Clinical trial results:
A Double-blind, Randomized, Active-controlled, Parallel Group, Phase 3 Study to Compare Efficacy and Safety of CT-P39 and Xolair in Patients With Chronic Spontaneous Urticaria Who Remain Symptomatic despite H1-antihistamine Treatment

Summary

EudraCT number	2020-000952-36
Trial protocol	HU PL BG GR
Global end of trial date	11 September 2023

Results information

Result version number	v1 (current)
This version publication date	30 October 2024
First version publication date	30 October 2024

Trial information

Trial identification

Sponsor protocol code	CT-P39_3.1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04426890
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	Keum Young Ahn, Celltrion Inc., 82 328504190, KeumYoung.Ahn@celltrion.com
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Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	11 September 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 September 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the equivalence of CT P39 to Xolair at a dose of 300 mg in terms of efficacy in patients with chronic spontaneous urticaria (CSU) as determined by change from baseline in weekly itch severity score (ISS7) at Week 12

Protection of trial subjects:

The study was conducted according to the protocol and in compliance with the International Council for Harmonisation (ICH) E6(R2) with the Declaration of Helsinki (World Medical Association, 2013). The Investigator conducted all aspects of this study in accordance with all national, state, and local laws or regulations.
An informed consent document approved by each study site’s IEC/IRB was signed by the patient/legal guardian after the Investigator assured that the patient/legal guardian understands the implications of participating in the study. The authorized person obtained the informed consent before the patient entered in the study.
Patients aged 12 to 17 years (both inclusive) provided their consent on adolescent assent form and the consent was also taken by their parent/legal guardian. Patients aged ≥ 18 years provided their consent on adult ICF.

Background therapy:

All patients continued to concomitantly receive an approved dose of nonsedating H1-antihistamine treatment throughout the study.

Evidence for comparator: -

Actual start date of recruitment	13 November 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: 262
Country: Number of subjects enrolled	Bulgaria: 125
Country: Number of subjects enrolled	Greece: 6
Country: Number of subjects enrolled	Hungary: 6
Country: Number of subjects enrolled	Korea, Republic of: 119
Country: Number of subjects enrolled	Ukraine: 101
Worldwide total number of subjects	619
EEA total number of subjects	399

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)	12
Adults (18-64 years)	569
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

First patient assigned to treatment date was on 09 December 2020.
A total of 783 patients were screened from 64 study centers in 6 countries (Bulgaria, Greece, Hungary, Poland, South Korea, and Ukraine) and 634 patients were enrolled from 62 study centers in this study.

Pre-assignment

Screening details:

Male or female patients with a history of at least 6 months of CSU who had hives and itching for 6 consecutive weeks or more despite current use of H1-antihistamines for this time period were enrolled in the study if they had met all of the inclusion criteria and none of the exclusion criteria.

Pre-assignment period milestones

Number of subjects started	783[1]
Number of subjects completed	619

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Inclusion/Exclusion criteria not met: 83
Reason: Number of subjects	Consent withdrawn by subject: 42
Reason: Number of subjects	Other: 24
Reason: Number of subjects	GCP noncompliant site: 15

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: A total of 783 patients were screened and 634 were enrolled, of which 15 patients were excluded from all analyses due to the site being non-GCP compliant

Period 1

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

Blinding implementation details:

To minimize the risk of unblinding, the study drug was administered by pre-defined unblinded site personnel. The unblinded sponsor and CRO personnel responsible for the randomization or administration of study drugs were pre-defined and were not permitted to conduct any patient assessments. Also, to maintain the study blind with respect to the 2-dose levels (300 mg versus 150 mg), patients who received one (150 mg) injection of study drug, also received additional placebo.

Arms

Are arms mutually exclusive?	Yes
Arm title	CT-P39 300 mg

Arm description:

CT-P39 300 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)

Arm type	Experimental
Investigational medicinal product name	CT-P39
Investigational medicinal product code	
Other name	omalizumab, Omlyclo
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details: 300 mg injected subcutaneously every 4 weeks	

Arm title	Xolair 300 mg
Arm description: Xolair 300 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Arm type	Active comparator
Investigational medicinal product name	Xolair
Investigational medicinal product code	
Other name	omalizumab
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details: 300 mg injected subcutaneously every 4 weeks	
Arm title	CT-P39 150 mg
Arm description: CT-P39 150 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Arm type	Experimental
Investigational medicinal product name	CT-P39
Investigational medicinal product code	
Other name	omalizumab, Omlyclo
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details: 150 mg injected subcutaneously every 4 weeks	
Arm title	Xolair 150 mg
Arm description: Xolair 150 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Arm type	Active comparator
Investigational medicinal product name	Xolair
Investigational medicinal product code	
Other name	omalizumab
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details: 150 mg injected subcutaneously every 4 weeks	

Number of subjects in period 1	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg
Started	204	205	107
Completed	187	193	101
Not completed	17	12	6
Patient refusal	1	1	1
Consent withdrawn by subject	7	6	4
Disease progression	1	1	-

Adverse event, non-fatal	3	1	-
Other	4	-	-
Randomized by mistake	1	-	-
Lost to follow-up	-	-	1
Protocol deviation	-	3	-

Number of subjects in period 1	Xolair 150 mg
Started	103
Completed	98
Not completed	5
Patient refusal	-
Consent withdrawn by subject	5
Disease progression	-
Adverse event, non-fatal	-
Other	-
Randomized by mistake	-
Lost to follow-up	-
Protocol deviation	-

Period 2

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

Blinding implementation details:

To minimize the risk of unblinding, the study drug was administered by pre-defined unblinded site personnel. The unblinded sponsor and CRO personnel responsible for the randomization or administration of study drugs were pre-defined and were not permitted to conduct any patient assessments.

Arms

Are arms mutually exclusive?	Yes
Arm title	CT-P39 300 mg maintenance

Arm description:

Received CT-P39 300 mg in TP1 and continued on CT-P39 300 mg in TP2 (Week 12, 16, 20)

Arm type	Experimental
Investigational medicinal product name	CT-P39
Investigational medicinal product code	
Other name	omalizumab, Omlyclo
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg injected subcutaneously every 4 weeks

Arm title	Switched to CT-P39 300 mg

Arm description:

Received Xolair 300 mg in TP1 and re-randomized to receive CT-P39 300 mg in TP2 (Week 12, 16, 20)

Arm type	Experimental
Investigational medicinal product name	CT-P39
Investigational medicinal product code	
Other name	omalizumab, Omlyclo
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg injected subcutaneously every 4 weeks

Arm title	Xolair 300 mg maintenance

Arm description:

Received Xolair 300 mg in TP1 and re-randomized to continue on Xolair 300 mg in TP2 (Week 12, 16, 20)

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

Dosage and administration details:

300 mg injected subcutaneously every 4 weeks

Arm title	CT-P39 Dose increased

Arm description:

Received CT-P39 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; CT-P39 300 mg in TP2 (Week 12, 16, 20)

Arm type	Experimental
Investigational medicinal product name	CT-P39
Investigational medicinal product code	
Other name	omalizumab, Omlyclo
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg injected subcutaneously every 4 weeks

Arm title	Xolair Dose increased

Arm description:

Received Xolair 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; Xolair 300 mg in TP2 (Week 12, 16, 20)

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

Dosage and administration details:

300 mg injected subcutaneously every 4 weeks

Number of subjects in period 2	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance
Started	187	96	97
Completed	181	94	94
Not completed	6	2	3
Consent withdrawn by subject	3	1	-
Physician decision	-	-	1
Disease progression	1	-	-
Adverse event, non-fatal	1	-	-
Other	1	1	-
Randomized by mistake	-	-	1
Lost to follow-up	-	-	1

Number of subjects in period 2	CT-P39 Dose increased	Xolair Dose increased
Started	101	98
Completed	99	94
Not completed	2	4
Consent withdrawn by subject	-	2
Physician decision	1	-
Disease progression	-	-
Adverse event, non-fatal	-	-
Other	-	1
Randomized by mistake	-	-
Lost to follow-up	1	1

Period 3	
Period 3 title	Follow up period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor
Blinding implementation details:	
No treatment was administered during the Follow up Period	

Arms	
Are arms mutually exclusive?	Yes

Arm title	Follow up Period: CT-P39 300 mg Maintenance
Arm description:	
Patients who were in the CT-P39 300 mg arm in TP1 and continued on CT-P39 300 mg during TP2 (Weeks 12, 16, 20) and entered the Follow up Period.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Arm title	Follow up Period: Switched to CT-P39 300 mg
Arm description:	
Received Xolair 300 mg in TP1 and re-randomized to CT-P39 300 mg in TP2 (Weeks 12, 16, 20) and entered the Follow up Period	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Arm title	Follow up Period: Xolair 300 mg maintenance
Arm description:	
Received Xolair 300 mg in TP1 and re-randomized to continue on Xolair 300 mg in TP2 (Weeks 12, 16, 20) and entered the Follow up Period	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Arm title	Follow up Period: CT-P39 Dose increased
Arm description:	
Received CT-P39 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; CT-P39 300 mg in TP2 (Week 12, 16, 20) and entered the Follow up Period	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Arm title	Follow up Period: Xolair Dose increased
Arm description:	
Received Xolair 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; Xolair 300 mg in TP2 (Week 12, 16, 20) and entered the Follow up Period	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 3[2]	Follow up Period: CT-P39 300 mg Maintenance	Follow up Period: Switched to CT-P39 300 mg	Follow up Period: Xolair 300 mg maintenance
Started	180	90	92
Completed	170	84	86
Not completed	10	6	6
Consent withdrawn by subject	4	-	4
Physician decision	2	1	1
Other	4	5	-
Lost to follow-up	-	-	1

Number of subjects in period 3[2]	Follow up Period: CT-P39 Dose increased	Follow up Period: Xolair Dose increased
Started	97	90
Completed	90	83
Not completed	7	7

Consent withdrawn by subject	2	4
Physician decision	-	-
Other	4	3
Lost to follow-up	1	-

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Some patients were withdrawn from treatment but continued with the study assessments (they were withdrawn from treatment but not terminated from the study)

Baseline characteristics

Reporting groups	
Reporting group title	CT-P39 300 mg
Reporting group description:	
CT-P39 300 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Reporting group title	Xolair 300 mg
Reporting group description:	
Xolair 300 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Reporting group title	CT-P39 150 mg
Reporting group description:	
CT-P39 150 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Reporting group title	Xolair 150 mg
Reporting group description:	
Xolair 150 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	

Reporting group values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg
Number of subjects	204	205	107
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	43.2	42.9	42.9
standard deviation	± 13.3	± 13.7	± 15.0
Gender categorical Units: Subjects			
Female	133	131	67
Male	71	74	40
Baseline ISS7 Units: Subjects			
< 13 points	36	42	20
>= 13 points	168	163	87
Weight on Day 1 Units: Subjects			
< 80 kg	123	125	65
>= 80 kg	81	80	42
Country Units: Subjects			

Bulgaria	40	42	23
Greece	3	1	1
Hungary	1	2	2
Korea	38	40	21
Poland	87	87	43
Ukraine	35	33	17

Reporting group values	Xolair 150 mg	Total	
Number of subjects	103	619	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	41.5		
standard deviation	± 13.8	-	
Gender categorical Units: Subjects			
Female	72	403	
Male	31	216	
Baseline ISS7 Units: Subjects			
< 13 points	17	115	
>= 13 points	86	504	
Weight on Day 1 Units: Subjects			
< 80 kg	65	378	
>= 80 kg	38	241	
Country Units: Subjects			
Bulgaria	20	125	
Greece	1	6	
Hungary	1	6	
Korea	20	119	
Poland	45	262	
Ukraine	16	101	

End points

End points reporting groups

Reporting group title	CT-P39 300 mg
Reporting group description:	
CT-P39 300 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Reporting group title	Xolair 300 mg
Reporting group description:	
Xolair 300 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Reporting group title	CT-P39 150 mg
Reporting group description:	
CT-P39 150 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Reporting group title	Xolair 150 mg
Reporting group description:	
Xolair 150 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)	
Reporting group title	CT-P39 300 mg maintenance
Reporting group description:	
Received CT-P39 300 mg in TP1 and continued on CT-P39 300 mg in TP2 (Week 12, 16, 20)	
Reporting group title	Switched to CT-P39 300 mg
Reporting group description:	
Received Xolair 300 mg in TP1 and re-randomized to receive CT-P39 300 mg in TP2 (Week 12, 16, 20)	
Reporting group title	Xolair 300 mg maintenance
Reporting group description:	
Received Xolair 300 mg in TP1 and re-randomized to continue on Xolair 300 mg in TP2 (Week 12, 16, 20)	
Reporting group title	CT-P39 Dose increased
Reporting group description:	
Received CT-P39 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; CT-P39 300 mg in TP2 (Week 12, 16, 20)	
Reporting group title	Xolair Dose increased
Reporting group description:	
Received Xolair 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; Xolair 300 mg in TP2 (Week 12, 16, 20)	
Reporting group title	Follow up Period: CT-P39 300 mg Maintenance
Reporting group description:	
Patients who were in the CT-P39 300 mg arm in TP1 and continued on CT-P39 300 mg during TP2 (Weeks 12, 16, 20) and entered the Follow up Period.	
Reporting group title	Follow up Period: Switched to CT-P39 300 mg
Reporting group description:	
Received Xolair 300 mg in TP1 and re-randomized to CT-P39 300 mg in TP2 (Weeks 12, 16, 20) and entered the Follow up Period	
Reporting group title	Follow up Period: Xolair 300 mg maintenance
Reporting group description:	
Received Xolair 300 mg in TP1 and re-randomized to continue on Xolair 300 mg in TP2 (Weeks 12, 16, 20) and entered the Follow up Period	
Reporting group title	Follow up Period: CT-P39 Dose increased
Reporting group description:	
Received CT-P39 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; CT-P39 300 mg in TP2 (Week 12, 16, 20) and entered the Follow up Period	
Reporting group title	Follow up Period: Xolair Dose increased
Reporting group description:	
Received Xolair 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; Xolair 300 mg in TP2 (Week 12, 16, 20) and entered the Follow up Period	

Primary: Change from Baseline in Weekly Itch Severity Score (ISS7) at Week 12

End point title	Change from Baseline in Weekly Itch Severity Score (ISS7) at Week 12[1]

End point description:

The primary efficacy evaluations is to compare mean change from baseline in ISS7 of 300 mg of CT-P39 and 300 mg of Xolair at Week 12, calculated as ISS7 at Week 12 minus the baseline ISS7. The statistical analysis of mean change from baseline in ISS7 at Week 12 between CT-P39 300 mg arm and Xolair 300 mg arm using analysis of covariate (ANCOVA) was conducted. The ANCOVA model included the treatment group as a fixed effect and baseline ISS7, body weight on Day 1 and country as covariates.

End point type	Primary

End point timeframe:

Week 12

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only the CT-P39 300 mg and Xolair 300 mg arms in Treatment Period 1 were included in the primary efficacy endpoint.

End point values	CT-P39 300 mg	Xolair 300 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	186	192		
Units: score				
least squares mean (standard error)	-9.21 (± 0.796)	-9.98 (± 0.798)		

Statistical analyses

Statistical analysis title	Primary efficacy: Estimate of treatment difference

Statistical analysis description:

The primary efficacy evaluation was comparison of mean change from baseline in ISS7 of 300 mg of CT-P39 (Arm 1) and 300 mg of Xolair (Arm 2) at Week 12, calculated as ISS7 at Week 12 minus the baseline ISS7. The analysis was conducted by analysis of covariance (ANCOVA). The ANCOVA model included the treatment group as a fixed effect and baseline ISS7, body weight on Day 1 and country as covariates.

Comparison groups	CT-P39 300 mg v Xolair 300 mg
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	equivalence[2]
Method	ANCOVA
Parameter estimate	Treatment difference
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	1.9

Notes:

[2] - For the demonstration of efficacy, point estimate and 95% CI for the difference in the mean change from baseline in ISS7 at Week 12 between CT-P39 (300 mg) and Xolair (300 mg) will be computed. Therapeutic equivalence will be concluded if the 95% CI for the treatment difference is

entirely within an equivalence margin of [-2.0, 2.0]

Secondary: Relative Potency of CT-P39 compared with Xolair

End point title	Relative Potency of CT-P39 compared with Xolair

End point description:

The relative potency of CT-P39 to Xolair was defined as the ratio of equally effective dose of CT-P39 relative to that of Xolair. The therapeutic response was estimated by the change from baseline in ISS7 at Week 12. Since the 2 treatments were compared at the same 2-dose levels (300 mg and 150 mg), a 4-point assay was to be used to calculate the relative potency and its CI.
Log dose-therapeutic response curves for each treatment group was to be estimated by linear regression. The change from baseline in ISS7 at Week 12 and dose in the log scale were to be considered as a response variable and independent variable respectively. The baseline ISS7, body weight and country were to be included in a model as covariates. The log relative potency was estimated as the ratio between the estimate of the overall product effect and the estimate of the common slope of log dose. The overall product effect was defined as the difference in response between treatment groups (y-intercepts difference).

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203[3]	205[4]	107[5]	103[6]
Units: Ratio				
number (not applicable)	0	0	0	0

Notes:

[3] - Relative potency was not calculated due to assumption of parallel-line assay not being met.

[4] - Relative potency was not calculated due to assumption of parallel-line assay not being met.

[5] - Relative potency was not calculated due to assumption of parallel-line assay not being met.

[6] - Relative potency was not calculated due to assumption of parallel-line assay not being met.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Weekly Itch Severity Score (ISS7) at Week 12

End point title	Change from Baseline in Weekly Itch Severity Score (ISS7) at Week 12

End point description:

The change from baseline in ISS7 at Week 12 was calculated as ISS7 at Week 12 minus the baseline ISS7. ISS7 can range from 0 to 21.

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	186	192	101	94
Units: Score				
arithmetic mean (standard deviation)	-9.31 (± 6.20)	-9.99 (± 6.18)	-9.56 (± 5.87)	-8.73 (± 6.65)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Weekly Itch Severity Score (ISS7) at Week 24

End point title	Change from Baseline in Weekly Itch Severity Score (ISS7) at Week 24

End point description:

The change from baseline in ISS7 at Week 24 was calculated as ISS7 at Week 24 minus the baseline ISS7. ISS7 can range from 0 to 21.

End point type	Secondary

End point timeframe:

Week 24

End point values	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance	CT-P39 Dose increased
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	88	82	90
Units: Score				
arithmetic mean (standard deviation)	-11.22 (± 6.21)	-12.24 (± 5.69)	-11.19 (± 5.88)	-11.76 (± 5.61)

End point values	Xolair Dose increased			
Subject group type	Reporting group			
Number of subjects analysed	86			
Units: Score				
arithmetic mean (standard deviation)	-10.70 (± 6.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Minimally Important Difference (MID) Responders in ISS7 at Week 12

End point title	Percentage of Minimally Important Difference (MID)

	Responders in ISS7 at Week 12

End point description:

Number of patients who achieved MID response at Week 12 were presented. MID response is a change from baseline in ISS7 of ≤ -5. If a patient had missing weekly scores for the given week the patient was classified as a non-responder.

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203[7]	205[8]	107[9]	103[10]
Units: Responder	141	152	78	65

Notes:

[7] - Percent MID responders = 69.5%

[8] - Percent MID responders = 74.1%

[9] - Percent MID responders = 72.9%

[10] - Percent MID responders = 63.1%

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Minimally Important Difference (MID) Responders in ISS7 at Week 24

End point title	Percentage of Minimally Important Difference (MID) Responders in ISS7 at Week 24

End point description:

Patients who achieved MID response at Week 24 were presented. MID response is a change from baseline in ISS7 of ≤ -5. If a patient had missing weekly scores for the given week the patient was classified as a non-responder.

End point type	Secondary

End point timeframe:

Week 24

End point values	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance	CT-P39 Dose increased
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	187[11]	96[12]	96[13]	101[14]
Units: Patients	146	78	71	76

Notes:

[11] - Percent MID responders = 78.1%

[12] - Percent MID responders = 81.3%

[13] - Percent MID responders = 74.0%

[14] - Percent MID responders = 75.2%

End point values	Xolair Dose increased			

Subject group type	Reporting group			
Number of subjects analysed	98[15]			
Units: Patients	72			

Notes:

[15] - Percent MID responders = 73.5%

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Weekly Urticaria Activity Score (UAS7) at Week 12

End point title	Change from Baseline in Weekly Urticaria Activity Score (UAS7) at Week 12

End point description:

The change from baseline in UAS7 at Week 12 was calculated as UAS7 at Week 12 minus the baseline UAS7. UAS7 can range from 0 to 42.

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	186	192	101	94
Units: Score				
arithmetic mean (standard deviation)	-19.27 (± 12.53)	-20.54 (± 12.69)	-19.84 (± 12.02)	-18.21 (± 13.06)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Weekly Urticaria Activity Score (UAS7) at Week 24

End point title	Change from Baseline in Weekly Urticaria Activity Score (UAS7) at Week 24

End point description:

The change from baseline in UAS7 at Week 24 was calculated as UAS7 at Week 24 minus the baseline UAS7. UAS7 can range from 0 to 42.

End point type	Secondary

End point timeframe:

Week 24

End point values	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance	CT-P39 Dose increased
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	88	82	90
Units: Score				
arithmetic mean (standard deviation)	-23.08 (± 12.30)	-24.96 (± 11.79)	-23.55 (± 12.08)	-24.50 (± 11.13)

End point values	Xolair Dose increased			
Subject group type	Reporting group			
Number of subjects analysed	86			
Units: Score				
arithmetic mean (standard deviation)	-22.48 (± 11.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Patients with UAS7 of ≤ 6 points and complete responders at Week 12

End point title	Percentage of Patients with UAS7 of ≤ 6 points and complete responders at Week 12

End point description:

Percentage of patients with Weekly Urticaria Activity Score (UAS7) of ≤ 6 points and complete responders (UAS7 = 0) at Week 12 is presented. If a patient had missing weekly scores for the given week the patient was classified as a non-responder.

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203[16]	205[17]	107[18]	103[19]
Units: Patients				
Patients with UAS7 ≤ 6	77	83	41	33
Patients with UAS7 = 0 (complete responder)	48	63	23	14

Notes:

[16] - Patients with UAS7 ≤ 6 was 37.9%
Patients with UAS7 = 0 was 23.6%
[17] - Patients with UAS7 ≤ 6 was 40.5%
Patients with UAS7 = 0 was 30.7%
[18] - Patients with UAS7 ≤ 6 was 38.3%
Patients with UAS7 = 0 was 21.5%
[19] - Patients with UAS7 ≤ 6 was 32.0%

Patients with UAS7 = 0 was 13.6%

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Patients with UAS7 of ≤ 6 points and complete responders at Week 24

End point title	Percentage of Patients with UAS7 of ≤ 6 points and complete responders at Week 24

End point description:

The number of patients with Weekly Urticaria Activity Score (UAS7) of ≤ 6 points and complete responders (UAS7 = 0) at Week 24 is presented. If a patient had missing weekly scores for the given week the patient was classified as a non-responder.

End point type	Secondary

End point timeframe:

Week 24

End point values	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance	CT-P39 Dose increased
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	187[20]	96[21]	96[22]	101[23]
Units: Patients				
Patients with UAS7 ≤ 6	102	65	46	55
Patients with UAS7 = 0 (complete responder)	75	49	36	39

Notes:

[20] - Patients with UAS7 ≤ 6 was 54.5%
Patients with UAS7 = 0 was 40.1%

[21] - Patients with UAS7 ≤ 6 was 67.7%
Patients with UAS7 = 0 was 51.0%

[22] - Patients with UAS7 ≤ 6 was 47.9%
Patients with UAS7 = 0 was 37.5%

[23] - Patients with UAS7 ≤ 6 was 54.5%
Patients with UAS7 = 0 was 38.6%

End point values	Xolair Dose increased			
Subject group type	Reporting group			
Number of subjects analysed	98[24]			
Units: Patients				
Patients with UAS7 ≤ 6	41			
Patients with UAS7 = 0 (complete responder)	31			

Notes:

[24] - Patients with UAS7 ≤ 6 was 41.8%
Patients with UAS7 = 0 was 31.6%

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Minimally Important Difference (MID) Responders in ISS7 by Week 12

End point title	Number of Minimally Important Difference (MID) Responders in ISS7 by Week 12

End point description:

Minimally important differece (MID) in ISS7 is a reduction of ≥ 5 points from baseline. The number of responders achieving MID response by Week 12 are presented.

End point type	Secondary

End point timeframe:

Up to Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203[25]	205[26]	107[27]	103[28]
Units: Responders	173	173	88	87

Notes:

[25] - Percent of MID responders = 85.2%

[26] - Percent of MID responders = 84.4%

[27] - Percent of MID responders = 82.2%

[28] - Percent of MID responders = 84.5%

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Minimally Important Difference (MID) in ISS7 by Week 12

End point title	Time to Minimally Important Difference (MID) in ISS7 by Week 12

End point description:

Time to MID response was the time (in weeks) from Day 1 to the study week when reduction of 5 points or more from baseline for ISS7 was first achieved up to Week 12. If a patient failed to achieve an MID response up to Week 12 or terminated the study prior to Week 12 without achieving MID response, the patient was censored at the date (in weeks) of the last non-missing ISS7 evaluation. Time to MID was estimated by Kaplan-Meier method.

End point type	Secondary

End point timeframe:

Up to Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	203	205	107	103
Units: Weeks				
median (confidence interval 95%)	2.00 (2.00 to 3.00)	2.00 (2.00 to 3.00)	2.00 (2.00 to 3.00)	2.00 (2.00 to 3.00)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Weekly Hives Severity Score (HSS7) at Week 12

End point title	Change from Baseline in Weekly Hives Severity Score (HSS7) at Week 12

End point description:

The change from baseline in HSS7 at Week 12 was calculated as HSS7 at Week 12 minus the baseline HSS7. HSS7 can range from 0 to 21.

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	186	192	101	94
Units: Score				
arithmetic mean (standard deviation)	-9.96 (± 6.88)	-10.55 (± 6.93)	-10.29 (± 6.75)	-9.48 (± 6.93)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Weekly Hives Severity Score (HSS7) at Week 24

End point title	Change from Baseline in Weekly Hives Severity Score (HSS7) at Week 24

End point description:

The change from baseline in HSS7 at Week 24 was calculated as HSS7 at Week 24 minus the baseline HSS7. HSS7 can range from 0 to 21.

End point type	Secondary

End point timeframe:

Week 24

End point values	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance	CT-P39 Dose increased
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	88	82	90
Units: Score				
arithmetic mean (standard deviation)	-11.86 (± 6.72)	-12.72 (± 6.72)	-12.36 (± 6.64)	-12.74 (± 6.01)

End point values	Xolair Dose increased			
Subject group type	Reporting group			
Number of subjects analysed	86			
Units: Score				
arithmetic mean (standard deviation)	-11.77 (± 6.20)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Angioedema-Free Days from Week 4 to Week 12

End point title	Percentage of Angioedema-Free Days from Week 4 to Week 12

End point description:

The proportion of angioedema-free days from Week 4 to Week 12 is defined as the number of days for which the patient indicated a 'No' response to the angioedema question in the patient eDiary divided by the total number of days with a non-missing diary entry starting on Week 4 visit date and ending the day prior to Week 12 visit date. Patients who had missing responses for > 40% of the daily diary entries between Week 4 visit date and Week 12 visit date were not included in this analysis.

End point type	Secondary

End point timeframe:

From Week 4 to Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	189	190	99	97
Units: percent				
arithmetic mean (standard deviation)	93.47 (± 17.95)	90.14 (± 25.64)	96.94 (± 10.83)	93.77 (± 18.01)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Number of Tablets/Week of Rescue Therapy at

Week 12

End point title	Change from Baseline in Number of Tablets/Week of Rescue Therapy at Week 12

End point description:

The change in the number of tablets/week of rescue therapy used from baseline at Week 12 is presented.
The number of tablets for each week of rescue therapy will be defined as the sum of daily use of rescue therapy over the study days which make up a given study week. If a subject switched rescue therapy medication and started a different medication or the prescribed dose of the rescue therapy medication changed during the study, the subject was excluded from the summary.

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	180	92	85
Units: tablets/week				
arithmetic mean (standard deviation)	-1.33 (± 3.73)	-1.45 (± 3.16)	-1.19 (± 2.71)	-1.53 (± 3.42)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Number of Tablets/Week of Rescue Therapy at Week 24

End point title	Change from Baseline in Number of Tablets/Week of Rescue Therapy at Week 24

End point description:

The change in the number of tablets/week of rescue therapy used from baseline at Week 24 is presented.
The number of tablets for each week of rescue therapy will be defined as the sum of daily use of rescue therapy over the study days which make up a given study week. If a subject switched rescue therapy medication and started a different medication or the prescribed dose of the rescue therapy medication changed during the study, the subject was excluded from the summary.

End point type	Secondary

End point timeframe:

Week 24

End point values	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance	CT-P39 Dose increased
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	154	78	79	81
Units: tablets/week				
arithmetic mean (standard deviation)	-1.40 (± 3.79)	-1.75 (± 3.67)	-1.74 (± 2.98)	-1.50 (± 3.36)

End point values	Xolair Dose increased			
Subject group type	Reporting group			
Number of subjects analysed	78			
Units: tablets/week				
arithmetic mean (standard deviation)	-1.77 (± 3.33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Serum Concentration of Omalizumab at Week 12

End point title	Trough Serum Concentration of Omalizumab at Week 12

End point description:

The mean serum concentration of omalizumab for samples taken at Week 12, prior to the study drug administration, was summarized. All concentration below lower limit of quantification (BLQ) values were treated as zero (0) for PK parameter summary.

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	187	193	101	97
Units: microgram/mL				
arithmetic mean (standard deviation)	31.50791 (± 12.11966)	31.35679 (± 13.44334)	14.67465 (± 6.31588)	15.80010 (± 7.65671)

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Serum Concentration of Omalizumab at Week 24

End point title	Trough Serum Concentration of Omalizumab at Week 24

End point description:

The mean serum concentration of omalizumab for samples taken at Week 24 End of Treatment Visit was summarized. All concentration below lower limit of quantification (BLQ) values were treated as zero (0) for PK parameter summary.

End point type	Secondary

End point timeframe:

Week 24

End point values	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance	CT-P39 Dose increased
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	177	92	94	97
Units: microgram/mL				
arithmetic mean (standard deviation)	35.43099 (± 14.98897)	35.87102 (± 18.09287)	33.50606 (± 14.25536)	30.41523 (± 13.16691)

End point values	Xolair Dose increased			
Subject group type	Reporting group			
Number of subjects analysed	92			
Units: microgram/mL				
arithmetic mean (standard deviation)	33.63630 (± 16.55088)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Overall Dermatology Life Quality Index (DLQI) Score at Week 12

End point title	Change from Baseline in the Overall Dermatology Life Quality Index (DLQI) Score at Week 12

End point description:

The change from baseline in mean overall DLQI score at Week 12 is presented.
The DLQI is a 10-item dermatology-specific health-related questionnaire across 6 domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Patients rated their dermatology symptoms as well as the impact of their skin condition on various aspect of their lives. Each question is scored from 0 to 3. Overall DLQI ranges on a scale of 0 to 30.

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	169	179	98	91
Units: Score				
arithmetic mean (standard deviation)	-8.9 (± 7.5)	-9.0 (± 6.7)	-9.2 (± 7.0)	-8.9 (± 8.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Overall Dermatology Life Quality Index (DLQI) Score at Week 24

End point title	Change from Baseline in the Overall Dermatology Life Quality Index (DLQI) Score at Week 24

End point description:

The change from baseline in mean overall DLQI score at Week 24 is presented.
The DLQI is a 10-item dermatology-specific health-related questionnaire across 6 domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Patients rated their dermatology symptoms as well as the impact of their skin condition on various aspect of their lives. Each question is scored from 0 to 3. Overall DLQI ranges on a scale of 0 to 30.

End point type	Secondary

End point timeframe:

Week 24

End point values	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance	CT-P39 Dose increased
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	161	87	87	93
Units: Score				
arithmetic mean (standard deviation)	-9.4 (± 6.9)	-10.4 (± 7.3)	-9.8 (± 6.9)	-10.5 (± 7.7)

End point values	Xolair Dose increased			
Subject group type	Reporting group			
Number of subjects analysed	89			
Units: Score				
arithmetic mean (standard deviation)	-10.1 (± 7.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Overall Chronic Urticaria Quality of Life Questionnaire Score (CU-Q2oL) Score at Week 12

End point title	Change from Baseline in the Overall Chronic Urticaria Quality of Life Questionnaire Score (CU-Q2oL) Score at Week 12

End point description:

The change from baseline in mean overall CU-Q2oL score at Week 12 is presented.
The CU-Q2oL is a 23-item CSU specific health-related QoL questionnaire across 6 domains: pruritus, swelling, impact on life activities, sleep problems, limits, and looks. Patients rated their CSU symptoms and the impact of their CSU on various aspects of their lives. Each question was scored from 1 (not at all) to 5 (extremely), and overall raw score, on a scale of 23 to 115, was calculated by summing the individual raw domain scores.
Overall raw scores of CU-Q2oL were converted to 0 to 100 point scores according to the following formula:

[(sum of items – minimum) / (maximum – minimum)] × 100, where minimum=23 (1 score for all 23 items), maximum=115 (5 score for all 23 items).

End point type	Secondary

End point timeframe:

Week 12

End point values	CT-P39 300 mg	Xolair 300 mg	CT-P39 150 mg	Xolair 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	178	186	100	94
Units: Score				
arithmetic mean (standard deviation)	-25.40 (± 20.33)	-28.11 (± 19.93)	-27.32 (± 20.81)	-26.51 (± 23.27)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Overall Chronic Urticaria Quality of Life Questionnaire Score (CU-Q2oL) Score at Week 24

End point title	Change from Baseline in the Overall Chronic Urticaria Quality of Life Questionnaire Score (CU-Q2oL) Score at Week 24

End point description:

The change from baseline in mean overall CU-Q2oL score at Week 24 is presented.
The CU-Q2oL is a 23-item CSU specific health-related QoL questionnaire across 6 domains: pruritus, swelling, impact on life activities, sleep problems, limits, and looks. Patients rated their CSU symptoms and the impact of their CSU on various aspects of their lives. Each question was scored from 1 (not at all) to 5 (extremely), and overall raw score, on a scale of 23 to 115, was calculated by summing the individual raw domain scores.
Overall raw scores of CU-Q2oL were converted to 0 to 100 point scores according to the following formula:
[(sum of items – minimum) / (maximum – minimum)] × 100, where minimum=23 (1 score for all 23 items), maximum=115 (5 score for all 23 items).

End point type	Secondary

End point timeframe:

Week 24

End point values	CT-P39 300 mg maintenance	Switched to CT-P39 300 mg	Xolair 300 mg maintenance	CT-P39 Dose increased
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	167	90	89	94
Units: Score				
arithmetic mean (standard deviation)	-29.19 (± 18.76)	-31.33 (± 21.95)	-31.88 (± 22.33)	-31.71 (± 19.96)

End point values	Xolair Dose increased			
Subject group type	Reporting group			
Number of subjects analysed	90			
Units: Score				
arithmetic mean (standard deviation)	-30.88 (± 22.22)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment Period 1: TEAE with start date prior to the first study drug administration in TP2
Treatment Period 2: TEAE with start date from W12 administration to W24 (end of treatment visit) day
Follow up Period: TEAE with start date after W24 visit

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Treatment Period 1: CT-P39 300 mg

Reporting group description:

CT-P39 300 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)

Reporting group title	Treatment Period 1: Xolair 300 mg

Reporting group description:

Xolair 300 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)

Reporting group title	Treatment Period 1: CT-P39 150 mg

Reporting group description:

CT-P39 150 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)

Reporting group title	Treatment Period 1: Xolair 150 mg

Reporting group description:

Xolair 150 mg every 4 weeks in Treatment Period 1 (TP1) (Weeks 0, 4, 8)

Reporting group title	Treatment Period 2: CT-P39 300 mg maintenance

Reporting group description:

Received CT-P39 300 mg in TP1 and maintained on CT-P39 300 mg in TP2 (Week 12, 16, 20)

Reporting group title	Treatment Period 2: Switched to CT-P39 300 mg

Reporting group description:

Received Xolair 300 mg in TP1 and re-randomized to receive CT-P39 300 mg in TP2 (Week 12, 16, 20)

Reporting group title	Treatment Period 2: Xolair 300 mg maintenance

Reporting group description:

Received Xolair 300 mg in TP1 and re-randomized to continue on Xolair 300 mg in TP2 (Week 12, 16, 20)

Reporting group title	Treatment Period 2: CT-P39 Dose increased

Reporting group description:

Received CT-P39 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; CT-P39 300 mg in TP2 (Week 12, 16, 20)

Reporting group title	Treatment Period 2: Xolair Dose increased

Reporting group description:

Received Xolair 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; Xolair 300 mg in TP2 (Week 12, 16, 20)

Reporting group title	Follow up Period: CT-P39 300 mg maintenance

Reporting group description:

Received CT-P39 300 mg in TP1 and maintained on CT-P39 300 mg in TP2 (Week 12, 16, 20)

Reporting group title	Follow up Period: Switched from Xolair to CT-P39 300 mg

Reporting group description:

Received Xolair 300 mg in TP1 and re-randomized to receive CT-P39 300 mg in TP2 (Week 12, 16, 20)

Reporting group title	Follow up Period: Xolair 300 mg maintenance

Reporting group description:

Received Xolair 300 mg in TP1 and re-randomized to continue on Xolair 300 mg in TP2 (Week 12, 16, 20)

Reporting group title	Follow up Period: CT-P39 Dose Increased
Reporting group description:	
Received CT-P39 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; CT-P39 300 mg in TP2 (Week 12, 16, 20)	

Reporting group title	Follow up Period: Xolair Dose Increased
Reporting group description:	
Received Xolair 150 mg in TP1 and dose increased from 150 mg to 300 mg from Week 12; Xolair 300 mg in TP2 (Week 12, 16, 20)	

Serious adverse events	Treatment Period 1: CT-P39 300 mg	Treatment Period 1: Xolair 300 mg	Treatment Period 1: CT-P39 150 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 203 (1.97%)	2 / 205 (0.98%)	2 / 107 (1.87%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Tryptase increased			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Papillary thyroid cancer			
subjects affected / exposed	0 / 203 (0.00%)	1 / 205 (0.49%)	0 / 107 (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
Ureteric cancer			
subjects affected / exposed	0 / 203 (0.00%)	1 / 205 (0.49%)	0 / 107 (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 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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			
Joint dislocation			

subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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
Ligament sprain			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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
Radius fracture			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Behcet's syndrome			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial ischaemia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 205 (0.00%)	0 / 107 (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
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	1 / 203 (0.49%)	0 / 205 (0.00%)	0 / 107 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 203 (0.49%)	0 / 205 (0.00%)	0 / 107 (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
Femoral hernia			

subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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
Haemorrhoids			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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
Menometrorrhagia			
subjects affected / exposed	1 / 203 (0.49%)	0 / 205 (0.00%)	0 / 107 (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
Vaginal haemorrhage			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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			
Arthropathy			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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
COVID-19			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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
Chronic tonsillitis			
subjects affected / exposed	0 / 203 (0.00%)	1 / 205 (0.49%)	0 / 107 (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
Coronavirus infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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
Infection			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (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	Treatment Period 1: Xolair 150 mg	Treatment Period 2: CT-P39 300 mg maintenance	Treatment Period 2: Switched to CT-P39 300 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 103 (2.91%)	5 / 187 (2.67%)	0 / 96 (0.00%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Investigations			
Tryptase increased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Papillary thyroid cancer			

subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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
Ureteric cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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
Uterine leiomyoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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			
Joint dislocation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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
Ligament sprain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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
Radius fracture			
subjects affected / exposed	0 / 103 (0.00%)	1 / 187 (0.53%)	0 / 96 (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
Vascular disorders			
Behcet's syndrome			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial ischaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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			
Oedema peripheral			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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
Femoral hernia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 187 (0.00%)	0 / 96 (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
Haemorrhoids			
subjects affected / exposed	0 / 103 (0.00%)	1 / 187 (0.53%)	0 / 96 (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
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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
Menometrorrhagia			
subjects affected / exposed	0 / 103 (0.00%)	1 / 187 (0.53%)	0 / 96 (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
Vaginal haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			

subjects affected / exposed	0 / 103 (0.00%)	1 / 187 (0.53%)	0 / 96 (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
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 103 (0.00%)	1 / 187 (0.53%)	0 / 96 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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
COVID-19			
subjects affected / exposed	1 / 103 (0.97%)	0 / 187 (0.00%)	0 / 96 (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
Chronic tonsillitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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
Coronavirus infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 187 (0.00%)	0 / 96 (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
Infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (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	Treatment Period 2: Xolair 300 mg maintenance	Treatment Period 2: CT-P39 Dose increased	Treatment Period 2: Xolair Dose increased
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 96 (2.08%)	0 / 101 (0.00%)	0 / 98 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Investigations			
Tryptase increased			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Papillary thyroid cancer			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Ureteric cancer			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Uterine leiomyoma			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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			
Joint dislocation			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Ligament sprain			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Radius fracture			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Behcet's syndrome			
subjects affected / exposed	1 / 96 (1.04%)	0 / 101 (0.00%)	0 / 98 (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
Cardiac disorders			
Myocardial ischaemia			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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			
Oedema peripheral			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Femoral hernia			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Haemorrhoids			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Menometrorrhagia			

subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Vaginal haemorrhage			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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			
Arthropathy			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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 / 96 (1.04%)	0 / 101 (0.00%)	0 / 98 (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	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Chronic tonsillitis			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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
Coronavirus infection			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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

Infection			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (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	Follow up Period: CT-P39 300 mg maintenance	Follow up Period: Switched from Xolair to CT-P39 300 mg	Follow up Period: Xolair 300 mg maintenance
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 187 (0.53%)	3 / 96 (3.13%)	1 / 96 (1.04%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Tryptase increased			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Papillary thyroid cancer			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Ureteric cancer			
subjects affected / exposed	0 / 187 (0.00%)	1 / 96 (1.04%)	0 / 96 (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 / 187 (0.00%)	1 / 96 (1.04%)	0 / 96 (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
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Ligament sprain			

subjects affected / exposed	0 / 187 (0.00%)	1 / 96 (1.04%)	0 / 96 (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
Radius fracture			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Behcet's syndrome			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial ischaemia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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			
Oedema peripheral			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Femoral hernia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Haemorrhoids			

subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	1 / 187 (0.53%)	0 / 96 (0.00%)	0 / 96 (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
Menometrorrhagia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Vaginal haemorrhage			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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			
Arthropathy			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
COVID-19			

subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Chronic tonsillitis			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Coronavirus infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (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
Infection			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Follow up Period: CT-P39 Dose Increased	Follow up Period: Xolair Dose Increased	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 101 (2.97%)	0 / 98 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Tryptase increased			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Papillary thyroid cancer			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureteric cancer			

subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (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	1 / 101 (0.99%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Joint dislocation			
subjects affected / exposed	1 / 101 (0.99%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Behcet's syndrome			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial ischaemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Oedema peripheral			

subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral hernia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (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 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menometrorrhagia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (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			
Appendicitis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 98 (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 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic tonsillitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronavirus infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (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: 2 %

Non-serious adverse events	Treatment Period 1: CT-P39 300 mg	Treatment Period 1: Xolair 300 mg	Treatment Period 1: CT-P39 150 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 203 (11.33%)	24 / 205 (11.71%)	16 / 107 (14.95%)
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	3 / 107 (2.80%)
occurrences (all)	0	0	3
Headache			
subjects affected / exposed	5 / 203 (2.46%)	5 / 205 (2.44%)	0 / 107 (0.00%)
occurrences (all)	6	6	0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	5 / 203 (2.46%)	9 / 205 (4.39%)	1 / 107 (0.93%)
occurrences (all)	5	13	1
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
Infections and infestations			
COVID-19			
subjects affected / exposed	5 / 203 (2.46%)	7 / 205 (3.41%)	4 / 107 (3.74%)
occurrences (all)	5	7	4
Nasopharyngitis			
subjects affected / exposed	7 / 203 (3.45%)	4 / 205 (1.95%)	7 / 107 (6.54%)
occurrences (all)	7	4	7
Tonsillitis			
subjects affected / exposed	2 / 203 (0.99%)	1 / 205 (0.49%)	0 / 107 (0.00%)
occurrences (all)	2	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 203 (0.00%)	3 / 205 (1.46%)	1 / 107 (0.93%)
occurrences (all)	0	3	1
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	0 / 203 (0.00%)	0 / 205 (0.00%)	0 / 107 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Treatment Period 1: Xolair 150 mg	Treatment Period 2: CT-P39 300 mg maintenance	Treatment Period 2: Switched to CT-P39 300 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 103 (11.65%)	18 / 187 (9.63%)	8 / 96 (8.33%)
Nervous system disorders			

Dizziness			
subjects affected / exposed	2 / 103 (1.94%)	0 / 187 (0.00%)	0 / 96 (0.00%)
occurrences (all)	2	0	0
Headache			
subjects affected / exposed	4 / 103 (3.88%)	1 / 187 (0.53%)	1 / 96 (1.04%)
occurrences (all)	4	1	1
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	3 / 103 (2.91%)	1 / 187 (0.53%)	3 / 96 (3.13%)
occurrences (all)	4	1	4
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 103 (0.97%)	5 / 187 (2.67%)	2 / 96 (2.08%)
occurrences (all)	1	5	2
Nasopharyngitis			
subjects affected / exposed	2 / 103 (1.94%)	6 / 187 (3.21%)	2 / 96 (2.08%)
occurrences (all)	2	6	2
Tonsillitis			
subjects affected / exposed	0 / 103 (0.00%)	2 / 187 (1.07%)	0 / 96 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 103 (0.97%)	3 / 187 (1.60%)	0 / 96 (0.00%)
occurrences (all)	1	3	0
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 187 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Treatment Period 2: Xolair 300 mg maintenance	Treatment Period 2: CT-P39 Dose increased	Treatment Period 2: Xolair Dose increased
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 96 (11.46%)	8 / 101 (7.92%)	5 / 98 (5.10%)
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 96 (2.08%)	0 / 101 (0.00%)	1 / 98 (1.02%)
occurrences (all)	3	0	1
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	2 / 96 (2.08%)	1 / 101 (0.99%)	1 / 98 (1.02%)
occurrences (all)	3	1	1
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	2 / 96 (2.08%)	0 / 101 (0.00%)	0 / 98 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 96 (1.04%)	2 / 101 (1.98%)	3 / 98 (3.06%)
occurrences (all)	1	2	3
Nasopharyngitis			
subjects affected / exposed	4 / 96 (4.17%)	1 / 101 (0.99%)	0 / 98 (0.00%)
occurrences (all)	4	1	0
Tonsillitis			
subjects affected / exposed	1 / 96 (1.04%)	0 / 101 (0.00%)	0 / 98 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 96 (0.00%)	4 / 101 (3.96%)	1 / 98 (1.02%)
occurrences (all)	0	4	1
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	0 / 96 (0.00%)	0 / 101 (0.00%)	0 / 98 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Follow up Period: CT-P39 300 mg maintenance	Follow up Period: Switched from Xolair to CT-P39 300 mg	Follow up Period: Xolair 300 mg maintenance
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 187 (4.28%)	11 / 96 (11.46%)	7 / 96 (7.29%)
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 187 (1.07%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	2 / 187 (1.07%)	5 / 96 (5.21%)	3 / 96 (3.13%)
occurrences (all)	2	5	3
Nasopharyngitis			
subjects affected / exposed	3 / 187 (1.60%)	4 / 96 (4.17%)	2 / 96 (2.08%)
occurrences (all)	3	4	2
Tonsillitis			
subjects affected / exposed	0 / 187 (0.00%)	2 / 96 (2.08%)	0 / 96 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 187 (0.53%)	0 / 96 (0.00%)	2 / 96 (2.08%)
occurrences (all)	1	0	2
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	0 / 187 (0.00%)	0 / 96 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Follow up Period: CT-P39 Dose Increased	Follow up Period: Xolair Dose Increased	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 101 (8.91%)	9 / 98 (9.18%)	
Nervous system disorders			

Dizziness			
subjects affected / exposed	1 / 101 (0.99%)	0 / 98 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	3 / 101 (2.97%)	1 / 98 (1.02%)	
occurrences (all)	3	1	
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Immunisation reaction			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
COVID-19			
subjects affected / exposed	4 / 101 (3.96%)	5 / 98 (5.10%)	
occurrences (all)	4	5	
Nasopharyngitis			
subjects affected / exposed	1 / 101 (0.99%)	1 / 98 (1.02%)	
occurrences (all)	1	1	
Tonsillitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 98 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Hypertriglyceridaemia			
subjects affected / exposed	1 / 101 (0.99%)	2 / 98 (2.04%)	
occurrences (all)	1	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 August 2020	• A secondary efficacy endpoint 'Change from baseline in number of tablets/week of rescue therapy at Weeks 8, 12, and 24' was added to address a possible imbalance in rescue therapy use between the treatment arms. • A patient was allowed to take additional H1-antihistamine in case a patient discontinued the study drug during the study treatment periods. • A patient had to return to the study center by regular scheduled time intervals even if a patient discontinued the study drug during the treatment period to apply treatment policy estimand. • The following statement "Back-up samples for PK, immunogenicity, and free IgE will be retained at the central laboratory as a back-up and blood samples for free IgE assessments can be used for additional analysis for either free or total IgE" was added. • History of and/or concomitant myocardial infarction' was added to exclusion criteria considering myocardial infarction is specified as contraindications in Korea Ministry Food and Drug Safety label.
03 September 2020	• Details of analytical facilities was referred to the ICF instead of containing those details in the protocol. This change was done to prevent the protocol to be amended each time laboratory information is updated.
04 November 2020	• Immunogenicity timepoint was added to Weeks 4, 8, 16, and 20 to reflect FDA's comment. • 'Benefits and risk assessment and risk mitigation for COVID-19' was added in accordance with Polish Ministry of Health. • Approval of omalizumab for the treatment of chronic rhinosinusitis with nasal polyps in Europe was updated.
10 August 2021	• The start time of background medication was changed to at least 3 days before start recording the baseline ISS7 which was the earliest valid efficacy data. • Risk assessment for concomitant use of a COVID-19 vaccine during the study was added. • 'Patient missed at least 1 dose before Week 12' was deleted from the study treatment discontinuation reason. • It was changed to allow the patients who showed positive result of antibody test due to the past hepatitis C infection to be enrolled in the study. • The description of conversion method for calculating rescue medications was added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Due to the global impact of the COVID-19 pandemic, the Sponsor took proactive measures for the safety of participants. Due to the war in Ukraine during the study, increase in protocol deviations was unavoidable and some procedures were changed.

Notes: