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Trial record **1 of 2** for: CAIN457A2211
Previous Study | Return to List | Next Study

AIN457 Regimen Finding Study in Patients With Moderate to Severe Psoriasis

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT00941031

First received: July 16, 2009
Last updated: July 30, 2015
Last verified: March 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: January 30, 2015

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Chronic Plaque-type Psoriasis
Interventions:	Drug: AIN457 Drug: AIN457A Drug: Placebo

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
No text entered.

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
Induction Single Dose	Induction with single injection - "Single": secukinumab (AIN457) 150 mg s.c. administered at Week 1, Baseline through Week 12
Induction Monthly Dose	Induction with monthly injections - "Monthly": secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 5, 9, Baseline through Week 12
Induction Early Loading	Early loading induction - "Early": secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 2, 3, 5, Baseline through Week 12
Placebo Dose	Placebo administered at weeks 1, 2, 3, 5, 9, Baseline through Week 12
Fixed Interval	Fixed-time interval regimen - "FI": secukinumab (AIN457) 150 mg s.c. administered at Week 13 and at Week 25 and placebo at regular scheduled visit at which a start of relapse was observed, Week 21 to Week 29
Start of Relapse	Treatment at start of relapse regimen - "SR": Placebo administered at Week 13 and possibly at Week 25 if no start of relapse observed, and secukinumab (AIN457) 150 mg s.c. administered at regular scheduled visit at which a start of relapse was observed, Week 21 to Week 29
Open Label	Non responders and partial responders at Week 13 and patients who experienced 2 consecutive relapses at scheduled visits from Week 13 onwards were eligible to enter the Open Label phase - "OL": secukinumab (AIN457) 150 mg s.c. administered every 4 weeks.21 to Week 29

Participant Flow for 2 periods

Period 1: Induction Period

	Induction Single Dose	Induction Monthly Dose	Induction Early Loading	Placebo Dose	Fixed Interval	Start of Relapse	Open Label
STARTED	66	138	133	67	0	0	0
COMPLETED	61	134	127	58	0	0	0
NOT COMPLETED	5	4	6	9	0	0	0
Lack of Efficacy	2	1	0	5	0	0	0
Withdrawal by Subject	1	2	2	2	0	0	0
Adminstative Problems	1	1	1	0	0	0	0
Adverse Event	1	0	3	2	0	0	0

Period 2: Maintenance Period

	Induction Single Dose	Induction Monthly Dose	Induction Early Loading	Placebo Dose	Fixed Interval	Start of Relapse	Open Label
STARTED	0 [1]	0 [1]	0 [1]	0 [2]	65 [1]	67 [1]	247 [2]
COMPLETED	0 [1]	0 [1]	0 [1]	0 [2]	56	61	204
NOT COMPLETED	0	0	0	0	9	6	43
Withdrawal by Subject	0	0	0	0	6	2	13
Administrative Problems	0	0	0	0	1	0	1
Protocol Violation	0	0	0	0	0	0	1
Adverse Event	0	0	0	0	0	2	8
Lost to Follow-up	0	0	0	0	2	2	7
Lack of Efficacy	0	0	0	0	0	0	13

[1] Responders at week 13 were re randomized to one of the maintenance treatment arms in a ratio of 1:1
[2] Non Responders treated with an open label regimen.

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
Induction Single Dose	Baseline through Week 12
Induction Monthly Dose	No text entered.
Induction Early Loading Dose	No text entered.
Placebo	No text entered.
Total	Total of all reporting groups

Baseline Measures

	Induction Single Dose	Induction Monthly Dose	Induction Early Loading Dose	Placebo	Total
Number of Participants [units: participants]	**66**	**138**	**133**	**67**	**404**
Age [units: Years] Mean (Standard Deviation)	**42.7 (11.32)**	**44.2 (12.96)**	**44.5 (12.45)**	**44.2 (12.59)**	**44.1 (12.44)**
Gender [units: Participants]					
Female	**13**	**34**	**28**	**23**	**98**
Male	**53**	**104**	**105**	**44**	**306**
Race (NIH/OMB) [units: Participants]					
American Indian or Alaska Native	**0**	**0**	**0**	**0**	**0**
Asian	**7**	**17**	**14**	**8**	**46**
Native Hawaiian or Other Pacific Islander	**0**	**0**	**0**	**1**	**1**
Black or African American	**0**	**1**	**0**	**1**	**2**
White	**59**	**120**	**118**	**56**	**353**
More than one race	**0**	**0**	**0**	**0**	**0**
Unknown or Not Reported	**0**	**0**	**1**	**1**	**2**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously in Patients With Moderate to Severe Chronic Plaque-type Psoriasis With Respect to PASI 75 Achievement After 12 Weeks of Treatment, Compared to Placebo. [Time Frame: 13 weeks]

Measure Type	Primary
Measure Title	The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously in Patients With Moderate to Severe Chronic Plaque-type Psoriasis With Respect to PASI 75 Achievement After 12 Weeks of Treatment, Compared to Placebo.
Measure Description	Number (%) of patients achieving PASI 50, PASI 75, PASI 90, by visit and induction treatment
Time Frame	13 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, LOCF) Number (%) of patients achieving PASI 50, PASI 75, PASI 90, by visit and induction treatment

Reporting Groups

	Description
Induction Single Dose	Induction with single injection – “Single”: secukinumab (AIN457) 150 mg s.c. administered at Week 1, Baseline through Week 12
Induction Monthly Dose	Induction with monthly injections – “Monthly”: secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 5, 9, Baseline through Week 12
Induction Early Loading Dose	Early loading induction – “Early”: secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 2, 3, 5, Baseline through Week 12
Placebo Dose	Placebo administered at weeks 1, 2, 3, 5, 9, Baseline through Week 12

Measured Values

	Induction Single Dose	Induction Monthly Dose	Induction Early Loading Dose	Placebo Dose

Number of Participants Analyzed [units: participants]	**66**	**138**	**132**	**66**
The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously in Patients With Moderate to Severe Chronic Plaque-type Psoriasis With Respect to PASI 75 Achievement After 12 Weeks of Treatment, Compared to Placebo. [units: Participants achieving goal]				
PASI 50	**18**	**83**	**101**	**7**
PASI 75	**7**	**58**	**72**	**1**
PASI 90	**2**	**24**	**42**	**1**

No statistical analysis provided for The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously in Patients With Moderate to Severe Chronic Plaque-type Psoriasis With Respect to PASI 75 Achievement After 12 Weeks of Treatment, Compared to Placebo.

2. Secondary: The Efficacy of Two Maintenance Regimens of AIN457 With Respect to PASI 75 Achievement at Least Once From Week 21 to 29 [Time Frame: week 21 to 29]

Measure Type	Secondary
Measure Title	The Efficacy of Two Maintenance Regimens of AIN457 With Respect to PASI 75 Achievement at Least Once From Week 21 to 29
Measure Description	No text entered.
Time Frame	week 21 to 29
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, LOCF)

Reporting Groups

	Description
Maintenance Fixed Interval	Fixed-time interval regimen – “FI”: secukinumab (AIN457) 150 mg s.c. administered at Week 13 and at Week 25 and placebo at regular scheduled visit at which a start of relapse was observed, Week 21 to Week 29
Maintenance Start of Relapse	Treatment at start of relapse regimen – “SR”: Placebo administered at Week 13 and possibly at Week 25 if no start of relapse observed, and secukinumab (AIN457) 150 mg s.c. administered at regular scheduled visit at which a start of relapse was observed, Week 21 to Week 29
Maintenance Open Label	Non responders and partial responders at Week 13 and patients who experienced 2 consecutive relapses at scheduled visits from Week 13 onwards were eligible to enter the Open Label phase – “OL”: secukinumab (AIN457) 150 mg s.c. administered every 4 weeks.21 to Week 29

Measured Values

	Maintenance Fixed Interval	**Maintenance Start of Relapse**	**Maintenance Open Label**
Number of Participants Analyzed [units: participants]	**65**	**67**	**247**
The Efficacy of Two Maintenance Regimens of AIN457 With Respect to PASI 75 Achievement at Least Once From Week 21 to 29 [units: Participants achieving goal]			
PASI 50	**64**	**60**	**200**
PASI 75	**55**	**45**	**114**
PASI 90	**38**	**14**	**53**

No statistical analysis provided for The Efficacy of Two Maintenance Regimens of AIN457 With Respect to PASI 75 Achievement at Least Once From Week 21 to 29

3. Secondary: The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously With Respect Participants Who Reported Either an IGA 0 or 1 After 12 Weeks of Treatment, Compared to Placebo [Time Frame: 13 weeks]

Measure Type	Secondary
Measure Title	The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously With Respect Participants Who Reported Either an IGA 0 or 1 After 12 Weeks of Treatment, Compared to Placebo
Measure Description	The investigator's global assessment (IGA) was used to evaluate overall psoriatic disease, with scores ranging from 0 (clear) to 5 (very severe disease). Treatment success was defined as patients who achieved IGA 0 or 1 and improvement of at least 2 points on the IGA scale compared to baseline. The IGA rating score for involvement of hands and feet ranged from 0 (clear) to 4 (severe).
Time Frame	13 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

Reporting Groups

	Description
Induction Single Dose	Induction with single injection – "Single": secukinumab (AIN457) 150 mg s.c. administered at Week 1, Baseline through Week 12
Induction Monthly Dose	Induction with monthly injections – "Monthly": secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 5, 9, Baseline through Week 12
Induction Early Loading Dose	Early loading induction – "Early": secukinumab (AIN457) 150 mg s.c. administered at weeks 1, 2, 3, 5, Baseline through Week 12
Placebo Dose	Placebo administered at weeks 1, 2, 3, 5, 9, Baseline through Week 12

Measured Values

	Induction Single Dose	**Induction Monthly Dose**	**Induction Early Loading Dose**	**Placebo Dose**
Number of Participants Analyzed [units: participants]	**66**	**137**	**132**	**66**
The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously With Respect Participants Who Reported Either an IGA 0 or 1 After 12 Weeks of Treatment, Compared to Placebo [units: Participants achieving goal]				
0=clear	**0**	**2**	**17**	**1**
1= almost clear	**3**	**29**	**32**	**0**
2= mild disease	**17**	**42**	**38**	**3**
3= moderate disease	**28**	**44**	**33**	**26**
4=severe disease	**15**	**18**	**12**	**29**
5= very serious disease	**3**	**2**	**0**	**7**

No statistical analysis provided for The Efficacy of Three Induction Regimens of AIN457 Administered Subcutaneously With Respect Participants Who Reported Either an IGA 0 or 1 After 12 Weeks of Treatment, Compared to Placebo

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
INDUCTION: Single	INDUCTION: Early loading induction - 'Early'
INDUCTION: Monthly	INDUCTION: with monthly injections - 'Monthly'

INDUCTION: Early	INDUCTION: with single injection - 'Single'
INDUCTION: Placebo	INDUCTION: Placebo - 'Placebo'
MAINTENANCE: Fixed Interval	MAINTENANCE: Fixed-time interval regimen - 'FI'
MAINTENANCE: Start of Relapse	MAINTENANCE: Treatment at start of relapse regimen - 'SR'
MAINTENANCE: Open Label	MAINTENANCE: Open label Non responders and partial responders at Week 13 and patients who experienced 2 consecutive relapses at scheduled visits from Week 13 onwards were eligible to enter the Open Label phase – "OL": secukinumab (AIN457) 150 mg s.c. administered every 4 weeks.
FOLLOW-UP: Fixed Interval	FOLLOW-UP: Fixed-time interval regimen - 'FI'
FOLLOW-UP: Start of Relapse	FOLLOW-UP: Treatment at start of relapse regimen - 'SR'
FOLLOW-UP: Open Label	FOLLOW-UP: Open label

Serious Adverse Events

	INDUCTION: Single	INDUCTION: Monthly	INDUCTION: Early	INDUCTION: Placebo	MAINTENANCE: Fixed Interval	MAINTENANCE: Start of Relapse	MAINTENANCE: Open Label	FOLLOW-UP: Fixed Interval	FOLLOV UP: Start Relapse
Total, serious adverse events									
# participants affected / at risk	**3/66 (4.55%)**	**3/138 (2.17%)**	**6/133 (4.51%)**	**1/67 (1.49%)**	**4/65 (6.15%)**	**2/67 (2.99%)**	**12/247 (4.86%)**	**0/17 (0.00%)**	**0/15 (0.00**
Cardiac disorders									
Angina pectoris † 1									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**1/133 (0.75%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Arrhythmia † 1									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**1/247 (0.40%)**	**0/17 (0.00%)**	**0/15 (0.00**
Coronary artery disease † 1									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**1/133 (0.75%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Ventricular fibrillation † 1									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Eye disorders									
Cataract † 1									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**1/247 (0.40%)**	**0/17 (0.00%)**	**0/15 (0.00**
Gastrointestinal disorders									
Abdominal pain † 1									
# participants affected / at risk	**0/66 (0.00%)**	**1/138 (0.72%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Colonic stenosis † 1									
#									

participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	1/247 (0.40%)	0/17 (0.00%)	0/15 (0.00
Lower gastrointestinal haemorrhage † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	1/67 (1.49%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00
Hepatobiliary disorders									
Hepatic cirrhosis † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	1/65 (1.54%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00
Infections and infestations									
Acute tonsillitis † 1									
# participants affected / at risk	1/66 (1.52%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00
Anal abscess † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	1/65 (1.54%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00
Appendicitis † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	1/247 (0.40%)	0/17 (0.00%)	0/15 (0.00
Enterocolitis infectious † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	1/67 (1.49%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00
Pneumonia bacterial † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	1/133 (0.75%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00
Septic shock † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00
Staphylococcal infection † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	1/247 (0.40%)	0/17 (0.00%)	0/15 (0.00
Injury, poisoning and procedural complications									
Injury † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	1/133 (0.75%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00

Muscle injury † [1]									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**1/247 (0.40%)**	**0/17 (0.00%)**	**0/15 (0.00**
Road traffic accident † [1]									
# participants affected / at risk	**0/66 (0.00%)**	**1/138 (0.72%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Upper limb fracture † [1]									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**1/65 (1.54%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Musculoskeletal and connective tissue disorders									
Back pain † [1]									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**1/65 (1.54%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Intervertebral disc disorder † [1]									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**1/65 (1.54%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Rhabdomyolysis † [1]									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**1/247 (0.40%)**	**0/17 (0.00%)**	**0/15 (0.00**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
Bladder cancer † [1]									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**1/247 (0.40%)**	**0/17 (0.00%)**	**0/15 (0.00**
Colon adenoma † [1]									
# participants affected / at risk	**1/66 (1.52%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Colon cancer † [1]									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**1/247 (0.40%)**	**0/17 (0.00%)**	**0/15 (0.00**
Lung neoplasm malignant † [1]									
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**	**0/15 (0.00**
Malignant melanoma in situ † [1]									

# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00
Testis cancer † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	1/247 (0.40%)	0/17 (0.00%)	0/15 (0.00
Renal and urinary disorders									
Nephrolithiasis † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	1/247 (0.40%)	0/17 (0.00%)	0/15 (0.00
Respiratory, thoracic and mediastinal disorders									
Acute respiratory failure † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	1/133 (0.75%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00
Skin and subcutaneous tissue disorders									
Erythrodermic psoriasis † 1									
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	1/133 (0.75%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	1/247 (0.40%)	0/17 (0.00%)	0/15 (0.00
Psoriasis † 1									
# participants affected / at risk	0/66 (0.00%)	1/138 (0.72%)	0/133 (0.00%)	1/67 (1.49%)	0/65 (0.00%)	0/67 (0.00%)	1/247 (0.40%)	0/17 (0.00%)	0/15 (0.00
Vascular disorders									
Hypertensive crisis † 1									
# participants affected / at risk	1/66 (1.52%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)	0/15 (0.00

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

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
INDUCTION: Single	INDUCTION: Early loading induction - 'Early'
INDUCTION: Monthly	INDUCTION: with monthly injections - 'Monthly'
INDUCTION: Early	INDUCTION: with single injection - 'Single'
INDUCTION: Placebo	INDUCTION: Placebo - 'Placebo'
MAINTENANCE: Fixed Interval	MAINTENANCE: Fixed-time interval regimen - 'FI'
MAINTENANCE: Start of Relapse	MAINTENANCE: Treatment at start of relapse regimen - 'SR'
MAINTENANCE: Open Label	MAINTENANCE: Open label Non responders and partial responders at Week 13 and patients who experienced 2 consecutive relapses at scheduled visits from Week 13 onwards were eligible to enter the Open Label phase – "OL": secukinumab (AIN457) 150 mg s.c. administered every 4 weeks.
FOLLOW-UP: Fixed Interval	FOLLOW-UP: Fixed-time interval regimen - 'FI'
FOLLOW-UP: Start of Relapse	FOLLOW-UP: Treatment at start of relapse regimen - 'SR'
FOLLOW-UP: Open Label	FOLLOW-UP: Open label

Other Adverse Events

	INDUCTION: Single	INDUCTION: Monthly	INDUCTION: Early	INDUCTION: Placebo	MAINTENANCE: Fixed Interval	MAINTENANCE: Start of Relapse	MAINTENANCE: Open Label	FOLLOW-UP: Fixed Interval
Total, other (not including serious) adverse events								
# participants affected / at risk	23/66 (34.85%)	53/138 (38.41%)	46/133 (34.59%)	29/67 (43.28%)	16/65 (24.62%)	16/67 (23.88%)	83/247 (33.60%)	3/17 (17.65%)
General disorders								
Inflammation † 1								
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)
Infections and infestations								
Nasopharyngitis † 1								
# participants affected / at risk	8/66 (12.12%)	31/138 (22.46%)	30/133 (22.56%)	12/67 (17.91%)	6/65 (9.23%)	5/67 (7.46%)	35/247 (14.17%)	0/17 (0.00%)
Upper respiratory tract infection † 1								
# participants affected / at risk	3/66 (4.55%)	6/138 (4.35%)	2/133 (1.50%)	6/67 (8.96%)	2/65 (3.08%)	0/67 (0.00%)	17/247 (6.88%)	0/17 (0.00%)
Musculoskeletal and connective tissue disorders								
Arthralgia † 1								
# participants affected / at risk	2/66 (3.03%)	8/138 (5.80%)	0/133 (0.00%)	0/67 (0.00%)	1/65 (1.54%)	1/67 (1.49%)	9/247 (3.64%)	0/17 (0.00%)
Flank pain † 1								
# participants affected / at risk	0/66 (0.00%)	0/138 (0.00%)	0/133 (0.00%)	0/67 (0.00%)	0/65 (0.00%)	0/67 (0.00%)	0/247 (0.00%)	0/17 (0.00%)
Nervous system								

disorders								
Headache † 1								
# participants affected / at risk	**6/66 (9.09%)**	**8/138 (5.80%)**	**11/133 (8.27%)**	**3/67 (4.48%)**	**3/65 (4.62%)**	**1/67 (1.49%)**	**13/247 (5.26%)**	**0/17 (0.00%)**
Migraine with aura † 1								
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**0/133 (0.00%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**0/247 (0.00%)**	**0/17 (0.00%)**
Sinus headache † 1								
# participants affected / at risk	**0/66 (0.00%)**	**0/138 (0.00%)**	**1/133 (0.75%)**	**0/67 (0.00%)**	**0/65 (0.00%)**	**1/67 (1.49%)**	**0/247 (0.00%)**	**1/17 (5.88%)**
Respiratory, thoracic and mediastinal disorders								
Cough † 1								
# participants affected / at risk	**1/66 (1.52%)**	**2/138 (1.45%)**	**4/133 (3.01%)**	**4/67 (5.97%)**	**0/65 (0.00%)**	**0/67 (0.00%)**	**8/247 (3.24%)**	**0/17 (0.00%)**
Skin and subcutaneous tissue disorders								
Psoriasis † 1								
# participants affected / at risk	**6/66 (9.09%)**	**7/138 (5.07%)**	**4/133 (3.01%)**	**6/67 (8.96%)**	**4/65 (6.15%)**	**6/67 (8.96%)**	**16/247 (6.48%)**	**2/17 (11.76%)**
Vascular disorders								
Hypertension † 1								
# participants affected / at risk	**3/66 (4.55%)**	**1/138 (0.72%)**	**2/133 (1.50%)**	**1/67 (1.49%)**	**2/65 (3.08%)**	**5/67 (7.46%)**	**5/247 (2.02%)**	**0/17 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.1

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:

Paul C, Reich K, Gottlieb AB, Mrowietz U, Philipp S, Nakayama J, Harfst E, Guettner A, Papavassilis C; CAIN457A2211 study group. Secukinumab improves hand, foot and nail lesions in moderate-to-severe plaque psoriasis: subanalysis of a randomized, double-blind, placebo-controlled, regimen-finding phase 2 trial. J Eur Acad Dermatol Venereol. 2014 Dec;28(12):1670-5. doi: 10.1111/jdv.12359. Epub 2014 Jan 7.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
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