Anhang 4-G - Analyseergebnisse und Abbildungen, SAkuraStar (BN40900), SAkuraSky (BN40898)

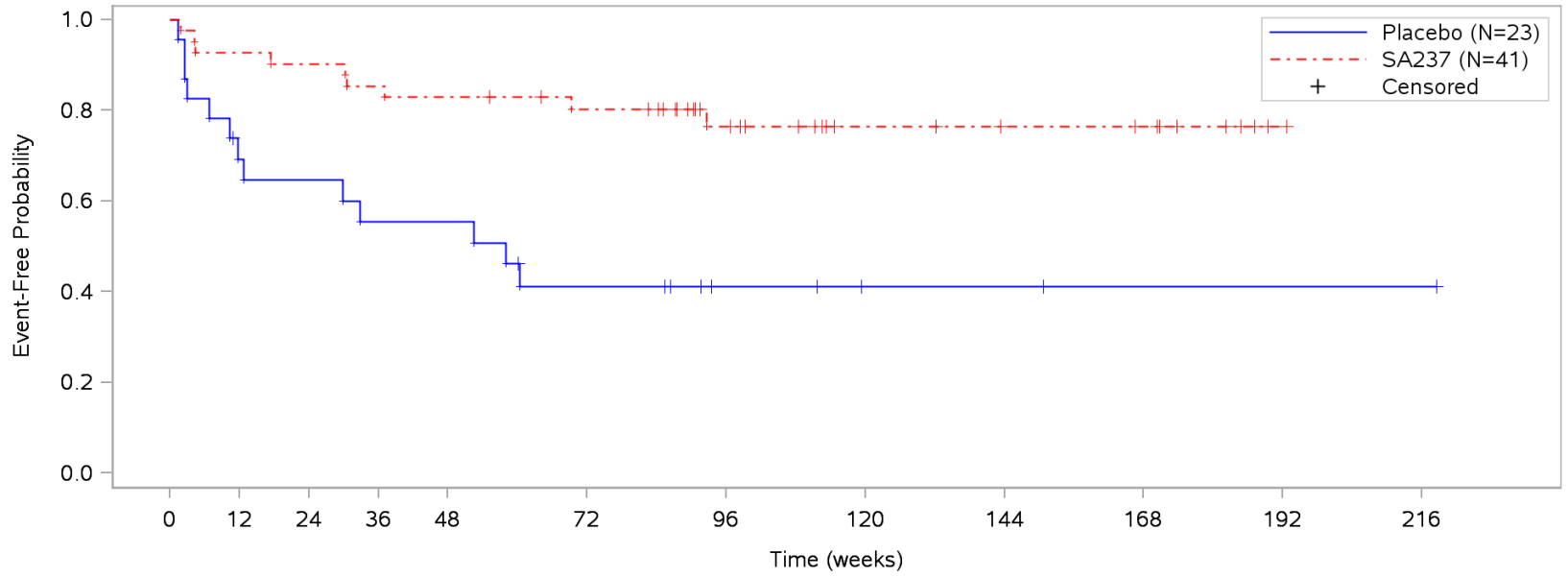
POPULATION: AQP4 Positive Population
ENDPOINT: Protocol Defined Relapse
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Time to event analysis (efficacy)

		SA237												Placebo												SA237 vs. Placebo					
		Patients		Patients with		Censored		Time To Event						Patients		Patients with		Censored		Time To Event						Log-rank	Hazard Ratio				
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	41	100,0	9	22,0	32	78,0	NE	30,3	NE	NE	NE	NE	23	100,0	13	56,5	10	43,5	10,3	1,4	32,9	58,0	11,7	NE	0,0014	0,26	0,11	0,63		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_309_12OCT2018_AQPP_PDR01DB_ST.xls
24MAR2020 14:37

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Relapse, Protocol Defined Relapse
MODEL: --
STUDY: BN40900
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	23	15	14	12	12	8	4	2	2	1	1	1
SA237	41	38	37	35	34	31	20	11	9	8	1	NE
Patients censored												
Placebo	0	1	1	1	1	2	6	8	8	9	9	9
SA237	0	0	0	0	0	2	12	21	23	24	31	NE

Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_eff_tte_km.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_eff_tte_km_309_12OCT2018_AQPP_PDR01DB.pdf
25NOV2019 22:53

POPULATION: AQP4 Positive Population
ENDPOINT: Relapse-free subjects, Protocol Defined Relapse
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Dichotomous analysis (efficacy)

		SA237				Placebo				SA237 vs. Placebo												SA237 vs. Placebo					Placebo vs. SA237				
		Patients		Patients with Event		Patients		Patients with Event		Odds Ratio					Absolute Risk Difference							Relative Risk					Relative Risk				
Subgroup	Level	n	%	n	%	n	%	n	%	Odds Ratio		Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL			Relative Risk		Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)	Relative Risk		Convergence Reason	95% Lower CI	95% Upper CI
All	n/a	41	100,0	32	78,0	23	100,0	10	43,5	4,94		Algorithm converged.	1,58	15,41	0,343		Algorithm converged.	0,103	0,583			1,78		Algorithm converged.	1,09	2,92	0,0219	0,56		Algorithm converged.	0,34	0,92

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/eff_resp.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/eff_resp_309_12OCT2018_AQPP_PDR01DB_ST.xls
25NOV2019 18:23

POPULATION: AQP4 Positive Population
ENDPOINT: Annualized Relapse Rate, Protocol Defined Relapse
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Repeated event analysis (efficacy)

		(N=41)										(N=23)										Adjusted Analysis: Difference between Treatments					
		Patients		Relapses	Patient Years	Naive Annualized Relapse Rate			Adjusted Annualized Relapse Rate			Patients		Relapses	Patient Years	Naive Annualized Relapse Rate			Adjusted Annualized Relapse Rate			lr	Rate Ratio				
Subgroup	Level	n	%	Total	Total	Rate	95% Lower CL	95% Upper CL	Adjusted Rate	95% Lower CL	95% Upper CL	n	%	Total	Total	Rate	95% Lower CL	95% Upper CL	Adjusted Rate	95% Lower CL	95% Upper CL	p-value	Rate Ratio	95% Lower CL	95% Upper CL		Convergence Reason
All	n/a	41	100,0	9	79,26	0,114	0,052	0,216	0,271	0,077	0,96	23	100,0	13	25,16	0,517	0,275	0,884	2,85	0,792	10,258	0,0092	0,095	0,019	0,475		Algorithm converged.

Rate (raw) defined as the total number of relapses for all patients in the treatment group divided by the total patient-years of exposure to that treatment.
Based on negative binomial model. Factors/covariates: treatment. Adjusted for randomization stratification factors. Log (time in study [in years] per patient) as offset-variable.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/eff_nb.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/eff_nb_309_12OCT2018_AQPP_PDR01DB_ST.xls
25NOV2019 18:40

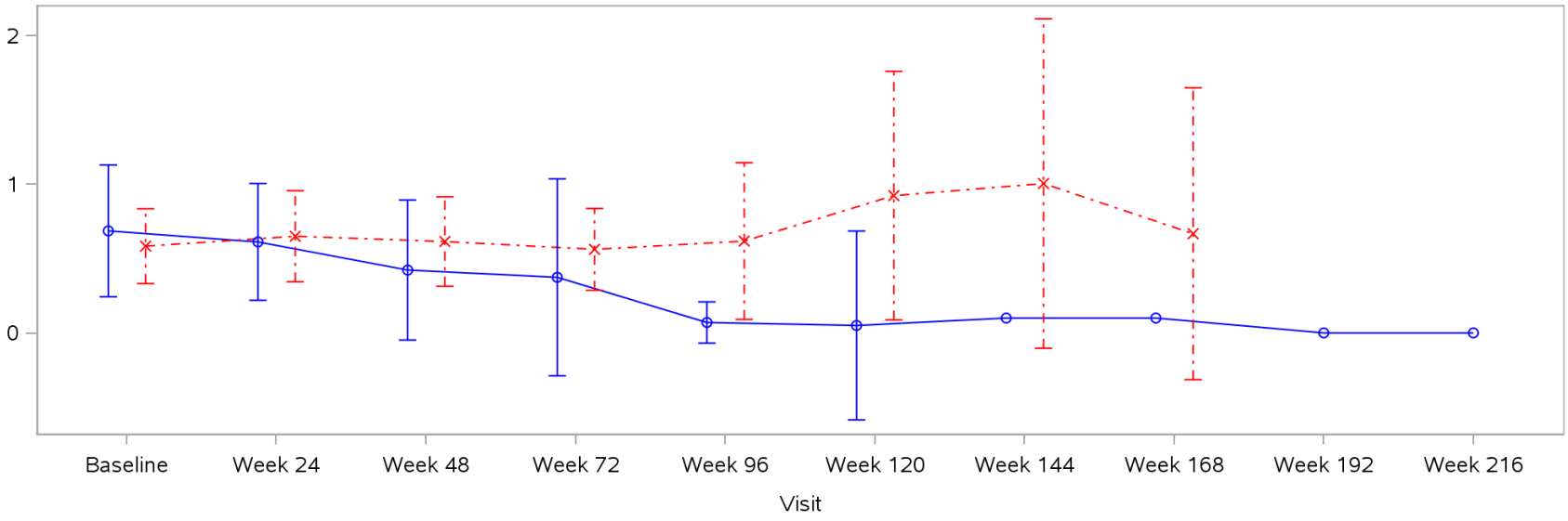
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Visual Acuity Score (Snellen Chart): OD
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	NE	NE	23	23	23	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
OD = Right Eye, OS = Left Eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_FSSVF1_ST.xls
09SEP2020 21:37

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Acuity Score (Snellen Chart): OD
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	11	8	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

OD = Right Eye, OS = Left Eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_FSSVF1.pdf
09SEP2020 20:15

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Acuity Score (Snellen Chart): OD
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	0,584	0,797	23	100,0	23	100,0	0,687	1,026
	Week 24	41	100,0	40	97,6	0,650	0,958	23	100,0	23	100,0	0,612	0,908
	Week 48	37	90,2	37	100,0	0,615	0,902	14	60,9	14	100,0	0,423	0,816
	Week 72	32	78,0	32	100,0	0,562	0,763	11	47,8	10	90,9	0,374	0,926
	Week 96	20	48,8	18	90,0	0,618	1,060	4	17,4	4	100,0	0,070	0,087
	Week 120	11	26,8	11	100,0	0,924	1,245	2	8,7	2	100,0	0,050	0,071
	Week 144	9	22,0	8	88,9	1,005	1,326	2	8,7	2	100,0	0,100	0,000
	Week 168	8	19,5	8	100,0	0,668	1,175	1	4,3	1	100,0	0,100	NE
	Week 192							1	4,3	1	100,0	0,000	NE
	Week 216							1	4,3	1	100,0	0,000	NE
	End of Study (Discontinued)	5	12,2	3	60,0	1,517	1,381	2	8,7	2	100,0	0,650	0,495

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
OD = Right Eye, OS = Left Eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_FSSVF1_SG.xls
09SEP2020 19:55

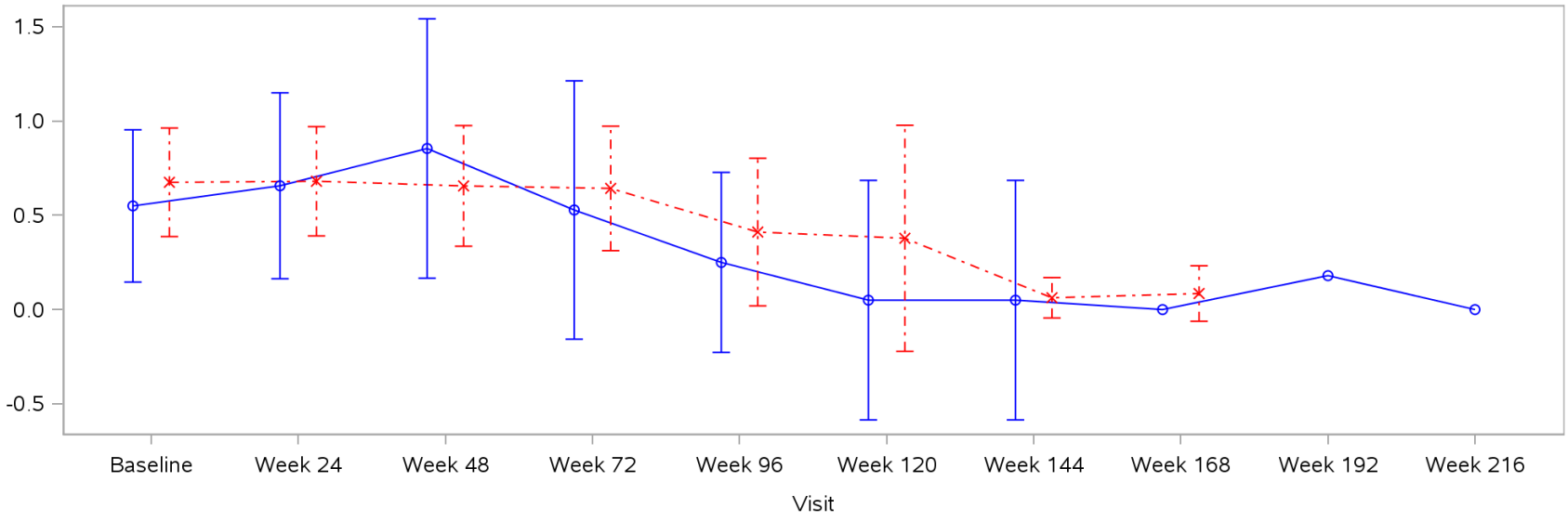
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Visual Acuity Score (Snellen Chart): OS
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	NE	NE	23	23	23	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
OD = Right Eye, OS = Left Eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_FSSVF2_ST.xls
09SEP2020 21:37

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Acuity Score (Snellen Chart): OS
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	10	8	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

OD = Right Eye, OS = Left Eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_FSSVF2.pdf
09SEP2020 20:16

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Acuity Score (Snellen Chart): OS
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	0,675	0,912	23	100,0	23	100,0	0,550	0,934
	Week 24	41	100,0	40	97,6	0,681	0,907	23	100,0	23	100,0	0,657	1,140
	Week 48	37	90,2	37	100,0	0,656	0,960	14	60,9	14	100,0	0,854	1,191
	Week 72	32	78,0	32	100,0	0,642	0,916	11	47,8	10	90,9	0,528	0,958
	Week 96	20	48,8	18	90,0	0,411	0,787	4	17,4	4	100,0	0,250	0,300
	Week 120	11	26,8	10	90,9	0,378	0,838	2	8,7	2	100,0	0,050	0,071
	Week 144	9	22,0	8	88,9	0,063	0,128	2	8,7	2	100,0	0,050	0,071
	Week 168	8	19,5	8	100,0	0,085	0,176	1	4,3	1	100,0	0,000	NE
	Week 192							1	4,3	1	100,0	0,180	NE
	Week 216							1	4,3	1	100,0	0,000	NE
	End of Study (Discontinued)	5	12,2	3	60,0	1,850	0,850	2	8,7	2	100,0	0,360	0,255

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
OD = Right Eye, OS = Left Eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_FSSVF2_SG.xls
09SEP2020 19:56

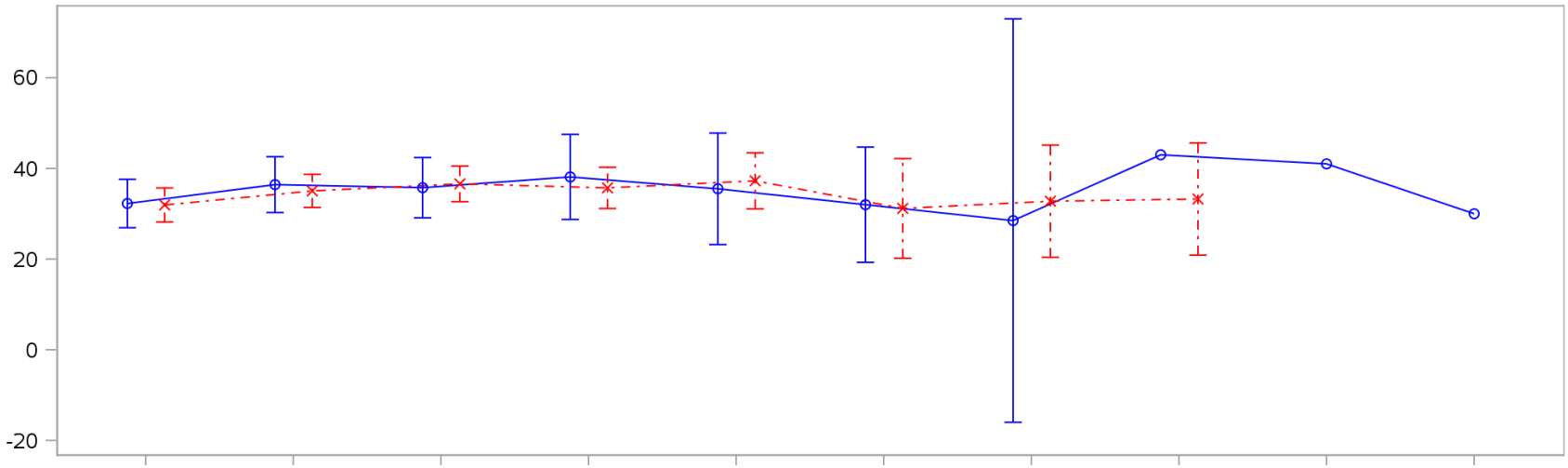
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional Assessment of Chronic Illness Therapy (FACIT): Fatigue Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	40	36	7,868	2,363	23	23	14	2,459	2,966	5,409	3,058	-0,793	11,611	0,0854	0,9259

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FACIT fatigue is scored on a scale of 0-52. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_TOTFACIT_ST.xls
08SEP2020 21:53

POPULATION: AQP4 Positive Population
ENDPOINT: Functional Assessment of Chronic Illness Therapy (FACIT): Fatigue Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	40	37	33	31	20	11	9	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The FACIT fatigue is scored on a scale of 0-52. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_TOTFACIT.pdf
29NOV2019 15:55

POPULATION: AQP4 Positive Population
ENDPOINT: Functional Assessment of Chronic Illness Therapy (FACIT): Fatigue Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	40	97,6	31,940	11,738	23	100,0	23	100,0	32,261	12,344
	Week 24	37	90,2	37	100,0	35,043	10,952	14	60,9	14	100,0	36,429	10,653
	Week 48	33	80,5	33	100,0	36,596	11,071	12	52,2	12	100,0	35,750	10,463
	Week 72	31	75,6	31	100,0	35,710	12,397	8	34,8	8	100,0	38,125	11,218
	Week 96	20	48,8	20	100,0	37,267	13,190	4	17,4	4	100,0	35,500	7,724
	Week 120	11	26,8	11	100,0	31,182	16,363	2	8,7	2	100,0	32,000	1,414
	Week 144	9	22,0	9	100,0	32,778	16,084	2	8,7	2	100,0	28,500	4,950
	Week 168	8	19,5	8	100,0	33,250	14,791	1	4,3	1	100,0	43,000	NE
	Week 192							1	4,3	1	100,0	41,000	NE
	Week 216							1	4,3	1	100,0	30,000	NE
	End of Study (Discontinued)	5	12,2	3	60,0	24,000	5,568	2	8,7	2	100,0	20,500	2,121

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FACIT fatigue is scored on a scale of 0-52. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_TOTFACIT_SG.xls
29NOV2019 13:26

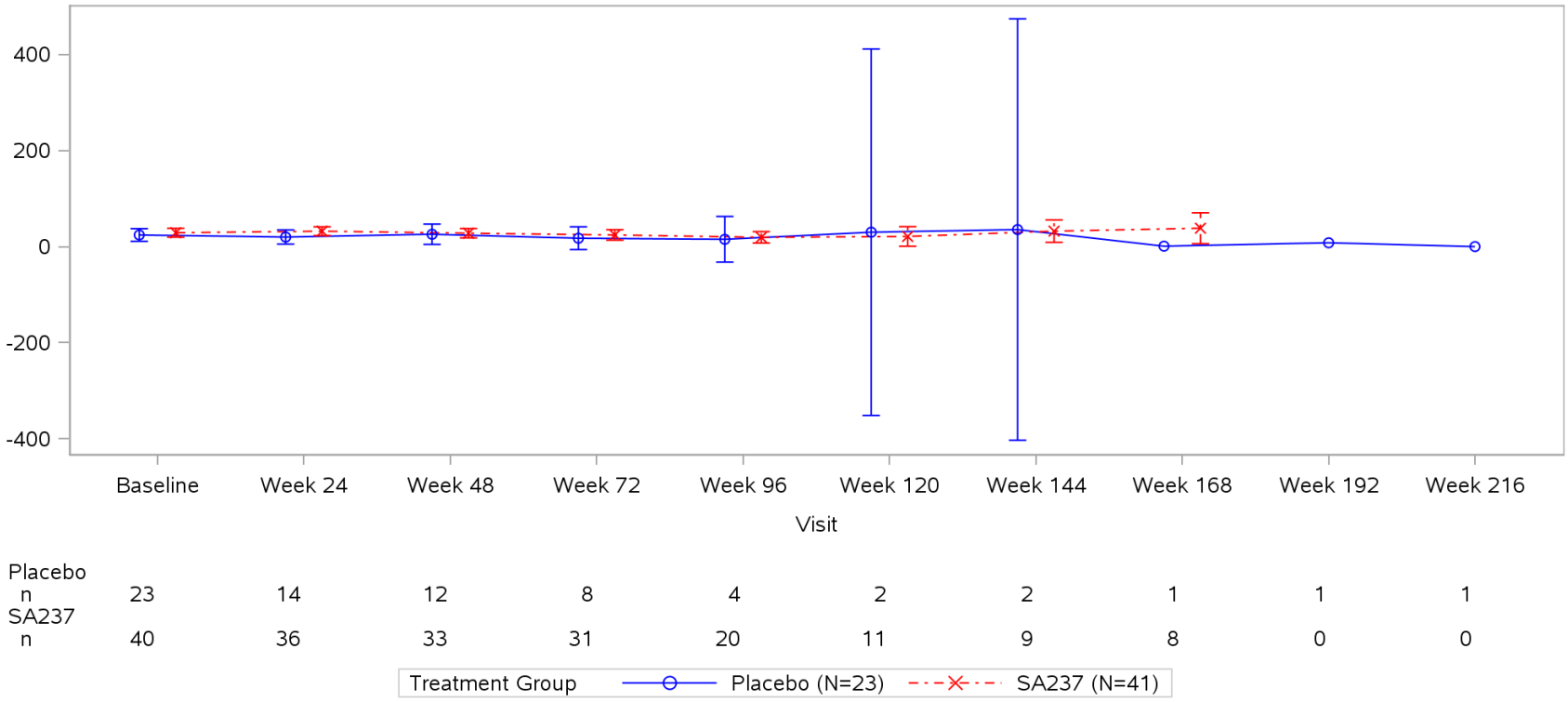
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Visual Analogue Scale (VAS): Pain Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	40	36	4,462	7,057	23	23	14	-2,192	8,552	6,654	9,045	-11,588	24,897	0,4659	0,5587

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The VAS pain is scored on a scale of 0-100. Lower scores reflect a better health state.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_VASPAIN_ST.xls
08SEP2020 21:53

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Analogue Scale (VAS): Pain Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	40	36	33	31	20	11	9	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The VAS pain is scored on a scale of 0-100. Lower scores reflect a better health state.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_VASPAIN.pdf
29NOV2019 15:54

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Analogue Scale (VAS): Pain Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	40	97,6	28,900	28,694	23	100,0	23	100,0	24,217	30,378
	Week 24	37	90,2	36	97,3	32,111	26,955	14	60,9	14	100,0	20,000	25,634
	Week 48	33	80,5	33	100,0	27,939	27,399	12	52,2	12	100,0	25,750	33,189
	Week 72	31	75,6	31	100,0	24,323	29,719	8	34,8	8	100,0	17,500	28,380
	Week 96	20	48,8	20	100,0	19,350	25,423	4	17,4	4	100,0	15,250	29,837
	Week 120	11	26,8	11	100,0	21,182	30,271	2	8,7	2	100,0	30,000	42,426
	Week 144	9	22,0	9	100,0	32,222	30,359	2	8,7	2	100,0	35,500	48,790
	Week 168	8	19,5	8	100,0	38,250	38,355	1	4,3	1	100,0	1,000	NE
	Week 192							1	4,3	1	100,0	8,000	NE
	Week 216							1	4,3	1	100,0	0,000	NE
	End of Study (Discontinued)	5	12,2	3	60,0	15,000	5,000	2	8,7	2	100,0	83,500	2,121

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The VAS pain is scored on a scale of 0-100. Lower scores reflect a better health state.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_VASPAIN_SG.xls
29NOV2019 13:25

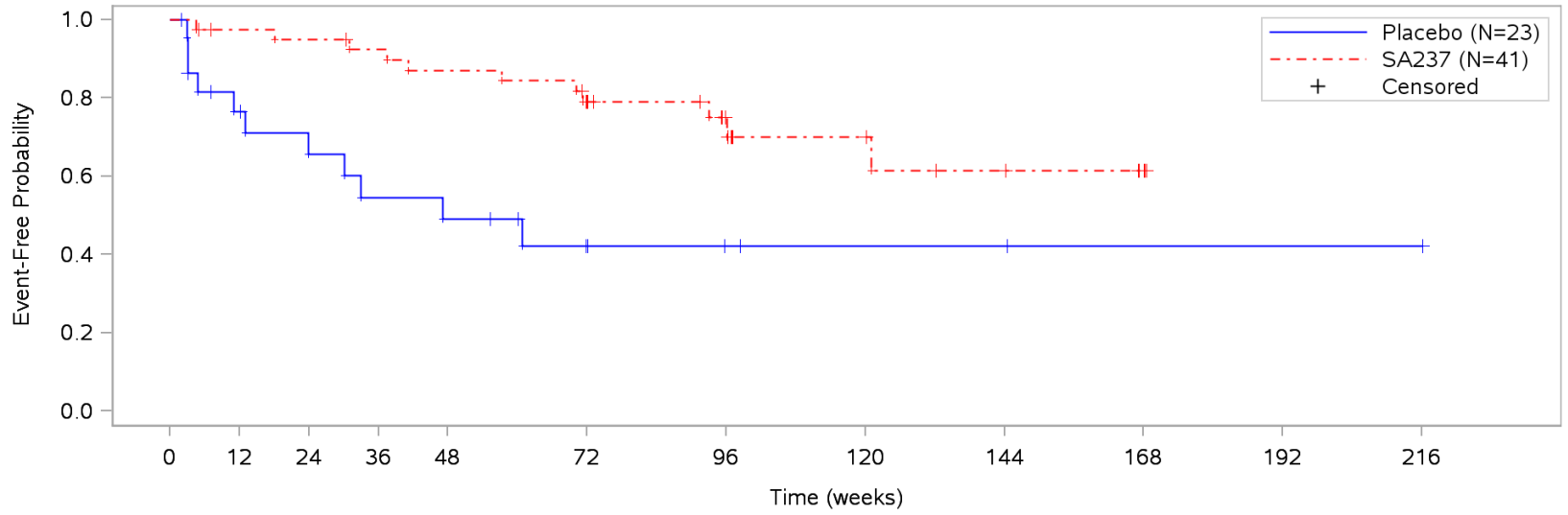
POPULATION: AQP4 Positive Population
ENDPOINT: Expanded Disability Status Scale (EDSS) Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Time to event analysis (PRO)

		SA237												Placebo												Log-rank	SA237 vs. Placebo				
		Patients		Patients with		Censored		Time To Event						Patients		Patients with		Censored		Time To Event							Hazard Ratio				
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	41	100,0	11	26,8	30	73,2	96,1	37,4	NE	NE	121,0	NE	23	100,0	11	47,8	12	52,2	13,0	3,0	33,0	47,1	13,0	NE	0,0124	0,34	0,14	0,82		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
The EDSS is scored on a scale of 0-10. Higher scores represent increased disability. EDSS worsening defined as (a) worsening of 2 or more points in EDSS score for patients with baseline score of 0,
(b) worsening of 1 or more points in EDSS score for patients with baseline score of 1 to 5, or (c) worsening of 0.5 points or more in EDSS score for patients with baseline score of 5.5 or more.
Patients were censored at the date of the last EDSS assessment in DB or if no EDSS assessment in DB was performed at the randomization date.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_tte.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_tte_309_12OCT2018_AQPP_FWORSDB_ST.xls
30AUG2020 15:52

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Worsening, Expanded Disability Status Scale (EDSS) Score
MODEL: --
STUDY: BN40900
Kaplan-Meier plot of time to first worsening (weeks)



Patients at risk												
Placebo	23	15	12	10	9	5	3	2	2	1	1	1
SA237	41	38	37	35	33	26	15	9	6	3	NE	NE
Patients censored												
Placebo	0	3	4	4	4	7	9	10	10	11	11	11
SA237	0	2	2	3	3	8	17	22	24	27	NE	NE

The EDSS is scored on a scale of 0-10. Higher scores represent increased disability. EDSS worsening defined as (a) worsening of 2 or more points in EDSS score for patients with baseline score of 0, (b) worsening of 1 or more points in EDSS score for patients with baseline score of 1 to 5, or (c) worsening of 0.5 points or more in EDSS score for patients with baseline score of 5.5 or more.
Patients were censored at the date of the last EDSS assessment in DB or if no EDSS assessment in DB was performed at the randomization date.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_tte_km.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_tte_km_309_12OCT2018_AQPP_FWORSDB.pdf
30AUG2020 16:07

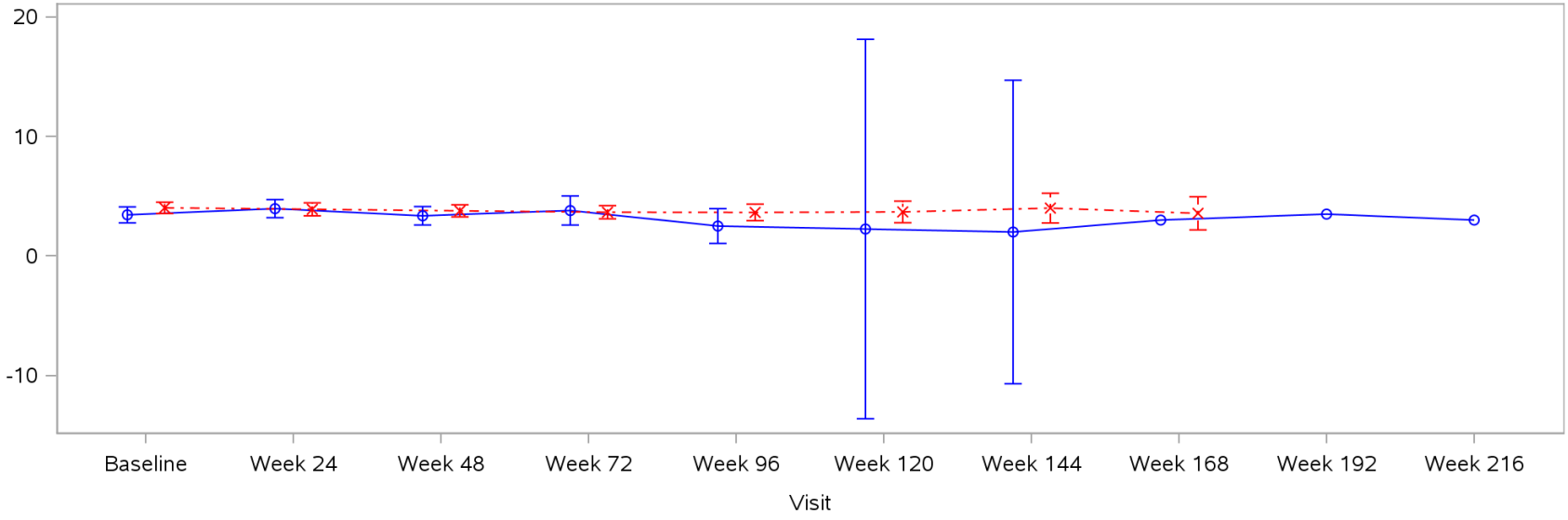
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Expanded Disability Status Scale (EDSS) Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	NE	NE	23	23	23	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The EDSS is scored on a scale of 0-10. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_EDSS_ST.xls
09SEP2020 21:36

POPULATION: AQP4 Positive Population
ENDPOINT: Expanded Disability Status Scale (EDSS) Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	11	8	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The EDSS is scored on a scale of 0-10. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_EDSS.pdf
09SEP2020 20:14

POPULATION: AQP4 Positive Population
ENDPOINT: Expanded Disability Status Scale (EDSS) Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100.0	41	100.0	4.024	1.504	23	100.0	23	100.0	3.435	1.547
	Week 24	41	100.0	40	97.6	3.900	1.699	23	100.0	23	100.0	3.957	1.751
	Week 48	37	90.2	37	100.0	3.770	1.517	14	60.9	14	100.0	3.357	1.336
	Week 72	32	78.0	32	100.0	3.656	1.526	11	47.8	10	90.9	3.800	1.703
	Week 96	20	48.8	18	90.0	3.639	1.391	4	17.4	4	100.0	2.500	0.913
	Week 120	11	26.8	11	100.0	3.682	1.347	2	8.7	2	100.0	2.250	1.768
	Week 144	9	22.0	8	88.9	4.000	1.488	2	8.7	2	100.0	2.000	1.414
	Week 168	8	19.5	8	100.0	3.563	1.657	1	4.3	1	100.0	3.000	NE
	Week 192							1	4.3	1	100.0	3.500	NE
	Week 216							1	4.3	1	100.0	3.000	NE
	End of Study (Discontinued)	5	12.2	3	60.0	4.833	1.041	2	8.7	2	100.0	4.750	1.768

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The EDSS is scored on a scale of 0-10. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_EDSS_SG.xls
09SEP2020 19:54

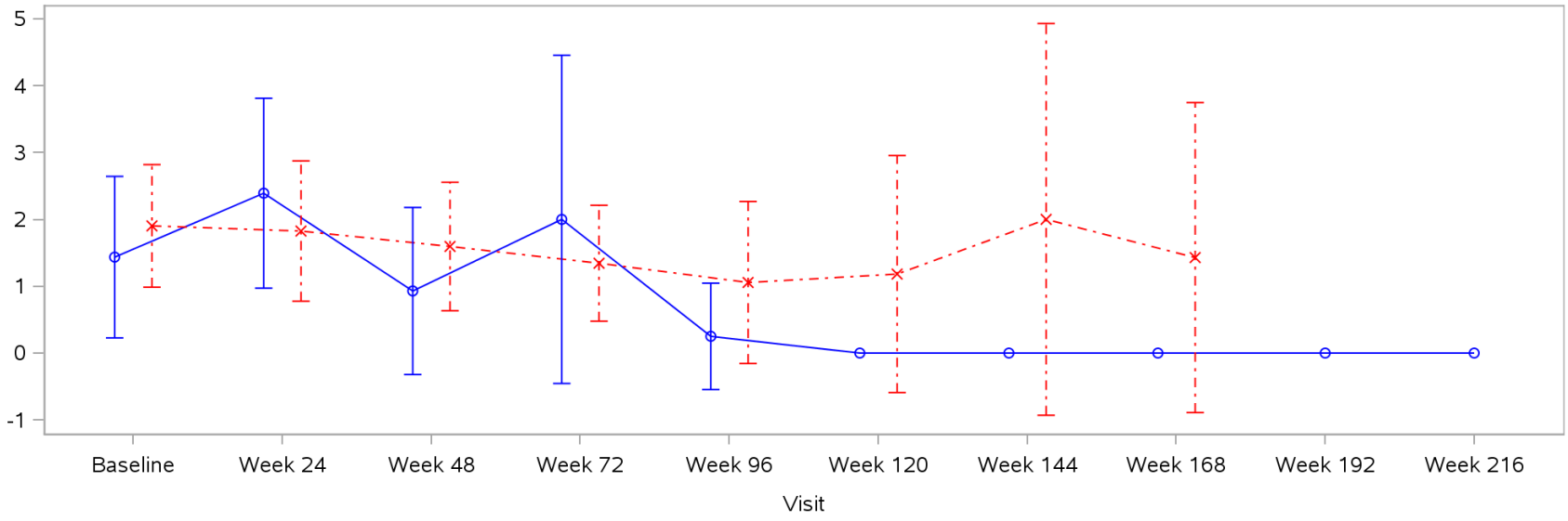
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Ambulation Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics					
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	NE	NE	23	23	23	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_FSSAMB_ST.xls
09SEP2020 21:36

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Ambulation Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	11	8	7	0	0

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_FSSAMB.pdf
09SEP2020 20:14

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Ambulation Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100.0	41	100.0	1.902	2.905	23	100.0	23	100.0	1.435	2.793
	Week 24	41	100.0	40	97.6	1.825	3.281	23	100.0	23	100.0	2.391	3.285
	Week 48	37	90.2	37	100.0	1.595	2.882	14	60.9	14	100.0	0.929	2.165
	Week 72	32	78.0	32	100.0	1.344	2.404	11	47.8	10	90.9	2.000	3.432
	Week 96	20	48.8	18	90.0	1.056	2.437	4	17.4	4	100.0	0.250	0.500
	Week 120	11	26.8	11	100.0	1.182	2.639	2	8.7	2	100.0	0.000	0.000
	Week 144	9	22.0	8	88.9	2.000	3.505	2	8.7	2	100.0	0.000	0.000
	Week 168	8	19.5	7	87.5	1.429	2.507	1	4.3	1	100.0	0.000	NE
	Week 192							1	4.3	1	100.0	0.000	NE
	Week 216							1	4.3	1	100.0	0.000	NE
	End of Study (Discontinued)	5	12.2	3	60.0	2.000	3.464	2	8.7	2	100.0	2.500	3.536

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_FSSAMB_SG.xls
09SEP2020 19:54

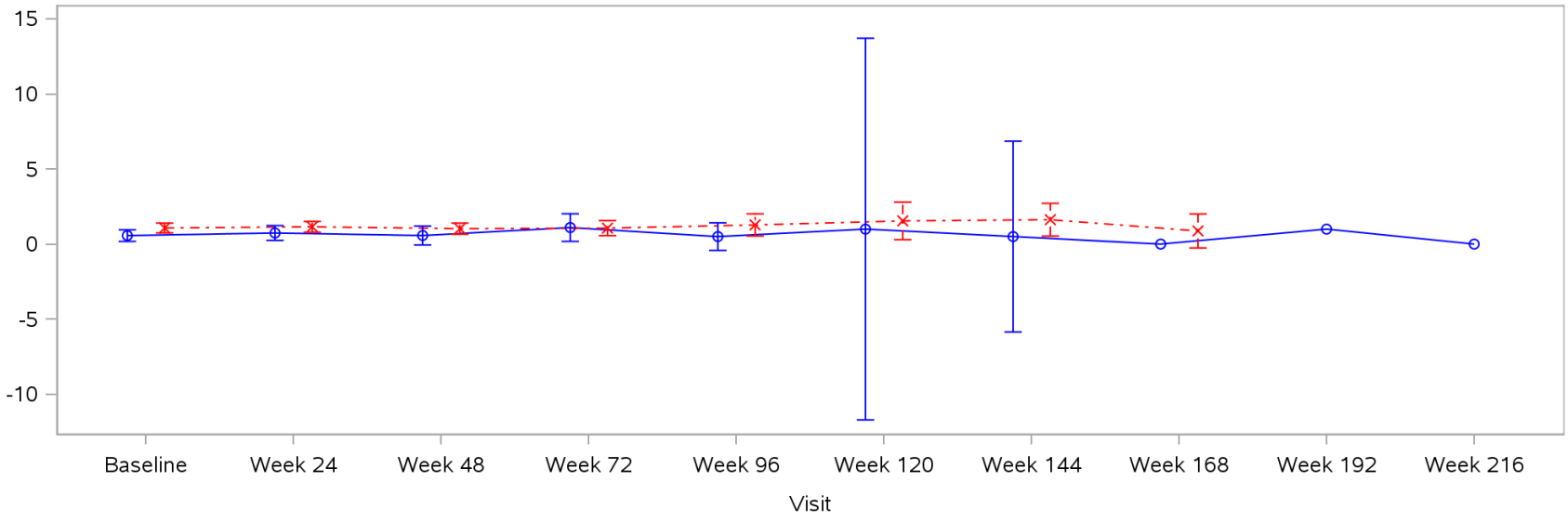
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Bowel and Bladder Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	NE	NE	23	23	23	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_FSSBOW_ST.xls
09SEP2020 21:35

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Bowel and Bladder Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	11	8	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_FSSBOW.pdf
09SEP2020 20:12

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Bowel and Bladder Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100.0	41	100.0	1.073	1.034	23	100.0	23	100.0	0.565	0.896
	Week 24	41	100.0	40	97.6	1.150	1.122	23	100.0	23	100.0	0.739	1.137
	Week 48	37	90.2	37	100.0	1.027	1.118	14	60.9	14	100.0	0.571	1.089
	Week 72	32	78.0	32	100.0	1.063	1.390	11	47.8	10	90.9	1.100	1.287
	Week 96	20	48.8	18	90.0	1.278	1.487	4	17.4	4	100.0	0.500	0.577
	Week 120	11	26.8	11	100.0	1.545	1.864	2	8.7	2	100.0	1.000	1.414
	Week 144	9	22.0	8	88.9	1.625	1.302	2	8.7	2	100.0	0.500	0.707
	Week 168	8	19.5	8	100.0	0.875	1.356	1	4.3	1	100.0	0.000	NE
	Week 192							1	4.3	1	100.0	1.000	NE
	Week 216							1	4.3	1	100.0	0.000	NE
	End of Study (Discontinued)	5	12.2	3	60.0	0.667	0.577	2	8.7	2	100.0	1.500	0.707

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_FSSBOW_SG.xls
09SEP2020 19:52

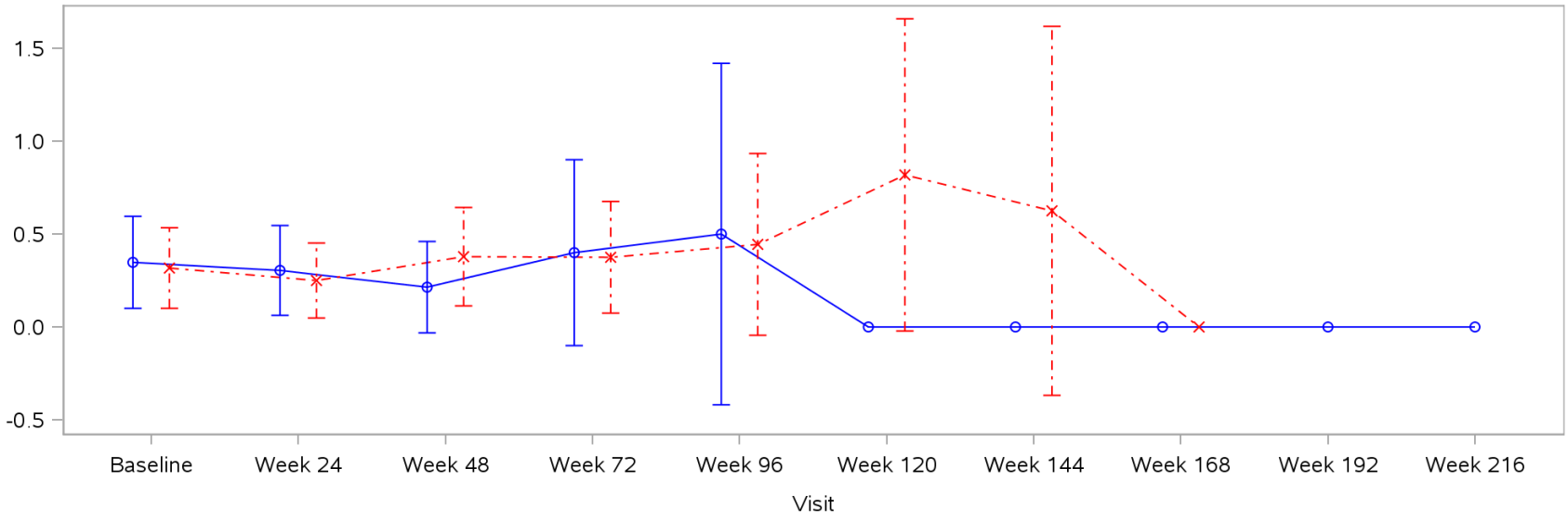
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Brainstem Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	NE	NE	23	23	23	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_FSSBRS_ST.xls
09SEP2020 21:33

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Brainstem Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	11	8	8	0	0

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_FSSBRS.pdf
09SEP2020 20:11

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Brainstem Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100.0	41	100.0	0.317	0.687	23	100.0	23	100.0	0.348	0.573
	Week 24	41	100.0	40	97.6	0.250	0.630	23	100.0	23	100.0	0.304	0.559
	Week 48	37	90.2	37	100.0	0.378	0.794	14	60.9	14	100.0	0.214	0.426
	Week 72	32	78.0	32	100.0	0.375	0.833	11	47.8	10	90.9	0.400	0.699
	Week 96	20	48.8	18	90.0	0.444	0.984	4	17.4	4	100.0	0.500	0.577
	Week 120	11	26.8	11	100.0	0.818	1.250	2	8.7	2	100.0	0.000	0.000
	Week 144	9	22.0	8	88.9	0.625	1.188	2	8.7	2	100.0	0.000	0.000
	Week 168	8	19.5	8	100.0	0.000	0.000	1	4.3	1	100.0	0.000	NE
	Week 192							1	4.3	1	100.0	0.000	NE
	Week 216							1	4.3	1	100.0	0.000	NE
	End of Study (Discontinued)	5	12.2	3	60.0	0.333	0.577	2	8.7	2	100.0	0.000	0.000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_FSSBRS_SG.xls
09SEP2020 19:51

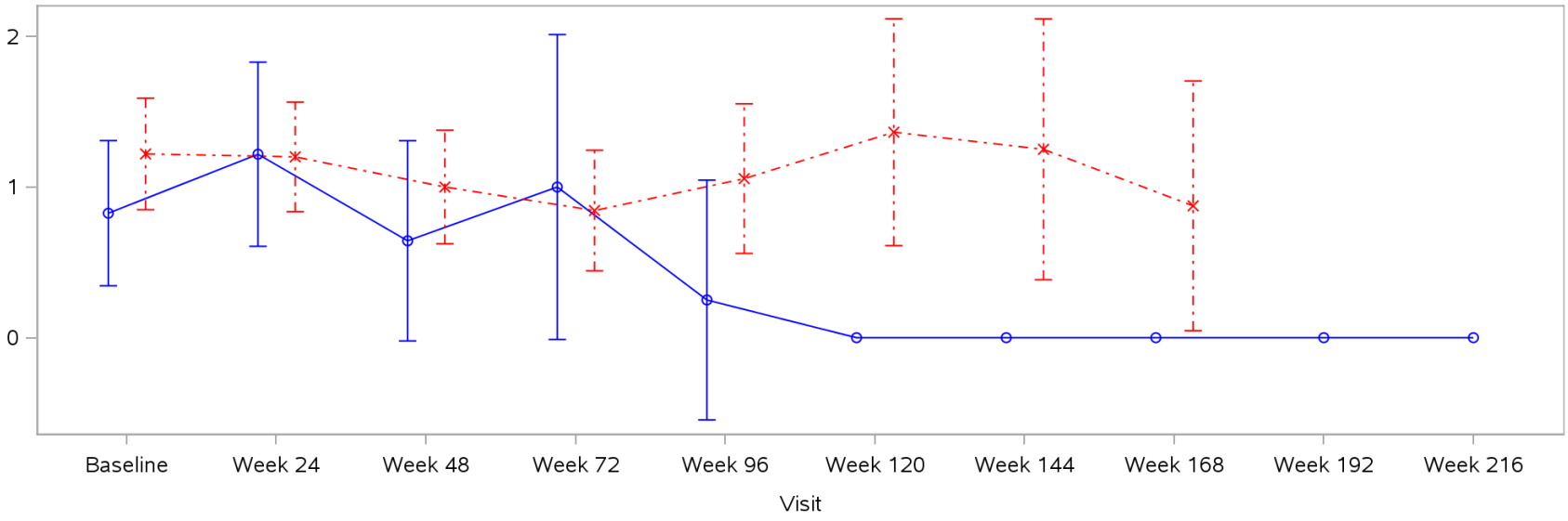
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Cerebellar Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	-0.370	0.216	23	23	23	-0.057	0.264	-0.313	0.255	-0.825	0.199	0.2261	0.4902

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_FSSCER_ST.xls
09SEP2020 21:33

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Cerebellar Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	11	8	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_FSSCER.pdf
09SEP2020 20:10

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Cerebellar Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100.0	41	100.0	1.220	1.173	23	100.0	23	100.0	0.826	1.114
	Week 24	41	100.0	40	97.6	1.200	1.137	23	100.0	23	100.0	1.217	1.413
	Week 48	37	90.2	37	100.0	1.000	1.130	14	60.9	14	100.0	0.643	1.151
	Week 72	32	78.0	32	100.0	0.844	1.110	11	47.8	10	90.9	1.000	1.414
	Week 96	20	48.8	18	90.0	1.056	0.998	4	17.4	4	100.0	0.250	0.500
	Week 120	11	26.8	11	100.0	1.364	1.120	2	8.7	2	100.0	0.000	0.000
	Week 144	9	22.0	8	88.9	1.250	1.035	2	8.7	2	100.0	0.000	0.000
	Week 168	8	19.5	8	100.0	0.875	0.991	1	4.3	1	100.0	0.000	NE
	Week 192							1	4.3	1	100.0	0.000	NE
	Week 216							1	4.3	1	100.0	0.000	NE
	End of Study (Discontinued)	5	12.2	3	60.0	1.000	1.000	2	8.7	2	100.0	1.500	2.121

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_FSSCER_SG.xls
09SEP2020 19:50

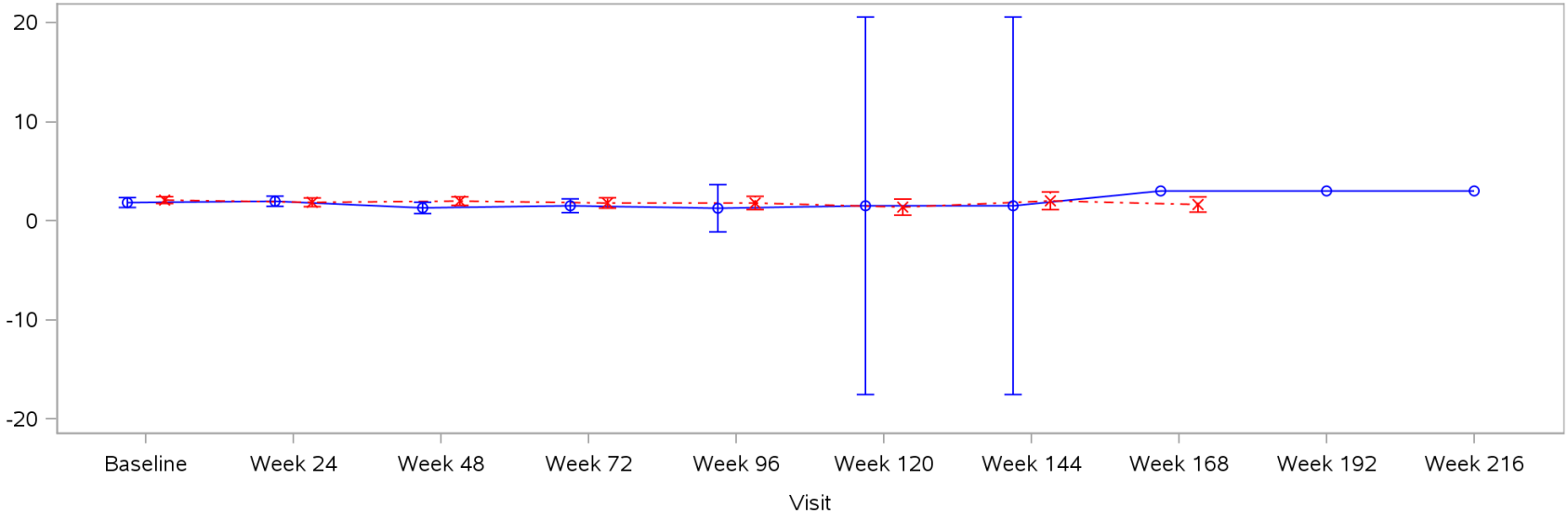
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Pyramidal Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	-0.356	0.219	23	23	23	-0.225	0.226	-0.131	0.211	-0.554	0.292	0.5381	0.4684

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_FSSPYR_ST.xls
09SEP2020 21:32

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Pyramidal Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	11	8	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_FSSPYR.pdf
09SEP2020 20:09

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Pyramidal Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100.0	41	100.0	2.073	1.081	23	100.0	23	100.0	1.826	1.154
	Week 24	41	100.0	40	97.6	1.850	1.369	23	100.0	23	100.0	1.957	1.186
	Week 48	37	90.2	37	100.0	1.973	1.280	14	60.9	14	100.0	1.286	0.994
	Week 72	32	78.0	32	100.0	1.781	1.453	11	47.8	10	90.9	1.500	0.972
	Week 96	20	48.8	18	90.0	1.778	1.353	4	17.4	4	100.0	1.250	1.500
	Week 120	11	26.8	11	100.0	1.364	1.206	2	8.7	2	100.0	1.500	2.121
	Week 144	9	22.0	8	88.9	2.000	1.069	2	8.7	2	100.0	1.500	2.121
	Week 168	8	19.5	8	100.0	1.625	0.916	1	4.3	1	100.0	3.000	NE
	Week 192							1	4.3	1	100.0	3.000	NE
	Week 216							1	4.3	1	100.0	3.000	NE
	End of Study (Discontinued)	5	12.2	3	60.0	1.333	1.155	2	8.7	2	100.0	2.000	1.414

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_FSSPYR_SG.xls
09SEP2020 19:50

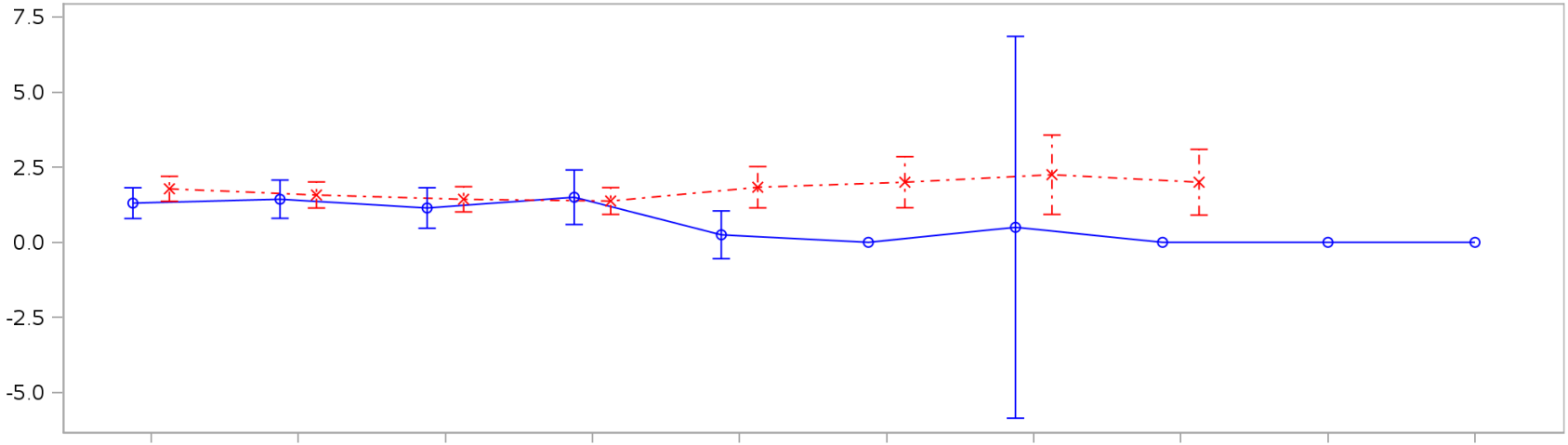
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Sensory Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics					
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	NE	NE	23	23	23	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_FSSSEN_ST.xls
09SEP2020 21:34

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Sensory Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



	Baseline	Week 24	Week 48	Week 72	Week 96	Week 120	Week 144	Week 168	Week 192	Week 216
Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	11	8	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_FSSSEN.pdf
09SEP2020 20:12

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Sensory Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100.0	41	100.0	1.780	1.314	23	100.0	23	100.0	1.304	1.185
	Week 24	41	100.0	40	97.6	1.575	1.357	23	100.0	23	100.0	1.435	1.472
	Week 48	37	90.2	37	100.0	1.432	1.259	14	60.9	14	100.0	1.143	1.167
	Week 72	32	78.0	32	100.0	1.375	1.238	11	47.8	10	90.9	1.500	1.269
	Week 96	20	48.8	18	90.0	1.833	1.383	4	17.4	4	100.0	0.250	0.500
	Week 120	11	26.8	11	100.0	2.000	1.265	2	8.7	2	100.0	0.000	0.000
	Week 144	9	22.0	8	88.9	2.250	1.581	2	8.7	2	100.0	0.500	0.707
	Week 168	8	19.5	8	100.0	2.000	1.309	1	4.3	1	100.0	0.000	NE
	Week 192							1	4.3	1	100.0	0.000	NE
	Week 216							1	4.3	1	100.0	0.000	NE
	End of Study (Discontinued)	5	12.2	3	60.0	1.000	1.732	2	8.7	2	100.0	2.000	0.000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_FSSSEN_SG.xls
09SEP2020 19:52

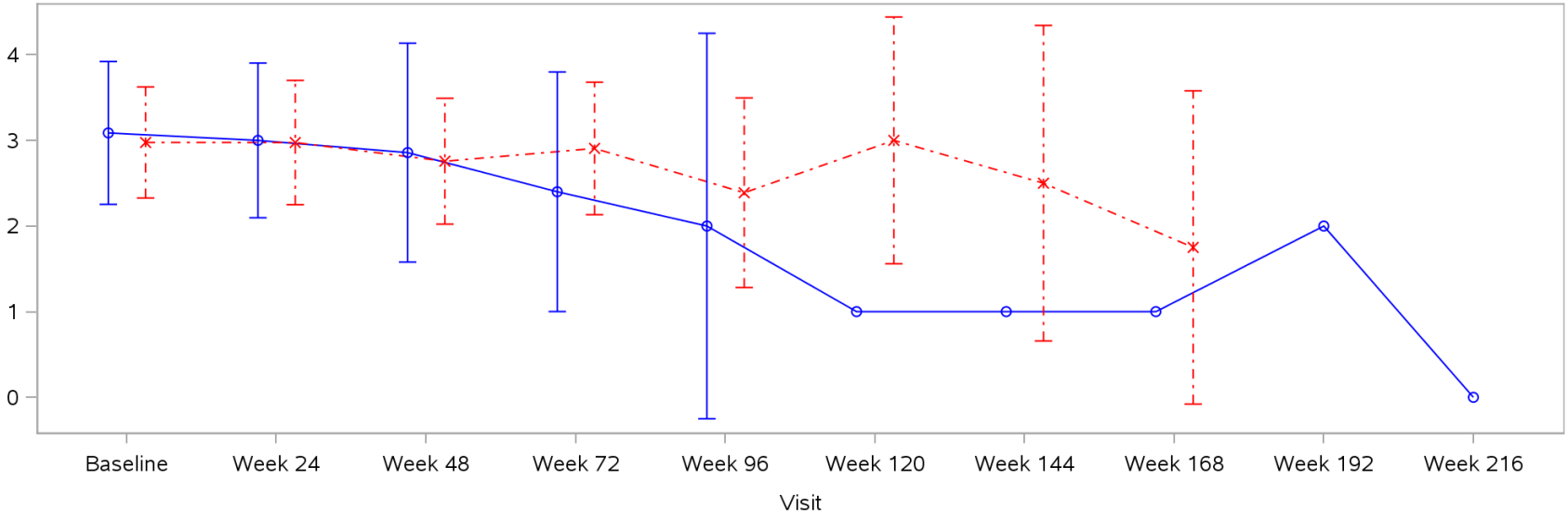
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Visual Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	41	-0.244	0.250	23	23	23	0.273	0.310	-0.517	0.320	-1.167	0.133	0.1154	0.5352

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_FSSVIS_ST.xls
09SEP2020 21:35

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Visual Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	23	14	10	4	2	2	1	1	1
SA237 n	41	40	37	32	18	11	8	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_FSSVIS.pdf
09SEP2020 20:13

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Visual Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100.0	41	100.0	2.976	2.055	23	100.0	23	100.0	3.087	1.929
	Week 24	41	100.0	40	97.6	2.975	2.270	23	100.0	23	100.0	3.000	2.089
	Week 48	37	90.2	37	100.0	2.757	2.204	14	60.9	14	100.0	2.857	2.214
	Week 72	32	78.0	32	100.0	2.906	2.146	11	47.8	10	90.9	2.400	1.955
	Week 96	20	48.8	18	90.0	2.389	2.227	4	17.4	4	100.0	2.000	1.414
	Week 120	11	26.8	11	100.0	3.000	2.145	2	8.7	2	100.0	1.000	0.000
	Week 144	9	22.0	8	88.9	2.500	2.204	2	8.7	2	100.0	1.000	0.000
	Week 168	8	19.5	8	100.0	1.750	2.188	1	4.3	1	100.0	1.000	NE
	Week 192							1	4.3	1	100.0	2.000	NE
	Week 216							1	4.3	1	100.0	0.000	NE
	End of Study (Discontinued)	5	12.2	3	60.0	5.333	1.155	2	8.7	2	100.0	4.000	1.414

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_FSSVIS_SG.xls
09SEP2020 19:53

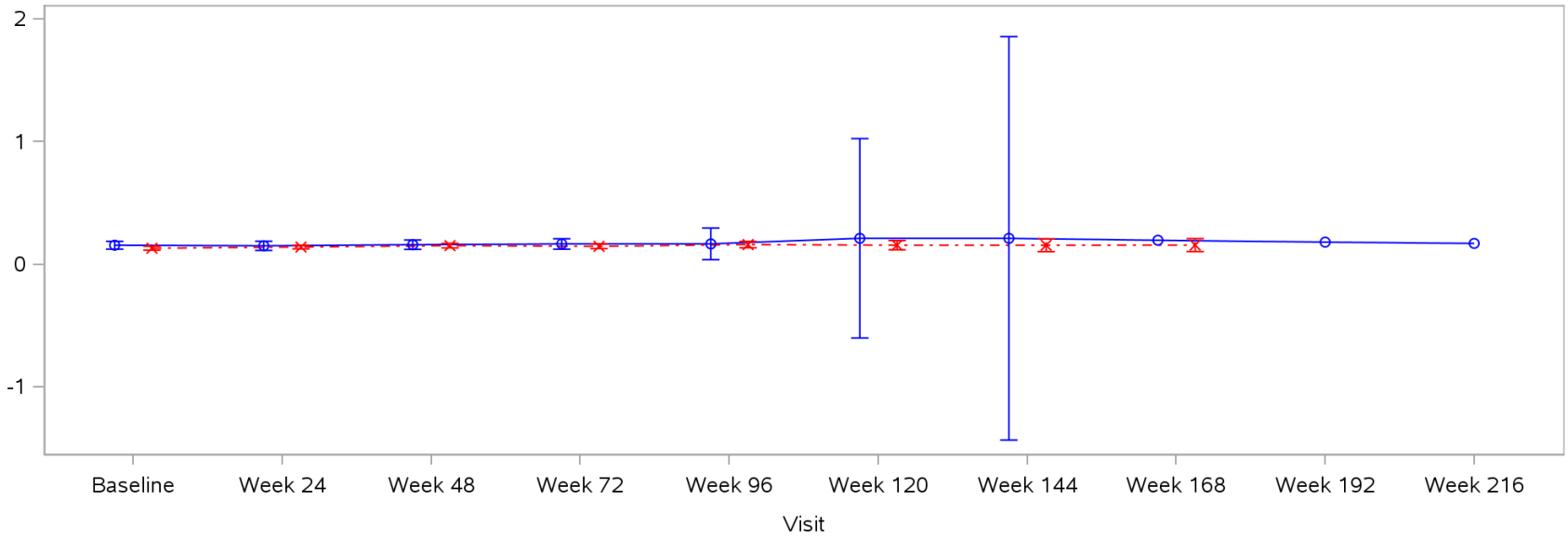
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Speed of Timed 25-Foot Walk (T25W)
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	0,009	0,008	23	22	14	0,012	0,009	-0,003	0,009	-0,022	0,016	0,7357	<.0001

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
Speed is calculated as 1/Timed 25-Foot Walk where time is measured in seconds.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_T25W_ST.xls
08SEP2020 22:01

POPULATION: AQP4 Positive Population
ENDPOINT: Speed of Timed 25-Foot Walk (T25W)
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	22	14	12	8	4	2	2	1	1	1
SA237 n	41	36	32	31	20	11	9	7	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

Speed is calculated as 1/Timed 25-Foot Walk where time is measured in seconds.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_T25W.pdf
29NOV2019 16:01

POPULATION: AQP4 Positive Population
ENDPOINT: Speed of Timed 25-Foot Walk (T25W)
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	0,129	0,051	23	100,0	22	95,7	0,154	0,072
	Week 24	37	90,2	36	97,3	0,139	0,044	14	60,9	14	100,0	0,149	0,065
	Week 48	33	80,5	32	97,0	0,150	0,052	12	52,2	12	100,0	0,158	0,060
	Week 72	31	75,6	31	100,0	0,145	0,051	8	34,8	8	100,0	0,164	0,051
	Week 96	20	48,8	20	100,0	0,159	0,056	4	17,4	4	100,0	0,164	0,081
	Week 120	11	26,8	11	100,0	0,154	0,056	2	8,7	2	100,0	0,210	0,091
	Week 144	9	22,0	9	100,0	0,154	0,068	2	8,7	2	100,0	0,209	0,183
	Week 168	8	19,5	7	87,5	0,155	0,057	1	4,3	1	100,0	0,194	NE
	Week 192							1	4,3	1	100,0	0,179	NE
	Week 216							1	4,3	1	100,0	0,168	NE
	End of Study (Discontinued)	5	12,2	2	40,0	0,171	0,053	2	8,7	2	100,0	0,122	0,078

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
Speed is calculated as 1/Timed 25-Foot Walk where time is measured in seconds.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_T25W_SG.xls
29NOV2019 13:30

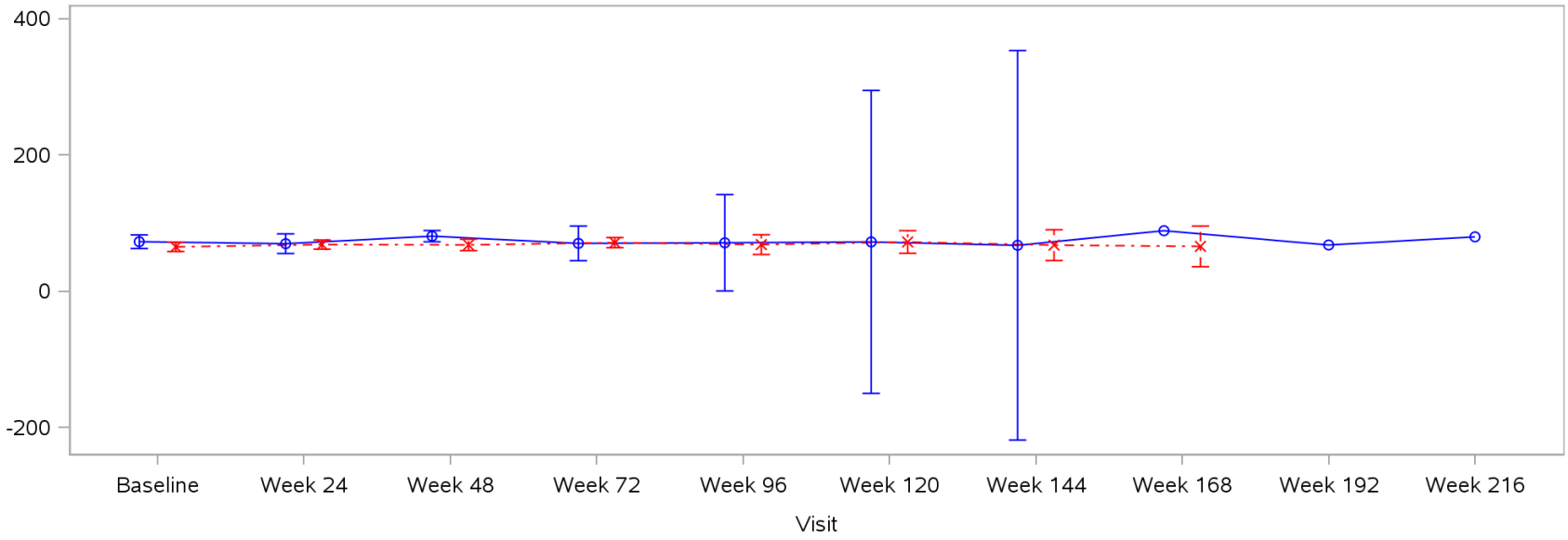
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, EuroQoL-5D (EQ-5D): VAS Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	40	36	-0,865	4,090	23	22	13	1,834	6,691	-2,699	7,310	-17,411	12,012	0,7136	0,7927

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The EQ-5D VAS is scored on a scale of 0-100. Higher scores reflect a better health state.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_EQ5DVAS_ST.xls
08SEP2020 22:00

POPULATION: AQP4 Positive Population
ENDPOINT: EuroQoL-5D (EQ-5D): VAS Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	22	14	12	8	4	2	2	1	1	1
SA237 n	40	37	33	31	20	11	9	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The EQ-5D VAS is scored on a scale of 0-100. Higher scores reflect a better health state.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_EQ5DVAS.pdf
29NOV2019 16:01

POPULATION: AQP4 Positive Population
ENDPOINT: EuroQoL-5D (EQ-5D): VAS Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	40	97,6	65,250	21,066	23	100,0	22	95,7	72,818	22,652
	Week 24	37	90,2	37	100,0	68,622	20,213	14	60,9	14	100,0	69,929	24,975
	Week 48	33	80,5	33	100,0	68,152	23,606	12	52,2	12	100,0	81,000	12,976
	Week 72	31	75,6	31	100,0	71,484	20,420	8	34,8	8	100,0	70,375	30,463
	Week 96	20	48,8	20	100,0	68,600	30,979	4	17,4	4	100,0	71,250	44,418
	Week 120	11	26,8	11	100,0	72,455	24,724	2	8,7	2	100,0	72,500	24,749
	Week 144	9	22,0	9	100,0	67,778	29,474	2	8,7	2	100,0	67,500	31,820
	Week 168	8	19,5	8	100,0	66,000	35,701	1	4,3	1	100,0	89,000	NE
	Week 192							1	4,3	1	100,0	68,000	NE
	Week 216							1	4,3	1	100,0	80,000	NE
	End of Study (Discontinued)	5	12,2	3	60,0	56,667	44,814	2	8,7	2	100,0	47,000	18,385

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The EQ-5D VAS is scored on a scale of 0-100. Higher scores reflect a better health state.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_EQ5DVAS_SG.xls
29NOV2019 13:30

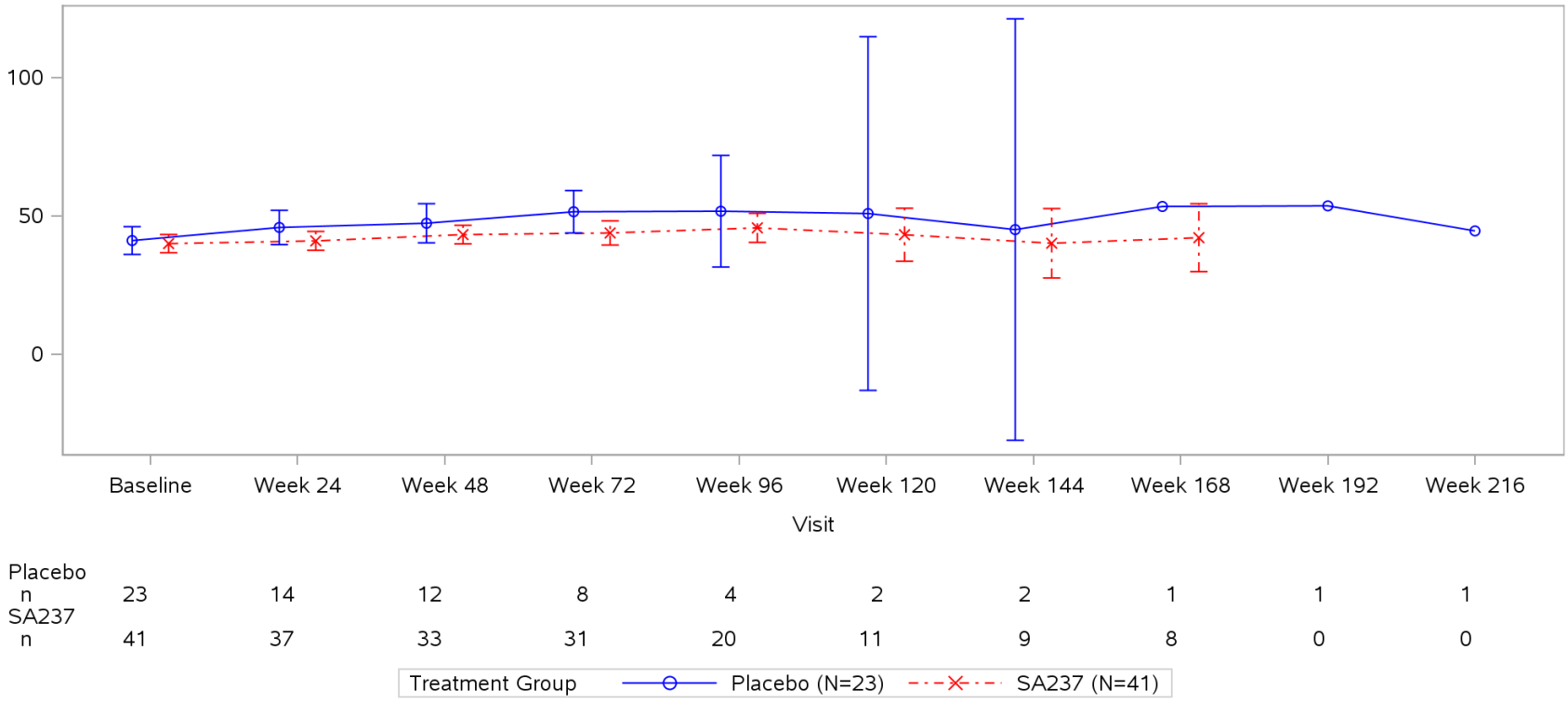
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Physical Health Component
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	5,843	1,425	23	23	14	7,388	1,908	-1,545	2,029	-5,644	2,554	0,4508	0,0807

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36PCS_ST.xls
08SEP2020 21:54

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Physical Health Component
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36PCS.pdf
29NOV2019 15:55

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Physical Health Component
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	39,963	10,434	23	100,0	23	100,0	41,070	11,619
	Week 24	37	90,2	37	100,0	40,954	10,239	14	60,9	14	100,0	45,816	10,735
	Week 48	33	80,5	33	100,0	43,231	9,475	12	52,2	12	100,0	47,330	11,145
	Week 72	31	75,6	31	100,0	43,815	11,904	8	34,8	8	100,0	51,488	9,187
	Week 96	20	48,8	20	100,0	45,661	11,238	4	17,4	4	100,0	51,683	12,684
	Week 120	11	26,8	11	100,0	43,174	14,275	2	8,7	2	100,0	50,835	7,121
	Week 144	9	22,0	9	100,0	40,094	16,333	2	8,7	2	100,0	45,040	8,485
	Week 168	8	19,5	8	100,0	42,104	14,707	1	4,3	1	100,0	53,410	NE
	Week 192							1	4,3	1	100,0	53,620	NE
	Week 216							1	4,3	1	100,0	44,570	NE
	End of Study (Discontinued)	5	12,2	3	60,0	33,310	7,972	2	8,7	2	100,0	36,950	6,421

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36PCS_SG.xls
29NOV2019 13:26

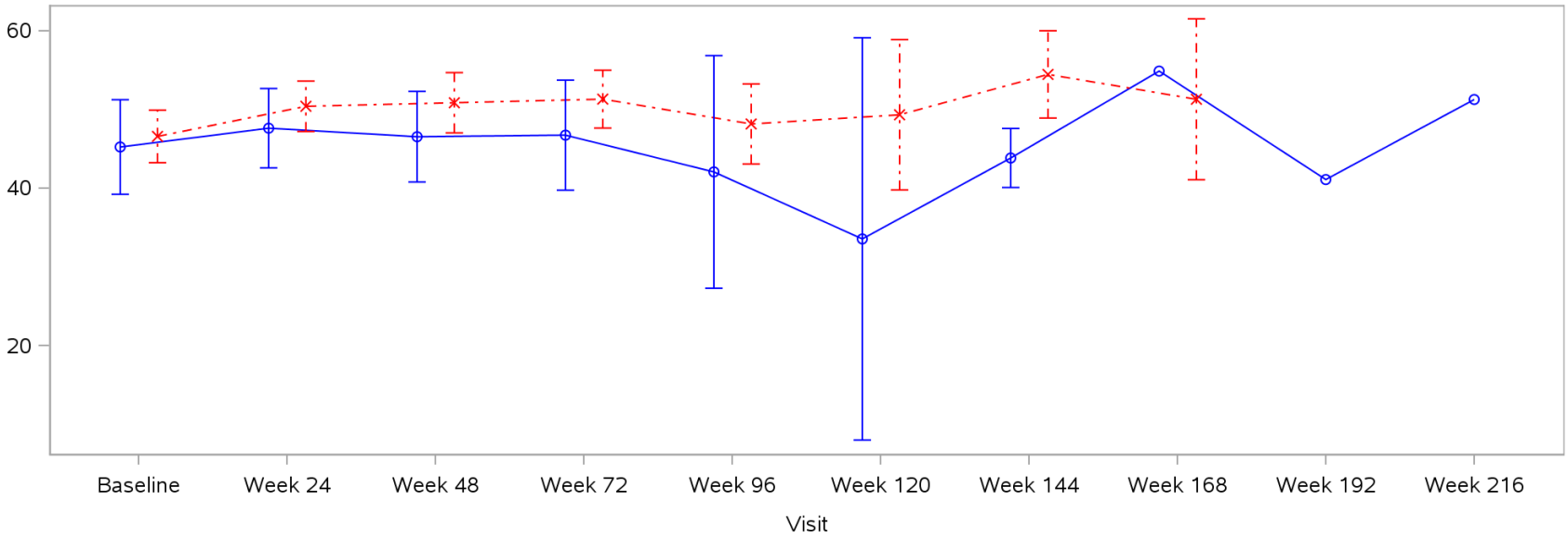
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Mental Health Component
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	5,798	1,791	23	23	14	-6,045	2,931	11,843	3,128	5,381	18,306	0,0009	0,1725

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36MCS_ST.xls
08SEP2020 21:54

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Mental Health Component
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36MCS.pdf
29NOV2019 15:56

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Mental Health Component
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	46,543	10,575	23	100,0	23	100,0	45,200	13,882
	Week 24	37	90,2	37	100,0	50,369	9,606	14	60,9	14	100,0	47,586	8,726
	Week 48	33	80,5	33	100,0	50,819	10,794	12	52,2	12	100,0	46,508	9,052
	Week 72	31	75,6	31	100,0	51,278	10,024	8	34,8	8	100,0	46,704	8,355
	Week 96	20	48,8	20	100,0	48,125	10,859	4	17,4	4	100,0	42,035	9,281
	Week 120	11	26,8	11	100,0	49,292	14,207	2	8,7	2	100,0	33,530	2,843
	Week 144	9	22,0	9	100,0	54,417	7,207	2	8,7	2	100,0	43,805	0,417
	Week 168	8	19,5	8	100,0	51,259	12,215	1	4,3	1	100,0	54,840	NE
	Week 192							1	4,3	1	100,0	41,070	NE
	Week 216							1	4,3	1	100,0	51,230	NE
	End of Study (Discontinued)	5	12,2	3	60,0	50,447	7,490	2	8,7	2	100,0	32,560	2,432

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36MCS_SG.xls
29NOV2019 13:26

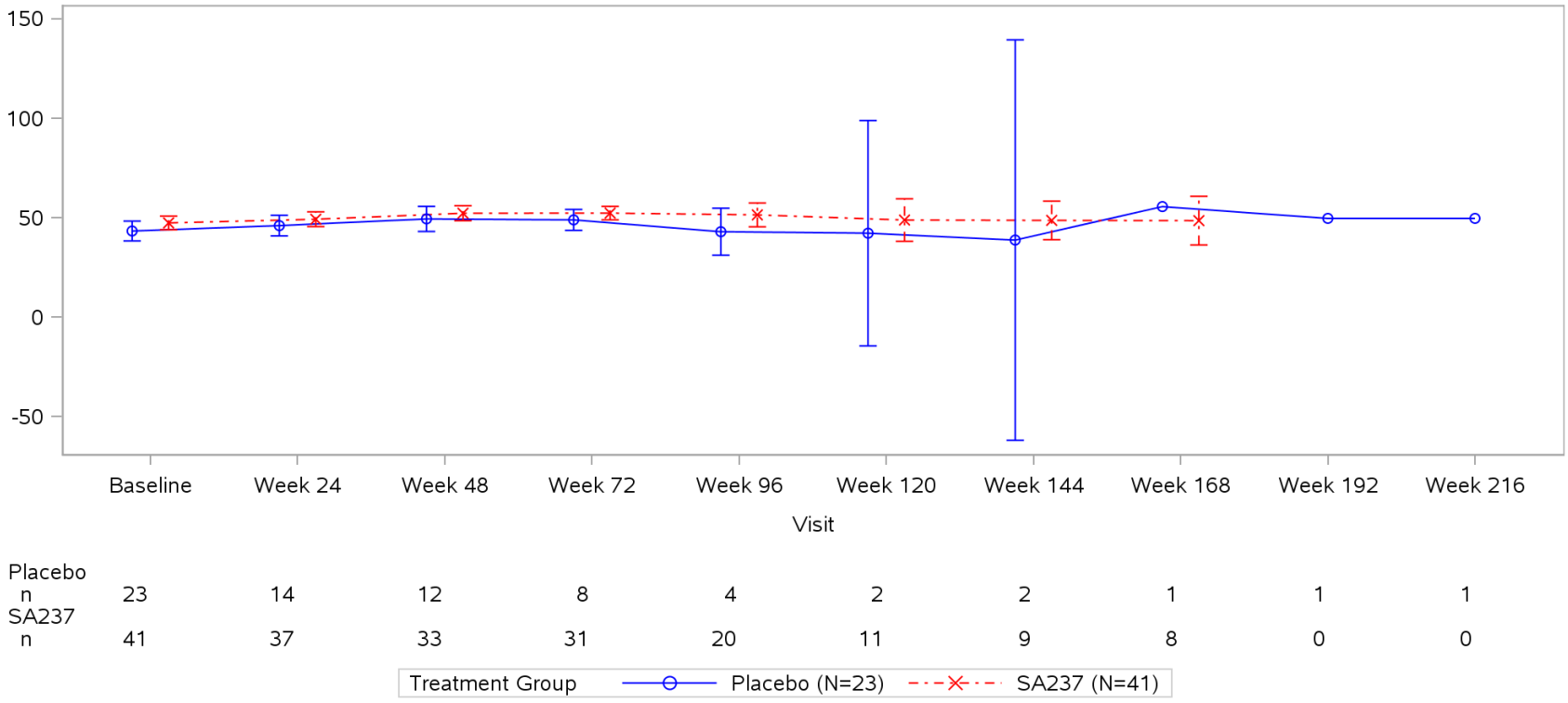
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Vitality Domain Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	7,734	2,386	23	23	14	2,508	2,987	5,226	3,016	-1,132	11,584	0,1011	0,4379

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36VTY_ST.xls
08SEP2020 21:55

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Vitality Domain Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36VTY.pdf
29NOV2019 15:56

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Vitality Domain Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	47,358	10,846	23	100,0	23	100,0	43,299	11,518
	Week 24	37	90,2	37	100,0	49,226	11,141	14	60,9	14	100,0	46,021	8,965
	Week 48	33	80,5	33	100,0	52,239	10,601	12	52,2	12	100,0	49,380	9,932
	Week 72	31	75,6	31	100,0	52,312	9,214	8	34,8	8	100,0	48,888	6,300
	Week 96	20	48,8	20	100,0	51,410	12,801	4	17,4	4	100,0	42,945	7,430
	Week 120	11	26,8	11	100,0	48,818	15,891	2	8,7	2	100,0	42,200	6,307
	Week 144	9	22,0	9	100,0	48,637	12,604	2	8,7	2	100,0	38,735	11,208
	Week 168	8	19,5	8	100,0	48,511	14,635	1	4,3	1	100,0	55,570	NE
	Week 192							1	4,3	1	100,0	49,630	NE
	Week 216							1	4,3	1	100,0	49,630	NE
	End of Study (Discontinued)	5	12,2	3	60,0	44,680	3,429	2	8,7	2	100,0	36,260	6,307

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36VTY_SG.xls
29NOV2019 13:27

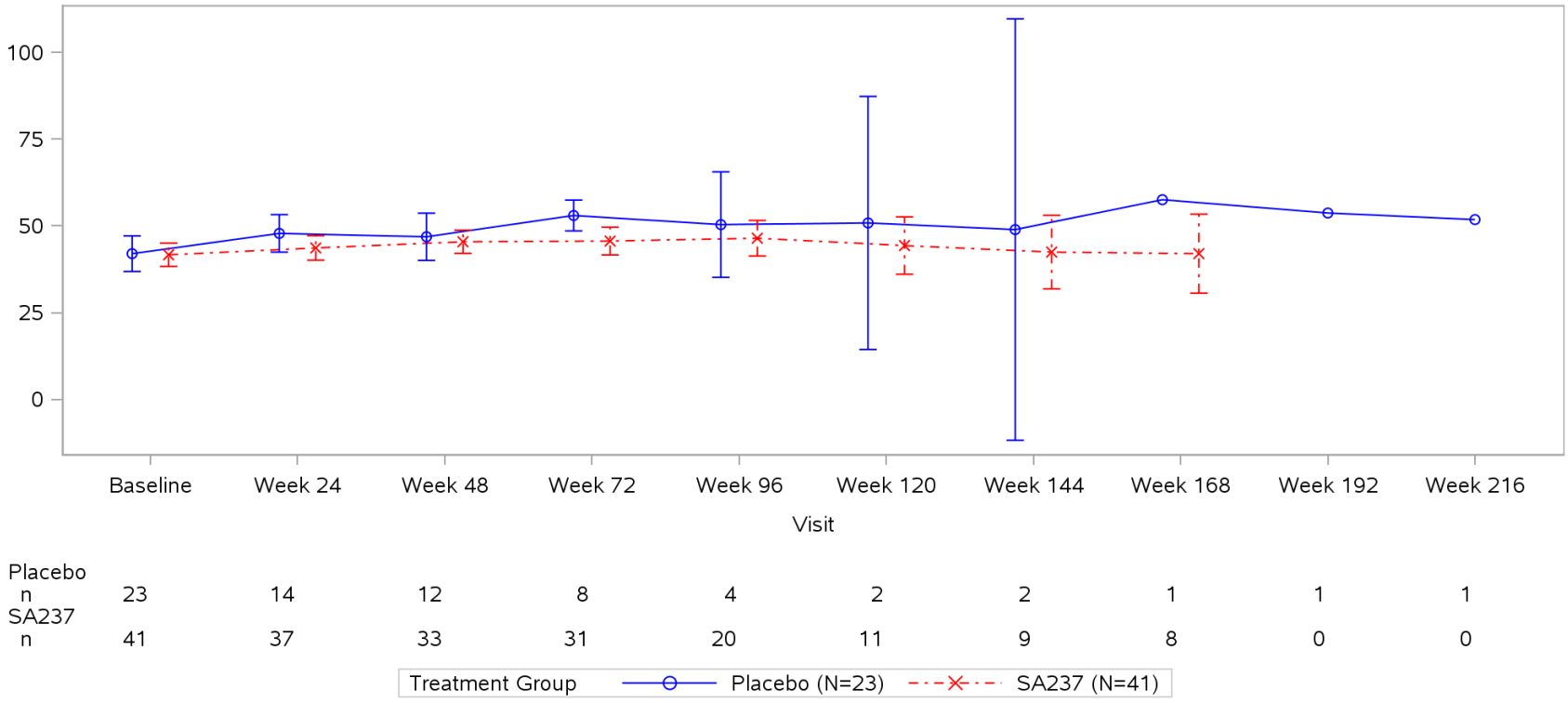
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Physical Functioning Domain Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	7,069	1,255	23	23	14	6,236	1,897	0,833	2,119	-3,430	5,096	0,6961	0,0005

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36PHF_ST.xls
08SEP2020 21:56

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Physical Functioning Domain Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36PHF.pdf
29NOV2019 15:57

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Physical Functioning Domain Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	41,662	10,614	23	100,0	23	100,0	41,981	11,857
	Week 24	37	90,2	37	100,0	43,637	10,579	14	60,9	14	100,0	47,835	9,360
	Week 48	33	80,5	33	100,0	45,419	9,420	12	52,2	12	100,0	46,855	10,717
	Week 72	31	75,6	31	100,0	45,625	10,890	8	34,8	8	100,0	52,995	5,310
	Week 96	20	48,8	20	100,0	46,441	10,960	4	17,4	4	100,0	50,365	9,553
	Week 120	11	26,8	11	100,0	44,318	12,297	2	8,7	2	100,0	50,840	4,059
	Week 144	9	22,0	9	100,0	42,442	13,783	2	8,7	2	100,0	48,930	6,760
	Week 168	8	19,5	8	100,0	41,991	13,627	1	4,3	1	100,0	57,540	NE
	Week 192							1	4,3	1	100,0	53,710	NE
	Week 216							1	4,3	1	100,0	51,800	NE
	End of Study (Discontinued)	5	12,2	3	60,0	40,313	10,655	2	8,7	2	100,0	37,445	12,183

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36PHF_SG.xls
29NOV2019 13:27

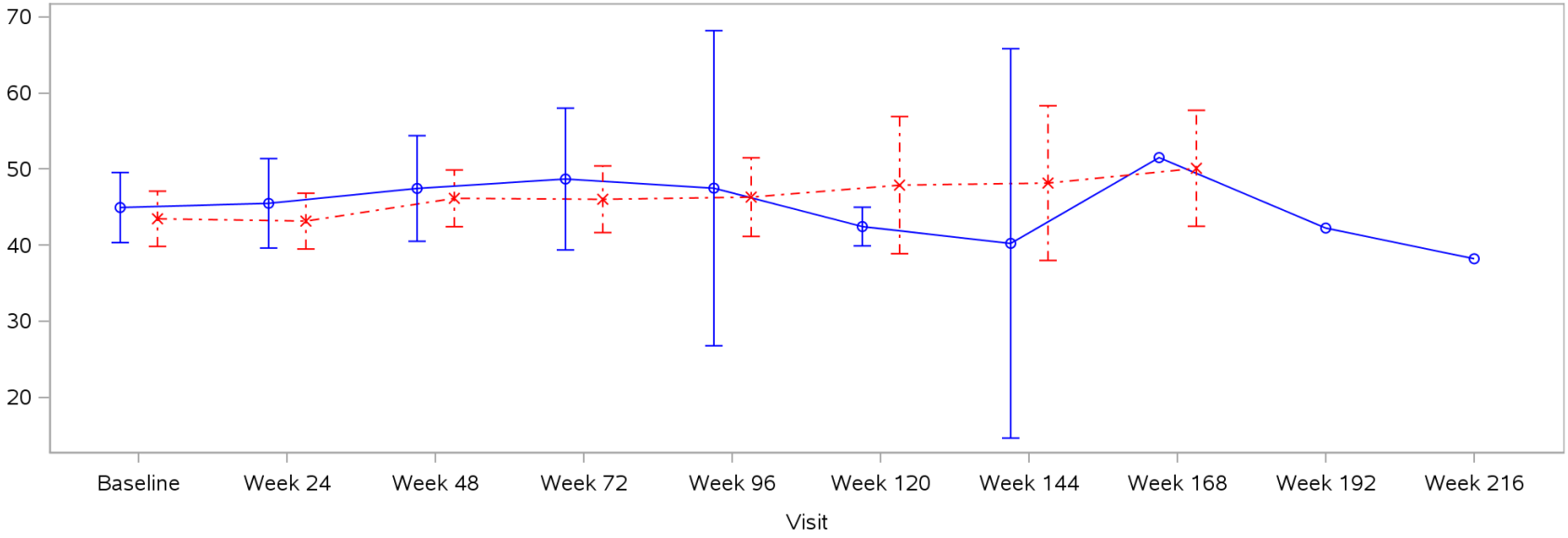
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Bodily Pain Domain Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	3,087	2,224	23	23	14	2,419	2,714	0,669	2,739	-4,879	6,216	0,8085	0,6438

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36BPN_ST.xls
08SEP2020 21:56

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Bodily Pain Domain Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36BPN.pdf
29NOV2019 15:57

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Bodily Pain Domain Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	43,461	11,504	23	100,0	23	100,0	44,941	10,658
	Week 24	37	90,2	37	100,0	43,157	11,004	14	60,9	14	100,0	45,496	10,187
	Week 48	33	80,5	33	100,0	46,153	10,511	12	52,2	12	100,0	47,450	10,929
	Week 72	31	75,6	31	100,0	46,028	11,946	8	34,8	8	100,0	48,693	11,154
	Week 96	20	48,8	20	100,0	46,314	11,046	4	17,4	4	100,0	47,485	13,020
	Week 120	11	26,8	11	100,0	47,886	13,414	2	8,7	2	100,0	42,440	0,283
	Week 144	9	22,0	9	100,0	48,156	13,236	2	8,7	2	100,0	40,225	2,850
	Week 168	8	19,5	8	100,0	50,104	9,118	1	4,3	1	100,0	51,510	NE
	Week 192							1	4,3	1	100,0	42,240	NE
	Week 216							1	4,3	1	100,0	38,210	NE
	End of Study (Discontinued)	5	12,2	3	60,0	34,043	10,895	2	8,7	2	100,0	32,365	8,266

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36BPN_SG.xls
29NOV2019 13:27

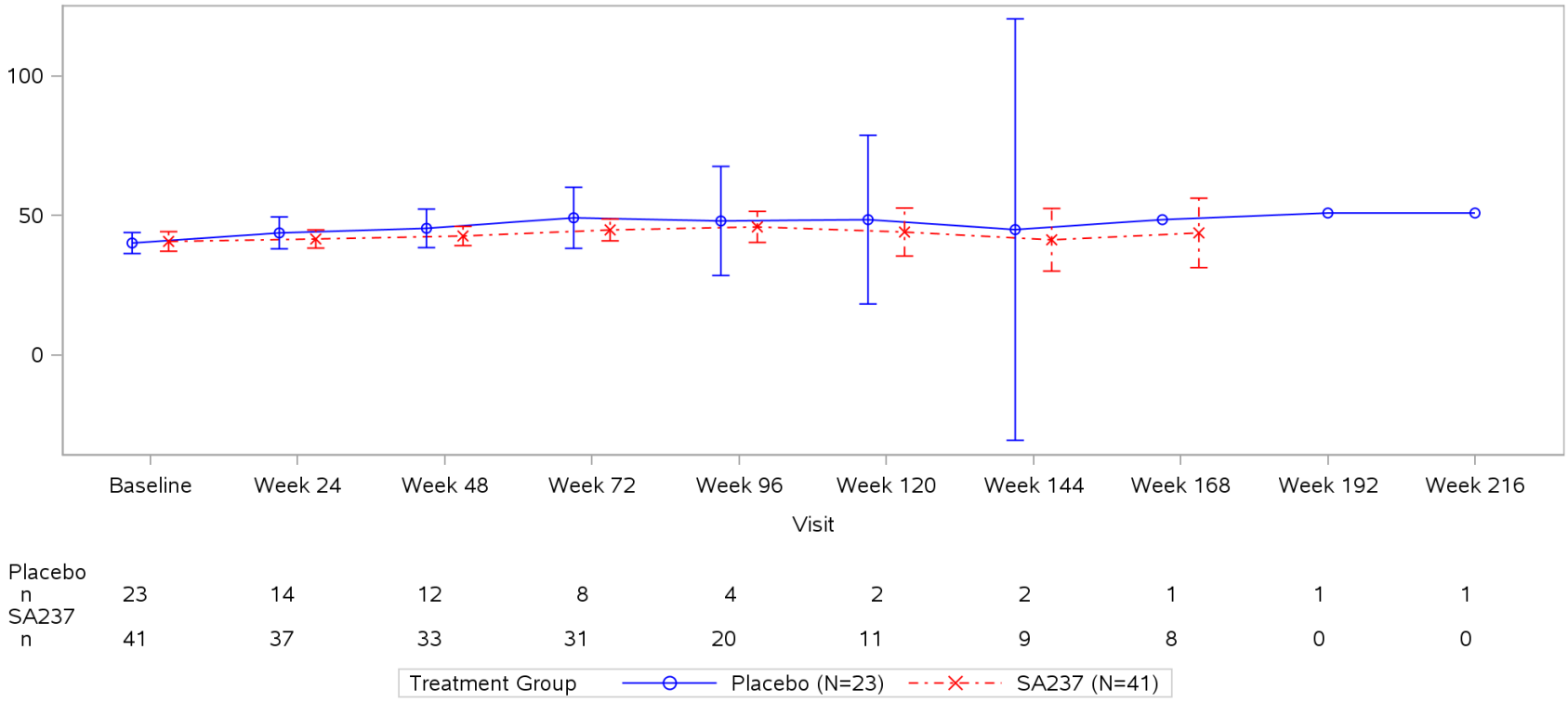
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): General Health Domain Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	4,455	2,443	23	23	14	5,540	2,680	-1,085	2,701	-6,549	4,379	0,6901	0,4362

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36GNH_ST.xls
08SEP2020 21:57

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): General Health Domain Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36GNH.pdf
29NOV2019 15:58

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): General Health Domain Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	40,615	11,123	23	100,0	23	100,0	40,037	8,717
	Week 24	37	90,2	37	100,0	41,491	9,811	14	60,9	14	100,0	43,676	9,905
	Week 48	33	80,5	33	100,0	42,566	9,721	12	52,2	12	100,0	45,302	10,854
	Week 72	31	75,6	31	100,0	44,751	10,685	8	34,8	8	100,0	49,085	13,103
	Week 96	20	48,8	20	100,0	45,817	11,891	4	17,4	4	100,0	47,958	12,286
	Week 120	11	26,8	11	100,0	43,980	12,798	2	8,7	2	100,0	48,430	3,366
	Week 144	9	22,0	9	100,0	41,196	14,610	2	8,7	2	100,0	44,865	8,407
	Week 168	8	19,5	8	100,0	43,678	14,884	1	4,3	1	100,0	48,430	NE
	Week 192							1	4,3	1	100,0	50,810	NE
	Week 216							1	4,3	1	100,0	50,810	NE
	End of Study (Discontinued)	5	12,2	3	60,0	40,663	5,947	2	8,7	2	100,0	30,840	13,449

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36GNH_SG.xls
29NOV2019 13:28

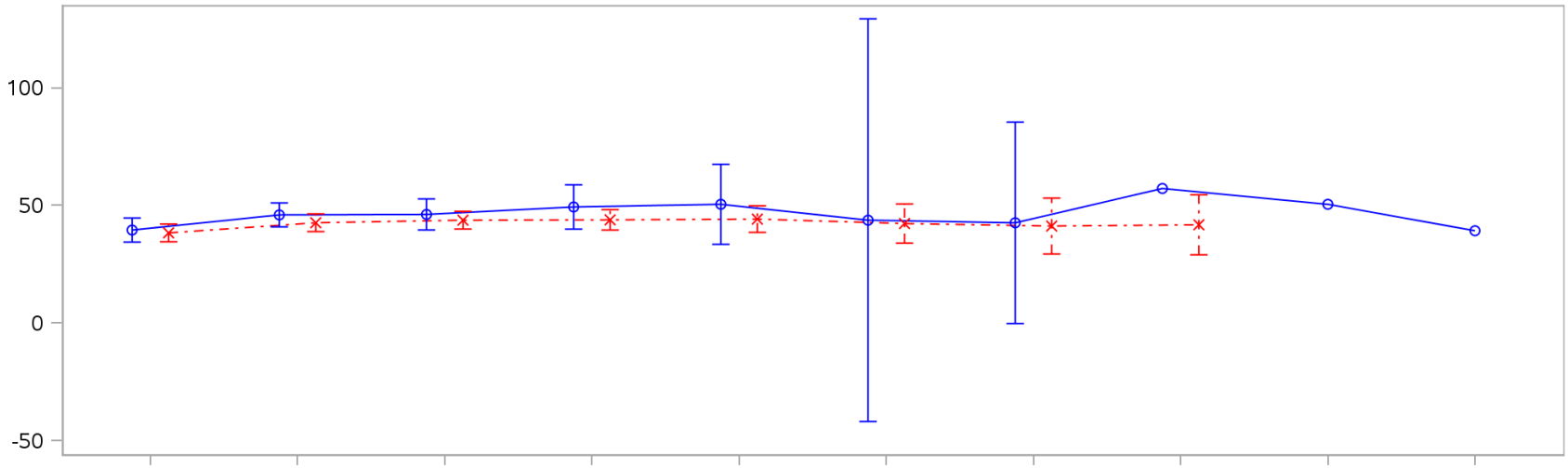
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Role-physical Domain Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	6,343	2,024	23	23	14	4,899	2,439	1,445	2,527	-3,639	6,528	0,5703	0,7221

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36RPY_ST.xls
08SEP2020 21:58

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Role-physical Domain Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36RPY.pdf
29NOV2019 15:58

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Role-physical Domain Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	38,280	11,976	23	100,0	23	100,0	39,486	11,830
	Week 24	37	90,2	37	100,0	42,591	11,249	14	60,9	14	100,0	45,929	8,808
	Week 48	33	80,5	33	100,0	43,683	10,608	12	52,2	12	100,0	46,116	10,378
	Week 72	31	75,6	31	100,0	43,829	11,840	8	34,8	8	100,0	49,300	11,261
	Week 96	20	48,8	20	100,0	44,134	12,052	4	17,4	4	100,0	50,420	10,693
	Week 120	11	26,8	11	100,0	42,255	12,394	2	8,7	2	100,0	43,685	9,525
	Week 144	9	22,0	9	100,0	41,189	15,454	2	8,7	2	100,0	42,560	4,766
	Week 168	8	19,5	8	100,0	41,719	15,252	1	4,3	1	100,0	57,160	NE
	Week 192							1	4,3	1	100,0	50,420	NE
	Week 216							1	4,3	1	100,0	39,190	NE
	End of Study (Discontinued)	5	12,2	3	60,0	33,203	5,652	2	8,7	2	100,0	38,070	1,584

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36RPY_SG.xls
29NOV2019 13:28

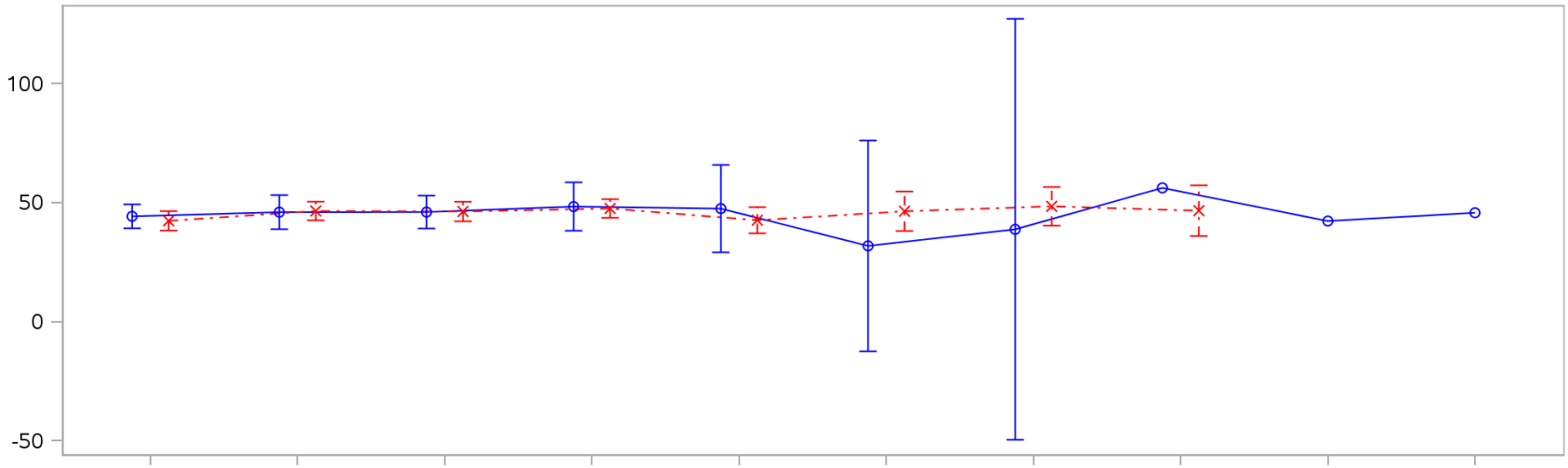
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Role-emotional Domain Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	7,112	2,231	23	23	14	-3,982	3,342	11,095	3,490	3,866	18,323	0,0043	<.0001

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36REM_ST.xls
08SEP2020 21:58

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Role-emotional Domain Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36REM.pdf
29NOV2019 15:59

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Role-emotional Domain Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	42,327	12,922	23	100,0	23	100,0	44,210	11,635
	Week 24	37	90,2	37	100,0	46,476	11,754	14	60,9	14	100,0	45,972	12,401
	Week 48	33	80,5	33	100,0	46,251	11,617	12	52,2	12	100,0	46,015	10,855
	Week 72	31	75,6	31	100,0	47,520	10,671	8	34,8	8	100,0	48,335	12,170
	Week 96	20	48,8	20	100,0	42,590	11,734	4	17,4	4	100,0	47,465	11,547
	Week 120	11	26,8	11	100,0	46,357	12,341	2	8,7	2	100,0	31,795	4,929
	Week 144	9	22,0	9	100,0	48,431	10,559	2	8,7	2	100,0	38,760	9,843
	Week 168	8	19,5	8	100,0	46,595	12,726	1	4,3	1	100,0	56,170	NE
	Week 192							1	4,3	1	100,0	42,240	NE
	Week 216							1	4,3	1	100,0	45,720	NE
	End of Study (Discontinued)	5	12,2	3	60,0	46,883	8,042	2	8,7	2	100,0	35,280	0,000

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36REM_SG.xls
29NOV2019 13:28

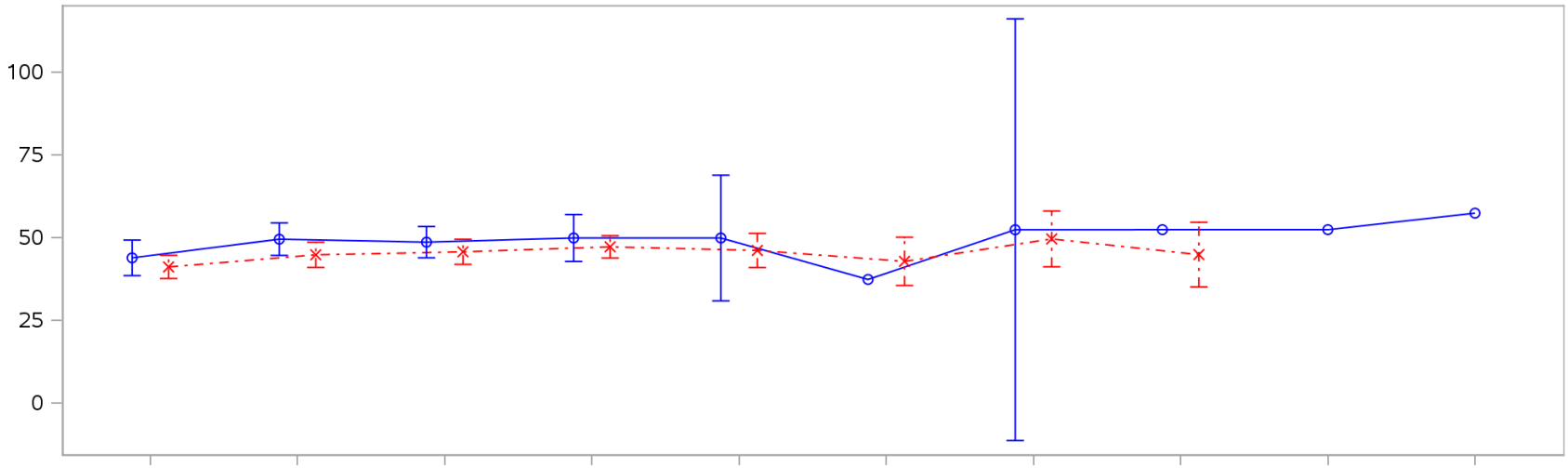
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Social Role Functioning Domain Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	7,256	2,171	23	23	14	5,286	2,896	1,970	3,061	-4,334	8,273	0,5257	0,1408

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36SRF_ST.xls
08SEP2020 21:59

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Social Role Functioning Domain Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

Treatment Group — Placebo (N=23) — SA237 (N=41)

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36SRF.pdf
29NOV2019 16:00

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Social Role Functioning Domain Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	41,077	11,085	23	100,0	23	100,0	43,825	12,413
	Week 24	37	90,2	37	100,0	44,740	11,433	14	60,9	14	100,0	49,464	8,506
	Week 48	33	80,5	33	100,0	45,642	10,683	12	52,2	12	100,0	48,567	7,443
	Week 72	31	75,6	31	100,0	47,152	9,197	8	34,8	8	100,0	49,820	8,474
	Week 96	20	48,8	20	100,0	46,059	11,017	4	17,4	4	100,0	49,820	11,936
	Week 120	11	26,8	11	100,0	42,755	10,858	2	8,7	2	100,0	37,290	0,000
	Week 144	9	22,0	9	100,0	49,541	10,958	2	8,7	2	100,0	52,325	7,092
	Week 168	8	19,5	8	100,0	44,806	11,681	1	4,3	1	100,0	52,330	NE
	Week 192							1	4,3	1	100,0	52,330	NE
	Week 216							1	4,3	1	100,0	57,340	NE
	End of Study (Discontinued)	5	12,2	3	60,0	40,630	5,785	2	8,7	2	100,0	32,275	7,092

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36SRF_SG.xls
29NOV2019 13:29

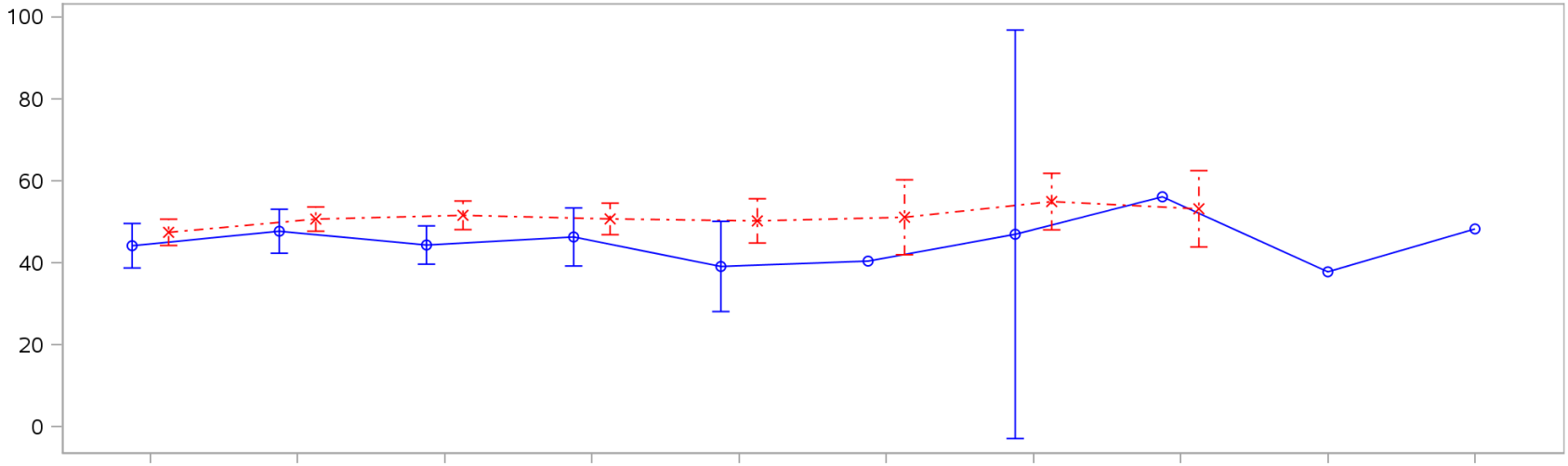
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Mental Health Domain Score
MODEL: Stratified analysis (stratification factors: prior therapy (B-cell depleting therapy or immunosuppressants/others); most recent attack (first attack or relapse))
STUDY: BN40900
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	41	41	37	5,908	1,744	23	23	14	-0,676	2,450	6,584	2,576	1,276	11,892	0,0171	0,0625

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_309_12OCT2018_AQPP_SF36MTH_ST.xls
08SEP2020 21:59

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Mental Health Domain Score
MODEL: --
STUDY: BN40900
Plot of Mean and 95% CI by Visit



Placebo n	23	14	12	8	4	2	2	1	1	1
SA237 n	41	37	33	31	20	11	9	8	0	0

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_309_12OCT2018_AQPP_SF36MTH.pdf
29NOV2019 16:00

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Mental Health Domain Score
MODEL: --
STUDY: BN40900
Compliance/Mean

		SA237 (N=41)						Placebo (N=23)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	41	100,0	41	100,0	47,423	10,157	23	100,0	23	100,0	44,157	12,566
	Week 24	37	90,2	37	100,0	50,656	8,902	14	60,9	14	100,0	47,692	9,300
	Week 48	33	80,5	33	100,0	51,582	9,860	12	52,2	12	100,0	44,328	7,355
	Week 72	31	75,6	31	100,0	50,700	10,484	8	34,8	8	100,0	46,290	8,477
	Week 96	20	48,8	20	100,0	50,215	11,540	4	17,4	4	100,0	39,095	6,919
	Week 120	11	26,8	11	100,0	51,106	13,618	2	8,7	2	100,0	40,400	0,000
	Week 144	9	22,0	9	100,0	54,937	8,979	2	8,7	2	100,0	46,945	5,551
	Week 168	8	19,5	8	100,0	53,158	11,138	1	4,3	1	100,0	56,100	NE
	Week 192							1	4,3	1	100,0	37,790	NE
	Week 216							1	4,3	1	100,0	48,250	NE
	End of Study (Discontinued)	5	12,2	3	60,0	49,123	7,994	2	8,7	2	100,0	30,595	0,926

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_309_12OCT2018_AQPP_SF36MTH_SG.xls
29NOV2019 13:29

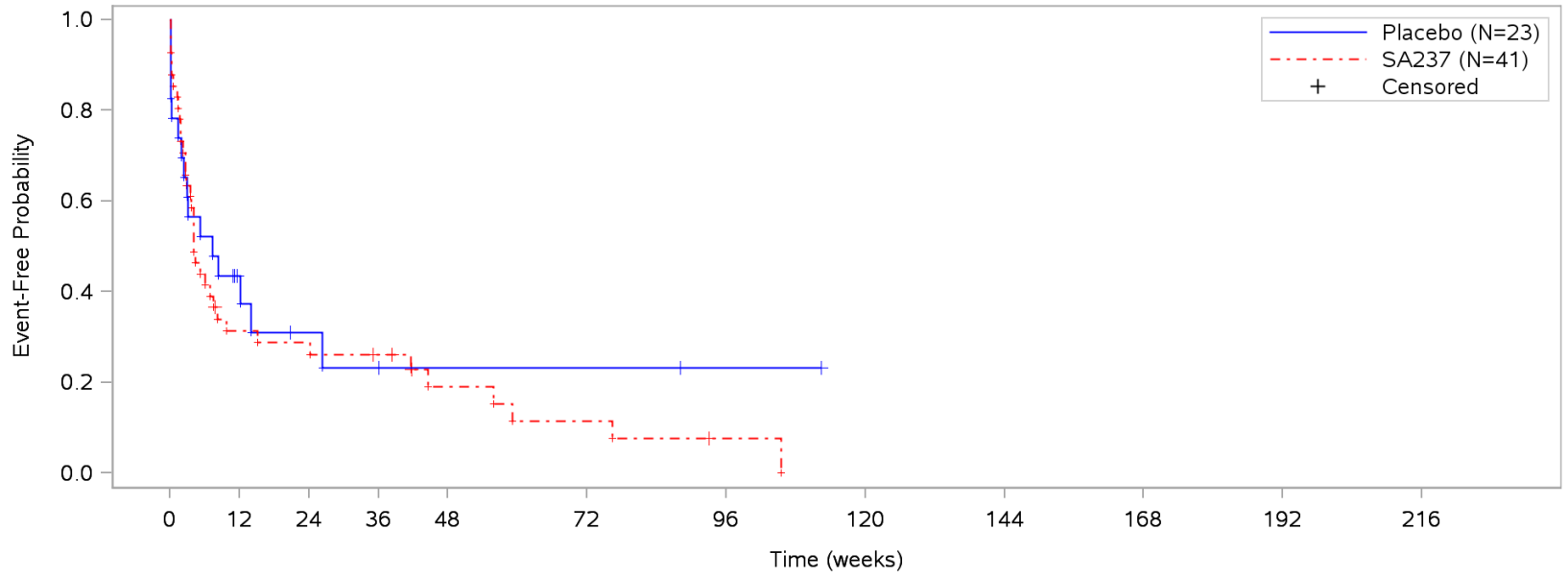
POPULATION: AQP4 Positive Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	36	87,8	5	12,2	1,9	0,3	3,6	4,1	2,7	8,1	23	100,0	16	69,6	7	30,4	1,4	0,1	3,1	7,4	2,0	26,3	0,4570	1,25	0,69	2,28		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_ANYAE_S1.xls
28MAR2020 15:40

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Any AEs
MODEL: --
STUDY: BN40900
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	23	7	4	3	2	2	1	NE	NE	NE	NE	NE
SA237	41	12	11	9	5	3	1	NE	NE	NE	NE	NE
Patients censored												
Placebo	0	3	4	5	5	5	6	NE	NE	NE	NE	NE
SA237	0	1	1	2	4	4	5	NE	NE	NE	NE	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_309_07JUN2019_SAQP_ANYAE.pdf
26MAR2020 19:38

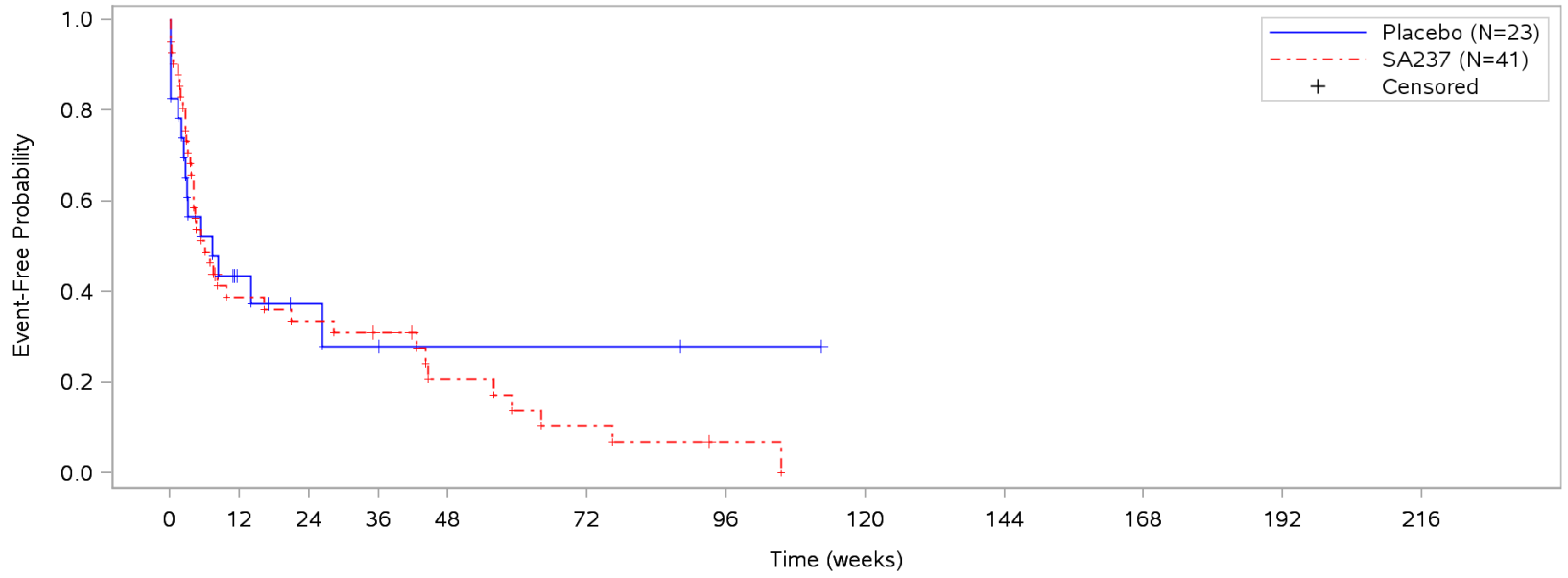
POPULATION: AQP4 Positive Population
ENDPOINT: Mild AEs
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	36	87,8	5	12,2	2,9	1,4	4,1	6,1	3,7	21,0	23	100,0	15	65,2	8	34,8	2,0	0,1	3,1	7,4	2,4	NE	0,5815	1,19	0,64	2,19	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AEMILD_S1.xls
28MAR2020 15:42

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Mild AEs
MODEL: --
STUDY: BN40900
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	23	7	4	3	2	2	1	NE	NE	NE	NE	NE
SA237	41	15	13	11	6	3	1	NE	NE	NE	NE	NE
Patients censored												
Placebo	0	3	5	6	6	6	7	NE	NE	NE	NE	NE
SA237	0	1	1	2	4	4	5	NE	NE	NE	NE	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_309_07JUN2019_SAQP_AEMILD.pdf
26MAR2020 19:39

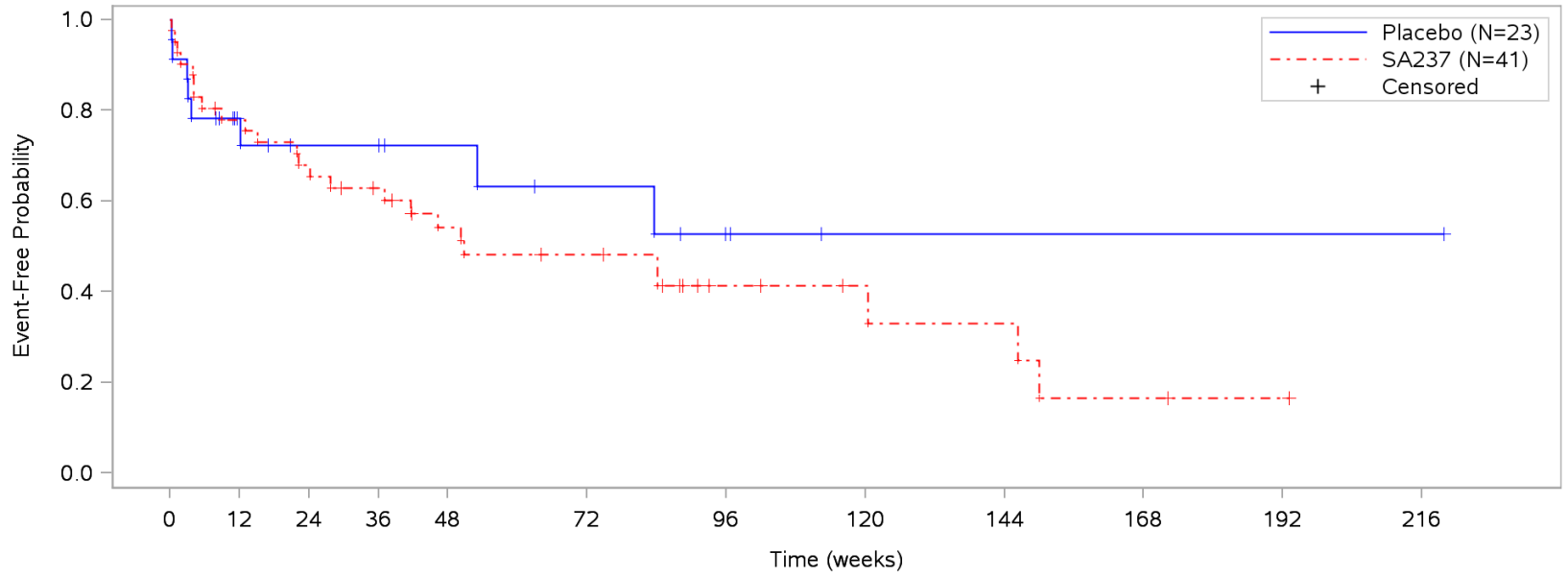
POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AEs
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	25	61,0	16	39,0	15,1	4,0	37,0	50,7	24,1	146,3	23	100,0	8	34,8	15	65,2	12,1	0,3	NE	NE	12,1	NE	0,4377	1,37	0,62	3,06		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AEMOD_S1.xls
28MAR2020 15:43

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Moderate AEs
MODEL: --
STUDY: BN40900
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	23	13	10	10	8	6	3	1	1	1	1	1
SA237	41	31	27	23	18	15	7	5	4	2	1	NE
Patients censored												
Placebo	0	5	7	8	9	10	12	14	14	14	14	14
SA237	0	1	1	3	5	6	12	14	14	14	15	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_309_07JUN2019_SAQP_AEMOD.pdf
26MAR2020 19:40

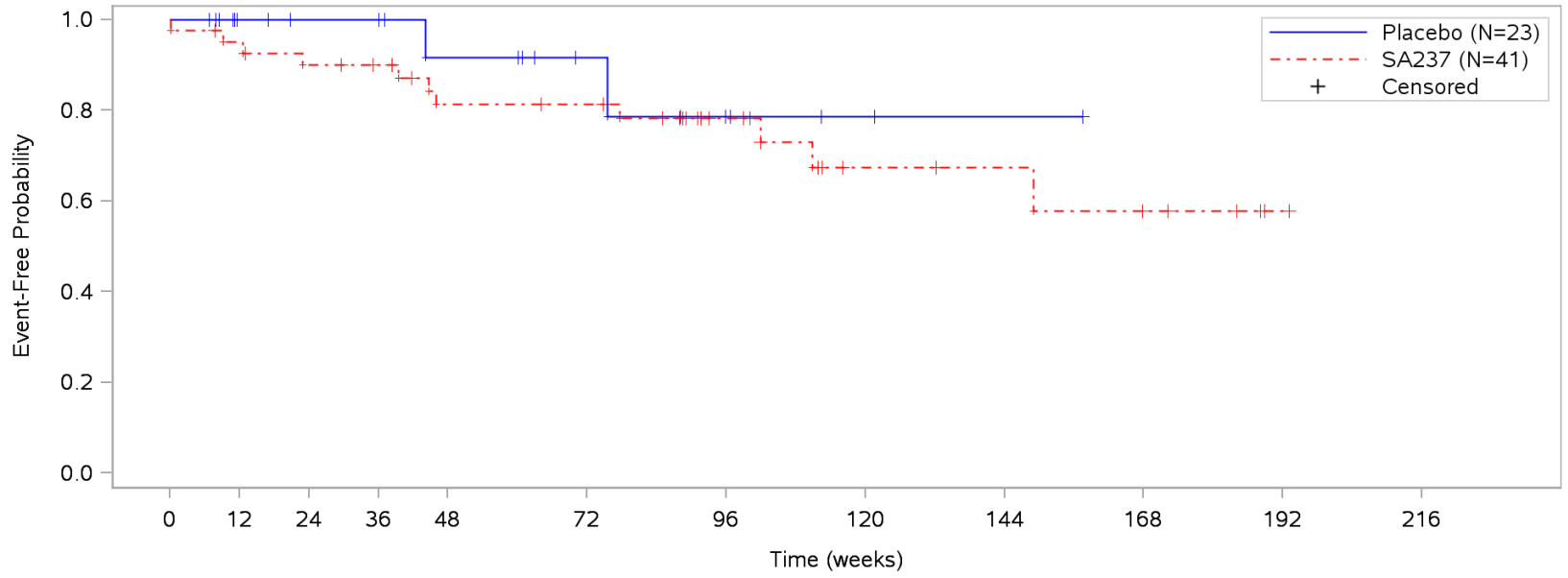
POPULATION: AQP4 Positive Population
ENDPOINT: Severe AEs
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	11	26,8	30	73,2	102,0	39,4	NE	NE	110,9	NE	23	100,0	2	8,7	21	91,3	NE	44,1	NE	NE	75,4	NE	0,4119	1,87	0,41	8,54		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AESEV_S1.xls
28MAR2020 15:44

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Severe AEs
MODEL: --
STUDY: BN40900
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	23	17	14	14	11	7	4	2	1	NE	NE	NE
SA237	41	38	35	33	28	27	17	8	7	5	1	NE
Patients censored												
Placebo	0	6	9	10	11	15	17	19	20	NE	NE	NE
SA237	0	1	2	4	6	7	16	23	24	25	29	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_309_07JUN2019_SAQP_AESEV.pdf
26MAR2020 19:41

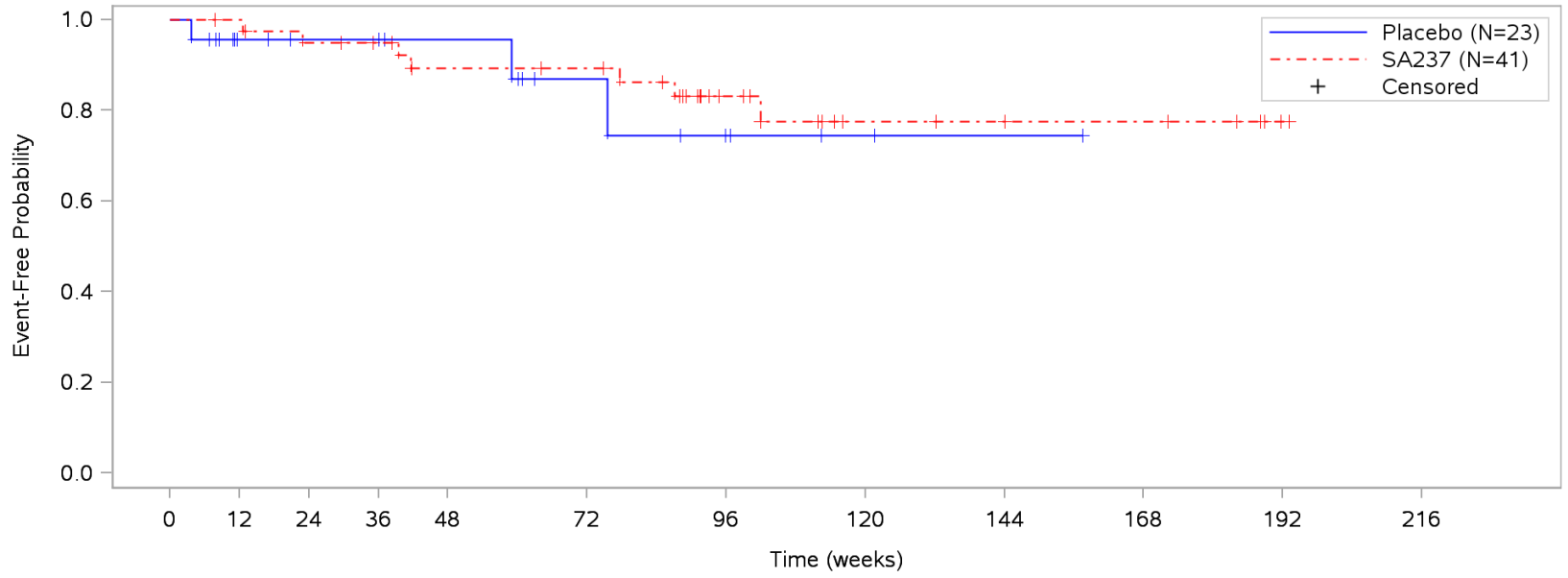
POPULATION: AQP4 Positive Population
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo					
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	7	17,1	34	82,9	NE	41,6	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	75,4	3,7	NE	NE	75,4	NE	0,6368	0,72	0,18	2,83	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AESAE_S1.xls
28MAR2020 15:47

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Any SAEs
MODEL: --
STUDY: BN40900
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	23	16	13	13	11	7	4	2	1	NE	NE	NE
SA237	41	40	37	35	31	30	17	8	7	6	1	NE
Patients censored												
Placebo	0	6	9	10	11	14	16	18	19	NE	NE	NE
SA237	0	1	2	4	6	7	18	26	28	28	33	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_309_07JUN2019_SAQP_AESAE.pdf
26MAR2020 19:44

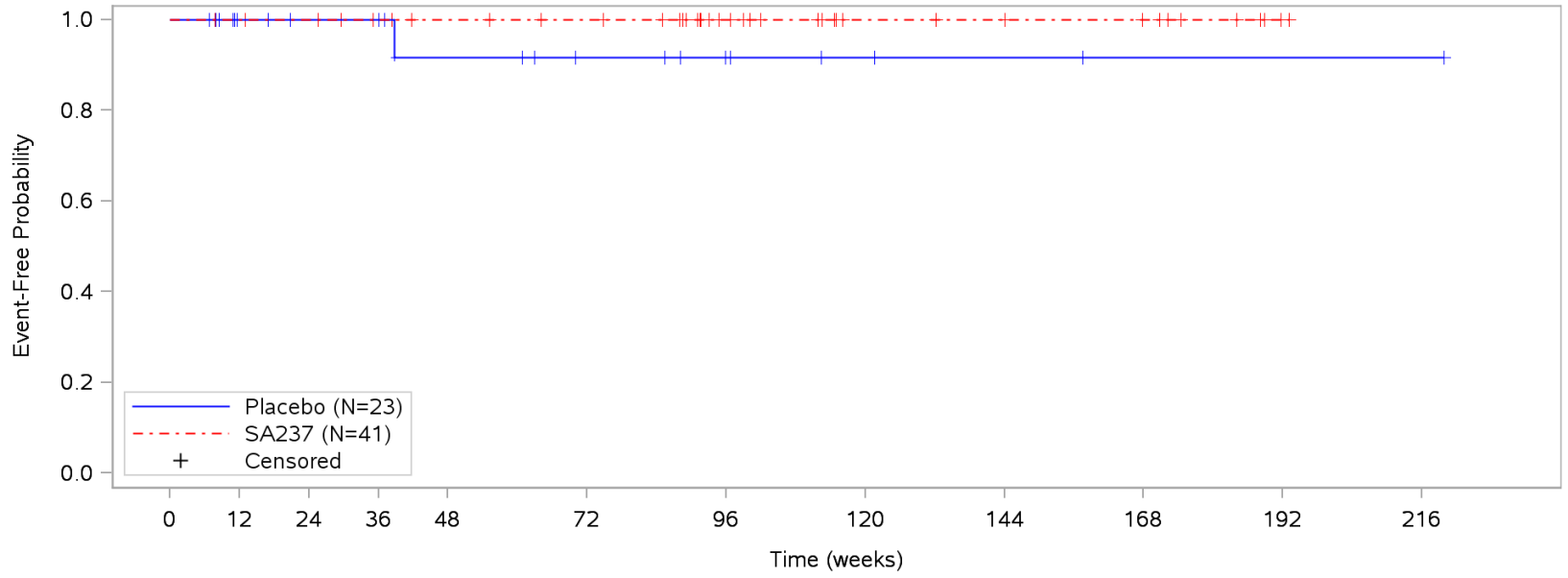
POPULATION: AQP4 Positive Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo					
		Patients		Censored		Time To Event						Patients	Patients with		Censored		Time To Event					Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	n %	n %	n %	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1 4,3	22 95,7	NE	38,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AEDISC_S1.xls
28MAR2020 18:54

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, AEs leading to treatment discontinuation
MODEL: --
STUDY: BN40900
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	23	17	14	14	11	8	5	3	2	1	1	1
SA237	41	40	39	36	34	32	21	11	10	8	1	NE
Patients censored												
Placebo	0	6	9	10	11	14	17	19	20	21	21	21
SA237	0	1	2	5	7	9	20	30	32	33	40	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_309_07JUN2019_SAQP_AEDISC.pdf
30MAR2020 9:38

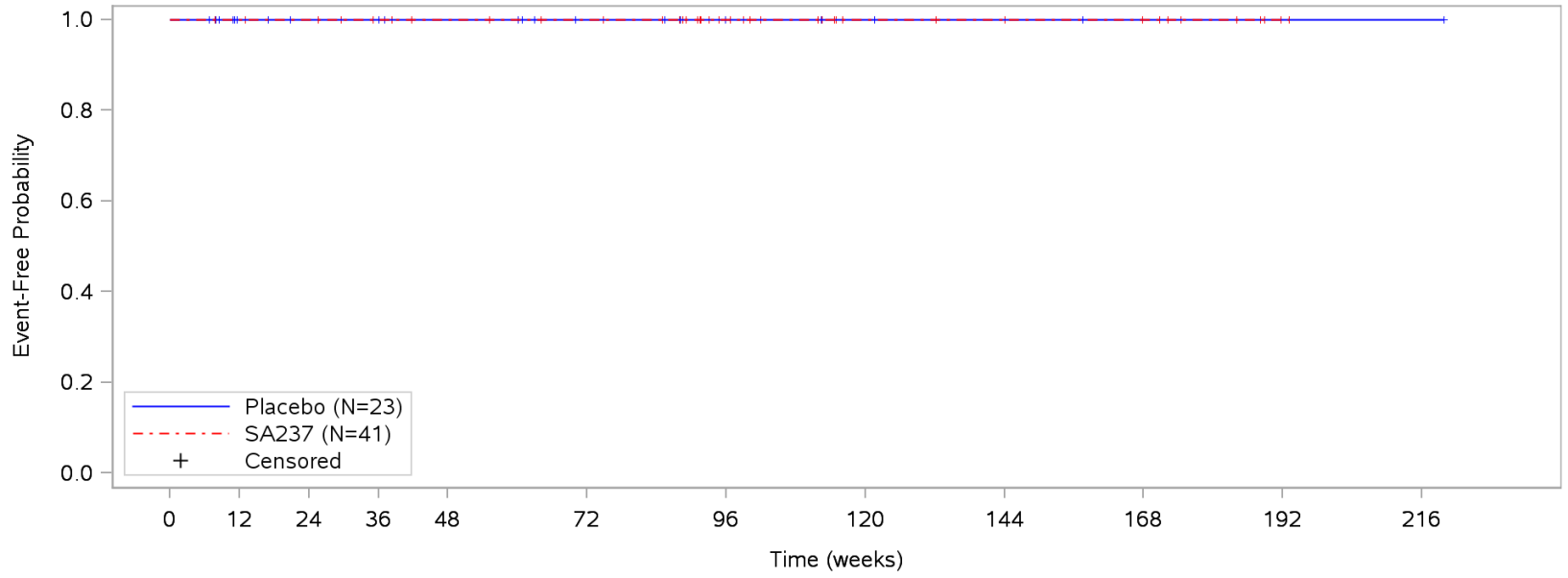
POPULATION: AQP4 Positive Population
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical studies/RO5333787/CDF70210/BN40900/data analysis/ACE 3MSU/prod/output/saf tte 309 07JUN2019 SAQP AEDTH S1.xls
28MAR2020 15:45

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, AEs Grade 5 (AEs leading to death)
MODEL: --
STUDY: BN40900
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	23	17	14	14	12	8	5	3	2	1	1	1
SA237	41	40	39	36	34	32	21	11	10	8	1	NE
Patients censored												
Placebo	0	6	9	10	11	15	18	20	21	22	22	22
SA237	0	1	2	5	7	9	20	30	32	33	40	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_309_07JUN2019_SAQP_AEDTH.pdf
26MAR2020 19:43

POPULATION: AQP4 Positive Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BN40980
Time to event analysis by SOC and PT (Safety)

			(N=41)											(N=23)										SA237 vs. Placebo					
			Patients		Patients with Event		Censored		Time To Event					Patients		Patients with Event		Censored		Time To Event					Log-rank	Hazard Ratio				Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value, test=logrank	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	-Total	n/a	41	100,0	13	31,7	28	68,3	56,9	8,1	NE	NE	87,6	NE	23	100,0	3	13,0	20	87,0	NE	8,3	NE	NE	NE	NE	0,3092	1,93	0,54	6,85	Convergence criterion (GCONV=1E-8) satisfied.	
	Anaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperfibrinogenaemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	20,9	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hypofibrinogenaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Iron deficiency anaemia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Leukopenia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Lymph node pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Lymphadenopathy	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Lymphopenia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Neutropenia	n/a	41	100,0	4	9,8	37	90,2	NE	87,6	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	8,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Neutrophilia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Polycythaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Thrombocytopenia	n/a	41	100,0	3	7,3	38	92,7	NE	120,4	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	21,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	-Total	n/a	41	100,0	3	7,3	38	92,7	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Bradycardia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Tachycardia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	-Total	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	95,4	NE	NE	95,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Deafness unilateral	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Ear pain	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	95,4	NE	NE	95,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Vertigo	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	-Total	n/a	41	100,0	9	22,0	32	78,0	110,9	41,6	NE	NE	136,2	NE	23	100,0	1	4,3	22	95,7	NE	8,2	NE	NE	NE	NE	0,2387	3,24	0,41	25,72	Convergence criterion (GCONV=1E-8) satisfied.	
	Asthenopia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Blepharospasm	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Conjunctivitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Corneal scar	n/a	41	100,0	1	2,4	40	97,6	NE	116,1	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Dry eye	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Episcleritis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Eye irritation	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Eye pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Eye pruritus	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Eyelid disorder	n/a	41	100,0	1	2,4	40	97,6	NE	136,3	NE	NE	136,3	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Keratoconus	n/a	41	100,0	1	2,4	40	97,6	NE	110,9	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Ocular hypertension	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Scotoma	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Vision blurred	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	8,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Visual impairment	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	-Total	n/a	41	100,0	16	39,0	25	61,0	33,6	11,7	72,0	NE	61,0	NE	23	100,0	11	47,8	12	52,2	15,1	8,1	83,6	83,6	15,1	NE	0,1787	0,59	0,27	1,28	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal discomfort	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal distension	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain	n/a	41	100,0	3	7,3	38	92,7	NE	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	197,6	8,1	197,6	197,6	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain lower	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain upper	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	84,1	NE	NE	84,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal tenderness	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Constipation	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	14,9	NE	NE	66,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Diarrhoea	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Dry mouth	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	12,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Flatulence	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Food poisoning	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	15,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Gastrooesophageal reflux disease	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	61,4	NE	NE	61,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Gingival pain	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	137,6	137,6	NE	NE	137,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Inguinal hernia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Irritable bowel syndrome	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Nausea	n/a	41	100,0	6	14,6	35	85,4	119,0	57,8	NE	NE	119,0	NE	23	100,0	2	8,7	21	91,3	NE	8,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Salivary gland pain	n/a	41	100,0	1	2,4	40	97,6	NE	95,4	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Varices oesophageal	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Vomiting	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	86,0	NE	NE	86,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	-Total	n/a	41	100,0	13	31,7	28	68,3	36,4	8,1	NE	NE	80,1	NE	23	100,0	3	13,0	20	87,0	NE	8,4	NE	NE	64,9	NE	0,2536	2,05	0,58	7,23	Convergence criterion (GCONV=1E-8) satisfied.	
	Chest pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Face oedema	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Fatigue	n/a	41	100,0	6	14,6	35	85,4	NE	36,4	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	8,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hypothermia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Influenza like illness	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	14,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

	Injection site reaction	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Local swelling	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Non-cardiac chest pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Oedema	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Oedema peripheral	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	64,9	NE	NE	64,9	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Hepatobiliary disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Hyperbilirubinaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Immune system disorders	-Total	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	66,0	NE	NE	66,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Allergy to metals	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	66,0	NE	NE	66,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Hypersensitivity	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Seasonal allergy	n/a	41	100,0	1	2,4	40	97,6	NE	110,9	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Infections and infestations	-Total	n/a	41	100,0	22	53,7	19	46,3	21,1	9,7	58,7	65,2	36,9	122,1	23	100,0	10	43,5	13	56,5	12,4	1,8	17,1	26,2	12,4	NE	0,1167	0,54	0,25	1,19	Convergence criterion (GCONV=1E-8) satisfied.				
	Adenoviral conjunctivitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Bronchitis	n/a	41	100,0	1	2,4	40	97,6	NE	185,4	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	29,7	NE	NE	93,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Bursitis infective	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Campylobacter gastroenteritis	n/a	41	100,0	1	2,4	40	97,6	NE	92,1	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Cellulitis	n/a	41	100,0	4	9,8	37	90,2	NE	125,9	NE	NE	125,0	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Cystitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Ear infection	n/a	41	100,0	2	4,9	39	95,1	176,0	127,4	NE	NE	176,0	NE	NE	23	100,0	1	4,3	22	95,7	NE	14,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Eye infection viral	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	21,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Folliculitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Fungal infection	n/a	41	100,0	2	4,9	39	95,1	189,4	189,4	NE	189,4	189,4	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Gastroenteritis	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Gastroenteritis viral	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	48,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Gingivitis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	88,1	NE	NE	88,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Helicobacter infection	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Herpes simplex	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	15,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Herpes zoster	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	214,6	NE	NE	214,6	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Hordeolum	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Influenza	n/a	41	100,0	3	7,3	38	92,7	NE	87,1	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	181,6	77,1	181,6	181,6	77,1	181,6	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Localised infection	n/a	41	100,0	1	2,4	40	97,6	NE	101,1	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Nasopharyngitis	n/a	41	100,0	5	12,2	36	87,8	NE	69,4	NE	NE	145,0	NE	NE	23	100,0	1	4,3	22	95,7	NE	54,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Oesophageal candidiasis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	82,4	NE	NE	82,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Oral candidiasis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	31,1	NE	NE	61,7	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Oral fungal infection	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Oral herpes	n/a	41	100,0	1	2,4	40	97,6	NE	151,9	NE	NE	151,9	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Pharyngitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Pulmonary sepsis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Pyelonephritis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Sinusitis	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Tonsillitis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	18,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Tooth abscess	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	26,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Tooth infection	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	25,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Upper respiratory tract infection	n/a	41	100,0	8	19,5	33	80,5	126,9	41,1	NE	NE	126,9	NE	NE	23	100,0	5	21,7	18	78,3	49,7	1,0	NE	NE	21,3	NE	0,1001	0,38	0,12	1,20	Convergence criterion (GCONV=1E-8) satisfied.				
	Urinary tract infection	n/a	41	100,0	8	19,5	33	80,5	126,9	41,1	NE	NE	126,9	NE	NE	23	100,0	5	21,7	18	78,3	49,7	1,0	NE	NE	21,3	NE	0,1001	0,38	0,12	1,20	Convergence criterion (GCONV=1E-8) satisfied.				
	Urosepsis	n/a	41	100,0	1	2,4	40	97,6	NE	122,1	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Vaginal infection	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	40,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Vaginitis bacterial	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Viral infection	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	57,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Vulvovaginal mycotic infection	n/a	41	100,0	1	2,4	40	97,6	NE	107,4	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Injury, poisoning and procedural complications	-Total	n/a	41	100,0	13	31,7	28	68,3	48,7	1,9	NE	NE	102,0	NE	NE	23	100,0	7	30,4	16	69,6	18,4	0,1	132,9	132,9	18,4	132,9	0,4292	0,69	0,26	1,78	Convergence criterion (GCONV=1E-8) satisfied.				
	Arthropod bite	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Contusion	n/a	41	100,0	3	7,3	38	92,7	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Excoriation	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	12,4	NE	NE	90,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Fall	n/a	41	100,0	4	9,8	37	90,2	NE	159,9	NE	NE	159,0	NE	NE	23	100,0	1	4,3	22	95,7	132,9	132,9	NE	NE	132,9	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Injection Related Reactions	n/a	41	100,0	4	9,8	37	90,2	NE	NE	NE	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	0,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Ligament sprain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Lip injury	n/a	41	100,0	1	2,4	40	97,6	NE	150,0	NE	NE	150,0	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Multiple injuries	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Muscle strain	n/a	41	100,0	1	2,4	40	97,6	NE	148,9	NE	NE	148,0	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Overdose	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	15,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Radius fracture	n/a	41	100,0	1	2,4	40	97,6	NE	102,9	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Wound	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Investigations	-Total	n/a	41	100,0	12	29,3	29	70,7	53,1	11,0	NE	NE	84,1	NE	23	100,0	6	26,1	17	73,9	52,4	2,0	NE	NE	52,4	NE	0,7985	0,88	0,33	2,36	Convergence criterion (GCONV=1E-8) satisfied.				
	Alanine aminotransferase increased	n/a	41	100,0	3	7,3	38	92,7	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Aspartate aminotransferase increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				

	Blood chloride decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	68,4	NE	NE	68,4	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood cholesterol increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood creatine phosphokinase increased	n/a	41	100,0	4	9,8	37	90,2	NE	100,1	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	52,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood creatinine decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood fibrinogen decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood glucose increased	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	15,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood parathyroid hormone increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood potassium decreased	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood pressure increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood uric acid decreased	n/a	41	100,0	1	2,4	40	97,6	NE	132,0	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Electrocardiogram T wave inversion	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Gamma-glutamyltransferase increased	n/a	41	100,0	1	2,4	40	97,6	NE	127,7	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Glucose urine present	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hepatic enzyme increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	20,9	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	International normalised ratio increased	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Low density lipoprotein increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Lymphocyte count decreased	n/a	41	100,0	2	4,9	39	95,1	NE	100,3	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Neutrophil count decreased	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Neutrophil percentage increased	n/a	41	100,0	1	2,4	40	97,6	NE	136,0	NE	NE	136,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Serum ferritin decreased	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Weight decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	White blood cell count decreased	n/a	41	100,0	3	7,3	38	92,7	NE	140,0	NE	NE	140,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	White blood cells urine positive	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	-Total	n/a	41	100,0	5	12,2	36	87,8	NE	48,1	NE	NE	150,0	NE	23	100,0	3	13,0	20	87,0	NE	2,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Decreased appetite	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Electrolyte imbalance	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypercholesterolaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperlipidaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	20,9	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypertriglyceridaemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	9,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperuricaemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypoglycaemia	n/a	41	100,0	2	4,9	39	95,1	NE	150,0	NE	NE	150,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypokalaemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	61,0	NE	NE	61,0	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypomagnesaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hyponatraemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	32,3	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	-Total	n/a	41	100,0	21	51,2	20	48,8	35,0	8,0	63,4	83,1	56,4	NE	23	100,0	4	17,4	19	82,6	126,1	38,7	181,6	126,1	85,7	181,6	0,0801	2,52	0,86	7,36		Convergence criterion (GCONV=1E-8) satisfied.	
	Arthralgia	n/a	41	100,0	6	14,6	35	85,4	NE	57,1	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Arthritis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Back pain	n/a	41	100,0	3	7,3	38	92,7	NE	167,1	NE	NE	167,1	NE	23	100,0	3	13,0	20	87,0	126,1	56,9	NE	126,1	85,7	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Bone pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Muscle spasms	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Muscular weakness	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Musculoskeletal discomfort	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Musculoskeletal pain	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	126,1	126,1	NE	NE	126,1	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Musculoskeletal stiffness	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Myalgia	n/a	41	100,0	3	7,3	38	92,7	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Neck pain	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	181,6	NE	NE	181,6	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Osteoporosis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Pain in extremity	n/a	41	100,0	6	14,6	35	85,4	NE	39,1	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	181,6	44,3	181,6	181,6	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Rotator cuff syndrome	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Spinal pain	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Synovial cyst	n/a	41	100,0	1	2,4	40	97,6	NE	111,7	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Systemic lupus erythematosus	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	38,7	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Tendonitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Trigger finger	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Acrochordon	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Squamous cell carcinoma	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	-Total	n/a	41	100,0	9	22,0	32	78,0	119,0	52,0	NE	NE	119,0	NE	23	100,0	7	30,4	16	69,6	56,9	0,3	NE	NE	31,7	NE	0,0469	0,35	0,12	1,03		Convergence criterion (GCONV=1E-8) satisfied.	
	Balance disorder	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	56,9	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Cervical radiculopathy	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	75,4	NE	NE	75,4	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Dizziness	n/a	41	100,0	2	4,9	39	95,1	NE	119,0	NE	NE	159,6	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Dysaesthesia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	56,9	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Headache	n/a	41	100,0	4	9,8	37	90,2	NE	76,3	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	0,3	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypoaesthesia	n/a	41	100,0	2	4,9	39	95,1	NE	182,0	NE	NE	182,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Migraine	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Migraine with aura	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Myoclonus	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	31,7	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

	Neuromyelitis optica	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,7	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Restless legs syndrome	n/a	41	100,0	1	2,4	40	97,6	NE	149,7	NE	NE	149,7	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Somnolence	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
Psychiatric disorders	-Total	n/a	41	100,0	8	19,5	33	80,5	146,0	30,1	NE	NE	146,0	NE	23	100,0	2	8,7	21	91,3	NE	12,1	NE	NE	62,7	NE	0,5568	1,59	0,33	7,54		Convergence criterion (GCONV=1E-8) satisfied.
	Anxiety	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	62,7	NE	NE	62,7	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Depressed mood	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Depression	n/a	41	100,0	4	9,8	37	90,2	NE	154,7	NE	NE	154,7	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Insomnia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	12,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Mental status changes	n/a	41	100,0	2	4,9	39	95,1	NE	146,0	NE	NE	146,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
Renal and urinary disorders	-Total	n/a	41	100,0	6	14,6	35	85,4	NE	41,0	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	3,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Cystitis noninfective	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Dysuria	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	3,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Haematuria	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	7,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Leukocyturia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Nephrolithiasis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Nocturia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Urinary retention	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
Reproductive system and breast disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	16,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Benign prostatic hyperplasia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Vulvovaginal discomfort	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	16,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
Respiratory, thoracic and mediastinal disorders	-Total	n/a	41	100,0	11	26,8	30	73,2	98,6	10,0	NE	NE	183,6	NE	23	100,0	3	13,0	20	87,0	87,1	10,0	NE	NE	87,1	NE	0,5341	1,50	0,41	5,48		Convergence criterion (GCONV=1E-8) satisfied.
	Apnoea	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Bronchial wall thickening	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Bronchospasm	n/a	41	100,0	1	2,4	40	97,6	NE	98,6	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Cough	n/a	41	100,0	2	4,9	39	95,1	NE	183,6	NE	NE	183,6	NE	23	100,0	1	4,3	22	95,7	NE	87,1	NE	NE	87,1	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Dyspnoea	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Laryngeal inflammation	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Oropharyngeal pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	10,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Productive cough	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Pulmonary oedema	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Respiratory tract congestion	n/a	41	100,0	2	4,9	39	95,1	187,9	187,9	NE	NE	187,9	NE	23	100,0	1	4,3	22	95,7	NE	56,6	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Rhinitis allergic	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Wheezing	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	88,1	NE	NE	88,1	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
Skin and subcutaneous tissue disorders	-Total	n/a	41	100,0	14	34,1	27	65,9	39,1	6,1	168,6	168,6	81,6	NE	23	100,0	2	8,7	21	91,3	NE	4,1	NE	NE	NE	NE	0,1070	3,18	0,72	14,09		Convergence criterion (GCONV=1E-8) satisfied.
	Alopecia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Dermatitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Dermatitis atopic	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Dermatitis contact	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Eczema	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	4,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Pain of skin	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	36,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Pruritus	n/a	41	100,0	4	9,8	37	90,2	NE	55,7	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Rash	n/a	41	100,0	6	14,6	35	85,4	168,6	81,6	NE	NE	132,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Rash generalised	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Skin disorder	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Skin irritation	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Skin lesion	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Skin mass	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
Vascular disorders	-Total	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Hypertension	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.
	Hypotension	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/saf_tsp.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tsp_309_07JUN2019_SAQP_ANYAE_S1.xls
25NOV2020 10:01

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AEs
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis by SOC and PT (Safety)

			(N=41)												(N=23)										SA237 vs. Placebo					
			Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	pvalue, test=logrank		95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	-Total	n/a	41	100,0	9	22,0	32	78,0	NE	31,3	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	8,3	NE	NE	NE	NE	0,7675	1,22	0,33	4,55	Convergence criterion (GCONV=1E-8) satisfied.	
	Anaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperfibrinogenaemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	20,9	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hypofibrinogenaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Iron deficiency anaemia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Leukopenia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Lymph node pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Lymphopenia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Neutropenia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	8,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Polycythaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Thrombocytopenia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	21,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	-Total	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Bradycardia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Tachycardia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Deafness unilateral	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	-Total	n/a	41	100,0	7	17,1	34	82,9	136,3	42,6	NE	NE	136,3	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Asthenopia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Blepharospasm	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Conjunctivitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Dry eye	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Eye irritation	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Eye pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Eye pruritus	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Eyelid disorder	n/a	41	100,0	1	2,4	40	97,6	NE	136,3	NE	NE	136,3	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Ocular hypertension	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Scotoma	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	-Total	n/a	41	100,0	12	29,3	29	70,7	61,0	20,9	NE	NE	100,3	NE	23	100,0	9	39,1	14	60,9	61,4	0,1	86,0	86,0	61,4	137,0	0,1557	0,54	0,22	1,28	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal discomfort	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal distension	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	197,6	NE	NE	197,6	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain upper	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	84,1	NE	NE	84,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal tenderness	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Constipation	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	14,9	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Diarrhoea	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Food poisoning	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	15,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Gastrooesophageal reflux disease	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	61,4	NE	NE	61,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Gingival pain	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	137,0	137,0	NE	NE	137,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Irritable bowel syndrome	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Nausea	n/a	41	100,0	4	9,8	37	90,2	NE	100,3	NE	NE	119,0	NE	23	100,0	2	8,7	21	91,3	NE	0,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Salivary gland pain	n/a	41	100,0	1	2,4	40	97,6	NE	95,4	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Varices oesophageal	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Vomiting	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	86,0	NE	NE	86,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	-Total	n/a	41	100,0	9	22,0	32	78,0	NE	12,1	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	17,4	NE	NE	NE	NE	0,1292	4,34	0,55	34,36	Convergence criterion (GCONV=1E-8) satisfied.	
	Face oedema	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Fatigue	n/a	41	100,0	4	9,8	37	90,2	NE	89,1	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Influenza like illness	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	17,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Injection site reaction	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Local swelling	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Oedema	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

	Oedema peripheral	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Hepatobiliary disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hyperbilirubinaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Immune system disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	66,6	NE	NE	66,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Allergy to metals	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	66,6	NE	NE	66,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypersensitivity	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Infections and infestations	-Total	n/a	41	100,0	19	46,3	22	53,7	23,6	16,3	62,3	105,4	59,1	NE	23	100,0	9	39,1	14	60,9	14,0	1,4	26,3	26,3	14,0	NE	0,1006	0,51	0,22	1,16	Convergence criterion (GCONV=1E-8) satisfied.
	Bronchitis	n/a	41	100,0	1	2,4	40	97,6	NE	105,4	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	93,6	NE	NE	93,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Campylobacter gastroenteritis	n/a	41	100,0	1	2,4	40	97,6	NE	92,1	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Cellulitis	n/a	41	100,0	3	7,3	38	92,7	NE	125,9	NE	NE	125,9	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Ear infection	n/a	41	100,0	2	4,9	39	95,1	176,9	127,4	NE	NE	176,9	NE	23	100,0	1	4,3	22	95,7	NE	14,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Eye infection viral	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	21,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Folliculitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Fungal infection	n/a	41	100,0	2	4,9	39	95,1	189,4	189,4	NE	189,4	189,4	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Gastroenteritis	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Gastroenteritis viral	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	61,6	NE	NE	61,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Gingivitis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	88,1	NE	NE	88,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Helicobacter infection	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Herpes simplex	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	15,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Herpes zoster	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	214,6	NE	NE	214,6	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hordeolum	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Influenza	n/a	41	100,0	3	7,3	38	92,7	NE	87,1	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	181,6	77,1	181,6	181,6	77,1	181,6	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Localised infection	n/a	41	100,0	1	2,4	40	97,6	NE	101,1	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Nasopharyngitis	n/a	41	100,0	3	7,3	38	92,7	NE	145,0	NE	NE	145,0	NE	23	100,0	1	4,3	22	95,7	NE	54,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oesophageal candidiasis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	82,4	NE	NE	82,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oral candidiasis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	61,7	NE	NE	61,7	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oral fungal infection	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oral herpes	n/a	41	100,0	1	2,4	40	97,6	NE	151,9	NE	NE	151,9	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pharyngitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Sinusitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Tonsillitis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	18,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Tooth abscess	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	26,9	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Upper respiratory tract infection	n/a	41	100,0	5	12,2	36	87,8	NE	71,9	NE	NE	NE	NE	23	100,0	5	21,7	18	78,3	26,3	1,4	NE	NE	26,3	NE	0,0350	0,27	0,08	0,98	Convergence criterion (GCONV=1E-8) satisfied.
	Urinary tract infection	n/a	41	100,0	7	17,1	34	82,9	166,4	41,1	NE	NE	141,1	NE	23	100,0	4	17,4	19	82,6	49,7	12,4	NE	NE	21,3	NE	0,1760	0,41	0,11	1,55	Convergence criterion (GCONV=1E-8) satisfied.
	Vaginal infection	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Vaginitis bacterial	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Viral infection	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	57,9	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Vulvovaginal mycotic infection	n/a	41	100,0	1	2,4	40	97,6	NE	107,4	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Injury, poisoning and procedural complications	-Total	n/a	41	100,0	8	19,5	33	80,5	148,9	23,7	NE	NE	148,9	NE	23	100,0	6	26,1	17	73,9	90,3	0,1	132,9	132,9	90,3	132,9	0,1546	0,45	0,15	1,39	Convergence criterion (GCONV=1E-8) satisfied.
	Contusion	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Excoriation	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	12,4	NE	NE	90,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Fall	n/a	41	100,0	3	7,3	38	92,7	NE	150,0	NE	NE	150,0	NE	23	100,0	1	4,3	22	95,7	132,9	132,9	NE	NE	132,9	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Injection Related Reactions	n/a	41	100,0	3	7,3	38	92,7	NE	NE	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	0,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Ligament sprain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Lip injury	n/a	41	100,0	1	2,4	40	97,6	NE	150,0	NE	NE	150,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Muscle strain	n/a	41	100,0	1	2,4	40	97,6	NE	148,9	NE	NE	148,9	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Wound	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Investigations	-Total	n/a	41	100,0	10	24,4	31	75,6	100,1	11,0	NE	NE	NE	NE	23	100,0	5	21,7	18	78,3	68,4	2,0	NE	NE	52,4	NE	0,8333	0,89	0,30	2,63	Convergence criterion (GCONV=1E-8) satisfied.
	Alanine aminotransferase increased	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Aspartate aminotransferase increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Blood chloride decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	68,4	NE	NE	68,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Blood cholesterol increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Blood creatine phosphokinase increased	n/a	41	100,0	4	9,8	37	90,2	NE	100,1	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	52,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Blood creatinine decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Blood fibrinogen decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Blood glucose increased	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	15,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.

	Blood potassium decreased	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood uric acid decreased	n/a	41	100,0	1	2,4	40	97,6	NE	132,0	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Electrocardiogram T wave inversion	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Gamma-glutamyltransferase increased	n/a	41	100,0	1	2,4	40	97,6	NE	127,7	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Glucose urine present	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hepatic enzyme increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	20,9	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Low density lipoprotein increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Lymphocyte count decreased	n/a	41	100,0	2	4,9	39	95,1	NE	100,3	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Neutrophil count decreased	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Neutrophil percentage increased	n/a	41	100,0	1	2,4	40	97,6	NE	136,0	NE	NE	136,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Serum ferritin decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Weight decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	White blood cell count decreased	n/a	41	100,0	3	7,3	38	92,7	NE	140,0	NE	NE	140,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	White blood cells urine positive	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	-Total	n/a	41	100,0	4	9,8	37	90,2	NE	48,1	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	2,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Decreased appetite	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Electrolyte imbalance	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypercholesterolaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperlipidaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	20,9	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypertriglyceridaemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	9,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperuricaemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	2,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypoglycaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypokalaemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	61,0	NE	NE	61,0	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypomagnesaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hyponatraemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	32,3	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	-Total	n/a	41	100,0	13	31,7	28	68,3	63,4	16,1	NE	NE	83,1	NE	23	100,0	2	8,7	21	91,3	181,6	85,7	181,6	181,6	85,7	181,6	0,1495	2,86	0,64	12,71		Convergence criterion (GCONV=1E-8) satisfied.	
	Arthralgia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Arthritis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Back pain	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	85,7	NE	NE	85,7	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Musculoskeletal stiffness	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Myalgia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Neck pain	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	181,6	NE	NE	181,6	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Pain in extremity	n/a	41	100,0	6	14,6	35	85,4	NE	39,1	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	181,6	NE	NE	181,6	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Rotator cuff syndrome	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Synovial cyst	n/a	41	100,0	1	2,4	40	97,6	NE	111,7	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Tendonitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Acrochordon	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	-Total	n/a	41	100,0	6	14,6	35	85,4	149,7	76,3	NE	NE	149,7	NE	23	100,0	4	17,4	19	82,6	64,7	1,7	NE	NE	64,7	NE	0,2933	0,50	0,13	1,86		Convergence criterion (GCONV=1E-8) satisfied.	
	Dizziness	n/a	41	100,0	2	4,9	39	95,1	NE	119,0	NE	NE	159,6	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Headache	n/a	41	100,0	3	7,3	38	92,7	NE	NE	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	1,7	NE	NE	64,7	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypoaesthesia	n/a	41	100,0	1	2,4	40	97,6	NE	182,0	NE	NE	182,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Myoclonus	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	31,7	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Restless legs syndrome	n/a	41	100,0	1	2,4	40	97,6	NE	149,7	NE	NE	149,7	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Somnolence	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	-Total	n/a	41	100,0	3	7,3	38	92,7	NE	154,7	NE	NE	154,7	NE	23	100,0	1	4,3	22	95,7	NE	62,7	NE	NE	62,7	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Anxiety	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	62,7	NE	NE	62,7	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Depressed mood	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Depression	n/a	41	100,0	2	4,9	39	95,1	NE	154,7	NE	NE	154,7	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	-Total	n/a	41	100,0	5	12,2	36	87,8	NE	49,9	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	7,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Cystitis noninfective	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Dysuria	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	17,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Haematuria	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	7,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Nephrolithiasis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Nocturia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

	Urinary retention	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Reproductive system and breast disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	16,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Benign prostatic hyperplasia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Vulvovaginal discomfort	n/a	43	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	16,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Respiratory, thoracic and mediastinal disorders	-Total	n/a	43	100,0	8	19,5	33	80,5	183,6	43,1	NE	NE	183,6	NE	23	100,0	2	8,7	21	91,3	NE	10,0	NE	NE	87,1	NE	0,6403	1,45	0,38	7,02	Convergence criterion (GCONV=1E-8) satisfied.
	Bronchial wall thickening	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Bronchospasm	n/a	43	100,0	1	2,4	40	97,6	NE	90,6	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Cough	n/a	43	100,0	2	4,9	39	95,1	NE	183,6	NE	NE	183,6	NE	23	100,0	1	4,3	22	95,7	NE	87,1	NE	NE	87,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oropharyngeal pain	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	10,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Productive cough	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Respiratory tract congestion	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rhinitis allergic	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Wheezing	n/a	43	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	88,1	NE	NE	88,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Skin and subcutaneous tissue disorders	-Total	n/a	43	100,0	11	26,8	30	73,2	132,0	6,1	168,6	168,6	132,0	NE	23	100,0	2	8,7	21	91,3	NE	4,1	NE	NE	NE	NE	0,2215	2,49	0,55	11,35	Convergence criterion (GCONV=1E-8) satisfied.
	Alopecia	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dermatitis	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dermatitis atopic	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dermatitis contact	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Eczema	n/a	43	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	4,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pain of skin	n/a	43	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	36,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pruritus	n/a	43	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rash	n/a	43	100,0	8	14,6	35	85,4	168,6	81,0	NE	NE	132,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rash generalised	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Skin disorder	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Skin lesion	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Vascular disorders	-Total	n/a	43	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypertension	n/a	43	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypotension	n/a	43	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/saf_tsp.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tsp_309_07JUN2019_SAQP_AEMILD_S1.xls
25NOV2020 10:05

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AEs
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis by SOC and PT (Safety)

			(N=41)												(N=23)												SA237 vs. Placebo						
			Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status		p-value (likelihood ratio)
Blood and lymphatic system disorders	-Total	n/a	41	100,0	7	17,1	34	82,9	120,4	55,4	NE	NE	120,4	NE	23	100,0	1	4,3	22	95,7	NE	100,4	NE	NE	100,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Iron deficiency anaemia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Lymphadenopathy	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Neutropenia	n/a	41	100,0	3	7,3	38	92,7	NE	87,8	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	100,4	NE	NE	100,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Neutrophilia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Thrombocytopenia	n/a	41	100,0	3	7,3	38	92,7	NE	120,4	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
Ear and labyrinth disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	95,4	NE	NE	95,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Ear pain	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	95,4	NE	NE	95,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Vertigo	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
Eye disorders	-Total	n/a	41	100,0	3	7,3	38	92,7	NE	116,1	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	0,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Corneal scar	n/a	41	100,0	1	2,4	40	97,6	NE	116,1	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Episcleritis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Vision blurred	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	0,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Visual impairment	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
Gastrointestinal disorders	-Total	n/a	41	100,0	6	14,6	35	85,4	NE	55,8	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	8,1	NE	NE	83,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Abdominal pain	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	8,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Abdominal pain lower	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Diarrhoea	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Dry mouth	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	12,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Flatulence	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Food poisoning	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Gastrooesophageal reflux disease	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	83,6	NE	NE	83,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Inguinal hernia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Nausea	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Vomiting	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
General disorders and administration site conditions	-Total	n/a	41	100,0	4	9,8	37	90,2	NE	43,6	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	0,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Fatigue	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	0,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Influenza like illness	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	14,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Non-cardiac chest pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
Immune system disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Hypersensitivity	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Seasonal allergy	n/a	41	100,0	1	2,4	40	97,6	NE	110,0	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
Infections and infestations	-Total	n/a	41	100,0	11	26,8	30	73,2	121,3	36,9	146,3	146,3	121,3	NE	23	100,0	4	17,4	19	82,6	59,0	1,0	NE	NE	53,0	NE	0,9104	0,94	0,38	2,36	Convergence criterion (GCONV=1E-8) satisfied.		
	Adenoviral conjunctivitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Bronchitis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	29,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Bursitis infective	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Cystitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Gastroenteritis viral	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	48,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Nasopharyngitis	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Oral candidiasis	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	31,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Sinusitis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Tooth infection	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	35,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Upper respiratory tract infection	n/a	41	100,0	2	4,9	39	95,1	NE	121,3	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	59,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Urinary tract infection	n/a	41	100,0	4	9,8	37	90,2	146,3	126,9	NE	NE	146,3	NE	23	100,0	2	8,7	21	91,3	NE	1,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Urosepsis	n/a	41	100,0	1	2,4	40	97,6	NE	122,1	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Vaginal infection	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	40,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
Injury, poisoning and procedural complications	-Total	n/a	41	100,0	3	7,3	38	92,7	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	18,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Arthropod bite	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		
	Contusion	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.		

	Fall	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Overdose	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	18,4	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Investigations	-Total	n/a	41	100,0	4	9,8	37	90,2	NE	72,3	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Alanine aminotransferase increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood parathyroid hormone increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Blood pressure increased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	International normalised ratio increased	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Serum ferritin decreased	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Metabolism and nutrition disorders	-Total	n/a	41	100,0	2	4,9	39	95,1	NE	150,0	NE	NE	150,0	NE	23	100,0	1	4,3	22	95,7	NE	85,3	NE	NE	85,3	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Electrolyte imbalance	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypoglycaemia	n/a	41	100,0	2	4,9	39	95,1	NE	150,0	NE	NE	150,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hyponatraemia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	85,3	NE	NE	85,3	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	-Total	n/a	41	100,0	12	29,3	29	70,7	89,1	24,1	167,1	NE	97,9	NE	23	100,0	2	8,7	21	91,3	126,1	38,7	NE	126,1	126,1	NE	0,2900	2,21	0,49	9,96		Convergence criterion (GCONV=1E-8) satisfied.	
	Arthralgia	n/a	41	100,0	3	7,3	38	92,7	NE	97,9	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Back pain	n/a	41	100,0	3	7,3	38	92,7	NE	167,1	NE	NE	167,1	NE	23	100,0	2	8,7	21	91,3	126,1	56,9	NE	126,1	126,1	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Bone pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Muscle spasms	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Muscular weakness	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Musculoskeletal discomfort	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Musculoskeletal pain	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	126,1	126,1	NE	NE	126,1	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Musculoskeletal stiffness	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Myalgia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Osteoporosis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Pain in extremity	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	44,3	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Spinal pain	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Systemic lupus erythematosus	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	38,7	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Trigger finger	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Squamous cell carcinoma	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	-Total	n/a	41	100,0	4	9,8	37	90,2	NE	63,4	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	0,3	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Balance disorder	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	56,9	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Dysaesthesia	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	56,9	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Headache	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	0,3	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypoaesthesia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Migraine	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Migraine with aura	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Neuromyelitis optica	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,7	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	-Total	n/a	41	100,0	5	12,2	36	87,8	NE	41,4	NE	NE	146,0	NE	23	100,0	1	4,3	22	95,7	NE	12,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Anxiety	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Depression	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Insomnia	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	12,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Mental status changes	n/a	41	100,0	1	2,4	40	97,6	NE	146,0	NE	NE	146,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Dysuria	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Leukocyturia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	-Total	n/a	41	100,0	5	12,2	36	87,8	187,9	187,9	NE	NE	187,9	NE	23	100,0	1	4,3	22	95,7	NE	56,6	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Cough	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Dyspnoea	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Laryngeal inflammation	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Respiratory tract congestion	n/a	41	100,0	1	2,4	40	97,6	NE	187,9	NE	NE	187,9	NE	23	100,0	1	4,3	22	95,7	NE	56,6	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Skin and subcutaneous tissue disorders	-Total	n/a	41	100,0	4	9,8	37	90,2	NE	39,1	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Pruritus	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Rash	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Skin irritation	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Skin mass	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tsp_309_07JUN2019_SAQP_AEMOD_S1.xls
29MAR2020 0:18

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AEs
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis by SOC and PT (Safety)

			SA237												Placebo										SA237 vs. Placebo					
			Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event					Log-rank	Hazard Ratio				Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	pvalue, test=logrank	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	pvalue (likelihood ratio)
Cardiac disorders	-Total	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Bradycardia	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	-Total	n/a	41	100.0	2	4.9	39	95.1	NE	110.9	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Eye pain	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Keratoconus	n/a	41	100.0	1	2.4	40	97.6	NE	110.9	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	-Total	n/a	41	100.0	NE	NE	41	100.0	NE	NE	NE	NE	NE	NE	23	100.0	1	4.3	22	95.7	NE	66.0	NE	NE	66.0	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Constipation	n/a	41	100.0	NE	NE	41	100.0	NE	NE	NE	NE	NE	NE	23	100.0	1	4.3	22	95.7	NE	66.0	NE	NE	66.0	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	-Total	n/a	41	100.0	3	7.3	38	92.7	NE	NE	NE	NE	NE	NE	23	100.0	1	4.3	22	95.7	NE	64.9	NE	NE	64.9	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Chest pain	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Fatigue	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperthermia	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Pain	n/a	41	100.0	NE	NE	41	100.0	NE	NE	NE	NE	NE	NE	23	100.0	1	4.3	22	95.7	NE	64.3	NE	NE	64.3	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	-Total	n/a	41	100.0	4	9.8	37	90.2	NE	149.0	NE	NE	149.0	NE	23	100.0	1	4.3	22	95.7	NE	44.1	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Cellulitis	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Pulmonary sepsis	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Pyelonephritis	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Tooth abscess	n/a	41	100.0	NE	NE	41	100.0	NE	NE	NE	NE	NE	NE	23	100.0	1	4.3	22	95.7	NE	44.1	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Urinary tract infection	n/a	41	100.0	1	2.4	40	97.6	NE	149.0	NE	NE	149.0	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	-Total	n/a	41	100.0	3	7.3	38	92.7	NE	102.0	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Injection Related Reactions	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Multiple injuries	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Radius fracture	n/a	41	100.0	1	2.4	40	97.6	NE	102.0	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Musculoskeletal and connective tissue disorders	-Total	n/a	41	100.0	2	4.9	39	95.1	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Arthralgia	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Back pain	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Spinal pain	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	-Total	n/a	41	100.0	NE	NE	41	100.0	NE	NE	NE	NE	NE	NE	23	100.0	1	4.3	22	95.7	NE	75.4	NE	NE	75.4	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Cervical radiculopathy	n/a	41	100.0	NE	NE	41	100.0	NE	NE	NE	NE	NE	NE	23	100.0	1	4.3	22	95.7	NE	75.4	NE	NE	75.4	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	-Total	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Mental status changes	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	-Total	n/a	41	100.0	2	4.9	39	95.1	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Apnoea	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Pulmonary oedema	n/a	41	100.0	1	2.4	40	97.6	NE	NE	NE	NE	NE	NE	23	100.0	NE	NE	23	100.0	NE	NE	NE	NE	NE	NE		-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/saf_tsp.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MDD/prod/output/saf_tsp_309_07JUN2019_SAQP_ASSEV_01.xls
25NOV2020 10:11

POPULATION: AQP4 Positive Population
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis by SOC and PT (Safety)

			SA237												Placebo												SA237 vs. Placebo						
			Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
Cardiac disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Bradycardia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Visual impairment	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	-Total	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hypothermia	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	-Total	n/a	41	100,0	4	9,8	37	90,2	NE	87,1	NE	NE	122,1	NE	23	100,0	1	4,3	22	95,7	NE	59,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Influenza	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Pulmonary sepsis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Pyelonephritis	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Upper respiratory tract infection	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	59,0	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Urosepsis	n/a	41	100,0	1	2,4	40	97,6	NE	122,1	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	-Total	n/a	41	100,0	2	4,9	39	95,1	NE	102,0	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Multiple injuries	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Radius fracture	n/a	41	100,0	1	2,4	40	97,6	NE	102,0	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	-Total	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	2	8,7	21	91,3	NE	3,7	NE	NE	75,4	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Cervical radiculopathy	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	75,4	NE	NE	75,4	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Neuromyelitis optica	n/a	41	100,0	NE	NE	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1	4,3	22	95,7	NE	3,7	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	-Total	n/a	41	100,0	2	4,9	39	95,1	NE	146,0	NE	NE	146,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Mental status changes	n/a	41	100,0	2	4,9	39	95,1	NE	146,0	NE	NE	146,0	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Respiratory, thoracic and mediastinal disorders	-Total	n/a	41	100,0	2	4,9	39	95,1	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Apnoea	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Pulmonary oedema	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	NE	NE	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tsp_309_07JUN2019_SAQP_AESAE_S1.xls
29MAR2020 0:24

POPULATION: AQP4 Positive Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis by SOC and PT (Safety)

			SA237										Placebo										SA237 vs. Placebo						
			Patients		Censored		Time To Event						Patients		Patients with		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
SOC	PT	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Musculoskeletal and connective tissue disorders	-Total	n/a	41	100.0	41	100.0	NE	.	.	NE	NE	NE	22	100.0	1	4.3	22	95.7	NE	38.7	NE	NE	NE	NE	.	.	.	.	Convergence criterion (GCONV=1E-8) satisfied.	
	Systemic lupus erythematosus	n/a	41	100.0	41	100.0	NE	.	.	NE	NE	NE	22	100.0	1	4.3	22	95.7	NE	38.7	NE	NE	NE	NE	.	.	.	.	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_BMSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_BMSU/prod/output/saf_tsp_309_07JUN2019_SAQP_AEDISC_S1.xls
29MAR2020 12:28

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AESIALT_S1.xls
28MAR2020 15:48

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MIAESIAL_S1.xls
28MAR2020 15:54

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MOAESIAL_S1.xls
28MAR2020 16:00

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SEAESIAL_S1.xls
28MAR2020 16:07

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo					
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SAESIALT_S1.xls
28MAR2020 16:13

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AESISUS_S1.xls
28MAR2020 15:49

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MIAESISU_S1.xls
28MAR2020 15:55

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MOAESISU_S1.xls
28MAR2020 16:02

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo					
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SEAESISU_S1.xls
28MAR2020 16:08

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo					
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SAESISUS_S1.xls
28MAR2020 16:14

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo									SA237 vs. Placebo						
		Patients		Patients with		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	6	14,6	35	85,4	149,0	77,6	NE	NE	149,0	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AESIINF_S1.xls
28MAR2020 15:50

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo										SA237 vs. Placebo						
		Patients		Patients with		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	1	2,4	40	97,6	NE	141,1	NE	NE	141,1	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MIAESIIN_S1.xls
28MAR2020 15:56

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo									SA237 vs. Placebo						
		Patients		Patients with		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	3	7,3	38	92,7	NE	122,1	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MOAESIIN_S1.xls
28MAR2020 16:03

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo									SA237 vs. Placebo						
		Patients		Patients with		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	4	9,8	37	90,2	NE	149,0	NE	NE	149,0	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SEAESIIN_S1.xls
28MAR2020 16:09

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo									SA237 vs. Placebo					
		Patients		Patients with		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	3	7,3	38	92,7	NE	122,1	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SAESIINF_S1.xls
28MAR2020 16:15

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	2	4,9	39	95,1	NE	151,9	NE	NE	151,9	NE	23	100,0	4	17,4	19	82,6	82,4	15,6	NE	NE	61,7	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AESIOPP_S1.xls
28MAR2020 15:52

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	2	4,9	39	95,1	NE	151,9	NE	NE	151,9	NE	23	100,0	3	13,0	20	87,0	82,4	15,6	NE	NE	61,7	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MIAESIOP_S1.xls
28MAR2020 15:58

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo					
		Patients		Censored		Time To Event						Patients	Patients with		Censored		Time To Event					Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	n %	n %	n %	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	1 4,3	22 95,7	NE	31,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MOAESIOP_S1.xls
28MAR2020 16:04

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SEAESIOP_S1.xls
28MAR2020 16:10

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SAESIOPP_S1.xls
28MAR2020 16:16

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	4	9,8	37	90,2	NE	NE	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	0,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_AESIIRR_S1.xls
28MAR2020 15:53

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	3	7,3	38	92,7	NE	NE	NE	NE	NE	NE	23	100,0	3	13,0	20	87,0	NE	0,1	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MIAESIIR_S1.xls
28MAR2020 15:59

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_MOAESIIR_S1.xls
28MAR2020 16:05

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237												Placebo										SA237 vs. Placebo						
		Patients		Patients with		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	1	2,4	40	97,6	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SEAESIIR_S1.xls
28MAR2020 16:11

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40900
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	41	100,0	41	100,0	NE	NE	NE	NE	NE	NE	23	100,0	23	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDF70210/BN40900/data_analysis/ACE_3MSU/prod/output/saf_tte_309_07JUN2019_SAQP_SAESIIRR_S1.xls
28MAR2020 16:17

POPULATION: AQP4 Positive Population
ENDPOINT: --
MODEL: --
STUDY: BN40900
Demographic data and baseline disease characteristics

	Placebo (N=23) n (%)	SA237 (N=41) n (%)	Total (N=64) n (%)
Age (years)			
n	23	41	64
Mean (SD)	40.1 (11.5)	46.0 (12.0)	43.9 (12.1)
Min - Max	20 - 56	22 - 70	20 - 70
Median	43	47	45
Age Group			
n	23	41	64
<65 years	23 (100%)	40 (97.6%)	63 (98.4%)
>=65 years	0	1 (2.4%)	1 (1.6%)
Gender			
n	23	41	64
Male	1 (4.3%)	10 (24.4%)	11 (17.2%)
Female	22 (95.7%)	31 (75.6%)	53 (82.8%)
Race			
n	23	41	64
American Indian/Alaska Native	0	2 (4.9%)	2 (3.1%)
Asian [Japanese]	0	0	0
Asian [Non-Japanese]	6 (26.1%)	7 (17.1%)	13 (20.3%)
Black/African American	3 (13.0%)	11 (26.8%)	14 (21.9%)
Native Hawaiian/other Pacific Islander	0	0	0
White	13 (56.5%)	19 (46.3%)	32 (50.0%)
Other	1 (4.3%)	2 (4.9%)	3 (4.7%)

Geographic Region1			
n	23	41	64
Asia	5 (21.7%)	5 (12.2%)	10 (15.6%)
Europe/US/Other	18 (78.3%)	36 (87.8%)	54 (84.4%)
Geographic Region2			
n	23	41	64
Asia	5 (21.7%)	5 (12.2%)	10 (15.6%)
Europe/Other	6 (26.1%)	8 (19.5%)	14 (21.9%)
North America	12 (52.2%)	28 (68.3%)	40 (62.5%)
Ethnicity			
n	23	41	64
Hispanic or Latino	3 (13.0%)	7 (17.1%)	10 (15.6%)
Not Hispanic or Latino	20 (87.0%)	30 (73.2%)	50 (78.1%)
Not reported	0	4 (9.8%)	4 (6.3%)
Unknown	0	0	0
Height (cm)			
n	23	40	63
Mean (SD)	163.80 (6.16)	164.42 (8.30)	164.19 (7.54)
Min - Max	154.9 - 182.0	152.4 - 185.4	152.4 - 185.4
Median	162	165,05	163
Body Weight (kg)			
n	23	41	64
Mean (SD)	67.13 (17.49)	76.60 (22.77)	73.20 (21.38)
Min - Max	42.1 - 117.3	46.0 - 151.0	42.1 - 151.0
25%-ile	53,5	62	58,95
Median	67,2	75	70,5
75%-ile	75	83,8	80,85
Weight Category			
n	23	41	64
< Median	15 (65.2%)	19 (46.3%)	34 (53.1%)
>= Median	8 (34.8%)	22 (53.7%)	30 (46.9%)
BMI (kg/m2)			

n	23	40	63
Mean (SD)	24.92 (6.03)	28.46 (8.91)	27.17 (8.11)
Min - Max	17.5 - 44.1	18.0 - 62.2	17.5 - 62.2
Median	24,27	27,16	25,6
BMI Category (kg/m2)			
n	23	40	63
<18.5	2 (8.7%)	1 (2.5%)	3 (4.8%)
18.5 to <25	12 (52.2%)	16 (40.0%)	28 (44.4%)
25 to <30	6 (26.1%)	11 (27.5%)	17 (27.0%)
>=30	3 (13.0%)	12 (30.0%)	15 (23.8%)
Diagnosis			
n	23	41	64
NMO	15 (65.2%)	26 (63.4%)	41 (64.1%)
NMOSD	8 (34.8%)	15 (36.6%)	23 (35.9%)
Prior therapy			
n	23	41	64
B-cell depleting therapy	4 (17.4%)	5 (12.2%)	9 (14.1%)
Immunosuppresants/Others	19 (82.6%)	36 (87.8%)	55 (85.9%)
Most recent attack			
n	23	41	64
First attack	4 (17.4%)	5 (12.2%)	9 (14.1%)
Relapse	19 (82.6%)	36 (87.8%)	55 (85.9%)
Baseline EDSS			
n	23	41	64
Mean (SD)	3.43 (1.55)	4.02 (1.50)	3.81 (1.53)
Min - Max	1.0 - 6.5	1.5 - 6.5	1.0 - 6.5
Median	3,5	4	3,5

n represents the number of patients contributing to summary statistics. Percentages are based on n (number of valid values).
Age calculated as the number of complete years between a patient's birth date and the date of first informed consent.
AQP4=Aquaporin-4, NMO=Neuromyelitis Optica, NMOSD=Neuromyelitis Optica Spectrum Disorder and EDSS=Expanded Disability Status Scale.
The EDSS is scored on a scale of 0-10. Higher scores represent increased disability.
Clinical cut-off: 12OCT2018

Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/oth_demo_309_12OCT2018_AQPP.xls
12DEC2019 19:12

POPULATION: AQP4 Positive Population
ENDPOINT: --
MODEL: --
STUDY: BN40900
Number of centers/countries/geographical regions with <10, >=10 patients per arm

	Center				Country				Geographical region (3)			
Category	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)
Overall	34	100.00%	64	100.00%	11	100.00%	64	100.00%	3	100.00%	64	100.00%
with <10 patients per arm (1)	34	100.00%	64	100.00%	10	90.90%	30	46.90%	2	66.70%	24	37.50%
with >=10 patients per arm (2)	0	0.00%	0	0.00%	1	9.10%	34	53.10%	1	33.30%	40	62.50%

(1): "<10 patients" category if at least one treatment arm has <10 patients. (2): ">=10 patients" category if all treatment arms have >=10 patients.
(3): Geographical regions: Europe, Asia, Others. (4): Number of centers/countries/geographical regions. (5): % of centers/countries/geographical regions compared to overall number.
(6): Number of patients randomized in the corresponding category (e.g. number of patients randomized in centers with <10 patients per arm).
(7): % of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients).
Clinical cut-off: 12OCT2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/program/oth_center.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40900/data_analysis/ACE_CSRPrimary/prod/output/oth_center_309_12OCT2018_AQPP.xls
12DEC2019 19:10

Duration of Double-Blind Period for Safety Analysis, AQP4 Positive, Safety-Evaluable Population
Protocol: SA-309JG
CCOD : SA309 CSR: 12OCT2018

	Placebo (N=23)	SA237 (N=41)
Duration (Weeks)		
0 - 23	9 (39.1%)	3 (7.3%)
24 - 47	2 (8.7%)	4 (9.8%)
48 - 71	4 (17.4%)	2 (4.9%)
72 - 95	4 (17.4%)	11 (26.8%)
96 - 119	2 (8.7%)	10 (24.4%)
120 - 143	0	2 (4.9%)
144 - 167	1 (4.3%)	1 (2.4%)
168 - 191	0	7 (17.1%)
192 - 215	0	1 (2.4%)
216 - 239	1 (4.3%)	0
Mean (SD)	60.7 (54.3)	102.3 (51.9)
Median	60.1	96.7
Min - Max	7 - 219	8 - 193

AQP4=Aquaporin-4
Double-blind period starts on the day of first dose. The double-blind period ends on the earliest day of 1) clinical cutoff date, 2) the day before the first treatment in the extension period, 3) the end of the study, or 4) last contact for Patients lost to follow up.

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_CSR_adhocs/prod/program/t_ex_sty_9824.sas
Output: root/clinical_studies/RO5333787/CDP70210/share/pool_CSR_adhocs/prod/output/t_ex_sty_9824_309_AQPPOS_DBSAF_SE.out
10JUL2020 16:46 Page 1 of 1

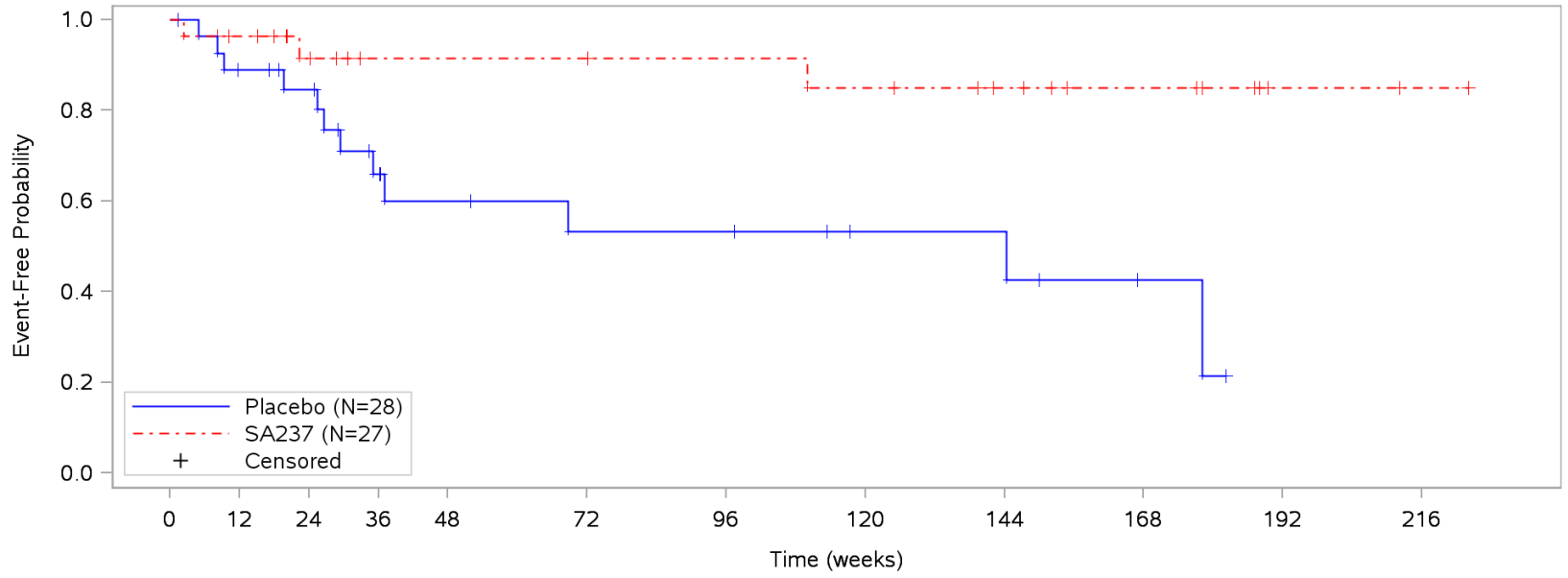
POPULATION: AQP4 Positive Population
ENDPOINT: Protocol Defined Relapse
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Time to event analysis (efficacy)

		SA237												Placebo											SA237 vs. Placebo					
		Patients		Patients with		Censored		Time To Event						Patients		Patients with		Censored		Time To Event						Log-rank	Hazard Ratio				
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	27	100,0	3	11,1	24	88,9	NE	22,3	NE	NE	NE	NE	28	100,0	12	42,9	16	57,1	29,4	8,1	68,7	144,3	29,4	NE	0,0086	0,21	0,06	0,75		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/eff_tte_307_06JUN2018_AQPP_PDR01DB_ST.xls
22MAR2020 12:15

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Relapse, Protocol Defined Relapse
MODEL: --
STUDY: BN40898
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	28	23	20	13	10	8	8	5	5	2	NE	NE
SA237	27	24	19	15	15	15	14	13	10	7	2	1
Patients censored												
Placebo	0	2	4	7	9	10	10	13	13	15	NE	NE
SA237	0	2	6	10	10	10	11	11	14	17	22	23

Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_eff_tte_km_307_06JUN2018_AQPP_PDR01DB.pdf
22MAR2020 12:36

POPULATION: AQP8 Positive Population
ENDPOINT: Relapse-free subjects, Protocol Defined Relapse
MODEL: Stratified analysis (stratification factors: baseline ANR (1, >1); geographic region (Asia, EU/Other))
STUDY: MS03258
Dichotomous analysis (efficacy)

		RA237			Placebo			RA237 vs. Placebo										RA237 vs. Placebo							Placebo vs. RA237						
		Patients	Patients with		Patients	Patients with		Odds Ratio				Absolute Risk Difference						Relative Risk							Relative Risk						
Subgroup	Level	N	n	%	N	n	%	Odds Ratio	Convergence Reason	95% Lower CL	95% Upper CL	Absolute Risk		Convergence Reason	95% Lower CL	95% Upper CL		Relative Risk		Convergence Reason	95% Lower CI	95% Upper CI	p-value (Wald)		Relative Risk		Convergence Reason	95% Lower CI	95% Upper CI	
All	n/a	23	100,0	24	88,9	16	57,1	4,15	Algorithm converged.	1,48	25,52	0,351	*	WARNING: The relative Hessian convergence criterion of 0.0044729928 is greater than the limit of 0.0001. The convergence is questionable.	0,070	0,632	1,56	*	WARNING: The relative Hessian convergence criterion of 1.0211445031 is greater than the limit of 0.0001. The convergence is questionable.	0,71	3,39	0,2264		0,63	*	WARNING: The relative Hessian convergence criterion of 1.0211445031 is greater than the limit of 0.0001. The convergence is questionable.	0,29	1,34	

* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 04JUN2018

Program: root/clinical_studies/MS5333787/CSP70210/MM40898/data_analysis/ACE_CSRPrimary/prod/program/eff_resp.sas
Output: root/clinical_studies/MS5333787/CSP70210/MM40898/data_analysis/ACE_CSRPrimary/prod/output/eff_resp_R17_04JUN2018_AQPP_PUMSIDM_ST.xls
22OCT2019 14:24

POPULATION: AQP4 Positive Population
ENDPOINT: Annualized Relapse Rate, Protocol Defined Relapse
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Repeated event analysis (efficacy)

		(N=27)										(N=28)										Adjusted Analysis: Difference between Treatments					
		Patients		Relapses	Patient Years	Naive Annualized Relapse Rate			Adjusted Annualized Relapse Rate			Patients		Relapses	Patient Years	Naive Annualized Relapse Rate			Adjusted Annualized Relapse Rate			lr	Rate Ratio				
Subgroup	Level	n	%	Total	Total	Rate	95% Lower CL	95% Upper CL	Adjusted Rate	95% Lower CL	95% Upper CL	n	%	Total	Total	Rate	95% Lower CL	95% Upper CL	Adjusted Rate	95% Lower CL	95% Upper CL	p-value	Rate Ratio	95% Lower CL	95% Upper CL		Convergence Reason
All	n/a	27	100,0	3	50,44	0,059	0,012	0,174	0,063	0,018	0,228	28	100,0	12	32,12	0,374	0,193	0,653	0,52	0,18	1,5	0,0039	0,122	0,027	0,546		Algorithm converged.

Rate (raw) defined as the total number of relapses for all patients in the treatment group divided by the total patient-years of exposure to that treatment.
Based on negative binomial model. Factors/covariates: treatment. Adjusted for randomization stratification factors. Log (time in study [in years] per patient) as offset-variable.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/eff_nb.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/eff_nb_307_06JUN2018_AQPP_PDR01DB_ST.xls
22OCT2019 20:03

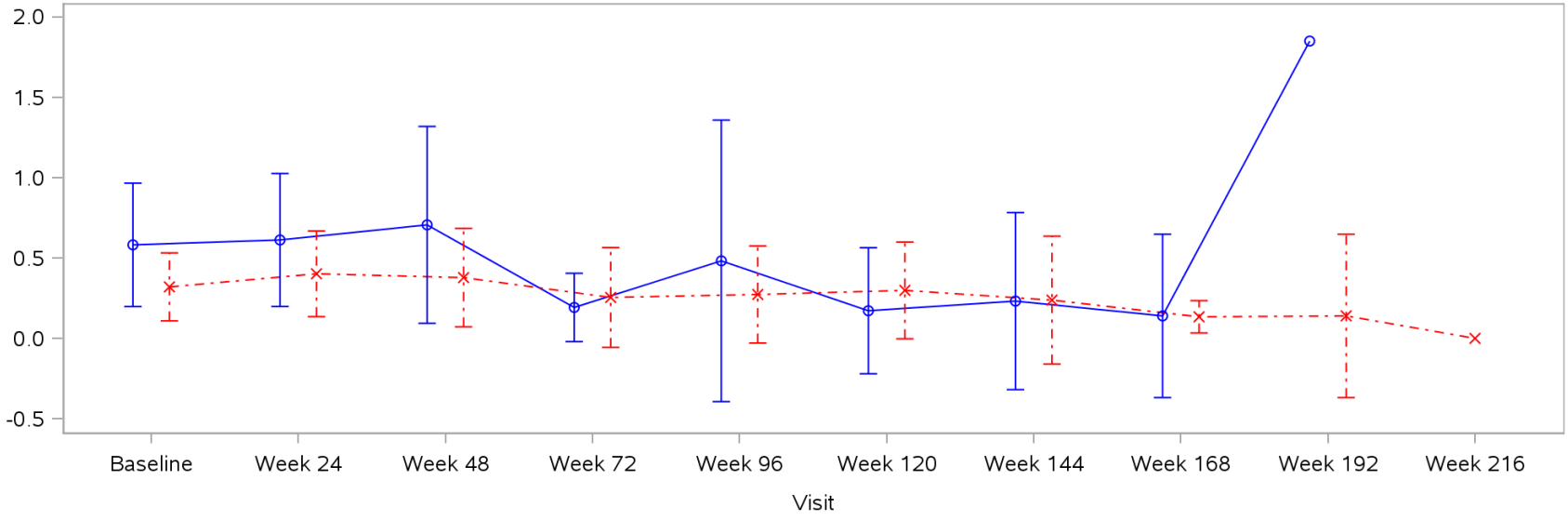
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Visual Acuity Score (Snellen Chart): OD
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	0,048	0,046	28	28	24	0,043	0,053	0,006	0,071	-0,140	0,152	0,9370	0,2870

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
OD = Right eye, OS = Left eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/eff_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/eff_mmrm_307_06JUN2018_AQPP_FSSVF1_ST.xls
11SEP2020 19:44

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Acuity Score (Snellen Chart): OD
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	24	16	8	8	5	5	2	1	0
SA237 n	27	25	18	15	15	15	11	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

OD = Right eye, OS = Left eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_eff_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_eff_mean_307_06JUN2018_AQPP_FSSVF1.pdf
11SEP2020 18:53

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Acuity Score (Snellen Chart): OD
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	% with value[1]		% mean[2]	SD	in study[1]		% with value[1]		% mean[2]	SD		
All														
n/a	Baseline		27	100,0	27	100,0	0,320	0,535	28	100,0	28	100,0	0,582	0,990
	Week 24		25	92,6	25	100,0	0,402	0,645	24	85,7	24	100,0	0,613	0,980
	Week 48		18	66,7	18	100,0	0,378	0,616	16	57,1	16	100,0	0,706	1,150
	Week 72		16	59,3	15	93,8	0,255	0,561	9	32,1	8	88,9	0,193	0,254
	Week 96		15	55,6	15	100,0	0,273	0,546	8	28,6	8	100,0	0,483	1,048
	Week 120		15	55,6	15	100,0	0,299	0,544	5	17,9	5	100,0	0,172	0,316
	Week 144		11	40,7	11	100,0	0,238	0,592	5	17,9	5	100,0	0,232	0,444
	Week 168		7	25,9	7	100,0	0,134	0,109	2	7,1	2	100,0	0,140	0,057
	Week 192		2	7,4	2	100,0	0,140	0,057	1	3,6	1	100,0	1,850	NE
	Week 216		1	3,7	1	100,0	0,000	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	0,093	0,090	6	21,4	5	83,3	1,020	1,397

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
OD = Right eye, OS = Left eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/eff_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/eff_mean_307_06JUN2018_AQPP_FSSVF1_SG.xls
11SEP2020 18:28

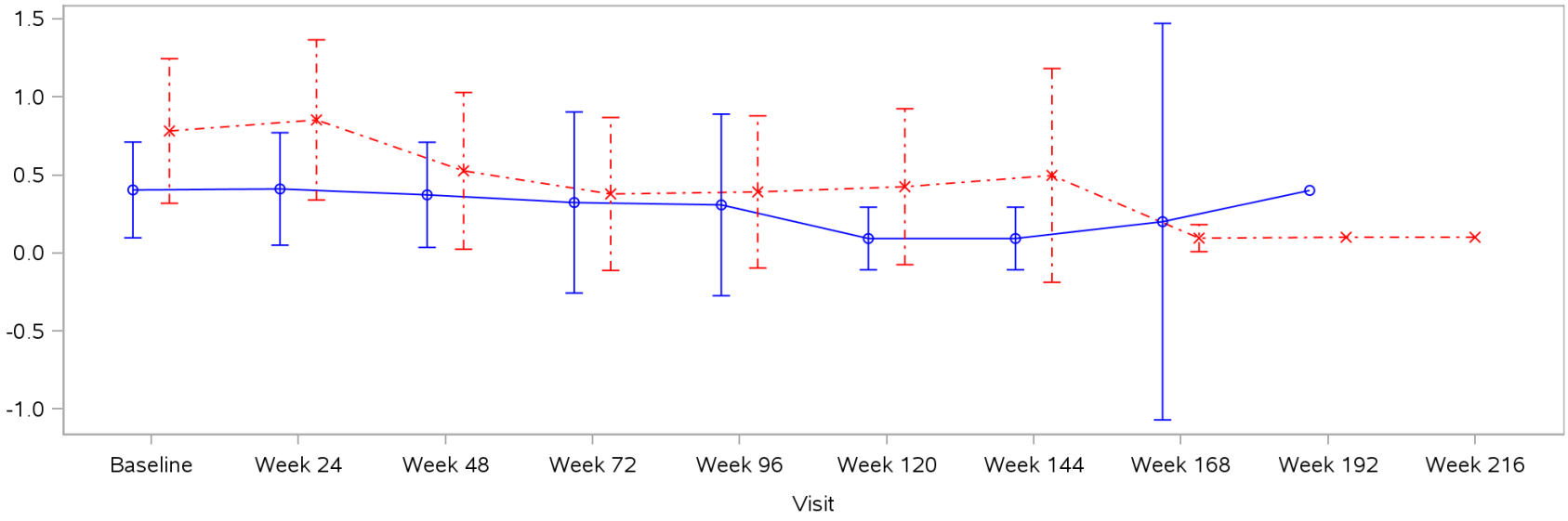
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Visual Acuity Score (Snellen Chart): OS
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	0,130	0,081	28	28	24	0,026	0,087	0,103	0,118	-0,141	0,347	0,3916	0,3621

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
OD = Right eye, OS = Left eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/eff_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/eff_mmrm_307_06JUN2018_AQPP_FSSVF2_ST.xls
11SEP2020 19:48

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Acuity Score (Snellen Chart): OS
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	24	16	8	8	5	5	2	1	0
SA237 n	27	25	18	15	15	15	11	7	2	1

OD = Right eye, OS = Left eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_eff_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_eff_mean_307_06JUN2018_AQPP_FSSVF2.pdf
11SEP2020 18:54

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Acuity Score (Snellen Chart): OS
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	% with value[1]		% mean[2]	SD	in study[1]		% with value[1]		% mean[2]	SD		
All														
n/a	Baseline		27	100,0	27	100,0	0,781	1,172	28	100,0	28	100,0	0,403	0,791
	Week 24		25	92,6	25	100,0	0,852	1,244	24	85,7	24	100,0	0,410	0,854
	Week 48		18	66,7	18	100,0	0,526	1,011	16	57,1	16	100,0	0,372	0,632
	Week 72		16	59,3	15	93,8	0,377	0,885	9	32,1	8	88,9	0,323	0,694
	Week 96		15	55,6	15	100,0	0,391	0,880	8	28,6	8	100,0	0,308	0,696
	Week 120		15	55,6	15	100,0	0,424	0,902	5	17,9	5	100,0	0,092	0,162
	Week 144		11	40,7	11	100,0	0,496	1,020	5	17,9	5	100,0	0,092	0,162
	Week 168		7	25,9	7	100,0	0,094	0,094	2	7,1	2	100,0	0,200	0,141
	Week 192		2	7,4	2	100,0	0,100	0,000	1	3,6	1	100,0	0,400	NE
	Week 216		1	3,7	1	100,0	0,100	NE						
	End of Study (Discontinued)		3	11,1	3	100,0	0,700	1,127	6	21,4	5	83,3	0,436	0,881

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
OD = Right eye, OS = Left eye. Lower values indicate better visual acuity.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/eff_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/eff_mean_307_06JUN2018_AQPP_FSSVF2_SG.xls
11SEP2020 18:30

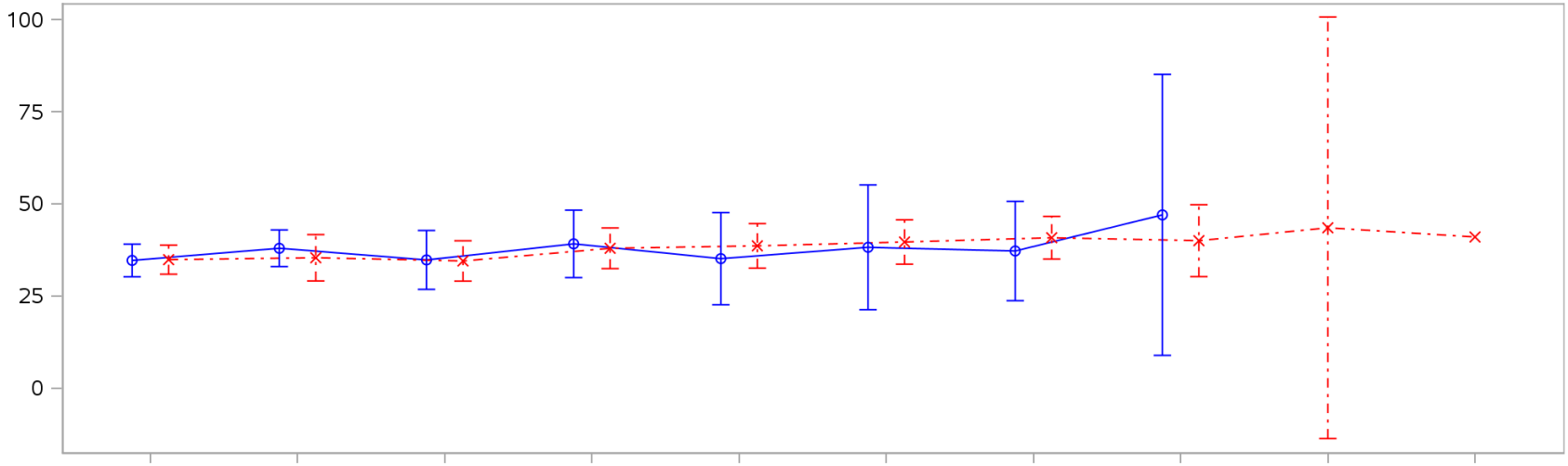
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional Assessment of Chronic Illness Therapy (FACIT): Fatigue Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	-0,517	1,028	28	28	19	2,751	1,219	-3,268	1,612	-6,632	0,096	0,0563	0,6158

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FACIT fatigue is scored on a scale of 0-52. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_FACITOT_ST.xls
11SEP2020 15:56

POPULATION: AQP4 Positive Population
ENDPOINT: Functional Assessment of Chronic Illness Therapy (FACIT): Fatigue Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	19	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The FACIT fatigue is scored on a scale of 0-52. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_FACITOT.pdf
02NOV2019 9:51

POPULATION: AQP4 Positive Population
ENDPOINT: Functional Assessment of Chronic Illness Therapy (FACIT): Fatigue Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	34,852	9,972	28	100,0	28	100,0	34,643	11,409
	Week 24		19	70,4	19	100,0	35,368	13,048	20	71,4	19	95,0	37,947	10,309
	Week 48		16	59,3	16	100,0	34,500	10,270	9	32,1	9	100,0	34,778	10,390
	Week 72		16	59,3	16	100,0	37,938	10,357	8	28,6	7	87,5	39,143	9,890
	Week 96		15	55,6	15	100,0	38,600	10,920	8	28,6	8	100,0	35,125	14,952
	Week 120		14	51,9	14	100,0	39,643	10,412	5	17,9	5	100,0	38,200	13,627
	Week 144		10	37,0	10	100,0	40,800	8,094	5	17,9	5	100,0	37,200	10,849
	Week 168		7	25,9	7	100,0	40,000	10,536	2	7,1	2	100,0	47,000	4,243
	Week 192		2	7,4	2	100,0	43,500	6,364						
	Week 216		1	3,7	1	100,0	41,000	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	37,333	6,658	6	21,4	6	100,0	33,833	9,988

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FACIT fatigue is scored on a scale of 0-52. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_FACITOT_SG.xls
01NOV2019 20:38

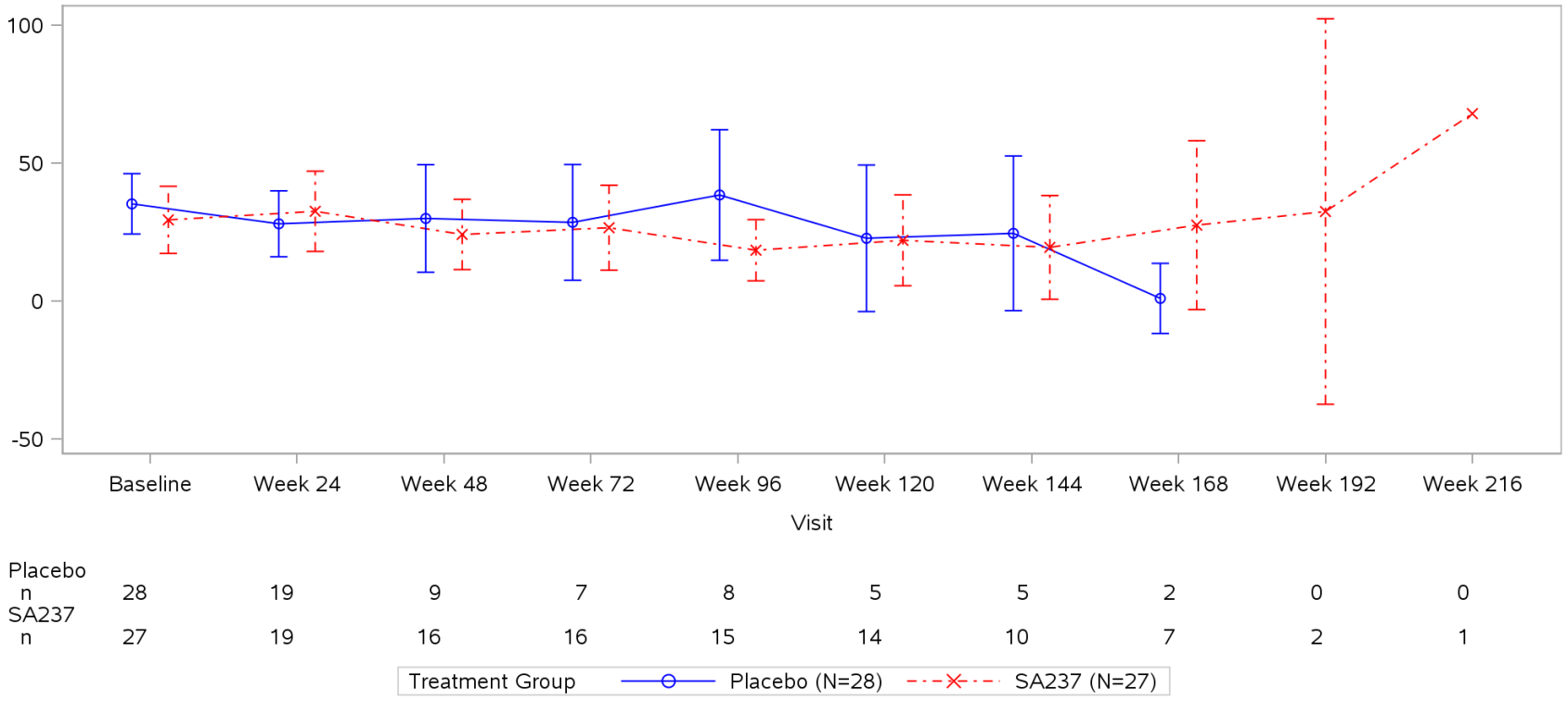
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Visual Analogue Scale (VAS): Pain Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	6,089	4,012	28	28	19	-2,363	4,731	8,452	6,228	-4,241	21,145	0,1844	0,8029

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The VAS pain is scored on a scale of 0-100. Lower scores reflect a better health state.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_VASPAIN_ST.xls
11SEP2020 16:17

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Analogue Scale (VAS): Pain Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	19	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

The VAS pain is scored on a scale of 0-100. Lower scores reflect a better health state.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_VASPAIN.pdf
02NOV2019 10:02

POPULATION: AQP4 Positive Population
ENDPOINT: Visual Analogue Scale (VAS): Pain Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	29,481	30,748	28	100,0	28	100,0	35,286	28,208
	Week 24		19	70,4	19	100,0	32,579	30,165	20	71,4	19	95,0	28,053	24,798
	Week 48		16	59,3	16	100,0	24,188	23,912	9	32,1	9	100,0	30,000	25,367
	Week 72		16	59,3	16	100,0	26,625	28,900	8	28,6	7	87,5	28,571	22,700
	Week 96		15	55,6	15	100,0	18,467	20,042	8	28,6	8	100,0	38,500	28,320
	Week 120		14	51,9	14	100,0	22,071	28,518	5	17,9	5	100,0	22,800	21,394
	Week 144		10	37,0	10	100,0	19,500	26,273	5	17,9	5	100,0	24,600	22,579
	Week 168		7	25,9	7	100,0	27,571	33,095	2	7,1	2	100,0	1,000	1,414
	Week 192		2	7,4	2	100,0	32,500	7,778						
	Week 216		1	3,7	1	100,0	68,000	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	30,333	6,110	6	21,4	6	100,0	53,167	40,142

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The VAS pain is scored on a scale of 0-100. Lower scores reflect a better health state.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_VASPAIN_SG.xls
01NOV2019 20:46

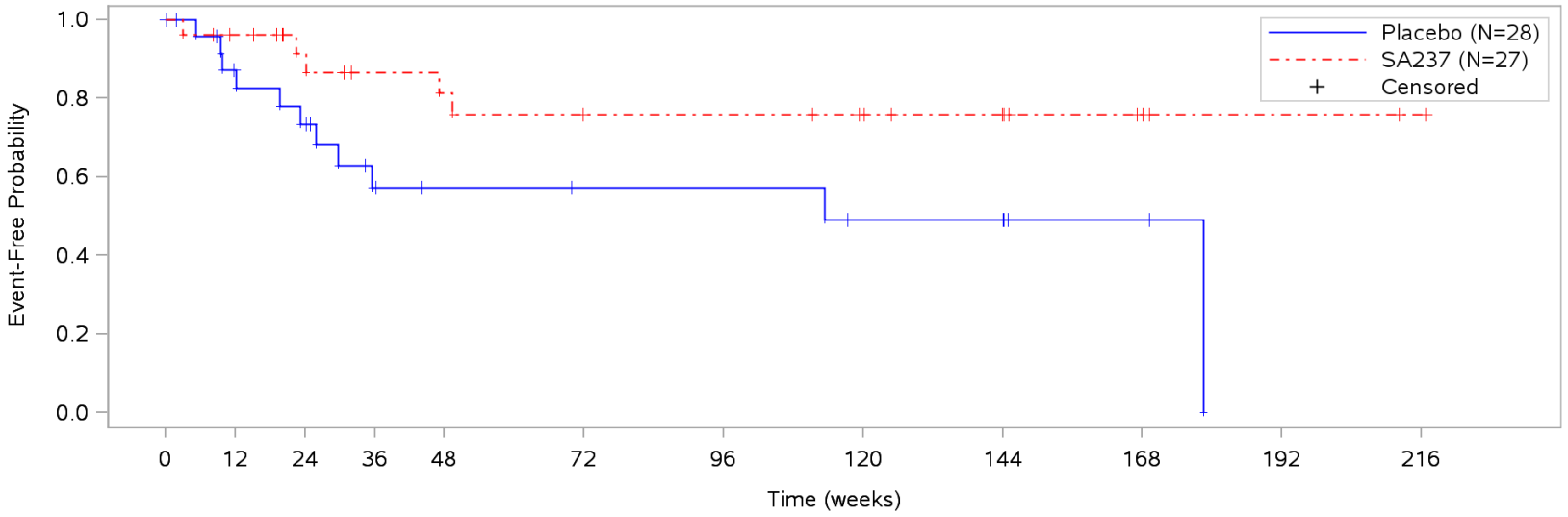
POPULATION: AQP4 Positive Population
ENDPOINT: Expanded Disability Status Scale (EDSS) Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Time to event analysis (PRO)

		SA237												Placebo											SA237 vs. Placebo					
		Patients		Patients with		Censored		Time To Event						Patients		Patients with		Censored		Time To Event						Log-rank	Hazard Ratio				
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status
All	n/a	27	100,0	5	18,5	22	81,5	NE	22,4	NE	NE	NE	NE	27	96,4	11	40,7	16	59,3	23,1	5,3	113,4	113,4	23,1	178,6	0,0529	0,36	0,12	1,06		Convergence criterion (GCONV=1E-8) satisfied.

* indicates convergence problem. Result is uninterpretable.
The EDSS is scored on a scale of 0-10. Higher scores represent increased disability. EDSS worsening defined as (a) worsening of 2 or more points in EDSS score for patients with baseline score of 0,
(b) worsening of 1 or more points in EDSS score for patients with baseline score of 1 to 5, or (c) worsening of 0.5 points or more in EDSS score for patients with baseline score of 5.5 or more.
Patients were censored at the date of the last EDSS assessment in DB or if no EDSS assessment in DB was performed at the randomization date.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_tte.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_tte_307_06JUN2018_AQPP_FWORSDB_ST.xls
30AUG2020 19:46

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Worsening, Expanded Disability Status Scale (EDSS) Score
MODEL: --
STUDY: BN40898
Kaplan-Meier plot of time to first worsening (weeks)



Patients at risk												
Placebo	27	19	16	10	8	7	7	5	5	2	NE	NE
SA237	27	24	19	16	15	13	13	11	8	5	2	1
Patients censored												
Placebo	0	5	5	8	10	11	11	12	13	15	NE	NE
SA237	0	2	6	8	8	9	9	11	14	17	20	21

The EDSS is scored on a scale of 0-10. Higher scores represent increased disability. EDSS worsening defined as (a) worsening of 2 or more points in EDSS score for patients with baseline score of 0, (b) worsening of 1 or more points in EDSS score for patients with baseline score of 1 to 5, or (c) worsening of 0.5 points or more in EDSS score for patients with baseline score of 5.5 or more.
Patients were censored at the date of the last EDSS assessment in DB or if no EDSS assessment in DB was performed at the randomization date.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_tte_km.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_tte_km_307_06JUN2018_AQPP_FWORSDB.pdf
30AUG2020 18:44

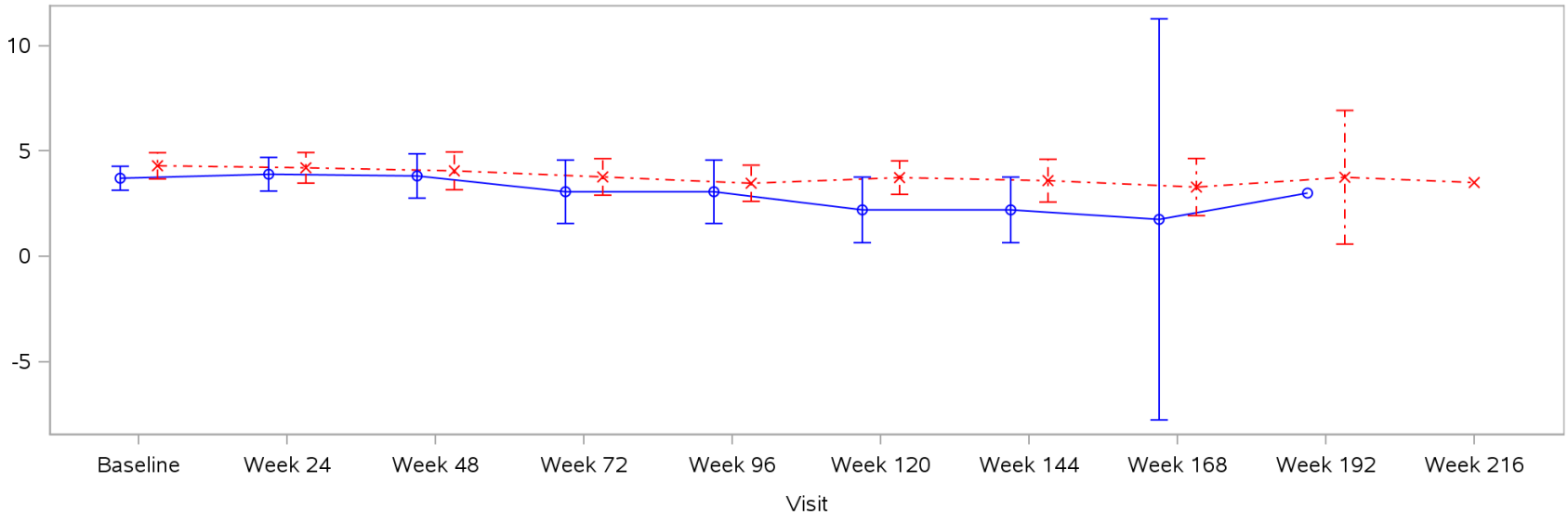
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Expanded Disability Status Scale (EDSS) Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	-0,058	0,221	28	27	24	0,345	0,252	-0,403	0,339	-1,099	0,293	0,2450	0,3971

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The EDSS is scored on a scale of 0-10. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_EDSS_ST.xls
11SEP2020 16:07

POPULATION: AQP4 Positive Population
ENDPOINT: Expanded Disability Status Scale (EDSS) Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	27	24	16	8	8	5	5	2	1	0
SA237 n	27	25	18	15	15	15	11	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The EDSS is scored on a scale of 0-10. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_EDSS.pdf
11SEP2020 10:32

POPULATION: AQP4 Positive Population
ENDPOINT: Expanded Disability Status Scale (EDSS) Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	4,296	1,577	28	100,0	27	96,4	3,704	1,436
	Week 24		25	92,6	25	100,0	4,200	1,762	25	89,3	24	96,0	3,896	1,894
	Week 48		18	66,7	18	100,0	4,056	1,806	16	57,1	16	100,0	3,813	1,974
	Week 72		16	59,3	15	93,8	3,767	1,568	9	32,1	8	88,9	3,063	1,802
	Week 96		15	55,6	15	100,0	3,467	1,552	8	28,6	8	100,0	3,063	1,802
	Week 120		15	55,6	15	100,0	3,733	1,438	5	17,9	5	100,0	2,200	1,255
	Week 144		11	40,7	11	100,0	3,591	1,514	5	17,9	5	100,0	2,200	1,255
	Week 168		7	25,9	7	100,0	3,286	1,468	2	7,1	2	100,0	1,750	1,061
	Week 192		2	7,4	2	100,0	3,750	0,354	1	3,6	1	100,0	3,000	NE
	Week 216		1	3,7	1	100,0	3,500	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	3,500	0,500	6	21,4	5	83,3	4,000	2,031

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The EDSS is scored on a scale of 0-10. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_EDSS_SG.xls
11SEP2020 8:43

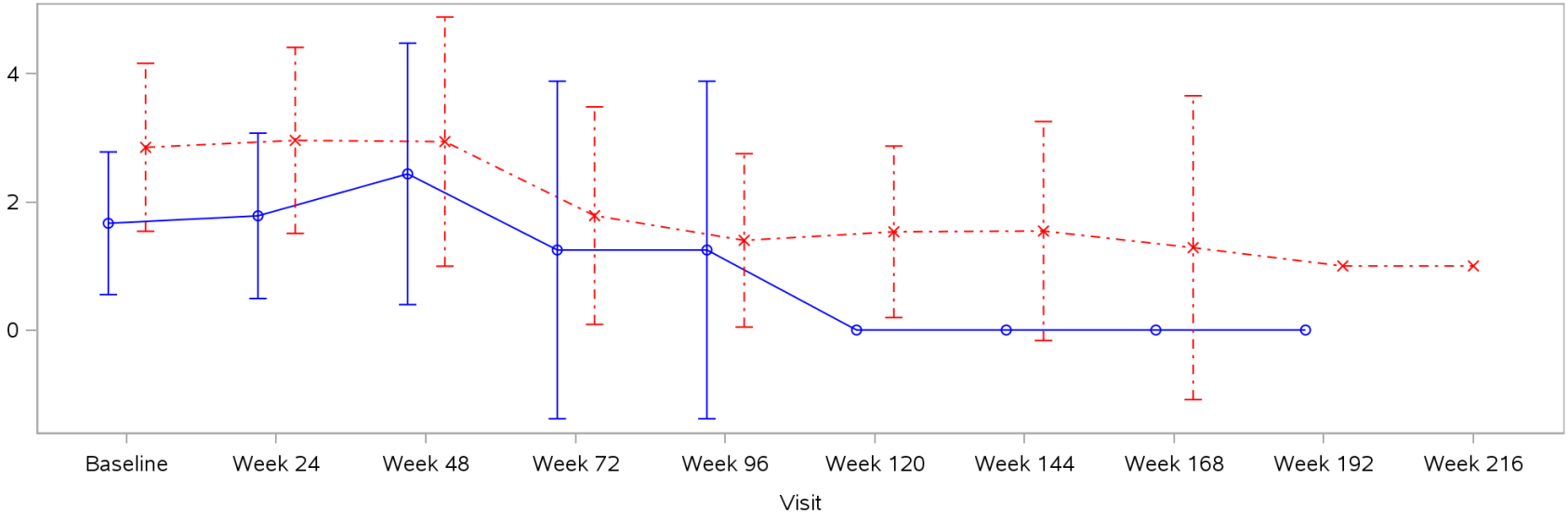
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Ambulation Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	NE	NE	28	27	23	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_FSSAMB_ST.xls
11SEP2020 16:08

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Ambulation Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	27	23	16	8	8	5	5	2	1	0
SA237 n	27	25	17	14	15	15	11	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_FSSAMB.pdf
11SEP2020 10:33

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Ambulation Score
MODEL: --
STUDY: BN40898
Compliance/Mean

		SA237 (N=27)						Placebo (N=28)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	27	100,0	27	100,0	2,852	3,313	28	100,0	27	96,4	1,667	2,815
	Week 24	25	92,6	25	100,0	2,960	3,518	25	89,3	23	92,0	1,783	2,984
	Week 48	18	66,7	17	94,4	2,941	3,783	16	57,1	16	100,0	2,438	3,829
	Week 72	16	59,3	14	87,5	1,786	2,940	9	32,1	8	88,9	1,250	3,151
	Week 96	15	55,6	15	100,0	1,400	2,444	8	28,6	8	100,0	1,250	3,151
	Week 120	15	55,6	15	100,0	1,533	2,416	5	17,9	5	100,0	0,000	0,000
	Week 144	11	40,7	11	100,0	1,545	2,544	5	17,9	5	100,0	0,000	0,000
	Week 168	7	25,9	7	100,0	1,286	2,563	2	7,1	2	100,0	0,000	0,000
	Week 192	2	7,4	2	100,0	1,000	0,000	1	3,6	1	100,0	0,000	NE
	Week 216	1	3,7	1	100,0	1,000	NE						
	End of Study (Discontinued)	3	11,1	3	100,0	0,333	0,577	6	21,4	5	83,3	2,400	4,827

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_FSSAMB_SG.xls
11SEP2020 8:44

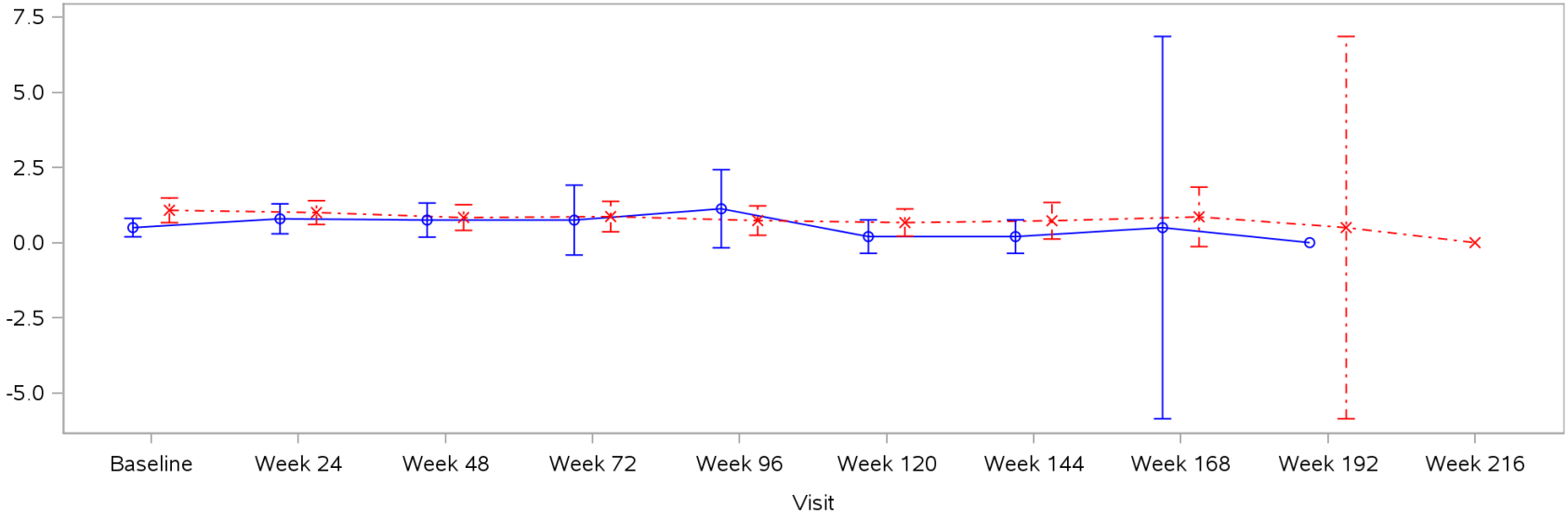
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Bowel and Bladder Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	NE	NE	28	28	24	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_FSSBOW_ST.xls
11SEP2020 16:13

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Bowel and Bladder Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	24	16	8	8	5	5	2	1	0
SA237 n	27	25	18	15	15	15	11	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_FSSBOW.pdf
11SEP2020 10:40

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Bowel and Bladder Score
MODEL: --
STUDY: BN40898
Compliance/Mean

		SA237 (N=27)						Placebo (N=28)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	27	100,0	27	100,0	1,074	1,035	28	100,0	28	100,0	0,500	0,793
	Week 24	25	92,6	25	100,0	1,000	0,957	25	89,3	24	96,0	0,792	1,179
	Week 48	18	66,7	18	100,0	0,833	0,857	16	57,1	16	100,0	0,750	1,065
	Week 72	16	59,3	15	93,8	0,867	0,915	9	32,1	8	88,9	0,750	1,389
	Week 96	15	55,6	15	100,0	0,733	0,884	8	28,6	8	100,0	1,125	1,553
	Week 120	15	55,6	15	100,0	0,667	0,816	5	17,9	5	100,0	0,200	0,447
	Week 144	11	40,7	11	100,0	0,727	0,905	5	17,9	5	100,0	0,200	0,447
	Week 168	7	25,9	7	100,0	0,857	1,069	2	7,1	2	100,0	0,500	0,707
	Week 192	2	7,4	2	100,0	0,500	0,707	1	3,6	1	100,0	0,000	NE
	Week 216	1	3,7	1	100,0	0,000	NE						
	End of Study (Discontinued)	3	11,1	3	100,0	0,667	0,577	6	21,4	5	83,3	1,600	1,817

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_FSSBOW_SG.xls
11SEP2020 8:47

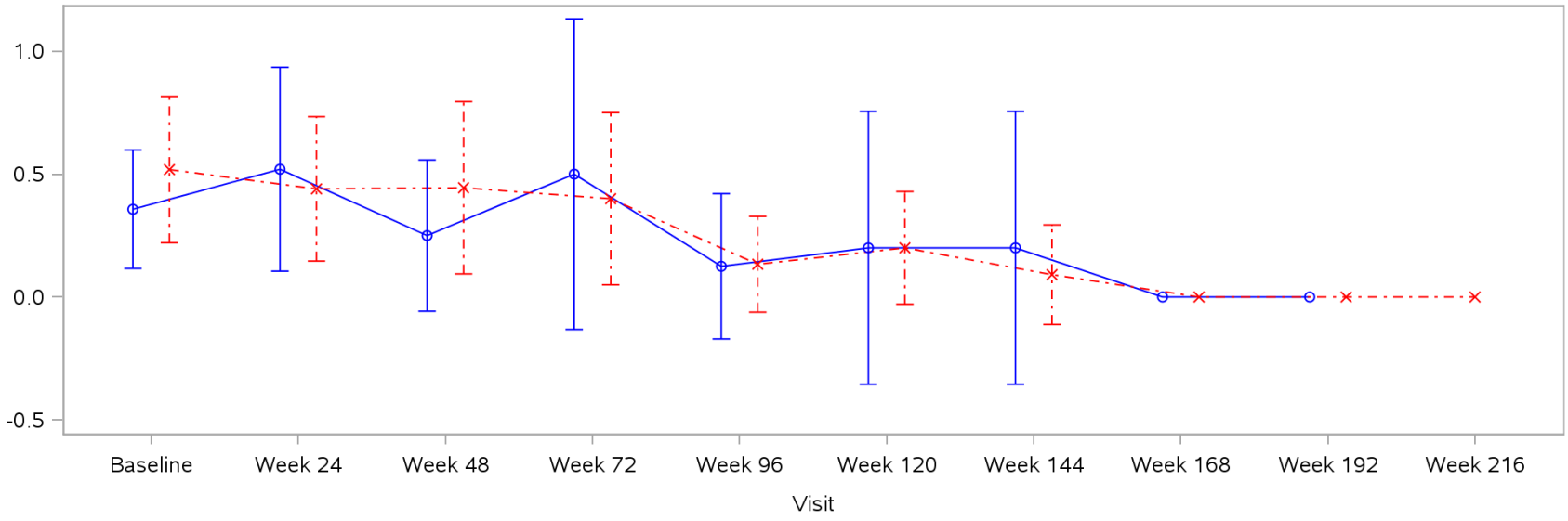
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Brainstem Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	NE	NE	28	28	25	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_FSSBRS_ST.xls
11SEP2020 16:15

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Brainstem Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	25	16	8	8	5	5	2	1	0
SA237 n	27	25	18	15	15	15	11	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_FSSBRS.pdf
11SEP2020 10:42

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Brainstem Score
MODEL: --
STUDY: BN40898
Compliance/Mean

		SA237 (N=27)						Placebo (N=28)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	27	100,0	27	100,0	0,519	0,753	28	100,0	28	100,0	0,357	0,621
	Week 24	25	92,6	25	100,0	0,440	0,712	25	89,3	25	100,0	0,520	1,005
	Week 48	18	66,7	18	100,0	0,444	0,705	16	57,1	16	100,0	0,250	0,577
	Week 72	16	59,3	15	93,8	0,400	0,632	9	32,1	8	88,9	0,500	0,756
	Week 96	15	55,6	15	100,0	0,133	0,352	8	28,6	8	100,0	0,125	0,354
	Week 120	15	55,6	15	100,0	0,200	0,414	5	17,9	5	100,0	0,200	0,447
	Week 144	11	40,7	11	100,0	0,091	0,302	5	17,9	5	100,0	0,200	0,447
	Week 168	7	25,9	7	100,0	0,000	0,000	2	7,1	2	100,0	0,000	0,000
	Week 192	2	7,4	2	100,0	0,000	0,000	1	3,6	1	100,0	0,000	NE
	Week 216	1	3,7	1	100,0	0,000	NE						
	End of Study (Discontinued)	3	11,1	3	100,0	0,000	0,000	6	21,4	5	83,3	0,400	0,548

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_FSSBRS_SG.xls
11SEP2020 8:48

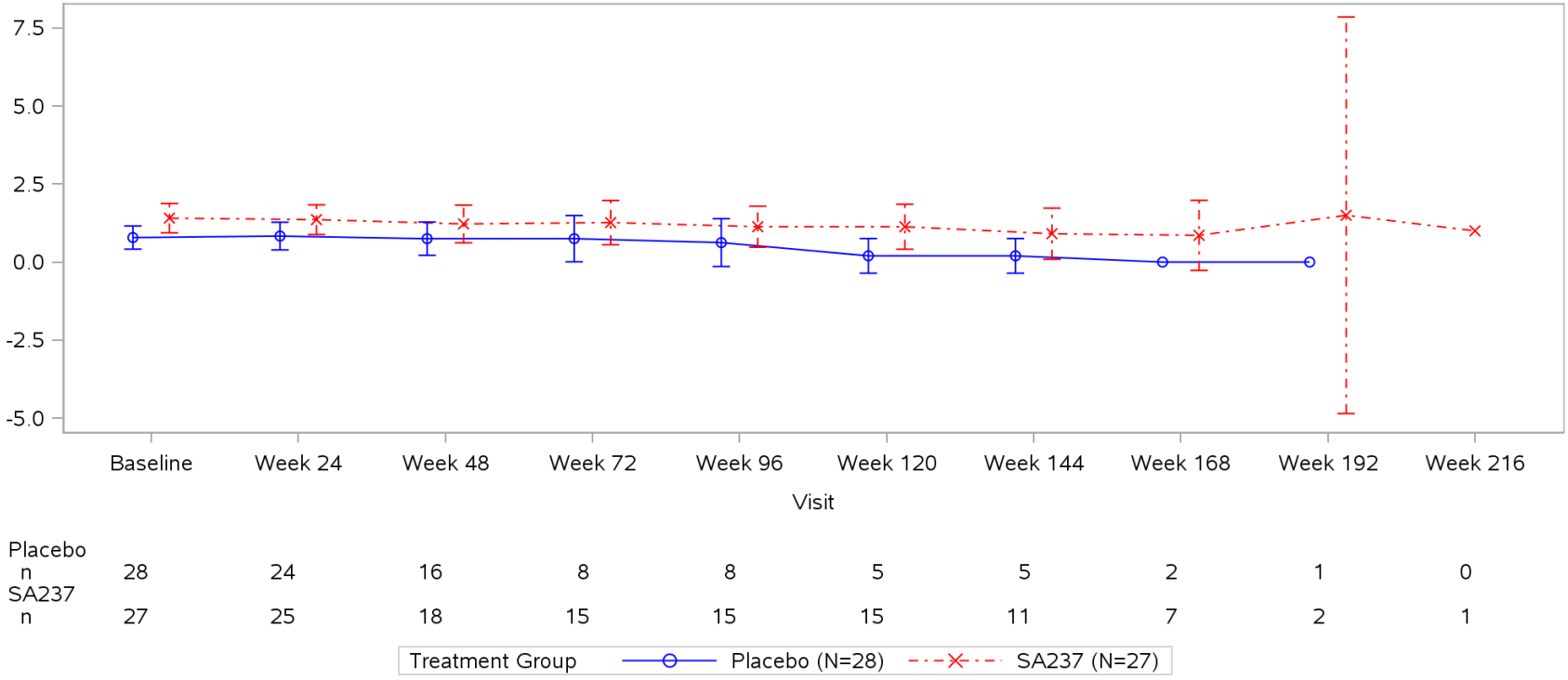
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Cerebellar Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	NE	NE	28	28	24	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_FSSCER_ST.xls
11SEP2020 16:09

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Cerebellar Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



	Baseline	Week 24	Week 48	Week 72	Week 96	Week 120	Week 144	Week 168	Week 192	Week 216
Placebo n	28	24	16	8	8	5	5	2	1	0
SA237 n	27	25	18	15	15	15	11	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_FSSCER.pdf
11SEP2020 10:34

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Cerebellar Score
MODEL: --
STUDY: BN40898
Compliance/Mean

		SA237 (N=27)						Placebo (N=28)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	27	100,0	27	100,0	1,407	1,185	28	100,0	28	100,0	0,786	0,957
	Week 24	25	92,6	25	100,0	1,360	1,150	25	89,3	24	96,0	0,833	1,049
	Week 48	18	66,7	18	100,0	1,222	1,215	16	57,1	16	100,0	0,750	1,000
	Week 72	16	59,3	15	93,8	1,267	1,280	9	32,1	8	88,9	0,750	0,886
	Week 96	15	55,6	15	100,0	1,133	1,187	8	28,6	8	100,0	0,625	0,916
	Week 120	15	55,6	15	100,0	1,133	1,302	5	17,9	5	100,0	0,200	0,447
	Week 144	11	40,7	11	100,0	0,909	1,221	5	17,9	5	100,0	0,200	0,447
	Week 168	7	25,9	7	100,0	0,857	1,215	2	7,1	2	100,0	0,000	0,000
	Week 192	2	7,4	2	100,0	1,500	0,707	1	3,6	1	100,0	0,000	NE
	Week 216	1	3,7	1	100,0	1,000	NE						
	End of Study (Discontinued)	3	11,1	3	100,0	1,000	1,000	6	21,4	5	83,3	0,400	0,894

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_FSSCER_SG.xls
11SEP2020 8:45

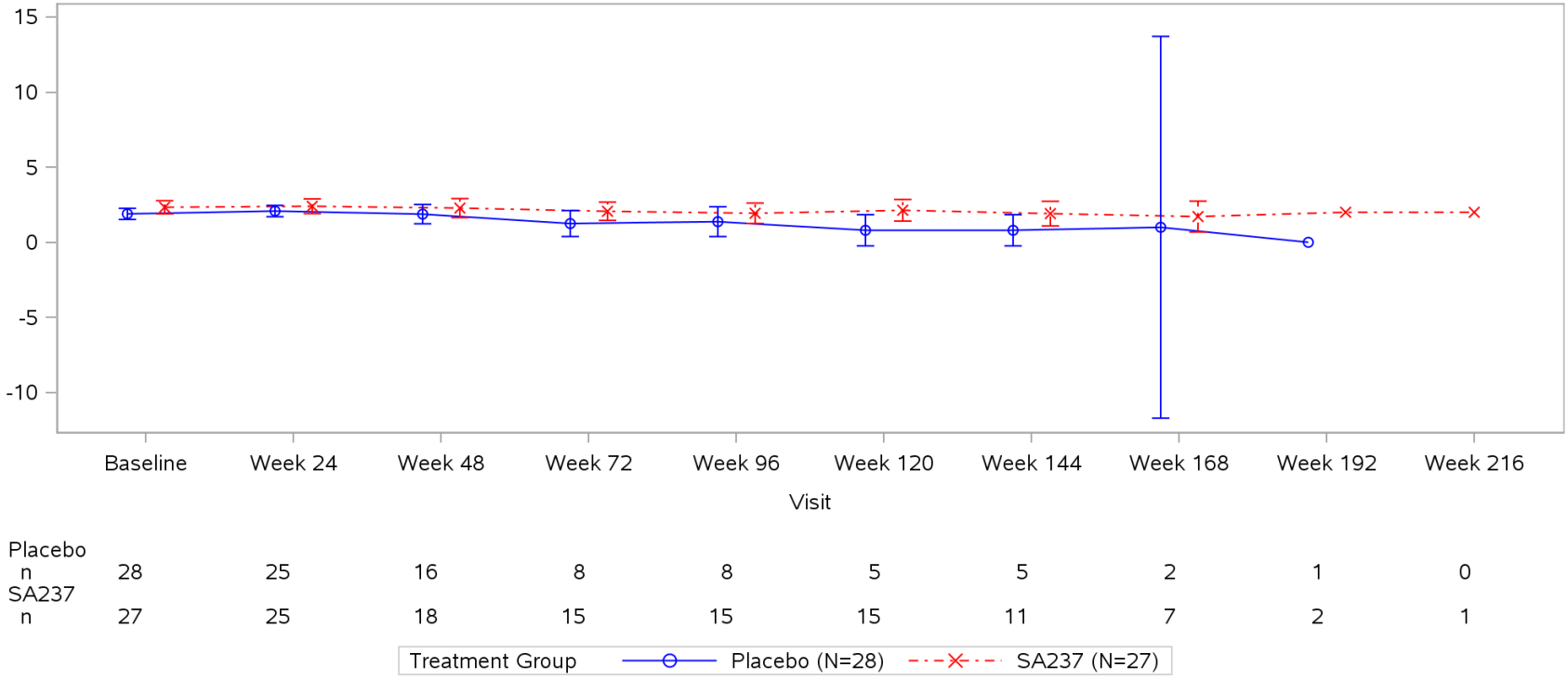
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Pyramidal Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	0,117	0,949	28	28	25	-0,185	1,315	0,302	1,663	-8,614	9,218	0,8759	0,6310

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_FSSPYR_ST.xls
11SEP2020 16:10

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Pyramidal Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	25	16	8	8	5	5	2	1	0
SA237 n	27	25	18	15	15	15	11	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_FSSPYR.pdf
11SEP2020 10:36

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Pyramidal Score
MODEL: --
STUDY: BN40898
Compliance/Mean

		SA237 (N=27)						Placebo (N=28)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	27	100,0	27	100,0	2,333	1,109	28	100,0	28	100,0	1,893	0,956
	Week 24	25	92,6	25	100,0	2,400	1,190	25	89,3	25	100,0	2,080	0,909
	Week 48	18	66,7	18	100,0	2,278	1,274	16	57,1	16	100,0	1,875	1,204
	Week 72	16	59,3	15	93,8	2,067	1,100	9	32,1	8	88,9	1,250	1,035
	Week 96	15	55,6	15	100,0	1,933	1,223	8	28,6	8	100,0	1,375	1,188
	Week 120	15	55,6	15	100,0	2,133	1,302	5	17,9	5	100,0	0,800	0,837
	Week 144	11	40,7	11	100,0	1,909	1,221	5	17,9	5	100,0	0,800	0,837
	Week 168	7	25,9	7	100,0	1,714	1,113	2	7,1	2	100,0	1,000	1,414
	Week 192	2	7,4	2	100,0	2,000	0,000	1	3,6	1	100,0	0,000	NE
	Week 216	1	3,7	1	100,0	2,000	NE						
	End of Study (Discontinued)	3	11,1	3	100,0	2,000	1,000	6	21,4	5	83,3	1,800	1,643

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_FSSPYR_SG.xls
11SEP2020 8:46

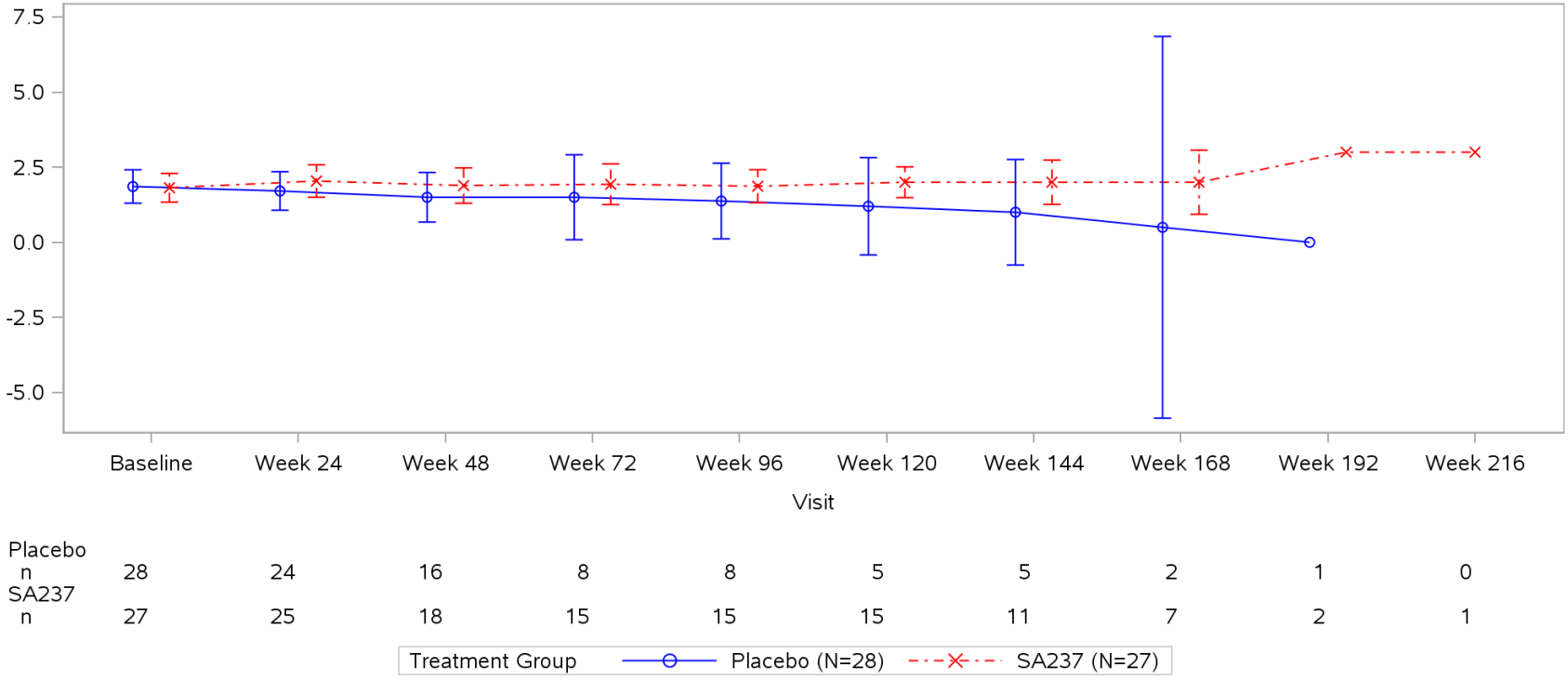
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Sensory Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	NE	NE	28	28	24	NE	NE	NE	NE	NE	NE	NE	NE

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_FSSSEN_ST.xls
11SEP2020 16:12

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Sensory Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



	Baseline	Week 24	Week 48	Week 72	Week 96	Week 120	Week 144	Week 168	Week 192	Week 216
Placebo n	28	24	16	8	8	5	5	2	1	0
SA237 n	27	25	18	15	15	15	11	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_FSSSEN.pdf
11SEP2020 10:38

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Sensory Score
MODEL: --
STUDY: BN40898
Compliance/Mean

		SA237 (N=27)						Placebo (N=28)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	27	100,0	27	100,0	1,815	1,210	28	100,0	28	100,0	1,857	1,433
	Week 24	25	92,6	25	100,0	2,040	1,306	25	89,3	24	96,0	1,708	1,517
	Week 48	18	66,7	18	100,0	1,889	1,183	16	57,1	16	100,0	1,500	1,549
	Week 72	16	59,3	15	93,8	1,933	1,223	9	32,1	8	88,9	1,500	1,690
	Week 96	15	55,6	15	100,0	1,867	0,990	8	28,6	8	100,0	1,375	1,506
	Week 120	15	55,6	15	100,0	2,000	0,926	5	17,9	5	100,0	1,200	1,304
	Week 144	11	40,7	11	100,0	2,000	1,095	5	17,9	5	100,0	1,000	1,414
	Week 168	7	25,9	7	100,0	2,000	1,155	2	7,1	2	100,0	0,500	0,707
	Week 192	2	7,4	2	100,0	3,000	0,000	1	3,6	1	100,0	0,000	NE
	Week 216	1	3,7	1	100,0	3,000	NE						
	End of Study (Discontinued)	3	11,1	3	100,0	1,667	1,528	6	21,4	5	83,3	1,400	1,342

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_FSSSEN_SG.xls
11SEP2020 8:46

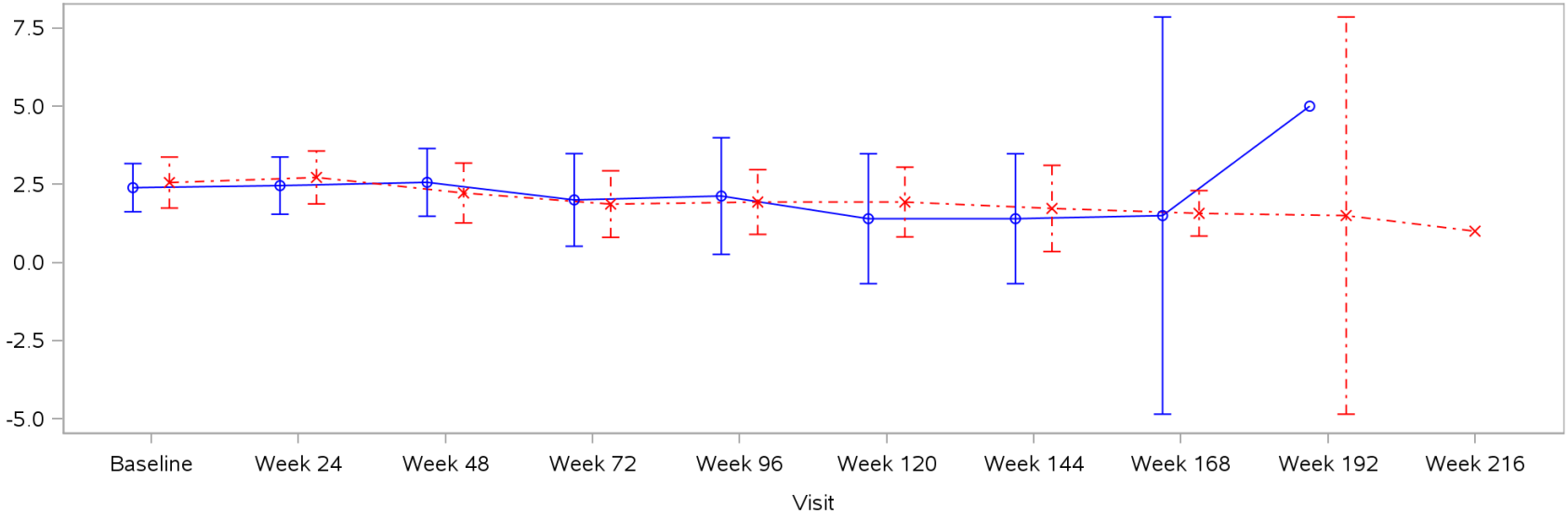
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Functional System Score (FSS): Visual Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	25	0,151	0,175	28	28	24	0,203	0,198	-0,053	0,263	-0,588	0,483	0,8430	0,8501

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_FSSVIS_ST.xls
11SEP2020 16:14

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Visual Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	24	16	8	8	5	5	2	1	0
SA237 n	27	25	18	15	15	15	11	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_FSSVIS.pdf
11SEP2020 10:41

POPULATION: AQP4 Positive Population
ENDPOINT: Functional System Score (FSS): Visual Score
MODEL: --
STUDY: BN40898
Compliance/Mean

		SA237 (N=27)						Placebo (N=28)					
		Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD
All													
n/a	Baseline	27	100,0	27	100,0	2,556	2,063	28	100,0	28	100,0	2,393	1,988
	Week 24	25	92,6	25	100,0	2,720	2,052	25	89,3	24	96,0	2,458	2,167
	Week 48	18	66,7	18	100,0	2,222	1,927	16	57,1	16	100,0	2,563	2,032
	Week 72	16	59,3	15	93,8	1,867	1,922	9	32,1	8	88,9	2,000	1,773
	Week 96	15	55,6	15	100,0	1,933	1,870	8	28,6	8	100,0	2,125	2,232
	Week 120	15	55,6	15	100,0	1,933	2,017	5	17,9	5	100,0	1,400	1,673
	Week 144	11	40,7	11	100,0	1,727	2,054	5	17,9	5	100,0	1,400	1,673
	Week 168	7	25,9	7	100,0	1,571	0,787	2	7,1	2	100,0	1,500	0,707
	Week 192	2	7,4	2	100,0	1,500	0,707	1	3,6	1	100,0	5,000	NE
	Week 216	1	3,7	1	100,0	1,000	NE						
	End of Study (Discontinued)	3	11,1	3	100,0	2,333	2,517	6	21,4	5	83,3	3,400	2,302

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The FSS is scored on a scale of 0 to 5 or 6. Ambulation score is on a scale of 0 to 12. Higher scores represent increased disability.
Last extra visit following relapse is mapped to the closest next regular visit.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_FSSVIS_SG.xls
11SEP2020 8:48

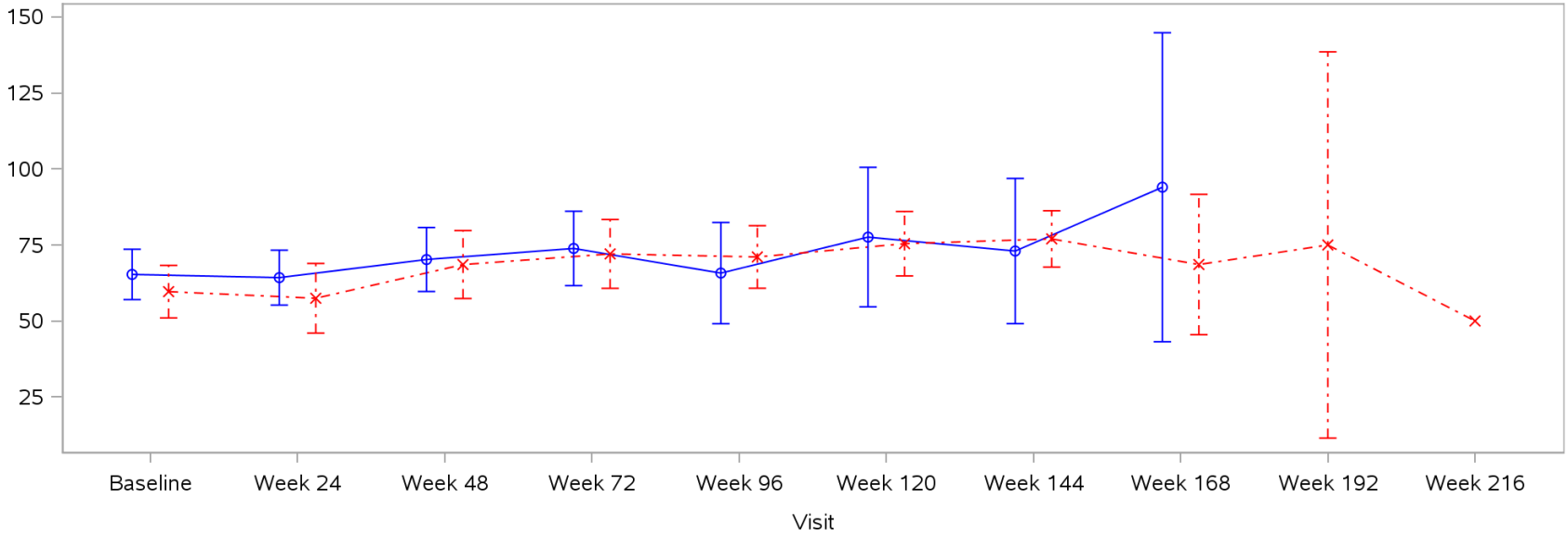
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, EuroQoL-5D (EQ-5D): VAS Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	26	18	0,196	3,053	28	28	19	1,301	3,734	-1,105	4,890	-11,189	8,979	0,8231	0,1366

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The EQ-5D VAS is scored on a scale of 0-100. Higher scores reflect a better health state.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_EQ5DVAS_ST.xls
11SEP2020 16:18

POPULATION: AQP4 Positive Population
ENDPOINT: EuroQoL-5D (EQ-5D): VAS Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	19	9	7	8	5	5	2	0	0
SA237 n	26	19	16	16	15	14	10	7	2	1

The EQ-5D VAS is scored on a scale of 0-100. Higher scores reflect a better health state.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_EQ5DVAS.pdf
02NOV2019 10:03

POPULATION: AQP4 Positive Population
ENDPOINT: EuroQoL-5D (EQ-5D): VAS Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	26	96,3	59,654	21,401	28	100,0	28	100,0	65,321	21,339
	Week 24		19	70,4	19	100,0	57,474	23,757	20	71,4	19	95,0	64,263	18,732
	Week 48		16	59,3	16	100,0	68,563	20,967	9	32,1	9	100,0	70,222	13,691
	Week 72		16	59,3	16	100,0	72,063	21,240	8	28,6	7	87,5	73,857	13,234
	Week 96		15	55,6	15	100,0	71,067	18,588	8	28,6	8	100,0	65,750	19,927
	Week 120		14	51,9	14	100,0	75,429	18,354	5	17,9	5	100,0	77,600	18,474
	Week 144		10	37,0	10	100,0	77,000	12,953	5	17,9	5	100,0	73,000	19,235
	Week 168		7	25,9	7	100,0	68,571	24,952	2	7,1	2	100,0	94,000	5,657
	Week 192		2	7,4	2	100,0	75,000	7,071						
	Week 216		1	3,7	1	100,0	50,000	NE						
	End of Study (Discontinued)		3	11,1	3	100,0	62,000	22,068	6	21,4	6	100,0	51,167	26,977

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The EQ-5D VAS is scored on a scale of 0-100. Higher scores reflect a better health state.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_EQ5DVAS_SG.xls
01NOV2019 20:46

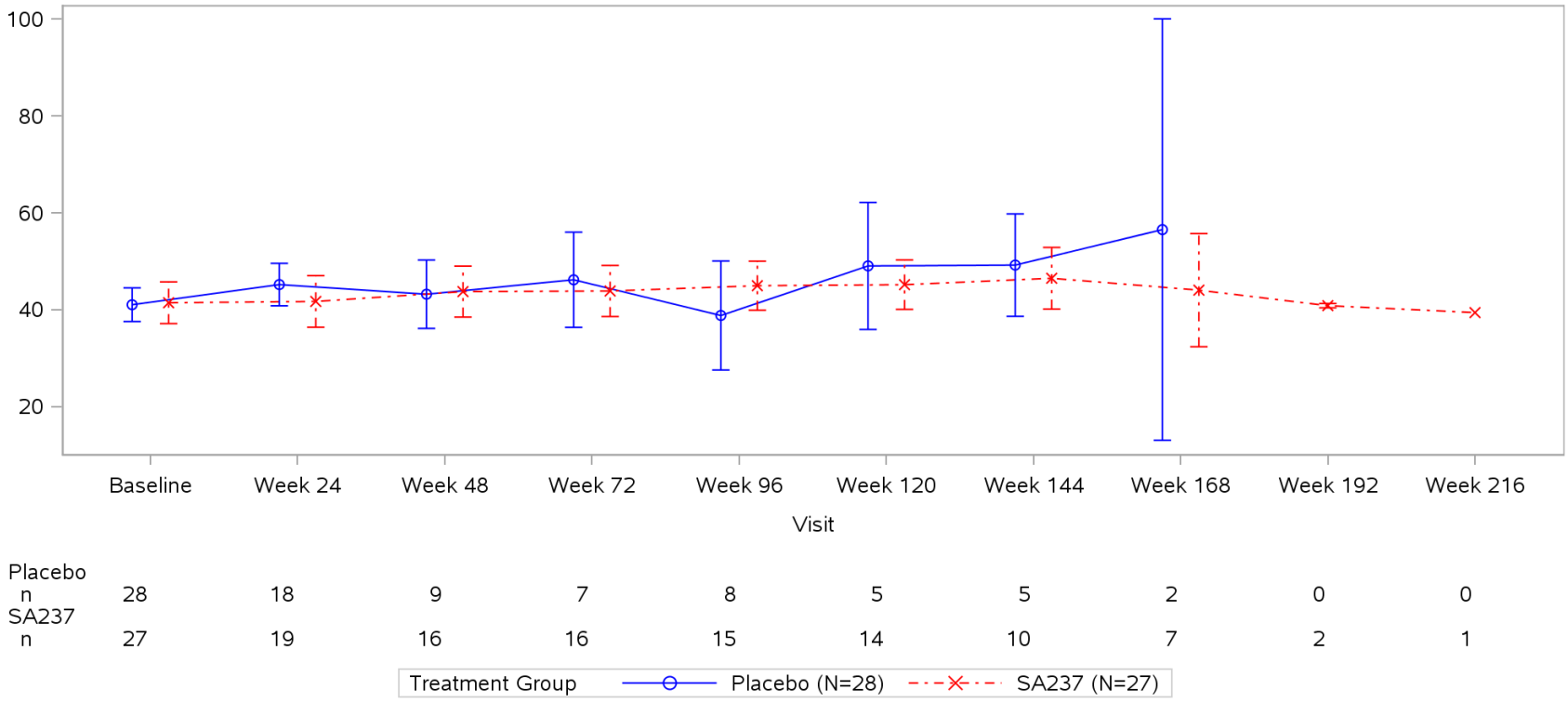
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Physical Health Component
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	0,651	1,255	28	28	19	1,497	1,549	-0,846	1,995	-5,004	3,312	0,6759	0,2949

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36PCS_ST.xls
11SEP2020 15:56

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Physical Health Component
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	18	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36PCS.pdf
02NOV2019 9:51

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Physical Health Component
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	41,446	10,880	28	100,0	28	100,0	41,040	8,955
	Week 24		19	70,4	19	100,0	41,716	11,044	20	71,4	18	90,0	45,202	8,818
	Week 48		16	59,3	16	100,0	43,749	9,887	9	32,1	9	100,0	43,203	9,186
	Week 72		16	59,3	16	100,0	43,873	9,897	8	28,6	7	87,5	46,190	10,627
	Week 96		15	55,6	15	100,0	44,965	9,147	8	28,6	8	100,0	38,810	13,462
	Week 120		14	51,9	14	100,0	45,177	8,838	5	17,9	5	100,0	49,050	10,564
	Week 144		10	37,0	10	100,0	46,499	8,903	5	17,9	5	100,0	49,214	8,518
	Week 168		7	25,9	7	100,0	44,044	12,632	2	7,1	2	100,0	56,555	4,844
	Week 192		2	7,4	2	100,0	40,845	0,049						
	Week 216		1	3,7	1	100,0	39,410	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	45,880	1,833	6	21,4	6	100,0	36,953	9,390

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36PCS_SG.xls
01NOV2019 20:38

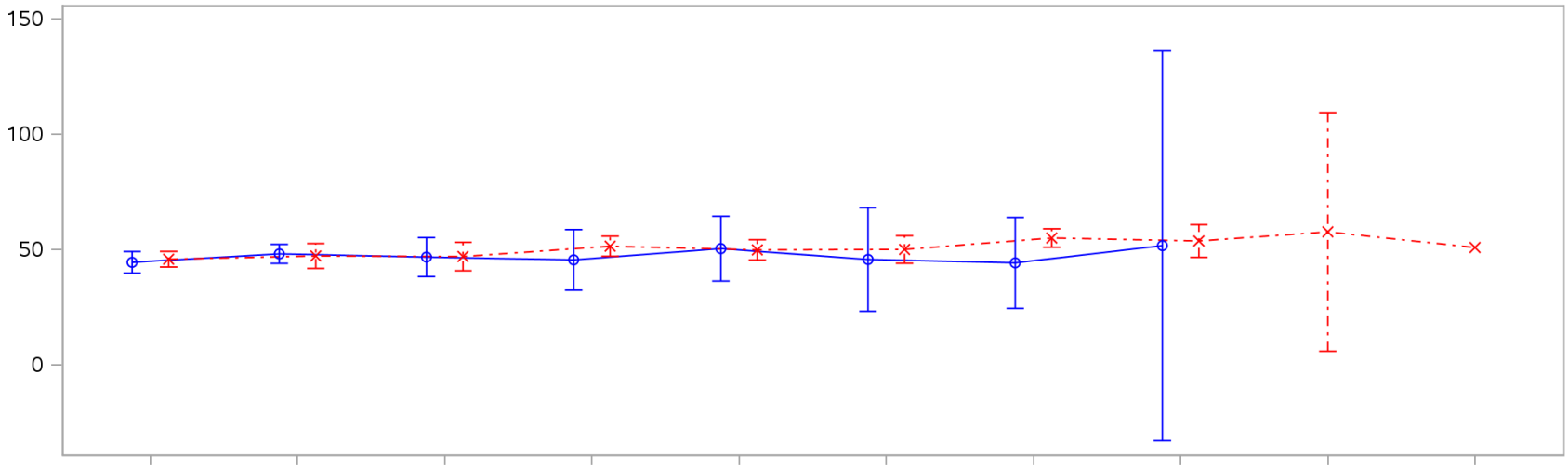
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Mental Health Component
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	-0,107	1,539	28	28	19	4,010	1,832	-4,118	2,452	-9,152	0,917	0,1048	0,7384

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36MCS_ST.xls
11SEP2020 15:57

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Mental Health Component
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	18	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36MCS.pdf
02NOV2019 9:52

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Mental Health Component
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	45,691	8,544	28	100,0	28	100,0	44,351	12,056
	Week 24		19	70,4	19	100,0	47,104	11,164	20	71,4	18	90,0	48,009	8,279
	Week 48		16	59,3	16	100,0	46,859	11,577	9	32,1	9	100,0	46,602	11,015
	Week 72		16	59,3	16	100,0	51,333	8,186	8	28,6	7	87,5	45,406	14,204
	Week 96		15	55,6	15	100,0	49,733	7,978	8	28,6	8	100,0	50,279	16,821
	Week 120		14	51,9	14	100,0	49,923	10,368	5	17,9	5	100,0	45,596	18,088
	Week 144		10	37,0	10	100,0	54,893	5,601	5	17,9	5	100,0	44,112	15,883
	Week 168		7	25,9	7	100,0	53,613	7,681	2	7,1	2	100,0	51,565	9,412
	Week 192		2	7,4	2	100,0	57,565	5,763						
	Week 216		1	3,7	1	100,0	50,770	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	37,190	17,855	6	21,4	6	100,0	41,042	10,110

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36MCS_SG.xls
01NOV2019 20:38

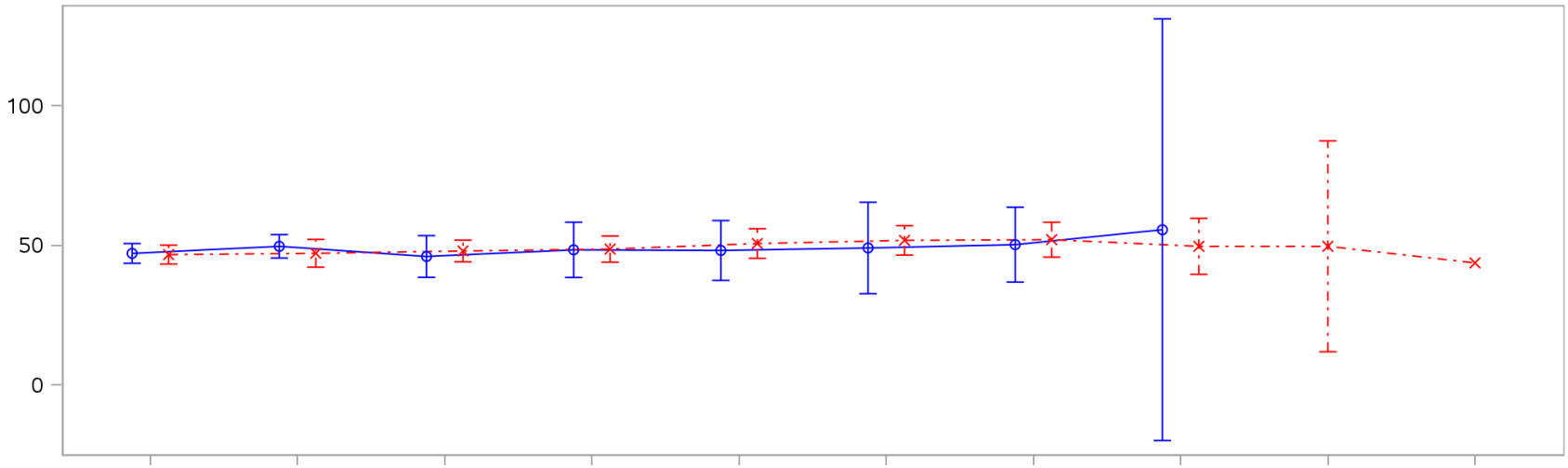
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Vitality Domain Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	-0,019	1,197	28	28	19	2,454	1,509	-2,473	1,953	-6,487	1,540	0,2165	0,3200

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36VTY_ST.xls
11SEP2020 16:05

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Vitality Domain Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	19	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36VTY.pdf
02NOV2019 9:56

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Vitality Domain Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	46,658	8,564	28	100,0	28	100,0	47,083	9,102
	Week 24		19	70,4	19	100,0	47,126	10,305	20	71,4	19	95,0	49,628	8,691
	Week 48		16	59,3	16	100,0	47,958	7,274	9	32,1	9	100,0	45,998	9,716
	Week 72		16	59,3	16	100,0	48,638	8,769	8	28,6	7	87,5	48,356	10,692
	Week 96		15	55,6	15	100,0	50,619	9,571	8	28,6	8	100,0	48,143	12,803
	Week 120		14	51,9	14	100,0	51,751	9,132	5	17,9	5	100,0	49,034	13,187
	Week 144		10	37,0	10	100,0	52,005	8,723	5	17,9	5	100,0	50,222	10,795
	Week 168		7	25,9	7	100,0	49,627	10,849	2	7,1	2	100,0	55,570	8,400
	Week 192		2	7,4	2	100,0	49,630	4,200						
	Week 216		1	3,7	1	100,0	43,690	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	41,707	13,397	6	21,4	6	100,0	44,677	8,119

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36VTY_SG.xls
01NOV2019 20:42

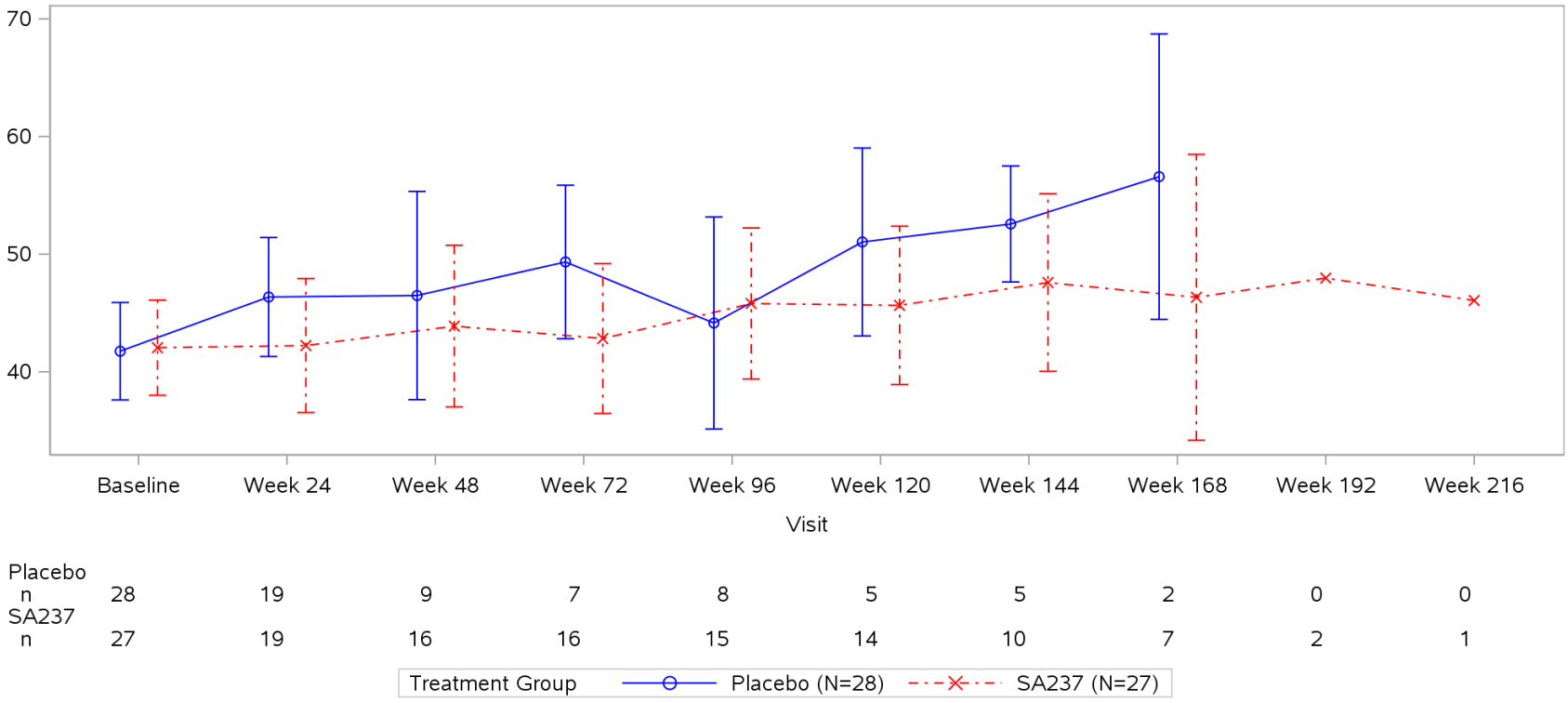
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Physical Functioning Domain Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	-0,698	1,547	28	28	19	4,923	1,804	-5,621	2,376	-10,782	-0,461	0,0351	0,9217

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36PHF_ST.xls
11SEP2020 16:01

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Physical Functioning Domain Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	19	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36PHF.pdf
02NOV2019 9:54

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Physical Functioning Domain Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	% with value[1]		% mean[2]	SD	in study[1]		% with value[1]		% mean[2]	SD		
All														
n/a	Baseline		27	100,0	27	100,0	42,048	10,225	28	100,0	28	100,0	41,751	10,682
	Week 24		19	70,4	19	100,0	42,231	11,815	20	71,4	19	95,0	46,361	10,487
	Week 48		16	59,3	16	100,0	43,884	12,897	9	32,1	9	100,0	46,484	11,514
	Week 72		16	59,3	16	100,0	42,827	11,956	8	28,6	7	87,5	49,337	7,051
	Week 96		15	55,6	15	100,0	45,803	11,594	8	28,6	8	100,0	44,144	10,779
	Week 120		14	51,9	14	100,0	45,647	11,658	5	17,9	5	100,0	51,034	6,431
	Week 144		10	37,0	10	100,0	47,588	10,552	5	17,9	5	100,0	52,564	3,970
	Week 168		7	25,9	7	100,0	46,330	13,141	2	7,1	2	100,0	56,585	1,351
	Week 192		2	7,4	2	100,0	47,970	0,000						
	Week 216		1	3,7	1	100,0	46,060	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	49,243	1,103	6	21,4	6	100,0	40,952	13,019

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36PHF_SG.xls
01NOV2019 20:40

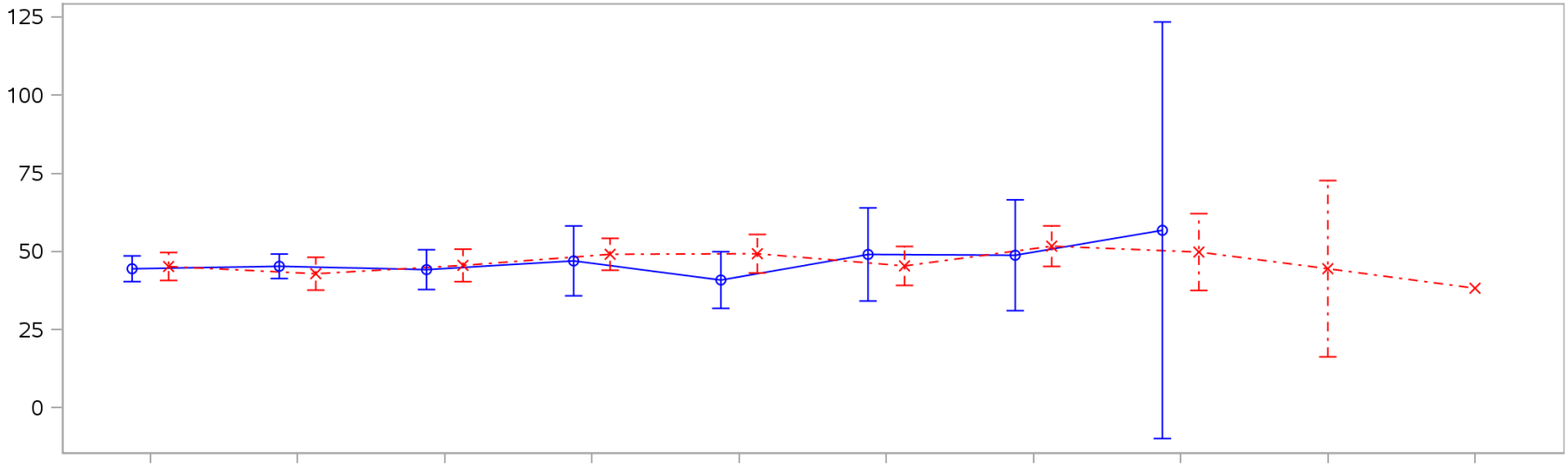
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Bodily Pain Domain Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	0,480	1,618	28	28	19	1,624	2,177	-1,144	2,737	-6,825	4,538	0,6802	0,1239

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36BPN_ST.xls
11SEP2020 15:57

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Bodily Pain Domain Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	19	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36BPN.pdf
02NOV2019 9:52

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Bodily Pain Domain Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	45,169	11,304	28	100,0	28	100,0	44,445	10,605
	Week 24		19	70,4	19	100,0	42,858	10,894	20	71,4	19	95,0	45,235	8,120
	Week 48		16	59,3	16	100,0	45,519	9,761	9	32,1	9	100,0	44,170	8,288
	Week 72		16	59,3	16	100,0	49,070	9,581	8	28,6	7	87,5	46,966	12,086
	Week 96		15	55,6	15	100,0	49,259	11,124	8	28,6	8	100,0	40,833	10,847
	Week 120		14	51,9	14	100,0	45,353	10,791	5	17,9	5	100,0	49,016	11,999
	Week 144		10	37,0	10	100,0	51,677	9,064	5	17,9	5	100,0	48,772	14,284
	Week 168		7	25,9	7	100,0	49,789	13,287	2	7,1	2	100,0	56,755	7,418
	Week 192		2	7,4	2	100,0	44,460	3,140						
	Week 216		1	3,7	1	100,0	38,210	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	48,157	8,948	6	21,4	6	100,0	37,738	9,845

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36BPN_SG.xls
01NOV2019 20:39

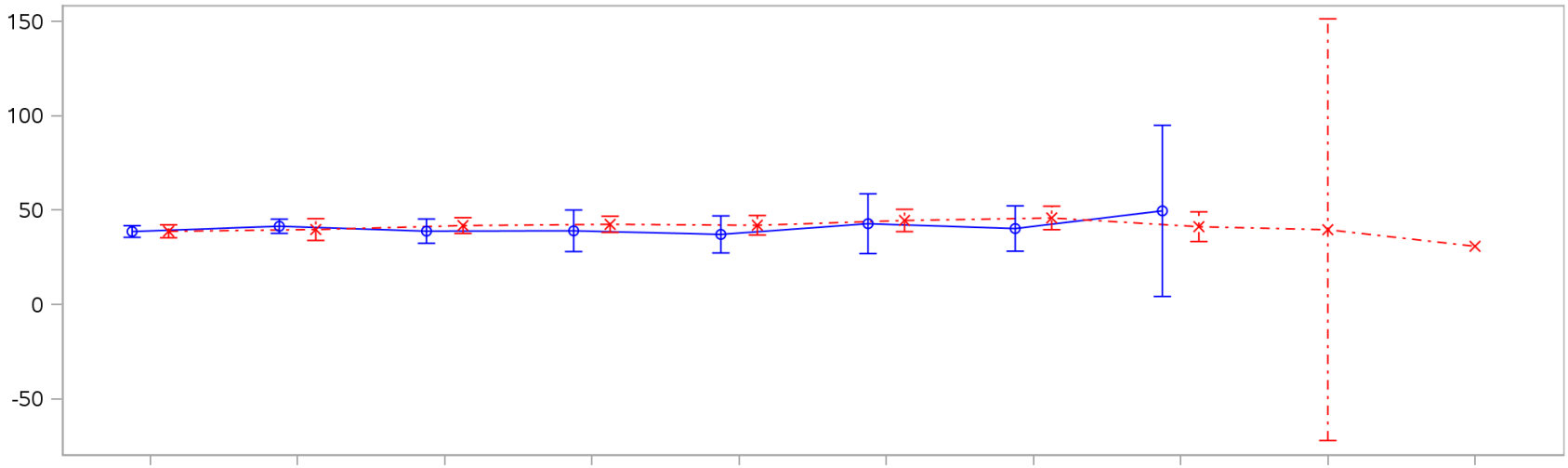
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): General Health Domain Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	1,369	1,056	28	28	19	-0,458	1,328	1,827	1,706	-1,659	5,313	0,2927	0,3116

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36GNH_ST.xls
11SEP2020 15:58

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): General Health Domain Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	19	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36GNH.pdf
02NOV2019 9:53

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): General Health Domain Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	38,793	8,719	28	100,0	28	100,0	38,683	7,978
	Week 24		19	70,4	19	100,0	39,723	11,973	20	71,4	19	95,0	41,475	7,844
	Week 48		16	59,3	16	100,0	41,833	7,854	9	32,1	9	100,0	38,871	8,385
	Week 72		16	59,3	16	100,0	42,487	8,032	8	28,6	7	87,5	39,059	11,896
	Week 96		15	55,6	15	100,0	41,997	9,316	8	28,6	8	100,0	37,139	11,753
	Week 120		14	51,9	14	100,0	44,526	10,215	5	17,9	5	100,0	42,818	12,751
	Week 144		10	37,0	10	100,0	45,865	8,690	5	17,9	5	100,0	40,252	9,667
	Week 168		7	25,9	7	100,0	41,231	8,498	2	7,1	2	100,0	49,620	5,049
	Week 192		2	7,4	2	100,0	39,635	12,438						
	Week 216		1	3,7	1	100,0	30,840	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	36,227	13,749	6	21,4	6	100,0	27,033	4,253

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36GNH_SG.xls
01NOV2019 20:39

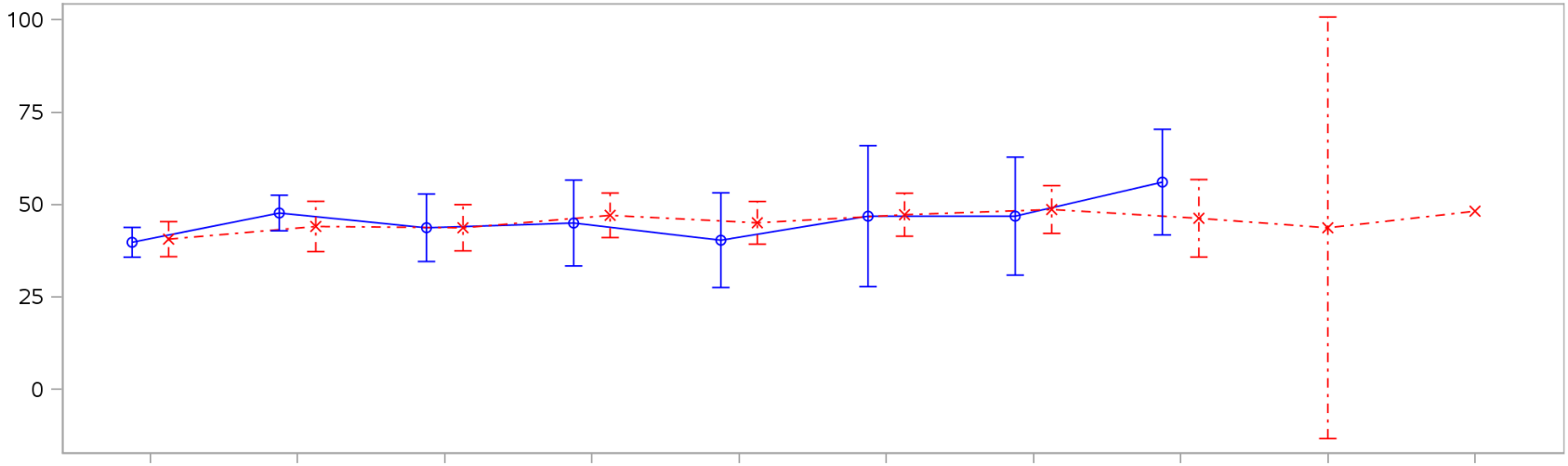
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Role-physical Domain Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	1,980	1,421	28	28	19	4,394	1,682	-2,414	2,207	-6,992	2,165	0,2860	0,3288

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36RPY_ST.xls
11SEP2020 16:03

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Role-physical Domain Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	18	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36RPY.pdf
02NOV2019 9:55

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Role-physical Domain Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	40,606	11,983	28	100,0	28	100,0	39,754	10,401
	Week 24		19	70,4	19	100,0	44,038	14,129	20	71,4	18	90,0	47,676	9,668
	Week 48		16	59,3	16	100,0	43,683	11,740	9	32,1	9	100,0	43,684	11,882
	Week 72		16	59,3	16	100,0	47,051	11,303	8	28,6	7	87,5	44,964	12,563
	Week 96		15	55,6	15	100,0	45,030	10,424	8	28,6	8	100,0	40,315	15,324
	Week 120		14	51,9	14	100,0	47,212	10,071	5	17,9	5	100,0	46,828	15,362
	Week 144		10	37,0	10	100,0	48,623	9,033	5	17,9	5	100,0	46,826	12,860
	Week 168		7	25,9	7	100,0	46,250	11,337	2	7,1	2	100,0	56,035	1,591
	Week 192		2	7,4	2	100,0	43,680	6,350						
	Week 216		1	3,7	1	100,0	48,170	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	38,443	4,673	6	21,4	6	100,0	39,565	10,475

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36RPY_SG.xls
01NOV2019 20:41

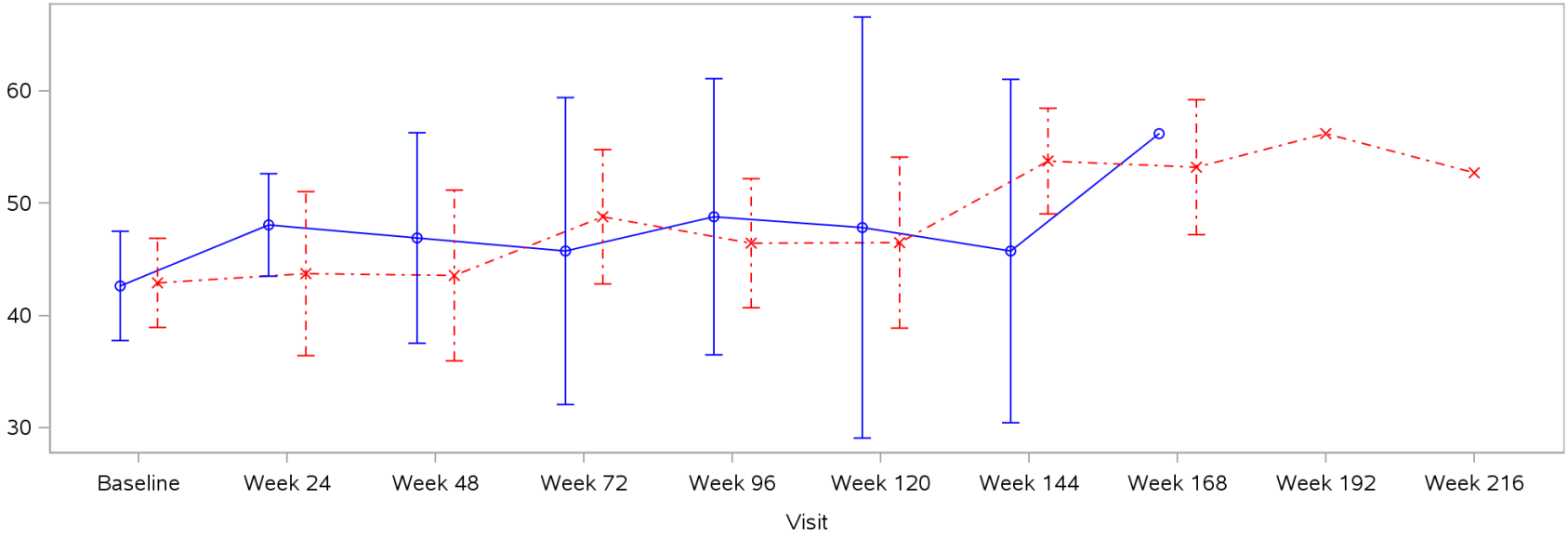
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Role-emotional Domain Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	-0,108	1,555	28	28	19	5,067	1,868	-5,175	2,450	-10,270	-0,081	0,0468	0,8289

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36REM_ST.xls
11SEP2020 16:02

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Role-emotional Domain Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	18	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36REM.pdf
02NOV2019 9:55

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Role-emotional Domain Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	% with value[1]		% mean[2]	SD	in study[1]		% with value[1]		% mean[2]	SD		
All														
n/a	Baseline		27	100,0	27	100,0	42,886	10,038	28	100,0	28	100,0	42,615	12,548
	Week 24		19	70,4	19	100,0	43,708	15,146	20	71,4	18	90,0	48,044	9,174
	Week 48		16	59,3	16	100,0	43,547	14,264	9	32,1	9	100,0	46,884	12,187
	Week 72		16	59,3	16	100,0	48,770	11,221	8	28,6	7	87,5	45,723	14,774
	Week 96		15	55,6	15	100,0	46,419	10,380	8	28,6	8	100,0	48,771	14,706
	Week 120		14	51,9	14	100,0	46,470	13,183	5	17,9	5	100,0	47,812	15,097
	Week 144		10	37,0	10	100,0	53,733	6,575	5	17,9	5	100,0	45,722	12,311
	Week 168		7	25,9	7	100,0	53,186	6,492	2	7,1	2	100,0	56,170	0,000
	Week 192		2	7,4	2	100,0	56,170	0,000						
	Week 216		1	3,7	1	100,0	52,690	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	39,920	7,244	6	21,4	6	100,0	40,500	14,396

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36REM_SG.xls
01NOV2019 20:40

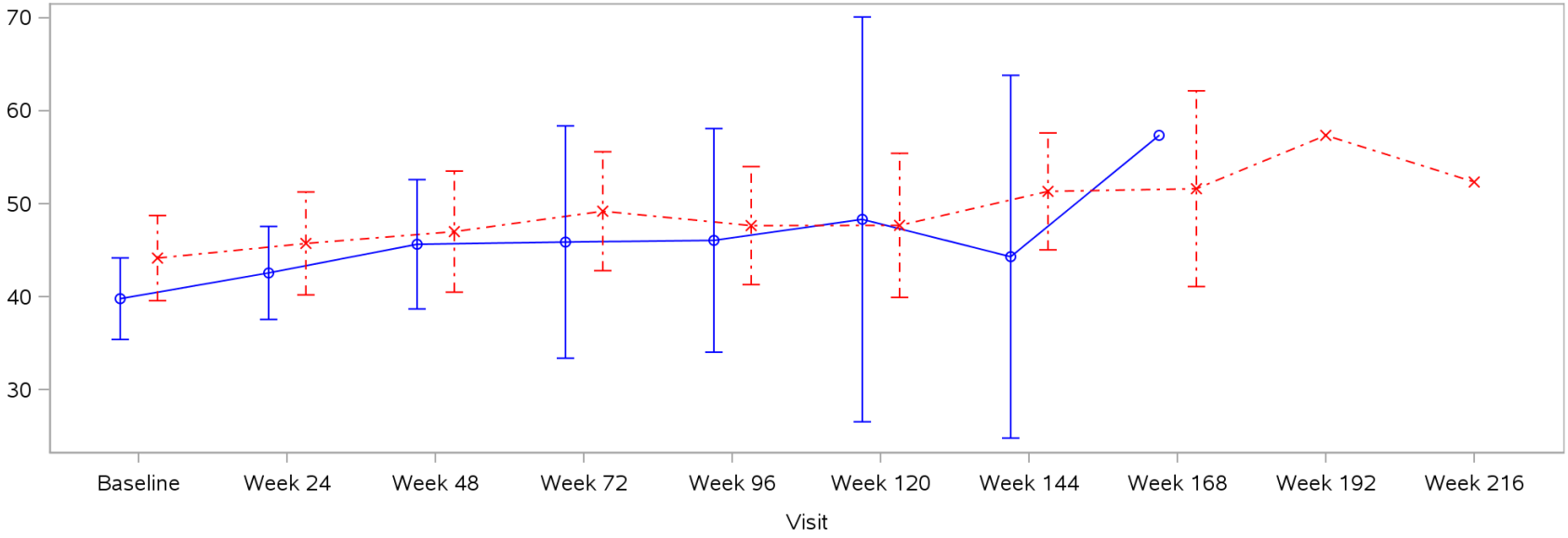
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Social Role Functioning Domain Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	-0,378	1,649	28	28	19	3,007	2,085	-3,384	2,702	-8,884	2,116	0,2193	0,7730

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36SRF_ST.xls
11SEP2020 16:04

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Social Role Functioning Domain Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	19	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36SRF.pdf
02NOV2019 9:56

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Social Role Functioning Domain Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	44,157	11,562	28	100,0	28	100,0	39,793	11,293
	Week 24		19	70,4	19	100,0	45,731	11,463	20	71,4	19	95,0	42,564	10,365
	Week 48		16	59,3	16	100,0	47,001	12,206	9	32,1	9	100,0	45,642	9,038
	Week 72		16	59,3	16	100,0	49,194	11,987	8	28,6	7	87,5	45,881	13,490
	Week 96		15	55,6	15	100,0	47,648	11,442	8	28,6	8	100,0	46,060	14,369
	Week 120		14	51,9	14	100,0	47,671	13,404	5	17,9	5	100,0	48,316	17,512
	Week 144		10	37,0	10	100,0	51,323	8,780	5	17,9	5	100,0	44,304	15,696
	Week 168		7	25,9	7	100,0	51,610	11,369	2	7,1	2	100,0	57,340	0,000
	Week 192		2	7,4	2	100,0	57,340	0,000						
	Week 216		1	3,7	1	100,0	52,330	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	38,957	16,116	6	21,4	6	100,0	37,285	10,028

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36SRF_SG.xls
01NOV2019 20:41

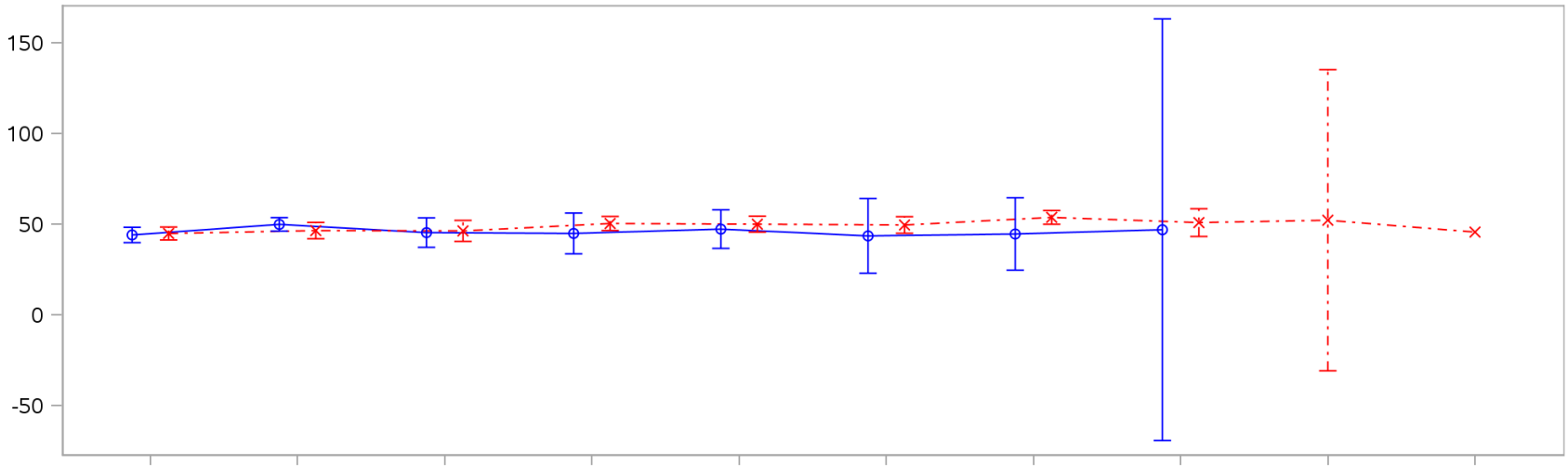
POPULATION: AQP4 Positive Population
ENDPOINT: Change from baseline, Short Form Generic Health Survey (SF-36): Mental Health Domain Score
MODEL: Stratified analysis (stratification factors: baseline ARR (1, >1); geographic region (Asia, EU/Other))
STUDY: BN40898
Analysis of MMRM

		SA237					Placebo					Difference between Treatments (SA237 vs Placebo)				Effects	
		N			Statistics		N			Statistics		Statistics				Statistics	
Subgroup	Level	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	Total	with baseline value	included in analysis[1]	LSMeans[2]	SE (LSMeans)	LSMeans[3]	SE (LSMeans)	95% Lower CL	95% Upper CL	p-value (treatment)	p-value (visit)
All	n/a	27	27	19	1,403	1,415	28	28	19	2,711	1,830	-1,308	2,366	-6,167	3,550	0,5850	0,4558

[1] Patients with a value at baseline and at least one post-baseline value. [2] LSMeans of change from baseline from MMRM (including all available records from all visits). [3] Contrasts from MMRM.
Factors/covariates: treatment, visit, treatment-by-visit interaction, baseline value. Adjusted for randomization stratification factors.
The output is restricted to Week 144 due to low number of observations at later visits leading to non-convergence.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_ACE_SA237/prod/program/pro_mmrm.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mmrm_307_06JUN2018_AQPP_SF36MTH_ST.xls
11SEP2020 15:59

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Mental Health Domain Score
MODEL: --
STUDY: BN40898
Plot of Mean and 95% CI by Visit



Placebo n	28	19	9	7	8	5	5	2	0	0
SA237 n	27	19	16	16	15	14	10	7	2	1

Treatment Group — Placebo (N=28) — SA237 (N=27)

The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/g_pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/g_pro_mean_307_06JUN2018_AQPP_SF36MTH.pdf
02NOV2019 9:53

POPULATION: AQP4 Positive Population
ENDPOINT: Short Form Generic Health Survey (SF-36): Mental Health Domain Score
MODEL: --
STUDY: BN40898
Compliance/Mean

			SA237 (N=27)						Placebo (N=28)					
			Patients				Statistics		Patients				Statistics	
Subgroup Level	Visit	in study[1]	%	with value[1]	%	mean[2]	SD	in study[1]	%	with value[1]	%	mean[2]	SD	
All														
n/a	Baseline		27	100,0	27	100,0	44,860	9,027	28	100,0	28	100,0	44,048	10,946
	Week 24		19	70,4	19	100,0	46,463	9,353	20	71,4	19	95,0	49,903	7,711
	Week 48		16	59,3	16	100,0	46,289	10,871	9	32,1	9	100,0	45,346	10,581
	Week 72		16	59,3	16	100,0	50,376	7,289	8	28,6	7	87,5	44,889	12,151
	Week 96		15	55,6	15	100,0	49,996	7,951	8	28,6	8	100,0	47,270	12,735
	Week 120		14	51,9	14	100,0	49,560	7,930	5	17,9	5	100,0	43,542	16,585
	Week 144		10	37,0	10	100,0	53,746	5,297	5	17,9	5	100,0	44,590	16,082
	Week 168		7	25,9	7	100,0	50,869	8,274	2	7,1	2	100,0	46,945	12,947
	Week 192		2	7,4	2	100,0	52,180	9,249						
	Week 216		1	3,7	1	100,0	45,640	NE						
		End of Study (Discontinued)	3	11,1	3	100,0	38,660	18,372	6	21,4	6	100,0	39,532	8,857

[1] in study: number of subjects in study at respective visit; % based on baseline.
with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.
[2] mean: descriptive statistics - absolute values.
The SF36 domain and component scores range from 0-100. Higher scores indicate better quality of life.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/pro_mean.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/pro_mean_307_06JUN2018_AQPP_SF36MTH_SG.xls
01NOV2019 20:40

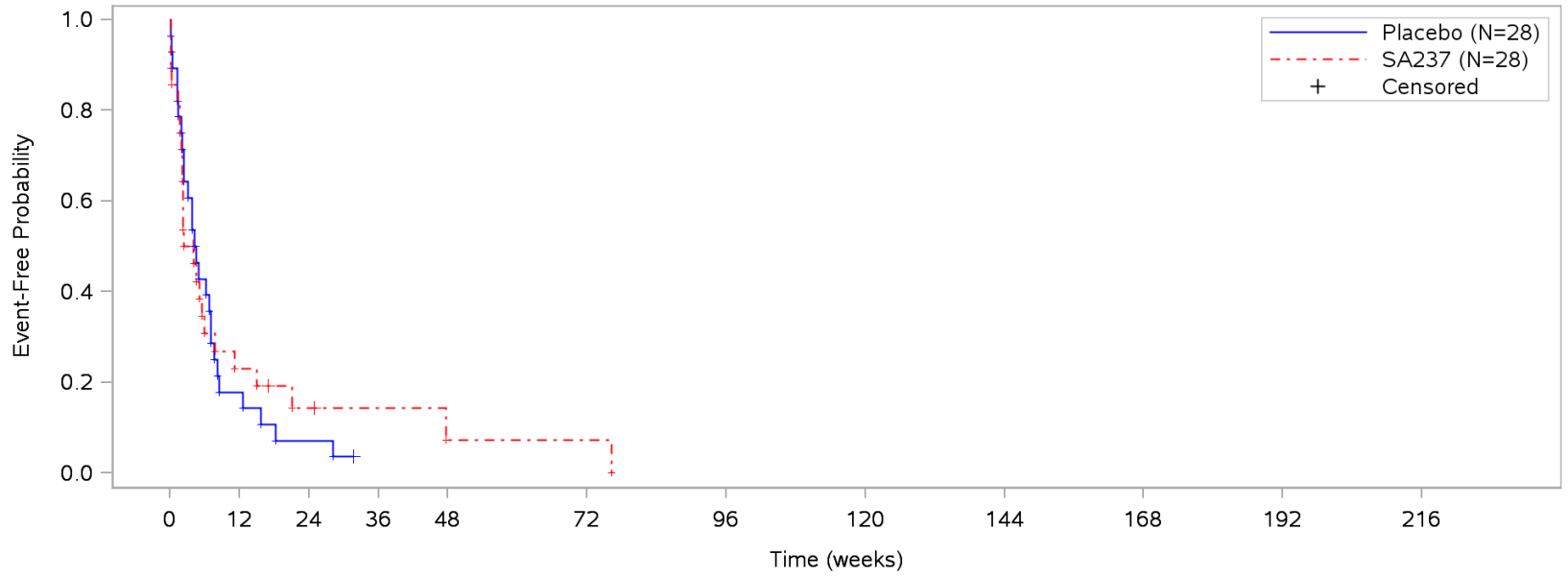
POPULATION: AQP4 Positive Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237												Placebo										SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	25	89.3	3	10.7	1.9	0.1	2.3	3.3	2.1	6.0	28	100.0	27	96.4	1	3.6	2.1	0.3	3.9	4.4	2.4	7.1	0.6854	0.89	0.51	1.57		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_ANYAE_S1.xls
24MAR2020 15:22

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Any AEs
MODEL: --
STUDY: BN40898
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	28	5	2	NE	NE	NE	NE	NE	NE	NE	NE	NE
SA237	28	6	3	2	1	1	NE	NE	NE	NE	NE	NE
Patients censored												
Placebo	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE
SA237	0	1	2	3	3	3	NE	NE	NE	NE	NE	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_307_07JUN2019_SAQP_ANYAE.pdf
24MAR2020 17:23

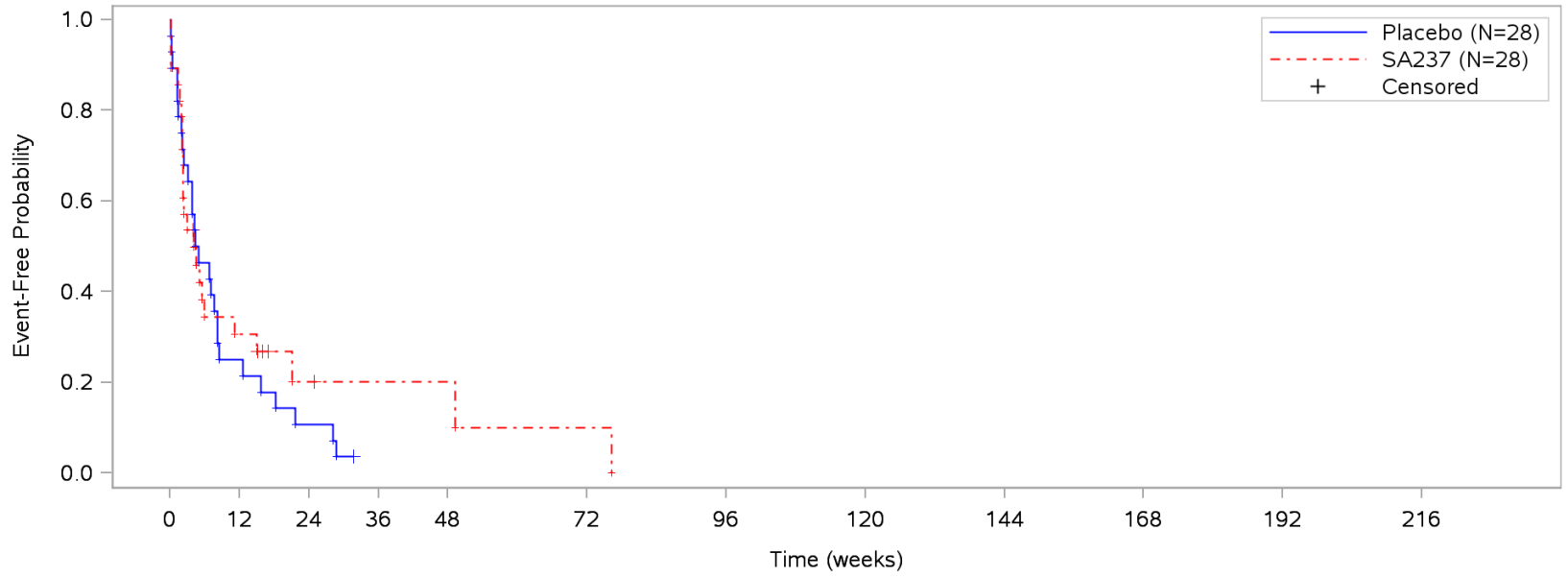
POPULATION: AQP4 Positive Population
ENDPOINT: Mild AEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237											Placebo											SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event					Patients		Patients with Event		Censored		Time To Event					Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	23	82.1	5	17.9	2.1	0.1	2.4	4.1	2.3	11.1	28	100.0	27	96.4	1	3.6	2.1	0.3	3.9	4.7	2.4	8.1	0.5169	0.83	0.46	1.47	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_AEMILD_S1.xls
24MAR2020 15:24

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Mild AEs
MODEL: --
STUDY: BN40898
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	28	7	3	NE	NE	NE	NE	NE	NE	NE	NE	NE
SA237	28	8	3	2	2	1	NE	NE	NE	NE	NE	NE
Patients censored												
Placebo	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE
SA237	0	1	4	5	5	5	NE	NE	NE	NE	NE	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_307_07JUN2019_SAQP_AEMILD.pdf
24MAR2020 17:23

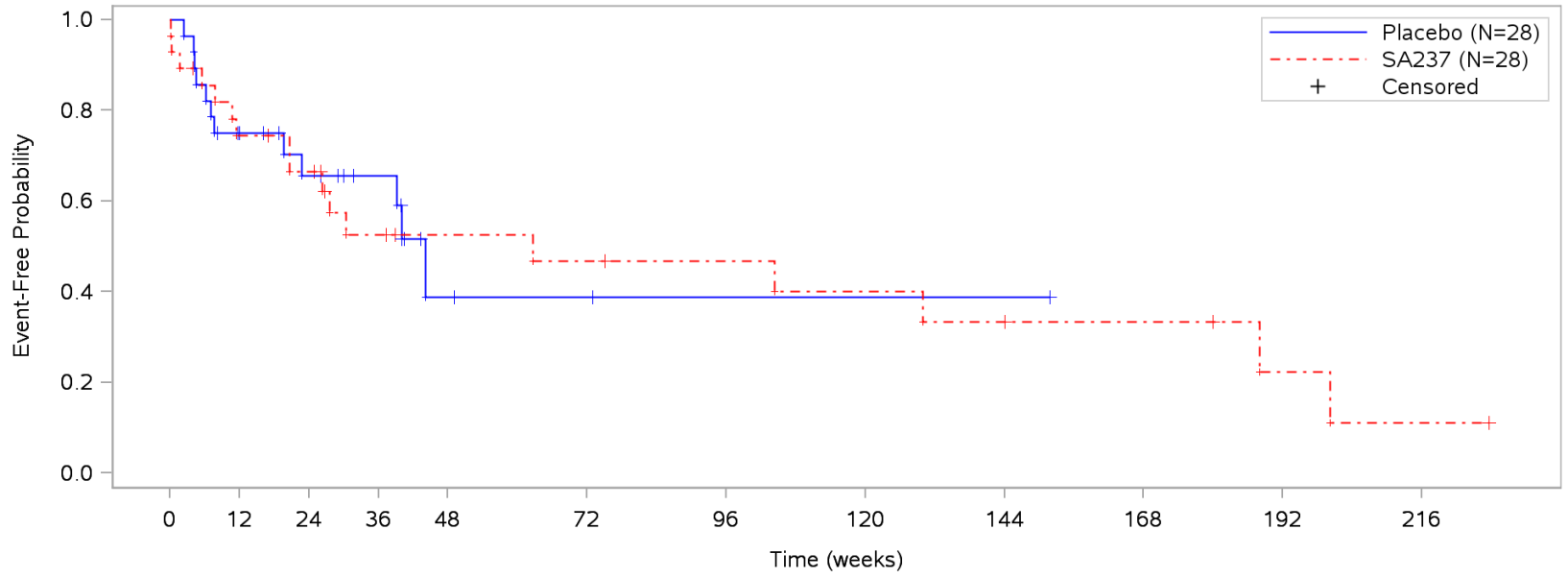
POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	17	60.7	11	39.3	11.4	0.3	27.6	62.6	20.7	188.0	28	100.0	12	42.9	16	57.1	13.7	4.1	40.0	44.1	19.7	NE	0.9805	1.01	0.46	2.20		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_AEMOD_S1.xls
25MAR2020 12:45

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Moderate AEs
MODEL: --
STUDY: BN40898
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	28	19	14	10	3	2	1	1	1	NE	NE	NE
SA237	28	20	17	11	9	8	7	6	5	4	2	1
Patients censored												
Placebo	0	3	5	9	13	14	15	15	15	NE	NE	NE
SA237	0	1	2	5	7	7	8	8	9	9	10	10

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_307_07JUN2019_SAQP_AEMOD.pdf
24MAR2020 17:24

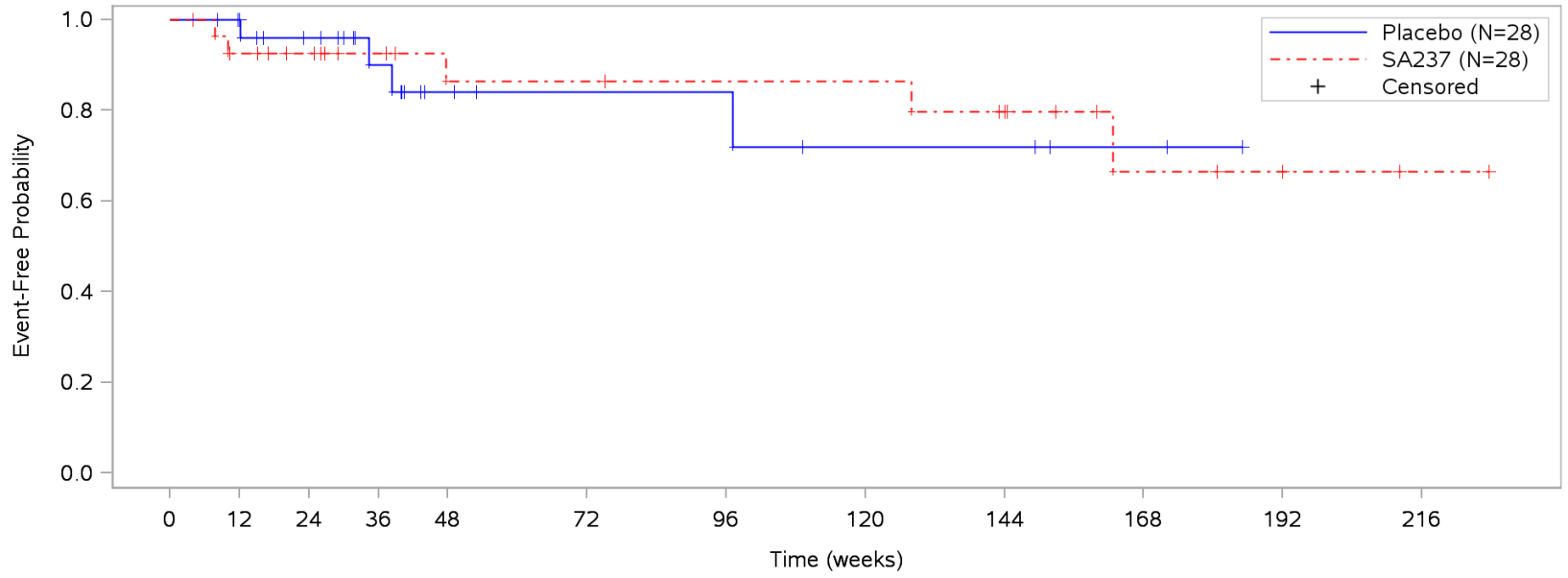
POPULATION: AQP4 Positive Population
ENDPOINT: Severe AEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo							
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio						Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL			Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	5	17.9	23	82.1	162.7	10.0	NE	NE	162.7	NE	28	100.0	4	14.3	24	85.7	97.1	12.1	NE	NE	97.1	NE	-	-	-	-			Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_AESEV_S1.xls
24MAR2020 15:26

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Severe AEs
MODEL: --
STUDY: BN40898
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	28	26	21	15	9	7	7	5	5	3	NE	NE
SA237	28	24	21	17	14	14	13	13	10	5	4	1
Patients censored												
Placebo	0	3	6	11	16	18	18	19	19	21	NE	NE
SA237	0	2	5	9	11	11	12	12	15	18	21	22

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_307_07JUN2019_SAQP_AESEV.pdf
24MAR2020 17:25

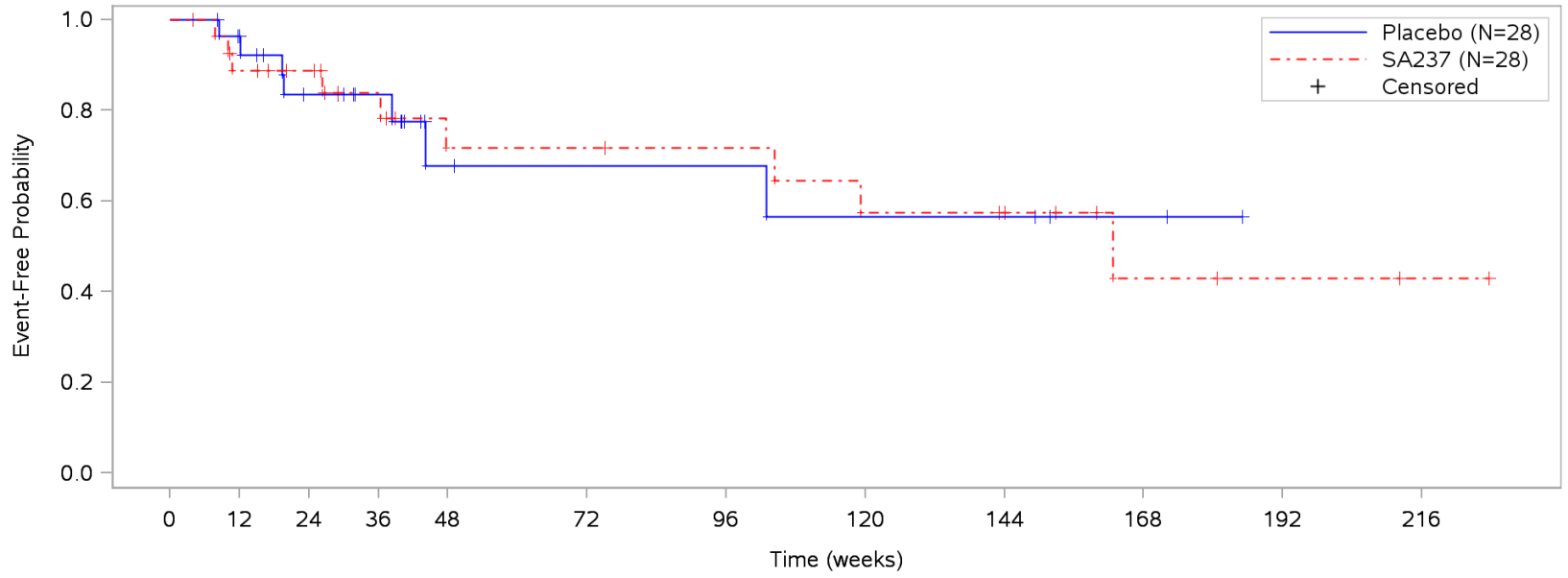
POPULATION: AQP4 Positive Population
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237												Placebo										SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	9	32.1	19	67.9	47.7	10.0	162.7	162.7	47.7	NE	28	100.0	7	25.0	21	75.0	44.1	12.1	NE	NE	44.1	NE	0.8796	1.08	0.40	2.92		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_AESAE_S1.xls
24MAR2020 15:29

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, Any SAEs
MODEL: --
STUDY: BN40898
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	28	25	18	14	7	6	6	5	5	3	NE	NE
SA237	28	23	20	15	11	11	10	8	7	3	2	1
Patients censored												
Placebo	0	3	6	10	15	16	16	16	16	18	NE	NE
SA237	0	2	5	9	11	11	12	12	14	16	17	18

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_307_07JUN2019_SAQP_AESAE.pdf
24MAR2020 17:26

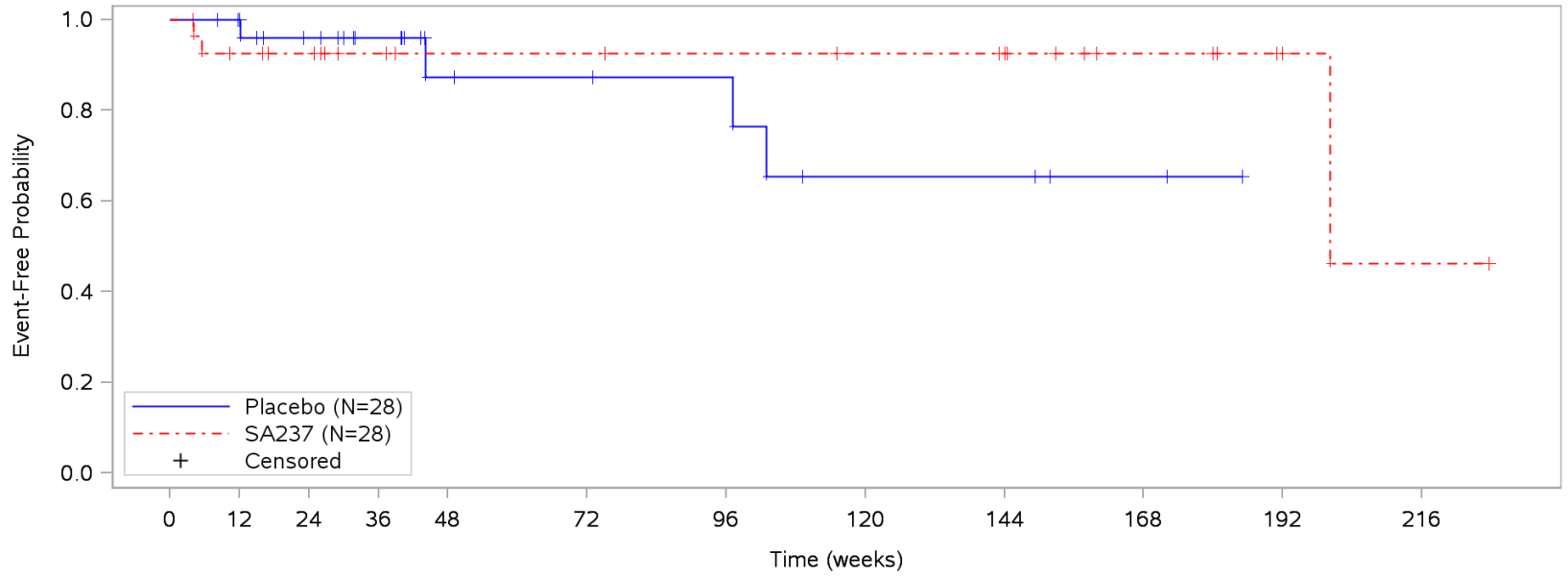
POPULATION: AQP4 Positive Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)												(N=28)											
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event					
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	28	100.0	3	10.7	25	89.3	200.1	5.6	NE	200.1	200.1	NE	28	100.0	4	14.3	24	85.7	102.9	12.1	NE	NE	97.1	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_ttd_307_07JUN2019_SAQP_AEDISC_S1.xls
24MAR2020 16:45

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, AEs leading to treatment discontinuation
MODEL: --
STUDY: BN40898
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	28	26	21	16	10	9	8	5	5	3	NE	NE
SA237	28	24	22	18	16	16	15	14	12	7	4	1
Patients censored												
Placebo	0	3	6	11	16	17	18	19	19	21	NE	NE
SA237	0	2	4	8	10	10	11	12	15	19	24	24

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_307_07JUN2019_SAQP_AEDISC.pdf
26MAR2020 18:31

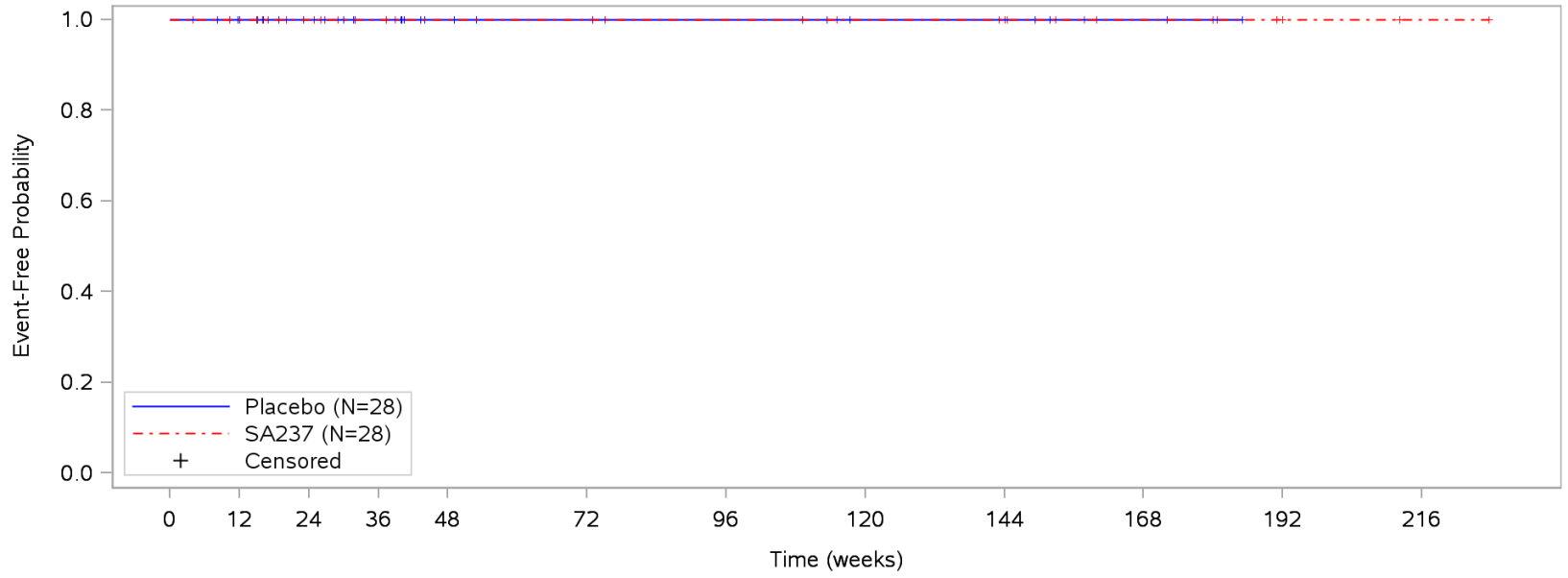
POPULATION: AQP4 Positive Population
ENDPOINT: AEs Grade 5 (AEs leading to death)
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical studies/RO5333787/CDP70210/BN40898/data analysis/ACE 3MSU/prod/output/saf tte 307 07JUN2019 SAQP AEDTH S1.xls
24MAR2020 15:27

POPULATION: AQP4 Positive Population
ENDPOINT: Time to First Event, AEs Grade 5 (AEs leading to death)
MODEL: --
STUDY: BN40898
Kaplan-Meier plot of time to first event (weeks)



Patients at risk												
Placebo	28	26	21	16	11	9	8	5	5	3	NE	NE
SA237	28	26	22	18	16	16	15	14	12	7	4	1
Patients censored												
Placebo	0	3	7	12	17	19	20	23	23	25	NE	NE
SA237	0	2	6	10	12	12	13	14	17	21	26	27

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/g_saf_tte_km_307_07JUN2019_SAQP_AEDTH.pdf
24MAR2020 17:26

POPULATION: AQP4 Positive Population
ENDPOINT: Any AEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis by SOC and PT (Safety)

			SA237											Placebo									SA237 vs. Placebo					
			Patients		Patients with		Censored		Time To Event					Patients		Patients with		Censored		Time To Event					Log-rank	Hazard Ratio				Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	pvalue, test=logrank	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	-Total	n/a	28	100,0	12	42,9	16	57,1	56,3	2,0	76,1	76,1	56,3	NE	28	100,0	7	25,0	21	75,0	40,6	4,3	NE	NE	40,6	NE	0,3835	1,52	0,59	3,93	Convergence criterion (GCONV=1E-8) satisfied.	
	Anaemia	n/a	28	100,0	3	10,7	25	89,3	NE	20,7	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	13,1	NE	NE	90,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Anaemia macrocytic	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Autoimmune thrombocytopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	44,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperfibrinogenaemia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	4,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hypochromic anaemia	n/a	28	100,0	1	3,6	27	96,4	NE	76,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hypofibrinogenaemia	n/a	28	100,0	1	3,6	27	96,4	NE	76,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Iron deficiency anaemia	n/a	28	100,0	2	7,1	26	92,9	NE	24,1	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	109,0	NE	NE	109,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Leukocytosis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Leukopenia	n/a	28	100,0	3	10,7	25	89,3	NE	76,1	NE	NE	NE	NE	28	100,0	4	14,3	24	85,7	76,0	28,1	NE	NE	76,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Lymphopenia	n/a	28	100,0	2	7,1	26	92,9	NE	56,3	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	12,9	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Neutropenia	n/a	28	100,0	1	3,6	27	96,4	NE	80,4	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	13,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Pancytopenia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Thrombocytopenia	n/a	28	100,0	1	3,6	27	96,4	NE	39,3	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	117,3	NE	NE	117,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	9,7	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Angina pectoris	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Bradycardia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Palpitations	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	111,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Gilbert's syndrome	n/a	28	100,0	1	3,6	27	96,4	NE	111,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	29,1	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Tinnitus	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	70,1	NE	NE	70,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Vertigo	n/a	28	100,0	2	7,1	26	92,9	NE	29,1	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	35,7	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	16,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Cushingoid	n/a	28	100,0	1	3,6	27	96,4	NE	65,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hypothyroidism	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	16,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Thyroiditis	n/a	28	100,0	1	3,6	27	96,4	NE	35,7	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	-Total	n/a	28	100,0	5	17,9	23	82,1	104,3	10,0	NE	NE	104,3	NE	28	100,0	2	7,1	26	92,9	NE	31,3	NE	NE	61,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Asthenopia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	31,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Cataract	n/a	28	100,0	1	3,6	27	96,4	NE	104,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Conjunctival haemorrhage	n/a	28	100,0	1	3,6	27	96,4	NE	52,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Conjunctivitis	n/a	28	100,0	1	3,6	27	96,4	NE	75,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Conjunctivitis allergic	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Dry eye	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Optic nerve cupping	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	61,3	NE	NE	61,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Retinal haemorrhage	n/a	28	100,0	1	3,6	27	96,4	NE	17,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	-Total	n/a	28	100,0	12	42,9	16	57,1	11,1	0,3	81,0	144,1	15,0	NE	28	100,0	12	42,9	16	57,1	19,7	6,6	44,1	50,3	28,6	NE	0,8956	0,93	0,42	2,14	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal distension	n/a	28	100,0	2	7,1	26	92,9	NE	156,9	NE	NE	156,9	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain	n/a	28	100,0	1	3,6	27	96,4	202,0	202,0	NE	NE	202,0	NE	28	100,0	1	3,6	27	96,4	NE	19,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain upper	n/a	28	100,0	1	3,6	27	96,4	NE	81,0	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	70,1	NE	NE	70,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Cheilitis	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Colitis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Constipation	n/a	28	100,0	2	7,1	26	92,9	NE	0,3	NE	NE	NE	NE	28	100,0	6	21,4	22	78,6	70,0	7,9	NE	NE	70,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Dental caries	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	112,0	NE	NE	112,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Diarrhoea	n/a	28	100,0	1	3,6	27	96,4	NE	27,4	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	39,7	NE	NE	148,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Dyspepsia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Flatulence	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	98,9	NE	NE	98,9	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Gastritis	n/a	28	100,0	4	14,3	24	85,7	NE	15,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

	Gastrointestinal disorder	n/a	28	100,0	1	3,6	27	96,4	NE	104,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Gastrooesophageal reflux disease	n/a	28	100,0	1	3,6	27	96,4	NE	102,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Gingival bleeding	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	44,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Glossitis	n/a	28	100,0	1	3,6	27	96,4	NE	18,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Haemorrhoids	n/a	28	100,0	2	7,1	26	92,9	NE	18,7	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hiatus hernia	n/a	28	100,0	1	3,6	27	96,4	NE	37,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Large intestine polyp	n/a	28	100,0	1	3,6	27	96,4	NE	41,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Nausea	n/a	28	100,0	2	7,1	26	92,9	NE	81,0	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	28,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oesophagitis	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oral mucosa erosion	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Stomatitis	n/a	28	100,0	1	3,6	27	96,4	NE	144,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Toothache	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Vomiting	n/a	28	100,0	1	3,6	27	96,4	NE	81,0	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	28,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
General disorders and administration site conditions	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	161,0	NE	NE	161,0	NE	28	100,0	8	28,6	20	71,4	34,4	1,3	NE	NE	34,4	NE	0,0188	0,19	0,04	0,89	Convergence criterion (GCONV=1E-8) satisfied.
	Asthenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	28,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Chest discomfort	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Chest pain	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	50,7	NE	NE	50,7	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Face oedema	n/a	28	100,0	1	3,6	27	96,4	NE	161,0	NE	NE	161,0	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Malaise	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Non-cardiac chest pain	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	70,1	NE	NE	70,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oedema peripheral	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pyrexia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	5	17,9	23	82,1	NE	1,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Hepatobiliary disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	92,1	32,9	NE	NE	60,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hepatic function abnormal	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	92,1	NE	NE	92,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hyperbilirubinaemia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypertransaminasaemia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	32,9	NE	NE	60,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Immune system disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	38,1	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	103,1	NE	NE	103,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Allergy to arthropod sting	n/a	28	100,0	1	3,6	27	96,4	NE	38,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Drug hypersensitivity	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	103,1	NE	NE	103,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Infections and infestations	-Total	n/a	28	100,0	19	67,9	9	32,1	4,3	1,7	14,7	21,1	7,9	46,9	28	100,0	18	64,3	10	35,7	9,3	3,1	28,7	31,1	10,9	48,4	0,4766	1,27	0,66	2,42	Convergence criterion (GCONV=1E-8) satisfied.
	Appendicitis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	38,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Bacteriuria	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	19,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Bronchitis	n/a	28	100,0	2	7,1	26	92,9	NE	16,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Cystitis	n/a	28	100,0	2	7,1	26	92,9	188,0	188,0	NE	NE	188,0	NE	28	100,0	3	10,7	25	89,3	NE	4,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Ear infection	n/a	28	100,0	1	3,6	27	96,4	NE	81,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Escherichia sepsis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	106,1	NE	NE	106,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Gastroenteritis	n/a	28	100,0	1	3,6	27	96,4	NE	25,9	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	75,7	NE	NE	75,7	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Herpes simplex	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	34,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Herpes zoster	n/a	28	100,0	1	3,6	27	96,4	NE	103,9	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Influenza	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	50,1	43,7	NE	NE	46,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Lower respiratory tract infection	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	100,1	NE	NE	100,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Nail infection	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Nasopharyngitis	n/a	28	100,0	8	28,6	20	71,4	66,1	7,9	203,1	203,1	66,1	203,1	28	100,0	5	17,9	23	82,1	62,4	10,1	NE	NE	62,4	NE	0,8313	1,13	0,36	3,62	Convergence criterion (GCONV=1E-8) satisfied.
	Onychomycosis	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oral herpes	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	14,4	NE	NE	90,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Periodontitis	n/a	28	100,0	1	3,6	27	96,4	NE	150,1	NE	NE	150,1	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pertussis	n/a	28	100,0	1	3,6	27	96,4	NE	78,4	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pharyngitis	n/a	28	100,0	3	10,7	25	89,3	NE	65,9	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	180,0	48,4	NE	180,0	180,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pneumonia	n/a	28	100,0	1	3,6	27	96,4	NE	26,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rhinitis	n/a	28	100,0	1	3,6	27	96,4	NE	46,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Salpingitis	n/a	28	100,0	1	3,6	27	96,4	NE	21,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Sinusitis	n/a	28	100,0	1	3,6	27	96,4	NE	85,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Tinea cruris	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	13,9	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.

	Tinea versicolour	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	85,1	NE	NE	85,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Tooth abscess	n/a	28	100,0	1	3,6	27	96,4	NE	20,4	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Upper respiratory tract infection	n/a	28	100,0	5	17,9	23	82,1	NE	1,7	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	85,7	37,0	NE	NE	85,7	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Urinary tract infection	n/a	28	100,0	4	14,3	24	85,7	NE	4,3	NE	NE	NE	NE	28	100,0	5	17,9	23	82,1	97,1	24,1	NE	NE	71,9	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Viral upper respiratory tract infection	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	110,3	NE	NE	110,3	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
Injury, poisoning and procedural complications	-Total	n/a	28	100,0	7	25,0	21	75,0	132,3	2,5	218,6	218,6	132,3	218,6	28	100,0	5	17,9	23	82,1	67,4	22,7	NE	NE	67,4	NE	0,6702	0,76	0,22	2,64		Convergence criterion (GCONV=1E-8) satisfied.					
	Compression fracture	n/a	28	100,0	2	7,1	26	92,9	218,6	138,9	218,6	218,6	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Contusion	n/a	28	100,0	1	3,6	27	96,4	NE	36,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Excoriation	n/a	28	100,0	1	3,6	27	96,4	NE	96,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Fall	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	22,7	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Femur fracture	n/a	28	100,0	1	3,6	27	96,4	NE	36,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Injection Related Reactions	n/a	28	100,0	2	7,1	26	92,9	NE	2,3	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	84,4	NE	NE	84,4	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Joint injury	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	22,7	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Laceration	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	29,0	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Ligament sprain	n/a	28	100,0	1	3,6	27	96,4	NE	132,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Limb injury	n/a	28	100,0	1	3,6	27	96,4	NE	85,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Rib fracture	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	67,4	NE	NE	67,4	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Spinal compression fracture	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Thermal burn	n/a	28	100,0	1	3,6	27	96,4	NE	78,6	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	134,6	NE	NE	134,6	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Wound	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
Investigations	-Total	n/a	28	100,0	9	32,1	19	67,9	29,3	4,1	200,1	200,1	29,3	NE	28	100,0	10	35,7	18	64,3	21,1	2,1	98,4	98,4	85,1	NE	0,2944	0,60	0,23	1,56		Convergence criterion (GCONV=1E-8) satisfied.					
	Alanine aminotransferase increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	36,1	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Aspartate aminotransferase increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	36,1	NE	NE	128,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Blood alkaline phosphatase increased	n/a	28	100,0	1	3,6	27	96,4	NE	28,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Blood cholesterol increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Blood creatine phosphokinase increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	85,1	NE	NE	85,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Blood fibrinogen increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Blood lactate dehydrogenase increased	n/a	28	100,0	1	3,6	27	96,4	NE	92,6	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Blood sodium increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Blood triglycerides increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	98,4	NE	NE	98,4	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Hepatitis B DNA assay positive	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	International normalised ratio increased	n/a	28	100,0	1	3,6	27	96,4	NE	79,4	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Low density lipoprotein increased	n/a	28	100,0	1	3,6	27	96,4	NE	132,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Lymphocyte count decreased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Neutrophil count decreased	n/a	28	100,0	2	7,1	26	92,9	200,1	27,6	NE	200,1	200,1	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Protein urine present	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Serum ferritin decreased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	16,9	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Urobilinogen urine increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Weight decreased	n/a	28	100,0	1	3,6	27	96,4	NE	29,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Weight increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	120,1	NE	NE	120,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	White blood cell count decreased	n/a	28	100,0	1	3,6	27	96,4	NE	27,6	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
Metabolism and nutrition disorders	-Total	n/a	28	100,0	6	21,4	22	78,6	73,1	2,5	NE	NE	73,1	NE	28	100,0	7	25,0	21	75,0	61,1	8,1	178,6	178,6	61,1	178,6	0,5823	0,73	0,24	2,25		Convergence criterion (GCONV=1E-8) satisfied.					
	Dyslipidaemia	n/a	28	100,0	1	3,6	27	96,4	NE	144,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Glucose tolerance impaired	n/a	28	100,0	1	3,6	27	96,4	216,7	NE	NE	216,7	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Hypercholesterolaemia	n/a	28	100,0	3	10,7	25	89,3	NE	51,6	NE	NE	NE	NE	28	100,0	5	17,9	23	82,1	61,1	11,4	NE	NE	61,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Hyperglycaemia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	178,6	178,6	NE	178,6	178,6	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Hyperlipidaemia	n/a	28	100,0	2	7,1	26	92,9	NE	32,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Iron deficiency	n/a	28	100,0	2	7,1	26	92,9	NE	18,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Obesity	n/a	28	100,0	1	3,6	27	96,4	NE	112,6	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
Musculoskeletal and connective tissue disorders	-Total	n/a	28	100,0	10	35,7	18	64,3	31,6	20,7	135,6	152,1	31,6	NE	28	100,0	6	21,4	22	78,6	62,0	12,6	NE	NE	62,0	NE	0,6946	1,23	0,44	3,48		Convergence criterion (GCONV=1E-8) satisfied.					
	Arthralgia	n/a	28	100,0	3	10,7	25	89,3	NE	23,7	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					
	Back pain	n/a	28	100,0	3	10,7	25	89,3	NE	42,3	NE	NE	NE	NE	28	100,0	4	14,3	24	85,7	131,4	27,6	NE	NE	68,4	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.					

	Musculoskeletal disorder	n/a	28	100,0	1	3,6	27	96,4	NE	135,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Musculoskeletal stiffness	n/a	28	100,0	1	3,6	27	96,4	NE	59,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Myalgia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	12,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Myopathy toxic	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	68,7	NE	NE	68,7	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pain in extremity	n/a	28	100,0	1	3,6	27	96,4	NE	30,4	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	62,0	NE	NE	62,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Sjogren's syndrome	n/a	28	100,0	1	3,6	27	96,4	NE	152,1	NE	NE	152,1	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Spinal osteoarthritis	n/a	28	100,0	1	3,6	27	96,4	NE	20,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Spinal pain	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	34,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	28	100,0	3	10,7	25	89,3	162,7	155,3	NE	NE	155,3	NE	NE	28	100,0	2	7,1	26	92,9	NE	12,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Colon adenoma	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hepatic cancer	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	12,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Lipoma	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	15,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Thyroid neoplasm	n/a	28	100,0	1	3,6	27	96,4	NE	155,3	NE	NE	155,3	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Uterine leiomyoma	n/a	28	100,0	1	3,6	27	96,4	NE	162,7	NE	NE	162,7	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Nervous system disorders	-Total	n/a	28	100,0	9	32,1	19	67,9	19,3	8,1	NE	NE	72,0	NE	NE	28	100,0	7	25,0	21	75,0	48,1	16,0	107,1	107,1	48,1	NE	0,6415	1,27	0,47	3,43	Convergence criterion (GCONV=1E-8) satisfied.
	Balance disorder	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	31,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Burning sensation	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	50,7	NE	NE	50,7	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Cognitive disorder	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	21,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dizziness	n/a	28	100,0	2	7,1	26	92,9	NE	81,0	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dysaesthesia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	107,1	NE	NE	107,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Headache	n/a	28	100,0	8	28,6	20	71,4	72,0	8,1	NE	NE	72,0	NE	NE	28	100,0	3	10,7	25	89,3	106,0	40,4	NE	NE	106,0	NE	0,1505	2,57	0,68	9,75	Convergence criterion (GCONV=1E-8) satisfied.
	Intercostal neuralgia	n/a	28	100,0	1	3,6	27	96,4	NE	70,3	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	95,3	NE	NE	95,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Muscle spasticity	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	16,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Myelopathy	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Paraesthesia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	34,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Restless legs syndrome	n/a	28	100,0	1	3,6	27	96,4	NE	38,9	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Tension headache	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Psychiatric disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	47,7	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Anxiety	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Depression	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Suicide attempt	n/a	28	100,0	1	3,6	27	96,4	NE	47,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Renal and urinary disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	31,9	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	19,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dysuria	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	19,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Leukocyturia	n/a	28	100,0	2	7,1	26	92,9	NE	31,9	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Reproductive system and breast disorders	-Total	n/a	28	100,0	6	21,4	22	78,6	101,0	6,0	NE	NE	42,9	NE	NE	28	100,0	2	7,1	26	92,9	NE	15,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Amenorrhoea	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Cervical dysplasia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dysmenorrhoea	n/a	28	100,0	1	3,6	27	96,4	NE	42,9	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Genital haemorrhage	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Menstrual disorder	n/a	28	100,0	1	3,6	27	96,4	NE	29,3	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Uterine cervical erosion	n/a	28	100,0	1	3,6	27	96,4	NE	34,9	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Uterine polyp	n/a	28	100,0	1	3,6	27	96,4	NE	101,0	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	15,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Vulvovaginal dryness	n/a	28	100,0	1	3,6	27	96,4	NE	116,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Respiratory, thoracic and mediastinal disorders	-Total	n/a	28	100,0	6	21,4	22	78,6	81,7	11,1	NE	NE	81,7	NE	NE	28	100,0	4	14,3	24	85,7	147,0	15,1	NE	NE	147,0	NE	0,7080	1,28	0,36	4,58	Convergence criterion (GCONV=1E-8) satisfied.
	Cough	n/a	28	100,0	1	3,6	27	96,4	NE	51,1	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	27,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Epistaxis	n/a	28	100,0	2	7,1	26	92,9	NE	11,1	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oropharyngeal pain	n/a	28	100,0	3	10,7	25	89,3	NE	22,4	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	15,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rhinitis allergic	n/a	28	100,0	2	7,1	26	92,9	NE	81,7	NE	NE	179,0	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rhinorrhoea	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	147,0	NE	NE	147,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Skin and subcutaneous tissue disorders	-Total	n/a	28	100,0	10	35,7	18	64,3	87,1	2,3	102,7	130,6	87,1	NE	NE	28	100,0	6	21,4	22	78,6	155,1	4,0	NE	NE	155,1	NE	0,5421	1,37	0,49	3,82	Convergence criterion (GCONV=1E-8) satisfied.
	Acne	n/a	28	100,0	1	3,6	27	96,4	NE	81,7	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Alopecia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dermatitis allergic	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	25,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.

	Eczema	n/a	28	100,0	2	7,1	26	92,9	NE	87,1	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Erythema	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	20,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Haemorrhage subcutaneous	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	22,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Papule	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	159,6	159,6	NE	NE	159,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pruritus	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	107,1	NE	NE	107,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rash	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	155,1	155,1	NE	NE	155,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rash pruritic	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Seborrhoeic dermatitis	n/a	28	100,0	1	3,6	27	96,4	NE	102,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Skin exfoliation	n/a	28	100,0	1	3,6	27	96,4	NE	102,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Solar dermatitis	n/a	28	100,0	1	3,6	27	96,4	NE	130,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Urticaria	n/a	28	100,0	2	7,1	26	92,9	NE	88,9	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Vascular disorders	-Total	n/a	28	100,0	3	10,7	25	89,3	NE	67,7	NE	NE	138,9	NE	NE	28	100,0	1	3,6	27	96,4	NE	13,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hot flush	n/a	28	100,0	1	3,6	27	96,4	NE	67,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypertension	n/a	28	100,0	2	7,1	26	92,9	NE	131,9	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypotension	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	13,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CD970210/share/pool_ACE_SA237/work/work_all/program/saf_tsp.sas
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25NOV2020 16:16

POPULATION: AqP4 Positive Population
ENDPOINT: Mild AEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis by SOC and PT (Safety)

			SA237											Placebo									SA237 vs. Placebo					
			Patients		Patients with		Censored		Time To Event					Patients		Patients with		Censored		Time To Event					Log-rank	Hazard Ratio				Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	pvalue, test=logrank	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	-Total	n/a	28	100,0	10	35,7	18	64,3	56,3	2,0	76,1	77,1	56,3	NE	28	100,0	7	25,0	21	75,0	40,6	21,1	109,0	109,0	40,6	NE	0,7574	1,17	0,43	3,15	Convergence criterion (GCONV=1E-8) satisfied.	
	Anaemia	n/a	28	100,0	2	7,1	26	92,9	NE	76,1	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	90,1	29,1	NE	NE	72,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperfibrinogenaemia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hypochromic anaemia	n/a	28	100,0	1	3,6	27	96,4	NE	76,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hypofibrinogenaemia	n/a	28	100,0	1	3,6	27	96,4	NE	76,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Iron deficiency anaemia	n/a	28	100,0	1	3,6	27	96,4	NE	24,1	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	109,0	NE	NE	109,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Leukocytosis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	65,1	NE	NE	65,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Leukopenia	n/a	28	100,0	3	10,7	25	89,3	NE	76,1	NE	NE	NE	NE	28	100,0	4	14,3	24	85,7	92,4	21,1	NE	NE	92,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Lymphopenia	n/a	28	100,0	2	7,1	26	92,9	NE	56,3	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	12,9	NE	NE	62,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Neutropenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	65,1	NE	NE	65,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Pancytopenia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Thrombocytopenia	n/a	28	100,0	1	3,6	27	96,4	NE	39,3	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	117,3	NE	NE	117,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Cardiac disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	9,7	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Angina pectoris	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Bradycardia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Palpitations	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Congenital, familial and genetic disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	111,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Gilbert's syndrome	n/a	28	100,0	1	3,6	27	96,4	NE	111,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Ear and labyrinth disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	29,1	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Tinnitus	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	70,1	NE	NE	70,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Vertigo	n/a	28	100,0	2	7,1	26	92,9	NE	29,1	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Endocrine disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	35,7	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	16,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Cushingoid	n/a	28	100,0	1	3,6	27	96,4	NE	65,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hypothyroidism	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	16,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Thyroiditis	n/a	28	100,0	1	3,6	27	96,4	NE	35,7	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	-Total	n/a	28	100,0	4	14,3	24	85,7	NE	10,0	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	31,3	NE	NE	61,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Asthenopia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	31,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Conjunctival haemorrhage	n/a	28	100,0	1	3,6	27	96,4	NE	52,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Conjunctivitis	n/a	28	100,0	1	3,6	27	96,4	NE	75,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Conjunctivitis allergic	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Dry eye	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Optic nerve cupping	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	61,3	NE	NE	61,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Retinal haemorrhage	n/a	28	100,0	1	3,6	27	96,4	NE	17,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	-Total	n/a	28	100,0	10	35,7	18	64,3	15,0	3,3	144,1	NE	18,7	NE	28	100,0	10	35,7	18	64,3	44,1	6,6	98,9	98,9	44,1	NE	0,8775	0,93	0,38	2,27	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal distension	n/a	28	100,0	2	7,1	26	92,9	NE	156,9	NE	NE	156,9	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain	n/a	28	100,0	1	3,6	27	96,4	202,0	202,0	NE	NE	202,0	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain upper	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	70,1	NE	NE	70,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Cheilitis	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Colitis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Constipation	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	5	17,9	23	82,1	104,7	7,9	NE	NE	70,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Dental caries	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Diarrhoea	n/a	28	100,0	1	3,6	27	96,4	NE	27,4	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	148,6	NE	NE	148,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Dyspepsia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Flatulence	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	98,9	NE	NE	98,9	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Gastritis	n/a	28	100,0	4	14,3	24	85,7	NE	15,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Gingival bleeding	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	44,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Glossitis	n/a	28	100,0	1	3,6	27	96,4	NE	18,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Haemorrhoids	n/a	28	100,0	2	7,1	26	92,9	NE	18,7	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

	Hiatus hernia	n/a	28	100,0	1	3,6	27	96,4	NE	37,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Large intestine polyp	n/a	28	100,0	1	3,6	27	96,4	NE	41,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Nausea	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	28,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oesophagitis	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oral mucosa erosion	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Stomatitis	n/a	28	100,0	1	3,6	27	96,4	NE	144,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Vomiting	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	28,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
General disorders and administration site conditions	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	161,0	NE	NE	161,0	NE	28	100,0	7	25,0	21	75,0	70,1	1,3	NE	NE	70,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Asthenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	28,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Chest discomfort	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Face oedema	n/a	28	100,0	1	3,6	27	96,4	NE	161,0	NE	NE	161,0	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Malaise	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Non-cardiac chest pain	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	70,1	NE	NE	70,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oedema peripheral	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pyrexia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	5	17,9	23	82,1	84,4	1,3	NE	NE	84,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Hepatobiliary disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	27,9	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	92,1	32,9	NE	NE	60,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hepatic function abnormal	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	92,1	NE	NE	92,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hyperbilirubinaemia	n/a	28	100,0	1	3,6	27	96,4	NE	27,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypertransaminasaemia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	32,9	NE	NE	60,3	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Immune system disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	38,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Allergy to arthropod sting	n/a	28	100,0	1	3,6	27	96,4	NE	38,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Infections and infestations	-Total	n/a	28	100,0	17	60,7	11	39,3	4,6	2,3	21,1	25,6	11,1	49,1	28	100,0	15	53,6	13	46,4	12,4	3,1	31,1	43,7	19,4	85,1	0,4241	1,33	0,66	2,71	Convergence criterion (GCONV=1E-8) satisfied.
	Bacteriuria	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	19,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Bronchitis	n/a	28	100,0	1	3,6	27	96,4	NE	21,6	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Cystitis	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Gastroenteritis	n/a	28	100,0	1	3,6	27	96,4	NE	25,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Herpes zoster	n/a	28	100,0	1	3,6	27	96,4	NE	103,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Influenza	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	43,7	NE	NE	70,9	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Nail infection	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Nasopharyngitis	n/a	28	100,0	7	25,0	21	75,0	79,6	7,9	203,1	203,1	79,6	203,1	28	100,0	4	14,3	24	85,7	NE	10,1	NE	NE	NE	NE	0,6737	1,31	0,37	4,71	Convergence criterion (GCONV=1E-8) satisfied.
	Onychomycosis	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oral herpes	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	14,4	NE	NE	90,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pharyngitis	n/a	28	100,0	2	7,1	26	92,9	NE	65,9	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	180,0	48,4	NE	180,0	180,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rhinitis	n/a	28	100,0	1	3,6	27	96,4	NE	46,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Salpingitis	n/a	28	100,0	1	3,6	27	96,4	NE	21,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Sinusitis	n/a	28	100,0	1	3,6	27	96,4	NE	85,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Tinea cruris	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	13,9	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Tinea versicolour	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	85,1	NE	NE	85,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Tooth abscess	n/a	28	100,0	1	3,6	27	96,4	NE	20,4	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Upper respiratory tract infection	n/a	28	100,0	4	14,3	24	85,7	NE	4,6	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	85,7	37,0	NE	NE	85,7	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Urinary tract infection	n/a	28	100,0	3	10,7	25	89,3	NE	4,3	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	24,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Viral upper respiratory tract infection	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Injury, poisoning and procedural complications	-Total	n/a	28	100,0	5	17,9	23	82,1	218,6	2,3	218,6	218,6	NE	NE	28	100,0	5	17,9	23	82,1	84,4	22,7	NE	134,6	84,4	NE	0,3172	0,50	0,13	1,98	Convergence criterion (GCONV=1E-8) satisfied.
	Compression fracture	n/a	28	100,0	2	7,1	26	92,9	218,6	138,9	218,6	218,6	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Contusion	n/a	28	100,0	1	3,6	27	96,4	NE	36,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Excoriation	n/a	28	100,0	1	3,6	27	96,4	NE	96,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Injection Related Reactions	n/a	28	100,0	2	7,1	26	92,9	NE	2,3	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	84,4	NE	NE	84,4	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Joint injury	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	22,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Laceration	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	29,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Ligament sprain	n/a	28	100,0	1	3,6	27	96,4	NE	132,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Thermal burn	n/a	28	100,0	1	3,6	27	96,4	NE	78,6	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	134,6	NE	NE	134,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Wound	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Investigations	-Total	n/a	28	100,0	6	21,4	22	78,6	132,0	5,6	NE	NE	132,0	NE	28	100,0	8	28,6	20	71,4	85,1	2,1	NE	NE	85,1	NE	0,2996	0,57	0,19	1,68	Convergence criterion (GCONV=1E-8) satisfied.

	Alanine aminotransferase increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	36,1	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Aspartate aminotransferase increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	36,1	NE	NE	128,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Blood alkaline phosphatase increased	n/a	28	100,0	1	3,6	27	96,4	NE	28,1	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Blood cholesterol increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Blood creatine phosphokinase increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	85,1	NE	NE	85,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Blood fibrinogen increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Blood lactate dehydrogenase increased	n/a	28	100,0	1	3,6	27	96,4	NE	92,6	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Blood sodium increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Blood triglycerides increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	98,4	NE	NE	98,4	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Hepatitis B DNA assay positive	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Low density lipoprotein increased	n/a	28	100,0	1	3,6	27	96,4	NE	132,0	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Lymphocyte count decreased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Protein urine present	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Serum ferritin decreased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	21,1	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Urobilinogen urine increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Weight decreased	n/a	28	100,0	1	3,6	27	96,4	NE	29,3	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Metabolism and nutrition disorders	-Total	n/a	28	100,0	6	21,4	22	78,6	119,9	4,1	NE	NE	119,9	NE	NE	28	100,0	3	10,7	25	89,3	NE	8,1	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Dyslipidaemia	n/a	28	100,0	1	3,6	27	96,4	NE	144,1	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Glucose tolerance impaired	n/a	28	100,0	1	3,6	27	96,4	216,7	NE	NE	216,7	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Hypercholesterolaemia	n/a	28	100,0	3	10,7	25	89,3	NE	51,6	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	11,4	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Hyperglycaemia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Hyperlipidaemia	n/a	28	100,0	2	7,1	26	92,9	NE	32,1	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Iron deficiency	n/a	28	100,0	2	7,1	26	92,9	NE	18,3	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Musculoskeletal and connective tissue disorders	-Total	n/a	28	100,0	6	21,4	22	78,6	135,6	23,7	NE	NE	135,6	NE	NE	28	100,0	6	21,4	22	78,6	68,7	12,6	NE	NE	40,6	NE	0,4472	0,63	0,19	2,07		Convergence criterion (GCONV=1E-8) satisfied.				
	Arthralgia	n/a	28	100,0	3	10,7	25	89,3	NE	23,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Back pain	n/a	28	100,0	1	3,6	27	96,4	NE	42,3	NE	NE	NE	NE	NE	28	100,0	4	14,3	24	85,7	131,4	27,6	NE	NE	68,4	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Musculoskeletal disorder	n/a	28	100,0	1	3,6	27	96,4	NE	135,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Musculoskeletal stiffness	n/a	28	100,0	1	3,6	27	96,4	NE	59,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Myalgia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	12,6	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Myopathy toxic	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	68,7	NE	NE	68,7	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Sjogren's syndrome	n/a	28	100,0	1	3,6	27	96,4	NE	152,1	NE	NE	152,1	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Spinal pain	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	34,7	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	15,7	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Colon adenoma	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Lipoma	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	15,7	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Nervous system disorders	-Total	n/a	28	100,0	7	25,0	21	75,0	72,6	8,1	NE	NE	72,0	NE	NE	28	100,0	6	21,4	22	78,6	48,1	21,6	107,1	107,1	48,1	NE	0,9397	0,96	0,32	2,89		Convergence criterion (GCONV=1E-8) satisfied.				
	Balance disorder	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	31,6	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Cognitive disorder	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	21,6	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Dizziness	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Dysaesthesia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	107,1	NE	NE	107,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Headache	n/a	28	100,0	7	25,0	21	75,0	76,6	8,1	NE	NE	76,6	NE	NE	28	100,0	3	10,7	25	89,3	106,0	40,4	NE	NE	106,0	NE	0,3473	1,90	0,49	7,43		Convergence criterion (GCONV=1E-8) satisfied.				
	Paraesthesia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	34,7	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Restless legs syndrome	n/a	28	100,0	1	3,6	27	96,4	NE	38,9	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Psychiatric disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Anxiety	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Depression	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Renal and urinary disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	31,9	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	19,4	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Dysuria	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	19,4	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Leukocyturia	n/a	28	100,0	2	7,1	26	92,9	NE	31,9	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
Reproductive system and breast disorders	-Total	n/a	28	100,0	6	21,4	22	78,6	116,7	6,0	NE	NE	42,9	NE	NE	28	100,0	2	7,1	26	92,9	NE	15,7	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Amenorrhoea	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				
	Cervical dysplasia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.				

	Dysmenorrhoea	n/a	28	100,0	1	3,6	27	96,4	NE	42,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Genital haemorrhage	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Menstrual disorder	n/a	28	100,0	1	3,6	27	96,4	NE	29,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Uterine cervical erosion	n/a	28	100,0	1	3,6	27	96,4	NE	34,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Uterine polyp	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	15,7	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Vulvovaginal dryness	n/a	28	100,0	1	3,6	27	96,4	NE	116,7	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Respiratory, thoracic and mediastinal disorders	-Total	n/a	28	100,0	4	14,3	24	85,7	NE	11,1	NE	NE	NE	NE	28	100,0	4	14,3	24	85,7	147,0	15,1	NE	NE	147,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Cough	n/a	28	100,0	1	3,6	27	96,4	NE	51,1	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	27,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Epistaxis	n/a	28	100,0	2	7,1	26	92,9	NE	11,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Oropharyngeal pain	n/a	28	100,0	3	10,7	25	89,3	NE	22,4	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	15,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rhinorrhoea	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	147,0	NE	NE	147,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Skin and subcutaneous tissue disorders	-Total	n/a	28	100,0	7	25,0	21	75,0	102,6	2,3	NE	NE	102,6	NE	28	100,0	6	21,4	22	78,6	155,1	4,0	NE	NE	155,1	NE	0,9472	0,96	0,32	2,95	Convergence criterion (GCONV=1E-8) satisfied.
	Acne	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Alopecia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dermatitis allergic	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	25,6	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Eczema	n/a	28	100,0	2	7,1	26	92,9	NE	87,1	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Erythema	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	20,0	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Haemorrhage subcutaneous	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	22,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Papule	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	159,6	159,6	NE	NE	159,6	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pruritus	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	107,1	NE	NE	107,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rash	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	155,1	155,1	NE	NE	155,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rash pruritic	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Seborrhoeic dermatitis	n/a	28	100,0	1	3,6	27	96,4	NE	102,6	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Skin exfoliation	n/a	28	100,0	1	3,6	27	96,4	NE	102,7	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Urticaria	n/a	28	100,0	1	3,6	27	96,4	NE	88,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Vascular disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	131,9	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	13,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypertension	n/a	28	100,0	2	7,1	26	92,9	NE	131,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypotension	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	13,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CD970210/share/pool_ACE_SA237/work/work_all/program/saf_tsp.sas
Output: root/clinical_studies/RO5333787/CD970210/BN40898/data_analysis/ACE_NMSO/work/work_all/output/saf_tsp_307_07JUN2019_SAQP_AEMILD_S1.xls
25NOV2020 16:20

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis by SOC and PT (Safety)

			SA237												Placebo										SA237 vs. Placebo					
			Patients		Patients with		Censored		Time To Event						Patients		Patients with		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		85% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	-Total	n/a	28	100,0	4	14,3	24	85,7	NE	20,7	NE	NE	80,4	NE	28	100,0	4	14,3	24	85,7	NE	4,6	NE	NE	44,1	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Anaemia	n/a	28	100,0	1	3,6	27	96,4	NE	20,7	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	13,1	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Anaemia macrocytic	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Autoimmune thrombocytopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	44,1	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperfibrinogenaemia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	64,1	NE	NE	64,1	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Iron deficiency anaemia	n/a	28	100,0	1	3,6	27	96,4	NE	40,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Leukocytosis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Leukopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Lymphopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	38,0	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Neutropenia	n/a	28	100,0	1	3,6	27	96,4	NE	80,4	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	13,1	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	104,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Cataract	n/a	28	100,0	1	3,6	27	96,4	NE	104,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	-Total	n/a	28	100,0	3	10,7	25	89,3	NE	0,3	NE	NE	NE	NE	28	100,0	4	14,3	24	85,7	112,0	19,7	NE	NE	112,0	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	19,7	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain upper	n/a	28	100,0	1	3,6	27	96,4	NE	81,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Constipation	n/a	28	100,0	2	7,1	26	92,9	NE	0,3	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	39,1	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Dental caries	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	112,0	NE	NE	112,0	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Diarrhoea	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	39,7	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Gastrointestinal disorder	n/a	28	100,0	1	3,6	27	96,4	NE	104,1	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Gastrooesophageal reflux disease	n/a	28	100,0	1	3,6	27	96,4	NE	102,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Nausea	n/a	28	100,0	1	3,6	27	96,4	NE	81,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Toothache	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Vomiting	n/a	28	100,0	1	3,6	27	96,4	NE	81,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	-Total	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	37,0	NE	NE	50,7	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Chest pain	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	50,7	NE	NE	50,7	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Pyrexia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	37,0	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
Hepatobiliary disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Hyperbilirubinaemia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
Immune system disorders	-Total	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	103,1	NE	NE	103,1	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Drug hypersensitivity	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	103,1	NE	NE	103,1	NE					Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	-Total	n/a	28	100,0	10	35,7	18	64,3	77,3	1,9	188,0	188,0	77,3	NE	28	100,0	7	25,0	21	75,0	62,4	6,3	109,1	75,7	46,4	NE	0,5926	0,76	0,27	2,11	Convergence criterion (GCONV=1E-8) satisfied.	
	Bronchitis	n/a	28	100,0	2	7,1	26	92,9	NE	16,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Cystitis	n/a	28	100,0	1	3,6	27	96,4	NE	188,0	NE	NE	188,0	NE	28	100,0	3	10,7	25	89,3	NE	22,1	NE	NE	57,4	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Ear infection	n/a	28	100,0	1	3,6	27	96,4	NE	81,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Gastroenteritis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	75,7	NE	NE	75,7	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Herpes simplex	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	34,7	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Herpes zoster	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Influenza	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	46,4	NE	NE	50,1	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Lower respiratory tract infection	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	100,1	NE	NE	100,1	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Nasopharyngitis	n/a	28	100,0	1	3,6	27	96,4	NE	62,6	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	62,4	NE	NE	62,4	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Oral herpes	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	40,0	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Periodontitis	n/a	28	100,0	1	3,6	27	96,4	NE	150,1	NE	NE	150,1	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Pertussis	n/a	28	100,0	1	3,6	27	96,4	NE	78,4	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Pharyngitis	n/a	28	100,0	1	3,6	27	96,4	NE	129,9	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Pneumonia	n/a	28	100,0	1	3,6	27	96,4	NE	26,3	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Upper respiratory tract infection	n/a	28	100,0	3	10,7	25	89,3	NE	77,3	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	106,0	NE	NE	106,0	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Urinary tract infection	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	71,9	NE	NE	71,9	NE					Convergence criterion (GCONV=1E-8) satisfied.	
	Viral upper respiratory tract infection	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	110,3	NE	NE	110,3	NE					Convergence criterion (GCONV=1E-8) satisfied.	

Injury, poisoning and procedural complications	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	36,3	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	22,7	NE	NE	67,4	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Fall	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	22,7	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Femur fracture	n/a	28	100,0	1	3,6	27	96,4	NE	36,3	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Limb injury	n/a	28	100,0	1	3,6	27	96,4	NE	85,0	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rib fracture	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	67,4	NE	NE	67,4	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Investigations	-Total	n/a	28	100,0	4	14,3	24	85,7	200,1	27,6	NE	200,1	200,1	NE	NE	28	100,0	3	10,7	25	89,3	120,1	16,9	NE	NE	120,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Alanine aminotransferase increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Aspartate aminotransferase increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	International normalised ratio increased	n/a	28	100,0	1	3,6	27	96,4	NE	79,4	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Neutrophil count decreased	n/a	28	100,0	2	7,1	26	92,9	200,1	27,6	NE	200,1	200,1	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Serum ferritin decreased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	16,9	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Weight increased	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	120,1	NE	NE	120,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	White blood cell count decreased	n/a	28	100,0	1	3,6	27	96,4	NE	27,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Metabolism and nutrition disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	112,6	NE	NE	NE	NE	NE	28	100,0	4	14,3	24	85,7	178,6	12,3	178,6	178,6	61,1	178,6	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hypercholesterolaemia	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	12,3	NE	NE	61,1	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hyperglycaemia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	178,6	178,6	NE	NE	178,6	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Obesity	n/a	28	100,0	1	3,6	27	96,4	NE	112,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Musculoskeletal and connective tissue disorders	-Total	n/a	28	100,0	4	14,3	24	85,7	NE	20,7	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	62,0	NE	NE	62,0	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Back pain	n/a	28	100,0	2	7,1	26	92,9	NE	100,3	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Myalgia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Pain in extremity	n/a	28	100,0	1	3,6	27	96,4	NE	30,4	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	62,0	NE	NE	62,0	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Spinal osteoarthritis	n/a	28	100,0	1	3,6	27	96,4	NE	20,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	155,3	NE	NE	155,3	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Thyroid neoplasm	n/a	28	100,0	1	3,6	27	96,4	NE	155,3	NE	NE	155,3	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Nervous system disorders	-Total	n/a	28	100,0	4	14,3	24	85,7	NE	11,7	NE	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	95,3	16,0	NE	NE	95,3	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Burning sensation	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	50,7	NE	NE	50,7	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Dizziness	n/a	28	100,0	1	3,6	27	96,4	NE	81,0	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Headache	n/a	28	100,0	2	7,1	26	92,9	NE	13,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Intercostal neuralgia	n/a	28	100,0	1	3,6	27	96,4	NE	70,3	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	95,3	NE	NE	95,3	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Muscle spasticity	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	16,0	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Myelopathy	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Reproductive system and breast disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	101,0	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Uterine polyp	n/a	28	100,0	1	3,6	27	96,4	NE	101,0	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Respiratory, thoracic and mediastinal disorders	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	81,7	NE	NE	179,0	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Rhinitis allergic	n/a	28	100,0	2	7,1	26	92,9	NE	81,7	NE	NE	179,0	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Skin and subcutaneous tissue disorders	-Total	n/a	28	100,0	3	10,7	25	89,3	NE	81,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Acne	n/a	28	100,0	1	3,6	27	96,4	NE	81,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Solar dermatitis	n/a	28	100,0	1	3,6	27	96,4	NE	130,6	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Urticaria	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
Vascular disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	67,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.
	Hot flush	n/a	28	100,0	1	3,6	27	96,4	NE	67,7	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CD970210/BN40898/data_analysis/ACE_SMSU/prod/program
Output: root/clinical_studies/RO5333787/CD970210/BN40898/data_analysis/ACE_SMSU/prod/output/saf_tsp_307_07JUN2019_SAGP_ASMOD_S1.xls
25MAR2020 15:09

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis by SOC and PT (Safety)

			SA237												Placebo										SA237 vs. Placebo					
			Patients		Patients with		Censored		Time To Event						Patients		Patients with		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	pvalue, test=logrank		95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	-Total	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	76,0	NE	NE	76,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Leukopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	76,0	NE	NE	76,0	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
General disorders and administration site conditions	-Total	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	34,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Pyrexia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	34,4	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	-Total	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	2	7,1	26	92,9	NE	38,3	NE	NE	106,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Appendicitis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	38,3	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Escherichia sepsis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	106,1	NE	NE	106,1	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	128,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Injection Related Reactions	n/a	28	100,0	1	3,6	27	96,4	NE	128,0	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Spinal compression fracture	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	162,7	NE	NE	162,7	NE	28	100,0	1	3,6	27	96,4	NE	12,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Hepatic cancer	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	12,1	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Uterine leiomyoma	n/a	28	100,0	1	3,6	27	96,4	NE	162,7	NE	NE	162,7	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Tension headache	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	47,7	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	
	Suicide attempt	n/a	28	100,0	1	3,6	27	96,4	NE	47,7	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CD970210/share/pool_ACE_SA237/work/work_all/program/saf_tsp.sas
Output: root/clinical_studies/RO5333787/CD970210/BN40898/data_analysis/ACE_BMS0/work/work_all/output/saf_tsp_307_07JUN2019_SAQP_AESEV_S1.xls
25NOV2020 16:22

POPULATION: AQP4 Positive Population
ENDPOINT: Any SAEs
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis by SOC and PT (Safety)

			SA237														Placebo									SA237 vs. Placebo						
			Patients		Patients with		Censored		Time To Event								Patients		Patients with		Censored		Time To Event							Log-rank	Hazard Ratio					Interaction Test
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median			n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median		p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
Blood and lymphatic system disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE			28	100,0	3	10,7	25	89,3	102,9	44,1	NE	NE	102,9	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Anaemia macrocytic	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Autoimmune thrombocytopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	44,1	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Leukopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Lymphopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	102,9	NE	NE	102,9	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Eye disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	104,3	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Cataract	n/a	28	100,0	1	3,6	27	96,4	NE	104,3	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Gastrointestinal disorders	-Total	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	19,7	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Abdominal pain	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	19,7	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Infections and infestations	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	26,3	NE	NE	NE	NE			28	100,0	3	10,7	25	89,3	106,1	38,3	NE	NE	71,9	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Appendicitis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	38,3	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Escherichia sepsis	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	106,1	NE	NE	106,1	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Pneumonia	n/a	28	100,0	1	3,6	27	96,4	NE	26,3	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Urinary tract infection	n/a	28	100,0	1	3,6	27	96,4	NE	49,1	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	71,9	NE	NE	71,9	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Injury, poisoning and procedural complications	-Total	n/a	28	100,0	2	7,1	26	92,9	NE	36,3	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Femur fracture	n/a	28	100,0	1	3,6	27	96,4	NE	36,3	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Spinal compression fracture	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	162,7	NE	NE	162,7	NE			28	100,0	1	3,6	27	96,4	NE	12,1	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Hepatic cancer	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	12,1	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Uterine leiomyoma	n/a	28	100,0	1	3,6	27	96,4	NE	162,7	NE	NE	162,7	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Nervous system disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Tension headache	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Psychiatric disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	47,7	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Suicide attempt	n/a	28	100,0	1	3,6	27	96,4	NE	47,7	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Renal and urinary disorders	-Total	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	19,4	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Dysuria	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	19,4	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
Reproductive system and breast disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	119,1	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	15,7	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Cervical dysplasia	n/a	28	100,0	1	3,6	27	96,4	NE	119,1	NE	NE	NE	NE			28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	
	Uterine polyp	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE			28	100,0	1	3,6	27	96,4	NE	15,7	NE	NE	NE	NE		-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tsp_307_07JUN2019_SAQP_AESAE_S1.xls
25MAR2020 15:15

POPULATION: AQP4 Positive Population
ENDPOINT: AEs leading to treatment discontinuation
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis by SOC and PT (Safety)

			SA237												Placebo									
			Patients		Patients with		Censored		Time To Event						Patients		Patients with		Censored		Time To Event					
SOC	PT	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median
Blood and lymphatic system disorders	-Total	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	102,9	44,1	NE	NE	97,1	NE
	Autoimmune thrombocytopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	44,1	NE	NE	NE	NE
	Leukopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	97,1	NE	NE	97,1	NE
	Lymphopenia	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	102,9	NE	NE	102,9	NE
Investigations	-Total	n/a	28	100,0	2	7,1	26	92,9	200,1	200,1	NE	200,1	200,1	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE
	Alanine aminotransferase increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE
	Aspartate aminotransferase increased	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE
	Neutrophil count decreased	n/a	28	100,0	1	3,6	27	96,4	200,1	200,1	NE	NE	200,1	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	12,1	NE	NE	NE	NE
	Hepatic cancer	n/a	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	12,1	NE	NE	NE	NE
Skin and subcutaneous tissue disorders	-Total	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE
	Urticaria	n/a	28	100,0	1	3,6	27	96,4	NE	NE	NE	NE	NE	NE	28	100,0	NE	NE	28	100,0	NE	NE	NE	NE	NE	NE

Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tsd_307_07JUN2019_SAQP_AEDISC_S1.xls
25MAR2020 19:52

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_AESIALT_S1.xls
24MAR2020 15:30

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)										(N=28)										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MIAESIAL_S1.xls
24MAR2020 15:36

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)										(N=28)										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MOAESIAL_S1.xls
24MAR2020 15:42

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SEAESIAL_S1.xls
24MAR2020 15:48

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Elevated ALT or AST (>3*ULN) in combination with either an elevated bilirubin (>2*ULN) or clinical jaundice
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)										(N=28)										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SAESIALT_S1.xls
25MAR2020 12:49

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_AESISUS_S1.xls
24MAR2020 15:31

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)										(N=28)										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MIAESISU_S1.xls
24MAR2020 15:37

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)										(N=28)										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MOAESISU_S1.xls
24MAR2020 15:43

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SEAESISU_S1.xls
24MAR2020 15:49

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Suspected transmission of an infectious agent by the study drug
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SAESISUS_S1.xls
24MAR2020 15:54

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237											Placebo										SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event					Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio				Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL	Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	2	7.1	26	92.9	NE	26.3	NE	NE	NE	NE	28	100.0	3	10.7	25	89.3	NE	19.4	NE	NE	71.9	NE	-	-	-	-	Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_AESIINF_S1.xls
24MAR2020 15:32

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)												(N=28)										SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	1	3,6	27	96,4	NE	49,1	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	19,4	NE	NE	NE	NE	.	.	.	.		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MIAESIIN_S1.xls
24MAR2020 15:38

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)												(N=28)										SA237 vs. Placebo							
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	1	3,6	27	96,4	NE	26,3	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	71,9	NE	NE	71,9	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MOAESIIN_S1.xls
24MAR2020 15:44

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients	Patients with Event		Censored		Time To Event					Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	n %	n %	n %	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	1 3.6	27 96.4	NE	38.3	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SEAESITN_S1.xls
24MAR2020 15:50

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Infections treated with IV treatment
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	2	7.1	26	92.9	NE	26.3	NE	NE	NE	NE	28	100.0	2	7.1	26	92.9	NE	38.3	NE	NE	71.9	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SAESIINF_S1.xls
24MAR2020 15:56

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237											Placebo										SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event					Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	1	3.6	27	96.4	NE	103.9	NE	NE	NE	NE	28	100.0	5	17.9	23	82.1	90.6	8.4	NE	NE	90.6	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_AESIOPP_S1.xls
24MAR2020 15:34

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)												(N=28)												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	1	3,6	27	96,4	NE	103,9	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	14,4	NE	NE	90,6	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MIAESIOP_S1.xls
24MAR2020 15:40

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)										(N=28)										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients	Patients with Event		Censored		Time To Event					Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	3	10,7	25	89,3	NE	34,7	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MOAESIOP_S1.xls
24MAR2020 15:46

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SEAESIOP_S1.xls
24MAR2020 15:51

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Potential opportunistic infections
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SAESIOPP_S1.xls
24MAR2020 15:57

POPULATION: AQP4 Positive Population
ENDPOINT: AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237												Placebo										SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	2	7.1	26	92.9	NE	2.3	NE	NE	NE	NE	28	100.0	1	3.6	27	96.4	NE	84.4	NE	NE	84.4	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_AESIIRR_S1.xls
24MAR2020 15:35

POPULATION: AQP4 Positive Population
ENDPOINT: Mild AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)												(N=28)												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Patients with Event		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	2	7,1	26	92,9	NE	2,3	NE	NE	NE	NE	28	100,0	1	3,6	27	96,4	NE	84,4	NE	NE	84,4	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MIAESIIR_S1.xls
24MAR2020 15:41

POPULATION: AQP4 Positive Population
ENDPOINT: Moderate AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		(N=28)										(N=28)										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	28	100,0	28	100,0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_MOAESIIR_S1.xls
25MAR2020 12:47

POPULATION: AQP4 Positive Population
ENDPOINT: Severe AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237												Placebo												SA237 vs. Placebo						
		Patients		Patients with Event		Censored		Time To Event						Patients		Censored		Time To Event								Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value	Hazard Ratio	95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	1	3.6	27	96.4	NE	128.0	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SEAESIIR_S1.xls
24MAR2020 15:52

POPULATION: AQP4 Positive Population
ENDPOINT: Serious AESI: Injection-related reactions
MODEL: Unstratified analysis
STUDY: BN40898
Time to event analysis (Safety)

		SA237										Placebo										SA237 vs. Placebo						
		Patients		Censored		Time To Event						Patients		Censored		Time To Event						Log-rank	Hazard Ratio					Interaction Test
Subgroup	Level	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	n	%	n	%	Q1 (weeks)	95% Lower CL for Q1	95% Upper CL for Q1	Median (weeks)	95% Lower CL for Median	95% Upper CL for Median	p-value		95% Lower CL	95% Upper CL		Convergence Status	p-value (likelihood ratio)
All	n/a	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	28	100.0	28	100.0	NE	NE	NE	NE	NE	NE	-	-	-	-		Convergence criterion (GCONV=1E-8) satisfied.	

Test for interaction based on Likelihood-Ratio test for interaction with treatment effect.
* indicates convergence problem. Result is uninterpretable.
Clinical cut-off: 07JUN2019

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/program
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_3MSU/prod/output/saf_tte_307_07JUN2019_SAQP_SAESIIRR_S1.xls
24MAR2020 15:59

POPULATION: AQP4 Positive Population
ENDPOINT: --
MODEL: --
STUDY: BN40898
Demographic data and baseline disease characteristics

	Placebo (N=28) n (%)	SA237 (N=27) n (%)	Total (N=55) n (%)
Age (years)			
n	28	27	55
Mean (SD)	43.4 (12.9)	44.4 (15.7)	43.9 (14.2)
Min - Max	14 - 65	13 - 73	13 - 73
Median	45	44	44
Age Group			
n	28	27	55
<18 years	2 (7.1%)	1 (3.7%)	3 (5.5%)
>=18 years	26 (92.9%)	26 (96.3%)	52 (94.5%)
Gender			
n	28	27	55
Male	0	0	0
Female	28 (100%)	27 (100%)	55 (100%)
Race			
n	28	27	55
American Indian/Alaska Native	0	0	0
Asian [Japanese]	9 (32.1%)	10 (37.0%)	19 (34.5%)
Asian [Non-Japanese]	4 (14.3%)	4 (14.8%)	8 (14.5%)
Black/African American	2 (7.1%)	0	2 (3.6%)
Native Hawaiian/other Pacific Islander	0	0	0
White	12 (42.9%)	13 (48.1%)	25 (45.5%)
Other	1 (3.6%)	0	1 (1.8%)
Racial Subgroup			
n	28	27	55
Japanese	9 (32.1%)	10 (37.0%)	19 (34.5%)
Non-Japanese	19 (67.9%)	17 (63.0%)	36 (65.5%)
Geographic Region			
n	28	27	55
Asia	13 (46.4%)	13 (48.1%)	26 (47.3%)
Europe/Other	15 (53.6%)	14 (51.9%)	29 (52.7%)

Ethnicity			
n	28	27	55
Hispanic or Latino	0	0	0
Not Hispanic or Latino	28 (100%)	27 (100%)	55 (100%)
Not reported	0	0	0
Height (cm)			
n	28	27	55
Mean (SD)	163.23 (5.99)	160.16 (8.15)	161.72 (7.23)
Min - Max	150.0 - 174.0	146.5 - 174.0	146.5 - 174.0
Median	164	161	162,5
Body Weight (kg)			
n	28	27	55
Mean (SD)	64.61 (18.35)	59.96 (13.38)	62.32 (16.13)
Min - Max	39.4 - 140.4	45.3 - 99.0	39.4 - 140.4
25%-ile	54,7	51	54
Median	62,1	56,4	58,4
75%-ile	72	59,4	65
BMI (kg/m2)			
n	28	27	55
Mean (SD)	24.13 (6.03)	23.44 (5.21)	23.80 (5.60)
Min - Max	16.7 - 47.9	17.4 - 37.7	16.7 - 47.9
Median	23,07	21,64	22,83
BMI Category (kg/m2)			
n	28	27	55
<18.5	2 (7.1%)	2 (7.4%)	4 (7.3%)
18.5 to <25	19 (67.9%)	17 (63.0%)	36 (65.5%)
25 to <30	3 (10.7%)	5 (18.5%)	8 (14.5%)
>=30	4 (14.3%)	3 (11.1%)	7 (12.7%)
Weight Category			
n	28	27	55
< Median	11 (39.3%)	16 (59.3%)	27 (49.1%)
>= Median	17 (60.7%)	11 (40.7%)	28 (50.9%)
Baseline ARR			
n	28	27	55
Mean (SD)	1.41 (0.55)	1.39 (0.51)	1.40 (0.52)
Min - Max	1.0 - 3.0	1.0 - 3.0	1.0 - 3.0
Median	1	1	1
Baseline ARR Category			

n	28	27	55
1	15 (53.6%)	14 (51.9%)	29 (52.7%)
>1	13 (46.4%)	13 (48.1%)	26 (47.3%)
Diagnosis			
n	28	27	55
NMO	14 (50.0%)	19 (70.4%)	33 (60.0%)
NMOSD	14 (50.0%)	8 (29.6%)	22 (40.0%)
Baseline Treatment			
n	28	27	55
Azathioprine	11 (39.3%)	11 (40.7%)	22 (40.0%)
Mycophenolate Mofetil	3 (10.7%)	1 (3.7%)	4 (7.3%)
Oral Corticosteroids	13 (46.4%)	14 (51.9%)	27 (49.1%)
Azathioprine + Oral Corticosteroids	0	0	0
Mycophenolate Mofetil + Oral Corticosteroids	1 (3.6%)	1 (3.7%)	2 (3.6%)
Baseline EDSS			
n	27	27	54
Mean (SD)	3.70 (1.44)	4.30 (1.58)	4.00 (1.52)
Min - Max	1.5 - 6.5	1.0 - 6.5	1.0 - 6.5
Median	3,5	4	3,5

n represents the number of patients contributing to summary statistics. Percentages are based on n (number of valid values).
Age calculated as the number of complete years between a patient's birth date and the date of first informed consent.
AQP4=Aquaporin-4, ARR=Annualized Relapse Rate, NMO=Neuromyelitis Optica, NMOSD=Neuromyelitis Optica Spectrum Disorder and EDSS=Expanded Disability Status Scale.
ARR was entered into IxRS and used for stratified randomization. The EDSS is scored on a scale of 0-10. Higher scores represent increased disability.
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/oth_demo.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/oth_demo_307_06JUN2018_AQPP.xls
26NOV2019 14:03

POPULATION: AQP4 Positive Population
ENDPOINT: --
MODEL: --
STUDY: BN40898
Number of centers/countries/geographical regions with <10, >=10 patients per arm

	Center				Country				Geographical region (3)			
Category	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)
Overall	28	100,00%	55	100,00%	9	100,00%	55	100,00%	3	100,00%	55	100,00%
with <10 patients per arm (1)	28	100,00%	55	100,00%	9	100,00%	55	100,00%	1	33,30%	2	3,60%
with >=10 patients per arm (2)	0	0,00%	0	0,00%	0	0,00%	0	0,00%	2	66,70%	53	96,40%

(1): "<10 patients" category if at least one treatment arm has <10 patients. (2): ">=10 patients" category if all treatment arms have >=10 patients.
(3): Geographical regions: Europe, Asia, Others. (4): Number of centers/countries/geographical regions. (5): % of centers/countries/geographical regions compared to overall number.
(6): Number of patients randomized in the corresponding category (e.g. number of patients randomized in centers with <10 patients per arm).
(7): % of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients).
Clinical cut-off: 06JUN2018

Program: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/program/oth_center.sas
Output: root/clinical_studies/RO5333787/CDP70210/BN40898/data_analysis/ACE_CSRPrimary/prod/output/oth_center_307_06JUN2018_AQPP.xls
26NOV2019 14:08

Duration of Double-Blind Period for Safety Analysis, AQP4 Positive, Safety-Evaluable Population
Protocol: SA-307JG
CCOD : SA307 CSR: 06JUN2018

	Placebo (N=28)	SA237 (N=27)
Duration (Weeks)		
0 - 23	7 (25.0%)	5 (18.5%)
24 - 47	11 (39.3%)	6 (22.2%)
48 - 71	1 (3.6%)	0
72 - 95	1 (3.6%)	1 (3.7%)
96 - 119	3 (10.7%)	1 (3.7%)
120 - 143	0	4 (14.8%)
144 - 167	3 (10.7%)	3 (11.1%)
168 - 191	2 (7.1%)	5 (18.5%)
192 - 215	0	1 (3.7%)
216 - 239	0	1 (3.7%)
Mean (SD)	64.2 (56.6)	104.6 (74.2)
Median	40.2	139.4
Min - Max	8 - 185	10 - 224

AQP4=Aquaporin-4
Double-blind period starts on the day of first dose. The double-blind period ends on the earliest day of 1) clinical cutoff date, 2) the day before the first treatment in the extension period, 3) the end of the study, or 4) last contact for Patients lost to follow up.

Program: root/clinical_studies/RO5333787/CDP70210/share/pool_CSR_adhocs/prod/program/t_ex_sty_9824.sas
Output: root/clinical_studies/RO5333787/CDP70210/share/pool_CSR_adhocs/prod/output/t_ex_sty_9824_307_AQPPOS_DBSAF_SE.out