Clinical trial results:
A randomized, double-blind, placebo controlled, multicenter study of subcutaneous secukinumab in prefilled syringes to demonstrate efficacy after twelve weeks of treatment, and to assess the safety, tolerability, usability and long-term efficacy in patients with chronic plaque-type psoriasis

Summary

EudraCT number	2011-006057-28
Trial protocol	EE DE
Global end of trial date	24 October 2016

Results information

Result version number	v1 (current)
This version publication date	08 November 2017
First version publication date	08 November 2017

Trial information

Trial identification

Sponsor protocol code	CAIN457A2308

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01555125
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	24 October 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 October 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to demonstrate the efficacy of secukinumab (150 mg and 300 mg) in patients with moderate to severe chronic plaque-type psoriasis with respect to both PASI 75 and IGA 0 or 1 response (co-primary endpoints) at Week 12 compared to placebo.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 May 2012
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	2 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 19
Country: Number of subjects enrolled	Estonia: 32
Country: Number of subjects enrolled	France: 30
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	United States: 81
Worldwide total number of subjects	177
EEA total number of subjects	77

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	162
From 65 to 84 years	15
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

"Study terminated by Sponsor" refers to the fact that - as per protocol – patients had to stop participating in the study in a given country where Secukinumab became available following approval.

Pre-assignment

Screening details:

This was a multicenter, randomized, double-blind, placebo-controlled, parallel-group study in patients with moderate to severe chronic, plaque-type psoriasis. There were 177 patients who were randomized and treated.

Period 1

Period 1 title	Induction Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	AIN457 150 mg

Arm description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing

Arm type	Experimental
Investigational medicinal product name	secukinumab 150 mg
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150mg

Arm title	AIN457 300 mg

Arm description:

Patients received two secukinumab 150 mg s.c. injections at each dosing

Arm type	Experimental
Investigational medicinal product name	secukinumab 300 mg
Investigational medicinal product code	AIN457
Other name	secukinumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300mg

Arm title	Placebo

Arm description:

Patients received placebo secukinumab (2 s.c. injections) at each dosing

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	AIN457
Other name	Placebo
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo

Number of subjects in period 1	AIN457 150 mg	AIN457 300 mg	Placebo
Started	59	59	59
Completed	58	56	56
Not completed	1	3	3
Adverse event, serious fatal	1	-	-
Adverse event, non-fatal	-	1	1
Lost to follow-up	-	2	-
Subject/guardian decision	-	-	2

Period 2

Period 2 title	Maintenance Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	AIN457 150 mg

Arm description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing

Arm type	Experimental
Investigational medicinal product name	secukinumab 150 mg
Investigational medicinal product code	AIN457
Other name	Secukinumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

secukinumab 150 mg

Arm title	AIN457 300 mg

Arm description:

Patients received two secukinumab 150 mg s.c. injections at each dosing

Arm type	Experimental
Investigational medicinal product name	secukinumab 300 mg
Investigational medicinal product code	AIN457
Other name	Secukinumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300mg

Arm title	Placebo - AIN457 150mg

Arm description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re- randomized to AIN457 150 mg for the remainder of the study

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	AIN457
Other name	Placebo
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150mg

Arm title	Placebo - AIN457 300mg

Arm description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re- randomized to AIN457 300 mg for the remainder of the study

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	AIN457
Other name	Placebo
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300mg

Number of subjects in period 2	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150mg
Started	58	56	29
Completed	48	52	25
Not completed	10	4	4
Adverse event, serious fatal	-	-	-
Physician decision	-	-	1
Adverse event, non-fatal	1	1	-
Lost to follow-up	2	-	-

Subject/guardian decision	1	2	-
Lack of efficacy	6	1	3

Number of subjects in period 2	Placebo - AIN457 300mg
Started	27
Completed	25
Not completed	2
Adverse event, serious fatal	1
Physician decision	-
Adverse event, non-fatal	-
Lost to follow-up	1
Subject/guardian decision	-
Lack of efficacy	-

Period 3

Period 3 title	Extension
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	AIN457 150 mg

Arm description:

Secukinumab 150 mg regimen group administered secukinumab 150 mg s.c. injection plus a placebo secukinumab s.c. injection at each dosing

Arm type	Experimental
Investigational medicinal product name	secukinumab 150 mg
Investigational medicinal product code	AIN457
Other name	secukinumab 150 mg
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150mg

Arm title	AIN457 300 mg

Arm description:

Secukinumab 300 mg regimen group administered secukinumab 300 mg as 2 s.c. injections of the 150 mg dose at each dosing

Arm type	Experimental
Investigational medicinal product name	secukinumab 300 mg
Investigational medicinal product code	AIN457
Other name	secukinumab 300 mg
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300mg

Arm title	Placebo - AIN457 150mg

Arm description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re- randomized to AIN457 150 mg for the remainder of the study

Arm type	Placebo
Investigational medicinal product name	Placebo - AIN457 150mg
Investigational medicinal product code	AIN457
Other name	Placebo - AIN457 150mg
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150

Arm title	Placebo - AIN457 300mg

Arm description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Arm type	Placebo
Investigational medicinal product name	Placebo - AIN457 300mg
Investigational medicinal product code	AIN457
Other name	Placebo - AIN457 300mg
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300

Number of subjects in period 3[1]	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150mg
Started	46	51	23
Completed	1	0	0
Not completed	45	51	23
Adverse event, non-fatal	1	2	1
Protocol deviation	1	-	-
Technical Problems	1	-	-
Study terminated by sponsor	32	33	16
Lost to follow-up	2	1	2
Subject/guardian decision	1	9	1
Lack of efficacy	7	6	3

Number of subjects in period 3[1]	Placebo - AIN457 300mg
Started	23
Completed	1
Not completed	22
Adverse event, non-fatal	1
Protocol deviation	-
Technical Problems	1
Study terminated by sponsor	20
Lost to follow-up	-
Subject/guardian decision	-
Lack of efficacy	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: The number of subjects reported is correct

Period 4

Period 4 title	Follow-Up Period
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	AIN457 150 mg

Arm description:

Secukinumab 150 mg regimen group administered secukinumab 150 mg s.c. injection plus a placebo secukinumab s.c. injection at each dosing

Arm type	Experimental
Investigational medicinal product name	secukinumab 150 mg
Investigational medicinal product code	AIN457
Other name	secukinumab 150 mg
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150mg

Arm title	AIN457 300 mg

Arm description:

Secukinumab 300 mg regimen group administered secukinumab 300 mg as 2 s.c. injections of the 150 mg dose at each dosing

Arm type	Experimental
Investigational medicinal product name	secukinumab 300 mg
Investigational medicinal product code	AIN457
Other name	secukinumab 300 mg
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300mg

Arm title	Placebo - AIN457 150mg

Arm description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re- randomized to AIN457 150 mg for the remainder of the study

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	AIN457
Other name	Placebo
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo 150mg

Arm title	Placebo - AIN457 300mg

Arm description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Arm type	Placebo
Investigational medicinal product name	Placebo 300mg
Investigational medicinal product code	AIN457
Other name	Placebo 300mg
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300mg

Number of subjects in period 4	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150mg
Started	36	31	19
Completed	32	30	18
Not completed	4	1	1
Lost to follow-up	1	-	-
Subject/guardian decision	3	1	1

Number of subjects in period 4	Placebo - AIN457 300mg
Started	18
Completed	17
Not completed	1
Lost to follow-up	-
Subject/guardian decision	1

Baseline characteristics

Reporting groups	
Reporting group title	AIN457 150 mg
Reporting group description:	
Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing	

Reporting group title	AIN457 300 mg
Reporting group description:	
Patients received two secukinumab 150 mg s.c. injections at each dosing	

Reporting group title	Placebo
Reporting group description:	
Patients received placebo secukinumab (2 s.c. injections) at each dosing	

Reporting group values	AIN457 150 mg	AIN457 300 mg	Placebo
Number of subjects	59	59	59
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	51	58	53
From 65-84 years	8	1	6
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	46	45.1	46.5
standard deviation	± 15.09	± 12.57	± 14.14
Gender, Male/Female Units: Subjects			
Female	19	21	20
Male	40	38	39

Reporting group values	Total		
Number of subjects	177		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		

Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	162		
From 65-84 years	15		
85 years and over	0		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female Units: Subjects			
Female	60		
Male	117		

End points

End points reporting groups

Reporting group title	AIN457 150 mg

Reporting group description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing

Reporting group title	AIN457 300 mg

Reporting group description:

Patients received two secukinumab 150 mg s.c. injections at each dosing

Reporting group title	Placebo

Reporting group description:

Patients received placebo secukinumab (2 s.c. injections) at each dosing

Reporting group title	AIN457 150 mg

Reporting group description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing

Reporting group title	AIN457 300 mg

Reporting group description:

Patients received two secukinumab 150 mg s.c. injections at each dosing

Reporting group title	Placebo - AIN457 150mg

Reporting group description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re- randomized to AIN457 150 mg for the remainder of the study

Reporting group title	Placebo - AIN457 300mg

Reporting group description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re- randomized to AIN457 300 mg for the remainder of the study

Reporting group title	AIN457 150 mg

Reporting group description:

Secukinumab 150 mg regimen group administered secukinumab 150 mg s.c. injection plus a placebo secukinumab s.c. injection at each dosing

Reporting group title	AIN457 300 mg

Reporting group description:

Secukinumab 300 mg regimen group administered secukinumab 300 mg as 2 s.c. injections of the 150 mg dose at each dosing

Reporting group title	Placebo - AIN457 150mg

Reporting group description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re- randomized to AIN457 150 mg for the remainder of the study

Reporting group title	Placebo - AIN457 300mg

Reporting group description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Reporting group title	AIN457 150 mg

Reporting group description:

Secukinumab 150 mg regimen group administered secukinumab 150 mg s.c. injection plus a placebo secukinumab s.c. injection at each dosing

Reporting group title	AIN457 300 mg

Reporting group description:

Secukinumab 300 mg regimen group administered secukinumab 300 mg as 2 s.c. injections of the 150 mg dose at each dosing

Reporting group title	Placebo - AIN457 150mg

Reporting group description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re- randomized to AIN457 150 mg for the remainder of the study

Reporting group title	Placebo - AIN457 300mg

Reporting group description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Subject analysis set title	placebo
Subject analysis set type	Full analysis

Subject analysis set description:

placebo secukinumab (2 s.c. injections) at each dosing

Subject analysis set title	placebo-AIN457 150mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re- randomized to AIN457 150 mg for the remainder of the study

Subject analysis set title	Placebo-AIN457 300mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Subject analysis set title	Placebo - AIN457 300 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Subject analysis set title	Placebo-AIN457 300mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Subject analysis set title	placebo
Subject analysis set type	Full analysis

Subject analysis set description:

placebo secukinumab (2 s.c. injections) at each dosing

Subject analysis set title	placebo
Subject analysis set type	Full analysis

Subject analysis set description:

placebo secukinumab (2 s.c. injections) at each dosing

Subject analysis set title	Placebo-AIN457 300mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Subject analysis set title	placebo
Subject analysis set type	Full analysis

Subject analysis set description:

placebo secukinumab (2 s.c. injections) at each dosing

Subject analysis set title	Placebo - AIN457 300 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Subject analysis set title	Placebo-AIN457 300mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study

Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis

Subject analysis set description:

Full analysis set (FAS) - All patients to whom study treatment was assigned

Primary: Efficacy of secukinumab compared to placebo in subjects with moderate to severe chronic plaque-type psoriasis at week 12 Measure: PASI 75 (psoriasis area and severity index) response"

End point title	Efficacy of secukinumab compared to placebo in subjects with moderate to severe chronic plaque-type psoriasis at week 12 Measure: PASI 75 (psoriasis area and severity index) response"[1]

End point description:

A 75% reduction in the Psoriasis Area and Severity Index (PASI) score (PASI 75) is the current benchmark of primary endpoints for most clinical trials of psoriasis

End point type	Primary

End point timeframe:

12 weeks

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	59	58	59	
Units: Percentage of participants				
number (not applicable)	69.5	75.9	0	

Statistical analyses

Statistical analysis title	secukinumab 150 mg
Comparison groups	AIN457 150 mg v placebo
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Fisher exact

Statistical analysis title	secukinumab 300 mg, placebo
Comparison groups	AIN457 300 mg v placebo
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Fisher exact

Primary: Efficacy of secukinumab compared to placebo in subjects with moderate to severe chronic plaque-type psoriasis Measure:IGA (investigator's global assessment) with a 0 or 1 response at Week 12

End point title	Efficacy of secukinumab compared to placebo in subjects with moderate to severe chronic plaque-type psoriasis Measure:IGA (investigator's global assessment) with a 0 or 1 response at Week 12[2]

End point description:

The IGA scale has been developed based on a previous version of the scale used in secukinumab phase II studies in collaboration with health authorities, in particular the FDA. The explanations/descriptions of the points on the scale have been improved to ensure appropriate differentiation between the points. The IGA used in this study is static, i.e. it refers exclusively to the subject's disease state at the time of the assessments, and does not attempt a comparison with any of the subject's previous disease states, whether at baseline or at a previous visit. IGA has a scale of 0-4 with the lower scores correlating to better performance. A score of 0= clear skin, 1= almost clear skin, 2=mild, 3=moderate,4=severe

End point type	Primary

End point timeframe:

12 weeks

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	59	58	59	
Units: Percentage of Participants				
number (not applicable)	52.5	69	0	

Statistical analyses

Statistical analysis title	Efficacy of secukinumab compared to placebo
Comparison groups	AIN457 150 mg v placebo
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Fisher exact

Statistical analysis title	Efficacy of secukinumab compared to placebo
Comparison groups	AIN457 300 mg v placebo
Number of subjects included in analysis	117
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Fisher exact

Secondary: Absolute change from baseline in Self Injection Assessment Questionnaire (SIAQ) Domain Scores at Week 12

End point title	Absolute change from baseline in Self Injection Assessment Questionnaire (SIAQ) Domain Scores at Week 12[3]

End point description:

The three domains of the POST SIAQ are feelings about injections, self-image, self-confidence, injection-site reactions, ease of use, and satisfaction with self-injection. The SIAQ items are scored on a semantic Likert-type scale where lower numbers indicate a worse experience. Domain scores range from 0 to 10. Subjects self-injecting at this visit completed this SIAQ questionnaire. The POST-SIAQ is taken after the injection at that visit.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	59	59	59	
Units: Score				
arithmetic mean (standard deviation)				
Feelings about injections	1.07 (± 1.912)	0.85 (± 1.685)	0.57 (± 1.509)	
Self confidence	1.10 (± 2.331)	1.08 (± 2.197)	1.26 (± 2.009)	
Satisfaction with self-injection	1.64 (± 2.163)	1.62 (± 2.667)	1.32 (± 2.629)	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline in Self-Injection Assessment Questionnaire (SIAQ) Domain Scores at week 48

End point title	Absolute change from baseline in Self-Injection Assessment Questionnaire (SIAQ) Domain Scores at week 48[4]

End point description:

To measure subject satisfaction with the secukinumab PFS" Pre Filled Syringes. The SIAQ items are scored on a semantic Likert-type scale where lower numbers indicate a worse experience. Domain scores range from 0 to 10. Subjects self-injecting at this visit completed this SIAQ questionnaire. The POST-SIAQ is taken after the injection at that visit.

End point type	Secondary

End point timeframe:

Baseline, Week 48

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo-AIN457 300mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	58	56	29	27
Units: Score				
arithmetic mean (standard deviation)				
Feelings about injections (n=45, 52, 25, 24)	0.93 (± 1.752)	1.01 (± 2.103)	0.63 (± 1.449)	0.76 (± 1.321)
Self-confidence (n=45, 51, 25, 24)	1.63 (± 3.173)	1.24 (± 2.400)	0.97 (± 1.811)	0.94 (± 1.521)
Satisfaction, self-injection (n=43, 50, 25, 23)	1.92 (± 2.239)	2.15 (± 2.673)	1.90 (± 3.250)	0.54 (± 1.840)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with potential use related hazards at week 1

End point title	Percentage of subjects with potential use related hazards at week 1[5]

End point description:

To assess potential use-related hazards with the secukinumab PFS for the subject

End point type	Secondary

End point timeframe:

Week 1

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	59	59	59	
Units: Percentage of participants				
number (not applicable)				
Needle stick in a critical area (n=0,0,0)	0	0	0	
Needle stick in non-critical area (n=0,0,1)	0	0	1.7	
Any part of the device swallowed (n=0,0,0)	0	0	0	
Allergic reaction to devise material (n=0,0,0)	0	0	0	
Pain due to bent needle (n=0,0,0)	0	0	0	
Any breakage of the devise (0,0,0)	0	0	0	
Swallowing of material debris observed (n=0,0,0)	0	0	0	
Any other problem (n=1,0,0)	1.7	0	0	
Less than full dose administered (n=1,0,0)	1.7	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with successful self administration of study drug at week 1

End point title	Percentage of subjects with successful self administration of study drug at week 1[6]

End point description:

To assess the subject’s ability to follow instructions for use with the secukinumab PFS

End point type	Secondary

End point timeframe:

Week 1

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	58	57	59	
Units: Percentage of participants	100	100	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent of Responders with PASI equal to or greater than 50, PASI 75, PASI 90, PASI 100, (induction) with non-responder imputation

End point title	Percent of Responders with PASI equal to or greater than 50, PASI 75, PASI 90, PASI 100, (induction) with non-responder imputation[7]

End point 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.

End point type	Secondary

End point timeframe:

Week 12

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	59	59	59	
Units: Percentage of participants				
number (not applicable)				
Week 12 PASI 75	69.5	75.9	0.0	
Week 12 PASI 50	86.4	87.9	5.1	
Week 12 PASI 90	45.8	60.3	0	
Week 12 PASI 100	8.5	43.1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percent of Responders with PASI equal to or greater than 50, PASI 75, PASI 90, PASI 100, (Maintenance, observed data)

End point title	Percent of Responders with PASI equal to or greater than 50, PASI 75, PASI 90, PASI 100, (Maintenance, observed data)[8]

End point 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.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	59	58	29	27
Units: Percentage of participants				
number (not applicable)				
Week 52 PASI 75	71.4	84.6	72.0	96.0
Week 52 PASI 50	89.8	96.2	84.0	100.0
Week 52 PASI 90	59.2	69.2	64.0	76.0
Week 52 PASI 100	36.7	48.1	52.0	44.0

Statistical analyses

No statistical analyses for this end point

Secondary: Percent of responders with IGA mod 2011 score of 0 or 1, (Maintenance; observed data)

End point title	Percent of responders with IGA mod 2011 score of 0 or 1, (Maintenance; observed data)[9]

End point description:

The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	59	59	29	27
Units: Percentage of participants				
number (not applicable)	51	71.2	72	92

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline for PASI score at Week 12, (induction)

End point title	Absolute change from baseline for PASI score at Week 12, (induction)[10]

End point 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)

End point type	Secondary

End point timeframe:

Week 12

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	59	59	59	
Units: Units on a scale				
arithmetic mean (standard deviation)	-16.33 (± 8.49)	-17.90 (± 8.74)	0.50 (± 7.22)	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline for PASI score over time up to week 52, (Maintenance; observed data)

End point title	Absolute change from baseline for PASI score over time up to week 52, (Maintenance; observed data)[11]

End point 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)

End point type	Secondary

End point timeframe:

Week 52

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	59	58	29	27
Units: Units on a scale				
arithmetic mean (standard deviation)	-16.9 (± 8.27)	-18.7 (± 8.48)	-15.2 (± 5.38)	-20 (± 7.96)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in each IGA mod 2011 category at Week 12, (induction)

End point title	Percentage of participants in each IGA mod 2011 category at Week 12, (induction)[12]

End point description:

The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe

End point type	Secondary

End point timeframe:

Week 12

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	59	58	59	
Units: Percentage of participants				
number (not applicable)				
clear (n=6, 26, 0)	10.2	44.8	0.0	
almost clear (n=26, 17, 0)	44.1	29.3	0.0	
mild (n=12, 9,1)	20.3	15.5	1.7	
moderate (n=14, 5, 34)	23.7	8.6	57.6	
severe (n=1,1, 24)	1.7	1.7	40.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in each IGA mod 2011 category over time up to week 52, (Maintenance; observed data)

End point title	Percentage of participants in each IGA mod 2011 category over time up to week 52, (Maintenance; observed data)[13]

End point description:

The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe.

End point type	Secondary

End point timeframe:

Week 52

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	59	59	29	27
Units: Percentage of participants				
number (not applicable)				
Clear	36.7	48.1	52	44
Almost clear	14.3	23.1	20	48
Mild	18.4	19.2	4	4
Moderate	26.5	9.6	20	4
Severe	4.1	0	4	0

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in EQ-5D at week 12 (induction)

End point title	Change from baseline in EQ-5D at week 12 (induction)[14]

End point 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)

End point type	Secondary

End point timeframe:

Week 12

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	59	59	59	
Units: Units on a scale				
arithmetic mean (standard deviation)	12.1 (± 24.03)	11.2 (± 18.02)	0.8 (± 16.12)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in EQ-5D at week 12 and over time up to week 52, (Maintenance)

End point title	Change from baseline in EQ-5D at week 12 and over time up to week 52, (Maintenance)[15]

End point 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)

End point type	Secondary

End point timeframe:

Week 52

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo-AIN457 300mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	57	57	29	26
Units: Units on a scale				
arithmetic mean (standard deviation)	11.4 (± 24.79)	13.5 (± 15.69)	12.2 (± 15.05)	19.7 (± 17.16)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) total score, (Induction)

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI) total score, (Induction)[16]

End point 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

End point type	Secondary

End point timeframe:

Week 12

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	56	53	54	
Units: Units on a scale				
median (confidence interval 95%)	-78.6 (-85.9 to -67.5)	-85.0 (-90.9 to -77.7)	-16.7 (-25.3 to -3.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) score over time up to week 52, (Maintenance)

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI) score over time up to week 52, (Maintenance)[17]

End point 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

End point type	Secondary

End point timeframe:

Week 52

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo-AIN457 300mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	57	56	29	26
Units: Units on a scale				
median (confidence interval 95%)	-71.4 (-83.3 to -61.9)	-90.5 (-95.7 to -84.2)	-91.7 (-100 to -81.7)	-97.2 (-100 to -83.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a DLQI score of 0 or 1 at week 12, (Induction)

End point title	Percentage of participants achieving a DLQI score of 0 or 1 at week 12, (Induction)[18]

End point 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

End point type	Secondary

End point timeframe:

Week 12

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	57	53	54	
Units: Percentage of participants				
number (not applicable)	54.4	54.7	7.4	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a DLQI score of 0 or 1 over time up to week 52, (Maintenance)

End point title	Percentage of participants achieving a DLQI score of 0 or 1 over time up to week 52, (Maintenance)[19]

End point 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

End point type	Secondary

End point timeframe:

Week 52

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo-AIN457 300mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	28	35	18	20
Units: Percentage of participants				
number (not applicable)	48.3	62.5	62.1	76.9

Statistical analyses

No statistical analyses for this end point

Secondary: Percent of Responders with PASI equal to or greater than 50, PASI 75, PASI 90, PASI 100 after week 52

End point title	Percent of Responders with PASI equal to or greater than 50, PASI 75, PASI 90, PASI 100 after week 52[20]

End point 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.

End point type	Secondary

End point timeframe:

Week 172

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	27	32	13	19
Units: Percentage of participants				
number (not applicable)				
Week 172 PASI 75 (n=26, 25, 9, 17)	96.3	78.1	69.2	89.5
Week 172 PASI 50 (n=27, 32, 12, 18)	100	100	92.3	94.7
Week 172 PASI 90 (14, 21, 9, 11)	51.9	65.6	69.2	57.9

Week 172 PASI 100 (n=6, 16, 6, 7)	22.2	50.0	46.2	36.8

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline for PASI score after Week 52, (observed data)

End point title	Absolute change from baseline for PASI score after Week 52, (observed data)[21]

End point 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)

End point type	Secondary

End point timeframe:

Week 172

Notes:

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	27	32	13	19
Units: Units on a scale				
arithmetic mean (standard deviation)	-18 (± 6.97)	-18.7 (± 8.36)	-14.7 (± 5.97)	-19.4 (± 9.02)

Statistical analyses

No statistical analyses for this end point

Secondary: Percent of participants in each IGA mod 2011 category after Week 52 (observed data)

End point title	Percent of participants in each IGA mod 2011 category after Week 52 (observed data)[22]

End point 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

End point type	Secondary

End point timeframe:

Week 172

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: All arms do not apply to this end point

End point values	AIN457 150 mg	AIN457 300 mg	placebo-AIN457 150mg	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	27	32	13	19
Units: Percentage of participants				
number (not applicable)				
Clear (7, 15, 7, 7)	25.9	46.9	53.8	36.8
Almost clear (n=3,4,1,2)	11.1	12.5	7.7	10.5
Mild (n=16,6,3,6)	59.3	18.8	23.1	31.6
Moderate (n=1,7,1,4)	3.7	21.9	7.7	21.1
Severe (n=0,0,1,0)	0.0	0.0	7.7	0.0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants developing treatment emergent anti-secukinumab antibodies, immunogenicity

End point title	Number of participants developing treatment emergent anti-secukinumab antibodies, immunogenicity

End point 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 8 weeks after last treatment

End point type	Secondary

End point timeframe:

Baseline and at Week 12, 24, 52, 100, 148, and 196, 204

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	placebo-AIN457 150mg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	59	59	3	29
Units: Number of participants	3	0	0	0

End point values	Placebo-AIN457 300mg			
Subject group type	Subject analysis set			
Number of subjects analysed	27			

Units: Number of participants	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups

Reporting group title	Induction AIN457 150 mg

Reporting group description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing

Reporting group title	Induction Placebo

Reporting group description:

placebo secukinumab (2 s.c. injections) at each dosing

Reporting group title	Induction AIN457 300 mg

Reporting group description:

Patients received two secukinumab 150 mg s.c. injections at each dosing

Reporting group title	Entire Any AIN457 300 mg

Reporting group description:

Includes all patients in the AIN457 300 mg and in the placebo- AIN457 300 mg treatment groups

Reporting group title	Entire Any AIN457 150 mg

Reporting group description:

Includes all patients in the AIN457 150 mg and in the placebo- AIN457 150 mg treatment groups

Serious adverse events	Induction AIN457 150 mg	Induction Placebo	Induction AIN457 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 59 (1.69%)	1 / 59 (1.69%)	3 / 59 (5.08%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOSQUAMOUS CELL LUNG CANCER			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLADDER CANCER			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LYMPHOPROLIFERATIVE DISORDER			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
THROMBOSIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
POSTMENOPAUSAL HAEMORRHAGE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
DEPRESSION			

subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ALCOHOL POISONING			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIORBITAL HAEMATOMA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

TACHYCARDIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIZZINESS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOSS OF CONSCIOUSNESS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SCIATICA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
CROHN'S DISEASE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RECTAL HAEMORRHAGE			

subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
DERMATITIS EXFOLIATIVE			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUMBAR SPINAL STENOSIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOARTHRITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
CELLULITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA INFLUENZAL			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPSIS			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC VASCULITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
DIABETES MELLITUS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Entire Any AIN457 300 mg	Entire Any AIN457 150 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	10 / 86 (11.63%)	10 / 88 (11.36%)	
number of deaths (all causes)	1	1	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ADENOSQUAMOUS CELL LUNG CANCER			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
BASAL CELL CARCINOMA			

subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BLADDER CANCER			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHOPROLIFERATIVE DISORDER			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
THROMBOSIS			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
COMPLICATION ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
POSTMENOPAUSAL HAEMORRHAGE			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VAGINAL HAEMORRHAGE			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
DEPRESSION			

subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
ALCOHOL POISONING			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
HIP FRACTURE			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
PERIORBITAL HAEMATOMA			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE CONGESTIVE			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIO-RESPIRATORY ARREST			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
CORONARY ARTERY DISEASE			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

TACHYCARDIA			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIZZINESS			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LOSS OF CONSCIOUSNESS			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SCIATICA			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
CROHN'S DISEASE			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
RECTAL HAEMORRHAGE			

subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
DERMATITIS EXFOLIATIVE			
subjects affected / exposed	0 / 86 (0.00%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUMBAR SPINAL STENOSIS			
subjects affected / exposed	1 / 86 (1.16%)	0 / 88 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
OSTEOARTHRITIS			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
CELLULITIS			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences causally related to treatment / all	0 / 0	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA			

subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONIA INFLUENZAL			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPSIS			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SEPTIC VASCULITIS			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
DIABETES MELLITUS			
subjects affected / exposed	0 / 86 (0.00%)	1 / 88 (1.14%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Induction AIN457 150 mg	Induction Placebo	Induction AIN457 300 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 59 (49.15%)	22 / 59 (37.29%)	24 / 59 (40.68%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MELANOCYTIC NAEVUS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
SKIN PAPILLOMA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
SQUAMOUS CELL CARCINOMA			

subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
HYPERTENSION			
subjects affected / exposed	2 / 59 (3.39%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	2	1	1
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	2 / 59 (3.39%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	2	0	0
FATIGUE			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE OEDEMA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
INJECTION SITE PAIN			
subjects affected / exposed	1 / 59 (1.69%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	4	1	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	1
PYREXIA			
subjects affected / exposed	2 / 59 (3.39%)	2 / 59 (3.39%)	2 / 59 (3.39%)
occurrences (all)	2	2	2
Immune system disorders			
SEASONAL ALLERGY			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

DYSMENORRHOEA			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	2 / 59 (3.39%)
occurrences (all)	0	2	3
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	2 / 59 (3.39%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	2	0	1
DYSPNOEA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	2 / 59 (3.39%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	2	0	1
SINUS CONGESTION			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
WHEEZING			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			
subjects affected / exposed	2 / 59 (3.39%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	2	0	1
INSOMNIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0

BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
VITAMIN D DECREASED			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
FALL			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
LIGAMENT SPRAIN			

subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
MUSCLE STRAIN			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
SKIN ABRASION			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	4 / 59 (6.78%)	4 / 59 (6.78%)	0 / 59 (0.00%)
occurrences (all)	11	4	0
MIGRAINE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
SINUS HEADACHE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
SYNCOPE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			

ANAEMIA			
subjects affected / exposed	2 / 59 (3.39%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	2	0	0
EOSINOPHILIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	1
Eye disorders			
BLEPHARITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
ABDOMINAL PAIN			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 59 (1.69%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	1	1	1
COLITIS			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
CONSTIPATION			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
DENTAL CARIES			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	3 / 59 (5.08%)	1 / 59 (1.69%)	5 / 59 (8.47%)
occurrences (all)	3	1	6
DYSPEPSIA			

subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
FLATULENCE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	3 / 59 (5.08%)
occurrences (all)	0	1	3
TOOTHACHE			
subjects affected / exposed	2 / 59 (3.39%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	2	2	0
VOMITING			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	2 / 59 (3.39%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
ACTINIC KERATOSIS			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
ALOPECIA			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
DERMAL CYST			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
DERMATITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
DERMATITIS CONTACT			

subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	2 / 59 (3.39%)
occurrences (all)	0	0	2
ECZEMA			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
PRURITUS			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	0	1	1
PSORIASIS			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
URTICARIA PAPULAR			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
GLYCOSURIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
HAEMATURIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
BACK PAIN			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	3 / 59 (5.08%)
occurrences (all)	0	0	3
BURSITIS			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	2 / 59 (3.39%)
occurrences (all)	1	0	2
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			

subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
MUSCULAR WEAKNESS			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
MYALGIA			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	1	0	0
NECK PAIN			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	1
PSORIATIC ARTHROPATHY			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
SPINAL PAIN			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
TENDONITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
ABSCESS ORAL			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
ACARODERMATITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
BRONCHITIS			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	0	1	1
CELLULITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

CONJUNCTIVITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
CYSTITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
GASTROENTERITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
INFLUENZA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
LABYRINTHITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	3 / 59 (5.08%)	5 / 59 (8.47%)	3 / 59 (5.08%)
occurrences (all)	4	5	3
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	2
ORAL HERPES			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
OTITIS MEDIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

OTITIS MEDIA BACTERIAL			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
PERIODONTITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	1
PNEUMONIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	2 / 59 (3.39%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	2	0	1
SINUSITIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
SKIN BACTERIAL INFECTION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
TINEA PEDIS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
TONGUE FUNGAL INFECTION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
TONSILLITIS			
subjects affected / exposed	0 / 59 (0.00%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	0	1	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

TOOTH INFECTION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	2 / 59 (3.39%)	1 / 59 (1.69%)	0 / 59 (0.00%)
occurrences (all)	2	1	0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	1
VULVOVAGINAL CANDIDIASIS			
subjects affected / exposed	1 / 59 (1.69%)	0 / 59 (0.00%)	1 / 59 (1.69%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
DIABETES MELLITUS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	2 / 59 (3.39%)	1 / 59 (1.69%)	1 / 59 (1.69%)
occurrences (all)	2	1	1
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
HYPOKALAEMIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
HYPOSIDERAEMIA			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0
TYPE 2 DIABETES MELLITUS			
subjects affected / exposed	0 / 59 (0.00%)	0 / 59 (0.00%)	0 / 59 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Entire Any AIN457 300 mg	Entire Any AIN457 150 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	74 / 86 (86.05%)	70 / 88 (79.55%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
MELANOCYTIC NAEVUS			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	3	0	
SKIN PAPILLOMA			
subjects affected / exposed	2 / 86 (2.33%)	1 / 88 (1.14%)	
occurrences (all)	2	1	
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	3 / 86 (3.49%)	0 / 88 (0.00%)	
occurrences (all)	3	0	
HYPERTENSION			
subjects affected / exposed	3 / 86 (3.49%)	3 / 88 (3.41%)	
occurrences (all)	3	3	
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	1 / 86 (1.16%)	4 / 88 (4.55%)	
occurrences (all)	1	4	
FATIGUE			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
INJECTION SITE OEDEMA			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	2	
INJECTION SITE PAIN			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	6	
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	2 / 86 (2.33%)	2 / 88 (2.27%)	
occurrences (all)	2	2	

OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	2	
PYREXIA			
subjects affected / exposed	3 / 86 (3.49%)	6 / 88 (6.82%)	
occurrences (all)	3	9	
Immune system disorders			
SEASONAL ALLERGY			
subjects affected / exposed	5 / 86 (5.81%)	3 / 88 (3.41%)	
occurrences (all)	5	3	
Reproductive system and breast disorders			
DYSMENORRHOEA			
subjects affected / exposed	3 / 86 (3.49%)	0 / 88 (0.00%)	
occurrences (all)	12	0	
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	9 / 86 (10.47%)	8 / 88 (9.09%)	
occurrences (all)	10	9	
DYSPNOEA			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
NASAL CONGESTION			
subjects affected / exposed	4 / 86 (4.65%)	3 / 88 (3.41%)	
occurrences (all)	4	3	
OROPHARYNGEAL PAIN			
subjects affected / exposed	10 / 86 (11.63%)	5 / 88 (5.68%)	
occurrences (all)	13	5	
SINUS CONGESTION			
subjects affected / exposed	2 / 86 (2.33%)	2 / 88 (2.27%)	
occurrences (all)	2	2	
WHEEZING			
subjects affected / exposed	2 / 86 (2.33%)	2 / 88 (2.27%)	
occurrences (all)	2	2	
Psychiatric disorders			
ANXIETY			

subjects affected / exposed	3 / 86 (3.49%)	3 / 88 (3.41%)	
occurrences (all)	3	4	
DEPRESSION			
subjects affected / exposed	2 / 86 (2.33%)	6 / 88 (6.82%)	
occurrences (all)	2	6	
INSOMNIA			
subjects affected / exposed	1 / 86 (1.16%)	3 / 88 (3.41%)	
occurrences (all)	1	3	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	3	
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	3	
BLOOD TRIGLYCERIDES INCREASED			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	3	
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
HEPATIC ENZYME INCREASED			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	3	0	
VITAMIN D DECREASED			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	5	
WEIGHT DECREASED			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
WEIGHT INCREASED			

subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	2	
CONTUSION			
subjects affected / exposed	1 / 86 (1.16%)	4 / 88 (4.55%)	
occurrences (all)	1	4	
FALL			
subjects affected / exposed	2 / 86 (2.33%)	1 / 88 (1.14%)	
occurrences (all)	2	1	
LIGAMENT SPRAIN			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	2	
LIMB INJURY			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	2	
MUSCLE STRAIN			
subjects affected / exposed	4 / 86 (4.65%)	2 / 88 (2.27%)	
occurrences (all)	4	2	
ROAD TRAFFIC ACCIDENT			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	2	
SKIN ABRASION			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	2	
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	2	
Nervous system disorders			
HEADACHE			
subjects affected / exposed	6 / 86 (6.98%)	5 / 88 (5.68%)	
occurrences (all)	20	34	
MIGRAINE			

subjects affected / exposed	3 / 86 (3.49%)	1 / 88 (1.14%)	
occurrences (all)	3	1	
SCIATICA			
subjects affected / exposed	5 / 86 (5.81%)	0 / 88 (0.00%)	
occurrences (all)	5	0	
SINUS HEADACHE			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
SYNCOPE			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 86 (0.00%)	5 / 88 (5.68%)	
occurrences (all)	0	5	
EOSINOPHILIA			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	3	
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	3 / 86 (3.49%)	2 / 88 (2.27%)	
occurrences (all)	3	3	
Eye disorders			
BLEPHARITIS			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	3	
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
ABDOMINAL PAIN			
subjects affected / exposed	2 / 86 (2.33%)	3 / 88 (3.41%)	
occurrences (all)	9	4	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	4 / 86 (4.65%)	1 / 88 (1.14%)	
occurrences (all)	7	3	
COLITIS			

subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	4	3	
CONSTIPATION			
subjects affected / exposed	2 / 86 (2.33%)	5 / 88 (5.68%)	
occurrences (all)	2	5	
DENTAL CARIES			
subjects affected / exposed	2 / 86 (2.33%)	1 / 88 (1.14%)	
occurrences (all)	2	1	
DIARRHOEA			
subjects affected / exposed	7 / 86 (8.14%)	10 / 88 (11.36%)	
occurrences (all)	16	11	
DYSPEPSIA			
subjects affected / exposed	5 / 86 (5.81%)	2 / 88 (2.27%)	
occurrences (all)	12	2	
FLATULENCE			
subjects affected / exposed	3 / 86 (3.49%)	0 / 88 (0.00%)	
occurrences (all)	7	0	
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	5 / 86 (5.81%)	5 / 88 (5.68%)	
occurrences (all)	5	7	
NAUSEA			
subjects affected / exposed	5 / 86 (5.81%)	4 / 88 (4.55%)	
occurrences (all)	5	5	
TOOTHACHE			
subjects affected / exposed	4 / 86 (4.65%)	10 / 88 (11.36%)	
occurrences (all)	4	12	
VOMITING			
subjects affected / exposed	6 / 86 (6.98%)	4 / 88 (4.55%)	
occurrences (all)	6	4	
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	0 / 86 (0.00%)	3 / 88 (3.41%)	
occurrences (all)	0	3	
ACTINIC KERATOSIS			

subjects affected / exposed	3 / 86 (3.49%)	1 / 88 (1.14%)	
occurrences (all)	5	1	
ALOPECIA			
subjects affected / exposed	3 / 86 (3.49%)	0 / 88 (0.00%)	
occurrences (all)	3	0	
DERMAL CYST			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	2	
DERMATITIS			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	2	2	
DERMATITIS CONTACT			
subjects affected / exposed	5 / 86 (5.81%)	2 / 88 (2.27%)	
occurrences (all)	7	2	
ECZEMA			
subjects affected / exposed	5 / 86 (5.81%)	3 / 88 (3.41%)	
occurrences (all)	5	3	
PRURITUS			
subjects affected / exposed	3 / 86 (3.49%)	2 / 88 (2.27%)	
occurrences (all)	3	2	
PSORIASIS			
subjects affected / exposed	3 / 86 (3.49%)	6 / 88 (6.82%)	
occurrences (all)	3	8	
URTICARIA PAPULAR			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
Renal and urinary disorders			
GLYCOSURIA			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	3	
HAEMATURIA			
subjects affected / exposed	2 / 86 (2.33%)	3 / 88 (3.41%)	
occurrences (all)	2	4	
Musculoskeletal and connective tissue disorders			

ARTHRALGIA				
subjects affected / exposed	11 / 86 (12.79%)	7 / 88 (7.95%)		
occurrences (all)	15	10		
BACK PAIN				
subjects affected / exposed	6 / 86 (6.98%)	4 / 88 (4.55%)		
occurrences (all)	19	6		
BURSITIS				
subjects affected / exposed	3 / 86 (3.49%)	1 / 88 (1.14%)		
occurrences (all)	3	1		
INTERVERTEBRAL DISC PROTRUSION				
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)		
occurrences (all)	2	0		
MUSCLE SPASMS				
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)		
occurrences (all)	2	0		
MUSCULAR WEAKNESS				
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)		
occurrences (all)	0	2		
MYALGIA				
subjects affected / exposed	2 / 86 (2.33%)	3 / 88 (3.41%)		
occurrences (all)	2	3		
NECK PAIN				
subjects affected / exposed	1 / 86 (1.16%)	3 / 88 (3.41%)		
occurrences (all)	1	3		
PAIN IN EXTREMITY				
subjects affected / exposed	6 / 86 (6.98%)	5 / 88 (5.68%)		
occurrences (all)	7	5		
PSORIATIC ARTHROPATHY				
subjects affected / exposed	3 / 86 (3.49%)	2 / 88 (2.27%)		
occurrences (all)	3	2		
SPINAL PAIN				
subjects affected / exposed	3 / 86 (3.49%)	0 / 88 (0.00%)		
occurrences (all)	11	0		
TENDONITIS				

subjects affected / exposed	3 / 86 (3.49%)	2 / 88 (2.27%)	
occurrences (all)	3	2	
Infections and infestations			
ABSCESS ORAL			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
ACARODERMATITIS			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
BRONCHITIS			
subjects affected / exposed	4 / 86 (4.65%)	5 / 88 (5.68%)	
occurrences (all)	5	5	
CELLULITIS			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
CONJUNCTIVITIS			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	2	3	
CYSTITIS			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	2	
EAR INFECTION			
subjects affected / exposed	2 / 86 (2.33%)	1 / 88 (1.14%)	
occurrences (all)	2	1	
FOLLICULITIS			
subjects affected / exposed	2 / 86 (2.33%)	2 / 88 (2.27%)	
occurrences (all)	2	3	
GASTROENTERITIS			
subjects affected / exposed	4 / 86 (4.65%)	5 / 88 (5.68%)	
occurrences (all)	4	5	
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	2	
INFLUENZA			
subjects affected / exposed	6 / 86 (6.98%)	4 / 88 (4.55%)	
occurrences (all)	6	5	

LABYRINTHITIS			
subjects affected / exposed	1 / 86 (1.16%)	3 / 88 (3.41%)	
occurrences (all)	1	3	
NASOPHARYNGITIS			
subjects affected / exposed	17 / 86 (19.77%)	21 / 88 (23.86%)	
occurrences (all)	32	37	
ORAL CANDIDIASIS			
subjects affected / exposed	2 / 86 (2.33%)	1 / 88 (1.14%)	
occurrences (all)	8	1	
ORAL HERPES			
subjects affected / exposed	5 / 86 (5.81%)	0 / 88 (0.00%)	
occurrences (all)	5	0	
OTITIS MEDIA			
subjects affected / exposed	2 / 86 (2.33%)	1 / 88 (1.14%)	
occurrences (all)	2	2	
OTITIS MEDIA BACTERIAL			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	3	
PERIODONTITIS			
subjects affected / exposed	2 / 86 (2.33%)	1 / 88 (1.14%)	
occurrences (all)	2	2	
PHARYNGITIS			
subjects affected / exposed	4 / 86 (4.65%)	3 / 88 (3.41%)	
occurrences (all)	9	3	
PNEUMONIA			
subjects affected / exposed	3 / 86 (3.49%)	0 / 88 (0.00%)	
occurrences (all)	3	0	
RHINITIS			
subjects affected / exposed	5 / 86 (5.81%)	7 / 88 (7.95%)	
occurrences (all)	5	9	
SINUSITIS			
subjects affected / exposed	3 / 86 (3.49%)	7 / 88 (7.95%)	
occurrences (all)	4	8	
SKIN BACTERIAL INFECTION			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	2	

STAPHYLOCOCCAL INFECTION			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
TINEA PEDIS			
subjects affected / exposed	3 / 86 (3.49%)	0 / 88 (0.00%)	
occurrences (all)	3	0	
TONGUE FUNGAL INFECTION			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	
TONSILLITIS			
subjects affected / exposed	2 / 86 (2.33%)	5 / 88 (5.68%)	
occurrences (all)	2	5	
TOOTH ABSCESS			
subjects affected / exposed	2 / 86 (2.33%)	2 / 88 (2.27%)	
occurrences (all)	2	2	
TOOTH INFECTION			
subjects affected / exposed	2 / 86 (2.33%)	3 / 88 (3.41%)	
occurrences (all)	2	3	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	16 / 86 (18.60%)	16 / 88 (18.18%)	
occurrences (all)	30	22	
URINARY TRACT INFECTION			
subjects affected / exposed	4 / 86 (4.65%)	5 / 88 (5.68%)	
occurrences (all)	4	9	
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	3 / 86 (3.49%)	6 / 88 (6.82%)	
occurrences (all)	4	8	
VULVOVAGINAL CANDIDIASIS			
subjects affected / exposed	5 / 86 (5.81%)	2 / 88 (2.27%)	
occurrences (all)	7	3	
Metabolism and nutrition disorders			
DIABETES MELLITUS			
subjects affected / exposed	2 / 86 (2.33%)	3 / 88 (3.41%)	
occurrences (all)	2	3	
HYPERCHOLESTEROLAEMIA			

subjects affected / exposed	2 / 86 (2.33%)	5 / 88 (5.68%)	
occurrences (all)	2	5	
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	1 / 86 (1.16%)	2 / 88 (2.27%)	
occurrences (all)	1	2	
HYPOKALAEMIA			
subjects affected / exposed	0 / 86 (0.00%)	2 / 88 (2.27%)	
occurrences (all)	0	2	
HYPOSIDERAEMIA			
subjects affected / exposed	2 / 86 (2.33%)	1 / 88 (1.14%)	
occurrences (all)	2	2	
TYPE 2 DIABETES MELLITUS			
subjects affected / exposed	2 / 86 (2.33%)	0 / 88 (0.00%)	
occurrences (all)	2	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 March 2012	The opportunity for the patient to enter an extension study instead of a non-treatment follow-up period upon completion of the core study treatment period was described For permitted concomitant medications, the requirement of a stable dose for at least four weeks before Randomization was removed Urine pregnancy testing was clarified as not required for post-menopausal women Procedures at Screening for misrandomized patients were specified Corrections and clarifications were made to the study protocol, including inclusion of immunogenicity and PK sample analysis method and procedures, blinding
20 March 2013	Provided continued treatment for another 156 weeks or until the drug is available in the country of participation for eligible patients who were on active therapy during the Maintenance period Allowed for rescreening of patients, and specified rescreening procedures Specified that at Week 52 the sites will become aware which patients received placebo during the Maintenance period. After the Week 52 data base lock, the study will be open label Introduced home administration of study treatment for certain visits of the extension treatment period Clarified that abnormalities in vital signs or laboratory evaluations did not require protocol specified actions, but actions to be determined by the Investigator Provided instructions to report defects, malfunctions or product complaints of the prefilled syringe

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Efficacy results after Wk 172 can't be interpreted meaningfully due to low # of evaluable patients. As per protocol, availability of AIN457 in participating countries led to discontinuation of most patients before they reached the later visits.

Notes: