



Clinical trial results:

A Randomized, Double-Blind, Placebo-Controlled, 52-Week Study to Assess the Efficacy and Safety of Etrasimod in Subjects with Moderately Active Ulcerative Colitis

Summary

EudraCT number	2020-003507-34
Trial protocol	CZ BE FR HU PT BG IT
Global end of trial date	19 June 2024

Results information

Result version number	v1 (current)
This version publication date	04 July 2025
First version publication date	04 July 2025

Trial information

Trial identification

Sponsor protocol code	APD334-210
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04607837
WHO universal trial number (UTN)	-
Other trial identifiers	C5041011: C5041011

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	66 Hudson Boulevard East, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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	10 April 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to assess the efficacy of etrasimod on clinical remission in participants with moderately active ulcerative colitis (UC) after 52 weeks of treatment.

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 Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 April 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 36
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	France: 4
Country: Number of subjects enrolled	Germany: 1
Country: Number of subjects enrolled	Italy: 13
Country: Number of subjects enrolled	Portugal: 1
Country: Number of subjects enrolled	Spain: 1
Country: Number of subjects enrolled	Belarus: 20
Country: Number of subjects enrolled	Bulgaria: 7
Country: Number of subjects enrolled	Czechia: 9
Country: Number of subjects enrolled	Georgia: 30
Country: Number of subjects enrolled	Hungary: 9
Country: Number of subjects enrolled	Poland: 35
Country: Number of subjects enrolled	Russian Federation: 24
Country: Number of subjects enrolled	Ukraine: 17
Country: Number of subjects enrolled	Australia: 9
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	Korea, Republic of: 10
Worldwide total number of subjects	233
EEA total number of subjects	84

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	223
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants with moderately active ulcerative colitis (UC) were enrolled in the study.

Pre-assignment

Screening details:

A total of 234 participants were enrolled in the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

This was a double-blind study. The treatment each participant received was not disclosed to the Investigator, study site staff, subject, Sponsor personnel involved with the conduct of the study (with the exception of the clinical supply staff and designated safety staff), or study vendors

Arms

Are arms mutually exclusive?	Yes
Arm title	Etrasimod

Arm description:

Participants with moderately active UC were randomised to receive Etrasimod 2 milligrams (mg) tablet orally once daily (QD) for 52-Week.

Arm type	Experimental
Investigational medicinal product name	Etrasimod
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants were randomized to receive Etrasimod 2 mg tablet orally daily.

Arm title	Placebo
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Arm description:

Participants with moderately active UC were randomised to receive placebo matched to Etrasimod tablet orally QD for 52-Week.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants were randomized to receive placebo matching to Etrasimod tablet orally daily.

Number of subjects in period 1	Etrasimod	Placebo
Started	154	79
Safety set	154	79
Primary analysis set	127	60
Completed	97	34
Not completed	57	45
Consent withdrawn by subject	8	7
Physician decision	2	-
Adverse event, non-fatal	8	2
Study termination by sponsor	1	-
Disease worsening	36	36
Lack of efficacy	2	-

Baseline characteristics

Reporting groups

Reporting group title	Etrasimod
Reporting group description:	
Participants with moderately active UC were randomised to receive Etrasimod 2 milligrams (mg) tablet orally once daily (QD) for 52-Week.	
Reporting group title	Placebo
Reporting group description:	
Participants with moderately active UC were randomised to receive placebo matched to Etrasimod tablet orally QD for 52-Week.	

Reporting group values	Etrasimod	Placebo	Total
Number of subjects	154	79	233
Age categorical			
Units: Subjects			
In Utero	0	0	0
Preterm newborn infants (gestional 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
12 - 17 years	0	0	0
Adults (18 - 64 years)	147	76	223
From 65 - 84 years	7	3	10
85 years and over	0	0	0
Age continuous			
Units: years			
arithmetic mean	41.6	40.8	
standard deviation	± 13.15	± 13.00	-
Gender categorical			
Units: Subjects			
Male	91	39	130
Female	63	40	103
Race			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	8	7	15
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	1	3
White	143	67	210
More than one race	0	0	0
Unknown or Not Reported	1	4	5
Ethnicity			
Units: Subjects			
Hispanic or Latino	6	6	12
Not Hispanic or Latino	146	73	219
Unknown or Not Reported	2	0	2

End points

End points reporting groups

Reporting group title	Etrasimod
Reporting group description: Participants with moderately active UC were randomised to receive Etrasimod 2 milligrams (mg) tablet orally once daily (QD) for 52-Week.	
Reporting group title	Placebo
Reporting group description: Participants with moderately active UC were randomised to receive placebo matched to Etrasimod tablet orally QD for 52-Week.	

Primary: Percentage of Participants Achieving Clinical Remission (CR) at Week 52 Using Modified Mayo Score (MMS)

End point title	Percentage of Participants Achieving Clinical Remission (CR) at Week 52 Using Modified Mayo Score (MMS)
End point description: MMS assesses UC disease activity with three components: endoscopic score(ES),rectal bleeding(RB),stool frequency(SF).Each component score ranges from 0 to 3(0=normal,1=mild,2=moderate,3=severe); higher scores indicating more severe disease.ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, scores ranged from 0(normal or inactive disease) to 3(severe disease [spontaneous bleeding, ulceration]).RB reported most severe amount of blood passed per rectum in 24-hour period, scores ranged from 0(no blood seen) to 3(blood alone passes).SF reported number of stools in 24-hour period relative to normal number of stools for that participant in same period,scores ranged from 0(normal number of stools) to 3(5 or more stools than normal).CR per FDA draft guidance defined as:SF=0 or 1 and no greater than baseline, RB=0,ES less than or equal to (\leq)1(excluding friability).Percentage of participants achieving CR at Week 52 was evaluated. Primary analysis set was analysed.	
End point type	Primary
End point timeframe: Week 52	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	26.0	18.3		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description: Difference (%) for etrasimod minus placebo was based on estimated common risk difference using the Mantel- Haenszel weights. The 2-sided p-value was used to test the hypothesis of the risk difference being 0.	
Comparison groups	Placebo v Etrasimod

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2524
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	7.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.24
upper limit	19.94

Secondary: Percentage of Participants Achieving Clinical Remission at Week 12 Using MMS

End point title	Percentage of Participants Achieving Clinical Remission at Week 12 Using MMS
End point description:	
MMS assesses UC disease activity with three components: ES, RB and SF. Each component score ranges from 0 to 3 (0=normal, 1=mild, 2=moderate, 3=severe); higher scores indicating more severe disease. ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, scores ranged from 0 (normal or inactive disease) to 3 (severe disease [spontaneous bleeding, ulceration]). RB reported the most severe amount of blood passed per rectum in a 24-hour period; scores ranged from 0 (no blood seen) to 3 (blood alone passes). SF reported number of stools in a 24-hour period relative to normal number of stools for that participant in the same period, score ranged from 0 (normal number of stools) to 3 (5 or more stools than normal). CR per FDA draft guidance was defined as: SF=0 or =1 and no greater than baseline, RB=0, and ES <=1 (excluding friability). Percentage of participants achieving CR at Week 12 was evaluated in this endpoint. Primary analysis set was analysed.	
End point type	Secondary
End point timeframe:	
Week 12	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	28.3	11.7		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description:	
Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.	
Comparison groups	Etrasimod v Placebo

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0068
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	15.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.31
upper limit	26.91

Secondary: Percentage of Participants Achieving Endoscopic Improvement at Week 52

End point title	Percentage of Participants Achieving Endoscopic Improvement at Week 52
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End point description:

Endoscopic improvement was defined as ES ≤1 (excluding friability). ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, score ranged from 0 (normal or inactive disease) to 3 (severe disease [spontaneous bleeding, ulceration]), higher scores = more severity. Percentage of participants achieving endoscopic improvement at Week 52 was evaluated in this endpoint. Primary analysis set was analysed.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	32.3	23.3		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2302
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	8.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.22
upper limit	21.71

Secondary: Percentage of Participants Achieving Symptomatic Remission at Week 52

End point title	Percentage of Participants Achieving Symptomatic Remission at Week 52
End point description:	
Symptomatic remission was defined as SF =0 (or = 1 with a ≥ 1 point decrease from baseline) and RB =0. SF subscore: reported number of stools in a 24-hour period relative to normal number of stools for that participant in the same period, scores ranged from 0 (normal number of stools) to 3 (5 or more stools than normal), higher scores = more severity. RB subscore: reported the most severe amount of blood passed per rectum in a 24-hour period, score ranged from 0 (no blood seen) to 3 (blood alone passes), higher scores = more severity. Percentage of participants achieving symptomatic remission at Week 52 was evaluated in this endpoint. Primary analysis set was analysed.	
End point type	Secondary
End point timeframe:	
Week 52	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	37.0	30.0		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description:	
Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights, where only participants with an assessment at Baseline and the corresponding visit are included. The 2-sided Nominal p-value was used to test the hypothesis of the RD being 0.	
Comparison groups	Etrasimod v Placebo

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3339
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	7.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.32
upper limit	21.55

Secondary: Percentage of Participants Achieving Complete Symptomatic Remission at Week 52

End point title	Percentage of Participants Achieving Complete Symptomatic Remission at Week 52
End point description: Complete symptomatic remission was defined as participants with RB = 0 and SF = 0. SF subscore: reported number of stools in a 24-hour period relative to normal number of stools for that participant in the same period, scores ranged from 0 (normal number of stools) to 3 (5 or more stools than normal), higher scores = more severity. RB subscore: reported the most severe amount of blood passed per rectum in a 24-hour period, score ranged from 0 (no blood seen) to 3 (blood alone passes), higher scores = more severity. Percentage of participants achieving complete symptomatic remission at Week 52 was evaluated in this endpoint. Primary analysis set was analysed.	
End point type	Secondary
End point timeframe: Week 52	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	20.5	20.0		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description: Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights, where only participants with an assessment at Baseline and the corresponding visit are included. The 2-sided Nominal p-value was used to test the hypothesis of the RD being 0.	
Comparison groups	Etrasimod v Placebo

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9141
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.76
upper limit	13.13

Secondary: Percentage of Participants Achieving Histologic-Endoscopic Mucosal Improvement at Week 52

End point title	Percentage of Participants Achieving Histologic-Endoscopic Mucosal Improvement at Week 52
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End point description:

Histologic-endoscopic mucosal improvement was defined as ES \leq 1 (excluding friability) with Geboes score $<$ 2.0. ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, score ranged from 0 (normal or inactive disease) to 3 (severe disease [spontaneous bleeding, ulceration]), higher scores = more severity. The Geboes score grading system was a validated score for evaluating histologic disease activity in UC as follows: grade 0 = structural and architectural changes; grade 1 = chronic inflammatory infiltrate; grade 2 = lamina propria neutrophils and eosinophils; grade 3 = neutrophils in the epithelium; grade 4 = crypt destruction; grade 5 = erosions or ulceration. A higher Geboes score indicated more severe disease. Percentage of participants achieving mucosal improvement at Week 52 was evaluated in this endpoint. Primary analysis set was analysed.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	25.2	15.0		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1089
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	9.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.13
upper limit	21.25

Secondary: Percentage of Participants Achieving Clinical Remission at Both Weeks 12 and 52 [Combined] Using MMS

End point title	Percentage of Participants Achieving Clinical Remission at Both Weeks 12 and 52 [Combined] Using MMS
End point description:	MMS assesses UC disease activity with three components: ES, RB, and SF. Each ranged from 0 to 3 (0=normal, 1=mild, 2=moderate, 3=severe); higher scores=severe disease. ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, scores ranged from 0 (normal or inactive disease) to 3 (severe disease [spontaneous bleeding, ulceration]). RB reported most severe amount of blood passed per rectum in a 24-hour period, scores ranged from 0 (no blood seen) to 3 (blood alone passes). SF reported number of stools in a 24-hour period relative to normal number of stools for that participant in the same period, scores ranged from 0 (normal number of stools) to 3 (5 or more stools than normal). CR (per FDA draft guidance): SF=0 or =1 and no greater than baseline, RB=0, and ES <=1 (excluding friability). Percentage of participants who achieved CR at both the time points Week 12 and Week 52 [Combined] are reported. Primary analysis set was analysed.
End point type	Secondary
End point timeframe:	Weeks 12 and 52 [Combined]

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	16.5	5.0		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description:	Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.
Comparison groups	Etrasimod v Placebo

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0104
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	11.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.63
upper limit	19.75

Secondary: Percentage of Participants With 12-Week Corticosteroid-Free Clinical Remission at Week 52 Among Participants Receiving Corticosteroids at Baseline Using MMS

End point title	Percentage of Participants With 12-Week Corticosteroid-Free Clinical Remission at Week 52 Among Participants Receiving Corticosteroids at Baseline Using MMS
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End point description:

MMS components: ES, RB and SF. Score ranges from 0 to 3 (0=normal, 1=mild, 2=moderate, 3=severe); higher scores=more severe disease. ES: worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, scores ranged=0(normal or inactive disease) to 3 (severe disease). RB: most severe amount of blood passed per rectum in a 24-hour period, scores ranged= 0 (no blood seen) to 3 (blood alone passes). SF: number of stools in a 24-hour period relative to normal number of stools for that participant in same period, scores ranged= 0 (normal number of stools) to 3 (5 or more stools than normal). CR per FDA draft guidance: SF =0 or =1 and no greater than baseline, RB=0, and ES <=1 (excluding friability). 12-week corticosteroid-free CR: CR at Week 52 and corticosteroid-free for >=12 weeks immediately prior to Week 52. Primary analysis set was analysed. Here, "Subjects Analysed" signifies participants evaluable for this outcome measure who received oral corticosteroids for UC at baseline.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	18		
Units: Percentage of participants				
number (not applicable)	16.2	16.7		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9203
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.06
upper limit	19.92

Secondary: Percentage of Participants With 12-Week Corticosteroid-Free Clinical Remission at Week 52 Using MMS

End point title	Percentage of Participants With 12-Week Corticosteroid-Free Clinical Remission at Week 52 Using MMS
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End point description:

MMS has following components: ES, RB and SF. Each component score ranges from 0 to 3 (0=normal,1=mild,2=moderate,3=severe); higher scores indicating more severe disease. ES: worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, score ranged from 0(normal or inactive disease) to 3 (severe disease). RB: most severe amount of blood passed per rectum in a 24-hour period, score ranged from 0(no blood seen) to 3 (blood alone passes). SF: number of stools in a 24-hour period relative to normal number of stools for that participant in the same period, score ranged from 0(normal number of stools) to 3 (5 or more stools than normal). CR per FDA draft guidance as: SF =0 or =1 and no greater than baseline, RB=0, and ES <=1(excluding friability). 12-week corticosteroid-free CR was defined as CR at Week 52 and corticosteroid-free for >=12 weeks immediately prior to Week 52. Primary analysis set was analysed.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	25.2	16.7		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1726
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	8.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.71
upper limit	20.68

Secondary: Percentage of Participants Achieving 4-Week Corticosteroid-Free Clinical Remission at Week 52 Among Participants Receiving Corticosteroids at Baseline Using MMS

End point title	Percentage of Participants Achieving 4-Week Corticosteroid-Free Clinical Remission at Week 52 Among Participants Receiving Corticosteroids at Baseline Using MMS
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End point description:

MMS components: ES, RB and SF. Score ranges from 0 to 3 (0=normal, 1=mild, 2=moderate, 3=severe); higher scores=more severe disease. ES: worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, scores ranged=0(normal or inactive disease) to 3 (severe disease). RB: most severe amount of blood passed per rectum in a 24-hour period, scores ranged= 0 (no blood seen) to 3 (blood alone passes). SF: number of stools in a 24-hour period relative to normal number of stools for that participant in same period, scores ranged= 0 (normal number of stools) to 3 (5 or more stools than normal). CR per FDA draft guidance: SF =0 or =1 and no greater than baseline, RB=0, and ES <=1 (excluding friability). 4-week corticosteroid-free CR: CR at Week 52 and corticosteroid-free for >=4 weeks immediately prior to Week 52. Primary analysis set was analysed. Here, "Subjects Analysed" signifies participants evaluable for this outcome measure who received oral corticosteroids for UC at baseline.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	10		
Units: Percentage of participants				
number (not applicable)	30.0	30.0		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9272
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-1.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.31
upper limit	34.9

Secondary: Percentage of Participants With 4-Week Corticosteroid-Free Clinical Remission at Week 52 Using MMS

End point title	Percentage of Participants With 4-Week Corticosteroid-Free Clinical Remission at Week 52 Using MMS
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End point description:

MMS has following components: ES, RB and SF. Each component score ranges from 0 to 3 (0=normal,1=mild,2=moderate,3=severe); where total score is sum of three components giving total MMS score as 0 to 9; higher scores indicating more severe disease. ES: worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, score ranged from 0(normal or inactive disease) to 3 (severe disease). RB: most severe amount of blood passed per rectum in a 24-hour period, score ranged from 0(no blood seen) to 3 (blood alone passes). SF: number of stools in a 24-hour period relative to normal number of stools for that participant in the same period, score ranged from 0(normal number of stools) to 3 (5 or more stools than normal). CR per FDA draft guidance as: SF =0 or =1 and no greater than baseline, RB=0, and ES <=1(excluding friability). 4-week corticosteroid-free CR was defined as CR at Week 52 and corticosteroid-free for >=4 weeks immediately prior to Week 52. Primary analysis set was

End point type	Secondary
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End point timeframe:

Week 52

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	25.2	16.7		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1726
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	8.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.71
upper limit	20.68

Secondary: Percentage of Participants Achieving Clinical Response at Week 12 Using MMS

End point title	Percentage of Participants Achieving Clinical Response at Week 12 Using MMS
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End point description:

Clinical response was defined as a ≥ 2 -point and ≥ 30 percentage (%) decrease from baseline in MMS, and a ≥ 1 -point decrease from baseline in RB subscore or an absolute RB subscore ≤ 1 and is as per FDA draft guidance. MMS was used to assess disease activity in participants with UC and has following components: ES, RB and SF. Each component score ranges from 0 to 3 (0= normal, 1= mild, 2= moderate, 3= severe); where total score is sum of three components giving total MMS score as 0 to 9; higher scores indicating more severe disease. ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, score ranged from 0 (normal or inactive disease) to 3 (severe disease [spontaneous bleeding, ulceration]). Percentage of participants achieving clinical response at Week 12 was evaluated in this endpoint. Primary analysis set was analysed.

End point type	Secondary
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End point timeframe:

Week 12

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	55.9	36.7		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0151
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	18.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.61
upper limit	33.67

Secondary: Percentage of Participants Achieving Clinical Response at Week 52 Using MMS

End point title	Percentage of Participants Achieving Clinical Response at Week 52 Using MMS
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End point description:

Clinical response was defined as a ≥ 2 -point and ≥ 30 % decrease from baseline in MMS, and a ≥ 1 -point decrease from baseline in RB subscore or an absolute RB subscore ≤ 1 and is as per FDA draft guidance. MMS is used to assess disease activity in participants with UC and has following components: ES, RB and SF. Each component scores ranges from 0 to 3 (0= normal, 1= mild, 2= moderate, 3= severe); where total score is sum of three components giving total MMS score as 0 to 9; higher scores indicating more severe disease. ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, scores ranged from 0 (normal or inactive disease) to 3 (severe disease [spontaneous bleeding, ulceration]). Percentage of participants achieving clinical response at Week 52 was evaluated in this endpoint. Primary analysis set was analysed.

End point type	Secondary
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End point timeframe:

Week 52

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	44.1	38.3		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4419
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	5.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.22
upper limit	21.13

Secondary: Percentage of Participants Achieving Endoscopic Improvement at Week 12

End point title	Percentage of Participants Achieving Endoscopic Improvement at Week 12
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End point description:

Endoscopic improvement was defined as ES ≤1 (excluding friability). ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, scores ranged from 0 (normal or inactive disease) to 3 (severe disease [spontaneous bleeding, ulceration]), higher scores = more severity. Percentage of participants achieving endoscopic improvement at Week 12 was evaluated in this endpoint. Primary analysis set was analysed.

End point type	Secondary
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End point timeframe:

Week 12

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	44.1	20.0		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0007
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	23.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.78
upper limit	36.89

Secondary: Percentage of Participants Achieving Histologic-Endoscopic Mucosal Improvement at Week 12

End point title	Percentage of Participants Achieving Histologic-Endoscopic Mucosal Improvement at Week 12
End point description: Histologic-endoscopic mucosal improvement was defined as ES ≤1 (excluding friability) with Geboes score <2.0. ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, scores ranged from 0 (normal or inactive disease) to 3 (severe disease [spontaneous bleeding, ulceration]), higher scores = more severity. The Geboes score grading system was a validated score for evaluating histologic disease activity in UC as follows: grade 0 = structural and architectural changes; grade 1 = chronic inflammatory infiltrate; grade 2 = lamina propria neutrophils and eosinophils; grade 3 = neutrophils in the epithelium; grade 4 = crypt destruction; grade 5 = erosions or ulceration. A higher Geboes score indicated more severe disease. Percentage of participants achieving mucosal improvement at Week 12 was evaluated in this endpoint. Primary analysis set was analysed.	
End point type	Secondary
End point timeframe: Week 12	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	29.1	13.3		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description: Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights. The 2-sided p-value was used to test the hypothesis of the RD being 0.	
Comparison groups	Etrasimod v Placebo

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0128
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	14.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.19
upper limit	26.79

Secondary: Percentage of Participants Achieving Symptomatic Remission at Week 12

End point title	Percentage of Participants Achieving Symptomatic Remission at Week 12
End point description: Symptomatic remission was defined as SF =0 (or = 1 with a ≥ 1 point decrease from baseline) and RB =0. SF subscore: reported number of stools in a 24-hour period relative to normal number of stools for that participant in the same period, scores ranged from 0 (normal number of stools) to 3 (5 or more stools than normal), higher scores = more severity. RB subscore: reported the most severe amount of blood passed per rectum in a 24-hour period, scores ranged from 0 (no blood seen) to 3 (blood alone passes), higher scores = more severity. Percentage of participants achieving symptomatic remission at Week 12 was evaluated in this endpoint. Primary analysis set was analysed.	
End point type	Secondary
End point timeframe: Week 12	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	36.2	25.0		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description: Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights, where only participants with an assessment at Baseline and the corresponding visit are included. The 2-sided Nominal p-value was used to test the hypothesis of the RD being 0.	
Comparison groups	Etrasimod v Placebo

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1492
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	10.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.67
upper limit	24.14

Secondary: Percentage of Participants Achieving Complete Symptomatic Remission at Week 12

End point title	Percentage of Participants Achieving Complete Symptomatic Remission at Week 12
End point description: Complete symptomatic remission was defined as participants with RB = 0 and SF = 0. SF subscore: reported number of stools in a 24-hour period relative to normal number of stools for that participant in the same period, scores ranged from 0 (normal number of stools) to 3 (5 or more stools than normal), higher scores = more severity. RB subscore: reported the most severe amount of blood passed per rectum in a 24-hour period, scores ranged from 0 (no blood seen) to 3 (blood alone passes), higher scores = more severity. Percentage of participants achieving complete symptomatic remission at Week 12 was evaluated in this endpoint. Primary analysis set was analysed.	
End point type	Secondary
End point timeframe: Week 12	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	20.5	20.0		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description: Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights, where only participants with an assessment at Baseline and the corresponding visit are included. The 2-sided Nominal p-value was used to test the hypothesis of the RD being 0.	
Comparison groups	Etrasimod v Placebo

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9774
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.18
upper limit	12.53

Secondary: Percentage of Participants Achieving Change From Baseline in Both ES and RB or in Both ES and SF at Week 12

End point title	Percentage of Participants Achieving Change From Baseline in Both ES and RB or in Both ES and SF at Week 12
End point description:	
ES reported worst appearance of mucosa on flexible sigmoidoscopy or colonoscopy, scores ranged from 0 (normal or inactive disease) to 3 (severe disease [spontaneous bleeding, ulceration]), higher scores = more severity. RB: reported the most severe amount of blood passed per rectum in a 24-hour period, scores ranged from 0 (no blood seen) to 3 (blood alone passes), higher scores = more severity. SF reported number of stools in a 24-hour period relative to normal number of stools for that participant in the same period, score ranged from 0 (normal number of stools) to 3 (5 or more stools than normal), higher scores = more severity. Percentage of participants with reduction from baseline in both ES and RB or in both ES and SF at Week 12 was evaluated in this endpoint. The baseline primary analysis set was balanced between treatment groups and representative of participants with mildly to moderately active UC. Primary analysis set was analysed.	
End point type	Secondary
End point timeframe:	
Baseline to Week 12	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	44.9	21.7		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description:	
Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights, where only participants with an assessment at Baseline and the corresponding visit are included. The 2-sided Nominal p-value was used to test the hypothesis of the RD being 0.	
Comparison groups	Etrasimod v Placebo

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0011
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	22.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.17
upper limit	36.49

Secondary: Percentage of Participants Achieving Histologic Response Based on the Geboes Grading System at Week 12

End point title	Percentage of Participants Achieving Histologic Response Based on the Geboes Grading System at Week 12
End point description:	
<p>Histologic response based on the Geboes grading system was defined as Geboes score ≤ 3.1. The Geboes score grading system is a validated score for evaluating histologic disease activity in UC as follows: grade 0 = structural and architectural changes; grade 1 = chronic inflammatory infiltrate; grade 2 = lamina propria neutrophils and eosinophils; grade 3 = neutrophils in the epithelium; grade 4 = crypt destruction; grade 5 = erosions or ulceration. A higher Geboes score indicated more severe disease. Percentage of participants achieving histologic response based on the Geboes grading system at week 12 was evaluated in this endpoint. Primary analysis set was analysed.</p>	
End point type	Secondary
End point timeframe:	
Week 12	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	44.9	33.3		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
Statistical analysis description:	
<p>Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights, where only participants with an assessment at Baseline and the corresponding visit are included. The 2-sided Nominal p-value was used to test the hypothesis of the RD being 0.</p>	
Comparison groups	Etrasimod v Placebo

Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1513
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	10.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.95
upper limit	25.56

Secondary: Percentage of Participants Achieving Histologic Response Based on Roberts Histopathology Index (RHI) at Week 12

End point title	Percentage of Participants Achieving Histologic Response Based on Roberts Histopathology Index (RHI) at Week 12
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End point description:

RHI is an evaluative index, derived from the Geboes score, that is designed to be reproducible and responsive to clinically meaningful change in disease activity over time. Histologic response based on RHI was defined as decrease in RHI of ≥ 7 points from baseline. Total RHI score ranges from 0 (no disease activity) to 33 (severe disease activity), higher score = more severity. Percentage of participants achieving histologic response based on RHI at Week 12 was evaluated in this endpoint. Primary analysis set was analysed.

End point type	Secondary
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End point timeframe:

Week 12

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	60		
Units: Percentage of participants				
number (not applicable)	46.5	35.0		

Statistical analyses

Statistical analysis title	Etrasimod versus placebo
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Statistical analysis description:

Difference (%) for etrasimod minus placebo was based on estimated common RD using the Mantel-Haenszel weights, where only participants with an assessment at Baseline and the corresponding visit are included. The 2-sided Nominal p-value was used to test the hypothesis of the RD being 0.

Comparison groups	Etrasimod v Placebo
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Number of subjects included in analysis	187
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1823
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	10.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.73
upper limit	24.87

Other pre-specified: Number of Participants With Adverse Events (AEs)

End point title	Number of Participants With Adverse Events (AEs)
End point description:	
An AE was any untoward medical occurrence in a participant or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. A serious adverse event (SAE) was any untoward medical occurrence at any dose that: resulted in death; was life-threatening; required inpatient hospitalisation or prolongation of existing hospitalisation; resulted in persistent or significant disability/ incapacity; resulted in congenital anomaly/birth defect. AEs included both SAEs and all non-SAEs. Safety set included all randomised participants who received at least 1 dose of study treatment.	
End point type	Other pre-specified
End point timeframe:	
From first dose of study treatment up to 4 weeks post last dose of study treatment (up to 56 Weeks)	

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	154	79		
Units: Participants	101	49		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of Participants With AEs Based on Severity

End point title	Number of Participants With AEs Based on Severity
End point description:	
An AE was any untoward medical occurrence in a participant or clinical investigational participant administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An AE was therefore any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Severity was classified using common terminology criteria for adverse events (CTCAE), version 5.0, where Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe, Grade 4 = life-threatening, Grade 5 = death related to AE. Only those categories in which at least 1 participant had data for any reporting group were reported. Safety set included all randomised participants who received at least 1 dose of	

study treatment.

End point type	Other pre-specified
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End point timeframe:

From first dose of study treatment up to 4 weeks post last dose of study treatment (up to 56 Weeks)

End point values	Etrasimod	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	154	79		
Units: Participants				
Grade 1	48	23		
Grade 2	42	24		
Grade 3	11	2		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study treatment up to 4 weeks post last dose of study treatment (up to 56 Weeks)

Adverse event reporting additional description:

Same event may occur as both non-SAE and SAE but are distinct events. An event may be categorised as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and non-SAE. Safety set included all randomised participants who received at least 1 dose of study treatment.

Assessment type	Non-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	Placebo
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Reporting group description:

Participants with moderately active UC were randomised to receive placebo matched to Etrasimod tablet orally QD for 52-Week.

Reporting group title	Etrasimod
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Reporting group description:

Participants with moderately active UC were randomised to receive Etrasimod 2 mg tablet orally QD for 52-Week.

Serious adverse events	Placebo	Etrasimod	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 79 (1.27%)	10 / 154 (6.49%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Incisional hernia			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			

subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 79 (0.00%)	4 / 154 (2.60%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Post procedural infection			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			

subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Placebo	Etrasimod	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 79 (60.76%)	100 / 154 (64.94%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma of bone			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Anogenital warts			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Eye naevus			
subjects affected / exposed	0 / 79 (0.00%)	2 / 154 (1.30%)	
occurrences (all)	0	2	
Haemangioma of liver			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Skin papilloma			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Squamous cell carcinoma			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Lipoma			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Vascular disorders			
Orthostatic hypotension			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Hot flush			

subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Hypertension			
subjects affected / exposed	0 / 79 (0.00%)	3 / 154 (1.95%)	
occurrences (all)	0	3	
Hypotension			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Vessel puncture site haematoma			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Pyrexia			
subjects affected / exposed	1 / 79 (1.27%)	2 / 154 (1.30%)	
occurrences (all)	1	2	
Pain			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Injection site pain			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Influenza like illness			
subjects affected / exposed	0 / 79 (0.00%)	3 / 154 (1.95%)	
occurrences (all)	0	4	
Hyperpyrexia			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Fatigue			
subjects affected / exposed	0 / 79 (0.00%)	5 / 154 (3.25%)	
occurrences (all)	0	5	
Early satiety			
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)	
occurrences (all)	1	1	
Chest pain			

subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	1 / 154 (0.65%) 1	
Immune system disorders Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Social circumstances Postmenopause subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Reproductive system and breast disorders Heavy menstrual bleeding subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Nasal inflammation subjects affected / exposed occurrences (all) Obstructive airways disorder subjects affected / exposed occurrences (all) Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0 0 / 79 (0.00%) 0 0 / 79 (0.00%) 0 3 / 79 (3.80%) 3	3 / 154 (1.95%) 3 1 / 154 (0.65%) 1 1 / 154 (0.65%) 1 0 / 154 (0.00%) 0	
Psychiatric disorders Depressed mood subjects affected / exposed occurrences (all) Anxiety subjects affected / exposed occurrences (all) Insomnia	0 / 79 (0.00%) 0 1 / 79 (1.27%) 1	1 / 154 (0.65%) 1 0 / 154 (0.00%) 0	

subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 79 (0.00%)	3 / 154 (1.95%)	
occurrences (all)	0	3	
Alanine aminotransferase increased			
subjects affected / exposed	1 / 79 (1.27%)	13 / 154 (8.44%)	
occurrences (all)	1	15	
Blood urine present			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	2	
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 79 (1.27%)	3 / 154 (1.95%)	
occurrences (all)	1	4	
Blood bilirubin increased			
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)	
occurrences (all)	1	2	
Blood cholesterol increased			
subjects affected / exposed	0 / 79 (0.00%)	3 / 154 (1.95%)	
occurrences (all)	0	4	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 79 (0.00%)	5 / 154 (3.25%)	
occurrences (all)	0	5	
Blood creatinine increased			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Blood glucose increased			
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)	
occurrences (all)	1	1	
Blood phosphorus decreased			
subjects affected / exposed	1 / 79 (1.27%)	2 / 154 (1.30%)	
occurrences (all)	1	2	
Blood phosphorus increased			

subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Blood pressure increased		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Blood thyroid stimulating hormone decreased		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	2
Blood triglycerides increased		
subjects affected / exposed	1 / 79 (1.27%)	8 / 154 (5.19%)
occurrences (all)	1	9
Blood uric acid increased		
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)
occurrences (all)	1	1
Aspartate aminotransferase increased		
subjects affected / exposed	1 / 79 (1.27%)	8 / 154 (5.19%)
occurrences (all)	2	10
Electrocardiogram QT prolonged		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Heart rate decreased		
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)
occurrences (all)	1	0
Hepatic enzyme increased		
subjects affected / exposed	0 / 79 (0.00%)	2 / 154 (1.30%)
occurrences (all)	0	2
Lung diffusion test decreased		
subjects affected / exposed	2 / 79 (2.53%)	1 / 154 (0.65%)
occurrences (all)	2	1
Weight decreased		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Gamma-glutamyltransferase increased		

subjects affected / exposed occurrences (all)	2 / 79 (2.53%) 2	13 / 154 (8.44%) 20	
Injury, poisoning and procedural complications			
Cataract operation complication			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Epicondylitis			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Face injury			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Immunisation reaction			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Muscle strain			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Radius fracture			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Skin laceration			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Sunburn			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)	
occurrences (all)	1	1	
Bradycardia			
subjects affected / exposed	0 / 79 (0.00%)	2 / 154 (1.30%)	
occurrences (all)	0	2	
Arrhythmia			

subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Bundle branch block right subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	2 / 154 (1.30%) 2	
Tachycardia paroxysmal subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	2 / 79 (2.53%) 2	5 / 154 (3.25%) 7	
Headache subjects affected / exposed occurrences (all)	3 / 79 (3.80%) 3	9 / 154 (5.84%) 10	
Loss of consciousness subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Memory impairment subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Migraine subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	2 / 154 (1.30%) 2	
Nerve compression subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Paraesthesia subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Restless legs syndrome subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	

Somnolence subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	3 / 154 (1.95%) 3	
Vertebrobasilar insufficiency subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Blood and lymphatic system disorders			
Iron deficiency anaemia subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Coagulopathy subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Anaemia subjects affected / exposed occurrences (all)	6 / 79 (7.59%) 6	4 / 154 (2.60%) 5	
Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	1 / 154 (0.65%) 1	
Splenic cyst subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Neutropenia subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	2 / 154 (1.30%) 2	
Ear and labyrinth disorders			
Vertigo subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Tinnitus subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	2 / 154 (1.30%) 2	
Eye disorders			
Eye haemorrhage subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Eye irritation			

subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Eye pain		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Epiretinal membrane		
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)
occurrences (all)	1	0
Conjunctivitis allergic		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Cataract		
subjects affected / exposed	0 / 79 (0.00%)	2 / 154 (1.30%)
occurrences (all)	0	2
Blepharitis		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	2
Eyelid thickening		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Floppy eyelid syndrome		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Macular degeneration		
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)
occurrences (all)	1	0
Vitreoretinal traction syndrome		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Vision blurred		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Uveitis		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Photophobia		

subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Macular oedema			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Dry mouth			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	2 / 79 (2.53%)	2 / 154 (1.30%)	
occurrences (all)	3	2	
Colitis ulcerative			
subjects affected / exposed	8 / 79 (10.13%)	19 / 154 (12.34%)	
occurrences (all)	9	19	
Abdominal tenderness			
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)	
occurrences (all)	1	2	
Abdominal pain upper			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Abdominal pain lower			
subjects affected / exposed	2 / 79 (2.53%)	0 / 154 (0.00%)	
occurrences (all)	2	0	
Abdominal pain			
subjects affected / exposed	3 / 79 (3.80%)	4 / 154 (2.60%)	
occurrences (all)	3	4	
Abdominal distension			
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)	
occurrences (all)	1	1	
Rectal polyp			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Rectal haemorrhage			
subjects affected / exposed	1 / 79 (1.27%)	2 / 154 (1.30%)	
occurrences (all)	1	2	

Oesophageal polyp		
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)
occurrences (all)	2	0
Nausea		
subjects affected / exposed	2 / 79 (2.53%)	2 / 154 (1.30%)
occurrences (all)	2	2
Large intestine polyp		
subjects affected / exposed	0 / 79 (0.00%)	3 / 154 (1.95%)
occurrences (all)	0	4
Intestinal polyp		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Toothache		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Gastrooesophageal reflux disease		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Gastritis		
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)
occurrences (all)	1	1
Gastric polyps		
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)
occurrences (all)	1	0
Frequent bowel movements		
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)
occurrences (all)	1	0
Dyspepsia		
subjects affected / exposed	1 / 79 (1.27%)	2 / 154 (1.30%)
occurrences (all)	1	2
Duodenal polyp		
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)
occurrences (all)	1	0
Haemorrhoids		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1

Vomiting subjects affected / exposed occurrences (all)	2 / 79 (2.53%) 2	2 / 154 (1.30%) 2	
Hepatobiliary disorders			
Gallbladder polyp subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Cholestasis subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Skin and subcutaneous tissue disorders			
Cold sweat subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Acne subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	2 / 154 (1.30%) 2	
Alopecia subjects affected / exposed occurrences (all)	3 / 79 (3.80%) 3	1 / 154 (0.65%) 1	
Dermal cyst subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Drug eruption subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Erythema nodosum subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Hyperhidrosis subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Night sweats subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Onychoclasia			

subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Rash			
subjects affected / exposed occurrences (all)	2 / 79 (2.53%) 2	3 / 154 (1.95%) 3	
Skin fibrosis			
subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Skin irritation			
subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Skin lesion			
subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Dermatitis allergic			
subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Nephrolithiasis			
subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Renal cyst			
subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Renal pain			
subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Urine abnormality			
subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	2 / 154 (1.30%) 4	
Crystalluria			
subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	

Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Autoimmune thyroiditis			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 79 (2.53%)	5 / 154 (3.25%)	
occurrences (all)	2	8	
Back pain			
subjects affected / exposed	1 / 79 (1.27%)	5 / 154 (3.25%)	
occurrences (all)	1	5	
Costochondritis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Enthesopathy			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Intervertebral disc protrusion			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Joint range of motion decreased			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Muscle spasms			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Myalgia			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Osteoarthritis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Osteochondrosis			

subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Sacroiliitis			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Arthritis reactive			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Infections and infestations			
Bacteriuria			
subjects affected / exposed	0 / 79 (0.00%)	2 / 154 (1.30%)	
occurrences (all)	0	2	
Acute sinusitis			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Pyuria			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Respiratory tract infection			
subjects affected / exposed	1 / 79 (1.27%)	2 / 154 (1.30%)	
occurrences (all)	1	2	
Pneumonia			
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	
Pharyngitis			
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)	
occurrences (all)	1	1	
Otitis externa			
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)	
occurrences (all)	1	0	
Oral herpes			
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)	
occurrences (all)	1	1	
Nasopharyngitis			
subjects affected / exposed	3 / 79 (3.80%)	5 / 154 (3.25%)	
occurrences (all)	3	6	

Intervertebral discitis		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Influenza		
subjects affected / exposed	0 / 79 (0.00%)	4 / 154 (2.60%)
occurrences (all)	0	4
Infected bite		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Herpes zoster		
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)
occurrences (all)	1	0
COVID-19		
subjects affected / exposed	7 / 79 (8.86%)	15 / 154 (9.74%)
occurrences (all)	7	16
Conjunctivitis		
subjects affected / exposed	1 / 79 (1.27%)	3 / 154 (1.95%)
occurrences (all)	1	3
Clostridium difficile infection		
subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)
occurrences (all)	0	1
Post-acute COVID-19 syndrome		
subjects affected / exposed	1 / 79 (1.27%)	0 / 154 (0.00%)
occurrences (all)	1	0
Respiratory tract infection viral		
subjects affected / exposed	0 / 79 (0.00%)	2 / 154 (1.30%)
occurrences (all)	0	2
Sinusitis		
subjects affected / exposed	0 / 79 (0.00%)	2 / 154 (1.30%)
occurrences (all)	0	3
Upper respiratory tract infection		
subjects affected / exposed	4 / 79 (5.06%)	3 / 154 (1.95%)
occurrences (all)	5	3
Urinary tract infection		
subjects affected / exposed	1 / 79 (1.27%)	1 / 154 (0.65%)
occurrences (all)	1	1

Vaginal infection subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Metabolism and nutrition disorders			
Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Dyslipidaemia subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Hyperglycaemia subjects affected / exposed occurrences (all)	2 / 79 (2.53%) 2	1 / 154 (0.65%) 1	
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 2	3 / 154 (1.95%) 5	
Hyperuricaemia subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Hypoglycaemia subjects affected / exposed occurrences (all)	1 / 79 (1.27%) 1	0 / 154 (0.00%) 0	
Hypovitaminosis subjects affected / exposed occurrences (all)	0 / 79 (0.00%) 0	1 / 154 (0.65%) 1	
Increased appetite			

subjects affected / exposed	0 / 79 (0.00%)	1 / 154 (0.65%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 August 2022	Updated safety-related reporting guidance and procedures to align with Pfizer safety related reporting procedures.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported