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Efficacy and Safety of Subcutaneous Secukinumab (AIN457) for Moderate to Severe Chronic Plaque-type Psoriasis Assessing Different Doses and Dose Regimens (SCULPTURE)

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

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

ClinicalTrials.gov Identifier:
NCT01406938

First received: July 12, 2011
Last updated: April 30, 2015
Last verified: April 2015
History of Changes

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Results First Received: February 13, 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: AIN457 150mg Drug: AIN457 300mg

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
966 patients randomized to two groups, induction secukinumab 150 mg or secukinumab 300 mg. Most randomized patients, 928/966 completed the 12-week induction period. 928 completed the induction period, a total of 843 were re-randomized to the maintenance period to either fixed interval dosing or start of relapse dosing at their respective dose level

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
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Participant Flow for 3 periods

Period 1: Induction Period

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**

STARTED	482	484	0	0	0	0
FAS:Patients Assigned Study Treatment	482	483	0	0	0	0
COMPLETED	464	464	0	0	0	0
NOT COMPLETED	18	20	0	0	0	0
Subject/guardian decision	6	8	0	0	0	0
Protocol deviation	1	0	0	0	0	0
Adverse Event	8	9	0	0	0	0
Lack of Efficacy	1	0	0	0	0	0
Lost to Follow-up	2	3	0	0	0	0

Period 2: Maintenance Period

	AIN457150 mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	AIN457 150 mg - Fixed Interval (FI)	AIN457 300 mg FI	AIN457 150 mg- Start of Relapse (SoR)	AIN457 300 mg- SoR
STARTED	0	0	203	217	206	217
FAS: Patients Assigned Treatment Drug	0	0	203	216	206	217
COMPLETED	0	0	186	199	181	201
NOT COMPLETED	0	0	17	18	25	16
Adverse Event	0	0	2	8	4	2
Death	0	0	0	0	1	0
Subject/guardian decision	0	0	11	7	10	7
Protocol Violation	0	0	2	2	2	2
Pregnancy	0	0	0	0	1	0
Lost to Follow-up	0	0	0	0	4	0
Lack of Efficacy	0	0	2	1	3	5

Period 3: Follow up

	AIN457150 mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	AIN457 150 mg - Fixed Interval (FI)	AIN457 300 mg FI	AIN457 150 mg- Start of Relapse (SoR)	AIN457 300 mg- SoR
STARTED	26	23	40	39	40	35
COMPLETED	18	18	32	36	31	32
NOT COMPLETED	8	5	8	3	9	3
Lack of Efficacy	3	2	1	0	0	0
Patient/guardian decision	4	2	4	2	4	1
Protocol Violation	0	0	1	0	0	0
Physician Decision	0	0	2	0	3	1
Lost to Follow-up	1	1	0	1	2	1

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.
The Full analysis set (FAS) was comprised of all patients to whom study treatment had been assigned.

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
Total	Total of all reporting groups

Baseline Measures

	AIN457150 mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	Total
Number of Participants [units: participants]	**482**	**484**	**966**
Age [units: Years] Mean (Standard Deviation)	**45.3 (12.83)**	**46.7 (12.83)**	**46.0 (12.84)**
Gender [units: Participants]			
Female	**177**	**151**	**328**
Male	**305**	**333**	**638**

Outcome Measures

Hide All Outcome Measures

1. Primary: For the Fixed Interval Group and the Start of Relapse (SoR) Group, the Percentage of Participants (Who Responded to Treatment at Week 12) Maintaining a 75% Improvement From Baseline in Psoriasis Area and Severity Index (PASI) Score at Week 52 [Time Frame: Week 40 , week 52]

Measure Type	Primary
Measure Title	For the Fixed Interval Group and the Start of Relapse (SoR) Group, the Percentage of Participants (Who Responded to Treatment at Week 12) Maintaining a 75% Improvement From Baseline in Psoriasis Area and Severity Index (PASI) Score at Week 52
Measure Description	PASI: 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 40 , week 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) - All patients to whom study treatment was assigned.

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150		AIN457		AIN457	

	mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	150 mg - Fixed Interval (FI)	AIN457 300 mg FI	150 mg- Start of Relapse (SoR)	AIN457 300 mg- SoR
Number of Participants Analyzed [units: participants]	**0**	**0**	**203**	**216**	**206**	**217**
For the Fixed Interval Group and the Start of Relapse (SoR) Group, the Percentage of Participants (Who Responded to Treatment at Week 12) Maintaining a 75% Improvement From Baseline in Psoriasis Area and Severity Index (PASI) Score at Week 52 [units: Percent of participants]			**62.1**	**78.2**	**52.4**	**67.7**

No statistical analysis provided for For the Fixed Interval Group and the Start of Relapse (SoR) Group, the Percentage of Participants (Who Responded to Treatment at Week 12) Maintaining a 75% Improvement From Baseline in Psoriasis Area and Severity Index (PASI) Score at Week 52

2. Secondary: Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week 2, 4, 6, 8, 12 [Time Frame: Baseline, week 2, 3 , 4, 8, 12]

Measure Type	Secondary
Measure Title	Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week 2, 4, 6, 8, 12
Measure Description	PASI: 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:01, arms:0.2 body:0.3 legs:0.4)
Time Frame	Baseline, week 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	AIN457 150 mg - Fixed Interval (FI)	AIN457 300 mg FI	AIN457 150 mg- Start of Relapse (SoR)	AIN457 300 mg- SoR
Number of Participants Analyzed [units: participants]	**482**	**483**	**0**	**0**	**0**	**0**
Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week 2, 4, 6, 8, 12 [units: Units on a scale] Mean (Standard Deviation)						
Week 2	**-7.46 (6.338)**	**-9.28 (6.752)**				
Week 3	**-11.13 (7.826)**	**-12.97 (7.826)**				
		-15.90				

Week 4	**-14.18 (8.956)**	**(8.838)**				
Week 8	**-18.69 (10.147)**	**-19.56 (9.356)**				
Week 12	**-20.71 (10.804)**	**-20.89 (9.584)**				

No statistical analysis provided for Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week 2, 4, 6, 8, 12

3. Secondary: Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week at Week 16, 20, 24,28,32,36,40,44,48,and Week 52 [Time Frame: Baseline, week 12,16,20,24,28,32,36,40,44,48 and week 52]

Measure Type	Secondary
Measure Title	Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week at Week 16, 20, 24,28,32,36,40,44,48,and Week 52
Measure Description	PASI: 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:01, arms:0.2 body:0.3 legs:0.4)
Time Frame	Baseline, week 12,16,20,24,28,32,36,40,44,48 and week 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**
Number of Participants Analyzed [units: participants]	**0**	**0**	**203**	**216**	**206**	**217**
Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week at Week 16, 20, 24,28,32,36,40,44,48,and Week 52 [units: Units on a scale] Mean (Standard Deviation)						
Week 12			**-21.52 (9.553)**	**-22.32 (8.943)**	**-23.19 (11.063)**	**-21.58 (9.448)**
Week 16			**-21.23 (9.676)**	**-22.61 (9.310)**	**-23.26 (11.158)**	**-21.58 (9.626)**
Week 20			**-20.79 (9.739)**	**-22.47 (9.237)**	**-22.28 (11.548)**	**-20.97 (9.787)**

Week 24			**-20.61 (9.745)**	**-22.30 (9.262)**	**-21.36 (11.938)**	**-20.09 (9.904)**
Week 28			**-20.29 (9.730)**	**-22.13 (9.244)**	**-20.53 (11.754)**	**-19.27 (9.844)**
Week 32			**-20.11 (9.847)**	**-21.98 (9.195)**	**-19.41 (10.962)**	**-18.68 (9.983)**
Week 36			**-19.82 (9.908)**	**-21.79 (9.324)**	**-18.86 (10.625)**	**-18.14 (9.352)**
Week 40			**-19.51 (9.821)**	**-21.71 (9.369)**	**-18.30 (10.660)**	**-17.89 (9.837)**
Week 44			**-19.40 (9.691)**	**-21.58 (9.398)**	**-17.73 (11.041)**	**-17.03 (9.876)**
Week 48			**-19.04 (10.093)**	**-21.34 (9.681)**	**-17.48 (10.638)**	**-16.58 (9.040)**
Week 52			**-18.79 (9.904)**	**21.47 (9.402)**	**-17.40 (10.719)**	**-16.33 (8.322)**

No statistical analysis provided for Absolute Change From Baseline for PASI 50 / 75 / 90 / 100 and IGA 2011 Score of 0 or 1 at Week at Week 16, 20, 24,28,32,36,40,44,48,and Week 52

4. Secondary: Percent of Participants Achieving Psoriasis Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Induction) [Time Frame: Baseline, week 2, 4, 6, 8, 12]

Measure Type	Secondary
Measure Title	Percent of Participants Achieving Psoriasis Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Induction)
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	Baseline, week 2, 4, 6, 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg-Induction Period Only(IPO)	AIN457 300 mg - IPO	AIN457 150 mg - Fixed Interval (FI)	AIN457 300 mg FI	AIN457 150 mg- Start of Relapse (SoR)	AIN457 300 mg-SoR
Number of Participants Analyzed [units: participants]	482	483	0	0	0	0
Percent of Participants Achieving Psoriasis Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Induction) [units: Percent of participant]						
Week 2 IGA 0/1	1.2	3.1				
Week 2 PASI 75	1.9	5.2				
Week 2 PASI 50	20.2	32.9				
Week 2 PASI 90	0	0.2				
Week 2 PASI 100	0	0.2				
Week 3 IGA 0/1	5.2	9.3				
Week 3 PASI 75	11	19.3				
Week 3 PASI 50	43	63.6				
Week 3 PASI 90	1.5	3.1				
Week 3 PASI 100	0	0.6				
Week 4 IGA 0/1	15.6	25.5				
Week 4 PASI 75	27.9	42.9				
Week 4 PASI 50	66.3	81.8				
Week 4 PASI 90	6.7	13.7				
Week 4 PASI 100	0.4	2.3				
Week 8 IGA 0/1	47.8	59.4				
Week 8 PASI 75	63.8	76.8				
Week 8 PASI 50	88.4	93				
Week 8 PASI 90	32.4	45.8				
Week 8 PASI 100	8.3	13.9				
Week 12 IGA 0/1	62.8	76				
Week 12 PASI 75	84.4	90.1				
Week 12 PASI 50	93.1	96.1				
Week 12 PASI 90	49.3	64.2				
Week 12 PASI 100	16.2	25.7				

No statistical analysis provided for Percent of Participants Achieving Psoriasis Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Induction)

5. Secondary: Percent of Participants Achieving Psoriasis Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Maintenance Period)) [Time Frame: Baseline, week 16,20,24,28,32,36,40,44,48, and Week 52]

Measure Type	Secondary
Measure Title	Percent of Participants Achieving Psoriasis Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Maintenance Period))
Measure Description	The IGA mod 2011 is a static scale, i.e., it refers exclusively to the participant's disease state at the time of the assessments and does not attempt a comparison to any of the participant's previous disease states at prior visits. The score ranges from 0 (clear) to 4 (severe. The score 0 is clear, 1 is almost clear, 2 is mild, 3 is moderate, and 4 is severe
Time Frame	Baseline, week 16,20,24,28,32,36,40,44,48, and Week 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**
Number of Participants Analyzed [units: participants]	**0**	**0**	**203**	**216**	**206**	**217**
Percent of Participants Achieving Psoriasis Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Maintenance Period)) [units: Percent of participants]						
Week 16 IGA 0/1			**70.9**	**82.4**	**74.8**	**83.4**
Week 16 PASI 75			**90.1**	**92.1**	**92.7**	**94.9**
Week 16 PASI 50			**96.1**	**97.7**	**98.1**	**98.2**
Week 16 PASI 90			**59.1**	**75.5**	**68.4**	**76.5**
Week 16 PASI 100			**27.6**	**31.5**	**22.3**	**38.2**
Week 20 IGA 0/1			**69**	**75.5**	**64.6**	**77**
Week 20 PASI 75			**85.7**	**90.3**	**81.6**	**87.1**
Week 20 PASI 50			**94.6**	**97.7**	**92.2**	**97.2**
Week 20 PASI 90			**62.6**	**74.5**	**55.8**	**72.8**
Week 20 PASI 100			**29.1**	**35.6**	**24.8**	**35.5**
Week 24 IGA 0/1			**67.5**	**76.9**	**56.3**	**65.9**
Week 24 PASI 75			**80.3**	**88**	**72.3**	**77.9**
Week 24 PASI 50			**93.1**	**94.9**	**89.3**	**94**
Week 24 PASI 90			**66.5**	**74.1**	**51.5**	**59.9**
Week 24 PASI 100			**29.1**	**36.1**	**19.9**	**26.3**
Week 28 IGA 0/1			**65.5**	**72.7**	**44.7**	**52.5**
Week 28 PASI 75			**77.3**	**85.6**	**65**	**71.4**
Week 28 PASI 50			**92.6**	**93.5**	**87.4**	**94**
Week 28 PASI 90			**60.6**	**70.4**	**40.8**	**50.2**
Week 28 PASI 100			**29.6**	**38**	**15.5**	**23**
Week 32 IGA 0/1			**64**	**74.1**	**33.5**	**46.1**
Week 32 PASI 75			**74.9**	**84.3**	**50.5**	**63.1**
Week 32 PASI 50			**91.1**	**92.6**	**82**	**90.3**
Week 32 PASI 90			**58.6**	**74.1**	**32.5**	**41.5**
Week 32 PASI 100			**30.5**	**38.9**	**10.7**	**15.7**

Week 36 IGA 0/1			**59.6**	**70.4**	**27.2**	**33.6**
Week 36 PASI 75			**71.4**	**82.9**	**45.1**	**58.1**
Week 36 PASI 50			**87.7**	**91.2**	**78.6**	**94**
Week 36 PASI 90			**54.7**	**68.1**	**24.8**	**35.5**
Week 36 PASI 100			**28.6**	**38.9**	**2.9**	**7.4**
Week 40 IGA 0/1			**53.2**	**68.5**	**26.2**	**35.5**
Week 40 PASI 75			**68**	**81.5**	**42.2**	**58.5**
Week 40 PASI 50			**87.7**	**90.7**	**74.8**	**88.9**
Week 40 PASI 90			**52.2**	**68.5**	**18.9**	**26.7**
Week 40 PASI 100			**26.1**	**38**	**1.9**	**7.4**
Week 44 IGA 0/1			**52.7**	**64.8**	**20.4**	**27.6**
Week 44 PASI 75			**66**	**80.1**	**37.4**	**51.2**
Week 44 PASI 50			**84.2**	**92.1**	**72.8**	**82.5**
Week 44 PASI 90			**49.8**	**66.2**	**16.5**	**22.1**
Week 44 PASI 100			**22.7**	**39.8**	**1.5**	**4.6**
Week 48 IGA 0/1			**51.7**	**64.8**	**20.4**	**21.7**
Week 48 PASI 75			**65.5**	**78.7**	**33**	**45.6**
Week 48 PASI 50			**83.3**	**89.8**	**74.8**	**82**
Week 48 PASI 90			**49.8**	**62.5**	**12.6**	**14.7**
Week 48 PASI 100			**21.2**	**38.4**	**1**	**3.7**
Week 52 IGA 0/1			**47.3**	**59.3**	**18**	**20.3**
Week 52 PASI 75			**62.1**	**78.2**	**35**	**41**
Week 52 PASI 50			**83.7**	**87.5**	**73.8**	**81.1**
Week 52 PASI 90			**45.8**	**59.7**	**11.2**	**13.8**
Week 52 PASI 100			**21.2**	**36.6**	**2.4**	**5.1**

No statistical analysis provided for Percent of Participants Achieving Psoriasis Area & Severity Index (PASI) Score and IGA Mod 2011 0 or 1 Score Over Time at Week 12 and 52 (Maintenance Period))

6. Secondary: Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Induction) [Time Frame: Baseline to week 2, 4, 8, 12]

Measure Type	Secondary
Measure Title	Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Induction)
Measure Description	ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five domains are assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with three possible score: 1 indicates no problems, better state of health; 3 indicates worst state of health (example “confined to bed”) A visual analog scale (VAS) assesses the health status from 0 (worst possible health state) to 100 (best possible health state)
Time Frame	Baseline to week 2, 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection

AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	AIN457 150 mg - Fixed Interval (FI)	AIN457 300 mg FI	AIN457 150 mg- Start of Relapse (SoR)	AIN457 300 mg- SoR
Number of Participants Analyzed [units: participants]	**482**	**483**	**0**	**0**	**0**	**0**
Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Induction) [units: Units on a scale] Mean (Standard Deviation)						
Week 2	**5.9 (14.64)**	**7.6 (12.86)**				
Week 4	**10.8 (17.79)**	**13.6 (18.63)**				
Week 8	**17.5 (20.79)**	**18.3 (21.51)**				
Week 12	**20.2 (23.47)**	**21.2 (24.08)**				

No statistical analysis provided for Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Induction)

7. Secondary: Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Maintenance) [Time Frame: Baseline to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 52.]

Measure Type	Secondary
Measure Title	Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Maintenance)
Measure Description	ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five domains are assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with three possible score: 1 indicates no problems, better state of health; 3 indicates worst state of health (example “confined to bed”) A visual analog scale (VAS) assesses the health status from 0 (worst possible health state) to 100 (best possible health state)
Time Frame	Baseline to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	AIN457 150 mg - Fixed Interval (FI)	AIN457 300 mg FI	AIN457 150 mg- Start of Relapse (SoR)	AIN457 300 mg- SoR
Number of Participants Analyzed						

[units: participants]	0	0	203	216	206	217
Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Maintenance) [units: Units on a scale] Mean (Standard Deviation)						
Week 16			**21.4 (25.11)**	**23 (22.44)**	**23.4 (25.31)**	**23.9 (26.09)**
Week 20			**20.6 (25.07)**	**23 (23.27)**	**22.1 (26.04)**	**22.4 (27.45)**
Week 24			**20.6 (25.05)**	**22.9 (23.32)**	**20 (26.66)**	**22.3 (26.47)**
Week 28			**19.4 (26.46)**	**23 (22.71)**	**19.3 (25.07)**	**20.4 (26.26)**
Week 32			**20.4 (24.95)**	**22.8 (23.22)**	**17.9 (24.97)**	**18.8 (25.90)**
Week 36			**19.6 (25.79)**	**23 (22.67)**	**17.4 (24.30)**	**17.7 (26.15)**
Week 40			**19.8 (25.39)**	**22.8 (22.69)**	**16.3 (23.53)**	**16.4 (26.38)**
Week 44			**19.8 (25.53)**	**22.3 (23.10)**	**15.4 (23.70)**	**14.9 (26.81)**
Week 48			**19.7 (25.33)**	**22.7 (22.85)**	**16.2 (23.17)**	**13.4 (26.65)**
Week 52			**18.3 (25.63)**	**23 (22.40)**	**16.7 (23.30)**	**13.4 (25.68)**

No statistical analysis provided for Change From Baseline in EQ-5D at Each Visit, up to Week 52, (Maintenance)

8. Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Induction) [Time Frame: Baseline to week 2, 4, 8, 12]

Measure Type	Secondary
Measure Title	Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Induction)
Measure Description	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions
Time Frame	Baseline to week 2, 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	AIN457 150 mg - Fixed Interval (FI)	AIN457 300 mg FI	AIN457 150 mg- Start of Relapse (SoR)	AIN457 300 mg- SoR
Number of Participants Analyzed [units: participants]	**482**	**483**	**0**	**0**	**0**	**0**
Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Induction) [units: Units on a scale] Mean (Standard Deviation)						
Week 2 DLQI total score	**-5.5 (5.02)**	**-6 (5.10)**				
Week 4 DLQI total score	**-8.2 (6.11)**	**-8.7 (6.29)**				
Week 8 DLQI total score	**-10.2 (6.40)**	**-10.3 (6.73)**				
Week 12 DLQI total score	**-10.8 (6.75)**	**-11 (7.01)**				

No statistical analysis provided for Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Induction)

9. Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Maintenance) [Time Frame: Baseline to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 52.]

Measure Type	Secondary
Measure Title	Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Maintenance)
Measure Description	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions
Time Frame	Baseline to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	AIN457 150 mg - Fixed Interval (FI)	AIN457 300 mg FI	AIN457 150 mg- Start of Relapse (SoR)	AIN457 300 mg- SoR
Number of Participants Analyzed [units: participants]	**0**	**0**	**203**	**216**	**206**	**217**
Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Maintenance)						

[units: Units on a scale] Mean (Standard Deviation)						
Week 16			-11 (6.63)	-11.4 (7.12)	-11.4 (6.98)	-11.3 (7.58)
Week 20			-10.6 (6.50)	-11 (7.18)	-10.6 (7.55)	-11 (7.64)
Week 24			-10.5 (6.67)	-11.1 (7.39)	-10.1 (7.65)	-10.3 (7.71)
Week 28			-10.5 (6.68)	-11 (7.22)	-9.7 (7.39)	-9.5 (7.46)
Week 32			-10.5 (6.76)	-10.9 (7.17)	-8.6 (7.66)	-8.9 (7.61)
Week 36			-10.2 (6.94)	-10.9 (7.30)	-8.6 (7.55)	-8.5 (7.79)
Week 40			-10.1 (6.83)	-10.8 (7.33)	-8.4 (7.22)	-8.5 (7.59)
Week 44			-10.2 (6.72)	-10.8 (7.46)	-8.4 (7.07)	-8.6 (7.29)
Week 48			-10 (6.57)	-10.8 (7.38)	-8.6 (7.41)	7.9 (7.02)
Week 52			-9.8 (7.06)	-10.9 (7.31)	-8.4 (7.46)	-7.6 (7.14)

No statistical analysis provided for Change From Baseline in Dermatology Life Quality Index (DLQI) Score. up to Week 52, (Maintenance)

10. Secondary: % of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Induction) [Time Frame: Baseline to week 2, 4, 6, 8, 12]

Measure Type	Secondary
Measure Title	% of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Induction)
Measure Description	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions
Time Frame	Baseline to week 2, 4, 6, 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**

Number of Participants Analyzed [units: participants]	**482**	**484**	**0**	**0**	**0**	**0**
% of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Induction) [units: Percent of participants]						
Week 2 (n=463,471)	**9.5**	**13.8**				
Week 4 (n=479,482)	**23.2**	**33.2**				
Week 8 (n=479,482)	**44.7**	**52.1**				
Week 12 (n=479,482)	**53.4**	**63.1**				

No statistical analysis provided for % of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Induction)

11. Secondary: % of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Maintenance). [Time Frame: Baseline to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 52]

Measure Type	Secondary
Measure Title	% of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Maintenance).
Measure Description	The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions
Time Frame	Baseline to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**
Number of Participants Analyzed [units: participants]	**0**	**0**	**203**	**216**	**206**	**217**
% of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Maintenance). [units: Percent of participant]						
Week 16 (n=199,209,202,215)			**59.8**	**66.5**	**58.4**	**72.1**
Week 20 (n=202,213,205,217)			**57.4**	**67.6**	**58**	**69.6**
Week 24 (n=202,214,206,217)			**58.4**	**68.7**	**53.9**	**65.4**
Week 28 (n=202,214,206,217)			**57.9**	**70.1**	**47.6**	**51.6**
Week 32 (n=202,214,206,217)			**57.9**	**67.8**	**37.9**	**47.5**

Week 36 (n=202,214,206,217)			**58.4**	**65**	**39.8**	**39.6**
Week 40 (n=202,214,206,217)			**55**	**66.4**	**35**	**42.4**
Week 44 (n=202,214,206,217)			**59.9**	**68.7**	**31.6**	**43.3**
Week 48 (n=202,214,206,217)			**54**	**67.3**	**32**	**40.6**
Week 52 (n=202,214,206,217)			**56.4**	**69.2**	**31.1**	**37.3**

No statistical analysis provided for % of Participants Achieving a DLQI Score of 0 or 1 at Each Visit up to Week 52, (Maintenance).

12. Secondary: Median Time to Relapse (Weeks) From Week 12. [Time Frame: Week 12 to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 52.]

Measure Type	Secondary
Measure Title	Median Time to Relapse (Weeks) From Week 12.
Measure Description	Median time to relapse (weeks) from week 12. Relapse is defined as greater than 50% loss of the maximal PASI improvement from baseline. 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 12 to week 16, 20, 24, 28, 32, 36, 40, 44, 48, and Week 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**
Number of Participants Analyzed [units: participants]	**0**	**0**	**203**	**216**	**206**	**217**
Median Time to Relapse (Weeks) From Week 12. [units: Number of weeks] Median (95% Confidence Interval)			**NA** [1]	**NA** [1]	**NA** [1]	**302** [1]

[1] not estimable due to insufficient events at the time of analysis

No statistical analysis provided for Median Time to Relapse (Weeks) From Week 12.

13. Secondary: Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a Previous Biologic Psoriasis Therapy [Time Frame: Week 12]

Measure Type	Secondary
Measure Title	Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a Previous Biologic Psoriasis Therapy
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	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) - All patients to whom study treatment was assigned, only participants with evaluable data were included

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**
Number of Participants Analyzed [units: participants]	**64**	**74**	**0**	**0**	**0**	**0**
Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a Previous Biologic Psoriasis Therapy [units: Percent of participants]						
Week 12 IGA 0/1	**42.2**	**62.2**				
Week 12 PASI 50	**87.5**	**90.5**				
Week 12 PASI 75	**68.8**	**86.5**				
Week 12 PASI 90	**26.6**	**56.8**				
Week 12 PASI 100	**6.3**	**21.6**				

No statistical analysis provided for Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a Previous Biologic Psoriasis Therapy

14. Secondary: Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a Previous Biologic Psoriasis Therapy [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a Previous Biologic Psoriasis Therapy
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	Week 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) - All patients to whom study treatment was assigned, only participants with evaluable data were included

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**
Number of Participants Analyzed [units: participants]	**0**	**0**	**21**	**36**	**23**	**28**
Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a Previous Biologic Psoriasis Therapy [units: Percent of participants]						
Week 52 IGA 0/1			**42.9**	**66.7**	**4.3**	**14.3**
Week 52 PASI 50			**81**	**86.1**	**60.9**	**75**
Week 52 PASI 75			**47.6**	**77.8**	**21.7**	**32.1**
Week 52 PASI 90			**33.3**	**66.7**	**13**	**7.1**
Week 52 PASI 100			**28.6**	**52.8**	**0**	**3.6**

No statistical analysis provided for Percent of Responders With PASI Equal to or Greater Than 50, PASI 75, PASI 90, PASI 100 and Percent of Responders With IGA Score of 0 or 1 Who Failed to Respond to a Previous Biologic Psoriasis Therapy

15. Secondary: Number of Visits With PASI 50, 75, 90, 100 Score and IGA Mod 2011 0 or 1 [Time Frame: Week 16, 20, 24,28,32,36,40,44,48,and Week 52]

Measure Type	Secondary
Measure Title	Number of Visits With PASI 50, 75, 90, 100 Score and IGA Mod 2011 0 or 1
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	Week 16, 20, 24,28,32,36,40,44,48,and Week 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**
Number of Participants Analyzed [units: participants]	**0**	**0**	**203**	**216**	**206**	**217**
Number of Visits With PASI 50, 75, 90, 100 Score and IGA Mod 2011 0 or 1 [units: Percent of participants]						
PASI 50 Visit 0			**1.5**	**0.9**	**0.5**	**0.5**
PASI 50 Visit 1			**1**	**0.5**	**1.5**	**0.5**
PASI 50 Visit 2			**2.5**	**0.5**	**3.4**	**0.5**
PASI 50 Visit 3			**0.5**	**1.9**	**3.4**	**0.5**
PASI 50 Visit 4			**1.5**	**2.8**	**4.4**	**1.8**
PASI 50 Visit 5			**3.4**	**0.5**	**2.4**	**1.8**
PASI 50 Visit 6			**2.5**	**0.5**	**4.9**	**0.9**
PASI 50 Visit 7			**3**	**3.2**	**6.8**	**5.5**
PASI 50 Visit 8			**3**	**1.9**	**10.2**	**12.4**
PASI 50 Visit 9			**8.4**	**7.9**	**8.7**	**16.6**
PASI 50 Visit 10			**72.9**	**79.6**	**53.9**	**59**
PASI 75 Visit 0			**4.9**	**3.2**	**3.9**	**2.8**
PASI 75 Visit 1			**5.9**	**2.8**	**6.8**	**2.3**
PASI 75 Visit 2			**5.4**	**2.8**	**8.3**	**4.1**
PASI 75 Visit 3			**3**	**3.2**	**7.8**	**6.9**
PASI 75 Visit 4			**4.9**	**1.9**	**11.2**	**8.3**
PASI 75 Visit 5			**3.4**	**1.9**	**10.7**	**10.6**
PASI 75 Visit 6			**4.9**	**1.9**	**11.7**	**8.3**
PASI 75 Visit 7			**4.4**	**3.7**	**9.2**	**11.1**
PASI 75 Visit 8			**2.5**	**4.2**	**9.7**	**18.4**
PASI 75 Visit 9			**7.4**	**8.8**	**10.7**	**15.2**
PASI 75 Visit 10			**53.2**	**65.7**	**10.2**	**12**
PASI 90 Visit 0			**24.6**	**12**	**23.8**	**15.7**
PASI 90 Visit 1			**4.4**	**5.1**	**15**	**7.8**

PASI 90 Visit 2			**2.5**	**3.7**	**8.3**	**12**
PASI 90 Visit 3			**5.4**	**4.2**	**6.8**	**11.1**
PASI 90 Visit 4			**4.4**	**2.3**	**11.2**	**11.1**
PASI 90 Visit 5			**3.9**	**1.4**	**8.7**	**6.5**
PASI 90 Visit 6			**3.4**	**5.1**	**9.7**	**8.8**
PASI 90 Visit 7			**3.9**	**4.6**	**7.3**	**10.6**
PASI 90 Visit 8			**5.4**	**6.5**	**2.9**	**8.3**
PASI 90 Visit 9			**13.8**	**13.4**	**2.9**	**3.7**
PASI 90 Visit 10			**28.1**	**41.7**	**3.4**	**4.6**
PASI 100 Visit 0			**53.2**	**41.2**	**65**	**51.2**
PASI 100 Visit 1			**5.9**	**6.5**	**9.7**	**7.8**
PASI 100 Visit 2			**5.9**	**4.2**	**6.3**	**12.4**
PASI 100 Visit 3			**3.4**	**4.6**	**7.3**	**8.8**
PASI 100 Visit 4			**3.4**	**2.3**	**6.3**	**6.9**
PASI 100 Visit 5			**3**	**5.6**	**2.9**	**6.5**
PASI 100 Visit 6			**4.9**	**5.1**	**1**	**1.8**
PASI 100 Visit 7			**4.4**	**3.7**	**0.5**	**2.3**
PASI 100 Visit 8			**2.5**	**5.6**	**0**	**0.9**
PASI 100 Visit 9			**4.4**	**7.9**	**0**	**0.5**
PASI 100 Visit 10			**8.9**	**13.4**	**1**	**0.9**
IGA mod 2011 0 or 1 response Visit 0			**19.2**	**11.6**	**20.4**	**12**
IGA mod 2011 0 or 1 response Visit 1			**5.4**	**3.7**	**10.2**	**6.5**
IGA mod 2011 0 or 1 response Visit 2			**2**	**3.7**	**9.7**	**7.4**
IGA mod 2011 0 or 1 response Visit 3			**5.4**	**5.1**	**9.2**	**10.6**
IGA mod 2011 0 or 1 response Visit 4			**3.9**	**3.2**	**8.3**	**12**
IGA mod 2011 0 or 1 response Visit 5			**3.4**	**1.9**	**10.2**	**13.8**
IGA mod 2011 0 or 1 response Visit 6			**6.4**	**4.6**	**9.2**	**7.8**
IGA mod 2011 0 or 1 response Visit 7			**6.4**	**3.7**	**7.8**	**10.1**
IGA mod 2011 0 or 1 response Visit 8			**5.9**	**2.8**	**5.8**	**8.3**
IGA mod 2011 0 or 1 response Visit 9			**6.4**	**12.5**	**3.9**	**6**
IGA mod 2011 0 or 1 response Visit 10			**35.5**	**47.2**	**5.3**	**5.5**

No statistical analysis provided for Number of Visits With PASI 50, 75, 90, 100 Score and IGA Mod 2011 0 or 1

16. Secondary: Number of Secukinumab Injections Needed to Regain PASI 75 Response From Start of Relapse After Week 12 [Time Frame: week 16, 20, 24,28,32,36,40,44,48,and Week 52]

Measure Type	Secondary
Measure Title	Number of Secukinumab Injections Needed to Regain PASI 75 Response From Start of Relapse After Week 12
Measure Description	The number of secukinumab injections needed for participants to regain PASI 75 response from the start of relapse after week 12
Time Frame	week 16, 20, 24,28,32,36,40,44,48,and Week 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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	AIN457 300 mg - IPO	AIN457 150 mg - Fixed Interval (FI)	AIN457 300 mg FI	AIN457 150 mg- Start of Relapse (SoR)	AIN457 300 mg- SoR
Number of Participants Analyzed [units: participants]	**0**	**0**	**0**	**0**	**176**	**185**
Number of Secukinumab Injections Needed to Regain PASI 75 Response From Start of Relapse After Week 12 [units: percent of participants]						
SoR: one, Regain PASI 75 Injection 0 (n=97,128)					**4.1**	**0.8**
SoR: one, Regain PASI 75 Injection 1 (n=97,128)					**40.2**	**0**
SoR: one, Regain PASI 75 Injection 2 (n=97,128)					**27.8**	**45.3**
SoR: one, Regain PASI 75 Injection 3 (n=97,128)					**11.3**	**0**
SoR: one, Regain PASI 75 Injection 4 (n=97,128)					**6.2**	**31.3**
SoR: one, Regain PASI 75 Injection 5 (n=97,128)					**4.1**	**0**
SoR: one, Regain PASI 75 Injection 6 (n=97,128)					**4.1**	**14.1**
SoR: one, Regain PASI 75 Injection 7 (n=97,128)					**1**	**0**
SoR: one, Regain PASI 75 Injection 8 (n=97,128)					**1**	**3.1**
SoR: one, Regain PASI 75 Injection 10 (n=97,128)					**0**	**3.9**
SoR: one, Regain PASI 75 Injection 12 (n=97,128)					**0**	**1.6**
SoR: Two, Regain PASI 75 Injection 0 (n=21,36)					**0**	**5.6**
SoR: Two, Regain PASI 75 Injection 1 (n=21,36)					**47.6**	**0**
SoR: Two, Regain PASI 75 Injection 2 (n=21,36)					**42.9**	**58.3**
SoR: Two, Regain PASI 75 Injection 3 (n=21,36)					**4.8**	**0**
SoR: Two, Regain PASI 75 Injection 4 (n=21,36)					**0**	**19.4**
SoR: Two, Regain PASI 75 Injection 6 (n=21,36)					**4.8**	**8.3**
SoR: Two, Regain PASI 75 Injection 8 (n=21,36)					**0**	**8.3**
SoR: Three, Regain PASI 75 Injection 2 (n=0,4)					**NA** [1]	**100**

[1] No evaluable participants

No statistical analysis provided for Number of Secukinumab Injections Needed to Regain PASI 75 Response From Start of Relapse After Week 12

17. Secondary: Number of Participants Developing Anti-secukinumab Antibodies [Time Frame: Baseline, weeks 12, 24, 52 and 60]

Measure Type	Secondary
Measure Title	Number of Participants Developing Anti-secukinumab Antibodies
Measure Description	The development of anti-secunimubab anti-bodies will decrease a participant's ability to respond to secukinumab treatment. The number of participants developing anti-secukinumab anti-bodies was measured from Baseline to week 12, 24, 52 and 8 weeks after treatment at week 60
Time Frame	Baseline, weeks 12, 24, 52 and 60
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) - All patients to whom study treatment was assigned

Reporting Groups

	Description
AIN457150 mg- Induction Period Only(IPO)	secukinumab 150 mg (1 injection per dose) and placebo to secukinumab 150 mg (1 injection per dose). Induction period only (IPO)
AIN457 300 mg - IPO	secukinumab- 2 x 150mg injections per dose
AIN457 150 mg - Fixed Interval (FI)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO (placebo) secukinumab injection
AIN457 300 mg FI	2 s.c. secukinumab 150 mg injections
AIN457 150 mg- Start of Relapse (SoR)	1 s.c. secukinumab 150 mg injection + 1 s.c. PBO secukinumab injection
AIN457 300 mg- SoR	2 s.c. secukinumab 150 mg injections

Measured Values

	AIN457150 mg- Induction Period Only(IPO)	**AIN457 300 mg - IPO**	**AIN457 150 mg - Fixed Interval (FI)**	**AIN457 300 mg FI**	**AIN457 150 mg- Start of Relapse (SoR)**	**AIN457 300 mg- SoR**
Number of Participants Analyzed [units: participants]	**0**	**0**	**203**	**216**	**206**	**217**
Number of Participants Developing Anti-secukinumab Antibodies [units: Number of participants]			**2**	**1**	**1**	**1**

No statistical analysis provided for Number of Participants Developing 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
ENTIRE-AIN457 150mg	ENTIRE-AIN457 150mg
ENTIRE-AIN457 300mg	ENTIRE-AIN457 300mg
ENTIRE-AIN457 150 mg SoR	ENTIRE-AIN457 150 mg SoR
ENTIRE-AIN457 300 mg SoR	ENTIRE-AIN457 300 mg SoR
FOLLOW UP-AIN457 150mg IPO	FOLLOW UP-AIN457 150mg IPO
FOLLOW UP-AIN457 300mg IPO	FOLLOW UP-AIN457 300mg IPO
FOLLOW UP-AIN457 150 mg	FOLLOW UP-AIN457 150 mg

FOLLOW UP-AIN457 300 mg	FOLLOW UP-AIN457 300 mg
FOLLOW UP-AIN457 150 mg SoR	FOLLOW UP-AIN457 150 mg SoR
FOLLOW UP-AIN457 300 mg SoR	FOLLOW UP-AIN457 300 mg SoR

Serious Adverse Events

	INDUCTION-AIN457 150mg	INDUCTION-AIN457 300mg	ENTIRE-AIN457 150mg	ENTIRE-AIN457 300mg	ENTIRE-AIN457 150 mg SoR	ENTIRE-AIN457 300 mg SoR	FOLLOW UP-AIN457 150mg IPO	FOLLOW UP-AIN457 300mg IPO	F UP 15
Total, serious adverse events									
# participants affected / at risk	8/482 (1.66%)	10/484 (2.07%)	12/203 (5.91%)	18/217 (8.29%)	12/205 (5.85%)	14/217 (6.45%)	1/27 (3.70%)	0/23 (0.00%)	2/4(
Cardiac disorders									
ACUTE MYOCARDIAL INFARCTION † 1									
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
ANGINA PECTORIS † 1									
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
AORTIC VALVE INCOMPETENCE † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
ATRIAL FIBRILLATION † 1									
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
CORONARY ARTERY STENOSIS † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
MYOCARDIAL ISCHAEMIA † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PALPITATIONS † 1									
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Congenital, familial and genetic disorders									
FIBROUS DYSPLASIA OF BONE † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
HYDROCELE † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Ear and labyrinth disorders									
VESTIBULAR DISORDER † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Gastrointestinal disorders									
ABDOMINAL PAIN † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4

ABDOMINAL PAIN LOWER † 1									
# participants affected / at risk	**1/482 (0.21%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
ABDOMINAL PAIN UPPER † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
CROHN'S DISEASE † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
GASTROOESOPHAGEAL REFLUX DISEASE † 1									
# participants affected / at risk	**0/482 (0.00%)**	**1/484 (0.21%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
ILEUS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
NAUSEA † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
PANCREATITIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
VOMITING † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
General disorders									
GENERALISED OEDEMA † 1									
# participants affected / at risk	**1/482 (0.21%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
Hepatobiliary disorders									
CHOLECYSTITIS ACUTE † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
CHOLELITHIASIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
HEPATIC CIRRHOSIS † 1									
# participants affected / at risk	**1/482 (0.21%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
HEPATIC STEATOSIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
HEPATITIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
HEPATOTOXICITY † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
LIVER INJURY † 1									
# participants affected / at risk	**0/482 (0.00%)**	**1/484 (0.21%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
PORTAL HYPERTENSION † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**

Infections and infestations									
ABSCESS BACTERIAL † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
ABSCESS OF SALIVARY GLAND † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
APPENDICITIS † 1									
# participants affected / at risk	**1/482 (0.21%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
CELLULITIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**1/4**
CHRONIC TONSILLITIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**1/484 (0.21%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
GROIN ABSCESS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
HELICOBACTER GASTRITIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
HEPATITIS B † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**1/27 (3.70%)**	**0/23 (0.00%)**	**0/4**
INFLUENZA † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
OOPHORITIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
PHARYNGEAL ABSCESS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
PNEUMONIA † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**1/217 (0.46%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
PNEUMONIA VIRAL † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
POST PROCEDURAL INFECTION † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
SEPSIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
TONSILLITIS BACTERIAL † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
VULVAL ABSCESS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**

Injury, poisoning and procedural complications									
CONCUSSION † [1]									
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
FALL † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
FEMUR FRACTURE † [1]									
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
HAND FRACTURE † [1]									
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
LUMBAR VERTEBRAL FRACTURE † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PANCREATIC INJURY † [1]									
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
POST-TRAUMATIC PAIN † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
SPINAL CORD INJURY † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
TENDON RUPTURE † [1]									
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	2/217 (0.92%)	0/27 (0.00%)	0/23 (0.00%)	0/4
THORACIC VERTEBRAL FRACTURE † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Investigations									
URINE ANALYSIS ABNORMAL † [1]									
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Metabolism and nutrition disorders									
GOUT † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Musculoskeletal and connective tissue disorders									
CHONDROMALACIA † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
FRACTURE NONUNION † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
INTERVERTEBRAL DISC PROTRUSION † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4

OSTEOARTHRITIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
BASAL CELL CARCINOMA † 1									
# participants affected / at risk	**0/482 (0.00%)**	**1/484 (0.21%)**	**0/203 (0.00%)**	**2/217 (0.92%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
BENIGN BREAST NEOPLASM † 1									
# participants affected / at risk	**0/482 (0.00%)**	**1/484 (0.21%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
PITUITARY TUMOUR BENIGN † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
Nervous system disorders									
CENTRAL NERVOUS SYSTEM INFLAMMATION † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**1/4**
HAEMORRHAGIC STROKE † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
HYPOAESTHESIA † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
LOSS OF CONSCIOUSNESS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
MULTIPLE SCLEROSIS † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
SCIATICA † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
SYNCOPE † 1									
# participants affected / at risk	**0/482 (0.00%)**	**1/484 (0.21%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
VASCULAR HEADACHE † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
Psychiatric disorders									
ALCOHOL ABUSE † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**1/217 (0.46%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
ALCOHOL WITHDRAWAL SYNDROME † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**
ALCOHOLISM † 1									
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**1/217 (0.46%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**	**0/23 (0.00%)**	**0/4**

DEPRESSION † [1]									
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PANIC ATTACK † [1]									
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Renal and urinary disorders									
CALCULUS URETERIC † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
IGA NEPHROPATHY † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
NEPHROLITHIASIS † [1]									
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
RENAL COLIC † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
RENAL TUBULAR NECROSIS † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Reproductive system and breast disorders									
BENIGN PROSTATIC HYPERPLASIA † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
METRORRHAGIA † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)	0/23 (0.00%)	0/4
VARICOCELE † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
VULVA CYST † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Respiratory, thoracic and mediastinal disorders									
CHRONIC OBSTRUCTIVE PULMONARY DISEASE † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PLEURAL EFFUSION † [1]									
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PLEURISY † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PNEUMONITIS † [1]									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
SLEEP APNOEA SYNDROME † [1]									
# participants	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4

affected / at risk									
Skin and subcutaneous tissue disorders									
DERMAL CYST † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
DERMATITIS CONTACT † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PEMPHIGUS † 1									
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PHOTOSENSITIVITY REACTION † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PSORIASIS † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PUSTULAR PSORIASIS † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
Vascular disorders									
FEMORAL ARTERY OCCLUSION † 1									
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
GRANULOMATOSIS WITH POLYANGIITIS † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
HYPERTENSION † 1									
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4
PERIPHERAL ARTERY STENOSIS † 1									
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)	0/23 (0.00%)	0/4

† 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
ENTIRE-AIN457 150mg	ENTIRE-AIN457 150mg

ENTIRE-AIN457 300mg	ENTIRE-AIN457 300mg
ENTIRE-AIN457 150 mg SoR	ENTIRE-AIN457 150 mg SoR
ENTIRE-AIN457 300 mg SoR	ENTIRE-AIN457 300 mg SoR
FOLLOW UP-AIN457 150mg IPO	FOLLOW UP-AIN457 150mg IPO
FOLLOW UP-AIN457 300mg IPO	FOLLOW UP-AIN457 300mg IPO
FOLLOW UP-AIN457 150 mg	FOLLOW UP-AIN457 150 mg
FOLLOW UP-AIN457 300 mg	FOLLOW UP-AIN457 300 mg
FOLLOW UP-AIN457 150 mg SoR	FOLLOW UP-AIN457 150 mg SoR
FOLLOW UP-AIN457 300 mg SoR	FOLLOW UP-AIN457 300 mg SoR

Other Adverse Events

	INDUCTION-AIN457 150mg	INDUCTION-AIN457 300mg	ENTIRE-AIN457 150mg	ENTIRE-AIN457 300mg	ENTIRE-AIN457 150 mg SoR	ENTIRE-AIN457 300 mg SoR	FOLLOW UP-AIN457 150mg IPO
Total, other (not including serious) adverse events							
# participants affected / at risk	**190/482 (39.42%)**	**178/484 (36.78%)**	**134/203 (66.01%)**	**137/217 (63.13%)**	**120/205 (58.54%)**	**126/217 (58.06%)**	**6/27 (22.22%)**
Blood and lymphatic system disorders							
IRON DEFICIENCY ANAEMIA † 1							
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**
LYMPHADENOPATHY † 1							
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**
Eye disorders							
CATARACT † 1							
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**
CONJUNCTIVITIS † 1							
# participants affected / at risk	**0/482 (0.00%)**	**3/484 (0.62%)**	**3/203 (1.48%)**	**5/217 (2.30%)**	**3/205 (1.46%)**	**3/217 (1.38%)**	**0/27 (0.00%)**
Gastrointestinal disorders							
ABDOMINAL TENDERNESS † 1							
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**1/27 (3.70%)**
APHTHOUS STOMATITIS † 1							
# participants affected / at risk	**2/482 (0.41%)**	**1/484 (0.21%)**	**0/203 (0.00%)**	**2/217 (0.92%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**1/27 (3.70%)**
CONSTIPATION † 1							
# participants affected / at risk	**0/482 (0.00%)**	**2/484 (0.41%)**	**0/203 (0.00%)**	**3/217 (1.38%)**	**2/205 (0.98%)**	**0/217 (0.00%)**	**0/27 (0.00%)**
DIARRHOEA † 1							
# participants affected / at risk	**7/482 (1.45%)**	**8/484 (1.65%)**	**6/203 (2.96%)**	**7/217 (3.23%)**	**8/205 (3.90%)**	**10/217 (4.61%)**	**0/27 (0.00%)**
GASTROOESOPHAGEAL REFLUX DISEASE † 1							
# participants affected / at risk	**2/482 (0.41%)**	**4/484 (0.83%)**	**5/203 (2.46%)**	**4/217 (1.84%)**	**0/205 (0.00%)**	**2/217 (0.92%)**	**0/27 (0.00%)**
HYPERCHLORHYDRIA † 1							
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**

NAUSEA † [1]							
# participants affected / at risk	**10/482 (2.07%)**	**4/484 (0.83%)**	**5/203 (2.46%)**	**3/217 (1.38%)**	**5/205 (2.44%)**	**1/217 (0.46%)**	**0/27 (0.00%)**
TOOTHACHE † [1]							
# participants affected / at risk	**3/482 (0.62%)**	**0/484 (0.00%)**	**4/203 (1.97%)**	**1/217 (0.46%)**	**4/205 (1.95%)**	**2/217 (0.92%)**	**0/27 (0.00%)**
VOMITING † [1]							
# participants affected / at risk	**2/482 (0.41%)**	**3/484 (0.62%)**	**2/203 (0.99%)**	**5/217 (2.30%)**	**1/205 (0.49%)**	**1/217 (0.46%)**	**0/27 (0.00%)**
General disorders							
ASTHENIA † [1]							
# participants affected / at risk	**1/482 (0.21%)**	**3/484 (0.62%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**2/205 (0.98%)**	**3/217 (1.38%)**	**0/27 (0.00%)**
INFLUENZA LIKE ILLNESS † [1]							
# participants affected / at risk	**1/482 (0.21%)**	**0/484 (0.00%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**
INJECTION SITE PAIN † [1]							
# participants affected / at risk	**3/482 (0.62%)**	**4/484 (0.83%)**	**0/203 (0.00%)**	**4/217 (1.84%)**	**3/205 (1.46%)**	**5/217 (2.30%)**	**0/27 (0.00%)**
OEDEMA PERIPHERAL † [1]							
# participants affected / at risk	**4/482 (0.83%)**	**4/484 (0.83%)**	**4/203 (1.97%)**	**3/217 (1.38%)**	**2/205 (0.98%)**	**3/217 (1.38%)**	**1/27 (3.70%)**
PYREXIA † [1]							
# participants affected / at risk	**3/482 (0.62%)**	**0/484 (0.00%)**	**4/203 (1.97%)**	**5/217 (2.30%)**	**5/205 (2.44%)**	**2/217 (0.92%)**	**0/27 (0.00%)**
Infections and infestations							
BRONCHITIS † [1]							
# participants affected / at risk	**3/482 (0.62%)**	**6/484 (1.24%)**	**11/203 (5.42%)**	**7/217 (3.23%)**	**1/205 (0.49%)**	**7/217 (3.23%)**	**1/27 (3.70%)**
EAR INFECTION † [1]							
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**2/217 (0.92%)**	**1/27 (3.70%)**
FOLLICULITIS † [1]							
# participants affected / at risk	**3/482 (0.62%)**	**3/484 (0.62%)**	**2/203 (0.99%)**	**6/217 (2.76%)**	**3/205 (1.46%)**	**6/217 (2.76%)**	**1/27 (3.70%)**
GASTROENTERITIS † [1]							
# participants affected / at risk	**5/482 (1.04%)**	**2/484 (0.41%)**	**7/203 (3.45%)**	**5/217 (2.30%)**	**4/205 (1.95%)**	**5/217 (2.30%)**	**0/27 (0.00%)**
HERPES ZOSTER † [1]							
# participants affected / at risk	**3/482 (0.62%)**	**1/484 (0.21%)**	**3/203 (1.48%)**	**1/217 (0.46%)**	**1/205 (0.49%)**	**2/217 (0.92%)**	**0/27 (0.00%)**
INFLUENZA † [1]							
# participants affected / at risk	**6/482 (1.24%)**	**6/484 (1.24%)**	**9/203 (4.43%)**	**6/217 (2.76%)**	**5/205 (2.44%)**	**8/217 (3.69%)**	**1/27 (3.70%)**
NASOPHARYNGITIS † [1]							
# participants affected / at risk	**48/482 (9.96%)**	**46/484 (9.50%)**	**37/203 (18.23%)**	**36/217 (16.59%)**	**32/205 (15.61%)**	**42/217 (19.35%)**	**0/27 (0.00%)**
ORAL HERPES † [1]							
# participants affected / at risk	**3/482 (0.62%)**	**2/484 (0.41%)**	**2/203 (0.99%)**	**2/217 (0.92%)**	**4/205 (1.95%)**	**2/217 (0.92%)**	**0/27 (0.00%)**
PERIODONTITIS † [1]							
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**2/205 (0.98%)**	**2/217 (0.92%)**	**0/27 (0.00%)**
PHARYNGITIS † [1]							
# participants affected / at risk	**4/482 (0.83%)**	**9/484 (1.86%)**	**8/203 (3.94%)**	**12/217 (5.53%)**	**2/205 (0.98%)**	**7/217 (3.23%)**	**0/27 (0.00%)**

PHARYNGITIS BACTERIAL † [1]							
# participants affected / at risk	**1/482 (0.21%)**	**1/484 (0.21%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**5/217 (2.30%)**	**0/27 (0.00%)**
RHINITIS † [1]							
# participants affected / at risk	**5/482 (1.04%)**	**3/484 (0.62%)**	**4/203 (1.97%)**	**6/217 (2.76%)**	**4/205 (1.95%)**	**4/217 (1.84%)**	**0/27 (0.00%)**
SINUSITIS † [1]							
# participants affected / at risk	**5/482 (1.04%)**	**3/484 (0.62%)**	**3/203 (1.48%)**	**6/217 (2.76%)**	**7/205 (3.41%)**	**4/217 (1.84%)**	**0/27 (0.00%)**
UPPER RESPIRATORY TRACT INFECTION † [1]							
# participants affected / at risk	**17/482 (3.53%)**	**17/484 (3.51%)**	**16/203 (7.88%)**	**16/217 (7.37%)**	**11/205 (5.37%)**	**14/217 (6.45%)**	**0/27 (0.00%)**
VIRAL UPPER RESPIRATORY TRACT INFECTION † [1]							
# participants affected / at risk	**0/482 (0.00%)**	**3/484 (0.62%)**	**3/203 (1.48%)**	**4/217 (1.84%)**	**0/205 (0.00%)**	**5/217 (2.30%)**	**0/27 (0.00%)**
Injury, poisoning and procedural complications							
JOINT DISLOCATION † [1]							
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**0/203 (0.00%)**	**0/217 (0.00%)**	**0/205 (0.00%)**	**0/217 (0.00%)**	**0/27 (0.00%)**
PROCEDURAL PAIN † [1]							
# participants affected / at risk	**2/482 (0.41%)**	**2/484 (0.41%)**	**1/203 (0.49%)**	**0/217 (0.00%)**	**1/205 (0.49%)**	**1/217 (0.46%)**	**0/27 (0.00%)**
Investigations							
GAMMA-GLUTAMYLTRANSFERASE INCREASED † [1]							
# participants affected / at risk	**4/482 (0.83%)**	**3/484 (0.62%)**	**4/203 (1.97%)**	**1/217 (0.46%)**	**5/205 (2.44%)**	**3/217 (1.38%)**	**0/27 (0.00%)**
Metabolism and nutrition disorders							
DIABETES MELLITUS † [1]							
# participants affected / at risk	**5/482 (1.04%)**	**0/484 (0.00%)**	**3/203 (1.48%)**	**1/217 (0.46%)**	**4/205 (1.95%)**	**0/217 (0.00%)**	**0/27 (0.00%)**
DYSLIPIDAEMIA † [1]							
# participants affected / at risk	**5/482 (1.04%)**	**2/484 (0.41%)**	**2/203 (0.99%)**	**1/217 (0.46%)**	**6/205 (2.93%)**	**1/217 (0.46%)**	**0/27 (0.00%)**
HYPERCHOLESTEROLAEMIA † [1]							
# participants affected / at risk	**5/482 (1.04%)**	**5/484 (1.03%)**	**3/203 (1.48%)**	**5/217 (2.30%)**	**3/205 (1.46%)**	**2/217 (0.92%)**	**0/27 (0.00%)**
HYPERGLYCAEMIA † [1]							
# participants affected / at risk	**0/482 (0.00%)**	**0/484 (0.00%)**	**2/203 (0.99%)**	**1/217 (0.46%)**	**1/205 (0.49%)**	**0/217 (0.00%)**	**0/27 (0.00%)**
HYPERLIPIDAEMIA † [1]							
# participants affected / at risk	**2/482 (0.41%)**	**2/484 (0.41%)**	**2/203 (0.99%)**	**6/217 (2.76%)**	**2/205 (0.98%)**	**1/217 (0.46%)**	**0/27 (0.00%)**
HYPERTRIGLYCERIDAEMIA † [1]							
# participants affected / at risk	**2/482 (0.41%)**	**0/484 (0.00%)**	**2/203 (0.99%)**	**0/217 (0.00%)**	**3/205 (1.46%)**	**0/217 (0.00%)**	**0/27 (0.00%)**
Musculoskeletal and connective tissue disorders							
ARTHRALGIA † [1]							
# participants affected / at risk	**9/482 (1.87%)**	**9/484 (1.86%)**	**8/203 (3.94%)**	**11/217 (5.07%)**	**12/205 (5.85%)**	**13/217 (5.99%)**	**0/27 (0.00%)**

BACK PAIN † [1]							
# participants affected / at risk	10/482 (2.07%)	4/484 (0.83%)	12/203 (5.91%)	9/217 (4.15%)	9/205 (4.39%)	7/217 (3.23%)	0/27 (0.00%)
INTERVERTEBRAL DISC PROTRUSION † [1]							
# participants affected / at risk	1/482 (0.21%)	1/484 (0.21%)	3/203 (1.48%)	1/217 (0.46%)	3/205 (1.46%)	1/217 (0.46%)	0/27 (0.00%)
PAIN IN EXTREMITY † [1]							
# participants affected / at risk	6/482 (1.24%)	2/484 (0.41%)	5/203 (2.46%)	4/217 (1.84%)	6/205 (2.93%)	2/217 (0.92%)	0/27 (0.00%)
PSORIATIC ARTHROPATHY † [1]							
# participants affected / at risk	4/482 (0.83%)	1/484 (0.21%)	5/203 (2.46%)	2/217 (0.92%)	6/205 (2.93%)	2/217 (0.92%)	0/27 (0.00%)
SPINAL OSTEOARTHRITIS † [1]							
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
BASAL CELL CARCINOMA † [1]							
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	1/217 (0.46%)	2/205 (0.98%)	0/217 (0.00%)	0/27 (0.00%)
SEBORRHOEIC KERATOSIS † [1]							
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)
Nervous system disorders							
HEADACHE † [1]							
# participants affected / at risk	22/482 (4.56%)	17/484 (3.51%)	14/203 (6.90%)	11/217 (5.07%)	14/205 (6.83%)	11/217 (5.07%)	1/27 (3.70%)
PARAESTHESIA † [1]							
# participants affected / at risk	1/482 (0.21%)	1/484 (0.21%)	2/203 (0.99%)	2/217 (0.92%)	1/205 (0.49%)	0/217 (0.00%)	0/27 (0.00%)
Psychiatric disorders							
INSOMNIA † [1]							
# participants affected / at risk	9/482 (1.87%)	1/484 (0.21%)	6/203 (2.96%)	1/217 (0.46%)	3/205 (1.46%)	1/217 (0.46%)	0/27 (0.00%)
Renal and urinary disorders							
DYSURIA † [1]							
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	1/203 (0.49%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)
GLYCOSURIA † [1]							
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)
KETONURIA † [1]							
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)
Respiratory, thoracic and mediastinal disorders							
COUGH † [1]							
# participants affected / at risk	10/482 (2.07%)	10/484 (2.07%)	13/203 (6.40%)	11/217 (5.07%)	8/205 (3.90%)	8/217 (3.69%)	0/27 (0.00%)
OROPHARYNGEAL PAIN † [1]							
# participants affected / at risk	3/482 (0.62%)	7/484 (1.45%)	3/203 (1.48%)	10/217 (4.61%)	3/205 (1.46%)	7/217 (3.23%)	0/27 (0.00%)
SINUS CONGESTION † [1]							

# participants affected / at risk	6/482 (1.24%)	3/484 (0.62%)	5/203 (2.46%)	1/217 (0.46%)	0/205 (0.00%)	3/217 (1.38%)	0/27 (0.00%)
Skin and subcutaneous tissue disorders							
DERMATITIS † 1							
# participants affected / at risk	1/482 (0.21%)	3/484 (0.62%)	0/203 (0.00%)	5/217 (2.30%)	5/205 (2.44%)	1/217 (0.46%)	0/27 (0.00%)
DERMATITIS CONTACT † 1							
# participants affected / at risk	2/482 (0.41%)	1/484 (0.21%)	3/203 (1.48%)	5/217 (2.30%)	4/205 (1.95%)	3/217 (1.38%)	0/27 (0.00%)
ECZEMA † 1							
# participants affected / at risk	1/482 (0.21%)	6/484 (1.24%)	0/203 (0.00%)	8/217 (3.69%)	1/205 (0.49%)	7/217 (3.23%)	0/27 (0.00%)
ERYTHEMA † 1							
# participants affected / at risk	1/482 (0.21%)	2/484 (0.41%)	1/203 (0.49%)	2/217 (0.92%)	1/205 (0.49%)	2/217 (0.92%)	0/27 (0.00%)
ERYTHRODERMIC PSORIASIS † 1							
# participants affected / at risk	1/482 (0.21%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	1/205 (0.49%)	1/217 (0.46%)	0/27 (0.00%)
PAIN OF SKIN † 1							
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)
PRURITUS † 1							
# participants affected / at risk	20/482 (4.15%)	12/484 (2.48%)	12/203 (5.91%)	13/217 (5.99%)	17/205 (8.29%)	6/217 (2.76%)	0/27 (0.00%)
PSORIASIS † 1							
# participants affected / at risk	1/482 (0.21%)	7/484 (1.45%)	0/203 (0.00%)	3/217 (1.38%)	1/205 (0.49%)	6/217 (2.76%)	0/27 (0.00%)
PUSTULAR PSORIASIS † 1							
# participants affected / at risk	0/482 (0.00%)	1/484 (0.21%)	0/203 (0.00%)	1/217 (0.46%)	0/205 (0.00%)	1/217 (0.46%)	0/27 (0.00%)
SEBORRHOEIC DERMATITIS † 1							
# participants affected / at risk	4/482 (0.83%)	2/484 (0.41%)	5/203 (2.46%)	6/217 (2.76%)	3/205 (1.46%)	1/217 (0.46%)	0/27 (0.00%)
SKIN LESION † 1							
# participants affected / at risk	0/482 (0.00%)	0/484 (0.00%)	0/203 (0.00%)	0/217 (0.00%)	0/205 (0.00%)	0/217 (0.00%)	0/27 (0.00%)
URTICARIA † 1							
# participants affected / at risk	3/482 (0.62%)	4/484 (0.83%)	6/203 (2.96%)	2/217 (0.92%)	1/205 (0.49%)	4/217 (1.84%)	0/27 (0.00%)
Vascular disorders							
HYPERTENSION † 1							
# participants affected / at risk	11/482 (2.28%)	11/484 (2.27%)	9/203 (4.43%)	17/217 (7.83%)	9/205 (4.39%)	12/217 (5.53%)	0/27 (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
A limitation of this study is the lack of a placebo group; however, because the placebo response is very low in psoriasis, it is inappropriate to maintain patients on placebo for 52 weeks. .

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:

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