



## Clinical trial results:

### A Multicenter, 48-Week, Double-Blind, Placebo-Controlled, Parallel-Group 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           | 2016-001892-57    |
| Trial protocol           | HU CZ PL          |
| Global end of trial date | 25 September 2018 |

#### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1 (current)    |
| This version publication date  | 12 October 2019 |
| First version publication date | 12 October 2019 |

#### Trial information

##### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | PS0011 |
|-----------------------|--------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT03010527 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | UCB Biopharma, SPRL   |
| 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                       | 20 November 2018  |
| Is this the analysis of the primary completion data? | No                |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 25 September 2018 |
| Was the trial ended prematurely?                     | No                |

Notes:

## General information about the trial

Main objective of the trial:

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                          | 14 December 2016 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | Yes              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Canada: 36         |
| Country: Number of subjects enrolled | Czech Republic: 20 |
| Country: Number of subjects enrolled | Hungary: 16        |
| Country: Number of subjects enrolled | Japan: 11          |
| Country: Number of subjects enrolled | Poland: 99         |
| Country: Number of subjects enrolled | United States: 35  |
| Worldwide total number of subjects   | 217                |
| EEA total number of subjects         | 135                |

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) | 199 |
| From 65 to 84 years  | 18  |
| 85 years and over    | 0   |

## Subject disposition

### Recruitment

Recruitment details:

The study started to enroll participants in December 2016 and concluded in September 2018. Among the 217 participants in PS0011, no participants were assigned to receive placebo.

### Pre-assignment

Screening details:

Participant Flow refers to the Full Analysis Set (FAS), which consisted of all enrolled participants who received at least 1 dose of the investigational medicinal product (IMP) and had a valid measurement of the primary efficacy variable at Baseline of PS0011.

### Period 1

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

### Arms

|                              |                    |
|------------------------------|--------------------|
| Are arms mutually exclusive? | Yes                |
| <b>Arm title</b>             | Bimekizumab Dose 1 |

Arm description:

Participants received bimekizumab Dose 1 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 1 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011.

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | Bimekizumab            |
| Investigational medicinal product code | BKZ                    |
| Other name                             | UCB4940                |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Subcutaneous use       |

Dosage and administration details:

Participants were administered different dosages of BKZ, by subcutaneous (sc) injection, every four weeks (Q4W).

|                  |                    |
|------------------|--------------------|
| <b>Arm title</b> | Bimekizumab Dose 2 |
|------------------|--------------------|

Arm description:

Participants received bimekizumab Dose 2 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 loading dose (w/LD) Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 w/LD Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011.

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | Bimekizumab            |
| Investigational medicinal product code | BKZ                    |
| Other name                             | UCB4940                |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Subcutaneous use       |

Dosage and administration details:

Participants were administered different dosages of BKZ, by subcutaneous (sc) injection, every four weeks (Q4W).

|                  |                    |
|------------------|--------------------|
| <b>Arm title</b> | Bimekizumab Dose 3 |
|------------------|--------------------|

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**Arm description:**

Participants received bimekizumab Dose 3 injections, sc every four weeks (Q4W). Participants receiving bimekizumab Dose 3 Q4W and bimekizumab Dose 4 Q4W, in PS0010 were assigned to receive bimekizumab Dose 3 Q4W in PS0011, regardless of their PASI90 response at Week 12 in PS0010.

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | Bimekizumab            |
| Investigational medicinal product code | BKZ                    |
| Other name                             | UCB4940                |
| Pharmaceutical forms                   | Solution for injection |
| Routes of administration               | Subcutaneous use       |

**Dosage and administration details:**

Participants were administered different dosages of BKZ, by subcutaneous (sc) injection, every four weeks (Q4W).

| <b>Number of subjects in period 1</b> | Bimekizumab Dose 1 | Bimekizumab Dose 2 | Bimekizumab Dose 3 |
|---------------------------------------|--------------------|--------------------|--------------------|
| Started                               | 15                 | 111                | 91                 |
| Completed                             | 15                 | 92                 | 75                 |
| Not completed                         | 0                  | 19                 | 16                 |
| WITHDRAWAL CRITERIA #9                | -                  | 4                  | 6                  |
| Adverse event, serious fatal          | -                  | -                  | 1                  |
| Consent withdrawn by subject          | -                  | 3                  | 4                  |
| Adverse event, non-fatal              | -                  | 4                  | 2                  |
| PDILI and WITHDRAWAL CRITERIA #9      | -                  | 1                  | -                  |
| Lost to follow-up                     | -                  | 2                  | 1                  |
| WITHDRAWAL CRITERIA #12               | -                  | 4                  | 2                  |
| Protocol deviation                    | -                  | 1                  | -                  |

## Baseline characteristics

### Reporting groups

|   |                    |
|---|--------------------|
| Reporting group title   | Bimekizumab Dose 1 |
| Reporting group description:  |                    |
| Participants received bimekizumab Dose 1 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 1 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011.  |                    |
| Reporting group title   | Bimekizumab Dose 2 |
| Reporting group description:  |                    |
| Participants received bimekizumab Dose 2 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 loading dose (w/LD) Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 w/LD Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011. |                    |
| Reporting group title   | Bimekizumab Dose 3 |
| Reporting group description:  |                    |
| Participants received bimekizumab Dose 3 injections, sc every four weeks (Q4W). Participants receiving bimekizumab Dose 3 Q4W and bimekizumab Dose 4 Q4W, in PS0010 were assigned to receive bimekizumab Dose 3 Q4W in PS0011, regardless of their PASI90 response at Week 12 in PS0010.  |                    |

| Reporting group values                | Bimekizumab Dose 1 | Bimekizumab Dose 2 | Bimekizumab Dose 3 |
|---------------------------------------|--------------------|--------------------|--------------------|
| Number of subjects                    | 15                 | 111                | 91                 |
| Age categorical<br>Units: Subjects    |                    |                    |                    |
| <=18 years                            | 0                  | 1                  | 2                  |
| Between 18 and 65 years               | 14                 | 105                | 77                 |
| >=65 years                            | 1                  | 5                  | 12                 |
| Age continuous<br>Units: years        |                    |                    |                    |
| arithmetic mean                       | 44.5               | 44.5               | 43.5               |
| standard deviation                    | ± 14.7             | ± 12.8             | ± 14.7             |
| Gender categorical<br>Units: Subjects |                    |                    |                    |
| Male                                  | 9                  | 71                 | 60                 |
| Female                                | 6                  | 40                 | 31                 |

| Reporting group values             | Total |  |  |
|------------------------------------|-------|--|--|
| Number of subjects                 | 217   |  |  |
| Age categorical<br>Units: Subjects |       |  |  |
| <=18 years                         | 3     |  |  |
| Between 18 and 65 years            | 196   |  |  |
| >=65 years                         | 18    |  |  |
| Age continuous<br>Units: years     |       |  |  |
| arithmetic mean                    |       |  |  |
| standard deviation                 | -     |  |  |

|                    |     |  |  |
|--------------------|-----|--|--|
| Gender categorical |     |  |  |
| Units: Subjects    |     |  |  |
| Male               | 140 |  |  |
| Female             | 77  |  |  |

## End points

### End points reporting groups

|  |   |
|--|---|
| Reporting group title  | Bimekizumab Dose 1                            |
| Reporting group description:<br>Participants received bimekizumab Dose 1 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 1 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011.   |   |
| Reporting group title  | Bimekizumab Dose 2                            |
| Reporting group description:<br>Participants received bimekizumab Dose 2 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 loading dose (w/LD) Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 w/LD Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011.  |   |
| Reporting group title  | Bimekizumab Dose 3                            |
| Reporting group description:<br>Participants received bimekizumab Dose 3 injections, sc every four weeks (Q4W). Participants receiving bimekizumab Dose 3 Q4W and bimekizumab Dose 4 Q4W, in PS0010 were assigned to receive bimekizumab Dose 3 Q4W in PS0011, regardless of their PASI90 response at Week 12 in PS0010.   |   |
| Subject analysis set title   | Bimekizumab Dose 1 (SS)                       |
| Subject analysis set type  | Safety analysis                               |
| Subject analysis set description:<br>Participants received bimekizumab Dose 1 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 1 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants who received at least one dose of the IMP formed the Safety Set (SS).   |   |
| Subject analysis set title   | Bimekizumab Dose 2 (SS)                       |
| Subject analysis set type  | Safety analysis                               |
| Subject analysis set description:<br>Participants received bimekizumab Dose 2 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 loading dose (w/LD) Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 w/LD Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011. Participants who received at least one dose of the IMP formed the SS. |   |
| Subject analysis set title   | Bimekizumab Dose 3 (SS)                       |
| Subject analysis set type  | Safety analysis                               |
| Subject analysis set description:<br>Participants received bimekizumab Dose 3 injections, sc every four weeks (Q4W). Participants receiving bimekizumab Dose 3 Q4W and bimekizumab Dose 4 Q4W, in PS0010 were assigned to receive bimekizumab Dose 3 Q4W in PS0011, regardless of their PASI90 response at Week 12 in PS0010. Participants who received at least one dose of the IMP formed the SS.  |   |
| Subject analysis set title   | Bimekizumab Dose 1/Bimekizumab Dose 1/R (FAS) |
| Subject analysis set type  | Full analysis                                 |
| Subject analysis set description:<br>Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 1 Q4W in PS0011. Participants formed the Full Analysis Set (FAS).   |   |
| Subject analysis set title   | Bimekizumab Dose 2/Bimekizumab Dose 2/R (FAS) |
| Subject analysis set type  | Full analysis                                 |
| Subject analysis set description:<br>Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 loading dose (w/LD) Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants formed the FAS.   |   |



|   |  |
|---|--|
| Subject analysis set title  | Bimekizumab Dose 3/Bimekizumab Dose 3/R (FAS)  |
| Subject analysis set type   | Full analysis                                  |
| Subject analysis set description:   |  |
| Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 3 Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011. Participants formed the FAS.                                       |  |
| Subject analysis set title  | Bimekizumab Dose 4/Bimekizumab Dose 3/R (FAS)  |
| Subject analysis set type   | Full analysis                                  |
| Subject analysis set description:   |  |
| Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 4 Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011. Participants formed the FAS.                                       |  |
| Subject analysis set title  | Placebo/Bimekizumab Dose 2/NR (FAS)            |
| Subject analysis set type   | Full analysis                                  |
| Subject analysis set description:   |  |
| Participants who did not achieve PASI90 response at Week 12 and received placebo Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants formed the FAS.   |  |
| Subject analysis set title  | Bimekizumab Dose 1/Bimekizumab Dose 2/NR (FAS) |
| Subject analysis set type   | Full analysis                                  |
| Subject analysis set description:   |  |
| Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants formed the FAS.                                |  |
| Subject analysis set title  | Bimekizumab Dose 2/Bimekizumab Dose 3/NR (FAS) |
| Subject analysis set type   | Full analysis                                  |
| Subject analysis set description:   |  |
| Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 w/LD Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011. Participants formed the FAS. |  |
| Subject analysis set title  | Bimekizumab Dose 3/Bimekizumab Dose 3/NR (FAS) |
| Subject analysis set type   | Full analysis                                  |
| Subject analysis set description:   |  |
| Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 3 Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011. Participants formed the FAS.                                |  |
| Subject analysis set title  | Bimekizumab Dose 4/Bimekizumab Dose 3/NR (FAS) |
| Subject analysis set type   | Full analysis                                  |
| Subject analysis set description:   |  |
| Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 4 Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011. Participants formed the FAS.                                |  |

### **Primary: Incidence of Treatment Emergent Adverse Events (TEAEs) adjusted by duration of subject exposure to treatment**

|   |   |
|---|---|
| End point title   | Incidence of Treatment Emergent Adverse Events (TEAEs) adjusted by duration of subject exposure to treatment <sup>[1]</sup> |
| End point description:  |   |
| Treatment-emergent Adverse Events (TEAEs) were defined as those events which started on or after the date of first dose of PS0011 investigational medicinal product (IMP), or events in which severity worsened on or after the date of first dose of PS0011 study medication.<br>The exposure adjusted incidence rate (EAIR) is defined as the number of subjects (n) with a specific AE adjusted for the exposure and was scaled to 100 subject-years: where the numerator is the total number of subjects experiencing the AE and the denominator is the total time at risk scaled to 100 subject-years; that is, the total summation of individual subject-years at risk up to the first occurrence of the AE for subjects with that AE, and the total subject-years at risk for those subjects not experiencing that AE, divided by 100. |   |
| End point type  | Primary   |
| End point timeframe:  |   |
| From Baseline 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 study. Results were summarized as descriptive statistics only.

| End point values                               | Bimekizumab<br>Dose 1 (SS) | Bimekizumab<br>Dose 2 (SS) | Bimekizumab<br>Dose 3 (SS) |  |
|--|----------------------------|----------------------------|----------------------------|--|
| Subject group type                             | Subject analysis set       | Subject analysis set       | Subject analysis set       |  |
| Number of subjects analysed                    | 15                         | 111                        | 91                         |  |
| Units: no. of new events per 100 subject-years |                            |                            |                            |  |
| number (confidence interval 95%)               | 110.68 (53.08 to 203.55)   | 225.26 (182.88 to 274.53)  | 206.82 (162.95 to 258.86)  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of participants with Psoriasis Area Severity Index (PASI90) response over time

|                 |   |
|-----------------|---|
| End point title | Percentage of participants with Psoriasis Area Severity Index (PASI90) response over time |
|-----------------|---|

End point description:

The PASI90 response assessments are based on at least 90% improvement in the PASI score from Baseline. It averages the redness, thickness, and scaliness of the psoriatic lesions (on a 0-4 scale) and weights the resulting score by the area of skin involved. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks.

Assignment of an average score for the redness, thickness, and scaling for each of the 4 body areas with a score of 0 (clear) to 4 (very marked). The PASI score ranges from 0 to 72 with a higher score indicating increased disease severity.

PASI90 response is defined to be equal to 1 if the percentage improvement from Baseline in the PASI scores is 90% or greater and 0 if the percentage improvement from Baseline is less than 90%.

This Outcome Measure presents results relative to PS0010 Baseline starting at PS0011 Baseline by PS0010 Week 12 response status.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From Baseline during the Treatment Period (up to Week 48)

| End point values                  | Bimekizumab<br>Dose<br>1/Bimekizumab<br>Dose 1/R (FAS) | Bimekizumab<br>Dose<br>2/Bimekizumab<br>Dose 2/R (FAS) | Bimekizumab<br>Dose<br>3/Bimekizumab<br>Dose 3/R (FAS) | Bimekizumab<br>Dose<br>4/Bimekizumab<br>Dose 3/R (FAS) |
|-----------------------------------|--|--|--|--|
| Subject group type                | Subject analysis set                                   | Subject analysis set                                   | Subject analysis set                                   | Subject analysis set                                   |
| Number of subjects analysed       | 15   | 55   | 33   | 30   |
| Units: percentage of participants |  |  |  |  |
| number (not applicable)           |  |  |  |  |
| PS0011 Baseline                   | 100  | 100  | 100  | 100  |
| Week 4                            | 100  | 100  | 97.0   | 100  |
| Week 8                            | 100  | 96.4   | 100  | 100  |
| Week 12                           | 100  | 96.4   | 100  | 96.7   |
| Week 16                           | 100  | 92.7   | 100  | 96.7   |

|         |      |      |      |      |
|---------|------|------|------|------|
| Week 20 | 100  | 89.1 | 93.9 | 96.7 |
| Week 24 | 100  | 85.5 | 97.0 | 96.7 |
| Week 28 | 93.3 | 90.9 | 97.0 | 96.7 |
| Week 32 | 100  | 89.1 | 97.0 | 93.3 |
| Week 36 | 100  | 85.5 | 97.0 | 93.3 |
| Week 40 | 100  | 83.6 | 87.9 | 86.7 |
| Week 44 | 100  | 81.8 | 87.9 | 86.7 |
| Week 48 | 100  | 80.0 | 87.9 | 86.7 |

| <b>End point values</b>           | Placebo/Bimekizumab Dose 2/NR (FAS) | Bimekizumab Dose 1/Bimekizumab Dose 2/NR (FAS) | Bimekizumab Dose 2/Bimekizumab Dose 3/NR (FAS) | Bimekizumab Dose 3/Bimekizumab Dose 3/NR (FAS) |
|-----------------------------------|-------------------------------------|--|--|--|
| Subject group type                | Subject analysis set                | Subject analysis set                           | Subject analysis set                           | Subject analysis set                           |
| Number of subjects analysed       | 37                                  | 19   | 14   | 6  |
| Units: percentage of participants |                                     |  |  |  |
| number (not applicable)           |                                     |  |  |  |
| PS0011 Baseline                   | 0                                   | 0  | 0  | 0  |
| Week 4                            | 45.9                                | 42.1   | 42.9   | 66.7   |
| Week 8                            | 67.6                                | 73.7   | 57.1   | 83.3   |
| Week 12                           | 81.1                                | 78.9   | 64.3   | 100  |
| Week 16                           | 83.8                                | 78.9   | 64.3   | 100  |
| Week 20                           | 89.2                                | 84.2   | 78.6   | 83.3   |
| Week 24                           | 83.8                                | 78.9   | 71.4   | 83.3   |
| Week 28                           | 91.9                                | 84.2   | 71.4   | 83.3   |
| Week 32                           | 91.9                                | 73.7   | 71.4   | 83.3   |
| Week 36                           | 91.9                                | 73.7   | 71.4   | 66.7   |
| Week 40                           | 89.2                                | 78.9   | 71.4   | 83.3   |
| Week 44                           | 89.2                                | 78.9   | 71.4   | 83.3   |
| Week 48                           | 91.9                                | 68.4   | 71.4   | 66.7   |

| <b>End point values</b>           | Bimekizumab Dose 4/Bimekizumab Dose 3/NR (FAS) |  |  |  |
|-----------------------------------|--|--|--|--|
| Subject group type                | Subject analysis set                           |  |  |  |
| Number of subjects analysed       | 8  |  |  |  |
| Units: percentage of participants |  |  |  |  |
| number (not applicable)           |  |  |  |  |
| PS0011 Baseline                   | 0  |  |  |  |
| Week 4                            | 50.0   |  |  |  |
| Week 8                            | 50.0   |  |  |  |
| Week 12                           | 62.5   |  |  |  |
| Week 16                           | 62.5   |  |  |  |
| Week 20                           | 62.5   |  |  |  |
| Week 24                           | 75.0   |  |  |  |
| Week 28                           | 50.0   |  |  |  |

|         |      |  |  |  |
|---------|------|--|--|--|
| Week 32 | 50.0 |  |  |  |
| Week 36 | 50.0 |  |  |  |
| Week 40 | 50.0 |  |  |  |
| Week 44 | 50.0 |  |  |  |
| Week 48 | 50.0 |  |  |  |

## 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) over time

|                 |   |
|-----------------|---|
| 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) over time |
|-----------------|---|

End point description:

The Investigator's Global Assessment (IGA) measures the overall severity following a 5-point scale (0-4), where scale 0= clear, no signs of psoriasis; presence of post-inflammatory hyperpigmentation, scale 1= almost clear, no thickening; normal to pink coloration; no to minimal focal scaling, scale 2= mild thickening, pink to light red coloration and predominately fine scaling, 3= moderate, clearly distinguishable to moderate thickening; dull to bright red, clearly distinguishable to moderate thickening; moderate scaling and 4= severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions.

IGA response is defined as clear (0) or almost clear (1) with at least a two category improvement from Baseline.

This Outcome Measure presents results relative to PS0010 Baseline starting at PS0011 Baseline by PS0010 Week 12 response status.

|                |           |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

From Baseline during the Treatment Period (up to Week 48)

| End point values                  | Bimekizumab Dose 1/Bimekizumab Dose 1/R (FAS) | Bimekizumab Dose 2/Bimekizumab Dose 2/R (FAS) | Bimekizumab Dose 3/Bimekizumab Dose 3/R (FAS) | Bimekizumab Dose 4/Bimekizumab Dose 3/R (FAS) |
|-----------------------------------|---|---|---|---|
| Subject group type                | Subject analysis set                          | Subject analysis set                          | Subject analysis set                          | Subject analysis set                          |
| Number of subjects analysed       | 15  | 55  | 33  | 30  |
| Units: percentage of participants |   |   |   |   |
| number (not applicable)           |   |   |   |   |
| PS0011 Baseline                   | 100   | 96.4  | 100   | 100   |
| Week 4                            | 100   | 98.2  | 97.0  | 100   |
| Week 8                            | 100   | 96.4  | 97.0  | 100   |
| Week 12                           | 100   | 92.7  | 97.0  | 96.7  |
| Week 16                           | 100   | 90.9  | 97.0  | 96.7  |
| Week 20                           | 100   | 85.5  | 93.9  | 96.7  |
| Week 24                           | 100   | 81.8  | 97.0  | 93.3  |
| Week 28                           | 93.3  | 89.1  | 97.0  | 93.3  |
| Week 32                           | 100   | 85.5  | 93.9  | 93.3  |
| Week 36                           | 100   | 81.8  | 90.9  | 93.3  |

|         |     |      |      |      |
|---------|-----|------|------|------|
| Week 40 | 100 | 83.6 | 87.9 | 86.7 |
| Week 44 | 100 | 81.8 | 87.9 | 86.7 |
| Week 48 | 100 | 78.2 | 87.9 | 86.7 |

| <b>End point values</b>           | Placebo/Bimekizumab Dose 2/NR (FAS) | Bimekizumab Dose 1/Bimekizumab Dose 2/NR (FAS) | Bimekizumab Dose 2/Bimekizumab Dose 3/NR (FAS) | Bimekizumab Dose 3/Bimekizumab Dose 3/NR (FAS) |
|-----------------------------------|-------------------------------------|--|--|--|
| Subject group type                | Subject analysis set                | Subject analysis set                           | Subject analysis set                           | Subject analysis set                           |
| Number of subjects analysed       | 37                                  | 19   | 14   | 6  |
| Units: percentage of participants |                                     |  |  |  |
| number (not applicable)           |                                     |  |  |  |
| PS0011 Baseline                   | 5.4                                 | 10.5   | 35.7   | 50.0   |
| Week 4                            | 56.8                                | 57.9   | 42.9   | 66.7   |
| Week 8                            | 75.7                                | 84.2   | 57.1   | 83.3   |
| Week 12                           | 81.1                                | 89.5   | 64.3   | 83.3   |
| Week 16                           | 83.8                                | 78.9   | 57.1   | 66.7   |
| Week 20                           | 89.2                                | 84.2   | 71.4   | 66.7   |
| Week 24                           | 83.8                                | 84.2   | 64.3   | 83.3   |
| Week 28                           | 86.5                                | 84.2   | 71.4   | 66.7   |
| Week 32                           | 89.2                                | 78.9   | 71.4   | 66.7   |
| Week 36                           | 86.5                                | 78.9   | 71.4   | 66.7   |
| Week 40                           | 86.5                                | 78.9   | 71.4   | 66.7   |
| Week 44                           | 83.8                                | 78.9   | 71.4   | 66.7   |
| Week 48                           | 89.2                                | 68.4   | 71.4   | 66.7   |

| <b>End point values</b>           | Bimekizumab Dose 4/Bimekizumab Dose 3/NR (FAS) |  |  |  |
|-----------------------------------|--|--|--|--|
| Subject group type                | Subject analysis set                           |  |  |  |
| Number of subjects analysed       | 8  |  |  |  |
| Units: percentage of participants |  |  |  |  |
| number (not applicable)           |  |  |  |  |
| PS0011 Baseline                   | 25.0   |  |  |  |
| Week 4                            | 62.5   |  |  |  |
| Week 8                            | 62.5   |  |  |  |
| Week 12                           | 62.5   |  |  |  |
| Week 16                           | 62.5   |  |  |  |
| Week 20                           | 75.0   |  |  |  |
| Week 24                           | 62.5   |  |  |  |
| Week 28                           | 62.5   |  |  |  |
| Week 32                           | 50.0   |  |  |  |
| Week 36                           | 37.5   |  |  |  |
| Week 40                           | 50.0   |  |  |  |
| Week 44                           | 50.0   |  |  |  |
| Week 48                           | 62.5   |  |  |  |

## **Statistical analyses**

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From PS0011 Baseline and up to Safety-Follow Up (SFU)

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 19.0 |
|--------------------|------|

### Reporting groups

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Bimekizumab Dose 1 (SS) |
|-----------------------|-------------------------|

Reporting group description:

Participants received bimekizumab Dose 1 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 1 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 1 Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants who received at least one dose of the IMP formed the Safety Set (SS).

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Bimekizumab Dose 3 (SS) |
|-----------------------|-------------------------|

Reporting group description:

Participants received bimekizumab Dose 3 injections, sc every four weeks (Q4W). Participants receiving bimekizumab Dose 3 Q4W and bimekizumab Dose 4 Q4W, in PS0010 were assigned to receive bimekizumab Dose 3 Q4W in PS0011, regardless of their PASI90 response at Week 12 in PS0010. Participants who received at least one dose of the IMP formed the SS.

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Bimekizumab Dose 2 (SS) |
|-----------------------|-------------------------|

Reporting group description:

Participants received bimekizumab Dose 2 injections, sc every four weeks (Q4W). Participants who achieved PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 loading dose (w/LD) Q4W in PS0010, were assigned to bimekizumab Dose 2 Q4W in PS0011. Participants who did not achieve PASI90 response at Week 12 and received bimekizumab Dose 2 Q4W or bimekizumab Dose 2 w/LD Q4W in PS0010, were assigned to bimekizumab Dose 3 Q4W in PS0011. Participants who received at least one dose of the IMP formed the SS.

| Serious adverse events  | Bimekizumab Dose 1 (SS) | Bimekizumab Dose 3 (SS) | Bimekizumab Dose 2 (SS) |
|---|-------------------------|-------------------------|-------------------------|
| Total subjects affected by serious adverse events                   |                         |                         |                         |
| subjects affected / exposed   | 1 / 15 (6.67%)          | 7 / 91 (7.69%)          | 7 / 111 (6.31%)         |
| number of deaths (all causes)                                       | 0                       | 2                       | 0                       |
| number of deaths resulting from adverse events                      | 0                       | 0                       | 0                       |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                         |                         |                         |
| Acute myeloid leukaemia   |                         |                         |                         |
| subjects affected / exposed   | 0 / 15 (0.00%)          | 0 / 91 (0.00%)          | 1 / 111 (0.90%)         |
| occurrences causally related to treatment / all                     | 0 / 0                   | 0 / 0                   | 0 / 1                   |
| deaths causally related to treatment / all                          | 0 / 0                   | 0 / 0                   | 0 / 0                   |
| Vascular disorders  |                         |                         |                         |
| Circulatory collapse  |                         |                         |                         |

|  |                |                |                 |
|--|----------------|----------------|-----------------|
| subjects affected / exposed                          | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 1          | 0 / 0           |
| Hypovolaemic shock                                   |                |                |                 |
| subjects affected / exposed                          | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 1          | 0 / 0           |
| Surgical and medical procedures                      |                |                |                 |
| Abortion induced                                     |                |                |                 |
| subjects affected / exposed                          | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0           |
| General disorders and administration site conditions |                |                |                 |
| Non-cardiac chest pain                               |                |                |                 |
| subjects affected / exposed                          | 1 / 15 (6.67%) | 0 / 91 (0.00%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1          | 0 / 0          | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0           |
| Reproductive system and breast disorders             |                |                |                 |
| Uterine cervix stenosis                              |                |                |                 |
| subjects affected / exposed                          | 0 / 15 (0.00%) | 0 / 91 (0.00%) | 1 / 111 (0.90%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 0          | 0 / 0           |
| Respiratory, thoracic and mediastinal disorders      |                |                |                 |
| Dyspnoea   |                |                |                 |
| subjects affected / exposed                          | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 2          | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 1          | 0 / 0           |
| Respiratory failure                                  |                |                |                 |
| subjects affected / exposed                          | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0          | 0 / 1          | 0 / 0           |
| Investigations                                       |                |                |                 |
| Hepatic enzyme increased                             |                |                |                 |



|   |                |                |                 |
|---|----------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 91 (0.00%) | 1 / 111 (0.90%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Injury, poisoning and procedural complications  |                |                |                 |
| Humerus fracture                                |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Tibia fracture                                  |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Cardiac disorders                               |                |                |                 |
| Cardiac failure                                 |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 91 (0.00%) | 1 / 111 (0.90%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Nervous system disorders                        |                |                |                 |
| Carpal tunnel syndrome                          |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 2          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Eye disorders                                   |                |                |                 |
| Cataract  |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Renal and urinary disorders                     |                |                |                 |
| IgA nephropathy                                 |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 91 (0.00%) | 1 / 111 (0.90%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Nephrolithiasis                                 |                |                |                 |

|   |                |                |                 |
|---|----------------|----------------|-----------------|
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 91 (0.00%) | 1 / 111 (0.90%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Ureterolithiasis                                |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 91 (0.00%) | 1 / 111 (0.90%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Renal colic                                     |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 91 (0.00%) | 1 / 111 (0.90%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 2           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Infections and infestations                     |                |                |                 |
| Otitis externa bacterial                        |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |
| Staphylococcal abscess                          |                |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%) | 0 / 91 (0.00%) | 1 / 111 (0.90%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0           |

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

| <b>Non-serious adverse events</b>                                   | Bimekizumab Dose 1 (SS) | Bimekizumab Dose 3 (SS) | Bimekizumab Dose 2 (SS) |
|---|-------------------------|-------------------------|-------------------------|
| Total subjects affected by non-serious adverse events               |                         |                         |                         |
| subjects affected / exposed   | 10 / 15 (66.67%)        | 51 / 91 (56.04%)        | 56 / 111 (50.45%)       |
| Investigations  |                         |                         |                         |
| Gamma-glutamyl-transferase increased                                |                         |                         |                         |
| subjects affected / exposed   | 1 / 15 (6.67%)          | 3 / 91 (3.30%)          | 4 / 111 (3.60%)         |
| occurrences (all)   | 1                       | 4                       | 6                       |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                         |                         |                         |
| Benign ovarian tumour   |                         |                         |                         |
| subjects affected / exposed   | 1 / 15 (6.67%)          | 0 / 91 (0.00%)          | 0 / 111 (0.00%)         |
| occurrences (all)   | 1                       | 0                       | 0                       |

|   |                 |                |                 |
|---|-----------------|----------------|-----------------|
| Injury, poisoning and procedural complications  |                 |                |                 |
| Joint injury                                    |                 |                |                 |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 0 / 91 (0.00%) | 0 / 111 (0.00%) |
| occurrences (all)                               | 1               | 0              | 0               |
| Procedural pain                                 |                 |                |                 |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 0 / 91 (0.00%) | 0 / 111 (0.00%) |
| occurrences (all)                               | 2               | 0              | 0               |
| Vascular disorders                              |                 |                |                 |
| Hypertension                                    |                 |                |                 |
| subjects affected / exposed                     | 2 / 15 (13.33%) | 4 / 91 (4.40%) | 8 / 111 (7.21%) |
| occurrences (all)                               | 2               | 4              | 10              |
| Ear and labyrinth disorders                     |                 |                |                 |
| External ear inflammation                       |                 |                |                 |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences (all)                               | 1               | 1              | 0               |
| Gastrointestinal disorders                      |                 |                |                 |
| Diarrhoea                                       |                 |                |                 |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 1 / 91 (1.10%) | 0 / 111 (0.00%) |
| occurrences (all)                               | 1               | 1              | 0               |
| Flatulence                                      |                 |                |                 |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 0 / 91 (0.00%) | 0 / 111 (0.00%) |
| occurrences (all)                               | 1               | 0              | 0               |
| Hepatobiliary disorders                         |                 |                |                 |
| Non-alcoholic fatty liver                       |                 |                |                 |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 0 / 91 (0.00%) | 1 / 111 (0.90%) |
| occurrences (all)                               | 1               | 0              | 1               |
| Respiratory, thoracic and mediastinal disorders |                 |                |                 |
| Oropharyngeal pain                              |                 |                |                 |
| subjects affected / exposed                     | 0 / 15 (0.00%)  | 6 / 91 (6.59%) | 6 / 111 (5.41%) |
| occurrences (all)                               | 0               | 8              | 6               |
| Skin and subcutaneous tissue disorders          |                 |                |                 |
| Dermatitis contact                              |                 |                |                 |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 3 / 91 (3.30%) | 5 / 111 (4.50%) |
| occurrences (all)                               | 1               | 3              | 6               |
| Seborrhoeic dermatitis                          |                 |                |                 |
| subjects affected / exposed                     | 1 / 15 (6.67%)  | 2 / 91 (2.20%) | 3 / 111 (2.70%) |
| occurrences (all)                               | 1               | 2              | 4               |

|   |                      |                        |                         |
|---|----------------------|------------------------|-------------------------|
| Pruritus generalised<br>subjects affected / exposed<br>occurrences (all)  | 1 / 15 (6.67%)<br>1  | 1 / 91 (1.10%)<br>1    | 0 / 111 (0.00%)<br>0    |
| Psoriasis<br>subjects affected / exposed<br>occurrences (all)   | 2 / 15 (13.33%)<br>2 | 5 / 91 (5.49%)<br>5    | 5 / 111 (4.50%)<br>6    |
| Musculoskeletal and connective tissue disorders<br>Arthralgia<br>subjects affected / exposed<br>occurrences (all) | 0 / 15 (0.00%)<br>0  | 6 / 91 (6.59%)<br>7    | 3 / 111 (2.70%)<br>4    |
| Infections and infestations<br>Oral candidiasis<br>subjects affected / exposed<br>occurrences (all)               | 1 / 15 (6.67%)<br>2  | 15 / 91 (16.48%)<br>19 | 13 / 111 (11.71%)<br>17 |
| Skin candida<br>subjects affected / exposed<br>occurrences (all)  | 1 / 15 (6.67%)<br>1  | 0 / 91 (0.00%)<br>0    | 0 / 111 (0.00%)<br>0    |
| Angular cheilitis<br>subjects affected / exposed<br>occurrences (all)   | 1 / 15 (6.67%)<br>1  | 0 / 91 (0.00%)<br>0    | 2 / 111 (1.80%)<br>3    |
| Gingivitis<br>subjects affected / exposed<br>occurrences (all)  | 1 / 15 (6.67%)<br>1  | 0 / 91 (0.00%)<br>0    | 0 / 111 (0.00%)<br>0    |
| Vulvovaginal mycotic infection<br>subjects affected / exposed<br>occurrences (all)                                | 1 / 15 (6.67%)<br>2  | 0 / 91 (0.00%)<br>0    | 1 / 111 (0.90%)<br>1    |
| Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)   | 2 / 15 (13.33%)<br>4 | 11 / 91 (12.09%)<br>14 | 15 / 111 (13.51%)<br>20 |
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)                             | 1 / 15 (6.67%)<br>1  | 9 / 91 (9.89%)<br>12   | 10 / 111 (9.01%)<br>12  |
| Pharyngitis<br>subjects affected / exposed<br>occurrences (all)   | 1 / 15 (6.67%)<br>1  | 3 / 91 (3.30%)<br>3    | 1 / 111 (0.90%)<br>1    |
| Urinary tract infection   |                      |                        |                         |

|                                    |                 |                |                 |
|------------------------------------|-----------------|----------------|-----------------|
| subjects affected / exposed        | 2 / 15 (13.33%) | 1 / 91 (1.10%) | 1 / 111 (0.90%) |
| occurrences (all)                  | 3               | 2              | 1               |
| Respiratory tract infection viral  |                 |                |                 |
| subjects affected / exposed        | 1 / 15 (6.67%)  | 1 / 91 (1.10%) | 1 / 111 (0.90%) |
| occurrences (all)                  | 1               | 1              | 1               |
| Metabolism and nutrition disorders |                 |                |                 |
| Hyperphagia                        |                 |                |                 |
| subjects affected / exposed        | 1 / 15 (6.67%)  | 0 / 91 (0.00%) | 0 / 111 (0.00%) |
| occurrences (all)                  | 1               | 0              | 0               |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date           | Amendment   |
|----------------|---|
| 12 August 2016 | <p>This substantial amendment revised the study design of PS0011 to allow participants who were responding to placebo or the lowest dose of bimekizumab (Dose 1 Q4W) in PS0010 to continue into PS0011 with no change in treatment, while protecting the study blind. The study design changed from an open-label to a double-blind, placebo-controlled, parallel-group extension study with additional treatment groups included for consistency with PS0010.</p> <p>Following other changes were made:</p> <ul style="list-style-type: none"><li>•Added details on study revisions, including study type, description, rationale for the revised design, and addition of placebo.</li><li>•Clarified treatment arms and criteria and methods for treatment assignment</li><li>•Reduced number of secondary objectives and reassigned secondary variables to other objectives</li><li>•Classified efficacy variables into secondary and other efficacy variables</li><li>•Extended timing of SFU Visit and maximum duration of subject participation</li><li>•Adjustment and/or clarification of schedule for hematology, biochemistry, urinalysis, bimekizumab plasma concentrations, anti bimekizumab antibody levels, and Hospital Anxiety and Depression Scale</li><li>•Removed population PK, legal representative for consent and exclusion of pre-existing clinically active or medically significant infection</li><li>•Adjusted details on contraception requirements</li><li>•Included eligibility requirement for negative interferon-gamma release assay and for completion of PS0010</li><li>•Clarifications to withdrawal criteria regarding concurrent illness, pustular psoriasis, topical treatments, HADS and PASI thresholds, AEs, and clinical laboratory values.</li><li>•Provided details on maintaining and emergency breaking of the study blinding</li><li>•Provided additional detail for recording the severity of AEs, duration of AE follow-up and adverse events for special monitoring (AESM)</li><li>•Removed alcohol test in the potential drug-induced liver injury urine toxicology screen</li><li>•Added clarifications to the statistics section and adapted sections that impacted by design change.</li></ul> |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported