



Clinical trial results:

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose Ranging Study to Evaluate the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of Bimekizumab in Adult subjects With Moderate to Severe Chronic Plaque Psoriasis

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2016-001891-31 |
| Trial protocol | HU CZ PL |
| Global end of trial date | 10 July 2017 |

Results information

| | |
|--------------------------------|--|
| Result version number | v2 (current) |
| This version publication date | 12 December 2020 |
| First version publication date | 26 July 2018 |
| Version creation reason | <ul style="list-style-type: none">• Correction of full data set Alignment with final posting on ClinicalTrials.gov after NIH review. |

Trial information

Trial identification

| | |
|-----------------------|--------|
| Sponsor protocol code | PS0010 |
|-----------------------|--------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02905006 |
| 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 | 31 July 2017 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 10 July 2017 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the dose response of bimekizumab administered subcutaneously (sc) for 12 weeks in the treatment of participants with moderate to severe chronic plaque psoriasis.

Protection of trial subjects:

Patients were given the opportunity to discuss the study with the study doctor and ask questions before deciding to participate. The Study doctors asked about any problems patients had since the last visit, and what medications patients were taking. Routine safety blood and urine samples taken, electrocardiography (ECG), physical examinations and vital signs were taken, as well as questions about mental health were being asked to monitor the patient's safety.

Background therapy:

Topical medications

Participants continued to use topical moisturizers or emollients, bath oils, or oatmeal bath preparations for skin conditions during the study, as needed. Over-the-counter shampoos for the treatment of psoriasis of the scalp were also permitted. Participants who used prohibited topical medications were allowed to stay in the study but were counseled to not use them further. No other topical preparations were allowed in the 2 weeks before randomization or during the study unless medically required to treat an Adverse Event (AE).

Other medications

Participants who were already receiving an established non-steroidal anti-inflammatory drug (NSAID) regimen (at least 8 weeks prior to Baseline) and have been on a stable dose for at least 4 weeks prior to Baseline continued the use during the study. However, initiation of, or increase in dosage of, NSAIDs during the study (especially in participants with a history of gastrointestinal [GI] intolerance to NSAIDs or a history of GI ulceration) should have been done with caution. Intra-articular steroid injections for arthritis of the knee were allowed.

Participants who were already receiving an established anti-depressant regimen should have been on a stable dose of anti-depressant for 12 weeks prior to Baseline.

Evidence for comparator:

Not applicable

| | |
|---|------------------|
| Actual start date of recruitment | 25 August 2016 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Efficacy, Safety |
| Long term follow-up duration | 11 Months |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Canada: 39 |
| Country: Number of subjects enrolled | Czechia: 22 |
| Country: Number of subjects enrolled | Hungary: 18 |
| Country: Number of subjects enrolled | Japan: 12 |

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Poland: 115 |
| Country: Number of subjects enrolled | United States: 44 |
| Worldwide total number of subjects | 250 |
| EEA total number of subjects | 155 |

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) | 228 |
| From 65 to 84 years | 22 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

The study started to enroll participants in August 2016 and concluded in July 2017.

Pre-assignment

Screening details:

The study included a 2-4 week Screening Period and a 12-week Treatment Period. Completed study was defined as completed the 12-week double-blind Treatment Period. After Treatment Period participants either enrolled in an extension study (PS0011) or entered a 20-week Safety Follow-Up Period.

Participant Flow refers to the Randomized Set.

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 | Subject, Investigator, Monitor, Carer, Assessor |

Arms

| | |
|------------------------------|---------|
| Are arms mutually exclusive? | Yes |
| Arm title | Placebo |

Arm description:

Participants randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W).

| | |
|--|------------------------|
| Arm type | Placebo |
| 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:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also be administered at Week 12 for all participants entering the open-label extension study.

| | |
|------------------|-----------------------|
| Arm title | Bimekizumab 64 mg Q4W |
|------------------|-----------------------|

Arm description:

Participants were randomized to receive subcutaneous injections of 64 mg bimekizumab Q4W.

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

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all participants entering the open-label extension study.

| | |
|------------------|------------------------|
| Arm title | Bimekizumab 160 mg Q4W |
|------------------|------------------------|

| | |
|--|------------------------|
| Arm description: | |
| Participants were randomized to receive subcutaneous injections of 160 mg bimekizumab Q4W. | |
| Arm type | Experimental |
| Investigational medicinal product name | Bimekizumab |
| Investigational medicinal product code | UCB4940 |
| Other name | UCB4940 |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all participants entering the open-label extension study.

| | |
|------------------|------------------------------|
| Arm title | Bimekizumab 160 mg w/ LD Q4W |
|------------------|------------------------------|

Arm description:

Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W.

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

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all participants entering the open-label extension study.

| | |
|------------------|------------------------|
| Arm title | Bimekizumab 320 mg Q4W |
|------------------|------------------------|

Arm description:

Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab Q4W.

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

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all participants entering the open-label extension study.

| | |
|------------------|------------------------|
| Arm title | Bimekizumab 480 mg Q4W |
|------------------|------------------------|

Arm description:

Participants were randomized to receive subcutaneous injections of 480 mg bimekizumab Q4W.

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

Dosage and administration details:

The study medication was administered in the clinic by study site staff as 3 subcutaneous (sc) injections. Suitable areas for sc injections were the lateral abdominal wall and upper outer thigh. During each dosing visit (Baseline, Week 4, and Week 8), each of the 3 injections were administered at a separate injection site. Study medication were also administered at Week 12 for all participants entering the open-label extension study.

| Number of subjects in period 1 | Placebo | Bimekizumab 64 mg Q4W | Bimekizumab 160 mg Q4W |
|---------------------------------------|------------------|-----------------------|------------------------|
| Started | 42 | 39 | 43 |
| Completed Treatment period | 37 | 36 | 38 |
| Enrolled in extension study (PS0011) | 38 | 35 ^[1] | 39 |
| Entered Safety Follow-up Period | 4 ^[2] | 4 ^[3] | 4 ^[4] |
| Completed | 37 | 36 | 38 |
| Not completed | 5 | 3 | 5 |
| Positive for Tuberculosis | - | 1 | - |
| Consent withdrawn by subject | - | - | 1 |
| Lab withdrawal criterion met | - | 1 | 2 |
| Adverse event, non-fatal | 1 | 1 | 1 |
| Screening exclusion criteria met | 1 | - | - |
| Patient moved abroad | - | - | - |
| Subject positive for Hep B | - | - | 1 |
| Lost to follow-up | - | - | - |
| Patient randomized by mistake | - | - | - |
| Lack of efficacy | 1 | - | - |
| Protocol deviation | 2 | - | - |

| Number of subjects in period 1 | Bimekizumab 160 mg w/ LD Q4W | Bimekizumab 320 mg Q4W | Bimekizumab 480 mg Q4W |
|---------------------------------------|------------------------------|------------------------|------------------------|
| Started | 40 | 43 | 43 |
| Completed Treatment period | 34 | 40 | 39 |
| Enrolled in extension study (PS0011) | 38 | 42 | 40 |
| Entered Safety Follow-up Period | 2 ^[5] | 1 ^[6] | 3 ^[7] |
| Completed | 34 | 40 | 39 |
| Not completed | 6 | 3 | 4 |
| Positive for Tuberculosis | - | - | - |
| Consent withdrawn by subject | 1 | - | 1 |
| Lab withdrawal criterion met | 2 | 2 | 1 |
| Adverse event, non-fatal | 1 | - | 1 |
| Screening exclusion criteria met | - | - | - |
| Patient moved abroad | 1 | - | - |

| | | | |
|-------------------------------|---|---|---|
| Subject positive for Hep B | - | - | - |
| Lost to follow-up | 1 | 1 | - |
| Patient randomized by mistake | - | - | 1 |
| Lack of efficacy | - | - | - |
| Protocol deviation | - | - | - |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Number of participants at the milestones reflects those who enrolled in the extension study (PS0011).

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Number of participants at the milestones reflects those who entered a 20-week Safety Follow-Up Period.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Number of participants at the milestones reflects those who entered a 20-week Safety Follow-Up Period.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Number of participants at the milestones reflects those who entered a 20-week Safety Follow-Up Period.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Number of participants at the milestones reflects those who entered a 20-week Safety Follow-Up Period.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Number of participants at the milestones reflects those who entered a 20-week Safety Follow-Up Period.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Number of participants at the milestones reflects those who entered a 20-week Safety Follow-Up Period.

Baseline characteristics

Reporting groups

| | |
|--|------------------------------|
| Reporting group title | Placebo |
| Reporting group description: Participants randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W). | |
| Reporting group title | Bimekizumab 64 mg Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 64 mg bimekizumab Q4W. | |
| Reporting group title | Bimekizumab 160 mg Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 160 mg bimekizumab Q4W. | |
| Reporting group title | Bimekizumab 160 mg w/ LD Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W. | |
| Reporting group title | Bimekizumab 320 mg Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab Q4W. | |
| Reporting group title | Bimekizumab 480 mg Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 480 mg bimekizumab Q4W. | |

| Reporting group values | Placebo | Bimekizumab 64 mg Q4W | Bimekizumab 160 mg Q4W |
|---------------------------------------|---------|-----------------------|------------------------|
| Number of subjects | 42 | 39 | 43 |
| Age categorical Units: Subjects | | | |
| <=18 years | 0 | 1 | 0 |
| Between 18 and 65 years | 39 | 36 | 40 |
| >=65 years | 3 | 2 | 3 |
| Age continuous Units: years | | | |
| arithmetic mean | 46.7 | 44.2 | 43.4 |
| standard deviation | ± 12.3 | ± 13.8 | ± 12.4 |
| Gender categorical Units: Subjects | | | |
| Female | 17 | 19 | 11 |
| Male | 25 | 20 | 32 |

| Reporting group values | Bimekizumab 160 mg w/ LD Q4W | Bimekizumab 320 mg Q4W | Bimekizumab 480 mg Q4W |
|------------------------------------|------------------------------|------------------------|------------------------|
| Number of subjects | 40 | 43 | 43 |
| Age categorical Units: Subjects | | | |
| <=18 years | 0 | 0 | 2 |
| Between 18 and 65 years | 35 | 39 | 36 |
| >=65 years | 5 | 4 | 5 |

| | | | |
|---|----------------|----------------|----------------|
| Age continuous Units: years arithmetic mean standard deviation | 46.5 ± 15.2 | 42.6 ± 13.6 | 42.9 ± 15.2 |
| Gender categorical Units: Subjects | | | |
| Female | 11 | 15 | 14 |
| Male | 29 | 28 | 29 |

| | | | |
|---|-------|--|--|
| Reporting group values | Total | | |
| Number of subjects | 250 | | |
| Age categorical Units: Subjects | | | |
| ≤18 years | 3 | | |
| Between 18 and 65 years | 225 | | |
| ≥65 years | 22 | | |
| Age continuous Units: years arithmetic mean standard deviation | - | | |
| Gender categorical Units: Subjects | | | |
| Female | 87 | | |
| Male | 163 | | |

End points

End points reporting groups

| | |
|--|------------------------------------|
| Reporting group title | Placebo |
| Reporting group description: Participants randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W). | |
| Reporting group title | Bimekizumab 64 mg Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 64 mg bimekizumab Q4W. | |
| Reporting group title | Bimekizumab 160 mg Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 160 mg bimekizumab Q4W. | |
| Reporting group title | Bimekizumab 160 mg w/ LD Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W. | |
| Reporting group title | Bimekizumab 320 mg Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab Q4W. | |
| Reporting group title | Bimekizumab 480 mg Q4W |
| Reporting group description: Participants were randomized to receive subcutaneous injections of 480 mg bimekizumab Q4W. | |
| Subject analysis set title | Placebo (FAS) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Participants randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W). Participants formed the Full Analysis Set (FAS). | |
| Subject analysis set title | Bimekizumab 64 mg Q4W (FAS) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 64 mg bimekizumab Q4W. Participants formed the FAS. | |
| Subject analysis set title | Bimekizumab 160 mg Q4W (FAS) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 160 mg bimekizumab Q4W. Participants formed the FAS. | |
| Subject analysis set title | Bimekizumab 160 mg w/ LD Q4W (FAS) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W. Participants formed the FAS. | |
| Subject analysis set title | Bimekizumab 320 mg Q4W (FAS) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab Q4W. Participants formed the FAS. | |
| Subject analysis set title | Bimekizumab 480 mg Q4W (FAS) |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 480 mg bimekizumab Q4W. Participants formed the FAS. | |

| | |
|---|---------------------------------------|
| Subject analysis set title | Placebo (PK-PPS) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Participants randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W). Participants formed the Pharmacokinetics Per-Protocol Set (PK-PPS). | |
| Subject analysis set title | Bimekizumab 64 mg Q4W (PK-PPS) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 64 mg bimekizumab Q4W. Participants formed the PK-PPS. | |
| Subject analysis set title | Bimekizumab 160 mg Q4W (PK-PPS) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 160 mg bimekizumab Q4W. Participants formed the PK-PPS. | |
| Subject analysis set title | Bimekizumab 160 mg w/ LD Q4W (PK-PPS) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W. Participants formed the PK-PPS. | |
| Subject analysis set title | Bimekizumab 320 mg Q4W (PK-PPS) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab Q4W. Participants formed the PK-PPS. | |
| Subject analysis set title | Bimekizumab 480 mg Q4W (PK-PPS) |
| Subject analysis set type | Per protocol |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 480 mg bimekizumab Q4W. Participants formed the PK-PPS. | |
| Subject analysis set title | Placebo (SS) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Participants randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W). Participants formed the Safety Set (SS). | |
| Subject analysis set title | Bimekizumab 64 mg Q4W (SS) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 64 mg bimekizumab Q4W. Participants formed the SS. | |
| Subject analysis set title | Bimekizumab 160 mg Q4W (SS) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 160 mg bimekizumab Q4W. Participants formed the SS. | |
| Subject analysis set title | Bimekizumab 160 mg w/ LD Q4W (SS) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W. Participants formed the SS. | |
| Subject analysis set title | Bimekizumab 320 mg Q4W (SS) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 320 mg bimekizumab Q4W. Participants formed the SS. | |

| | |
|--|--|
| Subject analysis set title | Bimekizumab 480 mg Q4W (SS) |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Participants were randomized to receive subcutaneous injections of 480 mg bimekizumab Q4W. Participants formed the SS. | |
| Subject analysis set title | Placebo (SS) Treatment Period |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: During the Treatment Period participants randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W). Participants formed the Safety Set (SS). | |
| Subject analysis set title | Bimekizumab 64 mg Q4W (SS) Treatment Period |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: During the Treatment Period participants were randomized to receive subcutaneous injections of 64 mg bimekizumab Q4W. Participants formed the SS. | |
| Subject analysis set title | Bimekizumab 160 mg Q4W (SS) Treatment Period |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: During the Treatment Period participants were randomized to receive subcutaneous injections of 160 mg bimekizumab Q4W. Participants formed the SS. | |
| Subject analysis set title | Bimekizumab 160 mg w/ LD Q4W (SS) Treatment Period |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: During the Treatment Period participants were randomized to receive subcutaneous injections of 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W. Participants formed the SS. | |
| Subject analysis set title | Bimekizumab 320 mg Q4W (SS) Treatment Period |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: During the Treatment Period participants were randomized to receive subcutaneous injections of 320 mg bimekizumab Q4W. Participants formed the SS. | |
| Subject analysis set title | Bimekizumab 480 mg Q4W (SS) Treatment Period |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: During the Treatment Period participants were randomized to receive subcutaneous injections of 480 mg bimekizumab Q4W. Participants formed the SS. | |
| Subject analysis set title | Placebo (SS) Post-Treatment Period |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: At Week 12, participants who were randomized to receive Placebo during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication. Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS. | |
| Subject analysis set title | Bimekizumab 64 mg Q4W (SS) Post-Treatment Period |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: At Week 12, participants who were randomized to receive 64 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication. Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS. | |
| Subject analysis set title | Bimekizumab 160 mg Q4W (SS) Post-Treatment Period |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

At Week 12, participants who were randomized to receive 160 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

| | |
|----------------------------|---|
| Subject analysis set title | Bimekizumab 160 mg w/ LD Q4W (SS) Post-Treatment Period |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

At Week 12, participants who were randomized to receive 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

| | |
|----------------------------|---|
| Subject analysis set title | Bimekizumab 320 mg Q4W (SS) Post-Treatment Period |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

At Week 12, participants who were randomized to receive 320 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

| | |
|----------------------------|---|
| Subject analysis set title | Bimekizumab 480 mg Q4W (SS) Post-Treatment Period |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

At Week 12, participants who were randomized to receive 480 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

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

Subject analysis set description:

Participants were randomized to receive subcutaneous injections of placebo or bimekizumab in different dosages: 64 mg Q4W, 160 mg Q4W, 320 mg loading dose at Baseline followed by 160 mg Q4W, 320 mg Q4W, 480 mg Q4W during the 12-week Treatment Period. Participants formed the PK-PPS.

Primary: Percentage of participants achieving a 90% or higher improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 12

| | |
|-----------------|---|
| End point title | Percentage of participants achieving a 90% or higher improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 12 |
|-----------------|---|

End point description:

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

The FAS consisted of all randomized participants who received at least 1 dose of medication and had a valid measurement of the primary efficacy at Baseline.

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

End point timeframe:

Week 12

| End point values | Placebo (FAS) | Bimekizumab 64 mg Q4W (FAS) | Bimekizumab 160 mg Q4W (FAS) | Bimekizumab 160 mg w/ LD Q4W (FAS) |
|-----------------------------------|----------------------|-----------------------------------|------------------------------------|--|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 46.2 | 67.4 | 75.0 |

| End point values | Bimekizumab 320 mg Q4W (FAS) | Bimekizumab 480 mg Q4W (FAS) | | |
|-----------------------------------|------------------------------------|------------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 79.1 | 72.1 | | |

Statistical analyses

| Statistical analysis title | Statistical analysis 1 |
|---|---|
| Comparison groups | Placebo (FAS) v Bimekizumab 64 mg Q4W (FAS) |
| Number of subjects included in analysis | 81 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[1] |
| Method | Regression, Logistic |

Notes:

[1] - P-value evaluating dose response excludes the BKZ Dose 3 group; is based on a logistic regression model with fixed effects for region, prior biologic exposure, continuous treatment variable with values of -2, -1, 0, 1, 2 for the remaining groups.

| Statistical analysis title | Statistical analysis 2 |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[2] |
| Method | Regression, Logistic |

Notes:

[2] - P-value evaluating dose response excludes the BKZ Dose 3 group; is based on a logistic regression model with fixed effects for region, prior biologic exposure, continuous treatment variable with values of -2, -1, 0, 1, 2 for the remaining groups.

| Statistical analysis title | Statistical analysis 3 |
|----------------------------|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 320 mg Q4W (FAS) |

| | |
|---|-------------------------|
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[3] |
| Method | Regression, Logistic |

Notes:

[3] - P-value evaluating dose response excludes the BKZ Dose 3 group; is based on a logistic regression model with fixed effects for region, prior biologic exposure, continuous treatment variable with values of -2, -1, 0, 1, 2 for the remaining groups.

| | |
|---|--|
| Statistical analysis title | Statistical analysis 4 |
| Comparison groups | Placebo (FAS) v Bimekizumab 480 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[4] |
| Method | Regression, Logistic |

Notes:

[4] - P-value evaluating dose response excludes the BKZ Dose 3 group; is based on a logistic regression model with fixed effects for region, prior biologic exposure, continuous treatment variable with values of -2, -1, 0, 1, 2 for the remaining groups.

Secondary: Percentage of participants with Investigator's Global Assessment (IGA) (Clear or Almost Clear with at least 2 category improvement from Baseline) response at Week 12

| | |
|-----------------|---|
| End point title | Percentage of participants with Investigator's Global Assessment (IGA) (Clear or Almost Clear with at least 2 category improvement from Baseline) response at Week 12 |
|-----------------|---|

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.

The Full Analysis Set (FAS) consisted of all randomized participants who received at least 1 dose of the study medication and had a valid measurement of the primary efficacy variable at Baseline.

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

End point timeframe:

Week 12

| End point values | Placebo (FAS) | Bimekizumab 64 mg Q4W (FAS) | Bimekizumab 160 mg Q4W (FAS) | Bimekizumab 160 mg w/ LD Q4W (FAS) |
|-----------------------------------|----------------------|-----------------------------|------------------------------|------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 4.8 | 51.3 | 74.4 | 75.0 |

| | | | | |
|-------------------------|------------------------|------------------------|--|--|
| End point values | Bimekizumab 320 mg Q4W | Bimekizumab 480 mg Q4W | | |
|-------------------------|------------------------|------------------------|--|--|

| | (FAS) | (FAS) | | |
|-----------------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 86.0 | 76.7 | | |

Statistical analyses

| Statistical analysis title | Statistical analysis 1 |
|--|---|
| Statistical analysis description: | |
| Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure. | |
| Comparison groups | Placebo (FAS) v Bimekizumab 64 mg Q4W (FAS) |
| Number of subjects included in analysis | 81 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 21.43 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.51 |
| upper limit | 101.88 |

| Statistical analysis title | Statistical analysis 2 |
|--|--|
| Statistical analysis description: | |
| Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure. | |
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 63.21 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 12.9 |
| upper limit | 309.83 |

| | |
|--|--|
| Statistical analysis title | Statistical analysis 3 |
| Statistical analysis description: | |
| Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure. | |
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg w/ LD Q4W (FAS) |
| Number of subjects included in analysis | 82 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 62.35 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 12.61 |
| upper limit | 308.29 |

| | |
|--|--|
| Statistical analysis title | Statistical analysis 4 |
| Statistical analysis description: | |
| Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure. | |
| Comparison groups | Placebo (FAS) v Bimekizumab 320 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 130.35 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 24.5 |
| upper limit | 693.51 |

| | |
|--|--|
| Statistical analysis title | Statistical analysis 5 |
| Statistical analysis description: | |
| Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure. | |
| Comparison groups | Placebo (FAS) v Bimekizumab 480 mg Q4W (FAS) |

| | |
|---|----------------------|
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 69.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 14.07 |
| upper limit | 342.4 |

Secondary: Percentage of participants with Investigator's Global Assessment (IGA) (Clear or Almost Clear with at least 2 category improvement from Baseline) response at Week 8

| | |
|-----------------|--|
| End point title | Percentage of participants with Investigator's Global Assessment (IGA) (Clear or Almost Clear with at least 2 category improvement from Baseline) response at Week 8 |
|-----------------|--|

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.

The Full Analysis Set (FAS) consisted of all randomized participants who received at least 1 dose of the study medication and had a valid measurement of the primary efficacy variable at Baseline.

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

End point timeframe:

Week 8

| End point values | Placebo (FAS) | Bimekizumab 64 mg Q4W (FAS) | Bimekizumab 160 mg Q4W (FAS) | Bimekizumab 160 mg w/ LD Q4W (FAS) |
|-----------------------------------|----------------------|-----------------------------|------------------------------|------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 4.8 | 46.2 | 62.8 | 77.5 |

| End point values | Bimekizumab 320 mg Q4W (FAS) | Bimekizumab 480 mg Q4W (FAS) | | |
|-----------------------------------|------------------------------|------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 86.0 | 72.1 | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Statistical analysis 1 |
| Statistical analysis description: Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure. | |
| Comparison groups | Placebo (FAS) v Bimekizumab 64 mg Q4W (FAS) |
| Number of subjects included in analysis | 81 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0003 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 18.23 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.79 |
| upper limit | 87.76 |

| | |
|---|--|
| Statistical analysis title | Statistical analysis 2 |
| Statistical analysis description: Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure. | |
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 39.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 8.19 |
| upper limit | 191.59 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for

treatment, region, prior bio-exposure.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg w/ LD Q4W (FAS) |
| Number of subjects included in analysis | 82 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 77.27 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 15.19 |
| upper limit | 392.93 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 320 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 141.99 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 26.26 |
| upper limit | 767.72 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 5 |
|-----------------------------------|------------------------|

Statistical analysis description:

Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 480 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 58.52 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 11.89 |
| upper limit | 288 |

Secondary: Percentage of participants achieving a 90% or higher improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 8

| | |
|-----------------|--|
| End point title | Percentage of participants achieving a 90% or higher improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 8 |
|-----------------|--|

End point description:

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

The FAS consisted of all randomized participants who received at least 1 dose of medication and had a valid measurement of the primary efficacy at Baseline.

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

End point timeframe:

Week 8

| End point values | Placebo (FAS) | Bimekizumab 64 mg Q4W (FAS) | Bimekizumab 160 mg Q4W (FAS) | Bimekizumab 160 mg w/ LD Q4W (FAS) |
|-----------------------------------|----------------------|-----------------------------|------------------------------|------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 41.0 | 58.1 | 67.5 |

| End point values | Bimekizumab 320 mg Q4W (FAS) | Bimekizumab 480 mg Q4W (FAS) | | |
|-----------------------------------|------------------------------|------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 86.0 | 69.8 | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Statistical analysis 1 |
| Comparison groups | Placebo (FAS) v Bimekizumab 64 mg Q4W (FAS) |
| Number of subjects included in analysis | 81 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[5] |
| Method | Fisher exact |

Notes:

[5] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

| | |
|---|--|
| Statistical analysis title | Statistical analysis 2 |
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[6] |
| Method | Fisher exact |

Notes:

[6] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

| | |
|---|--|
| Statistical analysis title | Statistical analysis 3 |
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg w/ LD Q4W (FAS) |
| Number of subjects included in analysis | 82 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[7] |
| Method | Fisher exact |

Notes:

[7] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

| | |
|---|--|
| Statistical analysis title | Statistical analysis 4 |
| Comparison groups | Placebo (FAS) v Bimekizumab 320 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[8] |
| Method | Fisher exact |

Notes:

[8] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

| | |
|---|--|
| Statistical analysis title | Statistical analysis 5 |
| Comparison groups | Placebo (FAS) v Bimekizumab 480 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 ^[9] |
| Method | Fisher exact |

Notes:

[9] - The placebo treatment group contained no PASI90 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

Secondary: Percentage of participants achieving a 75% or higher improvement in Psoriasis Area and Severity Index (PASI) score at Week 12

| | |
|-----------------|---|
| End point title | Percentage of participants achieving a 75% or higher improvement in Psoriasis Area and Severity Index (PASI) score at Week 12 |
|-----------------|---|

End point description:

PASI75 response assessments are based on at least 75% improvement in PASI score from Baseline. This scoring system averages the redness/thickness/scaliness of the psoriatic lesions and weights the resulting score by the area of skin involved. Body divided into 4 areas: head/arms/trunk to groin/legs to top of buttocks. Assignment of an average score for the redness/thickness/scaling for each of the 4 body areas with a score of 0 (clear)-4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0-6 scale. Final PASI=average redness/thickness/scaliness of psoriatic skin lesions multiplied by the involved psoriasis area score and weighted by the percentage of the person's affected skin for the respective section. Min PASI score is 0=no disease, max score is 72=maximal disease.

The FAS consisted of all randomized participants who received at least 1 dose of medication and had a valid measurement of the primary efficacy at Baseline.

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

End point timeframe:

Week 12

| End point values | Placebo (FAS) | Bimekizumab 64 mg Q4W (FAS) | Bimekizumab 160 mg Q4W (FAS) | Bimekizumab 160 mg w/ LD Q4W (FAS) |
|-----------------------------------|----------------------|-----------------------------|------------------------------|------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 4.8 | 61.5 | 81.4 | 85.0 |

| End point values | Bimekizumab 320 mg Q4W (FAS) | Bimekizumab 480 mg Q4W (FAS) | | |
|-----------------------------------|------------------------------|------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 93.0 | 83.7 | | |

Statistical analyses

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 1 |
|----------------------------|------------------------|

Statistical analysis description:

Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure.

| | |
|-------------------|---|
| Comparison groups | Placebo (FAS) v Bimekizumab 64 mg Q4W (FAS) |
|-------------------|---|

| | |
|---|----------------------|
| Number of subjects included in analysis | 81 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 32.65 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.82 |
| upper limit | 156.38 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 2 |
|-----------------------------------|------------------------|

Statistical analysis description:

Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 94.51 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 18.54 |
| upper limit | 481.86 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 3 |
|-----------------------------------|------------------------|

Statistical analysis description:

Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg w/ LD Q4W (FAS) |
| Number of subjects included in analysis | 82 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 117.66 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 22.08 |
| upper limit | 626.89 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 4 |
|-----------------------------------|------------------------|

Statistical analysis description:

Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 320 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 280.76 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 44.06 |
| upper limit | 1789.24 |

| | |
|-----------------------------------|------------------------|
| Statistical analysis title | Statistical analysis 5 |
|-----------------------------------|------------------------|

Statistical analysis description:

Confidence intervals, odds ratios, p-values derived from a logistic regression model with fixed effects for treatment, region, prior bio-exposure.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 480 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 107.83 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 20.82 |
| upper limit | 558.57 |

Secondary: Percentage of participants achieving a 100% improvement from Baseline in Psoriasis Area and Severity Index (PASI) score at Week 12

| | |
|-----------------|---|
| End point title | Percentage of participants achieving a 100% improvement |
|-----------------|---|

End point description:

PASI correlates to the physician's assessment of psoriasis symptoms including redness of lesions, thickness of lesions, scaliness of lesions and extent of disease. Each parameter is graded from 0-4, 0 refers to no disease and 4 to severe involvement. The body is divided into 4 areas for scoring (head, arms, trunk to groin, legs to top of buttocks), and the final score ranges from 0-72. The PASI 100 response rate at Week 12 is measured as the percentage of participants who achieved 100% improvement from baseline PASI at Week 12.

The Full Analysis Set (FAS) consisted of all randomized participants who received at least 1 dose of the study medication and had a valid measurement of the primary efficacy variable at Baseline.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 12 | |

| End point values | Placebo (FAS) | Bimekizumab 64 mg Q4W (FAS) | Bimekizumab 160 mg Q4W (FAS) | Bimekizumab 160 mg w/ LD Q4W (FAS) |
|-----------------------------------|----------------------|-----------------------------|------------------------------|------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 28.2 | 27.9 | 60.0 |

| End point values | Bimekizumab 320 mg Q4W (FAS) | Bimekizumab 480 mg Q4W (FAS) | | |
|-----------------------------------|------------------------------|------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 55.8 | 48.8 | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Statistical analysis 1 |
| Statistical analysis description: | |
| The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test. | |
| Comparison groups | Placebo (FAS) v Bimekizumab 64 mg Q4W (FAS) |
| Number of subjects included in analysis | 81 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0001 |
| Method | Fisher exact |

| | |
|----------------------------|------------------------|
| Statistical analysis title | Statistical analysis 2 |
|----------------------------|------------------------|

Statistical analysis description:

The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0002 |
| Method | Fisher exact |

Statistical analysis title

Statistical analysis 3

Statistical analysis description:

The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 160 mg w/ LD Q4W (FAS) |
| Number of subjects included in analysis | 82 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Fisher exact |

Statistical analysis title

Statistical analysis 4

Statistical analysis description:

The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 320 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Fisher exact |

Statistical analysis title

Statistical analysis 5

Statistical analysis description:

The placebo treatment group contained no PASI100 responders and as such the p-values for the pairwise comparisons are based upon the Fisher's exact test.

| | |
|---|--|
| Comparison groups | Placebo (FAS) v Bimekizumab 480 mg Q4W (FAS) |
| Number of subjects included in analysis | 85 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Fisher exact |

Secondary: Plasma concentrations of bimekizumab during the study

| | |
|-----------------|---|
| End point title | Plasma concentrations of bimekizumab during the study |
|-----------------|---|

End point description:

Bimekizumab plasma concentration was expressed in micrograms per milliliter (µg/mL).

Values Below Limit of Quantification (BLQ) were replaced by the value of lower limit of quantification (LLOQ) divided by 2 = 0.075 µg/mL in the calculations of geometric mean and CIs. Geometric mean was only calculated if at least two-thirds of the concentrations were quantified at the respective time point. The PK-PPS consisted of all randomized participants who took at least 1 dose of the IMP and provided at least 1 quantifiable plasma concentration postdose and had no important protocol deviations affecting the PK variables.

Note 1: 999 is used as a placeholder for values below the level of detection since participants had no prior BKZ treatment (Baseline) and for values below the level of detection.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Bimekizumab 64 mg Q4W (PK-PPS) | Bimekizumab 160 mg Q4W (PK-PPS) | Bimekizumab 160 mg w/ LD Q4W (PK-PPS) | Bimekizumab 320 mg Q4W (PK-PPS) |
|---|--------------------------------------|---------------------------------------|---|---------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 39 | 42 | 40 | 43 |
| Units: µg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Baseline (39, 42, 40, 43, 43) | 999 (999 to 999) | 999 (999 to 999) | 999 (999 to 999) | 999 (999 to 999) |
| Week 1 (39, 42, 40, 43, 43) | 4.4490 (3.7526 to 5.2746) | 9.2481 (6.9779 to 12.2569) | 20.7892 (14.9192 to 28.9688) | 21.8622 (16.0624 to 29.7563) |
| Week 2 (39, 41, 39, 42, 42) | 3.4704 (3.0167 to 3.9923) | 8.6862 (7.5316 to 10.0179) | 19.0428 (16.5381 to 21.9267) | 19.0324 (16.8925 to 21.4434) |
| Week 4 (39, 41, 39, 41, 40) | 2.1282 (1.8398 to 2.4617) | 5.3751 (4.5233 to 6.3872) | 11.2903 (9.4809 to 13.4450) | 11.9194 (10.4503 to 13.5951) |
| Week 8 (38, 38, 37, 40, 40) | 2.3069 (1.7780 to 2.9931) | 7.1859 (5.3747 to 9.6075) | 10.2208 (8.8561 to 11.7957) | 16.3187 (13.9947 to 19.0285) |
| Week 12 (38, 38, 33, 40, 39) | 2.3121 (1.6037 to 3.3335) | 9.5278 (8.0614 to 11.2608) | 10.2557 (8.6807 to 12.1165) | 18.3166 (15.1652 to 22.1228) |
| SFU (4, 4, 2, 1, 3) | 999 (999 to 999) | 999 (999 to 999) | 999 (999 to 999) | 999 (999 to 999) |

| End point values | Bimekizumab 480 mg Q4W (PK-PPS) | | | |
|-----------------------------|---------------------------------------|--|--|--|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 43 | | | |
| Units: µg/mL | | | | |

| | | | | |
|--|---------------------------------|--|--|--|
| geometric mean (confidence interval 95%) | | | | |
| Baseline (39, 42, 40, 43, 43) | 999 (999 to 999) | | | |
| Week 1 (39, 42, 40, 43, 43) | 31.8019 (23.3488 to 43.3154) | | | |
| Week 2 (39, 41, 39, 42, 42) | 27.5641 (23.8485 to 31.8586) | | | |
| Week 4 (39, 41, 39, 41, 40) | 17.1811 (14.7612 to 19.9977) | | | |
| Week 8 (38, 38, 37, 40, 40) | 23.3285 (19.8863 to 27.3665) | | | |
| Week 12 (38, 38, 33, 40, 39) | 28.0908 (23.2463 to 33.9448) | | | |
| SFU (4, 4, 2, 1, 3) | 0.5165 (0.0032 to 84.5222) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Population PK (apparent total clearance (CL/F)) of bimekizumab

| | |
|-----------------|--|
| End point title | Population PK (apparent total clearance (CL/F)) of bimekizumab |
|-----------------|--|

End point description:

The data were presented as population estimates of CL/F. Given the sparse nature of PK sampling, CL/F cannot be estimated for each treatment group.

It was prespecified in the data analysis plan to combine doses to perform Population PK and PK/PD analysis based on a prior determination that the PK parameters are not dose-dependent.

The PK-PPS consisted of all randomized participants who took at least 1 dose of the IMP and provided at least 1 quantifiable plasma concentration postdose and had no important protocol deviations affecting the PK variables. Given the sparse nature of PK sampling, CL/F cannot be estimated for each treatment group.

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

End point timeframe:

From Baseline (Week 0) until Safety Follow-Up Visit (20 weeks after the last dose; Up to Week 28)

| | | | | |
|---|---------------------------|--|--|--|
| End point values | All participants (PK-PPS) | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 249 | | | |
| Units: L/Day | | | | |
| geometric mean (geometric coefficient of variation) | 0.362 (± 41.7) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Population PK (apparent volume of distribution (V/F)) of bimekizumab

| | |
|-----------------|--|
| End point title | Population PK (apparent volume of distribution (V/F)) of bimekizumab |
|-----------------|--|

End point description:

The data were presented as population estimates of V/F. Given the sparse nature of PK sampling, V/F cannot be estimated for each treatment group.

It was prespecified in the data analysis plan to combine doses to perform Population PK and PK/PD analysis based on a prior determination that the PK parameters are not dose-dependent.

The PK-PPS consisted of all randomized participants who took at least 1 dose of the IMP and provided at least 1 quantifiable plasma concentration postdose and had no important protocol deviations affecting the PK variables. Given the sparse nature of PK sampling, V/F cannot be estimated for each treatment group.

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

End point timeframe:

From Baseline (Week 0) until Safety Follow-Up Visit (20 weeks after the last dose; Up to Week 28)

| | | | | |
|---|---------------------------|--|--|--|
| End point values | All participants (PK-PPS) | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 249 | | | |
| Units: liters | | | | |
| geometric mean (geometric coefficient of variation) | 11.5 (\pm 146) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of bimekizumab leading to 50% of maximum effect (EC50)

| | |
|-----------------|--|
| End point title | Concentration of bimekizumab leading to 50% of maximum effect (EC50) |
|-----------------|--|

End point description:

The data were presented as population estimates of EC50. EC50 was estimated based on all available data and cannot be derived for each treatment arm.

It was prespecified in the data analysis plan to combine doses to perform Population PK and PK/PD analysis based on a prior determination that the PK parameters are not dose-dependent.

The PK-PPS consisted of all randomized participants who took at least 1 dose of the IMP and provided at least 1 quantifiable plasma concentration postdose and had no important protocol deviations affecting the PK variables. EC50 was estimated based on all available data and cannot be derived for each treatment arm.

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

End point timeframe:

From Baseline (Week 0) until Safety Follow-Up Visit (20 weeks after the last dose; Up to Week 28)

| | | | | |
|---|---------------------------|--|--|--|
| End point values | All participants (PK-PPS) | | | |
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 249 | | | |
| Units: µg/mL | | | | |
| geometric mean (geometric coefficient of variation) | 0.55 (± 126) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with a positive anti-bimekizumab antibody (AbAb) status prior to study treatment

| | |
|---|---|
| End point title | Percentage of participants with a positive anti-bimekizumab antibody (AbAb) status prior to study treatment |
| End point description: | |
| Antibody positive status prior study treatment was defined as having an antibody level greater than (>) 28.5% at Baseline (Week 0). | |
| The Pharmacokinetics Per-Protocol Set (PK-PPS) consisted of all randomized participants who took at least 1 dose of the IMP and provided at least 1 quantifiable plasma concentration postdose and had no important protocol deviations affecting the PK variables. | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Week 0) | |

| | | | | |
|-----------------------------------|----------------------|--------------------------------|---------------------------------|---------------------------------------|
| End point values | Placebo (PK-PPS) | Bimekizumab 64 mg Q4W (PK-PPS) | Bimekizumab 160 mg Q4W (PK-PPS) | Bimekizumab 160 mg w/ LD Q4W (PK-PPS) |
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 0 | 0 | 2.5 |

| | | | | |
|-----------------------------------|---------------------------------|---------------------------------|--|--|
| End point values | Bimekizumab 320 mg Q4W (PK-PPS) | Bimekizumab 480 mg Q4W (PK-PPS) | | |
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with an overall positive anti-bimekizumab antibody (AbAb) status following study treatment

| | |
|-----------------|---|
| End point title | Percentage of participants with an overall positive anti-bimekizumab antibody (AbAb) status following study treatment |
|-----------------|---|

End point description:

Overall antibody positive was defined as having a value of > 28.5% at any time in the Treatment Period. The Treatment Period did not include Baseline/pre-treatment samples.

The Pharmacokinetics Per-Protocol Set (PK-PPS) consisted of all randomized participants who took at least 1 dose of the IMP and provided at least 1 quantifiable plasma concentration postdose and had no important protocol deviations affecting the PK variables.

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

End point timeframe:

From Week 4 until the Safety Follow-Up visit (20 weeks after the last dose; Up to Week 28)

| End point values | Placebo (PK-PPS) | Bimekizumab 64 mg Q4W (PK-PPS) | Bimekizumab 160 mg Q4W (PK-PPS) | Bimekizumab 160 mg w/ LD Q4W (PK-PPS) |
|-----------------------------------|----------------------|--------------------------------|---------------------------------|---------------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 10.3 | 4.8 | 5.0 |

| End point values | Bimekizumab 320 mg Q4W (PK-PPS) | Bimekizumab 480 mg Q4W (PK-PPS) | | |
|-----------------------------------|---------------------------------|---------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one adverse event (AE) during the study

| | |
|-----------------|--|
| End point title | Percentage of participants with at least one adverse event (AE) during the study |
|-----------------|--|

End point description:

An adverse event (AE) was any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of investigational medicinal product (IMP), whether or not considered related to the IMP. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of IMP.

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

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

End point timeframe:

From Screening to End of Safety Follow-up (up to Week 32)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|-----------------------------------|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 38.1 | 76.9 | 55.8 | 65.0 |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|-----------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 60.5 | 60.5 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with at least one adverse event (AE) during the study by severity

| | |
|-----------------|--|
| End point title | Percentage of participants with at least one adverse event (AE) during the study by severity |
|-----------------|--|

End point description:

An adverse event (AE) was any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of investigational medicinal product (IMP), whether or not considered related to the IMP. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of IMP.

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

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

End point timeframe:

From Screening to End of Safety Follow-up (up to Week 32)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|-----------------------------------|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Mild | 11.9 | 43.6 | 27.9 | 22.5 |
| Moderate | 26.2 | 30.8 | 27.9 | 40.0 |
| Severe | 0 | 2.6 | 0 | 2.5 |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|-----------------------------------|-----------------------------|-----------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Mild | 39.5 | 44.2 | | |
| Moderate | 20.9 | 11.6 | | |
| Severe | 0 | 4.7 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (platelets)

| | |
|-----------------|--|
| End point title | Change from Baseline until Safety Follow-up Visit in hematology parameters (platelets) |
|-----------------|--|

End point description:

Platelets was measured in number of platelets per liter ($10^9/L$).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: 10 ⁹ platelets per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | 12.1 (± 34.7) | 3.2 (± 21.0) | -4.6 (± 30.8) | -14.0 (± 30.8) |
| Week 2 (41, 39, 40, 39, 41, 41) | 6.4 (± 37.8) | -8.6 (± 26.8) | -5.6 (± 36.4) | -8.9 (± 27.8) |
| Week 4 (41, 39, 41, 39, 40, 40) | -0.1 (± 32.0) | -5.8 (± 28.3) | -8.6 (± 40.1) | -11.4 (± 21.8) |
| Week 6 (40, 38, 38, 36, 39, 40) | 5.6 (± 47.5) | -5.2 (± 26.3) | -13.6 (± 34.3) | -5.6 (± 30.3) |
| Week 8 (39, 37, 38, 35, 40, 40) | 6.9 (± 37.6) | -2.3 (± 44.7) | -6.1 (± 43.7) | 6.3 (± 35.6) |
| Week 12 (39, 38, 37, 35, 40, 38) | 2.8 (± 36.7) | -6.0 (± 36.2) | -13.2 (± 40.1) | -3.6 (± 37.5) |
| SFU (4, 4, 4, 2, 1, 3) | 14.8 (± 33.3) | -30.3 (± 71.6) | 7.8 (± 20.0) | -33.0 (± 31.1) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--|-----------------------------|-----------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 42 | | |
| Units: 10 ⁹ platelets per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | 3.5 (± 25.2) | -0.1 (± 35.0) | | |
| Week 2 (41, 39, 40, 39, 41, 41) | 7.8 (± 31.2) | -3.9 (± 41.8) | | |
| Week 4 (41, 39, 41, 39, 40, 40) | -7.0 (± 28.9) | -7.5 (± 36.8) | | |
| Week 6 (40, 38, 38, 36, 39, 40) | -0.3 (± 44.0) | -7.6 (± 37.3) | | |
| Week 8 (39, 37, 38, 35, 40, 40) | 0.7 (± 39.5) | -4.7 (± 36.4) | | |
| Week 12 (39, 38, 37, 35, 40, 38) | -5.4 (± 36.1) | -5.5 (± 38.8) | | |
| SFU (4, 4, 4, 2, 1, 3) | 39.0 (± 999) | 39.3 (± 27.4) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular hemoglobin (HGB) concentration, hemoglobin)

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular hemoglobin (HGB) concentration, hemoglobin) |
|-----------------|---|

End point description:

Erythrocytes mean corpuscular hemoglobin concentration (MCHC) and hemoglobin were measured in grams per liter (g/L).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|---|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: g/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| MCHC Week 1 (42, 39, 42, 40, 43, 42) | 0.1 (± 8.1) | -2.0 (± 10.3) | -0.3 (± 8.8) | -1.0 (± 11.6) |
| MCHC Week 2 (41, 39, 41, 39, 41, 41) | 0.1 (± 7.9) | 1.1 (± 6.6) | 1.6 (± 9.4) | -0.3 (± 9.8) |
| MCHC Week 4 (41, 39, 41, 39, 41, 40) | -0.2 (± 9.1) | 0.2 (± 8.3) | -0.1 (± 9.9) | -2.9 (± 6.3) |
| MCHC Week 6 (40, 38, 38, 37, 40, 40) | -2.5 (± 11.0) | -1.7 (± 8.6) | -0.5 (± 9.4) | -2.9 (± 7.0) |
| MCHC Week 8 (39, 37, 38, 35, 40, 40) | -2.2 (± 8.0) | -1.4 (± 12.7) | 0.3 (± 10.3) | -2.5 (± 7.9) |
| MCHC Week 12 (39, 38, 37, 35, 40, 38) | -6.3 (± 12.5) | -2.2 (± 14.7) | -1.6 (± 9.1) | -4.5 (± 10.1) |
| MCHC Week SFU (4, 4, 4, 2, 1, 3) | -12.5 (± 11.0) | 5.3 (± 26.2) | -5.5 (± 10.6) | -9.5 (± 7.8) |
| Hemoglobin Week 1 (42, 39, 42, 40, 43, 42) | -2.9 (± 7.3) | 0.1 (± 6.1) | 1.0 (± 6.8) | -2.6 (± 5.2) |
| Hemoglobin Week 2 (41, 39, 41, 39, 41, 41) | -3.0 (± 6.7) | 0.5 (± 5.3) | 0.6 (± 6.0) | -1.5 (± 7.5) |
| Hemoglobin Week 4 (41, 39, 41, 39, 41, 40) | -2.9 (± 8.2) | 0.8 (± 6.1) | -0.9 (± 6.2) | -2.1 (± 5.9) |
| Hemoglobin Week 6 (40, 38, 38, 37, 40, 40) | -2.4 (± 7.8) | 0.7 (± 6.3) | -0.3 (± 6.6) | -1.2 (± 4.8) |
| Hemoglobin Week 8 (39, 37, 38, 35, 40, 40) | -2.7 (± 8.0) | 1.1 (± 7.6) | 0.8 (± 7.1) | -0.6 (± 7.5) |
| Hemoglobin Week 12 (39, 38, 37, 35, 40, 38) | -1.8 (± 9.1) | 3.2 (± 9.6) | -0.1 (± 8.1) | -1.0 (± 8.5) |
| Hemoglobin SFU (4, 4, 4, 2, 1, 3) | -4.8 (± 7.4) | 7.8 (± 31.0) | -6.5 (± 4.7) | -8.5 (± 2.1) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 42 | | |
| Units: g/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| MCHC Week 1 (42, 39, 42, 40, 43, 42) | 0.5 (± 8.6) | 0.3 (± 8.1) | | |
| MCHC Week 2 (41, 39, 41, 39, 41, 41) | 2.6 (± 7.9) | 1.8 (± 8.8) | | |
| MCHC Week 4 (41, 39, 41, 39, 41, 40) | 0.1 (± 8.0) | -0.4 (± 11.7) | | |
| MCHC Week 6 (40, 38, 38, 37, 40, 40) | -0.5 (± 7.8) | -1.3 (± 8.9) | | |
| MCHC Week 8 (39, 37, 38, 35, 40, 40) | -2.1 (± 9.2) | -2.9 (± 9.2) | | |
| MCHC Week 12 (39, 38, 37, 35, 40, 38) | -2.0 (± 12.7) | -3.6 (± 13.7) | | |
| MCHC Week SFU (4, 4, 4, 2, 1, 3) | -2.0 (± 9.9) | -22.0 (± 18.0) | | |
| Hemoglobin Week 1 (42, 39, 42, 40, 43, 42) | -1.0 (± 7.0) | -0.8 (± 5.0) | | |
| Hemoglobin Week 2 (41, 39, 41, 39, 41, 41) | -1.1 (± 7.0) | 0.5 (± 6.6) | | |

| | | | | |
|---|--------------|---------------|--|--|
| Hemoglobin Week 4 (41, 39, 41, 39, 41, 40) | -1.8 (± 8.7) | -0.4 (± 6.3) | | |
| Hemoglobin Week 6 (40, 38, 38, 37, 40, 40) | -2.1 (± 8.4) | 0.9 (± 6.3) | | |
| Hemoglobin Week 8 (39, 37, 38, 35, 40, 40) | -1.8 (± 8.1) | 0.9 (± 6.5) | | |
| Hemoglobin Week 12 (39, 38, 37, 35, 40, 38) | -1.2 (± 9.3) | 0.3 (± 7.1) | | |
| Hemoglobin SFU (4, 4, 4, 2, 1, 3) | 6.0 (± 999) | -6.7 (± 11.0) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular hemoglobin (HGB))

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular hemoglobin (HGB)) |
|-----------------|---|

End point description:

Erythrocytes mean corpuscular hemoglobin (HGB) was measured in picograms (pg).
The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--------------------------------------|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: picograms (pg) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | -0.09 (± 0.57) | -0.01 (± 0.56) | -0.10 (± 0.55) | 0.07 (± 0.51) |
| Week 2 (41, 39, 41, 39, 41, 41) | -0.04 (± 0.59) | 0.04 (± 0.54) | 0.05 (± 0.49) | 0.10 (± 0.78) |
| Week 4 (41, 39, 41, 39, 41, 40) | -0.07 (± 0.66) | 0.10 (± 0.84) | -0.07 (± 0.63) | -0.01 (± 0.42) |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.17 (± 0.64) | -0.09 (± 0.84) | -0.16 (± 0.61) | -0.11 (± 0.47) |
| Week 8 (39, 37, 38, 35, 40, 40) | -0.19 (± 0.64) | 0.09 (± 1.09) | -0.16 (± 1.10) | -0.16 (± 0.64) |
| Week 12 (39, 38, 37, 35, 40, 38) | -0.34 (± 0.71) | 0.09 (± 1.53) | -0.08 (± 0.58) | -0.14 (± 0.66) |
| SFU (4, 4, 4, 2, 1, 3) | -0.33 (± 0.79) | 2.93 (± 6.66) | -0.15 (± 0.17) | -0.55 (± 0.78) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--------------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 42 | | |
| Units: picograms (pg) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | -0.09 (± 0.87) | 0.00 (± 0.53) | | |
| Week 2 (41, 39, 41, 39, 41, 41) | -0.03 (± 0.60) | 0.14 (± 0.54) | | |
| Week 4 (41, 39, 41, 39, 41, 40) | -0.10 (± 0.68) | 0.04 (± 0.50) | | |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.12 (± 0.84) | -0.04 (± 0.60) | | |
| Week 8 (39, 37, 38, 35, 40, 40) | -0.26 (± 0.99) | -0.16 (± 0.53) | | |
| Week 12 (39, 38, 37, 35, 40, 38) | -0.09 (± 1.14) | -0.16 (± 0.67) | | |
| SFU (4, 4, 4, 2, 1, 3) | 0.70 (± 999) | -0.60 (± 1.10) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular volume)

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes mean corpuscular volume) |
|-----------------|---|

End point description:

Erythrocytes mean corpuscular volume was measured in femtolitres (fL).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--------------------------------------|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: femtolitres (fL) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | -0.35 (± 1.55) | 0.52 (± 2.29) | -0.25 (± 1.64) | 0.51 (± 2.63) |
| Week 2 (41, 39, 41, 39, 41, 41) | -0.14 (± 1.65) | -0.16 (± 1.31) | -0.33 (± 1.96) | 0.31 (± 1.32) |
| Week 4 (41, 39, 41, 39, 41, 40) | -0.11 (± 1.60) | 0.23 (± 1.89) | -0.25 (± 1.81) | 0.67 (± 1.76) |
| Week 6 (40, 38, 38, 37, 40, 40) | 0.20 (± 2.84) | 0.14 (± 2.47) | -0.29 (± 1.90) | 0.39 (± 1.79) |
| Week 8 (39, 37, 38, 35, 40, 40) | 0.05 (± 2.11) | 0.71 (± 2.88) | -0.54 (± 2.57) | 0.16 (± 2.57) |
| Week 12 (39, 38, 37, 35, 40, 38) | 0.76 (± 3.81) | 0.87 (± 3.23) | 0.17 (± 2.39) | 0.78 (± 2.55) |

| | | | | |
|------------------------|---------------|----------------|---------------|---------------|
| SFU (4, 4, 4, 2, 1, 3) | 2.58 (± 5.10) | 7.80 (± 14.07) | 0.90 (± 2.38) | 0.85 (± 0.35) |
|------------------------|---------------|----------------|---------------|---------------|

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--------------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 42 | | |
| Units: femtolitres (fL) | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | -0.23 (± 2.14) | -0.04 (± 1.37) | | |
| Week 2 (41, 39, 41, 39, 41, 41) | -0.64 (± 1.40) | -0.05 (± 1.60) | | |
| Week 4 (41, 39, 41, 39, 41, 40) | -0.10 (± 1.64) | 0.22 (± 2.87) | | |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.02 (± 1.92) | 0.25 (± 1.85) | | |
| Week 8 (39, 37, 38, 35, 40, 40) | -0.02 (± 2.29) | 0.36 (± 2.37) | | |
| Week 12 (39, 38, 37, 35, 40, 38) | 0.47 (± 2.88) | 0.51 (± 3.89) | | |
| SFU (4, 4, 4, 2, 1, 3) | 2.80 (± 999) | 4.87 (± 8.46) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes)

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in hematology parameters (erythrocytes) |
|-----------------|---|

End point description:

Erythrocytes was measured in number of red blood cells per liter ($10^{12}/L$).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: 10^{12} red blood cells per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | -0.081 (± 0.282) | 0.004 (± 0.213) | 0.047 (± 0.238) | -0.095 (± 0.184) |

| | | | | |
|----------------------------------|------------------|------------------|------------------|------------------|
| Week 2 (41, 39, 41, 39, 41, 41) | -0.088 (± 0.220) | 0.010 (± 0.193) | 0.014 (± 0.215) | -0.060 (± 0.282) |
| Week 4 (41, 39, 41, 39, 41, 40) | -0.085 (± 0.274) | 0.019 (± 0.217) | -0.018 (± 0.193) | -0.066 (± 0.215) |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.053 (± 0.277) | 0.038 (± 0.218) | 0.011 (± 0.243) | -0.019 (± 0.145) |
| Week 8 (39, 37, 38, 35, 40, 40) | -0.062 (± 0.320) | 0.022 (± 0.245) | 0.048 (± 0.219) | 0.009 (± 0.224) |
| Week 12 (39, 38, 37, 35, 40, 38) | -0.007 (± 0.314) | 0.092 (± 0.258) | 0.011 (± 0.271) | -0.005 (± 0.297) |
| SFU (4, 4, 4, 2, 1, 3) | -0.090 (± 0.346) | -0.135 (± 0.184) | -0.195 (± 0.165) | -0.215 (± 0.035) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 42 | | |
| Units: 10 ¹² red blood cells per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | -0.029 (± 0.259) | -0.026 (± 0.178) | | |
| Week 2 (41, 39, 41, 39, 41, 41) | -0.041 (± 0.231) | -0.001 (± 0.232) | | |
| Week 4 (41, 39, 41, 39, 41, 40) | -0.053 (± 0.281) | -0.015 (± 0.216) | | |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.060 (± 0.278) | 0.035 (± 0.224) | | |
| Week 8 (39, 37, 38, 35, 40, 40) | -0.028 (± 0.240) | 0.056 (± 0.238) | | |
| Week 12 (39, 38, 37, 35, 40, 38) | -0.036 (± 0.297) | 0.039 (± 0.228) | | |
| SFU (4, 4, 4, 2, 1, 3) | 0.080 (± 999) | -0.123 (± 0.491) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (hematocrit)

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in hematology parameters (hematocrit) |
|-----------------|---|

End point description:

Hematocrit was measured in volume percentage (%) of red blood cells in blood.
The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--------------------------------------|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: volume % of red blood cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | -0.88 (± 2.49) | 0.27 (± 2.07) | 0.33 (± 2.31) | -0.58 (± 2.14) |
| Week 2 (41, 39, 41, 39, 41, 41) | -0.86 (± 2.02) | 0.00 (± 1.65) | -0.04 (± 2.15) | -0.42 (± 2.61) |
| Week 4 (41, 39, 41, 39, 41, 40) | -0.81 (± 2.40) | 0.24 (± 2.07) | -0.26 (± 1.86) | -0.26 (± 1.80) |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.33 (± 2.46) | 0.41 (± 1.88) | -0.04 (± 2.18) | 0.02 (± 1.73) |
| Week 8 (39, 37, 38, 35, 40, 40) | -0.52 (± 2.37) | 0.55 (± 2.51) | 0.18 (± 1.84) | 0.14 (± 2.61) |
| Week 12 (39, 38, 37, 35, 40, 38) | 0.32 (± 2.87) | 1.25 (± 2.29) | 0.18 (± 2.57) | 0.30 (± 2.99) |
| SFU (4, 4, 4, 2, 1, 3) | 0.20 (± 1.44) | 1.98 (± 6.92) | -1.20 (± 1.90) | -1.50 (± 0.14) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--------------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 42 | | |
| Units: volume % of red blood cells | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 42) | -0.36 (± 2.31) | -0.23 (± 1.62) | | |
| Week 2 (41, 39, 41, 39, 41, 41) | -0.65 (± 2.09) | -0.02 (± 2.03) | | |
| Week 4 (41, 39, 41, 39, 41, 40) | -0.48 (± 2.57) | -0.03 (± 2.02) | | |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.51 (± 2.59) | 0.44 (± 1.90) | | |
| Week 8 (39, 37, 38, 35, 40, 40) | -0.22 (± 2.46) | 0.67 (± 2.03) | | |
| Week 12 (39, 38, 37, 35, 40, 38) | -0.05 (± 2.75) | 0.59 (± 2.02) | | |
| SFU (4, 4, 4, 2, 1, 3) | 2.10 (± 999) | 1.00 (± 0.85) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in hematology parameters (basophils, eosinophils, leukocytes, lymphocytes, monocytes, neutrophils)

| | |
|-----------------|--|
| End point title | Change from Baseline until Safety Follow-up Visit in hematology parameters (basophils, eosinophils, leukocytes, lymphocytes, monocytes, neutrophils) |
|-----------------|--|

End point description:

Basophils, eosinophils, leukocytes, lymphocytes, monocytes and neutrophils were measured in number of white blood cells per liter ($10^9/L$).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 41 | 40 |
| Units: 10 ⁹ white blood cells per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Basophils Week 1 (42, 39, 41, 40, 43, 42) | 0.01 (± 0.03) | 0.01 (± 0.03) | 0.00 (± 0.03) | 0.01 (± 0.03) |
| Basophils Week 2 (41, 38, 41, 39, 40, 41) | 0.00 (± 0.02) | 0.00 (± 0.04) | 0.01 (± 0.04) | 0.01 (± 0.04) |
| Basophils Week 4 (41, 39, 41, 39, 41, 40) | 0.00 (± 0.03) | 0.00 (± 0.05) | 0.00 (± 0.03) | 0.01 (± 0.02) |
| Basophils Week 6 (40, 38, 38, 36, 40, 40) | 0.01 (± 0.03) | 0.00 (± 0.04) | 0.00 (± 0.04) | 0.01 (± 0.02) |
| Basophils Week 8 (39, 37, 37, 34, 40, 40) | 0.00 (± 0.04) | -0.01 (± 0.04) | 0.02 (± 0.01) | 0.00 (± 0.00) |
| Basophils Week 12 (38, 38, 37, 34, 40, 38) | 0.00 (± 0.03) | 0.00 (± 0.04) | 0.01 (± 0.03) | 0.00 (± 0.02) |
| Basophils SFU (4, 4, 4, 2, 1, 3) | 0.03 (± 0.05) | -0.03 (± 0.05) | 0.00 (± 0.00) | 0.00 (± 0.00) |
| Eosinophils Week 1 (42, 39, 43, 40, 43, 42) | 0.02 (± 0.06) | 0.02 (± 0.12) | 0.01 (± 0.07) | 0.04 (± 0.10) |
| Eosinophils Week 2 (41, 38, 41, 39, 40, 41) | 0.02 (± 0.08) | 0.04 (± 0.26) | 0.00 (± 0.08) | 0.05 (± 0.11) |
| Eosinophils Week 4 (41, 39, 41, 39, 41, 40) | 0.03 (± 0.09) | 0.04 (± 0.26) | 0.01 (± 0.08) | 0.02 (± 0.11) |
| Eosinophils Week 6 (40, 38, 38, 36, 40, 40) | 0.04 (± 0.10) | 0.02 (± 0.19) | 0.00 (± 0.08) | 0.01 (± 0.09) |
| Eosinophils Week 8 (39, 37, 37, 34, 40, 40) | 0.01 (± 0.09) | 0.01 (± 0.18) | 0.01 (± 0.08) | 0.04 (± 0.17) |
| Eosinophils Week 12 (38, 38, 37, 34, 40, 38) | 0.02 (± 0.09) | 0.03 (± 0.22) | 0.00 (± 0.09) | 0.00 (± 0.08) |
| Eosinophils SFU (4, 4, 4, 2, 1, 3) | 0.05 (± 0.06) | 0.08 (± 0.10) | 0.10 (± 0.00) | 0.00 (± 0.00) |
| Leukocytes Week 1 (42, 39, 42, 40, 43, 42) | 0.16 (± 1.30) | -0.59 (± 1.34) | -0.15 (± 1.43) | -0.63 (± 1.82) |
| Leukocytes Week 2 (41, 38, 41, 39, 40, 41) | 0.18 (± 1.36) | -0.56 (± 1.31) | -0.22 (± 1.43) | -0.42 (± 1.34) |
| Leukocytes Week 4 (41, 39, 41, 39, 41, 40) | 0.17 (± 1.51) | -0.36 (± 1.31) | -0.23 (± 1.38) | -0.54 (± 1.14) |
| Leukocytes Week 6 (40, 38, 38, 37, 40, 40) | -0.22 (± 1.25) | -0.50 (± 1.95) | -0.47 (± 1.49) | -0.57 (± 1.34) |
| Leukocytes Week 8 (39, 37, 38, 35, 40, 40) | -0.10 (± 1.34) | -0.67 (± 1.55) | -0.24 (± 1.94) | -0.37 (± 1.55) |
| Leukocytes Week 12 (39, 38, 37, 34, 40, 38) | 0.00 (± 1.37) | -0.28 (± 1.68) | -0.47 (± 1.67) | -0.51 (± 1.41) |

| | | | | |
|--|----------------|----------------|----------------|----------------|
| Leukocytes SFU (4, 4, 4, 2, 1, 3) | -0.05 (± 0.98) | 1.15 (± 2.54) | 0.95 (± 1.43) | -0.65 (± 0.78) |
| Lymphocytes Week 1 (42, 39, 41, 40, 43, 42) | 0.12 (± 0.36) | -0.05 (± 0.30) | 0.15 (± 0.42) | 0.13 (± 0.34) |
| Lymphocytes Week 2 (41, 38, 41, 39, 40, 41) | 0.08 (± 0.32) | -0.11 (± 0.30) | 0.09 (± 0.34) | 0.09 (± 0.40) |
| Lymphocytes Week 4 (41, 39, 41, 39, 41, 40) | 0.06 (± 0.40) | -0.04 (± 0.33) | 0.15 (± 0.43) | 0.08 (± 0.42) |
| Lymphocytes Week 6 (40, 38, 38, 36, 40, 40) | 0.08 (± 0.46) | -0.08 (± 0.43) | 0.03 (± 0.31) | 0.04 (± 0.43) |
| Lymphocytes Week 8 (39, 37, 37, 34, 40, 40) | 0.02 (± 0.37) | -0.04 (± 0.31) | 0.09 (± 0.40) | 0.11 (± 0.33) |
| Lymphocytes Week 12 (38, 38, 37, 34, 40, 38) | 0.08 (± 0.38) | 0.01 (± 0.35) | 0.06 (± 0.38) | 0.07 (± 0.48) |
| Lymphocytes SFU (4, 4, 4, 2, 1, 3) | 0.25 (± 0.24) | 0.25 (± 0.40) | 0.23 (± 0.19) | 0.25 (± 0.21) |
| Monocytes Week 1 (42, 39, 41, 40, 43, 42) | 0.02 (± 0.16) | -0.01 (± 0.12) | 0.02 (± 0.15) | 0.02 (± 0.11) |
| Monocytes Week 2 (41, 38, 41, 39, 40, 41) | 0.00 (± 0.14) | -0.04 (± 0.13) | 0.00 (± 0.14) | 0.04 (± 0.15) |
| Monocytes Week 4 (41, 39, 41, 39, 41, 40) | 0.03 (± 0.16) | -0.01 (± 0.11) | 0.01 (± 0.15) | 0.03 (± 0.13) |
| Monocytes Week 6 (40, 38, 38, 36, 40, 40) | 0.01 (± 0.15) | -0.01 (± 0.18) | 0.02 (± 0.15) | 0.00 (± 0.11) |
| Monocytes Week 8 (39, 37, 37, 34, 40, 40) | -0.02 (± 0.15) | -0.03 (± 0.11) | 0.00 (± 0.16) | -0.01 (± 0.14) |
| Monocytes Week 12 (38, 38, 37, 34, 40, 38) | 0.01 (± 0.16) | 0.00 (± 0.14) | -0.02 (± 0.15) | -0.01 (± 0.18) |
| Monocytes SFU (4, 4, 4, 2, 1, 3) | 0.10 (± 0.22) | 0.10 (± 0.22) | 0.03 (± 0.10) | 0.00 (± 0.00) |
| Neutrophils Week 1 (42, 39, 41, 40, 43, 42) | -0.02 (± 1.16) | -0.55 (± 1.12) | -0.32 (± 1.25) | -0.81 (± 1.81) |
| Neutrophils Week 2 (41, 38, 41, 39, 40, 41) | 0.09 (± 1.29) | -0.43 (± 1.05) | -0.31 (± 1.33) | -0.59 (± 1.09) |
| Neutrophils Week 4 (41, 39, 41, 39, 41, 40) | 0.04 (± 1.30) | -0.35 (± 1.07) | -0.39 (± 1.31) | -0.68 (± 1.02) |
| Neutrophils Week 6 (40, 38, 38, 36, 40, 40) | -0.36 (± 0.98) | -0.43 (± 1.64) | -0.49 (± 1.38) | -0.54 (± 1.16) |
| Neutrophils Week 8 (39, 37, 37, 34, 40, 40) | -0.13 (± 1.18) | -0.61 (± 1.40) | -0.34 (± 1.72) | -0.57 (± 1.28) |
| Neutrophils Week 12 (38, 38, 37, 34, 40, 38) | -0.11 (± 1.17) | -0.33 (± 1.50) | -0.49 (± 1.50) | -0.57 (± 1.20) |
| Neutrophils SFU (4, 4, 4, 2, 1, 3) | -0.45 (± 0.79) | 0.75 (± 1.88) | 0.65 (± 1.20) | -0.95 (± 0.49) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 42 | | |
| Units: 10 ⁹ white blood cells per liter | | | | |
| arithmetic mean (standard deviation) | | | | |
| Basophils Week 1 (42, 39, 41, 40, 43, 42) | 0.00 (± 0.04) | 0.01 (± 0.03) | | |
| Basophils Week 2 (41, 38, 41, 39, 40, 41) | 0.01 (± 0.04) | 0.00 (± 0.03) | | |
| Basophils Week 4 (41, 39, 41, 39, 41, 40) | 0.01 (± 0.05) | 0.00 (± 0.04) | | |
| Basophils Week 6 (40, 38, 38, 36, 40, 40) | 0.00 (± 0.04) | 0.00 (± 0.04) | | |

| | | | | |
|--|----------------|----------------|--|--|
| Basophils Week 8 (39, 37, 37, 34, 40, 40) | 0.02 (± 0.04) | 0.00 (± 0.05) | | |
| Basophils Week 12 (38, 38, 37, 34, 40, 38) | 0.01 (± 0.04) | 0.00 (± 0.04) | | |
| Basophils SFU (4, 4, 4, 2, 1, 3) | 0.00 (± 999) | 0.03 (± 0.06) | | |
| Eosinophils Week 1 (42, 39, 43, 40, 43, 42) | 0.02 (± 0.11) | -0.02 (± 0.12) | | |
| Eosinophils Week 2 (41, 38, 41, 39, 40, 41) | 0.00 (± 0.11) | 0.01 (± 0.11) | | |
| Eosinophils Week 4 (41, 39, 41, 39, 41, 40) | 0.03 (± 0.09) | 0.00 (± 0.18) | | |
| Eosinophils Week 6 (40, 38, 38, 36, 40, 40) | 0.05 (± 0.16) | -0.01 (± 0.17) | | |
| Eosinophils Week 8 (39, 37, 37, 34, 40, 40) | 0.05 (± 0.18) | -0.03 (± 0.16) | | |
| Eosinophils Week 12 (38, 38, 37, 34, 40, 38) | 0.03 (± 0.13) | -0.03 (± 0.11) | | |
| Eosinophils SFU (4, 4, 4, 2, 1, 3) | -0.10 (± 999) | 0.07 (± 0.06) | | |
| Leukocytes Week 1 (42, 39, 42, 40, 43, 42) | -0.19 (± 1.51) | -0.48 (± 0.90) | | |
| Leukocytes Week 2 (41, 38, 41, 39, 40, 41) | -0.31 (± 1.80) | -0.46 (± 1.29) | | |
| Leukocytes Week 4 (41, 39, 41, 39, 41, 40) | -0.36 (± 1.73) | -0.34 (± 1.24) | | |
| Leukocytes Week 6 (40, 38, 38, 37, 40, 40) | -0.45 (± 2.02) | -0.45 (± 1.12) | | |
| Leukocytes Week 8 (39, 37, 38, 35, 40, 40) | -0.30 (± 1.76) | -0.45 (± 0.87) | | |
| Leukocytes Week 12 (39, 38, 37, 34, 40, 38) | -0.50 (± 1.44) | -0.48 (± 1.09) | | |
| Leukocytes SFU (4, 4, 4, 2, 1, 3) | 0.20 (± 999) | 0.30 (± 0.40) | | |
| Lymphocytes Week 1 (42, 39, 41, 40, 43, 42) | 0.14 (± 0.46) | 0.00 (± 0.45) | | |
| Lymphocytes Week 2 (41, 38, 41, 39, 40, 41) | 0.12 (± 0.34) | -0.08 (± 0.37) | | |
| Lymphocytes Week 4 (41, 39, 41, 39, 41, 40) | 0.11 (± 0.36) | 0.06 (± 0.36) | | |
| Lymphocytes Week 6 (40, 38, 38, 36, 40, 40) | 0.05 (± 0.37) | -0.05 (± 0.40) | | |
| Lymphocytes Week 8 (39, 37, 37, 34, 40, 40) | 0.15 (± 0.45) | 0.06 (± 0.42) | | |
| Lymphocytes Week 12 (38, 38, 37, 34, 40, 38) | 0.14 (± 0.38) | -0.04 (± 0.37) | | |
| Lymphocytes SFU (4, 4, 4, 2, 1, 3) | 0.00 (± 999) | 0.50 (± 0.44) | | |
| Monocytes Week 1 (42, 39, 41, 40, 43, 42) | 0.02 (± 0.17) | -0.03 (± 0.14) | | |
| Monocytes Week 2 (41, 38, 41, 39, 40, 41) | -0.04 (± 0.17) | -0.03 (± 0.15) | | |
| Monocytes Week 4 (41, 39, 41, 39, 41, 40) | -0.01 (± 0.17) | 0.02 (± 0.17) | | |
| Monocytes Week 6 (40, 38, 38, 36, 40, 40) | -0.02 (± 0.22) | -0.03 (± 0.18) | | |
| Monocytes Week 8 (39, 37, 37, 34, 40, 40) | -0.04 (± 0.17) | -0.02 (± 0.15) | | |
| Monocytes Week 12 (38, 38, 37, 34, 40, 38) | -0.07 (± 0.17) | -0.01 (± 0.14) | | |
| Monocytes SFU (4, 4, 4, 2, 1, 3) | -0.30 (± 999) | -0.07 (± 0.21) | | |
| Neutrophils Week 1 (42, 39, 41, 40, 43, 42) | -0.37 (± 1.20) | -0.44 (± 0.76) | | |
| Neutrophils Week 2 (41, 38, 41, 39, 40, 41) | -0.41 (± 1.64) | -0.36 (± 1.13) | | |

| | | | | |
|--|----------------|----------------|--|--|
| Neutrophils Week 4 (41, 39, 41, 39, 41, 40) | -0.48 (± 1.60) | -0.40 (± 1.18) | | |
| Neutrophils Week 6 (40, 38, 38, 36, 40, 40) | -0.50 (± 1.78) | -0.36 (± 1.01) | | |
| Neutrophils Week 8 (39, 37, 37, 34, 40, 40) | -0.45 (± 1.61) | -0.47 (± 0.80) | | |
| Neutrophils Week 12 (38, 38, 37, 34, 40, 38) | -0.59 (± 1.28) | -0.39 (± 0.93) | | |
| Neutrophils SFU (4, 4, 4, 2, 1, 3) | 0.50 (± 999) | -0.13 (± 0.38) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in biochemistry parameters (calcium, chloride, potassium, magnesium, sodium, urea nitrogen, cholesterol, glucose)

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in biochemistry parameters (calcium, chloride, potassium, magnesium, sodium, urea nitrogen, cholesterol, glucose) |
|-----------------|---|

End point description:

Calcium, chloride, potassium, magnesium, sodium, urea nitrogen, cholesterol and glucose were measured in millimoles per liter (mmol/L).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Calcium Week 1 (42, 39, 42, 40, 43, 43) | -0.010 (± 0.076) | 0.011 (± 0.088) | -0.021 (± 0.126) | -0.017 (± 0.076) |
| Calcium Week 2 (42, 39, 41, 39, 42, 42) | -0.003 (± 0.082) | 0.034 (± 0.094) | -0.007 (± 0.092) | 0.004 (± 0.074) |
| Calcium Week 4 (41, 39, 41, 39, 41, 41) | -0.029 (± 0.073) | 0.012 (± 0.099) | -0.020 (± 0.106) | -0.008 (± 0.074) |
| Calcium Week 6 (40, 38, 38, 37, 40, 40) | -0.033 (± 0.070) | 0.009 (± 0.079) | -0.019 (± 0.091) | -0.008 (± 0.092) |
| Calcium Week 8 (39, 38, 38, 34, 40, 40) | -0.023 (± 0.084) | 0.001 (± 0.106) | -0.027 (± 0.099) | 0.019 (± 0.089) |
| Calcium Week 12 (39, 38, 38, 35, 40, 39) | -0.011 (± 0.095) | 0.025 (± 0.092) | -0.038 (± 0.120) | 0.001 (± 0.093) |

| | | | | |
|---|------------------|------------------|------------------|------------------|
| Calcium SFU (4, 4, 4, 2, 1, 3) | -0.095 (± 0.083) | -0.050 (± 0.109) | -0.073 (± 0.045) | -0.125 (± 0.134) |
| Chloride Week 1 (42, 39, 42, 40, 43, 43) | 0.5 (± 1.8) | 0.6 (± 2.0) | 0.6 (± 2.3) | 0.6 (± 2.5) |
| Chloride Week 2 (42, 39, 41, 39, 42, 43) | 0.0 (± 2.3) | 0.1 (± 2.4) | -0.3 (± 2.2) | 0.4 (± 2.3) |
| Chloride Week 4 (41, 39, 41, 39, 41, 41) | 0.1 (± 1.8) | 0.8 (± 2.1) | 0.0 (± 2.5) | 0.2 (± 2.3) |
| Chloride Week 6 (40, 38, 38, 37, 40, 40) | -0.1 (± 2.1) | 0.0 (± 2.3) | -0.6 (± 1.7) | 0.0 (± 2.4) |
| Chloride Week 8 (39, 38, 38, 34, 40, 40) | 0.2 (± 2.1) | 0.3 (± 2.3) | 0.3 (± 2.0) | -0.1 (± 2.9) |
| Chloride Week 12 (39, 38, 38, 35, 40, 39) | 0.3 (± 1.7) | -0.1 (± 2.5) | -0.2 (± 2.0) | 0.2 (± 2.3) |
| Chloride SFU (4, 4, 4, 2, 1, 3) | 1.0 (± 1.6) | 3.0 (± 2.7) | 0.5 (± 5.4) | 2.0 (± 0.0) |
| Potassium Week 1 (42, 39, 42, 40, 43, 42) | 0.08 (± 0.45) | 0.08 (± 0.33) | 0.05 (± 0.41) | 0.02 (± 0.36) |
| Potassium Week 2 (42, 39, 41, 39, 42, 42) | 0.03 (± 0.30) | 0.08 (± 0.33) | 0.02 (± 0.32) | -0.06 (± 0.29) |
| Potassium Week 4 (41, 39, 41, 39, 41, 40) | 0.09 (± 0.40) | 0.12 (± 0.41) | 0.09 (± 0.38) | 0.01 (± 0.34) |
| Potassium Week 6 (39, 38, 38, 37, 40, 40) | -0.04 (± 0.32) | 0.11 (± 0.35) | -0.03 (± 0.31) | -0.07 (± 0.33) |
| Potassium Week 8 (39, 38, 38, 34, 40, 40) | 0.01 (± 0.39) | 0.07 (± 0.36) | 0.12 (± 0.38) | -0.06 (± 0.38) |
| Potassium Week 12 (39, 37, 38, 35, 40, 39) | -0.05 (± 0.35) | 0.08 (± 0.34) | 0.08 (± 0.37) | -0.06 (± 0.37) |
| Potassium SFU (4, 4, 4, 2, 1, 3) | 0.10 (± 0.36) | 0.10 (± 0.37) | -0.10 (± 0.29) | -0.45 (± 0.07) |
| Magnesium Week 1 (42, 39, 42, 40, 43, 43) | -0.010 (± 0.074) | -0.002 (± 0.052) | -0.020 (± 0.069) | 0.005 (± 0.079) |
| Magnesium Week 2 (41, 39, 41, 39, 42, 42) | -0.012 (± 0.063) | -0.004 (± 0.064) | -0.010 (± 0.065) | 0.001 (± 0.068) |
| Magnesium Week 4 (41, 39, 41, 39, 41, 41) | -0.023 (± 0.077) | -0.004 (± 0.062) | -0.017 (± 0.046) | 0.008 (± 0.071) |
| Magnesium Week 6 (40, 38, 38, 37, 40, 40) | -0.013 (± 0.054) | -0.014 (± 0.053) | -0.013 (± 0.057) | -0.008 (± 0.065) |
| Magnesium Week 8 (39, 38, 38, 34, 40, 40) | -0.026 (± 0.070) | -0.023 (± 0.042) | -0.023 (± 0.063) | 0.003 (± 0.071) |
| Magnesium Week 12 (39, 38, 38, 35, 40, 39) | -0.014 (± 0.093) | 0.007 (± 0.074) | -0.025 (± 0.069) | 0.009 (± 0.074) |
| Magnesium SFU (4, 4, 4, 2, 1, 3) | 0.053 (± 0.093) | 0.110 (± 0.295) | -0.035 (± 0.047) | -0.050 (± 0.057) |
| Sodium Week 1 (42, 39, 42, 40, 43, 43) | -0.1 (± 1.8) | 0.2 (± 1.7) | 0.3 (± 2.7) | 0.1 (± 1.9) |
| Sodium Week 2 (41, 39, 41, 39, 42, 42) | -0.3 (± 1.7) | -0.2 (± 1.4) | -0.4 (± 1.8) | 0.0 (± 2.0) |
| Sodium Week 4 (41, 39, 41, 39, 41, 41) | -0.2 (± 1.7) | 0.2 (± 1.7) | 0.2 (± 1.7) | -0.2 (± 1.7) |
| Sodium Week 6 (40, 38, 38, 37, 40, 40) | -0.5 (± 2.0) | -0.1 (± 2.1) | -0.8 (± 1.6) | -0.1 (± 1.9) |
| Sodium Week 8 (39, 38, 38, 34, 40, 40) | -0.6 (± 2.0) | 0.0 (± 2.8) | -0.2 (± 1.8) | -0.2 (± 2.0) |
| Sodium Week 12 (39, 38, 38, 35, 40, 39) | -0.4 (± 2.0) | -0.2 (± 1.7) | -0.1 (± 1.7) | -0.2 (± 2.0) |
| Sodium SFU (4, 4, 4, 2, 1, 3) | -0.5 (± 2.1) | 0.8 (± 1.7) | -2.0 (± 2.2) | -2.0 (± 2.8) |
| Urea Nitrogen Week 1 (42, 39, 42, 40, 43, 43) | -0.16 (± 1.09) | 0.11 (± 1.12) | 0.27 (± 1.19) | 0.34 (± 1.22) |
| Urea Nitrogen Week 2 (42, 39, 41, 39, 42, 42) | 0.00 (± 1.16) | -0.03 (± 1.25) | 0.24 (± 1.16) | 0.16 (± 1.17) |
| Urea Nitrogen Week 4 (41, 39, 41, 39, 41, 41) | -0.14 (± 1.16) | 0.48 (± 1.52) | 0.50 (± 1.31) | -0.03 (± 1.20) |
| Urea Nitrogen Week 6 (40, 38, 38, 37, 40, 40) | -0.12 (± 0.96) | 0.21 (± 1.40) | 0.41 (± 1.14) | 0.19 (± 1.31) |
| Urea Nitrogen Week 8 (39, 38, 38, 34, 40, 40) | -0.28 (± 1.29) | 0.14 (± 1.33) | 0.32 (± 1.08) | -0.08 (± 1.58) |

| | | | | |
|--|----------------|----------------|----------------|----------------|
| Urea Nitrogen Week 12 (39, 38, 38, 35, 40, 39) | -0.17 (± 1.35) | -0.04 (± 1.37) | 0.39 (± 1.14) | 0.08 (± 1.13) |
| Urea Nitrogen SFU (4, 4, 4, 2, 1, 3) | 0.65 (± 1.74) | 0.80 (± 1.19) | 0.78 (± 3.27) | -0.65 (± 2.05) |
| Cholesterol Week 1 (42, 39, 42, 40, 43, 43) | -0.04 (± 0.47) | -0.06 (± 0.54) | 0.00 (± 0.65) | -0.09 (± 0.59) |
| Cholesterol Week 2 (42, 39, 41, 39, 42, 42) | -0.13 (± 0.71) | 0.03 (± 0.63) | 0.12 (± 0.58) | -0.11 (± 0.52) |
| Cholesterol Week 4 (41, 39, 41, 39, 41, 41) | -0.06 (± 0.59) | 0.04 (± 0.63) | 0.17 (± 0.55) | -0.31 (± 0.88) |
| Cholesterol Week 6 (40, 38, 38, 37, 40, 40) | 0.05 (± 0.46) | -0.02 (± 0.73) | 0.17 (± 0.56) | -0.24 (± 0.70) |
| Cholesterol Week 8 (39, 38, 38, 34, 40, 40) | -0.08 (± 0.67) | -0.17 (± 0.68) | 0.16 (± 0.64) | -0.13 (± 0.83) |
| Cholesterol Week 12 (39, 38, 38, 35, 40, 39) | -0.20 (± 0.88) | -0.07 (± 0.62) | 0.11 (± 0.62) | -0.18 (± 0.77) |
| Cholesterol SFU (4, 4, 4, 2, 1, 3) | -0.28 (± 0.30) | -0.83 (± 1.56) | 0.38 (± 0.52) | -0.80 (± 0.14) |
| Glucose Week 1 (42, 39, 42, 40, 43, 42) | 0.50 (± 1.59) | 0.12 (± 0.82) | -0.14 (± 1.00) | -0.06 (± 1.14) |
| Glucose Week 2 (41, 39, 41, 39, 42, 42) | 0.29 (± 1.62) | 0.17 (± 1.23) | -0.05 (± 0.92) | -0.20 (± 1.13) |
| Glucose Week 4 (41, 39, 41, 39, 41, 40) | 0.37 (± 1.42) | 0.25 (± 1.22) | -0.12 (± 1.03) | -0.09 (± 1.24) |
| Glucose Week 6 (39, 38, 38, 37, 40, 40) | 0.44 (± 1.42) | 0.30 (± 1.15) | -0.04 (± 1.26) | 0.02 (± 1.60) |
| Glucose Week 8 (39, 38, 38, 34, 40, 40) | 0.37 (± 1.48) | 0.22 (± 1.48) | -0.15 (± 0.87) | -0.06 (± 1.43) |
| Glucose Week 12 (39, 37, 38, 35, 40, 39) | 0.22 (± 1.27) | 0.01 (± 1.08) | 0.02 (± 1.35) | -0.17 (± 1.23) |
| Glucose SFU (4, 4, 4, 2, 1, 3) | -0.40 (± 0.48) | 0.75 (± 0.89) | -0.33 (± 0.67) | -0.25 (± 0.49) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: mmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Calcium Week 1 (42, 39, 42, 40, 43, 43) | 0.000 (± 0.077) | -0.010 (± 0.080) | | |
| Calcium Week 2 (42, 39, 41, 39, 42, 42) | 0.006 (± 0.088) | -0.006 (± 0.085) | | |
| Calcium Week 4 (41, 39, 41, 39, 41, 41) | 0.005 (± 0.099) | -0.010 (± 0.084) | | |
| Calcium Week 6 (40, 38, 38, 37, 40, 40) | -0.026 (± 0.086) | -0.027 (± 0.100) | | |
| Calcium Week 8 (39, 38, 38, 34, 40, 40) | -0.002 (± 0.089) | -0.016 (± 0.084) | | |
| Calcium Week 12 (39, 38, 38, 35, 40, 39) | -0.019 (± 0.121) | -0.001 (± 0.092) | | |
| Calcium SFU (4, 4, 4, 2, 1, 3) | 0.020 (± 999) | 0.020 (± 0.193) | | |
| Chloride Week 1 (42, 39, 42, 40, 43, 43) | 0.3 (± 2.1) | 0.1 (± 1.8) | | |
| Chloride Week 2 (42, 39, 41, 39, 42, 43) | 0.5 (± 2.1) | 0.1 (± 1.9) | | |
| Chloride Week 4 (41, 39, 41, 39, 41, 41) | -0.1 (± 2.6) | -0.1 (± 1.9) | | |
| Chloride Week 6 (40, 38, 38, 37, 40, 40) | -0.1 (± 3.0) | 0.1 (± 2.0) | | |
| Chloride Week 8 (39, 38, 38, 34, 40, 40) | 0.1 (± 2.4) | 0.1 (± 2.3) | | |

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|--|------------------|------------------|--|--|
| Chloride Week 12 (39, 38, 38, 35, 40, 39) | 0.8 (± 2.4) | 0.1 (± 2.2) | | |
| Chloride SFU (4, 4, 4, 2, 1, 3) | 0.0 (± 999) | 0.3 (± 2.1) | | |
| Potassium Week 1 (42, 39, 42, 40, 43, 42) | -0.03 (± 0.32) | 0.04 (± 0.29) | | |
| Potassium Week 2 (42, 39, 41, 39, 42, 42) | 0.05 (± 0.37) | -0.03 (± 0.39) | | |
| Potassium Week 4 (41, 39, 41, 39, 41, 40) | 0.05 (± 0.40) | 0.03 (± 0.33) | | |
| Potassium Week 6 (39, 38, 38, 37, 40, 40) | -0.07 (± 0.34) | -0.02 (± 0.35) | | |
| Potassium Week 8 (39, 38, 38, 34, 40, 40) | -0.12 (± 0.40) | 0.02 (± 0.35) | | |
| Potassium Week 12 (39, 37, 38, 35, 40, 39) | -0.07 (± 0.37) | -0.06 (± 0.33) | | |
| Potassium SFU (4, 4, 4, 2, 1, 3) | 0.20 (± 999) | -0.20 (± 0.30) | | |
| Magnesium Week 1 (42, 39, 42, 40, 43, 43) | -0.007 (± 0.077) | -0.009 (± 0.064) | | |
| Magnesium Week 2 (41, 39, 41, 39, 42, 42) | -0.017 (± 0.086) | 0.005 (± 0.075) | | |
| Magnesium Week 4 (41, 39, 41, 39, 41, 41) | -0.017 (± 0.067) | -0.013 (± 0.070) | | |
| Magnesium Week 6 (40, 38, 38, 37, 40, 40) | -0.020 (± 0.073) | -0.017 (± 0.063) | | |
| Magnesium Week 8 (39, 38, 38, 34, 40, 40) | -0.019 (± 0.072) | -0.021 (± 0.058) | | |
| Magnesium Week 12 (39, 38, 38, 35, 40, 39) | -0.017 (± 0.075) | -0.008 (± 0.056) | | |
| Magnesium SFU (4, 4, 4, 2, 1, 3) | -0.060 (± 999) | -0.023 (± 0.025) | | |
| Sodium Week 1 (42, 39, 42, 40, 43, 43) | 0.0 (± 2.2) | 0.0 (± 1.4) | | |
| Sodium Week 2 (41, 39, 41, 39, 42, 42) | 0.2 (± 2.3) | 0.0 (± 1.5) | | |
| Sodium Week 4 (41, 39, 41, 39, 41, 41) | -0.1 (± 2.3) | -0.2 (± 1.7) | | |
| Sodium Week 6 (40, 38, 38, 37, 40, 40) | -0.1 (± 2.9) | -0.3 (± 1.7) | | |
| Sodium Week 8 (39, 38, 38, 34, 40, 40) | -0.1 (± 2.2) | -0.6 (± 2.0) | | |
| Sodium Week 12 (39, 38, 38, 35, 40, 39) | -0.2 (± 2.4) | -0.3 (± 1.9) | | |
| Sodium SFU (4, 4, 4, 2, 1, 3) | -1.0 (± 999) | -1.7 (± 1.2) | | |
| Urea Nitrogen Week 1 (42, 39, 42, 40, 43, 43) | 0.27 (± 1.24) | 0.21 (± 0.88) | | |
| Urea Nitrogen Week 2 (42, 39, 41, 39, 42, 42) | 0.27 (± 1.17) | 0.37 (± 1.03) | | |
| Urea Nitrogen Week 4 (41, 39, 41, 39, 41, 41) | -0.11 (± 1.08) | 0.15 (± 1.04) | | |
| Urea Nitrogen Week 6 (40, 38, 38, 37, 40, 40) | 0.29 (± 1.14) | 0.12 (± 0.93) | | |
| Urea Nitrogen Week 8 (39, 38, 38, 34, 40, 40) | 0.33 (± 1.30) | 0.35 (± 0.88) | | |
| Urea Nitrogen Week 12 (39, 38, 38, 35, 40, 39) | 0.13 (± 1.08) | 0.01 (± 0.85) | | |
| Urea Nitrogen SFU (4, 4, 4, 2, 1, 3) | -0.30 (± 999) | 0.77 (± 1.27) | | |
| Cholesterol Week 1 (42, 39, 42, 40, 43, 43) | 0.12 (± 0.65) | 0.06 (± 0.34) | | |
| Cholesterol Week 2 (42, 39, 41, 39, 42, 42) | 0.12 (± 1.04) | 0.05 (± 0.57) | | |
| Cholesterol Week 4 (41, 39, 41, 39, 41, 41) | 0.00 (± 1.30) | 0.05 (± 0.66) | | |
| Cholesterol Week 6 (40, 38, 38, 37, 40, 40) | -0.24 (± 1.32) | 0.08 (± 0.60) | | |

| | | | | |
|--|----------------|----------------|--|--|
| Cholesterol Week 8 (39, 38, 38, 34, 40, 40) | -0.17 (± 1.22) | 0.01 (± 0.48) | | |
| Cholesterol Week 12 (39, 38, 38, 35, 40, 39) | 0.01 (± 1.29) | -0.05 (± 0.76) | | |
| Cholesterol SFU (4, 4, 4, 2, 1, 3) | 0.20 (± 999) | 0.40 (± 0.44) | | |
| Glucose Week 1 (42, 39, 42, 40, 43, 42) | 0.07 (± 1.10) | 0.22 (± 0.70) | | |
| Glucose Week 2 (41, 39, 41, 39, 42, 42) | 0.03 (± 1.09) | 0.05 (± 0.67) | | |
| Glucose Week 4 (41, 39, 41, 39, 41, 40) | 0.37 (± 1.20) | 0.19 (± 0.92) | | |
| Glucose Week 6 (39, 38, 38, 37, 40, 40) | 0.21 (± 1.30) | 0.29 (± 1.27) | | |
| Glucose Week 8 (39, 38, 38, 34, 40, 40) | 0.11 (± 1.10) | 0.03 (± 0.97) | | |
| Glucose Week 12 (39, 37, 38, 35, 40, 39) | -0.15 (± 0.88) | 0.04 (± 0.95) | | |
| Glucose SFU (4, 4, 4, 2, 1, 3) | 0.20 (± 999) | -0.17 (± 0.61) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in biochemistry parameters (lactate dehydrogenase, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, gamma glutamyl transferase)

| | |
|-----------------|--|
| End point title | Change from Baseline until Safety Follow-up Visit in biochemistry parameters (lactate dehydrogenase, alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, gamma glutamyl transferase) |
|-----------------|--|

End point description:

Lactate dehydrogenase (LDH), alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST) and gamma glutamyl transferase (GGT) were measured in units per liter (U/L). The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--------------------------------------|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: U/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| LDH Week 1 (42, 39, 42, 40, 43, 43) | -2.0 (± 29.4) | 1.1 (± 24.8) | -5.0 (± 24.1) | -0.3 (± 21.4) |
| LDH Week 2 (42, 39, 41, 39, 42, 42) | -4.9 (± 26.4) | -2.5 (± 25.2) | -3.5 (± 22.1) | 0.4 (± 27.6) |
| LDH Week 4 (41, 39, 41, 39, 41, 41) | -4.9 (± 22.4) | 1.7 (± 31.9) | -8.1 (± 16.7) | 5.0 (± 43.5) |
| LDH Week 6 (40, 38, 38, 37, 40, 40) | -5.0 (± 27.7) | -1.4 (± 25.2) | -7.3 (± 20.3) | 2.0 (± 16.2) |
| LDH Week 8 (39, 38, 38, 34, 40, 40) | -5.5 (± 27.4) | 0.5 (± 25.2) | -12.3 (± 22.2) | -0.8 (± 18.9) |

| | | | | |
|--------------------------------------|---------------|---------------|---------------|----------------|
| LDH Week 12 (39, 38, 38, 35, 40, 39) | -4.9 (± 28.1) | 2.9 (± 26.7) | -7.5 (± 25.1) | -0.3 (± 20.6) |
| LDH SFU (4, 4, 4, 2, 1, 3) | -1.5 (± 12.9) | -5.0 (± 18.4) | 3.3 (± 81.2) | -45.5 (± 16.3) |
| ALP Week 1 (42, 39, 42, 40, 43, 43) | -1.8 (± 6.3) | -0.5 (± 6.0) | -3.5 (± 8.2) | -3.8 (± 7.7) |
| ALP Week 2 (42, 39, 41, 39, 42, 42) | -3.0 (± 12.7) | 0.0 (± 7.4) | -2.5 (± 10.5) | -2.7 (± 8.2) |
| ALP Week 4 (41, 39, 41, 39, 41, 41) | -2.4 (± 8.7) | -1.9 (± 9.2) | -6.2 (± 9.8) | -4.3 (± 9.4) |
| ALP Week 6 (40, 38, 38, 37, 40, 40) | -3.0 (± 8.3) | -1.8 (± 9.0) | -5.5 (± 10.0) | -2.4 (± 8.6) |
| ALP Week 8 (39, 38, 38, 34, 40, 40) | -4.3 (± 12.2) | -1.7 (± 8.0) | -4.2 (± 11.2) | -2.1 (± 10.0) |
| ALP Week 12 (39, 38, 38, 35, 40, 39) | -2.0 (± 8.1) | 0.3 (± 7.2) | -2.4 (± 11.8) | -0.4 (± 9.0) |
| ALP SFU (4, 4, 4, 2, 1, 3) | -0.5 (± 7.4) | 9.8 (± 8.9) | 7.8 (± 15.3) | -3.0 (± 5.7) |
| ALT Week 1 (42, 39, 42, 40, 43, 43) | 2.0 (± 7.7) | 2.1 (± 10.4) | -1.7 (± 13.7) | 1.6 (± 12.2) |
| ALT Week 2 (42, 39, 41, 39, 42, 42) | 0.3 (± 6.5) | 1.9 (± 9.0) | 2.0 (± 29.8) | -0.9 (± 7.7) |
| ALT Week 4 (41, 39, 41, 39, 41, 41) | -0.2 (± 7.0) | 1.1 (± 8.6) | 0.8 (± 18.7) | -0.4 (± 10.2) |
| ALT Week 6 (40, 38, 38, 37, 40, 40) | 3.9 (± 18.9) | 1.1 (± 8.9) | -0.6 (± 11.7) | 3.5 (± 20.9) |
| ALT Week 8 (39, 38, 38, 34, 40, 40) | 1.8 (± 10.8) | 2.2 (± 10.2) | 0.1 (± 10.5) | -0.4 (± 9.7) |
| ALT Week 12 (39, 38, 38, 35, 40, 39) | -1.3 (± 7.5) | 1.8 (± 9.9) | -1.0 (± 10.8) | -0.9 (± 9.1) |
| ALT SFU (4, 4, 4, 2, 1, 3) | -3.8 (± 3.0) | 4.3 (± 3.4) | 26.5 (± 42.1) | -6.0 (± 8.5) |
| AST Week 1 (42, 39, 42, 40, 43, 43) | 0.5 (± 6.1) | 2.0 (± 10.8) | -3.0 (± 15.2) | 1.9 (± 11.5) |
| AST Week 2 (42, 39, 41, 39, 42, 42) | -1.0 (± 3.8) | 0.4 (± 4.9) | -1.9 (± 19.1) | -0.9 (± 4.7) |
| AST Week 4 (41, 39, 41, 39, 41, 41) | -1.1 (± 4.8) | -0.1 (± 5.8) | -2.5 (± 17.5) | -0.4 (± 5.9) |
| AST Week 6 (40, 38, 38, 37, 40, 40) | 1.5 (± 10.6) | 0.8 (± 6.0) | -0.9 (± 9.5) | 4.0 (± 15.7) |
| AST Week 8 (39, 38, 38, 34, 40, 40) | 0.0 (± 5.1) | 0.2 (± 6.7) | -1.4 (± 5.4) | -1.4 (± 4.6) |
| AST Week 12 (39, 38, 38, 35, 40, 39) | -1.3 (± 5.5) | 1.1 (± 7.9) | -1.4 (± 8.3) | -0.3 (± 4.8) |
| AST SFU (4, 4, 4, 2, 1, 3) | -2.8 (± 1.7) | -0.3 (± 2.1) | 11.5 (± 23.5) | -4.0 (± 2.8) |
| GGT Week 1 (42, 39, 42, 40, 43, 43) | 0.6 (± 6.4) | -0.8 (± 14.1) | -2.0 (± 10.7) | -7.5 (± 42.1) |
| GGT Week 2 (42, 39, 41, 39, 42, 42) | 0.2 (± 8.7) | -1.6 (± 11.1) | 0.2 (± 14.2) | -1.2 (± 8.0) |
| GGT Week 4 (41, 39, 41, 39, 41, 41) | -0.7 (± 8.5) | -1.9 (± 11.8) | 1.8 (± 18.6) | -2.6 (± 12.8) |
| GGT Week 6 (40, 38, 38, 37, 40, 40) | 1.8 (± 10.5) | -1.8 (± 13.8) | -2.9 (± 13.1) | -2.9 (± 7.3) |
| GGT Week 8 (39, 38, 38, 34, 40, 40) | 2.4 (± 13.7) | -1.9 (± 14.9) | -0.9 (± 18.4) | -2.6 (± 13.6) |
| GGT Week 12 (39, 38, 38, 35, 40, 39) | -0.4 (± 10.9) | -2.2 (± 13.3) | -1.1 (± 21.7) | -0.6 (± 11.2) |
| GGT SFU (4, 4, 4, 2, 1, 3) | -8.0 (± 13.4) | 1.3 (± 3.9) | 19.8 (± 23.3) | -16.5 (± 24.7) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--------------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: U/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| LDH Week 1 (42, 39, 42, 40, 43, 43) | -4.6 (± 18.9) | -3.4 (± 19.7) | | |
| LDH Week 2 (42, 39, 41, 39, 42, 42) | -7.6 (± 27.4) | -5.1 (± 20.1) | | |
| LDH Week 4 (41, 39, 41, 39, 41, 41) | -4.5 (± 37.7) | -4.4 (± 15.4) | | |
| LDH Week 6 (40, 38, 38, 37, 40, 40) | -11.0 (± 27.5) | -3.5 (± 22.6) | | |
| LDH Week 8 (39, 38, 38, 34, 40, 40) | -10.7 (± 33.1) | -3.7 (± 27.5) | | |
| LDH Week 12 (39, 38, 38, 35, 40, 39) | -5.6 (± 33.1) | -4.4 (± 24.8) | | |
| LDH SFU (4, 4, 4, 2, 1, 3) | 15.0 (± 999) | 32.3 (± 34.2) | | |
| ALP Week 1 (42, 39, 42, 40, 43, 43) | -1.9 (± 5.3) | -2.3 (± 5.7) | | |
| ALP Week 2 (42, 39, 41, 39, 42, 42) | -1.6 (± 6.5) | -1.7 (± 7.7) | | |
| ALP Week 4 (41, 39, 41, 39, 41, 41) | -2.6 (± 8.1) | -1.7 (± 7.8) | | |
| ALP Week 6 (40, 38, 38, 37, 40, 40) | -2.1 (± 9.6) | -1.4 (± 7.5) | | |
| ALP Week 8 (39, 38, 38, 34, 40, 40) | -1.1 (± 11.3) | -1.9 (± 7.2) | | |

| | | | | |
|--------------------------------------|---------------|---------------|--|--|
| ALP Week 12 (39, 38, 38, 35, 40, 39) | -0.5 (± 10.4) | -0.4 (± 8.4) | | |
| ALP SFU (4, 4, 4, 2, 1, 3) | 3.0 (± 999) | 3.0 (± 1.0) | | |
| ALT Week 1 (42, 39, 42, 40, 43, 43) | 0.7 (± 8.9) | 1.2 (± 9.1) | | |
| ALT Week 2 (42, 39, 41, 39, 42, 42) | -0.2 (± 10.2) | 1.6 (± 11.5) | | |
| ALT Week 1 (41, 39, 41, 39, 41, 41) | 0.4 (± 14.7) | 1.0 (± 13.3) | | |
| ALT Week 6 (40, 38, 38, 37, 40, 40) | -1.7 (± 13.7) | 1.1 (± 12.5) | | |
| ALT Week 8 (39, 38, 38, 34, 40, 40) | -1.1 (± 14.5) | 0.8 (± 9.0) | | |
| ALT Week 12 (39, 38, 38, 35, 40, 39) | -0.9 (± 14.6) | -0.4 (± 10.6) | | |
| ALT SFU (4, 4, 4, 2, 1, 3) | 16.0 (± 999) | -3.3 (± 3.1) | | |
| AST Week 1 (42, 39, 42, 40, 43, 43) | 0.3 (± 6.3) | -0.5 (± 7.2) | | |
| AST Week 2 (42, 39, 41, 39, 42, 42) | -0.5 (± 6.1) | 0.9 (± 13.4) | | |
| AST Week 4 (41, 39, 41, 39, 41, 41) | 0.6 (± 8.2) | -0.4 (± 7.5) | | |
| AST Week 6 (40, 38, 38, 37, 40, 40) | -1.4 (± 7.0) | -1.4 (± 6.5) | | |
| AST Week 8 (39, 38, 38, 34, 40, 40) | -0.4 (± 8.3) | -0.8 (± 6.3) | | |
| AST Week 12 (39, 38, 38, 35, 40, 39) | -0.5 (± 7.3) | -0.9 (± 5.2) | | |
| AST SFU (4, 4, 4, 2, 1, 3) | 9.0 (± 999) | 0.7 (± 2.5) | | |
| GGT Week 1 (42, 39, 42, 40, 43, 43) | 1.6 (± 22.9) | -0.8 (± 6.3) | | |
| GGT Week 2 (42, 39, 41, 39, 42, 42) | -1.9 (± 6.5) | 0.4 (± 15.0) | | |
| GGT Week 4 (41, 39, 41, 39, 41, 41) | -0.4 (± 8.4) | -1.4 (± 14.1) | | |
| GGT Week 6 (40, 38, 38, 37, 40, 40) | -2.1 (± 9.3) | -1.1 (± 12.9) | | |
| GGT Week 8 (39, 38, 38, 34, 40, 40) | -2.5 (± 9.4) | 3.1 (± 29.5) | | |
| GGT Week 12 (39, 38, 38, 35, 40, 39) | -0.4 (± 11.1) | -0.9 (± 12.2) | | |
| GGT SFU (4, 4, 4, 2, 1, 3) | 37.0 (± 999) | 3.0 (± 3.5) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in biochemistry parameters (creatinine, bilirubin)

| | |
|-----------------|--|
| End point title | Change from Baseline until Safety Follow-up Visit in biochemistry parameters (creatinine, bilirubin) |
|-----------------|--|

End point description:

Creatinine and bilirubin were measured in micromols per liter (µmol/L).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|---|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: µmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Creatinine Week 1 (42, 39, 42, 40, 43, 43) | 0.6 (± 7.0) | 2.7 (± 10.1) | 1.4 (± 8.6) | 0.6 (± 8.1) |
| Creatinine Week 2 (42, 39, 41, 39, 42, 42) | 0.0 (± 7.1) | -0.8 (± 8.2) | -0.4 (± 10.1) | -0.7 (± 8.5) |
| Creatinine Week 4 (41, 39, 41, 39, 41, 41) | 0.0 (± 5.8) | 1.3 (± 9.1) | 0.6 (± 7.9) | -1.7 (± 8.1) |
| Creatinine Week 6 (40, 38, 38, 37, 40, 40) | -1.1 (± 7.8) | 1.6 (± 10.5) | -0.1 (± 10.6) | -0.6 (± 7.9) |
| Creatinine Week 8 (39, 38, 38, 34, 40, 40) | -1.1 (± 6.2) | -0.4 (± 7.4) | -1.0 (± 9.6) | -2.6 (± 8.4) |
| Creatinine Week 12 (39, 38, 38, 35, 40, 39) | -1.6 (± 7.8) | -0.2 (± 7.0) | 0.7 (± 12.0) | -0.7 (± 9.1) |
| Creatinine SFU (4, 4, 4, 2, 1, 3) | 1.5 (± 4.4) | 6.0 (± 4.3) | -6.5 (± 4.4) | -10.5 (± 16.3) |
| Bilirubin Week 1 (42, 39, 42, 40, 43, 43) | -0.53 (± 3.10) | -1.79 (± 4.50) | -0.52 (± 2.81) | -0.55 (± 4.49) |
| Bilirubin Week 2 (42, 39, 41, 39, 42, 42) | -0.35 (± 2.85) | -0.86 (± 5.05) | -0.48 (± 3.40) | -0.38 (± 3.60) |
| Bilirubin Week 4 (41, 39, 41, 39, 41, 41) | -0.70 (± 3.26) | -1.70 (± 4.92) | -0.26 (± 3.53) | -0.04 (± 2.74) |
| Bilirubin Week 6 (40, 38, 38, 37, 40, 40) | -0.51 (± 3.13) | -1.15 (± 4.59) | 0.35 (± 3.44) | -0.33 (± 3.94) |
| Bilirubin Week 8 (39, 38, 38, 34, 40, 40) | -0.21 (± 3.81) | -0.98 (± 4.68) | -0.30 (± 3.20) | -0.43 (± 4.52) |
| Bilirubin Week 12 (39, 38, 38, 35, 40, 39) | -0.74 (± 3.43) | -1.02 (± 5.24) | -0.73 (± 2.98) | -1.20 (± 3.37) |
| Bilirubin SFU (4, 4, 4, 2, 1, 3) | 2.05 (± 2.16) | -1.23 (± 2.62) | -0.30 (± 3.87) | -0.25 (± 0.78) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|---|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: µmol/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Creatinine Week 1 (42, 39, 42, 40, 43, 43) | 0.7 (± 8.4) | -0.7 (± 7.7) | | |
| Creatinine Week 2 (42, 39, 41, 39, 42, 42) | -0.1 (± 8.3) | 0.0 (± 7.1) | | |
| Creatinine Week 4 (41, 39, 41, 39, 41, 41) | 0.6 (± 8.1) | 1.6 (± 7.2) | | |
| Creatinine Week 6 (40, 38, 38, 37, 40, 40) | -0.1 (± 8.1) | -0.5 (± 11.1) | | |
| Creatinine Week 8 (39, 38, 38, 34, 40, 40) | -0.1 (± 7.6) | 0.1 (± 8.3) | | |
| Creatinine Week 12 (39, 38, 38, 35, 40, 39) | 0.1 (± 9.0) | -0.7 (± 7.2) | | |
| Creatinine SFU (4, 4, 4, 2, 1, 3) | 9.0 (± 999) | 1.3 (± 6.4) | | |
| Bilirubin Week 1 (42, 39, 42, 40, 43, 43) | 0.57 (± 5.73) | 0.14 (± 4.16) | | |

| | | | | |
|--|----------------|----------------|--|--|
| Bilirubin Week 2 (42, 39, 41, 39, 42, 42) | -0.99 (± 2.98) | 0.27 (± 3.69) | | |
| Bilirubin Week 4 (41, 39, 41, 39, 41, 41) | 0.76 (± 4.27) | 0.70 (± 4.52) | | |
| Bilirubin Week 6 (40, 38, 38, 37, 40, 40) | 0.11 (± 4.19) | -0.30 (± 4.28) | | |
| Bilirubin Week 8 (39, 38, 38, 34, 40, 40) | -0.15 (± 3.79) | -0.02 (± 4.41) | | |
| Bilirubin Week 12 (39, 38, 38, 35, 40, 39) | -0.43 (± 3.68) | -0.34 (± 3.45) | | |
| Bilirubin SFU (4, 4, 4, 2, 1, 3) | -1.50 (± 999) | 1.40 (± 2.96) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in biochemistry parameters (C Reactive Protein)

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in biochemistry parameters (C Reactive Protein) |
|-----------------|---|

End point description:

C Reactive Protein was measured in milligrams per liters (mg/L).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed and for groups that had 0 participants analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--------------------------------------|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (15, 10, 6, 8, 12, 10) | -2.110 (± 5.255) | -5.367 (± 11.806) | -0.775 (± 2.020) | -2.635 (± 2.550) |
| Week 2 (11, 10, 7, 9, 9, 9) | 1.821 (± 6.974) | -6.985 (± 11.064) | 0.576 (± 2.898) | 2.743 (± 15.212) |
| Week 4 (11, 10, 6, 7, 10, 8) | 1.338 (± 11.182) | -5.835 (± 8.594) | -1.722 (± 5.596) | 0.929 (± 8.047) |
| Week 6 (14, 8, 7, 4, 8, 6) | 2.978 (± 13.162) | -5.930 (± 9.560) | -4.516 (± 11.304) | -0.595 (± 7.346) |
| Week 8 (12, 8, 7, 4, 9, 5) | 3.153 (± 18.764) | -6.891 (± 15.192) | -3.143 (± 10.844) | 2.590 (± 7.755) |
| Week 12 (10, 11, 6, 4, 8, 8) | 7.279 (± 13.546) | -5.193 (± 10.817) | 0.695 (± 6.381) | -3.033 (± 7.261) |

| | | | | |
|------------------------|---------------|-------------|-------------|-------------|
| SFU (1, 0, 0, 0, 0, 0) | 8.000 (± 999) | 999 (± 999) | 999 (± 999) | 999 (± 999) |
|------------------------|---------------|-------------|-------------|-------------|

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--------------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: mg/L | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (15, 10, 6, 8, 12, 10) | -5.108 (± 10.013) | -3.732 (± 3.997) | | |
| Week 2 (11, 10, 7, 9, 9, 9) | -6.763 (± 13.211) | -3.042 (± 1.989) | | |
| Week 4 (11, 10, 6, 7, 10, 8) | -4.226 (± 9.865) | 7.141 (± 32.344) | | |
| Week 6 (14, 8, 7, 4, 8, 6) | 1.799 (± 14.635) | -6.598 (± 6.278) | | |
| Week 8 (12, 8, 7, 4, 9, 5) | 12.434 (± 47.447) | -1.104 (± 5.201) | | |
| Week 12 (10, 11, 6, 4, 8, 8) | -9.890 (± 10.729) | -5.368 (± 5.322) | | |
| SFU (1, 0, 0, 0, 0, 0) | 999 (± 999) | 999 (± 999) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in urinalysis parameters (pH)

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in urinalysis parameters (pH) |
|-----------------|---|

End point description:

Urine pH was measured on a pH scale.

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--------------------------------------|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 41 | 40 |
| Units: ph | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 41, 40, 43, 43) | 0.00 (± 0.79) | -0.10 (± 0.79) | -0.13 (± 0.88) | -0.20 (± 0.88) |
| Week 2 (42, 39, 39, 39, 42, 42) | 0.06 (± 0.86) | -0.06 (± 0.86) | -0.10 (± 0.77) | -0.23 (± 0.92) |
| Week 4 (41, 39, 41, 39, 41, 40) | 0.05 (± 0.87) | -0.09 (± 0.76) | -0.11 (± 0.95) | -0.26 (± 0.89) |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.01 (± 0.73) | -0.03 (± 0.68) | -0.17 (± 0.69) | -0.18 (± 0.86) |
| Week 8 (39, 38, 38, 35, 40, 40) | -0.03 (± 0.92) | -0.07 (± 0.83) | -0.12 (± 1.07) | -0.34 (± 0.79) |
| Week 12 (39, 38, 37, 34, 40, 39) | -0.14 (± 0.79) | -0.01 (± 0.85) | 0.01 (± 0.70) | -0.28 (± 0.85) |
| SFU (4, 4, 4, 2, 1, 3) | 0.25 (± 1.04) | -0.25 (± 0.87) | 0.50 (± 1.22) | -1.00 (± 1.41) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--------------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: ph | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 41, 40, 43, 43) | -0.08 (± 0.82) | -0.07 (± 0.90) | | |
| Week 2 (42, 39, 39, 39, 42, 42) | -0.18 (± 0.76) | 0.06 (± 0.65) | | |
| Week 4 (41, 39, 41, 39, 41, 40) | -0.07 (± 0.73) | -0.04 (± 0.74) | | |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.13 (± 0.81) | 0.05 (± 0.86) | | |
| Week 8 (39, 38, 38, 35, 40, 40) | -0.30 (± 0.91) | 0.08 (± 0.75) | | |
| Week 12 (39, 38, 37, 34, 40, 39) | -0.21 (± 0.99) | -0.01 (± 0.85) | | |
| SFU (4, 4, 4, 2, 1, 3) | 0.50 (± 999) | -0.17 (± 0.29) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Week 12 in urinalysis parameters (leukocyte esterase)

| | |
|-----------------|--|
| End point title | Percentage of participants who shifted from Baseline until Week 12 in urinalysis parameters (leukocyte esterase) |
|-----------------|--|

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 12.

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Number of participants reflect those with non-missing urinalysis results at Baseline and at Week 12.

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

End point timeframe:

From Baseline (Week 0) until Week 12

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|-----------------------------------|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 39 | 38 | 37 | 34 |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 Normal | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 High | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Normal | 84.6 | 84.2 | 97.3 | 88.2 |
| Baseline Normal – Week 12 High | 2.6 | 0 | 2.7 | 5.9 |
| Baseline High – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline High – Week 12 Normal | 7.7 | 15.8 | 0 | 2.9 |
| Baseline High – Week 12 High | 5.1 | 0 | 0 | 2.9 |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|-----------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 40 | 39 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | | |
| Baseline Low – Week 12 Normal | 0 | 0 | | |
| Baseline Low – Week 12 High | 0 | 0 | | |
| Baseline Normal – Week 12 Low | 0 | 0 | | |
| Baseline Normal – Week 12 Normal | 90.0 | 92.3 | | |
| Baseline Normal – Week 12 High | 5.0 | 0 | | |
| Baseline High – Week 12 Low | 0 | 0 | | |
| Baseline High – Week 12 Normal | 5.0 | 7.7 | | |
| Baseline High – Week 12 High | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Week 12 in urinalysis parameters (nitrite)

| | |
|-----------------|---|
| End point title | Percentage of participants who shifted from Baseline until Week 12 in urinalysis parameters (nitrite) |
|-----------------|---|

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 12.

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.
Number of participants reflect those with non-missing urinalysis results at Baseline and at Week 12.

| | |
|--------------------------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| From Baseline (Week 0) until Week 12 | |

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|-----------------------------------|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 39 | 38 | 37 | 34 |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 Normal | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 High | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Normal | 97.4 | 97.4 | 100 | 100 |
| Baseline Normal – Week 12 High | 0 | 2.6 | 0 | 0 |
| Baseline High – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline High – Week 12 Normal | 0 | 0 | 0 | 0 |
| Baseline High – Week 12 High | 2.6 | 0 | 0 | 0 |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|-----------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 40 | 39 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | | |
| Baseline Low – Week 12 Normal | 0 | 0 | | |
| Baseline Low – Week 12 High | 0 | 0 | | |
| Baseline Normal – Week 12 Low | 0 | 0 | | |
| Baseline Normal – Week 12 Normal | 95.0 | 94.9 | | |
| Baseline Normal – Week 12 High | 2.5 | 2.6 | | |
| Baseline High – Week 12 Low | 0 | 0 | | |
| Baseline High – Week 12 Normal | 0 | 2.6 | | |
| Baseline High – Week 12 High | 2.5 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Week 12 in

urinalysis parameters (occult blood)

| | |
|-----------------|--|
| End point title | Percentage of participants who shifted from Baseline until Week 12 in urinalysis parameters (occult blood) |
|-----------------|--|

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 12.

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Number of participants reflect those with non-missing urinalysis results at Baseline and at Week 12.

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

End point timeframe:

From Baseline (Week 0) until Week 12

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|-----------------------------------|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 39 | 38 | 37 | 34 |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 Normal | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 High | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Normal | 76.9 | 86.8 | 83.8 | 79.4 |
| Baseline Normal – Week 12 High | 0 | 5.3 | 0 | 5.9 |
| Baseline High – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline High – Week 12 Normal | 10.3 | 5.3 | 5.4 | 8.8 |
| Baseline High – Week 12 High | 12.8 | 2.6 | 10.8 | 5.9 |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|-----------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 40 | 39 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | | |
| Baseline Low – Week 12 Normal | 0 | 0 | | |
| Baseline Low – Week 12 High | 0 | 0 | | |
| Baseline Normal – Week 12 Low | 0 | 0 | | |
| Baseline Normal – Week 12 Normal | 77.5 | 89.7 | | |
| Baseline Normal – Week 12 High | 5.0 | 2.6 | | |
| Baseline High – Week 12 Low | 0 | 0 | | |
| Baseline High – Week 12 Normal | 15.0 | 5.1 | | |
| Baseline High – Week 12 High | 2.5 | 2.6 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Week 12 in urinalysis parameters (urine glucose)

| | |
|-----------------|---|
| End point title | Percentage of participants who shifted from Baseline until Week 12 in urinalysis parameters (urine glucose) |
|-----------------|---|

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 12.

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Number of participants reflect those with non-missing urinalysis results at Baseline and at Week 12.

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

End point timeframe:

From Baseline (Week 0) until Week 12

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|-----------------------------------|----------------------|----------------------------------|-----------------------------------|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 39 | 38 | 37 | 34 |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 Normal | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 High | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Normal | 94.9 | 94.7 | 97.3 | 97.1 |
| Baseline Normal – Week 12 High | 0 | 2.6 | 2.7 | 2.9 |
| Baseline High – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline High – Week 12 Normal | 0 | 0 | 0 | 0 |
| Baseline High – Week 12 High | 5.1 | 2.6 | 0 | 0 |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|-----------------------------------|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 40 | 39 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | | |
| Baseline Low – Week 12 Normal | 0 | 0 | | |
| Baseline Low – Week 12 High | 0 | 0 | | |
| Baseline Normal – Week 12 Low | 0 | 0 | | |
| Baseline Normal – Week 12 Normal | 95.0 | 94.9 | | |
| Baseline Normal – Week 12 High | 0 | 0 | | |
| Baseline High – Week 12 Low | 0 | 0 | | |
| Baseline High – Week 12 Normal | 2.5 | 0 | | |

| | | | | |
|------------------------------|-----|-----|--|--|
| Baseline High – Week 12 High | 2.5 | 5.1 | | |
|------------------------------|-----|-----|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants who shifted from Baseline until Week 12 in urinalysis parameters (albumin)

| | |
|-----------------|---|
| End point title | Percentage of participants who shifted from Baseline until Week 12 in urinalysis parameters (albumin) |
|-----------------|---|

End point description:

Percentages were based on the number of participants with non-missing urinalysis results at Baseline and at Week 12.

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Number of participants reflect those with non-missing urinalysis results at Baseline and at Week 12.

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

End point timeframe:

From Baseline (Week 0) until Week 12

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|-----------------------------------|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 39 | 38 | 37 | 34 |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 Normal | 0 | 0 | 0 | 0 |
| Baseline Low – Week 12 High | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline Normal – Week 12 Normal | 94.9 | 89.5 | 86.5 | 91.2 |
| Baseline Normal – Week 12 High | 0 | 7.9 | 2.7 | 2.9 |
| Baseline High – Week 12 Low | 0 | 0 | 0 | 0 |
| Baseline High – Week 12 Normal | 5.1 | 2.6 | 10.8 | 5.9 |
| Baseline High – Week 12 High | 0 | 0 | 0 | 0 |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|-----------------------------------|-----------------------------|-----------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 40 | 39 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline Low – Week 12 Low | 0 | 0 | | |

| | | | | |
|----------------------------------|------|------|--|--|
| Baseline Low – Week 12 Normal | 0 | 0 | | |
| Baseline Low – Week 12 High | 0 | 0 | | |
| Baseline Normal – Week 12 Low | 0 | 0 | | |
| Baseline Normal – Week 12 Normal | 95.0 | 92.3 | | |
| Baseline Normal – Week 12 High | 2.5 | 0 | | |
| Baseline High – Week 12 Low | 0 | 0 | | |
| Baseline High – Week 12 Normal | 2.5 | 2.6 | | |
| Baseline High – Week 12 High | 0 | 5.1 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in vital signs (blood pressure)

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in vital signs (blood pressure) |
|-----------------|---|

End point description:

Blood pressure (BP) was measured in millimeters of mercury (mmHg).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Systolic BP Week 1 (42, 39, 42, 40, 43, 43) | 1.2 (± 10.7) | 2.2 (± 7.1) | -3.9 (± 8.3) | 1.7 (± 9.3) |
| Systolic BP Week 2 (42, 39, 41, 39, 42, 42) | -1.1 (± 9.7) | 2.1 (± 9.4) | -2.7 (± 12.5) | 0.2 (± 13.6) |
| Systolic BP Week 4 (42, 39, 41, 39, 41, 41) | -2.3 (± 10.0) | 2.1 (± 7.9) | -1.9 (± 11.3) | 0.1 (± 12.4) |
| Systolic BP Week 6 (40, 38, 38, 37, 40, 40) | -1.4 (± 9.8) | -1.3 (± 10.7) | -4.3 (± 10.6) | 0.1 (± 12.8) |
| Systolic BP Week 8 (39, 38, 38, 37, 40, 40) | -0.8 (± 12.1) | -1.3 (± 13.0) | -3.4 (± 8.0) | 0.1 (± 12.3) |
| Systolic BP Week 12 (39, 38, 38, 35, 40, 39) | -1.3 (± 10.9) | 2.2 (± 9.0) | -2.9 (± 10.3) | -0.3 (± 11.8) |
| Systolic BP SFU (4, 4, 4, 2, 1, 3) | -7.0 (± 12.7) | -10.5 (± 17.0) | -1.3 (± 10.4) | 4.5 (± 7.8) |

| | | | | |
|---|--------------|--------------|--------------|--------------|
| Diastolic BP Week 1 (42, 39, 42, 40, 43, 43) | -0.4 (± 7.4) | 0.9 (± 10.0) | -2.1 (± 7.3) | 0.6 (± 6.5) |
| Diastolic BP Week 2 (42, 39, 41, 39, 42, 42) | -1.5 (± 6.9) | 0.4 (± 8.7) | -1.2 (± 7.1) | 2.1 (± 8.3) |
| Diastolic BP Week 4 (42, 39, 41, 39, 41, 41) | -0.3 (± 7.8) | 0.6 (± 9.2) | -0.3 (± 7.9) | 0.6 (± 7.3) |
| Diastolic BP Week 6 (40, 38, 38, 37, 40, 40) | 0.3 (± 7.6) | 0.0 (± 9.7) | -3.1 (± 7.9) | 1.3 (± 8.6) |
| Diastolic BP Week 8 (39, 38, 38, 37, 40, 40) | -1.1 (± 8.9) | -0.3 (± 9.1) | -1.2 (± 7.3) | 2.8 (± 8.7) |
| Diastolic BP Week 12 (39, 38, 38, 35, 40, 39) | -2.3 (± 5.8) | 0.5 (± 6.3) | -1.7 (± 6.4) | 3.1 (± 8.4) |
| Diastolic BP SFU (4, 4, 4, 2, 1, 3) | 1.3 (± 8.5) | -9.0 (± 9.1) | 0.8 (± 8.8) | -4.5 (± 0.7) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|---|-----------------------------------|-----------------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: mmHg | | | | |
| arithmetic mean (standard deviation) | | | | |
| Systolic BP Week 1 (42, 39, 42, 40, 43, 43) | 0.2 (± 12.1) | -1.0 (± 9.9) | | |
| Systolic BP Week 2 (42, 39, 41, 39, 42, 42) | -0.6 (± 8.4) | -3.2 (± 11.2) | | |
| Systolic BP Week 4 (42, 39, 41, 39, 41, 41) | -0.1 (± 11.3) | -0.5 (± 10.8) | | |
| Systolic BP Week 6 (40, 38, 38, 37, 40, 40) | -0.9 (± 10.9) | -2.4 (± 9.2) | | |
| Systolic BP Week 8 (39, 38, 38, 37, 40, 40) | 0.5 (± 12.5) | -1.0 (± 10.7) | | |
| Systolic BP Week 12 (39, 38, 38, 35, 40, 39) | -1.2 (± 10.4) | -2.4 (± 10.1) | | |
| Systolic BP SFU (4, 4, 4, 2, 1, 3) | -2.0 (± 999) | -2.0 (± 2.6) | | |
| Diastolic BP Week 1 (42, 39, 42, 40, 43, 43) | 0.3 (± 7.4) | 0.1 (± 6.7) | | |
| Diastolic BP Week 2 (42, 39, 41, 39, 42, 42) | 0.0 (± 7.2) | 0.2 (± 7.0) | | |
| Diastolic BP Week 4 (42, 39, 41, 39, 41, 41) | 0.0 (± 7.7) | 0.3 (± 8.1) | | |
| Diastolic BP Week 6 (40, 38, 38, 37, 40, 40) | 0.1 (± 7.3) | -1.6 (± 7.3) | | |
| Diastolic BP Week 8 (39, 38, 38, 37, 40, 40) | -0.7 (± 7.7) | -0.6 (± 8.2) | | |
| Diastolic BP Week 12 (39, 38, 38, 35, 40, 39) | -1.1 (± 6.7) | -1.1 (± 7.3) | | |
| Diastolic BP SFU (4, 4, 4, 2, 1, 3) | -9.0 (± 999) | -4.0 (± 6.6) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in vital signs (pulse

rate)

| | |
|-----------------|---|
| End point title | Change from Baseline until Safety Follow-up Visit in vital signs (pulse rate) |
|-----------------|---|

End point description:

Pulse rate was measured in beats per minute (beats/min).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--------------------------------------|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: beats/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 43) | 1.7 (± 9.5) | -1.6 (± 9.1) | 3.2 (± 8.0) | -1.8 (± 8.1) |
| Week 2 (42, 39, 41, 39, 42, 42) | 1.2 (± 8.4) | -1.3 (± 9.9) | 1.1 (± 7.8) | -1.0 (± 10.4) |
| Week 4 (42, 39, 41, 39, 41, 41) | 1.0 (± 10.2) | -3.1 (± 9.9) | 0.6 (± 7.8) | -3.6 (± 9.0) |
| Week 6 (40, 38, 38, 37, 40, 40) | 0.9 (± 9.8) | 1.2 (± 10.7) | 1.4 (± 8.3) | -2.6 (± 9.7) |
| Week 8 (39, 38, 38, 37, 40, 40) | 1.7 (± 8.9) | -3.2 (± 9.3) | 0.4 (± 9.2) | -1.8 (± 8.5) |
| Week 12 (39, 38, 38, 35, 40, 39) | 0.9 (± 8.4) | -1.9 (± 6.8) | 1.8 (± 11.0) | -3.1 (± 8.5) |
| SFU (4, 4, 4, 2, 1, 3) | -2.8 (± 2.6) | -2.5 (± 12.0) | 2.3 (± 6.0) | 1.5 (± 4.9) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--------------------------------------|-----------------------------|-----------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: beats/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 43) | 0.1 (± 6.4) | -0.4 (± 7.7) | | |
| Week 2 (42, 39, 41, 39, 42, 42) | -2.2 (± 7.9) | 0.5 (± 9.5) | | |
| Week 4 (42, 39, 41, 39, 41, 41) | -1.6 (± 6.5) | 1.6 (± 8.0) | | |
| Week 6 (40, 38, 38, 37, 40, 40) | -1.7 (± 9.3) | 2.6 (± 8.0) | | |
| Week 8 (39, 38, 38, 37, 40, 40) | 0.5 (± 8.2) | 0.6 (± 6.7) | | |
| Week 12 (39, 38, 38, 35, 40, 39) | -1.7 (± 9.1) | 0.0 (± 7.5) | | |
| SFU (4, 4, 4, 2, 1, 3) | -7.0 (± 999) | 7.3 (± 3.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline until Safety Follow-up Visit in vital signs (temperature)

| | |
|-----------------|--|
| End point title | Change from Baseline until Safety Follow-up Visit in vital signs (temperature) |
|-----------------|--|

End point description:

Temperature was measured in degrees Celsius (°C).

The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

Note 1: 999 is used as a placeholder for values not evaluable because only one participant was analyzed.

Note 2: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W).

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

End point timeframe:

Baseline (Week 0), Week 1, Week 2, Week 4, Week 6, Week 8, Week 12, and Safety Follow-Up visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|--------------------------------------|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 42 | 40 |
| Units: °C | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 43) | -0.07 (± 0.23) | -0.04 (± 0.22) | 0.02 (± 0.30) | -0.11 (± 0.32) |
| Week 2 (42, 39, 41, 39, 42, 42) | 0.00 (± 0.26) | 0.02 (± 0.26) | 0.01 (± 0.33) | 0.01 (± 0.35) |
| Week 4 (42, 39, 41, 39, 41, 41) | -0.05 (± 0.29) | 0.03 (± 0.24) | 0.00 (± 0.42) | -0.04 (± 0.24) |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.03 (± 0.29) | -0.02 (± 0.25) | -0.01 (± 0.22) | -0.06 (± 0.43) |
| Week 8 (39, 38, 38, 37, 40, 40) | 0.01 (± 0.24) | -0.02 (± 0.28) | 0.00 (± 0.33) | -0.03 (± 0.41) |
| Week 12 (39, 38, 38, 35, 40, 39) | 0.10 (± 0.27) | 0.00 (± 0.27) | 0.06 (± 0.36) | -0.04 (± 0.28) |
| SFU (4, 4, 4, 2, 1, 3) | 0.08 (± 0.22) | 0.15 (± 0.33) | -0.03 (± 0.05) | 0.10 (± 0.00) |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|--------------------------------------|-----------------------------|-----------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: °C | | | | |
| arithmetic mean (standard deviation) | | | | |
| Week 1 (42, 39, 42, 40, 43, 43) | -0.07 (± 0.30) | 0.02 (± 0.35) | | |
| Week 2 (42, 39, 41, 39, 42, 42) | -0.04 (± 0.36) | -0.01 (± 0.35) | | |
| Week 4 (42, 39, 41, 39, 41, 41) | -0.03 (± 0.26) | -0.01 (± 0.41) | | |
| Week 6 (40, 38, 38, 37, 40, 40) | -0.03 (± 0.38) | 0.07 (± 0.24) | | |
| Week 8 (39, 38, 38, 37, 40, 40) | 0.00 (± 0.35) | 0.02 (± 0.31) | | |
| Week 12 (39, 38, 38, 35, 40, 39) | 0.00 (± 0.33) | 0.00 (± 0.30) | | |

| | | | | |
|------------------------|-------------------|--------------------|--|--|
| SFU (4, 4, 4, 2, 1, 3) | 0.10 (\pm 999) | 0.43 (\pm 0.31) | | |
|------------------------|-------------------|--------------------|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with clinically significant physical examination abnormalities

| | |
|-----------------|---|
| End point title | Percentage of participants with clinically significant physical examination abnormalities |
|-----------------|---|

End point description:

The physical examination included general appearance; ear, nose, and throat; eyes, hair, and skin; respiratory; CV; GI; musculoskeletal; hepatic; neurological (including limb reflexes); and mental status. Any clinically significant abnormal findings during the study were captured as adverse events. The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP.

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

End point timeframe:

At Screening, Week 12/Early Withdrawal Visit and the Safety Follow-Up Visit (20 weeks after the last dose)

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|-----------------------------------|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | 23.8 | 7.7 | 11.6 | 10.0 |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|-----------------------------------|-----------------------------|-----------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 9.3 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with clinically significant abnormal 12-Lead electrocardiogram (ECG) findings

| | |
|---|--|
| End point title | Percentage of participants with clinically significant abnormal 12-Lead electrocardiogram (ECG) findings |
| End point description: | |
| Percentages were based on the number of participants with a non-missing measurement for that variable at the visit. | |
| The Safety Set (SS) consisted of all participants who received at least 1 dose of the IMP. | |
| Note: The number of participants analyzed for each timepoint is presented in parentheses following this model (PBO, BKZ 64 mg Q4W, BKZ 160 mg Q4W, BKZ 160 mg w/ LD Q4W, BKZ 320 mg Q4W, BKZ 480 mg Q4W). | |
| End point type | Secondary |
| End point timeframe: | |
| Baseline (Week 0), Week 2, Week 4, Week 6, Week 12, and Safety Follow-Up visit (20 weeks after the last dose) | |

| End point values | Placebo (SS) | Bimekizumab 64 mg Q4W (SS) | Bimekizumab 160 mg Q4W (SS) | Bimekizumab 160 mg w/ LD Q4W (SS) |
|-----------------------------------|----------------------|----------------------------|-----------------------------|-----------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 42 | 39 | 43 | 40 |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline (42, 39, 43, 40, 43, 43) | 0 | 0 | 0 | 2.5 |
| Week 2 (42, 39, 41, 39, 42, 42) | 0 | 0 | 0 | 2.6 |
| Week 4 (42, 39, 41, 39, 41, 41) | 0 | 0 | 0 | 0 |
| Week 6 (40, 38, 38, 36, 40, 40) | 0 | 0 | 0 | 0 |
| Week 12 (39, 38, 38, 34, 39, 39) | 0 | 0 | 0 | 0 |
| SFU (4, 4, 4, 2, 1, 3) | 0 | 0 | 0 | 0 |

| End point values | Bimekizumab 320 mg Q4W (SS) | Bimekizumab 480 mg Q4W (SS) | | |
|-----------------------------------|-----------------------------|-----------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 43 | 43 | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Baseline (42, 39, 43, 40, 43, 43) | 0 | 0 | | |
| Week 2 (42, 39, 41, 39, 42, 42) | 0 | 0 | | |
| Week 4 (42, 39, 41, 39, 41, 41) | 0 | 0 | | |
| Week 6 (40, 38, 38, 36, 40, 40) | 0 | 0 | | |
| Week 12 (39, 38, 38, 34, 39, 39) | 0 | 0 | | |
| SFU (4, 4, 4, 2, 1, 3) | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) were collected from Baseline (Week 0) to End of Safety Follow-up (up to Week 28)

Adverse event reporting additional description:

It was pre-specified to report AEs that have a start date on or following the first administration of treatment. TEAEs counts for each study period: Treatment Period (Wk1-12) for all participants who received at least 1 treatment and Post-Treatment Period for those who either enrolled in an extension study (PS0011) or entered a 20-week SFU Period.

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

Dictionary used

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

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

Reporting groups

| | |
|-----------------------|-------------------------------|
| Reporting group title | Placebo (SS) Treatment Period |
|-----------------------|-------------------------------|

Reporting group description:

During the Treatment Period participants randomized to the placebo group, received a combination of several injections of placebo, subcutaneously every 4 weeks (Q4W). Participants formed the Safety Set (SS).

| | |
|-----------------------|---|
| Reporting group title | Bimekizumab 64 mg Q4W (SS) Treatment Period |
|-----------------------|---|

Reporting group description:

During the Treatment Period participants were randomized to receive subcutaneous injections of 64 mg bimekizumab Q4W. Participants formed the SS.

| | |
|-----------------------|--|
| Reporting group title | Bimekizumab 160 mg Q4W (SS) Treatment Period |
|-----------------------|--|

Reporting group description:

During the Treatment Period participants were randomized to receive subcutaneous injections of 160 mg bimekizumab Q4W. Participants formed the SS.

| | |
|-----------------------|--|
| Reporting group title | Bimekizumab 160 mg w/ LD Q4W (SS) Treatment Period |
|-----------------------|--|

Reporting group description:

During the Treatment Period participants were randomized to receive subcutaneous injections of 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W. Participants formed the SS.

| | |
|-----------------------|--|
| Reporting group title | Bimekizumab 320 mg Q4W (SS) Treatment Period |
|-----------------------|--|

Reporting group description:

During the Treatment Period participants were randomized to receive subcutaneous injections of 320 mg bimekizumab Q4W. Participants formed the SS.

| | |
|-----------------------|--|
| Reporting group title | Bimekizumab 480 mg Q4W (SS) Treatment Period |
|-----------------------|--|

Reporting group description:

During the Treatment Period participants were randomized to receive subcutaneous injections of 480 mg bimekizumab Q4W. Participants formed the SS.

| | |
|-----------------------|------------------------------------|
| Reporting group title | Placebo (SS) Post-Treatment Period |
|-----------------------|------------------------------------|

Reporting group description:

At Week 12, participants who were randomized to receive Placebo during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

| | |
|-----------------------|--|
| Reporting group title | Bimekizumab 64 mg Q4W (SS) Post-Treatment Period |
|-----------------------|--|

Reporting group description:

At Week 12, participants who were randomized to receive 64 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-

Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

| | |
|-----------------------|---|
| Reporting group title | Bimekizumab 160 mg Q4W (SS) Post-Treatment Period |
|-----------------------|---|

Reporting group description:

At Week 12, participants who were randomized to receive 160 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

| | |
|-----------------------|---|
| Reporting group title | Bimekizumab 160 mg w/ LD Q4W (SS) Post-Treatment Period |
|-----------------------|---|

Reporting group description:

At Week 12, participants who were randomized to receive 320 mg bimekizumab loading dose at Baseline followed by 160 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

| | |
|-----------------------|---|
| Reporting group title | Bimekizumab 320 mg Q4W (SS) Post-Treatment Period |
|-----------------------|---|

Reporting group description:

At Week 12, participants who were randomized to receive 320 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

| | |
|-----------------------|---|
| Reporting group title | Bimekizumab 480 mg Q4W (SS) Post-Treatment Period |
|-----------------------|---|

Reporting group description:

At Week 12, participants who were randomized to receive 480 mg bimekizumab Q4W during the Treatment Period and who enrolled in the extension study (PS0011), underwent the Week 12 study assessments and then received their first extension study dose of study treatment. All participants who did not enroll in the extension study had the Week 12 study assessments and entered the Safety Follow-Up (SFU) Period, 20 weeks after the last dose of study medication.

Participants did not receive any treatment during the Post-Treatment Period. Participants formed the SS.

| Serious adverse events | Placebo (SS) Treatment Period | Bimekizumab 64 mg Q4W (SS) Treatment Period | Bimekizumab 160 mg Q4W (SS) Treatment Period |
|---|----------------------------------|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 39 (0.00%) | 0 / 43 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Colon cancer | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Myocardial infarction | | | |

| | | | |
|---|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Large intestine polyp | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Meningitis viral | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 39 (0.00%) | 0 / 43 (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 |

| Serious adverse events | Bimekizumab 160 mg w/ LD Q4W (SS) Treatment Period | Bimekizumab 320 mg Q4W (SS) Treatment Period | Bimekizumab 480 mg Q4W (SS) Treatment Period |
|---|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 1 / 43 (2.33%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Colon cancer | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 1 / 43 (2.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Large intestine polyp | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 1 / 43 (2.33%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |

| | | | |
|---|----------------|----------------|----------------|
| Meningitis viral | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Placebo (SS) Post-Treatment Period | Bimekizumab 64 mg Q4W (SS) Post-Treatment Period | Bimekizumab 160 mg Q4W (SS) Post-Treatment Period |
|---|------------------------------------|--|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 39 (2.56%) | 0 / 43 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Colon cancer | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 1 / 39 (2.56%) | 0 / 43 (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 |
| Gastrointestinal disorders | | | |
| Large intestine polyp | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Meningitis viral | | | |
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| Serious adverse events | Bimekizumab 160 mg w/ LD Q4W (SS) Post-Treatment Period | Bimekizumab 320 mg Q4W (SS) Post-Treatment Period | Bimekizumab 480 mg Q4W (SS) Post-Treatment Period |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |

| | | | |
|---|----------------|----------------|----------------|
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Colon cancer | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Large intestine polyp | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Meningitis viral | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | Placebo (SS) Treatment Period | Bimekizumab 64 mg Q4W (SS) Treatment Period | Bimekizumab 160 mg Q4W (SS) Treatment Period |
|---|----------------------------------|---|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 8 / 42 (19.05%) | 16 / 39 (41.03%) | 12 / 43 (27.91%) |
| Investigations | | | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 0 / 39 (0.00%) | 3 / 43 (6.98%) |
| occurrences (all) | 1 | 0 | 3 |
| Vascular disorders | | | |
| Hypertension | | | |

| | | | |
|---|--|--|--|
| subjects affected / exposed occurrences (all) | 3 / 42 (7.14%) 3 | 1 / 39 (2.56%) 1 | 1 / 43 (2.33%) 1 |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 2 / 39 (5.13%) 2 | 0 / 43 (0.00%) 0 |
| Blood and lymphatic system disorders Neutropenia subjects affected / exposed occurrences (all) Leukopenia subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 0 / 42 (0.00%) 0 | 2 / 39 (5.13%) 2 2 / 39 (5.13%) 3 | 0 / 43 (0.00%) 0 0 / 43 (0.00%) 0 |
| Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 2 / 39 (5.13%) 2 | 0 / 43 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 2 / 39 (5.13%) 2 | 0 / 43 (0.00%) 0 |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Respiratory tract infection subjects affected / exposed occurrences (all) Tonsillitis subjects affected / exposed occurrences (all) Oral candidiasis | 2 / 42 (4.76%) 2 1 / 42 (2.38%) 1 1 / 42 (2.38%) 1 0 / 42 (0.00%) 0 Oral candidiasis | 5 / 39 (12.82%) 5 5 / 39 (12.82%) 5 2 / 39 (5.13%) 2 2 / 39 (5.13%) 3 | 3 / 43 (6.98%) 3 2 / 43 (4.65%) 3 1 / 43 (2.33%) 1 2 / 43 (4.65%) 2 |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 42 (2.38%) | 2 / 39 (5.13%) | 1 / 43 (2.33%) |
| occurrences (all) | 1 | 2 | 1 |

| Non-serious adverse events | Bimekizumab 160 mg w/ LD Q4W (SS) Treatment Period | Bimekizumab 320 mg Q4W (SS) Treatment Period | Bimekizumab 480 mg Q4W (SS) Treatment Period |
|---|--|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 12 / 40 (30.00%) | 14 / 43 (32.56%) | 10 / 43 (23.26%) |
| Investigations | | | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 2 / 40 (5.00%) | 1 / 43 (2.33%) | 0 / 43 (0.00%) |
| occurrences (all) | 2 | 2 | 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 0 / 43 (0.00%) | 1 / 43 (2.33%) |
| occurrences (all) | 1 | 0 | 1 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 1 / 43 (2.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 2 / 43 (4.65%) | 0 / 43 (0.00%) |
| occurrences (all) | 1 | 3 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 1 / 43 (2.33%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 40 (2.50%) | 1 / 43 (2.33%) | 3 / 43 (6.98%) |
| occurrences (all) | 1 | 3 | 5 |

| | | | |
|--|---------------------|----------------------|---------------------|
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 3 | 6 / 43 (13.95%) 6 | 4 / 43 (9.30%) 5 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 3 / 40 (7.50%) 3 | 2 / 43 (4.65%) 2 | 0 / 43 (0.00%) 0 |
| Respiratory tract infection subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 1 / 43 (2.33%) 1 | 0 / 43 (0.00%) 0 |
| Tonsillitis subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 43 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Oral candidiasis subjects affected / exposed occurrences (all) | 1 / 40 (2.50%) 1 | 3 / 43 (6.98%) 3 | 0 / 43 (0.00%) 0 |
| Rhinitis subjects affected / exposed occurrences (all) | 0 / 40 (0.00%) 0 | 0 / 43 (0.00%) 0 | 1 / 43 (2.33%) 1 |

| Non-serious adverse events | Placebo (SS) Post-Treatment Period | Bimekizumab 64 mg Q4W (SS) Post-Treatment Period | Bimekizumab 160 mg Q4W (SS) Post-Treatment Period |
|---|------------------------------------|--|---|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 0 / 42 (0.00%) | 0 / 39 (0.00%) | 0 / 43 (0.00%) |
| Investigations Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Vascular disorders Hypertension subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---------------------|---------------------|---------------------|
| Neutropenia subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Leukopenia subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Tonsillitis subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Oral candidiasis subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |
| Rhinitis subjects affected / exposed occurrences (all) | 0 / 42 (0.00%) 0 | 0 / 39 (0.00%) 0 | 0 / 43 (0.00%) 0 |

| Non-serious adverse events | Bimekizumab 160 mg w/ LD Q4W (SS) Post-Treatment Period | Bimekizumab 320 mg Q4W (SS) Post-Treatment Period | Bimekizumab 480 mg Q4W (SS) Post-Treatment Period |
|--|---|---|---|
| Total subjects affected by non-serious | | | |

| | | | |
|---|----------------|----------------|----------------|
| adverse events | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| Investigations | | | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Leukopenia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |

| | | | |
|-----------------------------|----------------|----------------|----------------|
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 40 (0.00%) | 0 / 43 (0.00%) | 0 / 43 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|--------------|---|
| 08 July 2016 | <p>Protocol Amendment 1, dated 08 Jul 2016, was implemented to make the following substantial changes:</p> <ul style="list-style-type: none">•Extended the timing of the Safety Follow Up (SFU) Visit to 20 weeks after the last dose of investigational medicinal product (IMP).•Removed references to legal representatives being able to provide consent on behalf of participants. Participants who lacked the capacity to consent were not included in the study.•Clarified the exclusion criterion regarding laboratory values.•Clarified that participants with any pustular psoriasis (ie, localized or generalized) were ineligible for study participation and that development of any form of pustular psoriasis (ie, localized or generalized) during the study would have resulted in withdrawal from the study.•Clarified the Hospital Anxiety and Depression Scale (HADS) thresholds for study eligibility in the Exclusion Criteria and for withdrawal of a participant in the Withdrawal Criteria.•Clarified withdrawal criteria regarding participants who developed illnesses that would have interfered with study participation and regarding the withdrawal of participants due to Adverse Events (AEs) and clinical laboratory values.•Clarified the timing of the optional study exit interview.•Clarified the AEs for special monitoring.•Provided additional detail and a reference for recording the severity of AEs.•Removed the requirement to test for alcohol in the potential drug-induced liver injury (PDILI) urine toxicology screen.•Clarified the subgroup analyses that were performed. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported