Clinical trial results:
A Dose-Ranging And Efficacy Study of LY2439821 (An Anti-IL-17 Antibody) In Patients With Moderate-To-Severe Psoriasis

Summary

EudraCT number	2010-018948-14
Trial protocol	DK
Global end of trial date	02 August 2016

Results information

Result version number	v1 (current)
This version publication date	18 August 2017
First version publication date	18 August 2017

Trial information

Trial identification

Sponsor protocol code	I1F-MC-RHAJ

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01107457
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 12060

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	02 August 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 August 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary purpose for this study is to help answer the following research questions
•The safety of ixekizumab (LY2439821) and any side effects that might be associated with it.
•Whether ixekizumab can help participants with Psoriasis.
•How much ixekizumab should be given to participants.

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	19 April 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	5 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 3
Country: Number of subjects enrolled	United States: 139
Worldwide total number of subjects	142
EEA total number of subjects	3

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)	134
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study has 3 parts:Part A is a randomized, double-blind, placebo-controlled, parallel-group, dose ranging design (approximately 20-40 weeks [wks]).Treatment durability (sustained efficacy off treatment) from Week 20 up to Week 32 was evaluated during Part A.

Pre-assignment

Screening details:

Part B is an optional extension period with an open-label design (approximately 240 weeks). Part C is an additional optional extension period with an open-label design(up to approximately 104 weeks).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Part A:

Placebo given on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

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

Dosage and administration details:

Placebo given on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Arm title	10 mg ixekizumab

Arm description:

Part A:

10 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Arm type	Experimental
Investigational medicinal product name	ixekizumab
Investigational medicinal product code	
Other name	LY2439821,Taltz
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

10 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Arm title	25 mg ixekizumab

Arm description:

Part A:

25 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	
Other name	LY2439821,Taltz
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

25 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Arm title	75 mg ixekizumab

Arm description:

Part A:

75 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	
Other name	LY2439821,Taltz
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

75 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Arm title	150 mg ixekizumab

Arm description:

Part A:

150 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	
Other name	LY2439821,Taltz
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Number of subjects in period 1	Placebo	10 mg ixekizumab	25 mg ixekizumab
Started	27	28	30
Received at Least 1 Dose of Study Drug	27	28	30
Completed	22	21	29
Not completed	5	7	1
Consent withdrawn by subject	3	3	-
Adverse event, non-fatal	1	2	1
Lost to follow-up	-	1	-
Lack of efficacy	1	-	-
Protocol deviation	-	1	-

Number of subjects in period 1	75 mg ixekizumab	150 mg ixekizumab
Started	29	28
Received at Least 1 Dose of Study Drug	29	28
Completed	26	27
Not completed	3	1
Consent withdrawn by subject	3	1
Adverse event, non-fatal	-	-
Lost to follow-up	-	-
Lack of efficacy	-	-
Protocol deviation	-	-

Period 2

Period 2 title	Part B and C
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	120 mg/80 mg Total Ixekizumab

Arm description:

Part B: (optional)
120 mg ixekizumab given SC Q4W. Subsequent to an amendment on May 2012, administration changed to 80 mg Q4W through Week 236.

Part C: (optional)
80 mg ixekizumab given SC Q4W through week 344.

Part C was stopped once ixekizumab became available through marketing authorization.
Only participants with neutropenia entered the post treatment safety visits.
No participants completed the study as Part C was stopped.

Arm type	Experimental
Investigational medicinal product name	Ixekizumab
Investigational medicinal product code	
Other name	LY2439821,Taltz
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Part B: (optional)

120 mg ixekizumab given SC Q4W. Subsequent to an amendment on May 2012, administration changed to 80 mg Q4W through Week 236.

Part C: (optional)

80 mg ixekizumab given SC Q4W through week 344.

Note: The pharmaceutical form of drug in the first part of Part B was powder for solution for injection.

Number of subjects in period 2[1]	120 mg/80 mg Total Ixekizumab
Started	120
Completed Part B (Week 240)	74
Completed Part C	0
Post Treatment Safety Visits	6
Completed	0
Not completed	120
Inclusion/Exclusion Criteria Not Met	1
Physician decision	3
Consent withdrawn by subject	16
Clinical Relapse	4
Adverse event, non-fatal	12
Sponsor Decision	66
Lost to follow-up	10
Lack of efficacy	7

Protocol deviation	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: 80 and 120 mg ixekizumab were only administered during Part B and C. Not all participants that participated in Part A moved to Part B and C.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description: Part A: Placebo given on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.	

Reporting group title	10 mg ixekizumab
Reporting group description: Part A: 10 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.	

Reporting group title	25 mg ixekizumab
Reporting group description: Part A: 25 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.	

Reporting group title	75 mg ixekizumab
Reporting group description: Part A: 75 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.	

Reporting group title	150 mg ixekizumab
Reporting group description: Part A: 150 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.	

Reporting group values	Placebo	10 mg ixekizumab	25 mg ixekizumab
Number of subjects	27	28	30
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			

Age Continuous Units: years			
arithmetic mean	45	47.65	45.93
standard deviation	± 12.76	± 11.2	± 14.53
Gender, Male/Female Units: Participants			
Female	13	12	12
Male	14	16	18
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	5	7
Not Hispanic or Latino	22	23	23
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	1
Asian	0	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	1
White	25	27	28
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
United States	27	27	29
Denmark	0	1	1
Baseline in Psoriasis Area and Severity Index (PASI)			
PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs). For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (none) to 4 (very severe). Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor (head [0.1], upper limbs [0.2], trunk [0.3], lower limbs [0.4]).Overall scores range from 0 (no psoriasis) to 72(the most severe disease).			
Units: units on a scale			
arithmetic mean	16.45	19.18	18.55
standard deviation	± 5.26	± 7.96	± 4.94

Reporting group values	75 mg ixekizumab	150 mg ixekizumab	Total
Number of subjects	29	28	142
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0

Age Continuous Units: years			
arithmetic mean	46.37	45.97	
standard deviation	± 12.5	± 13	-
Gender, Male/Female Units: Participants			
Female	10	14	61
Male	19	14	81
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	4	4	25
Not Hispanic or Latino	25	24	117
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1	0	2
Asian	2	1	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	2	7
White	24	25	129
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
United States	28	28	139
Denmark	1	0	3
Baseline in Psoriasis Area and Severity Index (PASI)			
PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs). For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (none) to 4 (very severe). Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor (head [0.1], upper limbs [0.2], trunk [0.3], lower limbs [0.4]).Overall scores range from 0 (no psoriasis) to 72(the most severe disease).			
Units: units on a scale			
arithmetic mean	17.2	17.7	
standard deviation	± 4.26	± 6.21	-

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Part A:

Placebo given on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Reporting group title	10 mg ixekizumab

Reporting group description:

Part A:

10 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Reporting group title	25 mg ixekizumab

Reporting group description:

Part A:

25 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Reporting group title	75 mg ixekizumab

Reporting group description:

Part A:

75 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Reporting group title	150 mg ixekizumab

Reporting group description:

Part A:

150 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Reporting group title	120 mg/80 mg Total Ixekizumab

Reporting group description:

Part B: (optional)
120 mg ixekizumab given SC Q4W. Subsequent to an amendment on May 2012, administration changed to 80 mg Q4W through Week 236.

Part C: (optional)
80 mg ixekizumab given SC Q4W through week 344.

Part C was stopped once ixekizumab became available through marketing authorization.
Only participants with neutropenia entered the post treatment safety visits.
No participants completed the study as Part C was stopped.

Subject analysis set title	All Participants on Ixekizumab(10mg,25mg,75mg &150mg)
Subject analysis set type	Full analysis

Subject analysis set description:

The population pharmacokinetic (PK) modeling value for systemic clearance was based on data from week 1 to week 32 for all participants in all ixekizumab treatment arms.

10 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

25 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

75 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

150 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations

Analysis Population Description (APD): All randomized participants who received at least 1 dose of study drug and had evaluable PK data.

Primary: Percentage of Participants Achieving Psoriasis Area and Severity Index ≥75% (PASI 75) Improvement

End point title	Percentage of Participants Achieving Psoriasis Area and Severity Index ≥75% (PASI 75) Improvement

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms and legs). For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90% - 100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0(none) to 4(very severe). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor (head [0.1], upper limbs [0.2], trunk [0.3], lower limbs [0.4]). Overall scores range from 0 (no psoriasis) to 72 (the most severe disease). Participants achieving PASI 75 were defined as having an improvement of ≥75% in the PASI score compared to baseline.

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	28	30	29
Units: percentage of participants				
number (not applicable)	7.7	28.6	76.7	82.8

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: percentage of participants				
number (not applicable)	82.1			

Statistical analyses

Statistical analysis title	PASI75_STATISTICAL_ANALYSIS_Placebo_vs_10 mg_Ixe
Comparison groups	Placebo v 10 mg ixekizumab

Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.079
Method	Fisher exact
Confidence interval	
sides	2-sided

Statistical analysis title	PASI75_STATISTICAL_ANALYSIS_Placebo_vs_25 mg Ixe
Comparison groups	Placebo v 25 mg ixekizumab
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Fisher exact
Confidence interval	
sides	2-sided

Statistical analysis title	PASI75_STATISTICAL_ANALYSIS_Placebo_vs_75 mg Ixe
Comparison groups	Placebo v 75 mg ixekizumab
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Fisher exact
Confidence interval	
sides	2-sided

Statistical analysis title	PASI75_STATISTICAL_ANALYSIS_Placebo_vs_150 mg Ixe
Comparison groups	Placebo v 150 mg ixekizumab
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Fisher exact
Confidence interval	
sides	2-sided

Primary: Percentage of PASI Improvement from Baseline to 12 Week endpoint	
End point title	Percentage of PASI Improvement from Baseline to 12 Week endpoint

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs). For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90% - 100%) and severity was estimated by clinical signs of erythema,induration and scaling with a scores range from 0(none) to 4(very severe). Each area is scored by itself and the scores were then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region*area score*weighing factor(head[0.1],upper limbs[0.2],trunk[0.3],lower limbs[0.4]). Overall scores range from 0(no psoriasis) to 72(the most severe disease).Least squares(LS) mean values were calculated using MMRM and controlled for baseline as a covariate,visit,treatment and visit by treatment interaction as fixed effects, with variance-covariance structure set to unstructured.

APD: All randomized participants who received at least 1 dose of study drug, had at least 1 post-baseline PASI assessment.

End point type	Primary

End point timeframe:

Baseline to Week 12

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	23	27	29	29
Units: Percentage of improvement in PASI score				
least squares mean (confidence interval 95%)	16.22 (4.44 to 28.01)	49.33 (38.25 to 60.41)	78.48 (67.67 to 89.29)	85.69 (74.87 to 96.5)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	26			
Units: Percentage of improvement in PASI score				
least squares mean (confidence interval 95%)	87.12 (75.94 to 98.29)			

Statistical analyses

Statistical analysis title	PASI_STATISTICAL_ANALYSIS_Placebo_vs_ 10 mg Ixe
Comparison groups	Placebo v 10 mg ixekizumab
Number of subjects included in analysis	50
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Statistical analysis title	PASI_STATISTICAL_ANALYSIS_Placebo_vs_ 25 mg Ixe
Comparison groups	Placebo v 25 mg ixekizumab
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Statistical analysis title	PASI_STATISTICAL_ANALYSIS_Placebo_vs_75 mg Ixe
Comparison groups	Placebo v 75 mg ixekizumab
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Statistical analysis title	PASI_STATISTICAL_ANALYSIS_Placebo_vs_150 mg Ixe
Comparison groups	Placebo v 150 mg ixekizumab
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed models analysis
Confidence interval	
sides	2-sided

Secondary: Percentage of Participants With a Static Physician's Global Assessment (sPGA) Score of Cleared (0) or Minimal (1) With at Least a 2 Point Improvement" at Week 12

End point title	Percentage of Participants With a Static Physician's Global Assessment (sPGA) Score of Cleared (0) or Minimal (1) With at Least a 2 Point Improvement" at Week 12

End point description:

The sPGA of psoriasis is scored on a 6-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored separately over the whole body according to a 6 point severity scale (0 [clear] to 5 [severe]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the sPGA score and category (0=clear; 1=minimal; 2=mild; 3=moderate; 4=marked; 5 = severe). As defined by protocol, a responder is a participant who has a post-baseline sPGA score of '0' or a post-baseline score of '1' with at least a 2 point improvement from baseline.

APD:All randomized participants who received at least 1 dose of study drug and had at least 1 post-

baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	28	30	29
Units: percentage of participants				
number (not applicable)	7.7	25	70	72.4

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: percentage of participants				
number (not applicable)	71.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment Emergent Adverse Events Up to 20 Weeks

End point title	Number of Participants With Treatment Emergent Adverse Events Up to 20 Weeks

End point description:

Treatment-emergent adverse events (TEAEs) are events which were not present at baseline or pre-existing conditions at baseline that worsened in severity following the start of treatment. A summary of other non-serious Adverse Events (AEs), and all Serious Adverse Events (SAE's), regardless of causality, is located in the Reported Adverse Events section.

APD: All randomized participants who received at least 1 dose of study drug.

End point type	Secondary

End point timeframe:

Baseline Up to 20 Weeks

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27	28	30	29
Units: Participants				
number (not applicable)	17	21	21	17

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Participants				
number (not applicable)	13			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hospital Anxiety and Depression Scale (HADS) Score at Week 16

End point title	Change from Baseline in Hospital Anxiety and Depression Scale (HADS) Score at Week 16

End point description:

The HADS is a 14-item, participant self-reported scale that consists of an anxiety scale and a depression scale, each with 7 items. Items are rated on a 4-point Likert-type scale ranging from 0 (low level of anxiety or depression) to 3 (high level of anxiety or depression). Each subscale score ranges from 0 to 21 with higher scores indicating greater symptom severity. The classification is defined: 0-7 normal, 8-10 Borderline, 11-21 Abnormal. LS mean was calculated using the analysis of covariance (ANCOVA) model including treatment as fixed effect and baseline as covariate.

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	28	29	29
Units: units on a scale				
least squares mean (standard error)				
Anxiety	-0.86 (± 0.58)	-1.97 (± 0.55)	-2.1 (± 0.54)	-2.17 (± 0.54)
Depression	0.17 (± 0.54)	-1.86 (± 0.51)	-1.75 (± 0.51)	-2.52 (± 0.51)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: units on a scale				
least squares mean (standard error)				
Anxiety	-2.81 (± 0.55)			
Depression	-2.01 (± 0.51)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in 16-Item Quick Inventory of Depressive Symptoms- Self Rated (QIDS-SR16) Total Score at Week 16

End point title	Change from Baseline in 16-Item Quick Inventory of Depressive Symptoms- Self Rated (QIDS-SR16) Total Score at Week 16

End point description:

The QIDS-SR16 is a self-administered, 16-item instrument in which a participant is asked to consider each statement as it relates to the way they have felt for the past 7 days. There is a 4-point scale for each item ranging from 0 (best) to 3 (worst). The 16 items are scored to give 9 individual depression domains (sad mood, concentration, self-criticism, suicidal ideation, interest, energy/fatigue, sleep disturbance [initial, middle and late insomnia or hypersomnia], decrease/increase in appetite/weight, and psychomotor agitation/retardation), which are summed to give a single score ranging from 0 to 27, with higher scores denoting greater symptom severity. The LS Mean (no multiplicity adjustments) are presented for each treatment versus placebo comparison at each visit and use an analysis of covariance (ANCOVA) model including baseline as a covariate and treatment as fixed effect in the model.

End point type	Secondary

End point timeframe:

Baseline, Week 16
APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	27	26	27
Units: units on a scale				
least squares mean (standard error)	-0.49 (± 0.56)	-1.56 (± 0.52)	-1.48 (± 0.53)	-2.13 (± 0.52)

End point values	150 mg ixekizumab			

Subject group type	Reporting group			
Number of subjects analysed	25			
Units: units on a scale				
least squares mean (standard error)	-2.21 (± 0.54)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Patient Global Assessment (PatGA) at Week 12

End point title	Change from Baseline in Patient Global Assessment (PatGA) at Week 12

End point description:

The PatGA is a single-item self-reported instrument asking the participant to rate the severity of their psoriasis "today" by circling a number on the numeric rating scale from 0 (Clear = no psoriasis) to 5 (Severe = the worst their psoriasis has ever been). The LS Mean (no multiplicity adjustments) are presented for each treatment versus placebo comparison at each visit and use an analysis of covariance (ANCOVA) model including baseline as a covariate and treatment as fixed effect in the model.

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point type	Secondary

End point timeframe:

Baseline, 12 Weeks

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	28	30	29
Units: units on a scale				
least squares mean (standard error)	-0.6 (± 0.3)	-1.1 (± 0.3)	-2.3 (± 0.2)	-2.9 (± 0.3)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: units on a scale				
least squares mean (standard error)	-2.5 (± 0.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Pain Visual Analog scale (VAS) at Week 12

End point title	Change from Baseline in Pain Visual Analog scale (VAS) at Week 12

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 placing a single mark on the horizontal 100-mm scale from 0mm (no pain) to 100 mm (pain as severe as you can imagine). A mixed effects model for repeated measures analysis was used. Least Squares (LS) Mean values were calculated using MMRM and were controlled for baseline as a covariate, visit, treatment and visit by treatment interaction as fixed effects, with variance-covariance structure set to unstructured.

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Only participants with self-reported psoriatic arthritis at baseline were included in the analysis. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	7	11	8
Units: millimeter (mm)				
least squares mean (confidence interval 95%)	3.87 (-20.9 to 28.64)	-4.32 (-23.05 to 14.41)	-19.36 (-34.31 to -4.4)	-21.24 (-37.89 to -4.58)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: millimeter (mm)				
least squares mean (confidence interval 95%)	-34.24 (-51.83 to -16.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Medical Outcomes Study Sleep Scale (MOS-S) at Week 16

End point title	Change from Baseline in Medical Outcomes Study Sleep Scale (MOS-S) at Week 16

End point description:

MOS-S provides a concise assessment of important dimensions of sleep, including initiation, maintenance, respiratory problems, quantity, perceived adequacy, and somnolence during the past 4 weeks. Scoring based on 7 subscales: sleep disturbance, snoring, awakened short of breath or with headache, sleep adequacy, and somnolence (range:0-100,with higher scores for more impairment); sleep quantity (range:0-24), and optimal sleep (yes:1, no:0). Six(6) and 9 item index measures of sleep

disturbance were constructed to provide composite scores. Scores are transformed (actual raw score minus lowest possible score divided by possible raw score range * 100); total score range: 0 to 100; higher score = higher scores indicate greater problems with the attribute. The LS Mean (no multiplicity adjustments) was calculated using an analysis of covariance (ANCOVA) model including baseline as a covariate and treatment as fixed effect in the model.

End point type	Secondary

End point timeframe:

Baseline, Week 16

APD:All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	28	29	29
Units: units on a scale				
least squares mean (standard error)				
Sleep Problems Index I	-0.05 (± 2.61)	-5.35 (± 2.46)	-8.78 (± 2.42)	-7.97 (± 2.42)
Sleep Problems Index II	0.21 (± 2.37)	-6.42 (± 2.24)	-9.23 (± 2.2)	-8.43 (± 2.2)
Sleep Adequacy	-2.83 (± 4.73)	5.63 (± 4.47)	11.35 (± 4.39)	8.81 (± 4.39)
Sleep Disturbance	-1.47 (± 3.27)	-8.56 (± 3.1)	-10.02 (± 3.03)	-11.5 (± 3.04)
Sleep Somnolence	1.12 (± 2.73)	-2.32 (± 2.58)	-7.14 (± 2.53)	-5.8 (± 2.53)
Snoring	-2.85 (± 4.22)	-0.47 (± 3.94)	2.94 (± 3.88)	-3.24 (± 3.87)
Sleep Short of Breath/headache	4.34 (± 3.1)	-5.45 (± 2.92)	-2.84 (± 2.87)	-2.65 (± 2.87)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: units on a scale				
least squares mean (standard error)				
Sleep Problems Index I	-2.38 (± 2.47)			
Sleep Problems Index II	-2.48 (± 2.24)			
Sleep Adequacy	-0.41 (± 4.48)			
Sleep Disturbance	-4.67 (± 3.09)			
Sleep Somnolence	-0.76 (± 2.58)			
Snoring	-3.81 (± 3.94)			
Sleep Short of Breath/headache	-3.46 (± 2.91)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who received Medical Care measured by Medical Care Resource Utilization (PMRU))

End point title	Number of Participants who received Medical Care measured by Medical Care Resource Utilization (PMRU))

End point description:

The PMRU is a 3item participant-reported questionnaire on health care resource utilization due to psoriasis for physician/clinic visits, emergency room visits, and inpatient hospital admissions since the last study visit.

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	28	30	29
Units: participants				
number (not applicable)				
Week 16 - Office or Clinic(n=23,24,29,28,27)	1	0	0	1
Week 16 - Emergency Room(ER)(n=23, 24, 29, 28, 27)	0	0	0	0
Week 16 - Admitted thru ER (n=26,28,30,29,28)	0	0	0	0
Week 16 - Hospital Stay (n=26,28,30,29,28)	0	0	0	0

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: participants				
number (not applicable)				
Week 16 - Office or Clinic(n=23,24,29,28,27)	3			
Week 16 - Emergency Room(ER)(n=23, 24, 29, 28, 27)	1			
Week 16 - Admitted thru ER (n=26,28,30,29,28)	0			
Week 16 - Hospital Stay (n=26,28,30,29,28)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI Q) at Week 16

End point title	Change from Baseline in Work Productivity and Activity Impairment Questionnaire (WPAI Q) at Week 16

End point description:

The WPAI questionnaire has six questions to assess whether the participant was currently employed (Q1); how many hours from work were missed due to problems associated with psoriasis (Q2) or any other reason (Q3); hours actually worked (Q4); degree that psoriasis affected productivity while working (Q5); and degree that psoriasis affected regular activities (Q6) over the past 7 days. Four separate overall scores were calculated, Absenteeism (work time missed) = (Q2/(Q2+Q4))*100, Presenteeism (impairment at work/reduced on-the-job effectiveness) = (Q5/10) *100, Work productivity loss(overall work impairment /absenteeism plus presenteeism) = (Q2/(Q2+Q4)+[(1-Q2/(Q2+Q4))x(Q5/10)]) * 100 and Activity Impairment = (Q6/10) * 100. Each score ranges from 0 to 100 with higher scores indicating greater impairment and less productivity (worse outcomes). The LS Mean was calculated using ANCOVA model including baseline as a covariate and treatment as fixed effect in the model.

End point type	Secondary

End point timeframe:

Baseline, Week 16

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	28	30	29
Units: units on a scale				
least squares mean (standard error)				
Absenteeism (n=15,19,14,19,16)	-1.91 (± 1.88)	0.71 (± 1.68)	-0.83 (± 1.94)	-2.64 (± 1.67)
Presenteeism (n=15,20,16,19,16)	-3.38 (± 3.99)	-0.99 (± 3.47)	-4.59 (± 3.87)	-14.48 (± 3.55)
Work productivity loss (n=15,19,14,19,16)	-3.65 (± 4.3)	1.74 (± 3.82)	-4.65 (± 4.45)	-14.76 (± 3.82)
Activity Impairment (n=25,28,28,29,27)	-0.68 (± 4.19)	-9.76 (± 3.96)	-14.96 (± 3.95)	-12.81 (± 3.9)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: units on a scale				
least squares mean (standard error)				
Absenteeism (n=15,19,14,19,16)	-1.96 (± 1.82)			
Presenteeism (n=15,20,16,19,16)	-10.69 (± 3.9)			
Work productivity loss (n=15,19,14,19,16)	-11.12 (± 4.17)			
Activity Impairment (n=25,28,28,29,27)	-14.79 (± 4.03)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Medical Outcomes Study Short-Form 36 (SF-36) - Physical Component Score (PCS) and Mental Component Score (MCS) at Week 16

End point title	Change from Baseline in Medical Outcomes Study Short-Form 36 (SF-36) - Physical Component Score (PCS) and Mental Component Score (MCS) at Week 16

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. The recall period was the past 4 weeks. The LS Mean was calculated using ANCOVA model including baseline as a covariate and treatment as fixed effect in the model.

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	28	28	29
Units: units on a scale				
least squares mean (standard error)				
PCS	-1.22 (± 2.15)	2.41 (± 2.03)	1.95 (± 2.03)	3.94 (± 2)
MCS	-0.56 (± 2.29)	7.27 (± 2.19)	5.16 (± 2.18)	4.13 (± 2.13)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: units on a scale				
least squares mean (standard error)				
PCS	5.72 (± 2.03)			
MCS	4.15 (± 2.16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Nail Psoriasis Severity Index (NAPSI) in Participants with Nail Psoriasis at Week 12

End point title	Change from Baseline in Nail Psoriasis Severity Index (NAPSI) in Participants with Nail Psoriasis at Week 12

End point description:

The NAPSI is physician-rated and quantifies the severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix and nail bed. Each finger nail is divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis (range from 0 [absence of psoriasis] to 4 [presence of psoriasis in all 4 quadrants]). Participant's fingers and toes were evaluated and the sum of the scores was added resulting in a range of 0 to 160; higher scores indicate greater severity. If an individual toe or finger assessment was missing (not done), the average of the remaining measured digits was imputed and added to the sum. If <50% of the toes or finger assessments were missing, the imputation was performed. If >50% of the assessments were missing, then the sum of the scores was left as missing. LS mean was calculated using MMRM with baseline score as covariate, visit, treatment and visit by treatment interaction as fixed effects.

End point type	Secondary

End point timeframe:

Baseline, Week 12

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Only participants with baseline nail involvement were included in the analysis.

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	13	10	10
Units: units on a scale				
least squares mean (confidence interval 95%)	2.21 (-5.17 to 9.58)	-4.85 (-12.82 to 3.12)	-3.65 (-12.73 to 5.43)	-15.89 (-24.98 to -6.81)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	10			
Units: units on a scale				
least squares mean (confidence interval 95%)	-19.91 (-29 to -10.83)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Palmoplantar Psoriasis Severity Index (PPASI) in Participants with Palmoplantar Psoriasis at Week 12

End point title	Change from Baseline in Palmoplantar Psoriasis Severity Index (PPASI) in Participants with Palmoplantar Psoriasis at Week 12

End point description:

The PPASI is a physician-assessed composite score derived from the summed scores for erythema, induration, and desquamation multiplied by a score for the extent of palm and sole area involvement. The PPASI score ranges from 0 to 72, with higher scores representing greater severity of palmoplantar psoriasis.LS mean was calculated using MMRM with baseline score as covariate, visit, treatment and visit by treatment interaction as fixed effects, with variance-covariance structure set to symmetric.

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Only participants with palmoplantar involvement were included in the analysis.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	4	4	2
Units: units on a scale				
least squares mean (confidence interval 95%)	-1 (-10.3 to 8.3)	-6.4 (-12.3 to -0.5)	-4.6 (-10.3 to 1.2)	-3.4 (-11.5 to 4.8)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: units on a scale				
least squares mean (confidence interval 95%)	-12.8 (-20.9 to -4.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Scalp Psoriasis Severity Index (PSSI) in Participants with Scalp Psoriasis at Week 12

End point title	Change from Baseline in Scalp Psoriasis Severity Index (PSSI) in Participants with Scalp Psoriasis at Week 12

End point description:

The PSSI is a physician-assessed composite score derived from the summed scores for erythema, induration, and desquamation multiplied by a score for the extent of scalp area involved. The PSSI score ranges from 0 to 72, with higher scores representing greater severity of scalp psoriasis.LS mean was calculated using MMRM with baseline score as covariate, visit, treatment and visit by treatment interaction as fixed effects, with variance-covariance structure set to unstructured.

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Only participants with baseline scalp involvement were included in the analysis.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	17	21	24	18
Units: units on a scale				
least squares mean (confidence interval 95%)	-7.3 (-11.2 to -3.5)	-10.2 (-13.9 to -6.6)	-15.8 (-19.2 to -12.4)	-15 (-18.9 to -11)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: units on a scale				
least squares mean (confidence interval 95%)	-17.2 (-20.8 to -13.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Ixekizumab Systemic Clearance (CL) (Serum Concentrations of Ixekizumab from Baseline through 32 Weeks)

End point title	Ixekizumab Systemic Clearance (CL) (Serum Concentrations of Ixekizumab from Baseline through 32 Weeks)

End point description:

The population pharmacokinetic (PK) modeling value for systemic clearance was based on data from week 1 to week 32 for all participants in all ixekizumab treatment arms.

APD: All randomized participants who received at least 1 dose of study drug and had evaluable PK data.

End point type	Secondary

End point timeframe:

Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28 and Week 32

End point values	All Participants on Ixekizumab(10 mg,25mg,75m g &150mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	115			
Units: liters per hour (L/hr)				
arithmetic mean (confidence interval 95%)	0.0177 (0.016 to 0.0199)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score Total Score at Week 16

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI) Total Score Total Score at Week 16

End point description:

The DLQI is a 10-item, participant-administered dermatology-specific questionnaire that assess health related quality of life that covers 6 domains including symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. The DLQI items response categories are scored 0 (not relevant) to 3 (very much) with a total score range of 0 to 30; higher scores indicate poor quality of life and a 5-point change from baseline is considered clinically relevant. The LS Mean(no multiplicity adjustments) are presented for each treatment versus placebo comparison at each visit and use an analysis of covariance (ANCOVA) model including baseline as a covariate and treatment as fixed effect in the model.

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	28	29	29
Units: units on a scale				
least squares mean (standard error)	-1.24 (± 0.97)	-6.35 (± 0.92)	-6.59 (± 0.9)	-8.39 (± 0.9)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: units on a scale				
least squares mean (standard error)	-8.17 (± 0.92)			

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions(head,trunk,arms,and legs).For each region the percent area of skin involved was estimated from 0(0%) to 6(90%-100%) and severity was estimated by clinical signs of erythema,induration and scaling with a scores range from 0(none) to 4(very severe).Each area is scored by itself and the scores were then combined for the final PASI.Final PASI calculated as:sum of severity parameters for each region*area score*weighing factor (head[0.1],upper limbs[0.2],trunk[0.3],lower limbs [0.4]).Overall scores range from 0(no psoriasis) to 72(most severe disease).The LS mean are presented for each treatment versus placebo comparison at each visit and use ANCOVA model including baseline PASI covariate and treatment as fixed effect in the model.Results at Week 12 are summarized as Improvement in PASI which is defined as a reduction in the PASI calculated score at a visit as compared to the score calculated at the baseline visit.

End point type	Secondary

End point timeframe:

Baseline, Week 12

APD: All randomized participants who received at least 1 dose of study drug and had at least 1 post-baseline PASI assessment. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	26	28	30	29
Units: units on a scale				
least squares mean (standard error)	3.5 (± 1.21)	8.2 (± 1.17)	13.56 (± 1.12)	14.99 (± 1.14)

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	28			

Units: units on a scale				
least squares mean (standard error)	15.38 (± 1.16)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who achieve a 75% Improvement in the Psoriasis Area and Severity Index (PASI 75)

End point title	Percentage of Participants who achieve a 75% Improvement in the Psoriasis Area and Severity Index (PASI 75)

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs). For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (none) to 4 (very severe). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor (head [0.1], upper limbs [0.2], trunk [0.3], lower limbs [0.4]). Overall scores range from 0 (no psoriasis) to 72 (the most severe disease). Participants achieving PASI 75 were defined as having an improvement of ≥75% in the PASI score compared to baseline.

End point type	Secondary

End point timeframe:

Week 32

APD:Randomized participants who received at least 1 dose of drug, completed study treatment in Part A,achieved PASI 75 at Week 20 and who were followed for treatment durability up to Week 32.LOCF was used to impute missing post-baseline values.

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	22	23	23
Units: percentage of participants				
number (not applicable)	0	50	59.1	56.5

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: percentage of participants				
number (not applicable)	82.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of PASI Improvement from Baseline through 32 Weeks

End point title	Percentage of PASI Improvement from Baseline through 32 Weeks

End point description:

The PASI combines the extent of body surface involvement in 4 anatomical regions(head, trunk, arms, and legs).For each region the percent area of skin involved was estimated from 0(0%) to 6(90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0(none) to 4(very severe).Each area is scored by itself and the scores were then combined for the final PASI.Final PASI calculated as: sum of severity parameters for each region*area score*weighing factor(head[0.1],upper limbs [0.2], trunk [0.3],lower limbs [0.4]).Overall scores range from 0(no psoriasis) to 72(the most severe disease).Improvement in PASI is defined as improvement in the PASI calculated score at a visit as compared to the score calculated at the baseline visit.

APD: All randomized participants who received at least 1 dose of study drug,completed study treatment in Part A,achieved PASI 75 at Week 20 and who were followed for treatment durability up to Week 32.

End point type	Secondary

End point timeframe:

Baseline Through 32 Weeks

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[1]	4	16	18
Units: Percentage PASI improvement				
arithmetic mean (standard deviation)	()	80.55 (± 17.69)	85.6 (± 12.74)	85.16 (± 15.3)

Notes:

[1] - Zero participants in the placebo arm had data.

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	21			
Units: Percentage PASI improvement				
arithmetic mean (standard deviation)	88.11 (± 11.35)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with a Static Physician's Global Assessment (sPGA) Score of Cleared (0) or Minimal (1) with at least a 2 point Improvement

End point title	Percentage of Participants with a Static Physician's Global Assessment (sPGA) Score of Cleared (0) or Minimal (1) with at least a 2 point Improvement

End point description:

The sPGA of psoriasis is scored on a 6-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored

separately over the whole body according to a 6-point severity scale (0 [clear] to 5 [severe]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the sPGA score and category (0=clear; 1=minimal; 2=mild; 3=moderate; 4=marked; 5 = severe). As defined by protocol, a responder is a participant who has a post-baseline sPGA score of '0' or a post-baseline score of '1' with at least a 2 point improvement from baseline.

APD: All randomized participants who received at least 1 dose of study drug, completed study treatment in Part A, achieved PASI 75 at Week 20 and who were followed for treatment durability up to Week 32. Last Observation Carried Forward (LOCF) was used to impute missing post-baseline values.

End point type	Secondary

End point timeframe:

Week 32

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[2]	6	22	23
Units: percentage of participants				
number (not applicable)		33.3	45.5	47.8

Notes:

[2] - Zero participants in the placebo arm had data.

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	23			
Units: percentage of participants				
number (not applicable)	65.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Anti-Ixekizumab Antibodies

End point title	Percentage of Participants With Anti-Ixekizumab Antibodies

End point description:

Percentage of participants with treatment-emergent positive anti-ixekizumab antibodies was summarized by treatment group. Percentage was calculated based on the number of evaluable participants and was calculated by number of participants with treatment-emergent positive anti-ixekizumab antibodies / number of evaluable participants * 100%.

APD: All randomized participants who received at least one dose of study drug and had a baseline and at least one post-baseline antibody assessment.

End point type	Secondary

End point timeframe:

Baseline through Week 20

End point values	Placebo	10 mg ixekizumab	25 mg ixekizumab	75 mg ixekizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	24	30	29
Units: percentage of participants				
number (not applicable)	4	54.2	40	17.2

End point values	150 mg ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: percentage of participants				
number (not applicable)	22.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Static Physician's Global Assessment (sPGA) of (0,1)

End point title	Percentage of Participants with Static Physician's Global Assessment (sPGA) of (0,1)

End point description:

The sPGA of psoriasis is scored on a 6-point scale, reflecting a global consideration of the erythema, induration, and scaling across all psoriatic lesions. Average erythema, induration, and scaling are scored separately over the whole body according to a 6-point severity scale (0 [clear] to 5 [severe]). The total score was calculated as average of the 3 severity scores and rounded to the nearest whole number score to determine the sPGA score and category (0=clear; 1=minimal; 2=mild; 3=moderate; 4=marked; 5 = severe). As defined by protocol, a responder is a participant who has a post-baseline sPGA score of '0' or a post-baseline score of '1' with at least a 2 point improvement from baseline.

APD: All enrolled participants who had PASI 75 response at Week 20.

End point type	Secondary

End point timeframe:

Baseline Up to 240 Weeks

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: percentage of participants				
number (not applicable)	78.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Treatment Emergent Adverse Events up to 344 Weeks

End point title	Number of Treatment Emergent Adverse Events up to 344 Weeks

End point description:

Treatment-emergent adverse events (TEAEs) are events which were not present at baseline or pre-existing conditions at baseline that worsened in severity following the start of treatment. A summary of other non-serious Adverse Events (AEs), and all Serious Adverse Events (SAE's), regardless of causality, is located in the Reported Adverse Events section.

APD: All enrolled participants.

End point type	Secondary

End point timeframe:

Baseline Up to 344 Weeks

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	120			
Units: Participants				
number (not applicable)	105			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Hospital Anxiety and Depression Scale (HADS)

End point title	Change from Baseline in Hospital Anxiety and Depression Scale (HADS)

End point description:

The HADS is a 14-item, participant self-reported scale that consists of an anxiety scale and a depression scale, each with 7 items. Items are rated on a 4-point Likert-type scale ranging from 0 (low level of anxiety or depression) to 3 (high level of anxiety or depression). Each subscale score ranges from 0 to 21 with higher scores indicating greater symptom severity. The classification is defined: 0-7 normal, 8-10 Borderline, 11-21 Abnormal.

APD: All enrolled participants who had PASI 75 response at Week 20.

End point type	Secondary

End point timeframe:

Baseline Up to 240 Weeks

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: units on a scale				
arithmetic mean (standard deviation)				
Anxiety	-3 (± 3.4)			
Depression	-2.8 (± 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Patient's Global Assessment of Disease Activity (PatGA)

End point title	Number of Participants with Patient's Global Assessment of Disease Activity (PatGA)

End point description:

The PatGA is a single-item self-reported instrument asking the participant to rate the severity of their psoriasis "today" by circling a number on the numeric rating scale from 0 (Clear = no psoriasis) to 5 (Severe = the worst their psoriasis has ever been).

APD: All enrolled participants who had PASI 75 response at Week 20.

End point type	Secondary

End point timeframe:

Week 240

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: Participants				
number (not applicable)				
Zero(Clear)	40			
One	26			
Two	4			
Three	2			
Four	2			
Five(Severe)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Pain Visual Analog scale (VAS)

End point title	Change from Baseline in Pain Visual Analog scale (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 placing a single mark on the horizontal 100-mm scale from 0mm (no pain) to 100 mm (pain as severe as you can imagine). A mixed effects model for repeated measures analysis was used.

APD: All enrolled participants with data available.

End point type	Secondary

End point timeframe:

Baseline Up to 240 Weeks

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	24			
Units: Millimeters (mm)				
arithmetic mean (standard error)	-13.25 (± 32.34)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline up to 240 Weeks in Nail Psoriasis Severity Index (NAPSI) in Participants with Nail Psoriasis

End point title	Change from Baseline up to 240 Weeks in Nail Psoriasis Severity Index (NAPSI) in Participants with Nail Psoriasis

End point description:

The NAPSI is physician-rated and quantifies the severity of nail psoriasis by evaluating the presence or absence of psoriatic manifestations on the nail matrix and nail bed. Each finger nail is divided with imaginary lines into quadrants and scored for both nail matrix and nail bed psoriasis(range from 0[absence of psoriasis] to 4[presence of psoriasis in all 4 quadrants]).Participant's fingers and toes were evaluated and the sum of the scores was added resulting in a range of 0 to 160;higher scores indicate greater severity.If an individual toe or finger assessment was missing(not done),the average of the remaining measured digits was imputed and added to the sum.If <50% of the toes or finger assessments were missing,the imputation was performed.If >50% of the assessments were missing,then the sum of the scores was left as missing.
Baseline is defined as the last available value prior to the first dose in Part A of the study.
APD:Enrolled participants with baseline nail psoriasis.

End point type	Secondary

End point timeframe:

Baseline Up to 240 Weeks

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: units on a scale				
arithmetic mean (standard deviation)	-33.62 (± 30.48)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline up to 240 Weeks in Scalp Psoriasis Severity Index (PSSI) in Participants with Scalp Psoriasis

End point title	Change from Baseline up to 240 Weeks in Scalp Psoriasis Severity Index (PSSI) in Participants with Scalp Psoriasis

End point description:

The PSSI is a physician-assessed composite score derived from the summed scores for erythema, induration, and desquamation multiplied by a score for the extent of scalp area involved. The PSSI score ranges from 0 to 72, with higher scores representing greater severity of scalp psoriasis.

Baseline is defined as the last available value prior to the first dose in Part A of the study.

APD: All enrolled participants with baseline scalp psoriasis.

End point type	Secondary

End point timeframe:

Baseline Up to 240 Weeks

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	56			
Units: units on a scale				
arithmetic mean (standard deviation)	-19.89 (± 13.68)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline up to 240 Weeks in Palmoplantar Psoriasis Severity Index (PPASI) in Participants with Palmoplantar Psoriasis

End point title	Change from Baseline up to 240 Weeks in Palmoplantar Psoriasis Severity Index (PPASI) in Participants with Palmoplantar Psoriasis

End point description:

The PPASI is a physician-assessed composite score derived from the summed scores for erythema,

induration, and desquamation multiplied by a score for the extent of palm and sole area involvement. The PPASI score ranges from 0 to 72, with higher scores representing greater severity of palmoplantar psoriasis.LS mean was calculated using MMRM with baseline score as covariate, visit, treatment and visit by treatment interaction as fixed effects, with variance-covariance structure set to symmetric.

APD: All enrolled participants with baseline palmoplantar psoriasis.

End point type	Secondary

End point timeframe:

Baseline Up to 240 Weeks

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: units on a scale				
arithmetic mean (standard deviation)	-9.1 (± 7.59)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Psoriasis Area and Severity Index ≥75% (PASI 75) Improvement

End point title	Percentage of Participants Achieving Psoriasis Area and Severity Index ≥75% (PASI 75) Improvement

End point description:

PASI combines the extent of body surface involvement in 4 anatomical regions (head, trunk, arms, and legs). For each region the percent area of skin involved was estimated from 0 (0%) to 6 (90%-100%) and severity was estimated by clinical signs of erythema, induration and scaling with a scores range from 0 (none) to 4 (very severe). Each area is scored separately and the scores then combined for the final PASI. Final PASI calculated as: sum of severity parameters for each region * area score * weighing factor (head [0.1], upper limbs [0.2], trunk [0.3], lower limbs [0.4]). Overall scores range from 0 (no psoriasis) to 72 (the most severe disease).Participants achieving PASI 75 were defined as having an improvement of ≥75% in the PASI score compared to baseline.

APD: All enrolled participants who had PASI 75 response at Week 20.

End point type	Secondary

End point timeframe:

Week 240

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: percentage of participants				
number (not applicable)	97.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI)

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

End point description:

The DLQI is a 10-item, participant-administered dermatology-specific questionnaire that assess health related quality of life that covers 6 domains including symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. The DLQI items response categories are scored 0 (not relevant) to 3 (very much) with a total score range of 0 to 30; higher scores indicate poor quality of life and a 5-point change from baseline is considered clinically relevant.

Baseline is defined as the last available value prior to the first dose in Part A of the study.

APD: All enrolled participants who had PASI 75 response at Week 20.

End point type	Secondary

End point timeframe:

Baseline Up to 240 Weeks

End point values	120 mg/80 mg Total Ixekizumab			
Subject group type	Reporting group			
Number of subjects analysed	74			
Units: units on a scale				
arithmetic mean (standard deviation)	-9.2 (± 5.6)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

Treatment durability refers to participants who had a PASI 75 response at Week 20 and remained in Part A of the study from Week 20-32 (treatment-free period). These participants moved to Part B of the study upon completion of Part A through Week 32 or upon loss of PASI75 response during the Part A treatment-free period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Placebo Part A

Reporting group description:

Part A: Placebo given on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Reporting group title	10mg LY2439821 Part A

Reporting group description:

Part A: 10 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Reporting group title	25mg LY2439821 Part A

Reporting group description:

Part A: 25 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Reporting group title	Post Treatment Safety Visits

Reporting group description:

Participants who were followed due to neutropenia.

Reporting group title	150mg LY2439821 Part A

Reporting group description:

Part A: 150 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Reporting group title	Treatment Durability Period

Reporting group description:

Part A: Treatment durability/safety follow-up period:12 to 20 weeks.

Reporting group title	120 mg and 80 mg Total Ixekizumab

Reporting group description:

Part B: (optional)

120 mg ixekizumab given SC Q4W. Subsequent to an amendment on May 2012, administration changed to 80 mg Q4W through Week 236.

Reporting group title	75mg LY2439821 Part A

Reporting group description:

Part A: 75 mg ixekizumab given SC on weeks 0, 2, 4, 8, 12 and 16 for a total of six administrations.

Serious adverse events	Placebo Part A	10mg LY2439821 Part A	25mg LY2439821 Part A
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 27 (3.70%)	1 / 28 (3.57%)	1 / 30 (3.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from	0	0	0

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
non-small cell lung cancer metastatic			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
rectal adenocarcinoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
rectal adenoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed[1]	0 / 13 (0.00%)	0 / 12 (0.00%)	0 / 12 (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
Pregnancy, puerperium and perinatal conditions			
abortion missed			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed[2]	0 / 13 (0.00%)	0 / 12 (0.00%)	0 / 12 (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

Respiratory, thoracic and mediastinal disorders			
breast cyst			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
dysmenorrhoea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed[3]	1 / 13 (7.69%)	0 / 12 (0.00%)	0 / 12 (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
dyspnoea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
laryngeal oedema			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
suicide attempt			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

fall			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
fibula fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
laceration			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
tibia fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
wrist fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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 disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
atrial fibrillation			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
mitral valve prolapse			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 28 (3.57%)	0 / 30 (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			
cerebrovascular accident			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
pancreatitis acute			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
hidradenitis			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract obstruction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
cervical spinal stenosis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abdominal abscess			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
cellulitis			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
incision site infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
influenza			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
pyelonephritis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
soft tissue infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
wound infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (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
Metabolism and nutrition disorders			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Post Treatment Safety Visits	150mg LY2439821 Part A	Treatment Durability Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	1 / 74 (1.35%)
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)			
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
non-small cell lung cancer metastatic			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
rectal adenocarcinoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
rectal adenoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed[1]	0 / 4 (0.00%)	0 / 14 (0.00%)	0 / 33 (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
Pregnancy, puerperium and perinatal conditions			
abortion missed			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed[2]	0 / 4 (0.00%)	0 / 14 (0.00%)	0 / 33 (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
Respiratory, thoracic and mediastinal disorders			
breast cyst			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
dysmenorrhoea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed[3]	0 / 4 (0.00%)	0 / 14 (0.00%)	0 / 33 (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
dyspnoea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
laryngeal oedema			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
suicide attempt			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
fibula fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
laceration			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
tibia fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
wrist fracture			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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 disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
atrial fibrillation			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
mitral valve prolapse			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebrovascular accident			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
pancreatitis acute			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
hidradenitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	1 / 74 (1.35%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract obstruction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
cervical spinal stenosis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
abdominal abscess			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
cellulitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
incision site infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
influenza			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
pyelonephritis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
soft tissue infection			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
wound infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (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
Metabolism and nutrition disorders			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	120 mg and 80 mg Total Ixekizumab	75mg LY2439821 Part A	
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 120 (20.00%)	0 / 29 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
invasive ductal breast carcinoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
non-small cell lung cancer metastatic			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal adenocarcinoma			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
rectal adenoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
uterine leiomyoma			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed[1]	1 / 50 (2.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
abortion missed			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed[2]	1 / 50 (2.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
breast cyst			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dysmenorrhoea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed[3]	0 / 50 (0.00%)	0 / 10 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
dyspnoea			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
laryngeal oedema			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicide attempt			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fibula fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
laceration			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
tibia fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
wrist fracture			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
acute coronary syndrome			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
arteriosclerosis coronary artery			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cardiac failure congestive			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
mitral valve prolapse			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
cerebrovascular accident			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
pancreatitis acute			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
hidradenitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
nephrolithiasis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	2 / 120 (1.67%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
urinary tract obstruction			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
cervical spinal stenosis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
intervertebral disc protrusion			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
abdominal abscess			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
cellulitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
incision site infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
influenza			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
pyelonephritis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
soft tissue infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 120 (0.83%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	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	Placebo Part A	10mg LY2439821 Part A	25mg LY2439821 Part A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 27 (48.15%)	15 / 28 (53.57%)	12 / 30 (40.00%)
Injury, poisoning and procedural complications			
laceration			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	1
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	2 / 28 (7.14%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
headache			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 27 (3.70%)	4 / 28 (14.29%)	4 / 30 (13.33%)
occurrences (all)	1	7	11
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	3 / 30 (10.00%)
occurrences (all)	0	0	4
peripheral swelling			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	2 / 27 (7.41%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	3	0	0
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 27 (3.70%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 27 (3.70%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
dry skin			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	1

back pain			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	2 / 27 (7.41%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
ear infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	2 / 28 (7.14%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
influenza			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 28 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	5 / 27 (18.52%)	3 / 28 (10.71%)	3 / 30 (10.00%)
occurrences (all)	5	3	3
sinusitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
tooth infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 28 (3.57%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	1 / 27 (3.70%)	1 / 28 (3.57%)	3 / 30 (10.00%)
occurrences (all)	1	1	3
urinary tract infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 28 (3.57%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Metabolism and nutrition disorders			
hypertriglyceridaemia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	2 / 27 (7.41%)	0 / 28 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0

Non-serious adverse events	Post Treatment Safety Visits	150mg LY2439821 Part A	Treatment Durability Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 6 (16.67%)	11 / 28 (39.29%)	11 / 74 (14.86%)
Injury, poisoning and procedural complications			
laceration			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 28 (3.57%)	1 / 74 (1.35%)
occurrences (all)	0	1	1
muscle strain			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 28 (3.57%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	0 / 6 (0.00%)	1 / 28 (3.57%)	3 / 74 (4.05%)
occurrences (all)	0	1	3
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	2 / 28 (7.14%)	0 / 74 (0.00%)
occurrences (all)	0	3	0
peripheral swelling			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	1 / 6 (16.67%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 28 (3.57%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	2 / 28 (7.14%)	0 / 74 (0.00%)
occurrences (all)	0	2	0

dry skin			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	2 / 28 (7.14%)	1 / 74 (1.35%)
occurrences (all)	0	2	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
psoriatic arthropathy			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 28 (3.57%)	1 / 74 (1.35%)
occurrences (all)	0	1	1
nasopharyngitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	4 / 28 (14.29%)	2 / 74 (2.70%)
occurrences (all)	0	4	2
sinusitis			

alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	1 / 74 (1.35%)
occurrences (all)	0	0	1
tooth infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 28 (3.57%)	0 / 74 (0.00%)
occurrences (all)	0	1	0
urinary tract infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	1 / 28 (3.57%)	2 / 74 (2.70%)
occurrences (all)	0	1	2
Metabolism and nutrition disorders			
hypertriglyceridaemia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 6 (0.00%)	0 / 28 (0.00%)	0 / 74 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	120 mg and 80 mg Total Ixekizumab	75mg LY2439821 Part A	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	82 / 120 (68.33%)	10 / 29 (34.48%)	
Injury, poisoning and procedural complications			
laceration			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	3 / 120 (2.50%)	2 / 29 (6.90%)	
occurrences (all)	3	2	
muscle strain			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	8 / 120 (6.67%)	1 / 29 (3.45%)	
occurrences (all)	11	1	
Vascular disorders			

hypertension			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	7 / 120 (5.83%)	1 / 29 (3.45%)	
occurrences (all)	8	1	
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 120 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
headache			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	12 / 120 (10.00%)	1 / 29 (3.45%)	
occurrences (all)	20	1	
General disorders and administration site conditions			
injection site reaction			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	4 / 120 (3.33%)	1 / 29 (3.45%)	
occurrences (all)	17	1	
peripheral swelling			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
hypersensitivity			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 120 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	9 / 120 (7.50%)	1 / 29 (3.45%)	
occurrences (all)	13	1	
nausea			
alternative dictionary used: MedDRA 19.0			

subjects affected / exposed	5 / 120 (4.17%)	2 / 29 (6.90%)	
occurrences (all)	7	2	
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	5 / 120 (4.17%)	2 / 29 (6.90%)	
occurrences (all)	5	2	
Skin and subcutaneous tissue disorders			
dermatitis contact			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	8 / 120 (6.67%)	0 / 29 (0.00%)	
occurrences (all)	15	0	
dry skin			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	0 / 120 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	7 / 120 (5.83%)	1 / 29 (3.45%)	
occurrences (all)	7	1	
back pain			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	8 / 120 (6.67%)	0 / 29 (0.00%)	
occurrences (all)	8	0	
psoriatic arthropathy			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	6 / 120 (5.00%)	0 / 29 (0.00%)	
occurrences (all)	6	0	
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	10 / 120 (8.33%)	0 / 29 (0.00%)	
occurrences (all)	16	0	
ear infection			

alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	6 / 120 (5.00%)	0 / 29 (0.00%)	
occurrences (all)	6	0	
influenza			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	9 / 120 (7.50%)	0 / 29 (0.00%)	
occurrences (all)	10	0	
nasopharyngitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	29 / 120 (24.17%)	3 / 29 (10.34%)	
occurrences (all)	57	3	
sinusitis			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	17 / 120 (14.17%)	1 / 29 (3.45%)	
occurrences (all)	24	1	
tooth infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	11 / 120 (9.17%)	1 / 29 (3.45%)	
occurrences (all)	12	1	
upper respiratory tract infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	15 / 120 (12.50%)	1 / 29 (3.45%)	
occurrences (all)	21	1	
urinary tract infection			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	13 / 120 (10.83%)	0 / 29 (0.00%)	
occurrences (all)	23	0	
Metabolism and nutrition disorders			
hypertriglyceridaemia			
alternative dictionary used: MedDRA 19.0			
subjects affected / exposed	3 / 120 (2.50%)	0 / 29 (0.00%)	
occurrences (all)	3	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 May 2010	Protocol amendment a - The primary endpoint was changed to Week 12, updates to the inclusion criteria, and the addition of the sPGA scale with revisions to the secondary objective.
02 September 2010	Protocol amendment b - The overall study design and study objectives was revised to include an extended LY2439821 treatment period to provide long-term monitoring of safety and efficacy. As such, the double-blind treatment period of the original study design study was denoted as Part A, and an OLE period was added to the study as Part B.
15 May 2012	Protocol amendment c - Changed Part B dose to 80 mg ixekizumab Q4W to a dose strength and regimen that is consistent with the highest maintenance dose regimen being explored in Phase 3 clinical trials with ixekizumab.
17 April 2015	Protocol Amendment d - Was implemented to add an additional optional, open-label extended treatment period to Study RHAJ (Part C) where patients continued treatment with ixekizumab for up to 104 weeks, until ixekizumab has local commercial availability, or until study termination, whichever is soonest and discontinuation criteria was updated to align with ixekizumab Phase 3 protocols.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study stopped prior to the completion of Part C per protocol due to commercial availability of Taltz (ixekizumab) in all countries participating in the study. This decision was per protocol and did not adversely impact the objects of the trial.

Notes: