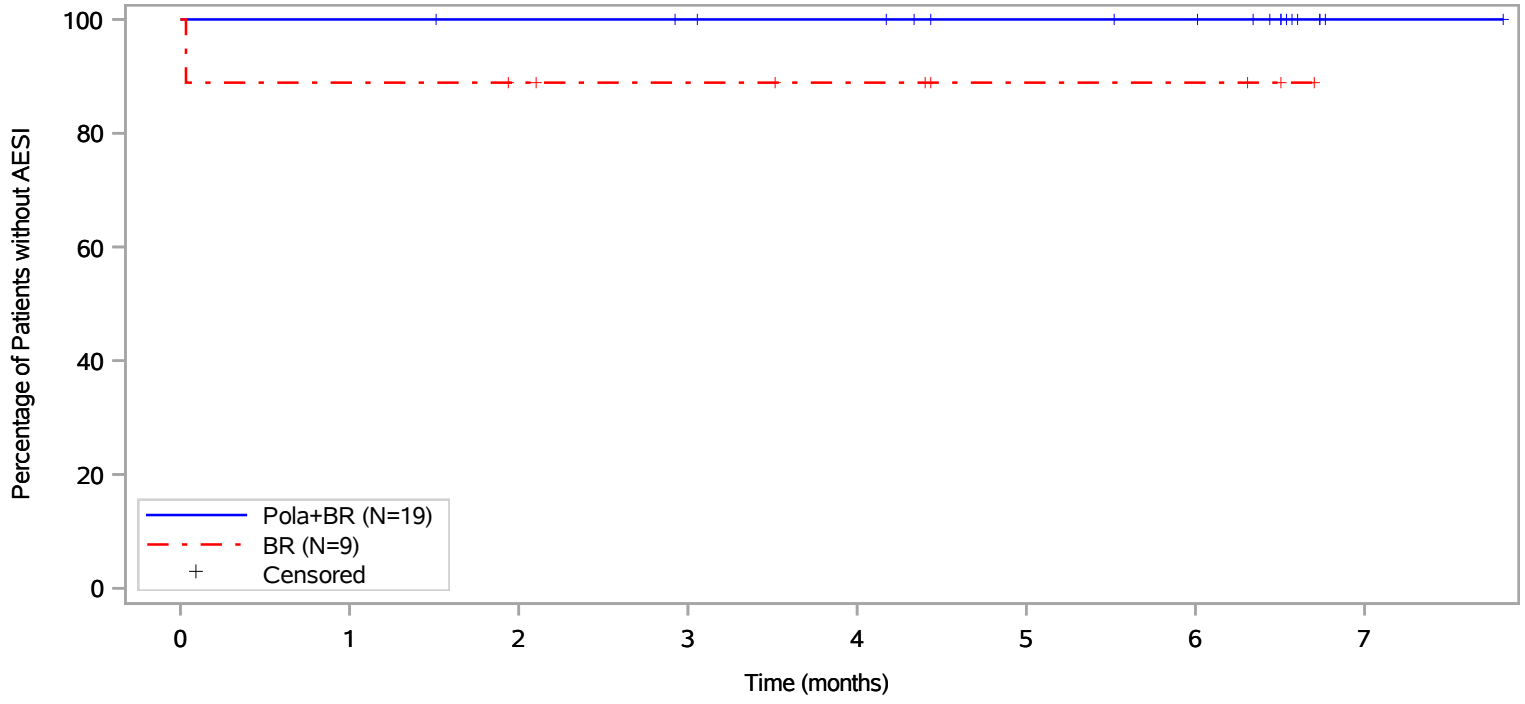
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1967	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	1	50.0	1	50.0	0.2207	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPAIN_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 18:08

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	7	6	5	3	3	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..INAL_CSR_Pooled/prod/output_Polarose/g_km_TTPAIN_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 21:45

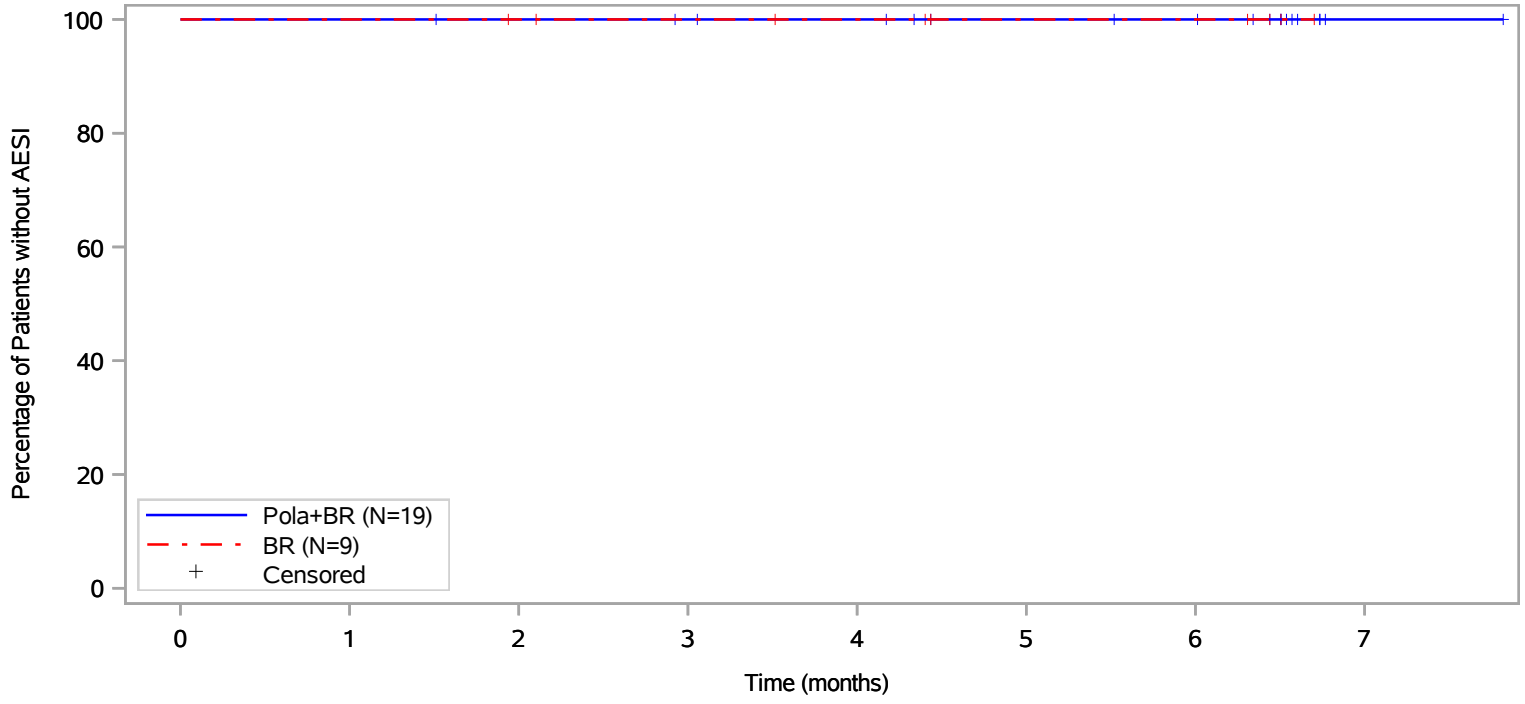
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPAIN35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:48

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Joint Pains, Arthralgia, Skeletal Pains of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTPAIN35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 23:54

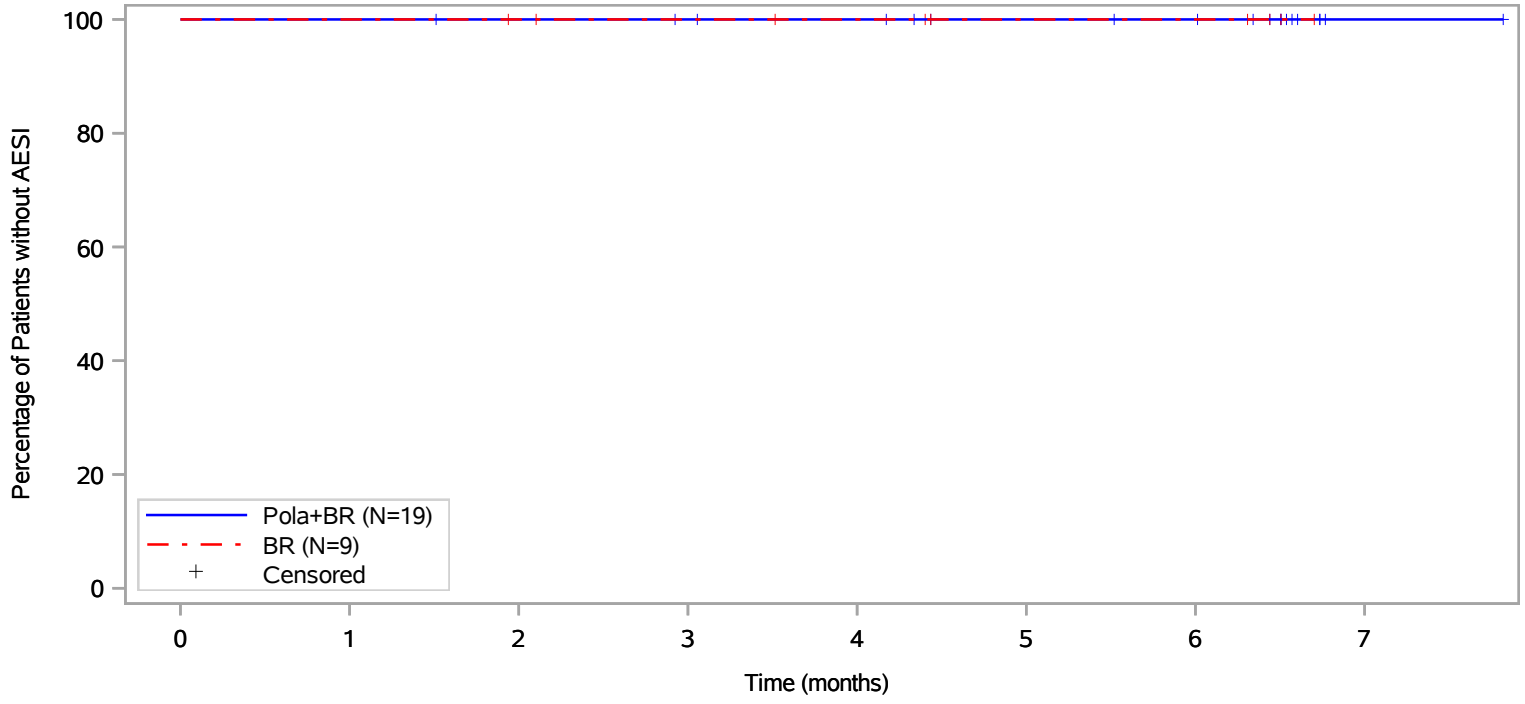
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPAINS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:51

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Joint Pains, Arthralgia, Skeletal Pains
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..NAL_CSR_Pooled/prod/output_Polarose/g_km_TTPAINS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 2:09

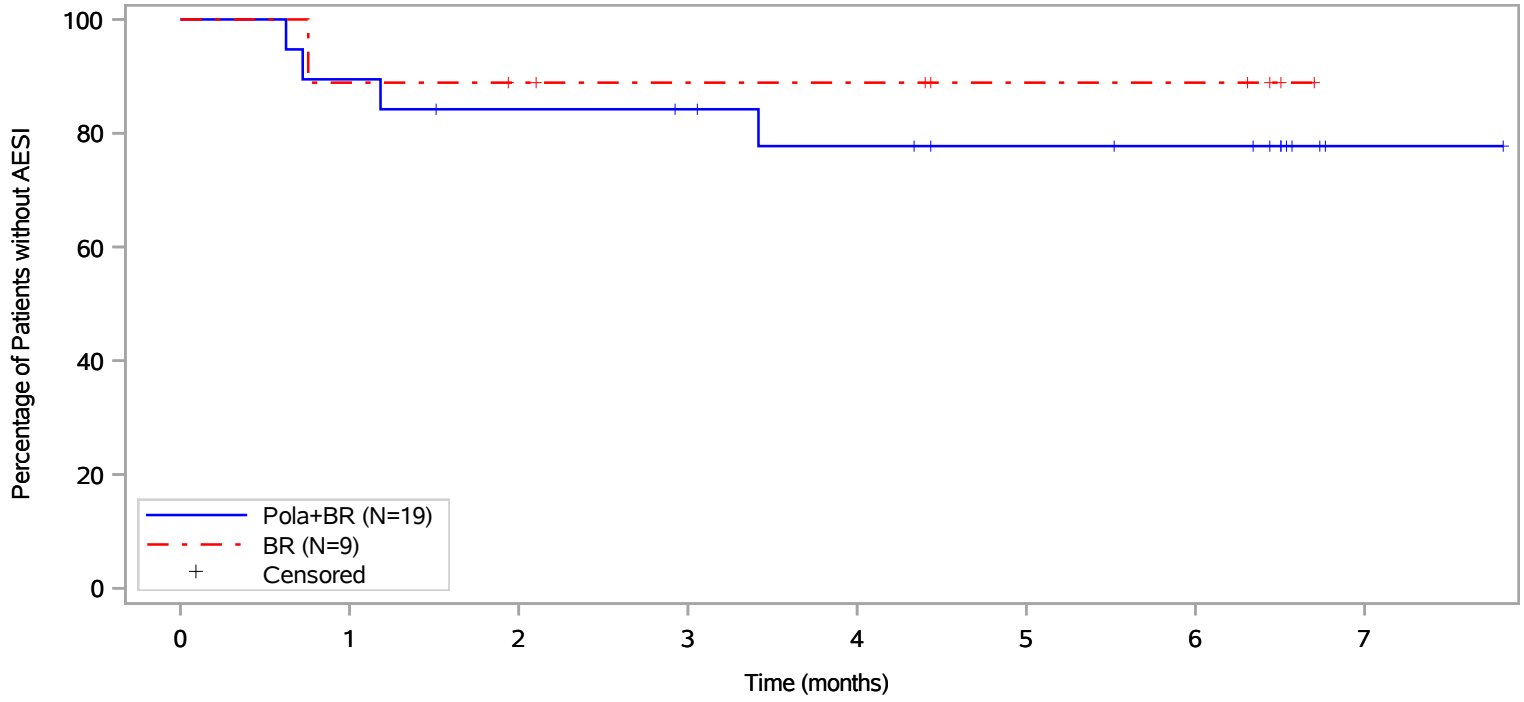
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	4	21.1	15	78.9	9	100.0	1	11.1	8	88.9	0.5439	1.95	0.22	17.43		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.8897	1.17	0.12	11.35		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	3	18.8	13	81.3	7	77.8	1	14.3	6	85.7	0.8221	1.30	0.13	12.52		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	0	-	2	100.0	0.4142	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	3	21.4	11	78.6	6	66.7	1	16.7	5	83.3	0.7926	1.35	0.14	13.02		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	4	21.1	15	78.9	9	100.0	1	11.1	8	88.9	0.5439	1.95	0.22	17.43		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPHENEU_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 0:38

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	17	15	14	12	10	9	1
BR (N=9)	9	8	7	6	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	5	6	14
BR (N=9)	0	0	1	2	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:37

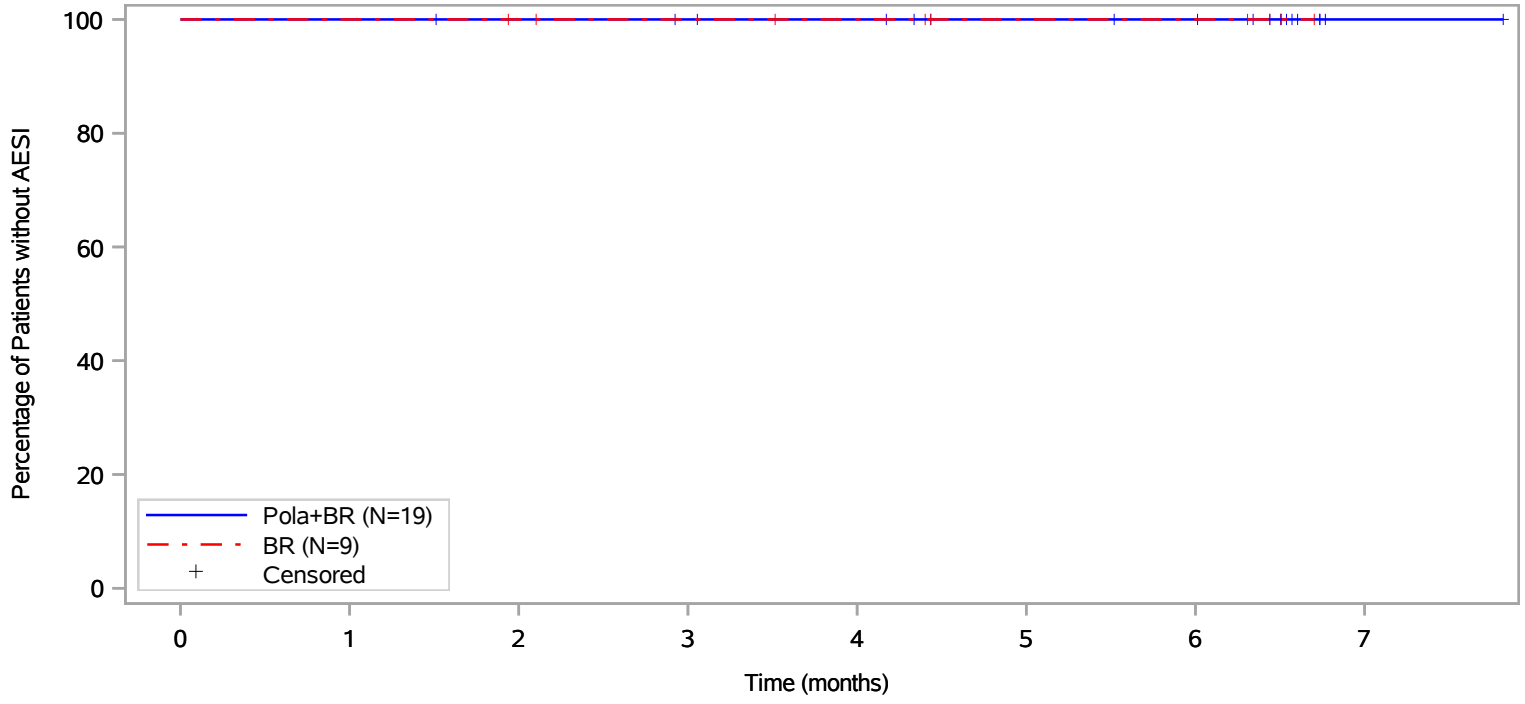
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPHENEU35_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 20:16

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Peripheral Neuropathy of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._CSR_Pooled/prod/output_Polarose/g_km_TTPHENEU35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 22:41

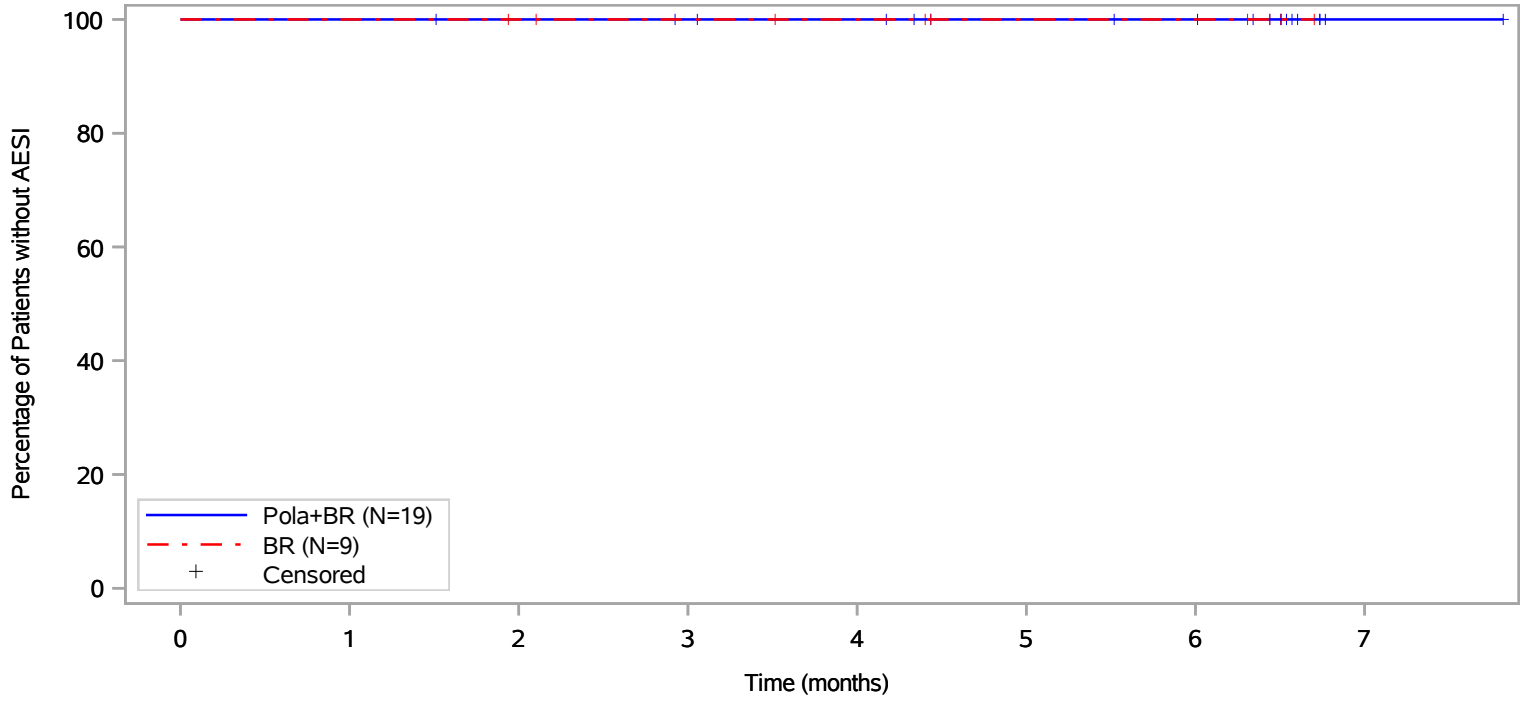
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPHENEUS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 20:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Peripheral Neuropathy
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTPHENEUS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 0:49

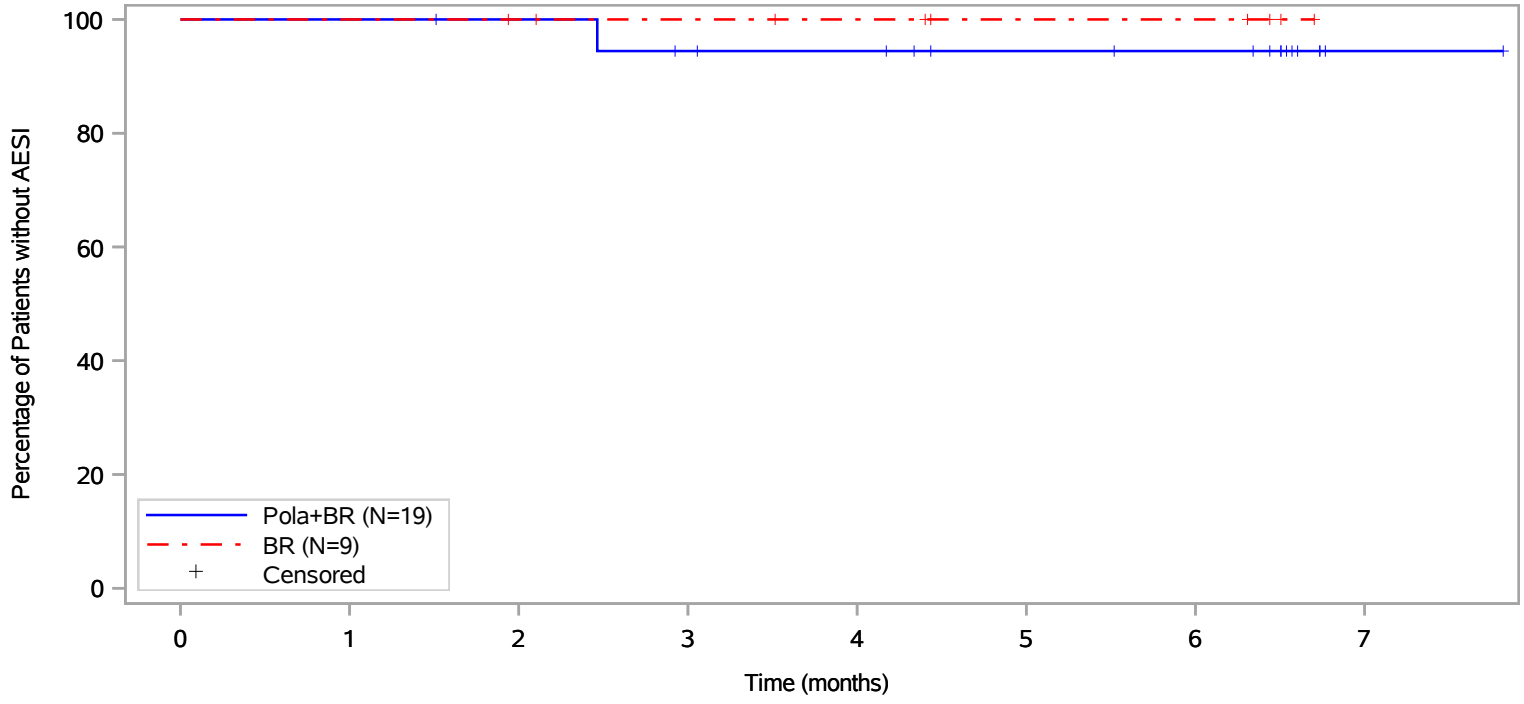
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPULTOX_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 18:19

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTPULTOX_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 21:38

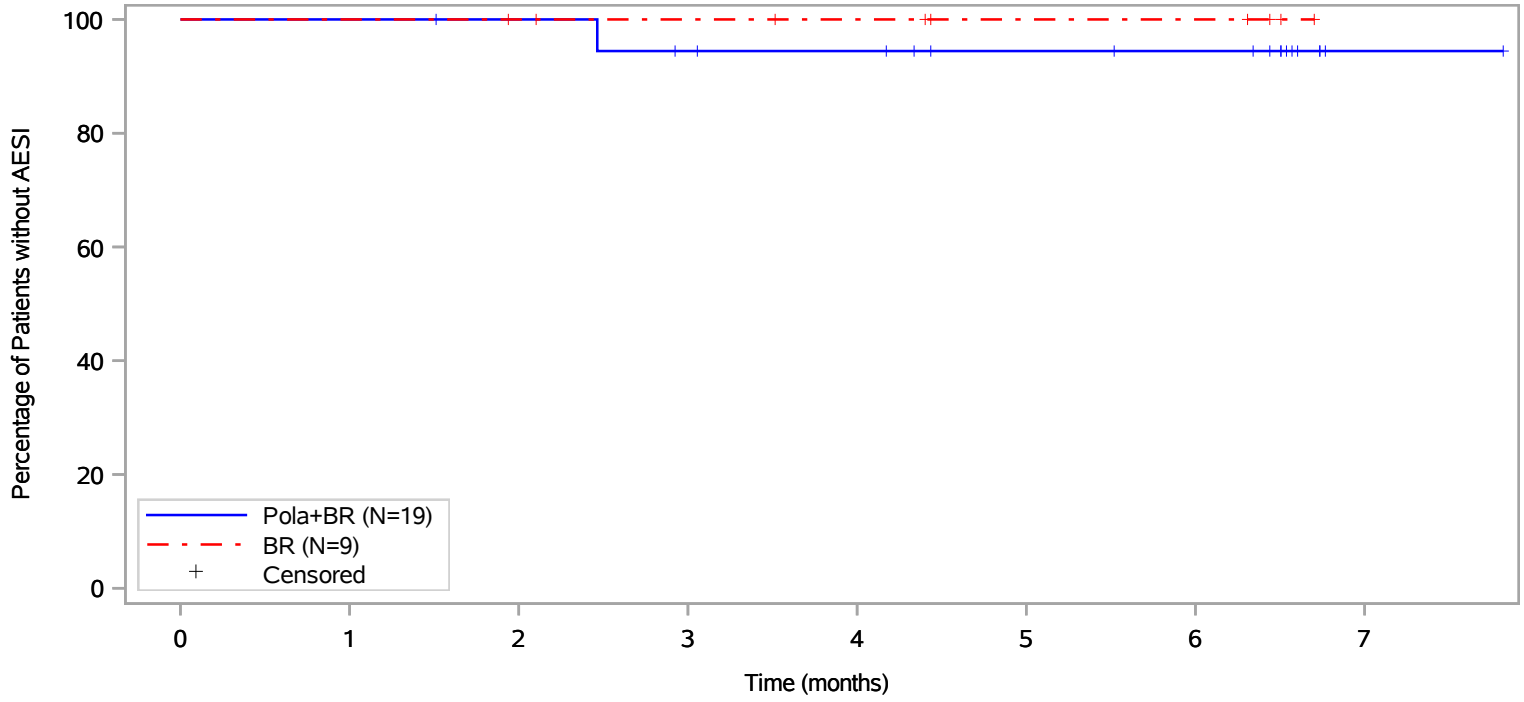
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPULTOX35_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 18:25

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Pulmonary Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._CSR_Pooled/prod/output_Polarose/g_km_TTPULTOX35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 23:49

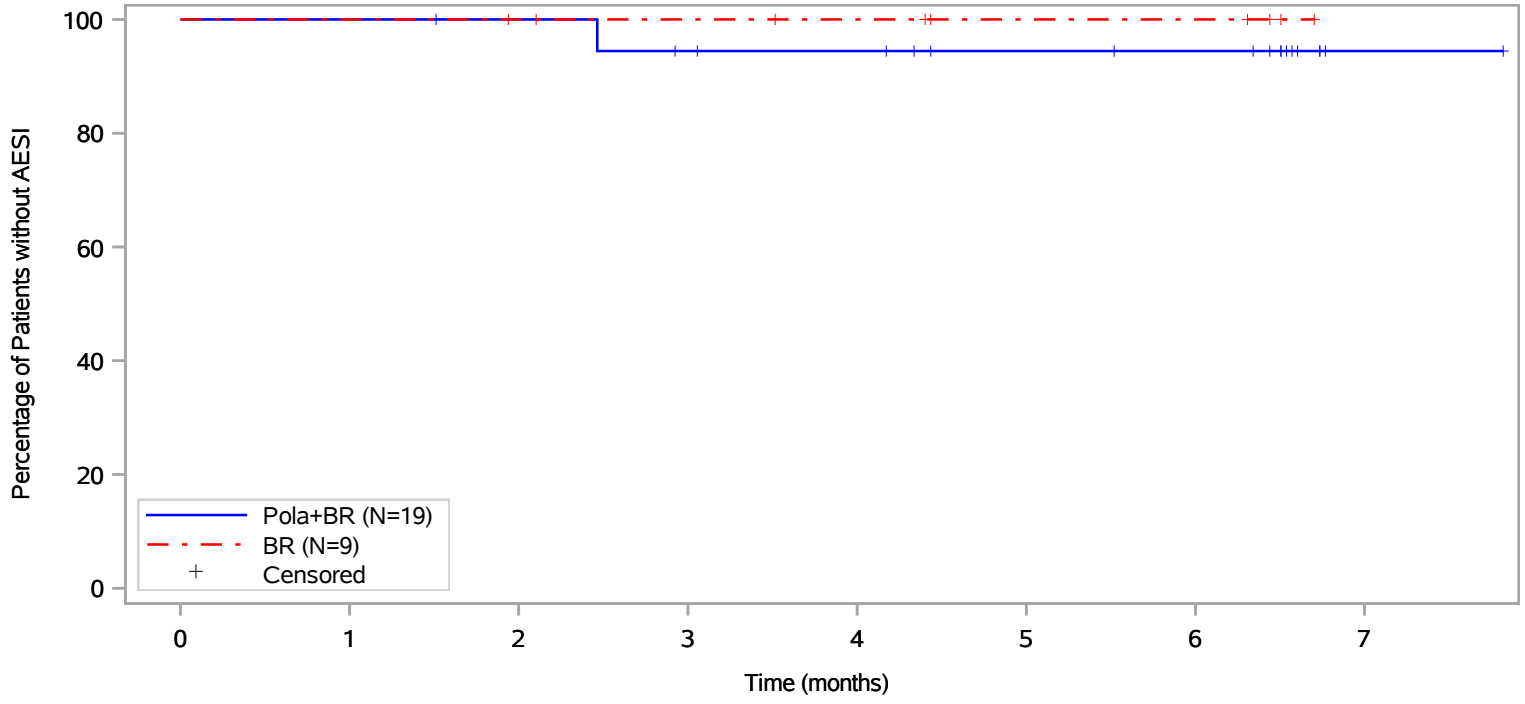
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	1	6.3	15	93.8	7	77.8	0	-	7	100.0	0.5762	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	1	5.3	18	94.7	9	100.0	0	-	9	100.0	0.5329	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTPULTOXS_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 18:30

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Pulmonary Toxicity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	16	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	17
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTPULTOXS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 2:02

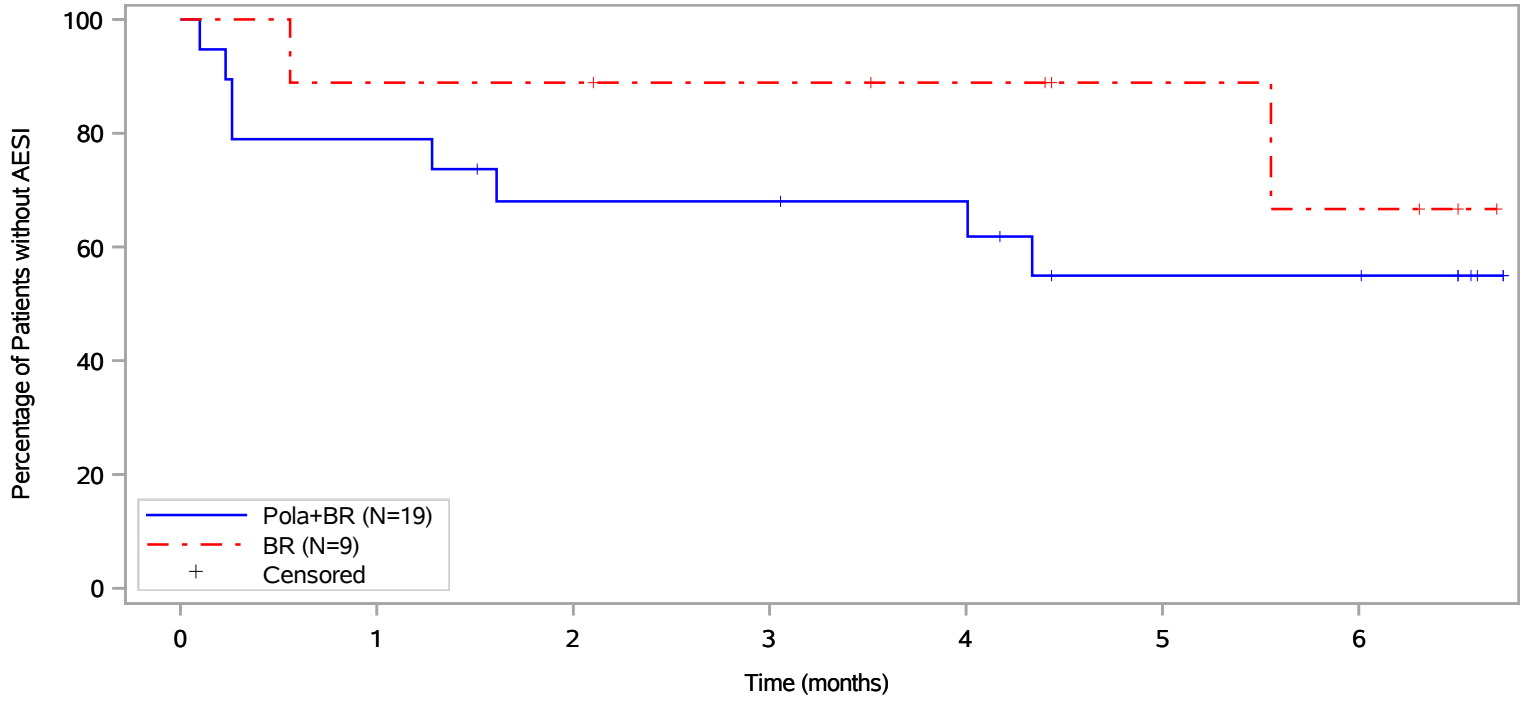
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	8	42.1	11	57.9	9	100.0	2	22.2	7	77.8	0.2984	2.23	0.47	10.57		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	8	57.1	6	42.9	6	66.7	1	16.7	5	83.3	0.1453	4.17	0.52	33.63		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	1	33.3	2	66.7	0.1573	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	7	43.8	9	56.3	7	77.8	1	14.3	6	85.7	0.2212	3.44	0.42	28.15		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	1	33.3	2	66.7	2	22.2	1	50.0	1	50.0	0.8084	1.41	0.08	23.57		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	6	42.9	8	57.1	6	66.7	2	33.3	4	66.7	0.6941	1.38	0.28	6.83		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	8	42.1	11	57.9	9	100.0	2	22.2	7	77.8	0.2984	2.23	0.47	10.57		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTRENTOX_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 6:02

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	15	12	12	11	7	7
BR (N=9)	9	8	8	7	6	4	3
Patients censored							
Pola+BR (N=19)	0	0	1	1	2	4	4
BR (N=9)	0	0	0	1	2	4	4

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTRENTOX_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 21:27

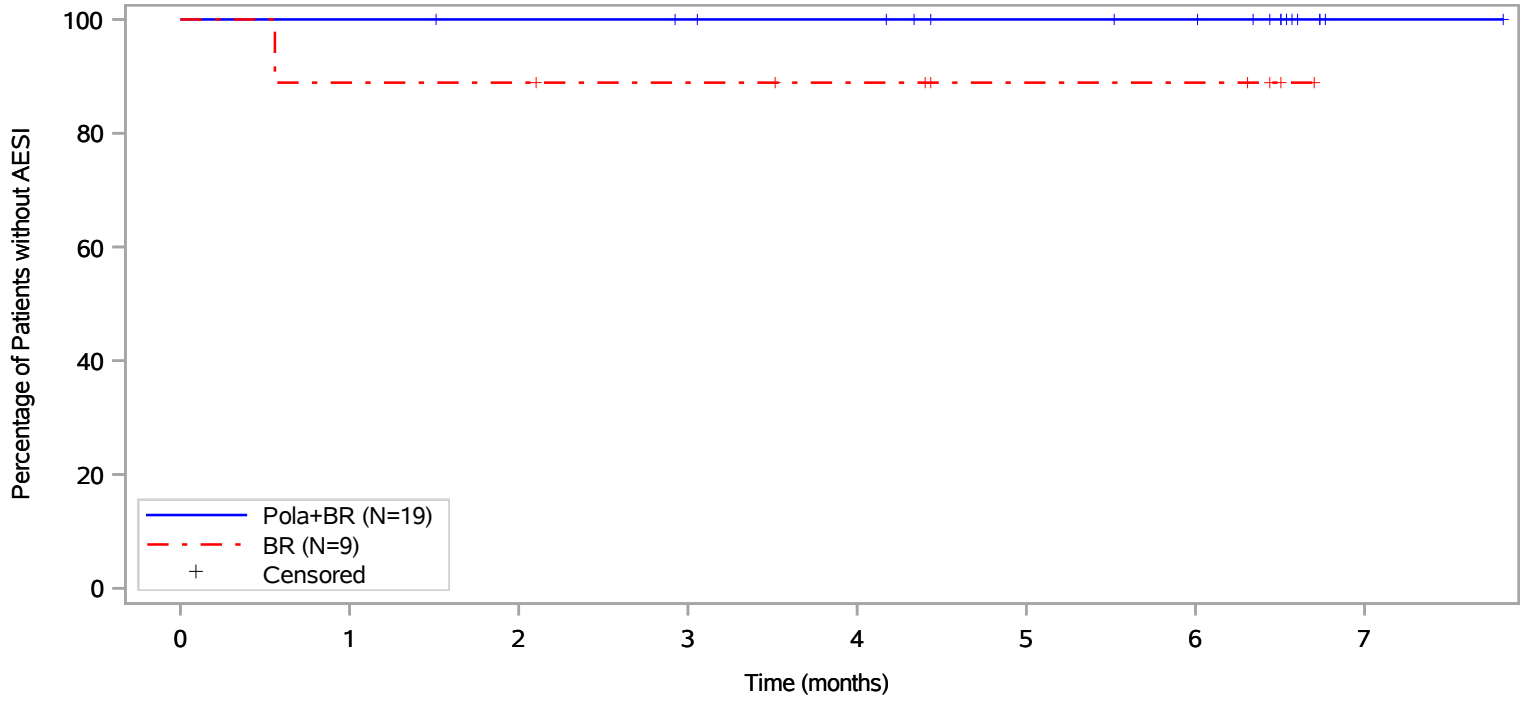
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	1	14.3	6	85.7	0.1306	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	1	16.7	5	83.3	0.1266	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	1	11.1	8	88.9	0.1462	0.00	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTRENTOX35_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 18:36

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Renal Toxicity of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	8	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	0	1	2	4	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: .._CSR_Pooled/prod/output_Polarose/g_km_TTRENTOX35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 23:39

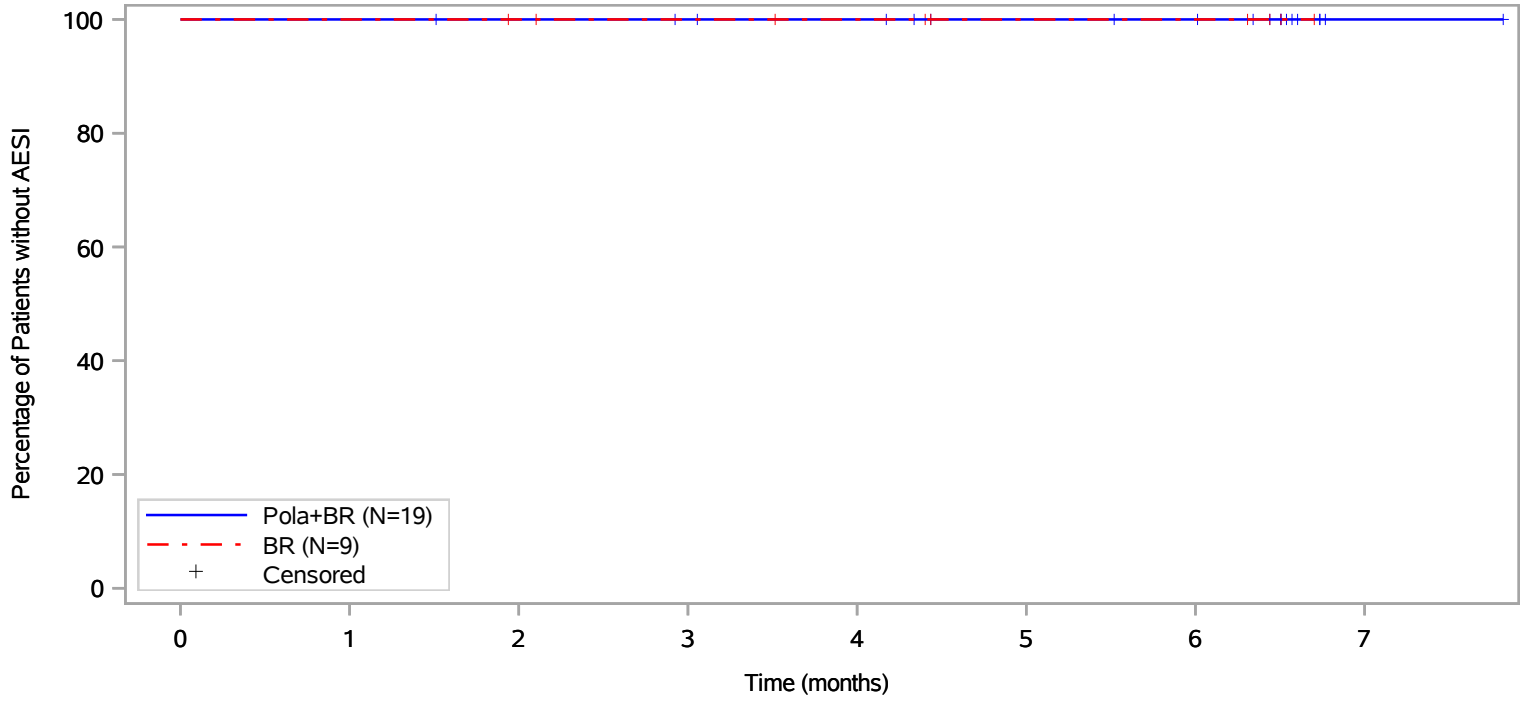
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Renal Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTRENTOXS_L3PLUS_Polarose_SE_29365_41543.xls
02DEC2022 21:25

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Renal Toxicity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTRENTOXS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 1:46

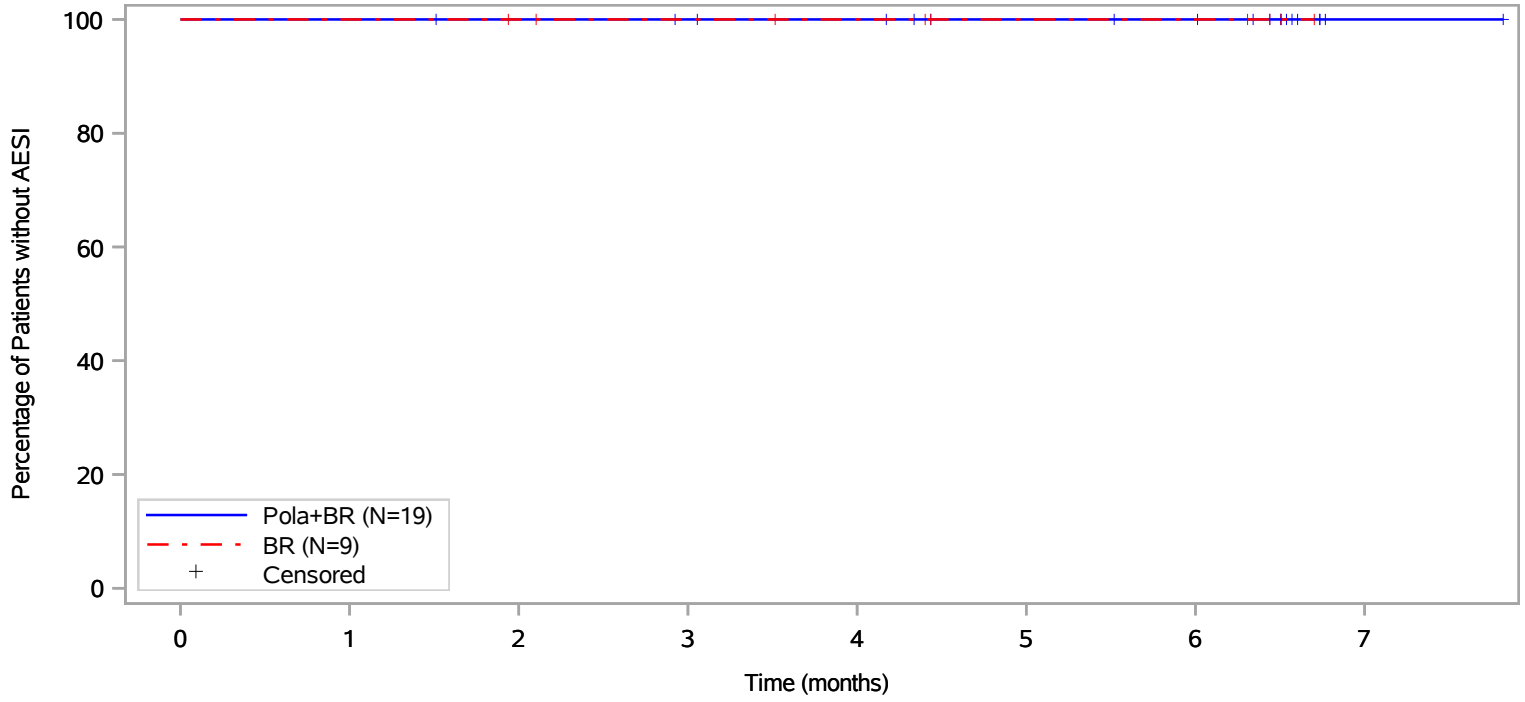
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Reproductive Toxicity
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTREPROD_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 4:30

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Reproductive Toxicity
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTREPROD_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 21:10

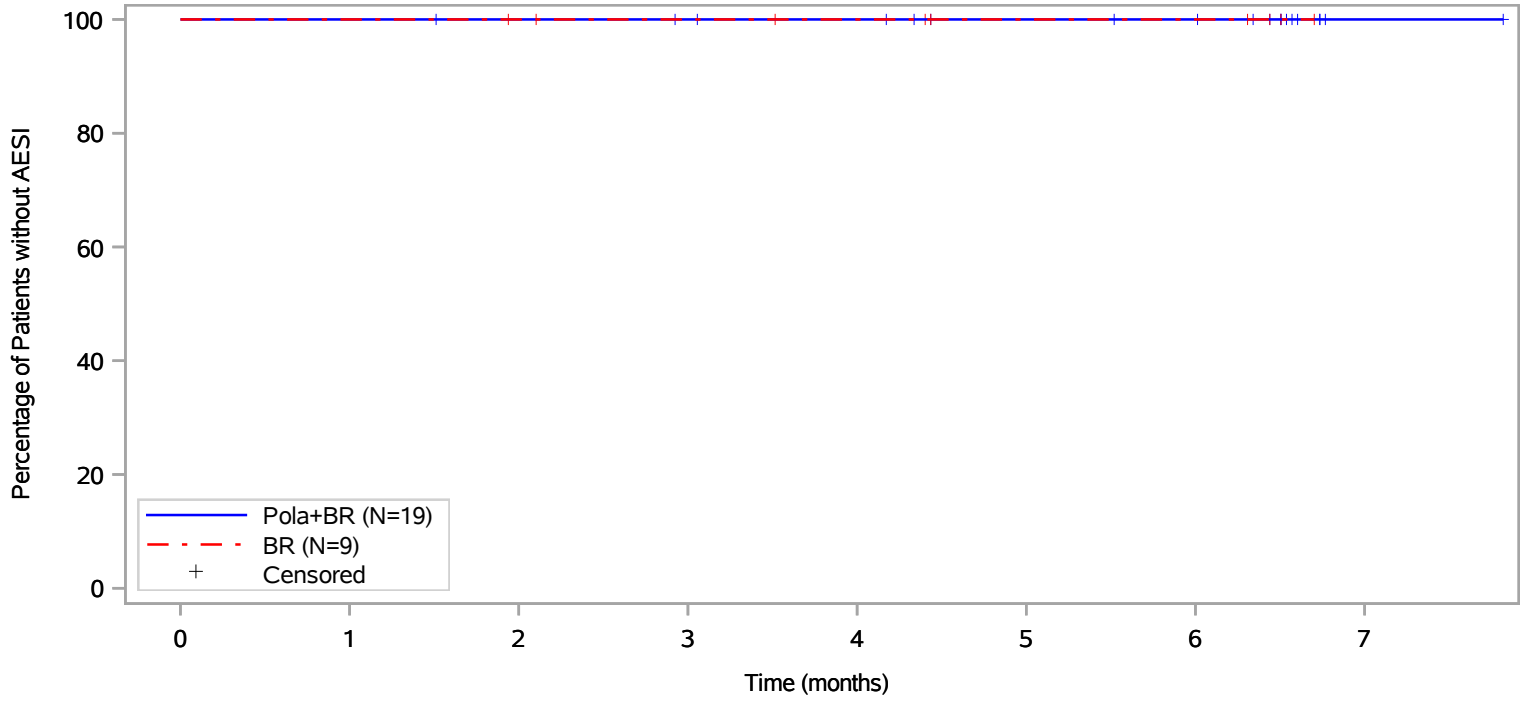
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTSTIAMP_L3PLUS_Polarose_SE_29365_41543.xls
04DEC2022 13:07

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to AE sus.of transmission of Infectious Agent via Med. Prod.
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTSTIAMP_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 14:22

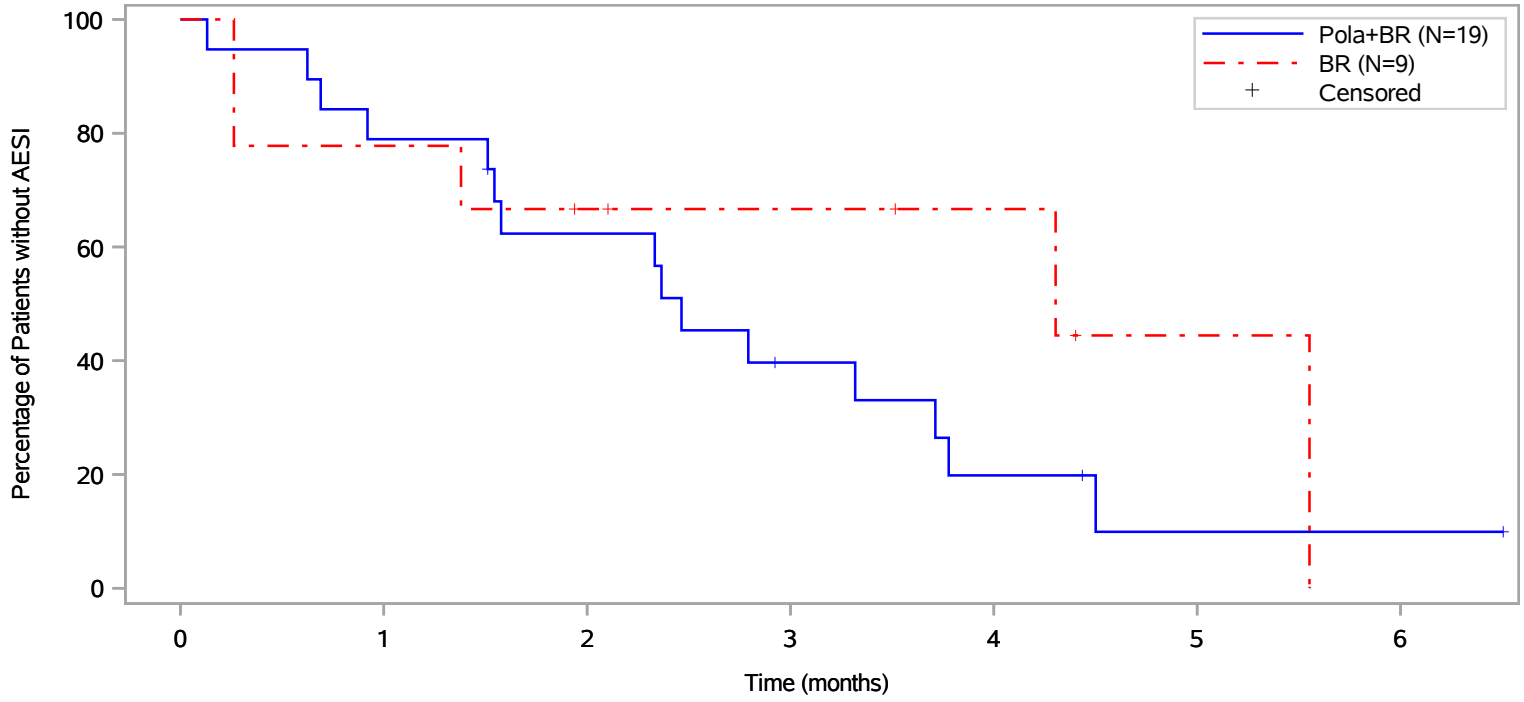
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	15	78.9	4	21.1	9	100.0	5	55.6	4	44.4	0.3785	1.58	0.57	4.38		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	11	78.6	3	21.4	6	66.7	2	33.3	4	66.7	0.4465	1.80	0.39	8.29		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	4	80.0	1	20.0	3	33.3	3	100.0	0	-	0.8746	1.13	0.24	5.22		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	13	81.3	3	18.8	7	77.8	3	42.9	4	57.1	0.2395	2.10	0.59	7.42		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	2	66.7	1	33.3	2	22.2	2	100.0	0	-	0.7822	1.41	0.12	15.84		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	10	71.4	4	28.6	6	66.7	3	50.0	3	50.0	0.3807	1.77	0.48	6.49		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	5	100.0	0	-	3	33.3	2	66.7	1	33.3	0.8639	1.16	0.21	6.51		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	15	78.9	4	21.1	9	100.0	5	55.6	4	44.4	0.3785	1.58	0.57	4.38		Convergence criterion (GCONV=1E-8) satisfied.	NE

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTTHROM_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 2:14

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	15	11	6	3	1	1
BR (N=9)	9	7	5	4	3	1	NE
Patients censored							
Pola+BR (N=19)	0	0	1	2	2	3	3
BR (N=9)	0	0	1	2	3	4	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
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03DEC2022 20:48

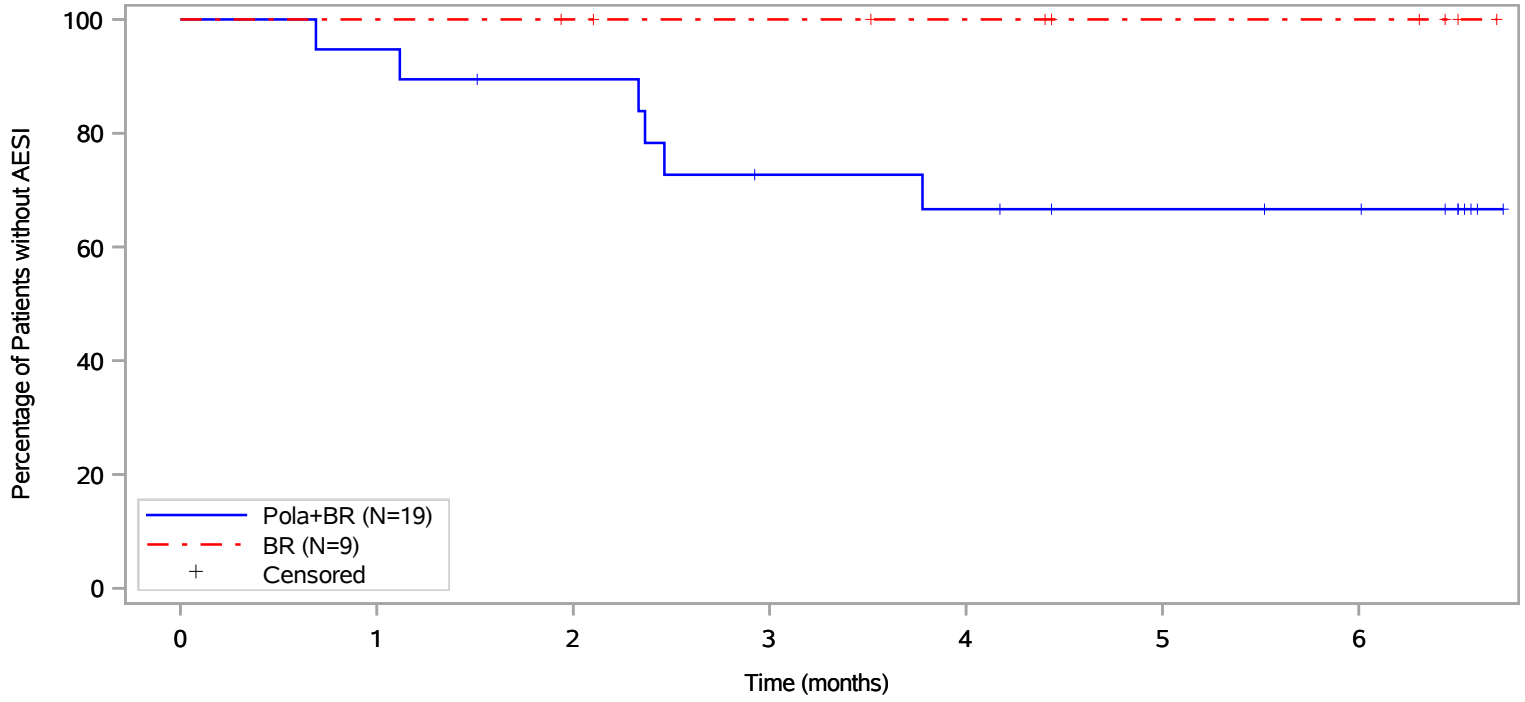
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0898	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	5	35.7	9	64.3	6	66.7	0	-	6	100.0	0.1681	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	6	37.5	10	62.5	7	77.8	0	-	7	100.0	0.1167	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	4	28.6	10	71.4	6	66.7	0	-	6	100.0	0.2080	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	2	40.0	3	60.0	3	33.3	0	-	3	100.0	0.2457	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	6	31.6	13	68.4	9	100.0	0	-	9	100.0	0.0898	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTTHROM35_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 18:39

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Thrombocytopenia of Grade 3/4/5
STUDIES: GO29365, YO41543



Patients at risk							
Pola+BR (N=19)	19	18	16	12	11	9	8
BR (N=9)	9	9	8	7	6	4	4
Patients censored							
Pola+BR (N=19)	0	0	1	2	2	4	5
BR (N=9)	0	0	1	2	3	5	5

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..L_CSR_Pooled/prod/output_Polarose/g_km_TTTHROM35_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 22:53

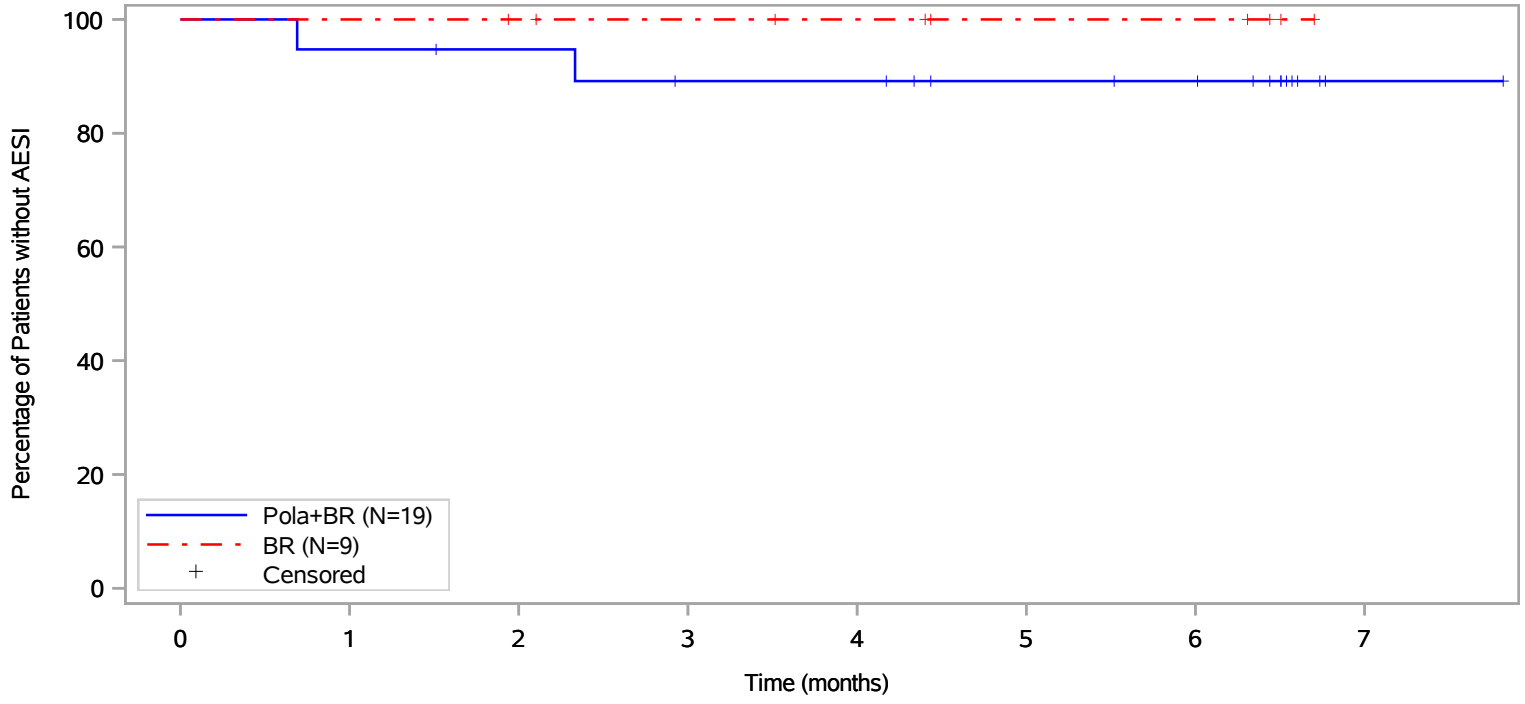
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Thrombocytopenia
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3468	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5791	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	2	12.5	14	87.5	7	77.8	0	-	7	100.0	0.3803	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	1	7.1	13	92.9	6	66.7	0	-	6	100.0	0.5127	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	1	20.0	4	80.0	3	33.3	0	-	3	100.0	0.4386	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	2	10.5	17	89.5	9	100.0	0	-	9	100.0	0.3468	>999.99	0.00	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTTHROMS_L3PLUS_Polarose_SE_29365_41543.xls
24JAN2023 18:43

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Serious Thrombocytopenia
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	18	17	15	15	12	11	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	2	5	6	16
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..AL_CSR_Pooled/prod/output_Polarose/g_km_TTTHROMS_L3PLUS_Polarose_SE_29365_41543.pdf
04DEC2022 1:01

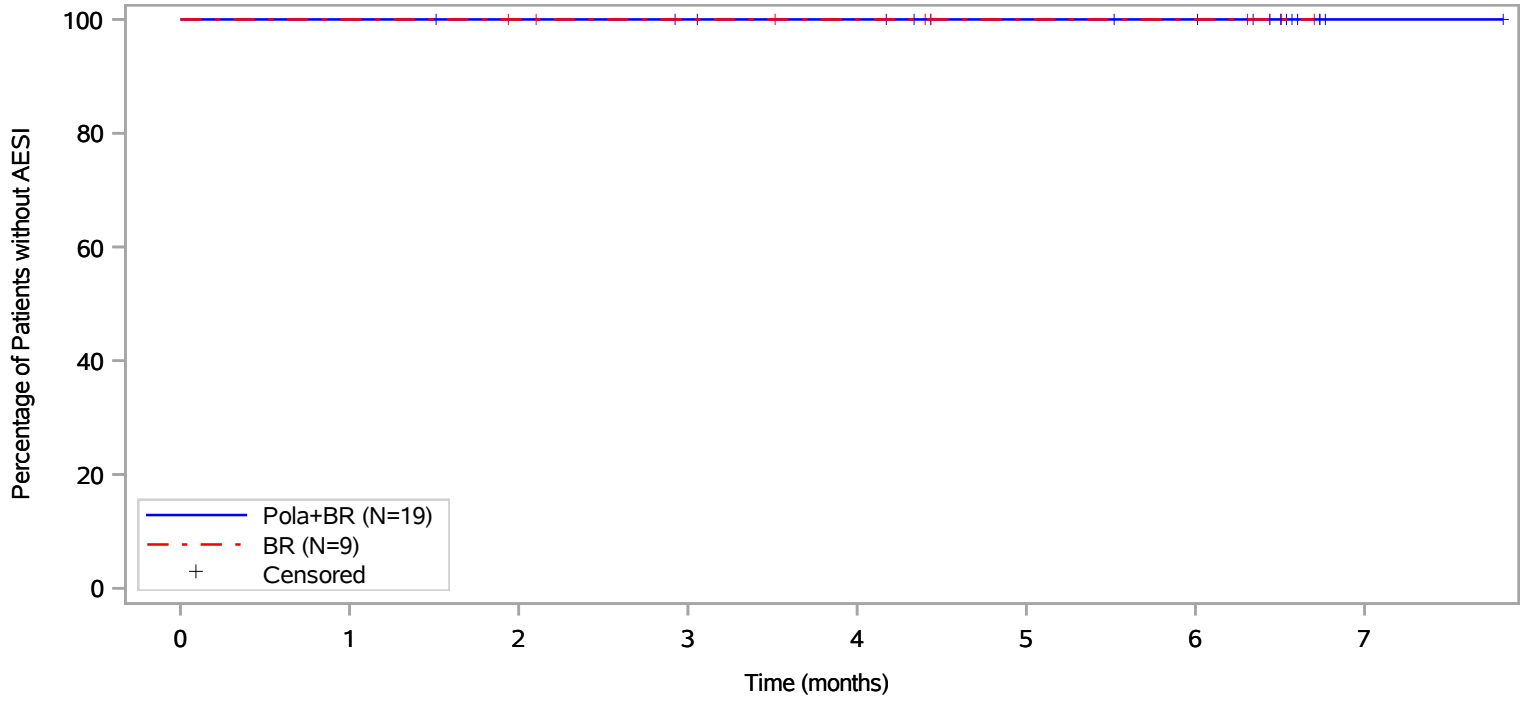
POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
MODEL: Unstratified analysis
STUDIES: GO29365, YO41543
Time to Event Analysis by Subgroups (Safety)

		Pola+BR (N=19)						BR (N=9)						Pola + BR vs. BR						
		Patients		Patients with Event		Censored		Patients		Patients with Event		Censored		log-rank	Hazard Ratio					Interaction Test
Name	Level	n	%	n	%	n	%	n	%	n	%	n	%	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All		19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Sex	Male	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	Female	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Age (years)	< 65	16	84.2	0	-	16	100.0	7	77.8	0	-	7	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	>= 65	3	15.8	0	-	3	100.0	2	22.2	0	-	2	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
IPI at study entry	>=3	14	73.7	0	-	14	100.0	6	66.7	0	-	6	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-
	<3	5	26.3	0	-	5	100.0	3	33.3	0	-	3	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	
Geographic region	Non-Europe	19	100.0	0	-	19	100.0	9	100.0	0	-	9	100.0	NE	NE	NE	NE		Convergence criterion (GCONV=1E-8) satisfied.	-

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ttae.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ttae_sg1_TTTLS_L3PLUS_Polarose_SE_29365_41543.xls
01DEC2022 21:27

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: Time to Tumour Lysis Syndrome
STUDIES: GO29365, YO41543



Patients at risk								
Pola+BR (N=19)	19	19	18	17	16	13	12	1
BR (N=9)	9	9	8	7	6	4	4	NE
Patients censored								
Pola+BR (N=19)	0	0	1	2	3	6	7	18
BR (N=9)	0	0	1	2	3	5	5	NE

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: ..O5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/g_km.sas
Output: ..FINAL_CSR_Pooled/prod/output_Polarose/g_km_TTTLS_L3PLUS_Polarose_SE_29365_41543.pdf
03DEC2022 22:16

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=19)															BR (N=9)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																														
All	426	350	82.2	0	0.0	50	11.7	0	0.0	25	5.9	1	0.2	0	0.0	99	68	68.7	0	0.0	23	23.2	1	1.0	7	7.1	0	0.0	0	0.0
Grade 1	243	209	86.0	0	0.0	19	7.8	0	0.0	15	6.2	0	0.0	0	0.0	53	37	69.8	0	0.0	14	26.4	0	0.0	2	3.8	0	0.0	0	0.0
Grade 2	99	76	76.8	0	0.0	16	16.2	0	0.0	6	6.1	1	1.0	0	0.0	26	19	73.1	0	0.0	2	7.7	0	0.0	5	19.2	0	0.0	0	0.0
Grade 3	62	47	75.8	0	0.0	13	21.0	0	0.0	2	3.2	0	0.0	0	0.0	14	10	71.4	0	0.0	4	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	22	18	81.8	0	0.0	2	9.1	0	0.0	2	9.1	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
AEs Grade >=3																														
All	84	65	77.4	0	0.0	15	17.9	0	0.0	4	4.8	0	0.0	0	0.0	20	12	60.0	0	0.0	7	35.0	1	5.0	0	0.0	0	0.0	0	0.0
Grade 3	62	47	75.8	0	0.0	13	21.0	0	0.0	2	3.2	0	0.0	0	0.0	14	10	71.4	0	0.0	4	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	22	18	81.8	0	0.0	2	9.1	0	0.0	2	9.1	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
AEs Grade 3																														
All	62	47	75.8	0	0.0	13	21.0	0	0.0	2	3.2	0	0.0	0	0.0	14	10	71.4	0	0.0	4	28.6	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	62	47	75.8	0	0.0	13	21.0	0	0.0	2	3.2	0	0.0	0	0.0	14	10	71.4	0	0.0	4	28.6	0	0.0	0	0.0	0	0.0	0	0.0
AEs Grade 4																														
All	22	18	81.8	0	0.0	2	9.1	0	0.0	2	9.1	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	22	18	81.8	0	0.0	2	9.1	0	0.0	2	9.1	0	0.0	0	0.0	5	2	40.0	0	0.0	3	60.0	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																														
All	14	9	64.3	0	0.0	4	28.6	0	0.0	1	7.1	0	0.0	0	0.0	3	0	0.0	0	0.0	2	66.7	1	33.3	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	8	6	75.0	0	0.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	5	2	40.0	0	0.0	2	40.0	0	0.0	1	20.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: GO29365 21OCT2021 and YO41543 07FEB2022

Program: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/program/t_s_ae_resolved.sas
Output: root/clinical_studies/RO5541077/CDPT7898/GO29365/data_analysis/ACE_FINAL_CSR_Pooled/prod/output_Polarose/t_s_ae_resolved_L3PLUS_Polarose_SE_29365_41543.xls
29NOV2022 8:52

POPULATION: Safety-Evaluable Patients, Study YO41543, Third-line or beyond (3L+) Patients
ENDPOINT: All patients
MODEL: --
STUDIES: GO29365, YO41543
Outcome of Adverse Events

	Pola+BR (N=19)															BR (N=9)													
	Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING		Total	RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events Grade	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Neutropenia Including Febrile Neutropenia																														
All	87	80	92.0	0	0.0	7	8.0	0	0.0	0	0.0	0	0.0	0	0.0	37	31	83.8	0	0.0	5	13.5	0	0.0	1	2.7	0	0.0	0	0.0
Grade 1	13	13	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9	9	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	30	28	93.3	0	0.0	2	6.7	0	0.0	0	0.0	0	0.0	0	0.0	15	12	80.0	0	0.0	2	13.3	0	0.0	1	6.7	0	0.0	0	0.0
Grade 3	29	24	82.8	0	0.0	5	17.2	0	0.0	0	0.0	0	0.0	0	0.0	11	9	81.8	0	0.0	2	18.2	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	15	15	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Neutropenia Including Febrile Neutropenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Peripheral Neuropathy																														
All	5	4	80.0	0	0.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
Grade 1	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Peripheral Neuropathy																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Anemia																														
All	24	18	75.0	0	0.0	4	16.7	0	0.0	2	8.3	0	0.0	0	0.0	5	3	60.0	0	0.0	0	0.0	0	0.0	2	40.0	0	0.0	0	0.0
Grade 1	7	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	11	9	81.8	0	0.0	1	9.1	0	0.0	1	9.1	0	0.0	0	0.0	2	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0
Grade 3	6	2	33.3	0	0.0	3	50.0	0	0.0	1	16.7	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Anemia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Thrombocytopenia																														
All	22	17	77.3	0	0.0	4	18.2	0	0.0	1	4.5	0	0.0	0	0.0	8	5	62.5	0	0.0	2	25.0	0	0.0	1	12.5	0	0.0	0	0.0
Grade 1	12	12	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	3	60.0	0	0.0	2	40.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2	66.7	0	0.0	0	0.0	0	0.0	1	33.3	0	0.0	0	0.0
Grade 3	2	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	4	2	50.0	0	0.0	1	25.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Thrombocytopenia																														
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Infections and Infestations																														
All	9	6	66.7	0	0.0	2	22.2	0	0.0	1	11.1	0	0.0	0	0.0	2	1	50.0	0	0.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0
Grade 1	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	5	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	2	0	0.0	0	0.0	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
Serious Infections and Infestations																														
All	6	4	66.7	0	0.0	1	16.7	0	0.0	1	16.7	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
Grade 3	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	2	0	0.0	0	0.0	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 5	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
Infusion Related Reactions																														
All	8	7	87.5	0	0.0	1	12.5	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	4	3	75.0	0	0.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	4	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Infusion Related Reactions																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hepatic Toxicity																														
All	32	24	75.0	0	0.0	3	9.4	0	0.0	5	15.6	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	20	16	80.0	0	0.0	1	5.0	0	0.0	3	15.0	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	11	7	63.6	0	0.0	2	18.2	0	0.0	2	18.2	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hepatic Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Reproductive Toxicity																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Fatigue and Asthenia																														
All	8	5	62.5	0	0.0	1	12.5	0	0.0	2	25.0	0	0.0	0	0.0	4	1	25.0	0	0.0	3	75.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	5	3	60.0	0	0.0	0	0.0	0	0.0	2	40.0	0	0.0	0	0.0	4	1	25.0	0	0.0	3	75.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	3	2	66.7	0	0.0	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Fatigue and Asthenia																														
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Hyperglycemias																														
All	3	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Hyperglycemias																														

All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Renal Toxicity																																
All	15	12	80.0	0	0.0	2	13.3	0	0.0	1	6.7	0	0.0	0	0.0	3	1	33.3	0	0.0	2	66.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	15	12	80.0	0	0.0	2	13.3	0	0.0	1	6.7	0	0.0	0	0.0	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 4	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Renal Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Gastrointestinal Toxicity																																
All	48	40	83.3	0	0.0	5	10.4	0	0.0	2	4.2	1	2.1	0	0.0	8	6	75.0	0	0.0	2	25.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	35	30	85.7	0	0.0	3	8.6	0	0.0	2	5.7	0	0.0	0	0.0	5	4	80.0	0	0.0	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	12	9	75.0	0	0.0	2	16.7	0	0.0	0	0.0	1	8.3	0	0.0	2	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Gastrointestinal Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pulmonary Toxicity																																
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Pulmonary Toxicity																																
All	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 3	2	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Joint Pains, Arthralgia, Skeletal Pain																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Joint Pains, Arthralgia, Skeletal Pain																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Alopecia																																
All	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Alopecia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Cardiac Toxicity and Arrhythmias																																
All	2	1	50.0	0	0.0	0	0.0	0	0.0	1	50.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 1	1	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Grade 2	1	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Cardiac Toxicity and Arrhythmias																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Ocular Toxicity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Dysgeusia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Dysgeusia																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Tumor Lysis Syndrome																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Genotoxicity Carcinogenecity																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Serious Drug Drug Interaction																																
All	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0