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Trial record **2 of 2** for: CAIN457A2307
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Efficacy and Safety of Intravenous and Subcutaneous Secukinumab in Moderate to Severe Chronic Plaque-type Psoriasis (STATURE)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01412944

First received: August 5, 2011
Last updated: March 17, 2015
Last verified: March 2015
History of Changes

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Results First Received: January 28, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Plaque-type Psoriasis
Interventions:	Drug: secukinumab 150mg Drug: secukinumab 10mg/kg i.v. regimen

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
This study consisted of 3 study periods: I.V. (I.V. infusion and subcutaneous (s.c.) regimens given in a double-blind fashion), Maintenance and follow-up. Participants, who were identified as partial responders at week 12 of study CAIN457A2304 (NCT01406938), were eligible to roll into CAIN457A2307.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Participants of the CAIN457A2304 150 mg or AIN457 300 mg treatment groups, who were partial responders at week 12 of CAIN457A2304, were randomized in a 1:1 ratio to the AIN457 300 mg s.c. or AIN457 10 mg/kg I.V. treatment groups of CAIN457A2307.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	No text entered.
AIN457 300 mg - AIN457 300 mg s.c.	No text entered.
AIN457 150 mg - AIN457 10 mg/kg I.V.	No text entered.
AIN457 300 mg - AIN457 10 mg/kg I.V.	No text entered.

Participant Flow for 5 periods

Period 1: IV: Per Previous CAIN457A2304 Treatment

	AIN457 Subcutaneous (s.c.)	AIN457 I.V.	I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	AIN457 300 mg - AIN457 300 mg s.c.	AIN457 150 mg - AIN457 10 mg/kg I.V.	AIN457 300 mg - AIN457 10 mg/kg I.V.
STARTED	0	0	15	6	14	8
COMPLETED	0	0	14	6	14	6
NOT COMPLETED	0	0	1	0	0	2
Withdrawal by Subject	0	0	1	0	0	0
Protocol deviation	0	0	0	0	0	1
Lost to Follow-up	0	0	0	0	0	1

Period 2: IV: Per CAIN457A2307

	AIN457 Subcutaneous (s.c.)	AIN457 I.V.	I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	AIN457 300 mg - AIN457 300 mg s.c.	AIN457 150 mg - AIN457 10 mg/kg I.V.	AIN457 300 mg - AIN457 10 mg/kg I.V.
STARTED	21	22	0	0	0	0
COMPLETED	20	20	0	0	0	0
NOT COMPLETED	1	2	0	0	0	0
Withdrawal by Subject	1	0	0	0	0	0
Protocol deviation	0	1	0	0	0	0
Lost to Follow-up	0	1	0	0	0	0

Period 3: Entire: IV + Maintenance

	AIN457 Subcutaneous (s.c.)	AIN457 I.V.	I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	AIN457 300 mg - AIN457 300 mg s.c.	AIN457 150 mg - AIN457 10 mg/kg I.V.	AIN457 300 mg - AIN457 10 mg/kg I.V.
STARTED	0	0	15	6	14	8
COMPLETED	0	0	14	5	11	6
NOT COMPLETED	0	0	1	1	3	2
Withdrawal by Subject	0	0	1	1	1	0
Adverse Event	0	0	0	0	1	0
Protocol deviation	0	0	0	0	0	1
Lost to Follow-up	0	0	0	0	0	1
Lack of Efficacy	0	0	0	0	1	0

Period 4: Entire: IV + Maintenance

	AIN457 Subcutaneous (s.c.)	AIN457 I.V.	I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	AIN457 300 mg - AIN457 300 mg s.c.	AIN457 150 mg - AIN457 10 mg/kg I.V.	AIN457 300 mg - AIN457 10 mg/kg I.V.
STARTED	21	22	0	0	0	0
COMPLETED	19	17	0	0	0	0
NOT COMPLETED	2	5	0	0	0	0
Withdrawal by Subject	2	1	0	0	0	0

Protocol deviation	0	1	0	0	0	0
Lost to Follow-up	0	1	0	0	0	0
Lack of Efficacy	0	1	0	0	0	0
Adverse Event	0	1	0	0	0	0

Period 5: Follow-up

	AIN457 Subcutaneous (s.c.)	AIN457 I.V.	I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	AIN457 300 mg - AIN457 300 mg s.c.	AIN457 150 mg - AIN457 10 mg/kg I.V.	AIN457 300 mg - AIN457 10 mg/kg I.V.
STARTED	0	0	2	1	2	0
COMPLETED	0	0	2	1	2	0
NOT COMPLETED	0	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 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
Total	Total of all reporting groups

Baseline Measures

	AIN457 Subcutaneous (s.c.)	AIN457 I.V.	Total
Number of Participants [units: participants]	21	22	43
Age [units: Years] Mean (Standard Deviation)	47.6 (14.53)	45.7 (12.14)	46.6 (13.24)
Gender [units: Participants]			
Female	5	9	14
Male	16	13	29

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in Psoriasis Area and Severity Index (PASI) After 12 Weeks of Treatment in Study AIN457A2304) With 75% Improvement From Baseline in PASI [Time Frame: Week 8]

Measure Type	Primary

Measure Title	Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in Psoriasis Area and Severity Index (PASI) After 12 Weeks of Treatment in Study AIN457A2304) With 75% Improvement From Baseline in PASI
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	Week 8
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.
The full analysis set (FAS) population was used for this analysis. The FAS included all participants to whom treatment was assigned. Only participants from the FAS, who had week 8 values, were included in the analysis.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	**AIN457 I.V.**
Number of Participants Analyzed [units: participants]	**21**	**21**
Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in Psoriasis Area and Severity Index (PASI) After 12 Weeks of Treatment in Study AIN457A2304) With 75% Improvement From Baseline in PASI [units: Percentage of participants]	**66.7**	**90.5**

No statistical analysis provided for Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in Psoriasis Area and Severity Index (PASI) After 12 Weeks of Treatment in Study AIN457A2304) With 75% Improvement From Baseline in PASI

2. Primary: Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in PASI After 12 Weeks of Treatment in Study AIN457A2304) With Investigator's Global Assessment Model 2011 (IGA Mod 2011) 0 or 1 Response [Time Frame: Week 8]

Measure Type	Primary
Measure Title	Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in PASI After 12 Weeks of Treatment in Study AIN457A2304) With Investigator's Global Assessment Model 2011 (IGA Mod 2011) 0 or 1 Response
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	Week 8
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.
The full analysis set (FAS) population was used for this analysis. The FAS included all participants to whom treatment was assigned. Only participants from the FAS, who had week 8 values, were included in the analysis.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week

	4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	AIN457 I.V.
Number of Participants Analyzed [units: participants]	**21**	**21**
Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in PASI After 12 Weeks of Treatment in Study AIN457A2304) With Investigator's Global Assessment Model 2011 (IGA Mod 2011) 0 or 1 Response [units: Percentage of participants]	**66.7**	**33.3**

No statistical analysis provided for Percentage of Participants (Who Achieved a Partial Response Defined as ≥ 50% But < 75% Improvement in PASI After 12 Weeks of Treatment in Study AIN457A2304) With Investigator's Global Assessment Model 2011 (IGA Mod 2011) 0 or 1 Response

3. Secondary: Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response [Time Frame: Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36 and 40]

Measure Type	Secondary
Measure Title	Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response
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 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	Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36 and 40
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.
The full analysis set (FAS) population was used for this analysis. The FAS included all participants to whom treatment was assigned. Only participants from the FAS, who had values at a given week, were included in the analysis for that week.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	AIN457 I.V.
Number of Participants Analyzed [units: participants]	**21**	**21**
Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response [units: Percentage of participants]		
Week 2 IGA 0/1	**9.5**	**9.5**
Week 2 PASI 75	**19.0**	**47.6**
Week 2 PASI 50	**85.7**	**100.0**

Week 2 PASI 90	**0.0**	**19.0**
Week 2 PASI 100	**0.0**	**0.0**
Week 4 IGA 0/1	**9.5**	**47.6**
Week 4 PASI 75	**33.3**	**76.2**
Week 4 PASI 50	**85.7**	**95.2**
Week 4 PASI 90	**4.8**	**28.6**
Week 4 PASI 100	**0.0**	**9.5**
Week 8 IGA 0/1	**33.3**	**66.7**
Week 8 PASI 75	**66.7**	**90.5**
Week 8 PASI 50	**90.5**	**95.2**
Week 8 PASI 90	**9.5**	**61.9**
Week 8 PASI 100	**0.0**	**14.3**
Week 12 IGA 0/1	**38.1**	**71.4**
Week 12 PASI 75	**61.9**	**85.7**
Week 12 PASI 50	**85.7**	**95.2**
Week 12 PASI 90	**19.0**	**66.7**
Week 12 PASI 100	**0.0**	**14.3**
Week 16 IGA 0/1	**28.6**	**66.7**
Week 16 PASI 75	**66.7**	**81.0**
Week 16 PASI 50	**85.7**	**85.7**
Week 16 PASI 90	**14.3**	**57.1**
Week 16 PASI 100	**0.0**	**19.0**
Week 20 IGA 0/1	**23.8**	**61.9**
Week 20 PASI 75	**66.7**	**81.0**
Week 20 PASI 50	**81.0**	**85.7**
Week 20 PASI 90	**14.3**	**57.1**
Week 20 PASI 100	**4.8**	**14.3**
Week 24 IGA 0/1	**23.8**	**47.6**
Week 24 PASI 75	**52.4**	**76.2**
Week 24 PASI 50	**81.0**	**85.7**
Week 24 PASI 90	**19.0**	**57.1**
Week 24 PASI 100	**9.5**	**14.3**
Week 28 IGA 0/1	**23.8**	**42.9**
Week 28 PASI 75	**61.9**	**61.9**
Week 28 PASI 50	**76.2**	**85.7**
Week 28 PASI 90	**23.8**	**38.1**
Week 28 PASI 100	**0.0**	**14.3**
Week 32 IGA 0/1	**14.3**	**42.9**
Week 32 PASI 75	**57.1**	**66.7**
Week 32 PASI 50	**76.2**	**81.0**
Week 32 PASI 90	**19.0**	**42.9**
Week 32 PASI 100	**0.0**	**9.5**
Week 36 IGA 0/1	**19.0**	**52.4**
Week 36 PASI 75	**57.1**	**61.9**
Week 36 PASI 50	**81.0**	**76.2**
Week 36PASI 90	**23.8**	**47.6**
Week 36 PASI 100	**0.0**	**9.5**

Week 40 IGA 0/1	**28.6**	**42.9**
Week 40 PASI 75	**47.6**	**61.9**
Week 40 PASI 50	**85.7**	**71.4**
Week 40 PASI 90	**23.8**	**47.6**
Week 40 PASI 100	**0.0**	**14.3**

No statistical analysis provided for Percentage of Participants Achieving PASI 50/75/90/100 Response or IGA 0 or 1 Response

4. Secondary: Mean Percent Change From Baseline in PASI Scores [Time Frame: Baseline, weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36 and 40]

Measure Type	Secondary
Measure Title	Mean Percent Change From Baseline in PASI Scores
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, weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36 and 40
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.
The full analysis set (FAS) population was used for this analysis. The FAS included all participants to whom treatment was assigned. Only participants from the FAS, who had post-baseline values at the given weeks, were included in the analysis for that week.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	**AIN457 I.V.**
Number of Participants Analyzed [units: participants]	**21**	**21**
Mean Percent Change From Baseline in PASI Scores [units: Percent change] Mean (Standard Deviation)		
Week 2	**-65.427 (14.1732)**	**-74.824 (10.6180)**
Week 4	**-69.804 (14.4443)**	**-83.063 (10.7849)**
Week 8	**-75.422 (15.0913)**	**-90.980 (9.6116)**
Week 12	**-76.026 (17.0949)**	**-89.754 (11.1194)**
Week 16	**-75.079 (18.6092)**	**-89.645 (13.4471)**
Week 20	**-74.494 (20.5253)**	**-86.816 (19.4202)**
Week 24	**-72.703 (22.4086)**	**-85.803 (19.8869)**
Week 28	**-72.281 (23.4549)**	**-80.487 (25.7435)**
Week 32	**-71.770 (22.7398)**	**-79.557 (27.2634)**
Week 36	**-72.151 (21.4637)**	**-79.329 (27.2362)**
Week 40	**-73.663 (18.2709)**	**-77.416 (28.5592)**

No statistical analysis provided for Mean Percent Change From Baseline in PASI Scores

5. Secondary: Percentage of Participants in Each IGA Mod 2011 Score Category [Time Frame: Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36 and 40]

Measure Type	Secondary
Measure Title	Percentage of Participants in Each IGA Mod 2011 Score Category
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	Weeks 2, 4, 8, 12, 16, 20, 24, 28, 32, 36 and 40
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.
The full analysis set (FAS) population was used for this analysis. The FAS included all participants to whom treatment was assigned. Only participants from the FAS, who had post-baseline values at the given weeks, were included in the analysis for that week.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	**AIN457 I.V.**
Number of Participants Analyzed [units: participants]	**21**	**21**
Percentage of Participants in Each IGA Mod 2011 Score Category [units: Percentage of participants]		
week 2 - clear	**0.0**	**0.0**
week 2 - almost clear	**9.5**	**9.5**
week 2 - mild	**57.1**	**66.7**
week 2 - moderate	**33.3**	**23.8**
week 2 - severe	**0.0**	**0.0**
week 4 - clear	**0.0**	**9.5**
week 4 - almost clear	**9.5**	**38.1**
week 4 - mild	**61.9**	**47.6**
week 4 - moderate	**28.6**	**4.8**
week 4 - severe	**0.0**	**0.0**
week 8 - clear	**0.0**	**19.0**
week 8 - almost clear	**33.3**	**47.6**
week 8 - mild	**38.1**	**23.8**
week 8 - moderate	**28.6**	**9.5**
week 8 - severe	**0.0**	**0.0**
week 12 - clear	**0.0**	**14.3**
week 12 - almost clear	**38.1**	**57.1**
week 12 - mild	**33.3**	**19.0**
week 12 - moderate	**28.6**	**9.5**

week 12 - severe	**0.0**	**0.0**
week 16 - clear	**0.0**	**19.0**
week 16 - almost clear	**28.6**	**52.4**
week 16 - mild	**42.9**	**19.0**
week 16 - moderate	**28.6**	**9.5**
week 16 - severe	**0.0**	**0.0**
week 20 - clear	**4.8**	**14.3**
week 20 - almost clear	**19.0**	**52.4**
week 20 - mild	**47.6**	**23.8**
week 20 - moderate	**28.6**	**9.5**
week 20 - severe	**0.0**	**0.0**
week 24 - clear	**9.5**	**14.3**
week 24 - almost clear	**14.3**	**38.1**
week 24 - mild	**33.3**	**28.6**
week 24 - moderate	**42.9**	**14.3**
week 24 - severe	**0.0**	**4.8**
week 28 - clear	**9.5**	**4.8**
week 28 - almost clear	**14.3**	**42.9**
week 28 - mild	**47.6**	**28.6**
week 28 - moderate	**28.6**	**23.8**
week 28 - severe	**0.0**	**0.0**
week 32 - clear	**4.8**	**4.8**
week 32 - almost clear	**9.5**	**42.9**
week 32 - mild	**47.6**	**23.8**
week 32 - moderate	**38.1**	**23.8**
week 32 - severe	**0.0**	**4.8**
week 36 - clear	**0.0**	**4.8**
week 36 - almost clear	**19.0**	**52.4**
week 36 - mild	**42.9**	**19.0**
week 36 - moderate	**38.1**	**19.0**
week 36 - severe	**0.0**	**4.8**
week 40 - clear	**0.0**	**14.3**
week 40 - almost clear	**28.6**	**33.3**
week 40 - mild	**33.3**	**23.8**
week 40 - moderate	**38.1**	**23.8**
week 40 - severe	**0.0**	**4.8**

No statistical analysis provided for Percentage of Participants in Each IGA Mod 2011 Score Category

6. Secondary: Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 [Time Frame: Baseline, Week 8, Week 16, Week 24, Week 32,up to Week 40]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1
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 warts. 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 DLQI of 0 or 1 indicates no impairment or little impairment, respectively. A negative mean

	percentage change from baseline indicates improvement.
Time Frame	Baseline, Week 8, Week 16, Week 24, Week 32,up to Week 40
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.
The full analysis set (FAS) population was used for this analysis. The FAS included all participants to whom treatment was assigned. Only participants from the FAS, who had post-baseline values at the given weeks, were included in the analysis for that week.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	**AIN457 I.V.**
Number of Participants Analyzed [units: participants]	**21**	**21**
Percentage of Participants Who Achieved Dermatology Life Quality Index (DLQI) of 0 or 1 [units: Percentage of participants]		
Baseline	**0.0**	**4.8**
Week 8 (n=20,20)	**25.0**	**75.0**
Week 16 (n=20,20)	**40.0**	**70.0**
Week 24 (n=20,20)	**40.0**	**55.0**
Week 32 (n=20,20)	**40.0**	**55.0**
Week 40 (n=20,20)	**40.0**	**55.0**

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

7. Secondary: Mean Percent Change From Baseline in Dermatology Life Quality Index (DLQI) Scores [Time Frame: Baseline, weeks 8, 16, 24, 32 and 40]

Measure Type	Secondary
Measure Title	Mean Percent Change From Baseline in Dermatology Life Quality Index (DLQI) Scores
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, weeks 8, 16, 24, 32 and 40
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.
The FAS population was used for this analysis. The FAS included all participants to whom treatment was assigned. Only participants from the FAS, who had post-baseline values at the given weeks, were included in the analysis for that week.

Reporting Groups

	Description

AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	**AIN457 I.V.**
Number of Participants Analyzed [units: participants]	**20**	**20**
Mean Percent Change From Baseline in Dermatology Life Quality Index (DLQI) Scores [units: Percent change] Mean (Standard Deviation)		
week 8	**-67.1 (28.35)**	**-82.4 (31.13)**
week 16	**-68.7 (32.34)**	**-74.8 (42.19)**
week 24	**-66.9 (29.27)**	**-63.2 (42.65)**
week 32	**-65.4 (34.64)**	**-58.1 (53.40)**
week 40	**-74.2 (24.25)**	**-53.8 (56.21)**

No statistical analysis provided for Mean Percent Change From Baseline in Dermatology Life Quality Index (DLQI) Scores

8. Secondary: Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100) [Time Frame: Baseline, weeks 8, 16, 24, 32 and 40]

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)
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, weeks 8, 16, 24, 32 and 40
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.
The FAS population was used for this analysis. The FAS included all participants to whom treatment was assigned. Only participants from the FAS, who had values at a given week, were included in the analysis for that week.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	**AIN457 I.V.**
Number of Participants Analyzed [units: participants]	**20**	**20**
Mean Percent Change From Baseline in EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) Health State Assessment (From 0 to 100)		

[units: Percent change] Mean (Standard Deviation)		
week 8	71.0 (157.11)	73.1 (99.42)
week 16	76.9 (153.63)	57.5 (98.10)
week 24	74.6 (171.69)	45.3 (82.05)
week 32	80.2 (177.33)	40.9 (80.96)
week 40	87.2 (173.59)	41.3 (86.92)

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)

9. Secondary: Number of Participants Who Developed Anti-secukinumab Antibodies [Time Frame: Baseline, weeks 12, 24 and 40]

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	Baseline, weeks 12, 24 and 40
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.
Participants from full analysis set (FAS), who had values at baseline and post-baseline, were included in the analysis. The FAS included all participants to whom treatment was assigned.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	**AIN457 I.V.**
Number of Participants Analyzed [units: participants]	**20**	**20**
Number of Participants Who Developed Anti-secukinumab Antibodies [units: Number of participants]	**0**	**0**

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

10. Secondary: Relationship Between Response to AIN457 and Failed Response to Previous Biologic Psoriasis Therapy [Time Frame: End of study]

Measure Type	Secondary
Measure Title	Relationship Between Response to AIN457 and Failed Response to Previous Biologic Psoriasis Therapy
Measure Description	This outcome measure was not analyzed due to the small sample size of the study (43 participants).
Time Frame	End of study
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.
No text entered.

Reporting Groups

	Description
AIN457 Subcutaneous (s.c.)	During the intravenous (I.V.) period, participants received two 150 mg s.c. injections of AIN457 at randomization and week 4, and AIN457 placebo I.V. at randomization, week 2 and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.
AIN457 I.V.	During the I.V. period, participants received AIN457 10mg/kg I.V. at randomization, week 2 and week 4, and AIN457 placebo s.c. at randomization and week 4. During the maintenance period, participants received 300 mg s.c. of open-label AIN457.

Measured Values

	AIN457 Subcutaneous (s.c.)	**AIN457 I.V.**
Number of Participants Analyzed [units: participants]	**0**	**0**
Relationship Between Response to AIN457 and Failed Response to Previous Biologic Psoriasis Therapy		

No statistical analysis provided for Relationship Between Response to AIN457 and Failed Response to Previous Biologic Psoriasis Therapy

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	No text entered.
I.V. Period: AIN457 300 mg - AIN457 300 mg s.c.	No text entered.
I.V. Period: AIN457 150 mg - AIN457 10 mg/kg i.v.	No text entered.
I.V. Period: AIN457 300 mg - AIN457 10 mg/kg i.v.	No text entered.
Entire Period: AIN457 150 mg - AIN457 300 mg s.c.	No text entered.
Entire Period: AIN457 300 mg - AIN457 300 mg s.c.	No text entered.
Entire Period: AIN457 150 mg - AIN457 10 mg/kg i.v.	No text entered.
Entire Period: AIN457 300 mg - AIN457 10 mg/kg i.v.	No text entered.
Follow up: AIN457 300 mg - AIN457 300 mg s.c.	No text entered.
Follow-up: AIN457 300 mg - 10 mg/kg i.v.	No text entered.
Follow-up: AIN457 150 mg - 300 mg s.c.	No text entered.
Follow-up: AIN457 150 mg - 10 mg/kg i.v.	No text entered.

Serious Adverse Events

	I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	**I.V. Period: AIN457 300 mg - AIN457 300 mg s.c.**	**I.V. Period: AIN457 150 mg - AIN457 10 mg/kg i.v.**	**I.V. Period: AIN457 300 mg - AIN457 10 mg/kg i.v.**	**Entire Period: AIN457 150 mg - AIN457 300 mg s.c.**	**Entire Period: AIN457 300 mg - AIN457 300 mg s.c.**	**Entire Period: AIN457 150 mg - AIN457 10 mg/kg i.v.**	**Entire Period: AIN457 300 mg - AIN457 10 mg/kg i.v.**	**Follow up: AIN457 300 mg - AIN457 300 mg s.c.**	**Follow-up: AIN457 300 mg - 10 mg/kg i.v.**	**Foll up: Al 150 r 300 s.c**
Total, serious adverse events											
# participants											

affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)	0/0	0/2 (0.
Skin and subcutaneous tissue disorders											
DERMATITIS ALLERGIC † 1											
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)	0/0	0/2 (0

† 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	5%

Reporting Groups

	Description
I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	No text entered.
I.V. Period: AIN457 300 mg - AIN457 300 mg s.c.	No text entered.
I.V. Period: AIN457 150 mg - AIN457 10 mg/kg i.v.	No text entered.
I.V. Period: AIN457 300 mg - AIN457 10 mg/kg i.v.	No text entered.
Entire Period: AIN457 150 mg - AIN457 300 mg s.c.	No text entered.
Entire Period: AIN457 300 mg - AIN457 300 mg s.c.	No text entered.
Entire Period: AIN457 150 mg - AIN457 10 mg/kg i.v.	No text entered.
Entire Period: AIN457 300 mg - AIN457 10 mg/kg i.v.	No text entered.
Follow up: AIN457 300 mg - AIN457 300 mg s.c.	No text entered.
Follow-up: AIN457 300 mg - 10 mg/kg i.v.	No text entered.
Follow-up: AIN457 150 mg - 300 mg s.c.	No text entered.
Follow-up: AIN457 150 mg - 10 mg/kg i.v.	No text entered.

Other Adverse Events

	I.V. Period: AIN457 150 mg - AIN457 300 mg s.c.	I.V. Period: AIN457 300 mg - AIN457 300 mg s.c.	I.V. Period: AIN457 150 mg - AIN457 10 mg/kg i.v.	I.V. Period: AIN457 300 mg - AIN457 10 mg/kg i.v.	Entire Period: AIN457 150 mg - AIN457 300 mg s.c.	Entire Period: AIN457 300 mg - AIN457 300 mg s.c.	Entire Period: AIN457 150 mg - AIN457 10 mg/kg i.v.	Entire Period: AIN457 300 mg - AIN457 10 mg/kg i.v.	Follow up: AIN457 300 mg - AIN457 300 mg s.c.
Total, other (not including serious) adverse events									
# participants affected / at risk	7/15 (46.67%)	4/6 (66.67%)	5/14 (35.71%)	5/8 (62.50%)	10/15 (66.67%)	5/6 (83.33%)	12/14 (85.71%)	6/8 (75.00%)	1/1 (100.00%
Blood and lymphatic system disorders									
LYMPHADENOPATHY † 1									

# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
Cardiac disorders									
ATRIAL FIBRILLATION † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
ATRIOVENTRICULAR BLOCK FIRST DEGREE † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
Eye disorders									
CONJUNCTIVITIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
CONJUNCTIVITIS ALLERGIC † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
EYELIDS PRURITUS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
Gastrointestinal disorders									
DIARRHOEA † 1									
# participants affected / at risk	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	1/8 (12.50%)	0/1 (0.00%)
GINGIVITIS ULCERATIVE † 1									
# participants affected / at risk	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
ILEAL ULCER † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
TOOTHACHE † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
General disorders									
CHEST PAIN † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
FATIGUE † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
INJECTION SITE PAIN † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
Immune system disorders									
ALLERGY TO PLANTS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
SEASONAL ALLERGY † 1									
# participants	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)

affected / at risk									
Infections and infestations									
BRONCHITIS † 1									
# participants affected / at risk	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
BRONCHITIS BACTERIAL † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
EAR INFECTION † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	1/8 (12.50%)	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	1/8 (12.50%)	0/1 (0.00%)
FOLLICULITIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	2/14 (14.29%)	1/8 (12.50%)	0/1 (0.00%)
HELICOBACTER INFECTION † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
HERPES ZOSTER † 1									
# participants affected / at risk	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
INFLUENZA † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
NASOPHARYNGITIS † 1									
# participants affected / at risk	2/15 (13.33%)	1/6 (16.67%)	1/14 (7.14%)	1/8 (12.50%)	3/15 (20.00%)	1/6 (16.67%)	3/14 (21.43%)	2/8 (25.00%)	0/1 (0.00%)
ONYCHOMYCOSIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
ORAL CANDIDIASIS † 1									
# participants affected / at risk	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
PHARYNGITIS † 1									
# participants affected / at risk	0/15 (0.00%)	1/6 (16.67%)	1/14 (7.14%)	0/8 (0.00%)	1/15 (6.67%)	1/6 (16.67%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
PHARYNGITIS STREPTOCOCCAL † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
PILONIDAL CYST † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
RHINITIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
SINUSITIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	1/8 (12.50%)	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	1/8 (12.50%)	0/1 (0.00%)
TINEA PEDIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
TONSILLITIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)

UPPER RESPIRATORY TRACT INFECTION † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**1/14 (7.14%)**	**1/8 (12.50%)**	**1/15 (6.67%)**	**0/6 (0.00%)**	**1/14 (7.14%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
UPPER RESPIRATORY TRACT INFECTION BACTERIAL † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**1/15 (6.67%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Injury, poisoning and procedural complications									
EXCORIATION † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/15 (0.00%)**	**1/6 (16.67%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
FALL † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**1/14 (7.14%)**	**0/8 (0.00%)**	**0/15 (0.00%)**	**0/6 (0.00%)**	**1/14 (7.14%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
JOINT INJURY † 1									
# participants affected / at risk	**1/15 (6.67%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**1/15 (6.67%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
LIMB INJURY † 1									
# participants affected / at risk	**1/15 (6.67%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**1/15 (6.67%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
TOOTH FRACTURE † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/15 (0.00%)**	**0/6 (0.00%)**	**1/14 (7.14%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
UPPER LIMB FRACTURE † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
Investigations									
HAEMOGLOBIN DECREASED † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/15 (0.00%)**	**1/6 (16.67%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
WEIGHT DECREASED † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/15 (0.00%)**	**1/6 (16.67%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Metabolism and nutrition disorders									
DEHYDRATION † 1									
# participants affected / at risk	**0/15 (0.00%)**	**1/6 (16.67%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/15 (0.00%)**	**1/6 (16.67%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
TYPE 2 DIABETES MELLITUS † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/15 (0.00%)**	**1/6 (16.67%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**
Musculoskeletal and connective tissue disorders									
BACK PAIN † 1									
# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**1/8 (12.50%)**	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**1/8 (12.50%)**	**0/1 (0.00%)**
INTERVERTEBRAL DISC PROTRUSION †									

[1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
MUSCLE SPASMS † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
MYALGIA † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	1/8 (12.50%)	0/1 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
PYOGENIC GRANULOMA † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
SKIN PAPILLOMA † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
Nervous system disorders									
HEADACHE † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	2/14 (14.29%)	0/8 (0.00%)	0/1 (0.00%)
SCIATICA † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	1/8 (12.50%)	0/1 (0.00%)
TENSION HEADACHE † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
Renal and urinary disorders									
ENURESIS † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	1/8 (12.50%)	0/1 (0.00%)
NEPHROLITHIASIS † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
Reproductive system and breast disorders									
ERECTILE DYSFUNCTION † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
Respiratory, thoracic and mediastinal disorders									
EPISTAXIS † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	1/8 (12.50%)	0/1 (0.00%)
OROPHARYNGEAL PAIN † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
PHARYNGEAL OEDEMA † [1]									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)

PRODUCTIVE COUGH † 1									
# participants affected / at risk	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
SINUS CONGESTION † 1									
# participants affected / at risk	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
Skin and subcutaneous tissue disorders									
ALOPECIA † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
DERMATITIS BULLOUS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
DERMATITIS CONTACT † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
ECCHYMOSIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
ECZEMA † 1									
# participants affected / at risk	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
INTERTRIGO † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	1/8 (12.50%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	1/8 (12.50%)	0/1 (0.00%)
PRURITUS GENERALISED † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
PSORIASIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/1 (100.00%
SEBORRHOEIC DERMATITIS † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	1/8 (12.50%)	0/1 (0.00%)
SKIN FISSURES † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	1/8 (12.50%)	0/1 (0.00%)
SKIN LESION † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
Vascular disorders									
FLUSHING † 1									
# participants affected / at risk	0/15 (0.00%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/15 (0.00%)	1/6 (16.67%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
HYPERTENSION † 1									
# participants affected / at risk	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	1/14 (7.14%)	0/8 (0.00%)	0/1 (0.00%)
HYPOTENSION † 1									
# participants affected / at risk	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	1/15 (6.67%)	0/6 (0.00%)	0/14 (0.00%)	0/8 (0.00%)	0/1 (0.00%)
THROMBOPHLEBITIS † 1									

# participants affected / at risk	**0/15 (0.00%)**	**0/6 (0.00%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/15 (0.00%)**	**1/6 (16.67%)**	**0/14 (0.00%)**	**0/8 (0.00%)**	**0/1 (0.00%)**

† 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 (i.e., data from all sites) in the clinical trial or disclosure of trial results in their entirety.

Results Point of Contact:

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

No publications provided

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT01412944 History of Changes
Other Study ID Numbers:	**CAIN457A2307** 2011-002510-36 (EudraCT Number)
Study First Received:	August 5, 2011
Results First Received:	January 28, 2015
Last Updated:	March 17, 2015
Health Authority:	United States: Food and Drug Administration Austria: Agency for Health and Food Safety Bulgaria: Bulgarian Drug Agency Canada: Health Canada Czech Republic: State Institute for Drug Control France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Paul-Ehrlich-Institut India: Drugs Controller General of India Italy: The Italian Medicines Agency Japan: Ministry of Health, Labor and Welfare Peru: Ministry of Health Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Singapore: Health Sciences Authority Slovakia: State Institute for Drug Control Switzerland: Swissmedic Taiwan: Department of Health United Kingdom: Medicines and Healthcare Products Regulatory Agency Vietnam: Ministry of Health