Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Bimekizumab in Subjects With Active Nonradiographic Axial Spondyloarthritis

Summary

EudraCT number	2017-003064-13
Trial protocol	DE BE CZ FR HU GB BG NL
Global end of trial date	17 April 2023

Results information

Result version number	v2 (current)
This version publication date	31 January 2025
First version publication date	02 May 2024
Version creation reason	• Correction of full data set Correction of posted results.

Trial information

Trial identification

Sponsor protocol code	AS0010

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03928704
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	05 May 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 June 2022
Global end of trial reached?	Yes
Global end of trial date	17 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Demonstrate the efficacy of bimekizumab (BKZ) administered subcutaneously (sc) compared to placebo in the treatment of participants with active nonradiographic axial spondyloarthritis (nr-axSpA).

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	25 April 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	United Kingdom: 7
Country: Number of subjects enrolled	United States: 18
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Bulgaria: 9
Country: Number of subjects enrolled	Czechia: 53
Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Germany: 24
Country: Number of subjects enrolled	Hungary: 11
Country: Number of subjects enrolled	Poland: 71
Country: Number of subjects enrolled	Spain: 26
Country: Number of subjects enrolled	China: 36
Country: Number of subjects enrolled	Japan: 12
Worldwide total number of subjects	274
EEA total number of subjects	201

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)	268
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Among total of 274 participants, a total of 254 were enrolled under global study protocol by June 2021, including 16 enrolled in China. The enrolment was extended in China to achieve the target of 36 participants as agreed with the local agency and additional 20 Chinese participants were enrolled by February 2022 in the China Extension population.

Pre-assignment

Screening details:

The study started to enroll participants in April 2019 and concluded in April 2023. The Participant Flow refers to Randomized Set. Out of 36 Chinese participants, 16 participants were included in the analysis of global population and the results of the remaining 20 Chinese participants are reported separately as the China extension population.

Period 1

Period 1 title	Double-Blind Treatment Period:Week 1-16
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo (up to Week 16) (Global Population)

Arm description:

Participants received placebo matched to bimekizumab 160 milligrams (mg) every 4 weeks (Q4W) subcutaneously until Week 16.

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 160 mg Q4W (up to Week 16) (Global Population)

Arm description:

Participants received bimekizumab 160 mg Q4W subcutaneously until Week 16.

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 bimekizumab 160 mg Q4W at prespecified time points.

Arm title	Placebo (up to Week 16) (China Extension Population)

Arm description:

Participants in the China Extension Population received placebo matched to bimekizumab 160 mg Q4W subcutaneously until Week 16.

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	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)

Arm description:

Participants in the China Extension Population received bimekizumab 160 mg Q4W subcutaneously until Week 16.

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 bimekizumab 160 mg Q4W at prespecified time points.

Number of subjects in period 1	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)
Started	126	128	11
Started Chinese participants	7 [1]	9 [2]	11
Completed	118	126	11
Not completed	8	2	0
Consent withdrawn by subject	4	-	-
Adverse Event	3	1	-
Patient Compliance	-	1	-
Lack of efficacy	1	-	-

Number of subjects in period 1	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Started	9
Started Chinese participants	9
Completed	9
Not completed	0
Consent withdrawn by subject	-
Adverse Event	-
Patient Compliance	-
Lack of efficacy	-

Notes:

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

Justification: The number of participants in the milestone reflect the number of chinese participants in the study.

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

Justification: The number of participants in the milestone reflect the number of chinese participants in the study.

Period 2

Period 2 title	Maintenance Period: Week 16-52
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	BKZ 160 mg Q4W (Weeks 16 up to 52) (Global Population)

Arm description:

At the end of the 16-week Double-Blind Treatment Period, study participants receiving placebo were re-allocated to bimekizumab treatment at Week 16. Participants from both placebo and bimekizumab arm received bimekizumab 160 mg Q4W subcutaneously from Week 16 until Week 48 during maintenance period. Participants entering the extension study received bimekizumab 160 mg Q4W subcutaneously until Week 52.

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 bimekizumab 160 mg Q4W at prespecified time points.

Arm title	BKZ 160 mg Q4W (Weeks 16 up to 52)(China Extension Population)

Arm description:

At the end of the 16-week Double-Blind Treatment Period, study participants in China Extension Population receiving placebo were re-allocated to bimekizumab treatment at Week 16. Participants from both placebo and bimekizumab arm received bimekizumab 160 mg Q4W subcutaneously from Week 16 until Week 48 during maintenance period. Participants entering the extension study received bimekizumab 160 mg Q4W subcutaneously until Week 52.

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 bimekizumab 160 mg Q4W at prespecified time points.

Number of subjects in period 2[3]	BKZ 160 mg Q4W (Weeks 16 up to 52) (Global Population)	BKZ 160 mg Q4W (Weeks 16 up to 52)(China Extension Population)
Started	242	20
Completed	220	17
Not completed	22	3
Consent withdrawn by subject	12	-
Adverse Event	5	-
Lost to follow-up	1	-
Non- Compliance	-	1
Lack of efficacy	4	-
COVID-19 pandemic situation & site restrictions	-	2

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Placebo=116+ BKZ=126. 2 participants Completed the 16-Week Double-Blind Period but did not enter the Maintenance Period because of the below reason: Adverse event.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo (up to Week 16) (Global Population)
Reporting group description:	
Participants received placebo matched to bimekizumab 160 milligrams (mg) every 4 weeks (Q4W) subcutaneously until Week 16.	
Reporting group title	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Reporting group description:	
Participants received bimekizumab 160 mg Q4W subcutaneously until Week 16.	
Reporting group title	Placebo (up to Week 16) (China Extension Population)
Reporting group description:	
Participants in the China Extension Population received placebo matched to bimekizumab 160 mg Q4W subcutaneously until Week 16.	
Reporting group title	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Reporting group description:	
Participants in the China Extension Population received bimekizumab 160 mg Q4W subcutaneously until Week 16.	

Reporting group values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)
Number of subjects	126	128	11
Age Categorical Units: Participants			
18 - <65	123	125	11
65 - <85	3	3	0
>= 85	0	0	0
Sex: Female, Male Units: Participants			
Female	61	55	7
Male	65	73	4

Reporting group values	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)	Total	
Number of subjects	9	274	
Age Categorical Units: Participants			
18 - <65	9	268	
65 - <85	0	6	
>= 85	0	0	
Sex: Female, Male Units: Participants			
Female	2	125	
Male	7	149	

End points

End points reporting groups

Reporting group title	Placebo (up to Week 16) (Global Population)

Reporting group description:

Participants received placebo matched to bimekizumab 160 milligrams (mg) every 4 weeks (Q4W) subcutaneously until Week 16.

Reporting group title	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)

Reporting group description:

Participants received bimekizumab 160 mg Q4W subcutaneously until Week 16.

Reporting group title	Placebo (up to Week 16) (China Extension Population)

Reporting group description:

Participants in the China Extension Population received placebo matched to bimekizumab 160 mg Q4W subcutaneously until Week 16.

Reporting group title	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)

Reporting group description:

Participants in the China Extension Population received bimekizumab 160 mg Q4W subcutaneously until Week 16.

Reporting group title	BKZ 160 mg Q4W (Weeks 16 up to 52) (Global Population)

Reporting group description:

At the end of the 16-week Double-Blind Treatment Period, study participants receiving placebo were re-allocated to bimekizumab treatment at Week 16. Participants from both placebo and bimekizumab arm received bimekizumab 160 mg Q4W subcutaneously from Week 16 until Week 48 during maintenance period. Participants entering the extension study received bimekizumab 160 mg Q4W subcutaneously until Week 52.

Reporting group title	BKZ 160 mg Q4W (Weeks 16 up to 52)(China Extension Population)

Reporting group description:

At the end of the 16-week Double-Blind Treatment Period, study participants in China Extension Population receiving placebo were re-allocated to bimekizumab treatment at Week 16. Participants from both placebo and bimekizumab arm received bimekizumab 160 mg Q4W subcutaneously from Week 16 until Week 48 during maintenance period. Participants entering the extension study received bimekizumab 160 mg Q4W subcutaneously until Week 52.

Subject analysis set title	Overall Period (up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(GP)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received bimekizumab 160 mg Q4W subcutaneously from Day 1 up to Week 48 and participants who switched from placebo arm at Week 16 to receive bimekizumab 160 mg Q4W subcutaneously up to Week 48 were included in this group.

Subject analysis set title	Overall Period (up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(CP)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants in the China Extension Population who received bimekizumab 160 mg Q4W subcutaneously from Day 1 up to Week 48 and participants who switched from placebo arm at Week 16 to receive bimekizumab 160 mg Q4W subcutaneously up to Week 48 were included in this group.

Primary: Percentage of Participants With Assessment of SpondyloArthritis International Society 40% response criteria (ASAS40) response at Week 16

End point title	Percentage of Participants With Assessment of SpondyloArthritis International Society 40% response criteria (ASAS40) response at Week 16

End point description:

ASAS40 response is defined as relative improvements of at least 40% and absolute improvement of at

least 2 units in at least 3 of the 4 following components:1)Patient's Global Assessment of Disease Activity (PGADA) assessed on a scale ranging from 0 [not active] to 10 [very active], higher score=higher disease activity, 2)Spinal Pain assessed on a scale ranging from 0 [no pain] to 10 [most severe pain], higher score= higher pain intensity, 3)Bath Ankylosing Spondylitis Functional Index (BASFI) assessing participant's level of ability on a scale ranging from of 0 [easy] to 10 [impossible] on 10 physical activities, 4)morning stiffness, assessed as the mean of Q5 (intensity) and Q6 (duration) from the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), each assessed on a scale ranging from 0 [none / 0 hour] to 10 [very severe / 2 or more hours], higher score=higher severity; and no worsening at all in the remaining component. RS consisted of all randomized study participants.

End point type	Primary

End point timeframe:

Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: percentage of participants				
number (not applicable)	21.4	47.7	27.3	33.3

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	2
upper limit	6.16

Secondary: Percentage of Participants With Assessment of SpondyloArthritis International Society 40% response criteria (ASAS40) response in TNFα inhibitor-naïve subjects at Week 16

End point title	Percentage of Participants With Assessment of SpondyloArthritis International Society 40% response criteria (ASAS40) response in TNFα inhibitor-naïve subjects at Week 16

End point description:

ASAS40 response is defined as relative improvements of at least 40% and absolute improvement of at least 2 units in at least 3 of the 4 following components:1) PGADA assessed on a scale ranging from 0 [not active] to 10 [very active], higher score=higher disease activity, 2) Spinal Pain assessed on a scale ranging from 0 [no pain] to 10 [most severe pain], higher score= higher pain intensity, 3) BASFI assessing participant's level of ability on a scale ranging from of 0 [easy] to 10 [impossible] on 10 physical activities, 4) morning stiffness, assessed as the mean of Q5 (intensity) and Q6 (duration) from the BASDAI, each assessed on a scale ranging from 0 [none / 0 hour] to 10 [very severe / 2 or more hours], higher score=higher severity; and no worsening at all in the remaining component. The Randomized (RS) Set consisted of all randomized study participants. Participants analyzed are those from the RS who are TNFα inhibitor-naïve.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	109	118	11	8
Units: percentage of Participants				
number (not applicable)	22.9	46.6	27.3	37.5

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	227
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.71
upper limit	5.54

Secondary: Change from Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) total score at Week 16

End point title	Change from Baseline in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) total score at Week 16

End point description:

BASDAI is a well-established patient-reported outcome measure assessing severity of AS symptoms. It is made of 6 items assessing severity of fatigue, spinal pain, peripheral joint pain & swelling, enthesitis, & morning stiffness (both severity & duration). Each question is rated using a numerical rating scale ranging from 0 (none) to 10 (very severe), higher score=higher symptom severity. BASDAI score is calculated by computing mean of questions 5 & 6 and adding it to the sum of questions 1 to 4. This score is then divided by 5. Total BASDAI score ranges from 0=no disease activity to 10=maximal disease activity, where higher score indicates higher symptom severity. A negative change reflects improvement. Missing & non-missing data after intercurrent event are imputed using multiple imputation (MI) based on a reference-based (RB) approach.RS=all randomized participants.99999=Analysis was planned to be performed based on RB MI.No imputation done for CEP, so, no data has been presented.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: score on a scale				
least squares mean (standard error)	-1.55 (± 0.22)	-3.07 (± 0.21)	99999 (± 99999)	99999 (± 99999)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-1.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.04
upper limit	-0.98

Secondary: Percentage of Participants With Ankylosing Spondylitis Disease Activity Score major improvement (ASDAS-MI) at Week 16

End point title	Percentage of Participants With Ankylosing Spondylitis Disease

	Activity Score major improvement (ASDAS-MI) at Week 16

End point description:

ASDAS-MI is achieved when there is a reduction (improvement) greater or equal to (>=) 2.0 in ASDAS relative to Baseline. ASDAS is calculated by adding the 5 following components: 1) 0.121 × Neck, back or hip pain (BASDAI Q2), 2) 0.058 × Duration of morning stiffness (BASDAI Q6), 3) 0.110 × Patient's Global Assessment of Disease Activity (PGADA), 4) 0.073 × Peripheral pain/swelling in joints (BASDAI Q3), 5) 0.579 × (natural logarithm of the C-reactive protein (CRP) [mg/L] + 1). Q2, Q3 and Q6 from BASDAI and PGADA, are all assessed on a numerical scale from 0 [none / not active] to 10 [very severe / very active]. There is a minimum score of 0.980 for ASDAS (as a fixed value of 2 is assumed for values of hs-CRP below the LLOQ), but no defined upper score. Higher ASDAS scores reflect higher disease activity and participants achieving ASDAS-MI are considered to have a major improvement in their disease. The Randomized Set consisted of all randomized study participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: percentage of participants				
number (not applicable)	7.1	27.3	9.1	11.1

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	5.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.41
upper limit	12.23

Secondary: Percentage of Participants With Assessment of SpondyloArthritis International Society 20% response criteria (ASAS20) response at Week 16

End point title	Percentage of Participants With Assessment of

	SpondyloArthritis International Society 20% response criteria (ASAS20) response at Week 16

End point description:

ASAS20 response is defined as relative improvements of at least 20% and absolute improvement of at least 1 unit in at least 3 of the 4 following components:1) PGADA assessed on a scale ranging from 0 [not active] to 10 [very active], higher score=higher disease activity, 2) Spinal Pain assessed on a scale ranging from 0 [no pain] to 10 [most severe pain], higher score= higher pain intensity, 3) BASFI assessing participant's level of ability on a scale ranging from 0 [easy] to 10 [impossible] on 10 physical activities, 4) morning stiffness, assessed as the mean of Q5 (intensity) and Q6 (duration) from the BASDAI, each assessed on a scale ranging from 0 [none / 0 hour] to 10 [very severe / 2 or more hours], higher score=higher severity; and no worsening at all in the remaining component. The Randomized Set consisted of all randomized study participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: percentage of participants				
number (not applicable)	38.1	68.8	54.5	44.4

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.17
upper limit	6.26

Secondary: Percentage of Participants With Assessment of SpondyloArthritis International Society (ASAS) partial remission (PR) at Week 16

End point title	Percentage of Participants With Assessment of SpondyloArthritis International Society (ASAS) partial

	remission (PR) at Week 16

End point description:

The Assessment of SpondyloArthritis International Society partial remission (ASAS-PR) is defined as a score of less than or equal to (<=) 2 units in each of the 4 following components: 1) PGADA assessed on a scale ranging from 0 [not active] to 10 [very active], higher score=higher disease activity, 2) Spinal Pain assessed on a scale ranging from 0 [no pain] to 10 [most severe pain], higher score= higher pain intensity, 3) BASFI assessing participant's level of ability on a scale ranging from 0 [easy] to 10 [impossible] on 10 physical activities, and 4) morning stiffness, assessed as the mean of Q5 (intensity) and Q6 (duration) from the BASDAI scale, each assessed on a scale ranging from 0 [none / 0 hour] to 10 [very severe / 2 or more hours], higher score=higher severity. The Randomized Set consisted of all randomized study participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: percentage of participants				
number (not applicable)	7.1	25.8	9.1	33.3

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.06
upper limit	9.93

Secondary: Change from Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI) at Week 16

End point title	Change from Baseline in Bath Ankylosing Spondylitis Functional Index (BASFI) at Week 16

End point description:

The BASFI is a well-established PRO measure of physical functioning used in AxSpA trials. It assesses participants' level of ability during the past week in conducting 10 physical activities on a scale ranging from 0 [easy] to 10 [impossible]. The BASFI score is the mean of the 10 item scores and ranges from 0 to 10, with lower scores indicating better physical function. A negative change in BASFI indicates improvement. The higher the negative value the better the improvement. Missing data at Week 16 and non-missing data after intercurrent event (which are reset to missing) are imputed using MI based on a reference-based approach, in which the MI model is based on data from the placebo group. The Randomized Set consisted of all randomized study participants.99999=Analysis was planned to be performed based on RB MI.No imputation done for CEP, so, no data has been presented.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: score on a scale				
least squares mean (standard error)	-0.91 (± 0.22)	-2.39 (± 0.21)	99999 (± 99999)	99999 (± 99999)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-1.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.99
upper limit	-0.97

Secondary: Percentage of Participants With Assessment of SpondyloArthritis International Society (ASAS) 5/6 response at Week 16

End point title	Percentage of Participants With Assessment of SpondyloArthritis International Society (ASAS) 5/6 response at Week 16

End point description:

ASAS 5/6 response is defined as achieving at least 20% improvement in 5 of the following 6 components: 1)PGADA assessed on a scale ranging from 0 [not active] to 10 [very active], higher score=higher disease activity, 2)Spinal Pain assessed on a scale ranging from 0 [no pain] to 10 [most intense pain], higher score=higher pain intensity, 3)BASFI assessing participant's level of ability on a scale ranging from 0 [easy] to 10 [impossible] on 10 physical activities, 4)morning stiffness, assessed as mean of Q5 (intensity) and Q6 (duration) from BASDAI scale, each assessed on a scale ranging from 0 [none/ 0 hour] to 10 [very severe / 2 or more hours], higher score=higher severity; 5)spinal mobility (ie, lateral spinal flexion component of Bath Ankylosing Spondylitis Disease Metrology Index) on a scale ranging from 0 [no limitation of movement] to 10 [very severe limitation of movement] and 6) high sensitivity C-reactive protein (hs-CRP). RS consisted of all randomized study participants.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: percentage of participants				
number (not applicable)	20.6	45.3	18.2	44.4

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.87
upper limit	5.84

Secondary: Change from Baseline in Ankylosing Spondylitis Quality of Life (ASQoL) total score at Week 16

End point title	Change from Baseline in Ankylosing Spondylitis Quality of Life (ASQoL) total score at Week 16

End point description:

The Ankylosing Spondylitis Quality of Life (ASQoL) is an 18-item PRO measure developed specifically for measuring health-related quality of life (HRQoL) in participants with ankylosing spondylitis and validated in the full spectrum of axial spondyloarthritis (axSpA). Each item is given a score of 1 for positive responses indicating impaired quality of life, and a score of 0 for negative responses. All item scores are summed to generate the total score ranging from 0 to 18 with a higher score indicating worse HRQoL. A negative change represents an improvement. Missing data at Week 16 and non-missing data after intercurrent event (which are reset to missing) are imputed using MI based on a reference-based approach, in which the MI model is based on data from the placebo group. The Randomized Set consisted of all randomized study participants.99999=Analysis was planned to be performed based on RB MI.No imputation done for CEP, so, no data has been presented.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: score on a scale				
least squares mean (standard error)	-2.30 (± 0.43)	-4.94 (± 0.42)	99999 (± 99999)	99999 (± 99999)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-2.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.66
upper limit	-1.61

Secondary: Change from Baseline in nocturnal spinal pain score Numeric Rating Scale (NRS) at Week 16

End point title	Change from Baseline in nocturnal spinal pain score Numeric Rating Scale (NRS) at Week 16

End point description:

Nocturnal spinal pain experienced by participants with axial spondyloarthritis (axSpA) was assessed on a numerical rating scale ranging from of 0 (no pain) to 10 (most severe pain). A lower score indicates less pain and a negative change represents an improvement. Missing data at Week 16 and non-missing data after intercurrent event(s) (which are reset to missing) are imputed using MI based on a reference-based approach, in which the MI model is based on data from the placebo group.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: score on a scale				
least squares mean (standard error)	-1.71 (± 0.27)	-3.51 (± 0.25)	99999 (± 99999)	99999 (± 99999)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.42
upper limit	-1.18

Secondary: Change from Baseline in Bath Ankylosing Spondylitis Disease Metrology Index (BASMI) at Week 16

End point title	Change from Baseline in Bath Ankylosing Spondylitis Disease Metrology Index (BASMI) at Week 16

End point description:

The BASMI characterizes the spinal mobility of participants with axial Spondyloarthritis (SpA) and Ankylosing Spondylitis. It is a disease-specific measure consisting of 5 clinical measures to reflect participant axial status: cervical rotation; tragus to wall distance; lateral lumbar flexion; lumbar flexion

(modified Schober test); intermalleolar distance. According to the linear definition of the BASMI a score of 0 to 10 was calculated for each item based on the measurement. The mean of the 5 scores provides the total BASMI score (ranging from 0 to 10). The higher the BASMI score, the more severe the participant's limitation of movement due to their axial SpA. A negative value in BASMI change from Baseline indicates an improvement from Baseline. The higher the negative value, the better the improvement. The Randomized Set consisted of all randomized study participants.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: score on a scale				
least squares mean (standard error)	-0.11 (± 0.08)	-0.44 (± 0.08)	0.12 (± 0.211)	-0.38 (± 0.232)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.52
upper limit	-0.14

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:

SF-36 is a 36-item HRQoL instrument that uses a recall period of 4 weeks. Items are grouped into 8 domains: Physical Functioning (10 items), Role Physical (4 items), Bodily Pain (2 items), General Health (5 items),Vitality (4 items), Social Functioning (2 items), Role Emotional (3 items), Mental Health (5 items), & 1 item for perceived stability or change in health (Health Transition). In addition to domain

scores, PCS & MCS scores are calculated from 8 domains (excluding Health Transition item). Each of SF-36 derived raw scores & domain scores range from 0 to 100 with a higher score=better function.2 component summary scores & 8 domains scores are standardized with a mean of 50 & S.D. of 10 in general US population (Maruish, 2011). A positive change reflects improvement. Missing & non-missing data are imputed using MI based on a RB approach. Analysis set was RS.99999=Analysis was planned to be performed based on RB MI.No imputation done for CEP,so,no data has been presented.

End point type	Secondary
End point timeframe:	
Baseline, Week 16	

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	128	11	9
Units: score on a scale				
least squares mean (standard error)	5.36 (± 0.79)	9.32 (± 0.76)	99999 (± 99999)	99999 (± 99999)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	254
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	3.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.08
upper limit	5.83

Secondary: Percentage of Participants With Enthesitis-free state at Week 16 based on the Maastricht Ankylosing Spondylitis Enthesitis Index (MASES) Index in the subgroup of participants with enthesitis at Baseline

End point title	Percentage of Participants With Enthesitis-free state at Week 16 based on the Maastricht Ankylosing Spondylitis Enthesitis Index (MASES) Index in the subgroup of participants with enthesitis at Baseline

End point description:

The Maastricht Ankylosing Spondylitis Enthesitis is an index that measures the severity (ie, intensity and extent) of enthesitis through the assessment of 13 entheses (bilateral costochondral 1, costochondral 7, anterior superior iliac spine, posterior iliac spine, iliac crest and proximal insertion of the Achilles tendon sites, and the fifth lumbar vertebral body spinous process) each scored as 0 or 1 and then summed for a possible score of 0 to 13. Enthesitis free state is defined as having a MASES score of 0. A higher score reflects higher severity and a negative change represents an improvement. Subgroup of study participants in Randomized Set with enthesitis at Baseline (MASES index score > 0).

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	94	5	3
Units: percentage of participants				
number (not applicable)	23.9	51.1	60.0	66.7

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.84
upper limit	6.62

Secondary: Change from Baseline in the Maastricht Ankylosing Spondylitis Enthesitis (MASES) Index in the subgroup of participants with enthesitis at Baseline at Week 16

End point title	Change from Baseline in the Maastricht Ankylosing Spondylitis Enthesitis (MASES) Index in the subgroup of participants with enthesitis at Baseline at Week 16

End point description:

The Maastricht Ankylosing Spondylitis Enthesitis is an index that measures the severity (ie, intensity and extent) of enthesitis through the assessment of 13 entheses (bilateral costochondral 1, costochondral 7, anterior superior iliac spine, posterior iliac spine, iliac crest and proximal insertion of the Achilles tendon sites, and the fifth lumbar vertebral body spinous process), each scored as 0 or 1 and then summed for a possible score of 0 to 13. A higher score reflects higher severity and a negative change represents an improvement. Subgroup of study participants in Randomized Set with enthesitis at Baseline (MASES index score > 0).

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	92	94	5	3
Units: score on a scale				
least squares mean (standard error)	-1.11 (± 0.38)	-2.16 (± 0.37)	-1.35 (± 0.692)	-1.80 (± 0.871)

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo (up to Week 16) (Global Population) v Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013
Method	ANCOVA
Parameter estimate	LS Mean difference
Point estimate	-1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.88
upper limit	-0.23

Secondary: 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

End point description:

TEAEs are defined as those AEs that have a start date on or following the first dose of study treatment

through the final dose of study treatment + 140 days (covering the 20-week Safety follow up (SFU)). TEAEs were analyzed and have been reported separately for Double-Blind Treatment Period (Safety set),Maintenance Period (MP) (Maintenance Set) and Overall Period (Safety set) which includes all participants who received BKZ 160 mg Q4W during the study. The overall period arm reports repeated TEAEs from the double blind treatment period arm and maintenance period arm. As pre-specified in SAP, Maintenance Period (MP) included AEs of Safety follow up period for participants who did not enter the open label extension or discontinued early in MP. The Safety Set consisted of all randomized study participants who received at least 1 dose of investigational medicinal product (IMP).

End point type	Secondary

End point timeframe:

From Baseline (Day 1) until Safety-Follow-Up (up to Week 68) (Week 48 last IMP intake + 20 weeks SFU)

End point values	Placebo (up to Week 16) (Global Population)	BKZ 160 mg Q4W (Weeks 16 up to 52) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	BKZ 160 mg Q4W (Weeks 16 up to 52)(China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	242	128	20
Units: percentage of participants				
number (not applicable)	56.3	67.8	62.5	80.0

End point values	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)	Overall Period (up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(GP)	Overall Period (up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(CP)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	9	244	20
Units: percentage of participants				
number (not applicable)	72.7	100	75.0	90.0

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

SAE is any untoward medical occurrence that at any dose resulted in 1) Death, 2) Life-threatening (Life-threatening does not include a reaction that might have caused death had it occurred in a more severe form.), 3) Significant or persistent disability/incapacity, 4) Congenital anomaly/birth defect (including that occurring in a fetus), 5) Important medical event that, based upon appropriate medical judgment, may jeopardize the participant or participant may require medical or surgical intervention to prevent any of the above, 6) Initial inpatient hospitalization or prolongation of hospitalization. The overall period arm reports repeated SAEs from the double blind treatment period arm and maintenance period arm. As pre-

specified in SAP, MP included SAEs of Safety follow up period for participants who did not enter the open label extension or discontinued early in MP. The Safety Set consisted of all randomized study participants who received at least 1 dose of IMP.

End point type	Secondary

End point timeframe:

From Baseline (Day 1) until Safety Follow-Up (up to Week 68)

End point values	Placebo (up to Week 16) (Global Population)	BKZ 160 mg Q4W (Weeks 16 up to 52) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	BKZ 160 mg Q4W (Weeks 16 up to 52)(China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	242	128	20
Units: percentage of participants				
number (not applicable)	0.8	3.7	0	15.0

End point values	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)	Overall Period (up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(GP)	Overall Period (up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(CP)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	9	244	20
Units: percentage of participants				
number (not applicable)	0	0	3.7	15.0

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

TEAEs are defined as those AEs that have a start date on or following the first dose of study treatment through the final dose of study treatment + 140 days (covering the 20-week SFU period). The overall period arm reports repeated events from the double blind treatment period arm and maintenance period arm. As pre-specified in SAP, MP included events of Safety follow up period for participants who did not enter the open label extension or discontinued early in MP. The Safety Set consisted of all randomized study participants who received at least 1 dose of IMP.

End point type	Secondary

End point timeframe:

From Baseline (Day 1) until Safety-Follow-Up (up to Week 68)

End point values	Placebo (up to Week 16) (Global Population)	BKZ 160 mg Q4W (Weeks 16 up to 52) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	BKZ 160 mg Q4W (Weeks 16 up to 52)(China Extension Population)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	242	128	20
Units: percentage of participants				
number (not applicable)	4.0	2.5	1.6	0

End point values	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)	Overall Period (up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(GP)	Overall Period (up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(CP)
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	9	244	20
Units: percentage of participants				
number (not applicable)	0	0	3.3	0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline (Day 1) until Safety Follow-Up (up to Week 68)

Adverse event reporting additional description:

As prespecified in SAP, Maintenance Period (MP) included AEs of SFU period for participants who did not enter OLE or discontinued early in MP. participants who rolled over to OLE study did not have SFU visit. TEAEs have been reported separately for DBTP (SS), MP (MS) and Overall Period (OP) (SS). OP arm reports repeated TEAEs from the DBTP and MP.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	Placebo (up to Week 16) (Global Population)

Reporting group description:

Participants received placebo matched to bimekizumab 160 mg Q4W subcutaneously until Week 16.

Reporting group title	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)

Reporting group description:

Participants received bimekizumab 160 mg Q4W subcutaneously until Week 16.

Reporting group title	BKZ 160 mg Q4W (Weeks 16 up to 52)(Global Population)

Reporting group description:

At the end of the 16-week Double-Blind Treatment Period, study participants receiving placebo were re-allocated to bimekizumab treatment at Week 16. Participants from both placebo and bimekizumab arm received bimekizumab 160 mg Q4W subcutaneously from Week 16 until Week 48 during maintenance period. Participants entering the extension study received bimekizumab 160 mg Q4W subcutaneously until Week 52.

Reporting group title	Overall Period(up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(GP)

Reporting group description:

Participants who received bimekizumab 160 mg Q4W subcutaneously from Day 1 up to Week 48 and participants who switched from placebo arm at Week 16 to receive bimekizumab 160 mg Q4W subcutaneously up to Week 48 were included in this group.

Reporting group title	Placebo (up to Week 16) (China Extension Population)

Reporting group description:

Participants in the China Extension Population received placebo matched to bimekizumab 160 mg Q4W subcutaneously until Week 16.

Reporting group title	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)

Reporting group description:

Participants in the China Extension Population received bimekizumab 160 mg Q4W subcutaneously until Week 16.

Reporting group title	BKZ 160 mg Q4W (Weeks 16 up to 52)(China Extension Population)

Reporting group description:

At the end of the 16-week Double-Blind Treatment Period, study participants in China Extension Population receiving placebo were re-allocated to bimekizumab treatment at Week 16. Participants from both placebo and bimekizumab arm received bimekizumab 160 mg Q4W subcutaneously from Week 16 until Week 48 during maintenance period. Participants entering the extension study received bimekizumab 160 mg Q4W subcutaneously until Week 52.

Reporting group title	Overall Period (up to Week 48+20 Week SFU):BKZ 160 mg Q4W(CP)

Reporting group description:

Participants in the China Extension Population who received bimekizumab 160 mg Q4W subcutaneously

from Day 1 up to Week 48 and participants who switched from placebo arm at Week 16 to receive bimekizumab 160 mg Q4W subcutaneously up to Week 48 were included in this group.

Serious adverse events	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	BKZ 160 mg Q4W (Weeks 16 up to 52)(Global
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 126 (0.79%)	0 / 128 (0.00%)	9 / 242 (3.72%)
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)			
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
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			
Abdominal adhesions			
subjects affected / exposed	1 / 126 (0.79%)	0 / 128 (0.00%)	0 / 242 (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
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (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
Abortion induced			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Nasal crusting			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Intentional self-injury			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
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			
Appendicitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	2 / 242 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis bacterial			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Overall Period(up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(GP)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 244 (3.69%)	0 / 11 (0.00%)	0 / 9 (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)			
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	0 / 9 (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
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	0 / 9 (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
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 244 (0.00%)	0 / 11 (0.00%)	0 / 9 (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
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 244 (0.00%)	0 / 11 (0.00%)	0 / 9 (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
Abortion induced			
subjects affected / exposed	0 / 244 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Nasal crusting			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	0 / 9 (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
Psychiatric disorders			
Intentional self-injury			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	0 / 9 (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

Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	2 / 244 (0.82%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	0 / 9 (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
Tonsillitis bacterial			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	0 / 9 (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	BKZ 160 mg Q4W (Weeks 16 up to 52)(China Extension Population)	Overall Period (up to Week 48+20 Week SFU):BKZ 160 mg Q4W(CP)	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)	3 / 20 (15.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abortion induced			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Nasal crusting			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Intentional self-injury			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Erysipelas			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis bacterial			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo (up to Week 16) (Global Population)	Bimekizumab 160 mg Q4W (up to Week 16) (Global Population)	BKZ 160 mg Q4W (Weeks 16 up to 52)(Global
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 126 (23.81%)	40 / 128 (31.25%)	94 / 242 (38.84%)
Investigations			
Blood cholesterol increased			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences (all)	0	0	2
Low density lipoprotein increased			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	3 / 242 (1.24%)
occurrences (all)	0	0	3
Blood bilirubin increased			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences (all)	0	0	1
Liver function test increased			
subjects affected / exposed	1 / 126 (0.79%)	1 / 128 (0.78%)	0 / 242 (0.00%)
occurrences (all)	1	1	0
Liver function test abnormal			

subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Chillblains			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 126 (1.59%)	4 / 128 (3.13%)	10 / 242 (4.13%)
occurrences (all)	5	6	12
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	2 / 126 (1.59%)	2 / 128 (1.56%)	3 / 242 (1.24%)
occurrences (all)	3	2	7
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 126 (0.00%)	2 / 128 (1.56%)	1 / 242 (0.41%)
occurrences (all)	0	2	1
Leukopenia			
subjects affected / exposed	0 / 126 (0.00%)	1 / 128 (0.78%)	3 / 242 (1.24%)
occurrences (all)	0	1	4
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	2 / 126 (1.59%)	3 / 128 (2.34%)	6 / 242 (2.48%)
occurrences (all)	2	4	6
Gastritis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	1 / 126 (0.79%)	0 / 128 (0.00%)	7 / 242 (2.89%)
occurrences (all)	1	0	8
Mouth ulceration			

subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Oligomenorrhoea			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	4 / 242 (1.65%)
occurrences (all)	0	0	4
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 126 (0.00%)	3 / 128 (2.34%)	0 / 242 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences (all)	0	0	1
Synovial cyst			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences (all)	0	0	1
Axial spondyloarthritis			
subjects affected / exposed	2 / 126 (1.59%)	0 / 128 (0.00%)	2 / 242 (0.83%)
occurrences (all)	2	0	2
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	6 / 126 (4.76%)	13 / 128 (10.16%)	18 / 242 (7.44%)
occurrences (all)	6	13	21
Upper respiratory tract infection			
subjects affected / exposed	10 / 126 (7.94%)	9 / 128 (7.03%)	15 / 242 (6.20%)
occurrences (all)	11	9	17

Corona virus infection			
subjects affected / exposed	1 / 126 (0.79%)	1 / 128 (0.78%)	17 / 242 (7.02%)
occurrences (all)	1	1	17
Helicobacter infection			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 126 (0.00%)	4 / 128 (3.13%)	17 / 242 (7.02%)
occurrences (all)	0	5	20
Urinary tract infection			
subjects affected / exposed	2 / 126 (1.59%)	3 / 128 (2.34%)	4 / 242 (1.65%)
occurrences (all)	2	3	6
Tinea versicolour			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	0 / 242 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	1 / 242 (0.41%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	2 / 126 (1.59%)	2 / 128 (1.56%)	2 / 242 (0.83%)
occurrences (all)	2	2	2
Hyperlipidaemia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 128 (0.00%)	3 / 242 (1.24%)
occurrences (all)	0	0	3

Non-serious adverse events	Overall Period(up to Week 48+20 Weeks SFU):BKZ 160 mg Q4W(GP)	Placebo (up to Week 16) (China Extension Population)	BKZ 160 mg Q4W (up to Week 16) (China Extension Population)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	114 / 244 (46.72%)	8 / 11 (72.73%)	9 / 9 (100.00%)
Investigations			
Blood cholesterol increased			
subjects affected / exposed	1 / 244 (0.41%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Low density lipoprotein increased			
subjects affected / exposed	0 / 244 (0.00%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	0	1	0

Lymphocyte count decreased			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Weight decreased			
subjects affected / exposed	3 / 244 (1.23%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	3	0	1
Blood bilirubin increased			
subjects affected / exposed	1 / 244 (0.41%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Liver function test increased			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	2
Liver function test abnormal			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Injury, poisoning and procedural complications			
Chillblains			
subjects affected / exposed	0 / 244 (0.00%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Headache			
subjects affected / exposed	14 / 244 (5.74%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	18	0	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	5 / 244 (2.05%)	2 / 11 (18.18%)	0 / 9 (0.00%)
occurrences (all)	9	2	0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	3 / 244 (1.23%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	3	0	1
Leukopenia			
subjects affected / exposed	3 / 244 (1.23%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Eye disorders			

Vision blurred			
subjects affected / exposed	0 / 244 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	9 / 244 (3.69%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	10	0	1
Gastritis			
subjects affected / exposed	0 / 244 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	7 / 244 (2.87%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	8	0	1
Mouth ulceration			
subjects affected / exposed	0 / 244 (0.00%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Oligomenorrhoea			
subjects affected / exposed	0 / 244 (0.00%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 244 (0.00%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Eczema			
subjects affected / exposed	4 / 244 (1.64%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	4	1	0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	1 / 244 (0.41%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal pain			
subjects affected / exposed	3 / 244 (1.23%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	3	1	0
Musculoskeletal stiffness			

subjects affected / exposed	1 / 244 (0.41%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Synovial cyst			
subjects affected / exposed	1 / 244 (0.41%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Axial spondyloarthritis			
subjects affected / exposed	2 / 244 (0.82%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	30 / 244 (12.30%)	1 / 11 (9.09%)	0 / 9 (0.00%)
occurrences (all)	34	1	0
Upper respiratory tract infection			
subjects affected / exposed	23 / 244 (9.43%)	3 / 11 (27.27%)	1 / 9 (11.11%)
occurrences (all)	26	5	1
Corona virus infection			
subjects affected / exposed	17 / 244 (6.97%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	18	0	0
Helicobacter infection			
subjects affected / exposed	0 / 244 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	18 / 244 (7.38%)	0 / 11 (0.00%)	0 / 9 (0.00%)
occurrences (all)	25	0	0
Urinary tract infection			
subjects affected / exposed	7 / 244 (2.87%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	9	0	1
Tinea versicolour			
subjects affected / exposed	0 / 244 (0.00%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Tinea pedis			
subjects affected / exposed	1 / 244 (0.41%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Hypercholesterolaemia			

subjects affected / exposed	3 / 244 (1.23%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	4	0	2
Hyperlipidaemia			
subjects affected / exposed	3 / 244 (1.23%)	0 / 11 (0.00%)	1 / 9 (11.11%)
occurrences (all)	3	0	1

Non-serious adverse events	BKZ 160 mg Q4W (Weeks 16 up to 52)(China Extension Population)	Overall Period (up to Week 48+20 Week SFU):BKZ 160 mg Q4W(CP)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 20 (65.00%)	16 / 20 (80.00%)	
Investigations			
Blood cholesterol increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Low density lipoprotein increased			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Lymphocyte count decreased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Weight decreased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Blood bilirubin increased			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Liver function test increased			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	2	
Liver function test abnormal			
subjects affected / exposed	1 / 20 (5.00%)	3 / 20 (15.00%)	
occurrences (all)	1	3	
Injury, poisoning and procedural complications			
Chillblains			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	

Nervous system disorders			
Headache			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences (all)	1	2	
Leukopenia			
subjects affected / exposed	2 / 20 (10.00%)	2 / 20 (10.00%)	
occurrences (all)	3	3	
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Gastritis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Abdominal pain			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Mouth ulceration			
subjects affected / exposed	2 / 20 (10.00%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
Reproductive system and breast disorders			
Oligomenorrhoea			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			

Dermal cyst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Musculoskeletal stiffness			
subjects affected / exposed	1 / 20 (5.00%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Synovial cyst			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Axial spondyloarthritis			
subjects affected / exposed	2 / 20 (10.00%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	3 / 20 (15.00%)	4 / 20 (20.00%)	
occurrences (all)	3	4	
Corona virus infection			
subjects affected / exposed	4 / 20 (20.00%)	4 / 20 (20.00%)	
occurrences (all)	4	4	
Helicobacter infection			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	
occurrences (all)	1	2	
Oral candidiasis			

subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Tinea versicolour			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	
occurrences (all)	1	2	
Tinea pedis			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	
occurrences (all)	1	2	
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	
occurrences (all)	2	4	
Hyperlipidaemia			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 September 2019	Protocol Amendment 1 (11 Sep 2019) implemented changes in response to scientific discussions and feedback provided at meetings with Investigators and advisors or for clarifications. Mainly, imaging assessments were amended with sacroiliac joints and spine MRIs performed at Weeks 16 and 52 for all consenting study participants participating in the MRI substudy regardless of MRI positivity at Baseline. These additional MRIs allowed an exploratory evaluation of any changes in the sacroiliac joints or spine after 16 or 52 weeks in study participants who were MRI-negative at Baseline and on early signals such as the impact on erosions and fatty lesions at Week 16. Additionally, including MRI-positive and MRI-negative study participants in the substudy was considered a more holistic strategy comparable to the approach used for other compounds. At the same time, the number of participating study participants was expanded to include study participants in the substudy without restriction.
17 October 2019	Protocol Amendment 2 (17 Oct 2019) was implemented to update Inclusion Criterion to reflect the treatment guidelines for axSpA, as presented in the recent European League Against Rheumatism/ASAS and American College of Rheumatology/Spondyloarthritis Research and Treatment Network guidelines. In addition, a minor update for consistency was made.
16 February 2021	Protocol Amendment 4 (16 Feb 2021) updated the handling of missing data for the statistical analysis of the primary endpoint in response to an agency request. The COVID-19 Free Set (CFS) was added in response to industry recommendations for evaluating the impact of the pandemic. In addition, other previously planned supportive analyses defined in the Statistical Analysis Plan (SAP) were added for completeness.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported