



Clinical trial results:

A Multicenter, Randomized, Subject-Blind, Investigator-Blind Study to Evaluate the Time Course of Pharmacodynamic Response, Safety and Pharmacokinetics of Bimekizumab in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis

Summary

EudraCT number	2016-002368-15
Trial protocol	DE
Global end of trial date	11 December 2017

Results information

Result version number	v1 (current)
This version publication date	16 October 2022
First version publication date	16 October 2022

Trial information

Trial identification

Sponsor protocol code	PS0016
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03025542
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 April 2018
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 December 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the time-course of Psoriasis Area and Severity Index (PASI) over a 28-week period following the administration of bimekizumab given at Baseline and Week 4 to subjects with moderate to severe chronic plaque psoriasis.

Protection of trial subjects:

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

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	27 December 2016
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	Canada: 12
Country: Number of subjects enrolled	Australia: 19
Country: Number of subjects enrolled	Moldova, Republic of: 17
Country: Number of subjects enrolled	United States: 1
Worldwide total number of subjects	49
EEA total number of subjects	0

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)	46
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll patients in December 2016 and concluded in December 2017.

Pre-assignment

Screening details:

Participant Flow refers to the Safety Set (SS).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	BKZ 320 mg + PBO

Arm description:

Bimekizumab 320 milligrams (mg) administered subcutaneously (sc) at Baseline and Week 4, and placebo administered at Week 16.

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:

Subjects were administered 320 milligrams (mg) of bimekizumab as a subcutaneous (sc) injection.

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:

Subjects were administered matching placebo subcutaneous injections.

Arm title	BKZ 320 mg
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Arm description:

Bimekizumab 320 mg administered sc at Baseline and Weeks 4 and 16.

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:

Subjects were administered 320 milligrams (mg) of bimekizumab as a subcutaneous (sc) injection.

Number of subjects in period 1	BKZ 320 mg + PBO	BKZ 320 mg
Started	32	17
Completed	30	15
Not completed	2	2
Consent withdrawn by subject	1	-
Adverse event, non-fatal	-	2
Lost to follow-up	1	-

Baseline characteristics

Reporting groups

Reporting group title	BKZ 320 mg + PBO
Reporting group description: Bimekizumab 320 milligrams (mg) administered subcutaneously (sc) at Baseline and Week 4, and placebo administered at Week 16.	
Reporting group title	BKZ 320 mg
Reporting group description: Bimekizumab 320 mg administered sc at Baseline and Weeks 4 and 16.	

Reporting group values	BKZ 320 mg + PBO	BKZ 320 mg	Total
Number of subjects	32	17	49
Age categorical			
Units: Subjects			
<=18 years	0	0	0
Between 18 and 65 years	30	16	46
>=65 years	2	1	3
Age continuous			
Units: years			
arithmetic mean	41.8	45.9	
standard deviation	± 14.1	± 10.4	-
Gender categorical			
Units: Subjects			
Female	17	6	23
Male	15	11	26

End points

End points reporting groups

Reporting group title	BKZ 320 mg + PBO
Reporting group description: Bimekizumab 320 milligrams (mg) administered subcutaneously (sc) at Baseline and Week 4, and placebo administered at Week 16.	
Reporting group title	BKZ 320 mg
Reporting group description: Bimekizumab 320 mg administered sc at Baseline and Weeks 4 and 16.	
Subject analysis set title	BKZ 320 mg + PBO (SS)
Subject analysis set type	Safety analysis
Subject analysis set description: Bimekizumab 320 milligrams (mg) administered subcutaneously (sc) at Baseline and Week 4, and placebo administered at Week 16.	
Subject analysis set title	BKZ 320 mg (SS)
Subject analysis set type	Safety analysis
Subject analysis set description: Bimekizumab 320 mg administered sc at Baseline and Weeks 4 and 16.	
Subject analysis set title	BKZ 320 mg + PBO (PK-PPS)
Subject analysis set type	Per protocol
Subject analysis set description: Bimekizumab 320 milligrams (mg) administered subcutaneously (sc) at Baseline and Week 4, and placebo administered at Week 16.	
Subject analysis set title	BKZ 320 mg (PK-PPS)
Subject analysis set type	Per protocol
Subject analysis set description: Bimekizumab 320 mg administered sc at Baseline and Weeks 4 and 16.	
Subject analysis set title	BKZ 320 mg + PBO (FAS)
Subject analysis set type	Full analysis
Subject analysis set description: Bimekizumab 320 milligrams (mg) administered subcutaneously (sc) at Baseline and Week 4, and placebo administered at Week 16.	
Subject analysis set title	BKZ 320 mg (FAS)
Subject analysis set type	Full analysis
Subject analysis set description: Bimekizumab 320 mg administered sc at Baseline and Weeks 4 and 16.	

Primary: Change from Baseline in Psoriasis Area and Severity Index (PASI) at Week 28

End point title	Change from Baseline in Psoriasis Area and Severity Index (PASI) at Week 28 ^[1]
End point description: The PASI is the most commonly used and validated assessment for grading the severity of psoriasis in clinical studies. The PASI quantifies the severity and extent of the disease and weighs these with the percentage of body surface area (BSA) involvement. The percent area of involvement (BSA%) is estimated across 4 body areas; head (10%), upper limbs (20%), trunk (30%), and lower limbs (40%) and then transferred into a grade. The Investigator assesses the average redness, thickness, and scaliness of lesions in each body area (each on a 5 point scale); 0=none, 1=slight, 2=moderate, 3=marked, and 4=very marked. The PASI score ranges from 0 to 72 with a higher score indicating increased disease severity.	
End point type	Primary
End point timeframe: From Baseline to Week 28	

Notes:

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

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

End point values	BKZ 320 mg + PBO (FAS)	BKZ 320 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	17		
Units: scores on a scale				
arithmetic mean (standard deviation)				
Mean (Standard Deviation)	-10.76 (\pm 7.58)	-19.74 (\pm 8.77)		

Statistical analyses

No statistical analyses for this end point

Primary: Mean plasma concentration of bimekizumab at Week 16

End point title	Mean plasma concentration of bimekizumab at Week 16 ^[2]
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End point description:

Plasma concentration was expressed as geometric mean concentrations (GMCs) and measured in micrograms per milliliter ($\mu\text{g/mL}$). Note: Means, Lower confidence interval (LCI), Upper confidence interval (UCI) are only calculated if at least 2/3 of the concentrations were quantified at the respective time point. Values below limit of quantification (BLQ) are replaced by value of lower limit of quantification (LLOQ)/2 ($=0.075\mu\text{g/mL}$) in calculations of means.

End point type	Primary
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End point timeframe:

At Week 16

Notes:

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

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

End point values	BKZ 320 mg + PBO (PK-PPS)	BKZ 320 mg (PK-PPS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31	15		
Units: $\mu\text{g/mL}$				
geometric mean (confidence interval 95%)				
Geometric Mean (95% CI)	2.200 (1.6 to 3.0)	2.293 (1.4 to 3.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants reporting positive Anti-Drug-Antibodies (ADA)

titre prior to and following study treatment with bimekizumab at Baseline

End point title	Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Baseline ^[3]
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End point description:

An ADA status of positive was concluded for any subject with an ADA level that was above cut point (ACP) and 'confirmed positive' (CP) at any time point. A subject was classified as having treatment-induced ADA positivity when meeting one of the following criteria: -The Baseline result was either below cut point (BCP) or ACP and 'not confirmed positive' (NCP), and at least 1 post Baseline time point was ACP and CP. -The Baseline result was positive (ACP and CP) and at least one post-Baseline measurement showed a pre-defined fold increase in titre from the Baseline value. Note: The overall status of a subject is 'Positive' if at any post-Baseline visit the result was ACP and confirmed positive.

End point type	Primary
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End point timeframe:

At Baseline

Notes:

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

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

End point values	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	17		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	3.1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 4

End point title	Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 4 ^[4]
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End point description:

An ADA status of positive was concluded for any subject with an ADA level that was above cut point (ACP) and 'confirmed positive' (CP) at any time point. A subject was classified as having treatment-induced ADA positivity when meeting one of the following criteria: -The Baseline result was either below cut point (BCP) or ACP and 'not confirmed positive' (NCP), and at least 1 post Baseline time point was ACP and CP. -The Baseline result was positive (ACP and CP) and at least one post-Baseline measurement showed a pre-defined fold increase in titre from the Baseline value. Note: The overall status of a subject is 'Positive' if at any post-Baseline visit the result was ACP and confirmed positive.

End point type	Primary
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End point timeframe:

At Week 4

Notes:

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

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

End point values	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31	17		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 8

End point title	Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 8 ^[5]
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End point description:

An ADA status of positive was concluded for any subject with an ADA level that was above cut point (ACP) and 'confirmed positive' (CP) at any time point. A subject was classified as having treatment-induced ADA positivity when meeting one of the following criteria: -The Baseline result was either below cut point (BCP) or ACP and 'not confirmed positive' (NCP), and at least 1 post Baseline time point was ACP and CP. -The Baseline result was positive (ACP and CP) and at least one post-Baseline measurement showed a pre-defined fold increase in titre from the Baseline value. Note: The overall status of a subject is 'Positive' if at any post-Baseline visit the result was ACP and confirmed positive.

End point type	Primary
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End point timeframe:

At Week 8

Notes:

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

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

End point values	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31	16		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 12

End point title	Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 12 ^[6]
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End point description:

An ADA status of positive was concluded for any subject with an ADA level that was above cut point (ACP) and 'confirmed positive' (CP) at any time point. A subject was classified as having treatment-induced ADA positivity when meeting one of the following criteria: -The Baseline result was either below cut point (BCP) or ACP and 'not confirmed positive' (NCP), and at least 1 post Baseline time point was ACP and CP. -The Baseline result was positive (ACP and CP) and at least one post-Baseline measurement showed a pre-defined fold increase in titre from the Baseline value. Note: The overall status of a subject is 'Positive' if at any post-Baseline visit the result was ACP and confirmed positive.

End point type	Primary
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End point timeframe:

At Week 12

Notes:

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

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

End point values	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31	15		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	3.2	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 16

End point title	Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 16 ^[7]
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End point description:

An ADA status of positive was concluded for any subject with an ADA level that was above cut point (ACP) and 'confirmed positive' (CP) at any time point. A subject was classified as having treatment-induced ADA positivity when meeting one of the following criteria: -The Baseline result was either below cut point (BCP) or ACP and 'not confirmed positive' (NCP), and at least 1 post Baseline time point was ACP and CP. -The Baseline result was positive (ACP and CP) and at least one post-Baseline measurement showed a pre-defined fold increase in titre from the Baseline value. Note: The overall status of a subject is 'Positive' if at any post-Baseline visit the result was ACP and confirmed positive.

End point type	Primary
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End point timeframe:

At Week 16

Notes:

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

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

End point values	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31	15		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	3.2	6.7		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 20

End point title	Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 20 ^[8]
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End point description:

An ADA status of positive was concluded for any subject with an ADA level that was above cut point (ACP) and 'confirmed positive' (CP) at any time point. A subject was classified as having treatment-induced ADA positivity when meeting one of the following criteria: -The Baseline result was either below cut point (BCP) or ACP and 'not confirmed positive' (NCP), and at least 1 post Baseline time point was ACP and CP. -The Baseline result was positive (ACP and CP) and at least one post-Baseline measurement showed a pre-defined fold increase in titre from the Baseline value. Note: The overall status of a subject is 'Positive' if at any post-Baseline visit the result was ACP and confirmed positive.

End point type	Primary
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End point timeframe:

At Week 20

Notes:

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

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

End point values	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31	15		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	12.9	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 24

End point title	Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 24 ^[9]
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End point description:

An ADA status of positive was concluded for any subject with an ADA level that was above cut point (ACP) and 'confirmed positive' (CP) at any time point. A subject was classified as having treatment-induced ADA positivity when meeting one of the following criteria: -The Baseline result was either below cut point (BCP) or ACP and 'not confirmed positive' (NCP), and at least 1 post Baseline time point was ACP and CP. -The Baseline result was positive (ACP and CP) and at least one post-Baseline measurement showed a pre-defined fold increase in titre from the Baseline value. Note: The overall status of a subject is 'Positive' if at any post-Baseline visit the result was ACP and confirmed positive.

End point type	Primary
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End point timeframe:

At Week 24

Notes:

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

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

End point values	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	15		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	14.3	6.7		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 28

End point title	Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 28 ^[10]
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End point description:

An ADA status of positive was concluded for any subject with an ADA level that was above cut point (ACP) and 'confirmed positive' (CP) at any time point. A subject was classified as having treatment-induced ADA positivity when meeting one of the following criteria: -The Baseline result was either below cut point (BCP) or ACP and 'not confirmed positive' (NCP), and at least 1 post Baseline time point was ACP and CP. -The Baseline result was positive (ACP and CP) and at least one post-Baseline measurement showed a pre-defined fold increase in titre from the Baseline value. Note: The overall status of a subject is 'Positive' if at any post-Baseline visit the result was ACP and confirmed positive.

End point type	Primary
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End point timeframe:

At Week 28

Notes:

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

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

End point values	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	13		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	26.9	30.8		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects who experienced at least one adverse events (AEs)

End point title	Percentage of subjects who experienced at least one adverse events (AEs) ^[11]
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End point description:

An Adverse Event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment.

End point type	Primary
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End point timeframe:

From Baseline to Safety Follow Up Visit (Week 36)

Notes:

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

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

End point values	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	17		
Units: percentage of subjects				
number (not applicable)				
percentage of subjects	87.5	88.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a 75% or higher improvement from Baseline in PASI (Psoriasis Area and Severity Index) score at Week 16

End point title	Percentage of subjects achieving a 75% or higher improvement from Baseline in PASI (Psoriasis Area and Severity Index) score at Week 16
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End point description:

The PASI75 response assessments are based on at least 75% improvement in the PASI score from Baseline. This is a scoring system that averages the redness, thickness, and scaliness of the psoriatic lesions (on a 0-4 scale), and weights the resulting score by the area of skin involved. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for the redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear) to 4 (very

marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0 to 6 scale. Final PASI= average redness, thickness, and scaliness of the psoriatic skin lesions, multiplied by the involved psoriasis area score of the respective section, and weighted by the percentage of the person's affected skin for the respective section. The minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease.

End point type	Secondary
End point timeframe:	
From Baseline to Week 16	

End point values	BKZ 320 mg + PBO (FAS)	BKZ 320 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	17		
Units: percentage of subjects				
number (not applicable)				
percentage of responders	93.8	88.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a 90% or higher improvement in PASI (Psoriasis Area and Severity Index) score at Week 16

End point title	Percentage of subjects achieving a 90% or higher improvement in PASI (Psoriasis Area and Severity Index) score at Week 16
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End point description:

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

End point type	Secondary
End point timeframe:	
From Baseline to Week 16	

End point values	BKZ 320 mg + PBO (FAS)	BKZ 320 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	17		
Units: percentage of subjects				
number (not applicable)				
percentage of responders	84.4	70.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects achieving a 100% improvement from Baseline in PASI (Psoriasis Area and Severity Index) score at Week 16

End point title	Percentage of subjects achieving a 100% improvement from Baseline in PASI (Psoriasis Area and Severity Index) score at Week 16
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End point description:

The PASI100 response assessments are based on at least 100% improvement in the PASI score from Baseline. This is a scoring system that averages the redness, thickness, and scaliness of the psoriatic lesions (on a 0-4 scale), and weights the resulting score by the area of skin involved. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for the redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear) to 4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0 to 6 scale. Final PASI= average redness, thickness, and scaliness of the psoriatic skin lesions, multiplied by the involved psoriasis area score of the respective section, and weighted by the percentage of the person's affected skin for the respective section. The minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease.

End point type	Secondary
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End point timeframe:

From Baseline to Week 16

End point values	BKZ 320 mg + PBO (FAS)	BKZ 320 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	17		
Units: percentage of subjects				
number (not applicable)				
percentage of responders	46.9	52.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with IGA (Investigator's Global Assessment) response at Week 16

End point title	Percentage of subjects with IGA (Investigator's Global Assessment) response at Week 16
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End point description:

The Investigator's Global Assessment (IGA) measures the overall psoriasis severity following a 5-point scale (0-4), where scale 0= clear, no signs of psoriasis; presence of post-inflammatory hyperpigmentation, scale 1= almost clear, no thickening; normal to pink coloration; no to minimal focal scaling, scale 2= mild thickening, pink to light red coloration and predominately fine scaling, 3=

moderate, clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling and 4= severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions.

End point type	Secondary
End point timeframe:	
At Week 16	

End point values	BKZ 320 mg + PBO (FAS)	BKZ 320 mg (FAS)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	32	17		
Units: percentage of subjects				
number (not applicable)				
percentage of responders	81.3	64.7		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline to Week 36

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	BKZ 320 mg + PBO (SS)
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Reporting group description:

Bimekizumab 320 milligrams (mg) administered subcutaneously (sc) at Baseline and Week 4, and placebo administered at Week 16.

Reporting group title	BKZ 320 mg (SS)
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Reporting group description:

Bimekizumab 320 mg administered sc at Baseline and Weeks 4 and 16.

Serious adverse events	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 32 (6.25%)	1 / 17 (5.88%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 32 (3.13%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral sensorimotor neuropathy			
subjects affected / exposed	1 / 32 (3.13%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Pancreatitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			

Cholecystitis acute			
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	BKZ 320 mg + PBO (SS)	BKZ 320 mg (SS)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 32 (87.50%)	15 / 17 (88.24%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 32 (6.25%)	3 / 17 (17.65%)	
occurrences (all)	3	3	
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 32 (6.25%)	3 / 17 (17.65%)	
occurrences (all)	4	7	
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 32 (6.25%)	2 / 17 (11.76%)	
occurrences (all)	2	4	
Neutrophil count decreased			
subjects affected / exposed	1 / 32 (3.13%)	3 / 17 (17.65%)	
occurrences (all)	1	3	
Blood cholesterol increased			
subjects affected / exposed	1 / 32 (3.13%)	2 / 17 (11.76%)	
occurrences (all)	1	2	
Blood bilirubin increased			
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Lymphocyte count decreased			
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Mean cell haemoglobin concentration decreased			

subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Platelet count decreased subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 3	
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Seborrhoeic keratosis subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 2	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	3 / 32 (9.38%) 3	1 / 17 (5.88%) 1	
Tension headache subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Blood and lymphatic system disorders Hypochromic anaemia subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 2	
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	1 / 17 (5.88%) 1	
Abdominal discomfort subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Anal pruritus subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Dental necrosis			

subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Irritable bowel syndrome subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Hepatobiliary disorders Non-alcoholic fatty liver subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Skin and subcutaneous tissue disorders Pruritus generalised subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	1 / 17 (5.88%) 1	
Psoriasis subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	1 / 17 (5.88%) 1	
Dermatitis subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	1 / 17 (5.88%) 1	
Back pain subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	1 / 17 (5.88%) 1	
Neck pain subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Infections and infestations Upper respiratory tract infection			

subjects affected / exposed	6 / 32 (18.75%)	3 / 17 (17.65%)
occurrences (all)	8	3
Nasopharyngitis		
subjects affected / exposed	2 / 32 (6.25%)	4 / 17 (23.53%)
occurrences (all)	2	4
Urinary tract infection		
subjects affected / exposed	4 / 32 (12.50%)	0 / 17 (0.00%)
occurrences (all)	4	0
Viral upper respiratory tract infection		
subjects affected / exposed	2 / 32 (6.25%)	2 / 17 (11.76%)
occurrences (all)	2	3
Gastroenteritis viral		
subjects affected / exposed	2 / 32 (6.25%)	1 / 17 (5.88%)
occurrences (all)	2	1
Oral candidiasis		
subjects affected / exposed	2 / 32 (6.25%)	0 / 17 (0.00%)
occurrences (all)	2	0
Viral infection		
subjects affected / exposed	0 / 32 (0.00%)	2 / 17 (11.76%)
occurrences (all)	0	2
Bacterial diarrhoea		
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	1
Conjunctivitis		
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	1
Conjunctivitis bacterial		
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	1
Ear infection		
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	1
Localised infection		
subjects affected / exposed	0 / 32 (0.00%)	1 / 17 (5.88%)
occurrences (all)	0	1
Postoperative wound infection		

subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 17 (5.88%) 1	
Metabolism and nutrition disorders			
White blood cell count decreased			
subjects affected / exposed	2 / 32 (6.25%)	3 / 17 (17.65%)	
occurrences (all)	2	5	
Hyperkalaemia			
subjects affected / exposed	4 / 32 (12.50%)	1 / 17 (5.88%)	
occurrences (all)	6	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 September 2016	The purpose of this amendment is the following: •Add an exclusion criterion to exclude subjects that had been admitted to a mental hospital or other institution by an order of the court •Clarify wording in the ribonucleic acid (RNA), proteins, and metabolite variables section •Add a Baseline blood sample for anti-bimekizumab antibodies •Specify the study stopping rules •Delete Section 4.3.4 header: Non-hereditary pharmacogenomics variables. This section had no content and the header was included in error.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

PS0016 has not been conducted in the European Economic Area (EEA) and therefore did not meet the criteria for the results posting on EudraCT. Nevertheless, due to data transparency reason, UCB decided to post the respective results.

Notes: