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Trial record **2 of 2** for: CAIN457A2302
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Efficacy and Safety of Subcutaneous Secukinumab for Moderate to Severe Chronic Plaque-type Psoriasis for up to 1 Year (ERASURE)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT01365455

First received: June 1, 2011
Last updated: January 19, 2016
Last verified: January 2016
History of Changes

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Results First Received: February 16, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Moderate to Severe Plaque-type Psoriasis
Interventions:	Drug: secukinumab 150 mg Drug: placebo to secukinumab 150 mg

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Not all patients that completed Maintenance Period continued in the follow-up Period. Many patients from Maintence rolled into CAIN457A2302E1 study

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 150mg From Placebo	Patients randomized to AIN457 150mg in Maintenance phase when they were on Placebo in Induction Phase because they were PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 300mg From Placebo	Patients randomized to AIN457 300mg in Maintenance phase when they were on Placebo in Induction Phase. PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Participant Flow for 3 periods

Period 1: Induction Period

	AIN457 150 mg	AIN457 300 mg	Placebo	AIN457 150mg From Placebo	AIN457 300mg From Placebo
STARTED	245	245	248	0	0
COMPLETED	230	238	232	0	0
NOT COMPLETED	15	7	16	0	0
Adverse Event	5	3	4	0	0
Lack of Efficacy	1	1	0	0	0
Pregnancy	0	1	0	0	0
Protocol deviation	0	1	1	0	0
Subject/guardian decision	9	1	8	0	0
Lost to Follow-up	0	0	3	0	0

Period 2: Maintenance Period

	AIN457 150 mg	AIN457 300 mg	Placebo	AIN457 150mg From Placebo	AIN457 300mg From Placebo
STARTED	230	238	18	109	105
COMPLETED	201	215	15	100	92
NOT COMPLETED	29	23	3	9	13
Adverse Event	12	5	1	2	4
Lack of Efficacy	10	2	0	2	2
Lost to Follow-up	2	4	0	0	3
Non-compliance with study treatment	0	0	0	1	0
Physician Decision	0	1	0	0	1
Pregnancy	0	4	0	0	2
Protocol deviation	1	1	0	0	0
Subject/guardian decision	4	6	2	4	1

Period 3: Follow-up Period

	AIN457 150 mg	AIN457 300 mg	Placebo	AIN457 150mg From Placebo	AIN457 300mg From Placebo
STARTED	58	47	18	0	0
COMPLETED	58	47	18	0	0
NOT COMPLETED	0	0	0	0	0

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description

AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
Total	Total of all reporting groups

Baseline Measures

	AIN457 150 mg	AIN457 300 mg	Placebo	Total
Number of Participants [units: participants]	**245**	**245**	**248**	**738**
Age [units: years] Mean (Standard Deviation)	**44.9 (13.33)**	**44.9 (13.46)**	**45.4 (12.63)**	**45.1 (13.13)**
Gender [units: participants]				
Female	**77**	**76**	**76**	**229**
Male	**168**	**169**	**172**	**509**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Who Achieved >75 or Higher (Psoriasis Area and Severity Index) PASI Score at 12 Weeks [Time Frame: 12 weeks]

Measure Type	Primary
Measure Title	Percentage of Participants Who Achieved >75 or Higher (Psoriasis Area and Severity Index) PASI Score at 12 Weeks
Measure Description	A 75% reduction in the Psoriasis Area and Severity Index (PASI) score (PASI 75) is the current benchmark of primary endpoints for most clinical trials of psoriasis. PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**243**	**245**	**246**
Percentage of Participants Who Achieved >75 or Higher (Psoriasis Area and Severity Index) PASI Score at 12 Weeks [units: Percentage of participants]	**71.6**	**81.6**	**4.5**

No statistical analysis provided for Percentage of Participants Who Achieved >75 or Higher (Psoriasis Area and Severity Index) PASI Score at 12 Weeks

2. Primary: Percentage of Participants Who Achieved (Investigator's Global Assessment) IGA Score of 0 or 1 [Time Frame: 12 weeks]

Measure Type	Primary
Measure Title	Percentage of Participants Who Achieved (Investigator's Global Assessment) IGA Score of 0 or 1
Measure Description	The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, and 4 = severe. Treatment success was defined as achievement of IGA mod 2001 score of 0 or 1. IGA score of 0 or 1 as an indicator of efficacy.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**244**	**245**	**246**
Percentage of Participants Who Achieved (Investigator's Global Assessment) IGA Score of 0 or 1 [units: Percentage of Participants]	**51.2**	**65.3**	**2.4**

No statistical analysis provided for Percentage of Participants Who Achieved (Investigator's Global Assessment) IGA Score of 0 or 1

3. Secondary: Percentage of Participants Who Achieved a PASI (Psoriasis Area and Severity Index) Score of 90 or Better at Week 12 [Time Frame: 12 weeks]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved a PASI (Psoriasis Area and Severity Index) Score of 90 or Better at Week 12

Measure Description	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 90 was defined as participants who achievied ≥ 90% improvement from baseline.
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	**AIN457 300 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**243**	**245**	**246**
Percentage of Participants Who Achieved a PASI (Psoriasis Area and Severity Index) Score of 90 or Better at Week 12 [units: Percentage of Participants]	**39.1**	**59.2**	**1.2**

No statistical analysis provided for Percentage of Participants Who Achieved a PASI (Psoriasis Area and Severity Index) Score of 90 or Better at Week 12

4. Secondary: Number of Participants That Maintained the Psoriasis Area and Severity Index (PASI) 75 Response at 52 Weeks of Treatment for Participants Who Were PASI 75 Responders at Week 12 [Time Frame: 12 and 52 weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Maintained the Psoriasis Area and Severity Index (PASI) 75 Response at 52 Weeks of Treatment for Participants Who Were PASI 75 Responders at Week 12
Measure Description	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4).
Time Frame	12 and 52 weeks
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**245**	**245**	**248**
Number of Participants That Maintained the Psoriasis Area and Severity Index (PASI) 75 Response at 52 Weeks of Treatment for Participants Who Were PASI 75 Responders at Week 12 [units: number of participants]			
PASI 75 response at Week 12 (n=243, 245, 246)	**174**	**200**	**11**
Maintained PASI 75 response at Wk 52(n=174,200,11)	**126**	**161**	**NA [1]**

[1] After W12: Efficacy was not focus for PBO group and therefore no data was provided at Week 52

No statistical analysis provided for Number of Participants That Maintained the Psoriasis Area and Severity Index (PASI) 75 Response at 52 Weeks of Treatment for Participants Who Were PASI 75 Responders at Week 12

5. Secondary: Number of Participants That Maintained the IGA Mod 2011 0 or 1 Response at 52 Weeks of Treatment for Participants Who Were IGA Mod 2011 0 or 1 Responders at Week 12 [Time Frame: 12 and 52 weeks]

Measure Type	Secondary
Measure Title	Number of Participants That Maintained the IGA Mod 2011 0 or 1 Response at 52 Weeks of Treatment for Participants Who Were IGA Mod 2011 0 or 1 Responders at Week 12
Measure Description	The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, and 4 = severe. Treatment success was defined as achievement of IGA mod 2001 score of 0 or 1.
Time Frame	12 and 52 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
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Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo

	injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**245**	**245**	**248**
Number of Participants That Maintained the IGA Mod 2011 0 or 1 Response at 52 Weeks of Treatment for Participants Who Were IGA Mod 2011 0 or 1 Responders at Week 12 [units: number of participants]			
IGA mod2011 0or1 response at Wk 12(n=244,245,246)	**125**	**160**	**6**
Maintained IGAmod2011 0or1 resp atWk52 n=125,160,6	**74**	**119**	**NA [1]**

[1] After W12: Efficacy was not focus for PBO group and therefore no data was provided at Week 52

No statistical analysis provided for Number of Participants That Maintained the IGA Mod 2011 0 or 1 Response at 52 Weeks of Treatment for Participants Who Were IGA Mod 2011 0 or 1 Responders at Week 12

6. Secondary: Change From Baseline to Week 12 in Psoriasis Symptom Diary Items Itching, Pain and Scaling in AIN457 vs Placebo [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Change From Baseline to Week 12 in Psoriasis Symptom Diary Items Itching, Pain and Scaling in AIN457 vs Placebo
Measure Description	The Psoriasis Symptom Diary©, a 16-item patient reported outcome (PRO) measure developed and validated in accordance with the FDA PRO Guidance (FDA Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, 2009), demonstrated favorable psychometric properties and usefulness for treatment efficacy evaluation alongside other measures of disease severity in clinical trials for chronic plaque psoriasis.Weekly averages will be derived for each of the 16 questions of the Psoriasis Diary up to Week 12. A weekly average is the sum of the scored item over the course of the study week divided by the number of days on which the item was completed and will be set to missing if four or more daily assessments were missing of the corresponding question. A reduction in score from baseline shows efficacy. Each question has a score of 0 (no symptoms) up to 10 (Severe symptoms)
Time Frame	Week 12
Safety Issue	No

Population Description

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Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
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Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**245**	**245**	**248**
Change From Baseline to Week 12 in Psoriasis Symptom Diary Items Itching, Pain and Scaling in			

AIN457 vs Placebo [units: Scores on a Scale] Mean (Standard Error)			
itching (n=86,79,84)	-4.86 (0.299)	-545 (0.276)	-0.22 (0.260)
pain (n=86,79,84)	-3.92 (0.337)	-4.59 (0.322)	0.06 (0.246)
scaling (n=86,79,84)	-4.74 (0.307)	-5.49 (0.289)	-0.11 (0.248)

No statistical analysis provided for Change From Baseline to Week 12 in Psoriasis Symptom Diary Items Itching, Pain and Scaling in AIN457 vs Placebo

7. Secondary: Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response up to 12 Weeks Induction Period [Time Frame: Week 1,2,3,4,8,12,]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response up to 12 Weeks Induction Period
Measure Description	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (max). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.
Time Frame	Week 1,2,3,4,8,12,
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo
Number of Participants Analyzed [units: participants]	245	245	247
Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response up to 12 Weeks Induction Period [units: Percentage of participants]			
Week 1 IGA 0/1 (n=244,245,246)	0.0	0.0	0.0
Week 1 PASI 75 (n=243,245,246)	0.0	0.0	0.0
Week 1 PASI 50 (n=243,245,246)	2.1	4.5	0.4

Week 1 PASI 90 (n=243,245,246)	**0.0**	**0.0**	**0.0**
Week 1 PASI 100 (n=243,245,246)	**0.0**	**0.0**	**0.0**
Week 2 IGA 0/1 n=244,245,246)	**1.2**	**4.5**	**0.0**
Week 2 PASI 75 (n=243,245,246)	**0.8**	**4.1**	**0.0**
Week 2 PASI 50 (n=243,245,246)	**18.5**	**28.2**	**3.3**
Week 2 PASI 90 (n=243,245,246)	**0.0**	**0.8**	**0.0**
Week 2 PASI 100 (n=243,245,246)	**0.0**	**0.0**	**0.0**
Week 3 IGA 0/1(n=244,245,246)	**6.6**	**11.0**	**0.4**
Week 3 PASI 75 (n=243,245,246)	**8.2**	**15.5**	**1.2**
Week 3 PASI 50 (n=243,245,246)	**41.2**	**53.1**	**4.9**
Week 3 PASI 90 (n=243,245,246)	**0.8**	**2.9**	**0.0**
Week 3 PASI 100 (n=243,245,246)	**0.0**	**0.8**	**0.0**
Week 4 IGA 0/1(n=244,245,246)	**17.2**	**26.1**	**1.2**
Week 4 PASI 75 (n=243,245,246)	**24.3**	**38.0**	**0.8**
Week 4 PASI 50 (n=243,245,246)	**63.0**	**74.7**	**7.3**
Week 4 PASI 90 (n=243,245,246)	**5.8**	**10.6**	**0.4**
Week 4 PASI 100 (n=243,245,246)	**0.8**	**3.7**	**0.0**
Week 8 IGA 0/1(n=244,245,246)	**42.2**	**60.0**	**1.6**
Week 8 PASI 75 (n=243,245,246)	**61.7**	**76.7**	**2.8**
Week 8 PASI 50 (n=243,245,246)	**88.5**	**92.2**	**9.3**
Week 8 PASI 90 (n=243,245,246)	**28.8**	**47.8**	**1.2**
Week 8 PASI 100 (n=243,245,246)	**8.2**	**16.7**	**0.0**
Week 12 IGA 0/1(n=244,245,246)	**51.2**	**65.3**	**2.4**
Week 12 PASI 75 (n=243,245,246)	**71.6**	**81.6**	**4.5**
Week 12 PASI 50 (n=243,245,246)	**83.5**	**90.6**	**8.9**
Week 12 PASI 90 (n=243,245,246)	**39.1**	**59.2**	**1.2**
Week 12 PASI 100 (n=243,245,246)	**12.8**	**28.6**	**0.8**

No statistical analysis provided for Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response up to 12 Weeks Induction Period

8. Secondary: Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response Maintenance Period After Week 12 to Week 52
[Time Frame: Week 13,14,15,16,20,24,28,32,36,40,44,48,52]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response Maintenance Period After Week 12 to Week 52
Measure Description	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (max). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.
Time Frame	Week 13,14,15,16,20,24,28,32,36,40,44,48,52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 150mg From Placebo	Patients randomized to AIN457 150mg in Maintenance phase when they were on Placebo in Induction Phase because they were PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 300mg From Placebo	Patients randomized to AIN457 300mg in Maintenance phase when they were on Placebo in Induction Phase. PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo	AIN457 150mg From Placebo	AIN457 300mg From Placebo
Number of Participants Analyzed [units: participants]	**245**	**245**	**18**	**108**	**105**
Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response Maintenance Period After Week 12 to Week 52 [units: Percentage of participants]					
Week 13 IGA 0/1 (n=244,245,18, 108, 104)	**51.6**	**66.9**	**33.3**	**0.9**	**1.9**
Week 13 PASI 75 (n=243,245,18, 108, 104)	**70.8**	**79.6**	**55.6**	**2.8**	**0.0**
Week 13 PASI 50 (n=243,245,18, 108, 104)	**81.5**	**87.3**	**77.8**	**12.0**	**13.5**
Week 13 PASI 90 (n=243,245,18, 108, 104)	**44.9**	**60.8**	**22.2**	**0.9**	**0.0**
Week 13 PASI 100 (n=243,245,18, 108, 104)	**14.0**	**30.2**	**11.1**	**0.0**	**0.0**
Week 14 IGA 0/1 (n=244,245,18, 108, 104)	**55.3**	**74.7**	**33.3**	**4.6**	**10.6**
Week 14 PASI 75 (n=243,245,18, 108, 104)	**72.0**	**86.1**	**55.6**	**7.4**	**14.4**
Week 14 PASI 50 (n=243,245,18, 108, 104)	**83.1**	**91.4**	**83.3**	**34.3**	**38.5**
Week 14 PASI 90 (n=243,245,18, 108, 104)	**48.6**	**68.2**	**27.8**	**0.9**	**0.0**
Week 14 PASI 100 (n=243,245,18, 108, 104)	**16.5**	**35.5**	**11.1**	**0.0**	**0.0**
Week 15 IGA 0/1 (n=244,245,18, 108, 104)	**57.4**	**75.1**	**33.3**	**13.0**	**19.2**
Week 15 PASI 75 (n=243,245,18, 108, 104)	**75.3**	**87.8**	**55.6**	**13.9**	**26.9**
Week 15 PASI 50 (n=243,245,18, 108, 104)	**86.4**	**92.2**	**72.2**	**55.6**	**66.3**
Week 15 PASI 90 (n=243,245,18, 108, 104)	**51.0**	**68.6**	**27.8**	**2.8**	**6.7**
Week 15 PASI 100 (n=243,245,18, 108, 104)	**19.8**	**40.8**	**11.1**	**0.0**	**0.0**
Week 16 IGA 0/1 (n=244,245,18, 108, 104)	**58.2**	**73.5**	**38.9**	**25.9**	**30.8**
Week 16 PASI 75 (n=243,245,18, 108, 104)	**77.4**	**86.1**	**61.1**	**33.3**	**47.1**
Week 16 PASI 50 (n=243,245,18, 108, 104)	**87.2**	**91.4**	**77.8**	**68.5**	**81.7**
Week 16 PASI 90 (n=243,245,18, 108, 104)	**53.5**	**69.8**	**33.3**	**10.2**	**15.4**
Week 16 PASI 100 (n=243,245,18, 108, 104)	**21.0**	**41.6**	**22.2**	**0.9**	**4.8**
Week 20 IGA 0/1 (n=244,245,18, 108, 104)	**57.4**	**74.7**	**38.9**	**51.9**	**55.8**
Week 20 PASI 75 (n=243,245,18, 108, 104)	**77.0**	**86.9**	**72.2**	**66.7**	**75.0**
Week 20 PASI 50 (n=243,245,18, 108, 104)	**89.3**	**92.7**	**88.9**	**87.0**	**91.3**
Week 20 PASI 90 (n=243,245,18, 108, 104)	**51.9**	**69.8**	**38.9**	**38.0**	**50.0**
Week 20 PASI 100 (n=243,245,18, 108, 104)	**21.8**	**43.3**	**16.7**	**5.6**	**19.2**

Week 24 IGA 0/1 (n=244,245,18, 108, 104)	**58.2**	**71.4**	**50.0**	**57.4**	**72.1**
Week 24 PASI 75 (n=243,245,18, 108, 104)	**77.8**	**85.7**	**66.7**	**76.9**	**81.7**
Week 24 PASI 50 (n=243,245,18, 108, 104)	**86.8**	**91.0**	**88.9**	**91.7**	**93.3**
Week 24 PASI 90 (n=243,245,18, 108, 104)	**54.7**	**70.2**	**38.9**	**50.9**	**62.5**
Week 24 PASI 100 (n=243,245,18, 108, 104)	**23.9**	**42.4**	**16.7**	**16.7**	**26.0**
Week 28 IGA 0/1 (n=244,245,18, 108, 104)	**53.7**	**68.6**	**50.0**	**61.1**	**76.0**
Week 28 PASI 75 (n=243,245,18, 108, 104)	**72.4**	**82.9**	**72.2**	**74.1**	**87.5**
Week 28 PASI 50 (n=243,245,18, 108, 104)	**84.4**	**90.2**	**83.3**	**91.7**	**93.3**
Week 28 PASI 90 (n=243,245,18, 108, 104)	**53.1**	**68.6**	**50.0**	**50.0**	**71.2**
Week 28 PASI 100 (n=243,245,18, 108, 104)	**24.3**	**43.3**	**16.7**	**24.1**	**33.7**
Week 32 IGA 0/1 (n=244,245,18, 108, 104)	**50.8**	**68.2**	**44.4**	**57.4**	**76.0**
Week 32 PASI 75 (n=243,245,18, 108, 104)	**72.0**	**81.2**	**61.1**	**75.0**	**89.4**
Week 32 PASI 50 (n=243,245,18, 108, 104)	**86.4**	**88.6**	**77.8**	**88.9**	**94.2**
Week 32 PASI 90 (n=243,245,18, 108, 104)	**48.1**	**68.2**	**44.4**	**50.9**	**70.2**
Week 32 PASI 100 (n=243,245,18, 108, 104)	**22.2**	**43.7**	**16.7**	**22.2**	**39.4**
Week 36 IGA 0/1 (n=244,245,18, 108, 104)	**48.0**	**66.9**	**38.9**	**60.2**	**70.2**
Week 36 PASI 75 (n=243,245,18, 108, 104)	**67.5**	**79.2**	**61.1**	**73.1**	**86.5**
Week 36 PASI 50 (n=243,245,18, 108, 104)	**80.2**	**86.9**	**88.9**	**88.9**	**89.4**
Week 36 PASI 90 (n=243,245,18, 108, 104)	**44.4**	**67.3**	**44.4**	**52.8**	**64.4**
Week 36 PASI 100 (n=243,245,18, 108, 104)	**22.2**	**42.4**	**16.7**	**25.0**	**43.3**
Week 40 IGA 0/1 (n=244,245,18, 108, 104)	**47.1**	**64.9**	**44.4**	**57.4**	**69.2**
Week 40 PASI 75 (n=243,245,18, 108, 104)	**65.4**	**76.7**	**66.7**	**69.4**	**81.7**
Week 40 PASI 50 (n=243,245,18, 108, 104)	**78.6**	**84.9**	**83.3**	**88.0**	**88.5**
Week 40 PASI 90 (n=243,245,18, 108, 104)	**44.0**	**64.9**	**44.4**	**50.9**	**65.4**
Week 40 PASI 100 (n=243,245,18, 108, 104)	**21.0**	**40.8**	**27.8**	**24.1**	**42.3**
Week 44 IGA 0/1 (n=244,245,18, 108, 104)	**44.3**	**60.4**	**44.4**	**57.4**	**72.1**
Week 44 PASI 75 (n=243,245,18, 108, 104)	**63.4**	**79.2**	**61.1**	**68.5**	**79.8**
Week 44 PASI 50 (n=243,245,18, 108, 104)	**77.4**	**84.5**	**83.3**	**89.8**	**89.4**
Week 44 PASI 90 (n=243,245,18, 108, 104)	**42.8**	**61.2**	**38.9**	**47.2**	**66.3**
Week 44 PASI 100 (n=243,245,18, 108, 104)	**21.8**	**37.1**	**11.1**	**23.1**	**38.5**
Week 48 IGA 0/1 (n=244,245,18, 108, 104)	**41.4**	**62.9**	**27.8**	**50.0**	**69.2**
Week 48 PASI 75 (n=243,245,18, 108, 104)	**62.1**	**77.6**	**66.7**	**68.5**	**76.9**
Week 48 PASI 50 (n=243,245,18, 108, 104)	**77.4**	**84.9**	**83.3**	**86.1**	**83.7**
Week 48 PASI 90 (n=243,245,18, 108, 104)	**39.5**	**63.7**	**38.9**	**45.4**	**63.5**
Week 48 PASI 100 (n=243,245,18, 108, 104)	**22.2**	**40.4**	**11.1**	**20.4**	**37.5**
Week 52 IGA 0/1 (n=244,245,18, 108, 104)	**73.4**	**87.3**	**38.9**	**76.9**	**66.3**
Week 52 PASI 75 (n=243,245,18, 108, 104)	**86.8**	**94.3**	**66.7**	**88.0**	**73.1**
Week 52 PASI 50(n=243,245,18, 108, 104)	**91.8**	**95.9**	**83.3**	**96.3**	**81.7**
Week 52 PASI 90 (n=243,245,18, 108, 104)	**73.3**	**84.5**	**33.3**	**66.7**	**62.5**
Week 52 PASI 100 (n=243,245,18, 108, 104)	**41.2**	**62.0**	**11.1**	**36.1**	**43.3**

No statistical analysis provided for Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response Maintenance Period After Week 12 to Week 52

9. Secondary: Mean Percent Change From Baseline in PASI Scores up to Week 12 - Induction Period [Time Frame: Baseline, Week 1,2,3,4,8,12,]

Measure Type	Secondary

Measure Title	Mean Percent Change From Baseline in PASI Scores up to Week 12 - Induction Period
Measure Description	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). A negative mean percentage change indicates improvement.
Time Frame	Baseline, Week 1,2,3,4,8,12,
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	**AIN457 300 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**245**	**245**	**247**
Mean Percent Change From Baseline in PASI Scores up to Week 12 - Induction Period [units: Percent Change] Mean (Standard Deviation)			
Week 1 (n=243,243,242)	**-12.08 (19.225)**	**-17.50 (17.317)**	**-3.70 (14.756)**
Week 2 (n=243,245,243)	**-28.61 (21.982)**	**-36.51 (21.850)**	**-5.63 (23.616)**
Week 3 (n=243,245,243)	**-42.79 (23.695)**	**-51.59 (22.415)**	**-8.62 (25.785)**
Week 4 (n=243,245,245)	**-55.73 (24.252)**	**-64.61 (22.080)**	**-8.89 (28.165)**
Week 8 (n=243,245,245)	**-76.35 (20.427)**	**-82.98 (19.331)**	**-8.15 (32.755)**
Week 12 (n=243,245,245)	**-80.87 (20.512)**	**-87.72 (17.729)**	**-5.89 (36.606)**

No statistical analysis provided for Mean Percent Change From Baseline in PASI Scores up to Week 12 - Induction Period

10. Secondary: Mean Percent Change From Baseline in PASI Scores Maintenance Period After Week 12 to Week 52 [Time Frame: Week 13,14,15,16,20,24,28,32,36,40,44,48,52]

Measure Type	Secondary
Measure Title	Mean Percent Change From Baseline in PASI Scores Maintenance Period After Week 12 to Week 52
Measure Description	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72(maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). A negative mean percentage change indicates improvement.
Time Frame	Week 13,14,15,16,20,24,28,32,36,40,44,48,52

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 150mg From Placebo	Patients randomized to AIN457 150mg in Maintenance phase when they were on Placebo in Induction Phase because they were PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 300mg From Placebo	Patients randomized to AIN457 300mg in Maintenance phase when they were on Placebo in Induction Phase. PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo	AIN457 150mg From Placebo	AIN457 300mg From Placebo
Number of Participants Analyzed [units: participants]	**245**	**245**	**18**	**108**	**105**
Mean Percent Change From Baseline in PASI Scores Maintenance Period After Week 12 to Week 52 [units: Percent change] Mean (Standard Deviation)					
Week 13 (n=243,245,18,102,96)	**-83.12 (19.313)**	**-89.55 (15.935)**	**-63.10 (36.827)**	**-21.03 (28.240)**	**-21.66 (29.891)**
Week 14 (n=243,245,18,107,102)	**-84.47 (18.832)**	**-90.83 (15.013)**	**-68.74 (30.225)**	**-39.20 (26.228)**	**-41.97 (28.809)**
Week 15 (n=243,245,18,107,103)	**-84.67 (19.407)**	**-91.40 (14.769)**	**-67.15 (32.972)**	**-51.78 (23.561)**	**-57.77 (23.166)**
Week 16 (n=243,245,18,107,103)	**-85.20 (19.213)**	**-91.37 (15.367)**	**-73.38 (28.051)**	**-62.19 (23.591)**	**-70.15 (20.686)**
Week 20 (n=243,245,18,107,103)	**-85.75 (17.904)**	**-90.86 (16.263)**	**-80.57 (22.454)**	**-77.75 (20.587)**	**-84.53 (16.030)**
Week 24 (n=243,245,18,107,103)	**-85.46 (20.240)**	**-90.83 (16.652)**	**-78.06 (25.062)**	**-83.19 (18.635)**	**-89.20 (13.969)**
Week 28 (n=243,245,18,107,103)	**-84.72 (20.417)**	**-90.15 (17.600)**	**-79.55 (23.943)**	**-84.07 (19.819)**	**-91.24 (11.849)**
Week 32 (n=243,245,18,107,103)	**-83.98 (21.887)**	**-89.90 (17.775)**	**-75.94 (25.879)**	**-84.26 (20.622)**	**-91.09 (13.240)**
Week 36(n=243,245,18,107,103)	**-81.87 (25.048)**	**-90.04 (17.981)**	**-78.37 (24.608)**	**-83.68 (20.328)**	**-89.97 (16.373)**
Week 40(n=243,245,18,107,103)	**-81.37 (25.395)**	**-89.62 (17.385)**	**-78.32 (24.770)**	**-82.83 (20.762)**	**-89.76 (17.029)**
Week 44 (n=243,245,18,107,103)	**-80.81 (25.651)**	**-88.97 (17.804)**	**-79.96 (22.354)**	**-83.44 (18.277)**	**-89.37 (17.176)**
Week 48(n=243,245,18,107,103)	**-79.78 (26.471)**	**-89.35 (17.281)**	**-79.54 (21.506)**	**-83.40 (18.736)**	**-88.44 (18.083)**

Week 52 (n=243,245,18,107,103)	**-79.74 (26.524)**	**-88.42 (19.132)**	**-79.64 (22.169)**	**-82.14 (18.554)**	**-87.66 (20.615)**

No statistical analysis provided for Mean Percent Change From Baseline in PASI Scores Maintenance Period After Week 12 to Week 52

11. Secondary: Percentage of Participants in Each IGA Mod 2011 Score Category up to Week 12 - Induction Period [Time Frame: Baseline, Week 1,2,3,4,8,12,]

Measure Type	Secondary
Measure Title	Percentage of Participants in Each IGA Mod 2011 Score Category up to Week 12 - Induction Period
Measure Description	The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, and 4 = severe.
Time Frame	Baseline, Week 1,2,3,4,8,12,
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	**AIN457 300 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**245**	**245**	**247**
Percentage of Participants in Each IGA Mod 2011 Score Category up to Week 12 - Induction Period [units: Percentage of participants]			
Week 1 (n=244,243,243) clear	**0.0**	**0.0**	**0.0**
Week 1 (n=244,243,243) almost clear	**0.0**	**0.0**	**0.0**
Week 1 (n=244,243,243) mild	**6.6**	**9.1**	**4.1**
Week 1 (n=244,243,243) moderate	**66.4**	**68.7**	**60.9**
Week 1 (n=244,243,243) severe	**27.0**	**22.2**	**35.0**
Week 2 (n=244,245,244) clear	**0.0**	**0.0**	**0.0**
Week 2 (n=244,245,244) almost clear	**1.2**	**4.5**	**0.0**
Week 2 (n=244,245,244) mild	**23.0**	**27.8**	**5.3**
Week 2 (n=244,245,244) moderate	**57.0**	**55.5**	**59.8**
Week 2 (n=244,245,244) severe	**18.9**	**12.2**	**34.8**
Week 3 (n=244,245,244) clear	**0.0**	**1.2**	**0.0**
Week 3 (n=244,245,244) almost clear	**6.6**	**9.8**	**0.4**
Week 3 (n=244,245,244) mild	**34.0**	**43.3**	**7.0**

Week 3 (n=244,245,244) moderate	**49.2**	**40.4**	**58.6**
Week 3 (n=244,245,244) severe	**10.2**	**5.3**	**34.0**
Week 4 (n=244,245,246) clear	**0.4**	**3.7**	**0.0**
Week 4 (n=244,245,246) almost clear	**16.8**	**22.9**	**1.6**
Week 4 (n=244,245,246) mild	**40.2**	**43.7**	**7.3**
Week 4 (n=244,245,246) moderate	**37.3**	**26.5**	**58.1**
Week 4 (n=244,245,246) severe	**5.3**	**3.3**	**32.9**
Week 8 (n=244,245,246) clear	**10.2**	**20.4**	**0.0**
Week 8 (n=244,245,246) almost clear	**32.0**	**39.6**	**1.6**
Week 8 (n=244,245,246) mild	**38.9**	**29.0**	**8.1**
Week 8 (n=244,245,246) moderate	**16.4**	**10.2**	**53.3**
Week 8 (n=244,245,246) severe	**2.5**	**0.8**	**37.0**
Week 12 (n=244,245,246) clear	**16.4**	**32.2**	**0.8**
Week 12 (n=244,245,246) almost clear	**38.5**	**36.3**	**1.6**
Week 12 (n=244,245,246) mild	**29.1**	**23.3**	**6.5**
Week 12 (n=244,245,246) moderate	**14.8**	**6.9**	**55.3**
Week 12 (n=244,245,246) severe	**1.2**	**1.2**	**35.8**

No statistical analysis provided for Percentage of Participants in Each IGA Mod 2011 Score Category up to Week 12 - Induction Period

12. Secondary: Percentage of Participants in Each IGA Mod 2011 Score Category Maintenance Period After Week 12 to Week 52 [Time Frame: Week 13,14,15,16,20,24,28,32,36,40,44,48,52]

Measure Type	Secondary
Measure Title	Percentage of Participants in Each IGA Mod 2011 Score Category Maintenance Period After Week 12 to Week 52
Measure Description	The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate, and 4 = severe.
Time Frame	Week 13,14,15,16,20,24,28,32,36,40,44,48,52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 150mg From Placebo	Patients randomized to AIN457 150mg in Maintenance phase when they were on Placebo in Induction Phase because they were PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

AIN457 300mg From Placebo	Patients randomized to AIN457 300mg in Maintenance phase when they were on Placebo in Induction Phase. PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo	AIN457 150mg From Placebo	AIN457 300mg From Placebo
Number of Participants Analyzed [units: participants]	**245**	**245**	**18**	**108**	**105**
Percentage of Participants in Each IGA Mod 2011 Score Category Maintenance Period After Week 12 to Week 52 [units: Percentage of participants]					
Week 13 (n=244,245,18,103,96) clear	**17.6**	**38.0**	**11.1**	**0.0**	**0.0**
Week 13 (n=244,245,18,103,96) almost clear	**40.6**	**35.9**	**22.2**	**1.0**	**2.1**
Week 13 (n=244,245,18,103,96) mild	**27.0**	**19.2**	**27.8**	**15.5**	**14.6**
Week 13 (n=244,245,18,103,96) moderate	**12.7**	**6.5**	**27.8**	**61.2**	**59.4**
Week 13 (n=244,245,18,103,96) severe	**2.0**	**0.4**	**11.1**	**22.3**	**24.0**
Week 14 (n=244,245,18,108,102) clear	**19.3**	**41.6**	**16.7**	**0.0**	**0.0**
Week 14 (n=244,245,18,108,102)almost clear	**42.3**	**36.7**	**16.7**	**4.6**	**10.8**
Week 14 (n=244,245,18,108,102) mild	**25.0**	**13.5**	**33.3**	**30.6**	**27.5**
Week 14 (n=244,245,18,108,102)moderate	**12.3**	**7.3**	**22.2**	**56.5**	**50.0**
Week 14 (n=244,245,18,108,102)severe	**1.2**	**0.8**	**11.1**	**8.3**	**11.8**
Week 15 (n=244,245,18,108,103) clear	**22.1**	**45.3**	**11.1**	**0.0**	**1.9**
Week 15 (n=244,245,18,108,103) almost clear	**38.9**	**33.9**	**22.2**	**13.9**	**17.5**
Week 15 (n=244,245,18,108,103) mild	**27.5**	**14.7**	**33.3**	**38.9**	**39.8**
Week 15 (n=244,245,18,108,103) moderate	**10.2**	**5.3**	**22.2**	**42.6**	**35.9**
Week 15 (n=244,245,18,108,103) severe	**1.2**	**0.8**	**11.1**	**4.6**	**4.9**
Week 16 (n=244,245,18,108,103) clear	**23.8**	**47.3**	**22.2**	**0.0**	**6.8**
Week 16 (n=244,245,18,108,103) almost clear	**37.7**	**30.6**	**16.7**	**0.0**	**24.3**
Week 16 (n=244,245,18,108,103) mild	**26.6**	**15.9**	**27.8**	**7.4**	**39.8**
Week 16 (n=244,245,18,108,103) moderate	**10.7**	**5.3**	**22.2**	**57.4**	**26.2**
Week 16 (n=244,245,18,108,103) severe	**1.2**	**0.8**	**11.1**	**35.2**	**2.9**
Week 20 (n=244,245,18,108,103) clear	**23.8**	**46.1**	**16.7**	**0.0**	**26.2**
Week 20 (n=244,245,18,108,103) almost clear	**37.3**	**31.8**	**22.2**	**1.0**	**31.1**
Week 20 (n=244,245,18,108,103) mild	**26.2**	**14.3**	**33.3**	**15.5**	**32.0**
Week 20 (n=244,245,18,108,103) moderate	**11.5**	**7.3**	**16.7**	**61.2**	**10.7**
Week 20 (n=244,245,18,108,103) severe	**1.2**	**0.4**	**11.1**	**22.3**	**0.0**
Week 24 (n=244,245,18,108,103) clear	**27.0**	**46.5**	**16.7**	**0.0**	**32.0**
Week 24 (n=244,245,18,108,103) almost clear	**35.7**	**29.0**	**33.3**	**4.6**	**41.7**
Week 24 (n=244,245,18,108,103) mild	**24.6**	**15.1**	**22.2**	**30.6**	**20.4**
Week 24 (n=244,245,18,108,103) moderate	**10.7**	**7.8**	**16.7**	**56.5**	**5.8**
Week 24 (n=244,245,18,108,103) severe	**2.0**	**1.6**	**11.1**	**8.3**	**0.0**
Week 28 (n=244,245,18,108,103) clear	**26.6**	**46.5**	**11.1**	**0.0**	**38.8**
Week 28 (n=244,245,18,108,103) almost clear	**32.8**	**26.5**	**38.9**	**13.9**	**40.8**
Week 28 (n=244,245,18,108,103) mild	**25.8**	**16.7**	**16.7**	**38.9**	**14.6**
Week 28 (n=244,245,18,108,103) moderate	**12.7**	**9.4**	**27.8**	**42.6**	**5.8**
Week 28 (n=244,245,18,108,103) severe	**2.0**	**0.8**	**5.6**	**4.6**	**0.0**
Week 32 (n=244,245,18,108,103) clear	**26.2**	**46.5**	**16.7**	**29.6**	**42.7**
Week 32 (n=244,245,18,108,103) almost clear	**30.3**	**26.5**	**27.8**	**30.6**	**35.9**

Week 32 (n=244,245,18,108,103) mild	**27.0**	**16.7**	**27.8**	**22.2**	**13.6**
Week 32 (n=244,245,18,108,103) moderate	**14.3**	**9.0**	**22.2**	**14.8**	**7.8**
Week 32 (n=244,245,18,108,103) severe	**2.0**	**1.2**	**5.6**	**2.8**	**0.0**
Week 36 (n=244,245,18,108,103) clear	**28.3**	**46.5**	**11.1**	**28.7**	**45.6**
Week 36 (n=244,245,18,108,103) almost clear	**27.0**	**26.9**	**27.8**	**33.3**	**29.1**
Week 36 (n=244,245,18,108,103) mild	**25.4**	**16.7**	**33.3**	**18.5**	**16.5**
Week 36 (n=244,245,18,108,103) moderate	**16.8**	**8.2**	**16.7**	**16.7**	**8.7**
Week 36 (n=244,245,18,108,103) severe	**2.5**	**1.6**	**11.1**	**2.8**	**0.0**
Week 40 (n=244,245,18,108,103) clear	**28.7**	**46.1**	**22.2**	**25.9**	**44.7**
Week 40 (n=244,245,18,108,103) almost clear	**25.8**	**25.3**	**22.2**	**34.3**	**31.1**
Week 40 (n=244,245,18,108,103) mild	**25.0**	**17.1**	**27.8**	**21.3**	**11.7**
Week 40 (n=244,245,18,108,103) moderate	**18.4**	**10.2**	**16.7**	**15.7**	**11.7**
Week 40 (n=244,245,18,108,103) severe	**2.0**	**1.2**	**11.1**	**2.8**	**1.0**
Week 44 (n=244,245,18,108,103) clear	**27.5**	**42.9**	**5.6**	**25.9**	**40.8**
Week 44 (n=244,245,18,108,103) almost clear	**25.0**	**24.1**	**38.9**	**33.3**	**36.9**
Week 44 (n=244,245,18,108,103) mild	**25.4**	**20.4**	**22.2**	**20.4**	**8.7**
Week 44 (n=244,245,18,108,103) moderate	**20.1**	**11.8**	**27.8**	**17.6**	**11.7**
Week 44 (n=244,245,18,108,103) severe	**2.0**	**0.8**	**5.6**	**2.8**	**1.9**
Week 48 (n=244,245,18,108,103) clear	**27.0**	**44.5**	**11.1**	**25.9**	**43.7**
Week 48 (n=244,245,18,108,103) almost clear	**22.1**	**25.3**	**16.7**	**28.7**	**34.0**
Week 48 (n=244,245,18,108,103) mild	**27.9**	**16.3**	**50.0**	**27.8**	**9.7**
Week 48 (n=244,245,18,108,103) moderate	**20.1**	**12.7**	**16.7**	**14.8**	**11.7**
Week 48 (n=244,245,18,108,103) severe	**2.9**	**1.2**	**5.6**	**2.8**	**1.0**
Week 52 (n=244,245,18,108,103) clear	**25.8**	**43.3**	**11.1**	**21.3**	**44.7**
Week 52 (n=244,245,18,108,103) almost clear	**24.2**	**24.1**	**27.8**	**31.5**	**29.1**
Week 52 (n=244,245,18,108,103) mild	**29.1**	**19.6**	**27.8**	**28.7**	**12.6**
Week 52 (n=244,245,18,108,103) moderate	**16.0**	**11.4**	**27.8**	**15.7**	**11.7**
Week 52 (n=244,245,18,108,103) severe	**4.9**	**1.6**	**5.6**	**2.8**	**1.9**

No statistical analysis provided for Percentage of Participants in Each IGA Mod 2011 Score Category Maintenance Period After Week 12 to Week 52

13. Secondary: Time to PASI 75 Response up to 12 Weeks [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Time to PASI 75 Response up to 12 Weeks
Measure Description	PASI is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (max). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 75 was defined as participants achieving ≥ 75% improvement from baseline.
Time Frame	Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**245**	**245**	**247**
Time to PASI 75 Response up to 12 Weeks [units: days] Median (Inter-Quartile Range)	**57 (55 to 85)**	**57 (29 to 59)**	**NA [1]**

[1] median could not be calculated because less than 50% of the participants achieved PASI 75

No statistical analysis provided for Time to PASI 75 Response up to 12 Weeks

14. Secondary: Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100) Induction Period [Time Frame: Baseline, Week 4,8, 12]

Measure Type	Secondary
Measure Title	Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100) Induction Period
Measure Description	The EQ-5D is an instrument used to assess a participant's health status. The instrument includes a descriptive profile and a visual analog scale (VAS). The descriptive profile includes 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension had 3 response levels: no problems, some problems and severe problems. The VAS is a vertical scale that assesses the health status from 0 (worst possible health state) to 100 (best possible health state). This outcome measures the percent change in VAS score. Positive mean percent changes indicate improvement.
Time Frame	Baseline, Week 4,8, 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457	AIN457	Placebo

	150 mg	300 mg	
Number of Participants Analyzed [units: participants]	**245**	**245**	**247**
Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100) Induction Period [units: percent change] Mean (Standard Deviation)			
Week 4 (238, 236,235)	**38.1 (95.93)**	**57.1 (234.10)**	**6.3 (59.30)**
Week 8 (241, 242,241)	**52.3 (142.28)**	**72.7 (306.36)**	**6.3 (65.47)**
Week 12 (242, 242,242)	**58.5 (158.66)**	**76.3 (281.48)**	**5.4 (67.60)**

No statistical analysis provided for Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100) Induction Period

15. Secondary: Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100) Maintenance Period [Time Frame: Week 12, 24, 36, 52]

Measure Type	Secondary
Measure Title	Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100) Maintenance Period
Measure Description	The EQ-5D is an instrument used to assess a participant's health status. The instrument includes a descriptive profile and a visual analog scale (VAS). The descriptive profile includes 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension had 3 response levels: no problems, some problems and severe problems. The VAS is a vertical scale that assesses the health status from 0 (worst possible health state) to 100 (best possible health state). This outcome measures the percent change in VAS score. Positive mean percent changes indicate improvement.
Time Frame	Week 12, 24, 36, 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 150mg From Placebo	Patients randomized to AIN457 150mg in Maintenance phase when they were on Placebo in Induction Phase because they were PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 300mg From Placebo	Patients randomized to AIN457 300mg in Maintenance phase when they were on Placebo in Induction Phase. PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457	AIN457		AIN457	AIN457

	150 mg	300 mg	Placebo	150mg From Placebo	300mg From Placebo
Number of Participants Analyzed [units: participants]	**245**	**245**	**18**	**108**	**105**
Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100) Maintenance Period [units: Percent Change] Mean (Standard Deviation)					
Week 12 (242, 242,18, 108, 104)	**58.5 (158.66)**	**76.3 (281.48)**	**37.7 (83.41)**	**-0.1 (38.95)**	**3.3 (79.45)**
Week 24 (242, 242,18, 108, 97)	**55.8 (140.46)**	**78.0 (299.91)**	**48.1 (92.06)**	**28.1 (55.71)**	**39.7 (80.03)**
Week 36 (242, 242,18, 108, 100)	**55.1 (129.87)**	**80.5 (300.89)**	**45.3 (77.11)**	**28.5 (60.39)**	**43.8 (100.57)**
Week 52 (242, 242,18, 108,100)	**54.3 (128.86)**	**76.9 (299.07)**	**43.9 (81.50)**	**28.3 (60.68)**	**41.3 (95.90)**

No statistical analysis provided for Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100) Maintenance Period

16. Secondary: Percentage Changes in the Dermatology Life Quality Index (DLQI) During Induction Period [Time Frame: Baseline, Week 4, 8 & 12]

Measure Type	Secondary
Measure Title	Percentage Changes in the Dermatology Life Quality Index (DLQI) During Induction Period
Measure Description	The DLQI is a ten item general dermatology disability index designed to assess health-related quality of life in adult participants with skin diseases such as eczema, psoriasis, acne and viral worts. It is a self-administered questionnaire which includes domains of daily activity, leisure, personal relationships, symptoms and feelings, treatment and school/work activities. Each domain has 4 response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" is a valid score also and is scored as 0. The DLQI total score is a sum of all 10 responses. Scores range from 0 to 30 with higher scores indicating greater health-related quality of life impairment. A negative mean percentage change from baseline indicates improvement.
Time Frame	Baseline, Week 4, 8 & 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	AIN457 300 mg	Placebo
Number of Participants Analyzed [units: participants]	**245**	**245**	**247**

Percentage Changes in the Dermatology Life Quality Index (DLQI) During Induction Period [units: Percent Change] Median (95% Confidence Interval)			
Week 4 (n=237,236,232)	**-55.0 (-58.9 to -50.7)**	**-62.5 (-66.7 to -58.6)**	**-5.0 (-10.1 to 0.0)**
Week 8 (n=241,242,239)	**-73.1 (-76.7 to -69.2)**	**-81.5 (-84.4 to -79.0)**	**-8.3 (-13.3 to -2.6)**
Week 12 (n=242,242,240)	**-77.8 (-81.3 to -75.0)**	**-86.4 (-88.9 to -83.3)**	**-9.1 (-15.6 to -3.3)**

No statistical analysis provided for Percentage Changes in the Dermatology Life Quality Index (DLQI) During Induction Period

17. Secondary: Percentage Changes in the Dermatology Life Quality Index (DLQI) During Maintenance Period [Time Frame: Week 12,24, 36 & 52]

Measure Type	Secondary
Measure Title	Percentage Changes in the Dermatology Life Quality Index (DLQI) During Maintenance Period
Measure Description	The DLQI is a ten item general dermatology disability index designed to assess health-related quality of life in adult participants with skin diseases such as eczema, psoriasis, acne and viral worts. It is a self-administered questionnaire which includes domains of daily activity, leisure, personal relationships, symptoms and feelings, treatment and school/work activities. Each domain has 4 response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" is a valid score also and is scored as 0. The DLQI total score is a sum of all 10 responses. Scores range from 0 to 30 with higher scores indicating greater health-related quality of life impairment. A negative mean percentage change from baseline indicates improvement.
Time Frame	Week 12,24, 36 & 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 150mg From Placebo	Patients randomized to AIN457 150mg in Maintenance phase when they were on Placebo in Induction Phase because they were PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 300mg From Placebo	Patients randomized to AIN457 300mg in Maintenance phase when they were on Placebo in Induction Phase. PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	**AIN457 300 mg**	**Placebo**	**AIN457 150mg From Placebo**	**AIN457 300mg From Placebo**
Number of Participants Analyzed [units: participants]	**245**	**245**	**18**	**108**	**105**
Percentage Changes in the Dermatology Life Quality Index (DLQI) During Maintenance Period [units: Percent Change]					

Median (95% Confidence Interval)					
Week 12 (242,242,17,108,104)	**-77.8 (-81.3 to -75.0)**	**-86.4 (-88.9 to -83.3)**	**-58.3 (-80.0 to -41.7)**	**-7.1 (-16.7 to 3.4)**	**-4.4 (-13.9 to 3.4)**
Week 24 (242,242,17,108,97)	**-83.3 (-87.5 to -79.4)**	**-89.6 (-92.5 to -86.0)**	**-76.6 (-88.9 to -59.6)**	**-83.3 (-87.5 to -76.7)**	**-83.3 (-89.9 to -76.6)**
Week 36 (242,242,17,108,100)	**-78.6 (-83.3 to -75.0)**	**-91.7 (-94.2 to -88.9)**	**-77.9 (-93.3 to -47.2)**	**-78.5 (-85.7 to -66.7)**	**-90.0 (-93.3 to -82.7)**
Week 52 (242,242,17,108,100)	**-76.5 (-80.6 to -72.3)**	**-88.9 (-92.3 to -85.7)**	**-64.4 (-83.3 to -12.5)**	**-75.0 (-82.8 to -66.2)**	**-88.9 (-92.9 to -82.9)**

No statistical analysis provided for Percentage Changes in the Dermatology Life Quality Index (DLQI) During Maintenance Period

18. Secondary: Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 During Induction Period [Time Frame: Week 4, 8, 12]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 During Induction Period
Measure Description	The DLQI is a ten item general dermatology disability index designed to assess health-related quality of life in adult participants with skin diseases such as eczema, psoriasis, acne and viral worts. It is a self-administered questionnaire which includes domains of daily activity, leisure, personal relationships, symptoms and feelings, treatment and school/work activities. Each domain has 4 response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" is a valid score also and is scored as 0. The DLQI total score is a sum of all 10 responses. Scores range from 0 to 30 with higher scores indicating greater health-related quality of life impairment. A negative mean percentage change from baseline indicates improvement.
Time Frame	Week 4, 8, 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	**AIN457 300 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**245**	**245**	**247**
Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 During Induction Period [units: Percentage of Participants]			

Week 4 (238, 237, 235)	**17.6**	**23.6**	**6.4**
Week 8 (242,243,241)	**39.7**	**48.1**	**10.0**
Week 12 (243,243,243)	**46.1**	**58.8**	**10.3**

No statistical analysis provided for Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 During Induction Period

19. Secondary: Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 During Maintenance Period [Time Frame: Week 12,24,36, & 52]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 During Maintenance Period
Measure Description	The DLQI is a ten item general dermatology disability index designed to assess health-related quality of life in adult participants with skin diseases such as eczema, psoriasis, acne and viral worts. It is a self-administered questionnaire which includes domains of daily activity, leisure, personal relationships, symptoms and feelings, treatment and school/work activities. Each domain has 4 response categories ranging from 0 (not at all) to 3 (very much). "Not relevant" is a valid score also and is scored as 0. The DLQI total score is a sum of all 10 responses. Scores range from 0 to 30 with higher scores indicating greater health-related quality of life impairment. A negative mean percentage change from baseline indicates improvement.
Time Frame	Week 12,24,36, & 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 150mg From Placebo	Patients randomized to AIN457 150mg in Maintenance phase when they were on Placebo in Induction Phase because they were PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.
AIN457 300mg From Placebo	Patients randomized to AIN457 300mg in Maintenance phase when they were on Placebo in Induction Phase. PASI 75 non-responders and received their treatment on Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	**AIN457 300 mg**	**Placebo**	**AIN457 150mg From Placebo**	**AIN457 300mg From Placebo**
Number of Participants Analyzed [units: participants]	**245**	**245**	**18**	**108**	**105**
Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 During Maintenance Period [units: Percentage of Participants]					
Week 12 (243,243,18,108,105)	**46.1**	**58.8**	**27.8**	**10.2**	**8.6**
Week 24 (243,243,18,108,98)	**54.7**	**64.6**	**50.0**	**53.7**	**67.3**
Week 36 (243,243,18,108,101)	**51.9**	**68.7**	**50.0**	**56.5**	**69.3**

Week 52 (243,243,18,108,101)	**48.6**	**66.3**	**22.2**	**52.8**	**67.3**

No statistical analysis provided for Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 During Maintenance Period

20. Secondary: Percentage of Participants Achieving PASI 75, PASI 90 and IGA Mod 2011 0 or 1 Response at Week 12 by Previous Exposure to Biologic Systemic Therapy or Anti-TNF-α Therapy and Failed to Respond to a Previous Biologic or Anti-TNF-α Therapy Psoriasis Therapy [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving PASI 75, PASI 90 and IGA Mod 2011 0 or 1 Response at Week 12 by Previous Exposure to Biologic Systemic Therapy or Anti-TNF-α Therapy and Failed to Respond to a Previous Biologic or Anti-TNF-α Therapy Psoriasis Therapy
Measure Description	PASI is an assessment of lesion severity & affected area into a single score:0(no disease)to 72(max. disease).Body is divided into 4 areas for scoring(head,arms,trunk,legs)each area is scored separately & then added for final PASI.For each area, % of skin involved is estimated:0(0%)to 6(90-100%)& severity is estimated by clinical signs, erythema,induration & desquamation;scale 0(none) to 4(max). Final PASI=sum of severity parameters for each area* area score weight of section(head:0.1,arms:0.2 body:0.3 legs:0.4).PASI 75, 90 is patients achieving≥75%or90% improvement from baseline.The IGA mod 2011 scale is static, exclusively to the patients disease at assessment,& not with any of the patient's previous disease states at other visits.The scores are:0=clear,1=almost clear,2= mild,3=moderate&4=severe.Response variables PASI 75,90, IGA mod 2011 0 or 1 response at wk 12 was scored versus previous psoriasis systemic therapy & response to previous biologic systemic therapy by treatment
Time Frame	Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	**AIN457 300 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**245**	**245**	**247**
Percentage of Participants Achieving PASI 75, PASI 90 and IGA Mod 2011 0 or 1 Response at Week 12 by Previous Exposure to Biologic Systemic Therapy or Anti-TNF-α Therapy and Failed to Respond to a Previous Biologic or Anti-TNF-α Therapy Psoriasis Therapy [units: Percentage of participants]			
IGA 0/1 biologic (29, 19, 24)	**41.4**	**57.9**	**4.2**
PASI 75 biologic (29, 19, 24)	**48.3**	**57.9**	**12.5**
PASI 90 biologic (29, 19, 24)	**24.1**	**31.6**	**4.2**
IGA 0/1 anti-TNF-α therapy (18,17,21)	**50.0**	**64.7**	**4.8**
PASI 75 anti-TNF-α therapy (18,17,21)	**55.6**	**64.7**	**14.3**

PASI 90 anti-TNF-α therapy (18,17,21)	**33.3**	**35.3**	**4.8**

No statistical analysis provided for Percentage of Participants Achieving PASI 75, PASI 90 and IGA Mod 2011 0 or 1 Response at Week 12 by Previous Exposure to Biologic Systemic Therapy or Anti-TNF-α Therapy and Failed to Respond to a Previous Biologic or Anti-TNF-α Therapy Psoriasis Therapy

21. Secondary: Number of Participants Who Developed Anti-secukinumab Antibodies [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Number of Participants Who Developed Anti-secukinumab Antibodies
Measure Description	The development of anti-secunimubab anti-bodies would decrease a participant's ability to respond to secukinumab treatment.
Time Frame	Week 12
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Full analysis set (FAS): The FAS was comprised of all patients to whom study treatment had been assigned. Following the intent-to-treat principle, patients were analyzed according to the treatment assigned to at randomization. If the actual stratum was different to the assigned stratum in IRT, the actual stratum was used in analyses.

Reporting Groups

	Description
AIN457 150 mg	AIN457 secukinumab 150 mg subcutaneous (s.c.) injection plus a placebo secukinumab s.c. injection once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4 and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
AIN457 300 mg	AIN457 secukinumab 300 mg (two s.c. injections of 150 mg) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks, starting at Week 4, and until Week 48, except for Weeks 13, 14, and 15 when they received two s.c. injections of placebo per week
Placebo	placebo secukinumab (two s.c. injections per dose) once weekly for 4 weeks (at randomization, Weeks 1, 2, and 3), followed by dosing every 4 weeks (Weeks 4 and 8). Prior to receiving the Week 12 dose, all patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response at Week 12. PASI 75 responders: continued on placebo and received their placebo injections at Weeks 12, 13, 14, 15, and then every 4 weeks starting at Week 16 until Week 48.

Measured Values

	AIN457 150 mg	**AIN457 300 mg**	**Placebo**
Number of Participants Analyzed [units: participants]	**245**	**245**	**247**
Number of Participants Who Developed Anti-secukinumab Antibodies [units: participants]	**2**	**0**	**0**

No statistical analysis provided for Number of Participants Who Developed Anti-secukinumab Antibodies

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
INDUCTION-AIN457 150mg	INDUCTION-AIN457 150mg
INDUCTION-AIN457 300mg	INDUCTION-AIN457 300mg
INDUCTION-Placebo	INDUCTION-Placebo
ENTIRE-AIN457 150mg	ENTIRE-AIN457 150mg
ENTIRE-AIN457 300mg	ENTIRE-AIN457 300mg

ENTIRE-Any AIN457 150mg	ENTIRE-Any AIN457 150mg
ENTIRE-Any AIN457 300mg	ENTIRE-Any AIN457 300mg
ENTIRE-Placebo	ENTIRE-Placebo
FOLLOW UP-Any AIN457 150mg	FOLLOW UP-Any AIN457 150mg
FOLLOW UP-Any AIN457 300mg	FOLLOW UP-Any AIN457 300mg
FOLLOW UP-Placebo	FOLLOW UP-Placebo

Serious Adverse Events

	INDUCTION-AIN457 150mg	INDUCTION-AIN457 300mg	INDUCTION-Placebo	ENTIRE-AIN457 150mg	ENTIRE-AIN457 300mg	ENTIRE-Any AIN457 150mg	ENTIRE-Any AIN457 300mg	ENTIRE-Placebo	FO UP AI 150
Total, serious adverse events									
# participants affected / at risk	**4/245 (1.63%)**	**6/245 (2.45%)**	**4/247 (1.62%)**	**15/245 (6.12%)**	**17/245 (6.94%)**	**19/353 (5.38%)**	**19/349 (5.44%)**	**5/247 (2.02%)**	**1/58 (**
Blood and lymphatic system disorders									
HAEMORRHAGIC ANAEMIA † 1									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
LYMPHADENOPATHY † 1									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
Cardiac disorders									
ANGINA UNSTABLE † 1									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**1/245 (0.41%)**	**1/353 (0.28%)**	**1/349 (0.29%)**	**0/247 (0.00%)**	**0/58**
ARRHYTHMIA † 1									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
CARDIAC FAILURE † 1									
# participants affected / at risk	**1/245 (0.41%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**1/245 (0.41%)**	**1/353 (0.28%)**	**1/349 (0.29%)**	**0/247 (0.00%)**	**0/58**
CORONARY ARTERY DISEASE † 1									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**1/245 (0.41%)**	**1/353 (0.28%)**	**1/349 (0.29%)**	**0/247 (0.00%)**	**0/58**
MYOCARDIAL INFARCTION † 1									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**0/245 (0.00%)**	**1/245 (0.41%)**	**0/353 (0.00%)**	**1/349 (0.29%)**	**0/247 (0.00%)**	**0/58**
Ear and labyrinth disorders									
SUDDEN HEARING LOSS † 1									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**0/245 (0.00%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
Gastrointestinal disorders									
ABDOMINAL HERNIA OBSTRUCTIVE † 1									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
COLITIS									

ULCERATIVE † [1]									
# participants affected / at risk	0/245 (0.00%)	1/245 (0.41%)	0/247 (0.00%)	1/245 (0.41%)	1/245 (0.41%)	1/353 (0.28%)	1/349 (0.29%)	0/247 (0.00%)	0/58
GASTRITIS † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
INTESTINAL HAEMORRHAGE † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
PANCREATITIS † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
General disorders									
ASTHENIA † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
HERNIA † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
NON-CARDIAC CHEST PAIN † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	1/247 (0.40%)	0/245 (0.00%)	0/245 (0.00%)	0/353 (0.00%)	0/349 (0.00%)	1/247 (0.40%)	1/58
Hepatobiliary disorders									
CHOLECYSTITIS † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
CHOLELITHIASIS † [1]									
# participants affected / at risk	0/245 (0.00%)	1/245 (0.41%)	0/247 (0.00%)	1/245 (0.41%)	1/245 (0.41%)	1/353 (0.28%)	1/349 (0.29%)	0/247 (0.00%)	0/58
Infections and infestations									
BACTERAEMIA † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
CELLULITIS † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	1/247 (0.40%)	0/245 (0.00%)	0/245 (0.00%)	0/353 (0.00%)	0/349 (0.00%)	1/247 (0.40%)	0/58
GASTROENTERITIS † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
PNEUMONIA † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	2/245 (0.82%)	0/353 (0.00%)	2/349 (0.57%)	0/247 (0.00%)	0/58
PYELONEPHRITIS † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
UROSEPSIS † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	1/349 (0.29%)	0/247 (0.00%)	0/58
Injury, poisoning and procedural complications									
COMMINUTED FRACTURE † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58

CONCUSSION † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
CONTUSION † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
LARYNGEAL INJURY † [1]									
# participants affected / at risk	0/245 (0.00%)	1/245 (0.41%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
MULTIPLE INJURIES † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
PELVIC FRACTURE † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
PULMONARY CONTUSION † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
RADIUS FRACTURE † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
RIB FRACTURE † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
TOXICITY TO VARIOUS AGENTS † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
WOUND † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
Metabolism and nutrition disorders									
ELECTROLYTE IMBALANCE † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
HYPOALBUMINAEMIA † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
HYPOPROTEINAEMIA † [1]									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
TYPE 2 DIABETES MELLITUS † [1]									
# participants affected / at risk	1/245 (0.41%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
Musculoskeletal and connective tissue disorders									
BURSITIS † [1]									
# participants affected / at risk	0/245 (0.00%)	1/245 (0.41%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
Neoplasms benign,									

malignant and unspecified (incl cysts and polyps)									
BASAL CELL CARCINOMA † [1]									
# participants affected / at risk	**1/245 (0.41%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
BENIGN NEOPLASM OF SKIN † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/353 (0.00%)**	**0/349 (0.00%)**	**1/247 (0.40%)**	**0/58**
BLADDER CANCER † [1]									
# participants affected / at risk	**1/245 (0.41%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
FOLLICULAR THYROID CANCER † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
THYROID CANCER † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
UTERINE LEIOMYOMA † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**1/245 (0.41%)**	**0/247 (0.00%)**	**0/245 (0.00%)**	**1/245 (0.41%)**	**0/353 (0.00%)**	**1/349 (0.29%)**	**0/247 (0.00%)**	**0/58**
Nervous system disorders									
CAROTID ARTERY DISSECTION † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/353 (0.00%)**	**1/349 (0.29%)**	**0/247 (0.00%)**	**0/58**
CEREBROVASCULAR ACCIDENT † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/353 (0.00%)**	**1/349 (0.29%)**	**0/247 (0.00%)**	**0/58**
HEADACHE † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**0/245 (0.00%)**	**1/245 (0.41%)**	**0/353 (0.00%)**	**1/349 (0.29%)**	**0/247 (0.00%)**	**0/58**
ISCHAEMIC STROKE † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
SYNCOPE † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
Psychiatric disorders									
ALCOHOL WITHDRAWAL SYNDROME † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**1/247 (0.40%)**	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/353 (0.00%)**	**0/349 (0.00%)**	**1/247 (0.40%)**	**0/58**
HALLUCINATION, AUDITORY † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**0/245 (0.00%)**	**0/245 (0.00%)**	**1/353 (0.28%)**	**0/349 (0.00%)**	**0/247 (0.00%)**	**0/58**
MENTAL STATUS CHANGES † [1]									
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**1/245 (0.41%)**	**1/245 (0.41%)**	**1/353 (0.28%)**	**1/349 (0.29%)**	**0/247 (0.00%)**	**0/58**
PANIC ATTACK † [1]									

# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	1/247 (0.40%)	0/245 (0.00%)	0/245 (0.00%)	0/353 (0.00%)	0/349 (0.00%)	1/247 (0.40%)	0/58
Renal and urinary disorders									
NEPHROLITHIASIS † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
OBSTRUCTIVE UROPATHY † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
RENAL FAILURE ACUTE † 1									
# participants affected / at risk	0/245 (0.00%)	1/245 (0.41%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
Respiratory, thoracic and mediastinal disorders									
PNEUMOTHORAX † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
PULMONARY MASS † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
PULMONARY OEDEMA † 1									
# participants affected / at risk	1/245 (0.41%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
Skin and subcutaneous tissue disorders									
PSORIASIS † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	1/247 (0.40%)	0/245 (0.00%)	0/245 (0.00%)	0/353 (0.00%)	0/349 (0.00%)	1/247 (0.40%)	0/58
Surgical and medical procedures									
ABORTION INDUCED † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	0/245 (0.00%)	0/353 (0.00%)	0/349 (0.00%)	0/247 (0.00%)	0/58
Vascular disorders									
AORTIC ANEURYSM † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
AORTIC THROMBOSIS † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)	0/247 (0.00%)	0/58
HYPERTENSION † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58
HYPERTENSIVE CRISIS † 1									
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)	0/247 (0.00%)	0/58

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 16.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	2%

Reporting Groups

	Description
INDUCTION-AIN457 150mg	INDUCTION-AIN457 150mg
INDUCTION-AIN457 300mg	INDUCTION-AIN457 300mg
INDUCTION-Placebo	INDUCTION-Placebo
ENTIRE-AIN457 150mg	ENTIRE-AIN457 150mg
ENTIRE-AIN457 300mg	ENTIRE-AIN457 300mg
ENTIRE-Any AIN457 150mg	ENTIRE-Any AIN457 150mg
ENTIRE-Any AIN457 300mg	ENTIRE-Any AIN457 300mg
ENTIRE-Placebo	ENTIRE-Placebo
FOLLOW UP-Any AIN457 150mg	FOLLOW UP-Any AIN457 150mg
FOLLOW UP-Any AIN457 300mg	FOLLOW UP-Any AIN457 300mg
FOLLOW UP-Placebo	FOLLOW UP-Placebo

Other Adverse Events

	INDUCTION-AIN457 150mg	INDUCTION-AIN457 300mg	INDUCTION-Placebo	ENTIRE-AIN457 150mg	ENTIRE-AIN457 300mg	ENTIRE-Any AIN457 150mg	ENTIRE-Any AIN457 300mg
Total, other (not including serious) adverse events							
# participants affected / at risk	**108/245 (44.08%)**	**102/245 (41.63%)**	**77/247 (31.17%)**	**172/245 (70.20%)**	**161/245 (65.71%)**	**228/353 (64.59%)**	**229/349 (65.62%)**
Blood and lymphatic system disorders							
LYMPHADENOPATHY † 1							
# participants affected / at risk	**2/245 (0.82%)**	**3/245 (1.22%)**	**0/247 (0.00%)**	**6/245 (2.45%)**	**3/245 (1.22%)**	**6/353 (1.70%)**	**3/349 (0.86%)**
Cardiac disorders							
SUPRAVENTRICULAR TACHYCARDIA † 1							
# participants affected / at risk	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/247 (0.00%)**	**0/245 (0.00%)**	**0/245 (0.00%)**	**0/353 (0.00%)**	**0/349 (0.00%)**
Gastrointestinal disorders							
CONSTIPATION † 1							
# participants affected / at risk	**1/245 (0.41%)**	**1/245 (0.41%)**	**1/247 (0.40%)**	**4/245 (1.63%)**	**5/245 (2.04%)**	**4/353 (1.13%)**	**5/349 (1.43%)**
DIARRHOEA † 1							
# participants affected / at risk	**4/245 (1.63%)**	**5/245 (2.04%)**	**3/247 (1.21%)**	**9/245 (3.67%)**	**11/245 (4.49%)**	**10/353 (2.83%)**	**16/349 (4.58%)**
DYSPEPSIA † 1							
# participants affected / at risk	**1/245 (0.41%)**	**1/245 (0.41%)**	**0/247 (0.00%)**	**6/245 (2.45%)**	**2/245 (0.82%)**	**6/353 (1.70%)**	**4/349 (1.15%)**
GASTROOESOPHAGEAL REFLUX DISEASE † 1							

# participants affected / at risk	0/245 (0.00%)	3/245 (1.22%)	0/247 (0.00%)	1/245 (0.41%)	5/245 (2.04%)	3/353 (0.85%)	5/349 (1.43%)
NAUSEA † 1							
# participants affected / at risk	6/245 (2.45%)	1/245 (0.41%)	6/247 (2.43%)	7/245 (2.86%)	2/245 (0.82%)	8/353 (2.27%)	3/349 (0.86%)
TOOTHACHE † 1							
# participants affected / at risk	3/245 (1.22%)	2/245 (0.82%)	2/247 (0.81%)	8/245 (3.27%)	4/245 (1.63%)	8/353 (2.27%)	5/349 (1.43%)
VOMITING † 1							
# participants affected / at risk	2/245 (0.82%)	5/245 (2.04%)	2/247 (0.81%)	3/245 (1.22%)	6/245 (2.45%)	4/353 (1.13%)	7/349 (2.01%)
General disorders							
FATIGUE † 1							
# participants affected / at risk	8/245 (3.27%)	2/245 (0.82%)	2/247 (0.81%)	9/245 (3.67%)	3/245 (1.22%)	10/353 (2.83%)	3/349 (0.86%)
INFLUENZA LIKE ILLNESS † 1							
# participants affected / at risk	3/245 (1.22%)	5/245 (2.04%)	3/247 (1.21%)	15/245 (6.12%)	11/245 (4.49%)	17/353 (4.82%)	14/349 (4.01%)
Infections and infestations							
ABSCESS LIMB † 1							
# participants affected / at risk	1/245 (0.41%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	0/349 (0.00%)
BRONCHITIS † 1							
# participants affected / at risk	2/245 (0.82%)	3/245 (1.22%)	1/247 (0.40%)	7/245 (2.86%)	11/245 (4.49%)	8/353 (2.27%)	17/349 (4.87%)
FOLLICULITIS † 1							
# participants affected / at risk	4/245 (1.63%)	2/245 (0.82%)	2/247 (0.81%)	10/245 (4.08%)	6/245 (2.45%)	12/353 (3.40%)	9/349 (2.58%)
FURUNCLE † 1							
# participants affected / at risk	1/245 (0.41%)	2/245 (0.82%)	0/247 (0.00%)	5/245 (2.04%)	4/245 (1.63%)	5/353 (1.42%)	4/349 (1.15%)
GASTROENTERITIS † 1							
# participants affected / at risk	1/245 (0.41%)	2/245 (0.82%)	1/247 (0.40%)	6/245 (2.45%)	4/245 (1.63%)	7/353 (1.98%)	7/349 (2.01%)
INFLUENZA † 1							
# participants affected / at risk	4/245 (1.63%)	1/245 (0.41%)	2/247 (0.81%)	8/245 (3.27%)	7/245 (2.86%)	8/353 (2.27%)	10/349 (2.87%)
NASOPHARYNGITIS † 1							
# participants affected / at risk	23/245 (9.39%)	22/245 (8.98%)	19/247 (7.69%)	53/245 (21.63%)	45/245 (18.37%)	69/353 (19.55%)	57/349 (16.33%)
ORAL HERPES † 1							
# participants affected / at risk	0/245 (0.00%)	3/245 (1.22%)	2/247 (0.81%)	4/245 (1.63%)	6/245 (2.45%)	6/353 (1.70%)	8/349 (2.29%)
OTITIS MEDIA † 1							
# participants affected / at risk	0/245 (0.00%)	3/245 (1.22%)	1/247 (0.40%)	1/245 (0.41%)	6/245 (2.45%)	2/353 (0.57%)	6/349 (1.72%)
PERIODONTITIS † 1							
# participants affected / at risk	2/245 (0.82%)	1/245 (0.41%)	1/247 (0.40%)	3/245 (1.22%)	5/245 (2.04%)	3/353 (0.85%)	7/349 (2.01%)
PHARYNGITIS † 1							
# participants affected / at risk	2/245 (0.82%)	3/245 (1.22%)	0/247 (0.00%)	8/245 (3.27%)	7/245 (2.86%)	9/353 (2.55%)	9/349 (2.58%)
RHINITIS † 1							
# participants affected / at risk	2/245 (0.82%)	2/245 (0.82%)	1/247 (0.40%)	3/245 (1.22%)	6/245 (2.45%)	4/353 (1.13%)	7/349 (2.01%)
TINEA PEDIS † 1							
# participants affected /	2/245 (0.82%)	2/245 (0.82%)	0/247 (0.00%)	4/245 (1.63%)	6/245 (2.45%)	8/353 (2.27%)	10/349 (2.87%)

at risk							
UPPER RESPIRATORY TRACT INFECTION † [1]							
# participants affected / at risk	10/245 (4.08%)	9/245 (3.67%)	0/247 (0.00%)	28/245 (11.43%)	26/245 (10.61%)	36/353 (10.20%)	32/349 (9.17%)
VIRAL UPPER RESPIRATORY TRACT INFECTION † [1]							
# participants affected / at risk	2/245 (0.82%)	4/245 (1.63%)	2/247 (0.81%)	6/245 (2.45%)	8/245 (3.27%)	7/353 (1.98%)	11/349 (3.15%)
VULVOVAGINAL MYCOTIC INFECTION † [1]							
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	0/245 (0.00%)	1/245 (0.41%)	0/353 (0.00%)	1/349 (0.29%)
Injury, poisoning and procedural complications							
CONTUSION † [1]							
# participants affected / at risk	2/245 (0.82%)	5/245 (2.04%)	1/247 (0.40%)	5/245 (2.04%)	5/245 (2.04%)	5/353 (1.42%)	7/349 (2.01%)
EXCORIATION † [1]							
# participants affected / at risk	2/245 (0.82%)	2/245 (0.82%)	0/247 (0.00%)	2/245 (0.82%)	5/245 (2.04%)	3/353 (0.85%)	7/349 (2.01%)
LIGAMENT SPRAIN † [1]							
# participants affected / at risk	1/245 (0.41%)	1/245 (0.41%)	0/247 (0.00%)	2/245 (0.82%)	7/245 (2.86%)	3/353 (0.85%)	8/349 (2.29%)
MUSCLE STRAIN † [1]							
# participants affected / at risk	3/245 (1.22%)	4/245 (1.63%)	0/247 (0.00%)	7/245 (2.86%)	6/245 (2.45%)	8/353 (2.27%)	7/349 (2.01%)
Investigations							
BLOOD CREATININE INCREASED † [1]							
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	1/247 (0.40%)	1/245 (0.41%)	0/245 (0.00%)	1/353 (0.28%)	1/349 (0.29%)
GAMMA-GLUTAMYLTRANSFERASE INCREASED † [1]							
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	5/245 (2.04%)	2/353 (0.57%)	5/349 (1.43%)
Metabolism and nutrition disorders							
HYPERLIPIDAEMIA † [1]							
# participants affected / at risk	1/245 (0.41%)	3/245 (1.22%)	2/247 (0.81%)	8/245 (3.27%)	6/245 (2.45%)	13/353 (3.68%)	9/349 (2.58%)
HYPERTRIGLYCERIDAEMIA † [1]							
# participants affected / at risk	0/245 (0.00%)	1/245 (0.41%)	0/247 (0.00%)	2/245 (0.82%)	5/245 (2.04%)	4/353 (1.13%)	7/349 (2.01%)
Musculoskeletal and connective tissue disorders							
ARTHRALGIA † [1]							
# participants affected / at risk	6/245 (2.45%)	2/245 (0.82%)	7/247 (2.83%)	9/245 (3.67%)	9/245 (3.67%)	13/353 (3.68%)	14/349 (4.01%)
BACK PAIN † [1]							
# participants affected / at risk	3/245 (1.22%)	2/245 (0.82%)	4/247 (1.62%)	7/245 (2.86%)	7/245 (2.86%)	9/353 (2.55%)	9/349 (2.58%)
INTERVERTEBRAL DISC PROTRUSION † [1]							
# participants affected / at risk	0/245 (0.00%)	0/245 (0.00%)	0/247 (0.00%)	1/245 (0.41%)	0/245 (0.00%)	2/353 (0.57%)	0/349 (0.00%)
MYALGIA † [1]							

# participants affected / at risk	1/245 (0.41%)	1/245 (0.41%)	4/247 (1.62%)	4/245 (1.63%)	5/245 (2.04%)	5/353 (1.42%)	5/349 (1.43%)
PAIN IN EXTREMITY † 1							
# participants affected / at risk	3/245 (1.22%)	4/245 (1.63%)	2/247 (0.81%)	6/245 (2.45%)	7/245 (2.86%)	8/353 (2.27%)	8/349 (2.29%)
PSORIATIC ARTHROPATHY † 1							
# participants affected / at risk	1/245 (0.41%)	0/245 (0.00%)	3/247 (1.21%)	4/245 (1.63%)	6/245 (2.45%)	5/353 (1.42%)	7/349 (2.01%)
Nervous system disorders							
HEADACHE † 1							
# participants affected / at risk	13/245 (5.31%)	12/245 (4.90%)	7/247 (2.83%)	19/245 (7.76%)	22/245 (8.98%)	24/353 (6.80%)	30/349 (8.60%)
Psychiatric disorders							
DEPRESSION † 1							
# participants affected / at risk	0/245 (0.00%)	1/245 (0.41%)	0/247 (0.00%)	6/245 (2.45%)	1/245 (0.41%)	8/353 (2.27%)	2/349 (0.57%)
INSOMNIA † 1							
# participants affected / at risk	3/245 (1.22%)	0/245 (0.00%)	0/247 (0.00%)	6/245 (2.45%)	0/245 (0.00%)	10/353 (2.83%)	2/349 (0.57%)
Respiratory, thoracic and mediastinal disorders							
COUGH † 1							
# participants affected / at risk	2/245 (0.82%)	4/245 (1.63%)	3/247 (1.21%)	3/245 (1.22%)	11/245 (4.49%)	5/353 (1.42%)	16/349 (4.58%)
OROPHARYNGEAL PAIN † 1							
# participants affected / at risk	10/245 (4.08%)	4/245 (1.63%)	3/247 (1.21%)	11/245 (4.49%)	7/245 (2.86%)	12/353 (3.40%)	12/349 (3.44%)
RHINITIS ALLERGIC † 1							
# participants affected / at risk	0/245 (0.00%)	3/245 (1.22%)	0/247 (0.00%)	2/245 (0.82%)	5/245 (2.04%)	2/353 (0.57%)	6/349 (1.72%)
Skin and subcutaneous tissue disorders							
DERMATITIS CONTACT † 1							
# participants affected / at risk	0/245 (0.00%)	2/245 (0.82%)	1/247 (0.40%)	1/245 (0.41%)	7/245 (2.86%)	1/353 (0.28%)	11/349 (3.15%)
ECZEMA † 1							
# participants affected / at risk	2/245 (0.82%)	3/245 (1.22%)	0/247 (0.00%)	7/245 (2.86%)	7/245 (2.86%)	11/353 (3.12%)	9/349 (2.58%)
PRURITUS † 1							
# participants affected / at risk	9/245 (3.67%)	11/245 (4.49%)	6/247 (2.43%)	13/245 (5.31%)	14/245 (5.71%)	15/353 (4.25%)	19/349 (5.44%)
PSORIASIS † 1							
# participants affected / at risk	4/245 (1.63%)	0/245 (0.00%)	7/247 (2.83%)	7/245 (2.86%)	1/245 (0.41%)	8/353 (2.27%)	3/349 (0.86%)
URTICARIA † 1							
# participants affected / at risk	3/245 (1.22%)	3/245 (1.22%)	0/247 (0.00%)	8/245 (3.27%)	8/245 (3.27%)	9/353 (2.55%)	9/349 (2.58%)
Vascular disorders							
HYPERTENSION † 1							
# participants affected / at risk	9/245 (3.67%)	0/245 (0.00%)	3/247 (1.21%)	16/245 (6.53%)	11/245 (4.49%)	21/353 (5.95%)	15/349 (4.30%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 16.0

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. ☑ **Restriction Description:** The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (ie, data from all sites) in the clinical trial

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Gottlieb AB, Langley RG, Philipp S, Sigurgeirsson B, Blauvelt A, Martin R, Papavassilis C, Mpofu S. Secukinumab Improves Physical Function in Subjects With Plaque Psoriasis and Psoriatic Arthritis: Results from Two Randomized, Phase 3 Trials. J Drugs Dermatol. 2015 Aug;14(8):821-33.

Ohtsuki M, Morita A, Abe M, Takahashi H, Seko N, Karpov A, Shima T, Papavassilis C, Nakagawa H; ERASURE Study Japanese subgroup. Secukinumab efficacy and safety in Japanese patients with moderate-to-severe plaque psoriasis: subanalysis from ERASURE, a randomized, placebo-controlled, phase 3 study. J Dermatol. 2014 Dec;41(12):1039-46. doi: 10.1111/1346-8138.12668. Epub 2014 Oct 30.

Langley RG, Elewski BE, Lebwohl M, Reich K, Griffiths CE, Papp K, Puig L, Nakagawa H, Spelman L, Sigurgeirsson B, Rivas E, Tsai TF, Wasel N, Tyring S, Salko T, Hampele I, Notter M, Karpov A, Helou S, Papavassilis C; ERASURE Study Group; FIXTURE Study Group. Secukinumab in plaque psoriasis--results of two phase 3 trials. N Engl J Med. 2014 Jul 24;371(4):326-38. doi: 10.1056/NEJMoa1314258. Epub 2014 Jul 9.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01365455 History of Changes
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Study First Received:	June 1, 2011
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Health Authority:	United States: Food and Drug Administration Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Canada: Health Canada Colombia: INVIMA Instituto Nacional de Vigilancia de Medicamentos y Alimentos Estonia: The State Agency of Medicine Iceland: Icelandic Medicines Control Agency Israel: Ministry of Health Japan: Ministry of Health, Labor and Welfare Latvia: State Agency of Medicines Lithuania: State Medicine Control Agency - Ministry of Health Mexico: Federal Commission for Sanitary Risks Protection Panama: Ministry of Health Peru: Ministry of Health Russia: Ministry of Health of the Russian Federation Taiwan: Department of Health