Results Registration Form

Point of Contact

Name or Official Title:	Study Director
Organization Name:	Novartis Pharmaceuticals
Phone:	862-778-8300
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Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.
The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial or disclosure of trial results in their entirety.

Participant Flow

Recruitment Details	
Pre-assignment Details	

Type of Units Assigned:

Period: Overall Study

	ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.	**Total** *(=sum per row)*
Started	Participants 5	Participants 6	Participants 5	16 *(calculated)*

Pharmacodynamic (PD) analysis set	Participants 5	Participants 6	Participants 4 One patient excluded: did not receive study drug; received placebo caps. and infusion only in error.	15 *(calculated)*
Completed	Participants 3	Participants 5	Participants 4	12 *(calculated)*
Not Completed: *(=Started - Completed)*	2 *(calculated)*	1 *(calculated)*	1 *(calculated)*	4 *(calculated)*
Reason for Not Completed				
Total: *(=sum per column)*	2 *(calculated)*	1 *(calculated)*	1 *(calculated)*	4 *(calculated)*
Withdrawal by Subject	0	1	0	1 *(calculated)*
Other **Protocol deviation**	0	0	1	1 *(calculated)*
Other **Administrative problems**	1	0	0	1 *(calculated)*
Adverse Event	1	0	0	1 *(calculated)*

Baseline Characteristics

Overall Number of Baseline Participants				
	ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.	**Total(=sum across Arm/Groups)**
Overall Number of Baseline Participants	5	6	5	16 *(calculated)*
Overall Number Of Units Analyzed **Type Of Units Analyzed**:				Unknown *(calculated)*
Baseline Analysis Population Description				

Baseline measure title = "Age Continuous"

Age Continuous
Units: years
Parameter type: Mean
Dispersion type: Standard Deviation

Row	Category	**ACZ885** On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.	**Total**
	Number Analyzed:	5 Participants	6 Participants	5 Participants	16 *(calculated)* Participants
		67.2 (9.09)	68.8 (8.61)	69.4 (7.89)	68.5 (8.02)

Baseline measure title = "Sex: Female, Male"

Sex: Female, Male
Parameter type: Count of Participants
Dispersion type: Not Applicable

Row	Category	**ACZ885** On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.	**Total** *(=sum per row)*
	Number Analyzed:	5 Participants	6 Participants	5 Participants	

					16 *(calculated)* Participants
	Female	4	2	5	11 *(calculated)*
	Male	1	4	0	5 *(calculated)*

Outcome Measures

ALERT: Outcome measures from protocol are not used when records include results.

1. Primary: Polymyalgia Rheumatica Activity Score (PMR-AS)

Reporting Status: Posted

Description: The efficacy of a single dose of AIN457 and ACZ885 (canakinumab) was measured by the polymyalgia rheumatica activity score. A composite PMR-AS was developed from the following components: measure of C-reactive protein (CRP), measure of Erythrocyte Sedimentation Rate (ESR), assessment of early morning stiffness, assessment of the patient's elevation on upper limbs, patient's assessment of pain, and physician's global assessment of disease activity. Treatment effect was measured by the percent reduction in PMR-AS. N=3 for the ACZ885 arm because CRP values at Day 15 were missing for 2 participants.

Time Frame: Baseline, Day 15

Safety Issue: No

Measure Type: Least Squares Mean

Method of Dispersion: Standard Error

Unit of Measure: Percent reduction

Type of Units Analyzed:

Analysis Population Description: Pharmacodynamic (PD) Analysis Set: This set included participants who received at least one dose of study medication and had no major protocol deviation that may impact the PD data.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.	
	Number of Participants Analyzed:	3		6		4	
Polymyalgia Rheumatica Activity Score	Category	Least Squares Mean	Standard Error	Least Squares Mean	Standard Error	Least Squares Mean	Standard Error

(PMR-AS) Units: Percent reduction							
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	3 Participants		6 Participants		4 Participants	
		64.5	0.68	51.7	0.47	91.9	86.2

2. Secondary: Time to partial clinical response

Reporting Status: Posted

Description: The time to partial clinical response was assessed in patients who received a single dose of AIN457 or ACZ885 (canakinumab). Daily monitoring (home-based) of CRP was performed. This outcome shows the percentage of patients who achieved a partial clinical response at Day 15. A participant was defined as a partial responder if the participant had:
>50% reduction in patient global assessment visual analogue scale (VAS) compared with baseline and morning stiffness < 60 minutes.

Time Frame: Day 15

Safety Issue: No

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: Percentage of participants

Type of Units Analyzed:

Analysis Population Description: PD analysis set

	ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders	**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their

		continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	steroid treatment according to standard care. Non-responders were discontinued from the study.
	Number of Participants Analyzed:	5	6	4
Time to partial clinical response Units: Percentage of participants	Category	Number	Number	Number
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	5 Participants	6 Participants	4 Participants
		20.0	16.7	75.0

3. Secondary: Time to complete clinical response

Reporting Status: Posted

Description: The time to complete clinical response was assessed in patients who received a single dose of AIN457 or ACZ885 (canakinumab). Daily monitoring (home-based) of CRP was performed. This outcome shows the percentage of patients who achieved a complete clinical response at Day 15. A participant was defined as a complete responder if the participant had: >70% reduction in patient global assessment VAS compared with baseline, morning stiffness < 30 min, CRP < 1.0 mg/dL and/or ESR < 30 mm/1st hr.

Time Frame: Day 15

Safety Issue: No

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: Percentage of participants

Type of Units Analyzed:

Analysis Population Description: PD analysis set

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.
	Number of Participants Analyzed:	5	6	4
Time to complete clinical response Units: Percentage of participants	Category	Number	Number	Number
	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	5 Participants	6 Participants	4 Participants
		0.0	0.0	25.0

4. Secondary: Time to first flare

Reporting Status: Posted

Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. Only 1 participant experienced a flare, in the AIN457 treatment group. The flare for this one participant occurred on study day 44

Time Frame: 6 months

Safety Issue: No

Measure Type: Number

Method of Dispersion: Not Applicable

Unit of Measure: Days

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. Only 1 participant experienced a flare, in the AIN457 treatment group. The flare for this one participant occurred on study day 44

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.
	Number of Participants Analyzed:	0	1	0
Time to first flare Units: Days	Category	Number	Number	Number
Time to first flare in Days	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	1 Participants	0 Participants
			44	

5. Secondary: Number of flares over a 6 month period

Reporting Status:	Posted
Description:	This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.
Time Frame:	6 months
Safety Issue:	No
Measure Type:	Number
Method of Dispersion:	Not Applicable
Unit of Measure:	Participant
Type of Units Analyzed:	
Analysis Population Description:	This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

	ACZ885	**AIN457**	**Prednisone**
	On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or	On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or	On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.

		prednisolone followed by standard steroid tapering.	prednisolone followed by standard steroid tapering.	
	Number of Participants Analyzed:	0	1	0
Number of flares over a 6 month period Units: Participant	Category	Number	Number	Number
Number of Participants with 1 Flare	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	1 Participants	0 Participants
			1	

6. Secondary: Mean steroid dose over a 6 month period

Reporting Status: Posted

Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

Time Frame: 6 months

Safety Issue: No

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: Number of doses

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.
	Number of Participants Analyzed:	3	4	4

Mean steroid dose over a 6 month period Units: Number of doses	Category	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Mean steroid dose over a 6 month period	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	3 Participants		4 Participants		4 Participants	
		276.8	46.34	256.7	27.89	428.9	131.44

7. Secondary: Number of patients who experienced adverse events, serious adverse events and deaths

Reporting Status:	Posted
Description:	
Time Frame:	6 months
Safety Issue:	Yes
Measure Type:	Number
Method of Dispersion:	Not Applicable
Unit of Measure:	Participants
Type of Units Analyzed:	
Analysis Population Description:	Safety analysis set: This set included all participants who received at least one dose of study medication.

	ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of	**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued

		ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	from the study.
	Number of Participants Analyzed:	5	6	5
Number of patients who experienced adverse events, serious adverse events and deaths Units: Participants	Category	Number	Number	Number
Adverse Events (serious and non-serious)	Number Analyzed:	5 Participants	6 Participants	5 Participants
		3	2	5
Serious Adverse Events	Number Analyzed:	5 Participants	6 Participants	5 Participants
		0	0	0
Deaths	Number Analyzed:	5 Participants	6 Participants	5 Participants
		0	0	0

8. Secondary: Comparison between the initial response to AIN457 and ACZ885 and the response after re-dosing of AIN457 and ACZ885 - assessed by the number of flares after redosing.

Reporting Status:	Posted
Description:	One participant experienced one flare after initial dose but this participant had no flare after a redose. This patient was in the AIN457 arm. NOTE: Outcome Measure Description is shorter than the Outcome Measure Title.
Time Frame:	6 months
Safety Issue:	No
Measure Type:	Number
Method of Dispersion:	Not Applicable
Unit of Measure:	Partiipant
Type of Units Analyzed:	
Analysis Population Description:	One participant experienced one flare after initial dose but this participant had no flare after a redose. This patient was in the AIN457 arm.

		ACZ885 On day 1,	**AIN457** On day 1,	**Prednisone** On day 1,

		patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.
	Number of Participants Analyzed:	0	0	0
Comparison between the initial response to AIN457 and ACZ885 and the response after re-dosing of AIN457 and ACZ885 - assessed by the number of flares after redosing. Units: Partiipant	Category	Number	Number	Number
Number of Participants with Flares after redosing	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	0 Participants	0 Participants	0 Participants
		0	0	0

NOTE: Outcome Measure Description is shorter than the Outcome Measure Title.

9. Secondary: Effect on health-related quality of life via the Short Form-36 (SF-36) Questionnaire

Reporting Status: Posted

Description: The Short Form-36 (SF-36) Questionnaire is a 36-item questionnaire yields an 8-scale health profile as well as summary measures of individual patients.. The scores range for each subscale from 0 to 10, and the composite score ranges from 0 to 100, with higher scores indicative of better health.

Time Frame: 6 months

Safety Issue: No

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: Scores on a scale

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.	
	Number of Participants Analyzed:	5		6		4	
Effect on health-related quality of life via the Short Form-36 (SF-36) Questionnaire Units: Scores on a scale	Category	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Physical component score at baseline	Number Analyzed:	5 Participants		6 Participants		4 Participants	
		26.126	8.1517	29.009	4.3115	27.001	5.2561
Physical component score at EOS / Month 6 (n=4,6,2)	Number Analyzed:	4 Participants		6 Participants		2 Participants	
		44.293	12.6038	48.496	8.2306	34.544	7.7632
Mental component score at baseline	Number Analyzed:	5 Participants		6 Participants		4 Participants	
		30.490	11.2875	35.779	5.9113	29.673	6.1925
Mental component	Number	4 Participants		6 Participants		2 Participants	

score at month 6 / EOS (n=4,6,2)	Analyzed:						
		44.668	20.3716	54.136	8.8815	55.233	2.8274

10. Secondary: Effect on health-related quality of life via the Health Assessment Questionnaire (HAQ)

Reporting Status: Posted

Description: HAQ: The scores range from 0 (min) to 3 (max). Higher scores = more disability; lower scores = less disability.

Time Frame: baseline and at month 6

Safety Issue: No

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: Scores on a scale

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.	
	Number of Participants Analyzed:	5		6		4	
Effect on health-related quality of life via the Health Assessment Questionnaire (HAQ) Units: Scores on a scale	Category	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
standard disability score at baseline	Number Analyzed:	5 Participants		6 Participants		4 Participants	

		1.900	0.6869	1.646	0.2896	2.063	0.2394
standard disability score at EOS / Month 6 (n=4,6,3)	Number Analyzed:	4 Participants		6 Participants		3 Participants	
		0.719	1.0225	0.188	0.3513	0.958	0.3819

11. Secondary: Effect on health-related quality of life via the Health Assessment Questionnaire (HAQ) - % change from baseline in the standard disability score at EOS / Month 6

Reporting Status: Posted

Description: HAQ: The scores range from 0 (min) to 3 (max). Higher scores = more disability; lower scores = less disability.
NOTE: Outcome Measure Description is shorter than the Outcome Measure Title.

Time Frame: 6 months

Safety Issue: No

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: Percentage

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**Prednisone** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.	
	Number of Participants Analyzed:	4		6		3	
Effect on health-related quality of life via the Health Assessment Questionnaire (HAQ) - %	Category	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation

change from baseline in the standard disability score at EOS / Month 6 Units: Percentage							
% change from baseline in the standard disability score at EOS / Month 6	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	4 Participants		6 Participants		3 Participants	
		-68.06	36.781	-86.83	25.478	-54.04	12.296

NOTE: Outcome Measure Description is shorter than the Outcome Measure Title.

12. Secondary: Pharmacokinetics of AIN457 and ACZ885 - Cmax

Reporting Status: Posted

Description:

Time Frame: Day 15

Safety Issue: No

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: microgram/mL

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurement for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.
	Number of Participants Analyzed:	4	3

Pharmacokinetics of AIN457 and ACZ885 - Cmax Units: microgram/mL	Category	Mean	Standard Deviation	Mean	Standard Deviation
Cmax (microg/mL)	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	4 Participants		3 Participants	
		69.9	5.58	46.8	2.85

13. Secondary: Pharmacokinetics of AIN457 and ACZ885 - Tmax

Reporting Status: Posted

Description:

Time Frame: Day 15

Safety Issue: No

Measure Type: Median

Method of Dispersion: Full Range

Unit of Measure: days

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurement for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	
	Number of Participants Analyzed:	4		3	
Pharmacokinetics of AIN457 and ACZ885 - Tmax Units: days	Category	Median	Full Range	Median	Full Range
Tmax (day)	Number Analyzed: NOTE: Number Analyzed row will not	4 Participants		3 Participants	

	be displayed in PRS when single Measure Row.				
		0.0868	0.0833 to 1.97	0.107	0.0868 to 0.167

14. Secondary: Pharmacokinetics of AIN457 and ACZ885 - AUCinf and AUClast

Reporting Status: Posted

Description:

Time Frame: Day 15

Safety Issue: No

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: microg/day/mL

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	
	Number of Participants Analyzed:	3		2	
Pharmacokinetics of AIN457 and ACZ885 - AUCinf and AUClast Units: microg/day/mL	Category	Mean	Standard Deviation	Mean	Standard Deviation
AUCinf (microg/day/mL)	Number Analyzed:	3 Participants		2 Participants	
		1570	80	1260	134
AUClast (microg/day/mL)	Number Analyzed:	3 Participants		2 Participants	
		1560	74.7	1200	132

15. Secondary: Pharmacokinetics of AIN457 and ACZ885 - CL

Reporting Status: Posted

Description:

Time Frame: Day 15

Safety Issue: No

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: L/day

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	
	Number of Participants Analyzed:	3		2	
Pharmacokinetics of AIN457 and ACZ885 - CL Units: L/day	Category	Mean	Standard Deviation	Mean	Standard Deviation
CL (L/day)	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	3 Participants		2 Participants	
		0.171	0.440	0.157	0.0106

16. Secondary: Pharmacokinetics of AIN457 and ACZ885 - Vz

Reporting Status: Posted

Description:

Time Frame: Day 15

Safety Issue: No

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: L

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	
	Number of Participants Analyzed:	3		2	
Pharmacokinetics of AIN457 and ACZ885 - Vz Units: L	Category	Mean	Standard Deviation	Mean	Standard Deviation
Vz (L)	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	3 Participants		2 Participants	
		6.49	1.19	9.85	1.29

17. Secondary: Pharmacokinetics of AIN457 and ACZ885 - T1/2

Reporting Status: Posted

Description:

Time Frame: Day 15

Safety No

Issue:

Measure Type: Mean

Method of Dispersion: Standard Deviation

Unit of Measure: Day

Type of Units Analyzed:

Analysis Population Description: This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period. The summary statistics include patients with a valid measurements for the outcome measure.

		ACZ885 On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.		**AIN457** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	
	Number of Participants Analyzed:	3		4	
Pharmacokinetics of AIN457 and ACZ885 - T1/2 Units: Day	Category	Mean	Standard Deviation	Mean	Standard Deviation
T1/2 (day)	Number Analyzed: NOTE: Number Analyzed row will not be displayed in PRS when single Measure Row.	3 Participants		4 Participants	
		26.6	2.38	40.2	4.47

Limitations and Caveats

Description	This study was terminated because the data did not show that the two biologic treatments impacted PMR disease activity to the same degree as steroid treatment within a 2-week treatment period.

Adverse Events

Time Frame	Adverse events were reported from first dose of study treatment until end of study treatment plus 30 days post treatment, up to a maximum duration of 239 days
Adverse Event Reporting Description	

Source Vocabulary for Table Default	
Collection Approach for Table Default	NOTE: An Collection Approach for Table Default has not been specified.

All-Cause Mortality

	ACZ885 3mg/kg On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457 3mg/kg** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**Prednisone 20mg** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.
Total Number Affected	0	0	0
Total Number At Risk	5	6	5

Serious Adverse Events

	ACZ885 3mg/kg On day 1, patients received a single intravenous dose of ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**AIN457 3mg/kg** On day 1, patients received a single intravenous dose of AIN457 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	**Prednisone 20mg** On day 1, patients received daily oral doses of prednisone 20 mg along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.
Total # Affected by any Serious Adverse Event	0	0	0
Total # at Risk by any Serious Adverse Event	5	6	5

†	Events were collected by systematic assessment
1	Term from vocabulary,

Other Adverse Events

Frequency Threshold for reporting Other Adverse Events: 5

	ACZ885 3mg/kg On day 1, patients received a single intravenous dose of	**AIN457 3mg/kg** On day 1, patients received a single intravenous dose of AIN457	**Prednisone 20mg** On day 1, patients received daily oral doses of prednisone 20 mg

	ACZ885 3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of ACZ885 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	3mg/kg along with a placebo intravenous infusion in a double dummy manner to maintain the blind. On day 15, partial and complete responders continued in the open label phase of this treatment arm where they were eligible to receive one re-dose of AIN457 upon confirmed disease flare. Non-responders started a 20 mg dose cycle of prednisone or prednisolone followed by standard steroid tapering.	along with daily oral placebo doses to in a double-dummy manner to maintain the blind. On day 15, partial and complete responders continued in the study and tapered their steroid treatment according to standard care. Non-responders were discontinued from the study.
Total # Affected by any Other Adverse Event	3	2	5
Total # at Risk by any Other Adverse Event	5	6	5

	Ear and labyrinth disorders		
Vertigo[1, †]			
Number of participants affected	0	0	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5

	Eye disorders		
Eye pain[1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5

	Gastrointestinal disorders		
Abdominal pain upper[1, †]			
Number of participants affected	0	0	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Dyspepsia[1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Gastrooesophageal reflux disease[1, †]			
Number of participants affected	1	0	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5

Oral mucosal blistering[1, †]			
Number of participants affected	0	0	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Toothache[1, †]			
Number of participants affected	1	0	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5

	Infections and infestations		
Bronchitis[1, †]			
Number of participants affected	0	0	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Nasopharyngitis[1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Sinusitis[1, †]			
Number of participants affected	1	0	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Upper respiratory tract infection[1, †]			
Number of participants affected	1	0	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5

	Investigations		
Blood pressure increased[1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Weight increased[1, †]			
Number of participants affected	0	0	1
Number of events			

Number of participants at risk [blank=Total]	5	6	5

	Metabolism and nutrition disorders		
Type 2 diabetes mellitus[1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5

	Musculoskeletal and connective tissue disorders		
Arthralgia[1, †]			
Number of participants affected	1	1	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Arthritis[1, †]			
Number of participants affected	0	0	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Joint swelling[1, †]			
Number of participants affected	1	1	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Muscle spasms[1, †]			
Number of participants affected	0	0	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Seronegative arthritis[1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5

	Nervous system disorders		
Headache[1, †]			
Number of participants affected	0	1	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5

Lethargy[1, †]			
Number of participants affected	0	1	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Presyncope[1, †]			
Number of participants affected	0	0	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5

	Psychiatric disorders		
Insomnia[1, †]			
Number of participants affected	1	0	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5
Sleep disorder[1, †]			
Number of participants affected	0	1	1
Number of events			
Number of participants at risk [blank=Total]	5	6	5

	Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain[1, †]			
Number of participants affected	1	0	0
Number of events			
Number of participants at risk [blank=Total]	5	6	5

†	Events were collected by systematic assessment
1	Term from vocabulary, *MedDRA*
2	Term from vocabulary,