



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 Crohn's Disease

Summary

EudraCT number	2019-001087-30
Trial protocol	LV CZ SK FR PL DE GR HU ES AT BG HR IT RO
Global end of trial date	22 August 2023

Results information

Result version number	v1 (current)
This version publication date	23 March 2024
First version publication date	23 March 2024

Trial information

Trial identification

Sponsor protocol code	CT-P13_3.8
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03945019
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Celltrion Inc.
Sponsor organisation address	23 Academy-ro, Yeonsu-gu, Incheon, Korea, Republic of, 22014
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	23 November 2022
Global end of trial reached?	Yes
Global end of trial date	22 August 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 and endoscopic response 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	16 July 2019
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: 97
Country: Number of subjects enrolled	Romania: 3
Country: Number of subjects enrolled	Slovakia: 8
Country: Number of subjects enrolled	Spain: 3
Country: Number of subjects enrolled	Croatia: 17
Country: Number of subjects enrolled	Bulgaria: 11
Country: Number of subjects enrolled	Czechia: 13
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Greece: 3
Country: Number of subjects enrolled	Hungary: 12

Country: Number of subjects enrolled	Italy: 18
Country: Number of subjects enrolled	Latvia: 3
Country: Number of subjects enrolled	Belarus: 6
Country: Number of subjects enrolled	India: 6
Country: Number of subjects enrolled	Israel: 20
Country: Number of subjects enrolled	Japan: 6
Country: Number of subjects enrolled	Mexico: 15
Country: Number of subjects enrolled	Moldova, Republic of: 1
Country: Number of subjects enrolled	Peru: 4
Country: Number of subjects enrolled	Russian Federation: 70
Country: Number of subjects enrolled	Serbia: 14
Country: Number of subjects enrolled	South Africa: 7
Country: Number of subjects enrolled	Türkiye: 2
Country: Number of subjects enrolled	Ukraine: 45
Country: Number of subjects enrolled	United States: 6
Worldwide total number of subjects	396
EEA total number of subjects	194

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)	388
From 65 to 84 years	8
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 787 patients from 148 study centers in 26 countries were screened and 396 patients from 114 study centers in 26 countries were enrolled in this study.

Pre-assignment

Screening details:

Male or female aged 18 to 75 years old, inclusive, with moderately to severely active CD who had a CDAI score of 220 to 450 points at screening and had an inadequate response to conventional therapy were considered for enrollment in the study if they met all the inclusion criteria and none of the exclusion criteria.

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
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Arm description:

Patient treated with CT-P13 IV 5 mg/kg at Weeks 0, 2 and 6

Arm type	Experimental
Investigational medicinal product name	CT-P13
Investigational medicinal product code	
Other name	Remsima
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Induction dose of CT-P13 5 mg/kg via IV infusion at Weeks 0, 2 and 6

Number of subjects in period 1	CT-P13 IV 5 mg/kg
Started	396
Completed	343
Not completed	53
Physician decision	1
Consent withdrawn by subject	12
Death	1
Adverse event	11
Progressive disease	2
Non-responder at Week 10	22
Lost to follow-up	2
Protocol deviation	2

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:

Patient treated with CT-P13 SC 120 mg every 2 weeks from Week 10 through 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
Investigational medicinal product code	
Other name	Remsima SC, Zymfentra
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

CT-P13 120 mg SC via pre-filled syringe

Arm title	Placebo
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Arm description:

Patient treated with placebo SC every 2 weeks from Week 10 through 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 for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo SC via pre-filled syringe

Notes:

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

Justification: All patients were randomized after completion of period 1. Patients in Period 2 are considered as baseline as 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	231	112
Completed	192	86
Not completed	39	26
Physician decision	7	5
Consent withdrawn by subject	7	8
Death	1	-
Pregnancy	1	-
Adverse event	8	6
Progressive disease	13	6
Lost to follow-up	1	1
Protocol deviation	1	-

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: All patients were randomized after completion of period 1. Patients in Period 2 are considered as baseline as 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 or auto-injector (AI) 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
Investigational medicinal product code	
Other name	Remsima SC, Zymfentra
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

CT-P13 120 mg SC via pre-filled syringe or auto-injector

Arm title	Placebo
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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 or auto-injector (AI) 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
Investigational medicinal product code	
Other name	Remsima SC, Zymfentra
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

CT-P13 120 mg SC via pre-filled syringe or auto-injector

Number of subjects in period 3	CT-P13 SC 120 mg	Placebo
Started	192	86
Completed	166	75
Not completed	26	11
Physician decision	1	-
Consent withdrawn by subject	10	4
Other	-	1
Adverse event	6	3
Progressive disease	5	2
Lost to follow-up	4	-
Protocol deviation	-	1

Baseline characteristics

Reporting groups

Reporting group title	CT-P13 SC 120 mg
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Reporting group description:

Patient treated with CT-P13 SC 120 mg every 2 weeks from Week 10 through 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
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Reporting group description:

Patient treated with placebo SC every 2 weeks from Week 10 through 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	231	112	343
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)	225	111	336
From 65-84 years	6	1	7
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	36.0	32.3	
standard deviation	± 12.53	± 11.53	-
Gender categorical Units: Subjects			
Female	97	43	140
Male	134	69	203
Race Units: Subjects			
American Indian or Alaska Native	8	5	13
Asian	9	4	13
Black or African American	1	0	1
White	211	101	312
Other	2	2	4

End points

End points reporting groups

Reporting group title	CT-P13 IV 5 mg/kg
Reporting group description: Patient treated with CT-P13 IV 5 mg/kg at Weeks 0, 2 and 6	
Reporting group title	CT-P13 SC 120 mg
Reporting group description: Patient treated with CT-P13 SC 120 mg every 2 weeks from Week 10 through 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: Patient treated with placebo SC every 2 weeks from Week 10 through 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 or auto-injector (AI) 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 or auto-injector (AI) 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: Percentage of Patients Achieving Clinical Remission (Based on CDAI) at Week 54

End point title	Percentage of Patients Achieving Clinical Remission (Based on CDAI) at Week 54
End point description: Clinical remission was defined as an absolute Crohn's Disease Activity Index (CDAI) score of <150 points. The total CDAI scores range from 0 to over 600 with higher scores indicating increased severity of disease. The index is the sum of 8 components; number of liquid or very soft stools, abdominal pain, general well-being, CD complications, taking antidiarrheal drugs, abdominal mass, hematocrit, and weight. 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	231	112		
Units: Number of subjects	144	36		

Statistical analyses

Statistical analysis title	Clinical Remission
Comparison groups	CT-P13 SC 120 mg v Placebo
Number of subjects included in analysis	343
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel

Primary: Percentage of Patients Achieving Endoscopic Response (Based on Central SES-CD) at Week 54

End point title	Percentage of Patients Achieving Endoscopic Response (Based on Central SES-CD) at Week 54
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End point description:

Endoscopic response was defined as a 50% decrease in Simplified Endoscopic Activity Score for Crohn's Disease (SES-CD) score from the baseline value.

The SES-CD assesses the size of mucosal ulcers, ulcerated surface, endoscopic extension and the presence of stenosis. Each item is scored from 0-3, with total score from 0-60. Higher score indicates more severe endoscopic activity.

Patients with dose adjustment to CT-P13 SC 240 mg prior to Week 54 were considered as non-responder.

Statistical testing for this outcome based on the colonoscopy (SES-CD) was conducted using the colonoscopy reading results of central level.

End point type	Primary
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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	231	112		
Units: Number of subjects	118	20		

Statistical analyses

Statistical analysis title	Endoscopic response
Comparison groups	CT-P13 SC 120 mg v Placebo

Number of subjects included in analysis	343
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel

Secondary: Percentage of Patients Achieving CDAI-100 Response at Week 54

End point title	Percentage of Patients Achieving CDAI-100 Response at Week 54
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End point description:

Crohn's Disease Activity Index (CDAI)-100 response was defined as a decrease in CDAI score of 100 points or more from the baseline value.

The total CDAI scores range from 0 to over 600 with higher scores indicating increased severity of disease. The index is the sum of 8 components; number of liquid or very soft stools, abdominal pain, general well-being, CD complications, taking antidiarrheal drugs, abdominal mass, hematocrit, and weight.

Patients with dose adjustment to CT-P13 SC 240 mg prior to Week 54 were considered as non-responder.

End point type	Secondary
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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	231	112		
Units: Number of subjects	152	43		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Patients Achieving Clinical Remission (Based on AP and SF) at Week 54

End point title	Percentage of Patients Achieving Clinical Remission (Based on AP and SF) at Week 54
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End point description:

Clinical remission was defined as an average worst daily Abdominal Pain (AP) score of ≤ 1 (using 4-point scale) and an average daily loose/watery Stool Frequency (SF) score of ≤ 3 (of Type 6 or Type 7 on Bristol Stool Form Scale (BSFS)) with no worsening in either average score compared with the baseline value.

AP score is patient recorded score on a scale 0 to 3 (none, mild, moderate, or severe) and higher score indicates severe abdominal pain. SF score is patient recorded number of loose/watery stool defined as BSFS type 6 or 7 per day. BSFS is an ordinal scale of stool types ranging from the hardest (Type 1) to the softest (Type 7).

Patients with dose adjustment to CT-P13 SC 240 mg prior to Week 54 were considered as non-remitter.

End point type	Secondary
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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	231	112		
Units: Number of subjects	131	35		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Patients Achieving Endoscopic Remission (Based on Central SES-CD) at Week 54

End point title	Percentage of Patients Achieving Endoscopic Remission (Based on Central SES-CD) at Week 54
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End point description:

Endoscopic remission was defined as an absolute Simplified Endoscopic Activity Score for Crohn's Disease (SES-CD) score of ≤ 4 and at least 2-point reduction from the baseline value with no segment sub-score of > 1 .

The SES-CD assesses the size of mucosal ulcers, ulcerated surface, endoscopic extension and the presence of stenosis. Each item is scored from 0-3, with total score from 0-60. Higher score indicates more severe endoscopic activity.

Patients with dose adjustment to CT-P13 SC 240 mg prior to Week 54 were considered as non-remitter.

End point type	Secondary
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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	231	112		
Units: Number of subjects	80	12		

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 5mg/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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

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

Patients who administered CT-P13 SC 120 mg every 2 weeks from Week 10 to Week 54. For patients who received adjusted dose of CT-P13 SC 240mg, data collected before initiation of dose adjustment are included.

Reporting group title	Placebo - Maintenance
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Reporting group description:

Patients who administered Placebo every 2 weeks from Week 10 to Week 54. For patients who received adjusted dose of CT-P13 SC 240mg, data collected before initiation of dose adjustment are included.

Reporting group title	CT-P13 SC 120 mg - Extension
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Reporting group description:

Patients who administered CT-P13 SC 120 mg every 2 weeks from Week 56 to Week 102. Patients who received adjusted dose of CT-P13 SC 240mg are also included.

Reporting group title	Placebo - Extension
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Reporting group description:

Patients who administered Placebo every 2 weeks from Week 10 to Week 54, followed by CT-P13 SC 120 mg every 2 weeks from Week 56 to Week 102. For patients who received adjusted dose of CT-P13 SC 240mg are 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	12 / 396 (3.03%)	15 / 238 (6.30%)	8 / 105 (7.62%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Colon cancer stage III			

subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory pseudotumour			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
General disorders and administration site conditions			
Accidental death			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (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
Pulmonary embolism			
subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (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
Psychiatric disorders			
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
Psychotic disorder			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	2 / 396 (0.51%)	0 / 238 (0.00%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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 disorders			
Cardiovascular insufficiency			
subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (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
Acute coronary syndrome			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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			
Altered state of consciousness			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
Neurovascular conflict			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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

Transient ischaemic attack subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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			
Anemia			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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			
Crohn's disease			
subjects affected / exposed	6 / 396 (1.52%)	3 / 238 (1.26%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (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 perforation			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fistula			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Mesenteric artery embolism			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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

Short-bowel syndrome			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Subileus			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Skin and subcutaneous tissue disorders			
Acne fulminans			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
Renal and urinary disorders			
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc degeneration			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
Infections and infestations			
Abdominal abscess			

subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (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
Abdominal sepsis			
subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (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
Abdominal wall abscess			
subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (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
Abscess intestinal			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
Anal abscess			
subjects affected / exposed	1 / 396 (0.25%)	1 / 238 (0.42%)	0 / 105 (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
Appendicitis			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
Arthritis bacterial			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
Bartholinitis			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
Bronchiolitis			

subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Cytomegalovirus colitis			
subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (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
Gastroenteritis Escherichia coli			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Gastroenteritis viral			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Intestinal tuberculosis			
subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	1 / 396 (0.25%)	0 / 238 (0.00%)	0 / 105 (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
Peritonitis			
subjects affected / exposed	2 / 396 (0.51%)	0 / 238 (0.00%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal disease			

subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Pneumonia			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Rectal abscess			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Septic shock			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Tick-borne viral encephalitis			
subjects affected / exposed	0 / 396 (0.00%)	0 / 238 (0.00%)	0 / 105 (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
Urinary tract infection			
subjects affected / exposed	0 / 396 (0.00%)	1 / 238 (0.42%)	0 / 105 (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

Serious adverse events	CT-P13 SC 120 mg - Extension	Placebo - Extension	
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 238 (6.72%)	4 / 105 (3.81%)	
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) Colon cancer stage III			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammatory pseudotumour			
subjects affected / exposed	0 / 238 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Accidental death			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (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			
Acute respiratory failure			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Humerus fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (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 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiovascular insufficiency			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (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			
Altered state of consciousness			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurovascular conflict			

subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (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			
Anemia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (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	0 / 238 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	1 / 238 (0.42%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	0 / 238 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fistula			
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery embolism			

subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Short-bowel syndrome			
subjects affected / exposed	0 / 238 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (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 acute			
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Acne fulminans			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (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			
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Intervertebral disc degeneration			

subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess intestinal			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (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	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bartholinitis			

subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis		
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (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	1 / 238 (0.42%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cytomegalovirus colitis		
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis Escherichia coli		
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastroenteritis viral		
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal tuberculosis		
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Orchitis		
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (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 / 238 (0.00%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pilonidal disease		
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pyelonephritis acute		
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rectal abscess		
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Septic shock		
subjects affected / exposed	0 / 238 (0.00%)	1 / 105 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Tick-borne viral encephalitis		
subjects affected / exposed	1 / 238 (0.42%)	0 / 105 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Urinary tract infection		
subjects affected / exposed	0 / 238 (0.00%)	0 / 105 (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: 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	35 / 396 (8.84%)	51 / 238 (21.43%)	27 / 105 (25.71%)
Nervous system disorders			
Headache			
subjects affected / exposed	18 / 396 (4.55%)	18 / 238 (7.56%)	5 / 105 (4.76%)
occurrences (all)	23	31	14
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	10 / 396 (2.53%)	11 / 238 (4.62%)	17 / 105 (16.19%)
occurrences (all)	13	12	17
Infections and infestations			
COVID-19			
subjects affected / exposed	10 / 396 (2.53%)	22 / 238 (9.24%)	5 / 105 (4.76%)
occurrences (all)	10	22	5

Non-serious adverse events	CT-P13 SC 120 mg - Extension	Placebo - Extension	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 238 (15.97%)	15 / 105 (14.29%)	
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 238 (1.26%)	3 / 105 (2.86%)	
occurrences (all)	5	7	
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	8 / 238 (3.36%)	4 / 105 (3.81%)	
occurrences (all)	9	4	
Infections and infestations			
COVID-19			
subjects affected / exposed	29 / 238 (12.18%)	10 / 105 (9.52%)	
occurrences (all)	30	10	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 May 2019	<ul style="list-style-type: none">• New sections for New York Heart Association Functional Classification and drug-induced liver injury monitoring added to the protocol• Cardiovascular, tuberculosis, PK, usability, safety assessment details were modified• General and TB exclusion criteria were updated to include detailed exclusion criteria of hepatitis C and TB• Changed some phrases in study design for clarification and specified which teams will be unblinded• Study design, figures and treatment period sections were updated to clarify which patients will go through the dose adjustment and which treatment the patients will receive during the extension phase• Treatment period section was updated to clarify how dose adjusted patients will be analyzed• Study design for induction and maintenance phase and figure were updated to explain when the additional PK sampling visits will occur as well as changed some phrases for clarification• Added a secondary endpoint to aid in establishing remission thresholds for AP and loose SF and other secondary endpoints were edited to clarify the definition of sustained clinical remission• Added a statement to include detailed role of DSMB in safety monitoring• Changed statistical analysis method per regulatory agency's recommendation as well as added a statement in efficacy analysis section to clarify how dose adjusted patients will be analyzed• Added a statement to clarify which colonoscopy reading results will be used for a statistical testing as well as a statement to clarify how dose adjusted patients will be analyzed• Patient withdrawal and discontinuation details were revised• Training for self-Injection was modified to correspond with the current regulatory guidelines• Added a hypersensitivity monitoring point for patients who will self-inject the study drug• Physical examination details and definitions of AESIs were modified to correspond with the current regulatory guidelines
26 July 2019	<ul style="list-style-type: none">• Section added for guidelines for individual patient withdrawal criteria• Added an appendix to specify objective individual stopping criteria based on the known safety profile and mechanism of action of the drug• Added statement in study overview and treatments administered sections and schedule of events table to clarify that the Week 56 visit will be only reserved for the patients who will self-inject CT-P13 SC via AI• Repetitive text removed from protocol section withdrawal of patients from the study• Withdrawal of patients from the study section was updated to remove repetitive text and to clarify detailed role of DSMB for safety monitoring• Contacts details of analytical facilities were updated• Text was revised to include detailed overall study stopping criteria and its associated roles of DSMB

29 October 2019	<ul style="list-style-type: none"> • Increased the number of centers for study conduct • Clinical studies updated with the most current data in the introduction section • Previous exposure to biologic agent and/or JAK inhibitors added as stratification for randomization and as an exclusion criterion • Week 56 visit was only reserved for the patients who self-inject CT-P13 SC via AI • Changed to shorter period since no significant effect on the efficacy results; this also facilitates patient enrollment for oral budesonide • New section and appendix added to clarify premature discontinuation of patients and to include guidelines for individual patient withdrawal criteria • Added a statement to include detailed roles of DSMB • Clarification added for dose adjustment • Clarification added that blood samples for PK and immunogenicity analysis are to be collected before study drug administration • Clarification added on tapering of corticosteroids and oral budesonide • Assessment schedule for Ctrough changed from Week 52 to Week 100 • Clarification added for PK sample collation for dose adjustment • Additional usability endpoint and assessment as "device integrity" for PFS and AI added • Additional hypersensitivity assessment timeframe added • Added definition and assessment details for ADE and serious ADE • Added additional Medical Affairs/Pharmacovigilance content details for SAE reporting • Added additional requirement to report the SAEs associated with device to the regulatory authorities • Reduced the timeframe from 1 hour to 15 minutes to collate the patient's assessment of local site pain after the end of administration of study drug • Updated the schedule of events tables for induction, maintenance, and extension phases in accordance with the corresponding updates within the protocol
27 April 2020	<ul style="list-style-type: none"> • Sample size and key secondary effect size were modified based on adjusted statistical power considering sponsor's risk assessment. Additionally, non-responder rate was modified referring to current Crohn's disease studies of CT-P13
03 August 2020	<ul style="list-style-type: none"> • Deleted the table with analytical facility details since its information was duplicated in the ICF • Explanation added on how the number of enrolled patients could vary • General exclusion criteria updated in consideration of the risk assessment of each infection • General exclusion criteria for drug or alcohol abuse updated in consideration of the risk assessment • Clinical studies updated with the most current data in the introduction section • Clarification added for the reason for patient withdrawal • Clarification added for prohibited therapies • Clarification added on how laboratory results are to be collected • Text added to allow the usage of external colonoscopy video at screening • Text added to allow retest of clinical laboratory assessments at screening • Text added to clarify the purpose of additional blood sampling for PK PD modeling • Text added to clarify how immunoassay is to be conducted • As the feasibility of FC sampling and handling at all sites was confirmed some text for sampling and handling of FC at qualified or feasible sites removed • Study blinding section updated based on the internal sponsor standard operating procedure • Updated the schedule of events tables for induction, maintenance, and extension phases in accordance with the corresponding updates within the protocol

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported