Clinical trial results:
A 52-Week Multicenter, Randomized, Open-Label, Parallel-Group Study Evaluating the Efficacy and Safety of Ixekizumab versus Adalimumab in Patients with Psoriatic Arthritis Who Are Biologic Disease-Modifying Anti-Rheumatic Drug Naive

Summary

EudraCT number	2016-004585-25
Trial protocol	HU FI DE NL BE AT SE DK ES GB FR IT PL
Global end of trial date	04 September 2019

Results information

Result version number	v1 (current)
This version publication date	16 September 2020
First version publication date	16 September 2020

Trial information

Trial identification

Sponsor protocol code	I1F-MC-RHCF

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03151551
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 16687

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	04 September 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 September 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to evaluate the effectiveness and safety of ixekizumab versus adalimumab in participants with psoriatic arthritis (PsA) who are biologic disease-modifying anti-rheumatic drugs (DMARD) naive.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 August 2017
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	Argentina: 58
Country: Number of subjects enrolled	Hungary: 33
Country: Number of subjects enrolled	Ukraine: 26
Country: Number of subjects enrolled	United Kingdom: 20
Country: Number of subjects enrolled	Switzerland: 4
Country: Number of subjects enrolled	India: 46
Country: Number of subjects enrolled	Spain: 42
Country: Number of subjects enrolled	Canada: 10
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	Austria: 8
Country: Number of subjects enrolled	Netherlands: 3
Country: Number of subjects enrolled	Belgium: 11
Country: Number of subjects enrolled	Finland: 11
Country: Number of subjects enrolled	Poland: 53
Country: Number of subjects enrolled	Denmark: 4
Country: Number of subjects enrolled	Mexico: 65
Country: Number of subjects enrolled	South Africa: 36
Country: Number of subjects enrolled	Italy: 39
Country: Number of subjects enrolled	Israel: 28

Country: Number of subjects enrolled	Australia: 17
Country: Number of subjects enrolled	France: 12
Country: Number of subjects enrolled	Germany: 34
Worldwide total number of subjects	566
EEA total number of subjects	276

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)	519
From 65 to 84 years	47
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Per protocol and statistical analysis plan (SAP), the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

Pre-assignment

Screening details:

Open-Label Treatment Period from Week 0 to Week 52 inclusive followed by Post-Treatment Follow-Up Period of up to a minimum of 12 weeks.

Period 1

Period 1 title	Open-Label Treatment Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

A blinded assessor completed the following assessments: Tender joint count/Swollen joint count (TJC/SJC), Psoriasis Area and Severity Index (PASI), Percentage of body surface area (BSA), Enthesitis, Leeds Dactylitis Index—Basic (LDI-B), Nail Psoriasis Severity Index (NAPSI) Fingernails and static Physician Global Assessment of psoriasis (sPGA).

Arms

Are arms mutually exclusive?	Yes
Arm title	Ixekizumab

Arm description:

160 milligrams (mg) ixekizumab (IXE) given subcutaneously (SC) at baseline for all participants.

80 mg ixekizumab given once every 2 weeks (Q2W) SC from week 2 to week 12 and once every 4 weeks (Q4W) thereafter for participants with moderate-to-severe plaque Ps.

80 mg ixekizumab given SC Q4W starting week 4 for participants not meeting criteria for moderate-to-severe plaque Ps.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	
Other name	LY2439821
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC

Arm title	Adalimumab

Arm description:

80 mg adalimumab (ADA) given SC at baseline followed by 40 mg Q2W given SC starting week 1 for participants with moderate-to-severe plaque Ps.

40 mg adalimumab given Q2W SC at baseline followed by 40 mg Q2W starting at Week 2 given SC for participants not meeting criteria for moderate-to-severe plaque Ps.

Arm type	Active comparator

Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC

Number of subjects in period 1	Ixekizumab	Adalimumab
Started	283	283
Received at least one dose of study drug	283	283
IXE 160 mg at baseline, 80 mg Q2W/Q4W	49 [1]	0 [2]
IXE 160 mg at baseline, 80 mg Q4W	218 [3]	0 [4]
ADA 80 mg at baseline, 40 mg Q2W	0 [5]	51 [6]
ADA 40 mg at baseline, 40 mg Q2W	0 [7]	219 [8]
Completed	265	259
Not completed	18	24
Consent withdrawn by subject	12	18
Physician decision	3	-
Protocol Deviation	1	2
Adverse event, non-fatal	-	2
Lost to follow-up	1	1
Lack of efficacy	1	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants in this milestone represents only participants who received Ixekizumab.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants in these milestone represents only participants who received Adalimumab.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants in this milestone represents only participants who received Ixekizumab.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants in this milestone represents only participants who received Adalimumab.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: The number of participants in this milestones represents only participants who received Ixekizumab.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The number of participants in this milestone represents only participants who received Adalimumab.
[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The number of participants in this milestone represents only participants who received Ixekizumab.
[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: The number of participants in this milestone represents only participants who received Adalimumab.

Period 2

Period 2 title	Post-Treatment Follow-Up Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Ixekizumab

Arm description:

160 milligrams (mg) ixekizumab (IXE) given subcutaneously (SC) at baseline for all participants.

80 mg ixekizumab given once every 2 weeks (Q2W) SC from week 2 to week 12 and once every 4 weeks (Q4W) thereafter for participants with moderate-to-severe plaque Ps.

80 mg ixekizumab given SC Q4W starting week 4 for participants not meeting criteria for moderate-to-severe plaque Ps.

Follow-up: Participants did not receive drug during the Post-Treatment Follow-Up Period.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	
Other name	LY2439821
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered SC

Arm title	Adalimumab

Arm description:

80 mg adalimumab (ADA) given SC at baseline followed by 40 mg Q2W given SC starting week 1 for participants with moderate-to-severe plaque Ps.

40 mg adalimumab given Q2W SC at baseline followed by 40 mg Q2W starting at Week 2 given SC for participants not meeting criteria for moderate-to-severe plaque Ps.

Follow-up: Participants did not receive drug during the Post-Treatment Follow-Up Period.

Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
Administered SC

Number of subjects in period 2[9]	Ixekizumab	Adalimumab
Started	265	258
Completed	240	230
Not completed	25	28
Consent withdrawn by subject	20	22
Physician decision	-	1
Adverse event, non-fatal	1	3
Lost to follow-up	4	2

Notes:
[9] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: All participants who received at least one dose of study drug could enter the follow-up period.

Baseline characteristics

Reporting groups

Reporting group title	Ixekizumab

Reporting group description:

160 milligrams (mg) ixekizumab (IXE) given subcutaneously (SC) at baseline for all participants.

80 mg ixekizumab given once every 2 weeks (Q2W) SC from week 2 to week 12 and once every 4 weeks (Q4W) thereafter for participants with moderate-to-severe plaque Ps.

80 mg ixekizumab given SC Q4W starting week 4 for participants not meeting criteria for moderate-to-severe plaque Ps.

Reporting group title	Adalimumab

Reporting group description:

80 mg adalimumab (ADA) given SC at baseline followed by 40 mg Q2W given SC starting week 1 for participants with moderate-to-severe plaque Ps.

40 mg adalimumab given Q2W SC at baseline followed by 40 mg Q2W starting at Week 2 given SC for participants not meeting criteria for moderate-to-severe plaque Ps.

Reporting group values	Ixekizumab	Adalimumab	Total
Number of subjects	283	283	566
Age categorical Units: Subjects			
Age continuous Units: years			
median	47.5	48.3	
standard deviation	± 12.02	± 12.30	-
Gender categorical Units: Subjects			
Female	121	133	254
Male	162	150	312
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	63	65	128
Not Hispanic or Latino	198	194	392
Unknown or Not Reported	22	24	46
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	27	27	54
Asian	29	33	62
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	1
White	222	211	433
More than one race	5	11	16
Unknown or Not Reported	0	0	0

Region of Enrollment Units: Subjects			
Argentina	31	27	58
Hungary	15	18	33
Ukraine	15	11	26
United Kingdom	13	7	20
Switzerland	1	3	4
India	20	26	46
Spain	24	18	42
Canada	5	5	10
Sweden	3	3	6
Austria	4	4	8
Netherlands	2	1	3
Belgium	6	5	11
Finland	5	6	11
Poland	24	29	53
Denmark	1	3	4
Mexico	32	33	65
South Africa	15	21	36
Italy	14	25	39
Israel	14	14	28
Australia	12	5	17
France	9	3	12
Germany	18	16	34

End points

End points reporting groups

Reporting group title	Ixekizumab

Reporting group description:

160 milligrams (mg) ixekizumab (IXE) given subcutaneously (SC) at baseline for all participants.

80 mg ixekizumab given once every 2 weeks (Q2W) SC from week 2 to week 12 and once every 4 weeks (Q4W) thereafter for participants with moderate-to-severe plaque Ps.

80 mg ixekizumab given SC Q4W starting week 4 for participants not meeting criteria for moderate-to-severe plaque Ps.

Reporting group title	Adalimumab

Reporting group description:

80 mg adalimumab (ADA) given SC at baseline followed by 40 mg Q2W given SC starting week 1 for participants with moderate-to-severe plaque Ps.

40 mg adalimumab given Q2W SC at baseline followed by 40 mg Q2W starting at Week 2 given SC for participants not meeting criteria for moderate-to-severe plaque Ps.

Reporting group title	Ixekizumab

Reporting group description:

160 milligrams (mg) ixekizumab (IXE) given subcutaneously (SC) at baseline for all participants.

80 mg ixekizumab given once every 2 weeks (Q2W) SC from week 2 to week 12 and once every 4 weeks (Q4W) thereafter for participants with moderate-to-severe plaque Ps.

80 mg ixekizumab given SC Q4W starting week 4 for participants not meeting criteria for moderate-to-severe plaque Ps.

Follow-up: Participants did not receive drug during the Post-Treatment Follow-Up Period.

Reporting group title	Adalimumab

Reporting group description:

80 mg adalimumab (ADA) given SC at baseline followed by 40 mg Q2W given SC starting week 1 for participants with moderate-to-severe plaque Ps.

40 mg adalimumab given Q2W SC at baseline followed by 40 mg Q2W starting at Week 2 given SC for participants not meeting criteria for moderate-to-severe plaque Ps.

Follow-up: Participants did not receive drug during the Post-Treatment Follow-Up Period.

Primary: Percentage of Participants Simultaneously Achieving American College of Rheumatology 50 (ACR50) and Psoriasis Area and Severity Index 100 (PASI100)

End point title	Percentage of Participants Simultaneously Achieving American College of Rheumatology 50 (ACR50) and Psoriasis Area and Severity Index 100 (PASI100)

End point description:

ACR50 response is a ≥50% improvement from baseline for tender joint count(TJC)& swollen joint count (SJC)& in at least 3 of the following 5 criteria: Participant's(pts) assessment of joint pain Visual Analog Scale (VAS),Pts Global Assessment of Disease Activity (PatGA)VAS, Physician's Global Assessment of Disease Activity (PGA)VAS, Pts assessment of physical function using the Health Assessment Questionnaire-Disability Index(HAQ-DI), or High Sensitivity(assay)C-Reactive Protein (hs-CRP). PASI is an index combining assessments of the extent of body-surface involvement in head, trunk, arms, legs, and severity of desquamation, erythema and plaque thickness in each region, yielding overall score of 0-

no involvement, to 72-most severe involvement. Pts achieving PASI100 were defined as having 100% improvement in the PASI score compared to baseline. Pts with active plaque PsO with a BSA≥3% & PASI=0 at baseline were considered PASI100 responders if they had achieved PASI=0 & BSA=0 at week 24.

End point type	Primary

End point timeframe:

Week 24

Analysis Population Description: All randomized participants. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab versus all adalimumab participants.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	283		
Units: percentage of participants				
number (confidence interval 95%)	36 (30.4 to 41.6)	27.9 (22.7 to 33.1)		

Statistical analyses

Statistical analysis title	% of Participants Achieving ACR50 & PASI100

Statistical analysis description:

After data lock and initial analysis run, a medical inconsistency in baseline PASI data was identified (PASI=0 but BSA≥3%). The scenario was not anticipated or described in protocol or SAP. The inconsistency was resolved using medical judgment. The impacted participants had met baseline criteria for active psoriasis. Therefore, in the primary analysis, participants with baseline PASI=0 & BSA≥3% were considered PASI100 responders if, and only if, PASI=0 & BSA=0 achieved at week 24.

Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	15.8

Secondary: Percentage of Participants Achieving ACR50

End point title	Percentage of Participants Achieving ACR50

End point description:

ACR50 response is defined as a ≥50% improvement from baseline for tender joint count (TJC) and swollen joint count (SJC) and in at least 3 of the following 5 criteria: Participant's assessment of joint

pain Visual Analog Scale (VAS), Participant's Global Assessment of Disease Activity (PatGA) VAS, Physician's Global Assessment of Disease Activity (PGA) VAS, participant's assessment of physical function using the Health Assessment Questionnaire-Disability Index (HAQ-DI), or High Sensitivity (assay) C-Reactive Protein (hs-CRP).

Analysis Population description (APD): All randomized participants. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Secondary

End point timeframe:

Week 24

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	283		
Units: percentage of participants				
number (confidence interval 95%)	50.5 (44.7 to 56.4)	46.6 (40.8 to 52.5)		

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving ACR50

Statistical analysis description:

If the lower bound of the 2-sided 95% CI for the difference in proportions of responders on IXE minus ADA is greater than the pre-specified margin -12%, IXE will be deemed non-inferior to ADA.

Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Rate Difference
Point estimate	3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	12.1

Secondary: Percentage of Participants Achieving PASI100

End point title	Percentage of Participants Achieving PASI100

End point description:

PASI is an index combining assessments of the extent of body-surface involvement in head, trunk, arms, legs, and severity of desquamation, erythema and plaque thickness in each region, yielding overall score of 0-no involvement, to 72-most severe involvement. Participants achieving PASI100 were defined as having 100% improvement in the PASI score compared to baseline. Any participants with active plaque psoriasis (PsO) with a BSA ≥3% and PASI = 0 at baseline were considered PASI100 responders if & only if they had achieved PASI=0 & BSA=0 at week 24.

Analysis Population Description: All randomized participants. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Secondary

End point timeframe:

Week 24

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	283		
Units: percentage of participants				
number (confidence interval 95%)	60.1 (54.4 to 65.8)	46.6 (40.8 to 52.5)		

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving PASI100

Statistical analysis description:

After data lock and initial analysis run, a medical inconsistency in baseline PASI data was identified (PASI=0 but BSA≥3%). The scenario was not anticipated or described in protocol or SAP. The inconsistency was resolved using medical judgment. The impacted participants had met baseline criteria for active psoriasis. Therefore, in the primary analysis, participants with baseline PASI=0 & BSA≥3% were considered PASI100 responders if, and only if, PASI=0 & BSA=0 achieved at week 24.

Comparison groups	Adalimumab v Ixekizumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	13.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.3
upper limit	21.6

Other pre-specified: Change from Baseline in Tender Joint Counts (TJC)

End point title	Change from Baseline in Tender Joint Counts (TJC)

End point description:

TJC is the number of tender and painful joints determined for each participant by examination of 68 joints.Joints were assessed by pressure and joint manipulation on physical examination. Participants were asked for pain sensations on these manipulations and watched for spontaneous pain reactions.Any positive response on pressure, movement, or both was translated into a single tender-versus-nontender dichotomy. LS mean was calculated using MMRM model that included treatment group, concomitant conventional synthetic disease-modifying anti-rheumatic drugs (csDMARD) use at baseline, moderate-

to-severe plaque psoriasis involvement,visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

Analysis Population Description: All randomized participants who had a baseline and at least one post-baseline TJC value.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	242	239		
Units: score on a scale				
least squares mean (standard error)	-15.91 (± 0.566)	-14.88 (± 0.569)		

Statistical analyses

Statistical analysis title	Change from Baseline in TJC
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	481
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.155
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.46
upper limit	0.39
Variability estimate	Standard error of the mean
Dispersion value	0.725

Other pre-specified: Change from Baseline in Swollen Joint Counts (SJC)

End point title	Change from Baseline in Swollen Joint Counts (SJC)

End point description:

SJC is the number of swollen joints determined for each participant by examination of 66 joints. Joints were classified as either swollen or not swollen. Swelling was defined as palpable fluctuating synovitis of the joint. LS mean was calculated using MMRM model that included treatment group, concomitant conventional synthetic disease-modifying anti-rheumatic drugs (csDMARD) use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

Analysis Population Description: All randomized participants who had a baseline and at least one post-

baseline SJC value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	242	239		
Units: score on a scale				
least squares mean (standard error)	-9.58 (± 0.196)	-9.53 (± 0.198)		

Statistical analyses

Statistical analysis title	Change from Baseline in SJC
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	481
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.823
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.54
upper limit	0.43
Variability estimate	Standard error of the mean
Dispersion value	0.249

Other pre-specified: Change from Baseline in Participant's Assessment of Pain Visual analogue score (VAS)

End point title	Change from Baseline in Participant's Assessment of Pain Visual analogue score (VAS)

End point description:

The pain VAS is a participant-administered single-item scale designed to measure current joint pain from Psoriatic arthritis (PsA) using a 100-millimeter(mm) horizontal VAS. Overall severity of participant's joint pain from PsA is indicated by marking a vertical tick on the horizontal 100-mm scale, where the left end from 0 mm (no pain) to right end 100 mm (worst possible joint pain). LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

APD: All randomized participants who had a baseline and at least one post-baseline VAS value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all

ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	242	246		
Units: millimeters (mm)				
least squares mean (standard error)	-37.21 (± 1.623)	-36.54 (± 1.621)		

Statistical analyses

Statistical analysis title	Change from Baseline in Participant's Pain VAS
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	488
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.752
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	3.47
Variability estimate	Standard error of the mean
Dispersion value	2.104

Other pre-specified: Change from Baseline in Participant's Global Assessment of Disease Activity (PatGA)

End point title	Change from Baseline in Participant's Global Assessment of Disease Activity (PatGA)

End point description:

The patient's overall assessment of his or her PsA activity was recorded using a 100-mm horizontal VAS, where 0 represents no disease activity and 100 represents extremely active disease. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

APD: All randomized participants who had a baseline and at least one post-baseline VAS value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	242	246		
Units: Millimeter (mm)				
least squares mean (standard error)	-40.61 (± 1.594)	-37.82 (± 1.596)		

Statistical analyses

Statistical analysis title	Change from Baseline in PatGA
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	488
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.177
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.83
upper limit	1.26
Variability estimate	Standard error of the mean
Dispersion value	2.06

Other pre-specified: Change from Baseline in Physician's Global Assessment of Disease Activity (PhyGA)

End point title	Change from Baseline in Physician's Global Assessment of Disease Activity (PhyGA)

End point description:

The investigator was asked to give an overall assessment of the severity of the participant's current PsA activity using a 100-mm horizontal VAS, where 0 represents no disease activity and 100 represents extremely active disease. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

APD: All randomized participants who had a baseline and at least one post-baseline VAS value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	223	230		
Units: Millimeter (mm)				
least squares mean (standard error)	-48.15 (± 1.113)	-46.79 (± 1.097)		

Statistical analyses

Statistical analysis title	Change from Baseline in PhyGA
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	453
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.332
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.08
upper limit	1.38
Variability estimate	Standard error of the mean
Dispersion value	1.391

Other pre-specified: Change from Baseline in C-Reactive Protein (CRP)

End point title	Change from Baseline in C-Reactive Protein (CRP)

End point description:

CRP is the ACR Core Set laboratory measure of acute-phase reactant. It was measured with a high sensitivity assay at the central laboratory to help assess the effect of ixekizumab on the participant's PsA. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

APD: All randomized participants who had a baseline and at least one post-baseline CRP value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	234	238		
Units: Milligram per Liter (mg/L)				
least squares mean (standard error)	-5.68 (± 0.462)	-6.01 (± 0.461)		

Statistical analyses

Statistical analysis title	Change from Baseline in CRP
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	472
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.592
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.86
upper limit	1.5
Variability estimate	Standard error of the mean
Dispersion value	0.599

Other pre-specified: Change from Baseline in HAQ-DI

End point title	Change from Baseline in HAQ-DI

End point description:

HAQ-DI is a participant reported questionnaire that measures disease-associated disability (physical function). It consists of 24 questions with 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and other daily activities. The disability section scores the participant's self-perception on the degree of difficulty (0 = without any difficulty, 1 = with some difficulty, 2 = with much difficulty, and 3 = unable to do), covering the 8 domains. The reported use of special aids or devices and/or the need for assistance of another person to perform these activities is assessed. The HAQ-DI is a composite ranging from 0-3 with lower scores indicating less functional disability. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52
All randomized participants who had a baseline and at least one post-baseline HAQ-DI value.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	242	246		
Units: score on a scale				
least squares mean (standard error)	-0.68 (± 0.035)	-0.62 (± 0.035)		

Statistical analyses

Statistical analysis title	Change from Baseline in HAQ-DI
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	488
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.176
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.15
upper limit	0.03
Variability estimate	Standard error of the mean
Dispersion value	0.045

Other pre-specified: Percentage of Participants Simultaneously Achieving ACR50 and PASI100

End point title	Percentage of Participants Simultaneously Achieving ACR50 and PASI100

End point description:

ACR50 response is a ≥50% improvement from baseline for TJC and SJC and in at least 3 of the following 5 criteria: Participant's assessment of VAS, Pts Global Assessment of Disease Activity (PatGA) VAS, Physician's Global Assessment of Disease Activity (PGA)VAS, participant assessment of physical function using the HAQ-DI, or High Sensitivity(assay) C-Reactive Protein (hs-CRP). PASI is an index combining assessments of the extent of body-surface involvement in head, trunk, arms, legs, and severity of desquamation, erythema and plaque thickness in each region, yielding overall score of 0-no involvement, to 72-most severe involvement. Participant achieving PASI100 were defined as having 100% improvement in the PASI score compared to baseline. Pts achieving PASI100 were defined as having 100% improvement in the PASI score compared to baseline. Pts with active plaque PsO with a BSA≥3% & PASI=0 at baseline were considered PASI100 responders if they had achieved PASI=0 & BSA=0 at week 52.

End point type	Other pre-specified

End point timeframe:

Week 52

APD: All randomized participants who had a baseline and at least one post-baseline ACR50 and PASI100 value.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	283		
Units: percentage of participants				
number (confidence interval 95%)	39.2 (33.5 to 44.9)	26.1 (21.0 to 31.3)		

Statistical analyses

Statistical analysis title	% of Participants Achieving ACR50 & PASI100

Statistical analysis description:

After data lock and initial analysis run, a medical inconsistency in baseline PASI data was identified (PASI=0 but BSA≥3%). The scenario was not anticipated or described in protocol or SAP. The inconsistency was resolved using medical judgment. The impacted participants had met baseline criteria for active psoriasis. Therefore, in the primary analysis, participants with baseline PASI=0 & BSA≥3% were considered PASI100 responders if, and only if, PASI=0 & BSA=0 achieved at week 52.

Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	13.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.4
upper limit	20.7

Other pre-specified: Change from Baseline in Disease Activity Score-CRP (DAS28-CRP)

End point title	Change from Baseline in Disease Activity Score-CRP (DAS28-CRP)

End point description:

The DAS28-CRP is a measure of disease activity in 28 joints that consists of a composite numerical score with the following variables: TJC28, SJC28, hs-CRP (measured in milligrams per liter), and Participant's Global Assessment of Disease Activity recorded by participants on a 0 to 100 VAS. For DAS28-CRP, the Tender Joint Count 28 (TJC28) and Swollen Joint Count (SJC28) are a subset of TJC and SJC, and include 14 joints on each side of the body: 2 shoulders, 2 elbows, 2 wrists, 10 metacarpophalangeal joints, the 2 interphalangeal joints of the thumb, the 8 proximal interphalangeal joints, and the 2 knees. DAS28 values range from 0 to 9.4. Higher values indicate more severe symptoms and greater functional impairment. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

APD: All randomized participants who had a baseline and at least one post-baseline DAS28-CRP value.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	226	228		
Units: score on a scale				
least squares mean (standard error)	-2.45 (± 0.071)	-2.36 (± 0.071)		

Statistical analyses

Statistical analysis title	Change From Baseline in DAS28-CRP
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	454
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.368
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	0.1
Variability estimate	Standard error of the mean
Dispersion value	0.091

Other pre-specified: Percentage of Participants Achieving Minimal Disease Activity (MDA)

End point title	Percentage of Participants Achieving Minimal Disease Activity (MDA)

End point description:

MDA is a composite of 7 key outcome measures: TJC ≤1; SJC ≤1; psoriasis activity and severity index (PASI total score) ≤1 or BSA ≤3; participant pain VAS score of ≤15; participant global disease activity VAS score of ≤20; HAQ-DI score ≤0.5; and tender entheseal points ≤1. Participants are classified as achieving MDA if they fulfill 5 of 7 outcome measures.

APD: All randomized participants who had a baseline and at least one post-baseline MDA value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	283		
Units: percentage of participants				
number (confidence interval 95%)				
MDA-6 Entheseal Points	48.1 (42.2 to 53.9)	42.8 (37.0 to 48.5)		
MDA-18 Entheseal Points	47.3 (41.5 to 53.2)	41.0 (35.3 to 46.7)		

Statistical analyses

Statistical analysis title	% of Participants Achieving MDA-18 Entheseal Point
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.108
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	6.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	14.5

Statistical analysis title	% of Participants Achieving MDA-6 Entheseal Points
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.179
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	5.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	13.5

Other pre-specified: Percentage of Participants Achieving Psoriatic Arthritis Response Criteria (PsARC)

End point title	Percentage of Participants Achieving Psoriatic Arthritis Response Criteria (PsARC)

End point description:

The PsARC is a composite criteria reported in terms of the percentage of participants achieving response according to the following criterion: TJC, SJC, PGA, and PatGA. Overall response is defined by improvement from baseline assessment in 2 of 4 criteria, 1 of which must be a joint count; there must not be worsening in any of the 4 criteria: at least 30% reduction in TJC, at least 30% reduction in SJC, at least a 20 millimeter (mm) reduction in PGA and at least a 20 mm reduction in PatGA.

APD: All randomized participants who had a baseline and at least one post-baseline PsARC value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	283		
Units: percentage of participants				
number (confidence interval 95%)	66.8 (61.3 to 72.3)	65.7 (60.2 to 71.3)		

Statistical analyses

Statistical analysis title	Percentage of Participants Achieving PsARC
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.846
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	-1.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.9
upper limit	6.7

Other pre-specified: Change from Baseline in Modified Composite Psoriatic Disease

Activity Index (mCPDAI) Score

End point title	Change from Baseline in Modified Composite Psoriatic Disease Activity Index (mCPDAI) Score

End point description:

The CPDAI is a validated instrument intended to assess composite psoriatic disease activity and response to therapy. Domains include peripheral arthritis as assessed by the number of tender and swollen joints and the HAQ-DI, skin as assessed by the PASI and the Dermatology Life Quality Index (DLQI), enthesitis as assessed by the number of sites with enthesitis and the HAQ-DI, and dactylitis as assessed by the number of digits affected. Each domain with the exception of spinal disease is scored from 0-3. Individual domain scores are summed to give an overall composite score (range 0-12) with a higher score indicating higher disease activity. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

All randomized participants who had a baseline and at least one post-baseline CPDAI value.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	237	234		
Units: score on a scale				
least squares mean (standard error)	-4.35 (± 0.136)	-3.85 (± 0.136)		

Statistical analyses

Statistical analysis title	Change from Baseline in mCPDAI
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	471
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.83
upper limit	-0.16
Variability estimate	Standard error of the mean
Dispersion value	0.17

Other pre-specified: Change from Baseline in the Spondyloarthritis Research

Consortium of Canada (SPARCC) Enthesitis Index in Participants with Enthesitis at Baseline

End point title	Change from Baseline in the Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index in Participants with Enthesitis at Baseline

End point description:

The SPARCC enthesitis index evaluates tenderness in a total of 16 entheseal sites: the greater trochanter (right/left [R/L]), quadriceps tendon insertion into the patella (R/L), patellar ligament insertion into the patella and tibial tuberosity (R/L), Achilles tendon insertion (R/L), plantar fascia insertion (R/L), medial epicondyles of humerus (R/L),Lateral epicondyle humerus (R/L) and the supraspinatus insertion (R/L). Tenderness at each site is quantified on a dichotomous basis: 0 = nontender and 1 = tender. The results from each site are then added to produce a total score (range 0 to 16) with the Higher scores indicating more severe enthesitis. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

APD: All randomized participants who had a baseline SPARCC score > 0.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	139		
Units: score on a scale				
least squares mean (standard error)	-3.93 (± 0.234)	-4.06 (± 0.241)		

Statistical analyses

Statistical analysis title	Change from Baseline in SPARCC Enthesitis Index
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	302
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.687
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	0.72
Variability estimate	Standard error of the mean
Dispersion value	0.305

Other pre-specified: Change from Baseline in the Leeds Enthesitis Index (LEI) in Participants with Enthesitis at Baseline

End point title	Change from Baseline in the Leeds Enthesitis Index (LEI) in Participants with Enthesitis at Baseline

End point description:

The LEI was developed specifically for use in PsA. It measures enthesitis at 6 sites (lateral epicondyle of humerus, right/left (R/L); medial femoral condyle,(R/L); Achilles tendon insertion, (R/L)). Each site is assigned a score of 0 (absent) or 1 (present); the results from each site are then added to produce a total score (range 0 to 6) with the higher scores indicating more severe enthesitis. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

APD: All randomized participants who had a baseline enthesitis (LEI >0). Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	141	121		
Units: score on a scale				
least squares mean (standard error)	-1.93 (± 0.113)	-2.02 (± 0.116)		

Statistical analyses

Statistical analysis title	Change from Baseline in LEI
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	262
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.507
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.19
upper limit	0.38
Variability estimate	Standard error of the mean
Dispersion value	0.144

Other pre-specified: Change from Baseline in the Leeds Dactylitis Index-Basic (LDI-B) in Participants with Dactylitis at Baseline

End point title	Change from Baseline in the Leeds Dactylitis Index-Basic (LDI-B) in Participants with Dactylitis at Baseline

End point description:

The LDI-B measures the severity of dactylitis. In each digit, the ratio of the circumference of the affected digit to the circumference of the digit on the opposite hand or foot measured in mm. Each dactylitic digit is defined by a minimum increase of 10% in circumference over the contra-lateral digit. If the same digits on each hand or foot were thought to be involved, the clinician referred to a table of normative values for a value which was used to provide the comparison. The calculated ratio was multiplied by a tenderness score of 0 (not tender) or 1 (tender). Tenderness was assessed in the area between the joints. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

APD: All randomized participants who had a baseline dactylitis (LDI-B >0).

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	47		
Units: score on a scale				
least squares mean (standard error)	-52.28 (± 11.495)	-48.89 (± 9.855)		

Statistical analyses

Statistical analysis title	Change from Baseline in LDI-B
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.82
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.78
upper limit	25.99
Variability estimate	Standard error of the mean
Dispersion value	14.951

Other pre-specified: Change from Baseline in Psoriasis Body Surface Area (BSA)

End point title	Change from Baseline in Psoriasis Body Surface Area (BSA)

End point description:

The investigator evaluates the percentage involvement of psoriasis on each participant's BSA on a continuous scale from 0% = no involvement to 100% = full involvement, where 1% corresponded to the size of the participant's handprint including the palm, fingers, and thumb. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

APD: All randomized participants who had a baseline and at least one post-baseline BSA value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	246	246		
Units: units on a scale				
least squares mean (standard error)	-12.33 (± 0.623)	-10.79 (± 0.613)		

Statistical analyses

Statistical analysis title	Change from Baseline in BSA
Comparison groups	Adalimumab v Ixekizumab
Number of subjects included in analysis	492
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.052
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.09
upper limit	0.02
Variability estimate	Standard error of the mean
Dispersion value	0.79

Other pre-specified: Change from Baseline in the Nail Psoriasis Severity Index (NAPSI) Fingernails Score in the Subgroup of Participants with Fingernail Involvement at Baseline

End point title	Change from Baseline in the Nail Psoriasis Severity Index (NAPSI) Fingernails Score in the Subgroup of Participants with Fingernail Involvement at Baseline

End point description:

The NAPSI scale is used to evaluate the severity of fingernail bed Ps and fingernail matrix Ps by area of involvement. The fingernail is divided into quadrants. Each fingernail is given a score for fingernail bed Ps 0 (none) to 4 (Ps in 4 quadrants of the fingernail) and fingernail matrix Ps 0 (none) to 4 (Ps in 4 quadrants of the matrix), depending on the presence (score of 1) or absence (score of 0) of any of the features of fingernail bed or matrix Ps in each quadrant. The sum of all fingernails equals the total NAPSI score range is from 0 (no effect) to 80 (more severe psoriasis). LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

APD: All randomized participants who had baseline fingernail involvement (NAPSI >0).

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	169	154		
Units: score on a scale				
least squares mean (standard error)	-17.78 (± 0.731)	-15.08 (± 0.742)		

Statistical analyses

Statistical analysis title	Change from Baseline in NAPSI Fingernails Score
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	323
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.005
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.57
upper limit	-0.84
Variability estimate	Standard error of the mean
Dispersion value	0.949

Other pre-specified: Change from Baseline in the Itch NRS

End point title	Change from Baseline in the Itch NRS

End point description:

The Itch NRS is a participant-administered, 11-point horizontal scale anchored at 0 and 10, with 0 representing "no itch" and 10 representing "worst itch imaginable." Overall severity of a participant's itching from psoriasis is indicated by circling the number that best described the worst level of itching in the past 24 hours. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

APD: All randomized participants who had a baseline and at least one post-baseline NRS value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	242	246		
Units: score on a scale				
least squares mean (standard error)	-3.83 (± 0.159)	-3.54 (± 0.159)		

Statistical analyses

Statistical analysis title	Change from Baseline in Itch NRS
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	488
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.158
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.68
upper limit	0.11
Variability estimate	Standard error of the mean
Dispersion value	0.202

Other pre-specified: Change from Baseline in Fatigue Severity NRS (Fatigue NRS) Score

End point title	Change from Baseline in Fatigue Severity NRS (Fatigue NRS) Score

End point description:

The Fatigue Severity NRS is a participant-administered single-item 11-point horizontal scale anchored at

0 and 10, with 0 representing "no fatigue" and 10 representing "as bad as you can imagine." Participants rate their fatigue (weariness, tiredness) by circling the 1 number that described their worst level of fatigue during the past 24 hours. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

APD: All randomized participants who had a baseline and at least one post-baseline Fatigue NRS value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	241	246		
Units: score on a scale				
least squares mean (standard error)	-3.03 (± 0.161)	-2.95 (± 0.161)		

Statistical analyses

Statistical analysis title	Change from Baseline in Fatigue NRS
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	487
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.711
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	0.33
Variability estimate	Standard error of the mean
Dispersion value	0.21

Other pre-specified: Change From Baseline in Medical Outcomes Study 36-item Short Form Health Survey (SF-36): Physical Component Summary (PCS)

End point title	Change From Baseline in Medical Outcomes Study 36-item Short Form Health Survey (SF-36): Physical Component Summary (PCS)

End point description:

The SF-36 is a participant-reported outcome measure evaluating participant's health status. It

comprises 36 items covering 8 domains: physical functioning, role physical, role emotional, bodily pain, vitality, social functioning, mental health, and general health. Items are answered on Likert scales of varying lengths. The 8 domains are regrouped into the PCS and MCS scores. The summary scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

APD: All randomized participants who had a baseline and at least one post-baseline PCS value.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	240	246		
Units: score on a scale				
least squares mean (standard error)	10.07 (± 0.526)	9.55 (± 0.524)		

Statistical analyses

Statistical analysis title	Change From Baseline in SF-36: PCS
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	486
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.439
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	1.85
Variability estimate	Standard error of the mean
Dispersion value	0.674

Other pre-specified: Change From Baseline in SF-36: Mental Component Summary (MCS)

End point title	Change From Baseline in SF-36: Mental Component Summary (MCS)

End point description:

The SF-36 is a participant-reported outcome measure evaluating participant's health status. It

comprises 36 items covering 8 domains: physical functioning, role physical, role emotional, bodily pain, vitality, social functioning, mental health, and general health. Items are answered on Likert scales of varying lengths. The 8 domains are regrouped into the PCS and MCS scores. The summary scores range from 0 to 100, with higher scores indicating better levels of function and/or better health. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52
APD: All randomized participants who had a baseline and at least one post-baseline MCS value.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	240	246		
Units: score on a scale				
least squares mean (standard error)	5.23 (± 0.660)	4.77 (± 0.656)		

Statistical analyses

Statistical analysis title	Change From Baseline in SF-36: MCS
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	486
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.594
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.23
upper limit	2.15
Variability estimate	Standard error of the mean
Dispersion value	0.86

Other pre-specified: Change from Baseline in Measures of Health Utility (EuroQol-5 Dimensions 5 Level [EQ-5D 5L]) United Kingdom(UK) Population-Based Index Score

End point title	Change from Baseline in Measures of Health Utility (EuroQol-5 Dimensions 5 Level [EQ-5D 5L]) United Kingdom(UK) Population-Based Index Score

End point description:

The EQ-5D-5L consists of 2 components: a descriptive system of the respondent's health and a rating of his/her current health state. Each dimension has 5 levels: no problems, slight problems, moderate

problems, severe problems, and extreme problems. The descriptive part is comprised of the following 5 participant-reported dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.The EQ-5D-5L health states were converted into a single summary index by applying a crosswalk using a UK Population value set to each of the levels in each dimension.This produced participant-level index scores between -0.594 and 1.0 (worse to better health). LS mean was calculated using MMRM model that included treatment group,concomitant csDMARD use at baseline,moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

APD: All randomized participants who had a baseline and at least one post-baseline EQ-5D 5L value.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	240	245		
Units: millimeters (mm)				
least squares mean (standard deviation)	0.21 (± 0.013)	0.21 (± 0.013)		

Statistical analyses

Statistical analysis title	Change from Baseline in EQ-5D 5L Index Score (UK)
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	485
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.979
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.03
upper limit	0.03
Variability estimate	Standard error of the mean
Dispersion value	0.017

Other pre-specified: Change from Baseline in Measures of Health Utility (EuroQol-5 Dimensions 5 Level [EQ-5D 5L]) VAS Score

End point title	Change from Baseline in Measures of Health Utility (EuroQol-5 Dimensions 5 Level [EQ-5D 5L]) VAS Score

End point description:

EQ-5D-5L is a standardized measure of health status used to provide a simple, generic measure of health for clinical and economic appraisal. The EQ-5D-5L consists of 2 components: a descriptive system of the respondent's health and a rating of his/her current health state using a 0 (worst health you can

imagine) to 100mm VAS (best health you can imagine). LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

APD: All randomized participants who had a baseline and at least one post-baseline EQ-5D 5L value. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	240	245		
Units: millimeters (mm)				
least squares mean (standard deviation)	22.26 (± 1.37)	17.48 (± 1.36)		

Statistical analyses

Statistical analysis title	Change from Baseline in EQ-5D VAS
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	485
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.008
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.28
upper limit	8.28
Variability estimate	Standard error of the mean
Dispersion value	1.782

Other pre-specified: Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score

End point description:

The DLQI is a simple, participant-administered, 10 question, validated, quality-of-life questionnaire that covers 6 domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. The recall period of this scale is over the last "week." Response categories include "not at all," "a lot," and "very much," with corresponding scores of 1, 2, and 3, respectively, and unanswered ("not relevant") responses scored as "0." Scores range from 0 to 30 (less to more

impairment), and a 4-point change from baseline is considered as the minimal clinically important difference threshold. LS mean was calculated using MMRM model that included treatment group, concomitant csDMARD use at baseline, moderate-to-severe plaque psoriasis involvement, visit as fixed factors, baseline value as covariate and baseline-by-visit and treatment-by-visit interactions terms.

End point type	Other pre-specified

End point timeframe:

Baseline, Week 52

APD: All randomized participants who had a baseline and at least one post-baseline DLQI value.

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	241	246		
Units: score on a scale				
least squares mean (standard error)	-8.03 (± 0.273)	-6.91 (± 0.272)		

Statistical analyses

Statistical analysis title	Change from Baseline in DLQI
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	487
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.78
upper limit	-0.46
Variability estimate	Standard error of the mean
Dispersion value	0.335

Other pre-specified: Percentage of Participants Answering "Mostly Satisfied" to Each Question in Treatment Satisfaction Questionnaire (TSQ)

End point title	Percentage of Participants Answering "Mostly Satisfied" to Each Question in Treatment Satisfaction Questionnaire (TSQ)

End point description:

The TSQ is a clinician-administered questionnaire that provides an assessment of the patient’s opinion of the effectiveness, safety, and overall satisfaction of the study medication. Participants were asked to respond to questionnaire items using a 4-point Likert scale (from "mostly satisfied" to "mostly dissatisfied").

APD: All randomized participants who had a baseline and at least one post-baseline TSQ value. Per

protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

End point type	Other pre-specified
End point timeframe:	
Week 52	

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	283		
Units: percentage of participants				
number (confidence interval 95%)				
Effectiveness of Medication	64.3 (58.7 to 69.9)	58.7 (52.9 to 64.4)		
Effectiveness over Time of Medication	62.9 (57.3 to 68.5)	56.2 (50.4 to 62.0)		
Long Term Safety of Medication	63.3 (57.6 to 68.9)	58.7 (52.9 to 64.4)		
Overall Satisfaction with Medication	64.0 (58.4 to 69.6)	59.0 (53.3 to 64.7)		
Mostly Satisfied to any Questions	70.0 (64.6 to 75.3)	67.8 (62.4 to 73.3)		

Statistical analyses

Statistical analysis title	% of TSQ: Effectiveness of Medication
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.165
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	5.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	13.7

Statistical analysis title	% of TSQ: Effectiveness over Time of Medication
Comparison groups	Ixekizumab v Adalimumab

Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.098
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	6.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	14.8

Notes:

[1] - Effectiveness over Time of Medication

Statistical analysis title	% of TSQ: Long Term Safety of Medication
Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.241
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	4.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	12.6

Notes:

[2] - Long Term Safety of Medication

Statistical analysis title	% of TSQ: Overall Satisfaction with Medication
Comparison groups	Adalimumab v Ixekizumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.215
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	4.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.1
upper limit	13

Notes:

[3] - Overall Satisfaction with Medication

Statistical analysis title	% of TSQ: Mostly Satisfied to any Questions

Comparison groups	Ixekizumab v Adalimumab
Number of subjects included in analysis	566
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	= 0.561
Method	Regression, Logistic
Parameter estimate	Rate Difference
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	9.7

Notes:

[4] - Mostly Satisfied to any Questions

Other pre-specified: Number of Participants Who Answered "Yes" to any 10 Questions in Columbia Suicide Severity Rating Scale (C-SSRS)

End point title	Number of Participants Who Answered "Yes" to any 10 Questions in Columbia Suicide Severity Rating Scale (C-SSRS)

End point description:

The C-SSRS is a scale that captures the occurrence, severity, and frequency of suicide-related ideations and behaviors during the assessment period.

1. Wish to be dead
2. Non-specific active suicidal thoughts
3. Active suicidal ideation with any methods (not plan) without intent to act
4. Active suicidal ideation with some intent to act, without specific plan
5. Active suicidal ideation with specific plan and intent
6. Preparatory acts or behavior
7. Aborted attempt
8. Interrupted attempt
9. Non-fatal suicide attempt
10. Completed suicide

APD: All randomized participants.

End point type	Other pre-specified

End point timeframe:

Week 52

End point values	Ixekizumab	Adalimumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	283	283		
Units: participants	9	7		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up To Week 52

Adverse event reporting additional description:

All participants who received at least one dose of study drug. Per protocol and statistical analysis plan, the primary and secondary analysis were performed to compare all ixekizumab participants together versus all adalimumab participants together.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Ixekizumab

Reporting group description:

160 milligrams (mg) ixekizumab (IXE) given subcutaneously (SC) at baseline for all participants.

80 mg ixekizumab given once every 2 weeks (Q2W) SC from week 2 to week 12 and once every 4 weeks (Q4W) thereafter for participants with moderate-to-severe plaque Ps.

80 mg ixekizumab given SC Q4W starting week 4 for participants not meeting criteria for moderate-to-severe plaque Ps.

Reporting group title	Adalimumab

Reporting group description:

80 mg adalimumab (ADA) given SC at baseline followed by 40 mg Q2W given SC starting week 1 for participants with moderate-to-severe plaque Ps.

40 mg adalimumab given Q2W SC at baseline followed by 40 mg Q2W starting at Week 2 given SC for participants not meeting criteria for moderate-to-severe plaque Ps

Reporting group title	Adalimumab Follow-up

Reporting group description:

Follow-up: Participants did not receive drug during the Post-Treatment Follow-Up Period.

Reporting group title	Ixekizumab Follow-up

Reporting group description:

Follow-up: Participants did not receive drug during the Post-Treatment Follow-Up Period.

Serious adverse events	Ixekizumab	Adalimumab	Adalimumab Follow-up
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 283 (4.24%)	35 / 283 (12.37%)	4 / 260 (1.54%)
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)			
basal cell carcinoma			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal stromal tumour			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
pituitary tumour benign			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	0 / 260 (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
rectal adenocarcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
necrosis ischaemic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral artery occlusion			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	1 / 260 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
injection site rash			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	0 / 260 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
pyrexia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	2 / 283 (0.71%)	1 / 283 (0.35%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	1 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
menometrorrhagia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[1]	1 / 121 (0.83%)	0 / 133 (0.00%)	0 / 123 (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
prostatitis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed[2]	0 / 162 (0.00%)	1 / 150 (0.67%)	0 / 137 (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			
dyspnoea			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	0 / 260 (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
vocal cord thickening			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
Investigations			
hepatic enzyme increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
fall			

alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	2 / 283 (0.71%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hip fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
humerus fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
maternal exposure during pregnancy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed[3]	0 / 121 (0.00%)	1 / 133 (0.75%)	0 / 123 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
tendon rupture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
upper limb fracture			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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			
angina unstable			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
atrial fibrillation			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	1 / 283 (0.35%)	1 / 260 (0.38%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial flutter			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure congestive			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	0 / 260 (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
myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	0 / 260 (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
myocardial ischaemia			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
haemorrhagic stroke			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
polyneuropathy			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
radiologically isolated syndrome			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	0 / 260 (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
sciatica			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
seizure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	1 / 260 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	0 / 260 (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
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	1 / 260 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
acute abdomen			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	0 / 260 (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
Hepatobiliary disorders			
cholecystitis chronic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
cholelithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
Skin and subcutaneous tissue disorders			
erythrodermic psoriasis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	0 / 260 (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
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
renal failure			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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			
bursitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	0 / 260 (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			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
pain in extremity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	0 / 260 (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
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
appendicitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	1 / 283 (0.35%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arthritis bacterial			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	0 / 260 (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
cellulitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	1 / 283 (0.35%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	0 / 260 (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
lower respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
lymph node tuberculosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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

meningitis viral			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
pneumonia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 283 (0.35%)	0 / 283 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia legionella			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
pyelonephritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
pyoderma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (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
staphylococcal sepsis			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	0 / 260 (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
viral infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	0 / 283 (0.00%)	1 / 260 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
diabetic ketoacidosis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 283 (0.00%)	1 / 283 (0.35%)	0 / 260 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Ixekizumab Follow-up		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 265 (2.64%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
basal cell carcinoma			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastrointestinal stromal tumour			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pituitary tumour benign			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rectal adenocarcinoma				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
squamous cell carcinoma of skin				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	1 / 265 (0.38%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
necrosis ischaemic				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peripheral artery occlusion				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
asthenia				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
injection site rash				
alternative dictionary used: MedDRA 21.1				

subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
non-cardiac chest pain				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyrexia				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
menometrorrhagia				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed[1]	0 / 111 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
prostatitis				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed[2]	0 / 154 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
dyspnoea				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	1 / 265 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
vocal cord thickening				
alternative dictionary used: MedDRA 21.1				

subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
hepatic enzyme increased			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
fall			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hip fracture			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
humerus fracture			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
maternal exposure during pregnancy				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed[3]	0 / 111 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
road traffic accident				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tendon rupture				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
upper limb fracture				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
angina unstable				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atrial fibrillation				
alternative dictionary used: MedDRA 21.1				

subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
atrial flutter			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 265 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
cardiac failure congestive			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 265 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
myocardial infarction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 265 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
myocardial ischaemia			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
haemorrhagic stroke			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
polyneuropathy			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
radiologically isolated syndrome				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sciatica				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
seizure				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
transient ischaemic attack				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
anaemia				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
acute abdomen				
alternative dictionary used: MedDRA 21.1				

subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 265 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
cholecystitis chronic			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cholelithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
erythrodermic psoriasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	1 / 265 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
renal failure			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
bursitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
osteoarthritis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pain in extremity			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
appendicitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
arthritis bacterial			
alternative dictionary used: MedDRA 21.1			

subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
large intestine infection				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lower respiratory tract infection				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lymph node tuberculosis				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
meningitis viral				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

pneumonia legionella				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyelonephritis				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyoderma				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	1 / 265 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
sepsis				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
staphylococcal sepsis				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	1 / 265 (0.38%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
viral infection				
alternative dictionary used: MedDRA 21.1				
subjects affected / exposed	0 / 265 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
diabetic ketoacidosis				
alternative dictionary used: MedDRA 21.1				

subjects affected / exposed	0 / 265 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

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

Non-serious adverse events	Ixekizumab	Adalimumab	Adalimumab Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	65 / 283 (22.97%)	44 / 283 (15.55%)	5 / 260 (1.92%)
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	16 / 283 (5.65%)	4 / 283 (1.41%)	0 / 260 (0.00%)
occurrences (all)	30	9	0
Infections and infestations			
nasopharyngitis			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	38 / 283 (13.43%)	23 / 283 (8.13%)	3 / 260 (1.15%)
occurrences (all)	46	26	3
upper respiratory tract infection			
alternative dictionary used: MedDRA 21.1			
subjects affected / exposed	18 / 283 (6.36%)	18 / 283 (6.36%)	2 / 260 (0.77%)
occurrences (all)	21	23	2

Non-serious adverse events	Ixekizumab Follow-up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 265 (3.02%)		
General disorders and administration site conditions			

injection site reaction alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	 0 / 265 (0.00%) 0		
Infections and infestations nasopharyngitis alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	 5 / 265 (1.89%) 5		
upper respiratory tract infection alternative dictionary used: MedDRA 21.1 subjects affected / exposed occurrences (all)	 3 / 265 (1.13%) 3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 May 2017	Protocol Amendment (a): Changes to bring adverse event (AE) information in line with updated risk profile and Informed Consent Document (ICD).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported