Clinical trial results:
A Phase 2 Multicenter, Investigator-Blind, Subject-Blind, Placebo-Controlled Study of the Efficacy, Safety, and Pharmacokinetics of Bimekizumab in Subjects with Moderate to Severe Hidradenitis Suppurativa

Summary

EudraCT number	2017-000892-10
Trial protocol	DE BE DK GR
Global end of trial date	21 February 2019

Results information

Result version number	v1 (current)
This version publication date	07 March 2020
First version publication date	07 March 2020

Trial information

Trial identification

Sponsor protocol code	HS0001

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03248531
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	28 March 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 February 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the efficacy of bimekizumab in subjects with moderate to severe Hidradenitis Suppurativa (HS).

Protection of trial subjects:

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

Background therapy:

Subject agreed to daily use (and throughout the entirety of the study) of 1 of the following over-the-counter topical antiseptics on their HS lesions: chlorhexidine gluconate, triclosan, benzoyl peroxide, or dilute bleach in bathwater.
Concomitant use of oral antibiotic therapy for treatment of HS was allowed provided the dosing regimen (dose and frequency) had been stable for at least 4 consecutive weeks (28 days) prior to Baseline.

Evidence for comparator:

Adalimumab is the only approved medicinal product for the treatment of moderate to severe HS with an inadequate response to conventional systemic HS therapy (approved in Sep 2015).

Actual start date of recruitment	22 September 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 19
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Denmark: 3
Country: Number of subjects enrolled	Germany: 8
Country: Number of subjects enrolled	Norway: 2
Country: Number of subjects enrolled	Russian Federation: 11
Country: Number of subjects enrolled	United States: 46
Worldwide total number of subjects	90
EEA total number of subjects	14

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	89
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll patients in September 2017 and concluded in February 2019.

Pre-assignment

Screening details:

The study included a Screening Period (≥ 2 weeks up to a maximum of 4 weeks prior to randomization), a Treatment Period (12 weeks), and a Safety Follow-Up (SFU) Period (20 weeks after the last dose of investigational medicinal product (IMP)).
Participant Flow refers to the Randomized Set.

Period 1

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

Blinding implementation details:

For reporting of this study, due to limitations of the drop-down list for blinding, the wording Double Blind was utilized instead of Investigator- and Subject-Blind.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received several placebo applications to keep the blinding and as a control group.

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

Dosage and administration details:

Placebo will be provided for blinding and as a control group.

Arm title	Adalimumab

Arm description:

Participants received one Adalimumab loading dose 1, one Adalimumab dose 2 application and several Adalimumab dose 3 applications.

Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	Humira®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab in different dosages (dose 1, 2 and 3).

Arm title	Bimekizumab

Arm description:

Participants received one Bimekizumab loading dose 1 and several Bimekizumab dose 2 applications.

Arm type	Experimental

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

Dosage and administration details:

Bimekizumab in different dosages (dose 1 and 2).

Number of subjects in period 1	Placebo	Adalimumab	Bimekizumab
Started	22	22	46
Completed Week 12	19	18	42
Completed	18	17	38
Not completed	4	5	8
Consent withdrawn by subject	3	3	2
Adverse event, non-fatal	-	-	1
Lost to follow-up	1	-	5
Sponsor Request	-	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received several placebo applications to keep the blinding and as a control group.	
Reporting group title	Adalimumab
Reporting group description:	
Participants received one Adalimumab loading dose 1, one Adalimumab dose 2 application and several Adalimumab dose 3 applications.	
Reporting group title	Bimekizumab
Reporting group description:	
Participants received one Bimekizumab loading dose 1 and several Bimekizumab dose 2 applications.	

Reporting group values	Placebo	Adalimumab	Bimekizumab
Number of subjects	22	22	46
Age categorical Units: Subjects			
<=18 years	0	0	2
Between 18 and 65 years	21	22	44
>=65 years	1	0	0
Age continuous Units: years			
arithmetic mean	40.7	31.0	37.4
standard deviation	± 12.5	± 9.2	± 11.9
Gender categorical Units: Subjects			
Male	7	4	16
Female	15	18	30

Reporting group values	Total		
Number of subjects	90		
Age categorical Units: Subjects			
<=18 years	2		
Between 18 and 65 years	87		
>=65 years	1		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Male	27		
Female	63		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants received several placebo applications to keep the blinding and as a control group.	
Reporting group title	Adalimumab
Reporting group description:	
Participants received one Adalimumab loading dose 1, one Adalimumab dose 2 application and several Adalimumab dose 3 applications.	
Reporting group title	Bimekizumab
Reporting group description:	
Participants received one Bimekizumab loading dose 1 and several Bimekizumab dose 2 applications.	
Subject analysis set title	Placebo (PPS)
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received several placebo applications to keep the blinding and as a control group, forming the Per-Protocol Set (PPS).	
Subject analysis set title	Adalimumab (PPS)
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received one Adalimumab loading dose 1, one Adalimumab dose 2 application and several Adalimumab dose 3 applications, forming the PPS.	
Subject analysis set title	Bimekizumab (PPS)
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received one Bimekizumab loading dose 1 and several Bimekizumab dose 2 applications, forming the PPS.	
Subject analysis set title	Bimekizumab (PK-PPS)
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants received one Bimekizumab loading dose 1 and several Bimekizumab dose 2 applications, forming the Pharmacokinetic Per-Protocol Set (PK-PPS).	
Subject analysis set title	Placebo (SS)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received several placebo applications to keep the blinding and as a control group, forming the Safety Set (SS).	
Subject analysis set title	Adalimumab (SS)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received one Adalimumab loading dose 1, one Adalimumab dose 2 application and several Adalimumab dose 3 applications, forming the SS.	
Subject analysis set title	Bimekizumab (SS)
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants received one Bimekizumab loading dose 1 and several Bimekizumab dose 2 applications, forming the SS.	

Primary: Percentage of subjects achieving clinical response as measured by Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 12

End point title	Percentage of subjects achieving clinical response as measured by Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 12

End point description:

HiSCR was defined as at least a 50 % reduction from Baseline in the total abscess and inflammatory nodule (AN) count, with no increase from Baseline in abscess or draining fistula count.
Missing data were handled using non-response imputation (NRI) methods.

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo (PPS)	Adalimumab (PPS)	Bimekizumab (PPS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	20	20	44	
Units: percentage of participants				
number (confidence interval 95%)	23.7 (10.2 to 45.8)	59.8 (37.0 to 79.0)	56.9 (41.4 to 71.2)	

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

Results were based on a Bayesian logistic regression model where the number of responders was assumed to follow a binomial distribution. Treatment and Baseline Hurley Stage were included as predictors in the model.
95% credible intervals were presented for the BKZ vs PBO comparison.

Comparison groups	Placebo (PPS) v Bimekizumab (PPS)
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	other
Method	Regression, Logistic
Parameter estimate	Mean posterior difference
Point estimate	31.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	11
upper limit	50.4
Variability estimate	Standard deviation
Dispersion value	10.1

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

Results were based on a Bayesian logistic regression model where the number of responders was assumed to follow a binomial distribution. Treatment and Baseline Hurley Stage were included as predictors in the model.
60% credible intervals were presented for the BKZ vs ADA comparison.

Comparison groups	Adalimumab (PPS) v Bimekizumab (PPS)
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	other
Method	Regression, Logistic
Parameter estimate	Mean posterior difference
Point estimate	-2.2
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.2
upper limit	6.6
Variability estimate	Standard deviation
Dispersion value	10.6

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Results were based on a Bayesian logistic regression model where the number of responders was assumed to follow a binomial distribution. Treatment and Baseline Hurley Stage were included as predictors in the model.
Pr[Diff > 0%](%) refers to the probability that the BKZ response rate was greater than the PBO response rate.
0% Confidence Interval (CI) [0,999] was used a placeholder.

Comparison groups	Placebo (PPS) v Bimekizumab (PPS)
Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	other
Method	Regression, Logistic
Parameter estimate	Pr [Diff>0%] (%)
Point estimate	99.8
Confidence interval	
level	Other: 0 %
sides	2-sided
lower limit	0
upper limit	999

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Results were based on a Bayesian logistic regression model where the number of responders was assumed to follow a binomial distribution. Treatment and Baseline Hurley Stage were included as predictors in the model.
Pr[Diff > 0%](%) refers to the probability that the BKZ response rate was greater than the ADA response rate.
0% Confidence Interval (CI) [0,999] was used a placeholder.

Comparison groups	Adalimumab (PPS) v Bimekizumab (PPS)

Number of subjects included in analysis	64
Analysis specification	Pre-specified
Analysis type	other
Method	Regression, Logistic
Parameter estimate	Pr[Diff > 0%](%)
Point estimate	42.1
Confidence interval	
level	Other: 0 %
sides	2-sided
lower limit	0
upper limit	999

Secondary: Bimekizumab plasma concentration at Day 1

End point title	Bimekizumab plasma concentration at Day 1

End point description:

Plasma concentration of Bimekizumab was expressed in nanograms per milliliter (ng/mL).
Values Below Limit of Quantification (BLQ) were replaced by value of Lower Limit of Quantification (LLOQ) divided by 2 (75 ng/mL) in calculations of Means and Coefficient of Variations (CVs).
Means and CVs were only calculated if at least 2/3 of the concentrations were quantified at the respective visit.

Note: 999 is being used as a placeholder for values not reportable as per BLQ rules.

End point type	Secondary

End point timeframe:

Day 1

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	46			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	999 (± 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bimekizumab plasma concentration at Week 2

End point title	Bimekizumab plasma concentration at Week 2

End point description:

Plasma concentration of Bimekizumab was expressed in ng/mL.
Values BLQ were replaced by value of LLOQ/2 (75 ng/mL) in calculations of Means and CVs.
Means and CVs were only calculated if at least 2/3 of the concentrations were quantified at the respective visit.

End point type	Secondary

End point timeframe:

Week 2

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	45			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	24086.4 (± 56.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bimekizumab plasma concentration at Week 4

End point title	Bimekizumab plasma concentration at Week 4

End point description:

Plasma concentration of Bimekizumab was expressed in ng/mL.
Values BLQ were replaced by value of LLOQ/2 (75 ng/mL) in calculations of Means and CVs.
Means and CVs were only calculated if at least 2/3 of the concentrations were quantified at the respective visit.

End point type	Secondary

End point timeframe:

Week 4

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	46			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	26572.6 (± 57.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bimekizumab plasma concentration at Week 8

End point title	Bimekizumab plasma concentration at Week 8

End point description:

Plasma concentration of Bimekizumab was expressed in ng/mL.
Values BLQ were replaced by value of LLOQ/2 (75 ng/mL) in calculations of Means and CVs.
Means and CVs were only calculated if at least 2/3 of the concentrations were quantified at the

respective visit.

End point type	Secondary

End point timeframe:

Week 8

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	30222.6 (± 54.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bimekizumab plasma concentration at Week 12

End point title	Bimekizumab plasma concentration at Week 12

End point description:

Plasma concentration of Bimekizumab was expressed in ng/mL.
Values BLQ were replaced by value of LLOQ/2 (75 ng/mL) in calculations of Means and CVs.
Means and CVs were only calculated if at least 2/3 of the concentrations were quantified at the respective visit.

End point type	Secondary

End point timeframe:

Week 12

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	25319.0 (± 116.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Bimekizumab plasma concentration at Week 30

End point title	Bimekizumab plasma concentration at Week 30

End point description:

Plasma concentration of Bimekizumab was expressed in ng/mL.
Values BLQ were replaced by value of LLOQ/2 (75 ng/mL) in calculations of Means and CVs.
Means and CVs were only calculated if at least 2/3 of the concentrations were quantified at the respective visit.

Note: 999 is being used as a placeholder for values not reportable as per BLQ rules.

End point type	Secondary

End point timeframe:

Week 30

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	35			
Units: ng/mL				
geometric mean (geometric coefficient of variation)	999 (± 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one adverse event during the study

End point title	Percentage of participants with at least one adverse event during the study

End point description:

An adverse event (AE) was any untoward medical occurrence in a patient or clinical investigation study participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)	61.9	71.4	71.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one adverse event categorized by maximum severity during the study

End point title	Percentage of participants with at least one adverse event categorized by maximum severity during the study

End point description:

An adverse event (AE) was any untoward medical occurrence in a patient or clinical investigation study participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Mild	47.6	66.7	63.0	
Moderate	33.3	42.9	39.1	
Severe	4.8	9.5	6.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one serious adverse event during the study

End point title	Percentage of participants with at least one serious adverse event during the study

End point description:

A serious adverse event (SAE) was any untoward medical occurrence that at any dose:
- Resulted in death
- Was life-threatening
- Required in patient hospitalization or prolongation of existing hospitalisation
- Was a congenital anomaly or birth defect
- Was an infection that required treatment parenteral antibiotics
- Other important medical events which based on medical or scientific judgement may have jeopardised the patients, or may have required medical or surgical intervention to prevent any of the above.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)	9.5	4.8	4.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one serious adverse event categorized by severity during the study

End point title	Percentage of participants with at least one serious adverse event categorized by severity during the study

End point description:

A serious adverse event (SAE) was any untoward medical occurrence that at any dose:
- Resulted in death
- Was life-threatening
- Required in patient hospitalization or prolongation of existing hospitalisation
- Was a congenital anomaly or birth defect
- Was an infection that required treatment parenteral antibiotics
- Other important medical events which based on medical or scientific judgement may have jeopardised the patients, or may have required medical or surgical intervention to prevent any of the above.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Mild	0	4.8	0	
Moderate	4.8	0	0	
Severe	4.8	4.8	4.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants that withdrew due to adverse events during

the study

End point title	Percentage of participants that withdrew due to adverse events during the study

End point description:

An adverse event (AE) was any untoward medical occurrence in a patient or clinical investigation study participant administered a pharmaceutical product that did not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)	0	0	2.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in vital signs (blood pressure)

End point title	Change from Baseline until Safety Follow-up Visit in vital signs (blood pressure)

End point description:

Blood pressure was measured in millimeters of mercury (mmHg).

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: mmHg				
arithmetic mean (standard deviation)				
Systolic Blood Pressure (n= 18, 19, 38)	-2.9 (± 14.8)	4.5 (± 14.5)	-0.4 (± 13.8)	

Diastolic Blood Pressure (n= 18, 19, 38)	-1.8 (± 8.4)	-0.6 (± 9.1)	-2.2 (± 11.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in vital signs (pulse rate)

End point title	Change from Baseline until Safety Follow-up Visit in vital signs (pulse rate)
End point description:	
Pulse rate was measured in beats per minute (beats/min).	
End point type	Secondary
End point timeframe:	
From Screening to Safety Follow-Up (Week 30)	

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	19	38	
Units: beats/min				
arithmetic mean (standard deviation)	-1.4 (± 10.2)	-1.8 (± 10.8)	-1.6 (± 10.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in body weight

End point title	Change from Baseline until Safety Follow-up Visit in body weight
End point description:	
Body weight was measured in kilograms (kg).	
End point type	Secondary
End point timeframe:	
From Screening to Safety Follow-Up (Week 30)	

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	19	38	
Units: kg				
arithmetic mean (standard deviation)	0.90 (± 7.39)	1.82 (± 3.94)	0.42 (± 6.89)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in ECG parameters (ECG Mean Heart Rate)

End point title	Change from Baseline until Safety Follow-up Visit in ECG parameters (ECG Mean Heart Rate)

End point description:

Electrocardiogram (ECG) Mean Heart Rate was measured in beats/min.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	18	15	37	
Units: beats/min				
arithmetic mean (standard deviation)	-2.1 (± 12.4)	-2.1 (± 11.1)	1.5 (± 10.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in ECG parameters (PR Interval, QRS duration, QT interval, QTcF Interval)

End point title	Change from Baseline until Safety Follow-up Visit in ECG parameters (PR Interval, QRS duration, QT interval, QTcF Interval)

End point description:

PR Interval, QRS duration, QT interval and QT corrected for heart rate using Fridericia's correction (QTcF) Interval were measured in milliseconds (msec).

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:
From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: msec				
arithmetic mean (standard deviation)				
PR Interval (n= 18, 15, 37)	0.8 (± 18.8)	2.4 (± 10.5)	3.6 (± 18.7)	
QRS duration (n= 18, 15, 37)	-0.3 (± 7.1)	0.2 (± 5.2)	0.6 (± 7.4)	
QT interval (n= 18, 15, 37)	4.8 (± 20.2)	4.2 (± 26.7)	1.8 (± 27.7)	
QTcF Interval (n= 18, 15, 37)	-11.7 (± 49.9)	-0.3 (± 14.4)	2.4 (± 12.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes)

End point title	Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes)

End point description:
Erythrocytes was measured in number of red blood cells per liter (10^12/L).

End point type	Secondary

End point timeframe:
From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	18	33	
Units: 10^12 red blood cells per liter				
arithmetic mean (standard deviation)	0.144 (± 0.349)	-0.151 (± 0.416)	-0.013 (± 0.274)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (hematocrit)

End point title	Change from Baseline until Safety Follow-up Visit in

	hematology parameters (hematocrit)

End point description:

Hematocrit was measured in volume percentage (%) of red blood cells in blood.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	18	33	
Units: volume % of red blood cells				
arithmetic mean (standard deviation)	2.01 (± 2.83)	-0.81 (± 4.30)	0.39 (± 2.69)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (hemoglobin, erythrocytes mean corpuscular hemoglobin (HGB) concentration)

End point title	Change from Baseline until Safety Follow-up Visit in hematology parameters (hemoglobin, erythrocytes mean corpuscular hemoglobin (HGB) concentration)

End point description:

Hemoglobin, erythrocytes mean corpuscular hemoglobin (HGB) concentration were measured in grams per liter (g/L).

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: g/L				
arithmetic mean (standard deviation)				
Hemoglobin (n= 14, 18, 33)	5.3 (± 11.6)	-3.7 (± 11.6)	1.1 (± 7.6)	
Erythrocytes mean corpuscular HGB (n= 14, 18, 33)	-1.4 (± 16.2)	-2.6 (± 13.4)	-0.2 (± 13.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular hemoglobin (HGB))

End point title	Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular hemoglobin (HGB))

End point description:

Erythrocytes mean corpuscular hemoglobin (HGB) was measured in picograms (pg).

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	18	33	
Units: picograms (pg)				
arithmetic mean (standard deviation)	0.29 (± 0.76)	0.21 (± 0.78)	0.30 (± 0.99)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular volume)

End point title	Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular volume)

End point description:

Erythrocytes mean corpuscular volume was measured in femtolitres (fL).

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	18	33	
Units: femtolitres (fL)				
arithmetic mean (standard deviation)	1.49 (± 2.95)	1.36 (± 3.21)	1.04 (± 4.03)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (platelets)

End point title	Change from Baseline until Safety Follow-up Visit in hematology parameters (platelets)

End point description:

Platelets was measured in number of platelets per liter (10^9/L).

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	18	33	
Units: 10^9 platelets per liter				
arithmetic mean (standard deviation)	-17.4 (± 38.7)	2.3 (± 61.6)	-19.2 (± 51.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (leukocytes, basophils, eosinophils, lymphocytes, monocytes, neutrophils)

End point title	Change from Baseline until Safety Follow-up Visit in hematology parameters (leukocytes, basophils, eosinophils, lymphocytes, monocytes, neutrophils)

End point description:

Leukocytes, basophils, eosinophils, lymphocytes, monocytes and neutrophils were measured in number of white blood cells per liter (10^9/L).

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: 10^9 white blood cells per liter				
arithmetic mean (standard deviation)				
Leukocytes (n= 14, 18, 33)	-0.281 (± 2.621)	-0.114 (± 2.997)	-0.122 (± 2.308)	
Basophils (n= 14, 18, 33)	0.009 (± 0.026)	0.033 (± 0.077)	0.015 (± 0.048)	
Eosinophils (n= 14, 18, 33)	0.007 (± 0.077)	-0.012 (± 0.100)	0.002 (± 0.056)	
Lymphocytes (n= 14, 18, 33)	0.029 (± 0.812)	0.241 (± 0.682)	0.038 (± 0.570)	
Monocytes (n= 14, 18, 33)	0.072 (± 0.420)	-0.032 (± 0.322)	0.060 (± 0.192)	
Neutrophils (n= 14, 18, 33)	-0.396 (± 2.076)	-0.341 (± 2.460)	-0.240 (± 2.234)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (basophils/leukocytes, eosinophils/leukocytes, lymphocytes/leukocytes, monocytes/leukocytes, neutrophils/leukocytes)

End point title	Change from Baseline until Safety Follow-up Visit in hematology parameters (basophils/leukocytes, eosinophils/leukocytes, lymphocytes/leukocytes, monocytes/leukocytes, neutrophils/leukocytes)

End point description:

Basophils/leukocytes, eosinophils/leukocytes, lymphocytes/leukocytes, monocytes/leukocytes and neutrophils/leukocytes were measured in percentages (%).

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: % of white blood cells per leukocytes				
arithmetic mean (standard deviation)				
Basophils/leukocytes (n= 14, 18, 33)	0.13 (± 0.23)	0.42 (± 0.93)	0.13 (± 0.65)	
Eosinophils/leukocytes (n= 14, 18, 33)	-0.12 (± 1.92)	-0.03 (± 1.09)	0.12 (± 1.12)	
Lymphocytes/leukocytes (n= 14, 18, 33)	1.43 (± 5.47)	2.04 (± 6.73)	2.04 (± 8.07)	
Monocytes/leukocytes (n= 14, 18, 33)	0.49 (± 4.35)	-0.20 (± 2.79)	1.00 (± 2.17)	
Neutrophils/leukocytes (n= 14, 18, 33)	-1.93 (± 6.84)	-2.24 (± 7.50)	-3.29 (± 9.55)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in biochemistry parameters (bicarbonate, chloride, potassium, sodium, calcium, magnesium, urea nitrogen, cholesterol, glucose)

End point title	Change from Baseline until Safety Follow-up Visit in biochemistry parameters (bicarbonate, chloride, potassium, sodium, calcium, magnesium, urea nitrogen, cholesterol, glucose)

End point description:

Bicarbonate, chloride, potassium, sodium, calcium, magnesium, urea nitrogen, cholesterol and glucose were measured in millimoles per liter (mmol/L).

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: mmol/L				
arithmetic mean (standard deviation)				
Bicarbonate (n= 15, 19, 36)	-0.1 (± 2.1)	0.7 (± 2.8)	0.6 (± 2.3)	
Chloride (n= 15, 19, 36)	0.9 (± 1.5)	1.3 (± 2.4)	0.1 (± 2.2)	
Potassium (n= 15, 19, 36)	-0.13 (± 0.79)	-0.09 (± 0.37)	0.03 (± 0.41)	
Sodium (n= 15, 19, 36)	0.4 (± 1.5)	0.4 (± 1.6)	0.1 (± 2.2)	
Calcium (n= 15, 19, 36)	0.027 (± 0.065)	0.008 (± 0.144)	0.067 (± 0.095)	

Magnesium (n= 15, 19, 36)	-0.029 (± 0.087)	-0.027 (± 0.052)	-0.009 (± 0.081)	
Urea nitrogen (n= 15, 19, 36)	0.00 (± 1.46)	-0.43 (± 1.37)	0.29 (± 1.79)	
Cholesterol (n= 15, 19, 36)	-0.311 (± 0.667)	-0.177 (± 0.634)	0.157 (± 0.585)	
Glucose (n= 15, 19, 36)	1.049 (± 1.835)	0.436 (± 2.990)	0.439 (± 2.212)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in biochemistry parameters (creatinine, bilirubin, direct bilirubin, urate)

End point title	Change from Baseline until Safety Follow-up Visit in biochemistry parameters (creatinine, bilirubin, direct bilirubin, urate)

End point description:

Creatinine, bilirubin, direct bilirubin, urate were measured in micromols per liter (µmol/L).

Note 1: 999 was used as a placeholder for the values that were not calculated.
Note 2: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: µmol/L				
arithmetic mean (standard deviation)				
Creatinine (n= 15, 19, 36)	-1.73 (± 9.92)	-1.72 (± 9.04)	3.84 (± 9.22)	
Bilirubin (n= 15, 19, 34)	0.17 (± 3.48)	-1.38 (± 3.04)	0.18 (± 4.35)	
Direct bilirubin (n= 0, 0, 0)	999 (± 999)	999 (± 999)	999 (± 999)	
Urate (n= 15, 19, 34)	8.7 (± 52.2)	-8.9 (± 50.5)	1.5 (± 43.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in biochemistry parameters (C reactive protein high sensitivity)

End point title	Change from Baseline until Safety Follow-up Visit in

	biochemistry parameters (C reactive protein high sensitivity)

End point description:

C reactive protein high sensitivity was measure in milligrams per liters (mg/L).

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	19	36	
Units: mg/L				
arithmetic mean (standard deviation)	-2.801 (± 16.851)	-4.865 (± 21.863)	-2.810 (± 10.853)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in biochemistry parameters (alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, gamma glutamyl transferase, lactate dehydrogenase)

End point title	Change from Baseline until Safety Follow-up Visit in biochemistry parameters (alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, gamma glutamyl transferase, lactate dehydrogenase)

End point description:

Alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, gamma glutamyl transferase, lactate dehydrogenase were measured in units per liter (U/L).

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: U/L				
arithmetic mean (standard deviation)				
Alanine aminotransferase (n= 15, 19, 34))	-3.3 (± 8.3)	-3.6 (± 9.8)	3.6 (± 23.8)	
Alkaline phosphatase (n= 15, 19, 36)	-2.0 (± 12.2)	-2.4 (± 13.5)	-3.4 (± 11.6)	

Aspartate aminotransferase (n= 15, 19, 36)	-0.6 (± 3.6)	-1.0 (± 5.8)	2.0 (± 13.3)	
Gamma glutamyl transferase (n= 15, 19, 36)	-2.0 (± 9.5)	1.8 (± 14.2)	2.3 (± 10.1)	
Lactate dehydrogenase (n= 15, 19, 36)	-17.0 (± 29.9)	-16.3 (± 35.6)	-12.8 (± 61.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine urobilinogen)

End point title	Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine urobilinogen)

End point description:

Urine urobilinogen was measured in Ehrlich units per deciliter (EU/dL).

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	16	31	
Units: EU/dL				
arithmetic mean (standard deviation)	0.00 (± 0.00)	-0.05 (± 0.20)	0.08 (± 0.24)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine pH)

End point title	Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine pH)

End point description:

Urine pH was measured on a pH scale.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	14	16	31	
Units: pH				
arithmetic mean (standard deviation)	-0.43 (± 0.98)	-0.25 (± 0.55)	-0.03 (± 0.69)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine albumin)

End point title	Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine albumin)

End point description:

Urine albumin was measured in milligrams per liter (mg/L).

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	18	34	
Units: mg/L				
arithmetic mean (standard deviation)	50.80 (± 211.30)	-28.25 (± 121.29)	0.49 (± 19.92)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine albumin/creatinine)

End point title	Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine albumin/creatinine)

End point description:

Urine albumin/creatinine was measured in milligrams per millimol (mg/mmol).

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	17	33	
Units: mg/mmol				
arithmetic mean (standard deviation)	2.46 (± 9.83)	-1.34 (± 4.98)	-0.19 (± 1.82)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine creatinine)

End point title	Change from Baseline until Safety Follow-up Visit in urinalysis parameters (urine creatinine)

End point description:

Urine creatinine was measured in millimoles per liter (mmol/L).

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	15	18	34	
Units: mmol/L				
arithmetic mean (standard deviation)	-0.92 (± 7.33)	0.63 (± 7.82)	3.99 (± 10.27)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine bilirubin)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine bilirubin)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Low – Week 30 Normal (14, 16, 31)	0	0	0	
Baseline Low – Week 30 High (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Normal (14, 16, 31)	92.9	93.8	90.3	
Baseline Normal – Week 30 High (14, 16, 31)	0	0	9.7	
Baseline High – Week 30 Low (14, 16, 31)	0	0	0	
Baseline High – Week 30 Normal (14, 16, 31)	0	6.3	0	
Baseline High – Week 30 High (14, 16, 31)	7.1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine glucose)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine glucose)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Low – Week 30 Normal (14, 16, 31)	0	0	0	
Baseline Low – Week 30 High (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Normal (14, 16, 31)	85.7	87.5	90.3	
Baseline Normal – Week 30 High (14, 16, 31)	7.1	6.3	0	
Baseline High – Week 30 Low (14, 16, 31)	0	0	0	
Baseline High – Week 30 Normal (14, 16, 31)	0	6.3	3.2	
Baseline High – Week 30 High (14, 16, 31)	7.1	0	6.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine hemoglobin)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine hemoglobin)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Low – Week 30 Normal (14, 16, 31)	0	0	0	
Baseline Low – Week 30 High (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Normal (14, 16, 31)	64.3	50.0	80.6	
Baseline Normal – Week 30 High (14, 16, 31)	0	12.5	3.2	
Baseline High – Week 30 Low (14, 16, 31)	0	0	0	
Baseline High – Week 30 Normal (14, 16, 31)	14.3	18.8	12.9	
Baseline High – Week 30 High (14, 16, 31)	21.4	18.8	3.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine ketones)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine ketones)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Low – Week 30 Normal (14, 16, 31)	0	0	0	
Baseline Low – Week 30 High (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Normal (14, 16, 31)	71.4	87.5	87.1	
Baseline Normal – Week 30 High (14, 16, 31)	14.3	6.3	12.9	
Baseline High – Week 30 Low (14, 16, 31)	0	0	0	
Baseline High – Week 30 Normal (14, 16, 31)	7.1	6.3	0	
Baseline High – Week 30 High (14, 16, 31)	7.1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine leukocyte esterase)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine leukocyte esterase)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Low – Week 30 Normal (14, 16, 31)	0	0	0	
Baseline Low – Week 30 High (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Normal (14, 16, 31)	57.1	56.3	61.3	
Baseline Normal – Week 30 High (14, 16, 31)	14.3	0	19.4	
Baseline High – Week 30 Low (14, 16, 31)	0	0	0	
Baseline High – Week 30 Normal (14, 16, 31)	14.3	18.8	19.4	
Baseline High – Week 30 High (14, 16, 31)	14.3	25.0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine nitrite)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine nitrite)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Low – Week 30 Normal (14, 16, 31)	0	0	0	
Baseline Low – Week 30 High (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Normal (14, 16, 31)	92.9	93.8	100	
Baseline Normal – Week 30 High (14, 16, 31)	0	0	0	
Baseline High – Week 30 Low (14, 16, 31)	0	0	0	
Baseline High – Week 30 Normal (14, 16, 31)	7.1	6.3	0	
Baseline High – Week 30 High (14, 16, 31)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine protein)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine protein)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Low – Week 30 Normal (14, 16, 31)	0	0	0	
Baseline Low – Week 30 High (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Low (14, 16, 31)	0	0	0	
Baseline Normal – Week 30 Normal (14, 16, 31)	50.0	75.0	61.3	
Baseline Normal – Week 30 High (14, 16, 31)	14.3	6.3	19.4	
Baseline High – Week 30 Low (14, 16, 31)	0	0	0	
Baseline High – Week 30 Normal (14, 16, 31)	28.6	12.5	9.7	
Baseline High – Week 30 High (14, 16, 31)	7.1	6.3	9.7	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine bacteria)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine bacteria)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (3, 6, 2)	0	0	0	
Baseline Low – Week 30 Normal (3, 6, 2)	0	0	0	
Baseline Low – Week 30 High (3, 6, 2)	0	0	0	
Baseline Normal – Week 30 Low (3, 6, 2)	0	0	0	
Baseline Normal – Week 30 Normal (3, 6, 2)	0	0	0	
Baseline Normal – Week 30 High (3, 6, 2)	0	0	0	
Baseline High – Week 30 Low (3, 6, 2)	0	0	0	
Baseline High – Week 30 Normal (3, 6, 2)	0	0	0	
Baseline High – Week 30 High (3, 6, 2)	100	100	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine erythrocytes)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine erythrocytes)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (3, 1, 1)	0	0	0	
Baseline Low – Week 30 Normal (3, 1, 1)	0	0	0	

Baseline Low – Week 30 High (3, 1, 1)	0	0	0	
Baseline Normal – Week 30 Low (3, 1, 1)	0	0	0	
Baseline Normal – Week 30 Normal (3, 1, 1)	33.3	0	100	
Baseline Normal – Week 30 High (3, 1, 1)	0	0	0	
Baseline High – Week 30 Low (3, 1, 1)	0	0	0	
Baseline High – Week 30 Normal (3, 1, 1)	0	0	0	
Baseline High – Week 30 High (3, 1, 1)	66.7	100	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine mucus)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine mucus)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (0, 1, 3)	0	0	0	
Baseline Low – Week 30 Normal (0, 1, 3)	0	0	0	
Baseline Low – Week 30 High (0, 1, 3)	0	0	0	
Baseline Normal – Week 30 Low (0, 1, 3)	0	0	0	
Baseline Normal – Week 30 Normal (0, 1, 3)	0	100	0	
Baseline Normal – Week 30 High (0, 1, 3)	0	0	33.3	
Baseline High – Week 30 Low (0, 1, 3)	0	0	0	
Baseline High – Week 30 Normal (0, 1, 3)	0	0	33.3	

Baseline High – Week 30 High (0, 1, 3)	0	0	33.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine squamous epithelial cells)

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in urinalysis parameters (urine squamous epithelial cells)

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 30.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Low – Week 30 Low (4, 6, 7)	0	0	0	
Baseline Low – Week 30 Normal (4, 6, 7)	0	0	0	
Baseline Low – Week 30 High (4, 6, 7)	0	0	0	
Baseline Normal – Week 30 Low (4, 6, 7)	0	0	0	
Baseline Normal – Week 30 Normal (4, 6, 7)	0	33.3	28.6	
Baseline Normal – Week 30 High (4, 6, 7)	25.0	0	28.6	
Baseline High – Week 30 Low (4, 6, 7)	0	0	0	
Baseline High – Week 30 Normal (4, 6, 7)	25.0	0	14.3	
Baseline High – Week 30 High (4, 6, 7)	50.0	66.7	28.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Safety Follow-up Visit in physical examination

End point title	Percentage of participants who shifted from Baseline until Safety Follow-up Visit in physical examination

End point description:

Percentages were based on the number of participants with non-missing physical exam results at Baseline and at Week 30 and on the number of participants with a normal/at least one abnormal physical examination assessment.

Note: The number of participants analyzed in Week 30 (Safety Follow-Up) for each parameter is presented in parentheses following this model (n= n1, n2, n3) where:
n1 = number of participants analyzed in the Placebo (SS) group;
n2 = number of participants analyzed in the Adalimumab (SS) group;
n3 = number of participants analyzed in the Bimekizumab (SS) group.

End point type	Secondary

End point timeframe:

From Screening to Safety Follow-Up (Week 30)

End point values	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	21	21	46	
Units: percentage of participants				
number (not applicable)				
Baseline Normal – Week 30 Normal (18, 19, 38)	77.8	78.9	73.7	
Baseline Normal – Week 30 Abnormal (18, 19, 38)	5.6	10.5	13.2	
Baseline Abnormal – Week 30 Normal (18, 19, 38)	5.6	5.3	2.6	
Baseline Abnormal – Week 30 Abnormal (18, 19, 38)	11.1	5.3	10.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Day 1

End point title	Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Day 1

End point description:

The overall status of a study participant was ‘Positive’ if at any post-Baseline visit the result was positive.
Percentages were based on the number of study participants with a non-missing measurement, from samples that did not contain BKZ concentration levels above the drug tolerance, at the visit.

End point type	Secondary

End point timeframe:

Day 1

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	46			
Units: percentage of participants				
number (not applicable)	4.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Week 2

End point title	Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Week 2

End point description:

The overall status of a study participant was 'Positive' if at any post-Baseline visit the result was positive.
Percentages were based on the number of study participants with a non-missing measurement, from samples that did not contain BKZ concentration levels above the drug tolerance, at the visit.

End point type	Secondary

End point timeframe:

Week 2

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	45			
Units: percentage of participants				
number (not applicable)	4.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Week 4

End point title	Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Week 4

End point description:

The overall status of a study participant was 'Positive' if at any post-Baseline visit the result was positive.
Percentages were based on the number of study participants with a non-missing measurement, from

samples that did not contain BKZ concentration levels above the drug tolerance, at the visit.

End point type	Secondary

End point timeframe:

Week 4

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	46			
Units: percentage of participants				
number (not applicable)	4.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Week 8

End point title	Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Week 8

End point description:

The overall status of a study participant was ‘Positive’ if at any post-Baseline visit the result was positive.
Percentages were based on the number of study participants with a non-missing measurement, from samples that did not contain BKZ concentration levels above the drug tolerance, at the visit.

End point type	Secondary

End point timeframe:

Week 8

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of participants				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Week 12

End point title	Percentage of participants with positive Bimekizumab anti-drug

	antibody (ADA) concentration at Week 12

End point description:

The overall status of a study participant was 'Positive' if at any post-Baseline visit the result was positive.
Percentages were based on the number of study participants with a non-missing measurement, from samples that did not contain BKZ concentration levels above the drug tolerance, at the visit.

End point type	Secondary

End point timeframe:

Week 12

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: percentage of participants				
number (not applicable)	9.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Week 30

End point title	Percentage of participants with positive Bimekizumab anti-drug antibody (ADA) concentration at Week 30

End point description:

The overall status of a study participant was 'Positive' if at any post-Baseline visit the result was positive.
Percentages were based on the number of study participants with a non-missing measurement, from samples that did not contain BKZ concentration levels above the drug tolerance, at the visit

End point type	Secondary

End point timeframe:

Week 30

End point values	Bimekizumab (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	36			
Units: percentage of participants				
number (not applicable)	13.9			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse events were collected from Baseline (Day 1) until the Safety Follow-Up Visit (Week 30)	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups	
Reporting group title	Placebo (SS)
Reporting group description:	
Participants received several placebo applications to keep the blinding and as a control group, forming the Safety Set (SS).	
Reporting group title	Adalimumab (SS)
Reporting group description:	
Participants received one Adalimumab loading dose 1, one Adalimumab dose 2 application and several Adalimumab dose 3 applications, forming the SS.	
Reporting group title	Bimekizumab (SS)
Reporting group description:	
Participants received one Bimekizumab loading dose 1 and several Bimekizumab dose 2 applications, forming the SS.	

Serious adverse events	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 21 (9.52%)	1 / 21 (4.76%)	2 / 46 (4.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 21 (4.76%)	0 / 21 (0.00%)	0 / 46 (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
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 21 (4.76%)	0 / 21 (0.00%)	0 / 46 (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
Dizziness			

subjects affected / exposed	1 / 21 (4.76%)	0 / 21 (0.00%)	0 / 46 (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
Hypoaesthesia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 21 (0.00%)	0 / 46 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 21 (4.76%)	0 / 46 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Empyema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	1 / 46 (2.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo (SS)	Adalimumab (SS)	Bimekizumab (SS)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 21 (23.81%)	12 / 21 (57.14%)	21 / 46 (45.65%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Nervous system disorders			
Headache			

subjects affected / exposed	3 / 21 (14.29%)	0 / 21 (0.00%)	3 / 46 (6.52%)
occurrences (all)	4	0	4
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 21 (0.00%)	2 / 21 (9.52%)	4 / 46 (8.70%)
occurrences (all)	0	2	4
Pyrexia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 21 (9.52%)	1 / 46 (2.17%)
occurrences (all)	0	2	2
Injection site reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	4
Injection site pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 21 (0.00%)	3 / 46 (6.52%)
occurrences (all)	0	0	3
Injection site pruritus			
subjects affected / exposed	0 / 21 (0.00%)	2 / 21 (9.52%)	2 / 46 (4.35%)
occurrences (all)	0	2	2
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 21 (4.76%)	3 / 46 (6.52%)
occurrences (all)	0	2	5
Nausea			
subjects affected / exposed	0 / 21 (0.00%)	1 / 21 (4.76%)	3 / 46 (6.52%)
occurrences (all)	0	1	3
Skin and subcutaneous tissue disorders			
Hidradenitis			
subjects affected / exposed	3 / 21 (14.29%)	6 / 21 (28.57%)	8 / 46 (17.39%)
occurrences (all)	3	6	9
Intertrigo			
subjects affected / exposed	0 / 21 (0.00%)	1 / 21 (4.76%)	3 / 46 (6.52%)
occurrences (all)	0	1	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 21 (4.76%)	2 / 21 (9.52%)	1 / 46 (2.17%)
occurrences (all)	1	2	3

Infections and infestations			
Oral candidiasis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 21 (4.76%)	3 / 46 (6.52%)
occurrences (all)	0	1	4
Influenza			
subjects affected / exposed	0 / 21 (0.00%)	3 / 21 (14.29%)	0 / 46 (0.00%)
occurrences (all)	0	3	0
Nasopharyngitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 21 (4.76%)	3 / 46 (6.52%)
occurrences (all)	0	1	4
Upper respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	2 / 21 (9.52%)	2 / 46 (4.35%)
occurrences (all)	0	2	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 March 2018	Protocol Amendment 1 was dated 08 Mar 2018. The purpose of this substantial amendment was to revise the withdrawal criteria to provide instructions for the management of study participants with newly diagnosed inflammatory bowel disease (IBD) or with IBD flares during the study. Other key changes included the following: The statistical analysis section of the protocol was also updated to include text describing the planned analysis of the primary efficacy variable, and text describing the planned interim analyses and sample size re-estimation was revised. The rationale for this was that the observed pattern of study participant recruitment was not as expected at the time of study planning. Consequently, an insufficient number of study participants would have completed the Week 12 visit and would be evaluable for response at the time of the first interim analysis. The risk of performing an analysis with a very small amount of data was that the estimates obtained from the analysis would be unstable and the risk of committing a Type II error would be inflated. To mitigate these risks it was decided to remove the formal futility and sample size re-estimation aspects from the first interim analysis. Additional changes included updates to study contact information; minor formatting corrections were also made.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported