



## Clinical trial results:

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

#### Summary

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

#### Results information

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

#### Trial information

##### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | PS0016 |
|-----------------------|--------|

##### Additional study identifiers

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

Notes:

#### Sponsors

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

Notes:

#### Paediatric regulatory details

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

Notes:

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**Results analysis stage**

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

Notes:

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**General information about the trial**

Main objective of the trial:

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

Protection of trial subjects:

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

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

|                                                           |                  |
|-----------------------------------------------------------|------------------|
| Actual start date of recruitment                          | 27 December 2016 |
| Long term follow-up planned                               | No               |
| Independent data monitoring committee (IDMC) involvement? | Yes              |

Notes:

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**Population of trial subjects****Subjects enrolled per country**

|                                      |                          |
|--------------------------------------|--------------------------|
| Country: Number of subjects enrolled | Canada: 12               |
| Country: Number of subjects enrolled | Australia: 19            |
| Country: Number of subjects enrolled | Moldova, Republic of: 17 |
| Country: Number of subjects enrolled | United States: 1         |
| Worldwide total number of subjects   | 49                       |
| EEA total number of subjects         | 0                        |

Notes:

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**Subjects enrolled per age group**

|                                           |   |
|-------------------------------------------|---|
| In utero                                  | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days)                      | 0 |
| Infants and toddlers (28 days-23 months)  | 0 |
| Children (2-11 years)                     | 0 |
| Adolescents (12-17 years)                 | 0 |

|                      |    |
|----------------------|----|
| Adults (18-64 years) | 46 |
| From 65 to 84 years  | 3  |
| 85 years and over    | 0  |

## Subject disposition

### Recruitment

Recruitment details:

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

### Pre-assignment

Screening details:

Participant Flow refers to the Safety Set (SS).

### Period 1

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

### Arms

|                              |                  |
|------------------------------|------------------|
| Are arms mutually exclusive? | Yes              |
| <b>Arm title</b>             | BKZ 320 mg + PBO |

Arm description:

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

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

Dosage and administration details:

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

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

Dosage and administration details:

Subjects were administered matching placebo subcutaneous injections.

|                  |            |
|------------------|------------|
| <b>Arm title</b> | BKZ 320 mg |
|------------------|------------|

Arm description:

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

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

Dosage and administration details:

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

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

## Baseline characteristics

### Reporting groups

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

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

## End points

### End points reporting groups

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

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

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

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

## Primary: Mean plasma concentration of bimekizumab at Week 16

|                 |                                                                    |
|-----------------|--------------------------------------------------------------------|
| End point title | Mean plasma concentration of bimekizumab at Week 16 <sup>[2]</sup> |
|-----------------|--------------------------------------------------------------------|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At Week 16

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

## titre prior to and following study treatment with bimekizumab at Baseline

|                 |                                                                                                                                                                   |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Baseline <sup>[3]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

### End point timeframe:

At Baseline

### Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |                                                                                                                                                                 |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 4 <sup>[4]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|

### End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

### End point timeframe:

At Week 4

### Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |                                                                                                                                                                 |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 8 <sup>[5]</sup> |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At Week 8

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |                                                                                                                                                                  |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 12 <sup>[6]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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**End point description:**

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

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|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

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End point timeframe:

At Week 12

Notes:

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

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

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

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**Statistical analyses**

No statistical analyses for this end point

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

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|                 |                                                                                                                                                                  |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 16 <sup>[7]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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End point description:

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

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|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

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End point timeframe:

At Week 16

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |                                                                                                                                                                  |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 20 <sup>[8]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At Week 20

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |                                                                                                                                                                  |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 24 <sup>[9]</sup> |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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**End point description:**

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

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|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

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**End point timeframe:**

At Week 24

**Notes:**

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

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

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

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**Statistical analyses**

No statistical analyses for this end point

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

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|                 |                                                                                                                                                                   |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of participants reporting positive Anti-Drug-Antibodies (ADA) titre prior to and following study treatment with bimekizumab at Week 28 <sup>[10]</sup> |
|-----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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**End point description:**

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

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|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

---

**End point timeframe:**

At Week 28

**Notes:**

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

|                 |                                                                                          |
|-----------------|------------------------------------------------------------------------------------------|
| End point title | Percentage of subjects who experienced at least one adverse events (AEs) <sup>[11]</sup> |
|-----------------|------------------------------------------------------------------------------------------|

End point description:

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

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

From Baseline to Safety Follow Up Visit (Week 36)

Notes:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

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

## Statistical analyses

No statistical analyses for this end point

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

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

#### End point description:

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

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

#### End point timeframe:

From Baseline to Week 16

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

## Statistical analyses

No statistical analyses for this end point

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

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

#### End point description:

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

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

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: |           |
| At Week 16           |           |

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

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From Baseline to Week 36

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

### Dictionary used

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

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

### Reporting groups

|                       |                       |
|-----------------------|-----------------------|
| Reporting group title | BKZ 320 mg + PBO (SS) |
|-----------------------|-----------------------|

Reporting group description:

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

|                       |                 |
|-----------------------|-----------------|
| Reporting group title | BKZ 320 mg (SS) |
|-----------------------|-----------------|

Reporting group description:

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

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

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

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

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

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

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

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

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

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

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

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

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

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

Notes: