



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
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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 $\geq 10\%$

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
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Arm title	BAT2306
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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
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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
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Reporting group description: -

Reporting group title	Cosentyx
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Reporting group description: -

Reporting group values	BAT2306	Cosentyx	Total
Number of subjects	252	250	502
Age categorical			
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			
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 (\pm 1.2595)	-90.454 (\pm 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 (\pm 1.1135)	-93.056 (\pm 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
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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 occurrences (all)	0 / 252 (0.00%) 0	0 / 250 (0.00%) 0	0 / 243 (0.00%) 0
Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 252 (0.00%) 0	0 / 250 (0.00%) 0	1 / 243 (0.41%) 1
Glucose urine present subjects affected / exposed occurrences (all)	0 / 252 (0.00%) 0	0 / 250 (0.00%) 0	0 / 243 (0.00%) 0
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	3 / 252 (1.19%) 3	5 / 250 (2.00%) 5	3 / 243 (1.23%) 3
Cardiac disorders Sinus arrhythmia subjects affected / exposed occurrences (all)	2 / 252 (0.79%) 2	4 / 250 (1.60%) 4	3 / 243 (1.23%) 3
Sinus bradycardia subjects affected / exposed occurrences (all)	1 / 252 (0.40%) 1	4 / 250 (1.60%) 4	3 / 243 (1.23%) 3
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	2 / 252 (0.79%) 2	4 / 250 (1.60%) 4	2 / 243 (0.82%) 2
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	7 / 252 (2.78%) 8	3 / 250 (1.20%) 4	1 / 243 (0.41%) 1
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	2 / 252 (0.79%) 2	2 / 250 (0.80%) 2	6 / 243 (2.47%) 7
Hepatobiliary disorders Hepatic function abnormal subjects affected / exposed occurrences (all)	4 / 252 (1.59%) 4	5 / 250 (2.00%) 5	3 / 243 (1.23%) 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 subjects affected / exposed occurrences (all)	2 / 118 (1.69%) 2	0 / 113 (0.00%) 0	
Blood triglycerides increased subjects affected / exposed occurrences (all)	1 / 118 (0.85%) 1	0 / 113 (0.00%) 0	
White blood cells urine positive subjects affected / exposed occurrences (all)	1 / 118 (0.85%) 1	2 / 113 (1.77%) 2	
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 118 (0.00%) 0	0 / 113 (0.00%) 0	
Weight increased subjects affected / exposed occurrences (all)	1 / 118 (0.85%) 1	2 / 113 (1.77%) 2	
Weight decreased subjects affected / exposed occurrences (all)	2 / 118 (1.69%) 2	0 / 113 (0.00%) 0	
Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 118 (0.00%) 0	2 / 113 (1.77%) 2	
Glucose urine present subjects affected / exposed occurrences (all)	2 / 118 (1.69%) 3	0 / 113 (0.00%) 0	
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	1 / 118 (0.85%) 1	0 / 113 (0.00%) 0	
Cardiac disorders Sinus arrhythmia subjects affected / exposed occurrences (all)	0 / 118 (0.00%) 0	0 / 113 (0.00%) 0	
Sinus bradycardia subjects affected / exposed occurrences (all)	1 / 118 (0.85%) 1	0 / 113 (0.00%) 0	
Blood and lymphatic system disorders			

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

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 December 2022	<ul style="list-style-type: none">• 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•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