Clinical trial results:
A Phase 2b Double-blind, Multi-dose, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI2070 in Subjects with Moderate to Severe Crohn's Disease Who Have Failed or Are Intolerant to Anti-tumor Necrosis Factor-alpha Therapy

Summary

EudraCT number	2015-000609-38
Trial protocol	DE CZ NL ES BG HU BE IT GB
Global end of trial date	29 January 2018

Results information

Result version number	v1 (current)
This version publication date	15 February 2019
First version publication date	15 February 2019

Trial information

Trial identification

Sponsor protocol code	D5170C00002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02574637
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Allergan plc
Sponsor organisation address	Clonshaugh Business & Technology Park, Coolock, Dublin, Ireland, D17 E400
Public contact	Clinical Trials Registry Team, Allergan plc, 001 8772778566, IR-CTRegistration@Allergan.com
Scientific contact	Therapeutic Area Head, Allergan plc, 001 862-261-7000, IR-CTRegistration@Allergan.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 January 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 January 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to evaluate the efficacy of MEDI2070 versus placebo to induce clinical remission based on the Crohn's Disease Activity Index (CDAI) score at Week 8 in participants with moderate to severe Crohn's disease (CD) who have failed or are intolerant to anti-tumor necrosis factor-alpha (TNFα) therapy.

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 January 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Hungary: 2
Country: Number of subjects enrolled	Italy: 1
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	Australia: 1
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	United States: 14
Worldwide total number of subjects	29
EEA total number of subjects	13

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)	28
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study enrolled 29 participants who were randomized to one of five treatment groups (Placebo/ Brazikumab High dose/ Brazikumab High-Medium dose/ Brazikumab Low dose/ Brazikumab Low-Medium dose). This study was early terminated.

Period 1

Period 1 title	Double-blind Treatment Period, Week 0-24
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo-matching brazikumab intravenous (IV) infusion and subcutaneous (SC) injection at Weeks 0 and 4 followed by placebo-matching brazikumab SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Placebo-matching brazikumab SC injection and IV infusion at Weeks 0 and 4 followed by placebo-matching brazikumab SC injection every 4 weeks starting at Week 8 up to Week 24 in the induction and maintenance phases.

Arm title	Brazikumab High Dose

Arm description:

Brazikumab 700 mg, IV infusion and placebo-matching brazikumab, SC injection at Weeks 0 and 4 followed by brazikumab 210 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.

Arm type	Experimental
Investigational medicinal product name	Brazikumab
Investigational medicinal product code	
Other name	MEDI2070
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Brazikumab 700 mg, IV infusion at Weeks 0 and 4 followed by brazikumab 210 mg, SC injection, every 4 weeks starting at Week 8 up to Week 24 in the induction and maintenance phases.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo-matching brazikumab, SC injection at Weeks 0 and 4 in the induction phase.

Arm title	Brazikumab High- Medium Dose

Arm description:

Brazikumab 280 mg, IV infusion and placebo-matching brazikumab, SC injection at Week 0 followed by brazikumab 210 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 4, followed by brazikumab 210 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Placebo-matching brazikumab, SC injection at Week 0 followed by placebo-matching brazikumab, IV infusion at Week 4 in the induction phase.

Investigational medicinal product name	Brazikumab
Investigational medicinal product code	
Other name	MEDI2070
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Brazikumab 280 mg, IV infusion at Week 0 followed by brazikumab 210 mg, SC injection every 4 weeks starting at Week 4 up to Week 24 in the induction and the maintenance phases.

Arm title	Brazikumab Low- Medium Dose

Arm description:

Brazikumab 210 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 0 followed by brazikumab 105 mg, SC injection and placebo-matching brazikumab, IV infusion at Weeks 4, followed by brazikumab 105 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.

Arm type	Experimental
Investigational medicinal product name	Brazikumab
Investigational medicinal product code	
Other name	MEDI2070
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Brazikumab 210 mg, SC injection at Week 0 followed by brazikumab 105 mg, every 4 weeks, starting at Week 4 up to Week 24 in the induction and maintenance phases.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Placebo-matching brazikumab, IV infusion at Weeks 0 and 4 in the induction phase.

Arm title	Brazikumab Low Dose

Arm description:

Brazikumab 70 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 0 followed by

brazikumab 35 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 4, followed by brazikumab 35 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Placebo-matching brazikumab, IV infusion at Weeks 0 and 4 in the induction phase.

Investigational medicinal product name	Brazikumab
Investigational medicinal product code	
Other name	MEDI2070
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Brazikumab 70 mg, SC injection at Week 0 followed by brazikumab 35 mg, SC injection every 4 weeks starting at Week 4 up to Week 24 in the induction phase and the maintenance phases.

Number of subjects in period 1	Placebo	Brazikumab High Dose	Brazikumab High-Medium Dose
Started	5	5	9
Completed	2	4	2
Not completed	3	1	7
Adverse Event	1	-	-
Protocol Deviation	1	-	-
Study Terminated By Sponsor	1	1	5
Non-Compliance With Study Drug	-	-	-
Other Miscellaneous Reasons	-	-	-
Lack of efficacy	-	-	2

Number of subjects in period 1	Brazikumab Low-Medium Dose	Brazikumab Low Dose
Started	7	3
Completed	3	1
Not completed	4	2
Adverse Event	-	-
Protocol Deviation	-	-
Study Terminated By Sponsor	2	2
Non-Compliance With Study Drug	1	-
Other Miscellaneous Reasons	1	-
Lack of efficacy	-	-

Period 2	
Period 2 title	Intermediate Period, Week 25-27
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded
Arms	
Are arms mutually exclusive?	Yes
Arm title	Placebo
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Brazikumab High Dose
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Brazikumab High- Medium Dose
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Brazikumab Low- Medium Dose
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Brazikumab Low Dose
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	Placebo	Brazikumab High Dose	Brazikumab High-Medium Dose
Started	2	4	2
Completed	2	3	2
Not completed	0	1	0
Other Miscellaneous Reasons	-	1	-

Number of subjects in period 2	Brazikumab Low-Medium Dose	Brazikumab Low Dose
Started	3	1
Completed	3	1
Not completed	0	0
Other Miscellaneous Reasons	-	-

Period 3

Period 3 title	Open-label (OL) Period, Week 28-48
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo/Brazikumab 210 mg in OL Period

Arm description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received placebo-matching brazikumab in the double-blind treatment period.

Arm type	Experimental
Investigational medicinal product name	Brazikumab
Investigational medicinal product code	
Other name	MEDI2070
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Brazikumab 210 mg, SC injection, every 4 weeks starting at Week 28 up to Week 48 in the open-label period.

Arm title	Brazikumab High Dose/Brazikumab 210 mg in OL Period

Arm description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received high dose of brazikumab in the double-blind treatment period.

Arm type	Experimental
Investigational medicinal product name	Brazikumab
Investigational medicinal product code	
Other name	MEDI2070
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Brazikumab 210 mg, SC injection, every 4 weeks starting at Week 28 up to Week 48 in the open-label period.

Arm title	Brazikumab High- Medium Dose/Brazikumab 210 mg in OL Period

Arm description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received high-medium dose of brazikumab in the double-blind treatment period.

Arm type	Experimental
Investigational medicinal product name	Brazikumab
Investigational medicinal product code	
Other name	MEDI2070
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use

Dosage and administration details:

Brazikumab 210 mg, SC injection, every 4 weeks starting at Week 28 up to Week 48 in the open-label period.

Arm title	Brazikumab Low-Medium Dose/Brazikumab 210 mg in OL Period

Arm description:	
Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received low-medium dose of brazikumab in the double-blind treatment period.	
Arm type	Experimental
Investigational medicinal product name	Brazikumab
Investigational medicinal product code	
Other name	MEDI2070
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use
Dosage and administration details:	
Brazikumab 210 mg, SC injection, every 4 weeks starting at Week 28 up to Week 48 in the open-label period.	
Arm title	Brazikumab Low Dose/Brazikumab 210 mg in OL Period
Arm description:	
Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received low dose of brazikumab in the double-blind treatment period.	
Arm type	Experimental
Investigational medicinal product name	Brazikumab
Investigational medicinal product code	
Other name	MEDI2070
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Subcutaneous use
Dosage and administration details:	
Brazikumab 210 mg, SC injection, every 4 weeks starting at Week 28 up to Week 48 in the open-label period.	

Number of subjects in period 3	Placebo/Brazikumab 210 mg in OL Period	Brazikumab High Dose/Brazikumab 210 mg in OL Period	Brazikumab High-Medium Dose/Brazikumab 210 mg in OL Period
Started	2	3	2
Completed	0	1	1
Not completed	2	2	1
Adverse Event	-	-	-
Study Terminated By Sponsor	1	2	1
Withdrawal by Subject	1	-	-

Number of subjects in period 3	Brazikumab Low-Medium Dose/Brazikumab 210 mg in OL Period	Brazikumab Low Dose/Brazikumab 210 mg in OL Period
Started	3	1
Completed	1	0
Not completed	2	1
Adverse Event	1	-
Study Terminated By Sponsor	1	-
Withdrawal by Subject	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo-matching brazikumab intravenous (IV) infusion and subcutaneous (SC) injection at Weeks 0 and 4 followed by placebo-matching brazikumab SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	
Reporting group title	Brazikumab High Dose
Reporting group description:	
Brazikumab 700 mg, IV infusion and placebo-matching brazikumab, SC injection at Weeks 0 and 4 followed by brazikumab 210 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	
Reporting group title	Brazikumab High- Medium Dose
Reporting group description:	
Brazikumab 280 mg, IV infusion and placebo-matching brazikumab, SC injection at Week 0 followed by brazikumab 210 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 4, followed by brazikumab 210 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	
Reporting group title	Brazikumab Low- Medium Dose
Reporting group description:	
Brazikumab 210 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 0 followed by brazikumab 105 mg, SC injection and placebo-matching brazikumab, IV infusion at Weeks 4, followed by brazikumab 105 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	
Reporting group title	Brazikumab Low Dose
Reporting group description:	
Brazikumab 70 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 0 followed by brazikumab 35 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 4, followed by brazikumab 35 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	

Reporting group values	Placebo	Brazikumab High Dose	Brazikumab High-Medium Dose
Number of subjects	5	5	9
Age Categorical Units: Subjects			
Adults (18-64 years)	5	5	8
From 65-84 years	0	0	1
Age Continuous Units: years			
arithmetic mean	34.6	37.2	38.3
standard deviation	± 9.07	± 13.29	± 15.03
Gender Categorical Units: Subjects			
Female	3	3	6
Male	2	2	3

Reporting group values	Brazikumab Low-Medium Dose	Brazikumab Low Dose	Total
Number of subjects	7	3	29
Age Categorical Units: Subjects			
Adults (18-64 years)	7	3	28

From 65-84 years	0	0	1

Age Continuous Units: years			
arithmetic mean	39.9	40.7	
standard deviation	± 13.89	± 11.37	-
Gender Categorical Units: Subjects			
Female	4	1	17
Male	3	2	12

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo-matching brazikumab intravenous (IV) infusion and subcutaneous (SC) injection at Weeks 0 and 4 followed by placebo-matching brazikumab SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	
Reporting group title	Brazikumab High Dose
Reporting group description:	
Brazikumab 700 mg, IV infusion and placebo-matching brazikumab, SC injection at Weeks 0 and 4 followed by brazikumab 210 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	
Reporting group title	Brazikumab High- Medium Dose
Reporting group description:	
Brazikumab 280 mg, IV infusion and placebo-matching brazikumab, SC injection at Week 0 followed by brazikumab 210 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 4, followed by brazikumab 210 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	
Reporting group title	Brazikumab Low- Medium Dose
Reporting group description:	
Brazikumab 210 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 0 followed by brazikumab 105 mg, SC injection and placebo-matching brazikumab, IV infusion at Weeks 4, followed by brazikumab 105 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	
Reporting group title	Brazikumab Low Dose
Reporting group description:	
Brazikumab 70 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 0 followed by brazikumab 35 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 4, followed by brazikumab 35 mg, SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Brazikumab High Dose
Reporting group description: -	
Reporting group title	Brazikumab High- Medium Dose
Reporting group description: -	
Reporting group title	Brazikumab Low- Medium Dose
Reporting group description: -	
Reporting group title	Brazikumab Low Dose
Reporting group description: -	
Reporting group title	Placebo/Brazikumab 210 mg in OL Period
Reporting group description:	
Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received placebo-matching brazikumab in the double-blind treatment period.	
Reporting group title	Brazikumab High Dose/Brazikumab 210 mg in OL Period
Reporting group description:	
Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received high dose of brazikumab in the double-blind treatment period.	
Reporting group title	Brazikumab High- Medium Dose/Brazikumab 210 mg in OL Period
Reporting group description:	
Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received high-medium dose of brazikumab in the double-blind treatment period.	
Reporting group title	Brazikumab Low-Medium Dose/Brazikumab 210 mg in OL Period

Reporting group description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received low-medium dose of brazikumab in the double-blind treatment period.

Reporting group title	Brazikumab Low Dose/Brazikumab 210 mg in OL Period

Reporting group description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received low dose of brazikumab in the double-blind treatment period.

Primary: Percentage of Participants With Crohn's Disease Activity Index (CDAI) Remission at Week 8

End point title	Percentage of Participants With Crohn's Disease Activity Index (CDAI) Remission at Week 8[1]

End point description:

CDAI remission was defined as a CDAI score of <150 at Week 8. CDAI score was calculated by summing weighted scores for subjective items [number of liquid or very soft stools, abdominal pain (on a scale of 0=none to 3=severe) and general well-being (on a scale of 1=generally well to 4=terrible)] recorded by a diary during a 1-week period, and objective items [associated symptoms, taking antidiarrheal agents such as loperamide/opiates, abdominal mass, hematocrit, daily morning temperature, and body weight]. CDAI scores range from 0 to approximately 600 points, higher score indicates higher disease activity.

End point type	Primary

End point timeframe:

Week 8

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No data was collected for this endpoint.

End point values	Placebo	Brazikumab High Dose	Brazikumab High- Medium Dose	Brazikumab Low- Medium Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[2]	0[3]	0[4]	0[5]
Units: percentage of participants				
number (not applicable)				

Notes:

[2] - This endpoint was not performed as the study was terminated.

[3] - This endpoint was not performed as the study was terminated.

[4] - This endpoint was not performed as the study was terminated.

[5] - This endpoint was not performed as the study was terminated.

End point values	Brazikumab Low Dose			
Subject group type	Reporting group			
Number of subjects analysed	0[6]			
Units: percentage of participants				
number (not applicable)				

Notes:

[6] - This endpoint was not performed as the study was terminated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Simple Endoscopic Score for Crohn's Disease (SES-CD) Remission at Weeks 16 and 28

End point title	Percentage of Participants With Simple Endoscopic Score for Crohn's Disease (SES-CD) Remission at Weeks 16 and 28

End point description:

SES-CD remission was defined as a Total SES-CD score of ≤4 and no subscore >2. The SES-CD evaluates 4 endoscopic variables [ulcer size, proportion of the surface area that is ulcerated, proportion of the surface area affected, and stenosis] each rated from 0 (best) to 3 (worst) in 5 segments evaluated during ileocolonoscopy [ileum, right colon, transverse colon, left colon, and rectum]. The score for each endoscopic variable is the sum of values obtained for each segment. The SES-CD total is the sum of the 4 endoscopic variable scores from 0 to 60, where higher scores indicate more severe disease.

End point type	Secondary

End point timeframe:

Weeks 16 and 28

End point values	Placebo	Brazikumab High Dose	Brazikumab High- Medium Dose	Brazikumab Low- Medium Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[7]	0[8]	0[9]	0[10]
Units: percentage of participants				
number (not applicable)				

Notes:

[7] - This endpoint was not performed as the study was terminated.

[8] - This endpoint was not performed as the study was terminated.

[9] - This endpoint was not performed as the study was terminated.

[10] - This endpoint was not performed as the study was terminated.

End point values	Brazikumab Low Dose			
Subject group type	Reporting group			
Number of subjects analysed	0[11]			
Units: percentage of participants				
number (not applicable)				

Notes:

[11] - This endpoint was not performed as the study was terminated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SES-CD Response at Week 16

End point title	Percentage of Participants With SES-CD Response at Week 16

End point description:

SES-CD response was defined as a decrease from baseline in SES-CD score ≥ 50%. The SES-CD evaluates 4 endoscopic variables [ulcer size, proportion of the surface area that is ulcerated, proportion of the surface area affected, and stenosis] each rated from 0 (best) to 3 (worst) in 5 segments evaluated during ileocolonoscopy [ileum, right colon, transverse colon, left colon, and rectum]. The score for each endoscopic variable is the sum of values obtained for each segment. The SES-CD total is the sum of the 4 endoscopic variable scores from 0 to 60, where higher scores indicate more severe disease.

End point type	Secondary

End point timeframe:

Baseline to Week 16

End point values	Placebo	Brazikumab High Dose	Brazikumab High- Medium Dose	Brazikumab Low- Medium Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[12]	0[13]	0[14]	0[15]
Units: percentage of participants				
number (not applicable)				

Notes:

[12] - This endpoint was not performed as the study was terminated.

[13] - This endpoint was not performed as the study was terminated.

[14] - This endpoint was not performed as the study was terminated.

[15] - This endpoint was not performed as the study was terminated.

End point values	Brazikumab Low Dose			
Subject group type	Reporting group			
Number of subjects analysed	0[16]			
Units: percentage of participants				
number (not applicable)				

Notes:

[16] - This endpoint was not performed as the study was terminated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Patient Response Outcome-2 (PRO2) Remission at Weeks 8, 16 and 28

End point title	Percentage of Participants With Patient Response Outcome-2 (PRO2) Remission at Weeks 8, 16 and 28

End point description:

PRO2 evaluated 2 patient-reported symptoms: the frequency of liquid or soft stools and abdominal pain. A weekly score was calculated for the liquid or soft stool frequency and a separate weekly score was calculated for abdominal pain, in each case based on daily symptom reporting. PRO2-remission was defined as PRO2 less than 8 points. PRO2 is a composite index consisting of weighted scoring of both variables. PRO2 scores ranges from 0 to approximately 45, higher score indicates higher disease activity.

End point type	Secondary

End point timeframe:

Weeks 8, 16 and 28

End point values	Placebo	Brazikumab High Dose	Brazikumab High- Medium Dose	Brazikumab Low- Medium Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[17]	0[18]	0[19]	0[20]
Units: percentage of participants				
number (not applicable)				

Notes:

[17] - This endpoint was not performed as the study was terminated.

[18] - This endpoint was not performed as the study was terminated.

[19] - This endpoint was not performed as the study was terminated.

[20] - This endpoint was not performed as the study was terminated.

End point values	Brazikumab Low Dose			
Subject group type	Reporting group			
Number of subjects analysed	0[21]			
Units: percentage of participants				
number (not applicable)				

Notes:

[21] - This endpoint was not performed as the study was terminated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With PRO2 Response at Weeks 8 and 16

End point title	Percentage of Participants With PRO2 Response at Weeks 8 and 16

End point description:

PRO2 evaluated 2 patient-reported symptoms: the frequency of liquid or soft stools and abdominal pain. PRO2 response was defined as remission or response in one symptom (either abdominal pain or stool frequency) plus response in the other: a) abdominal pain remission: On an 11-point (0 to 10) pain scale: During 1 week, no daily score > 2, b) abdominal pain response: On an 11-point (0 to 10) pain scale: ≥ 30% reduction in weekly pain score from baseline, c) loose/liquid stool frequency remission: Counting stools identified as Type 6 or 7 on Bristol Stool Form Scale (BSFS), (The BSFS is a scale between 1-7, where 1 correlates with the firmest stool and 7 correlates with entirely liquid stool), during 1 week, each daily loose/liquid stool count ≤ 3, d) loose/liquid stool frequency response: Counting stools identified as Type 6 or 7 on BSFS, ≥ 30% reduction in weekly loose/liquid stool count compared to baseline.

End point type	Secondary

End point timeframe:

Baseline to Weeks 8 and 16

End point values	Placebo	Brazikumab High Dose	Brazikumab High- Medium Dose	Brazikumab Low- Medium Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[22]	0[23]	0[24]	0[25]
Units: percentage of participants				
number (not applicable)				

Notes:

[22] - This endpoint was not performed as the study was terminated.

[23] - This endpoint was not performed as the study was terminated.

[24] - This endpoint was not performed as the study was terminated.

[25] - This endpoint was not performed as the study was terminated.

End point values	Brazikumab Low Dose			
Subject group type	Reporting group			
Number of subjects analysed	0[26]			
Units: percentage of participants				
number (not applicable)				

Notes:

[26] - This endpoint was not performed as the study was terminated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With CDAI Clinical Remission at Week 28

End point title	Percentage of Participants With CDAI Clinical Remission at Week 28

End point description:

CDAI remission was defined as a CDAI score of <150 at Week 28. CDAI score was calculated by summing weighted scores for subjective items [number of liquid or very soft stools, abdominal pain (on a scale of 0=none to 3=severe) and general well-being (on a scale of 1=generally well to 4=terrible)] recorded by a diary during a 1-week period, and objective items [associated symptoms, taking antidiarrheal agents such as loperamide/opiates, abdominal mass, hematocrit, daily morning temperature, and body weight]. CDAI scores range from 0 to approximately 600 points, higher score indicates higher disease activity.

End point type	Secondary

End point timeframe:

Week 28

End point values	Placebo	Brazikumab High Dose	Brazikumab High- Medium Dose	Brazikumab Low- Medium Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[27]	0[28]	0[29]	0[30]
Units: percentage of participants				
number (not applicable)				

Notes:

[27] - This endpoint was not performed as the study was terminated.

[28] - This endpoint was not performed as the study was terminated.

[29] - This endpoint was not performed as the study was terminated.

[30] - This endpoint was not performed as the study was terminated.

End point values	Brazikumab Low Dose			
Subject group type	Reporting group			
Number of subjects analysed	0[31]			
Units: percentage of participants				

number (not applicable)				

Notes:

[31] - This endpoint was not performed as the study was terminated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With CDAI Modified Sustained Clinical Remission at Both Weeks 8 and 28

End point title	Percentage of Participants With CDAI Modified Sustained Clinical Remission at Both Weeks 8 and 28

End point description:

CDAI modified sustained clinical remission was defined as a CDAI score of <150 at both Week 8 and Week 28. CDAI score was calculated by summing weighted scores for subjective items [number of liquid or very soft stools, abdominal pain (on a scale of 0=mild to 3=severe) and general well-being (on a scale of 1=generally well to 4=terrible)] recorded by a diary during a 1-week period, and objective items [associated symptoms, taking antidiarrheal agents such as loperamide/opiates, abdominal mass, hematocrit, daily morning temperature and body weight]. CDAI scores range from 0 to approximately 600 points, higher score indicates higher disease activity.

End point type	Secondary

End point timeframe:

Weeks 8 and 28

End point values	Placebo	Brazikumab High Dose	Brazikumab High- Medium Dose	Brazikumab Low- Medium Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[32]	0[33]	0[34]	0[35]
Units: percentage of participants				
number (not applicable)				

Notes:

[32] - This endpoint was not performed as the study was terminated.

[33] - This endpoint was not performed as the study was terminated.

[34] - This endpoint was not performed as the study was terminated.

[35] - This endpoint was not performed as the study was terminated.

End point values	Brazikumab Low Dose			
Subject group type	Reporting group			
Number of subjects analysed	0[36]			
Units: percentage of participants				
number (not applicable)				

Notes:

[36] - This endpoint was not performed as the study was terminated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SES-CD Modified Sustained Remission at Both Weeks 16 and 28

End point title	Percentage of Participants With SES-CD Modified Sustained Remission at Both Weeks 16 and 28

End point description:

SES-CD modified sustained remission was defined as remission at both Week 16 and Week 28. Endoscopic remission was defined as a SES-CD score of ≤4. The SES-CD evaluates 4 endoscopic variables [ulcer size, proportion of the surface area that is ulcerated, proportion of the surface area affected, and stenosis] each rated from 0 (best) to 3 (worst) in 5 segments evaluated during ileocolonoscopy [ileum, right colon, transverse colon, left colon, and rectum]. The score for each endoscopic variable is the sum of values obtained for each segment. The SES-CD total is the sum of the 4 endoscopic variable scores from 0 to 60, where higher scores indicate more severe disease.

End point type	Secondary

End point timeframe:

Weeks 16 and 28

End point values	Placebo	Brazikumab High Dose	Brazikumab High- Medium Dose	Brazikumab Low- Medium Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[37]	0[38]	0[39]	0[40]
Units: percentage of participants				
number (not applicable)				

Notes:

[37] - This endpoint was not performed as the study was terminated.

[38] - This endpoint was not performed as the study was terminated.

[39] - This endpoint was not performed as the study was terminated.

[40] - This endpoint was not performed as the study was terminated.

End point values	Brazikumab Low Dose			
Subject group type	Reporting group			
Number of subjects analysed	0[41]			
Units: percentage of participants				
number (not applicable)				

Notes:

[41] - This endpoint was not performed as the study was terminated.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With PRO2 Modified Sustained Remission at Both Weeks 8 and 28

End point title	Percentage of Participants With PRO2 Modified Sustained Remission at Both Weeks 8 and 28

End point description:

PRO2 modified sustained remission was defined as PRO2 less than 8 points at both Week 8 and Week 28. PRO2 evaluated 2 patient-reported symptoms: the frequency of liquid or soft stools and abdominal pain. A weekly score was calculated for the liquid or soft stool frequency and a separate weekly score

was calculated for abdominal pain, in each case based on daily symptom reporting. PRO2-remission was defined as PRO2 less than 8 points. PRO2 is a composite index consisting of weighted scoring of both variables. PRO2 scores ranges from 0 to approximately 45, higher score indicates higher disease activity.

End point type	Secondary

End point timeframe:

Weeks 8 and 28

End point values	Placebo	Brazikumab High Dose	Brazikumab High- Medium Dose	Brazikumab Low- Medium Dose
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[42]	0[43]	0[44]	0[45]
Units: percentage of participants				
number (not applicable)				

Notes:

[42] - This endpoint was not performed as the study was terminated.

[43] - This endpoint was not performed as the study was terminated.

[44] - This endpoint was not performed as the study was terminated.

[45] - This endpoint was not performed as the study was terminated.

End point values	Brazikumab Low Dose			
Subject group type	Reporting group			
Number of subjects analysed	0[46]			
Units: percentage of participants				
number (not applicable)				

Notes:

[46] - This endpoint was not performed as the study was terminated.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study drug up to 28 weeks post last dose (approximately up to Week 80)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups

Reporting group title	Placebo in Double-blind Treatment Period

Reporting group description:

Placebo-matching brazikumab IV infusion and SC injection at Weeks 0 and 4 followed by placebo-matching brazikumab SC injection at Weeks 8 and 12 in the induction phase and at Weeks 16, 20 and 24 in the maintenance phase.

Reporting group title	Brazikumab High Dose in Double-blind Treatment Period

Reporting group description:

Brazikumab 700 mg, IV infusion and placebo-matching brazikumab, SC injection at Weeks 0 and 4 followed by brazikumab 210 mg, SC injection at Weeks 8, 12, 20 and 24 in the induction and the maintenance phase.

Reporting group title	Brazikumab High- Medium dose in Double-blind Treatment Period

Reporting group description:

Brazikumab 280 mg, IV infusion and placebo-matching brazikumab, SC injection at Week 0 followed by brazikumab 210 mg, SC injection and placebo-matching brazikumab, IV infusion at Weeks 4, followed by brazikumab 210 mg, SC injection at Weeks 8, 12, 20 and 24 in the induction and the maintenance phase.

Reporting group title	Brazikumab Low- Medium Dose in Double-blind Treatment Period

Reporting group description:

Brazikumab 210 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 0 followed by brazikumab 105 mg, SC injection and placebo-matching brazikumab, IV infusion at Weeks 4, followed by brazikumab 105 mg, SC injection at Weeks 8, 12, 20 and 24 in the induction and the maintenance phase.

Reporting group title	Brazikumab Low Dose in Double-blind Treatment Period

Reporting group description:

Brazikumab 70 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 0 followed by brazikumab 35 mg, SC injection and placebo-matching brazikumab, IV infusion at Week 4, followed by brazikumab 35 mg, SC injection at Weeks 8, 12, 20 and 24 in the induction and the maintenance phase.

Reporting group title	Placebo/Brazikumab 210 mg in OL Period

Reporting group description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received placebo-matching brazikumab in the double-blind treatment period.

Reporting group title	Brazikumab High Dose/Brazikumab 210 mg in OL Period

Reporting group description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received high dose of brazikumab in the double-blind treatment period.

Reporting group title	Brazikumab High- Medium Dose/Brazikumab 210 mg in OL Period

Reporting group description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received high-medium dose of brazikumab in the double-blind treatment period.

Reporting group title	Brazikumab Low-Medium Dose/Brazikumab 210 mg in OL Period

Reporting group description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to

Week 48. Participants received low-medium dose of brazikumab in the double-blind treatment period.

Reporting group title	Brazikumab Low Dose/Brazikumab 210 mg in OL Period

Reporting group description:

Brazikumab 210 mg, SC injection every 4 weeks in the open-label period starting at Week 28 up to Week 48. Participants received low dose of brazikumab in the double-blind treatment period.

Serious adverse events	Placebo in Double-blind Treatment Period	Brazikumab High Dose in Double-blind Treatment Period	Brazikumab High-Medium dose in Double-blind Treatment Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (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			
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (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

Serious adverse events	Brazikumab Low-Medium Dose in Double-blind Treatment Period	Brazikumab Low Dose in Double-blind Treatment Period	Placebo/Brazikumab 210 mg in OL Period
Total subjects affected by serious adverse events			

subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (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
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (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	Brazikumab High Dose/Brazikumab 210 mg in OL Period	Brazikumab High-Medium Dose/Brazikumab 210 mg in OL Period	Brazikumab Low-Medium Dose/Brazikumab 210 mg in OL Period
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Crohn's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (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			
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (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	Brazikumab Low Dose/Brazikumab 210 mg in OL Period		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Crohn's disease			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 1 (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: 0 %

Non-serious adverse events	Placebo in Double-blind Treatment Period	Brazikumab High Dose in Double-blind Treatment Period	Brazikumab High-Medium dose in Double-blind Treatment Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	4 / 5 (80.00%)	8 / 9 (88.89%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Eye naevus			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Melanocytic naevus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Phlebitis superficial			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Non-cardiac chest pain			

subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Drug intolerance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Respiratory symptom			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vitamin D decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
White blood cell count increased			

subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	3
Spinal compression fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Procedural nausea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Eye disorders			

Cataract			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Iritis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Crohn's disease			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Gastritis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Defaecation urgency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Abdominal discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anal fissure			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	1 / 5 (20.00%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Arthritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Joint swelling			

subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Folliculitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 5 (20.00%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	2 / 5 (40.00%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Oral candidiasis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Oral fungal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Postoperative abscess			
subjects affected / exposed	1 / 5 (20.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Enterobiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 5 (0.00%)	0 / 5 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Brazikumab Low-Medium Dose in Double-blind Treatment Period	Brazikumab Low Dose in Double-blind Treatment Period	Placebo/Brazikumab 210 mg in OL Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	1 / 3 (33.33%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Eye naevus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Vascular disorders			

Phlebitis superficial			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Feeling hot			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Drug intolerance			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Respiratory symptom			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Depression			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Stress			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 7 (14.29%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Paraesthesia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Iritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Crohn's disease			
subjects affected / exposed	2 / 7 (28.57%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Defaecation urgency			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Anal fissure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Pollakiuria			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Folliculitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			

subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Skin candida			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 3 (33.33%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Postoperative abscess			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 3 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 3 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Brazikumab High Dose/Brazikumab 210 mg in OL Period	Brazikumab High-Medium Dose/Brazikumab 210 mg in OL Period	Brazikumab Low-Medium Dose/Brazikumab 210 mg in OL Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	1 / 2 (50.00%)	1 / 3 (33.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Eye naevus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Melanocytic naevus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Phlebitis superficial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug intolerance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory symptom			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitamin D decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Spinal compression fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Procedural nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iritis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Crohn's disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Defaecation urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Folliculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			

subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Postoperative abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Enterobiasis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Brazikumab Low Dose/Brazikumab 210 mg in OL Period		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Eye naevus			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Melanocytic naevus			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Phlebitis superficial			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Feeling hot			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Drug intolerance			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Respiratory symptom			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Upper respiratory tract congestion			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Stress			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Vitamin D decreased			

subjects affected / exposed occurrences (all) White blood cell count increased subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0		
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all) Spinal compression fracture subjects affected / exposed occurrences (all) Procedural nausea subjects affected / exposed occurrences (all)	 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0		
Cardiac disorders Palpitations subjects affected / exposed occurrences (all)	 0 / 1 (0.00%) 0		
Nervous system disorders Headache subjects affected / exposed occurrences (all) Paraesthesia subjects affected / exposed occurrences (all) Hypoaesthesia subjects affected / exposed occurrences (all)	 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0		
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	 0 / 1 (0.00%) 0		
Ear and labyrinth disorders Tinnitus			

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Eye disorders			
Cataract			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Conjunctivitis allergic			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Iritis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Crohn's disease			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Defaecation urgency			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Abdominal discomfort			

subjects affected / exposed occurrences (all) Anal fissure subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0		
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all) Eczema subjects affected / exposed occurrences (all) Erythema subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all)	 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0		
Renal and urinary disorders Pollakiuria subjects affected / exposed occurrences (all)	 0 / 1 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Arthritis	 0 / 1 (0.00%) 0 0 / 1 (0.00%) 0		

subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Folliculitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Herpes simplex			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Oral fungal infection			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Viral infection			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Skin candida			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		
Subcutaneous abscess			
subjects affected / exposed	0 / 1 (0.00%)		
occurrences (all)	0		

Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Postoperative abscess subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Enterobiasis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Gastroenteritis subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Metabolism and nutrition disorders Hypokalaemia subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		
Iron deficiency subjects affected / exposed occurrences (all)	0 / 1 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 November 2015	The following changes were made by Amendment 1: 1) Inclusion criterion 9 was modified to state that the male condom plus spermicide method must be used in conjunction with another method specified. 2) Modified criteria for discontinuation of investigational product 3) Text was modified to clarify that screening assessments may be carried out over more than one visit to the site. 4) Text was modified to clarify that the investigators may use their own assessment of the SES-CD score to decide whether or not to begin oral glucocorticosteroid tapering after Week 16.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Study was terminated for business reasons.

Notes: