Clinical trial results:
A randomized, double-blind, placebo-controlled, multicenter, exploratory evaluation of surrogate markers of cardiovascular risk in patients with active chronic plaque-type psoriasis treated for 52 weeks with subcutaneous (s.c.) secukinumab (300 mg and 150 mg)

Summary

EudraCT number	2013-002266-40
Trial protocol	DE
Global end of trial date	21 April 2016

Results information

Result version number	v1 (current)
This version publication date	05 May 2017
First version publication date	05 May 2017

Trial information

Trial identification

Sponsor protocol code	CAIN457ADE02

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02559622
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	21 April 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to evaluate flow mediated dilation (FMD) by Doppler ultrasound at week 12 in subjects treated with 300 milligrams (mg) secukinumab compared to the pooled group of subjects treated with placebo up to week 12.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2014
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	Germany: 151
Worldwide total number of subjects	151
EEA total number of subjects	151

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)	140
From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 23 centres in Germany.

Pre-assignment

Screening details:

A total of 151 subjects were randomised and treated in the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Secukinumab 300 mg

Arm description:

Subjects were administered with 300 mg secukinumab subcutaneously (s.c.) using pre-filled syringe every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection).

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with 300 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks until week 48 (last injection).

Arm title	Secukinumab 150 mg

Arm description:

Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection).

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks until week 48 (last injection).

Arm title	Placebo followed by 300 mg secukinumab

Arm description:

Subjects were administered with placebo until week 12 followed by 300 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection).

Arm type	Experimental

Investigational medicinal product name	Secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with 300 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks until week 48 (last injection).

Arm title	Placebo followed by 150 mg secukinumab

Arm description:

Subjects were administered with placebo until week 12 followed by 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection).

Arm type	Experimental
Investigational medicinal product name	Secukinumab
Investigational medicinal product code	AIN457
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks until week 48 (last injection).

Number of subjects in period 1	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab
Started	48	54	26
Completed	47	49	24
Not completed	1	5	2
Adverse event, non-fatal	-	2	2
Progressive disease	-	1	-
Subject/guardian decision	1	2	-

Number of subjects in period 1	Placebo followed by 150 mg secukinumab
Started	23
Completed	20
Not completed	3
Adverse event, non-fatal	2
Progressive disease	-
Subject/guardian decision	1

Baseline characteristics

Reporting groups	
Reporting group title	Secukinumab 300 mg
Reporting group description:	
Subjects were administered with 300 mg secukinumab subcutaneously (s.c.) using pre-filled syringe every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection).	
Reporting group title	Secukinumab 150 mg
Reporting group description:	
Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection).	
Reporting group title	Placebo followed by 300 mg secukinumab
Reporting group description:	
Subjects were administered with placebo until week 12 followed by 300 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection).	
Reporting group title	Placebo followed by 150 mg secukinumab
Reporting group description:	
Subjects were administered with placebo until week 12 followed by 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection).	

Reporting group values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab
Number of subjects	48	54	26
Age categorical Units: Subjects			
Adults (18-64 years)	46	46	26
From 65-84 years	2	8	0
Age continuous Units: years			
arithmetic mean	44.2	46	43.7
standard deviation	± 12.9	± 14.4	± 11.4
Gender categorical Units: Subjects			
Female	11	23	8
Male	37	31	18

Reporting group values	Placebo followed by 150 mg secukinumab	Total	
Number of subjects	23	151	
Age categorical Units: Subjects			
Adults (18-64 years)	22	140	
From 65-84 years	1	11	
Age continuous Units: years			
arithmetic mean	46.8		
standard deviation	± 13.1	-	

Gender categorical Units: Subjects			
Female	7	49	
Male	16	102	

End points

End points reporting groups

Reporting group title	Secukinumab 300 mg
Reporting group description:	
Subjects were administered with 300 mg secukinumab subcutaneously (s.c.) using pre-filled syringe every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection).	
Reporting group title	Secukinumab 150 mg
Reporting group description:	
Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection).	
Reporting group title	Placebo followed by 300 mg secukinumab
Reporting group description:	
Subjects were administered with placebo until week 12 followed by 300 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection).	
Reporting group title	Placebo followed by 150 mg secukinumab
Reporting group description:	
Subjects were administered with placebo until week 12 followed by 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection).	
Subject analysis set title	Placebo (Pooled)
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects were administered with placebo until week 12 followed by 150 mg or 300 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg or 300 mg secukinumab respectively every 4 weeks until week 48 (last injection).	

Primary: Flow Mediated Dilation (FMD) at Week 12 followed by secukinumab 300 mg vs pooled placebo treatment

End point title	Flow Mediated Dilation (FMD) at Week 12 followed by secukinumab 300 mg vs pooled placebo treatment[1]
End point description:	
Flow Mediated Dilation (FMD) is non-invasive method evaluated by Doppler Ultrasound test, to assess endothelial function. FMD was calculated as the percent maximal deviation from the baseline arterial diameter (D):FMD = 100*[(D maximum – D baseline) / D baseline]. Here, arterial diameter (brachial artery) was measured at rest (1 minute), during inflation of the distal cuff to 100 millimeter of mercury (mmHg) for 4.5 minutes and for 4.5 minutes following deflation. The analysis was performed in Full analysis set (FAS) population, defined as all subjects from the randomized set who received at least one dose of study drug. Here, "Number of subjects analyzed" signifies subjects evaluable for FMD at Week 12 for each arm, respectively.	
End point type	Primary
End point timeframe:	
Week 12	

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: The endpoint was planned to evaluate statistics for the specified arm only.

End point values	Secukinumab 300 mg	Placebo (Pooled)		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	39	38		
Units: Percentage maximal increase in diameter				
arithmetic mean (standard deviation)	5.23 (± 5.3)	3.65 (± 4.07)		

Statistical analyses

Statistical analysis title	Flow Mediated Dilation (FMD) at Week 12
Comparison groups	Secukinumab 300 mg v Placebo (Pooled)
Number of subjects included in analysis	77
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.223
Method	ANCOVA
Parameter estimate	Least Square (LS) mean difference
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.72
upper limit	3.06

Secondary: Change From Baseline in Flow Mediated Dilation (FMD) at Week 4, 12, 24 and 52

End point title	Change From Baseline in Flow Mediated Dilation (FMD) at Week 4, 12, 24 and 52

End point description:

FMD is non-invasive method evaluated by Doppler Ultrasound test, to assess endothelial function. FMD was calculated as the percent maximal deviation from the baseline arterial diameter (D):FMD = 100*[(D maximum – D baseline) / D baseline]. Here, arterial diameter (brachial artery) was measured at rest (1 minute), during inflation of the distal cuff to 100 mmHg for 4.5 minutes and for 4.5 minutes following deflation. A positive change in FMD (NOT arterial pulse wave velocity) constitutes an improvement in endothelial function. The analysis was performed in FAS population. Here, "Number of subjects analyzed" signifies subjects evaluable for FMD at Week 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: Percentage change in FMD				
arithmetic mean (confidence interval 95%)				

Week 4 (n = 37,47,21,16)	-0.7 (-1.9 to 0.5)	-0.9 (-2.4 to 0.7)	0.7 (-1 to 2.5)	1.4 (-0.8 to 3.6)
Week 12 (n = 39,48,21,17)	0.5 (-1.1 to 2.1)	0.1 (-1.2 to 1.5)	-0.1 (-2.7 to 2.4)	0.1 (-2.1 to 2.3)
Week 24 (n = 35,39,19,16)	-0.8 (-1.9 to 0.3)	1 (-0.4 to 2.4)	0 (-2.6 to 2.6)	0.9 (-1 to 2.9)
Week 52 (n = 38,43,20,17)	2.1 (0.8 to 3.3)	2.1 (0.7 to 3.4)	2.2 (-0.5 to 4.9)	1.2 (-1 to 3.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Aortic Augmentation Index at Heart Rate of 75 (AIx-75) at Week 4, 12, 24 and 52

End point title	Change From Baseline in Aortic Augmentation Index at Heart Rate of 75 (AIx-75) at Week 4, 12, 24 and 52

End point description:

Pulse wave analysis was performed on the central aortic pressure waveform as derived by SphygmoCor XCEL from the brachial pressure waveform recorded in a partially-inflated blood pressure cuff around the upper arm. The waveform derivation employs a validated generalized transfer function to convert a brachial waveform to a central waveform and has been shown to produce measurement results corresponding to measurements using intra-arterial pressure catheters. The augmentation index is derived from the waveform by determining the percentage of the central pulse pressure during systole due to wave reflection. AIx was heart-rate corrected to calculate the AIx at a heart rate of 75 bpm, i.e. AIx-75. The analysis was performed in FAS population. Here, "Number of subjects analyzed" signifies subjects evaluable for FMD at Week 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: Percentage change in Alx-75				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 47,52,25,21)	0 (-2.8 to 2.9)	0.3 (-2 to 2.7)	1.1 (-1.7 to 3.8)	-0.1 (-3 to 2.9)
Week 12 (n = 48,52,26,21)	-0.5 (-3 to 2.1)	1 (-1.7 to 3.8)	-1.1 (-5.4 to 3.3)	-0.1 (-3.4 to 3.2)
Week 24 (n = 47,50,24,21)	3 (0.3 to 5.6)	1.8 (-0.6 to 4.3)	1.3 (-2.7 to 5.3)	0.7 (-2.7 to 4.1)
Week 52 (n = 47,49,25,20)	1.3 (-1.5 to 4.2)	-0.1 (-2.8 to 2.7)	-1.4 (-5.8 to 2.9)	-0.9 (-4.2 to 2.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Pulse Wave Velocity (PWV) at Week 4, 12, 24 and 52

End point title	Change From Baseline in Pulse Wave Velocity (PWV) at Week 4, 12, 24 and 52

End point description:

Regional arterial pulse wave velocity (PWV) was directly related to arterial stiffness and was defined as the time it takes for the blood pressure wave to travel from a proximal site to a distal site (relative to the heart) divided by the distance (PWV = Δdistance/Δtime [m/s]). The foot of the arterial pulse wave was being recorded by using the SphygmoCor XCEL device. XCEL simultaneously measures the pressure waveform at the femoral site (using a partially inflated custom blood pressure cuff) and the carotid site (using hand-held applanation tonometry). The foot-to-foot time between the two pressure waveforms was the time interval used in the PWV calculation. The analysis was performed in FAS population. Here, "n" signifies the sum of subjects for all repeated measurements during calculation of mean, evaluable for PWV at defined time-frame for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: meters per second (m/s)				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 192, 262, 133, 104)	0 (-0.2 to 0.2)	-0.2 (-0.3 to 0)	0 (-0.1 to 0.2)	-0.2 (-0.5 to 0.2)
Week 12 (n = 214, 255, 116, 133)	0.4 (0.2 to 0.6)	0.1 (-0.1 to 0.2)	0.1 (-0.2 to 0.4)	0.4 (0.1 to 0.7)
Week 24 (n = 205, 255, 100, 100)	0.2 (-0.1 to 0.5)	0 (-0.2 to 0.1)	0.2 (0.1 to 0.4)	-0.1 (-0.5 to 0.2)
Week 52 (n = 191, 228, 115, 101)	-0.1 (-0.3 to 0)	0.2 (-0.1 to 0.5)	0.1 (-0.2 to 0.4)	-0.2 (-0.6 to 0.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Average Wall Area Assessed as a Measure of Total Plaque Burden at Week 12

End point title	Change From Baseline in Average Wall Area Assessed as a Measure of Total Plaque Burden at Week 12

End point description:

Magnetic resonance imaging (MRI) was used to evaluate vessel wall morphometry to determine plaque burden. As a measure of plaque burden, average wall area was computed by subtracting vessel lumen area from total vessel area. Exploratory 3.0 Tesla MRI technique was applied to assess structure and function of the carotid and the aorta. A 2D axial dark blood T1, T2, proton density weighted spin echo

based images and time of flight images were acquired from the bilateral carotid arteries as well as the descending aorta. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for MRI sub-study at week 12 for each arm, respectively. MRI was applied in a sub-study population of 33 subjects.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: millimeter square (mm^2)				
arithmetic mean (confidence interval 95%)				
Ascending thoracic aorta (n = 10,11,4,6)	15.35 (-8.23 to 38.92)	5.91 (-13.09 to 24.91)	9.92 (-58.24 to 78.08)	6.45 (-9.26 to 22.15)
Descending thoracic aorta (n = 10,11,4,7)	2.69 (-14.18 to 19.56)	-2.94 (-13.44 to 7.57)	-4.04 (-29.61 to 21.53)	3.16 (-13.73 to 20.05)
Carotid bifurcation left (n = 11,11,4,7)	0.52 (-2.72 to 3.77)	-1.08 (-3.85 to 1.69)	3.63 (-7.82 to 15.08)	1.12 (-2.04 to 4.28)
Carotid bifurcation right (n = 11,11,4,7)	-0.77 (-3.6 to 2.06)	1.75 (-0.71 to 4.21)	-1.26 (-7.64 to 5.12)	-1.07 (-4.24 to 2.1)
Common carotid left (n = 11,11,4,6)	0.17 (-1.64 to 1.99)	1.12 (-1.8 to 4.03)	0.69 (-5.21 to 6.59)	0.12 (-1.91 to 2.15)
Common carotid right (n = 11,11,4,7)	-0.12 (-2.17 to 1.92)	0.3 (-2.76 to 3.36)	-0.38 (-6.56 to 5.8)	-0.14 (-1.6 to 1.32)
Internal carotid left (n = 9,10,4,5)	3.79 (-0.19 to 7.78)	2.09 (-0.57 to 4.75)	2.59 (-0.58 to 5.77)	-1.74 (-4.55 to 1.08)
Internal carotid right (n = 11,11,4,7)	-0.69 (-1.9 to 0.51)	0.17 (-1.96 to 2.3)	0.68 (-3.97 to 5.33)	-1.37 (-4.37 to 1.62)
Descending abdominal aorta (n = 8,9,4,6)	8.71 (-6.33 to 23.76)	-3.79 (-21.9 to 14.32)	4.56 (-52.64 to 61.77)	-0.58 (-15.51 to 14.35)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Average Wall Area Assessed as a Measure of Total Plaque Burden at Week 52

End point title	Change From Baseline in Average Wall Area Assessed as a Measure of Total Plaque Burden at Week 52

End point description:

Magnetic resonance imaging (MRI) was used to evaluate vessel wall morphometry to determine plaque burden. As a measure of plaque burden, average wall area was computed by subtracting vessel lumen area from total vessel area. Exploratory 3.0 Tesla MRI technique was applied to assess structure and function of the carotid and the aorta. A 2D axial dark blood T1, T2, proton density weighted spin echo based images and time of flight images were acquired from the bilateral carotid arteries as well as the descending aorta. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for MRI sub-study at week 12 for each arm, respectively. MRI was applied in a sub-study population of 33 subjects.

End point type	Secondary

End point timeframe:

Baseline, Week 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: mm^2				
arithmetic mean (confidence interval 95%)				
Ascending thoracic aorta (n = 10,11,4,6)	14.42 (-14.93 to 43.76)	3.19 (-17.17 to 23.55)	-15.11 (-28.15 to -2.06)	9.54 (-14.71 to 33.79)
Descending thoracic aorta (n = 10,11,4,7)	3.97 (-13.42 to 21.37)	2.55 (-12.23 to 17.33)	-10.14 (-34.05 to 13.77)	1.14 (-26.76 to 29.05)
Carotid bifurcation left (n = 11,11,4,7)	2.45 (-1.55 to 6.45)	0.64 (-3.59 to 4.88)	0.58 (-9.03 to 10.2)	2.6 (-2.16 to 7.36)
Carotid bifurcation right (n = 11,11,4,7)	-1.64 (-6.02 to 2.74)	-0.05 (-3.62 to 3.51)	-3.23 (-9.86 to 3.4)	1.25 (-3.92 to 6.41)
Common carotid left (n = 11,11,4,6)	1.42 (-0.36 to 3.19)	1.21 (-1.51 to 3.93)	0.65 (-2.82 to 4.13)	1 (-0.83 to 2.82)
Common carotid right (n = 11,11,4,7)	0.02 (-2.54 to 2.58)	0.23 (-2.29 to 2.75)	-0.8 (-6.25 to 4.64)	-1.38 (-3.33 to 0.57)
Internal carotid left (n = 9,10,4,5)	5.43 (1.21 to 9.65)	3.59 (0.59 to 6.6)	1.06 (-2.66 to 4.78)	0.33 (-5.07 to 5.73)
Internal carotid right (n = 11,11,4,7)	-1.07 (-2.12 to -0.03)	0.71 (-1.78 to 3.21)	-0.2 (-3.89 to 3.49)	0.13 (-2.22 to 2.48)
Descending abdominal aorta (n = 8,9,4,6)	10.56 (-8.37 to 29.48)	-4.36 (-17.9 to 9.19)	12.46 (-46.12 to 71.05)	11.82 (-15.26 to 38.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in High sensitivity C-reactive protein (hsCRP) at Week 4, 12, 24 and 52

End point title	Change from Baseline in High sensitivity C-reactive protein (hsCRP) at Week 4, 12, 24 and 52

End point description:

High sensitivity C-reactive protein (hsCRP), a soluble biomarker of systemic inflammation was determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: Milligrams per decilitres (mg/dL)				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 48,53,26,21)	0 (-0.2 to 0.2)	-0.2 (-0.4 to -0.1)	0 (-0.2 to 0.2)	0.1 (-0.1 to 0.3)
Week 12 (n = 48,54,26,21)	0 (-0.3 to 0.3)	-0.2 (-0.3 to 0)	-0.3 (-0.8 to 0.1)	0.1 (-0.4 to 0.6)
Week 24 (n = 48,52,25,21)	0 (-0.3 to 0.2)	0 (-0.3 to 0.2)	0.1 (-0.2 to 0.4)	-0.4 (-0.9 to 0.1)
Week 52 (n = 48,50,26,20)	-0.1 (-0.3 to 0.1)	-0.2 (-0.4 to 0)	-0.3 (-0.8 to 0.2)	-0.5 (-1.1 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in S-100 protein B (total) at Week 4, 12, 24 and 52

End point title	Change from Baseline in S-100 protein B (total) at Week 4, 12, 24 and 52

End point description:

S100 calcium-binding protein B (S100B-protein), a soluble biomarker of systemic inflammation was determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: Micrograms per Litre (ug/L)				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 48,53,26,22)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Week 12 (n = 48,52,26,22)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Week 24 (n = 48,51,25,22)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Week 52 (n = 48,51,26,22)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Chemokine (c-c motif) ligand 5 (CCL5), Monocyte chemoattractant protein 1 (MCP-1) and Macrophage inflammatory proteins (MIP) 1 alpha and 1 beta at Week 4, 12, 24 and 52

End point title	Change from Baseline in Chemokine (c-c motif) ligand 5 (CCL5), Monocyte chemoattractant protein 1 (MCP-1) and Macrophage inflammatory proteins (MIP) 1 alpha and 1 beta at Week 4, 12, 24 and 52

End point description:

Chemokine (c-c motif) ligand 5 (CCL5), Monocyte chemoattractant protein 1 (MCP-1) and Macrophage inflammatory proteins (MIP) 1 alpha (1A) and 1 beta (1B), soluble biomarkers of systemic inflammation were determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	4	26	23
Units: picograms per millilitres (pg/mL)				
arithmetic mean (confidence interval 95%)				
CCL5 Week 4 (n = 48,54,26,22)	-1000 (-3106 to 1094)	1649 (-597 to 3895)	27 (-3943 to 3997)	-2000 (-5056 to 281.3)
CCL5 Week 12 (n = 48,54,26,22)	2116 (-2368 to 6599)	5185 (840.3 to 9530)	4393 (-1598 to 10383)	3002 (-1806 to 7809)
CCL5 Week 24 (n = 48,52,25,22)	7772 (3766 to 11777)	10000 (6437 to 14394)	11000 (2117 to 20176)	9168 (2124 to 16212)
CCL5 Week 52 (n = 48,51,25,22)	1515 (-2478 to 5507)	3577 (-737 to 7891)	-597 (-3340 to 2145)	2308 (-2558 to 7175)
MCP-1 Week 4 (n = 48,54,26,22)	-7 (-21.8 to 7.7)	1.4 (-17.4 to 20.2)	-25 (-57.2 to 8)	17.5 (-43.1 to 78)
MCP-1 Week 12 (n = 48,54,26,22)	18.4 (-1.9 to 38.7)	28.6 (-8.4 to 65.7)	11.3 (-40.9 to 63.5)	21.5 (-18.3 to 61.2)
MCP-1 Week 24 (n = 48,52,25,22)	39.8 (-0.6 to 80.3)	241 (-203 to 685.7)	-20 (-53.9 to 14.2)	33.4 (8.3 to 58.5)
MCP-1 Week 52 (n = 48,51,25,22)	22.1 (-18.1 to 62.4)	25.4 (-21.7 to 72.6)	-11 (-60.6 to 38.6)	109 (-13.3 to 230.9)
MIP-1A Week 4 (n = 48,54,26,22)	-0.1 (-2.1 to 1.9)	0.1 (-1.6 to 1.8)	0.5 (-2.5 to 3.5)	-0.6 (-2.3 to 1.2)
MIP-1A Week 12 (n = 48,54,26,22)	0.2 (-2.8 to 3.3)	2.2 (-1 to 5.3)	-3.6 (-7 to -0.3)	0.9 (-3 to 4.8)
MIP-1A Week 24 (n = 48,52,25,22)	-0.2 (-2.9 to 2.4)	-0.5 (-3.6 to 2.6)	-4.7 (-8.4 to -1)	1.7 (-1.3 to 4.7)
MIP-1A Week 52 (n = 48,51,25,22)	4.3 (-0.1 to 8.7)	0.8 (-3 to 4.5)	1.7 (-6 to 9.5)	20.1 (4.7 to 35.6)
MIP-1B Week 4 (n = 48,54,26,22)	-24 (-50.8 to 3)	-2.6 (-24.8 to 19.5)	-16 (-57.5 to 25.8)	-20 (-54.4 to 15.3)

MIP-1B Week 12 (n = 48,54,26,22)	-49 (-80.9 to -16.6)	-34 (-69 to 1.4)	-65 (-106 to -24.7)	-68 (-116 to -20.5)
MIP-1B Week 24 (n = 48,52,25,22)	-52 (-130 to 26.7)	-97 (-133 to -61.3)	-161 (-207 to -114)	79.4 (-261 to 420.3)
MIP-1B Week 52 (n = 48,51,25,22)	-41 (-73.6 to -8.6)	-59 (-89 to -29.7)	-73 (-122 to -24.2)	-31 (-109 to 46.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Fasting plasma glucose (FPG) at Week 4, 12, 24 and 52

End point title	Change from Baseline in Fasting plasma glucose (FPG) at Week 4, 12, 24 and 52

End point description:

Fasting plasma glucose (FPG), a soluble biomarker of dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on dysglycemia. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: mg/dL				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 47,53,26,22)	1.5 (-1 to 4)	-1.6 (-4.6 to 1.3)	0.9 (-4.4 to 6.1)	0.2 (-5.2 to 5.6)
Week 12 (n = 47,53,26,22)	3.5 (0 to 7)	1.1 (-4 to 6.2)	5.3 (-2.2 to 12.8)	-1.5 (-7.1 to 4)
Week 24 (n = 47,51,25,22)	2.5 (0 to 5)	1.4 (-6.3 to 9.1)	12.1 (-10.8 to 35)	-1.4 (-7.7 to 5)
Week 52 (n = 46,51,26,22)	-0.8 (-3.5 to 2)	0.7 (-3 to 4.4)	8.7 (-7.5 to 25)	0.9 (-6.7 to 8.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Fasting Insulin at Week 4, 12, 24 and 52

End point title	Change from Baseline in Fasting Insulin at Week 4, 12, 24 and 52

End point description:

Fasting Insulin, a soluble biomarker of dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on dysglycemia. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: micro units per milliliter (uU/mL)				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 48,53,26,22)	0.4 (-2 to 2.7)	0.4 (-2.3 to 3)	-4.7 (-17.4 to 8.1)	-0.5 (-4.8 to 3.7)
Week 12 (n = 48,52,26,22)	-1.4 (-5.1 to 2.4)	1.1 (-2.7 to 4.8)	-2.2 (-9.2 to 4.7)	-0.1 (-4.9 to 4.7)
Week 24 (n = 48,51,25,22)	-1 (-4.1 to 2)	0.5 (-3.7 to 4.8)	-5.3 (-18.5 to 8)	-2 (-6.1 to 2)
Week 52 (n = 48,51,26,22)	-0.4 (-4.3 to 3.6)	1.5 (-1.3 to 4.2)	-1.2 (-7.5 to 5.1)	3 (-5.2 to 11.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Homeostatic Model Assessment (HOMA) beta-cell function at Week 4, 12, 24 and 52

End point title	Change from Baseline in Homeostatic Model Assessment (HOMA) beta-cell function at Week 4, 12, 24 and 52

End point description:

Homeostatic Model Assessment (HOMA) beta-cell function, a soluble biomarker of dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on dysglycemia. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: Percentage				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 42,51,24,21)	-18 (-64.7 to 28.2)	-0.2 (-25.7 to 25.3)	-28 (-88.4 to 33)	-8.9 (-38.5 to 20.7)
Week 12 (n = 44,50,23,22)	-16 (-74.4 to 41.5)	3.9 (-32 to 39.8)	-29 (-100 to 41.6)	16.6 (-20.6 to 53.8)
Week 24 (n = 44,50,24,22)	-25 (-53.9 to 3.5)	-8.2 (-40.2 to 23.9)	-35 (-111 to 40.7)	-26 (-63.2 to 12)
Week 52 (n = 43,50,25,22)	11.5 (-40.5 to 63.5)	-1.6 (-32.6 to 29.4)	9.3 (-56.4 to 75.1)	11.6 (-26.6 to 49.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Homeostatic Model Assessment (HOMA) insulin resistance at Week 4, 12, 24 and 52

End point title	Change from Baseline in Homeostatic Model Assessment (HOMA) insulin resistance at Week 4, 12, 24 and 52

End point description:

HOMA insulin resistance, a soluble biomarker of dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on dysglycemia. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: Insulin Resistance Index				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 42,51,24,21)	0.3 (-0.6 to 1.2)	0.1 (-0.9 to 1)	-1.1 (-5.2 to 3.1)	-0.3 (-2 to 1.3)
Week 12 (n = 44,50,23,22)	-0.1 (-1.5 to 1.4)	0.6 (-0.7 to 1.8)	-0.1 (-2.5 to 2.3)	-0.4 (-2 to 1.3)
Week 24 (n = 44,50,24,22)	-0.3 (-1.1 to 0.6)	0.6 (-1.3 to 2.5)	-1.1 (-5 to 2.8)	-0.7 (-2.2 to 0.8)
Week 52 (n = 43,50,25,22)	-0.2 (-1.2 to 0.9)	0.6 (-0.3 to 1.4)	-0.2 (-2.8 to 2.4)	0.7 (-1.9 to 3.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hemoglobin A1c (glycated hemoglobin) at Week 4, 12, 24 and 52

End point title	Change from Baseline in Hemoglobin A1c (glycated hemoglobin) at Week 4, 12, 24 and 52

End point description:

Hemoglobin A1c (glycated hemoglobin), a soluble biomarker of dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on dysglycemia. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: millimoL/moL of Hemoglobin				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 48,52,26,22)	0.2 (-0.5 to 0.8)	-0.4 (-1 to 0.3)	-0.7 (-2.3 to 1)	-0.4 (-1.2 to 0.4)
Week 12 (n = 48,54,26,22)	0.4 (-0.7 to 1.5)	-0.4 (-2.2 to 1.4)	-1.2 (-3.8 to 1.3)	0.1 (-0.8 to 1)
Week 24 (n = 48,52,25,22)	-0.4 (-1.7 to 1)	-1.2 (-2.9 to 0.5)	-0.1 (-2.4 to 2.1)	-1.2 (-2.9 to 0.6)
Week 52 (n = 48,52,26,22)	-1.1 (-2.3 to 0.1)	-2.8 (-6.1 to 0.4)	-1.9 (-4.3 to 0.6)	-2.1 (-3 to -1.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Sex hormone-binding globulin (SHBG) at Week 4, 12, 24 and 52

End point title	Change from Baseline in Sex hormone-binding globulin (SHBG) at Week 4, 12, 24 and 52

End point description:

Sex hormone-binding globulin (SHBG), a soluble biomarker of dysglycemia was determined in fasting blood samples to evaluate the effect of secukinumab on dysglycemia. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: nmoL/L				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 48,53,26,21)	0.1 (-1.8 to 2.1)	3.7 (-3 to 10.4)	4.7 (-4.2 to 13.5)	-0.3 (-4 to 3.5)
Week 12 (n = 48,54,26,21)	-0.1 (-3.4 to 3.2)	1.1 (-1.8 to 4.1)	3.7 (-1.6 to 9.1)	4.1 (-0.2 to 8.4)
Week 24 (n = 48,52,25,21)	-1.5 (-5.1 to 2.2)	3.2 (-0.9 to 7.2)	1.7 (-2.9 to 6.3)	2.6 (-1.5 to 6.7)
Week 52 (n = 48,50,26,20)	-3.1 (-10.8 to 4.6)	5.9 (-1.3 to 13)	-2.6 (-14.9 to 9.6)	3.2 (-4.3 to 10.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Adiponectin at Week 4, 12, 24 and 52

End point title	Change from Baseline in Adiponectin at Week 4, 12, 24 and 52

End point description:

Adiponectin, a soluble biomarker of impaired lipid metabolism was determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: ug/mL				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 48,53,26,22)	-0.5 (-1 to -0.1)	0.2 (-0.4 to 0.8)	-0.1 (-0.8 to 0.5)	-0.6 (-1.2 to 0)
Week 12 (n = 48,52,26,22)	-0.5 (-1.1 to 0)	-0.2 (-0.7 to 0.3)	0.5 (0.1 to 0.9)	0.3 (-0.7 to 1.3)
Week 24 (n = 48,51,25,22)	0.3 (-0.3 to 0.9)	0.1 (-0.5 to 0.7)	0.7 (-0.3 to 1.8)	-0.6 (-1.6 to 0.3)
Week 52 (n = 48,51,26,22)	-1.1 (-1.6 to -0.6)	-0.9 (-1.5 to -0.3)	-0.4 (-1 to 0.2)	-1.1 (-2 to -0.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Leptin at Week 4, 12, 24 and 52

End point title	Change from Baseline in Leptin at Week 4, 12, 24 and 52

End point description:

Leptin, a soluble biomarker of impaired lipid metabolism was determined in fasting blood samples to evaluate the effect of secukinumab on systemic inflammation. The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: nanograms per millilitre (ng/mL)				
arithmetic mean (confidence interval 95%)				
Week 4 (n = 48,53,26,22)	-0.6 (-1.8 to 0.7)	1 (-0.1 to 2.2)	-0.2 (-1.6 to 1.2)	0.3 (-1.2 to 1.9)
Week 12 (n = 48,52,26,22)	0.2 (-0.7 to 1.1)	0.1 (-0.9 to 1.2)	0.7 (-1 to 2.4)	-0.3 (-1.7 to 1.2)
Week 24 (n = 48,51,25,22)	0.2 (-0.7 to 1.2)	1 (-0.5 to 2.4)	-0.3 (-2.8 to 2.3)	-1.4 (-4.9 to 2.1)
Week 52 (n = 48,51,26,22)	0.2 (-1 to 1.3)	-0.5 (-1.6 to 0.7)	-0.4 (-3.8 to 3)	-2.9 (-5.7 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Soluble biomarkers of impaired lipid metabolism at Week 4, 12, 24 and 52

End point title	Change from Baseline in Soluble biomarkers of impaired lipid metabolism at Week 4, 12, 24 and 52

End point description:

Soluble biomarkers were determined in fasting blood samples to evaluate the effect of secukinumab on impaired lipid metabolism. Soluble biomarkers included Triglycerides, Total cholesterol, Low density lipoprotein (LDL), High density lipoprotein (HDL), Apolipoprotein A-1 (ApoA-1) and Apolipoprotein B (ApoB). The analysis was performed in FAS population. Here, "n" signifies subjects evaluable for this outcome measure at weeks 4, 12, 24 and 52 for each arm, respectively.

End point type	Secondary

End point timeframe:

Baseline, Week 4, 12, 24 and 52

End point values	Secukinumab 300 mg	Secukinumab 150 mg	Placebo followed by 300 mg secukinumab	Placebo followed by 150 mg secukinumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	54	26	23
Units: mg/dL				
arithmetic mean (confidence interval 95%)				
Triglycerides Week 4 (n = 48,53,26,21)	-1.8 (-15.5 to 12)	6.5 (-5.9 to 18.9)	12.7 (-12.2 to 37.7)	27.5 (-6.6 to 61.6)
Triglycerides Week 12 (n = 48,54,26,21)	-9.3 (-20.8 to 2.3)	4 (-9.3 to 17.3)	5.9 (-32.4 to 44.2)	2.7 (-18.3 to 23.8)
Triglycerides Week 24 (n = 48,52,25,21)	4.6 (-16.6 to 25.8)	3.9 (-9.1 to 16.9)	32.8 (-19.7 to 85.2)	17.1 (-2.3 to 36.5)
Triglycerides Week 52 (n = 48,50,26,20)	64.6 (-44 to 173.2)	2.6 (-11.7 to 16.9)	-6 (-54.3 to 42.3)	11.9 (-8.6 to 32.3)
Total cholesterol Week 4 (n = 48,53,26,21)	0.4 (-6.4 to 7.1)	7.1 (1.1 to 13.2)	4.8 (-3.2 to 12.8)	-2.7 (-10 to 4.7)
Total cholesterol Week 12 (n = 48,54,26,21)	3.1 (-3.1 to 9.4)	3.6 (-4.1 to 11.2)	10 (2.8 to 17.1)	-4.2 (-11.2 to 2.8)
Total cholesterol Week 24 (n = 48,52,25,21)	0.9 (-5.2 to 7.1)	0.6 (-4.9 to 6.1)	7.2 (-1.5 to 16)	-3.2 (-12 to 5.5)
Total cholesterol Week 52 (n = 48,50,26,20)	7.8 (0 to 15.6)	2.3 (-5.2 to 9.9)	8.9 (2.1 to 15.7)	2.9 (-5.9 to 11.7)
LDL Week 4 (n = 48,53,26,21)	1.1 (-4.6 to 6.8)	6.8 (0.8 to 12.8)	5.2 (-2 to 12.4)	-5.6 (-12.1 to 0.8)
LDL Week 12 (n = 48,54,26,21)	2.9 (-2.2 to 7.9)	2.7 (-4.8 to 10.1)	9.5 (3.4 to 15.5)	-5.6 (-12.7 to 1.5)
LDL Week 24 (n = 48,52,25,21)	-2.7 (-8.1 to 2.7)	-1.3 (-6.9 to 4.4)	1.1 (-7.4 to 9.5)	-11 (-18.9 to -2.4)

LDL Week 52 (n = 48,50,26,20)	1.7 (-6.5 to 9.9)	-0.9 (-8.4 to 6.5)	8.2 (1.3 to 15)	1.1 (-8.4 to 10.5)
HDL Week 4 (n = 48,53,26,21)	-0.6 (-2.6 to 1.3)	0.4 (-1.5 to 2.2)	0.3 (-2.3 to 2.9)	-1.3 (-4.6 to 2)
HDL Week 12 (n = 48,54,26,21)	-0.4 (-2.4 to 1.6)	0.2 (-1.8 to 2.2)	1 (-1.2 to 3.3)	-0.5 (-4.9 to 3.8)
HDL Week 24 (n = 48,52,25,21)	1.2 (-1.5 to 3.9)	0.3 (-2.3 to 2.8)	-1.1 (-3.4 to 1.3)	0.5 (-4.1 to 5.1)
HDL Week 52 (n = 48,50,26,20)	0.1 (-2.1 to 2.4)	1.8 (-0.5 to 4.2)	-0.3 (-2.9 to 2.4)	-1.4 (-4.6 to 1.8)
ApoA-1 Week 4 (n = 48,53,26,21)	0.3 (-5.1 to 5.7)	0.9 (-4 to 5.7)	7.7 (-0.6 to 15.9)	-5.5 (-12 to 1)
ApoA-1 Week 12 (n = 48,54,26,21)	4 (-2 to 10.1)	2.4 (-1.9 to 6.8)	7.1 (1.2 to 12.9)	-3.3 (-12.1 to 5.5)
ApoA-1 Week 24 (n = 48,52,25,21)	5.5 (-0.9 to 12)	2.8 (-3 to 8.6)	3 (-3.3 to 9.3)	-3.1 (-11.3 to 5.1)
ApoA-1 Week 52 (n = 48,50,26,20)	-4.5 (-10 to 0.9)	-6 (-11.6 to -0.3)	-5.5 (-14.9 to 3.9)	-13 (-22.3 to -3.1)
ApoB Week 4 (n = 48,53,26,21)	1.5 (-2.7 to 5.6)	3.6 (0.5 to 6.6)	2.7 (-1.1 to 6.5)	-2.5 (-7.7 to 2.8)
ApoB Week 12 (n = 48,54,26,21)	4 (0.6 to 7.4)	3.4 (-0.5 to 7.3)	7.4 (3.9 to 11)	-1 (-7 to 4.9)
ApoB Week 24 (n = 48,52,25,21)	1 (-2.8 to 4.8)	2 (-1.3 to 5.3)	5.6 (1.4 to 9.9)	-4.2 (-10.7 to 2.3)
ApoB Week 52 (n = 48,50,26,20)	3.7 (-2.2 to 9.6)	2.3 (-1.8 to 6.4)	6.7 (3 to 10.5)	-0.2 (-5.4 to 5)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

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

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Secukinumab (300 mg) up to Week 12

Reporting group description:

Subjects were administered with 300 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 300 mg secukinumab up to 12 weeks.

Reporting group title	Secukinumab (150 mg) up to Week 12

Reporting group description:

Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg secukinumab up to 12 weeks.

Reporting group title	Placebo up to Week 12

Reporting group description:

Subjects were administered with placebo up to 12 weeks.

Reporting group title	Secukinumab (300 mg) after Week 12

Reporting group description:

Subjects were administered with 300 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection).

Reporting group title	Secukinumab (150 mg) after Week 12

Reporting group description:

Subjects were administered with 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection).

Reporting group title	Placebo followed by secukinumab (300 mg) after Week 12

Reporting group description:

Subjects were administered with placebo until week 12 followed by 300 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 300 mg secukinumab every 4 weeks until week 48 (last injection).

Reporting group title	Placebo followed by secukinumab (150 mg) after Week 12

Reporting group description:

Subjects were administered with placebo until week 12 followed by 150 mg secukinumab s.c. using pre-filled syringe every week for 4 weeks followed by 150 mg secukinumab every 4 weeks until week 48 (last injection).

Serious adverse events	Secukinumab (300 mg) up to Week 12	Secukinumab (150 mg) up to Week 12	Placebo up to Week 12
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	2 / 49 (4.08%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

OVARIAN CANCER			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
CLAVICLE FRACTURE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
JOINT DISLOCATION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
Ear and labyrinth disorders			
VESTIBULAR DISORDER			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
DUODENAL ULCER			

subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
GASTRIC ULCER			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
GASTRITIS EROSIVE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
UTERINE POLYP			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
HAEMARTHROSIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RHEUMATOID ARTHRITIS			

subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
VERTEBRAL FORAMINAL STENOSIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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			
ANAL ABSCESS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
ERYSIPELAS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (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
HELICOBACTER INFECTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA BACTERIAL			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 49 (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

Serious adverse events	Secukinumab (300 mg) after Week 12	Secukinumab (150 mg) after Week 12	Placebo followed by secukinumab (300 mg) after Week 12
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 48 (12.50%)	6 / 54 (11.11%)	0 / 26 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
OVARIAN CANCER			

subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 26 (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
Injury, poisoning and procedural complications			
CLAVICLE FRACTURE			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 26 (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
JOINT DISLOCATION			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (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
Nervous system disorders			
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 26 (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	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 26 (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
Ear and labyrinth disorders			
VESTIBULAR DISORDER			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (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			
COLITIS			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 26 (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
DUODENAL ULCER			

subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (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
GASTRIC ULCER			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (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
GASTRITIS EROSIVE			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (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
Reproductive system and breast disorders			
UTERINE POLYP			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (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
HAEMARTHROSIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (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
RHEUMATOID ARTHRITIS			

subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (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
VERTEBRAL FORAMINAL STENOSIS			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 26 (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
Infections and infestations			
ANAL ABSCESS			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (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 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (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
HELICOBACTER INFECTION			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo followed by secukinumab (150 mg) after Week 12		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 23 (4.35%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
OVARIAN CANCER			

subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
CLAVICLE FRACTURE			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
JOINT DISLOCATION			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
CEREBRAL INFARCTION			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
VESTIBULAR DISORDER			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
COLITIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
DUODENAL ULCER			

subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
GASTRIC ULCER			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
GASTRITIS EROSIVE			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
UTERINE POLYP			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HAEMARTHROSIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
RHEUMATOID ARTHRITIS			

subjects affected / exposed	1 / 23 (4.35%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
VERTEBRAL FORAMINAL STENOSIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
ANAL ABSCESS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ERYSIPELAS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HELICOBACTER INFECTION			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
PNEUMONIA BACTERIAL			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Secukinumab (300 mg) up to Week 12	Secukinumab (150 mg) up to Week 12	Placebo up to Week 12
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 48 (60.42%)	36 / 54 (66.67%)	35 / 49 (71.43%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
PYOGENIC GRANULOMA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

SKIN PAPILLOMA			
subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	2	0	0
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	1 / 48 (2.08%)	1 / 54 (1.85%)	1 / 49 (2.04%)
occurrences (all)	1	1	1
General disorders and administration site conditions			
FATIGUE			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
INJECTION SITE PAIN			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
DYSMENORRHOEA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	3 / 49 (6.12%)
occurrences (all)	2	0	3
NASAL INFLAMMATION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
OROPHARYNGEAL PAIN			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	1 / 49 (2.04%)
occurrences (all)	1	0	1
RHINITIS ALLERGIC			

subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
BURNS FIRST DEGREE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
BURSA INJURY			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	1 / 49 (2.04%)
occurrences (all)	0	2	1
LACERATION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
MUSCLE RUPTURE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
THERMAL BURN			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	1 / 48 (2.08%)	1 / 54 (1.85%)	1 / 49 (2.04%)
occurrences (all)	1	1	1
HEADACHE			
subjects affected / exposed	4 / 48 (8.33%)	6 / 54 (11.11%)	2 / 49 (4.08%)
occurrences (all)	5	6	2
PARAESTHESIA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

LYMPHADENOPATHY			
subjects affected / exposed	1 / 48 (2.08%)	2 / 54 (3.70%)	1 / 49 (2.04%)
occurrences (all)	1	2	2
NEUTROPENIA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
CONJUNCTIVITIS ALLERGIC			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
DRY EYE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
EYE SWELLING			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	1 / 49 (2.04%)
occurrences (all)	0	1	1
BURNING MOUTH SYNDROME			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
DIARRHOEA			
subjects affected / exposed	2 / 48 (4.17%)	2 / 54 (3.70%)	1 / 49 (2.04%)
occurrences (all)	2	2	1
DYSPEPSIA			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 49 (0.00%)
occurrences (all)	0	1	0
DYSPHAGIA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
GASTRITIS			

subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
GLOSSITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
NAUSEA			
subjects affected / exposed	1 / 48 (2.08%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	1	2	0
STOMATITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
TOOTHACHE			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
DERMATITIS ATOPIC			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
ECZEMA			
subjects affected / exposed	1 / 48 (2.08%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	1	2	0
ERYTHEMA			

subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
INTERTRIGO			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
PAPULE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
PRURITUS			
subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	2 / 49 (4.08%)
occurrences (all)	2	0	2
PSORIASIS			
subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	1 / 49 (2.04%)
occurrences (all)	2	0	1
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	2 / 49 (4.08%)
occurrences (all)	0	0	2
SKIN FISSURES			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
SKIN REACTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
HAEMATURIA			
subjects affected / exposed	2 / 48 (4.17%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	2	2	0
NEPHROLITHIASIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	1 / 48 (2.08%)	2 / 54 (3.70%)	5 / 49 (10.20%)
occurrences (all)	1	2	5
BACK PAIN			

subjects affected / exposed	2 / 48 (4.17%)	2 / 54 (3.70%)	1 / 49 (2.04%)
occurrences (all)	2	2	1
MUSCLE SPASMS			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
PAIN IN EXTREMITY			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
SPINAL PAIN			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	1 / 48 (2.08%)	1 / 54 (1.85%)	0 / 49 (0.00%)
occurrences (all)	1	1	0
CANDIDA INFECTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
ECTHYMA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
FUNGAL INFECTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	2	0	0
GASTROINTESTINAL CANDIDIASIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

GASTROINTESTINAL INFECTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	1
GINGIVITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 49 (2.04%)
occurrences (all)	0	0	2
HORDEOLUM			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
IMPETIGO			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
LARYNGITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	10 / 48 (20.83%)	14 / 54 (25.93%)	18 / 49 (36.73%)
occurrences (all)	10	17	19
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
ORAL HERPES			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
OTITIS EXTERNA			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	1	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
PERIODONTITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
PARONYCHIA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

PHARYNGITIS			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	0	3	0
PULPITIS DENTAL			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	2 / 49 (4.08%)
occurrences (all)	1	0	2
ROOT CANAL INFECTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0
SINUSITIS			
subjects affected / exposed	2 / 48 (4.17%)	1 / 54 (1.85%)	0 / 49 (0.00%)
occurrences (all)	2	2	0
SKIN CANDIDA			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 49 (0.00%)
occurrences (all)	0	2	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	1 / 49 (2.04%)
occurrences (all)	0	2	1
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 48 (0.00%)	3 / 54 (5.56%)	1 / 49 (2.04%)
occurrences (all)	0	3	1
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 49 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Secukinumab (300 mg) after Week 12	Secukinumab (150 mg) after Week 12	Placebo followed by secukinumab (300 mg) after Week 12
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 48 (75.00%)	43 / 54 (79.63%)	21 / 26 (80.77%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
PYOGENIC GRANULOMA			

subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
SKIN PAPILLOMA			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	1 / 48 (2.08%)	2 / 54 (3.70%)	1 / 26 (3.85%)
occurrences (all)	1	2	1
General disorders and administration site conditions			
FATIGUE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
INJECTION SITE PAIN			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
OEDEMA PERIPHERAL			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
DYSMENORRHOEA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
MENOPAUSAL SYMPTOMS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	2 / 48 (4.17%)	4 / 54 (7.41%)	1 / 26 (3.85%)
occurrences (all)	2	4	1
NASAL INFLAMMATION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
OROPHARYNGEAL PAIN			

subjects affected / exposed	1 / 48 (2.08%)	3 / 54 (5.56%)	1 / 26 (3.85%)
occurrences (all)	1	3	1
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	2 / 26 (7.69%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	2 / 48 (4.17%)	1 / 54 (1.85%)	1 / 26 (3.85%)
occurrences (all)	2	1	1
BURNS FIRST DEGREE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
BURSA INJURY			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
LACERATION			
subjects affected / exposed	3 / 48 (6.25%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	3	0	1
MUSCLE RUPTURE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	2
THERMAL BURN			
subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
HEADACHE			
subjects affected / exposed	7 / 48 (14.58%)	7 / 54 (12.96%)	2 / 26 (7.69%)
occurrences (all)	8	13	2
PARAESTHESIA			

subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
LYMPHADENOPATHY			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
NEUTROPENIA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Eye disorders			
CONJUNCTIVITIS ALLERGIC			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
DRY EYE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
EYE SWELLING			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
BURNING MOUTH SYNDROME			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
CONSTIPATION			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
DIARRHOEA			
subjects affected / exposed	0 / 48 (0.00%)	3 / 54 (5.56%)	3 / 26 (11.54%)
occurrences (all)	0	4	4
DYSPEPSIA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
DYSPHAGIA			

subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
GASTRITIS			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
GLOSSITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
HAEMORRHOIDS			
subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	2	0	1
NAUSEA			
subjects affected / exposed	1 / 48 (2.08%)	1 / 54 (1.85%)	1 / 26 (3.85%)
occurrences (all)	1	1	1
STOMATITIS			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
TOOTHACHE			
subjects affected / exposed	2 / 48 (4.17%)	1 / 54 (1.85%)	1 / 26 (3.85%)
occurrences (all)	2	1	1
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
DERMATITIS ATOPIC			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
DERMATITIS			
subjects affected / exposed	1 / 48 (2.08%)	1 / 54 (1.85%)	1 / 26 (3.85%)
occurrences (all)	1	1	1
ECZEMA			

subjects affected / exposed	1 / 48 (2.08%)	1 / 54 (1.85%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
ERYTHEMA			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
INTERTRIGO			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
PAPULE			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	1 / 26 (3.85%)
occurrences (all)	0	1	1
PRURITUS			
subjects affected / exposed	2 / 48 (4.17%)	2 / 54 (3.70%)	1 / 26 (3.85%)
occurrences (all)	2	2	1
PSORIASIS			
subjects affected / exposed	2 / 48 (4.17%)	1 / 54 (1.85%)	0 / 26 (0.00%)
occurrences (all)	2	1	0
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
SKIN FISSURES			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
SKIN REACTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
HAEMATURIA			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	2 / 26 (7.69%)
occurrences (all)	1	0	2
NEPHROLITHIASIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			

ARTHRALGIA			
subjects affected / exposed	5 / 48 (10.42%)	3 / 54 (5.56%)	0 / 26 (0.00%)
occurrences (all)	5	3	0
BACK PAIN			
subjects affected / exposed	4 / 48 (8.33%)	4 / 54 (7.41%)	5 / 26 (19.23%)
occurrences (all)	4	4	6
MUSCLE SPASMS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
MUSCULOSKELETAL PAIN			
subjects affected / exposed	2 / 48 (4.17%)	1 / 54 (1.85%)	1 / 26 (3.85%)
occurrences (all)	2	1	1
PAIN IN EXTREMITY			
subjects affected / exposed	3 / 48 (6.25%)	2 / 54 (3.70%)	1 / 26 (3.85%)
occurrences (all)	3	3	1
SPINAL PAIN			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	3 / 48 (6.25%)	1 / 54 (1.85%)	0 / 26 (0.00%)
occurrences (all)	3	1	0
CANDIDA INFECTION			
subjects affected / exposed	2 / 48 (4.17%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	2	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	2 / 26 (7.69%)
occurrences (all)	0	1	2
ECTHYMA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
FUNGAL INFECTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
GASTROENTERITIS			

subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
GASTROINTESTINAL CANDIDIASIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
GASTROINTESTINAL INFECTION			
subjects affected / exposed	2 / 48 (4.17%)	2 / 54 (3.70%)	0 / 26 (0.00%)
occurrences (all)	2	2	0
GINGIVITIS			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
HORDEOLUM			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
IMPETIGO			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	1 / 26 (3.85%)
occurrences (all)	0	2	1
LARYNGITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
NASOPHARYNGITIS			
subjects affected / exposed	21 / 48 (43.75%)	25 / 54 (46.30%)	10 / 26 (38.46%)
occurrences (all)	29	36	13
ORAL CANDIDIASIS			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	2	0	1
ORAL HERPES			
subjects affected / exposed	2 / 48 (4.17%)	2 / 54 (3.70%)	1 / 26 (3.85%)
occurrences (all)	3	2	1
OTITIS EXTERNA			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	1	0	1
OTITIS MEDIA			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
PERIODONTITIS			

subjects affected / exposed	1 / 48 (2.08%)	3 / 54 (5.56%)	1 / 26 (3.85%)
occurrences (all)	1	3	1
PARONYCHIA			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
PULPITIS DENTAL			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	2 / 48 (4.17%)	3 / 54 (5.56%)	1 / 26 (3.85%)
occurrences (all)	2	3	1
ROOT CANAL INFECTION			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1
SINUSITIS			
subjects affected / exposed	0 / 48 (0.00%)	2 / 54 (3.70%)	0 / 26 (0.00%)
occurrences (all)	0	2	0
SKIN CANDIDA			
subjects affected / exposed	0 / 48 (0.00%)	1 / 54 (1.85%)	0 / 26 (0.00%)
occurrences (all)	0	1	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 48 (2.08%)	0 / 54 (0.00%)	0 / 26 (0.00%)
occurrences (all)	1	0	0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 48 (2.08%)	1 / 54 (1.85%)	0 / 26 (0.00%)
occurrences (all)	1	1	0
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 48 (0.00%)	0 / 54 (0.00%)	1 / 26 (3.85%)
occurrences (all)	0	0	1

Non-serious adverse events	Placebo followed by secukinumab (150 mg) after Week 12		

Total subjects affected by non-serious adverse events subjects affected / exposed	19 / 23 (82.61%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps) PYOGENIC GRANULOMA subjects affected / exposed occurrences (all) SKIN PAPILLOMA subjects affected / exposed occurrences (all)	 1 / 23 (4.35%) 1 1 / 23 (4.35%) 1		
Vascular disorders HYPERTENSION subjects affected / exposed occurrences (all)	 0 / 23 (0.00%) 0		
General disorders and administration site conditions FATIGUE subjects affected / exposed occurrences (all) INJECTION SITE PAIN subjects affected / exposed occurrences (all) OEDEMA PERIPHERAL subjects affected / exposed occurrences (all)	 0 / 23 (0.00%) 0 1 / 23 (4.35%) 1 1 / 23 (4.35%) 1		
Reproductive system and breast disorders DYSMENORRHOEA subjects affected / exposed occurrences (all) MENOPAUSAL SYMPTOMS subjects affected / exposed occurrences (all)	 0 / 23 (0.00%) 0 0 / 23 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders COUGH subjects affected / exposed occurrences (all) NASAL INFLAMMATION	 0 / 23 (0.00%) 0 		

subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
RHINITIS ALLERGIC			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
BURNS FIRST DEGREE			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
BURSA INJURY			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
CONTUSION			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
LACERATION			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
MUSCLE RUPTURE			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
THERMAL BURN			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
HEADACHE			

subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
PARAESTHESIA			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
LYMPHADENOPATHY			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
NEUTROPENIA			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Eye disorders			
CONJUNCTIVITIS ALLERGIC			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
DRY EYE			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
EYE SWELLING			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
BURNING MOUTH SYNDROME			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
CONSTIPATION			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
DIARRHOEA			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	3		
DYSPEPSIA			

subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
DYSPHAGIA			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
GASTRITIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
GASTROOESOPHAGEAL REFLUX DISEASE			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
GLOSSITIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
HAEMORRHOIDS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
NAUSEA			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	2		
STOMATITIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
TOOTHACHE			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
ALOPECIA			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
DERMATITIS ATOPIC			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
DERMATITIS			

subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
ECZEMA			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
ERYTHEMA			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
INTERTRIGO			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
PAPULE			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
PRURITUS			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	2		
PSORIASIS			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
SKIN FISSURES			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
SKIN REACTION			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
Renal and urinary disorders			
HAEMATURIA			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
NEPHROLITHIASIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		

Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	3 / 23 (13.04%)		
occurrences (all)	6		
BACK PAIN			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	3		
MUSCLE SPASMS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
SPINAL PAIN			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
CANDIDA INFECTION			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
CONJUNCTIVITIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
ECTHYMA			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
FUNGAL INFECTION			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
GASTROENTERITIS			

subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
GASTROINTESTINAL CANDIDIASIS				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
GASTROINTESTINAL INFECTION				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
GINGIVITIS				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences (all)	1			
HORDEOLUM				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
IMPETIGO				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
LARYNGITIS				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences (all)	1			
NASOPHARYNGITIS				
subjects affected / exposed	10 / 23 (43.48%)			
occurrences (all)	19			
ORAL CANDIDIASIS				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
ORAL HERPES				
subjects affected / exposed	1 / 23 (4.35%)			
occurrences (all)	2			
OTITIS EXTERNA				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
OTITIS MEDIA				
subjects affected / exposed	0 / 23 (0.00%)			
occurrences (all)	0			
PERIODONTITIS				

subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
PARONYCHIA			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
PHARYNGITIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
PULPITIS DENTAL			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
RHINITIS			
subjects affected / exposed	4 / 23 (17.39%)		
occurrences (all)	5		
ROOT CANAL INFECTION			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
SINUSITIS			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
SKIN CANDIDA			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	1		
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 23 (4.35%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
DECREASED APPETITE			
subjects affected / exposed	0 / 23 (0.00%)		
occurrences (all)	0		

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