# Clinical trial results:
# A Multicenter, Randomized, Double-Blind, Parallel-Arm, Phase 3 Study to Compare Efficacy and Safety of BAT2306 with Cosentyx® in Patients with Moderate to Severe Plaque Psoriasis

## Summary

| | |
|---|---|
| EudraCT number | 2022-001770-59 |
| Trial protocol | HU |
| Global end of trial date | 24 May 2024 |

### Results information

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 20 June 2025 |
| First version publication date | 20 June 2025 |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | BAT-2306-002-CR |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05377944 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | China IND: CXSL2000344 |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Bio-Thera Solutions, Ltd. |
| Sponsor organisation address | Floor 5, Building A6 Science Enterprise Accelerator 11 Kaiyuan Avenue, Science City Huangpu District, Guangzhou, China, 510530 |
| Public contact | Xiaolei Yang, Bio-Thera Solutions, Ltd., +86 13538941739, xlyang@bio-thera.com |
| Scientific contact | Xiaolei Yang, Bio-Thera Solutions, Ltd., +86 13538941739, xlyang@bio-thera.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 | 05 July 2024 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 27 July 2023 |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 May 2024 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To demonstrate equivalent efficacy of BAT2306 and Cosentyx® in patients with moderate to severe plaque psoriasis.

Protection of trial subjects:

This study was conducted in accordance with the accepted version of the Declaration of Helsinki in compliance with ICH GCP guidelines, and according to the appropriate regulatory requirements in the countries where the study was conducted. The clinical study protocol, protocol amendments, informed consent forms (ICFs), and any other appropriate study-related documents were reviewed and approved by independent ethics committees(IECs) and institutional review boards (IRBs) for each study center. Before entering the study, the investigator (or designee) explained to each subject (or their legally acceptable representatives, if applicable) the nature of the study, its purpose, procedures, expected duration, alternative therapy available, and the benefits and risks involved in study participation. Subjects were given written information about the study, and, before any study procedures were performed, each subject voluntarily signed and dated the ICF.

Background therapy: -

Evidence for comparator:

Secukinumab (Cosentyx®) is a human IgG1 monoclonal antibody developed by Novartis. Secukinumab can inhibit IL-17 receptor via selectively binding to IL-17A, to inhibit its interaction with the IL-17 receptor and thus inhibiting the release of pro-inflammatory cytokines and chemokines. Cosentyx® has been marketed overseas in 2014 with approved indications such as moderate to severe plaque psoriasis (in adults who are candidates for systemic therapy or phototherapy [EU label for candidates of systematic therapy only]), psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis. Secukinumab has been marketed in China in March 2019 under the trade name of Cosentyx, and its approved indications are psoriasis and ankylosing spondylitis

| | |
|---|---|
| Actual start date of recruitment | 13 October 2022 |
| 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 | Poland: 112 |
| Country: Number of subjects enrolled | Hungary: 65 |
| Country: Number of subjects enrolled | China: 265 |
| Country: Number of subjects enrolled | Japan: 60 |
| Worldwide total number of subjects | 502 |
| EEA total number of subjects | 177 |

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) | 451 |
| From 65 to 84 years | 51 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Subjects were screened from 2022.Oct.13 to 2023.May.15. First patient was randomized on 2022.Oct.26 and Last patient was randomized on 2023.May.31
Subjects were recruited from Poland, Hungary, China and Japan.

### Pre-assignment

Screening details:

Patients should have moderate to severe plaque-type psoriasis as defined at screening and baseline by:
a. PASI ≥ 12,
b. IGA ≥ 3 (based on a scale of 0-4), and
c. BSA affected by chronic plaque-type psoriasis ≥ 10%

### 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 |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | BAT2306 |

Arm description: -

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BAT2306 Injection |
| Investigational medicinal product code | BAT2306 |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

300 mg (2 injections of 150 mg/1 ml) of BAT2306 or Cosentyx via PFS will be subcutaneously administered at weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks, thereafter up to Week 40.

| | |
|---|---|
| **Arm title** | Cosentyx |

Arm description: -

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | EU-approved Cosentyx |
| Investigational medicinal product code | Cosentyx |
| Other name | |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

300 mg (2 injections of 150 mg/1 ml) of BAT2306 or Cosentyx via PFS will be subcutaneously administered at weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks, thereafter up to Week 40.

| **Number of subjects in period 1** | BAT2306 | Cosentyx |
|---|---|---|
| Started | 252 | 250 |
| Completed | 234 | 223 |
| Not completed | 18 | 27 |
| Physician decision | 1 | 2 |
| Consent withdrawn by subject | 12 | 17 |
| Adverse event, non-fatal | - | 3 |
| Pregnancy | 1 | - |
| Imprisoned | - | 1 |
| Poor patient compliance | - | 1 |
| Lost to follow-up | 3 | 3 |
| Lack of efficacy | 1 | - |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | BAT2306 |
| Reporting group description: - | |
| Reporting group title | Cosentyx |
| Reporting group description: - | |

| Reporting group values | BAT2306 | Cosentyx | Total |
|---|---|---|---|
| Number of subjects | 252 | 250 | 502 |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 228 | 223 | 451 |
| From 65-84 years | 24 | 27 | 51 |
| 85 years and over | 0 | 0 | 0 |
| Gender categorical<br>Units: Subjects | | | |
| Female | 70 | 73 | 143 |
| Male | 182 | 177 | 359 |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | BAT2306 |
| Reporting group description: - | |
| Reporting group title | Cosentyx |
| Reporting group description: - | |
| Subject analysis set title | BAT2306 TP1 |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| The ITT Set will consist of all patients randomized into TP1. Patients will be analyzed under the treatment group as randomized. The ITT Set will be used for the primary analyses of efficacy. | |
| Subject analysis set title | Cosentyx TP1 |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| The ITT Set will consist of all patients randomized into TP1. Patients will be analyzed under the treatment group as randomized. The ITT Set will be used for the primary analyses of efficacy. | |
| Subject analysis set title | BAT2306 - BAT2306 TP2 |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| The ITT2 will consist of all patients rerandomized into TP2 at Week 24. Patients from the ITT2 will be analyzed under the treatment group as randomized. The ITT2 will be used for the analyses of efficacy during TP2. | |
| Subject analysis set title | Cosentyx - Cosentyx TP2 |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| The ITT2 will consist of all patients rerandomized into TP2 at Week 24. Patients from the ITT2 will be analyzed under the treatment group as randomized. The ITT2 will be used for the analyses of efficacy during TP2. | |
| Subject analysis set title | Cosentyx - BAT2306 TP2 |
| Subject analysis set type | Intention-to-treat |
| Subject analysis set description: | |
| The ITT2 will consist of all patients rerandomized into TP2 at Week 24. Patients from the ITT2 will be analyzed under the treatment group as randomized. The ITT2 will be used for the analyses of efficacy during TP2. | |

### Primary: EMA, PMDA, and Agencies other than the FDA and NMPA: Percent change from baseline in Psoriasis Area and Severity Index (PASI) score to Week 8

| | |
|---|---|
| End point title | EMA, PMDA, and Agencies other than the FDA and NMPA: Percent change from baseline in Psoriasis Area and Severity Index (PASI) score to Week 8 |
| End point description: | |
| | |
| End point type | Primary |
| End point timeframe: | |
| Baseline to Week 8 | |

| End point values | BAT2306 | Cosentyx | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 252 | 250 | | |
| Units: Percent change in PASI Score | | | | |
| least squares mean (standard error) | -88.906 (± 1.2595) | -90.454 (± 1.2469) | | |

**Statistical analyses**

| Statistical analysis title | Treatment Group :BAT2306 and Cosentyx |
|---|---|
| Comparison groups | BAT2306 v Cosentyx |
| Number of subjects included in analysis | 502 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| Parameter estimate | Mean difference (final values) |
| Point estimate | 1.549 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.954 |
| upper limit | 4.051 |

**Primary: Psoriasis Area and Severity Index Score at Week 12 (FDA and NMPA)**

| End point title | Psoriasis Area and Severity Index Score at Week 12 (FDA and NMPA) |
|---|---|

End point description:

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

End point timeframe:

Baseline to Week 12

| End point values | BAT2306 | Cosentyx | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 252 | 250 | | |
| Units: Percent change in PASI Score | | | | |
| least squares mean (standard error) | -93.405 (± 1.1135) | -93.056 (± 1.0978) | | |

**Statistical analyses**

| Statistical analysis title | Treatment Group :BAT2306 and Cosentyx |
|---|---|
| Comparison groups | BAT2306 v Cosentyx |

| | |
|---|---|
| Number of subjects included in analysis | 502 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| Parameter estimate | Mean difference (final values) |
| Point estimate | -0.349 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.579 |
| upper limit | 1.881 |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

For the purposes of this study, the period of observation for collection of AEs extends from the time immediately after obtaining the informed consent until the EOS visit on Week 52

| | |
|---|---|
| Assessment type | Systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 27.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | BAT2306 TP1 |
| Reporting group description: - | |
| Reporting group title | Cosentyx TP1 |
| Reporting group description: - | |
| Reporting group title | BAT2306 - BAT2306 TP2 |
| Reporting group description: - | |
| Reporting group title | Cosentyx - Cosentyx TP2 |
| Reporting group description: - | |
| Reporting group title | Cosentyx - BAT2306 TP2 |

Reporting group description: -

| Serious adverse events | BAT2306 TP1 | Cosentyx TP1 | BAT2306 - BAT2306 TP2 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 4 / 252 (1.59%) | 14 / 250 (5.60%) | 5 / 243 (2.06%) |
| 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) | | | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 1 / 243 (0.41%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thyroid adenoma | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 1 / 243 (0.41%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Behaviour disorder | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Mental disorder | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Affective disorder | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (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 |
| Injury, poisoning and procedural complications | | | |
| Compression fracture | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Meniscus injury | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Cataract traumatic | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (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 |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (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 | | | |

| | | | |
|---|---|---|---|
| Arrhythmia | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Arteriosclerosis coronary artery | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Carotid artery stenosis | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 1 / 243 (0.41%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear and labyrinth disorders | | | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 1 / 252 (0.40%) | 0 / 250 (0.00%) | 0 / 243 (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 |
| Eye disorders | | | |
| Lens dislocation | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (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 | | | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal ulcer | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatobiliary disorders | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Drug eruption | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dyshidrotic eczema | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pustular psoriasis | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 1 / 252 (0.40%) | 0 / 250 (0.00%) | 0 / 243 (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 |
| Glomerulonephritis chronic | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Ureterolithiasis | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (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 |

| | | | |
|---|---|---|---|
| Musculoskeletal and connective tissue disorders | | | |
| Intervertebral disc | | | |
| subjects affected / exposed | 1 / 252 (0.40%) | 0 / 250 (0.00%) | 0 / 243 (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 |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (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 | | | |
| Anal fistula infection | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (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 |
| Chronic tonsillitis | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 1 / 243 (0.41%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 1 / 252 (0.40%) | 0 / 250 (0.00%) | 0 / 243 (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 |
| Diabetes mellitus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 1 / 243 (0.41%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Cosentyx - Cosentyx TP2 | Cosentyx - BAT2306 TP2 | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 118 (2.54%) | 2 / 113 (1.77%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Rectal adenocarcinoma | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid adenoma | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Behaviour disorder | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mental disorder | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Affective disorder | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Compression fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ligament rupture | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus injury | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cataract traumatic | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Clavicle fracture | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 1 / 113 (0.88%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Arrhythmia | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arteriosclerosis coronary artery | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carotid artery stenosis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Deafness neurosensory | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Lens dislocation | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal ulcer | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Drug eruption | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyshidrotic eczema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pustular psoriasis | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis chronic | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureterolithiasis | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Intervertebral disc | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 1 / 113 (0.88%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Anal fistula infection | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Pneumonia | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic tonsillitis | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Type 2 diabetes mellitus | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes mellitus | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 0 / 113 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 1.5 %

| **Non-serious adverse events** | BAT2306 TP1 | Cosentyx TP1 | BAT2306 - BAT2306 TP2 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 144 / 252 (57.14%) | 158 / 250 (63.20%) | 129 / 243 (53.09%) |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 8 / 252 (3.17%) | 6 / 250 (2.40%) | 2 / 243 (0.82%) |
| occurrences (all) | 9 | 6 | 2 |
| Blood glucose increased | | | |
| subjects affected / exposed | 3 / 252 (1.19%) | 6 / 250 (2.40%) | 3 / 243 (1.23%) |
| occurrences (all) | 4 | 6 | 3 |
| Blood uric acid increased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 8 / 252 (3.17%) | 3 / 250 (1.20%) | 4 / 243 (1.65%) |
| occurrences (all) | 12 | 3 | 4 |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 8 / 252 (3.17%) | 5 / 250 (2.00%) | 4 / 243 (1.65%) |
| occurrences (all) | 9 | 6 | 4 |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 3 / 252 (1.19%) | 7 / 250 (2.80%) | 4 / 243 (1.65%) |
| occurrences (all) | 3 | 8 | 4 |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 6 / 252 (2.38%) | 2 / 250 (0.80%) | 2 / 243 (0.82%) |
| occurrences (all) | 6 | 2 | 2 |
| Protein urine present | | | |
| subjects affected / exposed | 4 / 252 (1.59%) | 5 / 250 (2.00%) | 2 / 243 (0.82%) |
| occurrences (all) | 4 | 6 | 2 |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 4 / 252 (1.59%) | 3 / 250 (1.20%) | 3 / 243 (1.23%) |
| occurrences (all) | 4 | 3 | 4 |
| Urinary occult blood positive | | | |
| subjects affected / exposed | 4 / 252 (1.59%) | 2 / 250 (0.80%) | 4 / 243 (1.65%) |
| occurrences (all) | 4 | 3 | 4 |
| Blood triglycerides increased | | | |
| subjects affected / exposed | 1 / 252 (0.40%) | 3 / 250 (1.20%) | 4 / 243 (1.65%) |
| occurrences (all) | 1 | 3 | 4 |
| White blood cells urine positive | | | |
| subjects affected / exposed | 2 / 252 (0.79%) | 2 / 250 (0.80%) | 4 / 243 (1.65%) |
| occurrences (all) | 2 | 2 | 4 |
| White blood cell count increased | | | |
| subjects affected / exposed | 1 / 252 (0.40%) | 0 / 250 (0.00%) | 4 / 243 (1.65%) |
| occurrences (all) | 1 | 0 | 4 |
| Weight increased | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Weight decreased | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood cholesterol increased | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 1 / 243 (0.41%) |
| occurrences (all) | 0 | 0 | 1 |
| Glucose urine present | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 3 / 252 (1.19%) | 5 / 250 (2.00%) | 3 / 243 (1.23%) |
| occurrences (all) | 3 | 5 | 3 |
| Cardiac disorders | | | |
| Sinus arrhythmia | | | |
| subjects affected / exposed | 2 / 252 (0.79%) | 4 / 250 (1.60%) | 3 / 243 (1.23%) |
| occurrences (all) | 2 | 4 | 3 |
| Sinus bradycardia | | | |
| subjects affected / exposed | 1 / 252 (0.40%) | 4 / 250 (1.60%) | 3 / 243 (1.23%) |
| occurrences (all) | 1 | 4 | 3 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 252 (0.79%) | 4 / 250 (1.60%) | 2 / 243 (0.82%) |
| occurrences (all) | 2 | 4 | 2 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 7 / 252 (2.78%) | 3 / 250 (1.20%) | 1 / 243 (0.41%) |
| occurrences (all) | 8 | 4 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 2 / 252 (0.79%) | 2 / 250 (0.80%) | 6 / 243 (2.47%) |
| occurrences (all) | 2 | 2 | 7 |
| Hepatobiliary disorders | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 4 / 252 (1.59%) | 5 / 250 (2.00%) | 3 / 243 (1.23%) |
| occurrences (all) | 4 | 5 | 3 |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|---|---|---|
| Eczema | | | |
| subjects affected / exposed | 12 / 252 (4.76%) | 7 / 250 (2.80%) | 11 / 243 (4.53%) |
| occurrences (all) | 13 | 8 | 12 |
| Urticaria | | | |
| subjects affected / exposed | 5 / 252 (1.98%) | 8 / 250 (3.20%) | 1 / 243 (0.41%) |
| occurrences (all) | 5 | 9 | 1 |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 252 (0.40%) | 3 / 250 (1.20%) | 2 / 243 (0.82%) |
| occurrences (all) | 2 | 3 | 2 |
| Acne | | | |
| subjects affected / exposed | 2 / 252 (0.79%) | 1 / 250 (0.40%) | 2 / 243 (0.82%) |
| occurrences (all) | 2 | 1 | 2 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 6 / 252 (2.38%) | 0 / 250 (0.00%) | 1 / 243 (0.41%) |
| occurrences (all) | 6 | 0 | 1 |
| Infections and infestations | | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 20 / 252 (7.94%) | 22 / 250 (8.80%) | 19 / 243 (7.82%) |
| occurrences (all) | 23 | 26 | 22 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 14 / 252 (5.56%) | 13 / 250 (5.20%) | 14 / 243 (5.76%) |
| occurrences (all) | 15 | 13 | 17 |
| Pharyngitis | | | |
| subjects affected / exposed | 7 / 252 (2.78%) | 6 / 250 (2.40%) | 2 / 243 (0.82%) |
| occurrences (all) | 7 | 6 | 2 |
| COVID-19 | | | |
| subjects affected / exposed | 6 / 252 (2.38%) | 1 / 250 (0.40%) | 4 / 243 (1.65%) |
| occurrences (all) | 6 | 1 | 4 |
| Otitis externa | | | |
| subjects affected / exposed | 5 / 252 (1.98%) | 3 / 250 (1.20%) | 2 / 243 (0.82%) |
| occurrences (all) | 4 | 3 | 2 |
| Tinea pedis | | | |
| subjects affected / exposed | 5 / 252 (1.98%) | 3 / 250 (1.20%) | 2 / 243 (0.82%) |
| occurrences (all) | 5 | 3 | 2 |
| Conjunctivitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 252 (1.19%) | 4 / 250 (1.60%) | 3 / 243 (1.23%) |
| occurrences (all) | 3 | 4 | 3 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 5 / 250 (2.00%) | 3 / 243 (1.23%) |
| occurrences (all) | 0 | 6 | 4 |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 252 (0.79%) | 3 / 250 (1.20%) | 0 / 243 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |
| Folliculitis | | | |
| subjects affected / exposed | 5 / 252 (1.98%) | 0 / 250 (0.00%) | 2 / 243 (0.82%) |
| occurrences (all) | 6 | 0 | 2 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 3 / 250 (1.20%) | 2 / 243 (0.82%) |
| occurrences (all) | 0 | 3 | 2 |
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 2 / 250 (0.80%) | 3 / 243 (1.23%) |
| occurrences (all) | 0 | 2 | 3 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 252 (0.40%) | 2 / 250 (0.80%) | 2 / 243 (0.82%) |
| occurrences (all) | 1 | 2 | 3 |
| Influenza | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 2 / 250 (0.80%) | 1 / 243 (0.41%) |
| occurrences (all) | 0 | 2 | 1 |
| Fungal foot infection | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Asymptomatic bacteriuria | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 1 / 250 (0.40%) | 0 / 243 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Paronychia | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 0 / 250 (0.00%) | 0 / 243 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 7 / 252 (2.78%) | 10 / 250 (4.00%) | 7 / 243 (2.88%) |
| occurrences (all) | 9 | 10 | 7 |

| | | | |
|---|---|---|---|
| Hyperuricaemia | | | |
| subjects affected / exposed | 6 / 252 (2.38%) | 9 / 250 (3.60%) | 6 / 243 (2.47%) |
| occurrences (all) | 7 | 11 | 6 |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 252 (0.00%) | 2 / 250 (0.80%) | 0 / 243 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |

| **Non-serious adverse events** | Cosentyx - Cosentyx TP2 | Cosentyx - BAT2306 TP2 | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 67 / 118 (56.78%) | 69 / 113 (61.06%) | |
| Investigations | | | |
| Alanine aminotransferase increased | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 3 / 113 (2.65%) | |
| occurrences (all) | 1 | 3 | |
| Blood glucose increased | | | |
| subjects affected / exposed | 3 / 118 (2.54%) | 2 / 113 (1.77%) | |
| occurrences (all) | 4 | 3 | |
| Blood uric acid increased | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 0 / 113 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Blood bilirubin increased | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 0 / 113 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Blood creatine phosphokinase increased | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 0 / 113 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Aspartate aminotransferase increased | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 3 / 113 (2.65%) | |
| occurrences (all) | 0 | 3 | |
| Protein urine present | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 1 / 113 (0.88%) | |
| occurrences (all) | 3 | 1 | |
| Gamma-glutamyltransferase increased | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 1 / 113 (0.88%) | |
| occurrences (all) | 1 | 1 | |

| | | | |
|---|---|---|---|
| Urinary occult blood positive<br>subjects affected / exposed<br>occurrences (all) | 2 / 118 (1.69%)<br>2 | 0 / 113 (0.00%)<br>0 | |
| Blood triglycerides increased<br>subjects affected / exposed<br>occurrences (all) | 1 / 118 (0.85%)<br>1 | 0 / 113 (0.00%)<br>0 | |
| White blood cells urine positive<br>subjects affected / exposed<br>occurrences (all) | 1 / 118 (0.85%)<br>1 | 2 / 113 (1.77%)<br>2 | |
| White blood cell count increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 118 (0.00%)<br>0 | 0 / 113 (0.00%)<br>0 | |
| Weight increased<br>subjects affected / exposed<br>occurrences (all) | 1 / 118 (0.85%)<br>1 | 2 / 113 (1.77%)<br>2 | |
| Weight decreased<br>subjects affected / exposed<br>occurrences (all) | 2 / 118 (1.69%)<br>2 | 0 / 113 (0.00%)<br>0 | |
| Blood cholesterol increased<br>subjects affected / exposed<br>occurrences (all) | 0 / 118 (0.00%)<br>0 | 2 / 113 (1.77%)<br>2 | |
| Glucose urine present<br>subjects affected / exposed<br>occurrences (all) | 2 / 118 (1.69%)<br>3 | 0 / 113 (0.00%)<br>0 | |
| Vascular disorders<br>Hypertension<br>subjects affected / exposed<br>occurrences (all) | 1 / 118 (0.85%)<br>1 | 0 / 113 (0.00%)<br>0 | |
| Cardiac disorders<br>Sinus arrhythmia<br>subjects affected / exposed<br>occurrences (all) | 0 / 118 (0.00%)<br>0 | 0 / 113 (0.00%)<br>0 | |
| Sinus bradycardia<br>subjects affected / exposed<br>occurrences (all) | 1 / 118 (0.85%)<br>1 | 0 / 113 (0.00%)<br>0 | |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Anaemia | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 1 / 113 (0.88%) | |
| occurrences (all) | 2 | 1 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 2 / 113 (1.77%) | |
| occurrences (all) | 1 | 2 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 1 / 113 (0.88%) | |
| occurrences (all) | 2 | 1 | |
| Hepatobiliary disorders | | | |
| Hepatic function abnormal | | | |
| subjects affected / exposed | 4 / 118 (3.39%) | 1 / 113 (0.88%) | |
| occurrences (all) | 4 | 1 | |
| Skin and subcutaneous tissue disorders | | | |
| Eczema | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 2 / 113 (1.77%) | |
| occurrences (all) | 1 | 2 | |
| Urticaria | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 1 / 113 (0.88%) | |
| occurrences (all) | 2 | 1 | |
| Dermatitis contact | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 2 / 113 (1.77%) | |
| occurrences (all) | 1 | 2 | |
| Acne | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 0 / 113 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 2 / 113 (1.77%) | |
| occurrences (all) | 1 | 2 | |
| Infections and infestations | | | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 12 / 118 (10.17%) | 10 / 113 (8.85%) | |
| occurrences (all) | 17 | 12 | |
| Nasopharyngitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 6 / 118 (5.08%) | 7 / 113 (6.19%) | |
| occurrences (all) | 6 | 7 | |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 0 / 113 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| COVID-19 | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 2 / 113 (1.77%) | |
| occurrences (all) | 2 | 2 | |
| Otitis externa | | | |
| subjects affected / exposed | 5 / 118 (4.24%) | 0 / 113 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Tinea pedis | | | |
| subjects affected / exposed | 5 / 118 (4.24%) | 0 / 113 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 2 / 113 (1.77%) | |
| occurrences (all) | 0 | 2 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 0 / 113 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 3 / 113 (2.65%) | |
| occurrences (all) | 1 | 3 | |
| Folliculitis | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 0 / 113 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 1 / 113 (0.88%) | |
| occurrences (all) | 2 | 2 | |
| Pulpitis dental | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 2 / 113 (1.77%) | |
| occurrences (all) | 0 | 2 | |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 118 (0.85%) | 0 / 113 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Influenza | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 118 (0.00%) | 2 / 113 (1.77%) | |
| occurrences (all) | 0 | 4 | |
| Fungal foot infection | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 2 / 113 (1.77%) | |
| occurrences (all) | 0 | 2 | |
| Asymptomatic bacteriuria | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 0 / 113 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Paronychia | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 2 / 113 (1.77%) | |
| occurrences (all) | 0 | 2 | |
| Metabolism and nutrition disorders | | | |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 3 / 113 (2.65%) | |
| occurrences (all) | 2 | 3 | |
| Hyperuricaemia | | | |
| subjects affected / exposed | 2 / 118 (1.69%) | 4 / 113 (3.54%) | |
| occurrences (all) | 2 | 5 | |
| Hypokalaemia | | | |
| subjects affected / exposed | 0 / 118 (0.00%) | 2 / 113 (1.77%) | |
| occurrences (all) | 0 | 2 | |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 27 December 2022 | • Patients not achieving a minimal clinically significant response (PASI-75) at the Week 24 assessment will be discontinued from the study treatment and followed up<br>•FDA and NMPA: Percent change from baseline in PASI score to Week 12. |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported