



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

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|--|----|
| 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 |

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 (\geq) 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 (\geq) 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 (\geq) 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 \geq 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 \geq 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 \geq 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

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|---|--|
| End point title | Plasma concentration of bimekizumab during the study |
| End point description: | |
| <p>Plasma concentration of Bimekizumab was expressed in micrograms per milliliter ($\mu\text{g/mL}$). Values Below Limit of Quantification (BLQ) were replaced by value of Lower Limit of Quantification (LLOQ) divided by 2 ($=0.075 \mu\text{g/mL}$) 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).</p> | |
| 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: $\mu\text{g/mL}$ | | | | |
| geometric mean (geometric coefficient of variation) | | | | |
| PS0018 Week 0 (n=43) | 999 (\pm 999) | | | |
| Week 4 (n=42) | 5.309 (\pm 47.8) | | | |
| Week 8 (n=40) | 7.304 (\pm 60.7) | | | |
| Week 12 (n=39) | 7.994 (\pm 53.9) | | | |
| Week 16 (n=37) | 8.700 (\pm 53.7) | | | |
| Week 28 (n=37) | 9.285 (\pm 49.7) | | | |
| Week 40 (n=36) | 9.238 (\pm 51.3) | | | |
| Week 48/ Withdrawal (n=36) | 9.056 (\pm 52.5) | | | |
| Follow-up (n=35) | 0.310 (\pm 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.

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|----------------|-----------|
| 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.

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|----------------|-----------|
| 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 $\geq 50\%$ 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: