Clinical trial results:
A Randomized, Active-Controlled, Double-Blind, Phase 3 Study to Compare the Efficacy and Safety of CT-P43 to Stelara in Patients with Moderate to Severe Plaque Psoriasis

Summary

EudraCT number	2020-001045-39
Trial protocol	EE
Global end of trial date	12 May 2022

Results information

Result version number	v1 (current)
This version publication date	19 May 2023
First version publication date	19 May 2023

Trial information

Trial identification

Sponsor protocol code	CT-P43_3.1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04673786
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Celltrion, Inc.
Sponsor organisation address	23, Academy-ro, Incheon, Korea, Republic of,
Public contact	Youn Jeong Choi, Celltrion, Inc., 82 32 850 5767, YounJeong.choi@celltrion.com
Scientific contact	Yun Ju Bae, Celltrion, Inc., 82 32 850 4160, YunJu.Bae@celltrion.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	12 May 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	12 May 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to demonstrate that CT-P43 is equivalent to EU-Stelara, in terms of efficacy as determined by the mean percent improvement from baseline in Psoriasis Area and Severity Index (PASI) score at Week 12.

Protection of trial subjects:

Hypersensitivity reactions will be assessed prior to the study drug administration and 1 hour (±10 minutes) after the end of the study drug administration by additional vital sign measurements including BP, pulse and respiratory rates, and body temperature. If patients have signs and symptoms of hypersensitivity/allergic reactions at home (hives, difficulty breathing, or swelling of face, eyes, lips, or mouth or any symptoms of cardiac origin), patients or caregivers should be advised to call the study center or get immediate help. In addition, hypersensitivity will be monitored by routine continuous clinical monitoring including patient-reported signs and symptoms. In case of hypersensitivity, emergency medication and equipment, such as adrenaline, antihistamines, corticosteroids, and respiratory support including inhalational therapy, oxygen, and artificial ventilation must be available and any types of ECG can be performed. For patients who experience or develop life-threatening treatment-related anaphylactic reactions, study drug must be stopped immediately and succeeding doses need to be discontinued.

Background therapy: -

Evidence for comparator:

CT-P43 has been developed as a proposed biosimilar product to Stelara (ustekinumab), a human IgG1κ monoclonal antibody that binds with high affinity and specificity to the p40 protein subunit used by both the interleukin (IL)-12 and IL-23 cytokines. The purpose of this study is to show that there are no clinical meaningful differences between the two products.

Actual start date of recruitment	14 December 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 377
Country: Number of subjects enrolled	Estonia: 11
Country: Number of subjects enrolled	Korea, Republic of: 48
Country: Number of subjects enrolled	Ukraine: 73
Worldwide total number of subjects	509
EEA total number of subjects	388

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)	483
From 65 to 84 years	26
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The first patient randomly assigned to study drug: 11 January 2021. The study was conducted at 34 study centers in Estonia, Korea, Poland and Ukraine.

Pre-assignment

Screening details:

Male or female patient aged 18-80 years with moderate to severe chronic plaque psoriasis (with or without psoriatic arthritis [PsA]) for at least 24 weeks

Pre-assignment period milestones

Number of subjects started	574[1]
Number of subjects completed	509

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Consent withdrawn by subject: 14
Reason: Number of subjects	Other: 2
Reason: Number of subjects	Inclusion/Exclusion criteria not met: 49

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: The 'Number of subjects reported to have started the pre-assignment period' means subjects who consented to participate in this trial through the Screening procedure. If these subjects meet Inclusion and Exclusion criteria defined by the protocol, they can be randomized which will have study drug administration. For this reason, 574 patients were screened and of these 509 patients were met Inclusion and Exclusion criteria and randomized to each arm.

Period 1

Period 1 title	Treatment Period I
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, patients, and other predefined personnel from the sponsor and CRO teams remained blinded until the EOS.

Arms

Are arms mutually exclusive?	Yes
Arm title	CT-P43

Arm description:

CT-P43 45mg or 90mg at Weeks 0 and 4

Arm type	Experimental
Investigational medicinal product name	CT-P43
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients who were initially randomly assigned to CT-P43 45 mg (who weighed ≤100 kg) or 90 mg (who weighed >100 kg) administered subcutaneously in Treatment Period I (at Weeks 0 and 4) based on patient's baseline body weight.

Arm title	EU-Stelara

Arm description:

EU-Stelara 45mg or 90mg at Weeks 0 and 4

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

Dosage and administration details:

Patients who were initially randomly assigned to EU-Stelara 45 mg (who weighed ≤100 kg) or 90 mg (who weighed >100 kg) administered subcutaneously in Treatment Period I (at Weeks 0 and 4) based on patient's baseline body weight.

Number of subjects in period 1	CT-P43	EU-Stelara
Started	256	253
Completed	253	249
Not completed	3	4
Consent withdrawn by subject	3	3
Lost to follow-up	-	1

Period 2

Period 2 title	Treatment Period II
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

The investigators, patients, and other predefined personnel from the sponsor and CRO teams remained blinded until the EOS.

Arms

Are arms mutually exclusive?	Yes
Arm title	CT-P43 Maintenance

Arm description:

All patients who received CT-P43 during Treatment Period I and continued to receive CT-P43 in Treatment Period II (at Weeks 16, 28 and 40).

Arm type	Experimental
Investigational medicinal product name	CT-P43
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients administered 45 mg (who weighed ≤100 kg) or 90 mg (who weighed >100 kg) of CT-P43 subcutaneously at Weeks 16, 28 and 40.

Arm title	EU-Stelara maintenance

Arm description:

Patients who were initially randomly assigned to EU-Stelara at Day 1 (Week 0) were to continue to receive EU-Stelara in Treatment Period II (at Weeks 16, 28 and 40).

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

Dosage and administration details:

Patients administered 45 mg (who weighed ≤100 kg) or 90 mg (who weighed >100 kg) of EU-Stelara subcutaneously at Weeks 16, 28 and 40.

Arm title	Switched to CT-P43

Arm description:

Patients who received EU-Stelara during Treatment Period I and re-randomized to receive CT-P43 in Treatment Period II (at Weeks 16, 28 and 40).

Arm type	Experimental
Investigational medicinal product name	CT-P43
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients were switched to administer 45 mg (who weighed ≤100 kg) or 90 mg (who weighed >100 kg) of CT-P43 subcutaneously at Weeks 16, 28 and 40.

Number of subjects in period 2	CT-P43 Maintenance	EU-Stelara maintenance	Switched to CT-P43
Started	253	125	124
Completed	239	122	122
Not completed	14	3	2
Consent withdrawn by subject	9	3	1
Adverse event, non-fatal	2	-	1
Death	1	-	-
Lost to follow-up	2	-	-

Baseline characteristics

Reporting groups	
Reporting group title	CT-P43
Reporting group description:	
CT-P43 45mg or 90mg at Weeks 0 and 4	
Reporting group title	EU-Stelara
Reporting group description:	
EU-Stelara 45mg or 90mg at Weeks 0 and 4	

Reporting group values	CT-P43	EU-Stelara	Total
Number of subjects	256	253	509
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)	242	241	483
From 65-84 years	14	12	26
85 years and over	0	0	0
Age continuous Units: years			
median	41	41	
full range (min-max)	18 to 74	18 to 77	-
Gender categorical Units: Subjects			
Female	95	80	175
Male	161	173	334
Presence of Psoriasis Arthritis at Screening Units: Subjects			
Yes	80	83	163
No	176	170	346
Time since Plaque-type Psoriasis Diagnosis Units: year			
arithmetic mean	17.81	15.56	
standard deviation	± 12.144	± 11.560	-

End points

End points reporting groups

Reporting group title	CT-P43
Reporting group description: CT-P43 45mg or 90mg at Weeks 0 and 4	
Reporting group title	EU-Stelara
Reporting group description: EU-Stelara 45mg or 90mg at Weeks 0 and 4	
Reporting group title	CT-P43 Maintenance
Reporting group description: All patients who received CT-P43 during Treatment Period I and continued to receive CT-P43 in Treatment Period II (at Weeks 16, 28 and 40).	
Reporting group title	EU-Stelara maintenance
Reporting group description: Patients who were initially randomly assigned to EU-Stelara at Day 1 (Week 0) were to continue to receive EU-Stelara in Treatment Period II (at Weeks 16, 28 and 40).	
Reporting group title	Switched to CT-P43
Reporting group description: Patients who received EU-Stelara during Treatment Period I and re-randomized to receive CT-P43 in Treatment Period II (at Weeks 16, 28 and 40).	

Primary: The Mean Percent Improvement From Baseline in PASI Score at Week 12

End point title	The Mean Percent Improvement From Baseline in PASI Score at Week 12
End point description: The mean percent improvement from baseline in Psoriasis Area and Severity Index (PASI) score at Week 12. PASI score can range from 0 (no psoriasis) to 72 (severe psoriasis).	
End point type	Primary
End point timeframe: From baseline to Week 12	

End point values	CT-P43	EU-Stelara		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	198[1]	194[2]		
Units: percent				
least squares mean (standard error)	78.26 (± 2.054)	77.33 (± 2.049)		

Notes:

[1] - The equivalence test was conducted with patients administered 45 mg only in Treatment Period I.

[2] - The equivalence test was conducted with patients administered 45 mg only in Treatment Period I.

Statistical analyses

Statistical analysis title	Primary efficacy analysis
Statistical analysis description: The equivalence test consisted of patients who are administered at least one 45 mg of study drug and had never received 90 mg of study drug in Treatment Period I. The primary efficacy analysis was	

conducted on the FAS using an analysis of covariance (ANCOVA) model considering the treatment as a fixed effect and country, baseline body weight, prior biologic use approved for psoriasis treatment and baseline PASI score as covariates.

Comparison groups	CT-P43 v EU-Stelara
Number of subjects included in analysis	392
Analysis specification	Pre-specified
Analysis type	equivalence[3]
Method	ANCOVA
Parameter estimate	Treatment difference (%) and 95% CI
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.29
upper limit	4.16

Notes:

[3] - Predefined equivalence margin: -15% to 15%

Secondary: The PASI score at Week 12

End point title	The PASI score at Week 12

End point description:

The percent improvement from baseline in Psoriasis Area and Severity Index (PASI) score at Week 12. PASI score can range from 0 (no psoriasis) to 72 (severe psoriasis).

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P43	EU-Stelara		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	256	248		
Units: score				
arithmetic mean (standard deviation)	2.98 (± 3.412)	3.44 (± 4.362)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Mean Percent Improvement From Baseline in PASI Score Through Week 52

End point title	The Mean Percent Improvement From Baseline in PASI Score Through Week 52

End point description:

The Psoriasis Area and Severity Index (PASI) score through Week 52. PASI score can range from 0 (no psoriasis) to 72 (severe psoriasis).

End point type	Secondary

End point timeframe:

Through Week 52

End point values	CT-P43 Maintenance	EU-Stelara maintenance	Switched to CT-P43	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242	122	123	
Units: percent				
arithmetic mean (standard deviation)	93.79 (± 11.794)	93.39 (± 14.947)	91.58 (± 13.264)	

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Patients Achieving PASI 50/75/90/100 Responses at Week 12

End point title	The Number of Patients Achieving PASI 50/75/90/100 Responses at Week 12

End point description:

The number of participants achieving at least 50%/75%/90%/100% improvement from baseline in Psoriasis Area and Severity Index (PASI) at Week 12. PASI score can range from 0 (no psoriasis) to 72 (severe psoriasis).

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P43	EU-Stelara		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	256	253		
Units: Responder				
PASI50	247	240		
PASI75	212	187		
PASI90	129	127		
PASI100	47	48		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Patients With sPGA Score of Clear (0) or Almost Clear (1) at Week 12

End point title	The Number of Patients With sPGA Score of Clear (0) or Almost Clear (1) at Week 12

End point description:

The sPGA is a 5-point score ranging from 0 to 4, based on the physician’s assessment of the erythema, average thickness, and scaling of all psoriatic lesions at a given time point. The sum of the 3 scales will be divided by 3 to obtain a final sPGA score.

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P43	EU-Stelara		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	256	253		
Units: Responder	219	201		

Statistical analyses

No statistical analyses for this end point

Secondary: The Change From Baseline in Dermatology Life Quality Index (DLQI) Through Week 52

End point title	The Change From Baseline in Dermatology Life Quality Index (DLQI) Through Week 52

End point description:

This DLQI is a 10-item patient-reported outcome questionnaire that, in addition to evaluating overall QoL, can be used to assess 6 different aspects that may affect QoL: symptoms and feelings, daily activities, leisure, work or school performance, personal relationships, and treatment. Total scores range from 0 to 30 (less to more impairment).

End point type	Secondary

End point timeframe:

Through Week 52

End point values	CT-P43 Maintenance	EU-Stelara maintenance	Switched to CT-P43	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	242	122	123	
Units: Score				
arithmetic mean (standard deviation)	-10.5 (± 7.24)	-8.5 (± 7.17)	-9.2 (± 6.93)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Through Week 52

Adverse event reporting additional description:

Treatment Period I: Week 0 to Week 16 pre-dose;
Treatment Period II: Week 16 to Week 52 (End-of-study visit)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Treatment Period I: CT-P43

Reporting group description:

CT-P43 45mg or 90mg at Weeks 0 and 4

Reporting group title	Treatment Period I: EU-Stelara

Reporting group description:

EU-Stelara 45mg or 90mg at Weeks 0 and 4

Reporting group title	Treatment Period II: CT-P43 maintenance

Reporting group description:

All patients who received CT-P43 during Treatment Period I and continued to receive CT-P43 in Treatment Period II (at Weeks 16, 28 and 40).

Reporting group title	Treatment Period II: EU-Stelara maintenance

Reporting group description:

Patients who were initially randomly assigned to EU-Stelara at Day 1 (Week 0) were to continue to receive EU-Stelara in Treatment Period II (at Weeks 16, 28 and 40).

Reporting group title	Treatment Period II: Switched to CT-P43

Reporting group description:

Patients who received EU-Stelara during Treatment Period I and re-randomized to receive CT-P43 in Treatment Period II (at Weeks 16, 28 and 40).

Serious adverse events	Treatment Period I: CT-P43	Treatment Period I: EU-Stelara	Treatment Period II: CT-P43 maintenance
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 256 (1.56%)	4 / 253 (1.58%)	5 / 253 (1.98%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon adenoma			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubular breast carcinoma			

subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 256 (0.00%)	1 / 253 (0.40%)	0 / 253 (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
Guillain-Barre syndrome			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	0 / 253 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 256 (0.00%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal inflammation			
subjects affected / exposed	1 / 256 (0.39%)	0 / 253 (0.00%)	0 / 253 (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
Pancreatitis acute			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Menstrual disorder			

subjects affected / exposed	0 / 256 (0.00%)	1 / 253 (0.40%)	0 / 253 (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
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	0 / 253 (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
Psychiatric disorders			
Bipolar disorder			
subjects affected / exposed	1 / 256 (0.39%)	0 / 253 (0.00%)	0 / 253 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	0 / 253 (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			
COVID-19 pneumonia			
subjects affected / exposed	2 / 256 (0.78%)	1 / 253 (0.40%)	0 / 253 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	0 / 253 (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
Tooth abscess			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
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	Treatment Period II: EU-Stelara maintenance	Treatment Period II: Switched to CT-P43	
Total subjects affected by serious			

adverse events			
subjects affected / exposed	3 / 125 (2.40%)	2 / 124 (1.61%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon adenoma			
subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubular breast carcinoma			
subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (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			
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal inflammation			

subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Menstrual disorder			
subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Respiratory failure			
subjects affected / exposed	0 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Bipolar disorder			
subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (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 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
COVID-19 pneumonia			
subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			

subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	0 / 125 (0.00%)	0 / 124 (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: 3 %

Non-serious adverse events	Treatment Period I: CT-P43	Treatment Period I: EU-Stelara	Treatment Period II: CT-P43 maintenance
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 256 (5.47%)	20 / 253 (7.91%)	35 / 253 (13.83%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	3 / 253 (1.19%)
occurrences (all)	0	0	3
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	2 / 253 (0.79%)
occurrences (all)	0	0	2
Infections and infestations			
COVID-19			
subjects affected / exposed	11 / 256 (4.30%)	12 / 253 (4.74%)	13 / 253 (5.14%)
occurrences (all)	11	12	13
Upper respiratory tract infection			
subjects affected / exposed	3 / 256 (1.17%)	8 / 253 (3.16%)	10 / 253 (3.95%)
occurrences (all)	3	8	10
Latent tuberculosis			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	7 / 253 (2.77%)
occurrences (all)	0	0	7
Nasopharyngitis			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	1 / 253 (0.40%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			

Hypertriglyceridaemia			
subjects affected / exposed	0 / 256 (0.00%)	0 / 253 (0.00%)	4 / 253 (1.58%)
occurrences (all)	0	0	4

Non-serious adverse events	Treatment Period II: EU-Stelara maintenance	Treatment Period II: Switched to CT-P43	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 125 (20.00%)	28 / 124 (22.58%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	3 / 125 (2.40%)	6 / 124 (4.84%)	
occurrences (all)	3	6	
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 125 (2.40%)	4 / 124 (3.23%)	
occurrences (all)	3	4	
Infections and infestations			
COVID-19			
subjects affected / exposed	11 / 125 (8.80%)	7 / 124 (5.65%)	
occurrences (all)	11	8	
Upper respiratory tract infection			
subjects affected / exposed	4 / 125 (3.20%)	7 / 124 (5.65%)	
occurrences (all)	4	8	
Latent tuberculosis			
subjects affected / exposed	4 / 125 (3.20%)	4 / 124 (3.23%)	
occurrences (all)	4	4	
Nasopharyngitis			
subjects affected / exposed	1 / 125 (0.80%)	4 / 124 (3.23%)	
occurrences (all)	1	4	
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	1 / 125 (0.80%)	4 / 124 (3.23%)	
occurrences (all)	1	5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 July 2021	Summary of significant changes included the following: • Changed the number of study center and countries. • Added the specific information on Inclusion/Exclusion Criterions for clarifying. • Revised the number of planned enrolled patients as actual number of enrolled patients were exceeded expectations. • Deleted the category of covariate of body weight on the primary efficacy analysis. • Added the plan for statistical test for secondary efficacy endpoints. • Supplemented the definition of major deviations. •Other editorial changes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to the conflict in Ukraine, sponsor provided guideline for exceptional allowance regarding visit window and study assessments (only EOS visit was affected) in order to ensure patients' safety and the robustness and integrity of data.

Notes: