Clinical trial results:
MAXIMISE (Managing AXIal Manifestations in Psoriatic Arthritis with SEcukinumab), a randomized, double-blind, placebo-controlled, multicenter, 52 week study to assess the efficacy and safety of secukinumab 150 mg or 300 mg s.c. in patients with active psoriatic arthritis and axial skeleton involvement who have inadequate response to non steroidal anti-inflammatory drugs (NSAIDs)

Summary

EudraCT number	2016-000814-31
Trial protocol	ES CZ FR GB HU EE IE BE FI DK DE BG GR PL IT
Global end of trial date	26 June 2019

Results information

Result version number	v1 (current)
This version publication date	26 August 2020
First version publication date	26 August 2020

Trial information

Trial identification

Sponsor protocol code	CAIN457F3302

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02721966
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	03 July 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 June 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that secukinumab 300 mg s.c. is superior to placebo in the achievement of ASAS 20 response at Week 12.

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	03 October 2016
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	Russian Federation: 44
Country: Number of subjects enrolled	Romania: 12
Country: Number of subjects enrolled	Poland: 121
Country: Number of subjects enrolled	United Kingdom: 32
Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Bulgaria: 26
Country: Number of subjects enrolled	Czech Republic: 33
Country: Number of subjects enrolled	Estonia: 19
Country: Number of subjects enrolled	Finland: 3
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	Germany: 36
Country: Number of subjects enrolled	Greece: 5
Country: Number of subjects enrolled	Hungary: 23
Country: Number of subjects enrolled	Ireland: 2
Country: Number of subjects enrolled	Switzerland: 13
Country: Number of subjects enrolled	Italy: 17
Country: Number of subjects enrolled	Israel: 18
Country: Number of subjects enrolled	Spain: 76

Worldwide total number of subjects	498
EEA total number of subjects	423

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	472
From 65 to 84 years	26
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

503 participants completed the screening period; as 5 participants were mis-randomized, the randomized set consists of 498 patients

Pre-assignment

Screening details:

95.9% of the randomized participants completed period 1 and continued to period 2; and 85.3% completed treatment period 2

Period 1

Period 1 title	Treatment Period 1 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo sc injections at baseline and weekly until Week 4 and at Week 8, followed by Secukinumab 150 mg or Secukinumab 300 mg injections every 4 weeks between Week 12 and Week 48

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

Dosage and administration details:

Placebo sc injections at baseline and weekly until week 4 and at week 8, followed by Secukinumab 150 mg injections every week between week 12 and week 48.

Arm title	AIN457 150 mg

Arm description:

Secukinumab 150 mg sc. injections at baseline and weekly until Week 4 followed by Secukinumab 150 mg inejections every 4 weeks between week 8 and week 48

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

Dosage and administration details:

Secukinumab 150 mg sc. injections at baseline and weekly until Week 4 followed by Secukinumab 150 mg inejections every 4 weeks between week 8 and week 48

Arm title	AIN457 300 mg

Arm description:

Secukinumab 300 mg sc injections at baseline and weekly until 4 weeks followed by Secukinumab 300 mg injections every 4 weeks between week 8 and week 48

Arm type	Experimental

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

Dosage and administration details:

Secukinumab 300 mg sc injections at baseline and weekly until 4 weeks followed by Secukinumab 300 mg injections every 4 weeks between week 8 and week 48

Number of subjects in period 1	Placebo	AIN457 150 mg	AIN457 300 mg
Started	166	165	167
Completed	145	142	138
Not completed	21	23	29
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	10	2	9
Physician decision	-	1	1
Did not continue to period 2	5	12	5
Adverse event, non-fatal	3	4	4
Pregnancy	-	-	1
Lost to follow-up	3	-	-
Lack of efficacy	-	4	7
Protocol deviation	-	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo sc injections at baseline and weekly until Week 4 and at Week 8, followed by Secukinumab 150 mg or Secukinumab 300 mg injections every 4 weeks between Week 12 and Week 48	
Reporting group title	AIN457 150 mg
Reporting group description:	
Secukinumab 150 mg sc. injections at baseline and weekly until Week 4 followed by Secukinumab 150 mg inejections every 4 weeks between week 8 and week 48	
Reporting group title	AIN457 300 mg
Reporting group description:	
Secukinumab 300 mg sc injections at baseline and weekly until 4 weeks followed by Secukinumab 300 mg injections every 4 weeks between week 8 and week 48	

Reporting group values	Placebo	AIN457 150 mg	AIN457 300 mg
Number of subjects	166	165	167
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	157	156	159
From 65-84 years	9	9	8
85 years and over	0	0	0
Age continuous			
mean age			
Units: years			
arithmetic mean	46.6	46.9	46.2
standard deviation	± 11.51	± 11.50	± 12.32
Gender categorical Units: Subjects			
Female	78	84	90
Male	88	81	77
Race Units: Subjects			
Black	0	0	1
Asian	2	0	0
White	164	159	162
Missing	0	6	4

Reporting group values	Total		
Number of subjects	498		

Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	472		
From 65-84 years	26		
85 years and over	0		
Age continuous			
mean age			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	252		
Male	246		
Race Units: Subjects			
Black	1		
Asian	2		
White	485		
Missing	10		

Subject analysis sets

Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

All participants randomized and fulfilling the key inclusion criteria for disease activity

Reporting group values	Full Analysis Set (FAS)		
Number of subjects	498		
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			

Age continuous			
mean age			
Units: years			
arithmetic mean			
standard deviation	±		
Gender categorical			
Units: Subjects			
Female			
Male			
Race			
Units: Subjects			
Black	1		
Asian	2		
White	485		
Missing	10		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo sc injections at baseline and weekly until Week 4 and at Week 8, followed by Secukinumab 150 mg or Secukinumab 300 mg injections every 4 weeks between Week 12 and Week 48	
Reporting group title	AIN457 150 mg
Reporting group description:	
Secukinumab 150 mg sc. injections at baseline and weekly until Week 4 followed by Secukinumab 150 mg inejections every 4 weeks between week 8 and week 48	
Reporting group title	AIN457 300 mg
Reporting group description:	
Secukinumab 300 mg sc injections at baseline and weekly until 4 weeks followed by Secukinumab 300 mg injections every 4 weeks between week 8 and week 48	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
All participants randomized and fulfilling the key inclusion criteria for disease activity	

Primary: PRIMARY OUTCOME MEASURE: Proportion of participants with response to treatment (300 mg AIN457) as assessed by the ASAS20 criteria at week 12

End point title	PRIMARY OUTCOME MEASURE: Proportion of participants with response to treatment (300 mg AIN457) as assessed by the ASAS20 criteria at week 12
End point description:	
Purpose of this measure: was to demonstrate that secukinumab 300 mg s.c. is superior to placebo in the achievement of ASAS20 response at Week 12 ASAS20 was defined as an improvement of ≥20% and absolute improvement of ≥10 unit (0-100 mm VAS) from baseline in ≥3 of the following 4 domains (and absence of deterioration in any domain): patient's global assessment of disease activity (PTGA), pain assessment (total pain score), Bath Ankylosing Spondylitis Functional Index (BASFI), and clinical inflammation (mean of 2 morning stiffness-related scores on the BASDAI)	
End point type	Primary
End point timeframe:	
at week 12	

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164	
Units: proportion of participants				
number (confidence interval 95%)	31.2 (24.6 to 38.7)	66.3 (58.4 to 73.3)	62.9 (55.2 to 70.0)	

Statistical analyses

Statistical analysis title	AIN457 300 mg vs palcebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	AIN457 300 mg v Placebo
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.41
upper limit	6.1

Notes:

[1] - Odds ratio, 95% CI for odds ratio, and p-value are from a logistic regression model with treatment (3 treatment groups), methotrexate usage status (yes, no) as explanatory variable

Secondary: KEY SECONDARY OUTCOME: Proportion of participants with response to treatment (150 mg AIN457) as assessed by the ASAS20 criteria at week 12

End point title	KEY SECONDARY OUTCOME: Proportion of participants with response to treatment (150 mg AIN457) as assessed by the ASAS20 criteria at week 12

End point description:

The purpose of this key secondary measure was to demonstrate that secukinumab 150 mg s.c. is superior to placebo in the achievement of ASAS 20 response at Week 12 after superiority of 300 mg was established. Note that 300mg and 150mg are presented side by side for clarity

ASAS20 was defined as an improvement of ≥20% and absolute improvement of ≥10 unit (0-100 mm VAS) from baseline in ≥3 of the following 4 domains (and absence of deterioration in any domain): patient's global assessment of disease activity (PTGA), pain assessment (total pain score), Bath Ankylosing Spondylitis Functional Index (BASFI), and clinical inflammation (mean of 2 morning stiffness-related scores on the BASDAI)

End point type	Secondary

End point timeframe:

at 12 weeks

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164	
Units: proportion of participants				
number (confidence interval 95%)	31.2 (24.6 to 38.7)	66.3 (58.4 to 73.3)	62.9 (55.2 to 70.0)	

Statistical analyses

Statistical analysis title	AIN457 150mg vs Placebo AIN457

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	Placebo v AIN457 150 mg
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.72
upper limit	7.01

Notes:

[2] - Odds ratio, 95% CI for odds ratio, and p-value are from a logistic regression model with treatment (3 treatment groups), methotrexate usage status (yes, no) as explanatory variables

Secondary: Proportion of participants with response to treatment (150 mg/300 mg AIN457) as assessed by the ASAS40 criteria at week 12

End point title	Proportion of participants with response to treatment (150 mg/300 mg AIN457) as assessed by the ASAS40 criteria at week 12

End point description:

Proportion of patients with response to treatment as assessed by the Assessment of spondyloarthritis international society (ASAS) 40 criteria at week 12

ASAS40 was defined as an improvement of ≥40% and absolute improvement of ≥20 unit (0-100 mm VAS) from baseline in ≥3 of the following 4 domains (and absence of deterioration in any domain): patient's global assessment of disease activity (PTGA), pain assessment (total pain score), Bath Ankylosing Spondylitis Functional Index (BASFI), and clinical inflammation (mean of 2 morning stiffness-related scores on the BASDAI)

End point type	Secondary

End point timeframe:

at 12 weeks

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164	
Units: proportion of participants				
number (confidence interval 95%)	12.2 (7.8 to 18.4)	39.5 (32.1 to 47.4)	43.6 (36.2 to 51.3)	

Statistical analyses

Statistical analysis title	AIN457 150 mg vs placebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	Placebo v AIN457 150 mg
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.67
upper limit	8.33

Notes:

[3] - Odds ratio, 95% CI for odds ratio, and p-value are from a logistic regression model with treatment (3 treatment groups), methotrexate usage status (yes, no) as explanatory variable

Statistical analysis title	AIN457 300 mg vs placebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	Placebo v AIN457 300 mg
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.2
upper limit	9.84

Notes:

[4] - Odds ratio, 95% CI for odds ratio, and p-value are from a logistic regression model with treatment (3 treatment groups), methotrexate usage status (yes, no) as explanatory variables

Secondary: Proportion of patients with response to treatment as assessed by BASDAI50 at week 12

End point title	Proportion of patients with response to treatment as assessed by BASDAI50 at week 12

End point description:

Bath ankylosing spondylitis disease activity index (BASDAI) 50 response

BASDAI 50 response is defined as at least 50% improvement (decrease) in total BASDAI score

End point type	Secondary

End point timeframe:

at 12 weeks

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164[5]	
Units: proportion of participants				
number (confidence interval 95%)	9.8 (5.9 to 15.6)	32.7 (25.8 to 40.5)	37.4 (30.1 to 45.4)	

Notes:

[5] - 164

Statistical analyses

Statistical analysis title	AIN457 150 mg vs placebo

Statistical analysis description:

Odds ratio, 95% CI for odds ratio, and p-value are from a logistic regression model with treatment (3 treatment groups), methotrexate usage status (yes, no) as explanatory variable

Comparison groups	Placebo v AIN457 150 mg
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.43
upper limit	8.33

Notes:

[6] - Up to week 12, all participants in the group "placebo AIN457" took placebo only

Statistical analysis title	AIN457 300 mg vs placebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	Placebo v AIN457 300 mg
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.04
upper limit	10.21

Notes:

[7] - Odds ratio, 95% CI for odds ratio, and p-value are from a logistic regression model with treatment (3 treatment groups), methotrexate usage status (yes, no) as explanatory variables

Secondary: Change from baseline in Spinal pain visual analog scale (VAS) - Pain at any time

End point title	Change from baseline in Spinal pain visual analog scale (VAS) - Pain at any time

End point description:

Change from baseline in Spinal pain visual analog scale (VAS) at week 12

VAS is a straight horizontal line of fixed length, usually 100 mm. The ends are defined as the extreme limits of the parameter to be measured (symptom,pain,health) orientated from the left (worst) to the right (best)

End point type	Secondary

End point timeframe:

at 12 weeks

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164	
Units: scores on a scale				
least squares mean (standard error)	-13.6 (± 1.83)	-28.5 (± 1.88)	-26.5 (± 1.84)	

Statistical analyses

Statistical analysis title	AIN457 150 mg vs placebo

Statistical analysis description:

Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline measurement in VAS as continuous covariate

Comparison groups	Placebo v AIN457 150 mg
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-14.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20
upper limit	-9.7
Variability estimate	Standard error of the mean
Dispersion value	2.62

Notes:

[8] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline measurement in VAS as continuous covariate

Statistical analysis title	AIN457 300 mg vs placebo
Comparison groups	Placebo v AIN457 300 mg
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-12.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18
upper limit	-7.8
Variability estimate	Standard error of the mean
Dispersion value	2.59

Notes:

[9] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline measurement in VAS as continuous covariate

Secondary: Change from baseline in Spinal pain visual analog scale (VAS) - Pain at night

End point title	Change from baseline in Spinal pain visual analog scale (VAS) - Pain at night

End point description:

Change from baseline in Spinal pain visual analog scale (VAS) at week 12

VAS is a straight horizontal line of fixed length, usually 100 mm. The ends are defined as the extreme limits of the parameter to be measured (symptom,pain,health) orientated from the left (worst) to the right (best)

End point type	Secondary

End point timeframe:

at 12 weeks

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164	
Units: scores on a scale				
least squares mean (standard error)	-15.2 (± 1.89)	-30.3 (± 1.95)	-30.2 (± 1.90)	

Statistical analyses

Statistical analysis title	AIN457 150 mg vs placebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	AIN457 150 mg v Placebo

Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-15.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.4
upper limit	-9.7
Variability estimate	Standard error of the mean
Dispersion value	2.71

Notes:

[10] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline measurement in VAS as continuous covariate

Statistical analysis title	AIN457 300 mg vs placebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	Placebo v AIN457 300 mg
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.3
upper limit	-9.8
Variability estimate	Standard error of the mean
Dispersion value	2.68

Notes:

[11] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline measurement in VAS as continuous covariate

Secondary: Change from baseline Spondyloarthritis Research Consortium of Canada (SPARCC) enthesitis index score at week 12

End point title	Change from baseline Spondyloarthritis Research Consortium of Canada (SPARCC) enthesitis index score at week 12

End point description:

The Spondyloarthritis Research Consortium of Canada (SPARCC) enthesitis index score range is 0-16, where 0 is the best outcome, and 16 the worst. The assessor determines whether the site shows tenderness and therefore would count as site with enthesitis. This is done by applying pressure to the site and getting feedback from patient about whether the site is tender.

End point type	Secondary

End point timeframe:
at 12 weeks

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164	
Units: scores on a scale				
least squares mean (standard error)	-1.7 (± 0.21)	-2.2 (± 0.22)	-2.4 (± 0.21)	

Statistical analyses

Statistical analysis title	AIN457 150 mg vs placebo
Statistical analysis description:	
Up to week 12, all participants in the group "placebo AIN457" took placebo only	
Comparison groups	Placebo v AIN457 150 mg
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[12]
P-value	= 0.0971
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	0.1
Variability estimate	Standard error of the mean
Dispersion value	0.3

Notes:

[12] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline SPARCC index as continuous covariate

Statistical analysis title	AIN457 300 mg vs placebo
Statistical analysis description:	
Up to week 12, all participants in the group "placebo AIN457" took placebo only	
Comparison groups	Placebo v AIN457 300 mg
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority[13]
P-value	= 0.0207
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	-0.1
Variability estimate	Standard error of the mean
Dispersion value	0.3

Notes:

[13] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline SPARCC index as continuous covariate

Secondary: Change from baseline in Health assessment questionnaire – disability index (HAQ-DI) score at week 12

End point title	Change from baseline in Health assessment questionnaire – disability index (HAQ-DI) score at week 12

End point description:

The Health assessment questionnaire disability index (HAQ-DI) is a questionnaire for the assessment of Rheumatoid Arthritis. The questionnaire is a patient reported outcome (PRO) which is usually self-administered by the patient.

The following categories are assessed by the HAQ-DI:

dressing and grooming
arising
eating
walking
hygiene
reach
grip
common daily activities

Patients report the amount of difficulty they have in performing some of these activities. Each question asks on a scale ranging from 0 to 3 if the categories can be performed without any difficulty (scale 0) up to cannot be done at all (scale 3)

End point type	Secondary

End point timeframe:

at 12 weeks

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164	
Units: scores on a scale				
least squares mean (standard error)	-0.155 (± 0.0351)	-0.330 (± 0.0360)	-0.389 (± 0.0353)	

Statistical analyses

Statistical analysis title	AIN457 150 mg vs placebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	Placebo v AIN457 150 mg
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[14]
P-value	= 0.0005
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-0.175
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.273
upper limit	-0.076
Variability estimate	Standard error of the mean
Dispersion value	0.0502

Notes:

[14] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline HAQ-DI index as continuous covariate

Statistical analysis title	AIN457 300 mg vs placebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	AIN457 300 mg v Placebo
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority[15]
P-value	< 0.0001 [16]
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-0.234
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.331
upper limit	-0.136
Variability estimate	Standard error of the mean
Dispersion value	0.0497

Notes:

[15] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline HAQ-DI index as continuous covariate

[16] - Up to week 12, all participants in the group "placebo AIN457" took placebo only

Secondary: Change from baseline in Functional assessment of chronic illness therapy fatigue scale (FACIT-Fatigue) at week 12

End point title	Change from baseline in Functional assessment of chronic illness therapy fatigue scale (FACIT-Fatigue) at week 12

End point description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

End point type	Secondary

End point timeframe:
at 12 weeks

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164	
Units: scores on a scale				
least squares mean (standard error)	4.2 (± 0.70)	8.0 (± 0.72)	7.6 (± 0.71)	

Statistical analyses

Statistical analysis title	AIN457 150 mg vs placebo
Statistical analysis description:	
Up to week 12, all participants in the group "placebo AIN457" took placebo only	
Comparison groups	Placebo v AIN457 150 mg
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[17]
P-value	= 0.0002
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.8
upper limit	5.7
Variability estimate	Standard error of the mean
Dispersion value	1.01

Notes:

[17] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline FACIT-Fatigue score as continuous covariate

Statistical analysis title	AIN457 300 mg vs placebo
Statistical analysis description:	
Up to week 12, all participants in the group "placebo AIN457" took placebo only	
Comparison groups	Placebo v AIN457 300 mg
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority[18]
P-value	= 0.0007
Method	ANCOVA
Parameter estimate	LS Mean of treatment Difference
Point estimate	3.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	5.3
Variability estimate	Standard error of the mean
Dispersion value	0.99

Notes:

[18] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group, visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline FACIT-Fatigue score as continuous covariate

Secondary: Change from Baseline in ASAS Health Index at week 12

End point title	Change from Baseline in ASAS Health Index at week 12
End point description:	
Up to week 12, all participants in the group "placebo AIN457" took placebo only	
End point type	Secondary
End point timeframe:	
at 12 weeks	

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	154	
Units: scores on a scale				
least squares mean (standard error)	-1.2 (± 0.28)	-2.9 (± 0.29)	-2.8 (± 0.28)	

Statistical analyses

Statistical analysis title	AIN457 150 mg vs placebo
Statistical analysis description:	
Up to week 12, all participants in the group "placebo AIN457" took placebo only	
Comparison groups	Placebo v AIN457 150 mg
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[19]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	-0.9

Notes:

[19] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group,visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline ASAS health index as continuous covariate

Statistical analysis title	AIN457 300 mg vs placebo
Comparison groups	Placebo v AIN457 300 mg
Number of subjects included in analysis	318
Analysis specification	Pre-specified
Analysis type	superiority[20]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	LS Mean of Treatment Difference
Point estimate	-1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	-0.9
Variability estimate	Standard error of the mean
Dispersion value	0.4

Notes:

[20] - Least squares (LS) mean, LS mean treatment difference, 95% confidence interval (CI) for treatment difference, and p-value are from MMRM (mixed model for repeated measures) with treatment group,visit, treatment*visit, baseline*visit and concomitant MTX intake status, as factors and baseline ASAS health index as continuous covariate

Secondary: Proportion of participants with response to treatment as assessed by the ACR20 criteria at week 12

End point title	Proportion of participants with response to treatment as assessed by the ACR20 criteria at week 12

End point description:

American College of Rheumatology 20% (ACR20) Response at Week 12 is the % of responders with at least 20% improvement from Baseline for tender joint count (TJC), swollen joint count (SJC), and at least 3 of the 5 remaining core set measures: 1)Health Assessment Questionnaire-Disability Index (HAQ-DI), 2)C-reactive Protein (CRP), 3) Patient's Assessment of Arthritis Pain-Visual Analog Scale (PAAP-VAS), 4) Patient's Global Assessment of Disease Activity-Visual Analog Scale (PtGADA-VAS), 5) Physician's Global Assessment of Disease Activity-Visual Analog Scale (PhGA-VAS)

End point type	Secondary

End point timeframe:

at 12 weeks

End point values	Placebo	AIN457 150 mg	AIN457 300 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	164	157	164	
Units: proportion of participants				
number (confidence interval 95%)	18.5 (13.1 to 25.5)	56.5 (47.5 to 65.1)	51.6 (43.4 to 59.8)	

Statistical analyses

Statistical analysis title	AIN457 150 mg vs placebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	Placebo v AIN457 150 mg
Number of subjects included in analysis	321
Analysis specification	Pre-specified
Analysis type	superiority[21]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.31
upper limit	9.95

Notes:

[21] - Odds ratio, 95% CI for odds ratio, and p-value are from a logistic regression model with treatment (3 treatment groups), methotrexate usage status (yes, no) as explanatory variables

Statistical analysis title	AIN457 300 mg vs placebo

Statistical analysis description:

Up to week 12, all participants in the group "placebo AIN457" took placebo only

Comparison groups	Placebo v AIN457 300 mg
Number of subjects included in analysis	328
Analysis specification	Pre-specified
Analysis type	superiority[22]
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.83
upper limit	8.16

Notes:

[22] - Odds ratio, 95% CI for odds ratio, and p-value are from a logistic regression model with treatment (3 treatment groups), methotrexate usage status (yes, no) as explanatory variables

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Entire treatment period (including 12 weeks after last study treatment)	
Adverse event reporting additional description:	
An adverse event (AE) is any untoward sign or symptom that occurs during the study treatment	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	Secukinumab 300 mg
Reporting group description:	
Secukinumab 300 mg s.c. injections weekly until Week 4 followed by Secukinumab 300 mg s.c. injections every 4 weeks between week 8 and week 48 and placebo-switchers to Secukinumab 300 mg s.c. injections at week 12 onwards	
Reporting group title	Secukinumab 150 mg
Reporting group description:	
Secukinumab 150 mg s.c. injections weekly until Week 4 followed by Secukinumab 150 mg s.c. injections every 4 weeks between week 8 and week 48 and placebo-switchers to Secukinumab 150 mg s.c. injections at week 12 onwards	
Reporting group title	Placebo
Reporting group description:	
Placebo s.c. injections at baseline and weekly until Week 4, then at Week 8	

Serious adverse events	Secukinumab 300 mg	Secukinumab 150 mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 248 (5.65%)	14 / 245 (5.71%)	4 / 166 (2.41%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 248 (0.40%)	1 / 245 (0.41%)	0 / 166 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyoma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 245 (0.00%)	1 / 166 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			

subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Small cell lung cancer			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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			
Ankle fracture			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Craniocerebral injury			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Fracture			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Hand fracture			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Head injury			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Overdose			
subjects affected / exposed	0 / 248 (0.00%)	0 / 245 (0.00%)	1 / 166 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			

subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Cardiac disorders			
Cardiogenic shock			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Ischaemic cardiomyopathy			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Transient ischaemic attack			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Crohn's disease			

subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Diverticulum			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Gastritis haemorrhagic			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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			
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 248 (0.00%)	0 / 245 (0.00%)	1 / 166 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Calculus urinary			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myositis			

subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Osteoarthritis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Spinal pain			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Diverticulitis			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Erysipelas			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Gastroenteritis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 245 (0.00%)	1 / 166 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genitourinary tract infection			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Peritonsillitis			

subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Pyoderma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 245 (0.00%)	1 / 166 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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
Tooth abscess			
subjects affected / exposed	0 / 248 (0.00%)	1 / 245 (0.41%)	0 / 166 (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			
Food intolerance			
subjects affected / exposed	1 / 248 (0.40%)	0 / 245 (0.00%)	0 / 166 (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

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

Non-serious adverse events	Secukinumab 300 mg	Secukinumab 150 mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	116 / 248 (46.77%)	108 / 245 (44.08%)	47 / 166 (28.31%)
Investigations			
Blood creatinine increased			
subjects affected / exposed	8 / 248 (3.23%)	6 / 245 (2.45%)	0 / 166 (0.00%)
occurrences (all)	10	7	0
Hepatic enzyme increased			
subjects affected / exposed	5 / 248 (2.02%)	0 / 245 (0.00%)	0 / 166 (0.00%)
occurrences (all)	5	0	0
Vascular disorders			

Hypertension			
subjects affected / exposed	4 / 248 (1.61%)	10 / 245 (4.08%)	2 / 166 (1.20%)
occurrences (all)	4	11	2
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 248 (2.82%)	7 / 245 (2.86%)	6 / 166 (3.61%)
occurrences (all)	7	8	7
Sciatica			
subjects affected / exposed	1 / 248 (0.40%)	6 / 245 (2.45%)	2 / 166 (1.20%)
occurrences (all)	1	6	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	6 / 248 (2.42%)	3 / 245 (1.22%)	4 / 166 (2.41%)
occurrences (all)	7	3	4
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	16 / 248 (6.45%)	7 / 245 (2.86%)	4 / 166 (2.41%)
occurrences (all)	23	7	6
Vomiting			
subjects affected / exposed	5 / 248 (2.02%)	3 / 245 (1.22%)	1 / 166 (0.60%)
occurrences (all)	5	3	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	7 / 248 (2.82%)	6 / 245 (2.45%)	3 / 166 (1.81%)
occurrences (all)	7	6	3
Oropharyngeal pain			
subjects affected / exposed	5 / 248 (2.02%)	9 / 245 (3.67%)	4 / 166 (2.41%)
occurrences (all)	9	9	4
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 248 (0.00%)	5 / 245 (2.04%)	0 / 166 (0.00%)
occurrences (all)	0	5	0
Pruritus			
subjects affected / exposed	5 / 248 (2.02%)	2 / 245 (0.82%)	1 / 166 (0.60%)
occurrences (all)	6	2	1
Psoriasis			

subjects affected / exposed	5 / 248 (2.02%)	6 / 245 (2.45%)	2 / 166 (1.20%)
occurrences (all)	5	6	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 248 (2.02%)	7 / 245 (2.86%)	5 / 166 (3.01%)
occurrences (all)	5	8	6
Back pain			
subjects affected / exposed	9 / 248 (3.63%)	6 / 245 (2.45%)	6 / 166 (3.61%)
occurrences (all)	10	7	6
Psoriatic arthropathy			
subjects affected / exposed	4 / 248 (1.61%)	7 / 245 (2.86%)	1 / 166 (0.60%)
occurrences (all)	4	7	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	11 / 248 (4.44%)	9 / 245 (3.67%)	1 / 166 (0.60%)
occurrences (all)	12	9	1
Ear infection			
subjects affected / exposed	5 / 248 (2.02%)	2 / 245 (0.82%)	0 / 166 (0.00%)
occurrences (all)	6	2	0
Gastroenteritis			
subjects affected / exposed	5 / 248 (2.02%)	4 / 245 (1.63%)	2 / 166 (1.20%)
occurrences (all)	6	4	2
Nasopharyngitis			
subjects affected / exposed	34 / 248 (13.71%)	22 / 245 (8.98%)	11 / 166 (6.63%)
occurrences (all)	42	32	12
Pharyngitis			
subjects affected / exposed	7 / 248 (2.82%)	13 / 245 (5.31%)	5 / 166 (3.01%)
occurrences (all)	7	14	5
Rhinitis			
subjects affected / exposed	9 / 248 (3.63%)	5 / 245 (2.04%)	0 / 166 (0.00%)
occurrences (all)	10	7	0
Sinusitis			
subjects affected / exposed	4 / 248 (1.61%)	6 / 245 (2.45%)	0 / 166 (0.00%)
occurrences (all)	5	6	0
Tonsillitis			

subjects affected / exposed	7 / 248 (2.82%)	3 / 245 (1.22%)	0 / 166 (0.00%)
occurrences (all)	7	4	0
Upper respiratory tract infection			
subjects affected / exposed	12 / 248 (4.84%)	14 / 245 (5.71%)	5 / 166 (3.01%)
occurrences (all)	13	18	5
Urinary tract infection			
subjects affected / exposed	8 / 248 (3.23%)	11 / 245 (4.49%)	2 / 166 (1.20%)
occurrences (all)	8	15	3
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 248 (0.40%)	6 / 245 (2.45%)	1 / 166 (0.60%)
occurrences (all)	1	9	1

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