Clinical trial results:
A Multicenter, Randomized, Double-Blind, Parallel-Arm, Phase 3 Study to Compare Efficacy and Safety of BAT2206 with Stelara® in Patients with Moderate to Severe Plaque Psoriasis

Summary

EudraCT number	2020-004504-33
Trial protocol	BG
Global end of trial date	07 July 2023

Results information

Result version number	v1 (current)
This version publication date	06 June 2024
First version publication date	06 June 2024

Trial information

Trial identification

Sponsor protocol code	BAT-2206-002-CR

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04728360
WHO universal trial number (UTN)	-
Other trial identifiers	China IND: CXSL1900103

Notes:

Sponsors

Sponsor organisation name	Bio-Thera Solutions, Ltd.
Sponsor organisation address	Floor 5, Building A6, 11 Kai-Yuan Blvd, Huangpu District, Guangzhou, China, 510530
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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	07 July 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 July 2023
Global end of trial reached?	Yes
Global end of trial date	07 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study is to demonstrate equivalent efficacy of BAT2206 and Stelara in patients with moderate to severe 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:

NA

Evidence for comparator:

Ustekinumab belongs to the pharmacologic class of interleukin (IL)-23 and IL-12 antagonists. In the United States and the European Union, the approved indications include the treatment of moderate to severe plaque psoriasis, active psoriatic arthritis, moderately to severely active Crohn’s disease, and moderately to severely active ulcerative colitis.

Actual start date of recruitment	22 June 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	China: 187
Country: Number of subjects enrolled	Georgia: 58
Country: Number of subjects enrolled	Russian Federation: 54
Country: Number of subjects enrolled	Poland: 184
Country: Number of subjects enrolled	Bulgaria: 73
Worldwide total number of subjects	556
EEA total number of subjects	257

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)	521
From 65 to 84 years	35
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 41 investigators at 41 sites in 5 countries (China, Poland, Bulgaria, Russia, and Georgia) received IEC approval to participate in this study. 187 subjects were from China, 184 subjects were from Poland, 54 subjects were from Russia, 58 subjects were from Georgia, and 73 subjects were from Bulgaria.

Pre-assignment

Screening details:

Subjects with moderate to severe plaque-type psoriasis were screened in this study. A total of 773 subjects were screened and 556 subjects were randomized. Investigators completed the protocol defined screening procedures during ≤28-day screening period.

Period 1

Period 1 title	Overall study overall period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

the investigators, site staff assessing the safety and efficacy, other related study staff (including contract research organization and sponsor), all subjects, and central laboratories would remain blinded to the study treatment assignment throughout this study. The unblinded site staff who were involved in study treatment administration and also were responsible for preparing the injection.The treatment assignment was not disclosed to any blinded personnel during study.

Arms

Are arms mutually exclusive?	Yes
Arm title	BAT2206 Group

Arm description:

Participants received SC injection of BAT2206, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. At Week 28, participants with an improvement in PASI score of ≥75% were re-randomized to receive BAT2206 at Weeks 28 and 40.

Arm type	Experimental
Investigational medicinal product name	BAT2206
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of BAT2206, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. At Week 28, participants with an improvement in PASI score of ≥75% were re-randomized to receive BAT2206 at Weeks 28 and 40.

Arm title	Stelara Group

Arm description:

Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16.At Week 28, participants with an improvement in PASI score of ≥75% were re-randomized to continue receiving ustekinumab , or to receive BAT2206 at Weeks 28 and 40.

Arm type	Active comparator

Investigational medicinal product name	Stelara
Investigational medicinal product code	
Other name	ustekinumab
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. At Week 28, participants with an improvement in PASI score of ≥75% were re-randomized to continue receiving ustekinumab , or to receive BAT2206 at Weeks 28 and 40.

Number of subjects in period 1	BAT2206 Group	Stelara Group
Started	278	278
Completed	259	256
Not completed	19	22
Consent withdrawn by subject	5	10
Protocol specified withdrawal criterion met	4	2
Adverse event, non-fatal	1	1
Pregnancy	-	1
Lost to follow-up	4	3
Lack of efficacy	1	-
other reason	4	5

Baseline characteristics

Reporting groups	
Reporting group title	BAT2206 Group
Reporting group description:	
Participants received SC injection of BAT2206, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. At Week 28, participants with an improvement in PASI score of ≥75% were re-randomized to receive BAT2206 at Weeks 28 and 40.	
Reporting group title	Stelara Group
Reporting group description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16.At Week 28, participants with an improvement in PASI score of ≥75% were re-randomized to continue receiving ustekinumab , or to receive BAT2206 at Weeks 28 and 40.	

Reporting group values	BAT2206 Group	Stelara Group	Total
Number of subjects	278	278	556
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)	262	259	521
From 65-84 years	16	19	35
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	96	86	182
Male	182	192	374
Region Units: Subjects			
Central Europe	184	185	369
Asia Pacific	94	93	187
Race Units: Subjects			
White	183	185	368
Asian	95	93	188
PASI Score			
The PASI is a measure of the average redness (erythema), thickness (induration), and scaliness (scaling; each graded on a 0-4 scale [0 = clear; 1-4 = increasing severity]) of the lesions, weighted by the area of involvement in the four main body areas (i.e., head, arms, trunk to groin, and legs to top of buttocks). The PASI score ranges from 0 to 72. Higher scores represent worse symptom severity.			
Units: Score on a scale			
median	21.20	22.3	
full range (min-max)	12.0 to 66.0	12.0 to 65.0	-
sPGA			
The sPGAStatic Physician Global Assessment of Psoriasisis a 6-point scale ranging from 0 (clear) to 5			

(very severe) used to measure the severity of disease (induration, scaling, and erythema). A sPGA response was defined as a sPGA value of clear (score 0) or almost clear (score 1). Higher scores represent worse symptom severity.			
Units: Score on a scale			
median	3.0	3.0	
full range (min-max)	3 to 5	3 to 5	-
Psoriasis Body Surface Area (BSA)			
The percentage of BSA affected was estimated by assuming that the participant's palm, excluding the fingers and thumb, represents roughly 1% of the body's surface.			
Units: Percentage of BSA			
median	26.00	29.00	
full range (min-max)	10.0 to 85.5	10.0 to 86.0	-
DLQI			
The DLQI is a simple, self-administered questionnaire designed to measure the health-related quality of life of an adult suffering from a skin disease. It consists of 10 questions (each scored from 0 to 3) concerning patients' perception of the impact of skin disease on different aspects of their health-related quality of life over the last week.			
Units: Score on a scale			
median	15	14	
full range (min-max)	0 to 30	1 to 30	-

End points

End points reporting groups

Reporting group title	BAT2206 Group
Reporting group description:	
Participants received SC injection of BAT2206, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. At Week 28, participants with an improvement in PASI score of ≥75% were re-randomized to receive BAT2206 at Weeks 28 and 40.	
Reporting group title	Stelara Group
Reporting group description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16.At Week 28, participants with an improvement in PASI score of ≥75% were re-randomized to continue receiving ustekinumab , or to receive BAT2206 at Weeks 28 and 40.	
Subject analysis set title	Through week28 BAT2206
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received SC injection of BAT2206, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16.	
Subject analysis set title	Through week28Stelara
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16.	
Subject analysis set title	Post week28 :Stelara /BAT2206
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. participants with an improvement in PASI score of ≥75% at Week 28 , were re-randomized to receive BAT2206 at Weeks 28 and 40.	
Subject analysis set title	Post week28 :Stelara /Stelara
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. participants with an improvement in PASI score of ≥75% at Week 28 , were re-randomized to continue receiving ustekinumab at week 28 and 40.	
Subject analysis set title	Post week28 :BAT2206 /BAT2206
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants received SC injection of BAT2206, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. At Week 28, participants with an improvement in PASI score of ≥75% were re-randomized to continue receiving BAT2206 at Weeks 28 and 40.	

Primary: Percent change from baseline (CfB) in Psoriasis Area and Severity Index (PASI) score to Week 8

End point title	Percent change from baseline (CfB) in Psoriasis Area and Severity Index (PASI) score to Week 8
End point description:	
PASI is a measure of psoriatic disease severity taking into account qualitative lesion characteristics (erythema, induration/thickness, and scaling) and percentage of affected skin surface area on defined anatomical regions.	
End point type	Primary
End point timeframe:	
Baseline and Week8	

End point values	BAT2206 Group	Stelara Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	275	274		
Units: Percent change in PASI Score				
least squares mean (standard error)	-75.543 (± 2.6847)	-76.507 (± 2.6526)		

Statistical analyses

Statistical analysis title	Treatment Group :BAT2206 and Stelara

Statistical analysis description:

Clinical equivalence of the primary endpoint was evaluated by comparing the 2-sided 90% confidence interval (CI) of the difference between treatments in mean %PASI CfB to Week 8 is entirely contained within the equivalence margin of [-13%, +13%] between BAT 2206 versus (vs) ustekinumab.

Multiple imputation was applied for the point estimate and CI of the difference between treatments in mean %PASI CfB to Week 8 between the 2 groups.

Comparison groups	BAT2206 Group v Stelara Group
Number of subjects included in analysis	549
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	0.964
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.751
upper limit	4.679

Primary: Percent change from baseline (CfB) in Psoriasis Area and Severity Index (PASI) score to Week 12

End point title	Percent change from baseline (CfB) in Psoriasis Area and Severity Index (PASI) score to Week 12

End point description:

PASI is a measure of psoriatic disease severity taking into account qualitative lesion characteristics (erythema, induration/thickness, and scaling) and percentage of affected skin surface area on defined anatomical regions.

End point type	Primary

End point timeframe:

Baseline and week 12

End point values	BAT2206 Group	Stelara Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	274	275		
Units: Percent change in PASI score				
least squares mean (standard error)	-85.039 (± 2.0731)	-86.813 (± 2.0105)		

Statistical analyses

Statistical analysis title	Treatment Group :BAT2206 and Stelara

Statistical analysis description:

Clinical equivalence of the primary endpoint was evaluated by comparing the 2-sided 90% confidence interval (CI) of the difference between treatments in mean %PASI CfB to Week 12 is entirely contained within the equivalence margin of [-10%, +10%] between BAT 2206 versus (vs) ustekinumab.

Multiple imputation was applied for the point estimate and CI of the difference between treatments in mean %PASI CfB to Week 12 between the 2 groups.

Comparison groups	BAT2206 Group v Stelara Group
Number of subjects included in analysis	549
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	1.774
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.679
upper limit	4.227

Primary: Percent change from baseline (CfB) in Psoriasis Area and Severity Index (PASI) score to Week 12

End point title	Percent change from baseline (CfB) in Psoriasis Area and Severity Index (PASI) score to Week 12

End point description:

PASI is a measure of psoriatic disease severity taking into account qualitative lesion characteristics (erythema, induration/thickness, and scaling) and percentage of affected skin surface area on defined anatomical regions.

End point type	Primary

End point timeframe:

Baseline and week12

End point values	BAT2206 Group	Stelara Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	274	275		
Units: Percent change in PASI score				
least squares mean (standard error)	-85.039 (± 2.0731)	-86.813 (± 2.0105)		

Statistical analyses

Statistical analysis title	Treatment Group :BAT2206 and Stelara

Statistical analysis description:

Clinical equivalence of the primary endpoint was evaluated by comparing the 2-sided 95% confidence interval (CI) of the difference between treatments in mean %PASI CfB to Week 12 is entirely contained within the equivalence margin of [-13%, +13%] between BAT 2206 versus (vs) ustekinumab.

Multiple imputation was applied for the point estimate and CI of the difference between treatments in mean %PASI CfB to Week 12 between the 2 groups.

Comparison groups	BAT2206 Group v Stelara Group
Number of subjects included in analysis	549
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	1.774
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.149
upper limit	4.697

Secondary: Percent change from baseline (CfB) in PASI at other timepoints

End point title	Percent change from baseline (CfB) in PASI at other timepoints

End point description:

PASI is a measure of psoriatic disease severity taking into account qualitative lesion characteristics (erythema, induration/thickness, and scaling) and percentage of affected skin surface area on defined anatomical regions.

End point type	Secondary

End point timeframe:

Weeks 4, 16, 20, 28

End point values	Through week28 BAT2206	Through week28Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	278	278		
Units: Percent change in PASI Score				
least squares mean (standard error)				

week 4	-50.39 (± 3.011)	-49.80 (± 2.951)		
week 16	-86.38 (± 2.046)	-87.46 (± 2.012)		
week 20	-88.76 (± 1.849)	-89.56 (± 1.786)		
week 28	-90.54 (± 1.292)	-91.13 (± 1.265)		

Statistical analyses

Statistical analysis title	week 28 Group BAT2206 VS Group Stelara
Comparison groups	Through week28 BAT2206 v Through week28Stelara
Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	0.59
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.95
upper limit	2.13

Secondary: Proportion of patients who achieve at least 75% improvement from baseline in PASI at weeks 8, 12,16, 28, 40,52

End point title	Proportion of patients who achieve at least 75% improvement from baseline in PASI at weeks 8, 12,16, 28, 40,52
End point description:	
End point type	Secondary
End point timeframe:	
weeks 8, 12, 16,28, 40,52	

End point values	Through week28 BAT2206	Through week28Stelara	Post week28 :Stelara /BAT2206	Post week28 :Stelara /Stelara
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	278	278	131	133
Units: Proportion of Subjects				
number (not applicable)				
Week 8 (N = 275; 274; 0; 0; 0)	54.66	55.01	0	0
Week 12 (N = 274; 275; 0; 0; 0)	76.32	78.36	0	0
Week 16 (N = 275; 275; 0; 0; 0)	83.54	83.89	0	0
Week 28(N = 271; 269; 0; 0; 0)	97.7	98.09	0	0
Week 40 (N = 0; 0; 129; 132; 262)	0	0	92.4	94.7

Week 52 (N = 0; 0; 126; 128; 258)	0	0	87.8	91.7

End point values	Post week28 :BAT2206 /BAT2206			
Subject group type	Subject analysis set			
Number of subjects analysed	264			
Units: Proportion of Subjects				
number (not applicable)				
Week 8 (N = 275; 274; 0; 0; 0)	0			
Week 12 (N = 274; 275; 0; 0; 0)	0			
Week 16 (N = 275; 275; 0; 0; 0)	0			
Week 28(N = 271; 269; 0; 0; 0)	0			
Week 40 (N = 0; 0; 129; 132; 262)	96.2			
Week 52 (N = 0; 0; 126; 128; 258)	93.2			

Statistical analyses

Statistical analysis title	Proportion of Subjects Achieving PASI-75% at W12
Comparison groups	Through week28 BAT2206 v Through week28Stelara
Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	% Estimated treatment difference
Point estimate	-2.03
Confidence interval	
level	90 %
sides	2-sided
lower limit	-7.99
upper limit	3.92

Secondary: Proportion of Subjects With Static Physician’s Global Assessment Score on a 6-item Scale of Cleared (0) or Minimal (1) at weeks 8, 12,16,28

End point title	Proportion of Subjects With Static Physician’s Global Assessment Score on a 6-item Scale of Cleared (0) or Minimal (1) at weeks 8, 12,16,28

End point description:

The sPGA is a 6-point scale ranging from 0 (clear) to 5 (very severe) used to measure the severity ofdisease (induration, scaling, and erythema). A sPGA response was defined as a sPGA value of clear(score 0) or almost clear (score 1). Higher scores represent worse symptom severity

End point type	Secondary

End point timeframe:

week 8,12,16,28

End point values	Through week28 BAT2206	Through week28Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	278	278		
Units: Proportion of Subjects				
number (not applicable)				
Week 8(N = 269; 266)	63.41	59.55		
Week 12(N = 264; 264)	80.08	76.34		
Week 16(N = 271; 269)	81.95	85.85		
Week 28(N = 271; 268)	89.46	88.63		

Statistical analyses

No statistical analyses for this end point

Secondary: AUEC for Psoriasis Area and Severity Index From Baseline at Weeks 8, 12, and 28

End point title	AUEC for Psoriasis Area and Severity Index From Baseline at Weeks 8, 12, and 28

End point description:

End point type	Secondary

End point timeframe:

week 81228

End point values	Through week28 BAT2206	Through week28Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	278	278		
Units: Area Under the Effect Curve for PASI				
least squares mean (standard error)				
Week 8	818.95 (± 44.969)	847.11 (± 44.112)		
Week 12	961.12 (± 57.052)	990.23 (± 56.007)		
Week 28	1294.80 (± 92.974)	1317.35 (± 91.115)		

Statistical analyses

Statistical analysis title	AUEC for PASI From Baseline at week 28
Statistical analysis description: AUEC Area Under the Effect Curve	
Comparison groups	Through week28 BAT2206 v Through week28Stelara
Number of subjects included in analysis	556
Analysis specification	Pre-specified
Analysis type	equivalence
Parameter estimate	Mean difference (final values)
Point estimate	-22.56
Confidence interval	
level	90 %
sides	2-sided
lower limit	-133.54
upper limit	88.43

Secondary: Change From Baseline in Dermatology Life Quality Index Score at Weeks 8, 12, 28

End point title	Change From Baseline in Dermatology Life Quality Index Score at Weeks 8, 12, 28
End point description: The DLQI is a simple, self-administered questionnaire designed to measure the health-related quality of life of an adult suffering from a skin disease. It consists of 10 questions (each scored from 0 to 3) concerning patients' perception of the impact of skin disease on different aspects of their health-related quality of life over the last week.	
End point type	Secondary
End point timeframe: Weeks 8,12, 28	

End point values	Through week28 BAT2206	Through week28Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	278	278		
Units: Score				
arithmetic mean (standard deviation)				
Week 8 (N = 275; 274)	-10.4 (± 6.85)	-9.4 (± 6.83)		
Week 12 (N = 274; 275	-11.6 (± 7.12)	-11.1 (± 6.79)		
Week 28 (N = 271; 269	-12.3 (± 7.22)	-11.9 (± 6.97)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Affected Body Surface Area at weeks 8, 12, 28

End point title	Change From Baseline in Affected Body Surface Area at weeks 8, 12, 28

End point description:

BSA is a measurement of the affected skin area. The overall BSA affected by psoriasis is estimated on the basis of the palm area of the patient's hand (entire palmar surface or "handprint" including the fingers), which equates to approximately 1% of total BSA.

End point type	Secondary

End point timeframe:

weeks 8,12,28

End point values	Through week28 BAT2206	Through week28Stelara		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	278	278		
Units: Score				
arithmetic mean (standard deviation)				
Week 8 (N = 275; 274)	-18.43 (± 14.992)	-19.29 (± 15.083)		
Week 12 (N = 274; 275)	-23.04 (± 16.085)	-24.67 (± 15.290)		
Week 28 (N = 271; 269)	-28.29 (± 15.867)	-28.64 (± 14.740)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Day 1 (Week 0) to Week 28; Week 28 to Week 52	
Adverse event reporting additional description:	
up to Week 28: Safety Analysis Set 1. Post Week 28: Safety Analysis Set 2	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups	
Reporting group title	Through week28 : BAT2206
Reporting group description:	
Participants received SC injection of BAT2206, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16.	
Reporting group title	Through week28 : Stelara
Reporting group description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg Baseline body weight > 100 kg) at Weeks 0, 4, and week16.	
Reporting group title	Post week28 :Stelara /BAT2206
Reporting group description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. participants with an improvement in PASI score of ≥75% at Week 28 , were re-randomized to receive BAT2206 at Weeks 28 and 40.	
Reporting group title	Post week28 :Stelara /Stelara
Reporting group description:	
Participants received SC injection of ustekinumab, 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. participants with an improvement in PASI score of ≥75% at Week 28 , were re-randomized to continue receiving ustekinumab at week 28 and week 40 .	
Reporting group title	Post week28 :BAT2206 /BAT2206
Reporting group description:	
Participants received SC injection of BAT2206 , 45 mg (Baseline body weight <= 100 kg) or 90 mg (Baseline body weight > 100 kg) at Weeks 0, 4, and 16. participants with an improvement in PASI score of ≥75% at Week 28 , were re-randomized to continue receiving BAT2206 at week28 and week 40 .	

Serious adverse events	Through week28 : BAT2206	Through week28 : Stelara	Post week28 :Stelara /BAT2206
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 277 (1.81%)	4 / 278 (1.44%)	1 / 131 (0.76%)
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)			
Breast cancer			
subjects affected / exposed	0 / 277 (0.00%)	1 / 278 (0.36%)	0 / 131 (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

Polycythaemia vera			
subjects affected / exposed	1 / 277 (0.36%)	0 / 278 (0.00%)	0 / 131 (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
Lipoma			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	0 / 131 (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			
Forearm fracture			
subjects affected / exposed	1 / 277 (0.36%)	0 / 278 (0.00%)	0 / 131 (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
Humerus fracture			
subjects affected / exposed	0 / 277 (0.00%)	1 / 278 (0.36%)	0 / 131 (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
Spinal cord injury lumbar			
subjects affected / exposed	1 / 277 (0.36%)	0 / 278 (0.00%)	0 / 131 (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
Spinal compression fracture			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	1 / 131 (0.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	0 / 131 (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
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	0 / 131 (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			
Coronary artery disease			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	0 / 131 (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
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	1 / 277 (0.36%)	0 / 278 (0.00%)	0 / 131 (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
Hepatobiliary disorders			
Cholecystitis chronic			
subjects affected / exposed	0 / 277 (0.00%)	1 / 278 (0.36%)	0 / 131 (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
Cholangitis			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	0 / 131 (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
Cholelithiasis			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	0 / 131 (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
Respiratory, thoracic and mediastinal disorders			
Interstitial lung disease			
subjects affected / exposed	1 / 277 (0.36%)	0 / 278 (0.00%)	0 / 131 (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
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	0 / 131 (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			
Epiglottitis			

subjects affected / exposed	0 / 277 (0.00%)	1 / 278 (0.36%)	0 / 131 (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
Respiratory tract infection viral			
subjects affected / exposed	1 / 277 (0.36%)	0 / 278 (0.00%)	0 / 131 (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
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	0 / 131 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Post week28 :Stelara /Stelara	Post week28 :BAT2206 /BAT2206	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 133 (0.75%)	5 / 264 (1.89%)	
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)			
Breast cancer			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polycythaemia vera			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	1 / 133 (0.75%)	0 / 264 (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			
Forearm fracture			

subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord injury lumbar			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 133 (0.00%)	1 / 264 (0.38%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 133 (0.00%)	1 / 264 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Coronary artery disease			
subjects affected / exposed	0 / 133 (0.00%)	1 / 264 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hepatobiliary disorders			
Cholecystitis chronic			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 133 (0.00%)	1 / 264 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 133 (0.00%)	1 / 264 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Interstitial lung disease			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (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			
Eczema			
subjects affected / exposed	0 / 133 (0.00%)	1 / 264 (0.38%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Epiglottitis			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection viral			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (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			
Hypokalaemia			

subjects affected / exposed	0 / 133 (0.00%)	1 / 264 (0.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Through week28 : BAT2206	Through week28 : Stelara	Post week28 :Stelara /BAT2206
Total subjects affected by non-serious adverse events			
subjects affected / exposed	79 / 277 (28.52%)	76 / 278 (27.34%)	42 / 131 (32.06%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	7 / 277 (2.53%)	10 / 278 (3.60%)	5 / 131 (3.82%)
occurrences (all)	7	11	5
Gamma-glutamyltransferase increased			
subjects affected / exposed	5 / 277 (1.81%)	6 / 278 (2.16%)	3 / 131 (2.29%)
occurrences (all)	5	7	3
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 277 (2.17%)	5 / 278 (1.80%)	0 / 131 (0.00%)
occurrences (all)	6	5	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	0 / 131 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 277 (0.00%)	0 / 278 (0.00%)	2 / 131 (1.53%)
occurrences (all)	0	0	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 277 (1.44%)	6 / 278 (2.16%)	3 / 131 (2.29%)
occurrences (all)	4	6	3
Infections and infestations			
COVID-19			
subjects affected / exposed	17 / 277 (6.14%)	20 / 278 (7.19%)	21 / 131 (16.03%)
occurrences (all)	17	21	21

Upper respiratory tract infection			
subjects affected / exposed	23 / 277 (8.30%)	17 / 278 (6.12%)	6 / 131 (4.58%)
occurrences (all)	28	21	6
Nasopharyngitis			
subjects affected / exposed	12 / 277 (4.33%)	9 / 278 (3.24%)	1 / 131 (0.76%)
occurrences (all)	14	12	1
Urinary tract infection			
subjects affected / exposed	6 / 277 (2.17%)	3 / 278 (1.08%)	1 / 131 (0.76%)
occurrences (all)	6	3	1
Metabolism and nutrition disorders			
Hyperlipidaemia			
subjects affected / exposed	7 / 277 (2.53%)	9 / 278 (3.24%)	3 / 131 (2.29%)
occurrences (all)	8	10	3
Hyperuricaemia			
subjects affected / exposed	8 / 277 (2.89%)	6 / 278 (2.16%)	0 / 131 (0.00%)
occurrences (all)	9	6	0

Non-serious adverse events	Post week28 :Stelara /Stelara	Post week28 :BAT2206 /BAT2206	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	39 / 133 (29.32%)	74 / 264 (28.03%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 133 (1.50%)	5 / 264 (1.89%)	
occurrences (all)	2	5	
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 133 (1.50%)	1 / 264 (0.38%)	
occurrences (all)	2	1	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 133 (0.00%)	6 / 264 (2.27%)	
occurrences (all)	0	6	
Hepatobiliary disorders			

Hepatic function abnormal			
subjects affected / exposed	4 / 133 (3.01%)	3 / 264 (1.14%)	
occurrences (all)	4	4	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 133 (0.75%)	2 / 264 (0.76%)	
occurrences (all)	1	2	
Infections and infestations			
COVID-19			
subjects affected / exposed	21 / 133 (15.79%)	39 / 264 (14.77%)	
occurrences (all)	22	39	
Upper respiratory tract infection			
subjects affected / exposed	7 / 133 (5.26%)	14 / 264 (5.30%)	
occurrences (all)	9	14	
Nasopharyngitis			
subjects affected / exposed	2 / 133 (1.50%)	10 / 264 (3.79%)	
occurrences (all)	2	12	
Urinary tract infection			
subjects affected / exposed	3 / 133 (2.26%)	3 / 264 (1.14%)	
occurrences (all)	3	3	
Metabolism and nutrition disorders			
Hyperlipidaemia			
subjects affected / exposed	3 / 133 (2.26%)	5 / 264 (1.89%)	
occurrences (all)	3	5	
Hyperuricaemia			
subjects affected / exposed	0 / 133 (0.00%)	0 / 264 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported