Clinical trial results:
Multicenter, rAndomized, double-blind, placebo-conTrolled, 52-week stUdy to demonstRatE the efficacy, safety and tolerability of secukinumab injections with 2 mL auto-injectors (300 mg) in adult subjects with plaque psoriasis (MATURE)

Summary

EudraCT number	2018-000518-39
Trial protocol	DE ES PL IS
Global end of trial date	05 August 2020

Results information

Result version number	v1 (current)
This version publication date	28 July 2021
First version publication date	28 July 2021

Trial information

Trial identification

Sponsor protocol code	CAIN457A2325

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03589885
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, 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)	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	05 August 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 November 2019
Global end of trial reached?	Yes
Global end of trial date	05 August 2020
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 300 mg when administered in 2 mL Auto-Injector (AI) in subjects with plaque-type psoriasis with respect to both Psoriasis Area and Severity Index (PASI) 75 and Investigator's Global Assessment modified 2011 (IGA mod 2011) 0 or 1 response (co-primary endpoint) at Week 12, compared to placebo.

The key secondary objective was to demonstrate the efficacy of secukinumab 300 mg when administered in 2 mL AI in subjects with plaque-type psoriasis with respect to PASI 90 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	19 December 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	Germany: 17
Country: Number of subjects enrolled	Iceland: 22
Country: Number of subjects enrolled	Poland: 17
Country: Number of subjects enrolled	Spain: 13
Country: Number of subjects enrolled	United States: 38
Worldwide total number of subjects	122
EEA total number of subjects	69

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	112
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 144 subjects were screened at 22 study centers in 6 countries, and 122 subjects were randomized.

Pre-assignment

Screening details:

A total of 144 subjects were screened at 22 study centers in 6 countries, and 122 subjects were randomized.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Secukinumab 300 mg 2 mL Auto-Injector (AI)

Arm description:

Secukinumab 300 mg provided in 2 mL auto-injector form

Arm type	Experimental
Investigational medicinal product name	Secukinumab 300 mg (2 mL AI)
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab 300 mg provided in 2 mL auto-injector form

Arm title	Secukinumab 300 mg 2x 1 mL Prefilled Syringe (PFS)

Arm description:

Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL

Arm type	Experimental
Investigational medicinal product name	Secukinumab 300 mg (2x 1 mL PFS)
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab 300 mg provided as 2x 1mL prefilled syringe of 150 mg/mL

Arm title	Placebo

Arm description:

Placebo of Secukinumab

Arm type	Placebo

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

Dosage and administration details:

Placebo of Secukinumab

Number of subjects in period 1	Secukinumab 300 mg 2 mL Auto-Injector (AI)	Secukinumab 300 mg 2x 1 mL Prefilled Syringe (PFS)	Placebo
Started	41	41	40
Completed	41	39	37
Not completed	0	2	3
Consent withdrawn by subject	-	-	1
Adverse event, non-fatal	-	1	-
Lost to follow-up	-	1	-
Lack of efficacy	-	-	2

Period 2

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Secukinumab 300 mg 2 mL Auto-Injector (AI)

Arm description:

Secukinumab 300 mg provided in 2 mL auto-injector form

Arm type	Experimental
Investigational medicinal product name	Secukinumab 300 mg (2 mL AI)
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab 300 mg provided in 2 mL auto-injector form

Arm title	Secukinumab 300 mg 2x 1 mL Prefilled Syringe (PFS)

Arm description:

Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL

Arm type	Experimental

Investigational medicinal product name	Secukinumab 300 mg (2x 1 mL PFS)
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Secukinumab 300 mg (2x 1 mL PFS) provided as 2x 1mL prefilled syringe of 150 mg/mL

Arm title	Placebo

Arm description:

Placebo of Secukinumab

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

Dosage and administration details:

Placebo of Secukinumab

Arm title	Placebo-Secukinumab 300 mg 2 mL Auto-Injector (AI)

Arm description:

Placebo patients up to Week 12 who thereafter received secukinumab in 2 mL AI up to the end of the study, if PASI 90 non-responders at Week 12

Arm type	Experimental
Investigational medicinal product name	Placebo-Secukinumab 300 mg 2 mL auto-injector (AI)
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo and Secukinumab 300 mg provided in 2mL auto-injector form

Arm title	Placebo-Secukinumab 300 mg 2 x 1 mL Prefilled Syringe (PFS)

Arm description:

Placebo patients up to Week 12 who thereafter received secukinumab in 2 x 1 mL PFS up to the end of the study, if PASI 90 non-responders at Week 12

Arm type	Experimental
Investigational medicinal product name	Placebo-Secukinumab 300 mg (2 x 1 mL PFS)
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo and Secukinumab provided as 2x 1mL prefilled syringe of 150 mg/mL

Number of subjects in period 2	Secukinumab 300 mg 2 mL Auto-Injector (AI)	Secukinumab 300 mg 2x 1 mL Prefilled Syringe (PFS)	Placebo
Started	41	39	4
Completed	40	34	3
Not completed	1	5	1
Consent withdrawn by subject	-	1	-
Adverse event, non-fatal	-	1	-
Pregnancy	1	-	-
Lost to follow-up	-	3	1

Number of subjects in period 2	Placebo-Secukinumab 300 mg 2 mL Auto-Injector (AI)	Placebo-Secukinumab 300 mg 2 x 1 mL Prefilled Syringe (PFS)
Started	16	17
Completed	16	16
Not completed	0	1
Consent withdrawn by subject	-	-
Adverse event, non-fatal	-	-
Pregnancy	-	-
Lost to follow-up	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Secukinumab 300 mg 2 mL Auto-Injector (AI)
Reporting group description:	
Secukinumab 300 mg provided in 2 mL auto-injector form	
Reporting group title	Secukinumab 300 mg 2x 1 mL Prefilled Syringe (PFS)
Reporting group description:	
Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	
Reporting group title	Placebo
Reporting group description:	
Placebo of Secukinumab	

Reporting group values	Secukinumab 300 mg 2 mL Auto-Injector (AI)	Secukinumab 300 mg 2x 1 mL Prefilled Syringe (PFS)	Placebo
Number of subjects	41	41	40
Age Categorical Units: Participants			
< 65	39	37	36
≥ 65	2	4	4
Age continuous			
Age Mean and Standard Deviation per Arm			
Units: years			
arithmetic mean	44.0	44.7	43.6
standard deviation	± 13.81	± 12.79	± 14.08
Sex: Female, Male Units: Participants			
Female	13	12	12
Male	28	29	28
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	1	1	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	39	39	37

Reporting group values	Total		
Number of subjects	122		
Age Categorical Units: Participants			
< 65	112		
≥ 65	10		
Age continuous			
Age Mean and Standard Deviation per Arm			
Units: years			
arithmetic mean			
standard deviation	-		

Sex: Female, Male Units: Participants			
Female	37		
Male	85		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1		
Asian	5		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	1		
White	115		

Subject analysis sets

Subject analysis set title	Secukinumab 300 mg 2 mL Auto-Injector
Subject analysis set type	Full analysis
Subject analysis set description: Secukinumab 300 mg provided in 2 mL auto-injector form	
Subject analysis set title	Secukinumab 300 mg 2x 1 mL Prefilled Syringe
Subject analysis set type	Full analysis
Subject analysis set description: Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	
Subject analysis set title	Placebo-Secukinumab 300 mg (2 mL Auto-Injector)
Subject analysis set type	Full analysis
Subject analysis set description: Placebo patients up to Week 12 who thereafter received Secukinumab 300 mg in 2 mL auto-injector up to the end of the study, if PASI 90 non-responders at Week 12	
Subject analysis set title	Placebo-Secukinumab 300 mg (2x 1 mL Prefilled Syringe)
Subject analysis set type	Full analysis
Subject analysis set description: Placebo patients up to Week 12 who thereafter received Secukinumab 300 mg in 2x 1mL PFS up to the end of the study, if PASI 90 non-responders at Week 12	
Subject analysis set title	Placebo
Subject analysis set type	Full analysis
Subject analysis set description: Placebo to Secukinumab 300 mg	
Subject analysis set title	PRE-Module By Visit
Subject analysis set type	Safety analysis
Subject analysis set description: PRE-Module by Visit Score (Entire Treatment Period). Safety Set was used for this analysis	
Subject analysis set title	POST-Module By Visit
Subject analysis set type	Safety analysis
Subject analysis set description: POST-Module by Visit Score (Entire Treatment Period). Safety Set was used for this analysis	
Subject analysis set title	Absolute Change POST -Module-PRE Module
Subject analysis set type	Safety analysis
Subject analysis set description: Absolute Change POST-Module/PRE-Module Scores	

Reporting group values	Secukinumab 300 mg 2 mL Auto-Injector	Secukinumab 300 mg 2x 1 mL Prefilled Syringe	Placebo-Secukinumab 300 mg (2 mL Auto-Injector)
Number of subjects	41	41	16
Age Categorical Units: Participants			
< 65	39	37	13
≥ 65	2	4	3
Age continuous			
Age Mean and Standard Deviation per Arm			
Units: years			
arithmetic mean	44.0	44.7	45.6
standard deviation	± 13.81	± 12.79	± 16.60
Sex: Female, Male Units: Participants			
Female	13	12	3
Male	28	29	13
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	1	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	39	39	16

Reporting group values	Placebo-Secukinumab 300 mg (2x 1 mL Prefilled Syringe)	Placebo	PRE-Module By Visit
Number of subjects	17	40	122
Age Categorical Units: Participants			
< 65	16	36	0
≥ 65	1	4	0
Age continuous			
Age Mean and Standard Deviation per Arm			
Units: years			
arithmetic mean	43.5	43.6	0.0
standard deviation	± 13.00	± 14.08	± 0.0
Sex: Female, Male Units: Participants			
Female	6	12	0
Male	11	28	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	3	0
Native Hawaiian or Other Pacific Islander		0	0
Black or African American	0	0	0
White	14	37	0

Reporting group values	POST-Module By Visit	Absolute Change POST -Module-PRE Module	
Number of subjects	122	122	
Age Categorical			
Units: Participants			
< 65	0	0	
≥ 65	0	0	
Age continuous			
Age Mean and Standard Deviation per Arm			
Units: years			
arithmetic mean	0.0	0.0	
standard deviation	± 0.0	± 0.0	
Sex: Female, Male			
Units: Participants			
Female	0	0	
Male	0	0	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	0	0	

End points

End points reporting groups

Reporting group title	Secukinumab 300 mg 2 mL Auto-Injector (AI)
Reporting group description: Secukinumab 300 mg provided in 2 mL auto-injector form	
Reporting group title	Secukinumab 300 mg 2x 1 mL Prefilled Syringe (PFS)
Reporting group description: Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	
Reporting group title	Placebo
Reporting group description: Placebo of Secukinumab	
Reporting group title	Secukinumab 300 mg 2 mL Auto-Injector (AI)
Reporting group description: Secukinumab 300 mg provided in 2 mL auto-injector form	
Reporting group title	Secukinumab 300 mg 2x 1 mL Prefilled Syringe (PFS)
Reporting group description: Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	
Reporting group title	Placebo
Reporting group description: Placebo of Secukinumab	
Reporting group title	Placebo-Secukinumab 300 mg 2 mL Auto-Injector (AI)
Reporting group description: Placebo patients up to Week 12 who thereafter received secukinumab in 2 mL AI up to the end of the study, if PASI 90 non-responders at Week 12	
Reporting group title	Placebo-Secukinumab 300 mg 2 x 1 mL Prefilled Syringe (PFS)
Reporting group description: Placebo patients up to Week 12 who thereafter received secukinumab in 2 x 1 mL PFS up to the end of the study, if PASI 90 non-responders at Week 12	
Subject analysis set title	Secukinumab 300 mg 2 mL Auto-Injector
Subject analysis set type	Full analysis
Subject analysis set description: Secukinumab 300 mg provided in 2 mL auto-injector form	
Subject analysis set title	Secukinumab 300 mg 2x 1 mL Prefilled Syringe
Subject analysis set type	Full analysis
Subject analysis set description: Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	
Subject analysis set title	Placebo-Secukinumab 300 mg (2 mL Auto-Injector)
Subject analysis set type	Full analysis
Subject analysis set description: Placebo patients up to Week 12 who thereafter received Secukinumab 300 mg in 2 mL auto-injector up to the end of the study, if PASI 90 non-responders at Week 12	
Subject analysis set title	Placebo-Secukinumab 300 mg (2x 1 mL Prefilled Syringe)
Subject analysis set type	Full analysis
Subject analysis set description: Placebo patients up to Week 12 who thereafter received Secukinumab 300 mg in 2x 1mL PFS up to the end of the study, if PASI 90 non-responders at Week 12	
Subject analysis set title	Placebo
Subject analysis set type	Full analysis
Subject analysis set description: Placebo to Secukinumab 300 mg	
Subject analysis set title	PRE-Module By Visit

Subject analysis set type	Safety analysis
Subject analysis set description:	
PRE-Module by Visit Score (Entire Treatment Period). Safety Set was used for this analysis	
Subject analysis set title	POST-Module By Visit
Subject analysis set type	Safety analysis
Subject analysis set description:	
POST-Module by Visit Score (Entire Treatment Period). Safety Set was used for this analysis	
Subject analysis set title	Absolute Change POST -Module-PRE Module
Subject analysis set type	Safety analysis
Subject analysis set description:	
Absolute Change POST-Module/PRE-Module Scores	

Primary: PASI 75 response after 12 weeks of treatment

End point title	PASI 75 response after 12 weeks of treatment[1]
End point description:	
Percentage of participants who achieve ≥ 75% reduction in PASI compared to baseline. A PASI (Psoriasis Area and Severity Index) score is a tool used to measure the severity and extent of psoriasis. The score ranges from 0 (no signs of psoriasis) to a theoretic maximum of 72. The intensity of redness, thickness and scaling of the psoriasis is assessed as none (0), mild (1), moderate (2), severe (3) or very severe (4).	
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: Statistical Analysis was not performed on all arms for this endpoint. Arms with statistical analysis are presented.

End point values	Placebo	Secukinumab 300 mg 2 mL Auto-Injector	Secukinumab 300 mg 2x 1 mL Prefilled Syringe	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	40	41	41	
Units: Participants	4	39	34	

Statistical analyses

Statistical analysis title	Secukinumab 300 mg 2mL Auto-Injector vs Placebo
Statistical analysis description:	
PASI 75	
Comparison groups	Placebo v Secukinumab 300 mg 2 mL Auto-Injector
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	1014.07

Confidence interval	
level	95 %
sides	2-sided
lower limit	68.83
upper limit	14940.62

Statistical analysis title	Secukinumab 300 mg 2x 1mL PFS vs Placebo

Statistical analysis description:

PASI 75

Comparison groups	Placebo v Secukinumab 300 mg 2x 1 mL Prefilled Syringe
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	96.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.22
upper limit	537.78

Primary: IGA mod 2011 0 or 1 response after 12 weeks of treatment

End point title	IGA mod 2011 0 or 1 response after 12 weeks of treatment[2]

End point description:

Percentage of participants who achieve IGA mod 2011 0 or 1, and improved by at least 2 points on the IGA scale compared to baseline. This scale ranges from 0 (clear, no signs of psoriasis) to 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: Statistical Analysis was not performed on all arms for this endpoint. Arms with statistical analysis are presented.

End point values	Placebo	Secukinumab 300 mg 2 mL Auto-Injector	Secukinumab 300 mg 2x 1 mL Prefilled Syringe	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	40	41	41	
Units: Participants	3	31	28	

Statistical analyses

Statistical analysis title	Secukinumab 300 mg 2mL Auto-Injector vs Placebo
Comparison groups	Placebo v Secukinumab 300 mg 2 mL Auto-Injector
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	51.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.95
upper limit	221.64

Statistical analysis title	Secukinumab 300 mg 2x1 mL PFS vs Placebo
Comparison groups	Placebo v Secukinumab 300 mg 2x 1 mL Prefilled Syringe
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	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.38
upper limit	119.57

Secondary: PASI 90 response	
End point title	PASI 90 response[3]
End point description:	
Percentage of participants who achieve ≥ 90% reduction in PASI compared to baseline	
End point type	Secondary
End point timeframe:	
12 weeks	

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: Statistical Analysis was not performed on all arms for this endpoint. Arms with statistical analysis are presented.

End point values	Placebo	Secukinumab 300 mg 2 mL Auto-Injector	Secukinumab 300 mg 2x 1 mL Prefilled Syringe	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	40	41	41	
Units: Participants	2	31	26	

Statistical analyses

Statistical analysis title	Secukinumab 300 mg 2mL Auto-Injector vs Placebo
Comparison groups	Placebo v Secukinumab 300 mg 2 mL Auto-Injector
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	88.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.15
upper limit	484.52

Statistical analysis title	Secukinumab 300 mg 2x 1 mL PFS vs Placebo
Comparison groups	Placebo v Secukinumab 300 mg 2x 1 mL Prefilled Syringe
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	37.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.6
upper limit	189.01

Secondary: PASI 50, 75, 90 and 100 and IGA mod 2011 0 or 1 response

End point title	PASI 50, 75, 90 and 100 and IGA mod 2011 0 or 1 response[4]

End point description:

Percentage of participants who achieve ≥ 50%, 75%, 90% and 100% reduction in PASI and achieve IGA mod 2011 0 or 1, and improved by at least 2 points on the IGA scale compared to baseline at each visit

up to 52 weeks

End point type	Secondary

End point timeframe:

52 weeks

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: Statistical Analysis was not performed on all arms for this endpoint. Arms with statistical analysis are presented.

End point values	Placebo	Secukinumab 300 mg 2 mL Auto-Injector	Secukinumab 300 mg 2x 1 mL Prefilled Syringe	Placebo-Secukinumab 300 mg (2 mL Auto-Injector)
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	40	41	41	16
Units: Participants				
PASI 50	4	41	40	15
PASI 75	1	38	37	13
PASI 90	0	30	28	12
PASI 100	0	23	18	11
IGA 0/1	0	30	33	12

End point values	Placebo-Secukinumab 300 mg (2x 1 mL Prefilled Syringe)			
Subject group type	Subject analysis set			
Number of subjects analysed	17			
Units: Participants				
PASI 50	15			
PASI 75	14			
PASI 90	14			
PASI 100	11			
IGA 0/1	13			

Statistical analyses

No statistical analyses for this end point

Secondary: Successful self-injection

End point title	Successful self-injection

End point description:

Subject usability (ability to follow instructions for use and potential use-related hazards) and satisfaction with the new secukinumab 2 mL AI utilizing a self-administered Self-Injection Assessment Questionnaire (SIAQ) and investigator/site staff observation of secukinumab
300 mg 2 mL AI administration. The Satisfaction with Self-Injection (SA) domain score ranges from 0 (worst experience) to 10 (best experience).

End point type	Secondary

End point timeframe:

From randomization until Week 28

End point values	PRE-Module By Visit	POST-Module By Visit	Absolute Change POST - Module-PRE Module	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	113[5]	113[6]	113[7]	
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Baseline	5.75 (± 2.442)	0.0 (± 0.0)	0.0 (± 0.0)	
Baseline (1) POST-module at baseline visit	5.75 (± 2.452)	7.52 (± 2.046)	1.77 (± 2.789)	
Week 1	5.72 (± 2.463)	8.11 (± 1.759)	2.39 (± 3.169)	
Week 4	5.70 (± 2.495)	8.27 (± 1.731)	2.57 (± 3.080)	
Week 8	5.68 (± 2.490)	8.62 (± 1.545)	2.94 (± 2.869)	
Week 12	5.70 (± 2.523)	8.56 (± 1.623)	2.86 (± 2.985)	
Week 28	5.62 (± 2.485)	8.69 (± 1.681)	3.07 (± 3.238)	

Notes:

[5] - Baseline Number Analyzed was 114. Baseline (1) Post-Module at Baseline Visit 113

[6] - Baseline Number Analyzed was 0. Baseline (1) Post-Module at Baseline Visit 113

[7] - Baseline Number Analyzed was 0. Baseline (1) Post-Module at Baseline Visit 113

Statistical analyses

No statistical analyses for this end point

Secondary: Dermatology Life Quality Index, (DLQI) 0 or 1 score (total score)

End point title	Dermatology Life Quality Index, (DLQI) 0 or 1 score (total score)[8]

End point description:

The impact of psoriasis on various aspects of subject's health-related quality of life assessed by the subject

End point type	Secondary

End point timeframe:

Change from Baseline up to 52 weeks

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: Statistical Analysis was not performed on all arms for this endpoint. Arms with statistical analysis are presented.

End point values	Placebo	Secukinumab 300 mg 2 mL Auto-Injector	Secukinumab 300 mg 2x 1 mL Prefilled Syringe	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	40	41	41	
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Week 12	-1.97 (± 6.966)	-13.21 (± 7.701)	-11.95 (± 7.861)	

Week 28	-13.00 (± 12.490)	-13.59 (± 7.639)	-12.23 (± 8.438)	
Week 52	-14.33 (± 11.240)	-12.44 (± 8.219)	-12.23 (± 8.408)	

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 of study treatment until end of study treatment (Week 48) plus 4 weeks post treatment.	
Adverse event reporting additional description:	
Any sign or symptom that occurs during the study treatment plus the 4 weeks post treatment.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups	
Reporting group title	Secukinumab 300 mg (2 mL AI)
Reporting group description:	
Secukinumab 300 mg (2 mL AI)	
Reporting group title	Secukinumab 300 mg (2 x 1 mL PFS)
Reporting group description:	
Secukinumab 300 mg (2 x 1 mL PFS)	
Reporting group title	Any Secukinumab 300 mg (2 mL AI)
Reporting group description:	
Any Secukinumab 300 mg (2 mL AI)	
Reporting group title	Any Secukinumab 300 mg (2 x 1 mL PFS)
Reporting group description:	
Any Secukinumab 300 mg (2 x 1 mL PFS)	
Reporting group title	Placebo
Reporting group description:	
Placebo to Secukinumab	
Reporting group title	Any Secukinumab 300 mg
Reporting group description:	
Any Secukinumab 300 mg	

Serious adverse events	Secukinumab 300 mg (2 mL AI)	Secukinumab 300 mg (2 x 1 mL PFS)	Any Secukinumab 300 mg (2 mL AI)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 41 (2.44%)	3 / 41 (7.32%)	1 / 57 (1.75%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 57 (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
Head injury			

subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 57 (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
Road traffic accident			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 57 (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 / 41 (0.00%)	1 / 41 (2.44%)	0 / 57 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 41 (0.00%)	0 / 41 (0.00%)	0 / 57 (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			
Appendicitis			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 57 (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
COVID-19			
subjects affected / exposed	0 / 41 (0.00%)	1 / 41 (2.44%)	0 / 57 (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
Device related infection			
subjects affected / exposed	1 / 41 (2.44%)	0 / 41 (0.00%)	1 / 57 (1.75%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Any Secukinumab 300 mg (2 x 1 mL PFS)	Placebo	Any Secukinumab 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 58 (6.90%)	0 / 40 (0.00%)	5 / 115 (4.35%)

number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	1 / 58 (1.72%)	0 / 40 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	1 / 58 (1.72%)	0 / 40 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 58 (1.72%)	0 / 40 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 58 (1.72%)	0 / 40 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 58 (1.72%)	0 / 40 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 58 (1.72%)	0 / 40 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 58 (1.72%)	0 / 40 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Device related infection			
subjects affected / exposed	0 / 58 (0.00%)	0 / 40 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Secukinumab 300 mg (2 mL AI)	Secukinumab 300 mg (2 x 1 mL PFS)	Any Secukinumab 300 mg (2 mL AI)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 41 (46.34%)	16 / 41 (39.02%)	24 / 57 (42.11%)
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 41 (9.76%)	2 / 41 (4.88%)	5 / 57 (8.77%)
occurrences (all)	4	2	5
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 41 (4.88%)	4 / 41 (9.76%)	3 / 57 (5.26%)
occurrences (all)	2	7	3
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	3 / 41 (7.32%)	3 / 41 (7.32%)	4 / 57 (7.02%)
occurrences (all)	4	7	5
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	0 / 41 (0.00%)	3 / 41 (7.32%)	0 / 57 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	3 / 41 (7.32%)	2 / 41 (4.88%)	3 / 57 (5.26%)
occurrences (all)	3	2	3
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	6 / 41 (14.63%)	6 / 41 (14.63%)	8 / 57 (14.04%)
occurrences (all)	7	6	10
Upper respiratory tract infection			
subjects affected / exposed	3 / 41 (7.32%)	4 / 41 (9.76%)	4 / 57 (7.02%)
occurrences (all)	3	5	4

Non-serious adverse events	Any Secukinumab 300 mg (2 x 1 mL PFS)	Placebo	Any Secukinumab 300 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 58 (36.21%)	5 / 40 (12.50%)	45 / 115 (39.13%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 58 (3.45%)	0 / 40 (0.00%)	7 / 115 (6.09%)
occurrences (all)	2	0	7
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 58 (6.90%)	1 / 40 (2.50%)	7 / 115 (6.09%)
occurrences (all)	7	1	10
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	3 / 58 (5.17%)	1 / 40 (2.50%)	7 / 115 (6.09%)
occurrences (all)	7	1	12
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	3 / 58 (5.17%)	0 / 40 (0.00%)	3 / 115 (2.61%)
occurrences (all)	3	0	3
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	3 / 58 (5.17%)	2 / 40 (5.00%)	6 / 115 (5.22%)
occurrences (all)	3	2	6
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	8 / 58 (13.79%)	0 / 40 (0.00%)	16 / 115 (13.91%)
occurrences (all)	8	0	18
Upper respiratory tract infection			
subjects affected / exposed	6 / 58 (10.34%)	1 / 40 (2.50%)	10 / 115 (8.70%)
occurrences (all)	7	1	11

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported