# Clinical trial results:
# A Multicenter, Open-Label Extension Study to Evaluate the Long Term Safety and Efficacy of Bimekizumab in Subjects with Ankylosing Spondylitis

## Summary

| | |
|---|---|
| EudraCT number | 2017-001002-15 |
| Trial protocol | HU CZ DE BG ES |
| Global end of trial date | 19 October 2022 |

### Results information

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 03 November 2023 |
| First version publication date | 03 November 2023 |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | AS0009 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03355573 |
| WHO universal trial number (UTN) | - |

Notes:

### Sponsors

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

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 20 January 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 19 October 2022 |
| Global end of trial reached? | Yes |
| Global end of trial date | 19 October 2022 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

Assess the long-term safety and tolerability of bimekizumab administered over a period of up to 4 years.

Protection of trial subjects:

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

Background therapy:

Background therapy as permitted in the protocol.

Evidence for comparator:

Not applicable

| | |
|---|---|
| Actual start date of recruitment | 28 November 2017 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Bulgaria: 9 |
| Country: Number of subjects enrolled | Canada: 2 |
| Country: Number of subjects enrolled | Czechia: 72 |
| Country: Number of subjects enrolled | Germany: 10 |
| Country: Number of subjects enrolled | Hungary: 7 |
| Country: Number of subjects enrolled | Poland: 89 |
| Country: Number of subjects enrolled | Russian Federation: 32 |
| Country: Number of subjects enrolled | Spain: 8 |
| Country: Number of subjects enrolled | Ukraine: 20 |
| Country: Number of subjects enrolled | United States: 6 |
| Worldwide total number of subjects | 255 |
| EEA total number of subjects | 195 |

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) | 245 |
| From 65 to 84 years | 10 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

The study started to enroll study participants in November 2017 and concluded in October 2022. Participants who completed AS0008 (NCT02963506) participated in this study.

### Pre-assignment

Screening details:

The Participant Flow refers to the Safety Set.

### Period 1

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

### Arms

| | |
|---|---|
| **Arm title** | Bimekizumab |

Arm description:

Participants received bimekizumab 160 milligrams (mg) every 4 weeks (Q4W) up to 4 years.

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

Dosage and administration details:

Participants received bimekizumab 160 mg Q4W at prespecified time points.

| **Number of subjects in period 1** | Bimekizumab |
|---|---|
| Started | 255 |
| Completed | 202 |
| Not completed | 53 |
| Sponsor's decision | 1 |
| Consent withdrawn by subject | 23 |
| PI's decision | 2 |
| Adverse Event, non-fatal | 17 |
| Withdrew consent:refused treatment to AE latent TB | 1 |
| Lost to follow-up | 4 |
| Participant withdrew consent due to AEs | 1 |
| Adverse Event, serious fatal | 2 |
| Lack of efficacy | 2 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Bimekizumab |
| Reporting group description: | |
| Participants received bimekizumab 160 milligrams (mg) every 4 weeks (Q4W) up to 4 years. | |

| Reporting group values | Bimekizumab | Total | |
|---|---|---|---|
| Number of subjects | 255 | 255 | |
| Age Categorical<br>Units: participants | | | |
| <=18 years | 0 | 0 | |
| Between 18 and 65 years | 245 | 245 | |
| >=65 years | 10 | 10 | |
| Age Continuous<br>Units: years | | | |
| arithmetic mean | 41.8 | | |
| standard deviation | ± 11.4 | - | |
| Sex: Female, Male<br>Units: participants | | | |
| Female | 38 | 38 | |
| Male | 217 | 217 | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| White | 253 | 253 | |
| Other/Mixed | 2 | 2 | |
| Race/Ethnicity, Customized<br>Units: Subjects | | | |
| Hispanic or Latino | 1 | 1 | |
| Not Hispanic or Latino | 254 | 254 | |

## End points

### End points reporting groups

| Reporting group title | Bimekizumab |
|---|---|

Reporting group description:

Participants received bimekizumab 160 milligrams (mg) every 4 weeks (Q4W) up to 4 years.

### Primary: Percentage of Participants with treatment-emergent adverse events (TEAEs) during the study

| End point title | Percentage of Participants with treatment-emergent adverse events (TEAEs) during the study[1] |
|---|---|

End point description:

An Adverse Event (AE) is any untoward medical occurrence in a participant or clinical investigation participant administered a pharmaceutical product, which does not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. Treatment emergent adverse events were defined as those events with onset date on or after the first administration of study medication in AS0009 and on or before 140 days after the final study medication administration. The Safety Set consisted of all participants in the enrolled set who received at least one dose of study medication in AS0009.

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

End point timeframe:

From Entry Visit (Visit 1) until Safety Follow Up (up to Week 224)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

| End point values | Bimekizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 255 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 92.9 | | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Percentage of Participants with serious adverse event (SAE) during the study

| End point title | Percentage of Participants with serious adverse event (SAE) during the study[2] |
|---|---|

End point description:

A serious adverse event (SAE) is any untoward medical occurrence that at any dose: 1) Results in death 2) Is life-threatening 3) Requires in participant hospitalisation or prolongation of existing hospitalisation 4) Is a congenital anomaly or birth defect 5) Is an infection that requires treatment with parenteral antibiotics 6) Other important medical events which based on medical or scientific judgement may jeopardise the participants, or may require medical or surgical intervention to prevent any of the above. The Safety Set consisted of all participants in the enrolled set who received at least one dose of study

medication in AS0009.

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

End point timeframe:

From Entry Visit (Visit 1) until Safety Follow Up (up to Week 224)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No formal statistical hypothesis testing was planned for this study. Results were summarized in tables as descriptive statistics only.

| **End point values** | Bimekizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 255 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 18.0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants with Axial Spondyloarthritis International Society 40% response criteria (ASAS40) at Week 48 calculated relative to Baseline of AS0008

| End point title | Percentage of Participants with Axial Spondyloarthritis International Society 40% response criteria (ASAS40) at Week 48 calculated relative to Baseline of AS0008 |
|---|---|

End point description:

ASAS40 response:relative improvements of at least 40% and absolute improvement of at least 2 units on a 0 to 10 Numeric Rating Scale (NRS), where 0 is "not active" and 10 is "very active" in at least 3 of 4 domains: Patient's Global Assessment of Disease Activity (PGADA) (score range:0(not active)-10(very active)), Pain assessment (total spinal pain NRS score) (assessed on a scale of 0(no pain) -10(severe pain)), Function (Bath Ankylosing Spondylitis Functional Index (BASFI)) (score range:0(easy)-10(impossible)), Inflammation (mean of Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) questions 5 and 6 concerning morning stiffness intensity and duration) (score range:0(none)-10(very severe) and no worsening at all in remaining domain.FAS:all enrolled participants who received at least 1 dose of IMP and had a valid measurement for at least 1 efficacy variable at AS0009 study entry. NRI and OCS have been reported. Number analyzed=participants evaluable at specified categories.

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

End point timeframe:

Baseline of AS0008, Week 48 (AS0009)

| **End point values** | Bimekizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 249 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Non-responder imputation (n=249) | 67.1 | | | |
| Observed case (n=237) | 70.5 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants who withdrew due to an treatment-emergent adverse event (TEAE) during the study

| End point title | Percentage of Participants who withdrew due to an treatment-emergent adverse event (TEAE) during the study |
|---|---|

End point description:

An Adverse Event (AE) is any untoward medical occurrence in a participant or clinical investigation participant administered a pharmaceutical product, which does not necessarily have a causal relationship with this treatment. An AE could therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. Treatment emergent adverse events were defined as those events with onset date on or after the first administration of study medication in AS0009 and on or before 140 days after the final study medication administration. The Safety Set consisted of all participants in the enrolled set who received at least one dose of study medication in AS0009.

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

End point timeframe:

From Entry Visit (Visit 1) until Safety Follow Up (up to Week 224)

| **End point values** | Bimekizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 255 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | 6.7 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Participants with Axial Spondyloarthritis International Society 20% response criteria (ASAS20) at Week 48 calculated relative to Baseline of AS0008

| End point title | Percentage of Participants with Axial Spondyloarthritis International Society 20% response criteria (ASAS20) at Week 48 calculated relative to Baseline of AS0008 |
|---|---|

End point description:

ASAS20 response: relative improvements of at least 20% and absolute improvement of at least 1 unit on a 0 to 10 NRS, where 0 is "not active" and 10 is "very active" in at least 3 of 4 domains: PGADA (score range: 0 (not active) to 10 (very active), Pain assessment (total spinal pain NRS score) (assessed on a scale of 0 (no pain)-10 (severe pain)), Function (BASFI) (score ranged from 0 (easy)-10 (impossible)), Inflammation (mean of BASDAI) questions 5 and 6 concerning morning stiffness intensity

and duration) (score ranged from 0 (none)-10 (very severe) and no worsening at all in the remaining domain. Full Analysis Set consisted of all enrolled participants who received at least 1 dose of IMP and had a valid measurement for at least 1 efficacy variable at AS0009 study entry. Both Non-responder imputation (NRI) and observed case (OC) analysis have been reported in this endpoint. Number analyzed=participants evaluable at specified categories.

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

End point timeframe:

Baseline of AS0008, Week 48 (AS0009)

| **End point values** | Bimekizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 249 | | | |
| Units: percentage of participants | | | | |
| number (not applicable) | | | | |
| Non-responder imputation (n=249) | 79.9 | | | |
| Observed case (n=237) | 84.0 | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Baseline of AS0008 in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) total score to Week 48

| End point title | Change from Baseline of AS0008 in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) total score to Week 48 |
|---|---|

End point description:

BASDAI is a validated self-reported instrument, which consisted of 6 questions to measure the disease activity of ankylosing spondylitis (AS) from the participant's perspective. It measured the severity of fatigue, spinal and peripheral joint pain and swelling, enthesitis, and morning stiffness (both severity and duration). Each question was rated using a numerical rating scale from 0 (none) to 10 (very severe), higher score=high disease activity. The BASDAI score was calculated by computing the mean of questions 5 and 6 and adding it to the sum of questions 1 to 4. This score was then divided by 5. The total BASDAI score was ranged from 0=none to 10= very severe, where higher score indicated high disease activity. A negative value indicated improvement and a positive value indicated worsening. The Full Analysis Set consisted of all enrolled participants who received at least 1 dose of the IMP and had a valid measurement for at least 1 efficacy variable at AS0009 study entry.

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

End point timeframe:

Baseline of AS0008, Week 48 (AS0009)

| **End point values** | Bimekizumab | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 249 | | | |
| Units: scores on a scale | | | | |
| arithmetic mean (standard error) | -3.79 (± 0.13) | | | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

From Entry Visit (Visit 1) until Safety Follow Up (up to Week 224)

Adverse event reporting additional description:

Treatment emergent adverse events were defined as those events with onset date on or after the first administration of study medication in AS0009 and on or before 140 days after the final study medication administration. The Safety Set consisted of all participants in the enrolled set who received at least one dose of study medication in AS0009.

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 19.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Bimekizumab |

Reporting group description:

Participants received Bimekizumab 160 mg Q4W up to 4 years.

| Serious adverse events | Bimekizumab | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 46 / 255 (18.04%) | | |
| number of deaths (all causes) | 2 | | |
| number of deaths resulting from adverse events | 0 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Lung neoplasm malignant | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Testicular seminoma (pure) | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Uterine leiomyoma | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Subclavian steal syndrome | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Varicose vein | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Female genital tract fistula | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Benign prostatic hyperplasia | | | |
| subjects affected / exposed | 2 / 255 (0.78%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Suicidal ideation | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Mental disorder | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bipolar disorder | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Meniscus injury | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Humerus fracture | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tibia fracture | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Periprosthetic fracture | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Road traffic accident | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 1 | | | |
| Skull fracture | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Post procedural haematuria | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Cardiac disorders | | | | |
| Coronary artery disease | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Coronary artery stenosis | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardiac failure | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cardio-respiratory arrest | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Nervous system disorders | | | |
| Carpal tunnel syndrome | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ear and labyrinth disorders | | | |
| Endolymphatic hydrops | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Inguinal hernia | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Umbilical hernia | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|---|---|---|
| Colitis ulcerative | | | |
| subjects affected / exposed | 2 / 255 (0.78%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Crohn's disease | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Hepatotoxicity | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Psoriasis | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Calculus urinary | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Tendonitis | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bursitis | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Fracture delayed union | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Joint instability | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Osteoarthritis | | | | |
| subjects affected / exposed | 2 / 255 (0.78%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Spinal instability | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ankylosing spondylitis | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Infections and infestations | | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 3 / 255 (1.18%) | | | |
| occurrences causally related to treatment / all | 1 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Post procedural infection | | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Empyema | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastroenteritis bacterial | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Abdominal wall abscess | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Perirectal abscess | | | |
| subjects affected / exposed | 2 / 255 (0.78%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Corona virus infection | | | |
| subjects affected / exposed | 3 / 255 (1.18%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Peritonsillar abscess | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 255 (0.39%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| **Non-serious adverse events** | Bimekizumab | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 176 / 255 (69.02%) | | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 19 / 255 (7.45%) | | |
| occurrences (all) | 26 | | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 13 / 255 (5.10%) | | |
| occurrences (all) | 17 | | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 14 / 255 (5.49%) | | |
| occurrences (all) | 16 | | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 13 / 255 (5.10%) | | |
| occurrences (all) | 16 | | |
| Skin and subcutaneous tissue disorders | | | |
| Psoriasis | | | |
| subjects affected / exposed | 13 / 255 (5.10%) | | |
| occurrences (all) | 16 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 15 / 255 (5.88%) | | |
| occurrences (all) | 17 | | |
| Infections and infestations | | | |
| Oral candidiasis | | | |
| subjects affected / exposed | 17 / 255 (6.67%) | | |
| occurrences (all) | 21 | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 46 / 255 (18.04%) | | |
| occurrences (all) | 65 | | |
| Upper respiratory tract infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 33 / 255 (12.94%) | | |
| occurrences (all) | 48 | | |
| Pharyngitis | | | |
| subjects affected / exposed | 18 / 255 (7.06%) | | |
| occurrences (all) | 24 | | |
| Sinusitis | | | |
| subjects affected / exposed | 15 / 255 (5.88%) | | |
| occurrences (all) | 17 | | |
| Tonsillitis | | | |
| subjects affected / exposed | 15 / 255 (5.88%) | | |
| occurrences (all) | 21 | | |
| Corona virus infection | | | |
| subjects affected / exposed | 30 / 255 (11.76%) | | |
| occurrences (all) | 33 | | |
| Bronchitis | | | |
| subjects affected / exposed | 21 / 255 (8.24%) | | |
| occurrences (all) | 23 | | |
| Metabolism and nutrition disorders | | | |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 16 / 255 (6.27%) | | |
| occurrences (all) | 17 | | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 21 March 2018 | Protocol Amendment 2 was dated 21 Mar 2018. The purpose of this amendment was to:<br>• Update the study contact details for the Sponsor Study Physician, CPM, and Clinical Trial Biostatistician<br>• Amend the open-label Treatment Period for clarification, as per request from the regulatory agency<br>• Amend the study procedures and assessments to be performed at the SFU Visit; efficacy assessments were removed since they were not required at the SFU visit<br>• Amend the time frame for the availability of negative results from the QuantiFERON tuberculosis (TB) Test, to be aligned with the TB standard operating procedure (SOP)<br>• Include additional wording to the inclusion criteria listing acceptable methods of contraception for female study participants |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported