Clinical trial results:
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Ranging Study to Evaluate the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Bimekizumab in Adult subjects With Moderate to Severe Chronic Plaque Psoriasis

Summary

EudraCT number	2016-001891-31
Trial protocol	HU CZ PL
Global end of trial date	10 July 2017

Results information

Result version number	v1
This version publication date	26 July 2018
First version publication date	26 July 2018

Trial information

Trial identification

Sponsor protocol code	PS0010

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02905006
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SPRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, B-1070
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 July 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 July 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the dose response of bimekizumab administered subcutaneously (sc) every 4 weeks for 12 weeks in the treatment of subjects with moderate to severe chronic plaque psoriasis.

Protection of trial subjects:

Patients were given the opportunity to discuss the study with the study doctor and ask questions before deciding to participate. The Study doctors asked about any problems patients had since the last visit, and what medications patients were taking. Routine safety blood and urine samples taken, electrocardiography (ECG), physical examinations and vital signs were taken, as well as questions about mental health were being asked to monitor the patient's safety.

Background therapy:

Topical medications
Subjects continued to use topical moisturizers or emollients, bath oils, or oatmeal bath preparations for skin conditions during the study, as needed. Over-the-counter shampoos for the treatment of psoriasis of the scalp were also permitted. Subjects who used prohibited topical medications were allowed to stay in the study but were counseled to not use them further. No other topical preparations were allowed in the 2 weeks before randomization or during the study unless medically required to treat an Adverse Event (AE).
Other medications
Subjects who were already receiving an established non-steroidal anti-inflammatory drug (NSAID) regimen (at least 8 weeks prior to Baseline) and have been on a stable dose for at least 4 weeks prior to Baseline continued the use during the study. However, initiation of, or increase in dosage of, NSAIDs during the study (especially in subjects with a history of gastrointestinal [GI] intolerance to NSAIDs or a history of GI ulceration) should have been done with caution. Intra-articular steroid injections for arthritis of the knee were allowed.
Subjects who were already receiving an established anti-depressant regimen should have been on a stable
dose of anti-depressant for 12 weeks prior to Baseline.

Evidence for comparator:

Not applicable

Actual start date of recruitment	25 August 2016
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	11 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 39
Country: Number of subjects enrolled	Czech Republic: 22
Country: Number of subjects enrolled	Hungary: 18

Country: Number of subjects enrolled	Japan: 12
Country: Number of subjects enrolled	Poland: 115
Country: Number of subjects enrolled	United States: 44
Worldwide total number of subjects	250
EEA total number of subjects	155

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)	228
From 65 to 84 years	22
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll subjects in August 2016 and concluded in July 2017.

Pre-assignment

Screening details:

The study included a 2-4 weeks Screening Period, a 12 weeks Treatment Period and a 20 weeks Safety Follow-Up Period. 250 subjects were included in the Safety Set, shown in the Participant Flow.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W).

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

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also be administered at Week 12 for all subjects entering the open-label extension study.

Arm title	Bimekizumab 64 mg

Arm description:

Subjects were randomized to receive subcutaneous injections of 64 milligrams (mg) bimekizumab, every 4 weeks (Q4W).

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	UCB4940
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all subjects entering the open-label extension study.

Arm title	Bimekizumab 160 mg

Arm description:

Subjects were randomized to receive subcutaneous injections of 160 milligrams (mg) bimekizumab, every 4 weeks (Q4W).

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	UCB4940
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all subjects entering the open-label extension study.

Arm title	Bimekizumab 160 mg w/ LD

Arm description:

Subjects were randomized to receive 320 milligrams (mg) loading dose subcutaneous injections of bimekizumab at Baseline, followed by 160 mg bimekizumab every 4 weeks (Q4W).

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	UCB4940
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all subjects entering the open-label extension study.

Arm title	Bimekizumab 320 mg

Arm description:

Subjects were randomized to receive 320 milligrams (mg) subcutaneous injections of bimekizumab, every 4 weeks (Q4W).

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	UCB4940
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all subjects entering the open-label extension study.

Arm title	Bimekizumab 480 mg

Arm description:

Subjects were randomized to receive 480 milligrams (mg) subcutaneous injections of bimekizumab, every 4 weeks (Q4W).

Arm type	Experimental

Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	UCB4940
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all subjects entering the open-label extension study.

Number of subjects in period 1	Placebo	Bimekizumab 64 mg	Bimekizumab 160 mg
Started	42	39	43
Completed	37	36	38
Not completed	5	3	5
Positive for Tuberculosis	-	1	-
Consent withdrawn by subject	-	-	1
Lab withdrawal criterion met	-	1	2
Adverse event, non-fatal	1	1	1
Screening exclusion criteria met	1	-	-
Patient moved abroad	-	-	-
Subject positive for Hep B	-	-	1
Lost to follow-up	-	-	-
Patient randomized by mistake	-	-	-
Lack of efficacy	1	-	-
Protocol deviation	2	-	-

Number of subjects in period 1	Bimekizumab 160 mg w/ LD	Bimekizumab 320 mg	Bimekizumab 480 mg
Started	40	43	43
Completed	34	40	39
Not completed	6	3	4
Positive for Tuberculosis	-	-	-
Consent withdrawn by subject	1	-	1
Lab withdrawal criterion met	2	2	1
Adverse event, non-fatal	1	-	1
Screening exclusion criteria met	-	-	-
Patient moved abroad	1	-	-
Subject positive for Hep B	-	-	-
Lost to follow-up	1	1	-
Patient randomized by mistake	-	-	1

Lack of efficacy	-	-	-
Protocol deviation	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 64 mg
Reporting group description:	
Subjects were randomized to receive subcutaneous injections of 64 milligrams (mg) bimekizumab, every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 160 mg
Reporting group description:	
Subjects were randomized to receive subcutaneous injections of 160 milligrams (mg) bimekizumab, every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 160 mg w/ LD
Reporting group description:	
Subjects were randomized to receive 320 milligrams (mg) loading dose subcutaneous injections of bimekizumab at Baseline, followed by 160 mg bimekizumab every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 320 mg
Reporting group description:	
Subjects were randomized to receive 320 milligrams (mg) subcutaneous injections of bimekizumab, every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 480 mg
Reporting group description:	
Subjects were randomized to receive 480 milligrams (mg) subcutaneous injections of bimekizumab, every 4 weeks (Q4W).	

Reporting group values	Placebo	Bimekizumab 64 mg	Bimekizumab 160 mg
Number of subjects	42	39	43
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	39	37	40
>=65 years	3	2	3
Age continuous Units: years			
arithmetic mean	46.7	44.2	43.4
standard deviation	± 12.3	± 13.8	± 12.4
Gender categorical Units: Subjects			
Female	17	19	11
Male	25	20	32

Reporting group values	Bimekizumab 160 mg w/ LD	Bimekizumab 320 mg	Bimekizumab 480 mg
Number of subjects	40	43	43
Age categorical Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	35	39	38

>=65 years	5	4	5

Age continuous			
Units: years			
arithmetic mean	46.5	42.6	42.9
standard deviation	± 15.2	± 13.6	± 15.2
Gender categorical			
Units: Subjects			
Female	11	15	14
Male	29	28	29

Reporting group values	Total		
Number of subjects	250		
Age categorical			
Units: Subjects			
<=18 years	0		
Between 18 and 65 years	228		
>=65 years	22		
Age continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	87		
Male	163		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 64 mg
Reporting group description:	
Subjects were randomized to receive subcutaneous injections of 64 milligrams (mg) bimekizumab, every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 160 mg
Reporting group description:	
Subjects were randomized to receive subcutaneous injections of 160 milligrams (mg) bimekizumab, every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 160 mg w/ LD
Reporting group description:	
Subjects were randomized to receive 320 milligrams (mg) loading dose subcutaneous injections of bimekizumab at Baseline, followed by 160 mg bimekizumab every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 320 mg
Reporting group description:	
Subjects were randomized to receive 320 milligrams (mg) subcutaneous injections of bimekizumab, every 4 weeks (Q4W).	
Reporting group title	Bimekizumab 480 mg
Reporting group description:	
Subjects were randomized to receive 480 milligrams (mg) subcutaneous injections of bimekizumab, every 4 weeks (Q4W).	
Subject analysis set title	Placebo (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	
Subject analysis set title	Bimekizumab 64 mg (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects were randomized to receive subcutaneous injections of 64 milligrams (mg) bimekizumab, every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	
Subject analysis set title	Bimekizumab 160 mg (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects were randomized to receive subcutaneous injections of 160 milligrams (mg) bimekizumab, every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	
Subject analysis set title	Bimekizumab 160 mg w/ LD (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects were randomized to receive 320 milligrams (mg) loading dose subcutaneous injections of bimekizumab at Baseline, followed by 160 mg bimekizumab every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	
Subject analysis set title	Bimekizumab 320 mg (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
Subjects were randomized to receive 320 milligrams (mg) subcutaneous injections of bimekizumab,	

every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).

Subject analysis set title	Bimekizumab 480 mg (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects were randomized to receive 480 milligrams (mg) subcutaneous injections of bimekizumab, every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).

Primary: Percentage of subjects achieving a 90% or higher improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 12

End point title	Percentage of subjects achieving a 90% or higher improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 12

End point description:

The PASI90 response assessments are based on at least 90% improvement in the PASI score from Baseline. This is a scoring system that averages the redness, thickness, and scaliness of the psoriatic lesions (on a 0-4 scale), and weights the resulting score by the area of skin involved. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for the redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear) to 4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0 to 6 scale. Final PASI= average redness, thickness, and scaliness of the psoriatic skin lesions, multiplied by the involved psoriasis area score of the respective section, and weighted by the percentage of the person's affected skin for the respective section. The minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease.

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo (FAS)	Bimekizumab 64 mg (FAS)	Bimekizumab 160 mg (FAS)	Bimekizumab 160 mg w/ LD (FAS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	43	40
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	0	46.2	67.4	75.0

End point values	Bimekizumab 320 mg (FAS)	Bimekizumab 480 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	43		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	79.1	72.1		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (FAS) v Bimekizumab 64 mg (FAS)
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [1]
Method	Regression, Logistic

Notes:

[1] - P-value evaluating dose response excludes the BKZ 160mg w/LD group; is based on a logistic regression model with fixed effects for region, prior biologic exposure, continuous treatment variable with values of -2, -1, 0, 1, 2 for the remaining groups.

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (FAS) v Bimekizumab 160 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [2]
Method	Regression, Logistic

Notes:

[2] - P-value evaluating dose response excludes the BKZ 160mg w/LD group; is based on a logistic regression model with fixed effects for region, prior biologic exposure, continuous treatment variable with values of -2, -1, 0, 1, 2 for the remaining groups.

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo (FAS) v Bimekizumab 320 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [3]
Method	Regression, Logistic

Notes:

[3] - P-value evaluating dose response excludes the BKZ 160mg w/LD group; is based on a logistic regression model with fixed effects for region, prior biologic exposure, continuous treatment variable with values of -2, -1, 0, 1, 2 for the remaining groups.

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo (FAS) v Bimekizumab 480 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [4]
Method	Regression, Logistic

Notes:

[4] - P-value evaluating dose response excludes the BKZ 160mg w/LD group; is based on a logistic regression model with fixed effects for region, prior biologic exposure, continuous treatment variable with values of -2, -1, 0, 1, 2 for the remaining groups.

Secondary: Percentage of subjects with Investigator's Global Assessment (IGA) response at Week 12

End point title	Percentage of subjects with Investigator's Global Assessment (IGA) response at Week 12

End point description:

The Investigator's Global Assessment (IGA) measures the overall psoriasis severity following a 5-point scale (0-4), where scale 0= clear, no signs of psoriasis; presence of post-inflammatory hyperpigmentation, scale 1= almost clear, no thickening; normal to pink coloration; no to minimal focal

scaling, scale 2= mild thickening, pink to light red coloration and predominately fine scaling, 3= moderate, clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling and 4= severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo (FAS)	Bimekizumab 64 mg (FAS)	Bimekizumab 160 mg (FAS)	Bimekizumab 160 mg w/ LD (FAS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	43	40
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	4.8	51.3	74.4	75.0

End point values	Bimekizumab 320 mg (FAS)	Bimekizumab 480 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	43		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	86.0	76.7		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (FAS) v Bimekizumab 64 mg (FAS)
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	21.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.51
upper limit	101.88

Statistical analysis title	Statistical analysis 2

Comparison groups	Placebo (FAS) v Bimekizumab 160 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	63.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.9
upper limit	309.83

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo (FAS) v Bimekizumab 160 mg w/ LD (FAS)
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	62.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.61
upper limit	308.29

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo (FAS) v Bimekizumab 320 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	130.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.5
upper limit	693.51

Statistical analysis title	Statistical analysis 5
Comparison groups	Placebo (FAS) v Bimekizumab 480 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	69.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.07
upper limit	342.4

Secondary: Percentage of subjects with Investigator's Global Assessment (IGA) response at Week 8

End point title	Percentage of subjects with Investigator's Global Assessment (IGA) response at Week 8

End point description:

The Investigator's Global Assessment (IGA) measures the overall psoriasis severity following a 5-point scale (0-4), where scale 0= clear, no signs of psoriasis; presence of post-inflammatory hyperpigmentation, scale 1= almost clear, no thickening; normal to pink coloration; no to minimal focal scaling, scale 2= mild thickening, pink to light red coloration and predominately fine scaling, 3= moderate, clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling and 4= severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo (FAS)	Bimekizumab 64 mg (FAS)	Bimekizumab 160 mg (FAS)	Bimekizumab 160 mg w/ LD (FAS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	43	40
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	4.8	46.2	62.8	77.5

End point values	Bimekizumab 320 mg (FAS)	Bimekizumab 480 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	43		
Units: percentage of subjects				
number (not applicable)				

percentage of subjects	86.0	72.1		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (FAS) v Bimekizumab 64 mg (FAS)
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	18.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.79
upper limit	87.76

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (FAS) v Bimekizumab 160 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	39.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.19
upper limit	191.59

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo (FAS) v Bimekizumab 160 mg w/ LD (FAS)

Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	77.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.19
upper limit	392.93

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo (FAS) v Bimekizumab 320 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	141.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	26.26
upper limit	767.72

Statistical analysis title	Statistical analysis 5
Comparison groups	Placebo (FAS) v Bimekizumab 480 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	58.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.89
upper limit	288

Secondary: Percentage of subjects achieving a 90% or higher improvement from

Baseline in Psoriasis Area and Severity Index (PASI) score at Week 8

End point title	Percentage of subjects achieving a 90% or higher improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 8

End point description:

The PASI90 response assessments are based on at least 90% improvement in the PASI score from Baseline. This is a scoring system that averages the redness, thickness, and scaliness of the psoriatic lesions (on a 0-4 scale), and weights the resulting score by the area of skin involved. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for the redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear) to 4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0 to 6 scale. Final PASI= average redness, thickness, and scaliness of the psoriatic skin lesions, multiplied by the involved psoriasis area score of the respective section, and weighted by the percentage of the person's affected skin for the respective section. The minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo (FAS)	Bimekizumab 64 mg (FAS)	Bimekizumab 160 mg (FAS)	Bimekizumab 160 mg w/ LD (FAS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	43	40
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	0	41.0	58.1	67.5

End point values	Bimekizumab 320 mg (FAS)	Bimekizumab 480 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	43		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	86.0	69.8		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (FAS) v Bimekizumab 64 mg (FAS)
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [5]
Method	Fisher exact

Notes:

[5] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (FAS) v Bimekizumab 160 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [6]
Method	Fisher exact

Notes:

[6] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo (FAS) v Bimekizumab 160 mg w/ LD (FAS)
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [7]
Method	Fisher exact

Notes:

[7] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo (FAS) v Bimekizumab 320 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [8]
Method	Fisher exact

Notes:

[8] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Statistical analysis title	Statistical analysis 5
Comparison groups	Placebo (FAS) v Bimekizumab 480 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [9]
Method	Fisher exact

Notes:

[9] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Secondary: Percentage of subjects achieving a 75% or higher improvement in Psoriasis Area and Severity Index (PASI) score at Week 12

End point title	Percentage of subjects achieving a 75% or higher improvement in Psoriasis Area and Severity Index (PASI) score at Week 12

End point description:

The PASI75 response assessments are based on at least 75% improvement in the PASI score from

Baseline. This is a scoring system that averages the redness, thickness, and scaliness of the psoriatic lesions (on a 0-4 scale), and weights the resulting score by the area of skin involved. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for the redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear) to 4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0 to 6 scale. Final PASI= average redness, thickness, and scaliness of the psoriatic skin lesions, multiplied by the involved psoriasis area score of the respective section, and weighted by the percentage of the person's affected skin for the respective section. The minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo (FAS)	Bimekizumab 64 mg (FAS)	Bimekizumab 160 mg (FAS)	Bimekizumab 160 mg w/ LD (FAS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	43	40
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	4.8	61.5	81.4	85.0

End point values	Bimekizumab 320 mg (FAS)	Bimekizumab 480 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	43		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	93.0	83.7		

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (FAS) v Bimekizumab 64 mg (FAS)
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	32.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.82
upper limit	156.38

Statistical analysis title	Statistical analysis 2
Comparison groups	Placebo (FAS) v Bimekizumab 160 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	94.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.54
upper limit	481.86

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo (FAS) v Bimekizumab 160 mg w/ LD (FAS)
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	117.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	22.08
upper limit	626.89

Statistical analysis title	Statistical analysis 4
Comparison groups	Placebo (FAS) v Bimekizumab 320 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	280.76

Confidence interval	
level	95 %
sides	2-sided
lower limit	44.06
upper limit	1789.24

Statistical analysis title	Statistical analysis 5
Comparison groups	Placebo (FAS) v Bimekizumab 480 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	107.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.82
upper limit	558.57

Secondary: Percentage of subjects achieving a 100% improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 12

End point title	Percentage of subjects achieving a 100% improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 12

End point description:

PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 100 response rate at Week 12 is measured as the percentage of participants who achieved 100% improvement from baseline PASI at Week 12.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo (FAS)	Bimekizumab 64 mg (FAS)	Bimekizumab 160 mg (FAS)	Bimekizumab 160 mg w/ LD (FAS)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	42	39	43	40
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	0	28.2	27.9	60.0

End point values	Bimekizumab 320 mg (FAS)	Bimekizumab 480 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43	43		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	55.8	48.8		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Comparison groups	Placebo (FAS) v Bimekizumab 64 mg (FAS)
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001
Method	Fisher exact

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Comparison groups	Placebo (FAS) v Bimekizumab 160 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	Fisher exact

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Comparison groups	Placebo (FAS) v Bimekizumab 160 mg w/ LD (FAS)

Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Fisher exact

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Comparison groups	Placebo (FAS) v Bimekizumab 320 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Fisher exact

Statistical analysis title	Statistical analysis 5

Statistical analysis description:

The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Comparison groups	Placebo (FAS) v Bimekizumab 480 mg (FAS)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Fisher exact

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
During Treatment Period (up to 12 weeks)	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups	
Reporting group title	Placebo (FAS)
Reporting group description:	
Subjects randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	
Reporting group title	Bimekizumab 64 mg (FAS)
Reporting group description:	
Subjects were randomized to receive subcutaneous injections of 64 milligrams (mg) bimekizumab, every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	
Reporting group title	Bimekizumab 160 mg (FAS)
Reporting group description:	
Subjects were randomized to receive subcutaneous injections of 160 milligrams (mg) bimekizumab, every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	
Reporting group title	Bimekizumab 160 mg w/ LD (FAS)
Reporting group description:	
Subjects were randomized to receive 320 milligrams (mg) loading dose subcutaneous injections of bimekizumab at Baseline, followed by 160 mg bimekizumab every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	
Reporting group title	Bimekizumab 320 mg (FAS)
Reporting group description:	
Subjects were randomized to receive 320 milligrams (mg) subcutaneous injections of bimekizumab, every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	
Reporting group title	Bimekizumab 480 mg (FAS)
Reporting group description:	
Subjects were randomized to receive 480 milligrams (mg) subcutaneous injections of bimekizumab, every 4 weeks (Q4W) and had a valid measurement of the primary efficacy variable at Baseline, forming the Full Analysis Set (FAS).	

Serious adverse events	Placebo (FAS)	Bimekizumab 64 mg (FAS)	Bimekizumab 160 mg (FAS)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 43 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			

subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 43 (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			
Large intestine polyp			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 43 (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			
Meningitis viral			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	0 / 43 (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

Serious adverse events	Bimekizumab 160 mg w/ LD (FAS)	Bimekizumab 320 mg (FAS)	Bimekizumab 480 mg (FAS)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 43 (2.33%)
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)			
Colon cancer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Large intestine polyp			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 43 (2.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Meningitis viral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	0 / 43 (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

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

Non-serious adverse events	Placebo (FAS)	Bimekizumab 64 mg (FAS)	Bimekizumab 160 mg (FAS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 42 (19.05%)	16 / 39 (41.03%)	12 / 43 (27.91%)
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 42 (2.38%)	0 / 39 (0.00%)	3 / 43 (6.98%)
occurrences (all)	1	0	3
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 42 (7.14%)	1 / 39 (2.56%)	1 / 43 (2.33%)
occurrences (all)	3	1	1
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 42 (0.00%)	2 / 39 (5.13%)	0 / 43 (0.00%)
occurrences (all)	0	2	0
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 42 (0.00%)	2 / 39 (5.13%)	0 / 43 (0.00%)
occurrences (all)	0	2	0
Leukopenia			
subjects affected / exposed	0 / 42 (0.00%)	2 / 39 (5.13%)	0 / 43 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 42 (0.00%)	2 / 39 (5.13%)	0 / 43 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 42 (0.00%)	2 / 39 (5.13%)	0 / 43 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 42 (4.76%)	5 / 39 (12.82%)	3 / 43 (6.98%)
occurrences (all)	2	5	3
Upper respiratory tract infection			

subjects affected / exposed	1 / 42 (2.38%)	5 / 39 (12.82%)	2 / 43 (4.65%)
occurrences (all)	1	5	3
Respiratory tract infection			
subjects affected / exposed	1 / 42 (2.38%)	2 / 39 (5.13%)	1 / 43 (2.33%)
occurrences (all)	1	2	1
Tonsillitis			
subjects affected / exposed	0 / 42 (0.00%)	2 / 39 (5.13%)	2 / 43 (4.65%)
occurrences (all)	0	3	2
Oral candidiasis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 39 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	1 / 42 (2.38%)	2 / 39 (5.13%)	1 / 43 (2.33%)
occurrences (all)	1	2	1

Non-serious adverse events	Bimekizumab 160 mg w/ LD (FAS)	Bimekizumab 320 mg (FAS)	Bimekizumab 480 mg (FAS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 40 (30.00%)	14 / 43 (32.56%)	10 / 43 (23.26%)
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 40 (5.00%)	1 / 43 (2.33%)	0 / 43 (0.00%)
occurrences (all)	2	2	0
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 40 (2.50%)	0 / 43 (0.00%)	1 / 43 (2.33%)
occurrences (all)	1	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	1 / 40 (2.50%)	2 / 43 (4.65%)	0 / 43 (0.00%)
occurrences (all)	1	3	0
Leukopenia			

subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 40 (2.50%)	1 / 43 (2.33%)	3 / 43 (6.98%)
occurrences (all)	1	3	5
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	3 / 40 (7.50%)	6 / 43 (13.95%)	4 / 43 (9.30%)
occurrences (all)	3	6	5
Upper respiratory tract infection			
subjects affected / exposed	3 / 40 (7.50%)	2 / 43 (4.65%)	0 / 43 (0.00%)
occurrences (all)	3	2	0
Respiratory tract infection			
subjects affected / exposed	1 / 40 (2.50%)	1 / 43 (2.33%)	0 / 43 (0.00%)
occurrences (all)	1	1	0
Tonsillitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	0 / 43 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	1 / 40 (2.50%)	3 / 43 (6.98%)	0 / 43 (0.00%)
occurrences (all)	1	3	0
Rhinitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 43 (0.00%)	1 / 43 (2.33%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 July 2016	Protocol Amendment 1, dated 08 Jul 2016, was implemented to make the following substantial changes: •Extended the timing of the Safety Follow Up (SFU) Visit to 20 weeks after the last dose of investigational medicinal product (IMP). •Removed references to legal representatives being able to provide consent on behalf of subjects. Subjects who lacked the capacity to consent were not included in the study. •Clarified the exclusion criterion regarding laboratory values. •Clarified that subjects with any pustular psoriasis (ie, localized or generalized) were ineligible for study participation and that development of any form of pustular psoriasis (ie, localized or generalized) during the study would have resulted in withdrawal from the study. •Clarified the Hospital Anxiety and Depression Scale (HADS) thresholds for study eligibility in the Exclusion Criteria and for withdrawal of a subject in the Withdrawal Criteria. •Clarified withdrawal criteria regarding subjects who developed illnesses that would have interfered with study participation and regarding the withdrawal of subjects due to Adverse Events (AEs) and clinical laboratory values. •Clarified the timing of the optional study exit interview. •Clarified the AEs for special monitoring. •Provided additional detail and a reference for recording the severity of AEs. •Removed the requirement to test for alcohol in the potential drug-induced liver injury (PDILI) urine toxicology screen. •Clarified the subgroup analyses that were performed.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported