Clinical trial results:
A multicenter, 48-week, open-label extension study to assess the long-term safety, tolerability, and efficacy of bimekizumab in adult subjects with moderate to severe chronic plaque psoriasis

Summary

EudraCT number	2016-002934-57
Trial protocol	DE
Global end of trial date	06 March 2019

Results information

Result version number	v1 (current)
This version publication date	11 October 2022
First version publication date	11 October 2022

Trial information

Trial identification

Sponsor protocol code	PS0018

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03230292
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	17 May 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 March 2019
Global end of trial reached?	Yes
Global end of trial date	06 March 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to assess the long-term safety and tolerability of bimekizumab.

Protection of trial subjects:

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

Background therapy:

Background therapy as permitted in the protocol.

Evidence for comparator:

Not Applicable

Actual start date of recruitment	03 July 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 17
Country: Number of subjects enrolled	Canada: 12
Country: Number of subjects enrolled	Moldova, Republic of: 13
Country: Number of subjects enrolled	United States: 1
Worldwide total number of subjects	43
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)	40
From 65 to 84 years	3

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll patients in July 2017 and concluded in March 2019.

Pre-assignment

Screening details:

Participant Flow refers to the Safety Set.

Period 1

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

Arms

Arm title	BKZ All participants

Arm description:

Participants received bimekizumab (BKZ) 160 milligrams (mg) every 4 weeks (Q4W) subcutaneously (sc) during the 48-week Open Label Treatment Period. The Investigator could increase the dose to BKZ 320 mg Q4W if the participant's Psoriasis Area and Severity Index (PASI) response was greater than or equal to (>=) 50% to less than (<) 75% reduction from the Baseline of PS0016 at Week 12 or later. If the participant's disease was adequately controlled on BKZ 320 mg Q4W, they could return to BKZ 160 mg Q4W at the discretion of the Investigator.

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 (BKZ) was administered as one sc injection for 160 mg Q4W or as 2 sc injections for 320 mg Q4W. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh.

Number of subjects in period 1	BKZ All participants
Started	43
Completed	37
Not completed	6
Consent withdrawn by subject	3
Adverse event, non-fatal	1
Lost to follow-up	1
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	BKZ All participants

Reporting group description:

Participants received bimekizumab (BKZ) 160 milligrams (mg) every 4 weeks (Q4W) subcutaneously (sc) during the 48-week Open Label Treatment Period. The Investigator could increase the dose to BKZ 320 mg Q4W if the participant's Psoriasis Area and Severity Index (PASI) response was greater than or equal to (>=) 50% to less than (<) 75% reduction from the Baseline of PS0016 at Week 12 or later. If the participant's disease was adequately controlled on BKZ 320 mg Q4W, they could return to BKZ 160 mg Q4W at the discretion of the Investigator.

Reporting group values	BKZ All participants	Total	
Number of subjects	43	43	
Age categorical Units: Subjects			
<=18 years	0	0	
Between 18 and 65 years	40	40	
>=65 years	3	3	
Age continuous Units: years			
arithmetic mean	45.0		
standard deviation	± 12.8	-	
Gender categorical Units: Subjects			
Male	23	23	
Female	20	20	

End points

End points reporting groups

Reporting group title	BKZ All participants

Reporting group description:

Participants received bimekizumab (BKZ) 160 milligrams (mg) every 4 weeks (Q4W) subcutaneously (sc) during the 48-week Open Label Treatment Period. The Investigator could increase the dose to BKZ 320 mg Q4W if the participant's Psoriasis Area and Severity Index (PASI) response was greater than or equal to (>=) 50% to less than (<) 75% reduction from the Baseline of PS0016 at Week 12 or later. If the participant's disease was adequately controlled on BKZ 320 mg Q4W, they could return to BKZ 160 mg Q4W at the discretion of the Investigator.

Subject analysis set title	BKZ All participants (SS)
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received BKZ 160 mg Q4W sc during the 48-week Open Label Treatment Period. The Investigator could increase the dose to BKZ 320 mg Q4W if the participant's PASI response was >= 50% to < 75% reduction from the Baseline of PS0016 at Week 12 or later. If the participant's disease was adequately controlled on BKZ 320 mg Q4W, they could return to BKZ 160 mg Q4W at the discretion of the Investigator. Participants formed the Safety Set (SS).

Subject analysis set title	BKZ All participants (PK-PPS)
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received BKZ 160 mg Q4W sc during the 48-week Open Label Treatment Period. The Investigator could increase the dose to BKZ 320 mg Q4W if the participant's PASI response was >= 50% to < 75% reduction from the Baseline of PS0016 at Week 12 or later. If the participant's disease was adequately controlled on BKZ 320 mg Q4W, they could return to BKZ 160 mg Q4W at the discretion of the Investigator. Participants formed the Pharmacokinetic-Per Protocol Set (PK-PPS).

Subject analysis set title	BKZ All participants (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received BKZ 160 mg Q4W sc during the 48-week Open Label Treatment Period. The Investigator could increase the dose to BKZ 320 mg Q4W if the participant's PASI response was >= 50% to < 75% reduction from the Baseline of PS0016 at Week 12 or later. If the participant's disease was adequately controlled on BKZ 320 mg Q4W, they could return to BKZ 160 mg Q4W at the discretion of the Investigator. Participants formed the Full Analysis Set (FAS).

Primary: Incidence of Treatment Emergent Adverse Event (TEAE) adjusted by duration of participant exposure to treatment

End point title	Incidence of Treatment Emergent Adverse Event (TEAE) adjusted by duration of participant exposure to treatment[1]

End point description:

TEAEs were events that had a start date on or after the first administration of study treatment in PS0018 until the last received dose of investigational medicinal product (IMP) +140 days [which covered the 20-week Safety Follow-Up (SFU) Visit]. The number of TEAEs adjusted by duration of exposure to study treatment was scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the adverse event (AE) being considered. If a participant had no events, the total time at risk was used. The Safety Set consisted of all participants who received at least 1 dose of the study medication in PS0018.

End point type	Primary

End point timeframe:

From Baseline (Week 0) until Safety Follow Up Visit (up to Week 64)

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 outcome. Results were summarized as descriptive statistics only.

End point values	BKZ All participants (SS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	76.00 (53.8 to 104.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma concentration of bimekizumab during the study

End point title	Plasma concentration of bimekizumab during the study

End point description:

Plasma concentration of Bimekizumab was expressed in micrograms per milliliter (µg/mL). Values Below Limit of Quantification (BLQ) were replaced by value of Lower Limit of Quantification (LLOQ) divided by 2 (=0.075 µg/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 timepoint. The Pharmacokinetics Per-Protocol Set consisted of all enrolled participants who received at least 1 dose of the study medication and provided at least 1 quantifiable plasma concentration postdose in PS0018. Here, 'n' signifies participants who were evaluable at specified time points. Note: 999 was used a placeholder for the value that was not calculated (Participants had no prior BKZ treatment and thus no BKZ levels at Baseline).

End point type	Secondary

End point timeframe:

From Baseline (Week 0) until Safety Follow Up Visit (up to Week 64)

End point values	BKZ All participants (PK-PPS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
PS0018 Week 0 (n=43)	999 (± 999)			
Week 4 (n=42)	5.309 (± 47.8)			
Week 8 (n=40)	7.304 (± 60.7)			
Week 12 (n=39)	7.994 (± 53.9)			
Week 16 (n=37)	8.700 (± 53.7)			
Week 28 (n=37)	9.285 (± 49.7)			
Week 40 (n=36)	9.238 (± 51.3)			
Week 48/ Withdrawal (n=36)	9.056 (± 52.5)			
Follow-up (n=35)	0.310 (± 164.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with positive anti-bimekizumab (BZK) antibody levels prior to study treatment

End point title	Percentage of participants with positive anti-bimekizumab (BZK) antibody levels prior to study treatment

End point description:

For a given visit / time point, an Anti-BKZ status of positive was concluded for any participant with an anti-drug antibody (ADA) level that was above cut point (ACP) and CP at that visit/ time point. A participant was classified as overall positive if at least one PS0018 measurement is ACP and CP (this included participants who had negative results at PS0016 Baseline). Percentages were based on the number of participants with a non-missing measurement, from samples that did not contain BKZ concentration levels above the drug tolerance, at the visit. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Safety Set consisted of all participants who received at least 1 dose of the study medication in PS0018.

End point type	Secondary

End point timeframe:

Baseline of study PS0016 [NCT03025542]

End point values	BKZ All participants (SS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)	2.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with overall positive anti-bimekizumab (BZK) antibody levels following study treatment

End point title	Percentage of participants with overall positive anti-bimekizumab (BZK) antibody levels following study treatment

End point description:

For a given visit / time point, an Anti-BKZ status of positive was concluded for any participant with an anti-drug antibody (ADA) level that was above cut point (ACP) and CP at that visit/ time point. A participant was classified as overall positive if at least one PS0018 measurement is ACP and CP (this included participants who had negative results at PS0016 Baseline). Percentages were based on the number of participants with a non-missing measurement, from samples that did not contain BKZ concentration levels above the drug tolerance, at the visit. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Safety Set consisted of all

participants who received at least 1 dose of the study medication in PS0018. The number of participants analyzed reflects participants with a non-missing measurement.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (SS)			
Subject group type	Subject analysis set			
Number of subjects analysed	39			
Units: percentage of participants				
number (not applicable)	25.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a 50% or higher improvement in Psoriasis Area and Severity Index (PASI) during the study

End point title	Percentage of participants achieving a 50% or higher improvement in Psoriasis Area and Severity Index (PASI) during the study

End point description:

The PASI quantifies the severity and extent of the disease and weighs these with the percentage of body surface area (BSA) involvement. The degree of involvement is estimated across 4 body areas; head, upper limbs, trunk, and lower limbs and then transferred into a grade. The Investigator assessed 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. The PASI50 responses were based on at least 50% improvement in the PASI score at the Baseline of PS0016. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and had a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (confidence interval 95%)				
PS0018 Week 0	60.5 (45.6 to 73.6)			

Week 4	95.3 (84.5 to 98.7)			
Week 8	95.3 (84.5 to 98.7)			
Week 12	95.3 (84.5 to 98.7)			
Week 16	97.7 (87.9 to 99.6)			
Week 20	95.3 (84.5 to 98.7)			
Week 24	93.0 (81.4 to 97.6)			
Week 28	93.0 (81.4 to 97.6)			
Week 32	90.7 (78.4 to 96.3)			
Week 36	90.7 (78.4 to 96.3)			
Week 40	88.4 (75.5 to 94.9)			
Week 44	90.7 (78.4 to 96.3)			
Week 48/ Withdrawal	88.4 (75.5 to 94.9)			
Follow-Up	79.1 (64.8 to 88.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a 75% or higher improvement in Psoriasis Area and Severity Index (PASI) during the study

End point title	Percentage of participants achieving a 75% or higher improvement in Psoriasis Area and Severity Index (PASI) during the study

End point description:

The PASI quantifies the severity and extent of the disease and weighs these with the percentage of body surface area (BSA) involvement. The degree of involvement is estimated across 4 body areas; head, upper limbs, trunk, and lower limbs and then transferred into a grade. The Investigator assessed 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. The PASI75 responses were based on at least 75% improvement in the PASI score at the Baseline of PS0016. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and had a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (confidence interval 95%)				
PS0018 Week 0	44.2 (30.4 to 58.9)			
Week 4	88.4 (75.5 to 94.9)			
Week 8	95.3 (84.5 to 98.7)			
Week 12	90.7 (78.4 to 96.3)			
Week 16	93.0 (81.4 to 97.6)			
Week 20	90.7 (78.4 to 96.3)			
Week 24	90.7 (78.4 to 96.3)			
Week 28	88.4 (75.5 to 94.9)			
Week 32	90.7 (78.4 to 96.3)			
Week 36	90.7 (78.4 to 96.3)			
Week 40	86.0 (72.7 to 93.4)			
Week 44	90.7 (78.4 to 96.3)			
Week 48/ Withdrawal	86.0 (72.7 to 93.4)			
Follow-up	65.1 (50.2 to 77.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a 90% or higher improvement in Psoriasis Area and Severity Index (PASI) during the study

End point title	Percentage of participants achieving a 90% or higher improvement in Psoriasis Area and Severity Index (PASI) during the study

End point description:

The PASI quantifies the severity and extent of the disease and weighs these with the percentage of body surface area (BSA) involvement. The degree of involvement is estimated across 4 body areas; head, upper limbs, trunk, and lower limbs and then transferred into a grade. The Investigator assessed 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. The PASI90 responses were based on at least 90% improvement in the PASI score at the Baseline of PS0016. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and had a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (confidence interval 95%)				
PS0018 Week 0	20.9 (11.4 to 35.2)			
Week 4	53.5 (38.9 to 67.5)			
Week 8	79.1 (64.8 to 88.6)			
Week 12	79.1 (64.8 to 88.6)			
Week 16	86.0 (72.7 to 93.4)			
Week 20	79.1 (64.8 to 88.6)			
Week 24	79.1 (64.8 to 88.6)			
Week 28	81.4 (67.4 to 90.3)			
Week 32	81.4 (67.4 to 90.3)			
Week 36	86.0 (72.7 to 93.4)			
Week 40	76.7 (62.3 to 86.8)			
Week 44	86.0 (72.7 to 93.4)			
Week 48/ Withdrawal	79.1 (64.8 to 88.6)			
Follow-up	58.1 (43.3 to 71.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a 100% improvement in Psoriasis Area and Severity Index (PASI) during the study

End point title	Percentage of participants achieving a 100% improvement in Psoriasis Area and Severity Index (PASI) during the study

End point description:

The PASI quantifies the severity and extent of the disease and weighs these with the percentage of body surface area (BSA) involvement. The degree of involvement is estimated across 4 body areas; head, upper limbs, trunk, and lower limbs and then transferred into a grade. The Investigator assessed 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. The PASI100 responses were based on 100% improvement in the PASI score at the Baseline of PS0016. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and had a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (confidence interval 95%)				
PS0018 Week 0	4.7 (1.3 to 15.5)			
Week 4	23.3 (13.2 to 37.7)			
Week 8	37.2 (24.4 to 52.1)			
Week 12	46.5 (32.5 to 61.1)			
Week 16	39.5 (26.4 to 54.4)			
Week 20	48.8 (34.6 to 63.2)			
Week 24	41.9 (28.4 to 56.7)			
Week 28	46.5 (32.5 to 61.1)			
Week 32	41.9 (28.4 to 56.7)			
Week 36	41.9 (28.4 to 56.7)			
Week 40	46.5 (32.5 to 61.1)			
Week 44	46.5 (32.5 to 61.1)			
Week 48/ Withdrawal	46.5 (32.5 to 61.1)			
Follow-up	18.6 (9.7 to 32.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with Investigator´s Global Assessment response (Clear or Almost clear with at least a 2 category improvement from Baseline on a 5-point scale) during the study

End point title	Percentage of participants with Investigator´s Global Assessment response (Clear or Almost clear with at least a 2 category improvement from Baseline on a 5-point scale) during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0=Clear to 4=Severe. The response was defined as clear [0] or almost clear [1] with at least 2 category improvement from PS0016 Baseline. Clear was defined as no signs of PSO; post-inflammatory hyperpigmentation may be present. Almost clear was defined as no thickening; normal to pink coloration; no to minimal focal scaling. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (confidence interval 95%)				
PS0018 Week 0	18.6 (9.7 to 32.6)			
Week 4	62.8 (47.9 to 75.6)			
Week 8	79.1 (64.8 to 88.6)			
Week 12	79.1 (64.8 to 88.6)			
Week 16	81.4 (67.4 to 90.3)			
Week 20	79.1 (64.8 to 88.6)			
Week 24	76.7 (62.3 to 86.8)			
Week 28	79.1 (64.8 to 88.6)			
Week 32	86.0 (72.7 to 93.4)			
Week 36	81.4 (67.4 to 90.3)			
Week 40	79.1 (64.8 to 88.6)			
Week 44	83.7 (70.0 to 91.9)			
Week 48/ Withdrawal	79.1 (64.8 to 88.6)			
Follow-Up	51.2 (36.8 to 65.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from PS0016 [NCT03025542] Baseline in PASI score during the study

End point title	Mean change from PS0016 [NCT03025542] Baseline in PASI score during the study

End point description:

The total PASI score ranges from 0 to 72 with a reduction from PS0016 Baseline indicating improvement. Missing data was imputed using Last observation carried forward (LOCF) at all visits. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: score on a scale				
arithmetic mean (standard deviation)				
PS0018 Week 0	-11.21 (± 9.13)			
Week 4	-16.79 (± 6.72)			
Week 8	-18.12 (± 7.41)			
Week 12	-18.70 (± 7.89)			
Week 16	-19.01 (± 8.70)			
Week 20	-18.91 (± 8.70)			
Week 24	-19.08 (± 8.66)			
Week 28	-19.13 (± 8.79)			
Week 32	-19.30 (± 8.66)			
Week 36	-19.27 (± 8.68)			
Week 40	-19.22 (± 8.82)			
Week 44	-19.32 (± 8.68)			
Week 48/ Withdrawal	-19.20 (± 8.76)			
Follow-Up	-15.93 (± 9.29)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from PS0016 [NCT03025542] Baseline in PASI score during the study

End point title	Mean percentage change from PS0016 [NCT03025542] Baseline in PASI score during the study

End point description:

A negative percentage change from PS0016 baseline indicated improvement in Total PASI score. The total PASI score ranges from 0 to 72 with a reduction from PS0016 Baseline indicating improvement. Missing data was imputed using Last Observation Carried Forward (LOCF) at all visits. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage change				
arithmetic mean (standard deviation)				
PS0018 Week 0	-56.45 (± 38.26)			
Week 4	-87.71 (± 15.52)			
Week 8	-93.28 (± 12.13)			
Week 12	-94.50 (± 8.22)			
Week 16	-95.15 (± 8.43)			
Week 20	-94.84 (± 9.02)			
Week 24	-95.69 (± 6.77)			
Week 28	-95.72 (± 7.35)			
Week 32	-96.85 (± 4.81)			
Week 36	-96.66 (± 4.88)			
Week 40	-96.13 (± 6.38)			

Week 44	-96.98 (± 4.14)			
Week 48/ Withdrawal	-96.10 (± 7.45)			
Follow-Up	-81.98 (± 25.45)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to clear IGA score during the study

End point title	Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to clear IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Moderate IGA was defined as clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling. Clear IGA was defined as no signs of PSO; post-inflammatory hyperpigmentation may be present. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	4.7			
Week 4	23.3			
Week 8	37.2			
Week 12	44.2			
Week 16	34.9			
Week 20	41.9			
Week 24	37.2			
Week 28	39.5			
Week 32	37.2			
Week 36	37.2			
Week 40	37.2			
Week 44	37.2			
Week 48/ Withdrawal	39.5			

Follow-up	18.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to almost clear IGA score during the study

End point title	Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to almost clear IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Moderate IGA was defined as clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling. Almost clear was defined as no thickening; normal to pink coloration; no to minimal focal scaling. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	11.6			
Week 4	37.2			
Week 8	32.6			
Week 12	23.3			
Week 16	37.2			
Week 20	23.3			
Week 24	30.2			
Week 28	30.2			
Week 32	37.2			
Week 36	30.2			
Week 40	27.9			
Week 44	32.6			
Week 48/ Withdrawal	25.6			
Follow-up	30.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to mild IGA score during the study

End point title	Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to mild IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Moderate IGA was defined as clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling. Mild was defined as just detectable to mild thickening; pink to light red coloration; predominately fine scaling. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	25.6			
Week 4	18.6			
Week 8	14.0			
Week 12	11.6			
Week 16	9.3			
Week 20	14.0			
Week 24	9.3			
Week 28	7.0			
Week 32	2.3			
Week 36	9.3			
Week 40	9.3			
Week 44	2.3			
Week 48/ Withdrawal	7.0			
Follow-up	11.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to moderate IGA score during the study

End point title	Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to moderate IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Moderate IGA was defined as clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	25.6			
Week 4	4.7			
Week 8	0			
Week 12	2.3			
Week 16	2.3			
Week 20	2.3			
Week 24	2.3			
Week 28	2.3			
Week 32	0			
Week 36	0			
Week 40	2.3			
Week 44	4.7			
Week 48/ Withdrawal	4.7			
Follow-up	11.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to severe IGA score during the study

End point title	Percentage of participants who shifted from moderate Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to severe IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Moderate IGA was defined as clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling. Severe was defined as severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	16.3			
Week 4	0			
Week 8	0			
Week 12	0			
Week 16	0			
Week 20	0			
Week 24	0			
Week 28	0			
Week 32	0			
Week 36	0			
Week 40	0			
Week 44	0			
Week 48/ Withdrawal	0			
Follow-up	4.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to clear IGA score during the study

End point title	Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to clear IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Severe IGA was defined as severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions. Clear was defined as no signs of PSO; post-inflammatory hyperpigmentation may be present. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	0			
Week 4	0			
Week 8	0			
Week 12	2.3			
Week 16	4.7			
Week 20	7.0			
Week 24	4.7			
Week 28	7.0			
Week 32	4.7			
Week 36	7.0			
Week 40	11.6			
Week 44	9.3			
Week 48/ Withdrawal	9.3			
Follow-up	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to almost clear IGA score during the study

End point title	Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to almost clear IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Severe IGA was defined as severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions. Almost clear was defined as no thickening; normal to pink coloration; no to minimal focal scaling. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	2.3			
Week 4	2.3			
Week 8	9.3			
Week 12	9.3			
Week 16	4.7			
Week 20	7.0			
Week 24	4.7			
Week 28	2.3			
Week 32	7.0			
Week 36	7.0			
Week 40	2.3			
Week 44	4.7			
Week 48/ Withdrawal	4.7			
Follow-up	2.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to mild IGA score during the study

End point title	Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to mild IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Severe IGA was defined as severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions. Mild was defined as just detectable to mild thickening; pink to light red coloration; predominately fine scaling. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	2.3			
Week 4	9.3			
Week 8	2.3			
Week 12	0			
Week 16	4.7			
Week 20	0			
Week 24	4.7			
Week 28	4.7			
Week 32	2.3			
Week 36	0			
Week 40	0			
Week 44	0			
Week 48/ Withdrawal	0			
Follow-up	7.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to moderate IGA score during the study

End point title	Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to moderate IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Severe IGA was defined as severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions. Moderate was defined as clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	2.3			
Week 4	2.3			
Week 8	0			
Week 12	2.3			
Week 16	0			
Week 20	0			
Week 24	0			
Week 28	0			
Week 32	0			
Week 36	0			
Week 40	0			
Week 44	0			
Week 48/ Withdrawal	0			
Follow-up	2.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to severe IGA score during the study

End point title	Percentage of participants who shifted from severe Investigator´s Global Assessment (IGA) score at PS0016 [NCT03025542] Baseline to severe IGA score during the study

End point description:

A static IGA for Psoriasis (PSO) was used to assess disease severity in all study participants during the study. IGA is a 5 point scale ranging from 0 = Clear to 4 = Severe. Severe IGA was defined as severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0018 Week 0	9.3			
Week 4	2.3			
Week 8	2.3			
Week 12	0			
Week 16	0			
Week 20	0			
Week 24	0			
Week 28	0			
Week 32	0			
Week 36	0			
Week 40	0			
Week 44	0			
Week 48/ Withdrawal	0			
Follow-up	2.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage in the Body Surface Area (BSA) affected by psoriasis during the study

End point title	Mean percentage in the Body Surface Area (BSA) affected by psoriasis during the study

End point description:

The BSA palm method was used for the evaluation of BSA as follows: Body surface area estimation used the palm (study participant's flat hand and thumb together, fingers included) as representing around 1% of the total BSA. Missing data was imputed using Last Observation Carried forward (LOCF) at all visits. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of BSA				
arithmetic mean (standard deviation)				
PS0016 Baseline	25.8 (± 17.5)			
PS0018 Week 0	8.6 (± 10.7)			
Week 4	5.2 (± 12.6)			
Week 8	3.0 (± 10.9)			
Week 12	2.0 (± 4.8)			
Week 16	1.0 (± 1.6)			
Week 20	1.2 (± 2.2)			
Week 24	1.2 (± 1.9)			
Week 28	0.9 (± 1.6)			
Week 32	0.8 (± 1.1)			
Week 36	0.7 (± 1.1)			
Week 40	0.8 (± 1.2)			
Week 44	0.7 (± 1.0)			
Week 48/ Withdrawal	0.7 (± 1.2)			
Follow-up	4.8 (± 13.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean percentage change from PS0016 [NCT03025542] Baseline in the Body Surface Area (BSA) affected by psoriasis during the study

End point title	Mean percentage change from PS0016 [NCT03025542] Baseline in the Body Surface Area (BSA) affected by psoriasis during the study

End point description:

The percentage BSA (0 to 100 %) affected by PSO was listed by PS0016 randomized treatment, by study participant and visit including the percentage change from PS0016 Baseline. The BSA palm method was used for the evaluation of BSA as follows: Body surface area estimation used the palm (study participant's flat hand and thumb together, fingers included) as representing around 1% of the total BSA. Missing data was imputed using Last observation carried forward (LOCF) at all visits. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

From Baseline of study PS0016 [NCT03025542] until Safety Follow Up Visit (up to Week 64) of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage change				
arithmetic mean (standard deviation)				
PS0018 Week 0	-61.0 (± 41.5)			
Week 4	-83.0 (± 23.7)			
Week 8	-91.1 (± 15.9)			
Week 12	-92.9 (± 10.9)			
Week 16	-95.5 (± 7.4)			
Week 20	-94.4 (± 9.1)			
Week 24	-94.8 (± 7.8)			
Week 28	-95.4 (± 8.7)			
Week 32	-96.1 (± 6.7)			
Week 36	-96.5 (± 5.7)			
Week 40	-95.8 (± 8.5)			
Week 44	-96.3 (± 6.2)			
Week 48/ Withdrawal	-95.6 (± 10.0)			
Follow-up	-81.5 (± 33.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from PS0016 [NCT03025542] Baseline in Hospital Anxiety and Depression Scale – Anxiety (HADS-A) score during the study

End point title	Mean change from PS0016 [NCT03025542] Baseline in Hospital Anxiety and Depression Scale – Anxiety (HADS-A) score during the study

End point description:

HADS-A score is the sum of the 7 individual scores in the anxiety domain and ranges from 0 to 21 with higher scores indicating worse state. A score below 8 was considered normal whereas a score of 15 and above was considered severe. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

Week 0, 12, 24, 36, and 48 of study PS0018, Relative to Baseline of study PS0016 [NCT03025542]

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: score on a scale				
arithmetic mean (standard deviation)				
PS0018 Week 0	-1.5 (± 2.3)			
Week 12	-2.0 (± 1.8)			
Week 24	-2.0 (± 2.4)			
Week 36	-2.0 (± 2.4)			
Week 48/ Withdrawal	-1.5 (± 2.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from PS0016 [NCT03025542] Baseline in Hospital Anxiety and Depression Scale – Depression (HADS-D) score during the study

End point title	Mean change from PS0016 [NCT03025542] Baseline in Hospital Anxiety and Depression Scale – Depression (HADS-D) score during the study

End point description:

HADS-D score is the sum of the 7 individual scores in the depression domain and ranges from 0 to 21 with higher scores indicating worse state. A score below 8 was considered normal whereas a score of 15 and above was considered severe. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018.

End point type	Secondary

End point timeframe:

Week 0, 12, 24, 36, and 48 of study PS0018, Relative to Baseline of study PS0016 [NCT03025542]

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: score on a scale				
arithmetic mean (standard deviation)				
PS0018 Week 0	-1.0 (± 1.4)			
Week 12	-0.8 (± 2.1)			
Week 24	-1.0 (± 1.7)			
Week 36	-1.1 (± 1.7)			
Week 48/ Withdrawal	-1.0 (± 1.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with scores below 8 in HADS-A (participants with normal scores) during the study

End point title	Percentage of participants with scores below 8 in HADS-A (participants with normal scores) during the study

End point description:

HADS-A score is the sum of the 7 individual scores in the anxiety domain and ranges from 0 to 21 with higher scores indicating worse state. A score below 8 was considered normal. Percentages were based on the number of participants with a non-missing measurement at the visit. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018. Here, 'n' signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline of study PS0016 [NCT03025542], Week 0, 12, 24, 36, and 48 of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0016 Baseline (n=43)	83.7			
PS0018 Week 0 (n=43)	88.4			
Week 12 (n=42)	95.2			
Week 24 (n=42)	90.5			
Week 36 (n=39)	89.7			
Week 48/ Withdrawal (n=39)	87.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with scores below 8 in HADS-D (participants with normal scores) during the study

End point title	Percentage of participants with scores below 8 in HADS-D (participants with normal scores) during the study

End point description:

HADS-D score is the sum of the 7 individual scores in the depression domain and ranges from 0 to 21 with higher scores indicating worse state. A score below 8 was considered normal. Percentages were based on the number of participants with a non-missing measurement at the visit. Baseline was defined as the last available value prior to the first injection of study medication in the PS0016 study. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the study medication and have a valid efficacy measurement for PASI at Baseline of PS0018. Here, 'n' signifies participants who were evaluable at specified time points.

End point type	Secondary

End point timeframe:

Baseline of study PS0016 [NCT03025542], Week 0, 12, 24, 36, and 48 of study PS0018

End point values	BKZ All participants (FAS)			
Subject group type	Subject analysis set			
Number of subjects analysed	43			
Units: percentage of participants				
number (not applicable)				
PS0016 Baseline (n=43)	93.0			
PS0018 Week 0 (n=43)	97.7			
Week 12 (n=42)	95.2			
Week 24 (n=42)	97.6			
Week 36 (n=39)	94.9			
Week 48/ Withdrawal (n=39)	97.4			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from the PS0018 Baseline until the Safety Follow-Up Visit [20 weeks after the last dose (up to Week 64)]

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	BKZ All participants (SS)

Reporting group description:

Participants received BKZ 160 mg Q4W sc during the 48-week Open Label Treatment Period. The Investigator could increase the dose to BKZ 320 mg Q4W if the participant's PASI response was >= 50% to < 75% reduction from the Baseline of PS0016 at Week 12 or later. If the participant's disease was adequately controlled on BKZ 320 mg Q4W, they could return to BKZ 160 mg Q4W at the discretion of the Investigator. Participants formed the Safety Set (SS).

Serious adverse events	BKZ All participants (SS)		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 43 (6.98%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Anaemia postoperative			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 43 (2.33%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	BKZ All participants (SS)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 43 (62.79%)		
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	5 / 43 (11.63%)		
occurrences (all)	7		
Alanine aminotransferase increased			
subjects affected / exposed	4 / 43 (9.30%)		
occurrences (all)	5		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	8 / 43 (18.60%)		
occurrences (all)	12		
Nasopharyngitis			
subjects affected / exposed	7 / 43 (16.28%)		
occurrences (all)	10		
Viral upper respiratory tract infection			
subjects affected / exposed	5 / 43 (11.63%)		
occurrences (all)	6		
Oral candidiasis			
subjects affected / exposed	4 / 43 (9.30%)		
occurrences (all)	6		
Pharyngitis			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		
Staphylococcal pharyngitis			
subjects affected / exposed	3 / 43 (6.98%)		
occurrences (all)	3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 February 2018	Protocol amendment 3, dated 16 Feb 2018, was implemented to make the following changes: • Revised the withdrawal criteria to provide instructions for the management of study participants with newly diagnosed inflammatory bowel disease or with inflammatory bowel disease flares during the study • Updated the study contact information.

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.

PS0018 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: