Clinical trial results:
A Randomized, Placebo Controlled, Double-Blind, Phase 3 Study to Evaluate the Efficacy and Safety of the Subcutaneous Injection of CT-P13 (CT-P13 SC) as Maintenance Therapy in Patients with Moderately to Severely Active Ulcerative Colitis

Summary

EudraCT number	2019-003849-15
Trial protocol	FR AT BG ES CZ PL GR HR IT
Global end of trial date	11 July 2023

Results information

Result version number	v1 (current)
This version publication date	08 March 2024
First version publication date	08 March 2024

Trial information

Trial identification

Sponsor protocol code	CT-P13_3.7

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04205643
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Celltrion, Inc.
Sponsor organisation address	23, Academy-ro, Yeonsu-gu, Incheon, 22014, Korea, Republic of,
Public contact	Yun Ju Bae, Celltrion, Inc., 82 328504160, yunju.bae@celltrion.com
Scientific contact	Yun Ju Bae, Celltrion, Inc., 82 328504160, 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	03 January 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 December 2022
Global end of trial reached?	Yes
Global end of trial date	11 July 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate superiority of CT-P13 SC over Placebo SC based on clinical remission at Week 54

Protection of trial subjects:

Hypersensitivity monitoring (including delayed hypersensitivity) was assessed by vital signs (including blood pressure, heart and respiratory rates, and body temperature) at the following time points at each visit specified in the schedule of events.
- Prior to the beginning of study drug administration
- Within 15 minutes after the end of study drug administration
- 1 hour (+10 minutes) after the end of study drug administration

If patients had signs and symptoms of hypersensitivity at home (such as but not limited to skin rash, hives, difficulty breathing, or swelling of face, lips, or mouth, or swelling of the hands, feet, or ankles), patients or caregivers were advised to call the study center or get immediate help. In addition, hypersensitivity was monitored by routine continuous clinical monitoring including patient-reported signs and symptoms. In case of hypersensitivity, emergency equipment, such as adrenaline, antihistamines, corticosteroids, and respiratory support including inhalational therapy, oxygen, and artificial ventilation, were available; in addition, any type of ECG could have been performed. For patients who experienced or developed life-threatening treatment-related anaphylactic reactions, study drug was stopped immediately, and the patient was withdrawn from the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 July 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: 247
Country: Number of subjects enrolled	Croatia: 14
Country: Number of subjects enrolled	Bulgaria: 8
Country: Number of subjects enrolled	Czechia: 14
Country: Number of subjects enrolled	Italy: 25
Country: Number of subjects enrolled	Latvia: 7
Country: Number of subjects enrolled	Belarus: 3
Country: Number of subjects enrolled	Israel: 5
Country: Number of subjects enrolled	Mexico: 16
Country: Number of subjects enrolled	Russian Federation: 94
Country: Number of subjects enrolled	Serbia: 25
Country: Number of subjects enrolled	South Africa: 4

Country: Number of subjects enrolled	Türkiye: 15
Country: Number of subjects enrolled	Ukraine: 71
Worldwide total number of subjects	548
EEA total number of subjects	315

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)	529
From 65 to 84 years	19
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 800 patients from 104 study centers in 15 countries were screened and 548 patients from 92 study centers in 14 countries were enrolled in this study.

Pre-assignment

Screening details:

Key Inclusion Criteria
-Age of 18 to 75 years patients
-UC patients with a modified Mayo score of 5-9 points with endoscopic subscore of >=2 points at Screening
-Patients with failure of conventional therapy including corticosteroids and/or immunosuppressants
-Patients who previously received less than 2 biologic agents and/or JAK inhibitors

Period 1

Period 1 title	Induction Phase
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	CT-P13 IV 5 mg/kg

Arm description:

Patient treated with CT-P13 (5 mg/kg, IV) for Week 0, Week 2, and Week 6.

Arm type	Induction medication

No investigational medicinal product assigned in this arm

Number of subjects in period 1	CT-P13 IV 5 mg/kg
Started	548
Completed	438
Not completed	110
Consent withdrawn by subject	15
Physician decision	5
Other	1
Adverse event	13
Lost to follow-up	2
Progressive disease	6
Non-responder at Week 10	65
Protocol deviation	3

Period 2

Period 2 title	Maintenance Phase
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Blinding implementation details:

This study had a double blind maintenance phase, the treatment assignment for the maintenance phase was blinded to the investigators, patients, and predefined CELLTRION, Inc. and CRO blinded teams until the final CSR was generated. The blind could be broken only if specific emergency treatment would be dictated by knowing the study drug assignment was required for medical management.

Arms

Are arms mutually exclusive?	Yes
Arm title	CT-P13 SC 120 mg

Arm description:

Patients who were classified as clinical responder at Week 10 received CT-P13 120mg subcutaneously every 2 weeks from Week 10 to Week 54. From Week 22, patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.

Arm type	Experimental
Investigational medicinal product name	CT-P13 SC 120 mg
Investigational medicinal product code	
Other name	Remsima SC, Zymfentra
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients who were classified as clinical responder at Week 10 received CT-P13 120mg subcutaneously every 2 weeks from Week 10 to Week 54. From Week 22, patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.

Arm title	Placebo

Arm description:

Patients who were classified as clinical responder at Week 10 received placebo-matching subcutaneously every 2 weeks from Week 10 to Week 54. From Week 22, patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients who were classified as clinical responder at Week 10 received placebo-matching subcutaneously every 2 weeks from Week 10 to Week 54. From Week 22, patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Only for patients in Period 2 were considered as baseline as per objective of this study was to demonstrate superiority of CT-P13 SC over Placebo.

Number of subjects in period 2[2]	CT-P13 SC 120 mg	Placebo
Started	294	144
Completed	237	111
Not completed	57	33
Physician decision	4	2
Consent withdrawn by subject	24	12
Other	2	1
Adverse event	11	9
Progressive disease	13	9
Non-responder at Week 10	1	-
Lost to follow-up	2	-

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Only for patients in Period 2 were considered as baseline as per objective of this study was to demonstrate superiority of CT-P13 SC over Placebo.

Period 3

Period 3 title	Extension Phase
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	CT-P13 SC 120 mg

Arm description:

In the open-label extension phase, all patients who completed the maintenance phase up to Week 54 and may benefit from continued treatment, in the opinion of the investigator, received active treatment with CT-P13 SC 120 mg via PFS from Week 56. The patients who received the adjusted dose of CT-P13 SC 240 mg in the Maintenance Phase continued receiving the same doses of CT-P13 SC for the study treatment in the Extension Phase. Patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.

Arm type	Experimental
Investigational medicinal product name	CT-P13 SC 120 mg
Investigational medicinal product code	
Other name	Remsima SC, Zymfentra
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients who completed the Maintenance Phase CT-P13 SC treatment up to Week 54 and may benefit from continued treatment, in the opinion of the investigator, received active treatment with CT-P13 SC 120 mg via PFS from Week 56 to Week 102. The patients who received the adjusted dose of CT-P13 SC 240 mg in the Maintenance Phase continued receiving the same doses of CT-P13 SC for the study treatment in the Extension Phase. Patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.

Arm title	Placebo

Arm description:

In the open-label extension phase, all patients who completed the maintenance phase up to Week 54 and may benefit from continued treatment, in the opinion of the investigator, received active treatment with CT-P13 SC 120 mg via PFS from Week 56. The patients who received the adjusted dose of CT-P13

SC 240 mg in the Maintenance Phase continued receiving the same doses of CT-P13 SC for the study treatment in the Extension Phase. Patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.

Arm type	Placebo
Investigational medicinal product name	CT-P13 SC 120 mg
Investigational medicinal product code	
Other name	Remsima SC, Zymfentra
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Patients who completed the Maintenance Phase Placebo SC treatment up to Week 54 and may benefit from continued treatment, in the opinion of the investigator, received active treatment with CT-P13 SC 120 mg via PFS from Week 56 to Week 102. The patients who received the adjusted dose of CT-P13 SC 240 mg in the Maintenance Phase continued receiving the same doses of CT-P13 SC for the study treatment in the Extension Phase. Patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.

Number of subjects in period 3	CT-P13 SC 120 mg	Placebo
Started	237	111
Completed	208	95
Not completed	29	16
Physician decision	2	3
Consent withdrawn by subject	11	5
Other	1	-
Pregnancy	1	-
Adverse event	5	1
Progressive disease	5	4
Lost to follow-up	4	3

Baseline characteristics

Reporting groups	
Reporting group title	CT-P13 SC 120 mg
Reporting group description:	
Patients who were classified as clinical responder at Week 10 received CT-P13 120mg subcutaneously every 2 weeks from Week 10 to Week 54. From Week 22, patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.	
Reporting group title	Placebo
Reporting group description:	
Patients who were classified as clinical responder at Week 10 received placebo-matching subcutaneously every 2 weeks from Week 10 to Week 54. From Week 22, patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.	

Reporting group values	CT-P13 SC 120 mg	Placebo	Total
Number of subjects	294	144	438
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)	286	138	424
From 65-84 years	8	6	14
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	38.2	40.4	
standard deviation	± 12.78	± 13.49	-
Gender categorical Units: Subjects			
Female	131	61	192
Male	163	83	246
Race Units: Subjects			
American Indian or Alaska Native	6	4	10
Asian	0	0	0
Black or African American	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
White	288	140	428
Not allowed by investigator country regulations	0	0	0
Other	0	0	0

End points

End points reporting groups

Reporting group title	CT-P13 IV 5 mg/kg
Reporting group description:	
Patient treated with CT-P13 (5 mg/kg, IV) for Week 0, Week 2, and Week 6.	
Reporting group title	CT-P13 SC 120 mg
Reporting group description:	
Patients who were classified as clinical responder at Week 10 received CT-P13 120mg subcutaneously every 2 weeks from Week 10 to Week 54. From Week 22, patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.	
Reporting group title	Placebo
Reporting group description:	
Patients who were classified as clinical responder at Week 10 received placebo-matching subcutaneously every 2 weeks from Week 10 to Week 54. From Week 22, patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.	
Reporting group title	CT-P13 SC 120 mg
Reporting group description:	
In the open-label extension phase, all patients who completed the maintenance phase up to Week 54 and may benefit from continued treatment, in the opinion of the investigator, received active treatment with CT-P13 SC 120 mg via PFS from Week 56. The patients who received the adjusted dose of CT-P13 SC 240 mg in the Maintenance Phase continued receiving the same doses of CT-P13 SC for the study treatment in the Extension Phase. Patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.	
Reporting group title	Placebo
Reporting group description:	
In the open-label extension phase, all patients who completed the maintenance phase up to Week 54 and may benefit from continued treatment, in the opinion of the investigator, received active treatment with CT-P13 SC 120 mg via PFS from Week 56. The patients who received the adjusted dose of CT-P13 SC 240 mg in the Maintenance Phase continued receiving the same doses of CT-P13 SC for the study treatment in the Extension Phase. Patients who initially responded but then lost response could increase the dose to CT-P13 SC 240mg (double injection [2 shots] of CT-P13 SC 120 mg) every 2 weeks.	

Primary: Number of Patients Achieving Clinical Remission at Week 54

End point title	Number of Patients Achieving Clinical Remission at Week 54
End point description:	
Clinical remission defined by modified Mayo score (ranges from 0 to 9, including Stool frequency subscore, Rectal bleeding subscore and Endoscopic subscore), stool frequency subscore of 0 or 1 point, and rectal bleeding subscore of 0 point, and an endoscopic subscore of 0 or 1 point. Patients with dose adjustment to CT-P13 SC 240 mg prior to Week 54 were considered as non-remitter.	
End point type	Primary
End point timeframe:	
Week 54	

End point values	CT-P13 SC 120 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	294	144		
Units: number of patients	127	30		

Statistical analyses

Statistical analysis title	Clinical Remission
Comparison groups	CT-P13 SC 120 mg v Placebo
Number of subjects included in analysis	438
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference estimated using CMH weights
Point estimate	21.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.8
upper limit	29.3

Secondary: Number of Patients Achieving Clinical Response at Week 54

End point title	Number of Patients Achieving Clinical Response at Week 54

End point description:

Clinical response defined by decrease in modified Mayo score from baseline of at least 2 points and at least 30%, with an accompanying decrease in the rectal bleeding subscore of at least 1 point or an absolute rectal bleeding subscore of 0 or 1 point. Patients with dose adjustment to CT-P13 SC 240 mg prior to Week 54 were considered as non-responder.

End point type	Secondary

End point timeframe:

Week 54

End point values	CT-P13 SC 120 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	294	144		
Units: number of patients	158	45		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Patients Achieving Endoscopic-Histologic Mucosal Improvement at Week 54

End point title	Number of Patients Achieving Endoscopic-Histologic Mucosal Improvement at Week 54

End point description:

Endoscopic-histologic mucosal improvement defined as an absolute endoscopic subscore of 0 or 1 point from modified Mayo score and an absolute RHI score of 3 points or less with an accompanying lamina propria neutrophils and neutrophils in epithelium subscore of 0 point. Patients with dose adjustment to CT-P13 SC 240 mg prior to Week 54 were considered as endoscopic-histologic mucosal improvement not achieved.

End point type	Secondary

End point timeframe:

Week 54

End point values	CT-P13 SC 120 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	294	144		
Units: number of patients	105	24		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Patients Achieving Corticosteroid-Free Remission at Week 54

End point title	Number of Patients Achieving Corticosteroid-Free Remission at Week 54

End point description:

Corticosteroid-free remission defined as being in clinical remission by modified Mayo score in addition to not requiring any treatment with corticosteroid for at least 8 weeks at Week 54, among the patients who used oral corticosteroids at baseline. Patients with dose adjustment to CT-P13 SC 240 mg prior to Week 54 were considered as non-remitter.

End point type	Secondary

End point timeframe:

Week 54

End point values	CT-P13 SC 120 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120	61		
Units: number of patients	44	11		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-Emergent Adverse Events for CT-P13 IV 5 mg/kg group during induction phase (Week 0 to 10), CT-P13 SC 120 mg and placebo groups during the maintenance phase (from Week 10 to Week 54) and extension phase (From Week 56 to Week 102) were reported.

Adverse event reporting additional description:

Safety analyses were pre-specified to only report the most severe event if the same events were occurred to the same patient. For CT-P13 IV 5 mg/kg group, the safety analyses were performed ITT population. For CT-P13 SC 120 mg and Placebo groups, the safety analyses were performed in the safety population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	CT-P13 IV 5 mg/kg - Induction

Reporting group description:

Patients who administered CT-P13 IV 5mg/kg at Week 0, 2, and 6.

Reporting group title	CT-P13 SC 120 mg - Maintenance

Reporting group description:

Patients who administered CT-P13 SC 120 mg every 2 weeks from W10 to Week 54. For patients with dose adjustment, only data before initiation of dose adjustment are included.

Reporting group title	Placebo - Maintenance

Reporting group description:

Patients who administered Placebo every 2 weeks from W10 to Week 54. For patients with dose adjustment, only data before initiation of dose adjustment are included.

Reporting group title	CT-P13 SC 120 mg - Extension

Reporting group description:

Patients who administered CT-P13 SC 120 mg every 2 weeks from Maintenacne Phase to Week 102. Patients who received adjusted dose of CT-P13 SC 240mg which is allowed from Week 22 are also included.

Reporting group title	Placebo - Extension

Reporting group description:

Patients who administered Placebo SC every 2 weeks from Maintenance and switched to CT-P13 SC 120 mg from Week 56. Patients who received adjusted dose of CT-P13 SC 240mg which is allowed from Week 22 are also included.

Serious adverse events	CT-P13 IV 5 mg/kg - Induction	CT-P13 SC 120 mg - Maintenance	Placebo - Maintenance
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 548 (4.20%)	15 / 296 (5.07%)	4 / 140 (2.86%)
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)			
Colorectal adenoma			

subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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
Uterine leiomyoma			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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			
Anastomotic leak			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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
Clavicle fracture			
subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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
Infusion related reaction			
subjects affected / exposed	3 / 548 (0.55%)	0 / 296 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	1 / 140 (0.71%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Aortic valve incompetence			
subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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
Cardiac failure			
subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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

Myocardial infarction			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Nervous system disorders			
Neuromyopathy			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	1 / 140 (0.71%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Syncope			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 548 (0.55%)	1 / 296 (0.34%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	2 / 548 (0.36%)	1 / 296 (0.34%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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	3 / 548 (0.55%)	2 / 296 (0.68%)	1 / 140 (0.71%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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
Duodenal ulcer perforation			
subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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
Intestinal obstruction			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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
Intestinal strangulation			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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
Large intestine perforation			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	1 / 140 (0.71%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast			

disorders			
Cervical dysplasia			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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
Cystocele			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Menstruation irregular			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Ovarian cyst			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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
Calculus urinary			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Endocrine disorders			
Thyroiditis			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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			
Arthritis			

subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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
Intervertebral disc degeneration			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Periarthritis			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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
Synovitis			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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			
Appendicitis			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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
COVID-19			
subjects affected / exposed	1 / 548 (0.18%)	1 / 296 (0.34%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	2 / 548 (0.36%)	2 / 296 (0.68%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	1 / 140 (0.71%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			

subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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
Cytomegalovirus infection			
subjects affected / exposed	2 / 548 (0.36%)	0 / 296 (0.00%)	0 / 140 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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
Pneumonia			
subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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
Salpingitis			
subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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
Urinary tract infection			
subjects affected / exposed	0 / 548 (0.00%)	1 / 296 (0.34%)	0 / 140 (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
Urosepsis			
subjects affected / exposed	1 / 548 (0.18%)	0 / 296 (0.00%)	0 / 140 (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
Anal abscess			
subjects affected / exposed	0 / 548 (0.00%)	0 / 296 (0.00%)	0 / 140 (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	CT-P13 SC 120 mg - Extension	Placebo - Extension	

Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 296 (4.05%)	5 / 140 (3.57%)	
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)			
Colorectal adenoma			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine leiomyoma			
subjects affected / exposed	0 / 296 (0.00%)	1 / 140 (0.71%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Anastomotic leak			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clavicle fracture			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Aortic valve incompetence			

subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Neuromyopathy			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			

subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 296 (0.00%)	1 / 140 (0.71%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer perforation			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal strangulation			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (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 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (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			
Cervical dysplasia			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystocele			
subjects affected / exposed	0 / 296 (0.00%)	1 / 140 (0.71%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menstruation irregular			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Ureterolithiasis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Endocrine disorders			
Thyroiditis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (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			
Arthritis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc degeneration			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periarthritis			
subjects affected / exposed	0 / 296 (0.00%)	1 / 140 (0.71%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Synovitis			
subjects affected / exposed	0 / 296 (0.00%)	1 / 140 (0.71%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (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	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			

subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytomegalovirus infection			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (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 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Salpingitis			
subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (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 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			

subjects affected / exposed	0 / 296 (0.00%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 296 (0.34%)	0 / 140 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	CT-P13 IV 5 mg/kg - Induction	CT-P13 SC 120 mg - Maintenance	Placebo - Maintenance
Total subjects affected by non-serious adverse events			
subjects affected / exposed	91 / 548 (16.61%)	64 / 296 (21.62%)	39 / 140 (27.86%)
Nervous system disorders			
Headache			
subjects affected / exposed	30 / 548 (5.47%)	15 / 296 (5.07%)	7 / 140 (5.00%)
occurrences (all)	46	30	8
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	34 / 548 (6.20%)	11 / 296 (3.72%)	5 / 140 (3.57%)
occurrences (all)	36	12	5
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	13 / 548 (2.37%)	13 / 296 (4.39%)	13 / 140 (9.29%)
occurrences (all)	14	14	14
Infections and infestations			
COVID-19			
subjects affected / exposed	13 / 548 (2.37%)	26 / 296 (8.78%)	9 / 140 (6.43%)
occurrences (all)	13	27	9
Nasopharyngitis			
subjects affected / exposed	9 / 548 (1.64%)	5 / 296 (1.69%)	7 / 140 (5.00%)
occurrences (all)	9	5	7
Upper respiratory tract infection			
subjects affected / exposed	4 / 548 (0.73%)	6 / 296 (2.03%)	3 / 140 (2.14%)
occurrences (all)	4	8	5

Non-serious adverse events	CT-P13 SC 120 mg - Extension	Placebo - Extension	
Total subjects affected by non-serious adverse events subjects affected / exposed	43 / 296 (14.53%)	25 / 140 (17.86%)	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	5 / 296 (1.69%) 10	2 / 140 (1.43%) 2	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	4 / 296 (1.35%) 4	2 / 140 (1.43%) 2	
Gastrointestinal disorders Colitis ulcerative subjects affected / exposed occurrences (all)	11 / 296 (3.72%) 14	5 / 140 (3.57%) 6	
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	15 / 296 (5.07%) 16	12 / 140 (8.57%) 13	
Nasopharyngitis subjects affected / exposed occurrences (all)	4 / 296 (1.35%) 7	3 / 140 (2.14%) 3	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	11 / 296 (3.72%) 13	8 / 140 (5.71%) 11	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 January 2020	• Inclusion criteria was updated to be consistent with approved label of Infliximab. • Prohibited therapy section was updated according to the drug interaction description in the label of Remsima®. • Revised PD sampling to allow all sites to sample and handle the fecal calprotectin and updated the footnotes in the schedule of events tables since all sites were allowed to sample and handle the fecal calprotectin. • Analytical facilities table was updated due to a change in the analytical facilities. • Updated the Mayo scoring system to reflect FDA guideline. • Other administrative changes.
18 February 2020	• Exclusion criteria was revised in consideration of the potential risk of the infection. • Exclusion criteria was revised to clarify the patient who requires full colonoscopy at Screening. • Exclusion criteria were updated to specify the timeframe for current or history of drug or alcohol abuse. • Study design section was updated to clarify use of endoscopy and biopsy for the evaluation of Mayo score and mucosal healing at Week 10. • Updated the number of countries where the patients will be enrolled. • Corticosteroid tapering regimen was revised to allow local clinical practice for tapering regimen of Budesonide. • Update Mayo score diary collection method to reflect FDA guideline and clarify diary collection methods. • Specified the full colonoscopy required criteria, endoscopic subscore evaluation method and assessment window of endoscopy to clarify. • Revised window of biopsy to clarify histologic assessment window. • Revised immunogenicity testing to analysis further NAb assays, in consideration of the Regulatory authority’s suggestions. • Added text to allow retesting once during Screening. • Added statistical method of endoscopic subscore and RHI score for clarification. • Revised analytic facilities to update information of analytical facilities. • Updated schedule of events for clarification. • Other administrative changes.
04 August 2020	• Add text to explain how the number of enrolled patients may vary. • Exclusion criteria was revised in consideration of the potential risk of the infection. • Revised study design and study overview for clarification. • Revised study design for induction and maintenance phase, and study design for extension phase to clarify. • Added withdrawal criteria to clarify the reason for withdrawal. • Binding and unblinding details were updated based on CELLTRION, Inc. internal standard operating procedure (SOP). • Added further PK-PD modelling for possible PK-PD modelling. • Added text for biopsy sampling for histologic assessment collections. • Deleted analytical facilities to simplify analytical facilities section. • Updated schedule of events to clarify the time points of efficacy assessments and dosing window. • Other administrative changes.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported