Clinical trial results:
A Phase 2, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Study of LY3074828 in Subjects with Moderate to Severe Ulcerative Colitis

Summary

EudraCT number	2015-003123-57
Trial protocol	BE GB CZ HU NL LT DK PL
Global end of trial date	07 May 2019

Results information

Result version number	v1 (current)
This version publication date	23 May 2020
First version publication date	23 May 2020

Trial information

Trial identification

Sponsor protocol code	I6T-MC-AMAC

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02589665
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 15829

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon Fri 9 AM 5 PM EST, Eli Lilly and Company, 1 8772854559,

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	07 May 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 May 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study is to test the hypothesis that treatment with mirikizumab is superior to placebo in providing clinical benefit to participants with moderate to severe ulcerative colitis (UC). This study will also investigate how the body processes the drug.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 December 2015
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	Belgium: 21
Country: Number of subjects enrolled	Denmark: 1
Country: Number of subjects enrolled	Poland: 49
Country: Number of subjects enrolled	Georgia: 14
Country: Number of subjects enrolled	Lithuania: 9
Country: Number of subjects enrolled	Australia: 7
Country: Number of subjects enrolled	United States: 50
Country: Number of subjects enrolled	Czech Republic: 2
Country: Number of subjects enrolled	Moldova, Republic of: 24
Country: Number of subjects enrolled	Hungary: 18
Country: Number of subjects enrolled	Japan: 31
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Netherlands: 11
Worldwide total number of subjects	249
EEA total number of subjects	117

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)	232
From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Available

Pre-assignment

Screening details:

No Text Available

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Induction: Placebo IV Q4W

Arm description:

Placebo administered every 4 weeks (Q4W) intravenously (IV) during the induction period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Placebo administered every 4 weeks (Q4W) intravenously (IV).

Arm title	Induction: 50 mg Mirikizumab IV Q4W

Arm description:

50 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period.

Participants who do not have a clinical response may choose to participate in the unblinded study extension period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

50 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV).

Arm title	Induction: 200 mg Mirikizumab IV Q4W

Arm description:

200 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period.

Participants who do not have a clinical response may choose to participate in the unblinded study extension period.

Arm type	Experimental

Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV).

Arm title	Induction: 600 mg Mirikizumab IV Q4W

Arm description:

600 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period.

Participants who do not have a clinical response may choose to participate in the unblinded study extension period.

Arm type	Placebo
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

600 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV).

Number of subjects in period 1	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W
Started	63	63	62
Received at least one dose of study drug	63	63	62
Completed	60	61	60
Not completed	3	2	2
Consent withdrawn by subject	-	1	-
Adverse event, non-fatal	3	-	2
Did not receive drug	-	-	-
Protocol deviation	-	1	-

Number of subjects in period 1	Induction: 600 mg Mirikizumab IV Q4W
Started	61
Received at least one dose of study drug	60
Completed	57
Not completed	4
Consent withdrawn by subject	1
Adverse event, non-fatal	2
Did not receive drug	1
Protocol deviation	-

Period 2

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

Arms

Are arms mutually exclusive?	No
Arm title	Maintenance: Placebo SC Q4W

Arm description:

Induction placebo responders: Placebo administered subcutaneously (SC) Q4W during the maintenance period.

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:

Placebo administered subcutaneously (SC) Q4W.

Arm title	Maintenance: 200 mg Mirikizumab SC Q4W

Arm description:

Induction mirikizumab responders were re-randomized: 200 mg mirikizumab administered subcutaneously (SC) Q4W during the maintenance period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

200 mg mirikizumab administered subcutaneously (SC).

Arm title	Maintenance: 200 mg Mirikizumab SC Q12W

Arm description:

Induction mirikizumab responders were re-randomized: 200 mg mirikizumab administered subcutaneously (SC) once every 12 weeks (Q12W) during the maintenance period.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

200 mg mirikizumab administered subcutaneously (SC).

Number of subjects in period 2	Maintenance: Placebo SC Q4W	Maintenance: 200 mg Mirikizumab SC Q4W	Maintenance: 200 mg Mirikizumab SC Q12W
Started	13	47	46
Completed	0	0	0
Not completed	13	47	46
Rolled Over to Study AMAP (NCT03519945)	7	41	39
Consent withdrawn by subject	4	2	4
Physician decision	-	1	-
Adverse event, non-fatal	-	-	2
Reason Not Collected	-	1	1
Lost to follow-up	-	1	-
Lack of efficacy	2	1	-

Period 3

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

Arms

Are arms mutually exclusive?	No
Arm title	Induction Extension: 600mg Mirikizumab IV Q4W

Arm description:

Induction non-responders: 600 mg mirikizumab administered intravenously (IV) once every 4 weeks (Q4W) during the Extension Open-Label.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

600 mg mirikizumab administered intravenously (IV).

Arm title	Induction Extension: 1000mg Mirikizumab IV Q4W

Arm description:

Induction non-responders: 1000 mg mirikizumab administered intravenously (IV) once every 4 weeks (Q4W) during the Extension Open-Label.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

1000 mg mirikizumab administered intravenously (IV).

Number of subjects in period 3	Induction Extension: 600mg Mirikizumab IV Q4W	Induction Extension: 1000mg Mirikizumab IV Q4W
Started	32	96
Completed	30	84
Not completed	2	12
Consent withdrawn by subject	2	3
Physician decision	-	1
Adverse event, non-fatal	-	4
Reason Not Collected	-	1
Lack of efficacy	-	3

Period 4

Period 4 title	Maintenance Extension Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Arm title	Maintenance Extension: 200mg Mirikizumab SC Q4W

Arm description:

Extension Induction responders: 200 mg mirikizumab administered subcutaneously (SC) once every 4 weeks (Q4W) during the Extension Open-Label.

Arm type	Experimental
Investigational medicinal product name	Mirikizumab
Investigational medicinal product code	
Other name	LY3074828
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

200 mg mirikizumab administered subcutaneously (SC).

Number of subjects in period 4	Maintenance Extension: 200mg Mirikizumab SC Q4W
Started	68
Completed	0
Not completed	68
Rolled Over to Study AMAP (NCT03519945)	57
Consent withdrawn by subject	4
Adverse event, non-fatal	2
Non-responder	1
Lack of efficacy	4

Baseline characteristics

Reporting groups	
Reporting group title	Induction: Placebo IV Q4W
Reporting group description:	
Placebo administered every 4 weeks (Q4W) intravenously (IV) during the induction period.	
Reporting group title	Induction: 50 mg Mirikizumab IV Q4W
Reporting group description:	
50 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period. Participants who do not have a clinical response may choose to participate in the unblinded study extension period.	
Reporting group title	Induction: 200 mg Mirikizumab IV Q4W
Reporting group description:	
200 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period. Participants who do not have a clinical response may choose to participate in the unblinded study extension period.	
Reporting group title	Induction: 600 mg Mirikizumab IV Q4W
Reporting group description:	
600 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period. Participants who do not have a clinical response may choose to participate in the unblinded study extension period.	

Reporting group values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W
Number of subjects	63	63	62
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	42.62	41.83	43.35
standard deviation	± 13.47	± 14.06	± 14.75
Gender categorical Units: Subjects			
Female	27	25	25
Male	36	38	37
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	3	2
Not Hispanic or Latino	60	58	59
Unknown or Not Reported	3	2	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	10	5	13
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	1	5
White	52	57	44

More than one race	0	0	0
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Hungary	5	3	6
Czechia	1	0	0
Japan	8	5	13
United Kingdom	2	2	0
Moldova	5	7	5
Canada	2	1	0
Netherlands	1	4	4
Belgium	4	7	3
Denmark	0	0	0
Poland	15	14	12
Georgia	4	7	2
Lithuania	4	1	3
Australia	1	3	1
United States	11	9	13

Reporting group values	Induction: 600 mg Mirikizumab IV Q4W	Total	
Number of subjects	61	249	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	42.44		
standard deviation	± 13.371	-	
Gender categorical Units: Subjects			
Female	23	100	
Male	38	149	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	7	
Not Hispanic or Latino	54	231	
Unknown or Not Reported	5	11	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	5	33	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	7	
White	56	209	
More than one race	0	0	
Unknown or Not Reported	0	0	
Region of Enrollment Units: Subjects			
Hungary	4	18	
Czechia	1	2	

Japan	5	31	
United Kingdom	2	6	
Moldova	7	24	
Canada	3	6	
Netherlands	2	11	
Belgium	7	21	
Denmark	1	1	
Poland	8	49	
Georgia	1	14	
Lithuania	1	9	
Australia	2	7	
United States	17	50	

End points

End points reporting groups

Reporting group title	Induction: Placebo IV Q4W
Reporting group description:	
Placebo administered every 4 weeks (Q4W) intravenously (IV) during the induction period.	
Reporting group title	Induction: 50 mg Mirikizumab IV Q4W
Reporting group description:	
50 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period. Participants who do not have a clinical response may choose to participate in the unblinded study extension period.	
Reporting group title	Induction: 200 mg Mirikizumab IV Q4W
Reporting group description:	
200 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period. Participants who do not have a clinical response may choose to participate in the unblinded study extension period.	
Reporting group title	Induction: 600 mg Mirikizumab IV Q4W
Reporting group description:	
600 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period. Participants who do not have a clinical response may choose to participate in the unblinded study extension period.	
Reporting group title	Maintenance: Placebo SC Q4W
Reporting group description:	
Induction placebo responders: Placebo administered subcutaneously (SC) Q4W during the maintenance period.	
Reporting group title	Maintenance: 200 mg Mirikizumab SC Q4W
Reporting group description:	
Induction mirikizumab responders were re-randomized: 200 mg mirikizumab administered subcutaneously (SC) Q4W during the maintenance period.	
Reporting group title	Maintenance: 200 mg Mirikizumab SC Q12W
Reporting group description:	
Induction mirikizumab responders were re-randomized: 200 mg mirikizumab administered subcutaneously (SC) once every 12 weeks (Q12W) during the maintenance period.	
Reporting group title	Induction Extension: 600mg Mirikizumab IV Q4W
Reporting group description:	
Induction non-responders: 600 mg mirikizumab administered intravenously (IV) once every 4 weeks (Q4W) during the Extension Open-Label.	
Reporting group title	Induction Extension: 1000mg Mirikizumab IV Q4W
Reporting group description:	
Induction non-responders: 1000 mg mirikizumab administered intravenously (IV) once every 4 weeks (Q4W) during the Extension Open-Label.	
Reporting group title	Maintenance Extension: 200mg Mirikizumab SC Q4W
Reporting group description:	
Extension Induction responders: 200 mg mirikizumab administered subcutaneously (SC) once every 4 weeks (Q4W) during the Extension Open-Label.	
Subject analysis set title	Placebo IV Q4W
Subject analysis set type	Per protocol
Subject analysis set description:	
Placebo administered every 4 weeks (Q4W) intravenously (IV).	
Subject analysis set title	50 mg Mirikizumab IV Q4W
Subject analysis set type	Per protocol

Subject analysis set description:

50 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV).

Participants who do not have a clinical response may choose to participate in the unblinded study extension period.

Subject analysis set title	200 mg Mirikizumab IV Q4W
Subject analysis set type	Per protocol

Subject analysis set description:

200 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV).

Participants who do not have a clinical response may choose to participate in the unblinded study extension period.

Subject analysis set title	600 mg Mirikizumab IV Q4W
Subject analysis set type	Per protocol

Subject analysis set description:

600 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV).

Participants who do not have a clinical response may choose to participate in the unblinded study extension period.

Subject analysis set title	Placebo SC Q4W
Subject analysis set type	Per protocol

Subject analysis set description:

Placebo administered subcutaneously (SC) Q4W during the maintenance period.

Subject analysis set title	200 mg Mirikizumab SC Q4W
Subject analysis set type	Per protocol

Subject analysis set description:

200 mg mirikizumab administered subcutaneously (SC) Q4W during the maintenance period.

Subject analysis set title	200 mg Mirikizumab SC Q12W
Subject analysis set type	Per protocol

Subject analysis set description:

200 mg mirikizumab administered subcutaneously (SC) once every 12 weeks (Q12W) during the maintenance period

Primary: Induction Period: Percentage of Participants with Clinical Remission at Week 12

End point title	Induction Period: Percentage of Participants with Clinical Remission at Week 12

End point description:

Clinical remission at week 12 is a defined as achieving a 9-pt Mayo subscore for rectal bleeding=0, stool frequency=0 or 1 with ≥ 1 point decrease from baseline, and endoscopy=0 or 1, excluding PGA.

•Stool Frequency Subscore , based on the participant's diary and scored from 0 (normal number of stools) to 3 (5 or more stools than normal);
•Rectal Bleeding Subscore , based on the participant's diary and scored from 0 (no blood) to 3 (blood only passed);
•Endoscopy Subscore , based on colonoscopy or sigmoidoscopy and scored from 0 (normal or inactive disease) to 3 (severe disease, spontaneous bleeding, ulceration);
•Physician's Global Assessment subscore, based on the physician's overall assessment, and scored from zero (normal) to 3 (severe disease).

The total score ranges from 0 to 9 points, with higher scores representing more severe disease.

End point type	Primary

End point timeframe:

Week 12

Analysis Population Description: All randomized participants.

End point values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	63	62	61
Units: percentage of participants				
number (confidence interval 95%)	4.8 (0.0 to 10.0)	15.9 (6.8 to 24.9)	22.6 (12.2 to 33.0)	11.5 (3.5 to 19.5)

Statistical analyses

Statistical analysis title	Induction Period: Clinical Remission at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	2.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	12.27

Statistical analysis title	Induction Period: Clinical Remission at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 200 mg Mirikizumab IV Q4W
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	7.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.88
upper limit	27.65

Statistical analysis title	Induction Period: Clinical Remission at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 50 mg Mirikizumab IV

	Q4W
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	3.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	14.17

Secondary: Induction Period: Percentage of Participants with Clinical Response at Week 12

End point title	Induction Period: Percentage of Participants with Clinical Response at Week 12

End point description:

Clinical response at week 12 is defined as a decrease in the 9-point Mayo subscores (rectal bleeding, stool frequency and the endoscopic findings) inclusive of >= 2 points and >=35% from baseline with either a decrease of rectal bleeding subscore of >=1 or rectal bleeding subscore of 0 or 1.
The Mayo score is a composite score of ulcerative colitis disease activity calculated as the sum of four subscores:
•Stool Frequency Subscore , based on the participant's diary and scored from 0 (normal number of stools) to 3 (5 or more stools than normal);
•Rectal Bleeding Subscore, based on the participant's diary and scored from 0 (no blood) to 3 (blood only passed);
•Endoscopy Subscore , based on colonoscopy or sigmoidoscopy and scored from 0 (normal or inactive disease) to 3 (severe disease, spontaneous bleeding, ulceration);

The total score ranges from 0 to 9 points, with higher scores representing more severe disease.

End point type	Secondary

End point timeframe:

Week 12

Analysis Population Description: All randomized participants.

End point values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	63	62	61
Units: percentage of participants				
number (confidence interval 95%)	20.6 (10.6 to 30.6)	41.3 (29.1 to 53.4)	59.7 (47.5 to 71.9)	49.2 (36.6 to 61.7)

Statistical analyses

Statistical analysis title	Induction Period: Clinical Response at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	3.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.73
upper limit	8.98

Statistical analysis title	Induction Period: Clinical Response at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 200 mg Mirikizumab IV Q4W
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	6.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.94
upper limit	15.63

Statistical analysis title	Induction Period: Clinical Response at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 50 mg Mirikizumab IV Q4W
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	2.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.23
upper limit	6.29

Secondary: Induction Period: Percentage of Participants with Endoscopic Remission

at Week 12

End point title	Induction Period: Percentage of Participants with Endoscopic Remission at Week 12

End point description:

Endoscopic remission at week 12 is defined as achieving a Mayo endoscopic score of 0 at Week 12. Endoscopy Subscore is based on colonoscopy or sigmoidoscopy and scored from 0 (normal or inactive disease) to 3 (severe disease, spontaneous bleeding, ulceration);

The total score ranges from 0 to 3 points, with higher scores representing more severe disease.

Analysis Population Description: All randomized participants.

End point type	Secondary

End point timeframe:

Week 12

End point values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	63	62	61
Units: percentage of participants				
number (confidence interval 95%)	1.6 (0.0 to 4.7)	3.2 (0.0 to 7.5)	3.2 (0.0 to 7.6)	1.6 (0.0 to 4.8)

Statistical analyses

Statistical analysis title	Induction Period: Endoscopic Remission at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.986
Method	Mantel-Haenszel

Statistical analysis title	Induction Period: Endoscopic Remission at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 200 mg Mirikizumab IV Q4W
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.553
Method	Mantel-Haenszel

Statistical analysis title	Induction Period: Endoscopic Remission at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 50 mg Mirikizumab IV Q4W
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.56
Method	Mantel-Haenszel

Secondary: Maintenance period: Percentage of Participants with Endoscopic Remission at Week 52

End point title	Maintenance period: Percentage of Participants with Endoscopic Remission at Week 52

End point description:

Endoscopic remission at week 52 is defined as achieving a Mayo endoscopic subscore of 0 at Week 52. Endoscopy Subscore is based on colonoscopy or sigmoidoscopy and scored from 0 (normal or inactive disease) to 3 (severe disease, spontaneous bleeding, ulceration);

The total score ranges from 0 to 3 points, with higher scores representing more severe disease.

Analysis Population Description: All randomized participants in maintenance period.

End point type	Secondary

End point timeframe:

Week 52

End point values	Maintenance: Placebo SC Q4W	Maintenance: 200 mg Mirikizumab SC Q4W	Maintenance: 200 mg Mirikizumab SC Q12W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	47	46	
Units: percentage of participants				
number (confidence interval 95%)	7.7 (0.0 to 22.2)	14.9 (4.7 to 25.1)	28.3 (15.2 to 41.3)	

Statistical analyses

Statistical analysis title	Maintenance period:Endoscopic Remission at Week 52
Comparison groups	Maintenance: 200 mg Mirikizumab SC Q4W v Maintenance: 200 mg Mirikizumab SC Q12W

Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Odds ratio (OR)
Point estimate	2.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	6.55

Secondary: Induction Period: Change from Baseline to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Total Score

End point title	Induction Period: Change from Baseline to Week 12 in Inflammatory Bowel Disease Questionnaire (IBDQ) Total Score

End point description:

The IBDQ is a 32-item subject-completed questionnaire that measures 4 aspects of subjects' lives: symptoms directly related to the primary bowel disturbance, systemic symptoms, emotional function, and social function (Guyatt et al. 1989). Responses are graded on a 7-point. Likert scale in which 7 denotes "not a problem at all" and 1 denotes "a very severe problem." Scores range from 32 to 224; a higher score indicates a better quality of life. LS Mean was calculated using MMRM model for post-baseline measures: Variable = Baseline + Geographical Region + Prior Biologic Therapy Group (N) + Treatment + Time + Treatment*Time (Type III sum of squares).

Analysis Population Description: All randomized participants who had a baseline and at least one post-baseline value.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60	56
Units: score on a scale				
least squares mean (standard error)	22.3 (± 4.41)	33.0 (± 4.52)	42.8 (± 4.40)	45.2 (± 4.54)

Statistical analyses

Statistical analysis title	Induction Period: IBDQ Total Score
Comparison groups	Induction: Placebo IV Q4W v Induction: 600 mg Mirikizumab IV Q4W

Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	22.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	11
upper limit	34.9

Statistical analysis title	Induction Period: IBDQ Total Score
Comparison groups	Induction: Placebo IV Q4W v Induction: 200 mg Mirikizumab IV Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	20.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.7
upper limit	32.3

Statistical analysis title	Induction Period: IBDQ Total Score
Comparison groups	Induction: Placebo IV Q4W v Induction: 50 mg Mirikizumab IV Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	10.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1
upper limit	22.5

Secondary: Induction Period: Change from Baseline to Week 12 in 36-Item Short Form Health Survey (SF-36)

End point title	Induction Period: Change from Baseline to Week 12 in 36-Item Short Form Health Survey (SF-36)

End point description:

SF-36 Health Status Survey is a generic, health-related scale assessing participant’s quality of life on 8

domains: physical functioning, social functioning, bodily pain, vitality, mental health, role-physical, role-emotional and general health. Domain scores: general health (range: 5-25); physical functioning (range: 10-30); role-physical (range: 4-8); role-emotional (range: 3-15); social functioning (range: 2-10); bodily pain (range: 2-12); vitality (range: 4-20); mental health (range: 5-25). Each raw scale score was converted to a scale score ranging from 0-100 points, with higher values representing a better outcome [(Raw score) − min{raw score}] / (max {raw score} − min{raw score}) x 100]. LS Mean was calculated using Mixed effect Model Repeat Measurement (MMRM) model for post-baseline measures: Variable = Baseline + Geographical Region + Prior Biologic Therapy Group (N) + Treatment + Time + Treatment*Time (Type III sum of squares).

End point type	Secondary

End point timeframe:

Baseline, Week 12

Analysis Population Description: All randomized participants who had a baseline and at least one post-baseline value.

End point values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60[1]	56
Units: score on a scale				
least squares mean (standard error)				
Physical Component Score	3.4 (± 0.83)	6.2 (± 0.86)	5.9 (± 0.83)	6.9 (± 0.85)
Mental Component Score	3.2 (± 1.22)	4.5 (± 1.26)	6.8 (± 1.20)	8.8 (± 1.25)
Physical Functioning	2.1 (± 0.76)	3.7 (± 0.78)	4.6 (± 0.74)	6.2 (± 0.77)
Role-Physical	4.5 (± 1.19)	7.5 (± 1.22)	7.2 (± 1.17)	8.0 (± 1.22)
Bodily Pain	3.7 (± 1.15)	7.9 (± 1.18)	8.9 (± 1.14)	10.0 (± 1.18)
General Health	3.1 (± 0.93)	3.8 (± 0.96)	4.3 (± 0.92)	5.1 (± 0.96)
Vitality	3.3 (± 1.25)	6.5 (± 1.28)	7.5 (± 1.23)	9.7 (± 1.28)
Social Functioning	6.5 (± 1.22)	8.0 (± 1.26)	9.4 (± 1.21)	11.6 (± 1.26)
Role-Emotional	3.0 (± 1.22)	3.7 (± 1.26)	5.5 (± 1.20)	7.6 (± 1.25)
Mental Health	1.9 (± 1.18)	3.7 (± 1.22)	6.4 (± 1.17)	7.6 (± 1.21)

Notes:

[1] - Physical Component Score and Mental Component Score n=59.

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Period: Change from Baseline to Week 12 in Patient's Global Impressions of Severity (PGI-S) Score

End point title	Induction Period: Change from Baseline to Week 12 in Patient's Global Impressions of Severity (PGI-S) Score

End point description:

PGI-S is a 1-item subject-rated questionnaire designed to assess the subject's impression of their disease symptoms at baseline (Guy 1976; Yalcin and Bump 2003). Responses are graded on a 7-point scale in which a score of 1 indicates that the subject's symptom(s) are "normal," a score of 2 indicates that the subject feels "borderline ill," a score of 3 indicates that the subject feels "mildly ill," a score of 4 indicates that the subject(s) feel "moderately ill," and scores of 5, 6, and 7 indicate that the subject

feels "markedly ill," "severely ill," and "extremely ill," respectively. LS Mean was calculated using MMRM model for post-baseline measures: Variable = Baseline + Geographical Region + Prior Biologic Therapy Group (N) + Treatment + Time + Treatment*Time (Type III sum of squares).

Analysis Population Description: Induction Period: All randomized participants who had a baseline and at least one post-baseline value.

End point type	Secondary
End point timeframe:	
Baseline, Week 12	

End point values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	60	60	56
Units: score on a scale				
least squares mean (standard error)	-0.84 (± 0.19)	-1.43 (± 0.20)	-1.90 (± 0.18)	-1.74 (± 0.19)

Statistical analyses

Statistical analysis title	Induction Period: PGI-S Score
Comparison groups	Induction: Placebo IV Q4W v Induction: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	-0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.39
upper limit	-0.41

Statistical analysis title	Induction Period: PGI-S Score
Comparison groups	Induction: Placebo IV Q4W v Induction: 200 mg Mirikizumab IV Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	-1.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.54
upper limit	-0.59

Statistical analysis title	Induction Period: PGI-S Score
Comparison groups	Induction: Placebo IV Q4W v Induction: 50 mg Mirikizumab IV Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	-0.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.07
upper limit	-0.11

Secondary: Induction Period: Patient's Global Impressions of Improvement (PGI-I) Score at Week 12

End point title	Induction Period: Patient's Global Impressions of Improvement (PGI-I) Score at Week 12

End point description:

PGI-I scale is a subject-rated instrument designed to assess the subject’s impression of change in their symptom(s) (Guy 1976; Yalcin and Bump 2003). Responses are graded on a 7-point Likert scale in which a score of 1 indicates that the subject’s symptom(s) is “very much better,” a score of 4 indicates that the subject’s symptom(s) has experienced “no change,” and a score of 7 indicates that the subject’s symptom(s) is “very much worse.”

Analysis Population Description: All randomized participants who had a baseline and at least one post-baseline PGI-I value.

End point type	Secondary

End point timeframe:

Week 12

End point values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	62	61	60
Units: score on a scale				
arithmetic mean (standard deviation)	3.37 (± 1.46)	2.69 (± 1.31)	2.39 (± 0.99)	2.53 (± 1.16)

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacokinetics (PK): Area Under the Concentration-Time Curve During Dosing Interval at Steady State (AUCss, tau) of Mirikizumab

End point title	Pharmacokinetics (PK): Area Under the Concentration-Time Curve During Dosing Interval at Steady State (AUCss, tau) of Mirikizumab[2]

End point description:

Pharmacokinetics (PK): Area Under the Concentration-Time Curve During Dosing Interval at Steady State (AUCss, tau) of Mirikizumab

Analysis Population Description: All participants who received at least one dose of mirikizumab in the induction and maintenance period.

End point type	Secondary

End point timeframe:

Induction Period: Day (D) 1, D15 ± 2d, D29 ± 2d, D43 ± 2d, D57 ± 2d, D78-85; Maintenance Period: D85-92,D113± 7d,D141± 7d,D169± 7d,D225 ±7d,D281 ±7d,D337 ±7d,D393± 7d,D448± 7d,D504± 7d,D560± 7d,D616± 7d,D672± 7d,D728± 7d,D784± 7d,D840± 7d

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, not all arms were reported for PK data.

End point values	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W	Maintenance: 200 mg Mirikizumab SC Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	62	61	47
Units: Microgram*hour/ml (ug*hr/ml)				
geometric mean (geometric coefficient of variation)	3330 (± 42.5)	10100 (± 35.0)	24900 (± 36.6)	3700 (± 41.5)

End point values	Maintenance: 200 mg Mirikizumab SC Q12W			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: Microgram*hour/ml (ug*hr/ml)				
geometric mean (geometric coefficient of variation)	1270 (± 42.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Induction Period: Percentage of Participants With Symptomatic Remission at Week 12

End point title	Induction Period: Percentage of Participants With Symptomatic Remission at Week 12

End point description:

Symptomatic remission is defined as a stool frequency score of 0 or 1 and a rectal bleeding score of 0.
•Stool Frequency Subscore is based on the participant's diary and scored from 0 (normal number of stools) to 3 (5 or more stools than normal).
•Rectal Bleeding Subscore is based on the participant's diary and scored from 0 (no blood) to 3 (blood only passed).

The total score ranges from 0 to 1 points, with higher scores representing more severe disease.

The percentage of response is calculated by dividing number of participants in the specified category by number of participants with non-missing values multiplied by 100.

Analysis Population Description: All randomized participants.

End point type	Secondary

End point timeframe:

Week 12

End point values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	63	62	61
Units: percentage of participants				
number (confidence interval 95%)	20.6 (10.6 to 30.6)	36.5 (24.6 to 48.4)	58.1 (45.8 to 70.3)	45.9 (33.4 to 58.4)

Statistical analyses

Statistical analysis title	Participants With Symptomatic Remission at Week 12
Comparison groups	Induction: 600 mg Mirikizumab IV Q4W v Induction: Placebo IV Q4W

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	3.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.57
upper limit	8.31

Statistical analysis title	Participants With Symptomatic Remission at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 200 mg Mirikizumab IV Q4W
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	6.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.81
upper limit	15.2

Statistical analysis title	Participants With Symptomatic Remission at Week 12
Comparison groups	Induction: Placebo IV Q4W v Induction: 50 mg Mirikizumab IV Q4W
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.054
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.98
upper limit	5.22

Secondary: Maintenance Period: Percentage of Participants With Symptomatic Remission at Week 52

End point title	Maintenance Period: Percentage of Participants With Symptomatic Remission at Week 52

End point description:

Symptomatic remission is defined as a stool frequency score of 0 or 1 and a rectal bleeding score of 0.
•Stool Frequency Subscore , based on the participant's diary and scored from 0 (normal number of stools) to 3 (5 or more stools than normal);
•Rectal Bleeding Subscore , based on the participant's diary and scored from 0 (no blood) to 3 (blood only passed);
•Endoscopy Subscore , based on colonoscopy or sigmoidoscopy and scored from 0 (normal or inactive disease) to 3 (severe disease, spontaneous bleeding, ulceration);
•Physician's Global Assessment subscore, based on the physician's overall assessment, and scored from zero (normal) to 3 (severe disease).

The total score ranges from 0 to 1 points, with higher scores representing more severe disease.

The percentage of response is calculated by dividing number of participants in the specified category by number of participants with non-missing values multiplied by 100.

End point type	Secondary

End point timeframe:

Week 52

Analysis Population Description: All randomized participants in maintenance period.

End point values	Maintenance: Placebo SC Q4W	Maintenance: 200 mg Mirikizumab SC Q4W	Maintenance: 200 mg Mirikizumab SC Q12W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	47	46	
Units: Percentage of Participants				
number (confidence interval 95%)	53.8 (26.7 to 80.9)	76.6 (64.5 to 88.7)	65.2 (51.5 to 79.0)	

Statistical analyses

Statistical analysis title	Participants With Symptomatic Remission at Week 52
Comparison groups	Maintenance: 200 mg Mirikizumab SC Q12W v Maintenance: 200 mg Mirikizumab SC Q4W
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.131
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.48

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.19
upper limit	1.24

Secondary: Induction Period: Percentage of Participants With Endoscopic Improvement at Week 12

End point title	Induction Period: Percentage of Participants With Endoscopic Improvement at Week 12

End point description:

Endoscopic Improvement defined as achieving an endoscopic findings subscore of 0 or 1. Endoscopy Subscore is based on colonoscopy or sigmoidoscopy and scored from 0 (normal or inactive disease) to 3 (severe disease, spontaneous bleeding, ulceration). The percentage of response is calculated by dividing number of participants in the specified category by number of participants with non-missing values multiplied by 100.

Analysis Population Description: All randomized participants.

End point type	Secondary

End point timeframe:

Week 12

End point values	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab IV Q4W	Induction: 200 mg Mirikizumab IV Q4W	Induction: 600 mg Mirikizumab IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	63	62	61
Units: Percentage of participants				
number (confidence interval 95%)	6.3 (0.3 to 12.4)	23.8 (13.3 to 34.3)	30.6 (19.2 to 42.1)	13.1 (4.6 to 21.6)

Statistical analyses

Statistical analysis title	Participants With Endoscopic Improvement at Week12
Comparison groups	Induction: Placebo IV Q4W v Induction: 600 mg Mirikizumab IV Q4W
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.215
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.25

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	8.07

Statistical analysis title	Participants With Endoscopic Improvement at Week12
Comparison groups	Induction: Placebo IV Q4W v Induction: 200 mg Mirikizumab IV Q4W
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	7.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.37
upper limit	25

Statistical analysis title	Participants With Endoscopic Improvement at Week12
Comparison groups	Induction: Placebo IV Q4W v Induction: 50 mg Mirikizumab IV Q4W
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	4.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.41
upper limit	15.14

Secondary: Maintenance Period: Percentage of Participants With Endoscopic Improvement at Week 52

End point title	Maintenance Period: Percentage of Participants With Endoscopic Improvement at Week 52

End point description:

Endoscopic Improvement defined as achieving an endoscopic findings subscore of 0 or 1. Endoscopy Subscore is based on colonoscopy or sigmoidoscopy and scored from 0 (normal or inactive disease) to 3

(severe disease, spontaneous bleeding, ulceration). The percentage of response is calculated by dividing number of participants in the specified category by number of participants with non-missing values multiplied by 100.

Analysis Population Description: All randomized participants in maintenance period.

End point type	Secondary
End point timeframe:	
Week 52	

End point values	Maintenance: Placebo SC Q4W	Maintenance: 200 mg Mirikizumab SC Q4W	Maintenance: 200 mg Mirikizumab SC Q12W	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	47	46	
Units: Percentage of Participants				
number (confidence interval 95%)	15.4 (0.0 to 35.0)	57.4 (43.3 to 71.6)	47.8 (33.4 to 62.3)	

Statistical analyses

Statistical analysis title	Participants With Endoscopic Improvement at Week52
Comparison groups	Maintenance: 200 mg Mirikizumab SC Q12W v Maintenance: 200 mg Mirikizumab SC Q4W
Number of subjects included in analysis	93
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.428
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.31
upper limit	1.65

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up To 39 Months

Adverse event reporting additional description:

All participants who received at least one dose of study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups

Reporting group title	Induction: Placebo IV Q4W

Reporting group description:

Placebo administered every 4 weeks (Q4W) intravenously (IV) during the induction period.

Reporting group title	Induction: 50 mg Mirikizumab Administered Every 4 Weeks (Q4W)

Reporting group description:

50 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period.

Participants who do not have a clinical response may choose to participate in the unblinded study extension period.

Reporting group title	Induction: 200 mg Mirikizumab IV Q4W

Reporting group description:

200 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period.

Participants who do not have a clinical response may choose to participate in the unblinded study extension period.

Reporting group title	Induction: 600 mg Mirikizumab IV Q4W

Reporting group description:

600 mg mirikizumab administered every 4 weeks (Q4W) intravenously (IV) during the induction period.

Participants who do not have a clinical response may choose to participate in the unblinded study extension period.

Reporting group title	Maintenance: Placebo SC Q4W

Reporting group description:

Induction placebo responders: Placebo administered subcutaneously (SC) Q4W during the maintenance period.

Reporting group title	Maintenance: 200 mg Mirikizumab SC Q4W

Reporting group description:

Induction mirikizumab responders were re-randomized: 200 mg mirikizumab administered subcutaneously (SC) Q4W during the maintenance period.

Reporting group title	Maintenance: 200 mg Mirikizumab SC Q12W

Reporting group description:

Induction mirikizumab responders were re-randomized: 200 mg mirikizumab administered subcutaneously (SC) once every 12 weeks (Q12W) during the maintenance period.

Reporting group title	Induction Extension: 600mg Mirikizumab IV Q4W

Reporting group description:

Induction non-responders: 600 mg mirikizumab administered intravenously (IV) once every 4 weeks (Q4W) during the Extension Open-Label.

Reporting group title	Induction Extension:1000mg Mirikizumab IV Q4W

Reporting group description:

Induction non-responders: 1000 mg mirikizumab administered intravenously (IV) once every 4 weeks (Q4W) during the Extension Open-Label.

Reporting group title	Maintenance Extension: 200mg Mirikizumab SC Q4W

Reporting group description:

Extension Induction responders: 200 mg mirikizumab administered subcutaneously (SC) once every 4 weeks (Q4W) during the Extension Open-Label.

Serious adverse events	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab Administered Every 4 Weeks (Q4W)	Induction: 200 mg Mirikizumab IV Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 63 (3.17%)	0 / 63 (0.00%)	2 / 62 (3.23%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (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
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (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
Investigations			
platelet count increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
head injury			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (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
hip fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (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
large intestine perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 62 (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			
drug dependence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (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			
polyarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (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
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
streptococcal bacteraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (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
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 62 (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

Serious adverse events	Induction: 600 mg Mirikizumab IV Q4W	Maintenance: Placebo SC Q4W	Maintenance: 200 mg Mirikizumab SC Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 60 (5.00%)	2 / 13 (15.38%)	2 / 47 (4.26%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (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
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 60 (1.67%)	0 / 13 (0.00%)	0 / 47 (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
Investigations			
platelet count increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
head injury			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hip fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 60 (1.67%)	0 / 13 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (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
large intestine perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
drug dependence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (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			
polyarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	1 / 47 (2.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 60 (1.67%)	0 / 13 (0.00%)	0 / 47 (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
streptococcal bacteraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (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: 200 mg Mirikizumab SC Q12W	Induction Extension: 600mg Mirikizumab IV Q4W	Induction Extension:1000mg Mirikizumab IV Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 46 (2.17%)	1 / 32 (3.13%)	5 / 96 (5.21%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	1 / 32 (3.13%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	2 / 96 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
platelet count increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
head injury			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hip fracture			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
transient ischaemic attack			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 32 (0.00%)	2 / 96 (2.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal obstruction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
large intestine perforation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
drug dependence			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
polyarthritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	1 / 96 (1.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
streptococcal bacteraemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Maintenance Extension: 200mg Mirikizumab SC Q4W		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 68 (4.41%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast neoplasm			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
rectal cancer			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
squamous cell carcinoma of skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
platelet count increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
head injury			
alternative dictionary used:			

MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hip fracture				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
transient ischaemic attack				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
colitis ulcerative				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intestinal obstruction				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
large intestine perforation				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
drug dependence				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	1 / 68 (1.47%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
polyarthritis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
appendicitis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
clostridium difficile infection				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastroenteritis				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
streptococcal bacteraemia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
viral upper respiratory tract infection				
alternative dictionary used: MedDRA 22.0				

subjects affected / exposed	0 / 68 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Induction: Placebo IV Q4W	Induction: 50 mg Mirikizumab Administered Every 4 Weeks (Q4W)	Induction: 200 mg Mirikizumab IV Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 63 (28.57%)	14 / 63 (22.22%)	8 / 62 (12.90%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
breast mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			

alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 27 (0.00%)	0 / 25 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 63 (6.35%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	4	0	0
epistaxis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Investigations			
vitamin b12 decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
vitamin d decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 63 (4.76%)	3 / 63 (4.76%)	1 / 62 (1.61%)
occurrences (all)	3	3	1
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 63 (4.76%)	4 / 63 (6.35%)	2 / 62 (3.23%)
occurrences (all)	3	4	2
leukocytosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
abdominal distension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	6 / 63 (9.52%)	2 / 63 (3.17%)	1 / 62 (1.61%)
occurrences (all)	6	2	1
constipation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
haematochezia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
mucous stools			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 63 (6.35%)	2 / 63 (3.17%)	2 / 62 (3.23%)
occurrences (all)	5	2	2
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
dry skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
stress urinary incontinence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 63 (9.52%)	5 / 63 (7.94%)	3 / 62 (4.84%)
occurrences (all)	7	5	3
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Induction: 600 mg Mirikizumab IV Q4W	Maintenance: Placebo SC Q4W	Maintenance: 200 mg Mirikizumab SC Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 60 (23.33%)	11 / 13 (84.62%)	27 / 47 (57.45%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	4 / 47 (8.51%)
occurrences (all)	0	1	4
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	2 / 13 (15.38%)	1 / 47 (2.13%)
occurrences (all)	0	3	1
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	2 / 13 (15.38%)	3 / 47 (6.38%)
occurrences (all)	0	2	14
injection site reaction			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	3
Reproductive system and breast disorders			
breast mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 22 (0.00%)	1 / 5 (20.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 60 (3.33%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences (all)	2	0	0
epistaxis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Investigations			
vitamin b12 decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
vitamin d decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			

contusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 60 (6.67%)	1 / 13 (7.69%)	5 / 47 (10.64%)
occurrences (all)	5	1	9
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 60 (3.33%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences (all)	2	0	0
leukocytosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
abdominal distension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	2 / 47 (4.26%)
occurrences (all)	0	1	3
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	1 / 47 (2.13%)
occurrences (all)	0	2	2

abdominal pain upper			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 60 (1.67%)	7 / 13 (53.85%)	4 / 47 (8.51%)
occurrences (all)	1	10	4
constipation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	1 / 47 (2.13%)
occurrences (all)	0	1	2
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	5
dyspepsia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
flatulence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
haematochezia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
mucous stools			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	3 / 60 (5.00%)	2 / 13 (15.38%)	3 / 47 (6.38%)
occurrences (all)	3	2	3
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
dry skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	1 / 47 (2.13%)
occurrences (all)	0	2	1
Renal and urinary disorders			
stress urinary incontinence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	6 / 47 (12.77%)
occurrences (all)	0	0	9
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	3 / 13 (23.08%)	1 / 47 (2.13%)
occurrences (all)	0	3	1
myalgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	0 / 47 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	1 / 47 (2.13%)
occurrences (all)	0	1	2
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	2 / 47 (4.26%)
occurrences (all)	0	1	2
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	4 / 47 (8.51%)
occurrences (all)	0	0	4
herpes zoster			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	2 / 13 (15.38%)	1 / 47 (2.13%)
occurrences (all)	0	2	1
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	3 / 47 (6.38%)
occurrences (all)	0	0	5
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 60 (8.33%)	1 / 13 (7.69%)	6 / 47 (12.77%)
occurrences (all)	5	2	12
pharyngitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	2 / 47 (4.26%)
occurrences (all)	0	0	2
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	0 / 47 (0.00%)
occurrences (all)	0	1	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	0 / 13 (0.00%)	1 / 47 (2.13%)
occurrences (all)	0	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	3 / 13 (23.08%)	5 / 47 (10.64%)
occurrences (all)	0	7	7
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 60 (0.00%)	1 / 13 (7.69%)	1 / 47 (2.13%)
occurrences (all)	0	1	3

Non-serious adverse events	Maintenance: 200 mg Mirikizumab SC Q12W	Induction Extension: 600mg Mirikizumab IV Q4W	Induction Extension:1000mg Mirikizumab IV Q4W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 46 (65.22%)	9 / 32 (28.13%)	8 / 96 (8.33%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 46 (4.35%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 46 (6.52%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	6	0	0
injection site pain			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	2 / 46 (4.35%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	2	0	0
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
breast mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
vaginal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 24 (0.00%)	0 / 12 (0.00%)	0 / 33 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
epistaxis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Investigations			
vitamin b12 decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
vitamin d decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 46 (6.52%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	3	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
abdominal distension			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	2 / 46 (4.35%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	2	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
colitis ulcerative			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	7 / 46 (15.22%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	7	0	0
constipation			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	1	0	0
diarrhoea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
flatulence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
haematochezia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	1	0	0

mucous stools			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	1	0	0
nausea			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	1	0	0
dry skin			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	2 / 32 (6.25%)	1 / 96 (1.04%)
occurrences (all)	0	2	1
rash			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
stress urinary incontinence			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	1	0	0
back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 46 (6.52%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	3	0	0

myalgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	1 / 46 (2.17%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	1	0	0
herpes zoster			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 46 (8.70%)	3 / 32 (9.38%)	0 / 96 (0.00%)
occurrences (all)	5	3	0
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	8 / 46 (17.39%)	5 / 32 (15.63%)	7 / 96 (7.29%)
occurrences (all)	10	5	8
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 46 (6.52%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	4	0	0
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 46 (0.00%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 46 (8.70%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	5	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 46 (6.52%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	3	0	0
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	3 / 46 (6.52%)	0 / 32 (0.00%)	0 / 96 (0.00%)
occurrences (all)	4	0	0

Non-serious adverse events	Maintenance Extension: 200mg Mirikizumab SC Q4W		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 68 (44.12%)		
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
injection site pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
injection site reaction			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
breast mass			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
vaginal haemorrhage			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed[1]	0 / 25 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
epistaxis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
Investigations			
vitamin b12 decreased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
vitamin d decreased			
alternative dictionary used:			

MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
weight increased			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
leukocytosis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 68 (0.00%)			
occurrences (all)	0			
abdominal distension				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences (all)	0			
abdominal pain				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences (all)	0			
abdominal pain upper				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	4 / 68 (5.88%)			
occurrences (all)	4			
colitis ulcerative				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	7 / 68 (10.29%)			
occurrences (all)	7			
constipation				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences (all)	0			
diarrhoea				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences (all)	0			
dyspepsia				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences (all)	0			
flatulence				
alternative dictionary used: MedDRA 22.0				
subjects affected / exposed	0 / 68 (0.00%)			
occurrences (all)	0			

haematochezia alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	0 / 68 (0.00%) 0		
mucous stools alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	0 / 68 (0.00%) 0		
nausea alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	0 / 68 (0.00%) 0		
Skin and subcutaneous tissue disorders acne alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	0 / 68 (0.00%) 0		
dry skin alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	0 / 68 (0.00%) 0		
rash alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	0 / 68 (0.00%) 0		
Renal and urinary disorders stress urinary incontinence alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	0 / 68 (0.00%) 0		
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 22.0 subjects affected / exposed occurrences (all)	0 / 68 (0.00%) 0		

back pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 68 (8.82%)		
occurrences (all)	7		
myalgia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	5 / 68 (7.35%)		
occurrences (all)	5		
spinal pain			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
clostridium difficile infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
cystitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
gastroenteritis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
herpes zoster			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
influenza			
alternative dictionary used: MedDRA 22.0			

subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
nasopharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	14 / 68 (20.59%)		
occurrences (all)	21		
pharyngitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
pneumonia			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		
sinusitis			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	4 / 68 (5.88%)		
occurrences (all)	8		
upper respiratory tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	6 / 68 (8.82%)		
occurrences (all)	7		
urinary tract infection			
alternative dictionary used: MedDRA 22.0			
subjects affected / exposed	0 / 68 (0.00%)		
occurrences (all)	0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 October 2016	Amendment b: Change in dosing of the Investigational Medicinal Product (IMP) in the extension phase from 600mg IV to 1000mg IV.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported