



Clinical trial results:

A Multicenter, Open-Label Extension Study to Evaluate the Long Term Safety and Efficacy of Bimekizumab in Subjects with Ankylosing Spondylitis

Summary

EudraCT number	2017-001002-15
Trial protocol	HU CZ DE BG ES
Global end of trial date	19 October 2022

Results information

Result version number	v1 (current)
This version publication date	03 November 2023
First version publication date	03 November 2023

Trial information

Trial identification

Sponsor protocol code	AS0009
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03355573
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 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	20 January 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 October 2022
Global end of trial reached?	Yes
Global end of trial date	19 October 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Assess the long-term safety and tolerability of bimekizumab administered over a period of up to 4 years.

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Background therapy as permitted in the protocol.

Evidence for comparator:

Not applicable

Actual start date of recruitment	28 November 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 9
Country: Number of subjects enrolled	Canada: 2
Country: Number of subjects enrolled	Czechia: 72
Country: Number of subjects enrolled	Germany: 10
Country: Number of subjects enrolled	Hungary: 7
Country: Number of subjects enrolled	Poland: 89
Country: Number of subjects enrolled	Russian Federation: 32
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	Ukraine: 20
Country: Number of subjects enrolled	United States: 6
Worldwide total number of subjects	255
EEA total number of subjects	195

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)	245
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll study participants in November 2017 and concluded in October 2022. Participants who completed AS0008 (NCT02963506) participated in this study.

Pre-assignment

Screening details:

The Participant Flow refers to the Safety Set.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Bimekizumab
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Arm description:

Participants received bimekizumab 160 milligrams (mg) every 4 weeks (Q4W) up to 4 years.

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

Dosage and administration details:

Participants received bimekizumab 160 mg Q4W at prespecified time points.

Number of subjects in period 1	Bimekizumab
Started	255
Completed	202
Not completed	53
Sponsor's decision	1
Consent withdrawn by subject	23
PI's decision	2
Adverse Event, non-fatal	17
Withdrew consent:refused treatment to AE latent TB	1
Lost to follow-up	4
Participant withdrew consent due to AEs	1
Adverse Event, serious fatal	2
Lack of efficacy	2

Baseline characteristics

Reporting groups

Reporting group title	Bimekizumab
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Reporting group description:

Participants received bimekizumab 160 milligrams (mg) every 4 weeks (Q4W) up to 4 years.

Reporting group values	Bimekizumab	Total	
Number of subjects	255	255	
Age Categorical			
Units: participants			
<=18 years	0	0	
Between 18 and 65 years	245	245	
>=65 years	10	10	
Age Continuous			
Units: years			
arithmetic mean	41.8		
standard deviation	± 11.4	-	
Sex: Female, Male			
Units: participants			
Female	38	38	
Male	217	217	
Race/Ethnicity, Customized			
Units: Subjects			
White	253	253	
Other/Mixed	2	2	
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic or Latino	1	1	
Not Hispanic or Latino	254	254	

End points

End points reporting groups

Reporting group title	Bimekizumab
Reporting group description:	
Participants received bimekizumab 160 milligrams (mg) every 4 weeks (Q4W) up to 4 years.	

Primary: Percentage of Participants with treatment-emergent adverse events (TEAEs) during the study

End point title	Percentage of Participants with treatment-emergent adverse events (TEAEs) during the study ^[1]
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End point description:

An Adverse Event (AE) is any untoward medical occurrence in a participant or clinical investigation participant 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. Treatment emergent adverse events were defined as those events with onset date on or after the first administration of study medication in AS0009 and on or before 140 days after the final study medication administration. The Safety Set consisted of all participants in the enrolled set who received at least one dose of study medication in AS0009.

End point type	Primary
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End point timeframe:

From Entry Visit (Visit 1) until Safety Follow Up (up to Week 224)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

End point values	Bimekizumab			
Subject group type	Reporting group			
Number of subjects analysed	255			
Units: percentage of participants				
number (not applicable)	92.9			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants with serious adverse event (SAE) during the study

End point title	Percentage of Participants with serious adverse event (SAE) during the study ^[2]
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End point description:

A serious adverse event (SAE) is any untoward medical occurrence that at any dose: 1) Results in death 2) Is life-threatening 3) Requires in participant hospitalisation or prolongation of existing hospitalisation 4) Is a congenital anomaly or birth defect 5) Is an infection that requires treatment with parenteral antibiotics 6) Other important medical events which based on medical or scientific judgement may jeopardise the participants, or may require medical or surgical intervention to prevent any of the above. The Safety Set consisted of all participants in the enrolled set who received at least one dose of study

medication in AS0009.

End point type	Primary
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End point timeframe:

From Entry Visit (Visit 1) until Safety Follow Up (up to Week 224)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

End point values	Bimekizumab			
Subject group type	Reporting group			
Number of subjects analysed	255			
Units: percentage of participants				
number (not applicable)	18.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Axial Spondyloarthritis International Society 40% response criteria (ASAS40) at Week 48 calculated relative to Baseline of AS0008

End point title	Percentage of Participants with Axial Spondyloarthritis International Society 40% response criteria (ASAS40) at Week 48 calculated relative to Baseline of AS0008
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End point description:

ASAS40 response: relative improvements of at least 40% and absolute improvement of at least 2 units on a 0 to 10 Numeric Rating Scale (NRS), where 0 is "not active" and 10 is "very active" in at least 3 of 4 domains: Patient's Global Assessment of Disease Activity (PGADA) (score range: 0(not active)-10(very active)), Pain assessment (total spinal pain NRS score) (assessed on a scale of 0(no pain) -10(severe pain)), Function (Bath Ankylosing Spondylitis Functional Index (BASFI)) (score range: 0(easy)-10(impossible)), Inflammation (mean of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) questions 5 and 6 concerning morning stiffness intensity and duration) (score range: 0(none)-10(very severe) and no worsening at all in remaining domain. FAS: all enrolled participants who received at least 1 dose of IMP and had a valid measurement for at least 1 efficacy variable at AS0009 study entry. NRI and OCS have been reported. Number analyzed=participants evaluable at specified categories.

End point type	Secondary
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End point timeframe:

Baseline of AS0008, Week 48 (AS0009)

End point values	Bimekizumab			
Subject group type	Reporting group			
Number of subjects analysed	249			
Units: percentage of participants				
number (not applicable)				
Non-responder imputation (n=249)	67.1			
Observed case (n=237)	70.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who withdrew due to an treatment-emergent adverse event (TEAE) during the study

End point title	Percentage of Participants who withdrew due to an treatment-emergent adverse event (TEAE) during the study
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End point description:

An Adverse Event (AE) is any untoward medical occurrence in a participant or clinical investigation participant 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. Treatment emergent adverse events were defined as those events with onset date on or after the first administration of study medication in AS0009 and on or before 140 days after the final study medication administration. The Safety Set consisted of all participants in the enrolled set who received at least one dose of study medication in AS0009.

End point type	Secondary
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End point timeframe:

From Entry Visit (Visit 1) until Safety Follow Up (up to Week 224)

End point values	Bimekizumab			
Subject group type	Reporting group			
Number of subjects analysed	255			
Units: percentage of participants				
number (not applicable)	6.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Axial Spondyloarthritis International Society 20% response criteria (ASAS20) at Week 48 calculated relative to Baseline of AS0008

End point title	Percentage of Participants with Axial Spondyloarthritis International Society 20% response criteria (ASAS20) at Week 48 calculated relative to Baseline of AS0008
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End point description:

ASAS20 response: relative improvements of at least 20% and absolute improvement of at least 1 unit on a 0 to 10 NRS, where 0 is "not active" and 10 is "very active" in at least 3 of 4 domains: PGADA (score range: 0 (not active) to 10 (very active), Pain assessment (total spinal pain NRS score) (assessed on a scale of 0 (no pain)-10 (severe pain)), Function (BASFI) (score ranged from 0 (easy)-10 (impossible)), Inflammation (mean of BASDAI) questions 5 and 6 concerning morning stiffness intensity

and duration) (score ranged from 0 (none)-10 (very severe) and no worsening at all in the remaining domain. Full Analysis Set consisted of all enrolled participants who received at least 1 dose of IMP and had a valid measurement for at least 1 efficacy variable at AS0009 study entry. Both Non-responder imputation (NRI) and observed case (OC) analysis have been reported in this endpoint. Number analyzed=participants evaluable at specified categories.

End point type	Secondary
End point timeframe:	
Baseline of AS0008, Week 48 (AS0009)	

End point values	Bimekizumab			
Subject group type	Reporting group			
Number of subjects analysed	249			
Units: percentage of participants				
number (not applicable)				
Non-responder imputation (n=249)	79.9			
Observed case (n=237)	84.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline of AS0008 in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) total score to Week 48

End point title	Change from Baseline of AS0008 in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) total score to Week 48
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End point description:

BASDAI is a validated self-reported instrument, which consisted of 6 questions to measure the disease activity of ankylosing spondylitis (AS) from the participant's perspective. It measured the severity of fatigue, spinal and peripheral joint pain and swelling, enthesitis, and morning stiffness (both severity and duration). Each question was rated using a numerical rating scale from 0 (none) to 10 (very severe), higher score=high disease activity. The BASDAI score was calculated by computing the mean of questions 5 and 6 and adding it to the sum of questions 1 to 4. This score was then divided by 5. The total BASDAI score was ranged from 0=none to 10= very severe, where higher score indicated high disease activity. A negative value indicated improvement and a positive value indicated worsening. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the IMP and had a valid measurement for at least 1 efficacy variable at AS0009 study entry.

End point type	Secondary
End point timeframe:	
Baseline of AS0008, Week 48 (AS0009)	

End point values	Bimekizumab			
Subject group type	Reporting group			
Number of subjects analysed	249			
Units: scores on a scale				
arithmetic mean (standard error)	-3.79 (± 0.13)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Entry Visit (Visit 1) until Safety Follow Up (up to Week 224)

Adverse event reporting additional description:

Treatment emergent adverse events were defined as those events with onset date on or after the first administration of study medication in AS0009 and on or before 140 days after the final study medication administration. The Safety Set consisted of all participants in the enrolled set who received at least one dose of study medication in AS0009.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	Bimekizumab
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Reporting group description:

Participants received Bimekizumab 160 mg Q4W up to 4 years.

Serious adverse events	Bimekizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	46 / 255 (18.04%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung neoplasm malignant			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Testicular seminoma (pure)			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Subclavian steal syndrome			

subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicose vein			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Female genital tract fistula			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 255 (0.78%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mental disorder			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bipolar disorder			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Meniscus injury			

subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Periprosthetic fracture			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Skull fracture			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post procedural haematuria			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery stenosis			

subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Nervous system disorders			
Carpal tunnel syndrome			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Endolymphatic hydrops			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Colitis ulcerative			
subjects affected / exposed	2 / 255 (0.78%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Crohn's disease			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatotoxicity			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Tendonitis			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bursitis			

subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fracture delayed union			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint instability			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	2 / 255 (0.78%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Spinal instability			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ankylosing spondylitis			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	3 / 255 (1.18%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Empyema			

subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis bacterial			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal wall abscess			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Perirectal abscess			
subjects affected / exposed	2 / 255 (0.78%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Corona virus infection			
subjects affected / exposed	3 / 255 (1.18%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonsillar abscess			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	1 / 255 (0.39%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Bimekizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	176 / 255 (69.02%)		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	19 / 255 (7.45%)		
occurrences (all)	26		
Aspartate aminotransferase increased			
subjects affected / exposed	13 / 255 (5.10%)		
occurrences (all)	17		
Vascular disorders			
Hypertension			
subjects affected / exposed	14 / 255 (5.49%)		
occurrences (all)	16		
Nervous system disorders			
Headache			
subjects affected / exposed	13 / 255 (5.10%)		
occurrences (all)	16		
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	13 / 255 (5.10%)		
occurrences (all)	16		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	15 / 255 (5.88%)		
occurrences (all)	17		
Infections and infestations			
Oral candidiasis			
subjects affected / exposed	17 / 255 (6.67%)		
occurrences (all)	21		
Nasopharyngitis			
subjects affected / exposed	46 / 255 (18.04%)		
occurrences (all)	65		
Upper respiratory tract infection			

subjects affected / exposed	33 / 255 (12.94%)		
occurrences (all)	48		
Pharyngitis			
subjects affected / exposed	18 / 255 (7.06%)		
occurrences (all)	24		
Sinusitis			
subjects affected / exposed	15 / 255 (5.88%)		
occurrences (all)	17		
Tonsillitis			
subjects affected / exposed	15 / 255 (5.88%)		
occurrences (all)	21		
Corona virus infection			
subjects affected / exposed	30 / 255 (11.76%)		
occurrences (all)	33		
Bronchitis			
subjects affected / exposed	21 / 255 (8.24%)		
occurrences (all)	23		
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	16 / 255 (6.27%)		
occurrences (all)	17		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 March 2018	<p>Protocol Amendment 2 was dated 21 Mar 2018. The purpose of this amendment was to:</p> <ul style="list-style-type: none">• Update the study contact details for the Sponsor Study Physician, CPM, and Clinical Trial Biostatistician• Amend the open-label Treatment Period for clarification, as per request from the regulatory agency• Amend the study procedures and assessments to be performed at the SFU Visit; efficacy assessments were removed since they were not required at the SFU visit• Amend the time frame for the availability of negative results from the QuantiFERON tuberculosis (TB) Test, to be aligned with the TB standard operating procedure (SOP)• Include additional wording to the inclusion criteria listing acceptable methods of contraception for female study participants

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported