Clinical trial results:
A proof of concept study to evaluate the efficacy, safety and tolerability of secukinumab 300 mg over 32 weeks in adult patients with biopsy-proven forms of lichen planus not adequately controlled with topical therapies - PRELUDE

Summary

EudraCT number	2019-003588-24
Trial protocol	DE FR
Global end of trial date	03 May 2022

Results information

Result version number	v1 (current)
This version publication date	04 May 2023
First version publication date	04 May 2023

Trial information

Trial identification

Sponsor protocol code	CAIN457S12201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04300296
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 May 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 May 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to demonstrate the clinical efficacy of secukinumab 300 mg every 4 weeks (Q4W) in subjects with cutaneous lichen planus (CLP), mucosal lichen planus (MLP), or lichen planopilaris (LPP) inadequately controlled by topical therapies, with respect to improvement in Investigator's Global Assessment.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 July 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 28
Country: Number of subjects enrolled	Germany: 34
Country: Number of subjects enrolled	United States: 49
Worldwide total number of subjects	111
EEA total number of subjects	62

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	87

From 65 to 84 years	24
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

163 subjects (3 cohorts) were screened and 111 were randomized. Subjects in the AIN457 300 mg Q4W group in TP1 continued on AIN457 300mg Q4W in TP2. Subjects in the Placebo group in TP1 received AIN457 300mg Q2W in TP2. Patients in the Placebo group with spontaneous remission at Week 16 entered the Follow-up period.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Assessor

Arms

Are arms mutually exclusive?	No
Arm title	AIN457 300 mg Q4W - TP 1 - CLP cohort

Arm description:

AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe

Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg every 4 weeks (Q4W)

Arm title	Placebo - TP 1 - CLP cohort

Arm description:

Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe

Arm type	Placebo
Investigational medicinal product name	Matching placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Matching placebo every 4 weeks (Q4W)

Arm title	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort

Arm description:

AIN457 300 mg every 4 weeks administered via a pre-filled syringe. Participants on AIN457 in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.

Arm type	Experimental

Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg every 4 weeks (Q4W)

Arm title	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort

Arm description:

Placebo non-responders during TP 1 received AIN457 300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.

Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg every 2 weeks (Q2W)

Arm title	AIN457 300 mg Q4W - TP 1 - MLP cohort

Arm description:

AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe

Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg every 4 weeks (Q4W)

Arm title	Placebo - TP 1 - MLP cohort

Arm description:

Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe

Arm type	Placebo
Investigational medicinal product name	Matching placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Matching placebo every 4 weeks (Q4W)

Arm title	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort

Arm description:

AIN457 300 mg every 4 weeks administered via a pre-filled syringe. Participants on AIN457 in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg every 4 weeks (Q4W)

Arm title	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort

Arm description:

Placebo non-responders during TP 1 received AIN457 300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.

Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg every 2 weeks (Q2W)

Arm title	AIN457 300 mg Q4W - TP 1 - LPP cohort

Arm description:

AIN457457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe

Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg every 4 weeks (Q4W)

Arm title	Placebo - TP 1 - LPP cohort

Arm description:

Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe

Arm type	Placebo
Investigational medicinal product name	Matching placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Matching placebo every 4 weeks (Q4W)

Arm title	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort

Arm description:

AIN457 300 mg every 4 weeks administered via a pre-filled syringe. Participants on AIN457 in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg every 4 weeks (Q4W)

Arm title	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort

Arm description:

Placebo non-responders during TP 1 received AIN457 300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.

Arm type	Experimental
Investigational medicinal product name	secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection/infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg every 2 weeks (Q2W)

Number of subjects in period 1	AIN457 300 mg Q4W - TP 1 - CLP cohort	Placebo - TP 1 - CLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort
Started	25	12	25
Completed	22	10	16
Not completed	3	2	9
Discontinued TP and went to Follow-up	1	-	1
Subject/Guardian decision - TP 2	-	-	2
Subject/Guardian decision - TP 1	1	2	-
Adverse Event - TP 1	-	-	-
Adverse Event - TP 2	-	-	1
Discontinued study in TP 1	-	-	3
Progressive Disease - TP 1	1	-	-
Protocol Deviation-TP 2	-	-	-
Placebo Responder in TP1	-	-	-
Progressive Disease - TP 2	-	-	2

Number of subjects in period 1	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort	AIN457 300 mg Q4W - TP 1 - MLP cohort	Placebo - TP 1 - MLP cohort
Started	12	24	13
Completed	7	23	13
Not completed	5	1	0
Discontinued TP and went to Follow-up	-	1	-
Subject/Guardian decision - TP 2	-	-	-
Subject/Guardian decision - TP 1	-	-	-
Adverse Event - TP 1	-	-	-
Adverse Event - TP 2	-	-	-
Discontinued study in TP 1	3	-	-
Progressive Disease - TP 1	-	-	-

Protocol Deviation-TP 2	1	-	-
Placebo Responder in TP1	1	-	-
Progressive Disease - TP 2	-	-	-

Number of subjects in period 1	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort	AIN457 300 mg Q4W - TP 1 - LPP cohort
Started	24	13	24
Completed	16	10	23
Not completed	8	3	1
Discontinued TP and went to Follow-up	4	2	-
Subject/Guardian decision - TP 2	1	1	-
Subject/Guardian decision - TP 1	-	-	-
Adverse Event - TP 1	-	-	1
Adverse Event - TP 2	2	-	-
Discontinued study in TP 1	-	-	-
Progressive Disease - TP 1	-	-	-
Protocol Deviation-TP 2	-	-	-
Placebo Responder in TP1	-	-	-
Progressive Disease - TP 2	1	-	-

Number of subjects in period 1	Placebo - TP 1 - LPP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort
Started	13	24	13
Completed	12	18	11
Not completed	1	6	2
Discontinued TP and went to Follow-up	-	-	1
Subject/Guardian decision - TP 2	-	3	-
Subject/Guardian decision - TP 1	1	-	1
Adverse Event - TP 1	-	-	-
Adverse Event - TP 2	-	1	-
Discontinued study in TP 1	-	-	-
Progressive Disease - TP 1	-	-	-
Protocol Deviation-TP 2	-	-	-
Placebo Responder in TP1	-	-	-
Progressive Disease - TP 2	-	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study
Reporting group description: -	

Reporting group values	Overall Study	Total	
Number of subjects	111	111	
Age Categorical Units: Participants			
18 to <65 years	84	84	
> or = 65 years	27	27	
Sex: Female, Male Units: Participants			
Female	79	79	
Male	32	32	
Race/Ethnicity, Customized Units: Subjects			
Asian (Indian)	2	2	
Black or African American	14	14	
White	94	94	
White, American Indian or Alaska Native	1	1	
Baseline of Investigator's Global Assessment (IGA)			
The IGA provides a harmonized, 5-point grading system to assess disease severity for subjects of all 3 subtypes entering the study. The predominant subtype alone defined the IGA score of the subject and was collected separately for concomitant subtypes, if present (0=clear, 1=minimal, 2=mild, 3=moderate, 4=severe).			
Units: Subjects			
0=Clear	0	0	
1=Minimal	1	1	
2=Mild	0	0	
3=Moderate	82	82	
4=Severe	28	28	

Subject analysis sets	
Subject analysis set title	AIN457 300 mg Q4W - TP 1 - CLP cohort BL
Subject analysis set type	Full analysis
Subject analysis set description: Baseline (BL) for AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	
Subject analysis set title	Placebo - TP 1 - CLP cohort BL
Subject analysis set type	Full analysis
Subject analysis set description: Baseline (BL) for matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	
Subject analysis set title	AIN457 300 mg Q4W - TP 1 - MLP cohort BL
Subject analysis set type	Full analysis
Subject analysis set description: Baseline (BL) for AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	

Subject analysis set title	Placebo - TP 1 - MLP cohort Matching placebo BL
Subject analysis set type	Full analysis
Subject analysis set description: Baseline (BL) for matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	
Subject analysis set title	AIN457 300 mg Q4W - TP 1 - LPP cohort BL
Subject analysis set type	Full analysis
Subject analysis set description: Baseline (BL) for AIN457457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	
Subject analysis set title	Placebo - TP 1 - LPP cohort Matching placebo BL
Subject analysis set type	Full analysis
Subject analysis set description: Baseline (BL) for matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	

Reporting group values	AIN457 300 mg Q4W - TP 1 - CLP cohort BL	Placebo - TP 1 - CLP cohort BL	AIN457 300 mg Q4W - TP 1 - MLP cohort BL
Number of subjects	25	12	24
Age Categorical Units: Participants			
18 to <65 years	22	9	14
> or = 65 years	3	3	10
Sex: Female, Male Units: Participants			
Female	15	8	14
Male	10	4	10
Race/Ethnicity, Customized Units: Subjects			
Asian (Indian)	0	0	2
Black or African American	6	0	2
White	19	8	19
White, American Indian or Alaska Native	0	0	1
Baseline of Investigator's Global Assessment (IGA)			
The IGA provides a harmonized, 5-point grading system to assess disease severity for subjects of all 3 subtypes entering the study. The predominant subtype alone defined the IGA score of the subject and was collected separately for concomitant subtypes, if present (0=clear, 1=minimal, 2=mild, 3=moderate, 4=severe).			
Units: Subjects			
0=Clear	0	0	0
1=Minimal	1	0	0
2=Mild	0	0	0
3=Moderate	16	9	22
4=Severe	8	3	2

Reporting group values	Placebo - TP 1 - MLP cohort Matching placebo BL	AIN457 300 mg Q4W - TP 1 - LPP cohort BL	Placebo - TP 1 - LPP cohort Matching placebo BL
Number of subjects	13	24	13
Age Categorical Units: Participants			
18 to <65 years	8	19	12
> or = 65 years	5	5	1

Sex: Female, Male Units: Participants			
Female	12	20	10
Male	1	4	3
Race/Ethnicity, Customized Units: Subjects			
Asian (Indian)	0	0	0
Black or African American	1	1	0
White	12	23	13
White, American Indian or Alaska Native	0	0	0
Baseline of Investigator's Global Assessment (IGA)			
The IGA provides a harmonized, 5-point grading system to assess disease severity for subjects of all 3 subtypes entering the study. The predominant subtype alone defined the IGA score of the subject and was collected separately for concomitant subtypes, if present (0=clear, 1=minimal, 2=mild, 3=moderate, 4=severe).			
Units: Subjects			
0=Clear	0	0	0
1=Minimal	0	0	0
2=Mild	0	0	0
3=Moderate	8	17	10
4=Severe	5	7	3

End points

End points reporting groups

Reporting group title	AIN457 300 mg Q4W - TP 1 - CLP cohort
Reporting group description:	
AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	
Reporting group title	Placebo - TP 1 - CLP cohort
Reporting group description:	
Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	
Reporting group title	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort
Reporting group description:	
AIN457 300 mg every 4 weeks administered via a pre-filled syringe. Participants on AIN457 in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.	
Reporting group title	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort
Reporting group description:	
Placebo non-responders during TP 1 received AIN457 300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.	
Reporting group title	AIN457 300 mg Q4W - TP 1 - MLP cohort
Reporting group description:	
AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	
Reporting group title	Placebo - TP 1 - MLP cohort
Reporting group description:	
Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	
Reporting group title	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort
Reporting group description:	
AIN457 300 mg every 4 weeks administered via a pre-filled syringe. Participants on AIN457 in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.	
Reporting group title	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort
Reporting group description:	
Placebo non-responders during TP 1 received AIN457 300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.	
Reporting group title	AIN457 300 mg Q4W - TP 1 - LPP cohort
Reporting group description:	
AIN457457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	
Reporting group title	Placebo - TP 1 - LPP cohort
Reporting group description:	
Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	
Reporting group title	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort
Reporting group description:	
AIN457 300 mg every 4 weeks administered via a pre-filled syringe. Participants on AIN457 in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.	
Reporting group title	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort
Reporting group description:	
Placebo non-responders during TP 1 received AIN457 300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.	
Subject analysis set title	AIN457 300 mg Q4W - TP 1 - CLP cohort BL
Subject analysis set type	Full analysis
Subject analysis set description:	
Baseline (BL) for AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	
Subject analysis set title	Placebo - TP 1 - CLP cohort BL
Subject analysis set type	Full analysis

Subject analysis set description:

Baseline (BL) for matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe

Subject analysis set title	AIN457 300 mg Q4W - TP 1 - MLP cohort BL
Subject analysis set type	Full analysis

Subject analysis set description:

Baseline (BL) for AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe

Subject analysis set title	Placebo - TP 1 - MLP cohort Matching placebo BL
Subject analysis set type	Full analysis

Subject analysis set description:

Baseline (BL) for matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe

Subject analysis set title	AIN457 300 mg Q4W - TP 1 - LPP cohort BL
Subject analysis set type	Full analysis

Subject analysis set description:

Baseline (BL) for AIN457457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe

Subject analysis set title	Placebo - TP 1 - LPP cohort Matching placebo BL
Subject analysis set type	Full analysis

Subject analysis set description:

Baseline (BL) for matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe

Primary: Response rate of Investigator Global Assessment (IGA) score of 2 or lower at week 16 for CLP, MLP and LPP

End point title	Response rate of Investigator Global Assessment (IGA) score of 2 or lower at week 16 for CLP, MLP and LPP[1]

End point description:

Number of treatment responders at week 16, where response is defined as an Investigator's Global Assessment (IGA) score of 2 or lower at Week 16. IGA is measured on a scale from 0 - 4 with 0 = Clear, 1 = Minimal; 2 = Mild; 3 = Moderate; and 4 = Severe with 0 being best score and 4 being worst score. CLP=Cutaneous lichen planus, MLP=Mucosal lichen planus, LPP=Lichen planopilaris. Posterior median and 95% credible interval (instead of 95% confidence interval) were derived using Bayesian method based on beta-binomial model.

End point type	Primary

End point timeframe:

Baseline up to week 16

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoints reported by cohort.

End point values	AIN457 300 mg Q4W - TP 1 - CLP cohort	Placebo - TP 1 - CLP cohort	AIN457 300 mg Q4W - TP 1 - MLP cohort	Placebo - TP 1 - MLP cohort
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	12	24	13
Units: scores on a scale				
median (confidence interval 95%)	44.0 (25.8 to 63.32)	58.2 (31.0 to 82.6)	37.5 (20.3 to 57.2)	23.1 (6.5 to 49.2)

End point values	AIN457 300 mg Q4W - TP 1 - LPP cohort	Placebo - TP 1 - LPP cohort		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	13		
Units: scores on a scale				

median (confidence interval 95%)	37.6 (20.2 to 57.3)	30.9 (10.8 to 57.6)		

Statistical analyses

Statistical analysis title	CLP cohort
Comparison groups	AIN457 300 mg Q4W - TP 1 - CLP cohort v Placebo - TP 1 - CLP cohort
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Posterior median difference
Point estimate	-13.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.8
upper limit	19.3

Statistical analysis title	MLP cohort
Comparison groups	AIN457 300 mg Q4W - TP 1 - MLP cohort v Placebo - TP 1 - MLP cohort
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Posterior median difference
Point estimate	14.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17
upper limit	40.7

Statistical analysis title	LPP cohort
Comparison groups	AIN457 300 mg Q4W - TP 1 - LPP cohort v Placebo - TP 1 - LPP cohort
Number of subjects included in analysis	37
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Posterior median difference
Point estimate	6.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.4
upper limit	35.4

Secondary: Number (%) of subjects with IGA ≤ 2 response, IGA ≥2 points improvement response, and IGA 0 or 1 response by visit – CLP cohort (BOCF)- Entire Treatment Period (FAS)

End point title	Number (%) of subjects with IGA ≤ 2 response, IGA ≥2 points improvement response, and IGA 0 or 1 response by visit – CLP cohort (BOCF)- Entire Treatment Period (FAS)[2]

End point description:

Number of subjects with IGA of 2 or lower, improvement in the IGA score of at least 2 points, or IGA score of 0/1. IGA is measured on a scale from 0-4 with 0=Clear, 1=minimal, 2=mild, 3=moderate, and 4=severe with 0 being best score and 4 being worst score.

End point type	Secondary

End point timeframe:

Baseline up to week 32

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - CLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	25	10	
Units: participants				
Week 2 IGA <=2	1	5	0	
Week 2 IGA improvement >=2 n=25,12,0	0	2	0	
Week 2 IGA 0/1 n=25,12,0	0	2	0	
Week 4 IGA <=2 n=24,11,0	2	9	0	
Week 4 IGA improvement. >=2 n=24,11,0	0	3	0	
Week 4 IGA 0/1 n=24,11,0	0	2	0	
Week 8 IGA <=2 n=25,11,0	3	10	0	
Week 8 IGA improvement. >=2 n=25,11,0	1	4	0	
Week 8 IGA 0/1 n=25,11,0	1	3	0	
Week 12 IGA <=2 n=25,12,0	4	10	0	
Week 12 IGA improvement. >=2 n=25,12,0	2	3	0	
Week 12 IGA 0/1 n=25,12,0	1	4	0	
Week16 IGA <=2 n=25,12,10	7	11	5	
Week 16 IGA improvement. >=2 n=25,12,10	3	4	1	
Week 16 IGA 0/1 n=25,12,10	2	4	0	
Week 20 IGA <=2 n=24,0,10	0	11	1	
Week 20 IGA improvement. >=2 n=24,0,10	0	5	1	

Week 20 IGA 0/1 n=24,0,10	0	5	1	
Week 24 IGA <=2 n=25,0,10	0	14	3	
Week 24 IGA improvement. >=2 n=25,0,10	0	10	2	
Week 24 IGA 0/1 n=25,0,10	0	10	1	
Week 28 IGA <=2 n=23,0,10	0	12	4	
Week 28 IGA improvement. >=2 n=23,0,10	0	7	1	
Week 28 IGA 0/1 n=23,0,10	0	6	1	
Week 32 IGA <=2 n=24,0,9	0	9	2	
Week 32 IGA improvement. >=2 n=24,0,9	0	7	2	
Week 32 IGA 0/1 n=24,0,9	0	6	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of subjects with IGA ≤ 2 response, IGA ≥2 points improvement response, and IGA 0 or 1 response by visit – MLP cohort (BOCF)- Entire Treatment Period (FAS)

End point title	Number (%) of subjects with IGA ≤ 2 response, IGA ≥2 points improvement response, and IGA 0 or 1 response by visit – MLP cohort (BOCF)- Entire Treatment Period (FAS)[3]

End point description:

Number of subjects with IGA of 2 of lower, improvement in the IGA score of at least 2 points, or IGA score of 0/1. IGA is measured on a scale from 0-4 with 0=Clear, 1=minimal, 2=mild, 3=moderate, and 4=severe with 0 being best score and 4 being worst score.

End point type	Secondary

End point timeframe:

Baseline up to week 32

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - MLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	11	
Units: participants				
Week 2 IGA <=2 n=24,12,0	3	5	0	
Week 2 IGA improvement >=2 n=24,12,0	1	1	0	
Week 2 IGA 0/1 n=24,12,0	1	1	0	
Week 4 IGA <=2 n=24,13,0	2	4	0	
Week 4 IGA improvement. >=2 n=24,13,0	1	1	0	
Week 4 IGA 0/1 n=24,13,0	1	1	0	
Week 8 IGA <=2 n=24,13,0	3	5	0	
Week 8 IGA improvement. >=2 n=24,13,0	2	0	0	

Week 8 IGA 0/1 n=24,13,0	1	0	0	
Week 12 IGA <=2 n=24,13,0	4	5	0	
Week 12 IGA improvement. >=2 n=24,13,0	4	5	0	
Week 12 IGA 0/1 n=24,13,0	2	4	0	
Week16 IGA <=2 n=24,13,11	3	9	1	
Week 16 IGA improvement. >=2 n=24,13,11	3	5	1	
Week 16 IGA 0/1 n=24,13,11	2	4	0	
Week 20 IGA <=2 n=24,0,11	0	10	3	
Week 20 IGA improvement. >=2 n=24,0,11	0	5	2	
Week 20 IGA 0/1 n=24,0,11	0	5	1	
Week 24 IGA <=2 n=24,0,10	0	10	4	
Week 24 IGA improvement. >=2 n=24,0,10	0	3	2	
Week 24 IGA 0/1 n=24,0,10	0	3	0	
Week 28 IGA <=2 n=23,0,11	0	7	4	
Week 28 IGA improvement. >=2 n=23,0,11	0	1	3	
Week 28 IGA 0/1 n=23,0,11	0	1	0	
Week 32 IGA <=2 n=23,0,10	0	9	2	
Week 32 IGA improvement. >=2 n=23,0,10	0	2	1	
Week 32 IGA 0/1 n=23,0,10	0	2	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of subjects with IGA ≤ 2 response, IGA ≥2 points improvement response, and IGA 0 or 1 response by visit – LPP cohort (BOCF)- Entire Treatment Period (FAS)

End point title	Number (%) of subjects with IGA ≤ 2 response, IGA ≥2 points improvement response, and IGA 0 or 1 response by visit – LPP cohort (BOCF)- Entire Treatment Period (FAS)[4]

End point description:

Number of subjects with IGA of 2 or lower, improvement in the IGA score of at least 2 points, or IGA score of 0/1. IGA is measured on a scale from 0-4 with 0=Clear, 1=minimal, 2=mild, 3=moderate, and 4=severe with 0 being best score and 4 being worst score.

End point type	Secondary

End point timeframe:

Baseline up to week 32

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are reported by cohort.

End point values	Placebo - TP 1 - LPP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	13	
Units: participants				
Week 2 IGA <=2 n=24,13,0	1	4	0	
Week 2 IGA improvement >=2 n=24,13,0	0	1	0	
Week 2 IGA 0/1 n=24,13,0	0	1	0	
Week 4 IGA <=2 n=24,13,0	2	9	0	
Week 4 IGA improvement. >=2 n=24,13,0	1	2	0	
Week 4 IGA 0/1 n=24,13,0	1	2	0	
Week 8 IGA <=2 n=24,13,0	3	8	0	
Week 8 IGA improvement. >=2 n=24,13,0	1	3	0	
Week 8 IGA 0/1 n=24,13,0	1	3	0	
Week 12 IGA <=2 n=24,13,0	4	8	0	
Week 12 IGA improvement. >=2 n=24,13,0	2	3	0	
Week 12 IGA 0/1 n=24,13,0	2	2	0	
Week16 IGA <=2 n=24,13,13	4	9	4	
Week 16 IGA improvement. >=2 n=24,13,13	0	3	0	
Week 16 IGA 0/1 n=24,13,13	0	2	0	
Week 20 IGA <=2 n=24,0,13	0	10	6	
Week 20 IGA improvement. >=2 n=24,0,13	0	6	1	
Week 20 IGA 0/1 n=24,0,13	0	4	0	
Week 24 IGA <=2 n=23,0,13	0	10	8	
Week 24 IGA improvement. >=2 n=23,0,13	0	7	3	
Week 24 IGA 0/1 n=23,0,13	0	6	2	
Week 28 IGA <=2 n=24,0,13	0	10	9	
Week 28 IGA improvement. >=2 n=24,0,13	0	6	4	
Week 28 IGA 0/1 n=24,0,13	0	5	3	
Week 32 IGA <=2 n==24,0,11	0	11	7	
Week 32 IGA improvement. >=2 n==24,0,11	0	5	5	
Week 32 IGA 0/1 n==24,0,11	0	4	4	

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of subjects in each category in Physician´s assessment of surface area of disease (PSAD) - CLP (BOCF) – Entire treatment period (FAS)

End point title	Number (%) of subjects in each category in Physician´s assessment of surface area of disease (PSAD) - CLP (BOCF) – Entire treatment period (FAS)[5]

End point description:

The Physician Assessment of Surface Area of Disease (PSAD) evaluates the extent of cutaneous lesions estimated by investigator or qualified designee. Assessment scores range from 0-5, with lower scores corresponding to lower percentages of surface area with disease: 0=clear, 1=<2%, 2=2-9%, 3=10-29%, 4=30-50%, 5=>50% of total body surface

End point type	Secondary

End point timeframe:

Baseline up to week 32

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - CLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	25	10	
Units: participants				
Baseline 0 Score	0	0	0	
Baseline 1 score	0	3	0	
Baseline 2 score	0	6	0	
Baseline 3 score	3	6	0	
Baseline 4 score	6	5	0	
Baseline 5 score	3	5	0	
Week 2 0 score	0	0	0	
Week 2 1 score	0	6	0	
Week 2 2 score	1	5	0	
Week 2 3 score	3	9	0	
Week 2 4 score	5	3	0	
Week 2 5 score	3	2	0	
Week 4 0 score	0	0	0	
Week 4 1 score	0	3	0	
Week 4 2 score	0	8	0	
Week 4 3 score	3	8	0	
Week 4 4 score	5	3	0	
Week 4 5 score	3	2	0	
Week 8 0 score	0	0	0	
Week 8 1 score	1	7	0	
Week 8 2 score	1	5	0	
Week 8 3 score	2	7	0	
Week 8 4 score	4	4	0	
Week 8 5 score	3	2	0	
Week 12 0 score	0	0	0	
Week 12 1 score	1	6	0	
Week 12 2 score	2	7	0	
Week 12 3 score	0	7	0	
Week 12 4 score	7	3	0	
Week 12 5 score	2	2	0	
Week 16 0 score	0	0	0	
Week 16 1 score	2	4	0	
Week 16 2 score	3	12	3	
Week 16 3 score	3	5	3	

Week 16 4 score	4	2	4	
Week 16 5 score	0	2	0	
Week 20 0 score	0	0	0	
Week 20 1 score	0	6	0	
Week 20 2 score	0	12	3	
Week 20 3 score	0	3	2	
Week 20 4 score	0	1	3	
Week 20 5 score	0	2	2	
Week 24 0 score	0	1	0	
Week 24 1 score	0	8	0	
Week 24 2 score	0	10	2	
Week 24 3 score	0	1	2	
Week 24 4 score	0	2	4	
Week 24 5 score	0	3	2	
Week 28 0 score	0	0	0	
Week 28 1 score	0	6	0	
Week 28 2 score	0	11	2	
Week 28 3 score	0	1	3	
Week 28 4 score	0	3	3	
Week 28 5 score	0	2	2	
Week 32 0 score	0	2	0	
Week 32 1 score	0	5	1	
Week 32 2 score	0	10	0	
Week 32 3 score	0	3	4	
Week 32 4 score	0	1	2	
Week 32 5 score	0	3	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0/1) up to Week 32 - CLP cohort - Entire treatment period (FAS)

End point title	Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0/1) up to Week 32 - CLP cohort - Entire treatment period (FAS)[6]

End point description:

The DLQI is a 10-item general dermatology disability index designed to assess health-related quality of life (HRQoL) in adult subjects with skin diseases such as eczema, psoriasis, acne, and viral warts (Finlay and Khan 1994). The measure is self-administered and includes domains of daily activities, leisure, personal relationships, symptoms and feelings, treatment, and work/school. The recall period is the last week, and the instrument requires 1 to 2 minutes for completion. Each item has four response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions. Scores range from 0 to 30, with higher scores indicating greater HRQoL impairment.

End point type	Secondary

End point timeframe:

Baseline up to week 32

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - CLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	25	10	
Units: participants				
Baseline n=25,12,0	0	0	0	
Week 4 n=24,11,0	0	2	0	
Week 8 n=25,11,0	0	2	0	
Week 12 n=25,12,0	1	3	0	
Week 16 n=25,12,10	2	3	2	
Week 20 n=24,0,10	0	3	1	
Week 24 n=25,0,10	0	4	1	
Week 28 n=23,0,10	0	3	1	
Week 32 n=25,0,9	0	2	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0/1) up to Week 32 - MLP cohort - Entire treatment period (FAS)

End point title	Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0/1) up to Week 32 - MLP cohort - Entire treatment period (FAS)[7]

End point description:

The DLQI is a 10-item general dermatology disability index designed to assess health-related quality of life (HRQoL) in adult subjects with skin diseases such as eczema, psoriasis, acne, and viral warts (Finlay and Khan 1994). The measure is self-administered and includes domains of daily activities, leisure, personal relationships, symptoms and feelings, treatment, and work/school. The recall period is the last week, and the instrument requires 1 to 2 minutes for completion. Each item has four response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions. Scores range from 0 to 30, with higher scores indicating greater HRQoL impairment.

End point type	Secondary

End point timeframe:

Baseline up to week 32

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - MLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	11	
Units: participants				
Baseline n=24,13,0	0	0	0	
Week 4 n=24,13,0	1	2	0	
Week 8 n=24,13,0	1	4	0	
Week 12 n=24,13,0	2	4	0	

Week 16 n=24,13,11	3	5	2	
Week 20 n=24,0,11	0	7	2	
Week 24 n=24,0,10	0	7	3	
Week 28 n=23,0,11	0	3	2	
Week 32 n=23,0,10	0	4	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0/1) up to Week 32 - LPP cohort - Entire treatment period (FAS)

End point title	Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0/1) up to Week 32 - LPP cohort - Entire treatment period (FAS)[8]

End point description:

The DLQI is a 10-item general dermatology disability index designed to assess health-related quality of life (HRQoL) in adult subjects with skin diseases such as eczema, psoriasis, acne, and viral warts (Finlay and Khan 1994). The measure is self-administered and includes domains of daily activities, leisure, personal relationships, symptoms and feelings, treatment, and work/school. The recall period is the last week, and the instrument requires 1 to 2 minutes for completion. Each item has four response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions. Scores range from 0 to 30, with higher scores indicating greater HRQoL impairment.

End point type	Secondary

End point timeframe:

Baseline up to week 32

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - LPP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	13	
Units: participants				
Baseline n=24,13,0	0	0	0	
Week 4 n=24,13,0	1	3	0	
Week 8 n=24,13,0	1	3	0	
Week 12 n=24,13,0	2	2	0	
Week 16 n=24,13,13	1	2	1	
Week 20 n=24,0,13	0	4	3	
Week 24 n=23,0,13	0	2	3	
Week 28 n=24,0,13	0	2	2	
Week 32 n=24,0,11	0	1	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline for Patient Assessment of Itch using numeric rating scale (NRS) by question – CLP cohort (BOCF) (FAS)

End point title	Summary of baseline score and change from baseline for Patient Assessment of Itch using numeric rating scale (NRS) by question – CLP cohort (BOCF) (FAS)[9]

End point description:

Itch is assessed with the following questions: • "Overall, how severe was your lichen planus-related itching during the past 24 hours?" • "How severe was your lichen planus-related itching at the worst moment during the past 24 hours?" • "Overall, how bothered were you by your lichen planus-related itching during the past 24 hours?" Answers are given on a numeric rating scale (NRS) from 0 to 10, with 0 meaning "no itch" and 10 meaning "the worst itch imaginable".

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - CLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	25	10	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline - Question 1	5.7 (± 2.77)	5.1 (± 2.66)	5.8 (± 3.01)	
Week 16 Severity of itch n=25,12,10	-2.3 (± 3.25)	-0.8 (± 1.91)	-2.0 (± 3.53)	
Week 32 Severity of itch n=25,0,9	999 (± 999)	-1.5 (± 2.24)	-1.1 (± 2.42)	
Baseline- Question 2	6.3 (± 2.86)	5.6 (± 2.72)	5.9 (± 3.03)	
Week 16 How severe at worst moment n=25,12,10	-2.7 (± 3.73)	-0.9 (± 2.52)	-1.9 (± 3.54)	
Week 32 How severe st worst moment n=25,0,9	999 (± 999)	-1.3 (± 2.13)	-1.2 (± 2.49)	
Baseline- Question 3	6.1 (± 2.94)	4.8 (± 3.08)	6.1 (± 3.21)	
Week 16 How bothered by Itch n=25,12,10	-2.7 (± 3.55)	-1.0 (± 2.65)	-2.4 (± 3.84)	
Week 32 How bothered by Itch n=25,0,9	999 (± 999)	-1.1 (± 2.45)	-1.2 (± 2.28)	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline for Patient Assessment of Itch using numeric rating scale (NRS) by question – MLP cohort (BOCF) (FAS)

End point title	Summary of baseline score and change from baseline for Patient Assessment of Itch using numeric rating scale (NRS) by question – MLP cohort (BOCF) (FAS)[10]

End point description:

Itch is assessed with the following questions: • "Overall, how severe was your lichen planus-related itching during the past 24 hours?" • "How severe was your lichen planus-related itching at the worst moment during the past 24 hours?" • "Overall, how bothered were you by your lichen planus-related itching during the past 24 hours?" Answers are given on a numeric rating scale (NRS) from 0 to 10, with 0 meaning "no itch" and 10 meaning "the worst itch imaginable".

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - MLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	13	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline - Question 1 n=24,13,11	3.8 (± 3.81)	2.5 (± 2.83)	4.3 (± 3.93)	
Week 16 Severity of itch n=23,13,11	-0.2 (± 3.41)	-0.3 (± 3.26)	-0.3 (± 3.72)	
Week 32 Severity of itch n=22,0,10	999 (± 999)	0.1 (± 2.97)	-0.4 (± 3.37)	
Baseline - Question 2 n=24,13,11	3.6 (± 3.99)	2.4 (± 2.90)	4.1 (± 4.16)	
Week 16 How severe at worst moment n=23,13,11	0.4 (± 3.25)	0.8 (± 3.04)	0.4 (± 3.56)	
Week 32 How severe at worst moment n=22,0,10	999 (± 999)	0.3 (± 2.43)	0.4 (± 3.81)	
Baseline - Question 3 n=24,13,11	4.0 (± 4.14)	3.4 (± 3.41)	4.5 (± 4.27)	
Week 16 How bothered by Itch n=23,13,11	0.1 (± 3.12)	-0.5 (± 2.95)	0.0 (± 3.41)	
Week 32 How bothered by Itch n=22,0,10	999 (± 999)	-0.4 (± 1.33)	-0.4 (± 4.25)	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline for Patient Assessment of Itch using numeric rating scale (NRS) by question – LPP cohort (BOCF) (FAS)

End point title	Summary of baseline score and change from baseline for Patient Assessment of Itch using numeric rating scale (NRS) by question – LPP cohort (BOCF) (FAS)[11]

End point description:

Itch is assessed with the following questions: • "Overall, how severe was your lichen planus-related itching during the past 24 hours?" • "How severe was your lichen planus-related itching at the worst moment during the past 24 hours?" • "Overall, how bothered were you by your lichen planus-related itching during the past 24 hours?" Answers are given on a numeric rating scale (NRS) from 0 to 10, with 0 meaning "no itch" and 10 meaning "the worst itch imaginable".

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - LPP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	12	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline - Question 1 n=24,13,12	3.8 (± 3.81)	2.5 (± 2.83)	4.3 (± 3.93)	
Week 16 Severity of itch n=24,13,11	-1.1 (± 2.47)	-0.5 (± 2.25)	-1.1 (± 2.47)	
Week 32 Severity of itch n=24,0,11	999 (± 999)	-1.6 (± 2.06)	-2.4 (± 2.84)	
Baseline - Question 2 n=24,13,11	3.6 (± 3.99)	2.4 (± 2.90)	4.1 (± 4.16)	
Week 16 How severe at worst moment n=24,13,11	-1.3 (± 2.81)	-0.7 (± 2.35)	-1.3 (± 2.81)	
Week 32 How severe at worst moment n=24,0,11	999 (± 999)	-1.8 (± 2.23)	-2.6 (± 3.01)	
Baseline - Question 3 n=24,13,11	4.0 (± 4.14)	3.4 (± 3.41)	4.5 (± 4.27)	
Week 16 How bothered by Itch n=24,13,11	-1.2 (± 3.02)	-0.4 (± 2.43)	-1.2 (± 3.02)	
Week 32 How bothered by Itch n=24,0,11	999 (± 999)	-1.7 (± 2.08)	-2.2 (± 2.44)	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline for Patient Assessment of Pain using numeric rating scale (NRS) by question – CLP cohort (BOCF) (FAS)

End point title	Summary of baseline score and change from baseline for Patient Assessment of Pain using numeric rating scale (NRS) by question – CLP cohort (BOCF) (FAS)[12]

End point description:

Pain is assessed with the following questions: • "Overall, how severe was your lichen planus-related pain during the past 24 hours?" • "How severe was your lichen planus-related pain at the worst moment during the past 24 hours?" • "Overall, how bothered were you by your lichen planus-related pain during the past 24 hours?" Answers are given on a numeric rating scale (NRS) from 0 to 10, with 0 meaning "no pain" and 10 meaning "the worst pain imaginable".

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - CLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	25	10	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline - Question 1 n=25,12,10	3.4 (± 2.61)	1.09 (± 2.05)	3.5 (± 2.51)	
Week 16 Severity of pain n=25,12,10	-0.8 (± 1.40)	0.2 (± 1.48)	-0.8 (± 1.48)	
Week 32 Severity of pain n=25,0,9	999 (± 999)	-0.3 (± 1.65)	-0.3 (± 2.29)	
Baseline - Question 2 n=25,12,10	3.9 (± 3.23)	2.2 (± 2.48)	3.9 (± 3.03)	
Week 16 How severe at worst moment n=25,12,10	-1.2 (± 1.70)	0.1 (± 2.03)	-1.0 (± 1.56)	
Week 32 How severe at worst moment n=25,0,9	999 (± 999)	-0.4 (± 2.35)	-0.4 (± 2.70)	
Baseline - Question 3 n=25,12,10	3.7 (± 2.96)	2.1 (± 2.55)	3.8 (± 2.94)	
Week 16 How bothered by pain n=25,12,10	-0.6 (± 1.62)	0.1 (± 2.09)	0.5 (± 1.72)	
Week 32 How bothered by pain n=25, 0,9	999 (± 999)	-0.2 (± 1.71)	-0.3 (± 2.45)	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline for Patient Assessment of Pain using numeric rating scale (NRS) by question –MLP cohort (BOCF) (FAS)

End point title	Summary of baseline score and change from baseline for Patient Assessment of Pain using numeric rating scale (NRS) by question –MLP cohort (BOCF) (FAS)[13]

End point description:

Pain is assessed with the following questions: • "Overall, how severe was your lichen planus-related pain during the past 24 hours?" • "How severe was your lichen planus-related pain at the worst moment during the past 24 hours?" • "Overall, how bothered were you by your lichen planus-related pain during the past 24 hours?" Answers are given on a numeric rating scale (NRS) from 0 to 10, with 0 meaning "no pain" and 10 meaning "the worst pain imaginable".

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - MLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	11	
Units: scores on a scale				
arithmetic mean (standard deviation)				

Baseline - Question 1 n=24,13,11	5.9 (± 3.09)	5.1 (± 2.86)	6.3 (± 3.23)	
Week 16 Severity of pain n=24,13,11	-0.1 (± 3.01)	-0.5 (± 3.08)	0.0 (± 3.29)	
Week 32 Severity of pain n=23,0,10	999 (± 999)	-0.3 (± 2.18)	-0.6 (± 2.59)	
Baseline - Question 2 n=24,13,11	6.4 (± 3.15)	5.4 (± 2.99)	6.7 (± 3.26)	
Week 16 How severe at worst moment n=24,13,11	-0.3 (± 2.75)	-0.5 (± 3.13)	-0.2 (± 2.99)	
Week 32 How severe at worst moment n=23,0,10	999 (± 999)	-0.3 (± 2.06)	-0.5 (± 2.46)	
Baseline - Question 3 n=24,13,11	6.5 (± 2.76)	5.5 (± 3.35)	6.8 (± 2.79)	
Week 16 How bothered by pain n=24,13,11	-0.3 (± 2.21)	-0.8 (± 3.54)	-0.1 (± 2.34)	
Week 32 How bothered by pain n=23,0,10	999 (± 999)	-0.5 (± 2.74)	-0.9 (± 2.69)	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline for Patient Assessment of Pain using numeric rating scale (NRS) by question – LPP cohort (BOCF) (FAS)

End point title	Summary of baseline score and change from baseline for Patient Assessment of Pain using numeric rating scale (NRS) by question – LPP cohort (BOCF) (FAS)[14]

End point description:

Pain is assessed with the following questions: • "Overall, how severe was your lichen planus-related pain during the past 24 hours?" • "How severe was your lichen planus-related pain at the worst moment during the past 24 hours?" • "Overall, how bothered were you by your lichen planus-related pain during the past 24 hours?" Answers are given on a numeric rating scale (NRS) from 0 to 10, with 0 meaning "no pain" and 10 meaning "the worst pain imaginable".

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - LPP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	12	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline - Question 1 n=24,13,12	2.0 (± 2.38)	2.5 (± 2.43)	2.0 (± 2.38)	
Week 16 Severity of pain past 24 hours n=24,13,12	-0.5 (± 1.90)	0.3 (± 2.61)	-0.5 (± 1.90)	
Week 32 Severity of pain p ast 24 hours n=24,0,11	999 (± 999)	-0.6 (± 1.72)	-1.5 (± 2.02)	
Baseline - Question 2 24,13,12	2.5 (± 2.73)	2.8 (± 2.68)	2.5 (± 2.73)	
Week 16 How severe at worst moment n=24,13,12	-0.9 (± 2.25)	0.2 (± 3.16)	-0.9 (± 2.25)	

Week 32 How severe at worst moment n=24,0,11	999 (± 999)	-0.8 (± 2.06)	-2.0 (± 2.45)	
Baseline - Question 3 n=24,13,12	2.4 (± 2.75)	2.7 (± 2.56)	2.4 (± 2.75)	
Week 16 How bothered by pain n=24,13,12	-1.1 (± 2.25)	0.0 (± 2.87)	-1.1 (± 2.25)	
Week 32 How bothered by pain n=24,0,11	999 (± 999)	-0.8 (± 1.79)	-1.9 (± 2.51)	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline in Oral Lichen Planus Symptom Severity Measure (OLPSSM) - MLP Cohort - (BOCF) – Entire treatment period

End point title	Summary of baseline score and change from baseline in Oral Lichen Planus Symptom Severity Measure (OLPSSM) - MLP Cohort - (BOCF) – Entire treatment period[15]

End point description:

OLPSSM is a self-administered assessment of the symptom experience of subjects with oral LP in clinical studies. It includes 7 triggers contributing to soreness of oral lichen planus: Brushing teeth, eating food, drinking liquids, smiling, breathing through mouth, talking and touching. These 7 items contributed equally to a total OLP symptom severity score, ranging from 0 to 28, with higher scores indicating worse severity.

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - MLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	12	21	10	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline n=21,12,10	13.4 (± 5.50)	11.0 (± 5.98)	13.9 (± 5.78)	
Week 16 n=21,12,10	0.8 (± 6.47)	-1.0 (± 6.82)	-0.4 (± 7.09)	
Week 32 n=20,0,9	999 (± 999)	-1.8 (± 5.67)	-0.7 (± 7.00)	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline in Reticular Erythematous Ulcerative score (REU) - MLP Cohort - (BOCF) – Entire treatment period

End point title	Summary of baseline score and change from baseline in Reticular Erythematous Ulcerative score (REU) - MLP Cohort - (BOCF) – Entire treatment period[16]

End point description:

REU measured disease severity based on 3 dimensions: reticulation, erythema and ulceration for all subjects in the MLP cohort who had an oral presentation of the disease. The total score ranged from 0-115 with higher values corresponding to higher activity of the disease.

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints are reported by cohort.

End point values	Placebo - TP 1 - MLP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	21	10	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline n=21,12,10	25.29 (± 9.102)	21.31 (± 8.747)	26.95 (± 8.855)	
Week 16 n=21,12,10	-5.79 (± 14.476)	-4.83 (± 11.102)	-4.10 (± 15.196)	
Week 32 n=20,0,9	999 (± 999)	-6.08 (± 10.206)	-2.17 (± 15.802)	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline for Lichen Planopilaris Activity Index (LPPAI)– LPP cohort (BOCF) (FAS)

End point title	Summary of baseline score and change from baseline for Lichen Planopilaris Activity Index (LPPAI)– LPP cohort (BOCF) (FAS)[17]

End point description:

The LPPAI assesses symptoms (pruritus, pain, burning), signs (erythema, perifollicular erythema and scale), a measure of activity (pull test) and extension of disease. These subjective and objective measures are assigned numeric values to establish a disease activity score. The total score ranges from 0 to 10, with higher scores corresponding to higher disease activity

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - LPP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	13	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline n=24,13,13	5.95 (± 1.767)	5.92 (± 2.071)	5.95 (± 1.767)	
Week 16 n=24,13,13	-2.24 (± 2.522)	-1.44 (± 2.517)	-2.24 (± 2.522)	
Week 32 n=24,0,13	999 (± 999)	-2.44 (± 2.428)	-3.20 (± 2.927)	

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of baseline score and change from baseline for Scalpdex – LPP cohort (BOCF) (FAS)

End point title	Summary of baseline score and change from baseline for Scalpdex – LPP cohort (BOCF) (FAS)[18]

End point description:

Scalpdex is a self-administered, health-related quality of life instrument originally developed for scalp dermatitis. This survey includes 23 items, each item scored on a scale of 0-100, where 0=never, 25=rarely, 50=sometimes, 75=often and 100=all the time. The 23 items pertain to 3 domains: symptom, emotions and functioning. Subjects were asked to score themselves on how true each of the 23 statements has been for them over the past four weeks. the total score is the average of the scores of the 23 items. A higher total score indicated a higher impairment in quality of life.

End point type	Secondary

End point timeframe:

Baseline, Week 16 and Week 32

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Endpoints reported by cohort.

End point values	Placebo - TP 1 - LPP cohort	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	24	12	
Units: scores on a scale				
arithmetic mean (standard deviation)				
Baseline n=24,13,12	54.01 (± 23.252)	55.75 (± 16.476)	54.01 (± 23.252)	
Week 16 n=24,13,12	-6.94 (± 11.508)	1.86 (± 10.695)	-6.94 (± 11.508)	
Week 32 n=24,0,11	999 (± 999)	-4.26 (± 12.876)	-14.43 (± 16.464)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were reported from first dose of study treatment up to a maximum of 300 days which included an approximate follow up period of 8 weeks for AIN457 treatment groups.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	Placebo to AIN457 300mg Q2W – CLP cohort

Reporting group description:

Placebo non-responders during TP1 received AIN457 300mg every 2 weeks from Week 16 to Week 32 in TP2 via a pre-filled syringe

Reporting group title	AIN457 300mg Q4W – CLP cohort

Reporting group description:

AIN457 300mg every 4 weeks up to 32 Weeks administered via a pre-filled syringe

Reporting group title	Any AIN457 300mg – CLP cohort

Reporting group description:

AIN457 300mg administered every 4 weeks or every 2 weeks via a pre-filled syringe

Reporting group title	Any AIN457 300mg – MLP cohort

Reporting group description:

AIN457 300mg administered every 4 weeks or every 2 weeks via a pre-filled syringe

Reporting group title	Placebo – MLP cohort

Reporting group description:

Matching placebo administered every 4 weeks up to 16 Weeks via a pre-filled syringe

Reporting group title	AIN457 300mg Q4W – LPP cohort

Reporting group description:

AIN457 300mg every 4 weeks up to 32 Weeks administered via a pre-filled syringe

Reporting group title	Placebo to AIN457 300mg Q2W – LPP cohort

Reporting group description:

Placebo non-responders during TP1 received AIN457 300mg every 2 weeks from Week 16 to Week 32 in TP2 via a pre-filled syringe

Reporting group title	Any AIN457 300mg – LPP cohort

Reporting group description:

AIN457 300mg administered every 4 weeks or every 2 weeks via a pre-filled syringe

Reporting group title	Placebo – LPP cohort

Reporting group description:

Matching placebo administered every 4 weeks up to 16 Weeks via a pre-filled syringe

Reporting group title	AIN457 300mg Q4W – MLP cohort

Reporting group description:

AIN457 300mg every 4 weeks up to 32 Weeks administered via a pre-filled syringe

Reporting group title	Placebo – CLP cohort

Reporting group description:

Matching placebo administered every 4 weeks up to 16 Weeks via a pre-filled syringe

Reporting group title	Placebo to AIN457 300mg Q2W – MLP cohort

Reporting group description:

Placebo non-responders during TP1 received AIN457 300mg every 2 weeks from Week 16 to Week 32 in TP2 via a pre-filled syringe

Serious adverse events	Placebo to AIN457 300mg Q2W – CLP cohort	AIN457 300mg Q4W – CLP cohort	Any AIN457 300mg – CLP cohort
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neuralgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleurisy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Any AIN457 300mg – MLP cohort	Placebo – MLP cohort	AIN457 300mg Q4W – LPP cohort
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 35 (5.71%)	0 / 13 (0.00%)	0 / 24 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neuralgia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleurisy			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Osteoarthritis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo to AIN457 300mg Q2W – LPP cohort	Any AIN457 300mg – LPP cohort	Placebo – LPP cohort
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	1 / 13 (7.69%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neuralgia			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleurisy			

subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	AIN457 300mg Q4W – MLP cohort	Placebo – CLP cohort	Placebo to AIN457 300mg Q2W – MLP cohort
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	1 / 12 (8.33%)	1 / 11 (9.09%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Neuralgia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Pleurisy			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Placebo to AIN457 300mg Q2W – CLP cohort	AIN457 300mg Q4W – CLP cohort	Any AIN457 300mg – CLP cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 8 (75.00%)	15 / 25 (60.00%)	21 / 33 (63.64%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 8 (0.00%)	2 / 25 (8.00%)	2 / 33 (6.06%)
occurrences (all)	0	2	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	1 / 25 (4.00%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
Asthenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Injection site haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 8 (0.00%)	2 / 25 (8.00%)	2 / 33 (6.06%)
occurrences (all)	0	2	2
Oedema peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	0 / 8 (0.00%)	3 / 25 (12.00%)	3 / 33 (9.09%)
occurrences (all)	0	8	8
Seasonal allergy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast cyst			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Ligament sprain			

subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Traumatic fracture			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Tendon rupture			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Cardiac disorders			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 8 (0.00%)	3 / 25 (12.00%)	3 / 33 (9.09%)
occurrences (all)	0	6	6
Dizziness			
subjects affected / exposed	0 / 8 (0.00%)	1 / 25 (4.00%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Blood and lymphatic system disorders			

Lymph node pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Auricular swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 8 (12.50%)	2 / 25 (8.00%)	3 / 33 (9.09%)
occurrences (all)	1	2	3
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 8 (0.00%)	2 / 25 (8.00%)	2 / 33 (6.06%)
occurrences (all)	0	2	2
Leukoplakia oral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Dermal cyst			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	2	0	2
Dermatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Skin burning sensation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Lichen planus			
subjects affected / exposed	1 / 8 (12.50%)	3 / 25 (12.00%)	4 / 33 (12.12%)
occurrences (all)	1	3	4
Urticaria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0

Renal and urinary disorders			
Micturition urgency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Osteonecrosis of jaw			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Exostosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 25 (4.00%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
Plantar fasciitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0

Fungal skin infection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Ear infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 8 (12.50%)	1 / 25 (4.00%)	2 / 33 (6.06%)
occurrences (all)	1	1	2
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 25 (4.00%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	1 / 25 (4.00%)	1 / 33 (3.03%)
occurrences (all)	0	2	2
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 8 (0.00%)	2 / 25 (8.00%)	2 / 33 (6.06%)
occurrences (all)	0	2	2
Herpes ophthalmic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 25 (4.00%)	1 / 33 (3.03%)
occurrences (all)	0	1	1

Superinfection			
subjects affected / exposed	1 / 8 (12.50%)	0 / 25 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Tongue fungal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 25 (4.00%)	1 / 33 (3.03%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
Vitamin D deficiency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 25 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Any AIN457 300mg – MLP cohort	Placebo – MLP cohort	AIN457 300mg Q4W – LPP cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 35 (74.29%)	8 / 13 (61.54%)	16 / 24 (66.67%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 35 (2.86%)	1 / 13 (7.69%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	4
Asthenia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Injection site haemorrhage			

subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	3
Peripheral swelling			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 35 (2.86%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	2 / 35 (5.71%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Breast cyst			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Traumatic fracture			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 35 (5.71%)	1 / 13 (7.69%)	5 / 24 (20.83%)
occurrences (all)	2	1	5
Dizziness			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymph node pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Auricular swelling			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 35 (0.00%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 35 (5.71%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
Abdominal pain upper			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	2
Colitis			
subjects affected / exposed	0 / 35 (0.00%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	3 / 35 (8.57%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			

subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Leukoplakia oral			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	2 / 35 (5.71%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
Oral pain			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 35 (0.00%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Dermal cyst			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	1 / 24 (4.17%)
occurrences (all)	0	0	1
Skin burning sensation			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	3 / 35 (8.57%)	0 / 13 (0.00%)	3 / 24 (12.50%)
occurrences (all)	6	0	4

Lichen planus			
subjects affected / exposed	5 / 35 (14.29%)	0 / 13 (0.00%)	1 / 24 (4.17%)
occurrences (all)	5	0	2
Urticaria			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Renal and urinary disorders			
Micturition urgency			
subjects affected / exposed	0 / 35 (0.00%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Micturition disorder			
subjects affected / exposed	0 / 35 (0.00%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Osteonecrosis of jaw			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 35 (0.00%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	0	1	0
Arthralgia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	2
Plantar fasciitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Gastroenteritis viral			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	1 / 35 (2.86%)	1 / 13 (7.69%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
COVID-19			
subjects affected / exposed	4 / 35 (11.43%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	4	0	0
Oral candidiasis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	2 / 24 (8.33%)
occurrences (all)	2	0	3
Oral herpes			
subjects affected / exposed	2 / 35 (5.71%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	8	0	0
Pneumonia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 35 (5.71%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0

Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Superinfection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Tongue fungal infection			
subjects affected / exposed	1 / 35 (2.86%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 35 (5.71%)	0 / 13 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	2 / 35 (5.71%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	2	1	0
Metabolism and nutrition disorders			
Vitamin D deficiency			
subjects affected / exposed	0 / 35 (0.00%)	0 / 13 (0.00%)	3 / 24 (12.50%)
occurrences (all)	0	0	3
Hypercholesterolaemia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 13 (7.69%)	0 / 24 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Placebo to AIN457 300mg Q2W – LPP cohort	Any AIN457 300mg – LPP cohort	Placebo – LPP cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 12 (50.00%)	22 / 36 (61.11%)	7 / 13 (53.85%)
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 12 (8.33%)	2 / 36 (5.56%)	2 / 13 (15.38%)
occurrences (all)	1	2	2
General disorders and administration site conditions			
Fatigue			

subjects affected / exposed	0 / 12 (0.00%)	2 / 36 (5.56%)	0 / 13 (0.00%)
occurrences (all)	0	4	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Injection site haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 12 (0.00%)	2 / 36 (5.56%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast cyst			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Meniscus injury			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Limb injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Traumatic fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 12 (0.00%)	5 / 36 (13.89%)	2 / 13 (15.38%)
occurrences (all)	0	5	2
Dizziness			

subjects affected / exposed	0 / 12 (0.00%)	1 / 36 (2.78%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Auricular swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	2 / 36 (5.56%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Colitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Haemorrhoids			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Leukoplakia oral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Actinic keratosis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dermal cyst			
subjects affected / exposed	1 / 12 (8.33%)	2 / 36 (5.56%)	0 / 13 (0.00%)
occurrences (all)	1	2	0
Dermatitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Intertrigo			
subjects affected / exposed	0 / 12 (0.00%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Skin burning sensation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	3 / 36 (8.33%)	1 / 13 (7.69%)
occurrences (all)	0	4	1
Lichen planus			
subjects affected / exposed	1 / 12 (8.33%)	2 / 36 (5.56%)	0 / 13 (0.00%)
occurrences (all)	1	3	0
Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	2 / 36 (5.56%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Renal and urinary disorders			
Micturition urgency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Osteonecrosis of jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Bone pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Arthralgia			

subjects affected / exposed	0 / 12 (0.00%)	2 / 36 (5.56%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Plantar fasciitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Fungal skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	1 / 12 (8.33%)	3 / 36 (8.33%)	0 / 13 (0.00%)
occurrences (all)	1	4	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Herpes ophthalmic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Superinfection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tongue fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 12 (8.33%)	1 / 36 (2.78%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
Vitamin D deficiency			
subjects affected / exposed	0 / 12 (0.00%)	3 / 36 (8.33%)	0 / 13 (0.00%)
occurrences (all)	0	3	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 36 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	AIN457 300mg Q4W – MLP cohort	Placebo – CLP cohort	Placebo to AIN457 300mg Q2W – MLP cohort
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 24 (75.00%)	7 / 12 (58.33%)	8 / 11 (72.73%)

Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Injection site haemorrhage			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Breast cyst			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Dyspnoea			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Traumatic fracture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arteriosclerosis coronary artery			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Dizziness			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymph node pain			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Auricular swelling			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2

Abdominal pain upper			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Colitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	2 / 11 (18.18%)
occurrences (all)	2	0	2
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukoplakia oral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Oral pain			
subjects affected / exposed	1 / 24 (4.17%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Toothache			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Actinic keratosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dermal cyst			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Skin burning sensation			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	3 / 24 (12.50%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	6	1	0
Lichen planus			
subjects affected / exposed	4 / 24 (16.67%)	1 / 12 (8.33%)	1 / 11 (9.09%)
occurrences (all)	4	1	1
Urticaria			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Micturition urgency			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Micturition disorder			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Osteonecrosis of jaw			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Limb discomfort			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Exostosis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Plantar fasciitis			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Gastroenteritis viral			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Furuncle			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)	2 / 11 (18.18%)
occurrences (all)	2	0	2
Oral candidiasis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0

Oral herpes			
subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	8	0	0
Pneumonia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Herpes ophthalmic			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Helicobacter infection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 24 (4.17%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Superinfection			
subjects affected / exposed	0 / 24 (0.00%)	1 / 12 (8.33%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Tongue fungal infection			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	2 / 24 (8.33%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	2	0	0
Urinary tract infection			
subjects affected / exposed	1 / 24 (4.17%)	1 / 12 (8.33%)	1 / 11 (9.09%)
occurrences (all)	1	1	1
Metabolism and nutrition disorders			
Vitamin D deficiency			

subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 April 2020	IGA score specifications were updated to make them more specific regarding certain aspects of the disease, for easier clinical application and to cover additional cases. The use of historical biopsies (if available) was allowed at screening for subjects with all 3 subtypes of LP instead of allowing it for the LPP cohort only. This made the study more subject friendly and reduced the need for biopsies. The protocol was adapted to pandemic/epidemic related challenges and the long term impact on clinical studies and to reduce the risk of infectious disease transmission. The protocol was amended to allow for home shipment of study drug and urine pregnancy tests as well as safety assessment by telephone.
26 October 2020	The use of biopsies assessed by local pathologists was allowed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

EudraCT system limitation does not accept blank data fields: 999 entered for blank mean data. 0 entered for blank countable data for Wk 20-32 (Placebo arm) and Wk 2-12 (Placebo to AIN457 arm) indicating no participants evaluated for that timepoint

Notes: