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Sponsor

Novartis

Generic Drug Name

Secukinumab

Trial Indication(s)

Lichen planus

Protocol Number

CAIN457S12201

Protocol Title

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

Clinical Trial Phase

Phase 2

Phase of Drug Development

Phase II

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Study Start/End Dates

Study Start Date: July 27, 2020 (Actual)
Primary Completion Date: November 16, 2021 (Actual)
Study Completion Date: May 03, 2022 (Actual)

Reason for Termination (If applicable)

Study Design/Methodology

This was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study assessing the efficacy and safety of secukinumab 300 mg in 2 different dosing regimens in subjects with biopsy-proven forms of lichen planus (LP). . There were 3 cohorts based on predominant subtypes: cutaneous lichen planus (CLP), mucosal lichen planus (MLP), lichen planopilaris (LPP).

The study consisted of: Screening (up to 4 weeks), Treatment Period 1 (16 weeks), Treatment Period 2 (16 weeks). Subjects who prematurely discontinued the study, or who completed the study, entered a post-treatment Follow-Up period (10 weeks).

During Treatment Period 1 from Week 0 (randomization visit) to Week 16, participants were randomized in a 2:1 ratio to 1 of the 2 treatment groups within their cohort: secukinumab 300 mg every 4 weeks (Q4W) or placebo.

Subjects who completed Treatment Period 1 rolled over into Treatment Period 2 at the Week 16 visit except placebo responders during Treatment Period 1 who entered the 8 week follow-up.

During Treatment Period 2 from Week 16 to Week 32, participants who had received secukinumab during Treatment Period 1 continued on 300 mg Q4W. Participants (non-responders) on placebo during Treatment Period 1 received secukinumab 300 mg every 2 weeks (Q2W).

Centers

35 centers in 3 countries: United States(15), Germany(11), France(9)

Publication

No data identified.

Objectives:Primary objective

• 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 (IGA) response by Week 16, compared to placebo.

Secondary objectives

• The secondary objectives of this trial comprise the following:

- evaluate the efficacy of secukinumab 300 mg Q4W compared to placebo throughout 16 weeks in Treatment Period 1;
- evaluate the long term efficacy of secukinumab 300 mg Q4W throughout 32 weeks in Treatment Period 2;
- evaluate the efficacy of secukinumab 300 mg Q2W in Treatment Period 2;
- evaluate the safety profile of secukinumab 300 mg throughout the duration of the study.

All subtypes

- Investigator's Global Assessment (IGA)
- Dermatology Life Quality Index (DLQI)
- Patient assessment of itch (NRS)
- Patient assessment of pain (NRS)
- To assess the safety and tolerability of secukinumab in subjects with lichen planus.

Cutaneous Lichen Planus (CLP)

- Physician Assessment of Surface Area of Disease (PSAD) for Skin Disease

Mucosal Lichen Planus (MLP)

- Reticular Erythematous Ulcerative (REU) score
- Oral Lichen Planus Symptoms Severity Measure (OLPSSM) score

Lichen Planopilaris (LPP)

- LPP Activity Index (LPPAI)
- SCALPDEX Questionnaire

Test Product (s), Dose(s), and Mode(s) of Administration

AIN457 - Secukinumab 300 mg was supplied to the investigators as 2 subcutaneous injections of 1 mL in a pre-filled syringe (PFS) . Each 1 mL syringe contained 150 mg secukinumab. Matching placebo was also provided as 2 subcutaneous injections of 1 mL PFS.

Statistical Methods

The primary endpoint of IGA response at Week 16 was a binary (yes/no) outcome. Bayesian inference based on the non-informative prior of Beta (1/3, 1/3) for each treatment group was used to obtain the posterior distribution of the treatment difference between secukinumab and placebo for the three subtypes, respectively. Estimates of the posterior probabilities of the difference of the IGA responder rates between the secukinumab 300 mg treatment and placebo groups at Week 16 were presented together with two sided 95% credibility intervals (2.5% to 97.5%).

Secondary efficacy endpoints up to Week 32 were analyzed separately for each independent cohort (CLP, MLP, LPP) or for 1 specific cohort. For discrete data, the number and proportions (%) of each category were presented by visit for each treatment group. For continuous data, the absolute and percentage change from baseline by visit for each treatment group were provided.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

1. Written informed consent must be obtained before any assessment is performed.
2. Female and male patients ≥ 18 years of age.
3. Subjects must have biopsy-confirmed forms of cutaneous lichen planus (CLP), mucosal lichen planus (MLP), or active lichen planopilaris (LPP) eligible for systemic therapy based on the following criteria:
   • rated IGA of ≥ 3 (moderate or severe) AND
   • inadequate response to topical corticosteroids of high-ultrahigh potency in the opinion of the investigator.
4. If using any of the allowed topical treatments on the affected areas, the dose and application frequency should remain stable for 2 weeks prior to randomization and until Week 16.

Exclusion Criteria:

1. Clinical history suspicious for lichenoid drug eruption.
2. Lichen planus pigmentosus.
3. Clinical picture or history suspicious of paraneoplastic mucosal lichen planus.
4. Subjects whose lichen planus is a predominantly bullous variant.
5. Mucosal LP of the oral cavity or gastrointestinal involvement requiring the patient to use parenteral nutrition or feeding tube.
6. Clinical picture of scarring alopecia without active inflammation.
7. Clinical picture of burnt-out cicatricial alopecia (alopecia of Brocque).
8. Patients diagnosed with frontal fibrosing alopecia (FFA) without active patches of LPP

9. Clinical picture of LPP in patients who have already failed 3 or more systemic immunosuppressive or immunomodulatory agents (e.g. systemic steroids, hydroxychloroquine, cyclosporine, methotrexate and mycophenolate mofetil).
10. Currently enrolled in any other clinical trial involving any investigational agent or device.
11. Previous exposure to any other biologic drug directly targeting IL-17A or IL-17RA (e.g. secukinumab, ixekizumab or brodalumab) or IL-23/p19 (e.g. tildrakizumab, guselkumab, risankizumab).
12. Diagnosis of active infectious diseases of the skin, scalp or mucosa (for example bacterial, viral or fungal infections of the mouth) that may interfere with the assessment of the study disease or require treatment with prohibited medications.
13. Diagnosis of active inflammatory diseases of the skin, scalp or mucosa other than lichen planus that may interfere with the assessment of the study disease or require treatment with prohibited medications.
14. Presence of any other skin condition that may affect the evaluations of the study disease.
15. Underlying conditions (including, but not limited to metabolic, hematologic, renal, hepatic, pulmonary, neurologic, endocrine, cardiac, infectious or gastrointestinal) and/or presence of laboratory abnormalities which in the opinion of the investigator significantly immunocompromises the subject and/or places the subject at unacceptable risk for receiving an immunomodulatory therapy.
16. Current, severe, progressive or uncontrolled diseases that render the patient unsuitable for the trial, including any medical or psychiatric condition that, in the Investigator's opinion, would preclude the participant from adhering to the protocol or completing the study per protocol.

Participant Flow Table

Treatment 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	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort	AIN457 300 mg Q4W - TP 1 - MLP cohort	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	AIN457 300 mg Q4W - TP 1 - LPP cohort	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	Total
Arm/Group Description	AIN457 300 mg every 4 weeks up to 16 weeks	Matching placebo administered every 4 weeks	AIN457 300 mg every 4 weeks administered via	Placebo non-responders during TP 1	AIN457 300 mg every 4 weeks up to 16 weeks	Matching placebo administered every 4 weeks	AIN457 300 mg every 4 weeks administered via	Placebo non-responders during TP 1	AIN457457 300 mg every 4 weeks up to 16	Matching placebo administered every 4 weeks	AIN457 300 mg every 4 weeks administered via	Placebo non-responders during TP 1	

	administered via a pre-filled syringe	up to 16 weeks via a pre-filled syringe	a pre-filled syringe. Participants on AIN457 in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.	received AIN457 300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.	administered via a pre-filled syringe	up to 16 weeks via a pre-filled syringe	a pre-filled syringe. Participants on AIN457 in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.	received AIN457 300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.	weeks administered via a pre-filled syringe	up to 16 weeks via a pre-filled syringe	a pre-filled syringe. Participants on AIN457 in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.	received AIN457 300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.	
Started	25	12	0	0	24	13	0	0	24	13	0	0	111
Placebo Responder	0	1	0	0	0	1	0	0	0	0	0	0	2
Completed	23	10	0	0	24	13	0	0	23	12	0	0	105
Not Completed	2	2	0	0	0	0	0	0	1	1	0	0	6
Progressive disease	1	0	0	0	0	0	0	0	0	0	0	0	1
Adverse Event	0	0	0	0	0	0	0	0	1	0	0	0	1
Subject/guardian decision	1	2	0	0	0	0	0	0	0	1	0	0	4

Treatment Period 2

	AIN457 300 mg Q4W - TP 1 -	**Placebo - TP 1 - CLP cohort**	**AIN457 300 mg Q4W - TP 1**	**Placebo to AIN457 300 mg**	**AIN457 300 mg Q4W - TP 1 -**	**Placebo - TP 1 - MLP cohort**	**AIN457 300 mg Q4W - TP 1**	**Placebo to AIN457 300 mg**	**AIN457 300 mg Q4W - TP 1 -**	**Placebo - TP 1 - LPP cohort**	**AIN457 300 mg Q4W - TP 1**	**Placebo to AIN457 300 mg**	**Total**

	CLP cohort		and TP 2 - CLP cohort	Q2W - TP 2 - CLP cohort	MLP cohort		and TP 2 - MLP cohort	Q2W TP 2 - MLP cohort	LPP cohort		and TP 2 - LPP cohort	Q2W - TP 2 - LPP cohort	
Arm/Group Description	AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.	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.	AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.	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.	AIN457457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.	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.	
Started	0	0	22	8	0	0	23	11	0	0	23	12	99
Completed	0	0	17	7	0	0	19	10	0	0	17	12	82
Not Completed	0	0	5	1	0	0	4	1	0	0	6	0	17
Adverse Event	0	0	1	0	0	0	2	0	0	0	1	0	4
Progressive disease	0	0	2	0	0	0	1	0	0	0	2	0	5
Protocol deviation	0	0	0	1	0	0	0	0	0	0	0	0	1

Subject/guardian decision	0	0	2	0	0	0	1	1	0	0	3	0	7

Baseline Characteristics

	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	AIN457 300 mg Q4W - TP 1 - LPP cohort	Placebo - TP 1 - LPP cohort	Total
Arm/Group Description	AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	
Number of Participants [units: participants]	25	12	24	13	24	13	111
Baseline Analysis Population Description							
Age, Customized (units: Participants) Analysis Population Type: Participants							
18 to <65 years	22	9	14	8	19	12	84
> or = 65 years	3	3	10	5	5	1	27
Sex: Female, Male (units: Participants) Analysis Population Type: Participants Count of Participants (Not Applicable)							
Female	15	8	14	12	20	10	79

Male	10	4	10	1	4	3	32
Race/Ethnicity, Customized (units: Participants) Analysis Population Type: Participants							
Asian (Indian)	0	0	2	0	0	0	2
Black or African American	6	4	2	1	1	0	14
White	19	8	19	12	23	13	94
White, American Indian or Alaska Native	0	0	1	0	0	0	1
Study Specific Characteristic **Baseline of Investigator's Global Assessment (IGA)** (units: Participants) Description: 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). Analysis Population Type: Participants Count of Participants (Not Applicable)							
0=Clear	0	0	0	0	0	0	0
1=Minimal	1	0	0	0	0	0	1
2=Mild	0	0	0	0	0	0	0
3=Moderate	16	9	22	8	17	10	82
4=Severe	8	3	2	5	7	3	28

Primary Outcome Result(s)

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

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.
Time Frame	Baseline up to week 16
Analysis Population Description	Full analysis set of participants with a baseline IGA score >= 3 were included

	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**	**AIN457 300 mg Q4W - TP 1 - LPP cohort**	**Placebo - TP 1 - LPP cohort**
Arm/Group Description	AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457457 300 mg every 4 weeks up to 16 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe
Number of Participants Analyzed [units: participants]	25	12	24	13	24	13
Response rate of Investigator Global Assessment (IGA) score of 2 or lower at week 16 for CLP, MLP and LPP (units: scores on a scale)	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**	**Median (95% Confidence Interval)**
	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)	37.6 (20.2 to 57.3)	30.9 (10.8 to 57.6)

Statistical Analysis

Groups	AIN457 300 mg Q4W - TP 1 - CLP cohort, Placebo - TP 1 - CLP cohort	
Type of Statistical Test	Other	
Other Posterior median difference	-13.9	Bayesian model to obtain the posterior distribution of the treatment difference between AIN457 and placebo
95 % Confidence Interval 2-Sided	-44.8 to 19.3	

Statistical Analysis

Groups	AIN457 300 mg Q4W - TP 1 - MLP cohort, Placebo - TP 1 - MLP cohort	
Type of Statistical Test	Other	
Other Posterior median difference	14.1	Bayesian model to obtain the posterior distribution of the treatment difference between AIN457 and placebo
95 % Confidence Interval 2-Sided	-17.0 to 40.7	

Statistical Analysis

Groups	AIN457 300 mg Q4W - TP 1 - LPP cohort, Placebo - TP 1 - LPP cohort	
Type of Statistical Test	Other	
Other Posterior median difference	6.5	Bayesian model to obtain the posterior distribution of the treatment difference between AIN457 and placebo
95 % Confidence Interval 2-Sided	-25.4 to 35.4	

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Secondary Outcome Result(s)

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)

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.
Time Frame	Baseline up to week 32
Analysis Population Description	Full analysis set with baseline observation carried forward

	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	Placebo - TP 1 - CLP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	25	12	10
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) (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Week 2 IGA <=2 n=25,12,0	5 (20%)	1 (8.33%)	(NaN%)

Week 2 IGA improvement >=2 n=25,12,0	2 (8%)	0 (%)	(NaN%)
Week 2 IGA 0/1 n=25,12,0	2 (8%)	0 (%)	(NaN%)
Week 4 IGA <=2 n=24,11,0	9 (37.5%)	2 (18.18%)	(NaN%)
Week 4 IGA improvement. >=2 n=24,11,0	3 (12.5%)	0 (%)	(NaN%)
Week 4 IGA 0/1 n=24,11,0	2 (8.33%)	0 (%)	(NaN%)
Week 8 IGA <=2 n=25,11,0	10 (40%)	3 (27.27%)	(NaN%)
Week 8 IGA improvement. >=2 n=25,11,0	4 (16%)	1 (9.09%)	(NaN%)
Week 8 IGA 0/1 n=25,11,0	3 (12%)	1 (9.09%)	(NaN%)
Week 12 IGA <=2 n=25,12,0	10 (40%)	4 (33.33%)	(NaN%)
Week 12 IGA improvement. >=2 n=25,12,0	3 (12%)	2 (16.67%)	(NaN%)
Week 12 IGA 0/1 n=25,12,0	4 (16%)	1 (8.33%)	(NaN%)
Week16 IGA <=2 n=25,12,10	11 (44%)	7 (58.33%)	5 (50%)
Week 16 IGA improvement. >=2 n=25,12,10	4 (16%)	3 (25%)	1 (10%)
Week 16 IGA 0/1 n=25,12,10	4 (16%)	2 (16.67%)	0 (%)
Week 20 IGA <=2 n=24,0,10	11 (45.83%)	(NaN%)	1 (10%)
Week 20 IGA improvement. >=2 n=24,0,10	5 (20.83%)	(NaN%)	1 (10%)

Week 20 IGA 0/1 n=24,0,10	5 (20.83%)	(NaN%)	1 (10%)
Week 24 IGA <=2 n=25,0,10	14 (56%)	(NaN%)	3 (30%)
Week 24 IGA improvement. >=2 n=25,0,10	10 (40%)	(NaN%)	2 (20%)
Week 24 IGA 0/1 n=25,0,10	10 (40%)	(NaN%)	1 (10%)
Week 28 IGA <=2 n=23,0,10	12 (52.17%)	(NaN%)	4 (40%)
Week 28 IGA improvement. >=2 n=23,0,10	7 (30.43%)	(NaN%)	1 (10%)
Week 28 IGA 0/1 n=23,0,10	6 (26.09%)	(NaN%)	1 (10%)
Week 32 IGA <=2 n=24,0,9	9 (37.5%)	(NaN%)	2 (22.22%)
Week 32 IGA improvement. >=2 n=24,0,9	7 (29.17%)	(NaN%)	2 (22.22%)
Week 32 IGA 0/1 n=24,0,9	6 (25%)	(NaN%)	1 (11.11%)

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)

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.
Time Frame	Baseline up to week 32
Analysis Population Description	Full analysis set with baseline observation carried forward

	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo - TP 1 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	24	13	11
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) (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Week 2 IGA <=2 n=24,12,0	5 (20.83%)	3 (25%)	(NaN%)
Week 2 IGA improvement >=2 n=24,12,0	1 (4.17%)	1 (8.33%)	(NaN%)
Week 2 IGA 0/1 n=24,12,0	1 (4.17%)	1 (8.33%)	(NaN%)
Week 4 IGA <=2 n=24,13,0	4 (16.67%)	2 (15.38%)	(NaN%)
Week 4 IGA improvement. >=2 n=24,13,0	1 (4.17%)	1 (7.69%)	(NaN%)
Week 4 IGA 0/1 n=24,13,0	1 (4.17%)	1 (7.69%)	(NaN%)
Week 8 IGA <=2 n=24,13,0	5 (20.83%)	3 (23.08%)	(NaN%)
Week 8 IGA improvement. >=2 n=24,13,0	0 (%)	2 (15.38%)	(NaN%)
Week 8 IGA 0/1 n=24,13,0	0 (%)	1 (7.69%)	(NaN%)
Week 12 IGA <=2 n=24,13,0	5 (20.83%)	4 (30.77%)	(NaN%)

Week 12 IGA improvement. >=2 n=24,13,0	5 (20.83%)	4 (30.77%)	(NaN%)
Week 12 IGA 0/1 n=24,13,0	4 (16.67%)	2 (15.38%)	(NaN%)
Week16 IGA <=2 n=24,13,11	9 (37.5%)	3 (23.08%)	1 (9.09%)
Week 16 IGA improvement. >=2 n=24,13,11	5 (20.83%)	3 (23.08%)	1 (9.09%)
Week 16 IGA 0/1 n=24,13,11	4 (16.67%)	2 (15.38%)	0 (%)
Week 20 IGA <=2 n=24,0,11	10 (41.67%)	(NaN%)	3 (27.27%)
Week 20 IGA improvement. >=2 n=24,0,11	5 (20.83%)	(NaN%)	2 (18.18%)
Week 20 IGA 0/1 n=24,0,11	5 (20.83%)	(NaN%)	1 (9.09%)
Week 24 IGA <=2 n=24,0,10	10 (41.67%)	(NaN%)	4 (40%)
Week 24 IGA improvement. >=2 n=24,0,10	3 (12.5%)	(NaN%)	2 (20%)
Week 24 IGA 0/1 n=24,0,10	3 (12.5%)	(NaN%)	0 (%)
Week 28 IGA <=2 n=23,0,11	7 (30.43%)	(NaN%)	4 (36.36%)
Week 28 IGA improvement. >=2 n=23,0,11	1 (4.35%)	(NaN%)	3 (27.27%)
Week 28 IGA 0/1 n=23,0,11	1 (4.35%)	(NaN%)	0 (%)
Week 32 IGA <=2 n=23,0,10	9 (39.13%)	(NaN%)	2 (20%)
Week 32 IGA improvement. >=2 n=23,0,10	2 (8.7%)	(NaN%)	1 (10%)

Week 32 IGA 0/1 n=23,0,10	2 (8.7%)	(NaN%)	0 (%)

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)

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.
Time Frame	Baseline up to week 32
Analysis Population Description	Full analysis set with baseline observation carried forward

	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	**Placebo - TP 1 - LPP cohort**	**Placebo to AIN457 300 mg Q2W - TP 2- LPP cohort**
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	Participants on placebo during Treatment 1 received AIN457 300 mg every 2 weeks administered via a pre-filled syringe
Number of Participants Analyzed [units: participants]	24	13	13
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) (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Week 2 IGA <=2 n=24,13,0	4 (16.67%)	1 (7.69%)	(NaN%)
Week 2 IGA improvement >=2 n=24,13,0	1 (4.17%)	0 (%)	(NaN%)
Week 2 IGA 0/1 n=24,13,0	1 (4.17%)	0 (%)	(NaN%)

Week 4 IGA <=2 n=24,13,0	9 (37.5%)	2 (15.38%)	(NaN%)
Week 4 IGA improvement. >=2 n=24,13,0	2 (8.33%)	1 (7.69%)	(NaN%)
Week 4 IGA 0/1 n=24,13,0	2 (8.33%)	1 (7.69%)	(NaN%)
Week 8 IGA <=2 n=24,13,0	8 (33.33%)	3 (23.08%)	(NaN%)
Week 8 IGA improvement. >=2 n=24,13,0	3 (12.5%)	1 (7.69%)	(NaN%)
Week 8 IGA 0/1 n=24,13,0	3 (12.5%)	1 (7.69%)	(NaN%)
Week 12 IGA <=2 n=24,13,0	8 (33.33%)	4 (30.77%)	(NaN%)
Week 12 IGA improvement. >=2 n=24,13,0	3 (12.5%)	2 (15.38%)	(NaN%)
Week 12 IGA 0/1 n=24,13,0	2 (8.33%)	2 (15.38%)	(NaN%)
Week16 IGA <=2 n=24,13,13	9 (37.5%)	4 (30.77%)	4 (30.77%)
Week 16 IGA improvement. >=2 n=24,13,13	3 (12.5%)	0 (%)	0 (%)
Week 16 IGA 0/1 n=24,13,13	2 (8.33%)	0 (%)	0 (%)
Week 20 IGA <=2 n=24,0,13	10 (41.67%)	(NaN%)	6 (46.15%)
Week 20 IGA improvement. >=2 n=24,0,13	6 (25%)	(NaN%)	1 (7.69%)
Week 20 IGA 0/1 n=24,0,13	4 (16.67%)	(NaN%)	0 (%)
Week 24 IGA <=2 n=23,0,13	10 (43.48%)	(NaN%)	8 (61.54%)

Week 24 IGA improvement. >=2 n=23,0,13	7 (30.43%)	(NaN%)	3 (23.08%)
Week 24 IGA 0/1 n=23,0,13	6 (26.09%)	(NaN%)	2 (15.38%)
Week 28 IGA <=2 n=24,0,13	10 (41.67%)	(NaN%)	9 (69.23%)
Week 28 IGA improvement. >=2 n=24,0,13	6 (25%)	(NaN%)	4 (30.77%)
Week 28 IGA 0/1 n=24,0,13	5 (20.83%)	(NaN%)	3 (23.08%)
Week 32 IGA <=2 n==24,0,11	11 (45.83%)	(NaN%)	7 (63.64%)
Week 32 IGA improvement. >=2 n==24,0,11	5 (20.83%)	(NaN%)	5 (45.45%)
Week 32 IGA 0/1 n==24,0,11	4 (16.67%)	(NaN%)	4 (36.36%)

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

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
Time Frame	Baseline up to week 32
Analysis Population Description	Full analysis set with baseline observation carried forward

	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	Placebo - TP 1 - CLP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort
Arm/Group Description	AIN457 300 mg every 4 weeks administered via a pre-filled syringe. Participants on AIN457	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	Placebo non-responders during TP 1 received AIN457 300 mg every 2 weeks from Week 16 to

	in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.		Week 32 in TP 2 via a pre-filled syringe.
Number of Participants Analyzed [units: participants]	25	12	10
Number (%) of subjects in each category in Physician´s assessment of surface area of disease (PSAD) - CLP (BOCF) – Entire treatment period (FAS) (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Baseline 0 Score	0 (%)	0 (%)	(NaN%)
Baseline 1 score	3 (12%)	0 (%)	(NaN%)
Baseline 2 score	6 (24%)	0 (%)	(NaN%)
Baseline 3 score	6 (25%)	3 (27.27%)	(NaN%)
Baseline 4 score	5 (20.83%)	6 (54.55%)	(NaN%)
Baseline 5 score	5 (20.83%)	3 (27.27%)	(NaN%)
Week 2 0 score	0 (%)	0 (%)	0 (NaN%)
Week 2 1 score	6 (24%)	0 (%)	(NaN%)
Week 2 2 score	5 (20%)	1 (9.09%)	(NaN%)
Week 2 3 score	9 (36%)	3 (25%)	(NaN%)
Week 2 4 score	3 (12%)	5 (41.67%)	(NaN%)
Week 2 5 score	2 (8%)	3 (25%)	(NaN%)

Week 4 0 score	0 (%)	0 (%)	(NaN%)
Week 4 1 score	3 (12%)	0 (%)	(NaN%)
Week 4 2 score	8 (32%)	0 (%)	(NaN%)
Week 4 3 score	8 (32%)	3 (25%)	(NaN%)
Week 4 4 score	3 (12%)	5 (41.67%)	(NaN%)
Week 4 5 score	2 (8%)	3 (25%)	(NaN%)
Week 8 0 score	0 (%)	0 (%)	(NaN%)
Week 8 1 score	7 (28%)	1 (8.33%)	(NaN%)
Week 8 2 score	5 (20%)	1 (8.33%)	(NaN%)
Week 8 3 score	7 (29.17%)	2 (18.18%)	(NaN%)
Week 8 4 score	4 (16.67%)	4 (36.36%)	(NaN%)
Week 8 5 score	2 (8.33%)	3 (27.27%)	(NaN%)
Week 12 0 score	0 (%)	0 (NaN%)	(NaN%)
Week 12 1 score	6 (24%)	1 (8.33%)	(NaN%)
Week 12 2 score	7 (28%)	2 (16.67%)	(NaN%)
Week 12 3 score	7 (30.43%)	0 (%)	(NaN%)

Week 12 4 score	3 (13.04%)	7 (58.33%)	(NaN%)
Week 12 5 score	2 (8.7%)	2 (16.67%)	(NaN%)
Week 16 0 score	0 (%)	0 (%)	0 (%)
Week 16 1 score	4 (16.67%)	2 (16.67%)	0 (%)
Week 16 2 score	12 (50%)	3 (25%)	3 (33.33%)
Week 16 3 score	5 (20%)	3 (25%)	3 (30%)
Week 16 4 score	2 (8%)	4 (33.33%)	4 (40%)
Week 16 5 score	2 (8%)	0 (%)	0 (%)
Week 20 0 score	0 (%)	(NaN%)	0 (%)
Week 20 1 score	6 (24%)	(NaN%)	0 (%)
Week 20 2 score	12 (48%)	(NaN%)	3 (30%)
Week 20 3 score	3 (12%)	(NaN%)	2 (20%)
Week 20 4 score	1 (4%)	(NaN%)	3 (30%)
Week 20 5 score	2 (8%)	(NaN%)	2 (20%)
Week 24 0 score	1 (4%)	(NaN%)	0 (%)
Week 24 1 score	8 (32%)	(NaN%)	0 (%)

Week 24 2 score	10 (40%)	(NaN%)	2 (20%)
Week 24 3 score	1 (4%)	(NaN%)	2 (20%)
Week 24 4 score	2 (8%)	(NaN%)	4 (40%)
Week 24 5 score	3 (12%)	(NaN%)	2 (20%)
Week 28 0 score	0 (%)	(NaN%)	0 (%)
Week 28 1 score	6 (24%)	(NaN%)	0 (%)
Week 28 2 score	11 (44%)	(NaN%)	2 (20%)
Week 28 3 score	1 (4%)	(NaN%)	3 (30%)
Week 28 4 score	3 (12%)	(NaN%)	3 (30%)
Week 28 5 score	2 (8%)	(NaN%)	2 (20%)
Week 32 0 score	2 (8%)	(NaN%)	0 (%)
Week 32 1 score	5 (20%)	(NaN%)	1 (10%)
Week 32 2 score	10 (40%)	(NaN%)	0 (%)
Week 32 3 score	3 (12%)	(NaN%)	4 (40%)
Week 32 4 score	1 (4%)	(NaN%)	2 (20%)
Week 32 5 score	3 (12%)	(NaN%)	2 (20%)

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

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.
Time Frame	Baseline up to week 32
Analysis Population Description	Full analysis set with baseline observation carried forward

	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	**Placebo - TP 1 - CLP cohort**	**Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort**
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	25	12	10
Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0/1) up to Week 32 - CLP cohort - Entire treatment period (FAS) (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Baseline n=25,12,0	0 (%)	0 (%)	(NaN%)
Week 4 n=24,11,0	2 (8.33%)	0 (%)	(NaN%)
Week 8 n=25,11,0	2 (8%)	0 (%)	(NaN%)

Week 12 n=25,12,0	3 (12%)	1 (8.33%)	(NaN%)
Week 16 n=25,12,10	3 (12%)	2 (16.67%)	2 (20%)
Week 20 n=24,0,10	3 (12.5%)	(NaN%)	1 (10%)
Week 24 n=25,0,10	4 (16%)	(NaN%)	1 (10%)
Week 28 n=23,0,10	3 (13.04%)	(NaN%)	1 (10%)
Week 32 n=25,0,9	2 (8%)	(NaN%)	1 (11.11%)

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

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.
Time Frame	Baseline up to week 32
Analysis Population Description	Full analysis set with baseline observation carried forward

	AIN457 300 mg Q4W - TP 1 and TP 2- MLP cohort	Placebo - TP 1 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.

Number of Participants Analyzed [units: participants]	24	13	11
Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0/1) up to Week 32 - MLP cohort - Entire treatment period (FAS) (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Baseline n=24,13,0	0 (%)	0 (%)	(NaN%)
Week 4 n=24,13,0	2 (8.33%)	1 (7.69%)	(NaN%)
Week 8 n=24,13,0	4 (16.67%)	1 (7.69%)	(NaN%)
Week 12 n=24,13,0	4 (16.67%)	2 (15.38%)	(NaN%)
Week 16 n=24,13,11	5 (20.83%)	3 (23.08%)	2 (18.18%)
Week 20 n=24,0,11	7 (29.17%)	(NaN%)	2 (18.18%)
Week 24 n=24,0,10	7 (29.17%)	(NaN%)	3 (30%)
Week 28 n=23,0,11	3 (13.04%)	(NaN%)	2 (18.18%)
Week 32 n=23,0,10	4 (17.39%)	(NaN%)	2 (20%)

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

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.

Time Frame	Baseline up to week 32
Analysis Population Description	Full analysis set with baseline observation carried forward

	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo - TP 1 - LPP cohort	Placebo to AIN457 300 mg Q2W TP 2 - LPP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	24	13	13
Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0/1) up to Week 32 - LPP cohort - Entire treatment period (FAS) (units: participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Baseline n=24,13,0	0 (%)	0 (%)	(NaN%)
Week 4 n=24,13,0	3 (12.5%)	1 (7.69%)	(NaN%)
Week 8 n=24,13,0	3 (12.5%)	1 (7.69%)	(NaN%)
Week 12 n=24,13,0	2 (8.33%)	2 (15.38%)	(NaN%)
Week 16 n=24,13,13	2 (8.33%)	1 (7.69%)	1 (7.69%)
Week 20 n=24,0,13	4 (16.67%)	(NaN%)	3 (23.08%)
Week 24 n=23,0,13	2 (8.7%)	(NaN%)	3 (23.08%)

Week 28 n=24,0,13	2 (8.33%)	(NaN%)	2 (15.38%)
Week 32 n=24,0,11	1 (4.17%)	(NaN%)	3 (27.27%)

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

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".
Time Frame	Baseline, Week 16 and Week 32
Analysis Population Description	Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	**Placebo - TP 1 - CLP cohort**	**Placebo to AIN457 300 mg Q2W TP 2 - CLP cohort**
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	Placebo non-responders during TP 1 received AIN457 300 mg every 2 weeks up to 16 weeks administered via a pre-filled syringe.
Number of Participants Analyzed [units: participants]	25	12	10
Summary of baseline score and change from baseline for Patient Assessment of Itch using numeric rating scale (NRS) by question – CLP cohort (BOCF) (FAS) (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline - Question 1	5.1 ± 2.66	5.7 ± 2.77	5.8 ± 3.01

Week 16 Severity of itch during past 24 hours n=25,12,10	-0.8 ± 1.91	-2.3 ± 3.25	-2.0 ± 3.53
Week 32 Severity of itch during past 24 hours n=25,0,9	-1.5 ± 2.24		-1.1 ± 2.42
Baseline- Question 2	5.6 ± 2.72	6.3 ± 2.86	5.9 ± 3.03
Week 16 How severe was itch at worst moment during past 24 hours n=25,12,10	-0.9 ± 2.52	-2.7 ± 3.73	-1.9 ± 3.54
Week 32 How severe was itch at worst moment during past 24 hours n=25,0,9	-1.3 ± 2.13		-1.2 ± 2.49
Baseline- Question 3	4.8 ± 3.08	6.1 ± 2.94	6.1 ± 3.21
Week 16 How bothered by Itch during past 24 hours n=25,12,10	-1.0 ± 2.65	-2.7 ± 3.55	-2.4 ± 3.84
Week 32 How bothered by Itch during past 24 hours n=25,0,9	-1.1 ± 2.45		-1.2 ± 2.28

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

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".
Time Frame	Baseline, Week 16 and Week 32
Analysis Population Description	Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo - TP 1 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort
Arm/Group Description	AIN457 300 mg every 4 weeks administered via a pre-filled syringe. Participants on AIN457	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	Placebo non-responders during TP 1 received AIN457 300 mg every 2 weeks from Week 16 to

	in TP 1 for 16 weeks continued AIN457 in TP 2 for 16 weeks.		Week 32 in TP 2 via a pre-filled syringe.
Number of Participants Analyzed [units: participants]	24	13	13
Summary of baseline score and change from baseline for Patient Assessment of Itch using numeric rating scale (NRS) by question – MLP cohort (BOCF) (FAS) (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline - Question 1 n=24,13,11	2.5 ± 2.83	3.8 ± 3.81	4.3 ± 3.93
Week 16 Severity of itch during past 24 hours n=23,13,11	-0.3 ± 3.26	-0.2 ± 3.41	-0.3 ± 3.72
Week 32 Severity of itch during past 24 hours n=22,0,10	0.1 ± 2.97		-0.4 ± 3.37
Baseline - Question 2 n=24,13,11	2.4 ± 2.90	3.6 ± 3.99	4.1 ± 4.16
Week 16 How severe was itch at worst moment during past 24 hours n=23,13,11	0.8 ± 3.04	0.4 ± 3.25	0.4 ± 3.56
Week 32 How severe was itch at worst moment during past 24 hours n=22,0,10	0.3 ± 2.43		0.4 ± 3.81
Baseline - Question 3 n=24,13,11	3.4 ± 3.41	4.0 ± 4.14	4.5 ± 4.27
Week 16 How bothered by Itch during past 24 hours n=23,13,11	-0.5 ± 2.95	0.1 ± 3.12	0.0 ± 3.41
Week 32 How bothered by Itch during past 24 hours n=22,0,10	-0.4 ± 1.33		-0.4 ± 4.25

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

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".
Time Frame	Baseline, Week 16 and Week 32

Analysis Population Description: Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo - TP 1 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	24	13	12
Summary of baseline score and change from baseline for Patient Assessment of Itch using numeric rating scale (NRS) by question – LPP cohort (BOCF) (FAS) (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline - Question 1 n=24,13,12	2.5 ± 2.83	3.8 ± 3.81	4.3 ± 3.93
Week 16 Severity of itch during past 24 hours n=24,13,11	-0.5 ± 2.25	-1.1 ± 2.47	-1.1 ± 2.47
Week 32 Severity of itch during past 24 hours n=24,0,11	-1.6 ± 2.06		-2.4 ± 2.84
Baseline - Question 2 n=24,13,11	2.4 ± 2.90	3.6 ± 3.99	4.1 ± 4.16
Week 16 How severe was itch at worst moment during past 24 hours n=24,13,11	-0.7 ± 2.35	-1.3 ± 2.81	-1.3 ± 2.81
Week 32 How severe was itch at worst moment during past 24 hours n=24,0,11	-1.8 ± 2.23		-2.6 ± 3.01
Baseline - Question 3 n=24,13,11	3.4 ± 3.41	4.0 ± 4.14	4.5 ± 4.27
Week 16 How bothered by Itch during past 24 hours n=24,13,11	-0.4 ± 2.43	-1.2 ± 3.02	-1.2 ± 3.02
Week 32 How bothered by Itch during past 24 hours n=24,0,11	-1.7 ± 2.08		-2.2 ± 2.44

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

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".
Time Frame	Baseline, Week 16 and Week 32
Analysis Population Description	Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 - CLP cohort	**Placebo - TP 1 - CLP cohort**	**Placebo to AIN457 300 mg Q2W - TP 2 - CLP cohort**
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	25	12	10
Summary of baseline score and change from baseline for Patient Assessment of Pain using numeric rating scale (NRS) by question – CLP cohort (BOCF) (FAS) (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline - Question 1 n=25,12,10	1.09 ± 2.05	3.4 ± 2.61	3.5 ± 2.51
Week 16 Severity of pain during past 24 hours n=25,12,10	0.2 ± 1.48	-0.8 ± 1.40	-0.8 ± 1.48
Week 32 Severity of pain during past 24 hours n=25,0,9	-0.3 ± 1.65		-0.3 ± 2.29
Baseline - Question 2 n=25,12,10	2.2 ± 2.48	3.9 ± 3.23	3.9 ± 3.03

Week 16 How severe was pain at worst moment during past 24 hours n=25,12,10	0.1 ± 2.03	-1.2 ± 1.70	-1.0 ± 1.56
Week 32 How severe was pain at worst moment during past 24 hours n=25,0,9	-0.4 ± 2.35		-0.4 ± 2.70
Baseline - Question 3 n=25,12,10	2.1 ± 2.55	3.7 ± 2.96	3.8 ± 2.94
Week 16 How bothered by pain during past 24 hour n=25,12,10	0.1 ± 2.09	-0.6 ± 1.62	0.5 ± 1.72
Week 32 How bothered by pain during past 24 hours n=25, 0,9	-0.2 ± 1.71		-0.3 ± 2.45

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

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".
Time Frame	Baseline, Week 16 and Week 32
Analysis Population Description	Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo - TP 1 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	24	13	11

Summary of baseline score and change from baseline for Patient Assessment of Pain using numeric rating scale (NRS) by question –MLP cohort (BOCF) (FAS) (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline - Question 1 n=24,13,11	5.1 ± 2.86	5.9 ± 3.09	6.3 ± 3.23
Week 16 Severity of pain during past 24 hours n=24,13,11	-0.5 ± 3.08	-0.1 ± 3.01	0.0 ± 3.29
Week 32 Severity of pain during past 24 hours n=23,0,10	-0.3 ± 2.18		-0.6 ± 2.59
Baseline - Question 2 n=24,13,11	5.4 ± 2.99	6.4 ± 3.15	6.7 ± 3.26
Week 16 How severe was pain at worst moment during past 24 hours n=24,13,11	-0.5 ± 3.13	-0.3 ± 2.75	-0.2 ± 2.99
Week 32 How severe was pain at worst moment during past 24 hours n=23,0,10	-0.3 ± 2.06		-0.5 ± 2.46
Baseline - Question 3 n=24,13,11	5.5 ± 3.35	6.5 ± 2.76	6.8 ± 2.79
Week 16 How bothered by pain during past 24 hour n=24,13,11	-0.8 ± 3.54	-0.3 ± 2.21	-0.1 ± 2.34
Week 32 How bothered by pain during past 24 hours n=23,0,10	-0.5 ± 2.74		-0.9 ± 2.69

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

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".
Time Frame	Baseline, Week 16 and Week 32
Analysis Population Description	Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo - TP 1 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	24	13	12
Summary of baseline score and change from baseline for Patient Assessment of Pain using numeric rating scale (NRS) by question – LPP cohort (BOCF) (FAS) (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline - Question 1 n=24,13,12	2.5 ± 2.43	2.0 ± 2.38	2.0 ± 2.38
Week 16 Severity of pain during past 24 hours n=24,13,12	0.3 ± 2.61	-0.5 ± 1.90	-0.5 ± 1.90
Week 32 Severity of pain during past 24 hours n=24,0,11	-0.6 ± 1.72		-1.5 ± 2.02
Baseline - Question 2 24,13,12	2.8 ± 2.68	2.5 ± 2.73	2.5 ± 2.73
Week 16 How severe was pain at worst moment during past 24 hours n=24,13,12	0.2 ± 3.16	-0.9 ± 2.25	-0.9 ± 2.25
Week 32 How severe was pain at worst moment during past 24 hours n=24,0,11	-0.8 ± 2.06		-2.0 ± 2.45
Baseline - Question 3 n=24,13,12	2.7 ± 2.56	2.4 ± 2.75	2.4 ± 2.75
Week 16 How bothered by pain during past 24 hour n=24,13,12	0.0 ± 2.87	-1.1 ± 2.25	-1.1 ± 2.25
Week 32 How bothered by pain during past 24 hours n=24,0,11	-0.8 ± 1.79		-1.9 ± 2.51

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

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.
Time Frame	Baseline, Week 16 and Week 32
Analysis Population Description	Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo - TP 1 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	21	13	10
Summary of baseline score and change from baseline in Reticular Erythematous Ulcerative score (REU) - MLP Cohort - (BOCF) – Entire treatment period (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline n=21,12,10	21.31 ± 8.747	25.29 ± 9.102	26.95 ± 8.855
Week 16 n=21,12,10	-4.83 ± 11.102	-5.79 ± 14.476	-4.10 ± 15.196
Week 32 n=20,0,9	-6.08 ± 10.206		-2.17 ± 15.802

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

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.

Time Frame: Baseline, Week 16 and Week 32

Analysis Population Description: Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 - MLP cohort	Placebo - TP 1 - MLP cohort	Placebo to AIN457 300 mg Q2W TP 2 - MLP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	21	12	10
Summary of baseline score and change from baseline in Oral Lichen Planus Symptom Severity Measure (OLPSSM) - MLP Cohort - (BOCF) – Entire treatment period (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline n=21,12,10	11.0 ± 5.98	13.4 ± 5.50	13.9 ± 5.78
Week 16 n=21,12,10	-1.0 ± 6.82	0.8 ± 6.47	-0.4 ± 7.09
Week 32 n=20,0,9	-1.8 ± 5.67		-0.7 ± 7.00

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

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

Time Frame: Baseline, Week 16 and Week 32

Analysis Population Description	Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 - LPP cohort	Placebo - TP 1 - LPP cohort	Placebo to AIN457 300 mg Q2W TP 2 - Lpp cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	24	13	13
Summary of baseline score and change from baseline for Lichen Planopilaris Activity Index (LPPAI)– LPP cohort (BOCF) (FAS) (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline n=24,13,13	5.92 ± 2.071	5.95 ± 1.767	5.95 ± 1.767
Week 16 n=24,13,13	-1.44 ± 2.517	-2.24 ± 2.522	-2.24 ± 2.522
Week 32 n=24,0,13	-2.44 ± 2.428		-3.20 ± 2.927

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

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.
Time Frame	Baseline, Week 16 and Week 32
Analysis Population Description	Full analysis set - for each visit, only participants with a value at both Baseline and the respective post-baseline visit are included

	AIN457 300 mg Q4W - TP 1 and TP 2 -LPP cohort	Placebo - TP 1 - LPP cohort	Placebo to AIN457 300 mg Q2W - TP 2 - LPP cohort
Arm/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.	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	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.
Number of Participants Analyzed [units: participants]	24	13	12
Summary of baseline score and change from baseline for Scalpdex – LPP cohort (BOCF) (FAS) (units: scores on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline n=24,13,12	55.75 ± 16.476	54.01 ± 23.252	54.01 ± 23.252
Week 16 n=24,13,12	1.86 ± 10.695	-6.94 ± 11.508	-6.94 ± 11.508
Week 32 n=24,0,11	-4.26 ± 12.876		-14.43 ± 16.464

Other Pre-Specified Outcome Result(s)

No data identified.

Post-Hoc Outcome Result(s)

No data identified.

Summary of Safety

Safety Results

Time Frame	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.

Source Vocabulary for Table Default	MedDRA (25.0)
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

	AIN457 300 mg Q4W - CLP cohort N = 25	Placebo - CLP cohort N = 12	Any AIN457 300 mg - CLP cohort N = 33	Placebo to AIN457 300 mg Q2W - CLP cohort N = 8	AIN457 300 mg Q4W - MLP cohort N = 24	Placebo - MLP cohort N = 13	Any AIN457 300 mg - MLP cohort N = 35	Placebo to AIN457 300 mg Q2W - MLP cohort N = 11	AIN457 300 mg Q4W - LPP cohort N = 24	Placebo - LPP cohort N = 13	Any AIN457 300 mg - LPP cohort N = 36	Placebo to AIN457 300 mg Q2W - LPP cohort N = 12
Arm/Group Description	AIN457 300 mg every 4 weeks up to 32 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457 300mg administered every 4 weeks or every 2 weeks via a pre-filled syringe	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.	AIN457 300 mg every 4 weeks up to 32 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457 300mg administered every 4 weeks or every 2 weeks via a pre-filled syringe	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.	AIN45745 7 300 mg every 4 weeks up to 32 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457 300mg administered every 4 weeks or every 2 weeks via a pre-filled syringe	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.

Total Number Affected	0	0	0	0	0	0	0	0	0	0	0	0
Total Number At Risk	25	12	33	8	24	13	35	11	24	13	36	12

Serious Adverse Events

	AIN457 300 mg Q4W - CLP cohort N = 25	**Placebo - CLP cohort N = 12**	**Any AIN457 300 mg - CLP cohort N = 33**	**Placebo to AIN457 300 mg Q2W - CLP cohort N = 8**	**AIN457 300 mg Q4W - MLP cohort N = 24**	**Placebo - MLP cohort N = 13**	**Any AIN457 300 mg - MLP cohort N = 35**	**Placebo to AIN457 300 mg Q2W - MLP cohort N = 11**	**AIN457 300 mg Q4W - LPP cohort N = 24**	**Placebo - LPP cohort N = 13**	**Any AIN457 300 mg - LPP cohort N = 36**	**Placebo to AIN457 300 mg Q2W - LPP cohort N = 12**
Arm/Group Description	AIN457 300 mg every 4 weeks up to 32 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457 300mg administered every 4 weeks or every 2 weeks via a pre-filled syringe	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.	AIN457 300 mg every 4 weeks up to 32 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457 300mg administered every 4 weeks or every 2 weeks via a pre-filled syringe	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.	AIN457457 300 mg every 4 weeks up to 32 weeks administered via a pre-filled syringe	Matching placebo administered every 4 weeks up to 16 weeks via a pre-filled syringe	AIN457 300mg administered every 4 weeks or every 2 weeks via a pre-filled syringe	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.

Total # Affected by any Serious Adverse Event	0	1	0	0	1	0	2	1	0	1	1	1
Total # at Risk by any Serious Adverse Event	25	12	33	8	24	13	35	11	24	13	36	12
Cardiac disorders												
Angina pectoris	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders												
Colitis ulcerative	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Musculoskeletal and connective tissue disorders												
Osteoarthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)												
Adenocarcinoma of colon	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Nervous system disorders												
Neuralgia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)
Respiratory, thoracic and mediastinal disorders												
Pleurisy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Other (Not Including Serious) Adverse Events

Frequent Event Reporting Threshold 5%

	AIN457 300 mg Q4W - CLP cohort N = 25	**Placebo - CLP cohort N = 12**	**Any AIN457 300 mg - CLP cohort N = 33**	**Placebo to AIN457 300 mg Q2W - CLP cohort N = 8**	**AIN457 300 mg Q4W - MLP cohort N = 24**	**Placebo - MLP cohort N = 13**	**Any AIN457 300 mg - MLP cohort N = 35**	**Placebo to AIN457 300 mg Q2W - MLP cohort N = 11**	**AIN457 300 mg Q4W - LPP cohort N = 24**	**Placebo - LPP cohort N = 13**	**Any AIN457 300 mg - LPP cohort N = 36**	**Placebo to AIN457 300 mg Q2W - LPP cohort N = 12**
Arm/Group Description	AIN457 300 mg every 4 weeks up to 32 weeks administered via a pre-	Matching placebo administered every 4 weeks up to 16 weeks via a	AIN457 300mg administered every 4 weeks or every 2 weeks via a	Placebo non-responders during TP 1 received AIN457	AIN457 300 mg every 4 weeks up to 32 weeks administered via a pre-	Matching placebo administered every 4 weeks up to 16 weeks via a	AIN457 300mg administered every 4 weeks or every 2 weeks via a	Placebo non-responders during TP 1 received AIN457	AIN457457 300 mg every 4 weeks up to 32 weeks administered via a pre-	Matching placebo administered every 4 weeks up to 16 weeks via a	AIN457 300mg administered every 4 weeks or every 2 weeks via a	Placebo non-responders during TP 1 received AIN457

	filled syringe	pre-filled syringe	pre-filled syringe	300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.	filled syringe	pre-filled syringe	pre-filled syringe	300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.	filled syringe	pre-filled syringe	pre-filled syringe	300 mg every 2 weeks from Week 16 to Week 32 in TP 2 via a pre-filled syringe.
Total # Affected by any Other Adverse Event	15	7	21	6	18	8	26	8	16	7	22	6
Total # at Risk by any Other Adverse Event	25	12	33	8	24	13	35	11	24	13	36	12
Blood and lymphatic system disorders												
Lymph node pain	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders												
Arteriosclerosis coronary artery	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Ear and labyrinth disorders												
Auricular swelling	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Eye disorders												

Dry eye	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders												
Abdominal discomfort	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Abdominal pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	2 (5.71%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain upper	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (9.09%)	2 (8.33%)	0 (0.00%)	2 (5.56%)	0 (0.00%)
Colitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	2 (8.00%)	0 (0.00%)	3 (9.09%)	1 (12.50%)	1 (4.17%)	0 (0.00%)	3 (8.57%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrooesophageal reflux disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)
Haemorrhoids	2 (8.00%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukoplakia oral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nausea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	1 (7.69%)	2 (5.71%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral pain	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
General disorders and administration site conditions												
Asthenia	0 (0.00%)	1 (8.33%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.78%)	0 (0.00%)

Fatigue	1 (4.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	2 (5.56%)	0 (0.00%)
Injection site haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Oedema peripheral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	1 (7.69%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral swelling	2 (8.00%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pyrexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	2 (5.56%)	0 (0.00%)
Immune system disorders												
Immunisation reaction	3 (12.00%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Seasonal allergy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations												
COVID-19	1 (4.00%)	0 (0.00%)	2 (6.06%)	1 (12.50%)	2 (8.33%)	0 (0.00%)	4 (11.43%)	2 (18.18%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Cystitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	1 (7.69%)	1 (2.86%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.78%)	0 (0.00%)
Ear infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fungal skin infection	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Furuncle	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Gastroenteritis viral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Helicobacter infection	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Herpes ophthalmic	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nasopharyngitis	2 (8.00%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral candidiasis	1 (4.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	3 (8.33%)	1 (8.33%)
Oral herpes	1 (4.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pneumonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Post-acute COVID-19 syndrome	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	1 (4.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)
Superinfection	0 (0.00%)	1 (8.33%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tongue fungal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urinary tract infection	1 (4.00%)	1 (8.33%)	1 (3.03%)	0 (0.00%)	1 (4.17%)	1 (7.69%)	2 (5.71%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)
Injury, poisoning and procedural complications												
Fall	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ligament sprain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)
Limb injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)

Meniscus injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)
Tendon rupture	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Traumatic fracture	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations												
Gamma-glutamyltransferase increased	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	1 (4.17%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
SARS-CoV-2 test positive	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Metabolism and nutrition disorders												
Hypercholesterolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vitamin D deficiency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (12.50%)	0 (0.00%)	3 (8.33%)	0 (0.00%)
Musculoskeletal and connective tissue disorders												
Arthralgia	1 (4.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	2 (5.56%)	0 (0.00%)
Bone pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Exostosis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)
Limb discomfort	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Muscle spasms	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Osteonecrosis of jaw	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Plantar fasciitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)
Nervous system disorders												
Dizziness	1 (4.00%)	0 (0.00%)	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	1 (7.69%)	1 (2.78%)	0 (0.00%)
Headache	3 (12.00%)	0 (0.00%)	3 (9.09%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	2 (5.71%)	2 (18.18%)	5 (20.83%)	2 (15.38%)	5 (13.89%)	0 (0.00%)
Paraesthesia	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Presyncope	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Syncope	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders												
Insomnia	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders												
Micturition disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Micturition urgency	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Reproductive system and breast disorders												
Breast cyst	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)

Respiratory, thoracic and mediastinal disorders												
Dyspnoea	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders												
Acne	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Actinic keratosis	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.78%)	0 (0.00%)
Dermal cyst	0 (0.00%)	0 (0.00%)	1 (3.03%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	2 (5.56%)	1 (8.33%)
Dermatitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.78%)	1 (8.33%)
Intertrigo	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (2.78%)	0 (0.00%)
Lichen planus	3 (12.00%)	1 (8.33%)	4 (12.12%)	1 (12.50%)	4 (16.67%)	0 (0.00%)	5 (14.29%)	1 (9.09%)	1 (4.17%)	0 (0.00%)	2 (5.56%)	1 (8.33%)
Pruritus	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	3 (12.50%)	0 (0.00%)	3 (8.57%)	0 (0.00%)	3 (12.50%)	1 (7.69%)	3 (8.33%)	0 (0.00%)
Skin burning sensation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urticaria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (8.33%)	0 (0.00%)	2 (5.56%)	0 (0.00%)
Vascular disorders												
Hypertension	2 (8.00%)	0 (0.00%)	2 (6.06%)	0 (0.00%)	1 (4.17%)	1 (7.69%)	1 (2.86%)	0 (0.00%)	1 (4.17%)	2 (15.38%)	2 (5.56%)	1 (8.33%)

Other Relevant Findings

Conclusion:

- The secukinumab 300 mg Q4W dose regimen showed numerically greater efficacy in Investigator's Global Assessment (IGA) ≤2 response compared to placebo in the mucosal lichen planus and lichen planopilaris cohorts at Week 16
- In the cutaneous lichen planus cohort, a similar IGA ≤2 response rate was seen from Week 16 to Week 32 in the secukinumab 300 mg Q4W dose regimen. No improvement was seen in IGA ≤2 response rate from Week 16 to Week 32 in the placebo-secukinumab 300 mg Q2W dose regimen. It is to be noted that at Week 16, response rates for the secukinumab Q4W dosing was not better than the placebo response rates on all IGA endpoints.
- In the mucosal lichen planus cohort, sustained IGA ≤2 response rate was observed from Week 16 to Week 32 in the secukinumab 300 mg Q4W dose regimen. The secukinumab 300 mg Q2W dose did not show any evidence of superior efficacy compared to secukinumab 300 mg Q4W. No improvement was noted in other IGA endpoints or Reticular Erythematous Ulcerative.
- In the lichen planopilaris cohort, the efficacy of secukinumab 300 mg Q4W slightly improved over time up to Week 32 in all the IGA endpoints. After the switch from placebo to secukinumab 300 mg Q2W, even with shorter exposure, a better response than the secukinumab 300 mg Q4W dosing group and good control over the disease (IGA 0/1, IGA improvement of at least 2 points andl Lichenp Planopilaris Activity Index response) was achieved in a notable percentage of subjects.
- Secukinumab was well tolerated at the 300 mg Q4W and Q2W dose regimens and safety was comparable across cohorts.
- The safety profile in this study was consistent with the known safety profile of secukinumab and showed no new or unexpected safety signals.

NOVARTIS

Date of Clinical Trial Report

November 10, 2022