Clinical trial results:
A Multicenter, Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating The Efficacy and Safety of Bimekizumab in The Treatment of Subjects With Active Psoriatic Arthritis

Summary

EudraCT number	2017-002804-29
Trial protocol	DE GB CZ IT HU
Global end of trial date	14 February 2022

Results information

Result version number	v1 (current)
This version publication date	26 February 2023
First version publication date	26 February 2023

Trial information

Trial identification

Sponsor protocol code	PA0011

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03896581
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium,
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	04 March 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 December 2021
Global end of trial reached?	Yes
Global end of trial date	14 February 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Demonstrate the clinical efficacy of bimekizumab administered subcutaneously compared with placebo in the treatment of tumor necrosis factor alpha-inadequate responders (TNFα-IR) participants with active Psoriatic Arthritis (PsA), as assessed by the American College of Rheumatology 50% improvement response.

Protection of trial subjects:

Participants were closely monitored and were expected to be treated for any worsening as per investigator judgement. Moreover, rescue medication could be added if participant was not having benefit of therapy, as per investigator discretion.

Background therapy:

No background therapy.

Evidence for comparator: -

Actual start date of recruitment	28 March 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Canada: 9
Country: Number of subjects enrolled	Czechia: 27
Country: Number of subjects enrolled	Germany: 22
Country: Number of subjects enrolled	Hungary: 8
Country: Number of subjects enrolled	Italy: 4
Country: Number of subjects enrolled	Japan: 12
Country: Number of subjects enrolled	Poland: 113
Country: Number of subjects enrolled	Russian Federation: 102
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	United States: 100
Worldwide total number of subjects	400
EEA total number of subjects	174

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)	337
From 65 to 84 years	62
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The study started to enroll study participants in March 2019 and concluded in February 2022.

Pre-assignment

Screening details:

Participant Flow refers to the Randomized Set.

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	Investigator, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo as a subcutaneous (sc) injection every 4 weeks (Q4W) for up to 16 weeks.

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

Dosage and administration details:

Participants received placebo Q4W at prespecified time points.

Arm title	Bimekizumab 160mg

Arm description:

Participants received bimekizumab (BKZ) 160 milligrams (mg) as a sc injection Q4W for up to 16 weeks.

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

Dosage and administration details:

Participants received BKZ 160 mg Q4W at prespecified time points.

Number of subjects in period 1	Placebo	Bimekizumab 160mg
Started	133	267
Completed	125	263
Not completed	8	4
Consent withdrawn by subject	4	1

Adverse event, non-fatal	-	2
Other (Covid-19 Pandemic Circumstances)	1	-
Lost to follow-up	1	-
Lack of efficacy	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo as a subcutaneous (sc) injection every 4 weeks (Q4W) for up to 16 weeks.	
Reporting group title	Bimekizumab 160mg
Reporting group description:	
Participants received bimekizumab (BKZ) 160 milligrams (mg) as a sc injection Q4W for up to 16 weeks.	

Reporting group values	Placebo	Bimekizumab 160mg	Total
Number of subjects	133	267	400
Age Categorical Units: participants			
<=18 years	0	0	0
Between 18 and 65 years	111	226	337
>=65 years	22	41	63
Age Continuous Units: years			
arithmetic mean	51.30	50.13	
standard deviation	± 12.876	± 12.382	-
Sex: Female, Male Units: participants			
Female	73	137	210
Male	60	130	190

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received placebo as a subcutaneous (sc) injection every 4 weeks (Q4W) for up to 16 weeks.	
Reporting group title	Bimekizumab 160mg
Reporting group description:	
Participants received bimekizumab (BKZ) 160 milligrams (mg) as a sc injection Q4W for up to 16 weeks.	

Primary: Percentage of Participants with American College of Rheumatology 50 (ACR50) response

End point title	Percentage of Participants with American College of Rheumatology 50 (ACR50) response
End point description:	
ACR50 response rate:50% or greater improvement of arthritis from Baseline. Those who met 3 conditions for improvement from Baseline met ACR50 response criteria: 1.Tender joint count (0-68 joints) ≥ 50% improvement; 2. Swollen joint count (0-66 joints) ≥ 50% improvement; and 3.≥ 50% improvement in at least 3 of the 5 below: Physician global assessment of disease activity [visual analog scale (VAS)(0-100 mm; no symptoms to severe)], Patient global assessment of disease activity [VAS-(0-100 mm; no limitation of normal activities to very poor)], Patient assessment of pain [VAS-(0-100 mm;no pain to most severe)], Health Assessment Questionnaire - Disability Index for degree of difficulty (20 queries from 8 domains of daily living activities scored 0-3, 0=less disability) High-sensitivity C-reactive protein (hsCRP). Analysis set:Randomized Set (RS). Non-responders: Those who missed ACR50 data at Week 16 or who discontinued study before Week 16 regardless of data present or not.	
End point type	Primary
End point timeframe:	
From Baseline to Week 16	

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	267		
Units: percentage of participants				
number (not applicable)	6.8	43.4		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Bimekizumab 160mg

Number of subjects included in analysis	400
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	11.139
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.402
upper limit	22.969

Secondary: Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) at Week 16

End point title	Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) at Week 16

End point description:

HAQ-DI contains 20 items that measured the degree of difficulty experienced in the following 8 categories of the daily living activities: dressing and grooming (2 items), arising (2 items), eating (3 items), walking (2 items), hygiene (3 items), reach (2 items), grip (3 items), and common daily activities (3 items). Each question was scored 0-3 (0 = without any difficulty, 1 = with some difficulty, 2 = with much difficulty, and 3 = unable to do). The overall HAQ-DI total score was calculated by dividing the sum of the highest category scores (0 to 24) by the number of categories with at least 1 question answered. Score ranges from 0 (no difficulty) to 3 (maximum difficulty). A lower HAQ-DI score indicated an improvement in function. A negative value in change from baseline indicated an improvement. RS consisted of all enrolled participants who had been randomized. Missing data and non-missing data preceded by a study treatment discontinuation were imputed using multiple imputation.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	267		
Units: score on a scale				
arithmetic mean (standard error)	-0.0701 (± 0.0432)	-0.3751 (± 0.0286)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Bimekizumab 160mg

Number of subjects included in analysis	400
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least square (LS) mean difference
Point estimate	-0.326
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.42
upper limit	-0.233

Secondary: Psoriasis Area Severity Index 90 (PASI90) response at Week 4 in the subgroup of participants with psoriasis (PSO) involving at least 3% body surface area (BSA) at Baseline

End point title	Psoriasis Area Severity Index 90 (PASI90) response at Week 4 in the subgroup of participants with psoriasis (PSO) involving at least 3% body surface area (BSA) at Baseline

End point description:

The PASI90 response assessments are based on at least 90% improvement in PASI score from Baseline. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for 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 respective section, and weighted by the percentage of the person's affected skin for respective section. The minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease. Subset of study participants in Randomized Set with psoriasis involving at least 3% BSA at Baseline. Non-responders: Missing PASI90 data at Week 4 or who discontinued study by Week 4 regardless of data present or not.

End point type	Secondary

End point timeframe:

From Baseline to Week 4

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	176		
Units: percentage of participants				
number (not applicable)	0	26.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Psoriasis Area Severity Index 90 response at Week 16 in the subgroup of participants with psoriasis involving at least 3% body surface area at Baseline

End point title	Psoriasis Area Severity Index 90 response at Week 16 in the

	subgroup of participants with psoriasis involving at least 3% body surface area at Baseline

End point description:

The PASI90 response assessments are based on at least 90% improvement in PASI score from Baseline. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for 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 respective section, and weighted by the percentage of the person's affected skin for respective section. The minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease. Subset of study participants in Randomized Set with psoriasis involving at least 3% BSA at Baseline. Non-responders: Missing PASI90 data at Week 16 or who discontinued study by Week 16 regardless of data present or not.

End point type	Secondary

End point timeframe:

From Baseline to Week 16

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	88	176		
Units: percentage of participants				
number (not applicable)	6.8	68.8		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Bimekizumab 160mg
Number of subjects included in analysis	264
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	30.237
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.365
upper limit	73.94

Secondary: Change from Baseline in the Short Form 36-item Health Survey (SF-36) Physical Component Summary (PCS) score at Week 16

End point title	Change from Baseline in the Short Form 36-item Health Survey (SF-36) Physical Component Summary (PCS) score at Week 16

End point description:

The SF-36 (version 2, standard recall) is a 36-item generic HRQoL instrument that uses a recall period of 4 weeks. The questionnaire has 36 questions composing the scale that represent 8 domains: 1)

physical functioning, 2) role physical, 3) bodily pain, 4) general health, 5) vitality, 6) social functioning, 7) role emotional, and 8) mental health. The scores for the 8 domains were combined into two summary scores: the physical component summary (PCS) score and the mental component summary (MCS) score. Domains 1 to 4 primarily contribute to the PCS score of the SF-36. Domains 5-8 primarily contribute to the MCS score of the SF-36. Each of the 8 domain scores and the component summary score range from 0=worst to 100=best. Higher scores represent better health status. A positive change in value indicated improvement from baseline. Randomized Set consisted of all enrolled participants who had been randomized.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	267		
Units: score on a scale				
arithmetic mean (standard error)	1.413 (± 0.714)	7.258 (± 0.531)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Bimekizumab 160mg
Number of subjects included in analysis	400
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	6.037
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.386
upper limit	7.688

Secondary: Minimal Disease Activity (MDA) at Week 16

End point title	Minimal Disease Activity (MDA) at Week 16

End point description:

MDA is a measure to indicate disease remission and is based on a composite score of 7 domains. A participant is considered as having achieved the MDA if participant fulfills at least 5 of following 7 criteria: Tender joint count (0-68 joints) <=1; Swollen joint count (0-66 joints) <=1; PASI <=1 for participants with psoriasis covering BSA <=3% [PASI evaluates severity and extent of psoriasis. In PASI, body is divided into four parts and each area is assessed for erythema, induration and scaling, each rated on a scale of 0 to 4. The total score ranges from 0 (no disease) to 72 (maximal disease)]; Patient's Assessment of Arthritis Pain <=15 [using VAS on a scale of 0 (no pain) to 100 (serious pain)]; Patient's Global Assessment of Disease Activity <=20 [using VAS on a scale of 0 (very well) to 100 (very poor)]; HAQ-DI score <=0.5; Leeds Enthesitis Index score <=1 for participants with enthesitis at

baseline. Randomized Set consisted of all enrolled participants who had been randomized.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	267		
Units: percentage of participants				
number (not applicable)	6.0	44.2		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo v Bimekizumab 160mg
Number of subjects included in analysis	400
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	13.089
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.119
upper limit	27.999

Secondary: Percentage of participants with American College of Rheumatology 70 (ACR70) response

End point title	Percentage of participants with American College of Rheumatology 70 (ACR70) response

End point description:

ACR70 response rate:70% or greater improvement of arthritis from Baseline. Those who met 3 conditions for improvement from Baseline met ACR70 response criteria: 1.Tender joint count (0-68 joints) ≥ 70% improvement; 2. Swollen joint count (0-66 joints) ≥ 70% improvement; and 3.≥ 70% improvement in at least 3 of the 5 below: Physician global assessment of disease activity [visual analog scale (VAS)(0-100 mm; no symptoms to severe)], Patient global assessment of disease activity [VAS-(0-100 mm; no limitation of normal activities to very poor)], Patient assessment of pain [VAS-(0-100 mm;no pain to most severe)], Health Assessment Questionnaire - Disability Index for degree of difficulty (20 queries from 8 domains of daily living activities scored 0-3, 0=less disability) High-sensitivity C-reactive protein (hsCRP). Analysis set:Randomized Set. Non-responders: Those who missed ACR70 data at Week 16 or who discontinued study before Week 16 regardless of data present or not.

End point type	Secondary

End point timeframe:

From Baseline to Week 16

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	267		
Units: percentage of participants				
number (not applicable)	0.8	26.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with American College of Rheumatology 20 (ACR20) response

End point title	Percentage of participants with American College of Rheumatology 20 (ACR20) response

End point description:

ACR20 response rate:20% or greater improvement of arthritis from Baseline. Those who met 3 conditions for improvement from Baseline met ACR20 response criteria: 1.Tender joint count (0-68 joints) ≥ 20% improvement; 2. Swollen joint count (0-66 joints) ≥ 20% improvement; and 3.≥ 20% improvement in at least 3 of the 5 below: Physician global assessment of disease activity [visual analog scale (VAS)(0-100 mm; no symptoms to severe)], Patient global assessment of disease activity [VAS-(0-100 mm; no limitation of normal activities to very poor)], Patient assessment of pain [VAS-(0-100 mm;no pain to most severe)], Health Assessment Questionnaire - Disability Index for degree of difficulty (20 queries from 8 domains of daily living activities scored 0-3, 0=less disability) High-sensitivity C-reactive protein (hsCRP). Analysis set:Randomized Set. Non-responders: Those who missed ACR20 data at Week 16 or who discontinued study before Week 16 regardless of data present or not.

End point type	Secondary

End point timeframe:

From Baseline to Week 16

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	267		
Units: percentage of participants				
number (not applicable)	15.8	67.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Investigator Global Assessment (IGA) response defined as score of 0 (clear) or 1 (almost clear) and at least a 2-grade reduction from Baseline at Week 4 in the subset of participants with psoriatic skin lesions at Baseline

End point title	Investigator Global Assessment (IGA) response defined as score of 0 (clear) or 1 (almost clear) and at least a 2-grade reduction from Baseline at Week 4 in the subset of participants with psoriatic skin lesions at Baseline

End point description:

IGA assessed the overall severity of PSO using a 5-point scale with scores 0=clear (No signs of PSO; post-inflammatory hyperpigmentation may be present), 1=almost clear (No thickening; normal to pink coloration; no to minimal focal scaling), 2=mild (Just detectable to mild thickening; pink to light red coloration; predominately fine scaling), 3=moderate (Clearly distinguishable to moderate thickening; dull to bright red, moderate scaling), and 4=severe (Severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions). The IGA response score of 0 (clear) or 1 (almost clear) indicated at least 2-category improvement relative to Baseline. Subset of study participants in Randomized Set with psoriatic skin lesions at Baseline. Non-responders: Participants who had missing data at the Week 4 or who discontinued study treatment before or at the Week 4 regardless of whether they had data or not.

End point type	Secondary

End point timeframe:

Baseline and Week 4

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	163		
Units: percentage of participants				
number (not applicable)	1.2	30.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Investigator Global Assessment (IGA) response defined as score of 0 (clear) or 1 (almost clear) AND at least a 2-grade reduction from Baseline at Week 16 in the subset of participants with psoriatic skin lesions at Baseline

End point title	Investigator Global Assessment (IGA) response defined as score of 0 (clear) or 1 (almost clear) AND at least a 2-grade reduction from Baseline at Week 16 in the subset of participants with psoriatic skin lesions at Baseline

End point description:

IGA assessed the overall severity of PSO using a 5-point scale with scores 0=clear (No signs of PSO; post-inflammatory hyperpigmentation may be present), 1=almost clear (No thickening; normal to pink coloration; no to minimal focal scaling), 2=mild (Just detectable to mild thickening; pink to light red coloration; predominately fine scaling), 3=moderate (Clearly distinguishable to moderate thickening; dull to bright red, moderate scaling), and 4=severe (Severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions). The IGA response score of 0 (clear) or 1 (almost clear) indicated at least 2-category improvement relative to Baseline. Subset of study participants in Randomized Set with psoriatic skin lesions at Baseline. Non-responders: Participants who had missing data at the Week 16 or who discontinued study treatment before or at the Week 16 regardless of whether they had data or not.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	82	163		
Units: percentage of participants				
number (not applicable)	3.7	60.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Patient's Assessment of Arthritis Pain (PtAAP) at Week 16

End point title	Change from Baseline in the Patient's Assessment of Arthritis Pain (PtAAP) at Week 16

End point description:

The PtAAP Visual Analog Scale (VAS) is part of the American College of Rheumatology core set of measures in arthritis. Participants assessed their arthritis pain using a VAS on a scale of 0 (very well) to 100 (very poor). A negative change from baseline indicates improvement. Randomized Set consisted of all enrolled participants who had been randomized.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	267		
Units: score on a scale				
arithmetic mean (standard error)	-4.5 (± 2.1)	-27.7 (± 1.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Psoriatic Arthritis Impact of Disease-12 (PsAID-12) total score at Week 16

End point title	Change from Baseline in Psoriatic Arthritis Impact of Disease-12 (PsAID-12) total score at Week 16

End point description:

The PsAID-12 is a patient-reported outcome measure for assessing the impact of Psoriatic Arthritis (PsA) in 12 physical and psychological domains, including pain, fatigue, skin problems, work and/or leisure activities, functional capacity, discomfort, sleep disturbance, coping, anxiety/fear/uncertainty,

embarrassment and/or shame, social participation, and depression. Each domain was assessed with a single question using a 0 to 10 numerical rating scale. Each domain score was multiplied by a weighting factor and the results were then summed to provide the total score. The total score ranged from 0 to 10, with higher scores indicating a worse status. A negative change from baseline indicates improvement. Randomized Set consisted of all enrolled participants who had been randomized.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	133	267		
Units: score on a scale				
arithmetic mean (standard error)	-0.32 (± 0.16)	-2.24 (± 0.13)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with treatment-emergent adverse events (TEAEs) during the study

End point title	Number of Participants with treatment-emergent adverse events (TEAEs) during the study

End point description:

An Adverse Event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product, which does not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. TEAEs were defined as any AEs with an onset date on or after the date of first IMP administration and up to 20 weeks after the last (most recent) dose of IMP. The Safety Set consisted of all participants who received at least 1 dose of the IMP.

End point type	Secondary

End point timeframe:

From Baseline until Safety Follow-Up (up to 37 weeks)

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	267		
Units: participants	44	108		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with treatment-emergent serious adverse events (SAEs) during the study

End point title	Number of Participants with treatment-emergent serious adverse events (SAEs) during the study

End point description:

A serious adverse event (SAE) is any untoward medical occurrence that at any dose: Results in death, Is life-threatening, Requires in patient hospitalization or prolongation of existing hospitalization; Is a congenital anomaly or birth defect; Is an infection that requires treatment parenteral antibiotics, Other important medical events which based on medical or scientific judgement may jeopardize the patients, or may require medical or surgical intervention to prevent any of the above. TEAEs were defined as any AEs with an onset date on or after the date of first IMP administration and up to 20 weeks after the last (most recent) dose of IMP. The Safety Set consisted of all participants who received at least 1 dose of the IMP.

End point type	Secondary

End point timeframe:

From Baseline until Safety Follow-Up (up to 37 weeks)

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	267		
Units: participants	0	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with treatment-emergent adverse events (TEAEs) leading to withdrawal from investigational medicinal product (IMP) during the study

End point title	Number of Participants with treatment-emergent adverse events (TEAEs) leading to withdrawal from investigational medicinal product (IMP) during the study

End point description:

An Adverse Event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product, which does not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. TEAEs were defined as any AEs with an onset date on or after the date of first IMP administration and up to 20 weeks after the last (most recent) dose of IMP. The Safety Set consisted of all participants who received at least 1 dose of the IMP.

End point type	Secondary

End point timeframe:

From Baseline until Safety Follow-Up (up to 37 weeks)

End point values	Placebo	Bimekizumab 160mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	267		
Units: participants	0	2		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline until Safety Follow-Up (up to 37 weeks)

Adverse event reporting additional description:

Treatment-emergent adverse events (TEAEs) were defined as any AEs with an onset date on or after the date of first IMP administration and up to 20 weeks after the last (most recent) dose of IMP. TEAEs were analyzed for Safety Set.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Bimekizumab 160mg

Reporting group description:

Participants received bimekizumab 160 mg as a sc injection Q4W for up to 16 weeks.

Reporting group title	Placebo

Reporting group description:

Participants received placebo as a sc injection Q4W for up to 16 weeks.

Serious adverse events	Bimekizumab 160mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 267 (1.87%)	0 / 132 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Joint injury			
subjects affected / exposed	1 / 267 (0.37%)	0 / 132 (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			
Toxic encephalopathy			
subjects affected / exposed	1 / 267 (0.37%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Intestinal obstruction			

subjects affected / exposed	1 / 267 (0.37%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 267 (0.37%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	1 / 267 (0.37%)	0 / 132 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Bimekizumab 160mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 267 (12.73%)	15 / 132 (11.36%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 267 (1.12%)	3 / 132 (2.27%)	
occurrences (all)	3	3	
Infections and infestations			
Corona virus infection			
subjects affected / exposed	5 / 267 (1.87%)	6 / 132 (4.55%)	
occurrences (all)	5	6	
Nasopharyngitis			
subjects affected / exposed	10 / 267 (3.75%)	1 / 132 (0.76%)	
occurrences (all)	11	1	
Urinary tract infection			
subjects affected / exposed	5 / 267 (1.87%)	3 / 132 (2.27%)	
occurrences (all)	6	3	
Upper respiratory tract infection			
subjects affected / exposed	6 / 267 (2.25%)	2 / 132 (1.52%)	
occurrences (all)	6	2	

Oral candidiasis subjects affected / exposed occurrences (all)	7 / 267 (2.62%) 9	0 / 132 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 May 2020	Protocol amendment 1 was implemented to update the completed and ongoing studies information, clarify study procedures, add re-screening rules, update the description of IMP, change the statistical hierarchy, and update the statistical section.
01 April 2021	Protocol Amendment 2 was implemented to modify the secondary variables and fixed sequence testing procedure, update the statistical section, and make other procedural clarifications.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported