Clinical trial results:
A randomized, double-blind, placebo- and active controlled multicenter trial to demonstrate efficacy of subcutaneous secukinumab compared to placebo and etanercept (in a single-blinded arm) after twelve weeks of treatment, and to assess the safety, tolerability, and long-term efficacy in
subjects from 6 to less than 18 years of age with severe chronic plaque psoriasis

Summary

EudraCT number	2014-005663-32
Trial protocol	LV EE DE BE ES HU FR GB PL IT
Global end of trial date	30 March 2023

Results information

Result version number	v1 (current)
This version publication date	15 October 2023
First version publication date	15 October 2023

Trial information

Trial identification

Sponsor protocol code	CAIN457A2310

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02471144
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000380-PIP01-08
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 March 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 March 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the superiority of secukinumab (low and high dose) in pediatric patients with severe chronic plaque psoriasis with respect to both PASI 75 and IGA mod 2011 0/1 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	29 September 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Estonia: 11
Country: Number of subjects enrolled	Latvia: 4
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	Belgium: 7
Country: Number of subjects enrolled	Hungary: 8
Country: Number of subjects enrolled	Israel: 10
Country: Number of subjects enrolled	Poland: 28
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	Guatemala: 10
Country: Number of subjects enrolled	Japan: 5
Country: Number of subjects enrolled	Germany: 25
Country: Number of subjects enrolled	Switzerland: 1
Country: Number of subjects enrolled	Colombia: 9
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Egypt: 11

Country: Number of subjects enrolled	Romania: 4
Country: Number of subjects enrolled	United States: 2
Country: Number of subjects enrolled	Russian Federation: 13
Worldwide total number of subjects	162
EEA total number of subjects	100

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)	37
Adolescents (12-17 years)	125
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in 57 investigative sites in 19 countries.

Pre-assignment

Screening details:

The screening period of up to 4 weeks was used to assess eligibility of the patients and to taper patients off prohibited medications.

Period 1

Period 1 title	Induction Period (Up to Week 12)
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 Low Dose (Induction Period)

Arm description:

Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) at each dosing

Arm type	Experimental
Investigational medicinal product name	AIN457
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) s.c. at each dosing.

Arm title	AIN457 High Dose (Induction Period)

Arm description:

Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) at each dosing

Arm type	Experimental
Investigational medicinal product name	AIN457
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) s.c. at each dosing.

Arm title	Placebo (Induction Period)

Arm description:

Patients received matching placebo to secukinumab at each dosing

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received placebo s.c. at each dosing.

Arm title	Etanercept Comparator (Induction Period)

Arm description:

Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg)

Arm type	Active comparator
Investigational medicinal product name	Etanercept Comparator
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg).

Number of subjects in period 1	AIN457 Low Dose (Induction Period)	AIN457 High Dose (Induction Period)	Placebo (Induction Period)
Started	40	40	41
Completed	39	38	39
Not completed	1	2	2
Adverse Event	-	1	1
Protocol Deviation	-	-	1
Subject/Guardian Decision	1	1	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Etanercept Comparator (Induction Period)
Started	41
Completed	40
Not completed	1
Adverse Event	-
Protocol Deviation	-
Subject/Guardian Decision	-
Lack of efficacy	1

Period 2

Period 2 title	Maintenance Period (Week 12 to Week 52)
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 Low Dose (Maintenance Period)

Arm description:

Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) at each dosing

Arm type	Experimental
Investigational medicinal product name	AIN457
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) s.c. at each dosing.

Arm title	AIN457 High Dose (Maintenance Period)

Arm description:

Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) at each dosing

Arm type	Experimental
Investigational medicinal product name	AIN457
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) s.c. at each dosing.

Arm title	Placebo-AIN457 Low Dose (Maintenance Period)

Arm description:

Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 Low Dose for the remainder of the study

Arm type	Experimental
Investigational medicinal product name	AIN457
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 Low Dose for the remainder of the study.

Arm title	Placebo-AIN457 High Dose (Maintenance Period

Arm description:

Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 High Dose for the remainder of the study

Arm type	Experimental

Investigational medicinal product name	AIN457
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 High Dose for the remainder of the study.

Arm title	Etanercept Comparator (Maintenance Period)

Arm description:

Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg)

Arm type	Active comparator
Investigational medicinal product name	Etanercept Comparator
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg).

Number of subjects in period 2[1]	AIN457 Low Dose (Maintenance Period)	AIN457 High Dose (Maintenance Period)	Placebo-AIN457 Low Dose (Maintenance Period)
Started	39	38	16
Completed	38	37	15
Not completed	1	1	1
Adverse Event	1	-	1
Protocol Deviation	-	-	-
Pregnancy	-	-	-
Lack of efficacy	-	1	-

Number of subjects in period 2[1]	Placebo-AIN457 High Dose (Maintenance Period	Etanercept Comparator (Maintenance Period)
Started	18	40
Completed	16	34
Not completed	2	6
Adverse Event	-	1
Protocol Deviation	2	1
Pregnancy	-	1
Lack of efficacy	-	3

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: Due to change of treatment and/or stopping of arms between periods, the number of subjects starting the period is not consistent with the number completing the preceding period.

Period 3

Period 3 title	Extension Period (Week 52 to Week 236)
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	Any AIN457 Low Dose (Extension Period)

Arm description:

Includes patients from the AIN457 Low Dose and from the Placebo-AIN457 Low Dose groups

Arm type	Experimental
Investigational medicinal product name	AIN457
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) s.c. at each dosing. Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 Low Dose for the remainder of the study.

Arm title	Any AIN457 High Dose (Extension Period)

Arm description:

Includes patients from the AIN457 High Dose and from the Placebo-AIN457 High Dose groups

Arm type	Experimental
Investigational medicinal product name	AIN457
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) s.c. at each dosing. Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 High Dose for the remainder of the study.

Number of subjects in period 3[2]	Any AIN457 Low Dose (Extension Period)	Any AIN457 High Dose (Extension Period)
Started	53	53
Completed	39	43
Not completed	14	10
Technical problems	1	-
Adverse event, non-fatal	2	2
Pregnancy	2	-
Subject/Guardian Decision	3	3
Lost to follow-up	-	2
Lack of efficacy	6	3

Notes:

[2] - 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: Due to change of treatment and/or stopping of arms between periods, the number of subjects starting the period is not consistent with the number completing the preceding period.

Baseline characteristics

Reporting groups	
Reporting group title	AIN457 Low Dose (Induction Period)
Reporting group description:	
Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) at each dosing	
Reporting group title	AIN457 High Dose (Induction Period)
Reporting group description:	
Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) at each dosing	
Reporting group title	Placebo (Induction Period)
Reporting group description:	
Patients received matching placebo to secukinumab at each dosing	
Reporting group title	Etanercept Comparator (Induction Period)
Reporting group description:	
Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg)	

Reporting group values	AIN457 Low Dose (Induction Period)	AIN457 High Dose (Induction Period)	Placebo (Induction Period)
Number of subjects	40	40	41
Age Categorical			
Age Categorical			
Units: Participants			
<12 years	8	9	10
>=12 years	32	31	31
Age Continuous			
Units: Years			
arithmetic mean	13.7	13.2	13.7
standard deviation	± 2.92	± 3.21	± 3.27
Sex: Female, Male			
Units: Participants			
Female	27	23	22
Male	13	17	19
Race/Ethnicity, Customized			
Units: Subjects			
Caucasian	34	34	36
Black	1	1	0
Asian	1	2	1
Native American	3	3	3
Other	1	0	1

Reporting group values	Etanercept Comparator (Induction Period)	Total	
Number of subjects	41	162	
Age Categorical			
Age Categorical			
Units: Participants			
<12 years	10	37	
>=12 years	31	125	

Age Continuous Units: Years			
arithmetic mean	13.5		
standard deviation	± 2.94	-	
Sex: Female, Male Units: Participants			
Female	25	97	
Male	16	65	
Race/Ethnicity, Customized Units: Subjects			
Caucasian	30	134	
Black	0	2	
Asian	3	7	
Native American	8	17	
Other	0	2	

Subject analysis sets

Subject analysis set title	AIN457 Low Dose
Subject analysis set type	Full analysis

Subject analysis set description:

Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) at each dosing

Subject analysis set title	AIN457 High Dose
Subject analysis set type	Full analysis

Subject analysis set description:

Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) at each dosing

Subject analysis set title	Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Patients received matching placebo to secukinumab at each dosing

Subject analysis set title	Etanercept
Subject analysis set type	Full analysis

Subject analysis set description:

Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg)

Subject analysis set title	Placebo - AIN457 Low Dose
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 Low Dose for the remainder of the study

Subject analysis set title	Placebo - AIN457 High Dose
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 High Dose for the remainder of the study

Reporting group values	AIN457 Low Dose	AIN457 High Dose	Placebo
Number of subjects	40	40	41
Age Categorical			
Age Categorical			
Units: Participants			
<12 years	8	9	10

>=12 years	32	31	31

Age Continuous			
Units: Years			
arithmetic mean	13.7	13.2	13.7
standard deviation	± 2.92	± 3.21	± 3.27
Sex: Female, Male			
Units: Participants			
Female	27	23	22
Male	13	17	19
Race/Ethnicity, Customized			
Units: Subjects			
Caucasian	34	34	36
Black	1	1	0
Asian	1	2	1
Native American	3	3	3
Other	1	0	1

Reporting group values	Etanercept	Placebo - AIN457 Low Dose	Placebo - AIN457 High Dose
Number of subjects	41	16	18
Age Categorical			
Age Categorical			
Units: Participants			
<12 years	10		
>=12 years	31		
Age Continuous			
Units: Years			
arithmetic mean	13.5		
standard deviation	± 2.94	±	±
Sex: Female, Male			
Units: Participants			
Female	25		
Male	16		
Race/Ethnicity, Customized			
Units: Subjects			
Caucasian	30		
Black	0		
Asian	3		
Native American	8		
Other	0		

End points

End points reporting groups

Reporting group title	AIN457 Low Dose (Induction Period)
Reporting group description:	
Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) at each dosing	
Reporting group title	AIN457 High Dose (Induction Period)
Reporting group description:	
Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) at each dosing	
Reporting group title	Placebo (Induction Period)
Reporting group description:	
Patients received matching placebo to secukinumab at each dosing	
Reporting group title	Etanercept Comparator (Induction Period)
Reporting group description:	
Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg)	
Reporting group title	AIN457 Low Dose (Maintenance Period)
Reporting group description:	
Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) at each dosing	
Reporting group title	AIN457 High Dose (Maintenance Period)
Reporting group description:	
Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) at each dosing	
Reporting group title	Placebo-AIN457 Low Dose (Maintenance Period)
Reporting group description:	
Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 Low Dose for the remainder of the study	
Reporting group title	Placebo-AIN457 High Dose (Maintenance Period
Reporting group description:	
Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 High Dose for the remainder of the study	
Reporting group title	Etanercept Comparator (Maintenance Period)
Reporting group description:	
Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg)	
Reporting group title	Any AIN457 Low Dose (Extension Period)
Reporting group description:	
Includes patients from the AIN457 Low Dose and from the Placebo-AIN457 Low Dose groups	
Reporting group title	Any AIN457 High Dose (Extension Period)
Reporting group description:	
Includes patients from the AIN457 High Dose and from the Placebo-AIN457 High Dose groups	
Subject analysis set title	AIN457 Low Dose
Subject analysis set type	Full analysis
Subject analysis set description:	
Patients received secukinumab 75mg (if weighing < 50kg) or 150 mg (if weighing >=50 kg) at each dosing	
Subject analysis set title	AIN457 High Dose
Subject analysis set type	Full analysis
Subject analysis set description:	
Patients received secukinumab 75mg (if weighing < 25kg) or 150 mg (if weighing 25 to < 50kg) or 300 mg (if weighing >=50 kg) at each dosing	
Subject analysis set title	Placebo

Subject analysis set type	Safety analysis
Subject analysis set description:	
Patients received matching placebo to secukinumab at each dosing	
Subject analysis set title	Etanercept
Subject analysis set type	Full analysis
Subject analysis set description:	
Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg)	
Subject analysis set title	Placebo - AIN457 Low Dose
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 Low Dose for the remainder of the study	
Subject analysis set title	Placebo - AIN457 High Dose
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Patients received placebo during Induction and if they were PASI 75 non-responders at Week 12 switched to AIN457 High Dose for the remainder of the study	

Primary: Number and Percentage of Participants achieving a 75% Improvement from Baseline in PASI Score at week 12

End point title	Number and Percentage of Participants achieving a 75% Improvement from Baseline in PASI Score at week 12
End point description:	
Psoriasis Area and Severity Index (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, trunk, upper limbs and lower limbs); 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,Thickening (plaque elevation, induration) & Scaling(desquamation). Scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head: 0.1, upper limbs: 0.2 trunk: 0.3 lower limbs: 0.4). Psoriasis Area and Severity Index (PASI) will be assessed/calculated as per standard procedure. PASI 75 represents the percentage (or number) of patients who have achieved a 75% or more reduction in their PASI score from baseline.	
End point type	Primary
End point timeframe:	
12 weeks	

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	41
Units: Participants	32	31	6	26

Statistical analyses

Statistical analysis title	PASI score
Comparison groups	AIN457 Low Dose v Placebo

Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	25.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.08
upper limit	114.66

Statistical analysis title	PASI score
Comparison groups	AIN457 High Dose v Placebo
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	22.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.31
upper limit	98.93

Primary: Number and Percentage of Participants who showed Investigator's Global Assessment (IGA) mod 2011 response of 0 or 1 at week 12

End point title	Number and Percentage of Participants who showed Investigator's Global Assessment (IGA) mod 2011 response of 0 or 1 at week 12

End point description:

IGA: The IGA mod 2011 scale has following different scores for the state of disease: 0: Clear, No signs of psoriasis. 1: Almost clear 2: Mild 3: Moderate 4 : Severe

End point type	Primary

End point timeframe:

12 Weeks

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	40	41
Units: Participants	28	24	2	14

Statistical analyses

Statistical analysis title	Investigator's Global Assessment (IGA)
Comparison groups	AIN457 High Dose v Placebo
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	32.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.48
upper limit	329.52

Statistical analysis title	Investigator's Global Assessment (IGA)
Comparison groups	AIN457 Low Dose v Placebo
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	51.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.02
upper limit	538.64

Secondary: Number and Percentage of Participants achieving a 90% Improvement from baseline in PASI score at week 12

End point title	Number and Percentage of Participants achieving a 90% Improvement from baseline in PASI score at week 12

End point description:

Psoriasis Area and Severity Index (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,

trunk, upper limbs and lower limbs); 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,Thickening (plaque elevation, induration) & Scaling(desquamation). Scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head: 0.1, upper limbs: 0.2 trunk: 0.3 lower limbs: 0.4). Psoriasis Area and Severity Index (PASI) will be assessed/calculated as per standard procedure. PASI 90 represents the percentage (or number) of patients who have achieved a 90% or more reduction in their PASI score from baseline.

End point type	Secondary

End point timeframe:

12 weeks

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	41
Units: Participants	29	27	1	12

Statistical analyses

Statistical analysis title	PASI score
Comparison groups	AIN457 High Dose v Placebo
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	67.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.8
upper limit	80.9

Statistical analysis title	PASI score
Comparison groups	AIN457 Low Dose v Placebo
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	72.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	55.9
upper limit	84.9

Secondary: Number and Percentage of Participants achieving a 50%, 75%, 90% or 100% Improvement from baseline in PASI Score and IGA mod 2011 score of 0 or 1 up to Week 12 (Induction)

End point title	Number and Percentage of Participants achieving a 50%, 75%, 90% or 100% Improvement from baseline in PASI Score and IGA mod 2011 score of 0 or 1 up to Week 12 (Induction)

End point description:

Psoriasis Area and Severity Index (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, trunk, upper limbs and lower limbs); 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, Thickening (plaque elevation, induration) & Scaling(desquamation). Scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head: 0.1, upper limbs: 0.2 trunk: 0.3 lower limbs: 0.4). PASI will be assessed/calculated as per standard procedure. IGA: The IGA mod 2011 scale has following different scores for the state of disease: 0: Clear, No signs of psoriasis. 1: Almost clear 2: Mild 3: Moderate 4 : Severe

End point type	Secondary

End point timeframe:

Weeks 4, 8

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	41
Units: Participants				
Week 4- IGA 0/1	6	13	0	1
Week 4- PASI 50	26	28	6	19
Week 4- PASI 75	13	22	0	5
Week 4- PASI 90	5	9	0	1
Week 4- PASI 100	3	3	0	0
Week 8- IGA 0/1	21	18	0	6
Week 8- PASI 50	32	32	11	30
Week 8- PASI 75	27	26	1	15
Week 8- PASI 90	20	20	0	4
Week 8-PASI 100	9	7	0	2

Statistical analyses

No statistical analyses for this end point

Secondary: Number and Percentage of Participants achieving a 50%, 100% Improvement from baseline in PASI score at week 12

End point title	Number and Percentage of Participants achieving a 50%, 100% Improvement from baseline in PASI score at week 12

End point description:

Psoriasis Area and Severity Index (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, trunk, upper limbs and lower limbs); 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,Thickening (plaque elevation, induration) & Scaling(desquamation). Scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head: 0.1, upper limbs: 0.2 trunk: 0.3 lower limbs: 0.4). Psoriasis Area and Severity Index (PASI) will be assessed/calculated as per standard procedure. PASI 50 represents the percentage (or number) of patients who have achieved a 50% or more reduction in their PASI score from baseline. PASI 100 indicates patients who have achieved a complete resolution of all disease.

End point type	Secondary

End point timeframe:

12 weeks

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	41
Units: Participants				
PASI 50	34	34	9	34
PASI 100	12	11	0	7

Statistical analyses

No statistical analyses for this end point

Secondary: Number and Percentage of Participants achieving a 50%, 75%, 90% or 100% Improvement from baseline in PASI Score and IGA mod 2011 score of 0 or 1 Up to Week 52 (Maintenance)

End point title	Number and Percentage of Participants achieving a 50%, 75%, 90% or 100% Improvement from baseline in PASI Score and IGA mod 2011 score of 0 or 1 Up to Week 52 (Maintenance)

End point description:

Psoriasis Area and Severity Index (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, trunk, upper limbs and lower limbs); 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, Thickening (plaque elevation, induration) & Scaling(desquamation). Scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head: 0.1, upper limbs: 0.2 trunk: 0.3 lower limbs: 0.4). PASI will be assessed/calculated as per standard procedure. IGA: The IGA mod 2011 scale has following different scores for the state of disease: 0: Clear, No signs of psoriasis. 1: Almost clear 2: Mild 3: Moderate 4 : Severe

End point type	Secondary

End point timeframe:

Weeks 16, 20, 24, 36, 48 and 52

End point values	AIN457 Low Dose	AIN457 High Dose	Etanercept	Placebo - AIN457 Low Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	16
Units: Participants				
Week 16- IGA 0/1	32	28	19	5
Week 16- PASI 50	37	35	30	11
Week 16- PASI 75	36	32	26	5
Week 16- PASI 90	33	30	16	4
Week 16- PASI 100	19	14	8	0
Week 20- IGA 0/1	33	28	21	12
Week 20- PASI 50	38	36	32	15
Week 20- PASI 75	38	35	29	13
Week 20- PASI 90	33	30	19	12
Week 20- PASI 100	20	16	8	5
Week 24- IGA 0/1	35	30	20	14
Week 24- PASI 50	38	37	31	15
Week 24- PASI 75	37	35	26	15
Week 24- PASI 90	33	31	19	13
Week 24- PASI 100	22	17	9	7
Week 36- IGA 0/1	32	29	21	14
Week 36- PASI 50	37	37	31	16
Week 36- PASI 75	35	35	26	16
Week 36-PASI 90	32	31	18	10
Week 36-PASI 100	17	20	10	10
Week 48- IGA 0/1	28	28	21	14
Week 48-PASI 50	38	35	31	15
Week 48- PASI 75	35	35	27	14
Week 48- PASI 90	29	30	23	12
Week 48- PASI 100	16	18	12	10
Week 52- 1GA 0/1	29	30	23	14
Week 52- PASI 50	39	37	32	15
Week 52- PASI 75	35	35	28	14
Week 52- PASI 90	30	32	21	13
Week 52- PASI 100	16	19	9	10

End point values	Placebo - AIN457 High Dose			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: Participants				
Week 16- IGA 0/1	8			
Week 16- PASI 50	16			
Week 16- PASI 75	11			

Week 16- PASI 90	7			
Week 16- PASI 100	1			
Week 20- IGA 0/1	13			
Week 20- PASI 50	17			
Week 20- PASI 75	15			
Week 20- PASI 90	12			
Week 20- PASI 100	4			
Week 24- IGA 0/1	14			
Week 24- PASI 50	16			
Week 24- PASI 75	14			
Week 24- PASI 90	12			
Week 24- PASI 100	6			
Week 36- IGA 0/1	14			
Week 36- PASI 50	16			
Week 36- PASI 75	16			
Week 36-PASI 90	7			
Week 36-PASI 100	7			
Week 48- IGA 0/1	14			
Week 48-PASI 50	15			
Week 48- PASI 75	15			
Week 48- PASI 90	14			
Week 48- PASI 100	8			
Week 52- 1GA 0/1	13			
Week 52- PASI 50	17			
Week 52- PASI 75	17			
Week 52- PASI 90	14			
Week 52- PASI 100	10			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area & Severity Index (PASI) score at Week 12

End point title	Change From Baseline in Psoriasis Area & Severity Index (PASI) score at Week 12

End point description:

Psoriasis Area and Severity Index (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, trunk, upper limbs and lower limbs); 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,Thickening (plaque elevation, induration) & Scaling(desquamation). Scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head: 0.1, upper limbs: 0.2 trunk: 0.3 lower limbs: 0.4). Psoriasis Area and Severity Index (PASI) will be assessed/calculated as per standard procedure. PASI 75 represents the percentage (or number)of patients who have achieved a 75% or more reduction in their PASI score from baseline. PASI 100 indicates patients who have achieved a complete resolution of all disease.

End point type	Secondary

End point timeframe:

Week 12

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	39	39	40	41
Units: Scores on a scale				
arithmetic mean (standard deviation)	-22.27 (± 8.518)	-22.67 (± 11.904)	-7.94 (± 9.396)	-20.91 (± 10.055)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants in IGA mod 2011 Score Categories at Week 12

End point title	Percentage of Participants in IGA mod 2011 Score Categories at Week 12

End point description:

IGA: The IGA mod 2011 scale has following different scores for the state of disease: 0: Clear, No signs of psoriasis. 1: Almost clear 2: Mild 3: Moderate 4 : Severe

End point type	Secondary

End point timeframe:

Week 12

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	41
Units: Participants				
Week 12- IGA Category: Clear	12	11	0	7
Week 12- IGA Category: Almost Clear	14	13	2	7
Week 12- IGA Category: Mild Disease	8	7	4	18
Week 12- IGA Category: Moderate Disease	3	4	11	6
Week 12- IGA Category: Severe Disease	2	4	23	3

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Psoriasis Area & Severity Index (PASI) scores at Week 52

End point title	Change From Baseline in Psoriasis Area & Severity Index (PASI) scores at Week 52

End point description:

Psoriasis Area and Severity Index (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, trunk, upper limbs and lower limbs); 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,Thickening (plaque elevation, induration) & Scaling(desquamation). Scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section(head: 0.1, upper limbs: 0.2 trunk: 0.3 lower limbs: 0.4). Psoriasis Area and Severity Index (PASI) will be assessed/calculated as per standard procedure. PASI 75 represents the percentage (or number)of patients who have achieved a 75% or more reduction in their PASI score from baseline. PASI 100 indicates patients who have achieved a complete resolution of all disease.

End point type	Secondary

End point timeframe:

Week 52

End point values	AIN457 Low Dose	AIN457 High Dose	Etanercept	Placebo - AIN457 Low Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	39	39	41	16
Units: Scores on a scale				
arithmetic mean (standard deviation)	-25.26 (± 7.150)	-25.75 (± 8.593)	-21.16 (± 11.779)	-28.49 (± 7.984)

End point values	Placebo - AIN457 High Dose			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: Scores on a scale				
arithmetic mean (standard deviation)	-24.69 (± 5.520)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants in IGA mod 2011 Score Categories at Week 52

End point title	Percentage of Participants in IGA mod 2011 Score Categories at Week 52

End point description:

IGA: The IGA mod 2011 scale has following different scores for the state of disease: 0: Clear, No signs of psoriasis. 1: Almost clear 2: Mild 3: Moderate 4 : Severe

End point type	Secondary

End point timeframe:

Week 52

End point values	AIN457 Low Dose	AIN457 High Dose	Etanercept	Placebo - AIN457 Low Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	16
Units: Participants				
Week 52- IGA Category: Clear	16	20	9	10
Week 52- IGA Category: Almost Clear	13	10	14	4
Week 52- IGA Category: Mild Disease	7	4	9	2
Week 52- IGA Category: Moderate Disease	2	2	4	0
Week 52- IGA Category: Severe Disease	1	3	5	0

End point values	Placebo - AIN457 High Dose			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: Participants				
Week 52- IGA Category: Clear	10			
Week 52- IGA Category: Almost Clear	4			
Week 52- IGA Category: Mild Disease	4			
Week 52- IGA Category: Moderate Disease	0			
Week 52- IGA Category: Severe Disease	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change from Baseline in Children's Dermatology Life Quality Index (cDLQI) score Up to Week 12 (Induction)

End point title	Percentage Change from Baseline in Children's Dermatology Life Quality Index (cDLQI) score Up to Week 12 (Induction)

End point description:

The CDLQI measures functional disability of subjects with dermatological disorders who are less than 18 years of age and it has been utilized as a relevant clinical measure in atopic dermatitis, as well as other dermatitis clinical trials. The CDLQI is a simple, validated, self-administered 10-item questionnaire. The instrument contains six functional scales (i.e., symptoms and feeling, leisure, school or holidays, personal relationships, sleep and treatment). The questions are based on the preceding week to permit accurate recall. For the CDLQI, each question will be answered on a 4-point Likert scale scored from 0 to 3. Seven scores will be derived from the CDLQI: the total score of each of the six dimensions as well as the total score over all items. The higher the score, the more quality of life is impaired.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	41
Units: percentage change of score				
arithmetic mean (standard deviation)				
Week 4	-47.71 (± 45.743)	-50.71 (± 37.003)	1.67 (± 104.216)	-35.13 (± 56.832)
Week 8	-61.60 (± 54.371)	-66.97 (± 32.040)	-17.77 (± 66.451)	-42.73 (± 54.026)
Week 12	-67.43 (± 41.602)	-62.5 (± 50.08)	-18.48 (± 80.018)	-62.80 (± 34.419)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change from Baseline in Children's Dermatology Life Quality Index (cDLQI) score Up to Week 52 (Maintenance)

End point title	Percentage Change from Baseline in Children's Dermatology Life Quality Index (cDLQI) score Up to Week 52 (Maintenance)

End point description:

The CDLQI measures functional disability of subjects with dermatological disorders who are less than 18 years of age and it has been utilized as a relevant clinical measure in atopic dermatitis, as well as other dermatitis clinical trials. The CDLQI is a simple, validated, self-administered 10-item questionnaire. The instrument contains six functional scales (i.e., symptoms and feeling, leisure, school or holidays, personal relationships, sleep and treatment). The questions are based on the preceding week to permit accurate recall. For the CDLQI, each question will be answered on a 4-point Likert scale scored from 0 to 3. Seven scores will be derived from the CDLQI: the total score of each of the six dimensions as well as the total score over all items. The higher the score, the more quality of life is impaired.

End point type	Secondary

End point timeframe:

Weeks 24, 36, 52

End point values	AIN457 Low Dose	AIN457 High Dose	Etanercept	Placebo - AIN457 Low Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	16
Units: percentage change of score				
arithmetic mean (standard deviation)				
Week 24	-73.7 (± 55.02)	-53.9 (± 74.63)	-55.0 (± 44.98)	40.3 (± 477.93)
Week 36	-79.0 (± 31.99)	-56.2 (± 107.65)	-47.7 (± 45.01)	-89.5 (± 19.11)
Week 52	-80.9 (± 39.38)	-58.6 (± 77.56)	-53.4 (± 56.99)	-89.0 (± 15.73)

End point values	Placebo - AIN457 High Dose			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: percentage change of score				
arithmetic mean (standard deviation)				
Week 24	-73.8 (± 53.09)			
Week 36	-69.4 (± 46.46)			
Week 52	-86.0 (± 23.19)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number and Percentage of participants achieving a Children's DLQI score of 0 or 1 over time up to Week 52 (Maintenance)

End point title	Number and Percentage of participants achieving a Children's DLQI score of 0 or 1 over time up to Week 52 (Maintenance)

End point description:

The CDLQI measures functional disability of subjects with dermatological disorders who are less than 18 years of age and it has been utilized as a relevant clinical measure in atopic dermatitis, as well as other dermatitis clinical trials. The CDLQI is a simple, validated, self-administered 10-item questionnaire. The instrument contains six functional scales (i.e., symptoms and feeling, leisure, school or holidays, personal relationships, sleep and treatment). The questions are based on the preceding week to permit accurate recall. For the CDLQI, each question will be answered on a 4-point Likert scale scored from 0 to 3. Seven scores will be derived from the CDLQI: the total score of each of the six dimensions as well as the total score over all items. The higher the score, the more quality of life is impaired.

End point type	Secondary

End point timeframe:

Weeks 24, 36, 52

End point values	AIN457 Low Dose	AIN457 High Dose	Etanercept	Placebo - AIN457 Low Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	16
Units: Participants				
Week 24	19	17	17	8
Week 36	21	21	12	9
Week 52	20	22	16	8

End point values	Placebo - AIN457 High Dose			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: Participants				
Week 24	9			
Week 36	8			
Week 52	11			

Statistical analyses

No statistical analyses for this end point

Secondary: Number and Percentage of participants achieving a Children's DLQI score of 0 or 1 over time up to Week 12 (Induction)

End point title	Number and Percentage of participants achieving a Children's DLQI score of 0 or 1 over time up to Week 12 (Induction)

End point description:

The CDLQI measures functional disability of subjects with dermatological disorders who are less than 18 years of age and it has been utilized as a relevant clinical measure in atopic dermatitis, as well as other dermatitis clinical trials. The CDLQI is a simple, validated, self-administered 10-item questionnaire. The instrument contains six functional scales (i.e., symptoms and feeling, leisure, school or holidays, personal relationships, sleep and treatment). The questions are based on the preceding week to permit accurate recall. For the CDLQI, each question will be answered on a 4-point Likert scale scored from 0 to 3. Seven scores will be derived from the CDLQI: the total score of each of the six dimensions as well as the total score over all items. The higher the score, the more quality of life is impaired.

End point type	Secondary

End point timeframe:

Weeks 4, 8, 12

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	40	41	41
Units: Participants				
Week 4	8	11	2	9
Week 8	15	19	7	10
Week 12	17	19	6	15

Statistical analyses

No statistical analyses for this end point

Secondary: Number and Percentage of participants with clinically important reduction in disability as evaluated by CHAQ questionnaire over time at Week 12

End point title	Number and Percentage of participants with clinically important reduction in disability as evaluated by CHAQ questionnaire over

	time at Week 12

End point description:

The CHAQ questionnaire is only done for children who in addition to psoriasis are also suffering from psoriatic arthritis. The questionnaire is completed by parent or legal guardian. It consists of multiple choice items concerning difficulty in performing eight common activities of daily living; dressing and grooming, arising, eating, walking, reaching, personal hygiene, gripping and other "activities". The person completing the questionnaire chooses from four response categories, ranging from 'without any difficulty' to 'unable to do'. Additionally two visual analog scales (overall well-being and pain of patient) must be performed.

End point type	Secondary

End point timeframe:

Week 12

End point values	AIN457 Low Dose	AIN457 High Dose	Placebo	Etanercept
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	2	2	3
Units: Participants	2	0	0	2

Statistical analyses

No statistical analyses for this end point

Secondary: Number and Percentage of participants with clinically important reduction in disability as evaluated by CHAQ questionnaire over time at Week 52

End point title	Number and Percentage of participants with clinically important reduction in disability as evaluated by CHAQ questionnaire over time at Week 52

End point description:

The CHAQ questionnaire is only done for children who in addition to psoriasis are also suffering from psoriatic arthritis. The questionnaire is completed by parent or legal guardian. It consists of multiple choice items concerning difficulty in performing eight common activities of daily living; dressing and grooming, arising, eating, walking, reaching, personal hygiene, gripping and other "activities". The person completing the questionnaire chooses from four response categories, ranging from 'without any difficulty' to 'unable to do'. Additionally two visual analog scales (overall well-being and pain of patient) must be performed.

End point type	Secondary

End point timeframe:

Week 52

End point values	AIN457 Low Dose	AIN457 High Dose	Etanercept	Placebo - AIN457 Low Dose
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	1	3	2
Units: Participants	2	0	2	1

End point values	Placebo - AIN457 High Dose			
Subject group type	Subject analysis set			
Number of subjects analysed	1			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from first dose until end of study treatment plus 16 weeks post-treatment follow-up period. In total up to 252 weeks for AIN457 low and high dose, 28 weeks for Placebo and 68 weeks for Etanercept).

Adverse event reporting additional description:

Adverse Events are reported according to the actual treatment received at the onset of the AE.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Any AIN457 low dose

Reporting group description:

Includes patients from the AIN457 Low Dose and from the Placebo-AIN457 Low Dose groups.
AEs were collected for up to 252 weeks.

Reporting group title	Any AIN457 high dose

Reporting group description:

Includes patients from the AIN457 High Dose and from the Placebo-AIN457 High Dose groups.
AEs were collected for up to 252 weeks.

Reporting group title	Etanercept

Reporting group description:

Patients received weekly open label etanercept 0.8 mg/kg of body weight (up to a maximum of 50 mg).
AEs were collected for up to 68 weeks.

Reporting group title	Placebo

Reporting group description:

Patients received matching placebo to secukinumab at each dosing.
AEs were collected for up to 28 weeks (12 weeks if participant switched to AIN457 at week 12).

Reporting group title	Any AIN457 dose

Reporting group description:

Any AIN457 dose
AEs were collected for up to 252 weeks.

Serious adverse events	Any AIN457 low dose	Any AIN457 high dose	Etanercept
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 56 (12.50%)	8 / 58 (13.79%)	6 / 41 (14.63%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Thrombophlebitis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Venous thrombosis limb			

subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 58 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Reproductive system and breast disorders			
Testicular torsion			
subjects affected / exposed	1 / 56 (1.79%)	0 / 58 (0.00%)	0 / 41 (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
Psychiatric disorders			
Major depression			
subjects affected / exposed	1 / 56 (1.79%)	0 / 58 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	1 / 56 (1.79%)	0 / 58 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 56 (1.79%)	0 / 58 (0.00%)	0 / 41 (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
Injury, poisoning and procedural complications			

Concussion			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Clavicle fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Contusion			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 56 (0.00%)	0 / 58 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal toxicity			
subjects affected / exposed	0 / 56 (0.00%)	0 / 58 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune pancreatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 58 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			

subjects affected / exposed	0 / 56 (0.00%)	0 / 58 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Hepatobiliary disorders			
Gallbladder polyp			
subjects affected / exposed	0 / 56 (0.00%)	0 / 58 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis reactive			
subjects affected / exposed	1 / 56 (1.79%)	0 / 58 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic arthropathy			
subjects affected / exposed	1 / 56 (1.79%)	0 / 58 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 58 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 58 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Lung abscess			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Enterocolitis bacterial			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Cellulitis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 58 (0.00%)	0 / 41 (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
Toxic shock syndrome			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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
Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	0 / 56 (0.00%)	1 / 58 (1.72%)	0 / 41 (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

Serious adverse events	Placebo	Any AIN457 dose	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 41 (0.00%)	15 / 114 (13.16%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
Thrombophlebitis			

subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 41 (0.00%)	0 / 114 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
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			
Testicular torsion			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Major depression			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
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			
Concussion			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 41 (0.00%)	0 / 114 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal toxicity			
subjects affected / exposed	0 / 41 (0.00%)	0 / 114 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune pancreatitis			

subjects affected / exposed	0 / 41 (0.00%)	0 / 114 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 41 (0.00%)	0 / 114 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal hernia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Gallbladder polyp			
subjects affected / exposed	0 / 41 (0.00%)	0 / 114 (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			
Arthritis reactive			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriatic arthropathy			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pilonidal disease			
subjects affected / exposed	0 / 41 (0.00%)	0 / 114 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis bacterial			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic shock syndrome			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Lactose intolerance			
subjects affected / exposed	0 / 41 (0.00%)	1 / 114 (0.88%)	
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: 5 %

Non-serious adverse events	Any AIN457 low dose	Any AIN457 high dose	Etanercept
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 56 (85.71%)	50 / 58 (86.21%)	30 / 41 (73.17%)
Investigations			
Glomerular filtration rate decreased			
subjects affected / exposed	7 / 56 (12.50%)	4 / 58 (6.90%)	1 / 41 (2.44%)
occurrences (all)	9	4	2
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 56 (3.57%)	4 / 58 (6.90%)	2 / 41 (4.88%)
occurrences (all)	2	4	2
Nervous system disorders			
Headache			
subjects affected / exposed	11 / 56 (19.64%)	11 / 58 (18.97%)	4 / 41 (9.76%)
occurrences (all)	35	22	4
Blood and lymphatic system disorders			
Eosinophilia			
subjects affected / exposed	3 / 56 (5.36%)	0 / 58 (0.00%)	0 / 41 (0.00%)
occurrences (all)	3	0	0
Neutropenia			
subjects affected / exposed	3 / 56 (5.36%)	1 / 58 (1.72%)	1 / 41 (2.44%)
occurrences (all)	5	1	1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 56 (5.36%)	3 / 58 (5.17%)	0 / 41 (0.00%)
occurrences (all)	6	3	0
Pyrexia			
subjects affected / exposed	4 / 56 (7.14%)	6 / 58 (10.34%)	2 / 41 (4.88%)
occurrences (all)	4	11	2
Asthenia			
subjects affected / exposed	1 / 56 (1.79%)	3 / 58 (5.17%)	0 / 41 (0.00%)
occurrences (all)	3	3	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 56 (7.14%)	6 / 58 (10.34%)	5 / 41 (12.20%)
occurrences (all)	10	10	5
Abdominal pain upper			

subjects affected / exposed	4 / 56 (7.14%)	5 / 58 (8.62%)	4 / 41 (9.76%)
occurrences (all)	5	5	5
Dental caries			
subjects affected / exposed	1 / 56 (1.79%)	3 / 58 (5.17%)	1 / 41 (2.44%)
occurrences (all)	1	3	1
Vomiting			
subjects affected / exposed	1 / 56 (1.79%)	5 / 58 (8.62%)	1 / 41 (2.44%)
occurrences (all)	1	7	1
Toothache			
subjects affected / exposed	1 / 56 (1.79%)	4 / 58 (6.90%)	2 / 41 (4.88%)
occurrences (all)	1	5	3
Nausea			
subjects affected / exposed	2 / 56 (3.57%)	2 / 58 (3.45%)	4 / 41 (9.76%)
occurrences (all)	3	2	4
Diarrhoea			
subjects affected / exposed	7 / 56 (12.50%)	7 / 58 (12.07%)	1 / 41 (2.44%)
occurrences (all)	8	10	2
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 56 (1.79%)	4 / 58 (6.90%)	2 / 41 (4.88%)
occurrences (all)	4	8	10
Menstruation irregular			
subjects affected / exposed	0 / 56 (0.00%)	3 / 58 (5.17%)	0 / 41 (0.00%)
occurrences (all)	0	3	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	4 / 56 (7.14%)	6 / 58 (10.34%)	1 / 41 (2.44%)
occurrences (all)	4	11	1
Nasal congestion			
subjects affected / exposed	3 / 56 (5.36%)	1 / 58 (1.72%)	0 / 41 (0.00%)
occurrences (all)	3	1	0
Epistaxis			
subjects affected / exposed	0 / 56 (0.00%)	3 / 58 (5.17%)	0 / 41 (0.00%)
occurrences (all)	0	4	0
Cough			

subjects affected / exposed	4 / 56 (7.14%)	9 / 58 (15.52%)	2 / 41 (4.88%)
occurrences (all)	4	11	2
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	7 / 56 (12.50%)	1 / 58 (1.72%)	4 / 41 (9.76%)
occurrences (all)	7	1	4
Pruritus			
subjects affected / exposed	3 / 56 (5.36%)	5 / 58 (8.62%)	2 / 41 (4.88%)
occurrences (all)	3	5	2
Intertrigo			
subjects affected / exposed	3 / 56 (5.36%)	1 / 58 (1.72%)	0 / 41 (0.00%)
occurrences (all)	5	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	2 / 56 (3.57%)	4 / 58 (6.90%)	1 / 41 (2.44%)
occurrences (all)	2	7	2
Acne			
subjects affected / exposed	8 / 56 (14.29%)	5 / 58 (8.62%)	0 / 41 (0.00%)
occurrences (all)	8	8	0
Eczema			
subjects affected / exposed	3 / 56 (5.36%)	5 / 58 (8.62%)	1 / 41 (2.44%)
occurrences (all)	7	5	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 56 (7.14%)	5 / 58 (8.62%)	2 / 41 (4.88%)
occurrences (all)	5	6	3
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 56 (5.36%)	6 / 58 (10.34%)	3 / 41 (7.32%)
occurrences (all)	4	8	3
COVID-19			
subjects affected / exposed	4 / 56 (7.14%)	5 / 58 (8.62%)	0 / 41 (0.00%)
occurrences (all)	4	5	0
Conjunctivitis			
subjects affected / exposed	2 / 56 (3.57%)	5 / 58 (8.62%)	1 / 41 (2.44%)
occurrences (all)	2	7	1
Folliculitis			

subjects affected / exposed	3 / 56 (5.36%)	4 / 58 (6.90%)	0 / 41 (0.00%)
occurrences (all)	3	4	0
Gastroenteritis			
subjects affected / exposed	5 / 56 (8.93%)	3 / 58 (5.17%)	1 / 41 (2.44%)
occurrences (all)	6	4	1
Gastroenteritis viral			
subjects affected / exposed	3 / 56 (5.36%)	1 / 58 (1.72%)	2 / 41 (4.88%)
occurrences (all)	3	1	2
Gastrointestinal infection			
subjects affected / exposed	2 / 56 (3.57%)	4 / 58 (6.90%)	0 / 41 (0.00%)
occurrences (all)	2	5	0
Paronychia			
subjects affected / exposed	1 / 56 (1.79%)	3 / 58 (5.17%)	1 / 41 (2.44%)
occurrences (all)	1	4	1
Oral herpes			
subjects affected / exposed	3 / 56 (5.36%)	2 / 58 (3.45%)	4 / 41 (9.76%)
occurrences (all)	4	13	5
Nasopharyngitis			
subjects affected / exposed	17 / 56 (30.36%)	25 / 58 (43.10%)	11 / 41 (26.83%)
occurrences (all)	47	61	15
Influenza			
subjects affected / exposed	4 / 56 (7.14%)	0 / 58 (0.00%)	3 / 41 (7.32%)
occurrences (all)	6	0	4
Impetigo			
subjects affected / exposed	0 / 56 (0.00%)	3 / 58 (5.17%)	1 / 41 (2.44%)
occurrences (all)	0	3	3
Pharyngitis			
subjects affected / exposed	9 / 56 (16.07%)	8 / 58 (13.79%)	3 / 41 (7.32%)
occurrences (all)	17	11	3
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 56 (5.36%)	4 / 58 (6.90%)	2 / 41 (4.88%)
occurrences (all)	5	13	2
Urinary tract infection			
subjects affected / exposed	5 / 56 (8.93%)	2 / 58 (3.45%)	1 / 41 (2.44%)
occurrences (all)	8	3	1
Upper respiratory tract infection			

subjects affected / exposed	7 / 56 (12.50%)	3 / 58 (5.17%)	3 / 41 (7.32%)
occurrences (all)	18	5	7
Tonsillitis			
subjects affected / exposed	11 / 56 (19.64%)	7 / 58 (12.07%)	1 / 41 (2.44%)
occurrences (all)	18	9	1
Sinusitis			
subjects affected / exposed	4 / 56 (7.14%)	2 / 58 (3.45%)	1 / 41 (2.44%)
occurrences (all)	4	2	1
Rhinitis			
subjects affected / exposed	5 / 56 (8.93%)	7 / 58 (12.07%)	1 / 41 (2.44%)
occurrences (all)	6	9	1
Respiratory tract infection			
subjects affected / exposed	3 / 56 (5.36%)	4 / 58 (6.90%)	0 / 41 (0.00%)
occurrences (all)	4	4	0
Pharyngotonsillitis			
subjects affected / exposed	4 / 56 (7.14%)	1 / 58 (1.72%)	0 / 41 (0.00%)
occurrences (all)	4	1	0

Non-serious adverse events	Placebo	Any AIN457 dose	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 41 (46.34%)	98 / 114 (85.96%)	
Investigations			
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 41 (0.00%)	11 / 114 (9.65%)	
occurrences (all)	0	13	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 41 (0.00%)	6 / 114 (5.26%)	
occurrences (all)	0	6	
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 41 (9.76%)	22 / 114 (19.30%)	
occurrences (all)	6	57	
Blood and lymphatic system disorders			
Eosinophilia			
subjects affected / exposed	1 / 41 (2.44%)	3 / 114 (2.63%)	
occurrences (all)	1	3	
Neutropenia			

subjects affected / exposed	0 / 41 (0.00%)	4 / 114 (3.51%)	
occurrences (all)	0	6	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 41 (2.44%)	6 / 114 (5.26%)	
occurrences (all)	1	9	
Pyrexia			
subjects affected / exposed	0 / 41 (0.00%)	10 / 114 (8.77%)	
occurrences (all)	0	15	
Asthenia			
subjects affected / exposed	1 / 41 (2.44%)	4 / 114 (3.51%)	
occurrences (all)	1	6	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 41 (0.00%)	10 / 114 (8.77%)	
occurrences (all)	0	20	
Abdominal pain upper			
subjects affected / exposed	2 / 41 (4.88%)	9 / 114 (7.89%)	
occurrences (all)	2	10	
Dental caries			
subjects affected / exposed	1 / 41 (2.44%)	4 / 114 (3.51%)	
occurrences (all)	1	4	
Vomiting			
subjects affected / exposed	0 / 41 (0.00%)	6 / 114 (5.26%)	
occurrences (all)	0	8	
Toothache			
subjects affected / exposed	0 / 41 (0.00%)	5 / 114 (4.39%)	
occurrences (all)	0	6	
Nausea			
subjects affected / exposed	2 / 41 (4.88%)	4 / 114 (3.51%)	
occurrences (all)	2	5	
Diarrhoea			
subjects affected / exposed	0 / 41 (0.00%)	14 / 114 (12.28%)	
occurrences (all)	0	18	
Reproductive system and breast disorders			

Dysmenorrhoea			
subjects affected / exposed	0 / 41 (0.00%)	5 / 114 (4.39%)	
occurrences (all)	0	12	
Menstruation irregular			
subjects affected / exposed	0 / 41 (0.00%)	3 / 114 (2.63%)	
occurrences (all)	0	3	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 41 (2.44%)	10 / 114 (8.77%)	
occurrences (all)	1	15	
Nasal congestion			
subjects affected / exposed	0 / 41 (0.00%)	4 / 114 (3.51%)	
occurrences (all)	0	4	
Epistaxis			
subjects affected / exposed	1 / 41 (2.44%)	3 / 114 (2.63%)	
occurrences (all)	2	4	
Cough			
subjects affected / exposed	0 / 41 (0.00%)	13 / 114 (11.40%)	
occurrences (all)	0	15	
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 41 (0.00%)	8 / 114 (7.02%)	
occurrences (all)	0	8	
Pruritus			
subjects affected / exposed	1 / 41 (2.44%)	8 / 114 (7.02%)	
occurrences (all)	1	8	
Intertrigo			
subjects affected / exposed	0 / 41 (0.00%)	4 / 114 (3.51%)	
occurrences (all)	0	6	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 41 (0.00%)	6 / 114 (5.26%)	
occurrences (all)	0	9	
Acne			
subjects affected / exposed	1 / 41 (2.44%)	13 / 114 (11.40%)	
occurrences (all)	1	16	
Eczema			

subjects affected / exposed	0 / 41 (0.00%)	8 / 114 (7.02%)	
occurrences (all)	0	12	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 41 (2.44%)	9 / 114 (7.89%)	
occurrences (all)	3	11	
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 41 (4.88%)	9 / 114 (7.89%)	
occurrences (all)	2	12	
COVID-19			
subjects affected / exposed	0 / 41 (0.00%)	9 / 114 (7.89%)	
occurrences (all)	0	9	
Conjunctivitis			
subjects affected / exposed	0 / 41 (0.00%)	7 / 114 (6.14%)	
occurrences (all)	0	9	
Folliculitis			
subjects affected / exposed	0 / 41 (0.00%)	7 / 114 (6.14%)	
occurrences (all)	0	7	
Gastroenteritis			
subjects affected / exposed	1 / 41 (2.44%)	8 / 114 (7.02%)	
occurrences (all)	1	10	
Gastroenteritis viral			
subjects affected / exposed	1 / 41 (2.44%)	4 / 114 (3.51%)	
occurrences (all)	1	4	
Gastrointestinal infection			
subjects affected / exposed	2 / 41 (4.88%)	6 / 114 (5.26%)	
occurrences (all)	2	7	
Paronychia			
subjects affected / exposed	0 / 41 (0.00%)	4 / 114 (3.51%)	
occurrences (all)	0	5	
Oral herpes			
subjects affected / exposed	1 / 41 (2.44%)	5 / 114 (4.39%)	
occurrences (all)	1	17	
Nasopharyngitis			

subjects affected / exposed	1 / 41 (2.44%)	42 / 114 (36.84%)	
occurrences (all)	1	108	
Influenza			
subjects affected / exposed	3 / 41 (7.32%)	4 / 114 (3.51%)	
occurrences (all)	3	6	
Impetigo			
subjects affected / exposed	0 / 41 (0.00%)	3 / 114 (2.63%)	
occurrences (all)	0	3	
Pharyngitis			
subjects affected / exposed	4 / 41 (9.76%)	17 / 114 (14.91%)	
occurrences (all)	4	28	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	7 / 114 (6.14%)	
occurrences (all)	0	18	
Urinary tract infection			
subjects affected / exposed	0 / 41 (0.00%)	7 / 114 (6.14%)	
occurrences (all)	0	11	
Upper respiratory tract infection			
subjects affected / exposed	3 / 41 (7.32%)	10 / 114 (8.77%)	
occurrences (all)	3	23	
Tonsillitis			
subjects affected / exposed	0 / 41 (0.00%)	18 / 114 (15.79%)	
occurrences (all)	0	27	
Sinusitis			
subjects affected / exposed	0 / 41 (0.00%)	6 / 114 (5.26%)	
occurrences (all)	0	6	
Rhinitis			
subjects affected / exposed	4 / 41 (9.76%)	12 / 114 (10.53%)	
occurrences (all)	4	15	
Respiratory tract infection			
subjects affected / exposed	0 / 41 (0.00%)	7 / 114 (6.14%)	
occurrences (all)	0	8	
Pharyngotonsillitis			
subjects affected / exposed	0 / 41 (0.00%)	5 / 114 (4.39%)	
occurrences (all)	0	5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 April 2015	The protocol was amended to provide more details and clarification on the duration of contraception requested during the study and to give option to align the duration on local label requirements.
10 February 2016	The protocol was amended to modify inclusion criterion 5 to align with the text agreed with the Pediatric Committee (PDCO) of the European Medicines Agency (EMA). Another key purpose of this Amendment, is to include the Childhood Health Assessment Questionnaire (CHAQ©) for those subjects with History of Psoriatic Arthritis. This addition is made following a request by the Japanese Health Authority. Further to that, some protocol text changes were undertaken following requests from IRBs.
16 April 2018	The protocol was amended to to include an additional Interim Analysis prior to the Week 24 analysis once sufficient safety and pharmacokinetic data have been collected. This analysis aligned with the efficacy extrapolation principle, is expected to provide the basis for a submission package to health authorities (HA), with the intent to allow earlier availability of secukinumab to pediatric patients in countries which accept a submission of clinical data with use of extrapolation methodology. This analysis may be performed before all subjects have reached the primary endpoint. In addition to that, some clarifications, as well as editorial changes were undertaken in the protocol.
18 September 2020	The protocol was amended to introduce a level of flexibility in drug dispensation, protocol assessments and visit schedule if a major health care event like COVID-19requires it, thus allowing patients to remain in the trial and continue treatment while being monitored for safety. In addition, renal and liver monitoring procedures will no longer be followed for subjects who reach adulthood (≥ 18 years).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported