



Clinical trial results:

A Multi-Center, Multi-National, Randomized, Double-Blind, Placebo-Controlled Induction and Long-term Controlled Study to Evaluate the Efficacy and Safety of CC-93538 in Adult and Adolescent Subjects with Active Eosinophilic Esophagitis

Summary

EudraCT number	2020-004336-16
Trial protocol	DE AT PT BE PL IT ES
Global end of trial date	29 August 2024

Results information

Result version number	v1 (current)
This version publication date	26 January 2025
First version publication date	26 January 2025

Trial information

Trial identification

Sponsor protocol code	cc-93538-ee-001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04753697
WHO universal trial number (UTN)	U1111-1263-4351

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, clinical.trials@bms.com
Scientific contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.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 October 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Study CC-93538-EE-001 is a Phase 3, multicenter, multinational, randomized, double-blind, placebo-controlled induction and maintenance study to evaluate the efficacy and safety of CC- 93538 in adult and adolescent participants with eosinophilic esophagitis (EoE).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 February 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 1
Country: Number of subjects enrolled	Australia: 38
Country: Number of subjects enrolled	Austria: 5
Country: Number of subjects enrolled	Belgium: 7
Country: Number of subjects enrolled	Canada: 53
Country: Number of subjects enrolled	Germany: 6
Country: Number of subjects enrolled	Israel: 6
Country: Number of subjects enrolled	Italy: 13
Country: Number of subjects enrolled	Japan: 22
Country: Number of subjects enrolled	Poland: 12
Country: Number of subjects enrolled	Portugal: 9
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	Switzerland: 4
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	United States: 244
Worldwide total number of subjects	430
EEA total number of subjects	59

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)	35
Adults (18-64 years)	391
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

805 participants were screened across 15 countries.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
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Arm title	CC-93538 360 mg QW
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Arm description:

Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase followed by 24-week maintenance phase.

Arm type	Experimental
Investigational medicinal product name	cendakimab
Investigational medicinal product code	CC-93538
Other name	
Pharmaceutical forms	Dispersion for injection, Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered 360 mg subcutaneously by self or caregiver

Arm title	CC-93538 360 mg QW/Q2W
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Arm description:

Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once in a week (QW) in the 24-week induction phase and once every other week in 24-week maintenance phase.

Arm type	Experimental
Investigational medicinal product name	cendakimab
Investigational medicinal product code	CC-93538
Other name	
Pharmaceutical forms	Dispersion for injection, Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered 360 mg subcutaneously by self or caregiver

Arm title	Placebo
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Arm description:

Participants with active eosinophilic esophagitis received CC-93538 matching placebo during 24-week induction phase followed by 24-week maintenance phase.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Self administered or by care giver

Number of subjects in period 1	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo
Started	143	143	144
Completed	143	141	143
Not completed	0	2	1
Other reasons	-	2	1

Period 2

Period 2 title	Induction Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	CC-93538 360 mg QW

Arm description:

Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase followed by 24-week maintenance phase.

Arm type	Experimental
Investigational medicinal product name	cendakimab
Investigational medicinal product code	CC-93538
Other name	
Pharmaceutical forms	Dispersion for injection, Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Administered 360 mg subcutaneously by self or caregiver

Arm title	CC-93538 360 mg QW/Q2W
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Arm description:

Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once in a week (QW) in the 24-week induction phase and once every other week in 24-week maintenance phase.

Arm type	Experimental
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Investigational medicinal product name	cendakimab
Investigational medicinal product code	CC-93538
Other name	
Pharmaceutical forms	Dispersion for injection, Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered 360 mg subcutaneously by self or caregiver	
Arm title	Placebo

Arm description:

Participants with active eosinophilic esophagitis received CC-93538 matching placebo during 24-week induction phase followed by 24-week maintenance phase.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Self administered or by care giver

Number of subjects in period 2	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo
Started	143	141	143
Completed	127	134	136
Not completed	16	7	7
Consent withdrawn by subject	12	5	6
Physician decision	1	-	-
Lost to follow-up	2	2	1
Lack of efficacy	1	-	-

Period 3

Period 3 title	Maintenance Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
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Arm title	CC-93538 360 mg QW
Arm description:	
Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase followed by 24-week maintenance phase.	
Arm type	Experimental
Investigational medicinal product name	cendakimab
Investigational medicinal product code	CC-93538
Other name	
Pharmaceutical forms	Dispersion for injection, Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered 360 mg subcutaneously by self or caregiver	
Arm title	CC-93538 360 mg QW/Q2W
Arm description:	
Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once in a week (QW) or once every other week in the 24-week maintenance phase.	
Arm type	Experimental
Investigational medicinal product name	cendakimab
Investigational medicinal product code	CC-93538
Other name	
Pharmaceutical forms	Dispersion for injection, Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Administered 360 mg subcutaneously by self or caregiver	
Arm title	Placebo
Arm description:	
Participants with active eosinophilic esophagitis received CC-93538 matching placebo during 24-week induction phase followed by 24-week maintenance phase.	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Self administered or by care giver	

Number of subjects in period 3^[1]	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo
Started	114	117	90
Completed	107	110	82
Not completed	7	7	8
Consent withdrawn by subject	3	4	6
Physician decision	-	-	1
NON-COMPLIANCE WITH STUDY DRUG	1	-	-
Adverse event, non-fatal	-	1	1

WITHDRAWAL BY PARENT/GUARDIAN	1	-	-
Lost to follow-up	2	2	-

Notes:

[1] - 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: 77 participants across 3 arms did not enter maintenance period.

Baseline characteristics

Reporting groups

Reporting group title	CC-93538 360 mg QW
Reporting group description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase followed by 24-week maintenance phase.	
Reporting group title	CC-93538 360 mg QW/Q2W
Reporting group description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once in a week (QW) in the 24-week induction phase and once every other week in 24-week maintenance phase.	
Reporting group title	Placebo
Reporting group description: Participants with active eosinophilic esophagitis received CC-93538 matching placebo during 24-week induction phase followed by 24-week maintenance phase.	

Reporting group values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo
Number of subjects	143	143	144
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)	9	17	9
Adults (18-64 years)	131	126	134
From 65-84 years	3	0	1
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	35.9	34.8	36.2
standard deviation	± 11.79	± 12.24	± 12.16
Sex: Female, Male Units: participants			
Female	53	33	45
Male	90	110	99
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	5	10	11
Native Hawaiian or Other Pacific Islander	1	0	1
Black or African American	2	3	0
White	134	128	130
More than one race	0	0	0
Unknown or Not Reported	1	1	2
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino	6	5	6
Not Hispanic or Latino	135	138	137
Unknown or Not Reported	2	0	1

Reporting group values	Total		
Number of subjects	430		
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)	35		
Adults (18-64 years)	391		
From 65-84 years	4		
85 years and over	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: participants			
Female	131		
Male	299		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	1		
Asian	26		
Native Hawaiian or Other Pacific Islander	2		
Black or African American	5		
White	392		
More than one race	0		
Unknown or Not Reported	4		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	17		
Not Hispanic or Latino	410		
Unknown or Not Reported	3		

End points

End points reporting groups

Reporting group title	CC-93538 360 mg QW
Reporting group description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase followed by 24-week maintenance phase.	
Reporting group title	CC-93538 360 mg QW/Q2W
Reporting group description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once in a week (QW) in the 24-week induction phase and once every other week in 24-week maintenance phase.	
Reporting group title	Placebo
Reporting group description: Participants with active eosinophilic esophagitis received CC-93538 matching placebo during 24-week induction phase followed by 24-week maintenance phase.	
Reporting group title	CC-93538 360 mg QW
Reporting group description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase followed by 24-week maintenance phase.	
Reporting group title	CC-93538 360 mg QW/Q2W
Reporting group description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once in a week (QW) in the 24-week induction phase and once every other week in 24-week maintenance phase.	
Reporting group title	Placebo
Reporting group description: Participants with active eosinophilic esophagitis received CC-93538 matching placebo during 24-week induction phase followed by 24-week maintenance phase.	
Reporting group title	CC-93538 360 mg QW
Reporting group description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase followed by 24-week maintenance phase.	
Reporting group title	CC-93538 360 mg QW/Q2W
Reporting group description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once in a week (QW) or once every other week in the 24-week maintenance phase.	
Reporting group title	Placebo
Reporting group description: Participants with active eosinophilic esophagitis received CC-93538 matching placebo during 24-week induction phase followed by 24-week maintenance phase.	
Subject analysis set title	Induction Phase - CC-93538 360 mg QW
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase.	
Subject analysis set title	Induction Phase - Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24-week induction phase.	
Subject analysis set title	Induction Phase - CC-93538 360 mg QW
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase.	

Subject analysis set title	Induction Phase - Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week induction phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg QW
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg Q2W
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every other week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - Placebo
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg QW
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg Q2W
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every other week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - Placebo
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Induction Phase - Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week induction phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg QW
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg Q2W
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every other week in the 24 week maintenance phase.	

Subject analysis set title	Maintenance Phase - Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Induction Phase - CC-93538 360 mg QW
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week induction phase.	
Subject analysis set title	Induction Phase - Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week induction phase.	
Subject analysis set title	Induction Phase - CC-93538 360 mg QW
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week induction phase.	
Subject analysis set title	Induction Phase - Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week induction phase.	
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Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week induction phase.	
Subject analysis set title	Induction Phase - CC-93538 360 mg QW
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week induction phase.	
Subject analysis set title	Induction Phase - Placebo
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week induction phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg QW
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg Q2W
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every other week in the 24 week maintenance phase.	
Subject analysis set title	Induction Phase - CC-93538 360 mg QW
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week induction phase.	

Subject analysis set title	Induction Phase - Placebo
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week induction phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg QW
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg Q2W
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every other week in the 24 week maintenance phase.	
Subject analysis set title	Induction Phase - CC-93538 360 mg QW
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week induction phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg QW
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week maintenance phase.	
Subject analysis set title	CC-93538 360 mg QW
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24-week induction phase followed by 24-week maintenance phase.	
Subject analysis set title	CC-93538 360 mg QW/Q2W
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once in a week (QW) or once every other week in the 24-week maintenance phase.	
Subject analysis set title	Placebo
Subject analysis set type	Safety analysis
Subject analysis set description: Participants with active eosinophilic esophagitis received CC-93538 matching placebo during 24-week induction phase followed by 24-week maintenance phase.	
Subject analysis set title	Induction Phase - Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24-week induction phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg QW
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week maintenance phase.	
Subject analysis set title	Maintenance Phase - CC-93538 360 mg Q2W
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every other week in the 24 week maintenance phase.	

Subject analysis set title	Maintenance Phase - Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week maintenance phase.	
Primary: Change from Baseline in Mean Dysphagia Days (DD) at Week 24	
End point title	Change from Baseline in Mean Dysphagia Days (DD) at Week 24
End point description:	
Dysphagia Days (DD) was assessed using a modified daily symptom diary (mDSD). The DD was evaluated over the prior 14-day period using the mDSD, which includes 6 primary questions. These questions assess solid food consumption that day (Q1), experience with trouble swallowing (Q2), food going down slowly (Q3), food getting stuck in the throat or chest (Q4), actions taken by participants to obtain relief (Q5), and any pain associated with swallowing (Q6). The number of DD was normalized by calculating the number of diary days with a "yes" to any or all of Q2, Q3, and Q4 in the 14-day period prior to a visit, dividing by the number of measurable diary days in the 14-day period, and then multiplying by the length of the period (14). A measurable diary day for DD is defined as a diary day for which Questions 2 to 4 are answered. Mean DD ranges from 0 to 14 for the 14-day period.	
End point type	Primary
End point timeframe:	
Baseline (Day 1) and Week 24	

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	236	124		
Units: days				
arithmetic mean (standard deviation)	-6.85 (± 5.259)	-4.98 (± 5.075)		

Statistical analyses

Statistical analysis title	Analysis 1
Comparison groups	Induction Phase - CC-93538 360 mg QW v Induction Phase - Placebo
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0005
Method	ANCOVA
Parameter estimate	Difference in Least Square Mean
Point estimate	-1.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.97
upper limit	-0.84

Variability estimate	Standard error of the mean
Dispersion value	0.544

Primary: Percentage of Participants with Peak Esophageal Eosinophil Count ≤ 6/high-power field (hpf) at Week 24

End point title	Percentage of Participants with Peak Esophageal Eosinophil Count ≤ 6/high-power field (hpf) at Week 24
End point description:	Blood samples were collected to assess esophageal eosinophil count.
End point type	Primary
End point timeframe:	Week 24

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	249	129		
Units: percentage of participants				
number (not applicable)	34.1	3.1		

Statistical analyses

Statistical analysis title	Analysis 1
Comparison groups	Induction Phase - CC-93538 360 mg QW v Induction Phase - Placebo
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in percentage
Point estimate	26.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.6
upper limit	32.2

Secondary: Percentage of Participants with Peak Esophageal Eosinophil Count ≤ 6/high-power field (hpf) at Week 48

End point title	Percentage of Participants with Peak Esophageal Eosinophil
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End point description:

Blood samples were collected to assess esophageal eosinophil count.

End point type Secondary

End point timeframe:

Week 48

End point values	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	108	82	
Units: percentage of participants				
number (not applicable)	37.5	34.3	4.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase - CC-93538 360 mg QW v Maintenance Phase - Placebo
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	DIFFERENCE IN RESPONSE RATE
Point estimate	18.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.3
upper limit	25.5

Statistical analysis title	Statistical Analysis 2
Comparison groups	Maintenance Phase - CC-93538 360 mg QW v Maintenance Phase - Placebo
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	DIFFERENCE IN RESPONSE RATE
Point estimate	17

Confidence interval	
level	95 %
sides	2-sided
lower limit	10.1
upper limit	24

Secondary: Percentage of Participants with Peak Esophageal Eosinophil count < 15/high-power field (hpf) at Week 24

End point title	Percentage of Participants with Peak Esophageal Eosinophil count < 15/high-power field (hpf) at Week 24
End point description: Blood samples were collected to assess esophageal eosinophil count.	
End point type	Secondary
End point timeframe: Week 24	

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	249	129		
Units: percentage of participants				
number (not applicable)	53.0	4.7		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Induction Phase - CC-93538 360 mg QW v Induction Phase - Placebo
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN RESPONSE RATE
Point estimate	40
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.3
upper limit	46.7

Secondary: Percentage of Participants with Peak Esophageal Eosinophil Count < 15/high-power field (hpf) at Week 48

End point title	Percentage of Participants with Peak Esophageal Eosinophil Count < 15/high-power field (hpf) at Week 48
End point description: Blood samples were collected to assess esophageal eosinophil count.	
End point type	Secondary
End point timeframe: Week 48	

End point values	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	108	82	
Units: percentage of participants				
number (not applicable)	50.0	50.0	8.5	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase - CC-93538 360 mg QW v Maintenance Phase - Placebo
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN RESPONSE RATE
Point estimate	25.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.8
upper limit	33.6

Statistical analysis title	Statistical Analysis 2
Comparison groups	Maintenance Phase - CC-93538 360 mg Q2W v Maintenance Phase - Placebo

Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN RESPONSE RATE
Point estimate	27.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.7
upper limit	35.7

Secondary: Change from Baseline in Mean Dysphagia Days (DD) at Week 48

End point title	Change from Baseline in Mean Dysphagia Days (DD) at Week 48
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End point description:

Dysphagia Days (DD) was assessed using a modified daily symptom diary (mDSD). The DD was evaluated over the prior 14-day period using the mDSD, which includes 6 primary questions. These questions assess solid food consumption that day (Q1), experience with trouble swallowing (Q2), food going down slowly (Q3), food getting stuck in the throat or chest (Q4), actions taken by participants to obtain relief (Q5), and any pain associated with swallowing (Q6). The number of DD was normalized by calculating the number of diary days with a "yes" to any or all of Q2, Q3, and Q4 in the 14-day period prior to a visit, dividing by the number of measurable diary days in the 14-day period, and then multiplying by the length of the period (14). A measurable diary day for DD is defined as a diary day for which Questions 2 to 4 are answered. Mean DD ranges from 0 to 14 for the 14-day period.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 48

End point values	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	101	75	
Units: days				
arithmetic mean (standard deviation)	-7.71 (± 5.401)	-8.07 (± 5.292)	-6.20 (± 5.118)	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Maintenance Phase - CC-93538 360 mg Q2W v Maintenance Phase - Placebo

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-2.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.78
upper limit	-1.2
Variability estimate	Standard error of the mean
Dispersion value	0.657

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase - CC-93538 360 mg QW v Maintenance Phase - Placebo
Number of subjects included in analysis	175
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0006
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-2.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.55
upper limit	-0.98
Variability estimate	Standard error of the mean
Dispersion value	0.655

Secondary: Change from Baseline in Eosinophilic Esophagitis (EoE) Endoscopic Reference Score (EREFS) at Week 24

End point title	Change from Baseline in Eosinophilic Esophagitis (EoE) Endoscopic Reference Score (EREFS) at Week 24
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End point description:

The EREFS, measures features of EoE including esophageal edema, fixed rings, exudates, furrows, and strictures. The instrument grades edema as none (0) or present (1) or severe; furrows as absent (0), present (1); rings as none (0), mild (1), moderate (2) and severe (3); exudates as none (0), mild (1) or severe (2); and strictures as absent (0) or present (1). Two sub-component scores will be calculated by adding up the grade from respective features across the 3 esophagus levels (proximal, mid, and distal). Inflammation composite score (ranging 0 to 12) includes edema, furrows and exudates while remodeling composite score (0 to 12) consist of stricture and fixed rings. The EREFS total score is the sum of the inflammation and remodeling composite scores. The EREFS total score ranges from 0 to 24. High score signifies severe condition.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) , Week 24

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	249	128		
Units: score on a scale				
arithmetic mean (standard deviation)	-6.0 (± 4.54)	-1.5 (± 4.26)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Induction Phase - CC-93538 360 mg QW v Induction Phase - Placebo
Number of subjects included in analysis	377
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	-3.2
Variability estimate	Standard error of the mean
Dispersion value	0.42

Secondary: Change from Baseline in Eosinophilic Esophagitis (EoE) Endoscopic Reference Score (EREFS) at Week 48

End point title	Change from Baseline in Eosinophilic Esophagitis (EoE) Endoscopic Reference Score (EREFS) at Week 48
End point description:	<p>The EREFS, measures features of EoE including esophageal edema, fixed rings, exudates, furrows, and strictures. The instrument grades edema as none (0) or present (1) or severe; furrows as absent (0), present (1); rings as none (0), mild (1), moderate (2) and severe (3); exudates as none (0), mild (1) or severe (2); and strictures as absent (0) or present (1). Two sub-component scores will be calculated by adding up the grade from respective features across the 3 esophagus levels (proximal, mid, and distal). Inflammation composite score (ranging 0 to 12) includes edema, furrows and exudates while remodeling composite score (0 to 12) consist of stricture and fixed rings. The EREFS total score is the sum of the inflammation and remodeling composite scores. The EREFS total score ranges from 0 to 24. High score signifies severe condition.</p>
End point type	Secondary

End point timeframe:

Baseline (Day 1) , Week 48

End point values	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	103	105	79	
Units: score on a scale				
arithmetic mean (standard deviation)	-6.6 (± 4.24)	-6.5 (± 4.57)	-3.2 (± 4.15)	

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Maintenance Phase - CC-93538 360 mg Q2W v Maintenance Phase - Placebo
Number of subjects included in analysis	184
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	-2.1
Variability estimate	Standard error of the mean
Dispersion value	0.51

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase - CC-93538 360 mg QW v Maintenance Phase - Placebo
Number of subjects included in analysis	182
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-3.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.5
upper limit	-2.4
Variability estimate	Standard error of the mean
Dispersion value	0.51

Secondary: Change from Baseline in Mean Adjusted Eosinophilic Esophagitis Histology Scoring System (EoEHSS) Grade Score at Week 24

End point title	Change from Baseline in Mean Adjusted Eosinophilic Esophagitis Histology Scoring System (EoEHSS) Grade Score at Week 24
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End point description:

EoEHSS evaluates the grade (severity) of multiple pathologic features in esophageal biopsies. It has 8 features eosinophil inflammation, basal zone hyperplasia, eosinophil abscess, eosinophil surface layering, dilated intercellular spaces, surface epithelial alteration, dyskeratotic epithelial cells, and lamina propria fibrosis. In 3 separate esophagus levels (proximal, mid, and distal), each feature is scored independently for grade using a 4-point Likert scale (0 [absent] to 3 [severe]). The mean adjusted grade score is calculated by averaging the adjusted scores for the 3 levels (proximal, mid, and distal). The mean adjusted scores range from 0 to 100. High score signifies severe condition.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Week 24

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	249	129		
Units: Score on a scale				
arithmetic mean (standard deviation)	-30.20 (\pm 15.811)	-6.47 (\pm 15.755)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Induction Phase - CC-93538 360 mg QW v Induction Phase - Placebo
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-22.51

Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.5
upper limit	-19.51
Variability estimate	Standard error of the mean
Dispersion value	1.528

Secondary: Change from Baseline in Mean Adjusted Eosinophilic Esophagitis Histology Scoring System (EoEHSS) Grade Score at Week 48

End point title	Change from Baseline in Mean Adjusted Eosinophilic Esophagitis Histology Scoring System (EoEHSS) Grade Score at Week 48
End point description:	
EoEHSS evaluates the grade (severity) of multiple pathologic features in esophageal biopsies. It has 8 features eosinophil inflammation, basal zone hyperplasia, eosinophil abscess, eosinophil surface layering, dilated intercellular spaces, surface epithelial alteration, dyskeratotic epithelial cells, and lamina propria fibrosis. In 3 separate esophagus levels (proximal, mid, and distal), each feature is scored independently for grade using a 4-point Likert scale (0 [absent] to 3 [severe]). The mean adjusted grade score is calculated by averaging the adjusted scores for the 3 levels (proximal, mid, and distal). The mean adjusted scores range from 0 to 100. High score signifies severe condition.	
End point type	Secondary
End point timeframe:	
Baseline (Day 1) , Week 48	

End point values	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	108	82	
Units: score on a scale				
arithmetic mean (standard deviation)	-30.35 (± 17.146)	-30.96 (± 15.864)	-6.17 (± 16.579)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase - CC-93538 360 mg QW v Maintenance Phase - Placebo
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-18.13

Confidence interval	
level	95 %
sides	2-sided
lower limit	-21.85
upper limit	-14.4
Variability estimate	Standard error of the mean
Dispersion value	1.9

Statistical analysis title	Statistical Analysis 2
Comparison groups	Maintenance Phase - CC-93538 360 mg Q2W v Maintenance Phase - Placebo
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-19.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.9
upper limit	-15.53
Variability estimate	Standard error of the mean
Dispersion value	1.88

Secondary: Change from Baseline in Mean Adjusted Eosinophilic Esophagitis Histology Scoring System (EoEHSS) Stage Score at Week 24

End point title	Change from Baseline in Mean Adjusted Eosinophilic Esophagitis Histology Scoring System (EoEHSS) Stage Score at Week 24
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End point description:

EoEHSS evaluates the stage (extent) of multiple pathologic features in esophageal biopsies. It has 8 features eosinophil inflammation (determined by peak EoS count(PEC)) and presence of basal zone hyperplasia, eosinophil abscess, eosinophil surface layering, dilated intercellular spaces, surface epithelial alteration, dyskeratotic epithelial cells, and lamina propria fibrosis in epithelium . In 3 separate esophagus levels (proximal, mid, and distal), each feature is scored independently for stage using a 4-point Likert scale (0 [absent], 1[PEC ≥15/hpf in <33% of hpfs or (any grade >0) <33% of epithelium for other features], 2 [PEC ≥15/hpf in 33-66% of hpfs or (any grade >0) in 33-66% of epithelium to 3 [PEC ≥15/hpf in >66% of hpfs or (any grade >0) in > 66% of epithelium]). The mean adjusted stage score is calculated by averaging the adjusted scores for the 3 levels (proximal, mid, and distal). The mean adjusted scores range from 0 to 100. High score signifies severe condition.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Week 24

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	249	129		
Units: Score on a scale				
arithmetic mean (standard deviation)	-36.71 (\pm 19.370)	-9.90 (\pm 17.583)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Induction Phase - CC-93538 360 mg QW v Induction Phase - Placebo
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-25.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.4
upper limit	-21.89
Variability estimate	Standard error of the mean
Dispersion value	1.793

Secondary: Change from Baseline in Mean Adjusted Eosinophilic Esophagitis Histology Scoring System (EoEHSS) Stage Score at Week 48

End point title	Change from Baseline in Mean Adjusted Eosinophilic Esophagitis Histology Scoring System (EoEHSS) Stage Score at Week 48
End point description:	<p>EoEHSS evaluates the stage (extent) of multiple pathologic features in esophageal biopsies. It has 8 features eosinophil inflammation (determined by peak EoS count(PEC)) and presence of basal zone hyperplasia, eosinophil abscess, eosinophil surface layering, dilated intercellular spaces, surface epithelial alteration, dyskeratotic epithelial cells, and lamina propria fibrosis in epithelium . In 3 separate esophagus levels (proximal, mid, and distal), each feature is scored independently for stage using a 4-point Likert scale (0 [absent], 1[PEC \geq15/hpf in <33% of hpfs or (any grade >0) <33% of epithelium for other features], 2 [PEC \geq15/hpf in 33-66% of hpfs or (any grade >0) in 33-66% of epithelium to 3 [PEC \geq15/hpf in >66% of hpfs or (any grade >0) in > 66% of epithelium]). The mean adjusted stage score is calculated by averaging the adjusted scores for the 3 levels (proximal, mid, and distal). The mean adjusted scores range from 0 to 100. High score signifies severe condition.</p>
End point type	Secondary
End point timeframe:	
Baseline (Day 1) , Week 48	

End point values	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	104	108	82	
Units: score on a scale				
arithmetic mean (standard deviation)	-36.30 (\pm 20.904)	-37.36 (\pm 19.290)	-8.38 (\pm 19.935)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase - CC-93538 360 mg QW v Maintenance Phase - Placebo
Number of subjects included in analysis	186
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-20.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.17
upper limit	-18.91
Variability estimate	Standard error of the mean
Dispersion value	2.229

Statistical analysis title	Statistical Analysis 2
Comparison groups	Maintenance Phase - CC-93538 360 mg Q2W v Maintenance Phase - Placebo
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-23.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.73
upper limit	-21.56

Variability estimate	Standard error of the mean
Dispersion value	2.222

Secondary: Change from Baseline in Modified Daily Symptom Diary (mDSD) Composite Score at Week 24

End point title	Change from Baseline in Modified Daily Symptom Diary (mDSD) Composite Score at Week 24
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End point description:

The mDSD composite score is evaluated over the prior 14-day period using the mDSD, which includes 6 primary questions. These questions assess solid food consumption that day (Q1), experience with trouble swallowing (Q2), food going down slowly (Q3), food getting stuck in the throat or chest (Q4), actions taken by participants to obtain relief (Q5), and any pain associated with swallowing (Q6). The daily symptom score (mDSD) is calculated by summing the responses to Q2, Q3, and Q4 (where "Yes" to any/all items equals 1, and "No" to all items equals 0), adding Q5 over the 14-day period prior to a visit, dividing by the number of measurable diary days over the 14-day period, and then multiplying by the length of the period (14). The daily symptom score ranges from 0 to 5, and the mDSD composite score ranges from 0 to 70 for the 14-day period. A higher composite diary score indicates more frequent and/or severe dysphagia symptoms.

End point type	Secondary
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End point timeframe:

Baseline (11 days prior to Day 1) and Week 24

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	236	124		
Units: Score on a scale				
arithmetic mean (standard deviation)	-14.78 (\pm 11.353)	-10.93 (\pm 11.234)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Induction Phase - CC-93538 360 mg QW v Induction Phase - Placebo
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-4.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.4
upper limit	-1.8
Variability estimate	Standard error of the mean
Dispersion value	1.174

Secondary: Change from Baseline in Modified Daily Symptom Diary (mDSD) Composite Score at Week 48

End point title	Change from Baseline in Modified Daily Symptom Diary (mDSD) Composite Score at Week 48
End point description:	
<p>The mDSD composite score is evaluated over the prior 14-day period using the mDSD, which includes 6 primary questions. These questions assess solid food consumption that day (Q1), experience with trouble swallowing (Q2), food going down slowly (Q3), food getting stuck in the throat or chest (Q4), actions taken by participants to obtain relief (Q5), and any pain associated with swallowing (Q6). The daily symptom score (mDSD) is calculated by summing the responses to Q2, Q3, and Q4 (where "Yes" to any/all items equals 1, and "No" to all items equals 0), adding Q5 over the 14-day period prior to a visit, dividing by the number of measurable diary days over the 14-day period, and then multiplying by the length of the period (14). The daily symptom score ranges from 0 to 5, and the mDSD composite score ranges from 0 to 70 for the 14-day period. A higher composite diary score indicates more frequent and/or severe dysphagia symptoms.</p>	
End point type	Secondary
End point timeframe:	
Baseline (Day 1) , Week 48	

End point values	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	100	101	75	
Units: score on a scale				
arithmetic mean (standard deviation)	-16.77 (± 11.297)	-16.45 (± 11.635)	-13.44 (± 10.862)	

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Comparison groups	Maintenance Phase - CC-93538 360 mg Q2W v Maintenance Phase - Placebo

Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8
upper limit	-2.41
Variability estimate	Standard error of the mean
Dispersion value	1.425

Statistical analysis title	Statistical Analysis 1
Comparison groups	Maintenance Phase - CC-93538 360 mg QW v Maintenance Phase - Placebo
Number of subjects included in analysis	175
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0022
Method	ANCOVA
Parameter estimate	DIFFERENCE IN LSM
Point estimate	-4.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.14
upper limit	-1.57
Variability estimate	Standard error of the mean
Dispersion value	1.42

Secondary: Percentage of Participants with a \geq 50% Decrease in Dysphagia Days(DD) from Baseline at Week 24

End point title	Percentage of Participants with a \geq 50% Decrease in Dysphagia Days(DD) from Baseline at Week 24
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End point description:

Dysphagia Days (DD) was assessed using a modified daily symptom diary (mDSD). The DD was evaluated over the prior 14-day period using the mDSD, which includes 6 primary questions. These questions assess solid food consumption that day (Q1), experience with trouble swallowing (Q2), food going down slowly (Q3), food getting stuck in the throat or chest (Q4), actions taken by participants to obtain relief (Q5), and any pain associated with swallowing (Q6). The number of DD was normalized by calculating the number of diary days with a "yes" to any or all of Q2, Q3, and Q4 in the 14-day period prior to a visit, dividing by the number of measurable diary days in the 14-day period, and then multiplying by the length of the period (14). A measurable diary day for DD is defined as a diary day for which Questions 2 to 4 are answered. DD ranges from 0 to 14 for the 14-day period.

End point type	Secondary
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End point timeframe:

Baseline (11 days prior to Day 1) and Week 24

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	236	124		
Units: percentage of participants				
number (not applicable)	65.7	50.0		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Induction Phase - CC-93538 360 mg QW v Induction Phase - Placebo
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0016
Method	ANCOVA
Parameter estimate	DIFFERENCE IN RESPONSE RATE
Point estimate	16.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.7
upper limit	27.2

Secondary: Percentage of Participants with a $\geq 50\%$ Decrease in Dysphagia Days(DD) from Baseline at Week 48

End point title	Percentage of Participants with a $\geq 50\%$ Decrease in Dysphagia Days(DD) from Baseline at Week 48
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End point description:

Dysphagia Days (DD) was assessed using a modified daily symptom diary (mDSD). The DD was evaluated over the prior 14-day period using the mDSD, which includes 6 primary questions. These questions assess solid food consumption that day (Q1), experience with trouble swallowing (Q2), food going down slowly (Q3), food getting stuck in the throat or chest (Q4), actions taken by participants to obtain relief (Q5), and any pain associated with swallowing (Q6). The number of DD was normalized by calculating the number of diary days with a "yes" to any or all of Q2, Q3, and Q4 in the 14-day period prior to a visit, dividing by the number of measurable diary days in the 14-day period, and then multiplying by the length of the period (14). A measurable diary day for DD is defined as a diary day for which Questions 2 to 4 are answered. DD ranges from 0 to 14 for the 14-day period.

End point type	Secondary
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End point timeframe:

Baseline (11 days prior to Day 1) and Week 48

End point values	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	143	143	144	
Units: percentage of participants				
number (not applicable)	50.3	53.8	50.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Mean Dysphagia Days (DD) through Week 24

End point title	Change from Baseline in Mean Dysphagia Days (DD) through Week 24
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End point description:

Dysphagia Days (DD) was assessed using a modified daily symptom diary (mDSD). The DD was evaluated over the prior 14-day period using the mDSD, which includes 6 primary questions. These questions assess solid food consumption that day (Q1), experience with trouble swallowing (Q2), food going down slowly (Q3), food getting stuck in the throat or chest (Q4), actions taken by participants to obtain relief (Q5), and any pain associated with swallowing (Q6). The number of DD was normalized by calculating the number of diary days with a "yes" to any or all of Q2, Q3, and Q4 in the 14-day period prior to a visit, dividing by the number of measurable diary days in the 14-day period, and then multiplying by the length of the period (14). A measurable diary day for DD is defined as a diary day for which Questions 2 to 4 are answered. Mean DD ranges from 0 to 14 for the 14-day period.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	264	144		
Units: days				
arithmetic mean (standard deviation)				
Week 2 (n=262, 139)	-1.26 (± 2.607)	-0.80 (± 2.651)		
Week 4 (n=264, 135)	-3.19 (± 4.073)	-1.75 (± 3.460)		
Week 8 (n=255, 132)	-5.04 (± 4.755)	-3.51 (± 4.132)		
Week 12 (n=244, 122)	-5.88 (± 5.071)	-3.88 (± 4.379)		
Week 16 (n=235, 121)	-6.39 (± 5.299)	-4.90 (± 4.851)		

Week 20 (n=229, 120)	-6.91 (± 5.321)	-4.98 (± 4.960)		
Week 24 (n=236, 124)	-6.85 (± 5.259)	-4.98 (± 5.075)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Modified Daily Symptom Diary (mDSD) Composite Score through Week 24

End point title	Change from Baseline in Modified Daily Symptom Diary (mDSD) Composite Score through Week 24
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End point description:

The mDSD composite score is evaluated over the prior 14-day period using the mDSD, which includes 6 primary questions. These questions assess solid food consumption that day (Q1), experience with trouble swallowing (Q2), food going down slowly (Q3), food getting stuck in the throat or chest (Q4), actions taken by participants to obtain relief (Q5), and any pain associated with swallowing (Q6). The daily symptom score (mDSD) is calculated by summing the responses to Q2, Q3, and Q4 (where "Yes" to any/all items equals 1, and "No" to all items equals 0), adding Q5 over the 14-day period prior to a visit, dividing by the number of measurable diary days over the 14-day period, and then multiplying by the length of the period (14). The daily symptom score ranges from 0 to 5, and the mDSD composite score ranges from 0 to 70 for the 14-day period. A higher composite diary score indicates more frequent and/or severe dysphagia symptoms.

End point type	Secondary
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End point timeframe:

Baseline (11 days prior to Day 1) and Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	264	139		
Units: Score on a scale				
arithmetic mean (standard deviation)				
Week 2 (n=262, 139)	-3.89 (± 7.126)	-3.25 (± 6.621)		
Week 4 (n=264, 135)	-8.02 (± 9.118)	-4.98 (± 8.902)		
Week 8 (n=255, 132)	-11.63 (± 10.515)	-7.59 (± 9.938)		
Week 12 (n=244, 122)	-13.22 (± 10.987)	-9.00 (± 10.051)		
Week 16 (n=235, 121)	-13.54 (± 11.623)	-10.43 (± 10.419)		
Week 20 (n=262, 139)	-14.71 (± 11.496)	-10.99 (± 10.353)		
Week 24 (n=229, 120)	-14.78 (± 11.353)	-10.93 (± 11.234)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Event of Eosinophilic Esophagitis (EoE) Flare

End point title	Time to First Event of Eosinophilic Esophagitis (EoE) Flare
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End point description:

First incidence of corresponding EoE flare event for any participant was considered in the analysis. Median and 95% CI are from Kaplan-Meier estimates. Participants without an event of EoE flare or discontinued the study by the end of maintenance phase were censored, if they are a dropout, they are censored at study discontinuation date, otherwise they are censored at either last dose date or last visit, whichever was longer.

End point type	Secondary
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End point timeframe:

From first dose (Day 1) and Up to Week 48

End point values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5 ^[1]	13 ^[2]	29 ^[3]	
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	

Notes:

[1] - 99999 stands for not estimable.

[2] - 99999 stands for not estimable.

[3] - 99999 stands for not estimable.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Use of Rescue Medication

End point title	Time to First Use of Rescue Medication
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End point description:

First use of rescue therapy including EoE standard of care pharmacotherapy, dietary modification (e.g., food elimination diet), and/or dilation procedure. was considered in the analysis. Median and 95% CI are from Kaplan-Meier estimates. Participants without an event or discontinued the study by the end of maintenance phase were censored, if they are a dropout, they are censored at study discontinuation date, otherwise they are censored at either last dose date or last visit, whichever was longer.

End point type	Secondary
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End point timeframe:

From first dose (Day 1) and Up to Week 48

End point values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7 ^[4]	10 ^[5]	20 ^[6]	
Units: days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	

Notes:

[4] - 99999 stands for not estimable.

[5] - 99999 stands for not estimable.

[6] - 99999 stands for not estimable.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Any Events of Use of Rescue Medication

End point title	Percentage of Participants with Any Events of Use of Rescue Medication
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End point description:

Use of rescue therapy including EoE standard of care pharmacotherapy, dietary modification (e.g., food elimination diet), and/or dilation procedure was considered in the analysis.

End point type	Secondary
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End point timeframe:

From first dose (Day 1) and up to Week 48

End point values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	143	143	144	
Units: percentage of participants				
number (not applicable)	4.9	7.0	13.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Eosinophilic Esophagitis (EoE) Flare

End point title	Percentage of Participants with Eosinophilic Esophagitis (EoE) Flare
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End point description:

First incidence of corresponding EoE flare event for any participant was considered in the analysis.

End point type	Secondary
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End point timeframe:

From first dose (Day 1) and up to Week 48

End point values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	143	143	144	
Units: percentage of participants				
number (not applicable)	3.5	9.1	20.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment Emergent Adverse Events (TEAEs)

End point title	Number of Participants with Treatment Emergent Adverse Events (TEAEs)
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End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a pre-existing medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment. A Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization.

End point type	Secondary
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End point timeframe:

From first dose (Day 1) till up to Week 48

End point values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	167	117	143	
Units: participants				
Treatment Emergent Adverse Events	140	99	105	
Treatment Emergent Serious Adverse Events	4	4	8	
Any Treatment Emergent Severe Adverse Events	7	6	13	
Any Treatment Emergent Moderate Adverse Events	68	55	48	
Any Treatment Emergent Mild Adverse Events	65	38	44	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Maximum Post-Baseline Clinical Laboratory Range Shift

End point title	Number of Participants with Maximum Post-Baseline Clinical Laboratory Range Shift
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End point description:

Blood samples were collected to assess clinical laboratory parameters. The row title contains parameter and category title contains shift. The category 'Normal to High' signifies the readings for the parameter were 'Normal' at baseline and it changed to 'High' post baseline.

End point type	Secondary
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End point timeframe:

From first dose (Day 1) till up to Week 48

End point values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	167	117	143	
Units: participants				
Sodium (mmol/L) Normal to Normal	158	113	138	
Potassium (mmol/L) Normal to Normal	159	108	137	
Chloride (mmol/L) Normal to Normal	162	116	139	
Calcium (mmol/L) Normal to Normal	161	114	136	
Magnesium (mmol/L) Normal to Normal	162	111	138	
Phosphate (mmol/L) Normal to Normal	159	112	136	
Blood Urea Nitrogen (mmol/L) Normal to Normal	160	108	137	
Glucose (mmol/L) Normal to Normal	101	69	88	
Albumin (g/L) Normal to Normal	94	60	76	
Alkaline Phosphatase (U/L) Normal to Normal	140	104	129	
Creatinine (umol/L) Normal to Normal	152	107	131	
Creatine Kinase (U/L) Normal to Normal	115	64	100	
Alanine Aminotransferase (U/L) Normal to Normal	131	88	111	
Aspartate Aminotransferase (U/L) Normal to Normal	143	93	120	
Gamma Glutamyl Transferase (U/L) Normal to Normal	149	103	122	
Amylase (U/L) Normal to Normal	128	98	127	
Total Bilirubin (umol/L) Normal to Normal	146	106	123	
Direct Bilirubin (umol/L) Normal to Normal	165	117	143	
C Reactive Protein (mg/L) Normal to Normal	107	70	85	
Cholesterol (mmol/L) Normal to Normal	116	91	102	
Triglycerides (mmol/L) Normal to Normal	124	93	105	
HDL Cholesterol (mmol/L) Normal to Normal	63	37	65	
LDL Cholesterol (mmol/L) Normal to Normal	111	88	101	
Erythrocytes (10 ¹² /L) Normal to Normal	154	113	138	
Leukocytes (10 ⁹ /L) Normal to Normal	148	108	131	
Basophils (10 ⁹ /L) Normal to Normal	154	113	137	
Basophils/Leukocytes (%) Normal to Normal	144	96	125	
Eosinophils (10 ⁹ /L) Normal to Normal	159	112	141	

Eosinophils/Leukocytes (%) Normal to Normal	124	75	113	
Lymphocytes (10 ⁹ /L) Normal to Normal	115	81	89	
Lymphocytes/Leukocytes (%) Normal to Normal	88	56	54	
Monocytes (10 ⁹ /L) Normal to Normal	157	113	138	
Monocytes/Leukocytes (%) Normal to Normal	148	108	131	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) Normal to Normal	154	109	134	
NEUTROPHILS/LEUKOCYTES (%) Normal to Normal	142	101	122	
PLATELETS (10 ⁹ /L) Normal to Normal	153	102	128	
HEMOGLOBIN (g/L) Normal to Normal	158	115	142	
HEMATOCRIT (VOLUME FRACTION) Normal to Normal	158	110	140	
ERY MEAN CORPUSCULAR VOLUME Normal to Normal	128	90	120	
ERY MEAN CORPUSCULAR HEMOGLOBIN Normal to Normal	160	115	141	
ERY. MEAN CORPUSCULAR HGB (g/L) Normal to Normal	164	114	140	
Sodium (mmol/L) Normal to Low	0	0	0	
Potassium (mmol/L) Normal to Low	0	0	0	
Chloride (mmol/L) Normal to Low	0	0	0	
Calcium (mmol/L) Normal to Low	0	0	0	
Magnesium (mmol/L) Normal to Low	0	0	0	
Phosphate (mmol/L) Normal to Low	0	0	0	
Blood Urea Nitrogen (mmol/L) Normal to Low	0	0	0	
Glucose (mmol/L) Normal to Low	0	0	0	
Albumin (g/L) Normal to Low	0	0	0	
Alkaline Phosphatase (U/L) Normal to Low	0	0	0	
Creatinine (umol/L) Normal to Low	0	0	0	
Creatine Kinase (U/L) Normal to Low	0	0	0	
Alanine Aminotransferase (U/L) Normal to Low	0	0	0	
Aspartate Aminotransferase (U/L) Normal to Low	0	0	0	
Gamma Glutamyl Transferase (U/L) Normal to Low	0	0	0	
Amylase (U/L) Normal to Low	1	0	0	
Total Bilirubin (umol/L) Normal to Low	1	0	0	
Direct Bilirubin (umol/L) Normal to Low	0	0	0	
C Reactive Protein (mg/L) Normal to Low	0	0	0	
Cholesterol (mmol/L) Normal to Low	3	3	1	
Triglycerides (mmol/L) Normal to Low	0	1	2	
HDL Cholesterol (mmol/L) Normal to Low	5	1	3	
LDL Cholesterol (mmol/L) Normal to Low	2	3	3	
Erythrocytes (10 ¹² /L) Normal to Low	1	0	0	
Leukocytes (10 ⁹ /L) Normal to Low	2	0	0	
Basophils (10 ⁹ /L) Normal to Low	0	0	0	

Basophils/Leukocytes (%) Normal to Low	0	0	0	
Eosinophils (10 ⁹ /L) Normal to Low	0	0	0	
Eosinophils/Leukocytes (%) Normal to Low	0	0	0	
Lymphocytes (10 ⁹ /L) Normal to Low	0	0	0	
Lymphocytes/Leukocytes (%) Normal to Low	0	0	0	
Monocytes (10 ⁹ /L) Normal to Low	0	0	0	
Monocytes/Leukocytes (%) Normal to Low	0	0	0	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) Normal to Low	3	0	0	
NEUTROPHILS/LEUKOCYTES (%) Normal to Low	1	0	0	
PLATELETS (10 ⁹ /L) Normal to Low	0	0	0	
HEMOGLOBIN (g/L) Normal to Low	1	0	0	
HEMATOCRIT (VOLUME FRACTION) Normal to Low	1	0	0	
ERY MEAN CORPUSCULAR VOLUME Normal to Low	0	0	0	
ERY MEAN CORPUSCULAR HEMOGLOBIN Normal to Low	0	0	0	
ERY. MEAN CORPUSCULAR HGB (g/L) Normal to Low	0	0	0	
Sodium (mmol/L) Normal to High	7	4	4	
Potassium (mmol/L) Normal to High	6	9	6	
Chloride (mmol/L) Normal to High	3	1	3	
Calcium (mmol/L) Normal to High	2	3	3	
Magnesium (mmol/L) Normal to High	3	4	4	
Phosphate (mmol/L) Normal to High	4	4	5	
Blood Urea Nitrogen (mmol/L) Normal to High	6	8	6	
Glucose (mmol/L) Normal to High	40	36	30	
Albumin (g/L) Normal to High	37	30	35	
Alkaline Phosphatase (U/L) Normal to High	9	4	7	
Creatinine (umol/L) Normal to High	7	6	7	
Creatine Kinase (U/L) Normal to High	39	39	36	
Alanine Aminotransferase (U/L) Normal to High	22	22	22	
Aspartate Aminotransferase (U/L) Normal to High	18	20	17	
Gamma Glutamyl Transferase (U/L) Normal to High	5	8	9	
Amylase (U/L) Normal to High	15	9	4	
Total Bilirubin (umol/L) Normal to High	8	5	9	
Direct Bilirubin (umol/L) Normal to High	1	0	0	
C Reactive Protein (mg/L) Normal to High	34	25	35	
Cholesterol (mmol/L) Normal to High	5	4	5	
Triglycerides (mmol/L) Normal to High	7	3	4	
HDL Cholesterol (mmol/L) Normal to High	15	10	9	
LDL Cholesterol (mmol/L) Normal to High	5	4	5	
Erythrocytes (10 ¹² /L) Normal to High	2	0	0	
Leukocytes (10 ⁹ /L) Normal to High	9	11	7	

Basophils (10 ⁹ /L) Normal to High	5	5	2	
Basophils/Leukocytes (%) Normal to High	36	37	26	
Eosinophils (10 ⁹ /L) Normal to High	32	22	41	
Eosinophils/Leukocytes (%) Normal to High	39	26	45	
Lymphocytes (10 ⁹ /L) Normal to High	6	1	4	
Lymphocytes/Leukocytes (%) Normal to High	14	6	8	
Monocytes (10 ⁹ /L) Normal to High	2	0	1	
Monocytes/Leukocytes (%) Normal to High	18	14	14	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) Normal to High	12	10	12	
NEUTROPHILS/LEUKOCYTES (%) Normal to High	15	7	14	
PLATELETS (10 ⁹ /L) Normal to High	7	11	11	
HEMOGLOBIN (g/L) Normal to High	4	0	0	
HEMATOCRIT (VOLUME FRACTION) Normal to High	4	2	0	
ERYT MEAN CORPUSCULAR VOLUME Normal to High	24	16	14	
ERYT MEAN CORPUSCULAR HEMOGLOBIN Normal to High	0	0	0	
ERY. MEAN CORPUSCULAR HGB Normal to High	0	0	0	
Sodium (mmol/L) Low to Normal	0	0	1	
Potassium (mmol/L) Low to Normal	1	0	1	
Chloride (mmol/L) Low to Normal	1	0	1	
Calcium (mmol/L) Low to Normal	2	0	1	
Magnesium (mmol/L) Low to Normal	0	0	0	
Phosphate (mmol/L) Low to Normal	2	0	1	
Blood Urea Nitrogen (mmol/L) Low to Normal	0	0	0	
Glucose (mmol/L) Low to Normal	3	0	2	
Albumin (g/L) Low to Normal	0	0	0	
Alkaline Phosphatase (U/L) Low to Normal	1	2	1	
Creatinine (umol/L) Low to Normal	1	0	0	
Creatine Kinase (U/L) Low to Normal	1	0	0	
Alanine Aminotransferase (U/L) Low to Normal	0	0	0	
Aspartate Aminotransferase (U/L) Low to Normal	0	0	1	
Gamma Glutamyl Transferase (U/L) Low to Normal	0	1	1	
Amylase (U/L) Low to Normal	4	2	4	
Total Bilirubin (umol/L) Low to Normal	5	2	6	
Direct Bilirubin (umol/L) Low to Normal	0	0	0	
C Reactive Protein (mg/L) Low to Normal	0	0	0	
Cholesterol (mmol/L) Low to Normal	14	5	6	
Triglycerides (mmol/L) Low to Normal	3	6	3	
HDL Cholesterol (mmol/L) Low to Normal	4	14	11	
LDL Cholesterol (mmol/L) Low to Normal	12	9	3	
Erythrocytes (10 ¹² /L) Low to Normal	5	2	3	

Leukocytes (10 ⁹ /L) Low to Normal	4	7	6	
Basophils (10 ⁹ /L) Low to Normal	0	0	0	
Basophils/Leukocytes (%) Low to Normal	0	0	0	
Eosinophils (10 ⁹ /L) Low to Normal	0	0	0	
Eosinophils/Leukocytes (%) Low to Normal	0	0	0	
Lymphocytes (10 ⁹ /L) Low to Normal	1	3	1	
Lymphocytes/Leukocytes (%) Low to Normal	1	1	3	
Monocytes (10 ⁹ /L) Low to Normal	5	7	3	
Monocytes/Leukocytes (%) Low to Normal	2	1	3	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) Low to Normal	7	10	5	
NEUTROPHILS/LEUKOCYTES (%) Low to Normal	4	7	3	
PLATELETS (10 ⁹ /L) Low to Normal	1	1	2	
HEMOGLOBIN (g/L) Low to Normal	1	0	1	
HEMATOCRIT (VOLUME FRACTION) Low to Normal	1	4	2	
ERY MEAN CORPUSCULAR VOLUME Low to Normal	6	3	4	
ERY MEAN CORPUSCULAR HEMOGLOBIN Low to Normal	3	0	1	
ERY. MEAN CORPUSCULAR HGB Low to Normal	0	3	2	
Sodium (mmol/L) Low to Low	0	0	0	
Potassium (mmol/L) Low to Low	0	0	0	
Chloride (mmol/L) Low to Low	0	0	0	
Calcium (mmol/L) Low to Low	0	0	0	
Magnesium (mmol/L) Low to Low	0	0	0	
Phosphate (mmol/L) Low to Low	0	0	0	
Blood Urea Nitrogen (mmol/L) Low to Low	0	0	0	
Glucose (mmol/L) Low to Low	0	0	0	
Albumin (g/L) Low to Low	0	0	0	
Alkaline Phosphatase (U/L) Low to Low	1	0	0	
Creatinine (umol/L) Low to Low	0	0	0	
Creatine Kinase (U/L) Low to Low	0	0	0	
Alanine Aminotransferase (U/L) Low to Low	0	0	0	
Aspartate Aminotransferase (U/L) Low to Low	0	0	0	
Gamma Glutamyl Transferase (U/L) Low to Low	2	0	0	
Amylase (U/L) Low to Low	3	0	0	
Total Bilirubin (umol/L) Low to Low	0	0	0	
Direct Bilirubin (umol/L) Low to Low	0	0	0	
C Reactive Protein (mg/L) Low to Low	0	0	0	
Cholesterol (mmol/L) Low to Low	2	5	0	
Triglycerides (mmol/L) Low to Low	0	1	0	
HDL Cholesterol (mmol/L) Low to Low	18	22	14	
LDL Cholesterol (mmol/L) Low to Low	8	4	10	
Erythrocytes (10 ¹² /L) Low to Low	1	1	1	
Leukocytes (10 ⁹ /L) Low to Low	0	0	0	

Basophils (10 ⁹ /L) Low to Low	0	0	0	
Basophils/Leukocytes (%) Low to Low	0	0	0	
Eosinophils (10 ⁹ /L) Low to Low	0	0	0	
Eosinophils/Leukocytes (%) Low to Low	0	0	0	
Lymphocytes (10 ⁹ /L) Low to Low	0	0	0	
Lymphocytes/Leukocytes (%) Low to Low	0	0	0	
Monocytes (10 ⁹ /L) Low to Low	2	1	4	
Monocytes/Leukocytes (%) Low to Low	0	0	0	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) Low to Low	0	0	0	
NEUTROPHILS/LEUKOCYTES (%) Low to Low	0	0	0	
PLATELETS (10 ⁹ /L) Low to Low	0	0	0	
HEMOGLOBIN (g/L) Low to Low	0	1	0	
HEMATOCRIT (VOLUME FRACTION) Low to Low	0	0	0	
ERY MEAN CORPUSCULAR VOLUME Low to Low	1	2	1	
ERYT MEAN CORPUSCULAR HEMOGLOBIN Low to Low	1	2	1	
ERY. MEAN CORPUSCULAR HGB (g/L) Low to Low	0	0	0	
Sodium (mmol/L) Low to High	0	0	0	
Potassium (mmol/L) Low to High	0	0	0	
Chloride (mmol/L) Low to High	0	0	0	
Calcium (mmol/L) Low to High	0	0	0	
Magnesium (mmol/L) Low to High	0	0	0	
Phosphate (mmol/L) Low to High	0	0	0	
Blood Urea Nitrogen (mmol/L) Low to High	0	0	0	
Glucose (mmol/L) Low to High	0	0	0	
Albumin (g/L) Low to High	0	0	0	
Alkaline Phosphatase (U/L) Low to High	0	0	0	
Creatinine (umol/L) Low to High	0	0	0	
Creatine Kinase (U/L) Low to High	0	0	0	
Alanine Aminotransferase (U/L) Low to High	0	0	0	
Aspartate Aminotransferase (U/L) Low to High	0	0	0	
Gamma Glutamyl Transferase (U/L) Low to High	0	0	0	
Amylase (U/L) Low to High	0	0	0	
Total Bilirubin (umol/L) Low to High	0	0	0	
Direct Bilirubin (umol/L) Low to High	0	0	0	
C Reactive Protein (mg/L) Low to High	0	0	0	
Cholesterol (mmol/L) Low to High	0	0	0	
Triglycerides (mmol/L) Low to High	0	0	0	
HDL Cholesterol (mmol/L) Low to High	0	0	0	
LDL Cholesterol (mmol/L) Low to High	0	0	0	
Erythrocytes (10 ¹² /L) Low to High	0	0	0	
Leukocytes (10 ⁹ /L) Low to High	0	0	0	
Basophils (10 ⁹ /L) Low to High	0	0	0	
Basophils/Leukocytes (%) Low to High	0	0	0	
Eosinophils (10 ⁹ /L) Low to High	0	0	0	

Eosinophils/Leukocytes (%) Low to High	0	0	0	
Lymphocytes (10 ⁹ /L) Low to High	0	0	0	
Lymphocytes/Leukocytes (%) Low to High	0	0	0	
Monocytes (10 ⁹ /L) Low to High	0	0	0	
Monocytes/Leukocytes (%) Low to High	0	0	0	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) Low to High	0	0	1	
NEUTROPHILS/LEUKOCYTES (%) Low to High	0	0	0	
PLATELETS (10 ⁹ /L) Low to High	0	0	0	
HEMOGLOBIN (g/L) Low to High	0	0	0	
HEMATOCRIT (VOLUME FRACTION) Low to High	0	0	0	
ERYT MEAN CORPUSCULAR VOLUME Low to High	0	0	0	
ERYT MEAN CORPUSCULAR HEMOGLOBIN Low to High	0	0	0	
ERY. MEAN CORPUSCULAR HGB (g/L) Low to High	0	0	0	
Sodium (mmol/L) High to Normal	1	0	0	
Potassium (mmol/L) High to Normal	0	0	0	
Chloride (mmol/L) High to Normal	0	0	0	
Calcium (mmol/L) High to Normal	1	0	3	
Magnesium (mmol/L) High to Normal	0	1	0	
Phosphate (mmol/L) High to Normal	0	0	1	
Blood Urea Nitrogen (mmol/L) High to Normal	0	0	0	
Glucose (mmol/L) High to Normal	5	2	2	
Albumin (g/L) High to Normal	10	2	9	
Alkaline Phosphatase (U/L) High to Normal	3	1	1	
Creatinine (umol/L) High to Normal	1	0	1	
Creatine Kinase (U/L) High to Normal	4	4	0	
Alanine Aminotransferase (U/L) High to Normal	2	1	3	
Aspartate Aminotransferase (U/L) High to Normal	2	0	1	
Gamma Glutamyl Transferase (U/L) High to Normal	2	0	1	
Amylase (U/L) High to Normal	3	0	0	
Total Bilirubin (umol/L) High to Normal	2	0	0	
Direct Bilirubin (umol/L) High to Normal	0	0	0	
C Reactive Protein (mg/L) High to Normal	1	4	4	
Cholesterol (mmol/L) High to Normal	3	3	2	
Triglycerides (mmol/L) High to Normal	6	3	7	
HDL Cholesterol (mmol/L) High to Normal	5	5	5	
LDL Cholesterol (mmol/L) High to Normal	2	0	2	
Erythrocytes (10 ¹² /L) High to Normal	0	0	0	
Leukocytes (10 ⁹ /L) High to Normal	2	1	3	
Basophils (10 ⁹ /L) High to Normal	0	0	0	
Basophils/Leukocytes (%) High to Normal	2	3	4	
Eosinophils (10 ⁹ /L) High to Normal	3	1	3	

Eosinophils/Leukocytes (%) High to Normal	7	7	4	
Lymphocytes (10 ⁹ /L) High to Normal	0	0	0	
Lymphocytes/Leukocytes (%) High to Normal	0	0	1	
Monocytes (10 ⁹ /L) High to Normal	0	0	0	
Monocytes/Leukocytes (%) High to Normal	0	0	1	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) High to Normal	1	1	3	
NEUTROPHILS/LEUKOCYTES (%) High to Normal	1	1	3	
PLATELETS (10 ⁹ /L) High to Normal	1	0	0	
HEMOGLOBIN (g/L) High to Normal	0	0	0	
HEMATOCRIT (VOLUME FRACTION) High to Normal	0	0	0	
ERY MEAN CORPUSCULAR VOLUME High to Normal	1	1	0	
ERY MEAN CORPUSCULAR HEMOGLOBIN High to Normal	0	0	0	
ERY. MEAN CORPUSCULAR HGB High to Normal	0	0	0	
Sodium (mmol/L) High to Low	0	0	0	
Potassium (mmol/L) High to Low	0	0	0	
Chloride (mmol/L) High to Low	0	0	0	
Calcium (mmol/L) High to Low	0	0	0	
Magnesium (mmol/L) High to Low	0	0	0	
Phosphate (mmol/L) High to Low	0	0	0	
Blood Urea Nitrogen (mmol/L) High to Low	0	0	0	
Glucose (mmol/L) High to Low	0	0	0	
Albumin (g/L) High to Low	0	0	0	
Alkaline Phosphatase (U/L) High to Low	0	0	0	
Creatinine (umol/L) High to Low	0	0	0	
Creatine Kinase (U/L) High to Low	0	0	0	
Alanine Aminotransferase (U/L) High to Low	0	0	0	
Aspartate Aminotransferase (U/L) High to Low	0	0	0	
Gamma Glutamyl Transferase (U/L) High to Low	0	0	0	
Amylase (U/L) High to Low	0	0	0	
Total Bilirubin (umol/L) High to Low	0	0	0	
Direct Bilirubin (umol/L) High to Low	0	0	0	
C Reactive Protein (mg/L) High to Low	0	0	0	
Cholesterol (mmol/L) High to Low	0	0	0	
Triglycerides (mmol/L) High to Low	0	0	0	
HDL Cholesterol (mmol/L) High to Low	0	0	0	
LDL Cholesterol (mmol/L) High to Low	0	0	0	
Erythrocytes (10 ¹² /L) High to Low	0	0	0	
Leukocytes (10 ⁹ /L) High to Low	0	0	0	
Basophils (10 ⁹ /L) High to Low	0	0	0	
Basophils/Leukocytes (%) High to Low	0	0	0	
Eosinophils (10 ⁹ /L) High to Low	0	0	0	
Eosinophils/Leukocytes (%) High to Low	0	0	0	
Lymphocytes (10 ⁹ /L) High to Low	0	0	0	

Lymphocytes/Leukocytes (%) High to Low	0	0	0	
Monocytes (10 ⁹ /L) High to Low	0	0	0	
Monocytes/Leukocytes (%) High to Low	0	0	0	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) High to Low	0	0	0	
NEUTROPHILS/LEUKOCYTES (%) High to Low	0	0	0	
PLATELETS (10 ⁹ /L) High to Low	0	0	0	
HEMOGLOBIN (g/L) High to Low	0	0	0	
HEMATOCRIT (VOLUME FRACTION) High to Low	0	0	0	
ERY MEAN CORPUSCULAR VOLUME High to Low	0	0	0	
ERY MEAN CORPUSCULAR HEMOGLOBIN High to Low	0	0	0	
ERY. MEAN CORPUSCULAR HGB (g/L) High to Low	0	0	0	
Sodium (mmol/L) High to High	0	0	0	
Potassium (mmol/L) High to High	0	0	0	
Chloride (mmol/L) High to High	0	0	0	
Calcium (mmol/L) High to High	0	0	0	
Magnesium (mmol/L) High to High	1	1	1	
Phosphate (mmol/L) High to High	1	1	0	
Blood Urea Nitrogen (mmol/L) High to High	0	1	0	
Glucose (mmol/L) High to High	17	10	21	
Albumin (g/L) High to High	25	25	23	
Alkaline Phosphatase (U/L) High to High	12	6	5	
Creatinine (umol/L) High to High	5	4	4	
Creatine Kinase (U/L) High to High	7	10	7	
Alanine Aminotransferase (U/L) High to High	11	6	7	
Aspartate Aminotransferase (U/L) High to High	3	4	4	
Gamma Glutamyl Transferase (U/L) High to High	8	10	10	
Amylase (U/L) High to High	12	6	8	
Total Bilirubin (umol/L) High to High	4	4	5	
Direct Bilirubin (umol/L) High to High	0	5	0	
C Reactive Protein (mg/L) High to High	18	8	13	
Cholesterol (mmol/L) High to High	1	4	2	
Triglycerides (mmol/L) High to High	3	0	5	
HDL Cholesterol (mmol/L) High to High	33	9	19	
LDL Cholesterol (mmol/L) High to High	2	3	1	
Erythrocytes (10 ¹² /L) High to High	1	6	2	
Leukocytes (10 ⁹ /L) High to High	3	25	2	
Basophils (10 ⁹ /L) High to High	0	2	0	
Basophils/Leukocytes (%) High to High	2	1	0	
Eosinophils (10 ⁹ /L) High to High	14	2	10	
Eosinophils/Leukocytes (%) High to High	30	0	40	
Lymphocytes (10 ⁹ /L) High to High	0	2	0	
Lymphocytes/Leukocytes (%) High to High	1	13	0	
Monocytes (10 ⁹ /L) High to High	1	28	1	

Monocytes/Leukocytes (%) High to High	4	0	1	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) High to High	3	2	2	
NEUTROPHILS/LEUKOCYTES (%) High to High	1	0	0	
PLATELETS (10 ⁹ /L) High to High	1	5	0	
HEMOGLOBIN (g/L) High to High	0	3	3	
HEMATOCRIT (VOLUME FRACTION) High to High	0	1	0	
ERY MEAN CORPUSCULAR VOLUME High to High	4	3	0	
ERYT MEAN CORPUSCULAR HEMOGLOBIN High to High	1	1	0	
ERY. MEAN CORPUSCULAR HGB High to High	1	1	0	
Sodium (mmol/L) Missing	1	5	0	
Potassium (mmol/L) Missing	1	0	0	
Chloride (mmol/L) Missing	1	0	0	
Calcium (mmol/L) Missing	1	0	0	
Magnesium (mmol/L) Missing	1	0	0	
Phosphate (mmol/L) Missing	1	0	0	
Blood Urea Nitrogen (mmol/L) Missing	1	0	0	
Glucose (mmol/L) Missing	1	0	0	
Albumin (g/L) Missing	1	0	0	
Alkaline Phosphatase (U/L) Missing	1	0	0	
Creatinine (umol/L) Missing	1	0	0	
Creatine Kinase (U/L) Missing	1	0	0	
Alanine Aminotransferase (U/L) Missing	1	0	0	
Aspartate Aminotransferase (U/L) Missing	1	0	0	
Gamma Glutamyl Transferase (U/L) Missing	1	0	0	
Amylase (U/L) Missing	1	0	0	
Total Bilirubin (umol/L) Missing	1	0	0	
Direct Bilirubin (umol/L) Missing	1	0	0	
C Reactive Protein (mg/L) Missing	7	9	6	
Cholesterol (mmol/L) Missing	23	3	16	
Triglycerides (mmol/L) Missing	24	4	17	
HDL Cholesterol (mmol/L) Missing	24	3	17	
LDL Cholesterol (mmol/L) Missing	25	7	18	
Erythrocytes (10 ¹² /L) Missing	3	0	0	
Leukocytes (10 ⁹ /L) Missing	3	0	0	
Basophils (10 ⁹ /L) Missing	3	0	0	
Basophils/Leukocytes (%) Missing	3	0	0	
Eosinophils (10 ⁹ /L) Missing	3	0	0	
Eosinophils/Leukocytes (%) Missing	3	0	0	
Lymphocytes (10 ⁹ /L) Missing	3	0	0	
Lymphocytes/Leukocytes (%) Missing	3	0	0	
Monocytes (10 ⁹ /L) Missing	3	0	0	
Monocytes/Leukocytes (%) Missing	3	0	0	
NEUTROPHILS, SEGMENTED (10 ⁹ /L) Missing	3	0	0	
NEUTROPHILS/LEUKOCYTES (%) Missing	3	0	0	
PLATELETS (10 ⁹ /L) Missing	4	0	0	

HEMOGLOBIN (g/L) Missing	3	0	0	
HEMATOCRIT (VOLUME FRACTION) Missing	3	0	1	
ERY MEAN CORPUSCULAR VOLUME Missing	3	0	1	
ERY MEAN CORPUSCULAR HEMOGLOBIN Missing	3	0	0	
ERY. MEAN CORPUSCULAR HGB Missing	3	0	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Post-Baseline Vital Sign Abnormalities

End point title	Number of Participants with Post-Baseline Vital Sign Abnormalities
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End point description:

Vital signs like heart rate (beats per minute) and systolic blood pressure (mmHg) and diastolic blood pressure (mmHg) was measured to assess the abnormalities.

End point type	Secondary
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End point timeframe:

From first dose (Day 1) till up to Week 48

End point values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W	Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	167	117	143	
Units: participants				
Hear rate (> 100 AND CHANGE FROM BASELINE > 30)	6	1	3	
Hear rate (< 55 AND CHANGE FROM BASELINE < -15)	0	0	0	
SBP (> 140 AND CHANGE FROM BASELINE > 20)	16	11	15	
SBP (< 90 AND CHANGE FROM BASELINE < -20)	0	0	0	
DBP > 90 AND CHANGE FROM BASELINE > 10	18	21	25	
DBP < 55 AND CHANGE FROM BASELINE < -10	4	6	8	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physical Parameters - Height at Week 24

End point title	Change from Baseline in Physical Parameters - Height at Week 24
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End point description:

Height was measured at specified timepoints to assess the change from baseline.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 24

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	225	115		
Units: cm				
arithmetic mean (standard deviation)	0.30 (\pm 1.479)	-0.08 (\pm 0.932)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physical Parameters - Height at Week 48

End point title	Change from Baseline in Physical Parameters - Height at Week 48
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End point description:

Height was measured at specified timepoints to assess the change from baseline.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 48

End point values	Maintenance Phase - Placebo	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	75	88	96	
Units: cm				
arithmetic mean (standard deviation)	0.12 (\pm 1.114)	0.42 (\pm 1.929)	0.42 (\pm 1.973)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physical Parameters - Weight at Week 24

End point title	Change from Baseline in Physical Parameters - Weight at Week 24
End point description: Weight was measured at specified timepoints to assess the change from baseline.	
End point type	Secondary
End point timeframe: Baseline (Day 1) and Week 24	

End point values	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	257	133		
Units: kg				
arithmetic mean (standard deviation)	0.35 (± 3.369)	0.24 (± 3.108)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physical Parameters - Weight at Week 48

End point title	Change from Baseline in Physical Parameters - Weight at Week 48
End point description: Weight was measured at specified timepoints to assess the change from baseline.	
End point type	Secondary
End point timeframe: Baseline (Day 1) and Week 48	

End point values	Maintenance Phase - Placebo	Maintenance Phase - CC-93538 360 mg QW	Maintenance Phase - CC-93538 360 mg Q2W	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	82	107	110	
Units: cm				
arithmetic mean (standard deviation)	0.22 (± 4.270)	0.11 (± 4.908)	1.26 (± 4.766)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physical Parameters - Body Mass Index at Week 24

End point title	Change from Baseline in Physical Parameters - Body Mass Index at Week 24
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End point description:

Data was collected for height and weight to assess body mass index.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 24

End point values	Induction Phase - Placebo	Induction Phase - CC-93538 360 mg QW		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	133	256		
Units: kg/m ²				
arithmetic mean (standard deviation)	0.084 (± 1.0676)	0.044 (± 1.1629)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Physical Parameters - Body Mass Index at Week 48

End point title	Change from Baseline in Physical Parameters - Body Mass Index at Week 48
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End point description:

Data was collected for height and weight to assess body mass index.

End point type	Secondary
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End point timeframe:

Baseline (Day 1) and Week 48

End point values	Maintenance Phase - Placebo	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - CC-93538 360 mg QW	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	82	110	106	
Units: kg/m ²				
arithmetic mean (standard deviation)	0.037 (± 1.4223)	0.350 (± 1.5218)	-0.074 (± 1.6716)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-Drug Antibodies (ADA)

End point title	Number of Participants with Anti-Drug Antibodies (ADA)
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End point description:

ADA status were categorized as Baseline ADA Positive: Pre-existing Immunoreactivity (baseline positive and 1) post baseline negative or 2) titer < 4-fold baseline titer). NAb+/baseline ADA+: At least one ADA positive sample with positive NAb in subject with pre-existing immunoreactivity. ADA Positive Status: 1) at least one positive response post first dose given negative or missing baseline; or 2) at least one post-baseline with titer greater than or equal to 4-fold of baseline titer given positive baseline. NAb+/ADA+: At least one ADA positive sample with positive NAb in ADA positive subjects.

End point type	Secondary
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End point timeframe:

Pre-dose Week 24 and Pre-dose Week 48

End point values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	167	117		
Units: participants				
BASELINE ADA POSITIVE (Week 24)	6	7		
BASELINE ADA POSITIVE (Week 48)	4	6		
NAB+/BASELINE ADA+ (Week 24)	2	1		
NAB+/BASELINE ADA+ (Week 48)	1	1		
ADA POSITIVE (Week 24)	12	13		
ADA POSITIVE (Week 48)	8	12		
NAB+/ADA+ (Week 24)	4	7		
NAB+/ADA+ (Week 48)	1	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Trough Concentration of CC-93538 at Week 24 and Week 48

End point title	Serum Trough Concentration of CC-93538 at Week 24 and Week 48
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End point description:

Blood samples were collected to assess trough concentration of CC-93538. The Evaluable PK population is defined as all participants in the PK population who have at least one evaluable trough concentration.

End point type	Secondary
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End point timeframe:

Pre-dose Week 24 and Pre-dose Week 48

End point values	CC-93538 360 mg QW	CC-93538 360 mg QW/Q2W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	97		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Pre-dose Week 24	148133.6 (± 69.9)	151735.2 (± 55.8)		
Pre-dose Week 48	138545.4 (± 121.1)	79884.3 (± 45.4)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All Serious AEs, Non-Serious AEs and all cause mortality were collected from signing of informed consent form (Day -28) until 16 weeks after the last dose of IP was administered (Up to approximately 21 months).

Adverse event reporting additional description:

The Safety population consist of all randomized subjects who received at least 1 dose of IP and analyzed based on the actual treatments they received.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.0
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Reporting groups

Reporting group title	Induction Phase - CC-93538 360 mg QW
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Reporting group description:

Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week induction phase.

Reporting group title	Induction Phase - Placebo
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Reporting group description:

Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week induction phase.

Reporting group title	Maintenance Phase - Placebo
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Reporting group description:

Participants with Eosinophilic Esophagitis received 360 mg CC-93538 matching placebo SC once every week in the 24 week maintenance phase.

Reporting group title	Maintenance Phase - CC-93538 360 mg Q2W
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Reporting group description:

Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every other week in the 24 week maintenance phase.

Reporting group title	Maintenance Phase - CC-93538 360 mg QW
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Reporting group description:

Participants with Eosinophilic Esophagitis received 360 mg CC-93538 SC once every week in the 24 week maintenance phase.

Serious adverse events	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo	Maintenance Phase - Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 284 (1.76%)	4 / 143 (2.80%)	8 / 143 (5.59%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Overdose			

subjects affected / exposed	1 / 284 (0.35%)	0 / 143 (0.00%)	0 / 143 (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
Traumatic haematoma			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	0 / 143 (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
Road traffic accident			
subjects affected / exposed	0 / 284 (0.00%)	1 / 143 (0.70%)	1 / 143 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	1 / 143 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 284 (0.35%)	0 / 143 (0.00%)	0 / 143 (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
Nervous system disorders			
Cerebral infarction			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	0 / 143 (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
Migraine			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	0 / 143 (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			
Complication associated with device			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	0 / 143 (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			
Eosinophilic oesophagitis			
subjects affected / exposed	2 / 284 (0.70%)	1 / 143 (0.70%)	1 / 143 (0.70%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	1 / 143 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	1 / 284 (0.35%)	0 / 143 (0.00%)	0 / 143 (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			
Depression suicidal			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	1 / 143 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	1 / 143 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	0 / 143 (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			
Arthralgia			
subjects affected / exposed	0 / 284 (0.00%)	1 / 143 (0.70%)	1 / 143 (0.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 284 (0.00%)	1 / 143 (0.70%)	2 / 143 (1.40%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 284 (0.00%)	0 / 143 (0.00%)	0 / 143 (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	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - CC-93538 360 mg QW	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 117 (3.42%)	4 / 167 (2.40%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 117 (0.00%)	1 / 167 (0.60%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma			
subjects affected / exposed	1 / 117 (0.85%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 117 (0.00%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 117 (0.00%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			

subjects affected / exposed	1 / 117 (0.85%)	0 / 167 (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			
Cerebral infarction			
subjects affected / exposed	0 / 117 (0.00%)	1 / 167 (0.60%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			
subjects affected / exposed	1 / 117 (0.85%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Complication associated with device			
subjects affected / exposed	1 / 117 (0.85%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Eosinophilic oesophagitis			
subjects affected / exposed	0 / 117 (0.00%)	2 / 167 (1.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 117 (0.00%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	0 / 117 (0.00%)	1 / 167 (0.60%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Depression suicidal			

subjects affected / exposed	0 / 117 (0.00%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status changes			
subjects affected / exposed	0 / 117 (0.00%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 117 (0.85%)	0 / 167 (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			
Arthralgia			
subjects affected / exposed	0 / 117 (0.00%)	0 / 167 (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	0 / 117 (0.00%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 117 (0.85%)	0 / 167 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Induction Phase - CC-93538 360 mg QW	Induction Phase - Placebo	Maintenance Phase - Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	150 / 284 (52.82%)	62 / 143 (43.36%)	69 / 143 (48.25%)
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	26 / 284 (9.15%) 40	10 / 143 (6.99%) 12	14 / 143 (9.79%) 17
General disorders and administration site conditions Injection site reaction subjects affected / exposed occurrences (all)	48 / 284 (16.90%) 169	20 / 143 (13.99%) 29	21 / 143 (14.69%) 34
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	8 / 284 (2.82%) 19 12 / 284 (4.23%) 13 12 / 284 (4.23%) 13 12 / 284 (4.23%) 19	5 / 143 (3.50%) 6 2 / 143 (1.40%) 2 2 / 143 (1.40%) 2 8 / 143 (5.59%) 9	5 / 143 (3.50%) 6 4 / 143 (2.80%) 4 6 / 143 (4.20%) 7 9 / 143 (6.29%) 10
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all) Arthralgia subjects affected / exposed occurrences (all)	7 / 284 (2.46%) 7 11 / 284 (3.87%) 11	3 / 143 (2.10%) 3 5 / 143 (3.50%) 5	4 / 143 (2.80%) 4 6 / 143 (4.20%) 6
Infections and infestations COVID-19 subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all) Upper respiratory tract infection	40 / 284 (14.08%) 40 8 / 284 (2.82%) 9	15 / 143 (10.49%) 15 1 / 143 (0.70%) 1	21 / 143 (14.69%) 21 2 / 143 (1.40%) 2

subjects affected / exposed	20 / 284 (7.04%)	10 / 143 (6.99%)	12 / 143 (8.39%)
occurrences (all)	20	10	15
Nasopharyngitis			
subjects affected / exposed	23 / 284 (8.10%)	10 / 143 (6.99%)	13 / 143 (9.09%)
occurrences (all)	27	11	15
Influenza			
subjects affected / exposed	5 / 284 (1.76%)	2 / 143 (1.40%)	4 / 143 (2.80%)
occurrences (all)	5	2	4
Gastroenteritis			
subjects affected / exposed	9 / 284 (3.17%)	1 / 143 (0.70%)	2 / 143 (1.40%)
occurrences (all)	9	1	2

Non-serious adverse events	Maintenance Phase - CC-93538 360 mg Q2W	Maintenance Phase - CC-93538 360 mg QW	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	73 / 117 (62.39%)	103 / 167 (61.68%)	
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 117 (5.98%)	20 / 167 (11.98%)	
occurrences (all)	8	45	
General disorders and administration site conditions			
Injection site reaction			
subjects affected / exposed	20 / 117 (17.09%)	32 / 167 (19.16%)	
occurrences (all)	96	155	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	6 / 117 (5.13%)	7 / 167 (4.19%)	
occurrences (all)	17	7	
Vomiting			
subjects affected / exposed	10 / 117 (8.55%)	6 / 167 (3.59%)	
occurrences (all)	11	7	
Nausea			
subjects affected / exposed	6 / 117 (5.13%)	11 / 167 (6.59%)	
occurrences (all)	7	11	
Diarrhoea			
subjects affected / exposed	8 / 117 (6.84%)	8 / 167 (4.79%)	
occurrences (all)	18	10	

Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	6 / 117 (5.13%)	7 / 167 (4.19%)	
occurrences (all)	7	7	
Arthralgia			
subjects affected / exposed	9 / 117 (7.69%)	8 / 167 (4.79%)	
occurrences (all)	9	8	
Infections and infestations			
COVID-19			
subjects affected / exposed	28 / 117 (23.93%)	29 / 167 (17.37%)	
occurrences (all)	29	31	
Urinary tract infection			
subjects affected / exposed	5 / 117 (4.27%)	9 / 167 (5.39%)	
occurrences (all)	8	10	
Upper respiratory tract infection			
subjects affected / exposed	11 / 117 (9.40%)	17 / 167 (10.18%)	
occurrences (all)	15	18	
Nasopharyngitis			
subjects affected / exposed	14 / 117 (11.97%)	16 / 167 (9.58%)	
occurrences (all)	20	24	
Influenza			
subjects affected / exposed	6 / 117 (5.13%)	3 / 167 (1.80%)	
occurrences (all)	6	4	
Gastroenteritis			
subjects affected / exposed	4 / 117 (3.42%)	10 / 167 (5.99%)	
occurrences (all)	4	11	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 September 2023	The purpose of this amendment was to update the statistical methodology, revise the study discontinuation criteria per Health Authority feedback, add the Pre-filled Syringe (PFS) Administration Questionnaire, as well as align this protocol with guidance provided across the development program.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported